
**Operator's Manual
BM/Hitachi 917**

BM/Hitachi 917

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Boehringer Mannheim GmbH, Mannheim

Production: P. Hirn, D.H. Jung, B. Koroknay, J. Lutzke, I. Reinhardt, J. Westera

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0. Potential Hazards and Safety Precautions

■ Safety Warnings

Before putting the analyzer into operation, you should become acquainted with all precautions and regulations concerning the handling of the analyzers electrical and mechanical components in order to rule out any potentially hazardous situations to yourself and your colleagues.

All safety warnings that the operator must consider in this manual are classified as below. Acquaint yourself with the following labels and pictures.

WARNING

If these instructions are not strictly adhered to, there is a risk of fatal injury e.g. from power supplies or infection.

CAUTION

If these instructions are not strictly adhered to, there is an increased risk of injury and/or serious functional disruptions to the analyzer.

ATTENTION

Identifies all other situations where increased attention is necessary (e.g. to avoid damage to the analyzer).

Note

Indicates information to be considered e.g. remarks, etc.

 is the international symbol for caution

■ Safety Precautions



WARNING



Electrical Safety

Never open the back or side panels when the analyzer is connected to the mains supply (wall socket)! Pull the plug out beforehand!

You can receive an electric shock by touching supply-carrying components.



CAUTION



Flammable and Explosive Materials

Avoid using flammable materials around the analyzer.

Electrical sparks can cause fires and explosions.



CAUTION



Analyzer in Operation

Never touch the sample pipetter, reagent pipetters, stirrer, rinse units and all other moving components when the analyzer is operating.

There is a risk of injury from the moving components and the analyzer can also be damaged.



WARNING



Photometer Lamp

Never look for long periods into the light of the photometer lamp without eye protection.

If this warning is not heeded, damage to the eyes can occur. Wear darkened protective goggles to protect yourself from ultra violet light, when you must look at the light transmitted from the photometer lamp for long periods.



WARNiNG



Samples

1. Avoid direct contact with samples that contain bacteria or are potentially infectious.
If sample material comes in contact with the analyzer surface, clean it up immediately with a towel.
2. Ensure that the sample contains no fibrin clots, dust or other insoluble contaminations.
If the sample contains insoluble material, false results can be produced. This applies especially when fibrin clots block the sample pipetter.



CAUTION



Liquid Waste

1. Potentially infectious waste must be disposed of according to the legal regulations.
There is a risk of contamination from potentially infectious waste.
2. Contact the manufacturer of the reagent, if you require more information about its environmental compatibility.



CAUTION



Correctness/Precision of the Measurements

To ensure that the analyzer operates correctly, controls must be measured and the functions must be monitored.

Erroneous measurements can lead to a false diagnosis resulting in an incorrect therapy that puts the patient at risk.

■ Safety Precautions During Operation



Correct Usage

1. The analyzer was designed for clinical-chemical analyses, electrolyte analyses, immunological tests and medical analyses using water-soluble samples and reagents.
Comply with the manufacturer regulations of the reagent when using the tests on the analyzer.
2. If reagents are used other than those developed by Boehringer Mannheim, then Boehringer Mannheim guarantees the technical specifications of the analyzer but takes no responsibility for the measured results.



Operator Qualifications

1. The operation of the analyzer should only be performed under the control of a qualified person, who has taken part in a recognized training from Boehringer Mannheim.
2. For clinical tests, the analyzer should only be controlled by a practitioner or a laboratory doctor.



Operation and Maintenance

1. The operation and maintenance of the analyzer may only be performed according to the described procedures. No other components other than those specified may be touched.
2. Never open the screwed down analyzer covers when the analyzer is connected to a power supply. Contact with the circuit boards can damage the electronic components.

3. Never touch the sample pipetter, reagent pipetter, stirrer, rinse units and all other moving components of the analyzer when it is in operation.
If this precaution is not adhered to, damage or interruption to the analyzer can occur.
4. Never touch the reaction disk, sample disk and reagent disk when they are rotating.
If this precaution is not adhered to, damage or interruption to the analyzer can occur.

 **CAUTION**

Environment Conditions (Installation Conditions)

Consider the specified installation conditions. If the analyzer is to be located somewhere else, contact Boehringer Mannheim customer support.

 **CAUTION**

Limitations for Samples and Reagents

1. The reaction cells, sample cups and the tubing for liquid waste are not impervious to organic solutions. Never use organic solutions.
2. Never use samples or reagents that can stick to the sample probe, reagent probes or the reaction cells. This also applies to samples and reagents that may block the sample probe or reagent probes. False measurements may be produced.

 **CAUTION**

Loading Samples and Reagents

Only load samples and reagents into the intended positions on the analyzer. Spilt samples and reagents can cause disruptions to the analyzer. Only load reagents when the analyzer is in the "stand-by" mode, or when the reagent stop function permits loading.

If this precaution is not adhered to, damage or interruption to the analyzer can occur.

 **CAUTION**

Analyzer Cover

The analyzer cover should always be closed during operation. Only open the cover to load samples, etc.

 **CAUTION**

Sample Disk

Never load new samples or change the sample disk when the LEDs, indicating that the disk is rotating, are lit or blinking.

LED 1 indicates that sample disk 1 is rotating.

LED 2 indicates that sample disk 2 is rotating.

If this precaution is not adhered to, the analyzer can be damaged.

 **CAUTION**

Reaction Disk

1. Never touch the reaction disk when the analyzer is operating.
2. Always follow the corresponding instructions when removing, loading or replacing the reaction disk or the reaction cell segments.

If this precaution is not adhered to, damage or interruption to the analyzer can occur.

 **CAUTION**

Reagent Disk

Only open the reagent disk cover in order to replace reagents.

If this precaution is not adhered to, the cooling can be affected thus causing the reagents to expire. Opening the cover during an analysis causes an analyzer alarm.

 CAUTION

Reaction Cells

If a reaction cell dries out after use, cracks can occur and contaminations may not be able to be removed. Therefore, the reaction cells must be stored after use in deionized water. If the analyzer is not going to be used for more than three days, the reaction cells must be removed from the reaction disk and must be stored in a 2% solution of Hitergent.

 CAUTION

Switching the Analyzer On

Never switch the analyzer off and then immediately back on. Wait at least 30 seconds before switching back on.

If this is not adhered to, the analyzer may be damaged.

 CAUTION

Handling Detergents

Never touch detergents with bare fingers, this can cause skin damage. Wear rubber gloves when handling detergents.

 CAUTION

Photometer Lamp

Do not touch the hot lamp or lamp housing, there is a risk of burns.

 CAUTION

Stirrer

Do not bend the stirring paddle. Bent stirring paddles can cause false measurements.

1. Introduction

1.1 Manual Outline

The Operator's Manual is a part of the documentation for the analyzer BM/Hitachi 917, which additionally includes the volume System Description and the Short Guide.

The volume Operator's Manual offers a detailed overview of all processes concerned with the daily operation and those processes required from the daily routine of the analyzer.

- In chapter 0 potentially hazardous sources are brought to light as well as safety notes and precautionary measures.
- Chapter 2 provides detailed information about the daily routine on the analyzer.
- Procedures for analyzer care and maintenance are described in detail in chapter 3.
- Chapter 4 deals with operation support that could be useful when tuning the analyzer to the laboratory requirements.
- In chapter 5 all printouts are described that can be requested from the analyzer.
- The 6th and last chapter describes errors and what measures must be taken to cure them.
- The Appendix consists of a Glossary and an Index, allowing you quick access to any required information.

2. Daily Routine

2.1 Introduction

In this chapter you find a description how the daily routine is prepared, performed and shut down. Step by step you will get to know how to switch on the analyzer, how to access the menus, how to determine the type and number of samples, how to allocate tests, how to start the analysis, and how to obtain results at the end of the analysis.

Your service person at Boehringer Mannheim

Name: _____

Address: _____

Tel.: _____

Fax.: _____

2.2 Daily Maintenance - Outline

Perform all daily operational checks prior to beginning the first run of the day. Each daily operational check should be logged on the MAINTENANCE LOG sub menu. Default daily maintenance items include:

1. Empty waste container
2. Check / replace cell detergent supply
3. Check / replace detergent supplies (1D1 - 2D3)
4. Check W1/W2 positions on sample disk 2
5. Clean sample and reagent probes
6. Clean stirrer paddles
7. Check paper supplies
8. Clean instrument surfaces
9. Clean cell rinse unit nozzles
10. Wash ISE unit with ISE Wash Solution (in position W2)
11. ISE prime/condition/calibrate
12. Check incubation bath temperature
13. Perform photometer check
14. Update Maintenance Log

The following table displays an overview of the above maintenance procedures. More detailed information can be found in chapter 3 Maintenance and Daily Care of the Operator's Manual.

No.	Maintenance Item	Material required	Note Details	Page
1	Empty waste container	disinfecting solution, water for rinsing, paper towels	Content of the waste container is potentially hazardous. Wear disposable gloves.	3-9
2	Check / replace cell detergent supply	Detergent 1 (NaOH-D)	Place both tube filters in the first NaOH-D bottle. Execute a Cell detergent prime, before running analysis.	3-10
3	Check / replace detergent supplies (1D1 - 2D3)	fresh detergent	Hitergent is used for position 1D1 and 2D1. NaOH-D (70 mL bottle) is used for position 1D2 and 2D2. Detergent for additional rinsing is used for position 1D3 and 2D3.	3-12
4	Check W1, W2 position on sample disk 2	NaOH-D ISE wash solution	NaOH-D is used for position W1. ISE wash solution is used for position W2.	3-5
5	Clean sample and reagent probes	alcohol, lint-free cloth	Switch off the instrument to move the pipettors.	3-13
6	Clean stirrer paddles	alcohol, lint-free cloth	Switch off the instrument to move the stirrer paddles.	3-14
7	Check paper supply	printer paper	Load new printer paper, if necessary.	3-15
8	Clean instrument surfaces	disinfecting solution, water, lint-free cloth	Clean all surfaces with a lint-free cloth and water or disinfecting solution, if needed.	3-15
9	Clean nozzles of the cell rinse unit	alcohol, lint-free cloth	Instrument must be in Standby or OFF.	3-15

Daily Maintenance - Outline

No.	Maintenance Item	Material required	Note Details	Page
10	Wash ISE Unit with ISE wash solution (in position W2)	ISE wash solution	ISE maintenance has to be performed once a day. Ensure that ISE conditioning and calibration are performed prior to the start of the next routine.	3-17
11	ISE prime/condition/calibration	ISE reagents, human sample, calibrators	Perform an ISE prime and calibration once a day.	3-16
12	Check incubation bath temperature		Check the incubation bath temperature displayed on the SAMPLE TRACKING global menu screen (Tolerance: 37°C ± 0.2 °C)	3-17
13	Perform photometer check		Check that the results do not exceed 16000	3-18
14	Update Maintenance log		in the MAINT LOG sub menu (MAINT/UTILITY main menu)	

2.3 System Start

2.3.1 Introduction

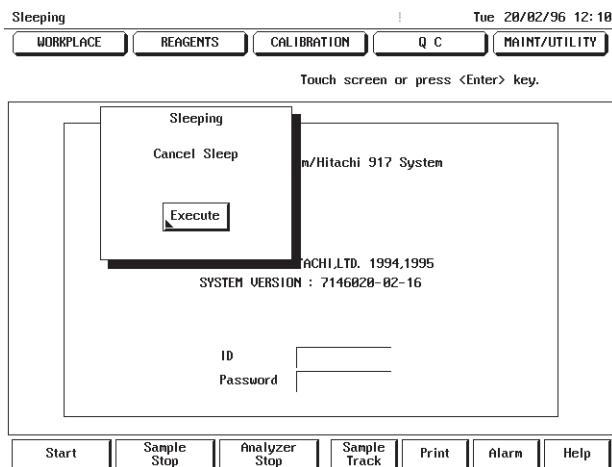
There are two ways to start the routine operation - by pressing the main switch of the analyzer (POWER ON) on the right side of the front panel, or by waking up the instrument from the SLEEP mode.

2.3.2 Power On

1. If necessary, turn on the external water supply and open the tap, before starting the daily routine operation.
2. Switch on the analyzer using the main switch (on the right side of the front panel). The computer, screen, and the printer are also switched on, if the main switches of these components are permanently left in the ON position.

2.3.3 Automatic Start Procedure

If the automatic start procedure is selected, the instrument initializes at a set time and performs the startup maintenance functions. Then it is ready for operation. The SLEEP mode can be canceled at any time by pressing the displayed EXECUTE button. If the SLEEP mode is automatically or manually canceled, the LOG ON screen is displayed again. After the initialization phase, the LOG ON screen is displayed.



Note

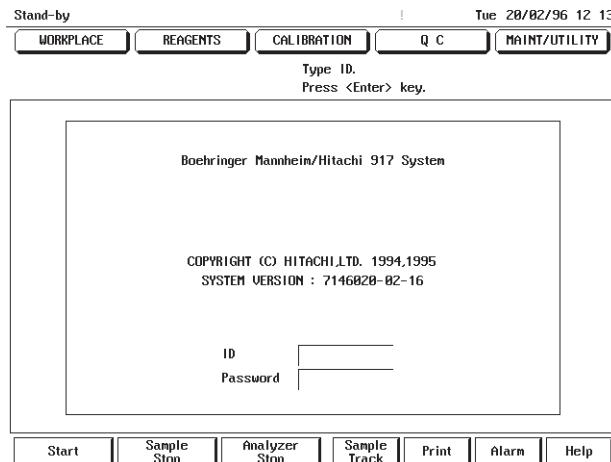
If the analyzer is automatically initialized ("waking up" from the SLEEP mode), a photometer check is automatically performed. If the instrument is manually started, a photometer check has to be requested manually in the MAINT LOG sub menu (MAINT/UTILITY main menu).

2.3.4 Log On/Log Off

Your service person activates the LOG ON function during installation.

■ Log On

1. Switch on the instrument. If the screen saver is on, just touch the screen to open the LOG ON screen.
2. When the analyzer is in STANDBY mode, enter your operator ID and password in the corresponding fields. If the entries are correct, you can now open the individual software menus.



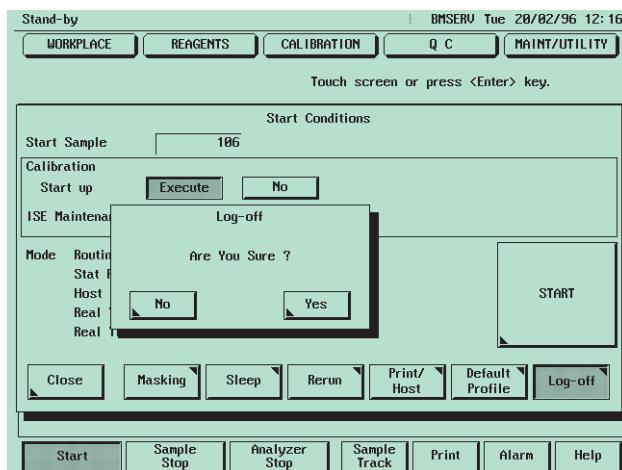
Note

A supervisor must assign operator IDs and the operator level from the MAINT/UTILITY main menu, SYSTEMS sub menu, LOG ON window.

If the Log On mode is not activated, the LOG ON screen is not displayed.

■ Log Off

1. When you have finished your routine work on the analyzer so that you are ready to log off, touch the START button to display the START CONDITIONS global menu.
2. Touch the LOG OFF button to display the LOG OFF window.



3. Touch YES to log off the analyzer.
4. The system returns to the LOG ON screen so that next operator can log on the system.

2.4 Daily Start Up

The automated start up procedures require minimal operator involvement. Do not omit any of the described procedures from your daily routine. Only touchscreen instructions for the following procedures are given. Most of the procedures may also be performed using the keyboard. Keyboard equivalents of the touchscreen navigation methods are described in the guidance field in the upper right-hand corner of the screen.

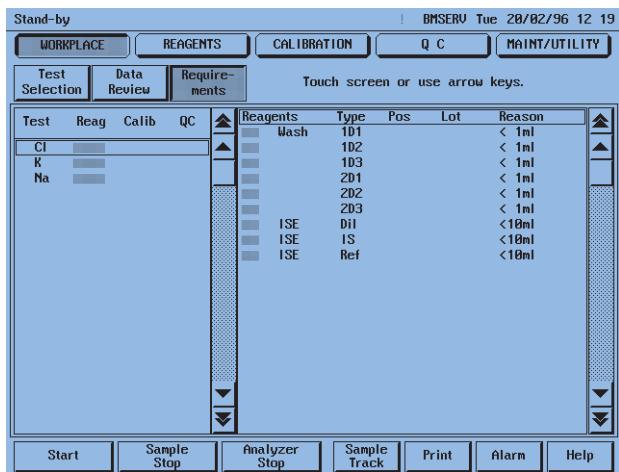
Safety Precautions:

While the analyzer is in operation, follow these precautions:

- Keep the top cover of the analyzer closed.
- Do not place, replace or remove samples while the sample disk is rotating.
- Avoid touching the sample probe, reagent probes, stirring paddles, and other moving parts.
- Do not remove or replace the reagent disk covers.
- Do not place reagent or sample containers on the cover of the analyzer.

2.4.1 Checking the Reagents REQUIREMENTS Screen

1. Touch WORKPLACE followed by REQUIREMENTS to display the REQUIREMENTS sub menu.



2. The screen is divided into two list boxes. The list box on the left displays the corresponding test.

Different highlight colors in the columns REAG, CALIB and QC are used to indicate the current status, e.g. which method requires reagent or if a calibration or control failure occurred.

The list box on the right displays detailed information about the specific highlighted test in the left list box:

For photometric reagents:

Red highlight indicates that there is no reagent volume or that the reagent bottle is missing. The bottle is canceled and the barcode cannot be reused.

Yellow highlight indicates that the remaining reagent volume is less than the reagent level defined for the analyzer. This number is defined on the MAINT/UTILITY, SYSTEM screen.

Purple highlight indicates that the remaining reagent volume is less than the reagent level check volume defined for that test. This number is defined in the REAGENT CHECK window of the REAGENTS main menu and can be different for each reagent. This number should be entered to reflect your workload needs.

For ISE reagents:

Red highlight indicates < 10 mL of any ISE reagent remains.

Yellow highlight indicates that < 50 mL of Internal Standard solution or < 30 mL of either KCl or diluent remain.

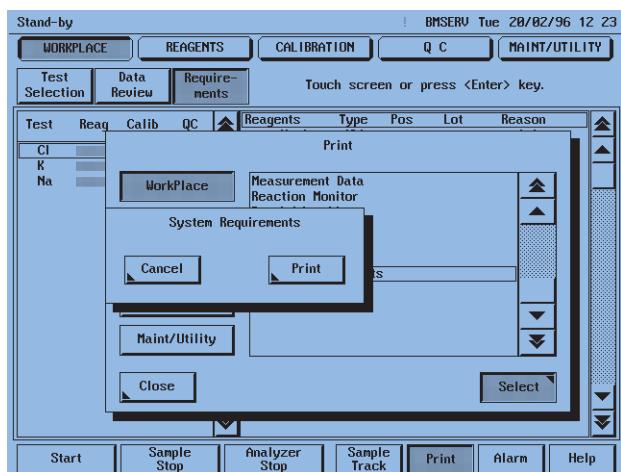
For calibrations:

Red highlight indicates that a calibration is required or that a calibration has failed.

For controls:

Red highlight indicates that a QC violation occurred and a random or system alarm was issued or that the control is not on the analyzer.

3. To print a copy of the list, if desired, touch the PRINT button to open the corresponding global menu. Touch SYSTEM REQUIREMENTS in the displayed list, then touch the PRINT button.

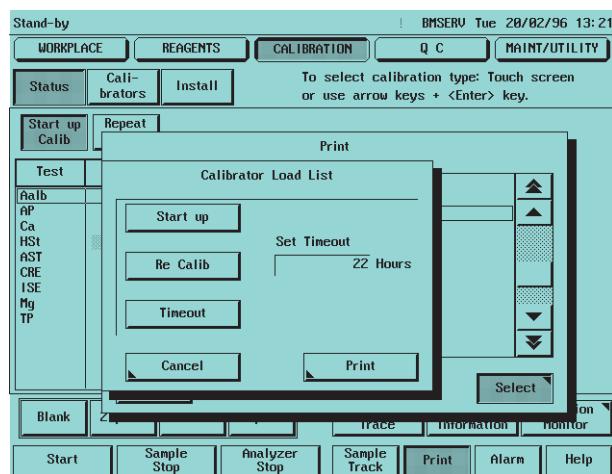


4. Put the required reagents into the corresponding reagent disks (see package insert for preparation details).

2.4.2 Reconstituting Calibrators and Controls

Quality control products are used to verify calibration as well as the precision and accuracy of the instrument. Controls should be performed after every calibration, or should be measured according to the corresponding legal guidelines. Additional control runs should be established by your laboratory, based upon its needs.

1. Reconstitute all calibrators and control materials according to the instructions provided with each kit of material or according to legal regulations.
2. Print out a calibrator load list.



BM/Hitachi 917

3. Touch QC, followed by CONTROLS to display the position list of the controls and calibrators in sample disk 2.

Stand-by BMSERV Tue 20/02/96 12 29

WORKPLACE		REAGENTS		CALIBRATION		Q C		MAINT/UTILITY	
Individual	Cumulative	Controls	Install	To select from list: Touch screen or use arrow keys.					
Pos	Sample Type	Name	Code	Lot	Exp Date	▲	▼	▼	▼
1	* Calibrator	NaCL	400	18689700	00/00	▲			
2	* Calibrator	CFAS	401	18718600	00/00				
3	* Calibrator	ISE LOW	003	1589623	96/81				
4	* Calibrator	*****	004	*****	**/*				
5	* Calibrator	ISE COMP	005	189653	96/81				
6	* QC	PNU		178965	96/81				
7	* QC	PpU		176698	95/12				
8									
9									
10									
11									
12									
13									
14									
15									

* Manual Setting ! Read ID ? Not Found ?? Read Error

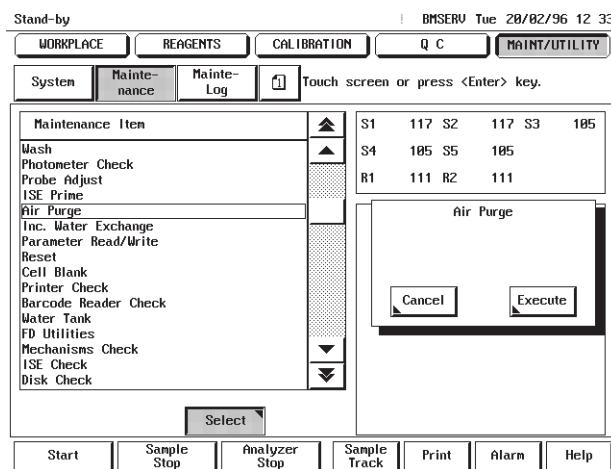
Assign Position Delete Position

Start Sample Stop Analyzer Stop Sample Track Print Alarm Help

4. Put calibrators and controls in the indicated positions.

2.4.3 Air Purge (Photometric System)

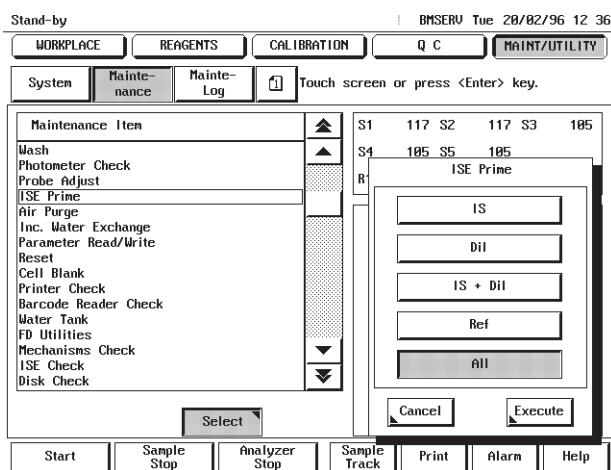
The air purge procedure occurs automatically when the instrument is powered ON or after Wake-Up. If you have not assayed any samples within an eight-hour period and (instrument in Stand-by), perform an air purge to ensure that there is no air in the hydraulic tubing between the probes (photometric reagent and sample) and their respective pipettors. Air in the syringes or tubings can result in imprecise pipetting. This procedure replaces the hydraulic line water with freshly degassed, DI water and takes approximately one minute to complete. This procedure does not purge the ISE system pipettors.



1. Touch MAINT/UTILITY.
2. Touch MAINTENANCE.
3. Touch AIR PURGE.
4. Touch SELECT.
5. Touch EXECUTE.
6. DI water will be flushed through the pipettor. Check the water jet ejecting from the pipettors. Check for leaks and excess air. Check the syringes for air bubbles.
7. Repeat steps 1-5, if necessary, to remove all air.

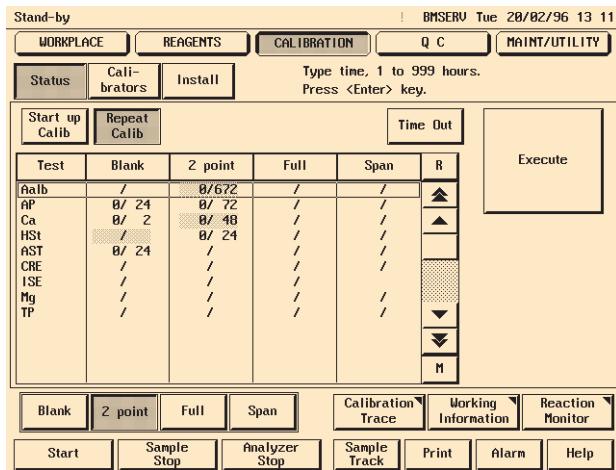
2.4.4 ISE Prime, Conditioning, Calibration

Perform an ISE prime if you have not assayed any samples within an eight-hour period (instrument in Stand-by) to ensure that there is no air in the hydraulic tubings. Replace used up reagent bottles by new one. If you are replacing ISE reagents, reset the reagent volumes by pressing the green ISE reset buttons (to the right of the ISE compartment) or enter the volume in the REAGENTS main menu. Never fill old reagent into the new bottles, which may result in bacterial growth.



- 1 Touch MAINT/UTILITY, followed by MAINTENANCE to open the corresponding sub menu. Touch ISE PRIME and SELECT to display the corresponding window. Select the ALL option and touch EXECUTE.
2. Condition the electrodes by performing an ISE measurement of 10 human serum samples.

3. Calibrate the ISE unit. Open the STATUS sub menu (CALIBRATION main menu) and touch the REPEAT CALIB button. Select the ISE item from the displayed list and touch FULL.



4. Touch the EXECUTE button in the STATUS sub menu to initiate the full ISE calibration. If the instrument is in Stand-by, touch the EXECUTE button in the START CONDITIONS global menu.

2.5 Calibration Test Selection

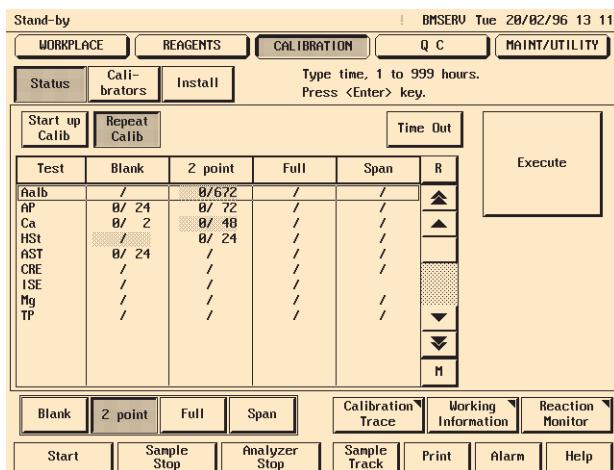
Your 917 analyzer offers the opportunity to select between the automatic calibration feature and a manually requested calibration. To ensure proper operation of your 917 analyzer, calibrate each Boehringer Mannheim assay at the recommended interval specified on the APPLICATION sub menu (MAINT/UTILITY main menu).

2.5.1 Automatic Calibration

Calibrations are recommended to be performed when the calibration expires (time out calibration) or a new bottle or lot is used up. Each Boehringer Mannheim test can be automatically calibrated. Controls are automatically run for each requested test following calibration, if requested.

■ Time Out Calibration

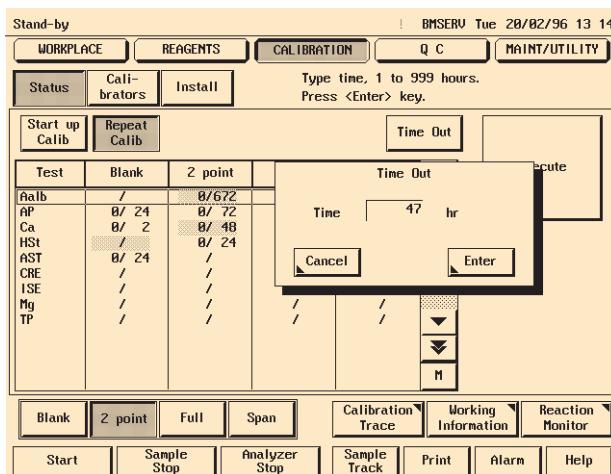
1. Touch CALIBRATION, followed by STATUS to display the STATUS sub menu. Then touch REPEAT CALIB.



2. The second number is the defined time interval. The remaining time is displayed as the first number, e.g. the 1 in 1/48. This means that during the next hour an automatic calibration is executed, and the time interval is 48 hours. After the calibration the time display is updated to 48/48.

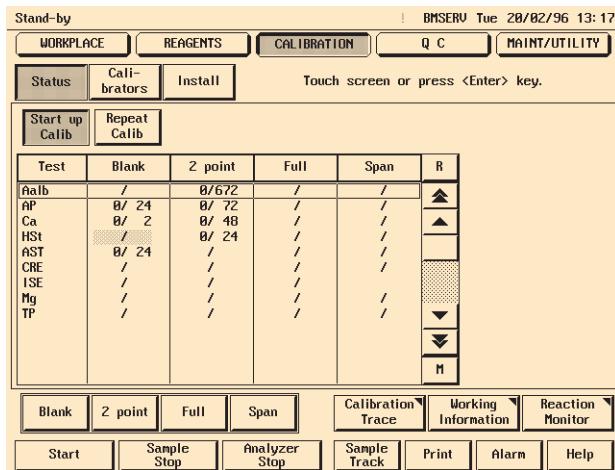
Calibration Test Selection

3. All tests requiring calibration within a defined time period (e.g. 5 hours) are highlighted. The tests have to be marked before. Then, press the TIME OUT button. Define the time period of all tests within this time period (yellow highlight). Tests with the remaining time interval zero are not displayed in yellow. They are automatically calibrated if the START button is pressed. Press EXECUTE to start the calibration. If you want to delete already entered control requests, touch the corresponding calibration type button (BLANK, 2 POINT, FULL or SPAN). The yellow highlight disappears again.



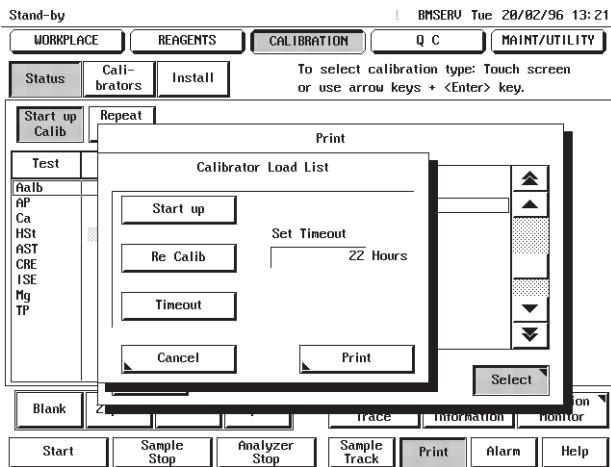
■ Start Up Calibration

Use the START UP CALIB button to display a list from which you can select tests for start up calibration. A start up calibration performs the calibration for the requested tests at the beginning of a run and can be initiated in Stand-by only.

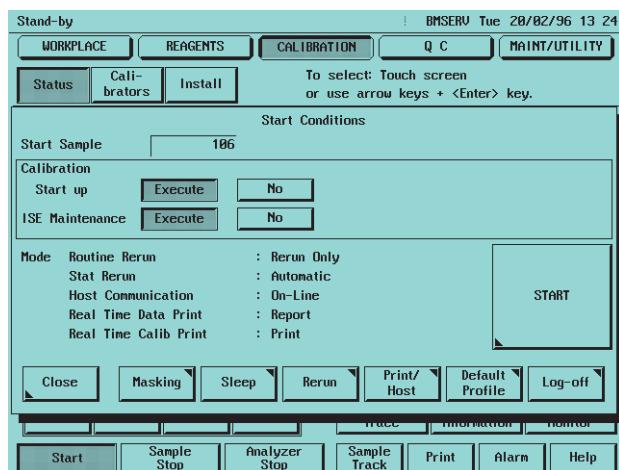


1. Touch CALIBRATION, followed by STATUS to display the STATUS sub menu.
2. Touch START UP CALIB.
3. Touch the tests in the list box which are to be calibrated.
4. Touch BLANK, 2 POINT, FULL or SPAN to choose a calibration option.
IF a calibrator load list is desired,
THEN proceed to step 5.
IF no calibrator load list is desired,
THEN proceed to step 8.
5. Touch PRINT to display the PRINT global menu.

Calibration Test Selection



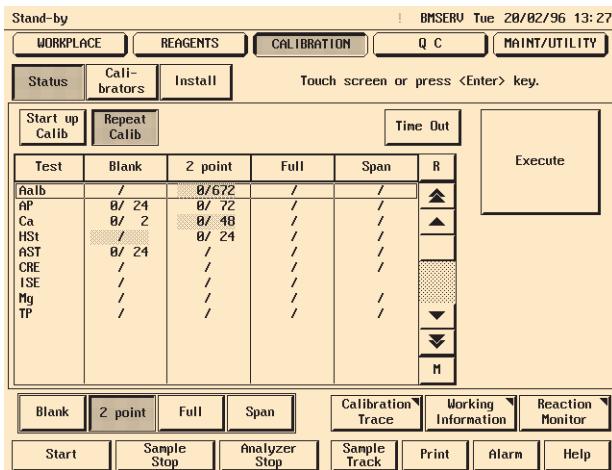
6. Touch CALIB LOAD LIST, then touch SELECT.
7. Touch START UP, then touch PRINT to print the calibrator load list.
8. Load calibrators and controls on sample disk 2 according to the printed load list.
9. Touch START, to display the START CONDITIONS global menu. Touch CALIBRATION START UP and EXECUTE to request a start up calibration. Press the START button in the START CONDITIONS global menu to activate the analyzer.



10. Verify that no alarms exist on the calibration and that the QC results are in range.

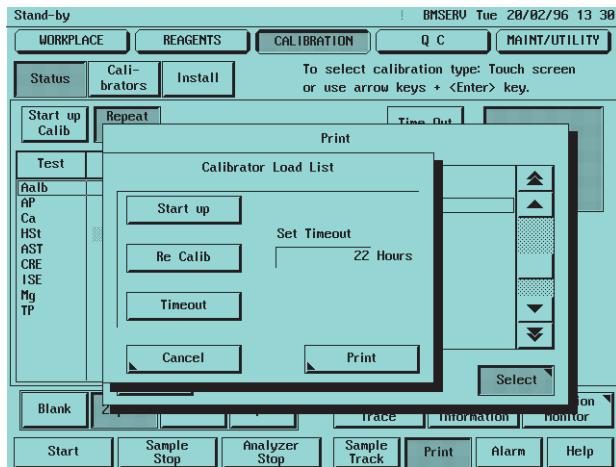
■ Repeat Calibration

Use the REPEAT CALIB button to request tests for a repeat calibration. Any failed calibrations are automatically put on the repeat list. A repeat calibration can either be performed in Stand-by or Operate mode.



1. Touch CALIBRATION, followed by STATUS to display the STATUS sub menu.
2. Touch REPEAT CALIB.
3. Touch the tests in the list box for which you want a repeat calibration.
4. Touch BLANK, 2 POINT, FULL or SPAN to choose a calibration option.
IF a calibrator load list is desired,
THEN proceed to step 5.
IF a calibrator load list is not desired,
THEN proceed to step 8.
5. Touch PRINT to display the PRINT global menu.

Calibration Test Selection

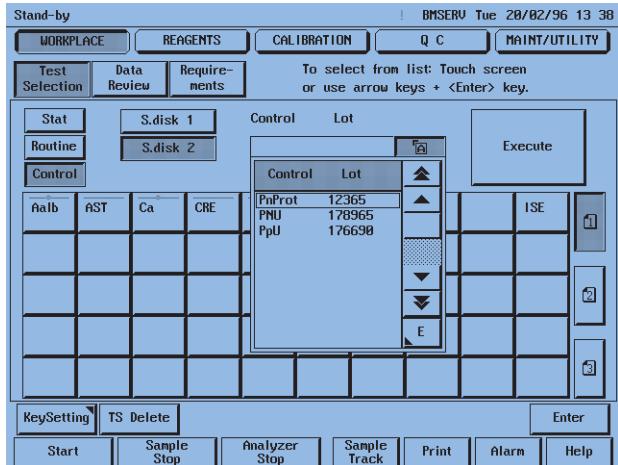


6. Touch CALIBRATION, followed by CALIB LOAD LIST, then touch SELECT.
7. Touch RE CALIB, then touch PRINT to print out the calibrator load list.
8. Load calibrators and controls on sample disk 2 according to the printed list of the required Standards.
9. If the analyzer is in operation, touch EXECUTE, followed by YES to start the repeat calibration.
If the analyzer is in Stand-by mode, touch EXECUTE, followed by YES and the START button in the START CONDITIONS global menu to start the analyzer.
10. Verify that no alarms exist on the calibration and that the QC results are in range.

2.5.2 Manual Control Test Selection (from Sample Disk 2)

Independent from calibrator or control intervals, controls can be requested and measured manually on sample disk 2 during operation.

1. Touch WORKPLACE, followed by TEST SELECTION. Touch the CONTROL button.
2. Touch the S. DISK 2 button only if the barcode reader is activated. Then open the CONTROL/LOT assist box.



3. Select the desired control from the list and press ENTER. The available tests for this control appear in the TEST KEY matrix field.
4. Select the desired test and press ENTER.
5. Touch the EXECUTE button to integrate the control test request in the processing run. If the analyzer is in Stand-by mode, the analyzer has to be started first.
6. The results are transferred to the INDIVIDUAL QC list. An automatic data evaluation in the REAL TIME QC is only possible, if the specifically defined controls are requested together.

Note

If the EXECUTE button is pressed several times, the control is nevertheless measured only once.

2.6 Initiate Run with Routine Patient Test Selections

Routine patient test selections can be made when the instrument is in Stand-by, Stop, Operate or Sample Stop mode. It is also possible to enter patient test selections manually with or without barcode reader in use.

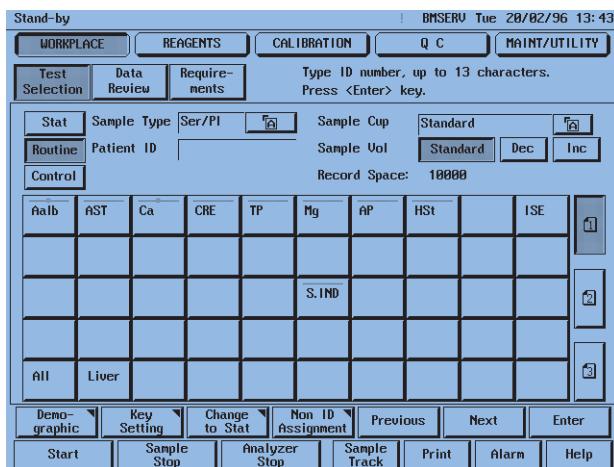
Patient test selections can either be entered manually or downloaded from a host computer with or without barcode reader in use.

Use this procedure to enter test selections manually for barcoded samples that are not downloaded from the host and for non-barcoded samples. The procedure varies slightly depending on whether:

- sample barcode reader is on or off
- host communication is on or off

2.6.1 Routine Patient Test Selection

1. Touch WORKPLACE, followed by TEST SELECTION to display the TEST SELECTION sub menu.



2. Touch ROUTINE to enter routine patient test selections.

3. For non-barcode mode:

Sample Type	Ser/PI	<input type="button" value="▲"/>
Sample No.	<input type="text"/>	
Patient ID	<input type="text"/>	

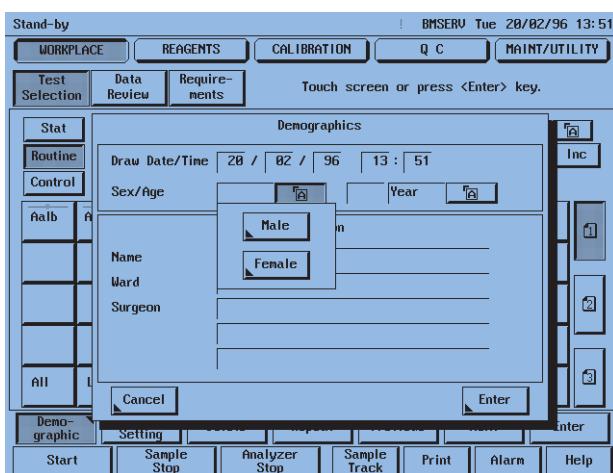
The SAMPLE NO. field is highlighted. Enter the first sample number, then press ENTER. Enter the sample disk number in the second field, followed by ENTER. Then proceed with entering the sample disk position number and confirm with ENTER. The cursor advances to the PATIENT ID text box. Type the PATIENT ID number, if required, then press ENTER.

For barcode mode:

Sample Type	Ser/PI	<input type="button" value="▲"/>
Patient ID	<input type="text"/>	

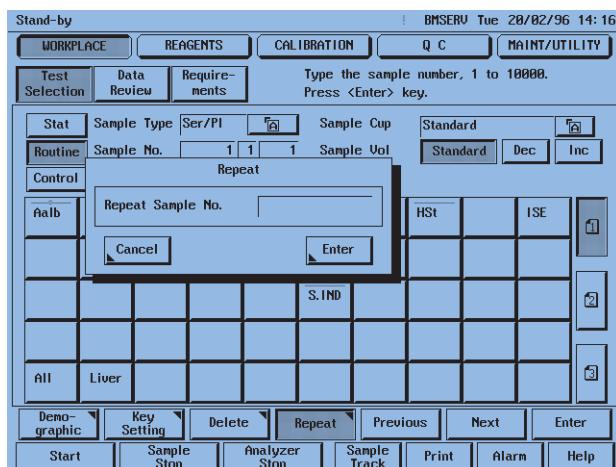
The PATIENT ID field is highlighted. Enter the barcode number of the sample, then press ENTER.

4. To change the default setting for the sample type, move the cursor to the SAMPLE TYPE assist box. Open the box and touch the desired sample type. The assist box closes and the selected sample type is displayed.
5. To change the default setting for the sample cup, move the cursor to the SAMPLE CUP assist box. Open the box and touch the desired sample cup. The assist box closes and the selected sample cup is displayed.
6. To change the default setting for the sample volume, touch STANDARD, DEC or INC to choose standard sample volume, decreased sample volume or increased sample volume respectively.
7. Touch the DEMOGRAPHIC button to display the DEMOGRAPHICS window. Enter all desired demographic information about the sample. Then, touch the ENTER button.

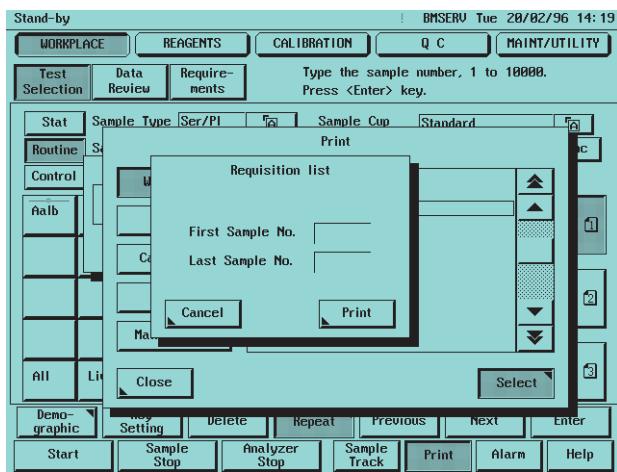


Initiate Run with Routine Patient Test Selections

8. Touch the desired test keys or profile keys on the test key matrix at the lower portion of the screen. Selecting a test individually or by profile key, results in the test key(s) on the screen turning white in color. When all desired tests for the sample have been selected, touch the ENTER button. The test selections are stored and the white color disappears.
 - If a yellow dot appears on the test key matrix for a specific test, this indicates that the test was masked by the operator in the START CONDITIONS global menu. Masked tests are not run.
 - If a red line appears on the test key matrix for a specific test, this indicates that the test is masked by the analyzer. Masked tests are not run. Check the REAGENTS main menu to resolve the situation that caused the test to be automatically masked.
9. The repeat function can be used only if the sample barcode reader is OFF. The repeat function is used for batch programming. It is available only after test selections are made for the first sample in the batch. Touch the REPEAT button to display the REPEAT window. Type the number of the last sample you want to be processed with the repeated test selections. Touch the ENTER button. (The sample number increments automatically.)



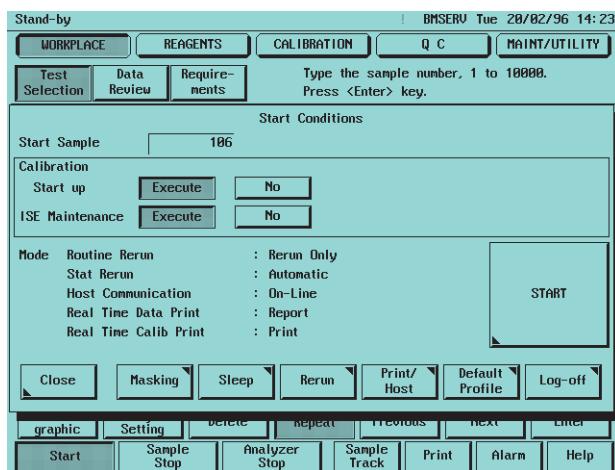
10. If you want to print out a load list of the test selections, touch the PRINT button to open the corresponding global menu. Touch WORKPLACE, followed by REQUISITION LIST. Then touch the SELECT button to display the REQUISITION LIST window. Enter the first and last sample number and then touch the PRINT button.



Initiate Run with Routine Patient Test Selections

2.6.2 Initiate Run Procedure

After the patient test selections have been made, touch the START button to display the START CONDITIONS global menu and to define the settings for the subsequent run.

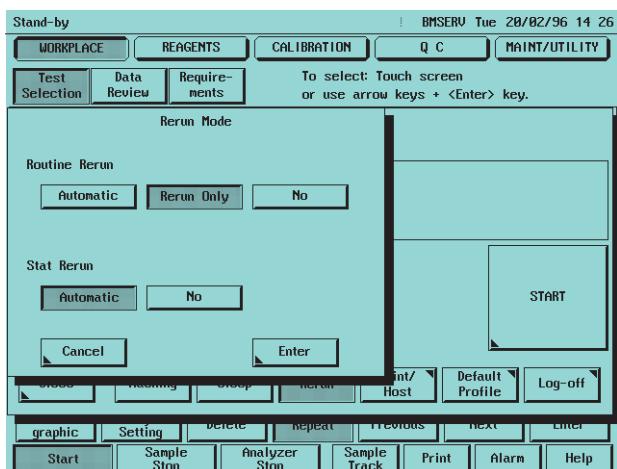


1. Touch the START button to open the START CONDITIONS global menu. Depending on barcode mode and host mode, entries vary as follows:

Sample barcode reader	Host communication	START SAMPLE	see
no	no	Start Sample <input type="text" value="106"/>	À
yes	yes	Start Sample <input type="text" value="106 : 0 1"/>	À
yes	no		
no	yes	Start Sample <input type="text" value="10 : 0 10 - 9 100"/>	Â

- ① If the analyzer is being operated without sample barcode reader and there is no host connection, then only 1 field is displayed. The sequence number that is used for the run start must be entered here.
- ② If the sample barcode reader is switched on, 3 fields appear, independent of whether there is a host connection present or not. The sequence number, disk number and disk position number that are used for the run start must be entered here.

- ③ If the analyzer is being operated without sample barcode reader but with host, then 5 fields appear. Sequence number, disk number, disk position number of the start sample, the last disk and last disk position number must be entered here.
2. You may request a start up calibration. Touch the START UP EXECUTE button to perform a start up calibration. A control measurement of all installed and active tests is automatically performed after the start up calibration.
 3. ISE maintenance should not be performed during daily routine. Touch the NO button. If YES is pressed, the analyzer performs after each run an automatic ISE maintenance with ISE wash solution on disk 2. Conditioning and ISE calibration is necessary after each ISE maintenance.
 4. Check the following mode settings to ensure parameters are set correctly for the run you are starting. Open the RERUN MODE window by touching the corresponding button in the START CONDITIONS global menu.



To change the routine rerun setting there are two options available in the opened window. If the AUTOMATIC option is selected, all tests with faulty results (outside the limits) are automatically rerun. Two modes are available:

REAL TIME: If this button is activated, this sample will be measured again during the current run.

AFTER 1ST: If this button is activated, the rerun will be carried out at the end of the run.

Initiate Run with Routine Patient Test Selections

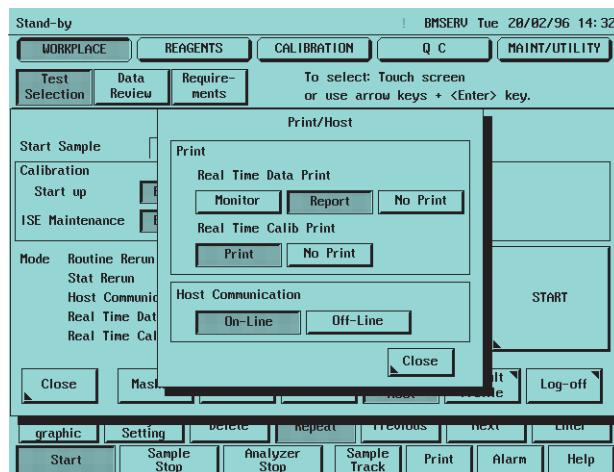
If the RERUN ONLY option is activated, samples that were scheduled for the rerun can be measured again. The system marks results in the DATA REVIEW sub menu (WORKPLACE main menu) that are outside the limits defined for the applications. These samples are scheduled for a rerun.

If the STAT RERUN option is activated, a rerun of STAT samples will be performed automatically under certain conditions.

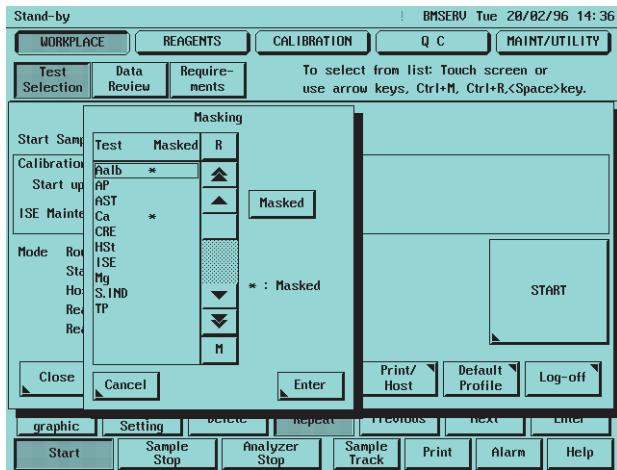
If the results of a STAT sample are outside the limits, the system will automatically measure that sample again. If the NO button is activated, the STAT sample will not be rerun.

5. To change the REAL TIME DATA PRINT and REAL TIME CALIB PRINT setting, touch the PRINT/HOST button in the START CONDITIONS global menu. Touch the print options you prefer. If the button MONITOR is activated, the results will be printed out in the monitor format. if REPORT is selected, the results will be printed out in the more extensive report format. If NO PRINT is activated, the results will not be printed out, but can be checked in the DATA REVIEW sub menu (WORKPLACE main menu) and printed out via the PRINT global menu.

To activate the HOST COMMUNICATION setting, touch the PRINT/HOST button. Touch ON-LINE or OFF-LINE to set the desired host communication mode. Then, touch the CLOSE button.



- To change any test masking, touch the MASKING button to open the corresponding window. A list of all tests appears in the list box. A masked test has an asterisk (*) following the test name. To mask a test, touch the test name in the list box and then the MASKED button. An asterisk (*) appears following the test name.



To unmask a test, touch first the test name in the list box and then the MASKED button. The asterisk following the test name disappears.

Touch the ENTER button to save any changes to test masking.

- Touch the CLOSE button to close the window. Touching CLOSE does not change any modifications you previously made to the START CONDITIONS global menu.

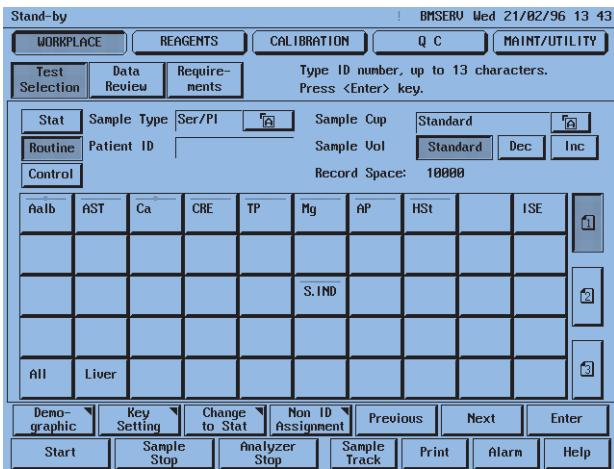
Initiate Run with Routine Patient Test Selections

Before you start the analysis:

8. Results of up to 10,000 samples are stored on the hard disk for later retrieval. You must ensure that each sequence number is used only once before archiving data and then clearing the data from the hard disk. The data with the same sequence number will be overwritten. If the sequence number reaches 10,000, the following sequence number (i.e. 1) will be overwritten.
9. Before you start the analysis, check the ALARM global menu for the presence of any alarms (as indicated by the ALARM button turning red). Review the alarm(s) and correct the condition(s) before continuing.
10. Place all patient samples, controls, and calibrators in their appropriate positions on the sample disks 1 and 2. Place a sample cup with a recommended wash solution in the "W" positions on sample disk 2.
11. Touch the START button when you are ready to initiate the run.

2.6.3 Entering Non-Barcoded or Unreadable Barcoded Samples (in the Barcode Mode)

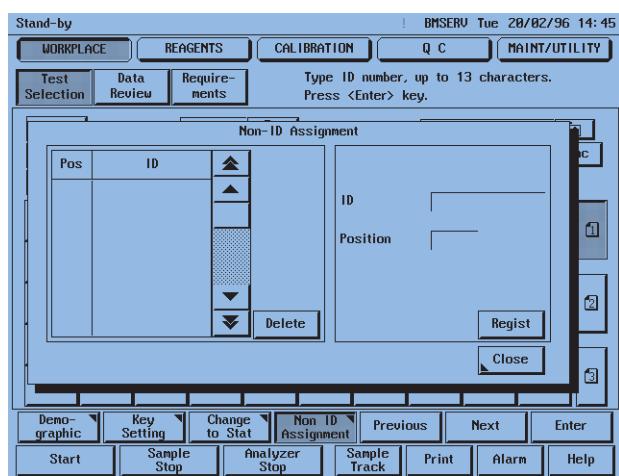
1. Touch WORKPLACE, followed by TEST SELECTION. Touch ROUTINE to enter routine patient test selections. The cursor will highlight the PATIENT ID text box.



2. To change the default setting for the sample type (e.g. serum/plasma, urine), touch the SAMPLE TYPE assist key. Touch the desired sample type in the displayed list. The assist box closes and the selected sample type is displayed.
3. To change the default setting for the sample cup, touch the SAMPLE CUP assist key. Touch the desired sample cup in the displayed list. The assist box closes and the selected sample cup is displayed.
4. To change the default setting for the sample volume, touch the desired SAMPLE VOL button, STANDARD, DEC or INC, to choose standard sample volume, decreased sample volume or increased sample volume respectively.
5. Enter the patient ID in the PATIENT ID text box and press ENTER. Touch the DEMOGRAPHIC button to display the DEMOGRAPHICS window. Enter all desired demographic information about the sample. Touch the ENTER button. If there are no requests from the host, touch the desired test key or profile key on the keyboard matrix. Selecting a test individually or by profile key results in the test key or keys on the screen turning white in color. When all desired tests for the sample have been selected, press ENTER.

Initiate Run with Routine Patient Test Selections

6. Touch the NON-ID ASSIGNMENT button to display the NON-ID ASSIGNMENT window. The NON-ID ASSIGNMENT function can be used if a barcode is damaged and cannot be read by the barcode reader. Enter a vacant, not registered, disk position number in the POSITION text box and press ENTER. Enter the patient ID number. Touch the REGIST button, and then the CLOSE button. The POS and patient ID number is displayed in the list box on the left side.

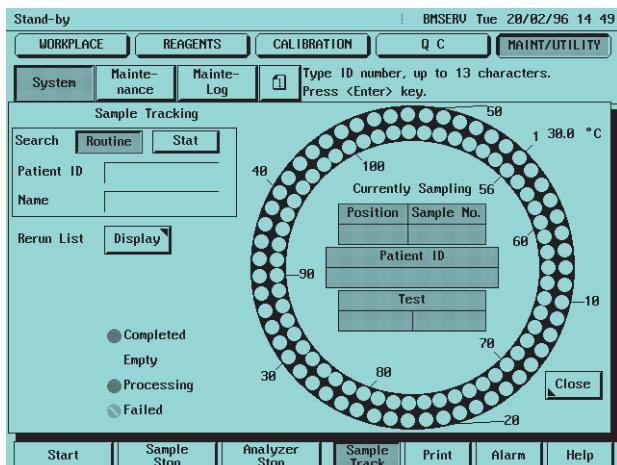


2.7 Sample Tracking

Use the SAMPLE TRACKING global menu to monitor the progress of samples through sample processing. Information about any sample currently being processed is displayed inside the sample disk ring on the screen. Samples can be searched by ID or by name. The sample ring has individual circles that represent each sample disk position.

These positions are highlighted as follows:

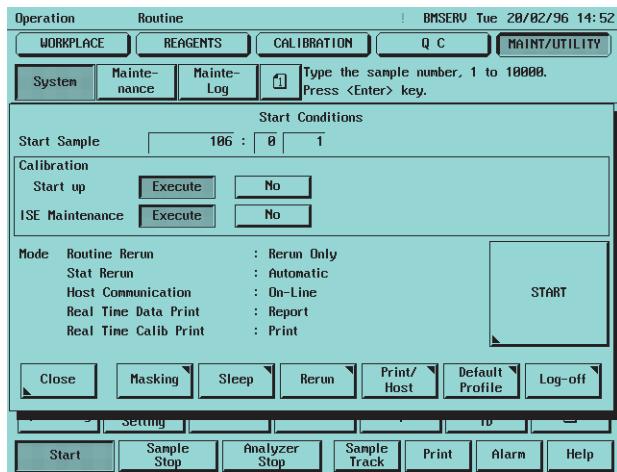
- indicates a completed sample
- indicates a sample that is in process
- indicates an open position
- ◐ indicates that the sample needs further attention from the operator and that the sample has to be measured again (rerun).



1. Touch SAMPLE TRACK, to display the SAMPLE TRACKING global menu.
2. The sample position and test currently being processed is automatically displayed in the text fields inside the graphic display of the sample disk.
3. To find a sample of the current run on the disk, you can use the SEARCH function, as indicated in the upper left corner of the screen. Touch ROUTINE or STAT and enter the PATIENT ID number or the SAMPLE number that you want to find. If the sample is found, it is marked with a "▼". A comment is also displayed for this particular sample.
4. In the RERUN list all reruns of the current run are displayed. Touch DISPLAY to display: the position, sample type, sample number and ID of the rerun. The rerun list selection lists contains all samples highlighted in red.

2.8 Measurement of Additional Routine Samples

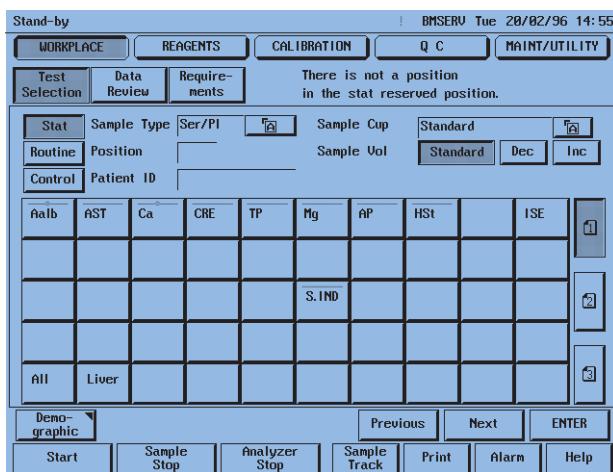
Additional routine samples may be requested at any time. Follow the procedure for programming routine samples. If the analyzer is not in operation, for example in Sampling Stop or Stand-by mode, you must touch START in the START CONDITIONS global menu to begin the run.



2.9 STAT Test Selections

STAT patient test selections can be made at any time, independent of the instrument mode. In the barcode mode STAT samples can be put in every position on the sample disk. In the non-barcode mode STAT samples can only be placed in the reserved positions. STAT samples are pipetted with the highest priority and are processed during the pipetting of routine samples.

1. Touch WORKPLACE, followed by TEST SELECTION. Touch STAT to enter STAT patient test selections.



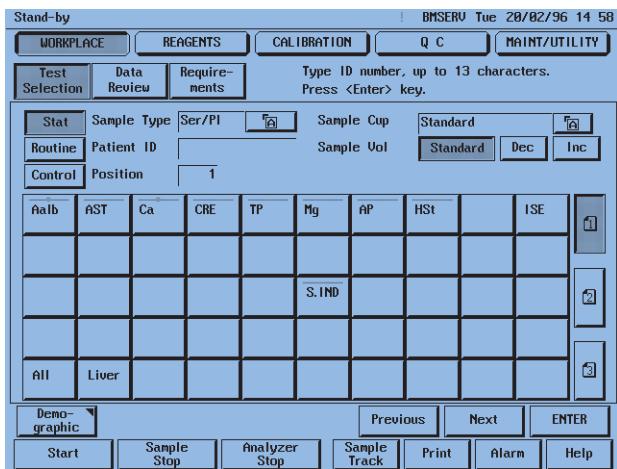
2. The cursor highlights the POSITION text box, if the barcode reader is off.

Sample Type	Ser/PI	<input type="button" value="F4"/>
Position	<input type="text"/>	
Patient ID	<input type="text"/>	

The cursor highlights the POSITION test box, if the barcode reader is on. Enter the position number and/or the patient ID number.

Sample Type	Ser/PI	<input type="button" value="F4"/>
Position	<input type="text"/>	
Patient ID	<input type="text"/>	

STAT Test Selection



3. To change the default setting for the sample type (e.g. to urine or CSF), touch the SAMPLE TYPE assist box. Touch the desired sample type in the displayed list. The assist box closes and the selected sample type is displayed.
4. To change the default setting for the sample cup, touch the SAMPLE CUP assist box. Touch the desired sample cup in the displayed list. The assist box closes and the selected sample cup is displayed.
5. To change the default setting for the sample volume, touch STANDARD, DEC or INC to choose standard sample volume, decreased sample volume or increased sample volume respectively.
6. Touch the DEMOGRAPHIC button to display the DEMOGRAPHIC window. Enter all desired demographic information about the sample. Touch the ENTER button. Request the desired tests or profiles by pressing the corresponding test keys and confirming with ENTER.
7. If there are no requests from the host, touch the desired test key or profile key on the keyboard matrix. Selecting a test individually or by profile key results in the test key or keys on the screen turning white in color. When all desired tests for the sample are selected, press ENTER.

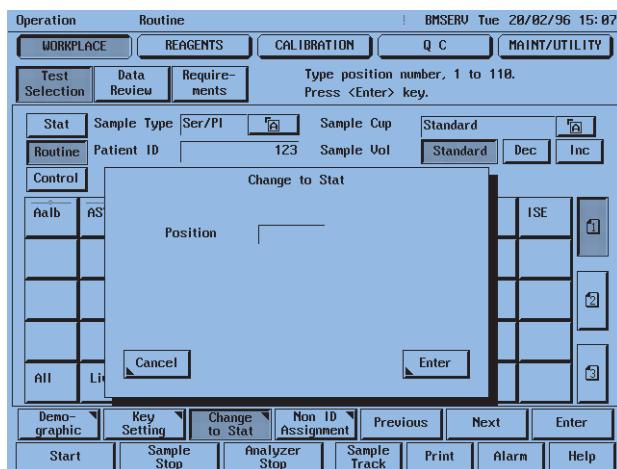
If a yellow dot appears on the test key matrix for a specific test, this indicates that the test is masked by the operator from the START CONDITIONS global menu.

If a red bar appears on the test key matrix for a specific test, this indicates that the test is masked by the analyzer. Masked tests may be requested, but are however not processed.

I Change Routine Sample to STAT Sample (in barcode mode only)

You may change a sample that has been programmed as a routine sample to a STAT sample. This enables the sample to be processed as a STAT, i.e. before any remaining routine samples.

1. Touch WORKPLACE, followed by TEST SELECTION and ROUTINE.
2. Type the PATIENT ID number and press ENTER.
3. Touch the CHANGE TO STAT button to display the CHANGE TO STAT window.



4. Enter the sample position number, corresponding to the sample's position on the sample disk, then press ENTER.
5. The sample located in this position will be processed as a STAT sample.

2.10 Processing of Rerun Samples

You may process rerun samples in two different ways, as automatic reruns or as manual reruns, requested by the operator.

All tests for a sample with results that do not meet the defined criteria are placed on a rerun list independent of the run mode.

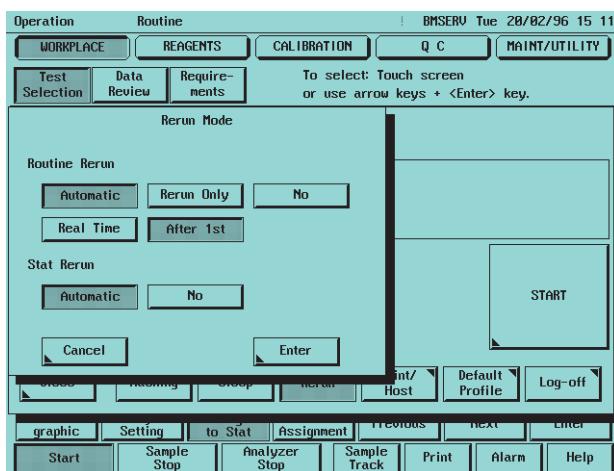
In the START CONDITIONS global menu, two different modes are selectable - REAL TIME and AFTER 1ST.

- REAL TIME: The sample is rerun without delay during the current run.
- AFTER 1ST: The rerun is performed at the end of the current analytical run.

The RERUN ONLY option can be used to request manually rerun samples. The instrument highlights in the DATA REVIEW sub menu (WORKPLACE main menu) all result that are outside the limits that are specified in the applications. These samples can be defined for a rerun.

2.10.1 Automatic Rerun

1. Touch the START button to display the START CONDITIONS global menu.
2. Touch the RERUN button to display the RERUN MODE window.
3. Touch AUTOMATIC to request that reruns be processed without operator intervention.
4. Touch REAL TIME if you want rerun samples to be processed during the current routine run. Touch AFTER 1ST if you want reruns processed at the end of the current run.
5. Touch the ENTER button to save the rerun settings.



2.10.2 Manual Rerun

1. Touch the START button to display the START CONDITIONS global menu.
2. Touch the RERUN button to display the RERUN MODE window.
3. Touch NO in the ROUTINE RUN area to request that reruns are not processed during or after routine runs.
4. Touch the ENTER button to save the rerun settings.
5. After the analytical run is finished: Touch WORKPLACE and DATA REVIEW to display the DATA REVIEW sub menu.

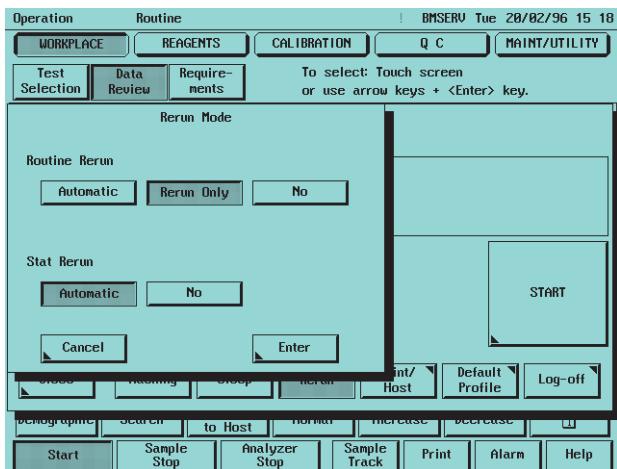
Sample barcode reader on

Sample barcode reader off

Samples that have incomplete results are marked with an I (left column on the left-hand side). Touch a sample you wish to review and the individual test results are displayed in the list on the right. Rerun tests are marked with a symbol. The symbol indicates the sample volume for rerun (■: normal, ▲: increased, ▼: decreased). If you want an other than the recommended volume, touch the respective buttons: Touch the NORMAL button to select tests for rerun with normal sample volumes. Touch the INCREASE button to select tests for rerun with increased sample volumes. Touch the DECREASE button to select test for rerun with decreased sample volumes. For each sample, additional test requests can be made in Stand-by mode. Touch the bars “---” at the end of the test result list and select the desired VOLUME. A window is displayed in which you can select a test for an additional rerun. Then, touch SELECT.

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6. Repeat step 5 for any other samples that have to be rerun.
7. Touch the START button to display the START CONDITIONS global menu.

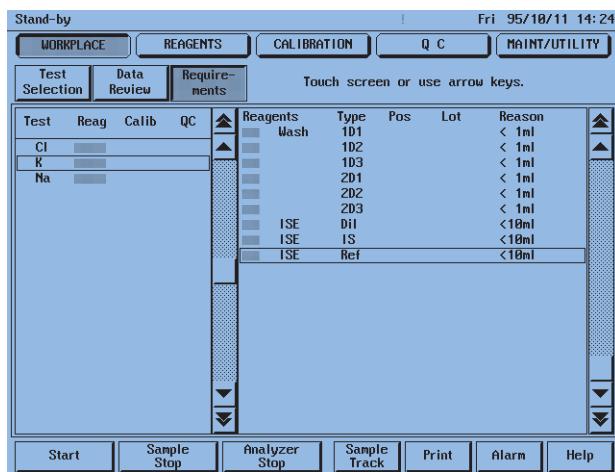


8. Touch the RERUN button to display the RERUN MODE window.
9. Touch RERUN ONLY to request rerun processing, then touch ENTER.
10. Enter the start sample number for the rerun in the START CONDITIONS global menu.
11. Press the START button.

2.11 Adding Reagent During a Run

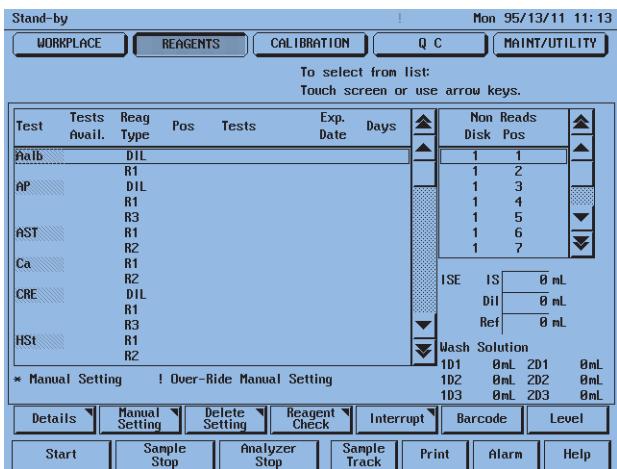
Use the REQUIREMENTS sub menu (WORKPLACE main menu) to check the levels of reagents.

If reagent levels are highlighted in yellow (REAG column) for any reagent, you may need to add reagent during the run. A reagent is highlighted in yellow when the defined number of remaining tests in the bottle reaches or falls below the limit that is set in the MAINT/UTILITY, SYSTEM, ALARM SETTING, REAGENT CHECK LEVEL screen.

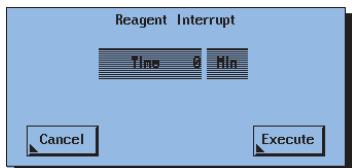


If reagents must be added during a running analysis, perform the following steps:

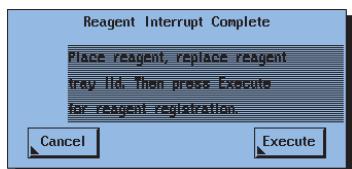
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1. Touch REAGENTS, followed by INTERRUPT to display the REAGENT INTERRUPT window in which the time remaining for the reload interrupt is specified. Then touch EXECUTE.



Press EXECUTE after adding reagent. The time remaining before you can add reagent counts down on the screen. After reaching zero, a message ("Place reagent replace reagent tray lid. Then press EXECUTE for reagent registration") is displayed in the window.



Place the reagent bottles into their assigned positions and touch the EXECUTE button.

2. The system automatically performs a reagent registration and resumes the current run.

2.12 Patient Reports

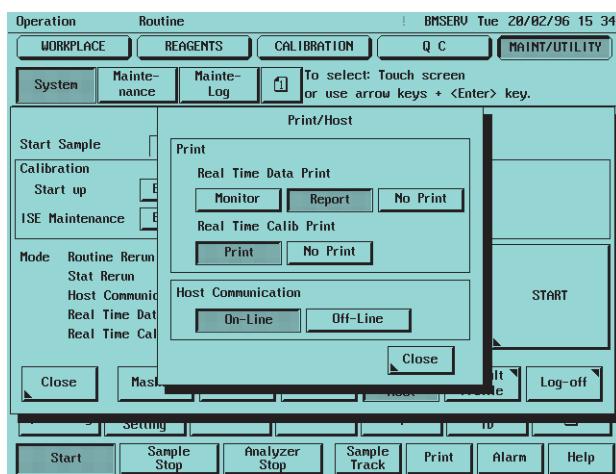
There are two patient result printout formats: MONITOR and REPORT.

- The MONITOR format is a shorter report format giving each test result. In the MONITOR format date and time, sample type, sequence number, ID number and comment 1 is printed out for each sample. The results are printed out next to each other with data flags.
- The REPORT format additionally gives the header, patient demographic information, results, units and expected values. Choose your format on the START CONDITIONS global menu, PRINT/HOST window.

You can request patient report print-outs automatically or manually. The report format can be customized to fit your laboratory needs (MAINT/UTILITY main menu, REPORT FORMAT sub menu).

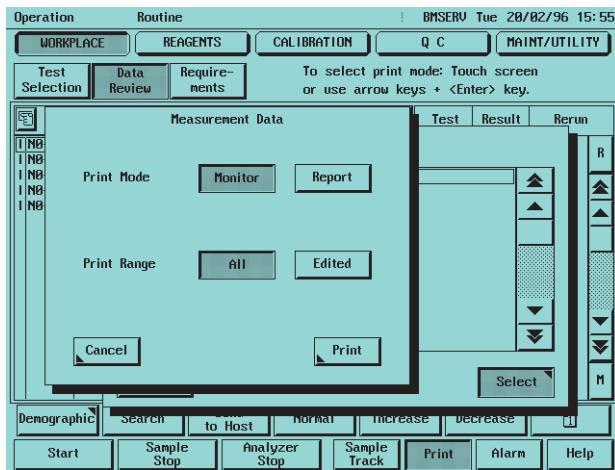
2.12.1 Selecting the Patient Report Format for Real Time Printing

1. Touch START followed by PRINT/HOST to display the PRINT/HOST window.
2. From the REAL TIME DATA PRINT selections, touch MONITOR to select the monitor format. Touch REPORT to select the report format. Touch NO PRINT to get no real time print.
3. Touch CLOSE to save the print settings.
4. The patient reports will print in real time, when all results for the patient sample are available.



2.12.2 Printing Patient Reports in Batch

1. Touch START followed by PRINT/HOST to display the PRINT/HOST window.
2. From the REAL TIME DATA PRINT selections, touch NO PRINT to select no real time report printing.
3. Touch CLOSE to save the print settings.
4. To print results at a later time, touch WORKPLACE, DATA REVIEW to display the DATA REVIEW sub menu.
5. Mark the data with the marking key M or R on the scrollbar. The scroll bars on the right side of each box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range of samples may be selected by touching the first and last sample in the desired range. When M is highlighted, multiple, non-consecutive samples may be selected. If neither is highlighted, only one sample at a time may be selected.
6. Touch the PRINT button to display the PRINT global menu.
7. Select MEASUREMENT DATA from the list box and touch SELECT. Touch MONITOR or REPORT to choose the report format.
8. Touch ALL or EDITED to print all results or only results that have been edited.
9. Touch PRINT to print out the patient reports.



2.13 Data Management

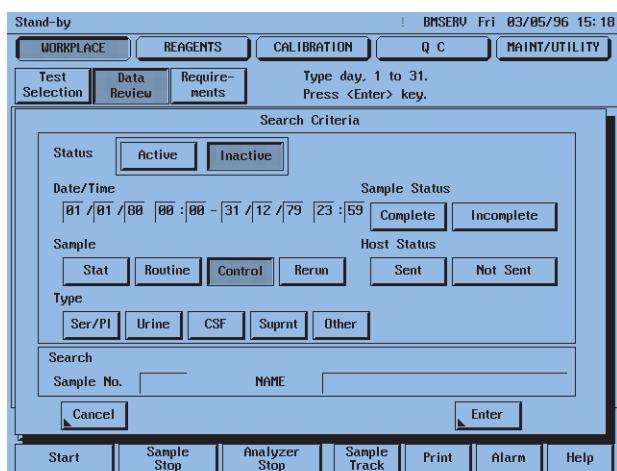
The way results are documented, depends on the mode settings selected from the START CONDITIONS global menu, PRINT/HOST window.

Data is saved on the hard drive but can also be saved on a floppy disk.

You may edit and delete data as necessary. Edited data can be printed out as a patient report or be transmitted to the host.

2.13.1 Reviewing Data

Use the DATA REVIEW sub menu and the steps below to review patient data:

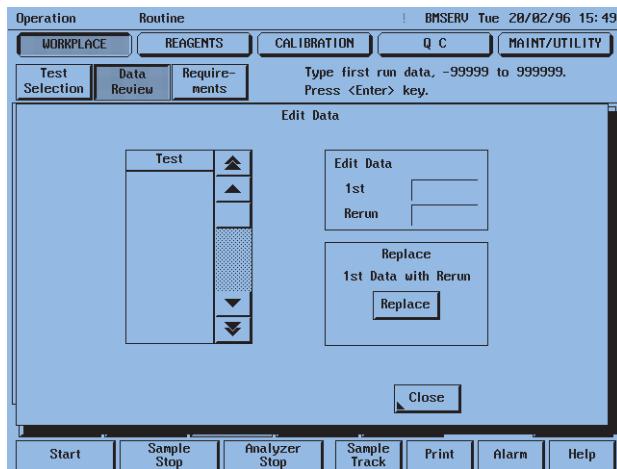


1. Touch WORKPLACE, followed by DATA REVIEW to display the DATA REVIEW sub menu.
2. Touch SEARCH to display the SEARCH CRITERIA window. Select the desired search criteria and touch the ENTER button.
3. All samples meeting the selected search criteria are displayed in the left box. If control is selected as the search criterion, all other search criteria have to be deactivated.

2.13.2 Editing Data

■ Overwrite First Result with Rerun Result

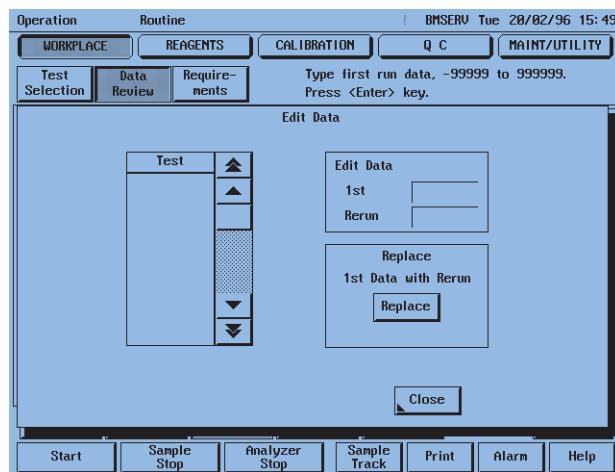
1. Touch the sample that needs to be edited in the left box. Details of the test information appear in the right box, including first run results and rerun results.
2. Touch the page key -1- to access the second window level and then the EDIT button to display the EDIT DATA window.



3. Touch the REPLACE button if you only need to replace first run results with rerun results. The replace function automatically overwrites all tests of this sample with the rerun result.
4. Touch the CLOSE button to close the window and save the edits.
5. Repeat steps 1-4 for all samples where the first result has to be overwritten by the rerun result.

■ Overwrite Results

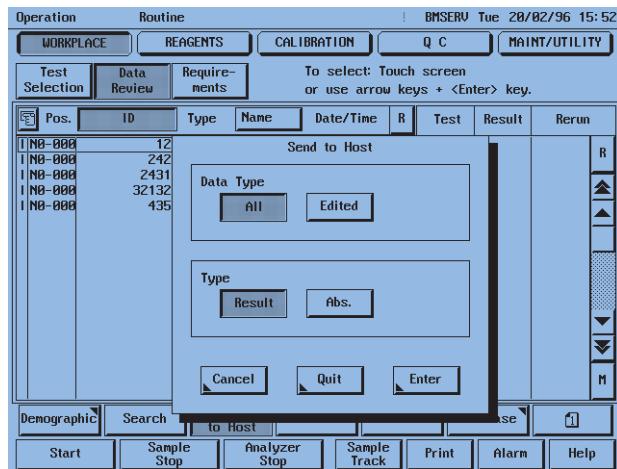
1. Touch the sample that needs to be edited in the left box. Details of the test information appear in the right box, including first run results and rerun results.
2. Touch the page key -1- to access the second window level and then the EDIT button to display the EDIT DATA window.



3. Touch the test name in the list box if you need to edit manually the result. The first run result and rerun result appear in the EDIT DATA text boxes. Enter the new results.
4. Touch the CLOSE button to close the window and save the edits.
5. Repeat steps 1-4 for all samples where the first result has to be overwritten by the rerun result.

■ Sending Edited Data to the Host

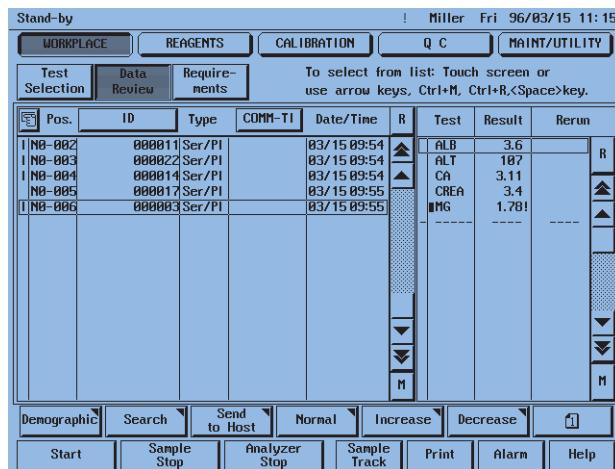
1. Mark the data on the DATA REVIEW sub menu with the marking keys R or M. The scroll bars on the right side of the sample list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range of samples may be transmitted by touching the first and last sample in the desired range. When M is highlighted, multiple, non-consecutive samples may be transmitted. If neither is highlighted, only one sample at a time may be transmitted.
2. Touch the SEND TO HOST button to display the SEND TO HOST window.



3. Touch ALL or EDITED to select which data is sent to the host. Touch EDITED to send only edited data to the host.
4. Touch RESULT to send the results to the host. Touching ABS. sends the absorbance readings.
5. Touch ENTER to begin the data transmission to the host.
6. Touch QUIT to stop host transmission.

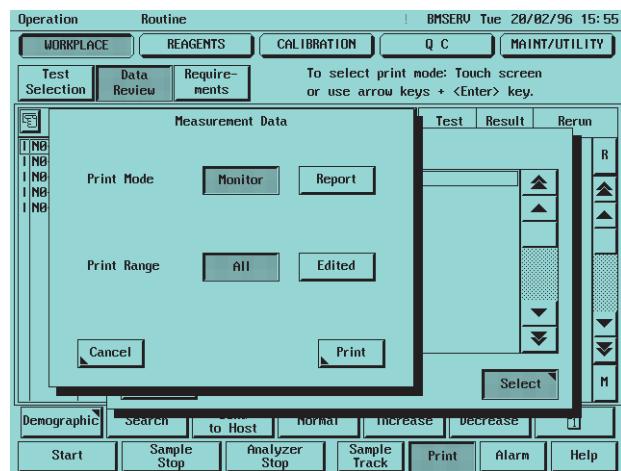
■ Printing Edited Data

1. Touch WORKPLACE, followed by DATA REVIEW to display the DATA REVIEW sub menu.



2. Mark the data in the DATA REVIEW sub menu with the marking keys M or R. The scroll bars on the right side of the sample list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range of samples may be printed by touching the first and last sample in the desired range. When M is highlighted, multiple, non-consecutive samples may be printed. If neither is highlighted, only one sample at a time may be printed.
3. Touch the PRINT button to display the PRINT global menu.
4. Touch WORKPLACE and select the MEASUREMENT DATA report from the list box. Touch SELECT to display the MEASUREMENT DATA window.

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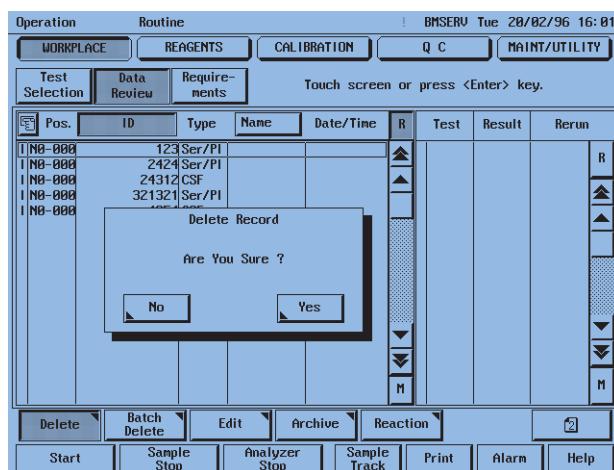
5. Touch MONITOR or REPORT to choose the report format.
6. Touch ALL or EDITED to print all results or only results that have been edited.
7. Touch PRINT to print out the patient reports.

2.13.3 Deleting Functions

■ Deleting Samples

1. Touch WORKPLACE, then DATA REVIEW to display the DATA REVIEW sub menu.
With the left list box selected:
2. Select the sample(s) to be deleted. You can delete a single sample, a range or all samples. The scroll bars on the right side of the sample list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range of samples may be deleted by touching the first and last sample in the desired range. When M is highlighted, multiple, non-consecutive samples may be deleted. If neither is highlighted, only one sample at a time may be deleted.
If you want to delete samples with all corresponding data:

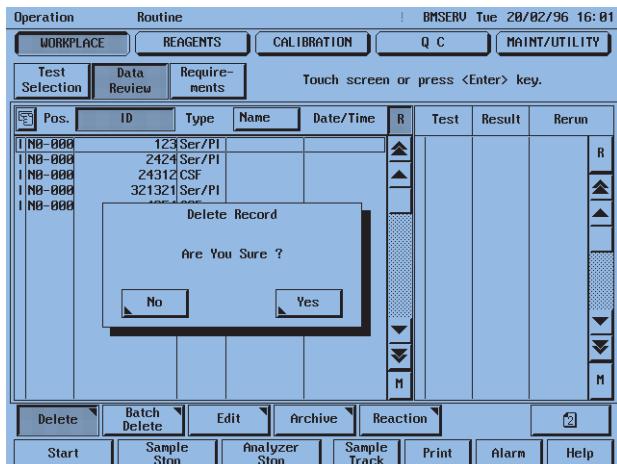
3. Touch the page key -1 - to access the second window level and then DELETE to open the corresponding window.



4. Touch YES to delete the highlighted samples. Note that the test selection is deleted together with the results.

■ Deleting Single Tests

1. Touch WORKPLACE and DATA REVIEW to display the DATA REVIEW sub menu.
2. Select the test(s) to be deleted in the left list box. You can delete a single test, a range of tests or all tests.
3. The scroll bars on the right side of the test list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range of tests for the selected sample may be deleted by touching the first and last test in the desired range. When M is highlighted, multiple, non-consecutive tests for the selected sample may be deleted. If neither is highlighted, the whole sample is deleted.
4. Touch DELETE to open the DELETE RECORD window.

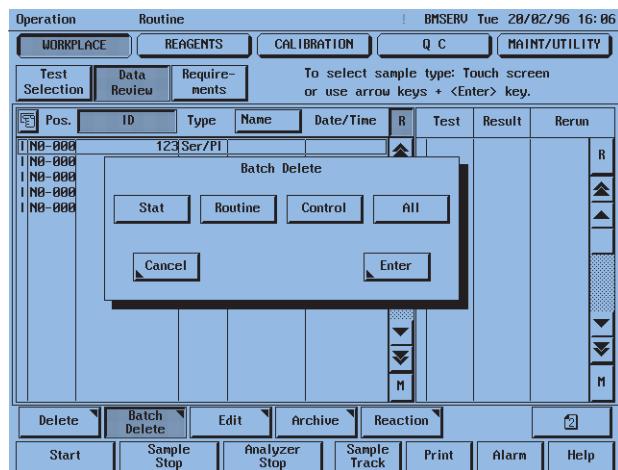


5. Touch YES to delete the selected test. Note that only the single test result but not the test selection is deleted.

■ Deleting Sample Types (Batch Delete)

To delete all samples of a sample type:

1. Touch WORKPLACE, DATA REVIEW to display the DATA REVIEW sub menu. Touch the BATCH DELETE button to display the BATCH DELETE window.



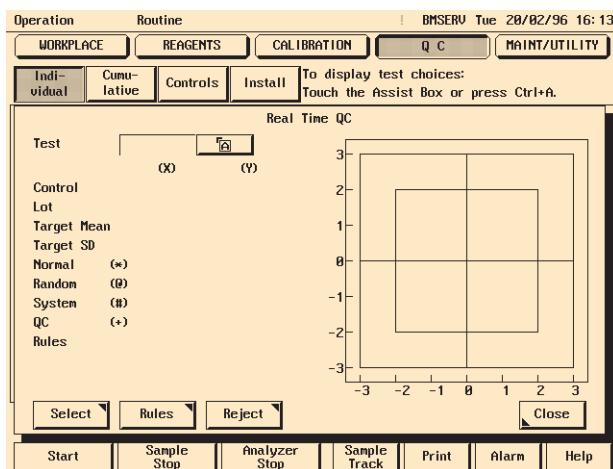
2. Touch STAT to delete all STAT sample data.
Touch ROUTINE to delete all routine sample data.
Touch CONTROL to delete all control sample data.
Touch ALL to delete all data.
3. Touch ENTER, followed by YES to delete the selected data.
4. Touch CANCEL to cancel the deletion of the selected data.

Note

This procedure deletes also the test selections.

2.14 Quality Control Procedures

During routine operation, the instrument compares paired (X) and (Y) control values against the mean and standard deviation entered for each control in the REAL TIME QC window (INDIVIDUAL QC sub menu). The REAL TIME QC screen evaluates quality control results by a multi-rule Shewhart method. The rules are selected by the operator.

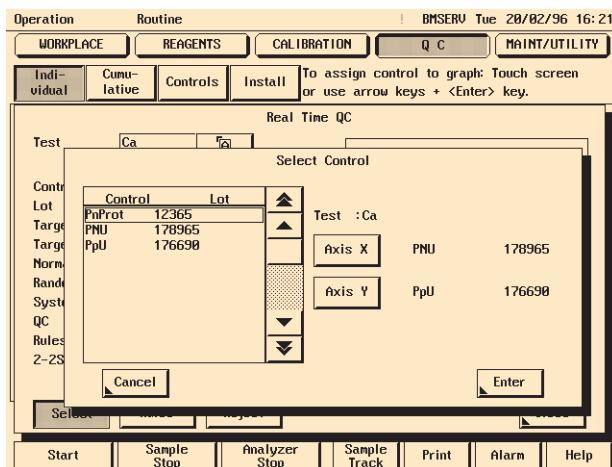


Each set of control results is either acceptable or causes a random, system, or QC error. If a random, systematic, or QC alarm occurs, an alarm message appears on the ALARM global menu.

In addition, an audible alarm occurs when an error of this type is detected. Consult the above screens during a test run to ensure that patient results are properly controlled.

2.14.1 Selecting Controls for Real Time QC

1. Touch QC, followed by INDIVIDUAL and REAL TIME QC to display the REAL TIME QC window. Daily QC results can be reviewed and checked in this window.
2. Touch the TEST assist box to display the list of tests. Touch the name of the test you want to review and press ENTER.
3. Touch the SELECT button to display the SELECT CONTROL window to choose the controls you wish to review.
4. Touch the control in the list, followed by AXIS X to assign a control to the X-axis.
5. Touch the control in the list, followed by AXIS Y to assign a control to the Y-axis. Touch ENTER to display the graph.



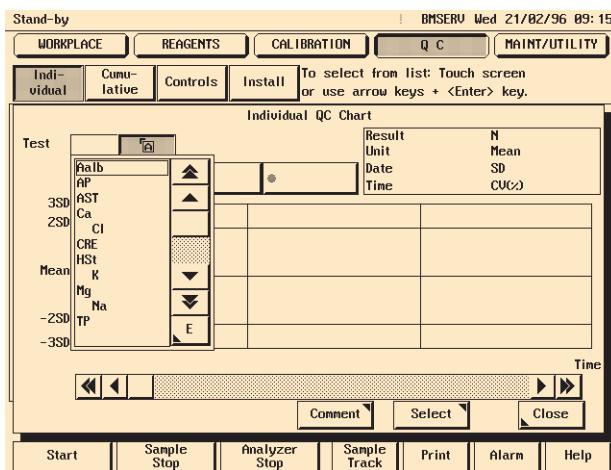
6. Touch RULES if you wish to change the rules by which the QC data are evaluated. The SELECT RULES window is displayed. Touch the rules you want used in the evaluation, followed by ENTER. The previously measured controls are not redrawn according to the rule selection.
7. The graph shown displays all of the QC results for the specified test and control levels. Random, System and QC errors are displayed along with normal QC data.

2.14.2 Individual QC List

1. Touch QC, followed by INDIVIDUAL to display the INDIVIDUAL QC LIST sub menu.
 2. All daily QC results for the selected test that have not been accumulated are displayed, even if the analyzer is powered off and powered on again.

2.14.3 Setting of Controls in the Individual QC Chart

1. Touch QC, followed by INDIVIDUAL and CHART to display the INDIVIDUAL QC CHART window.



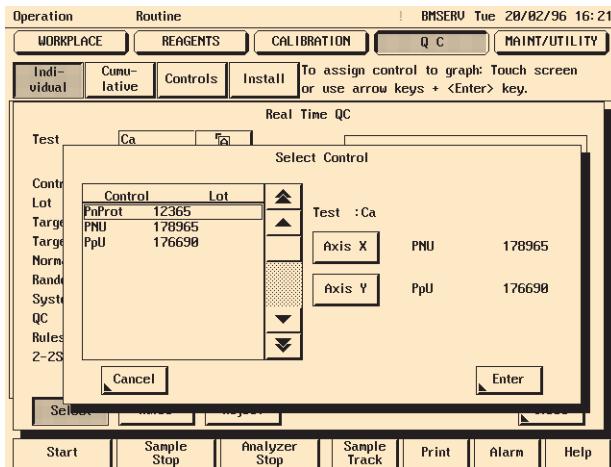
2. Touch the TEST assist box. Touch the test you want to review and press ENTER.
3. Touch SELECT to display the SELECT CONTROL window. Touch the control name followed by the PLOT button. This assigns the selected control to the selected plot. The selected control appears next to the PLOT button. Repeat the procedure for the other two controls you want displayed. Touch ENTER.

■ Validation of Controls with the Individual QC Chart

1. Touch QC, followed by INDIVIDUAL and CHART to display the INDIVIDUAL QC CHART window.
2. Touch the TEST assist box. Touch the test you want to review and press ENTER.
3. Up to three different controls can be displayed in the chart with three different symbols. Controls can be displayed (or not displayed) by pressing the corresponding control button. A yellow bar indicates that the controls are accumulated.
4. If you wish to exclude a control from the statistical evaluation, use the scrollbar and use the arrow keys to move the cursor to the desired control symbol. Then touch COMMENT. Enter the required comment into the comment line and confirm with ENTER. The excluded control is displayed as a non-filled-out symbol.

2.14.4 Validation of Individual QC with Real Time QC (Rejection of Single Test Couplings)

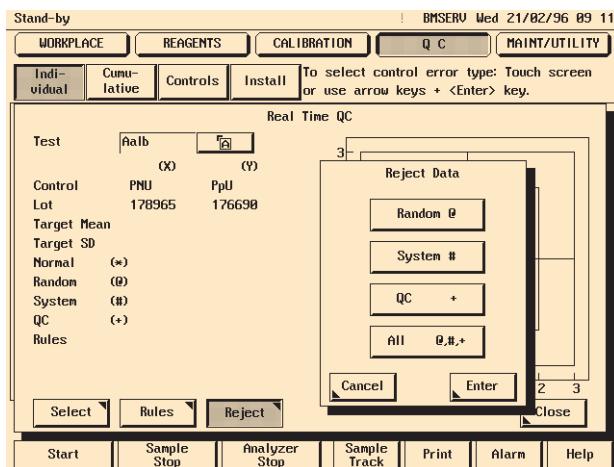
1. Touch QC, followed by INDIVIDUAL and REAL TIME QC to display the REAL TIME QC window.
2. Touch the TEST assist box to display the list of tests. Touch the name of the test you want to review and press ENTER.
3. Touch the SELECT button to display the SELECT CONTROL window.



Select the controls you wish to review. Previously defined controls are displayed on the X-axis and Y-axis.

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4. Touch REJECT to display the REJECT DATA window.



Touch the data type you want to reject (RANDOM, SYSTEM, QC or ALL). Then touch ENTER, followed by YES.

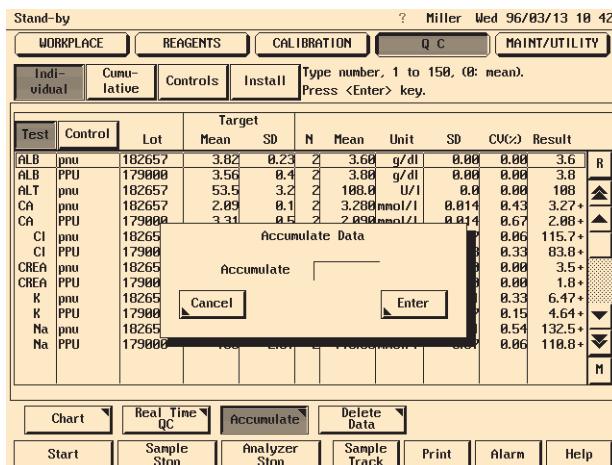
2.15 QC File Maintenance

Use the following procedures to accumulate and delete QC data on a regular basis:

2.15.1 Accumulate QC Data

1. Touch QC, followed by INDIVIDUAL to display the INDIVIDUAL QC LIST sub menu.
2. Touch the test(s) in the left list box which you want to accumulate.

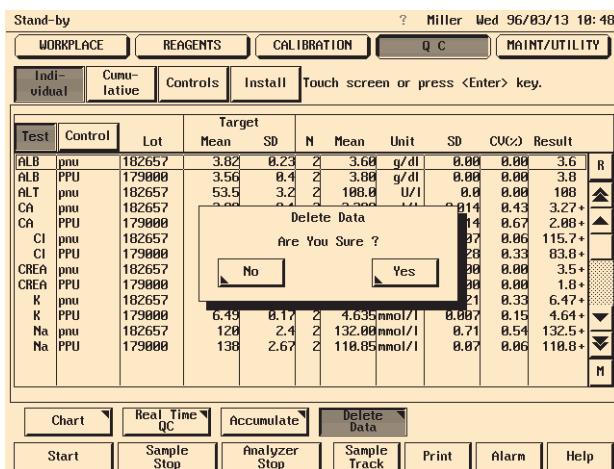
The scroll bars on the right side of the list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range data may be accumulated by touching the first and last result in the desired range. When M is highlighted, multiple, non-consecutive data for the selected test may be accumulated.



3. Touch the ACCUMULATE button to display the ACCUMULATE DATA window.
4. Enter the control number (see guidance box) to accumulate the selected data. Accumulating the data deletes the data from the INDIVIDUAL QC sub menu.

2.15.2 Deleting QC Data

1. Touch QC, followed by INDIVIDUAL to display the INDIVIDUAL QC LIST sub menu.



2. Touch the name of the test you want to delete.

The scroll bars on the right side of the list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range data may be deleted by touching the first and last result in the desired range. When M is highlighted, multiple, non-consecutive data for the selected test may be deleted. If neither is highlighted, only one set of data may be deleted at a time.

3. Touch the DELETE DATA button to display the corresponding window. Then touch YES, to delete the selected data.

2.15.3 Cumulative QC List

1. Touch QC, followed by CUMULATIVE, to display the CUMULATIVE QC LIST sub menu.

The screenshot shows a laboratory control software interface. At the top, it says "Stand-by" and "Miller Wed 96/03/13 10:52". Below that is a navigation bar with tabs: WORKPLACE, REAGENTS, CALIBRATION, QC (which is highlighted), and MAINT/UTILITY. Under the QC tab, there are sub-tabs: Individual, Cumulative (which is selected and highlighted in grey), Controls, and Install. A message "Touch screen or press <Enter> key." is displayed. The main area is a table titled "Target" with the following data:

Test	Control	Lot	Mean	SD	N	Unit	SD	CV(%)	Result
ALB	pnu	182657	3.82	0.23	2	3.68 g/dl	0.08	0.00	3.68 R
ALB	PPU	179000	3.56	0.4	2	3.75 g/dl	0.87	1.87	3.00
ALT	pnu	182657	53.5	3.2	2	188.0 U/l	0.0	0.00	188.0
CA	pnu	182657	2.89	0.1	2	3.270 nmol/l	0.014	0.43	3.200
CA	PPU	179000	3.31	0.5	2	2.890 nmol/l	0.000	0.00	2.890
Cl	pnu	182657	88.1	2.64	2	112.35 nmol/l	2.47	2.28	110.68
Cl	PPU	179000	189	3.3	2	83.65 nmol/l	0.49	0.59	84.00
CREA	pnu	182657	2.85	0.2	2	3.50 ng/dl	0.08	0.00	3.50
CREA	PPU	179000	4.82	0.5	2	1.88 ng/dl	0.08	0.00	1.00
K	pnu	182657	4.67	0.13	2	6.570 nmol/l	0.057	0.87	6.610
K	PPU	179000	6.49	0.17	2	4.680 nmol/l	0.014	0.38	4.610
Na	pnu	182657	120	2.4	2	134.50 nmol/l	0.57	0.42	134.98
Na	PPU	179000	138	2.67	2	118.80 nmol/l	0.57	0.51	110.40

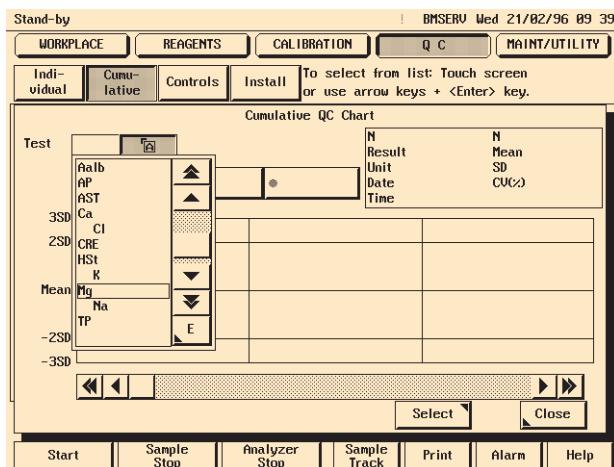
Buttons at the bottom include: Chart, Delete Data, Start, Sample Stop, Analyzer Stop, Sample Track, Print, Alarm, and Help.

2. Touch the TEST button. The CUMULATIVE QC list is sorted by test in alphabetical order. If you touch the CONTROL button, the CUMULATIVE QC list is sorted by control in alphabetical order.
3. The statistics e.g. number of accumulations, mean, SD, CV is displayed.

2.15.4 Validation of Cumulative QC

1. Touch QC, CUMULATIVE, CHART to display the CUMULATIVE QC CHART window.
2. Touch the TEST assist box. Touch the test you want to activate.
3. Up to three different controls can be displayed in the chart with three different symbols. Controls can be displayed (or not displayed) by pressing the corresponding control button.

Touch select to display the CHART SELECT window. Touch the control name followed by the PLOT button. This assigns the selected control to the selected plot. Repeat this steps for the other two controls you want to be displayed. Then touch ENTER.



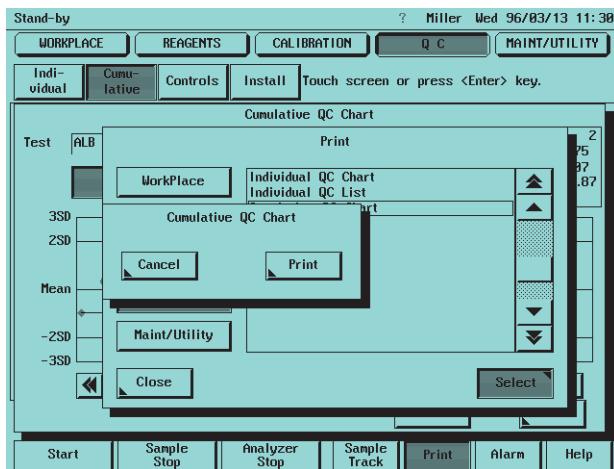
2.15.5 Printing the Cumulative QC List and Chart

1. Touch QC, followed by CUMULATIVE to display the CUMULATIVE QC LIST sub menu.
2. Touch the name of the test you want to print out.

The scroll bars on the right side of the list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range data may be printed by touching the first and last result in the desired range. When M is highlighted, multiple, non-consecutive data for the selected test may be printed. If neither is highlighted, only one set of data may be printed at a time.

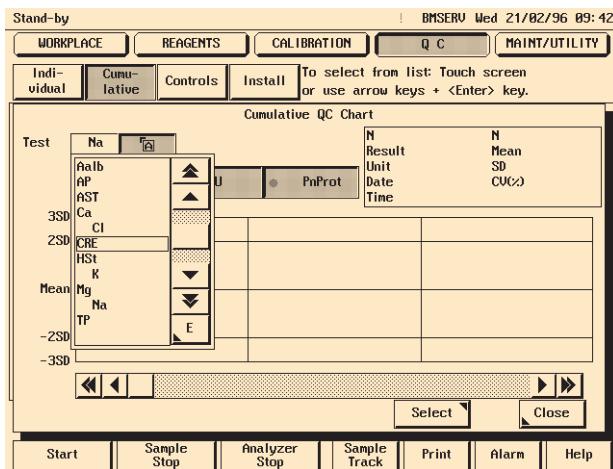
3. Touch the PRINT button, followed by QC and CUMULATIVE QC CHART or LIST. The CUMULATIVE QC CHART window or the CUMULATIVE QC LIST window opens. Press the PRINT button to print out the cumulative QC chart or cumulative QC list.

If the cumulative QC chart is printed out, the selected controls are printed out as well, together with statistic data.



2.15.6 Deleting the Cumulative QC

1. Touch QC, followed by CUMULATIVE to display the CUMULATIVE QC LIST sub menu.
2. Touch the name of the test you want to review. The scrollbars on the right side of the list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range data may be deleted by touching the first and last result in the desired range. When M is highlighted, multiple, non-consecutive data for the selected test may be deleted. If neither is highlighted, only one set of data may be deleted at a time.



3. Touch the DELETE DATA button to display the DELETE DATA window.
4. Touch YES to delete the selected data.

2.16 System Shutdown

There are two different ways to terminate the analyzer operation: Firstly, the instrument can be completely shut down. Secondly, the SLEEP mode can be activated which helps to save time when the analyzer is restarted.

2.16.1 Instrument Shutdown

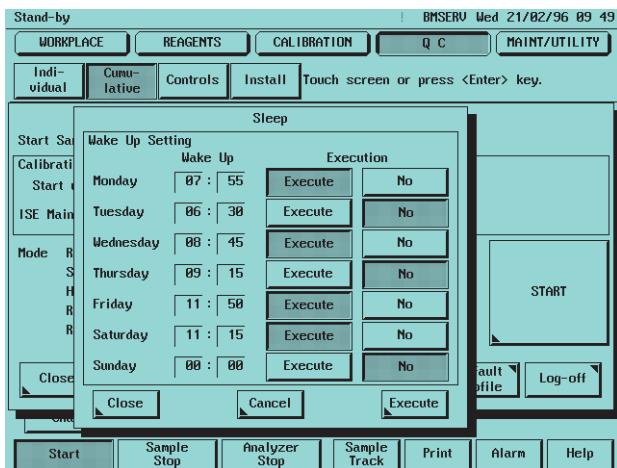
Perform the following steps to shut down completely the analyzer:

1. Push the POWER switch (on the right of the front panel of the analyzer) to OFF position.
The analyzer is now switched off. The computer, screen, and the printer are also switched off, if the main switches of these components are permanently left in the ON position.
2. Remove the patient samples from the sample disk 1.
3. Remove the calibrators/controls which are no longer needed from the sample disk 2.
4. Switch off the external water supply.

2.16.2 Activating the SLEEP Mode

Perform the following steps to activate the SLEEP mode:

1. The “wake-up” time of the instrument for a specific day can be set in the SLEEP window in the START CONDITIONS global menu.



Press the EXECUTE button to activate the timer. The instrument is automatically initialized at the specified time.

2. Remove the patient samples from the sample disk 1.
3. Remove the calibrators/controls which are no longer needed from the sample disk 2.
4. Switch off the external water supply.

Note

The SLEEP mode can be interrupted at any time by pressing the CANCEL button in the displayed SLEEPING window.

3. Maintenance and Daily Care

3.1 Introduction

As with all precision instruments the BM/Hitachi 917 requires preventative care and maintenance measures to ensure trouble-free functionality which in turn ensures correct results and error-free operation.

As well as the detailed instructions given in the maintenance schedule of this chapter, you should heed the following guidelines to avoid irregularities and any potential malfunctions resulting from the latter.

Comply with the maintenance and care schedule described below in this chapter. A trouble-free and long term operation of the analyzer can only be guaranteed, if the periodic maintenance measures are adhered to. Regular care and maintenance of the system prevents time-intensive repairs.

Inform your Boehringer Mannheim service representative about any unusual occurrences.

3.1.1 Necessary Material and Safety Precautions

At the beginning of each procedure in this chapter, the necessary materials and safety precautions are listed. Please comply with this information!



Warning

Strictly comply with the normal laboratory safety precautions and the safety precautions that are specified in the following instructions.

Extreme caution is necessary when handling supply-carrying, sharp-edged or pointed analyzer components. **Risk of injury!**

Wear protective gloves when handling potentially infectious materials and analyzer components that come in contact with these materials. **Health risk!**

Tools and Accessories

Phillips screwdriver for 2 mm and 4 mm screws (for removing covers)
Stainless steel wire with diameters of 0.2 mm and 0.5 mm (for cleaning probes)
Special syringe wrench (for syringes and seals)
Deionized water (conductivity < 1 µS/cm)
Lint-free towels (cleaning)
Vacuum cleaner, brush (for the dust filter of the cooling unit)
Tweezers (accessories)
A glass (500 mL)
Bucket
Commercial, disposable plastic syringe (50 mL or 100 mL)

Detergents

Hitergent

Load the bottles (70 mL) in positions 1D1 and 2D1 (compartments) next to reagent disks.
Hitergent is added after a water replacement in the incubation bath.

Detergent 1 (NaOH-D)

Place a container with this detergent in the appropriate position behind the front door.
Load the bottles (70 mL) containing this detergent in positions 1D2 and 2D2 in the marked compartments adjacent to the reagent disks. The detergent is used for cleaning the reaction cells and reagent probes.

Detergent 2

As an option, a second detergent can be loaded in the appropriate position behind the front door.



Warning

Detergents can cause skin rashes. Please wear rubber gloves.

Spare Parts and Consumables

Part/Nomenclature	Part Number	BM Order Number
Halogen lamp	705-0840	
Set of reaction cells (32 segments)	714-0650	156 8132
Hitergent (12 x 70 mL bottle)		155 5448
NaOH-D (70 mL bottle)		155 5430
NaOH-D (2 L bottle)		155 1540
Hitachi sample cup (quantity: 5000)		039 4246
Hitachi Micro Cup (quantity: 100)		122 9290
Upper seal for sample syringe	714-1360	156 8477
Spacer for sample syringe	714-1282	156 8523
Upper seal for sample syringe	714-1361	156 8485
Upper seal for reagent syringe	714-1362	156 8493
Spacer for reagent syringe	714-1291	156 8531
Lower seal for reagent syringe	714-1363	156 8507
Lower O-ring for sample/reagent syringe	L 456006	098 9142
Upper seal washer for syringes	L 443085	068 5917
Teflon block (nozzle tip)	714-2403	156 6466
Seal for ISE syringes	L 172108	082 5344
Lower O-ring for ISE syringe	737-1629	085 5766
Serum probe	714-0575	156 6083
Reagent probe	714-0570	156 6075
Stirrer paddle	714-0602	156 6105
Set of cleaning wires (0.5 mm und 0.2 mm)	705-0516	064 1766
Pinch valve tubing		140 2650
Na electrode		082 5468
K electrode		082 5441
Cl electrode		106 9004
ISE reference electrode		140 3826
Printer paper		082 5506
Printer ink ribbon cartridge		122 9346

3.1.2 Automatic System Cleaning (Daily)

During routine operation, the system rinses the reaction cells. The sample probe, the reagent probes, and the stirring paddles are automatically cleaned with water after each pipetting cycle in the rinse bath.

Safety Precautions

Normal laboratory procedures (e.g. protective gloves).

Necessary Material

Sample cups, detergent 1 (NaOH-D), ISE wash solution, Hitergent.



1. To clean the sample probe, load a sample cup containing approx. 1 mL of detergent 1 NaOH-D in position W1 on the sample disk 2.
2. If an ISE unit is used, load a sample cup containing approx. 1 mL ISE wash solution in position W2 on the sample disk 2.
3. Make sure that sufficient detergent 1 (NaOH-D), for cleaning the reaction cells, is in the container behind the front door of the analyzer.



4. Check whether there is sufficient Hitergent (at least 10 mL), is available in the compartments 1D1 and 2D1 (for the reaction bath). Also check there is sufficient NaOH-D (at least 50 mL) available in the compartments 1D2 and 2D2 next to the reagent disks.
5. Afterwards, start the routine as usual.

3.1.3 ERGO Console Cleaning

If necessary, the surfaces of the ERGO console can be cleaned with commercially available solutions.

3.1.4 Maintenance and Care Schedule

Perform the following maintenance and care measures in the order described below. The detailed descriptions of the following points can be found on the following pages of this chapter.

Note

The MAINT LOG sub menu (main menu MAINT/UTILITY) can be opened at any time to obtain information on the time that is left, until the next maintenance measure of the appropriate part of the analyzer must be performed. In this screen, the appropriate maintenance functions can also be started. In this case, the analyzer stores the date, time and operator ID, and also prints this information in the maintenance report.

Maintenance and care procedures when the analyzer is switched off:

	Page
Daily	
Emptying the waste container	3-9
Cleaning the reagent probes and sample probe	3-13
Cleaning the stirring unit	3-14
Cleaning the instrument surfaces	3-15
Cleaning the nozzles of the cell rinse unit	3-15
Weekly	
Cleaning the rinse bath for the sample probe, reagent probes and the stirring paddle	3-21
Monthly	
Replacing the reaction cell segments	3-22
Cleaning the incubation bath and incubation bath drain filter	3-24
Cleaning the inside of the sample and reagent disks	3-28
Cleaning the air filter	3-30
Replacing the ISE pinch valve tubing	3-32
Quarterly	
Cleaning the inlet water filter	3-33
Replacing the seals on the sample syringe	3-34
Replacing the seals on the reagent syringes	3-39
Replacing the seals on the ISE syringes	3-40

Every Six Months

Replacing the ISE reference electrode	3-42
Replacing the Teflon block (nozzle tip)	3-44

Maintenance and care procedures when the analyzer is switched on:

	Page
Daily	
Checking/replacing the detergent	3-10
Checking the detergent/replenishing the bottles	3-12
Checking the paper supply	3-15
Priming, conditioning and calibrating the ISE unit	3-16
Cleaning the ISE unit with ISE wash solution	3-17
Checking the temperature of the incubation bath	3-17
Performing the photometer check	3-18
Weekly	
Cleaning reaction cells	3-19
Performing the cell blank measurement	3-20

Analyzer Maintenance As Required

Emptying the vacuum tank	3-45
Replacing the photometer lamp	3-47
Cleaning/replacing clogged probes	3-52
Checking the alignments	3-54
Cleaning clogged cell rinse nozzles	3-63
Replacing stirring paddles	3-65
Replacing the ISE measurement electrodes (Na^+ , K^+ , Cl^-)	3-67
Printer maintenance	3-70

3.2 Daily System Maintenance

3.2.1 Emptying the Waste Container

Empty the container for the liquid waste of the reaction cells daily, before and after the routine. This prevents disruptions to the normal routine occurring. However, the system will issue an alarm on the screen, if the waste container is full. The waste container is located on the back panel of the analyzer.

Safety Precautions

The contents of the waste container are potentially infectious and should be disposed of in accordance with the normal laboratory safety precautions.

Necessary Material

Water for rinsing, disinfectant, paper towels.



1. Remove liquid level sensor and tube (locking position). Ensure that the tubes do not contain any residues and that the liquid level sensor is dried off (paper towels).
2. Empty waste container and rinse out thoroughly with water. Dispose of the liquid waste in accordance with the normal safety precautions for potentially infectious waste.
3. Prepare a commercially available disinfectant solution and pour it into the waste container up to a level of approx. 1 cm.
4. Refit the waste tube and liquid level sensor in the container and fit the waste container back in its location.

3.2.2 Checking/Replacing the Detergent

If the volume of the reaction cell detergent is insufficient, then a new bottle must be installed.

Safety Precautions

None.

Necessary Material

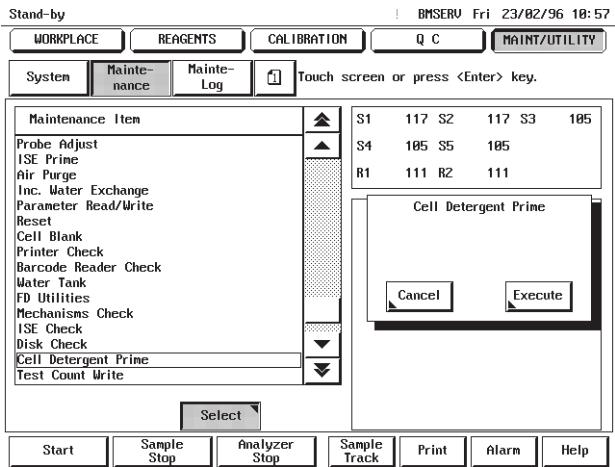
Detergent 1 (NaOH-D)



1. Place a new bottle with NaOH-D detergent in the position on the left. The position on the right is reserved for a second detergent. Make sure that the tube filter reaches the bottom of the bottle.

Daily System Maintenance

2. If no additional detergent is required, the second tube filter should also be placed in a bottle containing NaOH-D.



3. The detergent must be primed. Select the CELL DETERGENT PRIME menu option in the MAINTENANCE sub menu (MAINT/UTILITY main menu) and press SELECT. In the window that is now open, press the EXECUTE button. As soon as the priming process is completed, the system switches to the 'Ready' status. When the analyzer is switched on, priming is performed automatically.

3.2.3 Checking the Detergent/Replenishing the Bottles

Safety Precautions

None.

Necessary Material

Fresh detergent.



Detergent compartments for reaction probe 1 and 2

1. Check the volume of detergent 1D1/2D2 (Hitergent). This detergent is used for the reaction bath. Replace with a new bottle, if necessary.
2. Check the volume of detergent 1D2/2D2 (NaOH-D). This is used for the cell rinse function and to prevent reaction interference from reaction cells or reagent probes. Replace with a new bottle, if necessary.
3. Check the volume of detergent 1D3/2D3 (optional e.g. SMS). This is used to prevent carry-over from reaction cells or reagent probes. Replace with a new bottle, if necessary.

3.2.4 Cleaning the Reagent Probes and Sample Probe

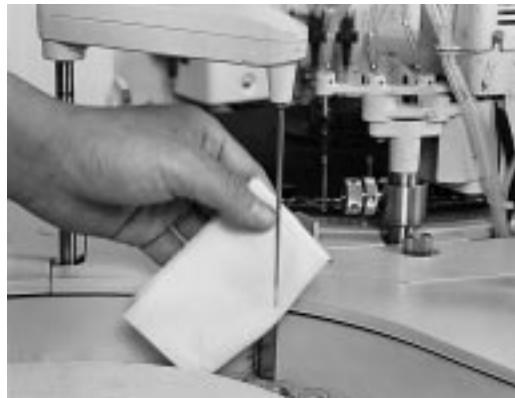
Wipe clean the reagent probes, the sample probe, and the stirring paddles daily to avoid contamination.

Safety Precautions

Switch off the analyzer.

Necessary Material

Alcohol, lint-free towel.



1. Move the probes (sample arm/reagent arms) manually, to gain access.
2. Clean the probes with a lint-free towel soaked in alcohol. Take care not to touch the probes with your bare fingers (electrostatic discharge). Try to avoid contacting any other parts of the analyzer other than the probes with alcohol.
3. As soon as the analyzer is switched on, the probes automatically return to their home-positions.
4. Check whether the sample and reagent probes are so adjusted that they are positioned above the center of the reaction cells (see also chapter 3.7.4 Checking the Alignment).



Caution

Handle the sample and reagent probes very carefully. They should never be bent. Bent probes can cause measurement and analyzer errors.

3.2.5 Cleaning the Stirring Unit

Safety Precautions

Switch off the analyzer.

Necessary Material

Alcohol, lint-free towel.



1. Rotate both of the stirring units so that the paddles can be easily accessed.
2. Clean the stirring paddles with a lint-free towel that has been soaked in alcohol. Ensure that other analyzer components do not come in contact with alcohol.
3. As soon as the analyzer is switched on, the stirring unit automatically return to their home-positions.



Caution

Handle the stirrer paddles very carefully. They should never be bent. Bent stirring paddles can cause measurement and analyzer errors.

3.2.6 Checking the Paper Supply

Ensure that there is sufficient printer paper before the routine is started.

Safety Precautions

None.

Necessary Material

Printer paper.

3.2.7 Cleaning the Instrument Surfaces

Clean the analyzer surfaces daily after the routine is complete to remove contaminations (e.g. reagent and sample deposits). Pay particular attention to the cover.

Safety Precautions

None.

Necessary Material

Lint-free towel, water for rinsing, disinfectant solution.

3.2.8 Cleaning the Nozzles of the Cell Rinse Unit

Wipe clean the rinse nozzles and the Teflon block with a lint-free towel which has been soaked in alcohol.

Safety Precautions

The analyzer should be in the stand-by mode or switched off.

Necessary Material

Alcohol, lint-free towel (gauze).

3.2.9 Priming, Conditioning and Calibrating the ISE Unit

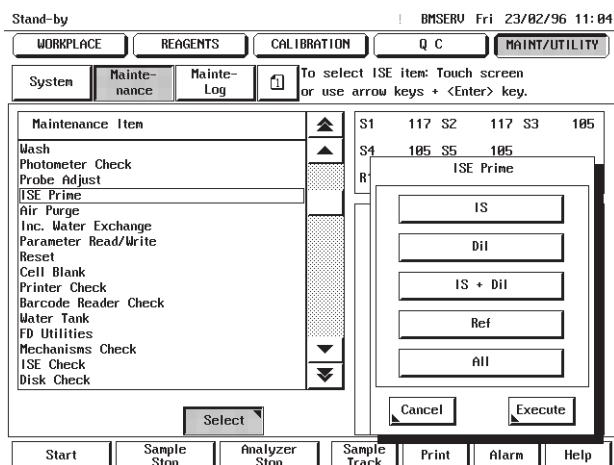
If the analyzer has not been operating for a longer time, then the reagents must be primed before the routine (ISE PRIME) and the ISE unit must be conditioned and calibrated.

Safety Precautions

None.

Necessary Material

Sufficient ISE reagents, sample and calibrators.



1. Open the MAINTENANCE sub menu in the MAINT/UTILITY main menu and select from the selection box ISE PRIME. Press the SELECT button and select the ALL option in the window that is now open. Then, press the EXECUTE button.
2. When the ISE PRIME is complete, perform an dummy analysis using human serum (10 ISE determinations) to condition the measurement electrodes.
3. Calibrate the ISE unit. Select in the CALIBRATION main menu, the STATUS sub menu and then select REPEAT CALIB. Select ISE from the list in this screen and press the FULL button.
4. Load a cup with ISE standard LOW and a cup with ISE standard HIGH as well as a cup with STD 3 (compensator) in the positions provided on sample disk 2. The positions for the ISE standards can be determined by checking the list in the sub menu CALIBRATORS.
5. Press the EXECUTE button in the STATUS sub menu to order a full calibration of the ISE.

3.2.10 Cleaning the ISE Unit with ISE Wash Solution

The ISE unit must be cleaned daily after the routine with ISE wash solution.

Safety Precautions

None.

Necessary Material

ISE cleaning solution.

1. Place approximately 1 mL ISE wash solution in the position W2 on the sample disk 2.
Open the MAINTENANCE screen in the MAINT/UTILITY main menu and select WASH.
Then press SELECT. Choose ISE in the displayed window and touch EXECUTE
2. When the rinse process is complete, perform an dummy analysis using human serum
(10 ISE determinations) to condition the measurement electrodes.
3. Calibrate the ISE unit.

Note

This cleaning process must to be carried out each day, irrespective of the workload of the ISE unit.

3.2.11 Checking the Temperature of the Incubation Bath

Safety Precautions

None.

Necessary Material

None.

After switch-on, the analyzer must be, at least, in STAND-BY mode. Press the SAMPLE TRACK button, in order to check the temperature of the incubation bath. In the appropriate screen, the actual temperature of the incubation bath is displayed. It should be $37\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$.

3.2.12 Performing a Photometer Check

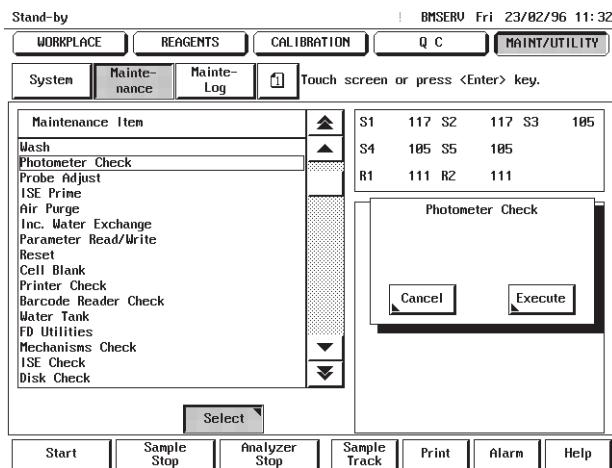
The photometer has to be checked each day before the routine, to prevent any possible error sources.

Safety Precautions

None.

Necessary Material

None.



1. Open the MAINTENANCE screen (MAINT/UTILITY main menu).
2. Select the PHOTOMETER CHECK menu option and press the SELECT button. In the window that is now open, press the EXECUTE button.
3. The light intensity of the photometer lamp is measured automatically. Subsequently, the system prints out the results.
4. Check that the results are not greater than 16000. Otherwise, the photometer lamp must be replaced and a cell blank measurement must be carried out.

3.3 Weekly System Maintenance

3.3.1 Cleaning the Reaction Cells

The separate cleaning process of the reaction cells must be carried out once a week.

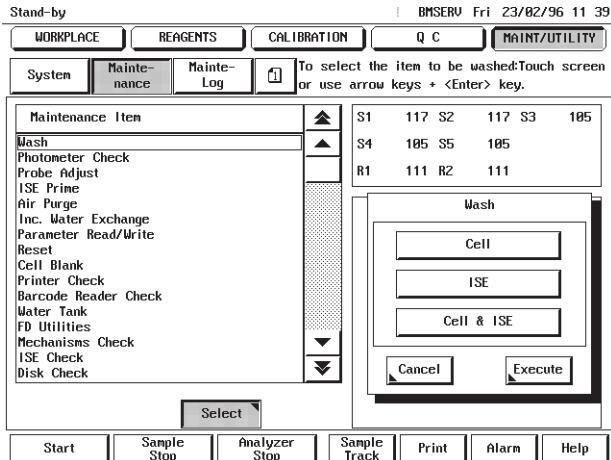
Safety Precautions

None.

Necessary Material

At least 50 mL of NaOH-D in the compartments 1D2/2D2.

1. Place approx. 1 mL NaOH-D in the position W1 on sample disk 2.
2. Check if there is at least 50 mL of NaOH-D present in the compartments 1D2 and 2D2.
If necessary, replenish up with NaOH-D.



3. Open the MAINTENANCE sub menu (MAINT/UTILITY main menu) and select the WASH option. Then press SELECT. In the window that is now open, select CELL and press EXECUTE.
4. Perform the reaction cell blank measurement and check the quality control values of the next routine.

3.3.2 Performing the Cell Blank Measurement

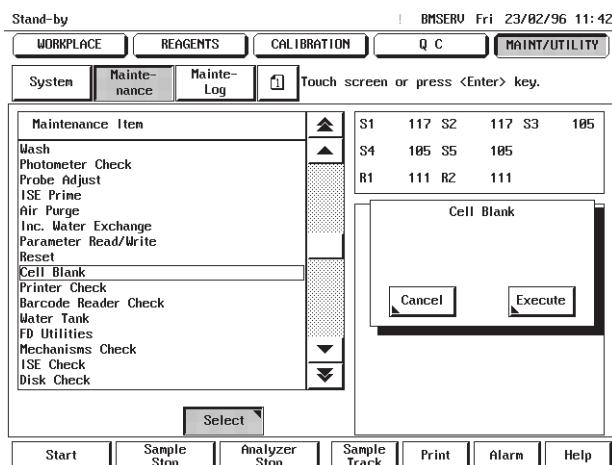
The system automatically measures the blank value of each reaction cell during each run, by comparing it with the previous cell blank measurement (is used as a reference). To bring the comparison values up to date, the cell blank measurement has to be performed separately once a week.

Safety Precautions

None.

Necessary Material

If necessary, new reaction cell segments.



1. Open the MAINTENANCE sub menu (MAINT/UTILITY main menu) and select the CELL BLANK item, then press SELECT. In the window that is now open, press EXECUTE.
2. Check the results. The result for reaction cell 1 must, for all wavelengths, be lower than 16000. The results of reaction cells 2 to 160 must not deviate by more than ± 800 compared to reaction cell 1, again for all wavelengths. If the results fall outside of this range, replace the appropriate reaction cell segments. Afterwards, repeat the cell blank measurement. If the reaction cells have been in use for longer than one month, they must be replaced.

3.3.3 Cleaning the Rinse Bath for the Sample Probe, Reagent Probes, and the Stirring Paddle

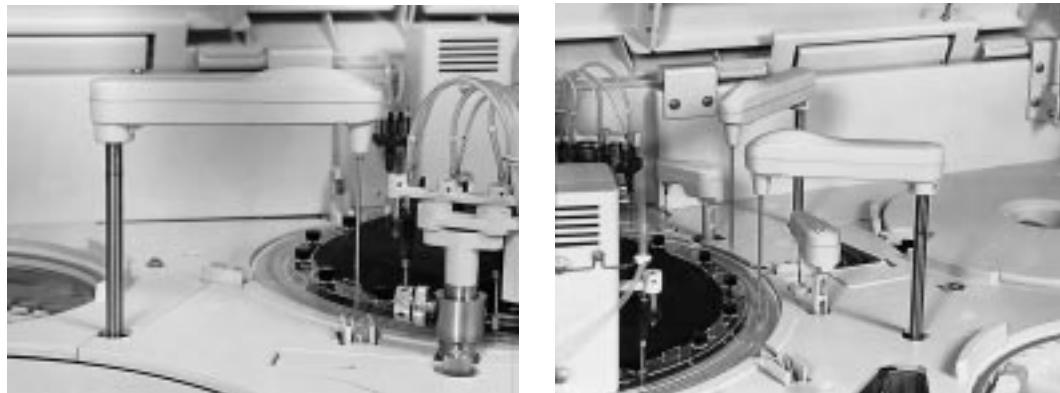
The rinse baths should be cleaned once a week. You thereby prevent contamination and bacterial development.

Safety Precautions

Switch off the analyzer.

Necessary Material

Sufficient sodium hypochlorite (NaOCl, min. 5%), deionized water.



1. Fill each rinse bath with approx. 10 mL of the 5 % sodium hypochlorite solution
2. Finally, fill rinse each bath with deionized water.

3.4 Monthly System Maintenance

3.4.1 Replacing the Reaction Cell Segments

If the reaction cells have been in use for longer than a month, they have to be replaced by new cells.

Safety Precautions

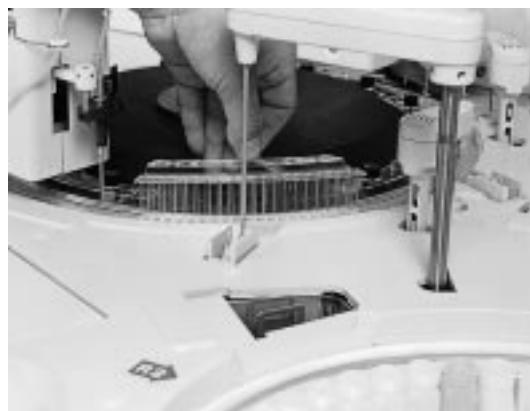
Switch off the analyzer.

Necessary Material

New reaction cell segments.



1. Remove the retaining screws on the segments.
2. Pull each reaction cell segment up and out of the analyzer. Dispose of the used segments according to the laboratory-specific requirements.



3. Fit the new reaction cell segments. Normally all eight segments should be replaced at the same time.
4. After replacement, a cell blank measurement should be performed on the new reaction cells (see chapter 3.3.2).
5. Check the quality control values of the next run.

Note

After replacement of a reaction cell segment, a cell blank measurement should be performed. It is recommended that the reaction bath should also be cleaned at the same time (see the next page).

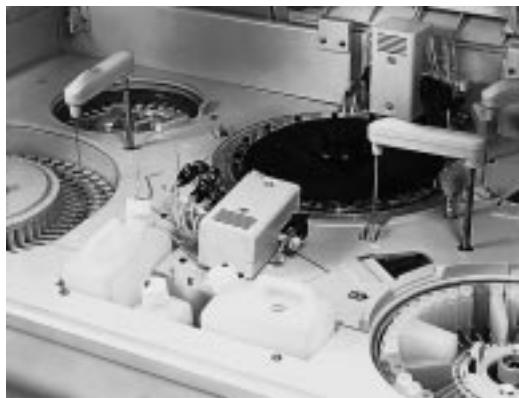
3.4.2 Cleaning the Incubation Bath and the Incubation Bath Drain Filter

Safety Precautions

Switch off the analyzer.

Necessary Material

Soft lint-free towel, water.



1. Remove rinse unit 1 (front rinse unit) by loosening the retaining screw and then pulling the unit up and out of the analyzer. Set the rinse unit down next to the holder.



2. Lift up rinse unit 2 (rear rinse unit) by loosening the retaining screw and then pulling the unit up. Retighten the retaining screw again and place the rinse unit on the retaining screw.

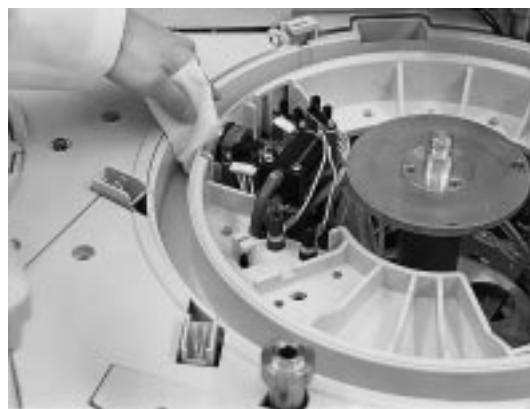
Note

Never close the cover of the analyzer, as this could damage rinse unit 2.



3. Loosen the retaining knob of the reaction disk and pull the disk up and out of the analyzer.

4. Now open the drain valve of the incubation bath on the rear of the analyzer and close it when the water has been drained off.



5. Clean the inner walls of the incubation bath using a soft, lint-free towel that has been moistened with water. Take care, when cleaning, not to scratch the photometer window.



6. Now clean the incubation bath drain filter, which is located in the bath itself. Pull the filter out as is shown above.
7. Wash the filter thoroughly with water.
8. Refit the filter.
9. To avoid foaming after switching on the analyzer, fill deionized water into the incubation bath. Refit the disk and tighten the retaining knob.

10. Switch on the analyzer. Wait, until the incubation bath has been completely filled.
11. Confirm that there are no particles of dirt in the incubation bath.



12. Refit the rinse unit and tighten the retaining screw. The rinse unit must audibly click into place.
13. Finally, carry out a cell blank measurement. This process is described in chapter 3.3.2.

3.4.3 Cleaning the Inside of the Sample and Reagent Disks

Both reagent and sample disks can be contaminated by dirt and spilt liquids. Clean them once a month.

Safety Precautions

The analyzer must be in stand-by mode or switched off.

Necessary Material

Soft, lint-free towel.



1. Lift up each disk in turn and clean the inside with a damp, soft, lint-free towel.

Monthly System Maintenance



2. Clean the barcode scan windows carefully but also thoroughly.
3. Place the disks back into their positions.

3.4.4 Cleaning the Air Filter

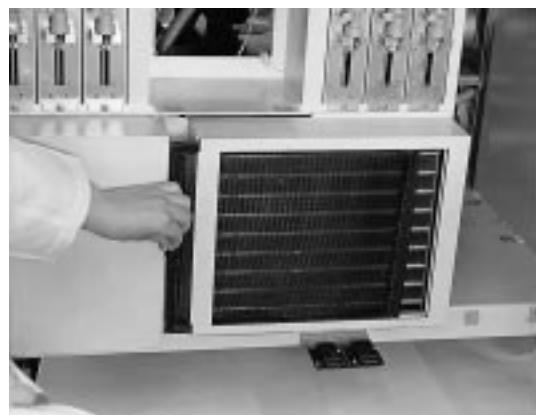
A dirty filter adversely affects air circulation and the cooling process becomes inadequate. Therefore clean the filter once a month to prevent this occurring.

Safety Precautions

The analyzer must be in Stand-by mode or switched off.

Necessary Material

Vacuum cleaner or brush.



1. The air filter is situated behind the left front door of the analyzer. Open the door and remove the filter from its holder.

Monthly System Maintenance



2. Vacuum any dust and dirt off the filter using a vacuum cleaner. Alternatively, clean the filter with a brush.
3. Refit the clean and dry filter back into the holder and close the door.

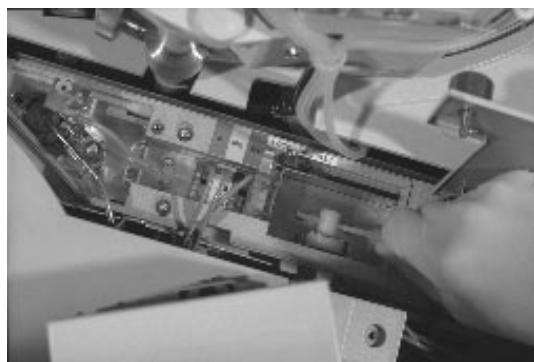
3.4.5 Replacing the ISE Pinch Valve Tubing

Safety Precautions

The analyzer must be in stand-by mode or switched off.

Necessary Material

Pinch valve tubing (original BM spare part)



1. Open the ISE measurement chamber.
2. Replace the sipper tube (only use the original spare part)
3. Close the ISE measurement chamber.
4. Now perform an ISE PRIME and a calibration as described in chapter 3.2.9.

3.5 Quarterly System Maintenance

3.5.1 Cleaning the Inlet Water Filter

If this filter is blocked, the water supply for the operation of the analyzer will not be sufficient. Inevitably, this will cause a STOP alarm to be issued. To avoid this, the filter should be checked and, if necessary, cleaned once a month.

Safety Precautions

The analyzer must be in stand-by mode or switched off and the water tap of the external water supply must be closed. Be aware of the pressure of the water in the tube.

Necessary Material

Bucket, cloth, water.



1. The water supply connection is situated on the back of the analyzer. Keep a bucket ready and unscrew the supply. Pull the filter out of its holder.
2. Rinse the filter thoroughly with water. Then refit it in the holder and finally refit the supply connection.

3.5.2 Replacing the Syringe Seals

Worn seals impair the accuracy of the pipette volumes. This can cause false measurement values. As a precautionary measure, the seals on the sample and reagent syringes should therefore be replaced every three months.

Safety Precautions

Switch off the analyzer.

Necessary Material

Seals, special syringe wrench, absorbent towel.

■ Replacing Seals on the Sample Syringe

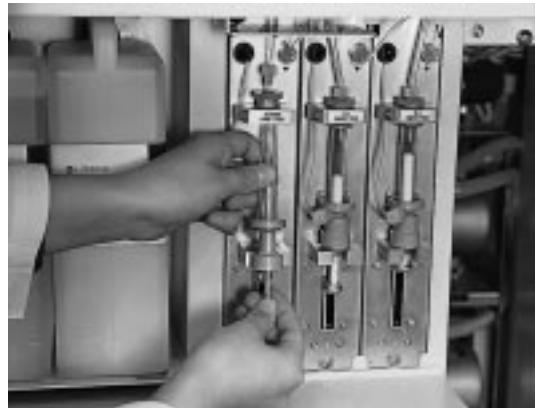


1. The sample syringe is situated behind the left front door. It is the first syringe to the right of the detergent bottles. Loosen the upper and lower tube connections by turning the retaining nuts in an anti-clockwise direction. Soak up any spilt water with an absorbent cloth.

Note

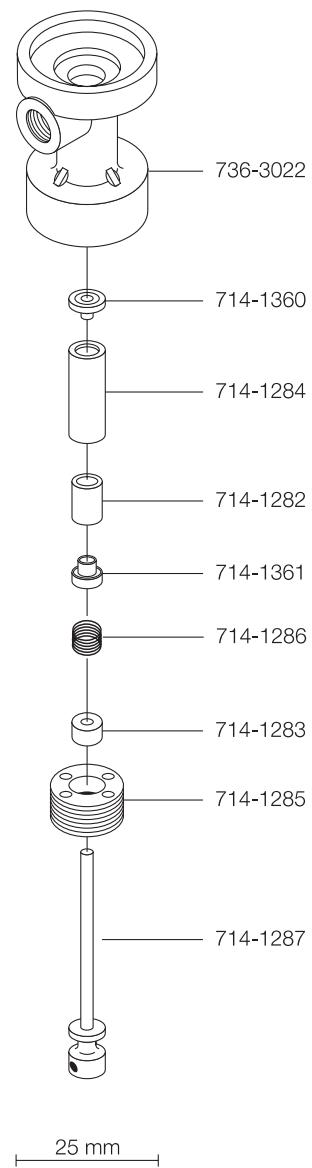
Avoid touching the syringe on the upper part of the glass cylinder.

2. Loosen the knurled screw (on the top of the syringe) by turning it anti-clockwise until the syringe rests loosely in the glass body. Carefully remove the glass body with the syringe from the holder. Remove the black O-ring from the top of the glass body.



3. Undo the retaining screw with the special syringe wrench and disassemble the syringe into its individual parts.
4. Clean the piston carefully with a lint-free cloth.

5. Reassemble the individual parts onto the piston. The correct sequence is illustrated below:



6. Tighten the screw with the special syringe wrench.



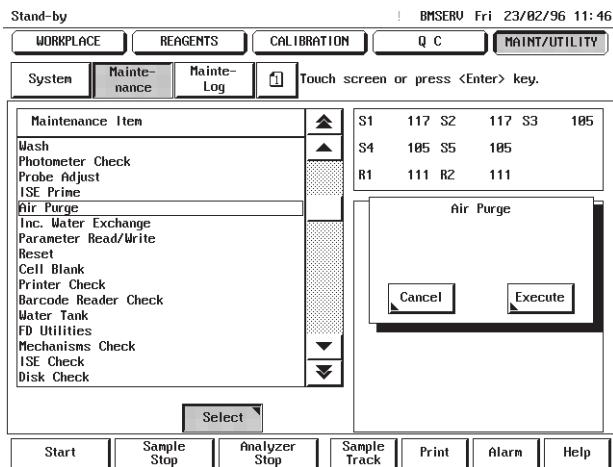
7. Refit the syringe with the glass body and the O-ring (L 456006 for sample/reagent syringes, 737-1629 for the ISE syringe) into the holder and tighten the knurled screw.

Note

Ensure that the piston is aligned with the piston guide.

8. Refit the black seal washer (L 443085) on top of the glass body with the help of a pair of tweezers.
9. Re-connect the tube connection and switch on the analyzer.

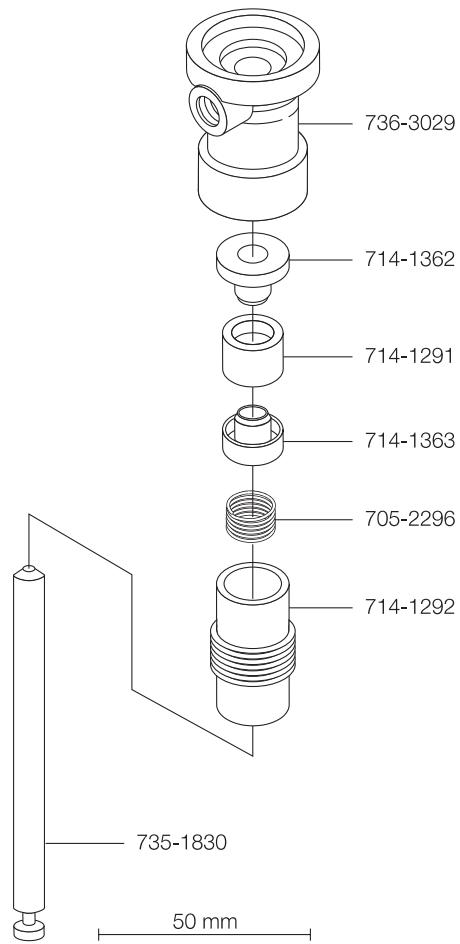
BM/Hitachi 917



10. To purge air out of the system, open the MAINTENANCE sub menu in the MAINT/UTILITY main menu, after the initialization is completed. Start the AIR PURGE menu option.
11. Check syringe and tube connections for leaks.
12. If air bubbles are seen on the piston, carefully tap on the blue piston body during the purging process using the handle of a screwdriver in order to remove the air bubbles.

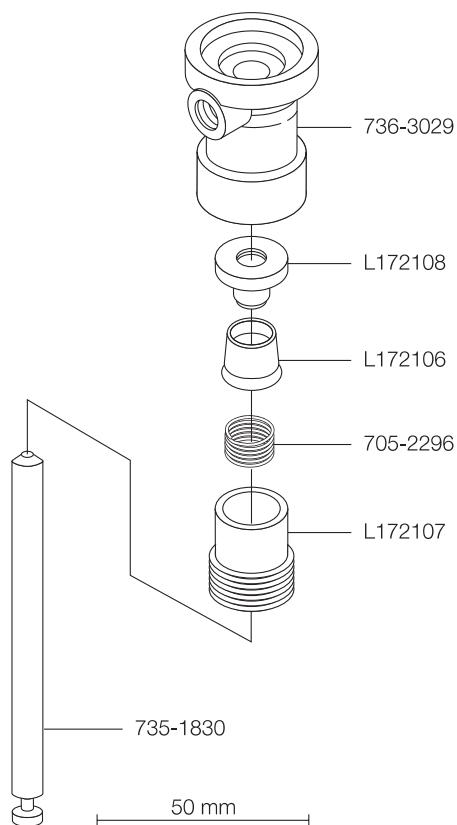
■ Replacing the Seals on the Reagent Syringes

The process for replacing the reagent syringe seal is the same as described on the previous page. The construction of the reagent syringe is illustrated below:



Replacing the Seals on the ISE Syringe

The process for replacing the ISE syringe seal is the same as described on the previous pages. The construction of the reagent syringe is illustrated below:



⚠ Caution

The sipper syringe is filled with diluted sample which is potentially infectious. When replacing seals, wear protective gloves to avoid infection.

⚠ Caution

The IS and DIL syringes of the ISE are filled with reagent which can cause skin rashes. Therefore avoid direct skin contact when replacing seals (wear protective gloves).

Note

The sipper syringe of the ISE aspirates diluted sample, or Internal Standard, out of the dilution cups. During this process air bubbles separate the individual sample pockets from one another. The air is deposited on the piston of the sipper syringe. In contrast to the other syringes, these air bubbles play an important role and do not affect the measurement results. The air remains present even after the priming process (AIR PURGE menu option, MAINTENANCE sub menu). Therefore it does not have to be removed (e.g. by tapping).

3.6 Six Monthly System Maintenance

3.6.1 Replacing the ISE Reference Electrode

Replace the ISE reference electrode under any of the following conditions:

- Generally after every six months.
- If all three EMF values for the Internal Standard are unstable at the same time or are outside the specified range.

Note

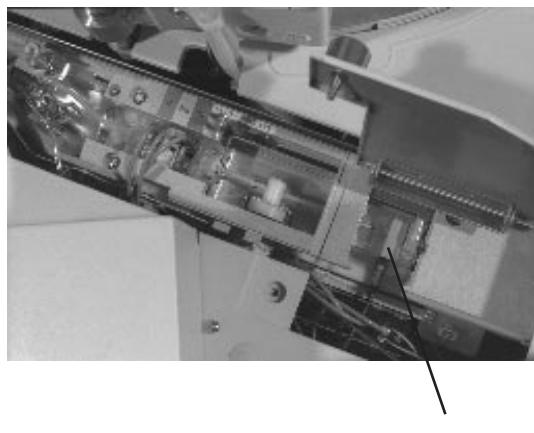
For EMF values outside the specified range, the analyzer issues the alarm code 90-1, 90-2 or 90-3.

Safety Precautions

Normal laboratory safety precautions.

Necessary Material

Reference cartridge, pair of tweezers, screwdriver, paper towels.



Reference electrode

Six Monthly System Maintenance

1. Open both covers of the ISE unit and the cover of the ISE reference electrode compartment. Disconnect the connection wires to the reference cartridge.
2. Push the lock/release lever to the right, until the entire compartment can be secured above the reference cartridge using the clamp lever.
3. Push the compartment approx. 3 mm to the left and pull the reference electrode out of the compartment with a pair of tweezers. If any salt residues have formed, clean the compartment with a damp towel.
4. Fit a new electrode. Make sure that the cartridge sits correctly in position.
5. Push the lock/release lever to the right until the clamp lever is released. Using spring force, the lock/release lever is then pushed to the left, until it engages in the locked-position.
6. Reconnect the wires to the reference cartridge.
7. Close the cover of the reference compartment and the ISE unit.
8. Afterwards, prime the ISE unit using the ISE reagent KCl (MAINTENANCE sub menu, MAINT/UTILITY main menu, ISE PRIME, REF menu option).
9. Finally, calibrate the ISE unit (see chapter 3.2.9).

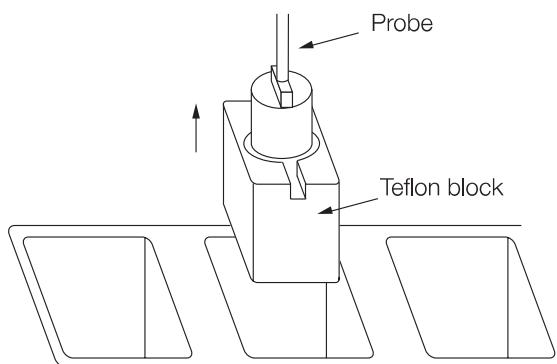
3.6.2 Replacing the Teflon Block (Nozzle Tip)

Safety Precautions

Switch off the analyzer.

Necessary Material

Teflon block.



1. Remove the rinse unit by releasing the retaining screw and lifting the unit up.
2. Pull the Teflon block off the probe, as illustrated in the diagram and fit a new block.
3. Refit the rinse unit and check if the probe with the Teflon block sits correctly in the reaction cell.

3.7 Analyzer Maintenance As Required

3.7.1 Emptying the Vacuum Tank

If the alarm code 38-1 (vacuum tank) occurs, the liquid has to be emptied out of the vacuum tank. If this alarm occurs frequently, the system is defective. In this case, contact Boehringer Mannheim Service.

Safety Precautions

Switch off the analyzer, pull out the mains plug.

Necessary Material

Screwdriver, bucket.



1. Remove the screws on the front of the analyzer as shown above and open the side door. Pull the rubber tube out of the vacuum tank.



2. Carefully pull off the thick rubber tube from the clip on the L-connection and let the liquid waste flow out into a bucket.
3. Reconnect the tube connection and finally close the side door.

3.7.2 Replacing the Photometer Lamp

When the performance of the photometer lamp decreases, the light intensity falls outside the photometrical range, thus making accurate measurements impossible. Replace the lamp in any of the following cases:

- If the results of the photometer check exceed 16000.
- If the lamp has been in operation for more than 750 hours.

Safety Precautions

Switch off the analyzer.

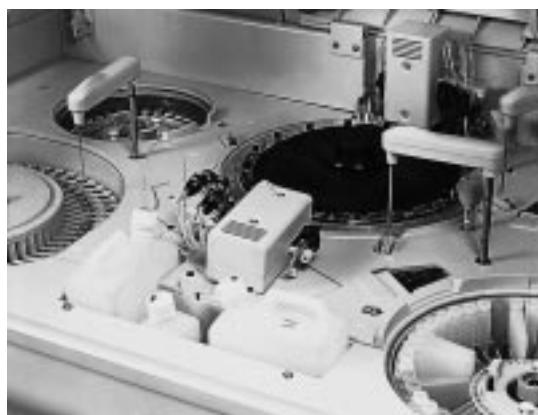
Necessary Material

Halogen lamp, screwdriver



Note

Never touch the glass body of the lamp with bare fingers, this can affect the lamp's life.



1. Remove rinse unit 1 (front rinse unit) by loosening the retaining screws and then pulling the unit up and out of the analyzer. Set the rinse unit down next to the holder.
2. Lift up rinse unit 2 (rear rinse unit) by loosening the retaining screw and then pulling the unit up. Retighten the retaining screw again and place the rinse unit on the retaining screw.

Note

Never close the cover of the analyzer, as this could damage rinse unit 2.

Analyzer Maintenance As Required



3. Loosen the retaining knob on the reaction disk and pull the disk up and out of the analyzer.



4. Loosen the connection screws for the lamp wires and disconnect the wires.



5. Loosen both retaining screws on the lamp housing with the screwdriver and remove the housing.
6. Loosen both retaining screws of the lamp on the housing and remove the lamp.



Caution

The glass body could be hot. Do not touch. **Risk of injury!**



7. Fit the new lamp and reassemble the lamp in reverse order (as illustrated).

 **Caution**

The cooling tube on the lamp housing must never be bent. Insufficient cooling reduces the life expectancy of the lamp.

8. Refit the reaction disk and install both rinse stations. Then switch the analyzer back on.
9. Wait for approx. 30 minutes, until the lamp intensity has stabilized.
10. Now perform a cell blank measurement (see chapter 3.3.2).

3.7.3 Cleaning/Replacing Clogged Probes

Clean the sample probe and the reagent probes from the inside, if they are clogged. Replace the probes, if they are visibly bent. Each probe has to be realigned after it has been replaced.

Safety Precautions

Switch off the analyzer.

Necessary Material

Stainless steel wire (0.2 mm diameter for the sample probe and 0.5 mm diameter for the reagent probes).



1. Remove the cover of the respective probe arm and disconnect the connection wires on the probe and serum tube. Make certain that the seal is not lost. Put it in a safe place.

Note

To remove the arm cover, press the quick release (as above).



2. Carefully remove the probe.



3. Using the cleaning wire (0.2 mm diameter for the sample probe and 0.5 mm diameter for the reagent probes) feed it into the probe. Push the wire up and down until the probe is no longer clogged.
4. Rebuild the probe in reverse order. If the old seal is worn, replace it with a new one. If a probe is bent or otherwise defective, replace it with a new one. Ensure during the rebuild that the wires are reconnected correctly: the outer sheath of the probe connects to the black connection, the inner part of the probe, plugs on to the white connection.
5. Close the arm cover and check if the probe can move up and down freely and check if the spring forces the probe back into its home-position.

3.7.4 Checking the Alignments

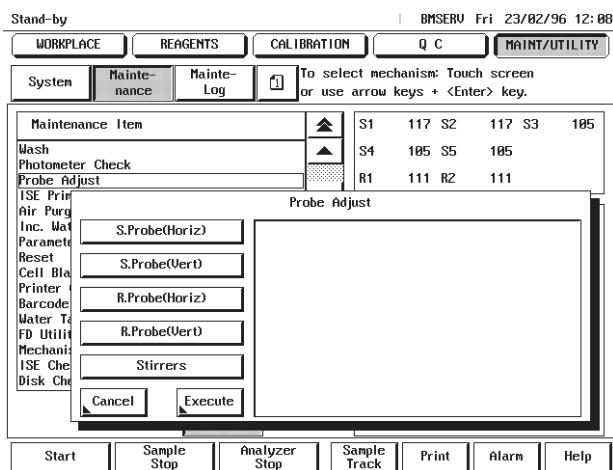
Each newly replaced probe must be realigned after installation. This applies to the horizontal as well as the vertical alignment.

Safety Precautions

Normal laboratory safety precautions.

Necessary Material

Positioning aid.



1. Open the MAINTENANCE sub menu (MAINT/UTILITY main menu). Select the PROBE ADJUST menu option and press SELECT. The different alignment options can be selected in the selection window.

Note

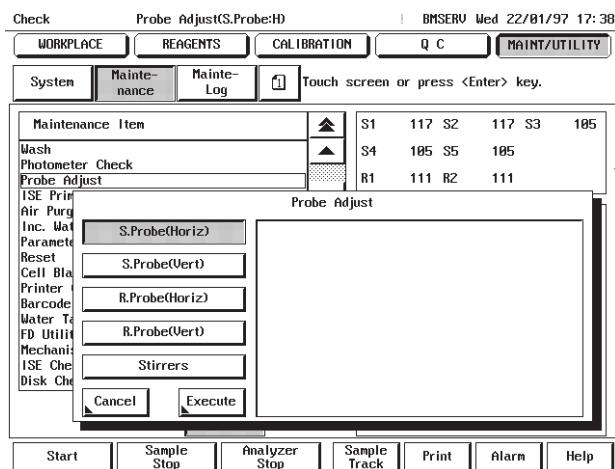
The horizontal alignment of the probe must be carried out prior to the vertical alignment. If this is not observed, correct functioning of the probe movement cannot be guaranteed.

■ Alignment of the sample probe (horizontally)

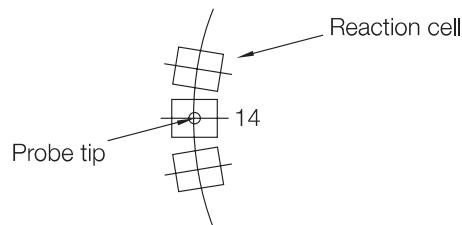
Note

Always ensure that there are no cups in positions 1 and 56 of the sample disk 1, and position 1 and rinse position 1 of the sample disk 2.

Please observe the following instructions for the horizontal alignment of the sample probe:



1. For the horizontal alignment of the sample probe, select the S.PROBE (HORIZ.) option in the window with the alignment options and press the EXECUTE button.



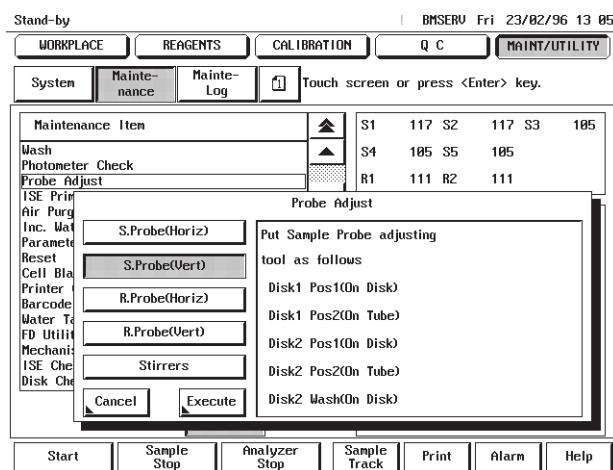
2. The system will move the reagent probe into a position above reaction cell number 14. Position the probe manually above the center of the reaction cell, as shown in the diagram.
3. To move the probe on to the next position, press SAMPLE STOP and YES. Check the centering above each respective position.
4. To stop the alignment check, press the ANALYZER STOP button and YES. The sample probe will move automatically to its home-position.

Note

The horizontal alignment can only be carried out fully by Boehringer Mannheim Service. The procedures described above only serve to check the alignment visually.

■ Alignment of the Sample Probe (Vertically)

Before carrying out the vertical alignment, the horizontal alignment must be completed. If this is not observed, correct functioning of the probe movement cannot be guaranteed. If the sample probe is not vertically aligned or it is misaligned, the SAMPLE PROBE alarm may be issued instead of the SAMPLE SHORT alarm. This can cause the routine to be canceled.



1. Place onto the positions 1 and 2 on sample disk 1 either: an adjustment tool without a sample cup, or an adjustment tool on a sample cup that is no higher than 100 mm and one that is used in the routine.
 2. Place onto the positions 1 and 2 on sample disk 2 either: an adjustment tool without a sample cup, or an alignment gauge on a sample cup that is no higher than 75 mm and one that is used in the routine.
- Finally, place an adjustment tool into the rinse station 1 on sample disk 2 (without a sample cup).
3. Press the S. PROBE (VERT.) button and then EXECUTE; the system will now start the automatic vertical alignment above the center of each adjustment tool. All positions, which have been equipped with an alignment gauge, are aligned in turn. The system will automatically adjust the correct immersion depth (distance) in the center above each positioning aid. The determined adjustments are saved to prevent the SAMPLE PROBE alarm being issued when there is insufficient sample present. The system lists the distance values which are determined during the vertical alignment in the MAINTENANCE sub menu under S1, S2, S3, S4, and S5 in mm.
 4. After completion of the alignment, remove the alignment gauges and sample cups from their respective positions.

■ **Checking the vertical alignment of the sample probe**

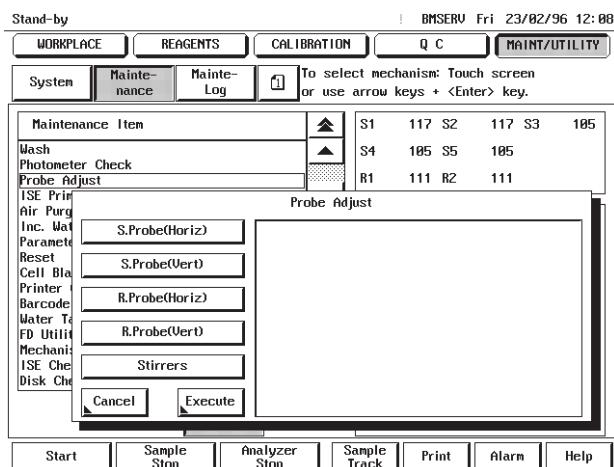
1. Instead of using positioning aids, place empty Hitachi cups in both of the sample disks (any position).
2. Program a test order so that the analyzer pipettes out of the empty cups.
3. Start a routine run.
4. Check whether the system issues the SAMPLE SHORT alarm.
5. If the analyzer issues the SAMPLE PROBE alarm, repeat the vertical alignment of the sample probe.

■ Checking the horizontal alignment of the reagent probes

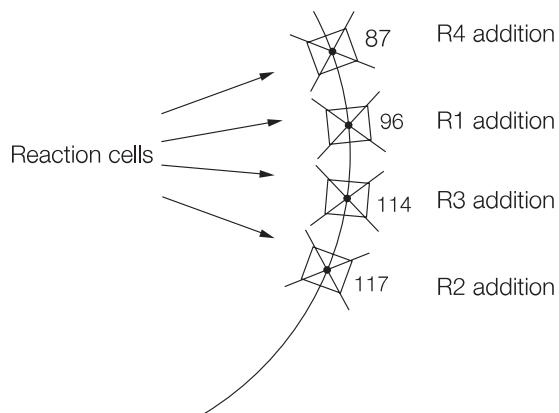
Note

The horizontal alignment of the probe must be carried out prior to the vertical alignment. Ensure that both reagent probes are positioned above the center of the respective reaction cell or above the reagent bottle opening.

Please observe the following instructions for the horizontal alignment of the reagent probe:



1. For the horizontal alignment of the sample probe, select the R. PROBE (HORIZ.) option in the window with the alignment options and press the EXECUTE button.



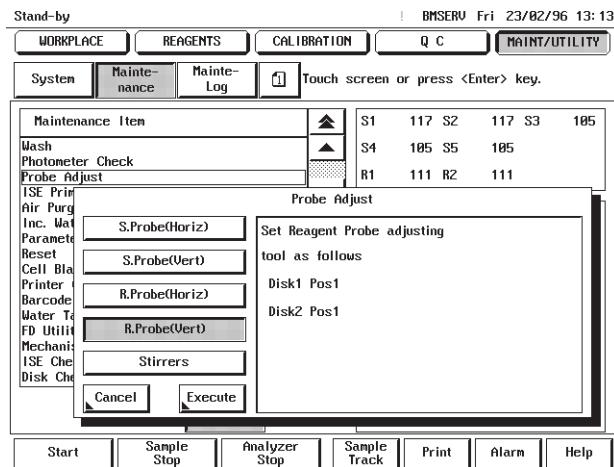
2. The system positions the R1 reagent probe above the reaction cell 87, in which R4 is dispensed, and the R2 probe is positioned above the reaction cell 114, in which R3 is dispensed. Manually position the probe above the center of each reaction cell, as shown in the diagram.
3. To move the probes on to the next positions, press SAMPLE STOP and YES. Probe R1 now moves to reaction cell 96 (where R1 is dispensed) and probe R2 moves to reaction cell 117 (where R2 is dispensed). Check whether both reagent probes are positioned above the center of the respective reaction cells or above the reagent and detergent bottle openings.
4. Press the ANALYZER STOP button and YES, to end the alignment. The reagent probes automatically move into their home-positions.

Note

The horizontal alignment can only be carried out fully by the BM Customer Technical Support. The procedures described above only serve to check the alignment visually.

■ Checking the vertical alignment of the reagent probes

Before carrying out the vertical alignment, the horizontal alignment must be completed. If this is not observed, correct functioning of the probe movement cannot be guaranteed.

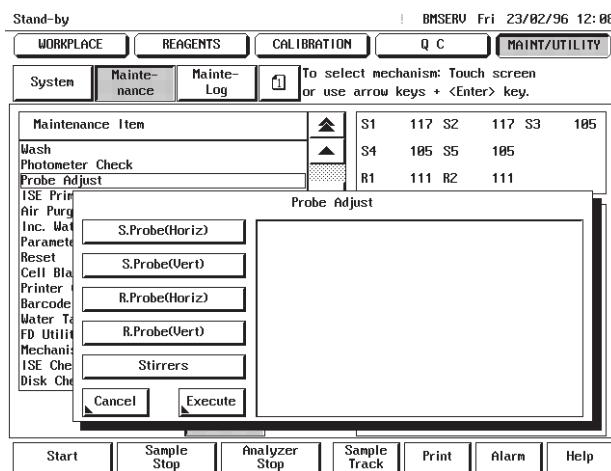


1. Place an alignment gauge on position 1 on the reagent disk 1 and on position 2 on the reagent disk 2.
2. Press the R. PROBE (VERT.) button and then EXECUTE; the system will now start the automatic vertical alignment above the center of each alignment gauge. The system will automatically adjust the correct immersion depth (distance) in the center above each positioning aid.

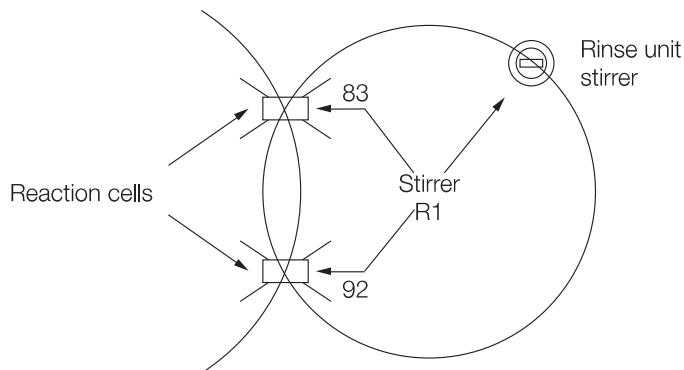
The determined adjustments are saved to calculate the correct amount of remaining reagent. The system lists the distance values which are determined during the vertical alignment in the MAINTENANCE sub menu under R1 and R2 in mm.

■ Alignment of the Stirring Unit

The stirring unit alignment can be checked here but not aligned. Make sure that both stirrers are positioned above the center of the appropriate reaction cells.



1. Press the STIRRERS button and then EXECUTE; the system begins the initialization of the stirring unit.

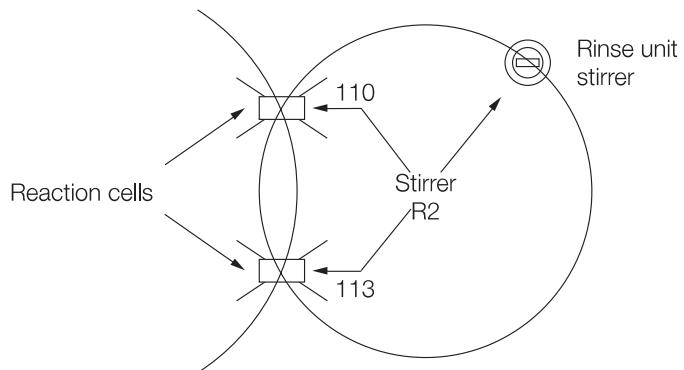


2. The system positions each stirring paddle above the appropriate reaction cell.

3. Every time SAMPLE STOP and YES are pressed, the stirring paddle moves to the next position. Check whether the stirring paddle is positioned above the center of the appropriate reaction cell. The stirring unit moves to the following reaction cells:

Stirrer R1: Reaction cells 83 and 92

Stirrer R2: Reaction cells 110 and 113.



4. Press ANALYZER STOP and YES to stop the this process. The respective stirring unit moves back into its home-position.

Note

The alignment must only be carried out by the Boehringer Mannheim Service. This function serves only to check the alignment.

3.7.5 Cleaning Clogged Rinse Nozzles

If the cell rinse nozzles are clogged, the reaction cells will not be rinsed adequately. This can cause false measurement values or the spillage of rinse water.

Safety Precautions

Normal laboratory safety precautions.

Necessary Material

0.5 mm cleaning wire.



1. Pull all tubes off the cell rinse nozzle that is to be cleaned. Press the retaining clamp of the cell rinse nozzle and pull the retaining clamp and the cell rinse nozzle out of the cell rinse unit.

Note

Make a note of the tubes and to which nozzle they belong. On rebuild, the "correct" tube must be refitted onto the "correct" nozzle.

2. Feed the cleaning wire (0.5 mm) into clogged nozzle. Push the wire up and down until the nozzle is no longer blocked. Make sure that the nozzle is not bent.
3. Refit the cell rinse nozzle in the reverse order.

Note

The Teflon block (nozzle tip) on the cell rinse nozzle must be removed before cleaning. After rebuild, ensure that the Teflon block sits correctly in the reaction cell.

3.7.6 Replacing the Stirring Paddles

Safety Precautions

Normal laboratory safety precautions.

Necessary Material

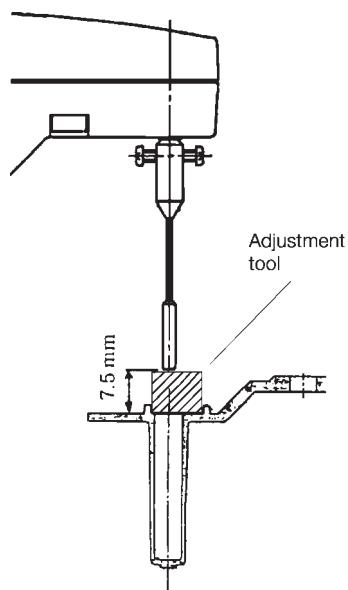
Screwdriver, new stirring paddles, alignment gauge.



1. Loosen the two retaining screws opposite each other and pull the paddle down and out.

Note

By turning the retaining screws through a quarter of a turn, the stirring paddle can be released.



2. Fit the new paddle in position and push it up to the upper stop on the drive shaft. Then tighten the screws.
3. Check the horizontal alignment of the stirring unit as described in chapter 3.7.4.
4. Place the adjustment tool, for the vertical alignment of the stirring unit, on the reaction cell above which the stirring paddle will be aligned, as illustrated above.
5. Move the stirring paddle above the adjustment tool using the PROBE ADJUST/STIRRERS function.
6. Loosen the retaining screws and place the stirring paddle on the adjustment tool. Retighten the screws.

3.7.7 Replacing the ISE Measurement Electrodes (Na^+ , K^+ , Cl^-)

Safety Precautions

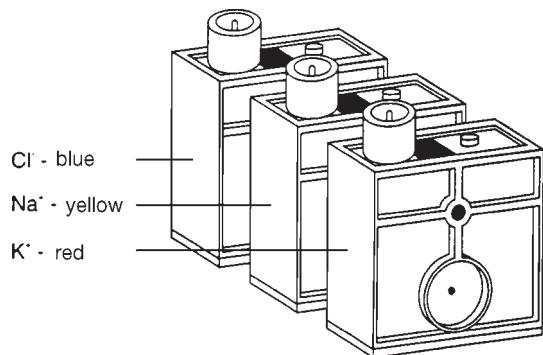
Normal laboratory safety precautions (e.g. gloves).

Necessary Material

Na^+ , K^+ , Cl^- electrodes (cartridges), towels, pair of tweezers.



1. Open the cover of the ISE measuring chamber and the cover of the ISE reference compartment on the analyzer.
2. Disconnect the colored connection wires from the cartridge.
3. Push the lock/release lever to the right, until the entire compartment can be secured above the reference electrode, using the clamp lever.
4. Lift out each electrode using the pair of tweezers.
5. Remove the two black transportation safety plugs from the flowpath of the new electrode.



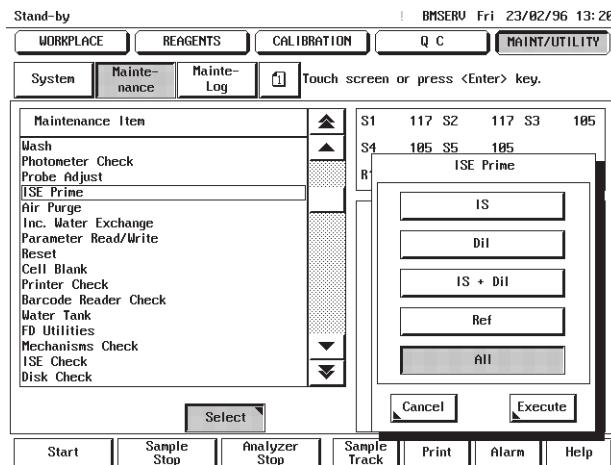
6. Fit the new cartridges into the ISE measuring chamber in the sequence shown above.
7. Push the lock/release lever to the right until the clamp lever is released. Using spring force, the lock/release lever is then pushed to the left until it engages into the locked position.

Note

If the electrodes are not in the correct position, leaks can occur in the ISE unit. This can cause false measurements values.

8. Reconnect the wires onto each new cartridge using the corresponding colors. Close the measuring chamber.

Analyzer Maintenance As Required



9. Select the ISE PRIME menu option in the MAINTENANCEsub menu and press SELECT. In the window that is now open, press EXECUTE. The system primes the ISE reagent.
10. When the priming has been completed, run a routine analysis using a human serum (10 x) to condition the electrodes.
11. Before analyzing normal patients samples, the ISE unit must be calibrated (see chapter 3.2.9).

3.8 Printer Maintenance

3.8.1 Start-Up

When the printer is switched on, mains voltage is applied. Do not touch the insides of the printer.

If operated continuously over a longer period, the print head and the material surrounding it will become hot. There is a risk of injury, when replacing the ink ribbon cartridge or adding paper.

Never start a printout, if there is no paper in the printer.

Safety Precautions

Switch the printer on after paper has been feed in.

Necessary Material

Printer paper, power supply cable.



1. The printer paper is situated behind the front door of the ERGO console.
2. Insert the paper.
3. Connect the power supply cable.

3.8.2 Replacing the Ink Ribbon Cartridge

Safety Precautions

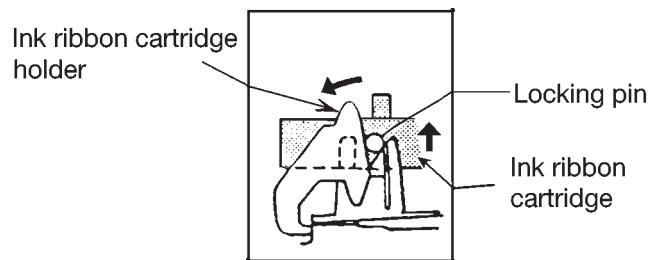
Switch the printer off, let it cool down.

Necessary Material

Ink ribbon cartridge.



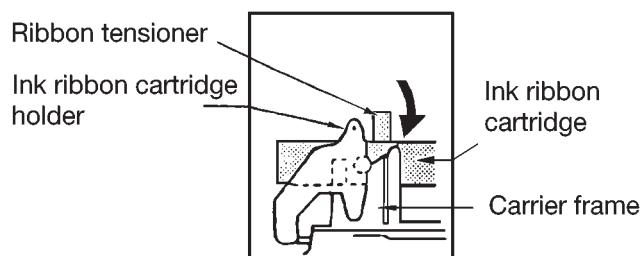
1. Open the front hinged access cover of the printer. With a finger, press on the cover from the inside and pull the cover upwards.
2. Position the print head in the center of the printer.



3. Pull the holder of the ink ribbon cartridge forwards, until it is loose. Pull the cartridge out.
4. Pull off the red paper strip from a new ink ribbon cartridge.

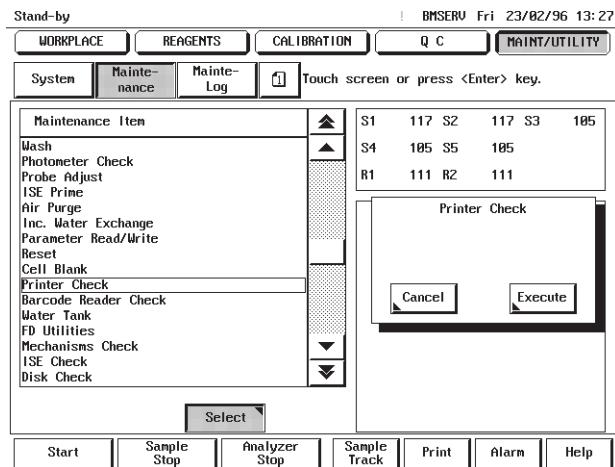


5. Fit the new ink ribbon cartridge as shown in the illustration. It must click obviously into place.



6. Press the knob on the ink ribbon cartridge down and turn it clockwise to tension the ribbon.
7. Close the printer cover and switch the printer on.
8. Add paper, if required (instructions for this process are described further on in this chapter) and press the ONLINE switch on the control panel of the printer. The green ONLINE-LED display must be lit.

Printer Maintenance



9. Select the PRINTER CHECK menu option in the MAINTENANCE sub menu and press SELECT. In the window that is now open, press EXECUTE. The system performs a printer check. The result is printed out as shown below.

Printer Check 17/08/95 13:18

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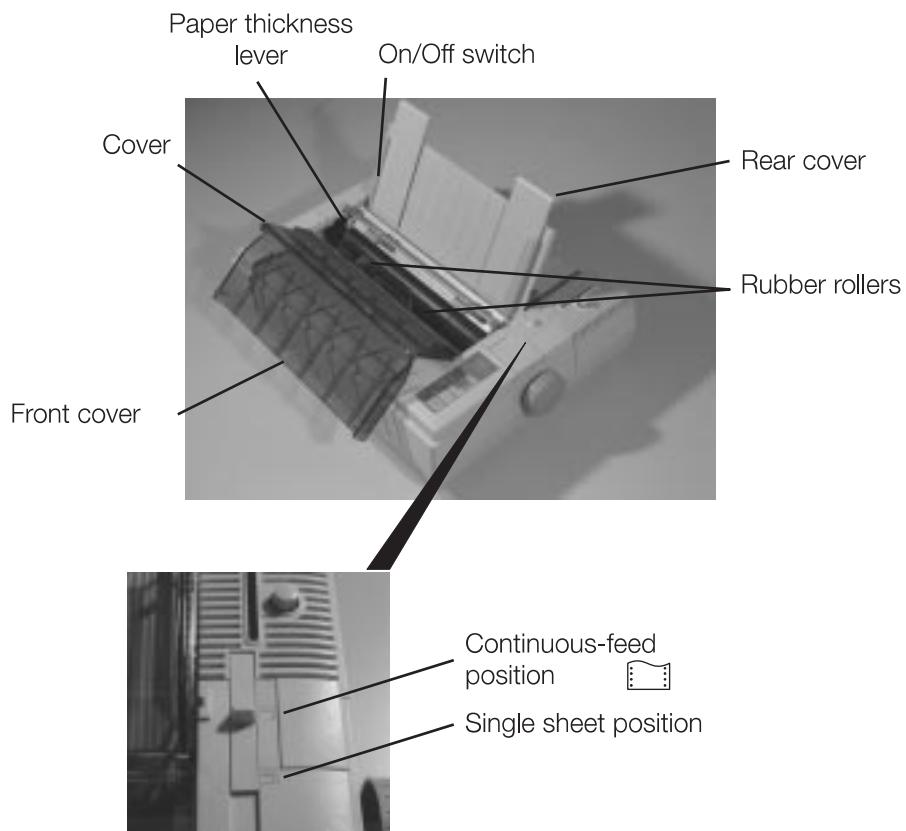
3.8.3 Loading Continuous-Feed Paper

Safety Precautions

None.

Necessary Material

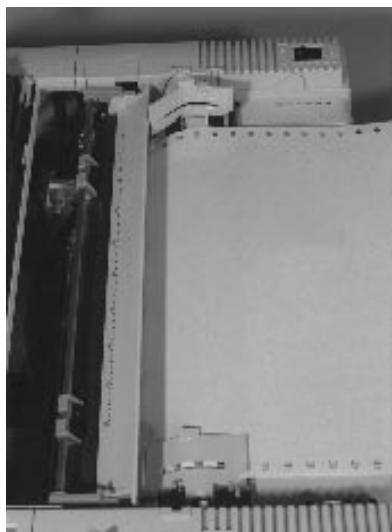
Box containing continuous-feed paper.



1. If necessary, switch the printer on. Ensure that the switch for the paper feed is switched to continuous-feed.

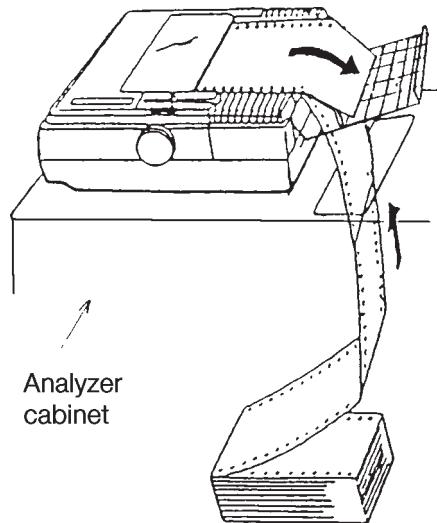


2. Open the cover. Take hold of the front hinged access cover with both thumbs and pull it upwards.
3. Switch the paper thickness to the correct setting. The lever is located inside the printer on the left. A detailed description of the procedure can be found in chapter 3.8.5.
4. Push the two rubber rollers on the paper feed apart so that they will press the paper (after it has been inserted) down on the rollers over its entire width.
5. Close the front hinged cover and the cover.
6. Lift up the rear cover.
7. Press the locks on each paper holder (left and right) back and push the two paper holders apart. The paper has to fit exactly between the two paper holders.



8. Push both paper holders up and feed the paper in.
9. Feed the paper in between the spiked wheels and the paper holder. Begin either on the left or on the right spiked wheel.
10. Pull the paper over each spiked wheel as evenly as possible, so that the guide holes on the paper edges are taken up by the spikes.
11. Close the first paper holder (shut down left or right side) and secure the lock (pull lever forward). The holder with the paper is now firmly aligned and mounted on the guide rail.
12. Push the other paper holder on the other side to the left or the right along the guide rail, so that the paper is pulled tight (but not too tight) between the holders.

13. Now, close the second paper holder (press down) and secure the lock (pull lever forward). Both holders with the paper are now firmly aligned and positioned on the guide rail.



14. Close the rear cover. The cover must sit horizontally, otherwise it could lead to a paper jam.
15. Ensure that the paper stack underneath the printer in the control unit is positioned as shown in the illustration.
16. Press the ONLINE switch on the control panel of the printer. The LED display must be lit.
17. Press the FF switch (Form Feed) to feed the paper forwards, sheet by sheet.
18. Use the transport wheel (on the right side of the printer) and feed the paper forwards until the perforation (end of one page and beginning of a new page) is up against the red marking on the print head.
19. Now switch the printer off and then on again immediately. After each future print job is completed, the printer will feed the paper one page further.

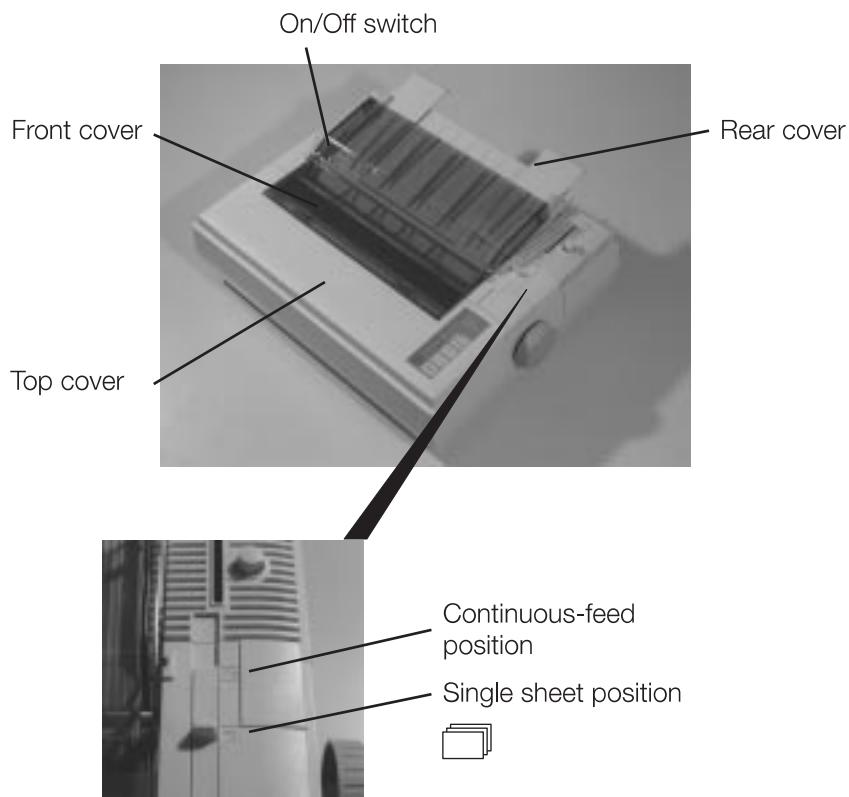
3.8.4 Inserting Single Sheets

Safety Precautions

None.

Necessary Material

Single sheet (e.g. A4).



1. If necessary, switch the printer on.
2. Open the cover.
3. Switch the paper feed to single sheet feed.

4. Take hold of the front hinged cover with both thumbs and pull it upwards.
5. Switch the paper thickness to the correct setting. The lever is located inside the printer on the left. A detailed description of the procedure can be found in chapter 3.8.5.
6. Push the two rubber rollers on the paper feed apart so that they will press the paper (after it has been inserted) down on the rollers over its entire width.
7. Close the cover.
8. Push the paper guides on the tray of the rear cover apart or together so that a single sheet can be inserted exactly.
9. Insert a sheet of paper into the paper guide.



10. Press the FF switch (Form Feed) on the control panel of the printer. The print head will now move into its home-position. The paper will be automatically pulled into the print start-position by approx. 7mm.

3.8.5 Setting the Paper Thickness

Safety Precautions

None.

Necessary Material

None.



1. Pull the cover up and open the printer cover.
2. Set the lever to the required position 1 to 4, as shown in the photo. Each position stands for a setting concerning the permitted paper thickness. The following table provides an overview of the paper thickness that can be used with each setting.

Number of Copies	Paper Thickness g/m ²	Requirements	Lever Position
5	40		4
4	40		4
3	40 – 64	52-64 only one sheet at the bottom	3
2	52 – 81	70 only one sheet at the bottom	2
1	52 – 81		1

Note

The number of copies include the top sheet (original).

The number of copies include the number of carbon sheets and non-carbon sheets.

If carbon paper is used with separating pages, each sheet is counted as a copy.

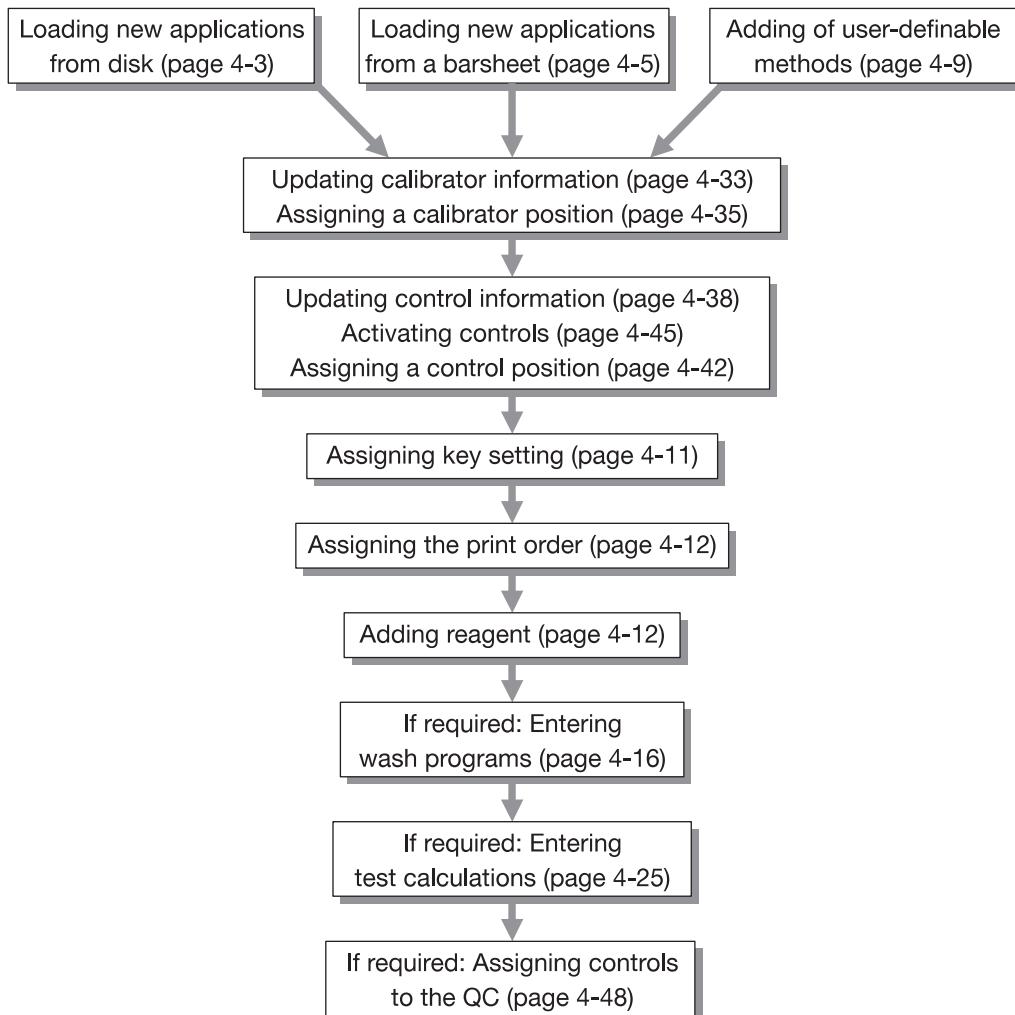
4. Operation Support

4.1 Adding a New Application

Use the following procedures to add new applications to the analyzer test menu. A new application can either be loaded from a floppy disk or from a barsheet that is added to the package insert.

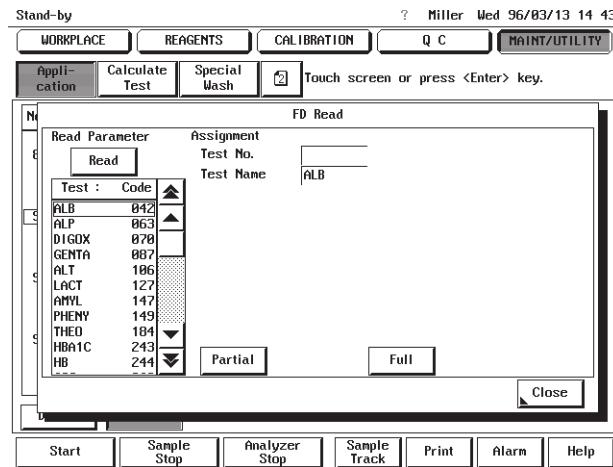
■ Sequence of steps for the adding of new applications

No matter whether you like to load an application from a floppy disk or from a barsheet, you should always follow the sequence of steps for entering application data.



4.1.1 Loading New Applications from Disk

1. Touch MAINT/UTILITY, followed by APPLICATION on the second sub menu level to display the APPLICATION sub menu.
2. Determine the next vacant test number in the list.
3. Insert an application disk into the floppy drive. Touch FD READ to open the corresponding window.
4. Touch the READ button in the window and confirm with ENTER. The FD READ window is displayed.



5. After touching the READ button the application from the disk are read and appear in the list box. Select the test you want to add from the list box.
6. Assign to the test the previously selected test number (see step 2). If required, enter the test name (short name, max. of 5 characters) in the TEST NAME field.
7. Touch FULL or PARTIAL, depending on whether you want to load all parameters or only those that are not user definable. Touch YES to read the parameters from the floppy disk to the analyzer's hard disk. See table on page 4-7 for further details.
8. Check the settings in the CALIB. window (APPLICATION sub menu in MAINT/UTILITY main menu) and change the recommended auto calibration settings, if necessary.
9. Check the settings in the RANGE window (APPLICATION sub menu in MAINT/UTILITY main menu) and modify the settings of the control interval, rerun limit, technical limit and expected values, if necessary.

10. Ensure that the concentration and calibrator codes that are displayed in the MAINT/UTILITY main menu are identical with the loaded calibrator data displayed in the CALIBRATION main menu.
-

Notes

If the test application is loaded the first time, only FULL is possible. Calibration and control values must be loaded again from a barsheet.

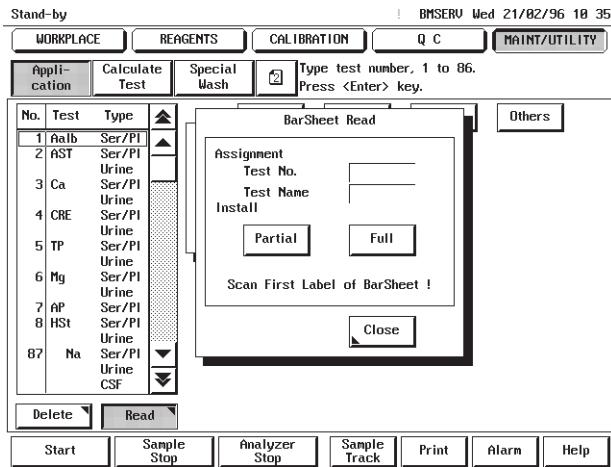
If test applications already exist for the selected test code, a warning window pops up. Touch YES to overwrite the parameters. Touch NO to cancel the parameters write.

If a test application is deleted and overwritten by a new application, the analyzer uses the relevant calibrator concentrations of the deleted application for the new application. This is why the calibrator code and the concentration should always be checked.

Before you install a new application, check the unit setting on the MAINT/UTILITY, RANGE screen. Changing to another unit after setting the calibration and control values deletes them.

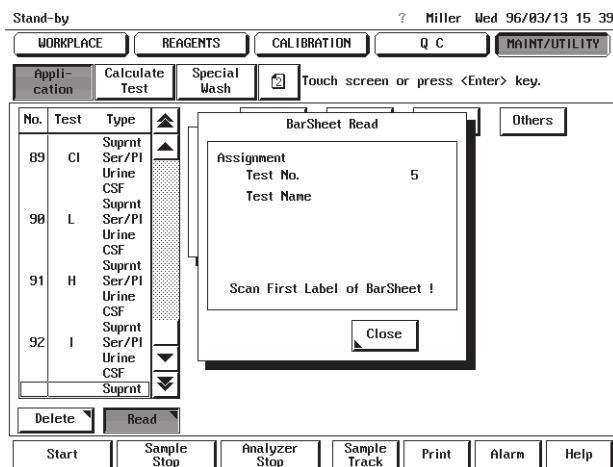
4.1.2 Loading New Applications from a Barsheet

1. Touch MAINT/UTILITY, followed by APPLICATION on the second sub menu level to display the APPLICATION sub menu.
2. Determine the next vacant test number in the list.
3. Touch the READ button to display the corresponding window.
4. Touch BARSHEET READ and press ENTER to display the corresponding window.

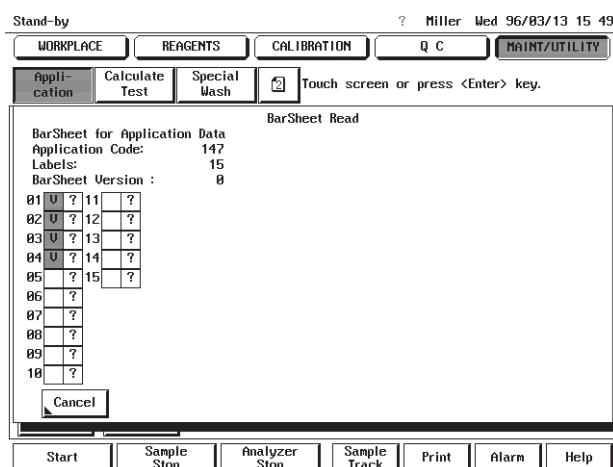


5. Assign to the test the previously selected test number (see step 2). If required, enter the test name (short name, max. of 5 characters) in the TEST NAME field.
6. Touch FULL or PARTIAL, depending on whether you want to load all parameters or only those that are not user definable. See table on page 4-8 for further details.

BM/Hitachi 917



7. Scan with the barsheet reader the first barcode on the barsheet that is added to the package insert. Keep the button on the barsheet reader pressed while scanning. After the scan is finished an audible signal is issued and ARE YOU SURE? appears in the screen.
8. Press YES. The BARSHEET READ window appears. The first scanned barcode is displayed, highlighted in yellow, together with a V flag.



9. Scan all subsequent barcodes. After the scanning of all barcodes is finished, the window closes automatically. The new test appears in the TEST list box.
10. Check the settings in the CALIB. window (APPLICATION sub menu in MAINT/UTILITY main menu) and change the recommended auto calibration settings, if necessary.
11. Check the settings in the RANGE window (APPLICATION sub menu in MAINT/UTILITY main menu) and change the control interval, rerun limit, technical limit, expected values, if necessary.

Note

Read carefully the notes following the section 4.1.1 Loading New Applications from Disk. They are also valid for the application loading from a barsheet.

The following table displays which settings of an already existing application are overwritten, when a new application is entered:

User-specific input field	Full application		Partial application	
	overwritten	not overwritten	overwritten	not overwritten
Sample Vol. (reduced)	X		X	
SD Limit, Duplicate Limit	X		X	
Sensitivity Limit, S1Abs Limit	X		X	
Auto Calibration	X			X
Data Mode	X		X	
Control Interval	o			X
Instr. Factor	X (FD)	X (Barsheet)	X (FD)	X (Barsheet)
Techn. Limit	o			X
Rerun Limit	o			X
Expected Value Range	o			X
Calibrator Code	X		X	

X = User-specific entries are overwritten, or not overwritten, by the original application data.

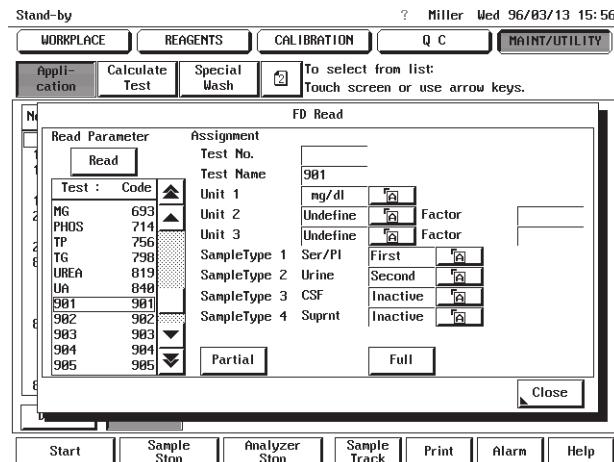
o = User-specific entries are overwritten by the original default application data which then have to be defined individually by the operator.

4.1.3 Adding of User-Definable Applications (901 to 905)

Use the following procedure to add user-definable applications. Up to five user-definable applications can be programmed on the 917.

■ Loading new parameters

1. Touch MAINT/UTILITY, followed by APPLICATION on the second sub menu level to display the APPLICATION sub menu.
2. Determine the next vacant test number.
3. Touch READ, followed by FD READ to open the FD READ window. Select the desired number 901 - 905 from the list box.

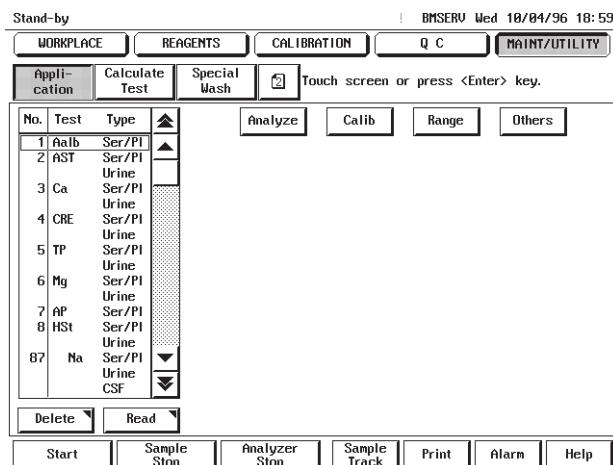


4. Enter the test number in the ASSIGNMENT TEST NO. assist box.
5. Enter the short name of the test (max. of 5 characters) in the test name field.
6. Select the unit for your test in the assist box list. Up to 3 different units can be selected for the test.
7. If more than one unit is being used, the conversion factors in the FACTOR field must be entered as follows in order to convert unit 1 to unit 2, or unit 3 respectively. Enter the corresponding factors in the FACTOR fields (assigned to the units 2 and 3). The selected units are displayed in the Unit assist box list in the APPLICATION, RANGE screen. The first defined unit appears automatically in the unit field.

Note

Changing to another unit deletes automatically the corresponding calibration and control data.

8. Select the sample type for your test. The APPLICATION is only displayed in the TEST SELECTION sub menu, if the set sample type is selected.
9. Touch FULL, followed by YES, to load all parameter settings for the test.
10. Enter the APPLICATION data for your test in the APPLICATION sub menu (ANALYZE, CALIB, RANGE, and OTHERS windows). For user-defined methods the calibrator code has to be entered in the OTHERS window. Refer to chapters 4.5 Updating Calibrator Information and 4.6 Updating Control Information for more details.

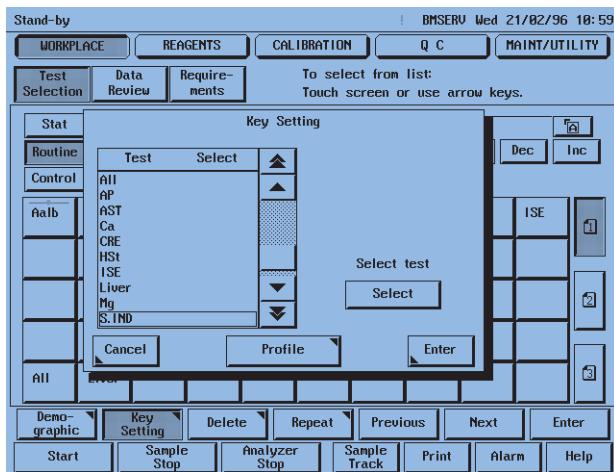


CAUTION

Before updating/entering control and calibrator information, check the unit setting in the MAINT/UTILITY main menu.

4.1.4 Key Setting

1. Touch WORKPLACE and TEST SELECTION to display the TEST SELECTION sub menu.
Touch the ROUTINE button.
2. Touch 1, 2 or 3 on the right-hand side of the screen to select the matrix you are assigning the test to.
3. Touch the KEY SETTING button.
4. Touch the test key in the matrix you are assigning the test to. The KEY SETTING window is displayed.



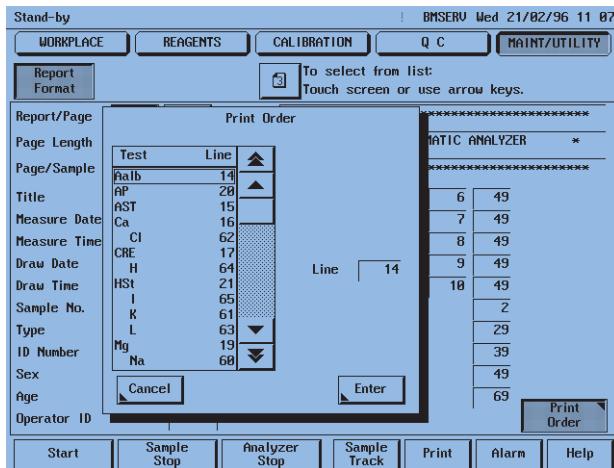
5. Touch the desired test name from the list box, followed by SELECT (a * is displayed in the SELECT column). Touch ENTER to assign the test to the selected key.

Note

The key setting for ROUTINE and STAT samples is assigned in the TEST SELECTION sub menu (WORKPLACE main menu). This has to be defined separately for each sample type. The key setting for controls is performed in the TEST SELECTION, control screen. No key setting for different sample types is required.

4.1.5 Assigning the Print Order

1. Touch MAINT/UTILITY, followed by REPORT FORMAT in the third sub menu level to display the corresponding sub menu.
2. Touch the PRINT ORDER button to display the corresponding window.



3. Touch the test name in the list box that you are assigning to a print order.
4. Enter the number of the print order in the LINE text box and confirm with ENTER. The entered line is displayed in the list box. Touch the ENTER button to save the print order assignment and to close the window.

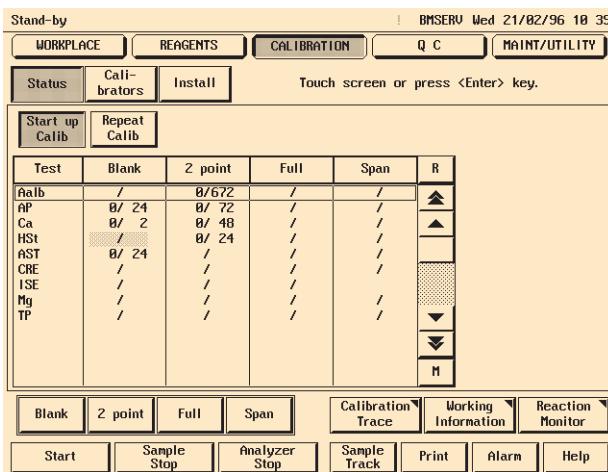
4.1.6 Reagent Registration

1. Place the reagent in a vacant position of the relevant reagent disk.
2. The red bar above the test name on the test key in the TEST SELECTION sub menu (WORKPLACE main menu) disappears after the barcode is registered.

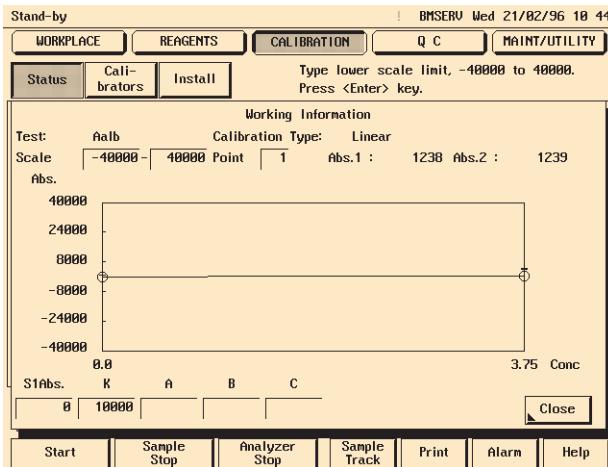
4.1.7 Programming Preset K Factors for Assays

If the APPLICATION has a preset K factor, this can be entered in the WORKING INFORMATION window.

1. Touch CALIBRATION, followed by STATUS to display the STATUS sub menu.



2. Touch the test to be programmed in the list box.
3. Touch the WORKING INFORMATION button to display the corresponding window.



4. Enter the K factor value in the K text box and press ENTER.
5. Touch CLOSE to close the window and to save the K factor.

4.2 Loading a Serum Index Application

Perform the following steps to load a test application for the measurement of a serum index.

1. Press MAINT/UTILITY, followed by APPLICATION on the second sub menu level.
2. Select a vacant test number in the list.
3. Insert the BM application floppy disk into the disk drive (the disk must lock in audibly). Then press READ.

If the barsheet reader is activated

Select FD READ in the relevant window and then press ENTER. The FD READ window is displayed.

If the barsheet reader is deactivated

The FD READ window is displayed.

4. Press READ to display the new applications in the list.
5. Select the BM application S.I. with the application number 850 from the list and assign the vacant test number to the S.I. test in the TEST NO. field; confirm by pressing ENTER on the keyboard. Enter a test shortname in the TEST NAME field and confirm by pressing ENTER on the keyboard.
6. Press FULL to load the application.

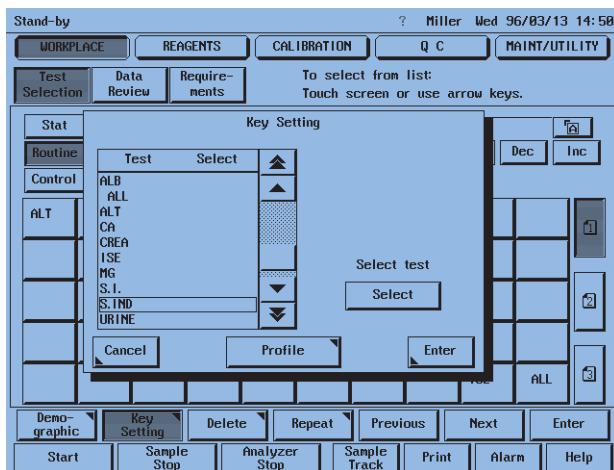
No.	Test	Type	Factor A	Factor B	Factor C	Factor D	Factor E	Factor F
19	MG	Ser/PI	40	122000	18	94	19000	180000
22	Ca	Ser/PI		(1)	0	0	0	0
23	S.I.	Urine		(2)	0	0	0	0
87	Na	Ser/PI		(3)	0	0	0	0
		Urine		(4)	0	0	0	0
		CSF		(5)	0	0	0	0
		Suprnt		(6)	0	0	0	0
88	K	Ser/PI						
		Urine						
		CSF						
		Suprnt						
89	Cl	Ser/PI						
		Urine						
		CSF						
		Suprnt						
98	L	Ser/PI						

Loading of a Serum Index Application

7. Select one of the tests L, H, and I from the test list and assign it to the S.I. application in the ANALYSIS window. If one parameter is assigned (e.g. L), the other two parameters (e.g. H and I) of the S.I. application are automatically assigned.
8. Check the factor values A to F and change the values according to the desired unit; Conventional Unit = mg/dL, International Unit (SI) = mmol/L. The following table displays the factor values to be entered for both units.

Units	A	B	C	D	E	F
Conventional	25	122000	10	1600	19000	180000
SI	40	122000	10	94	19000	180000

9. Reset the S.I. print order for the report format to 0 (zero) in the PRINT ORDER window (REPORT FORMAT sub menu). The S.I. is not displayed in the report. Refer to 4.1.6 Assigning Print Order for more details.
10. Perform a single blank calibration for the serum index test.
11. Assign a test key in the TEST SELECTION sub menu (WORKPLACE main menu) to request the serum index. Select S.IND. from the test list. See 4.1.5 Key Setting for more details.



S.IND must be requested, if the serum index of a sample is to be measured. In the printout the L, H and I values are displayed in the corresponding units.

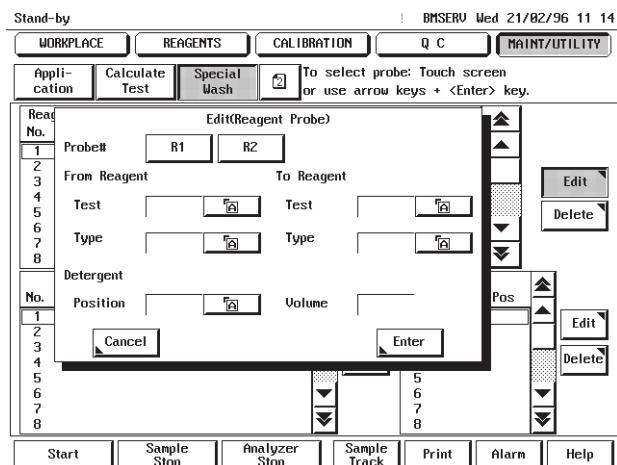
4.3 Special Wash Programming

4.3.1 Reagent Probe Wash

Up to 50 reagent probe wash programs can be assigned to both reagent pipettors. The reagent probe wash is executed during the pipetting of two reagents. Every additional wash step reduces the throughput.

■ To add a reagent probe wash

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch a vacant number in the REAGENT PROBE wash box.
3. Touch EDIT to the right-hand side of the list box to display the corresponding window.

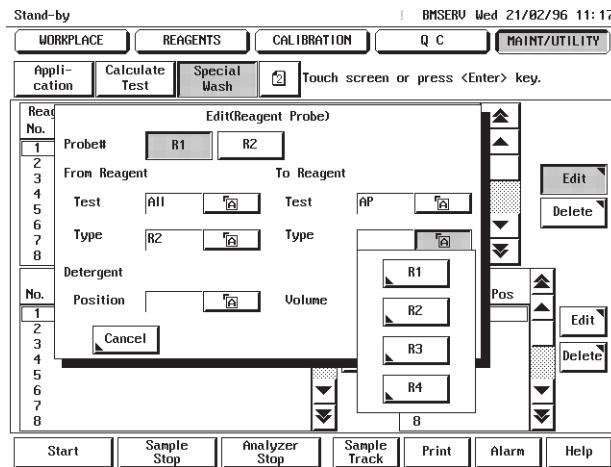


4. Touch the R1 or R2 button to select the desired reagent pipettor.
5. Touch the appropriate test name in the FROM REAGENT list box with which the wash is to begin and press the E button in the scrollbar. Touch the appropriate reagent type (e.g. R1) in the TYPE assist box.
6. Touch the appropriate test in the TO REAGENT list box which is to follow after the wash and press the E button in the scrollbar. Touch the appropriate reagent in the TYPE assist box.
7. Select the detergent position (1D1 to 2D3 or water) in the POSITION assist box. Enter the detergent volume in the VOLUME text box.
8. Touch ENTER to close the window.

■ To edit a reagent probe wash

Perform the following steps to edit a reagent probe wash:

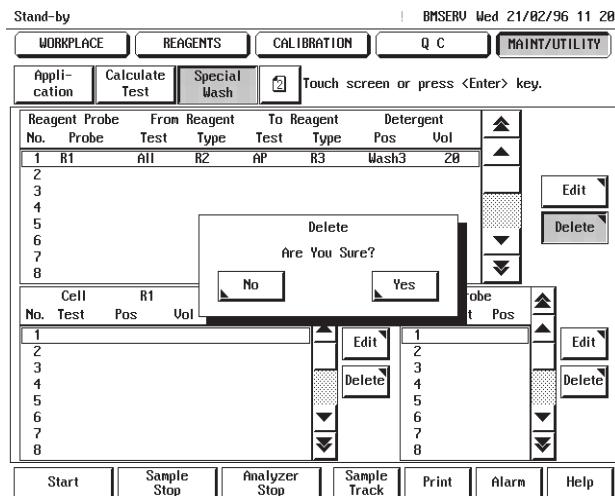
1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch the number in the REAGENT PROBE wash box you want to edit.
3. Touch EDIT to the right-hand side of the list box to display the EDIT (REAGENT PROBE) window. Perform the steps 4. to 6. of the section To program a reagent probe wash.



4. Touch the field you wish to edit. Enter the desired changes and confirm with ENTER.

■ To delete a reagent probe wash

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch the number in the REAGENT PROBE wash box you want to delete.
3. Touch DELETE to display the corresponding window. ARE YOU SURE? is displayed in the screen.



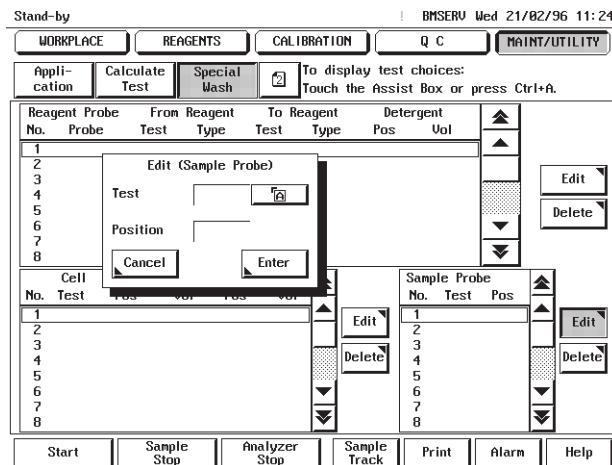
4. Touch YES to delete the wash programming.

4.3.2 Sample Probe Wash

Up to 50 sample probe wash programs can be defined. The sample probe wash is executed before the pipetting of the assigned tests is performed. Every additional wash step reduces the throughput.

■ To add a sample probe wash

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch a vacant number in the SAMPLE PROBE wash box that you want to assign to the wash program.
3. Touch EDIT to the right-hand side of the list box to display the EDIT (SAMPLE PROBE) window.

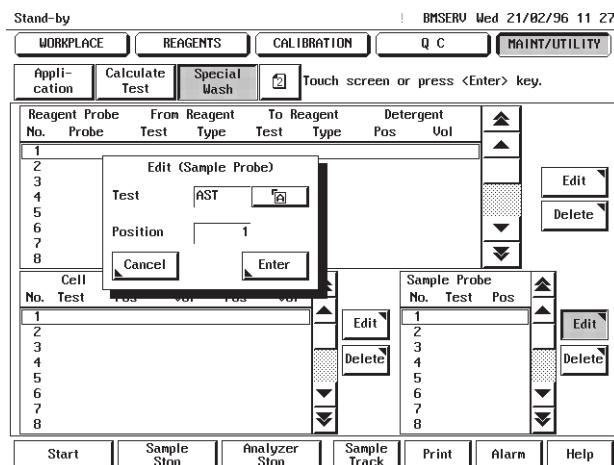


4. Touch the appropriate test name in the list box and press E on the scrollbar.
5. Select the detergent (W1 to W3) from sample disk 2 with which the sample probe is to be washed.
6. Touch ENTER to close the window.

■ To edit a sample probe wash

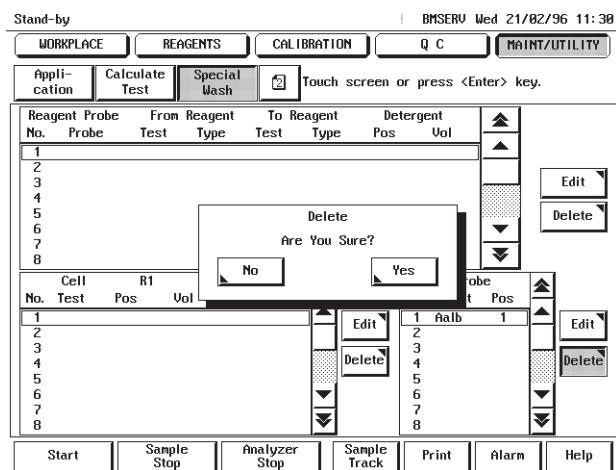
Perform the following steps in order to carry out a sample probe wash:

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch the number in the SAMPLE PROBE wash box you want to edit.
3. Touch EDIT to the right-hand side of the list box to display the EDIT (SAMPLE PROBE) window. Perform the steps 4. to 6. from the section To program a sample probe wash.



I To delete a sample probe wash

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch the number in the SAMPLE PROBE wash box you want to delete.
3. Touch DELETE on the right-hand side of the list box to display the corresponding window. ARE YOU SURE? is displayed in the screen.



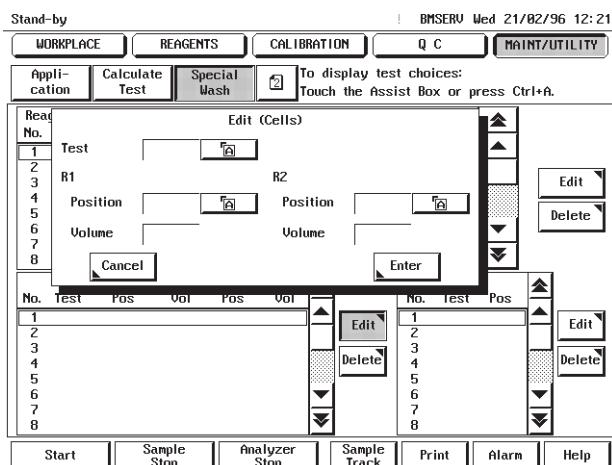
4. Touch YES to delete the wash programming.

4.3.3 Cell Wash

Up to 50 cell wash programs can be assigned. Each cell that is filled with the reagent of the assigned test is automatically washed.

■ To add a cell wash

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch a vacant number in the CELL wash box that you want to assign to the wash program.
3. Touch EDIT on the right-hand side of the list box to display the EDIT (CELLS) window.



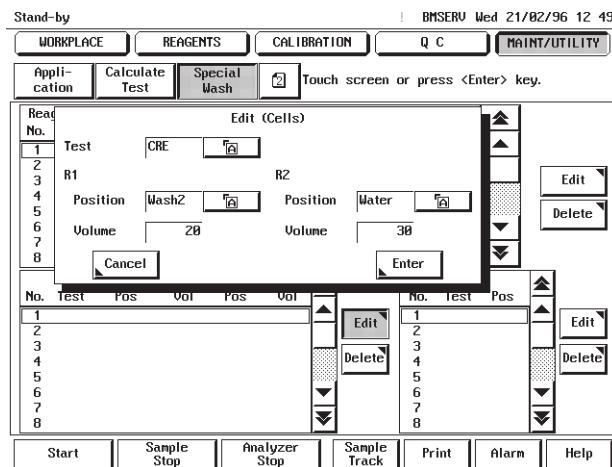
4. Select a test from the TEST assist box, then press E on the scrollbar.
5. Select the wash solution (1D2, 1D3, water) for the R1 pipettor from the R1 assist box.
6. Enter the detergent volume (max. 270 mL) in the VOLUME text box.
7. Select the wash solution (2D2, 2D3, water) for the R2 pipettor from the R2 assist box.
8. Enter the detergent volume (max. 270 mL) in the VOLUME text box.
9. Touch ENTER to close the window.

Special Wash Programming

■ To edit a cell wash

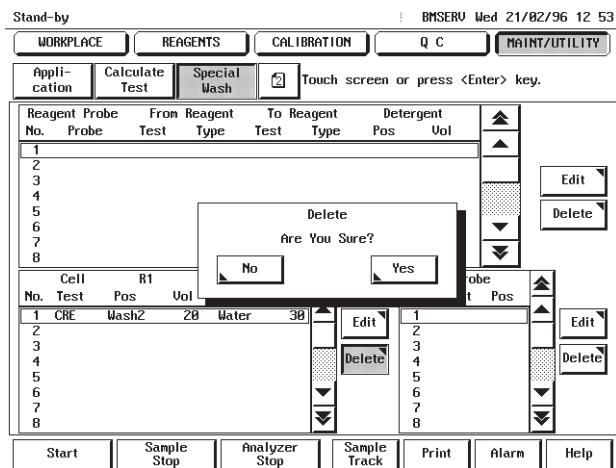
Perform the following steps in order to change a reaction cell program:

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch the number in the CELL wash box you want to edit.
3. Touch the field you wish to edit and enter the changes and confirm with ENTER.



■ To delete a cell wash

1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
2. Touch the number in the CELL wash box you want to delete.
3. Touch the DELETE button. ARE YOU SURE? is displayed in the screen.



4. Touch YES to delete the wash programming.

4.4 Calculated and Compensated Tests

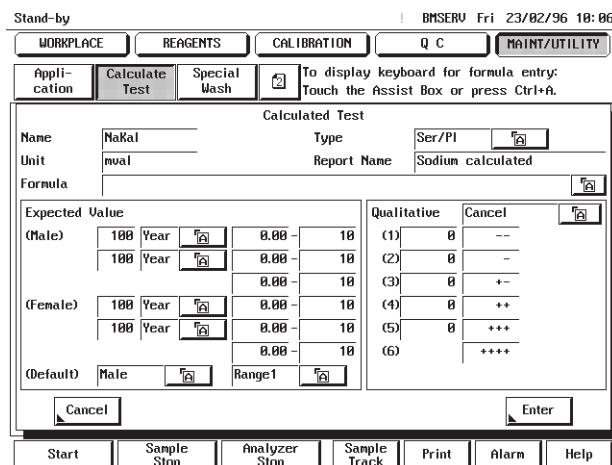
There are two different types of test calculations:

1. Calculated tests: Calculated test results are not performed on the analyzer but are derived from applying a calculated test formula to the results of tests that are actually performed on the analyzer. Up to 8 formulas can be defined. A QC of a calculated test is not possible.
2. Compensated tests: Compensated test results are run and adjusted by applying a compensated test formula. The QC-value is not adjusted to the compensated test formula. Up to 8 formulas can be defined.

4.4.1 Calculated Tests

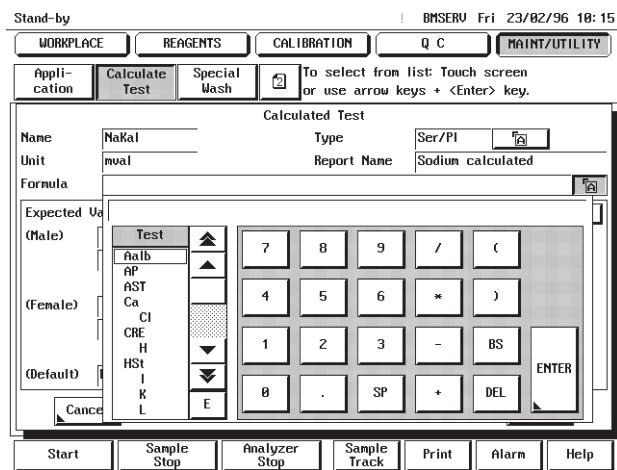
■ Entering a calculated test formula

1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch CALC.
2. Touch the number to which you want to assign the calculated test formula.
3. Touch EDIT below the list box to display the CALCULATED TEST window.



4. Enter the test name in the NAME field and the desired measuring unit in the UNIT field. Choose the sample type from the TYPE assist box. Enter the report name in the REPORT NAME field.

5. Touch the FORMULA assist box to display the TEST list box. Select the tests that are required for the calculation and confirm by pressing E on the scrollbar. Use the numeric key pad to enter operands and numerals. Use DEL to delete the whole formula, BS to delete only the last entry and SP to enter a space. Enter brackets according to mathematical principles.



6. Confirm the entire entry by pressing the ENTER button.
7. If you make an entry that is not allowed, you will receive an error message.
8. Choose the expected value ranges and enter the qualitative parameters, if necessary.
9. Touch ENTER to save the calculated test and to close the window.

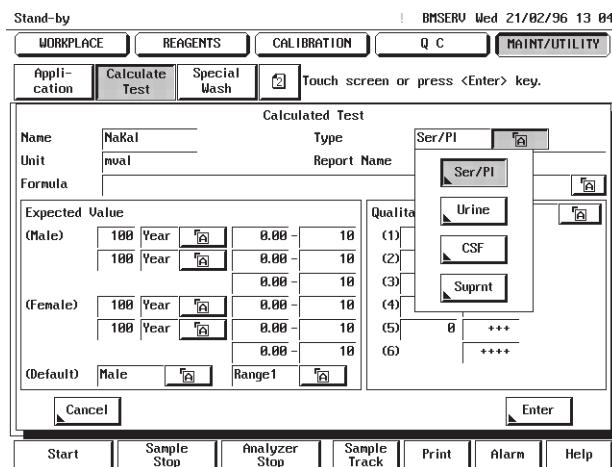
Note

In case of calculating ratios, a unit does not exist. However, the UNIT field requires an entry. Enter a "space" with the space bar on the keyboard.

If the calculated result is to be printed out with a decimal point, this option has to be defined first in the expected value fields by entering a corresponding value beforehand.

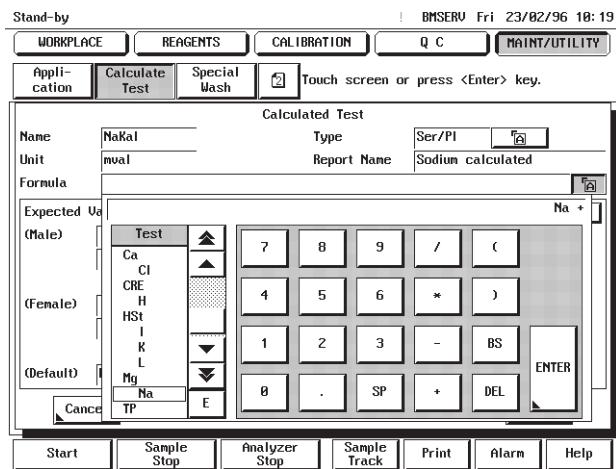
■ Editing a calculated test formula

1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch CALC.
2. Touch the number of the calculated formula you wish to edit.
3. Touch EDIT below the list box to display the CALCULATED TEST window.
4. Change any information in the corresponding fields (see section Entering a calculated test formula for more details).



5. Touch the FORMULA assist box to display the list box and numeric key pad used to change the formula. Use the list box to select any test name that is part of the formula. Confirm it with E on the scrollbar. Use the numeric key pad to enter operands and numerals. Use DEL to delete the whole formula, BS to delete only the last entry or SP to enter a space. Enter brackets according to mathematical principles.

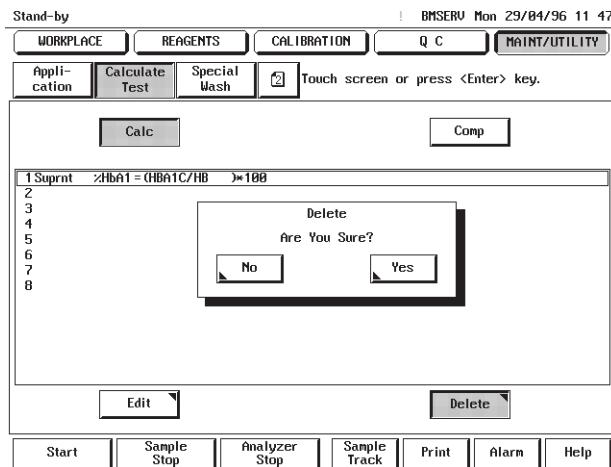
BM/Hitachi 917



6. Confirm the entire entry by pressing the ENTER button.
7. Touch ENTER to save the calculated test and to close the window.

■ Deleting a calculated test formula

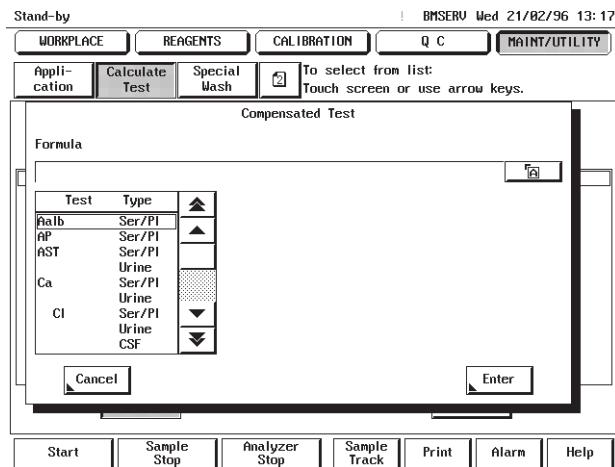
1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch CALC.
2. Touch the number of the calculated test you want to delete.
3. Touch DELETE to display the corresponding window. Select YES to delete the calculated test formula.



4.4.2 Compensated Tests

■ Entering a compensated test formula

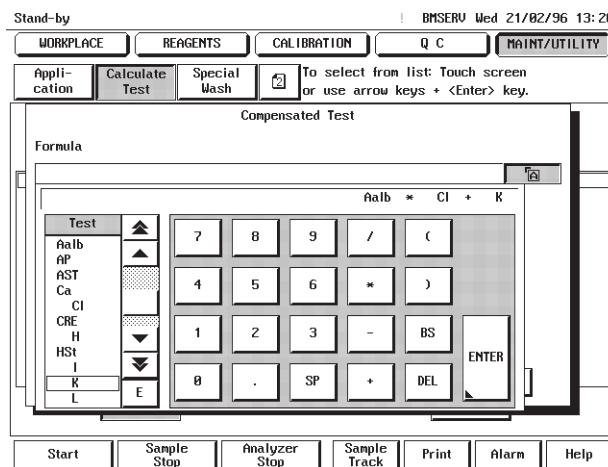
1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch COMP.
2. Touch the number you want to assign the compensated test formula to.
3. Touch EDIT below the list box to display the COMPENSATED TEST window.



4. Select the test to be compensated from the TEST list box.
5. Touch the FORMULA assist box to display the list box. The numeric key pad is used to enter the formula. Use the list box to select any test name that is part of the formula. Confirm it with E on the scrollbar. Use the numeric key pad to enter operands and numerals. Use DEL to delete the whole formula, BS to delete only the last entry or SP to enter a space. If you make an entry that is not allowed, you will receive an error message.
6. Confirm the entire entry by pressing the ENTER button.
7. Touch ENTER to save the compensated test and to close the window.

■ Editing a compensated test formula

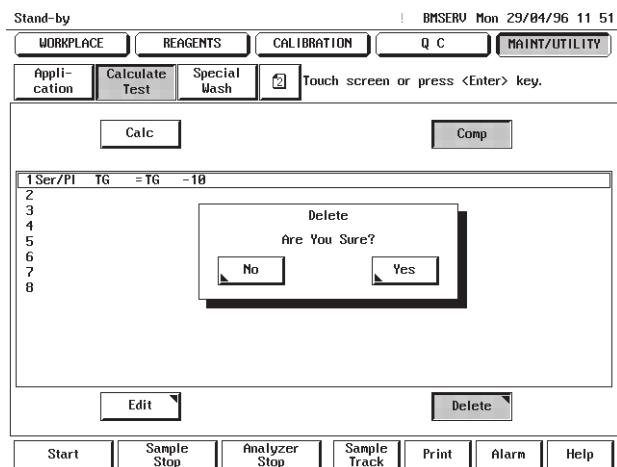
1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch COMP.
2. Touch the number of the compensated formula you wish to edit.
3. Touch EDIT below the list box to display the COMPENSATED TEST window.
4. Perform the desired changes in the relevant fields (see section Entering a compensated test formula).
5. Touch the FORMULA assist box to display the list box and numeric key pad used to change the formula. Use the list box to select any test name that is part of the formula. Confirm it with E on the scrollbar. Use the numeric key pad to enter operands and numerals. Use DEL to delete the whole formula, BS to delete only the last entry or SP to enter a space. Enter brackets according to mathematical principles.



6. Confirm the entire entry by pressing the ENTER button.
7. Touch ENTER to save the compensated test and to close the window.

■ Deleting a compensated test formula

1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch COMP.
2. Touch the number of the compensated test formula you want to delete.
3. Touch DELETE to display the corresponding window. Touch YES to delete the formula.

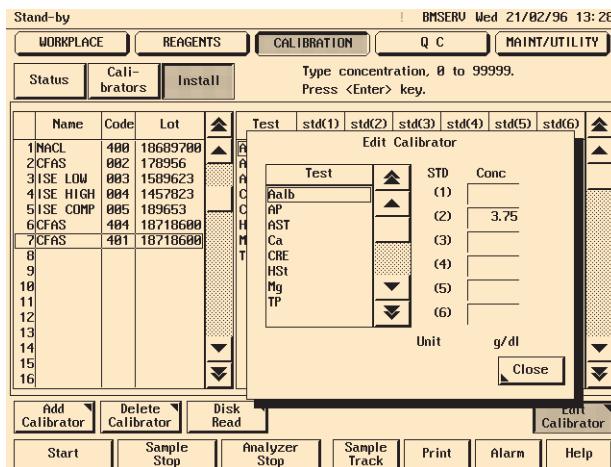


4.5 Loading Calibrator Information

Calibrators can either be loaded manually or from a barsheet. The settings have to be performed in the INSTALL sub menu and the CALIBRATORS sub menu (CALIBRATION main menu).

4.5.1 Manual Setting of Calibrator

1. Touch CALIBRATION, followed by INSTALL, to display the corresponding sub menu.
2. Touch the next vacant number in the list box on the left. Touch ADD CALIBRATOR to open the corresponding window.
3. Enter the name of the calibrator, code, lot number and expiration date. Confirm with ENTER to save the entry.
4. Touch EDIT CALIBRATOR to display the corresponding window. Enter the new calibrator setpoint in the corresponding field (e.g. "Cfas" in the STD 2 column).



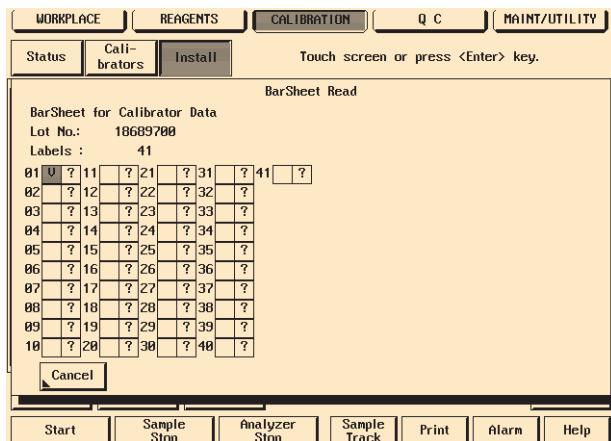
5. Touch ENTER to save the input and then CLOSE to close the window.

4.5.2 Loading Calibrator Setpoints from a Barsheet

1. Touch CALIBRATION, followed by INSTALL, to display the corresponding sub menu.
2. Touch the next vacant number in the list box on the left. Touch DISK READ to display the BARSHEET READ window.
3. Scan with the barsheet reader the first barcode on the barsheet that is added to the package insert. An audible signal is issued and another window is displayed. The scanned barcode is displayed, highlighted in yellow.

Note

If the lot number is already loaded in the system, you will receive a warning message.



4. Scan all subsequent barcodes. After the scanning of all barcodes is finished, the window closes automatically. Calibrator name and code are displayed in the left box. The corresponding concentrations appear in the right box.

Note

A manual editing of calibrator setpoints is possible.

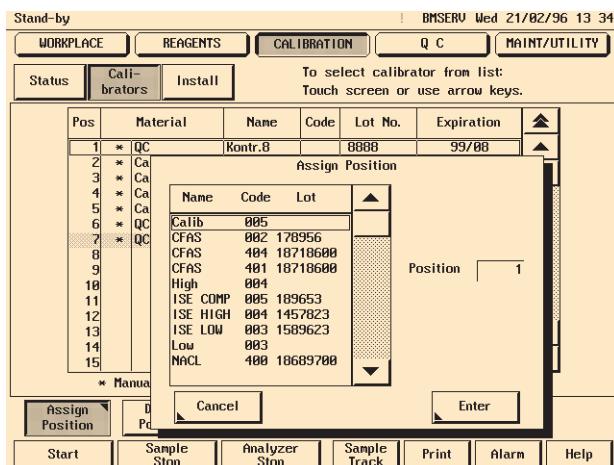
4.5.3 Assigning a Calibrator Position

1. Touch CALIBRATION, followed by CALIBRATORS, to display the corresponding sub menu. This list displays all calibrators and controls which are assigned to a position. Choose a position that is currently not assigned to another calibrator or control.

Note

Activated controls are highlighted in yellow.

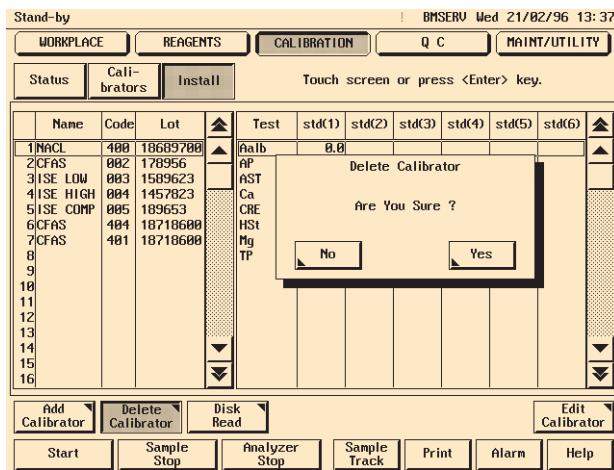
2. Touch ASSIGN POSITION to display the corresponding window. Touch the name of the calibrator from the list box. The chosen POSITION is displayed in the corresponding field. Touch ENTER to save the entry.



3. Touch CALIBRATION, followed by STATUS to select the method for start up calibration and to request the test. For further details see chapter 2.5, Calibration Test Selection.

4.5.4 Deleting a Calibrator

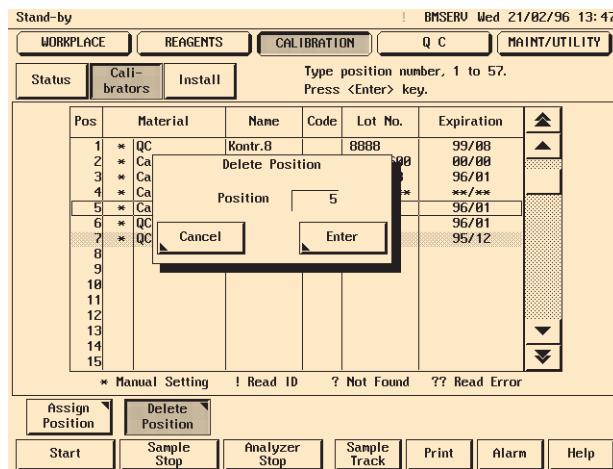
1. Touch CALIBRATION, followed by INSTALL, to display the corresponding sub menu.
2. Touch the calibrator name in the list box on the left that you want to delete. Touch DELETE CALIBRATOR to display the corresponding window.



3. Touch YES to delete the selected calibrator.

4.5.5 Deleting a Calibrator Position

1. Touch CALIBRATION, followed by CALIBRATORS to display the corresponding sub menu. This list displays all calibrators and controls which are assigned to a position. If a calibrator has been already deleted in the INSTALL sub menu, it is indicated with ***** (asterisks) in the list.
2. Choose the calibrator position that you want to delete.



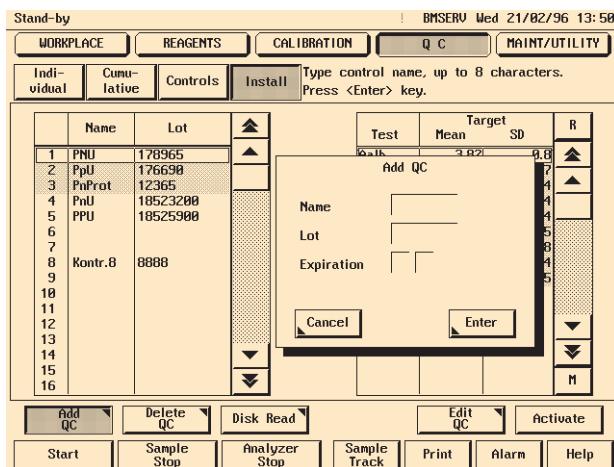
3. Touch DELETE POSITION to display the corresponding window. The chosen position is displayed in the corresponding field. Touch ENTER to delete the calibrator position.

4.6 Loading Control Information

Use the following procedures to add new control setpoints, either manually or from a barsheet. The settings are to be entered in the ADD QC window of the INSTALL sub menu (QC main menu).

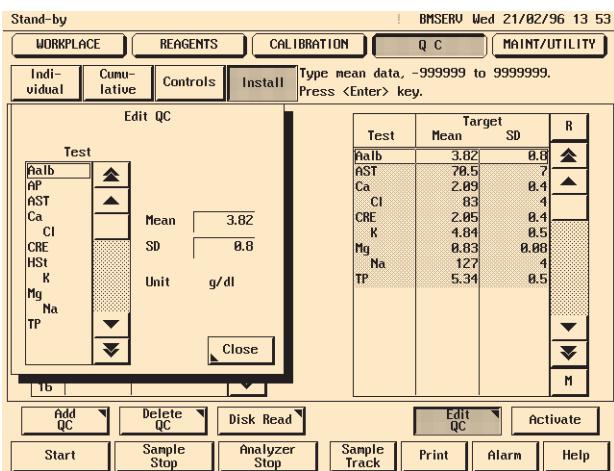
4.6.1 Manual Control Setting

1. Touch QC, followed by INSTALL, to display the corresponding sub menu.
2. Touch the next vacant number in the list box on the left. Touch ADD QC to open the corresponding window.



3. Enter the name of the control, lot number and expiration date. Press ENTER to save the entry.
4. Touch EDIT QC to display the corresponding window. Touch the test name you are entering control values for in the list box. Enter the Mean and 1 SD value. Repeat this procedure for all tests that need to be assigned to this control.

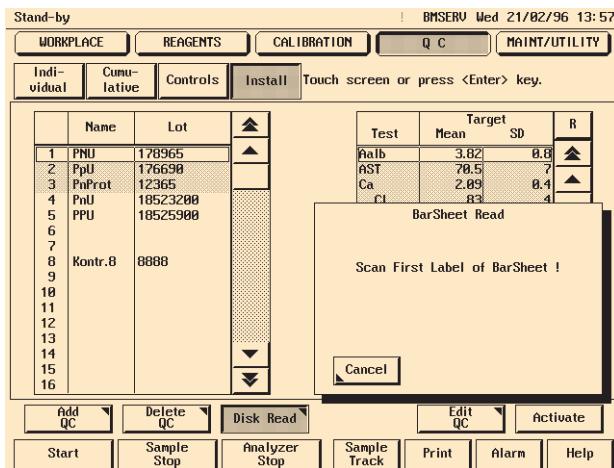
Loading Control Information



5. Touch CLOSE to close the window. The entered values are displayed in the right list box.

4.6.2 Loading Control Setpoints from a Barsheet

1. Touch QC, followed by INSTALL, to display the corresponding sub menu.
2. Touch the next vacant number in the list box on the left. Touch DISK READ to display the corresponding window.

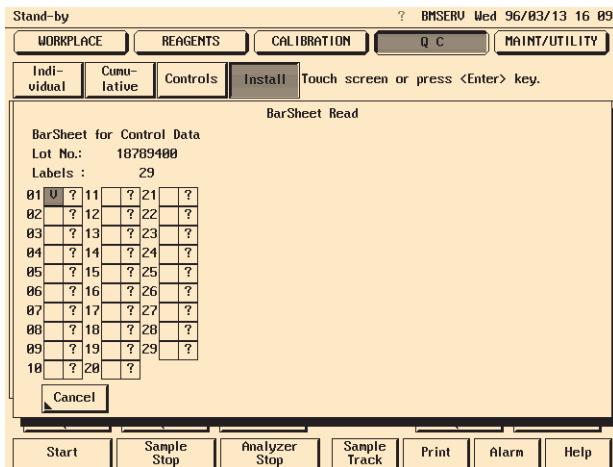


3. Scan the **first** barcode on the barsheet with the barsheet reader. An audible signal is issued and the BARSHEET READ window is displayed. The first successfully scanned barcode appears highlighted in yellow.

Note

If the lot number is already loaded in the system, you will receive a warning message.

Loading Control Information



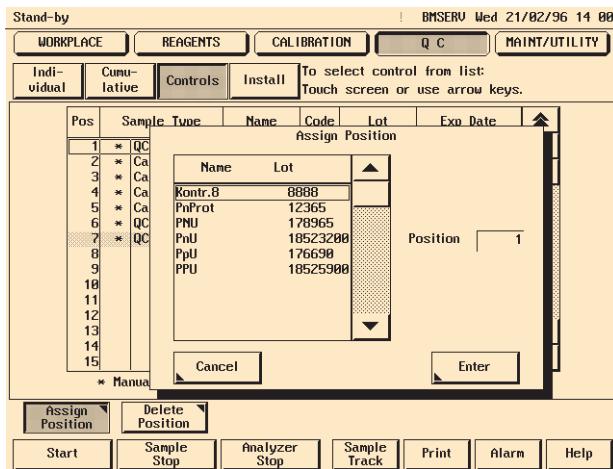
4. Scan all subsequent barcodes on the sheet. After the scanning is finished, the window closes automatically. Control name and lot number are displayed in the left box. The target mean and SD appear in the right box.

Note

A manual editing of control setpoints is possible (see section 4.6.1).

4.6.3 Assigning a Control Position

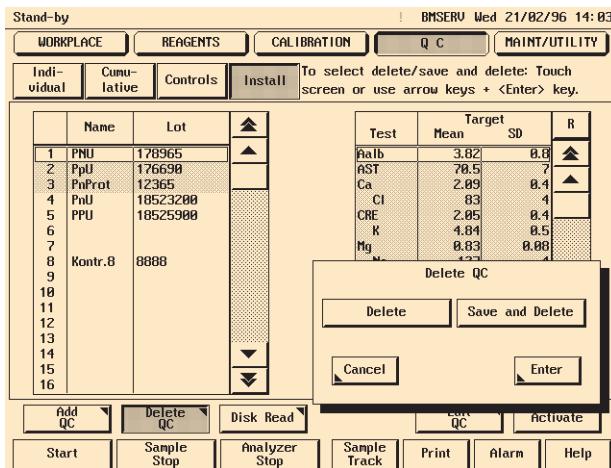
1. Touch QC, followed by CONTROLS, to display the corresponding sub menu. All calibrators and controls which are assigned to a position are displayed in this screen. Choose a position that is not currently assigned to another calibrator or control. Activated controls appear highlighted in yellow.



2. Touch ASSIGN POSITION to display the corresponding window. Touch the name of the control in the list box. The chosen position is displayed in the POSITION field. Touch ENTER to save the entry.

4.6.4 Deleting a Control

1. Touch QC, followed by INSTALL, to display the corresponding sub menu.
2. Touch the control name in the list box on the left that you want to delete. Touch DELETE QC to display the corresponding window.



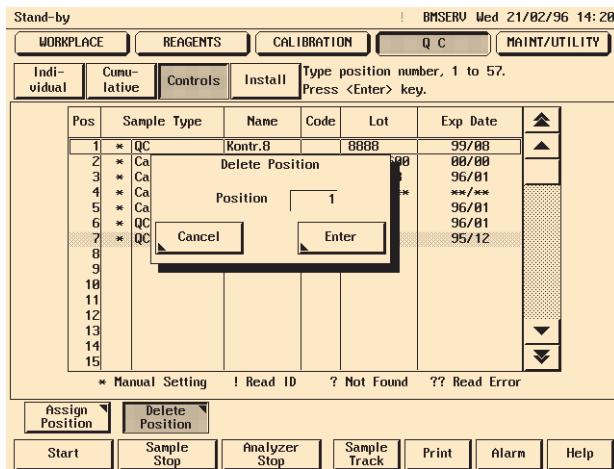
3. Touch the DELETE button or the SAVE AND DELETE button. Then touch ENTER, followed by YES to delete the entry.

Note

QC data (QC parameters, individual QC, cumulative QC) can be saved on a floppy disk. Insert a formatted FD into the FD drive, then touch the SAVE AND DELETE button. The data are stored on the disk in ASCII format and are deleted from the analyzer hard disk afterwards.

4.6.5 Deleting a Control Position

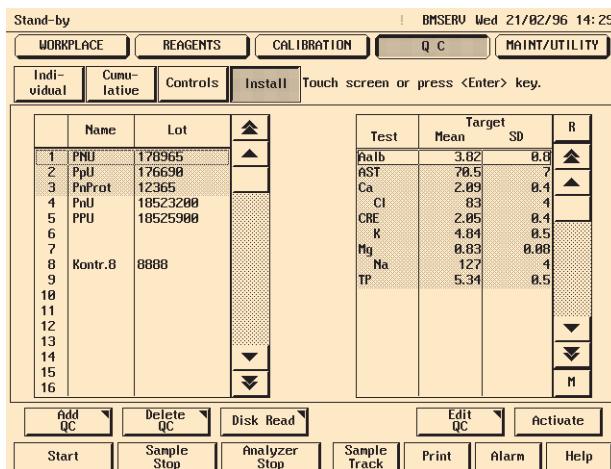
1. Touch QC, followed by CONTROLS, to display the corresponding sub menu. The list in the screen displays all calibrators and controls which are assigned to a position. If a control has been already deleted in the INSTALL sub menu, it is indicated with ***** (asterisks) in the list.
2. Touch the position you want to delete.



3. Touch DELETE POSITION to display the corresponding window. The chosen POSITION is displayed in the corresponding field. Touch ENTER, followed by YES to delete the control position.

4.6.6 Activating Controls

1. Touch QC, followed by INSTALL, to display the corresponding sub menu.



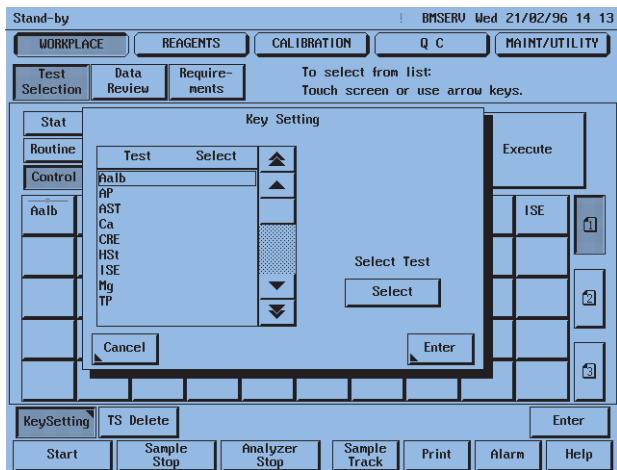
2. Touch the control name in the list box. Then touch ACTIVATE. The control is highlighted in yellow.
3. Mark all single tests of this control lot on the right list box. Touch the M button on the lower right side of the test list box. Touch the test name to be activated. Continue touching test names until all desired tests have been marked for activation. All selected tests are highlighted in green. Touch the ACTIVATE button to activate the tests for the selected control. The activated tests are highlighted in yellow.

Note

Controls are automatically measured after calibration. If a control interval is specified in the RANGE window of the APPLICATION sub menu (MAINT/UTILITY main menu), the controls are also automatically measured after recalibration and auto calibration. If you want to measure the controls without calibration, see section Control Request of the DAILY ROUTINE section of the HELP global menu or chapter 4.6.8 Manual Control Test Selections.

4.6.7 Key Setting for Controls

1. Touch WORKPLACE, followed by TEST SELECTION, to display the corresponding sub menu. Then touch CONTROL.
2. Touch 1, 2, or 3 on the right-hand side of the screen to select the matrix you are assigning the test to.
3. Touch the KEY SETTING button.
4. Touch the test key in the matrix you are assigning the test to. The KEY SETTING window is displayed.

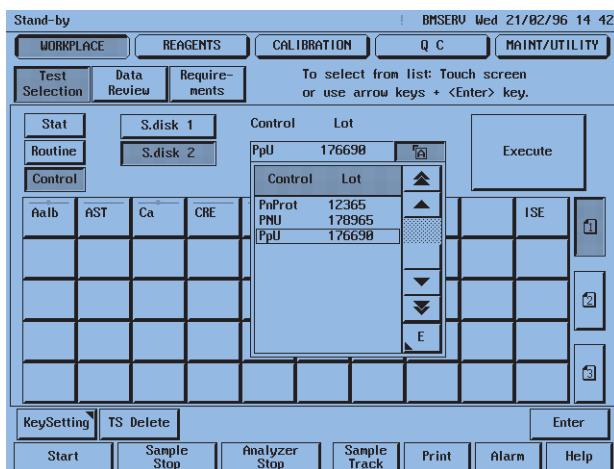


5. Touch the desired test name in the list box, followed by SELECT (a * is displayed in the SELECT column). Confirm with ENTER.

4.6.8 Manual Control Test Selections (Sample Disk 2)

Controls can be manually requested, independent from calibrations or control intervals.

1. Touch WORKPLACE followed by TEST SELECTION, to display corresponding sub menu. Then touch CONTROL.
 2. Touch S. DISK 2, followed by the CONTROL/LOT button to open the corresponding assist box.



3. Choose the desired control from the list and confirm with ENTER or the E button. The tests that are assigned to the control are displayed.
 4. Touch the test keys corresponding to the tests you want to run controls on and confirm with ENTER.
 5. Make sure the control is in position on sample disk 2 and touch EXECUTE. The manually requested control run is inserted in the routine run. If the instrument is in STANDBY it also has to be started.
 6. The results are transferred to the individual statistics calculation and the real time QC. An automatical evaluation of the real time QC is only then possible, if the required coupling was requested together.

4.6.9 Setting Controls for the QC

During routine operation, the instrument compares paired (X) and (Y) control values against the mean and standard deviation entered for each control on the REAL TIME QC sub menu. The REAL TIME QC window evaluates quality control results by a multi-rule Shewhart method. The rules are selected by the operator.

Each set of control results is either acceptable or causes a random, system, or QC error. If a random, systematic, or QC alarm occurs, an alarm message appears on the ALARMS global menu.

■ Setting controls for the real time QC

1. Touch QC, followed by INDIVIDUAL and REAL TIME QC to display the REAL TIME QC window. The daily QC results can be reviewed and checked in this screen.
2. Touch the TEST assist box to display the list of tests. Touch the name of the test you want to review and press E.
3. Touch the SELECT button to display the SELECT CONTROL window in which the desired controls can be reviewed.
4. Touch the control in the list, followed by AXIS X to assign a control to the X-axis.
5. Touch the control in the list, followed by AXIS Y to assign a control to the Y-axis. Touch ENTER to display the graph.
6. Touch RULES if you wish to change the rules by which the QC data are evaluated. The SELECT RULES window is displayed. Touch the rules you want used in the evaluation, followed by ENTER. The previously measured controls are not redrawn according to the rule selection.
7. The graph shown displays all of the QC results for the specified test and control levels. Random, System and QC errors are displayed along with normal QC data.

■ Individual QC list

1. Touch QC, followed by INDIVIDUAL to display the INDIVIDUAL QC sub menu.
2. All daily QC results for the selected test that have not been accumulated are displayed. Target values and statistics are displayed in this screen.

■ Setting controls in the individual QC chart

1. Touch QC, followed by INDIVIDUAL and CHART to display the INDIVIDUAL QC CHART window.
2. Touch the TEST assist box. Touch the test you want to review and press ENTER.
3. Touch SELECT to display the SELECT CONTROL window. Touch the control name followed by the PLOT button. This assigns the selected control to the selected plot. The selected control appears next to the PLOT button. Repeat the procedure for the other two controls you want displayed. Then touch ENTER.

■ Setting controls in the cumulative QC chart

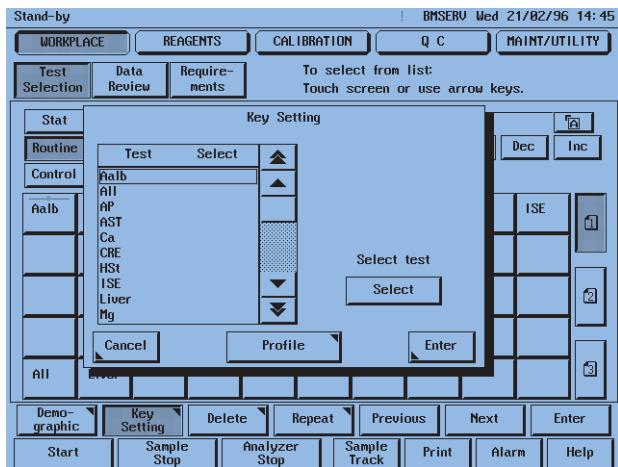
1. Touch QC, followed by CUMULATIVE and CHART to display the CUMULATIVE QC CHART window.
2. Touch the TEST assist box. Touch the test you want to review and press ENTER.
3. Touch SELECT to display the SELECT CONTROL window. Touch the control name followed by the PLOT button. This assigns the selected control to the selected plot. The selected control appears next to the PLOT button. Repeat the procedure for the other two controls you want displayed. Then touch ENTER.

4.7 Defining Profiles

A number of different tests can be combined to a "profile". Use the following procedures to define profiles.

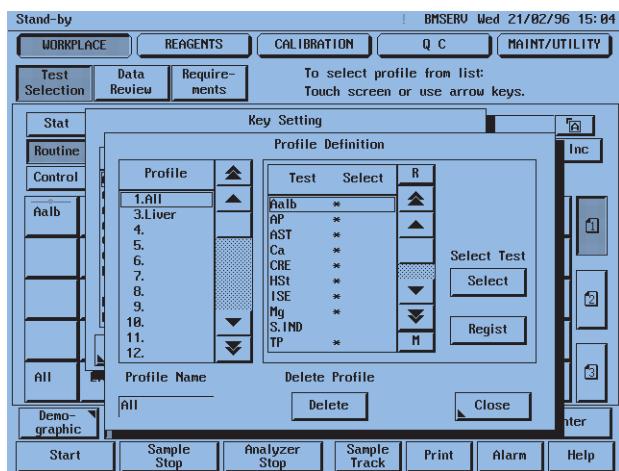
4.7.1 Adding a Profile

1. Touch WORKPLACE, followed by TEST SELECTION, to display the corresponding sub menu. Then touch ROUTINE.
2. Touch 1, 2, or 3 to select the matrix you are assigning the profile to.
3. Touch the KEY SETTING button to activate the key setting. Touch the test key in the matrix you are assigning the profile to.



4. The KEY SETTING window is displayed. Touch PROFILE to display the PROFILE DEFINITION window.

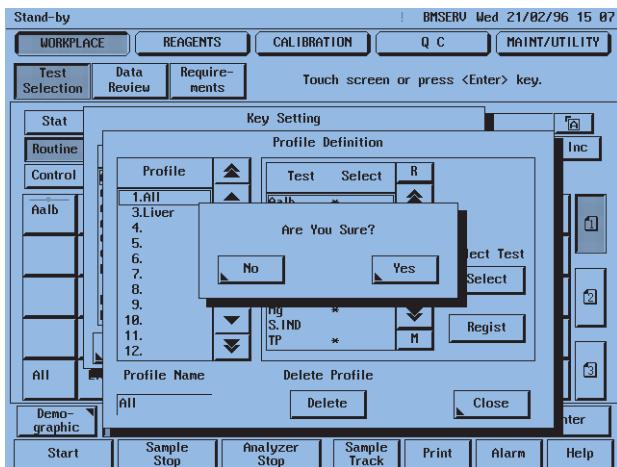
Defining Profiles



5. Touch the next vacant profile number in the left list box. Enter the profile name in the PROFILE NAME text box and press ENTER.
6. Touch a test in the list box and touch SELECT. An asterisk (*) appears beside the test name indicating that this test is assigned to the profile. Touch SELECT again to remove a test from the profile. The asterisk on the right of the test name disappears. Repeat this procedure for all tests you want to assign to this profile. Touch SELECT again to remove a profile from a test key. The asterisk (*) on the right of the profile name disappears.
7. If all desired tests are assigned, touch REGIST to save the profile. The profile name is displayed in the left list box.
8. Touch CLOSE to close the PROFILE DEFINITION window.
9. Select the profile name from the list in the KEY SETTING window. Then touch SELECT, followed by ENTER, to assign the profile to the selected key. Touch the test key in the matrix you are assigning the test to. The key setting window is displayed.
10. Touch SELECT again to remove a profile from a test key. The asterisk (*) on the right of the profile name disappears.

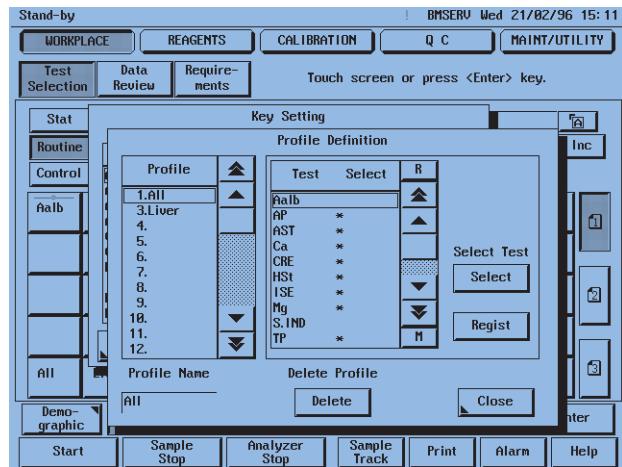
4.7.2 Deleting a Profile / Deleting a Test from a Profile

1. Touch WORKPLACE, followed by TEST SELECTION, to display the corresponding sub menu. Then touch ROUTINE.
2. Touch 1, 2, or 3 to select the matrix to which the profile is assigned to.
3. Touch the KEY SETTING button and then touch the key which is assigned to the profile you want to delete.
4. Touch the profile that you want to delete and activate the PROFILE button.
5. Touch DELETE below the PROFILE DELETE area, followed by YES in the opened window.



6. Touch the profile from which you want to delete a test in the left list box.
7. Highlight the test you want to delete in the list box and touch SELECT. The asterisk (*) beside the test name disappears. Repeat this procedure for all tests you want to delete from this profile. Then, touch REGIST to save the changes.

Defining Profiles

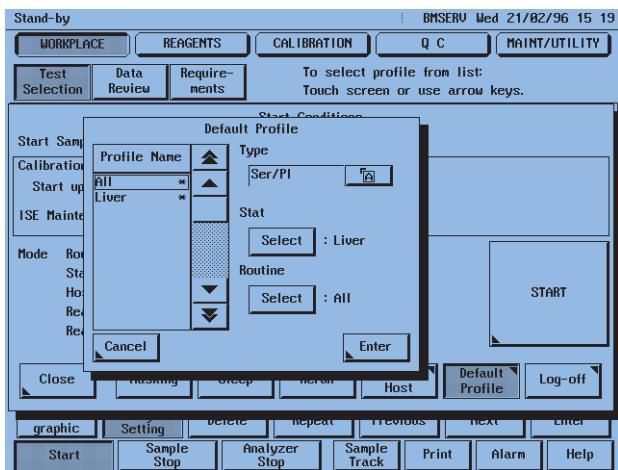


8. Touch CLOSE to close the PROFILE DEFINITION window. Then touch ENTER in the KEY SETTING window to confirm the entry.

4.7.3 Default Profiles

The analyzer can be programmed to run a default profile on any sample for which an ID number or a sequence number is available but for which there are no patient test selections in the system. Any profile that is defined may be selected as the default profile.

1. Touch START to display the START CONDITIONS global menu.
2. Touch DEFAULT PROFILE to display the corresponding window.



3. Open the TYPE assist box and touch the sample type (e.g. serum/plasma) for which you want to activate the default profile. Activate the desired profile.
4. Touch STAT SELECT to use the selected profile as a STAT default profile.
5. Touch ROUTINE SELECT to use the selected profile as a routine default profile.
6. Touch ENTER to save the entered default profile.

4.8 Operator ID / Password Management

There are two levels of password protection on the BM/Hitachi 917, operator and supervisor. Both, operators and supervisors, can edit data, make test selections, check requirements, request calibrations, perform maintenance and update logs.

The supervisor level has these additional access privileges: Add open system methods, change system parameters, adding calibrators and controls, maintenance log changes, special wash programming, calculated and compensated test programming and making test key assignments.

For more details, see chapter 8.5.1.6 in the volume System Description.

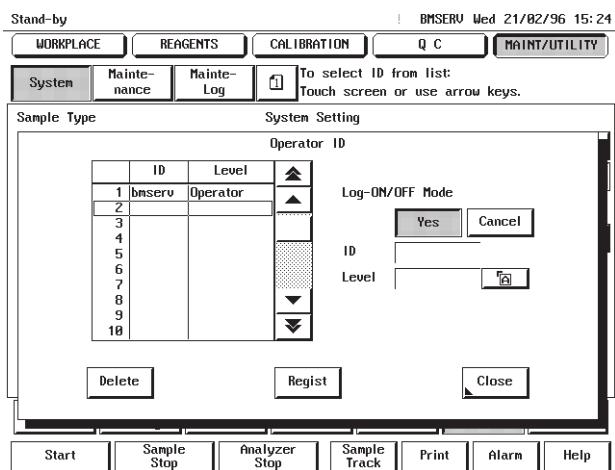
Operator IDs may consist of up to 6 characters.

Both operator and supervisor passwords consist of 4 alphanumeric characters.

Up to 20 Operator ID/password sets may be assigned at any time.

4.8.1 Assigning an Operator ID

1. Touch MAINT/UTILITY, followed by SYSTEM and OPERATOR ID, to display the OPERATOR ID window.



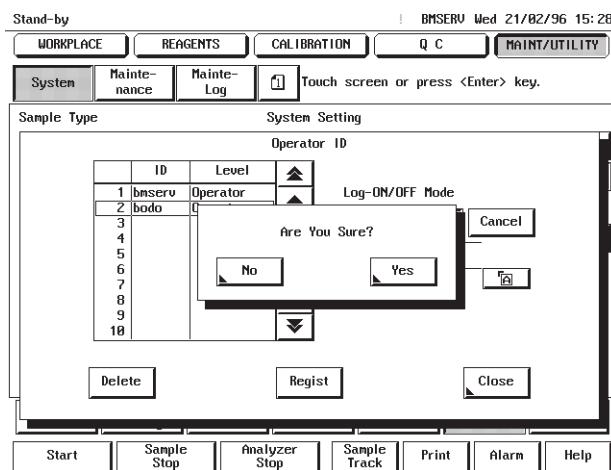
2. Touch the next vacant number in the list box.
3. Enter the operator ID in the ID text box.
4. Choose a security level (operator/supervisor) from the LEVEL assist box.
5. Touch REGIST, followed by CLOSE to save the ID.

Note

Operator IDs can only be assigned by the supervisor.

4.8.2 Delete Operator ID

1. Only supervisors can delete operator IDs. Touch MAINT/UTILITY, followed by SYSTEM on the first sub menu level and OPERATOR ID, to display the OPERATOR ID window.
2. Touch the ID in the list box you want to delete.



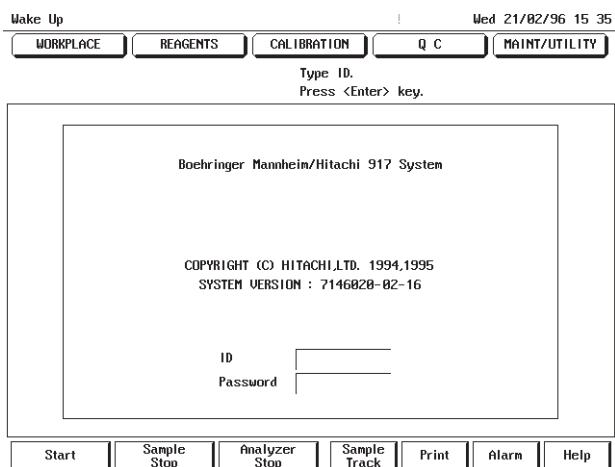
3. Touch DELETE, followed by YES to delete the operator ID.

Note

Operator IDs can only be deleted by the supervisor.

4.8.3 Password Registration

Each operator or supervisor password that is entered for the first time must be registered by the analyzer.



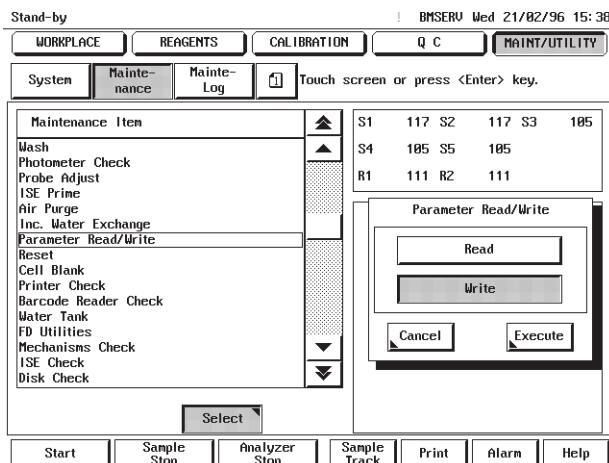
1. Enter your operator ID in the LOG ON screen. When you log on for the first time, enter your personal password. A row of asterisks (****) is displayed on the screen. Press ENTER to complete the registration.
2. If you have forgotten your password, the supervisor must delete the old ID and assign a new operator ID.

4.9 Disk Management

Use the following procedures to read and write application settings (parameters) and to format floppy disks.

4.9.1 Writing System Parameters (Application Settings) on a Floppy Disk

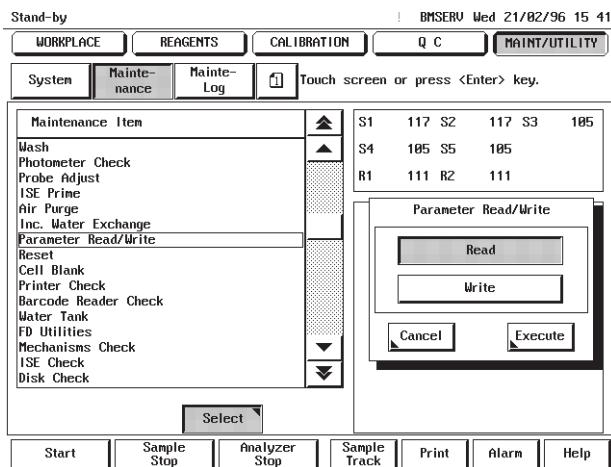
1. Use only formatted floppy disk to write the parameters on a disk. If the floppy disk is not formatted, use the option FD UTILITIES in the list in the MAINTENANCE sub menu.
2. Touch MAINT/UTILITY, followed by MAINTENANCE, to display the corresponding sub menu. Insert the floppy disk into the FD drive of the analyzer's computer. Touch PARAMETER READ/WRITE in the list box. Then, touch SELECT to display the PARAMETER READ/WRITE window.



3. Touch WRITE to write parameters on the floppy disk. Then touch EXECUTE, followed by YES, to perform the parameter write.

4.9.2 Reading System Parameters from a Floppy Disk

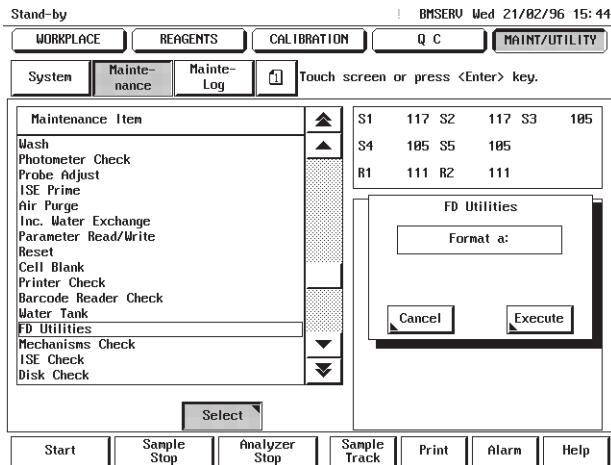
1. Insert the parameters floppy disk in drive a: of the analyzer.
2. Touch MAINT/UTILITY, followed by MAINTENANCE, to display the corresponding sub menu. Insert the floppy disk into the FD drive of the analyzer's computer. Touch PARAMETER READ/WRITE in the list box. Touch SELECT to display the PARAMETER READ/WRITE window.



3. Touch READ to read parameters from the floppy disk Then touch EXECUTE, followed by YES, to perform the parameter read.

4.9.3 Formatting a Floppy Disk

1. Touch MAINT/UTILITY followed by MAINTENANCE, to display the corresponding sub menu.
2. Touch FD UTILITIES in the list box. Touch SELECT to display the FD UTILITIES window.



3. Place the disk you want to format in drive a:.
4. Touch EXECUTE, followed by YES, to perform the formatting.

Note

Formatting a floppy disk deletes all data on the disk.

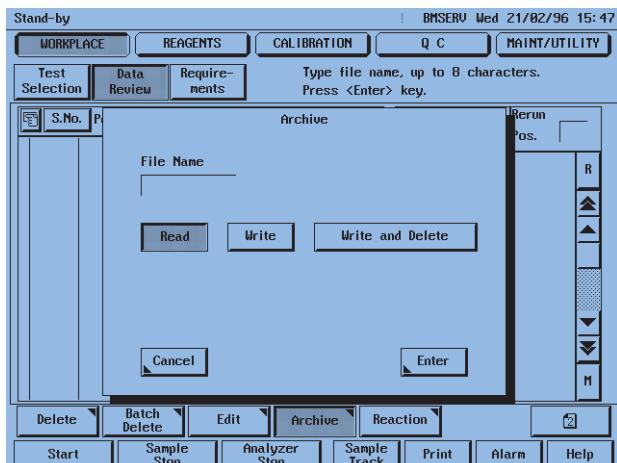
4.9.4 Archiving Data

Results of up to 500 patient samples can be stored on a floppy disk.

1. Touch WORKPLACE, followed by DATA REVIEW, to display the corresponding sub menu.
2. Select the samples to be archived.

The scrollbar on the right side of the sample list box has an R at the top and an M at the bottom. When R is highlighted, a consecutive range of samples may be archived by touching the first and last sample in the desired range. When M is highlighted, multiple, non-consecutive samples may be archived. If neither is highlighted, only one sample at a time may be archived.

3. Touch ARCHIVE on the second window level, to display the corresponding window.



4. Insert a formatted disk in the drive.
5. Enter the file name in the FILE NAME text box (up to 8 characters are permitted).
6. Touch WRITE to write the patient data on the floppy disk. Touch WRITE AND DELETE to write the data on the floppy disk and to delete the data from the hard disk afterwards.

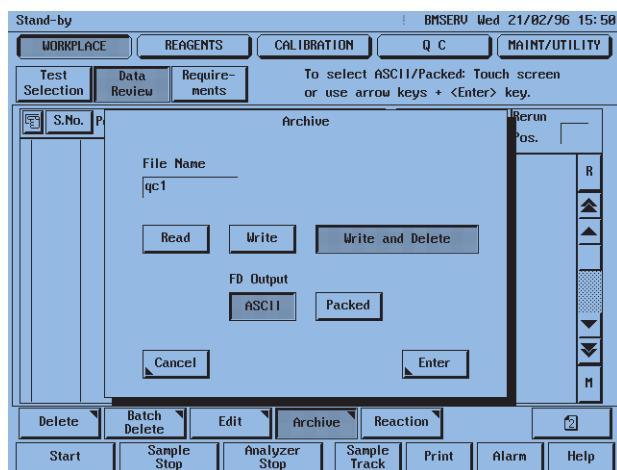
7. Touch the desired format.

You may choose to store the data in either ASCII or PACKED format. The ASCII format can be used by other PC programs, but cannot be restored on the analyzer. The PACKED format cannot be read by other computers, but can be restored on the analyzer.

8. Touch ENTER, followed by YES, to archive the data. Touch CANCEL to cancel the archive command.

4.9.5 Saving QC Data

If you select the option WRITE AND DELETE, a formatted floppy disk must be inserted in the analyzer's disk drive. The data are stored on the disk in ASCII format and are deleted from the analyzer hard disk afterwards.



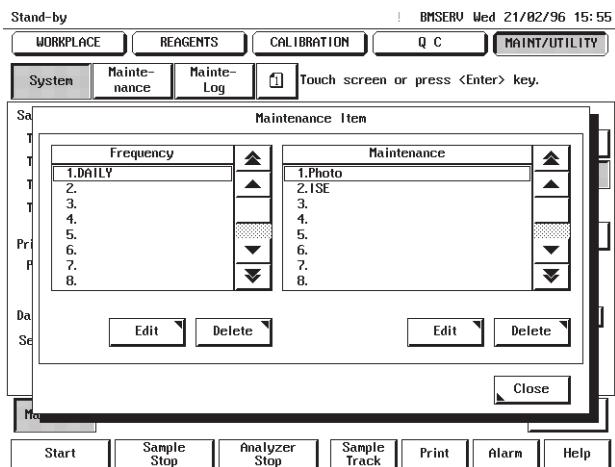
Refer to chapter 4.6.4, Deleting a Control, for further instructions.

4.10 Define Maintenance Frequency and Maintenance Item

Use the following procedure to set or edit the daily, weekly, monthly, and other maintenance frequencies and to define any special frequencies needed by your laboratory.

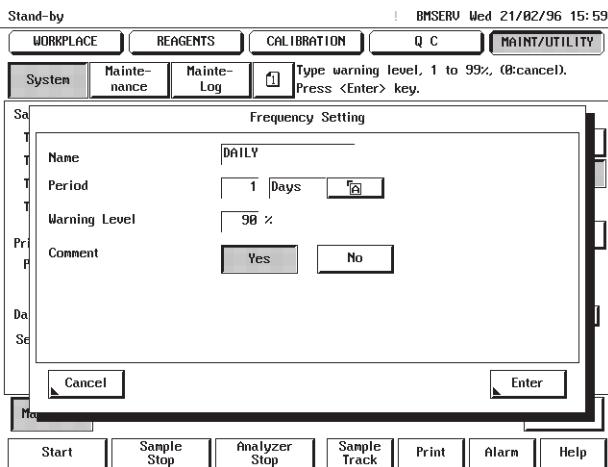
4.10.1 Defining the Maintenance Frequency

- 1 Touch MAINT/UTILITY and SYSTEM, to display the SYSTEM SETTING sub menu.
2. Touch the - 1 - button to call up the second window level. Then touch MAINT LOG to open the MAINTENANCE ITEM window.



3. Touch the next vacant number in the FREQUENCY list box on the left-hand side of the screen.
4. Press EDIT to call up the FREQUENCY SETTING window.

Define Maintenance Frequency and Maintenance Item



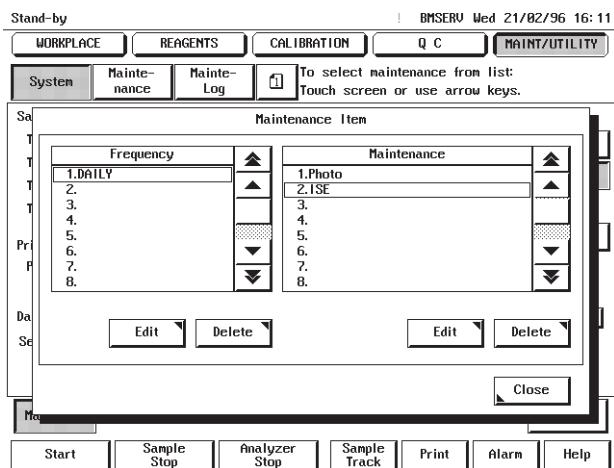
5. Enter the name of the frequency in the NAME text box, then press ENTER on the keyboard.
6. Enter the desired interval number in the PERIOD text box, then press ENTER on the keyboard.
7. Select the period interval (days, months) in the PERIOD assist box, then press ENTER on the keyboard.
8. Enter a percentage value in the WARNING LEVEL text box. If this percentage value is exceeded, the system issues a warning (Yellow question mark or red exclamation mark in the status line). Then press ENTER on the keyboard.
9. Touch YES to allow a COMMENT to be entered for this frequency's maintenance item in the MAINTE LOG sub menu and also to be printed out. Touch NO to deactivate the option.
10. Touch ENTER to save the entries and to close the window.

Note

If the warning level is reached, a yellow '?' appears in the status line. If the interval is elapsed, a red '!' appears in the status line. The maintenance item ought to be performed immediately.

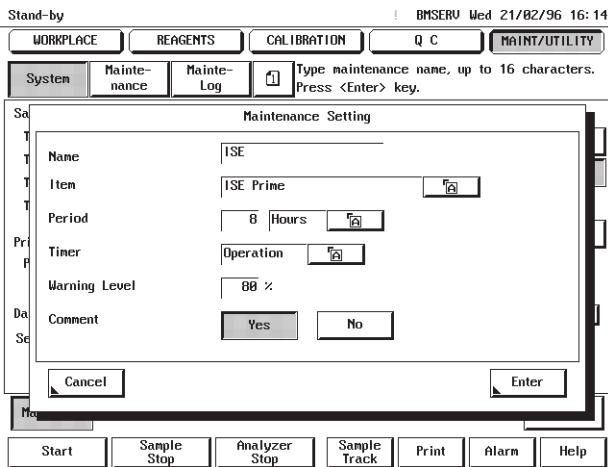
4.10.2 Defining the Maintenance Item

1. Touch MAINT/UTILITY, followed by SYSTEM, to display the SYSTEM SETTING sub menu.
2. Touch the - 1 - button to call up the second window level. Then touch MAINT LOG to open the MAINTENANCE ITEM window.



3. Touch the next vacant number in the MAINTENANCE list box on the right-hand side of the screen.
4. Press EDIT below the list box to call up the MAINTENANCE SETTING window.

Define Maintenance Frequency and Maintenance Item



5. Enter the name of the maintenance procedure in the name text box (e.g. photometer check), then press ENTER on the keyboard.
6. Select the item from the ITEM assist box (e.g. photometer check), then press ENTER on the keyboard.
7. Enter the number for the performance time in the PERIOD text box, then press ENTER on the keyboard.
8. Select the timer format in the TIMER assist box, then press ENTER on the keyboard, e.g. hour.
9. Enter a percentage value in the WARNING LEVEL text box. If this percentage value is exceeded, the system issues a warning (Yellow question mark or red exclamation mark in the status line). Then press ENTER on the keyboard.
10. Touch YES to allow a COMMENT to be entered for this frequency's maintenance item in the MAINTE LOG sub menu and also to be printed out. Touch NO to deactivate the option.
11. Touch ENTER to save the entries and to close the window.

Note

If the warning level is reached, a yellow '?' appears in the status line. If the interval is elapsed, a red '!' appears in the status line. The maintenance item ought to be performed immediately.

5. Printouts

5.1 MEASUREMENT DATA Printout

Dependent on the report format chosen in the START CONDITIONS global menu in the PRINT/HOST window, the measured data is either printed in the MONITOR or REPORT format. Additional information can be found in chapter 8.9.1.1 The PRINT MEASUREMENT DATA window in the volume System Description.

5.1.1 REPORT Format

Selection of the print mode is performed in the START CONDITIONS global menu in the PRINT/HOST window. The example shows a patient report printout in REPORT format, whose settings (e.g. page length) can be defined by yourself in the MAINT/UTILITY main menu, sub menu REPORT FORMAT. The reports that are to be printed out must be highlighted in the screen WORKPLACE, DATA REVIEW. In global menu PRINT, WORKPLACE, after selection of MEASUREMENT DATA, SELECT, REPORT, ALL and PRINT, the report will be printed out.

MEASUREMENT DATA Printout

One Report Per Page

Boehringer Mannheim GmbH BM/Hitachi 9 1 7					
[ID]	1234567	DATE	95/10/05 13:40		
[S.NO]	N00012 0-002	OPERATOR ID	Korokn		
[S.TYPE]	ser/pl	NAME	Jung		
[AGE]	35	WARD	intensive care		
[SEX]	11	OTHERS			
[DRAW DATE]	05/10/95	DRAW TIME	11:54		
[TEST]	[RESULT]	UNITS	EXPECTED VALUE	[REMARKS]	
Albumin	4.8	g/dl	(3.5- 5.0)		
GOT	25	U/l	(0- 37)		
Calcium	2.03 H	mmol/l	(2.15- 2.55)	LIMTH	

Boehringer Mannheim GmbH
BM/Hitachi 9 1 7 Example of a title header

- | | |
|--|---|
| [ID] Patient ID number, if available | [Operator ID] Operator ID of the user |
| [S.NO] Sample number | [NAME] Patient name |
| [S.TYPE] Sample type (e.g. serum/plasma) | [WARD] Ward, e.g. intensive care |
| [AGE] Patient's age | [OTHERS] Comment entry |
| [SEX] Patient's sex | [DRAW TIME] Request time, e.g. 11:54 |
| [DRAW DATE] Request date | [UNITS] Unit of the test result |
| [TEST] Test name | [EXPECTED VALUE] Reference range for the corresponding test |
| [RESULT] Test result | [REMARKS] Remarks, e.g. data alarms such as LIMTH. |

Two Reports Per Page

Selection of the report format is performed in the global menu START, PRINT/HOST menu. The example shows a report printout whose settings were made in the main menu MAINT/UTILITY, sub menu REPORT FORMAT. The page length in the following example is 66 lines. If two reports are to be printed out next to each other, it may occur due to limited space that not all the information appears on the report. In the following example, the reference values have not been printed out. Dependent on the paper format (66 lines per page, 72 characters per line) a maximum of 4 reports can be printed out next to each other. The reports that are to be printed out must be highlighted in menu WORKPLACE, DATA REVIEW. In global menu PRINT, WORKPLACE, after selection of MEASUREMENT DATA, SELECT, REPORT, ALL and PRINT, the report will be printed out. Using EDIT, only the edited data can be printed out. In addition to the information listed below, the title of the report (in this example Boehringer Mannheim) can be found at the top of the list.

Boehringer Mannheim GmbH BM/Hitachi 917	Boehringer Mannheim GmbH BM/Hitachi 917						
(95/10/05) (12:19) N00010 0-001 p Ser/Pl ID 1234567)	(95/10/05) 13:40 N00012 0-002 p Ser/Pl ID 7890123)						
TEST	RESULT	UNITS	REMARKS	TEST	RESULT	UNITS	REMARKS
Sodium	87	L mmol/l	LIMTL	Albumin	4.8	g/dl	
Potassium	4.9	H mmol/l		GOT	25	U/l	
Chloride	104	mmol/l		Calcium	2.83	H mmol/l	
				Creatinin	1.87	H mg/dl	
				Total Prot.	5.5	L g/dl	
				Magnesium	1.18	H mmol/l	
				Sodium	135	mmol/l	
				Potassium	5.2	H mmol/l	
				Chloride	111	H mmol/l	

(95/10/05) (12:19) Date and time of printout (Ser/Pl) Sample Type

(N00010 0-001 p) / (N00012 0-002 p) (TEST) Test name

Patient's sample number

(RESULT) Test result

(UNITS) Units of measure used

(REMARKS) Remarks, e.g. data alarms

(ID 7890123) (ID 7890123) Patient ID

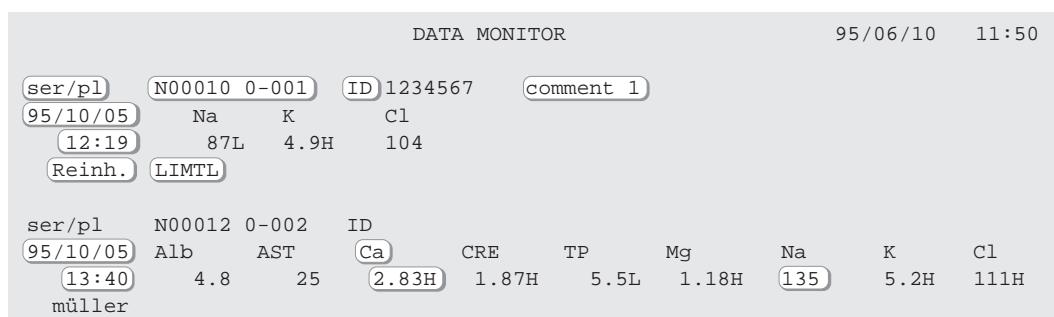
such as LIMTL.

numbers, if available.

MEASUREMENT DATA Printout

5.1.2 MONITOR Format

Selection of the monitor format is carried out in the START CONDITIONS global menu, PRINT/HOST window. The example shows a patient report printout in MONITOR format. The reports that are to be printed out must be highlighted in the WORKPLACE, DATA REVIEW screen. Then open the PRINT global menu and touch WORKPLACE, MEASUREMENT DATA, SELECT, MONITOR, ALL and PRINT IN in sequence. The report will be printed out. Using EDIT, only the edited data can be printed out. Additional information can be found in chapter 8.9.1.1 The PRINT MEASUREMENT DATA window in the volume System Description.



Ser/Pl Sample material

N00010 0-001 p Patient's sample number

ID Sample barcode, if available

Reinh. Example of the user's operator ID

LIMTL Data alarm

95/06/10 Draw date

Ca Test name

12:19 Draw time

2.83H H oder L indicates a result that is
outside the reference range.

135 Test result

comment 1 comment 1, as entered in
the DEMOGRAPHICS window (WORKPLACE
main menu)

5.2 REACTION MONITOR Printout

The reaction monitor of a test can be printed out as absorbances from primary and secondary wavelengths as well as from primary minus secondary wavelengths.

The absorbances are printed as $E \times 10^4$. The absorbance of the cell blank measurement has already been subtracted from absorbances of the measurement points. In addition to the information listed below, the date and time of the printout can be found in the header of the list. Further information about this procedure can be found in chapter 8.9.1.2 The PRINT REACTION MONITOR window in the volume System Description.

Reaction monitor for PRIMARY and SECONDARY WAVELENGTHS

The report of the reaction monitor shows all the measured absorbances of the primary (PRIMARY) and the secondary (SECONDARY) wavelengths. The tests that are to be printed out must be highlighted in menu WORKPLACE, DATA REVIEW. In global menu PRINT, WORKPLACE, after selection of REACTION MONITOR, SELECT, PRIMARY,2, PRINT, the report will be printed out.

REACTION MONITOR					95/10/19	11:13
Ser/Pl	N00001 1-001	CELL	016	(Ca)	2.38)
ID	100182					
*** [PRIMARY] ***						
CB1-4	1- 5	6-10	11-15	16-20		
		218	3697	3235	3222	
10511	324	3384	3225	3218		
*** [SECONDARY] ***						
CB1-4	1- 5	6-10	11-15	16-20		
		127	325	61	63	
9896	236	107	59	59		

Ser/Pl Sample type

N00001 1-001 Example of a sequence number

ID Sample barcode, e.g. 100182

CELL Reaction cell number, e.g. 016

Ca Test name and test result, e.g. 2.38

CB1-4 Reaction cell blank value 1-4,

6-10 Measurement points 6-10

e.g. 9896. In case of a rate assay only the stopped cell blank is printed; for endpoint assays, all three cell blanks are printed.

59 Example of an absorbance

PRIMARY Absorbance $\times 10^4$ of primary wavelength-cell blank

SECONDARY Absorbance $\times 10^4$ of secondary wavelength-cell blank

REACTION MONITOR Printout

Reaction monitor for PRIMARY minus SECONDARY WAVELENGTH

The reaction monitor report shows all the calculated absorbances from primary minus secondary wavelength. CV 1-4 (or CB1) are the measured reaction cell blank values. The tests that are to be printed out must be highlighted in menu WORKPLACE, DATA REVIEW. In global menu PRINT, WORKPLACE, after selection of REACTION MONITOR, SELECT, PRIMARY-2, PRINT, the report will be printed out.

REAKTION MONITOR					95/10/05	11:13
Ser/Pl	N00001 1-001	CELL	016	(Ca)	2.38)
ID 100182						
*** PRIMARY - SECONDARY ***						
CB1-4	1- 5	6-10	(11-15)	16-20		
	91	3372	3174	3159		
615	88	3277	3166	3159		
	98	3227	3165			
	97	3198	3163			
	97	3181	3160			

Ser/Pl Sample type

N00001 1-001 Example of a sequence

number

CELL Reaction cell number, e.g. 016

Ca Test name and test result, e.g. 2.38

ID Sample barcode, e.g. 100182

PRIMARY - SECONDARY Cell blank corrected absorbance of primary minus secondary wavelength

CB1-4 Reaction cell blank value 1 to 4 of primary minus secondary wavelength, e.g. 615. In case of a rate assay only the stopped cell blank is printed; for endpoint assays, all three cell blanks are printed.

11-15 Measurement points 11 to 15

3159 Example of an absorbance

5.3 REQUISITION LIST Printout

Both the following examples illustrate a requisition list for sample with and without barcodes.

5.3.1 Requisition List Without Sample Barcode

Example of a requisition list without sample barcodes. The scope of the report is chosen in the PRINT global menu under WORKPLACE and REQUISITION LIST. In the SELECT window, the first and last sample to be printed is entered. PRINT starts the report printout. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.1.3 The PRINT REQUISITION LIST window in the volume System Description.

REQUISITION LIST										95/10/05	11:56	
S.NO.	ID	S.TYP	S.CUP	NAME								
N00012		Ser/Pl	Standard	Koroknay								
	- Alb	AST	Ca	CRE	ISE	Mg	TP					
N00013		Ser/Pl	Standard									
	+ Alb	AP	AST	Ca	CRE	Hst	ISE	Mg	S.IND	TP		
N00022		Ser/Pl	Standard									
	Alb	AP	AST	Ca	CRE	Hst	ISE	Mg	S.IND	TP		
TEST COUNT												
	TEST	COUNT										
	Alb	3										
	AP	2										
	AST	3										

S.NO Sample number, sequence number

ID Sample ID, if available

S.TYP Sample type, e.g. serum/plasma

NAME Patient's name, if available

S.CUP Sample cup, e.g. Standard

- Alb + Alb Example of a requisition with decreased (-) or increased (+) sample volume

ISE Example of a requested test
requested

TEST Total number of test requisitions

REQUISITION LIST Printout

5.3.2 Requisition List With Sample Barcode

Example of a requisition list with sample barcodes. The scope of the report is chosen in the PRINT global menu under WORKPLACE and REQUISITION LIST. In the SELECT window, enter the first sample position number and and the total number of samples and press PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.1.3 The PRINT REQUISITION LIST window in the volume System Description.

REQUISITION LIST				95/10/05	11:33
ID	S.TYPE	S.CUP	NAME		
100182	Ser/Pl	Standard	Koroknay		
Alb	AST	CRE	ISE	TP	
100181	Ser/Pl	Standard	Hirn		
-Ca	CRE	Mg	TP		
100183	Ser/Pl	Standard	Reinhardt		
Ca	+CRE	ISE	Mg	S.IND	TP

TEST COUNT	
TEST	COUNT
Alb	1
AP	0
AST	1
Ca	2
CRE	3
Hst	0
ISE	2
Mg	2
S.IND	1
TP	3

[ID] Sample ID, if available

[S.TYPE] Sample type, e.g. serum/plasma

[S.CUP] Sample cup, e.g. Standard

[NAME] Patient's name, if available

[ISE] Example of a requested test

[-Ca] [+CRE] Example of a requisition with decreased (-) or increased (+) sample volume

[TEST] Test name

[COUNT] Total number of test requisitions

5.4 RERUN LIST Printout

The following example illustrates rerun lists with and without sample barcodes. In addition to the information listed below, the date and time of the printout can be found in the corresponding list header. Additional information can be found in chapter 8.9.1.4 The PRINT RERUN LIST window in the volume System Description.

Rerun list without sample barcode

Example of a rerun list without sample barcodes. The scope of the list must be highlighted beforehand in the menu WORKPLACE, DATA REVIEW. In the PRINT global menu, the printout is started by touching WORKPLACE, RERUN LIST, SELECT and PRINT.

RERUN LIST					95/10/05	12:14
S.NO.	Pos	ID	S.TYPE	S.CUP	NAME	
R00001	0-001	100182	Ser/Pl	Standard	Koroknay	
	ISE					
R00003	0-003	100183	Ser/Pl	Standard	Reinhardt	
	CRE(V)	(ISE(VVV))	Mg	TP(V)		
R00004	0-004	100181	Ser/Pl	Standard	Hirn	
	CRE(V)	Mg		TP(V)		
TEST COUNT						
[TEST]	[COUNT]					
Alb	0					
AP	0					
AST	0					
Ca	0					
CRE	2					
Hst	0					
ISE	2					
Mg	2					
TP	2					

S.NO Sample number, sequence number

POS Position number

ID Sample ID, if available

S.TYPE Sample type, e.g. serum/plasma

S.CUP Sample cup, e.g. Standard

NAME Patient's name, if available

(ISE(VVV)) Example of a requested test with
a previously occurring data alarm code "V"
(sample short)

TEST Test name

COUNT Total number of test requisitions

RERUN LIST Printout

Rerun list with sample barcodes

Example of a rerun list without sample barcodes. The scope of the list must be highlighted beforehand in the menu WORKPLACE, DATA REVIEW. In the global menu PRINT, WORK-RERUN LIST, SELECT and PRINT, the report printout is started.

RERUN LIST				95/10/05	11:33
ID	S.TYPE	S.CUP	NAME		
100182	Ser/Pl	Standard	Koroknay		
Alb	AST	CRE	ISE	TP	
100181	Ser/Pl	Standard	Hirn		
(Ca)	CRE	Mg	TP		
100183	Ser/Pl	Standard	Reinhardt		
Ca	CRE	ISE	Mg	S.IND	TP
TEST COUNT					
TEST	COUNT				
Alb	1				
AP	0				
AST	1				
Ca	2				
CRE	3				
Hst	0				
ISE	2				
Mg	2				
S.IND	1				
TP	3				

ID Sample ID, if available

S.TYPE Sample type, e.g. serum/plasma

Example: **100182**

S.CUP Sample cup, e.g. Standard

NAME Patient's name, if available

Ca **CRE** Example of a test name

TEST Test name

COUNT Total number of test requisitions

5.5 PRECISION CHECK Printout

Example of a precision check. The required data for calculation, must be highlighted beforehand in WORKPLACE, DATA REVIEW. In the PRINT global menu, the report printout is started by pressing WORKPLACE, PRECISION CHECK, SELECT and PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.1.5 The PRINT PRECISION CHECK window in the volume System Description.

PRECISION CHECK									95/10/05	13:44
TEST	N	MEAN	UNIT	RANGE	MAX.	MIN.	SD	CV (%)		
Ca	9	2.682	mmol/l	0.05	2.71	2.66	0.016	0.60		
Cl	9	104.7	mmol/l	4	107	103	1.1	1.05		
CRE	9	1.208	mg/dl	0.02	1.21	1.19	0.007	0.58		
K	9	4.92	mmol/l	0.1	5.0	4.9	0.04	0.81		
Mg	9	1.131	mmol/l	0.02	1.14	1.12	0.008	0.71		
TP	9	5.18	g/dl	0.1	5.2	5.1	0.04	0.77		

TEST Test name

N Number of measurements

MEAN Mean value

UNIT Unit of test result

RANGE Deviation (Max.-Min.)

MAX. Maximum value

MIN. Minimum value

SD Standard deviation

CV (%) Coefficient of variation

Note

Results with data flags are not considered in the precision calculation.

5.6 PROFILING LIST Printout

The following example illustrates a selection of defined profiles. In the column KEY PROFILE, the defined profiles are displayed. The asterisk (*) before the ALL profile name means that this profile has been chosen as a default profile. Each scanned sample without requisitions will be measured using this profile. The profile assignment is performed separately in the WORKPLACE, TEST SELECTION, KEY SETTING screen. The default profiles for Routine and STAT are assigned in the START CONDITIONS global menu, in the DEFAULT PROFILE window. To start the report printout, open the PRINT global menu and touch WORKPLACE, PROFILING LIST, SELECT and PRINT in sequence. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.1.6 The PRINT PROFILING LIST window in the volume System Description.

PROFILING LIST					95/10/05	14:10
[KEY PROFILE]	1	11	21	31	41	
	51	61	71	81		
(*) 1 ALL Ser/Pl	*****	-	-	-	-	**
2 ALL Urine	-*****-	-	-	-	-	-
3 LIVER Ser/Pl	-*-	-	-	-	-	-
[STAT PROFILE]						
Ser/Pl	-*-	-	-	-	-	-
(CH) TEST NAME	CH.TEST NAME	CH.TEST NAME	CH.TEST NAME			
1 Alb	ISE	45	67			
2 AST	S.Ind	46	68			
3 Ca	25	47	69			
4 CRE	26	48	70			
5 TP	27	49	71			
6 MG	28	50	72			
7 AP	29	51	73			

(*) Default profile for routine samples

(1) Profile number

(ALL) Example of a profile name

(Ser/Pl) Example of a sample type

(21) Example of a method number

(CH) Test number

(TEST NAME) Test name, e.g. Ca

5.7 SYSTEM REQUIREMENTS Printout

The list shows the needs of the actual system requirements. Messages for reagents, calibration and controls are displayed here. Reagent: if the missing reagents are replaced, the messages disappear. Calibrator and controls: if the corresponding calibration is successfully repeated, the appropriate message disappears. In the PRINT global menu, the report printout is started after touching WORKPLACE, SYSTEM REQUIREMENTS, SELECT and PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.1.7 The PRINT SYSTEM REQUIREMENTS window in the volume System Description.

SYSTEM REQUIREMENTS					95/10/05	16:36		
==== [REAGENT] =====								
TEST	TYP	POS.	LOT	REASON	REMAIN			
AP	R1			Not active				
	R3			Not active				
WASH	1D2			< 5ml)		1ml		
	2D2			<10ml		5ml		
Ca	R2	2-18	652499	< 200 daily requirement short	50			
==== [CALIBRATOR] ===								
NAME	POS.	LOT	REASON					
NACL	1(O)	18689700	no calib. material					
==== QC ===		NAME	POS.	LOT	REASON			
		PNU	2- 6(O)	18523200	QC error			
		PPU	2- 7(O)	18525900	QC error			

[REAGENT] [CALIBRATOR] [QC]

Material type

[TEST] Test name

[TYP] Reagent type, e.g. R1

[POS.] Disk position number (Reagent disk

[LOT] relevant lot

or sample disk 2)

[REASON] Message reason, e.g. volume

[REMAIN] remaining reagent volume in units

< 5 ml

of ml or number of tests; example:: 50

REAGENT STATUS Printout

5.8 REAGENT STATUS Printout

The following example illustrates a reagent status list. To start the report printout, select REAGENT STATUS, in the PRINT global menu followed by REAGENT and then SELECT. In the window that is now open select PRINT. In addition to the information listed below, the title, date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.2.1 The PRINT REAGENT STATUS window in the volume System Description.

REAGENT STATUS								95/10/13	17:07	
TEST	TYPE	POS.	TESTS	LOT	BOTTLE	EXP. Month	STAB.			
Ca	R1	1 40	210	651307	315	96/ 1	80			
	R1	2*29	230	651307	315	96/ 1	90			
	R2	2 18	50	652499	315	96/ 1	40			
CRE	DIL	1 14	58 ml	653228	951	97/ 3	0*			
	R1	1 37	250	651836	420	97/ 1	19			
	R3	2 13	70	651774	420	97/ 1	19			
Alb	DIL	1 14	58 ml	653228	951	97/ 3	0*			
	R1	1 42	110	654052	042	97/ 1	24			
	Mg	DIL	1 14	58 ml	653228	951	97/ 3			
AST		R1	1 33!	220	652840	693	96/ 5			
		R3	2 32	230	651063	693	96/ 5			
		R1	1 27*	260	655652	253	96/10			
TP	R2	2 10	260	655865	253	96/11	69			
	R1	1 10	550	651252	756	96/ 7	19			
	R2	2 16	600	651253	756	96/ 7	19			
AP	DIL	1 14	58 ml	653228	951	97/ 3	0*			
	R1									
	R3									
Hst	R1									
	R2									
	?????		2 15							
ISE	IS			111 ml						
	DIL			353 ml						
	Kcl			138 ml						
WASH S.	1D1			60 ml						
	2D1			59 ml						

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TEST	Test name	TYPE	Reagent type, e.g. R1; DIL stands for diluent (sample diluent)
POS.	Disk number and position	TESTS	Number of available tests, rounded down); diluent in ml
LOT	Lot number	BOTTLE	Application number
EXP. Month	Expiration year and month	STAB.	Stability on board in days
2*29	Reagent in incorrect disk	1_33!	Manually loaded reagent
1_27*	Reagent loaded twice (barcoded and manually)	?????	Barcode was recognized, corresponding application not available, thus no assignment possible
ISE	WASH S.	ISE and rinse solution in ml, e.g. 353 ml	

5.9 CALIBRATION MONITOR Printout

The calibration report is setup in the start conditions (START, PRINT/HOST window, Real Time Calib. Print, PRINT or NO PRINT). If the printout is selected, it is printed out after each measured calibration. If the printout is not to be performed during the routine, it can be started also after the current routine run. In the global menu PRINT, CALIBRATION, CALIBRATION MONITOR, SELECT and PRINT, the report printout is started. In addition to the information listed below, the title, date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.3.1 The PRINT CALIBRATION MONITOR window in the volume System Description.

5.9.1 CALIBRATION MONITOR Photometry

When a blank value or Std.low is measured, the absorbance details appear in the --S1-- column. If a 2-point calibration is measured, the absorbance values ($E \times 10^4$) appear in the --S1-- and --S2-- columns. For non-linear calibration, the absorbances are printed in the corresponding columns according to the number of calibrators. The calibration absorbances are calculated from the mean of the duplicate determination.

CALIBRATION MONITOR							95/10/13	14:07
TEST	----S1----	----S2----	----S3----	----S4----	----S5----	----S6----		
Mg	14878	22243	9040	18882				
	14903	22288	9097	18900				
CRE	3	317	18	961				
	-1	306	14	944				
Ca	1867	1902	3232	3369				
	1863	1900	3225	3359				
AST	-3	13697	-361	15251				
	-6	14785	-363	15337				
Alb	1236	1321	6531	7109				
	1234	1320	6550	7134				
SENS	(1)	(2)	(1)	(2)				

05/10/95 13:49 Date and time of

the printout

Koroknay Example of an operator ID

TEST Test name

SENS Example of a data alarm

① Absorbances from primary minus secondary wavelength

② Absorbances' from primary wavelength

Mg	14878	22243	9040	18882
	14903	22288	9097	18900

Example of an end-point measurement. 1st. line is the 1st. measurement of the duplicate determination. 2nd. line is the 2nd. measurement of the duplicate determination. The number in each of the first columns (e.g. 14878 and 9040) is always the end absorbance from primary minus secondary wavelength. The number in each of the second columns (e.g. 22243 and 18882) is always the absorbance of the primary wavelength.

CALIBRATION MONITOR Printout

AST	-3	13697	-361	15251
	-6	14785	-363	15337

Example of a rate reaction. 1st. line is the 1st. measurement of the duplicate determination. 2nd. line is the 2nd. measurement of the duplicate determination. The number in first column (e.g. -3 and -361) is the rate $\Delta E/\text{min.}$ for primary minus secondary wavelength. The number in the second column (e.g. 13697 and 15251) is the absorbance of the first measurement point for the primary wavelength of a rate assay.

Note

Calculation: Chapter 5. Theory Principles and chapter 6. Calibration in the volume System Description.

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■ Interpretation for calibration monitor

ENDPOINT, mp₁

S1

Bichromatic
ABS at mp₁

Monochromatic
ABS at mp₁

S2

Bichromatic
ABS at mp₁

Monochromatic
ABS at mp₁

ENDPOINT mp₁ → mp₂ (sample blanked)

S1

Bichromatic
ABS at mp₂ - d ·
bichromatic ABS
at mp₁

Monochromatic
ABS at mp₂

S2

Bichromatic
ABS at mp₂ - d ·
bichromatic ABS
at mp₁

RATE A, mp₁ → mp₂

S1

Bichromatic
 Δ ABS/min at
mp₁ → mp₂

Monochromatic
ABS at mp₁

RATE B, Mode 1 - Test A

S1

Bichromatic
 Δ ABS/min at
mp₁ → mp₂

Monochromatic
ABS at mp₁

RATE B, Mode 1 -Test B (Test B wavelenghts ≠ Test A wavelengths)

S1

Bichromatic
 Δ ABS/min at
mp₃ → mp₄

Monochromatic
ABS at mp₃

RATE B, Mode 1 - Test B (Test B wavelengths = Test A wavelengths)

— S1 —

Bichromatic	Monochromatic
$\Delta\text{ABS}/\text{min}$ at	ABS at mp_3
$\text{mp}_3 \rightarrow \text{mp}_4$ -	
d · bichromatic	
$\Delta\text{ABS}/\text{min}$ at	
$\text{mp}_1 \rightarrow \text{mp}_2$	

RATE B, Mode 2 - Test A

— S1 —

Bichromatic	Monochromatic
$\Delta\text{ABS}/\text{min}$ at	ABS at mp_1
$\text{mp}_1 \rightarrow \text{mp}_2$	

RATE B, Mode 1 - Test B (Test B wavelengths = or \neq Test A wavelengths)

— S1 —

Bichromatic	Monochromatic
$\Delta\text{ABS}/\text{min}$ at	ABS at mp_5
$\text{mp}_5 \rightarrow \text{mp}_6$ -	
d · bichromatic	
$\Delta\text{ABS}/\text{min}$ at	
$\text{mp}_3 \rightarrow \text{mp}_4$	

Legende

S1 = Standard 1

S2 = Standard 2

mp_1 = Photometric measurement point 1

.

.

.

.

mp_6 = Photometric measurement point 2

d = correction factor of liquid volume

Monochromatic ABS = Absorbance for primary wavelength

Bichromatic ABS = Absorbance of primary minus secondary wavelength

5.9.2 CALIBRATION MONITOR ISE

If a calibration with compensator (STD 3) is requested, the following values are printed out: S3 EMF, S3 CON. and C.VALUE. If a 2-point calibration is requested, the values IS EMF, S1 EMF, S2 EMF, SLOPE and IS.CONC. are printed out. The following is an example using a full calibration

CALIBRATION MONITOR									95/10/05	14:07
95/10/05 13:49	Hirn	TEST	IS EMF	S1 EMF	S2 EMF	S3 EMF	SLOPE	IS .CONC.	S3 CONC.	C. VALUE
Na		-32.2		-35.9	-28.8	-33.7	56.8	140	131.8	-1.8
K		-32.3		-45.2	-24.1	-34.9	57.3	5.0	4.51	-0.09
Cl		123.5		126.3	118.5	123.6	-44.3	93	92.3	1.7

95/10/05 13:49 Calibration date and time Hirn Example of an operator ID

TEST Test name

IS EMF Electromotive force (in mV) for Internal Standard, must lie between S1 EMF and S2 EMF

S2 EMF Electromotive force (in mV) for standard high

SLOPE Slope of the electrode in millivolts. The results must lie within the following ranges:

Na = 50 to 68, K = 50 to 68,
Cl = -68 to -40

S3 CONC. Calculated compensator concentration

S3 EMF Electromotive force (in mV) for compensator (STD 3)

IS .CONC.) Calculated Internal Standard concentration in mmol/L. The results must be as follows:

Na = 140 ± 10, K = 5 ± 1,
Cl = 100 ± 10.

C. VALUE Target value minus measured compensator concentration

Note

The EMF results must be within the defined ranges:

Na: -90 mV to -10 mV

K: -90 mV to -10 mV

Cl: 80 mV to 160 mV

5.10 REACTION MONITOR Printout

The following example shows the report printout of a reaction monitor. Highlight, before printing, the required test in the main menu CALIBRATION, sub menu STATUS. To start the printout, press the option REACTION MONITOR in the global menu PRINT, print menu CALIBRATION. Select the required print scope of the calibrators and their individual measurements in the window that is now open. The absorbances are printed in E x 10⁴. Select SELECT, PRIMARY,2ND or PRIMARY-2ND and then PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.1.2 The PRINT REACTION MONITOR window in the volume System Description.

5.10.1 The Primary and Secondary Wavelengths Option

When the option PRIMARY,2ND is selected in the REACTION MONITOR window, the absorbances of the primary and secondary wavelengths are printed out. PRINT closes the window and starts the printout.

REACTION MONITOR					95/10/13	17:58
(S21)	CELL 081	(AST)	(-341))		
LOT. 18718600						
*** (PRIMARY) ***						
CB1-4 1- 5 6-10 11-15 16-20						
	16479	15756	15259	14761		
12818	396	15668	15165	14668		
10042	348	15566	15053			
10390	1853	15464	14956			
10739	16298	15356	14851			
*** (SECONDARY) ***						
(CB1-4) 1- 5 (6-10) 11-15 16-20						
	259	182	194	192		
9872	335	188	199	193		
9872	327	189	(194)			
10159	984	194	194			
10644	219	193	193			

(S21) Calibrator (Standard) number:

(CELL 081) Reaction cell number, e.g. 081

Standard 2, measurement 1

(AST) Test name

(-341) Example of a measured test result
(for Standard Absorbance)

LOT. 18718600 Lot number

(CB1-4) Reaction cell blank value 1-4

(6-10) Measurement points 6-10

(194) example of an absorbance $\times 10^4$

(PRIMARY) Absorbance $\times 10^4$ of the
primary wavelength minus cell blank

(SECONDARY) Absorbance $\times 10^4$ of the
secondary wavelength minus cell blank

REACTION MONITOR Printout

5.10.2 The Primary Minus Secondary Wavelength Option

If the absorbances from the primary minus secondary wavelength are to be printed out, then the option PRIMARY-2ND, in the REACTION MONITOR window, must be chosen. PRINT closes the window and starts the printout

REACTION MONITOR					95/10/13	17:57
(S21)	(CELL 081)	(AST)	(-341))		
(LOT 18718600)						
*** (PRIMARY- SECONDARY) ***						
CB1-4	1- 5	6-10	(11-15)	16-20		
	16220	15574	15065	14569		
2946	61	15480	14966	(14475)		
170	21	15377	14859			
231	869	15270	14762			
95	16079	15163	14658			

(S21) Standard number: Standard 2,
measurement 1

(AST) Test name

(LOT 18718600) Lot number

(11-15) Measurement points 11-15

(CELL 081) Reaction cell number, e.g. 081

(-341) Measured test result (for Standard
Absorbance)

(PRIMARY- SECONDARY) absorbance from pri-
mary minus secondary wavelength

(14475) Example for an absorbance x 10⁴

5.11 CALIBRATION LOAD LIST Printout

The following example shows the report printout of a calibrator load list. To start the printout, press the options CALIBRATION, CALIB LOAD LIST and SELECT in the PRINT global menu. Choose the desired calibration type in the window that is now open (START UP, RE CALIB or TIMEOUT). A combination of TIMEOUT and START UP or RE CALIB can also be chosen. Enter, in the TIMEOUT field, the desired calibration period in hours and confirm by pressing ENTER on the keyboard. Then select PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.3.3 The PRINT CALIBRATOR LOAD LIST window in the volume System Description.

Note

Automatically blocked tests (reagent missing) are highlighted with a *. Masked tests (manually blocked) are not highlighted.

CALIBRATION LOAD LIST										95/07/25 11:51	
[Start up]		POS.NO.		NAME		LOT		TEST NAME			
1(O)	NACL	18689700	Alb	*AP	AST	Ca	CRE	*Hst	Mg	TP	
2(O)	CFAS	18718600	Alb	*AP	AST	Ca	CRE	*Hst	Mg	TP	
3(O)	ISE LOW		ISE								
4(O)	ISE HIGH		ISE								
5(O)	ISE COMP	189653	ISE								

[Start up] Chosen calibration type

POS.NO. Calibrator position on the sample disk 2. Example: 1 (O), indicates the outer ring. 36 (I) indicates the inner ring.

NAME Calibrator name

LOT Lot number of the calibrator

AST Test name

*AP Blocked test

1(O) Example of a sample on the outer ring. 36 (I) would be a sample on the inner ring.

5.12 CALIBRATION TRACE Printout

The following example shows a report printout of a calibration trace. In the main menu CALIBRATION, sub menu STATUS, CALIBRATION TRACE window, the last 50 calibrations graphically displayed for the test marked in the list. To start the printout. select the option CALIBRATION TRACE in the global menu PRINT, print menu CALIBRATION. Then select SELECT and PRINT. The entered comments in the CALIBRATION TRACE window are also printed out. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.3.3 The CALIBRATION TRACE window in the volume System Description

5.12.1 CALIBRATION TRACE Photometry, Rate

In this list, the data of the calibration report are printed out collectively. The absorbances of the blank values resp. standard 1 are printed out as primary wavelength. The standard 2-6 absorbances are printed out as primary minus secondary wavelength. The error codes next to the absorbances from standard 1 and 2-6 identify the type of error. The mean values of the duplicate determination are printed out for the calibration measurement.

CALIBRATION TRACE							95/01/26	10:18	
AST		DATE TIME	OP. ID	RESULT STD.LOT	RESULT STD.LOT.	LOT BOTTLE	LOT	BOTTLE	
						----(Std 1)-----	---(Std 2-6)---	-----R1-----	-----R3-----
								-----R2-----	-----R4-----
28/09	10:10	Korokn	14088B	18689700	362	18718600	655652	03771	
							655865	02550	
05/10	12:10	Reinh	13729	18689700	361	18718600	655652	03771	
							655865	02550	
09/10	14:17	Korokn	13528	18689700	-----	-----	655652	03771	
							655865	02550	
19/10	15:45	Reinh	13604	18689700	-341	18718600	655652	03771	
							655865	02550	

AST Test name

DATE TIME Date and time of settings

OP. ID Operator identification, e.g. Korokn

LOT BOTTLE Lot and bottle number of

RESULT STD.LOT Result and standard lot

the reagents. Example:

for Std1 or Std2 to 6. Example:

655865 Lot number of reagent 1 to 4.

----- Calibration was performed without
this standard

13604 = Initial absorbance for a rate
measurement (primary wavelength)

02550 Bottle number of reagent 1 to 4.

14088B "B" indicates a "Calib." data

-341 = ΔE/min. for rate measurement
(primary minus secondary wavelength).

alarm that has occurred for this calibration
(see table on page 29).

CALIBRATION TRACE Printout

Most Frequent Error Codes for Photometric Tests		Error Codes for ISE Tests	
Letter in the printout	Data Alarm	Letter in the printout	Data Alarm
S	Std?	N	Noise
Y	Sens	L	Level
B	Calib	E	Slope?
G	SD !	R	Margin
X	???	D	I.Std
		X	???

5.12.2 CALIBRATION TRACE Photometry, Endpoint

In this list, the data of the calibration report are printed out collectively. The absorbances of the blank values resp. standard 1 and the standards 2 to 6 are printed out as primary minus secondary wavelength. The error codes next to the absorbances from standard 1 and 2 identify the type of error.

CALIBRATION TRACE						95/10/20	10:31
TP	DATE	TIME	OP. ID	RESULT STD.LOT	RESULT STD.LOT	LOT BOTTLE	LOT BOTTLE
				----(Std 1)----	---(Std 2-6)---	-----R1-----	-----R3-----
						-----R2-----	-----R4-----
04/07	11:38	Reinh	(-977B)	123456	268B 178956	651252 00559	
						651253 01545	
04/07	13:25	Reinh	-807	123456	(238) 178956	651252 00559	
						651253 01545	
04/07	14:18	Reinh	-898	123456	273 178956	651252 00559	
						651253 01545	
19/10	15:45	Reinh	-1115	18689700	593 18718600	651252 00588	
						651252 02602	
19/10	16:10	Reinh	-1117	18689700	590 18718600	651252 00588	
						651253 02602	
19/10	16:22	Reinh	(-1116)	18689700	594 18718600	651252 00588	
						(651253) 02602	
COMMENT							
Please consider the error codes							

TP Method name

DATE TIME Date and time of settings

OP. ID Operator identification, e.g. Reinh

RESULT STD.LOT Result and lot number

LOT BOTTLE Lot and bottle number of

for Std1 or Std2 to 6. Example: (238)

the reagents R1-R4. Example:

End absorbance of the Standard for
primary minus secondary wave-
length (-1116)

(651253) lot number of reagent 1.

(02602) bottle number of reagent 1.

(-977B) "B" indicates a "Calib." data alarm
that has occurred for this calibration
(see table on page 29).

Please consider the error codes

Comment that has been entered in
CALIBRATION TRACE window

CALIBRATION TRACE Printout

5.12.3 CALIBRATION TRACE ISE

The compensator concentrations are printed out in the --(STD 3 CONC.)-- column. If a compensator has not been measured, ---- is printed out. The SLOPE column displays the measured slope. The error codes identify the type of error.

CALIBRATION TRACE				95/10/05 10:25				
[Na]	DATE	TIME	OP.ID	RESULT	CALIB.LOT	RESULT	HIGH LOT	LOW LOT
				--(Std 3 CONC.)--			-----	(SLOPE)-----
	04/07	11:37	Jung	131.0		55.2		
	04/07	13:23	Jung	131.0		54.4		
	04/07	14:16	Jung	130.0		55.2		
	21/07	14:19	Jung	-----	-----	56.8		
	24/07	10:31	Jung	127.0		53.6		
	24/07	14:24	Jung	127.0		56.0		
	24/07	14:35	Jung	128.0		55.2		
	25/07	12:02	Jung	127.0		55.2		
	28/07	08:58	Reinh	131.0	45.6R			
	28/07	12:02	Reinh	126.0	50.4			
	07/08	11:54	Korokn	-----	-----	-5.6E		
	07/08	11:58	Hirn	124.0		12.0E		
	07/08	12:14	Korokn	-----	-----	67.2E		
	07/08	12:19	Reinh	14.0B		6.4E		

[Na] Method name

[DATE TIME] Date and time of the settings

[OP.ID] Operator ID

[SLOPE] Slope

[Std 3 CONC.] Compensator
concentration, e.g. [124.0] in mmol/L

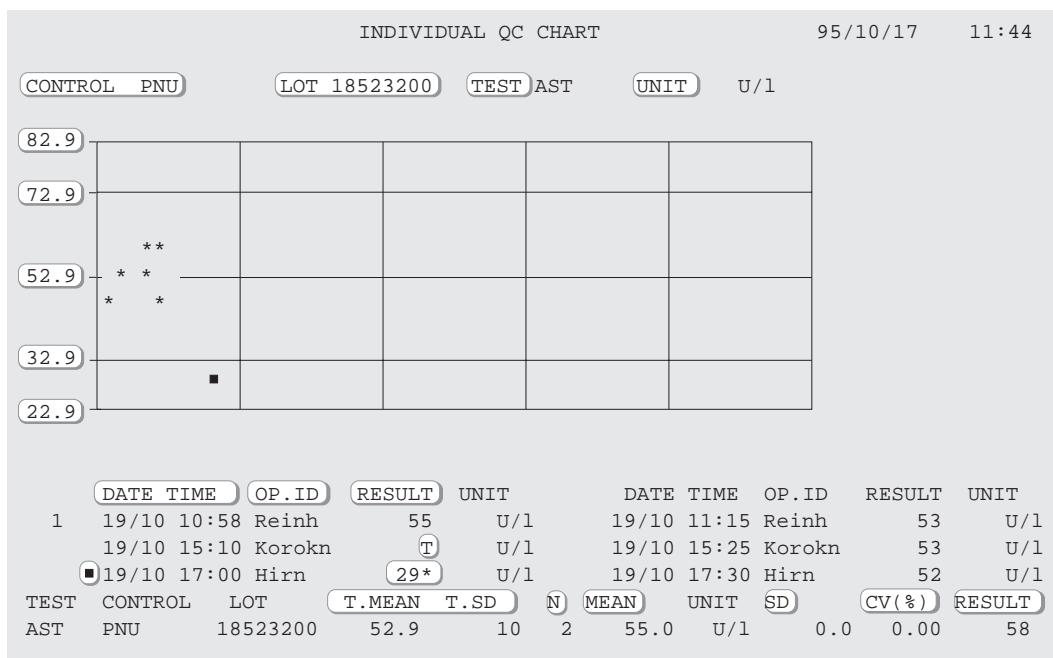
[45.6R] [-5.6E] Measured slope in mV
including data alarms (see table on page 29).

5.13 INDIVIDUAL QC CHART Printout

The following example shows the report printout of an individual quality control chart. Before the printout is started, the desired tests must be highlighted in the main menu QC, sub menu INDIVIDUAL. When the printout is started from the CHART window, the displayed control is taken as the selection criteria. To start the printout, press the option INDIVIDUAL QC CHART in the global menu PRINT, print menu QC followed by SELECT. Select the required options (ALL or NOT ACCUMULATE) in the window that is now displayed and press PRINT. The report printout (chart) can contain cumulative as well as non-cumulative daily data. Both data types are represented in the chart by an asterisk (*).

Accumulated data is indicated by an asterisk (*) in the list, below the chart, in front of the date. Data not included in the calculation is highlighted in the chart by a "■" and also in front of the date. The selection is performed by pressing the corresponding button in the main menu QC, sub menu INDIVIDUAL. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.4.1 The PRINT INDIVIDUAL QC CHART window in the volume System Description.

INDIVIDUAL QC CHART Printout



CONTROL PNU Control name, e.g. PNU

N Number of controls, e.g. 2

LOT.18523200 Control lot number

MEAN Mean value, e.g. 55.0

TEST Test name, e.g. AST

SD Standard deviation, e.g. 0.0

UNIT Units of measure

CV (%) Variationskoeffizient, z.B. 0.00

DATE TIME Date and time of requisition

RESULT Last measured result, e.g. 58

19/10 Value has already been accumulated

OP. ID Operator ID, e.g. Reinh

Graph:

82.9 +3SD range

72.9 +2SD range

52.9 Target value

32.9 -2SD range

22.9 -3SD range

T = data alarm instead of a result

29* = Result lies outside $\pm 2SD$; if a data alarm has occurred, the result will be printed out with the corresponding data flag.

T.MEAN T.SD Target mean value and target standard deviation, e.g. 52.9 = target mean value, 10 = target standard deviation

■ The result has been excluded from the calculation using the COMMENT function.

5.14 INDIVIDUAL QC LIST Printout

The following example shows the report printout of an individual quality control list. Before the printout is started, the desired tests must be highlighted in the main menu QC, sub menu INDIVIDUAL. The list can be printed out, sorted according to tests or controls. The required sort function must be chosen by pressing the appropriate sort button in the sub menu INDIVIDUAL. To start the printout, press the option INDIVIDUAL QC LIST in the global menu PRINT, print menu QC followed by SELECT and PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.4.2 The PRINT INDIVIDUAL QC LIST window in the volume System Description.

INDIVIDUAL QC LIST										20/10/95	12:29
TEST	CONTROL	LOT	T. MEAN	T. SD	N	MEAN	UNIT	SD	CV (%)	RESULT	
AST	PNU	18523200	52.9	10	2	55.0	U/l	0.0	0.00	58	
AST	PPU	18525900	144	26	3	147.7	U/l	5.8	3.93	151	
Ca	PNU	18523200	2.31	0.2	4	2.695mmol/l	0.636	23.60	2.25		
Ca	PPU	18525900	3.35	0	4	2.785mmol/l	0.958	34.40	3.62		
C1	PNU	18523200	86	2	4	83.0mmol/l	2.4	2.89	84		
C1	PPU	18525900	115	3	4	113.5mmol/l	2.6	2.29	114		
Mg	PNU	18523200	0.86	0.11	3	0.683mmol/l	0.006	0.88	0.68		
Mg	PPU	18525900	1.69	0	3	1.557mmol/l	0.006	0.39	1.56		

TEST Test name, e.g. AST

CONTROL Control name, e.g. PNU

LOT Lot number, e.g. 18523200

T. MEAN Target mean value, e.g. 1.69

T. SD Target standard deviation

N Number of control measurements, e.g. 3

MEAN Mean value

UNIT Units of measure, e.g. U/l

SD Standard deviation, e.g. 0.006

CV (%) Coefficient of variation, e.g. 0.39

RESULT Last measured value, e.g. 1.56

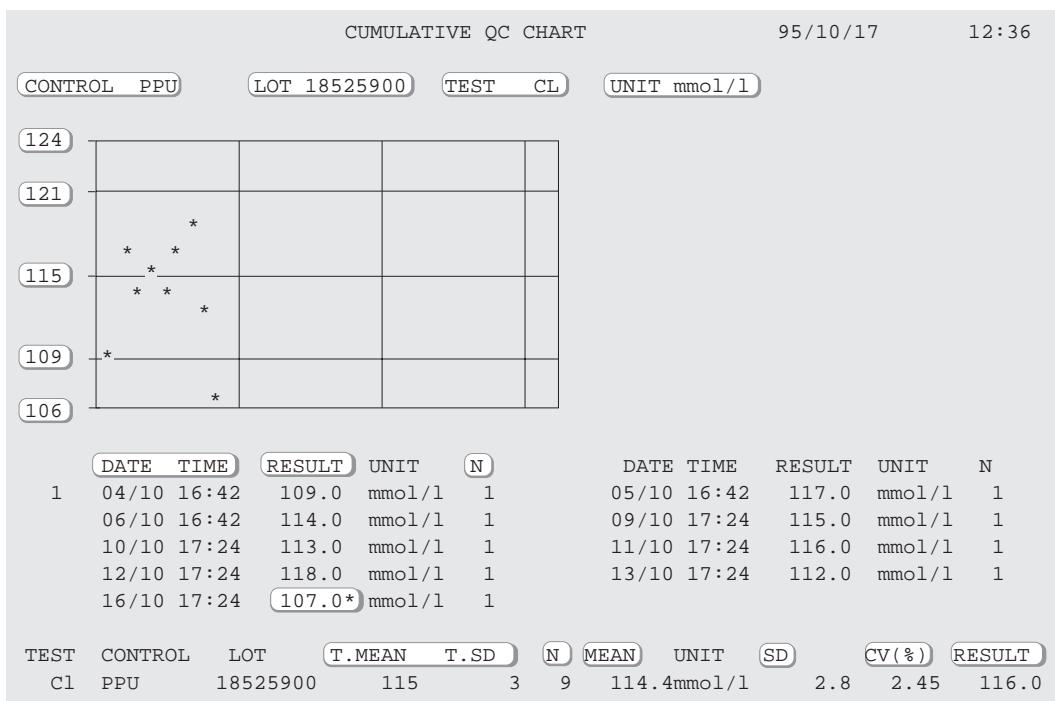
Note

Control results with data alarms are not considered in the calculation of the individual quality control.

5.15 CUMULATIVE QC CHART Printout

The following example shows the report printout of an cumulative quality control chart. Before the printout is started, the desired tests must be highlighted in the main menu QC, sub menu CUMULATIVE When the printout is started from the CHART window, the displayed control is the taken as the selection criterion. The list can be printed out, sorted according to tests or controls. The required sort function must be chosen by pressing the appropriate sort button in the CUMULATIVE sub menu. To start the printout, open the PRINT global menu and touch QC, CUMULATIVE QC CHART, SELECT and PRINT in sequence. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.4.3 The PRINT CUMULATIVE QC CHART window in the volume System Description.

BM/Hitachi 917



CONTROL PPU Control name, e.g. PPU

N Number of control measurements,

LOT 18525900 Control lot number

e.g. 9

TEST CL Test name, e.g. CL

MEAN Mean value, e.g. 114.4

UNIT mmol/l Units of measure, e.g.

SD Standard deviation, e.g. 2.8

mmol/l

CV (%) Coefficient of variation, e.g. 2.45

DATE TIME Date and time of calibration

Graph:

RESULT Calculated mean value, example:

124 +3SD range

107.0* = the result lies outside $\pm 2SD$.

121 +2SD range

N Number of controls, e.g. 9

115 Target value

RESULT Last measured result, e.g. 116.0

109 -2SD range

T.MEAN T.SD Target mean value and

106 -3SD range

target standard deviation, e.g. 115 =target mean value, 3 = target standard deviation

CUMULATIVE QC LIST Printout

5.16 CUMULATIVE QC LIST Printout

The following example shows the report printout of an cumulative quality control list. Before the printout is started, the desired tests must be highlighted in the main menu QC, sub menu CUMULATIVE. The list can be printed out, sorted according to tests or controls. The required sort function must be chosen by pressing the appropriate sort button in the sub menu CUMULATIVE. To start the printout, press the option CUMULATIVE QC LIST in the global menu PRINT, print menu QC followed by SELECT and PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.4.4 The PRINT CUMULATIVE QC LIST window in the volume System Description.

CUMULATIVE QC LIST										20/10/95	12:41
TEST	CONTROL	LOT	T.MEAN	T.SD	N	MEAN	UNIT	SD	CV (%)	RESULT	
C1	PNU	18523200	86	2	10	83.3mmol/l		1.3	1.55	83.0	
C1	PPU	18525900	115	3	9	114.4mmol/l		2.8	2.44	116.0	
K	PNU	18523200	4.5	0.3	10	4.60mmol/l		0.00	0.00	4.60	
K	PPU	18525900	6.50	0.3	9	6.36mmol/l		0.11	1.78	6.40	
Na	PNU	18523200	126	4	9	127.8mmol/l		0.7	0.52	127.0	
Na	PPU	18525900	140	2	9	138.4mmol/l		2.2	1.58	139.0	

TEST Test name, e.g. Cl

CONTROL Control name, e.g. PNU

LOT Lot number, e.g. 18523200

T.MEAN Target mean value, e.g. 140

T.SD Target standard deviation

N Number of control measurements, e.g. 9

MEAN Mean value

UNIT Units of measure, e.g. mmol/l

SD Standard deviation, e.g. 1.3

CV (%) Coefficient of variation, e.g. 1.58

RESULT Last measured value, e.g. 83.0

5.17 ALARM TRACE Printout

The following two reports are examples of alarm traces that can be requested in the PRINT global menu. Additional information can be found in chapter 8.9.5.1 The PRINT ALARM TRACE window in the volume System Description.

5.17.1 DAILY ALARM TRACE

This example shows a list of the daily alarms and status changes in coded form. This report printout assists BM-Service to troubleshoot.

To start the report printout, press the ALARM TRACE option in the PRINT global menu, MAINT/UTILITY print menu. Select the DAILY option in the window that is now open, followed by PRINT and ENTER. In addition to the information listed below, the date and time of the printout can be found in the list header.

DAILY ALARM TRACE			95/10/17	10:28
10/17 18:17	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:16	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:14	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:13	2	1 R 2-017-003-040	INCUBATION BATH WATER SHORT	
10/17 18:12	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:11	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:09	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:08	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:06	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:05	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:03	2	1 R 2-017-004-001	INCUBATION BATH WATER SHORT	
10/17 18:03	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:01	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 18:00	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:58	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:57	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:55	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:54	2	1 R 2-017-004-053	INCUBATION BATH WATER SHORT	
10/17 17:54	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:52	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:50	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:49	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	
10/17 17:47	2	1 A 2-123-001-065	Cell Rinse Cleaner Short	

05/10 10:10

1 A 1-062-015-000

Date and time of the alarm message

Coded alarm

CELL RINSE CLEANER SHORT

Example of an alarm message

5.17.2 CUMULATIVE ALARM TRACE

This example shows a list of the cumulative alarms and status changes in coded form. This report printout assists BM-Service to troubleshoot.

To start the report printout, press the ALARM TRACE option in the PRINT global menu, MAINT/UTILITY print menu. Select the CUMULATIVE option in the window that is now open, followed by PRINT and ENTER. In addition to the information listed below, the date and time of the printout can be found in the list header.

CUMULATIVE ALARM TRACE		95/10/17	10:29
5/10/95 10:07 10:29	A 2-093-003-003	ISE Slope Error	
	2-084-087-003	Calibration > 20% Change	
	2-084-088-003	Calibration > 20% Change	
	2-084-089-003	Calibration > 20% Change	
	2-083-087-003	Calibration Error	
	2-084-088-003	Calibration Error	
	2-084-089-003	Calibration Error	
	1-125-001-006	Printer Error	
	1-125-003-001	Printer Error	
R	2-017-219	INCUBATION BATH WATER SHORT	
	2-013-001	24V FOR DO2 PCB	
	2-018-043	DISTILLED WATER SHORT	
K	001-003	START	
	003-001	STOP	

5/10/95 10:07 10:29

Date and time of the alarm message

ISE Slope Error

Example of an error message

A 1-062-015-001

Coded error

5.18 SYSTEM COMMUNICATION TRACE Printout

The following is an example of the printout of a list, showing information about the communications between the Host computer and the analyzer. The System Communication Trace is useful when search for errors referring to the communication between the analyzer and the laboratory EDP. Additional information can be found in the Host Interface Manual and in chapter 8.9.5.2 PRINT COMMUNICATION TRACE window in the volume System Description. Contact BM-Service if any questions arise. The list can only be requested when the analyzer is connected to a laboratory EDP and the appropriate settings have been selected on the analyzer (global menu START, PRINT/HOST window).

To start the report printout, press the option SYSTEM COMMUNICATION TRACE in the global menu PRINT, print menu MAINT/UTILITY Select PRINT in the window that is now open, followed by ENTER. In addition to the information listed below, the date and time of the printout can be found in the list header.

The printout is laid out in reverse chronological order; i.e. the last message is printed out as the first one. For test selection and result messages, as long as an error did not occur during the transmission, only the first part of the message is listed (Sample Information).

For transmission and format errors, the entire message, including the corresponding error message, is displayed.

For each message, that is transmitted from the analyzer to the Host or vice versa, the following information is saved as well as printed out:

SYSTEM COMMUNICATION TRACE Printout

06:36:38 Time of transmission start
06:36:38 Time of transmission end
AU->HOST Transmission direction
274> Transmitter/Receiver identification,
here 2 = Host (receiver);
7 = Analyzer (transmitter); 4 = Example of
a consecutive number for the message
> = Frame Character

A1 Message identification
(Frame Character)
SUM ERROR Message content,
here: error message
100001 Message content,
here: sample number
ETX End of transmission (ETX)

5.19 OPERATOR ID TRACE Printout

The following is an example of a report printout of the Operator ID Trace. In this list the Login and Logoff times of the operators are documented. If the analyzer is switched off without the operator performing a Logoff in the global menu START, LOG-OFF window, then three stars (***) appear in the LOGOFF column. To start the printout, select the option OPERATOR ID TRACE in the global menu PRINT, MAINT/UTILITY. Set the time range of the report in the window that is now open and press PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.5.3 The PRINT OPERATOR ID TRACE in the volume System Description.

OPERATOR ID TRACE						95/10/18	10:16		
TERM 95/09/29 - 95/10/04									
DATE	OP.ID	LOGON	LOGOFF	OP.ID	LOGON	LOGOFF	OP.ID	LOGON	LOGOFF
05/10/95	Jung	10:17	***	Hirn	14:26	14:37	Reinh	14:40	14:40
	Reinh	14:40	14:41	Reinh	14:41	14:42	Korokn	14:42	14:42
	Jung	14:42	14:43	Jung	14:43	16:31	Korokn	16:31	***
06/10/95	Jung	10:08	10:15	Reinh	10:15	10:15	Korokn	10:16	10:16
	Jung	10:16	10:16						

[DATE] Date

(OP.ID) Operator ID

[LOGON] Login time (Log In)

(LOGOFF) Logoff time (Log Off)

******* The analyzer was switched off

without performing a LOGOFF

Note

This list can only be requested when the LOGON/LOGOFF function has been selected in the main menu MAINT/UTILITY, sub menu SYSTEM, OPERATOR ID window.

5.20 CUMULATIVE OPERATION LIST Printout

The following is an example of an analyzer report. Power-on and operating times are specified in hours. Test count is broken down into routine, calibrations, controls, reruns and STAT samples. The line at the bottom shows the totals of the performed analyses. To start the report printout, press the option CUMULATIVE OPERATIONS LIST in global menu PRINT, print menu MAINT/UTILITY, followed by PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.5.4 The PRINT CUMULATIVE OPERATION LIST in the volume System Description.

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CUMULATIVE OPERATION LIST					95/10/17	10:32	
1. POWER ON TIME		351	HOURS				
2. OPERATION		133	HOURS				
3. TEST COUNT							
TEST	APP. CODE	ROUTINE	CALIB.	CONT.	RERUN	STAT	TOTAL
Alb	042	33	66	9	3	2	113
AP	063	0	0	0	0	0	0
AST	253	5	4	2	0	0	11
Ca	315	142	78	94	13	12	339
CRE	420	130	88	37	89	8	352
Mg	693	174	44	71	27	14	330
TP	756	199	44	74	29	12	358
Hst	819	0	0	0	0	0	0
Na	989	207	229	150	95	40	721
K	990	207	229	150	95	40	721
Cl	991	207	229	150	95	40	721
TOTAL		1304	1011	737	446	168	3666
4. NO. OF SAMPLE		ROUTINE	RERUN	STAT	TOTAL		
		292	140	56	488		

1. POWER OF TIME Power-on time in hours, e.g. 351

2. OPERATION Operating time, e.g. 133

3. TEST COUNT Type and number of tests performed during the switched-on time broken down into

TEST Test name, e.g. Alb

CONT. Number of controls performed

APP. CODE Test application number,
e.g. 042

using this test

ROUTINE Number of routine determina-
tions performed using this test

RERUN Number of reruns performed
using this test, e.g. 3

CALIB. Number of calibrations performed
using this test, e.g. 66

STAT Number of STAT samples
performed using this test

TOTAL Grand total of all tests, e.g. 3666

TOTAL Total of all test types for this
test, e.g. 113

4. NO. OF SAMPLE Number of analyzed samples broken down into routine, rerun, STAT samples and total

5.21 MAINTENANCE REPORT Printout

The following is an example of a Maintenance Report. The Maintenance Report documents all confirmed care/maintenance operations, that were confirmed/Performed in the main menu MAINT/UTILITY, sub menu MAINT-LOG. To start the report printout, press the option MAINTENANCE REPORT in global menu PRINT, print menu MAINT/UTILITY, followed by PRINT in the window that is now open. In addition to the information listed below, the date and time of the printout can be found in the list header.

MAINTENANCE REPORT				95/10/18	17:33
PARTS	DATE	TIME	OP. ID	COMMENTS	
WEEKLY	10/10/95	17:31	Reinh	CELLS replaced	
	12/10/95	15:19	Korok		
CELL blank measurement	10/10/95	17:32	Hirn		
	12/10/95	15:17	Jung		
	05/10/95	16:47	Reinh		
Clean container	10/10/95	17:33	Korok	Condensation wiped away	
	12/10/95	15:13	Hirn		

PARTS Type and frequency of the maintenance

OP. ID Operator ID

WEEKLY Example of a maintenance cycle, that has been confirmed using the ALL COMPLETE in sub menu MAINT-LOG

COMMENTS Comment text (optional);

e.g. **Cells replaced**; if the comment is selected, the text appears here in the printout

DATE TIME Date and time when the maintenance procedure was performed

Cell blank measurement Example of a maintenance option

Note

Additional information about production of the maintenance report can be found in the global menu HELP, in the Help menus SCREEN and OTHERS or in chapter 8.9.5.5 The PRINT MAINTENANCE LOG window in the volume System Description.

5.22 REPORT EXAMPLE Printout

The following two examples show the different formats of a Report Example. This list is printed out according to the settings made beforehand in the main menu MAINT/UTILITY, sub menu REPORT FORMAT. The specifications for the list format in the form of line and character numbers are entered in the screen REPORT FORMAT. The order of the tests on the printout is determined in the PRINT ORDER window. To start the report printout, press the option REPORT EXAMPLE in global menu PRINT, print menu MAINT/UTILITY, followed by PRINT. Additional information can be found in chapter 8.9.5.6 The PRINT REPORT EXAMPLE window in the volume System Description.

Note

A DIN A4 page is made up of 80 characters/line and 72 lines/page. One page of continuous paper (US format) is made up of 80 characters/line and 66 lines/page. If 2 reports (or 4) are to be printed out one after the other, the page lengths must be halved. Therefore, in the sub menu REPORT FORMAT instead of setting 66 lines, set the number of lines to 33 (or instead of 72 lines set 36 lines. The start of the printout of the test results is determined by the test with the lowest print line.

REPORT EXAMPLE Printout

5.22.1 Setting ONE REPORT/PAGE

The printout is an example of a report where only one report per page is printed. There are 80 characters per line available. The corresponding settings can be taken from the following screenshot of the REPORT FORMAT sub menu.

Stand-by

BMSERV Wed 10/04/96 11 53

WORKPLACE REAGENTS CALIBRATION Q C MAINT/UTILITY

Report Format To select number of reports/page: Touch screen or use arrow keys + <Enter> key.

Report/Page	One	Two	Title	Boehringer Mannheim GmbH		
Page Length	66			BM/Hitachi 917		
Page/Sample	One	Two				
Title	(40)	1	22	NAME	(30) 6 49	
Measure Date	(8)	4	47	WARD	(25) 7 49	
Measure Time	(5)	4	56	OTHERS	(20) 8 49	
Draw Date	(8)	9	14		(15) 9 49	
Draw Time	(5)	9	47		(10) 10 49	
Sample No.	(13)	5	14	Test Name	(22) 18	
Type	(6)	6	14	Results	(8) 25	
ID Number	(13)	4	14	Unit	(6) 35	
Sex	(1)	8	14	Expected Value	(17) 44	
Age	(5)	7	14	Remarks	(6) 63	
Operator ID	(6)	5	49	Print Order		
Start	Sample Stop	Analyzer Stop	Sample Track	Print	Alarm	Help

BM/Hitachi 917

Boehringer Mannheim GmbH BM/Hitachi 9 1 7				
ID	1234567890123	DATE	06/10/95 11:43	
S.NO.	NR00001 0-001	OPERATOR ID	&&&&&	
S.TYP	*****	NAME	##Kommentar1#####	
AGE	100 J	WARD	%%Kommentar2%%%%%%%%%	
SEX	M	OTHERS	@@Kommentar3@@@@@@@	
DRAW DATE	06/10/95	DRAW TIME	11:43	
TEST	RESULT	UNITS	EXPECTED VALUE	REMARKS
Albumin	999999 H	g/dl	(-999999-999999)	*****
GOT	999999 H	U/l	(-999999-999999)	*****
Calcium	999999 H	mmol/l	(-999999-999999)	*****
Creatinine	999999 H	mg/dl	(-999999-999999)	*****
Total Prot.	999999 H	g/dl	(-999999-999999)	*****
Magnesium	999999 H	mmol/l	(-999999-999999)	*****
Alk. Phos.	999999 H	U/l	(-999999-999999)	*****
Bun.	999999 H	mg/dl	(-999999-999999)	*****
Sodium	999999 H	mmol/l	(-999999-999999)	*****
Potassium	999999 H	mmol/l	(-999999-999999)	*****
Chlorid	999999 H	mmol/l	(-999999-999999)	*****
Lip.	999999 H			*****
haemol.	999999 H			*****
Ict.	999999 H			*****

Boehringer Mannheim GmbH Example of a report title
BM/Hitachi 9 1 7

ID	Sample barcode number	DATE	Print date and time
S.NO.	Sample number	OPERATOR ID	Operator ID
S.TYP	Sample type	NAME	Comment 1 (here: NAME)
AGE	Patient's age	WARD	Comment 2 (here: WARD)
SEX	Patient's sex	OTHERS	Comment 3 (here: OTHERS)
DRAW DATE	Date of sample requisition	DRAW TIME	Time of sample requisition
TEST	Method name, e.g. Albumin ;		

the first test is always on the line that was defined as the lowest line in the window PRINT ORDER (line 12 in this example)

RESULT Report result, e.g. 999999 H for HIGH

UNITS Units of measure, e.g. mmol/L

EXPECTED VALUE Defined reference range

REMARKS Additional remarks

REPORT EXAMPLE Printout

5.22.2 Setting TWO REPORTS/PAGE

The printout is an example of a report where two reports per page are printed. There are 40 characters per line available. The corresponding settings can be taken from the following screenshot of the REPORT FORMAT sub menu. Please note that due to this format not all the information is printed out (e.g. reference ranges).

Note

A DIN A4 page is made up of 80 characters/line and 72 lines/page. One page of continuous paper (US format) is made up of 80 characters/line and 66 lines/page. If the setting for two reports/page is selected, the reports are printed out side by side (see printout example on page 50). If 2 reports are to be printed out one after the other on continuous paper (i.e. a total of 4 reports/page), the page lengths must be halved. Therefore, in the REPORT FORMAT sub menu instead of setting 66 lines, set the number of lines to 33 (or instead of 72 lines set 36 lines). The start of the printout of the test results is determined by the test with the lowest print line.

Stand-by ! BMSERV Tue 29/10/96 16 54

WORKPLACE REAGENTS CALIBRATION Q C MAINT/UTILITY

Report Format [3] To select number of reports/page: Touch screen or use arrow keys + <Enter> key.

Report/Page	One	Two	Title	*****	
Page Length	66		* B M - H I T A C H I 9 1 7 *		
Page/Sample	One	Two	*****		
Title	(40)	1	1	name	(30) 7 8
Measure Date	(8)	4	5	COMM-TITLE02	(25) 8 8
Measure Time	(5)	4	25	COMM-TITLE03	(20) 9 8
Draw Date	(8)	9	0	COMM-TITLE04	(15) 1 0
Draw Time	(5)	10	0	COMM-TITLE05	(10) 1 0
Sample No.	(14)	5	5	Test Name	(22) 1
Type	(6)	5	25	Results	(8) 15
ID Number	(13)	6	5	Unit	(6) 24
Sex	(1)	7	1	Expected Value	(17) 0
Age	(5)	8	1	Remarks	(6) 32
Operator ID	(6)	6	0	Print Order	

Start Sample Stop Analyzer Stop Sample Track Print Alarm Help

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Boehringer Mannheim GmbH BM/Hitachi 9 1 7	Boehringer Mannheim GmbH BM/Hitachi 9 1 7
06/10/95 11:48 NR00001 0-001 p ***** 1234567890123	06/10/95 11:48 NR00001 0-001 p ***** 1234567890123
(M) ##Comment1##### 100 y %%Comment2%%%%%% @@Comment3@@@@@@@	M ##Comment1##### 100 J %%Comment2%%%%%% @@Comment3@@@@@@@
TEST RESULT UNITS REMARKS	TEST RESULT UNITS REMARKS
Albumin 999999 H g/dl *****	Albumin 999999 H g/dl *****
GOT 999999 H U/l *****	GOT 999999 H U/l *****
Calcium 999999 H mmol/l *****	Calcium 999999 H mmol/l *****
Creatinine 999999 H mg/dl *****	Creatinine 999999 H mg/dl *****
Total Prot. 999999 H g/dl *****	Total Prot. 999999 H g/dl *****
Magnesium 999999 H mmol/l *****	Magnesium 999999 H mmol/l *****
Alk. Phos 999999 H U/l *****	Alk. Phos 999999 H U/l *****
Bun 999999 H mg/dl *****	Bun 999999 H mg/dl *****
Sodium 999999 H mmol/l *****	Sodium 999999 H mmol/l *****
Potassium 999999 H mmol/l *****	Potassium 999999 H mmol/l *****
Chlorid 999999 H mmol/l *****	Chlorid 999999 H mmol/l *****
Lip. 999999 H *****	Lip. 999999 H *****
haemol. 999999 H *****	haemol. 999999 H *****
Ict. 999999 H *****	Ict. 999999 H *****

06/10/95 Date of sample requisition

@@Comment3@@@@@@@

NR00001 0-001 p Sample number;
NR=Sample type (N=Routine, R=Rerun);
0001=Sequence number of sample;
0=Disk number; 001=Position on the
sample disk

Comment 3

1234567890123 Sample barcoder
number

according to the setting in the "Com-
ment 3" field, in this example: OTHERS

(M) Patient's sex

***** Sample type (list header)

100 y Patient's age

(TEST) Method name, e.g. Albumin;
the first test is always on the line that was
defined as the lowest line in the window
PRINT ORDER (line 12 in this example)

##Comment1#####

(RESULT) Report result, e.g. 999999 H
stands for HIGH (Result exceeds reference
range)

%%Comment2%%%%%%

(UNITS) Units of measure, e.g. mmol/L

@@Comment3@@@@@@@

(REMARKS) Additional remarks

Comment 1

according to the setting in the
"Comment 1" field, in this example: NAME

%%Comment2%%%%%%

Comment 2

according to the setting in the
"Comment 2" field, in this example: WARD

CELL BLANK MEASUREMENT Printout

5.23 CELL BLANK MEASUREMENT Printout

The following example illustrates a printout after a reaction cell blank measurement. The measured reaction cell blank values are stored on the hard disk and if required they can be printed out sorted according to the reaction cell number. Blank values of all reaction cells are measured and saved to detect reaction cell contamination or fluctuations of the lamp light intensity. On the printout, the absorbance (x 10000) of the first reaction cell and from the 2nd up to the 160th reaction cell the difference of absorbance to the first reaction cell are shown. If a difference of more than ± 800 is apparent, then the reaction cells must be cleaned or replaced. To start the report printout, press the option CELL BLANK MEASUREMENT in global menu PRINT, print menu MAINT/UTILITY, followed by PRINT. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.5.7 The PRINT CELL BLANK MEASUREMENT window in the volume System Description.

CELL BLANK MEASUREMENT												95/10/17	10:25
(NO.)	WAVE LENGTH(NM)												
	340	376	415	450	480	505	546	570	600	660	700	800	
1	[12340]	11558	10864	10581	10402	10335	10190	10129	9938	9842	9699	9456	
	[12338]	11557	10863	10582	10402	10334	10190	10127	9938	9840	9697	9455	
2	-317	-134	-155	-125	-110	-108	-100	-87	-79	-93	-85	-33	
	-316	-132	-154	-126	-109	-108	-100	-86	-79	-90	-82	-31	
3	-394	-250	-192	-146	-112	-98	-73	-60	-39	-18	-8	4	
	-394	-249	-191	-146	-112	-98	-73	-59	-39	-16	-5	5	
158	-308	-123	-152	-114	-100	-97	-92	-79	-71	-81	-79	-31	
	-305	-123	-151	-116	-101	-96	-92	-76	-71	-79	-77	-31	
159	-369	-217	-163	-127	-96	-83	-59	-50	-29	-14	-2	10	
	-367	-215	-163	-127	-96	-83	-59	-49	-29	-12	0	11	
160	-437	-289	-215	-173	-137	-124	-94	-87	-66	-49	-39	-29	

(NO.) Reaction cell number, e.g. [1]

[12340] Examples of absorbances (ADC1

[415] [450] [480] Measurement wavelength

[12338] and ADC2) of the first reaction cell

(in NM)

[-317] [-316] Example of absorbance-differences to the first reaction cell

Note

A printout during the reaction cell blank measurement differs in the reaction cell sequence (see chapter 5.25).

5.24 PHOTOMETER CHECK Printout

The following is an example of a printout of a Photometer Check. This check is performed to monitor the light intensity of the photometer lamp. By referring to the light intensity it can be ascertained whether or not the photometer lamp is functioning reliably. The actually measured data and the previous measurements are printed out together in a list. The absorbances of the wavelengths 340 to 800 should not be greater than approximately 16000. Incubation water, manual cleaning of the photometer window in the incubation bath and automatic cleaning of the reaction cells can influence the data. The photometer check is requested in the global menu MAINT/UTILITY, sub menu MAINTENANCE. Select in the list on the left of the screen the option PHOTOMETER CHECK and confirm with SELECT. Then press EXECUTE in the window that is now open. Additional information can be found in chapter 8.5.2.2 The PHOTOMETER CHECK function in the volume System Description.

PHOTOMETER CHECK				95/10/10	11:08
----- PREVIOUS DATA -----		----- CURRENT DATA -----			
DATE 11/10/95 00:05		DATE 12/10/95 11:08			
WV1 (2nd)	WV2 (PRI.)	WV1 (2nd)	WV2 (PRI.)		
340 NM	12930	12930	340 NM	12914	12915
376 NM	12118	12118	376 NM	12118	12120
415 NM	11307	11307	415 NM	11304	11306
450 NM	10991	10991	450 NM	10986	10988
480 NM	10765	10764	480 NM	10771	10772
505 NM	10671	10671	505 NM	10672	10674
546 NM	10481	10481	546 NM	10489	10490
570 NM	10412	10412	570 NM	10415	10418
600 NM	10207	10207	600 NM	10198	10199
660 NM	10064	10064	660 NM	10065	10066
700 NM	9904	9905	700 NM	9898	9901
800 NM	9593	9593	800 NM	9624	9625

----- PREVIOUS DATA -----

Data from the last measurement

800 NM Example of a wavelength (in NM)

WV2 (PRI.) Absorbance of the primary wavelength

----- CURRENT DATA -----

Data from the current measurement

WV1 (2nd) Absorbance of the secondary wavelength

CELL BLANK MEASUREMENT Printout

5.25 CELL BLANK MEASUREMENT Printout

The following example illustrates a printout during a reaction cell blank measurement. The function is selected when CELL BLANK is selected in the MAINT/UTILITY main menu, MAINTENANCE sub menu. Blank values of all reaction cells are measured and saved to detect reaction cell contamination or fluctuations of the lamp light intensity. On the printout, the absorbance ($\times 10000$) of the first reaction cell and from the 2nd up to the 160th reaction cell the difference of absorbance to the first reaction cell are shown. If a difference of more than ± 800 is apparent, then the reaction cells must be cleaned or replaced. To start the report printout, press the CELL BLANK MEASUREMENT option in PRINT global menu, MAINT/UTILITY print menu, followed by SELECT. Then press EXECUTE in the window that is now open. The printout order follows the actual reaction cell blank measurements. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.9.2.9 The CELL BLANK MEASUREMENT function in the volume System Description.

CELL BLANK MEASUREMENT												95/10/17	11:10	
WAVELENGTH (NM)														
No.	340	376	415	450	480	505	546	570	600	660	700	800		
(1)	12879	12057	11284	10965	10753	10660	10483	10408	10190	10073	9908	9616		
	12879	12055	11283	10964	10752	10659	10481	10407	10191	10071	9907	9614		
42	58	117	41	42	34	25	13	17	16	-14	-18	18		
	58	118	40	41	35	26	15	18	14	-13	-18	18		
83	-29	-8	0	9	21	27	29	36	43	44	47	50		
	-29	-7	1	10	21	27	31	37	41	45	46	51		
124	16	-31	-29	-27	-16	-13	-12	-10	-4	-8	-7	-15		
	14	-30	-28	-27	-15	-14	-11	-11	-5	-6	-8	-14		
5	-19	67	39	42	52	44	42	42	46	34	32	41		
	-22	68	39	43	52	45	43	43	43	35	31	41		
46	-100	-12	-29	-26	-23	-21	-29	-25	-22	-33	-28	-25		
	-102	-11	-28	-26	-22	-22	-27	-25	-25	-33	-27	-24		
87	-77	44	8	19	27	25	25	29	35	23	20	31		
	-77	45	9	18	27	25	26	29	33	23	21	32		

(No.) Reaction cell number, e.g. (1)

(10660) Examples of absorbances (ADC1

(340) (450) Measurement wavelength (in NM) (10659) and ADC2) of the first reaction cell

(15) (-8) Example of absorbance-

differences to the first reaction cell

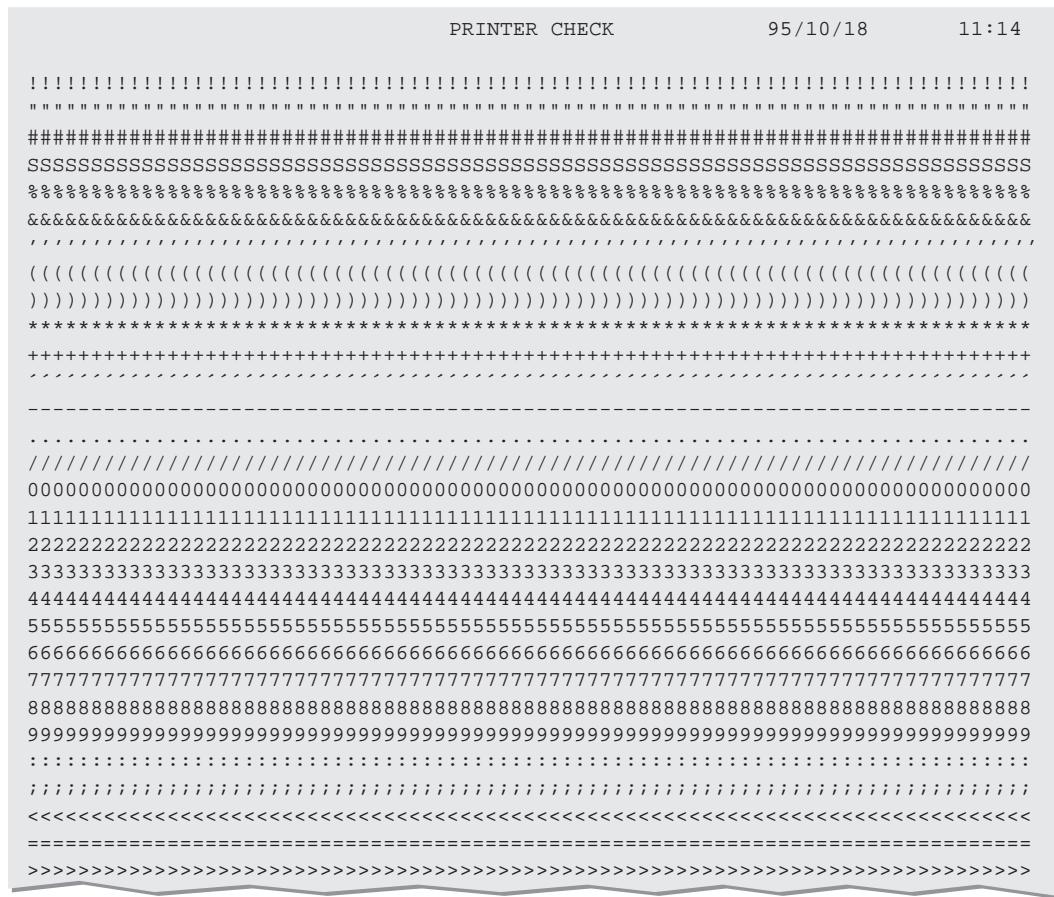
Note

A printout of the cell blank measurement sorted according to the reaction cell number can be requested using the CELL BLANK MEASUREMENT option in the PRINT global menu, MAINT/UTILITY print menu (see chapter 5.23).

PRINTER CHECK Printout

5.26 PRINTER CHECK Printout

This check is used to check the functionality of the printer. The check is requested in the MAINT/UTILITY main menu, MAINTENANCE sub menu. Select in the maintenance list the PRINTER CHECK option and press SELECT. Select EXECUTE in the window that is now open. The list is made up of a test print, title and the date and time of the printout. Additional information can be found in chapter 3.8 Printer Care.



5.27 BARCODE READER CHECK Printout

The following is an example of a Barcode Reader Check printout. This function is used to test the barcode reader. To activate the test function, select the BARCODE READER CHECK option in the MAINT/UTILITY main menu, MAINTENANCE sub menu. Then select SELECT. Enter the number of cycles required in the window that is now open and then press EXECUTE. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.5.2.11 The BARCODE READER CHECK function in the volume System Description.

BARCODE READER CHECK				12/10/95	11:18
POS.NO.	ID	POS.NO.	ID	POS.NO.	ID
RD 1001	042654052069290747	RD 2001	651653080005600026	SD 2001	100182
SD 1056					
RD 1002	315651307055980746	RD 2002	756651253026025456	SD 2002	
SD 1057					
RD 1003	756651252005885426	RD 2003	693651063024283686	SD 2003	100183
SD 1058					
RD 1004	951653228045232307	RD 2004	315651307050940746	SD 2004	100181
SD 1059					
RD 1005	420651836004780747	RD 2005	315652499051250046	SD 2005	100184
SD 1060					
RD 1006	693652840014013626	RD 2006	420651774016370077	SD 2006	100189
SD 1061					
RD 1007		RD 2007	253655865025508316	SD 2007	100190
SD 1062					

POS.NO. Identification of the disk,
disk number and position number
on the disk

RD 1001 Example: RD = reagent disk;
1001 = disk number 1 (1) and
and position 1 (001)

SD 2001 Example: SD = sample disk;
2001 = barcode reader on outer ring (2)
and position 1 (001)

----- ID ----- ID of the scanned
barcode

SD 1062 Example: SD = sample disk;
1062 = barcode reader on inner ring (1)
and position 62 (062)

042654052069290747 Example of a reagent
barcode

100182 Example of a sample barcode

Note

If the sample barcode reader is not active, the entries for PT1 and PT2 are omitted.

5.28 ISE CHECK Printout

The following is an example of a check to test the ISE unit. The EMFs (Electromotive Forces) of the Internal Standard solution are printed out. Trends and imprecisions can be recognized here. If these limits are exceeded, a corresponding alarm occurs. The printed out EMFs lie normally within the following ranges:

Na: -20 to -40 mV

K: -20 to -50 mV

Cl: 110 to 150 mV

Ref: -7 to 7 mV

The alarm LEVEL is displayed on the printout next to the corresponding EMF, when the following limits are exceeded or not reached:

Na: -90 to -10 mV

K: -90 to -10 mV

Cl: 80 to 160 mV

Ref: -7 to 7 mV

Within 30 cycles the difference from measurement to measurement should not be greater than 0.2 mV for Na, K and Cl, and $> \pm 2$ mV for the Ref. EMF over the total cycle range.

To select the test function, select the ISE CHECK option in the MAINT/UTILITY main menu, MAINTENANCE sub menu. Then select SELECT. Enter the number of cycles (30) required in the window that is now open and then press EXECUTE. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.5.2.15 The ISE CHECK function and in chapter 6.3 ISE Calibration, both in the volume System Description.

ISE CHECK					95/10/18 11:33
NO.	NA EMF	K EMF	CL EMF	REF.EMF	
1	-36.1	-36.5	120.5	0.8	
2	-36.2	-36.5	120.5	0.8	
3	-36.2	-36.5	120.5	0.8	
4	-36.2	-36.5	120.5	0.8	
5	-36.2	-36.5	120.5	0.8	
6	-36.2	-36.5	120.5	0.8	
7	-36.2	-36.5	120.5	0.8	
8	-36.2	-36.6	120.5	0.8	
9	-36.2	-36.6	120.5	0.8	
10	-36.2	-36.6	120.5	0.8	
11	-36.2	-36.6	120.5	0.8	
12	-36.2	-36.6	120.5	0.8	
13	-36.2	-36.6	120.5	0.8	
14	-36.2	-36.6	120.5	0.8	
15	-36.3	-36.6	120.5	0.8	

[NO.] Number of measurement cycle

[CL EMF] EMF of the Cl electrode

[NA EMF] EMF (Electromotive
force in mV) of the Na electrode

[REF.EMF] EMF of the reference electrode

[K EMF] EMF of the K electrode

5.29 HD CHECK Printout

The HD check is used to test the hard disk. A defect can be recognized by the printed out check sum. The software version is also printed out.

The following example shows the printout of the hard disk check. To activate the test function, select the DISK CHECK option in the MAINT/UTILITY main menu, MAINTENANCE sub menu. Then select SELECT. Enter the required option HD (for hard disk) in the window that is now open and then press EXECUTE. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.5.2.16 The DISK CHECK function in the volume System Description.

DIRECTORY C:\917\CU Directory name

FILE NO.) File number in the directory,

e.g. (4)

FILE NAME File name, e.g. CU.EXE

SIZE Size of the file, e.g. 2445570

DATE TIME Date and time of the Installation

TOTAL FILES Total number of files,

e.g. 24 FILE(S)

TOTAL SIZE Total size of the installed files (in bytes),
e.g. 75545792 BYTE(S)

SYSTEM PROGRAM VERSION installed software

version, e.g. (02-16)

CHECK SUM Check sum

FILE NAME SUM Check sum of the individual file; e.g. is (F94B) the check sum of the file (CU.EXE)

TOTAL SUM:0072 Total check sum

BM/Hitachi 917

HD CHECK		95/10/12	11:36
DIRECTORY C:\917\CU			
FILE NO.	FILE NAME	SIZE	DATE TIME
1	.	0	22/06/95 10:33
2	..	0	22/06/95 10:33
3	SYSVER	17	16/07/95 14:51
4	CU.EXE	2445570	16/07/95 14:42
5	MSGRUN	1086852	12/10/95 08:01
6	917.RES	569360	04/07/95 14:08
7	SYSFONT.FON	13825	31/10/94 10:12
8	FDFORMAT.INF	512	06/12/93 17:34
9	CEDIT.RGB	48	21/04/95 17:58
10	AUPROG1	137790	06/07/95 10:14
11	AUPROG2	743667	06/07/95 10:14
12	TMPARM1	24315	06/07/95 10:15
13	TMPROG1	304115	06/07/95 10:15
14	N_SMP.DAT	14624418	11/10/95 16:05
15	E_SMP.DAT	569602	10/10/95 17:24
16	C_SMP.DAT	25540044	11/10/95 11:02
17	K_SMP.DAT	6402	22/06/95 11:28
18	ABS.DAT	10238002	11/10/95 10:56
19	TM1.DAT	10470	12/10/95 11:12
20	HD_LIFO.DAT	2680604	22/06/95 11:32
21	A_TRACE.DAT	10462123	12/10/95 11:35
22	N_TS.DAT	3144674	11/10/95 16:05
23	PARAM.DAT	617230	12/10/95 11:31
24	MSG.OLD	1086852	16/07/95 14:40
TOTAL FILES		24 FILE(S)	
TOTAL SIZE		75545792 BYTE(S)	
SYSTEM PROGRAM VERSION: 02-16			
CHECK SUM			
FILE NAME	SUM		
CU.EXE	F94B		
MSGRUN	F7DC		
AUPROG1	1389		
AUPROG2	E0AD		
TMPROG1	B685		
TMPARM1	5C6C		
TOTAL SUM: 0072			

5.30 FD CHECK Printout

The following is an example of a floppy disk check. The floppy disks used to operate the analyzer can be checked using this function. Only the name and size of the files on the floppy disk are printed out. Parameters are saved under the file name PARAM.USR. Patient samples are saved under the specified file name using the file extension NRS (e.g. SEQ.NRS).

To activate this test function, select the DISK CHECK option in the MAINT/UTILITY main menu, MAINTENANCE sub menu. Then touch SELECT. Enter the required option FD (for floppy disk) in the window that is now open and then press EXECUTE. In addition to the information listed below, the date and time of the printout can be found in the list header. Additional information can be found in chapter 8.5.2.16 The DISK CHECK function in the volume System Description.

FD CHECK					95/10/18	14:16
DIRECTORY A:\						
FILE NO.	FILE NAME	SIZE	DATE	TIME		
1	PARAM.USR	0	10/10/95	17:36		
2	SEQ.NRS	31232	05/10/95	17:22		
3	ID.NRS	1664	05/10/95	18:05		
TOTAL FILES:		3 FILE(S)				
TOTAL SIZE:		32896 BYTE(S)				

DIRECTORY A:\ Drive identification

TOTAL FILES Total number of files on

FILE NO. File number

the floppy disk

FILE NAME File name

TOTAL SIZE Total size of the files

SIZE Size of the file (in bytes)

(in bytes)

DATE TIME Date and time of
installation

Note

Parameters are saved under the file name PARAM.USR, patient samples are saved using the file extension *.NRS.

6. Troubleshooting

6.1 Overview

To identify and isolate problems effectively, you need a good understanding of the theory of operation, operating procedures, emergency procedures and test reaction description covered in this manual. This chapter is intended to give you a detailed overall view of all data alarms and focuses on the following areas:

- High test results
- Low test results
- Erratic test results
- Problems with a single sample or control
- Problems with a single test
- Problems with tests with one calibration set point
- Problems with all tests with more than one calibration set point
- Problems with multiple tests (photometrics only)
- Problems with all tests including ISEs
- Problems with ISE, all results are erratic, excessive air in sipper syringe
- Erratic ISE results
- Problems with ISE, high internal standard values
- Problems with lowsodium or low chloride values
- Problems with biased enzymes

Overview

The following list displays an overview which data alarm is valid for the individual sample types and where to find a detailed description of the relevant alarms.

Data alarm	Printout	S. (1)	I. (2)	Photometry			ISE			Page	Note
				R/S	C	Std.	R/S	C	Std.		
Absorbance over	ABS?	Z	Z	o	o	o				6-28	
ADC abnormal	ADC?	A	A	o	o	o	o	o	o	6-29	
Absorbance maximum over	>AMAX	>	>	o						6-29	
Calculation test error	Calc?	%	%	o	o		o	o		6-30	
Calibration result abnormal	CalErr	!	!	o	o		o	o		6-30	
Calibration error	Calib	-	B			o				6-31	
Cell blank abnormal	Cell?	Q	Q	o	o	o				6-32	
Test-to-test comp. error	Cmp.T	C	C	o	o		o	o		6-33	
Test-to-test compensation disabled	Cmp.T!	M	M	o	o		o	o		6-34	4
Duplicate error	Dup	-	U			o				6-34	
Edited test	Edited	*	*	o	o		o	o		6-36	
Outside of reference value (high)	H	-	-	o			o			6-36	5
Internal standard concentration abnormal	I.Std	-	D						o	6-37	

(1) Screen display

(2) Interface = Transmission to the host

Data alarm	Printout	S. (1)	I. (2)	Photometry			ISE			Page	Note
				R/S	C	Std.	R/S	C	Std.		
Outside of reference value (low)	L	-	-	o			o		o	6-36	5
Level error	Level	L	L				o	o	o	6-38	
Reaction limit over	Limt0 Limt1 Limt2	I J K	I J K	o o o	o o o	o o o				6-41	
Technical value limit over	LIMTH LIMTL	\$ \$	\$ \$	o o			o o			6-40	
Linearity abnormal	Lin. Lin.8	W F	W F	o o	o o	o o				6-44	
ISE preparation abnormal	Margin	-	R						o	6-48	
Noise error	Noise	N	N				o	o	o	6-49	
Overflow	Over	O	O	o	o		o	o		6-50	4
Prozone error	Prozon	P	P	o	o	o				6-50	3
QC error 1	QCErr1	+	+		o			o		6-51	
QC error 2	QCErr2	+	+		o			o		6-52	
Random error	Random	@	@		o			o		6-53	
Reagent short	Reagn	T	T	o	o	o				6-54	2
Value outside repeat limit (high)	ReptH	=	=	o			o			6-55	
Value outside repeat limit (low)	ReptL	=	=	o			o			6-55	
Sample value abnormal	R.Over	&	&				o	o		6-55	
Standard 1 absorbance abnormal	S1Abs?	-	H			o				6-67	

Overview

Data alarm	Printout	S. (1)	I. (2)	Photometry			ISE			Page	Note
				R/S	C	Std.	R/S	C	Std.		
SD error	SD!	–	G			o				6-57	
Sample short	Sampl	V	V	o	o	o	o	o	o	6-56	2
Sensitivity error	Sens	–	Y			o				6-58	
Slope abnormal	Slope?	–	E						o	6-59	
STD error	Std?	–	S			o				6-60	
Systematic error 2 _{2SA} 2 _{2SW} 4 _{1SA} 4 _{1SW} 10 _{X_A} 10 _{X_W}	Systm1 Systm2 Systm3 Systm4 Systm5 Systm6	# # # # # #	# # # # # #		o			o		6-61 ff.	
Calculation disabled	???	X	X	o	o	o	o	o	o	6-27	4

Notes

- All If there are two or more data alarms occurring for the same sample type, only the first registered alarm is indicated.
- 1 o = Alarm refers to that sample type
R = Routine sample
S = STAT sample
C = Control
Std. = Calibrator (standard)
- 2 No result may be issued for the respective test.
3 The prozone value is only printed out in the real time monitor mode.
4 No result is issued for the respective test.
5 Can occur in combination with other alarms.
-

6.2 General Troubleshooting Strategy

Follow a sequence of steps to isolate a problem in one or more of the following areas:

1. Test problems with:

Reagents
Samples, controls, standards
operating errors
instrument errors

2. Instrument problems:

electrical/electronic problems
mechanical problems
operating error

3. Computer problems:

incorrect parameters, faulty test parameter data, faulty calibrator data
faulty system parameter on disk or disk load problems
operating error

4. Facility problems:

heat
humidity
power supply
Water supply
drain

In certain areas the operator is responsible for the troubleshooting (see also chapter 3. Maintenance and Daily Care). Before you switch on the analyzer, ensure that the following conditions are sufficiently met:

- reagent preparation and storage.
- sample preparation.
- instrument mechanical alignments and adjustments (home positions).
- computer parameters and general computer input/output operations.
- basic component replacement.
- Follow the basic computer operating instructions (e.g. for the start-up or shutdown).
- Follow the operating steps of chapter 3. Maintenance and Daily Care.

The operator is not responsible for troubleshooting electrical problems, except as covered in the operators manual. Never attempt to remove electronical components, such as printed circuit boards etc., unless specifically instructed to do so by a Boehringer Mannheim representative.

It is understood that each operator has different aptitudes in test, mechanics and electronics. Whatever the case, when a problem arises, consult Boehringer Mannheim's BM Customer Technical Support Department.

When troubleshooting, it is recommended to observe the alarms and to isolate the problem to the area denoted by the alarms. In many cases, you may be able to find the problem and to problem, correct it, and then resume with the analysis.

Calling the BM Customer Technical Support

If it becomes necessary to consult the BM Customer Technical Support to troubleshoot a test or instrument problem, please be prepared with the following information:

1. Test Problems:

account number, address, and telephone number
test(s) affected
description of the problem
catalogue and lot numbers of reagents, calibrators, and controls in use
calibration parameters from the last few calibrations performed
control results from the last few calibrations performed
patient results (with correlation results, if relevant)
Reaction Monitor report for affected test(s)

2. Instrument Problems:

account number, address, and telephone number
instrument serial number
description of the problem including relevant alarm(s)
other instrument or maintenance related information

6.2.1 Troubleshooting Conditions at power up

Certain conditions can affect instrument power up. These conditions are presented in the table below.

To troubleshoot a problem, find the category below (column “Cause/description”) that best describes the problem, and follow the recommended remedy:

Cause/description	Remedy
PROBLEM: The instrument does not power up.	<ol style="list-style-type: none">1. Instrument is unplugged.2. Main circuit switch in OFF position (right side of instrument).3. The CPU RUN light comes on, but no image appears on the screen. (The CPU run light is at the instrument's right rear, to the right of the connectors going to the control unit for the printer, keyboard, and screen.)4. The instrument's ON/OFF switch is tripped. <ol style="list-style-type: none">1. Plug instrument power cord into socket.2. Switch main circuit switch to the ON position.3. The brightness control of the screen may be turned down. Turn the brightness control up (control is below the screen, to the left of the screen ON/OFF switch).4. Have your service electrician check the appropriate ON/OFF switch.

6.2.2 Test troubleshooting

Mechanical problems can be identified by visual inspection or when the analyzer shows an alarm message. A test problem may display a data flag, or may only become evident with an unexpected result.

The following situations require troubleshooting:

Calibration error during calibration or in the calibration print-out.

Data flag for control or patient samples.

QC sample results fall outside defined ranges.

Patient tests yield unexpected results.

To troubleshoot effectively, use the calibration report print-out, quality control results, or patient results, and decide which of the following conditions apply. Then perform the checks associated with them:

High test results

Low test results

Erratic test results

Single sample affected - all tests

Single test affected -all samples

Multiple tests affected:

- all photometric tests
- only photometric tests using multiple reagents
- only photometric tests using one reagents
- all tests including ISEs
- all tests using two calibrators
- only rate tests
- only ISE affected
- sporadic errors
- systematic errors

6.2.3 Preparation of reagents, calibrators, controls

To identify the cause of high, low, or erratic test results, first verify the preparation of your reagents, calibrators and controls. Answer the following questions and review the corresponding sections of the manual or help texts.

When preparing reagents, calibrators and controls, **always read and follow the directions on the package insert or value sheet.**

When preparing reagents:

- Has the catalogue number changed?
- What is the correct preparation procedure?
- When does the prepared reagent expire?
- When does the reagent lot expire?
- Was fresh, bacteria-free, deionized water or the proper diluent used in reconstitution?
- Is the current application on board?

When reconstituting controls:

- Was the control properly stored, e.g. was it frozen?
- Are the target values correct, especially if the lot number has change?
- Was the correct reconstitution volume used?
- When does the reconstituted material expire?
- Was a volumetric pipette used to reconstitute?
- Was the appropriate diluent used in reconstitution?
- What is the expiration date of the control lot?

When reconstituting calibrators:

- Has the lot number changed?
- If the lot number has changed, are calibrator setpoints correctly loaded from the calibrator barsheet?
- What is the correct reconstitution volume?
- What is the recommended storage?
- What is the expiration date of the reconstituted material?
- Was a volumetric pipette used to reconstitute?
- When does the calibrator lot expire?
- Was the appropriate diluent used for the reconstitution?

After verifying the above information, proceed to the next sections, which list additional causes for high, low, or erratic results.

6.2.4 High test results

The following conditions may cause high test results:

1. Incubation bath temperature too high, $> 37^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$.
Check the calibrator preparation.
Check the calibrator data; repeat calibration if necessary.
2. Poor calibration results.
Check the calibrator preparation. Repeat calibration, if necessary.
3. Calibrators not properly prepared (correct preparation intervals, volume).
Check calibrator preparation. Repeat calibration, if necessary.
4. Evaporation of sample, calibrator, or control.
Repeat analysis with fresh sample, calibrator, and/or control.
5. Reagents not properly prepared.
Check reagent preparation.
6. Information not correct on CALIBRATION, INSTALL screen.
Check CALIBRATION, INSTALL screen and compare the displayed data with the calibrator value sheet for specific test (concentration, position and unit).
7. Incorrect sampling or dilution of sample.
Check correct assembly of sample probe and pipettor parts.
Check all fittings, tubes and syringes for leaks and air bubbles.
8. Insufficient reagent volume.
Check reagent pipetting system and syringes for leaks.
Replace reagent bottle and repeat analysis.

6.2.5 Low test results

The following conditions may cause low test results:

1. Reagents expired.

 Prepare new reagents See application sheet (stability of the prepared reagents).

2. Reagents not properly stored.

 Prepare new reagents. See application sheet (proper storage).

3. Reagents not properly prepared.

 Prepare new reagents. See application sheet (proper preparation instructions).

4. Incubation bath temperature too low.

 Insert thermometer in the opening near a reagent probe. If bath temperature does not read $37^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$, call the BM Customer Technical Support.

5. Calibrators not properly prepared (correct preparation intervals, volume).

 Check calibrator preparation. Repeat calibration, if necessary.

6. Information not correct on CALIBRATION, INSTALL screen.

 Check CALIBRATION, INSTALL screen and compare the data with the calibrator value sheet for specific tests (concentration, position and unit).

7. Check sample for fibrin clotting.

8. Check sample pipetting system for leaks and air bubbles.

9. Check sample probe for contaminations or obstructions.

10. Check sample probe for barbs.

6.2.6 Erratic test results

The following may cause erratic test results:

1. Fibrin clots in one sample cup or in sample probe (if low values are printed for several samples).

Check sample for fibrin clots.

Clean probe as outlined in the Operators Manual. Perform an air purge (MAINT/UTILITY, MAINTENANCE, AIR PURGE screen). Rerun the relevant samples, if necessary.

Replace sample probe and sample probe seal.

2. Sample probe does not reach the bottom of the reaction cell when dispensing sample.

Check the spring mechanism to make sure the probe moves up and down freely during routine operation.

Check the sample probe for barbs.

3. Maintenance not performed properly or at recommended frequency on sample or reagent pipettor or probes.

If maintenance has not been performed, check the maintenance log (MAINT-LOG sub menu) and perform all overdue maintenance functions.

If maintenance was recently performed on the sample or reagent probes or pipettors:

Was air purge performed after maintenance (MAINT/UTILITY, MAINTENANCE, AIR PURGE screen)?

Were all parts correctly assembled?

Have all tubes and seals been checked for air leaks?

Were sample and reagent probe seals replaced?

4. Information not correct on MAINT/UTILITY, APPLICATION screen.

Check MAINT/UTILITY, APPLICATION screen and compare it with the instructions and the calibrator value sheets of the relevant tests.

5. Insufficient sample volume.

Repeat analysis with sufficient sample.

6. Contaminated incubation bath.

Check for particles in the incubation bath. If you detect particles, perform the incubation cleaning procedure as described in the Operator's Manual.

Check for foaming. Remove it with an incubator water exchange.

Check for sufficient detergent.

Exchange the incubator bath water (MAINT/UTILITY, MAINTENANCE, INCUB. WATER EXCHANGE screen).

7. Check for sufficient volume of detergent (NaOH-D). Check the volume of Hitergent and/or cell wash solution (NaOH-D) using the screen REAGENT, 1D1 TO 2D3 screen. Perform a cell wash (MAINT/UTILITY, MAINTENANCE, WASH screen, CELL option).

6.2.7 Problems with a single sample or control

If you are having problems with a single sample or control, follow the steps below:

1. Are samples and controls placed in the proper positions?
If yes, proceed with step 3.
If no, proceed with step 2.
2. Correct the sample or control placement, if necessary, and rerun the sample.
3. Are the control value ranges and lot numbers entered on QC screen correct?
If yes, proceed with step 5.
If no, proceed with step 4.
4. Correct the control lot number and/or value range on the QC screen.
5. Is the sample volume sufficient, or has a “Sample short” alarm occurred?
If yes, proceed with step 6.
If no, proceed with step 7.
6. Increase the sample volume in the cup and rerun the sample. Check the selected sample cup in the WORKPLACE, TEST SELECTION screen.
7. Is the sample integrity acceptable (fibrin, lipemia, haemolysis, icterus)?
If yes, proceed with step 8.
If no, proceed with step 9.
8. Check the sample material.
9. Was the appropriate sample type selected (serum, plasma, CSF, urine)?
If yes, proceed with step 11.
If no, proceed with step 10.
10. Check sample type.
11. Is the sample fresh?
If yes, proceed with step 13.
If no, proceed with step 12.
12. Check sample collection date and time, if necessary.
13. Were incorrect test selections made?
If no, proceed with step 15.
If yes, proceed with step 14.
14. Check test selections on the TEST SELECTION screen (WORKPLACE main menu).
Correct the relevant selections and rerun the sample.
15. Call the BM Customer Technical Support.

6.2.8 Problems with a single test

If you are having problems with a single test, follow the steps below:

1. Are reagents prepared properly?
If yes, proceed with step 3.
If no, proceed with step 2.
2. Prepare new reagent using the package insert.
3. Are reagents expired, contaminated or discoloured?
If yes, proceed with step 4.
If no, proceed with step 5.
4. Prepare a new reagent using the package insert.
5. Is the correct information entered on the MAINT/UTILITY, APPLICATION screen and in the CALIBRATION, INSTALL screen?
If yes, proceed with step 7.
If no, proceed with step 6.
6. If the parameters are not correct, correct them and repeat calibration.
7. Is the relevant test automatically masked by the system?
If yes, proceed with step 8.
If no, proceed with step 9.
8. Check the reagent positions and volumes in the REAGENTS screen.
If the test was masked due to insufficient or wrong placed reagent, prepare new reagent, place it on the system and rerun the sample. Check if there is sufficient wash solution or diluent on board.
9. Is the test manually masked?
If yes, proceed with step 10.
If no, proceed with step 11.
10. Check in the START CONDITIONS, MASKING screen why the test is masked. Unmask it, if possible, and rerun the sample.
11. Check if a Special Wash program, if necessary, is correctly requested (MAINT/UTILITY, -2-, SPECIAL WASH screen).
12. Call the BM Customer Technical Support.

6.2.9 Problems with tests with one calibration set point

If you are having problems with tests with 1 standard, follow the steps below:

1. Was the calibrator properly prepared and stored?
 - If yes, proceed with step 3.
 - If no, proceed with step 2.
2. Check calibrator stability and rerun samples.
3. Is the temperature of the incubation bath correct?
 - If yes, proceed with step 5.
 - If no, proceed with step 4.
4. Check if the incubation bath temperature is $37^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$. If the temperature is not within range, call the BM Customer Technical Support.
5. Perform a PHOTOMETER CHECK. Is the photometer check report within acceptable limits (< 16000)?
 - If yes, proceed with step 7.
 - If no, proceed with step 6.
6. Replace photometer lamp. Perform a cell blank. Calibrate the relevant tests.
7. Call the BM Customer Technical Support.

6.2.10 Problems with all tests with more than one calibration set point

If you are having problems with all tests with more than one calibration set point, follow the steps below:

1. Were calibrators properly prepared and stored?
If yes, proceed with step 3.
If no, proceed with step 2.
2. Prepare new calibrators and recalibrate.
3. Are the assigned calibrators in the correct position?
If yes, proceed with step 5.
If no, proceed with step 4.
4. Place calibrator in correct position and rerun samples.
5. Do the calibrator set points agree with the value sheets?
If yes, proceed with step 7.
If no, proceed with step 6.
6. Check if the calibration curve and trace in the CALIBRATION TRACE window of the STATUS screen (in the WORKING INFORMATION window of the CALIBRATION main menu).
7. Call the BM Customer Technical Support.

6.2.11 Problems with multiple tests (photometrics only)

If you are having problems with multiple photometric tests, follow the steps below:

1. Are there sufficient volumes of detergents? Perform a probe and a cell wash (MAINT/UTILITY, SPECIAL WASH screen). Check the volumes of Hitergent and/or cell wash solution in the REAGENTS main menu (1D1 to 2D3). Check the cell detergents.
If yes, proceed with step 3.
If no, proceed with step 2.
2. Replace needed detergent and rerun samples.
3. Is the R1+R2 probes aligned properly?
If yes, proceed with step 5.
If no, proceed with step 4.
4. Adjust the probes.
5. Is the R1+R2 systems leaking?
If no, proceed with step 8.
If yes, proceed with step 6.
6. Check connections in the probe arm and pipettor (of R1 and R2). Check the seals. Perform an air purge. (MAINT/UTILITY, MAINTENANCE, AIR PURGE screen).
7. Check sample probe for barbs, obstructions or leaks (drops).
8. Is the incubation bath free of contaminations?
If yes, proceed with step 10.
If no, proceed with step 9.
9. Perform incubation bath maintenance and check/clean the rinse unit.
10. Perform a PHOTOMETER CHECK. Is the photometer check report within acceptable limits (< 16000)?
If yes, proceed with step 12.
If no, proceed with step 11.
11. Replace the photometer lamp. Perform a cell blank. Calibrate the required tests.
12. Call the BM Customer Technical Support.

6.2.12 Problems with all tests, including ISEs

If you are having problems with all tests, including ion-selective tests, follow the steps below:

1. Is the sample probe obstructed, blunt or has it barbs?
If no, proceed with step 3.
If yes, proceed with step 2.
2. Clean/replace probe. Perform an air purge (MAINT/UTILITY, MAINTENANCE, AIR PURGE screen). Check proper dispense during air purge function.
3. Is the sample system leaking?
If no, proceed with step 5.
If yes, proceed with step 4.
4. Check the tubings and connections. Perform an air purge (MAINT/UTILITY, MAINTENANCE, AIR PURGE screen) and check if there are air bubbles in the syringe.
5. Were controls/calibrators/samples properly prepared and stored?
If yes, proceed with step 7.
If no, proceed with step 6.
6. Prepare new controls/calibrators.
7. Call the BM Customer Technical Support.

6.2.13 Problems with ISE, all results are erratic, excessive air in sipper syringe

If you are having problems with erratic ISE results and there is excessive air in the sipper (KCl), IS and Diluent syringes, follow the steps below:

1. Check reagent volumes in the ISE reagent bottles. Are reagent volumes sufficient and are the reagent lines correctly inserted in the bottles?
If yes, proceed with step 3.
If no, proceed with step 2.
2. Replace the reagents, if necessary. Make sure that the reagent lines reach the bottom of the bottles Perform an ISE prime of the relevant reagents (MAINT/UTILITY, MAINTENANCE, ISE PRIME screen: select the desired reagent or ALL).
3. Is reagent being dispensed out of the IS and DIL nozzles into the ISE dilution vessel? Does the sipper nozzle move to the bottom of the dilution vessel when the sipper syringe aspirates liquid?
If yes, proceed with step 5.
If no, proceed with step 10.
4. Is the system leaking?
If no, proceed with step 6.
If yes, proceed with step 5.
5. Check all tubings for leaks. Tighten loose fittings. Check the seals of the IS and Diluent syringes and of the sipper syringe. Perform an ISE prime, Option ALL, in the MAINT/UTILITY, MAINTENANCE, ISE PRIME screen.
6. Check the position of the measuring electrodes?
If yes, proceed with step 8.
If no, proceed with step 7.
7. Place the electrodes in their correct positions. Perform an ISE prime (IS+DIL on the MAINT/UTILITY, MAINTENANCE, ISE PRIME screen).
8. Is the reference electrode placed properly?
If yes, proceed with step 10.
If no, proceed with step 9.
9. Place reference electrode in its proper position. Perform an ISE prime with KCL on the MAINT/UTILITY, MAINTENANCE, ISE PRIME screen.
10. Call the BM Customer Technical Support.

6.2.14 Erratic ISE results

If you are having problems with erratic ISE results, follow the steps below:

1. Are the reagent lines placed in the corresponding ISE bottles?
 - If yes, proceed with step 3.
 - If no, proceed with step 2.
2. Check line placement, prime reagents and rerun samples.
3. Is there salt build-up on electrodes/syringes, or are there any loose connections (tubes, wires etc.)?
 - If yes, proceed with step 4.
 - If no, proceed with step 5.
4. Tighten any loose or leaky connections, then clean all salt build-up with a damp cloth and rerun the samples.
5. Is the dilution vessel overflowing, is the dilution vessel properly aspirated?
 - If yes, proceed with step 6.
 - If no, proceed with step 7.
6. Check sipper line tubing for kinks or occlusions. Check the probe for clogging and clean it, if necessary.
 - If both are fine, proceed with step 7.
7. Perform an ISE check on the MAINT/UTILITY, MAINTENANCE, ISE CHECK screen (n=30). The Ref. EMF is allowed to be within -7 mV to +7mV. The maximum deviation for the entire cycle range should be no more than ± 2 mV for REF. EMF. The measurement-to-measurement difference within the 30 cycles interval should not be bigger than 0.2 mV for Na, K and Cl.
 - If results are not within range, proceed with step 8.
 - If results are OK, proceed with step 9.
8. Replace ISE reference electrode. Perform an ISE prime (KCl option) on the MAINT/UTILITY, MAINTENANCE, ISE PRIME screen. Recalibrate and rerun samples.
9. Are air bubbles in the diluent syringe?
 - If yes, proceed with step 11.
 - If no, proceed with step 10
10. Replace the syringe seal and prime the diluent (MAINT/UTILITY, MAINTENANCE, ISE PRIME screen).

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11. Is the ISE unit contaminated (high potassium K-values)?
If yes, proceed with step 12.
If no, proceed with step 13.
12. Clean the ISE unit as described in chapter 3. Maintenance and Daily Care of the Operator's Manual.
13. Call the BM Customer Technical Support.

6.2.15 Problems with ISE, high internal standard values

If you are having problems with high ISE internal standard values, follow the steps below:

1. Is the IS EMF and the IS concentration value higher than normal?

The Internal Standard EMF deviates ± 2 mV (max.) from the mean value between Standard Low and Standard High. The concentration of the Internal Standard ideally lies at:

Na: 140 mmol/l

K: 5 mmol/l

Cl: 100 mmol/l.

If not, proceed with step 3.

If yes, proceed with step 2.

2. Check the IS reagent preparation, set new reagent, if required, prime and calibrate.
3. Perform an ISE check ($n=30$). The EMF of the reference electrode must be between -7 mV and +7 mV. The maximum deviation for the entire cycle range should be no more than ± 2 mV.
 - a) If all values (Na, K or Cl) are too high or too low, replace the reference electrode. The Level alarm is displayed in the printout adjacent to the respective EMF, if the following limits are exceeded:

Na:	-90 to -10 mV
K:	-90 to -10 mV
Cl:	80 to 160 mV
 - b) If only single values (Na, K or Cl) are outside the range, replace the respective electrode.
4. Call the BM Customer Technical Support.

6.2.16 Problems with low sodium, potassium and chloride values

If you are having problems with low sodium, low potassium, and low chloride values, follow the steps below:

1. Are fresh BM ISE Low or High Standard used?
If yes, proceed with step 3.
If no, proceed with step 2 to 7.
2. Recalibrate with fresh calibrators for ISEs.
3. Are fresh ISE solutions used?
If no, proceed with step 4.
If yes, proceed with step 5.
4. Prepare fresh Internal Standard and diluent.
Wipe the ISE reagent lines with a damp cloth (deionized water).
Replace the old IS and diluent with fresh reagent.
Prime the fresh IS and diluent reagents.
Perform an ISE wash (MAINT/UTILITY, MAINTENANCE, WASH screen).
Run 10 dummy samples, then recalibrate and check the ISE calibration report print-out.
5. Is microbial growth present in the ISE system (high K-values)?
If yes, proceed with step 6.
If no, proceed with step 7.
6. Clean the ISE unit with fresh ISE Cleaning Solution (MAINT/UTILITY, MAINTENANCE, WASH screen, ISE option) and recalibrate.
7. Are the correct compensator values entered?
If yes, proceed with step 9.
If no, proceed with step 8.
8. Check the compensator values for Na, K and Cl in the MAINT/UTILITY, -2-, APPLICATION, CALIB screen.
9. If problem recurs, call the BM Customer Technical Support.

6.2.17 Problems with a biased enzymes

If you are having problems with biased enzymes, follow the steps below:

1. Are the correct, temperature-dependent concentration values entered in the INSTALL screen (CALIBRATION main menu)?
If yes, proceed with step 3.
If no, proceed with step 2.
2. Enter the correct values and perform a calibration.
3. Is the incubation bath level above the photometer lens?
If yes, proceed with step 5.
If no, proceed with step 4.
4. Initiate a bath exchange in the MAINT/UTILITY, MAINTENANCE, INCUB. WATER EX-CHANGE screen.
5. Is the incubation bath temperature displayed on the SAMPLE TRACKING global menu $37\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$?
If yes, proceed with step 7.
If no, proceed with step 6.
6. Initiate a bath exchange in the MAINT/UTILITY, MAINTENANCE, INCUB. WATER EX-CHANGE screen.
7. Are the sample and reagent pipettor seals and connections all right?
If yes, proceed with step 9.
If no, proceed with step 8.
8. Correct any loose pipettor fittings. Change the pipettor seals, if needed.
9. Were the controls prepared using a volumetric pipette?
If yes, proceed with step 12.
If no, proceed with step 10.
10. Prepare new controls using a volumetric pipette.
11. Perform a full calibration.
12. Call the BM Customer Technical Support.

6.3 Data Alarms

This section includes a detailed description of all data alarms and displays remedies how to solve them.

6.3.1 Calculation disabled

Alarm:	Calculation disabled
Printed Alarm:	???
Alarm Code in DATA REVIEW screen:	X
Description:	<ol style="list-style-type: none">1. During calculation, the denominator became zero.2. An overflow occurred in logarithmic or exponential calculation.3. An isoenzyme-Q calculation was not possible, because an isoenzyme-P was not possible or because the isoenzyme-P could not be measured.
Remedy:	<p>Note: Result is left blank.</p> <ol style="list-style-type: none">a. Check the test that is flagged with an error message in the calculation.b. Dilute the sample and rerun the sample.c. Check the CALIB field in the MAINT/UTILITY, APPLICATION, CALIBR screen.d. Resume operation. If the alarm recurs, inform the BM Customer Technical Support.

6.3.2 Absorbance over

Alarm:	Absorbance over
Printed Alarm:	ABS?
Alarm Code in DATA REVIEW screen:	Z
Description:	The absorbance value to be used for calculation after cell blank correction exceeded 3.3 ABS.
Remedy:	
If only one sample is affected:	Is sample lipemic or has it an extremely high value? Follow the instructions of your laboratory.
If only one test is affected:	Check reagent preparation for that test.
If all samples are affected:	<ol style="list-style-type: none">a. Check if the optical path of the photometer is translucent. Remove any obstacle in the optical path of the photometer. Make sure that the lamp is on.b. Perform an incubation bath exchange (MAINT/UTILITY, MAINTENANCE, INCUB. WATER EXCHANGE screen)c. Clean the incubation bath, if necessary. Follow the instructions in the Operators Manual.d. Perform a photometer check and check the printout (Abs. <16000).e. Exchange the photometer lamp, if necessary (see Operator's Manual, chapter 3).f. If the alarm still persists, inform the BM Customer Technical Support.
Additional Information:	
If all samples are affected intermittently, the error message CELL? is displayed	If a reaction cell is damaged, replace the cell segment.

6.3.3 Absorbance maximum over (non-linear calibration)

Alarm	Absorbance maximum over (non-linear calibration)
Printed Alarm:	>AMAX
Alarm Code in DATA REVIEW screen:	>
Description:	For the logistic methods 3P, 4P and 5P Logit-Log the absorbance value for the sample will be assessed prior to result calculation. If the absorbance of a sample is found equal or greater than the maximum theoretical concentration (a sample with infinite concentration), the data alarm “>AMAX” is printed out.
	The result field will be left blank on the report and the DATA REVIEW screen. This “blank result” is transmitted, together with the alarm code “>” to the host.
Remedy:	Dilute the sample and rerun. If automatic rerun is programmed, the sample will be rerun automatically with a decreased sample volume.

6.3.4 ADC abnormal

Alarm:	ADC abnormal
Printed Alarm:	ADC?
Alarm Code in DATA REVIEW screen:	A
Description:	The ADC (analogue-digital converter) value is abnormal.
Remedy:	<ol style="list-style-type: none">a. If any other instrument alarms are present, correct those alarms and resume operation.b. Touch MAINT/UTILITY; go to the MAINTENANCE screen and perform a reset.c. If problem recurs, call the BM Customer Technical Support.

6.3.5 Calculation test error

Alarm:	Calculation test error
Printed Alarm:	Calc?
Alarm Code in DATA REVIEW screen:	%
Description:	A data alarm has occurred at the test which is needed for the calculation. This is not valid for the errors: <ul style="list-style-type: none">- Calculation disabled (???)- Test-to-test compensation disabled (Cmpt!)- Expected value limit over (H,L)
Remedy:	Check and correct the data alarm on the test to be used for calculation. Rerun the affected test, if necessary.

6.3.6 Calibration result abnormal

Alarm:	Calibration result abnormal
Printed Alarm:	CalErr
Alarm Code in DATA REVIEW screen:	!
Description:	Any alarm (other than Calib), e.g. S1Abs?, Dup., Std?, has occurred during the last calibration.
Note:	The alarm CalErr appears on each control and patient sample using the affected test, until the calibration of this test is successful.
Remedy:	<ol style="list-style-type: none">a. Correct the condition causing the alarm that occurred during calibration.b. Recalibrate.c. If the alarm recurs, call the BM Customer Technical Support.

6.3.7 Calibration error

Alarm:	Calibration error
Printed Alarm:	Calib
Alarm Code in DATA REVIEW screen:	-
Description:	Photometric assays: During calibration, a K factor difference of $\pm 20\%$ or more between the current and the previous value is determined.
Remedy:	<ol style="list-style-type: none">Correct any other instrument and/or data alarms.Check standards, reagents, and controls. Recalibrate, if necessary.If the alarm recurs, call the BM Customer Technical Support.
Additional Information:	The Calib alarm is a warning only, not necessarily indicating a problem with the calibration. Check the changed control value of the test before accepting the new calibration result.
ISE:	The measured compensator concentration (S3) differs more than specified (in the COMPENSATE LIMIT fields for Na, K and Cl, in the CALIB screen, MAINT/UTILITY main menu, APPLICATION sub menu) from the previous compensator concentration. The same is valid for the slope.
Formula ISE:	$\frac{\text{previous value} - \text{current value}}{(\text{previous value} + \text{current value}) / 2} \cdot 100\%$

6.3.8 Cell blank abnormal

Alarm:	Cell blank abnormal
Printed Alarm:	Cell?
Alarm Code in DATA REVIEW screen:	Q
Description:	The difference between the current passed cell blanks and the previous cell blank measured by the cell blank is greater than 0.1 ABS (MAINT/UTILITY, MAINTENANCE, CELL BLANK screen).
Remedy:	<ol style="list-style-type: none">a. Check that reaction cells are not contaminated or cracked.b. Ensure that there is no excessive foaming or particles in the incubation bath.c. Wipe the outside of the reaction cells with a cloth moistened with incubation bath water.d. Ensure that the rinse water pressure is adequate. The cells must be completely filled.e. Touch MAINT/UTILITY; go to the MAINTENANCE, WASH screen and perform a cell wash. Check if there is sufficient NaOH-D (minimum of 60 mL) in the wash positions 1D2 and 2D2.f. Perform an incubation bath exchange. (Touch MAINT/UTILITY, then MAINTENANCE and INCUB. WATER EXCHANGE).g. Call up the MAINTENANCE screen and perform the CELL BLANK function. If the results for the first reagent cell are > 16000, or if the deviation of the reagent cells Küvetten 2-160 ≠ ±800, replace the reagent cells. Subsequently, repeat the reagent cell blank measurement.h. If the alarm recurs, call the BM Customer Technical Support.

6.3.9 Test-to-test compensation error

Alarm:	Test-to-test compensation error
Printed Alarm:	Cmp.T
Alarm Code in DATA REVIEW screen:	C
Description:	<ol style="list-style-type: none">1. In a test-to-test compensation calculation, any data alarm other than those shown below is indicated for the compensation test data used for calculation.2. In an isoenzyme-Q concentration calculation, any data alarm other than those shown below is indicated for the isoenzyme-P concentration:<ul style="list-style-type: none">– Calculation disabled (???)– Test-to-test compensation disabled (Cmp.T!)– Overflow (Over)– Random error (QC) (Random)– Systematic error (System)– Expected value limit over (H, L)
Exceptions:	
Remedy:	<ol style="list-style-type: none">a. Correct the data alarm for the test that caused the error message.b. Rerun the sample.

6.3.10 Test-to-test compensation disabled

Alarm:	Test-to-test compensation disabled
Printed Alarm:	Cmp.T!
Alarm Code in DATA REVIEW screen:	M
Description:	<ol style="list-style-type: none">1. During test-to-test compensation calculations, the denominator became zero.2. The test used for test-to-test compensation was not measured.3. The test used for test-to-test compensation has the data alarms “calculation disabled (???)” or “test-to-test compensation disabled (Cmp.T!)”.4. The test used in the compensation formula has a data alarm, e.g. “Sampl”, “Reagn”, etc. so that no result could be issued. the result field remains empty.
Remedy:	<ol style="list-style-type: none">a. Correct the data alarm for the compensated test.b. Rerun the sample.

6.3.11 Duplicate error

Alarm:	Duplicate error
Printed Alarm:	Dup
Alarm Code in DATA REVIEW screen:	Not Displayed (calibration data)
Description:	<p>An error message is calculated as follows:</p> <ol style="list-style-type: none">1. Each calibrator is measured twice (Abs 1 and Abs 2).2. The absorbance dup limit is firstly calculated in absolute numbers and then in percentages, if needed.

3. Is the ABS difference <ABS DUP Limit, as entered on the MAINT/UTILITY screen?
If no, proceed with step 5.
If yes, proceed with step 4.
4. The result calculations are continued.
No “Dup” alarm is issued.
5. Is the % error < the % Dup limit?
If no, proceed with step 6.
If yes, proceed with step 4.
6. A “dup” alarm is issued for this result.
 - a. Check reagent preparation and expiration date. Prepare new reagent, if necessary, and recalibrate.
 - b. Check the **Duplicate Limit** on the MAINT/UTILITY screen.
 - c. Check the sample pipettor for barbs.
 - d. If the alarm recurs, inform the BM Customer Technical Support.

Remedy:

Additional Information:

The Dup alarm is triggered when the replicate assays of a standard are outside of the limits as programmed via the Duplicate Limit field of the test's MAINT/UTILITY, Application screen. If this alarm occurs for one or more standards (S1, S2, etc.), it results in a Std? alarm being issued. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup and Sens.

6.3.12 Edited test

Alarm:	Edited test
Printed Alarm:	Edited
Alarm Code in DATA REVIEW screen:	*
Description:	A result was overwritten on the DATA REVIEW screen (WORKPLACE main menu) or a rerun result was overwritten. The result is marked with an “**” on the DATA REVIEW screen; on the patient report printouts the alarm is indicated by “Edited”. The edited flag will not appear for a control.

6.3.13 Outside of reference value

Alarm:	Outside of upper / lower reference value
Printed Alarms:	H, L, adjacent to the result
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	<p>H: For patient samples, the calculated concentration is larger than the upper limit of the expected value. For control samples, a concentration exceeded the value specified on the QC, INSTALL screen (2S-limit).</p> <p>L: For patient samples, the calculated concentration is smaller than the lower limit of the expected value. For control samples, a concentration was lower than the value specified on the QC, INSTALL screen (2S-limit).</p>
Note:	These alarms DO NOT cause an incomplete sample status flag (I) in the DATA REVIEW screen. The alarms H and L are only an additional information, the relevant result is correct.

6.3.14 Internal standard concentration abnormal

Alarm:	ISE Internal standard concentration abnormal
Printed Alarm:	I.Std
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	The concentration of Internal Standard solution was not within the following range: Na^+ : 120.0 mmol/L to 160.0 mmol/L K^+ : 3.0 mmol/L to 7.0 mmol/L Cl^- : 80.0 mmol/L to 120.0 mmol/L
Remedy:	<ol style="list-style-type: none">a. If other ISE alarms occur than "I.Std", correct these alarms first.b. Check the Internal Standard reagent volume and preparation. If necessary, prepare fresh reagent, prime and recalibrate.c. If the EMF of the IS solution is normal on the calibration report, check the ISE standards and diluent syringe. The Int. Std. EMF lies ideally midway between the Low and the High Standard (permitted deviation ± 2). The ideal concentration of the IS solution is Na: 140 mmol/L, K: 5 mmol/L, Cl: 100 mmol/L.d. If the alarm recurs, inform the BM Customer Technical Support.

6.3.15 Level error

Alarm:	Level error
Printed Alarm:	Level
Alarm Code in DATA REVIEW screen:	L
Description:	During the measurement of the Internal Standard solution, the EMF was not within the following range: Na^+ : -90,0 mV to -10 mV K^+ : -90.0 mV to -10 mV Cl^- : 80.0 mV to 160.0 mV
Remedy:	<ol style="list-style-type: none">a. Check for sufficient ISE reagent volume and make sure that the reagent lines are in the bottles.b. Check for excess air in the ISE syringe (a small number of air bubbles is normal). Examine pipettors and electrodes for leaks.c. Check the reference electrode placement.d. Check for salt bridges and clean if necessary.e. If other ISE alarms are present, correct those alarm conditions and recalibrate.f. Exchange the reference solution (KCl), perform an ISE prime recalibrate then.

- g. Perform an ISE check (N=30), on the MAINTENANCE screen,

If all values (Na, K, Cl) are too high or too low, exchange the reference electrode. EMF values must lie between -7 mV and +7 mV. The maximum deviation over the entire cycle range should not be more than ± 2 mV.

If only single values (Na, K or Cl) are outside the range, exchange the respective electrode.

- h. Perform an ISE prime. Run 10 dummy samples and calibrate the respective electrode.
- i. If the alarm recurs, inform the BM Customer Technical Support.

6.3.16 Technical value limit over

Alarm:	Technical value limit over
Printed Alarm:	LIMTH or LIMTL
Alarm Code in DATA REVIEW screen:	\$
Description:	<p>The measured value is outside the technical limit range as entered on the MAINT/UTILITY, APPLICATION, RANGE screen.</p> <p>Greater than the upper limit value (LIMTH).</p> <p>Less than the lower limit value (LIMTL).</p>
Remedy:	<ol style="list-style-type: none">a. In the case of LIMTH, rerun using decreased sample volume and check the measured value.b. In the case of LIMTL, rerun using increased sample volume and check the measured value.c. Check the Technical Limit on the MAINT/UTILITY screen.d. Dilute the sample (for LIMTH), if necessary.
Additional Information:	In the automatic rerun mode, the sample is automatically diluted by the system using a reduced or increased sample volume.

6.3.17 Reaction limit over at all points (Limit0)

Alarm: Reaction limit over at all points (rate assays only, including two-point rate assays)

Printed Alarm: Limit0

Alarm Code in DATA REVIEW screen: I

Description: The main wavelength absorbance exceeds the reaction limit at all photometric points that are used for calculation. No photometric measurement point lies within the reaction limit.

Remedy:

- a. Check the stability and preparation of the reagent. Replace the reagent, if necessary.
- b. Dilute and rerun the sample.
- c. Check in the calibration printout the initial absorbance (at the main wavelength) of Standard 1 and compare it with the absorbance limit on the MAINT/UTILITY, APPLICATION, ANALYZE screen.
- d. If the alarm recurs, inform the BM Customer Technical Support.

Additional Information: See Manual, Vol. System Description, chapter 5.4.3 Absorbance Limit.

The Abs?, Limt (0,1, 2), and Lin. (Lin.8) alarms are detected for all sample types. If this alarm occurs for a standard (Std1, Std2, etc.), it results in a Std? alarm. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup, Sens and S1Abs?.

6.3.18 Reaction limit over at 1 point (Limit1)

Alarm:	Reaction limit over at 1 point (rate assays only, including two-point rate assays)
Printed Alarm:	Limit1
Alarm Code in DATA REVIEW screen:	J
Description:	The main wavelength absorbance exceeds the reaction limit at the second and subsequent photometric points used for calculation. One photometric measurement point is within the reaction limit.
Remedy:	<ol style="list-style-type: none">a. Check the reaction for linearity on the REACTION MONITOR screen (WORKPLACE, DATA REVIEW).b. Check the stability and preparation of the reagent. Replace reagent, if necessary.c. Dilute and rerun the sample.d. Check in the calibration printout the initial absorbance (at the main wavelength) of Standard 1 and compare it with the absorbance limit on the MAINT/UTILITY, APPLICATION, ANALYZE screen.e. If the alarm recurs, inform the BM Customer Technical Support.
Additional Information:	<p>See Manual, Vol. System Description, chapter 5.4.3 Absorbance Limit.</p> <p>The Abs?, Limit (0,1, 2), and Lin. (Lin.8) alarms are detected for all sample types. If this alarm occurs for a standard (Std1, Std2, etc.), it results in a Std? alarm. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup, Sens and S1Abs?.</p>

6.3.19 Reaction limit over(Limt2)

Alarm: Reaction limit over (rate assays only, including two-point rate assays)

Printed Alarm: Limt2

Alarm Code in DATA REVIEW screen: K

Description: The main wavelength absorbance exceeded the reaction limit at the third or fourth and subsequent photometric points used for calculation. Two or more photometric points lie within the reaction limit.

Remedy:

- a. Check the reaction for linearity on the REACTION MONITOR screen (WORK-PLACE, DATA REVIEW).
- b. Check the stability and preparation of the reagent. Replace reagent, if necessary.
- c. Dilute and rerun the sample.
- d. Check in the calibration printout the initial absorbance (at the main wavelength) of Standard 1 and compare it with the absorbance limit on the MAINT/UTILITY, APPLICATION, ANALYZE screen.
- e. If the alarm recurs, inform the BM Customer Technical Support.

Additional Information: See Manual, Vol. System Description, chapter 5.4.3 Absorbance Limit.

The Abs?, Limt (0,1, 2), and Lin. (Lin.8) alarms are detected for all sample types. If this alarm occurs for a standard (Std1, Std2, etc.), it results in a Std? alarm. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup, Sens and S1Abs?.

16.3.20 Linearity abnormal (Lin.)

Alarm:

Linearity abnormal (for rate assays only)

Printed Alarm:

Lin.

Alarm Code in DATA REVIEW screen:

W

Description:

If the number of photometric measurement points within the reaction limit range is nine or more, the absorbance change per minute of the first and last six points is used for the linearity check. If the calculated value exceeds the check value that was entered in the ALARM SETTING window (MAINT/UTILITY, SYSTEM screen), the data alarm “Lin.” is issued together with the measured value.

Remedy:

- a. Rerun the sample with a reduced sample volume.
- b. Check the photometer lamp (MAINT/UTILITY, MAINTENANCE, PHOTOMETER CHECK screen).
- c. Ensure that the incubation bath is free of debris. Clean the incubation bath, if necessary, following the instructions in the Operators Manual.
- d. Check the stirring mechanism by performing a mechanism check from the MAINT/UTILITY, MAINTENANCE screen.
- e. Check Linearity Limit on the MAINT/UTILITY, SYSTEM, ALARM SETTINGS screen.
- f. If the alarm recurs, inform the BM Customer Technical Support.

Data Alarms

Additional Information:

The Abs?, Limt (0,1, 2), and Lin. (Lin.8) alarms are detected for all sample types. If this alarm occurs for a standard (Std1, Std2, etc.), it results in a Std? alarm. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup, Sens and S1Abs?.

If the absorbance rate/minute is less than 60×10^{-4} , the detection of linearity is disabled to minimise false “Lin.” and “Lin.8” alarms.

Samples with extremely high analyte concentration / activity have high initial rates and are flagged with a “Lin.” or “Lin.8” alarm; however, when an “Abs?” or “Limt (0,1,2)” alarm occurs the “Lin.” and “Lin.8” alarms are superseded by it. It is important that the ABS. LIMIT (Inc/Dec) field of each test’s MAINT/UTILITY, APPLICATION screen is programmed in accordance with the appropriate application.

6.3.21 Linearity abnormal (Lin.8)

Alarm:	Linearity abnormal (for rate assays only)
Printed Alarm:	Lin.8
Alarm Code in DATA REVIEW screen:	F
Description:	If the number of photometric points within the reaction limit range is eight or less, the absorbance change per minute of the first and last three points are used for the linearity check. If the calculated value exceeds the check value (by the percentage) that was entered in the ALARM SETTING window (MAINT/UTILITY, SYSTEM screen), the data alarm “Lin.” is issued together with the measured value.
Remedy:	<ol style="list-style-type: none">a. Dilute and rerun the sample.b. Check the photometer lamp.c. Ensure incubation bath is free of debris. Clean the incubation bath, if necessary. Follow the instructions in the Operators Manual.d. Check the stirring mechanism by performing a mechanism check from the MAINT/UTILITY, MAINTENANCE screen.e. Check Linearity Limit on the MAINT/UTILITY, SYSTEM, ALARM SETTINGS screen.f. Resume operation. If the alarm recurs, call the BM Customer Technical Support.

Data Alarms

Additional Information:

The Abs?, Limt (0,1, 2), and Lin. (Lin.8) alarms are detected for all sample types. If this alarm occurs for a standard (Std1, Std2, etc.), it results in a Std? alarm. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup, Sens and S1Abs?.

If the absorbance rate/minute is less than 60×10^{-4} , the detection of linearity is disabled to minimise false “Lin.” and “Lin.8” alarms.

Samples with extremely high analyte concentration / activity have high initial rates and are flagged with a “Lin.” or “Lin.8” alarm; however, when an “Abs?” or “Limt (0,1,2)” alarm occurs the “Lin.” and “Lin.8” alarms are superseded by it. It is important that the ABS. LIMIT (Inc/Dec) field of each test’s MAINT/UTILITY, APPLICATION screen is programmed in accordance with the appropriate application.

6.3.22 ISE Preparation abnormal

Alarm:	ISE preparation abnormal
Printed Alarm:	Margin
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	The troubleshooting procedure depends on the slope value. Thus, check first the Slope value.
Possibility 1	<p>The slope lies within the following limits:</p> <p>Na^+, K^+: between 45,0 and 49,9 mV, or bigger than 68,0</p> <p>Cl^-: between -35,0 and -39,9, or less than -68 mV.</p>
Remedy:	If the slope increases slowly over time and if the control values are within range, prepare a new electrode in order to perform an exchange after routine operation.
Possibility 2	<p>The slope lies within the following range:</p> <p>Na^+, K^+: between 50,0 and 68 mV</p> <p>Cl^-: between -68,0 and -40 mV.</p>
Remedy:	<ol style="list-style-type: none">a. Check the control results. If they are OK, perform step b. at the end of routine operation. If they are not OK, perform step b. immediately.b. Perform an ISE maintenance. Prime the solutions and recalibrate.

6.3.23 Noise error

Alarm:	Noise error
Printed Alarm:	Noise
Alarm Code in DATA REVIEW screen:	N
Description:	The ISE measuring signal is unstable.
Remedy:	<ul style="list-style-type: none">a. Check for sufficient ISE reagent volume and make sure that the reagent lines are in the bottles. Perform an ISE prime for all reagents.b. Check for excess air in the ISE reagent lines; examine pipettors, diluent vessel, external ISE drain and electrodes for leaks and salt bridges.c. If only one test is affected, check the relevant electrode. If all tests are affected, check the reference electrode.d. Check the sipper syringe for obstructions. Check the placement of the ISE electrodes and the sipper syringe for leaks.e. If the alarm occurred during calibration, correct the problem and recalibrate.f. If the alarm occurred during the sample processing, rerun the sample.g. If the alarm recurs, inform the BM Customer Technical Support.

6.3.24 Overflow

Alarm:	Overflow
Printed Alarm:	Over
Alarm Code in DATA REVIEW screen:	O
Description:	The result cannot be output in the specified number of digits. A blank space is left for the result.
Remedy:	<ol style="list-style-type: none">a. Dilute the sample and rerun.b. If all samples are concerned, control the digits on the right-hand side of the decimal point in the CALIBRATION, INSTALL, Std(1) screen.

6.3.25 Prozone error

Alarm:	Prozone error
Printed Alarm:	Prozon
Alarm Code in DATA REVIEW screen:	P
Description:	In a one-point or two-point assay with prozone check, the prozone check value (PC value) exceeds the specified upper/lower limit. Refer to the Vol. System Description, chapter 5. Theory Principles for more details.
Remedy:	<ol style="list-style-type: none">a. Repeat the measurement with the manually diluted sample volume or select the reduced sample volume option.b. Check if the reagent has been prepared properly.c. Check the upper/lower limit (Prozone Limit) on the MAINT/UTILITY, APPLICATION, ANALYZE screen.d. If the alarm recurs, inform the BM Customer Technical Support.

6.3.26 QC error 1

Alarm:	QC error 1
Printed Alarm:	QCErr1
Alarm Code in DATA REVIEW screen:	+
Description:	<ol style="list-style-type: none">1. The control X data value or control Y data value is larger than 3SD.2. The control X data value or control Y data value is smaller than -3SD.
Remedy:	<p>Note: This check is performed only when RULE 1-3SD is selected.</p> <ol style="list-style-type: none">a. Check if calibrators, controls, and reagents are properly prepared and stored.b. Check that calibrators and controls are properly positioned on the sample disk 2.c. Check proper lot number and expiration dates of calibrators, controls and reagents.d. Check that the mean value and SD for the specified assay are entered correctly on the QC, INSTALL screen.e. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.f. If the alarm recurs, call the BM Customer Technical Support.

6.3.27 QC error 2

Alarm:	QC error 2
Printed Alarm:	QCErr2
Alarm Code in DATA REVIEW screen:	+
Description:	<ol style="list-style-type: none">1. The control X data value or control Y data value is larger than 2.5SD.2. The control X data value or control Y data value is smaller than -2.5SD.
Remedy:	<p>Note: This check is performed only when RULE 1-2.5SD is selected.</p> <ol style="list-style-type: none">a. Check that calibrators, controls, and reagents are properly prepared and stored.b. Check that calibrators and controls are properly positioned on the sample disk 2.c. Check proper lot number and expiration dates of calibrators, controls and reagents.d. Check that the mean and SD for the specified assay are entered correctly via the QC, INSTALL screen.e. Check that calibrator values are correct via the CALIBRATION, INSTALL screen.f. Resume operation. If the alarm recurs, call the BM Customer Technical Support.

6.3.28 Random error

Alarm:	Random error
Printed Alarm:	Random
Alarm Code in DATA REVIEW screen:	@
Description:	<ol style="list-style-type: none">1. Any of the current and (N-1) preceding control X values are larger than 2SD and any of the current and (N-1) preceding control Y values are smaller than -2SD (range > 4 SD).2. Any of the current or preceding control X values are smaller than -2SD and any of the current or preceding control Y values are larger than 2SD
Legend for terms used in the QC alarm descriptions:	X: Control number entered for X on REAL TIME QC. Y: Control number entered for Y on REAL TIME QC. Mean, SD: Values specified on REAL TIME QC. Data: Measured value of the control.
Remedy:	Note: The check is performed only, if RULE R-4SD is selected. N = Control run number entered on REAL TIME QC screen. <ol style="list-style-type: none">a. Check that calibrators, controls, and reagents are properly prepared and stored.b. Check calibrators and controls are properly positioned on the sample disk 2.c. Check proper lot number and expiration dates of calibrators, controls, reagents.d. Check the mean and SD for the specified assay are entered correctly on the QC, INSTALL screen.e. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.f. Resume operation. If the alarm recurs, call the BM Customer Technical Support

6.3.29 Reagent short

Alarm:	Reagent short
Printed Alarm:	Reagn
Alarm Code in DATA REVIEW screen:	T
Description:	<p>There is insufficient or no reagent volume in the reagent bottle (photometric).</p> <p>If the alarm is associated with sodium, potassium and chloride values, it indicates insufficient ISE reagents.</p>
Remedy:	
For photometrics:	<ol style="list-style-type: none">a. Display the REAGENTS main menu; verify adequate reagent volumes. Replace new reagent, as necessary. If the system is in operation, it can be interrupted by pressing the INTERRUPT button (REAGENTS main menu) to allow reagent replacement.b. If adequate reagent volumes are present and alarm recurs, ensure that the reagent probe is correctly aligned and the probe wire is attached correctly.c. If the alarm recurs, call the BM Customer Technical Support.
For ISEs:	<ol style="list-style-type: none">a. Touch REAGENTS and check if the reagent volumes are sufficient. If the reagent volumes are OK check the volumes on the REAGENT STATUS screen. Update the values manually, if necessary.b. Instrument in STANDBY mode: Replace the reagent, if necessary, and press the RESET button to update the new reagent volume; (you can also enter the volume manually). Prime the new reagent and recalibrate then.c. If the alarm recurs, inform the BM Customer Technical Support.

6.3.30 Value outside repeat limit

Alarm:	Value outside upper/lower repeat limit
Printed Alarm:	ReptH or ReptL
Alarm Code in DATA REVIEW screen:	=
Description:	The measured value is outside the repeat limit programmed on the MAINT/UTILITY, APPLICATION, RANGE screen. ReptH = The result is greater than the upper limit value. ReptL = The result is less than the lower limit value.
Remedy:	This alarm can be enabled/disabled on the MAINT/UTILITY, APPLICATION, RANGE screen. If enabled, the analyzer can also be programmed to repeat this test automatically with normal sample volume.

6.3.31 Sample value abnormal

Alarm:	Sample value abnormal
Printed Alarm:	R.Over
Alarm Code in DATA REVIEW screen:	&
Description:	Only for ISEs: The concentration of sample was outside the following range: Na^+ : 10 mmol/L to 250 mmol/L K^+ : 1 mmol/L to 100 mmol/L Cl^- : 10 mmol/L to 250 mmol/L
Remedy:	Call the BM Customer Technical Support.

6.3.32 Sample short

Alarm:	Sample short
Printed Alarm:	Sampl
Alarm Code in DATA REVIEW screen:	V
Description:	There is insufficient sample volume in the sample cup.
Remedy:	<ol style="list-style-type: none">a. Add sample volume and rerun.b. Check if the actually used sample tube/cup on the disk corresponds to the one selected on the WORKPLACE, TEST SELECTION screen.c. Check the sample probe adjustment and the connecting wires.d. If the alarm recurs, inform the BM Customer Technical Support.

6.3.33 SD error

Alarm:	SD error
Printed Alarm:	SD!
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	During non-linear or multipoint linear calibration the SD value is larger than the SD limit that was programmed on the MAINT/UTILITY, APPLICATION, ANALYZE screen.
Note:	The calibration result is updated.
Remedy:	<ol style="list-style-type: none">a. Check the calibrator positions on sample disk 2 on the CALIBRATION, CALIBRATORS screen.b. Check the SD limit on the MAINT/UTILITY, APPLICATION, ANALYZE screen.c. For a calibration with automatic standard dilution: Check whether the ratio between concentration, sample, diluent volume and diluted sample is correct on the MAINT/UTILITY, APPLICATION, ANALYZE, STANDARDS screen.d. Check the preparation of the manually prediluted samples and the expiration dates of standards and reagents; recalibrate the affected tests.e. Check the standard concentrations on the CALIBRATION screen.f. If the alarm recurs, inform the BM Customer Technical Support.
Additional Information:	The SD! alarm indicates an error in calibration of non-linear tests (tests calibrated with more than two standards) and is programmed via the SD Limit field of the test's MAINT/UTILITY, APPLICATION screen.

6.3.34 Sensitivity error

Alarm:	Sensitivity error
Printed Alarm:	Sens
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	<p>Sensitivity is checked for linear (2 to 6 points), non-linear or isoenzyme-P calibration.</p> <p>This alarm is indicated if the difference in absorbance per unit of the test between Std1 and StdN* is smaller than the sensitivity limit (input value).</p> <p>*N =2: = two calibration points (linear 2-point calibration or isoenzyme-P). Sensitivity calculation with Standard 1 and 2.</p> <p>*N = 2-6: = Multipoint calibration, Sensitivity calculation with Standard 1 and Span point.</p>
Note:	For span calibration, the previous S1 mean value is used for the sensitivity check. This is valid for linear and non-linear calibrations.
Remedy:	<ol style="list-style-type: none">a. Check preparation and expiration dates of calibrators and reagents. Recalibrate the affected test.b. Check the sample pipettor for leaks and recalibrate the affected test.c. Check the sensitivity limit (MAINT/UTILITY, APPLICATION, CALIB screen) and recalibrate.d. If the alarm recurs, inform the BM Customer Technical Support.

6.3.35 Slope abnormal

Alarm:	Slope abnormal
Printed Alarm:	Slope?
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	Depending on the slope value, there are two possibilities for the remedy. Check first the slope value.
Possibility 1	The slope is within the following range: Na^+, K^+ : smaller than 45 mV Cl^- : bigger than - 35 mV
Remedy:	<ol style="list-style-type: none">If the slope has decreased gradually over time (CALIBRATION, STATUS, CALIBRATION TRACE screen), replace the electrode (see Operators Manual, chapter 3. Maintenance and Daily Care).If the slope decreases abruptly or shows other irregularities, check if there are leaks, contaminations or air bubbles in the ISE system.Check standards and reagents.Prime all reagents and recalibrate.Perform an ISE maintenance, prime the solutions, condition and recalibrate.If the alarm, call the BM Customer Technical Support.
Possibility 2	The slope is within the following range: Na^+, K^+ : between 50.0 and 68,0 mV Cl^- : between -68,0 and -40.0 mV
Remedy:	<ol style="list-style-type: none">Check the control results.Perform an ISE maintenance, prime the solutions, condition and recalibrate.

6.3.36 Standard error

Alarm:	Standard error
Printed Alarm:	Std?
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	<ol style="list-style-type: none">1. During photometric calibration one of the following alarms occurred: ADC abnormal, cell blank abnormal, sample short, reagent short, absorbance over, reaction limit over, linearity abnormal, prozone error, duplicate error, calculation disabled or Standard 1 absorbance abnormal.2. During calibration, no calculation could be performed.3. During non-linear calibration an extreme value occurred.4. During ISE calibration one of the following alarms occurred: ADC abnormal, sample short, calculation disabled, noise error or level error. The calibration is invalid.
Note:	The calibration is not updated, if this alarm is issued.
Remedy:	<ol style="list-style-type: none">a. Correct any other instrument and/or data alarm.b. Recalibrate the tests.c. Prepare fresh calibrator; place it on sample disk 2 and recalibrate.d. Prepare fresh reagent and recalibrate.e. If the alarm recurs, call the BM Customer Technical Support.

6.3.37 Systematic error 1

Alarm:	Systematic error 1
Printed Alarm:	Systm1
Alarm Code in DATA REVIEW screen:	#
Description:	<ol style="list-style-type: none">1. The control X and Y data values are larger than 2SD.2. The control X and Y data values are smaller than -2SD.
Note:	This check is performed only when RULE 2-2SD is selected.
Remedy:	<ol style="list-style-type: none">a. Check that calibrators, controls, and reagents are properly prepared and stored.b. Check that calibrators and controls are properly positioned on the sample disk 2.c. Check proper lot number and expiration dates of calibrators, controls and reagents.d. Check that the mean and SD for the specified assay are entered correctly via the QC, INSTALL screen.e. Check that calibrator values are correct via the CALIBRATION, INSTALL screen.f. If the alarm recurs, call the BM Customer Technical Support.

6.3.38 Systematic error 2

Alarm:	Systematic error 2
Printed Alarm:	Systm2
Alarm Code in DATA REVIEW screen:	#
Description:	<ol style="list-style-type: none">1. The last two control X data values are larger than 2SD.2. The last two control X data values are smaller than -2SD.3. The last two control Y data values are larger than 2SD.4. The last two control Y data values are smaller than -2SD.
Note:	This check is performed only when RULE 2-2SD is selected.
Remedy:	<ol style="list-style-type: none">a. Check how long the controls have been on board.b. Check that calibrators, controls, and reagents are properly prepared and stored.c. Check that calibrators and controls are properly positioned on the sample disk 2.d. Check proper lot number and expiration dates of calibrators, controls and reagents.e. Check that the mean and SD for the specified assay are entered correctly on the QC, INSTALL screen.f. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.g. If the alarm recurs, call the BM Customer Technical Support.

6.3.39 Systematic error 3

Alarm:	Systematic error 3
Printed Alarm:	Systm3
Alarm Code in DATA REVIEW screen:	#
Description:	<ol style="list-style-type: none">1. The last two control X and last two control Y data values are larger than 1SD.2. The last two control X and last two control Y data values are smaller than -1SD.
Note:	This check is performed only when RULE 4-1SD is selected.
Remedy:	<ol style="list-style-type: none">a. Check how long the controls have been on board.b. Check that calibrators, controls, and reagents are properly prepared and stored.c. Check that calibrators and controls are properly positioned on the sample disk 2.d. Check proper lot number and expiration dates of calibrators, controls and reagents.e. Check that the mean and SD for the specified assay are entered correctly on the QC, INSTALL screen.f. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.g. If the alarm recurs, call the BM Customer Technical Support.

6.3.40 Systematic error 4

Alarm:	Systematic error 4
Printed Alarm:	Systm4
Alarm Code in DATA REVIEW screen:	#
Description:	<ol style="list-style-type: none">1. The last four control X data values are larger than 1SD.2. The last four control X data values are smaller than -1SD.3. The last four control Y data values are larger than 1SD.4. The last four control Y data values are smaller than -1SD.
Note:	This check is performed only when RULE 4-1SD is selected.
Remedy:	<ol style="list-style-type: none">a. Check how long the controls have been on board.b. Check that calibrators, controls, and reagents are properly prepared and stored.c. Check that calibrators and controls are properly positioned on the sample disk 2.d. Check proper lot number and expiration dates of calibrators, controls and reagents.e. Check that the mean and SD for the specified assay are entered correctly on the QC, INSTALL screen.f. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.g. If the alarm recurs, call the BM Customer Technical Support.

6.3.41 Systematic error 5

Alarm:	Systematic error 5
Printed Alarm:	Systm5
Alarm Code in DATA REVIEW screen:	#
Description:	<ol style="list-style-type: none">1. The last five control X and last five control Y data values are positive / above the mean value.2. The last five control X and last five control Y data values are negative / below the mean value.
Note:	This check is performed only when RULE 10X is selected.
Remedy:	<ol style="list-style-type: none">a. Check how long the controls have been on board.b. Check that calibrators, controls, and reagents are properly prepared and stored.c. Check that calibrators and controls are properly positioned on the sample disk 2.d. Check proper lot number and expiration dates of calibrators, controls and reagents.e. Check that the mean and SD for the specified assay are entered correctly on the QC, INSTALL screen.f. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.g. If the alarm recurs, call the BM Customer Technical Support.

6.3.42 Systematic error 6

Alarm:	Systematic error 6
Printed Alarm:	Systm6
Alarm Code in DATA REVIEW screen:	#
Description:	<ol style="list-style-type: none">1. The last 10 control X data values are positive / above the mean value.2. The last 10 control X data values are negative / below the mean value.3. The last 10 control Y data values are positive / above the mean value.4. The last 10 control Y data values are negative / below the mean value.
Note:	This check is performed only when RULE 10X is selected.
Remedy:	<ol style="list-style-type: none">a. Check how long the controls have been on board.b. Check that calibrators, controls, and reagents are properly prepared and stored.c. Check that calibrators and controls are properly positioned on the sample disk 2.d. Check proper lot number and expiration dates of calibrators, controls and reagents.e. Check that the mean and SD for the specified assay are entered correctly on the QC, INSTALL screen.f. Check that calibrator values are correct on the CALIBRATION, INSTALL screen.g. If the alarm recurs, call the BM Customer Technical Support.

6.3.43 Standard 1 absorbance abnormal

Alarm:	Standard 1 absorbance abnormal
Printed Alarm:	S1Abs?
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	<p>During calibration, the expected absorbance of Standard 1 is outside the S1Abs Limit.</p> <p>A check is performed for the following methods:</p> <p>Rate assays: First measuring point (initial absorbance) at main wavelength.</p> <p>Endpoint assays: defined measurement point (endpoint) at bichromatic measurement (main wavelength minus sub wavelength).</p> <p>A Std? alarm is displayed, the calibration is not calculated.</p> <ol style="list-style-type: none">Check reagent preparation and calibration.Recalibrate.Check the S1Abs? Limit on the MAINT/UTILITY, APPLICATION screen.If the alarm recurs, call the BM Customer Technical Support.
Remedy:	
Additional Information:	The Abs?, Limt (0,1, 2), and Lin. (Lin.8) alarms are detected for all sample types. If this alarm occurs for a standard (Std1, Std2, etc.), it results in a Std? alarm. The Std? alarm prevents updating of calibration for the affected test and can be caused by other calibration-specific alarms such as Dup, Sens and S1Abs?.

Appendix

A.1 Glossary

A

air purge

Removal of air from the hydraulic tubing between the probes (photometric reagent or sample) and their respective pipettors.

ALARM global button

Button used to display the ALARMS global menu. Detailed information is displayed in the DETAILS window.

analyte

A specific constituent to be measured.

analytical unit

The hardware unit containing the sampling, reagent, cell rinse, photometric measuring and ISE systems.

application disk

A disk on which all BM applications are stored that can be run on the BM/Hitachi 917 analyzer.

assay

- A specific chemistry or immunoassay test.
- The process of measuring a substance.

automatic calibration

- a) Automatic time out calibration. Can be defined for each parameter separately. If the specified time interval is expired, an automatic calibration of this parameter is executed.
- b) Automatic calibration after bottle or lot exchange. Can be defined for each parameter separately. The automatic calibration is executed if a new bottle or lot is registered.

automatic rerun

The ability to repeat tests that have results with data alarms without operator intervention. Depending on the data flag, the rerun is measured with decreased, increased or normal sample volume. The automatic rerun can be executed in the realtime mode or after the 1st run.

B

barcode reader

The device that reads the code from either a sample or reagent bar code label.

barsheet

A sheet of paper on which all information is listed that is to be scanned by the system's software (e.g. control values, calibrator values, applications).

Glossary

bichromatic measurement	Difference between the measured absorbance of the primary wavelength and the measured absorbance of the secondary wavelength.
C	
calculated test	An additional test result that is not actually run on the analyzer, but calculated from other test results that have been run on the analyzer.
calibration	The process to standardise the instrument with samples of known concentration. This process establishes factors and or updates baselines to enable conversion of the response of the instrument to concentration (or activity) for the constituent being measured.
calibrator	A substance with known values used for calibration.
capacitance	Used in liquid level detection in the sample and reagent probes.
	The probes carry a high frequency low voltage electrical charge. The frequency and electrical charge capabilities are altered and sensed when the probe touches liquid.
CAUTION	A statement in this help text to make the operator aware of conditions that could result in instrument damage.
CEDIA®	A homogeneous enzyme immunoassay system.
cell blank	Process measuring absorbance of all 160 reaction cells, containing water, at all 12 wavelengths. The cell blank values are stored on the hard disk.
cell rinse units	Divided in two separate units for cleaning the reaction cells with detergent and water and for dispensing and aspirating cell blank water.
CHECK	The operational mode of the analyzer when a maintenance function is being performed.
chemistry analyzer	A set of interrelated systems capable of in vitro quantitative and qualitative determinations of a wide range of analytes through potentiometric and photometric assays.
cleaning solution	See wash solution

command button	A button in a screen that carries out an action.
compensated test	A test that has the result modified by a compensated formula.
consumables	Items which are used during test processing and must be replaced on a regular basis by the customer, i.e. reaction cells, printer paper, sample tubes etc.
control	Human based material with known values used to verify the precision and reliability of the chemistry assays and instrument.
control unit	The part of hardware that consists of the monitor, keyboard, CPU, touchscreen and printer.
CPU	(Central Processing Unit) the data processing unit of the system.
cumulative QC	The accumulated data and associated statistics of individual QC data.
cuvette	See reaction cell.

D

data alarms	Printed or displayed alarms or flags that indicate unusual reaction conditions (i.e. insufficient sample or reagent, substrate depletion, etc.).
data disk	The floppy disk used to store patient data.
diluent	a) Used to dilute a sample (i.e. saline). b) Used to dilute an ISE sample (i.e. Dil.).
duplicate limit	The limit which causes a DUP alarm, if exceeded by replicate assays of the standards.

E

emergency stop	An instrument alarm level that could result in damage to the instrument. All functions stop immediately.
endpoint assay	A determination in which measurements are taken after a reaction has stopped. The intensity of the coloured or turbid product is an indicator of the sample analyte concentration.
ESC key	Key on the keyboard used to close a window.

G

global menu buttons Command buttons that remain active on all screens and give access to the global menus which are: START, SAMPLE STOP, ANALYZER STOP, SAMPLE TRACKING, PRINT, ALARM and HELP.

H

Hitergent Surfactant which is added at each exchange of the incubation bath water. Positions 1D1 and 2D1.
host communication Information exchange with a Laboratory Information System (host computer).

I

incubation bath Temperature-controlled ($37^{\circ}\text{C} \pm 0.2$) water filled reservoir that surrounds the reaction cells (also called reaction bath).
in vitro qualitative assay A determination outside the living body of constituents of a substance without regard to quantity.
in vitro quantitative assay A determination outside the living body of constituents of a substance with regard to a specified number or amount.
incubation bath See reaction bath.
Initialization Operational mode that occurs immediately following power ON.
instrument alarms Displayed alarms that indicate unusual instrument conditions.
internal standard solution (Internal Standard) solution assayed between every ISE sample that compensates for electronic drift.
ISE (Ion Selective Electrode) a measuring device that is selective for the quantitation of an electrolyte such as sodium, potassium and chloride.
ISE dilution vessel A vessel into which sample is dispensed and diluted prior to analysis.
ISE prime Procedure that fills the ISE reagent lines and syringes with reagent.

K

K Factor A factor used in conversion of absorbance values to concentration values/activities.

L

liquid level detection Ability to sense liquid by the sample or reagent probes. The difference of the capacity is measured each time the probe senses liquid.

list box Within a screen, a type of box that lists available choices, for example, a list of available tests. If all the choices do not fit in the list box, there is a scroll bar.

LOG OFF key Key used to log off the analyzer's software. The operator ID is logged off the system if this function is activated in the corresponding window. After logging off, the LOG ON screen is displayed.

M

main menu buttons Command buttons that remain active in all screens and that are used to call up the main menus: These buttons are WORKPLACE, REAGENTS, CALIBRATION, QC and MAINT/UTILITY.

mean The average value of measurements.

measure point Mechanical cycle during which absorbance reading is taken and used to calculate results.

monochromatic Absorbance measurement at one (primary) wavelength.

M (multiple select) Ability to select multiple, non-consecutive samples from a list box. The M must be visible and selected on the scroll bar to utilise this function.

N

NaOH-D A detergent used in cell wash and probe wash

O

Operate The operational mode during which the instrument processes samples.

P

pipette	Aspiration and dispense of sample and reagent by the appropriate probe.
Parameter Check	The operational mode of the analyzer where the computer checks internal parameters (automatically occurs after START is pressed).
parameter disk	See application disk.
photometer	Device that measures the intensity of light or determines the light threshold.
photometric assay	Assays in which analytes are measured by a photometer.
potentiometric assay	Assays in which analytes (e.g. Na, K, Cl) are measured in millivolts by ion selective electrodes.
PRINT SCREEN	Key used to display the PRINT global menu.
profile	Individual chemistry tests programmed into a group of tests that is performed on a sample by pressing only one analyzer key.

Q

qualitative measurement	Report of a test concentration in qualitative symbols.
quantitative measurement	Test report including the concentration or activity of a test.
QC Button	Button used to display the QC main menu.

R

RAM	(Random Access Memory) the part of a computer's memory available to run the main program. The contents of RAM are lost when the computer is turned off.
R (range select)	The ability to select a range of consecutive data from a list box. The R must be visible and selected to utilise this function. The first and the last data have to be pressed in the screen.
rate assay	A determination in which measurements based on change in absorbance per minute are taken as the reaction proceeds. The rate of the reaction is proportional to the sample component being analysed.

reaction cell	Plastic cell where sample and reagent are delivered to process result for a specific analyte.
reaction disk	A large rotatable disk holding 160 reusable plastic reaction cells used for photometric measurement.
reagent compartment	Refrigerated compartment holding chemistry reagents and diluents.
reagent disk	Device in the reagent compartment into which the reagent bottles are placed.
reagent interrupt	Function that allows you to place reagents on the system in the Operation mode.
reagent probe	Probe used to carry reagent from the reagent disks to the reaction cells.
reagent probe arm	Moves the reagent probe between the reagent disk and reaction disk.
reagent probe rinse stations	Area located between the reagent disks and reaction disk where reagent probes are rinsed both internally and externally with water.
reagent syringe	The syringe-tube system is filled with water. Due to the up and down movement of the plunges in the syringe, reagent is aspirated and dispensed.
reagent tray	See reagent disk.
recalibration	To repeat a failed calibration.
reference electrode	The electrode through which the reference solution flows to set the electronic baseline to zero for ISE measurement (also called reference cartridge).
reference solution	(KCl) the solution pulled through the reference cartridge to set the electronic baseline to zero for ISE measurement.
repeat calibration	The repetition of a calibration.
repeat limit	User-definable limit at which a test is run again with normal sample volume if the result is outside the repeat limit.
Reset	The operational mode during which the analyzer sets and aligns all mechanical parts to their home positions.
rinse bath	See reagent or sample probe rinse stations.

S

sample disk 1	Disk containing samples to be processed.
sample disk 2	Disk containing standards and controls (refrigerated and covered).
sample predilution	Dilution of sample prior to analysis. Dilution of a sample in the reaction cell. The diluent can either be system water or diluent from reagent disk 1.
sample syringe	The syringe-tube system is filled with water. Due to the up and down movement of the plunges in the syringe, sample liquid is aspirated and dispensed.
sample probe	Probe used to carry sample from the sample disks to the reaction cells, between reaction cells and to the ISE dilution vessel.
sample probe arm	Moves the sample probe between the sample disk and reaction disk or ISE dilution vessel.
sample probe rinse station	Area located between the sample disk and reaction disk where the sample probe is rinsed both internally and externally with water.
SAMPLE STOP	Operational mode of the analyzer during which the aspiration of sample for analysis has been completed, but the testing and washing processes continue. The period of time between Operation and Stand-by.
sample tray	See sample disk.
sampling stop	(S. STOP) An instrument alarm level that indicates a problem with the sampling system. Sampling stops, but sample processing continues.
SAMPLE STOP button	Button used to stop sampling (global menu button).
scroll	To move through text or graphics (up, down, left, or right) in order to see parts of the file or list that cannot fit on the screen.
scroll arrow	An arrow on either end of a scroll bar that you use to scroll through the contents of the window or list box.
scroll bar	A bar that appears at the bottom and/or right edge of a window whose contents are not entirely visible. Each scroll bar contains a scroll box and two scroll arrows.

scroll box	In a scroll bar, the small box that shows the position of information currently in the window or list box relative to the contents of the entire window.
SD	Standard deviation, statistic used as a measure of the dispersion or variation in a distribution.
SELECT	To mark an item so that a subsequent action can be carried out on that item. You usually select an item by touching it in the screen or pressing a key.
serum indexes	Function by which the absorbance characteristics of the samples are determined to evaluate the presence of lipemia, haemolysis and icterus.
SMS	Selective Mode Solution; acid wash solution which can be used to wash reagent probes and cells as specified in the special wash sub menu.
Stand-by	Operational mode of the analyzer during which power is on, but no sample analysis or maintenance procedures are being performed.
START button	Button used to begin instrument operation.
STAT	Emergency sample processing. The samples are measured with a higher priority than routine samples.
stirrers	Small Teflon-coated paddles that lower into the reaction cells to mix the contents of the reaction cell.
stirring paddles	See stirrers.
stirring units	See stirrers.
Stop	<ul style="list-style-type: none">- The transitional operational mode immediately prior to Stand-by.- An instrument alarm level that indicates a situation that prevents completion of analysis in process. All mechanical functions stop at the end of the current 4.5-second cycle.
STOP button	Button used to stop all test processing functions at the end of the current mechanical cycle.
system cleaning solution	See wash solution.
system disk	Floppy disk on which all system settings are stored.

T

technical limit	Dynamic range of results on the analyzer beyond which samples are placed on a rerun list.
text box	A box in which you can type information needed to carry out a command. The text box may be blank or may contain text when selected.
time out	Automatic count down of calibration stability.

W

warning	<ul style="list-style-type: none">– A statement called out in this manual to make the operator aware of conditions that could cause personal injury.– An instrument alarm level that does not interrupt operation.
wash solution	<ul style="list-style-type: none">– A solution used to wash cells (Detergent-bottle in the instrument).– A solution used to wash the reagent probes as specified in the SPECIAL WASH sub menu (1D2, 1D3, 2D2, 2D3 positions).– A solution used to clean the sample unit and the ISE unit (W1-W3 positions on sample disk 2).
waste solution reservoir	Container that collects reaction waste.
window	Used to perform specific tasks on the system, displayed by touching a command button.

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