

AU640e[®]/AU640[®] Chemistry Analyzer

For *In Vitro* Diagnostic Use

CE

BM640V1AB
June 2013



Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.



AU640e® /AU640® Chemistry Analyzer
User's Guide
PN BM640V1AB (JUNE 2013)

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Change History

This document is revised as additional information is available.

DOCUMENT REVISION NUMBER	SOFTWARE VERSION	DATE	CHANGE DESCRIPTION
1			New Manual
2		December, 2002	Update #004: Please replace the method sheets in the Special Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification, On-Board Stability Chart.
3		March, 2003	Update #005: Please replace the method sheets in the Olympus TDM section. Replace the following: Methods Chapter Contents, Document Change Notification, Calibration and On Board Stability.
4		February, 2003	Update #009: Please replace the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
5		March 6, 2003	Update #010: Please replace the method sheets in the Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
6		March 17, 2004	Update #014: Please replace the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
7		March 31, 2004	Update #015; Please replace page F-73 within the Maintenance Chapter F, Document Change Notification.
8		May, 2003	Update #019: Please replace the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
9		May 9, 2003	Update #018: Please replace the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
10		May 14, 2003	Update #021: Please replace the method sheets in the Specific Proteins and Urine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification, On-Board Stability Chart.
11		May 14, 2003	Update #022: Please add the method sheets to the Routine Chemistries section.
12		May 14, 2003	Update #023: Please add the method sheets to the Specific Proteins section.
13		June 30, 2003	Update #028: Please replace the method sheets in the Olympus DAU and DAU's Plus sections. Replace the following: Methods Chapter Contents, Document Change Notification.
14		July 9, 2003	Update #024: Maintenance Chapter Enhancements. Please replace the Document Change Notification sheet in the front of the manual and replace the attached pages to the Maintenance Chapter of the User's Guide.
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16		September 4, 2003	Update #036: Please replace the method sheets in the Specific Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification.
17		September 30, 2003	Update #038: Please place the methods sheets in the Olympus TDM section. Replace the following: Methods Chapter Contents, Document Change Notification.
18		October 22, 2003	Update #043: Please replace the method sheets in methods section. Replace the following: Methods Chapter Contents, Document Change Notification. Calibration and On Board Stability Chart.
19		November 3, 2003	Update #040: Please replace the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
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21		December 5, 2003	Update #047: Please replace the method sheets in methods section. Replace the following: Methods Chapter Contents, Document Change Notification.
22		January 15, 2004	Update #051: Please replace the method sheets in Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
23		January 21, 2004	Update #053: Please replace the method sheets in Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
24		January 22, 2004	Update #017: Please add the method sheets to the Specific Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification.
25		January 23, 2004	Update #052: Please replace the attached pages in the appropriate chapters: Chapter D (Software): Pages D-95 – D-96. Document Change Notification: Replace all pages with DCN-1 – DCN-2.
26		February 5, 2004	Update #049: Please place the method sheets in Specific Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification.
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28		April 14, 2004	Update #055: Please place the method sheets in the Routine Chemistries, Urine Chemistries. Replace the following: Methods Chapter Contents, Document Change Notification.
29		April 14, 2004	Update #056: Please place the method sheets in the Specific Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification.
30		June 9, 2004	Update #062: Please place the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
31		July 16, 2004	Update #065: Please replace or add the attached pages in the appropriate chapters: Chapter D Software: D-125 – D-126 Chapter I Specifications: I-29 – I-30 Methods: Contaminations Parameters tab divider and parameters pages 1-2. Document Change Notification: Pages DCN-1 – DCN-2.
32		July 26, 2004	Update #067: Please place the method sheets in the Olympus TDM section. Replace the following: Methods Chapter Contents, Document Change Notification.
33		September 20, 2004	Update #070: Please place the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
34		October 01, 2004	Update #066: Please place the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
35		October 18, 2004	Update #071: Please replace or add the attached pages in the appropriate chapters: Chapter C – Basic Operations: C-1 – C-2, C-19 – C-22. Chapter D – Software D-43 – D-44, D-47 – D-50, D-65 – D-68. Chapter G – Error Flags G-1 – G-6. Document Change Notification: Pages DCN-1 – DCN-2.

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36		October 29, 2004	Update #073: Please place the method sheets in the Routine Chemistries, STAT Chemistries, and Urine Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.
37		December 20, 2004	Update #077: Please place the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
38		January 12, 2005	Update #072: Please replace or add the attached pages in the Update #069: Please place the method sheets in the Routine Chemistries and Urine Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.
39	7.0	February 1, 2005	Update #084: Please replace or add the attached pages in the appropriate chapters: Chapter C – Basic Operations: C-1 – C-2, C-19 – C-22, C-31 – C-34, C-49 – C-50. Chapter D – Software D-11 – D-12, D-33 – D-34, D-43 – D-44, D-47 – D-50, D-65 – D-68, D-159 – D-162. Chapter F – Maintenance F-47 – F-48 Chapter G – Error Flags G-1 – G-6. Document Change Notification: Pages DCN-3 – DCN-4
40		March 22, 2005	Update #078: Please place the method sheets in Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
41		May 04, 2005	Update #088: Please place the method sheets in the Urine Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.
42		May 12, 2005	Update #091: Please place the method sheet in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
43		May 20, 2005	Update #093: Please place the method sheets in the Specific Proteins, Olympus TDM and Thyroids sections. Replace the following: Methods Chapter Contents, Document Change Notification.
44		July 22, 2005	Update #095: Please place the method sheet in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
45		July 26, 2005	Update #096: Please place the contamination parameters in the Contamination section. Replace this Document Change Notification.
46		September 9, 2005	Update #098 Please place the method sheets in the DAU section. Replace the following: Methods Chapter Contents, Document Change Notification.
47		September 9, 2005	Update #099: Please place the method sheets in the Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
48		September 9, 2005	Update #100: Please place the method sheets in the Olympus DAU section. Replace the following: Methods Chapter Contents, Document Change Notification.
49		September 9, 2005	Update #101: Please place the method sheets in the Specific Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification.
50		November 04, 2005	Update #102: Please place the method sheets in the Routine Chemistries, Urine Chemistries, Specific Protein, and Olympus TDM Sections. Replace the following: Methods Chapter Contents, Document Change Notification.

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51		January 20, 2006	Update #103: Please replace or add the attached pages in the appropriate chapters: Chapter B – System Outline B-3 – B-4 Chapter D – Software D-83 – D-84, D-95 – D-96 Chapter H – Troubleshooting H-31 – H-32 Chapter I - Specifications I-11 – I-12 Document Change Notification: Pages DCN-1 – DCN-4
52		February 17, 2006	Update #105: Please replace the attached pages AU640e Chapter F - Maintenance F-1 – F-87 Document Change Notification: Pages DCN- 3 – DCN-4
53		February 24, 2006	Update #106: Please place the method sheet in the Urine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
54		May 15, 2006	Update #109: Please place the method sheet in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
55		June 16, 2006	Update #112: Please replace or add the attached pages in the appropriate chapters: Chapter C – Basic Operations C-31 – C-32 C-65 – C-66 C-93 – C-96 Chapter D – Software D-99 – D-100 D-125 – D-126 Chapter G – Error Flags G-21 – G-22 Chapter H – Troubleshooting H-13 – H-14 Chapter I - Specifications I-17 – I-18 Document Change Notification: Pages DCN-3 – DCN-4
56		July 14, 2006	Update #114: Please place the method sheets in the Routine Chemistries, Urine Chemistries, and Specific Protein sections. Replace the following: Methods Chapter Contents, Document Change Notification.
57		August 16, 2006	Update #115: Please place the method sheet in the Urine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
58		November 1, 2006	Update #117 & 119: Please place the method sheets in the Routine Chemistries, Urine Chemistries, and Specific Protein. Replace the following: Methods Chapter Contents, Document Change Notification.
59		November 30, 2006	Update #121: Please replace or add the attached pages in the appropriate chapters: Chapter G: G-11 - G-14 - Error Flags *, I, F, and G Document Change Notification: Pages DCN- 5
60		January 16, 2007	Update #123: Please place the method sheets in the Routine Chemistries. Replace the following: Methods Chapter Contents, Document Change Notification.

DOCUMENT REVISION NUMBER	SOFTWARE VERSION	DATE	CHANGE DESCRIPTION
61		March 2, 2007	Update #125: Please replace or add the attached pages in the appropriate chapters: Main Contents: 1-6 Chapter C: C-33-C-34 Chapter F: F-1-F-2 F-35-F-36 F-61-F-62b Chapter I: I-27-I-28 Document Change Notification: Pages DCN-5 – DCN-5
62		November 1, 2006	Update #124: Please place the method sheets in the Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
63		March 9, 2007	Update #126: Please replace or add the attached pages in the appropriate chapters: Chapter D-Software D-105-D-108 Document Change Notification: Pages DCN-5 – DCN-5
64		May 11, 2007	Update #129: Please place the method sheets in the Routine Chemistries and Urine Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.
65		July 6, 2007	Update #135: Please place the method sheets in the Specific Proteins section. Replace the following: Methods Chapter Contents, Document Change Notification.
66		August 3, 2007	Update #136: Please place the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
67		August 31, 2007	Update #137: Please place the method sheets in the Special Chemistries. Replace the following: Methods Chapter Contents, Document Change Notification.
68		September 5, 2007	Update #139: Please place the method sheets in the Routine Chemistries and STAT Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.
69		September 26, 2007	Update #140: Please place the method sheets in the Routine Chemistries and Specific Proteins sections. Replace the following: Methods Chapter Contents, Document Change Notification.
70		October 10, 2007	Update #141: Please place the method sheets in the Routine Chemistries and STAT Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.
71		January 25, 2008	Update #143: Please replace or add the attached pages in the appropriate chapters: Table of Contents AU640/640eUsers Guide Vol. 1 Chapter C: C-1-C-2 C-103-C-108 Chapter D: D-3-D-4 D139-D140 D-147-D152 Document Change Notification: Pages DCN-5 – DCN-6
72		February 15, 2008	Update #144: Please place the method sheets in the Routine Chemistries and Urine Chemistries sections. Replace the following: Methods Chapter Contents, Document Change Notification.

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73		April 18, 2008	Update #145: Please replace or add the attached pages in the appropriate chapters: Chapter D: D-81-D-86 Document Change Notification: Pages DCN-5 – DCN-6
74		August 29, 2008	Update #151: Please replace or add the attached pages in the appropriate chapters: Table of Contents Vol. II 1 – 2 Chapter F: F-1 – F-2 F-35 – F-36 F-54a – F-54d Chapter H: H-31 – H-32 Document Change Notification: Pages DCN- 5 – DCN- 6
75		October 31, 2008	Update #153: Please place the method sheets in the TDM and Olympus TDM sections. Replace the following: Methods Chapter Contents, Document Change Notification.
76		November 21, 2008	Update #145: Please replace or add the attached pages in the Update #154: Please place the method sheets in the Routine Chemistries and Olympus DAU sections. Replace the following: Methods Chapter Contents, Document Change Notification.
77		February 4, 2009	Update #156: Please place the method sheets in the Urine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
78		March 6, 2009	Update #157: Please place the method sheets in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
79		March 13, 2009	Update #158: Please place the method sheets in the Urine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
80		March 20, 2009	Update #159: Please replace or add the attached pages in the appropriate chapters: Chapter A: A-15 – A-16 Chapter D: D-115 – D-116 D-129 – D-130 D-133 – D-134 D-171 – D-172 Document Change Notification: Pages DCN-6 – DCN-7.
81		July 17, 2009	Update #163: Please replace or add the attached pages in the appropriate chapters: Chapter C: C-103 – 108 Chapter D: D-77 – D-78 Document Change Notification: Pages DCN- 7

DOCUMENT REVISION NUMBER	SOFTWARE VERSION	DATE	CHANGE DESCRIPTION
82		November 1, 2009	User Guide Re-branded to Beckman Coulter Inc Update #168: Please replace or add the attached pages in the appropriate chapters: Chapter A: A-5-A-6 A-9-A-10 Chapter C: C-77-C-78 Chapter H: H-31-H-32 Chapter G: G-5-G-12 Document Change Notification: Pages DCN-6 – DCN-7
83		April 14, 2010	BCI#A94088: Please replace or add the attached pages in the appropriate chapters: Chapter A: A-9 – A-10 Chapter C: C-9 – C-10 C-43 – C-44 C-107 – C-108 Table of Contents Volume II: 1-2 Chapter F: F-1 – F-4 F-7 – F-8 F-11 – F- 14 Pages DCN-7 – DCN-7
84		April 22, 2011	BCI# B08079: Please replace or add the attached pages in the appropriate chapters: Title and Copyright pages: Volumes I and II Document Change Notification: DCN-1 – DCN-8 Volume I Introduction: iv – vi Table of Contents Volume II: pg. 1 Chapter A: A-8 – A-9 Chapter F: F-2, F-35, F-47, F-49, F-51 Chapter H: H-38– H-39 Chapter I: I-42 – I-43
85		June 2013	Front matter: Title through table of content pages for volumes 1 and 2. Introduction: Renumbered. Chapter G: p G-1, G-12.

Note:

Updated User's Guide pages have a change bar next to the changed portion. The bar indicates the area on the page that includes the change.

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Introduction

Thank you for purchasing the Beckman Coulter AU640/AU640e automated chemistry analyzer. This manual is intended for operators who have completed the training course offered by Beckman Coulter, or operators who have been trained by those who have taken the Beckman Coulter training course. *Please read this manual carefully to understand instructions before operating the system. The following information describes how this manual is structured:*

Volume I: Precautions, System Outline, Basic Operations, and Software

Document Change Notification Sheet

This sheet lists all updates of the manual and corresponding software changes.

Chapter A Precautions and Installation Environments

This chapter describes necessary precautions and restrictions when using the system. It also describes installation environments, standard accessories, and caution labels.

Chapter B System Outline

This chapter explains system features, system configuration, basic screen operation, and system use.

Chapter C Basic Operations

This chapter is designed as a quick response section providing easy to follow basic operating procedures. It contains the following information: easy steps to prepare for and start analysis, how to obtain results and an operation flowchart. It also describes other frequently used procedures performed during daily routine operations.

Chapter D Software

This chapter describes the functions and operations related to each software screen.

Chapter E Software Menu Outline

This chapter outlines software menus.

Volume II: Maintenance, Error Flags, Troubleshooting, Specifications, and Methods

Chapter F Maintenance

Chapter F provides detailed information about routine and as needed maintenance procedures. Follow the procedures, and use the maintenance schedules provided in this section to track maintenance. *Performing scheduled maintenance is essential to the smooth operation of your instrument.*

Chapter G Error Flags

This chapter provides information on error flags that appear on your data printout as well as fatal and nonfatal system errors.

Chapter H Troubleshooting

This chapter provides information on: using on-line help, determining the cause and solution for abnormal data flags, and other general troubleshooting procedures.

Chapter I Specifications

This chapter provides an outline of system operation during analysis and hardware configuration descriptions of the analyzer. It shows the piping diagram and major specifications of the system. Also, terminology specific to the AU640/AU640e is described here.

Chapter J Methods

This chapter contains methodology sheets.

Conventions for this Manual

This manual uses the following symbols.

- Brackets ([and]) are used to enclose the name of a software menu.

Example:

Select [Start Condition] from the [Routine] menu on the menu bar.

Terms Used in This Manual

The following terms are used when appropriate. *Please pay attention to the following terms for safe and proper use of this system.*

Danger

Means severe injury to the operator can occur. Severe injury means loss of sight, wounds, burns (high or low temperatures), electric shock, fractures, poisoning, and other after effects, or requires a stay in a hospital or long-term treatment.

Warning

This is used when there is the *possibility* that severe injuries can occur.

Caution

Indicates that the operator should exercise care to prevent personal injury, physical damage, and serious adverse effect on analysis results. It also indicates biohazards. Personal injury is referred to as injuries such as mild burns and electric shock that do not require hospitalization or extensive medical attention. Physical damage is referred to as damage to the analyzer, the building and its contents.

Instruction

Provides information on the correct operation of the instrument. If instructions are not followed, system damage may occur because of incorrect operation.

Tip

Provides helpful tips on important information essential for understanding system operation and functions.

See Also

Gives reference locations for further information on a topic.

Notices on the Supplied Programs

- The floppy disks that contain AU640/AU640e software should be stored carefully in an appropriate place.
- The programs may not be copied except for backup purposes.
- The programs may not be subjected to any reverse engineering including decompiling, disassembling, etc.
- The programs, in part or in whole, may not be transferred, exchanged or leased to any party without the prior written consent of Beckman Coulter.

Trademarks

Corporate and product names that appear in this manual are their trademarks.

Warranty

Beckman Coulter America Inc. - Diagnostic Systems Division (Beckman Coulter) warrants that this Beckman Coulter clinical chemistry analyzer(s) or automated microplate system(s), and related Beckman Coulter accessories (individually a "Product" and collectively the "Products") will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of installation. If any Product proves to be defective within the foregoing warranty period, the customer must follow the procedure set forth below. **See "What to do when service is needed."** Beckman Coulter, at its sole discretion, will repair, replace, or adjust the defective Product, provided that Beckman Coulter investigation and inspection disclose that (i) such defect developed under normal and proper use and (ii) the Product is covered under this warranty. Repair, replacement, or adjustment of defective Products shall be Beckman Coulter's sole obligation and the customer's sole remedy hereunder. Beckman Coulter reserves the right to (i) use reconditioned, refurbished, and/or serviceable used parts (tested to Beckman Coulter's quality assurance standards) for warranty repairs and (ii) make any internal or external design and/or feature changes on or to its products without any liability to incorporate such changes on or to the Products. Repair parts will be free from defects in materials and workmanship under normal use and service for a period of ninety (90) days from the date of installation.

Excluded from this warranty and not warranted by Beckman Coulter in any fashion, either express, implied, or by statute, are:

- a. products not manufactured by Beckman Coulter and/or not bearing the "Beckman Coulter" brand label (the warranty coverage for products of other manufacturers, which may be distributed by Beckman Coulter, is the responsibility of the manufacturers of such products in accordance with the terms and duration of such manufacturers' warranties);
- b. any Product which has been disassembled, repaired, tampered with, altered, changed, or modified by persons other than Beckman Coulter's own authorized service personnel unless repair by others is made with the written consent of Beckman Coulter;
- c. defects or damage to the Products resulting from wear, tear, misuse, negligence, impact, improper storage, nonperformance of scheduled operator and maintenance items, or use of non-approved accessories, consumables, or supplies; and
- d. supplies, reagents, calibrators, and consumables, which may be covered under a separate warranty.

EXCEPT FOR THE LIMITED WARRANTY SET FORTH ABOVE, BECKMAN COULTER MAKES NO AND DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, CONCERNING THE PRODUCTS INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR CONCERNING ANY PATENTS OR TECHNOLOGY USED OR INCLUDED THEREIN. BECKMAN COULTER DOES NOT WARRANT THAT SOFTWARE WILL BE ERROR-FREE AND/OR UNINTERRUPTED. IF ANY IMPLIED WARRANTIES APPLY AS A MATTER OF LAW, THEY ARE LIMITED IN DURATION TO THE LENGTH OF THIS WARRANTY. ALL GUARANTIES, WARRANTIES, CONDITIONS, AND REPRESENTATIONS WHATSOEVER, EITHER EXPRESS OR IMPLIED, WHETHER ARISING UNDER ANY STATUTE, LAW, COMMERCIAL USAGE OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. SOME STATES MAY NOT RECOGNIZE A DISCLAIMER OR LIMITATION OF WARRANTIES AND/OR LIMITATION OF LIABILITY SO THE ABOVE DISCLAIMER MAY NOT APPLY. THE CUSTOMER MAY ALSO HAVE DIFFERENT AND/OR ADDITIONAL RIGHTS AND REMEDIES THAT VARY FROM STATE TO STATE.

THE CUSTOMER ACKNOWLEDGES AND AGREES THAT BECKMAN COULTER SHALL NOT BE RESPONSIBLE FOR ANY DAMAGES THAT THE CUSTOMER MAY INCUR FROM DELAYED SHIPMENT, PRODUCT FAILURE, PRODUCT DESIGN, SELECTION, OR PRODUCTION OR FROM ANY OTHER CAUSE, WHETHER LIABILITY IS ASSERTED

IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY) OR OTHERWISE. IN NO EVENT SHALL BECKMAN COULTER BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES OF ANY KIND (INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR LOSS OF USE), WHETHER OR NOT BECKMAN COULTER SHALL BE OR SHOULD BE AWARE OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE.

Representations and warranties made by any person, including dealers and representatives of Beckman Coulter, which are inconsistent or in conflict with the terms of this warranty, shall not be binding upon Beckman Coulter unless reduced to writing and approved by an express authorized officer of Beckman Coulter.

This warranty is the complete and exclusive statement of warranty which Beckman Coulter agrees to provide with respect to the Products and it shall supersede all prior and contemporaneous oral or written agreements, understandings, proposals, and communications pertaining to the subject matter hereof.

WHO IS COVERED BY THIS WARRANTY

This warranty is exclusively for the benefit of the original customer and cannot be transferred or assigned.

WHAT TO DO WHEN SERVICE IS NEEDED

Please call 1-800-223-0130 and speak with Beckman Coulter's Technical Services Department.

INTERNATIONAL WARRANTY SERVICE

Outside of the United States and Canada, international warranty service is NOT available under this warranty.

IF YOU HAVE QUESTIONS OR NEED HELP

If you have any questions or comments regarding the use or performance of your Products, or service performed in the United States or Canada which has not been resolved to your satisfaction; write directly to:

Beckman Coulter Inc.

Attention: Technical Services Manager

Chapter A

Precautions and Installation Environments

Introduction

This Chapter describes the precautions on system use, installation environments for proper operation, standard accessories, and alarm labels. To use the AU640^e safely and to obtain the highest possible system performance, be sure to observe the precautions listed on the following pages.

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1. Safety Precautions

To use your system safely and effectively, observe the following precautions.

Prevention of System Failures and Flammability

Observe the following precautions to prevent system problems.

Warning

-
- The instrument must be installed correctly according to the installation environment and the installation conditions shown in this manual.
 - Please contact Beckman Coulter Technical Services, or the Sales Department when the system status is to be changed.
-

Preventing Electric Shock

To avoid an electric shock, observe the following precautions.

Warning

-
- Never remove the covers secured by screws, such as the rear cover and side covers, unless being guided by an Beckman Coulter Representative.
 - If liquid spills or leaks occur inside the system, contact Beckman Coulter Technical Services. Careless operation with liquid present may result in an electric shock.
-

Preventing Personal Injury

To protect yourself from injury while using the system, observe the following precautions.

Caution

-
- While the system is operating, do not touch the moving parts. These include the sample probe, reagent probes, mix bars, wash stations, and rack feed unit. Do not insert your finger or hand in an opening.
 - To replace the photometer lamp, follow the procedures in “Chapter F, Maintenance.” Do not touch the lamp before it is cool or you may be burned.
 - Observe the precautions on the analyzer labels and in this manual.
 - For information about precautions regarding the printer, refer to the operator's manual supplied with the printer.
-

Eye Protection

To protect your eyes, observe the following precautions.

Caution

The photometer lamp is lit while the system is on. Do not look into the lamp or the laser beam from the barcode reader. Direct light from the photometer lamp or from the laser beam of the barcode reader may result in eye damage.

Accuracy and Precision of Analysis Data

To obtain accurate analysis results, observe the following precautions.

Caution

- **Do not open the upper cover and/or rear cover during analysis.**
 - Before using the system, perform quality control procedures to verify the system functions correctly.
 - Observe the instructions in this manual to inspect the system, perform maintenance, and replace parts.
 - Follow reagent manufacturer or distributor instructions when handling reagents, control serum, and reference material.
 - Handle the samples according to the instructions.
 - Do not open the reagent refrigerator cover and cuvette wheel cover during analysis.
-

Treating Waste Liquids

The waste liquid and mixtures may require special treatment before being discarded. This system is structured to discard concentrated waste liquids (mixtures) and washing waste liquids (washing water and detergents) separately. Observe the following precautions.

Caution

Some substances in the reagents, control serums, reference materials, and detergents are regulated under the FDA approval methods. Refer to the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 1984 for proper handling of substances with a biosafety level 2. Also, the following NCCLS document provides guidance on the safe handling and disposal of chemical, infectious, radioactive, and physical waste generated in the clinical laboratory. Refer to NCCLS document GP5-A Vol. 13 No. 22 "Clinical Laboratory Waste Management; Approved Guideline."

Preventing Infection

If samples used with the system are mishandled, there is a risk of being infected. To protect yourself from infection, observe the following precautions.

Caution

Do not touch the samples, mixtures, and waste liquids with bare hands. Be sure to wear gloves to protect yourself from infection. Should any samples come into contact with your skin, thoroughly wash the area that came into contact with the sample and consult a physician. Immediately wipe off any contaminants from the system.

Handling Reagents

Some reagents used with the system are strong acids or alkalis. To protect yourself from injury, observe the following precautions.

Warning

Some reagents are strong acids or alkalis. Exercise great care so that your hands and clothing do not come into contact with the reagents. If your hands or clothing come into contact with reagents, immediately wash them off with soap and water. If a reagent comes into contact with your eye(s), immediately rinse with water for at least 15 minutes and consult a physician. Consult the MSDS sheet for the particular reagent you have come into contact with for additional information.

Preventing Damage to Other Equipment and Facilities

Warning

Power outlet connections should be properly installed so as not to seriously affect other important equipment (e.g., surgical equipment power supply) or facilities due to system failure.

Caution

Checking test at analysis

To check tests following analysis, observe the system management and laboratory standards.

Before analysis, verify the following:

- Check the purified water quality
- Check the calibration analysis results
- Check the quality control data
- Check the analysis result
- Check the probes and tubing for leaks
- Check the samples for contaminants (dust, fibrin, etc.)
- Check each sample quantity and verify that bubbles are not present
- Check the reaction data

If any error flag (*, ?, @, \$, D, B, !) is generated in relation to the reaction OD, check the processed reaction data immediately before and after the flagged abnormal result. If any abnormality is present, check the cuvette and the cuvette washing station for an overflow, recheck any processed results before and after the flagged result.

Precautions for maintaining/inspecting the system and periodic replacement of parts.

- Maintain and inspect the system, replacing parts periodically according to the instructions in this manual. If the system is not correctly maintained, analysis results will be effected.
- After replacing main parts such as the photometer lamp, syringes, probes, and cuvettes, perform calibration. Follow the reagent manufacturer or distributor's instructions for information about timing, frequency, and materials required for calibration analysis.
- Use only detergents that meet type, density, and usage specifications specified in this manual. If the detergent does not meet specifications, or is used incorrectly, analysis will be effected.

Use of consumables

To avoid a decrease in system performance, use only consumables and parts recommended by Beckman Coulter.

Precautions for setting analysis parameters

The sample quantity, reagent quantity, measurement wavelength, calibrator value, etc., must be set on the analyzer before analysis can be performed. Use the values set in the package insert for the reagent etc. Make sure to follow the manufacturers or distributors instructions for the reagent and all the instructions outlined in this manual.

Other Cautions

If reagents or samples accidentally come in contact with the mucous membranes or are accidentally ingested, rinse immediately or induce vomiting. Follow the manufacturers or distributors instructions also located on the package insert, and contact a physician immediately.

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2. Precautions on Use

To use the system safely and effectively, observe the following precautions.

Special considerations when using the Windows operating system:

- Do not play audio CDs on the Windows computer. This may compromise the performance of the system.
- Do not press Control + Alt + Delete to access Windows programs. This compromises the integrity of the operating system.
- Only play the maintenance video clips in the Standby mode. Playing videos in a measure mode could compromise analyzer performance.
- To exit the menu and operation help programs, use "Exit Help" located in the bookmark column located to the left side of the screen. Do not click random areas of the screen to close help programs. The application will continue to run in the background.
- Do not press any keys on the keyboard when the analyzer is first turned on (booting-up). You may use the keyboard when the password or start-up screen appears.
- Do not attempt to change parameters during a measure mode. This will compromise the integrity of your system and data.
- Do not use a screen saver. This could cause the analyzer to function inappropriately.

General Precautions During Use of the System

Caution

Handling samples (Samples available for analysis)

- This system is designed to analyze serum, urine, and other body fluids. If problems are encountered when analyzing a specific test or when using a specific reagent, consult the reagent manufacturer or distributor.
- Use serum that is sufficiently separated from blood clots and urine that is free from suspended matter or the probe may be clogged and adverse affects on analysis may result. The analyzer clot detection function is affected by the amount of sample aspirated. Clot detection occurs inconsistently when the sample volume for a test is < 16uL.
- Exercise care when mixing chemicals (medicine, anticoagulant, preservative, etc.).

Handling samples (Pretreating samples)

- Fibrin suspended in the serum may clog the probe.
- Check that the blood is sufficiently coagulated prior to serum separation. Remove the suspended fibrin before placing serum on the system.
- If any suspended matter is recognized in the urine to be dispensed, perform centrifugal separation to precipitate the suspended matter before testing the urine specimen.

- If a sample requires pretreatment depending on the analysis test, consult the reagent manufacturer or distributor. For information about which serum separating medium is appropriate for the sample, consult the reagent manufacturer.
- A minimum quantity of sample is required for analysis. Set up an appropriate quantity of sample for correct sampling in the system, according to this manual.
- To prevent sample evaporation, do not leave samples unsealed for an extended period of time. If samples evaporate, correct analysis cannot be obtained.

Handling reagents, reference materials, and control serums

- To analyze serum, urine, or other samples using this system, the appropriate reagent, reference material, and control serum are required. For information about which products to use, consult the reagent manufacturer, the distributor, or Beckman Coulter Technical Services.
- For reagent reference material, or control serum storage and handling use the instructions of the reagent manufacturer or distributor.
- The methods used to store the reagents, reference materials, and control serums are described in each package insert. Observe the instructions. If reagents, reference materials, and control serums are stored improperly, results will be inaccurate even if they are used within effective periods. Also, top system performance may not be obtained.
- Consult the corresponding reagent manufacturer or distributor for the stability of the unsealed product.
- To place the reagent, etc., on the system, follow the instructions in this manual and those from the reagent manufacturer or distributor. Unless the reagent is placed properly, accurate analysis results cannot be obtained and damage to the system could occur.
- After replacing the reagent, follow the instructions on the package insert.

Reagent interference between analysis tests

If a reagent is contaminated with another reagent during analysis, results may be affected. The actual degree of interference differs depending on the reagent. For detailed information, contact the reagent manufacturer or distributor. For information on how to check for cross-contamination between tests, contact Beckman Coulter Technical Services.

Analysis performance

If the serum includes a high ratio of hemolysis, turbidity, or bilirubin, the drug used and its metabolite may affect the analysis result. For detailed information, contact the reagent manufacturer or distributor. Also consult the reagent manufacturer or distributor for detailed information about the analysis performance of each reagent.

Water supply and drain hoses

According to the description given in the "Installation Environments" section have the connection of hoses for water supply and drainage made by authorized personnel. If those hoses are connected to other facilities in other ways than specified, they may be disconnected during operation of the system. This will cause a serious problem such as water leakage in the system.

Electromagnetic waves of the CRT monitor and the data processing unit

Please do not place equipment generating electromagnetic waves, like computers, monitors, etc., close to the system. The CRT monitor and the data processing unit generate electromagnetic waves. Exposure to excessive amounts of electromagnetic waves may interfere with instrument operation.

Maintaining guaranteed system performance

Use the system between 18 and 32 °C, 40 and 80% RH, and ± 2 °C temperature fluctuation during analysis. If the system is operated outside of the above ranges, analyzer performance cannot be guaranteed.

Handling the keyboard and monitor

To prevent the keyboard or monitor from deteriorating, do not touch the keyboard or monitor with hands that are wet or have chemicals on them.

Operating the system

- Upon completion of analysis, check the sample numbers and sample IDs.
- To operate this system, observe the procedures described in this manual. Incorrect operation may result in improper analysis results or system failure.
- To learn about total system operations, take the training course offered by Beckman Coulter. This manual is intended for personnel who have completed the training course offered by Beckman Coulter, or personnel who have been trained by someone who has taken the course.

Checking tests at analysis

- To insure quality results, periodically check the following:
- Quality of purified water
- Calibration results
- QC data
- Analysis results
- Syringes and tubing for leaks
- Samples for contaminants (dust, fibrin, etc.)
- Quantity of each sample and that no bubbles are present

Precautions for maintaining/inspecting the system and periodic replacement of parts

- Maintain and inspect the system, and periodically replace the parts according to the instructions in this manual. If the system is not maintained correctly, reliable analysis results might not be obtained.
- If replacing main parts such as the photometer lamp, syringe, probe, or cuvette(s), follow any special instructions on the package insert. For information about timing, frequency, and reference materials required for calibration, follow the package inserts from the reagent manufacturer or distributor.
- Only use detergents that meet the type, density, and usage specified in this manual. If detergent is used in a manner other than specified, reliable analysis results might not be obtained.

Use of consumable items

If any consumable other than those recommended by Beckman Coulter are used, system performance may decrease. Always use parts that are recommended by Beckman Coulter.

Setting analysis parameters

This system needs the sample quantity, reagent quantity, measurement wavelength, calibrator value, etc., to be accurately specified in parameters. Set the values based on the package insert supplied with the product. To set the parameters correctly, follow the instructions of this manual, and those of the reagent manufacturer or distributor.

Other precautions

If reagents or samples are accidentally swallowed, refer to your MSDS sheets for specific directions. If reagents or samples come into contact with skin rinse the area immediately, then refer to your MSDS sheets.

Instruction

Backing up the data saved on the hard disk

If the data on the hard disk of the system has been deleted, or if the hard disk has been damaged due to a power failure, etc., the data cannot be recovered. Periodically, back up analysis data and parameters. To reserve sufficient space on the hard disk, delete unnecessary data.

Computer precautions

Never use the computer for a purpose other than that intended. Frequently scan diskettes or other media used in the AU640/AU640^e to avoid transmitting viruses. The danger of exposing the AU640/AU640^e computer to a software virus exists. A computer virus is malicious software, which is designed to intentionally destroy programs and data. Computer viruses make their way into computers by copying themselves inside programs or within data which is installed via a floppy disk or other media.

Cleaning contaminants from the covers

For optimum performance and extended life of the system, immediately wipe contaminants off of the covers.

General Precautions for Use of Medical Electronic Equipment (For Safe Operation)

Observe the following precautions for medical electronic equipment. Precautions specific to operating this system are given in this User Guide. To prevent system malfunctions, read and follow these precautions carefully.

- **This piece of medical electronic equipment should only be used by trained operators.**
- **When installing the equipment, observe the following precautions.**
 - Install the equipment in a place where it will not be splashed with water.
 - Install it in a place which is free from the adverse effects caused by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, and air containing salt or sulfur.
 - Rectify installation and transportation conditions that cause deviation from level, vibration, or mechanical shock (during transportation also).
 - Do not install it in a place where chemicals are stored or gases are generated.
 - Check the frequency, voltage, and current (or power consumption) of the power source.
 - Connect the ground wire correctly.

Before using the equipment, observe the following precautions.

- Check switch connections, etc.
- Check that the ground wire has been properly connected.
- Check that all the cords are correctly connected.
- If using with other equipment, exercise great care to prevent danger.

While using the equipment, observe the following precaution.

- Always monitor the equipment for any abnormalities.
- If any abnormality arises, stop operation in the most appropriate way according to the situation and take appropriate corrective measures.

After using the analyzer, observe the following precautions.

Follow proper shutdown procedures.

Use caution when performing troubleshooting procedures.

For assistance with troubleshooting, contact Beckman Coulter Technical Services

Do not modify the equipment.

Inspecting and maintaining the system.

- Be sure to perform scheduled analyzer maintenance.
- If the analyzer has not been used for an extended period of time, inspect it to ensure that it will operate properly and safely.

3. Installation Environments

The environment of the installation site for this system must not affect operation and analysis.

Installation Environment Conditions

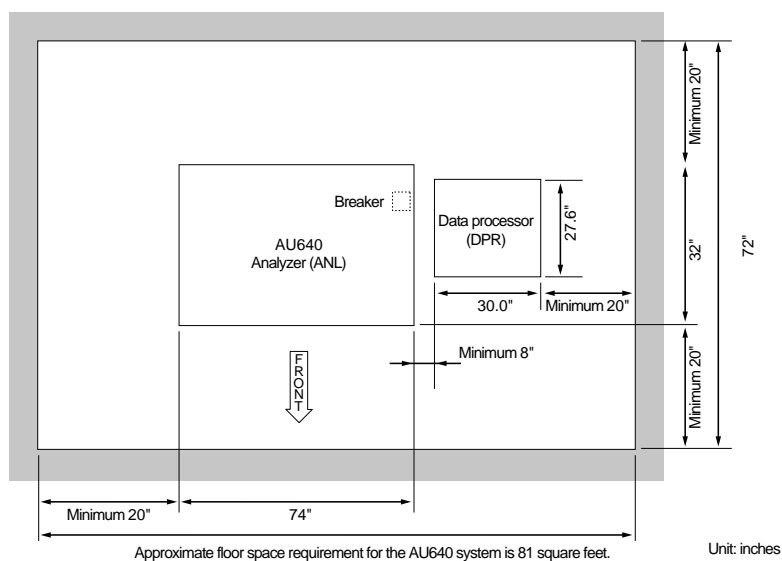
- Site not subject to direct sunlight
- Site with a minimum amount of dust
- Site that is flat (gradient: less than 1/200)
- Site with minimum vibration
- Site with floor construction that can support approximately 1430 lbs (650 kg).
- Site with a power source with minimum voltage fluctuation ($\pm 10\%$)
- Site which is free from machines that generate a large amount of electrical interference
- Site located less than 6,500 feet (2,000 m) above sea level.

Temperature and Humidity Conditions

- The temperature of the installation room should be between 18 and 32 °C, and the temperature fluctuation during a measure mode should be less than 2 °C.
- The humidity must be between 40 and 80% RH with no condensation.
- Temperature and humidity fluctuations must be within the specified range(s), otherwise the system cannot produce reliable data. If the temperature in the room fluctuates excessively, the room will require air-conditioning. The system transmits heat during operation. The back of the system is warmer than the environment since the heat inside the system is ventilated from the back. Install the system where air circulates well.
- The site should be well ventilated. Use ventilation equipment if necessary.
- The system should not be exposed to direct air flow from air conditioners.

Installation Space Requirements

As shown in the figure below, this system requires space around it for safe installation and maintenance.



Note

* To quickly turn off the breaker during an emergency, be sure to provide at least 9 inches of space.

Dimensions of main system units (Unit: inches)

Analyzer (ANL):	Width 74" x Depth 32" x Height 50"	Weight 1,166 lbs
Data processor (DPR):	Width 30.0" x Depth 27.6" x Height 63"	Weight 146 lbs

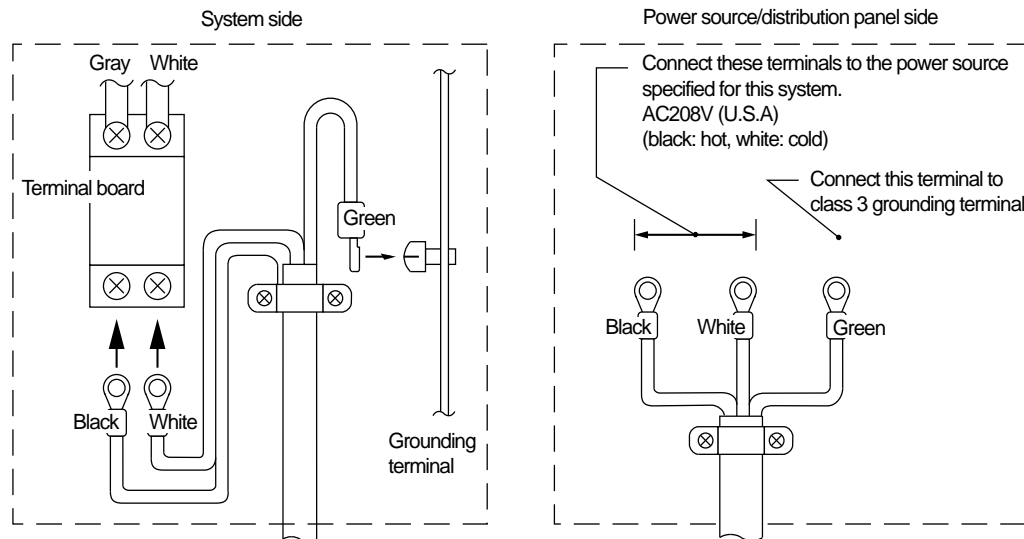
Power Source and Grounding

The power source shown below must be prepared before delivery of this system. The distribution panel should be located so that a power cable with a length of 30 feet will reach the system.

Power source

Voltage	AC208 V $\pm 10\%$ (U.S.A) AC230 V $\pm 10\%$ (Europe) AC240 V $\pm 10\%$ (AUSTRALIA)	60 Hz 50 Hz 50/60 Hz
Power:	4 kVA	
Distribution panel:	Within 30 feet of the system	

Connect the power cable to the distribution panel as shown in the following diagram.

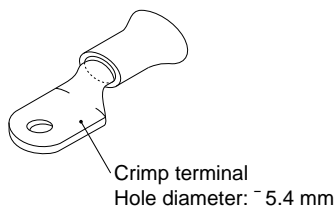


Grounding terminal

The grounding terminal should conform to class 3 grounding construction (less than 100 ohms of grounding resistance).

Warning

To be performed by Beckman Coulter personnel only: Install a grounding wire to prevent electric shock and to prevent system malfunction.



Water Supply and Drainage

The water supply and drainage facilities, shown below, must be prepared before delivery of this system. This system requires deionized water. A deionizer should be installed within 30 feet from the water tap. The deionizer and drain hole should be located so that 30 feet water supply and drain hoses will reach the system. For information about a deionizer, contact the manufacturer of the deionizer.

Water supply

WATER PRESSURE:	0.49 x 10⁵ TO 3.92 x 10⁵ PA (4-57 PSIG)
QUANTITY CONSUMED:	33 L/HOUR (50 Hz/60 Hz)
MAXIMUM CONSUMPTION:	1.5 L/MIN (50 Hz/60 Hz)

Drainage

Drain hole: Should be installed at a height of 4 inches or less from the installation floor. Can be installed at a height of 4 feet or less, if forced drainage equipment (optional) is used.

Some reagents ingredients are regulated under the FDA and Centers for Disease Control. Consult package inserts. Handle substances appropriately after reviewing accompanying documentation from the reagent manufacturer or distributor.

The following waste liquids are drained from the system:

Kind of waste liquid	Drain quantity/number of tests (precondition)
Concentrated waste liquid (sample + reagent)	2.7 1/800 tests (1 hour) (Reagent quantity: average 300 µl/test)
Washing waste liquid (washing water + detergent)	33 1/800 tests (1 hour)

Caution

Treat drain water as infectious waste. Connect the drain hose to the drain hole which leads to the infectious waste disposal facility. Otherwise, reserve the drain water and allow it to be disposed of by expert distributors

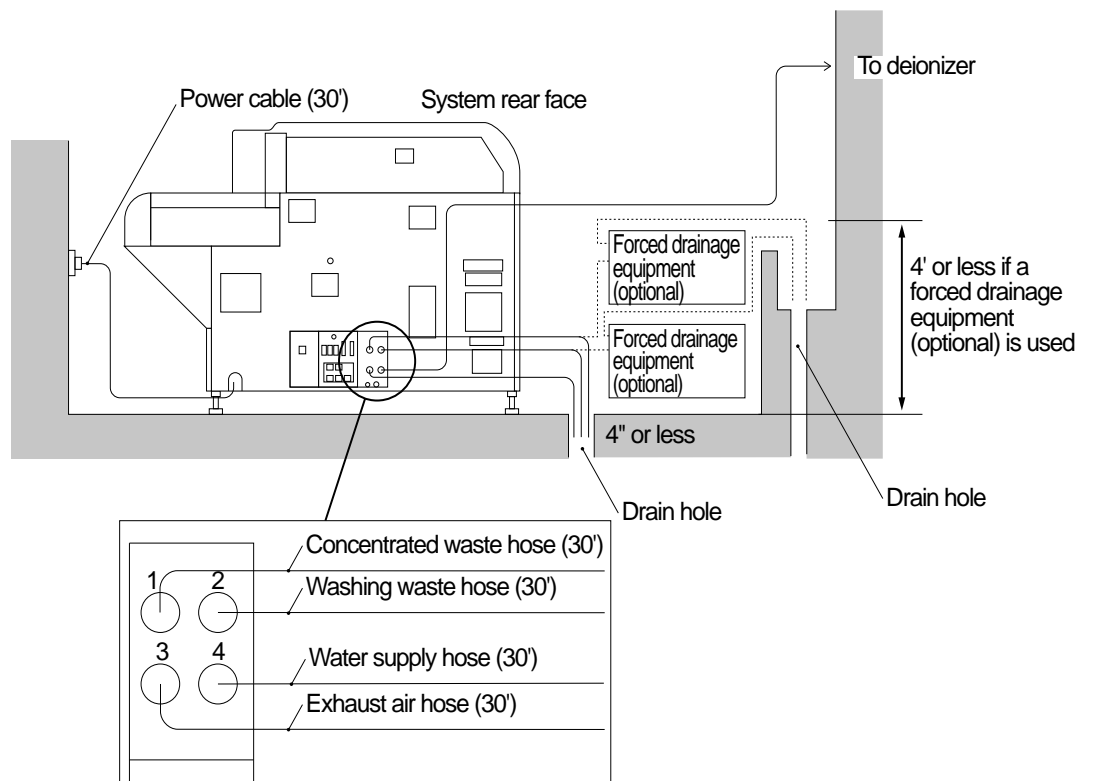
Installing a Deionizer

The AU640 requires deionized water for washing water and reagent diluent. Select a deionizer which can supply the average amount of water consumed, 33 Liters/hour, and the maximum instantaneous water consumption, 1.5 Liters/minute. For information about requirements for a deionizer, refer to the quantity consumed and maximum consumption of the AU640, described above in "Water Supply and Drainage." The purity of deionized water should meet the requirements of the College of American Pathologists (CAP) Type II, and its electric conductivity should be 2 µS/cm or less (resistivity: 0.5 MΩ cm or greater). To remove bacteria, use a 0.5 micron filter at the outlet of the deionizer.

Wiring and Piping

The wiring and piping of this system should conform to the following:

- The system should be installed within 30 feet of the distribution panel (within range of the power cable).
- The system should be installed within 30 feet of the water supply and drainage location (within range of the water supply and drain hoses).
- The drainage head should be at a height of 4 inches or less from the installation floor. It can be installed at a height of 4 feet or less if the forced drainage equipment (optional) is used.



See Also

For more information on system specifications, refer to the "Specifications Chapter."

4. List of Standard Accessories

The standard accessories of this system are listed below.

List of Standard Accessories

Item	Quantity	
Rack	15	White racks 10 Yellow, green, blue, red, orange rack each 1
Rack ID label	3 sets	No.1 to No.20 1 set (1pc. per No.) No.21 to No.40 1 set (1pc.per No.) No.1 to No.3 1 set (No1: 14pcs., No.2: 3pcs., No3:3 pcs)
Mandolin String	2	
Coolant	2	2 L-can
Curvette	1 set	10 Pcs.
Braided hose (supply)	2	
Braided hose (drain)	2	
Hose band	4	
Sample probe	1	
Reagent probe	2	
Photometer lamp	1	
Warranty	1	
User's Guide	1	
Quick Response Guide	1	
On-line Help	1	
Program	1set	
Wrench	1	
Separator	2 sets	20 pcs./set 30mL. bottles 15mL. bottles
Adapter A (for STAT table)	1 set	22 pcs
Stickers	1 set	4 kinds of stickers to label STAT table position
Communication cable	1	

ISE (optional)

P. tube	1
Pinch Valve tube	1
Warranty Card	1

Note

Additional accessories are normally included at delivery of the instrument. Those items vary depending on the particular application intended for the instrument. Consult your Beckman Coulter contact about additional items.

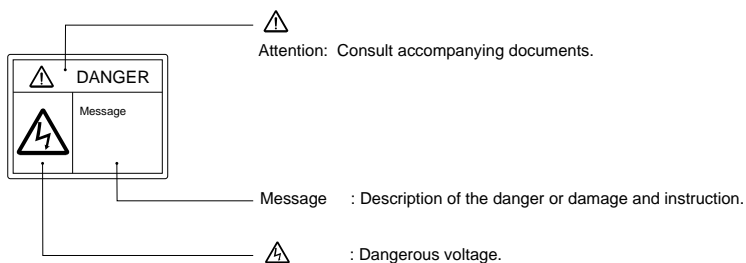
5. Analyzer Warning and Caution Labels

The following diagram shows alarm label locations and provides an explanation of the symbols.

Alarm Label Outline

- “Alarm labels” are attached to analyzer parts requiring special safety considerations. Please use the system safely and correctly according to the following instructions.
- Do not remove the contents of Alarm labels carelessly, and do not damage or remove “Alarm labels.”
- Please contact the Beckman Coulter Technical Services if "Alarm labels" have become illegible or if the labels have come off.
- The contents of the Alarm labels are organized according to the following:

Alarm Label Layout



Precautionary Marks and Terms

Danger

Means severe injury or death can occur to the operator. Severe injury means loss of sight, wounds, burns (high or low temperatures), electric shock, fractures, poisoning, and other after effects, or requires a stay in the hospital or long-term ambulatory treatment.

Warning

This is used when there is the possibility that severe injuries can occur.

Caution

Indicates that the operator should exercise care to prevent personal injury, physical damage, and serious adverse effect on analysis results. It also indicates biohazards. Personal injury is referred to as injuries such as mild burns and electric shock that do not require hospitalization or extensive medical attention. Physical damage is referred to as damage to the analyzer, the building and its contents.



Caution-Laser Radiation

Do not stare into the laser beam or view directly with optical instruments.

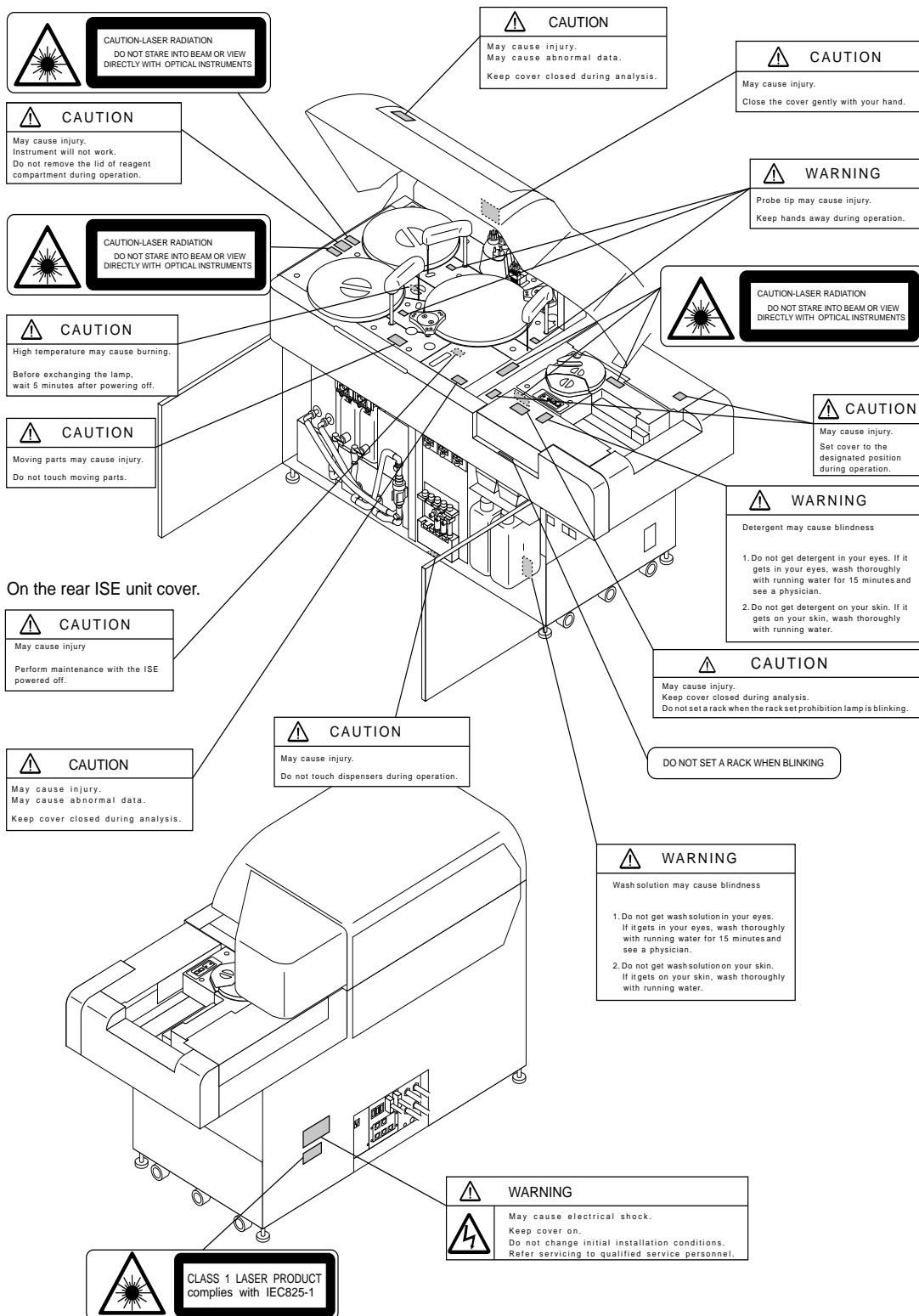
Instruction

Provides information on the correct handling of the instrument. If instructions are not followed, system damage may occur because of incorrect handling.

Warning/Caution Label Pictograms

General danger, warning, caution: 
 Electrical danger: 

Warning and Caution Label Position



Chapter B

System Outline



Introduction

This Chapter outlines the system and fundamental screen operations.

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1. Outline of Functions	B-3
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1. Outline of Functions

Purpose of the System

The AU640/640^e is a fully automated chemistry analyzer designed for operating ease, speed, and flexibility. It uses liquid, barcoded reagents, and user-friendly Microsoft Windows™ software. The operator is assured a fast turnaround time for response panels, maximum 1200 tests per hour with the ISE, 800 tests per hour photometric.

Analysis Method

There are three methods for performing normal analysis requisitions: requisition for individual samples, batch requisition, and batch or real-time downloading from a host computer. If normal analysis is being performed using the ISE unit, select the ISE tests (Na, K, Cl). Profiles can be created to requisition a common group of tests at once.

See Also

For more information on analysis methods, refer to “Preparing for Analysis” located in the Basic Operations Chapter.

Note: Create a new sample data index when switching between analysis methods.

Sequential Analysis

Using this method of analysis, the system reads the rack ID label, but does not read the specimen barcode label. Sample analysis data is managed by the order of the sample number. The samples must be placed on the system in the same order as the sample number order requisition. The system counts the samples, beginning with the start sample number specified in the start condition menu, each time the sample rack is processed.

Rack ID Analysis

Using this method of analysis, the system reads the rack ID on the rack but does not read the specimen barcode label. The rack ID label manages the sample analysis data. A rack ID label must be positioned on the front of each rack. The sample numbers are calculated using the following expression: $(\text{Rack ID}-1) \times 10 + \text{Cup position}$. Racks can be placed in any order on the rack feeder; however each rack requires sample numbers that corresponds to the rack ID to be placed on the system. For example:

Set the samples with sample numbers 1 to 10 in the rack of rack ID0001.

Set the samples with sample numbers 41 to 50 in the rack of rack ID0005.

The sample number is increment each time the rack is fed, beginning with the start sample number calculated from the rack ID. When the next rack is detected, the start sample number is calculated again from the rack ID.

Warning

Do not use duplicate rack numbers in the same data index when using “Rack ID analysis”. The system will use the original requisition containing the sample number, specimen barcode label (if entered) and tests).

S. ID (Barcode) Analysis

Using this method of analysis the system reads the rack ID label and the specimen barcode label. Sample analysis data is managed by the sample barcode information. A specimen barcode label must be placed on each sample cup. Racks can be placed in any order on the rack feeder. Sample cups can also be placed in any position.

Online Analysis and Keyboard Entry Analysis

Real-time Online

The host computer and AU640^e must be online. All barcode analyses are automatically processed according to the inquiry from the host computer.

Batch Online

The host computer and AU640^e must be online. Multiple sample requisitions are batch processed by the host computer through the operation of the AU640^e prior to sample analysis.

Keyboard Entry

Analysis is requisitioned by using the keyboard to enter the sample number or the barcode ID located on the sample cup. Test requisition will not be performed by the host if using this method.

Definition of Sample Numbers, Sample IDs, Rack IDs, System Date/Time and Index Date/Time

Sample Number

A four digit alphanumeric number used to identify individual samples. The calculation method of sample numbers differs depending on the analysis method.

Sample ID

The number identifies individual samples. In S. ID (barcode) analysis, the system reads the barcode label positioned on a sample cup to identify individual specimens.

Rack ID

The rack ID number identifies individual racks. In rack ID analysis the system automatically assigns the sample number calculated from the rack ID.

System date/time

The system date/time is controlled by the system clock.

Index date/time

The index date/time is used to store/retrieve the sample data. When the system is started, the referenced index date/time defaults to the system date/time. It can be modified to a given index date/time.

ISE Unit

Outline of electrolyte measuring unit (ISE)

This unit is provided with ion-selective electrodes (ISE) that measures a specific ion selectively, using the reference (REF) electrode as a base measurement. It measures the potential difference between the selective and reference electrodes when a sample passes through them. The following ion-selective electrodes are available.

- **Na electrode**
- **K electrode**
- **Cl electrode**

Printer

Outline of printer functions

This system is supplied with one standard printer. An additional printer can be added to the system to print different types of data lists at the same time. The standard printer prints analysis results in a real-time mode. For example, one printer prints analysis result reports, while the other printer prints repeat-run work lists.

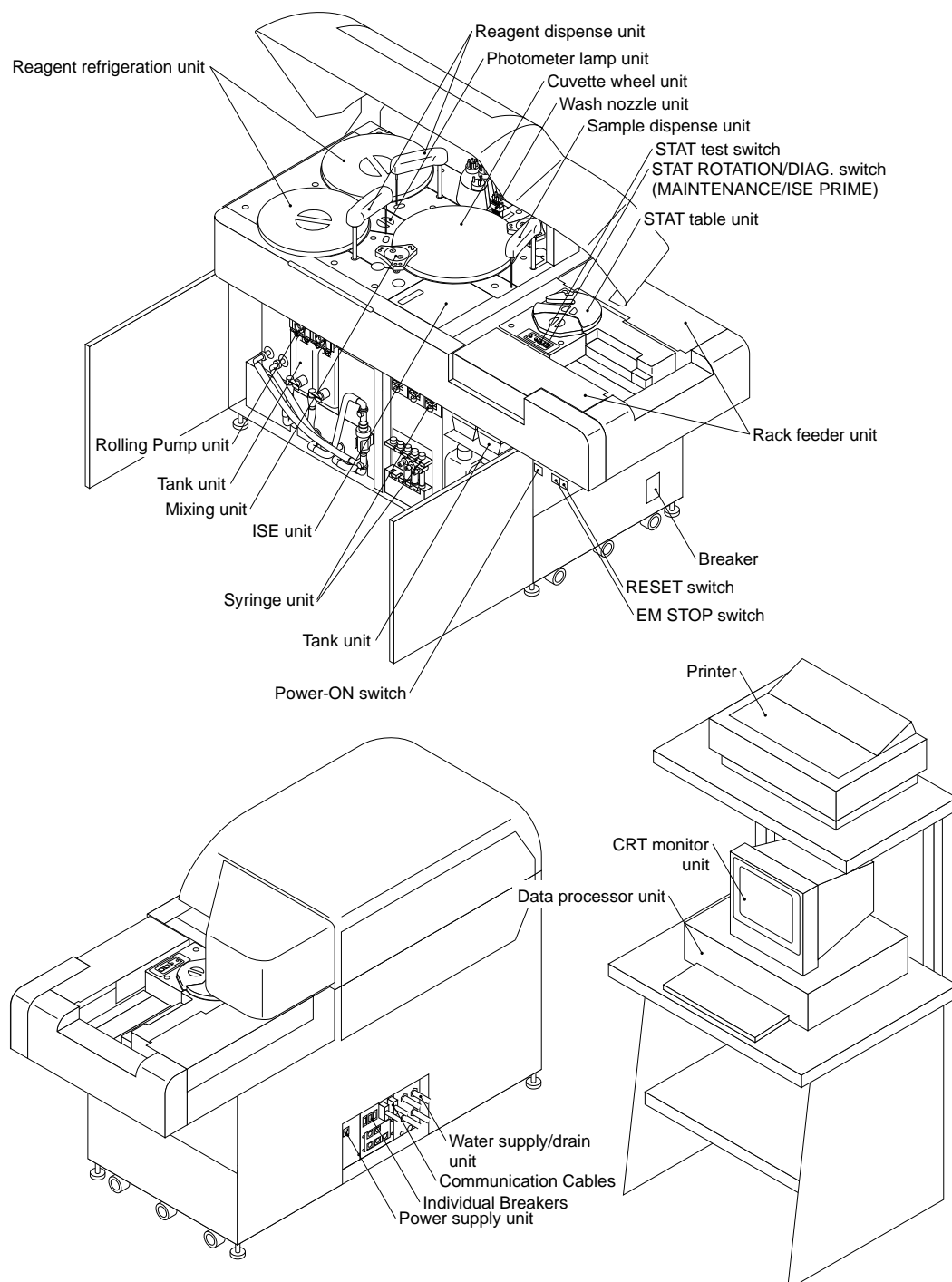
Modem

Outline of modem functions

The client AU640^e and Beckman Coulter service network can communicate via modem. This ensures quick action for data management services and troubleshooting.

2. Configuration of System Components

This chapter describes the configuration of each system component. Refer to this section prior to using the system.



Sample Dispense Unit

The sampling system consists of the sample probe/level detector, sample syringe, sample wash syringe, and solenoid valve. A single sample probe is needed to perform photometric and ISE analysis. The sample probe aspirates sample from a tube in a rack and then dispenses it into a cuvette.

Reagent Dispense Unit

The reagent dispensing components include the reagent syringes, reagent probes, reagent wash syringes, and solenoid valves. This is a positive displacement system where the probe aspirates only the required amount of reagent to perform a test. The syringe tubing and probes are normally filled with DI water. Reagent is dispensed by the syringe, into the cuvette, through the reagent probe.

Reagent Refrigeration Unit

This system is equipped with two reagent refrigerators. To prevent reagents from deterioration, each refrigerator always maintains a temperature between 4° and 12° C.

Wash Nozzle Unit

The nozzles aspirate the mixture from the cuvettes to allow them to be washed and dried.

Cuvette Wheel Unit

There are a total of 153 glass cuvettes. The light path of the cuvette is 6 mm and the maximum capacity is 750 uL. The reaction sequence is R1, mix, sample, mix, R2, mix. The wheel is maintained at 37 °C (+/-0.3) by an incubator (dry bath). The reaction time is 8 minutes and 15 seconds. A total of 800 photometric tests can be performed per hour, with a maximum of 1200 tests per hour with the ISE.

Mix Units

The mix unit contains teflon coated mix bars to prevent chipping. The mix bars are washed with diluted wash solution B, and rinsed between each cuvette mix in the mix bar wash wells. The mix bar unit rotates to the positions for mixing, washing and rinsing.

Photometry

The AU640^e has a polychromator photometry system. A halogen lamp transmits white light through the cuvette. A diffraction grating splits the white light into 13 wavelengths. A silicone photodiode array detects the amount of light transmitted through the cuvettes. Each cuvette is read 28 times (P0 to P27) with 18 seconds between each read point. The total reaction time is 8 minutes 15 seconds.

STAT Table

The STAT table is used for analyzing STAT samples, quality control, calibration, ISE calibration, and emergency samples. Samples are requisitioned and identified as priority STATs (P). Twenty-two positions are available for STAT analysis or repeats. The sensor identifies samples by numerical order on the table. To avoid errors, always remove tubes from the STAT table as soon as the table returns to its home position. The inner positions are used for ISE calibration and cleaning protocols.

Rack Feeder Unit

The unit where racks are placed to start analysis. Racks also return to the rack feeder unit when the samples on the rack are analyzed.

Printer

Prints analysis results.

Tank Units

This unit includes the deionized water tank, two concentrated detergent tanks and two diluted detergent tanks. Solution from each tank is dispensed according to analysis operations. The ISE unit is equipped with a buffer, mid-standard and reference solution.

Water & Waste

There are four lines located in the back of the analyzer: two are gravity waste lines, and one is an exhaust line from the vacuum pump. The fourth line is DI water going into the analyzer. For detailed information on DI water usage and waste, please refer to pages A-13 to A-14 in this User's Guide.

Computer System

The personal computer is equipped with a large hard drive to store analysis data, RAM, a disk drive to use floppy disks, and a CD-ROM drive. The AU640^e uses software with user-friendly displays that make the analyzer easy to learn and operate.

Breaker and Switches

If the main breaker for the power is turned on, the power to the incubator and the reagent refrigerator is turned on. If the Power-ON switch is turned on, the system starts and the operation screen appears. If the EM STOP switch is pressed, the main power is immediately turned off including the power to the incubator and the reagent refrigerator. The RESET switch returns power to the incubator and reagent refrigerator after an emergency stop or loss of power.

Communication Cables

Communication cables are used to exchange data between the analyzer unit (ANL) which performs analysis and the data processor unit (DPR) which processes data. The host computer and other external devices are connected at the rear of the DPR. The I/F cable connecting to the host need to be supplied by the user.

ISE Unit

This unit measures the potential difference between the Na, K, or Cl electrode and the REF electrode when a sample passes through them.

Syringe Unit

This unit consists of the sample dispenser for dispensing serum, urine, or other samples and the reagent dispenser for dispensing reagents. The system requires a very small quantity of serum, urine, reagent, etc., to be dispensed, so multiple syringes are used to retain the dispensing accuracy.

Rolling Pump Unit

This unit has two rolling pumps for detergent A and detergent B. Each pump supplies the detergent from the master tank to the diluent tanks.

Monitor Unit

Consists of the monitor that displays operating screens and the keyboard and mouse used for operation.

Water Supply/Drain Unit

This unit is where the water supply hose, concentrated waste liquid hose and washing waste liquid hose are connected.

Power Supply Unit

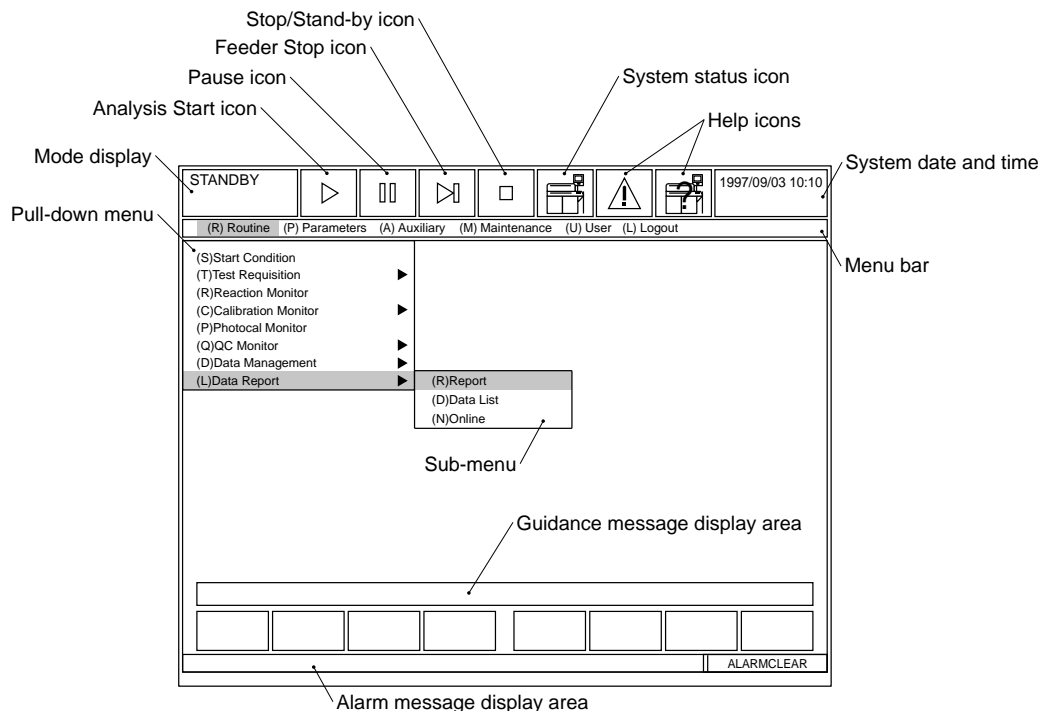
The power cable is connected to supply power to each system unit. To prevent the system from receiving excessive current, a circuit breaker is used as a safety device.

3. Outline of Screen Operations

This section explains how to view the display screen, keyboard names and functions, how to use the mouse and other fundamentals.

How to View the Display Screen – Main Screen Display Names

The following figure shows the main display screen and provides an explanation of icons and screen areas.



Mode display

Displays the system operation status, such as Standby.

System date and time

Displays the system date and time controlled by the system clock.

Menu bar

Displays the six main menus: [Routine], [Parameters], [Auxiliary], [Maintenance], [User], and [Logout]. If these menu items are selected, a pull-down menu is displayed.

Pull-down menu

A pull-down menu is displayed when one of the menu items on the menu bar is selected.

Submenu

Some menu items in a pull-down menu contain multiple functions. If such a menu item in a pull-down menu is selected, a submenu will be displayed.

Guidance message display area

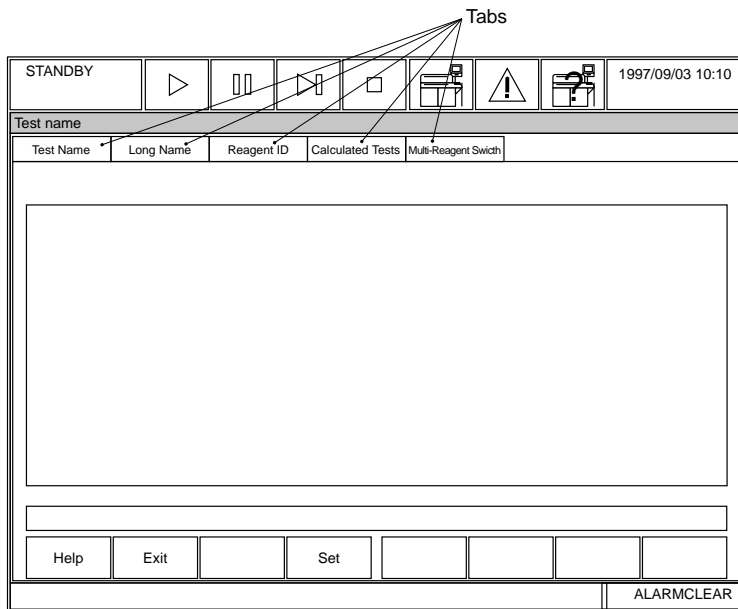
Description of main operations are displayed for guidance.

Alarm message display area

Displays a message if an error occurs or if the system changes the operation mode.

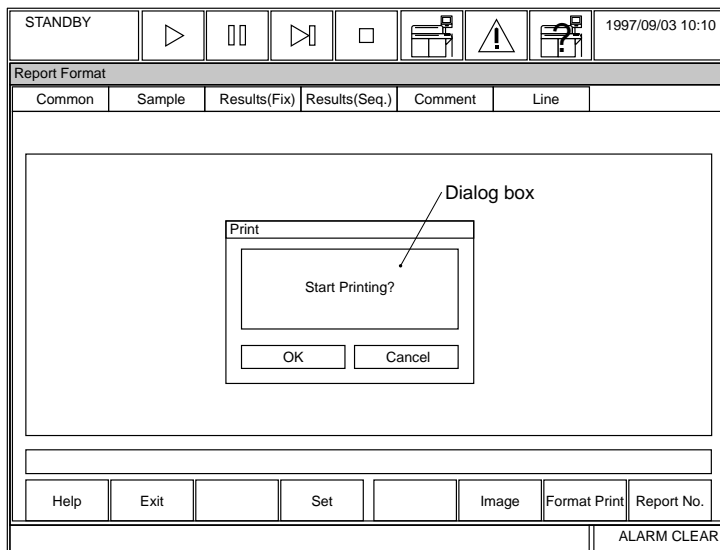
Example of Tabs

Display screens can be selected by clicking a tab. The following illustration displays an example of tabs.



Example of a Dialog Box

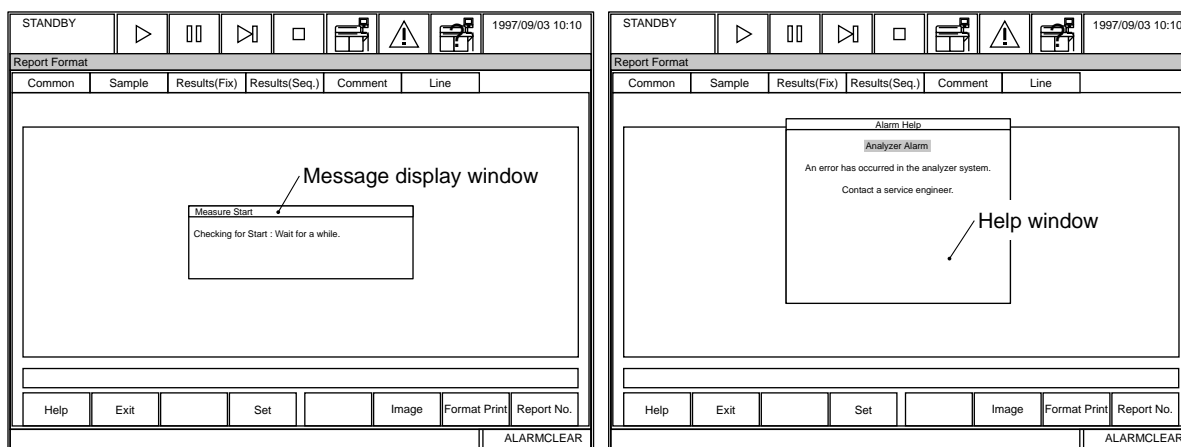
If a setup function is attempted, or if confirmation of a function is necessary, the following dialog box appears.



Tip

The term "dialog box" is also referred to as "prompt."

Example of a Window



Message display window

Displays information about notification messages, etc.

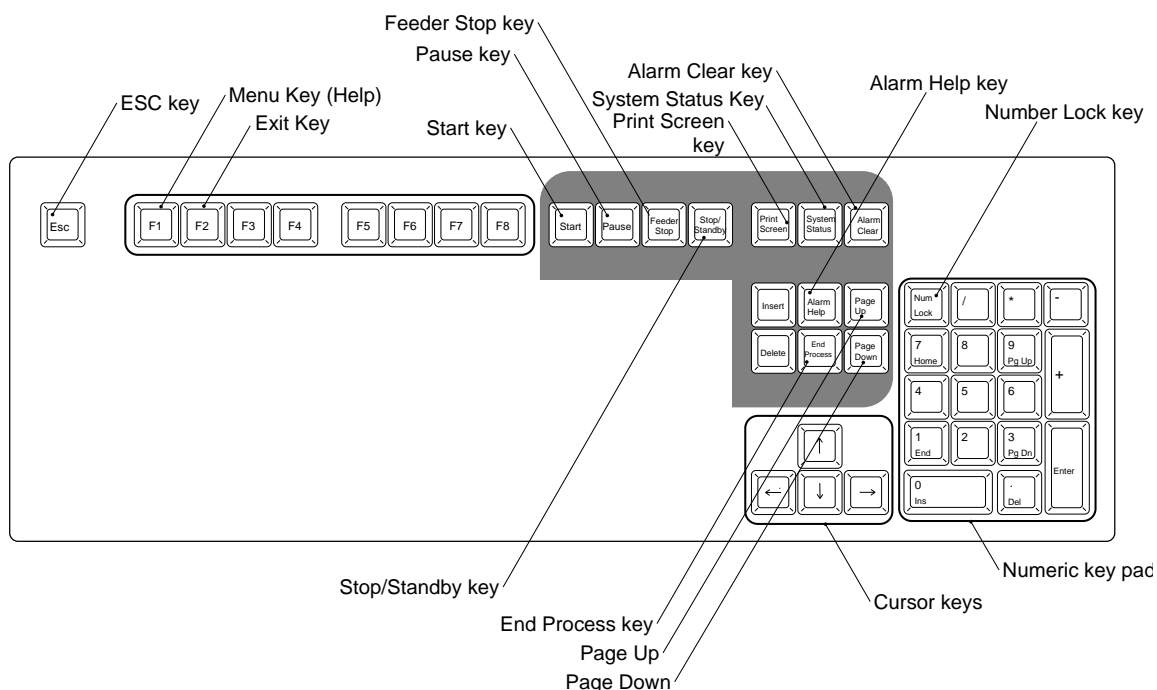
Help window

Displays the description of alarms or operations if the Help key is pressed.

3.1 Keyboard Functions

To perform screen operations smoothly, become familiar with the key names and functions of the keyboard.

Keyboard Appearance, Key Names and Functions



Start key

Starts analysis.

Stop/Standby key

Stops analysis. The system moves from Stop to Standby or Standby to Stop.

Pause key

Continues analyzing the current samples under analysis, then pauses. When pause is released by pressing start, analysis starts from the place it left off.

Feeder Stop key

Stops the rack feed operation of the transfer rack feeder.

Print Screen key

Prints the screen content currently displayed.

Alarm Clear key

Clears an alarm sound and alarm message. To clear the alarm sound, press the Alarm Clear key once. To clear the alarm message, press this key once more.

Alarm Help key

Displays the alarm help window.

Menu Help key

Displays the menu help window.

End Process key

Performs an End Process and turns off system power, but not the reagent refrigerator or incubator.

Cursor keys

Arrow keys: Moves the cursor in the direction indicated by the arrow.

Delete key: Deletes characters.

Backspace key: Deletes the character immediately before the cursor.

Num Lock key

This key changes the function of the ten-key pad. Press the Num Lock key to use the numbers on the ten-key pad. (Num Lock light will be lit).

ESC key

This key is used to cancel input.

System Status key

Used to enter the [System Status] menu.

System
Status Icon

STANDBY	▶	⏸	▶	□	🖨	⚠	🖨	1997/09/03 10:10
System Status								
(0) Reagent Status			(1) ISE Status			(2) Data Display		
Unchecked			Ready					
R1 R2			Electrode			(3) Alarm List		
Reagent of Group		Reagent of Group	Reagent			(4) Cuvette Status		
Status		Status						
(5) Analyzer Status			(6) DPR Status			(7) STAT Table Status		
Detergent Tank		D.I. Water	Measure S.No.:			END SET		
Vacuum		Drain	Input Online S.No.:					
Rack:			Output Online S.No.:			STAT Cal./QC Status		
Bath Temp.:		C	Printer:			Unchecked		
REF. Coolant Temp.:		C				Calibration:		
						QC:		
Help		Exit		W1 Start		W2 Start		Photocal Start
								One Touch
ALARMCLEAR								

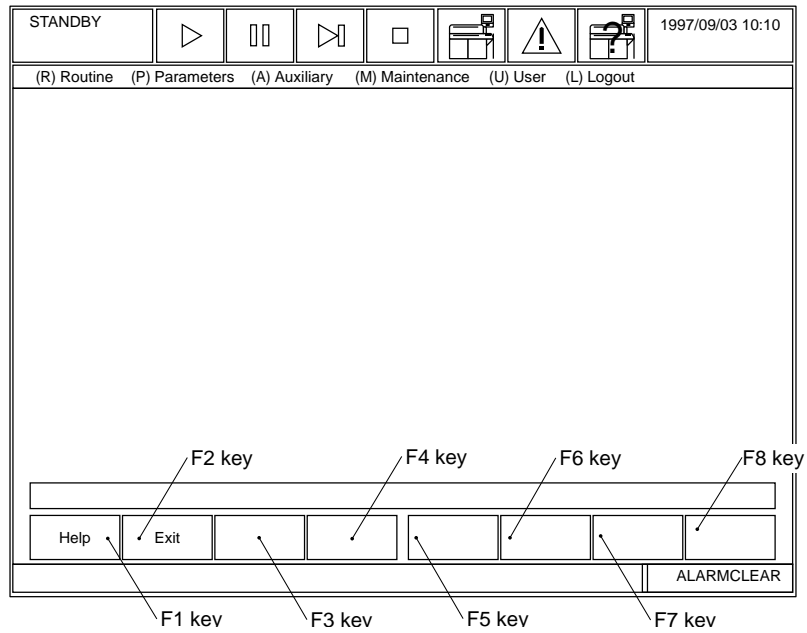
To return to the previous screen, press the [System Status] key again. This key will not function in the Initialize mode or the Maintenance mode.

See Also

For detailed information about the [System Status] key, refer to [System Status] in the Software Chapter.

Function key

Eight functions keys are displayed at the bottom of the screen.

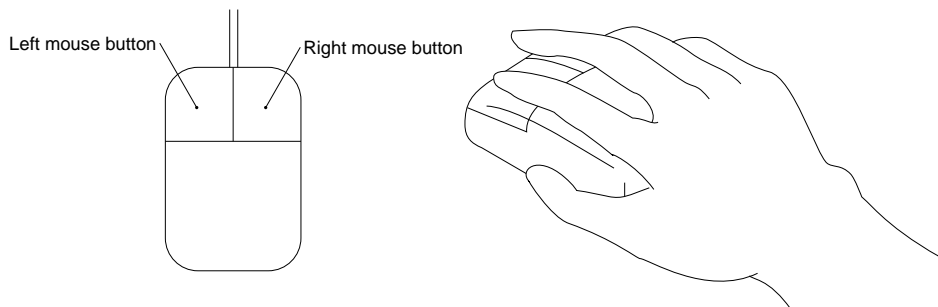


Each function displayed on the screen is executed by pressing the corresponding function key. For example, to close the currently displayed screen, press the F2 key, which corresponds to "Exit" on the screen.

3.2 Using the Mouse

The menus on the screen can be selected by using the mouse in place of using the keyboard.

Operating the Mouse



The arrow (pointer) will move in accordance with the mouse movement.

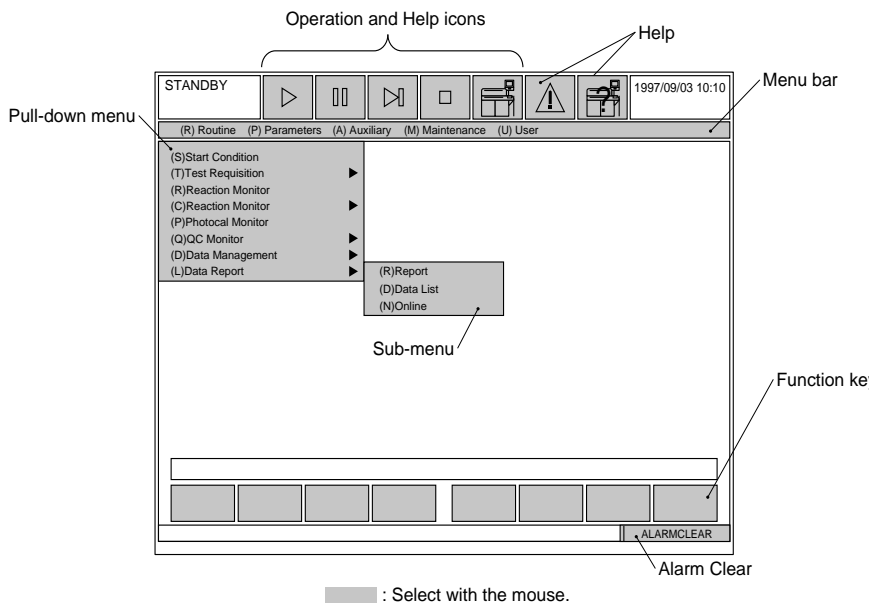
Selecting a Menu or Item Using the Mouse

1. Hold the mouse with your hand as shown in the figure.
2. To select a menu or function, position the mouse pointer on the menu or function to be selected.
3. Press and release the left mouse button quickly. *The item will be selected.*

Tip

Do not use the right mouse button. No function is assigned to the right mouse button.

The functions in the drawing below can be selected using the mouse.



3.3 Selecting Menus and Items

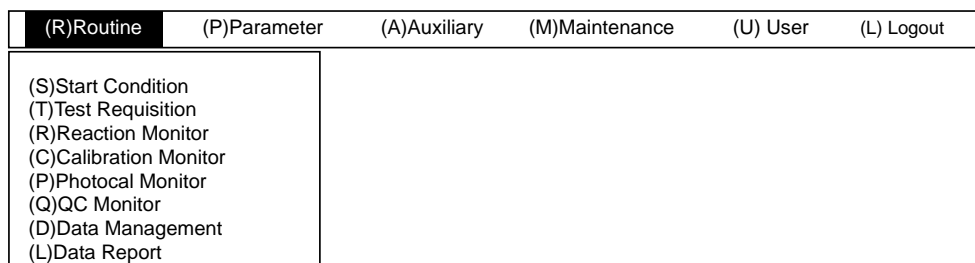
This section describes the procedure used for selecting menus or items using the cursor on the screen.

Selecting a Menu from the Menu Bar

There are two ways to select a menu from the menu bar. Use the arrow keys and Enter key, or use the short cut keys.

Selecting a menu using the arrow keys and Enter key

1. Move the cursor onto a desired menu on the menu bar using the arrows on the keyboard.
2. Press the Enter key or the down arrows key. *A pull-down menu will be displayed.*



Tip

In this stage the cursor can also be moved along the menu bar using the arrow keys. The cursor-highlighted menu will open the pull-down menu automatically. This method is helpful for searching or confirming the pull-down menu items.

3. Move the cursor onto a desired menu on the pull-down menu using the up or down arrow keys.
4. Press the Enter key. *If the menu does not contain a submenu, the selected menu is executed and the screen display changes. If the menu contains a submenu, perform steps 5 and 6.*
5. Move the cursor onto a desired menu on the submenu using the up or down arrow keys.
6. Press the Enter key. *The selected menu is executed and the screen display changes.*

Selecting a menu using the short cut keys

Letters or numbers are assigned to menu items on menu bars, pull-down menus, and submenus. These letters and numbers are called shortcut keys. When the shortcut key is pressed, the corresponding menu will be opened.

Exiting a Menu

To exit a menu, press function key F2.

Pressing the F2 key

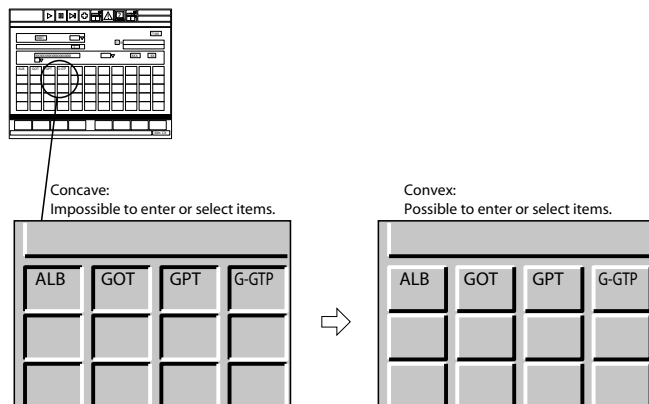
If function key F2 key is pressed, the current screen will close.

Tip

The F2 key can only be used to close the current screen.

Display Format: Entering or Selecting Functions

View the screen to determine how an item should be selected. If a button on screen is concave, an item cannot be selected or entered. If a button is convex, it is possible to enter or select an item. If the "Start Load" or "Setup" function is selected, the corresponding buttons on screen will change from concave to convex to enable entry or selection. A color change is also associated with entry or selection.



Selecting Screen Item(s)

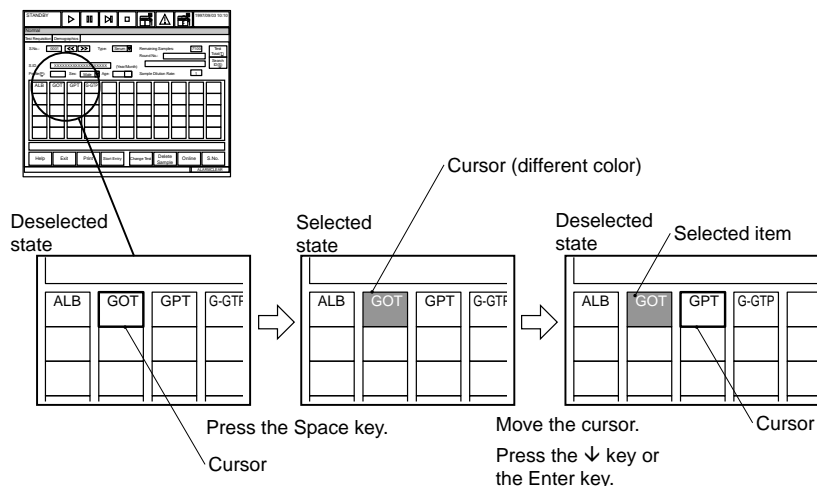
To select items on screen, the following two methods are available:

Selecting one item

This method is used to select one item (test, etc.) from the displayed list. It is used if the tests are processed sequentially one by one. *For example, if changing the type of each sample (serum, urine, etc.), move the cursor onto the type to be set in the sample type list, then press the Enter key. The test on which the cursor is placed will be set.*

Selecting multiple items by batch

This method is used to select multiple items (test, etc.) from the displayed list. It is used if multiple items are batch-processed. *For example, if printing reports for routine samples, emergency samples, etc., select the sample to print, then execute batch-processing for report printout. Use the spacebar to select an item. The selected item appears in a different color from that of the one that is not selected. If using the mouse, the selection and deselection of the item can be toggled each time the left mouse button is clicked.*



Entering Data or Modifying the Setting on the Screen

The following three methods are available for entering data or modifying the setting on the screen.

Tip

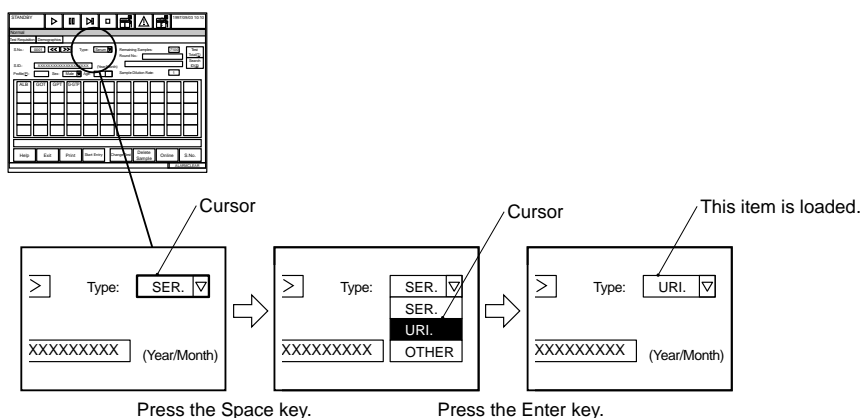
To load the entered data, always press the Enter key after entry. If the arrow keys, or another key is pressed without pressing the Enter key, the entered data may not be saved.

Entering the data directly

Move the cursor to a field, press the appropriate key on the keyboard to enter information directly. After entry, press the Enter key. The data is loaded and the cursor moves to the next field.

Selecting options from a pull-down menu

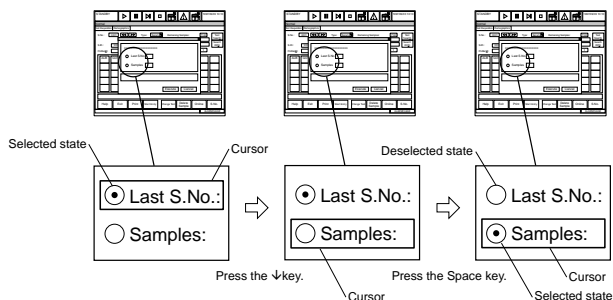
A pull-down menu lists options which can be selected. To use a pull-down menu, move the cursor to a field that displays an inverted triangle. Press the space key or click the left mouse button. The options for that field appear. To make your selection, use the up or down arrow key located on your keyboard. When the cursor is on the selection of your choice, press enter. If using a mouse, click the left mouse button. Your selection appears in that field.



Making a selection with an option button

Option buttons allow selection of one option from multiple choices.

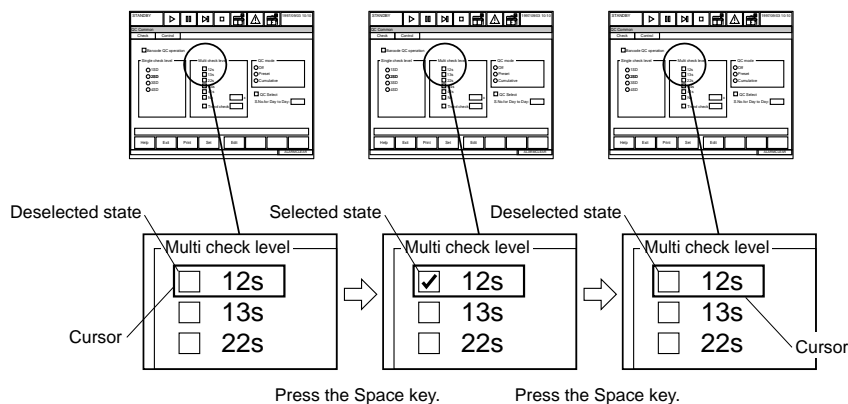
1. Move the cursor to your selection. Refer to the illustration.
2. Press the Space Key located on the keyboard. If using the mouse, click the left mouse button. A black dot appears within the circle next to your selection.



Selecting an item with a check box

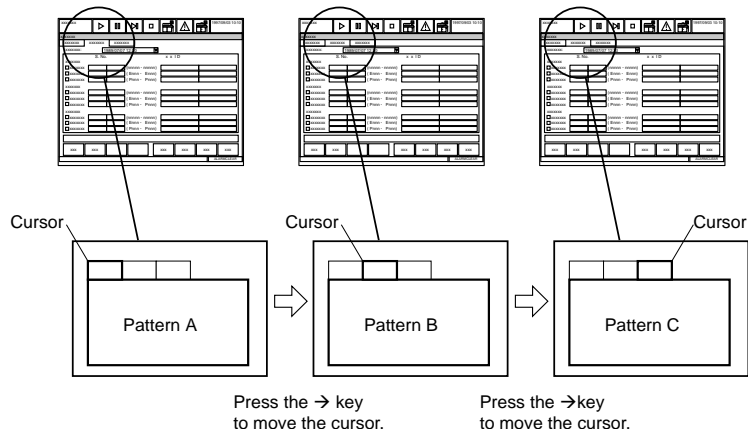
To select an item with a check box:

1. Move the cursor to your selection which has a box to the left.
2. Press the Space Key located on the keyboard. If using the mouse, click the left mouse button. A check will appear within the box next to your selection.



Displaying screens that have tabs

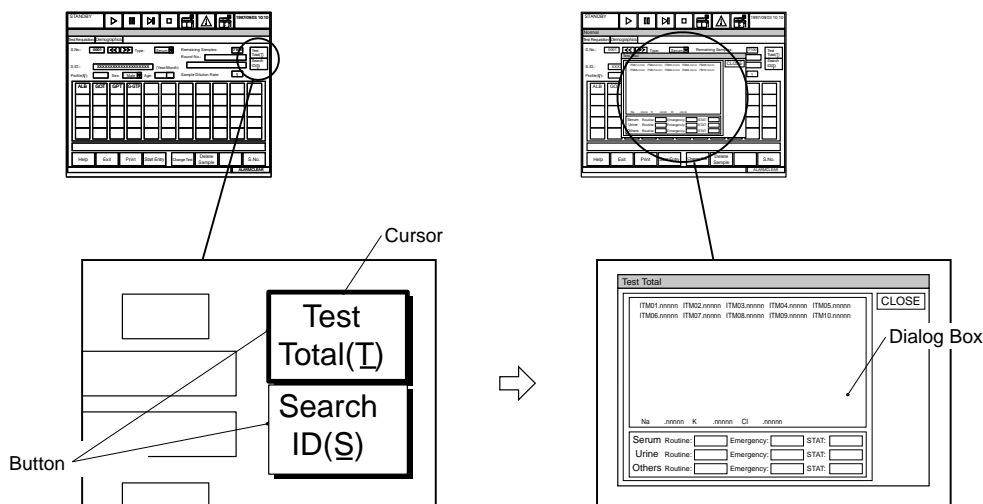
A tab layers one or more screen levels. To display a particular screen level, move the cursor to the desired tab or click on the tab with the left mouse button.



Selecting a button

To select an item with a button, use one of the following options:

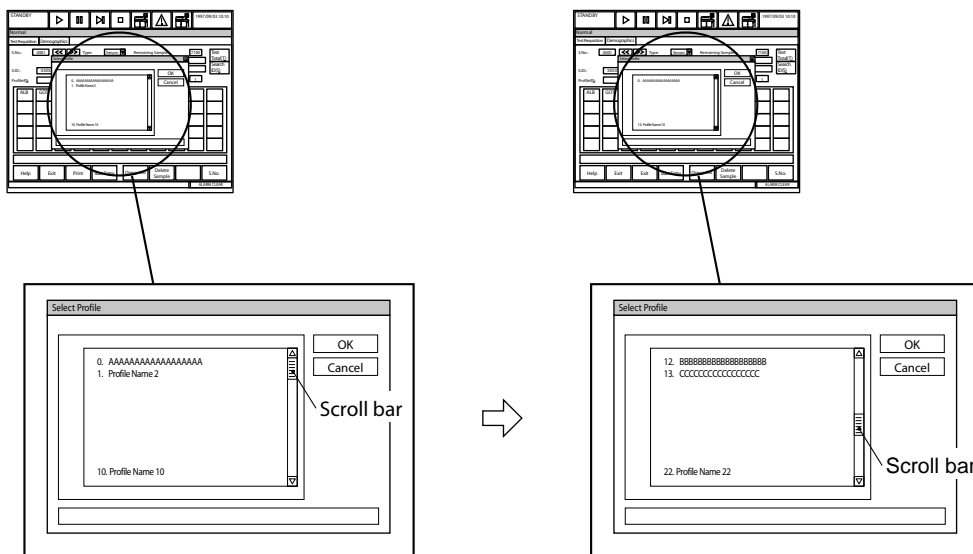
- Move the cursor to the button you want to select and press enter.
- Press the shortcut key in parenthesis () while holding the ALT Key down.
- Click on the button with the left mouse button.



Press the Enter key
or click the left mouse button.

Using the scroll bar

If the content of the screen exceeds the visible area of the screen, a scroll bar is displayed. Press the page up key or page down key located on the keyboard to view the rest of the screen. You can also use the mouse by pointing on the scroll bar and dragging it up or down. See the following illustration for details.

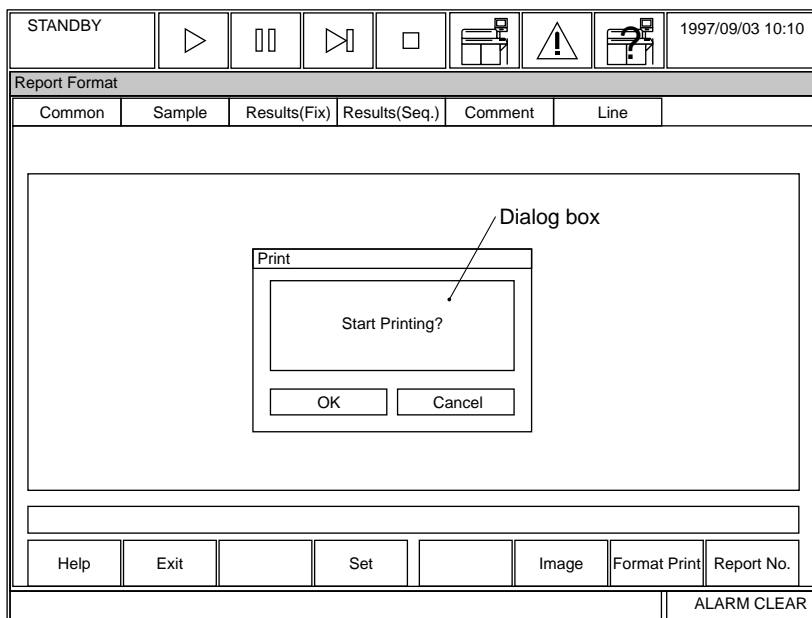


Press the Page Up key or Page Down key.
If using the mouse, drag the scroll bar.

How to use a dialog box

To select an item with a button, use one of the following options:

- Move the cursor to the button you want to select and press enter.
- Move the mouse to the button you want to select and click the left mouse button.



Key Entry Rule

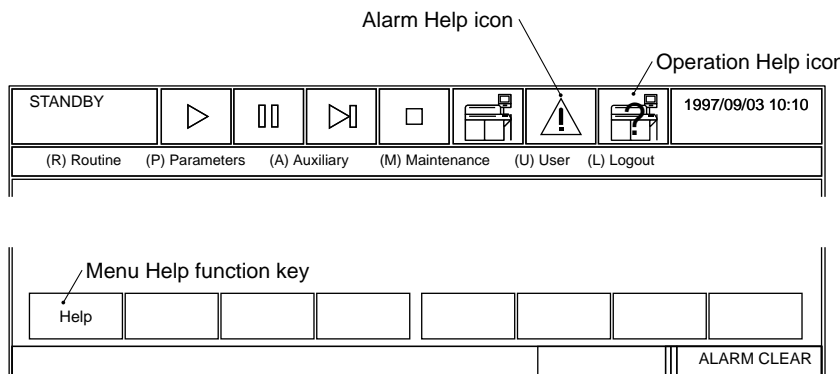
- Numeric entry: Enter a numeric value from the numeric key pad, then press the Enter key.
- Retaining the original data: Only press the Enter key.

Tip

-
- To load the entered data, be sure to press the Enter key after entry. If the screen is closed without loading, the entered data will not be valid.
 - If a multi-digit number contains zeros in the first digits, they do not need to be entered. To enter “0001,” for example, type “1” and press the Enter key and “0001” will automatically appear.
-

3.4 Help Functions

The AU640[®] is equipped with an on-line help function. The operator can easily obtain information on alarms, operations, and software menus.



Operation help

Provides the same procedures found in the User's Guide. This is an on-line guide that can be searched using Acrobat Reader. This help function also has QuickTime video clips illustrating more complex procedures.

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QuickTime is registered in the U.S. and other countries.

Menu help (Function Key F1)

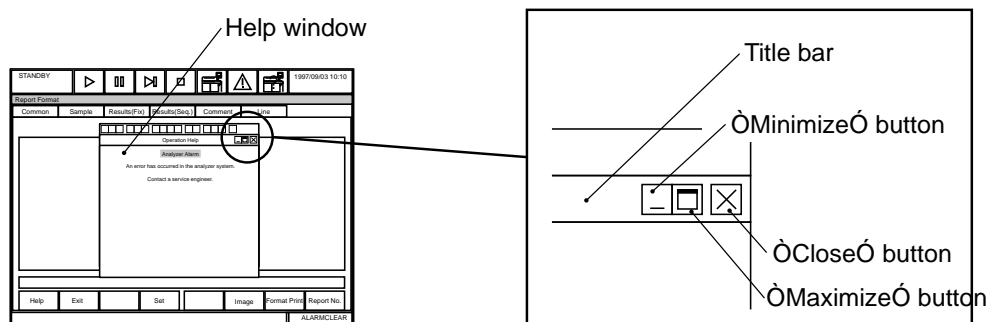
Describes how to use the selected software screen. *While a screen is selected, press the F1 key. If using the mouse, move the pointer onto function key F1 on screen, then click the left mouse button.*

Alarm help

Displays information about system alarms. *Press the help (home) key while the alarm message is displayed. If using the mouse, move the pointer onto the alarm help icon, then press the left mouse button.*

Window help

If the help window is displayed: 1. Use the scroll bar to view the entire message. 2. Press the "Close" button shown below to close the help window.



4. Login/Logout Function

Outline of Login/Logout Function

Software menu screens can be restricted to certain users for extra system security. The login/logout function is used to determine the range of menu items that the user can access, depending on the login name and password. The system registers the login names and passwords of the users. The access levels must be setup for the menu items and registered users. The user can access the menu items that are equivalent to or lower than the user access level.

Tip

The login names and access levels should be setup by the system administrator or qualified service personnel.

Login at System Start-up

Execute login when starting the system. The accessible menu range is determined at login. Menus which can be started immediately are displayed in blue. Menus with a level higher than the login level are displayed in a light color.

To avoid entering a login name and password, just press enter. The lowest level of menus are available. When login is executed, the login name and time are recorded in the alarm log list.

Procedure for Executing Login or Temporary Login

When the system is started, the window for inputting the login name and password will be displayed. (Note: Use the same procedure if one user has logged out and a different user is logging in.)

1. Input the login name and press the Enter key. *Move the cursor onto the password input field.*
2. Type the password and press the Enter key. *The system asks for a login name. If the password is consistent with the registered login name, the menu bar or selected screen will appear. If it is not consistent, the system returns to the wait state for a designated login name.*

Procedure for Executing Logout

Select [Logout] when the menu bar is displayed. After logging out, the name and time are recorded in the alarm log file.

5. *Description of Measure Modes*

AU640^e Measure Modes

Measure 1:

Sample analysis has started. Racks are moving from the feeder belt to the transfer belt.

Measure 2:

No more racks are detected on the feeder belt.

Measure 3:

All R1 dispensing is completed.

Measure End (4):

Final cuvette wash. (When using Auto Repeat, this will display as a Measure 4 rather than a Measure End.)

Measure End (5):

(Not displayed) A nonfatal mechanical error occurred during analysis with one or more samples having R2 mixed prior to the nonfatal mechanical error. Processing will finish for the samples that have R2 mixed.

One Touch Mode:

Preprogrammed STAT analysis mode. Sample requisition is not required.

Chapter C

Basic Operations

Introduction

This Chapter is designed as a quick response guide describing basic system operations. It contains information on: preparing and starting analysis, obtaining results, and finishing analysis. It also describes other frequently used procedures performed during daily routine operations.

Chapter C

Basic Operations

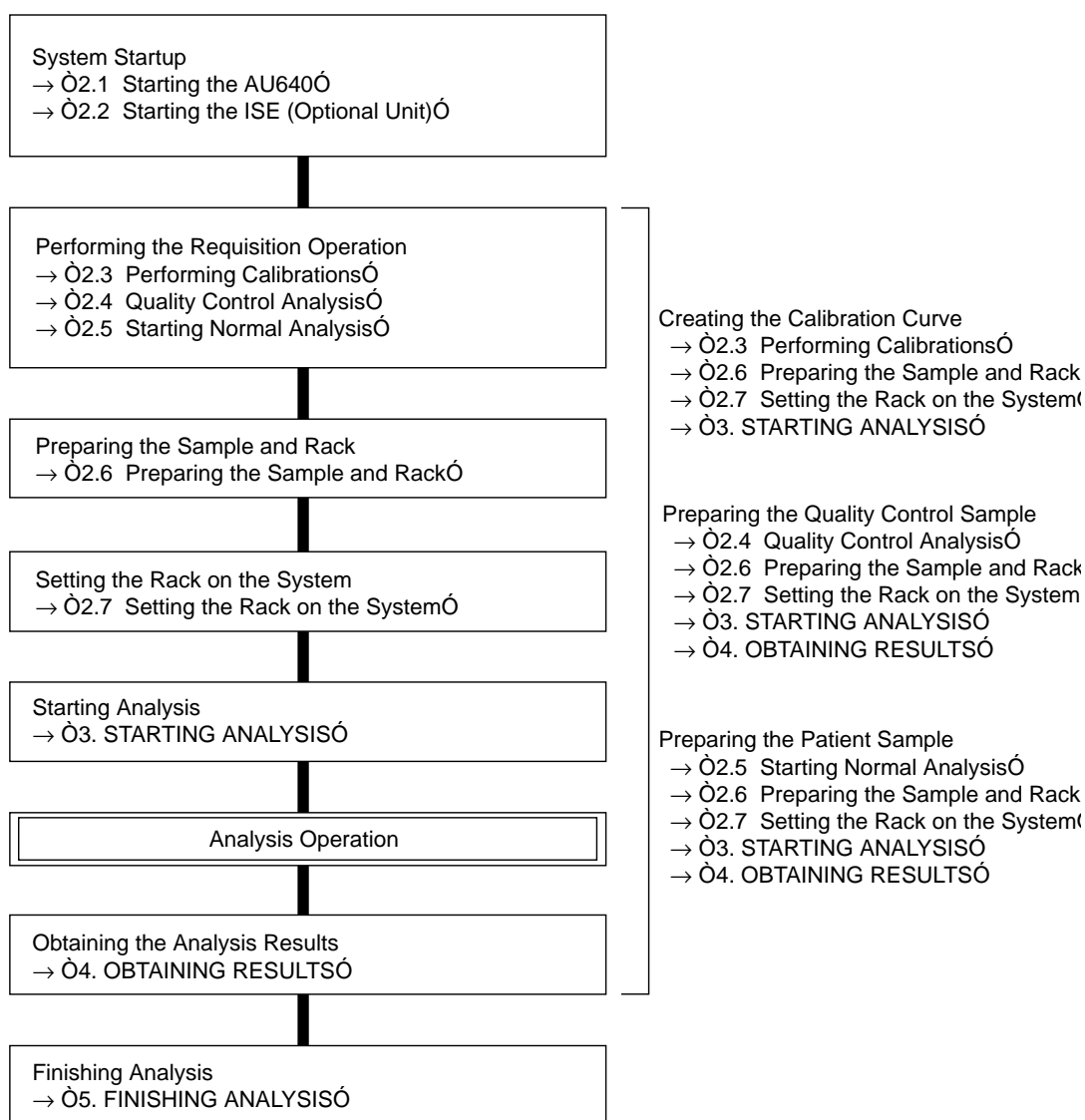
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1. General Operating Procedures

This chart illustrates the flow of normal operating procedures. To obtain accurate results, calibrate the analyzer based on the manufacturer's calibration stability claim after system start-up. This updates the calibration curve. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure. During operation of the AU640[®], at least two levels of control material should be tested a minimum of once a day. In addition, these controls should be performed after calibration, with each new lot of reagents, and after specific maintenance or troubleshooting steps described in the Maintenance Chapter or Troubleshooting Chapter in this guide.

Operation Chart



System Start-up

For detailed procedures, refer to the section “Starting the AU640^e.”

Creating Calibration Curves

To obtain accurate results after system start-up, calibrate the analyzer based on the manufacturer’s calibration stability recommendations. This updates the calibration curve. Based on the calibration results, the calibration curve is calculated from the absorbance (optical density [OD]) of the calibrator(s) measured during analysis.

See Also

For information on performing calibrations and a reagent blank on the STAT table, refer to “Preparing for Analysis.”

To create calibration curves:

1. Requisition for calibration analysis by selecting [Routine], [Test Requisition], [Calibration].
2. Use the blue rack for reagent blanks. Set a deionized water sample in position #1 for serum, position #10 for urine, or position #4 for other fluids. Place the calibrator in the yellow rack.
3. Start analysis.
4. Review the reagent blank(s) and calibrator(s) data, check that no calibration errors occur.
5. Confirm that the reagent blank value was updated by selecting [Routine], [Calibration Monitor], [Reagent Blank Monitor].
6. Confirm that the calibration factors are updated for each calibrated test by selecting [Routine], [Calibration Monitor], [Calibration Curve].

Measuring Quality Control Samples

After updating the calibration curves, quality control testing should be performed in accordance with regulatory requirements and each laboratory’s standard procedure to check for errors in the results. During operation of the AU640^e, at least two levels of control material should be tested a minimum of once a day. In addition, these controls should be performed after calibration, with each new lot of reagents, and after specific maintenance or troubleshooting steps described in the Maintenance Chapter or Troubleshooting Chapter in this guide. Quality control is performed to check for variations in the data.

Measure the control sample by performing the following operation:

1. Requisition for quality control by selecting [Routine], [Test Requisition], [QC].
2. Place the green rack with the control sample or barcoded control samples on the rack feeder unit.
3. Start analysis.
4. Review the QC results, check that there are no errors in the data.
5. Using [QC Monitor] from the [Routine] menu, check the daily variation chart and the day-to-day variation chart for abnormal data.

Commercial Control Sera for the ISE

When using commercial control sera for the ISE, be sure to consider the following:

- Commercial control sera contains additives for regulating the concentration of components, as well as various preservatives. If these kinds of control sera are measured using an ion-selective electrode, the added materials may adversely affect the electrode, and could cause measurement errors including abnormal data. It is possible that the effects of preservatives on results may change over time.
- Control sera recommended by Beckman Coulter are listed below. Changes in added components (especially preservatives) may occur in the future.

Recommended Control Sera

Control sera _____

Beckman Coulter Liquid Chemistry Control

(DR0061, DR0062)

Caution

- The following items affect measurement:
 - The K and Cl results are not affected by bilirubin, but small positive errors will occur in the Na results.
 - Positive errors will occur in the Cl results due to other halogen ions (Br, I).
 - If the hematocrit value for the total blood sample is 65% or more, positive errors may be recognized in the K results.
 - The measurements are not affected by ascorbic acid or lipemia (lipid emulsion additives).
 - When measuring plasma samples, use Beckman Coulter recommended anticoagulants. Any other anticoagulants could cause measurement errors.
 - In order to prevent fluctuations due to the sample evaporation, tightly cap and properly store samples.
-

Measuring the Patient Sample (Normal Analysis)

On the operation screen, measurement of the patient sample is called normal analysis.

See Also

For more information on normal analysis, refer to the section called “Starting Normal Analysis.”

Obtaining Appropriate Analysis Results

After starting analysis, check the quality-control charts, and patient results on the printout. Periodically check results after the sample has been analyzed.

Shutting Down the Analyzer

After all analysis is complete, perform an end operation. This turns off the sub-power to the system. The main power remains ON to maintain the temperature of the reagent refrigerators and reaction bath (incubator). Periodically, the ISE performs a prime cycle. After the end operation procedure, close the main valve to the deionized water.

Handling Alarms

If an error occurs while using the system, an alarm message is displayed on the monitor screen. Use the on-line help to assist in correcting the problem.

2. *Preparing for Analysis*

Before starting analysis, review the sections listed below:

Preparations for Analysis

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2.1 Starting the AU640e

Perform the following start-up and daily maintenance procedures before beginning analysis.

Tips

The AU640^e is supplied with main power and sub-power switches. The main power is turned on and off with the main breaker. In an emergency, perform the emergency stop procedure. *For detailed procedures, refer to the Troubleshooting Chapter.* Press the Reset switch to turn the main power back on. The sub-power is turned on with the On switch. The sub-power is turned off by pressing the End key on the keyboard. To start the AU640^e, both the main and sub-power must be turned on. *The main power should be on at all times except in an emergency! The main power supplies power for refrigerator, the incubator, and the automatic priming of the ISE.*

Starting the AU640^e

If the AU640^e system is off, perform the following procedures. If the AU640^e is on and a new index needs to be created, select [Routine], [Start Conditions], then skip to step 4.

1. Open the main deionized water supply valve.
2. Press the On switch: *Initialization occurs, the lamp comes on, and the software is loaded.*
3. After pressing the On switch, the [Start Up] screen will appear after 1 minute

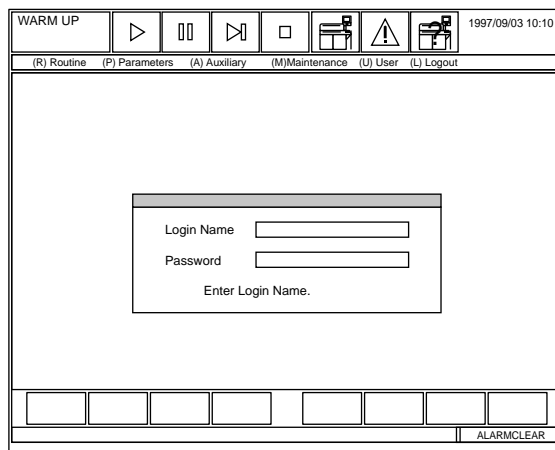
STANDBY	▶	⏸	▶	□	⚙	⚠	⚙	1998/11/03 10:10
Start Condition								
Data Index:	1993 / 12 / 13 11 : 59							
Round No.:	Routine							
Operator Name:								
Serum Start No.	Routine	Emergency	STAT	Calibration:				
Normal				Remaining Samples: nnnn				
Repeat								
Urine Start No.	Routine	Emergency	STAT					
Normal								
Repeat								
Others Start No.	Routine	Emergency	STAT					
Normal								
Repeat								
Help Exit Set Cal QC Default Start No. Data Index								
ALARMCLEAR								

4. Change the data index by selecting function key F4 (set). Use the pull-down menu to select "1. Current Time" to create a new index.

See Also

For information about the [Start Condition] screen, refer to the Software Chapter.

5. After confirmation, press function key F2 (exit).



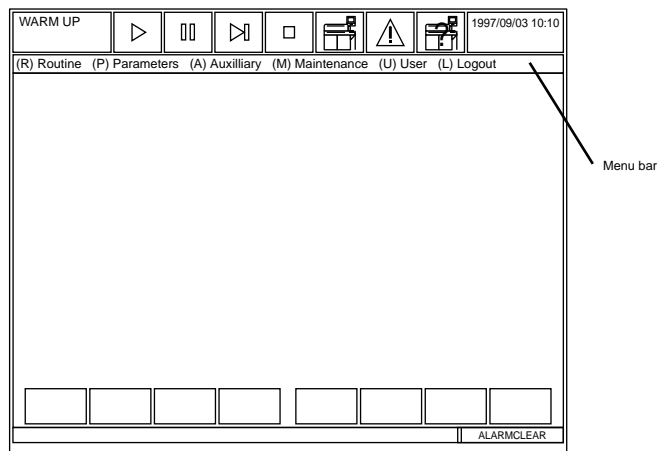
Note

The system security pop-up screen appears only if the analyzer options are activated. Enter the log-in name and password then press enter.

See Also

For information about creating passwords, refer to the Software Chapter.

The window closes and the main screen appears. *See the illustration below for the location of the menu bar.*



7. Perform the following daily maintenance procedures. Refer to the Maintenance Chapter for detailed procedures.

- Check the sample and reagent syringes for leaks or condensation.
- Check the wash solution rolling pump unit for leaks.
- Check the wash syringes for leaks.
- Inspect the stability of the upper cover.
- Fill the concentrated wash solution bottle. Analysis stops and a warning message displays on the screen if there is insufficient concentrated wash solution.
- Check the sample probe, reagent probes and mix bars. *The probes should be straight and clean. The mix bars should be clean with no chips in the Teflon.*

- Select the following menus: [Maintenance], [Analyzer Maintenance], H. Prime Washing-line. Press the STAT/ROT button. Verify that a thin, straight stream of diluent dispenses from all probes. If the probes or mix bars appear dirty, clean them with an alcohol prep.
- Verify that the printer “Ready” light is on and that there is sufficient printer paper.

See Also

For detailed information on analyzer maintenance, refer to the Maintenance Chapter.

8. Perform a Reagent Volume Check. Look at how many tests remain in each bottle and load any necessary reagents. If new bottles are added, perform another check.
 - A. Verify that reagents without barcodes are placed in the correct positions in the compartment. Reagents without barcodes need to be “fixed.” Refer to the procedure called “How to Fix a Reagent Position,” located in this chapter.
 - B. Select [System Status], then [Reagent Status]. Press function key F5 (check start), then select “Check for All Positions.”
 - C. Verify that the refrigerator lids are on. Click the “Start” button to begin and select “Yes” to start the check.
 - D. Verify “Checked” and “Reagent of Group” displays in blue. *If yellow or red appear, refer to “Reviewing reagent position errors” in [System Status], [Reagent Status] located in the Software Chapter of this Guide.*

See Also

For detailed information on the [Reagent Status] Screen, refer to the Software Chapter.

9. Verify that fixed reagents are in the correct positions.
10. Determine which tests need reagent blanks and/or calibrations. Press function key F8 (position display). Reagent bottle information displays. If a reagent expires, it will be highlighted in yellow and say “Expired” in the comment column. *For information on reagent position errors, refer to [System Status], [Reagent Status] in the Software Chapter of this Guide.*

Pos.	Test	Vol (mL)	Shot	Onboard Stability	Cal. Stability	Expired	Lot No.	Bottle No.	Seq.	Comment
1.	aaaaa	60				999	9999	999	1	R.ID Read Error

- 11 Error information such as “No reagent” is also highlighted in yellow in the “Comment” column. After checking the list, click the “close” button.

See Also

For detailed information on [System Status], refer to the Software Chapter.

12. Press function key F2 (exit) key. *The system status screen appears.* Press function key F2 (exit) again.

See Also

For detailed information on starting analysis, refer to the section in this chapter called “Starting Analysis.”

2.2 Starting the ISE

Perform the following ISE start-up and daily maintenance procedures before beginning analysis. For information on commercial control sera for the ISE, refer to the beginning of this chapter.

■ Starting the ISE Unit

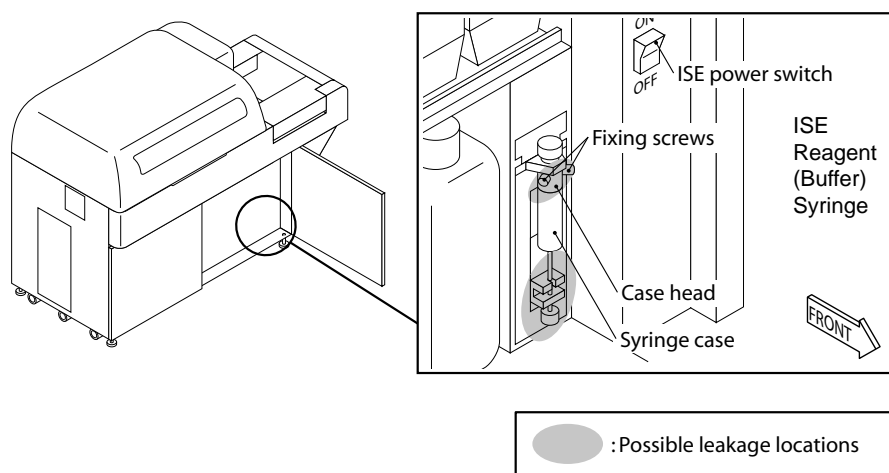
1. Verify the ISE power switch is on.
2. Verify that the ISE reagents have not expired. Refer to the package insert for information on open bottle stability

The liquid level of the tanks should be above the reference line shown on the bottle. If the liquid level is below the line, an insufficient liquid alarm will sound. After this alarm occurs, the following number of samples can be processed: 180 for Mid, 600 for Reference, and 240 for Buffer solution.

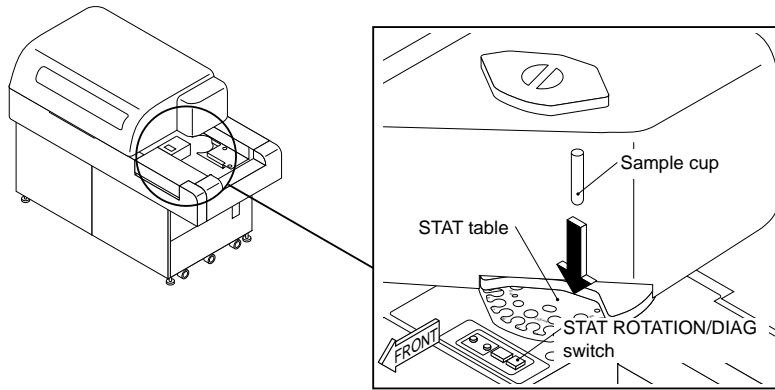
See Also

For more information about changing reagents, refer to the Maintenance Chapter.

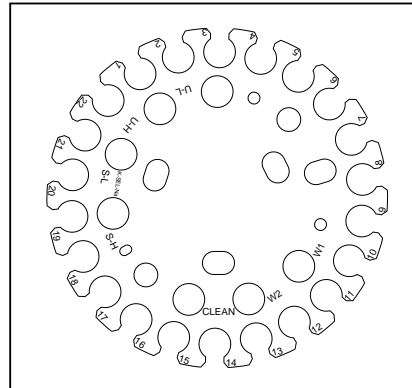
3. Verify the ISE buffer syringe is not leaking and that condensation is not visible.



4. Calibrate the ISE:
 - A. Remove the small STAT table cover.
 - B. Press the STAT ROTATION/DIAG Switch to rotate the STAT table so positions S-H, S-L, U-H and U-L can be accessed.
 - C. Place the serum and/or urine high and low standards in the labeled positions on the STAT table.



Top view of STAT table



- D. Replace the small STAT table cover.
- E. Select [System Status].
- F. On the [System Status] screen select [ISE Status].

System
Status Icon

STANDBY								1997/09/03 10:10	
ISE Status									
Result Cal.		Slope Chart		Result Select.					
Urine			Ready		Electrode		Reagent		
Date/Time	Na	K	Cl	Slope Na	Slope K	Slope Cl	MID Solution Factor Na	MID Solution Factor K	MID Solution Factor Cl
1994 / 12 / 18 13 : 33	60.0	55.1	Ø49.0	1.005	1.013	1.001			
1994 / 12 / 18 12 : 04	61.1	54.3	Ø52.7	1.006	0.997	1.000			
1994 / 12 / 18 11 : 56	59.0	54.7	Ø50.0	1.005	1.000	0.998			
1994 / 12 / 18 9 : 00	0.0	0.0	0.0	1.016	0.986	0.999			
1994 / 12 / 18 18 : 44	56.4	51.2	Ø48.9	1.003	1.003	1.000			
1994 / 12 / 18 13 : 01	55.3	49.5	Ø59.2	1.111	9.999	3.001			
1994 / 12 / 18 18 : 42	52.4	55.4	Ø52.3	1.026	1.259	0.222			
1994 / 12 / 18 12 : 33	52.2	55.2	Ø51.0	0.999	Ø7.945	1.003			
Normal Range	38-65		-38 - -65	0.75-1.25					
		38-65	0.80-1.20	0.75-1.25					
<input type="button" value="Help"/> <input type="button" value="Exit"/> <input type="button" value="ISE Stop"/> <input type="button" value="ISE Unit Start"/> <input type="button" value="Prime"/> <input type="button" value="Type Change"/>									
ALARMCLEAR									

- G. Select function key F5 (ISE unit start) Highlight: A. Cal for Serum, B. Cal for Urine, or C. Cal for Serum and Urine. When the prompt “Start Operation” appears, select “Yes.” It takes approximately 4 minutes to calibrate for serum and urine.
- H. When the calibration is complete, the results are displayed in a list. Verify the slope and mid-factor values are in range. If the values are out-of-range, (highlighted in yellow) perform calibration again. If the slope value or mid factor is still out of the normal range, the electrode may be deteriorating.

Slope:	38 to 65 (Cl is negative)
Mid Factor:	Na = 0.80 to 1.20 K = 0.75 to 1.25 Cl = 0.75 to 1.25

Mid Factor: Na = 0.80 to 1.20
K = 0.75 to 1.25
Cl = 0.75 to 1.25

- I. After checking results, press function key F2 (exit). *The main screen returns.*

See Also

For calibration errors, refer to the ISE section of the Troubleshooting Chapter. For information about replacing electrodes, refer to the Maintenance Chapter.

Commercial Control Serum for the ISE

When using the commercial control serum for the ISE, be sure to exercise great care for the following points:

- Commercial control serum contains additives for regulating the density of components, as well as various preservatives. If these kinds of control serums are measured using an ion-selective electrode, the added materials may adversely affect the electrode, and could cause measurement errors including abnormal data.
- The commercial control serums that Beckman Coulter recommends are listed below. Changes in added components (especially preservatives) are likely in the future.

Recommended Control Serums:

Control Serum	Manufacturer
AU control level 1	Beckman Coulter
AU control level 2	Beckman Coulter

Caution

The following items affect the measurements:

- The K and Cl electrodes are not affected by bilirubin, but small positive errors will occur in the Na electrode.
 - Positive errors will occur in the Cl electrode due to other halogen ions (Br, I).
 - A positive error will be recognized in the K electrode for samples where the hematocrit value is 65% or more. If a hemolytic sample is used, K shows an excessively positive error.
 - The measurements are not effected by ascorbic acid or lipemic (lipid emulsion additives).
 - Use the anticoagulant heparin Li or Heparin Na. Any other anticoagulants may cause an error in measured values. Use the anticoagulant immediately after collecting blood.
 - In order to prevent fluctuation due to the sample evaporation, blood serum and plasma samples should be kept in a tightly closed refrigerator. Also, samples stored in a refrigerator should be measured after the temperature of the sample has returned to room temperature.
-

2.3 Performing Calibrations and a Reagent Blank

This procedure explains how to requisition for reagent blanks and calibrators. Reagent blanks and calibrators must be requisitioned each time the reagent blank and calibrator racks are processed or testing is not performed. The [Start Condition] screen displays whether the reagent blank and calibrator have tests requisitioned.

Note: The software can be programmed to allow urine tests to use serum calibrators. This feature is selected in [Parameters], [Calibration], [Calibration Specific]. Use the **◆** at the “Test Name” field to select tests. Then use the **◆** at “Type” to select urine. Add a **☑** to “Use serum cal for urine tests.” This feature can be used for all Beckman Coulter chemistries except creatinine and total protein. They require different calibrators from those used for serum tests.

Performing a Calibration and Reagent Blank on the Analyzer

1. From the main screen, select [Routine], [Test Requisition] and [Calibration] in that order. The calibration requisition screen is displayed.

ALB	GOT	GPT	G-GTP								

2. Use the pull-down menu to select the sample type: serum, urine or other.
3. Press function key F4 (start entry).
4. Select the tests requiring calibration by using one of the following options. Blue indicates reagent blank only, yellow indicates reagent blank and calibration (All).
 - Enter a profile number (1-99) at the profile field.
 - Use the mouse or keyboard to select individual tests.
 - Select function key F6 (Change Option) to change between calibration and RB only.
 - Select function key F7 (Select All Tests) to requisition all reagent blanks and calibrators.
 - Select function key F8 (RB All) to requisition a reagent blank only on all tests.
5. Press function key F4 (entry). *Repeat steps 2-5 to requisition for another sample type if required.*
6. Press function key F2 (exit). Verify that all tests requiring a reagent blank or calibration are highlighted in yellow (reagent blank + calibration) or blue (reagent blank only).
7. Exit the [Calibration] screen.
8. Place the RB rack then the calibration rack on the analyzer.
9. Press Start.

Important

The highest calibration number (From 1-80) must be placed last in the rack.

1. Make sure the calibrator barcode operation option is selected in [Parameters], [Calibration], [Calibrator]. For information on programming a new calibrator, refer to [Parameters], [Calibration], [Calibrator] located in the Software Chapter.
2. From the main screen, select [Routine], [Test Requisition] and [Calibration] in that order. *The calibration requisition screen is displayed.*
3. Follow steps 2 through 6 listed in the procedure called “Performing a Calibration and Reagent Blank on the Analyzer” listed on the previous page. Place the calibrator with the appropriate barcode ID in any position on the yellow rack and start analysis.

Note: To change calibrators, select function key F5 (Cal).

Performing a Reagent Blank or Calibration on the STAT Table

When calibrators are assigned positions on the STAT table, perform the following procedure. The STAT table also needs to be checked again after an End Process is performed, the large part of the STAT table cover is removed, or if certain parameter screens are opened.

1. Perform a STAT table check:
 - A. From the main menu, select [System Status], [STAT Table Status].
 - B. Place reagent blank, calibrator, and QC material in the correct positions on the table. Use the STAT ROTATION/DIAG Switch to turn the table if necessary. *Only place calibrator and QC material on the STAT table if analysis from this material is required.*
 - C. Select function key F5 (check start). In the STAT Check Window, select “Yes” at the “Start Checking?” prompt.

Note:

The table rotates and senses if reagent blank, calibrator, and/or QC cups are loaded. Alarms are generated if the positions are defined for reagent blank, calibrator, or QC in [System Maintenance] and cups are not detected.

2. Requisition reagent blanks or calibrations for the STAT table:
 - A. Determine what tests need to be calibrated from [System Status], [Reagent Status].
 - B. Select [System Status], [STAT Table Status]. Make sure reagent blank and calibrator cup(s) are placed in the correct positions on the STAT table.
 - C. Select function key F6 (Cal. Req.). In the calibration window at the “Type” field use the pull-down menu to select serum, urine, or other sample types.
 - D. Select the Start Entry button.

- E. Select the tests requiring a reagent blank or calibration. The tests highlight in blue for reagent blank only or yellow for reagent blank + calibration (All).
 - F. Select the Entry button to save your selections. Verify the tests selected are highlighted.
 - G. Repeat the previous steps for all sample types in use.
 - H. Select the Close button to exit this screen.
3. Close the cover.
 4. Press the STAT button to start analysis. *If the STAT LED is on, press the STAT switch once to start. If the STAT LED is off, press the STAT switch twice to start. If errors are present, an error list window will appear. Review the error list and correct any problems before starting analysis.*

2.4 Quality Control Analysis

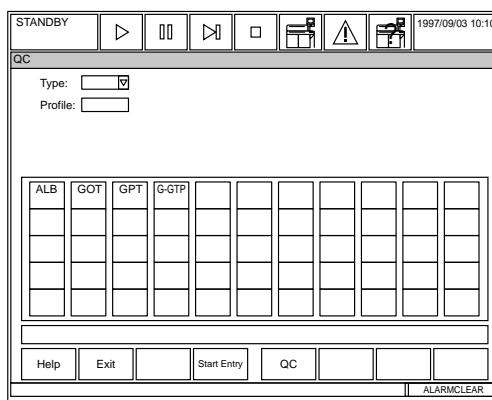
This procedure explains how to requisition for QC samples. Unlike the calibration requisition screen, the QC requisition screen defaults to perform all the QC tests. This procedure can also be used to deselect tests for the QC requisition that do not need QC analysis.

Requisitioning QC Samples

Note

- QC requisition defaults to all tests for bottle sequence 1 only.
- A reagent volume check resets [QC Requisition] to what the analyzer automatically requisitioned for QC. The analyzer automatically requisitions all QC for bottle sequence 1.
- Verify that [Reagent Status] is not red “Unchecked” before making any QC requisitions.

1. From the main menu [Routine], [Test Requisition], [QC]. The QC requisition screen appears.



2. At “Type,” select serum, urine, or others.
3. Select F4 Start Entry:
 - Select any tests that do not need QC to remove the blue highlight.
 - Select F8 Deselect All to remove the highlight from all tests. Select the test(s) required for QC analysis.
 - Select the Individual Requisition button to requisition sequenced bottles (1, 2, 3, 4, 5) of the same test.
 - Select the “All for One Test” button to requisition all sequenced bottles of the selected test.
 - Select the “All for All Tests” button to requisition all sequenced bottles for all tests.
4. Press F4 Entry. Verify QC requisitions. The tests to QC are highlighted in blue.
5. Repeat steps 2-4 to requisition another sample type if necessary.
6. Select F5 QC to view a picture of the racks and controls required. Select the Detail Inf. button to view the QC names and assigned positions.
7. Load the QC tubes in the correct green rack using the Detail Inf. Button or QC Rack Set-Up Charts.
8. Press the Start Key or icon.

Important

The highest QC number (From 1-60) must be placed last in the rack.

QC analysis with barcodes must be performed in a green rack.

1. From the main menu select the [Parameters], [QC Control], and [QC Common].
2. Place a check in the box by the “Barcode QC Operation” field under the “Check” tab.
3. Select the “control” tab on screen with the mouse.
4. Press function key F4 (set).
5. Press function key F5 (edit).
6. Set the control IDs of QC samples and select close.
7. Select function key F2 (exit) twice to return to the main menu.
8. Set sample containers on a green rack in any order.
9. Place racks on the analyzer.
10. Start analysis.

Performing QC on the STAT Table

When QC is assigned a position on the STAT table, perform the following procedure. The STAT table also needs to be checked again after an End Process is performed, the large part of the STAT table cover is removed, or if certain parameter screens are opened.

1. Perform a STAT table check:
 - A. From the main menu, select [System Status], [STAT Table Status].
 - B. Place reagent blank, calibrator, and QC material in the correct positions on the table. Use the STAT ROTATION/DIAG Switch to turn the table if necessary. Only place calibrator and QC material on the STAT table if analysis from this material is required.
 - C. Select function key F5 (check start). In the STAT Check Window, select Yes at the “Start Checking?” prompt.

Note

The table rotates and senses if reagent blank, calibrator, and/or QC cups are loaded. Alarms are generated if the positions are defined for reagent blank, calibrator, or QC in [System Maintenance] and cups are not detected.

2. Requisition QC for the STAT table:

The STAT table check resets the requisition screen to perform **ALL** QC tests (all tests are highlighted in blue). If you do not want to run all QC after the STAT table check, you must deselect the tests.

 - A. From [System Status], [STAT Table Status]. Make sure the QC is placed in the correct positions on the STAT table.
 - B. Select function key F7 (QC Req.). In the window at the “Type” field use the pull-down menu to select serum, urine, or other sample types.
 - C. Select the Start Entry button.

- D. If tests are highlighted in blue they are selected. Click the test with the mouse to deselect tests that do *not* require QC analysis.
 - E. Select the Entry button to save your selections. Verify the tests of your choice are selected (highlighted in blue).
 - F. Repeat the previous steps for all sample types in use.
 - G. Select the “Close” button to exit this screen.
3. Close the cover.
 4. Press the STAT button to start analysis. *If the STAT LED is on, press the STAT switch once to start. If the STAT LED is off, press the STAT switch twice to start. If errors are present, an error list window will appear. Review the error list and correct any problems before starting analysis.*

Performing Auto-calibrations and QC on the STAT Table

Reagent blanks, calibrations, and QC are performed automatically based on programming from [Parameters].

Note

[Stat Table Calibrations] and [STAT Table QC] in [Parameters] must be programmed to “Auto.”

1. From the main menu select the [System Status], [STAT Table Status].
2. Load the reagent blank, calibrators, or QC cup(s) in the correct positions on the STAT table. Use the STAT ROTATION/DIAG Switch if necessary. *Only place calibrator and QC material on the STAT table if analysis from this material is required.*
3. Perform a STAT table check:
 - A. From [STAT Table Status], place reagent blank, calibrator, and QC material in the correct positions on the table. Use the STAT ROTATION/DIAG Switch to turn the table if necessary.
 - B. Select function key F5 (check start). In the STAT Check Window, select “Yes” at the “Start Checking?” prompt.

Note: The table rotates and senses if reagent blank, calibrator, and/or QC cups are loaded. Alarms are generated if the positions are defined for reagent blank, calibrator, or QC in [System Maintenance] and cups are not detected.
4. Reagent blank, calibration and QC are performed automatically based on programming from the [Parameters] menu.

2.5 *Starting Normal Analysis*

Routine samples must have a requisition for the tests that will be run on each sample. Requisitions can be performed at the AU640^e in this screen, or downloaded from a host computer to the AU640^e. Requisitions are processed sequentially by sample number, or by the sample ID number. There are three methods for performing normal analysis requisitions: requisition for individual samples, batch requisition, and batch or real-time downloading from a host computer. If normal analysis is being performed using the ISE unit, select the ISE tests (Na, K, Cl) or requisitions can be downloaded from a host computer to the AU640^e. Profiles can be created to requisition a common group of tests at once.

Tips

If calibration or quality control is required with the normal patient samples (white racks), it is necessary to requisition for calibration and quality control in addition to the normal analysis procedure described here.

2.5.1 Entering Individual Requisitions (Routine, Emergency and Priority STATs)

For detailed information on performing priority STAT requisition and analysis, refer to “Performing Priority STAT Analysis.”

1. From the main menu, select [Routine], [Test Requisition] and [Normal], in that order. *The screen for requisitioning normal analysis is displayed.*

STANDBY 1997/09/03 10:10

Normal

Test Requisition Demographics

S.No.: 0001 Type: Serum Remaining Samples: 7100

S.ID.: XXXXXXXXXXXXXXXXXXXX (Year/Month)

Sex: Male Age: Sample Dilution Rate: 1

ALB	GOT	GPT	G-GTP								

Help Exit Print Start Entry Change Test Delete Sample Online S.No.

ALARMCLEAR

2. Select the following from the “type” pull-down menu: serum, urine or other.
3. Verify the sample number is correct for the next sample number to be processed on the AU640^e. *If you are processing emergency samples: Type an “E” to test emergency samples in the red rack or type a “P” to test emergency samples on the STAT table. Use function key F8 (S. No.) to select a specific sample number.*
4. Press function key F4 (start entry).
5. Enter the S. ID (sample ID or barcode) number if barcodes are in use or for manual entry that appears on the printout.
6. Highlight the tests to be performed in blue by clicking them with the mouse. Tests highlighted grey are not operational for the sample type selected.
7. Select function key F4 (entry). *The next sample number is available for requisition.*
8. Press function key F2 (exit) to return to the [Normal] screen. Repeat steps 2-7 for all sample types in use

9. Optional Step: When all requisitions are performed, select the [Demographics] tab and enter the patient information.

STANDBY [Play] [Pause] [Stop] [Printer] [Warning] [Printer] 1997/09/03 10:10

Normal

Test Requisition Demographics

S.No.: 0001 << >> Type: Serum Remaining Samples: 7100

S.ID.: XXXXXXXXXXXXXXXXXXXX

Sex: Male

Age: Year Month

Comment(C)

Help Exit Xn-Enter Entry Cancel Search S.ID Test Total S.No.

ALARMCLEAR

10. Press function key F2 (exit) twice to return to the main menu.

2.5.2 How to Requisition by a Profile (Routine, Emergency and Priority STATs)

Profiles can be used when requisitioning individual samples, or when entering group (batch) requisitions. For detailed information on performing priority STAT requisition and analysis, refer to “Performing Priority STAT Analysis.”

1. From the main menu, select [Routine], [Test Requisition] and [Normal], in that order. *The screen for requisitioning normal analysis is displayed.*

The screenshot displays the 'Normal' test requisition interface. At the top, there is a 'STANDBY' indicator and a row of function keys. The main area is divided into 'Test Requisition' and 'Demographics' sections. The 'Test Requisition' section includes fields for S.No. (0001), Type (Serum), Remaining Samples (7100), Round No., S.ID., Sex (Male), Age, and Sample Dilution Rate (1). The 'Demographics' section includes a grid for test results (ALB, GOT, GPT, G-GTP). At the bottom, there is a menu with buttons for Help, Exit, Print, Start Entry, Change Test, Delete Sample, Online, and S.No. An 'ALARMCLEAR' indicator is visible in the bottom right corner.

2. Select the following from the “type” pull-down menu: serum, urine or other.
3. Verify the sample number is correct for the next sample number to be processed on the AU640^e. *If you are processing emergency samples: Type an “E” to test emergency samples in the red rack or type a “P” to test emergency samples on the STAT table. Use function key F8 (S. No.) to select a specific sample number.*
4. Press function key F4 (start entry).
5. Enter the S. ID (sample ID or barcode) number if barcodes are in use or for manual entry that appears on the printout.
6. Click on the profile button to open the “select profile window.” Select a profile number (1-99) and click “OK.” Profile numbers can be generated with selected tests in [Parameters].
7. Press function key F4 (entry).
8. Press function key F2 (exit). Repeat steps for all sample types in use.

2.5.3 Entering Group (Batch) Requisitions (Routine, Emergency & Priority STATs)

Perform a batch requisition when analyzing the same tests for multiple samples. For detailed information on performing priority STAT requisition and analysis, refer to “Performing Priority STAT Analysis.”

1. From the main menu, select [Routine], [Test Requisition] and [Normal], in that order. *The screen for requisitioning normal analysis is displayed.*

The screenshot displays the 'Normal' test requisition screen. At the top, there is a 'STANDBY' indicator and a toolbar with icons for navigation and status. The main area is divided into 'Test Requisition' and 'Demographics' sections. The 'Test Requisition' section includes fields for S.No. (0001), Type (Serum), Remaining Samples (7100), Round No., S.ID., Sex (Male), Age, and Sample Dilution Rate (1). Below these fields is a grid of test buttons: ALB, GOT, GPT, G-GTP, and several empty cells. The 'Demographics' section is currently empty. At the bottom, there is a row of buttons: Help, Exit, Print, Start Entry, Change Test, Delete Sample, Online, S.No., and ALARMCLEAR.

2. Select the following from the “Type” pull-down menu: serum, urine or other.
3. Verify the sample number is correct for the next sample number to be processed on the AU640^e. *If you are processing emergency samples: Type an “E” to test emergency samples in the red rack or type a “P” to test emergency samples on the STAT table. Use function key F8 (S. No.) to select a specific sample number.*
4. Press function key F4 (start entry).
5. First, select tests individually or by a profile, and verify tests are highlighted.
Individually: Highlight the tests to be performed in blue by clicking them with your mouse. Tests highlighted grey are not operational for the sample type selected.
Profile: Click on the profile button to open the “select profile window.” Select a profile number (1-99) and click “OK.”
6. Press function key F3 (Xn-enter). Enter the last sample number of the batch, or enter the actual number of samples in the batch.
7. Click the “Execute” button. *The S. No. prompt advances to the next available sample number for requisitioning. If the barcode reader is on, the sample ID numbers increment by one.*
8. Press function key F2 (exit). *The main screen returns.*

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2.5.4 Performing Priority STAT Analysis

1. Requisition the tests:
 - A. From the main menu, select [Routine], [Test Requisition], [Normal]. The screen for requisitioning normal analysis is displayed.

The screenshot shows the 'Normal' test requisition screen. At the top, there is a 'STANDBY' indicator and a date/time stamp of '1997/09/03 10:10'. Below this is a navigation bar with icons for back, forward, and other functions. The main area is titled 'Normal' and contains several input fields: 'S.No.' with '0001', 'Type' set to 'Serum', 'Remaining Samples' at '7100', 'S.ID.' with a masked field 'XXXXXXXXXXXXXXXXXXXX', 'Profile', 'Sex' set to 'Male', 'Age', and 'Sample Dilution Rate' set to '1'. There is also a 'Round No.' field. A grid of test codes is displayed, with columns for ALB, GOT, GPT, and G-GTP. At the bottom, there are buttons for 'Help', 'Exit', 'Print', 'Start Entry', 'Change Test', 'Delete Sample', 'Online', and 'S.No.'. The status bar at the very bottom shows 'ALARMCLEAR'.

- B. From the “Type” pull-down menu select: serum, urine or other.
 - C. Verify the sample number is correct for the next sample number to be processed on the AU640e. Type a “P” to test emergency samples on the STAT table. Use function key F8 (S. No.) to select a specific sample number.
 - D. Press function key F4 (start entry).
 - E. First, select tests individually, by profile, or batch. If requisitions are required for more than one sample type, select function key F2 (exit) to return to “Type.”
 - Individually:** Highlight the tests to be performed in blue by clicking them with your mouse. Tests highlighted grey are not operational for the sample type selected.
 - Profile:** Click on the profile button to open the “select profile window.” Select a profile number (1-99) and click “OK.”
 - Batch:** Press function key F3 (Xn-enter). Enter the last sample number of the batch, or enter the actual number of samples in the batch.
2. Look at the Set Led. If it is off, press the STAT switch to turn on the Set Led. Do not load samples if the Set Led blinks or does not come on. The Set Led turns on when loading is possible.
 3. Select [System Status], [Stat Table Status] to determine where STATs can be loaded on the table. Press the STAT Rotation/Diag switch to turn the table if necessary.
 4. Place the sample in a correct position (STAT and sample type) on the table. If STATs are not barcoded, they must be placed in increasing numerical order on the table.

Warning

Close the STAT table cover after placing samples. A consistent temperature in the STAT table is important to the accuracy of your results.

5. Press the STAT switch to start STAT analysis. The End Led turns on when STAT sample aspiration is complete. Remove STATs from the table when the End Led is On.

2.5.5 Downloading Requisitions from a Host Computer

To manually download requisitions from a host computer, the system must be set to “Batch” in [Parameters] [Online]. The T.R.I. Receive prompt can be set to Real-time, Batch, or none. Set to “Batch” to manually download requisitions according to the following procedure:

1. From the main menu, select [Routine], [Test Requisition] and [Normal], in that order. *The screen for requisitioning normal analysis is displayed.*

ALB	GOT	GPT	G-GTP								

2. Press function key F7 (online). *The on-line requisition window is displayed.*
3. Specify the sample type. *The sample type can be selected by using the pull-down menu located by the “type” box.*
4. Enter the sample number(s) of the sample for which downloading is to be performed.
5. Click the “execute” button. *A message is displayed while the information is being read.*
6. After the information is downloaded, press the function key F2 (exit). *The main screen returns.*

Note

Manual requisitions have a higher priority than online requisitions. The barcode identification can be entered in the sample ID field, then select the desired tests following test requisition. The system will automatically process the barcoded sample with the revised requisition.

2.5.6 *Real-time Downloading of Requisitions from a Host Computer*

To automatically download requisitions from a host computer, the system must be set to “Real-time” in [Parameters] [Online]. The T.R.I. Receive prompt can be set to Real-time, Batch, or none. Set to “real-time” to automatically download requisitions according to the following procedure:

1. From the main menu, select [Parameters], [Online] in that order.
2. Press function key F4 (set).
3. Select the pull-down menu in each category on screen to select “Real Time” at any of the “Test Requisition Information” fields for automatic downloading by sequence or sample ID.

Tip

If an on-line error occurs during real-time online analysis, the analyzer defaults to test profile number 0.

Note Manual requisitions have a higher priority than online requisitions. The barcode identification can be entered in the sample ID field, then select the desired tests following test requisition. The system will automatically process the barcoded sample with the revised requisition.

2.6 Preparing Samples and Racks

Before starting analysis, blood collection tubes and sample cups (for serum or urine) must be prepared and placed in the appropriate racks. Commercial blood collection tubes may also be used. Follow hospital or laboratory protocol when preparing the samples and racks. The type (color) of rack used is different depending on the purpose of the analysis.

Conditions for the Sample Containers

Instruction

The sample containers should be at least 10 mm above the top surface of the rack and have an outer diameter of at least 11.5 mm. If a sample container is used that does not meet these specifications, analysis may not be performed. Damage to the analyzer could also occur. For more information on proper sample container and tube sizes, refer to the “Sampling Specifications” section of the Specifications Chapter.

Prepare the Sample and Dispense it into the Sample Containers

1. Prepare the sample containers.
 2. Dispense the serum, urine, or other fluid into the sample containers. Make sure the sample is free of clots, suspended matter and that there are no bubbles on the surface of the samples.
- OR
3. Process blood collection tubes according to standard laboratory protocol.

Prepare the Control Serum

In order to perform quality control, a control serum should be prepared in advance.

Obtain Racks

The type (color) of rack will be different depending on the type of sample to be analyzed.

Rack Types

There are six types of racks that are used in this system. A maximum of 10 sample containers can be set into one rack.

White Rack:

Use this rack to analyze normal patient samples. For barcode analysis, samples can be placed in any order. *For sequential analysis, the sample containers are placed in order of the sample number.* For rack ID analysis:

RACK ID	SAMPLE NUMBER
1	1-10
2	11-20
3	21-30
4	31-40 (Etc. up to Rack ID 400)

For all methods, all of the sample containers must have a requisition, or the default profile (#0) will be performed.

Blue Rack:

Use this rack to analyze the reagent blank. This is used for calculating the reagent blank to obtain the OD of the reagent without any sample. A reagent blank must be run with each calibration. Place deionized water in the following position(s):

If the sample is serum:	First position in the blue rack
If the sample is urine:	Tenth position in the blue rack
If the sample is other:	Fourth position in the blue rack

Yellow Rack

This rack is used when creating the calibration curves. With ACAL tests, the calibration curves are calculated from the standard solution concentration (known) and OD (obtained from yellow rack analysis). Place standard solutions in the yellow rack in the order of calibrator numbers that were set as parameters. *For barcoded analysis, samples can be placed in any order.* **Important:** *The highest calibrator number (From 1-200) must be placed last in the rack.* Calibrator No. (a two digit, alpha-numeric range from 1 to 200) corresponds to a combination of yellow rack ID (1 to 20) and sample positions (1 to 10). For example, 1 to 10 are the calibrator numbers and sample positions for the yellow rack of ID 0001, and 11 to 20 are the calibrator numbers and sample positions 1 to 10 for the yellow rack of ID 0002. User defined positions for serum, urine, and other calibrators are programmed in the [System Maintenance] screen. Serum, urine, and other calibrators need to be placed in the correct yellow rack designated by the rack ID and calibrator number. Rack IDs must be run consecutively.

Note

For detailed information on the relationship of Cup Positions to Calibrator No., please see the Calibration Section in chapter D of this User's Guide.

Green Rack

Use this rack to analyze quality control samples and barcoded quality control samples. *For barcoded analysis, samples can be placed in any order.* For samples without barcodes, place the control samples in the green rack in the order of the control numbers which were set as parameters. The control numbers correspond to the sample positions (1 to 60) in the green rack. For example: 1 to 10 are the control numbers and sample positions for the green rack of ID 1, and 11 to 20 are the control numbers and sample positions for the green rack of rack ID 2. **Important:** *For barcoded analysis, the highest QC number (from 1-60) must be placed last in the rack.*

Orange Rack

Use this rack for repeat-run analysis. In this system there are three methods of performing a repeat run: a method which uses the STAT table, a method which uses the orange rack, and a method which uses the white racks for an automatic repeat. Place sample containers in the orange rack in the order of the repeat-run sample numbers for sequential analysis. *Samples with an ID can be placed in any order in the orange rack for repeat analysis.*

Red Rack

Use this rack for analyzing "emergency" samples. In this system there are two methods for analyzing emergency samples: a method which uses the STAT table (priority samples), and a method which uses the red rack (emergency samples). The red rack is used if the tests in progress do not need to be interrupted for immediate results, but the sample needs to be designated as an "emergency" and separated from the normal routine samples. The STAT table is the fastest way to obtain results. There are no special restrictions on the order and

position for setting the sample containers. The sample numbers are automatically assigned to the emergency samples in the order they are placed in the racks. For example, if samples were set in rack IDs 1, 3 and 5 and analyzed, the assigned sample numbers (requisitioned with an E prefix) are E001, E002 and E003 sequentially. *If the sample containers are barcoded, they can be placed in any position on the rack.*

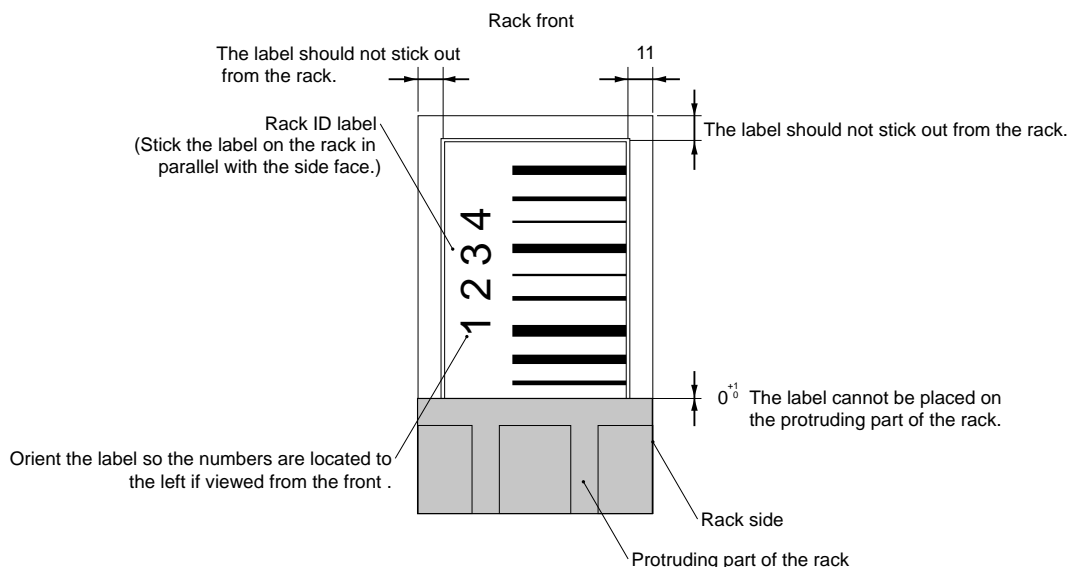
Placing the Rack ID Label

Instruction

Apply rack ID labels to all racks except the blue rack or analysis cannot be performed. Racks requiring labels are: orange, red, white, yellow, and green.

If a rack ID label peels off or becomes dirty, apply a new label:

- Place the label on the front surface of the rack.
- Place the label so that it is parallel with the sides of the rack.



Conditions for the Sample Containers (Serum)

Multiple tube and container sizes can be processed in racks. The dead volume probe stroke must be set appropriately for the range of tubes in use. Your Field Service Engineer must set all probe strokes for different racks and STAT table positions. The probe will crash if the operator runs Beckman Coulter tubes or places containers on the tops of tubes without adding sample. If there is sample in the tubes, the probe will not crash.

Warning

Use the appropriate sample container for the rack being used. If the wrong sample container is used, analysis may not be performed. Make sure the correct dead volume is set. Use the highest position so that the sample probe will not interfere with the sample container. If the adapter is in use on the Flex rack, multiple types (multiple sizes) of sample containers can be set in a single rack. However, since a dead volume can be adjusted for only one type of sample container, the dead volume in other containers will increase.

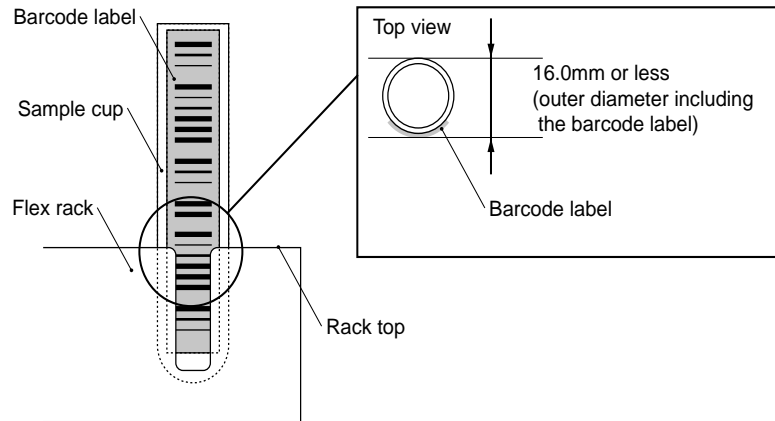
Use sample containers that meet the following conditions in the Flex rack.

Outer Diameter: 11.5 to 16.0 mm

Inner Diameter: 9.0 to 15.0 mm

Length: 55.0 to 102.0 mm

Note: Even if the conditions listed above are met, the Venoject-II type tubes cannot be used. The caps of adjacent sample tubes will interfere with each other. To insert sample containers in Flex racks with barcode labels, use containers up to 16.0 mm in diameter maximum.



Instruction

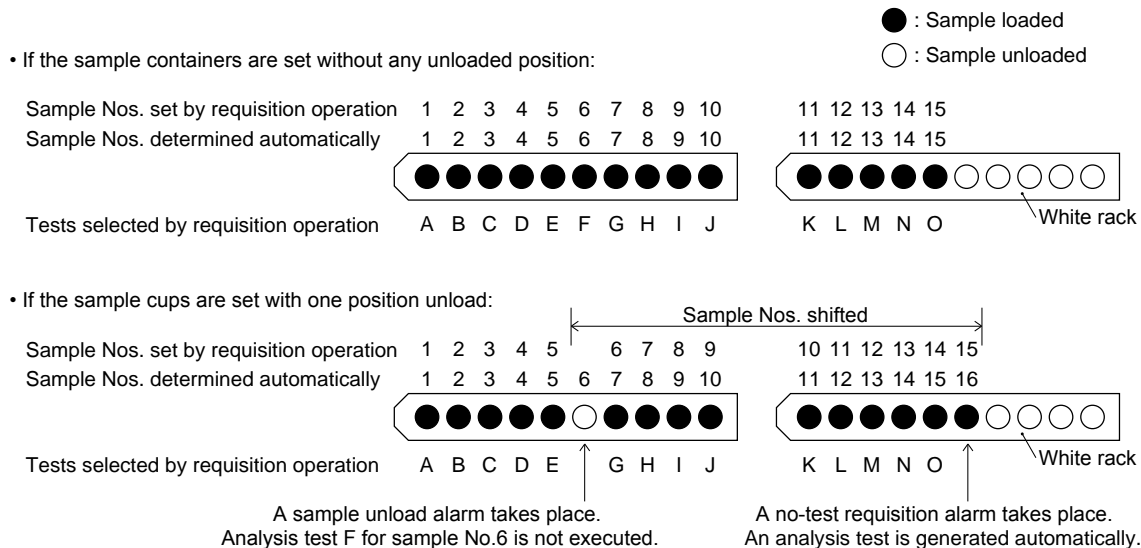
If a sample is centrifuged in a primary tube to be analyzed on the AU640/AU640e system, ensure that the serum is adequately separated from the red blood cells and does not contain clots or fibrin, and that the amount is sufficient for sample detection and analysis. The dead volume required for sample detection varies depending on the sample container type. If the serum height in the sample tube is less than the limit, transfer the serum into a smaller sample container, then start analysis. Otherwise, if the blood cells under the serum in the tube are aspirated, analysis and dispense abnormalities could occur.

Note

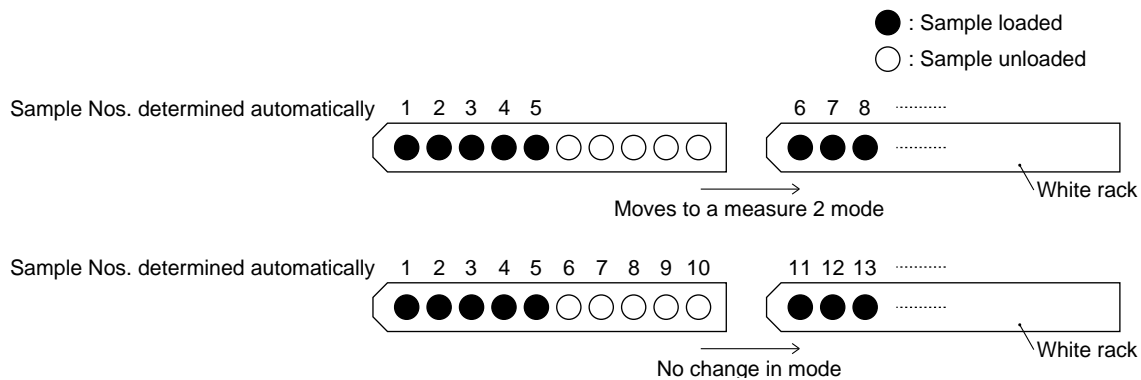
Nested cups used in analysis on the AU640/AU640e should meet the specifications for tubes and micro-cups, See *Chapter I - Analyzer Specifications, Sample cups and Placement*.

Warning

In sequential analysis, set sample containers on the white rack in sample number order without leaving any empty positions. If any position is different between the sample numbers set by the requisition operation and sample positions on the white rack, concordance errors will occur. The following example shows tests that were requisitioned for 15 samples:



If the analysis mode between racks changes, the sample numbers determined automatically according to a setting position on the rack will differ.



Flex Racks: Applying Barcode Labels to the Sample Containers

Instruction

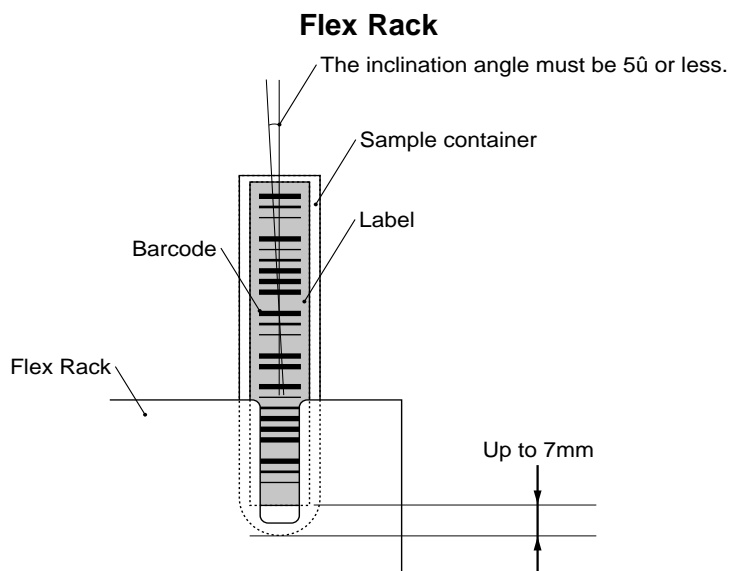
If using the conventional rack in place of the Flex rack, refer to the section called “Conventional Rack: Applying Barcode Labels to the Sample Containers.”

Place the barcode labels onto the sample containers so that they meet the following conditions:

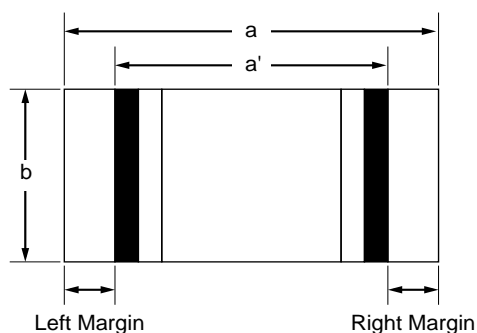
Do not allow the barcode to protrude from the top of a sample container

- Apply the barcode label at least 7 mm above the bottom of the sample container. If the label is applied below this position, the sample container may not be completely inserted because the label can get caught on the edge of the hole on the rack.
- Apply a barcode label with an angle of 5 degrees or less. (See the following illustration.)
- Make sure the entire surface of the label adheres to the container.
- Do not apply a sealant, etc., or mark the sample container below the barcode label. Do not insert foreign matter into the sample container between the lower edge of the label and the bottom. Any of the conditions above could cause the sample container sensor to fail.

If the conditions listed above cannot be met due to special requirements, please contact Beckman Coulter Technical Services.



Dimensions of Barcode Labels for Flex Racks



Label length
 $a < \text{Container length} - (7+5)$

7mm : Rack insertion portion
5mm : Vertical margin of barcode label to be applied

Barcode width
 $a' = a - \text{Right margin} - \text{Left margin}$
Both the Right Margin and Left margin should be 3mm or more.

Barcode height
 $b > 10$

Printing Barcode Labels

Print barcode labels according to the following specifications:

- PSC value

If NB (narrow bar) is between 0.165 and 0.50 mm : The PCS value should be 0.60 or more.

If NB (narrow bar) is between 0.130 and 0.156 mm : The PCS value should be 0.85 or more.

$\text{PSC value} = (\text{RL} - \text{R0})/\text{RL}$

RL: Reflectance of white bars and margins

R0: Reflectance of black bars

- The reflectance of white bars and margins should be more than 70%
- The following should not be present: Scratch with a diameter greater than 0.1 mm, omitted pattern, blur, or void (black point) on white bars.

Barcode Label Specifications for Flex Racks

Use barcode labels which conform to the following specifications:

- Type of barcode

Select one of the following types from [Parameters], [System], [System]: NW7, CODE39, CODE128, 2 of 5 standard, 2 of 5 interleaved, mixed, ISBT-128 (alone). If "mixed" is selected, analysis can be performed with multiple types of barcodes being mixed (except ISBT-128).

- Barcode check character

BARCODE	CHECK CHARACTER, METHOD
NW7	LEAST SIGNIFICANT DIGIT, MODULA-16
CODE39	LEAST SIGNIFICANT DIGIT, MODULA-43
CODE128	LEAST SIGNIFICANT DIGIT, MODULA-103
2 OF 5 INTERLEAVED	LEAST SIGNIFICANT DIGIT, MODULA-10

- Number of barcode digits

Maximum 20 digits (all)

ID Search Type

Real-time on-line entry

Batch Online

- Width of bar and space

NB (narrow bar) is standard. If you require a different bar width and space refer to the following specifications:

NB (Narrow Bar)	NS (Narrow Space)	WB (Wide Bar)	WS (Wide Space)	G (Gap)
0.2 to 0.5 mm	NB to 1.25NB	2.0NB to 3.0NB	2.0NB to 3.0NB	NB to 3.0NB
0.165 < 0.2 mm	NB to 1.25NB	2.2NB to 3.0NB	2.2NB to 3.0NB	NB to 3.0NB

If a high PCS value is obtained by printing a barcode clearly on a label with a high reflection factor and if the width of bars and spaces are retained as follows, the narrow barcode can be used only for NW7.

NB	NS	WB	WS	G
0.130 - 0.156MM	0.216 - 0.238MM	0.401 - 0.413MM	0.465 - 0.492	0.465 - 0.492MM

Caution

It is recommended to use bars and spaces of 2.5 NB or more so that WB (wide bar), WS (side space), and G (gap) can be identified easily. If less than 0.2 mm of NB (narrow bar) is used, it is recommended to use the barcode check character to retain the reliability of the barcode read.

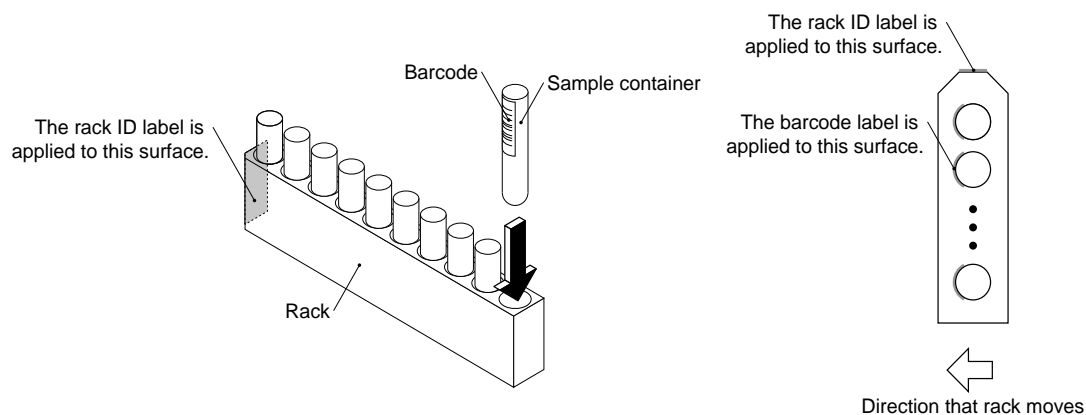
Setting Sample Containers into the Rack

Place the sample containers into the rack so that they meet the conditions shown in the figure below:

- Be sure to use the correct rack color.
- When using sample containers with a barcode label, position the barcode surface within ± 2 mm to the center of the side slit of each hole on the rack.

Instruction

Do not rotate the sample containers set in the rack to change their direction. The barcode may be contaminated or scratched resulting in a barcode read error. Remove the sample container from the rack, and then rotate the container in the correct direction before reinserting it into the hole.

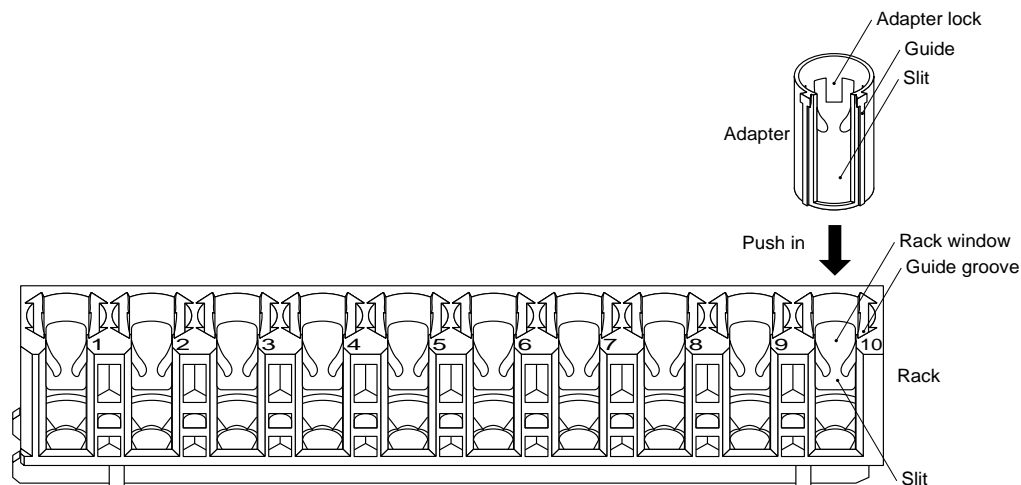


Flex Rack Adapters

The flex rack does not need adapters for sample containers with dimensions of 13.60 to 16.00 mm. This rack does need adapters for sample containers with dimensions of 11.5 to 13.6 mm. When using containers with a diameter of 14.0 to 15.0 mm, the operator will need to determine if an adapter is necessary since plastic sample containers may be tapered and the diameter may be difficult to judge.

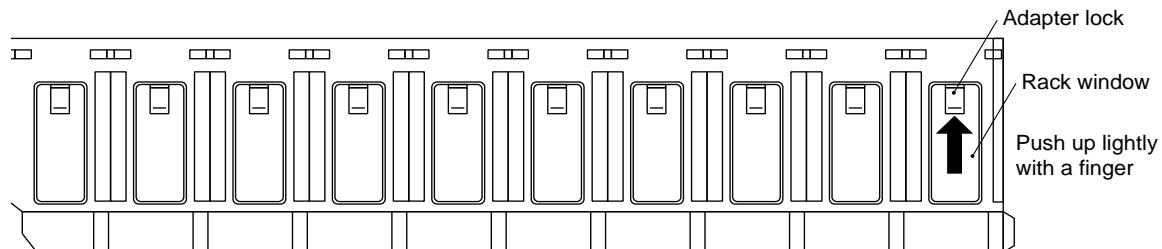
Flex Rack: Adapter Installation

1. Match the adapter slit and the rack slit as shown in the diagram below.
2. Slide the adapter guide into the guide groove of the rack and push the adapter into the rack.
3. A clicking sound verifies that the adapter lock is engaged on the rack.



Flex Rack: Adapter Removal

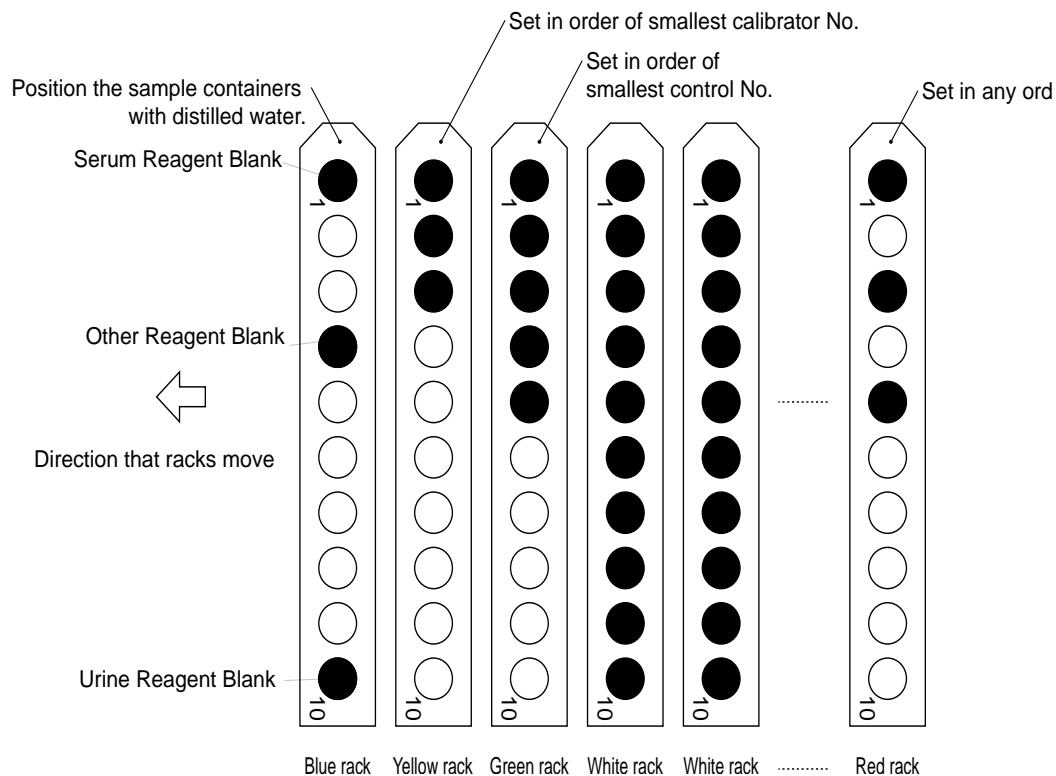
1. With your finger, push the adapter lock lightly from the outside of the rack window to disengage the lock.
2. When the upper edge of the adapter comes out from the rack, grasp the adapter and pull it out.



2.7 *Placing Racks on the Analyzer*

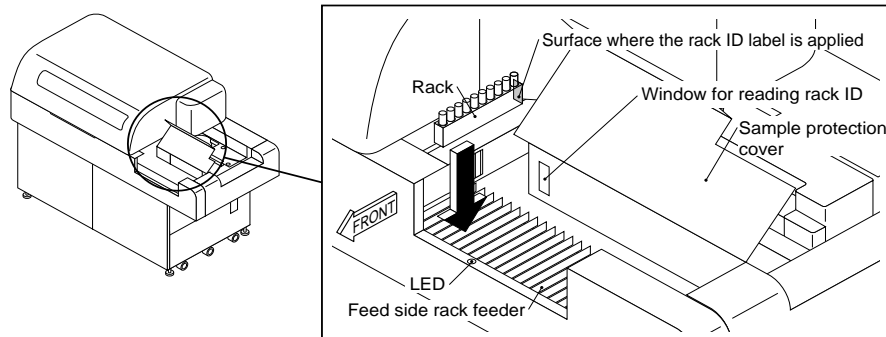
Order for Placing the Racks

The racks should be placed on the system according to rack type (color) and the function to be performed. Follow the order shown below:

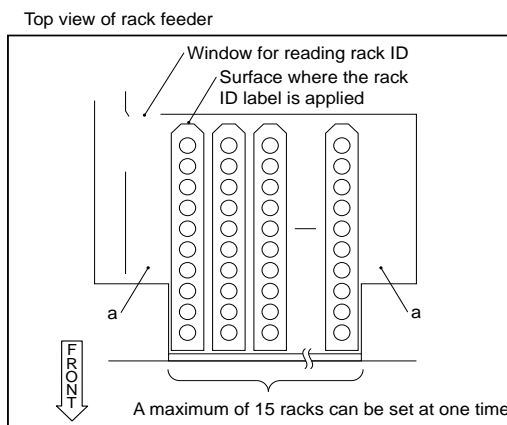


Placing Racks on the Analyzer

1. Open the cover for the samples on the rack feeder as shown in the diagram below.



Caution: Do not place racks when the LED is flashing. The racks are advancing when the LED is flashing.



Tips

Do not place racks in position "a" as shown in the drawing. Problems with analysis could occur.

2. Set the racks on the rack feeder so that they are oriented as described below. When setting the racks pay attention to the rack and sample order, and the rack direction. Make sure that the racks are set so the surface on which the rack ID label is placed is facing away from you.
Blue Rack:
If reagent blank or calibration is required, place the blue rack on the feeder first.
Yellow Rack:
If calibration is required, place yellow racks sequentially after the blue rack.

Green Rack:

Run QC before routine analysis.

White Rack:

For sequential analysis, place the racks in sample number order. The order for setting the racks is arbitrary for rack ID analysis and sample ID analysis.

Red Rack:

If emergency samples are to be processed, they can be run anytime during routine analysis by inserting red racks ahead of white racks.

Tips

A maximum of 15 racks can be set at one time.

2.8 *Daily Maintenance and Inspection*

The following list provides an overview of daily maintenance and inspection procedures. It is very important to perform maintenance on schedule so the analyzer runs efficiently. For detailed information on maintenance or inspection procedures, refer to the Maintenance Chapter.

2.8.1 *Periodic Maintenance*

The following procedures are based on 4,000 tests a day.

Analyzer Maintenance

Daily Maintenance

- Inspect the sample and reagent syringes.
- Inspect wash syringes.
- Check the wash solution rolling pump for leaks.
- Inspect the concentrated wash solution level.
- Inspect the stability of the upper cover.
- *Note: The analyzer will pause if wash solution is empty.*
- Inspect and clean the sample probe, reagent probe, and mix bars.
- Check the printer and printer paper.
- Prepare for a sample probe wash.

Weekly Maintenance

- Perform a W2 (automatic wash of the probes, mix bars and cuvettes).
- Perform a photocal (after the weekly W2).
- Perform a photometer check (after the photocal).

Monthly Maintenance

- Clean the sample and reagent probe wash wells.
- Clean the mix bar wash well.
- Clean the wash nozzles.
- Clean the deionized-water tank.
- Clean the deionized-water filter.
- Clean the sample probe filter.

Maintenance Required Every Three Months

- Replace the wash solution rolling tube.
- Clean the air filters.

As Needed Maintenance

- Replace cuvettes.
- Replace sample and reagent probes.
- Replace mix bars.
- Replace wash nozzle joint tubes.
- Replace sample and reagent syringes.
- Replace wash syringes.
- Replace the deionized water filter (Part of 6 month PM)

- Replace the sample probe filter (Part of 6 month PM).
- Replace the photometer lamp (Part of 6 month PM).
- Clean the cuvettes and cuvette wheel (Part of 6 month PM).
- Perform a W1.

ISE Maintenance

Daily:	Inspect the ISE reagent (buffer) syringe for leaks. Auto wash the sample pot and electrode lines.
Weekly:	Perform a selectivity check for the ISE Na/K electrodes. Clean the mix bars, liquid level sensors, sample pot tubing and sample pot.
Every Three Months:	Replace the mixture and mid-standard pump roller tubing. Replace the valve tubing.
As Needed:	Replace the reference electrode. Add reference electrode solution. Replace reagents. Replace the Na, K, and Cl electrodes. Replace the ISE reagent (buffer) syringe.

See Also

For detailed information on performing Maintenance, refer to the Maintenance Chapter.

2.8.2 Consumables

The following table lists consumable items and the consumption rate based on the number of samples analyzed (the frequency of analysis).

Types of Consumables and the Consumption Rate

Unit types	641-02	643-02	
		Standard	Detergent A (factory optional) equipped
Detergent A (factory optional) AU detergent acid or AU detergent alkali (used only for washing cuvettes)	Approx. 0.16 L (4000 tests/day)	-	Approx. 0.16 L (4000 tests/day)
Detergent B AU detergent alkali (used for washing cuvettes and mixing bars)	Approx. 1.3 L (4000 tests/day)	Approx. 0.8 L (4000 tests/day)	Approx. 0.64 L (4000 tests/day)
ISE buffer solution (optional)	Approx. 180 mL (Serum: 200 samples/day)		
ISE MID solution (optional)	Approx. 260 mL (Serum: 200 samples/day)		
ISE REF solution (optional)	Approx. 35 mL (Serum: 200 samples/day)		
ISE cleaning solution (optional)	Approx. 1 mL (Serum: 200 samples/day)		

Tips

The ISE buffer, MID and REF solutions mentioned above are required for ISE operation. The solutions are used during analysis, when performing periodic priming, and priming before analysis. The amount of reagent used differs depending on the number of samples analyzed. The standards listed in the table above are values calculated under the assumption that normal, routine work is being performed on the analyzer.

2.8.3 Changing Reagents

There are two methods for changing reagents: a method for setting individual reagent bottles, and a method for loading the reagent tray with reagent bottles already in place.

Prepare the Reagent

If necessary, prepare the bottles for the reagent corresponding to the type of analysis.

There are three kinds of reagent bottles used in this system:

60 mL reagent bottle

30 mL reagent bottle

15 mL reagent bottle

Beckman Coulter reagents have a reagent ID. Bottles can also be used without a reagent ID.

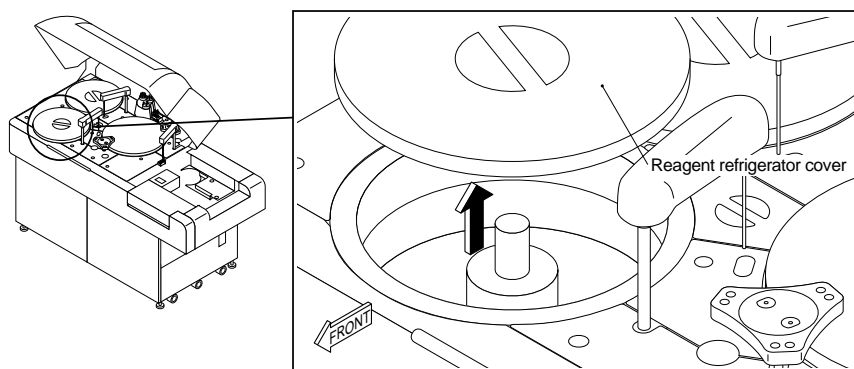
Load Reagent Bottles

The first and second reagent refrigerator can each hold 48 reagent bottles.

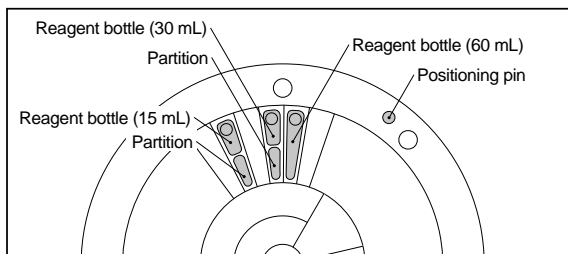
Warning

If you use 15 or 30 mL bottles, be sure to use the correct partitions as shown in the drawing below.

1. Open the analyzer cover.
2. Lift up on the R1 or R2 reagent refrigerator cover and remove it.



Top view of the reagent refrigerator



Tips

Condensation may appear in the reagent refrigerator under high-temperature and high-humidity environments. Remove the condensation by wiping the reagent refrigerator with a dry cloth.

3. Set the reagent bottles in the compartment by gently pressing down on the front and back of each bottle. Replace old bottles with new ones if the reagent level is low, or if the reagent stability or expiration date has expired.

Warning

It is imperative that the AU640 reagent bottles are placed correctly in the refrigerator. If the end of a bottle is up, reagent probe crashes could occur.

- Reagent bottles without barcodes: Place them in the reagent positions that have been set in [Reagent Status].
- Reagent bottles with barcodes: Once the Reagent ID code is set in [Parameters] the reagents can be placed in any position. Bottles with barcodes cannot be placed in “fixed” positions set in [Reagent Status].

Warning

When setting 15 mL or 30 mL reagent bottles, use a partition to secure the bottle.

4. Replace the R1 or R2 reagent refrigerator cover to its original position. *When installing the reagent refrigerator cover, make sure that the positioning pin on the reagent refrigerator is inserted in the hole in the reagent refrigerator cover. If the cover is not installed in the correct position, reagent will not be dispensed properly and reagent probe damage could occur.*
5. Select the [System Status] icon. *The [System Status] screen is displayed.*
6. Select [Reagent Status]. *A screen for checking the reagent status is displayed. When this screen is displayed, the reagent check status is “Unchecked.”*
7. Press function key F5 (check start). *The reagent check start window is displayed.*
8. Select “Check for all positions.” *The amount of remaining reagent is automatically checked. After the reagent has been checked, the reagent check status is displayed as “CHECKED.”*

Tip

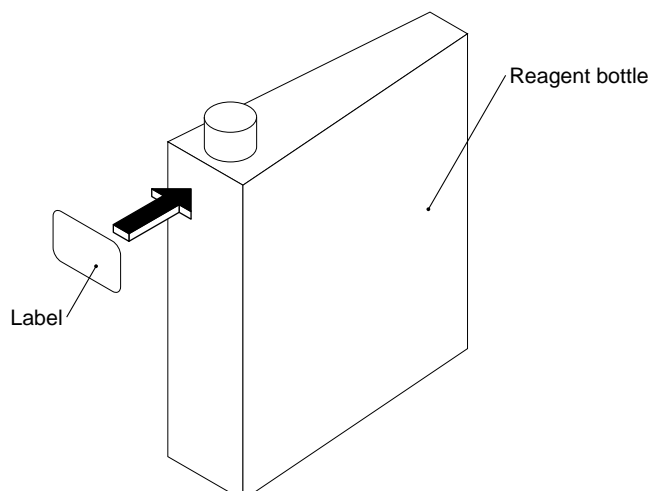
The “Check for all positions” function also checks reagent lot numbers. An alarm will occur if: 1. A different reagent lot number is used from those used for reagent blank or calibration. 2. If different reagent lot numbers are mixed for the same analysis item. If this occurs, use the same lot number of reagents. *If these problems are not corrected, accurate analysis results cannot be obtained. Note: If auto-cal/QC is enabled an alarm will not occur.*

Reagent Check Options:

- A. Reset Only: Resets the status from “Unchecked” to “Checked.” Volume check or reagent ID read is **not** performed.
 - B. Check Specified Position: Volume check one or more specific R1 and/or R2 positions. **Reagent ID’s are not read.** Use for **fixed** positions.
 - C. Check Specified Position (with ID): Reads reagent ID **and** volume checks one or more specific R1 and/or R2 positions.
 - D. Check changed position (with ID): Reads all positions for reagent ID. Volume checks any **new** or **moved** reagents.
 - D. Check for all Positions: Reads all positions for reagent ID and volume checks all reagents.
 - " with ID Read" is gray (not operational) when status is “Unchecked.” All positions are read for ID.
 - " with ID Read" is white when status is “Checked.” The check can be removed to volume check all reagents without reagent ID reading.
9. Press function key F2 (exit) twice. *The main screen returns.*

Notes for Using Reagent Bottles without Reagent ID Labels

If the color of the reagent bottle is very light, there is a possibility that it will not be detected properly by the sensor. If the bottle is not detected correctly, apply a label to the reagent bottle as shown below. If stains or condensation occur on the label, a barcode read error may occur.



2.8.4 How to Set (Fix) a Reagent Position

Reagents that are not barcoded or have a damaged barcode label must be assigned (fixed) in reagent positions. If a reagent is not barcoded, the operator must put the reagent in the correct position. This procedure can also temporarily correct for reagent ID read errors that are generated during the reagent volume check.

Note

Fix (assign) reagents that are not barcoded or have a damaged barcode.

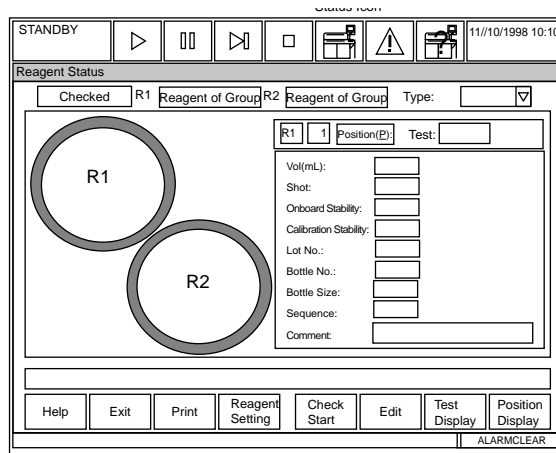
Place fixed reagents in the correct positions.

Both components of the R1/R2 pair must be set to fixed or reagent ID.

Caution

If a reagent position is edited, perform a reagent check using the “Check All Positions” (with ID read) option.

1. From the main menu, select [System Status], [Reagent Status].



2. Select the bottle position to fix the reagent.
3. Select F6 (edit). At “Test,” select the test to fix.
4. Select the “Fixed Reagent” field.
5. **Enter the lot number.** Refer to Chapter D, Section 1.3 Reagent Status; F8 Position Display, “Unpaired Reagent” for corrective actions if the lot number is not entered.
6. At “Bottle Size” select the correct bottle size of 120, 60, 30, or 15 mL. The default size is 15 mL. The bottle size is used in the reagent volume check calculations.
7. Select the “Close” button.
8. Perform a reagent volume check on the fixed reagent using the Check Specified Position option.

Note

Blue highlights on this screen indicate the reagents are checked and the status is good. If yellow highlights appear on a bottle position, or “Reagent of Group” is yellow, select function key F8 (Position Display) and review the comments. For more information on each comment refer to “Reviewing Reagent Position Errors” located in [System Status], [Reagent Status] of the Software Chapter.

2.8.5 Adding Wash Solution

If there is insufficient concentrated A or B wash solution, analysis pauses, and a warning message is displayed on the screen. Check the amount of wash solution in the concentrated wash solution tanks (A and B). If needed, add wash solution and press start to resume analysis.

Adding Concentrated Wash Solution

Warning

When removing the cap on the wash solution tank, be careful not to get any of the wash solution on your hands. If your hands or clothing come into contact with the wash solution, immediately wash it off with water. Also, if any wash solution gets in your eyes or mouth, rinse it out immediately and consult a physician.

See Also

For detailed procedures on adding wash solution, refer to the Maintenance Chapter.

3. Starting Analysis

This section describes the necessary procedures for starting analysis. Analysis should be started from the Standby mode.

Starting Analysis

After preparing for analysis, perform the following procedure.

See Also

For information about preparing for analysis, refer to the Basic Operations Chapter.

1. On the main screen, select [Routine] and [Start Conditions] in that order. *The start conditions are displayed.*

The screenshot shows the 'Start Condition' screen. At the top, it says 'STANDBY' and has several icons (play, pause, stop, square, printer, warning, printer) and the date/time '1998/11/03 10:10'. Below this is the 'Start Condition' section with the following fields:

- Data Index: 1993 / 12 / 13 11:59
- Round No.: Routine
- Operator Name: (empty field)
- Serum Start No. table:

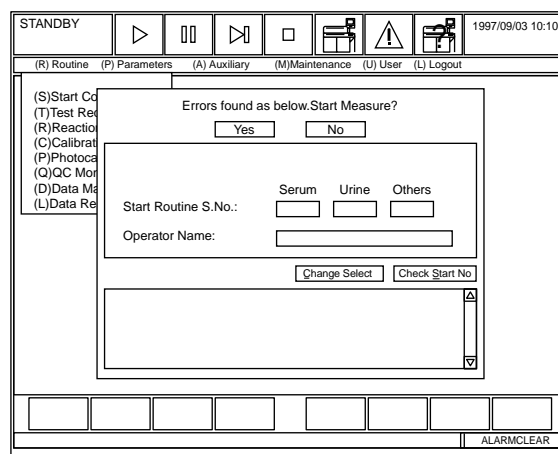
	Routine	Emergency	STAT
Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Repeat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Urine Start No. table:

	Routine	Emergency	STAT
Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Repeat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Others Start No. table:

	Routine	Emergency	STAT
Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Repeat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Calibration: (empty field)
- Remaining Samples: nnnn

At the bottom, there is a row of function keys: Help, Exit, (empty), Set, Cal, QC, Default Start No., Data Index. Below this row is an 'ALARMCLEAR' button.

2. Check the settings for the data index, round number, operator name. Also check the start number for serum, urine, and other samples. *If the round number is changed, another reagent check must be performed.*
3. Verify that calibration status is "Selected" if performing reagent blanks or calibrations. *If it is not selected, refer to "Performing Calibrations and a Reagent Blank" located in the Preparing for Analysis section of this chapter.*
4. Press function key F2 (exit). *The main screen is displayed.*
5. Press the start key. *The window for starting analysis is displayed.*



Tip

To change a setting such as the “Start Routine S. No.,” press function key F4 (set). Use the mouse to select the field.

6. Check the start routine and urine S. No., operator name, and error list. *If a fatal error (red) occurs, it is not possible to start analysis. It is possible to start analysis with nonfatal (yellow) errors. A message describing the error is displayed. Check the description of the error and press Yes to bypass the error and start analysis or press No to perform corrective actions before analysis. Follow the necessary corrective actions to recover from the error.*

See Also

For information on recovering from errors, refer to the Troubleshooting Chapter.

Tip

The “Check for all positions” function also checks reagent lot numbers. An alarm will occur if: 1. A different reagent lot number is used from those used for reagent blank or calibration. 2. If different reagent lot numbers are mixed for the same analysis item. If this occurs, use the same lot number of reagents. *If these problems are not corrected, accurate analysis results cannot be obtained. Note: If auto-cal/QC is enabled an alarm will not occur.*

7. After performing the above check, select “Yes” and press enter.
*The analysis operation starts. After “STANDBY → MEAS. 1” is displayed on the upper left of the screen, “MEAS. 1” is displayed.
 After starting analysis, the first result is calculated. Results print as they are completed for the sample.*

4. *Obtaining Results*

After the control sample is analyzed, check the QC data printout for error flags. If the QC falls out of a preset QC range, an alarm will be generated. To verify QC, there are three kinds of QC charts: daily variation chart, day-to-day variation chart and the twin plot chart. The quality control charts can be checked using [Daily Control], [Day to Day control], and [Twin Plot] screens.

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4.1 Checking Results

After analysis for one sample finishes, the results are immediately saved on the hard disk and a list of results are printed.

Checking Results

1. Look at the printout and check it for error flags. If error flags appear on the printout, perform the corrective action corresponding to that flag.
2. Perform corrective actions for any alarms generated during the run.

See Also

For information about error flags, refer to the Error Flags Chapter. For alarm information, click on the alarm help icon.

Analysis Results Printout

For a detailed description of the printout, please refer to your AU400^e Training Manual, in the Modes of Data Interpretation Section.

< Pattern 1 > Current Software Version

INDEX DATE											PAGE
12/10/2001 17:59											1
ROUND NO.1				ROUND - 01				OPETATOR			
											PRINT TIME [12/10/2001 18:19]
R001	-01	SEQ.	SERUM								
TP-1	0.0015	ALB-1	0.2628	BUN-1	1.6131	TCHO-1	0.0269	LDH-1	0.3703	AST-1	1.3843
GGT-1	0.3709										
TP-2	-0.2685	ALB-2	0.2692	BUN-2	1.6080	TCHO-2	0.0244	LDH-2	0.3709	AST-2	1.3776
GGT-2	0.3725										
A001	0001-01	CAL. NO. 1 - S. ID	SERUM				CAL. NAME				
TP-1	0.1621	TP-2	0.1615	TP-3	0.1621	TP-4	0.1608	ALB-1	0.7286	ALB-2	0.7358
ALB-3	0.7274	ALB-4	0.7381	BUN-1	0.1958	BUN-2	0.1974	BUN-3	0.1987	BUN-4	0.1944
TCHO-1	0.4023	TCHO-2	0.4016	TCHO-3	0.4017	TCHO-4	0.4017				
0001	0046-01	S. ID	AGE	MONTH	SEX	TYPE	SERUM				
TP	6.5	ALB	3.8	BUN	17.4	TCHO	181	LDH	239	AST	74
GGT	72	Na	124.4	K	4.57	Cl	97.3				
0002	0046-02	S. ID	AGE	MONTH	SEX	TYPE	SERUM				
TP	6.5	ALB	3.8	BUN	17.4	TCHO	181	LDH	235	AST	74
GGT	72	Na	123.8	K	4.55	Cl	97.3				
0003	0046-03	S. ID	AGE	MONTH	SEX	TYPE	SERUM				
TP	6.5	ALB	3.8	BUN	17.0	TCHO	181	LDH	236	AST	73
GGT	72	Na	123.9	K	4.55	Cl	96.9				

Reagent blank value

Calibration value

Analysis results

Sample No.

Rack No.
position

Abnormal data flag

Test name and
Analysis result

4.2 Checking Quality Control

After the control sample is analyzed, check the QC data printout for error flags. If the QC falls outside a preset QC range, an alarm will be generated. To verify QC, there are three kinds of QC charts: daily variation, day-to-day variation, and twin plot. The quality control charts can be checked using [Daily Control], [Day To Day Control] and [Twin Plot].

Checking the Daily Variation Chart

Before viewing charts, look up QC alarms using the on-line help function and check the QC samples listed on the printout for error flags. If an alarm or error flag occurs, correct the problem. QC samples must be run with no flags or alarms before routine sample results are valid.

See Also

For information about errors flags, refer to the Error Flags Chapter.

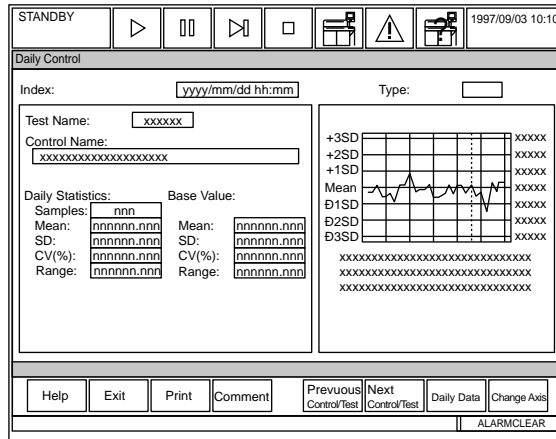
1. On the main screen, select [Routine], [QC Monitor] and [Daily Control] in that order. *The screen for selecting the control sample for quality control is displayed.*

The screenshot shows a software interface for 'Daily Control'. At the top, there's a 'STANDBY' indicator and a date/time stamp '1997/09/03 10:10'. Below that is a 'Daily Control' header with a 'Select' button and a 'QC Monitor' tab. The main area contains several input fields: 'Index' with a pull-down menu showing 'yyyymmddhh:mm', 'Type' with a pull-down menu showing 'Serum', and 'Control Name' with a pull-down menu showing '-'. Below these is a table with columns labeled 'ALB', 'GOT', 'GPT', 'G-GTP', and several empty columns. At the bottom of the table area, there are fields for 'Sample No.' with a pull-down menu showing 'Qnnn J Qnnn' and '(Qnnn B Qnnn)'. Below the table are buttons for 'Help', 'Exit', 'Comment', 'Change Test', 'Daily Data', and 'Control No.'. At the very bottom right, there is an 'ALARMCLEAR' button.

Note

The index, sample type, and control name can be selected by using the pull-down menu located by each box on the screen.

2. Press function key F8 (control no.). Enter the control number of the control sample to be referenced and choose "OK."
3. Select the test(s) to be referenced using the mouse.
4. Press function key F6 (daily data). *The chart with daily variation data is displayed.*



5. Check the chart for abnormal data.

See Also

For information about handling errors, refer to the Troubleshooting Chapter.

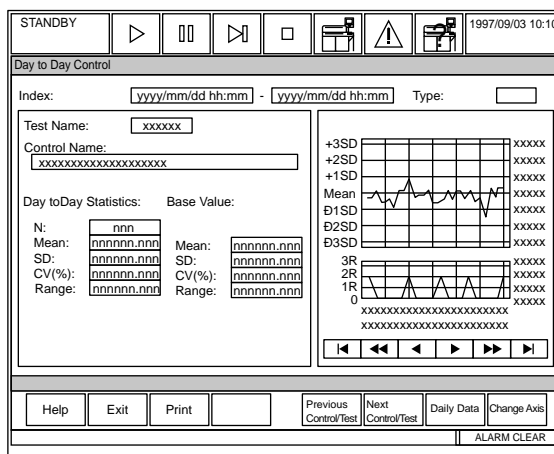
6. Use function key F5 (previous control test) and function key F6 (next control test) to look at other QC test charts.
7. Select function key F3 (print) to print statistics, data, graphs, or comments.
8. Optional Step: Select function key F4 (comment) if you want to enter a comment.
9. After checking the chart, press function key F2 (exit). *The main screen returns.*

Checking the Day-to-Day Variation Chart

1. On the main screen select [Routine], [QC Monitor] and [Day To Day Control] in that order. *The screen for selecting the control sample for quality control is displayed.*

Note: The index, sample type, and control name can be selected by using the pull-down menu located by each box on the screen.

2. Press function key F8 (control no.). Enter the control number of the control sample to be referenced and choose “OK.”
3. Select the test(s) to be referenced.
4. Press function key F6 (day to day). *The chart of day-to-day variation data is displayed.*



5. Check the chart for abnormal data.

See Also

For information about handling errors, refer to the Troubleshooting Chapter.

6. Use function key F5 (previous control test) and function key F6 (next control test) to look at other QC test charts.
7. Select function key F3 (print) to print statistics, data, graphs, or comments.
8. Optional Step: Select function key F4 (comment) if you want to enter a comment.
9. After checking the chart, press function key F2 (exit). *The main screen returns.*

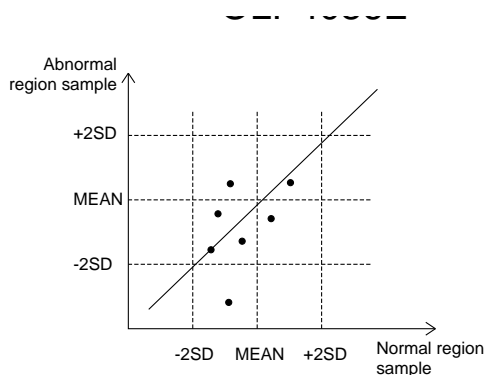
Twin Plot Chart

Before viewing charts, look up QC alarms using the alarm help function and check the QC samples listed on the printout for error flags. If an alarm or error flag occurs, correct the problem. QC samples must be run with no flags or alarms before routine sample results are valid.

See Also

For information about errors flags, refer to the Error Flags Chapter.

In quality control, usually a normal control and an abnormal control are used. The following figure shows a two-dimensional plot with the normal control on the x-axis and the abnormal control on the y-axis.



When the normal and abnormal controls are within a control limit, and both samples are high values or low values, perform a calibration to determine system errors. If the high value of an abnormal control is low, reagent deterioration may be the cause. The twin plot offers the advantage of classifying problems as either a system error or a random error. To be used, it must be programmed for multi-rule control procedures to determine if a drift is occurring or if the reagent is unstable.

See Also

For information about shifts and trends, refer to the Troubleshooting Chapter.

1. On the main screen, select [Routine], [QC Monitor] and [Twin Plot] in that order.
The screen for selecting the control sample for quality control is displayed.

Note

The index, sample type, and control name can be selected by using the pull-down menu located by each box on the screen.

2. Select tests to be viewed by using the mouse.
3. Press function key F6 (twin display plot). *The twin plot chart is displayed.*
4. Check the chart for abnormal data.

See Also

For information about handling errors, refer to the Troubleshooting Chapter. For more information on Quality Control, refer to the “Calculations” section of the Specifications Chapter.

5. Use function key F5 (previous test) and function key F6 (next test) to look at other QC test charts.
6. Optional Step: Select function key F7 (daily data), then select F4 (ref. comment) if you want to enter a comment. After entering a comment, select the “close” button.
7. After checking the chart, press function key F2 (exit) until the main screen returns.

4.3 *Performing a Repeat Run*

Perform a repeat run based on laboratory protocol for repeat analysis. There are three ways to perform a repeat run: automatically, manually using an orange rack, and using the STAT table.

Repeat parameters including test specific repeat ranges, sample volume, and abnormal flags can be programmed to automatically place a sample into the repeat data file.

If “Auto Repeat” is set in [Parameters], the repeat run will be performed automatically according to the information in the repeat-run data file.

If “Standard Repeat” is set in [Parameters], [System], [System], print the contents of the repeat-run data file in a work list. Perform a repeat run manually according to the contents of that file.

Important

The following repeat run procedures also explain how to program a repeat run. If the analyzer has been preprogrammed, refer to the AU640 Quick Response Guide for basic repeat run procedures

4.3.1 How to Print a Repeat Run Work List

To pick up a sample that requires a repeat run, print and check the repeat-run work list.

Printing and Checking the Repeat Run Work List:

1. On the main screen, select [Routine], [Test Requisition] and [Repeat] in that order.
The screen for performing the requisition operation for repeat-run analysis is displayed.

The screenshot shows a software interface titled "Repeat". At the top, there is a status bar with "STANDBY" and a date/time stamp "1997/09/03 10:10". Below this are several control icons. The main area contains the following fields and controls:

- S.No.: 0001 (with navigation arrows) Type: Serum (dropdown)
- Round No.: (empty field)
- Repeat S.No.: XXXX
- S.ID.: (field with a pattern of 'x' characters)
- Sample Dilution Rate: (empty field)
- Sex: Male Age: XXX XX (with a (Year/Month) label above)
- Test Total (T) (dropdown)
- Renum (N) (dropdown)
- Sample Dil. (D) (dropdown)
- List of Rep. (R) (dropdown)
- Normal (checkbox)
- Dilution (checkbox)
- Cond. (checkbox)

At the bottom, there is a menu bar with buttons: Help, Exit, Print, Start Entry, Change Test, Delete Sample, Online, and S.No. An "ALARMCLEAR" indicator is visible in the bottom right corner.

2. Press function key F3 (print). *The window for printing the work list displays.*
3. Select the sample type for which the repeat-run work list is to be printed.
4. Enter the range of sample numbers. *It is also possible to enter the range of sample IDs.*
5. If it is necessary to change the list number, use the pull-down menu located by the "Repeat Work List" field on screen.
6. Click the "OK" button twice. *The repeat-run work list begins printing.*
7. Check the contents of the repeat-run work list.
8. Use the worklist to perform a manual repeat, or modify the worklist before performing repeat analysis.

4.3.2 How to Modify the Repeat Work List:

1. On the main screen, select [Routine], [Test Requisition] and [Repeat] in that order.
The screen for performing the requisition operation for repeat-run analysis is displayed.

The screenshot shows the 'Repeat' screen with the following details:

- STANDBY status and date/time: 1997/09/03 10:10
- S.No.: 0001 (with navigation arrows)
- Type: Serum (pull-down menu)
- Round No.: (empty field)
- Repeat S.No.: XXXX
- S.ID.: (long alphanumeric string)
- Sample Dilution Rate: (empty field)
- Sex: Male | Age: XXX XX (Year/Month)
- Test selection grid:

ALB nnnnnnnn	GOT nnnnnnnn	G-GTP nnnnnnnn				
- Right-side options: Test Total(T), Renum (R), Sample Dil.(D), List of Rep.(R), Normal, Dilution, Cond.
- Bottom navigation buttons: Help, Exit, Print, Start Entry, Change Test, Delete Sample, Online, S.No.
- ALARMCLEAR indicator at the bottom right.

2. Enter the original sample number of the sample for which the repeat run is to be performed.
3. To select a sample type use the pull-down menu located by the box on screen.
4. Press function key F4 (start entry).
5. Select the test for which the repeat run is to be performed. *Tests that are selected will appear in color. Tests that are not selected will appear in white. It is possible to select several tests. Tests already requisitioned can be selected to remove them from the requisition.*
6. After selecting the test(s), press function key F4 (entry). If the repeat run is to be performed using the STAT table, press function key F6 (STAT repeat). *The settings will be registered, and the screen will change to the next sample number.*
7. Repeat the previous steps for all of the samples requiring a change in the repeat run requisition.
8. After the requisition operation is performed, press function key F2 (exit). *The main screen returns.*
9. Depending on the preferred repeat-run method, use one of the procedures on the following pages. If changes are made to the repeat run requisitions, always print an updated repeat run work list.

4.3.3 How to Perform an Auto-Repeat Run

The following procedure explains how to program and perform an auto-repeat run. If the system has been preprogrammed to perform an auto repeat run, follow the procedures in the AU640 Quick Response Guide.

The auto-repeat method involves preprogramming flags which will be used to generate repeat run requisitions. A repeat range can be programmed for each test. Any of the flags on the [Repeat Run Common] screen can be selected for repeat run analysis. When a test generates a specified flag, it is automatically requisitioned for repeat analysis. The white routine rack is fed back to the rack feeder area, and the entire rack goes back through the transport belt. Only the tests which generated a repeat requisition will be performed. Dilutions can be performed automatically. The analyzer stays in a measure 1 mode, and the rack feeder belt automatically advances every 30 seconds. Sample volumes can be programmed in volumes less than original volumes to perform “dilutions.”

In the [System] screen, if the “Auto/Standard Repeat” setting is set to “Auto Repeat Run,” and the [Repeat Common] screen is set to “Auto Repeat - Yes” the repeat-run sample is automatically extracted and the repeat run is performed according to the auto repeat-run extraction conditions set using [Parameters], [Repeat Parameters]. Once the system is programmed, repeats are performed automatically with no extra operator involvement.

Performing an Auto-Repeat Run

Warning

When running an “Auto Repeat Run”, if two racks with the same rack ID are processed in the same run, the data from the second rack will overwrite the data from the first rack, if “Repeat data overwrite” is checked in the [Repeat Common] screen.

Warning

Removing or repositioning samples/racks during an auto-repeat run may lead to concordance errors. **Samples/Racks associated with auto-repeat testing should not be removed until analysis is complete** and the racks have returned to the Collection area (Center location) of the rack feeder unit.

1. From the main menu, select [Parameters], [System], [System].
2. Select function key F4 (set).
3. Use the pull-down menu by the “Auto/Standard Repeat” field and select “Auto.”
4. Press function key F2 (exit) twice.
5. From the main menu select [Parameters], [Repeat Parameters], [Repeat Common].
6. Select function key F4 (set). Using the mouse, click on the box to the left of the Auto Repeat field on screen.
7. Using the mouse, select any flag to generate repeat requisitions. Flags can be set in one of the following categories.
 - A. The normal repeat mode uses the original sample volume to repeat the test.
 - B. The dilution repeat mode uses a user defined sample volume smaller than the original sample volume to perform a “dilution.” Results using the smaller volume are calculated and printed as the corrected result automatically.
 - C. The “OR mode” will requisition a repeat if any flag selected is generated.
 - D. The “AND mode” will requisition a repeat only if all flags selected are generated on a test.
 - E. The “Condense” category increases the sample volume for a repeat run.

8. If you want to set up specific test repeat ranges: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a range at the “Repeat Decision Level” to generate J (above the range) and K (below the range) flags.
9. If you want to perform a dilution, select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a smaller sample volume than the programmed volume (displayed from [Specific Test Parameters]) at the “Diluted Sample Volume” field.
10. Reset Reagent Status. Since parameters were changed it will reset back to red, uncheck status.
11. Press Start. *The analyzer will stay in a measure 1 mode, and the feeder belt will move automatically every 30 seconds for additional rack loading during an auto repeat run. The analyzer shifts to a measure 4 mode (Measure End) and then returns to standby when finished. Run routine samples and automatic repeats based on programmed repeat criteria.*
12. Repeat samples will have an “H” prefix on the data printout. For example, routine samples will print as H0001 and urine samples will print as HU001.

See Also

For information on how to print a repeat-run worklist and modify the worklist, refer to that procedure located in this section. For information about starting analysis, refer to the “Starting Analysis” section located in this chapter. For information on repeat results, refer to “Reporting Repeat Results or Original Results” in this section.

Tip

In this mode you can: repeat STATS on the STAT table, print a repeat list, move any P STAT that needs to be repeated to a position designated for STAT serum, urine or other repeat. (If no barcode is used, place the samples in numerical order and remove the samples when finished or concordance errors can occur.)

4.3.4 *How to Perform a Manual Repeat Run*

The following procedure explains how to program and perform a manual repeat run. If the system has been preprogrammed to perform a manual run, follow the procedures in the AU640 Quick Response Guide.

Any of the flags on the [Repeat Run Common] menu can be selected for repeat run analysis. J and K flags allow specific test ranges to be entered. Other error flags will not be test specific.

Performing a Manual Repeat Run Using the Orange Rack

1. From the main menu, select [Parameters], [System], [System].
2. Select function key F4 (set).
3. Use the pull-down menu by the “Auto/Standard Repeat” field and select “Standard.”
4. Press function key F2 (exit) twice.
5. From the main menu select [Parameters], [Repeat Parameters], [Repeat Common].
6. Select function key F4 (set). Using the mouse, click on the box to the left of the Auto Repeat field on screen.
7. Using the mouse, select any flag to generate repeat requisitions. Flags can be set in one of the following categories.
 - A. The normal repeat mode uses the original sample volume to repeat the test.
 - B. The dilution repeat mode uses a user defined sample volume smaller than the original sample volume to perform a “dilution.” Results using the smaller volume are calculated and printed as the corrected result automatically.
 - C. The “OR mode” will requisition a repeat if any flag selected is generated.
 - D. The “AND mode” will requisition a repeat only if all flags selected are generated on a test.
 - E. The “Condense” category increases the sample volume for a repeat run.
8. If you want to set up specific test repeat ranges: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a range at the “Repeat Decision Level” to generate J (above the range) and K (below the range) flags.
9. If you want to perform a dilution: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a smaller sample volume than the programmed volume (displayed from [Specific Test Parameters]) at the “Diluted Sample Volume” field.
10. Print a repeat run work list. Modify the work list if necessary, and print a new repeat run work list.
11. Pick up the repeat run samples according to the repeat run work list and load them into the orange racks. If samples are barcoded, they can be placed in any order. If samples are not barcoded, they must be placed in sequential order.
12. Press start. Repeat samples will have an “H” prefix on the data printout. For example, routine samples will print as H0001 and routine urine samples will print as HU001.

See Also

For additional information on repeat runs, refer to the beginning of the section called “Obtaining Results.”

4.3.5 *How to Perform a Manual Repeat Run Using the STAT Table*

To quickly perform repeat runs on a small number of samples, use the STAT table. The following procedure explains how to program and perform a manual repeat run. If the system has been preprogrammed to perform a manual repeat run, follow the procedures in the AU640 Quick Response Guide.

To repeat a priority STAT sample on the STAT table:

1. After running priority STAT samples, print a repeat run worklist.
2. From the main menu, select [Parameters], [System], [System].
3. Select function key F4 (set).
4. Use the pull-down menu by the "Auto/Standard Repeat" field and select "Standard."
5. Press function key F2 (exit) twice.
6. From the main menu select [Parameters], [Repeat Parameters], [Repeat Common].
7. Select function key F4 (set). Use the mouse to click on the box to the left of the Auto Repeat field on screen.
8. In the [Repeat Common] screen, select any flags to generate repeat requisitions. Flags can be set in one of the 5 following categories.
 - A. The normal repeat mode uses the original sample volume to repeat the test.
 - B. The dilution repeat mode uses a user defined sample volume smaller than the original sample volume to perform a "dilution." Results using the smaller volume are calculated and printed as the corrected result automatically.
 - C. The "OR mode" requisitions a repeat if any flag selected is generated.
 - D. The "AND mode" requisitions a repeat only if all flags selected are generated on a test.
 - E. The "Condense" category increases the sample volume for a repeat run.
9. If you want to set up specific test repeat ranges: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a range at the "Repeat Decision Level" to generate J (above the range) and K (below the range) flags.
10. If you want to perform a dilution: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a smaller sample volume than the programmed volume (displayed from [Specific Test Parameters]) at the "Diluted Sample Volume" field.
11. Place the STAT sample in a position on the STAT table for STAT serum repeat, STAT urine repeat, or STAT other repeat. If the sample containers are barcoded, they can be placed in any order in the designated areas of the STAT table. Press the STAT button to begin analysis. The first repeat sample number will be HP001, HUP001, or HXP001.

Tip

If the [Repeat Common] screen is set to “Auto Repeat” before a repeat list can be printed, one of the following additional steps must be performed.

- A. Select [Routine], [Test Requisition], [Repeat] to manually enter repeat run requisitions. Set the S. No. to the priority sample number to be repeated. Select function key F4 (start entry), choose the tests requiring repeat analysis, then select function key F4 (entry).
 - B. Use the [Routine], [Test Requisition], [Retrieve Repeat Data] screen to retrieve the repeat run requisitions based on the flags generated. Select the STAT type and number to “retrieve.” Select function key F5 (execute retrieve).
-

To repeat a sample from a routine rack on the STAT table:

1. From the main menu, select [Parameters], [System], [System].
2. Select function key F4 (set).
3. Use the pull-down menu by the “Auto/Standard Repeat” field and select “Standard.”
4. Press function key F2 (exit) twice.
5. From the main menu select [Parameters], [Repeat Parameters], [Repeat Common].
6. Select function key F4 (set). Using the mouse, click on the box to the left of the Auto Repeat field on screen.
7. In the [Repeat Common] screen, select any flags to generate repeat requisitions. Flags can be set in one of the 5 following categories.
 - A. The normal repeat mode uses the original sample volume to repeat the test.
 - B. The dilution repeat mode uses a user defined sample volume smaller than the original sample volume to perform a “dilution.” Results using the smaller volume are calculated and printed as the corrected result automatically.
 - C. The “OR mode” requisitions a repeat if any flag selected is generated.
 - D. The “AND mode” requisitions a repeat only if all flags selected are generated on a test.
 - E. The “Condense” category increases the sample volume for a repeat run.
8. If you want to set up specific test repeat ranges: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a range at the “Repeat Decision Level” to generate J (above the range) and K (below the range) flags.
9. If you want to perform a dilution: Select [Parameters], [Repeat Parameters], [Repeat Specific]. Enter a smaller sample volume than the programmed volume (displayed from [Specific Test Parameters]) at the “Diluted Sample Volume” field.

10. Select [Routine], [Test Requisition], [Repeat]. Select the tests that require repeat analysis based on flags generated from the data log printout. Select function key F6 (STAT repeat). The sample will be assigned a repeat sample number starting with HP001, HUP001, or HXP001.
11. Print a repeat run worklist.
12. Place the sample in a position on the STAT table designated for serum, urine, or other repeats. If the sample containers are barcoded, they can be placed in any order in the designated areas of the STAT table after being requisitioned for STAT table analysis. Press the STAT button.

See Also

For detailed information on using the STAT table, refer to the section called “Using the STAT Table: Normal Analysis Mode.”

4.3.6 Reporting Repeat Results or Original Results

Repeat results can be programmed to overwrite original results automatically, or the operator can select whether to use the original result or the repeat result. An “S” flag will be attached to data that is repeated and the original result is overwritten with the repeat result. The “S” flag will display on reprinted data from the AU640, or data that is batch transferred to a host computer.

There are two main fields in [Parameters] that affect final results:

[Parameters], [Repeat Parameters], [Repeat Common], “Repeat Data Overwrite”:

“Yes”: The automatic overwrite option is on.

“No”: The automatic overwrite option is off.

[Parameters], [Repeat Parameters], [Repeat Specific], “Auto Rewrite”:

“Yes”: Automatically overwrite the original data with repeat data for the specified test, if the automatic overwrite option is on.

“No”: The original data will not be automatically overwritten for the specified test.

How to Automatically Overwrite Original Results with Repeat Results:

1. In the [Parameters], [Repeat Parameters], [Repeat Common] screen, the “Repeat Data Overwrite” field must be selected. A check in the box indicates that it is selected.
2. Set the [Parameters], [Repeat Parameters], [Repeat Specific] screen to “Auto Rewrite” for any test to automatically overwrite the data. A check in the box indicates that “Auto Rewrite” is selected.

How to Manually Overwrite Original Results with Repeat Results:

1. In the [Parameters], [Repeat Parameters], [Repeat Common] screen, the “Repeat Data Overwrite” field can be selected to manually overwrite all original data. Select the check box by this field. Go to the [Repeat Specific] screen and deselect the check box by the “Auto Rewrite” to manually overwrite only selected tests.
2. After repeat analysis is complete, print a repeat list. Select [Routine], [Data Management], [Repeat Data Verification]. In the “Report Data List No” field, located at the bottom of the screen, use the pull-down menu to select a list. This is a list of the original sample results and repeat sample results for comparison. Determine which tests will need to be overwritten with repeat results. Press function key F3 (print).
3. From the [Repeat Data Verification] screen, select the repeat run sample type to be overwritten. Enter the range of sample numbers requiring data overwrite.
4. To overwrite by sample number: Use the pull-down menu by the “test name” field to select any original test results to be overwritten with the repeat result. The original sample and repeat sample with test results can be viewed one sample at a time. Select function key F5 (rewrite). The data should now have an “S” flag to indicate the test was repeated, and the original result overwritten with the repeat result.

5. To overwrite by test: Use the pull-down menu to select the test to rewrite. Press function key F8 (test no.) from the [Repeat Data Verification] screen. All of the original and repeat samples containing the specified test will display for easy overwriting of a single test. Select any original test results to be overwritten with the repeat result. Select F5 (rewrite). The data should now have an “S” flag to indicate the test was repeated, and the original result overwritten with the repeat result.

See Also

For more information about error flags, refer to the Error Flags Chapter.

4.4 Editing Results

Analysis results can be directly modified and edited as necessary.

CAUTION

Editing results is an operation performed by the operator to forcibly change test results that were analyzed according to a certain calibration and quality control. To prevent misdiagnosis due to incorrectly altered results, perform editing under the supervision of a doctor or laboratory manager.

Editing Results

1. On the main screen, select [Routine], [Data Management] and [Data Edit] in that order.
The screen for editing the data is displayed.

The screenshot shows the 'Data Edit' interface. At the top, there is a status bar with 'STANDBY' and several control icons. The date and time are '1997/09/03 10:10'. Below this is the 'Data Edit' title bar. The main area contains a form with the following fields and options:

- Index:** 1989/07/07 12:30
- Test Name..:** [Dropdown menu]
- Serum:**
 - Routine (nnnn - nnnn)
 - Emergency (Ennn - Ennn)
 - STAT (Pnnn - Pnnn)
- Urine:**
 - Routine (nnnn - nnnn)
 - Emergency (UEennn - UEennn)
 - STAT (UPnnnn - UPnnnn)
- Others:**
 - Routine (nnnn - nnnn)
 - Emergency (XEennn - XEennn)
 - STAT (XPnnnn - XPnnnn)

At the bottom, there are buttons for 'Help', 'Exit', 'Data Display', 'Search Add', and 'Test No.'. An 'ALARMCLEAR' indicator is also present.

2. Use the pull-down menu to select an index and test name.
3. Specify the type of the sample to be edited by clicking on the check box with the mouse.
4. Enter the range of sample numbers. It is also possible to enter the range of sample IDs.
Note: To edit according to test number, press function key F8 (test no.). A dialog box displays. Enter the test number and click the "OK" button.
5. Press function key F5 (data display). *The analysis results data is displayed for tests or samples.*

STANDBY [Play] [Pause] [Next] [Stop] [Print] [Warning] [Printer] 1997/09/03 10:10

Data Edit

Index: 1989/07/07 12:30 Test: G-GTP Type: 0001

S.No.	S.ID	Result	Flag
0001	12345678901234567890	102	JH
0002	12345678901234567890	102	JH
E001	12345678901234567890	102	JH

Help Exit Edit

ALARMCLEAR

STANDBY [Play] [Pause] [Next] [Stop] [Print] [Warning] [Printer] 1997/09/03 10:10

Data Edit

Index: 1989/07/07 12:30 Sample:

S.No.: 0001 [Left] [Right] S.ID: XXXXXXXXXXXX Type:

Sex: Male Age(Year/Month):

Test	Result	Flag	Test	Result	Flag
1.ITM01	1234567	H	10.ITM01	1234567	H
2.ITM02	1.1234 OD	JL	11.ITM02	22222	JL

Help Exit Edit Result Exit S.ID

ALARMCLEAR

6. Press function key F5 (edit) or F5 (edit results). *If samples were selected, the sample screen appears. If tests were selected, the test screen appears.*
7. Edit the displayed analysis results.
If the barcode type is set to ISBT128 in the [System] screen, the barcode ID entered as a sample ID is checked against ISO7046 Mod 37,2 for confirmation.
8. Select function key F2 (exit).
9. Press function key F2 (exit) again. *The main screen returns.*

4.5 Correcting Results

It is possible to correct the analysis results based on arbitrary correction factors.

Correction is performed using the following equation:

$$Y = AX + B$$

Y: Data after correction, **X:** Data before correction, **A =** Multiplication correction factor,

B = Addition correction factor

Caution

Correcting the analysis results is an operation that is performed by the operator to forcibly change the results of tests that were analyzed according to a certain calibration and quality control. To prevent misdiagnosis due to changing the analysis results, perform correcting under the supervision of a doctor or laboratory manager.

Correcting Results

1. On the main screen, select [Routine], [Data Management] and [Data Correction] in that order. *The screen for correcting the data is displayed.*

STANDBY	▶	⏸	▶	□	📄	⚠	🔧	1997/09/03 10:10
Data Edit								
Index:	1989/07/07 12:30							▼
Test Name:								▼
Serum								
<input type="checkbox"/> Routine			(nnnn - nnnn)					
<input type="checkbox"/> Emergency			(Ennn - Ennn)					
<input type="checkbox"/> STAT			(Pnnn - Pnnn)					
Urine								
<input type="checkbox"/> Routine			(nnnn - nnnn)					
<input type="checkbox"/> Emergency			(UEnnn - UEnnn)					
<input type="checkbox"/> STAT			(UPnnn - UPnnn)					
Others								
<input type="checkbox"/> Routine			(nnnn - nnnn)					
<input type="checkbox"/> Emergency			(XEnnn - XEnnn)					
<input type="checkbox"/> STAT			(XPnnn - XPnnn)					
Help Exit Data Display Search Add Test No. ALARM CLEAR								

2. Use the pull-down menu to select the index and test name. *To correct according to tests, press function key F8 (test no.). A dialog box displays. Enter the test number and click the "OK" button.*
3. Specify the type of the sample to be corrected.
4. Enter the range of sample numbers. It is also possible to enter the range of sample IDs.
5. Press function key F5 (correct data). *The window for entering correction factors displays.*
6. Enter correction factors A and B. Click the "OK" button. *The correction is executed.*
7. After correction has finished, press the function key F2 (exit). *The main screen returns.*

4.6 *Printing Edited or Corrected Data*

If analysis results were edited or corrected, print the data to confirm that the altered results are correct.

Print Edited or Corrected Data

The analyzer is in Standby Mode:

1. On the main screen select [Routine], [Data Report], and [Data List], in that order.
2. Select an index using the pull-down menu.
3. Specify the type of the sample to be printed.
4. Enter the range of sample numbers. It is also possible to enter the range of sample IDs.
5. Press function key F3 (print). *The print setup dialog box displays.*
6. Click the “OK” button. *Printing begins.*
7. Press function key F2 (exit). *The main screen returns.*

4.7 *How to Reprint Reagent Blank, Calibrator, QC and Patient Data*

Reprinting Data

The analyzer is in Standby Mode:

1. On the main screen select [Routine], [Data Report], and [Data List], in that order.
The screen for selecting the sample whose data is to be printed is displayed.
2. Select the Patient tab or QC/Cal tab located at the top of the screen.
3. Specify the index and type of the sample to be printed.
4. Enter the range of sample numbers. *It is also possible to enter the range of sample IDs.*
5. Press function key F3 (print). *Start Printing?* Select "OK."
6. After the data is printed, select function key F2 (exit).

The analyzer is in Measure Mode:

If a printer error occurs during a measure mode: The data that did not print will be stored in the printer buffer. The mode will display as Meas. to Meas. End. (The analyzer is not in the Standby mode.)

1. Select [System Status], [DPR Status].
2. Select function key F5 (printer control). *This only displays when a problem occurs and there is data to print.*
3. Correct the printer error.
4. A window appears to select "Resume Printing" or "Cancel Print."
5. All data will print if "Resume Printing" is selected.

4.8 Saving Parameters and Data to a Floppy Disk

Caution

Floppy disks increase the potential of harmful viruses infecting the analyzer's computer. To avoid damage to the computer and the data, before loading or saving data to a floppy disk, always perform a virus check on the floppy disk using any commercially available virus protection software, to ensure the disk is free from harmful viruses.

How to Save or Load Parameters to a Floppy Disk

Prepare an initialized floppy disk:

Note: Initialize a 3.5 floppy disk as a parameters disk one time before parameters are saved or loaded. The floppy disk can be 2HD or 2DD. Select [Maintenance], [Data Operation], [FD Data Management], FD Data Initialize Tab. Select the "Initialize Parameter FD" option. Insert the floppy disk in the computer. Select function key F5 (Start Initialize). From the "Insert FD Start" prompt, select yes. The message "Operating: Wait for a while" displays.

1. From the main menu select [Auxiliary], [Parameters Management].
2. Depending on your requirements, select either "Save Files to FD" or "Load Files from FD." *The save files to FD option will save files on the computer hard drive to the floppy disk. The load files from FD option will load files from the floppy disk onto the computer hard drive. Loading files onto the computer hard drive writes over the existing files with the same name.*

Important: A safer option can also be used. When saving files to a floppy disk, files can be saved to the hard drive by selecting the option called "Save files to HD." This keeps the hard drive current in case the "Load files from HD" option is accidentally selected.

3. Select one or more of the files in the "File" column by highlighting them with the mouse.
4. Insert the floppy disk in the computer. Select function key F5 (Execute). From the "Insert FD Start" prompt, select yes. The message "Operating: Wait for a while" displays.

How to Save Data to a Floppy Disk

Prepare an initialized floppy disk:

Note: Initialize a 3.5 floppy disk as a parameters disk one time before parameters are saved or loaded. The floppy disk can be 2HD or 2DD. Select [Maintenance], [Data Operation], [FD Data Management], FD Data Initialize Tab. Select the "Initialize Data FD" option. Insert the floppy disk in the computer. Select function key F5 (Start Initialize). From the "Insert FD, Start" prompt, select yes. The message "Operating: Wait for a while" displays.

1. From the main menu select [Maintenance], [Data Operation], [FD Data Management]. The screen will default to the "FD Data Save" tab.
2. From the "Index" field, use the pull-down menu to select the index that will be saved.
3. Place a check in the box by the sample type of your choice: Serum, urine, other, routine, emergency, or STAT.
4. From the sample number field, enter the range of sample numbers to save, or leave the asterisk (*) to save the entire range displayed. The samples can also be saved by entering a range of sample ID numbers from the sample ID field.
5. Insert the floppy disk in the computer. Select function key F5 (Start Save). From the "Insert FD Start" prompt, select yes. The message "Operating: Wait for a while" displays.

5. *Finishing Analysis*

After all of the samples are analyzed and scheduled maintenance is complete, perform an End Process. Even though analysis is finished, it does not mean that the power to the system is turned off completely. The reagent refrigerators and incubator require power to be maintained. The ISE unit also requires power to perform an automatic, periodic priming cycle.

Ending ISE Analysis

1. Perform Daily ISE Maintenance:
 - Fill an ISE cup with ISE cleaning solution, and place it on the “Clean” position on the STAT Table.
 - Select [System Status], [ISE Status], function key F5 (ISE unit start).
 - Select E. Cleaning. The ISE is cleaned automatically for about 3 minutes.
2. Return to the main menu. Press the End key located on the keyboard.

See Also

For detailed information about performing ISE Maintenance, refer to the Maintenance Chapter.

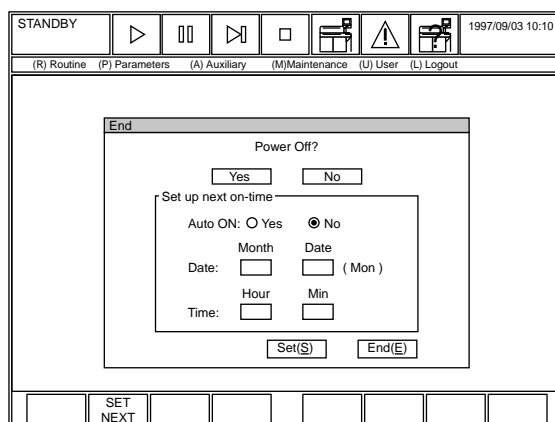
Ending Analyzer Analysis

The following procedure can be performed during a W2. The power to the system is automatically turned off after the W2 is complete.

Performing an End Process:

1. Check that all of the samples are analyzed.
2. Check that the system is in the Standby mode.
3. Check for floppy disks in the floppy disk drive. *If there is a floppy disk in the drive, remove it.*

4. From the Main Operation Menu, press the End Process Key located on the keyboard. *The window for finishing analysis is displayed. In this window, you can program the next automatic power on date and time. If automatic power on is selected, it is possible to schedule W1, Photocal or W1 + Photocal by selecting 'Yes' in the auto preparation part of the screen. Select "Yes" to power down.*



Warning

If maintenance (W1 or Photocal) is enabled in the Auto Power On screen, make sure all covers are closed and that warnings are posted, since the instrument will begin maintenance at the programmed time without any warning.

6. *As-Needed Tasks*

This section contains information about tasks that are performed on an as-needed basis. The following information is included:

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Checking Analysis Conditions

Select the [System Status] icon during analysis to check the current status of the analyzer, reagents, DPR, ISE and STAT table. Data can be displayed on the screen, the alarm list can be viewed and printed and cuvette status can be displayed.

Processing Priority or Emergency Samples

STAT samples can be processed by interrupting normal analysis. In this case, use the STAT table (priority) or red rack (emergency) before the normal samples. There are three methods for processing STAT samples:

- Processing priority samples using the STAT table: One-touch mode
- Processing priority samples using the STAT table: Press the STAT test switch in the normal analysis mode.
- Processing emergency samples using the red rack. Processing can be performed as a different sample type (E) ahead of routine samples.

Stop Operation

If analysis must be stopped in progress, press the stop function key on the screen or the Stop/Standby key on the keyboard. The analysis operation will come to a complete stop.

Emergency Stop

If all power to the system must be turned off, press the Emergency Stop Switch labeled “EM Stop.” *Refer to the Troubleshooting Chapter for more information on this switch.*

Pausing Analysis

During analysis, you might run out of reagent. If this occurs, use Pause on the screen or keyboard. The system can finish analyzing the current tests and then pause analysis. Press Start to resume analysis after loading reagents and performing a reagent volume check. No test results will be lost.

Stopping the Rack Feed Unit

During analysis, to insert a rack for an emergency sample, use the Feeder Stop key on the keyboard or icon on screen.

6.1 Checking Analysis Conditions

While analysis is in progress, it is possible to check the following: reagent status, analysis results, alarm list, cuvette information, ANL status and DPR status. Also, it is possible to check the status of ISE analysis.

See Also

For detailed information, refer to the [System Status] section located in the Software Chapter.

Checking the Analysis Conditions

1. Select the [System Status] icon. *The [System Status] screen is displayed.*

The screenshot shows the 'System Status' screen with a top bar containing 'STANDBY', navigation icons, and the date/time '1997/09/03 10:10'. The main area is divided into several sections:

- (0) Reagent Status:** Shows 'Unchecked' for R1 and R2, with sub-sections for 'Reagent of Group' and 'Status'.
- (1) ISE Status:** Shows 'Ready', 'Electrode', and 'Reagent'.
- (2) Data Display:** A blank box.
- (3) Alarm List:** A blank box.
- (4) Cuvette Status:** A blank box.
- (5) Analyzer Status:** Includes 'Detergent Tank', 'D.I. Water', 'Vacuum', 'Drain', 'Rack', 'Bath Temp.: C', and 'REF. Coolant Temp.: C'.
- (6) DPR Status:** Includes 'Measure S.No.', 'Input Online S.No.', 'Output Online S.No.', and 'Printer'.
- (7) STAT Table Status:** Includes 'END', 'SET', 'STAT Cal./QC Status', 'Unchecked', 'Calibration', and 'QC'.

At the bottom, there are buttons for 'Help', 'Exit', 'W1 Start', 'W2 Start', 'Photocal Start', 'One Touch', and 'ALARMCLEAR'.

2. Move the cursor to the item to be checked and press enter. *The screen related to the item to be checked is displayed.*

Reagent Status: View the reagent volume and shots (tests) remaining, reagent on-board stability, calibration stability, lot number, bottle sequence, and any reagent warnings.

ISE Status: When performing analysis using the ISE, it is possible to display the data and graph of the slope of the calibration curves for Na, K and Cl. It is also possible to display the MID-standard correction factor, selectivity check results, and ISE reagent status.

Data Display: Displays the analysis results in real-time.

Alarm List: Displays an alarm list of previous alarms. Use this menu to determine recent or common alarms, then use corrective actions found in the on-line help function.

Cuvette Status: Use this menu to check the mean cuvette check after a photocal is performed. It also displays a list of defective cuvettes and the date/time that the photocal measurement and W2 were executed.

ANL Status: Displays the status of the detergent, DI water, tank solution level, temperature of refrigerator and incubator.

DPR Status: Displays the sample number of the sample for which analysis has started and ended. Displays sample numbers that were input/output on-line between the system and host computer, and displays printer status. Use to resume printing if a printer error occurred during a measure mode.

STAT Table Status: Displays the presence or absence of sample containers on the STAT table, analysis progress, QC and calibration status performed on the STAT table and the type of operation to perform. The STAT LED light status is also displayed.

6.2 Processing Priority/Emergency Samples

Priority/Emergency samples can be processed prior to the routine samples by using the STAT table or red rack.

Summary of Processing Priority/Emergency Samples

There are three methods of processing priority/emergency samples. If there are only a few emergency samples to be processed, they can be processed quickly by using the STAT table. If there are many emergency samples to be processed, the red rack can be used.

Using the STAT Table: One-Touch Mode:

This processes priority samples in the one-touch mode. Analysis is performed simply by placing the sample container, containing the sample to be analyzed, on the STAT table in the one-touch mode position #1, and pressing the STAT test switch.

Using the STAT Table: Normal Analysis Mode

This is performed in the same way as the requisition operation for normal analysis except a "P" prefix is used. Analysis is started by pressing the STAT Switch.

Using the Red Rack:

If many emergency samples require analysis, use the red rack.

Instruction

If a sample is centrifuged in a primary tube to be analyzed on the AU640 system, check that there is sufficient serum for analysis, in addition to the dead volume required for sample detection. If the serum height in the sample tube is less than the limit, transfer the serum into a smaller sample container, then start analysis. Otherwise, if the blood cells under the serum in the container are aspirated, analysis and dispense abnormalities could occur.

STAT Table Adapters

The diameters of the standard sample container that can be set on the STAT table are 14 to 16 mm. It is possible to set sample containers on the STAT table whose diameters are outside the standard range. There are three kinds of adapters that can be used depending on the diameter of the sample container as shown in the table below:

SAMPLE CONTAINER DIAMETER	ADAPTER	PART NUMBER
Greater than 11.5mm and less than 14mm	Adapter A	MU8118
Greater than 13.5mm and less than 16mm	Adapter B	MU8119
14mm (ACA Cup)	Adapter C	MU8117

Sample containers with a diameter less than 11.5 mm cannot be used on the STAT table. Also it is not possible to use sample containers with a diameter exceeding 16 mm.

6.2.1 Using the STAT Table: One Touch Mode

To use the one-touch mode, it must be setup in advance. The One Touch mode is designed so an untrained operator can easily perform priority STAT analysis. To start analysis, simply set the sample container on the STAT table in position #1 and press the STAT Switch. Results are printed automatically.

Switching the System to the One-Touch Mode

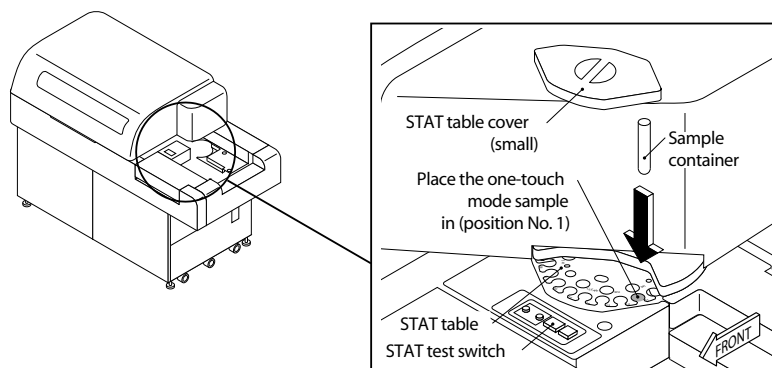
The system must be changed to the one-touch mode in advance by selecting [System Status].

STANDBY		▶	⏸	▶	□	🖨	⚠	🖨	1997/09/03 10:10
System Status									
(0) Reagent Status			(1) SE Status			(2) Data Display			
Unchecked			Ready						
R1		R2		Electrode			(3) Alarm List		
Reagent of Group		Reagent of Group		Reagent			(4) Cuvette Status		
Status		Status							
(5) Analyzer Status					(6) DPR Status		(7) STAT Table Status		
Detergent Tank		D.I. Water		Measure S.No.:		END SET			
Vacuum		Drain		Input Online S.No.:		STAT Cal./QC Status			
Rack:				Output Online S.No.:		Unchecked			
Bath Temp.:		C		Printer:		Calibration:			
REF.Coolant Temp.:		C				QC:			
Help		Exit		W1 Start		W2 Start		Photocal Start	One Touch
ALARMCLEAR									

1. Check for fatal or nonfatal errors: From the Standby mode, select the analyzer start key or icon to review the error list. If errors are present, perform corrective actions. *Select "No" at the measure start prompt.*
2. Select [System Status], then function key F8 (one touch).
3. When the prompt "Transfer to One Touch Mode" appears, select "Yes."
4. Select function key F5 (select profile). Any profile can be selected for the one touch mode. After selecting a profile, click the OK button.
5. To use the one touch option, remain in this menu. To end the one touch mode, select function key F2 (exit).
6. When the prompt "End One Touch Mode" appears, select "Yes."

Processing a priority sample using the STAT table: One-touch mode

After switching the system to the one-touch mode and selecting a profile, processing is performed by using the procedure below.



1. Place the STAT sample in position 1 on the STAT table.
2. Press the STAT Switch. *Analysis starts and the STAT button begins to blink. The sample number is automatically updated. The new sample number is the number of the priority sample before the STAT Switch was pressed plus 1 ($p^{***}+1$).*
3. Each time a STAT sample is performed, remove the current sample from position 1, and replace it with the next sample. Press the STAT Switch.

6.2.2 Using the STAT Table: Normal Analysis Mode

To obtain the quickest STAT results, use the STAT table. The priority STAT will interrupt the sample in progress to perform the STAT tests. The STAT table has 22 positions that can be programmed for user defined functions, one option is to assign the position for priority STAT analysis. The following procedure explains how to perform a priority STAT in the normal analysis mode instead of the one-touch mode. The requisition procedure is performed in the same way as normal analysis except in the “P” category.

Tip

If condensation appears on the STAT table or sample containers, be sure to wipe it off with a clean cloth.

Processing a Priority Sample using the STAT Table

Important

The 22 outer positions on the STAT table are assigned to STAT, repeat, reagent blank, calibration, or QC functions in the [System Maintenance] menu. Verify which positions can be used for serum, urine, or other priority STAT analysis on the analyzer.

1. From the main menu select [Routine], [Test Requisition], and [Normal], in that order. *The screen for requisitioning normal analysis is displayed.*
2. From the "S. No." field, type "P," then enter. *The next available priority sample number will display.*
3. From the "Type" field, use the pull-down menu to select serum, urine, or other.
4. Requisition tests individually, by profile, or batch. If requisitions are required for more than one sample type, select function key F2 (exit) to return to "Type."
5. Press the STAT switch to turn the STAT SET LED on. The STAT SET LED must be on before STATS can be loaded. Do not load samples if the SET LED blinks or does not come on. The SET LED turns on when loading is possible. If necessary, press the STAT ROTATION/DIAG Switch to rotate to the appropriate position to load samples.
6. Place the sample in a position assigned for the sample type on the table. *If STATS are not barcoded, they must always be placed in increasing numerical order on the table! Always remove STATS from the table as soon as the END LED is on.*

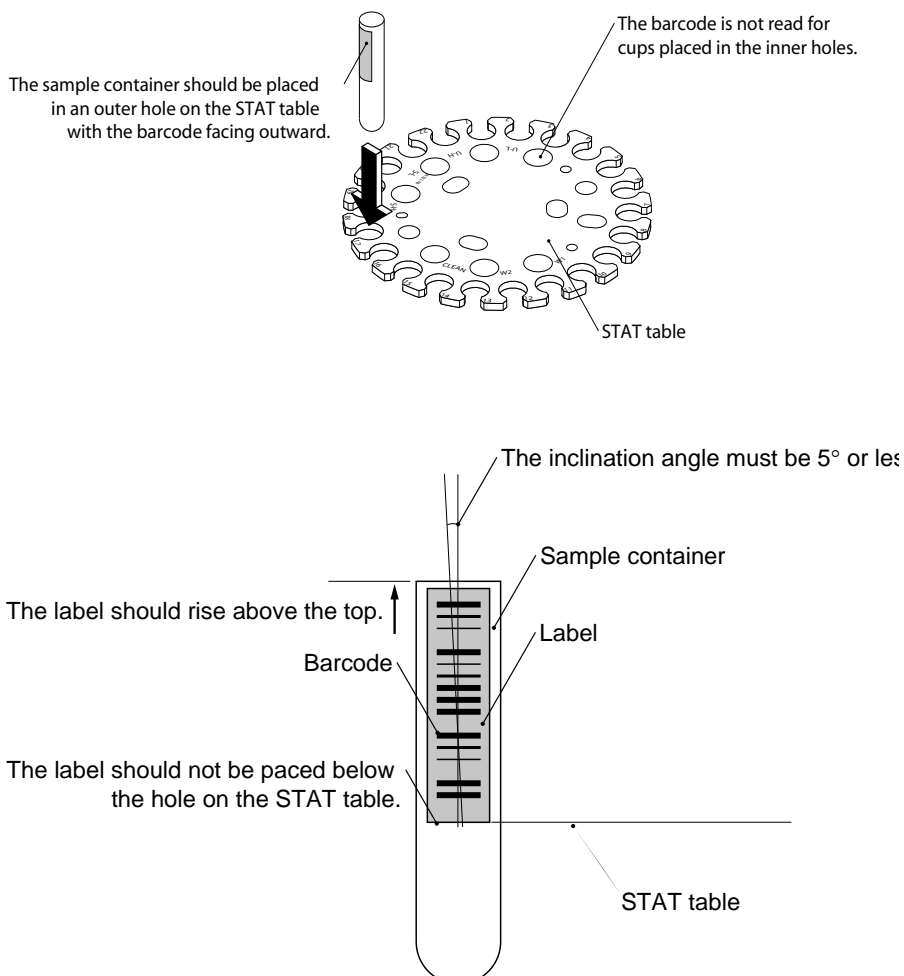
Warning

Close the STAT table cover after placing samples. A consistent temperature in the STAT table is important to the accuracy of the results.

7. Press the STAT Switch. *Analysis starts.*
8. The END LED comes on when STAT sample aspiration is complete. Remove containers from the STAT table.

How to Place a Sample Container with Barcode on the STAT Table

A sample container with a barcode attached should be placed on the STAT table with the barcode facing in the direction as shown in the figure below



Instruction

Do not place the barcode label below the holes on the STAT table. This may cause barcode read errors. The barcode label should be applied to the sample container as shown in the figure.

6.2.3 Using the Red Rack

Use the red rack when processing large quantities of emergency samples. The procedure for requisitioning emergency samples using the red rack is the same as that for normal analysis except they are requisitioned as “E” samples. An “E” will appear on the printout before the sample number indicating the emergency sample and data.

Tips

If there are white racks on the transport belt, the red rack cannot be analyzed until the white rack samples have been analyzed. If the emergency samples must be processed immediately, use the STAT table instead of the red rack.

Processing an Emergency Sample Using the Red Rack

The following explanation assumes that the system has already been started. First, display the screen for performing normal analysis requisition.

Tips

If normal analysis is in progress and emergency racks must be processed, press the feeder stop key. The window for stopping the feeder is displayed. Select “YES” and press enter. The rack feeding process stops.

1. On the main screen, select [Routine], [Test Requisition], and [Normal], in that order. *The screen for requisitioning normal analysis is displayed.*

The screenshot shows a software interface for requisitioning normal analysis. At the top, there is a status bar with 'STANDBY' and several icons, along with a date and time '1997/09/03 10:10'. Below this is a 'Normal' section with 'Test Requisition' and 'Demographics' tabs. The 'Test Requisition' tab is active, showing fields for 'S.No.' (0001), 'Type' (Serum), 'Remaining Samples' (7100), 'Round No.', 'S.ID.' (XXXXXXXXXXXXXXXXXXXX), 'Sex' (Male), 'Age', and 'Sample Dilution Rate' (1). There are also 'Test Total' and 'Search ID(S)' buttons. A grid of test selection buttons is visible, with columns for ALB, GOT, GPT, and G-GTP. At the bottom, there are buttons for 'Help', 'Exit', 'Print', 'Start Entry', 'Change Test', 'Delete Sample', 'Online', and 'S.No.'. An 'ALARMCLEAR' indicator is at the bottom right.

2. From the “S. No.” field, type “E,” then press enter. *The next available emergency sample number will display.*
3. Select the sample type.
4. Press function key F4 (start entry).
5. Enter sample ID, sex, age and profile if required.
6. Select the tests to be performed on the sample.
7. Press function key F4 (entry). *The next sample number is available for requisition.*

8. Repeat the previous steps for all emergency samples.
9. Set the sample container(s) with the emergency sample(s) into the red rack.

See Also

For information about how to place samples and racks, refer to “Preparing Samples and Racks” located in this Chapter.

10. Set the red rack in the rack feeder. *Any white racks on the rack feeder unit can be manually moved back, and the red rack placed in front for the next sample analysis.*
11. Press start to begin or resume analysis.

See Also

For information on how to start analysis, refer to “Starting Analysis” located in this Chapter.

6.3 *Performing a Stop or an Emergency Stop During Analysis*

In the event of an emergency, press the Orange (EM STOP) button on the front of the system. The main power is immediately turned off, including the power to the incubator and reagent refrigerator. To stop analysis, and leave the power on, select the Stop function key.

Caution

- In the event of a stop or an emergency stop, it is not possible to use the data. Analysis must be repeated.
- If analysis was in progress and a stop or an emergency stop was performed, reagent still remains in the cuvettes. This can cause damage or deterioration in the cuvettes, or may cause abnormal results. If reagent was in the cuvettes for a lengthy period of time, perform a W1 prior to restarting analysis.

Performing a Stop Function

A stop can be performed from most analyzer modes to stop analysis or maintenance procedures. This is not an emergency stop. *In the event of a stop or an emergency stop, it is not possible to use the data. Analysis must be repeated.*

1. Press the Stop key on the menu bar or press Stop on the keyboard during analysis. *The window for executing a stop is displayed.*
2. Select “YES,” then press enter. *A message indicating that a stop is being executed is displayed. The entire analysis operation stops, the system switches to the stop mode within 4.5 seconds.*

Resetting the System After a Stop

By pressing the Stop key again after the stop has been executed, it is possible to reset the system.

1. Remove any racks on the rack transfer belt.
2. After the stop is executed (stop mode), press the Stop key again. *The window for starting the reset operation is displayed.*
3. Select “Yes” and press enter. *The system is reset. After the system has been reset, it switches to the Standby mode.*
4. If in sequential analysis, reset the “Start Number” to the sample number after the last sample that was printed (completed analysis). *See [Routine], [Start Condition]. Move the first sample requiring analysis to the first position in the rack to be analyzed. If empty spaces are left in the rack, “no cup” alarms are generated and requisitions will not be performed. This could lead to concordance errors.*
5. Press start.

Performing an Emergency Stop

Note

The analyzer will stay in a Warm Up mode for 1 1/2 hours after an EM Stop is performed. To bypass this mode, select [Auxiliary], [Standby Set].

Caution

If the nature of the emergency compromises operator or instrument safety, press the Orange (EM Stop) button immediately. Please be aware that pressing the Orange (EM Stop) button without performing the other steps listed below could cause damage to the computer hard drive. Also the operating system and application files could become corrupted.

The following steps are the preferred method of shutting down the AU640/AU640^e during an emergency:

1. Press the following keys on the keyboard: CTRL + ALT + Delete. *The Task Manager will appear.*
2. From the Task Manager screen, select the Shutdown button. *The Windows Operating System will close all open files and databases.*
3. When the message “It is now safe to turn off your computer” appears, press the Orange (EM Stop) button on the front of the analyzer. All power to the system turns off.

Important

- In the event of a stop or an emergency stop, it is not possible to use the data. Analysis must be repeated.
 - If analysis was in progress and a stop or an emergency stop was performed, reagent still remains in the cuvettes. This can cause damage or deterioration in the cuvettes, or may cause abnormal results. If reagent was in the cuvettes for a lengthy period of time, perform a W1 prior to restarting analysis.
-

Resetting the System after an Emergency Stop

1. Press the Reset switch on the front of the analyzer.
2. After 10 seconds, press the Power On switch. *The software will load.*
3. From the [Routine], [Start Condition] screen, use the same index as before the emergency stop. Set the “Start Number” to the next sample number after any completed data (last sample that printed out results). *If you are performing sequential analysis, move the first sample requiring analysis to the first position in the rack to be analyzed. If empty spaces are left in the rack, “no cup” alarms are generated and requisitions will not be performed. Concordance errors could occur.*
4. If the reagent status says “unchecked,” select [System Status], [Reagent Status]. Select function key F5 (check start), “A. Reset Only.”
5. When Start is pressed, a warning will appear “ISE No Cal.” The ISE will continue to use the last ISE Cal. data performed, so “Yes” can be answered at the Start prompt.

6.4 Pausing Analysis

The analyzer shifts to a Pause mode due to insufficient wash solution, full rack collection area, or other error. Non-fatal errors can cause the analyzer to go into Pause mode.

The operator selected the Pause key or icon to get into Pause mode to load reagents.

Results in progress complete. No test results are lost.

Warning

Racks have stopped moving on the belts - **do not move the racks or errors will result!** All racks will start again when Start is selected from Pause.

Pausing Analysis

Warning

Only the Reset and Check Specified Position options are available, perform the Check Specified Positions on the new reagent(s). *The reagent check is only available **before** the Reagent Short alarm is generated*

1. Press the Pause function key or pause icon (||) on the menu bar during the analysis operation. *The window for executing the pause is displayed.*
2. The analyzer mode displays as Meas → Pause for 14 minutes while the testing in progress is completed. Next, the mode displays as Meas 4 (curvette washing) for 2 minutes, then displays Pause. In Pause, reagents can be loaded and a reagent volume check performed to update the new reagent volume. **A reagent check is the only procedure requiring the 14 minute wait.** *After adding Wash Solution or removing the racks from the collection area, press start to resume analysis.*

6.5 Stopping the Rack Feed Unit

Stopping the rack feed unit stops racks from being fed into the analyzer. When analysis is started again, the system begins feeding the rack that was at the start of the rack feeder when it was stopped. Use the stop rack feed function for such things as inserting an emergency rack (red rack) for analysis.

Stopping the Rack feeder

1. Press the Feeder Stop function key or icon (>|) on the menu bar during the analysis operation. *The window for stopping the feeder is displayed.*
2. Select "Yes" and press enter. *A message indicating that the rack feeder is being stopped is displayed. The analysis operation continues for racks that have already been fed from the feeder, and stops at the rack at the start of the rack feeder.*

Starting Analysis After the Rack Feeder Has Been Stopped

1. With the rack feeder stopped, perform the requisition operation in the same way as was done for normal analysis.

See Also

For information about how to perform the requisition operation for normal analysis, refer to "Chapter C, Starting Normal Analysis."

2. Start analysis. *Analysis begins with the first rack in the rack feeder.*

See Also

For information on how to start analysis, refer to Chapter C, "Starting Analysis."

6.6 *Creating a New Profile*

Individual tests are assigned for each profile. Profile number 0 is defined as the default profile. The default profile is automatically used in 3 situations: 1. Barcode read error in barcode analysis. 2. No requisition for a sample in the sequential analysis mode. 3. Online errors.

1. Select [Parameters], [Common Test Parameters], [Profile].
2. Select function key F4 (set).
3. Select function key F8 (profile no.) and enter a profile number to make a new profile.
4. Enter the profile name at the "Profile Name" field, then select "OK."
5. From the "Test No." field, select function key F5 (edit) and select the tests required for the profile. Select "Close" to set the profile.
6. Verify the tests selected appear on the screen with the correct profile number.
7. Select function key F2 (exit) to set the profile information.
8. Optional: Select function key F3 (print) for a list of the profile no., name, and tests selected in that profile.
9. Select function key F2 (exit) again to return to the main menu.

6.7 Changing QC Ranges

QC ranges can be set and changed when operating in the Preset Mode. The QC Mode is set in the [QC Common] screen to preset, cumulative, or none.

1. Select [Parameters], [QC Control], [QC Specific].
2. Use function key F8 (test no.) to get to a specific test number, or use the pull-down menu located next to the test name field.
3. Press function key F4 (set) then function key F5 (edit). Enter the new QC average (mean), standard deviation (SD), and range at the fields. The average is listed on the package insert. The range (2SD above and 2SD below the mean) is listed on the package insert. Type in the entire value of the range. The SD (1SD) is the range divided by 4.
4. Press the "Close" button and select function key F2 (exit) to set the new ranges.
5. Optional: Select function key F3 (print) to print a list of the new mean, SD, and range.

Example: The Beckman Coulter Control package insert lists the mean as 120, and the range as 115 to 125. You would type in 120 as the mean, 10 as the range and 2.5 as the SD.

6.8 *Changing Calibrator Set Points*

1. Select [Parameters], [Calibration], [Calibration Specific].
2. Use function key F8 (test no.) to get to a specific test number, or use the arrow buttons next to the test name field.
3. Select function key F4 (set). Enter the new calibrator concentration at the “CONC” field from the package insert.
4. Select function key F2 (exit) to set the new concentration.

6.9 *Turning on/off the Sample ID Barcode Reader:*

The sample ID reader can be turned on or off for racks (routine, emergency and/or priority STATs).

1. Select [Parameters], [System], [System].
2. Select function key F4 (set). From the “Test Requisition” field, select the pull-down menu next to the routine, emergency, or STAT field.
3. Select “Sequential” to turn off the barcode reader or select “Barcode” to turn on the barcode reader.

6.10 Programming the Auto Power On

1. Select [Parameters], [System], [Auto Power On].
2. Select function key F4 (set), then enter the day and time (based on a 24 hour clock) you want the analyzer to activate.
3. Select function key F2 (exit).
4. When the End key is selected, the next “On” time will be displayed. If you want to change the next “On” time, select the “set” button.

6.11 Creating a User Menu

This menu contains customized menu options. A maximum of 16 frequently used menus can be added in the [User] menu from any of the following menus: [Routine], [Parameters], [Auxiliary], and [Maintenance].

1. Select [Parameters], [System], [User Menu].
2. Use the mouse to select a blank line number. Select function key F5 (entry). *The User Menu set-up screen will display. Select the first menu to be part of the User Menu. Select "OK." The screen selected appears as part of the User Menu list on the right side of the screen.*
3. Use the mouse to select the next menu position in the User Menu.
4. Repeat steps 2 and 3 until all the screens you want to add are part of the User Menu. Press function key F2 (exit).
5. When [User Menu] is selected from the Main Menu, a pull-down menu of the choices selected will appear.

6.12 *Standby Mode*

Use [Standby Set] to shift the analyzer to Standby from Warm-up. If the system is in a Stop mode, shift to Standby using the Stop key or icon (yellow square) located at the top of the screen. If analysis is performed after shifting to Standby, results could be compromised since the system temperature or lamp did not have time to stabilize completely.

1. If the analyzer is in Warm-up, select [Auxiliary], [Standby Set].
If the analyzer is currently in Stop, select the Stop key again. The analyzer initializes and return to Standby.

6.13 Programming a New Test

The following procedure explains how to process a new test. For detailed information on each software screen refer to the “Software Chapter” located in this manual.

Assign Test Name, Reagent ID and Alarm Shot Volume:

1. Select [Parameter], [Common Test Parameters], [Test Name]. There are 6 tabs on this screen to choose from: Test Name, Long Name, Reagent ID, Calculated Tests, Multi-Reagent Switch and Alarm Shot.
2. In the “Test Name” tab, select F4: Set.
 - Select an available test number (1-95, Numbers 96-99 are set).
 - Select F5: Edit.
 - Enter the abbreviated test name, 1-5 characters. Select the “CLOSE” button.

Note

Do not change the test name without noting the time and date the change occurred. If the test name is changed it will affect all test results retrospectively with that test number. Consequently, any previously reported results (with the old name) will be assigned the new test name. Use extreme caution when making any changes to the test name and all recorded changes.

3. Select the Reagent ID tab. F4: Set.
 - Select the new test(s), and select F5: Edit.
 - At “Test Code”, enter the first 3 digits of the reagent ID, or refer to the Methodology sheet for the reagent ID 3 digit code. Select the “CLOSE” button.
4. Select the Multi-Reagent Switch Tab:
 - Select (highlight in blue) the new test(s). This causes the analyzer to switch to a new set of R1/R2 when either the R1 or R2 becomes empty if using more than 1 set of the same reagent.
5. Select the Alarm Shot Tab:
 - Select the new test(s) and select F5: Edit.
 - At “Alarm”, enter the “shots” to generate a reagent short alarm. The default is 32. Select the “CLOSE” button.

Note

Reagent Short alarms and comments in yellow in [Reagent Status] appear when the volume in the bottle is equivalent to the alarm shot programmed. The alarm shot volume is calculated as the Change/Dead Volume + [Reagent Dispense Volume + Dummy Dispense]* Alarm Shot Value. The largest reagent dispense volume of Serum, Urine, or Other triggers the reagent short alarms and comments in [Reagent Status], even when urine or other sample type is not in use (“Operation No.”). Example with a 30-mL bottle: Alarm shot (Vol) = 1000 ul + [180+5]* 32 = 6.920 mL.

Add the Test to the Round:

1. Select [Parameter], [Common Test Parameters], [Round].
2. At “Round Name”, select Round 1, 2, or 3 for the new test. A Round is the group of on-board tests that can be run at one time.
3. Select F4: Set, F5: Edit.
4. Select (highlight in blue) the test(s) to add to the Round.

Note

The order in which the tests are added to the round is the order they will print on the data log printout.

5. Select the “CLOSE” button.
6. Select F2: Exit to verify parameters, then F2: Exit to return to the Main Menu.

Enter Specific Test Parameters:

1. Select [Parameter], [Specific Test Parameters].
2. At “Test Name”, select the required test.
3. At “Type”, select Serum, Urine, or Other.
4. Select F4: Set.
5. At “Operation”, select “Yes” for the required sample type to run on the test. Verify “No” is selected for sample types not in use for the test.
6. Refer to the appropriate Methodology Sheet in the AU640 or AU640^e User’s Guide Volume 2, Methods Chapter to enter specific test parameters in the General Tab.
7. Select the Range Tab:
 - Set a generic reference range (“7. None Selected”) to generate “H” and “L” flags on samples when the range is exceeded.
 - Select F7: Decimal Places to set the appropriate decimal place for results.
 - Optional: At “Panic Value”, set a panic range for samples to generate an alarm and “p” flags when the range is exceeded.
8. Select F2: Exit to verify parameters, then F2: Exit to return to Main Menu.

Program New QC Material

1. Determine if it is necessary to program new QC material. Select [Parameter], [QC Control], [QC Common].
2. Select the Control Tab: Up to 60 different QC materials can be programmed for serum, urine, and other types.
3. If it is necessary to add new QC material, Select F4: Set.
 - Select an available QC Number (“No.”) with the appropriate sample type. The QC number is the position the control is placed in the green rack.
 - Select F5: Edit.
 - Enter the “Control Name”, “Control ID” (if using barcoded QC samples), “Expiration”, and “Lot No.” Select the “CLOSE” button.
 - Select F2: Exit to verify information, then F2: Exit to return to the Main Menu.

Program QC Ranges:

1. Select [Parameter], [QC Control], [QC Specific] (Preset Tab).
2. At “Test Name” select the required test.
3. At “Type”, select the required sample type.
4. Select F4: Set, F5: Edit.
 - At “Control Name” select the appropriate QC material
 - At “Multi/Single”, select “single”, or “multi” rules for evaluating QC data. “Refer to the AU640/AU640^e User’s Guide, Software Tab for more information on Single or Multi rules.
 - At “Mean”, enter the QC mean.
 - At “SD”, enter a one standard deviation value. One SD is the difference of the Range, divided by 4.

Example

The range on the QC package insert is 25-35. Enter “2.5” for SD ($35-25 = 10$, $10/4 = 2.5$).

- At “Range”, enter the difference of the range for acceptable QC.
 - Use the arrow button to move to the next QC material.
 - Select the “CLOSE” button
5. Select F2: Exit to verify the parameters, then F2: Exit to return to the Main Menu.

Program New Calibrator Material:

1. Determine if it is necessary to program new calibrator material. Select [Parameter], [Calibration], [Calibrator].
2. If it is necessary to add new calibrator material, select F4: Set. Up to 200 different calibrator materials can be programmed for serum, urine, and other types.
 - Select an available calibrator number (“No.”) with the appropriate sample type. The Calibrator number is the position the calibrator is placed in the yellow rack.
 - Select F5: Edit. Enter the “Calibrator Name”, “Calibrator ID” (if using barcoded calibrator samples), “Expiration” and “Lot No.”. Select the “CLOSE” button.
3. Select F2: Exit to verify parameters, then F2: Exit to return to the Main Menu.

Program Calibrator Set Points

1. Select [Parameters], [Calibration], [Calibration Specific], (General Tab).
2. At “Test Name”, select the required test. At “Type”, select the required sample type.
3. Select F4: Set.
4. Refer to the Methodology Sheet in the AU640 or the AU640^e User’s Guide Volume 2, Methods Chapter to determine if the “Calibration Type” is “AB” or “MB”, and enter Calibration Specific parameters.
5. If the “Calibration Type” is “AB”:
 - “Formula”: Refer to the methodology sheet.
 - “Counts”: (replicates) enter 1-4. Generally, Beckman Coulter recommends programming 2 replicates.
 - “Process”: enter “CONC” or “OD”. Refer to the AU640/AU640^e User’s Guide for more information.
 - “Cal. No.”: enter the calibrator number assigned to the appropriate calibrator material from the [Calibrator] menu.
 - “CONC”: enter the calibrator set point from the package insert.
 - “Factor/OD-L” and “Factor/OD-H”: refer to the methodology sheet.
 - “Advanced Calibration”: enter “Lot” or “Lot + Bottle”.
 - “Calibration Stability Period”: refer to the methodology sheet.
6. If the “Calibration Type” is “MB”
 - “Formula”: Refer to the methodology sheet.
 - “Counts”: (replicates) enter 1-4. Generally, Beckman Coulter recommends programming 2 replicates.
 - “Process”: enter “CONC” or “OD”. Refer to the AU640/AU640^e User’s Guide for more information.

- “Advanced Calibration”: enter “LOT” or “Lot + Bottle”.
 - “MB Type Factor”: refer to the methodology sheet.
7. Select F2: Exit to verify parameters, then F2: Exit to return to the Main Menu.

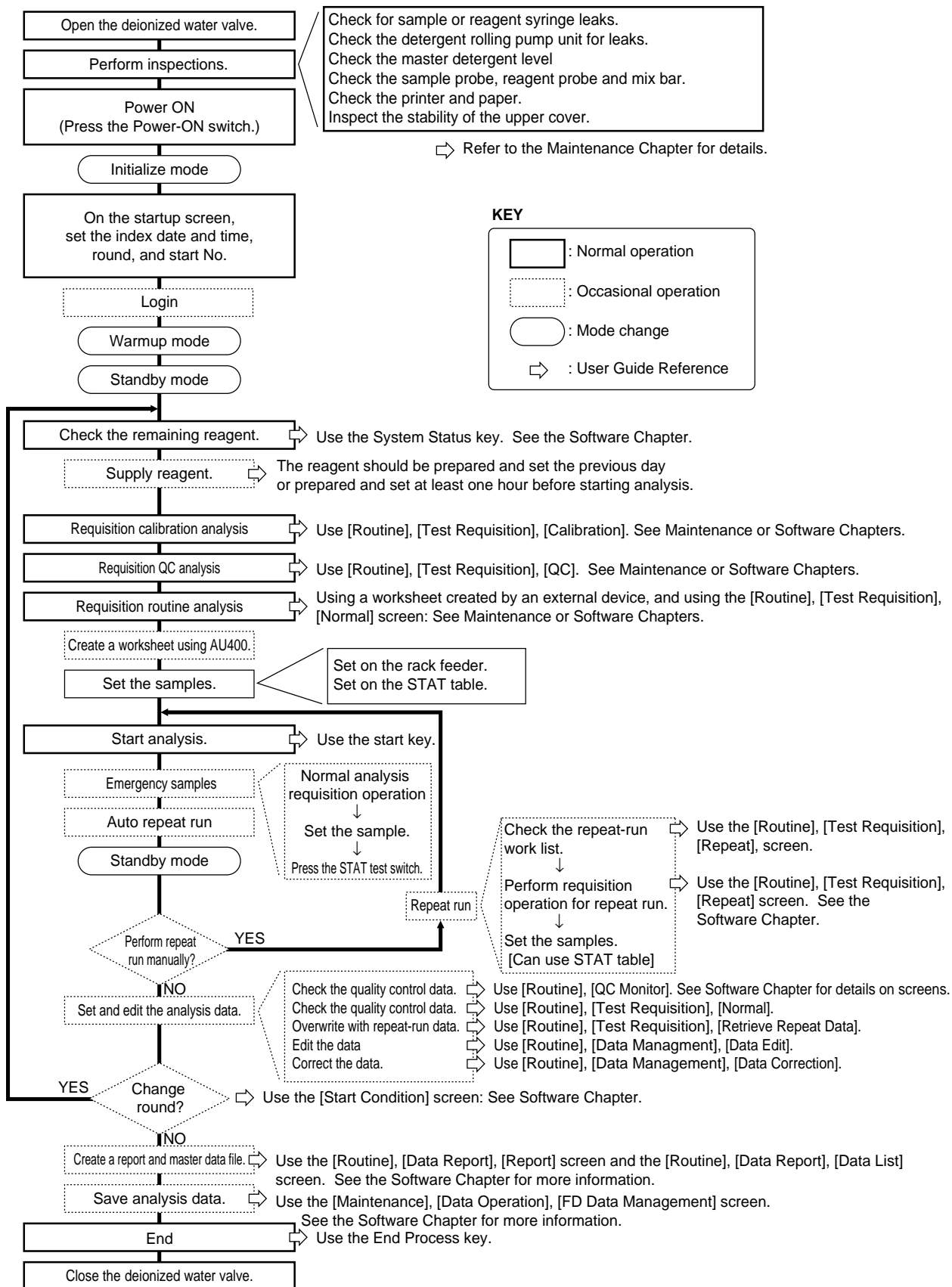
Program the Tests on Formatted Lists:

1. Add the test(s) to any formatted lists in use (worklist, pending list, data list, or repeat list).
2. Select [Parameter], [Format], [List Format].
3. At “List Name”, select the required list.
4. Select F4: Set, Test Tab.
5. Select (highlight in blue) the test(s) to add to the list.
6. Select F2: Exit to verify the parameters, then F2: Exit to return to the Main Menu.

Run the Tests to Verify Programming:

1. Load the reagents, on the analyzer.
2. Perform a reagent volume check on the new reagents.
3. Verify that calibration and QC is requisitioned for the new tests.
4. Place the reagent blank, calibration, and QC racks on the rack feeder unit and start the analyzer.
5. Review the printout and verify that all reagent blank, calibration and QC is within range.

7. Operation Guide



Chapter D

Software



Introduction

Use this Chapter to become familiar with software functions and operations. For information about frequently used operating procedures, refer to the Basic Operations Chapter.

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1.1 About System Status

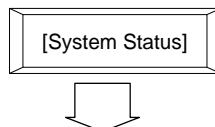
Information on the [System Status] screen will be updated in real-time. If problems occur or the system status changes during analysis, a message may appear or the background color of the screen may change. The following background colors usually indicate the following:

Blue: No error

Yellow: Error occurred but analysis is possible

Red: Error occurred and analysis is not possible

1.2 Performing a W1, W2, or Photocal, and using the One Touch Mode



System
Status Icon

STANDBY	▶	⏸	▶	□	🖨	⚠	🖨	1997/09/03 10:10	
System Status									
(0) Reagent Status			(1) ISE Status			(2) Data Display			
Unchecked			Ready						
R1		R2		Electrode			(3) Alarm List		
Reagent of Group		Reagent of Group		Reagent			(4) Cuvette Status		
Status		Status							
(5) Analyzer Status			(6) DPR Status			(7) STAT Table Status			
Detergent Tank		D.I. Water		Measure S.No.:			END SET		
Vacuum		Drain		Input Online S.No.:			STAT Cal./QC Status		
Rack:				Output Online S.No.:			Unchecked		
Bath Temp.:		C		Printer:			Calibration:		
REF.Coolant Temp.:		C					QC:		
Help		Exit		W1 Start		W2 Start		Photocal Start	
								One Touch	
ALARMCLEAR									

Description:

Perform a W1, W2, or Photocal according to the maintenance schedule located in the Maintenance Chapter to insure accurate analysis results. Use the [System Status] screen to perform these functions. Also, if you want to use the one touch mode (which is an easy operation mode for untrained operators) use the [System Status] screen to activate this function.

Use this software screen to:

Perform a W1:

For procedures, refer to the Maintenance Chapter, “Perform a W1.”

Perform a W2:

For procedures, refer to the Maintenance Chapter, “Perform a W2.”

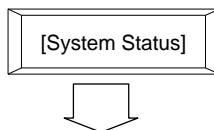
Perform a Photocal:

For procedures, refer to the Maintenance Chapter, “Perform a Photocal.”

Shift to the One Touch Mode:

For procedures, refer to the Basic Operations Chapter “Using the STAT Table: One Touch Mode.”

1.3 Reagent Status



Description:

Use this menu to perform a reagent volume check, assign (fix) positions for reagents which are not barcoded, and verify the remaining number of tests in the bottles. The following can be viewed or entered: tests per bottle, bottle volume, reagent on-board stability, calibration stability, reagent lot number and bottle sequence.

See Also

For information on correcting many of the following abnormal messages, refer to the “Fatal and Nonfatal Errors” section located in the Flags Chapter of the AU640^e User’s Guide Volume II.

Use this software screen to:

Check Reagent Integrity:

Checked/Checking/Unchecked

Indicates whether a reagent volume check was performed since the reagent compartment cover was opened.

Message	Meaning	Change in background color
Checked	Reagent check performed	Blue
Checking	Reagent check in progress	Red
Unchecked	Reagent check not performed	Red

Reagent of group

Indicates whether Reagent 1 and 2 are in place.

Message	Meaning	Change in background color
Reagent of group	All reagents are set	Blue
Reagent of group	Not all reagents are set	Yellow

This message does not notify the operator if an empty reagent bottle was placed on the analyzer. Also, it does not detect a bottle placed in the wrong position.

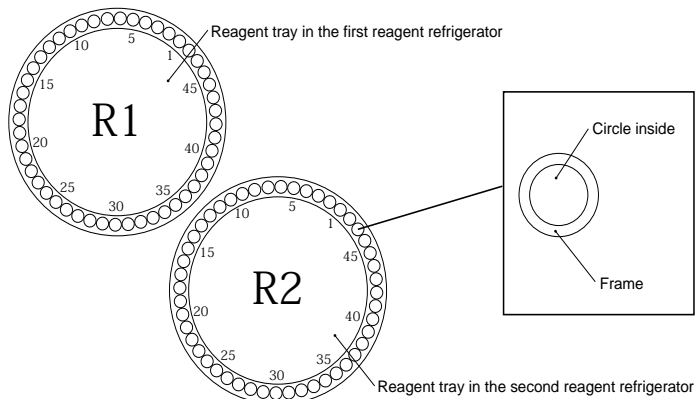
Status

Indicates the result of a volume check on Reagent 1 and 2, which is required for analysis.

Message	Meaning	Change in background color
Status	No error	Blue
Status	Error is present, but analysis is possible	Yellow
Status	Error is present, but analysis is impossible	Red

Illustration of Reagent Refrigerator

The reagent refrigerator is illustrated on the left side of the screen. This illustration shows the reagent type and status.



MEANING	FRAME COLOR
Fixed reagent	Blue
Reagent ID	White
Probe detergent	Green
Diluent	Blue

MEANING	INSIDE COLOR
No bottle	Background color
Reagent bottle (no error)	Blue
Probe detergent bottle (no error)	Blue
Diluent bottle (no error)	Blue
Reagent bottle (an error exists)	Yellow
Probe detergent bottle (an error exists)	Yellow
Diluent bottle (an error exists)	Yellow

MEANING	NUMBER IN THE CIRCLE
First reagent	1
Second reagent	2

Check reagent status:

To check the position in the reagent compartment, the reagent name, lot number, reagent onboard stability, calibration stability, remaining shots (tests), and remaining volume:

1. Select [System Status], [Reagent Status].

See Also

For information about troubleshooting reagents and samples, refer to the Troubleshooting Chapter "Troubleshooting Reagents and Samples."

“Reagent History” button

This button allows the reagent history to be referred to.

1. Select the “Reagent History” button. The information about reagent bottles used up to now is listed on the “Reagent History Display” dialog box for each reagent bottle. The reagent history is displayed in reverse chronological order from the top.

R1						R2					
Lot No.	Bottle No.	Onboard Stability	Exp. Date	Bottle Size	Pos.	Lot No.	Bottle No.	Onboard Stability	Exp. Date	Bottle Size	Pos.
0001	0006	02/22/2000	02/29/2000	30ml	2	0001	0001	03/13/2000	02/29/2000	30ml	1
0001	0006	03/13/2000	02/29/2000	30ml	2	0001	0003	03/13/2000	02/29/2000	30ml	3
0001	0004	02/20/2000	02/29/2000	30ml	4	0001	0001	03/12/2000	02/29/2000	30ml	1
0001	0004	03/12/2000	02/29/2000	30ml	4	0001	0002	03/12/2000	02/29/2000	30ml	2
0001	0005	03/12/2000	02/29/2000	30ml	6	0001	0003	03/12/2000	02/29/2000	30ml	3
0003	0001	03/12/2000	02/29/2000	30ml	3	0003	0001	03/12/2000	02/29/2000	30ml	5
0002	0001	03/12/2000	02/29/2000	30ml	5	0002	0001	03/12/2000	02/29/2000	30ml	4
0001	0005	03/12/2000	02/29/2000	30ml	2	0001	0002	03/12/2000	02/29/2000	30ml	2
0001	0004	03/12/2000	02/29/2000	30ml	4	0001	0003	03/12/2000	02/29/2000	30ml	3
0001	0005	03/12/2000	02/29/2000	30ml	6	0001	0001	03/12/2000	02/29/2000	30ml	1

Tip

In the above dialog box, it is possible to delete the specified line of reagent history. Move the cursor to the line of reagent history desired to be deleted, then select the “Delete” button.

2. Select the “Close” button after confirming the reagent information.

“Position” button

To specify a reagent position, click the circle indicating its position in the illustration to the left of the screen with the mouse, or observe the following procedure.

1. Select the “Position” button. The “Select Reagent Position” dialog box is displayed.
2. Enter the position No. of the reagent desired to refer to its detailed information.
3. Select the “OK” button.

Test (left box)

Displays the test name corresponding to the position.

Test (right box)

Displays either “R1” for the first reagent or “R2” for the second reagent.

“Next” button

This button is displayed only for the reagent that is to be used for two test items. Each time the button is selected, the item is toggled between the first test and the second test.

Vol(ml)

Displays the residual quantity of reagent.

Shot

Displays the number of reagent tests.

Onboard Stability

Displays the residual number of days for which the reagent is effective.

If “Onboard Stability Period” is set to “None” with the [Specific Test Parameters] submenu in the [Parameters] menu, “--” is displayed.

Calibration Stability

Displays the residual number of days for which the calibration is effective.

If “Calibration Stability Period” is set to “None” with the [Calibration] – [Calibration Specific] submenus in the [Parameters] menu, “– –” is displayed.

Sequence

Displays the supply sequence of reagents.

“Sequence” is a sequence of reagents to be used if there are multiple reagents for the same test item. Among reagents for the same test item “Sequence” is automatically assigned to each reagent by 1. Lot # (lowest), 2. on-board stability (lowest), 3. Shot (lowest), 4. Position (lowest).

Comment

Displays the contents of errors.

Lot No.

Displays the lot number according to the ID which was read from the barcode or edited in **F6: Edit**.

Bottle No.

Displays the bottle number according to the ID which was read from the barcode or edited in **F6: Edit**.

Bottle Size

Displays the size of reagent bottle in either 15, 30, or 60 according to the ID which was read from the barcode or edited in **F6: Edit**.

F3 : Print

This key can output detailed information about reagent bottles that have been set in the data list.

1. Press the F3 (Print) key. The Output Start dialog box is displayed.
2. Select the check box of the ANL unit, the status of which is to be printed out.
3. Select the “OK” button. The information will start being outputted.

F4 : Reagent Setting

When the F4 (Reagent Setting) key is pressed, the “Reagent Setting” dialog box is displayed.

This dialog box lists the reagents for the analysis items registered for the present round for which no reagent information has been set, reagent is not in refrigerator or cannot be assigned a sequence number due to error.

F5 : Check Start

Check the remaining quantity of reagents that are set in the reagent refrigerator.

1. Press the F5 (Check Start) key. The “Reagent check” dialog box is displayed.
2. Select a type of check to perform.
3. Select the “Start” button.

The types of checks available are shown below.

Reset only

Resets the status from “Unchecked” to “Checked.” Volume check or reagent ID read is **not** performed.

Check specified position:

Volume check one or more specific R1 and/or R2 positions. **Reagent ID's are not read.** Use for **fixed positions**.

Check specified position (with ID):

Reads reagent ID **and** volume checks one or more specific R1 and/or R2 positions.

Check changed positions (With ID)

Reads all positions for reagent ID. Volume checks any **new** or **moved** reagents.

Check all positions:

Reads all positions for reagent ID and volume checks all reagents.

- “ with ID Read” is gray (not operational) when status is “Unchecked.” All positions are read for ID.
- “ with ID Read” is white (operational) when status is “Checked.” The check can be removed to volume check all reagents **without** reagent ID reading.

F6 : Edit

It is possible to change the remaining amount and lot number for Reagent 1 and Reagent 2.

Caution

If a reagent position is edited, perform a reagent check using the “Check All Positions” (with ID read) option.

If the F6 (Edit) key is pressed, the “Edit” dialog box is displayed. In this dialog box, information about the position that was specified in the “Reagent Status” screen is displayed.

The screenshot shows a dialog box titled "Edit". At the top, there are two input boxes for "Position" with left and right arrow buttons, and a "Type:" label followed by an input box. Below this, there are two radio buttons: "Use Reagent ID" (which is selected) and "Fixed Reagent". Underneath, there is a "Test:" label followed by a dropdown menu. Below the dropdown are several fields: "Vol(ml):", "Onboard Stability:", "Calibration Stability:", "Lot No.:", "Bottle No.:", and "Bottle Size:". To the right of the "Onboard Stability:" and "Calibration Stability:" fields are buttons labeled "Reset(R)" and "First/Sec.(F)". At the bottom right of the dialog is a "Close" button.

Tip

If the system operation mode is set to Pause, the following item contents cannot be edited.

- USE Reagent ID/Fixed Reagent
- Test
- Lot No.
- Bottle No.
- Bottle Size

Position

Displays the position No. that was selected in the “Reagent Status” screen.

“<<” button/“>>” button

Each time either of these buttons is selected, the position No. being displayed is switched. It is also possible to switch position No. by keyboard operation.

Shift key + Page Down key	:Same as the function of the “<<” button
Shift key + Page Up key	:Same as the function of the “>>” button

Type

Displays either “Serum”, “Urine”, or “Others”.

“Use Reagent ID” and “Fixed Reagent” option buttons

Select either of the following option buttons.

Fixed Reagent	: Use a reagent bottle with its setting position fixed.
Use Reagent ID	: Use a reagent bottle by identifying it with the reagent ID.

Test

Select the test item to be set at the corresponding position from the pull-down list.

“R1” and “R2” option buttons

Set the object reagent to the first reagent or the second reagent. Select the corresponding option button.

“First/Sec.” button

If the reagent is used for two test items, either the first test or the second test that is to be edited is displayed. Each time this button is selected, the item to be edited is toggled between the first test and the second test.

Vol(ml)

Set the residual quantity of reagent within the range between 0 and 999mL.

Onboard Stability

Set the residual number of days for which the reagent is effective, within the range between 0 and the value that was set from “Onboard Stability Period” in the [Specific Test Parameters] submenu of the [Parameters] menu.

“Reset” button

Resets the residual period of effective reagent. If this button is selected, the value that has been set from “Onboard Stability Period” in the [Specific Test Parameters] submenu of the [Parameters] menu is reset.

Calibration Stability

Set the residual number of days for which the calibration is effective, within the range between 0 and the value that was set with the [Calibration] – [Calibration Specific] submenus in the [Parameters] menu.

Lot No.

Set the reagent lot No. within 4 digits.

Bottle No.

Set the bottle No. within the range between 0000 and 9999, or between A000 and Z999, or between a000 and z999.

Bottle Size

If the object position is on the outer circumference of the reagent tray, select either 15mL or 30mL from the pull-down list. If the object position is on the inner circumference of the reagent tray, select either 15mL, 30mL or 60mL from the pull-down list.

F7 : Test Display

The reagent status can be displayed for each reagent test item. Press the F7 (Test Display) key. The reagent use status is listed on the “Test Oriented Display” dialog box.

Test Oriented Display

Type:

Test	R1			R2		
	mL	Shot	Pos.	mL	Shot	Pos.
2.Tst02	236	8727	*	268	9918	*
3.Tst03	28	1011	*	---	----	--
4.Tst04	69	704	*	---	----	--
5.Tst05	93	3439	*	---	----	--
6.Tst06	0	0	--	---	----	--
1.Tst01	133	2679	*	153	3057	*
7.Tst07	91	3375	*	---	----	--
8.Tst08	46	1711	41	---	----	--
9.Tst09	---	---	--	---	----	--
10.Tst10	---	---	--	---	----	--
11.Tst11	93	1786	*	---	----	--
12.Tst12	49	1812	38	---	----	--

If a “sequence” exists in reagent bottles, detailed information about all reagent bottles to which a sequence number has been assigned can be referred to. Select the “Detail” button on the “ Test Oriented Display” dialog box. The reagent information for each reagent bottle is listed on the “Test Oriented Display (Detail)” dialog box.

Test Oriented Display(Detail)

Type:

Test	Pos.	Vol (mL)	Shot	Onboard Stability	Cal. Stability	Expired	Lot No.	Bottle No.	Seq.	Comment
1. R1 Tst01	6.	24	486	21		02/29/2000	0001	0005	1	
R2 Tst01	1.	31	623	21		02/29/2000	0001	0001	1	
R1 Tst01	4.	39	570	21		02/29/2000	0001	0004	2	
R2 Tst01	3.	33	655	21		02/29/2000	0001	0003	2	
R1 Tst01	2.	30	604	21		02/29/2000	0001	0006	3	
R2 Tst01	2.	27	667	21		02/29/2000	0001	0002	3	
R1 Tst01	5.	27	537	21		02/29/2000	0002	0001	4	
R2 Tst01	4.	24	534	21		02/29/2000	0002	0001	4	
R1 Tst01	3.	24	482	21		02/29/2000	0003	0001	5	
R2 Tst01	5.	29	578	21		02/29/2000	0003	0001	5	
2. R1 Tst02	8.	42	1564	31	2	03/31/2000	0001	0001	1	

F8 : Position Display

It is possible to display the reagent status by each reagent position in the reagent tray, as well as by each test item.

Press the F8 (Position Display) key.

The test name, onboard stability, Cal. stability, effective term, lot No., bottle No., SEQ., and error contents are displayed as a list.

To change the position No. to be displayed, scroll the screen.

Error contents indications and Error contents are shown below.

Indication	Contents
R.ID Read Error	A reagent bottle is present, but the reagent ID can not be read correctly.
Undefined Reagent	The read reagent ID code is not recorded in [Parameters] - [Common Test Parameters] - [Test Name].
R1 Reagent	The first reagent exists in the second reagent refrigerator.
Incorrect Reagent Type	The reagent type is abnormal for the read reagent ID.
Incorrect Size	The reagent bottle size is abnormal for the read reagent ID.
No Bottle	There is no reagent bottle at the position set for the fixed reagent.
No Blank Reagent	There is no reagent for the blank item set as a pair with the coloring item.
Not Assign Seq. No.	Indicates the reagent bottles to which no sequence number is assigned and which are not used for analysis for the following reasons: ¥ Sequence numbers up to 5 have already been assigned to reagent bottles for the same test item. ¥ For test items that have been set as the same-time reagent sequence items with the [Parameters] - [Common Test Parameters] - [Test Name] menus, the reagent bottle of the second reagent that forms a pair with the first reagent does not exist, or the reagent bottle of the first reagent that forms a pair with the second reagent does not exist.
R1/R2 Pair Mismatch	Indicates the reagent bottles to which no sequence number is assigned and which are not used for analysis for the following reasons: For test items that have been set as the same-time reagent sequence items with the [Parameters] - [Common Test Parameters] - [Test Name] menus, the reagent bottle of the second reagent that forms a pair with the first reagent does not have the required amount of reagent for ACAL measurement, the reagent bottle of the first reagent that forms a pair with the second reagent does not have the required amount of reagent for ACAL measurement or R1/R2 lot #s do not match.
No Reagent	The total residual quantity of the same reagent, including multi-reagent items (reagent of the same analysis item) is empty.
Bottle Empty	The residual sample quantity for one or more reagent bottles is empty for a reagent for which a multi-reagent item has been set.
No Reagent for Auto ACAL	The ACAL object reagent is insufficient at the time of ACAL measurement.
Cleaner Empty	The residual detergent quantity is empty.
Expired	The effective period for the reagent has been exceeded.
On Board Expired	The on-board stability value is zero.
CAL Expired	The calibration stability value is zero.
On Board Override	The on-board stability value has been changed in F6: Edit .
Cal Override	The calibration stability value has been changed in F6: Edit .
No RB Data	The 0-adjustment analysis (reagent blank analysis) has not been performed.
No Calibration Data	The calibration factor has not been calculated.

Review reagent position errors:

1. Press function key F8 (position display). *The test name, onboard stability, cal. stability, expiration date, lot number, bottle number, sequence, and error contents are displayed.*

Note

The following list shows the possible reagent errors. If a problem exists, these errors appear in the comment column.

2. To return to the reagent status screen, press the “Close” button. *The [Reagent Status] screen returns.*

Unchecked (in red): Reagents were not checked, the refrigerator door was opened, or [Parameter] screens were accessed.

Onboard Expired: The onboard stability has expired. Put on a new bottle of reagent and perform a reagent volume check.

Cal Expired: The calibration has expired. Requisition for calibration and calibrate that test(s).

Expired: The reagent has expired. Put on a new bottle of reagent, then perform a reagent volume check, and blank or calibrate the test if required.

No Reagent: This comment appears with “Reagent Short” alarms when 2 mL or less remains in a single bottle (sequence 1, no additional bottles). Put on a new bottle of reagent and perform a reagent volume check. If only one bottle of a test is present, the test volume diminishes to 0 mL, 0 shots and generates error flag “R” on the data printout. This indicates there is no more reagent. The test is no longer performed.

Bottle Empty: This comment appears when linked or sequenced bottles are in use. When the volume of bottle sequence 1 reaches 1 mL, “Bottle Empty” appears in [Reagent Status] and in the Start window. If sequenced bottles are in use, the bottle is changed to bottle sequence 2 at 1 mL in sequence 1. No alarms are generated indicating a new bottle sequence 2 is in use.

No Bottle: No bottle is present in a fixed position with a test assigned. Put the correct reagent in the fixed position and perform a reagent volume check. If you do not want a bottle in this position, click on that position, select function key F6 (Edit) and use the pull-down menu at the test prompt to select “None.”

R. ID Read Error: A reagent bottle is present, but the barcode cannot be read. Check the label and try the reagent volume check again. Fix the reagent position and edit the lot number. Perform a reagent volume check. If the test is R1 only, and the lot number is not entered, results print in OD with a “)” flag unless a new reagent blank or calibration is performed. Results in OD can be calculated to concentration in [Routine], [Data Management], [Data Correction]. Select function key F6 (Recal Data). To delete the “)” flag, select [Routine], [Data Management], [Data Edit] function key F5 (Data Display). Then select F5 (Edit), check the flag field and delete the “)” flag. If the test is R1/R2 and the lot number is not entered, “Unpaired Reagent” warnings are generated.

Unpaired Reagent: The lot number for a R1 and R2 reagent does not match. This occurs if the R1/R2 test is loaded with different lot numbers, or if a “Reagent ID Read Error” erased the lot number. Function key F4 (Reagent Setting) lists “Unpaired Reagents” and reagents not in the refrigerator. Select function key F6 (Edit) to edit the R1 or R2 lot number of an “Unpaired Reagent.” Perform a reagent volume check. “Incorrect Reagent Set, test name” appears in the Start window if “Unpaired Reagent” warnings are not corrected. If this nonfatal alarm is bypassed at Start, the test is not run and nothing appears on the printout for that test.

Reagent of Group (Yellow): A barcoded onboard reagent is not in the refrigerator, or “Unpaired Reagents” exist. Press function key F4 (Reagent Setting) to determine what reagent(s) is missing. Put the bottle in the refrigerator and perform a reagent volume check. If the bottle is in the refrigerator, the bottle itself may not have been detected. Place a small piece of tape on the upper part of the bottle near the barcode label to help detect the presence of a bottle. Repeat the reagent volume check.

Unset Reagent: The R1 or R2 of a reagent is missing or had a reagent ID read error. Select function key F4 (Reagent Setting) to determine what reagent is missing. Load the R1 or R2 and perform a reagent volume check. Refer to “Reagent ID Read Error” and “Unpaired Reagents.”

No Reagent Information or Unset Reagents: The “Round Number” is incorrect. Select [Routine], [Start Conditions] and verify the round number selected. If necessary, use the pull-down menu to change the round to 1, 2, or 3.

Used Reagents: This comment appears if sequenced bottles are in use and the multi-reagent switch tab in [Parameters], [Common Test Parameters] has tests selected. This feature switches the R1 and R2 from sequence 1 to sequence 2 when either the R1 or R2 is at 1 mL. The “Used Reagent” comment displays when the R1 or R2 has more than 1 mL of reagent (not empty). For more information on the multi-reagent switch feature, refer to step 1 in the procedure called “Programming a New Test” located in the As-Needed Tasks section of the Basic Operations Chapter.

Reagent Probe Level Detector Error: A reagent probe level detection error occurred. Verify no bubbles are present in the reagent bottle. Make sure the reagent bottle is not too full. Verify the correct bottle size is programmed, and water is present in the reagent probe wash well. If there is no water in the wash well at the start of the reagent volume check, verify the sample probe filter quick-release joints are properly connected. Refer to the procedure called “Clean the Sample Probe Filter” located in the Monthly Maintenance section of the Maintenance Chapter.

Undefined Reagent: The read reagent ID is not defined in [Parameters], [Common Test Parameters], [Test Name], or it is not defined in the round.

Incorrect Reagent Type: The reagent type is incorrect for the read reagent ID.

Incorrect Size: The reagent bottle size is incorrect for the read reagent ID.

No Blank Reagent: There is no reagent for the blank set as a pair with the color.

No Reagent for Auto ACAL: During automatic ACAL measurement, the quantity of reagent for the automatic ACAL is insufficient.

Diluent Empty: The diluent quantity has dropped below the volume set in the [System Maintenance] screen.

Cleaner Empty: The detergent quantity has dropped below the volume set in the [System Maintenance] screen.

Onboard “Override”: The onboard stability value was changed in [Parameters], [Specific Test Parameters].

Display tests remaining in reagent bottles:

1. Press function key F7 (tests display). *The status of reagents in use display by each test.*

Perform a reagent volume check:

For information about performing a reagent volume check, refer to “Starting the AU400” located in the Basic Operations Chapter.

Set (Fix) a reagent position:

For procedures, refer to the Basic Operations Chapter “How to Set (fix) a Reagent Position.”

Reagent

Indicates the quantities of the buffer, MID-standard, and REF solutions.

Message	Meaning	Change in background color
Reagent	Reagent sufficient	Blue
Reagent	Reagent empty	Yellow

Display calibration results:

Select [System Status], [ISE Status]. The following appears:

Date/Time

Date and time the calibration was executed.

Slopes of Na, K, and Cl

Indicates the calibration slopes for Na, K, and Cl. Slope values must be between 38 and 68 (Cl neg.) to be in-range. Slopes out-of-range will be highlighted in yellow.

MID SOL. factor

This is a value which is obtained based on the concentration of the MID standard to establish a reference for measuring Na, K, and Cl ion concentrations. Factors out-of-range will be highlighted in yellow.

Sample Type

The sample type (serum, urine) displays. To change the type press function key F8 (type change).

Display a slope chart:

Slope values obtained from calibration can be viewed by selecting the “slope chart” tab. *The most recent thirty slope values will display.* Slope charts of Na, K, and Cl are identified by their specific color. Also, the display range lies in a normal range (38 to 65).

(Na=yellow, K=orange, Cl=blue)

Display selectivity check results:

To view the date and time of a selectivity check as well as its results, select the “result select” tab. *A list of the most recent ten selectivity check results will be displayed.*

Start and calibrate the ISE:

For procedures on start-up and calibration, refer to “Starting the ISE” located in the Basic Operations Chapter.

Perform a selectivity check:

For procedures, refer to the Troubleshooting Chapter, “Selectivity Check.”

Clean the Sample Pot and Electrode Line:

For procedures, refer to the Maintenance Chapter, “Clean the Sample Pot and Electrode Line.”

Clean the Mix Bar, Liquid Level Sensors and Sample Pot:

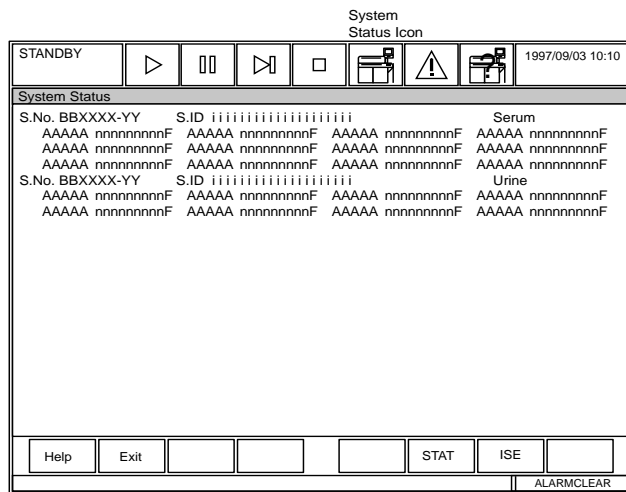
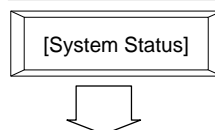
For procedures, refer to the Maintenance Chapter “Clean the Mix Bar, Liquid Level Sensors and Sample Pot.”

Prime the ISE:

The operator can drain or add liquid from/to the ISE tubing. The following procedures can be performed in this state:

- Electrode replacement
- All prime
- Buffer solution prime
- MID standard/Reference solution prime
- Waste liquid prime (bypass)
 1. Select [System Status], [ISE Status].
 2. From the “Result Cal,” “Slope Chart” or “Selectivity Check Results” tab, press function key F6 (prime). A window to select a prime operation item is displayed.
 3. Using your mouse, select from the following primes to be performed:
 - A/Replace Electrode
 - B/P Tube Exchange Prime
 - C/Total Prime
 - D/Buffer Prime
 - E/Mid/Ref Prime
 - F/Prime Bypass
 4. Press the STAT ROTATION/DIAG Switch. *The prime operation starts.*

1.5 Data Display



Description:

Use this screen to display results during analysis, or if real-time output with the printer is not functional. Analysis data displayed on the screen is updated when sample analysis is complete.

Use this software screen to:

Display sample data analyzed on the STAT table:

STAT table data can be displayed while analysis is in progress. Select [System Status], [Data display]. Then press function key F6 (STAT data). *Data analyzed on the STAT table is displayed.*

Display ISE related data:

Analyzed ISE data samples can be displayed while analysis is in progress. Select [System Status], [Data display]. Then press function key F7 (ISE data). *Only data related to Na, K, and Cl will be displayed.* Or press function key F6 (STAT data).

View analyzed data:

In [System Status], [Data Display] select function key F6 (STAT data) or F7 (ISE data). To view all data, select function key F5 (all data).

Displayed items should be read as follows:

Sample number and sample type:

A 4-digit value is displayed.

“BB” in the figure will be substituted by the following symbols that indicate each sample type.

Sample data prefixes:

- H: Repeat-run sample
- U: Urine sample
- E: Emergency sample
- X: Other sample
- P: Priority Stat sample
- No prefix: Serum sample (routine)

Prefix for reagent blank, calibrators and QC:

- A: Samples for ACAL (automatic calibration)
- Q: Samples for quality control
- R: Samples for reagent blank

The following symbols will be displayed in place of “YY” in the figure:

Samples for ACAL:	Calibrator number
Samples for QC:	Control number
Samples for reagent blanking:	Number to indicate whether the data is from photometry point 1 or 2

Note:

The sample type (serum, urine, or other) for calibration and QC samples will display to the right of the “sample ID” field.

Sample ID:

A sample ID consisting of a maximum of 20 digits is displayed.

Test name:

An analysis test name is displayed in the left column: “AAAAA.”

Sample data:

Sample data is displayed to the right of the “test name” column: “nnnnnnn.” Results from an analyzed sample will be displayed as a numerical value with a maximum of 9 digits, including any decimal points defined.

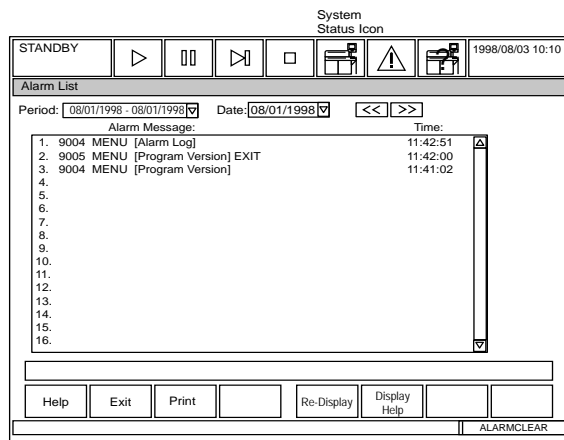
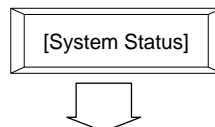
Error Flag:

Shown as “F” in the screen illustration on the previous page. If the analyzed result is abnormal, an error flag will be attached to the right of the sample data. *Although more than one error flag may be attached, only the one with the highest priority is displayed.*

See Also

For information about interpreting data, refer to the Basic Operations Chapter “Obtaining Results.” For more information about error flags, refer to the Error Flags Chapter.

1.6 Alarm List



Description:

Displays an alarm list of the last 2000 alarms. A maximum of 1000 alarm occurrences can be displayed per day. Use this menu to determine recent or common alarms. The most recent alarms are displayed at the top of the list. To view detailed information about an alarm, highlight the alarm then press function key F6 (Display Help). The alarm help screen will display.

Use this software screen to:

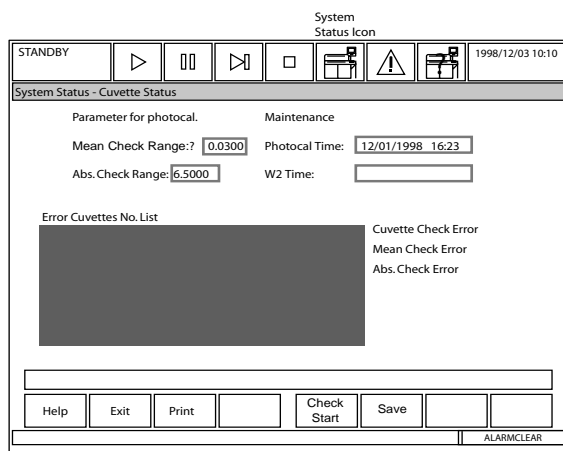
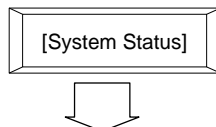
Display the alarm list:

Select [System Status], [Alarm list]. *The [Alarm list] screen is displayed. In this screen, the alarms that occurred on the current system date are displayed.* To display the most current alarms, select function key F5 (re-display). To view an alarm list on another date, use the arrow buttons next to the date field on screen.

Print an alarm list:

1. In the [Alarm list] screen press function key F3 (print). *A window to select the print range is displayed.*
2. Select either "Displayed Date" or "All Date" and select "OK."
Printing begins. To stop printing, select "CANCEL."

1.7 Cuvette Status



Description:

Use this screen to check the mean cuvette check after a photocal is performed. It also displays the date/time that the photocal measurement and W2 were executed.

The recommended mean cuvette check range is 0.03. The absolute check field should be set to 6.5 to maximize the range. The cuvettes are color coded as follows to indicate photocal status:

White	Cuvettes passed the photocal
Green	Failed the cuvette check
Red	Failed the mean check
Blue	Failed the absolute check

Use this software screen to:

Display cuvette information:

1. In the [System Status] screen move the cursor into the [Cuvette Information] column and press enter. The [Cuvette Information] screen appears. Check the following:

Parameters for photocal:

Internal Cuvette Check: The internal cuvette check range is 0.01. This is set in the software and cannot be altered.

Mean Check Range: Set an allowance of 0.03 for the difference between a Photocal measurement from a specific cuvette to the average of Photocal measurements from all cuvettes.

Absolute Check Range: Not performed in Beckman Coulter maintenance protocol. Select 6.5 to maximize the range.

Maintenance information:

The time displays the most recent Photocal and W2 procedure. In addition, the date of each procedure and the current date are compared. If the maintenance is overdue (displayed in the [Periodic Maintenance] screen) the background color of the date of the procedure will turn yellow.

Error cuvette number list:

A list of defective cuvette numbers will be displayed. A maximum of 153 cuvette numbers can be displayed in ascending order. The following error types can be identified by the display color of each cuvette number.

Errors in the cuvette check	Green
Errors in the mean check	Red
Errors in the base check (absolute check)	Blue

If one cuvette has more than one error, the cuvette number will be displayed for each error.

For procedures on performing a photocal, refer to the Maintenance Chapter.

Check cuvette status after the photocal:

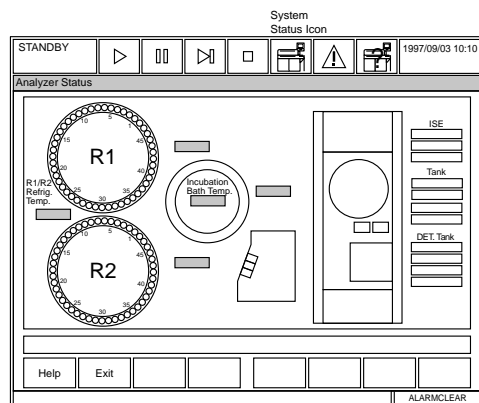
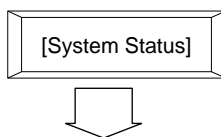
Refer to the Maintenance Chapter, "Perform a photocal" for procedures.

Print cuvette information:

It is possible to print a list of defective cuvettes. (*Cuvettes are considered defective if they did not pass photocal*).

1. In the [Cuv. Status] screen press function key F3 (print). *A window to start printing is displayed.*
2. Select "OK." *Printing begins.*

1.8 Analyzer (ANL) Status



Description:

This screen displays the status of the following:

- Detergent (Wash Solution)
- ISE reagent status
- DI water tank level
- R1/R2 refrigerator temperature
- Incubation Bath Temperature
- Cuvette wheel status
- Reagent Compartments
- Vacuum Tank

It also displays the sample number of the sample being analyzed in the R1, sample and R2 position.

See Also

For information on correcting many of the following abnormal messages, refer to the “Fatal and Nonfatal Errors” section located in the Flags Chapter.

Use this software screen to:

Check Analyzer Status:

Move the cursor onto the [ANL status] column, then press the Enter key. *The [ANL Status] screen is displayed.*

DI Water Tank

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
DI water	Deionized water tank is full (no error)	Blue
DI water	Deionized water tank has overflowed	Yellow
DI water	DI water tank is empty color	Red

Vacuum tank

Indicates whether there is liquid waste in the vacuum tank

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
Vacuum	Vacuum tank is not full.	Blue
Vacuum	Vacuum tank is full	Red

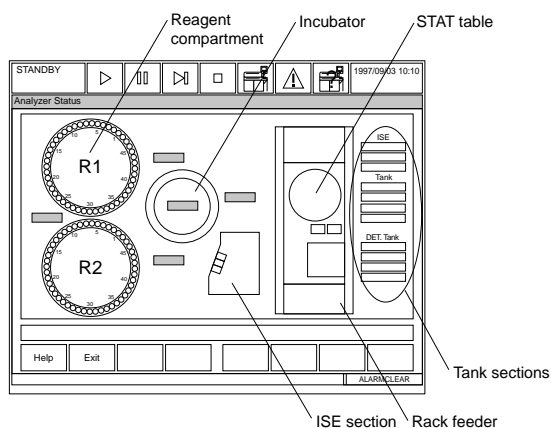
Conc. Waste/D. Waste

Indicates the status of the drain. Shows that the an optional waste pump is operating. This option is selected in [Parameters], [System], [Option].

Detergent (Wash Solution) tanks A & B

Indicates the status of the concentrated detergent tank and diluted detergent tank

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
DET. tank	No error	Blue
DET. tank	One or more tanks are empty	Red
DET. tank	1 or more tanks have overflowed	Yellow



Rack

Indicates the rack feeder status.

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
None	Rack feeder has space	Grey
Rack full	Rack feeder is full	Red

Reagent Compartments:

Coolant temperature in the reagent compartments

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
Temperature (4°C-12°C)	Within range	Blue
Temperature (lower than 4°C or higher than 12°C)	Out of range	Yellow

Open/Closed reagent compartment cover

MEANING	CHANGE IN BACKGROUND COLOR
Open	Red
Closed	Blue

Status of reagent by each position in the R1/R2 compartments (Including ISE Reagent in the ISE section)

MEANING	CHANGE IN BACKGROUND COLOR
Empty	Yellow
Full	Blue
Not in use	Grey

Incubator temperature

<i>MESSAGE</i>	<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Temp. display between 36.5 & 37.5°C	Within range	Blue
Other temp. display	Out of range	Yellow

Status of a cuvet

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Photocal data acceptable	Blue
One or more cuvettes exceeded the range	Yellow
One or more cuvettes were found abnormal	Yellow
Photocal not performed	Yellow

Other (Sample Progress)

- Sample No. at sample aspiration position.
- Sample No. at reagent 1 dispense position.
- Sample No. at reagent 2 dispense position.

ISE Electrode Status:

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Slope value is either greater than 68 or less than 38. (Na and K are positive. Cl is negative.)	Yellow
MID liquid correction factor exceeds the acceptable limit.	Yellow
Acceptable Limit Na 0.80 - 1.20 (MID liquid concentration is 140) K 0.75 - 1.25 (MID liquid concentration is 4.0) Cl 0.75 - 1.25 (MID liquid concentration is 100)	Blue

Operation mode

<i>MESSAGE</i>	<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
READY	Analysis is possible.	Blue
BUSY	Analysis is in progress.	Red
STOP	ISE is in the stop mode.	Yellow

Rack Feeder:

Rack Status:

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Rack tray is full	Red
Not Full	Grey

Tanks: Deionized Water Tank, & Detergent (Wash Solution) Tanks Status

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Tank is empty.	Red
Overflow	Yellow
No Error	Blue

STAT Table Status:

Cover Status

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Closed	Blue
Open	Red

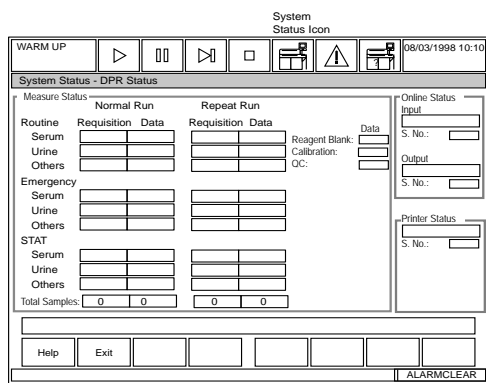
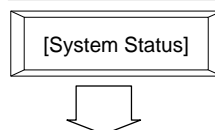
Sample Cup Set-up Enabled/Disabled

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Set-up Enabled	Blue
Set-up Disabled	Grey

Sample Aspiration Status

<i>MEANING</i>	<i>CHANGE IN BACKGROUND COLOR</i>
Aspiration complete	Blue
Aspiration Incomplete	Yellow

1.9 Data Processor (DPR) Status



Description:

This screen displays the sample number for which analysis has started and ended. It also displays sample numbers that were input/output on-line between the system and host computer, and the status of the printer.

Use this software screen to:

View sample analysis, data transfer, and printer status:

1. Select [System Status], [DPR Status].

Measure Status:

Sample numbers for which analysis has been started or completed

Displays the sample number for which analysis has started (Req column) and ended (Data column). If there are no corresponding samples, nothing is displayed.

Total number of samples

The total number of samples for which analysis has been started and completed displays. If no samples were run, "0" displays.

Online Input/Output Status:

Method of input and output

The selected method of input or output (ON-LINE) and "Real-time" or "Batch" will be displayed.

Sample number

Sample numbers for which the data was entered or printed displays.

Printer Status:

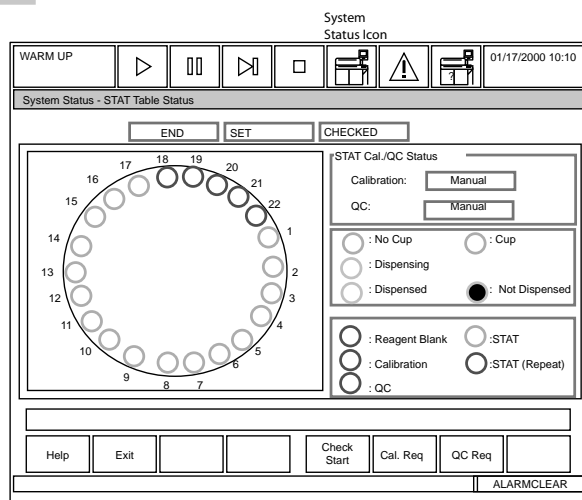
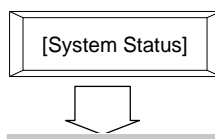
Printing status

While in real-time printing, "Real-time printing" displays. While in report printing, "Report printing" displays. In other printing states, "Batch printing" displays.

Sample number

The sample number printed displays while in real-time printing or report printing.

1.10 STAT Table Status



Description:

This screen displays the status of each position on the STAT table. The 22 outer positions of the STAT table are assigned to sample types in [System Maintenance]. User defined choices are reagent blank, calibrator, QC, STAT, or repeat STAT. Each sample category is also defined as serum, urine, or other sample type. This screen is used to view the status of the STAT table for loading, sample dispensing, and table check errors by color-coding. Calibrations and QC programmed in [Parameters] as “Manual” are requisitioned in this screen. If “Auto Calibration” is programmed in [Parameters], calibrations are performed automatically after a new bottle or a new lot number is detected. Auto QC is performed after a specified number of tests or samples, or after calibration.

Caution

It is recommended that the operator determine the acceptable length of time to leave samples on the STAT table. Although the STAT table is refrigerated, it should not be used to store samples for an extended period of time. Do not open and close the STAT table cover frequently. This will increase the temperature.

See Also

For information on correcting many of the following abnormal messages, refer to the “Fatal and Nonfatal Errors” section located in the Flags Chapter.

Use this software screen to:

Check the STAT Table Status:

To check STAT table status, select [System Status], [STAT Table Status]. The following list provides information on the fields within this screen.

End

Indicates the status of the STAT table sample aspiration.

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
END	Sample aspiration complete	Blue
END	Sample aspiration incomplete	Grey

Set

Indicates if the STAT table is ready to load sample cups.

MESSAGE	MEANING	CHANGE IN BACKGROUND COLOR
SET	Ready to place sample cups	Blue
SET	Not ready to place sample cups	Grey

Checked/Checking/Unchecked

Checks the STAT table for errors.

Message	Meaning	Change in background color
CHECKED	Check performed, no errors found	Blue
CHECKED	Check performed, errors found	Yellow
CHECKING	Check in progress, an error occurred	Red
UNCHECKED	Check not performed or check failed	Red

STAT Calibration/QC

Indicates whether the calibration/QC is manual or automatic.

Message	Background color
Manual	Grey
Automatic	Grey

Sample dispense

Indicates sample dispense status.

Circle Color ●

Red:	Not dispensed. Patient samples not analyzed due to no requisition or no reagent.
Blue;	Sample dispensed.
Yellow::	Dispensing sample.
White;	Cup detected.
Gray::	No cup detected.

Ring Color ○ (Indicates sample type)

Blue:	Reagent Blank
Yellow:	Calibrator
Green:	QC
Red:	STAT
Orange:	Repeat STAT

Requisition QC STAT analysis

For procedures, refer to the “Quality Control Analysis” section of the Basic Operations Chapter.

Requisition calibration STAT analysis

For procedures, refer to the “Performing Calibrations and a Reagent Blank” section of the Basic Operations Chapter.

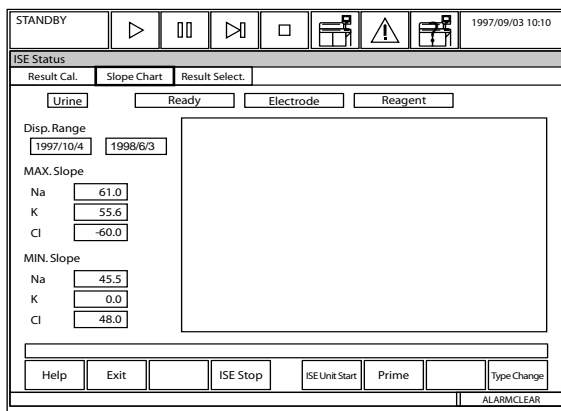
“ISE Status : Slope Chart tab” screen

Records of slope values obtained from calibration can be referred to in the form of polylines for each of Na, K, and Cl.

Select the tab of “Slope Chart”. The “ISE Status : Slope Chart tab” screen is displayed.

The most recent ten slope values will be displayed in a chart. At this time, slope charts of Na, K, and Cl are identified by their specific color. Also, the display range lies in a normal range (38 to 68).

In the left of the chart the maximum and minimum slope values of Na, K, and Cl are displayed.



Sample Type

Displays one of the sample types (serum or urine). To switch the sample type, press the F8 (Type Change) key.

ISE Status

Displays an ISE operation mode.

The display content is the same as that of “ISE Status” in the “ISE Status : Result Cal. tab” screen.

ISE Reagent Status

Indicates whether the buffer solution, MID solution, and REF solution that ISE uses are sufficient.

The display content is the same as that of “ISE Reagent Status” in the “ISE Status : Result Cal. tab” screen.

ISE Electrode Status

Indicates whether the latest slope value is within the normal range.

The display content is the same as that of “ISE Electrode Status” in the “ISE Status : Result Cal. tab” screen.

Disp. Range

Indicates the display range with the start and end dates.

MAX. Slope

Displays the maximum slope value for each Na, K, and Cl.

MIN. Slope

Displays the minimum slope value for each Na, K, and Cl.

Chart (on the right side of the screen)

Displays calibration execution dates and slope values as a chart.

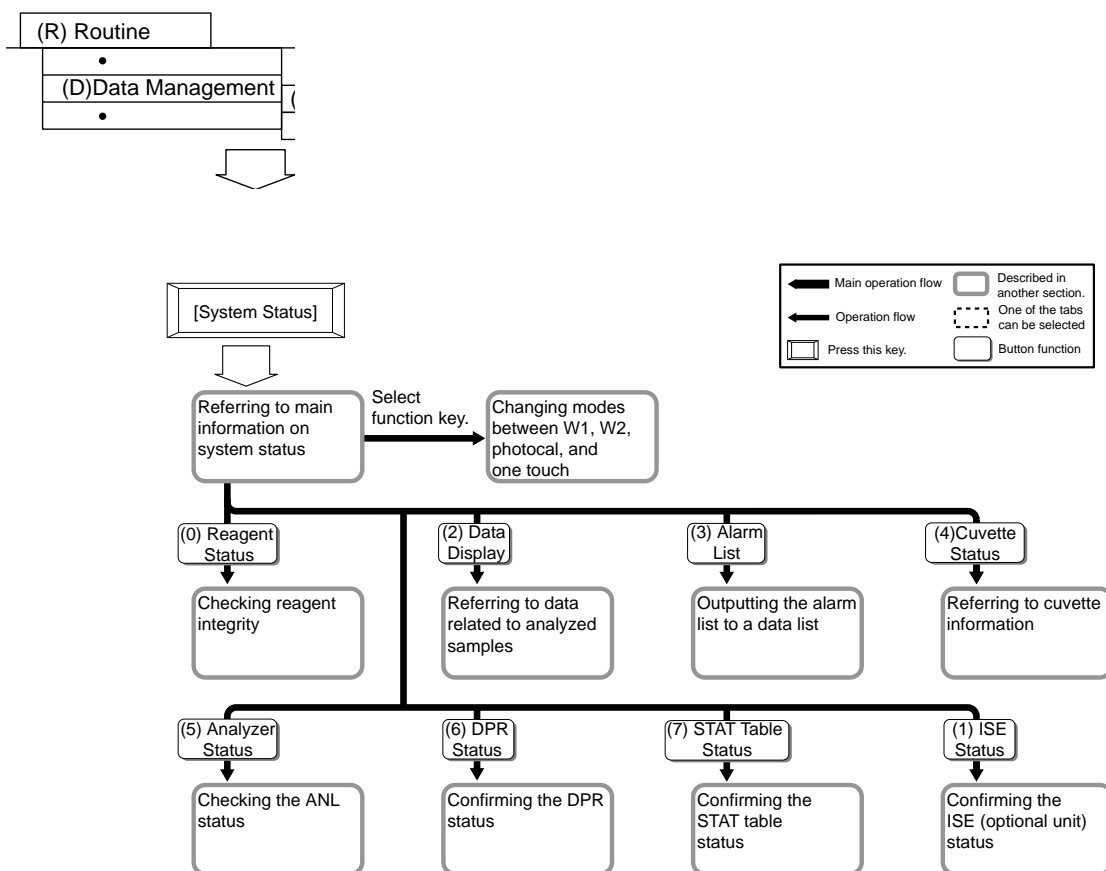
The X axis indicates calibration execution dates and the Y axis indicates slope values.

2. Routine Menu

This section explains [Routine] menu functions.

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2.1 Start Conditions



Description:

This screen displays when the system is started. Use this screen to set the following: index date and time, round number, operator name, and start number. The operator can change start conditions, confirm calibration, confirm QC, calibrator samples, and rack position.

Tips

Analysis cannot begin while the [Start Condition] screen is open. Start conditions cannot be changed in a measure 1 mode; however, they can be changed in Standby.

Use this software screen to:

Start Analysis:

Refer to the Basic Operations Chapter “Starting the AU640” for detailed procedures.

Change start conditions:

A data index can hold up to 8,000 samples. Three rounds of tests can be programmed, with up to 51 tests. The 51 tests include 48 photometric and 3 ISE tests. Sample types include: routine, serum, urine, and other; priority STATs, emergency STATs, and repeats. Ninety indexes or up to 30,000 samples (whichever comes first) can be stored on the hard drive.

1. After pressing “Power On,” the [Start Condition] screen will appear. *To change the data index, select function key F4 (set), then select function key F8 (data index). A new index can be created with the current date and time, or existing indexes can be accessed. Enter the date and time. Click “OK” using your mouse. The [Start Condition] screen can also be selected from [Routine], [Start Condition].*
2. Select function key F2 (exit) twice if no other items need to be changed.

Data index

A data index is a data file used to store analyzer data. Usually, one data file is used per day or per shift. This is a main search key for analyzed data. Enter a year, month, date and time in the format according to the displayed message. You can also use the pull-down menu by the date index field to select from a list of dates and times.

Round No.

A round is a group of user defined tests. Set, for example, chemistry tests to Round 1, and drugs to Round 2. *This allows the operator to be engaged in daily routine work under Round 1, and easily switch to drug analysis, if desired, by simply switching to Round 2. Use the pull-down menu located by the Round Number Field. Three different rounds can be created in [Parameters].*

Operator name

Any operator name can be entered using a maximum of 20 characters.

Serum Start No.

Serum start numbers can be entered for each of the samples classified as Routine, Emergency, and STAT. They can be selected for normal and repeat-run analysis.

Urine Start No.

Urine start numbers can be entered for each of the samples classified as Routine, Emergency, and STAT. They can be selected for normal and repeat-run analysis.

Other Start No.

Start numbers for the “other” sample type can be entered for Routine, Emergency, and STAT. They can be selected for normal and repeat-run analysis.

Calibration

Indicates whether a test was requisitioned for calibrators by stating “selected” or “not selected.”

Remaining samples

Shows how many more samples can be saved (8,000 max.) under the current index date and time.

Set the default start number:

1. Press function key F7 (default start number). *A window for setting a default value is displayed.*
2. If the operator wants to start at a number other than 1 each time a new index is created, enter default values of the routine, emergency, STAT, and repeat samples. Enter these values for serum, urine, and other samples.
3. After the entry is completed, select “OK.” *The current window is closed and the contents are saved.*
4. Press function key F2 (exit) twice to return to the main menu.

View the calibrator rack set-up:

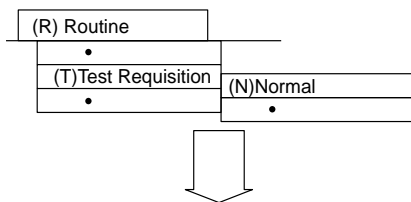
Press function key F5 (Cal). Use this screen to confirm calibration samples that correspond to their set positions on the yellow rack. It is also possible to confirm them as calibration samples with barcode IDs. Calibration samples without barcodes will also be illustrated. Each calibration sample is identified by its "CAL No." In cases where there is a barcode, a list of "CAL #s" "CAL IDs" and "CAL names" will display.

View the QC rack set-up:

Press function key F6 (QC). Use this screen to confirm control sample location for QC with respect to their position on the green rack. It is also possible to confirm barcode IDs of control samples. When green racks are used, a rack diagram appears on screen displaying QC. Each control sample is identified by the "QC No." In samples with a barcode, a list of "QC #s," "QC IDs," and "QC names" are displayed.

2.2 Test Requisition

2.2.1 Normal Analysis



The screenshot shows the 'Normal' test requisition screen. At the top, there is a 'STANDBY' indicator and a toolbar with icons for play, stop, next, previous, and other functions. The date and time are 1997/09/03 10:10. The screen is divided into 'Test Requisition' and 'Demographics' sections. The 'Test Requisition' section includes fields for S.No. (0001), Type (Serum), Remaining Samples (7100), Round No., S.ID. (XXXXXXXXXXXXXXXXXXXX), Profile(2), Sex (Male), Age, and Sample Dilution Rate (1). The 'Demographics' section is currently empty. Below these fields is a grid for test results with columns for ALB, GOT, GPT, G-GTP, and several empty columns. At the bottom, there are buttons for Help, Exit, Print, Start Entry, Change Test, Delete Sample, Online, and S.No. An 'ALARM/CLEAR' indicator is visible in the bottom right corner.

Description:

Routine samples must have a requisition for the tests that will be run on each sample. Requisitions can be performed on the AU640 in this screen, or downloaded from a host computer to the AU640. Requisitions are processed sequentially by sample number or by the sample ID number. There are three methods for performing normal analysis requisitions:

1. Individual sample requisition: Separately entering information for each sample.
2. Batch requisition: Requisitioning multiple samples.
3. Host requisitioning: Samples requisitioned by the host computer.

If normal analysis is being performed using the ISE unit, select the ISE tests (Na, K, Cl). Profiles can be created to requisition a common group of tests at once.

Use this software screen to:

Enter individual requisitions:

Refer to the Basic Operations Chapter for procedures.

Sample ID: The sample ID can be used when the check box is selected in [Parameters], [Format], [Requisition Format]. If barcodes are being used, a barcode is set as a sample ID. To enable the system to use barcode labels, they must be set in [Parameters], [System], [System].

Profile: A profile is a file in which analysis tests are preset according to categories such as electrolytes. Profiles are set-up in [Parameters], [Common Test Parameters], [Profile]. By selecting the profile option, you can requisition tests in a batch rather than individually.

Sex: Sex can be set when it is selected in the [Parameters], [Format], [Requisition Format] screen.

Age and Month: Age and Month can be set when it is selected in the [Parameters], [Format], [Requisition Format] screen.

Test: A maximum of 51 tests (with ISE) can be selected for 1 sample. Use function key F5 (change test) to display another list of test items.

Sample Dilution Rate: Select function key F7 (sample dilution). Enter a sample dilution ratio from 1 to 999.

Requisition by profile:

Refer to the Basic Operations Chapter “How to Requisition by a Profile” for procedures.

Enter group (batch) requisitions:

Refer to the Basic Operations Chapter “Entering Batch Requisitions” for procedures.

Download requisitions from a host computer:

Refer to the Basic Operations Chapter “Downloading Requisitions from a Host Computer” for procedures.

Delete sample requisitions:

To delete a sample requisition:

1. Select [Routine], [Test Requisition], [Normal].
2. Click on function key F6 (delete sample). *A window used to specify the range of sample numbers and sample types displays.*
3. Use your mouse to click the routine, emergency or STAT boxes located below the serum, urine, or other sample type categories.
4. You can delete samples by number or ID. Use your mouse and click in the first column under “Sample No” or “Sample ID.” Enter the beginning sample number or ID to be deleted. Click or tab in the next column and enter the ending sample number to be deleted. *If an asterisk (*) is entered, all sample numbers or IDs will be deleted.*
5. Click on the delete button using your mouse.

6. Select “Yes” at the prompt using your mouse. *The specified range of sample information will be deleted.*
7. Set the sample number to the first sample number deleted. *Use your mouse to click on the arrow buttons by the sample number field or click in the field to type a specific number.*

Display/enter patient demographics:

1. Select [Routine], [Test Requisition], [Normal].
2. Use your mouse to click on the “Demographics” tab located below the menu bar. *The [Demographics] screen will be displayed.*
3. Enter sex, age, demographics, and comment(s).

Tip

To set-up the patient information of other samples, do the following:

- A. Press function key F4 (start entry).
 - B. Press function key F8 (s. no.). *A window appears to select the sample number and sample type.*
 - C. Select “OK” to save changes.
-

4. After the entry is completed, press function key F4 (entry). *The setting contents are saved and the next sample number will be displayed.*

Display the total number of samples requisitioned:

The total number of samples requisitioned per test can be displayed as a list.

1. Select [Routine], [Test Requisition], [Normal].
2. Select the “Test Total” button located on the upper right portion of the screen. *The total number of samples will be displayed in a list.*
3. After viewing, press the “Close” button. *The window will close.*

Print a pending list or work list:

A pending list prints samples not yet run. A worklist prints all tests requisitioned.

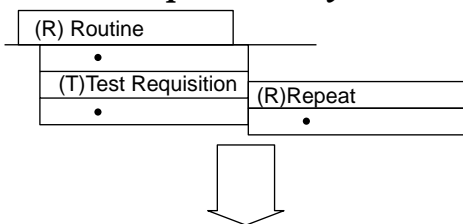
1. Select [Routine], [Test Requisition], [Normal].
2. Press function key F3 (print). *A window is displayed.* Select “pending list” or “work list.”
3. Specify the sample type to be printed.
4. Move the cursor to the “S. No.” column and enter the range of sample numbers. *A range of sample IDs can be entered instead.*

Tips

To modify the pending list number or the work list number, use the pull-down menu located by the field located on the lower left portion of the screen. Select a “List No.” that has been set in the [Parameters] menu, then press the Enter key.

5. Select the “OK” button. *A window to start printing is displayed.*
6. Select “OK” again. *Printing begins.*

2.2.2 Repeat Analysis



Description:

Perform a repeat run based on laboratory protocol for repeat analysis. There are three ways to perform a repeat run:

- Perform the repeat run automatically.
- Perform the repeat run manually using an orange rack.
- Perform the repeat run manually using the STAT table.

Repeat parameters including test specific repeat ranges, sample volume, and abnormal flags can be programmed to automatically place a sample into the repeat data file. If “Auto Repeat” is set in [Parameters], the repeat run will be performed automatically according to the information in the repeat-run data file. If “Standard Repeat” is set in [Parameters], [System], print the contents of the repeat-run data file in a work list. Perform a repeat run manually according to the contents of that file.

Use this software screen to:

Print a repeat run worklist:

Refer to the Basic Operations Chapter, “How to Print a Repeat Run Work List.”

Modify the repeat worklist:

Refer to the Basic Operations Chapter, “How to Modify a Repeat Run Work List.”

Perform an auto-repeat run:

Refer to the Basic Operations Chapter, “How to Perform an Auto-Repeat Run.”

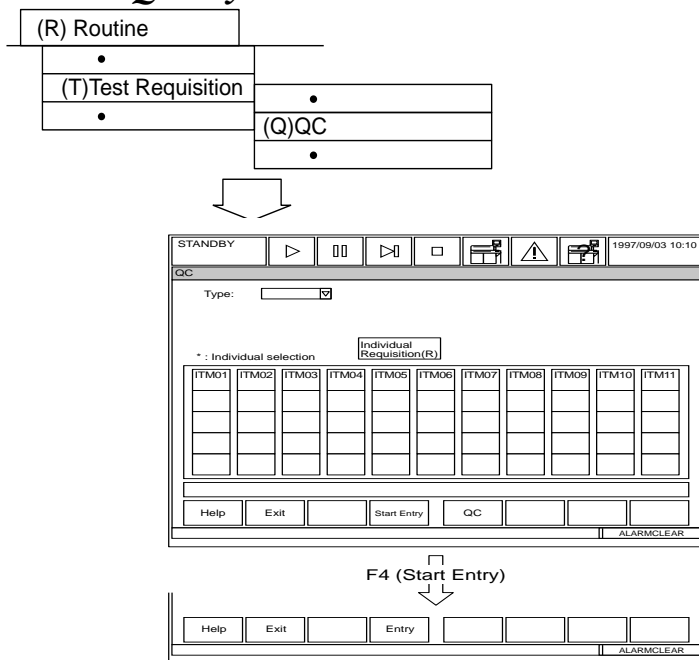
Perform a manual repeat run:

Refer to the Basic Operations Chapter, “How to Print a Manual Repeat Run.”

Report repeat results or original results:

Refer to the Basic Operations Chapter, “Reporting Repeat Results or Original Results.”

2.2.3 Quality Control



Description:

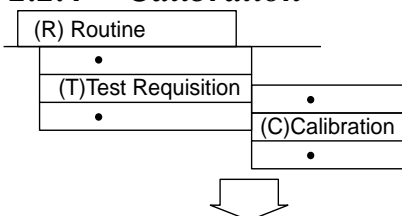
The QC requisition screen is used to select QC tests in green racks or barcoded QC samples only. This does not pertain to QC samples on the STAT table. This screen can be used to delete the QC requisition on the tests described above which do not need QC analysis. The QC screen default setting is to perform all tests.

Use this software screen to:

Requisition QC samples:

For procedures, refer to the Basic Operations Chapter, "Quality Control Analysis."

2.2.4 Calibration



STANDBY 1997/09/03 10:10

Calibration

Type:

Cuvette:

Profile:

Analyzer Requisition(A) Individual Requisition(R)

Calibration Options

Blue RB Only

Green One Point

Yellow All

* : Individual selection

ITM01	ITM02	ITM03	ITM04	ITM05	ITM06	ITM07	ITM08	ITM09	ITM10	ITM11

Help Exit Start Entry Cal.

ALARMCLEAR

F4 (Start Entry)

Help Exit Entry Cal. Change Option Select All Test RB All

ALARMCLEAR

Description:

Use this screen to requisition for reagent blanks and calibrators in racks. Reagent blanks and calibrators must be requisitioned each time the reagent blank and calibrator racks are processed or testing will not be performed. The Start window displays whether the reagent blank and calibrator have tests ordered (selected). Determine what tests need to be calibrated in the [System Status], [Reagent Status] screen.

Note: Calibration expiration is based on the real-time clock. For example, if a test is calibrated at 8:02 a.m. it expires at exactly 8:02 a.m. after counting the number of days.

Use this software screen to:

Requisition for a calibration:

For procedures, refer to "Performing Calibrations and a Reagent Blank" located in the Basic Operations Chapter.

Perform a calibration:

For procedures, refer to "Performing Calibrations and a Reagent Blank" located in the Basic Operations Chapter.

Requisition for a reagent blank:

For procedures, refer to "Performing Calibrations and a Reagent Blank" located in the Basic Operations Chapter.

Perform a reagent blank:

For procedures, refer to "Performing Calibrations and a Reagent Blank" located in the Basic Operations Chapter.

“Profile” button

To specify profiles, select the “Profile” button. The “Select Profile” dialog box is displayed. Select a profile from the profile list, and then select the “OK” button.

A profile is a file in which analysis tests are preset according to the categories such as liver function or electrolyte, etc. Profiles can be set up using the [Profile] sub-menu in the [Parameters] menu.

By specifying a profile, it is possible to register analysis tests, which have been set up in the corresponding profile as a group, into the system, without selecting them one by one.

For one sample multiple profiles can be set up.

Profile - right box

In order to requisition test items with a profile different from the currently displayed one move the cursor into the box located at the right of the “Profile” then enter a profile No. between 0 and 99.

“Analyzer Requisition” button

Select this button to perform automatic requisition of the calibration analysis based on:

1. Test items that have no calibration results for a new bottle or new lot number, if Advanced Calibration is programmed in [Parameters] - [Calibration] - [Calibration Specific].
2. Test items that have expire the calibration stability period.

“Individual Requisition” button

Select this button to perform individual requisition of the calibration analysis for the object test items (i.e. for all reagent bottles with an assigned sequence No.) for which advanced calibration is to be executed. Then, the “Individual Requisition” dialog box is displayed. The dialog box lists the information on each reagent bottle.

However, if the remaining amount of reagent has not been checked before executing the calibration analysis requisition, the “Individual Requisition” button on this screen cannot be selected.

2.2.5 Retrieve Repeat Data

The diagram shows three menu options: (R) Routine, (T) Test Requisition, and (S) Retrieve Repeat Data. Arrows indicate that these options lead to a software screen titled "Retrieve Repeat Data".

The software screen includes a top toolbar with icons for WARM UP, play, pause, stop, and printer, along with a date and time display (1998/08/03 10:10). The main area is titled "Retrieve Repeat Data" and contains a table for entering sample information:

	Sample No.	Sample ID
Serum		
<input type="checkbox"/> Routine	(nnnn - nnnn)	
<input type="checkbox"/> Emergency	(Eenn - Eenn)	
<input type="checkbox"/> STAT	(Pnnn - Pnnn)	
Urine		
<input type="checkbox"/> Routine	(nnnn - nnnn)	
<input type="checkbox"/> Emergency	(UEenn - UEenn)	
<input type="checkbox"/> STAT	(UPnnn - UPnnn)	
Others		
<input type="checkbox"/> Routine	(nnnn - nnnn)	
<input type="checkbox"/> Emergency	(XEenn - XEenn)	
<input type="checkbox"/> STAT	(XPnnn - XPnnn)	

At the bottom of the screen, there are buttons for Help, Exit, Execute Retrieve, and File Initialize, along with an ALARMCLEAR indicator.

Description:

This screen has two main functions:

1. Initialize the repeat data if changing between auto repeat and manual repeat. This initializes the repeat data file only.
2. This screen is also used to retrieve repeat requisitions with flags when using manual repeat methods. Function key F5 (execute retrieve) is used when performing this function.

Use this software screen to:

Initialize a repeat-run data file:

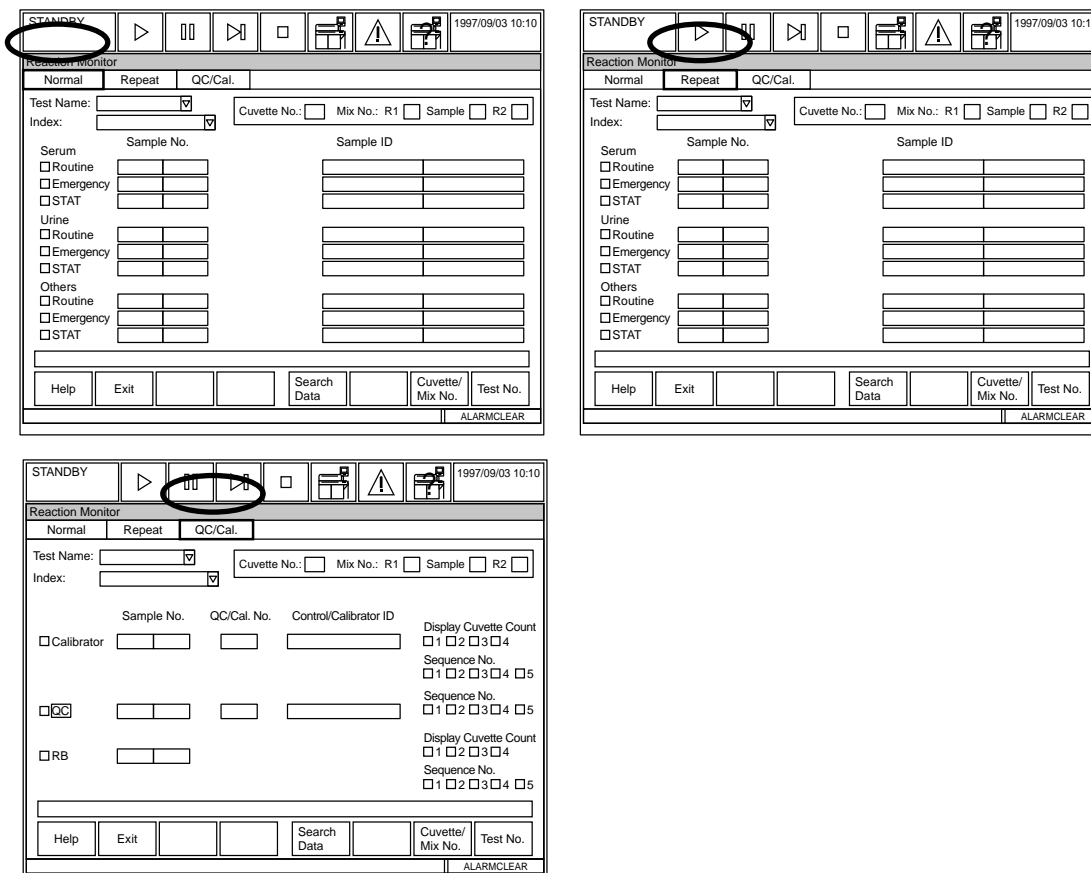
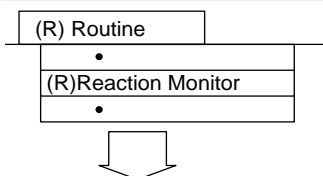
The operator can delete repeat-run samples that have been saved in a repeat-run data file.

1. Select [Routine], [Test Requisition], [Retrieve Repeat Data].
2. Press function key F6 (file initialize). *A window to start initialization is displayed.*
3. Select "OK." *Initialization starts.*

See Also

For procedures, refer to "Performing a Repeat Run" located in the Basic Operations Chapter.

2.3 Reaction Monitor



Description:

This screen displays the absorbance data by photometric point for a completed test. The reaction process can be viewed on either a graph or by data display. The displayed data can also be printed as a data list, or saved to a floppy disk. Data comparisons are useful for verifying or troubleshooting problems. The analyzer stores up to the last 10,000 tests.

Use this software screen to:

Specify search criteria using the Normal or Repeat tab:

Specify data search conditions where the reaction process is to be displayed by the type of: sample, analysis test, cuvette number, or mix bar.

1. Select [Routine], [Reaction Monitor].
2. To view original or repeat results, select the Normal or Repeat tab.
3. At "Test Name," select All or a specific test.
4. At "Index," select the index date and time.

5. An asterisk (*) appears in the search criteria fields. Unless these fields are changed, selecting F5 Search Data searches all data for the selected Test Name and Index.
6. To refine or limit the search, enter values in place of asterisks for the following criteria:
 - At “Cuvette,” enter 1-153 for a specific cuvette.
 - At “Mix No.,” enter mix bar number 1, 2, or 3 for the R1 mix, Sample Mix, and R2 mix to view tests performed with a specific mix bar.
 - Check the sample category (routine, emergency, or stat) for each sample type to view (Serum, Urine, or Others).
 - Enter a specific sample number or range, or a specific sample ID number or range.
7. To begin the search, Select F5 Search Data.

Specify search criteria using the Cal/QC tab:

1. Select [Routine], [Reaction Monitor].
2. To view calibration or QC results, select the Cal/QC tab.
3. At “Test Name,” select All or a specific test.
4. At “Index,” select the index date and time.
5. An asterisk (*) appears in the search criteria fields. Unless these fields are changed, selecting F5 Search Data searches all data for the selected Test Name and Index.
6. To refine or limit the search, enter values in place of asterisks for the following criteria:
 - Check Calibration, QC, and/or RB data.
 - Enter a specific sample number or range.
 - Enter a specific QC number (1-60) or cal number (1-200).
 - Enter the specific control or calibrator ID.
 - Check a specific cuvette count (replicate 1-4).
 - Check a specific sequence number (bottle #1-5)
7. To begin the search, Select F5 Search Data.

Display a reaction process:

Information about the reaction process searched according to the specified condition can be displayed as a graph. Specify the necessary search conditions in the [Reaction Monitor] screen, press function key F5 (search data). *A graph of the specified reaction process will be displayed after a message indicating that the search in progress is displayed. The lines of the primary wavelength, secondary wavelength, and net reaction data can be identified by color. If there is no corresponding data, a message will be displayed.*

Display a calibration of another test

Use the pull-down menu or click on the arrow buttons on screen using your mouse.

Display an updated calibration

Set display conditions:

By setting the conditions to display the Y-axis of a graph, it is possible to modify the display size of a reaction process curve on the graph.

1. In the [Reaction Curve] screen, press function key F7 (change axis). *A window to set-up the display conditions is displayed.*
2. Set the display scale to either “Manual” or “Auto.” If “Manual” is selected, set the lower and upper limit values. *A specific part of the graph will be magnified and displayed.* If “Auto” is selected, the largest possible graph will be displayed within an area in which all data can be contained.

Print the reaction process data list:

1. In the [Reaction Curve] screen, press function key F3 (print). *A window to specify the print mode is displayed.*
2. To print only the graphically displayed data into a data list, select “Display Data” and “OK.” To print all the data searched in a data list, select “All data” and “OK.” *Printing begins.*

Save the reaction monitor data:

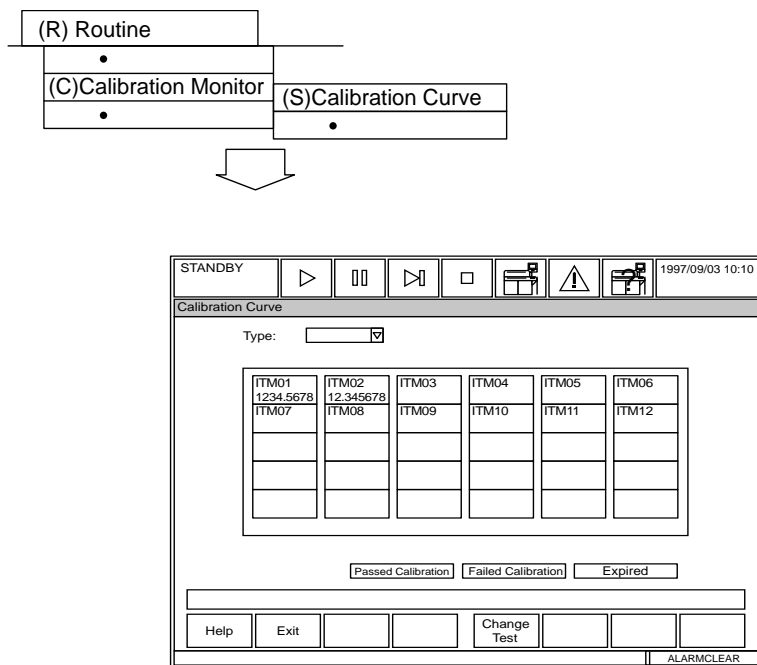
1. Initialize the floppy disk as a parameter disk.
 - Select [Maintenance], [Data Operation], [FD Data Management], FD Initialize Tab, “Initialize Parameter FD”, F5 Start Initialize.
2. Select [Routine], [Reaction Monitor].
 - Select sample search criteria. Select data to save from the Normal, Repeat, or Cal/QC Tabs. Select all tests or a specific test, index, sample type, and sample range.
 - Select F5 Search Data
 - Select F4 File. Select “Display Data” or “All Data”, then the OK button. A pop-up appears with “Printing”. This puts the data in the correct format to save to the floppy disk.
3. Select [Maintenance], [Maker Maintenance], [File Management].
 - Select “Monitor Reaction”.
 - Select “Save files to FD”.
 - Select F5 Execute. “Insert FD. Start?” Select the Yes button. “Operating Wait for awhile” appears while the data is saved to the floppy disk.

Note

Data from the floppy disk can then be imported into MicroSoft Excel and emailed to Beckman Coulter Technical Services for evaluation.

2.4 Calibration Monitor

2.4.1 Calibration Curve



Description:

Use this screen to confirm if a calibration has passed (black) or failed (yellow), or the calibration data has expired (orange). It is also possible to automatically recalculate the concentration from an absorbance based on the formula of calibration. This screen can also be used to print calibration data and to add comments.

Use this software screen to:

Recalculate, print and add comments:

1. Select the test for which calibration data is to be viewed and perform the following:
 - F5 (Recal) Recalculate the calibration factor.
 - F3 (Print) Print a list of calibration information.
 - F4 (Comment) Add a comment to the list print.

Display a calibration curve:

To display the date, time, and a graph of the calibration for each analysis test, select a test.

To display other information, click on a chemistry and the following operations can be performed:

Display a calibration of another test

Use the pull-down menu or click on the arrow buttons on screen using your mouse.

Display an updated calibration

The "Measured Date" field lists dates and times. Use the pull-down menu to make your selection.

Select another test for viewing:

While in the [Calibration Curve] screen, click on a chemistry. It is also possible to display a calibration for an analysis test other than that currently displayed, if another test number is specified.

1. Press function key F8 (test number). *A window appears.*
2. Enter a test number, then press the Enter key. *The test name and the latest calibration of the specified analysis test will be displayed.*

Perform another calculation:

If an update of calibration failed, it is possible to automatically recalculate the factor from an absorbance based on the calculation formula of calibration. When this recalculation is performed, the calibration will be properly updated.

1. In the [Calibration Curve] screen, click on a chemistry, select function key F2 (recal.). *A screen to execute the recalculation will appear.*
2. Move the cursor to a point where the update of calibration failed, then update the OD value and concentration value. *This recalculation can be performed using past analysis data. To display the previous or present data, use the pull-down menu located by the "Index Date" field. Modify the OD value and concentration value after referring to the display.*
3. Select the re-cal button. *A window to execute recalculation is displayed.*
4. Select "YES" and press the Enter key. *Recalculation starts. After recalculation is complete, a window to save the result displays.*
5. Select "OK." *The result of recalculation is saved and the calibration is updated. If you select "Cancel" here, the recalculation will not be saved.*

Enter a comment to an analysis test:

A comment can be attached to the calibration information of each analysis test.

1. On the [Calibration Curve] screen, press function key F4 (comment). *A comment window is displayed.*

2. Enter a comment using a maximum of 100 characters. To choose from a list of comments, select the "comment" button, click on your selection with the mouse and choose "OK."
3. Select "OK" again. *The comment is saved. If "Cancel" is selected, the comment is not entered and the window closes.*

Display a factor:

The operator can display a coefficient (factor) of the calibration calculation formula which corresponds to a slope of a calibration. Press function key F6 (factor). A list of factors will be displayed in the window.

Print calibration data:

1. Press function key F3 (print). *A window to specify the print mode is displayed.*
2. Select from the following choices by using your mouse.

Without factor:	All calibration data except the factors will be printed.
All data:	All calibration data will be printed.
Recent data:	The latest calibration data will be printed.
Trace data:	The trace data of calibration will be printed.
Current test:	Calibration data of only the currently displayed analysis tests will be printed.
All tests:	All the calibration data of all analysis tests will be printed

3. Select "OK." *Printing begins.*

"Calibration Curve" (Display curve) screen

With respect to each of the analysis tests, it is possible to refer to the date and time of generation and a graph of the calibration.

When an analysis test is selected in the "Calibration Curve" (Select) screen and the Enter key is pressed, a calibration of the selected analysis test will be displayed.

The screenshot shows the 'Calibration Curve' screen. At the top, there is a 'STANDBY' indicator and a date/time display '1997/09/03 10:10'. Below this is a control bar with icons for play, stop, and other functions. The main area is titled 'Calibration Curve' and contains a form with the following fields:

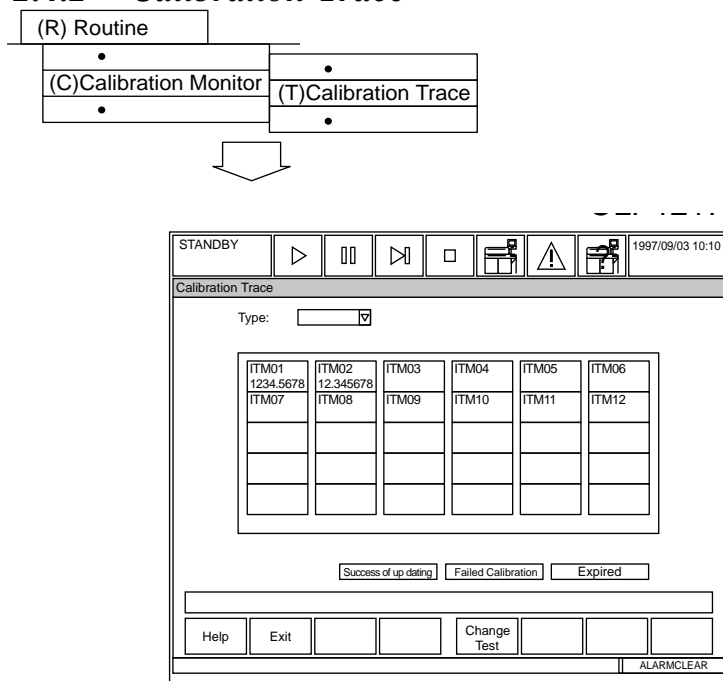
- Test Name: [dropdown]
- Type: [dropdown]
- Measured Date: [dropdown]

Below these are four rows of data entry fields:

Cal. No.	OD	CONC	Lot No.
1	[input]	[input]	R1: [input]
2	[input]	[input]	R2: [input]
3	[input]	[input]	Bottle No. [input]
4	[input]	[input]	R1: [input]
	[input]	[input]	R2: [input]
	[input]	[input]	R1 Pos.: [input]
	[input]	[input]	R2 Pos.: [input]

Below the data entry fields are 'Cal. type:' and 'Meas. Type:' dropdowns, a 'Formula:' text field, and 'Cal. Stability:' and 'Seq. No.' input fields. To the right of these fields is a graph area with a grid. The y-axis is labeled 'OD' and the x-axis is labeled 'CONC'. The graph area contains a grid of 10 columns and 10 rows, with some cells containing 'n' characters. At the bottom of the graph area is the label 'CONC'. At the bottom of the screen, there is a row of buttons: 'Help', 'Exit', 'Print', 'Comment', 'Re-Cal.', 'Factor', 'Change Axis', and 'Test No.'. Below the buttons is an 'ALARMCLEAR' indicator.

2.4.2 Calibration Trace



Description:

Use this screen to display the factors generated by the previous calibrations. Selecting a test displays the last 30 calibrations on a single graph. To check if tests have passed, failed, or expired, use the Calibration Curve screen.

See Also

For procedures, refer to "Performing Calibrations" located in the Basic Operations Chapter.

For procedures, refer to "How to reprint reagent blank, calibrator, QC and patient data" located in the Basic Operations Chapter.

Use this software screen to:

Display calibration results:

Calibration results can be displayed for each analysis test. Select a test and press the Enter key. Results of the selected analysis test will display in a graph of the last 30 acceptable calibrations.

1. Select [Routine], [Calibration Monitor], [Calibration Trace].
2. Select a chemistry using your mouse. *A graph appears and the following operation is permitted:*

Displaying a calibration of another analysis test

Click on the arrow buttons on screen using your mouse.

Displaying an updated calibration

In the "Measured Date" field, use the pull-down menu to select a date.

Modify display conditions:

To modify the display size of a graph, change the X and Y axis.

1. In the [Calibration Trace] screen, press function key F7 (change axis). A window appears to set the display conditions.
2. Set the display condition to either "Manual" or "Auto." If "Manual" is selected, set the lower and upper limit values for the Y-axis and the X-axis. A specific part of the graph will be magnified and displayed. If "Auto" is selected, the largest possible graph will be displayed within an area where all data can be contained.

Display comments:

Entered comments can be reviewed as necessary. Press function key F5 (ref. comment). Comments will be displayed in the window. To exit select "Close."

"Calibration Trace" (Display curve) screen

Records of calibration analysis results can be graphically displayed for each analysis test.

If an analysis test is selected in the "Calibration Trace" (Select) screen and the Enter key is pressed, records of the selected analysis test will be displayed in a graph.

Case of a biochemical test

STANDBY [Navigation icons] 1997/09/03 10:10

Calibration Trace

Test Name: [] Type: []

Measured Date: []

Cal. No. OD CONC

1	[]	[]	[]
2	[]	[]	[]
3	[]	[]	[]
4	[]	[]	[]

Cal. type: [] Meas. Type: []

Formula: []

Legend: P1: [] P2: [] P3: [] P4: [] P5: [] P6: [] P7: []

Bottom buttons: Help, Exit, Ref. History, RB/Cal. Rgt Inf, Ref. Comment, Factor, Change Axis, Test No., ALARMCLEAR

Case of an ISE (optional unit) test

STANDBY [Navigation icons] 1997/09/03 10:10

Calibration Trace

Test Name: [] Type: []

Measured Date: []

Offset: []

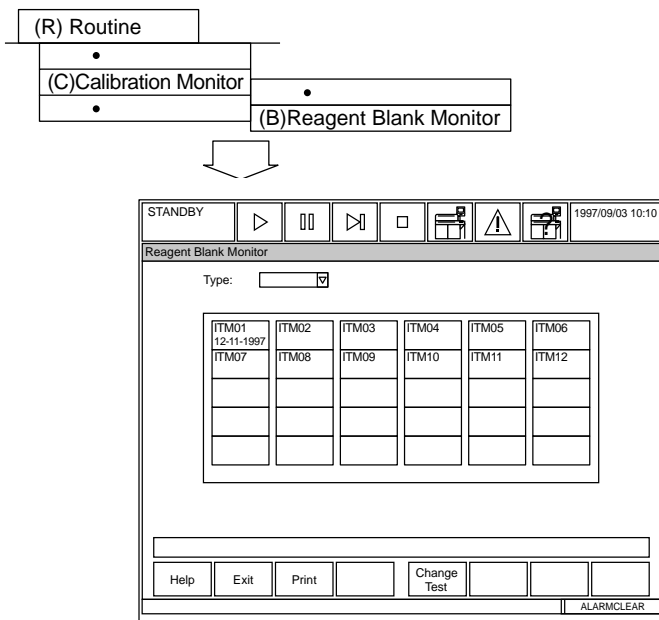
Meas. Type: []

Formula: []

Legend: P1: [] P2: [] P3: [] P4: [] P5: [] P6: [] P7: []

Bottom buttons: Help, Exit, Ref. Comment, Factor, Change Axis, Test No., ALARMCLEAR

2.4.3 Reagent Blank Monitor



Description:

Use this screen to review the current and past reagent blanks during reagent troubleshooting. These records can be reviewed either on a graph or from the data. Also, the data can be printed in a list. ISE tests and LIH tests cannot be monitored here.

Use this software screen to:

Display reagent blank data:

For each analysis test it is possible to refer to the reagent blank data for every absorbance read point (0 to 27). If R1 is less than 150, read point 11 to 27 will display. Select an analysis test. The following operations are permitted:

Display reagent blank data for a different test

Use the pull-down menu located by the test name field.

Display reagent blank data for a different date

Use the pull-down menu located by the "RB Measured Date" field.

Display a history of reagent blank data:

Press function key F6 (history) to graphically display the last 30 reagent blanks.

Print reagent blank data:

1. From the [Reagent Blank Monitor]. Select a test. When the new screen appears, press function key F3 (print). *A window to specify the printing mode is displayed.*
2. Select from the following print options:
 - Display Test: Prints only the data of currently displayed tests.
 - All Tests: Prints the data of all tests.
 - Data only: Prints data only. Comments won't be printed.
 - Data + Com.: Prints the data and comment at the same time
3. Select "OK." *Printing begins.*

Print reagent blank data:

1. From the [Reagent Blank Monitor]. Select a test. When the new screen appears, press function key F3 (print). A window to specify the printing mode is displayed.
2. Select from the following print options:

Display Test:	Prints only the data of currently displayed tests.
All Tests:	Prints the data of all tests.
Data only:	Prints data only. Comments won't be printed.
Data + Com.:	Prints the data and comment at the same time

3. Select "OK." Printing begins.

"Reagent Blank Monitor" (Display data) screen

For each analysis test it is possible to refer to the reagent blank data for every photometry read point (0 to 27).

Select an analysis test in the "Reagent Blank Monitor" (Select) screen to display the reagent blank data related to the selected analysis test.

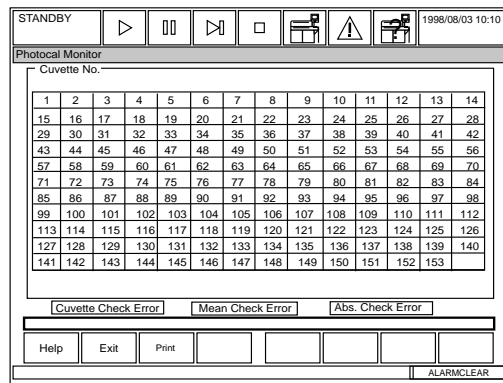
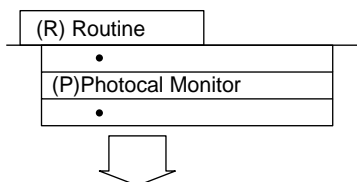
"Reagent Blank Monitor" (History) screen

Reagent blank analysis records can be displayed as a graph.

In the "Reagent Blank Monitor" (Display data) screen, press the F6 (History) key.

The record will be displayed as a graph.

2.5 Photocal Monitor



Description:

After a photocal measurement, always confirm the measured results. Use this screen to display cuvette status:

- White = Cuvettes passed the photocal
- Green = Failed the cuvette check
- Red = Failed the mean check
- Blue = Failed the base check (absolute check)

Use this software screen to:

Verify cuvette status:

Verify the status of all cuvettes from this screen. A list of cuvette numbers appear. The cuvettes are color-coded to indicate photocal status as shown above. *Any cuvette that failed the mean check or cuvette check will need to be corrected. For procedures, refer to "Perform a Photocal" located in the Maintenance Chapter.*

Display the latest photocal data in numeric values:

Using your mouse, select a cuvette number. *The latest photocal data is displayed.*

Display photocal history in a graph or data format:

1. Select [Routine], [Photocal Monitor].
2. Select a cuvette number.
3. Select function key F5 (history graph) to display data in a graph or F6 (history data) to display data in a list.

Print photocal measurement results:

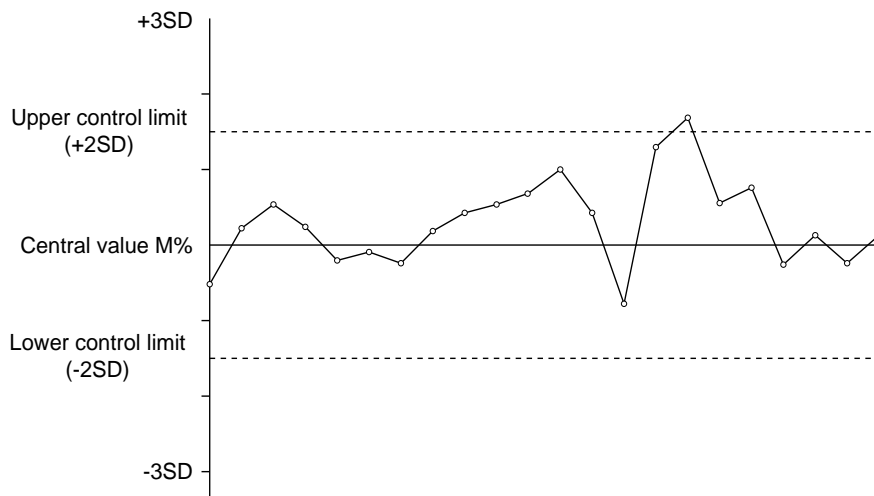
1. Press function key F3 (print). *A window to specify the printing mode is displayed.*
2. To print currently displayed data, select "Display Cuvette." To print all cuvette data, select "All cuvettes" and select "OK." *Printing begins.*

2.6 QC Monitor

After quality control analysis, check results. Two methods are provided to confirm results: one is by observing the daily variation and the other is by observing the day-to-day variation.

About Quality Control:

With the [Daily Control] screen and [Day To Day Control] screen each control chart can be generated. The maximum width of a chart will be a mean ± 3 SD. Two dotted lines are also drawn as the control limits (usually ± 2 SD).



If some data is outside the control limits, or if the data traces a slope or changes suddenly even though the data falls within the control limits, it is necessary to consider the causes and take the appropriate action. Possible causes are: deterioration of reagents, stained cuvettes, incorrect parameter settings, and deterioration of a control serum.

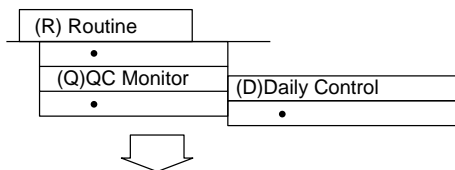
Tips

The mean value, upper control limit, and lower control limit of a chart should be set in the [Parameters,] [QC Control] screen.

See Also

For information about [QC Control], see [Quality Control] located in the parameters section of this chapter, or refer to the QC section of the Specifications Chapter.

2.6.1 Daily Control



Description:

Use this screen to observe quality control data on a specified analysis date. Also, QC daily statistics and graphs can be viewed, comments can be added, and a list of QC data can be printed. To compare the average of quality control data, go to the day to day control screen.

Use this software screen to:

Check the daily variation chart:

For procedures, refer to "Checking Quality Control" located in the Basic Operations Chapter.

Display a specific control sample:

1. Select [Routine], [QC Monitor], [Daily Control].
2. Select a sample type using the pull-down menu located by the "Type" field.
3. Select function key F8 (control no.), enter a control number of the control sample to view. Select "OK."
4. Select a test, then press function key F6 (daily data). *A daily variation chart related to the specified control sample will be displayed.*
5. To display the sample number, measuring type, control ID, result, flag, and lot number, press function key F7 (daily data). Select "Close" to exit the window.
6. Press function key F2 (exit) twice.

Add comments for the displayed daily variation data:

A comment can be added to each control sample.

1. Press function key F4 (comment). *A window to register a comment is displayed.*
2. Enter a comment. A maximum of 50 characters can be entered. To choose from a list of comments, select the comment button and highlight a comment with your mouse.
3. Select "OK." *The entered comment will be saved. If "Cancel" is selected, the comment will not be saved and the window will be closed.*

Set the display size:

To modify the display size of a graph, change the X axis.

1. Select [Routine], [QC Monitor], [Daily Control].
2. Select the tests displayed on screen using your mouse.
3. Press function key F6 (daily data).
4. Press function key F8 (change axis). *A window to set the display condition appears.*
5. Set the display to either manual or auto. *If "Manual" is selected, also specify a start data number and the number of data samples. The specified portion of the graph will be enlarged. When "Auto" is selected, the graph will display at the largest size at which all the data can be properly represented.*

Note

The X and Y axis indicate the following: X axis indicates the sample number. The Y axis (left side) indicates +3SD, +2SD, +1SD, Mean, -1SD, -2SD, -3SD. The Y axis (right side) indicates each value of the Y axis (left side)

Display previous results on each control sample:

1. Select [Routine], [QC Monitor], [Daily Control].
2. Select the "QC Monitor" tab.
3. Select the tests displayed on screen using your mouse.

QC Monitor Column displays:	
* Black	within ±1SD
1 Yellow, reverse video	Outside ±1SD and within ±2SD
2 Red, reverse video	Outside ±2SD and within ±3SD
3 Red, reverse video	Outside ±3SD
E Red, normal video	Error, no data value

4. Press function key F6 (daily data). The chart will display.
5. Press function key F2 (exit) twice.

Print the daily variation data:

1. Select [Routine], [QC Monitor], [Daily Control].
2. Select the tests displayed on screen using your mouse.
3. Press function key F6 (daily data).
4. Press function key F3 (print). *A window to specify the printing mode is displayed.*

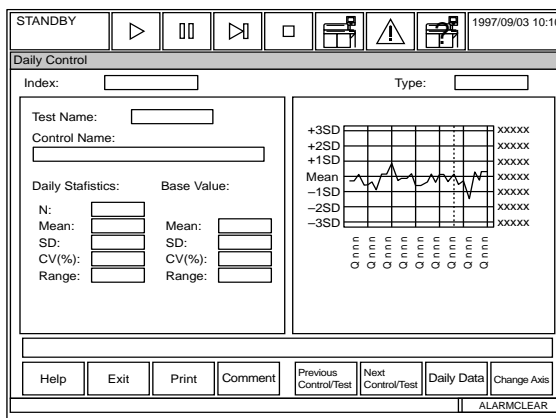
Select one of the following printing modes	
Statistic:	Prints only the statistical values.
Statistic + Data:	Prints the statistical values and numerical data.
Graph:	Prints only a graph. Comments will not be displayed.
Graph + Comment:	Prints a graph and comment.
All Data + Comment:	Prints the numerical data and comment

5. Select "OK." Printing Begins
6. Press function key F2 (exit) twice.

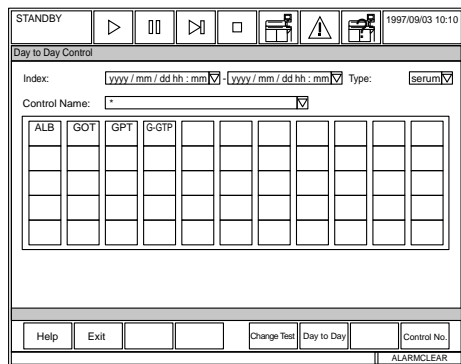
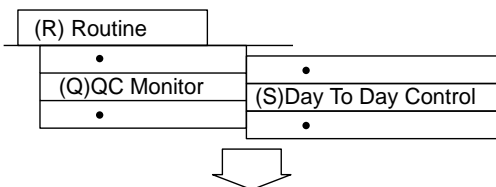
"Daily Control" (Display chart) screen

Press the F6 (Daily Data) key.

A daily variation chart related to the specified control sample will be displayed.



2.6.2 Day-to-Day Control



Description:

Use this screen to compare the average of quality control data and graphs by index. A maximum of 300 QC indexes can be displayed and saved. Day to day data and graphs can be printed, and comments added. To observe quality control data on the same analysis date, go to the daily control screen.

Use this software screen to:

Display and print day to day QC charts:

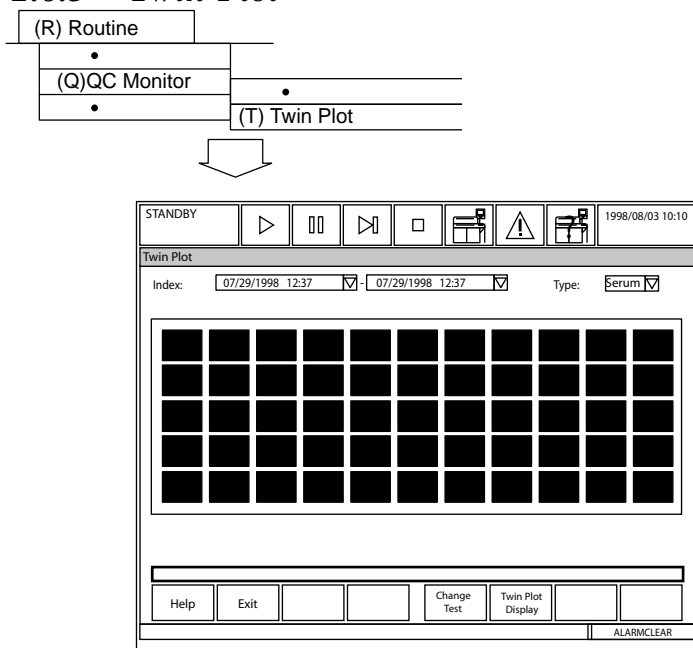
1. Select [Routine], [QC Monitor], [Day to Day Control].
2. Set the index using the pull-down menu next to the "index" field.
3. Highlight the tests to be displayed or printed.
4. Select function key F6 (day to day) to view the graphs and statistics of the indexes selected. Each index will be an average QC value.
5. To print, select function key F3 (print). Highlight the printing option you want to perform: day to day, daily data, graph, graph plus comment, or all data plus comment.
6. Select "OK" to start printing.
7. Select function key F2 (exit) twice.

Display daily statistical data:

1. Select [Routine], [QC Monitor], [Day to Day Control].

2. Set the index using the pull-down menu next to the "index" field.
3. Highlight the tests to be displayed or printed.
4. Select function key F6 (day to day) to view the graphs and statistics of the indexes selected. Each index will be an average QC value.
5. Press function key F7 (daily data) to refer to statistical values, such as the number of samples, mean, and standard deviation of the daily data. Items for which daily statistical values are displayed include the sample number and analysis result.

2.6.3 Twin Plot



Description:

The Twin Plot Chart displays QC points using their standard deviation from the mean as the axis units. A display of two controls on one graph, using a separate axis for each, is generated.

The chart displays a pair of multi-rule QC samples. The values for the first control are listed on the X-axis and the values for the second control are listed on the Y-axis. The coordinates are determined by the standard deviation from the mean of each control. The number of points are divided into equal groups of three. The first group is plotted using a plus (+), the second group a square, and the last group an X. The box in the center indicates the 2SD range. All points should fall within the box. The Mean and SD for each control is displayed.

Use this software screen to:

Display a Twin Plot Chart:

1. From the main menu select [Routine], [QC Monitor], [Twin Plot].
2. Use the pull down menu by the "Sample Type" field to select the sample type.
3. Select the control sample data using your mouse. *Each time the spacebar is pressed the item toggles between selected and deselected.*

Tip

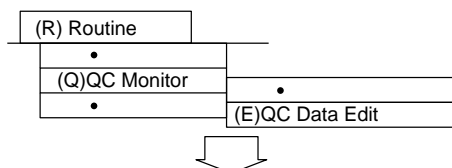
To modify the index date and time, use the pull-down menu located by the index field. Select a different index date and time with your mouse.

4. Select function key F6 (twin plot display). *The chart displays.*
5. Select function key F2 (exit) twice.

Display the number of samples, mean, and the standard deviation for QC:

1. From the main menu select [Routine], [QC Monitor], [Twin Plot].
2. Use the pull down menu by the sample type field to select the sample type.
3. Select the control sample data using your mouse. *Each time the spacebar is pressed the item toggles between selected and deselected.*
4. Select function key F6 (Twin Plot Display).
5. Select function key F7 (Daily Data). *Statistics for the control number selected will display.*

2.6.4 Data Edit (QC Monitor)



Description:

Edit QC data (change data or a flag). Any QC data that is edited has an “e” flag attached. Delete QC data points so they are not used in the calculation of QC statistics and do not display on the QC graphs. Display deleted QC data with a “d” flag.

Caution

The QC data edit screen permits the operator to modify the analysis results obtained. In order to reduce the possibility of an incorrect diagnosis because of modified quality control data, this editing operation should be performed under the supervision of a doctor or by qualified laboratory personnel.

Tip

When editing the QC data is complete, the day-to-day data are automatically calculated and stored in the QC day-to-day cumulative value data file.

Use this software screen to:

Search for data to be edited:

1. From the main menu select [Routine], [QC Monitor], [QC Data Edit].
2. To search for data by sample number, enter a QC sample number at the "sample number" field. To search for data by test, press function key F8 (test no.), then enter the test number in the "test number" field and select "OK." At the Index pull-down, set the index date and time
3. To begin the search, press function key F5 (data display).

Edit the data and/or error flags:

1. Select [Routine], [QC Monitor], [Data Edit].
2. At "Index" select the index to edit.
3. At "Test Name," select All tests or a specific test to edit.
4. Select F5 Data Display.
5. Move the cursor to the test to edit.
6. Select F5 Edit Result.
7. At "Result," enter a new QC test result.
8. Check "Flag," then edit or add a new flag.
9. Select the Close button.

Edit an index Common comment:

Index Common comments are attached to all QC tests in an index.

1. Select [Routine], [QC Monitor], [QC Edit], F5 Data Display, F6 Index Comment.
2. Enter a comment of 50 characters or less. Or, select the Comment button to enter a Master Comment programmed in [Parameters], [Comment Masters]. Select the OK button.
3. Print comments using F3 Print.

Edit a Test Specific Comment:

Test Specific comments are attached to the specific QC test selected.

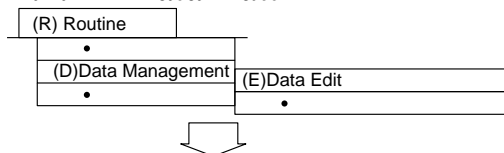
1. Select [Routine], [QC Monitor], [QC Edit], F5 Data Display, F7 Test Comment.
2. Enter a comment of 50 characters or less. Or, Select the Comment button to enter a Master Comment programmed in [Parameters], [Comment Masters]. Select the OK button.
3. Print comments using F3 Print.

Delete QC Data:

1. Select [Routine], [QC Monitor], [Data Edit].
2. At "Index" select the index to delete QC.
3. At "Test Name" select All or a specific test to delete.
4. Enter the QC sample number, or "*" to delete from the entire QC range displayed.
5. Select F5 Data Display.
6. To delete selected QC tests:
 - Move the cursor to the test to delete.
 - Select F5 Edit Result.
 - Enter a check by "Flag."
 - Enter a "d" flag to delete QC. Select the Close button.
7. To delete all QC tests of the displayed QC sample:
 - Select F8 Delete.
 - "Delete All Tests. OK?" select the OK button. The "d" flag appears by all tests, indicating the tests will be deleted.

2.7 Data Management

2.7.1 Data Edit



STANDBY	▶	⏏	▶	□	🖨	⚠	🖨	1997/09/03 10:10
Data Edit								
Index:	1989/07/07 12:30							▼
Test Name:								▼
	Sample No.		Sample ID					
Serum								
<input type="checkbox"/> Routine		(nnnn - nnnn)						
<input type="checkbox"/> Emergency		(Ennn - Ennn)						
<input type="checkbox"/> STAT		(Pnnn - Pnnn)						
Urine								
<input type="checkbox"/> Routine		(nnnn - nnnn)						
<input type="checkbox"/> Emergency		(UEnnn - UEnnn)						
<input type="checkbox"/> STAT		(UPnnn - UPnnn)						
Others								
<input type="checkbox"/> Routine		(nnnn - nnnn)						
<input type="checkbox"/> Emergency		(XEnnn - XEnnn)						
<input type="checkbox"/> STAT		(XPnnn - XPnnn)						
Help Exit Data Display Search Add Test No.								
ALARMCLEAR								

Description:

Use this screen to edit results. Result data can be displayed in two ways: by individual sample and by individual test. Edited data will have an "e" flag attached. Sample IDs and flags can be edited.

Caution

Editing analysis results permits the operator to modify analysis results. In order to avoid an incorrect diagnosis because of modified patient data, this editing operation should be performed under the supervision of a doctor or qualified laboratory personnel.

Use this software screen to:

Edit Results:

For procedures, refer to "Editing Results" in the Basic Operations Chapter.

Edit flags:

Flags on the sample results can be modified.

1. From the main menu select [Routine], [Data Management], [Data Edit].
2. Select a sample type and sample number or ID.
3. Select function key F5 (data display).
4. Press function key F5 (edit result). *A window appears.*
5. Use your mouse to click on the "Flag" field. Now enter a flag.
6. After the entry is completed, select "Close." *The settings will be saved.*
7. Select function key F2 (exit) twice.

Add a search key:

In addition to a sample type and analysis test, patient information, such as sex, and age can be specified as a search key for data search.

1. From the main menu select [Routine], [Data Management], [Data Edit].
2. Press function key F6 (search add). *The "Adding a search key" screen is displayed.*
3. Set "Sex," "Age (Low and high limit)," and 6 types of demographics.
4. After the entry is completed, select "YES." *The settings will be saved as search keys.*

Edit a sample in realtime mode:

For procedures, refer to "Editing Results" in the Basic Operations Chapter.

Edit a sample ID in batch or no host mode:

For procedures, refer to "Editing Results" in the Basic Operations Chapter.

Precaution:

If your analyzer is being operated in Sequential (non-barcoded) Mode and data editing is conducted during the analyzer's MEASURE modes (analyzer modes other than STOP, PAUSE, STANDBY or WARM UP) a database conflict may occur. If a database conflict occurs, it will result in a sample concordance error regarding the identification of a specific sample and the test results associated with the sample.

If you operate, or begin to operate, your analyzer in **Sequential Mode**, you must cease all Data Edit activities until **AFTER** the analyzer has shifted to the STOP, PAUSE, STANDBY, or WARM UP mode. **Do NOT edit** any data during analyzer **MEASURE modes** (MEASURE 1, MEASURE 2, MEASURE3 OR MEASURE END) as indicated on the analyzer screen mode display area.

2.7.2 Data Correction

The diagram shows a navigation menu with three items: (R) Routine, (D) Data Management, and (C) Data Correction. An arrow points from (D) Data Management to the Data Correction software interface.

The Data Correction software interface includes a toolbar with icons for STANDBY, play, pause, stop, and other functions. The main window displays the following fields and controls:

- Index: 1989/07/07 12:30
- Test Name: [Dropdown]
- Sample No. and Sample ID columns with checkboxes for Routine, Emergency, and STAT for Serum, Urine, and Others.
- Buttons: Help, Exit, Correct Data, Recal Data, Search Add, Test No.
- Status bar: ALARMCLEAR

Description:

Use this screen to recalculate and correct data:

Recalculate Data: If a calibration fails, use this screen to recalculate analysis results. Should a calibration analysis fail, it is still possible to obtain the valid calibration factor by performing another calibration and recalculating a factor based on a new cal. OD. The acceptable factor is then used to recalculate analysis results. The calibration process must be set to OD in [Parameters], [Calibration], [Calibration Specific].

Correct Data: After analysis is complete, use this screen to perform a batch correction of data by entry of a multiplication or addition/subtraction factor.

Caution

The data correction screen allows the operator to modify the analysis results. In order to avoid an incorrect diagnosis because of modified patient data, this editing operation should be performed under the supervision of a doctor or by qualified laboratory personnel.

Use this software screen to:

Correct results:

For procedures, refer to "Correcting Results" in the Basic Operations Chapter.

Recalculate data:

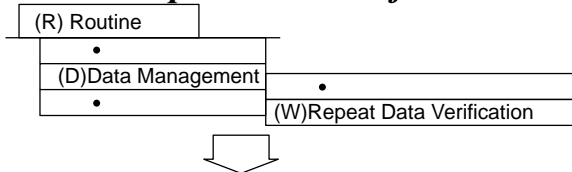
Concentration values for sample data can be recalculated based on the acceptable cal. OD values. *Do this only if cal. process is set to OD in the [Cal. Specific] screen.* As a result, the existing analysis data will be overwritten by the data after recalculation. Also, analysis tests subject to recalculation can't be printed for a report. Data can be sent on-line. A "c" flag is attached.

1. From the [Data Correction] screen, select from serum, urine, other; and routine, emergency, and STAT.
2. Press function key F6 (recal. data). *A window to execute recalculation is displayed.*
3. Select "OK." *Data recalculation starts.*

Tip

Data saved as an OD value can be modified by recalculating. Data saved as a concentration value cannot be modified.

2.7.3 Repeat Data Verification



WARM UP [Play] [Pause] [Stop] [Printer] [Warning] [Printer] 1998/08/03 10:10

Repeat Data Verification

Data Index: 1. 07/01/1998 11:59 [v]
Test Name: [All] [v]

Serum	Repeat Sample No.	
<input type="checkbox"/> Routine	[] []	(nnnn - nnnn)
<input type="checkbox"/> Emergency	[] []	(Ennn - Ennn)
<input type="checkbox"/> STAT	[] []	(Pnnn - Pnnn)

Urine

<input type="checkbox"/> Routine	[] []	(nnnn - nnnn)
<input type="checkbox"/> Emergency	[] []	(UEenn - UEenn)
<input type="checkbox"/> STAT	[] []	(UPnnn - UPnnn)

Others

<input type="checkbox"/> Routine	[] []	(nnnn - nnnn)
<input type="checkbox"/> Emergency	[] []	(XEnnn - XEnnn)
<input type="checkbox"/> STAT	[] []	(XPnnn - XPnnn)

Report Data List No.: (None) [v]

[Help] [Exit] [Print] [Rewrite] [Test No.]

ALARMCLEAR

Note

Entry of a sample ID range is not permitted. Specify a sample number range of repeat-run samples.

Description:

This screen is used to specify the repeat run data that will be written over original sample data. After data is rewritten, repeat data results will display with an “S” flag.

Use this software screen to:

Overwrite original data with repeat data:

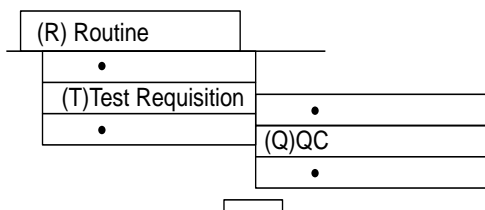
For procedures, refer to "Reporting Repeat Results or Original Results" located in the Basic Operations Chapter.

Print the repeat run data list:

1. In the [Repeat Data Verification] screen, press function key F3 (print). *A window to start printing is displayed.*
2. Select “OK.” *Printing begins.*

2.8 Data Report

2.8.1 Report



The screenshot shows the 'Report' software interface. At the top, there is a 'STANDBY' indicator and a date/time stamp '1997/09/03 10:10'. Below this is a 'Report' title bar. The main area contains a form with the following sections:

- Index:** A dropdown menu showing '1989/07/07 12:30'.
- Sample No. / Sample ID:** Two columns of input fields.
- Serum:** Three rows of checkboxes for 'Routine', 'Emergency', and 'STAT', each followed by a sample number field and a format code (e.g., '(nnnn - nnnn)').
- Urine:** Three rows of checkboxes for 'Routine', 'Emergency', and 'STAT', each followed by a sample number field and a format code (e.g., '(nnnn - nnnn)').
- Others:** Three rows of checkboxes for 'Routine', 'Emergency', and 'STAT', each followed by a sample number field and a format code (e.g., '(nnnn - nnnn)').
- Report No.:** A dropdown menu.

At the bottom, there are buttons for 'Help', 'Exit', 'Print', 'Search Add', and 'List Pending'. An 'ALARMCLEAR' button is located at the bottom right.

Description:

Use this screen to batch print data in a report format.

Use this software screen to:

Print Batch Reports:

Note: Reports must first be formatted in the [Report Format] screen. Refer to the "Report Format" section in this chapter for details.

1. Set up print options in the [Parameters], [Format], [Printer] screen: select "Batch Report." From the "Realtime Print" field, use the pull-down menu to select "Data Log List."
2. Press function key F2 (exit) twice.
3. Select [Routine], [Data Report], [Report] after analysis is complete for the reports to be printed. Use the pull-down menu to set the index.
4. Select the sample type and sample no. to print.

5. To add a report operator name, or restrict the printing by a certain sex and/or age, press function key F5 (search add). From the "Sex" field use the pull-down menu to select male or female. From the "Age" field enter the age range in years and months. From the "Report Operator" field, enter the name of the person who is printing the reports. To use this option, the coordinates for "Report Operator" must be set in [Parameters], [Format], [Report Format], under the "Common" tab. Verify the "Output Test" field is set to "All." Use the spacebar to change from "Test No Output."
6. Select function key F3 (print). *Start Printing? OK.*
7. Optional: Select function key F6 (list pending) to print a list of samples that have not had a report printed.

Set additional print conditions:

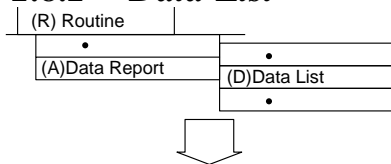
In addition to a sample type and a sample number, patient information such as sex and age can also be specified as a print condition.

1. Press function key F5 (search add). *The [Search Add] screen is displayed.*
2. Set the print conditions:

Sex:	Male, Female, None
Range of age:	0 to 150
Month:	0 to 11
Report operator:	Maximum 20 characters
Print Specs (Output Test):	All tests, Only tests not printed
Patient Info:	Maximum 20 characters. A maximum of 6 kinds of patient information can be set.

3. After the setting is completed, select "YES" at the prompt titled "Are the above criteria sufficient?"

2.8.2 Data List



WARM UP									1998/08/03 10:10
Data List									
Patient QC/Cal.									
Index: 1. 07/29/1998 12:30									
Serum		Sample No.			Sample ID				
<input type="checkbox"/> Routine				(nnnn - nnnn)					
<input type="checkbox"/> Emergency				(Eenn - Eenn)					
<input type="checkbox"/> STAT				(Pnnn - Pnnn)					
Urine									
<input type="checkbox"/> Routine				(nnnn - nnnn)					
<input type="checkbox"/> Emergency				(UEenn - UEenn)					
<input type="checkbox"/> STAT				(UPnnn - UPnnn)					
Others									
<input type="checkbox"/> Routine				(nnnn - nnnn)					
<input type="checkbox"/> Emergency				(XEenn - XEenn)					
<input type="checkbox"/> STAT				(XPnnn - XPnnn)					
Data List No.: 1.									
Help	Exit	Print		Search Add					ALARMCLEAR

Description:

Use this screen to reprint reagent blank, calibrator, QC, routine, emergency, and STAT data.

Use this software screen to:

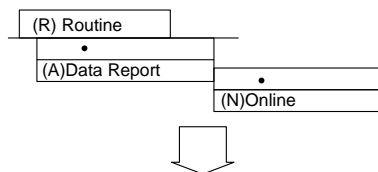
Reprint Reagent Blank, Calibrator, QC and Patient Data:

Refer to "How to reprint reagent blank, calibrator, QC and patient data" located in the Basic Operations Chapter

Tip

If new tests are added, they must be added to the format or the test won't print. Follow the procedure called "How to format a list" in the section called "List Format" located in this chapter.

2.8.3 On-line



WARM UP		▶		⏸		▶		□		🔧		⚠		🔧		1998/08/03 10:10	
Online																	
Normal Run Repeat Run QC/Cal.																	
Index 1. 08/01/1998 12:37 ▼																	
Serum		Sample No.				Sample ID											
<input type="checkbox"/> Routine		[][]		(nnnn - nnnn)		[][]		[][]									
<input type="checkbox"/> Emergency		[][]		(Eenn - Eenn)		[][]		[][]									
<input type="checkbox"/> STAT		[][]		(Pnnn - Pnnn)		[][]		[][]									
Urine																	
<input type="checkbox"/> Routine		[][]		(nnnn - nnnn)		[][]		[][]									
<input type="checkbox"/> Emergency		[][]		(UEenn - UEenn)		[][]		[][]									
<input type="checkbox"/> STAT		[][]		(UPnnn - UPnnn)		[][]		[][]									
Others																	
<input type="checkbox"/> Routine		[][]		(nnnn - nnnn)		[][]		[][]									
<input type="checkbox"/> Emergency		[][]		(XEenn - XEenn)		[][]		[][]									
<input type="checkbox"/> STAT		[][]		(XPnnn - XPnnn)		[][]		[][]									
Help		Exit		[][]		[][]		Data Transfer		Search Add		List Pending					
ALARMCLEAR																	

Note

Searching is only possible by sample number key and sample ID key.

Description:

Use this screen to send data to a host computer. To batch transfer data in this screen, the [Parameters], [Online] screen must be set to batch.

Use this software screen to:

Send data to a host computer:

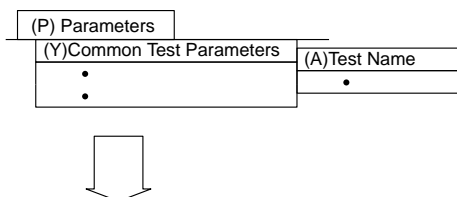
1. From the online screen, select the sample type of data to be transferred to the host. Set the sample no. range to be transferred, or enter * for all sample numbers. Use the tabs in the upper left corner of the screen to select "Repeat Run," and "QC/Cal."
 2. Select function key F5 (data transfer) and select "OK" at the prompt.
- The following steps are optional:
3. To change the index, use the pull-down menu located by the index field.
 4. Select function key F7 (list pending) to display a list of samples that have not been transferred to the host.
 5. Select function key F6 (search add.) to restrict the data transferred to a specific sex or age.

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3.1 Common Test Parameters

3.1.1 Test Name



Test Name	Long Name	Reagent ID	Calculated Tests	Multi-Reagent Switch
1. ?Alb	2. ALP	3. ALT	4. Army	5. AST
6. CO2	7. Tbili	8. Tbilb	9. Dbili	10. Dbilb
11. Cal	12. Chol	13. HDL-C	14. CK	15. CK-MB
16. Creat	17. GGT	18. Gluc	19. Phos	20. Iron
21. LDH	22. LIP	23. Mag	24. Tpro	25. Trig
26. UIBC	27. BUN	28. Uric	29. S-CAL	30. S-CRE
31. S-GLU	32. S-BUN	33. MPRO	34. Amyl	35. B2M
36. AAT	37. HAPT	38. PALB	39. MALB	40. CRP
41. RF	42. ASO	43. TRF	44. TIBC	45.
46.	47.	48.	49.	50.
51.	52.	53.	54.	55.
56.	57.	58.	59.	60.
61.	62.	63.	64.	65.
66.	67.	68.	69.	70.
71.	72.	73.	74.	75.
76.	77.	78.	79.	80.
81.	82.	83.	84.	85.
86.	87.	88.	89.	90.
91.	92.	93. Wat1	94. Wat2	95. Wat3
96. LIH	97. Na	98. K	99. C1	

LIH Reagent Test Name: 86.LIH

Help Exit Print Set ALARMCLEAR

Description:

Use this screen to define test names (regular allows five characters, long allows 20 characters) and reagent barcode numbers. Calculated tests can be named and set as a calculated test.

Use this software screen to:

Program a new test:

For procedures, refer to "Programming a New Test" located in the Basic Operations Chapter.

Note

Do not change the test name without noting the time and date the change occurred. If the test name is changed it will affect all test results retrospectively with that test number. Consequently, any previously reported results (with the old name) will be assigned the new test name. Use extreme caution when making any changes to the test name and all recorded changes.

Program a calculated test:

For procedures, refer to [Parameters], [Inter-related Tests], [Calculated Tests] located in this chapter.

Enter test names:

For procedures, refer to "Programming a New Test" located in the Basic Operations Chapter.

Assign a test name to a test number. Test numbers 96 through 99 cannot be modified.

Enter long test names:

For each individual analysis test, a long test name can be added in addition to the abbreviated test name.

1. In the [Test Name] screen, select the "Long Name" tab. *The [Long Name] screen is displayed.*
2. Press function key F4 (set).
3. Use your mouse to select a test number.
4. Press function key F5 (edit).
5. Enter a test name (20 characters max.). The arrow keys can be used to select test names sequentially for editing.
6. Repeat steps 3 through 5 for each test name you want to change, then select "Close."
7. After the entry is complete, press function key F2 (exit) twice. *The user-defined test name(s) are saved.*

Select a reagent ID:

Manufacturer codes and test codes used for each analysis test can be set as reagent IDs.

1. In the [Test Name] screen, select the "Reagent ID" tab. *The [Reagent ID] screen is displayed.*
2. Press function key F4 (set).
3. Use your mouse to select a test.
4. Press function key F5 (edit).
5. Enter a "Test code" and select "Close." (The reagent ID can be found in the package insert. It is also the first 3 numbers of the barcode located on the reagent bottle.)
6. Repeat steps 3 through 5 for each analysis test to be set or use the arrow keys to sequentially page through tests for editing.
7. After the entry is complete, press function key F2 (exit) twice. *The reagent IDs are saved.*

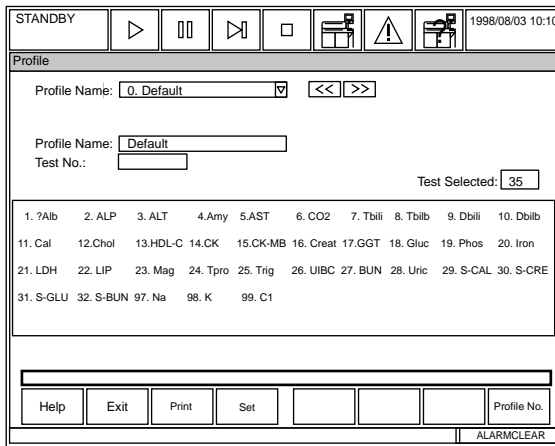
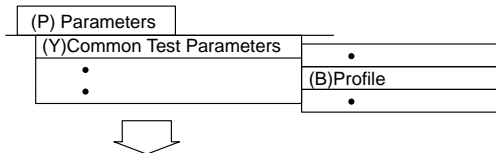
Print settings:

1. In the [Test Name] screen press function key F3 (print). *A window to start printing is displayed.*
2. Select "OK." *Printing begins.*

Select a multi-reagent item:

The multi-reagent tab is used to select reagents that will automatically calibrate new R1 & R2 simultaneously. If this screen is not used, new R1 will be calibrated with old R2, or old R1 will be calibrated with new R2 (depending on which bottle is empty first). For more information, refer to "Programming a New Test" located in the Basic Operations Chapter.

3.1.2 Profile



Description:

Use this screen to set up test panels. Individual tests are assigned for each profile. Profile number 0 is defined as the default profile. The default profile is automatically used in 3 situations: 1. Barcode read error in barcode analysis. 2. No requisition for a sample in the sequential analysis mode. 3. Online errors.

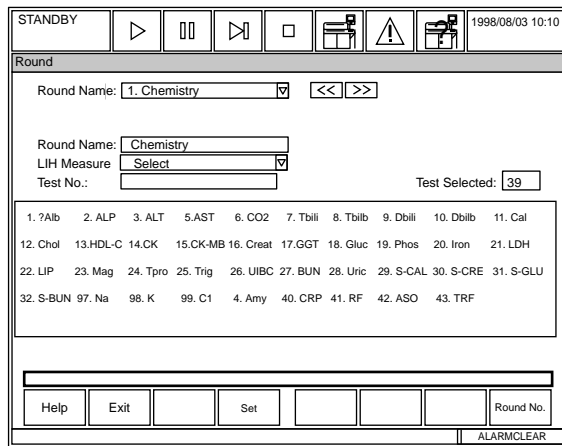
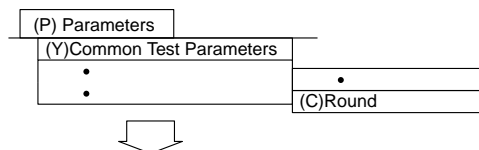
Note: If no tests are selected for profile number 0, nothing will be run on the sample and nothing will printout.

Use this software screen to:

Create a profile:

For procedures, refer to "Creating a New Profile" located in the Basic Operations Chapter.

3.1.3 Round



Description:

Use this screen to select tests for a maximum of three rounds. (Rounds are a set of similar analysis tests grouped together so that specific tests can be accessed quickly.) A maximum of 51 tests (including the ISE) can be set in a round.

Note: The order the tests are placed in the Round is the order the tests print on the data log printout.

Use this software screen to:

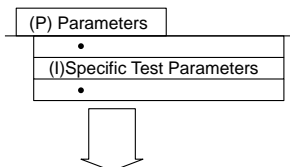
Add a new test(s) to the round:

For procedures, refer to "Programming a New Test" located in the Basic Operations Chapter.

Tip

The "LIH Measure" field can be set to "all" or "select" using the pull-down menu. This feature applies when using an existing on-board reagent for LIH screening. When set to "all," LIH analysis will be performed on all samples. When set to "select," LIH will only be performed on those samples with a requisition for the LIH linked reagent.

3.2 Specific Test Parameters



Description:

Use this screen to enter specific parameters for each of the individual tests. Enter specific parameters based on the reagent manufacturer's methodology sheet. Beckman Coulter methodology sheets are located in the User's Guide Vol II.

Use this software screen to:

View and/or Program specific test parameters:

1. Select [Parameters], [Specific Test Parameters].
2. Select a test for viewing by using the pull-down menu or ►◀ buttons by the "Test Name" field.
3. Select one of the following tabs: General, LIH, ISE, or Range.

Select the General Tab

Select function F4 Set to program parameters for the selected test.

Enter specific test parameters:

Operation:	Select "Yes" to perform the test for each sample type, or "No" not to.
Sample Vol.:	Sample Type Serum or Other 2.0 to 50 uL (in 0.5 uL increments) Urine 1.0 to 50 uL (in 0.5 uL increments)
Sample Dilution:	All sample types: Enter 0 or 10 uL. Note: If a sample dilution volume of 10 uL is entered, the maximum sample volume is 25 uL
Reagent 1 Volume and Dilution:	R1 Volume: Enter 25 to 300 uL (in 1.0 uL increments). Dilution: Enter 0 or 10 to 250 uL.
Reagent 2 Volume and Dilution	R2 Volume: Enter 0 (no R2 reagent) or 25 to 300 uL (in 1.0 uL increments) Dilution: Enter 0 or 10 to 250 uL..

Wavelength Pri:	340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, 800. Each assay must have a primary wavelength.
Wavelength Sec:	(None), 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, 800. The OD of the secondary wavelength will be subtracted from the OD of the primary wavelength whenever a secondary wavelength is present.
Method:	Select END, RATE, FIXED, END1, RATE1 or FIXED 1.
Reaction Slope:	Select + (increasing absorbance) or - (decreasing absorbance).
Measuring Point 1	Enter the primary read points, P0 to P27.
Measuring Point 2	Enter the secondary read points, P0 to P10.
Linearity (primary reaction):	A variance check for reactions with methods defined as Rate or Rate 1. The “*” flag is generated when the check is exceeded.
NO-LAG-TIME:	Used to determine the reaction rate for methods defined as Rate or Rate 1. No: The option is not used. Yes: The option is used
Reagent OD limit: Lower, first read point::	To enter “No setting,” enter a space.
Pre-Dilution Rate	Enter 0 (no dilution) or 5 to 100 uL. This setting allows the analyzer to pre-dilute the sample by making a “dilution cuvette”. Sample is aspirated from the dilution cuvette and dispensed into the testing cuvette. The reagent blank, calibration and QC samples are also pre-diluted for any tests programmed to pre-dilute. The result printed is correct for the programmed dilution.

Pre-dilution Rates: If the “Pre-dilution Rate” is set in the “Specific Test Parameters” screen, sample pre-dilution is performed according to the dilution rate (5 to 100). For reference see the dilution rate and sample volume required for dilution in the examples below:

SAMPLE PRE-DILUTION RATE	SAMPLE VOLUME (µL)	SAMPLE DILUTION (WATER, µL)	TOTAL
5	48	192	240
10	24	216	240
50	5	245	250
100	3	297	300

The reagent probe dispenses liquid into a “dilution” cuvette. Then the sample probe dispenses sample into the dilution cuvette to make the set pre-dilution. The sample probe then aspirates from the dilution cuvette into the test cuvette. Reagent blank, calibrators, and QC samples are also pre-diluted for tests programmed to pre-dilute.

Min. OD	An absorbance check for methods defined as Fixed, Fixed 1, Rate, or Rate 1. The B flag is generated for reactions less than the minimum OD.
Max OD	An absorbance check for methods defined as Fixed, Fixed 1, Rate, or Rate 1. The D flag is generated for reactions greater than the maximum OD.
Reagent OD limit:	Enter the acceptable ranges (L and H) for the Reagent Blank. The following Flags are generated when the ranges are exceeded: First L: u The reagent absorbance is below the programmed range at the first read point. Last L: U The reagent absorbance is below the programmed range at the last read point. First H: y The reagent absorbance is above the programmed range at the first read point. Last H: Y The reagent absorbance is above the programmed range at the last read point.
Dynamic Range	Enter the linear range for the test. The flags are generated: F: results are greater than the high end of the dynamic range. G: results are less than the low end of the dynamic.

Correlation Factor	The analyzer software is designed to perform the dynamic range check before the correlation factors are applied to the data. Therefore, consider adjustment of the dynamic range settings in accordance with the correlation factors. <ul style="list-style-type: none"> • $y = Ax + B$ • "A": Multiplication factor that defaults to 1.0 • "B": Addition/subtraction factor that defaults to 0.0 • Adjusts data realtime when factors are programmed.
ON BOARD STABILITY PERIOD (reagent stability period):	Enter 1 to 999 for the number of days a reagent is stable once it is placed on the analyzer. Press the spacebar, then enter, if no setting is desired. The "a" flag is generated when the onboard stability period is exceeded.

Select the LIH Tab

Set an LIH test:

There are two methods of LIH determination:

- **Beckman Coulter LIH Reagent** - OSR62166 (Barcoded with preset parameters, see Methodology sheet)
- **Saline**

The following is a procedure to program parameters using saline as the LIH reagent.

The following screen provides an example ONLY. Please contact Beckman Coulter Technical Services for additional information.

Precautions:

All LIH testing must be programmed to the dedicated LIH reagent (saline) in position number 96 in [Parameters], [Common Test Parameters], [Test Name], "LIH Reagent Test Name".

Use of an R1 chemistry reagent for LIH testing may cause a program error resulting in one chemistry assay being conducted using the parameters of a different chemistry assay, potentially generating erroneous sample results.

1. Verify that **Use Test Name** displays 96. LIH

Sample: Volume	Enter 2.0 to 50 μ L.
Sample dilution	Enter 0
Reagents: R1 Volume	Enter 25 to 300 μ L
Reagents: R1 Dilution	Enter 0 (no dilution) or 10 to 250 μ L.

Onboard Stability Period	Enter 1 to 999 for the number of days a reagent is stable once it is placed on the analyzer. Press the spacebar, then enter, if no setting is desired. The "a" flag is generated when the onboard stability period is exceeded.
Level: Lipemia, Icterus, Hemolysis	Define OD limits for each LIH flag level: +, ++, +++, +++, +++++. The OD limit for each subsequent level should be higher than the previous OD limit. The range available is 0.0000 to 2.0000. The LIH flag is the upper OD limit or maximum value that applies to that flag level. The flag is applied to samples with reactions ODs greater than the OD limit specified for the next lower level, but less than or equal to the OD limit specified for the printed flag for lipemia, icterus, or hemolysis. The LIH level applies to the reaction OD values after factor adjustment. <i>For example, a sample with a lipemia reaction OD of 0.0450 would be flagged LIP++, an icterus reaction OD of 0.0100 would be flagged ICT N and a hemolysis reaction OD of 0.0500 would be flagged HEM N based on the programmed values in the example screen.</i>

See Also

For more information on LIH, refer to the "Calculations" section located in the Specifications Chapter.

Select the ISE Tab

Set an ISE test:

1. Select the sample type (Serum or Urine).
2. At Operation, select Yes (to perform the test) or No (not to perform the test) for each sample type.

Note

Do not change any other information in this tab.

STANDBY [Play] [Pause] [Next] [Stop] [Printer] [Warning] [Printer] 1997/09/03 10:10

Specific Test Parameters

General LIH ISE Range

Test Name: [Dropdown] [Left Arrow] [Right Arrow] Type: [Serum] Operation: [YES]

Sample: [25.0] uL MID CONC: [145.0] mmol/L
Sample Dilution: [10] uL STD CONC: L [130.0] mmol/L
H [160.0] mmol/L

Dynamic range: L [-9999.999]
H [9999.999]

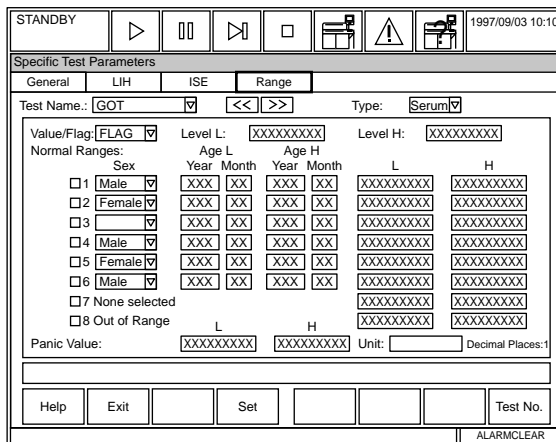
Correlation Factor: A [1.000000]
B [96.000000]

[Help] [Exit] [Set] [] [] [] [] [] []

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Select the Range Tab

Set a standard value range:



Verify the Test Name and the sample Type.

Value/Flag	Select Value to enter age and gender specific ranges to generate H or L flags for any data outside the programmed ranges. Select Flag to generate a P (positive) or N (negative) flags for DAU tests.
Sex	Select a box (1-6) to enter gender specific normal reference ranges
Age L (Year Month)	Enter the youngest age (year and month) to generate an L flag.
Age H (Year Month)	Enter the oldest age (year and month) to generate an H flag.
L	Enter the lowest reference range based upon the gender and age entered.
H	Enter the highest reference range based upon the gender and age entered.
None Selected	Enter a generic reference range (if boxes 1-6 are not defined) to generate an H or L flag.
Out of Range	A generic range used if boxes 1-6 are programmed and the patient demographic information does not match any of the gender and age specific ranges.
Panic Value	A critical range. Any sample exceeding this range generates an audible alarm and a "p" flag.
Unit	The unit of measurement for a test.
Decimal Places	Enter 0 for results to print without a decimal point. Enter 1 to 4 to set the appropriate decimal place for the results.

When all parameters are entered, press function key F2 (exit). *Parameters are set.* Press function key F2 (Exit) again to return to the main menu.

3.3 Inter-Related Tests

3.3.1 Calculated Tests

(P) Parameters	
•	
(H) Inter Related Tests	(A) Calculated Tests
•	•

STANDBY 1998/11/03 10:10

Calculated Tests

Calculated Test Name: 1. TIBC << >> Type: Serum

Test Name A: 20. Iron
B: 26. UIBC
C: (None)
D: (None)
E: (None)

Constant a:
b:
c:
d:

Formula: A + B

Help Exit Print Set ALARMCLEAR

Description:

Use this screen to name tests and set up the equations for calculated tests.

Use this software screen to:

Set inter-test calculation parameters:

1. Select [Parameters], [Inter-Related Tests], [Calculated Tests]. *The saved inter-test calculation parameters are displayed.*
2. Enter a calculated test name. *Use the pull-down menu located by the "Test Name" field. The << >> buttons can also be used to select a test name.*
3. Select a sample type. *Use the pull-down menu located by the "Type" field.*
4. Press function key F4 (set).
5. Set a test name, constant, and formula.

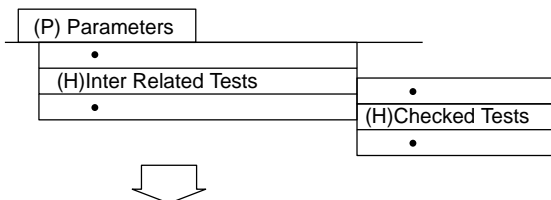
Test Name: Set analysis tests subject to calculation. Five analysis tests, from "A" to "E," can be assigned as calculated tests. Use the pull-down menu by each field. Test numbers without a test name cannot be entered.

Constant: Set the coefficients of a desired calculation formula for inter-test calculation. Four kinds of coefficients, from "a" to "d," can be set using a numerical value within the range of 9999999 to -9999999. Patient information (between 1 and 6), set in [Routine], [Normal], which has a numerical attribute can be set as a coefficient. To do this, use the "@n" (n = 1 to 6) format. In the "Coefficient" column, "Patient information" (i.e. Age 1, Weight 2, ...) will be displayed. To leave blank, enter a space.

Calculation formula: Use the entered calculated test numbers, "A" to "E" and coefficients "a" to "d," to define a calculation formula. The following symbols and alphanumeric characters can be used: +, -, *, /, (,), A, B, C, D, and E, and a, b, c, and d. A "/" denotes division and an "*" denotes multiplication. For example, specify a formula to obtain the A/G ratio from ALB and TP. Assign ALB and TP to calculated tests A and B respectively, and specify the $A / (B - A)$ formula. A calculation formula can use a maximum of 5 tests.

6. After the settings are complete, press function key F2 (exit). *Parameters are saved.*

3.3.2 Checked Tests



The screenshot shows the 'Checked Tests' software interface. At the top, there is a 'STANDBY' indicator and a date/time display '1998/08/03 10:10'. Below this is a toolbar with icons for play, pause, stop, and other functions. The main area is titled 'Checked Tests' and contains the following fields and controls:

- 'Inter-Test Check Name: 1' with a pull-down menu and '<<' '>>' buttons.
- 'Type: Serum' with a pull-down menu.
- 'Check Name:' with a text input field.
- 'Test Name' with dropdown menus for A, B, C, D, and E, all currently set to '(None)'. To the right is a 'Check Range' section with 'L' and 'H' labels and input fields for '0' and '0', and 'Decimal Places: 0'.
- 'Constant' with dropdown menus for a, b, c, and d.
- 'Formula:' with a text input field.

At the bottom, there are buttons for 'Help', 'Exit', 'Print', 'Set', and 'Inter-Test Check No'. An 'ALARMCLEAR' indicator is visible in the bottom right corner.

Description:

If a calculation formula and its associated coefficients are set in advance across multiple analysis items, it is possible to check whether the results fall within a predetermined range. It is also possible to append an error flag to analysis result data if it is outside the predetermined range.

Use this software screen to:

Set inter-test check parameters:

Set the check name and check range for each inter-test check.

1. Select [Parameters], [Inter-Related Tests], [Checked Tests].
2. Enter an "Inter-Test Check Name." Use the pull-down menu located by the "Inter-Test Check Name" field. The << >> buttons can also be used to select a test name.
3. Select a sample type. Use the pull-down menu located by the "Type" field.
4. Press function key F4 (set). Set the following: Check name, Test name, Constant, Formula, and Check range.

Check name: A maximum of 8 characters can be entered. In addition, using a format of "*nnn" permits the nnn'th comment to be set in the Comment Master File as a check name. To set "No designation," enter a space.

See Also

For information about the Comment Master File, refer to "Comment Master" located in the parameters section of this chapter.

Test Name: Set analysis tests subject to calculation. *Five kinds of analysis tests, from "A" to "E," can be assigned as the checked analysis tests. Use the pull-down menu to select a test or select (none). Test numbers of analysis tests that do not have a test name cannot be entered.*

Constant: Specify the coefficients of a calculation formula for inter-test calculation. *Four kinds of coefficients, from "a" to "d," can be set using a numerical value within the range between -9999999 and 9999999. Patient information (between 1 and 6), that has been set in the [Normal] submenu of the [Routine] menu, which has a numerical attribute can be set as a coefficient. To do this, use the "@n" (n = 1 to 6) format. In the "Coefficient" column "Patient Information" (i.e. Age 1, Weight 2, ..) will be displayed. To set "No designation," enter a space.*

Formula: Use the entered calculated tests numbers, "A" to "E" and coefficients "a" to "d," to define a calculation formula. *The following symbols and alphanumeric characters can be used: +, -, *, /, (,), A, B, C, D, and E, and a, b, c, and d. A "/" denotes division and an "*" denotes multiplication. For example, specify a formula such as (GOT / AST) / (GPT / ALT) using GOT / AST and GPT / ALT.*

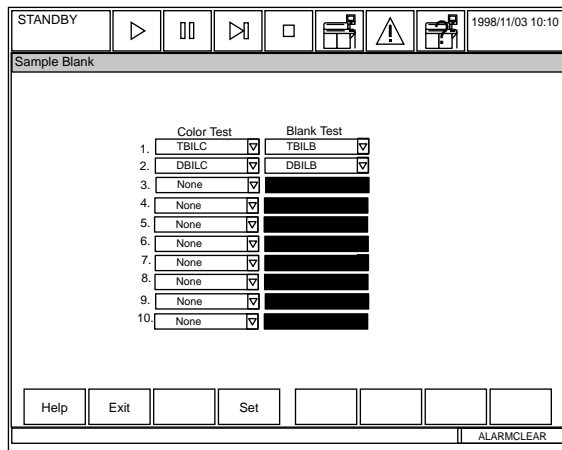
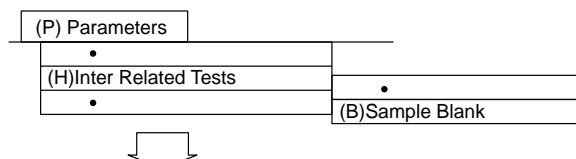
Check range: Set an upper limit and a lower limit of the normal value range of the inter-test check. *Specify a numerical value within the range between -9999999 and 9999999.*

5. After the setting is complete, press function key F2 (exit). *Parameters will be saved.*

Specify another inter-test check:

In the [Calculated Tests] screen, select function key F8 (Inter-test Check Number). *A window appears. Enter an inter-test check number between 1 and 10, then select "OK." To change the sample type, use the pull-down menu next to the "Type" field.*

3.3.3 Sample Blank



Description:

Use this screen to set 10 sample blank correction factors. To run a sample blank, the color test field and the blank test field must be defined in this screen.

Use this software screen to:

Set sample blank correction factors:

Define a combination of X (chromogenic test) and B (blank test) in calculation formula $Y=X-B$.

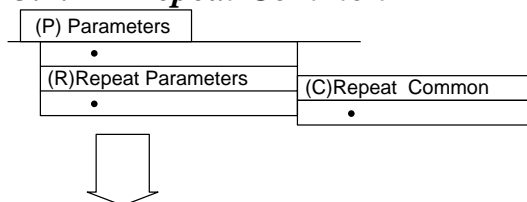
1. Select [Parameters], [Inter-Related Tests], [Sample Blank].
2. Press function key F4 (set). *The cursor appears in the "Color test" column.*
3. Enter a color test and blank test using the pull-down menus located by each field. *The test name is displayed. Note: Analysis tests without a test name, which have been assigned to inter-test calculation tests cannot be assigned as a chromogenic test or a blank test.*
4. Press function key F2 (exit) twice. *The settings will be saved.*

See Also

For more information on sample blanks, refer to the "Calculations" section of the Specifications Chapter.

3.4 Repeat Parameters

3.4.1 Repeat Common



STANDBY 1998/08/03 10:10

Repeat Common

Error Flag Group |

Auto Repeat Repeat Data Over Write

Select Error Flag

Normal OR-mode: (R#%?UuYy@SDB*&Z!FGpTPNHLJK/

Normal AND-mode: (R#%?UuYy@SDB*&Z!FGpTPNHLJK/

Diluted OR-mode: (R#%?UuYy@SDB*&Z!FGpTPNHLJK/

Diluted AND-mode: (R#%?UuYy@SDB*&Z!FGpTPNHLJK/

Condense OR-mode: (R#%?UuYy@SDB*&Z!FGpTPNHLJK/

Condense AND-mode: (R#%?UuYy@SDB*&Z!FGpTPNHLJK/

Help Exit Set ALARMCLEAR

Description:

Use this screen to define the overall settings for the auto repeat function. The flags triggering a repeat requisition are also chosen here for normal and diluted repeats. Reflex testing can also be defined in this menu. If any repeat data is to automatically overwrite the original data, select the repeat data overwrite check box.

See Also

For detailed information on performing a repeat run, refer to "Performing a Repeat Run" in the Obtaining Results section of the Basic Operations Chapter.

Use this software screen to:

Set repeat run parameters:

1. Select [Parameters], [Repeat Parameters], [Repeat Common].
2. Press function key F4 (set). *A cursor appears in the "Auto Repeat" field.*
3. Set auto repeat, repeat data overwrite, and select an error flag.

Auto Repeat: Specifies whether a repeat-run data list is generated.

Repeat Data Overwrite: Specifies whether the analysis data after a repeat run will automatically overwrite that of the original sample.

Select Error FLAG: Specify an error flag to be used when extracting samples that require a repeat run. For each of the normal repeat-run samples and diluted repeat-run samples, set both the repeat-run error marks, "OR mode" and "AND mode."

- **OR mode:**

Samples that are appended with any of the selected abnormal data symbols will be extracted as the repeat-run samples.

- **AND mode:**

Only samples that are appended with all of the selected abnormal data symbols will be extracted as the repeat-run samples.

4. When the above parameters are set, select the "Group" tab.

5. Set a deciding test and related test.

Deciding Test and Related Test: The operator is allowed to set one "deciding" analysis test and related tests.

For example:

If ALB and TP are set to the deciding test and the related test, respectively, and if the ALB is necessary for a repeat run, then the TP will be necessary for a repeat run also.

A maximum of 10 sets of combinations of a deciding test and a related test can be set. To set "No designation," enter a space. Also, analysis tests that do not have a test name or have been assigned to the inter-test calculation test cannot be specified as a deciding test or related test.

6. After the setting is completed, press function key F2 (exit). *Parameters will be saved.*

Perform "Reflex Testing"

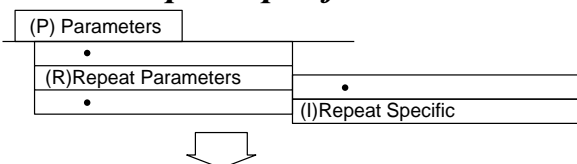
Reflex testing is the ability to repeat a test, whether it was requisitioned in the original run or not, based on another test generating a repeat flag. For example, if the TBIL fell outside of the dynamic range, you might want to repeat DBIL even if DBIL did not flag in the original run. Up to 10 sets of tests can be programmed as "reflex tests."

1. Select [Parameters], [Repeat Parameters], [Repeat Common].
2. Select the "Group" tab.
3. Select function key F4 (set). Select the "deciding test." When the "deciding test" generates a repeat flag, the related tests can be repeated.
4. Ten related tests can be selected. Related tests are the items to be repeated if the deciding test generates a repeat flag. After the set-up is complete, select function key F2 (exit).

Tip

Tests that do not have a test name, or have been assigned to the inter-item calculation test, cannot be selected as a deciding test or related test.

3.4.2 Repeat Specific



The screenshot shows the 'Repeat Specific' screen. At the top, there is a status bar with 'STANDBY', several icons, and the date/time '1997/09/03 10:10'. Below this is a title bar 'Repeat Specific'. The main area contains the following fields:
Test Name.: 1. Alb (dropdown menu) << >> Type: Serum (dropdown menu)
Diluted: Sample Volume: 1.0 ul, Dilution Volume: 0 ul, Pre-Dilution Rate: 1
Normal: Sample Volume: 2.0 ul, Dilution Volume: 0 ul, Pre-Dilution Rate: 1
Condense: Sample Volume: 1.0 ul, Dilution Volume: 0 ul, Pre-Dilution Rate: 1
Repeat Decision Level: L: -99999.9, H: 99999.9
Auto rewrite:
At the bottom, there are buttons for 'Help', 'Exit', 'Print', 'Set', and 'Test No.'. An 'ALARMCLEAR' indicator is visible in the bottom right corner.

Description:

Use this menu to set the diluted repeat sample volume, the repeat range to generate repeat requisitions, and automatic repeat overwrite for each test. J and K flags will be generated if the repeat range is exceeded in this screen.

Use this software screen to:

Specify an analysis test set with individual repeat run parameters:

For detailed procedures on performing repeat run analysis, refer to "Performing a Repeat Run" located in the Basic Operations Chapter.

1. Select [Parameters], [Repeat Parameters], [Repeat Specific]. *Entered individual test parameters related to a repeat run will be displayed.*
2. Select a test name using the pull-down menu by the "test name" field, or press function key F8 (Test No.). *A cursor appears at the "Test No." column.*
3. Specify a sample type. *Use the pull-down menu located by the "Type" field. A sample type cannot be set if a sample dispense quantity and sample diluent quantity are not defined.*
4. Press function key F2 (exit).

Set individual repeat run parameters:

For individual analysis tests it is possible to set repeat-run parameters. Repeat Specific Menu screen has existing pre-set values for the "Diluted" and "Condensed" sample volumes. DO NOT USE these defaulted settings. To avoid instrument use of the default settings when performing repeat analysis, "Diluted" and "Condensed" volumes should be entered as the same value as the "Normal" sample volume until such time as validated parameters for each analyte can be obtained.

1. In the [Repeat Specific] screen, press function key F4 (set). *The cursor moves over the "Repeat diluted s. vol." column.*
2. Set "Repeat Diluted Sample Volume" "Repeat Decision Level" and "Auto Rewrite."

Sample dispense quantity:

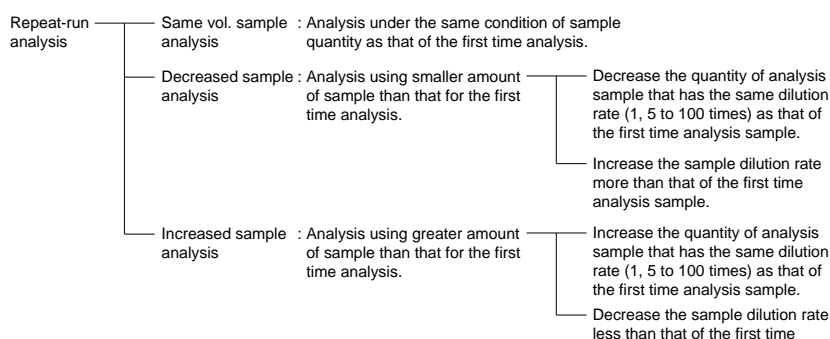
Use one of the following options for repeat analysis

- Diluted
- Normal
- Condensed

These options maybe used or not used with predilution rates. If the "Pre-dilution Rate" is set in the "Repeat Specific" screen, sample pre-dilution is performed according to the dilution rate (5 to 100). For reference see the dilution rate and sample volume required for dilution in the examples below:

SAMPLE PRE-DILUTION RATE	SAMPLE VOLUME (μL)	SAMPLE DILUTION (WATER, μL)	TOTAL
5	48	192	240
10	24	216	240
50	5	245	250
100	3	297	300

The reagent probe dispenses liquid from the pre-dilution bottle into a "dilution" cuvette. Then the sample probe dispenses sample into the dilution cuvette to make the set pre-dilution. The sample probe then aspirates from the dilution cuvette into the test cuvette. Reagent blank, calibrators, and OC samples are also pre-diluted for tests programmed to pre-dilute.

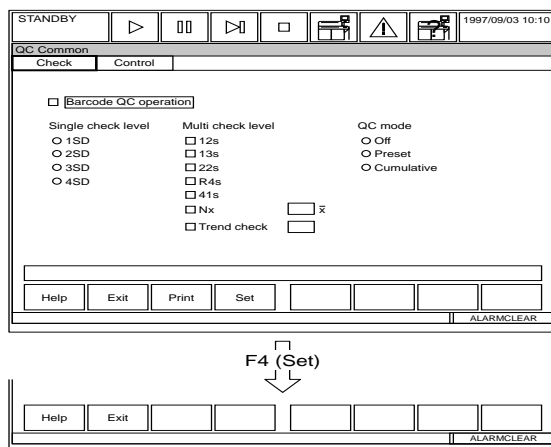
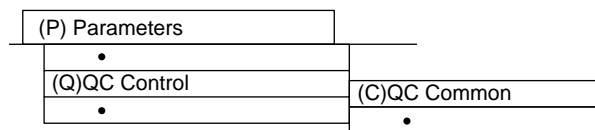


Repeat decision level: Set an acceptable range for extracting repeat-run samples. *Set both the lower (L) and upper (H) limits using a numeric value consisting of a maximum of 7 digits.*

3. After the setting is completed, press function key F2 (exit). *The settings are saved.*

3.5 Quality Control

3.5.1 QC Common



Description:

This screen sets the overall conditions for on-board QC data management. The selection of Westgard Rules and barcoded QC samples are made here. Use this screen to define up to 60 different control materials being used and positions in the green rack. The QC mode can be set to “preset” or “cumulative.” This screen is also used to define the QC number, name, ID number, expiration and lot number. The QC number is the position the QC material will be placed in on the green rack.

See Also

For more information, refer to "Quality Control Analysis" and "How to Reprint Reagent Blank, Calibrator, QC and Patient Data" located in the Basic Operations Chapter. Also, refer to "Quality Control" located in the Specifications Chapter.

Use this software screen to:

Program the barcode QC ID option:

For procedures, refer to the "Quality Control Analysis" procedure located in the Basic Operations Chapter.

Set common parameters related to quality control:

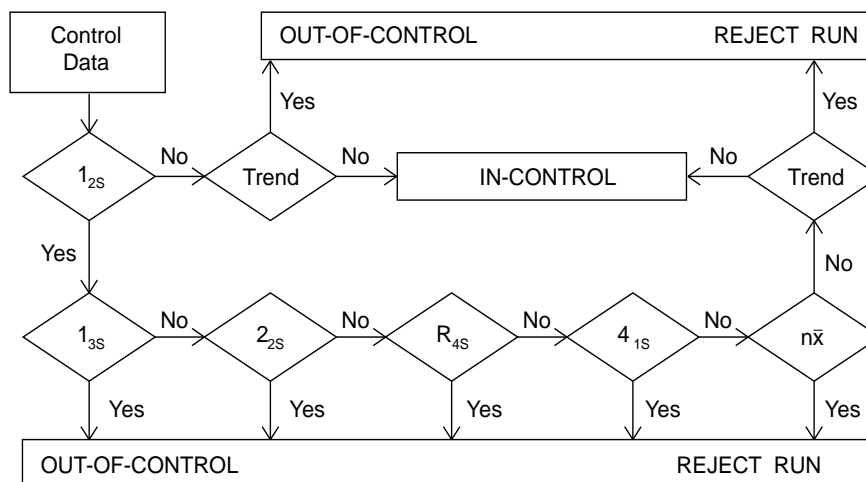
Use the following procedure to set barcode use with control samples and the control names, control ID, expiration, and lot number.

1. Select [Parameters], [QC Control], [QC Common].
2. Press function key F4 (set).
3. Set the barcode QC operation. Choose from the following options at each prompt:

Barcode QC operation: To use control samples with barcodes, select the check box using your mouse.

Single check level: Set the check limits of quality control data about a reference value (mean). This can be set to multiples of the set standard deviation of control rules.

Multi check level: Set the use of judgment items from the following criterion for multi-rule Westgard or Shewhart quality control.



Standard of judgement based on the multi-rule Shewhart technique.
(Logic diagram Applicable to Control Rules)

Caution

QC error flags may be compromised when a conflict between [QC Common] and [QC Specific] Single/Multi settings arise. Operator MUST ensure Single/Multi settings match in both [QC Common] and [QC Specific].

Trend check: The use of “Trend” in the above diagram can be selected and the number that constitutes a trend set from 4 to 10.

QC mode: Set a calculation method to obtain a reference value of a quality control chart. Set this to “Off,” “Preset,” or “Cumulative.” In the preset mode, a predefined value will be used as the reference value. In the cumulative value mode, an average of the daily data will be used as the reference value.

Note

These can be set using the mouse to click on the check box.

4. Select the "Control" tab located in the upper left corner of the screen.
5. Control names and control IDs for QC numbers 1 to 60 will be shown in a list.
6. Press function key F4 (set) to enter the control name, ID, expiration, and lot number.

Control name: Set a name for each control sample. Enter 20 characters maximum. Upper or lower case may be used.

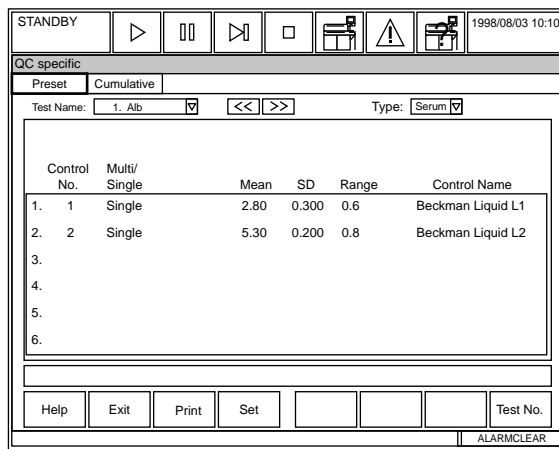
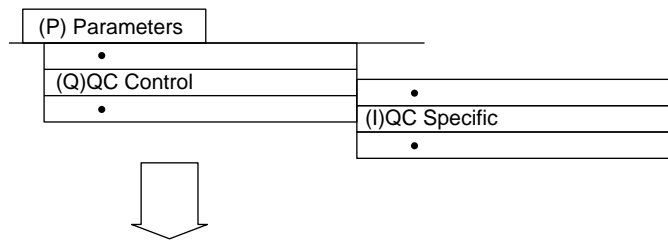
Control ID: Set a desired control ID for barcode identification of each control sample. Enter 20 characters maximum. The control ID must be matched to system barcode parameters.

Expiration: Set the expiration date of a control sample. To set “No designation” or leave blank, enter a space. Enter expiration date as MM/DD/YYYY (Example: 11/30/1997)

Lot No.: Enter 15 characters maximum.

7. Press the function key F2 (exit). *The settings are saved.*

3.5.2 QC Specific



Description:

Use this screen to define the preset control values for the mean, standard deviation, and range or to view the cumulative mean, N, standard deviation and range for a defined set of indices and a time period for cumulation. Also use this screen to determine if control results are interpreted using Westgard rules (multi) or standard deviation check (single). Up to 6 controls can be assigned for a test.

Use this software screen to:

View QC specific parameters:

Control test parameters used in the preset mode will display in the QC Specific screen if the "QC mode" is set to "preset" in [Parameters], [QC Control], [QC Common].

Control test parameters used in the cumulative value mode will display in the QC Specific screen if the "QC mode" is set to "cumulative" in [Parameters], [QC Control], [QC Common].

Set QC specific parameters:

Set the control test parameters to be used in the preset mode. For each test, a maximum of 6 levels of control test parameters can be set.

1. Select [Parameters], [QC Control], [QC Specific].
2. Press function key F4 (set).

3. For each control level, set the control number, multi/single rule, mean, SD, range, and control name.

Cnt. No.: From the control samples that are set by the [QC Common] menu for each control 1 to 6, set the control sample to be used here. Enter a numerical value between 1 and 60. This can also be set using the guide function key. The control name will appear in the last column to the right. To set the identical reagent specification of serum/urine to "None," enter a space.

Multi/Single: Specify whether quality control is performed according to the multi-rule. If so, set to MULTI; if not, set to SNGL for single rule.

The following fields set the QC monitor chart characteristics described:

Mean: Central target value (expected mean)

SD: Standard deviation

Range: Width of control range (maximum - minimum values)

The values entered into these fields should have the same number of decimal places as the associated Test, specified in the Decimal Places field in: [Parameters] [Specific Test Parameters], Range tab.

The display of the Mean and SD settings will contain more decimal places than what was entered because trailing zeros are automatically added to the software for QC data management purposes.

Caution

QC error flags may be compromised when a conflict between [QC Common] and [QC Specific] Single/Multi settings arise. Operator MUST ensure Single/Multi settings match in both [QC Common] and [QC Specific].

4. Press function key F2 (exit). *The parameters set in this process will be saved.*

Change QC ranges:

For procedures, refer to "Changing QC Ranges" located in the Basic Operations Chapter.

Display stack values of QC samples:

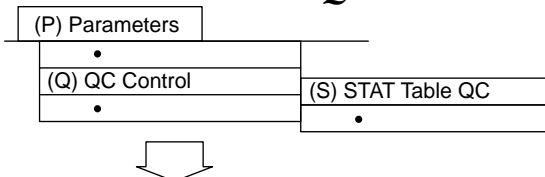
This system maintains the quality control data used to check all the "Multi-rule check levels" that were set.

1. Select [Parameters], [QC Control], [QC Specific].
2. Select the "cumulative" tab.
3. Press function key F5 (QC stack review). *The stored list of individual values for quality control samples will be displayed by control sample.*
4. Press the "Close" button to exit this window.

See Also

For more information, refer to "Quality Control Analysis" and "How to Reprint Reagent Blank, Calibrator, QC and Patient Data" located in the Basic Operations Chapter. Also, refer to "Quality Control" located in the Specifications Chapter.

3.5.3 STAT Table QC



Test Name	Available/ Unavailable	Cyclic Type	Count	Execution on Measuring Start	Excution after Calibration
ITM01	Available	Test	999	Yes	No
ITM02	Available	Sample	999	No	No
ITM03	Available	Test	999	Yes	No
ITM04	Unavailable				
ITM05	Available	Test	999	Yes	No

Description:

Use this screen to set the parameters for quality control analysis using the STAT table.

Caution

It is recommended that the operator determine the acceptable length of time to leave samples on the STAT table. Although the STAT table is cooled, it should not be used to store samples for an extended period of time. Do not open and close the STAT table cover frequently. This will increase the temperature.

See Also

For more information, refer to "Quality Control Analysis" and "How to Reprint Reagent Blank, Calibrator, QC and Patient Data" located in the Basic Operations Chapter. Also, refer to "Quality Control" located in the Specifications Chapter.

Use this software screen to:

Set STAT Table Control Positions:

1. Select [Parameters], [QC Control], [STAT Table QC].
2. Select the round name using the pull-down menu located by the "name" field.
3. Press function key F4 (set). From the "Operation" field select: auto, manual, or none.
4. Press function key F5 (edit). *The "Control setup" dialog box is displayed.*

5. At "Control Name" assign a QC material to a position on the stat table. The QC material is assigned to a QC No. [Parameters], [QC Control], [QC Common].
6. To change the position number use the "<<" or ">>" buttons located on screen. Repeat step 5 for each position that needs to be set.
7. After completing the settings, select the 'Close' button then press function key F2 (Exit).
The settings are saved.

Set STAT Table Parameters:

NOTE: QC positions and sample type must be assigned to the STAT table in [System Maintenance].

1. Select [Parameters], [QC Control], [STAT Table QC].
2. Select the "Test" tab located in the upper left corner of the screen using your mouse.
3. Select the round name at the round name prompt using the pull-down menu.
4. Press function key F4 (Set).
5. Select the test.
6. Press function key F5 (Edit).
7. Set the "Cyclic type," "Count," and "Execution on Measuring Start."

The following settings apply only if "Auto" is selected from the "Operation" field:

Available/Unavailable: Displays whether a test is available or unavailable.

Cyclic Type: Select "Test" or "Sample."

Count: A number between 1 and 999 can be selected. This determines the number of analyses performed before executing STAT Table QC analysis.

Execution on Measuring Start: To run QC STAT Table analysis when the analyzer is started, select this function. Use the space key to enable or disable this option.

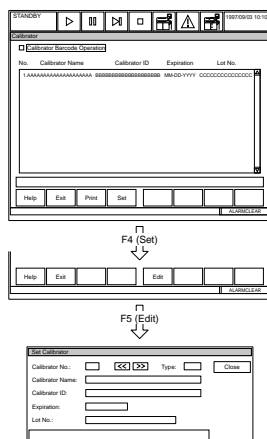
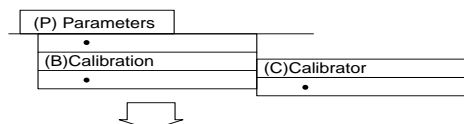
8. Enter the control name and select the "Close" button.

Perform QC on the STAT Table:

For procedures, refer to "Performing QC on the STAT Table" located in the "Quality Control Analysis" section of the Basic Operations Chapter.

3.6 Calibration

3.6.1 Calibrator



Description:

Use this screen to enable calibrator barcode operation and define calibrator demographics: calibrator number, calibrator ID, expiration date, and lot number. A maximum of 200 different calibrator materials can be assigned. The calibrator number is the position the calibrator will be placed in on the yellow rack. Calibrators are labeled for sample type using 'U' for urine, 'S' for serum and 'X' for other.

Tip

A maximum of two digits can be entered to specify a calibrator No. range. If specifying a range between 1 and 99, enter the two numeric values as they are. If specifying a range between 100 and 200, enter the alphanumeric value corresponding to the chart on page D-105 of the User Guide.

Calibrator barcode option: Selects whether a calibration sample is identified by a specific barcode.

Calibrator No.: The calibrator number will determine the position the calibrator will be placed on the yellow rack.

Calibrator name: For each calibration sample set a name. Use 26 characters maximum.

Calibrator ID: For each calibration sample set an ID. Use 26 characters maximum.

Expiration: Set the expiration date. To set "No setting," enter a space. Enter as month (2 digits), day (2 digits), year (4 digits).

Lot No.: Use 15 characters maximum.

Use this software screen to:

Program a new calibrator:

1. Select [Parameters], [Calibration], [Calibrator].
2. Press function key F4 (set).
3. Select "Calibrator Barcode Option" if required.

Calibrator barcode option: Selects whether a calibration sample is identified by a barcode for calibration analysis (Y) or calibration sample is identified by its cal. no. and rack position (N).

4. Move the cursor to a test.
5. Press function key F5 (edit).
6. Move the cursor to the next available calibration number and assign the following: calibrator name, calibrator ID (if in use), expiration, and lot number.
7. Select the "Close" button.
8. Repeat steps 4 -7 for each additional calibrator material.

See Also

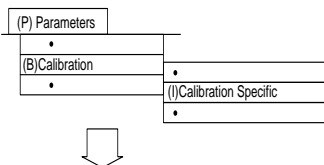
For more information refer to "Performing calibrations" and "How to reprint reagent blank, calibrator, QC and patient data" located in the Basic Operations Chapter.

Relationship of Cup Positions to Calibrator Numbers:

Refer to this chart to determine the specific rack yellow and cup number each calibrator will occupy.

Rack NO.	Cup Position	Calibrator NO.	Rack NO.	Cup Position	Calibrator NO.	Rack NO.	Cup Position	Calibrator NO.	Rack NO.	Cup Position	Calibrator NO.
0001	1	1	0006	1	51	0011	1	A1	0016	1	F1
	2	2		2	52		2	A2		2	F2
	3	3		3	53		3	A3		3	F3
	4	4		4	54		4	A4		4	F4
	5	5		5	55		5	A5		5	F5
	6	6		6	56		6	A6		6	F6
	7	7		7	57		7	A7		7	F7
	8	8		8	58		8	A8		8	F8
	9	9		9	59		9	A9		9	F9
	10	10		10	60		10	B0		10	G0
0002	1	11	0007	1	61	0012	1	B1	0017	1	G1
	2	12		2	62		2	B2		2	G2
	3	13		3	63		3	B3		3	G3
	4	14		4	64		4	B4		4	G4
	5	15		5	65		5	B5		5	G5
	6	16		6	66		6	B6		6	G6
	7	17		7	67		7	B7		7	G7
	8	18		8	68		8	B8		8	G8
	9	19		9	69		9	B9		9	G9
	10	20		10	70		10	C0		10	H0
0003	1	21	0008	1	71	0013	1	C1	0018	1	H1
	2	22		2	72		2	C2		2	H2
	3	23		3	73		3	C3		3	H3
	4	24		4	74		4	C4		4	H4
	5	25		5	75		5	C5		5	H5
	6	26		6	76		6	C6		6	H6
	7	27		7	77		7	C7		7	H7
	8	28		8	78		8	C8		8	H8
	9	29		9	79		9	C9		9	H9
	10	30		10	80		10	D0		10	I0
0004	1	31	0009	1	81	0014	1	D1	0019	1	I1
	2	32		2	82		2	D2		2	I2
	3	33		3	83		3	D3		3	I3
	4	34		4	84		4	D4		4	I4
	5	35		5	85		5	D5		5	I5
	6	36		6	86		6	D6		6	I6
	7	37		7	87		7	D7		7	I7
	8	38		8	88		8	D8		8	I8
	9	39		9	89		9	D9		9	I9
	10	40		10	90		10	E0		10	J0
0005	1	41	0010	1	91	0015	1	E1	0020	1	J1
	2	42		2	92		2	E2		2	J2
	3	43		3	93		3	E3		3	J3
	4	44		4	94		4	E4		4	J4
	5	45		5	95		5	E5		5	J5
	6	46		6	96		6	E6		6	J6
	7	47		7	97		7	E7		7	J7
	8	48		8	98		8	E8		8	J8
	9	49		9	99		9	E9		9	J9
	10	50		10	A0		10	F0		10	K0

3.6.2 Calibration Specific



The screenshot shows the 'Calibration Specific' software interface. At the top, there is a status bar with 'STANDBY', navigation icons, and the date/time '11/30/2000 10:10'. Below this is a tabbed interface with 'General' and 'ISE' tabs. The 'General' tab is active, showing fields for 'Test Name: GOT', 'Type: Serum', 'Calibration Type', 'Formula', 'Counts', and 'Process: CONC'. A table for calibration points is present, with columns for 'Cal. No.', 'OD', 'CONC', 'Factor/OD-L', and 'Factor/OD-H', and rows for 'Point 1' through 'Point 7'. At the bottom, there are buttons for 'Help', 'Exit', 'Print', 'Set', 'Inner/Outer', and 'Test No.', along with checkboxes for '1-Point Cal. Point', 'with CONC-0', 'Slope Check', and 'Advanced Calibration: Lo+Bottle'.

Description:

Use this screen to define the following for each test: calibration type, formula, calibration number, concentration, factor range, stability, and count. Calibration parameters are provided on the methodology sheets located in the User's Guide. Concentration is set using the calibrator package insert values.

See Also

For more information regarding calibration, refer to the Basic Operations Chapter.

Use this software screen to:

Set individual test parameters:

1. Select [Parameters], [Calibration], [Calibration Specific].
2. Use the pull-down menu or << >> buttons on screen to select a test name.
3. Select a sample type using the pull-down menu.
4. Press function key F4 (set). According to the messages displayed, set analysis parameters.

Use serum cal.: If this box is selected, the data is calculated in accordance with serum calibration during sample analysis. This box displays only if urine sample type is selected.
Cal. type: Select the calibration type for each analysis test from the pull-down menu.
Formula: Set a formula according to the calibration type using the pull-down menu.
Counts: Set the number of times to repeatedly perform calibration analysis and a reagent blank analysis. Enter a number between 1 and 4. Depending on the number, the following values will be used:

Set to 1: OD Values will be used.
Set to 2: An average of two values.
Set to 3: An average of two close values.
Set to 4: An average of two values, excluding maximum and minimum values.

Process: Set the method to be used if an update of the calibration fails. Set to either “OD” or “CONC.” To perform a concentration conversion using the existing factors, set to “CONC.” Otherwise, set to “OD” if a concentration conversion is not initially performed. Save the measured OD value, and batch-perform the concentration conversion after performing the calibration again. This can be set only if the calibration type is set to ACAL (AB, AA, 2AB-7AB).

Cal. No. of Calibrator specification point: Enter the calibration number from 1 to 200 defined in the [Parameters], [Calibration Parameters], [Calibrator] menu.

Tip

A maximum of two digits can be entered to specify a calibrator number. If specifying a range between 1 and 99, enter the two numeric values as they are. If specifying a range between 100 and 200, enter the alphanumeric value corresponding to the chart on page D-105 of the User Guide.

Cal. No. of Calibrator specification point 1: This can be set only if the calibration type is set to 2MB - 7MB, AB, AA or 2AB-7MB.

Cal. No. of Calibrator specification point 2: This can be set only if the calibration type is set to 2MB - 7MB, AA or 2AB - 7AB.

Cal. No. of Calibrator specification point 3: This can be set only if the calibration type is set to 3MB - 7MB or 3AB - 7AB.

Cal. No. of Calibrator specification point 4: This can be set only if the calibration type is set to 4MB - 7MB or 4AB - 7AB.

Cal. No. of Calibrator specification point 5: This can be set only if the calibration type is set to 5MB - 7MB or 5AB - 7AB.

Cal. No. of Calibrator specification point 6: This can be set only when the calibration type is set to 6MB - 7MB or 6AB - 7AB.

Cal. No. of Calibrator specification point 7: This can be set only if the calibration type is set to 7MB or 7AB.

Lower limit of a factor range or absorbance range of each calibrator specification point: This can be set only if the calibration type is set to ACAL (AB, AA, 2AB-7AB). Set a factor range if the formula approximation is for a line. Set an absorbance range if the formula approximation is for a curve.

Upper limit of a factor range or absorbance range of each calibrator specification point: This can be set only if the calibration type is set to ACAL (AB, AA, 2AB-7AB).

1-point cal. point: This can be set only if the calibration type is set to 2AB - 7AB. Set a cal. no. up to the maximum point that is specified according to the calibration type. This sets which calibrator will be used for single point calibration.

Slope Check: Has three settings:

“None” - The default setting.

“+” Positive slope check compares all increasing OD values to the next calibration point.

“-” Negative slope check compares all decreasing OD values to the next calibration point.

If an error occurs the user will hear an audible alarm and a error message will be generated.

Processing the Slope Check

When the AU640/640° performs a multi-point calibration, it compares the OD values with values for the setting (“+” or “-”) selected. If the result of this comparison does not agree with the values selected, an audible alarm is generated and the error message below is displayed, where “nn” is the item number and “xxxxx” is the test name that produced the error.

4060 MULTIPOINT-CAL. OD SLOPE CHECK ERROR (nn,xxxx)

If the slope check fails the results will print according to how the Process is set in “Calibration Specific Parameters” (OD or Conc).

MB type Factor: This can be set only if the calibration type is set to MB.

Calibration Stability Period: Enter the number of days, between 1 and 999. Enter the value from the methodology sheet. To set this field to “No setting,” enter a space.

with CONC-0: If there is a standard solution with a concentration value of 0, calibration can be performed at concentration value 0 and at 2 other points. If calibration is made at 2 points, check the check box.

Advanced Calibration: Sets the advanced calibration execution condition (reagent lot number unit or reagent bottle number unit) for the test items being displayed. Select "Lot" or "Lot + Bottle" from the pull-down list. If the advanced calibration is not to be executed, select "None" from the pull-down list.

5. Press function key F2 (exit). *Parameters set in this process will be saved.*

Set an ISE test:

Set the individual test parameters of each ISE test (Na, K, Cl). Perform the following using a test number set between 97 and 99 in the [Calibration Specific] screen.

1. Select [Parameters], [Calibration], [Calibration Specific].
2. Select the "ISE" tab located in the upper left corner of the screen.
3. Use the pull-down menu or << >> buttons on screen to select a test name.
4. Select a sample type using the pull-down menu.
5. Press function key F4 (set). According to the messages displayed, set analysis parameters.
6. According to the messages displayed, set the analysis parameters. For cal. types, AB factors, and/or calibrator.

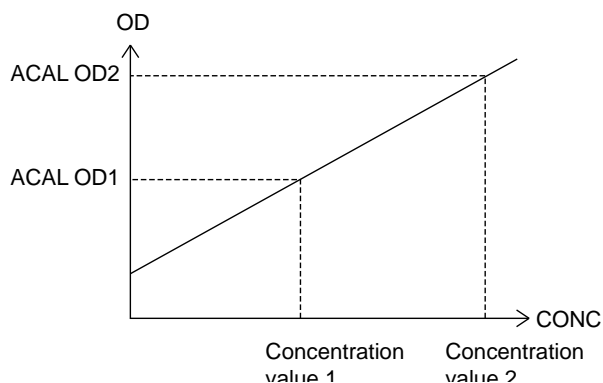
Cal. type: Set the calibration type for each analysis test to MCAL or ACAL. The default setting is MCAL. Counts: 1 to 4 for ACAL only. Factor A: slope or multiplier, B: offset or constant, cal. no., conc. factor range: for ACAL.

7. Press function key F2 (exit). *Parameters settings will be saved.*

Generate a summary of calibration types:

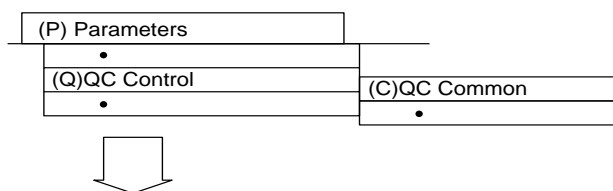
This system allows the operator to generate a maximum of 15 types of calibrations, depending on the analysis test. Five of the 15 major types of calibration plus 1-point recalibration will be described in the following:

ACAL AA



- Enter two kinds of standard liquid with a different concentration or a value of the calibrator, then set a calibration using an OD value obtained from the automatic calibration setting function.
- This can be applied to analysis items where the calibration chart is a line but does not pass through the origin (reagent blank). (An example analysis item: Calcium)

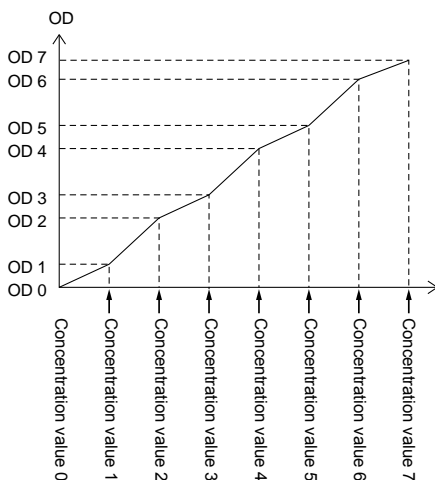
ACAL AB



Referring to check parameters related to quality control

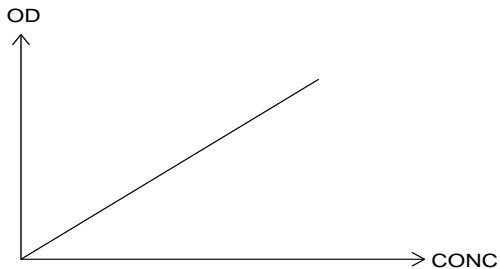
Referring to control parameters related to quality control

ACAL 7AB



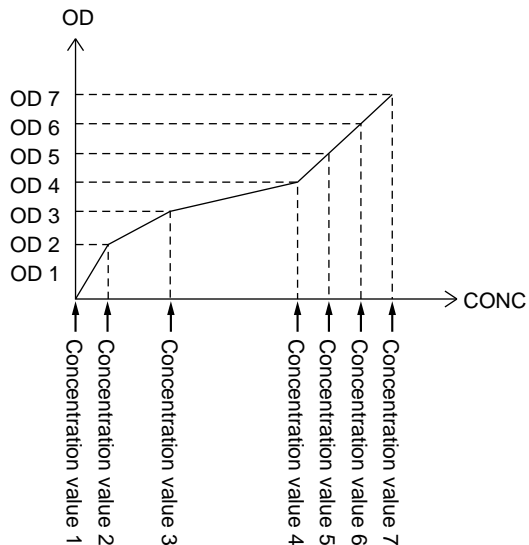
- By using 2 to 7 kinds of standard solutions or calibrator, and by entering the measured OD values and concentration values, set a calibration chart.
- This will be used for immunoassays and immunoturbidimetric items.

M CAL MB



- Set the calibration coefficient with the K factor.
- This is typically used for enzyme items through the rate assay method.

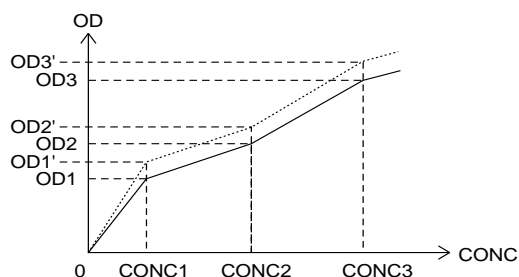
M CAL 7MB



- With a maximum of 7 points OD values and the entered concentration value, set a calibration.
- This will be applied to analysis items whose calibration is not a line but each of the curved sections has a constant slope. This is typically used for turbidometric and immunoassay items.

1-POINT CAL CORRECTION

Example 1: If none of multiple standard solutions has a concentration of 0



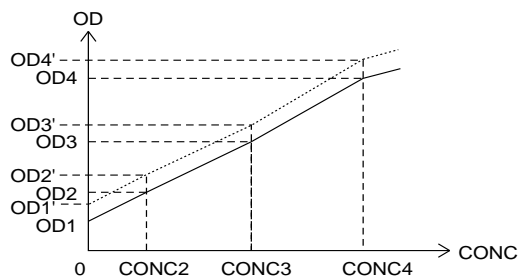
¥ If the single-point correction is performed for the CONC2 standard solution, execute the following calculation.

1. Perform the single-point correction.

$$ODn' = ODn \times \frac{OD2}{OD2'}$$

2. Recalculate for the calibration chart.

Example 2: If any standard solution has a concentration of 0



¥ If correction is performed with two points of CONC1 and another (CONC3), execute the following calculation.

1. Use the reaction OD values of CONC1 and CONC3 (OD1' and OD3') as they are.
2. Correct each point as follows.

$$ODn' = a \times (ODn - OD1) + b$$

$$a = \frac{OD3' - OD1'}{OD3 - OD1}$$

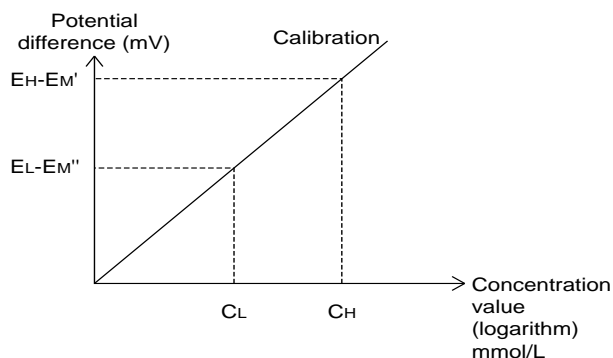
$$b = OD1'$$

ODn : previous OD value ODn' : OD value after correction

Process calibration on the ISE:

During ISE calibration, MID, HIGH, & LOW which have a known concentration, are measured. The relationship between the electrode potential and ion concentration at that time is obtained, and Na, K, and Cl calibration coefficient S (slope) is calculated.

Manual calibration:



CH : A known concentration of HIGH STANDARD liquid used for calibration

CL : A known concentration of LOW STANDARD liquid used for calibration

EH-EM': A potential difference between HIGH STANDARD liquid and MID liquid

EL-EM'': A potential difference between LOW STANDARD liquid and MID liquid

Set a calibration using a potential difference between the two points of known concentration.

Correction by M-CAL:

M-CAL for the ISE corrects results using this formula, $Y = AX + B$.

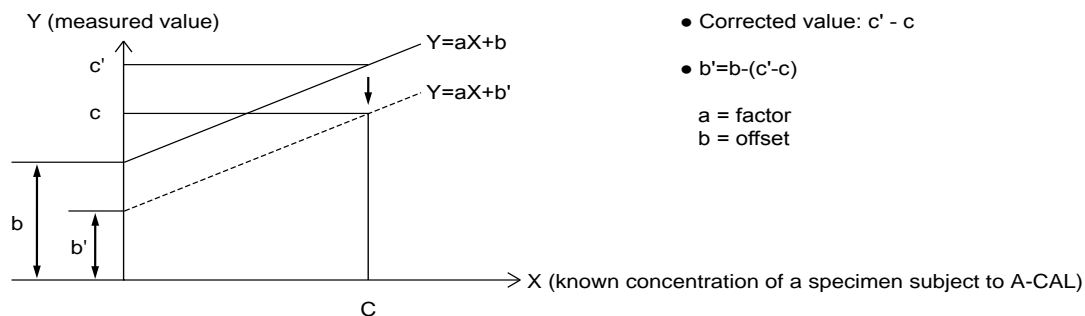
Coefficients A and B are obtained in the following way. Perform a regression analysis between measurement values from this system without an M-CAL data correction and a conventional or basic method: $Y=aX+b$

Where Y = measurements from this system, and

X = reference values using the conventional method or basic method.

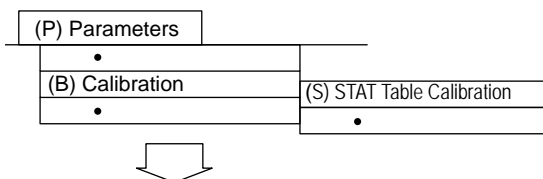
$X=(1/a) Y-(b / a)$. Thus, $A=1/a, B=-b/a$.

Correction by A-CAL:



To use ACAL, assay a calibrator with known concentration, C. The result obtained for this sample by A-CAL after an M-CAL correction will be C'. In order to correct the concentration of samples run for A-CAL, the instrument calculates the difference between C and C'. This A-CAL correction is applied to values in addition to any M-CAL correction coefficients B.

3.6.3 STAT Table Calibration



Position No.	Type	Calibrator No.	Calibrator Name
21.	Serum	1.	Beckman Liquid L1
22.	Serum	2.	Beckman Liquid L2

Description:

Use this screen to set the parameters for calibration analysis using the STAT table.

Caution

It is recommended that the operator determine the acceptable length of time to leave samples on the STAT table. Although the STAT table is cooled, it should not be used to store samples for an extended period of time. Do not open and close the STAT table cover frequently. This will increase the temperature.

See Also

For more information, refer to "Calibration Analysis" and "How to Reprint Reagent Blank, Calibrator, QC and Patient Data" located in the Basic Operations Chapter.

Use this software screen to:

Set STAT Table Calibration Positions:

1. Select [Parameters], [Calibration], [STAT Table Calibration].
2. Select the round name using the pull-down menu.
3. Press function key F4 (set). The cursor appears in the "Operation" field. Select "Auto," "Manual," or "None."

4. Press function key F5 (edit). *The "Calibrator setup" dialog box is displayed.*
5. Use the arrows at "Calibrator Name" to program a calibrator material to a position on the stat table. The calibrator material must have a previously assigned Calibrator No. programmed in [Parameters], [Calibration], [Calibrator].
6. To change the position number use the "<<" or ">>" buttons located on screen. Repeat step 5 for each position that needs to be set.
7. After completing the settings, select the 'Close' button then press function key F2 (Exit). *The settings are saved.*

Set STAT Table Parameters:

Note

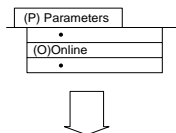
Calibration positions and sample types must be assigned to the STAT table in [System Maintenance].

1. Select [Parameters], [Calibration], [STAT Table Calibration].
2. Select the "Test" tab located in the upper left corner of the screen using your mouse.
3. Select the round name using the pull-down menu.
4. Press function key F4 (set).
5. Select the test(s).
6. Press function key F5 (edit).
7. Set the following:
 - Available/Unavailable:** Displays whether a test is available or unavailable.
 - Calibration Mode:** Use your mouse to select the pull-down menu. Select one of the following: All+RB, One Point+RB, or RB.
 - Execution Type:** The following selections are available: Change Bottle No. or Change Lot No. Use "Change Bottle No." when the reagent bottle number of a test you have selected has changed. Use "Change Lot No." when the reagent lot number of a test you have selected has changed.
 - Execution on measuring start:** To run STAT Table calibration when analysis is started, select this function. Use the space key to enable or disable this option.
8. Select the "Close" button. Press function key F2 (Exit). *The settings are saved.*

Perform Calibration on the STAT Table:

For procedures, refer to "Performing Calibrations and a Reagent Blank" located in the Basic Operations Chapter.

3.7 On-line



STANDBY								1998/08/03 10:10
Online								
Set Up	Protocol	Test No.						
Test Requisition Information Receive								
Routine Normal:	None	STAT Normal:	None					
Routine Repeat:	None	STAT Repeat:	None					
Emergency Normal:	None							
Emergency Repeat:	None							
Results Transfer								
Routine Normal:	Batch	STAT Normal:	Batch	QC:	Batch			
Routine Repeat:	Batch	STAT Repeat:	Batch	Calibration:	Batch			
Emergency Normal:	Batch	STAT Quick:	None	Reagent Blank:	Batch			
Emergency Repeat:	Batch							
Help	Exit	Print	Set					
								ALARMCLEAR

Description:

This screen is used to set communication protocols for the on-line connection to a host computer. Communication can be set to: none, batch, or realtime. The type of sample and the tests to be transmitted are also controlled here.

Use this software screen to:

Set on-line parameters:

It is also possible to define whether the reception of sample information and the transmission of analysis data are performed concurrently with system operation and the on-line communication protocol, etc.

1. Select [Parameters], [Online].
2. Press function key F4 (set).
3. According to the messages displayed, set the online parameters.
4. After the settings are complete, press function key F2 (exit). *Parameters are saved.*

Caution

If Real Time TRI Receive is used, check the Test Requisition setting in [Parameter], [System], [System] parameters. If it is set to Sequential, the instrument may use the next requisition sent by the host computer to process the sample unless a manual requisition has been entered. This can result in the wrong S. ID being associated with the test results.

Setting protocols

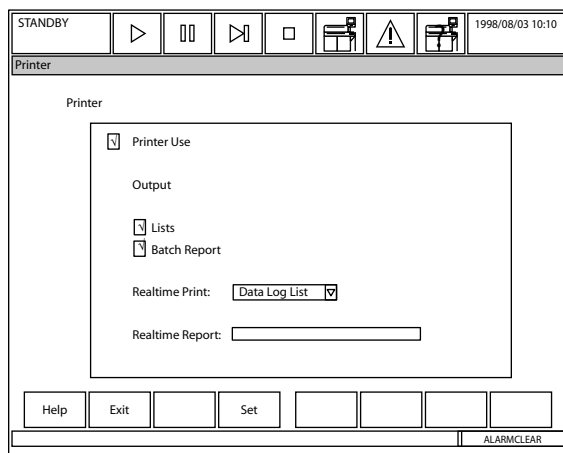
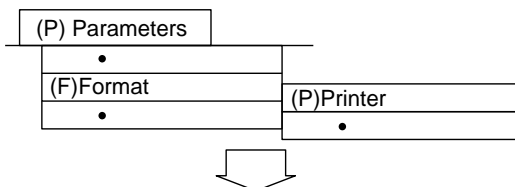
1. Select [Parameters], [Online].
2. Select the "Protocols" tab.
3. Press function key F4 (set).
4. According to the messages displayed, set the online parameters.
5. After the settings are complete, press function key F2 (exit). *Parameters are saved.*

Setting Online Test Numbers

1. Select [Parameters], [Online].
2. Select the "Test No." tab.
3. Press function key F4 (set).
4. Select a test.
5. Press function key F5 (edit). Enter the test number, then select the "Close" button.
6. Repeat steps 3-5 for each test to be set.
7. After the settings are complete, press function key F2 (exit). *Parameters are saved.*

3.8 Format

3.8.1 Printer



Description:

Use this screen to set printer parameters and to add and set parameters for a second printer. The printer can be set to print real-time reports or the usual data log list.

Use this software screen to:

Set general print options:

1. Select [Parameters], [Format], [Printer].
2. Press function key F4 (set).
3. Select the "Lists" field to print list options in the menus.
4. Select the "Batch Report" field to print reports after the sample data for each report is complete.
5. Move the cursor to the "Real-time Print" field. Use the pull-down menu to select:
 - Real-time Reports:** Prints reports on a real-time basis.
 - Data Log List:** Prints the data log list. Reports can be printed in the batch mode after analysis is complete.
 - No Real-time Print:** Nothing will print on a real-time basis

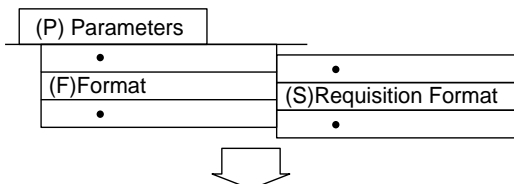
Print batch reports:

1. Select [Parameters], [Format], [Printer].
2. Press function key F4 (set).
3. Select the "Lists" field if you want to be able to print list options in the menus.
4. Select the "Batch Report" field.
5. Move the cursor to the "Real-time Print" field. Use the pull-down menu to select: Data Log List. Press function key F2 (exit) twice.
6. After analysis is complete, select [Routine], [Data Report], [Report], for the reports you want to print. Set the index from the pull-down menu.
7. Select the sample type and sample number or ID to print.
5. If you want to add a report operator name, or restrict the printing by a certain sex and/or age, select function key F5 (search add). From the "Sex" field, use the pull-down menu to select male or female. From the "Age" field, enter the age range in years and months. From the "Report Operator" field, enter the name of the person who is printing the reports. To use this option, the coordinates must be set in the [Common Format] screen for "Report Operator." Verify the "Output Test" field is set to "All Test" to print. Select "Yes."
6. Select function key F3 (print). *Start printing? OK*
7. *Optional: Select function key F6 (list pending) to print a list of samples that have not had a report printed yet.*

Set up a second printer:

1. First set the "second printer" field to "Yes" located in [Parameters], [System], [Option].
2. Select [Parameters], [Format], [Printer]. *Set the second printer fields for use as required in your laboratory.*

3.8.2 Requisition Format



The screenshot shows a software interface titled "Requisition Format". At the top, there is a status bar with "STANDBY" on the left, a series of control icons (play, stop, next, square, printer, warning, printer) in the center, and the date and time "1998/08/03 10:10" on the right. Below the title bar, the screen is divided into sections. The "Requisition Format" section contains three checkboxes: "Sample ID" (checked) with a text field containing "20", "Sex", and "Age". Below this is the "Patient Information" section, which has a table with three columns: "Attribute", "Title", and "Digits". There are six rows, each with a checkbox, a dropdown menu, a text field, and a text field. The first row has a checked checkbox, a dropdown with a checkmark, and two empty text fields. The second row has an unchecked checkbox, a dropdown with a checkmark, and two empty text fields. The third row has an unchecked checkbox, a dropdown with a checkmark, and two empty text fields. The fourth row has an unchecked checkbox, a dropdown with a checkmark, and two empty text fields. The fifth row has an unchecked checkbox, a dropdown with a checkmark, and two empty text fields. The sixth row has an unchecked checkbox, a dropdown with a checkmark, and two empty text fields. At the bottom of the screen, there are several buttons: "Help", "Exit", "Set", and three empty buttons. In the bottom right corner, there is a button labeled "ALARMCLEAR".

Description:

This screen is used to program patient demographics as part of the test requisition screen. It is also used to determine the number of digits in the sample ID barcode and the format for demographics for the "TRI" message. The titles are "user programmable" as are the maximum number of characters (20) and the type of response expected (text or numeric). Once the responses are defined in this screen, responses can be entered in the [Test Requisition] screen for each requisition. The patient information titles and response information from demographics will then print out on a formal report.

Use this software screen to:

Adding patient demographic information:

Conditions related to sample requisition will be displayed. Set the display conditions, etc., for sample requisition.

1. Select [Parameters], [Format], [Requisition Format].
2. Press function key F4 (set).
3. Set the following:

Sample ID: Select the check box for the sample ID to be in use. Enter the number of sample ID digits in use. (20 characters maximum). The number of ID digits defined here determines the ID field length that communicates with the host.

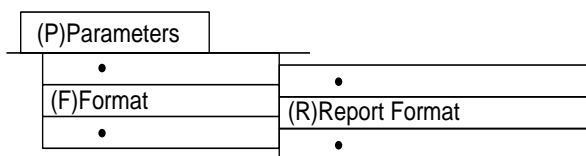
Sex (Optional): Select the check box for the sex field to be available for entry in the [Test Requisition] screen.

Age (Optional): Select the check box for the age field to be available for entry in the [Test Requisition] screen.

Patient Information (Optional): Select the check box. The "Attribute" can be set to "Characters" or "Value." Set the "Characters" field to enter titles from the [Test Requisition] screen. Set to "Value" field to enter a numerical value which can be used in the [Calculated Test] screen as a constant to pull up demographic information. From the "title" field, enter the title you want to appear in the [Test Requisition] screen and on the formal report. A maximum of 20 digits can be entered.

3. After completion, press function key F2 (exit) twice. *The settings are saved.*

3.8.3 Report Format



Description:

This screen defines how a report is formatted, what information is included and its position on the page. The locations are set in X (horizontal) and Y (vertical) coordinates. The layout of the page is also defined here. Up to five different user defined reports can be formatted.

Use this software screen to:

Format a report:

1. Select [Parameters], [Format], [Report Format].
2. Select function key F4 (set).

Report Name: Enter the name of the format report.

Sheet Type: Enter a number between 1 and 4. There are four possible sheet types. [1]

Change Page: Select the check box to print one report per page. [√]

Page Width: enter 80 for 8 1/2 by 11" paper maximum width. [80]

Sheet Type 1: Maximum column is 80, line 66.

Sheet Type 2: Maximum column is 40, line 66.

Sheet Type 3: Maximum column is 26, line 66.

Sheet Type 4: Maximum column is 20, line 66.

Page Length: Enter a value between 1 and 66. (66 is the maximum paper length). [66]

Test Name: Select abbreviated, user (full), or none (no test names will print) using the pull-down menu by this field. [Abr.]

Result Print: Set to [Fix] to print all test names in established coordinates on the page.

Set to [Seq.] to print only the test names that were requisitioned on a sample without any blank space between test names. Use the pull-down menu to make a selection.

		C. L
Index Date Title:	Enter the coordinates for "Index" to appear on the report.	[4] [8]
Index Date:	Enter the coordinates for the index date to appear on the report.	[10] [8]
Index Time Title:	Enter the coordinates for "Index Time" to appear on the report	[4] [9]
Index Time:	Enter the coordinates for the index time to appear on the report.	[10] [9]
Operator Title:	Enter the coordinates for "Operator" to appear on the report.	[4] [10]
Operator:	Enter the coordinates for the operator name to appear on the report.	[14] [10]
Report Operator Title:	Enter the coordinates for "Report Operator" to appear on the report.	[4] [11]
Report Operator:	Enter the coordinates for the name of the person printing reports.	[11] [11]
Print Date Title:	Enter the coordinates for "Print Date" to appear on the report.	[4] [12]
Print Date:	Enter the coordinates for the print date to appear on the report	[10] [12].
Print Time Title:	Enter the coordinates for "Print Time" to appear on the report.	[4] [13]
Print Time:	Enter the coordinates for the print time to appear on the report.	[10] [13]]

2. Select the "Sample" tab located in the upper left corner of the screen.

		C. L.
S. No. Title:	Enter the coordinates for "S. No." to appear on the report.	[4] [14]
S. No.:	Enter the coordinates for the sample number to print on the report.	[10] [14]
S. ID Title:	Enter the coordinates for "S. ID" to appear on the report	[4] [15]
S. ID:	Enter the coordinates for the sample ID (barcode #) to appear on the report.	[10] [15]
Type Title:	Enter the coordinates for "Type" to appear on the report.	[] []
Type:	Enter the coordinates "serum" or "urine" types appear on the report.	[] []
Sex Title:	Enter the coordinates for "Sex" to appear on the report	[4] [16]
Sex:	Enter the coordinates for male "M" or female "F" to appear on the reports.	[10] [16]
Age Title:	Enter the coordinates for "Age" to appear on the report.	[4] [17]
Age:	Enter the coordinates for the patient's age to appear on the report.	[10] [17]
Month Title:	Enter the coordinates for "Month" to appear on the report.	[] []
Month:	Enter the coordinates for the month of birth to appear on the report.	[] []
Patient INF-1 Title	Enter the coordinates for "Patient INF-1" to appear on the report	[4] [18]
Patient INF-1:	Enter the coordinates for the first user defined patient information to appea	[12] [18]

3. Select the "Result Fix" tab located in the upper left corner of the screen.

Select the check box for the "Test Result Print" field, and the "Name Print" field. Enter the coordinates for: test results, normal range, unit, and data flags to appear on the report. The "Spaces Name and Test Result" field is the number of spaces that will be placed between the test name and the test result.

Coordinates must be entered for each of the on-board tests that need to print on the formal report. Use the << >> buttons by the "Test Name" field to enter coordinates for all necessary tests. It will be necessary to increase the row coordinate by one for each test to print consecutively. Example for the next test [AST] all row coordinates are set to 26, [GLU] row coordinates are set to 27. Continue until all tests are completed.

4. Select the "Comment" tab located in the upper left corner of the screen.

A total of 20 possible comments can be entered. For each comment, enter the coordinates for the comment to print, the contents of the comment and the direction of the comment (horizontal or vertical).

5. Press function key F4 (set) if necessary

6. Highlight the comment number to enter.

7. Press function key F5 (edit). *A window appears.*

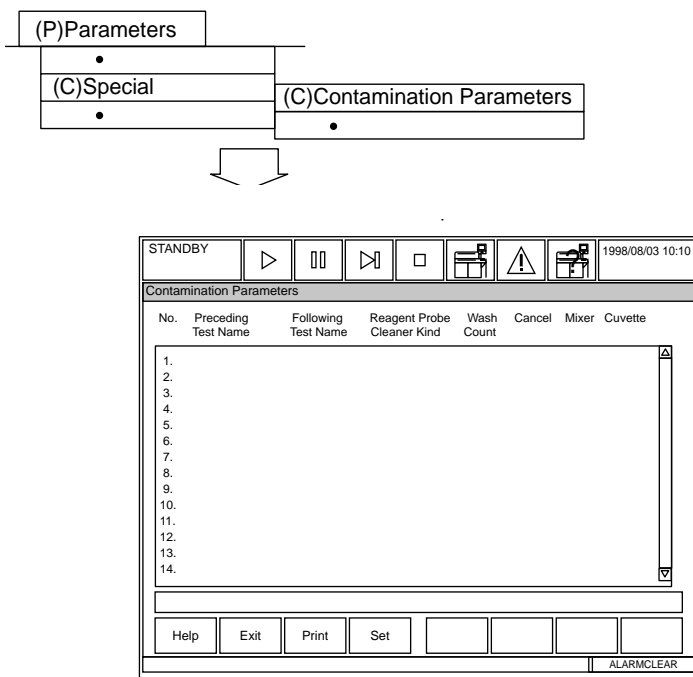
8. Enter the columns, lines, contents and direction.
9. Press the "Close" button.
10. Select the "Line" tab located in the upper left corner of the screen. A total of 50 lines can be added to reports. Enter the coordinates, length, and direction of each line to be drawn on the report. Line directions can be set to H (horizontal), or V (vertical). Press function key F5 (edit). *A window appears.* Select "Close" when finished.
11. Press function key F2 (exit) twice.
12. Select [Parameters], [Format], [Requisition Format]. Program any required patient information which can be entered in the [Test Requisition] screen and can print on the report.
For more information, refer to [Parameters], [Format], [Requisition Format] located in this chapter.
13. Program the printer.
For more information, refer to [Parameters], [Format], [Printer] located in this chapter.

Print a report according to the set parameters:

1. Select [Parameters], [Format], [Report Format].
2. Press function key F7 (format print). *A window to start printing is displayed.*
3. Select "OK." *Printing begins.*

3.9 Special

3.9.1 Contamination Parameters



Description

Use this screen to program a decontamination protocol when reagent cross-contamination is suspected. Enter the suspected test(s) in the "Preceding Test Name" and the affected test in the "Following Test Name". Choose what action the instrument should take if the identified tests are run consecutively.

Use This Software Screen to...

Set a Contamination Table

A maximum of 100 test combinations can be defined in contamination parameters.

1. Select [Parameters], [Special], [Contamination Parameters].
2. Select F4 (set).
3. Select the line number to begin with.
4. Select F5 (edit). *A window appears. (See the following page for information on each prompt.)*
5. When the parameter settings are completed, select "Close." *The parameters will be saved.*

Note

To delete a line of cross-contamination parameters, select the line. Select F5 (edit). Set the preceding test name to "None." Select the "Close" button.

All

The "All" option is selected from the pull-down menu where reagent tests are selected. If the "All" option is selected, extra wash cycles are implemented for the reagent probe to minimize contamination for the R1 and R2 of all tests items preceding the affected test.

Preceding Test Name

Use the pull-down menu to enter the test that causes contamination. *The operator is not permitted to specify an analysis test assigned to inter-test calculation. If "None" is selected, no other field can be accessed.*

Following Test Name

Use this column to enter the test that is affected by the preceding test. *"Following" tests can be set only if a "preceding" test has been set. Other conditions are the same as those for "Preceding."*

Cleaner Kind

Select solution for cleaning the reagent probe. Pull down menu options: Water, CLN1, CLN2, CLN3. CLN (1-3) are user-defined solutions used for extra probe washes during decontamination.

Refer to the Contamination Parameters section in the Method Parameters section for Beckman Coulter recommendations for specific test contamination requirements.

The designated CLN solution(s) are loaded in the reagent compartment. Assign the CLN position in [System Status], [Reagent Status]. The preferred positions are No 1, 2, and 3 in successive order. Double click a reagent position to enter edit mode. Select CLN-1, 2 or 3.

Wash Count

Enter a number 0, or 1-5. This is how many times the affected unit is washed.

Cancel

If cancel has a ✓, the analyzer will not perform the cleaning cycle with the appropriate cleaner if the probe has aspirated the contaminating reagent and has been able to run and wash with water for five cycles prior to aspirating the affected reagent. If cancel does not have a ✓, the probe will wash with the appropriate cleaner this occurs under all conditions. *Beckman Coulter strongly recommends against using the ✓ (except where indicated) because special wash procedures will NOT occur if the instrument goes to measure 2, stop, pause, or standby and restarts testing sensitive tests.*

Mixer (Mix Bar)

When this option is selected, the mix bar used for the test listed in the "Preceding" column will not be used for the test listed in the "Following" column.

Cuvette

Selecting this option instructs the instrument to avoid using the same cuvettes for selected tests.

Example:

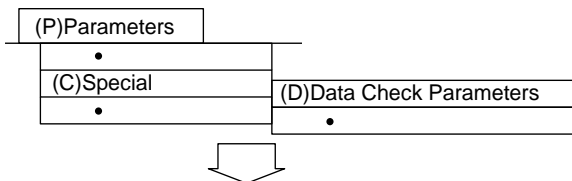
[PARAMETERS], [SPECIAL], [CONTAMINATION PARAMETERS]

No.	Preceding Test Name	Following Test Name	Reagent Probe Cleaner Kind	Wash Count	Cancel	Mixer	Cuvette
1	HDL-C	Lipase	CLN 1	3	No	Yes	No
2	LDL-C	Lipase	CLN 1	3	No	Yes	No
3	HDL-C	Lipase	CLN 1	3	No	Yes	No

Note

The above example is representative of the display screen seen when reviewing the contamination parameters. This screen uses "Yes" and "No" as indicators. When editing or programming contamination parameters "Yes" ✓ = Yes, "No" ✓ = No.

3.9.2 Data Check Parameters



STANDBY 1998/08/03 10:10

Data Check Parameters

Test Name: 1.Alb Type: Serum

Logic Check-1 Logic Check-2 Logic Check-3

Check Point-1: Check Point-1: Check Point-1:
Check Point-2: Check Point Interval: Check Point Interval:
Check Point-3: Decision Value-1: Decision Value-1:
Decision Value-1: Decision Value-2: Decision Value-2:
Decision Value-2: Limit Point 1: Limit Point 1:
Decision Value-3: Limit Point 2: Limit Point 2:
Limit Point 1:
Limit Point 2:

Help Exit Print Set Test No.

ALARMCLEAR

Description:

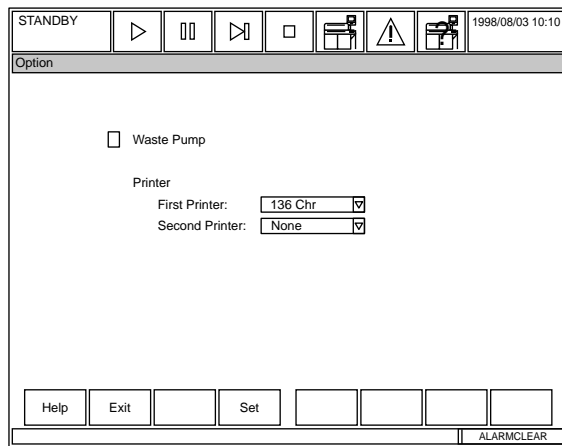
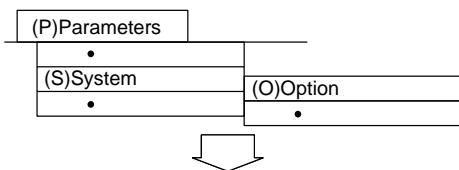
This screen is not used for routine analyzer functions. For the operator's general information, this screen is used to set-up check points and decision limits to detect 1 of 4 different abnormal reaction types for prozone effects in an increasing turbidimetric assay. For detailed procedures, contact a qualified Beckman Coulter representative.

See Also

For parameters, refer to C-Reactive Protein, Ferritin, IgA, IgG, and IgM located in the Methods Chapter.

3.10 System

3.10.1 Option



Description:

This screen is used to set up optional analyzer equipment such as an external automatic drainage unit and an additional printer.

Use this software screen to:

Display optional equipment settings:

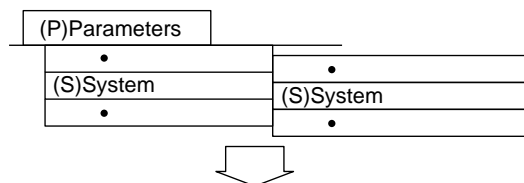
Current settings for the optional equipment can be referred to as required. The following optional conditions can be displayed.

- Waste pump
- Number of print characters for a standard printer
- Additional printer and number of print characters

Set optional conditions:

1. Select [Parameters], [System], [Option].
2. Press function key F4 (set).
3. Set the optional conditions using your mouse. Waste pump: Select the check box to add an external waste pump. First printer: Select 80, or 136. Second printer: Select none, 80, or 136
4. Press function key F2 (exit) twice.

3.10.2 System



The screenshot shows the 'System' menu interface. At the top, there is a status bar with 'STANDBY', navigation icons, and the date/time '1998/08/03 10:10'. The main area is titled 'System' and contains several settings:

- Test Requisition:** Routine: Sequential, Emergency: Sequential, STAT: Sequential. Auto/Standard Repeat: Standard.
- Barcode:** Type: NW7, Digits: (empty), Check Mode: No (No Chk. Chr).
- Rack No. Limit:** A table with columns for Serum, Urine, and Others, and rows for Routine, Emergency, Repeat Routine, and Repeat Emergency.

	Serum	Urine	Others
Routine:	0100	9999	
Emergency:	0100	9999	
Repeat Routine:	0100	9999	
Repeat Emergency:			

At the bottom, there are buttons for 'Help', 'Exit', 'Set.', and 'ALARMCLEAR'.

Description:

Use this menu to set the analysis mode for routine, emergency and STAT samples. Analysis mode options:

1. Sequential
2. Rack No. (Rack ID number determines sample number.
Example Rack #1 = 1-10, #2 = 11 - 20 etc.)
3. Barcode

The barcode parameters are programmed. The upper rack ID limit number for serum, urine, or other samples is designated. The repeat mode is set to auto or standard (manual).

Caution

When Test Requisition is set to Sequential, check the setting for Test Requisition Information Receive in [Parameters] [Online]. If it is set to Real Time, the instrument will query the host computer for the next sample requisition in the database and test the sample accordingly unless a manual requisition has been entered. This can result in the wrong S.ID being associated with the test results.

Use this software screen to:

Enter system set-up parameters:

Set system set-up parameters such as an analysis method and barcode specification.

1. Select [Parameters], [System], [System].
2. Press function key F4 (set).
3. Set the following: test requisition, barcode, rack number limit, and auto/standard repeat.

Test requisition: Set an analysis method. Possible choices are: "Sequential," "Rack No.," or "Barcode."

See Also

For detailed information about analysis methods, refer to the System Outline Chapter.

Barcode Specification: Set a type of barcode, the number of digits, and a check mode.

The following restrictions apply if either ISBT-128 or Mixed is selected from the barcode types:

If ISBT-128 is selected:

- Check that the mode is set to Yes
- The number of digits should be set to 13
- The first and last two characters on a barcode label are automatically ignored

If "Mixed" is selected:

- If no digit number is set, only the barcodes with readable digits can be recognized for the 2 of 5 interleaved and 2 of 5 standard types. For example, even if the MSD or LSD of a barcode cannot be read due to poor positioning of the label, the error will not be judged as incorrect. Position a barcode label correctly on a sample container.
- An ISBT-128 barcode is handled as a CODE-128 barcode.

The number of digits should be 20 characters or less. To leave blank, enter a space.

See Also

For detailed information about applying barcode labels, refer to "Preparing Samples and Racks" located in the Basic Operations Chapter.

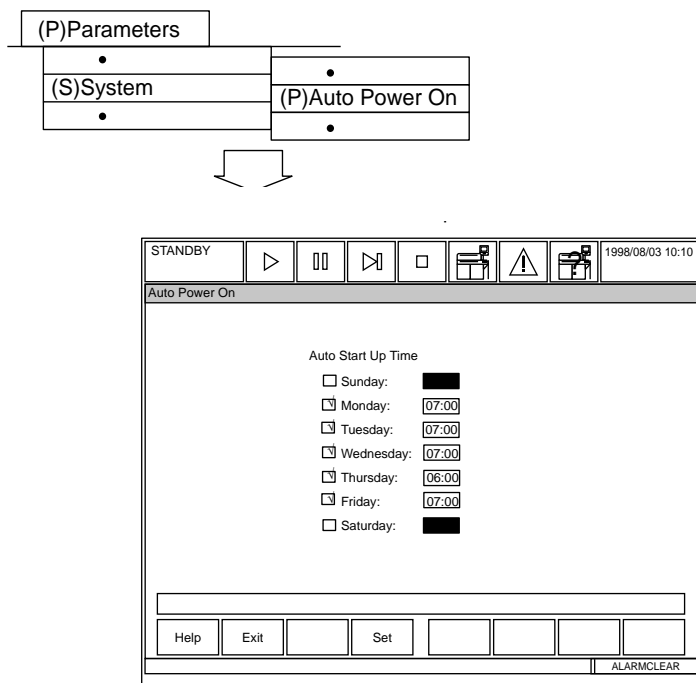
Rack No. Limit: Set the upper limit of rack numbers that can identify samples by their type. *For example: If the upper limit for routine serum sample racks is 100, the next number "101" will be identified as a urine sample rack. For routine and emergency samples, enter a value that satisfies "Upper limit of serum's rack No. ≤ Upper limit of urine's rack No."* For repeat-run samples, enter a value that satisfies "Routine sample (serum), Routine sample (urine), Routine sample (other). Emergency sample (serum), Emergency sample (urine), Emergency sample (other)." To set "No designation," enter a space.

Auto/Standard repeat: Set whether repeat run is performed automatically or manually.

Manual repeat run:	Set to "Standard"
Automatic repeat run:	Set to "Auto"

4. After settings are complete, press function key F2 (exit). *The settings are saved.*

3.10.3 Auto Power On



Description:

Use this screen to select an automatic power-on time and/or to perform a W1, photocal, or both when the instrument is powered-on. The system requires approximately 30 minutes from power-on for the photometer lamp to warm-up. Set this screen using military time.

Auto Start Up Time: Set a day and time to power-on the instrument.

Auto Preparation: Check the box in this column to perform the maintenance item(s) that were set-up in system maintenance. In system maintenance, it is possible to select a W1, a photocal or both.

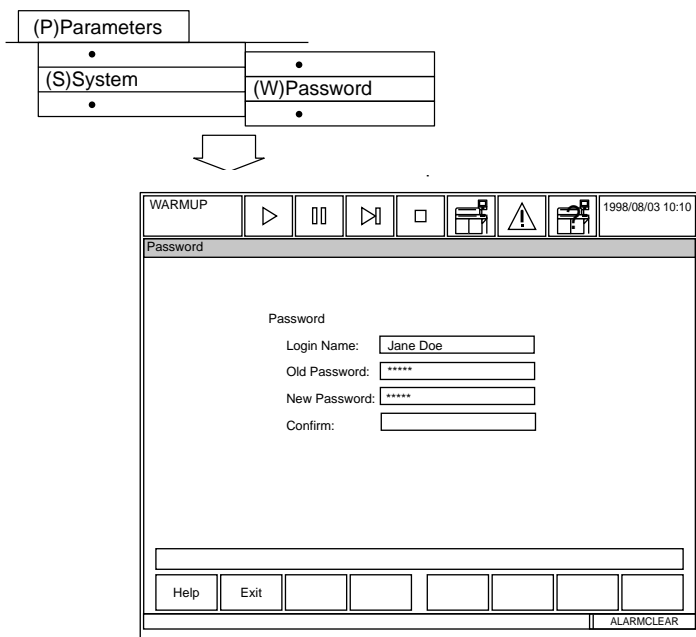
Use this software screen to:

Set an auto start-up time:

A list of auto start-up times are displayed here. It is possible to set a time to automatically start-up the system every week.

1. Select [Parameters], [System], [Auto Power On].
2. Press function key F4 (set). A cursor appears in the auto-start time column for "Sunday."
3. Use your mouse to select the check box by the day of the week. A check will appear in the box when the day is selected. Enter each auto start time in the corresponding field. Use the "HH:MM" format in military time.
4. After settings are complete, press function key F2 (exit). The settings are saved. 3.10.4 Password

3.10.4 Password



Description:

Use this screen to create a password, or change a password. This screen is activated in [Parameters], [System], [Login Name].

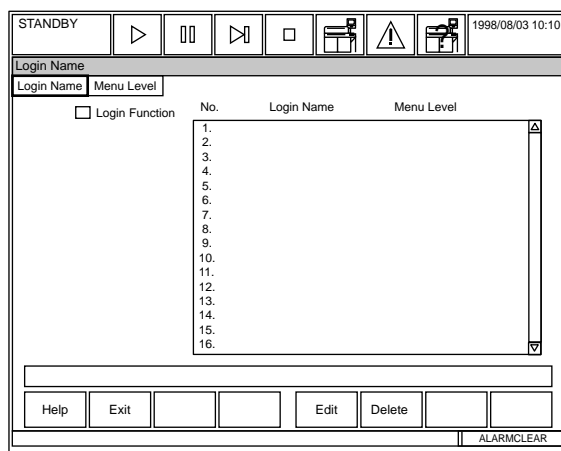
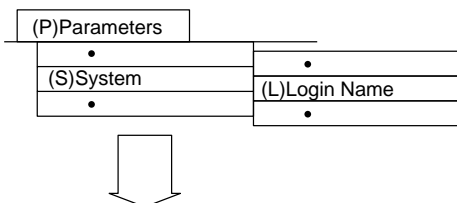
Use this software screen to:

Set up passwords:

A password system can be set up and customized for your laboratory requirements. All submenus have the ability to be selectively password protected.

1. Select [Parameters], [System], [Password]. *If the log-in function is disabled, the password screen will not display.*
2. Enter the old password. *If this is the first time a password is entered, just press the enter key.*
3. In the "New Password" field, type in your new password.
4. Enter the same password in the "confirm" field and press enter.
5. Select function key F2 (exit). *The new password is set, if the old and new passwords were typed consistently.*

3.10.5 Login Name & Menu Level



Description:

In order to restrict a user with the log-in/log-out function, it is necessary to set up a login name and menu level in advance. The maximum security level is 1 and the minimum security level is 10. A maximum of 30 login names and login levels can be set.

Use this software screen to:

Set a new log-in name and menu level:

1. From the main menu select [Parameters], [System], [Login Name].
2. Check the log-in function box.
3. Use the mouse to place the cursor under the log-in name column.
4. Select function key F5 (edit). *A window appears.*
5. Enter a log-in name. *Use 20 characters maximum.*
6. Enter a password. *Use 20 characters maximum.* Then confirm the password in the "Confirm" field.
7. Enter a menu level number between 1 and 10. Security levels from 1 to 10. A "1" has the most menu access, and a "10" the least menu access.
8. Select "Close" and press function key F2 (exit). *The change will not be enabled until the next power on.*
9. Select the Menu Level Tab. Enter the menu access level for each menu. The default menu level is 1, which is the highest security level. Be sure to program menus required for basic operation at level 10 so all operators have access.
10. Select function key F2 (exit). The message "This function will not be enabled until next Power On" displays.
11. Perform an End Process.
12. Press the green ON button. After function key F2 (exit) is selected from [Routine], [Start Condition], the Login Window appears.

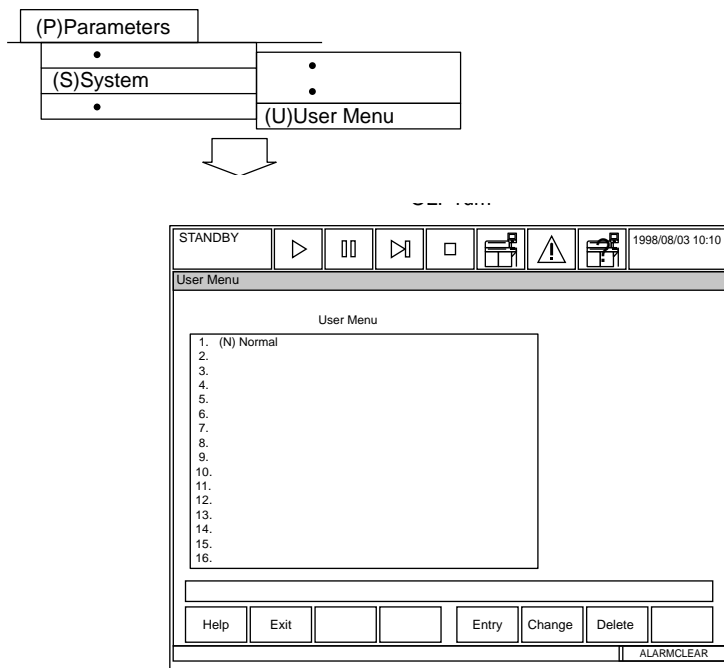
Edit a log-in name:

To edit a log-in name or menu level, select function key F5 (edit). Make your changes then select "Close."

Delete a new log-in name:

To delete a log-in name, select function key F6 (delete). *A window will appear confirming the deletion.* Select "OK."

3.10.6 User Menu



Description:

Use this screen to add frequently used menu options to the user menu. A maximum of 16 frequently used menus can be added from [Routine], [Parameters], [Auxiliary], and [Maintenance]. Once a list is created in this screen, it will appear in the “User” menu located on the main menu bar.

Use this software screen to:

Customize the user menu:

1. Select [Parameters], [System], [User Menu].
2. Using your mouse, select a blank line.
3. Press function key F5 (entry). *A window appears.*
4. Select the first screen to be part of the [User Menu] with your mouse.
5. Select "OK." *The menu selected will now appear as part of the User Menu.*
6. Use the mouse to select a new line.
7. Repeat steps 2 through 5 until all the screens you want to add are part of the User Menu.
8. Press function key F2 (exit).
9. When [User Menu] is selected from the Main Menu, a pull-down window of the added screens will appear.

Delete a menu item:

1. Move the cursor on the menu item and press function key F7 (delete). *A window to confirm the deletion will be displayed.*
2. Select "OK." *The screen where the cursor is positioned will be deleted. Screens below this line will be shifted up one line.*

Modify a shortcut key or screen name:**Warning**

Do not modify the software names unless instructed to do so by authorized Beckman Coulter personnel!

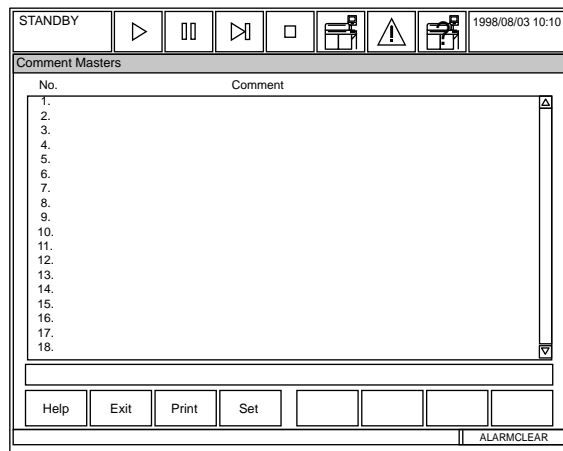
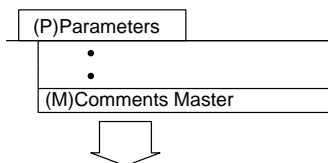
1. Move the cursor over a screen for which the shortcut key or name is to be modified, then press function key F6 (change). *A window to modify shortcut keys and menu names will be displayed.*

Tips

To stop this operation, press cancel at any time. *The [User Menu] screen will be restored.*

2. The cursor will appear in the "Title" field.
3. Enter 30 characters or less. Select "OK."
4. Select function key F2 (exit).

3.11 Comment Masters



Description:

Use this screen to create or edit a list of saved comments. Comments created here can be accessed by selecting a number from any screen where a "Comment" function is available such as the QC and calibration screens. Up to 240 comments can be added in this screen.

Use this software screen to:

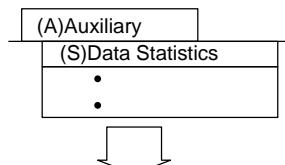
Create and edit comments:

1. Select [Parameters], [Comment Master].
2. Press function key F4 (set). *A cursor appears over the first available line number.*
3. Select function key F5 (edit). *A window appears.*
4. Enter a comment up to 50 characters maximum.
5. Select "Close."
6. Press function key F2 (exit) twice. *The settings are saved.*

4. *Auxiliary Menu Operations*

4.1	Data Statistics.....	D-140
4.2	Correlation Chart	D-142
4.3	Histogram	D-144
4.4	Reagent Consumption.....	D-146
4.5	Reagent Inventory	D-147a
4.6	Parameters Management	D-148
4.7	Calibration Verification	D-149
4.8	Standby Set	D-151

4.1 Data Statistics



Description:

This screen allows selection of the samples to be used in generating sample statistics. Statistics include the number of samples, mean, SD, CV, range, and min./max. value. Statistics can be calculated for routine, emergency, STAT, serum, urine, or other samples.

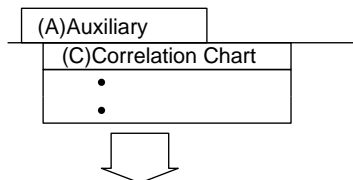
Use this software screen to:

Display statistic calculation results:

1. Select [Auxiliary], [Data Statistics].
2. Use the pull-down menu by the index field to select a range of indices to use in the calculations.
3. Specify a type of sample for statistic calculation. *Using your mouse, select the check box of your choice: Serum, Urine, or Other; Routine, Emergency, or STAT.*
4. Move the cursor to the "Sample No." column and enter a range of samples to be used in the calculations. *A sample ID range can also be entered. To specify the entire range of samples enter an "*".*
5. After calculation, the results are displayed in a list. Press function key F5 (Data Display). The following data will be displayed in a list:
 - Specified index date and time
 - Sample type of the selected sample(s)
 - Number of samples selected
 - Sample Numbers
 - Number of samples (N), mean, Standard Deviation (SD), CV(%), Range, Maximum Value, and Minimum Value of each test.

6. Press function key F3 (print). *A window to start printing is displayed.*
7. Select "OK." *Printing begins.*
8. Optional Step: To add a search key, select function key F6 (search add).
Set "Sex," "Age (Low and high limit)," and 6 types of demographics.
Select "Yes." The settings will be saved as search keys.
Note: An asterisk (*) can only be used if specific demographic fields are used in sample processing.

4.2 Correlation Chart



The screenshot shows the 'Correlation Chart' software interface. At the top, there is a status bar with 'STANDBY' and several control icons. Below this, the title 'Correlation Chart' is displayed. The main area contains several input fields: 'Index' (set to '1. 05/28/1998 12:30'), 'X-Test Name', and 'Y-Test Name'. Below these are three sections for selecting tests: 'Serum', 'Urine', and 'Others'. Each section has three rows of checkboxes for 'Routine', 'Emergency', and 'STAT' tests, with corresponding sample number ranges. At the bottom, there are buttons for 'Help', 'Exit', 'Display Chart', 'Search Add', and 'Test No.', along with an 'ALARM/CLEAR' indicator.

Description:

Use this screen to select tests and the database to be used in determining the statistical correlation between two tests.

Use this software screen to:

Create statistical correlations between tests:

The operator is allowed to specify a search key for searching the data on the correlation diagram after statistical calculation. However, a correlation diagram cannot be produced for serum samples versus urine samples.

First specify the test name of analysis tests to be displayed by a correlation diagram. Analysis tests must be assigned both for the X- and Y- axis. However, the analysis test cannot be specified at the same time for the X- and Y- axis. Specify the sample type and sample number range.

1. Select [Auxiliary], [Correlation Chart].
2. Use the pull-down menu by the index field to select an index date and time.
3. Use the pull-down menu by the X and Y test name fields to select tests.
4. Specify a type of sample for statistic calculation. *Using your mouse, select the check box by your choice: serum, urine or other; routine, emergency, or STAT.*
5. Move the cursor to the "Sample No." column and enter a sample number range.

- A sample ID range can also be entered. For sample types that do not need to be specified, enter a space. To specify the entire range of sample types enter an asterisk (*).*
6. Press function key F5 (display chart).

Set the display conditions for a correlation diagram:

By setting the display parameters for the X and Y axis of a correlation diagram, it is possible to modify the display size of a correlation diagram.

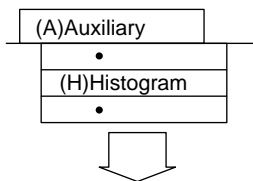
1. Press function key F6 (change axis). *A window to set-up display parameters appears.*
2. Set the display condition to either Auto or Manual and press the Enter key. *If "Auto" is selected, the correlation diagram displays at the largest possible size in which all the data can be viewed. If "Manual" is selected, specify a lower limit and an upper limit for each of the X and Y axis. The specified portion of the diagram enlarges.*

Delete data:

Specific data points can be removed from the correlation calculation. The analysis data itself will not be removed.

1. Press function key F2 (del. data display). *Sample numbers of data points displayed in the correlation diagram will be shown in a list.*
2. Move the cursor to the sample number of the data points to be removed and press the Enter key. *Each time enter is pressed, the selection changes between "Selected" and "Not selected."*
3. After specifying the sample number of data points to be removed, press function key F2 (delete). *A window to start removal is displayed.*
4. Select "YES" and press the Enter key. *The specified data will be removed from the calculation and a recalculated correlation diagram will be displayed.*

4.3 Histogram



The screenshot shows the "Histogram" software interface. At the top, there is a "STANDBY" indicator and a row of control icons including play, pause, stop, and alarm symbols. The date and time "08/03/1998 8:10" are displayed in the top right corner. The main area is titled "Histogram" and contains several fields: "Index:" with a pull-down menu showing "1. 07/29/1998 12:30", and "Test Name:" with a pull-down menu showing "1. Alb". Below these are three sections: "Serum", "Urine", and "Others". Each section has checkboxes for "Routine", "Emergency", and "STAT" next to a table with columns for "Sample No." and "Sample ID". The "Serum" section has sub-columns for "(nnnn - nnnn)", "(Ennn - Ennn)", and "(Pnnn - Pnnn)". The "Urine" section has sub-columns for "(nnnn - nnnn)", "(UEnnn - UEnnn)", and "(UPnnn - UPnnn)". The "Others" section has sub-columns for "(nnnn - nnnn)", "(XEnnn - XEnnn)", and "(XPnnn - XPnnn)". At the bottom, there is a row of buttons: "Help", "Exit", "Chart Display", "Data Display", "Search Add", and "Test No.". An "ALARMCLEAR" button is located at the bottom right.

Description:

Use this screen to select the database to be used in generating histograms. Histograms can be calculated for routine, emergency, and stat serum or urine samples. The number of samples, mean, SD, CV, range, and min./max. statistics will be calculated and displayed with the histogram. The data indicating the number and percent of samples in each bar graph can be displayed.

Use this software screen to:

Create a data histogram:

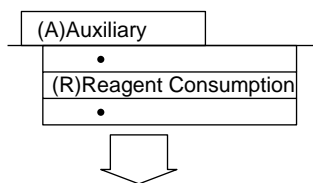
1. Select [Auxiliary], [Histogram].
2. Select an index using the pull-down menu by the index field.
3. Select a test name using the pull-down menu by the test name field.
4. Press function key F5 (chart display). *The normal histogram range displays in blue. The outside range of the histogram displays in yellow.*
To set display conditions:
A number of class intervals within the normal value range can be specified.
 - A. Press function key F5 (change axis). *A window will appear.*
 - B. Set the display condition to either "Auto" or "Manual." *When "Auto" is selected, the number will automatically be set to "7." If "Manual" is selected, specify the number of class intervals to be displayed using a value between 5 and 10. The entered value will be set and displayed in the normal value range.*

5. To print press function key F3 (print). Select "Display test" or "All tests" and select "OK." The "Display tests" selection prints only the data being displayed.

Display histogram information:

1. Frequency distribution and class marks can be referred to by their numerical values. In the [Histogram] screen, select function key F6 (Data Display). The following data will be displayed as a list in the window.
 - Upper and lower limit, number of samples, and % for each class interval.
 - Number of samples lower than the smallest class interval and its % to the whole.
 - Number of samples exceeding the largest class interval and its % to the whole.
2. Press function key F2 (exit). *The window will be closed.*

4.4 Reagent Consumption



STANDBY 1997/09/03 10:10

Reagent Consumption

Index: 1. 08/01/1998 08:24 - 1. 08/01/1998 08:24 Type: Serum

Test	Test Shots						Total Samples	
	ALB	ALP	ALT	AMY	AST	CO2	Total	Samples
Normal Routine	0	0	0	0	0	0	35	7
Emergency	0	0	0	0	0	0	0	0
STAT	0	0	0	0	0	0	0	0
Repeat	0	0	0	0	0	0	0	0
QC	0	0	0	0	0	0	18	3
Calibration	0	0	0	0	0	0	8	1
Reagent Blank	0	0	0	0	0	0	24	2
Total							85	13

Help Exit Print Reagent Volume Test Total Shot Total ALARMCLEAR

Description:

Use this screen to display information regarding the amount of reagent used for each test and the type of sample.

Use this software screen to:

Using the reagent consumption screen:

1. Select [Auxiliary], [Reagent Consumption].
2. Select the index, start date, end date, and sample type by using the pull-down menu located by each field.
3. To check the reagent volume, press function key F5 (reagent volume). The quantity of reagent assigned to R1 displays.
4. To check the reagent volume of R2, press function key F5 (R2). The quantity of the reagent assigned to R2 displays.

The analyzer consumption quantity is calculated as follows:

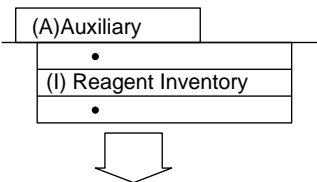
R1 reagent consumption = (Number of tests) x (R1 dispense quantity of individual test parameters + remaining dispense quantity)

R2 reagent consumption = (Number of tests) x (R2 dispense quantity of individual test parameters + remaining dispense quantity)

5. Press function key F2 (exit).
6. Press function key F6 (test total). *The number of tests analyzed within the selected index date and time will display.*

7. Press function key F2 (exit).
8. Press function key F7 (shot total). *The cumulative number of tests for each reagent displays. This includes repeat-run tests.*
9. To print reagent consumption information, select the screen you want to print from and press function key F3 (print). Select "OK" at the prompt.
10. Press function key F2 (exit) twice.

4.5 Reagent Inventory



STANDBY 2000/02/21 00:16

Reagent Inventory

Auto Manual

Start Index: 1. 02/18/2000/19:15 End Index: 1. 02/18/2000/19:15

Shots/Volume: Shots Type: All

Test	Tst01	Tst02	Tst03	Tst04	Tst05	Tst06	Tst07	Tst08
Monday	0	0	0	0	0	0	0	0
Tuesday	0	0	0	0	0	0	0	0
Wednesday	0	0	0	0	0	0	0	0
Thursday	0	0	0	0	0	0	0	0
Friday	18	4	0	41	0	0	2	0
Saturday	0	0	0	0	0	0	0	0
Sunday	0	0	0	0	0	0	0	0

Help Exit Print

ALARMCLEAR

Description:

Use this menu to determine the reagent inventory on board the instrument. This screen will reflect a shortage or surplus of reagents on the system. Under the “Auto” tab the instrument displays its automatic calculation of reagent consumption based on previous usage. Under the “Manual” tab an operator can manually set the expected reagent consumption for each day of the week

Start Index: Select an index to start the range of indices used to compile the data. Use the pull-down menu to select the index.

End Index: Select the final index in the range. Use the pull-down menu to select the index

Shots/Volume: Select the preferred unit of measurement for reagent consumption. The pull down menu contains two options, shots (the number of tests available) or volume in ml.

Type: Select the sample type from the pull-down menu: serum, urine, or other.

Test (Monday-Sunday): This chart displays the mean reagent consumption that has been calculated for each day of the week.

Use this software screen to:

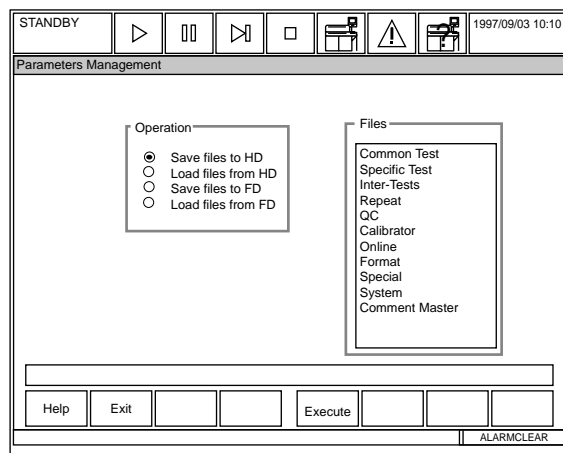
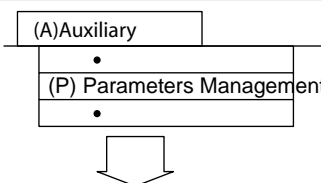
View and print reagent inventory

Press function key F3 (print) to print a reagent inventory.

Manually enter reagent consumption

1. From the main menu select [Auxiliary], [Reagent Inventory].
2. Select the tab labeled "Manual."
3. Move the cursor to the box for the desired test and day of the week.
4. Press function key F4 (edit). *A dialog box will appear.*
5. Enter a value for the expected reagent consumption.
6. Press the "Close" button.
7. Repeat steps 2 through 6 until all settings are complete.
8. Press function key F2 (exit).

4.6 Parameters Management



Description:

Use this screen to load parameters onto or from a formatted parameter disk. After the system is programmed, all parameter files should be saved to a floppy disk. If necessary, files could then be loaded from the floppy disk to avoid reprogramming. Individual files can be saved and loaded.

Use this software screen to:

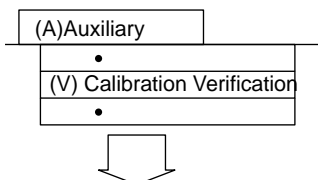
Save or load parameters to/from a back-up file on the hard drive:

1. Select [Auxiliary], [Parameters Management].
2. Using the mouse, select 1 of 4 operation options:
 - Save files to HD:** Parameters stored in a backup file on the hard drive will be overwritten by new parameters saved at this time. Save a copy of the old parameters on a floppy disk if they need to be retained.
 - Load files from HD:** Parameters currently set by each submenu of the [Parameters] menu will be overwritten by the parameters to be loaded. Save a copy of the old parameters on a floppy disk if they need to be retained.
 - Save files to FD:** Saves parameters on a separate floppy disk. Floppy disks for parameter storage have an "AU640PARAM" volume label. They can be formatted using [Maintenance], [FD Data Management].
 - Load files from FD:** Loading will overwrite the parameters set by each submenu of the [Parameters] menu with those which are loaded. Save the old parameters on another floppy disk if they need to be retained.
3. Select any number of parameters to save or load from the "Files" column. The following parameters can be selected: Common Test, Specific Test, Inter-tests, Repeat, QC, Calibrator, Online, Format, Special, System, and Comment Master.
4. Press function key F5 (execute). Select "YES" at the prompt.

Note

If you are using a floppy disk, make sure it is inserted into the drive before selecting "Yes."

4.7 Calibration Verification



The screenshot shows the 'Calibration Verification' screen. At the top, there is a status bar with 'STANDBY', several icons, and the date/time '1998/08/03 10:10'. Below this is a title bar 'Calibration Verification' and a tabbed interface with 'Select Sample' and 'Material Prm.' tabs. The 'Material Prm.' tab is active, showing fields for 'Index:' (1_08/01/1998 12:30), 'Test Name.: 1_Alb', 'Type: Serum', and 'Material No.: 1'. Below these fields is a table with two columns: 'Sample No.' and 'Sample ID', with rows for Level 1 through Level 6. At the bottom, there are buttons for 'Help', 'Exit', 'Display Chart', 'Set S. ID', and 'Test No.', along with an 'ALARMCLEAR' indicator.

Description:

Use this screen to select the data to be used in generating a calibration verification graph. Samples must be processed on the analyzer first.

Use this software screen to:

Perform a calibration verification:

Standard material can be run on the analyzer, and variance from the true values calculated. Up to three replicates of each test level can be plotted on a graph and the variance from the known standard materials displayed.

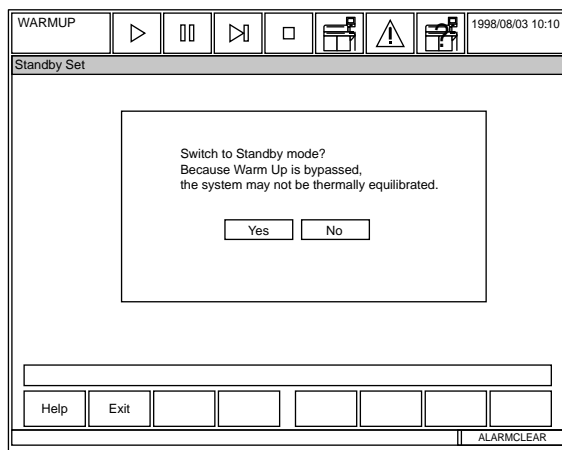
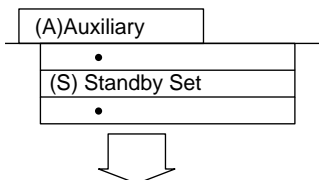
1. Run the standard material in routine racks.
2. Select [Auxiliary], [Calibration Verification].
3. Select an index using the pull-down menu located by the index field.
4. Select the test name and sample type from the pull-down menu located by each field.
5. Select the "Material Prm." tab.
6. Press function key F4 (set). Click on the level check box, then enter an expected value and tolerance. Refer to the package insert for values and tolerance.
7. Press function key F5 (material edit). A window appears. Enter the standard Material Name, Material ID, Expiration Date, and Lot Number. Select "Close."
8. Select function key F2 (exit).

9. Select the "Select Sample" tab. Enter the sample number or sample ID for the first level of samples. Repeat as many times as necessary.
10. Select function key F5 (display chart). A graph of the observed vs. expected values displays with all specified levels on a single graph. The symbols above the graph identify each replicate result. The acceptable tolerance is indicated by a vertical bar on the graph. Numerical values of expected values, observed values, and tolerance display for the first replicate.
11. Use the material number button << >> to change the display of the numerical values to the second and third replicates.
Note: "Change Mtr. No." is actually changing the replicate number that displays. Up to three replicates display.

Options:

1. Function key F5 (analyst initial): Allows the operator to enter their name or initials on the graph.
2. Function key F6 (note edit): Allows the operator to enter a "note" or comment on the graph.

4.8 Standby Set



Description:

Use this screen to shift the analyzer to Standby from a warm-up mode. If the system is in a stop mode, shift to standby using the stop key or icon (square located at the top of the screen). If an emergency stop is performed, the analyzer stays in a warm-up mode for 1.5 hours. Use this screen to bypass the warm-up time if necessary.

Caution

If analysis is performed after shifting to the Standby Mode, results could be compromised since the system temperature did not have time to stabilize completely.

Use this software screen to:

Shift to the Standby Mode:

For procedures, refer to "Standby Mode" located in the Basic Operations Chapter.

5. Maintenance Menu Operations

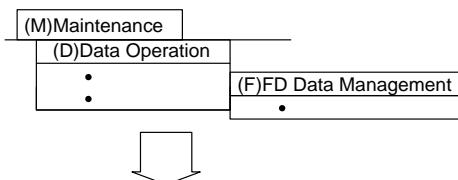
5.1 Data Operation.....	D-154
5.1.1 FD Data Management	D-154
5.1.2 Set Date & Time	D-156
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5.5.5 File Management.....	D-174

Caution

The [Maker Maintenance] submenu should be performed according to the instructions provided by Beckman Coulter Technical Services or authorized service personnel. The [Maker Maintenance] submenu will be used for service, inspection, and repair work performed on this system by service personnel.

5.1 Data Operation

5.1.1 FD Data Management



The screenshot shows the 'FD Data Management' window. At the top, there is a toolbar with icons for play, stop, fast forward, square, floppy disk, warning, and printer, along with a date and time display '1998/08/03 10:10'. Below the toolbar, the window title is 'FD Data Management'. There are three tabs: 'FD Data Save', 'FD Data Display', and 'FD Data Initialize'. The 'FD Data Save' tab is active. Below the tabs, there is a date and time field: 'Index: 1. 08/01/1998 12:30'. The main area is divided into three sections: 'Serum', 'Urine', and 'Others'. Each section has three rows of checkboxes: 'Routine', 'Emergency', and 'STAT'. Each row has two input fields for 'Sample No.' and 'Sample ID', followed by a label in parentheses indicating the format (e.g., '(nnnn - nnnn)'). At the bottom, there are buttons for 'Help', 'Exit', and 'Start Save'. A status bar at the very bottom contains the text 'ALARMCLEAR'.

Description:

Use this menu to save serum, urine or other sample data to or from a 3.5 floppy disk. The floppy disk must be formatted in the FD initialize screen as a data disk. If the disk is formatted as 2HD, 250 samples or 8 indexes can be saved per disk, whichever comes first. If the disk is 2DD, 120 samples or 8 indexes can be saved per disk, whichever comes first.

Use the "FD Initialize" tab to initialize (Format) a floppy disk. Initializing a floppy erases data from an old floppy or prepares a new floppy for use with this system. Floppy disks can be initialized for use as an AU640 parameter disk, or AU640 data disk.

Tips

Before initializing a floppy diskette, always make sure that the data saved on it can be erased. Initialization completely erases all the data on a floppy disk. Erased data cannot be restored.

Warning

Do not remove a floppy disk from the drive while data is being saved. Data may be lost.

Use this software screen to:

Save data to a floppy:

1. Select [Maintenance], [Data Operation], [FD Data Management].
2. Select the index, sample type, numbers or sample ID numbers to save to the floppy.
3. Select function key F5 (start save).
4. Insert the floppy disk. *Select "Yes" at the prompt.*

Load data from a floppy:

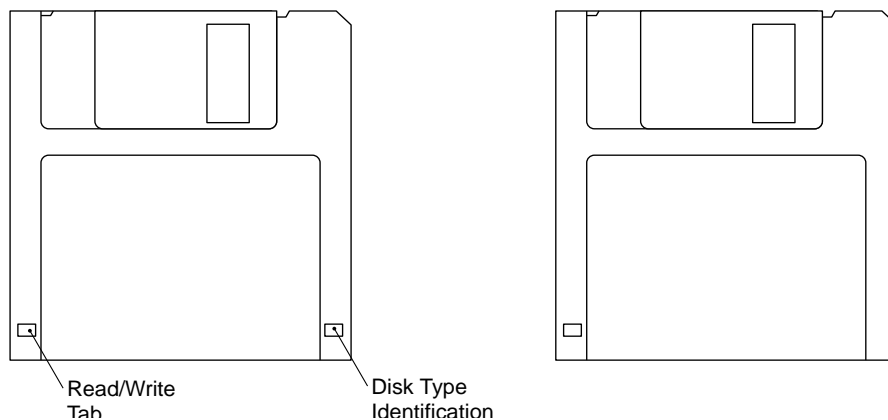
1. Select the "FD Data Display" tab.
2. Select the index, sample type, numbers or sample ID numbers to save from the floppy.
3. Select function key F5 (data disk content).
4. Insert a floppy into the disk drive. Then select "Yes" at the prompt.

Initialize a 3.5" floppy:

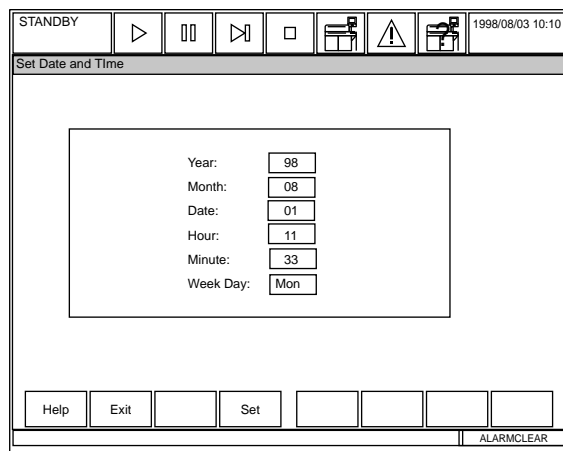
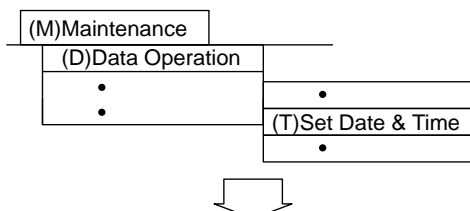
1. Select the "FD Data Initialize" tab.
2. Select the operation: Initialize Parameter FD, Initialize Data FD.
3. Select function key F5 (start initialize). Select "Ok" at the prompt.
Note: 2HD or 2DD indicates the storage capacity of the disk. If unsure, try either option and an error message will appear if the type is incorrect.

2HD floppy disk (1.44 MB)

2DD floppy disk (720 KB)



5.1.2 Set Date & Time



Description:

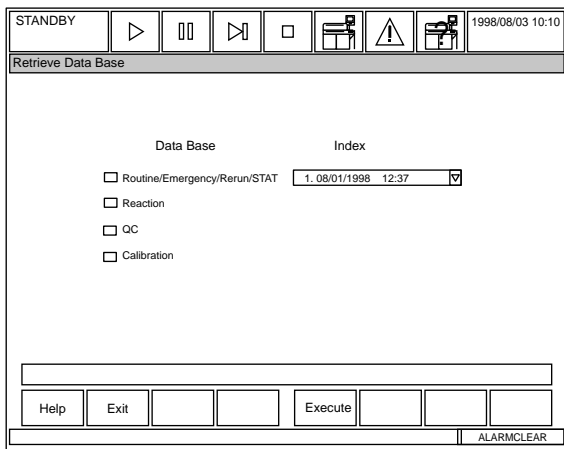
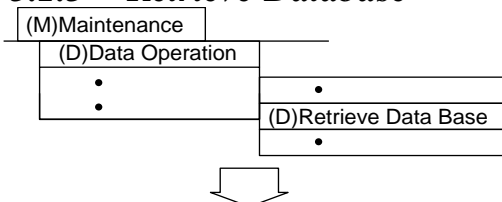
Use this screen to set the system date and time. This real-time clock appears in the upper right corner of the screen.

Use this software screen to:

Set the system time:

1. Select [Maintenance], [Data Operation], [Set Date & Time].
2. Press function key F4 (set). *A cursor appears in the "year" field.*
3. Make the necessary changes. Tab to the next field.
4. After the settings are complete, press function key F2 (exit) twice. *The settings are saved.*

5.1.3 Retrieve Database



Description:

Use this screen if errors occur in the database. Sample data stored on the hard disk is formatted in a database which has index dates and times for use as search keys.

Should an error occur in the database, the sample data may not be searched normally. If this happens, errors generated in the database can be repaired by rebuilding it.

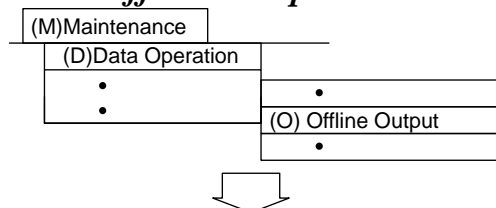
Use this software screen to:

Rebuild a database:

The databases are categorized into the following four types: 1. Routine, emergency, repeat, STAT 2. Reaction. 3. QC. 4. Calibration.

1. Select [Maintenance], [Data Operation], [Retrieve Data Base].
2. Use your mouse to select the type of database to be rebuilt and then select an index using the pull-down menu.
3. Press function key F5 (execute). *A window to start rebuilding displays.*
4. Select "Yes" at the prompt. *The rebuilding of the database begins.*

5.1.4 Off-line Output



Description:

Use this screen to save serum, urine, or other sample data to a 3.5" floppy disk in text format. This screen is used mainly by Beckman Coulter personnel. Data saved in text format cannot be loaded back onto an AU640. To use this function, the online selection in parameters must be set to batch.

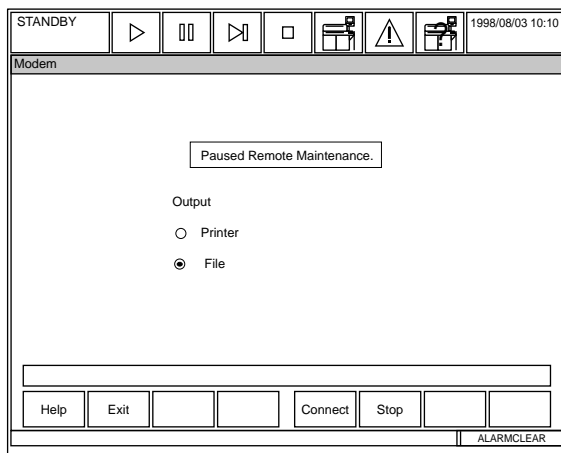
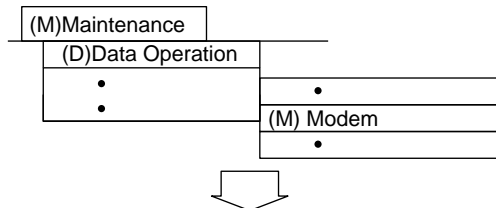
Note: Use the offline delimiter field to select offline punctuation characters. The following characters can be selected from the pull-down list: space, tab, comma, period, semicolon, colon, underline, slash, and pipe.

Use this software screen to:

Save data to floppy disks in text format:

1. Select [Maintenance], [Data Operation], [Offline Output].
2. Select the index, sample type, and range of sample numbers or sample ID numbers to be saved to the floppy.
3. Select function key F5 (Data Send).
4. Insert the floppy disk. Select "Yes" at the prompt.

5.1.5 Modem



Description:

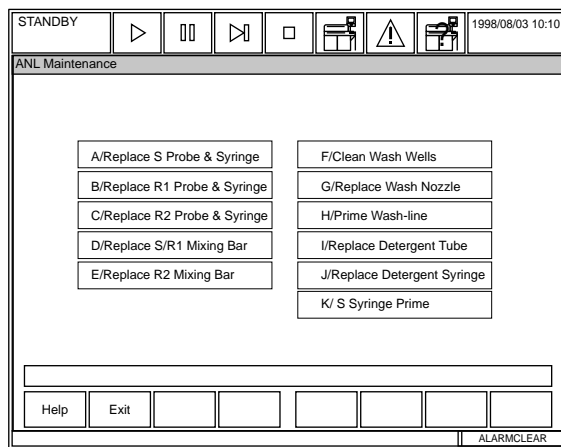
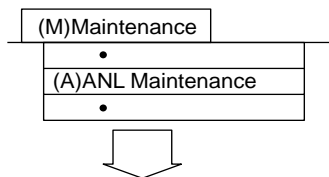
Use this screen to connect to remote technical support provided by Beckman Coulter Technical Services.

Use this software screen to:

Using the modem:

1. Select [Maintenance], [Data Operation], [Modem].
2. Press function key F5 (connect). Select "Yes" at the prompt.
3. To "output" maintenance data to a printer, select "printer." To output maintenance data to a file, select "file."
4. When you are ready to disconnect, select function key F6 (stop).

5.2 Analyzer Maintenance



Description:

Use this screen for performing maintenance procedures.

See Also

For details on maintenance procedures that use this screen, refer to the Maintenance Chapter.

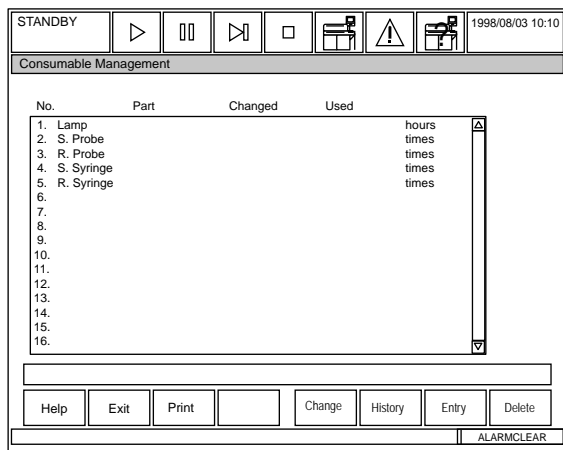
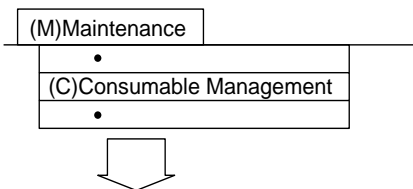
Use this software screen to:

Select a maintenance function:

When performing a maintenance procedure:

1. Select [Maintenance], [ANL Maintenance].
2. Select a maintenance function listed on the screen.
3. Press the STAT ROTATION/DIAG button. *The maintenance process starts.*

5.3 Consumable Management



Description:

Use this screen to track replacement and supply periods of consumables. This list makes it easy for maintenance personnel to schedule consumable purchasing and to observe maintenance periods. When a part achieves its projected life expectancy, the background screen color for that part changes to red. This color change does not indicate that the part must be replaced. To determine when to replace the part, consult the specific part guidelines.

Use this software screen to:

Update the consumable list:

1. After replacing or supplying a consumable, select [Maintenance], [Consumable Management].
2. Use your mouse to click on a part. Press function key F5 (change). Select "OK" at the prompt to register the current data in the "changed" column.

Note: To view a maintenance history, select function key F6 (history).

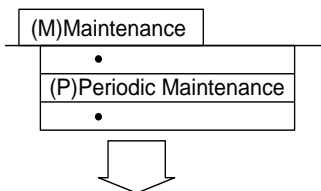
Print the consumable list:

1. Select [Maintenance], [Consumable Management].
2. Press function key F3 (print). *A window to specify the print mode is displayed.*
3. Specify the print mode. Select "Recent" or "History" and press the Enter key.

Recent: The most recent date of supply or replacement will be printed.

History: All the records, including all past dates of supply or replacement and the use values are printed. A message indicating printing is displayed.

5.4 Periodic Maintenance



The screenshot shows a software interface with a title bar containing "STANDBY", navigation icons, and the date/time "11/01/1998 10:10". Below the title bar is a section titled "Periodic Maintenance". It contains a table with the following data:

No.	Maintenance	Period	Executed	Next
1.	Inspect Sample & Reag. Syringes	Daily	11/01/1998	11/02/1998
2.	Inspect Wash Syringes	Daily		
3.	Check the Wash Solution Rolling Pump	Daily		
4.	Inspect the Concent. Wash Solution Level	Daily		
5.	Inspect/Clean the Sample Probes, Reag. Probes & Mix Bars	Daily		
6.	Inspect Printer & Paper	Daily		
7.	Prepare for a Sample Probe Wash	Daily		
8.	W2	Weekly		
9.	Photocal	Weekly		
10.	Photometer Check	Weekly		
11.	Clean Sample & Reagent Probe Wash Wells	Monthly		
12.	Clean the Mix Bar Wash Wells	Monthly		
13.	Clean the Wash Nozzle	Monthly		
14.	Clean the Deionized-Water Tank	Monthly		
15.	Clean the Deionized-Water Filter	Monthly		
16.	Clean the Sample Probe Filter	Monthly		

Below the table are buttons for "Help", "Exit", "Print", "Grid Display", "Execute", "History", "Entry", and "Delete". At the bottom right, there is an "ALARMCLEAR" indicator.

Description:

Use this screen to determine which maintenance items are to be performed and if periodic maintenance was executed on time. Use function key F4 (grid display) to display maintenance in a table format.

Use this software screen to:

Display periodic maintenance for a data list:

Records of previous periodic maintenance procedures can be referred to by selecting a maintenance item. In the [Periodic Maintenance] screen, move the cursor to a consumable and press function key F6 (history). Test names, execution intervals, the last ten execution dates, and future dates will be displayed in a list.

Display the maintenance schedule:

Select function key F4 (grid display) to graphically display the maintenance schedule.

Keep a record of periodic maintenance:

1. Move the cursor to the maintenance procedure that was performed.
2. Select function key F5 (execute). The "executed" date and "next" scheduled date will appear.

Note: The Photocal and W2 are automatically updated for the "executed" and "next" scheduled dates.

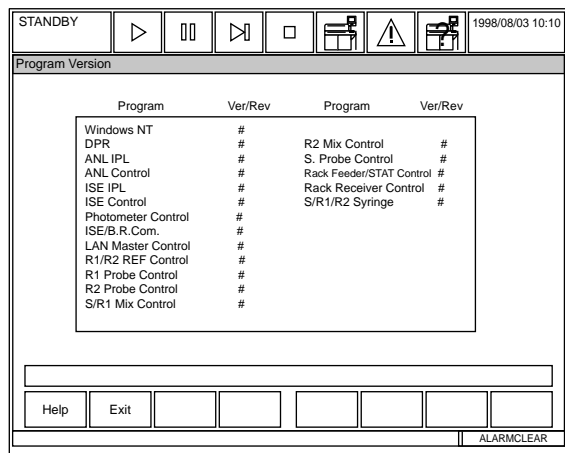
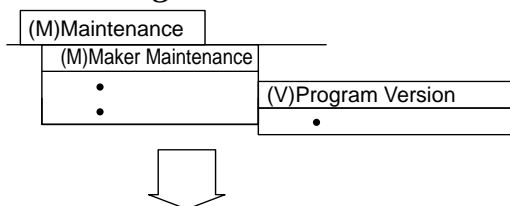
5.5 *Maker Maintenance*

This menu is used by authorized service personnel for service, inspection, and repair work performed on this system.

Caution

The [Maker Maintenance] submenu should be used according to the instructions provided by Beckman Coulter Technical Services or by authorized service personnel. This submenu is used for service, inspection, and repair work.

5.5.1 Program Version



Description:

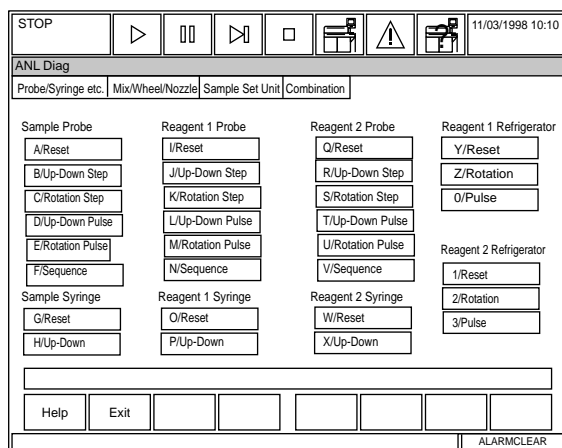
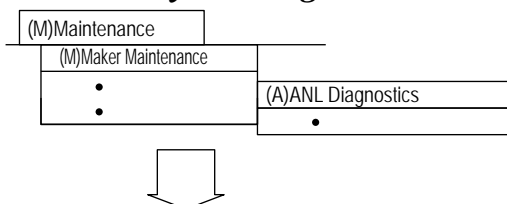
This screen displays current operating software versions.

Use this software screen to:

View current software versions

1. Select [Maintenance], [Maker Maintenance], [Program Version].
2. The screen appears with program, version and revision information.
3. After viewing the screen, press function key F2 (exit) to return to the main menu.

5.5.2 Analyzer Diagnostics



Description:

This menu is used by authorized service personnel for service, inspection, and repair work performed on this system.

Use this software screen to:

Perform analyzer diagnostics:

The analyzer must be in a stop mode before diagnostics can be accessed. The menu consists of 3 pages of mostly hardware components which can be reset or moved in their normal operation to test proper operation when troubleshooting.

1. Select [Maintenance], [Maker Maintenance], [ANL Diag.].
2. Use your mouse to select the item to check. *Explanations of each function follow this procedure.*
3. Press the STAT ROTATION/DIAG Switch on the analyzer to perform the selection.

Explanation of functions:

Sample Probe

A/Reset: Aligns the sample probe in its home position.

B/Up/Down Step: Moves the sample probe 1 step vertically (up/down).

C/Rotation Step: Moves one step between the wash station and items selected. Select the following: From (rack, cuvette, STAT table, or wash/STD table) and To (cuvette, or ISE).

D/Up-Down Pulse: Pulses the sample probe the number of steps specified from 1 to 999 (Up/Down).

E/Rotation Pulse: Pulses the sample probe clockwise or counterclockwise the number of steps specified from 1 to 999.

F/Sequence: Performs a sequence according to the selection.

Rack -Cuvette: Samples from the rack then dispenses into the cuvette.

Rack-ISE: Samples from the rack then dispenses into the ISE

STAT Outer-Cuvette: Samples from an outer STAT table position into the cuvette.

STAT Outer-ISE: Samples from an outer STAT table position into the ISE.

Dil. Cuvette: Performs a dilution.

STAT-Inner Wash: Samples from the inner position of the STAT table.

Sample Syringe

G/Reset: Aligns the sample syringe in its home position.

H/Up and Down: Moves the sample syringe 1 step vertically (up/down).

Reagent 1 Probe

I/Reset: Aligns the reagent probe in its home position.

J/Up and Down: Moves the reagent 1 probe 1 step vertically (up/down).

K/Rotation Step: Moves the reagent 1 probe 1 step horizontally. Select the following: (wash, reagent).

L/Up-Down Pulse: Pulses the reagent probe the number of steps specified from 1 to 999 (Up/Down).

M/Rotation Pulse: Pulses the reagent probe clockwise or counterclockwise the number of steps specified from 1 to 999.

N/Sequence: Performs a complete sequence including movement from the wash well, reagent compartment to cuvette wheel.

Reagent 1 Syringe

O/Reset: Aligns the reagent 1 syringe in its home position.

P/Up and Down: Moves the reagent 1 syringe 1 step (up/down).

Reagent 2 Probe

Q/Reset: Aligns the reagent probe in its home position.

R/Up and Down: Moves the reagent 2 probe 1 step vertically (up/down).

S/Rotation Step: Moves the reagent 2 probe 1 step horizontally. Select the following: (wash, reagent).

T/Up-Down Pulse: Pulses the reagent probe the number of steps specified from 1 to 999 (Up/Down).

U/Rotation Pulse: Pulses the reagent probe clockwise or counterclockwise the number of steps specified from 1 to 999.

V/Sequence: Performs a complete sequence including movement from the wash well, reagent compartment to cuvette wheel.

Reagent 2 Syringe

W/Reset: Aligns the reagent 2 syringe in its home position.

X/Up and Down: Moves the reagent 2 syringe 1 step (up/down).

Reagent 1 Refrigerator

Y/Reset: Resets the R1 compartment.

Z/Rotation: Rotates the R1 compartment according to user specifications (CW, CCW, Step 1-48. For complete rotation select 48.)

0/Pulse: Pulses the R1 compartment clockwise or counterclockwise the number of steps specified from 1 to 999.

Reagent 2 Refrigerator

1/Reset: Resets the R2 compartment.

2/Rotation: Rotates the R2 compartment according to user specifications (CW, CCW, Step 1-48. For complete rotation select 48.)

3/Pulse: Pulses R2 compartment clockwise or counterclockwise the number of steps specified from 1 to 999.

Select the tab located in the upper left corner of the screen called *Mix/Wheel/Nozzle*.

S/R1/Mix

A/Reset: Aligns the mix bar unit in its home position.

B/Up and Down Step: Moves the mix unit 1 step vertically (up/down).

C/Rotation Step: Moves the mix unit horizontally to the next position.

D/Up-Down Pulse: Pulses the mix unit the number of steps specified from 1 to 999 (Up/Down).

E/Rotation Pulse: Pulses the mix unit clockwise or counterclockwise the number of steps specified from 1 to 999.

F/Mix Rotation: Spins the mix bars.

G/Sequence: Performs a complete sequence from mixing to moving to the next position.

All Pump

H/On: Activates pumps.

I/Off: Deactivates pumps.

R2 Mix

J/Reset: Aligns the mix bar unit in its home position.

K/Up and Down Step: Moves the mix unit 1 step vertically (up/down).

L/Rotation Step: Moves the mix unit horizontally to the next position.

M/Up-Down Pulse: Pulses the mix unit the number of steps specified from 1 to 999 (Up/Down).

N/Rotation Pulse: Pulses the mix unit clockwise or counterclockwise the number of steps specified from 1 to 999.

O/Mix Rotation: Spins the mix bars.

P/Sequence: Performs a complete sequence from mixing to moving to the next position.

Wash Pump

Q/Reset: Wash syringes move to their home position.

R/Up-down step: Wash syringes move up and down.

Wash Nozzle

S/Reset: Aligns the wash nozzle in its home position.

T/Up and Down Step: Moves the wash nozzle unit 1 step vertically (up/down).

U/Up-Down Pulse: Pulses the wash nozzle unit the number of steps specified from 1 to 999 (Up/Down).

V/Sequence: Performs a wash nozzle sequence.

Cuvette Wheel

W/Reset: Aligns the cuvette wheel in its home position.

X/Rotation: Rotates the cuvette wheel according to user specifications. (Clockwise, counterclockwise, step 1 to 153)

Y/Pulse: Pulses the cuvette wheel the number of steps specified from 1 to 999.

Z/Magnet Off: Removes power to the pulse motor. To reset select "O/Reset."

Select the tab located in the upper left corner of the screen called *Sample Set Unit*.

Rack Receiver

A/Reset: Resets the rack receiver unit.

B/Push-Pull: Rack bar moves forward and backward.

Rack Collection (Vertical)

C/Reset: Rack holder moves to the right.

D/Step: The rack holder moves to the right if it is currently located to the left, or the rack holder will move to the left if it is currently located to the right.

Rack Collection (Stopper)

E/Stopper On-Off: Moves the stop bar forward and backward each time the STAT ROTATION/DIAG Switch is pressed.

Rack Collection (Horizontal)

F/Reset: Moves the rack push mechanism to its home position.

G/Normal Step: Moves the rack push mechanism forward.

H/Auto Repeat Run Step: Moves the rack push mechanism to the auto repeat run position.

Cup Position Rack Step

I/Reset: Resets the unit.

J/Step 1 (1 Pitch): Resets the pitch move motor at the cup position.

K/Step 2 (Release): Resets the pitch move motor at the sample position.

Sample Position Rack Step

L/Reset: Resets the unit.

M/Step 1 (1 Pitch): Resets the pitch move motor at the sample position.

N/Step 2 (Release): Retracts both pawls of the pitch feed assembly.

STAT

O/Reset: Aligns the STAT table in its home position.

P/Rotation: Rotates the STAT table according to user specs. (CW, CCW, step 1 to 22)

Q/Pulse: Pulses the STAT table the number of steps specified from 1 to 999.

Rack Feed

R/Normal: Feeds rack(s) onto the analyzer.

S/Auto Repeat Run: Feeds repeat rack(s) onto the analyzer.

Rack Feeder

T/Reset: Resets the rack feeder.

U/Forward: Moves rack(s) forward.

V/Back: Moves rack(s) backward.

Select the tab located in the upper left corner of the screen called *Combination*.

Photometer Check

A/0-100%: Performs a 0% and 100% photometer check on a specified cuvette. The check is performed at 13 wavelengths.

B/0-100% Sequence: The specified cuvette is measured 20 times. Results are calculated from the average value, range, SD & CV. Results are printed.

C/Rotation: Performs a 100% Photometer Check on cuvettes 1 to 153, using all wavelengths as primary and secondary.

D/Rotation Sequence: Performs a 100% Photometer Check on cuvettes 1 to 153, using all wavelengths as primary and secondary, measured 20 times.

Whole

E/Reset: Aligns all mechanical parts to their home position.

F/Magnet Off: Removes all power from pulse motors. To reset select "E/Reset."

Barcode Read

G/S. ID: Reads sample ID at cup position.

H/S. ID Movement: Performs a complete rack sequence and reads S. ID data.

I/Rack ID: The rack located in the "rack ID read position" is read.

J/Rack ID Movement: The barcode reader is activated.

K/STAT: The STAT cup data is read.

L/STAT Movement: Performs a STAT rotation then reads the S. ID data.

M/R1 ID: Reads reagent ID in the reagent compartment 1.

N/R1 ID Movement: Reads the reagent ID while moving in the reagent compartment 1.

O/R2 ID: Reads reagent ID in the reagent compartment 2.

P/R2 ID Movement: Reads the reagent ID while moving in the reagent compartment 2.

Q/Rack Kind: Identifies rack type in rack ID position.

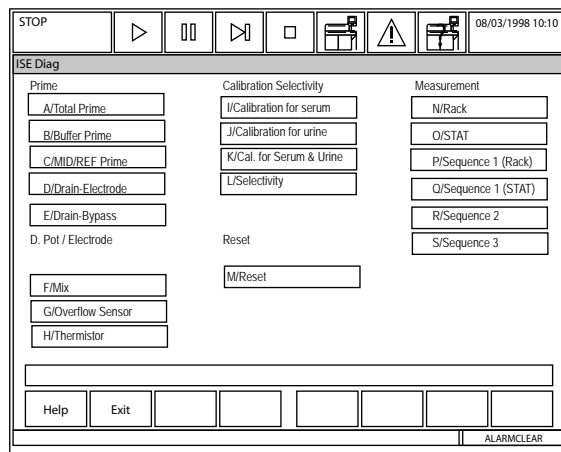
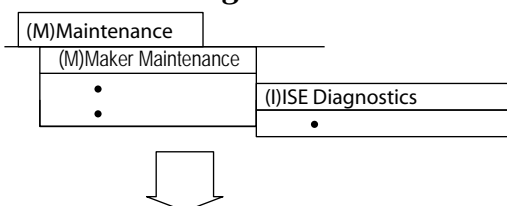
R/Sample Counter: Increments the sample counter.

S/Probe Wash: The wash wells are activated.

T/8 bit LED: Performs a diagnostic sequence of the 8 bit LED.

U/SUB CPU Check: Performs a diagnostics check of the photometer and optical sub-CPU's.

5.5.3 ISE Diagnostics



Description:

This menu is used by authorized service personnel for service, inspection, and repair work performed on this system.

Use this software screen to:

Perform ISE Diagnostics:

The analyzer must be in a stop mode before diagnostics can be accessed. The menu consists of 3 pages of mostly hardware components which can be reset or moved in their normal operation to test proper operation when troubleshooting.

1. Select [Maintenance], [Maker Maintenance], [ISE Diag].
2. Using your mouse, select the item to check. *Explanations of each function follow procedures.*
3. Press the STAT ROTATION/DIAG Switch on the analyzer to perform the selection.

Perform a calibration from diagnostics:

1. Place the analyzer in a stop mode. For information on preparing for a calibration, see the "Performing Calibrations and a Reagent Blank" section located in the Basic Operations Chapter.
2. Select [Maintenance], [Maker Maintenance], [ISE Diag].
3. The calibration begins as soon as one of the following is selected: *I/Calibration for serum, J/Calibration for urine, K/Calibration for serum +urine.*

4 . View the printout.

Analyze the calibration data printout:

If acceptable ranges are exceeded, and * will appear on the right of the data.						
ISE Calibration			Print Time [8-10-98 09:43]			
<<SERUM>>						
	Slope	Mid Factor	Std. H	Mid	Std. L	Mid
Na	59.5	0.965	-37.9	-81.6	-91.9	-82.0
K	55.2	0.997	133.5	35.6	-0.8	30.7
Cl	-49.9	0.947	1452.9	1504.2	1533.6	1510.2
* Voltage (Mid)						
	Former	Latter	The acceptable range between the former and latter is +/- 10			
Na	-83.4	-84.1				
K	31.3	30.2				
Cl	1507.1	1506.9				
*Voltage (Std. H)						
		1st	2nd	3rd	4th	
The acceptable range between the 3rd and 4th value is +/- 5 for all electrolytes except urine K, which is +/- 10						
Na Std. H		-38.6	-38.2	-37.9	-37.8	
Mid		-82.4	-81.9	-81.7	-81.5	
K Std. H		133.0	133.3	133.5	133.4	
Mid		35.0	35.6	35.8	35.4	
C1 Std. H		1452.8	1452.5	1452.8	1452.9	
Mid		1504.0	1504.2	1504.0	1504.4	
*Voltage (Std. L)						
		1st	2nd	3rd	4th	
Na Std. L		-94.8	-92.1	-91.8	-92.0	
Mid		-83.2	-83.1	-82.5	-81.5	
K Std. L		-2.6	-0.7	-0.6	-0.9	
Mid		30.0	29.9	30.3	31.0	
C1 Std. L		1532.7	1532.3	1533.1	1534.1	
Mid		1508.6	1509.1	1509.7	1510.7	

Perform a selectivity check from diagnostics:

1. Place the analyzer in a stop mode.
2. Select [Maintenance], [Maker Maintenance], [ISE Diag]. Place fresh selectivity solutions in the appropriate positions on the Stat table.
3. Select selectivity. *Start Check? Yes*

See Also

For information on setting up a selectivity check, refer to the "ISE Maintenance" section located in the Maintenance Chapter.

4. Verify the data printout results are within the acceptable range.

Perform a sequence 1 (rack):

The sequence 1 measurement will measure a sample 10 times and calculate statistics. Place the sample in a rack, or on the STAT table. ISE precision and performance can be analyzed.

1. Place a tube with the high serum standard or high control in position one in a rack.
2. Put the rack on the transport belt so the front of the rack is up to the pitch feeder in the sample aspiration position.
3. Select Seq. 1 (Rack). Start Sequential Meas. 1-Rack? Yes.
4. Analyze the data printout. The results of the 10 sequential samples will print with the average, max, min, range, and CV results. Verify the CV is within the acceptable range.

Test	Acceptable % CV
Na	0.6
K	2.0
C1	0.7

See Also

For procedures refer to the Troubleshooting Chapter "Sequential Sample Measure."

Explanation of functions:

Prime

A/Total Prime: Primes all solutions.

B/Buffer Prime: A one cycle buffer solution prime is performed.

C/Mid/Ref Prime: A one cycle Mid-Standard and Reference solution prime is performed.

D/Drain-Electrode: Liquid is drained from the sample pot through the electrodes the first time the Stat Rotation/Diag button is pressed. When the button is pressed the second time, mid standard is primed through the electrodes. Use this function when it is necessary to remove electrodes or when performing certain maintenance procedures to prevent mid standard electrode replacement.

E/Drain-Bypass: Liquid is drained from the sample pot through the bypass tubing.

D. Pot/Electrode

F/Mix: Mix rod is moved for 3 seconds.

G/Overflow Sensor: Checks the overflow sensor and thermistor.

H/Thermistor: Checks thermistor voltage.

Calibration Selectivity

I/Calibration for Serum: Calibrates serum.

J/Calibration for Urine: Calibrates urine.

K/Calibration for Serum & Urine: Calibrates serum and urine.

L/Selectivity: Performs a selectivity check.

Reset

M/Reset: Aligns all ISE mechanical parts in their home positions.

Measurement

N/Rack: A single sample from a rack.

O/STAT: A single sample from position #1 on the STAT table.

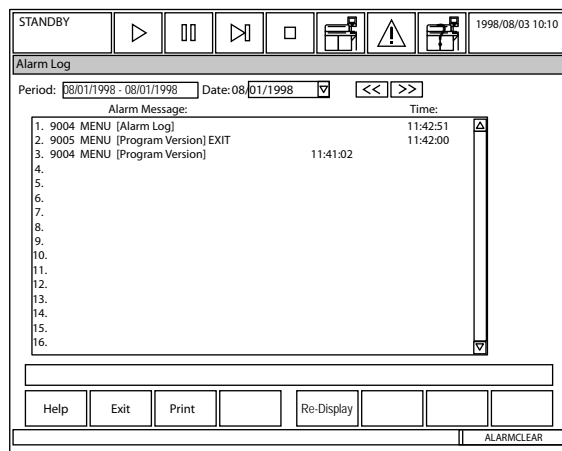
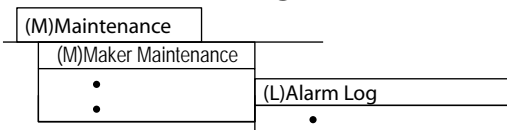
P/Sequence 1 (Rack): Samples 10 times from the same sample in the rack.

Q/ Sequence 1 (STAT): Samples 10 times from the same sample in STAT table position #1.

R/Sequence 2: Pulls mid-standard solution through the flowcell 10 times & calculates statistics.

S/Sequence 3: Mid-standard is pulled through the flowcell 1 time & measures 10 times.

5.5.4 Alarm Log



Description:

This screen displays an alarm list of previous alarms and screens accessed on the system. Use this menu to determine recent or common alarms (past alarms).

If an alarm is occurring at this time, corrective actions are located in the alarm help function. To start alarm help, select the icon located at the top of the screen with the triangle and exclamation point.

Use this software screen to:

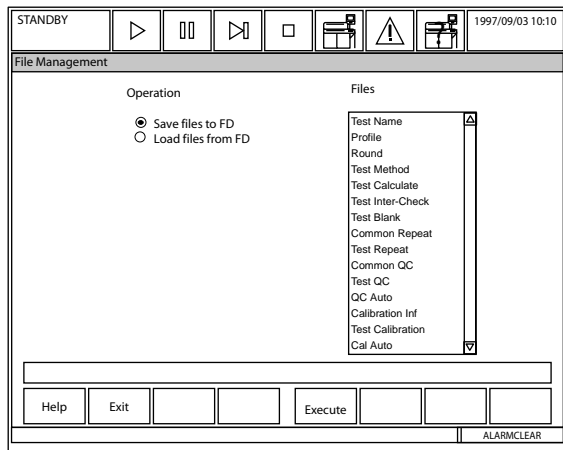
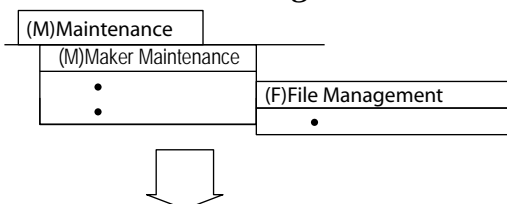
Display an alarm list:

1. Select [Maintenance], [Maker Maintenance], [Alarm Log].
2. Use the pull-down menu or << >> buttons to select a date on which you wish to view the alarm log.

Print an alarm list:

1. From the [Alarm Log] screen press function key F3 (print)
2. Choose "Displayed Date" and "All Date." Displayed date only prints the date selected. "All date" prints alarm logs for all dates.
3. Select "OK." *Printing begins.*

5.5.5 File Management



Description:

Use this screen to save/load parameters to/from a floppy disk.

Use this software screen to:

Save or load parameters to/from a floppy:

Instruction

If a floppy is removed from the drive while data is being saved, the data being saved or stored in the floppy may be lost. Floppy disks for parameter storage have an "AU640 PARAM" volume label. They can be formatted using the [FD Data Management] screen of the [Maintenance] menu.

1. Select [Maintenance], [Maker Maintenance], [File Management].
2. Under the "Operation" column, select either "Save Files to FD" or "Load Files from FD."
3. Under the "Files" column, select the parameters to save or load.
4. Select function key F5 (execute) and insert the floppy. *Start? Yes.*
5. The selected files will revert to the background color when the operation is complete.

6. User Menu Operations

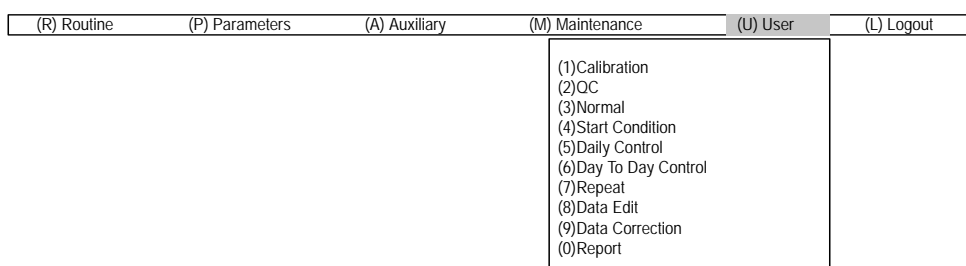
Description:

This menu contains customized menu options. A maximum of 16 frequently used menus can be added in the [User] menu from any of the following menus: [Routine], [Parameters], [Auxiliary], and [Maintenance].

Use this software screen to:

Create a [User] Menu:

1. Select the [User] menu from the menu bar. *Menu items added to the [User] menu will appear in a pull-down menu.*
2. Select a menu item from the pull-down menu. *The selected screen will appear.*



See Also

For information on customizing the [User] menu, refer to the section in this chapter under [Parameters], [System], [User Menu].

Chapter E

Software Menu Outline



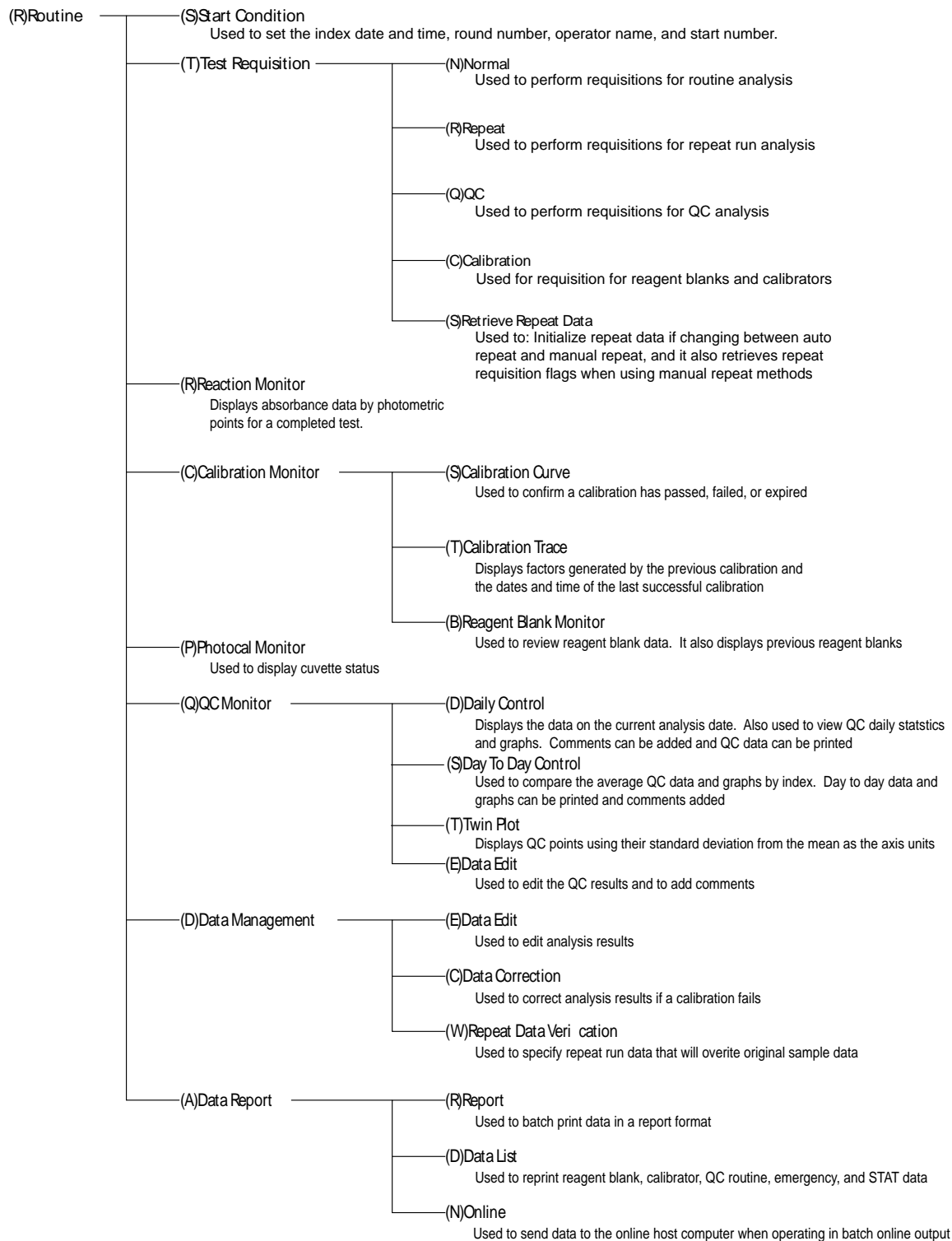
Chapter E Software Menu Outline

1. Routine Menu Outline	E-3
2. Parameter Menu Outline	E-4
3. Auxiliary Menu Outline	E-5
4. Maintenance Menu Outline.....	E-6
5. List of Screen Operations.....	E-7

1. Routine Menu Outline

This section lists the software architecture for the [Routine] menu. For detailed information on each screen, refer to the Software Chapter.

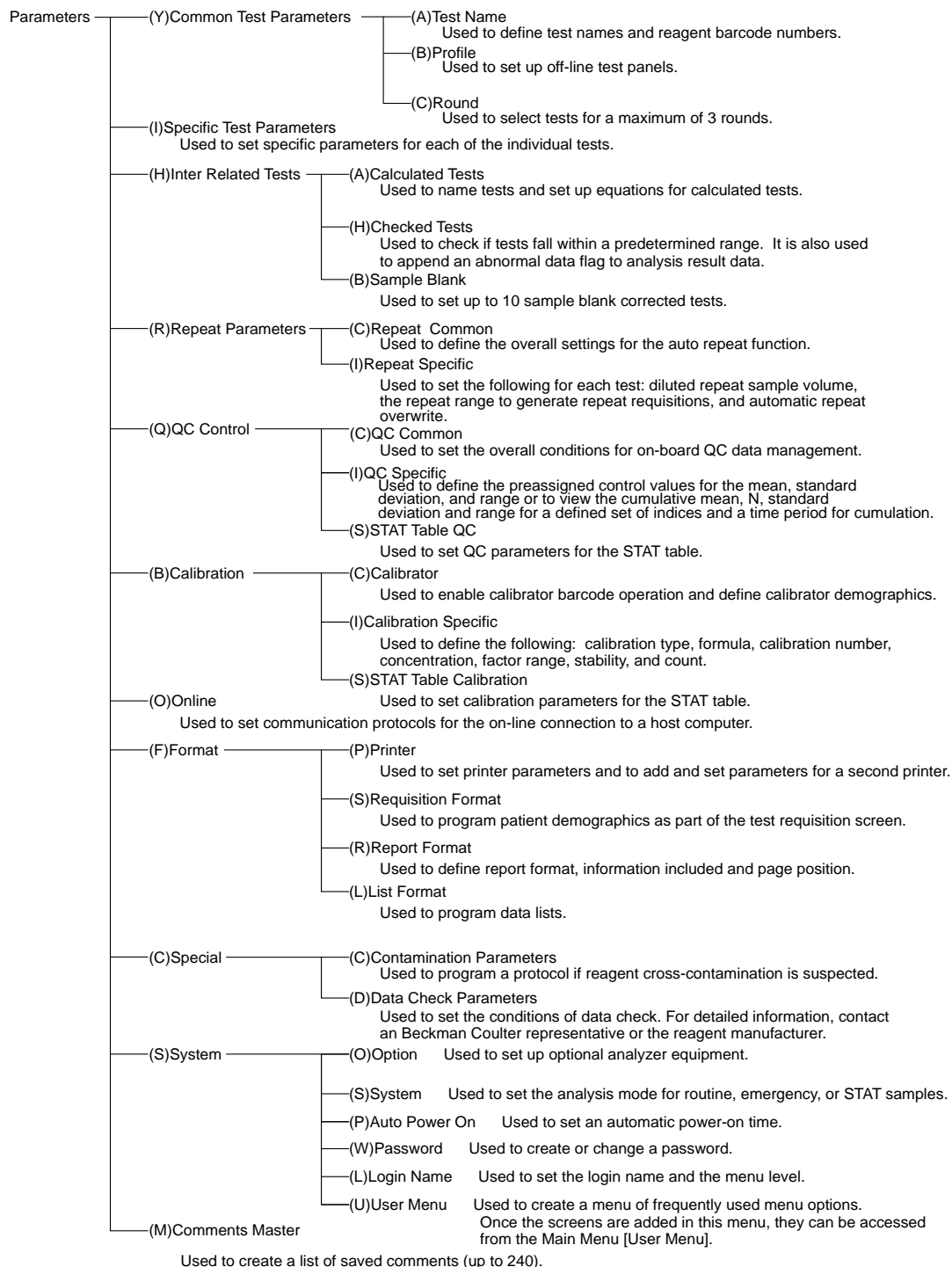
Routine Menu



2. Parameter Menu Outline

This section lists the software architecture for the [Parameter] menu. For detailed information on each screen, refer to the Software Chapter.

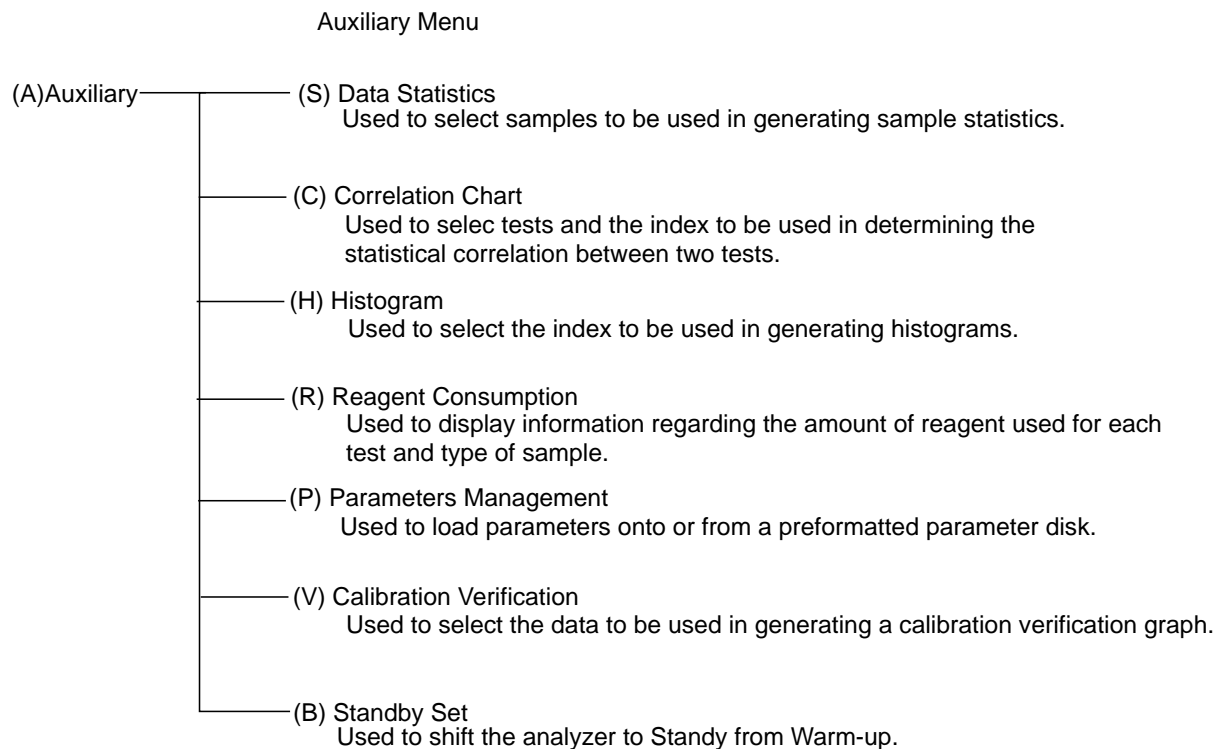
Parameter Menu



3. Auxiliary Menu Outline

This section lists the software architecture for the [Auxiliary] menu. For detailed information on each screen, refer to the Software Chapter.

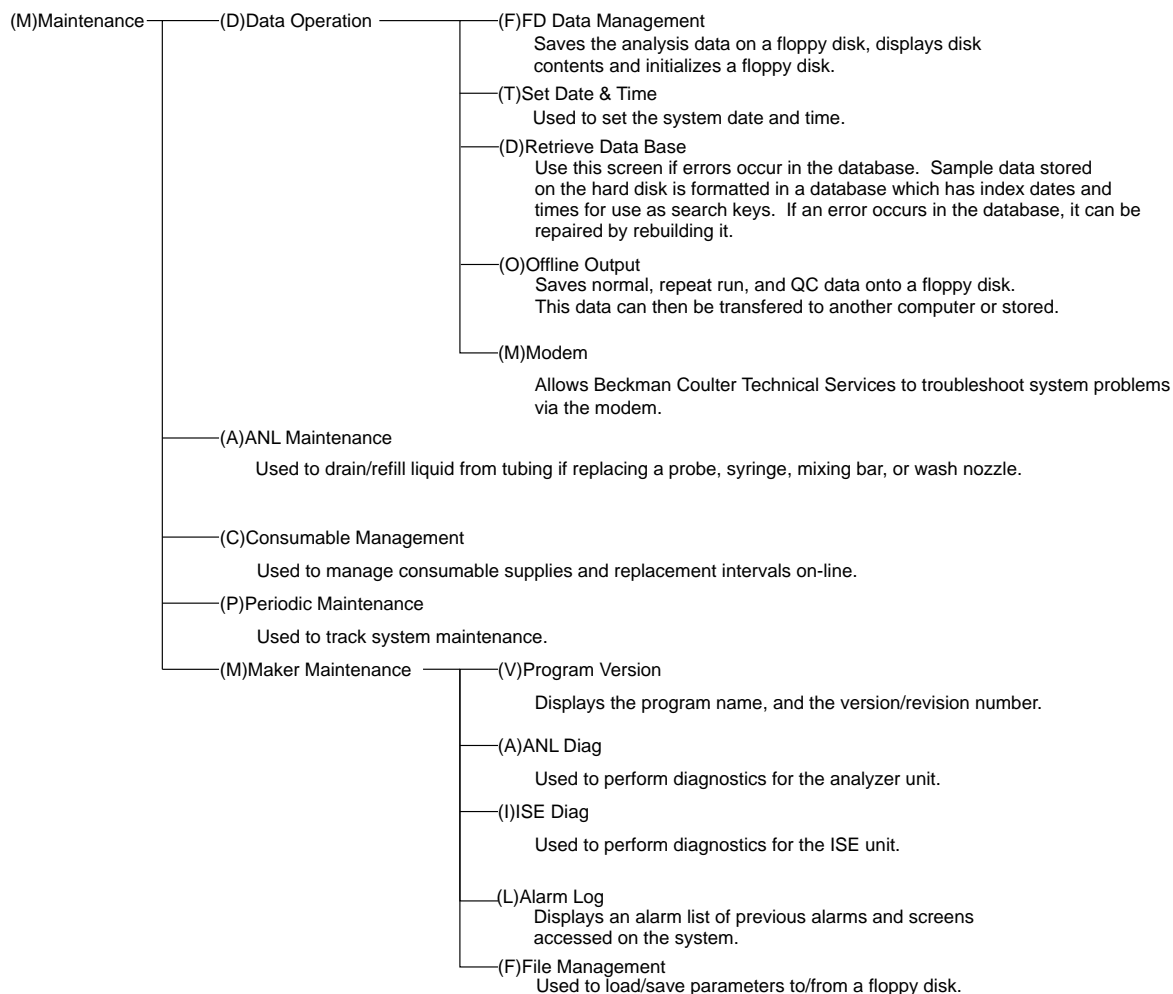
Auxiliary Menu



4. Maintenance Menu Outline

This section lists the software architecture for the [Maintenance] menu. For detailed information on each screen, refer to the Software Chapter.

Maintenance Menu



5. *List of Screen Operations*

This section lists the menus used for common operations.

List of screens used for Quality Control

- [Routine] - [Test Requisition] - [QC]
- [Routine] - [QC Monitor] - [Daily Control]
- [Routine] - [QC Monitor] - [Day to Day Control]
- [Routine] - [QC Monitor] - [Twin Plot]
- [Routine] - [QC Monitor] - [QC Data Edit]
- [Parameters] - [QC Control] - [QC Common]
- [Parameters] - [QC Control] - [QC Specific]
- [Parameters] - [QC Control] - [STAT Table QC]

List of screens used for Calibration

- [Routine] - [Test Requisition] - [Calibration]
- [Routine] - [Calibration Monitor] - [Calibration Curve]
- [Routine] - [Calibration Monitor] - [Calibration Trace]
- [Routine] - [Calibration Monitor] - [Reagent Blank Monitor]
- [Parameters] - [Calibration] - [Calibrator]
- [Parameters] - [Calibration] - [Calibration Specific]
- [Parameters] - [Calibration] - [STAT Table Calibration]

List of screens used for Repeat Run

- [Routine] - [Test Requisition] - [Repeat]
- [Routine] - [Test Requisition] - [Retrieve Repeat Data]
- [Routine] - [Data Management] - [Repeat Data Verification]
- [Parameters] - [Repeat Parameters] - [Repeat Common]
- [Parameters] - [Repeat Parameters] - [Repeat Specific]

List of screens used for Data Analysis

- [Routine] - [Reaction Monitor]
- [Routine] - [Data Management] - [Data Edit]
- [Routine] - [Data Management] - [Data Correction]
- [Auxiliary] - [Parameters Management]

List of screens used for Statistical Analysis

- [Auxiliary] - [Data Statistics]
- [Auxiliary] - [Correlation Chart]
- [Auxiliary] - [Histogram]

List of screens used for Maintenance

- [Maintenance] - [Data Operation] - [FD Data Management]
- [Maintenance] - [Data Operation] - [Set Date and Time]
- [Maintenance] - [Data Operation] - [Retrieve Database]
- [Maintenance] - [Data Operation] - [Offline Output]
- [Maintenance] - [Data Operation] - [Modem]
- [Maintenance] - [ANL Maintenance]
- [Maintenance] - [Consumables Management]
- [Maintenance] - [Periodic Maintenance]
- [Maintenance] - [Maker Maintenance], [Program Version]
- [Maintenance] - [Maker Maintenance], [ANL Diag]
- [Maintenance] - [Maker Maintenance], [ISE Diag]
- [Maintenance] - [Maker Maintenance], [Alarm Log]
- [Maintenance] - [Maker Maintenance], [File Management]
- [Auxiliary] - [Reagent Consumption]
- [Auxiliary] - [Standby Set]

