# Instructions for Use

**AU680 Chemistry Analyzer** 





# Instructions for Use AU680 Chemistry Analyzer

PN B04779AB (June 2015)

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**Original Instructions** 

# **Revision History**

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

# B04779AB, August 2015

Software version 4.0

This document was created to:

- Replace the current User's Guide with the Instructions for Use and Reference Manual.
- Improve the content and usability of the instructions.
- Change the corporate address.
- Add the Japan market information.
- Add the Interpreting Lipemia, Icterus, and Hemolysis (LIH) Results section.
- Update the Perform the ISE Startup (Option) section.
- Update the Order (Requisition) and Perform Calibration from the STAT Table section.
- Update the Order (Requisition) and Perform Quality Control (QC) from the STAT Table section.
- Add the Create a Profile section.
- Update the Placing Racks on the Rack Supply Component section.
- Add the Add On a Test for Rerun section.
- Add the Delete an Order (Requisition) section.
- Update the Batch Transfer Data to the Laboratory Information System section.
- Add the Sample Data section.
- Add the Reagent Blank, Calibration, and QC Data section.
- Add the Monitor Results section.
- Add the Identifying Sample Kinds and Types by Sample Data Prefix section.
- Update the Sample Status Screen section.
- Update the Inspect the Analyzer Status section.
- Update the Inspect the ISE Status section.
- Add the Add Adapters to the Reagent Tray section.
- Add the Identifying and Reanalyzing Samples after a Cuvette Overflow section.
- Add the Accessing Maintenance Operations section.
- Add the Dilution Ratios for Maintenance Solutions section.
- Update the Replace the Deionized Water or Diluent in the Pre-dilution Bottle section.
- Update the Replace the O-rings in the Water Supply Tube Mounting Joint section.
- Update the Clean or Replace the Anti-static Brushes section.
- Update the Perform a W1 section.
- Add the Replace the Photometer Lamp section.
- Add the Save Parameters section.
- Add the Replace the Wash Syringe section.

B04779AB iii

- Update the Replace the Mixture Aspiration and MID Standard Roller Pump Tubing section.
- Update the Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints section.
- Update the Replace Syringes or Syringe Case Heads section.
- Update the Clean or Replace Individual Cuvettes section.
- Update the Enhanced ISE Cleaning (Manual) section.
- Remove the 8Q: Previously-set QC data is out of the permissible range section.
- Add the M: Duplicate sample ID section.
- Add the Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of Final Result Flowchart section.
- Add the RTWB Troubleshooting Overview Flowchart section.
- Add the Recovering from a Photometry Error During a Cuvette Wash Alarm section.
- Add the Recovering from an Unstable Photometry Error section.
- Add information about compliance for WEEE.
- Add the following tables:
  - Table A.9 Cup or Tube Available for Racks or STAT Table
  - Table A.10 Cup Nested (Inserted) in Tube Available for Racks
  - Table A.11 Cup Nested (Inserted) in Tube Available for STAT Table
- Update the Environmental Requirements section.
- Update the Maintenance Schedule section.
- Update the maximum rack number for Rack No. analysis mode.
- Update the AU680 Hazards section.
- Update the Parts List for Analyzer Maintenance section.
- Update the Parts List for ISE Maintenance section.
- Update the !: Unable to calculate concentration section.

# Initial Issue, B04779AA, March 2011

Software version 3.5

This document was created to replace the current regional User's Guides with a single global document, and to improve the content and usability of the instructions.

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# Warranty

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter, and at the customer's expense.

B04779AB V

# Warranty

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# Safety Notice

Read all product manuals and consult with Beckman Coulter trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Beckman Coulter.

# Alerts for Warning, Caution, Important, Note, and Tip



Warning indicates a potentially hazardous situation which, if not avoided, could cause death or serious injury. Warning can indicate the possibility of erroneous data that could cause an incorrect diagnosis.



Caution indicates a potentially hazardous situation which, if not avoided, can cause minor or moderate injury. Caution can also alert against unsafe practices, or indicate the possibility of erroneous data that could cause an incorrect diagnosis.



Important indicates important information to follow.



Note indicates notable information to follow.



Tip indicates information to consider.

# **Summary of Hazards**

This section describes the possible hazards of the system. The hazards of individual procedures in this manual are included in the warnings or cautions within the instructions. Read this section before you operate this system.

Follow the power requirements in the system specifications. Follow the procedures and safety warnings throughout this manual.

B04779AB Vİİ

#### **Safety Notice**

Summary of Hazards

If you use the system in a manner not specified by Beckman Coulter, the protection provided by the system can be impaired and incorrect results or system failure can occur.

#### **Bar Code Reader**

Do not adjust or remove the housing of any bar code reader. The bar code readers use lasers and looking directly at the laser light can be hazardous. Assume that the laser is always on.

#### **Biohazardous and Chemical Materials**

Observe all biohazard precautions when doing maintenance, service, or troubleshooting on the system. Biohazard precautions include, but are not limited to, wearing gloves, eye shields, and lab coats, and washing hands after working on contaminated portions of the system.

Follow all laboratory procedures and policies for handling infectious and pathogenic materials.

Avoid skin contact with reagents and other chemical preparations. Wear Personal Protective Equipment (PPE) to work with reagents and other chemical preparations used with the system. For more information, refer to the related SDS (Safety Data Sheet).

Clean spills of biohazardous or other potentially hazardous substances on the system immediately. If the system must be decontaminated, contact Beckman Coulter.

Follow your laboratory procedure for biohazardous and hazardous material disposal.

## **Electric Shock**

Do not replace or service any components where you can contact hazardous parts that could cause electric shock. Beckman Coulter must perform this maintenance.

## **Electrical Ground**

Never operate the system until the power cord is connected correctly to an electrical ground.

Use a three-pronged (grounded) power cord to connect the system to a matching three-wire grounded outlet. Do not use an adapter to connect the power plug to a two-pronged outlet.

# **Electromagnetic Wave and Noise**

The system generates, uses, and can radiate radio frequency energy. If the system is not installed and operated correctly, this energy can cause interference with other equipment. In addition, other equipment can radiate radio frequency energy to which the system is sensitive. If you suspect interference between the system and other equipment, Beckman Coulter recommends the following actions to correct the interference:

VIII B04779AB

- Move the equipment so there is a greater distance between the equipment and the system.
- Reorient the equipment in relationship to the system.
- Confirm that the equipment is operating from a different power service connector than the power service connector for the system.
- Do not use mobile or cordless telephones and transceivers in the same room as the system.
- Do not use medical equipment that can be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the system.

#### Flammable Materials

Do not use this system near flammable materials.

## **Moving Parts**

While the system is in operation, do not touch or go close to any moving parts. Close protective guards and covers during operation. Failure to close covers correctly can cause injury or incorrect results.

# **Liquid Waste**

Handle all liquid waste as potentially infectious.

Some liquid waste can require special treatment before disposal. Follow your laboratory procedure.

Some substances in the reagents, control materials, calibrators, and wash solutions have disposal regulations. Follow your laboratory procedure.

#### Solid Waste

Handle all solid waste as potentially infectious.

Some solid waste can require special treatment before disposal. Follow your laboratory procedure.

Handle any used or replaced parts (such as tubes, mix bars, probes, cuvettes, and wash nozzles) as infectious waste materials. Follow your laboratory procedure.

#### **AU680 Hazards**

- A Beckman Coulter representative installs the system. If the system installation needs modification, contact Beckman Coulter.
- If the system malfunctions, power off the system completely using the main breaker located on the left side of the analyzer before any repair service.
- If fluid is spilled on the system, turn off the main breaker located on the left side of the analyzer immediately. Wipe up the spill only after turning off the main system breaker. If fluid enters the system after a spill, contact Beckman Coulter before restarting the analyzer.

B04779AB iX

- After transferring the analysis results to a laboratory information system, confirm that the sample numbers and sample IDs are correct.
- Substances such as Lipemia, Icterus, and Hemolysis can interfere with results. Refer to the reagent IFU for specific substance interference information.
- To be sure the analytical data is accurate:
  - Confirm the quality of deionized (DI) water is within specifications.
  - Confirm that all tests have passed calibration, and calibration is not expired.
  - Inspect the quality control data.
- Use the correct reagent, calibrator, and control to analyze samples.
- Avoid excessive reagent agitation, which can cause bubbles. If bubbles are visible on the surface of the reagent, remove them. Confirm that the reagent bottles are placed securely on the reagent tray with the correct adapters and partitions. If the bottles are tilted, incorrect results can occur, or you can damage the reagent probe.
- Prepare reagents, wash solutions, calibrators, and QC samples according to the Instructions for Use (IFU), paying particular attention to any reconstitution, mixing, and pretreatment instructions.
- Handling samples:
  - Sample to sample carryover is one potential source of analytical error in the clinical laboratory. Do not use the same sample run on an AU Chemistry system for analysis of analytes for which a small quantity of carryover could cause problems with the results.
  - This system analyzes serum, urine, plasma, other sample types, and whole blood (for HbA1c only). Other refers to other body fluids such as cerebrospinal fluid (CSF). Some samples cannot be analyzed depending on the analysis test, reagent, and sample tubes used. For questions regarding reagent and sample tube type, contact Beckman Coulter.
  - Use serum or plasma that is clot free, or urine that is free from suspended matter.
     If serum or urine contains clots or suspended matter, the probe can clog and cause problems with the analysis results.
  - Chemicals present in the sample (medicine, anticoagulant, preservative, and so on) can significantly interfere with the results.
  - Highly viscous samples can interfere with the testing of the samples and the reliability of data.
  - Refer to the Instructions for Use (IFU) for each test for correct sample collection and storage. Incorrect storage of samples can alter the analyte in a sample.
  - Use only sample containers and sample tubes specified by Beckman Coulter.
  - To reduce the risk of interference, centrifuge and then separate serum and plasma samples adequately from blood cells immediately. Before analysis, confirm that samples are free from suspended matter, such as fibrin. While the system has a sophisticated clot detection mechanism, this mechanism is not able to detect all clots. Carefully inspect the samples.
  - Collect urine samples using correct preservatives and remove any suspended matter using centrifugation before analysis (CLSI GP16-A2).
  - Confirm that any anticoagulants or collection devices that employ a barrier are compatible with the test reagent being used. Refer to the Instruction for Use for suitable and validated sample types. Use caution when using sample tubes containing barriers or gels. Confirm the suitability of all collection devices in use.
  - For information about whether a serum separating agent is correct or not, contact the chemical reagent manufacturer or distributor.

X B04779AB

- When using sample containers or tubes containing a separating medium, confirm that there is enough serum to avoid contaminating or blocking the sample probes with the separating medium.
- Confirm that there is enough sample for correct sampling to occur. The small amount of wash water left on the sample probe can dilute the volume of sample left in the sample tube.
- To prevent water leaks, confirm that Beckman Coulter has fitted water supply and drainage hoses according to local guidelines.
- To confirm system performance, maintain and inspect the system periodically by replacing the parts according to the instructions in this guide.
  - Have and follow a maintenance schedule for this system.
  - Create a maintenance routine for the computer software and hardware, including frequent backing up of data containing analysis settings, results history, and the alarm log list file.
  - Do not store backups onsite. Keep one copy on-site for reference and one copy offsite
- Before using the system for the first time, set parameters for the reagent and sample quantity, measurement wavelength, calibrator values, and so on. Enter test specific parameters from the chemistry setting sheet to have optimum system performance. Enter any updates to these settings into the system immediately.
- Dedicate the computer hardware to only running the system software. Do not connect the computer hardware to the Internet, unless instructed to do so by Beckman Coulter.
- Keep the analyzer covers closed except for startup procedures and maintenance. If the covers are open for extended periods of time, excess condensation can be generated in the reagent refrigerators and cause errors.

# **AU680 Hardware Labels**

The following hardware labels are attached to the AU680. Use caution, observe, and follow all warning labels. Do not cover or remove these labels. If the labels peel off or become illegible, contact Beckman Coulter to replace the labels. Orange labels indicate that there is a risk of Serious Injury. Yellow labels indicate that there is a risk of Personal Injury, Fire, or Damage.

## **Electric Shock Label**



This symbol indicates an area of the system that should not be accessed under any circumstances, due to risk of electrical shock. (Labeling Position: near the inlet of the power cord on the left side of the analyzer.)

# **High Temperature Danger Label**



B04779AB Xi

This symbol indicates the risk of burning by touching the hot photometer lamp directly when replacing it. (Labeling Position: near the light source lamp.)

#### **Biohazard Label**



This symbol indicates the use of biohazardous material. Wear protective clothing and follow universal precautions as dictated by local or national regulations (CLSI GP17-A2, ISO15190 or 29CFR 1910.1030).

Risk of biohazardous materials such as sample probes, mix bars, sample rack, wash nozzle component, cuvette, sample probe wash well, condensed waste liquid drain hole, ISE sample pot, ISE roller pump tubing, drain hole, and so forth. (Labeling Position: On the surface of the analyzer and the rear cover.)

#### **Laser Radiation Label**



CLASS 1 LASER PRODUCT complies with IEC60825-1. (Labeling Position: near the main switch on the left side of the analyzer.)

CAUTION-CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM. (Labeling position: near the interlock switch of the rack feeder module, near the interlock switch of the large STAT cover, and near the small STAT cover).

CAUTION-CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM. (Labeling Position: near the sample ID barcode reader window for the STAT table and rack feeder module.)

## **Personal Injury Label**



This symbol indicates areas where a risk of injury due to system movement is possible. Fingers or other body parts should be kept clear of these areas during system operation.

- Danger of injury by moving parts of the sample probe, reagent probes, mix bars, wash nozzle component, and so forth. (Labeling Position: on the analyzer surface and rear cover.)
- Danger of injury by operation parts of syringe. (Labeling Position: near the sample, reagent, and wash syringes.)
- Danger of injury by moving parts, for example the Wash Solution roller pump, and so forth. (Labeling Position: near the Wash Solution roller pump or other moving part.)
- Danger of injury by moving parts, for example the ISE roller pump, and so forth. (Labeling Position: back of the ISE cover)

XÍÍ B04779AB

# **Danger Label**



Indicates a potentially hazardous situation which, if not avoided, could result in operator's injury and/or serious physical damage.

- Danger of leak from water supply and discharge component. (Labeling Position: near the water outlet)
- To avoid electrical shock, do not remove the cover connector screws to access the water supply component. (Labeling Position: near the power outlet of water supply component (option).)
- Do not lean against the PC rack component (option), which could result in it falling down. (Labeling Position: near the keyboard for the PC rack component.)

# **Recycling Label**

This label is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this label indicates that:

- 1. the device was put on the European Market after August 13, 2005 and
- 2. the device is not to be disposed of via the municipal waste collection system of any member state of the European Union



Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, contact your dealer or local Beckman Coulter office for details on the take-back program that facilitates the correct collection, treatment, recovery, recycling and safe disposal of these products.

For the Japan Market:

This system is considered an industrial waste, subject to special controls for infectious waste. Prior to disposal of the system, refer to the "Waste Disposal and Public Cleaning Law" for compliance procedures.

#### **C-Tick Mark Label**



The C-Tick mark is intended for use on products that comply with the applicable Electromagnetic Compatibility (EMC) standards in the Australian or New Zealand market.

B04779AB Xiii

# Fluorocarbons Recovery and Destruction Law Label

This instrument contains fluorinated greenhouse gases covered by the Kyoto Protocol.

REFRIGERANT: HFC-134a

CHARGE: 0.125Kg

This product is a Class 1 product according to Fluorocarbons Recovery and Destruction Law.

This system uses a HFC (hydro fluorocarbon) cooling medium.

Chlorofluorocarbon (CFC) chemicals cannot be discharged indiscriminately. When the system is discarded, recover CFC chemicals.

The type and volume of the CFC chemicals are described on the refrigerator.

# **Restriction of Hazardous Substances (RoHS) Labels**

These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.

#### **RoHS Caution Label**



This logo indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture.

# **RoHS Environmental Label**



This logo indicates that the product does not contain any toxic or hazardous substances or elements. The "e" stands for electrical, electronic and environmental electronic information products. This logo indicates that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and is environmental. The outer

XÍV B04779AB

circle indicates that the product can be recycled. The logo also signifies that the product can be recycled after being discarded, and should not be casually discarded.

# For In Vitro Diagnostic Use Label



This symbol is for an in vitro diagnostic medical device.

# **AU680 System Display and Labels**

Figure 1 On Switch

Figure 2 Off Switch

Figure 3 Ground Terminal



## Labels

- Stripes Orange stripes affixed to the system surface indicate the movement areas of the hardware components. Avoid these areas during operation.
- Warning Labels Identify areas of the system where hazards exist and where caution should be taken to avoid serious injury or death.
- Instruction Labels Instruction labels are affixed on the system at relevant locations to alert the operator to operate the system correctly.

B04779AB XV

Figure 4 AU680 Labels AUTION-CLASS 2 LASER RADIATION WHE OPEN DO NOT STARE INTO THE BEAM AUTION-CLASS 2 LASER RADIATION WHI OPEN DO NOT STARE INTO THE BEAM AUTION-CLASS 2 LASER RADIATION WHEI OPEN DO NOT STARE INTO THE BEAM AUTION-CLASS 2 LASER RADIATION WHOPEN DO NOT STARE INTO THE BEAM CLASS 1 LASER PRODUCT complies with IEC60825-1

XVİ B04779AB

- 1. The label is attached to the inside of the lid.
- 2. Early production AU680s had labels applied to the (2) positions. Subsequent

AU680s have labels applied to the (1) positions.

B04779AB XVII

# **Safety Notice**

AU680 Hardware Labels

XVIII B04779AB

# Contents

```
Warranty, v
                      Safety Notice, vii
                      Introduction, xxix
                      System Overview, 1-1
CHAPTER 1:
                      Hardware Overview, 1-1
                               Hardware Component Overview, 1-1
                               Breakers and Fuses, 1-2
                               Operation Buttons, 1-3
                               Rack Feeder Module, 1-4
                               STAT Table, 1-5
                               Sample Transfer Component, 1-8
                               Reagent Transfer Component, 1-9
                               Mix Bar Component, 1-9
                               Cuvette Wheel Component, 1-10
                               Photometry Component, 1-11
                               Wash Nozzle Component, 1-11
                               Reagent Refrigerator Component, 1-13
                               Syringe Component, 1-14
                               Tank Storage, 1-15
                               Wash Solution Roller Pump, 1-16
                               ISE Module (Optional), 1-17
                               Data Processing Module (DPR), 1-20
                               Touch Screen, Mouse, and Keyboard, 1-21
                      Software Overview, 1-22
                               Organization of Operation Screen, 1-22
                               Main Button Area, 1-22
                               Using the System Help and Alarm List, 1-23
                               Home Outline, 1-25
                               Analyzer Modes, 1-27
CHAPTER 2:
                      Daily Startup, 2-1
                      Introduction, 2-1
                      Startup Procedure, 2-1
                      Turn on the System, 2-1
                               Set a New Index, 2-2
```

Revision History, iii

B04779AB XİX

**CHAPTER 3:** 

```
Perform Daily Maintenance, 2-4
         Inspect the Syringes for Leaks, 2-4
         Inspect the Wash Solution Roller Pump for Leaks, 2-8
         Inspect the Wash Solution and Replenish as Needed, 2-10
         Inspect the Stability of the Upper Cover, 2-12
         Inspect, Clean, and Prime the Sample Probes, Reagent Probes,
            and Mix Bars, 2-13
         Replace the Deionized Water or Diluent in the Pre-dilution
            Bottle, 2-15
         Inspect the Sample Probe Wash Solutions, 2-15
         Inspect the Printer and Paper, 2-16
Inspect the Analyzer Status, 2-16
Perform the ISE Startup (Option), 2-18
         Inspect the ISE Reagents, 2-18
         Replace the ISE Reagents, 2-19
         Clean the ISE, 2-21
         Calibrate the ISE, 2-22
Monitor the Reagent Status, 2-24
         Replace the Reagents, 2-31
Calibrate Tests, 2-33
         Order (Requisition) and Perform Calibration from the Racks, 2-35
         Order (Requisition) and Perform Calibration from the STAT
            Table, 2-37
Process Quality Control (QC), 2-40
         Order (Requisition) and Perform Quality Control (QC) from
            the Racks, 2-41
         Order (Requisition) and Perform Quality Control (QC) from
            the STAT Table, 2-43
Start Analysis, 2-45
         Start Rack Analysis, 2-45
         Start STAT Table Analysis, 2-46
System Setup, 3-1
Program a New Test, 3-1
Create a Profile, 3-6
         Create a Sample Profile, 3-7
         Create a Reagent Blank or Calibration Profile, 3-8
         Create a QC Profile, 3-9
Program Calibrator Concentrations, 3-10
Program Preset QC Mean and Range, 3-11
Program a User Menu, 3-11
         Edit the User Menu, 3-12
```

XX B04779AB

```
Sample Programming and Processing, 4-1
CHAPTER 4:
                      Sample Preparation, 4-1
                      Place the Sample Cups or Tubes in the Rack, 4-2
                               Place Samples into each Rack Type, 4-3
                               Place the Sample Cups or Tubes in a Rack, 4-5
                      Placing Racks on the Rack Supply Component, 4-7
                       Order (Requisition) for Routine and Emergency Samples, 4-9
                               Enter Manual Orders (Requisitions) for Routine and
                                  Emergency Samples, 4-10
                               Enter Batch Orders (Requisitions), 4-11
                               Add On a Test for Rerun, 4-13
                               Delete an Order (Requisition), 4-15
                               Download Orders (Requisitions) from a Laboratory
                                  Information System, 4-17
                      Processing Emergency Samples, 4-18
                      Priority STAT Samples, 4-18
                               Enter Manual Orders (Requisitions) for Priority STAT
                                  Samples, 4-18
                               Processing Priority STAT Samples, 4-19
                      Performing a Repeat Run, 4-23
                               Auto Repeat for Racks and the STAT Table, 4-24
                               Repeat Orders (Requisitions) for Manual Repeat, 4-24
                               Perform a Manual Repeat in an Orange Rack, 4-27
                               Perform a Manual Repeat from the STAT Table, 4-27
                       Print Results, 4-28
                               Print Sample Data Reports, 4-28
                               Print Reagent Blank, Calibration, and QC Results, 4-30
                       Batch Transfer Data to the Laboratory Information System, 4-32
                               Sample Data, 4-32
                               Reagent Blank, Calibration, and QC Data, 4-33
CHAPTER 5:
                       System Monitoring and Results, 5-1
                       Monitoring Analysis, 5-1
                               Monitor Results, 5-1
                               Identifying Sample Kinds and Types by Sample Data Prefix, 5-1
                               Sample Status Screen, 5-2
                               Inspect the Analyzer Status, 5-4
                               Inspect the ISE Status, 5-10
                       Disable a Test, 5-13
                      Review Results for Flags and Alarms, 5-14
                               Review Results for Flags, 5-14
                               Review Alarms, 5-14
                               Interpreting Lipemia, Icterus, and Hemolysis (LIH) Results, 5-16
```

**CHAPTER 6:** 

```
Reagent Management, 5-17
         Reagents, 5-17
         Add Adapters to the Reagent Tray, 5-20
         Remove Adapters from the Reagent Tray, 5-21
         Assign a Reagent Position, 5-22
         Edit a Reagent ID, 5-24
System Shutdown (End Process), 5-25
Pause Analysis, 5-26
         Resuming Analysis from Pause Mode, 5-27
Rack Feeder Stop, 5-27
         Stop the Rack Feeder, 5-28
         Restart Analysis After Rack Feeder Stop, 5-28
Stop Analysis, 5-28
        Return to Standby Mode from Stop Mode, 5-29
Perform an Emergency Stop, 5-29
         Return to Standby Mode After an Emergency Stop, 5-29
Identifying and Reanalyzing Samples after a Cuvette Overflow, 5-30
         Output the List to Media, 5-34
        Print the List, 5-35
Maintenance, 6-1
Introduction, 6-1
Warnings and Cautions, 6-1
Maintenance Schedule, 6-3
Maintenance Log, 6-8
        Add a Maintenance Procedure, 6-9
         Delete a Maintenance Procedure, 6-9
         Update the Maintenance Log, 6-10
         View Maintenance History, 6-10
Accessing Maintenance Operations, 6-11
Parts List for Analyzer Maintenance, 6-12
Dilution Ratios for Maintenance Solutions, 6-19
Daily Maintenance, 6-19
        Inspect the Syringes for Leaks, 6-20
        Inspect the Wash Solution Roller Pump for Leaks, 6-23
        Inspect the Wash Solution and Replenish as Needed, 6-25
        Inspect the Stability of the Upper Cover, 6-27
        Inspect, Clean, and Prime the Sample Probes, Reagent Probes,
            and Mix Bars, 6-28
         Replace the Deionized Water or Diluent in the Pre-dilution
            Bottle, 6-30
        Inspect the Sample Probe Wash Solutions, 6-30
```

XXII B04779AB

xxiii

Inspect the Printer and Paper, 6-31 Weekly Maintenance, 6-31 Clean the Sample Probe and Mix Bars, 6-32 Perform a W2, 6-35 Perform a Photocal, 6-39 Clean the Pre-dilution Bottle, 6-42 Monthly Maintenance, 6-43 Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells, 6-43 Clean the Mix Bar Wash Wells, 6-45 Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints, 6-47 Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter, 6-52 Quarterly Maintenance, 6-57 Clean the Air Filters, 6-58 Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring, 6-59 Replace the Wash Solution Roller Pump Tubing, 6-60 Six-Month Maintenance, 6-62 Clean the Cuvettes and the Cuvette Wheel, 6-63 Yearly Maintenance, 6-69 Replace the O-rings in the Water Supply Tube Mounting Joint, 6-69 As Needed Maintenance, 6-72 Clean the R1 or R2 Reagent Probes, 6-72 Replace a Sample or Reagent Probe, 6-73 Replace the Mix Bars, 6-75 Replace a Wash Nozzle Joint, 6-78 Replace the Packing in the Wash Nozzle Tube Mounting Joints, Replace Syringes or Syringe Case Heads, 6-83 Replace the Wash Syringe, 6-91 Clean the Interior of the Reagent Refrigerators and STAT Table Compartment, 6-99 Clean or Replace the Anti-static Brushes, 6-101 Replace the Sample or Reagent Probe Tubing, 6-103 Perform a W1, 6-104 Replace Rack ID Labels, 6-104 Clean or Replace Individual Cuvettes, 6-106 Replace the Photometer Lamp, 6-108

ISE Maintenance for All Markets Except Japan, 6-112

Save Parameters, 6-112

B04779AB

**CHAPTER 7:** 

ISE Tubing Block Diagram, 6-113 Parts List for ISE Maintenance, 6-114 ISE Daily Maintenance, 6-117 ISE Weekly Maintenance, 6-120 ISE Maintenance Every Other Week or Every 3,000 Samples, 6-124 ISE Maintenance Every Other Month or Every 20,000 **Samples**, 6-129 ISE Quarterly Maintenance or Maintenance Every 20,000 Samples, 6-130 ISE Six-Month Maintenance or Every 40,000 Samples, 6-141 ISE Maintenance Every Two Years or Every 150,000 Samples, 6-145 ISE As Needed Maintenance, 6-149 **Flags**, 7-1 **Flags**, 7-1 Summary of Flags (Alphabetical Order), 7-1 Summary of Flags (Priority Order), 7-3 Flag Details, 7-5 d: QC result is excluded by the operator, 7-5 e: Data edited by the operator, 7-6 (: Shortage of cleaning solution for contamination parameters, Wa: Test has been analyzed with an erroneous cuvette, 7-6 R: Insufficient reagent detected, 7-7 #: Insufficient sample detected, 7-7 %: Clot detected, 7-8 ?: Unable to calculate a result, 7-8 M: Duplicate sample ID, 7-9 n: LIH test not performed, 7-9 1: Result may be affected by lipemia, 7-9 i: Result may be affected by icterus, 7-9 h: Result may be affected by hemolysis, 7-9 Y: Reagent Blank OD exceeds the high limit set at the last photometric read point, 7-10 U: Reagent Blank OD exceeds the lower limit set at the last photometric read point, 7-10 y: Reagent blank or routine OD at first photometric point high, 7-10 u: Reagent blank or routine OD at first photometric point low, 7-11 @: OD is higher than 3.0, 7-11 \$: Not enough data to determine linearity of reaction, 7-12 D: OD of reaction is higher than the maximum OD range, 7-13 B: OD of reaction is lower than the minimum OD range, 7-14

XXIV B04779AB

- \*: Linearity error in rate method, 7-15
- &: Prozone test data is abnormal, 7-15
- Z: Prozone error, 7-16
- E: Overreaction in a rate assay detected, 7-16
- Fx: Result (OD) is higher than the dynamic range, 7-16
- Gx: Result (OD) is lower than the dynamic range, 7-16
- !: Unable to calculate concentration, 7-17
- ): Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration, 7-18
- a: Reagent expired, 7-18
- ba: No calibration data or expired, 7-18
- bh: The latest calibration/RB has not been used, 7-18
- bn: Mastercurve used, 7-19
- bz: Calibration curve for Prozone data used, 7-19
- F: Result is higher than the dynamic range, 7-19
- G: Result is lower than the dynamic range, 7-19
- Tx: Result of T-Hb or HbA1c is outside the dynamic range, 7-20
- ph: Result is higher than the upper panic value, 7-20
- pl: Result is lower than the low panic value, 7-20
- T: Abnormality found in inter-chemistry check, 7-20
- P: Positive, 7-20
- N: Negative, 7-21
- H: Result is higher than reference range, 7-21
- L: Result is lower than reference range, 7-21
- J: Result is higher than the repeat decision range, 7-21
- K: Result is lower than the repeat decision range, 7-21
- fh: Result is higher than the repeat run reflex range, 7-22
- fl: Result is lower than the repeat run reflex range, 7-22
- Va: Deviation of multiple measurements check is out of range, 7-22
- xQ: Multi-rule QC has detected failure on one control, 7-22
- 1Q: QC data exceeds the range entered in Single Check Level field, 7-23
- 2Q: QC data exceeds 1<sub>3s</sub> control range, 7-23
- 3Q: QC data exceeds 2<sub>2s</sub> control range, 7-23
- 4Q: QC data exceeds R<sub>4s</sub> control range, 7-24
- 5Q: QC data exceeds 4<sub>1s</sub> control range, 7-24
- 6Q: A preset number of consecutive QC results fall on one side of the mean, 7-24
- 7Q: Consecutive QC results show steadily increasing or decreasing values, 7-25
- S: Sample repeated and original results replaced by repeat result, 7-25
- /: Test pending or not analyzed, 7-25

B04779AB XXV

**CHAPTER 8:** 

**CHAPTER 9:** 

```
c: Result corrected by the operator, 7-26
Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of
  Final Result Flowchart, 7-26
Error Messages, 8-1
Error Messages, 8-1
Troubleshooting, 9-1
Introduction, 9-1
Reagent Blank Data, 9-1
Calibration Data, 9-1
QC Data, 9-2
Troubleshooting Reagents, Calibrators, Quality Control, and Samples, 9-2
         Reagent Blank Issues and Corrective Actions, 9-2
         Calibration Issues and Corrective Actions, 9-3
         QC Related Issues and Corrective Actions, 9-4
         Sample Related Issues, 9-4
         Wash Solution Related Issues, 9-5
         Deionized Water Related Issues, 9-5
        Items in Common on the AU680 that can Aid in
           Troubleshooting, 9-6
Mechanical Problems, 9-6
         Syringe Problems, 9-6
         Probe Problems, 9-7
        Abnormal Data Caused by Cuvette Wheel or Wash Nozzles, 9-7
         Abnormal Data Caused by Photometer Lamp or Photometer
            Component, 9-8
         Mixing Problems, 9-9
         Deionized Water Tank Problems, 9-9
         Deionized Water or Filter Problems, 9-9
        Incubation Temperature Problems, 9-9
        Tubing and Pump Problems, 9-10
         Reagent Refrigerator Problems, 9-10
         STAT Table Problems, 9-10
        Rack Problems, 9-11
System Problems, 9-12
         Alarm for Reagent Refrigerator Temp, 9-12
         Abnormal Sound from Inside the System, 9-12
         Alarm for Deionized Water, 9-12
         Leaks from the Wash Solution Roller Pump, 9-13
         Bar Code Label Errors, 9-13
        Leaks from the Bottom of the System, 9-14
```

r: Result has been transferred to laboratory information system through online communication, 7-25

B04779AB xxvi

No Sample Cup Alarm when Sample Cup is in the Rack, 9-14 No Sample Cup Alarm when Sample Cup is on the STAT Table, 9-15 Liquid Leaking from the Reagent Probe or Sample Probe, 9-15 Reagent Probe or Sample Probe not Aligned over the Cuvette, 9-15 Flag [#] (Sample Level Detection Error) Generated during the Sample Dispense Operation, 9-15 TEMP DIL Alarm for the Wash Water Heater, 9-15 Sample Rack Jammed, 9-15 Printer Problems, 9-16 Data Processor Problems, 9-16 Menu Cannot be Selected, 9-16 Number Key Pad on Keyboard Does Not Work, 9-17 Keyboard Not Responding, 9-17 Inaccessible Floppy Disk, 9-17 Results Do Not Print Automatically, 9-17 Online Auto-Output by Host Computer Not Executed, 9-18 Recovering from an Emergency Stop or Power Loss, 9-18 Perform an Emergency Stop, 9-18 Return to Standby Mode After an Emergency Stop, 9-18 RTWB Troubleshooting Overview Flowchart, 9-19 Recovering from a Photometry Error During a Cuvette Wash Alarm, 9-21 Inspect the Cuvettes to Determine if an Overflow Occurred, 9-21 Recovering from a Cuvette Wheel Overflow, 9-21 Overflow Causes, 9-21 Recognizing an Overflow, 9-22 Items to Confirm when Recovering from an Overflow, 9-22 After the Overflow is Corrected, 9-22 Recovering from an Unstable Photometry Error, 9-22 Inspect the Cuvette Placement, 9-23 Inspect the Cuvette Condition, 9-23 Inspect the Lamp, 9-25 Laboratory Automation System Problems, 9-26 System Specifications, A-1 **APPENDIX A:** System Specifications, A-1 General Specifications, A-8 Cups or Tubes Specifications, A-9 Sampling Specifications, A-11

No Wash Solution to Mix Bar Wash Wells, 9-14

Sample Alarm when Sufficient Sample Remains, 9-14

Reagent Alarm when Sufficient Reagent Remains in Bottles, 9-14

B04779AB XXVII

# **Contents**

Reagent Specifications, A-12
Reaction System Specifications, A-13
Analytical Method Specifications, A-14
Optical System Specifications, A-14
Data Processing Specifications, A-15
Calculation Processing Specifications, A-15
Input and Output Specifications, A-16
ISE Specifications, A-17
PC Rack Specifications, A-18

Glossary

XXVİİİ B04779AB

# Introduction

# **Intended Use**

The AU680 Chemistry Analyzer measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material, and other accessories. This system is for in vitro diagnostic use only.

B04779AB XXİX

# Introduction

Intended Use

XXX B04779AB

# System Overview

# **Hardware Overview**

This section provides a description and diagram with location of each hardware component and module.

# **Hardware Component Overview**

15 14 4 5 6 7 13 12 11 10 9

Figure 1.1 Hardware Overview (Top and Front View)

- 1. Reagent transfer component
- 2. Photometry component
- 3. Mix bar component
- 4. Cuvette wheel component
- 5. Wash nozzle component
- 6. Sample transfer component

- 7. Rack feeder module (standalone AU680)
- 8. STAT table
- 9. Operation buttons
- 10. Syringe component
- 11. ISE Module (option)
- 12. Wash solution roller pump

B04779AB 1-1

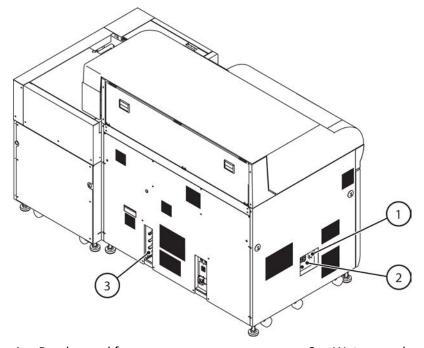
13. Tank storage

- 15. Upper cover
- 14. Reagent refrigerator component



The rack feeder module is not installed with the AU680 when the AU680 connects to a laboratory automation system.

Figure 1.2 Hardware Overview (Side and Back View)



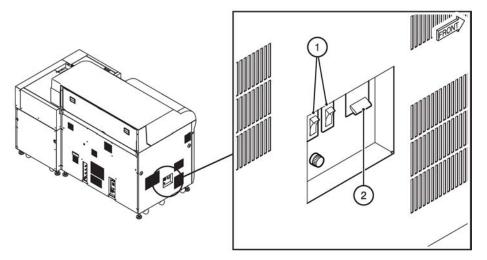
- 1. Breaker and fuses
- 2. Power supply component
- 3. Water supply and drain connections

## **Breakers and Fuses**

The main system breaker circuit board allows the power in specific areas of the system to be isolated. The main breaker (main power switch) automatically shuts down all the breaker switches. In normal conditions, all of the breaker switches are in the on position.

1-2 B04779AB

Figure 1.3 Breakers

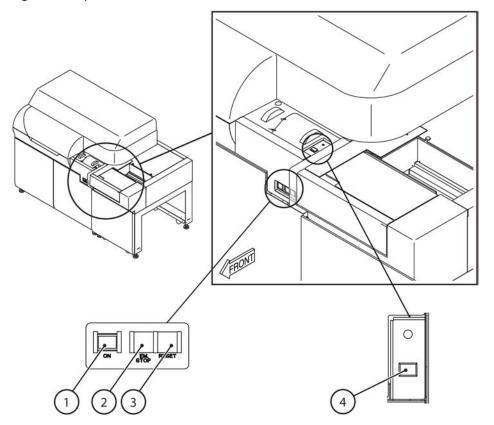


- 1. Sub-breakers
- 2. Main breaker

Main breaker and sub-breakers are on the left side of the analyzer.

# **Operation Buttons**

Figure 1.4 Operation Buttons



B04779AB 1-3

#### **System Overview**

Hardware Overview

- 1. ON button (Green)
- 2. EM STOP button (Orange)
- 3. RESET button (White)
- 4. TABLE ROTATION/DIAG button
  - On (sub power) button (ON) The ON button turns on the analyzer and PC, and the system initializes.
  - Emergency Stop button (**EM STOP**)- The **EM STOP** button turns off all power to the analyzer immediately. Use this button if there is an emergency, or to turn off the system completely after an End Process. The power to the PC is not turned off by pressing **EM STOP**.
  - Reset button (RESET) The RESET button supplies the main power to the system, and is used after an emergency stop or power failure. To be sure there is correct synchronization after an emergency stop, turn off the PC by performing an End Process. In rare cases, an End Process takes a long time or cannot be performed because there is no response from the analyzer. In these cases, select Ctrl + Alt + Delete, then select Shutdown to turn off the PC. To reboot the system, press RESET, and then press ON. After an emergency stop, wait 5 seconds before pressing RESET, then wait 5 seconds before pressing ON. Reset also resets the power failure detection circuit and generates the notification with the Power Failure Detected alarm.
  - Table Rotation and Diagnostic button (TABLE ROTATION/DIAG) The TABLE ROTATION/DIAG button rotates the STAT table for loading samples on the STAT table. In Maintenance and Diagnostics menus, this button initiates the maintenance or diagnostic function.

## **Rack Feeder Module**

This module is for loading and collecting racks.

Racks are loaded on the rack supply component. A bar code reader reads the rack ID and sample ID, and the information is automatically transferred to the analyzer PC. Covers prevent dirt or dust from getting into samples during analysis, and the main covers should be closed during normal operation.



When the AU680 connects to a laboratory automation system, the system is not installed with a rack feeder module.

1-4 B04779AB

5

Figure 1.5 Top View of Rack Feeder Module

- 1. Surface where rack ID label is applied
- 2. Window for reading rack ID
- 3. Sample protection cover
- 4. Bar code reader laser radiation (Sample ID)
- 5. Rack supply component
- 6. Rack

Table 1.1 Sample ID Bar Code Reader Specifications

Item	Specification
Wave length	650 nm
Maximum output	1.5 mW
Pulse width	65 μS
Frequency	500 Hz
Class	2
Beam divergence	60 degrees

## STAT Table

Use the STAT table to process priority STAT samples. The STAT table is the fastest method for processing a sample.

The STAT table compartment is maintained between 4  $^{\circ}$ C and 12  $^{\circ}$ C even after you turn off the system using an End Process.

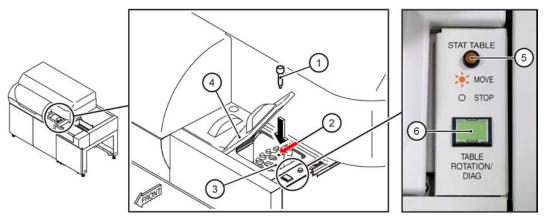
The STAT table has 22 operator-defined positions that can be programmed for priority STATs, repeats, calibrators, and QC. Inner positions on the STAT table are used for ISE calibration, ISE maintenance procedures, and reagent blank.

B04779AB 1-5

# **CAUTION**

To avoid injury, do not touch or open the STAT table cover while the amber STAT TABLE LED is blinking.

Figure 1.6 STAT Table (Top View)



- 1. Sample cup
- 2. Bar code reader laser radiation (Sample ID)
- 3. STAT table

- 4. Small STAT table cover
- 5. STAT TABLE LED
- 6. TABLE ROTATION/DIAG button

**Table 1.2** STAT Table Bar Code Reader Specifications

Item	Specification
Wave length	650 nm
Maximum output	1.5 mW
Pulse width	65 μS
Frequency	500 Hz
Class	2
Beam divergence	60 degrees

Table 1.3 STAT Table LED Status

LED	Description
Quick Blink	The STAT table rotates before sample aspiration. The sample probe moves over to the STAT table.
Slow Blink	The STAT table is in <i>Waiting</i> mode. The STAT table remains in <i>Waiting</i> mode when the analyzer is in <i>Measure</i> mode if:  • Contamination parameters for sample probe carryover are programmed.
	<ul> <li>Reagent blank or calibrators are programmed on the STAT table.</li> <li>Cyclic QC after a defined quantity of tests or samples is programmed on the STAT table.</li> </ul>

1-6 B04779AB

## IMPORTANT

An alarm is generated if the small STAT cover is opened when the STAT TABLE LED is blinking. Do not open the large STAT table cover when the analyzer is in *Measure* mode, or the system can go to *Stop* mode.

Figure 1.7 STAT Table (Top View)

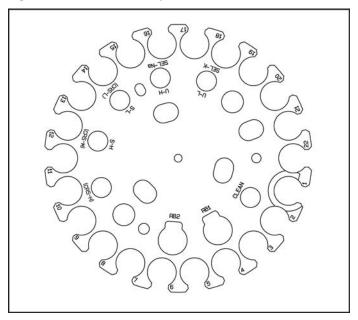


Table 1.4 STAT Table Positions

Position	Sample
No.1 to No.22	Priority STAT, repeat, calibrator, and QC
S-H	ISE Serum Standard Solution H
S-L	ISE Serum Standard Solution L
U-H	ISE Urine Standard Solution H
U-L	ISE Urine Standard Solution L
CRS-H	ISE Certified Reference Standard Solution H (Japan market only)
CRS-M	ISE Certified Reference Standard Solution M (Japan market only)
CRS-L	ISE Certified Reference Standard Solution L (Japan market only)
CLEAN	ISE Cleaning Solution
SEL-K	ISE Selectivity Check Solution (K)
SEL-Na	ISE Selectivity Check Solution (Na)
RB-1, RB-2	Reagent Blank



#### **NOTE**

When you program the STAT table for bar code analysis, the STAT table can only read bar code labels on samples placed on the outer positions of the STAT table.



#### NOTE

Always keep the cover on the table closed to maintain the temperature and sample integrity. Although the STAT table compartment is cooled, do not use it to store samples or leave samples for an extended time.



#### NOTE

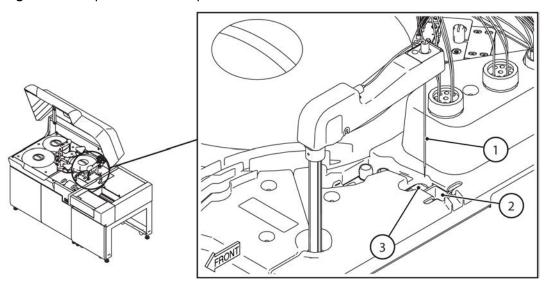
Only open the small STAT table cover to add or remove samples as required. Excessive opening and closing can damage the cover hinges.

## **Sample Transfer Component**

The sample probe (S) and liquid level detector dispenses sample or diluent, and detects liquid level. The sample probe has downward collision detection and clot detection. Sample is aspirated from the tube or cup and dispensed into the cuvette. The sample probe is rinsed with deionized water internally and externally in the sample probe wash well between each sample dispense. The HbA1c wash well is designed and used for whole blood to confirm that there is adequate cleaning.

When there is an ISE module installed, sample is aspirated from the tube or cup and dispensed into the ISE sample pot for analysis.





- 1. Sample probe
- 2. HbA1c wash well

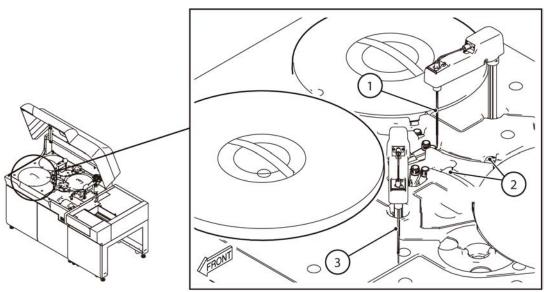
3. Wash well

1-8 B04779AB

## **Reagent Transfer Component**

Two reagent probes and liquid level detectors (R1 and R2) dispense reagent or diluent, and detect liquid level. The reagent probes have downward collision detection. Reagent is aspirated from the R1 and R2 refrigerators and dispensed into the cuvette. The probes are rinsed with deionized water internally and externally in the reagent probe wash well between each reagent dispense.

Figure 1.9 Reagent Transfer Components



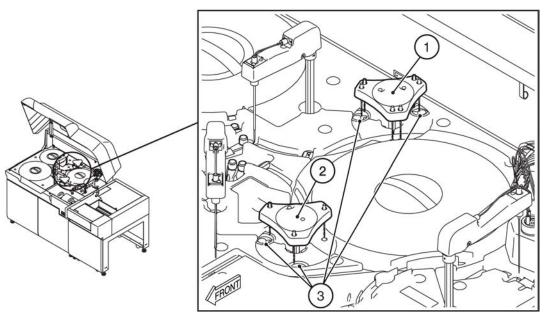
- 1. Reagent probe 2
- 2. Wash wells

## 3. Reagent probe 1

## **Mix Bar Component**

Mix bars are used to mix the reagent and sample in the cuvette. The R1/S mix bar component contains six mix bars. A mix occurs after R1 and sample dispense. The R2 mix bar component contains three mix bars. A third mix occurs after the R2 dispense. After mixing in the cuvette, the mix bars are cleaned in diluted wash solution, then rinsed in deionized water in the wash wells.

Figure 1.10 Mix Bar Component



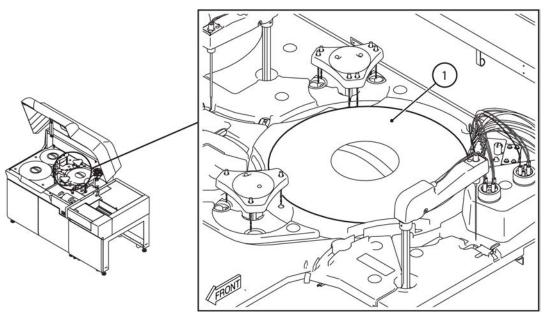
- 1. R1/S mix bar component
- 2. R2 mix bar component

3. Mix bar wash wells

# **Cuvette Wheel Component**

The incubation bath keeps the reaction temperature of the cuvettes at 37  $^{\circ}$ C. A cuvette is made from optical glass.

Figure 1.11 Cuvette Wheel Component



1. Cuvette wheel

1-10 B04779AB

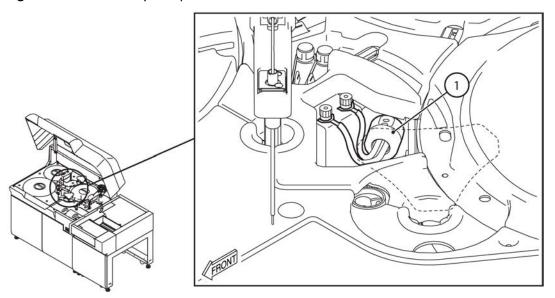
The cuvette wheel contains a total of 165 cuvettes in a single wheel. The wash nozzle component automatically cleans the cuvettes. The weekly photocal maintenance procedure monitors the cuvette integrity. From photocal results, clean and replace cuvettes as required.

Cuvettes are continuously monitored in *Measure* mode by the real-time water blank check method. The real-time water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the water blank reading check fails the specification, the system generates a Photometry Error During Cuvette Wash alarm. If the system detects a cuvette overflow and unstable photometry, the system generates a Photometry Error During Cuvette Wash alarm. For more information, refer to Recovering from a Photometry Error During a Cuvette Wash Alarm.

## **Photometry Component**

The photometry component includes a halogen lamp, lenses, a diffraction grating, and a photodetector to measure the amount of light transmitted through the reaction solution in the cuvette. The diffraction grating splits the light into 13 wavelengths.

Figure 1.12 Photometry Component



1. Lamp



Never touch the photometer lamp or look directly into the photometer lamp when the lamp is illuminated. The lamp is hot when the system is on.

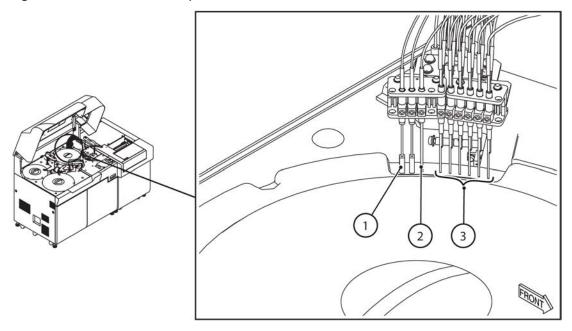
#### **Wash Nozzle Component**

The wash nozzle component cleans, rinses, and dries the cuvettes automatically. The wash nozzle component includes six wash nozzles, one aspiration nozzle, and two dry nozzles.

Each wash nozzle is a 3-way nozzle used to clean the cuvettes. The longest nozzle aspirates liquid, the middle nozzle dispenses, and the shortest nozzle aspirates any overflow liquid.

The aspiration nozzle aspirates any remaining liquid in the cuvette. The dry nozzle uses the fluorocarbon polymer tip to bring any remaining moisture to the bottom of the cuvette, then aspirates to dry the interior of the cuvette completely.

Figure 1.13 Wash Nozzle Component



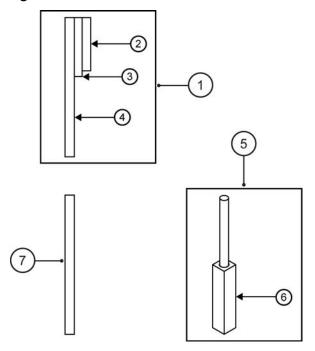
- 1. Dry nozzle
- 2. Aspiration nozzle
- 3. Wash nozzles

The dispensing sequence of the wash nozzles, from right to left in the diagram:

- Nozzle 1 and 2 Diluted Wash Solution
- Nozzle 3 to 6 Warm deionized water
- Nozzle 7 Aspiration
- Nozzle 8 and 9 Drying

1-12 B04779AB

Figure 1.14 Wash Nozzle



- 1. Wash nozzle
- 2. Overflow nozzle
- 3. Liquid (wash solution and warm deionized water) dispense nozzle
- 4. Liquid (reaction, wash solution, and warm deionized water) aspirating nozzle
- 5. Dry nozzle
- 6. Drying tip
- 7. Aspiration nozzle

## **Reagent Refrigerator Component**

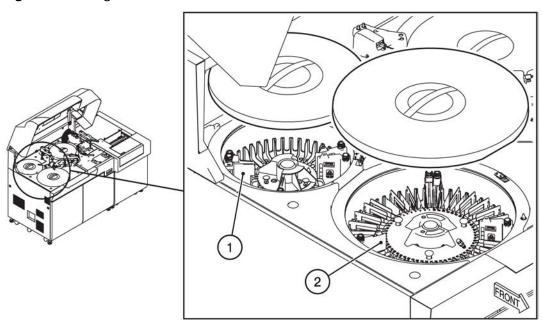
The R1 refrigerator contains the first reagent (R1), and the R2 refrigerator contains the second reagent (R2). Even when an End Process is performed, the temperature of the refrigerators is maintained between 4°C (39.2 °F) and 12°C (53.6 °F).

Place the reagent bottle on the corresponding tray (R1 or R2) in the R1 refrigerator or R2 refrigerator.

The R1 refrigerator has 60 positions and the R2 refrigerator has 48 positions. Each refrigerator uses applicable adapters or partitions for various sizes of reagent bottles: 15 mL, 30 mL, and 120 mL.

Each bottle position can be designated as reagent ID (bar code labeled) or fixed (not bar code labeled). During a reagent check, reagent bottles are detected, reagent IDs are read, and reagent volume is calculated.

Figure 1.15 Refrigerators



1. R2 refrigerator





Confirm that the reagent bottles are placed in the refrigerator with the reagent ID facing outwards. Confirm that all reagent bottle caps are removed before placing them in the refrigerator.

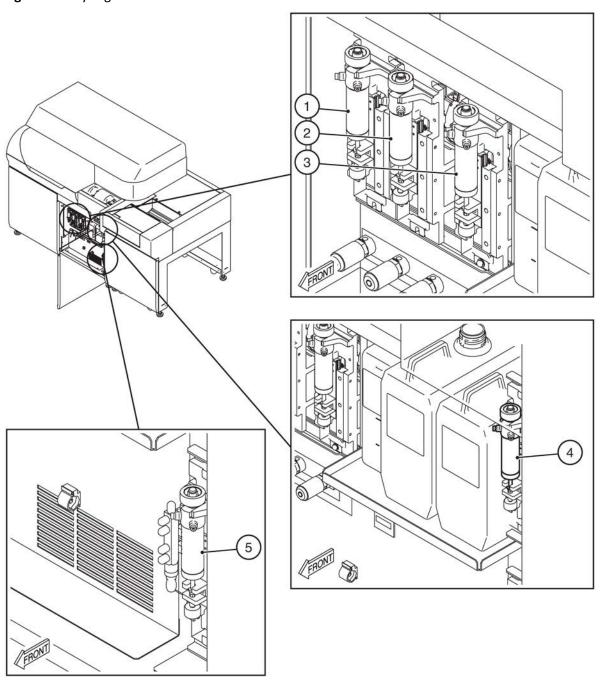
## **Syringe Component**

This system has a sample syringe (S), and two reagent syringes (R1 and R2). If the ISE Module is installed, the system has a syringe for the ISE Buffer Solution. Syringes are used to dispense the required volume of sample or reagent.

A wash syringe dispenses deionized water for the internal sample probe wash.

1-14 B04779AB

Figure 1.16 Syringe Locations



- 1. R2 syringe
- 2. R1 syringe
- 3. ISE buffer syringe

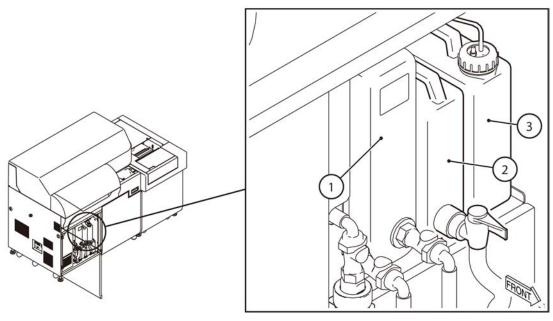
- 4. S syringe
- 5. Wash syringe

# **Tank Storage**

The tank storage area has a deionized water tank, a wash solution tank, and a diluted wash solution tank.

The system uses diluted wash solution (1%) to clean the cuvettes and mix bars. The system uses deionized water to dilute the wash solution, rinse analyzer components, and make dilutions.

Figure 1.17 Tank Locations



- 1. Deionized water tank
- 2. Diluted wash solution tank

3. Wash solution tank

#### **Diluted Wash Solution Tank**

The diluted wash solution tank has a capacity of 2 liters. A float sensor indicates when the volume in the tank is low. The tank automatically fills with wash solution and deionized water to make the diluted wash solution (1%).

#### **Wash Solution Tank**

The wash solution tank has a capacity of 2 liters. A float sensor indicates when the volume in the tank is low and generates an alarm to alert the operator to supply a new wash solution tank.

#### **Deionized Water Tank**

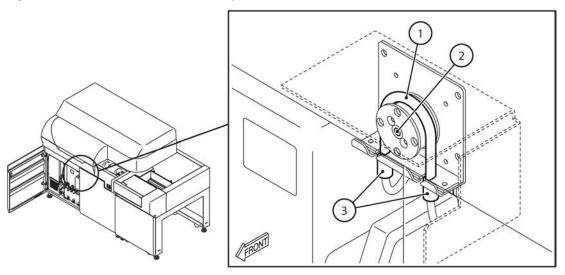
The deionized water tank has a capacity of 10 liters. A float sensor indicates when the volume in the tank is low and opens a valve to fill it automatically. For more information on specifications, refer to Water Supply and Drain.

## **Wash Solution Roller Pump**

The wash solution roller pump supplies wash solution to the diluted wash solution tank from the wash solution tank.

1-16 B04779AB

Figure 1.18 Wash Solution Roller Pump



- 1. Roller pump tubing
- 2. Wash solution roller pump

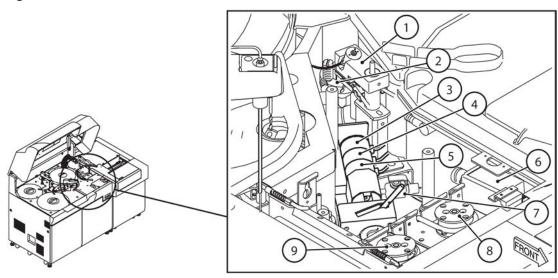
3. Connectors

## **ISE Module (Optional)**

Diluted sample passes through the Na, K, and Cl ion selective electrodes to determine the concentration by comparing the electrical potential difference to the REF electrode.

The system has a common sample probe and sample syringe for photometric and ISE analysis.

Figure 1.19 ISE Module



- 1. Mixing component
- 2. Sample pot
- 3. Cl electrode
- 4. Na electrode

- 5. K electrode
- 6. Pinch valve
- 7. REF electrode
- 8. Mixture aspiration roller pump

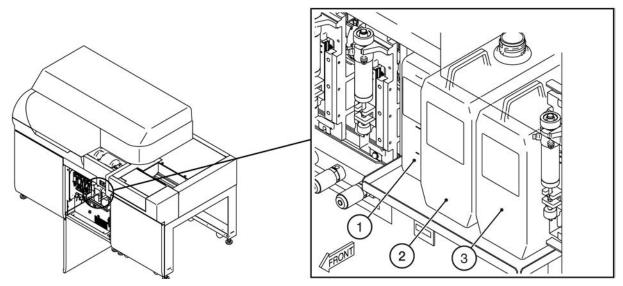
- 9. MID Standard roller pump
  - Mixing component The mixing component mixes sample and ISE Buffer Solution dispensed into the sample pot. It has two liquid-level sensors to detect correct drainage.
  - Sample pot Sample and ISE Buffer Solution are dispensed into the sample pot and mixed. The volumes dispensed for serum and urine:
    - ISE Buffer Solution: 618 µL (fixed)
    - Sample: 20 µL (fixed)
    - Deionized water: 10 μL (fixed)
  - Cl electrode, Na electrode, and K electrode These electrodes are used for measuring the potential of Cl, Na, and K ions in the sample and ISE MID Standard Solution. The concentrations of individual ions in the sample can be calculated from the potential differences between each ion in the sample and in the ISE MID Standard Solution.
  - REF electrode This electrode is the reference electrode for the Cl, Na, and K electrodes.
  - Pinch valve The pinch valve has two functions:
    - Allows sample in the sample pot to enter the flowcell for measurement.
    - Allows excess sample to pass through the bypass tubing to waste.
  - Roller pump
    - Mixture Aspiration Roller Pump (pump is on the right):
      - Aspirates liquid from the sample pot through the flowcell or bypass tubing and out to waste.
      - Aspirates ISE Reference Solution from the ISE Reference Solution bottle past the REF electrode and out to waste.
    - MID Standard Roller Pump (pump on left):
      - Aspirates ISE MID Standard Solution from the ISE MID Standard Solution bottle to the sample pot.
  - Roller pump tubing The roller pump tubing is made of rubber and wraps around the roller pump. As the roller pump rotates, the rollers on the pump squeeze the tubing, and solution is supplied or removed.

#### **ISE Reagent Bottles**

The ISE has an ISE Buffer Solution bottle, ISE MID Standard Solution bottle, and ISE Reference Solution bottle.

1-18 B04779AB

Figure 1.20 ISE Reagent Bottles

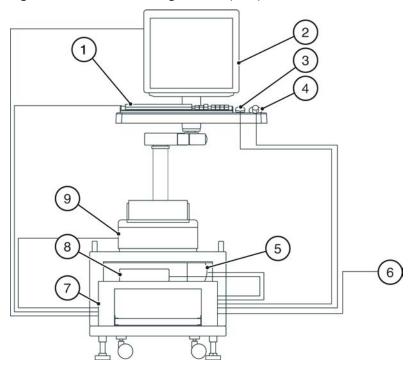


- 1. ISE Reference Solution bottle
- 2. ISE MID Standard Solution bottle
- 3. ISE Buffer Solution bottle
- ISE Buffer Solution bottle This bottle stores the ISE Buffer Solution. The system uses the ISE Buffer Solution for diluting the sample. The capacity of this container is 2 liters.
- ISE MID Standard Solution bottle This bottle stores the ISE MID Standard Solution. The system uses the ISE MID Standard Solution to condition the electrodes between analysis. The capacity of this container is 2 liters.
- ISE Reference Solution bottle This bottle stores the ISE Reference Solution. The system uses the ISE Reference Solution as a reference point relative to the three electrodes. The capacity of this container is 1 liter.

В04779АВ 1-19

## **Data Processing Module (DPR)**

Figure 1.21 Data Processing Module (DPR)



- 1. Keyboard
- 2. Monitor
- 3. Mouse
- 4. Hand scanner (option)
- 5. Speaker

- 6. Laboratory information system (LIS)
- 7. Computer
- 8. External memory component (option)
- 9. Printer (option)



Figure 1.21 Data Processing Module (DPR) is one example of the Data Processing Module (DPR) configuration available for the AU680.

#### Monitor

The monitor displays the operating software, and the keyboard and mouse allow operator input.

## Computer

The system uses a personal computer as the data processing component to perform data processing. The computer includes a hard disk to store programs, analysis parameters, an analysis database, USB drives, and a DVD R/W component. An external hard disk option is also available.

## **Printer (Optional)**

You can output results in operator-defined reports or lists.

1-20 B04779AB

## **Hand Scanner (Optional)**

The hand scanner reads bar code labels for input to the software. You can scan a sample ID in the Sample ID field in **Home > Rack Requisition Sample**.

Tests programmed with the Master Curve option require a 2-dimensional bar code label that contains calibration information. Use the hand scanner to manually scan the 2-dimensional bar code label located on the R1 bottle label of corresponding AU reagents.

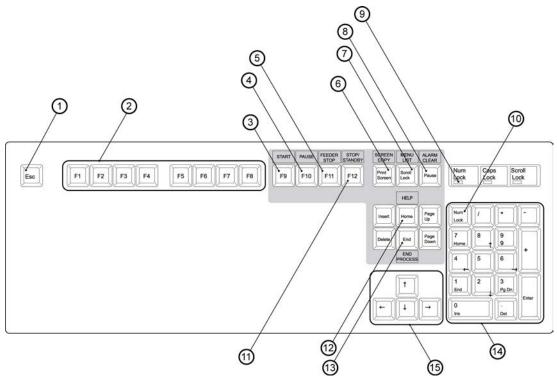
**Table 1.5** Hand Scanner Specifications

Item	Specification
Wavelength	630 to 680 nm
Output	1.0 mW
Class	2

## Touch Screen, Mouse, and Keyboard

You can operate the system in any combination of the touch screen, mouse, or keyboard.

Figure 1.22 Operation Keys on the Keyboard



- 1. ESC key
- 2. Function keys
- 3. Start key
- 4. Pause key
- 5. Feeder Stop key
- 6. Print Screen key

- 7. Menu List key
- 8. Alarm Clear key
- 9. Num Lock lamp
- 10. Num Lock key
- 11. Stop or Stand-by key
- 12. Home key

- 13. End Process key
- 14. Numeric key pad

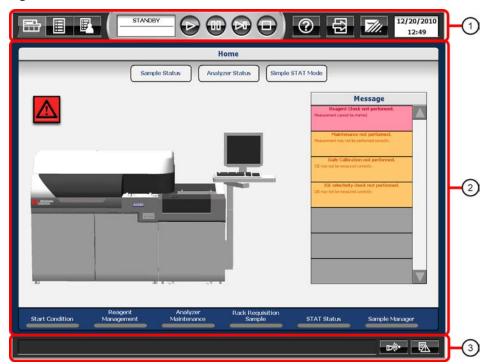
## 15. $\uparrow$ , $\downarrow$ , $\leftarrow$ , $\rightarrow$ Key

## **Software Overview**

## **Organization of Operation Screen**

The interface contains three areas, a main button bar, menu area, and alarm area.

Figure 1.23 Home Screen



- 1. Main button area The display area for the main buttons (Home, Menu List, and User Menu), Help, and operation area (Start, Pause, Feeder Stop, Stop, and End).
- 2. Menu area The display and operation area for the selected menu or button.
- 3. Alarm area The display area for the alarm messages generated during system operation, and the **Alarm Clear** and **Alarm List** buttons.

#### **Main Button Area**

Table 1.6 Main Button Area

Button	Name	Description
	Home	The system displays the Home screen.

1-22 B04779AB

Table 1.6 Main Button Area (Continued)

Button	Name	Description
	Menu List	The system displays the Menu List screen.
	User Menu	The system displays the User Menu screen. For more information, refer to Program a User Menu.
STANDBY	Mode Display area	The system displays the current mode. The system displays the time to completion for some maintenance procedures.
	Start	Starts analysis.
	Pause	Pauses analysis. The system pauses at the first test for which no R1 reagent was dispensed.
	Feeder Stop	Stops the rack supply component. The analysis of samples in racks that are loaded continues.
$lue{egin{array}{c}}$	Stop/ Standby	Stops analysis. In <i>Stop</i> mode, select this button to return the system to <i>Standby</i> mode.
?	Help	The system displays a menu for accessing the operator documentation and maintenance video directory.
<b>E</b>	Logout	Logs out and logs in an operator.
7//.	End	Shuts down the system (End Process). Shutting down the system turns off the auxiliary power supply, including the lamp and computer.
12/20/2010 12:49	Time Display area	The system displays the current date and time.

# **Using the System Help and Alarm List**

To have the system display a menu for accessing the operator documentation and maintenance video directory, select **Help**.

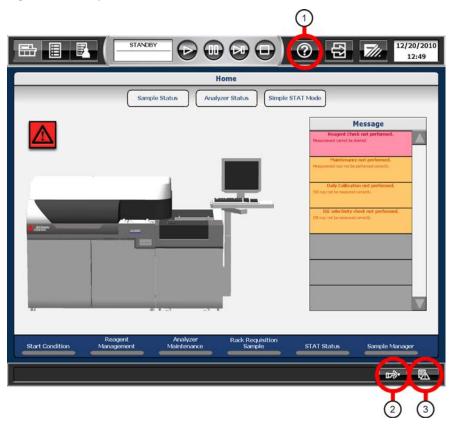


Figure 1.24 Help, Alarm Clear, and Alarm List Buttons

- 1. Help
- 2. Alarm Clear

3. Alarm List



Select **Alarm Clear** to stop the audible alarm. Select **Alarm Clear** a second time to clear the alarm message from the screen.

Table 1.7 Types of Help

Option	Description	
Help Button	The system displays the PDF version of the operator documentation and the maintenance video directory.	
	You can only access Help in Warm up, Standby, or Stop mode.	
	Help is inaccessible in <i>Measure</i> mode.	

1-24 B04779AB

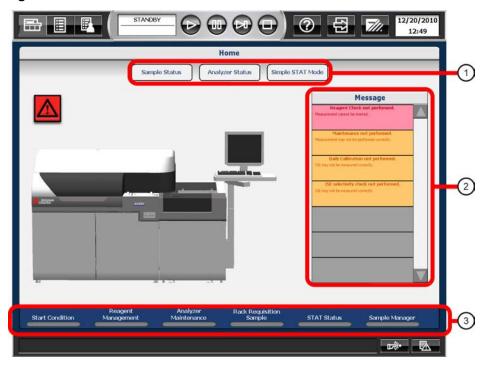
**Table 1.7** Types of Help (Continued)

Option	Description
Alarm List Button	The system displays the Alarm List dialog. To display the alarm description and the corrective actions, select an alarm to display, and then select <b>Help</b> on the Alarm List dialog. The system displays an Alarm Help dialog.
	The alarm help information is only available in the Alarm List.
	The AU680 Instructions for Use and AU680 Reference Manual do not contain alarm descriptions and corrective actions.
Input Help	The system displays the allowable input information for text fields. Move the cursor over the input area for the system to display the Input Help.
Button Help	The system displays the name of the buttons. Move the cursor over the button for the system to display the name of the button.

## **Home Outline**

Use the Home screen to view system messages regarding sample status and analyzer status. Shortcut buttons provide direct menu access to the most frequently used menus to simplify software access.

Figure 1.25 Home Screen



- 1. Menu buttons
- Message area

3. Shortcut buttons

#### **Menu Buttons**

Table 1.8 Menu Buttons

Button	Description
Sample Status	The system displays the sample status under analysis, estimated time of completion, and results.
Analyzer Status	The system displays the analyzer status and temperatures.
Simple STAT Mode	Processes STAT samples one at a time with minimal operator actions required. It is impossible to process samples in the normal analyzer operation modes.

## **Message Area**

In the message area, the system displays messages regarding system conditions that can affect analysis results. Colors indicate the level of the message.

Table 1.9 Message Area

Color	Definition	
Red	You cannot start analysis until you address message.	
	A red message or highlight on the analyzer picture indicates a condition that prevents you from starting the analyzer.	
Orange	You can start analysis. Review the message carefully and take the correct action.	
Yellow	You can start analysis. Review the message carefully and take correct action. The message can shift from yellow to orange status (more critical).	
Green	A notification of system status. The system has no operational problems.	

If a message is selected, the system displays a dialog with information and the corrective actions for the message. Select **OK** to close the dialog.

#### **Shortcut Buttons**

Shortcut buttons provide direct menu access to the most frequently used menus to simplify software access.

Table 1.10 Shortcut Buttons

Button	Description
Start Condition	Sets a new data index, the group of tests in use, the operator name, and start sample numbers.
Reagent Management	The system displays the R1 and R2 reagent status and cleaning solution status.
Analyzer Maintenance	The system displays the analyzer and ISE maintenance schedules. Use this menu to start some maintenance procedures and update the schedule when you perform maintenance.

1-26 B04779AB

**Table 1.10** Shortcut Buttons (Continued)

Button	Description
Rack Requisition Sample	The system displays sample information and test orders (requisitions) for patient samples, calibration, and QC.
STAT Status	The system displays, starts, and monitors priority STAT samples for analysis from the STAT table.
Sample Manager	Views, prints, and batch transfers reagent blank, calibration, QC, and sample data to the laboratory information system.

## **Analyzer Modes**

The system displays the modes in the Mode Display Area.

Table 1.11 Analyzer Modes

Mode	Contents
Initial	The system displays <i>Initial</i> after you press <b>ON</b> . The software loads and the hardware initializes.
Warm up	After the system initializes, the system changes the mode to <i>Warm up</i> for approximately 20 minutes to allow the lamp to warm up and stabilize.
Standby	When the system is ready to perform sample analysis, the operation mode changes to <i>Standby</i> . You can start analysis.
Measure 1	Measure 1 mode occurs when you select <b>Start</b> . Racks are on the rack supply component, and the racks move to the sample aspiration position.
Measure 2	Measure 2 mode occurs when there are no more racks on the rack supply component. To start more racks, select <b>Start</b> .
Stop	Stop mode occurs when there is a system error, or when the operator selects <b>Stop/Standby</b> . You cannot start the analyzer from Stop mode. To return to Standby mode, select <b>Stop/Standby</b> . The mode displays as Reset while the hardware is initializing, then it goes to Standby. Repeat all tests that are in progress.
Pause	Pause mode occurs when there is a system error or when the operator selects  Pause. You can restart analysis from Pause mode by selecting Start. The system completes all tests that are in progress.

## **Processing Time**

The analysis processing time is the time from aspiration of a sample by the sample probe until the end of measurement. The necessary time for analysis is approximately 8 minutes and 30 seconds.



If you perform a stop or emergency stop or a power loss occurs, sample can remain in the sample probe, and reagents can remain in the cuvettes. Perform a W1 to clean the sample probe and cuvettes after you restart the system. For more information, refer to Perform a W1.

# **System Overview**

Software Overview

1-28 B04779AB

## Introduction

These procedures confirm that your system has adequate supplies and calibrated reagent for your patient run, and include maintenance steps and quality control procedures for continued optimal performance.

## **Startup Procedure**

- **1** Turn on the System.
- 2 Set a New Index.
- **3** Perform Daily Maintenance.
- 4 Inspect the Analyzer Status.
- **5** Perform the ISE Startup (Option).
- **6** Monitor the Reagent Status.
- **7** Calibrate Tests.
- **8** Process Quality Control (QC).
- **9** Start Analysis

## Turn on the System

If the system is on, proceed to Set a New Index.

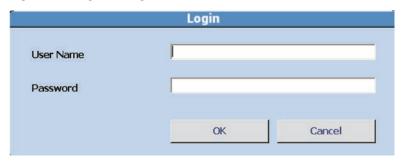
Press the green **ON** button on the front of the analyzer.

The computer loads the software and initializes the system. The system goes to *Warm up* mode for approximately 20 minutes, and then goes to *Standby*.

If the system was shut down without an End Process command, the system displays the System Start dialog. Select **OK**.

If your laboratory requires an operator to login, the system displays the Login dialog.

Figure 2.1 Login Dialog



**2** Enter the user name and password, and select **OK**. The system displays the New Index dialog.

Figure 2.2 New Index Dialog



**3** Select **New Index**, and then select the **Group of Tests** for processing. Select **OK** to close the dialog.

#### Set a New Index



If you set a new index in step 3 of Turn on the System, proceed to Perform Daily Maintenance.

If your system is on, use this procedure to create a new index, select a group of tests for processing, and enter the operator name.

An index, used to retrieve reagent blank, calibration, QC, and patient results, is a data file identified by the date and time. Create a new index daily, each shift, or as needed.

A maximum of 100,000 samples or 300 indexes can be saved on the hard drive. A maximum of 9,999 samples can be processed in an index.

1 Select Home > Start Condition.

2-2 B04779AB

The system displays the Start Condition screen.

Figure 2.3 Start Condition Screen



#### 2 Select Edit (F1)

3 Select **New Index**. The system displays the current date and time in the **Current Index** field.



To set a new index by date and time:

1. Select **Date Index (F8)**. The system displays the Creating a New Index dialog.

Figure 2.4 Creating a New Index Dialog



- 2. In **Index Date and Time**, select the date and time.
- 3. Select **OK**.
- 4 In **Group of Tests**, select the group of tests for processing.
- **5** (Optional) Enter the operator name in **Operator Name**.
- **6** Confirm that the **Start Sample No.** is 0001, or the default start number for each sample type and kind.
- 7 Select Confirm (F1).

The system displays the Start Condition dialog, with a confirmation message.

**8** Select **OK** to confirm the selections.

# **Perform Daily Maintenance**

Perform Daily Maintenance to maintain system performance and safety.



#### WARNING

Maintenance procedures can expose you to biohazards. Wear appropriate Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats. Handle and dispose of biohazards according to laboratory procedures.

- **1** Inspect the Syringes for Leaks.
- 2 Inspect the Wash Solution Roller Pump for Leaks.
- **3** Inspect the Wash Solution and Replenish as Needed.
- **4** Inspect the Stability of the Upper Cover.
- 5 Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.
- **6** Replace the Deionized Water or Diluent in the Pre-dilution Bottle.
- 7 Inspect the Sample Probe Wash Solutions.
- **8** Inspect the Printer and Paper.

#### **Inspect the Syringes for Leaks**

The system includes a sample syringe, a wash syringe, R1 and R2 reagent syringes. If your system includes an ISE, the system includes an ISE buffer syringe. All syringes are located inside the right front analyzer door. The procedure is identical for all syringes.

The sample and reagent syringes measure the volume of sample or reagent to be used in a reaction.

The wash syringe dispenses only deionized water for cleaning the interior of the sample probe.

The two types of wash syringes:

- Wash Syringe Type 1
- Wash Syringe Type 2

A Wash Syringe Type 1 or Wash Syringe Type 2 can be used on the AU680. To view the shape of each type of syringe, refer to Figure 2.6 Sample Syringe, Wash Syringe Type 1, Reagent, and ISE Buffer Syringe Parts and Figure 2.7 Wash Syringe Type 2 Parts.

2-4 B04779AB

The ISE buffer syringe measures the correct volume of buffer for the ISE.

If a syringe leaks, the leak causes possible failures to the syringe, probe, and analytes being tested.

Although the syringes are different sizes and serve different functions, you can inspect for correct performance using the same methods.

Inspect all components of the syringes, including the syringe case head, the syringe case, the fixing nut, and the piston fixing screw for leaks and correct installation.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

## Materials Required:

- Clean, dry, lint-free absorbent tissue
- **1** Confirm that the system is in *Warm up*, *Standby*, or *Stop* mode.
- **2** Open the right front door of the analyzer.



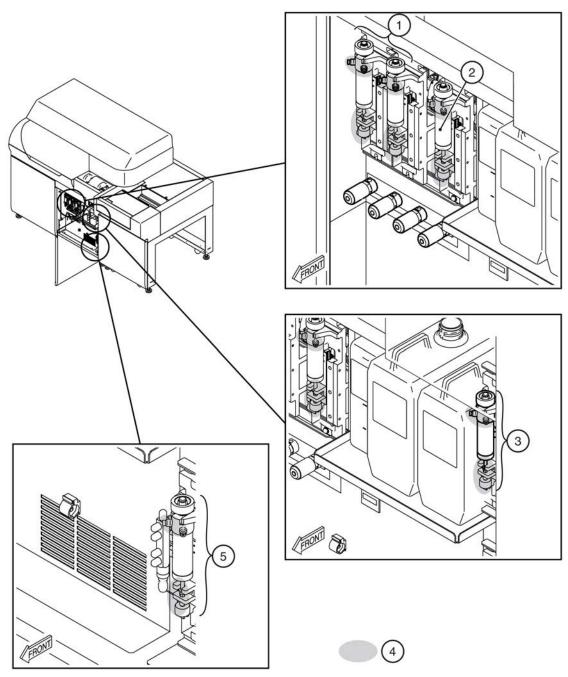
#### **CAUTION**

Do not allow a strong alkali, such as the wash solution, to contact the syringe case or syringe case head. If a strong alkali contacts the syringe case or syringe case head, cracks can occur.

If a strong alkali contacts the syringe case or syringe case head, remove the syringe case or syringe case head and rinse both with water.

3 Visually inspect each syringe case head for any cracks or leaks. Use the clean, dry, lint-free absorbent tissue to confirm that the top and bottom connections for the syringe case head and the bottom fixing screw have no leaks. If you find a crack or a leak, replace the syringe. For more information, refer to Replace Syringes or Syringe Case Heads.

Figure 2.5 Syringe Locations

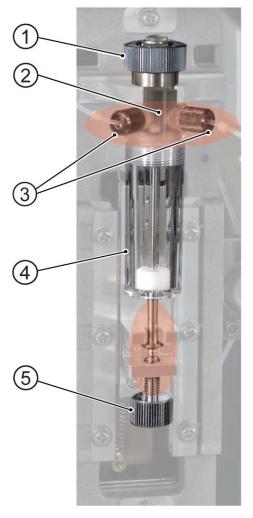


- 1. Reagent syringes (R1 and R2)
- 2. ISE buffer syringe
- 3. Sample syringe

- 4. Possible leakage locations
- 5. Wash syringe

2-6 B04779AB

Figure 2.6 Sample Syringe, Wash Syringe Type 1, Reagent, and ISE Buffer Syringe Parts





- 1. Fixing nut
- 2. Case head
- 3. Fixing screws

- 4. Syringe case
- 5. Piston fixing screw
- 6. Possible leakage locations

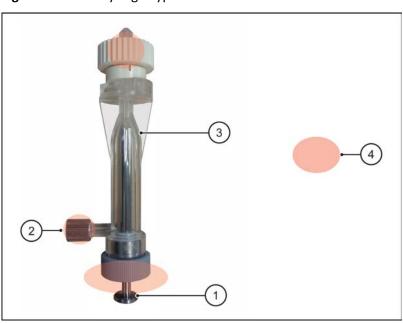


Figure 2.7 Wash Syringe Type 2 Parts

- 1. Piston
- 2. Seal assembly

- 3. Wash syringe
- 4. Possible leakage locations
- **4** Confirm that the fixing nuts and piston fixing screws are tight. If a leak persists after you tighten the screws, replace the syringe.



If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

- **5** Close all analyzer doors and covers.
- **6** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## **Inspect the Wash Solution Roller Pump for Leaks**

The wash solution roller pump supplies the required amount of wash solution to the diluted wash solution tank. If the wash solution roller pump tubing leaks, the concentration of diluted wash solution can be incorrect, or problems can occur with the wash solution roller pump.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

• Clean, dry, lint-free absorbent tissue

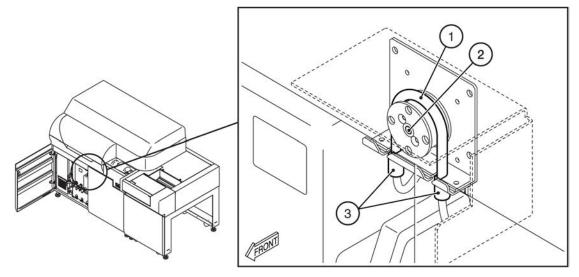
2-8 B04779AB

# ! CAUTION

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the left front door of the analyzer.
- Inspect the wash solution roller pump tubing for cracks or leaks. If you find a crack, replace the tubing and proceed to step 6. For more information, refer to Replace the Wash Solution Roller Pump Tubing.

Figure 2.8 Wash Solution Roller Pump



- 1. Wash Solution Roller Pump Tubing
- 2. Wash Solution Roller Pump
- 3. Connectors
- **4** Use the clean, dry, lint-free absorbent tissue to wipe the peripheral part of the tubing and the roller pump to inspect for leaks. Wipe any fluid with the clean, dry, lint-free absorbent tissue.
- **5** Confirm that the tubing connectors are tight. If a connector is loose, turn it clockwise to tighten. Wait five minutes, then inspect for leaks again. If the leak persists, replace the tubing. For more information, refer to Replace the Wash Solution Roller Pump Tubing.
- **6** Close all analyzer doors and covers.
- 7 Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## Inspect the Wash Solution and Replenish as Needed

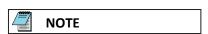
Inspect the wash solution level daily, and replenish as needed.



Confirm that the wash solution level is sufficient for typical daily analysis before you start sample processing. If the wash solution becomes empty during processing, the analyzer goes into *Pause* mode. Replenish the wash solution before resuming processing.

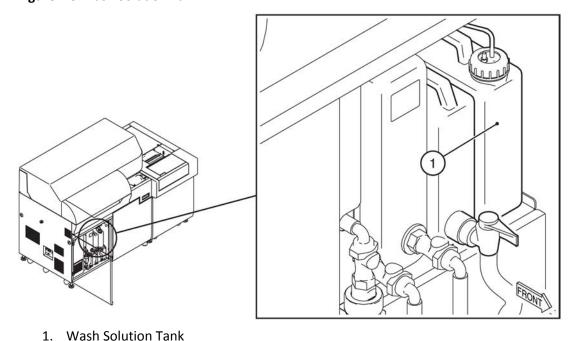
## **Inspect the Wash Solution Level**

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the left front door of the analyzer.
- **3** Confirm that the wash solution level is sufficient for daily analysis (0.5 L per day per 4,000 tests). If the level is insufficient, replenish the wash solution. For more information, refer to Replenish the Wash Solution.



The wash solution tank is 2 L. The volume of wash solution becomes insufficient when there is approximately 200 mL or 2 cm from the bottom of the wash solution tank.

Figure 2.9 Wash Solution Tank



4 Close all analyzer doors and covers.

2-10 B04779AB

## **Replenish the Wash Solution**

Replenish the wash solution when the volume is insufficient for daily processing.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.



If the wash solution splashes or spills outside the tank, follow your laboratory procedure to wipe up spills immediately. If any spill is left untreated, it can generate toxic gas and can cause parts of the analyzer to corrode.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

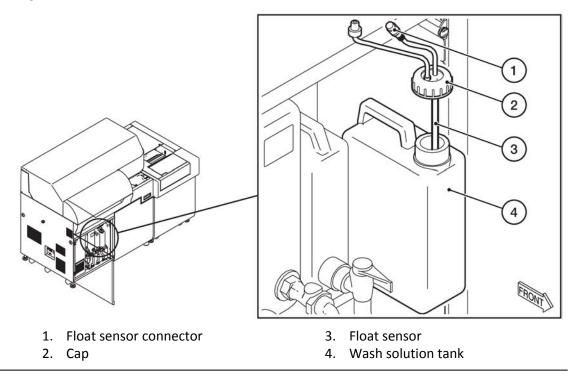
Materials Required:

- Wash solution
- **1** Place the new tank of wash solution next to the analyzer and remove the cap.
- **2** Disconnect the wash solution tank float sensor connector 869. Do not apply excess pressure to the float sensor cable.
- **3** Remove the wash solution roller pump tubing from the roller pump.
- **4** Carefully pull the wash solution tank forward to reach the tank cap.
- **5** Loosen the tank cap and remove the cap and float sensor from the tank.



The float sensor can drip when you remove it from the tank. Follow your laboratory procedure to wipe up spills immediately.

Figure 2.10 Wash Solution Tank



**6** Replace the tank with a new wash solution tank.



You can also add wash solution to the tank. Hold the cap and float sensor as you add wash solution up to the 2 L graduation mark on the front of the tank.

- 7 Insert the float sensor in the tank, and tighten the cap.
- **8** Replace the wash solution tank in the analyzer.
- **9** Reconnect the float sensor connector 869.
- **10** Replace the roller pump tubing on the roller pump.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## Inspect the Stability of the Upper Cover

Lift the upper cover of the analyzer and confirm that it is stable and remains in the raised position. If the cover starts to descend, contact Beckman Coulter to have the cover supports inspected and replaced.

2-12 B04779AB

#### Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars

The probes deliver precise quantities of reagent or sample to the cuvettes.

The mix bars mix the contents in the cuvettes.

If the mix bars or probes are bent or damaged, or if the probes are clogged, correct analysis cannot be achieved.

Before you begin analysis, inspect the sample probe, reagent probes, and mix bars for damage or deterioration. Confirm that each probe operates correctly.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

#### Materials Required:

• Alcohol prep pads (70% Isopropyl alcohol)

#### **Inspect the Sample Probe and Reagent Probes**

- **1** Lift the upper cover of the analyzer.
- **2** Visually inspect that each probe is not bent or damaged. If a probe is bent or damaged, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- 3 Inspect each probe for contaminants or crystallization. If a probe is dirty, wipe the surface with an alcohol prep pad (70% Isopropyl alcohol).



Do not bend the probe when cleaning.

**4** If a probe is incorrectly aligned, contact Beckman Coulter.

## **Inspect the Mix Bars**

- 1 Inspect each mix bar. If a mix bar is bent, scratched, or there are chips in the fluororesin coating, replace the mix bar. For more information, refer to Replace the Mix Bars.
- 2 Inspect each mix bar for contaminants or crystallization. If the mix bar is dirty, wipe the mix bar with an alcohol prep pad (70% Isopropyl alcohol).

## **Confirm Operation of the Probes and Mix Bars**

Prime the system to inspect the operation of the probes and mix bars.

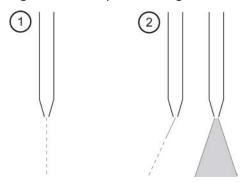
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.

- **3** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Prime Washing-line**. The system displays the Start dialog.
- **5** Select **OK**.
- **6** Press the **TABLE ROTATION/DIAG** button.

The system initializes the probes and mix bar components, then:

- 1. Dispenses deionized water from the sample probe
- 2. Dispenses deionized water from the R1 reagent probe
- 3. Dispenses deionized water from the R2 reagent probe
- 4. Activates the mix bar components and the wash nozzle component.
- **7** As the system dispenses water, confirm that each probe dispenses a thin, straight stream of water, and that water flows in the wash wells.

Figure 2.11 Sample and Reagent Probes



1. Correct Flow

- 2. Incorrect Flow
- **a.** If the water is spraying or dispensing at an angle, clean the probe. For more information, refer to Clean the Sample Probe and Mix Bars or Clean the R1 or R2 Reagent Probes.
- **b.** If cleaning does not correct the problem, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- **8** As the system activates the mix bar component, confirm that the mix bars align correctly in the wash wells. If a mix bar does not align correctly, contact Beckman Coulter.
- **9** Repeat steps 6 to 8 as required to inspect all probes and mix bars.
- **10** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

**2-14** B04779AB

### Replace the Deionized Water or Diluent in the Pre-dilution Bottle

- **1** Discard the water or diluent in the pre-dilution bottle, indicated by the 61. Diluent/W2 label near the R1 refrigerator.
- **2** Rinse the bottle twice with deionized water.
- **3** Fill the bottle with deionized water or diluent and replace the bottle on the analyzer.

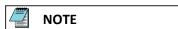
### **Inspect the Sample Probe Wash Solutions**

The sample probe wash solution bottles are located in the positions labeled 64. Det.-1/W2 and 65. Det.-2. For more information, refer to Dilution Ratios for Maintenance Solutions.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- 2% Wash solution
- Sodium hypochlorite solution (1.0%)
- 60 mL reagent bottle (2)



Sodium hypochlorite solution (1.0%) is only required for laboratories using the AU680 with high sample volume or dialysis patients.

If you have a normal volume of samples that are not highly viscous, fill the bottles with approximately 50 mL:

- Position 64. Det.-1/W2: 2% wash solution
- Position 65. Det.-2: 2% wash solution

If you have a high volume of samples or use the analyzer for dialysis patient samples, fill the bottles with approximately 50 mL:

- Position 64. Det.-1/W2: 2% wash solution
- Position 65. Det.-2: sodium hypochlorite solution (1.0%)

For more information on materials required, refer to Parts List for Analyzer Maintenance.

For more information, refer to Dilution Ratios for Maintenance Solutions.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.



When using sodium hypochlorite solution (1.0%) as a sample probe wash solution, follow these precautions:

- Prepare fresh sodium hypochlorite solution and completely replace the solution in the bottle once a day.
- If you will not use the analyzer for two days or longer, remove the solution from the system and discard the solution to prevent analyzer corrosion.
- If solution spills on the analyzer, clean the area with an absorbent tissue, and wipe dry with a clean absorbent tissue.
- Do not mix the solution with other chemicals. If the solution becomes contaminated, follow your laboratory procedure to dispose of the solution.
- **1** Remove each wash solution bottle and inspect the level of solution.
- **2** As required, fill each bottle to approximately 50 mL of the solution used in your laboratory.
- **3** Replace the bottle on the analyzer.
- **4** Close all analyzer doors and covers.

### **Inspect the Printer and Paper**

The printer is an optional part. Before you begin daily analysis, confirm that the printer is turned on and that there is enough paper in the printer.

For more information, refer to the manual supplied with the printer.

- **1** Confirm that the printer is on. The printer displays a ready message.
- **2** Confirm that there is enough paper in the printer.
- **3** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# **Inspect the Analyzer Status**

The Analyzer Status screen displays a color-coded overview of the system. The system monitors the status of the incubator, reagent refrigerators, the STAT table, deionized water tank, wash solution tanks, waste tanks, printer, and LIS communication.

The system monitors the ISE module and reagents when the ISE module is installed.

The colors of the system components indicate the status.

2-16 B04779AB

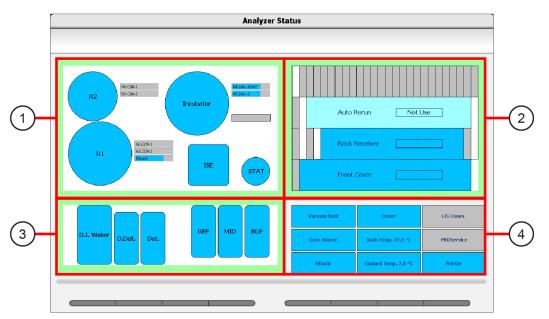
Table 2.1 Analyzer Status

Color	Status
Blue	No errors
Yellow or Orange	Non-fatal error. You can start the analyzer.
Red	Fatal error. You cannot start the analyzer.

### 1 Select Home > Analyzer Status.

The system displays the Analyzer Status screen.

Figure 2.12 Analyzer Status Screen



- 1. Analyzer Top status
- Rack Feeder status

- 3. Analyzer Front status
- I. Item status
- **2** Confirm that system components are within acceptable limits (blue). Investigate any yellow or red conditions.
  - **a.** Inspect the Analyzer Top status. Investigate any yellow or red conditions. For more information, refer to Analyzer Top Status.
  - **b.** Inspect the Rack Feeder status. Investigate any yellow or red conditions. For more information, refer to Rack Feeder Status.
  - **c.** Inspect the Analyzer Front status. Investigate any yellow or red conditions. For more information, refer to Analyzer Front Status.
  - **d.** Inspect each item status. Investigate any yellow or red conditions. For more information, refer to Item Status.

#### **Daily Startup**

Perform the ISE Startup (Option)

# **Perform the ISE Startup (Option)**

If your system includes an ISE module, confirm that sufficient ISE reagent is available and perform the ISE Daily Maintenance.

- 1 Inspect the ISE Reagents.
- **2** Replace the ISE Reagents.
- **3** Perform ISE Daily Maintenance.
  - a. Clean the ISE.
  - **b.** Calibrate the ISE.

### **Inspect the ISE Reagents**



If the ISE Buffer Solution, ISE MID Standard Solution, or ISE Reference Solution becomes empty during ISE sample analysis, the system can generate incorrect results. When the ISE Buffer Solution, ISE MID Standard Solution, and ISE Reference Solution become empty, the system does not go into *Stop* mode and continues to process samples.



### NOTE

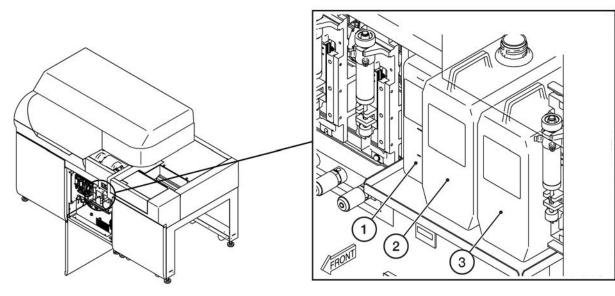
Confirm that the ISE reagent solution levels are sufficient for typical daily analysis before starting the sample processing.

If a reagent becomes empty during *Measure* mode, wait until the analyzer goes into *Standby* mode to replenish and prime the new reagent. Calibrate the ISE for all sample types in use.

- **1** Open the right front door of the analyzer.
- **2** Confirm that the ISE reagents are within the 90-day onboard stability limit.

2-18 B04779AB

Figure 2.13 ISE Reagents



- 1. ISE Reference Solution Bottle
- 2. ISE MID Standard Solution Bottle
- 3. ISE Buffer Solution Bottle
- **3** Confirm that the solution level is sufficient for typical daily analysis, or is above the ISE Reagent Short notification level (5.2 cm above the bottom of the bottle).



The number of samples the system can run after the alarm occurs for each reagent:

- ISE Buffer Solution 240 samples
- ISE MID Standard Solution 180 samples
- ISE Reference Solution 600 samples
- **4** Replace reagents as required. For more information, refer to Replace the ISE Reagents.
- **5** Close all analyzer doors and covers.

### **Replace the ISE Reagents**

Replace the ISE reagents when the on-board stability expires, the reagent expires, or the quantity of reagent is insufficient. The system displays an alarm message when an ISE reagent reaches the ISE Reagent Short notification level (5.2 cm above the bottom of the bottle). Replace the reagent before the bottle empties.

For on-board stability claims for the ISE, refer to the Chemistry Information Sheet.



### **CAUTION**

ISE Reference Solution is highly concentrated. Prevent contact between the ISE Reference Solution (bottle, cap, and aspiration tube) with the ISE Buffer Solution and ISE MID Standard Solution (bottle, cap, and aspiration tube).



#### **CAUTION**

Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

For more information on materials required, refer to Parts List for ISE Maintenance.

### Materials Required:

- ISE Buffer Solution
- ISE MID Standard Solution
- ISE Reference Solution
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the right front door of the analyzer.
- **3** Place the new bottle of reagent next to the analyzer and remove the cap.
- **4** Pull out the reagent bottle to replace.
- **5** Loosen the cap of the reagent bottle and remove the aspiration tube.



Do not touch the aspiration tube.

Dispose of the old solution according to your laboratory procedure.

- **6** Place the aspiration tube in the new bottle and tighten the cap.
- **7** Place the new bottle on the analyzer and push the bottle into position.
- 8 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **9** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **10** Select one of the following options. If all reagents are being replaced simultaneously, replace the reagents in the following order:
  - 1. For replacing ISE Buffer Solution, select **Buffer Prime**
  - 2. For replacing ISE MID Standard Solution, select MID/REF Prime

2-20 B04779AB

3. For replacing ISE Reference Solution, select MID/REF Prime

The system displays the Start dialog.

- **11** Select **OK**. Press the **TABLE ROTATION/DIAG** button to start the prime. The system primes the reagent for approximately 90 seconds.
- **12** Close all analyzer doors and covers.
- **13** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **14** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **15** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

#### Clean the ISE

Clean the sample pot and the electrode lines daily to prevent contamination and inaccurate results. This procedure requires approximately four minutes to complete.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle ISE Cleaning Solution. If the ISE Cleaning Solution contacts skin or clothes, rinse the affected area thoroughly with water. If the ISE Cleaning Solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.



If the analyzer does not run continuously, clean the ISE as part of the daily shutdown.

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- ISE Cleaning Solution
- Hitachi Cup
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the small STAT table cover.
- **4** Press the **TABLE ROTATION/DIAG** button to rotate the STAT table until the **CLEAN** position is accessible.

#### **Daily Startup**

Perform the ISE Startup (Option)

- **5** Fill the Hitachi cup with a minimum of 1 mL of ISE Cleaning Solution.
- **6** Place the Hitachi cup in the **CLEAN** position on the STAT table.



Wipe up ISE Cleaning Solution spills immediately. Follow your laboratory procedure.

- **7** Close the small STAT table cover.
- **8** Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.
- **9** Select **Cleaning (F5)**. The system displays the Start dialog.
- **10** Select **OK**. The system starts the cleaning operation.
- **11** When the cleaning operation is complete, remove the Hitachi cup from the STAT table and discard.
- **12** Close all analyzer doors and covers.

#### Calibrate the ISE

Calibrate the ISE once every 24 hours, following specific maintenance procedures, and when replacing the ISE reagents.



When the analysis is in process or the ISE status is *Busy*, do not open the STAT table covers to add Standard Solutions to the STAT table or place hands in the path of the sample probe.



Calibrating only serum or urine requires approximately four minutes to complete. Calibrating serum and urine together requires approximately seven minutes to complete.

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- Serum Standard Solution H
- Serum Standard Solution L
- Urine Standard Solution H and L
- Hitachi Cup (4)

2-22 B04779AB

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Perform a total prime. A total prime is required to clear the lines of ISE Cleaning Solution if you calibrate the ISE immediately after the Clean the ISE procedure.
  - **a.** Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.
  - **b.** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
  - c. Select **Total Prime**. The system displays the Start dialog.
  - d. Select OK.
  - **e.** Press the **TABLE ROTATION/DIAG** button to start the prime. The TABLE ROTATION/DIAG LED turns on after the priming is complete.
  - **f.** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **3** Lift the upper cover of the analyzer.
- **4** Open the small STAT table cover.
- **5** Press the **TABLE ROTATION/DIAG** button to rotate the STAT table until the **S-H**, **S-L**, **U-H**, and **U-L** positions are accessible.
- **6** Fill a Hitachi cup with approximately  $500 \mu L$  of Standard Solution as required for processing (determined by your laboratory processing serum, urine, or both sample types).
  - Serum Standard Solution Low
  - Serum Standard Solution High
  - Urine Standard Solution Low
  - Urine Standard Solution High
- **7** Place the Hitachi cups into the corresponding positions on the STAT table.
- **8** Close the small STAT table cover.
- 9 Select Home > Analyzer Maintenance > ISE Maintenance > Calibration. The system displays the ISE Maintenance: Calibration tab.

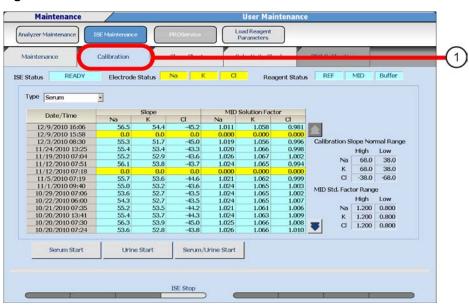


Figure 2.14 ISE Maintenance: Calibration Tab

- 1. Calibration tab
- **10** Select **Serum Start**, **Urine Start**, or **Serum/Urine Start** depending on the sample types to calibrate. The system displays the Start dialog.
- **11** Select **OK**. The system starts calibration.
- **12** When calibration is complete, confirm that the result for each electrode is within the ranges for the calibrated sample types.

The system highlights acceptable results in blue, and results that exceed the Calibration Slope Normal Range are yellow.

To determine calibration quality, compare the current results with previous results for consistency.

To switch from serum results to urine results, in **Type** select **Urine**.

- **13** Remove the Hitachi cups from the STAT table and discard.
- **14** Close all analyzer doors and covers.

# **Monitor the Reagent Status**

Monitor the reagent status to confirm the presence and status of reagents required for typical daily analysis. Replace reagents as needed.

Select Home > Reagent Management > Main.
The system displays the Reagent Management: Main tab.

2-24 B04779AB

Figure 2.15 Reagent Management: Main Tab

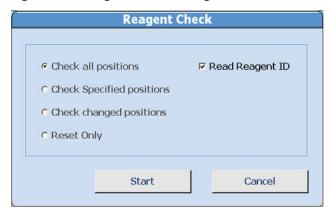
1. Reagent status

2. Test status

# 2 Select Reagent Check (F5).

The system displays the Reagent Check dialog.

Figure 2.16 Reagent Check Dialog



**Table 2.2** Reagent Check Dialog Options

Option	Description	
Check all positions	Determines the remaining volume of reagent at all positions, including the bottle position outside of the reagent refrigerator. Select this option as part of the daily startup, when changing any settings, changing the Group, and loading numerous reagents.	
Check specified positions	Determines the remaining volumes of reagent at the specified positions. Select this option when replacing a reagent bottle. If the reagent is an R1/R2, performs a reagent check for both the R1 and R2 reagent.	

Table 2.2 Reagent Check Dialog Options (Continued)

Option	Description	
Check changed positions	Determines the remaining reagent for any reagent ID that is new or has been moved since the previous reagent check.	
Reset Only	Select this option when the reagent refrigerator cover was only opened and closed without changing any reagent. The system resets to the latest volumes (shots) in the system memory.	
Read Reagent ID	Select this option for the system to read the reagent bar code label.	



### **NOTE**

If contamination prevention settings are programmed, the prevention settings are applied during a reagent check.



#### **NOTE**

When turning on the system, all tests initially show fewer than 30 shots without a volume indicator bar. Select **Reagent Check (F5)**, and then select **Check all positions** to determine the quantity of tests (shots) remaining.

**3** Select one of the reagent check options (refer to Figure 2.16 Reagent Check Dialog), and then select **Start**.

The system starts the reagent check. As the system progresses in the reagent check, the system displays the status **Checking** in the Reagent Status section (refer to Figure 2.15 Reagent Management: Main Tab), with the progress bar to indicate the progress. When the reagent check is complete, the status changes to **Checked**.



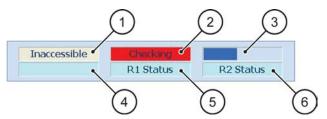
### **NOTE**

Select **Check all positions** once for daily startup to confirm all required reagents are onboard with sufficient volume for processing.

4 Review the Reagent Status section. For more information, refer to Figure 2.15 Reagent Management: Main Tab and Figure 2.17 Reagent Status. The colors on the screen indicate the status of the reagent refrigerator and reagent check.

If the system displays the status as yellow, orange, or red, review the Comment column in the Details tab.

Figure 2.17 Reagent Status



2-26 B04779AB

**Table 2.3** Reagent Status

	Status	Color	Description
1	Accessible	Light blue	Reagent bottles can be loaded
	Inaccessible	Gray	Reagent bottles cannot be loaded.
2	Unchecked	Red	The status of the reagent check.
	Checking	Red	
	Checked	Light blue	1
3	Progress bar	-	The system displays the progress of reagent check. The progress bar displays only when the system is performing the reagent check.
4	No Reagent	Orange	A reagent assigned to the Group is missing from the R1 or R2 refrigerator, the on-board stability is expired, the reagent is expired, or the bottle is empty.
	Reagent short	Yellow	Reagent volume is short (low).
	No display	Light blue	Necessary reagents are set.
5	R1 Status	Orange	The error level for reagents in the Reagent 1 refrigerator.
		Yellow	1
		Light blue	1
6	R2 Status	Orange	The error level for reagents in the Reagent 2 refrigerator.
		Yellow	
		Light blue	

**5** Review the Test Status section. For more information, refer to Figure 2.15 Reagent Management: Main Tab and Figure 2.18 Test Status. Confirm that required reagents are available and that all reagents have sufficient volume. Identify reagents to load.

Figure 2.18 Test Status

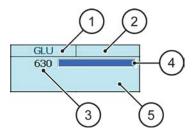


Table 2.4 Test Status

	Item	Description
1	Test name 1	The system displays test names in the output order programmed in the Group. ISE and non-dedicated LIH reagents are not displayed.

Table 2.4 Test Status (Continued)

	Item	Description	
2	Test name 2	If you program the same reagent for two tests, the system displays the second test name.	
3	Quantity of tests (shots) or volume remaining	The quantity of tests (shots) remaining or volume in mL. Select <b>Shot/Vol.</b> to change the display. Select <b>Type</b> to view the shots or volume for the specified sample type.	
4	Indicator	The remaining reagent volume. If more than one bottle is on the system, the total reagent volume displays. The length of the bar displays the maximum number of tests the system calculates in the Reagent Inventory screen, and estimates the reagent consumption required for the day.  Reagent quantity indicator bars: If Advanced Calibration is set to <b>No</b> and the Multi-Reagent Switch is set to <b>No</b> , the R1 indicator bar displays on top of the R2 indicator bar. In a 3-part reagent, the order of the bars is R1-1, R2-1, R1-2 from top to bottom. If Advanced Calibration is set to <b>Yes</b> and Multi-Reagent Switch is set to <b>Yes</b> , there is a single indicator bar even for an R1 and R2 test. Beckman Coulter recommends programming Multi-Reagent Switch to <b>Yes</b> .	
5	Color	<ul> <li>Orange - A reagent assigned to the Group is missing from the R1 or R2, the on-board stability is expired, the reagent is expired, or the bottle is empty.</li> <li>Yellow - Reagent volume is short (low).</li> <li>Light Blue - Required reagents are set.</li> <li>Gray - The test operation is programmed to No for the sample type displayed in Reagent Management &gt; Main. To change the sample type, select Type.</li> <li>Green - The remaining volume is less than the necessary volume determined by Reagent Inventory calculations.</li> </ul>	

- **6** Change the **Type** to view each sample type in use from the Main tab.
- 7 Select **Details** to review the Onboard Remaining, RB Stability Remaining, and Cal Stability Remaining columns for each reagent. The time listed in these columns must be sufficient for the expected processing volume. Identify reagents that are expired or low in volume, and the associated position on the reagent tray. For more information, refer to Replace the Reagents.

Review the Comment column and perform necessary corrective actions.

2-28 B04779AB

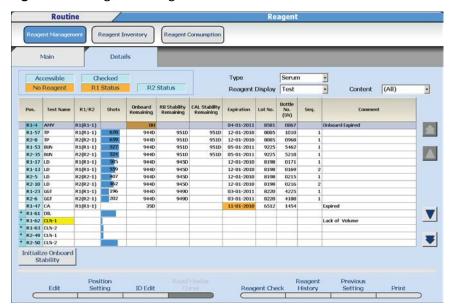


Figure 2.19 Reagent Management: Details Tab

Table 2.5 Reagent Management: Details Tab

Item	Description	
Туре	Serum, Urine, Other-1, Other-2, Whole Blood.	
Reagent Display	Displays test by test name (Test) or position (Position).	
Content	All or a specific test.	
Pos.	R1 or R2 reagent position.	
R1/R2	R1-1 and R2-1 are standard. R1-2 is for a 3-part reagent test.	
Shots	Quantity of tests remaining in the bottle. The blue indicator bar is proportional to the level in the bottle (0 to 100%).	
Onboard Remaining	Hours (H) or Days (D) remaining until the reagent on-board stability expires.	
RB Stability Remaining	Hours (H) or Days (D) remaining until the reagent blank stability expires.	
Cal Stability Remaining	Hours (H) or Days (D) remaining until the calibration stability expires.	
Expiration	The expiration date of the reagent lot number.	
Bottle No. (SN)	A unique 4-digit number to identify each bottle of reagent.	
Seq.	Sequence number 1 to 5 of the same reagent in the R1/R2.	
Comment	A caution or error message for the reagent.	
Edit (F1)	Edits the test name, lot number, bottle number, and bottle size for fixed reagents.	

Table 2.5	Reagent	Management:	Details Tab	(Continued)
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Item	Description
Position Setting (F2)	Assigns a position as Reagent ID or Fixed. The system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column.
ID Edit (F3)	Edits the 20-digit reagent ID. Use this option to edit the reagent ID after a reagent ID read error.
Read Master Curve (F4)	Scans the 2-dimensional reagent ID for master curve tests.
Reagent Check (F5)	Performs the reagent check.
Reagent History (F6)	Displays the lot number, bottle number, position, and on-board stability (hours) for 100 lines of data for R1 and R2 reagents.
Previous Setting (F7)	Displays the most recent reagent bottle position. Available only in <i>Pause</i> mode.
Print (F8)	Prints all the Details tab information.



### **NOTE**

The time remaining displays in hours (H) up to 72 hours, and days (D) over 72 hours.

If two tests are programmed to use one reagent, the RB Stability Remaining and Cal Stability Remaining display as lower Test No./higher Test No.

Selecting Initialize Onboard Stability resets the onboard stability for fixed reagents to the Onboard Stability Period programmed in Parameters > Specific Test Parameters. Using Edit (F1), enter the Lot No. and Bottle No. (SN) before the Initialize Onboard Stability function is operational.

- **8** Scroll to positions 61 through 65. Confirm that there is sufficient volume of each solution required.
  - R1-61 DIL: Deionized water or diluent for a dilution cuvette for Pre-Dilution or Repeat Dilution.
  - R1-62 CLN-1: If you program Contamination Parameters, the system uses cleaning solution 1.
  - R1-63 CLN-2: If you program Contamination Parameters, the system uses cleaning solution 2.
  - R2-49 CLN-1: If you program Contamination Parameters, the system uses cleaning solution 1.
  - R2-50 CLN-2: If you program Contamination Parameters, the system uses cleaning solution 2.
  - R1-64 DET-1: 2% Wash Solution for automatic sample probe cleaning.
  - R1-65 DET-2: 2% Wash Solution or sodium hypochlorite solution (1.0%) for automatic sample probe cleaning.

2-30 B04779AB

**<sup>9</sup>** Select **Type** from the Details tab to view any additional sample types in use.

**10** If reagent or required solution is missing, low, or empty, continue to Replace the Reagents.

### Replace the Reagents

Replace any reagent meeting any of the following conditions:

- Insufficient volume for the processing that day
- Onboard stability time remaining less than your laboratory requirements
- Expired

Remove the old reagent bottles and replace with a new set.

If the analyzer is in *Measure* mode and more than one sequence of bottles is on-board, the analyzer switches to the next bottle sequence when the current bottle sequence is empty, and not when the calibration or reagent is expired.



Bubbles in the reagent bottle can interfere with analysis. Inspect the reagent bottles for bubbles. Remove bubbles with a cotton-tipped applicator before loading the reagent.



Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

# IMPORTANT

Condensation can form on refrigerated reagent bottles. Inspect the reagent bottle opening and the bar code label area for condensation. Remove condensation with a clean, dry, lint-free absorbent tissue before loading the reagent.

If the bar code label is dirty or has moisture on it, the system cannot read the label. Inspect the bar code label and wipe off any dirt or moisture. If the system still cannot read the label, enter the reagent ID manually. For more information, refer to Edit a Reagent ID.



Insert partitions as needed for 15 mL, 30 mL, and 60 mL bottles.

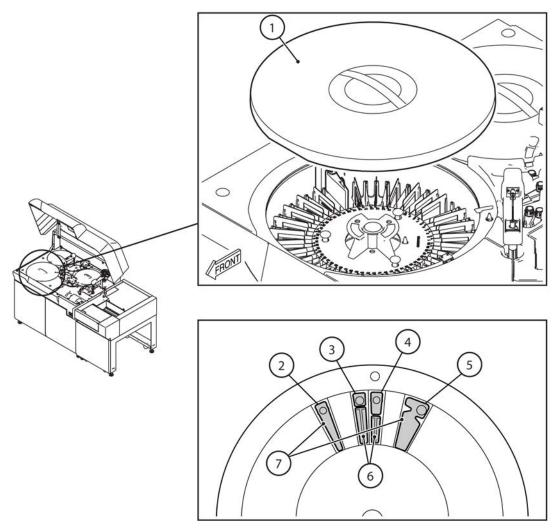
When placing 30 mL and 15 mL bottles on the reagent tray, use a partition and adapter to secure the bottles correctly. Confirm that the partitions and adapters are correctly inserted in the reagent tray. For more information, refer to Reagents and Add Adapters to the Reagent Tray.

The 120 mL bottles occupy two positions in the reagent trays. For the R1 refrigerator, remove a partition between the two fixed partitions for the 120 mL bottles. For the R2 refrigerator, remove a partition for the 120 mL bottle.

For two-part reagents, the reagent label indicates whether the reagent goes into the R1 or R2 refrigerator.

- **1** Lift the upper cover of the analyzer.
- **2** Lift and remove the reagent refrigerator covers.

Figure 2.20 Reagent Refrigerator



- 1. Reagent Refrigerator Cover
- 2. Reagent Bottle (60 mL)
- 3. Reagent Bottle (15 mL)
- 4. Reagent Bottle (30 mL)

- 5. Reagent Bottle (120 mL)
- 6. Adapters
- 7. Partitions

2-32 B04779AB

**<sup>3</sup>** Remove the on-board expired, expired, insufficient volume, and empty reagent bottles from each refrigerator.

The system displays the reagent positions on the Details tab. The system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column. For more information, refer to Assign a Reagent Position.

**4** Place the new bottles in the correct refrigerator. Use adapters and partitions as needed. For more information, refer to Reagents.



Confirm that 15 mL reagent bottles are placed on the reagent tray with the bar code label facing out. Incorrectly loaded bottles can damage the bottle or the reagent probe.



Place R1 bottles in the R1 refrigerator and R2 bottles in the R2 refrigerator.

If the bottle has a reagent ID, place the bottle in any available (not assigned) position in the R1 or R2 refrigerator.

If the bottle does not have a reagent ID, place the bottle in the appropriate assigned position. The system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column. For more information, refer to Assign a Reagent Position.

- **5** Replace the refrigerator covers.
- **6** Close all analyzer doors and covers.
- 7 After replacing reagents, select Reagent Check (F5), select the appropriate option, and then select Start. For more information, refer to Figure 2.16 Reagent Check Dialog.
- **8** When the reagent check is complete, review the Main and Detail tabs to confirm that all reagents are ready for processing.

### **Calibrate Tests**

The system automatically orders (requisitions) reagent blank and calibration for all tests with:

- Reagent blank or calibration expired
- Reagent blank or calibration expired soon.
- New bottle or lot number for the reagent (if you are using Advanced Calibration)
- Reagent blank or calibration failed



### **NOTE**

The expired-soon period is an operator-defined quantity of hours programmed in System Maintenance. The default setting is 180 minutes. For more information, contact Beckman Coulter.



#### **NOTE**

The automatic reagent blank and calibration order (requisition) occurs after a reagent check for analysis from racks and after selecting **Auto CAL/QC Requisition (F3)** for analysis from racks and the STAT table.



### **NOTE**

After the system performs a reagent check, the QC order (requisition) occurs with the Default QC Profile for analysis from racks. Selecting **Auto CAL/QC Requisition (F3)** automatically orders (requisitions) the same tests for QC that are ordered (requisitioned) for calibration for analysis from the racks and the STAT table.



#### **NOTE**

To determine the tests to calibrate, review the Comment column in **Reagent Management > Details**.

Calibration includes a reagent blank and calibration. You can perform calibration using the blue and yellow racks or the STAT table.



#### **NOTE**

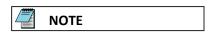
If you have a standalone analyzer, load calibrators in the blue and yellow racks. For more information, refer to Order (Requisition) and Perform Calibration from the Racks. If the AU680 connects to a laboratory automation system, use the STAT table to load calibrators. For more information, refer to Order (Requisition) and Perform Calibration from the STAT Table.



### NOTE

Before a profile is available to order (requisition), program calibration profiles in **Menu List > Parameters > Common Test Parameters > Profile > RB/Calibration**. You can program a maximum of 100 profiles (including daily, weekly, and monthly calibration requirements). For more information, refer to Create a Reagent Blank or Calibration **Profile**.

2-34 B04779AB



Before a test is available to order (requisition) by bottle sequence number in **Individual Requisition (F3)**, program the test for Advanced Calibration in **Menu List > Parameters > Calibration Parameters > Calibration Specific**. For more information, refer to the AU680 Reference Manual.

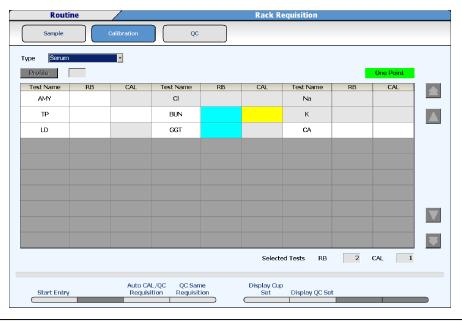
- Order (Requisition) and Perform Calibration from the Racks
- Order (Requisition) and Perform Calibration from the STAT Table

### Order (Requisition) and Perform Calibration from the Racks

1 Select Home > Rack Requisition Sample > Calibration.

The system displays the Rack Requisition: Calibration screen.

Figure 2.21 Rack Requisition: Calibration Screen



**2** In **Type**, select the sample type.

The system displays the tests automatically ordered (requisitioned) for calibration in yellow and reagent blank in blue for the selected sample type.



If you did not perform a reagent check, select **Auto CAL/QC Requisition (F3)** to select the automatic reagent blank and calibration order (requisition). Selecting **Auto CAL/QC Requisition (F3)** automatically orders (requisitions) the same tests for QC that are ordered (requisitioned) for calibration.

**3** Confirm that the automatic order (requisition) is correct for the processing.

- If the order (requisition) is correct, continue to step 4.
- To change the order (requisition):
- a. Select Start Entry (F1).

The system changes the screen to editing mode.

- To select a profile, select **Profile**. Select a profile, and then select **OK**.
- To select a specific test, select the test from the RB or CAL column.



Selecting from the RB column orders (requisitions) only a reagent blank. Selecting from the CAL column orders (requisitions) a reagent blank and calibration.

- To order (requisition) sequential bottles of the same test, select **Individual Requisition (F3)**.
  - To select a specific test and bottle sequence, select the RB or CAL column.
  - To order (requisition) all bottles for the selected test, select Select All by Test.
  - To order (requisition) all bottles for all tests, select **Select All**.
  - To save the order (requisition), select **Close**.
  - To cancel the order (requisition), select **Cancel**.
- **b.** Select **Entry (F1)** to save the order (requisition). Select **Exit (F2)** to cancel the order (requisition).
- 4 Select **Display Cup Set (F5)** to display the reagent blank, calibrators, racks, and positions required for reagent blank and calibrators.

Load the reagent blanks and calibrators according to the list in the blue and yellow racks. Select **Close** to close the dialog.



In the Display CAL Racks dialog, the Volume ( $\mu$ L) is the sample volume determined by the ordered (requisitioned) tests. The dead volume is not included.



If calibrator Barcode Operation is enabled, the system does not display a rack number for the calibrator racks.

**5** Load the racks on the rack supply component. Load the blue rack first, followed by the yellow racks.

6 Select Start .

2-36 B04779AB

### Order (Requisition) and Perform Calibration from the STAT Table

When the AU680 connects to a laboratory automation system, perform calibration from the STAT table. The STAT table has numerous options for calibrating, including Barcode Operation and Fixed, Variable, or Free calibrator positions. For more information, refer to the AU680 Reference Manual. For more information on programming the STAT table for calibration, contact Beckman Coulter.

In most cases when the AU680 connects to a laboratory automation system, Beckman Coulter recommends programming the STAT table as follows to maximize ease of use and throughput on the STAT table if the laboratory automation system is not functioning:

- Both Calibrator and QC Barcode Operation are enabled in the Calibrators and Controls screens.
- STAT table positions 1 to 22 are programmed as Free positions.



The system does not automatically order (requisition) calibration from the STAT table after a reagent check.

Select Home > STAT Status > Calibration.
The system displays the STAT Requisition: Calibration screen.



Figure 2.22 STAT Requisition: Calibration Screen

- **2** In **Type**, select the sample type.
- 3 Select Auto CAL/QC Requisition (F3) to order (requisition) the automatic reagent blank and calibration orders (requisitions).

The system displays the Calibration dialog.

#### 4 Select OK.

The system displays the tests automatically ordered (requisitioned) for calibration in yellow and reagent blank in blue for the selected sample type.



#### **NOTE**

The same tests are automatically ordered (requisitioned) for QC analysis.

- **5** Confirm that the automatic order (requisition) is correct for the processing.
  - If the order (requisition) is correct, continue to step 6.
  - To change the order (requisition):
  - a. Select Start Entry (F1).

The system changes the screen to editing mode.

- To select a profile, select **Profile**. Select a profile, and then select **OK**.
- To select a specific test, select the test from the RB or CAL column.



Selecting from the RB column orders (requisitions) only a reagent blank. Selecting from the CAL column orders (requisitions) a reagent blank and calibration.

- To order (requisition) sequential bottles of the same test, select **Individual Requisition (F3)**.
  - To select a specific test and bottle sequence, select the RB or CAL column.
  - To order (requisition) all bottles for the selected test, select Select All by Test.
  - To order (requisition) all bottles for all tests, select **Select All**.
  - To save the order (requisition), select **Close**.
  - To cancel the order (requisition), select **Cancel**.
- **b.** Select **Entry (F1)** to save the order (requisition). Select **Exit (F2)** to cancel the order (requisition).



**NOTE** 

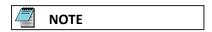
Select **QC Same Requisition (F4)** to order (requisition) QC for the same tests that are ordered (requisitioned) for calibration.

6 Select **Display Cup Set (F5)** to display the required calibrators and volumes determined by the order (requisition).

2-38 B04779AB



In the Cal/QC Position dialog, the Volume ( $\mu$ L) is the required sample volume determined by the ordered (requisitioned) tests. The dead volume is not included.

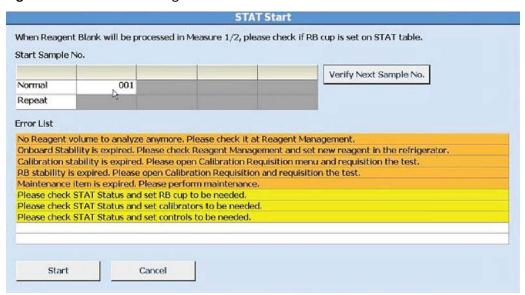


If Barcode Operation is not enabled, the system displays calibrator positions on the STAT table in the Cal/QC Position dialog.

- 7 Load the required reagent blank and calibrators on the STAT table. Press the **TABLE ROTATION/DIAG** button to rotate the table.
  - If the STAT table is programmed for Free positions, place the calibrators with bar code labels in any Free position.
  - If the Barcode Operation is enabled with Fixed or Variable Calibrator positions, place the calibrators in any calibrator position according to the Kind column in the Cal/QC Position dialog.
  - If the Barcode Operation is not enabled, place the reagent blank and calibrators in the correct positions according to the Pos. column in the Cal/QC Position dialog.
- **8** Select **STAT Status**, and then select **STAT Start (F1)**.

The system displays the STAT Start dialog.

Figure 2.23 STAT Start Dialog



**9** Review the Error List section of the dialog. Confirm that the required reagent blank and calibrators are on the STAT table.



To make any corrections, select **Cancel**. Make the corrections and select **STAT Start (F1)**.

В04779АВ 2-39

#### 10 Select Start.

The system rotates the STAT table and detects the presence of tubes to identify reagent blank and calibrators. If there are no STAT table errors, the system begins analysis. If there are STAT table errors, review the errors in the STAT Start dialog. Select **Start** to begin analysis, or **Cancel** to perform corrective actions.

# **Process Quality Control (QC)**

Perform Quality Control on the schedule determined by your laboratory protocol. Run control materials with each new calibration, with each new reagent lot, and after specific maintenance or troubleshooting activities. If you find any trends or sudden shift in results, review all operating settings. Follow your laboratory guidelines for corrective action if the QC results do not recover within the specified limits.

- Order (Requisition) and Perform Quality Control (QC) from the Racks
- Order (Requisition) and Perform Quality Control (QC) from the STAT Table



### **NOTE**

If you have a standalone analyzer, process QC from the green racks. For more information, refer to Order (Requisition) and Perform Quality Control (QC) from the Racks. If the AU680 connects to a laboratory automation system, use the STAT table to process QC. For more information, refer to Order (Requisition) and Perform Quality Control (QC) from the STAT Table .



### **NOTE**

In Reagent Management, if you perform any of the **Reagent Check (F5)** options, the system automatically orders (requisitions) the default QC profile for QC analysis from racks. The default QC profile is not available on the STAT table.



#### **NOTE**

Program a QC order (requisition) profile in **Menu List > Parameters > Common Test Parameters > Profile > QC**. For more information, refer to Create a QC Profile. The following specific profile numbers are designated as default QC profiles for each sample type and Group.

Table 2.6 Default QC Order (Requisition) Profile Numbers

Profile Number	Sample Type	Group
87	Serum	1
88	Serum	2
89	Serum	3
90	Urine	1

2-40 B04779AB

 Table 2.6
 Default QC Order (Requisition) Profile Numbers (Continued)

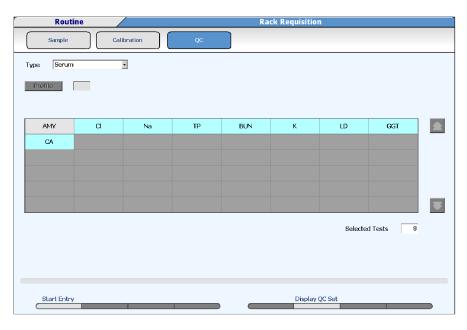
Profile Number	Sample Type	Group
91	Urine	2
92	Urine	3
93	Other-1	1
94	Other-1	2
95	Other-1	3
96	Other-2	1
97	Other-2	2
98	Other-2	3
99	Whole blood	1, 2, and 3

## Order (Requisition) and Perform Quality Control (QC) from the Racks

# 1 Select Home > Rack Requisition Sample > QC.

The system displays the Rack Requisition: QC screen.

Figure 2.24 Rack Requisition: QC Screen



2 In **Type**, select the sample type.

The system displays the tests automatically ordered (requisitioned) for QC in blue.



Tests are automatically ordered (requisitioned) for QC after the following:

- You perform a reagent check. This orders (requisitions) the Default QC profile.
- You select Auto CAL/QC Requisition (F3) or QC Same Requisition (F4) in the Calibration screen. This orders (requisitions) the same QC tests as were ordered (requisitioned) for reagent blank or calibration.
- **3** Confirm that the automatic QC order (requisition) is correct for the processing.
  - If the order (requisition) is correct, continue to step 4.
  - To change the order (requisition):
  - a. Select Start Entry (F1).

The system changes the screen to editing mode.

- To clear the tests for the default QC profile orders (requisitions), select **Deselect All Tests (F6)**.
- To select a profile, select **Profile**. Select a profile, and then select **OK**.
- To select a specific test, select the test.
- To order (requisition) sequential bottles of the same test, select **Individual Requisition (F3)**.
  - To select a specific test and bottle sequence, select the test.
  - To order (requisition) all bottles for the selected test, select Select All by Test.
  - To order (requisition) all bottles for all tests, select **Select All**.
  - To save the order (requisition), select **Close**.
  - To cancel the order (requisition), select **Cancel**.
- **b.** Select **Entry (F1)** to save the order (requisition). Select **Exit (F2)** to cancel the order (requisition).
- 4 Select **Display QC Set (F6)** to display the required control materials, racks, and positions.
- 5 Load the control materials in the green racks according to the list. Select Close.



In the Display QC Racks dialog, the Volume ( $\mu$ L) is the required sample volume determined by the ordered (requisitioned) tests. The dead volume is not included.



If QC Barcode Operation is enabled, the system does not display a rack number for the QC racks.

- **6** Load the racks on the rack supply component.
- 7 Select Start

2-42 B04779AB

### Order (Requisition) and Perform Quality Control (QC) from the STAT Table

When the AU680 connects to a laboratory automation system, perform QC from the STAT table. The STAT table has numerous options for performing QC from the STAT table, including Barcode Operation and Fixed, Variable, or Free control positions on the table. For more information, refer to the AU680 Reference Manual.

For more information on programming the STAT table for controls, contact Beckman Coulter.

In most cases when the AU680 connects to a laboratory automation system, Beckman Coulter recommends programming the STAT table as follows to maximize ease of use and throughput on the STAT table if the laboratory automation system is not functioning:

- Both Calibrator and QC Barcode Operation are enabled in the Calibrators and Controls screens.
- STAT table positions 1 to 22 are programmed as Free positions.

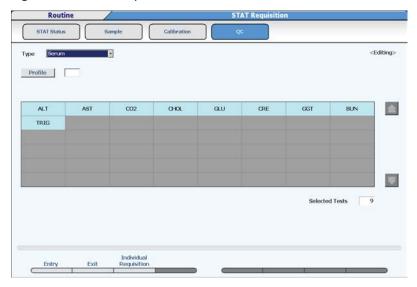


Manually order (requisition) QC before QC analysis from the STAT table. QC orders (requisitions) are not automatic from the STAT table.

## 1 Select Home > STAT Status > QC.

The system displays the STAT Requisition: QC screen.

Figure 2.25 STAT Requisition: QC Screen



2 In **Type**, select the sample type.



If you selected **Auto CAL/QC Requisition (F3)** or **QC Same Requisition (F4)** in **STAT Status > Calibration**, the tests ordered (requisitioned) for the calibration are also ordered (requisitioned) for QC (the system highlights the tests in blue).

**3** Select **Start Entry (F1)** to order (requisition) QC tests.

The system changes the screen to editing mode.

- To select a profile, select **Profile**. Select a profile, and then select **OK**.
- To select a specific test, select the test.
- To order (requisition) sequential bottles of the same test, select **Individual Requisition (F3)**.
  - To select a specific test and bottle sequence, select the test.
  - To order (requisition) all bottles for the selected test, select **Select All by Test**.
  - To order (requisition) all bottles for all tests, select **Select All**.
  - To save the order (requisition), select **Close**.
  - To cancel the order (requisition), select **Cancel**.
- 4 Select Entry (F1) to save the order (requisition). Select Exit (F2) to cancel the order (requisition).
- **5** Select **Display Cup Set (F5)** to display the list of required control materials and volumes determined by the order (requisition).



#### NOTE

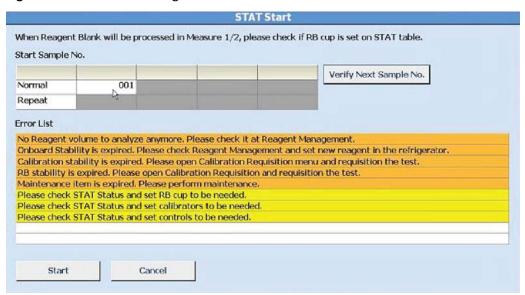
In the Cal/QC Position dialog, the Volume ( $\mu$ L) is the required sample volume determined by the ordered (requisitioned) tests. The dead volume is not included.

- **6** Load the required control materials on the STAT table. Press the **TABLE ROTATION/DIAG** button to rotate the table.
  - If the STAT table is programmed for Free positions, place the control materials with bar code labels in any Free position.
  - If the QC Barcode Operation is enabled with Fixed or Variable Control positions, place the control materials in any control position according to the Kind column in the Cal/QC Position dialog.
  - If the QC Barcode Operation is not enabled, place the control materials in the correct positions according to the Pos. column in the Cal/QC Position dialog.
- 7 Select STAT Status, and then select STAT Start (F1).

The system displays the STAT Start dialog.

2-44 R04779AB

Figure 2.26 STAT Start Dialog



**8** Review the Error List section of the dialog. Confirm that the required control materials are on the STAT table.



To make any corrections, select **Cancel**. Make the corrections and select **STAT Start (F1)**.

#### 9 Select Start.

The system rotates the STAT table and detects the presence of tubes to identify control materials. If there are no STAT table errors, the system begins analysis. If there are STAT table errors, review the errors in the STAT Start dialog. Select **Start** to begin analysis, or **Cancel** to perform corrective actions.

### **Start Analysis**

The reaction time is approximately 8 minutes and 33 seconds for the first result to be obtained after the sample is dispensed. The system can sample another test every 4.5 seconds.

When the AU680 connects to a laboratory automation system, add an extra 4.5 seconds for every sample. The extra time allows the sample to move from the sample aspiration position, and a new sample to advance to the sample aspiration position.

You can print and view results on the monitor.

### **Start Rack Analysis**

**1** Load sample racks (white, red, or orange) on the rack supply component.

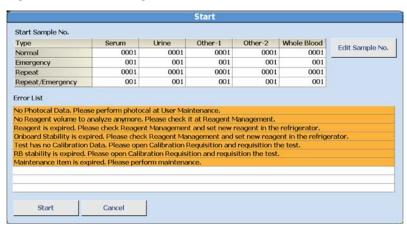
**2** To display the Start dialog with an error list for any errors, select **Start**. Review any errors carefully and perform necessary corrective actions before you start analysis. If an error is in red, it is necessary to perform the corrective actions before you can start the analyzer.



Select **Edit Sample No.** to edit the starting sample number. Editing the starting sample number is only necessary in Sequential analysis.

**3** Select **Start**. If the system does not detect any errors, the system initializes and analysis starts. The mode changes from *Standby* to *Measure 1*.

Figure 2.27 Start Dialog



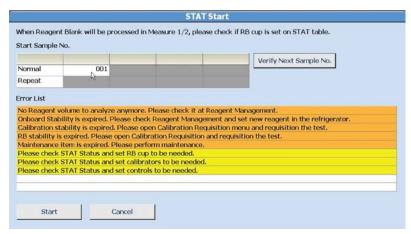
### **Start STAT Table Analysis**

For more information on processing STAT samples, refer to Enter Manual Orders (Requisitions) for Priority STAT Samples and Processing Priority STAT Samples.

- 1 Confirm that the amber STAT TABLE LED is not on or blinking, and then open the small STAT table cover.
- 2 Select STAT Status > STAT Start (F1). Review the Error List in the STAT Start dialog. Confirm that the required samples are on the STAT table.

2-46 B04779AB

Figure 2.28 STAT Start Dialog



- **3** Close the small STAT table cover.
- 4 Select **Start** to initiate the automatic STAT table check (detects samples), or select **Cancel** to take corrective actions.
- If there are no errors specific to the STAT table after the STAT table check, analysis starts. If there are STAT table errors, review the errors in the STAT Start dialog. Select **Start** to begin analysis, or select **Cancel** to perform corrective actions.



If the AU680 connects to a laboratory automation system:

- The AU680 must be in *Measure* mode before you start the laboratory automation. Select the **Start** button. When in *Measure* mode, the system performs analysis whenever a sample is carried to the AU680 from the laboratory automation.
- The AU680 remains in *Measure* mode, even after sample analysis is complete, until
  you select **Feeder Stop**. After you select **Feeder Stop**, the mode changes to *Measure*2, and then to *Standby*.

# **Daily Startup**

Start Analysis

2-48 B04779AB

# **Program a New Test**

Program the new test using the chemistry setting sheet. For more information, refer to the AU680 Reference Manual.

Test numbers 1 to 120 are pre-programmed as closed or open test numbers.

- Closed Test Numbers Beckman Coulter test parameters are available on a validated CD that a Beckman Coulter representative loads during installation. The Beckman Coulter tests are loaded onto closed test numbers. Closed test numbers reduce manual programming time and possible programming errors.
- Open Test Numbers The system supports the ability to add tests not from Beckman Coulter. Open test numbers are available for reagents not from Beckman Coulter.
- 1 Select Menu List > Parameters > Common Test Parameters > Test Name.
  - a. Select Edit (F1).
  - **b.** In **Name**, enter the name (maximum of 6 characters).



Changing the test name affects all results associated with that test number. Any previously reported results (with the old test name) are assigned the new test name. Use caution when changing the test name.

Do not change the test name without noting the time and date that the change occurred and then confirming any results printed before this time are reviewed and correctly identified.

Tests are processed on a sample in the test number order (1 to 120) displayed, with some exceptions. For information on contamination prevention, refer to the AU680 Reference Manual.

- **c.** (Optional) In **Long Name**, enter the name (maximum of 20 characters).
- **d.** For all markets except Japan: In **Reagent ID**, enter the first 3 digits of the reagent ID, or refer to the chemistry setting sheet for the reagent ID 3-digit code.
  - For the Japan market, the reagent ID includes the manufacturer ID and test code. In **Manufacturer ID**, enter the first 3 digits of the reagent ID. In **Test Code**, enter the 2 digits of the reagent ID following the first 3 digits. Refer to the chemistry setting sheet for the manufacturer ID and test code.
- **e.** In **Alarm Shots**, enter the remaining test number to generate a **Reagent Short** alarm. The default is 32.

- **f.** In **Multi-Reagent Switch**, select **Yes**. The Multi-Reagent Switch allows the analyzer to switch to a new sequence of R1 or R2 when either the R1 or R2 of a sequence becomes empty.
- g. Confirm that the information is correct, and then select **Confirm (F1)**.

#### 2 Select **Group of Tests**.

- **a.** In **Group**, select Group 1, 2, or 3.
- b. Select Edit (F1).
- c. Select Test Item Setting (F5).
- **d.** Select the test to add to the Group. The system displays the test name in blue. Select **Close**.
- **e.** To change the print order:
  - 1. Select a test to enable Forward (F2) and Backward (F3).
  - 2. Move the test in the Group to change the print order.
- **f.** Confirm that the information is correct, and then select **Confirm (F1)**.

### **3** (Optional) Select **Profile**.

- a. Select Edit (F1).
- **b.** Select **Sample**, **RB/Calibration**, and **QC** to add the test to any required profile.
- c. In Type, select the sample type.Confirm the sample type for each profile.



#### **NOTE**

In the Sample tab, you can program an operator-defined default profile (number 0) for each sample type. The system uses the sample default profile when there is no order (requisition) available for a sample, for example with a sample ID read error. In the QC tab, you can program default QC profiles (numbers 87 to 99) for each sample type and Group. The QC default profile is the automatic QC order (requisition) made after a reagent check.

- **d.** In **Profile Name**, select a profile.
- **e.** Select the test. The system displays the selected tests in blue.
- **f.** Confirm that the information is correct, and then select **Confirm (F1)**.

### 4 Select Menu List > Parameters > Specific Test Parameters > General.

- a. Select Edit (F1).
- **b.** In **Test Name**, select the test name.
- **c.** In **Type**, select the sample type.
- **d.** In **Operation**, confirm that **Yes** is selected for the sample type.
- **e.** Enter the specific test parameters from the chemistry setting sheet.
- **f.** Confirm that the information is correct, and then select **Confirm (F1)**.

3-2 B04779AB

# NOTE

The system can display the parameters for a maximum of 6 tests at a time for verification. Select **List Display (F7)**. In **Type**, select the sample type. Select a maximum of 6 tests from the test list, and then select **Display**. The parameters for the selected tests display. Clear the tests in blue in the List Display dialog to select and display other tests.

#### 5 Select Range.

- a. In **Test Name**, select the test name.
- **b.** In **Type**, select the sample type.
- c. Select Edit (F1).
- **d.** Select **Set Decimal Places (F5)**, and then select **0** to **4** for the decimal place for the results.
- e. Select Close.
- f. In Value/Flag:
  - Select **Value** to access **Specific Ranges** to set the high (H flag) and low ranges (L flag).
  - Select **Flag** to access **Level** to set a positive limit (P flag) or negative limit (N flag). This setting is typically used for drugs of abuse testing.
- g. Use Specific Ranges to set a reference range to generate high (H) and low (L) flags.
  - In 1 to 6, enter a range determined by sex and age.
  - In 7, **No demographics**, enter a generic reference range. The system uses the generic reference range for samples without patient demographic information (age and sex).
  - In 8, **Not within expected values**, the system uses the **Not within expected values** reference range for a sample with patient demographic information (age or sex), but the age or sex information did not meet the age and sex defined in the specific range 1 to 6.
- **h.** (Optional) Use **Panic Value** to set a range to generate a panic alarm and pl or ph flags.
- i. In **Unit**, enter the units. If the units are formatted on the report, the system prints the units.
- j. Confirm that the information is correct, and then select **Confirm (F1)**.

#### 6 Select Menu List > Parameters > Calibration Parameters > Calibrators.

- If it is not necessary to program a new calibrator material, continue to step 7.
- If it is necessary to program a new calibrator material:
- a. Select Edit (F1).
- **b.** Select an available calibrator **No.** and **Type**.
- c. Enter the Calibrator Name, Calibrator ID, Lot No., and Expiration.



The **Calibrator Name** identifies the calibrator material associated with the calibrator **No**. If Barcode Operation is enabled, it is necessary to enter the **Calibrator ID**. The **Lot No**. and **Expiration** are optional fields.

**d.** Confirm that the information is correct, and then select **Confirm (F1)**.

### 7 Select Calibration Specific.

- a. In **Test Name**, select the test name.
- **b.** In **Type**, select the sample type.
- c. Select Edit (F1).
- **d.** Refer to the chemistry setting sheet to determine if the **Calibration Type** is **AB** or **MB**, and enter calibration-specific parameters.

### — If the Calibration Type is AB:

- Refer to the chemistry setting sheet for the parameters for Formula, Slope Check, Factor Range, Allowable Range Check, Advanced Calibration, Lot Calibration, and Stability.
- For **Counts** (replicates), enter a number from 1 to 4. For more information, refer to the AU680 Reference Manual.
- Select the calibrator material from **Calibrator**.
- For **Conc**, enter the calibrator concentration from the calibrator insert (available in the calibrator kit).
- If the Calibration Type is **MB**:
  - Refer to the chemistry setting sheet for the settings for Formula, Allowable Range Check, Advanced Calibration, MB Type Factor, and Stability.
  - For **Counts** (replicates), enter a number from 1 to 4. For more information, refer to the AU680 Reference Manual.
- e. Confirm that the information is correct, and then select **Confirm (F1)**.



If you process calibration on the STAT table, program the STAT Table Calibration screen. For information on programming the STAT table for calibration, refer to the AU680 Reference Manual. If the AU680 connects to a laboratory automation system, calibration from the STAT table is the only option.

#### 8 Select Menu List > Parameters > QC Parameters > Controls.

- If it is not necessary to program a new control material, continue to step 9.
- If it is necessary to program a new control material:
- a. Select Edit (F1).
- **b.** Select an available **QC No.** and **Type**.
- c. Enter the Control Name, ID, Lot No., Expiration, and STAT Uses.

3-4 B04779AB



The **Control Name** identifies the control material associated with the **QC No**. If Barcode Operation is enabled, it is necessary to enter the **Control ID**. The **Lot No.**, **Expiration**, and **STAT Uses** are optional fields.

- **d.** Confirm that the information is correct, and then select **Confirm (F1)**.
- 9 Select QC Specific.
  - a. Select Preset.
  - **b.** In **Test Name**, select the test name.
  - **c.** In **Type**, select the sample type.
  - d. Select Edit (F1).
  - e. In Control, select the QC name.
  - f. In Multi/Single, select Multi or Single.
  - **g.** Use the QC package insert or known values to enter the **Mean**, **SD**, and **Range**. The system determines that QC is in or out of these preset ranges when the QC Mode is set to **Preset** (on the Check tab).
    - 1. In **Mean**, enter the QC mean.
    - 2. In **SD**, enter a 1 SD value.
    - 3. In **Range**, enter the value of the range. The range is the high value minus the low value.
  - **h.** Confirm that the information is correct, and then select **Confirm (F1)**.



If you process QC on the STAT table, program the STAT Table QC screen. For information on programming the STAT table for QC, refer to the AU680 Reference Manual. If the AU680 connects to a laboratory automation system, QC from the STAT table is the only option.

**10** Select Menu List > System > Format > List Format.



Do not change any parameters for items in **Basic Condition**, **Print Information**, or **Layout**. These parameters affect the format of the printout.

### 11 Select Test Item.

- a. Select Edit (F1).
- **b.** In **List Name**, select the required report or list. Select the test to add it to the report or list. When the test is selected, the system displays the test in blue.



#### **NOTE**

Before the tests print on the printout, add the new test to any required realtime printouts (reagent blank, calibration, QC, and samples).

- c. Confirm that the information is correct, and then select **Confirm (F1)**.
- 12 Select Menu List > Parameters > Misc. > Contamination Parameters.

Contact Beckman Coulter for test specific contamination parameters information.

- a. Select Edit (F1).
- b. Program the Contamination Avoidance Parameters as required for the Preceding Test Name, Following Test Name, Reagent Probe Cleaner Kind, Wash Count, Effective of Water Cleaning, Mixer, and Cuvette.
- **c.** Confirm that the information is correct, and then select **Confirm (F1)**.
- 13 If the system is using online communication with a laboratory information system, program an online test number. Select Menu List > System > Online > Online Test No.
  - a. Select Edit (F1).
  - **b.** Enter the **Online Test No**. The combination of the online test number and test must be the same as the laboratory information system. Set the number as a blank when online communication is not required.



When the test number on the laboratory information system and the online test number are different, the data cannot transmit correctly.

- c. Confirm that the information is correct, and then select **Confirm (F1)**.
- **14** Run the test to confirm the programming.
  - **a.** Load the reagent and any required cleaning solution on the analyzer.
  - **b.** Perform a reagent check.
  - **c.** Confirm that the system orders (requisitions) calibration for the new test.
  - **d.** If the test is not added to the default QC order (requisition), order (requisition) QC on the new test.
  - e. Perform a reagent blank, calibration, and QC on the new test.
  - f. Review the printout and confirm that the reagent blank, calibration, and QC data are correct.

### **Create a Profile**

A profile is a group of tests that are typically ordered (requisitioned) at the same time. Using a profile reduces the quantity of selections needed, as a single profile is selected instead of multiple tests. A maximum of 100 profiles (Number 0 to Number 99) can be programmed for samples, reagent blank, calibration, and QC. A maximum of 99 tests can be

3-6 B04779AB

programmed in a profile. The quantity of sample blank tests, LIH, and sample type limits the quantity of tests that can be programmed in a profile.

Each profile is assigned a profile name.

You cannot select unavailable tests.

For more information, contact Beckman Coulter.

### **Create a Sample Profile**

Profile 0 is the Default profile in the Sample tab. Profile 0 is automatically performed in the following situations:

- A bar code label read error occurs.
- No order (requisition) found for a sample.
- Online errors.

You can only select ISE tests when the sample type is **Serum** or **Urine**.

1 Select Menu List > Parameters > Common Test Parameters > Profile > Sample.

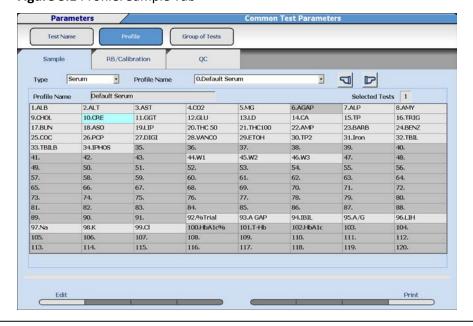


Figure 3.1 Profile: Sample Tab

- 2 Select Edit (F1).
- **3** In **Type**, select the sample type.
- 4 In **Profile Name**, select a profile number from 0 to 99.
- **5** For **Profile Name**, enter a profile name with a maximum of 20 characters.
- **6** Select the tests to include in the profile. The system displays selected tests in blue.

**7** Confirm that the information is correct, and then select **Confirm (F1)**.

### **Create a Reagent Blank or Calibration Profile**

You can select ISE tests when the ISE calibration type is ACAL.

1 Select Menu List > Parameters > Common Test Parameters > Profile > RB/Calibration.

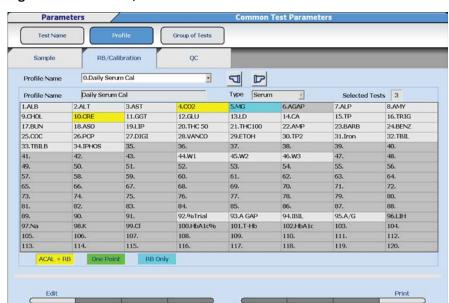


Figure 3.2 Profile: RB/Calibration Tab

- 2 Select Edit (F1).
- 3 In **Type**, select the sample type.
- 4 In **Profile Name**, select a profile number from 0 to 99.
- **5** For **Profile Name**, enter a profile name with a maximum of 20 characters.
- 6 Select the tests to include in the profile. The system displays the test in blue (RB Only), yellow (ACAL + RB), or green (One Point) determined by programming in the Calibration Specific screen. Select **Calibration Options (F5)** to change between the available options.



The programming in the Calibration Specific screen determines the calibration options available in **Calibration Options (F5)**.

7 Confirm that the information is correct, and then select **Confirm (F1)**.

3-8 B04779AB

### Create a QC Profile

QC profiles 87 to 99 are the default QC profiles that are automatically ordered (requisitioned) in **Home > Rack Requisition Sample > QC**. The QC profile numbers 87 to 99 correspond to a specific Group and sample type:

- Number 87: Serum: For Group 1
- Number 88: Serum: For Group 2
- Number 89: Serum: For Group 3
- Number 90: Urine: For Group 1
- Number 91: Urine: For Group 2
- Number 92: Urine: For Group 3
- Number 93: Other-1: For Group 1
- Number 94: Other-1: For Group 2
- Number 95: Other-1: For Group 3
- Number 96: Other-2: For Group 1
- Number 97: Other-2: For Group 2
- Number 98: Other-2: For Group 3
- Number 99: Whole Blood: For Groups 1, 2, and 3

You can only select ISE tests when the sample type is **Serum** or **Urine**.

# 1 Select Menu List > Parameters > Common Test Parameters > Profile > QC.

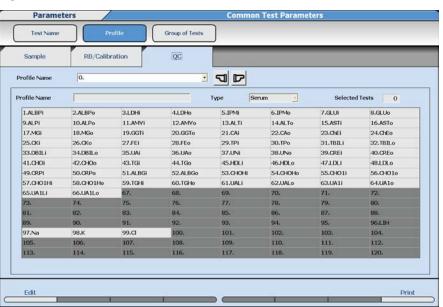


Figure 3.3 Profile: QC Tab

- 2 Select Edit (F1).
- **3** In **Type**, select the sample type.
- **4** In **Profile Name**, select a profile number from 0 to 99.
- **5** For **Profile Name**, enter a profile name with a maximum of 20 characters.

- **6** Select the tests to include in the profile. The system displays selected tests in blue.
- 7 Confirm that the information is correct, and then select **Confirm (F1)**.

# **Program Calibrator Concentrations**

Use this function to review and change calibrator concentrations. Select the calibrator name to review and change the concentrations of all tests in a calibrator from the same dialog. Use this function to change all concentrations when the calibrator lot number changes.



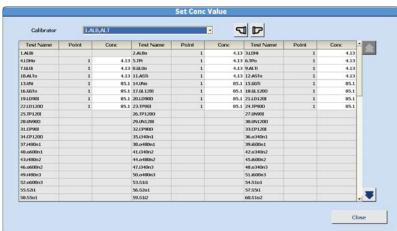
Confirm the calibrator concentration value in the Calibration Specific screen. It is critical that all calibrator values are entered correctly.

For more information, refer to the AU680 Reference Manual.

- 1 Select Menu List > Parameters > Calibration Parameters > Calibrators.
- **2** Select **Edit (F1)**. The system changes the screen to editing mode.
- **3** Select the calibrator name to edit.
- 4 Select Set Conc Value (F5).

The system displays the concentration values of the selected calibrator.

Figure 3.4 Set Conc Value Dialog



- **5** To display or edit a different calibrator, select the calibrator name from **Calibrator**.
- **6** Enter the concentration values (**Conc**) for each test (**Test Name**) for the calibrator. You can only enter concentration values for tests programmed to the calibrator in the Calibration Specific screen.

3-10 B04779AB

- 7 To review or change the concentration for any other calibrator, repeat steps 5 and 6.
- 8 Select Close.
- **9** If a calibrator concentration changes, the system displays a confirmation message. Select **OK**.
- **10** Confirm that the information is correct, and then select **Confirm (F1)**.

# **Program Preset QC Mean and Range**

Use this procedure to review and change the QC mean, standard deviation, and range. For detailed information, refer to the AU680 Reference Manual.

- 1 Select Menu List > Parameters > QC Parameters > QC Specific > Preset.
- **2** In **Test Name**, select the test name.
- **3** In **Type**, select the sample type.
- 4 Select Edit (F1).
- **5** In **Control**, select the QC name.
- 6 In Multi/Single, select Multi or Single.
- **7** Use the QC package insert or known values to enter the **Mean**, **SD**, and **Range**. The system determines that QC is in or out of these preset ranges when the QC Mode is set to **Preset** (on the Check tab).
  - a. In Mean, enter the QC mean.
  - **b.** In **SD**, enter a 1 SD value.
  - **c.** In **Range**, enter the value of the range. The range is the high value minus the low value.
- **8** Confirm that the information is correct, and then select **Confirm (F1)**.

# Program a User Menu

The User Menu function allows the selection of up to 16 menus most frequently used by the operator. Operator-defined menu names can be programmed. Menus selected from the **User Menu** button have direct access to the menu to save time.

The system displays the original menu name below the main button bar even when you access menus using the **User Menu** button.

### **Edit the User Menu**

- 1 Select Menu List > System > User Menu.
- 2 Select Edit (F1).

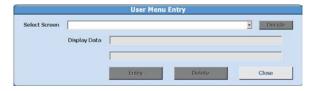
The system changes the next available menu from a gray box to a blue button.

Figure 3.5 User Menu Screen



- 1. Blue button
- **3** Select the blue button.

Figure 3.6 User Menu Entry Dialog



- 4 In **Select Screen**, select the menu to place in the User Menu list.
- **5** Select **Decide**.
- 6 In **Display Data**, enter the operator-defined menu name. You can enter up to 28 characters on each line.
- **7** Select Entry.
- **8** Confirm that the information is correct, and then select **Confirm (F1)**.

3-12 B04779AB

# Sample Programming and Processing

# **Sample Preparation**

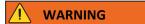
Confirm that there is sufficient sample for analysis along with the dead volume. To display the volume needed for the required tests, select **Home > Rack Requisition Sample** or **STAT Status > Sample**. The system displays the sample volume required for ordered (requisitioned) tests at the bottom right-hand side of the screen. The sample volume does not include the dead volume.

The minimum dead volume required for sample detection varies depending on the sample cup or tube.

After centrifuging sample tubes, confirm that there is sufficient volume of serum or plasma. If the serum or plasma level is too low, transfer it to a smaller cup or cup nested (inserted) in a tube. Refer to Cups or Tubes Specifications for validated cups and nested cups available for racks or the STAT table.

Follow your laboratory procedure to dispense the sample into the center of the cup or tube. Confirm that the sample surface is level without bubbles present before analysis.

Prevent sample evaporation and contamination before analysis.



If the following requirements are not met, results are affected and system errors occur.

- Do not have fibrous material or fibrin, except for whole blood, in the sample.
- Confirm that no air bubbles are in the samples, including samples transferred to the AU680 from a laboratory automation system.
- Dispense sample volume in the quantity required for analysis and the dead volume. For information about dead volumes for tubes and cups, refer to Cups or Tubes Specifications.
- In Specific Test Parameters, you can set the sample volume dilution to 0 μL (default) or 10 μL. When you set the Dilution to 0 μL, the system adds an extra 5 μL per test to the sample volume to ensure dispensing accuracy. For example, if the sample volume of a test is 3 μL, the system aspirates 8 μL per test. If 10 tests are ordered (requisitioned) on a sample, the system adds a total of 50 μL to the sample volume. When you set the Dilution to 10 μL, the system does not add any extra sample volume per test.
- After sample aspiration, the sample probe is rinsed in the wash well, and a small amount of water is transferred to the sample when the next test is aspirated. If there is a small initial sample volume, and 20 tests or more are being analyzed on the sample, add an extra 200 µL to the required sample volume to avoid diluting the sample.

### **Sample Programming and Processing**

Place the Sample Cups or Tubes in the Rack

- Confirm that a volume of serum or plasma sufficient for analysis plus the needed dead volume is in a primary tube. The dead volume required in a primary tube is 4 mm above the non-sample (cells or gel) layer.
- When the serum quantity is small, perform analysis after transferring the sample to a smaller cup or cup nested (inserted) in a tube. For more information, refer to Cups or Tubes Specifications.
- When the serum quantity is small, the system can aspirate blood cells below the serum and results can be affected.

If there is a height difference between tubes processed on a laboratory automation system, use the tube with the bottom that is furthest from the surface of the track to define the maximum probe stroke. This tube difference causes tubes with bottoms closer to the track surface to require a higher dead volume to have correct operation with the shallowest tube.

# Place the Sample Cups or Tubes in the Rack

When the AU680 connects to a laboratory automation system, analysis with racks is not available.

### **Rack Preparation**

Before you start analysis, dispense a sample into sample cups or tubes and set these cups or tubes in the correct rack. The racks come in six different colors. Each rack color has a specified purpose or application. Racks are placed on the rack supply component. A maximum of 15 racks, or 150 samples can be placed on the rack supply component. Racks can be continuously loaded on the rack supply component as space is available.

### **Rack Types**

The system identifies the rack type from the combination of magnets set into the rack bottom. The rack colors, applications, and magnet combinations are shown in the following table.

**Table 4.1** Rack Color, Application, and Magnet Position

Color	Rack Application	Magnet
		1, 2, 3
White	Used to analyze routine samples and Auto Repeat run samples.	• 0 0
Blue	Used to calculate reagent blanks for creating calibration curves.	● ○ ●

4-2 B04779AB

 Table 4.1
 Rack Color, Application, and Magnet Position (Continued)

Color	Rack Application	Magnet
		1, 2, 3
Yellow	Used to create calibration curves.	• • 0
Green	Used to analyze QC samples.	00•
Orange	Used to analyze Manual Repeat run on samples.	• • •
Red	Used to analyze emergency samples.	0 • 0

The rack positions are numbered 1 to 10. The magnets are located on the bottom of the rack at the position number 1 end.

### Place Samples into each Rack Type

The system designates white, red, and orange racks for Serum, Urine, Other-1, Other-2, or Whole Blood sample types in **Menu List > System > System Condition > Analysis mode**. Place samples in the correct rack for sample type.

### White Rack (Routine Analysis)

Set the sample cups or tubes according to the analysis mode.

- Barcode analysis Samples can be placed in any order.
- **Sequential analysis** Place cups or tubes in numeric order according to the order (requisition) without leaving empty spaces in the rack.
- Rack ID analysis Place samples in sample number order according to the rack ID and sample position (1 to 10) in the rack. The sample number equals (rack ID -1) x 10 + position. For example:

### **Sample Programming and Processing**

Place the Sample Cups or Tubes in the Rack

**Table 4.2** Sample Number according to the Rack ID and Position

Sample Number	Rack ID	Position
1	1	1
12	2	2
25	3	5



In sequential analysis, place samples in numeric sample number order according to the requisitioned order without leaving any empty positions in the racks. If there are empty positions in the racks, the ordered (requisitioned) sample number and the sample number determined during any analysis do not coincide, and concordance errors can occur. Beckman Coulter does not recommend running patient samples in sequential mode as positive patient identification cannot be maintained.

For more information, refer to the AU680 Reference Manual.

### **Blue Rack (Reagent Blank)**

Place a sample cup or tube filled with deionized water in position 1 in the blue rack. For more information, refer to the AU680 Reference Manual.

### Yellow Rack (Calibrators)

In **Calibration Parameters**, calibrator material is programmed to a calibrator number (1 to 200).

The system identifies calibrator numbers 1 to 200 by the rack ID and position. For example, calibrator numbers 1 to 10 are placed in rack ID 0001, calibrator numbers 11 to 20 are placed in rack ID 0002, and so on.

For more information, refer to the AU680 Reference Manual.

If you enable calibrator Barcode Operation, assign a calibrator ID to the calibrator material. Place calibrators with bar code labels in any position in the yellow racks.

### **Green Rack (Quality Control)**

In **QC Parameters**, a control material is programmed to a QC number (1 to 100).

The system identifies control numbers 1 to 100 by the rack ID and position. For example, control numbers 1 to 10 are placed in rack ID 0001, control numbers 11 to 20 are placed in rack ID 0002, and so on.

For more information, refer to the AU680 Reference Manual.

If you enable QC Barcode Operation, assign a QC ID to the control material. Place controls with bar code labels in any position in the green racks.

4-4 B04779AB

### **Orange Rack (Manual Repeats)**

For sequential analysis, place samples in numeric sample number order according to the repeat run order (requisition) without leaving empty positions in the racks. Use a rack that is programmed for the correct sample type.

For barcode analysis, place samples in any position in the rack programmed for the correct sample type.

### **Red Rack (Emergency Analysis)**

For sequential analysis, place samples in sequential order by their order (requisition) number. The system automatically assigns sample numbers from the tubes or cups detected, so you can leave empty spaces in the rack.

For example, if you order (requisition) three samples and place the samples in positions 1, 3, and 5, the system assigns E001 to the sample in position 1, E002 to the sample in position 3, and E003 to the sample in position 5.

Use a rack programmed for the correct sample type.

For barcode analysis, place samples in any position in the rack programmed for the correct sample type.



When you use red racks for sequential analysis, use a worklist to confirm that the results correspond to the samples as processed in the rack.



Beckman Coulter recommends using bar code labels for samples to guarantee positive patient identification.

# Place the Sample Cups or Tubes in a Rack

1 Place each sample in the correct rack.
Racks are color-coded. Each rack color indicates a different type of analysis. If you program racks for different sample types (serum, urine, other, whole blood), place the sample in the correct rack for the sample type.

For more information, refer to the AU680 Reference Manual.



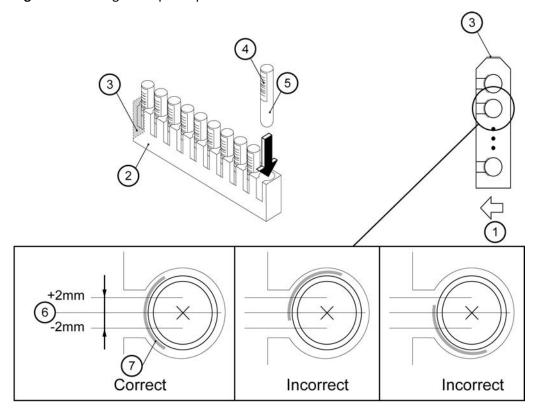
Insert the sample tubes or cups correctly into the rack. If the tube or cup is not pushed down to the bottom of the rack, cup detection does not work correctly and rack jams can occur.

**2** Look at each opening in the rack and confirm that you align the bar code label in the center. The bar code label can only deviate 2 mm from the center. If the bar code label is not aligned with the opening in the rack, lift it out and place it in correctly.



For sample tubes with bar code labels, do not rotate the tube while it is in the rack. Rotating can cause bar code label contamination or damage, resulting in bar code label read errors. Rotate sample tubes after they have been removed from the racks.

Figure 4.1 Placing a Sample Cup or Tube in a Rack



- 1. Direction that rack moves
- 2. NE rack
- 3. The rack ID label is applied to this surface.
- 4. Bar code label
- 5. Sample cup
- 6. Center
- 7. Bar code label



Use only NE racks. An NE rack has a window on the side to facilitate setting different sample cup types in the rack and not compromise bar code label readability.

4-6 B04779AB

Figure 4.2 Examples of Tubes and Cups Correctly Placed in Racks



- 1. Small diameter tube with ID
- 2. Large diameter tube with ID
- 3. Hitachi cup

4. Large diameter tube with ID and Hitachi cup

# **Placing Racks on the Rack Supply Component**

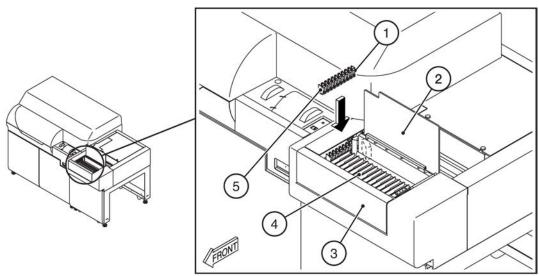
The rack supply component can hold a maximum of 15 racks (150 samples). Close the top and front covers immediately after placing the racks on the rack supply component. When the top or front cover is open, the rack supply component stops moving and the system does not process the racks. During *Measure* mode, open the top or front cover to add more racks, and close all covers after you place the racks on the rack supply component.



Never look directly into the bar code readers. The laser light can cause serious eye damage.

- **1** Open the top or front cover of the rack supply component.
- **2** Place the racks on the rack supply component.

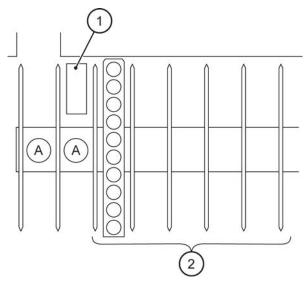
Figure 4.3 Placing Racks on the Rack Supply Component



- 1. Rack ID label surface
- 2. Top cover
- 3. Front cover

- 4. Rack supply component
- 5. Rack

Figure 4.4 Top View of Rack Supply Component



- 1. Rack identification sensor (white)
- 2. Rack loading position (up to 15 slots)

Place the first rack to the right of position A. The rack supply component does not operate correctly when you place it in position A.

**3** For calibration and QC, place the blue rack, and then the yellow racks, and then the green racks. Place the white racks for routine patient samples.

4-8 B04779AB

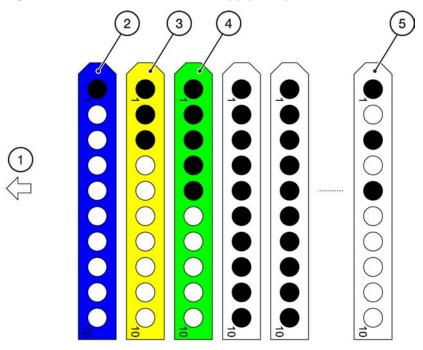


Figure 4.5 Place Racks on the Rack Supply Component

- 1. Direction that the racks move on the rack supply component.
- 2. Place a cup filled with deionized water or diluent in position 1 or 2
- 3. Place in any order
- 4. Place in any order
- 5. Place in any order

Assign deionized water or diluent to position 1 or 2 in the blue reagent blank rack in **RB** Sample Information for each sample type in **Parameters** > **Calibration Parameters** > **Calibrators**.



When several yellow racks are required for creation of calibration curves, set the yellow racks one after the other.

When several green racks are required for QC analysis, set the green racks one after the other.

**4** Close all analyzer doors and covers.

# **Order (Requisition) for Routine and Emergency Samples**

For each sample to analyze, enter the sample information and the order (requisition).

The system uses these orders to process each sample.

To run an emergency sample, order the sample as **Emergency**, and place the sample in a red rack. Place the red rack in front of routine white racks on the rack supply component.

### **Sample Programming and Processing**

Order (Requisition) for Routine and Emergency Samples

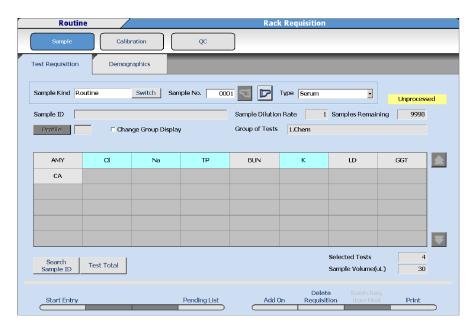
# **Enter Manual Orders (Requisitions) for Routine and Emergency Samples**



The following operations are not necessary when LIS programming is available. When the AU680 connects to a laboratory automation system, create orders from the laboratory information system.

1 Select Home > Rack Requisition Sample > Sample > Test Requisition. The system displays the group of tests from the selected **Group** in the Start Condition screen.

Figure 4.6 Rack Requisition Screen



- 2 In Sample Kind, select Switch to select Routine or Emergency.
  - Routine Analysis in a white rack
  - Emergency Analysis in a red rack
- **3** In **Type**, select the sample type.
- 4 Select Start Entry (F1).

The system changes the tab to editing mode.



When a test that you want to select is not available in the current Group, select the **Change Group Display**. The system displays tests for all Groups in the list.

5 In **Sample ID**, enter the sample bar code number.

4-10 B04779AB

- **6** If a manual dilution was made on the sample, select **Sample Dilution (F7)** and enter the sample dilution rate.
- **7** Select the tests to run on the sample. The system highlights the tests in blue when it is ordered. Select the test again to cancel the order. The system highlights tests in gray that are not available for the selected sample type.

When selecting a profile, either:

- Select **Profile** to open the profile dialog and select a profile (or multiple profiles).
- Use the keyboard to enter a profile number in **Profile**, and then select **Enter**.



#### NOTE

Before a profile is available to order, it is necessary to program profiles in **Menu List** > **Parameters** > **Common Test Parameters** > **Profile** > **Sample**. You can create a maximum of 99 profiles for each sample type. For more information, refer to Create a Sample Profile.

Each time you select a test, the system updates the **Selected Tests** and **Sample Volume** fields.



#### **CAUTION**

The Sample Volume ( $\mu L$ ) indicates the sample dispensing volume that the system uses for analysis. The Sample Volume ( $\mu L$ ) does not include the dead volume.

- **8** Select the Demographics tab to enter any required patient demographic information.
- **9** Confirm that the information is correct, and then select **Entry (F1)**.
- **10** Repeat steps 5 to 9 to requisition additional samples in the same Sample Kind and Type. To change the Sample Kind or Type, select **Exit (F2)** and repeat steps 2 to 9.
- 11 Select Exit (F2).



## NOTE

Select **Pending List (F4)** to view a list of samples that have been ordered (requisitioned), but not yet processed on the analyzer. Select a **Sample No.** or **Sample ID** number, then select **Go** to view the specific sample order (requisition).

### **Enter Batch Orders (Requisitions)**

To perform the same tests on a group of samples, enter the orders (requisitions) in a single batch.

If you order tests for one sample, the system orders the tests for all of the samples in the batch. If you enter patient information for a single sample in the Demographics tab, the system orders (requisitions) the patient information for all samples in the batch. If using

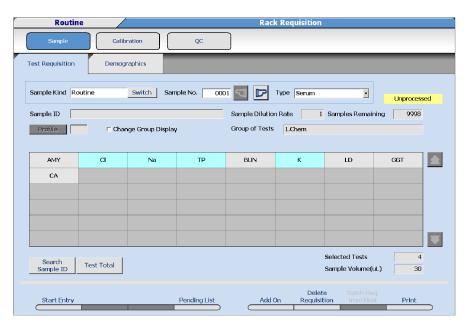
### **Sample Programming and Processing**

Order (Requisition) for Routine and Emergency Samples

bar code analysis, the Sample ID entered for the first sample automatically increases by one digit for subsequent samples.

1 Select Home > Rack Requisition Sample > Sample > Test Requisition. The system displays the group of tests from the selected **Group** in the Start Condition screen.

Figure 4.7 Test Requisition Tab



2 Select Start Entry (F1).

The system changes the screen to editing mode.

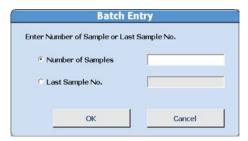
**3** Select the tests or profile for batch order (requisition) for one sample. For more information on manually ordering (requisitioning) tests, refer to Enter Manual Orders (Requisitions) for Routine and Emergency Samples.



If bar code analysis is in use, enter the first sample ID in the batch.

4 Select Batch Entry (F3).

Figure 4.8 Batch Entry Dialog



4-12 B04779AB

- **5** Select **Number of Samples** to enter the number of samples required in the batch, or select **Last Sample No.** to enter the last sample number in the batch.
- 6 Select OK.
- 7 Select Exit (F2).

### Add On a Test for Rerun

To add on one or more tests or rerun a test on a previously processed sample in a white or red rack, use the **Add On (F5)** button.

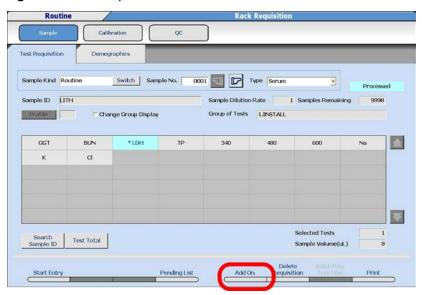
The system generates a Measure Completed for Read Sample ID alarm when the system reads a duplicate sample ID in the same index after adding on a test. This alarm is for information only. Confirm the sample is processing from the Sample Status screen.

1 Select Home > Rack Requisition Sample > Sample > Test Requisition.



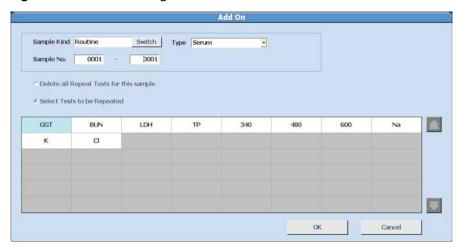
This procedure also applies to STAT samples. For the STAT samples, select **Home** > **STAT Status** > **Sample** > **Test Requisition**.

Figure 4.9 Test Requisition Tab



- **2** Select the **Sample Kind**, **Sample No.** and **Type** to reanalyze.
- 3 Select Add On (F5).

Figure 4.10 Add On Dialog



- 4 Confirm that the displayed **Sample Kind** and **Type** are for the sample being reanalyzed. If necessary, select **Switch** for **Sample Kind** to select **Routine** or **Emergency** samples, and select the sample type from **Type**.
- In **Sample No.**, enter the sample number (not the sample ID) or a starting and ending sample number to add on a test. To add on a test to one sample, enter the same sample number in the starting and ending **Sample No.** fields. If a starting and ending sample number is entered in the **Sample No.** fields, the system programs the same test order (requisition) for all sample numbers entered.
- **6** Select the tests to add on. You can select tests whether they are processed in the original run or not.



To delete all tests ordered (requisitioned) in the Add On dialog select **Delete all Repeat Tests** for this sample.

#### 7 Select OK.

**8** Confirm the order (requisition) by entering the sample number in **Sample No.**. The system displays previously processed tests in blue font. The system displays add on test orders (requisitions) in black font with an asterisk. The system displays the rerun test orders (requisitions) in blue font with an asterisk. The system only processes the tests with an asterisk.



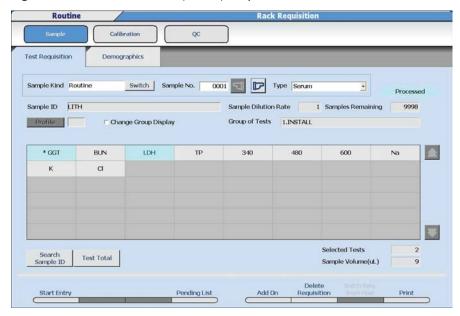
If you select the processed test in the original run for reanalysis, the system automatically overwrites the result.

4-14 B04779AB



The Sample Volume ( $\mu L$ ) indicates the sample dispensing volume that the system uses for analysis. The Sample Volume ( $\mu L$ ) does not include the dead volume.

Figure 4.11 Confirm Add On (Order) Requisition

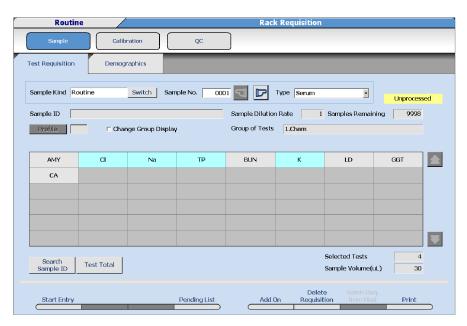


# **Delete an Order (Requisition)**

You can delete an order (requisition) before the system processes the sample.

1 Select Home > Rack Requisition Sample > Sample > Test Requisition.

Figure 4.12 Sample: Test Requisition Tab



2 Select Delete Requisition (F6).

Figure 4.13 Delete Requisition Dialog



3 To delete orders (requisitions), select the Sample Kind. Enter the Search Sample No., Search Sample ID, or leave the asterisk to delete all orders (requisitions) for the selected sample kind. Select the up and down arrow buttons to change the dialog between routine and emergency samples.



If a processed sample is included in the **Search Sample No.** or **Search Sample ID**, the system does not delete the order (requisition) for that **Sample Kind**. If the system does not delete the order (requisition), the system generates a **Failed** to delete sample alarm.

4 Select Delete.

4-16 B04779AB

# Download Orders (Requisitions) from a Laboratory Information System

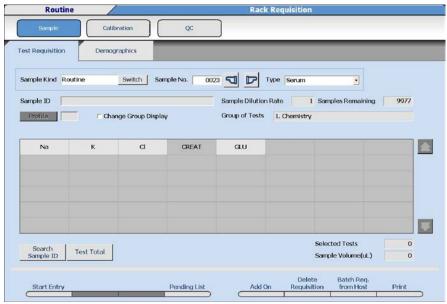
You can download orders (requisitions) from a laboratory information system. Downloading can be:

- Realtime The system downloads and executes orders (requisitions) automatically.
- Batch The system waits for an operator to instruct it to download and execute orders (requisitions).

For more information, refer to the AU680 Reference Manual.

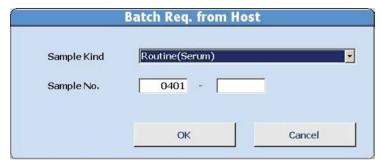
1 Select Home > Rack Requisition Sample > Sample > Test Requisition.





2 Select Batch Req. from Host (F7).

Figure 4.15 Batch Req. from Host Dialog



- **3** In **Sample Kind**, select the sample kind and type to download from the laboratory information system.
- **4** In **Sample No.**, enter the starting and ending sample numbers to download from the laboratory information system.

### 5 Select OK.

A message displays while the system downloads the orders (requisitions). When the download is complete, the system closes the message dialog.

# **Processing Emergency Samples**

The system uses red racks for analysis of emergency samples. Process emergency samples with priority over routine samples by placing the red racks in front of the white racks on the rack supply component. An E sample number prefix in the order (requisition) and sample results identifies an emergency sample.

The quickest way to process a sample is from the Priority STAT Table. For more information, refer to Processing Priority STAT Samples.

# **Priority STAT Samples**

The system uses the STAT table for analysis of priority STAT samples. Priority STAT samples run on the STAT table and interrupt the routine and emergency samples processing from the rack supply component. A priority STAT is the fastest way to process a sample. A P sample number prefix in the order (requisition) and sample results identifies a priority STAT sample.

### **Enter Manual Orders (Requisitions) for Priority STAT Samples**

If communication with the LIS is not functioning, you can manually order (requisition) priority STAT samples in the STAT Status screen.

The system cannot process whole blood samples from the STAT table.

1 Select Home > STAT Status > Sample > Test Requisition.

Figure 4.16 Sample: Test Requisition Tab



**2** In **Type**, select the sample type.

4-18 B04779AB

- 3 Select Start Entry (F1).
  - The system changes the screen to editing mode.
- 4 In Sample ID, enter the sample ID (number on the bar code label).
- **5** Select the tests or profile to perform.



The Sample Volume ( $\mu L$ ) indicates the sample dispensing volume that the system uses for analysis. The Sample Volume ( $\mu L$ ) does not include the dead volume.

- 6 Select Entry (F1).
- 7 To order another sample with the same sample type, repeat steps 4 to 6.
- **8** To end the order process, select **Exit (F2)**.
- **9** To order for a sample with a different sample type, repeat steps 2 to 8.

# **Processing Priority STAT Samples**

Use **STAT Status** to run and monitor the progress of priority STAT samples, reagent blank, calibrators, and controls on the STAT table.

Table 4.3 Options on the STAT Status Screen

Option	Description
STAT Start (F1):	Starts priority STAT analysis on the STAT table.
STAT Pause (F2):	Moves the STAT table to <i>Pause</i> . Use this button to load a new sample or remove dispensed samples when the amber STAT TABLE LED is blinking.
STAT Check (F3):	Determines the presence of a cup or tube and reads the sample ID (if the system is using barcode analysis) for all 22 STAT table positions. Use this button before you start analysis if STAT Operation is set to Manual in System > System Condition > Analysis mode. If STAT Operation is set to Auto, the STAT table check is automatically performed after you select STAT Start (F1).
CAL/QC Position (F5):	Displays the required calibrator and QC cup or tube positions on the STAT table determined by the calibrator and QC orders (requisitions).
Previous Cup Set (F7):	Displays the sample cup or tube positions on the STAT table that were analyzed during the previous run initiated by <b>STAT Start (F1)</b> . This button is only available if STAT Sequential Analysis is enabled.
Sample ID Edit (F8):	Allows editing of the sample ID for the selected position.

### **Processing Priority STAT Samples in Barcode Analysis**

The system processes the priority STAT samples from the STAT table positions programmed First Run (assigned position) or Free Position (open position). For more information, refer to the AU680 Reference Manual. In the STAT Status screen, the system displays the available sample kind and type for each STAT position. Place samples in the correct STAT table positions assigned per sample kind and type.

The system displays Kind as Normal for First Run, Repeat for Repeat Run, Cal for Fixed Position: Calibrator, QC for Fixed Position: Control and Free for Free Position. The system displays the type (serum, urine, other-1, or other-2) for normal and repeat samples. The system does not display a type for Cal, QC, and Free positions.

1 Select Home > STAT Status.

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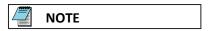
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Figure 4.17 STAT Status Screen

**2** Review the Pos., Kind and Status columns for available Normal and Free positions on the STAT table.



When the amber STAT TABLE LED is blinking, select **STAT Pause (F2)** to put the STAT table in *Pause* mode. To continue analysis, confirm that the STAT table cover is closed and select **STAT Start (F1)**.



If the STAT table is in *Pause* mode for an extended time, the analyzer changes to *Pause* mode. The time for the mode change depends on the reason that the STAT TABLE LED is continuously blinking slowly:

- Sample contamination settings
- Reagent blank or calibrator programmed on the STAT table
- Cyclic QC programmed on the STAT table

4-20 B04779AB

### IMPORTANT

Do not remove pending reagent blank, calibrator, QC, or samples from the STAT table. After you select **STAT Start (F1)**, the system generates an alarm if you removed pending samples from the STAT table.

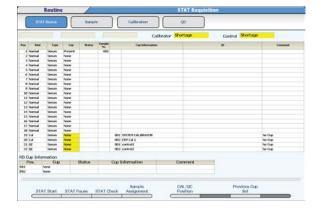
- **3** Open the small STAT table cover.
- **4** Load the samples. Press the **TABLE ROTATION/DIAG** button to rotate the STAT table as required.
- **5** Close the small STAT table cover.
- 6 Select STAT Start (F1).
- **7** Review the Error List in the STAT Start dialog.
- **8** To initiate the automatic STAT table check, select **Start**. To take corrective actions, select **Cancel**.
- **9** If there are no errors specific to the STAT table after the STAT table check, the system starts analysis. If there are STAT table errors, review the errors in the STAT Start dialog. To start analysis, select **Start**, or to perform corrective actions, select **Cancel**.
- **10** Confirm that the system displays the Cup column as Present for the corresponding positions, and review the Status and Comment columns.

The amber STAT TABLE LED blinks until the system completes sample aspiration. You can open the small STAT table cover when the amber STAT TABLE LED is not blinking to remove existing samples and load new samples. If you open the small STAT table cover when the amber STAT TABLE LED is blinking, the system generates a STAT Small Cover Open alarm.

### **Processing Priority STAT Samples in Sequential Analysis**

1 Select Home > STAT Status.

Figure 4.18 STAT Status Screen





#### **NOTE**

When the amber STAT TABLE LED is blinking, select **STAT Pause (F2)** to put the STAT table in *Pause* mode. To continue analysis, confirm that the STAT table cover is closed and select **STAT Start (F1)**.

# IMPORTANT

If the STAT table is in *Pause* mode for an extended time, the analyzer changes to *Pause* mode. The time for the mode change depends on the reason that the STAT TABLE LED is continuously blinking slowly:

- Sample contamination settings
- Reagent blank or calibrator programmed on the STAT table
- Cyclic QC programmed on the STAT table



Do not remove pending reagent blank, calibrator, QC, or samples from the STAT table. After you select **STAT Start (F1)**, the system generates an alarm if you removed pending samples from the STAT table.

- **2** Open the small STAT table cover.
- 3 Load the samples into the corresponding position for the sample kind and type. Inspect the sample positions. Each outer position of the STAT table (1-22) for kind (normal, repeat, calibrator, or QC) and type (serum, urine, other-1, or other-2) has been programmed to meet the sample kind and type requirements for your laboratory. Press the TABLE ROTATION/DIAG button to rotate the STAT table as required.
- **4** Close the small STAT table cover.
- 5 Select **STAT Check (F3)**, and then select **Start**. The table rotates and the system detects the tubes. The Cup column displays Present for each sample and the Comment column displays the Sample Assignment.

In Sequential Analysis on the STAT table, order (requisition) the STAT samples from **STAT Status > Sample**. For more information, refer to Enter Manual Orders (Requisitions) for Priority STAT Samples.

- 6 Select **Sample Assignment (F4)**. The system places a green highlight over Sample Assignment determined by the Kind and Type.
  - a. Confirm the kind (normal or repeat)
  - **b.** Confirm the type (serum, urine, other-1, or other-2)
  - **c.** In **Option**, select **Unprocessed** (for unprocessed samples) or **All Samples** (processed samples are inaccessible).
  - **d.** In **Pos.**, assign a position for each sample number on the STAT table.

4-22 B04779AB

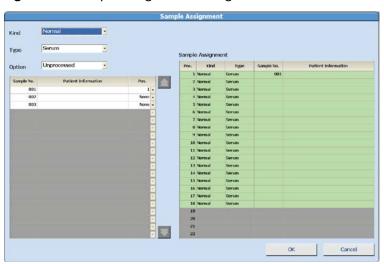


Figure 4.19 Sample Assignment Dialog

- 7 Select OK.
- 8 Select STAT Start (F1).
- **9** Review the Error List in the STAT Start dialog. To perform corrective actions, select **Cancel**.
- **10** Select **Start**. The system starts analysis.

The amber STAT TABLE LED blinks until the system completes sample aspiration. You can open the small STAT table cover when the amber STAT TABLE LED is not blinking to remove existing samples and load new samples. If you open the small STAT table cover when the amber STAT TABLE LED is blinking, the system generates a STAT Small Cover Open alarm.

# **Performing a Repeat Run**

You can perform a repeat for samples from the racks and the STAT table using two methods:

- Manual Program repeat run criteria in Parameters > Repeat Parameters > Repeat Common and Repeat Specific to generate repeat run orders (requisitions). View or print a repeat run worklist, and place the samples to repeat in the orange racks or programmed repeat positions on the STAT table.
- Automatic Program repeat run criteria in **Parameters > Repeat Parameters > Repeat Common** and **Repeat Specific** to generate repeat run orders (requisitions). The system performs the repeat run automatically on samples in white or red racks, or from the STAT table.

The operator is allowed to program whether the system rewrites the original data automatically with the result data of the repeat test.

### **Sample Programming and Processing**

Performing a Repeat Run

If the AU680 connects to a laboratory automation system, the laboratory information system determines repeat criteria and analysis. For samples transported directly to the AU680, the system processes samples like original samples with a repeat order (requisition) from the laboratory information system. For samples processed on the STAT table, the system processes samples as repeat samples with a repeat order (requisition) from the laboratory information system. You can enable **Auto Repeat** on the STAT table when the system is using a laboratory automation system.

For more information, refer to the AU680 Reference Manual.

# **Auto Repeat for Racks and the STAT Table**

The system enables the Auto Repeat feature in **Menu List > System > System Condition > Analysis mode**. For more information, refer to the AU680 Reference Manual.

The routine or emergency rack moves on the repeat bypass belt to the repeat sample aspiration position on the rack supply component. The system only performs the tests that generated a repeat order (requisition).



Do not use labels with the same rack ID on more than one rack. Using duplicate rack IDs can cause concordance errors between samples.

The system automatically repeats a priority STAT on the STAT table. To use Auto Repeat on the STAT table, set STAT analysis to **Barcode** in **Menu List > System > System Condition > Analysis mode**.

You cannot modify the repeat orders (requisitions). Repeats are automatic.

# **Repeat Orders (Requisitions) for Manual Repeat**

The system generates repeat run orders (requisitions) automatically from the repeat criteria programmed in **Parameters > Repeat Parameters > Repeat Common** and **Repeat Specific**. Confirm the samples to repeat using a repeat run worklist. Make changes to the worklist in the Repeat Order screen as required.

**Modify a Repeat Order (Requisition)** 

1 Select Menu List > Routine > Repeat Run > Repeat Order.

4-24 B04779AB



Figure 4.20 Repeat Order Screen

Table 4.4 Repeat Order (Requisition) Options

Option	Description
Search Sample ID	Search for samples using the sample ID.
Test Total	The system displays the test total for repeat runs.
Re-number Repeat Samples	If you delete repeat samples from the worklist, the repeat sample numbers are not sequential. Select <b>Re-number Repeat Sample</b> to renumber the repeat samples sequentially.
Repeat List	The system displays the repeat run candidate samples for which the system performed repeat run batch extraction. Repeat run candidate samples are samples for which the system has not established a repeat run sample number. If programmed in System Maintenance, the system automatically generates repeat run sample numbers. If the system is not automatically generating repeat sample numbers, contact Beckman Coulter.
Regenerate Repeat Req. (F2)	The system manually generates the repeat orders (requisitions) from the flags programmed in Repeat Parameters > Repeat Common > Data Flag. Use this option if you did not turn on the Auto Repeat Requisition option in Repeat Parameters > Repeat Common > Data Flag.
Initialize Repeat Data (F3)	The system deletes all repeat order (requisition) information.
Pending List (F4)	The system displays a list of pending repeat samples. Place the samples in an orange rack for repeat analysis.

2 In Sample Kind, select Switch to select Routine, Emergency, or STAT.

- **3** Enter the sample number of the sample to perform the repeat test.
- 4 In **Type**, select the sample type.
- 5 Select Start Entry (F1).

The system changes the screen to editing mode.

- **6** If the sample is manually diluted, select **Sample Dilution (F7)**. The system displays the Sample Dilution Rate dialog. Enter the dilution rate (1 to 999), and make a manual dilution of the sample. The system calculates the result according to the dilution rate. Select **OK**. The system changes the sample dilution rate.
- 7 To repeat specific tests in the sample, select a test. Select **Test Dilution (F8)** to change from normal (blue), diluted (green), or concentrated (yellow) analysis, according to the settings in the Repeat Specific screen.
- **8** Select **Entry (F1)**. After the settings have been entered, the system displays the order (requisition) for the next sample number.
- **9** To modify more repeat sample orders (requisitions) of the same sample kind or type, repeat steps 6 to 8.
- 10 Select Exit (F2).
- **11** To modify additional repeat sample orders (requisitions) with a different sample kind or type, repeat steps 2 to 10.
- **12** If you changed the repeat order (requisition), select **Pending List (F4)** or print a repeat worklist. For more information, refer to Print and Confirm the Repeat Run Worklist.

#### **Delete a Repeat Order (Requisition)**

- 1 Select Menu List > Routine > Repeat Run > Repeat Order.
- 2 Select Delete Requisition (F6).
- **3** Select the sample kind and sample type to delete.
- **4** Enter a specific sample number or Sample ID to delete. To delete all sample numbers, leave the asterisk.
- 5 Select Delete.
- 6 To renumber the repeat sample numbers sequentially, select Re-number Repeat Samples.
- **7** Print a repeat worklist. For more information, refer to Print and Confirm the Repeat Run Worklist.

4-26 B04779AB

#### **Print and Confirm the Repeat Run Worklist**

1 Select Menu List > Routine > Repeat Run > Repeat Order.



The Sample Volume ( $\mu$ L) indicates the sample dispensing volume that the system uses for analysis. The Sample Volume ( $\mu$ L) does not include the dead volume.

- 2 In Sample Kind, select Switch to select Routine, Emergency, or STAT.
- **3** Select **Print (F8)**. The system displays the Print dialog.
- 4 In **List Type**, select any print worklist. Before the list is available to print, format the list as a **Repeat List** in **System > Format > List Format**.
- 5 In **List Format**, select the list format to print.
  - In **Reporter**, the system displays the Operator Name entered in the Start Condition screen. If necessary, enter a new name or use **Select** to enter a pre-programmed comment. Reporter is an option that can be added to a list format, and only prints if it is formatted.
- **6** Select **Print**. The system prints the repeat run worklist.
- **7** Confirm the contents of the printed repeat run worklist. Process the repeat run samples from the worklist contents.

## Perform a Manual Repeat in an Orange Rack

Orange racks are defined for sample type (serum, urine, other-1, other-2, or whole blood) and sample kind (routine or emergency) in **System > System Condition > Analysis mode**.

- **1** Obtain the samples for the repeat run using the repeat run worklist.
- 2 Place the repeat samples in the correct orange rack for sample type and kind according to the repeat run order (requisition) in the worklist.
- **3** Place the orange racks on the rack supply component.
- **4** To start repeat analysis, select **Start**.

#### Perform a Manual Repeat from the STAT Table

- 1 To view a pending repeat list, select Menu List > Routine > Repeat Run > Repeat Order, and then select Pending List (F4). For more information, refer to Print and Confirm the Repeat Run Worklist.
- 2 Select Home > STAT Status.

**3** Review the Kind and Type columns. Place the samples in STAT table repeat positions assigned to the sample type. Press the **TABLE ROTATION/DIAG** button to rotate the STAT table as required.



#### **NOTE**

- If the system is in Barcode Analysis mode, samples can go in any order on the STAT table repeat positions.
- If the system is in sequential mode, select STAT Check (F3) and confirm that the system displays the cup if available. Select Sample Assignment (F4) and assign a position for each sample number. For more information, refer to Processing Priority STAT Samples in Sequential Analysis.
- 4 Select STAT Start (F1).
- **5** Review the Error List in the STAT Start dialog.
- **6** To initiate the automatic STAT table check, select **Start**. To take corrective actions, select **Cancel**.
- 7 If there are no errors specific to the STAT table after the STAT table check, the system starts analysis. If there are STAT table errors, review the errors in the STAT Start dialog. To start analysis, select **Start**, or to perform corrective actions, select **Cancel**.
- **8** Confirm that the system displays the Cup column as Present for the corresponding positions, and review the Status and Comment columns.
  - The amber STAT TABLE LED blinks until the system completes sample aspiration. You can open the small STAT table cover when the amber STAT TABLE LED is not blinking to remove existing samples and load new samples. If you open the small STAT table cover when the amber STAT TABLE LED is blinking, the system generates a STAT Small Cover Open alarm.

### **Print Results**

Print results in a report or data log list.



#### **NOTE**

Reports and lists are formatted for your laboratory during installation and as needed. For additional help with formatting a new or existing report or list, contact Beckman Coulter.

For more information on format and print options, refer to the AU680 Reference Manual.

#### **Print Sample Data Reports**

1 Select Home > Sample Manager > Sample > Main.

4-28 B04779AB

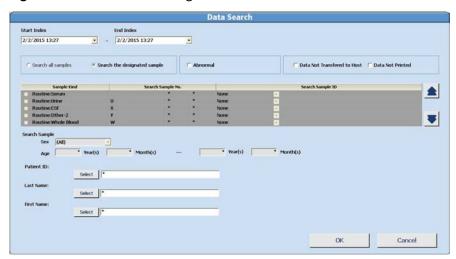
Figure 4.21 Sample Manager: Main Tab

- **2** The system displays the data from the current index with all samples selected (highlighted in gray).
  - Select **Select Samples Individually** to clear the selection of all samples from the list. You can then select specific samples to print from the list.
  - Select **Select All** to highlight all samples the system displays in the list.

Continue to step 4 to print the selected data from the current index. If the system does not display the desired sample data to print on the list, continue to step 3.

- 3 Select Data Search (F3) to search for data by an index range, sample numbers, sample ID, abnormal data, patient demographics, data not transferred to LIS, or data not printed.
  - To search for data in a specific index or index range, enter the Start Index and End Index, and then select OK.
  - To search for data by additional criteria in the index range, select **Search the designated sample**, enter the additional criteria, and then select **OK**.

Figure 4.22 Data Search Dialog



- **4** Select **Print (F8)**. The system displays the Print dialog.
- 5 In Data List No., select the report to print.

In **Reporter**, the system displays the Operator Name entered in the Start Condition screen. If necessary, enter a new name or use **Select** to enter a pre-programmed comment. Reporter is an option that can be added to a list format, and only prints if it is formatted.



Operators can select and print any available predefined report.

**6** Select **OK**. The system prints the report.



To cancel printing, select **Print Stop (F8)**.

# Print Reagent Blank, Calibration, and QC Results

1 Select Home > Sample Manager > RB/CAL/QC.

4-30 B04779AB



Figure 4.23 Sample Manager: RB/CAL/QC Screen

- **2** In **Index**, select the index of the reagent blank, calibration, or QC data to search.
- **3** Select the sample kind to print.
  - In **Search Sample No.**, enter the sample number range to print. To print all samples, leave the asterisk.



If **Search Sample No.** is empty, the system does not use search criteria for the search.

- In **QC/Cal No.**, enter the QC number (1 to 100) or the calibrator number (1 to 200). To print all QC and calibrator numbers, leave the asterisk.
- To print samples with a specific QC or calibrator ID, in **Control/Calibrator ID**, enter the QC or calibrator bar code number.
- To print only the reagent blank, calibrator, and QC samples that the system has not transferred to the laboratory information system, select **Data Not Transferred to Host**. To print only the reagent blank, calibrator, and QC samples that the system has not printed, select **Data Not Printed**.
- 4 Select Print (F8).
- 5 In Data List No., select the report to print.

In **Reporter**, the system displays the Operator Name entered in the Start Condition screen. If necessary, enter a new name or use **Select** to enter a pre-programmed comment. Reporter is an option that can be added to a list format, and only prints if it is formatted.

**6** Select **OK**. The system prints the report.

## **Sample Programming and Processing**

Batch Transfer Data to the Laboratory Information System



To cancel printing, select **Print Stop (F8)**.

# **Batch Transfer Data to the Laboratory Information System**



Before transferring data to the laboratory information system, confirm that the AU680 is online and connected to a laboratory information system.

## **Sample Data**

If the data does not automatically transfer to the laboratory information system, you can manually batch transfer the sample data to the laboratory information system.

The Online Transfer (F7) option is only available when Realtime or Batch for Results Transfer is programmed in Menu List > System > Online. If the system is set to Realtime, you can only transfer data in *Standby* mode.

1 Select Home > Sample Manager > Sample > Main.



Figure 4.24 Sample: Main Tab

- **2** The system displays the data from the current index with all samples selected (highlighted in gray).
  - Select **Select Samples Individually** to clear the selection of all samples from the list. You can then select specific samples to transfer from the list.
  - Select **Select All** to select all samples the system displays on the list.

4-32 B04779AB

Continue to step 4 to transfer the selected data from the current index. If the system does not display the desired sample data to transfer on the list, continue to step 3.

- 3 Select **Data Search (F3)** to search for data by an index range, sample numbers, sample ID, abnormal data, patient demographics, data not transferred to LIS, or data not printed.
  - To search for data in a specific index or index range, enter the **Start Index** and **End Index**, and then select **OK**.
  - To search for data by additional criteria in the index range, select **Search the designated sample**, enter the additional criteria, and then select **OK**.
- **4** Select **Online Transfer (F7)**. The system opens the Online Transfer dialog.
- 5 Select OK. The system transfers the data.
  The system attaches an r flag to data that was transferred to the laboratory information system.

## Reagent Blank, Calibration, and QC Data

You can transfer reagent blank, calibration, and QC data to a laboratory information system.

The **Online Transfer (F7)** option is only available when **Realtime** or **Batch** for **Results Transfer** is programmed in **Menu List > System > Online**. If the system is set to **Realtime**, you can only transfer data in *Standby* mode.

1 Select Home > Sample Manager > RB/CAL/QC.





- **2** In **Index**, select the index of the reagent blank, calibration, or QC data to search.
- **3** Select the sample kind to transfer.

# **Sample Programming and Processing**

Batch Transfer Data to the Laboratory Information System

— In **Search Sample No.**, enter the sample number range to transfer. To transfer all samples, leave the asterisk.



If **Search Sample No.** is empty, the system does not use search criteria for the search.

- In **QC/Cal No.**, enter the QC number (1 to 100) or the calibrator number (1 to 200). To transfer all QC and calibrator numbers, leave the asterisk.
- To transfer samples with a specific QC or calibrator ID, in **Control/Calibrator ID**, enter the QC or calibrator bar code number.
- To transfer only the reagent blank, calibrator, and QC samples that the system has not transferred to the laboratory information system, select **Data Not Transferred to Host**. To transfer only the reagent blank, calibrator, and QC samples that the system has not printed, select **Data Not Printed**.
- 4 Select Online Transfer (F7).
- **5** Select **OK**. The system performs the online transfer.



To stop the transfer, select **Online Transfer Stop (F7)**.

4-34 B04779AB

# System Monitoring and Results

# **Monitoring Analysis**

The system status is continuously updated while the system is operating. Progress is constantly monitored.

#### **Monitor Results**

Confirm that daily reagent blank, calibration, and control (QC) results are acceptable before reporting sample results. Review all results including reagent blank, calibration, QC, and samples for flags. Take corrective actions before reporting any results with flags. Review the **Alarm List** and take corrective actions for any generated alarms.

For more information on monitoring the results, refer to the AU680 Reference Manual.

For more information on troubleshooting and corrective actions, refer to Troubleshooting Reagents, Calibrators, Quality Control, and Samples.

# **Identifying Sample Kinds and Types by Sample Data Prefix**



The system displays the sample data prefix in front of the sample number.

Table 5.1 Sample Data Prefix

Туре		Normal Run	Repeat Run
Routine	Serum	(None)	Н
	Urine	U	HU
	Other-1	Х	нх
	Other-2	Υ	НҮ
	Whole Blood	W	HW
Emergency Sample	Serum	E	HE
	Urine	UE	HUE
	Other-1	XE	HXE
	Other-2	YE	HYE
	Whole Blood	WE	HWE

**Table 5.1** Sample Data Prefix (Continued)

Туре		Normal Run	Repeat Run
STAT Sample	Serum	Р	НР
	Urine	UP	HUP
	Other-1	ХР	НХР
	Other-2	YP	НҮР
QC		(	Ω
CAL		А	
RB		R	

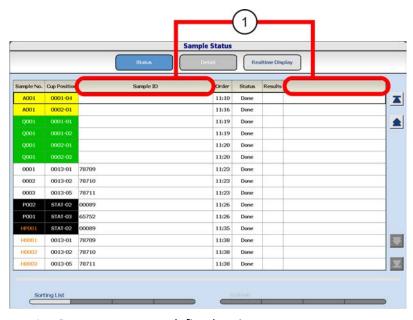
# **Sample Status Screen**

Select **Sample Status** to view sample information, estimated time of completion, and results.

1 Select Home > Sample Status > Status.

The system displays the Status screen.

Figure 5.1 Sample Status: Status Screen



1. Program operator-defined patient demographics

Table 5.2 Status Screen Items

Item	Description	
Sample No.	The sample number highlighted in the rack color.	
Cup Position	The rack ID and cup position highlighted in the rack color.	

5-2 B04779AB

Table 5.2 Status Screen Items (Continued)

Item	Description
Sample ID	The sample ID (number on the bar code label).
Order	The time the cup in the rack passed the cup detector on the rack transport belt.
Status	In Process during sample analysis, or Done after analysis is complete.
Results	The estimated completion time during sample analysis, or Error if the results have a flag.
Sorting List (F1)	Changes the sorting order of the list. Sort the items by Sample No., Cup Position, Sample ID, Order, Status Results, or operator-defined patient demographics.
Switch to Static View (F4) or Switch to Realtime View (F4)	Switches between Switch to Static View (F4) and Switch to Realtime View (F4). Selecting Switch to Static View (F4) temporarily prevents the sample status list from being updated. Use this function to review the status of processed samples. The sample status list does not reflect any updates on the sample status while Switch to Static View (F4) is selected. Selecting Switch to Realtime View (F4) resumes updating the sample status list.



# **NOTE**

You can program two operator-defined patient demographic items. For more information, refer to the AU680 Reference Manual.

2 Select a sample, and then select **Detail** to view detailed sample information. The system displays the test name with the result when the result is complete.



# **NOTE**

You cannot view detailed sample information for Reagent Blank, Calibration, and QC samples using the Detail screen.

Figure 5.2 Sample Status: Detail Screen

Select **Realtime Display** to view the sample results. The system displays tests without flags in black, and tests with flags in red. The All tab displays the samples in completion order when all tests ordered (requisitioned) on the sample are complete. The Quick tab displays results from the STAT table only. The Quick tab displays the ISE tests, and tests with only an R1 reagent with read points before P10, when the tests are complete. The ISE tab displays the ISE tests when the ISE tests are complete.



Figure 5.3 Sample Status: Realtime Display Screen

# **Inspect the Analyzer Status**

The Analyzer Status screen displays a color-coded overview of the system. The system monitors the status of the incubator, reagent refrigerators, the STAT table, deionized water tank, wash solution tanks, waste tanks, printer, and LIS communication.

The system monitors the ISE module and reagents when the ISE module is installed.

5-4 B04779AB

The colors of the system components indicate the status.

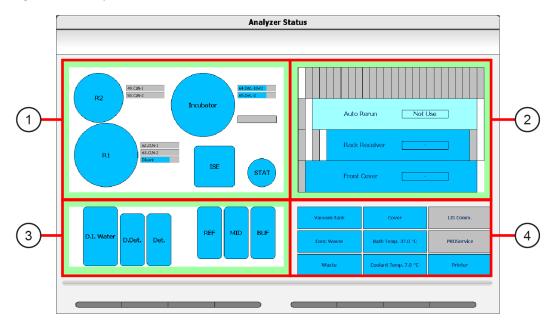
**Table 5.3** Analyzer Status

Color	Status
Blue	No errors
Yellow or Orange	Non-fatal error. You can start the analyzer.
Red	Fatal error. You cannot start the analyzer.

## **1** Select **Home > Analyzer Status**.

The system displays the Analyzer Status screen.

Figure 5.4 Analyzer Status Screen

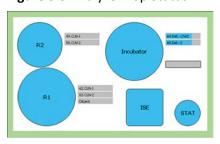


- 1. Analyzer Top status
- 2. Rack Feeder status

- 3. Analyzer Front status
- 4. Item status
- **2** Confirm that system components are within acceptable limits (blue). Investigate any yellow or red conditions.
  - **a.** Inspect the Analyzer Top status. Investigate any yellow or red conditions. For more information, refer to Analyzer Top Status.
  - **b.** Inspect the Rack Feeder status. Investigate any yellow or red conditions. For more information, refer to Rack Feeder Status.
  - **c.** Inspect the Analyzer Front status. Investigate any yellow or red conditions. For more information, refer to Analyzer Front Status.
  - **d.** Inspect each item status. Investigate any yellow or red conditions. For more information, refer to Item Status.

## **Analyzer Top Status**

Figure 5.5 Analyzer Top Status



# Reagent Refrigerator (R1 and R2)

Table 5.4 Reagent Refrigerator Status

Color	Status	
Blue	Normal	
Yellow	The temperature is outside the normal temperature range (4 °C to 12 °C).	
Red	The R1 or R2 refrigerator cover is open.	

#### Incubator

Table 5.5 Incubator Status

Color	Status
Blue	Normal
Yellow	The temperature is outside the normal temperature range (37 $^{\circ}$ C $\pm$ 0.3 $^{\circ}$ C), or a cuvette failed the photocal.
Red	A cuvette failed the photocal.



If a cuvette failed the photocal, the status can be yellow or red, depending on the system programming by Beckman Coulter.

# Cleaning Solution, Diluent, and Sample Wash Solution Bottle Status

The status of the R1 and R2 cleaning solution and diluent bottles (49. CLN-1, 50. CLN-2, 62. CLN-1, 63. CLN-2, and Diluent), and sample wash solution bottles (64. Det.-1/W2 and 65. Det.-2). The color indicates the volume remaining in the bottle.

**Table 5.6** Cleaning Solution, Diluent, and Sample Wash Solution Bottle Status

Color	Status	
49. CLN-1	More than 50 mL	
49. CLN-1	More than 30 mL and less than or equal to 50 mL	

5-6 B04779AB

 Table 5.6
 Cleaning Solution, Diluent, and Sample Wash Solution Bottle Status (Continued)

Color	Status		
49. CLN-1	More than 15 mL and less than or equal to 30 mL		
49. CLN-1	Less than or equal to 15 mL		
49. CLN-1	No remaining solution		
49. CLN-1	None of the tests in the group use the cleaning solution.		

## **STAT Table**

Table 5.7 STAT Table Status

Color	Status	
Blue	Normal	
Yellow	The temperature is outside the normal temperature range (4 °C to 12 °C).	
Red	The small or large STAT table cover is open.	

# **ISE Module (Optional)**

Table 5.8 ISE Module Status

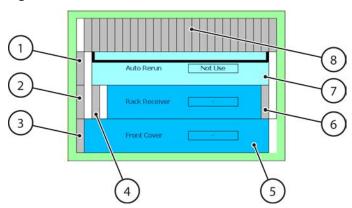
Color	Status	
Blue	Normal	
Yellow	The ISE is in <i>Stop</i> mode.	
Red	The ISE cover is open, or the ISE is busy (performing maintenance).	

## **Rack Feeder Status**



When the AU680 connects to a laboratory automation system, the system does not display the rack feeder module.

Figure 5.6 Rack Feeder Status



- 1. Sample aspiration position
- 2. Middle rack position
- 3. Sample ID read position
- 4. Auto repeat sample aspiration position
- 5. Rack supply component

- 6. Rack collection component (Rack Receiver)
- 7. Auto repeat rack feeder (Auto Rerun)
- 8. Rack buffer component

# **Auto Repeat Rack Feeder (Auto Rerun)**

Table 5.9 Auto Repeat Rack Feeder (Auto Rerun) Status

Color		Status
Light Blue		Normal
Red		Error
Text	Use	Auto Repeat is programmed to <b>Enabled</b> .
	Not Use	Auto Repeat is programmed to <b>Disabled</b> (unavailable).
	Error	The auto repeat rack feeder has an error when Auto Repeat is programmed to <b>Enabled</b> or <b>Disabled</b> .

## **Rack Collection Component**

Table 5.10 Rack Collection Component Status

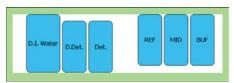
Color		Status	
Light Blue		Normal	
Red		The rack collection component is full, or there is a mechanical error.	
Text Rack full		The rack collection component is full.	
	-	The rack collection component is available.	

## **Rack Position**

The color depends on the rack type. If a rack is not present, the system displays the position in gray. If a rack is present, the system displays the rack ID number of the rack.

## **Analyzer Front Status**

Figure 5.7 Analyzer Front Status



5-8 B04779AB

**Monitoring Analysis** 

## Deionized Water, Diluted Wash Solution, and Wash Solution Tank

The status of the liquid quantity in the deionized water tank (D.I. Water), diluted wash solution tank (D. Det.), and wash solution tank (Det.). For more information, refer to Replenish the Wash Solution.

Table 5.11 Deionized Water, Diluted Wash Solution, and Wash Solution Tank Status

Color	Status
Blue	Normal
Yellow	Over-full
Red	Insufficient



The status becomes over-full when the top float sensor in the tank moves to the maximum up position. The status becomes insufficient when the bottom float sensor in the tank moves to the maximum down position.

#### **ISE Reagent Bottles**

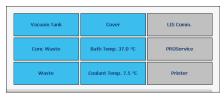
The status of liquid quantity in the ISE Reference Solution bottle, ISE MID Standard Solution bottle, ISE Buffer Solution bottle. For more information, refer to Replace the ISE Reagents.

Table 5.12 ISE Reagent Bottle Status

Color	Status
Blue	Normal
Yellow	Insufficient

# **Item Status**

Figure 5.8 Item Status





When the item is gray, the feature is not enabled.



Some printer errors cause the system to display the printer in red, a red Message on the Home screen, and a print error in the Start dialog. In this situation, the system

displays **Printer Control (F5)** on the Analyzer Status screen. To clear the error and resume normal operation, select **Printer Control (F5)** for options to resume (print any information that did not print) or cancel the print.

Table 5.13 Item Status

Item	Color			
	Blue	Yellow	Red	
Conc Waste	Normal	-	Full	
Waste	Normal	-	Full	
Cover	The R1, R2, STAT table (large and small), and ISE covers are closed.	-	One or more of the following covers is open: R1, R2, STAT table (large or small), or ISE.	
Vacuum Tank	m Tank Normal		Full	
Bath Temp	Normal	Exceeds temperature specification	-	
Coolant Temp	Normal	Exceeds temperature specification	-	
Printer	Normal	-	Error	
LIS Comm (RS232C)	Comm (RS232C) Under real-time online communication		-	
LIS Comm (TCP /IP)	Under communication	One or more ports is not connected.	All of the ports are not connected.	
PROService	Connected	Not connected	-	

# **Inspect the ISE Status**

1 Select Home > Analyzer Maintenance > ISE Maintenance > Calibration.

5-10 B04779AB



Figure 5.9 ISE Maintenance: Calibration Tab

- 2 Inspect the Calibration tab.
  - **a.** Inspect the ISE status.

Table 5.14 ISE Status

Status	Color	Description	
READY	Blue	Ready to start analysis or maintenance.	
BUSY	Red	Operating.	
MEASURE	Blue	Analysis is in progress (ISE).	
STOP	Yellow	The ISE is in <i>Stop</i> mode. Select <b>ISE Ready (F4)</b> to return the ISE to <i>Ready</i> mode.	
INITIAL	Yellow	The ISE is initializing.	

**b.** Inspect the electrode status. The electrode status indicates if the most recent slope value is in range for Na, K, and Cl.

Table 5.15 Electrode Status

Color	Description
Blue	The slope value is within the acceptable range, and ISE calibration was performed within 24 hours.
Yellow	<ul> <li>The slope value is not within the acceptable range.</li> <li>ISE calibration has not been performed within 24 hours. The system uses the most recent ISE calibration results.</li> </ul>
Gray	No calibration data exists for the electrode.

**c.** Inspect the reagent status. The reagent status indicates if the reagent level is short for ISE Buffer Solution, ISE MID Standard Solution, and ISE Reference Solution.

Table 5.16 Reagent Status

Color	Description	
Blue	The reagent level is above the reagent short level sensor, indicating reagent is sufficient.	
Yellow	The reagent is below the reagent short level sensor, indicating reagent is not sufficient.	

- **d.** The **Date/Time** indicates the date and time the system performed the calibration.
- **e.** The **Slope** indicates the calibration slope for Na, K, and Cl. A larger slope value indicates a steeper slope (a larger potential).
- **f.** The **MID Solution Factor** indicates the value that the system obtained from the concentration of the ISE MID Standard Solution to establish a reference for measuring Na, K, and Cl ion concentrations.
- **3** Inspect the slope chart. The slope chart contains records of slope values that the system obtained from calibration. You can view slope charts in graph form for Na, K, and Cl.
  - a. Select Slope Chart.

Maintenance

| See Maintenance | See Maintenance | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | December | Dece

Figure 5.10 Slope Chart Tab

**b.** To inspect the slope chart for each sample type, in **Type** select **Serum** or **Urine**.

The system displays the 30 most recent slope values in a chart. Identify the Na, K, and Cl slope charts by color. On the left of the chart the system displays the maximum and minimum Na, K, and Cl slope values.

Although Cl slope values are negative values, the slope chart displays their absolute values.

5-12 B04779AB

## **Disable a Test**

You can select specific tests to prevent analysis (the test is unavailable for patient analysis) even when the test has an order (requisition). If the calibration failed for that test, or QC fails and samples are in process, it can be useful to make a test unavailable.

You can make a test unavailable (disabled) or available (enabled) during *Measure* mode. Analysis of the test stops or restarts after you select **Disable (F7)**.

Reagent blank, calibration, and QC samples for the disabled tests remain available for analysis.

The system displays and prints tests that are unavailable (disabled) with a / flag, indicating that the test was ordered (requisitioned) but not performed.

Settings in the Disable dialog are in effect until a new index is set, or you shut down the system (End Process).

1 Select Home > Start Condition.

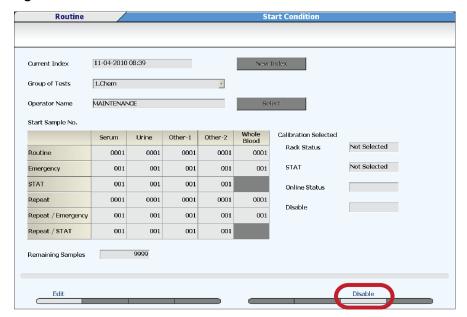
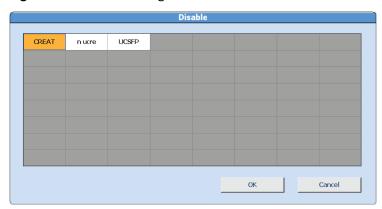


Figure 5.11 Start Condition Screen

2 Select **Disable (F7)**. The system opens the Disable dialog, and displays a list of tests to make unavailable (disable).

Figure 5.12 Disable Dialog



- **3** Select the tests to make unavailable (disable). The system highlights tests that are unavailable (disabled) in orange.
- **4** Select **OK** to save the settings. The system returns to the Start Condition screen.



The system displays a message if one or more tests are disabled on the Message Display on the Home screen.

# **Review Results for Flags and Alarms**

After the system generates results, review them for analytical validity.

Review the results using the Sample Status screen or the printout. For more information, refer to Sample Status Screen.

Review all results for flags and alarms, and confirm that all corrective actions are taken.

# **Review Results for Flags**

If a problem occurred during analysis, the system appends a flag to the analysis results. Review all results carefully for flags and take the correct action.

For more information, refer to Flags.

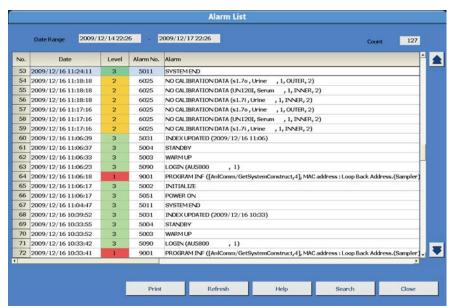
## **Review Alarms**

Review for alarms that occurred during analysis:

To display alarms, select **Alarm List** (the button on the lower-right corner of the screen).

5-14 B04779AB





The **Level** column displays the alarm level (numbers and color).

Table 5.17 Alarm Level

Level	Color	Description
Level 1	Red	A fatal system abnormality exists.
Level 2	Yellow	An abnormality influencing the data exists.
Level 3	Green	No system abnormality and the system displays the operation log.

The **Count** (at the top-right) indicates the quantity of alarms within the specified date range. The system can store and display a maximum of 999 cases. You can scroll using the scroll bar.

From the Alarm List screen, you can select:

- **Print** Prints a list of all alarms.
- **Refresh** The system returns the screen to the most recent alarms.
- **Help** The system displays a description of the alarm and the corrective actions.
- Search Search for alarms by date, alarm number, or alarm level.
- Close The system closes the Alarm List screen.



The alarm help information is only available in the **Alarm List**. The AU680 Instructions for Use and AU680 Reference Manual do not contain alarm descriptions and corrective actions.

## Interpreting Lipemia, Icterus, and Hemolysis (LIH) Results

#### Sample Specific LIH

Each sample prints with a flag for Normal (N) through Abnormal (ABN) for levels of:

- Lipemia (LIP)
- Icterus (ICT)
- Hemolysis (HEM)

The system generates each flag determined by the parameters in **Parameters > Specific Test Parameters > LIH** for the LIH test.

Table 5.18 Sample Specific LIH Flags

Name	Flags	
LIP (lipemia)	N + ++ +++ ++++ ABN	
ICT (icterus)	N + ++ +++ ++++ ABN	
HEM (hemolysis)	N + ++ +++ ++++ ABN	

A result of ABN (abnormal) means the mathematical logic in determining the amount of interference failed one or more internal evaluations. Visually inspect the sample to determine the amount of lipemia, icterus, and hemolysis present in the sample.

## **Test Specific LIH**

When the level of interfering substances exceeds the criteria programmed for a specific test in **Specific Test Parameters**, the system attaches an l, i, or h flag to the result affected by lipemia, icterus, or hemolysis.

When LIH testing is not performed on a sample, the system attaches an n flag to the result. The n flag differentiates LIH testing not being performed, and LIH not influencing the test. The system typically generates an n flag when the LIH reagent is empty, or the LIH test was not ordered (requisitioned).

Na, K, and Cl tests are not evaluated for assay specific LIH criteria and do not generate the n flag.

#### **LIH Reagent IFU**



The concentrations listed in the table are for reference. Depending on the matrix effect with an individual serum sample, some results may not meet the listed concentrations.

 Table 5.19
 Approximate Concentration of Chromatic Substance

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
N	<40	<2.5	<50
+	40 to 99	2.5 to 4.9	50 to 99

5-16 B04779AB

<b>Table 5.19</b>	<b>Approximate</b>	Concentration of	Chromatic Substance	(Continued)
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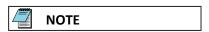
Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
++	100 to 199	5.0 to 9.9	100 to 199
+++	200 to 299	10.0 to 19.9	200 to 299
++++	300 to 500	20 to 40	300 to 500
+++++	>500	>40	>500

#### Figure 5.14 Example of LIH Evaluation

S.No. 0001	0003-01	S.ID 123456	
CRE 0.6	CHOL 280	TBIL 0.3	DBIL 0.3 h
LIP +	ICT N	HEM ++	

According to the Direct Bilirubin IFU (example), Interfering Substances are:

- Hemolysis: No significant interference up to 10 mg/dL Hemolysate
- Lipemia: No significant interference up to 300 mg/dL Intralipid



The interference information from the Direct Bilirubin IFU (example) is provided as an example. For the current interference information on direct bilirubin, refer to the Direct Bilirubin IFU.

According to the LIH Reagent IFU Table:

- A hemoglobin rating of ++ is equivalent to 100 to 199 mg/dL in the sample. Since the Direct Bilirubin IFU indicates no significant interference only up to 10 mg/dL, the system attaches an h flag in the printout to the DBIL result to indicate that the performance of this test could have been affected by hemolysis.
- A lipemia rating of + is equivalent to 40 to 99 mg/dL of Intralipid in the sample. Since the Direct Bilirubin IFU indicates no significant interference up to 300 mg/dL, the system does not attach an l flag to the DBIL result.

## **Reagent Management**

#### Reagents

Most Beckman Coulter reagents are liquid and ready to place in the reagent refrigerator after removing the cap. If a reagent requires preparation, refer to the Chemistry Information Sheet before loading the reagent into the reagent refrigerator.

The system can use four sizes of reagent bottles:

- 15 mL
- 30 mL
- 60 mL

#### • 120 mL

**Table 5.20** Adapter and Partition Part Numbers

Adapter	Part Number	Partition	Part Number
15 mL reagent bottle	MU852700	R1 reagent tray	MU852600
30 mL reagent bottle	MU852800	R2 reagent tray	MU825800

The reagent tray in an analyzer refrigerator uses partitions between  $15 \, \text{mL}$ ,  $30 \, \text{mL}$ , and  $60 \, \text{mL}$  bottles, and adapters to hold  $15 \, \text{mL}$  and  $30 \, \text{mL}$  reagent bottles securely in position.  $120 \, \text{mL}$  bottles occupy two positions on the reagent tray. If necessary, remove a partition to load a  $120 \, \text{mL}$  bottle on the tray.

The AU680 contains two reagent refrigerators, R1 and R2. You can use the 15 mL and 30 mL bottle adaptors in either refrigerator. Partitions, however, are specific to each refrigerator and cannot be interchanged. The partitions for the R1 refrigerator are taller than the ones for the R2.

Replace adapters when the pins are damaged, or when the adapter no long clicks into place on the reagent tray.

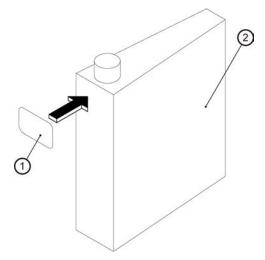
The R1 refrigerator holds up to 60 reagent bottles, and the R2 refrigerator holds up to 48. 120 mL reagent bottles occupy two positions on the reagent tray, and reduce the maximum quantity of bottles respectively.

#### **Commercial Reagent Bottles**

Commercial reagent bottles not sold by Beckman Coulter are available in the Japan and Asia markets.

If the color of the commercial reagent bottle is too light for the bottle sensor to detect, apply a label as shown in Figure 5.15 Apply a Label to a Reagent Bottle. The part number for the labels is MU987900.

Figure 5.15 Apply a Label to a Reagent Bottle



1. Label

2. Reagent bottle

5-18 B04779AB

When you use commercial reagent bottles, the test count displayed on the Reagent Management screen can differ from the remaining test count. The system uses the liquid level in the bottle to calculate the test count. Because the bottle is different from the Beckman Coulter reagent bottles, the calculation may be incorrect.

## **Fill Reagent Bottles**



## **CAUTION**

Bubbles in the reagent bottle can interfere with analysis. Inspect the reagent bottles for bubbles. Remove bubbles with a cotton-tipped applicator before loading the reagent.



#### **CAUTION**

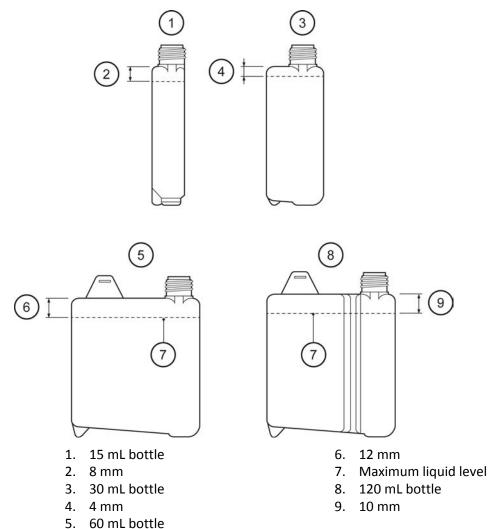
Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.



#### **CAUTION**

When you fill AU bottles with reagent, wash solution, or deionized water, do not exceed the maximum volume. The maximum volume depends on the bottle size. If a reagent bottle is filled over the maximum liquid level limit, bubbles can occur and cause a level detection error.

Figure 5.16 Maximum Liquid Level



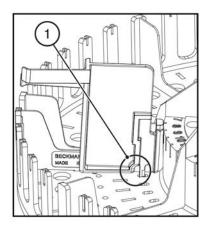
# Add Adapters to the Reagent Tray

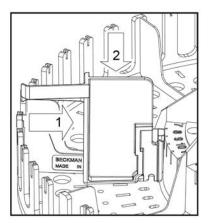
The 30 mL and 15 mL bottles require reagent tray adapters.

**1** Insert the long pin of the adapter into the elongated hole in the reagent tray.

5-20 B04779AB

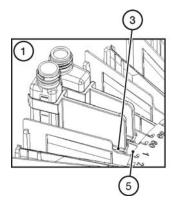
Figure 5.17 Insert Adapter

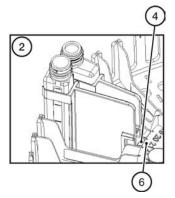




- 1. Elongated Hole
- **2** Push the adapter toward the center of the tray. Refer to arrow 1 in Figure 5.17 Insert Adapter.
- **3** Press the adapter down until it clicks into the other hole on the reagent tray. Refer to arrow 2 in Figure 5.17 Insert Adapter.
- 4 Confirm that the adapter is secure on the reagent tray. The top of the reagent tray (with the position numbers) must be level with the top of the adapter protrusion.

Figure 5.18 Confirm Adapter Placement in Reagent Tray





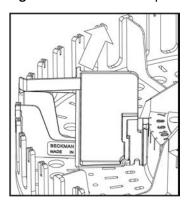
- 1. Adapter protrusion
- 2. Adapter protrusion
- 3. Top of the reagent tray with the position number
- 4. Top of the reagent tray with the position number

# **Remove Adapters from the Reagent Tray**

Replace adapters when the pins appear damaged, or the adapter no longer clicks when you place it on the reagent tray.

- **1** Hold the reagent tray so that reagents do not spill.
- **2** Lift the adapter in the direction shown in Figure 5.19 Remove Adapter from the Reagent Tray .

Figure 5.19 Remove Adapter from the Reagent Tray



# **Assign a Reagent Position**

You can place reagents that have bar code labels in any available (not assigned) position on the reagent tray. For reagents without bar code labels, assign the reagent to a fixed position. Place reagents without a bar code label in the correct assigned position.

1 Select Home > Reagent Management > Details.

The system displays the Reagent Management: Details tab. The system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column.



Before assigning a position, confirm that the reagent status is **Checked**. If the reagent status is **Unchecked**, select **Reagent Check (F5)**, and then select **Reset**.

5-22 B04779AB

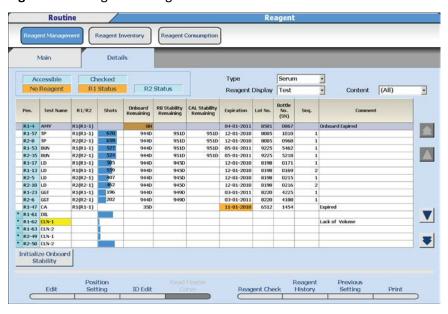


Figure 5.20 Reagent Management: Details Tab

- 2 In Reagent Display, select Position.
- **3** In **Content**, select **R1** to assign a position in the R1 refrigerator, or **R2** to assign a position in the R2 refrigerator.
- **4** Select an open position to assign to the reagent.
- Select Position Setting (F2).The system displays the Edit ID/Fix Reagent dialog for the selected position.

Figure 5.21 Edit ID/Fix Reagent Dialog



- 6 Select **Fixed Reagent**, and then select **Close**.

  The system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column.
- **7** Select **Edit (F1)**. The system displays the Reagent Edit dialog.

Figure 5.22 Reagent Edit Dialog



- a. In **Test Name**, select the test name.
- b. In Type, the system displays R1 (R1-1) or R2 (R2-1). If necessary, select R1 (R1-1) or R1 (R1-2).
- **c.** In **Lot No.**, enter a lot number according to your laboratory procedure.
- **d.** In **Bottle No.(SN)**, enter a bottle number according to your laboratory procedure.
- e. In Bottle Size, select the reagent bottle size.
- f. Select Close.
- **8** If the reagent has an R2 bottle, repeat steps 3 to 7 with **Content** selected for **R2**.
- **9** Confirm that the system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column.
- 10 Select Reagent Check (F5).

The system displays the Reagent Check dialog.

**11** Select **Check Specified positions**, and then select the positions that you assigned.

### 12 Select Start.

The system performs a reagent check at the specified positions, and updates the test count on the Details tab.

## **Edit a Reagent ID**

Edit the reagent ID after a reagent ID read error occurs on a bar code labeled reagent bottle.

A notification alarm occurs during the reagent check (Reagent ID Read Error), and the system displays the comment ID Edit until the reagent bottle is removed from the refrigerator.

- 1 Select Home > Reagent Management > Details.
- 2 In Reagent Display, select Position.
- **3** Place the cursor on the position with the reagent ID read error.

5-24 B04779AB

4 Select ID Edit (F3).

Figure 5.23 Edit Barcode ID Dialog



- Type in the 20-digit reagent ID from the reagent bottle. Select OK.
  The system updates the onboard stability, expiration, lot number, and bottle number with a No Volume to Process comment.
- 6 Select Reagent Check (F5), and then select Check Specified positions to update the test count. The system displays a Reagent ID Read Error alarm and ID Edit comment. The system updates the RB stability and cal stability.

# **System Shutdown (End Process)**

Shutting down the system (an End Process) turns off the analyzer lamp and the computer. The system maintains the refrigerator, incubator, and STAT table temperatures. The ISE module performs an automatic prime with ISE MID Standard Solution every hour to keep the electrodes conditioned.

You can initiate a system shutdown after you start a W2 or photocal. If you initiate a system shutdown after you start a W2 or photocal, the W2 or photocal completes, and then the system shuts down. For more information, refer to Perform a W2 or Perform a Photocal.

- 1 Select Home.
- Select **End** . The system displays the End dialog.

Figure 5.24 End Dialog



- **3** Review the next auto on time.
  - a. To set an auto on time, select **Setting**.
  - **b.** In Auto Start up, select Yes.
  - c. In **Date** and **Time**, select the date and time for the system to turn on.
  - **d.** To turn off the auto on time, in **Auto Start up** select **No**.
  - e. Select Confirm.



Beckman Coulter programs Auto Preparation in the System Maintenance menu during installation. Programming options include a daily time for Auto On and Auto Preparation. The Auto Preparation is the weekly photocal.

For more information, refer to the AU680 Reference Manual.

**4** Select **Yes**. The system shuts down.



Follow your laboratory procedure for turning off the deionized water supply.

## **Pause Analysis**

You can pause the analyzer to add reagent and then resume analysis.

5-26 B04779AB



Do not leave the system paused for an extended time. When you pause the analyzer for an extended time, the concentration of the samples in the sample cups increases from evaporation and the evaporation can affect results.



Do not remove or add racks while the system is paused, as it can cause concordance errors.

- 1 Select **Pause** . The system displays the Pause dialog.
- Select OK.

The system displays the analyzer mode as => *PAUSE* until the system completes all samples in progress. When the system changes the analyzer mode to *Pause*, you can add reagent and perform a reagent check.



To avoid injury or damage to the reagent probes, confirm that the analyzer is in *Pause* mode before adding reagents or performing a reagent check.

### Resuming Analysis from Pause Mode

Analysis starts at the next test for analysis after you selected **Pause**.

- **1** Select **Start**. The system displays the Start dialog.
- **2** Select **Start**. The system restarts analysis.

# Rack Feeder Stop

You can stop the rack feeder to insert an emergency or routine rack before other racks during analysis.

When you stop the rack feeder, analysis continues for the racks that were fed by the rack feeder.

When the AU680 connects to a laboratory automation system, selecting **Feeder Stop** does not stop the supply of samples to the system. For more information, refer to the Laboratory Automation System manual.

## **System Monitoring and Results**

Stop Analysis



Do not leave the rack feeder stopped for an extended time. When you stop the rack feeder for an extended time, the concentration of the samples in the sample cups increases from evaporation and can affect results.

## **Stop the Rack Feeder**

- Select **Feeder Stop** . The system displays the Feeder Stop dialog.
- **2** Select **OK**. The system displays the rack feed operation stop message. Racks that were moved from the rack supply module continue analysis.

## **Restart Analysis After Rack Feeder Stop**

- **1** When the rack feeder is stopped, use normal ordering (requisition) procedures. For more information, refer to Order (Requisition) for Routine and Emergency Samples.
- **2** Select **Start**. The system displays the Start dialog.
- **3** Select **Start**. The system restarts analysis.

# **Stop Analysis**

To stop analysis immediately, perform a system stop.



If you stop the system during *Measure* mode, any data that is not complete is lost and you must reanalyze the samples.



If you perform a stop or emergency stop or a power loss occurs, sample can remain in the sample probe, and reagents can remain in the cuvettes. Perform a W1 to clean the sample probe and cuvettes after you restart the system. For more information, refer to Perform a W1.

When the AU680 connects to a laboratory automation system, selecting **Stop/Standby** stops sample aspiration for the samples being routed to the AU680. For more information, refer to the Laboratory Automation System manual.

5-28 B04779AB

- Select **Stop/Standby** during analysis operation. The system displays the Stop dialog with a confirmation message.
- **2** Select **OK**. All analysis operation stops, and the system changes to *Stop* mode.
- **3** Remove racks from the rack transport belts.

### Return to Standby Mode from Stop Mode

- In *Stop*, select **Stop/Standby**. The system displays the Warmup/Standby dialog with a confirmation to reset the analyzer to *Standby* mode or *Warm up* mode.
- **2** Select **OK**. The system performs the reset operation. After the system completes the reset operation, the system changes to *Standby* mode or *Warm up* mode.
- **3** Perform a W1. For more information, refer to Perform a W1.

# **Perform an Emergency Stop**

An emergency stop turns off power immediately to the analyzer and ISE module.

- 1 Press the **EM STOP** button. All power to the analyzer and ISE module turns off immediately. The computer remains on. To turn off the computer, press [Ctrl] + [ALT] + [Delete]. The computer displays a Windows Security dialog. Select **Shut Down**.
- **2** Remove all racks from the rack transport belts.

### Return to Standby Mode After an Emergency Stop

- 1 Press the **RESET** button (white button on the front-right of the analyzer) to turn on the main power, and then wait 5 seconds.
- **2** Press the **ON** button (green button on the front-right of the analyzer). The lamp turns on and the software loads. The system displays a dialog to confirm retrieving the database.
- 3 Select OK.
- 4 In the New Index dialog, select **Current Index** to continue analysis in the current index.
- 5 The system is in *Warm up* mode for 1.5 hours. After the required 20-minute lamp warm up time, wait until the temperature of the cuvette wheel is 37 °C, and then select **Home** > **Analyzer Maintenance**. Select **Stand By (F4)** to return to *Standby* mode.
- **6** Perform a W1. For more information, refer to Perform a W1.

#### **System Monitoring and Results**

Identifying and Reanalyzing Samples after a Cuvette Overflow

# **Identifying and Reanalyzing Samples after a Cuvette Overflow**

A cuvette overflow could have occurred 60 minutes before the system generates the Photometry error during cuvette wash (###) alarm. The results measured during the 60 minutes before the alarm are invalid and must be reanalyzed.

The analyzer changes to *Stop* mode immediately after the system generates the Photometry error during cuvette wash (###) alarm.



#### **NOTE**

For example, in Photometry error during cuvette wash (###), the ### is the cuvette number (1 to 165) with a photometric error.



### **WARNING**

The tests performed during the 60 minutes before the Photometry error during cuvette wash (###) alarm can have an incorrect result caused by the overflow. The results are invalid and must be reanalyzed. If you have reported results or transferred the results to the laboratory information system, take corrective actions according to your laboratory procedure.

The 60-minute timeframe is the time that the analyzer was in *Measure* mode. If the analyzer went into *Standby* mode and did not remain in *Measure* mode for 60 consecutive minutes before the alarm, add *Standby* mode time to the 60-minute timeframe. For example, if the analyzer was in *Standby* mode for 20 minutes total, add 20 minutes to the 60 minutes and search for samples affected by the overflow in the past 80 minutes.

Search for samples affected by the overflow.

1 Select Home > Alarm List.

5-30 B04779AB





- 2 Search for the alarm message Photometry error during cuvette wash (###).
- 3 Note the date and time of the alarm.
  For example: 2012/03/21 11:32 PHOTOMETRY ERROR DURING CUVETTE WASH (36)
- 4 Search for the MEASURE START messages. Calculate the time between the Photometry error during cuvette wash (###) alarm and the most recent MEASURE START message.
  - If the time between the alarm and measure message is 60 minutes or longer, the timeframe for searching samples with invalid data is 60 minutes.
  - If the time between the alarm and the measure message is shorter than 60 minutes, determine the time in *Measure* mode, and add it to the next time in *Measure* mode, and continue adding the time until the total time in *Measure* mode is 60 minutes. Add the total time in *Standby* between the *Measure* modes and the Photometry error during cuvette wash (###) alarm, and add it to 60 minutes. The result is the timeframe for searching samples with invalid data.
- 5 Specify the start date and time for the search to identify all the affected indexes. In the following example, the timeframe for the search is 82 minutes (22 minutes of *Standby* time between 10:33 and 10:55 is added to 60 minutes of *Measure* time). Calculate backwards from the Photometry error during cuvette wash (###) alarm (2012/03/21 11:32) by 82 minutes to obtain the starting date and time for the search. The starting date and time for the search is then 2012/03/21 10:10.

The affected indexes include the index that was generated immediately before the starting date and time and all the indexes after the starting date and time. In this example, the two indexes in bold are the affected indexes.

Б04779АВ 5-31

2012/03/21	11:32	PHOTOMETRY ERROR DURING CUVETTE WASH (36)
2012/03/21	10:55	MEASURE START
2012/03/21	10:43	INDEX UPDATED (2012/03/21 10:43)
2012/03/21	10:33	STANDBY
2012/03/21	09:27	MEASURE START
2012/03/21	09:23	INDEX UPDATED (2012/03/21 09:23)
2012/03/21	09:10	STANDBY
2012/03/21	08:07	MEASURE START



This information is only an example. Typically, a new index is created once a day or once a shift.

The ending search date and time is the time when the system generated the Photometry error during cuvette wash (###) alarm. In this example, the time the system generated the alarm is 2012/03/21 11:32.

6 Select Menu List > Routine > Data Monitor > Reaction Monitor > Main.



Figure 5.26 Data Monitor: Reaction Monitor Screen

- 7 In Index, select the affected index or the oldest index among the affected indexes obtained in step 5. In this example, select 2012/03/21 09:23.
- **8** Select all of the available boxes for sample types and kinds that the system has processed.

5-32 B04779AB

9 Select Search Condition (F5).

Figure 5.27 Search Condition Dialog



- 10 Select Range of Date to specify the dates and times in From and To determined by steps 11 and 12. If you do not specify the date range, the system selects all samples within the index.
- **11** Enter the starting date and time for search obtained in step 5 in **From**. In this example, enter **2012/03/21 10:10**.
- **12** Enter the ending date and time for search obtained in step 5 in **To**. In this example, enter **2012/03/21 11:32**.
- 13 Select Sample No.
- 14 Select OK.
- **15** Select the **General** tab.

Figure 5.28 Reaction Monitor: General Tab

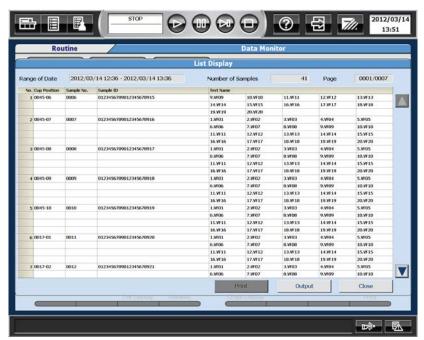


#### **System Monitoring and Results**

Identifying and Reanalyzing Samples after a Cuvette Overflow

**16** Select **List Display (F3)**. The system displays a list of samples with invalid data. Reanalyze these samples.

Figure 5.29 List Display Dialog



**17** Repeat steps 6 through 16 for all affected indexes.

### **Output the List to Media**

Precautions for using external storage:

- Format the floppy disk for data or parameters. Set the write protect tab to the lock position after saving data.
- Inspect for viruses on a separate computer for floppy disks, CD-Rs, or USB flash drives and confirm that no viruses are detected after saving data.
- When using a CD-R, write data on the CD-R and set it to unrecordable.

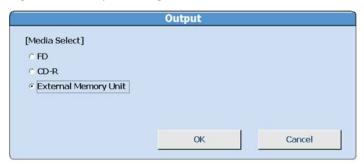


Virus pattern files are information files necessary for virus detection. Update antivirus software with the latest virus pattern files from the antivirus software manufacturer regularly. Contact the antivirus manufacturer if needed.

**1** Select **Output** from the List Display dialog.

5-34 B04779AB

Figure 5.30 Output Dialog



- 2 In [Media Select], select the media.
- **3** Select **OK**. The system displays the Data Output dialog.
- 4 Select **OK**. The Data Output dialog displays the save progress. The name of the saved file is MeasureList\_YYYYMMDD\_HHMM.csv, with YYYYMMDD\_HHMM as the name of the index.



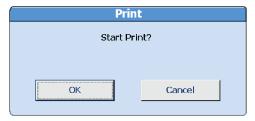
The system does not include pending samples in this list.

- **5** Select **OK** to return to the List Display dialog. Remove the media.
- **6** Data is saved as a csv file. Use a separate computer to open the file and view or print the list of samples with invalid data.

#### Print the List

1 Select **Print** from the List Display dialog.

Figure 5.31 Print Dialog



- 2 Select OK.
- 3 Select Close.

# **System Monitoring and Results**

Identifying and Reanalyzing Samples after a Cuvette Overflow

5-36 B04779AB

### Introduction

The maintenance frequency described in this chapter is determined by analysis of 4,000 or less tests per day.

Increase the amount of maintenance required depending on the quantity of tests and local environmental conditions.

Manage the ISE maintenance schedule for biweekly or longer periodic maintenance either periodically or by the quantity of samples analyzed. The ISE maintenance frequency described in this chapter is determined by analysis of 200 ISE samples per day.

Calibration may be required after replacement of key parts such as syringes or probes. After any part replacement or significant maintenance, Beckman Coulter recommends that you perform QC analysis. If any shifts are observed, calibrate all onboard tests.

Only Beckman Coulter is authorized to replace the fuse near the breaker on the back of the rack feeder module.

# **Warnings and Cautions**



Operate the analyzer with the covers down. If you need the covers up during maintenance, keep all body parts away from the probes and other moving parts of the analyzer. Serious injury can occur and you can damage the analyzer.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats when performing any procedure. To avoid injury, observe and follow all the warnings and cautions throughout this manual.



Failure to perform maintenance according to the instructions within this manual can cause problems with system performance and invalidate the service agreement.

#### Maintenance

**Warnings and Cautions** 



When you press the TABLE ROTATION/DIAG button the first time after you select a maintenance procedure option, the system initializes. To avoid injury, do not touch any moving parts until the system indicates that the analyzer is ready (as indicated by alarms, modes, and LEDs).

6-2 B04779AB

# **Maintenance Schedule**

Mark procedures off as you complete the maintenance procedure.



For the Japan market, refer to the Maintenance Schedule in the ISE Addendum.

 Table 6.1
 Daily Maintenance

Daily Maintenance	Month and Year:
Inspect the Syringes for Leaks	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect the Wash Solution Roller Pump for Leaks	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect the Wash Solution and Replenish as Needed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect the Stability of the Upper Cover	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Deionized Water or Diluent in the Pre-dilution Bottle	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect the Sample Probe Wash Solutions	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect the Printer and Paper	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the ISE (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Calibrate the ISE (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

 Table 6.2
 Weekly Maintenance

Weekly Maintenance	Month and Year:
Clean the Sample Probe and Mix Bars	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Weekly Maintenance	Month and Year:
Perform a W2	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Perform a Photocal	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the Pre-dilution Bottle	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Selectivity Check for the Na and K Electrodes (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Enhanced Cleaning of Electrode Line (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

 Table 6.3
 Every Other Week or 3,000 Samples (ISE Option)

Every Other Week or 3,000 Samples (ISE Option)	Month and Year:
Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

 Table 6.4
 Monthly Maintenance

Monthly Maintenance	Month and Year:
Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the Mix Bar Wash Wells	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

 Table 6.5
 Every Other Month or Every 20,000 Samples (ISE Option)

Every Other Month or Every 20,000 Samples (ISE Option)	Month and Year:
Inspect and Add ISE Internal Reference Solution (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Table 6.6 Quarterly Maintenance

Quarterly Maintenance	Month and Year:
Clean the Air Filters	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Wash Solution Roller Pump Tubing	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

# Table 6.7 Quarterly or Every 20,000 Samples (ISE Option)

Quarterly or Every 20,000 Samples (ISE Option)	Month and Year
Replace the Mixture Aspiration and MID Standard Roller Pump Tubing (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Tubing between the Sample Pot, Electrode Block, and T-Connector (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Manually Clean the Drain Well and, if Needed, Replace the Drain Tube (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

# Table 6.8 Every 6 Months Maintenance

Every 6 Months Maintenance	Month and Year
Clean the Cuvettes and the Cuvette Wheel	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

# Table 6.9 Every 6 Months or Every 40,000 Samples (ISE Option)

Every 6 Months or Every 40,000 Samples (ISE Option)	Month and Year:
Replace the Na, K, or Cl Electrode	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Every Two Years or Every 150,000 Samples (ISE Option)	Month and Year:
Replace the ISE REF Electrode and Packing (ISE Option)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

# Table 6.11 Yearly Maintenance

Yearly Maintenance	Month and Year:
Replace the O-rings in the Water Supply Tube Mounting Joint	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

# Table 6.12 As Needed Maintenance

As Needed Maintenance	Month and Year:
Clean the R1 or R2 Reagent Probes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace a Sample or Reagent Probe	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Mix Bars	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace a Wash Nozzle Joint	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Packing in the Wash Nozzle Tube Mounting Joints	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace Syringes or Syringe Case Heads	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Wash Syringe	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the Interior of the Reagent Refrigerators and STAT Table Compartment	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean or Replace the Anti-static Brushes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Sample or Reagent Probe Tubing	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Perform a W1	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace Rack ID Labels	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Table 6.12 As Needed Maintenance (Continued)

As Needed Maintenance	Month and Year:
Clean or Replace Individual Cuvettes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the Photometer Lamp	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Save Parameters	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

# Table 6.13 As Needed Maintenance (ISE Option)

As Needed Maintenance (ISE Option)	Month and Year:
Replace the Sample Pot	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Clean the ISE Electrode Block (Inlet Side)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Manually Clean the ISE K Electrode	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Manually Clean and Replace the ISE REF Electrode Block	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace the ISE Reagents	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace ISE Buffer Solution	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace ISE Reference Solution	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Replace ISE MID Standard Solution	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Enhanced ISE Cleaning (Manual)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

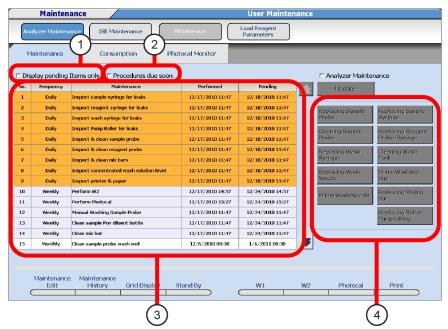
# **Maintenance Log**

The Maintenance Log displays the maintenance frequency, the maintenance procedure, the date the maintenance was performed, and the next date the maintenance is due.

To confirm the maintenance schedule:

1 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.

Figure 6.1 Analyzer Maintenance: Maintenance Tab



- 1. Display pending items only
- 2. Procedures due soon

- 3. Maintenance log
- 4. Maintenance operation buttons

The system displays any maintenance procedures that are overdue or about to expire:

- Orange overdue
- Yellow about to expire



#### **NOTE**

The system displays daily procedures with a yellow background three hours before the maintenance is due.

- **2** Confirm the maintenance procedure to perform. Identify maintenance procedures that are overdue or about to expire:
  - To display the overdue procedures, select **Display pending Items only**.
  - To display the maintenance procedure about to expire, select **Procedures due soon**.

6-8 B04779AB



If you select either **Display pending Items only** or **Procedures due soon**, the system does not list the unscheduled and as needed procedures.

#### Add a Maintenance Procedure

Operators can add procedures to the Maintenance Log.

The system is preprogrammed with maintenance procedures specified by Beckman Coulter.

- **1** Select a blank row from the Maintenance Log.
- **2** Select **Maintenance Edit (F1)**. The system displays the Item Edit dialog.

Figure 6.2 Item Edit Dialog



- **3** In **Maintenance**, enter the maintenance name.
- **4** In **Frequency**, select the performance interval (Day, Week, Month, or Year). Enter the interval value from 1 to 180.
- **5** Select **OK**. The system displays the added maintenance procedure in the Maintenance Log according to the frequency selected.

#### **Delete a Maintenance Procedure**

Operators can delete maintenance procedures programmed by operators.

You cannot delete maintenance procedures preprogrammed by Beckman Coulter.

If you delete any maintenance procedure, the history data is also deleted.

- **1** Select the maintenance procedure to delete.
- **2** Select **Maintenance Edit (F1)**. The system displays the Item Edit dialog.
- **3** Delete the maintenance name in the Maintenance column.
- **4** Select **OK**. The system displays a confirmation message dialog.
- **5** Select **OK**.

# **Update the Maintenance Log**

After you perform maintenance, update the Maintenance Log.

1 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.

or

Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.

- **2** Select the maintenance procedure on the list, and select **Update**. The system displays the User Maintenance dialog.
- 3 Select OK.

## **View Maintenance History**

The system maintains a list of the ten most recently completed maintenance procedures.

- **1** Select the maintenance procedure to view from the Maintenance Log.
- 2 Select Maintenance History (F2).

The system opens the Maintenance History dialog for the selected maintenance procedure. The system displays the last ten maintenance dates, the next due date, and the user name. The user name is the name used to log in with.

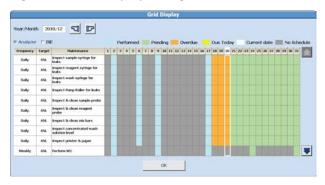
Figure 6.3 Maintenance History Dialog



- 3 Select OK.
- **4** Select **Grid Display (F3)** to confirm the maintenance history date as a list.

6-10 B04779AB

Figure 6.4 Grid Display Dialog



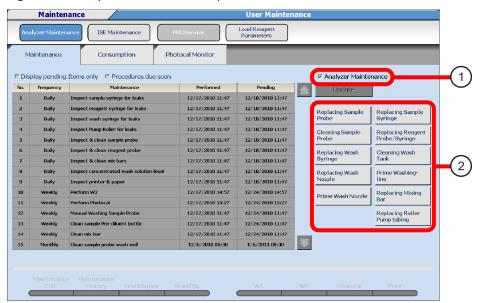
The Grid Display dialog displays scheduled maintenance procedures and status for the current month, preceding month, and following month.

If you select **ISE**, the dialog also displays the ISE maintenance procedures. The colors on the grid indicate the status of the maintenance procedure.

# **Accessing Maintenance Operations**

To perform many of the analyzer and ISE maintenance procedures, you need to access the maintenance operation buttons. The overall process is the same for all maintenance procedures, and the maintenance procedure instructs what specific maintenance operation button is required.

Figure 6.5 Analyzer Maintenance Operation Buttons



1. Analyzer Maintenance box

2. Maintenance operation buttons

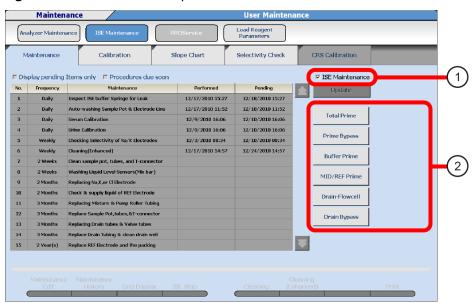


Figure 6.6 ISE Maintenance Operation Buttons

1. ISE Maintenance box

- 2. Maintenance operation buttons
- **1** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.

or

Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.

**2** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.

or

Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.

**3** Select the maintenance operation button according to the maintenance procedure.

# **Parts List for Analyzer Maintenance**

 Table 6.14
 Daily Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Inspect the Syringes for Leaks	Clean, dry, lint-free absorbent tissue	Commercial item
Inspect the Wash Solution Roller Pump for Leaks	Clean, dry, lint-free absorbent tissue	Commercial item

6-12 B04779AB

 Table 6.14 Daily Analyzer Maintenance (Continued)

Maintenance Procedure	Part	Part Number
Inspect the Wash Solution and Replenish as Needed	Wash solution	<ul><li>OSR0001 (Outside Japan)</li><li>MS028400 (Japan)</li></ul>
Inspect the Stability of the Upper Cover	-	-
Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
Replace the Deionized Water or Diluent in the Pre-dilution Bottle	Deionized water or diluent	-
Inspect the Sample Probe Wash Solutions	2% Wash solution or Sodium hypochlorite solution (1.0%)  • 5% Sodium Hypochlorite Solution diluted 1:5 (US) • Cleaning Solution diluted 1:5 (Outside US and Japan) • Sodium hypochlorite solution (5%) diluted 1:5 (Japan)	<ul> <li>OSR0001 (Outside Japan)</li> <li>MS028400 (Japan)</li> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>
	60 mL reagent bottle (2 bottles)	MU960500
Inspect the Printer and Paper	-	-

 Table 6.15
 Weekly Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Clean the Sample Probe and Mix Bars	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
	Stylet 0.2φ (diameter)	MU941300

 Table 6.15
 Weekly Analyzer Maintenance (Continued)

Maintenance Procedure	Part	Part Number
Perform a W2	1N hydrochloric acid	Commercial item
	Sodium hypochlorite solution (0.5%)  • 5% Sodium Hypochlorite Solution diluted 1:10 (US)  • Cleaning Solution diluted 1:10 (Outside US and Japan)  • Sodium hypochlorite solution (5%) diluted 1:10 (Japan)	<ul> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>
	60 mL reagent bottle (3 bottles)	MU960500
	<ul> <li>ISE Cleaning Solution</li> <li>ISE Cleaning Solution (US)</li> <li>Cleaning Solution (Outside US)</li> </ul>	<ul> <li>AUH1019 (US)</li> <li>66039 (Outside US)</li> <li>For the Japan market, refer to the ISE Addendum.</li> </ul>
	Hitachi Cup	MU853200
Perform a Photocal	-	-
Clean the Pre-dilution Bottle	Sodium hypochlorite solution (0.5%)  • 5% Sodium Hypochlorite Solution diluted 1:10 (US)  • Cleaning Solution diluted 1:10 (Outside US and Japan)  • Sodium hypochlorite solution (5%) diluted 1:10 (Japan)	<ul> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>
	60 mL reagent bottle	MU960500

6-14 B04779AB

 Table 6.16
 Monthly Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells	Sodium hypochlorite solution (0.5%)  • 5% Sodium Hypochlorite Solution diluted 1:10 (US)  • Cleaning Solution diluted 1:10 (Outside US and Japan)  • Sodium hypochlorite solution (5%) diluted 1:10 (Japan)	<ul> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>
	Cotton-tipped applicator	Commercial item
	Disposable pipette	Commercial item
Clean the Mix Bar Wash Wells	Sodium hypochlorite solution (0.5%)  • 5% Sodium Hypochlorite Solution diluted 1:10 (US)  • Cleaning Solution diluted 1:10 (Outside US and Japan)  • Sodium hypochlorite solution (5%) diluted 1:10 (Japan)	<ul> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>
	Cotton-tipped applicator	Commercial item
	Disposable pipette	Commercial item
Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints	Clean, dry, lint-free absorbent tissue	Commercial item
	Sonicator filled with deionized water	Commercial item

В04779АВ 6-15

 Table 6.16
 Monthly Analyzer Maintenance (Continued)

Maintenance Procedure	Part	Part Number
Clean the Deionized Water Tank, Deionized Water Filter, and	Clean, dry, lint-free absorbent tissue	Commercial item
Sample Probe Filter	Basin	Commercial item
	Sonicator filled with deionized water	Commercial item
	Extra deionized water tank, filled with 5 L of deionized water	MU959600
	Sodium hypochlorite solution (1.0%)  • 5% Sodium Hypochlorite Solution diluted 1:5 (US)  • Cleaning Solution diluted 1:5 (Outside US and Japan)  • Sodium hypochlorite solution (5%) diluted 1:5 (Japan)	<ul> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>

 Table 6.17
 Quarterly Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Clean the Air Filters	Air filters	MU853100 (96 x 126 mm) MU959300 (140 x 140 mm)
	Vacuum	Commercial item
Inspect and, if Needed, Replace	Sample Probe Filter	ZM307900
the Deionized Water Filter, Sample Probe Filter, and Replace	Deionized Water Filter	ZM307900
the O-Ring	O-rings	MU963700
Replace the Wash Solution Roller Pump Tubing	Roller pump tubing	MU962300

6-16 B04779AB

 Table 6.18
 Six-Month Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Clean the Cuvettes and the Cuvette Wheel	2% Wash solution	<ul><li>OSR0001 (Outside Japan)</li><li>MS028400 (Japan)</li></ul>
	Cotton-tipped applicator	Commercial item
	Clean, dry, lint-free absorbent tissue	Commercial item
	Sonicator	Commercial item
	Plastic containers to hold cuvettes in the sonicator	Commercial item

 Table 6.19
 Yearly Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Replace the O-rings in the Water	O-rings	MU963800
Supply Tube Mounting Joint	Clean, dry, lint-free absorbent tissue	Commercial item
	Pair of tweezers	Commercial item

 Table 6.20
 As Needed Analyzer Maintenance

Maintenance Procedure	Part	Part Number
Clean the R1 or R2 Reagent Probes	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
	Stylet φ0.3 (diameter)	ZM022700
Replace a Sample or Reagent	Sample probe	MU993400
Probe	Reagent probe	MU995800
Replace the Mix Bars (For all	R1/S: Spiral shape mix bar	MU959900
markets except Japan)	R2: L shape mix bar	MU826700
Replace the Mix Bars (For Japan only)	R1/S, R2: Spiral shape mix bar	MU959900
Replace a Wash Nozzle Joint	Wash nozzle joint	ZM113100
Replace the Packing in the Wash Nozzle Tube Mounting Joints	Packing	MU842700
	Pair of tweezers	Commercial item

 Table 6.20
 As Needed Analyzer Maintenance (Continued)

Maintenance Procedure	Part	Part Number
Replace Syringes or Syringe Case	Sample syringe (S syringe)	ZM011100
Heads	Reagent syringe (R syringe)	ZM011200
	S syringe case head	ZM022900
	R syringe case head	MU837000
	ISE buffer syringe case head	ZM136200
	Clean, dry, lint-free absorbent tissue	Commercial item
Replace the Wash Syringe	Wash Syringe Type 1 (R syringe)	ZM011200
	R syringe case head	MU837000
	Wash Syringe Type 2 (Wash Syringe)	B16554
	Seal Assembly	B21251
	Piston	B16681
	Clean, dry, lint-free absorbent tissue	Commercial item
	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
Clean the Interior of the Reagent Refrigerators and STAT Table	Clean, dry, lint-free absorbent tissue	Commercial item
Compartment	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
Clean or Replace the Anti-static	Anti-static brushes (2 pieces)	MU852500
Brushes	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
Replace the Sample or Reagent Probe Tubing	Sample probe tubing	MU851900
	R1 probe tubing	MU852000
	R2 probe tubing	MU852100
Perform a W1	-	-
Replace Rack ID Labels	Rack ID labels	MU906600 to MU908500

6-18 B04779AB

<b>Table 6.20</b>	As Needed Analyzer Maintenance (	Continued'	i
1 4510 0.20	As Neceaca Analyzer Maintenance (	Continuca	ı

Maintenance Procedure	Part	Part Number
Clean or Replace Individual Cuvettes	<ul> <li>6 x 5 mm Cuvettes (Outside Japan)</li> <li>5 x 5 mm Cuvettes (Japan)</li> </ul>	<ul><li>ZM063400 (Outside Japan)</li><li>MU846500 (Japan)</li></ul>
	Cotton-tipped applicator	Commercial item
	Clean, dry, lint-free absorbent tissue	Commercial item
	2% Wash solution	<ul><li>OSR0001 (Outside Japan)</li><li>MS028400 (Japan)</li></ul>
	Plastic container	Commercial item
	Sonicator	Commercial item
Replace the Photometer Lamp	Photometer lamp	MU988800
Save Parameters	-	-

# **Dilution Ratios for Maintenance Solutions**

Table 6.21 Sodium Hypochlorite Solution

Effective Chlorite Concentration for Maintenance Solutions	Dilution Ratio of 5% chlorite concentration:  5% Sodium Hypochlorite Solution (US)  ISE Cleaning Solution (Outside US and Japan)  Sodium hypochlorite solution (5%) (Japan)
0.5%	1:10
1.0%	1:5

Table 6.22 Wash Solution

Dilution for Maintenance Solutions	Dilution Ratio (Wash Solution)
1%	1:100
2%	1:50

# **Daily Maintenance**

Perform the following procedures daily.

- Inspect the Syringes for Leaks
- Inspect the Wash Solution Roller Pump for Leaks
- Inspect the Wash Solution and Replenish as Needed
- Inspect the Stability of the Upper Cover
- Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars

#### Maintenance

**Daily Maintenance** 

- Replace the Deionized Water or Diluent in the Pre-dilution Bottle
- Inspect the Sample Probe Wash Solutions
- Inspect the Printer and Paper

### **Inspect the Syringes for Leaks**

The system includes a sample syringe, a wash syringe, R1 and R2 reagent syringes. If your system includes an ISE, the system includes an ISE buffer syringe. All syringes are located inside the right front analyzer door. The procedure is identical for all syringes.

The sample and reagent syringes measure the volume of sample or reagent to be used in a reaction.

The wash syringe dispenses only deionized water for cleaning the interior of the sample probe.

The two types of wash syringes:

- Wash Syringe Type 1
- Wash Syringe Type 2

A Wash Syringe Type 1 or Wash Syringe Type 2 can be used on the AU680. To view the shape of each type of syringe, refer to Figure 6.8 Sample Syringe, Wash Syringe Type 1, Reagent, and ISE Buffer Syringe Parts and Figure 6.9 Wash Syringe Type 2 Parts.

The ISE buffer syringe measures the correct volume of buffer for the ISE.

If a syringe leaks, the leak causes possible failures to the syringe, probe, and analytes being tested.

Although the syringes are different sizes and serve different functions, you can inspect for correct performance using the same methods.

Inspect all components of the syringes, including the syringe case head, the syringe case, the fixing nut, and the piston fixing screw for leaks and correct installation.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Clean, dry, lint-free absorbent tissue
- **1** Confirm that the system is in *Warm up*, *Standby*, or *Stop* mode.
- **2** Open the right front door of the analyzer.



### **CAUTION**

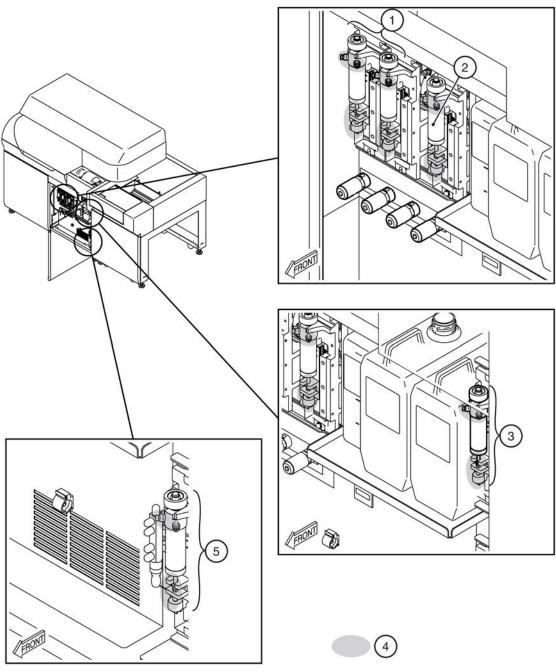
Do not allow a strong alkali, such as the wash solution, to contact the syringe case or syringe case head. If a strong alkali contacts the syringe case or syringe case head, cracks can occur.

If a strong alkali contacts the syringe case or syringe case head, remove the syringe case or syringe case head and rinse both with water.

6-20 B04779AB

3 Visually inspect each syringe case head for any cracks or leaks. Use the clean, dry, lint-free absorbent tissue to confirm that the top and bottom connections for the syringe case head and the bottom fixing screw have no leaks. If you find a crack or a leak, replace the syringe. For more information, refer to Replace Syringes or Syringe Case Heads.

Figure 6.7 Syringe Locations



- 1. Reagent syringes (R1 and R2)
- 2. ISE buffer syringe
- 3. Sample syringe

- 4. Possible leakage locations
- 5. Wash syringe

1 2 3 4

Figure 6.8 Sample Syringe, Wash Syringe Type 1, Reagent, and ISE Buffer Syringe Parts



- 1. Fixing nut
- 2. Case head
- 3. Fixing screws

- 4. Syringe case
- 5. Piston fixing screw
- 6. Possible leakage locations

6-22 B04779AB

3 —4

Figure 6.9 Wash Syringe Type 2 Parts

- 1. Piston
- 2. Seal assembly

- 3. Wash syringe
- 4. Possible leakage locations
- **4** Confirm that the fixing nuts and piston fixing screws are tight. If a leak persists after you tighten the screws, replace the syringe.



If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

- **5** Close all analyzer doors and covers.
- **6** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

### **Inspect the Wash Solution Roller Pump for Leaks**

The wash solution roller pump supplies the required amount of wash solution to the diluted wash solution tank. If the wash solution roller pump tubing leaks, the concentration of diluted wash solution can be incorrect, or problems can occur with the wash solution roller pump.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

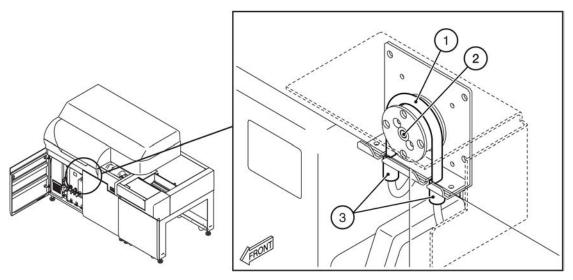
• Clean, dry, lint-free absorbent tissue

# / CAUTION

If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the left front door of the analyzer.
- **3** Inspect the wash solution roller pump tubing for cracks or leaks. If you find a crack, replace the tubing and proceed to step 6. For more information, refer to Replace the Wash Solution Roller Pump Tubing.

Figure 6.10 Wash Solution Roller Pump



- 1. Wash Solution Roller Pump Tubing
- 2. Wash Solution Roller Pump
- 3. Connectors
- **4** Use the clean, dry, lint-free absorbent tissue to wipe the peripheral part of the tubing and the roller pump to inspect for leaks. Wipe any fluid with the clean, dry, lint-free absorbent tissue.
- Confirm that the tubing connectors are tight. If a connector is loose, turn it clockwise to tighten. Wait five minutes, then inspect for leaks again. If the leak persists, replace the tubing. For more information, refer to Replace the Wash Solution Roller Pump Tubing.
- **6** Close all analyzer doors and covers.
- 7 Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

6-24 B04779AB

# Inspect the Wash Solution and Replenish as Needed

Inspect the wash solution level daily, and replenish as needed.



Confirm that the wash solution level is sufficient for typical daily analysis before you start sample processing. If the wash solution becomes empty during processing, the analyzer goes into *Pause* mode. Replenish the wash solution before resuming processing.

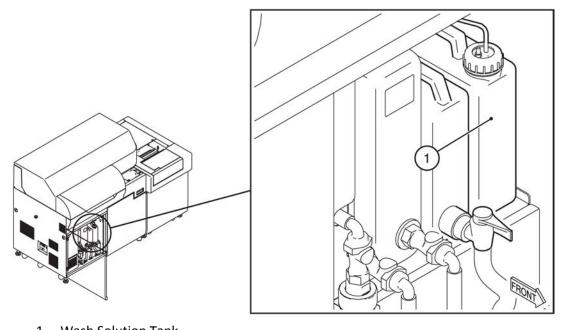
#### **Inspect the Wash Solution Level**

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the left front door of the analyzer.
- **3** Confirm that the wash solution level is sufficient for daily analysis (0.5 L per day per 4,000 tests). If the level is insufficient, replenish the wash solution. For more information, refer to Replenish the Wash Solution.



The wash solution tank is 2 L. The volume of wash solution becomes insufficient when there is approximately 200 mL or 2 cm from the bottom of the wash solution tank.

Figure 6.11 Wash Solution Tank



Wash Solution Tank

**4** Close all analyzer doors and covers.

### **Replenish the Wash Solution**

Replenish the wash solution when the volume is insufficient for daily processing.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.



If the wash solution splashes or spills outside the tank, follow your laboratory procedure to wipe up spills immediately. If any spill is left untreated, it can generate toxic gas and can cause parts of the analyzer to corrode.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

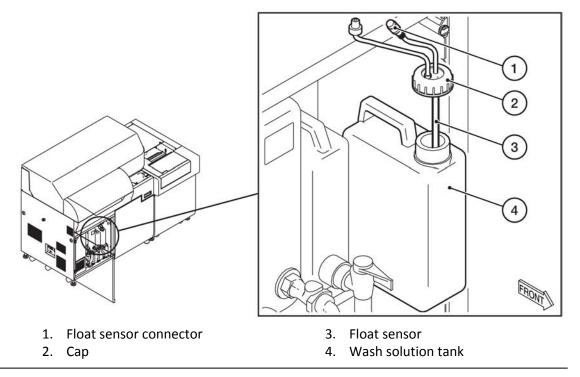
- Wash solution
- **1** Place the new tank of wash solution next to the analyzer and remove the cap.
- **2** Disconnect the wash solution tank float sensor connector 869. Do not apply excess pressure to the float sensor cable.
- **3** Remove the wash solution roller pump tubing from the roller pump.
- **4** Carefully pull the wash solution tank forward to reach the tank cap.
- **5** Loosen the tank cap and remove the cap and float sensor from the tank.



The float sensor can drip when you remove it from the tank. Follow your laboratory procedure to wipe up spills immediately.

6-26 B04779AB

Figure 6.12 Wash Solution Tank



**6** Replace the tank with a new wash solution tank.



You can also add wash solution to the tank. Hold the cap and float sensor as you add wash solution up to the 2 L graduation mark on the front of the tank.

- 7 Insert the float sensor in the tank, and tighten the cap.
- **8** Replace the wash solution tank in the analyzer.
- **9** Reconnect the float sensor connector 869.
- **10** Replace the roller pump tubing on the roller pump.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# Inspect the Stability of the Upper Cover

Lift the upper cover of the analyzer and confirm that it is stable and remains in the raised position. If the cover starts to descend, contact Beckman Coulter to have the cover supports inspected and replaced.

### Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars

The probes deliver precise quantities of reagent or sample to the cuvettes.

The mix bars mix the contents in the cuvettes.

If the mix bars or probes are bent or damaged, or if the probes are clogged, correct analysis cannot be achieved.

Before you begin analysis, inspect the sample probe, reagent probes, and mix bars for damage or deterioration. Confirm that each probe operates correctly.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

• Alcohol prep pads (70% Isopropyl alcohol)

#### **Inspect the Sample Probe and Reagent Probes**

- **1** Lift the upper cover of the analyzer.
- 2 Visually inspect that each probe is not bent or damaged. If a probe is bent or damaged, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- **3** Inspect each probe for contaminants or crystallization. If a probe is dirty, wipe the surface with an alcohol prep pad (70% Isopropyl alcohol).



Do not bend the probe when cleaning.

**4** If a probe is incorrectly aligned, contact Beckman Coulter.

### **Inspect the Mix Bars**

- 1 Inspect each mix bar. If a mix bar is bent, scratched, or there are chips in the fluororesin coating, replace the mix bar. For more information, refer to Replace the Mix Bars.
- 2 Inspect each mix bar for contaminants or crystallization. If the mix bar is dirty, wipe the mix bar with an alcohol prep pad (70% Isopropyl alcohol).

### **Confirm Operation of the Probes and Mix Bars**

Prime the system to inspect the operation of the probes and mix bars.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.

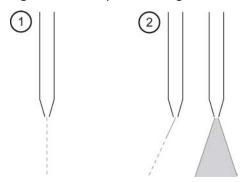
6-28 B04779AB

- **3** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Prime Washing-line**. The system displays the Start dialog.
- 5 Select OK.
- **6** Press the **TABLE ROTATION/DIAG** button.

The system initializes the probes and mix bar components, then:

- 1. Dispenses deionized water from the sample probe
- 2. Dispenses deionized water from the R1 reagent probe
- 3. Dispenses deionized water from the R2 reagent probe
- 4. Activates the mix bar components and the wash nozzle component.
- **7** As the system dispenses water, confirm that each probe dispenses a thin, straight stream of water, and that water flows in the wash wells.

Figure 6.13 Sample and Reagent Probes



Correct Flow

- 2. Incorrect Flow
- **a.** If the water is spraying or dispensing at an angle, clean the probe. For more information, refer to Clean the Sample Probe and Mix Bars or Clean the R1 or R2 Reagent Probes.
- **b.** If cleaning does not correct the problem, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- **8** As the system activates the mix bar component, confirm that the mix bars align correctly in the wash wells. If a mix bar does not align correctly, contact Beckman Coulter.
- **9** Repeat steps 6 to 8 as required to inspect all probes and mix bars.
- **10** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### Maintenance

**Daily Maintenance** 

# Replace the Deionized Water or Diluent in the Pre-dilution Bottle

- 1 Discard the water or diluent in the pre-dilution bottle, indicated by the 61. Diluent/W2 label near the R1 refrigerator.
- **2** Rinse the bottle twice with deionized water.
- **3** Fill the bottle with deionized water or diluent and replace the bottle on the analyzer.

#### **Inspect the Sample Probe Wash Solutions**

The sample probe wash solution bottles are located in the positions labeled 64. Det.-1/W2 and 65. Det.-2. For more information, refer to Dilution Ratios for Maintenance Solutions.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- 2% Wash solution
- Sodium hypochlorite solution (1.0%)
- 60 mL reagent bottle (2)



#### **NOTE**

Sodium hypochlorite solution (1.0%) is only required for laboratories using the AU680 with high sample volume or dialysis patients.

If you have a normal volume of samples that are not highly viscous, fill the bottles with approximately 50 mL:

- Position 64. Det.-1/W2: 2% wash solution
- Position 65. Det.-2: 2% wash solution

If you have a high volume of samples or use the analyzer for dialysis patient samples, fill the bottles with approximately 50 mL:

- Position 64. Det.-1/W2: 2% wash solution
- Position 65. Det.-2: sodium hypochlorite solution (1.0%)

For more information on materials required, refer to Parts List for Analyzer Maintenance.

For more information, refer to Dilution Ratios for Maintenance Solutions.



#### **WARNING**

Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle solution. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

6-30 B04779AB

# **CAUTION**

When using sodium hypochlorite solution (1.0%) as a sample probe wash solution, follow these precautions:

- Prepare fresh sodium hypochlorite solution and completely replace the solution in the bottle once a day.
- If you will not use the analyzer for two days or longer, remove the solution from the system and discard the solution to prevent analyzer corrosion.
- If solution spills on the analyzer, clean the area with an absorbent tissue, and wipe dry with a clean absorbent tissue.
- Do not mix the solution with other chemicals. If the solution becomes contaminated, follow your laboratory procedure to dispose of the solution.
- **1** Remove each wash solution bottle and inspect the level of solution.
- **2** As required, fill each bottle to approximately 50 mL of the solution used in your laboratory.
- **3** Replace the bottle on the analyzer.
- **4** Close all analyzer doors and covers.

#### **Inspect the Printer and Paper**

The printer is an optional part. Before you begin daily analysis, confirm that the printer is turned on and that there is enough paper in the printer.

For more information, refer to the manual supplied with the printer.

- **1** Confirm that the printer is on. The printer displays a ready message.
- **2** Confirm that there is enough paper in the printer.
- **3** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# **Weekly Maintenance**

Perform the following procedures weekly.

- Clean the Sample Probe and Mix Bars
- Perform a W2
- Perform a Photocal
- Clean the Pre-dilution Bottle

6-31 B04779AB

# **Clean the Sample Probe and Mix Bars**



If the sample probe or mix bars are contaminated or stained, carryover between samples can occur. Clean the sample probe and mix bars weekly to prevent contamination and to provide correct analysis and results.

# **Clean the Sample Probe**

For more information on materials required, refer to Parts List for Analyzer Maintenance.

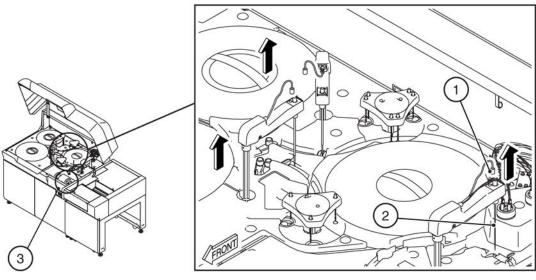
# Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)
- Stylet 0.2φ (diameter)
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Unscrew the connector above the sample probe.



Do not bend or damage the sample probe when you replace it.

Figure 6.14 Remove the Sample Probe for Cleaning



- 1. Connector
- 2. Sample probe

- 3. TABLE ROTATION/DIAG button
- **4** After all the liquid drips from the probe, lift the probe from the arm.
- **5** Wipe the tip of the probe with an alcohol prep pad (70% Isopropyl alcohol).

6-32 B04779AB

- **6** Carefully insert the stylet into the probe tip to remove any potential obstruction.
- **7** Reinstall the probe into the arm, attach the connector to the top of the probe, and tighten the connector.
- **8** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **9** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **10** Select **Replacing Sample Probe**. The system displays the Start dialog.
- **11** For **Times**, enter **3**, and then select **OK**.
- **12** Press the **TABLE ROTATION/DIAG** button. Confirm that a thin straight stream of water is dispensed from the probe, and that the water does not spray or dispense at an angle. If the water sprays or dispenses at an angle occurs, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- **13** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **14** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

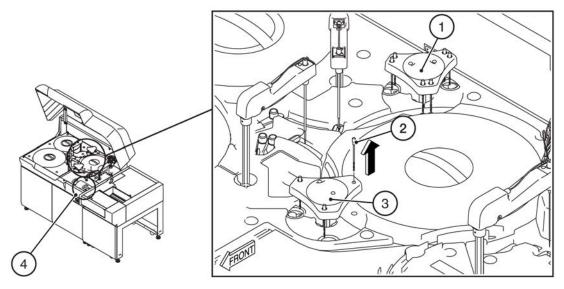
#### Clean the Mix Bars

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)
- 1 Lift the mix bars up to remove them and wipe them with an alcohol prep pad (70% Isopropyl alcohol).

Figure 6.15 Remove the Mix Bars for Cleaning



- 1. R1/S mix bar component
- 2. Mix bar

- 3. R2 mix bar component
- 4. TABLE ROTATION/DIAG button



When cleaning the mix bars, confirm that the mix bars are not bent and that the coating is not scratched. Replace the mix bars if they are damaged. When inserting the mix bars into the mix bar component, do not scratch the mix bars. Scratched or damaged mix bars can cause sample carryover and affect results.

**2** Insert the six mix bars in the positions labeled R1/S and the three mix bars in the positions labeled R2 for each mix bar component.

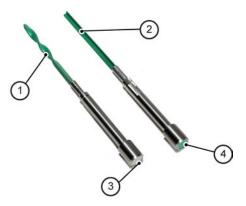


Do not scratch the mix bar when inserting the mix bar into the mix bar component. Scratched or damaged mix bars can cause sample carryover and affect results.

Rotate each mix bar slightly to insert completely.

6-34 B04779AB

Figure 6.16 Mix Bars



- 1. Spiral-shaped mix bar
- 2. L-shaped mix bar (All markets except Japan)
- 3. Silver
- 4. Green



For all markets except Japan: The shapes of the mix bars differ between mix types. If the spiral and L-shaped mix bars are not placed in the correct mix bar component, analysis results can be affected. The placement of each mix bar shape:

- R1 and S positions: Spiral-shaped mix bar
- R2 positions: L-shaped mix bar
- **3** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Replacing Mixing Bar**. The system displays the Start dialog.
- **5** For **Times**, enter **3**, and then select **OK**.
- **6** Press the **TABLE ROTATION/DIAG** button. Watch the mix bar component perform a sequence to confirm correct operation. If an abnormal noise occurs during mixing, replace the mix bar. For more information, refer to Replace the Mix Bars.
- **7** Close all analyzer doors and covers.
- **8** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **9** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### Perform a W2

To obtain correct analysis results, clean the cuvettes once a week. The sample probe, reagent probes, mix bars, and waste lines are thoroughly cleaned during the W2 process.

#### Maintenance

Weekly Maintenance

The W2 prepares the cuvettes for the photocal by thoroughly cleaning them. The sample probes, reagent probes, mix bars, and waste lines also benefit from the cleaning procedure.

Perform a photocal to inspect the integrity of the cuvettes. Clean or replace cuvettes that show an abnormal value during a photocal. For more information, refer to Perform a Photocal.

The W2 is accomplished by running 1N hydrochloric acid or sodium hypochlorite solution (0.5%) through the system.

- Each week, alternate the cleaning solution used.
- The 1N hydrochloric acid removes stains formed by protein deposits left in the cuvettes.
- The sodium hypochlorite solution (0.5%) removes a small quantity of inorganic substances such as metallic ions and any bacterial contamination.

A W2 takes about 30 minutes to complete from start to finish.



The mixing of sodium hypochlorite solution (0.5%) and hydrochloric acid causes the formation of chlorine gas, which is highly toxic. Do not mix sodium hypochlorite solution (0.5%) and hydrochloric acid. Confirm that all W2 cleaning solution containers on the analyzer contain the same cleaning solution. Clearly label containers designated for sodium hypochlorite solution (0.5%) and hydrochloric acid and confirm that all positions requiring W2 cleaners contain the same cleaning solution.

# WARNING

Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle hydrochloric acid or sodium hypochlorite solution (0.5%). If the hydrochloric acid or sodium hypochlorite solution (0.5%) contacts skin or clothes, rinse the affected area thoroughly with water. If the hydrochloric acid or sodium hypochlorite solution (0.5%) contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

# **NARNING**

Do not spill cleaning solution on the system. If cleaning solution is spilled on the system, follow your laboratory procedure to wipe up spills immediately.



For each procedure, prepare a fresh sodium hypochlorite solution (0.5%). Prepare a fresh solution to maintain effective cleaning. Without effective cleaning, analysis results can be affected.

6-36 B04779AB

The ISE Enhanced Cleaning procedure is optional during the W2. To run the ISE Enhanced Cleaning procedure separately from the W2, refer to Enhanced Cleaning of Electrode Line.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

#### Materials Required:

- Three 60 mL bottles:
  - Three 60 mL bottles labeled 1 N hydrochloric acid
  - or
  - Three 60 mL bottles labeled sodium hypochlorite solution (0.5%).
- Cleaning Solutions:
  - Approximately 180 mL of 1N hydrochloric acid or 180 mL of sodium hypochlorite solution (0.5%)

Materials required for ISE (optional module) Enhanced Cleaning during W2:

- Hitachi Cup
- ISE Cleaning Solution
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Fill the 60 mL bottles with approximately 60 mL of the cleaning solution selected for the procedure of the week. If sodium hypochlorite solution was used previously for the W2, use hydrochloric acid for the current procedure.

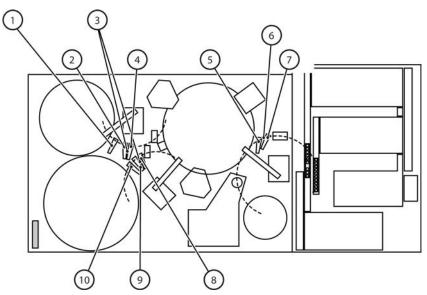
Do not fill into the neck of the bottle.



The mixing of sodium hypochlorite solution (0.5%) and hydrochloric acid causes the formation of chlorine gas, which is highly toxic. Do not mix sodium hypochlorite solution (0.5%) and hydrochloric acid. Confirm that all W2 cleaning solution containers on the analyzer contain the same cleaning solution. Clearly label containers designated for sodium hypochlorite solution (0.5%) and hydrochloric acid and confirm that all positions requiring W2 cleaners contain the same cleaning solution.

- **3** Lift the upper cover of the analyzer.
- 4 Place the bottles in the positions labeled W2 on the analyzer. Remove diluent and cleaning bottles as needed when placing the W2 bottles. If a photocal is also selected, close the upper cover.

Figure 6.17 W2 Positions



- 1. W2
- 2. 50. CLN 2
- 3. Cleaning Solution Bottles
- 4. 49. CLN 1
- 5. 64. Det. -1/W2

- 6. Sample Probe Wash Solution bottles
- 7. 65. Det. 2
- 8. 62. CLN 1
- 9. 63. CLN 2
- 10. 61. Diluent/W2

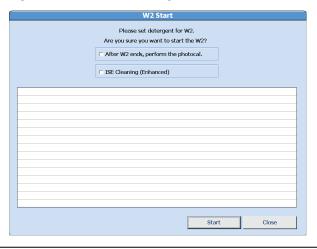


Do not spill cleaning solution on the system. If cleaning solution is spilled on the system, follow your laboratory procedure to wipe up spills immediately.

- **5** Fill a Hitachi cup with 1.5 mL ISE Cleaning Solution if **ISE Cleaning (Enhanced)** is selected. Place the cup in the **CLEAN** position on the STAT table.
- 6 Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **7** Select **W2 (F6)**. The system displays the W2 Start dialog.

6-38 B04779AB

Figure 6.18 W2 Start Dialog



- **8** Decide whether to start the photocal immediately when the W2 is complete, without operator input. Also, the weekly ISE Cleaning (Enhanced) procedure can be run with the W2 without adding any time to the procedure.
  - If you want to start the photocal after the W2 completes, select **After W2 ends**, **perform the photocal**.
  - To start the ISE cleaning procedure during the W2, select ISE Cleaning (Enhanced).
- 9 Select **Start**. The W2 starts and takes 30 minutes to complete. You can view the time countdown in the mode display area. If you selected **After W2 ends, perform the photocal** in step 8, the photocal starts automatically. If you did not select **After W2 ends, perform the photocal**, when the W2 completes, the analyzer enters *Standby* mode.



The cleaning solution bottles can generate gas. After the W2 is complete, immediately remove the W2 cleaning solution bottles from the system.

- **10** Remove all maintenance materials used for the W2 procedure. Replace the diluent and cleaning bottles into the corresponding positions on the analyzer.
- **11** The Maintenance Log is automatically updated.

#### Perform a Photocal

When the W2 is finished, perform a photocal. You can start the photocal from the W2 Start dialog. If you selected the photocal in the W2 procedure, refer to View the Photocal Results.

The photocal confirms the integrity of the cuvettes. The photocal detects dirt, stains, or scratches and identifies cuvettes that require cleaning or replacing.

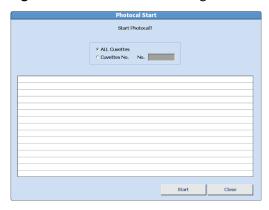
If you did not select the photocal with the W2 procedure, you can start the photocal using the following procedure.



For optimal results, only perform a photocal measurement when the photometer lamp is stabilized after the system starts up. The photometer lamp needs approximately 20 minutes to stabilize (warm up) after the system starts up.

- **1** Confirm that the system is in *Standby* mode.
- **2** Confirm that the upper cover is closed.
- 3 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.
- **4** Select **Photocal (F7)**. The system displays the Photocal Start dialog.

Figure 6.19 Photocal Start Dialog



**5** Select **ALL Cuvettes** to perform the photocal.



If individual cuvettes fail, the cuvette might need cleaning or replacement. To perform a photocal on an individual cuvette after it was cleaned or replaced, select **Cuvettes No.**, and enter the cuvette number.

**6** Select **Start**. The photocal starts. The photocal takes 30 minutes to complete. The system automatically moves to *Standby* mode after the photocal is complete. The Maintenance Log is automatically updated.



For a specific cuvette, the photocal takes approximately 7 minutes.

6-40 B04779AB



The system automatically saves the first photocal value after you update Replacing Photocal Lamp in the Consumption tab. The system uses this photocal value as the reference value in **Photocal Monitor > Detail(F5) > Graph**.

#### View the Photocal Results

If a cuvette fails the photocal, the system generates an audible alarm. Perform the following corrective action.

1 Select Home > Analyzer Maintenance > Photocal Monitor. If the cuvette failed the photocal, the system highlights the cuvette number.

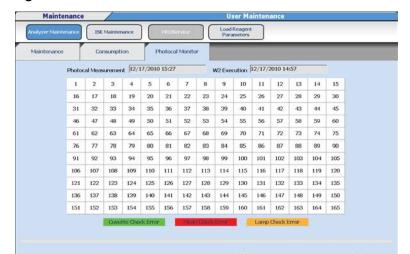


Figure 6.20 Photocal Monitor

- 2 Clean or replace any cuvettes failing the Mean Check or Cuvette Check.
  - The system displays cuvettes with a Mean Check Error in red. The cuvette is probably dirty and can be cleaned. For more information, refer to Clean or Replace Individual Cuvettes.
  - The system displays cuvettes with a Cuvette Check Error in green. The cuvette is probably scratched and needs replacement. For more information, refer to Clean or Replace Individual Cuvettes.
- **3** Replace the photometer lamp if any cuvettes failed the Lamp Check.
  - The system displays cuvettes with a Lamp Check Error in orange. The photometer lamp is deteriorating and needs replacement. For more information, refer to Replace the Photometer Lamp.
- **4** Select the Maintenance tab.
- **5** Select **Photocal (F7)**. The system displays the Photocal Start dialog.

#### Maintenance

Weekly Maintenance

- Repeat the photocal on each cuvette that failed the Mean Check or Cuvette Check. Select Cuvettes No., and enter the cuvette number to check. The photocal takes approximately 7 minutes to complete.
- Repeat the photocal on all cuvettes if any cuvettes failed the Lamp Check and the lamp was replaced, or numerous cuvettes failed the Mean Check or Cuvette Check. Select All Cuvettes in the Photocal Start dialog. The photocal takes 30 minutes to complete.
- **6** If any cuvettes fail the photocal again, repeat steps 1 to 5.
- 7 To print photocal results, go to the Photocal Monitor tab. Select **Print (F8)** and then **OK**.



**NOTE** 

The system only prints data for cuvettes that failed the photocal.



**NOTE** 

If a cuvette fails the photocal after cleaning, replace the cuvette with a new cuvette and repeat the photocal.

**8** Confirm that all cuvettes have passed the photocal and run QC before processing samples.

#### Clean the Pre-dilution Bottle

When the pre-dilution bottle remains on the analyzer without being periodically cleaned, bacterial contamination can occur.

To maintain the reliability of the analyzer and prevent contamination, clean the predilution bottle once each week.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Sodium hypochlorite solution (0.5%)
- Extra 60 mL bottles (optional)
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Remove the pre-dilution bottle from the analyzer and discard the deionized water. The pre-dilution bottle is located outside of the R1 refrigerator in the position labeled 61. Diluent/W2.
- **4** Wash the pre-dilution bottle by filling it with sodium hypochlorite solution (0.5%).
- **5** Rinse well using deionized water.

6-42 B04779AB

- **6** If an extra 60 mL bottle is available, fill it with deionized water and place it on the analyzer while you rinse and air dry the original bottle. Alternate the weekly use of each bottle. If an extra bottle is not available, thoroughly rinse the bottle to remove any sodium hypochlorite solution (0.5%) residue which affects analysis results.
- 7 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **8** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# **Monthly Maintenance**

Perform the following procedures monthly.

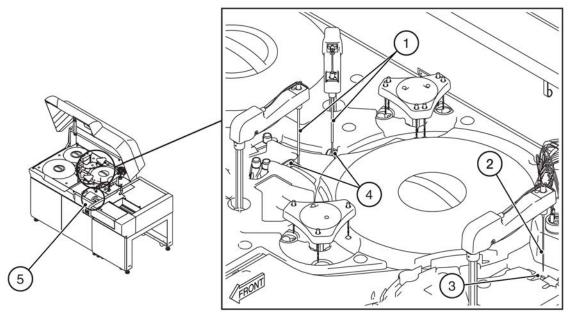
- Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells
- Clean the Mix Bar Wash Wells
- Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints
- Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter

## Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells

Dirty wash wells can cause incorrectly cleaned probes, which can then contaminate reagents or samples.

To maintain the reliability of the analyzer and prevent contamination, clean the wash wells monthly.

Figure 6.21 Reagent and Sample Probe Wash Wells



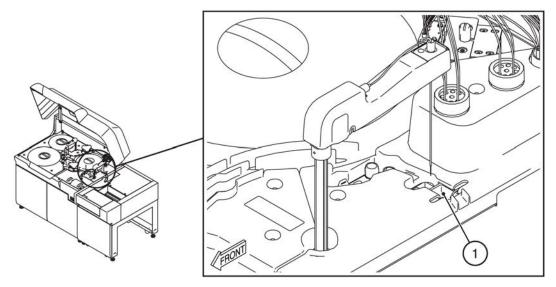
1. Reagent probes

2. Sample probe

- 3. Sample probe wash well
- 4. Reagent probe wash wells

5. TABLE ROTATION/DIAG button

Figure 6.22 HbA1c Wash Well



1. HbA1c wash well

For more information on materials required, refer to Parts List for Analyzer Maintenance.

### Materials Required:

- Sodium hypochlorite solution (0.5%)
- Cotton-tipped applicator
- Disposable pipette
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **4** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **5** Select **Cleaning Wash Tank**. The system displays the Start dialog.
- 6 Select OK.



When you press the TABLE ROTATION/DIAG button the first time after you select a maintenance procedure option, the system initializes. To avoid injury, do not touch any moving parts until the system indicates that the analyzer is ready (as indicated by alarms, modes, and LEDs).

6-44 B04779AB

**7** Press the **TABLE ROTATION/DIAG** button. The sample and reagent probes initialize. All probes move from their home positions over the wash wells to the cuvettes.



Do not spill sodium hypochlorite solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.



While cleaning the interior of the wash well, avoid touching the sample probe and reagent probe.

- **8** Using a pipette, dispense the sodium hypochlorite solution (0.5%) into each sample probe, reagent probe, and HbA1c wash well.
- **9** Use a cotton-tipped applicator to clean each well. Use a different cotton-tipped applicator for each wash well to avoid any contamination.
- **10** Press the **TABLE ROTATION/DIAG** button. All probes move back to the home position over the wash wells.
- **11** Select **Prime Washing-line**. The system displays the Start dialog.
- 12 Select OK.
- **13** Press the **TABLE ROTATION/DIAG** button. After initialization, the system primes water through the probes and wash wells. Inspect the probe wash wells visually for correct drainage. If drainage is poor, repeat steps 4 to 12.
- **14** Close all analyzer doors and covers.
- **15** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **16** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# Clean the Mix Bar Wash Wells

In normal operation, the mix bar wash wells clean the outside surface of each mix bar by washing in 1% wash solution and then rinsing with deionized water.

Dirty wash wells can cause incorrectly cleaned mix bars, which can cause carryover problems.

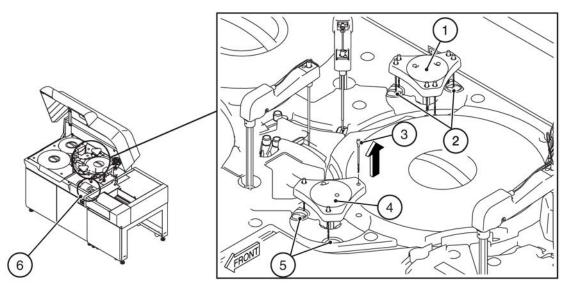
To maintain the reliability of the analyzer and prevent contamination, clean the wash wells monthly.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Sodium hypochlorite solution (0.5%)
- Cotton-tipped applicator
- Disposable pipette
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Manually turn the mix bar component so that the mix bars are not over the wash wells.

Figure 6.23 Mix Bar Wash Wells



- 1. R1/S mix bar component
- 2. Mix bar wash well
- 3. Mix bar

- 4. R2 mix bar component
- 5. Mix bar wash well
- 6. TABLE ROTATION/DIAG button



Do not spill sodium hypochlorite solution outside the wash well. Follow your laboratory procedure to wipe up spills immediately.

- **4** Using a pipette, dispense the sodium hypochlorite solution (0.5%) into each sample probe, reagent probe, and HbA1c wash well.
- **5** Use a cotton-tipped applicator to clean each well. Use a different cotton-tipped applicator for each wash well to avoid any contamination.
- **6** Turn the mix bar components so that the mix bars are over the mix bar wash wells.
- 7 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **8** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.

6-46 B04779AB

**9** Select **Replacing Mixing Bar**. The system displays the Start dialog.

Figure 6.24 Start Dialog



- 10 In Unit, select The First Mixer.
- **11** For **Times**, enter **1**, and then select **OK**.
- **12** Press the **TABLE ROTATION/DIAG** button. The R1/S mix bar component initializes and performs a sequence.
- **13** Visually inspect the mix bar wash wells for correct water drainage. If drainage is poor, repeat steps 3 to 12.
- 14 In Unit, select The Second Mixer.
- 15 For Times, enter 1, and then select OK.
- **16** Press the **TABLE ROTATION/DIAG** button. The R2 mix bar component initializes and a sequence.
- **17** Visually inspect the mix bar wash wells for correct water drainage. If drainage is poor, repeat steps 3 to 16.
- **18** Close all analyzer doors and covers.
- **19** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **20** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints

The wash nozzle component includes nine nozzles that aspirate liquid out of the cuvettes, dispense diluted wash solution and deionized water into the cuvettes, and dry the cuvettes.

If any of the nozzles become clogged, their functionality can suffer, resulting in inefficient cleaning of the cuvettes.

Inspect the mounting joints for cracks or leaks. If any damage exists, the aspiration and dispense by nozzles can be affected.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

# Materials Required:

- Clean, dry, lint-free absorbent tissue
- Sonicator filled with deionized water

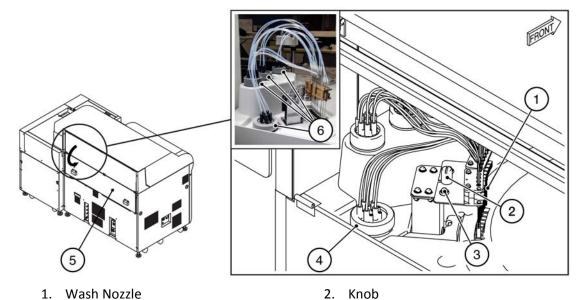
## Remove the Wash Nozzle Component and Inspect the Tube Mounting Joints

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the rear cover of the analyzer.
- **4** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **5** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **6** Select **Replacing Wash Nozzle**. The system displays the Start dialog.
- **7** Select **OK**.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the tubes.



Before cleaning or replacing the tube mounting joints, drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to Clean the Cuvettes and the Cuvette Wheel.

Figure 6.25 Wash Nozzle Component and Tube Mounting Joints



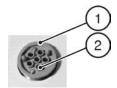
6-48 R04779AB

- 3. Positioning Screws4. Water Supply Tube Mounting Joint (Six O-rings installed inside the joint)
- 5. Rear Cover
- 6. Manifolds
- **9** Loosen the four manifolds and remove them from their mounting positions.



Six O-rings are inside the water supply tube mounting joint of the wash nozzle component. After removing the manifold, confirm that there are six O-rings seated inside the six grooves in the manifold base.

Figure 6.26 Manifold Base of the Water Supply Tube Mounting Joint



1. Manifold Base

2. O-Ring

If an O-ring is missing, inspect the manifold to confirm that the O-ring is not attached to the surface of the manifold. If it cannot be found, install a new O-ring in the groove in the manifold base. For more information, refer to Replace the O-rings in the Water Supply Tube Mounting Joint.



Inspect the packing inside each manifold of the three tube mounting joints. If the packing is damaged, replace the packing. For more information, refer to Replace the Packing in the Wash Nozzle Tube Mounting Joints.

- **10** Loosen the knob holding the wash nozzle component in position. Loosen the knob until it stops turning.
- **11** Lift the wash nozzle component up over the positioning screws. Do not bump or bend the nozzles.



Do not loosen or remove the positioning screws on either side of the knob when you loosen the knob on the wash nozzle component. The positioning screws are used for positioning the wash nozzle component.

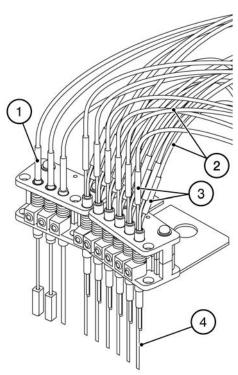


Figure 6.27 Wash Nozzle Component

- 1. Wash Nozzle Joint
- 2. Tubing

- 3. Wash Nozzle Joint
- 4. Wash Nozzle
- **12** Remove the wash nozzle component along with the tubing and inspect the joints for cracks. If a crack is found, replace the joint.

For more information, refer to Replace a Wash Nozzle Joint.

## **Clean and Inspect the Wash Nozzle Component**



Do not damage the nozzles when using a sonicator to clean the wash nozzle component.

Sonicate the wash nozzle component in deionized water for 15 minutes. Only submerge the nozzle portion. Do not get the springs above the nozzles wet. If water does get into the springs, dry them well using a clean, dry, lint-free absorbent tissue, or canned air. After cleaning the nozzles in water, wipe any drops using a clean, dry, lint-free absorbent tissue.

6-50 B04779AB

#### NOTE

Beckman Coulter recommends using a sonicator for cleaning the nozzles. If a sonicator is not available, clean the interior of each nozzle using the supplied stylet and deionized water.

- **2** Remove the wash nozzle component from the sonicator, and dry thoroughly with a clean, dry, lint-free absorbent tissue.
- **3** Inspect the O-rings inside the water supply tube mounting joint. Confirm that all six O-rings are correctly inserted in individual grooves. Confirm that the O-rings are not ripped or over-stretched. Look for dust or detergent crystals around each O-ring. If faults are found with the O-rings, replace the O-rings.

For more information, refer to Replace the O-rings in the Water Supply Tube Mounting Joint.

4 Return the wash nozzle component to its original position. Place the wash nozzle component over the positioning screws, then tighten the knob to hold the wash nozzle component in position.



Do not hit the nozzle tips on the cuvette wheel cover when installing the wash nozzle component.

**5** Return each of the manifolds to their original position. Match the colored dot on the manifold with the one next to its position. Tighten the manifolds without cross threading them. Confirm that the manifolds are finger-tight to prevent a cuvette wheel overflow, but do not over-tighten.



To avoid system damage and to perform tests correctly:

- When you install the manifolds, confirm that the manifolds are in the correct, colorcoded positions. Firmly tighten the manifolds.
- Confirm that all tubing from the nozzles to the tube mounting joints are connected.
- Do not damage any of the joints or tubing. Damaged components can cause leaks and can contaminate or flood the cuvette wheel.
- 6 Select Prime Wash Nozzle. The system displays the Start dialog.
- **7** For **Times**, enter **5**, and then select **OK**.
- **8** Press the **TABLE ROTATION/DIAG** button. The air in the tubing is purged as the wash nozzle component moves up and down.

#### Maintenance

Monthly Maintenance

#### IIII IMPORTANT

Confirm that the wash nozzle component moves freely without interference and that no leaks occur. If leaks occur, remove the water supply manifold, and confirm that there are six O-rings correctly placed in the grooves. Inspect each O-ring, and replace damaged O-rings.

- **9** Close all analyzer doors and covers.
- **10** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter

The deionized water filter and sample probe filter are used to prevent particles from entering the internal deionized water system. Clean the deionized water tank to avoid bacterial contamination of the system.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

#### Materials Required:

- Clean, dry, lint-free absorbent tissue
- Basin
- Sonicator filled with deionized water
- Extra deionized water tank, filled with 5 L of deionized water
- Sodium hypochlorite solution (1.0%)

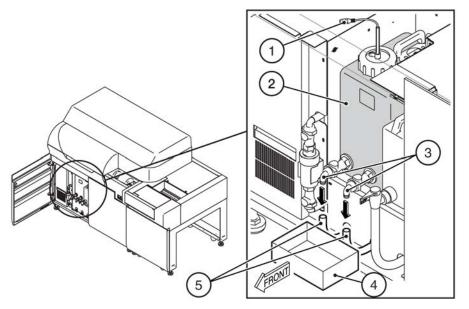
# IIII IMPORTANT

Before you start this procedure, turn off the system. If this procedure is performed with the system on (in *Standby* mode), the system supplies deionized water through the supply tube, the float sensor in the deionized water tank activates, and water drains continuously from the tube.

- To shut down the system, select End. For more information, refer to System Shutdown (End Process).
- **2** Open the left front door of the analyzer.
- **3** Position a basin on the floor under the deionized water tank to catch spilled water.

6-52 B04779AB

Figure 6.28 Deionized Water Tank



- 1. Connector
- 2. Deionized water tank
- 3. Quick disconnect joints

- 4. Basin
- 5. Deionized water drainage tubing
- **4** Unplug the black float sensor connector 868.
- **5** Press the gray buttons of the quick disconnect joints on the front of the tank and remove the tubes.



When the float sensor and tubing are removed from the tank, deionized water can drip. If the deionized water drips, immediately wipe off the water with a clean, dry lint-free absorbent tissue.

- **6** Pull the deionized water tank out of the analyzer. Confirm that the tubes clear the top of the tank and wrap them in a clean absorbent tissue.
- 7 Unscrew the cap of the tank and remove the float sensor and water supply tube.

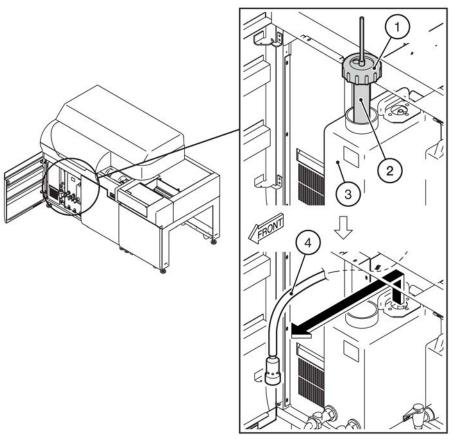


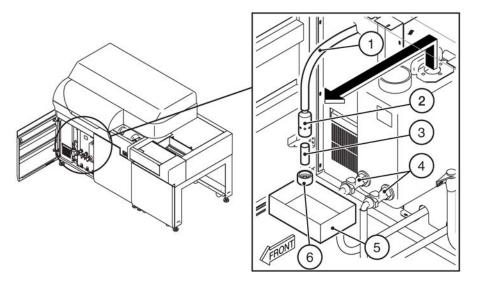
Figure 6.29 Float Sensor and Water Supply Tube

- 1. Cap
- 2. Float sensor

- 3. Deionized water tank
- I. Water supply tube
- **8** Discard the deionized water in the tank.
- **9** Clean the tank with sodium hypochlorite solution (1.0%).
- **10** Rinse the tank thoroughly using deionized water and set aside and allow the tank to dry.
- **11** Clean float sensor and the exterior part of the tubes with deionized water.
- **12** Remove the deionized water filter from the case attached to the water supply tube over the basin by unscrewing it. Water drips from it.

6-54 B04779AB

Figure 6.30 Deionized Water Filter



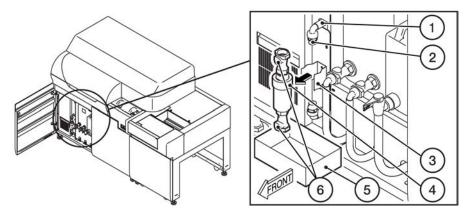
- 1. Water Supply tube
- 2. Filter case
- 3. Deionized water filter

- 4. Quick disconnect joints
- 5. Basin
- 6. Filter case cap
- **13** Locate the sample probe filter case directly to the left of the deionized water tank and remove it from the bracket.
- **14** Press the gray button of the quick disconnect joints and pull to remove the tubes from the top and bottom of the filter case.
- **15** Unscrew the filter case over the basin and remove the sample probe filter.



When working with the sample probe filter, do not lose the O-ring.

Figure 6.31 Sample Probe Filter



- 1. Tubing
- 2. Quick disconnect joint
- 3. Bracket

- 4. Filter case
- 5. Basin
- 6. Quick disconnect button

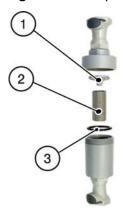
# Clean the Deionized Water Filter and Sample Probe Filter

- **1** Place the deionized water filter and the sample probe filter in the sonicator filled with deionized water.
- **2** Sonicate the filters for 10 minutes.
- **3** Reinsert the clean deionized water filter into its case and tighten the cap.
- **4** Reinsert the clean sample probe filter into the filter case.



When working with the sample probe filter, do not lose the O-ring.

Figure 6.32 Sample Probe Filter



- 1. Filter positioning insert
- 2. Sample probe filter

3. O-ring

**5** Tighten the filter case firmly.



Do not connect the filter case to the joints upside down. If you connect the filter case upside down, debris can cause data errors.

- **6** Reconnect the quick disconnects by forcing the tubes into their connections until you hear a distinct click.
- **7** Push the filter case into the metal bracket.

## **Replace the Deionized Water Tank**

**1** Fill the clean tank with 5 L of deionized water.

6-56 B04779AB

## IIII IMPORTANT

Fill the deionized water tank with 5 L of deionized water before turning the system on. If the deionized water tank is empty and the pump turns on, a malfunction can result when the system is turned on.

- **2** Place the float sensor into the deionized water tank. Tighten the cap.
- **3** Place the tank into the system and reinsert all water supply tubes into the top of the tank. Push the tank into place.
- **4** Reconnect each quick disconnect to the tank by forcing the tube into its connection until you hear a distinct click.
- **5** Reconnect the float sensor connector 868.
- **6** Wipe any spilled water from the analyzer surface and remove the basin.
- **7** Press the **ON** button. The system powers on and initializes, enters into *Warm up* for 20 minutes, and then enters *Standby*.

# Perform a Prime Washing Line

- 1 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **2** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **3** Select **Prime Washing-line**. The system displays the Start dialog.
- 4 For Times, enter 3, and then select **OK**.
- **5** Press the **TABLE ROTATION/DIAG** button. Watch the sample probe tubing, reagent probe tubing, and water supply tubing for the wash nozzle component as the system performs the prime. Repeat the prime until all bubbles are removed from the tubing by pressing the **TABLE ROTATION/DIAG** button.
- **6** Close all analyzer doors and covers.
- 7 Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **8** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# **Quarterly Maintenance**

Perform the following procedures quarterly (every three months).

• Clean the Air Filters

- Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring
- Replace the Wash Solution Roller Pump Tubing

#### Clean the Air Filters

The air filters prohibit dust and other contaminates from entering the analyzer.



Do not run the analyzer without filters in position. If filters are missing, heaters and the power supplies get dusty, which can cause a short circuit and fire.

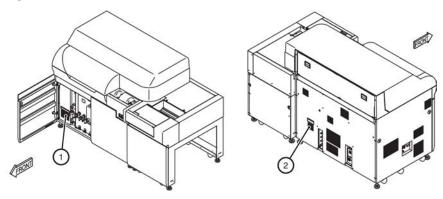
Materials Required:

- Air filters
- Vacuum

For more information on materials required, refer to Parts List for Analyzer Maintenance.

- 1 To shut down the system, select **End**. For more information, refer to System Shutdown (End Process).
- **2** Press **EM STOP** to completely turn off the power, including the fans. An emergency stop is necessary to avoid the risk of the fans bringing dust into the analyzer while the filters are removed.
- **3** Open the left front door of the analyzer.
- **4** Remove the two air filters.

Figure 6.33 Air Filter Locations



- 1. Air filter
- 2. Air filter
- **5** Vacuum the dust from the filters or clean the filters with water and allow the filters to completely dry.

Replace the air filters if they are torn.

6-58 B04779AB

The air filters can be cleaned with a vacuum without being removed from the analyzer. If the filter is moved from its original position after cleaning, reposition the filter to its original flat condition and position.



If you are cleaning the filters with water, confirm that the filters are completely dry before replacing them on the system to avoid moisture from getting into the system.

- **6** Replace the filters in their original positions.
- **7** Close all analyzer doors and covers.
- **8** Press the **RESET** button (white button on the front-right of the analyzer) to turn on the main power, and then wait 5 seconds.
- **9** Press the **ON** button (green button on the front-right of the analyzer). The lamp turns on and the software loads. The system displays a dialog to confirm retrieving the database.
- **10** The system is in *Warm up* mode for 1.5 hours. After the required 20-minute lamp warm up time, wait until the temperature of the cuvette wheel is 37 °C, and then select **Home** > **Analyzer Maintenance**. Select **Stand By (F4)** to return to *Standby* mode.
- **11** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **12** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring

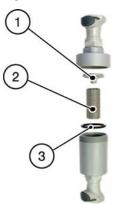
For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Sample Probe Filter
- Deionized Water Filter
- 0-rings

For information on how to remove the filters, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.

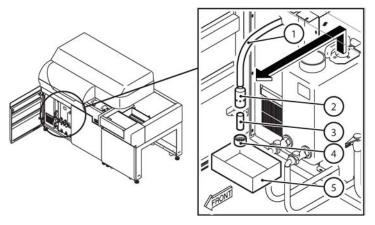
Figure 6.34 Parts in the Sample Probe Filter Case



- 1. Filter positioning insert
- 2. Sample probe filter

3. O-ring

Figure 6.35 Deionized Water Filter



- 1. Water supply tube
- 2. Filter case
- 3. Deionized water filter

- 4. Filter case cap
- 5. Basin
- **1** When the filters are removed for cleaning, inspect them. If the filters cannot be cleaned successfully, replace them.
- **2** Replace the O-ring. For more information, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
- **3** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## **Replace the Wash Solution Roller Pump Tubing**

The roller pump tubing deteriorates gradually caused by abrasion and vibration by the roller pump. If the roller pump tubing is used for an extended period, it does not function correctly. Replace the roller pump tubing with a new one every three months.

6-60 B04779AB

# / CAUTION

When replacing the roller pump tubing, wear appropriate PPE to prevent your hands from contacting the wash solution. Do not let the wash solution drip on the surrounding area. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

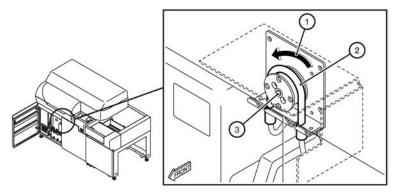
# Materials Required:

• Roller pump tubing

Perform the following procedure to avoid wash solution leaking from the connection tubing while the wash solution roller pump tubing is disconnected.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the left front door of the analyzer.
- **3** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **4** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **5** Select **Replacing Roller Pump tubing**. The system displays the Start dialog.
- 6 Select OK.
- **7** Press the **TABLE ROTATION/DIAG** button. The roller pump rotates in the reverse direction to drain the wash solution back to the wash solution tank.
- **8** Remove the tubing from the roller pump.

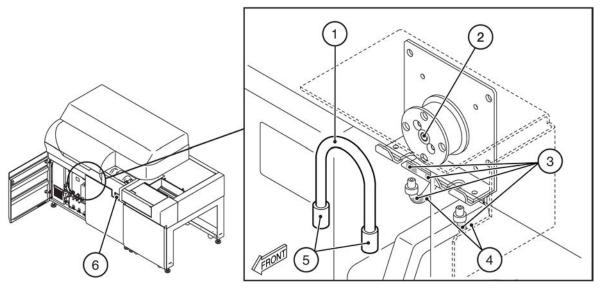
Figure 6.36 Wash Solution Roller Pump



- Normal rotation direction of roller pump
- 2. Roller pump tubing
- 3. Roller pump

**9** Remove the roller pump tubing from the relay tubes by unscrewing the connectors.

Figure 6.37 Wash Solution Roller Pump Tubing



- 1. Roller pump tubing
- 2. Roller pump
- 3. ID numbers

- 4. Relay tubes
- 5. Connectors
- 6. TABLE ROTATION/DIAG button
- **10** Connect the connectors of the new roller pump tubing to each relay tube.
- **11** Stretch the roller pump tubing around the roller pump, and slide the connectors into the grooves under the roller pump. Confirm that the ID numbers on the relay tubes match the ID numbers on the roller pump plate.
- **12** Press the **TABLE ROTATION/DIAG** button. The roller pump rotates in the normal direction to fill the tubing with wash solution.
- **13** Close all analyzer doors and covers.
- **14** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **15** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# **Six-Month Maintenance**

Perform the following procedures every six months.

• Clean the Cuvettes and the Cuvette Wheel

6-62 B04779AB

#### Clean the Cuvettes and the Cuvette Wheel

To maintain correct operation of the photometry system, the cuvettes and the wheel must be clean. The cuvette wheel has 165 cuvettes.

The cuvettes are checked weekly during the photocal procedure. This procedure is performed every six months to keep the cuvettes in optimal condition. Perform this procedure every six months or if a wheel overflow occurs. In the US market, Beckman Coulter performs this procedure as part of the preventive maintenance.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

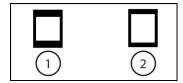
#### Materials Required:

- Cotton-tipped applicator
- 2% Wash solution
- Sonicator
- Clean, dry, lint-free absorbent tissue
- · Plastic containers to hold cuvettes in the sonicator



There are cuvettes with different interior dimension. For all markets except Japan, the AU680 uses cuvette PN ZM063400 with an interior dimension of 6 mm x 5 mm. For the Japan market, the AU680 uses cuvette PN MU846500 with an interior dimension of 5 mm x 5 mm. These cuvettes are different from the other AU analyzers. Do not use a cuvette from another AU analyzer on the AU680. Use of a cuvette other than the AU680 cuvette on the AU680 causes erroneous results.

**Figure 6.38 Cuvette Interior Dimension** 



1. PN MU846500 (5 mm x 5 mm)

2. PN ZM063400 (6 mm x 5 mm)

#### Remove the Cuvette Wheel

Perform this procedure on a work surface protected with lean, dry, lint-free absorbent tissue.

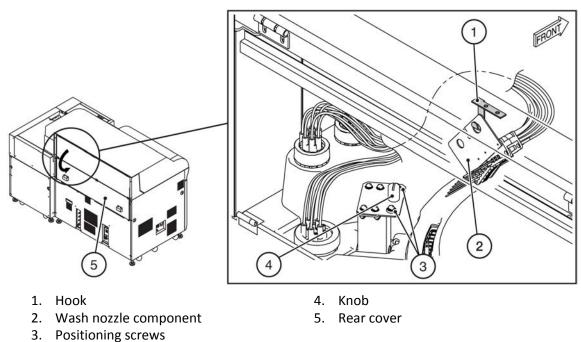
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the rear cover of the analyzer.
- **4** Loosen the knob of the wash nozzle component. Without disconnecting the tubing, remove the nozzle portion and hang it on the hook.

## IIII IMPORTANT

When hanging the wash nozzle component on the hook, do not damage the wash nozzles. Avoid contact between the wash nozzles and the cuvette wheel cover.

Do not loosen or remove the positioning screws on either side of the knob when you loosen the knob on the wash nozzle component. The positioning screws are used for positioning the wash nozzle component.

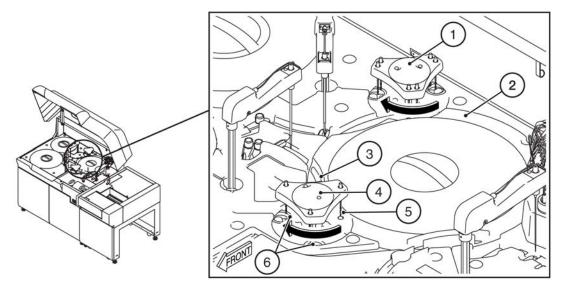
Figure 6.39 Remove Wash Nozzle Component



**5** Manually rotate the mix bar components approximately 60 degrees so the mix bars are not over the cuvette wheel cover.

6-64 B04779AB

Figure 6.40 Rotate Mix Bar Components



- 1. R1/S mix bar component
- 2. Cuvette wheel cover
- 3. Positioning pin of cuvette wheel cover
- R2 mix bar component
- Mix bar 5.
- Mix bar wash well
- Carefully lift the cuvette wheel cover and remove it from the analyzer.



When removing the cuvette wheel cover, do not damage the sample probe, reagent probes, or mix bars.

Remove the two black screws located on the cuvette wheel, refer to 3 in Figure 6.41 Remove the Cuvette Wheel. Tighten the screws into the two holes in the cuvette wheel, refer to 2 in Figure 6.41 Remove the Cuvette Wheel. Loosen the two black screws securing the cuvette wheel, refer to 4 in Figure 6.41 Remove the Cuvette Wheel.

6-65 B04779AB

Figure 6.41 Remove the Cuvette Wheel

- 1. Cuvette wheel cover
- 2. Holes (one hole is between cuvette numbers 1 and 17, the other hole is between cuvette numbers 83 and 100)
- 3. Black screws
- 4. Screws securing the cuvette wheel
- Positioning pins



Do not loosen or remove the positioning pins. The positioning pins keep the cuvette wheel in correct alignment. Incorrect results or system errors can occur.

**8** Use the two screws as handles, and lift the cuvette wheel carefully from the analyzer.



When removing the cuvette wheel, do not touch the peripheral components.



When handling cuvettes, do not scratch the cuvettes. If a cuvette is scratched, the photometric data is inaccurate, and the cuvette must be replaced.



To maintain correct photometric analysis, do not get fingerprints on the photometric surface of the cuvettes. Always wear gloves when handling the cuvettes.

6-66 B04779AB

# /! CAUTION

There are cuvettes with different interior dimension. For all markets except Japan, the AU680 uses cuvette PN ZM063400 with an interior dimension of 6 mm  $\times$  5 mm. For the Japan market, the AU680 uses cuvette PN MU846500 with an interior dimension of 5 mm  $\times$  5 mm. These cuvettes are different from the other AU analyzers. Do not use a cuvette from another AU analyzer on the AU680. Use of a cuvette other than the AU680 cuvette on the AU680 causes erroneous results.

**Figure 6.42 Cuvette Interior Dimension** 



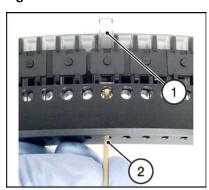
- 1. PN MU846500 (5 mm x 5 mm)
- 2. PN ZM063400 (6 mm x 5 mm)

#### Remove the Cuvettes from the Wheel

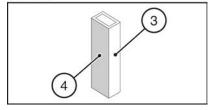
Perform this procedure over a protected work surface.

Use the reverse end of a cotton-tipped applicator to push each cuvette from the bottom to remove it from the wheel. Remove all 165 cuvettes.

Figure 6.43 Remove a Cuvette



Cuvette



- 1. Cuvette
- 2. Cotton-tipped applicator
- 3. Photometric face
- 4. Frosted glass face

#### Clean the Cuvettes and the Cuvette Wheel



When handling cuvettes, do not scratch the cuvettes. If a cuvette is scratched, the photometric data is inaccurate, and the cuvette must be replaced.

**1** Submerge all cuvettes in a plastic container filled with 2% wash solution.



Do not use wash solution to clean the cuvette wheel. If the wash solution is used to clean the cuvette wheel, the metallic plating on the wheel can be removed.

- **2** Sonicate for 15 minutes.
- **3** Thoroughly rinse the cuvettes in deionized water, or sonicate them in deionized water for 10 minutes to remove any residual wash solution.
- **4** Allow the cuvettes to dry completely.



Use one of the following cuvette drying methods:

- Allow cuvettes to air dry.
- Use an oven with the heat set under 50 °C (122 °F).
- Use a clean, dry, lint-free absorbent tissue.
- **5** Rinse the cuvette wheel with deionized water and dry thoroughly with a clean, dry, lint-free absorbent tissue.
- **6** Insert the cuvettes into the wheel. Confirm that each cuvette is gently pushed down completely into the wheel.



When handling cuvettes, do not scratch the cuvettes. If a cuvette is scratched, the photometric data is inaccurate, and the cuvette must be replaced.



Confirm that 165 cuvettes are correctly installed in the cuvette wheel. If one of the cuvettes is missing, the mixture, reagent, or wash solution spills into the cuvette wheel, causing a cuvette wheel overflow and preventing successful analysis.

6-68 B04779AB

# / CAUTION

Do not scratch the cuvettes when replacing cuvettes on the cuvette wheel. Never touch the photometric surface of a cuvette. If the photometric surface is stained, analysis data is inaccurate. Wear gloves when handling the cuvettes.

- **7** Dry the incubation bath with a lint-free absorbent tissue if the incubation bath is wet. The incubation bath is only wet if a cuvette overflow occurs.
- **8** Replace the cuvette wheel in the original position on the analyzer.
- **9** Remove the two screws used as handles to remove the wheel and return to the positions on the cuvette wheel.
- **10** Tighten the two black screws securing the cuvette wheel.
- **11** Replace the cuvette wheel cover and wash nozzle component. Rotate the mix bar components so the mix bars are over the cuvette wheel.
- **12** Close all analyzer doors and covers.
- **13** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **14** Perform a photocal. For more information, refer to Perform a Photocal.



After cleaning cuvettes, perform a photocal to confirm that the cuvettes were cleaned correctly.



To obtain optimal analysis data, do not start the photocal until the lamp is stable after turning on the system. The lamp requires 20 minutes to stabilize after you press the **ON** button.

**15** Confirm that all cuvettes have passed the photocal and run QC before processing samples.

# **Yearly Maintenance**

Perform the following procedures yearly.

Replace the O-rings in the Water Supply Tube Mounting Joint

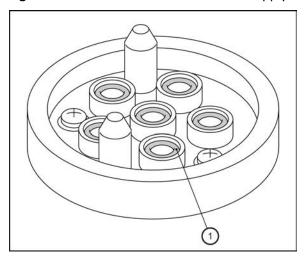
### Replace the O-rings in the Water Supply Tube Mounting Joint

Replace each O-ring in the water supply tube mounting joint with a new one yearly.

When installing the water supply tube mounting joint of the wash nozzle component, inspect the following items.

- All six O-rings are seated in a groove, refer to Figure 6.44 Manifold Base of the Water Supply Tube Mounting Joint.
- Particles such as dust or wash solution crystals are not be observed on or around the O-rings.

Figure 6.44 Manifold Base of the Water Supply Tube Mounting Joint



1. O-ring

For more information on materials required, refer to Parts List for Analyzer Maintenance.

# Materials Required:

- 0-rings
- Clean, dry, lint-free absorbent tissue
- Pair of tweezers
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the rear cover of the analyzer.
- 3 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.
- **4** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **5** Select **Replacing Wash Nozzle**. The system displays the Start dialog.
- 6 Select OK.
- **7** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the tubes.

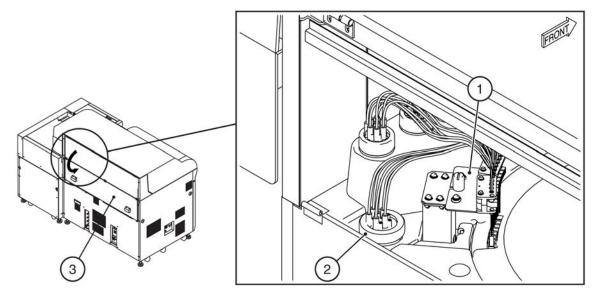
6-70 B04779AB

# / CAUTION

Before cleaning or replacing the tube mounting joints, drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to Clean the Cuvettes and the Cuvette Wheel.

**8** Loosen the manifold for the water supply tube mounting joint and remove from the mounting position.

Figure 6.45 Water Supply Tube Mounting Joint



- 1. Wash nozzle component
- Water supply tube mounting joint (Six O-rings are installed inside the joint)
- 3. Rear cover
- **9** Using a pair of tweezers, remove each 0-ring from the groove. Wipe away any crystallization or foreign matter found around 0-ring grooves.
- **10** Set new 0-rings into the grooves.
- 11 Replace the manifold into its position on the analyzer. Tighten the manifold without cross threading and do not over tighten. For more information, refer to Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints.
- **12** Select **Prime Wash Nozzle**. The system displays the Start dialog.
- **13** For **Times**, enter **5**, and then select **OK**.
- **14** Press the **TABLE ROTATION/DIAG** button.
- **15** Confirm that there are no leaks from the tube mounting joint. If you detect a leak, unscrew the manifold for the water supply tube mounting joint, and confirm that the Orings are installed correctly.

#### Maintenance

As Needed Maintenance

# IMPORTANT

If you use the O-rings for a long time without cleaning or if you replace the joint manifold without the O-rings correctly set, wash solution crystals can form, causing errors with the cuvettes. Inspect the O-rings along with the monthly maintenance of the wash nozzle component.

- **16** Close all analyzer doors and covers.
- **17** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **18** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## **As Needed Maintenance**

- Clean the R1 or R2 Reagent Probes
- Replace a Sample or Reagent Probe
- Replace the Mix Bars
- Replace a Wash Nozzle Joint
- Replace the Packing in the Wash Nozzle Tube Mounting Joints
- Replace Syringes or Syringe Case Heads
- Replace the Wash Syringe
- Clean the Interior of the Reagent Refrigerators and STAT Table Compartment
- Clean or Replace the Anti-static Brushes
- Replace the Sample or Reagent Probe Tubing
- Perform a W1
- Replace Rack ID Labels
- Clean or Replace Individual Cuvettes
- Replace the Photometer Lamp
- Save Parameters

#### Clean the R1 or R2 Reagent Probes



If reagent probes are contaminated or stained, carryover between reagents can occur. To prevent contamination and to provide correct analysis and results, clean the reagent probes as needed.

The cleaning procedure for each probe is identical.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Alcohol prep pads (70% Isopropyl alcohol)
- Stylet  $\varphi$ 0.3 (diameter)

6-72 B04779AB

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **3** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Replacing Reagent Probe/Syringe**. The system displays the Start dialog.
- 5 In **Unit**, select **R1** or **R2**. For **Times**, enter **3**, and then select **OK**.
- **6** Lift the upper cover of the analyzer.
- **7** Press the **TABLE ROTATION/DIAG** button. When you press the **TABLE ROTATION/DIAG** button, the selected probe initializes, then drains the deionized water in the probe.
- **8** Unscrew the connector above the probe.



When handling the probe, do not bend or damage the probe tip.

- **9** Lift the probe from the arm.
- **10** Wipe the tip of the probe with an alcohol prep pad.
- **11** Carefully insert the stylet into the probe tip to remove the obstruction.
- **12** Return the probe to its arm and tighten the connector over the top.
- **13** Press the **TABLE ROTATION/DIAG** button. Watch the dispense to confirm that you reinstalled the probe correctly.
- **14** If the water is spraying or not dispensing straight from the probe tip, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- **15** Close all analyzer doors and covers.
- **16** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- 17 Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

# **Replace a Sample or Reagent Probe**

The probes deliver precise quantities of sample or reagent to the cuvettes.

If the probes are clogged, bent, or damaged, correct analysis could be affected.

If the probes are still contaminated after cleaning, replace the probes.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

# Materials Required:

- Sample probe
- · Reagent probe

# IIII IMPORTANT

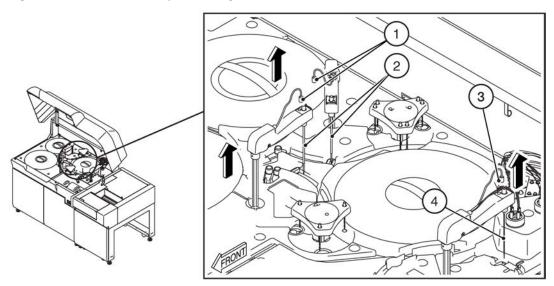
Confirm that the sample or reagent probe is above the wash well and then replace it with a new one. Deionized water drips from the probe tip as the connector is unscrewed.

# IIII IMPORTANT

When handling the probe, do not bend or damage the probe tip.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Unscrew the connector above the probe.

Figure 6.46 Remove a Sample or Reagent Probe



- 1. Reagent probe connectors
- 2. Reagent probes

- 3. Sample probe connector
- 4. Sample probe
- **4** Allow water to drip from the probe, then lift the probe from the arm.
- **5** Place the new probe into its position and tighten the connector over the top. Firmly tighten the connector so that no leaks occur.

6-74 B04779AB



If the probe connector does not fit, confirm that you are replacing the correct probe type. The sample probe has a smaller diameter than the reagent probe.

- **6** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **7** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **8** Select the option for the probe you are replacing.

Table 6.23 Probe Options

Probe	Maintenance Operation Button	
Sample probe	Replacing Sample Probe	
Reagent probe	Replacing Reagent Probe/Syringe	

The system displays the Start dialog.

- **9** If replacing a reagent probe, select **R1** or **R2**. For **Times**, enter **3**, and then select **OK**.
- **10** Press the **TABLE ROTATION/DIAG** button. Deionized water is dispensed from the probe tip. Confirm that the deionized water is dispensed in a thin straight stream, and does not spray or dispense at an angle.
- **11** Close all analyzer doors and covers.
- **12** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **13** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **14** Perform QC, inspect the data, and recalibrate if necessary.

# **Replace the Mix Bars**

Replace the mix bars if they are stained, damaged, or if the fluororesin coating is chipped.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

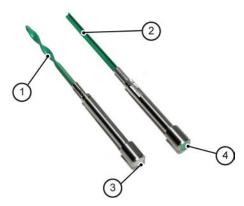
For all markets except Japan:

- R1/S: Spiral shape mix bar
- R2: L shape mix bar

For Japan:

• R1/S, R2: Spiral shape mix bar

Figure 6.47 Mix Bars



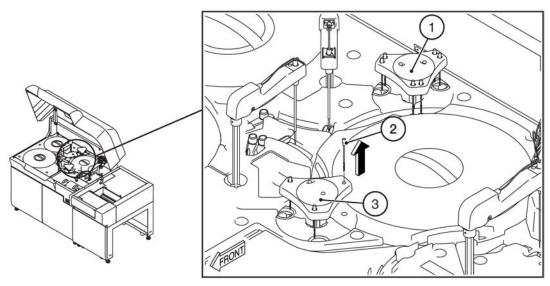
- 1. Spiral-shaped mix bar
- 2. L-shaped mix bar (all markets except Japan)
- 3. Silver
- 4. Green



Do not operate the mix bar component when replacing a mix bar. Replacement of the mix bar during operation can cause an injury.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Pull out the mix bar to be replaced.

Figure 6.48 Remove a Mix Bar



- 1. R1/S mix bar component
- 2. Mix bar

3. R2 mix bar component

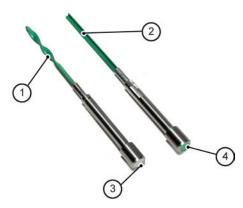
4 Insert the six mix bars in the positions labeled R1/S and the three mix bars in the positions labeled R2 for each mix bar component.



Do not scratch the mix bar when inserting the mix bar into the mix bar component. Scratched or damaged mix bars can cause sample carryover and affect results.

Rotate each mix bar slightly to insert completely.

Figure 6.49 Mix Bars



- 1. Spiral-shaped mix bar
- 2. L-shaped mix bar (All markets except Japan)
- 3. Silver
- 4. Green



For all markets except Japan: The shapes of the mix bars differ between mix types. If the spiral and L-shaped mix bars are not placed in the correct mix bar component, analysis results can be affected. The placement of each mix bar shape:

- R1 and S positions: Spiral-shaped mix bar
- R2 positions: L-shaped mix bar
- 5 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **6** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **7** Select **Replacing Mixing Bar**. The system displays the Start dialog.
- **8** In **Unit**, select the required mix bar component. The First Mixer is for R1/S mix bars, and the Second Mixer is for R2 mix bars.
- **9** For **Times**, enter **3**, and then select **OK**.

#### Maintenance

As Needed Maintenance

- **10** Press the **TABLE ROTATION/DIAG** button. The selected mix bar component initializes and performs a sequence three times.
- **11** Close all analyzer doors and covers.
- **12** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **13** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### Replace a Wash Nozzle Joint

If a wash nozzle joint is damaged or cracked, leaks or insufficient aspiration of a cuvette can occur. To avoid errors, immediately replace the damaged wash nozzle joint.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Wash nozzle joint
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the rear cover of the analyzer.
- **3** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **4** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **5** Select **Replacing Wash Nozzle**. The system displays the Start dialog.
- 6 Select OK.
- **7** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the tubes.



Before cleaning or replacing the wash nozzle joints, drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to Clean the Cuvettes and the Cuvette Wheel.

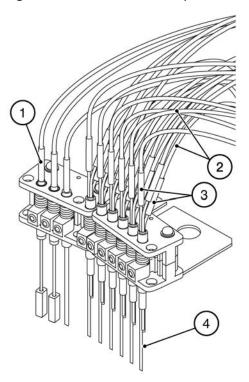
**8** Remove the wash nozzle component along with the tubing and place it on a clean surface.

For more information, refer to Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints.

6-78 B04779AB

Replace one wash nozzle joint at a time. If the tubing is not connected to the correct nozzle by the wash nozzle joint, correct analysis is not performed.

Figure 6.50 Wash Nozzle Component



- 1. Wash nozzle joint
- 2. Tubing

- 3. Wash nozzle joint
- 4. Wash nozzle



When handling the wash nozzle component, do not damage the wash nozzles.



When removing the wash nozzle component, do not touch the nozzle tips to the cuvette wheel cover.

- **9** Remove the wash nozzle joint to be replaced.
- **10** Insert the new wash nozzle joint onto the open end of the tube, and then insert the nozzle into the other end of the wash nozzle joint.

Center the tube and nozzle in the joint, allowing approximately 1 mm between them.

2 3 4 5 7

Figure 6.51 Replace a Wash Nozzle Joint

- 1. Wash nozzle component
- 2. Cross-sectional view
- 3. Position both ends of the tube and nozzle in the center of the wash nozzle joint
- 4. Tube
- 5. Wash nozzle joint
- 6. Approximately 1 mm
- 7. Nozzle



Confirm that the tubing does not cross. If the tubing crosses, it can pull out from the wash nozzle joint and affect correct functioning of the wash nozzle and cause a cuvette overflow and affect results.



When handling the wash nozzle component, do not damage the wash nozzles.



When installing the wash nozzle component, do not touch the nozzle tips to the cuvette wheel cover.

**11** Replace the wash nozzle component.

For more information, refer to Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints.

6-80 B04779AB

- **12** Press the **TABLE ROTATION/DIAG** button. Confirm that the wash nozzle component is placed correctly on the analyzer.
- **13** Select **Prime Wash Nozzle**. The system displays the Start dialog.
- 14 Select OK.
- **15** Press the **TABLE ROTATION/DIAG** button. The air in the tubing is purged as the wash nozzle component moves up and down. Confirm that the system moves the wash nozzle component up and down without interference.
- **16** Close all analyzer doors and covers.
- **17** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **18** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### Replace the Packing in the Wash Nozzle Tube Mounting Joints

When inspecting the wash nozzle tube mounting joints, replace the packing if it is overstretched, cracked, or torn.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Packing
- · Pair of tweezers
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the rear cover of the analyzer.
- 3 Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **4** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **5** Select **Replacing Wash Nozzle**. The system displays the Start dialog.
- 6 Select OK.
- **7** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the tubes.



Before cleaning or replacing the wash nozzle joints, drain the water remaining in the wash nozzles. If you loosen any manifold without draining the remaining

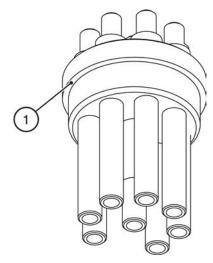
water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to Clean the Cuvettes and the Cuvette Wheel.

- **8** Remove all the wash nozzle tube mounting joints.
- **9** Remove the packing with tweezers from each tube mounting joint.
- **10** Install new packing on each tube mounting joint.



Place the packing in the groove of each tube mounting joint.

Figure 6.52 Wash Nozzle Tube Mounting Joint



- 1. Packing of the tube mounting joint
- **11** Install all the wash nozzle tube mounting joints into their original positions.



Install the tube mounting joints in the correct positions. The tube mounting joints are color-coded to match where the placement of each joint belongs on the analyzer.



Tighten the cap of each tube mounting joint firmly when replacing the tube mounting joints, otherwise leaks can result.

- **12** Select **Prime Wash Nozzle**. The system displays the Start dialog.
- **13** Press the **TABLE ROTATION/DIAG** button. Confirm that the wash nozzle component is operating correctly.
- **14** Close all analyzer doors and covers.

**16** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### **Replace Syringes or Syringe Case Heads**

For replacing a sample, reagent, or ISE buffer syringe, refer to this procedure.

For replacing a wash syringe, refer to Replace the Wash Syringe.

The procedures for replacing the sample syringe, reagent syringes, and ISE buffer syringe are identical.

If a leak, crack, or any other damage is found with a syringe, replace the syringe.

If syringe performance is questionable because of abnormal data, remove and inspect the syringe.

Replace a syringe if:

- There is not smooth resistance when pulling on the piston. A worn or damaged syringe has a pulling movement that is too hard or too loose.
- The fluorocarbon polymer tip is worn, damaged or there is evidence of the fluorocarbon polymers flaking.
- The syringe or case head leaks even after correct installation.
- The head of the syringe is cracked.

Replace a syringe case head if:

• The case head is chipped, worn, or damaged in any way.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

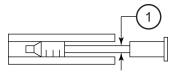
Materials Required:

- Sample syringe (S syringe)
- Reagent syringe (R syringe)
- · S syringe case head
- R syringe case head
- ISE buffer syringe case head
- Clean, dry, lint-free absorbent tissue



Identify the S syringe and R syringe using the diameter of the piston shaft. If you install the incorrect syringe, incorrect results are obtained.

Figure 6.53 Piston Shaft Diameter



1. 2 mm for S syringe and 5 mm for R syringe



Do not remove the piston from a new syringe. If you remove the piston, the performance of the syringe can be unreliable.

Figure 6.54 Sample, Reagent, and ISE Buffer Syringe Case Heads



- 1. Sample Syringe Case Head (Transparent)
- 2. Reagent Syringe Case Head (Transparent)
- 3. ISE Buffer Syringe Case Head (Gray)



The case heads of the S syringe, R syringe, and ISE Buffer syringe differ in shape and color.

6-84 B04779AB

		Syringe		Syringe Case Heads		
		S	R	S	R	ISE
Analyzer	Sample syringe	Х		Х		
	Reagent syringe		Х		Х	
ISE (Option)	Buffer syringe		Х			Х

# **Remove the Syringe**

**1** Confirm that the system is in *Warm up* or *Standby* mode.

 Table 6.24
 Combination of Syringes and Syringe Case Heads

- **2** Open the right front door of the analyzer.
- **3** Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe case from the mounting grooves.
- **4** Pull the syringe case forward to remove it from the installation grooves.

2 3 4) 3. ISE Buffer Syringe 1. R2 Syringe 2. R1 Syringe 4. S Syringe

Figure 6.55 Location of Sample, Reagent, and ISE Buffer Syringes



If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.

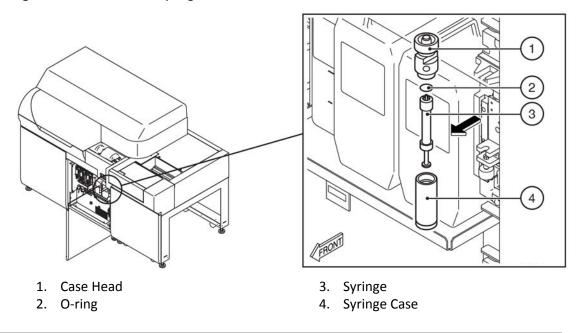


When removing the syringe case, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe case.

6-86 B04779AB

- **6** Remove the syringe case by turning it counterclockwise while holding the case head. Pull the syringe from the case head.
  - Do not lose the O-ring, which can drop from the case head. If the O-ring remains in the case head, carefully remove it with tweezers.

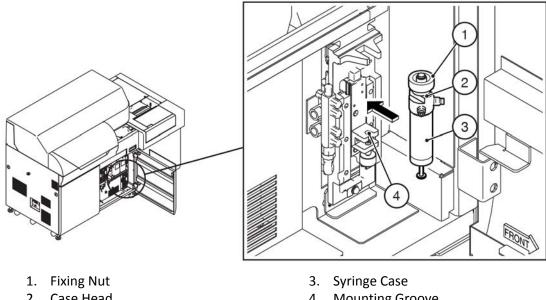
Figure 6.56 Remove the Syringe



#### Install a New Syringe or a New Syringe Case Head

- **1** Obtain a new syringe, and if necessary, a new syringe case head.
- **2** Insert the new syringe into the case head.
- 3 Dry excess water from the syringe and case head to prevent condensation from forming in the case. Screw the syringe case into the case head by twisting clockwise. Do not over tighten. Tighten the syringe case by 45 to 60 degrees from the position that it became tight.
- **4** Reinstall the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft.

Figure 6.57 Install the Syringe



2. Case Head

4. Mounting Groove



Do not allow a strong alkali, such as the wash solution, to contact the syringe case or syringe case head. If a strong alkali contacts the syringe case or syringe case head, cracks can occur.

If a strong alkali contacts the syringe case or syringe case head, remove the syringe case or syringe case head and rinse both with water.

Tighten the top fixing nut and then tighten the bottom piston fixing screw.

#### **Prime the New Syringe**

1 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.

or

Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.

**2** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.

or

Select the ISE Maintenance box. The system activates the maintenance operation buttons.

6-88 B04779AB **3** After replacing the syringe, select the maintenance operation button. The system displays the Start dialog.

 Table 6.25
 Sample, Reagent, and ISE Buffer Syringe Prime Function

Syringe	Maintenance Operation Button		
Sample syringe (S syringe)	Replacing Sample Syringe		
R1 or R2 reagent syringe (R syringe)	Replacing Reagent Probe/Syringe		
ISE buffer syringe (R syringe)	(ISE) Buffer Prime		

4 In the Start dialog, select the quantity of cycle times, and then select **OK**.

Table 6.26 Sample, Reagent, and ISE Prime Cycle Times

Maintenance Operation Button	Setting		
Replacing Sample Syringe	Times setting is preset at 260		
Replacing Reagent Probe/Syringe	For <b>Unit</b> , select R1 or R2 For <b>Times</b> , select 5 or more		
(ISE) Buffer Prime	Preset		

- **5** Press the **TABLE ROTATION/DIAG** button.
- **6** For the reagent syringe or ISE buffer syringe and tubing: If there are bubbles in the syringe after priming, repeat the prime until all bubbles are cleared. If you cannot clear the bubbles after the prime, perform the corrective actions. For more information, refer to Corrective Actions if Prime Fails for Reagent Syringe or ISE Buffer Syringe.

or

For the sample syringe and tubing: If the prime fails (air is still detected), the system displays a Sample Syringe Prime Incomplete alarm. Repeat the prime. If the system generates the alarm again, replace the syringe.



#### **NOTE**

The sample syringe prime can take from 12 to 44 minutes to complete. The sample syringe primes until the system detects no air using pressure changes.

- **7** Close all analyzer doors and covers.
- **8** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.

or

Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.

**9** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

**10** Perform QC, inspect the data, and recalibrate if necessary.

#### Corrective Actions if Prime Fails for Reagent Syringe or ISE Buffer Syringe

- **1** Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe case from the mounting grooves.
- **2** Pull the syringe case forward to remove it from the installation grooves.



If your skin, eyes, or mouth contact any liquid, immediately rinse the affected area with water. Follow your laboratory procedure.



When removing the syringe case, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe case.



Do not apply excessive force to the fixing screws when you remove the syringe case. Excessive force to the fixing screws damages the syringe case.

3 Slowly move the syringe piston up and down by hand. Confirm that there are no bubbles on the syringe tip.

If bubbles are there, move the piston up and down until the bubbles are purged.

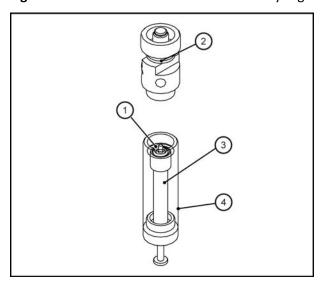


Do not move the piston by hand with the syringe case and case head disconnected.

If you move the syringe piston with the syringe case and case head disconnected, the accuracy is not retained because of the deformation of the piston. This deformation can decrease the time a syringe is in use before requiring replacement.

6-90 B04779AB

Figure 6.58 Confirm No Bubbles are on the Syringe Tip



- 1. Confirm that no bubbles are attached to the fluorocarbon polymer tip.
- 2. Case head
- 3. Syringe
- 4. Syringe case



This figure illustrates the disconnected syringe case and case head to show the location to inspect for bubbles. Do not disconnect the syringe case from the case head to confirm that there are no bubbles.

- Reinstall the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft.
- **5** Tighten the top fixing nut and then tighten the bottom piston fixing screw.

## Replace the Wash Syringe

If a leak, crack, or any other damage is found when the syringe is inspected, the syringe must be replaced.

If syringe performance is questionable because of abnormal data, remove and inspect the syringe.

The two types of wash syringes:

- Wash Syringe Type 1: R Syringe and R Syringe Case
- Wash Syringe Type 2: Wash Syringe, Seal Assembly, and Piston

Replace the Wash Syringe Type 1 if:

• There is not smooth resistance when pulling on the piston. A worn or damaged syringe has a pulling movement that is too hard or too loose.

6-91 B04779AB

- The fluorocarbon polymer tip is worn, damaged or there is evidence of the fluorocarbon polymers flaking.
- The syringe or case head leaks even after correct installation.
- The head of the syringe is cracked.

Replace the Wash Syringe Type 1 case head if:

• The case head is chipped, worn, or damaged in any way.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

## Materials Required:

For Wash Syringe Type 1:

- Clean, dry, lint-free absorbent tissue
- Wash Syringe Type 1 (R syringe)
- R syringe case head

For Wash Syringe Type 2:

- Clean, dry, lint-free absorbent tissue
- Wash Syringe Type 2
- Seal Assembly
- Piston
- Alcohol prep pads (70% Isopropyl alcohol)

Figure 6.59 Wash Syringe Type 1



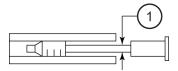
1. Wash Syringe Type 1 Case Head (Transparent)

6-92 B04779AB

# /! CAUTION

Identify the S syringe and R syringe using the diameter of the piston shaft. If you install the incorrect syringe, incorrect results are obtained.

**Figure 6.60 Piston Shaft Diameter** 



 2 mm for S syringe and 5 mm for R syringe



Do not remove the piston from a new syringe. If you remove the piston, the performance of the syringe can be unreliable.

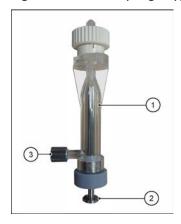
Replace Wash Syringe Type 2 and Seal Assembly if:

• Leaks around the syringe or seal assembly.

Replace Wash Syringe Type 2 piston if:

• A leak at the bottom of the syringe even after replacing the syringe.

Figure 6.61 Wash Syringe Type 2



- 1. Wash Syringe Type 2
- 2. Piston

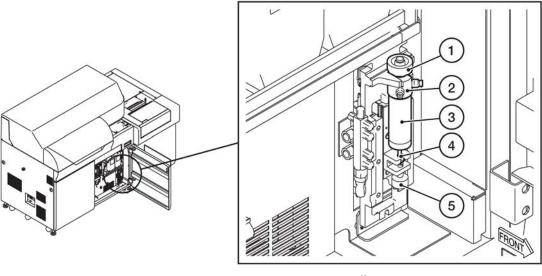
3. Seal Assembly

#### **Remove the Wash Syringe**

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.

- **3** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Replacing Wash Syringe**. The system displays the Start dialog.
- **5** For **Times**, enter **5**, and then select **OK**.
- **6** Open the right front door of the analyzer.
- **7** Loosen the bottom piston fixing screw and the top fixing nut to remove the syringe case from the mounting grooves.
- **8** Pull the syringe case forward to remove it from the installation grooves.

Figure 6.62 Location of Wash Syringe



- 1. Fixing nut
- 2. Case head
- 3. Syringe case

- 4. Installation groove
- 5. Piston fixing screw



When removing the syringe case, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe case.

**9** Tilt the syringe head and case upside down before removing the syringe. Tilting the syringe head and case prevents air from entering the tubing lines and keeps the water from leaking into the syringe case.

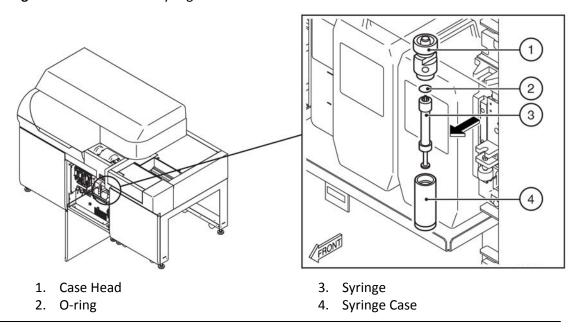
#### Install a New Syringe or a New Syringe Case Head (For Wash Syringe Type 1)

**1** Remove the syringe case by turning it counterclockwise while holding the case head. Pull the syringe from the case head.

6-94 B04779AB

Do not lose the O-ring, which can drop from the case head. If the O-ring remains in the case head, carefully remove it with tweezers.

Figure 6.63 Remove the Syringe



- **2** Obtain a new syringe, and if necessary, a new syringe case head.
- **3** Insert the new syringe into the case head.
- **4** Dry excess water from the syringe and case head to prevent condensation from forming in the case. Screw the syringe case into the case head by twisting clockwise. Do not over tighten. Tighten the syringe case by 45 to 60 degrees from the position that it became tight.
- **5** Reinstall the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft.
- **6** Tighten the top fixing nut and then tighten the bottom piston fixing screw.

## Install a New Wash Syringe and Seal Assembly (For Wash Syringe Type 2)

**1** Remove the wash syringe from the mounting groove.

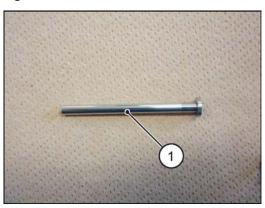
Figure 6.64 Wash Syringe Type 2

- 1. Seal Assembly
- 2. Wash Syringe Type 2

3. Piston

**2** Remove the piston from the wash syringe.

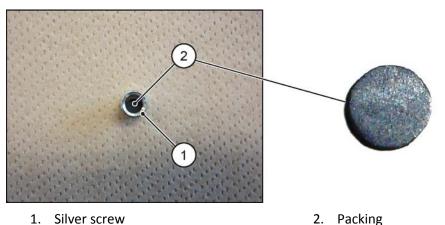
Figure 6.65 Piston



- 1. Piston
- **3** Wipe the piston with an alcohol prep pad (70% Isopropyl alcohol).
- 4 Unscrew the seal assembly, and install the new seal assembly.

6-96 B04779AB

Figure 6.66 Seal Assembly



Gently insert the piston into the new wash syringe.



Do not damage the piston. Confirm that the packing located in the screw of the new seal assembly is not loose. If you handle the packing carelessly, the packing can fall out because the packing is inserted into the screw and not glued.

- **6** Reinstall the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft.
- Tighten the top fixing nut and then tighten the bottom piston fixing screw.

#### **Prime the New Wash Syringe**

You must prime the new syringe.

- 1 Press the TABLE ROTATION/DIAG button.
- Watch the syringe prime and confirm that it is not leaking. If there is leaking, repeat Install a New Syringe or a New Syringe Case Head (For Wash Syringe Type 1) or Install a New Wash Syringe and Seal Assembly (For Wash Syringe Type 2) procedures.

#### Remove the Air Inside the Syringe for Wash Syringe Type 1

- **1** Select **Replacing Sample Syringe**. The system displays the Start dialog.
- Confirm that **Times** is set to **260**, and then select **OK**.
- **3** Press the **TABLE ROTATION/DIAG** button.
- **4** Confirm that the air is primed out of the syringe.
- Pull the syringe case forward to remove it from the installation grooves.

6-97 B04779AB

# IIII IMPORTANT

When removing the syringe case, hold the bottom with a clean, dry, lint-free absorbent tissue. Do not bend the tubing when removing the syringe case.



Do not apply excessive force to the fixing screws when you remove the syringe case. Excessive force to the fixing screws damages the syringe case.

6 Slowly move the syringe piston up and down by hand. Confirm that there are no bubbles on the syringe tip.

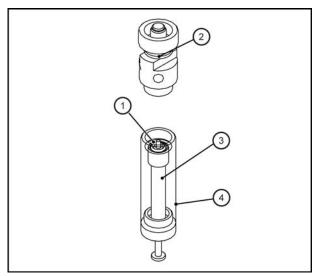
If bubbles are there, move the piston up and down until the bubbles are purged.



Do not move the piston by hand with the syringe case and case head disconnected.

If you move the syringe piston with the syringe case and case head disconnected, the accuracy is not retained because of the deformation of the piston. This deformation can decrease the time a syringe is in use before requiring replacement.

Figure 6.67 Confirm No Bubbles are on the Syringe Tip



- Confirm that no bubbles are attached to the fluorocarbon polymer tip.
- 2. Case head
- 3. Syringe
- 4. Syringe case

6-98 B04779AB

This figure illustrates the disconnected syringe case and case head to show the location to inspect for bubbles. Do not disconnect the syringe case from the case head to confirm that there are no bubbles.

- 7 Tighten the top fixing nut and then tighten the bottom piston fixing screw.
- **8** Perform QC, inspect the data, and recalibrate if necessary.

#### Remove the Air Inside the Syringe for Wash Syringe Type 2

- **1** Select **Replacing Sample Syringe**. The system displays the Start dialog.
- **2** Confirm that **Times** is set to **260**, and then select **OK**.
- **3** Press the **TABLE ROTATION/DIAG** button.
- **4** Confirm that the air is primed out of the syringe.
- **5** If bubbles are still present, tap the top of the wash syringe with your finger.



Do not touch the moving piston. Injury can result if your finger is caught in the syringe component.

It is not necessary to remove bubbles around the seal assembly or small bubbles less than 1 mm in diameter. Small bubbles have no affect on the accuracy of the syringe dispensing.

- **6** Close all analyzer doors and covers.
- 7 Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **8** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **9** Perform QC, inspect the data, and recalibrate if necessary.

#### Clean the Interior of the Reagent Refrigerators and STAT Table Compartment

Condensation forms inside the reagent refrigerators and STAT table compartment, caused by exposure to the outside air.

Keep the reagent refrigerator covers and STAT table compartment cover in position to diminish the amount of condensation formed.

Clean the interior of refrigerators or compartment when a reagent or sample is spilled, or as needed after inspection.

#### Maintenance

As Needed Maintenance

If bacterial contamination is suspected, or mold is observed, contact Beckman Coulter for the decontamination procedure.



Avoid wiping the bar code reader glass window inside the reagent refrigerators and STAT table compartment. If the glass window is smudged from wiping, reagent ID or sample ID read errors can occur.

#### **Clean the Interior of the Reagent Refrigerators**

For more information on materials required, refer to Parts List for Analyzer Maintenance.

## Materials Required:

- Clean, dry, lint-free absorbent tissue
- Alcohol prep pads (70% Isopropyl alcohol)
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Remove the reagent refrigerator covers.
- 4 Remove the reagents along with the reagent tray from each refrigerator by lifting the white securing pins until they unclip from the base. Lift the tray up from the center, and gently place the tray in a safe place.
- **5** Wipe off the condensation and stains on the wall, bottom, and central area inside the reagent refrigerators with a dry, clean absorbent tissue.
- **6** Wipe the same components again with an alcohol prep pad (70% Isopropyl alcohol) to clean the refrigerator. Then, rinse with deionized water and dry with a clean, dry, lint-free absorbent tissue.
- **7** Return reagents and reagent tray to its original position for each refrigerator. Set the tray onto the metal pin. Press down on the white securing pins to secure the reagent tray.
- **8** Replace the reagent refrigerator covers.
- **9** Close all analyzer doors and covers.
- **10** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### **Clean the Interior of the STAT Compartment**

**1** Confirm that the system is in *Warm up* or *Standby* mode.

6-100 B04779AB

- **2** Lift the upper cover of the analyzer.
- **3** Remove the large and small STAT table covers.
- **4** Loosen the two fixing screws near the center of the STAT table with your fingers. Remove the STAT table by lifting the central column. Place the STAT table gently in a safe place.
- **5** Wipe off the condensation and stains on the wall, bottom, and central area inside the STAT table compartment with a dry, clean absorbent tissue. Also wipe off the condensation and stains on the removed STAT table.
- **6** Wipe the wall, bottom, and central area inside the STAT table compartment and the STAT table with an alcohol prep pad (70% Isopropyl alcohol).
- **7** Replace the STAT table in the STAT table compartment. While engaging the guide hole on the STAT table with the guide pin on the table, tighten the two fixing screws near the center with your fingers.
- **8** Place the STAT table covers in the original position.
- **9** Close all analyzer doors and covers.
- **10** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **11** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## Clean or Replace the Anti-static Brushes

Anti-static brushes reduce the chance of static electricity affecting a sample by removing static electricity before sampling takes place.



To avoid infection, always wear gloves to clean or replace the anti-static brushes. If the solution contacts skin or clothes, rinse the affected area thoroughly with water. If the solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Follow your laboratory procedure.

When the AU680 connects to a laboratory automation system, the anti-static brushes are not part of the analyzer.

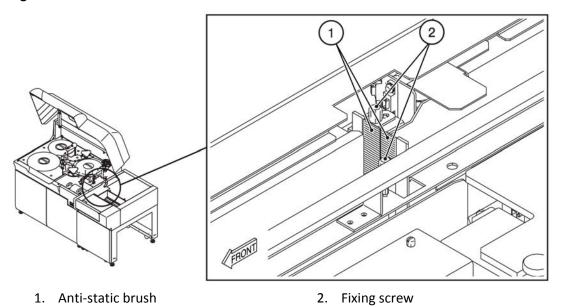
For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Anti-static brushes
- Alcohol prep pads (70% Isopropyl alcohol)

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Remove the dark acrylic cover from the rack feeder module.
- 4 Loosen the fixing screw at the top of the anti-static brush, and remove the anti-static brush.

Figure 6.68 Anti-static Brush



- **5** Follow the same procedure with the brush component on the other side of the rack transport.
- **6** Clean any stains on the brushes with an alcohol prep pad (70% Isopropyl alcohol) from the base to the end of the bristle tips.
- 7 If the static discharge brushes are still stained after cleaning or indicate wear, replace them.
- **8** Dispose of the old brushes in a receptacle for biohazard waste.
- **9** Reinstall the anti-static brush and tighten the fixing screw on top.
- **10** Replace the dark acrylic cover over the rack feeder.
- **11** Close all analyzer doors and covers.
- **12** Select **Home > Analyzer Maintenance > Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **13** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

6-102 B04779AB

# **Replace the Sample or Reagent Probe Tubing**

Replace the sample or reagent probe tubing if the tubing leaks or breaks.

Replace the sample probe or reagent probe tubing using the same procedure.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

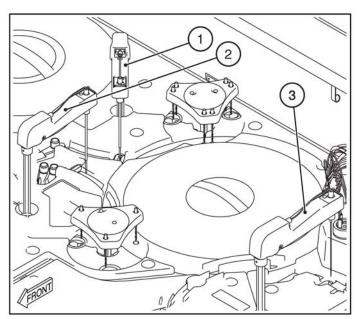
- Sample probe tubing
- R1 probe tubing
- R2 probe tubing



Before disconnecting the tubing, confirm that the probe is positioned over the wash well. Dripping from the probe can occur.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Loosen the connectors on both sides of the probe tubing to remove it.





- 1. R2 probe tubing
- 2. R1 probe tubing

- 3. Sample probe tubing
- **4** Tighten the new tubing connectors to secure both ends of the probe tubing. Tighten the connectors firmly so that no liquid leaks.

As Needed Maintenance

- 5 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.
- **6** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **7** Select **Prime Washing-line**. The system displays the Start dialog.
- **8** For **Times**, enter **3**, and then select **OK**.
- **9** Press the **TABLE ROTATION/DIAG** button. Confirm that the tubing is not leaking and that the probe is dispensing correctly.
- **10** Close all analyzer doors and covers.
- **11** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **12** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

#### Perform a W1

If the analyzer was put into *Stop* mode during analysis, reagents and sample remain in the cuvettes for longer than normal operation. A W1 cleans the entire cuvette wheel automatically using the wash nozzle component.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **3** Select **W1(F5)**. The system displays the W1 Start dialog.
- 4 Select **Start**. The system starts the W1. The W1 takes approximately 19 minutes. After the W1 is complete, the system automatically updates the maintenance log.

# **Replace Rack ID Labels**

If a rack ID label is scratched, stained, or deteriorated, an ID read error results. Replace the rack ID label with a new one.



Rack ID labels can deteriorate with time. If a rack ID read error occurs on an older label and the label shows no anomalies, the label is assumed to have deteriorated from discoloration or reduction in reflectivity. If the rack ID label is deteriorated, replace all the labels that have been used for the same time as the concerned label.

6-104 B04779AB

- The bar code label is faint, or scratched caused by abrasion or scraping.
- A label is stained or blurred caused by adhesion of foreign matters (liquid or solid).
- A label is peeled or torn.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

## Materials Required:

• New Rack ID labels

## IMPORTANT

If it is difficult to remove a label, dampen the label with water and use a tool to scrape it off, such as a razor blade or scissors.

Never use an organic solvent such as ethyl alcohol (ethanol). Organic solvents alter the quality of the plastic surface on a rack.

If you use water, wipe the water off completely so that no moisture remains on the rack.

Do not scratch the rack surface.

**1** Remove the rack ID label.

Figure 6.70 Rack ID Label on a Rack



**2** Attach a new rack ID label on the rack. Place the label on the beveled edge of the rack with the numbers on the left (when looking at the rack).

For more information, refer to the AU680 Reference Manual.



When replacing rack ID labels, do not use labels with the same rack ID on more than one rack. Using duplicate rack IDs can cause concordance errors between samples.

## **Clean or Replace Individual Cuvettes**



Confirm that 165 cuvettes are correctly installed in the cuvette wheel. If one of the cuvettes is missing, the mixture, reagent, or wash solution spills into the cuvette wheel, causing a cuvette wheel overflow and preventing successful analysis.

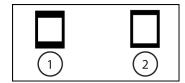


Do not scratch the cuvettes when replacing cuvettes on the cuvette wheel. Never touch the photometric surface of a cuvette. If the photometric surface is stained, analysis data is inaccurate. Wear gloves when handling the cuvettes.



There are cuvettes with different interior dimension. For all markets except Japan, the AU680 uses cuvette PN ZM063400 with an interior dimension of 6 mm x 5 mm. For the Japan market, the AU680 uses cuvette PN MU846500 with an interior dimension of 5 mm x 5 mm. These cuvettes are different from the other AU analyzers. Do not use a cuvette from another AU analyzer on the AU680. Use of a cuvette other than the AU680 cuvette on the AU680 causes erroneous results.

Figure 6.71 Cuvette Interior Dimension



1. PN MU846500 (5 mm x 5 mm)

2. PN ZM063400 (6 mm x 5 mm)

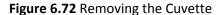
Clean or replace individual cuvettes that failed the weekly photocal procedure. If only a few cuvettes need cleaning or replacing after a cuvette wheel overflow, you can use this procedure.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

Materials Required:

- Cuvettes
- Cotton-tipped applicator

- Clean, dry, lint-free absorbent tissue
- 2% Wash solution
- Plastic container
- Sonicator
- **1** Confirm that the system is in *Warm up*, *Standby*, or *Stop* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the rear cover of the analyzer.
- **4** Loosen the knob of the wash nozzle component. Without disconnecting the tubing, remove the nozzle portion from its stand and hang it on the nearby hook.
- **5** Manually rotate the mix bar components approximately 60 degrees so they are not over the cuvette cover.
- **6** Lift the cuvette wheel cover, carefully remove it from the analyzer, and set it aside.
- **7** Locate the failed cuvette. Every 17th cuvette is numbered.
- **8** Using two cotton-tipped applicators, gently insert them in the cuvette to be removed and pull up.





- **9** Determine if the cuvette needs replacing or cleaning.
  - To replace individual cuvettes: Insert the new cuvette into the wheel. Gently push the cuvette completely into the wheel.
  - To clean individual cuvettes: Sonicate cuvettes in a 2% Wash Solution for 15 minutes. If a sonicator is not available, soak them in a 5% Wash Solution overnight. Rinse the cuvette in deionized water. Allow the cuvettes to completely dry.

As Needed Maintenance

- **10** Replace the new or cleaned cuvette into its position. Gently push the cuvette completely into the wheel.
- **11** Replace the cuvette wheel cover.
- **12** Manually turn the mix bar components back to their original position.
- **13** Replace the wash nozzle component.
- **14** Select **Home** > **Analyzer Maintenance** > **Maintenance**. The system displays the Analyzer Maintenance: Maintenance tab.
- **15** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- **16** Select **Prime Washing-line**. The system displays the Start dialog. Select **OK**.
- **17** Press the **TABLE ROTATION/DIAG** button. Watch as the wash nozzle component moves, and confirm that the downward motion is not inhibited.
- **18** Clear the **Analyzer Maintenance** box to deactivate the maintenance operation buttons.
- **19** Perform a photocal on the individual cuvette. For more information, refer to Perform a Photocal.

## Replace the Photometer Lamp

Over time, the intensity of the photometer lamp diminishes, and results are affected.

Beckman Coulter recommends replacing the photometer lamp every 1,000 hours. Replacement of the lamp at 1,000 hours ensures continuous and reliable lamp performance without unexpected analyzer down-time.

Replace the lamp when a cuvette displays in orange for a Lamp Check Error in the Photocal Monitor tab, or when troubleshooting indicates the need for a new lamp, even if 1,000 hours have not passed since the lamp was replaced.

After replacing the lamp, the system requires a photocal to evaluate the quality and intensity of the new lamp.



To prevent electric hazards, shut down the system (End Process) before replacing the photometer lamp. For more information, refer to System Shutdown (End Process).

Wait a minimum of 5 minutes after the system completes the shutdown process. Do not touch the lamp with your bare hands until the photometer lamp has cooled down completely. The lamp is hot and can cause burns.

6-108 B04779AB

# IIII IMPORTANT

Never touch the glass of the photometer lamp with your bare hands. If oil from skin or fingerprints are left on the glass, wipe them off with a clean, dry, lint-free absorbent tissue.

For more information on materials required, refer to Parts List for Analyzer Maintenance.

## Materials Required:

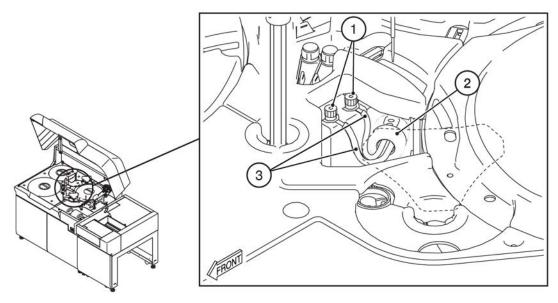
- Photometer lamp
- **1** To shut down the system, select **End**. For more information, refer to System Shutdown (End Process).
- **2** Allow the lamp to cool for a minimum of five minutes.
- **3** Lift the upper cover of the analyzer.
- **4** Remove the lamp cover.



Do not bump the cover against the reagent probe when removing the lamp cover.

**5** Loosen the two knobs on the terminals, then disconnect the lamp lead wires.

Figure 6.73 Lamp Components



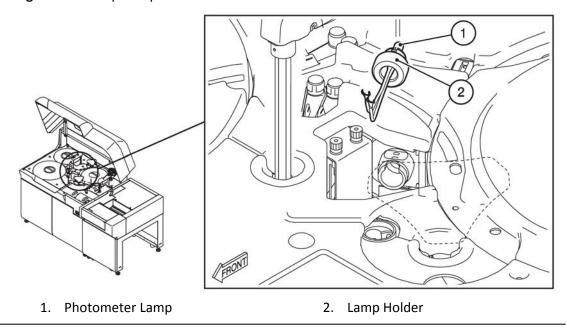
- 1. Knobs
- 2. Lamp Holder

- 3. Lamp Lead Wires
- **6** Remove the lamp by turning the lamp holder counterclockwise, then pulling the lamp from the lamp receptacle. Handle the lamp by the lead wires.

# IMPORTANT

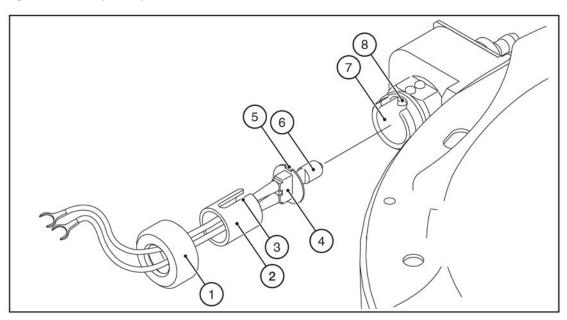
Never touch the glass of the photometer lamp with your bare hands. If oil from skin or fingerprints are left on the glass, wipe them off with a clean, dry, lint-free absorbent tissue.

Figure 6.74 Lamp Components



Remove the lamp holder and collar from the lamp and keep them for future use.





- 1. Lamp Holder
- 2. Collar

- 3. Collar Notch
- 4. Guide Key

- 5. Notch
- 6. Lamp

- 7. Lamp Receptacle
- 8. Protrusion
- **8** Obtain a new lamp. Handle the lamp using only the wires. If you touch the bulb, you can damage it.
- **9** Slide the collar along the lead wires with the opening of the notch toward the rear of the lamp. Align the notched collar with the notch of the guide key of the lamp.
- **10** Insert the lamp into the receptacle with the notches lined up on the top. Slide the notches into the keyed protrusion of the receptacle.
- **11** Slide the lamp holder along the wires behind the lamp and tighten to hold it in position.



Confirm that the lamp holder is securely in position. If the holder is loose, accurate analysis data is not obtained.

- **12** Connect the lead wires to the terminals and tighten with the knobs. Each lead wire can be connected to either terminal.
- **13** Replace the lamp cover.
- **14** Close all analyzer doors and covers.
- **15** Press the **ON** button. The system powers up and initializes.



After replacing the lamp, perform a photocal to confirm that the lamp does not have any defects. To obtain accurate analysis data, wait 20 minutes to stabilize the lamp after turning on the system, then perform the photocal.

- **16** Select Home > Analyzer Maintenance > Consumption.
- 17 Select Replacing Photometer Lamp.
- **18** Select **Update**. The system displays the User Maintenance dialog.
- **19** Select **OK** to indicate the lamp was replaced and reset the lamp used time.



The system automatically saves the first photocal value after you update Replacing Photocal Lamp in the Consumption tab. The system uses this photocal value as the reference value in **Photocal Monitor > Detail(F5) > Graph**.

- **20** Allow the lamp 20 minutes to warm up and come to the correct intensity before continuing to the next step.
- **21** Perform a photocal. For more information, refer to Perform a Photocal.

ISE Maintenance for All Markets Except Japan

**22** Confirm that all cuvettes have passed the photocal.

Errors can occur after the photocal. If numerous cuvettes fail the photocal, the lamp was incorrectly replaced or the lamp is defective. If only a few cuvettes fail the photocal, the cuvettes are dirty or stained. Clean the cuvettes. If the system still reports an error after cleaning, replace the cuvettes. For more information, refer to Clean or Replace Individual Cuvettes.

**23** Run QC before processing samples.

Analyze QC data, and recalibrate if necessary.

# **Save Parameters**

Beckman Coulter recommends saving parameters when programming changes are made or following your laboratory procedures.

If multiple AU680s are in the laboratory, Beckman Coulter recommends saving the parameter files for each AU680 to external media.

For more information, refer to the AU680 Reference Manual.

# **ISE Maintenance for All Markets Except Japan**

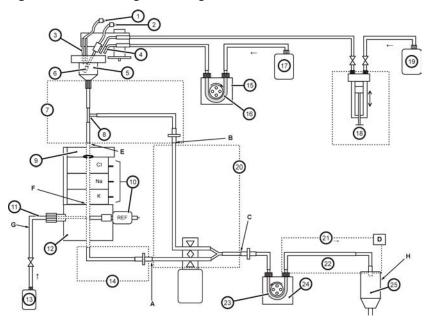


For the Japan market, refer to the Maintenance Schedule in the ISE Addendum.

6-112 B04779AB

# **ISE Tubing Block Diagram**

Figure 6.76 ISE Tubing Block Diagram



- 1. Level sensor connector
- 2. Mixing motor connector
- 3. Liquid level sensor
- 4. Nozzle
- 5. Sample pot
- 6. Mix bar
- 7. Tubes between the sample pot and flowcell (tube set)
- 8. T-connector
- 9. Electrode block (inlet)
- 10. Electrode
- 11. REF solution tube
- 12. REF electrode block
- 13. ISE Reference Solution

- 14. REF electrode block-side drain tube (Tube Set 2: labeled 6)
- 15. MID standard roller pump
- 16. Roller pump tubing
- 17. ISE MID Standard Solution
- 18. Buffer syringe
- 19. ISE Buffer Solution
- 20. Pinch valve tubing
- 21. Waste solution
- 22. Drain tube
- 23. Roller pump tubing
- 24. Mixture aspiration roller pump
- 25. Drain well



A to H: Tubing detachment locations. Refer to the specific maintenance procedure for a detailed diagram and description.

# **Parts List for ISE Maintenance**

 Table 6.27
 Daily ISE Maintenance

Maintenance Procedure	Part	Part Number
Clean the ISE	ISE Cleaning Solution     ISE Cleaning Solution (US)     Cleaning Solution (Outside US)	<ul> <li>AUH1019 (US)</li> <li>66039 (Outside US)</li> <li>For the Japan market, refer to the ISE Addendum.</li> </ul>
	Hitachi Cup	MU853200
Calibrate the ISE	Serum Standard Solution H	<ul><li>AUH1015 (US)</li><li>66316 (Outside US)</li></ul>
	Serum Standard Solution L	• AUH1014 (US) • 66317 (Outside US)
	Urine Standard Solution H and L	<ul><li>AUH1016 (US)</li><li>66315 (Outside US)</li></ul>
	Hitachi Cup (4 cups)	MU853200

Table 6.28 Weekly ISE Maintenance

Maintenance Procedure	Part	Part Number
Selectivity Check for the Na and K Electrodes	ISE Selectivity Check Solution (Na, K)	<ul><li>AUH1018 (US)</li><li>66313 (Outside US)</li></ul>
	Hitachi Cup (2 cups)	MU853200
Enhanced Cleaning of Electrode Line	ISE Cleaning Solution     ISE Cleaning Solution (US)     Cleaning Solution (Outside US)	<ul> <li>AUH1019 (US)</li> <li>66039 (Outside US)</li> <li>For the Japan market, refer to the ISE Addendum.</li> </ul>
	Hitachi Cup	MU853200

6-114 B04779AB

 Table 6.29
 Every Other Week or 3,000 Samples ISE Maintenance

Maintenance Procedure	Part	Part Number
Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing	Alcohol prep pads (70% Isopropyl alcohol)	Commercial item
	Clean, dry, lint-free absorbent tissue	Commercial item
	1% Wash solution	OSR0001 (Outside Japan)    MS028400 (Japan)
	Deionized water	-
	Sonicator	Commercial item

 Table 6.30
 Every Other Month or Every 20,000 Samples ISE Maintenance

Maintenance Procedure	Part	Part Number
Inspect and Add ISE Internal Reference Solution	ISE Internal Reference Solution	<ul><li>AUH1017 (US)</li><li>66314 (Outside US)</li></ul>

 Table 6.31
 Quarterly or Every 20,000 Samples ISE Maintenance

Maintenance Procedure	Part	Part Number
Replace the Mixture Aspiration and MID Standard Roller Pump Tubing	Roller pump tubing	MU962300
Replace the Tubing between the Sample Pot, Electrode Block, and T-Connector	Tube Set	MU538600
Replace the REF Electrode Block- side Drain Tube and Pinch Valve Tubing	Tube Set 2	MU824700
	Pinch Valve Tubing	ZM297000
Manually Clean the Drain Well	Drain Tube 2	MU830300
and, if Needed, Replace the Drain Tube	Sodium hypochlorite solution (0.5%)  • 5% Sodium Hypochlorite Solution diluted 1:10 (US)  • Cleaning Solution diluted 1:10 (Outside US and Japan)  • Sodium hypochlorite solution (5%) diluted 1:10 (Japan)	<ul> <li>A32319 (US)</li> <li>66039 (Outside US and Japan)</li> <li>Commercial item (Japan)</li> </ul>

 Table 6.32
 Every 6 Months or Every 40,000 Samples ISE Maintenance

Maintenance Procedure	Part	Part Number
Replace the Na, K, or Cl Electrode	Na Electrode	MU919400
	K Electrode	MU919500
	Cl Electrode	MU919600
	O-ring	MU990000

Table 6.33 Every Two Years or Every 150,000 Samples ISE Maintenance

Maintenance Procedure	Part	Part Number
Replace the REF Electrode and Packing	REF Electrode (with the packing)	MU919700
	REF Electrode Packing	MU920200

Table 6.34 As Needed ISE Maintenance

Maintenance Procedure	Part	Part Number
Replace the Sample Pot	Sample Pot	MU962700
Clean the ISE Electrode Block (Inlet Side)	Stylet φ0.3 (diameter)	ZM022700
Manually Clean the ISE K Electrode	Clean, dry, lint-free absorbent tissue	Commercial item
Manually Clean and Replace the	REF Electrode Block	MU824500
ISE REF Electrode Block	2% Wash solution	<ul><li>OSR0001 (Outside Japan)</li><li>MS028400 (Japan)</li></ul>
Replace the ISE Reagents	ISE Buffer Solution	• AUH1011 (US) • 66320 (Outside US)
	ISE MID Standard Solution	AUH1012 (US)     66319 (Outside US)
	ISE Reference Solution	AUH1013 (US)     66318 (Outside US)

6-116 B04779AB

**Maintenance Procedure Part Number Enhanced ISE Cleaning (Manual)** ISE Cleaning Solution diluted 1:10 AUH1019 (US) • 66039 (Outside US) • ISE Cleaning Solution diluted 1:10 (US) For the Japan market, refer to the ISE Addendum. Cleaning Solution diluted 1:10 (Outside US) ISE MID Standard Solution AUH1012 (US) 66319 (Outside US) Disposable pipette (that can Commercial item collect more than 1 mL of liquid)

Table 6.34 As Needed ISE Maintenance (Continued)

## **ISE Daily Maintenance**

Perform the following procedures daily.

- Clean the ISE
- Calibrate the ISE

Inspections for the ISE buffer syringe are in the analyzer daily maintenance section. For more information, refer to Inspect the Syringes for Leaks.

#### Clean the ISE

Clean the sample pot and the electrode lines daily to prevent contamination and inaccurate results. This procedure requires approximately four minutes to complete.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle ISE Cleaning Solution. If the ISE Cleaning Solution contacts skin or clothes, rinse the affected area thoroughly with water. If the ISE Cleaning Solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.



If the analyzer does not run continuously, clean the ISE as part of the daily shutdown.

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- ISE Cleaning Solution
- Hitachi Cup

6-117 B04779AB

ISE Maintenance for All Markets Except Japan

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the small STAT table cover.
- **4** Press the **TABLE ROTATION/DIAG** button to rotate the STAT table until the **CLEAN** position is accessible.
- **5** Fill the Hitachi cup with a minimum of 1 mL of ISE Cleaning Solution.
- **6** Place the Hitachi cup in the **CLEAN** position on the STAT table.



Wipe up ISE Cleaning Solution spills immediately. Follow your laboratory procedure.

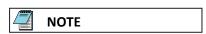
- **7** Close the small STAT table cover.
- 8 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **9** Select **Cleaning (F5)**. The system displays the Start dialog.
- **10** Select **OK**. The system starts the cleaning operation.
- **11** When the cleaning operation is complete, remove the Hitachi cup from the STAT table and discard.
- **12** Close all analyzer doors and covers.

#### Calibrate the ISE

Calibrate the ISE once every 24 hours, following specific maintenance procedures, and when replacing the ISE reagents.



When the analysis is in process or the ISE status is *Busy*, do not open the STAT table covers to add Standard Solutions to the STAT table or place hands in the path of the sample probe.



Calibrating only serum or urine requires approximately four minutes to complete. Calibrating serum and urine together requires approximately seven minutes to complete.

For more information on materials required, refer to Parts List for ISE Maintenance.

6-118 B04779AB

## Materials Required:

- · Serum Standard Solution H
- · Serum Standard Solution L
- Urine Standard Solution H and L
- Hitachi Cup (4)
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Perform a total prime. A total prime is required to clear the lines of ISE Cleaning Solution if you calibrate the ISE immediately after the Clean the ISE procedure.
  - a. Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
  - **b.** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
  - **c.** Select **Total Prime**. The system displays the Start dialog.
  - d. Select OK.
  - **e.** Press the **TABLE ROTATION/DIAG** button to start the prime. The TABLE ROTATION/ DIAG LED turns on after the priming is complete.
  - Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **3** Lift the upper cover of the analyzer.
- Open the small STAT table cover.
- 5 Press the TABLE ROTATION/DIAG button to rotate the STAT table until the S-H, S-L, U-H, and **U-L** positions are accessible.
- Fill a Hitachi cup with approximately 500 µL of Standard Solution as required for processing (determined by your laboratory processing serum, urine, or both sample types).
  - Serum Standard Solution Low
  - Serum Standard Solution High
  - Urine Standard Solution Low
  - Urine Standard Solution High
- **7** Place the Hitachi cups into the corresponding positions on the STAT table.
- Close the small STAT table cover.
- Select Home > Analyzer Maintenance > ISE Maintenance > Calibration. The system displays the ISE Maintenance: Calibration tab.

6-119 B04779AB



Figure 6.77 ISE Maintenance: Calibration Tab

- Calibration tab
- **10** Select **Serum Start**, **Urine Start**, or **Serum/Urine Start** depending on the sample types to calibrate. The system displays the Start dialog.
- **11** Select **OK**. The system starts calibration.
- **12** When calibration is complete, confirm that the result for each electrode is within the ranges for the calibrated sample types.

The system highlights acceptable results in blue, and results that exceed the Calibration Slope Normal Range are yellow.

To determine calibration quality, compare the current results with previous results for consistency.

To switch from serum results to urine results, in **Type** select **Urine**.

- **13** Remove the Hitachi cups from the STAT table and discard.
- **14** Close all analyzer doors and covers.

## **ISE Weekly Maintenance**

Perform the following procedures weekly.

- Selectivity Check for the Na and K Electrodes
- Enhanced Cleaning of Electrode Line

6-120 B04779AB

Selectivity Check for the Na and K Electrodes

The Na electrode and K electrode are ion-selective electrodes. If the selectivity of the electrodes deteriorates, ions other than Na or K can affect the electrodes, and results can be affected.

To confirm the ion selectivity of the electrodes, you must perform a selectivity check of the Na and K electrodes every week.

# IIII IMPORTANT

Do not leave the bottle of ISE Selectivity Check Solution open. Concentration or crystallization of the ISE Selectivity Check Solution can occur.

For more information on materials required, refer to Parts List for ISE Maintenance.

### Materials Required:

- ISE Selectivity Check Solution (Na, K)
- Hitachi Cup (2 cups)
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the small STAT table cover.
- **4** Press the **TABLE ROTATION/DIAG** button to rotate the STAT table until the **SEL-Na**, and **SEL-K** positions are accessible.
- 5 Fill the Hitachi cups with approximately 500  $\mu$ L of ISE Selectivity Check Solution (Na) and 500  $\mu$ L of ISE Selectivity Check Solution (K) separately.
- **6** Place the ISE Selectivity Check Solution (Na) in the **SEL-Na** position. Place the ISE Selectivity Check Solution (K) in the **SEL-K** position.
- **7** Close the small STAT table cover.
- 8 Select Home > Analyzer Maintenance > ISE Maintenance > Selectivity Check. The system displays the ISE Maintenance: Selectivity Check tab.

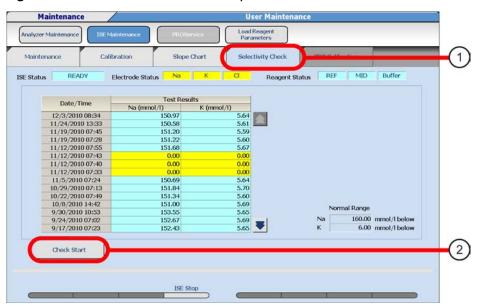


Figure 6.78 ISE Maintenance: Selectivity Check Tab

1. Selectivity Check tab

- 2. Check Start button
- **9** Select **Check Start**. The system displays the Selectivity Check dialog.

#### 10 Select OK.

**11** Confirm the selectivity check data.

For abnormal data, the background for the result is displayed in yellow. The system judges a result more than 160 mmol/L for Na electrode and a result more than 6 mmol/L for K electrode as abnormal data.

If the selectivity check results are abnormal, confirm the ISE Selectivity Check Solution (Na) and ISE Selectivity Check Solution (K) by repeating the procedure with new bottles of ISE Selectivity Check Solution (Na) and ISE Selectivity Check Solution (K). Perform the Selectivity Check with a valid ISE Calibration. However, if the ISE Calibration passes, and the Selectivity Check fails, replace the relevant electrode.

For more information, refer to Replace the Na, K, or Cl Electrode.

- **12** Perform a MID/REF Prime three times to clear the electrode flowcell of any ions remaining from the selectivity check procedure.
  - a. Select the Maintenance tab.
  - **b.** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
  - c. Select MID/REF Prime, and then select OK.
  - **d.** Press the **TABLE ROTATION/DIAG** button to start the priming. The TABLE ROTATION/DIAG LED turns on after the priming is complete.
  - **e.** Initiate the MID/REF prime two more times by pressing the **TABLE ROTATION/DIAG** button.
  - **f.** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.

6-122 B04779AB

- **13** After completing the operation, open the small STAT table cover, and then remove the Hitachi cups from the STAT table.
- **14** Close the small STAT table cover.
- **15** Close all analyzer doors and covers.

## **Enhanced Cleaning of Electrode Line**

If you do not perform the ISE enhanced cleaning cycle, contamination or inaccurate results can occur.

This cleaning procedure requires 30 minutes to complete. If the ISE enhanced cleaning is performed with the W2, both procedures are complete in approximately 30 minutes. For more information, refer to Perform a W2.

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

- ISE Cleaning Solution
- Hitachi Cup



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle ISE Cleaning Solution. If the ISE Cleaning Solution contacts skin or clothes, rinse the affected area thoroughly with water. If the ISE Cleaning Solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.
- **3** Open the small STAT table cover.
- **4** Press the **TABLE ROTATION/DIAG** button to rotate the STAT table until the **CLEAN** position is accessible.
- **5** Fill the Hitachi cup with approximately 1.5 mL of ISE Cleaning Solution.
- **6** Place the Hitachi cup in the **CLEAN** position on the STAT table.
- 7 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- 8 Select Cleaning (Enhanced) (F6), and then select OK. The system starts the enhanced cleaning operation. This process requires 30 minutes to complete.

ISE Maintenance for All Markets Except Japan

- **9** After performing the enhanced cleaning operation, open the small STAT table cover, and then remove the ISE Cleaning Solution.
- **10** Close the small STAT table cover.
- **11** Close all analyzer doors and covers.

## ISE Maintenance Every Other Week or Every 3,000 Samples

Perform the following procedures every other week or every 3,000 samples, whatever comes first.

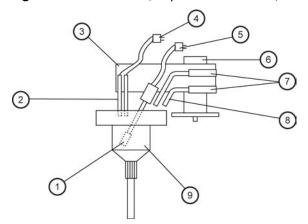
 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

## Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

To obtain accurate results and optimum system performance without unexpected analyzer downtime, perform the following ISE maintenance procedure every two weeks or every 3,000 samples, whatever comes first. Clean according to your laboratory procedures and after careful monitoring of calibration and QC data.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.79 ISE Mix Bar, Liquid Level Sensors, and Sample Pot



- 1. Mix bar
- 2. Liquid level sensor
- 3. Mixing component
- 4. Level sensor connector
- 5. Mixing motor connector

- 6. Mixing component knob
- 7. ISE Buffer Solution and ISE MID Standard Solution connecting tubes
- 8. Nozzle
- 9. Sample pot

6-124 B04779AB

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.
- **5** Select **OK**.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Clean the Nozzles, Mix Bar, and Liquid Level Sensors

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

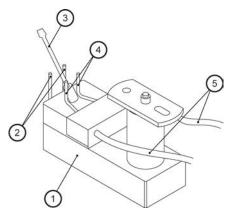
- Alcohol prep pads (70% Isopropyl alcohol)
- Clean, dry, lint-free absorbent tissue
- **1** Disconnect the level sensor connector 714 and mixing motor connector 706.
- **2** Loosen the knob securing the mixing component. Gently lift the mixing component to unseat it.



Do not bend or break the liquid level sensors when cleaning.

**3** Use an alcohol prep pad (70% Isopropyl alcohol) to wipe the two nozzles, the liquid level sensors, and the mix bar.

Figure 6.80 Mixing Component



- 1. Mixing component
- 2. Liquid level sensors
- 3. Mix bar

- 4. Nozzle
- 5. Connecting tubing
- **4** Place the mixing component on the mixing component holder.

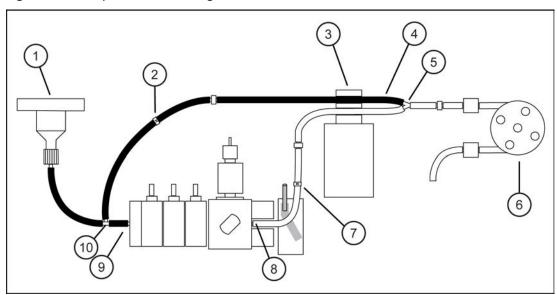


Do not change the orientation position of the two nozzles attached to the mixing component. Do not apply excess pressure to the tubing.

# Clean the Sample Pot and Tubing

For more information, refer to ISE Tubing Block Diagram.

Figure 6.81 Sample Pot and Tubing



6-126 B04779AB

- 1. Sample pot
- 2. Bypass tubing (labeled 5)
- 3. Pinch valve
- 4. Pinch valve tubing
- 5. Y-connector

- 6. Mixture aspiration roller pump
- 7. Tubing
- 8. REF Electrode block outlet
- 9. Electrode block inlet
- 10. T-connector

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

- Freshly prepared 1% Wash solution
- · Deionized water
- Clean, dry, lint-free absorbent tissue
- Sonicator
- 1 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.
- **2** Hold the sample pot with one hand while removing the sample pot tubing from the electrode block inlet.
  - **a.** Follow the bypass tubing (labeled 5) connected to the pinch valve tubing and remove it from the pinch valve.
  - **b.** Disconnect the pinch valve tubing at the Y-connector near the mixture aspiration roller pump.
- **3** Fill the sample pot tubing and bypass tubing with 1% wash solution. Use a disposable pipette tip attached to a squeeze bottle or a syringe to fill the sample pot tubing and bypass tubing.
  - **a.** Place the pipette tip or syringe inside the bottom of the sample pot tubing.
  - **b.** Force the wash solution through the sample pot tubing.
  - **c.** Place the pipette tip or syringe in the end of the bypass tubing. Force the wash solution through it.
- **4** Submerge the sample pot and all attached tubing into a beaker filled with 1% wash solution.
- **5** Place the beaker in the sonicator filled with deionized water and sonicate for 10 minutes.
- **6** Rinse the sample pot and tubing with deionized water.
  - **a.** Place the pipette tip or syringe at the bottom of the sample pot tubing.
  - **b.** Force deionized water through the sample pot tubing.
  - **c.** Place the pipette tip or syringe in the bypass tubing. Force deionized water through it
  - **d.** Confirm that the lines have been flushed thoroughly. Rinse the sample pot with deionized water.
- **7** Use a clean, dry, lint-free absorbent tissue to dry the sample pot and tubing before replacement.

## Reinstall the Sample Pot, Tubing, and Mixing Component

- **1** While holding the sample pot, connect the sample pot tubing to the electrode block inlet.
- **2** Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.
- **3** Connect the pinch valve tubing onto the Y-connector located near the mixture aspiration roller pump.
- **4** Slide the pinch valve tubing into the top slot of the pinch valve.
- **5** Replace the mixing component on the two positioning pins. Tighten the knob to secure the mixing component.
- **6** Reconnect the level sensor connector 714 and mixing motor connector 706.



The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.



When reinstalling the mixing component, confirm that the tubing is not pinched between the mixing component and its stand.

**7** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

**8** Perform a buffer prime.

During the prime, confirm that buffer is correctly dispensed into the sample pot and flows to waste without generating alarms:

- a. Select Buffer Prime. The system displays the Start dialog.
- **b.** Select **OK**.
- **c.** Press the **TABLE ROTATION/DIAG** button to start the priming. The TABLE ROTATION/DIAG LED turns on after the priming is complete.
- **9** Perform a total prime to prime the ISE module with fresh ISE Buffer Solution, ISE MID Standard Solution, and ISE Reference Solution.

6-128 B04779AB

- a. Select **Total Prime**. The system displays the Start dialog.
- **b.** Select **OK**.
- **c.** Press the **TABLE ROTATION/DIAG** button to start the priming. The TABLE ROTATION/DIAG LED turns on after the priming is complete.
- **10** Close all analyzer doors and covers.
- **11** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **12** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **13** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

## ISE Maintenance Every Other Month or Every 20,000 Samples

Perform the following procedures every other month or every 20,000 samples, whatever comes first.

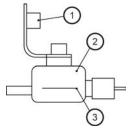
• Inspect and Add ISE Internal Reference Solution

## **Inspect and Add ISE Internal Reference Solution**

Visually inspect the REF electrode. Add ISE Internal Reference Solution when it is less than the reference line.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.82 REF Electrode



- 1. REF electrode cap
- 2. REF electrode

3. Reference line

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- ISE Internal Reference Solution
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Lift the upper cover of the analyzer.

ISE Maintenance for All Markets Except Japan

- 3 Open the ISE cover.
- **4** Open the cap of the REF electrode. Add ISE Internal Reference Solution up to, but not over the reference line.



Do not break or damage the glass REF electrode.

- **5** Replace the REF electrode cap.
- **6** Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.
- **7** Wait 15 minutes to allow the solution to equilibrate.
- **8** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **9** Select **Total Prime**. The system displays the Start dialog.
- 10 Select OK.
- **11** Press the **TABLE ROTATION/DIAG** button to start the prime. The TABLE ROTATION/DIAG LED turns on after the priming is complete.
- **12** Close all analyzer doors and covers.
- **13** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **14** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **15** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

# ISE Quarterly Maintenance or Maintenance Every 20,000 Samples

Perform the following procedures quarterly (every three months) or every 20,000 samples, whatever comes first.

- Replace the Mixture Aspiration and MID Standard Roller Pump Tubing
- Replace the Tubing between the Sample Pot, Electrode Block, and T-Connector
- Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing
- Manually Clean the Drain Well and, if Needed, Replace the Drain Tube

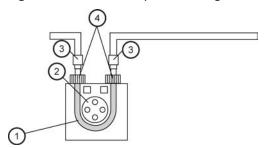
## Replace the Mixture Aspiration and MID Standard Roller Pump Tubing

The friction of each roller pump and vibrations causes the roller pump tubing to deteriorate. If the roller tubing is not replaced for an extended time, it can become flat or

6-130 B04779AB

worn and leaks can occur. Replace the roller pump tubing every three months or every 20,000 samples.

Figure 6.83 Roller Pump and Tubing



- 1. Roller pump tubing
- 2. Roller pump

- 3. Tube number
- 4. Tube connectors

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

Roller pump tubing

#### **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.
- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.

ISE Maintenance for All Markets Except Japan



#### NOTE

The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Replace the Mixture Aspiration and MID Standard Roller Pump Tubing

- **1** Remove each roller pump tubing from the pump brackets.
- **2** Remove the MID Standard roller pump tubing and the mixture aspiration roller pump tubing by twisting apart the connectors at each end.
- **3** Connect a new roller pump tubing. Turn the connectors at both ends to secure it.
- Place the roller pump tubing on the correct roller pump, then match the tubing connector number to their corresponding numbers on the pump bracket. Hook one end of the tubing in the bracket, stretch the tubing around the pump, and hook the other end in the bracket.



Confirm that the tubing is not twisted on the roller pump.





- 1. Tubing connector (labeled 2)
- 2. Pump bracket (labeled 2)
- **5** Select **Prime Bypass**. The system displays the Start dialog.
- 6 Select OK.
- **7** Press the **TABLE ROTATION/DIAG** button to start the prime. The two roller pumps are activated to prime liquid through the ISE. The roller pumps rotate for approximately one minute to remove the air from the tubing.
- **8** Close all analyzer doors and covers.

6-132 B04779AB

- **9** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **10** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## Replace the Tubing between the Sample Pot, Electrode Block, and T-Connector

If the system analyzes certain samples (such as dialysis samples) that contain large amounts of fibrin and protein, the fibrin and protein can accumulate near the T-connector between the sample pot and electrode block. Accumulation of fibrin and protein can cause errors.

To obtain accurate results and optimum system performance without unexpected analyzer downtime, perform the following ISE maintenance procedure quarterly or every 20,000 samples. Clean according to your laboratory procedures and after careful monitoring of calibration and QC data.

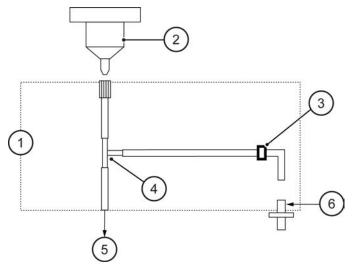
For more information on how to clean the sample pot, tubing, and T-connector, refer to Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing.

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

• Tube Set

Figure 6.85 Tubing Between the Sample Pot, Electrode Block, and T-Connector



- 1. Tubing between the sample pot and electrode block (tube set)
- 2. Sample pot
- 3. Bypass tubing (labeled 5)

- 4. T-connector
- 5. Electrode block
- 6. Tube joint

ISE Maintenance for All Markets Except Japan

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.
- **5** Select **OK**.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



## **NOTE**

The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Replace the Tubing between the Sample Pot, Electrode Block, and T-Connector

- **1** Disconnect the liquid level sensor connector 714 and mixing motor connector 706.
- **2** Loosen the knob securing the mixing component. Gently lift the mixing component to remove it and place it on the mixing component holder.
- **3** Loosen the retaining knob securing the sample pot, and lift the pot from the peg.
- **4** Follow the tubing from the bottom of the sample pot to its connection at the electrode block inlet. Disconnect the tubing from the electrode block inlet.
- **5** Follow the bypass tubing (labeled 5) from the T-connector to its junction with the pinch valve tubing. Disconnect the bypass tubing from the pinch valve tubing.
- **6** Unscrew the tubing connected to the bottom of the sample pot, and discard the tubing.
- **7** Connect the new set of tubing to the electrode block inlet, and then to the pinch valve tubing.

6-134 B04779AB

**8** Attach the tubing to the sample pot by screwing on the connector.



To connect the T-connector and tubing, push them completely so that each joint does not leak. To attach the tubing to the bottom of the sample pot, finger-tighten the connector.

- **9** Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.
- **10** Replace the mixing component on the two positioning pins. Tighten the knob to secure the mixing component.
- **11** Reconnect the level sensor connector 714 and mixing motor connector 706.



The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.



When reinstalling the mixing component, confirm that the tubing is not pinched between the mixing component and its stand.

- **12** Confirm that **Drain Flowcell** is selected.
- **13** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **14** Close all analyzer doors and covers.
- **15** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **16** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **17** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

## Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing

If the REF electrode block-side drain tube and the pinch valve tubing are used for an extended period of time, the tubing may deteriorate. Beckman Coulter recommends to replace the REF electrode block-side drain tube and pinch valve tubing every three months or every 20,000 samples.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.86 REF Electrode Block-side Drain Tube and Pinch Valve Tubing

- Tubing between the sample pot and electrode block (tube set)
- 2. Electrodes
- 3. REF electrode wire (green)
- 4. Pinch valve tubing
- 5. Pinch valve
- 6. REF electrode block-side drain tube (Tube Set 2: labeled 6)
- 7. REF electrode block
- 8. Tubing connection A
- 9. Tubing connection B
- 10. Tubing connection C
- 11. O-ring

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

- Tube Set 2
- Pinch Valve Tubing

6-136 B04779AB

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.
- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Replace the REF Electrode Block-side Drain Tubing



Always drain the flowcell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flowcell.

- **1** Move the lock lever to the left to release the electrodes.
- **2** Disconnect the green REF electrode wire.
- **3** Gently lift up the REF electrode block.

ISE Maintenance for All Markets Except Japan

- 4 While holding the REF electrode block, disconnect Tube Set 2. Tube Set 2 is the tubing (labeled 6) from the REF electrode block and connected to the pinch valve tubing. Refer to Figure 6.86 REF Electrode Block-side Drain Tube and Pinch Valve Tubing.
- **5** Attach a new Tube Set 2 by connecting the tubing (labeled 6) to the REF electrode block and the pinch valve tubing.
- **6** Place the REF electrode block in the original position and reconnect the green REF electrode wire.
- **7** Align the electrodes in a straight stack with the electrode pegs in the holes.
- **8** Move the lock lever to the right to lock the electrodes in position.

## **Replace the Pinch Valve Tubing**

- **1** Remove the pinch valve tubing from the pinch valve grooves by pulling out and then up.
- **2** Disconnect the pinch valve tubing at tubing connection A, tubing connection B, and tubing connection C. Refer to Figure 6.86 REF Electrode Block-side Drain Tube and Pinch Valve Tubing.
- **3** Replace the pinch valve tubing by connecting the short end to tubing connection C, the shorter of the two remaining pieces of tubing to tubing connection A, and the longest tubing to tubing connection B. Refer to Figure 6.86 REF Electrode Block-side Drain Tube and Pinch Valve Tubing.



Install the shorter tubing in the bottom groove of the pinch valve (between A and C in the tubing block diagram). Install the longer tubing in the top groove of the pinch valve (between B and C in the tubing block diagram). For more information, refer to ISE Tubing Block Diagram.

- Insert pinch valve tubing (for tubing connections A and B) into the grooves of the pinch valve. Confirm that the tubing is inserted completely into the groove. Put tubing labeled 6 (connected to tubing connection A) in the bottom groove of the pinch valve, and put tubing labeled 5 (connected to tubing connection B) in the top groove of the pinch valve. For more information, refer to Figure 6.86 REF Electrode Block-side Drain Tube and Pinch Valve Tubing.
- **5** Confirm that **Drain Flowcell** is selected.
- **6** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.

6-138 B04779AB



You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **7** Close all analyzer doors and covers.
- **8** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **9** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **10** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

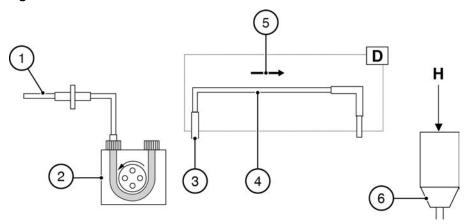
## Manually Clean the Drain Well and, if Needed, Replace the Drain Tube

If the system analyzes samples that contain large amounts of fibrin and protein, the fibrin and protein can accumulate by the drain tube outlet and drain well, possibly causing errors.

Manually clean the drain well quarterly, and replace the drain tube as needed.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.87 Drain Well and Drain Tube



- 1. Pinch valve tubing
- 2. Mixture aspiration roller pump
- 3. Tube Joint 3

- 4. Drain Tube
- 5. Flow direction of waste solution
- 6. Drain well

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- Drain Tube 2
- Sodium hypochlorite solution (0.5%)

ISE Maintenance for All Markets Except Japan

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.
- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



## **NOTE**

The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

### Clean the Drain Well

**1** Remove the drain tube from the hook over the drain well. For more information, refer to D in Figure 6.87 Drain Well and Drain Tube.



Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle hydrochloric acid or sodium hypochlorite solution (0.5%). If the hydrochloric acid or sodium hypochlorite solution (0.5%) contacts skin or clothes, rinse the affected area thoroughly with water. If the hydrochloric acid or sodium hypochlorite solution (0.5%) contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

**2** Prepare approximately 50 mL of sodium hypochlorite solution (0.5%). For more information, refer to Dilution Ratios for Maintenance Solutions.

6-140 B04779AB

- **3** Pour the sodium hypochlorite solution (0.5%) into the drain well directly from the top. For more information, refer to H in Figure 6.87 Drain Well and Drain Tube.
- 4 Allow the sodium hypochlorite solution (0.5%) to sit for approximately 10 minutes, and then pour enough deionized water into the drain well to rinse out the sodium hypochlorite solution.
- 5 Inspect the drain tube by confirming that the tubing is clear (transparent) and checking for internal surface damage. If the drain tube is opaque or damaged, replace it with a new drain tube.



Confirm that the drain tube is securely connected to the mixture aspiration roller pump tubing so leaks do not occur.

- **6** Replace the drain tube over the drain well.
- **7** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **8** Close all analyzer doors and covers.
- **9** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **10** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

## ISE Six-Month Maintenance or Every 40,000 Samples

Perform the following procedures every six months or every 40,000 samples, whatever comes first.

• Replace the Na, K, or Cl Electrode

## Replace the Na, K, or Cl Electrode

Replace the electrode when calibration or Selectivity Check results are out of range, and troubleshooting has been performed. Replacement of the electrode at every 40,000 samples or every six months ensures continuous and reliable electrode performance without unexpected analyzer down-time. If the electrodes have deteriorated, the system cannot obtain accurate analysis results.

ISE Maintenance for All Markets Except Japan

For more information, refer to ISE Tubing Block Diagram.

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- · Na Electrode
- K Electrode
- Cl Electrode
- 0-ring

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.
- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Replace the Na, K, and Cl Electrodes



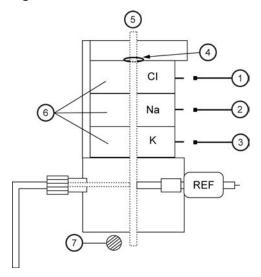
Always drain the flowcell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference

6-142 B04779AB

Solution only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flowcell.

- **1** Move the lock lever to the left to release the electrodes.
- **2** Remove the three electrodes.

Figure 6.88 Na, K, and Cl Electrodes



- 1. CI electrode wire (blue)
- 2. Na electrode wire (yellow)
- 3. K electrode wire (red)
- 4. O-ring

- 5. Sample pot
- 6. Electrodes
- 7. Lock lever
- **3** Disconnect the lead wires from each of the electrodes.
- **4** Replace the failed electrode with a new one.



The system uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location E in Figure 6.76 ISE Tubing Block Diagram). Do not lose the O-rings when removing the electrodes.

- **5** Connect the blue wire to the Cl electrode, yellow wire to the Na electrode, and red wire to the K electrode.
- **6** Confirm that the green wire connects to the REF electrode.
- **7** Before installing the electrodes, wipe the electrode block with a clean, dry, lint-free absorbent tissue.
- **8** Install the three electrodes on the electrode block. Install the electrodes according to the label of Cl, Na, and K from the sample pot side to the REF electrode block side.

ISE Maintenance for All Markets Except Japan



Confirm that all four O-rings are in position before using the lock lever to secure the electrodes. The O-rings are necessary to create an airtight seal for the flowcell.

- **9** Move the lock lever to the right to lock the electrodes in position.
- **10** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



#### **NOTE**

You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **11** Close all analyzer doors and covers.
- **12** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **13** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **14** The system displays the Electrode Serial No. dialog. Enter the serial number of the new electrodes.
- **15** Allow a minimum of five minutes after closing the covers, and then perform a calibration.

# IIII IMPORTANT

To obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

Table 6.35 Acceptable Differences Between First and Second MID Solution Factors

	Na	К	Cl
Difference between 1st and 2nd factors	0.020	0.045	0.025

For more information, refer to Figure 2.14 ISE Maintenance: Calibration Tab.

— If the difference in the MID Solution Factor value between the first and second calibrations is within the values in the above table, the electrodes are stable.

or

If the difference between the MID Solution Factor values is not within each value in the above table, or if the slope result is 0 at the first calibration:

Air can remain inside the flowcell. Perform a MID/REF prime.

1. Lift the upper cover of the analyzer.

- 2. Open the ISE cover.
- 3. Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.
- 4. Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 5. Select MID/REF Prime. The system displays the Start dialog.
- 6. Select OK.
- 7. Press the **TABLE ROTATION/DIAG** button.
- 8. Close all analyzer doors and covers.
- 9. Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- 10. Repeat the ISE calibration two more times and compare the results to the chart.
- If the slope results are 0 for both calibrations:
  - The electrodes might not be set correctly. Repeat the Replace the Na, K, or Cl Electrode procedure to confirm the electrodes are set correctly.

## ISE Maintenance Every Two Years or Every 150,000 Samples

Perform the following procedures every two years or every 150,000 samples, whatever comes first.

Replace the ISE REF Electrode and Packing

## Replace the ISE REF Electrode and Packing

Replace the REF electrode when calibration or Selectivity Check results are out of range for Na, K, and Cl, or the Na, K, and Cl results fluctuate significantly higher or lower than the previous measurement, and troubleshooting has been performed. Replacement of the electrode at 150,000 samples or 2 years, whatever comes first, ensures continuous and reliable electrode performance without unexpected analyzer down-time.

If all calibration measurement values of Na, K, and Cl fluctuate, higher or lower than previous measurements, or if the system displays an alarm message after replacing the REF electrode, contact Beckman Coulter.

For more information, refer to ISE Tubing Block Diagram.

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- REF Electrode (with the packing)
- REF Electrode Packing

ISE Maintenance for All Markets Except Japan

## IMPORTANT

Do not use force to install or uninstall the REF electrode. When installing or uninstalling the electrode, do not break the electrode.

#### **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 4 Select **Drain Flowcell**. The system displays the Start dialog.
- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## **Remove the REF Electrode and Packing**

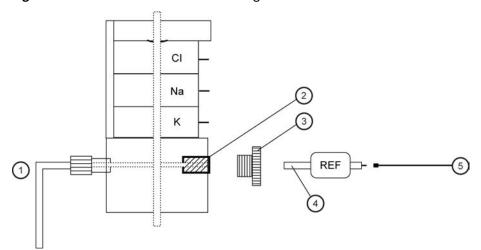


Always drain the flowcell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flowcell.

6-146 B04779AB

- **1** Move the lock lever to the left to release the electrodes.
- 2 Remove the Na, K, and Cl electrodes from the electrode block to keep these electrodes away from the REF electrode. Any contact with the ISE Reference Solution can deteriorate the Na, K, and Cl electrodes.
- **3** Disconnect the green wire from the REF electrode.
- **4** Gently lift the REF electrode block.
- **5** Carefully unscrew the REF electrode cap screw, then gently remove the REF electrode along with the cap screw.

Figure 6.89 ISE REF Electrode and Packing



- 1. REF solution tube
- 2. REF electrode packing
- 3. Cap screw

- 4. REF electrode
- 5. REF electrode wire (green)
- **6** Remove the REF electrode packing.

## Replace the REF Electrode and Packing

- 1 Confirm that no air bubbles are in the REF electrode tip. If air bubbles are found in the tip, remove the bubbles by pointing the electrode tip downward while tapping it with a finger.
- **2** Insert new packing into the REF electrode block.
- **3** Place the cap screw on the REF electrode, then place the REF electrode in the REF electrode block so that the electrode tip is centered in the packing.



Dampen the REF electrode tip with deionized water if you have difficulty inserting the REF electrode into the REF electrode block.

ISE Maintenance for All Markets Except Japan

- 4 Insert the cap screw into the REF electrode block and screw it in carefully. Finish tightening the cap screw by a quarter or half turn to orient the REF electrode correctly.
- **5** Reinstall the REF electrode block.
- **6** Connect the green REF electrode wire to the REF electrode.
- **7** Wipe the top of the block with a clean, dry, lint-free absorbent tissue. Rinse the ISE Reference Solution from your hands.
- **8** Replace the Na, K, and Cl electrodes.
- **9** Move the lock lever to the right to lock the electrodes in position.
- **10** Select MID/REF Prime. The system displays the Start dialog.
- 11 Select OK.
- **12** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



## **NOTE**

You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **13** Close all analyzer doors and covers.
- **14** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **15** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **16** The system displays the Electrode Serial No. dialog. Enter the serial number of the new REF electrode.
- **17** Allow a minimum of five minutes after closing the covers, and then perform a calibration.



To obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

6-148 B04779AB

 Table 6.36
 Acceptable Differences Between First and Second MID Solution Factors

	Na	К	Cl
Difference between 1st and 2nd factors	0.020	0.045	0.025

For more information, refer to Figure 2.14 ISE Maintenance: Calibration Tab.

— If the difference in the MID Solution Factor value between the first and second calibrations is within the values in the above table, the electrodes are stable.

or

If the difference between the MID Solution Factor values is not within each value in the above table, or if the slope result is 0 at the first calibration:

Air can remain inside the flowcell. Perform a MID/REF prime.

- 1. Lift the upper cover of the analyzer.
- 2. Open the ISE cover.
- 3. Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.
- 4. Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 5. Select MID/REF Prime. The system displays the Start dialog.
- 6. Select OK.
- 7. Press the **TABLE ROTATION/DIAG** button.
- 8. Close all analyzer doors and covers.
- 9. Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- 10. Repeat the ISE calibration two more times and compare the results to the chart.
- If the slope results are 0 for both calibrations:

The electrodes might not be set correctly. Repeat the Replace the ISE REF Electrode and Packing procedure to confirm the electrodes are set correctly.

#### ISE As Needed Maintenance

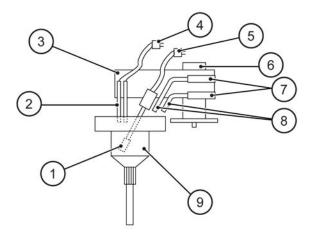
- Replace the Sample Pot
- Clean the ISE Electrode Block (Inlet Side)
- Manually Clean the ISE K Electrode
- Manually Clean and Replace the ISE REF Electrode Block
- Replace the ISE Reagents
- Enhanced ISE Cleaning (Manual)

## **Replace the Sample Pot**

Replace the sample pot if contaminants accumulate and cannot be removed during the every other week cleaning procedure. Also replace the pot if any cracks or flaws are found in the pot.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.90 Sample Pot and Mixing Component



- 1. Mix bar
- 2. Liquid level sensor
- 3. Mixing component
- 4. Level sensor connector
- 5. Mixing motor connector

- 6. Mixing component knob
- 7. Buffer solution and MID solution connecting tubes
- 8. Nozzles
- 9. Sample pot

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

• Sample Pot

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **4** Select **Drain Flowcell**. The system displays the Start dialog.

6-150 B04779AB

- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



#### **NOTE**

The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Replace the Sample Pot

- **1** Disconnect the liquid level sensor connector 714 and mixing motor connector 706.
- **2** Loosen the knob securing the mixing component. Gently lift the mixing component to remove it and place it on the mixing component holder.
- **3** Loosen the retaining knob securing the sample pot, and lift the pot from the peg.
- **4** Disconnect the sample pot from the tubing by twisting the connector from the bottom of the sample pot.
- **5** Reattach the tubing to the new sample pot.
- **6** Reinstall the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the retaining knob.
- **7** Replace the mixing component on the two positioning pins. Tighten the knob to secure the mixing component.
- **8** Reconnect the level sensor connector 714 and mixing motor connector 706.



The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.



When reinstalling the mixing component, confirm that the tubing is not pinched between the mixing component and its stand.

**9** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

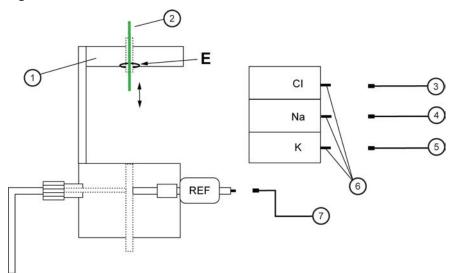
- **10** Close all analyzer doors and covers.
- **11** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **12** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **13** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

## Clean the ISE Electrode Block (Inlet Side)

Inspect the inlet side of the electrode block for contaminants that have accumulated. Perform maintenance to clean the inlet side of the electrode block as needed.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.91 Electrode Block



- 1. Electrode block (inlet side)
- 2. Stylet
- 3. Cl electrode wire (blue)
- 4. Na electrode wire (yellow)

- 5. K electrode wire (red)
- 6. Electrodes
- 7. REF electrode wire (green)

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

• Stylet  $\varphi$ 0.3 (diameter)

6-152 B04779AB

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- Confirm that the system is in *Warm up* or *Standby* mode.
- Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- Select the ISE Maintenance box. The system activates the maintenance operation buttons.
- Select **Drain Flowcell**. The system displays the Start dialog.
- Select **OK**. 5
- **6** Lift the upper cover of the analyzer.
- Open the ISE cover.
- Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



## **NOTE**

The first time you press the TABLE ROTATION/DIAG button, liquid is drained from the flowcell. Each additional time you press the TABLE ROTATION/DIAG button, the system primes ISE MID Standard Solution through the flowcell.

## Clean the ISE Electrode Block (Inlet Side)

## IIII IMPORTANT

Always drain the flowcell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flowcell.

- Move the lock lever to the left to release the electrodes.
- Remove the Na, K, and Cl electrodes from the electrode block.

6-153 B04779AB

ISE Maintenance for All Markets Except Japan

# IMPORTANT

The system uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the Cl electrode (location E in Figure 6.76 ISE Tubing Block Diagram). Do not lose the O-rings when removing the electrodes.

- **3** Disconnect the Na, K, and Cl lead wires.
- **4** Remove the tubing connecting to the sample pot from the electrode block inlet.
- **5** Pass the stylet through the flowcell hole on the inlet side of the electrode block. Contamination can lodge in the flowcell of the electrode block. Bind the stylet up to the maximum thickness that can pass through the flowcell.
- **6** Remove contamination in the block by turning the stylet. When there are contaminants on the stylet, wipe them with a clean, dry, lint-free absorbent tissue several times.
- **7** Connect the blue wire to the Cl electrode, yellow wire to the Na electrode, and red wire to the K electrode.
- **8** Install the three electrodes on the electrode block. Attach the electrodes in this order from the sample pot side:
  - 1. Cl
  - 2. Na
  - 3. K
- **9** Move the lock lever to the right to lock the electrodes in position.
- **10** Attach the tubing connecting the sample pot to the electrode block.
- **11** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



#### NOTE

You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **12** Close all analyzer doors and covers.
- **13** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **14** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **15** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

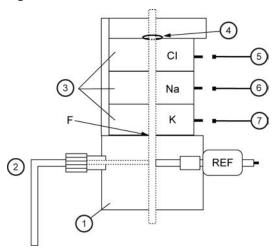
6-154 B04779AB

## Manually Clean the ISE K Electrode

If calibration errors, such as slope readings of 0, occur frequently for the K electrode only, the ISE Reference Solution can contaminate the K electrode. In this situation, perform the manual cleaning of the K electrode.

For more information, refer to ISE Tubing Block Diagram.

Figure 6.92 Electrode Block



- 1. REF electrode block
- 2. REF solution tube
- 3. Electrodes
- 4. O-ring

- 5. Cl electrode wire (blue)
- 6. Na electrode wire (yellow)
- 7. K electrode wire (red)

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

• Clean, dry, lint-free absorbent tissue

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 4 Select **Drain Flowcell**. The system displays the Start dialog.

ISE Maintenance for All Markets Except Japan

- **5** Select **OK**.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



## **NOTE**

The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Manually Clean the ISE K Electrode



Always drain the flowcell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flowcell.

- **1** Move the lock lever to the left to release the electrodes.
- **2** Remove the K electrode from the electrode block.

Figure 6.93 K Electrode



- 1. O-ring
- **3** Disconnect the lead wire of the K electrode.

6-156 B04779AB

- **4** Remove the O-ring of the K electrode.
- **5** Use a squeeze bottle to dispense deionized water to clean the O-ring and O-ring groove of the electrode. Deionized water that gets into the electrode flowcell does not cause a problem.
- **6** Wipe the side face (location F in Figure 6.76 ISE Tubing Block Diagram) of the REF electrode block that contacts the K electrode using a clean, dry, lint-free absorbent tissue dampened with deionized water.
- **7** Using a clean, dry, lint-free absorbent tissue, sufficiently dry the K electrode, O-ring, and REF electrode block surfaces.
- **8** Connect the red lead wire to the K electrode.
- **9** Install the three electrodes on the electrode block. Attach the electrodes in this order from the sample pot side:
  - 1. Cl
  - 2. Na
  - 3. K



The system uses four O-rings in the electrode block. The O-ring attaches to the outlet side of each electrode and the metal part that contacts the CI electrode (location E in Figure 6.76 ISE Tubing Block Diagram). Do not lose the O-rings when removing the electrodes.

- **10** Move the lock lever to the right to lock the electrodes in position.
- **11** Confirm that **Drain Flowcell** is selected.
- **12** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **13** Close all analyzer doors and covers.
- **14** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **15** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.

ISE Maintenance for All Markets Except Japan

**16** Allow a minimum of five minutes after closing the covers, and then perform a calibration.

# IIII IMPORTANT

To obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability:

 Table 6.37
 Acceptable Differences Between First and Second MID Solution Factors

	Na	К	Cl
Difference between 1st and 2nd factors	0.020	0.045	0.025

For more information, refer to Figure 2.14 ISE Maintenance: Calibration Tab.

— If the difference in the MID Solution Factor value between the first and second calibrations is within the values in the above table, the electrodes are stable.

or

If the difference between the MID Solution Factor values is not within each value in the above table, or if the slope result is 0 at the first calibration:

Air can remain inside the flowcell. Perform a MID/REF prime.

- 1. Lift the upper cover of the analyzer.
- 2. Open the ISE cover.
- 3. Select **Home > Analyzer Maintenance > ISE Maintenance > Maintenance**. The system displays the ISE Maintenance: Maintenance tab.
- 4. Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 5. Select MID/REF Prime. The system displays the Start dialog.
- 6. Select OK.
- 7. Press the **TABLE ROTATION/DIAG** button.
- 8. Close all analyzer doors and covers.
- 9. Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- 10. Repeat the ISE calibration two more times and compare the results to the chart.
- If the slope results are 0 for both calibrations:

The electrodes might not be set correctly. Repeat the Manually Clean the ISE K Electrode procedure to confirm the electrodes are set correctly.

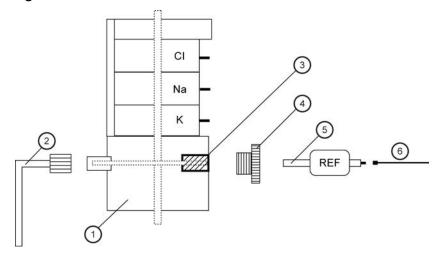
## Manually Clean and Replace the ISE REF Electrode Block

The accumulation of contaminants or crystals, a reduction in the flow rate, or noise interference can cause data problems. Manually clean or replace the ISE REF electrode block if the data indicates that it is needed.

6-158 B04779AB

For more information, refer to ISE Tubing Block Diagram.

Figure 6.94 ISE REF Electrode Block



- 1. REF electrode block
- 2. REF solution tube (location G in ISE Tubing Block Diagram)
- 3. REF electrode packing

- 4. Cap screw
- 5. REF Electrode
  - REF electrode wire (green)

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

- REF Electrode Block
- 2% Wash solution

## **Prepare the ISE for Maintenance**



Always prepare the ISE for maintenance procedures. The preparation procedure prevents the automatic ISE MID Standard Solution periodic (hourly) priming cycle from dispensing ISE MID Standard Solution.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 4 Select **Drain Flowcell**. The system displays the Start dialog.
- **5** Select **OK**.
- **6** Lift the upper cover of the analyzer.

ISE Maintenance for All Markets Except Japan

- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid drains from the flowcell.



#### **NOTE**

The first time you press the **TABLE ROTATION/DIAG** button, liquid is drained from the flowcell. Each additional time you press the **TABLE ROTATION/DIAG** button, the system primes ISE MID Standard Solution through the flowcell.

## Clean and Replace the REF Electrode Block



Always drain the flowcell before moving the lock lever to release the electrode block. If the ISE Reference Solution is not drained, ISE Reference Solution can flow up into the electrodes and cause problems with the electrode measuring capability. ISE Reference Solution only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. ISE Reference Solution is more concentrated than the ISE MID Standard Solution or samples that flow through the flowcell.

- **1** Move the lock lever to the left to release the electrodes.
- **2** Disconnect the Na, K, and Cl lead wires, and remove all three electrodes from the electrode block. If ISE Reference Solution contacts the electrodes, the electrodes can become contaminated.
- **3** Gently lift up the block on which the REF electrode is installed.
- **4** Disconnect the REF electrode wire (green) from the REF electrode.
- **5** Loosen the cap screw on the REF electrode and gently remove the electrode along with the cap screw. Remove the REF electrode packing in the block.
- **6** While holding the REF electrode block by hand, pull the drain tube 2 (waste liquid drain tubing, labeled 6) out of the REF electrode block.
- **7** Remove the REF solution tube (refer to Figure 6.94 ISE REF Electrode Block) connected to the lower side of the REF electrode block. Remove the REF electrode block.



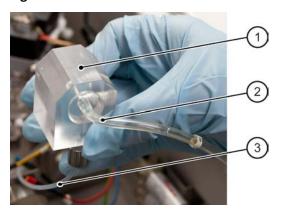
To prevent the REF electrode block from becoming deformed from ultrasonic cleaning, follow these precautions. If the REF electrode block has been deformed or cracked, replace it.

- Do not perform ultrasonic cleaning for more than 10 minutes.
- Use a cleaning liquid at room temperature.

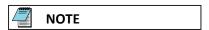
6-160 B04779AB

- Use a sonicator rated at 600 W or less. If the output of the sonicator is uncertain, contact the manufacturer of the sonicator.
- **8** To clean the REF electrode block, sonicate for 10 minutes in 2% wash solution. If a sonicator is not available, soak it in the 2% wash solution for more than 30 minutes. Confirm that 2% wash solution can flow through the flow path in the REF electrode block.
- **9** Thoroughly rinse the REF electrode block in deionized water, and dry with a clean, dry, lint-free absorbent tissue. If you are replacing the REF electrode block, obtain a new REF electrode block.

Figure 6.95 REF Electrode Block



- 1. REF electrode block
- Drain tube 2 (waste liquid drain tubing, labeled 6)
- 3. REF solution tube
- **10** Attach the drain tube 2 (waste liquid drain tubing, labeled 6) and the REF solution tube (refer to Figure 6.94 ISE REF Electrode Block) to the clean or a new REF electrode block.
- **11** Confirm that no air bubbles are in the REF electrode tip. If air bubbles are found in the tip, remove the bubbles by pointing the electrode tip downward while tapping it with a finger.
- **12** Insert the REF electrode packing into the REF electrode block. Confirm that the packing is not cracked or broken. If so, replace the packing.
- **13** Place the cap screw on the REF electrode, then place the REF electrode in the REF electrode block so that the electrode tip is centered in the packing.



Dampen the REF electrode tip with deionized water if you have difficulty inserting the REF electrode into the REF electrode block.

**14** Insert the cap screw into the REF electrode block and screw it in carefully. Finish tightening the cap screw by a quarter or half turn to orient the REF electrode correctly.

ISE Maintenance for All Markets Except Japan

- **15** Reinstall the REF electrode block.
- **16** Connect the green REF electrode wire to the REF electrode.
- **17** Wipe the top of the block with a clean, dry, lint-free absorbent tissue. Rinse the ISE Reference Solution from your hands.
- **18** Replace the Na, K, and Cl electrodes.
- **19** Move the lock lever to the right to lock the electrodes in position.
- **20** Connect the blue wire to the Cl electrode, yellow wire to the Na electrode, and red wire to the K electrode.
- **21** Confirm that **Drain Flowcell** is selected.
- **22** Press the **TABLE ROTATION/DIAG** button to reprime the lines with ISE MID Standard Solution. Confirm that liquid is correctly dispensed from the sample pot to the flowcell by confirming that no bubbles are in the tubing (labeled 6) coming from the flowcell.



#### **NOTE**

You may need to repeat this step five times. If bubbles are in the tubing after priming, confirm that the electrodes and tubing are installed correctly and the electrodes are secured with the lock lever.

- **23** Close all analyzer doors and covers.
- **24** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **25** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **26** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

#### **Replace the ISE Reagents**

Replace the ISE reagents when the on-board stability expires, the reagent expires, or the quantity of reagent is insufficient. The system displays an alarm message when an ISE reagent reaches the ISE Reagent Short notification level (5.2 cm above the bottom of the bottle). Replace the reagent before the bottle empties.

For on-board stability claims for the ISE, refer to the Chemistry Information Sheet.



ISE Reference Solution is highly concentrated. Prevent contact between the ISE Reference Solution (bottle, cap, and aspiration tube) with the ISE Buffer Solution and ISE MID Standard Solution (bottle, cap, and aspiration tube).

6-162 B04779AB



Do not add new reagent to existing bottles. Adding new reagent to existing bottles can affect results.

For more information on materials required, refer to Parts List for ISE Maintenance.

## Materials Required:

- ISE Buffer Solution
- ISE MID Standard Solution
- ISE Reference Solution
- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- **2** Open the right front door of the analyzer.
- **3** Place the new bottle of reagent next to the analyzer and remove the cap.
- **4** Pull out the reagent bottle to replace.
- **5** Loosen the cap of the reagent bottle and remove the aspiration tube.



Do not touch the aspiration tube.

Dispose of the old solution according to your laboratory procedure.

- **6** Place the aspiration tube in the new bottle and tighten the cap.
- **7** Place the new bottle on the analyzer and push the bottle into position.
- 8 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **9** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- **10** Select one of the following options. If all reagents are being replaced simultaneously, replace the reagents in the following order:
  - 1. For replacing ISE Buffer Solution, select Buffer Prime
  - 2. For replacing ISE MID Standard Solution, select MID/REF Prime
  - 3. For replacing ISE Reference Solution, select MID/REF Prime

The system displays the Start dialog.

**11** Select **OK**. Press the **TABLE ROTATION/DIAG** button to start the prime. The system primes the reagent for approximately 90 seconds.

ISE Maintenance for All Markets Except Japan

- **12** Close all analyzer doors and covers.
- **13** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **14** Update the Maintenance Log. For more information, refer to Update the Maintenance Log.
- **15** To confirm that the ISE is working correctly after the maintenance procedure, perform a calibration.

### **Enhanced ISE Cleaning (Manual)**

Use this method when the ISE calibration slopes are in the mid-to-low forties, or if there is a residue when you inspect the sample pot or T-tubing.

For more information on materials required, refer to Parts List for ISE Maintenance.

Materials Required:

- ISE Cleaning Solution diluted 1:10
- ISE MID Standard Solution
- Pipette (that is commercially available and can collect more than 1 mL of liquid)



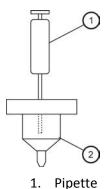
Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats, to handle ISE Cleaning Solution. If the ISE Cleaning Solution contacts skin or clothes, rinse the affected area thoroughly with water. If the ISE Cleaning Solution contacts the eyes or mouth, immediately flush with water. Seek medical attention. Refer to the Safety Data Sheets (SDS) for more information. Follow your laboratory procedure to wipe up spills immediately.

- **1** Confirm that the system is in *Warm up* or *Standby* mode.
- 2 Select Home > Analyzer Maintenance > ISE Maintenance > Maintenance. The system displays the ISE Maintenance: Maintenance tab.
- **3** Select the **ISE Maintenance** box. The system activates the maintenance operation buttons.
- 4 Select Drain Flowcell. The system displays the Start dialog.
- 5 Select OK.
- **6** Lift the upper cover of the analyzer.
- **7** Open the ISE cover.
- **8** Press the **TABLE ROTATION/DIAG** button. The liquid is drained from the flowcell.
- **9** Disconnect the mixing component liquid level sensors connector 714 and mixing motor connector 706.

6-164 B04779AB

- **10** Loosen the mixing component knob, lift the mixing component from the two positioning pins, and place the mixing component on the mixing component holder.
- **11** Remove the tubing (labeled 5 and 6) from the pinch valve.
- 12 For the first 2 minutes, pipette the ISE Cleaning Solution into the sample pot while manually turning the right roller pump component clockwise until most of the ISE Cleaning Solution empties from the sample pot into the tubing. Continue filling the sample pot with the ISE Cleaning Solution while turning the roller pump component. Do not completely empty the sample pot before adding more ISE Cleaning Solution. Confirm that the tubing is filled with the ISE Cleaning Solution.

Figure 6.96 Filling the Sample Pot



2. Sample Pot

- **13** Let the ISE Cleaning Solution remain in the tubing for 5 minutes.
- **14** Manually turn the roller pump to clear the ISE Cleaning Solution from the tubing.
- **15** Pipette 10 mL of ISE MID Standard Solution into the sample pot and manually turn the roller pump to clear the ISE MID Standard Solution. Repeat 3 times.
- **16** Replace the mixing component.
- **17** Replace the pinch valve tubing.



Refer to the label on the back of the ISE cover for placement of the pinch valve tubing. Install the tubing (labeled 5 and 6) in the correct grooves of the pinch valve.

- **18** Reconnect the mixing component liquid level sensors connector 714 and mixing motor connector 706.
- **19** Select MID/REF Prime. The system displays the Start dialog.
- 20 Select OK.
- **21** Press the **TABLE ROTATION/DIAG** button to start the prime.
- **22** Repeat the MID/REF prime two times.

ISE Maintenance for All Markets Except Japan

- 23 Select Total Prime. The system displays the Start dialog.
- 24 Select OK.
- **25** Press the **TABLE ROTATION/DIAG** button to start the prime.
- **26** Close all analyzer doors and covers.
- **27** Clear the **ISE Maintenance** box to deactivate the maintenance operation buttons.
- **28** Calibrate and process QC on the ISE.
- **29** If the tubing is not clean after performing this procedure, replace the tubing according to the following procedures:
  - Replace the Tubing between the Sample Pot, Electrode Block, and T-Connector
  - Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing
  - Manually Clean the Drain Well and, if Needed, Replace the Drain Tube

6-166 B04779AB

## **Flags**

The system generates flags when the system encounters a condition that can affect the result. This condition can range from minor warnings to severe errors that require attention immediately. Review each flag and identify the root cause, and perform the corrective action.

Do not report any result with an unresolved or unexpected flag. When in doubt, always consider repeating the sample analysis, and diluting or condensing the sample if necessary.

This chapter contains a list of all flags in priority order, suggestions of their cause, and action to take.

The priority determines what flags you see if a result generates multiple flags. A maximum of four flags can display.

## Summary of Flags (Alphabetical Order)

The following table summarizes the flags in alphabetical order:

**Table 7.1** Summary of Flags (Alphabetical Order)

Flag	Definition
!	Unable to calculate concentration
#	Insufficient sample detected
\$	Not enough data to determine linearity of reaction
%	Clot detected
&	Prozone test data is abnormal
(	Shortage of cleaning solution for contamination parameters
)	Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration
*	Linearity error in rate method
/	Test pending or not analyzed
?	Unable to calculate a result
@	OD is higher than 3.0
1Q	QC data exceeds the range entered in Single Check Level field
2Q	QC data exceeds 1 <sub>3s</sub> control range

 Table 7.1
 Summary of Flags (Alphabetical Order) (Continued)

Flag	Definition
3Q	QC data exceeds 2 <sub>2s</sub> control range
4Q	QC data exceeds R <sub>4s</sub> control range
5Q	QC data exceeds 4 <sub>1s</sub> control range
6Q	A preset number of consecutive QC results fall on one side of the mean
7Q	Consecutive QC results show steadily increasing or decreasing values
а	Reagent expired
В	OD of reaction is lower than the minimum OD range
ba	No calibration data or expired
bh	The latest calibration/RB has not been used
bn	Mastercurve used
bz	Calibration curve for Prozone data used
С	Result corrected by the operator
d	QC result is excluded by the operator
D	OD of reaction is higher than the maximum OD range
е	Data edited by the operator
Е	Overreaction in a rate assay detected
F	Result is higher than the dynamic range
fh	Result is higher than the repeat run reflex range
fl	Result is lower than the repeat run reflex range
Fx	Result (OD) is higher than the dynamic range
G	Result is lower than the dynamic range
Gx	Result (OD) is lower than the dynamic range
h	Result may be affected by hemolysis
Н	Result is higher than reference range
i	Result may be affected by icterus
J	Result is higher than the repeat decision range
K	Result is lower than the repeat decision range
I	Result may be affected by lipemia
L	Result is lower than reference range
М	Duplicate sample ID
n	LIH test not performed
N	Negative
P	Positive

7-2 B04779AB

 Table 7.1 Summary of Flags (Alphabetical Order) (Continued)

Flag	Definition
ph	Result is higher than the upper panic value
pl	Result is lower than the low panic value
R	Insufficient reagent detected
r	Result has been transferred to laboratory information system through online communication
S	Sample repeated and original results replaced by repeat result
Т	Abnormality found in inter-chemistry check
Tx	Result of T-Hb or HbA1c is outside the dynamic range
U	Reagent Blank OD exceeds the lower limit set at the last photometric read point
u	Reagent blank or routine OD at first photometric point low
Va	Deviation of multiple measurements check is out of range
Wa	Test has been analyzed with an erroneous cuvette
xQ	Multi-rule QC has detected failure on one control
Υ	Reagent Blank OD exceeds the high limit set at the last photometric read point
у	Reagent blank or routine OD at first photometric point high
Z	Prozone error

# **Summary of Flags (Priority Order)**

The following table summarizes the flags in priority order:

 Table 7.2
 Summary of Flags (Priority Order)

Flag	Definition
d	QC result is excluded by the operator
е	Data edited by the operator
(	Shortage of cleaning solution for contamination parameters
Wa	Test has been analyzed with an erroneous cuvette
R	Insufficient reagent detected
#	Insufficient sample detected
%	Clot detected
?	Unable to calculate a result
M	Duplicate sample ID
n	LIH test not performed
I	Result may be affected by lipemia
i	Result may be affected by icterus

7-3 B04779AB

 Table 7.2
 Summary of Flags (Priority Order) (Continued)

Flag	Definition
h	Result may be affected by hemolysis
Υ	Reagent Blank OD exceeds the high limit set at the last photometric read point
U	Reagent Blank OD exceeds the lower limit set at the last photometric read point
у	Reagent blank or routine OD at first photometric point high
u	Reagent blank or routine OD at first photometric point low
@	OD is higher than 3.0
\$	Not enough data to determine linearity of reaction
D	OD of reaction is higher than the maximum OD range
В	OD of reaction is lower than the minimum OD range
*	Linearity error in rate method
&	Prozone test data is abnormal
Z	Prozone error
Е	Overreaction in a rate assay detected
Fx	Result (OD) is higher than the dynamic range
Gx	Result (OD) is lower than the dynamic range
!	Unable to calculate concentration
)	Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration
a	Reagent expired
ba	No calibration data or expired
bh	The latest calibration/RB has not been used
bn	Mastercurve used
bz	Calibration curve for Prozone data used
F	Result is higher than the dynamic range
G	Result is lower than the dynamic range
Tx	Result of T-Hb or HbA1c is outside the dynamic range
ph	Result is higher than the upper panic value
pl	Result is lower than the low panic value
Т	Abnormality found in inter-chemistry check
P	Positive
N	Negative
Н	Result is higher than reference range
L	Result is lower than reference range

7-4 B04779AB

 Table 7.2
 Summary of Flags (Priority Order) (Continued)

Flag	Definition
J	Result is higher than the repeat decision range
К	Result is lower than the repeat decision range
fh	Result is higher than the repeat run reflex range
fl	Result is lower than the repeat run reflex range
Va	Deviation of multiple measurements check is out of range
xQ	Multi-rule QC has detected failure on one control
1Q	QC data exceeds the range entered in Single Check Level field
2Q	QC data exceeds 1 <sub>3s</sub> control range
3Q	QC data exceeds 2 <sub>2s</sub> control range
4Q	QC data exceeds R <sub>4s</sub> control range
5Q	QC data exceeds 4 <sub>1s</sub> control range
6Q	A preset number of consecutive QC results fall on one side of the mean
7Q	Consecutive QC results show steadily increasing or decreasing values
S	Sample repeated and original results replaced by repeat result
/	Test pending or not analyzed
r	Result has been transferred to laboratory information system through online communication
С	Result corrected by the operator

# **Flag Details**

# d: QC result is excluded by the operator

Possible Cause	Corrective Action
QC data has been manually excluded from calculation by the operator. This flag is applied in <b>Menu List &gt; QC &gt; QC Data Review</b> . For more information, refer to the AU680 Reference Manual.	No corrective action is required.  IMPORTANT  Before excluding any QC data, investigate and record the cause of the result with the flag. Follow your laboratory procedure.

## e: Data edited by the operator

Possible Cause	Corrective Action
Data has been edited. For more information, refer to the AU680 Reference Manual.	No corrective action is required.
	IIII IMPORTANT
	Before reporting results, review any edited or changed data carefully.

## (: Shortage of cleaning solution for contamination parameters

Possible Cause	Corrective Action	
One or more cleaning solutions programmed in the Contamination Parameters screen in Positions 62 and 63 for R1 and 49 and 50 for R2 are empty. Contamination parameters are suspended for the related cleaning solution. Carry-over might have occurred on tests that have this flag.	<ol> <li>Fill the cleaning solution bottles.</li> <li>Perform a reagent check on the cleaning solution bottles. For more information, refer to Monitor the Reagent Status.</li> <li>Repeat analysis for the flagged tests.</li> </ol>	

## Wa: Test has been analyzed with an erroneous cuvette

Possible Cause	Corrective Action
The test has been analyzed using a cuvette which failed photocal criteria.	Clean the affected cuvette and perform a photocal. For more information, refer to Clean or Replace Individual Cuvettes and Perform a Photocal.
	<ol> <li>If the error still occurs, replace the cuvette.         For more information, refer to Clean or         Replace Individual Cuvettes.</li> <li>Repeat the analysis.</li> </ol>

7-6 B04779AB

# R: Insufficient reagent detected

Possible Cause	Corrective Action
Level detection indicates reagent volume not sufficient for analysis.	1. Review all results generated immediately before this flag for consistency and validity (in particular the low or high results), and repeat analysis if necessary.
	Place new reagent onto the system and repeat analysis.
	3. If the flag occurs even though there is sufficient reagent, the reagent bottle can contain bubbles. Remove the bubbles and perform another reagent check.
	4. Dry the reagent bottle opening if it is wet. Inspect the reagent probe, and clean or replace as required. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars, Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells, and Replace a Sample or Reagent Probe.
	5. Confirm that the reagent probe is correctly installed and connected.

# #: Insufficient sample detected

Possible Cause	Corrective Action
<ul> <li>The sample probe cannot detect sufficient sample volume.</li> <li>Insufficient sample volume.</li> <li>Malfunction of the sample level detection system.</li> <li>Inappropriate sample cup or tube.</li> </ul>	1. Review all other results that were generated on the same sample before generating the flag to confirm validity and consistency (no extremely low or high values).
	2. Wipe the probe with an alcohol prep or 70% Isopropyl alcohol and inspect the probe to confirm that it is installed and connected correctly. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.
	3. Replace the sample probe. For more information, refer to Replace a Sample or Reagent Probe.
	Add more sample to the sample cup, and repeat the test.
	<ol> <li>Confirm that the correct sample cup or tube is in use. For more information, refer to Cups or Tubes Specifications.</li> </ol>

### %: Clot detected

Possible Cause	Corrective Action
The sample probe is blocked or partially blocked during sample aspiration.	Review all other results that were generated on the same sample before generating the flag to confirm validity and consistency (no extremely low or high values).
	Confirm that the sample is free of clots, and remove any that are in the sample. If necessary, centrifuge the sample and repeat analysis.
	3. If the error still occurs, clean or replace the sample probe. For more information, refer to Clean the Sample Probe and Mix Bars or Replace a Sample or Reagent Probe.

### ?: Unable to calculate a result

Possible Cause	Corrective Action
A result cannot be calculated for this sample because:  • In a rate reaction, fewer than three photometric readings satisfy the test criteria specified in <b>Specific Test Parameters</b> .	If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and repeat analysis.
Outside of cuvette walls or the cuvette wheel is wet.	2. Confirm the reagent condition.
is wet.  • A mechanical error has occurred.	3. The system generates a flag or alarm identifying the malfunction. Select <b>Alarm List</b> for a description of the alarm and corrective actions. When the problem is solved, repeat analysis. If the issue persists, contact Beckman Coulter.
	4. Analyze the reaction data including those processed immediately before and after the flagged result. In the presence of any abnormality, inspect the cuvettes and cuvette wheel for a possible overflow. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.
	5. If the AU680 connects to a laboratory automation system, confirm that the system does not have any errors. If the issue persists, contact Beckman Coulter.

7-8 B04779AB

### M: Duplicate sample ID

Possible Cause	Corrective Action
A duplicate sample ID has been read within the samples in process.	<ol> <li>Confirm that the results of the samples with the duplicate sample ID are correct.</li> <li>Follow laboratory procedure.</li> </ol>

### n: LIH test not performed

Possible Cause	Corrective Action
The LIH test has not been performed for tests with LIH Influence Check set to Yes in Specific Test Parameters > General.	<ol> <li>Examine the sample and repeat if necessary.</li> <li>Confirm the LIH reagent.</li> </ol>

### I: Result may be affected by lipemia

Possible Cause	Corrective Action
The result may be affected by lipemia or samples are turbid.	Follow laboratory procedure for lipemic samples.

# i: Result may be affected by icterus

Possible Cause	Corrective Action
The result may be affected by bilirubin.	Follow laboratory procedure for icteric samples.

# h: Result may be affected by hemolysis

Possible Cause	Corrective Action
The result may be affected by hemolysis.	Follow laboratory procedure for hemolytic samples.

#### Y: Reagent Blank OD exceeds the high limit set at the last photometric read point

Possible Cause	Corrective Action
Reagent blank OD is higher than the Reagent OD Limit range defined for the last photometric point. The Reagent OD Limit range is programmed in Menu List > Parameters > Specific Test	<ol> <li>Inspect the reagent expiration and on-board expiration date.</li> <li>Confirm that the reagent was prepared</li> </ol>
Parameters > General.	correctly.
This could be caused by:	3. Replace the reagent and repeat analysis.
<ul> <li>Reagent expired.</li> <li>Reagent contamination.</li> <li>Incorrectly prepared reagents.</li> <li>Incorrect range programmed.</li> </ul>	4. Confirm the Reagent OD Limit range programmed in <b>Specific Test Parameters</b> is correct.

### U: Reagent Blank OD exceeds the lower limit set at the last photometric read point

Possible Cause	Corrective Action
Reagent blank OD is lower than the Reagent OD Limit range defined for the last photometric point. The Reagent OD Limit range is programmed in Menu List > Parameters > Specific Test Parameters > General.	<ol> <li>Inspect the reagent expiration and on-board expiration date.</li> <li>Confirm that the reagent was prepared correctly.</li> </ol>
This could be caused by:  Reagent expired. Reagent contamination. Incorrectly prepared reagents. Incorrect range programmed.	<ol> <li>Replace the reagent and repeat analysis.</li> <li>Confirm the Reagent OD Limit range programmed in Specific Test Parameters is correct.</li> </ol>

# y: Reagent blank or routine OD at first photometric point high

Possible Cause	Corrective Action
The first photometric point OD of the reagent blank or the OD at PO of normal analysis is higher than the Reagent OD Limit range defined for the first photometric point. Reagent OD Limit is programmed in Menu List > Parameters > Specific Test Parameters > General.	<ol> <li>Inspect the reagent expiration and on-board expiration date.</li> <li>Confirm that the reagent was prepared correctly.</li> <li>Replace the reagent and repeat analysis.</li> </ol>
<ul> <li>This could be caused by:</li> <li>Reagent expired.</li> <li>Reagent contamination.</li> <li>Incorrectly prepared reagents.</li> <li>Incorrect range programmed.</li> </ul>	Confirm the Reagent OD Limit range programmed in <b>Specific Test Parameters</b> is correct.

7-10 B04779AB

# u: Reagent blank or routine OD at first photometric point low

Possible Cause	Corrective Action
The first photometric point OD of the reagent blank or the OD at PO of normal analysis is lower than the Reagent OD Limit range defined for the first photometric point. The Reagent OD Limit range is programmed in <b>Menu List &gt; Parameters &gt; Specific Test Parameters &gt; General</b> .	<ol> <li>Inspect the reagent expiration and on-board expiration date.</li> <li>Confirm that the reagent was prepared correctly.</li> </ol>
> Specific rest Parameters > General.	3. Replace the reagent and repeat analysis.
<ul> <li>This could be caused by:</li> <li>Reagent expired.</li> <li>Reagent contamination.</li> <li>Incorrectly prepared reagents.</li> <li>Incorrect range programmed.</li> </ul>	<ol> <li>Confirm the Reagent OD Limit range programmed in Specific Test Parameters is correct.</li> </ol>

# @: OD is higher than 3.0

Possible Cause	Corrective Action
An abnormally high value. A reaction OD has exceeded 3.0. In a dual wavelength measurement, an error occurs if either of the two wavelengths exceed 3.0 OD.  This error occurs if one of the following three conditions is met:	<ol> <li>Dilute the sample and repeat analysis.</li> <li>Perform a photocal to assess the condition of the lamp. Replace the lamp if the results are out of range. For more information, refer to Perform a Photocal or Replace the Photometer Lamp.</li> </ol>
<ul> <li>Primary wavelength is over the limit (3.0)</li> <li>Secondary wavelength is over the limit (3.0)</li> <li>Reaction wavelength is over the limit (3.0)</li> <li>This error only occurs on END or FIXED reaction methods, not on RATE reaction methods.</li> </ul>	3. Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.
<ul> <li>Sample quality. The sample is severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested.</li> <li>Faulty photometer lamp.</li> <li>Cuvette overflow.</li> </ul>	

# \$: Not enough data to determine linearity of reaction

Possible Cause	Corrective Action
Fewer than three read points of a RATE reaction are within the acceptable optical density range specified. To calculate a RATE reaction correctly, a minimum of three readings must be taken before reaching maximum or minimum optical density. If these optical density limits are exceeded, the reaction might go into substrate depletion caused by a high concentration or a problem with the condition of the reagent. Linearity calculations are not made when this flag occurs.	<ol> <li>If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and repeat analysis.</li> <li>Confirm that the probes and syringes are functioning correctly. For more information, refer to Inspect the Syringes for Leaks and Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.</li> <li>Analyze the reaction data including the reaction data processed immediately before</li> </ol>
	and after the flagged result. In the presence of any abnormality, inspect the cuvettes and cuvette wheel for a possible overflow. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.

7-12 B04779AB

# D: OD of reaction is higher than the maximum OD range

Possible Cause	Corrective Action
The OD of a RATE or FIXED reaction cannot meet the maximum OD criteria programmed in OD Limit in <b>Specific Test Parameters</b> :	If this flag is only generated on one or a few samples, inspect the sample quality:
<ul> <li>A specified read point FST+2 (first photometry point plus two) in a positive RATE reaction method: High concentration.</li> <li>A specified read point LST-2 (last photometry point minus two) in a negative RATE reaction method: Low concentration.</li> <li>A photometry read point in a positive FIXED reaction method: High concentration.</li> <li>A photometry read point in a negative FIXED reaction method: Low concentration.</li> </ul>	<ul> <li>If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and repeat analysis.</li> <li>If the sample has a low concentration, no reaction occurs in the cuvette. Confirm that there is enough sample volume in the tube.</li> <li>If this flag is only generated on one reagent, inspect the reagent quality and for reagent contamination:         <ul> <li>Inspect the reagent expiration, onboard expiration, and reagent blank expiration.</li> <li>Confirm that the reagent was prepared correctly.</li> <li>Confirm that fixed reagents are in the correct position.</li> </ul> </li> <li>If this flag is generated randomly on several samples and several different tests:         <ul> <li>Perform a photocal to assess the condition of the lamp. Replace the lamp if the results are out of range. For more information, refer to Perform a Photocal or Replace the Photometer Lamp.</li> <li>Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.</li> </ul> </li> </ul>

# B: OD of reaction is lower than the minimum OD range

	If this flag is only generated on one or a few samples, inspect the sample quality:  — If the sample has a high concentration, the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the
photometry point plus two) in a negative	the sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the
A photometry read point in a negative FIXED reaction method: High concentration.     A photometry read point in a positive FIXED reaction method: Low concentration.      I i	analyte being tested. Dilute the sample and repeat analysis.  — If the sample has a low concentration, no reaction occurs in the cuvette. Confirm that there is enough sample volume in the tube.  If this flag is only generated on one reagent, inspect the reagent quality and for reagent contamination:  — Inspect the reagent expiration, onboard expiration, and reagent blank expiration.  — Confirm that the reagent was prepared correctly.  — Confirm that fixed reagents are in the correct position.  If this flag is generated randomly on several samples and several different tests:  — Perform a photocal to assess the condition of the lamp. Replace the lamp if the results are out of range. For more information, refer to Perform a Photocal or Replace the Photometer Lamp.  — Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.

7-14 B04779AB

# \*: Linearity error in rate method

Possible Cause	Corrective Action
The system generates the * flag when the rate of a reaction varies by more than the defined % variance, as defined in <b>Menu List</b> > <b>Parameters</b>	Dilute the sample and run it again or perform a diluted repeat run.
> Specific Test Parameters > General and is therefore deemed non-linear, or the reverse	Replace reagent if contaminated or out-of- date.
<ul> <li>reaction check on a RATE reaction method failed.</li> <li>Unusually high result.</li> <li>Contaminated reagent.</li> </ul>	3. Clean all mix bars and inspect them for damage. Replace any that have scratches or chips in the fluororesin coating. For more information, refer to Replace the Mix Bars
<ul> <li>Dirty or defective mix bars.</li> <li>Defective cuvettes.</li> <li>Deteriorated lamp.</li> <li>Reagent or sample probe alignment problem.</li> <li>Outer cuvette walls or the cuvette wheel is wet.</li> <li>The concentration is near zero for DAU analysis using the RATE reaction method.</li> </ul>	4. Perform a photocal to assess the lamp and cuvette integrity. Replace the lamp or cuvettes as required and perform another photocal. For more information, refer to Replace the Photometer Lamp, Clean or Replace Individual Cuvettes, or Perform a Photocal.
analysis asing the twitz reaction method.	5. Confirm that the sample probe and reagent probe alignment. If the probe is bent, replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
	<ol> <li>Confirm that the cuvette wheel is not wet. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.</li> </ol>
	7. No action required. If the method is RATE, the reverse reaction check is performed. If the concentration is near zero, the reaction curve is flat and triggers the * flag. Confirm that there is no other cause for the * flag before reporting the result.

### &: Prozone test data is abnormal

Possible Cause	Corrective Action
The data for prozone judgement is abnormal.	Dilute the sample and repeat analysis. If the issue persists, contact Beckman Coulter.

#### **Z**: Prozone error

Possible Cause	Corrective Action
The data check equation for any one of logic check 1, 2 or 3 is satisfied. This is often caused by an abnormally high concentration of analyte in a sample.	Dilute the sample and repeat analysis.

# E: Overreaction in a rate assay detected

Possible Cause	Corrective Action
In the rate assay, the result is judged as an error by checking an overreaction in which the reaction was finished in an excessively short time.  • An abnormally high concentration of analyte in a sample.	Dilute the sample and repeat analysis.

# Fx: Result (OD) is higher than the dynamic range

Possible Cause	Corrective Action
No concentration could be calculated. The OD of the sample exceeded the OD of the upper limit of the dynamic range.	Dilute the sample and repeat analysis.

# Gx: Result (OD) is lower than the dynamic range

Possible Cause	Corrective Action
No concentration could be calculated. The OD of the sample is lower than the OD of the low limit of the dynamic range.	Review the result in the clinical context of the patient and repeat if necessary.
	Confirm the correct operation of the reagent probes.
	Confirm that the reagent bottles are in the correct position.
	4. Inspect the reagents for bubbles.

7-16 B04779AB

### !: Unable to calculate concentration

Possible Cause	Corrective Action
The system has failed to calculate a result.	If the flag is a single sample issue, repeat and dilute if necessary.
	2. If multiple samples are affected, review all operating parameters such as:
	<ul><li>Reagent quality</li><li>Calibration</li></ul>
	<ul><li>— Sample integrity</li><li>— General system issues</li></ul>
	3. Analyze the reaction data including the reaction data processed immediately before and after the flagged result. In the presence of any abnormality, inspect the cuvettes and cuvette wheel for a possible overflow. If the cuvette wheel is wet, perform appropriate corrective actions. For more information, refer to Recovering from a Cuvette Wheel Overflow and Clean the Cuvettes and the Cuvette Wheel.
	4. If the flag is generated on Na, K, or Cl, repeat a sufficient number of samples which preceded the appearance of the ! flag in order to confirm that the system did not report incorrect results. It is possible that air in the flowcell affected samples before the system generated the ! flag.
	<ul> <li>To make sure that there are no obstructions in the flowcell path, perform a MID/REF Prime and confirm that no bubbles are in the tubing at the bottom of the flowcell.</li> <li>Confirm that all tubing is connected correctly.</li> </ul>

# ): Reagent lot number used for sample analysis is different from the lot number used for RB/ Calibration

Possible Cause	Corrective Action
The reagent lot number does not match the calibrated reagent lot number.	Calibrate the reagent used for the test that generated the flag.
	<ol> <li>Calculate the results manually by selecting Menu List &gt; Routine &gt; Sample Manager &gt; Main. Select Recalculate Data (F5).</li> </ol>

#### a: Reagent expired

Possible Cause	Corrective Action
The reagent has either expired or has been on board beyond the period defined in <b>Specific Test Parameters</b> .	Replace the reagents and perform a reagent check and a calibration if necessary.

# ba: No calibration data or expired

Possible Cause	Corrective Action
No reagent blank or calibration data, or the data is expired.	Perform a calibration. For more information, refer to Calibrate Tests.
	<ol> <li>Review calibration in Menu List &gt;         Calibration &gt; Calibration Monitor.</li> </ol>
	Carefully review any results generated with this flag and repeat if necessary.

# bh: The latest calibration/RB has not been used

Possible Cause	Corrective Action
The most recent reagent blank or calibration failed or is expired. Results can be erroneous and should not be reported.	<ol> <li>Perform a calibration. For more information, refer to Calibrate Tests.</li> <li>Review calibration in Menu List &gt;</li> </ol>
	Calibration > Calibration Monitor.
	3. Repeat samples using a valid calibration.

7-18 B04779AB

#### bn: Mastercurve used

Possible Cause	Corrective Action
Calibration has either not been performed, or was not successful. The system has used the master curve to generate the result. Review calibration in Menu List > Calibration > Calibration Monitor.	<ol> <li>Perform a calibration. For more information, refer to Calibrate Tests.</li> <li>Repeat samples using a valid calibration.</li> </ol>
Results can be erroneous and should not be reported.	

#### bz: Calibration curve for Prozone data used

Possible Cause	Corrective Action
The system has used a calibration curve affected by prozone to generate the result, and the result is invalid. Only use the result as a reference to estimate the dilution rate for repeat analysis.	Carefully review any results generated with this flag and repeat the analysis with dilution.

# F: Result is higher than the dynamic range

The concentration of the sample is above the dynamic range high limit, programmed in <b>Menu</b> 1. Confirm that the correct dynamic range is a constant of the sample is above the dynamic range is defined as a constant of the sample is above the dynamic range high limit, programmed in <b>Menu</b> .	Possible Cause	Corrective Action
List > Parameters > Specific Test Parameters > General.  2. Dilute the sample and reanalyze. Dilute samples so that they yield a value in the middle of the analytical measuring range.	dynamic range high limit, programmed in <b>Menu List &gt; Parameters &gt; Specific Test Parameters &gt;</b>	programmed in <b>Specific Test Parameters</b> .  2. Dilute the sample and reanalyze. Dilute samples so that they yield a value in the

# G: Result is lower than the dynamic range

Possible Cause	Corrective Action
The concentration of the sample is below the dynamic range low limit, programmed in Menu List > Parameters > Specific Test Parameters >	Confirm that the correct dynamic range is programmed in Specific Test Parameters.
<b>General</b> , or the reagent was not dispensed correctly.	Review the result in the clinical context of the patient and repeat if necessary.
<ul> <li>Incorrect dynamic range is programmed.</li> <li>The clinical context of the patient.</li> </ul>	Confirm the correct operation of the reagent probes.
<ul><li>Insufficient reagent dispensing.</li><li>Insufficient sample dispensing</li></ul>	Confirm that the reagent bottles are in the correct position.
	5. Inspect the sample for bubbles.

### Tx: Result of T-Hb or HbA1c is outside the dynamic range

Possible Cause	Corrective Action
The result of T-Hb or HbA1c is outside the dynamic range programmed in Menu List > Parameters > Specific Test Parameters > HbA1c.	<ol> <li>Repeat the analysis.</li> <li>If the result is confirmed, report according to the reagent Instructions for Use.</li> </ol>

### ph: Result is higher than the upper panic value

Possible Cause	Corrective Action
The result is higher than the upper panic value. The upper panic value is programmed in <b>Menu</b>	This flag denotes that the result is outside operator-defined panic ranges. Follow laboratory procedure for abnormal results.
List > Parameters > Specific Test Parameters > Range.	procedure for abnormal results.

### pl: Result is lower than the low panic value

Possible Cause	Corrective Action
The result is lower than the low panic value. The lower panic value is programmed in Menu List > Parameters > Specific Test Parameters >	This flag denotes that the result is outside operator-defined panic ranges. Follow laboratory procedure for abnormal results.
Range.	

# T: Abnormality found in inter-chemistry check

Possible Cause	Corrective Action
A result exceeds the range specified in <b>Menu List</b> > <b>Parameters</b> > <b>Misc</b> . > <b>Checked Tests</b> .	<ol> <li>Repeat analysis.</li> <li>Follow laboratory procedure for abnormal results.</li> </ol>

#### P: Positive

Possible Cause	Corrective Action
Qualitative result: Sample result exceeds the upper value. The upper value is programmed in Menu List > Parameters > Specific Test Parameters > Range. Select Flag in the Value/Flag to enable programming in the Level High field. Results over the Level High generate the P flag.	Follow laboratory procedure.

7-20 B04779AB

### N: Negative

Possible Cause	Corrective Action
Qualitative result: Sample result is lower than the low value. The low value is programmed in <b>Menu List</b> > <b>Parameters</b> > <b>Specific Test Parameters</b> > <b>Range</b> . Select <b>Flag</b> in the <b>Value/Flag</b> to enable programming in the <b>Level Low</b> field. Results under the <b>Level Low</b> generate the N flag.	Follow laboratory procedure.

# H: Result is higher than reference range

Possible Cause	Corrective Action
Sample result is higher than the high value programmed in Specific Ranges in Menu List > Parameters > Specific Test Parameters > Range. For more information, refer to the AU680 Reference Manual.	Follow laboratory procedure for abnormal results.

### L: Result is lower than reference range

Possible Cause	Corrective Action
Sample result is lower than the low value programmed in Specific Ranges in Menu List > Parameters > Specific Test Parameters > Range. For more information, refer to the AU680 Reference Manual.	Follow laboratory procedure for abnormal results.

### J: Result is higher than the repeat decision range

Possible Cause	Corrective Action
The result is higher than the repeat decision range. The repeat decision range is programmed in	Follow laboratory procedure.
Menu List > Parameters > Repeat Parameters > Repeat Specific.	

### K: Result is lower than the repeat decision range

Possible Cause	Corrective Action
The result is lower than the repeat decision range. The repeat decision range is programmed in Menu List > Parameters > Repeat Parameters	Follow laboratory procedure.
> Repeat Specific.	

### fh: Result is higher than the repeat run reflex range

Possible Cause	Corrective Action
The result is higher than the operator specified reflex range, programmed in Menu List > Parameters > Repeat Parameters > Repeat Specific.	Follow laboratory procedure.

# fl: Result is lower than the repeat run reflex range

Possible Cause	Corrective Action
The result is lower than the operator specified reflex range, programmed in Menu List > Parameters > Repeat Parameters > Repeat Specific.	Follow laboratory procedure.

# Va: Deviation of multiple measurements check is out of range

Possible Cause	Corrective Action
The precision of replicates for the reagent blank or calibration exceeds the allowable range programmed in Menu List > Parameters > Calibration Parameters > Calibration Specific (Allowable Range Check).	<ol> <li>Perform the corresponding maintenance:         <ul> <li>Inspect the syringes. For more information, refer to Inspect the Syringes for Leaks.</li> <li>Inspect the sample probe. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.</li> </ul> </li> <li>Confirm the correct sample material was used for the reagent blank or calibration.</li> <li>Inspect for evidence of system contamination.</li> </ol>

#### xQ: Multi-rule QC has detected failure on one control

Possible Cause	Corrective Action
If one of the two pairs of data for QC using multicheck QC rules is out of range, the other piece of data is flagged. The range is programmed in <b>Menu List &gt; Parameter &gt; QC Parameters &gt; QC Specific</b> . For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:
	<ul> <li>Repeat with fresh QC material.</li> <li>Perform calibration as required.</li> <li>Perform maintenance as required.</li> </ul>

**7-22** B04779AB

### 1Q: QC data exceeds the range entered in Single Check Level field

Possible Cause	Corrective Action
One point of QC data exceeds the SD defined in the Single Check Level in Menu List > Parameters > QC Parameters > QC Specific > Check. For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

# 2Q: QC data exceeds $\mathbf{1}_{3s}$ control range

Possible Cause	Corrective Action
One point of QC data exceeds the ±3SD limit defined in the Multi Check Level in <b>Menu List</b> > <b>Parameters</b> > <b>QC Parameters</b> > <b>QC Specific</b> > <b>Check</b> . For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

# 3Q: QC data exceeds 2<sub>2s</sub> control range

Possible Cause	Corrective Action
Two contiguous QC data points exceed the control limit of ±2SD in the same direction. The data points are programmed in Multi Check Level in Menu List > Parameters > QC Parameters > QC Specific > Check. For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

# 4Q: QC data exceeds $R_{4s}$ control range

Possible Cause	Corrective Action
One of the two consecutive high and low concentration QC data points exceeds the control limit of +2SD and the other exceeds the control limit of -2SD, or the difference between the two controls exceeds 4 SD. The QC rule is selected in Multi Check Level in Menu List > Parameters > QC Parameters > QC Specific > Check. For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

# 5Q: QC data exceeds $\mathbf{4}_{1s}$ control range

Possible Cause	Corrective Action
Four consecutive QC data point results have exceeded the 1SD limit. The QC rule is selected in Multi Check Level in Menu List > Parameters > QC Parameters > QC Specific > Check. For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

# 6Q: A preset number of consecutive QC results fall on one side of the mean

Possible Cause	Corrective Action
Results for a preset number (7 to 10) of consecutive data points fall either above or below the mean. The setting is programmed in Multi Check Level in Menu List > Parameters > QC Parameters > QC Specific > Check. For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

**7-24** B04779AB

### 7Q: Consecutive QC results show steadily increasing or decreasing values

Possible Cause	Corrective Action
Results for a preset number (4 to 10) of consecutive data points are increasing or decreasing. The setting is programmed in Multi Check Level in Menu List > Parameters > QC Parameters > QC Specific > Check. For more information, refer to the AU680 Reference Manual.	If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters. Follow laboratory procedure for out-of-range QC results such as:  Repeat with fresh QC material. Perform calibration as required. Perform maintenance as required.

# S: Sample repeated and original results replaced by repeat result

Possible Cause	Corrective Action
A test has been repeated and this repeat result has replaced the previous result to become the final result.	No action required.

#### /: Test pending or not analyzed

Possible Cause	Corrective Action	
The test was not performed, even though it was ordered (requisitioned) (generally because of a reagent shortage), or the testing is still in process.	Review all results generated immediately before this flag for consistency and validity (especially low or high results) and repeat if necessary.	
	If the reagent is empty, place new reagent onto the system and repeat analysis.	
	Confirm that fixed reagents are in the correct position.	
	3. Inspect the reagent probe and clean or replace as required. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars or Replace a Sample or Reagent Probe.	
	4. Confirm that the reagent probe is correctly installed and connected.	

### r: Result has been transferred to laboratory information system through online communication

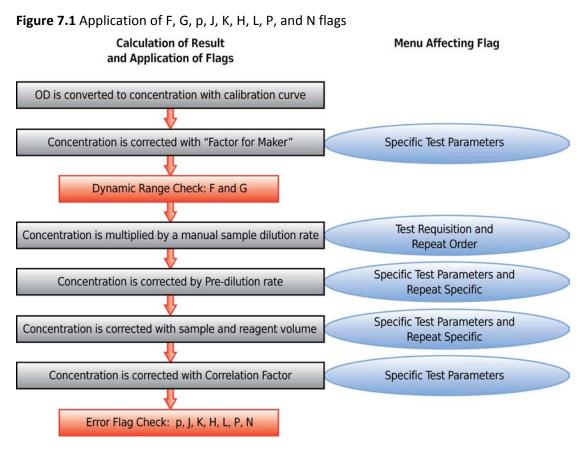
Possible Cause	Corrective Action
	No action required.

#### c: Result corrected by the operator

Possible Cause	Corrective Action
Data has been corrected. For more information, refer to the AU680 Reference Manual.	Follow laboratory procedure. Review any edited or changed data carefully before reporting.

# Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of Final Result Flowchart

This flowchart shows the calculations that occur to obtain the final concentration result, and when the system applies the flags.



Beckman Coulter programs Factor for Maker, and the system displays the setting in **Specific Test Parameters**. **A** is a multiplication factor and **B** is an addition and subtraction factor.

In the Test Requisition and Repeat Order (Requisition) menus, **Sample Dilution (F7)** allows input of a dilution rate when making a manual dilution of the sample for the original or repeat run.

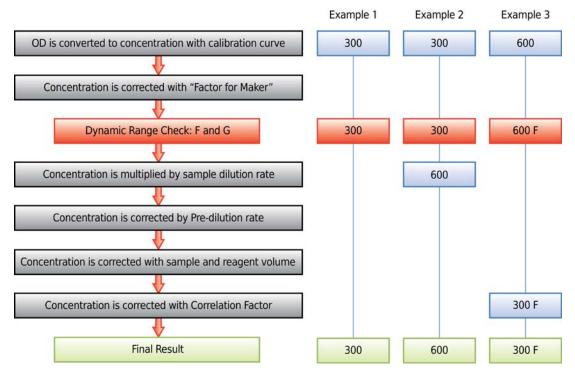
A calculation is made for **Pre-Dilution Rate** defined in **Specific Test Parameters**, as well as **Pre-Dilution Rate** defined in **Repeat Specific** for **Repeat with diluent** and **Repeat with condense**.

7-26 B04779AB

A calculation is made based on the sample and reagent volume defined in Specific Test Parameters and Repeat Specific.

The Correlation Factor is programmed in **Specific Test Parameters**. **A** is a multiplication factor and **B** is an addition or subtraction factor.

Figure 7.2 Examples with F flag: Dynamic Range is 1 to 500



#### Example 1

A final result of 300 without an F or a G flag.

#### Example 2

A final result of 600 without an F flag because the dynamic range check occurs (in range), then the concentration is multiplied by 2 for a manual dilution.

#### **Example 3**

A final result of 300 with an F flag because the dynamic range check occurs (over range), then a Correlation Factor **A** of 0.5 is applied.

7-27 B04779AB

# Flags

Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of Final Result Flowchart

7-28 B04779AB

# **Error Messages**

The system displays the following error messages after selecting the **Start** button. This chapter describes the cause of the error message and corrective actions to perform if the system has an error.

Table 8.1 Error Messages

Error Messages	Possible Cause	Corrective Action
After checking cups on STAT table, please perform STAT check in STAT Status menu.	The STAT table cover was opened, or a parameter was changed in <b>Parameters</b> .	<ol> <li>Confirm that the required sample cups are in the correct positions on the STAT table.</li> <li>Perform a STAT check in the STAT Status screen.</li> </ol>
After checking printer, please resume printer in Analyzer Status menu.	The printer status is abnormal.	<ol> <li>Confirm that the printer is turned on, and correct any errors with the printer.</li> <li>Select Home &gt; Analyzer Status.</li> <li>Select Printer Control (F5), then Resume or Cancel.</li> </ol>
Calibration requisition is renewed. Please set new calibrator on STAT table.	The calibration order (requisition) is renewed.	<ol> <li>Inspect the STAT Status to confirm the required calibrators are in the correct positions on the STAT table.</li> <li>If STAT Operation is programmed to Manual in the Analysis mode screen, perform a STAT check in the STAT Status screen.</li> </ol>
Calibration stability is expired. Please open Calibration Requisition menu and requisition the test.	Calibration data has expired.	<ol> <li>Order (requisition) the required test for calibration in the Calibration screen.</li> <li>Perform a calibration.</li> </ol>
Calibration stability will be expired soon.	Calibration data is close to expiration.	<ol> <li>Order (requisition) the required test for calibration in the Calibration screen.</li> <li>Perform a calibration.</li> </ol>

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
Can't perform Realtime online. Please reconnect LAN port or set unavailable at Start Condition menu.	The LAN port is disconnected.	Reconnect a LAN port, or stop the online communication in the Start Condition screen, and then select <b>Realtime Online (F8)</b> .
Cuvette Error found. Please check it at User Maintenance.	One or more cuvettes has failed the photocal.	Inspect the cuvette status in Home >     Analyzer Maintenance > Photocal     Monitor.
		2. Take corrective action based on the failure. For more information, refer to Clean the Cuvettes and the Cuvette Wheel, Clean or Replace Individual Cuvettes, or Replace the Photometer Lamp.
		3. Repeat the photocal on any cuvettes that failed the photocal. For more information, refer to Perform a Photocal.
Detergent short.	The wash solution is insufficient.	Inspect the wash solution and replenish as required. For more information, refer to Inspect the Wash Solution and Replenish as Needed.
Diluted Detergent short. The diluted wash solution is in	The diluted wash solution is insufficient.	Inspect the wash solution and replenish as required. For more information, refer to Inspect the Wash Solution and Replenish as Needed.
		Confirm that there is deionized water in the deionized water tank.
		Inspect the wash solution roller pump. For more information, refer to Inspect the Wash Solution Roller Pump for Leaks.
Full of Conc Waste tank.	The tank is full of concentrated liquid waste.	Contact Beckman Coulter.
Full of rack at Rack Collection.	The rack collection area is full.	Remove the racks from the rack collection area.
Full of Waste tank.	The waste tank is full of liquid waste.	Contact Beckman Coulter.
Incorrect parameter is found. Please open [MMMM/NNNN] menu and check the parameters.	A programming error exists in <b>Parameters</b> .	Inspect the Parameters screen listed in the Error Message for a programming error. The system displays the menu name instead of [MMMM/NNNN] in the Error Message.

8-2 B04779AB

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
ISE BUF Solution short.		Replace the ISE Buffer Solution bottle. For more information, refer to Replace the ISE Reagents.
ISE cover is open.		Close the ISE cover.
ISE MID Solution short.		Replace the ISE MID Standard Solution bottle. For more information, refer to Replace the ISE Reagents.
ISE REF Solution short.		Replace the ISE Reference Solution bottle. For more information, refer to Replace the ISE Reagents.
ISE select error(K).		<ol> <li>Perform a Selectivity Check. For more information, refer to Selectivity Check for the Na and K Electrodes.</li> <li>If the error is not resolved, replace the K electrode. For more information, refer to Replace the Na, K, or Cl Electrode. For Japan, refer to Replace the Na, K, or Cl Electrode in the ISE Addendum.</li> </ol>
ISE select error(Na).		<ol> <li>Perform a Selectivity Check. For more information, refer to Selectivity Check for the Na and K Electrodes.</li> <li>If the error is not resolved, replace the Na electrode. For more information, refer to Replace the Na, K, or Cl Electrode. For Japan, refer to Replace the Na, K, or Cl Electrode in the ISE Addendum.</li> </ol>
ISE slope is over (under) the range [MMMMMM, NNNN].		<ol> <li>Calibrate the ISE. For more information, refer to Calibrate the ISE.</li> <li>If the error is not resolved, replace the corresponding electrode. For more information, refer to Replace the Na, K, or CI Electrode. For Japan, refer to Replace the Na, K, or CI Electrode in the ISE Addendum.</li> <li>NOTE</li> <li>The system displays the ISE test name and sample type instead of [MMMMMM, NNNN] in the Error Message.</li> </ol>

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
ISE slope is zero [MMMMMM, NNNN].		<ol> <li>Calibrate the ISE. For more information, refer to Calibrate the ISE.</li> <li>If the error is not resolved, replace the corresponding electrode. For more information, refer to Replace the Na, K, or Cl Electrode. For Japan, refer to Replace the Na, K, or Cl Electrode in the ISE Addendum.</li> </ol> NOTE
		The system displays the ISE test name and sample type instead of [MMMMMM, NNNN] in the Error Message.
ISE Status is stop.	ISE is in STOP mode.	Select Home > Analyzer Maintenance > ISE Maintenance, and then select ISE Ready (F4) to reset the ISE to <i>Ready</i> mode.
Lack of Diluent. Please check it at Reagent Management.	The deionized water or diluent in the pre- dilution bottle is short.	<ol> <li>Replace the deionized water or diluent in the pre-dilution bottle.</li> <li>Perform a reagent check.</li> </ol>
Lack of R Probe Detergent. Please check it at Reagent Management.	The cleaning solution for contamination parameters in the cleaning solution bottle is short.	<ol> <li>Select Home &gt; Reagent Management         &gt; Details to determine which bottles are short.     </li> <li>Replace the cleaning solution for contamination prevention in the CLN-1 and CLN-2 bottles located on the analyzer by the reagent refrigerators.</li> <li>Perform a reagent check.</li> </ol>
Lack of S Probe Detergent. Please check it at Reagent Management.	The 2% Wash Solution in the sample probe wash solution bottle is short.	<ol> <li>Replace the 2% Wash Solution in the sample probe wash solution bottles.</li> <li>Perform a reagent check.</li> </ol>
LAN port is disconnect. Please check it Analyzer Status.	LAN port is disconnected.	<ol> <li>Inspect LAN port status in Analyzer Status screen.</li> <li>Reconnect the LAN port.</li> </ol>
Liquid is remained in vacuum tank.	Liquid waste exists in the vacuum tank.	Contact Beckman Coulter.

8-4 B04779AB

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
Maintenance item is expired. Please perform maintenance.	The maintenance procedure is expired.	<ol> <li>Review the Maintenance tab.</li> <li>Perform necessary maintenance.</li> </ol>
Maintenance item will be expired soon. Please check it.	The maintenance procedure is close to expiration.	<ol> <li>Review the Maintenance tab.</li> <li>Perform necessary maintenance.</li> </ol>
Master Curve is not scanned. Please check it at Reagent Management.	A new reagent lot is set in the reagent refrigerator and the 2-D bar code label was not scanned.	<ol> <li>Review the details in Home &gt; Reagent Management &gt; Details.</li> <li>Use the hand held scanner to scan the 2-D bar code label on the reagent.</li> <li>Perform a reagent check.</li> </ol>
No deionized water. Please check water supply valve.	Deionized water tank is empty.	<ol> <li>Inspect the water outlet valve on the deionized water system.</li> <li>If no abnormality is found in the deionized water system, contact Beckman Coulter.</li> </ol>
No Diluent. Please check it at Reagent Management menu.	The deionized water or diluent in the pre- dilution bottle is empty.	<ol> <li>Replace the deionized water or diluent in the pre-dilution bottle.</li> <li>Perform a reagent check.</li> </ol>
No Photocal Data. Please perform photocal at User Maintenance.	No photocal data exists.	Perform a photocal. For more information, refer to Perform a Photocal.
No R Probe detergent at Reagent Management menu.	The cleaning solution for contamination parameters in the cleaning solution bottle is empty.	<ol> <li>Select Home &gt; Reagent Management &gt; Details to determine which bottles are short.</li> <li>Replace the cleaning solution for contamination prevention in the CLN-1 and CLN-2 bottles located on the analyzer by the reagent refrigerators.</li> <li>Perform a reagent check.</li> </ol>
No Reagent. Please check it at Reagent Management.	A test cannot be performed caused by empty or missing reagent required for analysis.	<ol> <li>Select Home &gt; Reagent Management to determine the insufficient reagents.</li> <li>Place the required reagents in the reagent refrigerator.</li> <li>Perform a reagent check.</li> </ol>

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
No S Probe Detergent.	The 2% Wash Solution in the sample probe wash solution bottle is empty.	<ol> <li>Replace the 2% Wash Solution in the sample probe wash solution bottles.</li> <li>Perform a reagent check.</li> </ol>
Onboard Stability is expired. Please check Reagent Management and set new reagent in	A reagent has exceeded the onboard stability expiration date.	<ol> <li>Select Home &gt; Reagent Management</li> <li>Details to determine which bottles have expired.</li> </ol>
the refrigerator.		Replace the expired reagent bottle with a new reagent bottle.
		3. Perform a reagent check.
Overflow of Deionized water. Please check the tank.	Overflow of deionized water.	Confirm that the deionized water float sensor connector is plugged in correctly.
		If no abnormality is found in the deionized water float sensor, contact Beckman Coulter.
Overflow of Diluted detergent. Please check	Overflow of diluted wash solution.	Inspect the diluted wash solution tank.
the tank.		2. If no abnormality is found in the system, contact Beckman Coulter.
Please check STAT Status and set calibrators to be	The calibrators required for the calibration analysis are not set on the STAT table.	Review the <b>STAT Status</b> to determine which calibrators are required.
needed.		<ol><li>Place the calibrators in the corresponding positions on the STAT table.</li></ol>
		3. If <b>STAT Operation</b> is programmed to <b>Manual</b> in the Analysis mode screen, perform a STAT check in the STAT Status screen.
Please check STAT Status and set controls to be needed.	The controls required for the QC analysis are not set on the STAT table.	Review the <b>STAT Status</b> to determine which controls are needed.
		<ol><li>Place the controls in the corresponding positions on the STAT table.</li></ol>
		3. If <b>STAT Operation</b> is programmed to <b>Manual</b> in the Analysis mode screen, perform a STAT check in the STAT Status screen.

8-6 B04779AB

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
Please check STAT Status and set RB cup to be needed.	The RB cup required for the reagent blank analysis is not set on the STAT table.	<ol> <li>Review the <b>STAT Status</b> to determine which reagent blank is required.</li> <li>Place the reagent blank in the</li> </ol>
		corresponding position on the STAT table.
		3. If <b>STAT Operation</b> is programmed to <b>Manual</b> in the Analysis mode screen, perform a STAT check in the STAT Status screen.
Please perform Reagent	Reagent status is Unchecked because the	Select Home > Reagent Management.
Check.	reagent refrigerator cover was opened or a parameter was changed in <b>Parameters</b> .	Perform a reagent check.
QC requisition is renewed. Please set new control on STAT table.		Review the <b>STAT Status</b> to determine which controls are needed.
		2. If <b>STAT Operation</b> is programmed to <b>Manual</b> in the Analysis mode screen, perform a STAT check in the STAT Status screen.
RB stability is expired. Please open Calibration Requisition and	Reagent blank data has expired.	Order (requisition) the required test for reagent blank in the Calibration screen.
requisition the test.		2. Perform a reagent blank.
RB stability will be expired soon.	Reagent blank data is close to expiration.	Order (requisition) the required test for reagent blank in the Calibration screen.
		2. Perform a reagent blank.
Reagent error found. Please check it at Reagent Management.	An error has been found in the Reagent Management screen.	Select Home > Reagent Management >     Detail and review the Comment column for errors.
		2. Confirm the reagent bottle position.
		3. Perform a reagent check.
Reagent is expired. Please check Reagent Management and set new reagent in the	The reagent expiration date has been exceeded.	<ol> <li>Select Home &gt; Reagent Management</li> <li>&gt; Details to determine which bottles have expired.</li> </ol>
refrigerator.		2. Replace the expired reagent bottle with a new reagent bottle.
		3. Perform a reagent check.

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
Temperature of the incubator bath is over(under) the normal range.	The temperature of the cuvette wheel is out of specification.	Confirm that the cover is on the cuvette wheel. If the problem continues, contact Beckman Coulter.
Temperature of the refrigerator is over(under) the normal range.	The reagent refrigerator temperature is out of specification.	Confirm that the cover is on the reagent refrigerator. If the problem continues, contact Beckman Coulter.
Test has no Calibration Data. Please open Calibration Requisition and requisition the test.	No calibration data exists or calibration analysis failed.	<ol> <li>Order (requisition) the required test for calibration in the Calibration screen.</li> <li>Perform a calibration.</li> </ol>
Test has no RB Data. Please open Calibration Requisition menu and requisition the test.	No reagent blank data exists or reagent blank analysis failed.	<ol> <li>Order (requisition) the required test for reagent blank in the Calibration screen.</li> <li>Perform a reagent blank.</li> </ol>
Test item(s) is set as "Disabled" at Start Condition.	A test is programmed to disabled (unavailable) in the Start Condition screen. The disabled (unavailable) test is not analyzed for any patient samples.	
The cover of repeat Position is open.	The repeat run component cover is open.	Close the cover.
The cover of Dispensing Position is open.	The cover on the rack lane is open.	Close the cover.
The cover of Rack Feeder is open.	The rack supply component cover is open.	Close the cover.
The cover of reagent refrigerator is open.	The reagent 1 or reagent 2 refrigerator cover is open.	Close the cover.
The main cover of STAT table is open.	The STAT table cover (large) is open.	Close the cover.
The sample on STAT table is incorrect. Please check it on STAT status menu.	An error exists with a sample on the STAT table.	<ol> <li>Select STAT Status to review error information.</li> <li>Take the correct action for the error.</li> <li>If STAT Operation is programmed to Manual in the Analysis mode screen, perform a STAT check in the STAT Status screen.</li> </ol>
The sub cover of STAT table is open.	The STAT table cover (small) is open.	Close the cover.

8-8 B04779AB

Table 8.1 Error Messages (Continued)

Error Messages	Possible Cause	Corrective Action
The volume is reached to Alarm volume. Please check it at Reagent Management.	The remaining reagent shots (tests) have reached the Alarm Shots programmed in Parameters > Common Test Parameters.	<ol> <li>Select Home &gt; Reagent Management &gt; Details to determine which bottles are short.</li> <li>Add a new reagent bottle.</li> <li>Perform a reagent check.</li> </ol>
Under communicating with HOST.	The analyzer is communicating with the laboratory information system.	Review the analyzer for the status of communication with the laboratory information system in the Analyzer Status screen.
Under printing to printer.	Batch print or real-time print is being performed.	Review the printer status in the Analyzer Status screen.

В04779АВ 8-9

# **Error Messages**

Error Messages

8-10 B04779AB

#### Introduction

Regular preventative maintenance is essential for optimum system performance. Many problems outlined in this chapter are caused by neglecting to perform preventative maintenance and required care.

For each aspect of troubleshooting, you can find useful information by referring to the corresponding section of the maintenance chapter.

For more information, refer to Maintenance.

#### **Reagent Blank Data**

- **1** Review printout and look for any flags.
- 2 Review the Alarm List for RB Data Error alarms.
- **3** A reagent blank is a confirmation of the reagent system. Reagent System includes: Reagent, Reagent Probe, and Reagent Syringe.
- 4 Review reagent blank data in Menu List > Calibration > Calibration Monitor > RB History and RB Detail.

#### **Calibration Data**

- 1 Review the Alarm List for any Calibration alarms.
- **2** Review the printout.
- **3** Look at the precision of the replicates for each test. The OD readings should have a similar value.
- **4** Look for separation between calibrators for a multi-point calibration.
- 5 Calibration is a confirmation of the sampling system. The sampling system includes: the Sample, Sample Probe, Sample Syringe, and Wash Syringe.
- **6** If calibration replicates are 0 or close to 0, the problem can be:

#### **Troubleshooting**

**OC** Data

- Wrong calibrator used
- Sample did not dispense into cuvette (probe or syringe problem)
- Reagent
- 7 Review calibration data in Menu List > Calibration > Calibration Monitor > Calibration History and Calibration Detail.

#### **QC Data**

- **1** Review the **Alarm List** for QC alarms.
- **2** Review the printout for QC flags 1Q to 7Q.
- **3** Review the daily QC charts:
  - QC validates calibration.
  - If all QC is increasing or decreasing (one direction only), the QC problem can be related to the calibration factor and indicates calibration problems.
  - If you perform QC on multiple tests from the same QC material, but QC is only out of range for a specific test, confirm the QC test parameters, reagent, and calibration.
  - If tests from only one level of QC are out of range, confirm that you put the correct QC material into the cup.
- **4** If available, run a secondary QC (assayed) and view the results.

#### Troubleshooting Reagents, Calibrators, Quality Control, and Samples

#### **Reagent Blank Issues and Corrective Actions**

- Inspect the reagent system including the reagent, reagent probes, and reagent syringes. For more information, refer to Reagent Blank Corrective Actions.
- Review the printout and look for flags.
  - Flags u or y if the RB data of the first read point of the test fails.
  - Flags U or Y if the RB data of the last read point of the test fails.
  - Limits are programmed in Menu List > Parameters > Specific Test Parameters > General.
  - Review the **Alarm List** for RB Data Error alarms that the system generates if the reagent blank fails.

#### **Reagent Blank Corrective Actions**

- Reagent
  - Inspect the reagent expiration date.
  - Inspect the reagent on-board expiration date.
  - Confirm the correct reagent preparation.

9-2 B04779AB

- Confirm that fixed reagents are in the correct position.
- Put on a new bottle of reagent and perform a reagent blank or calibration.
- Confirm that a bar code labeled reagent is not in a position fixed for a different test.

#### Reagent Probes

- Inspect the reagent probes. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.
- Clean the reagent probes. For more information, refer to Clean the R1 or R2 Reagent Probes.
- Clean the reagent probe wash wells. For more information, refer to Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells.
- Replace the reagent probes. For more information, refer to Replace a Sample or Reagent Probe.
- Reagent Syringes
  - Inspect the reagent syringes. For more information, refer to Inspect the Syringes for Leaks.
  - Replace the reagent syringes. For more information, refer to Replace Syringes or Syringe Case Heads.

#### **Calibration Issues and Corrective Actions**

- Inspect the sampling system including the calibrator, sample probes, and sample syringes. For more information, refer to Calibration Corrective Actions.
- Review the **Alarm List** and printout:
  - If the calibration factor range programmed in Parameters > Calibration >
     Calibration Specific is exceeded, the system generates Calibration Factor
     High/Low and Calibration Error alarms.
  - Inspect for precision of the OD replicates on the printout.
  - Confirm that the OD is not zero, which can indicate the calibrator material was not aspirated.

#### **Calibration Corrective Actions**

- Calibrator
  - Confirm that the correct calibrator material was poured for the calibration.
  - Confirm the integrity of the calibrator material (expiration date, open-bottle stability, time at room temperature, and contamination).
  - Confirm that the calibrator is in the correct position in the yellow rack.
  - Confirm that the calibrator lot number in use and lot number concentration programmed in **Parameters** > **Calibration** > **Calibration** Specific are the same.
- Sample Probe
  - Inspect the sample probe. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.
  - Clean the sample probe. For more information, refer to Clean the Sample Probe and Mix Bars.
  - Clean the sample probe wash wells. For more information, refer to Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells.

#### **Troubleshooting**

Troubleshooting Reagents, Calibrators, Quality Control, and Samples

- Replace the sample probe. For more information, refer to Replace a Sample or Reagent Probe.
- Sample Syringe and Wash Syringe
  - Inspect the sample syringe and wash syringe. For more information, refer to Inspect the Syringes for Leaks.
  - Replace the sample syringe and wash syringe. For more information, refer to Replace Syringes or Syringe Case Heads.

#### **QC Related Issues and Corrective Actions**

- Perform QC on the system to validate the calibration. Inspect for a reagent, calibration, or QC issue . For more information, refer to Corrective Actions.
  - Reagent problem
  - Calibrator problem
  - QC problem
- Review the **Alarm List** and printout:
  - The system generates a QC [test name] over or under alarm if the QC range programmed in **Parameters** > **QC Parameters** > **QC Specific** is exceeded.
  - Review the printout for QC flags 1Q to 7Q.

#### **Corrective Actions**

- Review all Reagent Blank Issues and Corrective Actions.
- Review all Calibration Issues and Corrective Actions.
- Confirm the QC Sample:
  - Confirm that the correct QC material was poured for the QC analysis.
  - Confirm the integrity of the material: expiration date, open-bottle stability, time at room temperature, and contamination.
  - Confirm that the OC was placed in the correct position in the green rack.
  - Confirm that the QC lot number in use and range programmed in Parameters > QC
     Parameters > QC Specific are correct.
  - Run assayed QC material.

#### Sample Related Issues

The following two items cause most data problems:

- Sample evaporation Sample evaporation can cause unusually high results. Store samples correctly, and keep sample caps closed tightly if they need to be stored for a short period before analysis.
- Incorrect sample handling Refer to the relevant Instructions for Use supplied with reagents to find the correct procedures for sample collection, handling, and storage.

Note the following sample requirements:

• This system analyzes serum, urine, other fluids, and whole blood (HbA1c). If problems are encountered when analyzing a specific test, or when using a specific reagent, refer to the relevant reagent IFU or contact Beckman Coulter.

9-4 B04779AB

- Use serum or plasma that is adequately separated from cells, and urine that is free of suspended matter, to prevent the sample probe from becoming blocked, and adversely affecting analysis.
- Confirm that blood samples are sufficiently coagulated before serum separation. Remove any suspended fibrin before placing serum on the system.
- If there is any suspended matter present in urine to be tested, centrifuge the sample before testing.
- If a sample requires pretreatment depending on the analysis test, refer to the relevant reagent IFU.
- A minimum quantity of sample is required for analysis. Confirm that a sufficient quantity of sample is available for analysis. For more information, refer to Sample Preparation.
- To prevent sample evaporation, do not leave samples uncovered for an extended time. Evaporation can cause biased results being observed.
- Bubbles on the surface of samples, QC and calibrator material, can cause level sensing problems or erroneous results. Confirm that all bubbles are removed from the surface of the sample before placing onto the system.
- Confirm that the sample cups and racks are set correctly. For more information, refer to Place the Sample Cups or Tubes in the Rack.
- Inspect the serum for the extent of hemolysis, lipemia, bilirubin, and other sample quality issues according to your laboratory procedure.
- If the sample has evaporated or deteriorated, or if the QC sample was incorrectly prepared, obtain a new sample or correctly prepare the QC sample and repeat analysis.
- Precautions when using whole blood (HbA1c):
  - Clean the outside of the sample probe with an alcohol prep (70% Isopropyl alcohol) as required to remove coagulated blood adhering to the outside of the sample probe. Coagulated blood causes increased water being carried on the outside of the sample probe. For more information, refer to Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars.
  - If the blood has coagulated, obtain a new sample.
  - If the blood cells have precipitated, mix the whole blood by inverting gently.
  - Do not store whole blood samples for more than 2 hours after collection.

#### Wash Solution Related Issues

Wash solution is the only approved detergent for use on the system. Confirm that wash solution is in the wash solution tank. If it seems like there is contamination in the diluted wash solution tank, or the diluted wash solution does not seem like it is being used on the system, contact Beckman Coulter.

#### **Deionized Water Related Issues**

Inspect the following if the deionized water causes data problems:

- Confirm if the deionized water supply system needs servicing for the deionized water quality.
- If the deionized water tank is contaminated, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
- If the deionized water filter is dirty, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.

### Items in Common on the AU680 that can Aid in Troubleshooting

If you do not perform scheduled maintenance or maintenance is overdue, abnormal data can result. Perform all scheduled maintenance along with regular preventative maintenance. For more information, refer to Maintenance.

- Incoming water quality (purity, temperature, and conductivity) and circumstance can affect the analysis results. For more information, refer to System Specifications or contact Beckman Coulter.
- This system uses the specific sample probe, reagent probe, and cuvettes supplied by Beckman Coulter. Use only genuine Beckman Coulter parts.
- If a mosquito coil or insecticides are close to the system, it can affect the cholinesterase (CHE). If you experience an abnormality, replace the sample cups, reagents, and reagent bottles. Clean the sample probe, reagent probes, mix bars, and cuvettes. For more information, refer to Clean the Sample Probe and Mix Bars, Clean the R1 or R2 Reagent Probes, and Clean the Cuvettes and the Cuvette Wheel.

### **Mechanical Problems**

### **Syringe Problems**

### Inspect for:

- Water leaking at syringes: Tighten the syringe cases and case heads of the sample and reagent syringes.
  - Also, confirm that there is no damage to sample and reagent syringes, and the abrasion status of pistons. For more information, refer to Replace Syringes or Syringe Case Heads.
- Bubbles in the tubing connected to the syringe: Select Home > Analyzer Maintenance.
  Then select Prime Washing-line and press the TABLE ROTATION/DIAG button to start
  removing air from the tubing. For more information, refer to Replace Syringes or
  Syringe Case Heads.
- General Syringe Troubleshooting:
  - Confirm that the top and bottom screws are tightened.
  - Confirm that the bottom screw is finger tight against the piston. Over-tightening damages the syringe.
  - Confirm that there is a smooth resistant pull.
  - Confirm that the correct size syringe (sample or reagent) is in the correct position.
  - Confirm that only one O-ring is being used and that it is not flattened or damaged.
  - Confirm that the syringe is installed on the system correctly.
  - Inspect the tubing connected to the syringe head for scratches, bending, or leaks.
  - Confirm that the creases in the fluorocarbon polymer tip of the syringe do not have any buildup or flaking of the fluorocarbon polymer tip.
  - Confirm that the probes are not blocked. For more information, refer to Clean the Sample Probe and Mix Bars and Clean the R1 or R2 Reagent Probes. If the probes are blocked, syringe operation is affected.

9-6 B04779AB

#### **Probe Problems**

#### Inspect for:

- General Probe Troubleshooting:
  - Confirm that water dispenses in a straight stream.
  - Confirm that the metal screw cap for the probe connection is tight.
  - Confirm that the probe tubing does not have bubbles.
- The reagent or sample probe is leaking from loose probe connectors: Tighten the probe connectors. Confirm that the tubing is firmly connected.
- The reagent or sample probe is blocked: For more information, refer to Clean the Sample Probe and Mix Bars and Clean the R1 or R2 Reagent Probes.
- The reagent or sample probe is bent or damaged: Replace the probe. For more information, refer to Replace a Sample or Reagent Probe.
- The sample aspiration position of the sample probe is incorrect: The sample probe moves down to aspirate sample. The maximum distance the probe can move downward is defined in the system software, but a service engineer can change the programming. If the sample probe downward distance is programmed incorrectly, the probe might hit the bottom of the sample cup or tube. Contact Beckman Coulter.
- The reagent probe is not aligned over the refrigerator: If the R1 or R2 reagent probe is hitting the reagent bottle or refrigerator cover, examine the reagent probes for abnormalities. If the probe is bent, replace it. For more information, refer to Replace a Sample or Reagent Probe. If the probe is not bent, and the reagent aspiration position is still not correct, contact Beckman Coulter.
- The sample probe or reagent probe is not aligned over the cuvette: If the sample probe or reagent probe is contacting the cuvettes, examine the sample probe or reagent probe for abnormalities. If a probe is bent, replace it. For more information, refer to Replace a Sample or Reagent Probe. If the probe is not bent but still not aligned correctly, contact Beckman Coulter.
- Abnormal wash position of the reagent probe and sample probe: If the probe is hitting
  the wash well, examine the probe. If a probe is bent, replace it. For more information,
  refer to Replace a Sample or Reagent Probe. If the probe is not bent, but the probe
  wash position is still abnormal, contact Beckman Coulter.
- Basic troubleshooting for the reagent transfer components and sample transfer component: Confirm that no drops remain on the path of the transfer component. If drops are on the path of the sample or reagent transfer component, contact Beckman Coulter.
- The sample contains a significant amount of fibrin and protein.
  - Remove fibrin or filter the sample.
  - Inspect whether any other contaminant is mixed in the sample.
  - Remove any clots from the sample probe. For more information, refer to Clean the Sample Probe and Mix Bars.

### Abnormal Data Caused by Cuvette Wheel or Wash Nozzles

 Scratches, fingerprints, stains, or foreign matter on the cuvettes: Clean the cuvettes. If abnormal data is not corrected after cleaning, replace the cuvettes with new ones. For more information, refer to Clean the Cuvettes and the Cuvette Wheel or Clean or Replace Individual Cuvettes.

- The outside of the cuvette or the cuvette wheel is wet or flooded: Inspect the wash nozzle joints on the wash nozzle and tighten if they are loose. The wash nozzles can clog. Clean the wash nozzles.
  - For more information on how to clean the wash nozzles, refer to Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints.
  - Clean any cuvettes and the cuvette wheel where it is wet. For more information, refer to Clean the Cuvettes and the Cuvette Wheel.
- The deionized water or wash solution is dripping from the wash nozzles: Inspect the wash nozzle joints on the wash nozzles and tighten if they are loose. The wash nozzles can clog. Clean the wash nozzles. For more information, refer to Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints.
- After washing the cuvettes, a large amount of water remains in the cuvettes: Inspect the wash nozzle joints on the wash nozzles and tighten if they are loose. The wash nozzles can clog. Clean the wash nozzles.
  - For more information on how to clean the wash nozzles, refer to Clean the Wash Nozzle Component and Inspect the Tube Mounting Joints.
  - Remove the excess water from inside the cuvettes, refer to Clean the Cuvettes and the Cuvette Wheel.
- The tube in the wash solution tank floats: Straighten the tube, then insert it toward the tank bottom so that it does not contact the tank opening.
- The system has trouble with the float sensor in the wash solution tank or the diluted wash solution tank: Connect the float sensor connector firmly, and move the float sensor and tube in the tank so that they do not contact each other. If these changes do not correct the problem, contact Beckman Coulter to replace the float sensor.
- Some cuvettes are contaminated with foreign matter: Clean the cuvettes. If abnormal data is not corrected after cleaning the cuvettes or if any cuvettes are broken, replace those cuvettes. For more information, Clean the Cuvettes and the Cuvette Wheel or Clean or Replace Individual Cuvettes.
- The cuvette wheel was removed from the analyzer for an extended time, then placed on the analyzer: Do not use the analyzer immediately. It is necessary to leave the cuvette wheel in the dry bath incubator for a minimum of an hour for the cuvettes to stabilize to temperature specifications of  $37 \, ^{\circ}\text{C} \pm 0.3 \, ^{\circ}\text{C}$ .

### Abnormal Data Caused by Photometer Lamp or Photometer Component

- The quality of the photometer lamp has deteriorated: Inspect the record of photocal measurement results for abnormal data. If there is abnormal data, replace the photometer lamp.
  - For more information on the photocal measurement result record, refer to Perform a Photocal.
  - For more information on replacing the Photometer Lamp, refer to Replace the Photometer Lamp.
- The photometer lamp is not stable: Perform the photocal measurement twice to confirm the difference between two sets of measurement data. If there is a significant difference between the measurements, the photometer lamp can be defective. Replace the lamp. For more information, refer to Replace the Photometer Lamp.

9-8 B04779AB

### **Mixing Problems**

- The mix bars are contaminated: Clean the mix bars. For more information, refer to Clean the Sample Probe and Mix Bars.
- The fluororesin coating on the mix bars is chipped: Replace the mix bars. For more information, refer to Replace the Mix Bars.
- The mix bar component malfunctions, and there is abnormal noise from the system during the mixing motion: If there is an audible abnormal noise coming from the mix bar component, inspect for bent mix bars. If the mix bar is bent, replace the mix bar. For more information, refer to Replace the Mix Bars. If the mix bars are not bent, contact Beckman Coulter.
- The wash water and wash solution are not correctly drained from the mix bar wash wells: Contact Beckman Coulter.
- The mix bars are not positioned correctly causing contact between the mix bars and the mix bar wash well or the cuvettes: If the mix bar is bent, replace the mix bar. For more information, refer to Replace the Mix Bars. If the mix bar is not bent, contact Beckman Coulter.
- The mix bars are not correctly installed on the mix bar component, causing insufficient mixing of the sample and reagents: Install the mix bars correctly. For more information, refer to Replace the Mix Bars.

#### **Deionized Water Tank Problems**

- The deionized water tank is contaminated or dirty: If there are indications of particulate contamination on the interior of the tank, clean the tank thoroughly. For more information, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
- Residual sodium hypochlorite solution remains in the deionized water tank after cleaning: Clean the tank again and rinse thoroughly with deionized water. For more information, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.

### **Deionized Water or Filter Problems**

Confirm the water quality by assessing the following:

- Deionized water supply: Determine if the water supply meets the required specifications. For more information, refer to Water Supply and Drain.
- Dirty, stained or blocked filters: Clean the deionized water filter and the sample probe filter. Replace filters if data continues to be abnormal after cleaning. For more information, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
- Tap water below 5 °C used: The water supply to the deionizer must be above 5 °C. For more information, contact Beckman Coulter.

### **Incubation Temperature Problems**

- Confirm that there is adequate space surrounding the system for air to circulate effectively. Confirm that this space meets Beckman Coulter recommendations. For more information, refer to System Specifications.
- Do not fill adjoining space around analyzers with boxes or other equipment. Space left at installation is required for correct air circulation.

- Clean the air filters. For more information, refer to Clean the Air Filters.
- Confirm that the room temperature is between 18 °C and 32 °C and does not vary by more than ± 2 °C per hour. Failure to regulate room temperature causes more required calibration events.
- If the cuvette wheel was removed from the analyzer for an extended time, then placed on the analyzer, do not use the analyzer immediately. It is necessary to leave the cuvette wheel in the dry bath incubator for a minimum of an hour for the cuvettes to stabilize to temperature specifications of 37 °C  $\pm$  0.3 °C.

### **Tubing and Pump Problems**

The filters are dirty or clogged: Clean the deionized water filter and the sample probe filter. If abnormal data is not corrected after cleaning filters, replace the filters.

- For more information on how to clean the deionized water filter, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
- For more information on how to clean the sample probe filter, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
- For more information on how to replace the deionized water filter, refer to Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring.
- For more information on how to replace the sample probe filter, refer to Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring.

### **Reagent Refrigerator Problems**

If the reagent refrigerator temperature is out of range:

- 1 Select **Home** > **Analyzer Status** and inspect the coolant temperature for the reagent refrigerator.
- **2** Open the reagent refrigerator and confirm that the reagent bottles are cool.
- **3** If the problem persists, contact Beckman Coulter.

### **STAT Table Problems**

If the STAT table compartment temperature is out of range:

- 1 Select **Home** > **Analyzer Status** and inspect the coolant temperature of the STAT table compartment.
- **2** Confirm that the large and small STAT table covers are correctly installed. If the covers are opened frequently or for extended periods of time, the STAT table compartment temperature increases.
- **3** If the problem persists, contact Beckman Coulter.

9-10 B04779AB

#### **Rack Problems**

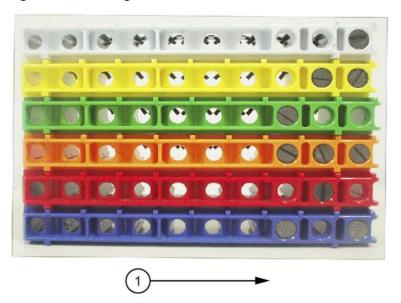
Inspect for the following general problems:

- Confirm that the rack is clean and that the surface is not sticky.
- Inspect bar code label positioning.
  - For more information on attaching the bar code label to the sample rack, refer to the AU680 Reference Manual.
  - For more information on placing the sample cups or tubes in the rack, refer to Place the Sample Cups or Tubes in the Rack.
- Confirm that the rack was loaded correctly.

For more information on loading racks, refer to Placing Racks on the Rack Supply Component.

• Confirm that the correct number of magnets are in the bottom of the rack. Compare the configuration of magnets on the underside of the rack with the magnets on another rack of the same color. The configuration for the two racks should be identical. Discard the rack if a magnet is missing.

Figure 9.1 Rack Magnet Positions



1. Magnets in rack positions 1, 2, or 3 (to the right of the arrow)

Table 9.1 Magnets in Rack Positions 1, 2 or 3

Rack Color	Magnet Position (1 to 3)	
White	Position 1	
Yellow	Positions 1 and 2	
Green	Position 3	
Orange	Positions 1, 2, and 3	
Red	Position 2	

Table 9.1 Magnets in Rack Positions 1, 2 or 3 (Continued)

Rack Color	Magnet Position (1 to 3)	
Blue	Positions 1 and 3	

### **System Problems**

### **Alarm for Reagent Refrigerator Temp**

- If there is a problem with the reagent refrigerator, confirm that there is adequate space surrounding the system for air to circulate effectively. For more information on installation environment precautions, refer to System Specifications.
- Confirm that the room temperature is from 18 °C to 32 °C with a ±2 °C variation. If the room temperature is over 32 °C, the reagent refrigerator temperature is over 12 °C. If the problem persists, contact Beckman Coulter.

### **Abnormal Sound from Inside the System**

• Air bubbles trapped in the tubing: Inspect the deionized water filter. If the filter is damaged, replace it. Inspect the sample probe filter for placement of the filter. For correct positioning of the filter, refer to Figure 9.2 Sample Probe Filter Replacement.

Figure 9.2 Sample Probe Filter Replacement



- Deionized water tank empty alarm: The ion-exchange capability of the deionizer can be insufficient. Replace the deionizer if it does not meet required specifications. Inspect the deionized water filter. If it has become dirty or blocked, clean or replace it.
  - For more information on cleaning the Deionized Water Filter and the Sample Probe Filter, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.
  - For more information on replacing the Deionized Water Filter and the Sample Probe Filter, refer to Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring and Replace the O-rings in the Water Supply Tube Mounting Joint.
- For all other sources of noise, contact Beckman Coulter.

#### **Alarm for Deionized Water**

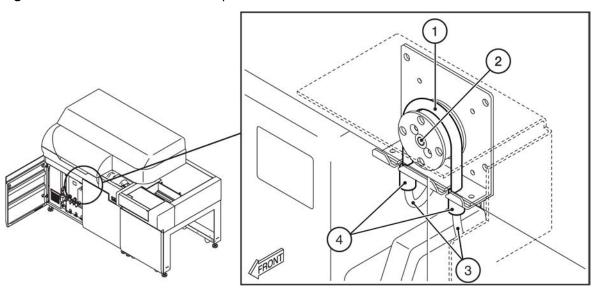
• The deionizer is turned off: Turn on the deionizer. Shut down the system (End Process), and then turn on the system.

9-12 B04779AB

- The ion exchange capability of the deionizer is insufficient: Confirm that the deionizer meets specifications. If the deionizer does not meet the specification, replace it. For detailed information, consult the deionizer manufacturer.
- The deionized water filter is clogged: Use your finger to determine if the deionized water filter is slimy. If the filter surface is slimy, the filter may be clogged. Clean the deionized water filter. For more information, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.

### **Leaks from the Wash Solution Roller Pump**

Figure 9.3 Wash Solution Roller Pump



- 1. Roller pump tubing
- 2. Wash solution roller pump
- 3. Relay tubes
- 4. Connector
- The roller pump tubing may be deteriorated: Inspect the roller pump tubing for cracks caused by deterioration. If deteriorated, replace the roller pump tubing. For more information, refer to Replace the Wash Solution Roller Pump Tubing.
- A connector may be loose: Inspect the connectors, and firmly tighten if the connectors are loose.

### **Bar Code Label Errors**

- Reagent bar code reader dirty: Wipe the bar code reader window with a clean, deionized water dampened, lint-free absorbent tissue to remove any particles on the read window. If necessary, follow up with a clean, dry, lint-free absorbent tissue to dry the reader so there are no smear marks left to cause errors.
- Bar code labels on sample cups or racks are damaged and discolored: Replace any sample or rack bar code labels that are worn or damaged.
- Bar code labels on reagent bottles are damaged: If the reagent ID is damaged, the operator can edit the reagent ID and still use the bottle of reagent. For more information, refer to Edit a Reagent ID.
- Bar code labels are not correctly attached to racks or sample cups: For more information, refer to the AU680 Reference Manual.



Never look directly into the bar code readers. The laser light can cause serious eye damage.

• For more information on replacing rack ID labels, refer to Replace Rack ID Labels.

### Leaks from the Bottom of the System

- Wash line obstructed: Inspect for obstructions in the wash wells for the sample probe and reagent probes. Clean the wells if any obstructions exist. For more information, refer to Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells.
- Waste line not installed correctly: If the waste line is leaking or if the tubing is too long, contact Beckman Coulter.
- Any leaks from the bottom of the analyzer are potentially dangerous: If the source is not clearly visible (for example a leaking syringe), contact Beckman Coulter.

#### No Wash Solution to Mix Bar Wash Wells

- The deionized water filter may be clogged. Confirm the last time the deionized water tank and filter were cleaned.
- Determine if the interior of the deionized water tank has slick or slimy buildup by sliding your gloved hand on the gray float sensor in the bottle or the side of the tank. This buildup can cause the deionized water and sample probe filters to become clogged. Clean both the deionized water and sample probe filters, and the deionized water tank.

For more information on how to clean the deionized water filter, sample probe filter, and deionized water tank, refer to Clean the Deionized Water Tank, Deionized Water Filter, and Sample Probe Filter.

#### **Reagent Alarm when Sufficient Reagent Remains in Bottles**

The liquid level sensor could be faulty. Select **Alarm List** for the cause and corrective actions.

- Inspect the reagent bottle for bubbles that occur from replacing reagents or for a bottle that is not correctly placed in the reagent refrigerator.
- Perform a reagent check to confirm that the alarm is still occurring.
- Contact Beckman Coulter.

### **Sample Alarm when Sufficient Sample Remains**

When there is a sample alarm and sufficient sample remains, there is a possibility that the sample probe did not move down to the liquid level of the sample. Incorrect detection of the height of the cup can cause this error. Confirm that the correct tube or cup is used and placed correctly in the rack. Inspect for bubbles in the sample cup. If an error still occurs, contact Beckman Coulter. For more information, refer to the AU680 Reference Manual.

### No Sample Cup Alarm when Sample Cup is in the Rack

Unspecified cup used: Confirm that the specified sample cups are in each rack. For more information, refer to Cups or Tubes Specifications.

9-14 B04779AB

### No Sample Cup Alarm when Sample Cup is on the STAT Table

- The required test was not requisitioned for the STAT sample, or the order (requisition) was not for the correct position on the STAT table. Repeat the STAT sample order.
- Confirm that the sample cup was placed correctly on the STAT table with the correct adaptor for the sample cup diameter.
- Confirm that the sample cup meets specifications. For more information, refer to Cups or Tubes Specifications.

### Liquid Leaking from the Reagent Probe or Sample Probe

Confirm that the reagent probe or sample probe is installed correctly:

- **1** Confirm that the probe connectors are tight.
- 2 Select Home > Analyzer Maintenance > Maintenance. The system displays the Analyzer Maintenance: Maintenance tab.
- **3** Select the **Analyzer Maintenance** box. The system activates the maintenance operation buttons.
- 4 Select Prime Washing Line.
- 5 Select **OK** to dispense water from the reagent probe and sample probe. If the deionized water does not dispense normally, a reagent probe or sample probe might be incorrectly installed. Inspect the reagent probe or sample probe installation. If it is necessary to replace the probe, refer to Replace a Sample or Reagent Probe.

#### Reagent Probe or Sample Probe not Aligned over the Cuvette

Inspect if the reagent probe or sample probe is bent: Examine the probe and replace it if it is bent. For more information, refer to Replace a Sample or Reagent Probe.

If the probe is not bent but still aligned incorrectly, contact Beckman Coulter.

### Flag [#] (Sample Level Detection Error) Generated during the Sample Dispense Operation

Determine if the sample volume is too low: Confirm that there is sufficient sample for the ordered (requisitioned) tests. Consider the dead volume for the different cups. For more information, refer to Cups or Tubes Specifications.

#### **TEMP DIL Alarm for the Wash Water Heater**

The water temperature is not within the specified range. Contact Beckman Coulter for assistance.

#### Sample Rack Jammed

Inspect for:

#### **Troubleshooting**

**Data Processor Problems** 

- Contamination on the rack: Confirm that nothing has fallen onto the rack and that the rack ID bar code label, or sample ID bar code labels have not peeled off, causing the rack to jam.
- Rack feeder module is sticky or dusty: Clean surfaces with deionized water using a lintfree, dampened absorbent tissue.
- Object attaching to the magnet on the bottom of a rack: Inspect for small metal objects such as staples or paper clips on the magnets on the bottom of a rack. If foreign matter attaches to the magnet, remove it from the magnet.

#### **Printer Problems**

Refer to the printer manual for assistance with all printer troubleshooting.

- Printer is disconnected. Inspect the plug and socket and connecting lead.
- The power to the printer is not turned on. Confirm that the power to the printer is turned on.
- Printer toner is empty and requires replacement.
- Confirm that the online button is on.
- Confirm that paper is loaded correctly.

#### **Data Processor Problems**

#### Menu Cannot be Selected

- Function is inaccessible: Menu items which are not available are inaccessible because of the programmed settings.
- System software crashes, to reset the system:
  - Press **Ctrl** + **Alt** + **Delete** together.
  - Select Shutdown, and then OK.
  - After the PC shuts down, press **EM STOP** and wait 5 seconds before pressing **RESET**, and then wait another 5 seconds before pressing **ON**.
  - The software and analyzer synchronize and load at the same time.
  - The system displays the System Start dialog with a Program Down Load to Analyzer message.
  - The System Start dialog displays a message to confirm database retrieval. Select **OK.**
  - The system displays a New Index dialog prompting the operator to create a new index. If the operator wants to remain in the current index, select **Index**. If a new index is necessary, select **New Index**.
  - The analyzer goes into *Warm up* mode for 90 minutes. If the analyzer has been down longer than 5 minutes, then allow the 20-minute warm up. The operator can then select **Home** > **Analyzer Maintenance**, and select **Stand By (F4)**. The analyzer bypasses *Warm up* to *Standby*.



The incubator remains red in the Analyzer Status screen until the temperature returns to 37  $^{\circ}$ C  $\pm$  0.3  $^{\circ}$ C.

• If you are unable to recover from a software crash, contact Beckman Coulter.

9-16 B04779AB

### Number Key Pad on Keyboard Does Not Work

**Num Lock** is not selected: Press the **Num Lock** key and then confirm that the LED light over **Num Lock** on the keyboard is on.

### **Keyboard Not Responding**

Possible causes:

- Keyboard cable: Confirm that the cable connector is in the correct socket in the back of the computer (color-coded).
- System crash: For more information, refer to Menu Cannot be Selected.
- System busy: The system might be saving data or performing a series of tasks simultaneously. Wait for a few minutes until the system is ready. If this error occurs frequently, contact Beckman Coulter.
- Data processing, such as data saving, is executing: Wait until data processing is complete.
- Electrical Noise: If you hear a buzzing noise, unplug the keyboard and then firmly plug in the cable connector.

### **Inaccessible Floppy Disk**

Inspect for:

- The floppy disk is not formatted correctly: Format the floppy disk. You can use these two types of disks:
  - 1. Formatted, 2HD 1.44 MB
  - 2. Formatted, 2DD 720 KB
- Floppy disk is write-protected: Slide the tab on the disk cover. If the diskette is punched, put in a new blank unpunched diskette.
- Floppy disk is damaged: If writing is continuously unsuccessful, the floppy disk is probably damaged. Use a new disk.
- Floppy disk drive damaged: If the floppy disk is new and correctly formatted and data still cannot be saved, then the floppy disk drive might be broken. Contact Beckman Coulter.

### **Results Do Not Print Automatically**

Inspect for:

Realtime output is not set: Set the realtime output of reports from Menu List > System > Format > List Format > Basic Condition, select Edit (F1), and then select Realtime List (F5).

For more information, refer to the AU680 Reference Manual.

- Printer is not available during analysis (out of paper, printer is turned off, or the printer is offline): Turn on the printer, confirm that the printer is online, and add paper as needed.
  - Select Home > Analyzer Status.
  - Select Printer Control (F5).
  - Select **Resume** to start printing the analyzed data.

#### **Troubleshooting**

Recovering from an Emergency Stop or Power Loss

### Online Auto-Output by Host Computer Not Executed

Inspect for:

- Interface cable to the laboratory information system disconnected: Connect the cable.
- Interface cable defective: Contact Beckman Coulter.
- Laboratory information system I/O settings incorrectly modified: Set the correct I/O settings in **System > Online**.

For more information, refer to the AU680 Reference Manual.

## **Recovering from an Emergency Stop or Power Loss**

If there is a power failure or an emergency stop, the main power is turned off immediately. Power to the incubator and reagent refrigerator is also turned off.



If an emergency stop or power failure occurs during *Measure* mode, any data that is not complete is lost and you must reanalyze the samples.



If you perform a stop or emergency stop or a power loss occurs, sample can remain in the sample probe, and reagents can remain in the cuvettes. Perform a W1 to clean the sample probe and cuvettes after you restart the system. For more information, refer to Perform a W1.



If the system is without power for a lengthy time after a power loss or an emergency stop, inspect the reagent integrity before resuming analysis.

#### **Perform an Emergency Stop**

An emergency stop turns off power immediately to the analyzer and ISE module.

- 1 Press the **EM STOP** button. All power to the analyzer and ISE module turns off immediately. The computer remains on. To turn off the computer, press **[Ctrl] + [ALT] + [Delete]**. The computer displays a Windows Security dialog. Select **Shut Down**.
- **2** Remove all racks from the rack transport belts.

### Return to Standby Mode After an Emergency Stop

1 Press the **RESET** button (white button on the front-right of the analyzer) to turn on the main power, and then wait 5 seconds.

9-18 B04779AB

- **2** Press the **ON** button (green button on the front-right of the analyzer). The lamp turns on and the software loads. The system displays a dialog to confirm retrieving the database.
- 3 Select OK.
- 4 In the New Index dialog, select **Current Index** to continue analysis in the current index.
- 5 The system is in *Warm up* mode for 1.5 hours. After the required 20-minute lamp warm up time, wait until the temperature of the cuvette wheel is 37 °C, and then select **Home** > Analyzer Maintenance. Select Stand By (F4) to return to *Standby* mode.
- **6** Perform a W1. For more information, refer to Perform a W1.

#### **Inspect Sample Results**

The following list is available for samples in the current index. If the operator shuts down the system (End Process) and the system turned on, the operator is prompted to create a new index in the New Index dialog.

- 1 Select Home > Sample Manager > Sample > Main. A list of samples processed in the current index displays.
- **2** Confirm the sample ID of the last completed sample.

#### **Performing a Reagent Check**

- 1 Select Home > Reagent Management > Main.
- **2** Select **Reagent Check (F5)**. The system displays the Reagent Check dialog.
- 3 Select Check all positions.
- 4 Select Start.

The system starts the reagent check. As the system progresses in the reagent check, the system displays the status **Checking** in the Reagent Status section (refer to Figure 2.15 Reagent Management: Main Tab), with the progress bar to indicate the progress. When the reagent check is complete, the status changes to **Checked**.

### **RTWB Troubleshooting Overview Flowchart**

The flowchart shows an overview of errors and corrective actions for monitoring the automatic RTWB check function while the system is in operation.

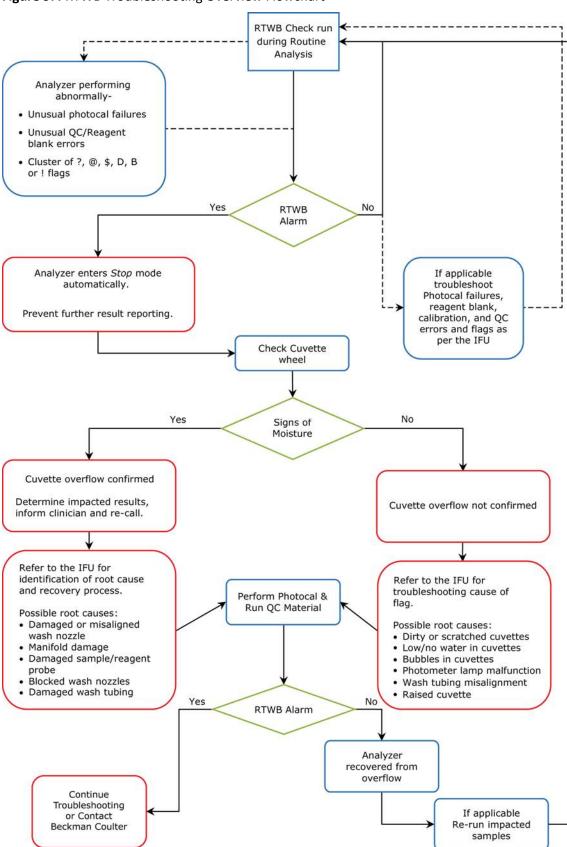


Figure 9.4 RTWB Troubleshooting Overview Flowchart

9-20 B04779AB

## **Recovering from a Photometry Error During a Cuvette Wash Alarm**

Inspect the cuvettes to determine if a cuvette overflow occurred when the system generated a Photometry Error During a Cuvette Wash alarm. The recovery procedures are different if a cuvette overflow occurred, or if unstable photometry caused the error.

The analyzer goes to *Stop* mode immediately after the system generates a Photometry Error During a Cuvette Wash alarm.

### Inspect the Cuvettes to Determine if an Overflow Occurred

To confirm that a cuvette overflow has occurred, remove the cuvette wheel cover after initializing system. The cuvettes are frosty or white. If the cuvettes are dark, black, or are wet when removed, a cuvette overflow has occurred. In addition, remove the cuvette number identified in the Photometry Error During a Cuvette Wash ### alarm. The ### identifies the cuvette number that generated this alarm (cuvette number 1 to 165). Visually inspect the cuvette to determine if it is wet. If the cuvette is wet on the outside, refer to Recovering from a Cuvette Wheel Overflow and perform all system recovery procedures. If the cuvette is not wet on the outside, refer to Recovering from an Unstable Photometry Error and perform the required system recovery procedures determined by the cause of the error.

For more information on how to remove the cuvette wheel, refer to Clean the Cuvettes and the Cuvette Wheel.

## **Recovering from a Cuvette Wheel Overflow**

The following procedure explains what can cause an overflow and how to recognize and recover from a cuvette wheel overflow.

Performing scheduled maintenance reduces the chances of a cuvette wheel overflow. For more information about maintenance for each system component, refer to Maintenance.

### **Overflow Causes**

The following can cause a cuvette wheel overflow:

- A wash nozzle is clogged or partially clogged. When the wash nozzle is clogged, liquid is not aspirated from the cuvette completely and eventually liquid spills over the side. A clogged wash nozzle can occur when the wash nozzles are not cleaned correctly, or when particles such as glass are aspirated into the nozzle.
- A wash nozzle is bent or damaged.
- Damaged or missing O-rings inside the water supply tube mounting joint.
- The reagent probe is bent. A bent probe could be dispensing outside of the cuvette.
- The sample probe is bent. A bent probe could be dispensing outside of the cuvette.
- Cuvettes are chipped or cracked caused by alignment problems with the reagent probes or wash nozzles.
- The wash nozzle tubing is not connected to the nozzle.

#### **Troubleshooting**

Recovering from an Unstable Photometry Error

### **Recognizing an Overflow**

The system generates a Photometry Error During a Cuvette Wash alarm. The overflow could have occurred 60 minutes before the system generated the alarm. Results obtained during the 60 minutes before the alarm are invalid and need reanalysis. The 60-minute timeframe is the time the analyzer was in *Measure* mode. For detailed instructions, refer to Identifying and Reanalyzing Samples after a Cuvette Overflow.

The flags \*, ?, @, \$, D, B, and ! can indicate a cuvette wheel overflow. The data, alarms, or flags vary depending on the severity of the overflow. An overflow can affect one or all tests. Items to inspect:

- QC flags or alarms
- Reagent blank flags
- Analyzer not performing as normal operation
- Numerous cuvettes fail after a photocal

Lift the cuvette wheel cover. The cuvettes are frosty or white. If they are dark, black, or wet when removed, the cuvette wheel has overflowed.

### Items to Confirm when Recovering from an Overflow



Perform corrective actions for an overflow immediately. If nothing is done to correct the problem, the wheel continues to overflow. Contact Beckman Coulter for assistance with performing these procedures.

- Align the wash nozzle component over the cuvettes. Visually inspect and confirm the wash nozzles are centered over the cuvettes and inspect the alignment.
- Sonicate and clean the wash nozzles with a stylet to remove any debris.
- Inspect the reagent and sample probes to confirm the probes are correctly aligned. Rotate the sample and reagent probes over the cuvette wheel.
- Inspect for chipped or cracked cuvettes. Replace them if necessary. For more information, refer to Clean the Cuvettes and the Cuvette Wheel.
- Confirm that the wash nozzle tubing connections are secure.
- Confirm that the O-rings inside the water supply tube mounting joint are in position and not damaged.

### After the Overflow is Corrected

After you correct the cuvette wheel overflow, refer to Clean the Cuvettes and the Cuvette Wheel.

## **Recovering from an Unstable Photometry Error**

When the system generates a Photometry Error During a Cuvette Wash alarm, and a cuvette overflow did not occur, unstable photometry causes the alarm. Incorrectly placed cuvettes in the cuvette wheel, an insufficient amount of wash solution being supplied to

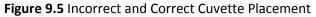
9-22 R04779AB

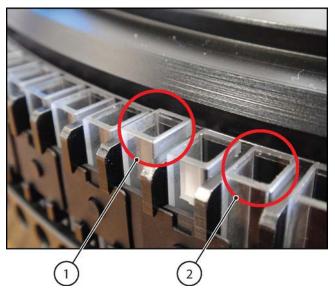
clean the cuvettes, bubbles in the bottom of the cuvettes, dirty or scratched cuvettes, or a deteriorating lamp can cause unstable photometry.

Perform the following procedures in this section. After the error is identified and corrected, perform a photocal. For more information, refer to Perform a Photocal. If the error still occurs, contact Beckman Coulter.

### **Inspect the Cuvette Placement**

Inspect the cuvette identified by the Photometry Error During a Cuvette Wash alarm to determine if it is placed in the cuvette wheel correctly. Push the cuvette down into the cuvette wheel until the top of the cuvette is even with the cuvette wheel.





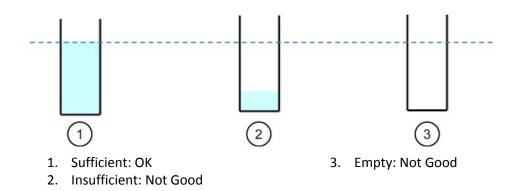
- 1. Incorrect cuvette placement
- 2. Correct cuvette placement

### **Inspect the Cuvette Condition**

1 Inspect the cuvettes identified by the Photometry Error During a Cuvette Wash alarm to determine if there is sufficient wash solution in the cuvette.

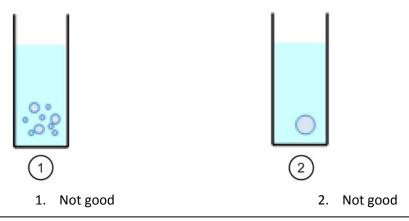
If the remaining wash solution volume is insufficient or empty, there is a possibility of system malfunction. Contact Beckman Coulter.

Figure 9.6 Wash Solution Level in Cuvette



**2** Inspect the cuvette to determine if there are any bubbles at the bottom of the cuvette.

Figure 9.7 Bubbles in Cuvette



- If bubbles exist in the cuvette, inspect the water and wash solution supply tubing on the wash nozzle component to determine if there are bubbles. The aspiration tubing has bubbles in normal operation.
- 4 If bubbles exist in the water and wash solution supply tubing on the wash nozzle component, tighten the tube mounting joints and remove the bubbles by performing a W1 or Prime Wash Nozzle.

For more information, refer to Perform a W1 and Replace the O-rings in the Water Supply Tube Mounting Joint.

9-24 B04779AB

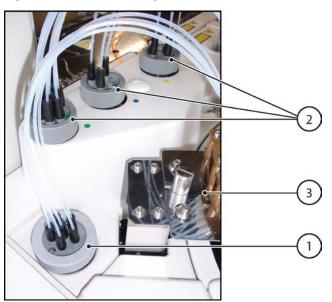
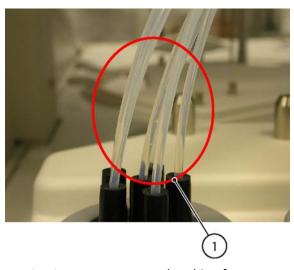


Figure 9.8 Tube Mounting Joint Manifolds

- Water supply tube mounting joint manifold (A total of six O-rings are used inside)
- 2. Wash nozzle tube mounting joint manifolds
- 3. Wash nozzle component

Figure 9.9 Water Supply Tubing



- 1. Inspect water supply tubing for bubbles
- 5 Inspect the cuvette to determine if it is dirty or scratched. Clean or replace the cuvette as required. For more information, refer to Clean or Replace Individual Cuvettes.

### **Inspect the Lamp**

Select Home > Analyzer Maintenance > Consumption.

### **Troubleshooting**

**Laboratory Automation System Problems** 

Confirm the number of hours the lamp has been in use. If the lamp has been in use for over 1,000 hours, replace the lamp.

For information on how to replace the photometer lamp, refer to Replace the Photometer Lamp.

### **Laboratory Automation System Problems**

To put the AU680 in *Standby* mode, select **Feeder Stop**.

For problems with the laboratory automation system, refer to the laboratory automation systems manual.

When problems exist on the laboratory automation system, you can analyze samples from the STAT table.

9-26 B04779AB

## **System Specifications**

This section summarizes AU680 information such as size, required clearances, power requirements, and temperature requirements. For more information on other configurations, contact Beckman Coulter.

#### **Placement**

To operate this system safely and accurately, confirm that the installation room:

- Is not subject to direct sunlight.
- Is not excessively dusty or subject to large amounts of airborne particles. This system withstands up to pollution degree 2 as defined by IEC and UL standards.
- Is level, with a gradient less than 1/200.
- Is not subject to vibration.
- Has a floor that can support a minimum of 700 kg (1540 pounds). This weight includes the personal computer attached to the system.
- Is located less than 6,561 feet or 2,000 meters above sea level.
- Contains no corrosive gases.

#### **Electrical and Noise Conditions**

Prepare the power source before system delivery.

- Have a power connector within 33 feet, or 10 meters of the location of the system.
- Have a 20A capacity of the circuit breaker on the power switchboard.
- Have a power source with maximum voltage fluctuations (± 10%) and transient overvoltage less than 2500 V.



To avoid electrical damage to the system caused by uneven current, use an uninterruptible power supply (UPS) to connect the system to electrical power. For more information, contact Beckman Coulter.

- Confirm that the system is always grounded. The grounding terminal is be less than  $100~\Omega$  of grounding resistance defined in the technical standards for electrical facilities.
- Do not locate this system near equipment that generates extreme levels of electromagnetic or electrical noise.
- Do not use mobile or cordless telephones and transceivers in the room where the system is installed.

• Do not use medical equipment that can be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the analyzer Data Processing Module (DPR) or the monitor.



Connect all the grounding terminals provided on the system and distribution panel to ground. Failure to ground the terminals can cause electric shock and system malfunction.

Figure A.1 Crimp Terminal Hole



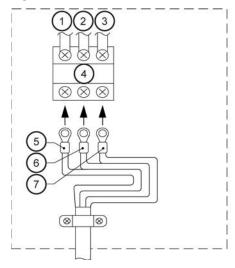
1. Crimp terminal hole diameter 5.4 mm



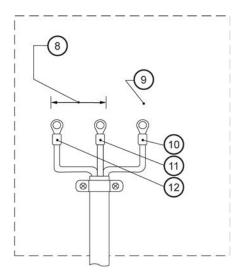
Only a Beckman Coulter representative can connect the power cable.

- When connecting the power cables to the system, connect the grounding terminal first. To disconnect the cables, disconnect the grounding terminal last.
- Connect the power cables to the distribution panel.

Figure A.2 Distribution Panel



- 1. Gray
- 2. White
- 3. Green
- 4. Terminal board
- 5. Black



- 6. White (All markets except Europe), or Blue (Europe market)
- 7. Green (All markets except Europe) or Yellow/Green (Europe market)

- 8. Connect these terminals to the power source specified for this system
- 9. Connect this terminal to a grounding terminal that measures less than 100  $\Omega$
- 10. Green (All markets except Europe), or Yellow/Green (Europe market)
- 11. White (All markets except Europe), or Blue (Europe market)
- 12. Black

For Europe, Black/Blue/Yellow Green is required for Live/Neutral/Ground.

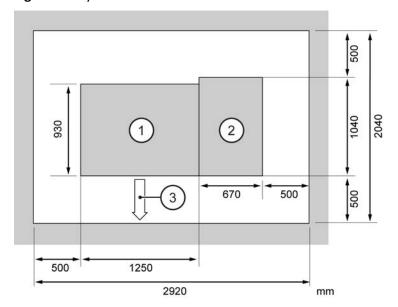
For all markets except Europe, Black/White/Green is required for Live/Neutral/Ground.

#### Clearance

The system includes the analyzer and the optional rack feeder module.

This system requires space of a minimum of 500 mm (20 inches) from the wall around it for safe installation and maintenance.

Figure A.3 System Clearance



1. AU680 Analyzer

- 3. Front
- 2. AU680 Rack Feeder Module

### **Dimensions**

Table A.1 Dimensions

Module	Dimensions				
	Length	Height	Depth	Weight	
	mm	mm	mm	kg	
Analyzer	1250	1280	930	460	
Rack Feeder Module	670	940	1040	130	

### **PC Rack Component (Option)**

When using a separate type PC rack component, this system requires space around it for safe installation and maintenance.

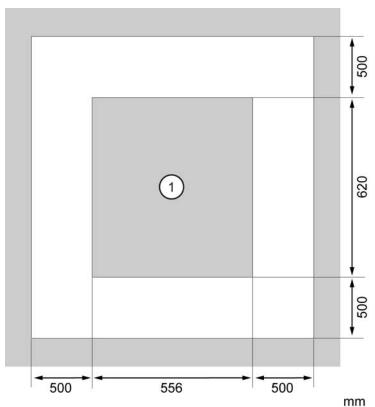


Figure A.4 PC Rack Component (Option)

Table A.2 PC Rack Component Dimensions

Module	Dimensions					
	Length Height Depth				pth	
	mm	feet	mm	feet	mm	feet
PC Rack Component	556	1.8	1550	5	620	2

### **Water Supply and Drain**

Table A.3 Water Supply and Drain

Specification	Requirement	
Deionized water conductivity	2.0 $\mu$ S/cm or less (water transmitted through a filter of 0.5 $\mu$ m or less)	
Water pressure	0.49×10 <sup>5</sup> to 3.92×10 <sup>5</sup> Pa (or 7 to 57 psi)	

A-4 B04779AB

Table A.3 Water Supply and Drain (Continued)

Specification	Requirement	
Water consumption	Average: 28 L/hour (50/60 Hz)	
	Maximum water demand: 1.0 L/minute (50/60 Hz)	
Deionized water temperature	5 to 28 °C (41 to 83 °F)	
Water-supply hose	12 mm x 18 mm x 10 m	
Concentrated waste solution hose, diluted waste solution hose	15 mm x 22 mm x 10 m	
Exhaust hose	12 mm x 18 mm x 10 m	
Drainage height	1.5 m or less from the floor	
Exhaust outlet	0.1 m or less from the floor surface	

The water supply and liquid waste facilities have the following additional requirements.

- The system is located within 10 m (33 feet) of the deionized water outlet. A drain is within 10 m (33 feet) and less than 1.5 meters high.
- Deionized water supplied to the system does not contain excessive air bubbles.

The system includes the following tubing:

- Water supply hose: Braided hose 12 mm (ID) x 18 mm (OD), L=10 m (33 feet), 1 piece.
- Exhaust Air hose: Braided hose 12 mm (ID) x 18 mm (OD), L=10 m (33 feet), 1 piece.
- Waste liquid hose: Braided hose 15 mm (ID) x 22 mm (OD), L=10 m (33 feet), 2 pieces



If the tap water temperature exceeds the optimal temperature range for the deionizer, consult the deionizer manufacturer. When using the existing water supply tubing and deionizer, confirm that it is micro-organism free.



The water pressure for this system operates at a range from  $0.49 \times 10^5$  to  $3.92 \times 10^5$  Pa. For the correct water pressure for the deionizer, contact the deionizer manufacturer. Beckman Coulter recommends use of a reverse osmotic membrane as the deionizer. For more information, contact Beckman Coulter.

#### **Drainage and Exhaust**



Follow your laboratory procedure for disposal of all liquid and infectious waste.

The system discharges waste liquids by forced drain and moist air containing the components of waste liquids.

- Condensed waste liquid: Compound liquid of sample and reagent retrieved from cuvettes and wash solution.
- Diluted waste liquid: Waste liquid used for washing cuvettes, mix bars, and so on.

### Requirements:

- Place the drain hole within 10 m (33 feet) from this system.
- Connect the drain to an infectious waste collection tank as required by law.
- The drain must be located no higher than 1.5 m and the exhaust no higher than 0.1 m above the system installation floor.
- Keep the ends of exhaust air hoses and the waste liquid hoses, which are inserted into the drain, above the liquid level of the drain.
- Confirm that the liquid waste hoses are not bent or crushed.
- Drainage capability for concentrated and diluted liquid waste is:
  - Concentrated waste liquid: 10 L/hour
  - Diluted waste liquid: 18 L/hour

### **Environmental Requirements**

### **Temperature and Humidity Conditions When in Use**

Heat output by the system during operation is approximately 9600 kj/h (9100 BTU).

When the specified room temperature and humidity ranges fluctuate, the system data may not be reliable. When the system is in operation, confirm that the following requirements are met.

Confirm that the system is not exposed to direct airflow from air conditioners.

**Table A.4** Temperature and Humidity

Specification	Requirement	
Temperature	18 to 32 °C (64 to 90 °F)	
Temperature fluctuation	±2 °C (3.6 °F) or less during measurement	
Humidity	20 to 80% RH (without condensation)	



The installation site must be well ventilated. For more information, refer to Clearance.

#### **Temperature and Humidity Conditions When Not in Use**

- The temperature is between 5 °C (41° F) and 40 °C (104° F).
- The humidity is between 15% RH and 90% RH.

A-6 B04779AB

### **Power Requirements**

**Table A.5** Power Requirements

Specification	Requirement
Voltage, Frequency	AC 208 V 50/60 Hz (USA)
	AC 230 V 50/60 Hz (Europe)
	AC 220 V 50/60 Hz (Asia)
	AC 240 V 50/60 Hz (Australia)
	AC 200 V 50/60 Hz (Japan)
Maximum rated power consumption	3.8 kVA

### **Bar Code Reader**

 Table A.6
 Sample ID Bar Code Reader Specifications

Item	Specification
Wave length	650 nm
Maximum output	1.5 mW
Pulse width	65 μS
Frequency	500 Hz
Class	2
Beam divergence	60 degrees

 Table A.7
 STAT Table Bar Code Reader Specifications

Item	Specification
Wave length	650 nm
Maximum output	1.5 mW
Pulse width	65 μS
Frequency	500 Hz
Class	2
Beam divergence	60 degrees

### **Hand Scanner**

**Table A.8** Hand Scanner Specifications

Item	Specification	
Wavelength	630 to 680 nm	
Output	1.0 mW	
Class	2	

### **System Specifications**

**General Specifications** 

### **Regulatory Compliance**

This system complies with IEC60825-1: 2007.

### **General Specifications**

#### **Method of Analysis**

Discrete method

### Configuration

Analyzer

Data processor

### **Option**

Rack feeder module<sup>1</sup>

**ISE** 

Printer

PROService kit

Rack tray

Hand scanner

DTS (Direct Track Sampling) kit

Water supply equipment

External storage device

PC rack component

LAN connections kit

#### Type of Sample

Serum, plasma, urine, other fluids with viscosities in the same range as serum, whole blood (HbA1c)

#### **Number of Simultaneous Analytes**

Maximum of 60 photometric + 3 ISE tests on board

### **Throughput**

Maximum 800 photometric tests/hour or 1200 photometric + ISE tests/hour Maximum 100 tests/hour for analysis of only HbA1c

When the AU680 connects to a laboratory automation system, throughput depends on the laboratory automation system.

#### **Data Input Methods**

Touch screen

A-8 B04779AB

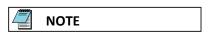
<sup>&</sup>lt;sup>1</sup> The rack feeder module is specific for the AU680 analyzer.

Keyboard Mouse Online (RS232C and TCP/IP) Hand scanner CD

### **Data Output Methods**

Monitor display
Printer (option)
Online (RS232C and TCP/IP)
External storage device (option)
PROService (option)
Internal hard disk

## **Cups or Tubes Specifications**



BD indicates a Becton Dickinson PN. The BD tube or its equivalent can be used.

**Table A.9** Cup or Tube Available for Racks or STAT Table

Cup or Tube	Size	PN	Dead Volume (μL)
Hitachi cup	2.0 mL	MU853200	50
Auto aliquot tube	13 mm	2910034	80
Serum Separator Tube	13 x 100 mm	BD 367986	4 mm above the non- sample (cells or gel) layer
Serum Separator Tube	16 x 100 mm	BD 367988	4 mm above the non- sample (cells or gel) layer
Lithium heparin with gel separator (light green top)	13 x 75 mm	BD 367960	4 mm above the non- sample (cells or gel) layer
Lithium heparin with gel separator (light green top)	13 x 100 mm	BD 367962	4 mm above the non- sample (cells or gel) layer
Lithium heparin (green top)	13 x 75 mm	BD 367884	4 mm above the non- sample (cells or gel) layer
Lithium heparin (green top)	13 x 100 mm	BD 367886	4 mm above the non- sample (cells or gel) layer
Primary tube (red top)	13 x 75 mm	BD 366668	140

 Table A.9
 Cup or Tube Available for Racks or STAT Table (Continued)

Cup or Tube	Size	PN	Dead Volume (μL)
Primary tube (red top)	13 x 100 mm	BD 367815	140

 Table A.10
 Cup Nested (Inserted) in Tube Available for Racks

Cup, Size	PN	Tube	PN	Dead Volume (μL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	50
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	50
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960	140
			BD 367884	
			BD 366668	
Access 2 cup, 1.0 mL	81915	13 x 100 mm	BD 367962	140
			BD 367886	
			BD 367815	
Hitachi cup, 2.0 mL	MU853200	SST 16x100 mm	BD 367988	50
EZ Nest cup	1270013000	13 x 75 mm	BD 367960	50
			BD 367884	
			BD 366668	
EZ Nest cup	1270013000	13 x 100 mm	BD 367962	50
			BD 367886	
			BD 367815	
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50
EZ Nest cup	1270016000	16 x 100 mm	BD 367988	50

 Table A.11
 Cup Nested (Inserted) in Tube Available for STAT Table

Cup, Size	PN	Tube	PN	Dead Volume (μL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	50
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	50

A-10 B04779AB

 Table A.11
 Cup Nested (Inserted) in Tube Available for STAT Table (Continued)

Cup, Size	PN	Tube	PN	Dead Volume (μL)
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960	140
			BD 367884	
			BD 366668	
EZ Nest cup	1270013000	13 x 75 mm	BD 367960	50
			BD 367884	
			BD 366668	
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50

## **Sampling Specifications**



### NOTE

When the AU680 connects to a laboratory automation system, the AU680 does not use racks. Refer to the laboratory automation system specifications for tubes and cups that can be used on the system.

### **Sample Capacity**

Maximum 150 samples (15 racks)

### **Sample Dispensing System**

Micro-syringe system

The system is provided with the following functions:

- Liquid level detection
- Clot detection
- Collision detection
- Pre-dilution

### Sample Volume

 Table A.12
 Sample Volume for All Markets Except Japan

Sample	Volume
Normal dispensing	1.6 to 25.0 μL/test, in steps of 0.1 μL
Dispensing with dilution	1.6 to 20.0 μL/test, in steps of 0.1 μL

Table A.13 Sample Volume for Japan Market

Sample	Volume
Normal dispensing	1.0 to 25.0 μL/test, in steps of 0.1 μL (Japan only)
Dispensing with dilution	1.0 to 20.0 μL/test, in steps of 0.1 μL (Japan only)

#### **Rack Type**

NE racks are required on the system.

- Blue rack
- Yellow rack
- Green rack
- White rack
- · Red rack
- Orange rack

## **Reagent Specifications**

### **Reagent Storage Capacity**

Table A.14 Reagent Storage Capacity

Module	Capacity
R1 refrigerator	60 with serial reagent bottle capability
R2 refrigerator	48 with serial reagent bottle capability

### Refrigeration

Refrigeration temperature: 4 to 12 °C (39.2 to 53.6 °F)

### **Reagent Setting Method**

· Turn table method

### **Type of Reagent**

- Normal concentration reagent
- · Highly concentrated reagent

### **Reagent Dispensing System**

Micro-syringe with collision detection function for the probe

### **Number of Reagent Steps**

Maximum 3 steps

A-12 B04779AB

### **Reagent Volume Setting Range**

### Table A.15 Reagent Volume for All Markets Except Japan

Reagent	Volume
Normal dispensing	15 to 250 μL in 1.0 μL increments
Dilution dispensing	10 to 235 μL in 1.0 μL increments

### **Table A.16** Reagent Volume for Japan Market

Reagent	Volume
Normal dispensing	10 to 250 μL in 1.0 μL increments (Japan only)
Dilution dispensing	10 to 240 μL in 1.0 μL increments (Japan only)

## **Reaction System Specifications**

#### **Reaction Incubation Method**

Dry bath system

### **Reaction Temperature**

Dry bath: 37± 0.3 °C (98.6± 0.5 °F)

### **Reaction Solution Amount**

- 120 to 420 μL (All markets except Japan)
- 90 to 350 μL (Japan market only)

### **Reaction Time**

Maximum 8 minutes 33 seconds

### **Mixing System**

Rotative mixing bar system

#### **Reaction Cell**

Glass square cuvette

- Optical path length: 6 mm (All markets except Japan)
- Optical path length: 5 mm (Japan market only)

#### **Reaction Line**

Rotary disk system: 165 cuvettes

## **Analytical Method Specifications**

### **Photometric points**

28

#### Type of Measurement

- End point assay
- · Rate assay
- · Fixed point assay
- Electrode method (ISE) (option)

## **Optical System Specifications**

#### **Photometer**

Multi-wavelength diffraction grating spectrophotometer

### **Photometric Modes**

Monochromatic or bichromatic

### Wavelengths

340 to 800 nm (13 steps of 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, and 800 nm)

### **Photodetector**

Silicon photodiode array

### **Light Source**

Halogen lamp 12 V/20 W

### **Measurable Absorbance Range**

0 to 3.0 Abs (converted in units of 10 mm of optical path length)

#### **Photometric resolution**

0.0001 Abs

A-14 B04779AB

## **Data Processing Specifications**

### **Storage Capacity**

Table A.17 Data Storage Capacity

Data	Hard Disk Storage Capacity
Patient Samples	100,000 samples 9999 samples/index Maximum 300 indexes Reaction Monitor data: A maximum of 10,000 tests per index and a maximum of 100,000 tests in multiple indexes
QC Samples	999 samples/index  Maximum 300 indexes

### **Data Processing Configuration**

• Hard disk: 200 GB or more

• Memory capacity: 2 GB or more

• Keyboard: 101-109 keyboard

• Touch panel monitor

• CD-R drive

• Printer (option)

## **Calculation Processing Specifications**

### Calculation

- Calibration
  - Analytical method
    - End point assay
    - Rate assay
    - Fixed point assay
    - Electrode method (ISE)
  - Calibration method
    - ACAL AA
    - ACAL AB
    - ACAL 2AB to ACAL 7AB
    - 4 MC to 10 MC
    - MCAL MB

### **System Specifications**

**Input and Output Specifications** 

- MCAL 2MB to MCAL 7MB
- Calibration curve type
  - Straight line
  - Polygonal line
  - Quadratic expression
  - Tertiary expression (2 types)
  - EIA-TYPE 1 to 4
  - Spline
- Correction
  - Water blank correction
  - Reagent blank correction
  - Sample blank correction
  - Data correction

### Quality control (QC)

- · QC samples
  - Maximum 10 types/test
  - Maximum 100 types in total
- · Quality control method
  - Shewhart day-to-day management (Levey-Jennings method)
  - Multi-rule control (Westgard method)
  - Twin-plot control

### **Input and Output Specifications**

#### Worksheet

- Routine sample worksheet
- Emergency sample worksheet
- Repeat sample worksheet
- · QC sample worksheet
- Calibration worksheet

#### **Data Input and Output**

- Test requisitions: Keyboard entry, real-time online, batch online
- Analysis result output: Real-time, batch online

### Input and Output To and From an External Device

- Online input and output
  - RS232C and TCP/IP
- Offline output
  - —CD-R
  - External storage device (HD) (option)

A-16 B04779AB

### — Floppy disk

## **ISE Specifications**

### Reagents

• ISE Buffer Solution: 2L bottle

ISE MID Standard Solution: 2L bottle
ISE Reference Solution: 1L bottle

#### **Measurement Method**

Indirect (diluted) ion-selective electrode

#### **Measurement Items**

Na, K, and Cl ions in serum or urine

### **Throughput**

200 samples per hour

### **Sample Volume**

20 μL plus 10 μL deionized water

### **Dilution Ratio**

32.4 times (deionized water 10  $\mu$ L, ISE Buffer Solution 618  $\mu$ L)

### Measuring Range (mmol/L)

Table A.18 Measuring Range (mmol/L)

Test Item	Serum	Urine
Na	50 to 200	10 to 400
К	1.0 to 10.0	2.0 to 200
CI	50 to 200	15 to 400

### **Calibration Curve**

Automatic calibration curve:

Measures the high-concentration calibrator and low-concentration calibrator to set two points on the chart.

#### **Data Correction**

Enables manual calibration chart correction (MCAL) and automatic calibration chart correction (ACAL, 3-point regression CAL).

#### **Drift Correction**

Automatic correction:

Measures the electrical potential of ISE MID Standard Solution for each sample to perform drift correction.

### **Types of Consumables and Appropriate Consumption**

 Table A.19
 Types of Consumables and Appropriate Consumption

Name	Approximate Daily Consumption
ISE Buffer Solution	Approx. 180 mL (in case of 200 serum samples/day)
ISE MID Standard Solution	Approx. 260 mL (in case of 200 serum samples/day)
ISE Reference Solution	Approx. 35 mL (in case of 200 serum samples/day)
ISE Cleaning Solution	Approx. 1 mL (in case of 200 serum samples/day)

## **PC Rack Specifications**

### **PC** Weight

Whole type: maximum of 15 kgSeparate type: 10 kg to 15 kg

### **Monitor Weight**

Maximum of 8 kg

### **Keyboard Weight**

Maximum of 2 kg

### **Printer (Option) Weight**

5 kg to 50 kg (separate type)

A-18 B04779AB

# Glossary

- ACAL (Auto Calibration) The AB type (or ACAL) uses calibrator material to calculate a calibration factor automatically and create a calibration curve each time the system calibrates. The calibration types are defined in parameters as AB (single point), AA, or 2AB-7AB (multi-point) for each test.
- Alarm Shots (Tests) The Alarm Shots (Tests) function enables the operator to set the quantity of remaining reagent tests (shots) which, when reached, prompts a reagent short alarm.
- Advanced Calibration The system can calibrate a maximum of 5 bottles or lot numbers of the same reagent before the system uses the reagent.
- **Auto Power On** Allows the operator to set a date and time when the system automatically powers on the analyzer.
- **Calibration Curve** A curve calculated from the absorbance and concentration of the calibrator. The system then calculates the analyte concentration for a sample using the calibration curve.
- **Calibration History** The system saves a maximum of 100 points of calibration data per sample type per test. View calibration data and status in the Calibration Monitor screen.
- **Calibrator** Material with a known value that the system uses to establish the measurement relationship.
- **Consumable** Analyzer parts replaced by the operator if they are damaged or on a periodic basis to maintain optimum performance of the analyzer. Includes photometer lamps, probes, and syringes.

- **Cuvette** A glass vessel the system uses as the reaction vessel, containing the sample and reagent.
- **Dead Volume (Reagent)** Reagent volume that the reagent probe cannot aspirate, and remains in the bottle. The dead volume depends on the size of the reagent bottle.
- **Dead Volume (Sample)** Sample volume that the sample probe cannot aspirate, and remains in the tube or cup. The dead volume depends on the type of cup or tube.
- Deciding Test Generates an automatic repeat order (requisition) for the Related Test when resulting in a repeat, fl, or fh flag. The system also orders (requisitions) the Deciding Test with a repeat flag, but does not order (requisition) it with a fh or fl flag. You can program a maximum of 10 tests as Deciding Test.
- Deionized Water (DI Water) Deionized water, also known as demineralized water, is water that has had its mineral ions removed, such as ions from sodium, calcium, iron, copper, and anions such as chloride and bromide.
- Disabling (a Test) Prevents the system from performing ordered (requisitioned) tests during analysis. Use this function when the preceding calibration or QC has failed for a test for samples that are loaded on the rack supply component. Only tests for patient samples can be disabled (unavailable). Tests for reagent blank, calibration, or QC cannot be disabled (unavailable).

B04779AB Glossary-1

**Dynamic Range** — The range the analyzer can measure for a reagent. If the range is exceeded, the system generates an F (over) or G (under) flag.

**End Point Assay (END)** — The three types of end point assays:

- 1-point assay is a general endpoint assay that determines the optical density of the reaction mixture from the optical density measured at a specified photometric measuring point.
- 2-Point assay (self-blank method) provides sample blank adjustment. The optical density values before dispensing reagent are eliminated as the sample blank. This optical density value is then subtracted from the values calculated after dispensing the second reagent. Any contribution to the final reaction optical density from the sample (turbidity, icterus, and so on) is removed to improve measurement reliability.
- Sample blank correction measures the blank item and then subtracts the value from the measured optical density, to calculate the optical density of the reaction. This method requires an extra blank.

END1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

Fixed Point Assay (FIXED) — A method of calculation that determines the difference between the optical densities at two specific time points within a reaction. FIXED1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

**Flag** — Symbols that display on analysis results, indicating that a problem or an error has occurred during analysis. A

result with a flag must be reviewed and have corrective actions performed before reporting results.

Group — An operator-defined group of tests that are selected in the Start Condition screen. The tests in the selected Group have reagents on-board the analyzer and are available to perform analysis. You can program three Groups in Menu List > Parameters > Common Test Parameters > Group of Tests. For example, designate the tests frequently used for routine analysis to Group 1, and the tests used for specific analysis to Group 2. Perform routine analysis under Group 1 and switch to Group 2 for specific analysis as required.

Index — A data file identified by date and time, used to retrieve reagent blank, calibration, QC, and patient results.

LAG\_TIME Check — If a reaction is terminated too quickly, effective data at two points or more may not be acquired. In this situation, the system can be set up to calculate the analysis result using the data in the lag phase. Used for tests in the rate assay method. Refer to the individual method parameters to determine the correct setting for the test.

LIH Testing - Serum Index — Evaluates and performs test of lipemia (L), icterus (I), and hemolysis (H) in serum and plasma. LIH is the symbol used for testing lipemia (L), icterus (I), and hemolysis (H).

**Linearity** — Ability of a measuring method to generate results that are proportional to the analyte concentration in a sample.

MCAL (MB) — A type of calibration that does not use any calibrator material. A preset MB factor has been determined and is entered per the chemistry setting sheet provided for this type of test.

Glossary-2 B04779AB

- Optical Density (OD) The measurement of the amount of light absorbed by a solution in the cuvette with the use of a photometer. The higher the optical density the lower the transmittance.
- Panic Value An operator-defined critical range. If the range is exceeded, the system generates a ph (high) or pl (low) flag. If the panic range is exceeded, the system also generates an audible alarm.
- Photocal Measurement Evaluates the integrity of the cuvettes used to obtain accurate analysis results. Confirm the photocal data obtained from a photocal measurement from Home > Analyzer Maintenance > Photocal Monitor. For more information, refer to Perform a Photocal.
- **QC Monitor** The QC Monitor gives an instant visual summary of QC analysis results.
- **QC Sample** Material used to confirm the performance characteristics of an in vitro diagnostic medical device.
- Quality Control (QC) Analysis The process of analyzing samples with known concentrations of analytes to test the quality of reagents, calibrators, analyzer, and procedures.

#### Rate Assay (RATE) —

- Normal rate assay measures the variation in the rate of absorbance per minute by calculating the average change in absorbance between two photometric points, using the least squares method.
- Double rate assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations between two measuring points, using the least squares method. The rate of absorbance before

dispensing reagent 2 is subtracted from the value calculated after dispensing the second reagent.

RATE1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

- Reagent Blank (RB) In routine analysis, the reagent blank serves as the reference value for the reagents at each photometric point of individual analysis tests. It also becomes the Y-intercept of calibration curves created by ACAL.
- **Reagent** A combination of chemicals that react with the target analyte in the sample. The AU680 uses either one (R1) or two reagents (R1 and R2) per analyte.
- **Reagent ID** The analyzer identifies reagents placed on-board the analyzer using the bar code label.
- Reflex Testing A function to generate a repeat order (requisition) automatically for the Related Test by linking the Related Test to the Deciding Test. Reflex testing occurs when the Deciding Test has resulted in a repeat, fl, or fh flag.
- Related Test The system automatically orders (requisitions) the test for repeat when the Deciding Test has resulted in a repeat, fl, or fh flag. A maximum of five tests can be programmed as Related Test in combination with a Deciding Test.
- **Repeat Run** A process whereby the analyzer tests the samples again, either manually or automatically.
- **Sample Diluent** Solution the system uses for a manual or automatic dilution of samples.
- **Sample ID** An alphanumeric code assigned and used to identify each

B04779AB Glossary-3

sample. The system reads the sample bar code label attached to the sample cup to identify the sample ID.

Sample Number (Sample No.) — A 4-digit number the analyzer generates and uses to identify each sample. The system displays a sample data prefix in front of the sample number indicating the sample type and repeat.

**Standard Deviation** — Measurement of statistical dispersion. In multiple measurements of the same sample, the standard deviation measures how spread out the values are.

**Test Order (Requisition)** — An instruction to perform tests on a sample. When a sample is placed on the analyzer, the system uses the test order (requisition) information to link the sample to the required tests.

Twin Plot — Determines whether the analyzer causes a problematic variation in QC or if the variation is a random error. Perform QC analysis using two controls: normal and abnormal. The twin plot function displays the first control on the x-axis of a 2-dimensional plot and the second control on the y-axis.

W1 — A maintenance procedure that automatically cleans cuvettes using the wash nozzle component before and after analysis in routine operation. For more information, refer to Perform a W1.

W2 — A maintenance procedure that automatically cleans cuvettes, the sample probe, reagent probes, and mix bars using either sodium hypochlorite solution (0.5%) or 1N hydrochloric acid. After performing the W2, perform a photocal. For more information, refer to Perform a W2.

Glossary-4 B04779AB

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