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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

# **CAUTION**

#### 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.



# **CAUTION**

#### **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.



### CAUTION

#### **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 Boerhinger 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 fro 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	e 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 solu- tion, 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

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 MAINTE LOG sub menu (MAINT/UTILITY main menu)	

# 2.3 System Start

### 2.3.1 Introduction

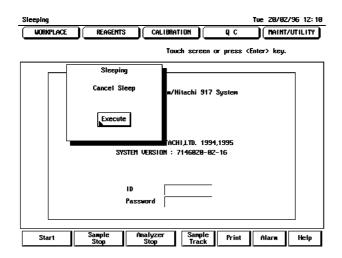
There are two ways to start the routine operation - by pressing the main switch of the analyzer (POWER ON) on the right side of the front panel, or by waking up the instrument from the SLEEP mode.

# 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

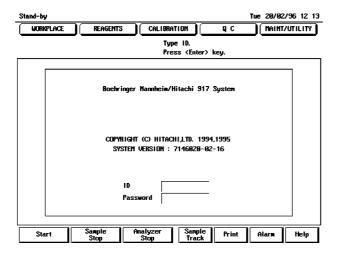
If the analyzer is automatically initialized ("waking up" from the SLEEP mode), a photometer check is automatically performed. If the instrument is manually started, a photometer check has to be requested manually in the MAINTE LOG sub menu (MAINT/UTILITY main menu).

### 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.



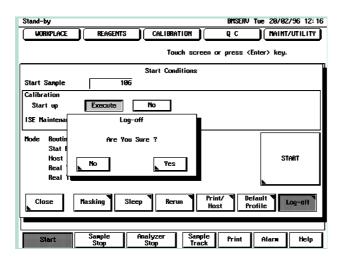
#### Note

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.

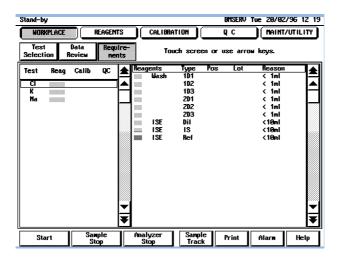
#### **Safety Precautions:**

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.

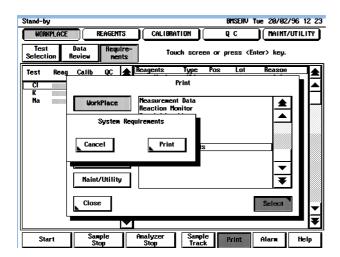
#### For calibrations:

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.

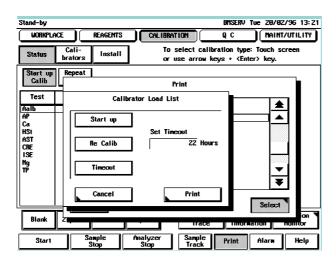


4. Put the required reagents into the corresponding reagent disks (see package insert for preparation details).

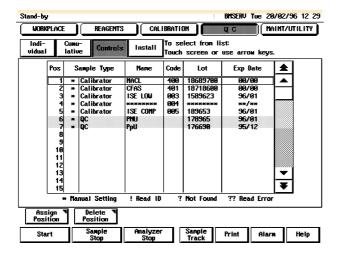
# 2.4.2 Reconstituting Calibrators and Controls

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.



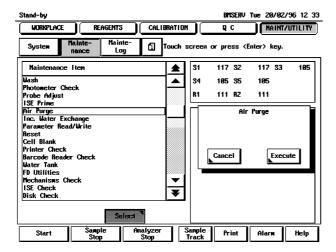
3. Touch QC, followed by CONTROLS to display the position list of the controls and calibrators in sample disk 2.



4. Put calibrators and controls in the indicated positions.

# 2.4.3 Air Purge (Photometric System)

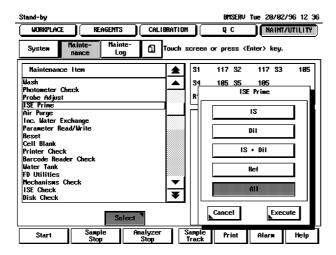
The air purge procedure occurs automatically when the instrument is powered ON or after Wake-Up. If you have not assayed any samples within an eight-hour period and (instrument in Stand-by), perform an air purge to ensure that there is no air in the hydraulic tubing between the probes (photometric reagent 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.

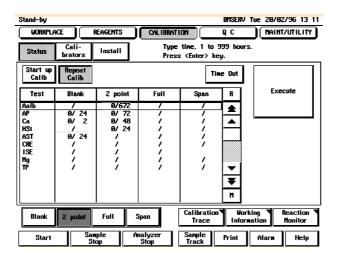
### 2.4.4 ISE Prime, Conditioning, Calibration

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

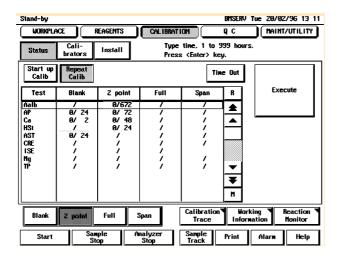
Your 917 analyzer offers the opportunity to select between the automatic calibration feature and a manually requested calibration. To ensure proper operation of your 917 analyzer, calibrate each Boehringer Mannheim assay at the recommended interval specified on the APPLICATION sub menu (MAINT/UTILITY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

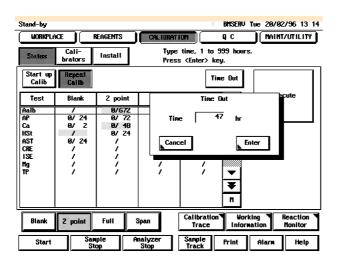
### ■ Time Out Calibration

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



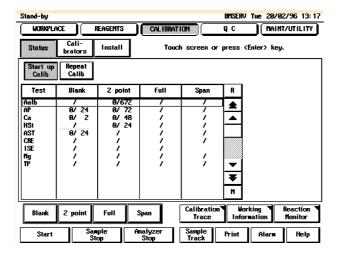
2. The second number is the defined time interval. The remaining time is displayed as the first number, e.g. the 1 in 1/48. This means that during the next hour an automatic calibration is executed, and the time interval is 48 hours. After the calibration the time display is updated to 48/48.

3. All tests requiring calibration within a defined time period (e.g. 5 hours) are high-lighted. 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.

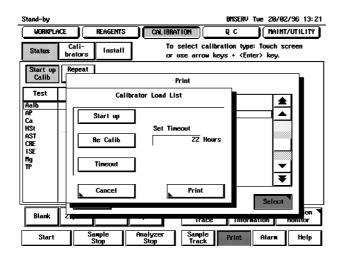
IF a calibrator load list is desired,

THEN proceed to step 5.

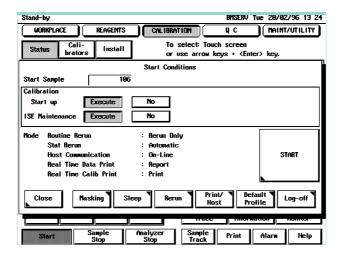
IF no calibrator load list is desired,

THEN proceed to step 8.

5. Touch PRINT to display the PRINT global menu.



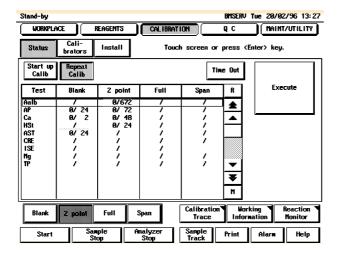
- 6. Touch CALIB LOAD LIST, then touch SELECT.
- 7. Touch START UP, then touch PRINT to print the calibrator load list.
- 8. Load calibrators and controls on sample disk 2 according to the printed load list.
- 9. Touch START, to display the START CONDITIONS global menu. Touch CALIBRATION START UP and 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.

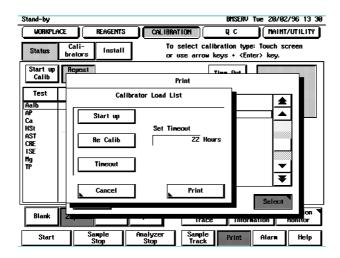
IF a calibrator load list is desired,

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.

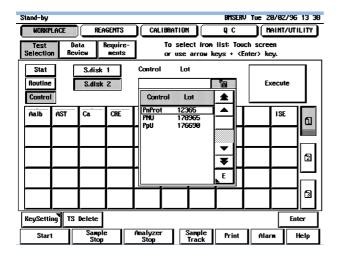


- 6. Touch CALIBRATION, followed by CALIB LOAD LIST, then touch SELECT.
- 7. Touch RE CALIB, then touch PRINT to print out the calibrator load list.
- 8. Load calibrators and controls on sample disk 2 according to the printed list of the required Standards.
- 9. If the analyzer is in operation, touch 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.

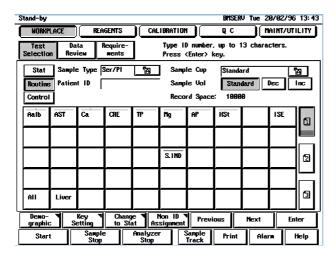
Patient test selections can either be entered manually or downloaded from a host computer with or without barcode reader in use.

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:

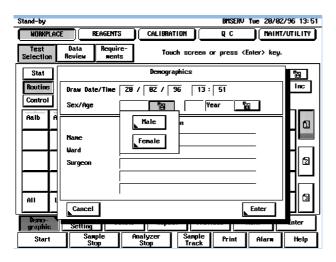
Sample	Туре	Ser/PI	A
Sample	No.		
Patient	ID		

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.

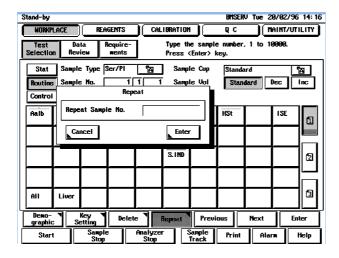
For barcode mode:	Sample Type Ser/PI
	Patient ID

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

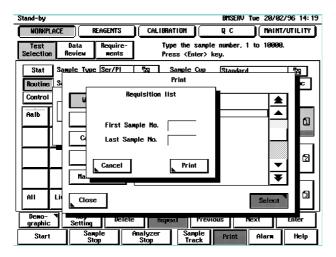
- 4. To change the default setting for the sample type, move the cursor to the SAMPLE TYPE assist box. Open the box and touch the desired sample type. The assist box closes and the selected sample type is displayed.
- 5. To change the default setting for the sample cup, move the cursor to the SAMPLE 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.



- 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 be 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 be 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.)

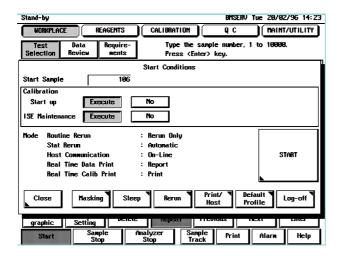


10. If you want to print out a load list of the test selections, touch the PRINT button to open the corresponding global menu. Touch WORKPLACE, followed by REQUISITION LIST. Then touch the SELECT button to display the REQUISITION LIST window. Enter the first and last sample number and then touch the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



### 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.

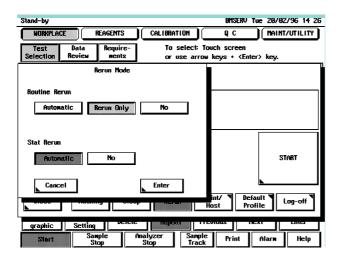


1. Touch the START button to open the START CONDITIONS global menu. Depending on barcode mode and host mode, entries vary as follows:

Sample barcode reader	Host communication	START SAMPLE	see
no	no	Start Sample 196	À
yes	yes	Start Sample 106 : 0 1	Á
yes	no	Start Sample   180 .   8   1	
no	yes	Start Sample 10 10 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.

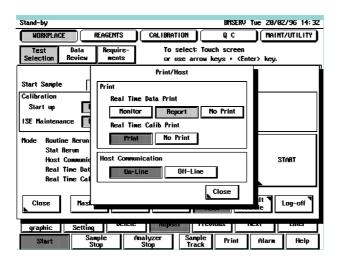
If the RERUN ONLY option is activated, samples that were scheduled for the rerun can be measured again. The system marks results in the DATA REVIEW sub menu (WORK-PLACE main menu) that are outside the limits defined for the applications. These samples are scheduled for a rerun.

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

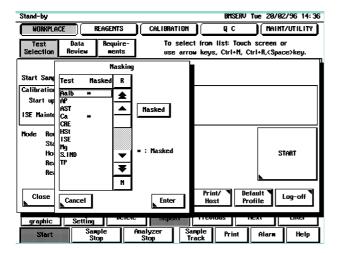
If the results of a STAT sample are outside the limits, the system will automatically measure that sample again. If the NO button is activated, the STAT sample will not be rerun.

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.



6. 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.

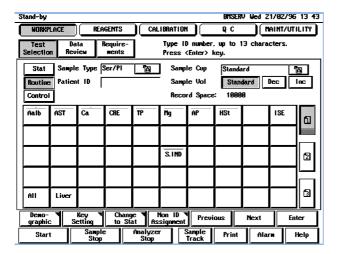
7. Touch the CLOSE button to close the window. Touching CLOSE does not change any modifications you previously made to the START CONDITIONS global menu.

### 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.

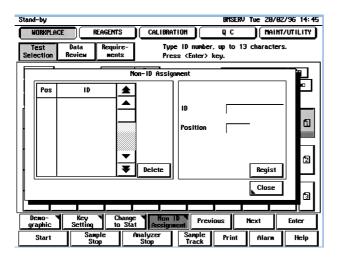
### 2.6.3 Entering Non-Barcoded or Unreadable Barcoded Samples (in the Barcode Mode)

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



- 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.
- 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 DEMO-GRAPHIC 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.

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.

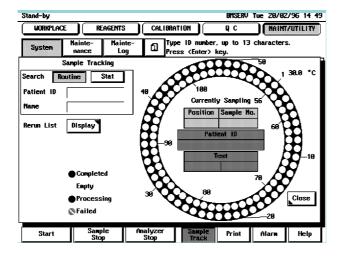


# 2.7 Sample Tracking

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:

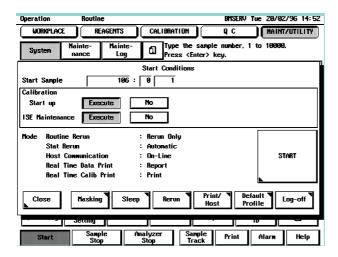
- indicates a completed sample
- indicates a sample that is in process
- indicates an open position
- indicates that the sample needs further attention from the operator and that the sample has to be measured again (rerun).



- 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

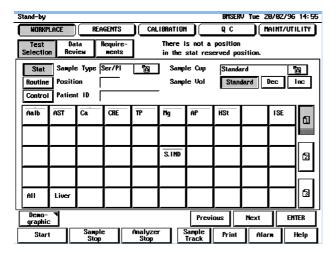
Additional routine samples may be requested at any time. Follow the procedure for programming routine samples. If the analyzer is not in operation, for example in Sampling Stop or Stand-by mode, you must touch START in the START CONDITIONS global menu to begin the run.



## 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.

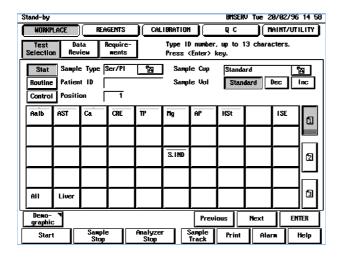


2. The cursor highlights the POSITION text box, if the barcode reader is off.



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





- 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.
- 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.
- 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.

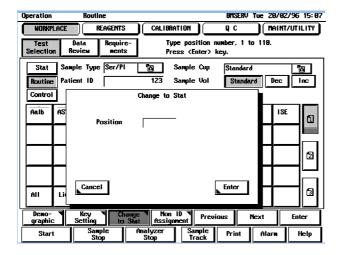
If a yellow dot appears on the test key matrix for a specific test, this indicates that the test is masked by the operator from the START CONDITIONS global menu.

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.

## ■ 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.

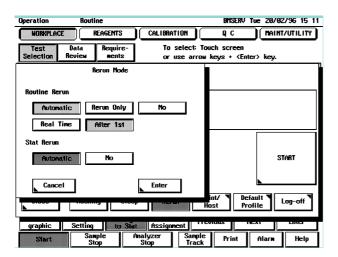
In the START CONDITIONS global menu, two different modes are selectable - REAL TIME and AFTER 1ST.

- 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.

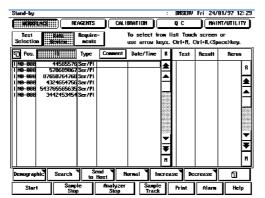
### 2.10.1 Automatic Rerun

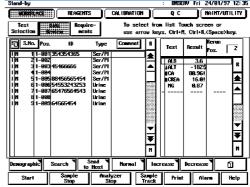
- 1. Touch the START button to display the START CONDITIONS global menu.
- 2. Touch the RERUN button to display the RERUN MODE window.
- 3. Touch AUTOMATIC to request that reruns be processed without operator intervention.
- 4. Touch REAL TIME if you want rerun samples to be processed during the current 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.
- 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.



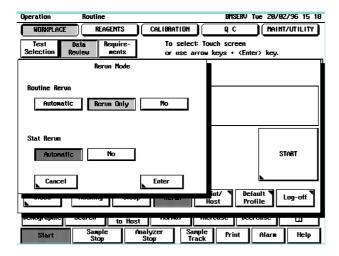


Sample barcode reader on

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 in-creased 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.

- 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.

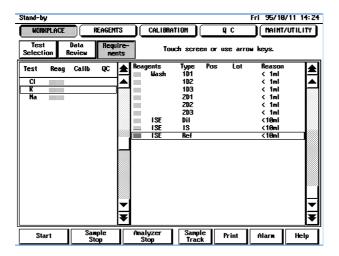


- 8. Touch the RERUN button to display the RERUN MODE window.
- 9. Touch RERUN ONLY to request rerun processing, then touch ENTER.
- 10. Enter the start sample number for the rerun in the START CONDITIONS global menu.
- 11. Press the START button.

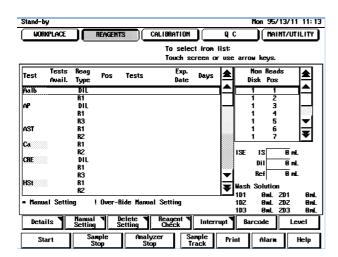
# 2.11 Adding Reagent During a Run

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

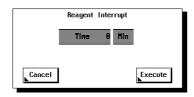
If reagent levels are highlighted in yellow (REAG column) for any reagent, you may need to add reagent during the run. A reagent is highlighted in yellow when the defined number of remaining tests in the bottle reaches or falls below the limit that is set in the MAINT/UTILITY, SYSTEM, ALARM SETTING,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



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



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

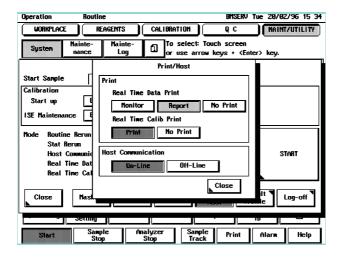
There are two patient result printout formats: MONITOR and REPORT.

- 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).

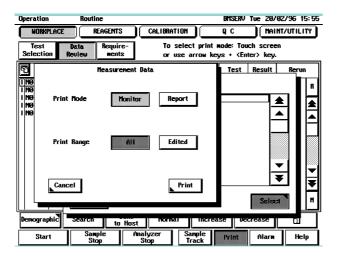
## 2.12.1 Selecting the Patient Report Format for Real Time Printing

- 1. Touch START followed by PRINT/HOST to display the PRINT/HOST window.
- 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

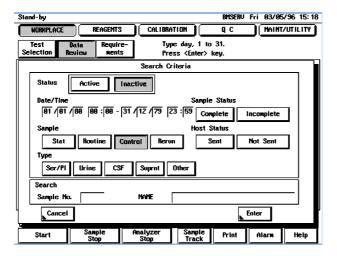
The way results are documented, depends on the mode settings selected from the START CONDITIONS global menu, PRINT/HOST window.

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:

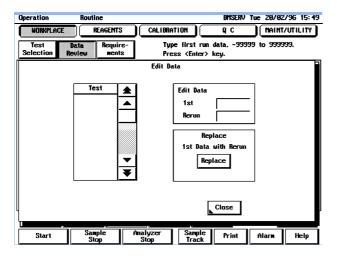


- 1. Touch WORKPLACE, followed by DATA REVIEW to display the DATA REVIEW sub menu.
- 2. Touch SEARCH to display the SEARCH CRITERIA window. Select the desired search criteria and touch the ENTER button.
- 3. All samples meeting the selected search criteria are displayed in the left box. If control is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

#### 2.13.2 Editing Data

#### ■ Overwrite First Result with Rerun Result

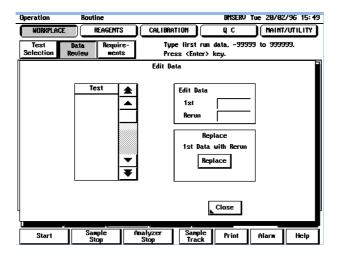
- 1. Touch the sample that needs to be edited in the left box. Details of the test information appear in the right box, including first run results and rerun results.
- 2. Touch the page key -1- to access the second window level and then the EDIT button to display the EDIT DATA window.



- 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

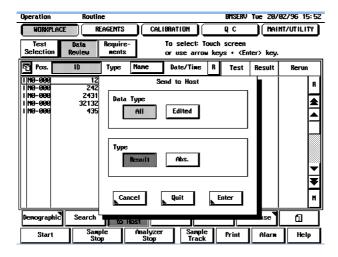
- 1. Touch the sample that needs to be edited in the left box. Details of the test information appear in the right box, including first run results and rerun results.
- 2. Touch the page key -1- to access the second window level and then the EDIT button to display the EDIT DATA window.



- 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

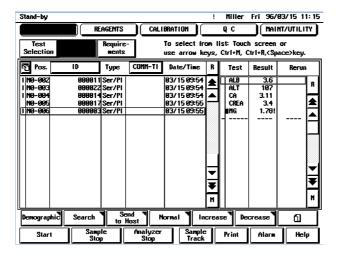
- 1. Mark the data on the DATA REVIEW sub menu with the marking keys R or M. The scroll bars on the right side of the sample list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range of samples may be transmitted by touching the first and last sample in the desired 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.



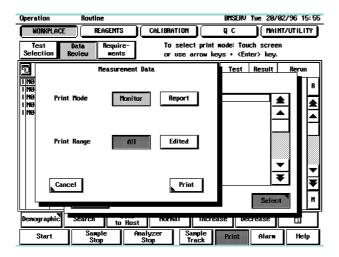
- 3 Touch ALL or EDITED to select which data is sent to the host. Touch EDITED to send only edited data to the host.
- 4. Touch RESULT to send the results to the host. Touching ABS. sends the absorbance readings.
- 5. Touch ENTER to begin the data transmission to the host.
- 6. Touch QUIT to stop host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



- 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.

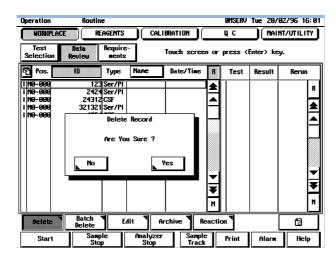
#### 2.13.3 Deleting Functions

#### 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:

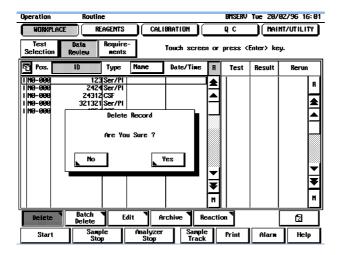
3. Touch the page key -1 - to access the second window level and then DELETE to open the corresponding window.



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.

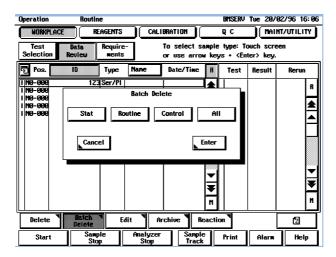


5. Touch YES to delete the selected test. Note that only the single test result but not the test selection is deleted.

## ■ 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.

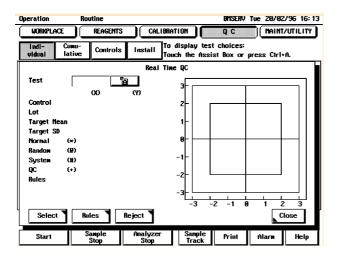
- 3. Touch ENTER, followed by YES to delete the selected data.
- 4 Touch CANCEL to cancel the deletion of the selected data.

#### 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.

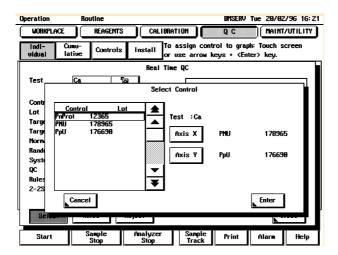


Each set of control results is either acceptable or causes a random, system, or QC error. If a random, systematic, or QC alarm occurs, an alarm message appears on the ALARM global menu.

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

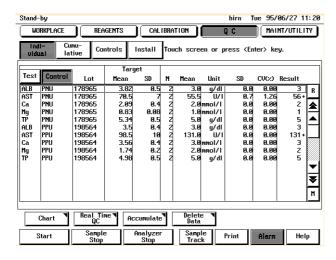
- 1. Touch QC, followed by INDIVIDUAL and REAL TIME QC to display the REAL TIME QC window. Daily QC results can be reviewed and checked in this window.
- 2. Touch the TEST assist box to display the list of tests. Touch the name of the test you want to review and press ENTER.
- 3. Touch the SELECT button 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.



- 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.

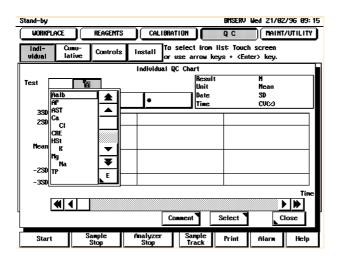
#### 2.14.2 Individual QC List

- 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.



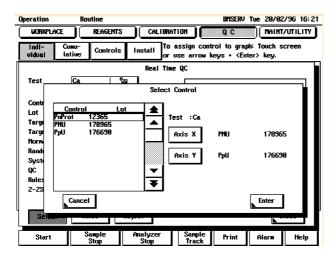
- 2. Touch the TEST assist box. Touch the test you want to review and press ENTER.
- 3. Touch SELECT to display the SELECT CONTROL window. Touch the control name followed by the PLOT button. This assigns the selected control to the selected plot. The selected control appears next to the PLOT button.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

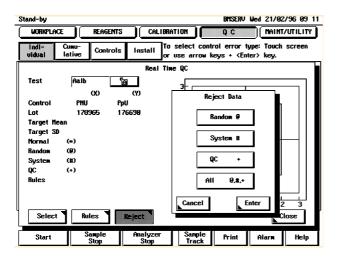
# 2.14.4 Validation of Individual QC with Real Time QC (Rejection of Single Test Couplings)

- 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.

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.

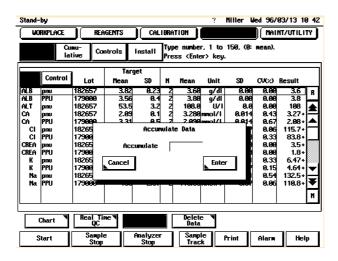
## 2.15 QC File Maintenance

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.

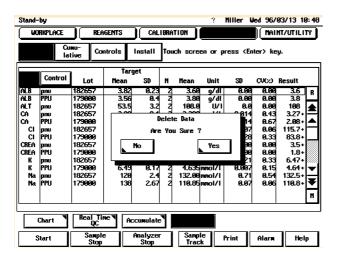
The scroll bars on the right side of the list box have an R at the top and an M at the bottom. When R is highlighted, a consecutive range data may be accumulated by touching the first and last result in the desired range. When M is highlighted, multiple, non-consecutive data for the selected test may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



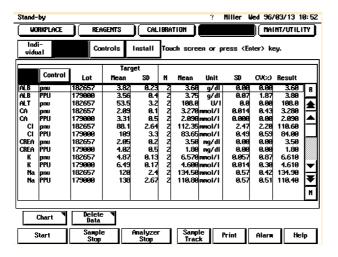
2. Touch the name of the test you want to delete.

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.

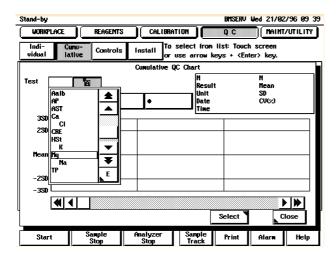


- 2. Touch the TEST button. The CUMULATIVE QC list is sorted by test in alphabetical order. If you touch the CONTROL button, the CUMULATIVE QC list is sorted by control in alphabetical order.
- 3. The statistics e.g. number of accumulations, mean, SD, CV is displayed.

#### 2.15.4 Validation of Cumulative QC

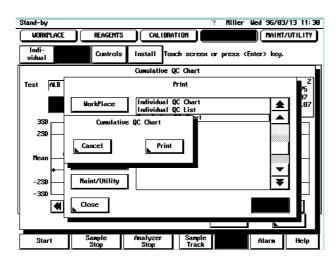
- 1. Touch QC, CUMULATIVE, CHART to display the CUMULATIVE QC CHART window.
- 2. Touch the TEST assist box. Touch the test you want to activate.
- 3. Up to three different controls can be displayed in the chart with three different symbols. Controls can be displayed (or not displayed) by pressing the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



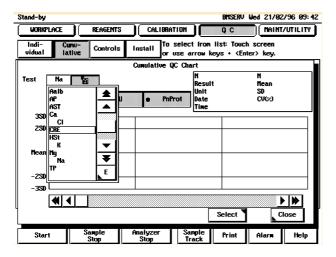
#### 2.15.5 Printing the Cumulative QC List and Chart

- 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

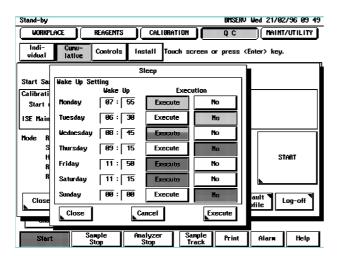
Perform the following steps to shut down completely the analyzer:

- 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
CI 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 MAINTE 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

# BM/Hitachi 917

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## 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.

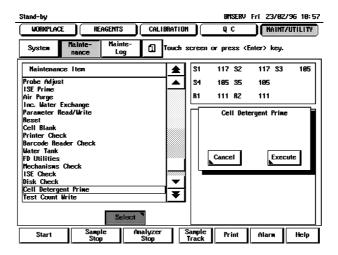
# **Necessary Material**

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.

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.

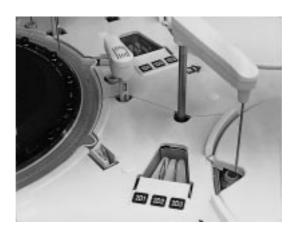
## 3.2.3 Checking the Detergent/Replenishing the Bottles

**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

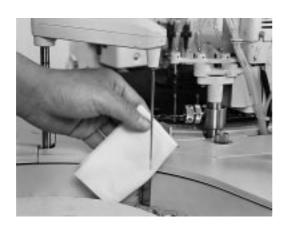
Wipe clean the reagent probes, the sample probe, and the stirring paddles daily to avoid contamination.

## **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).

# $\overline{\mathbb{A}}$

## 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.

## $\triangle$

## 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

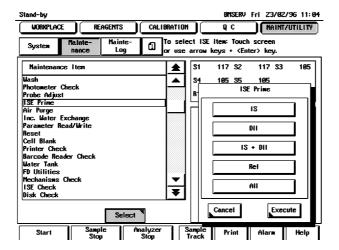
If the analyzer has not been operating for a longer time, then the reagents must be primed before the routine (ISE PRIME) and the ISE unit must be conditioned and calibrated.

#### 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.
- 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.

- 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 °C  $\pm$  0.2 °C.

## 3.2.12 Performing a Photometer Check

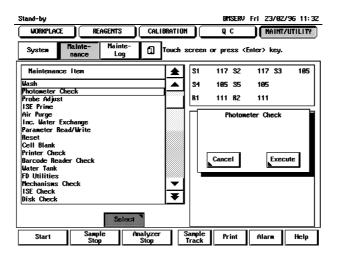
The photometer has to be checked each day before the routine, to prevent any possible error sources.

## **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.

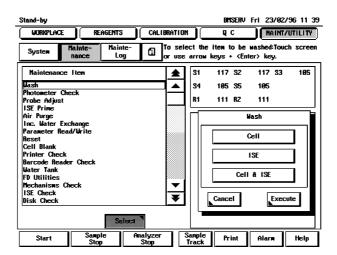
## **Safety Precautions**

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.



- 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

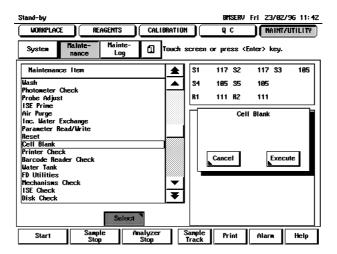
The system automatically measures the blank value of each reaction cell during each run, by comparing it with the previous cell blank measurement (is used as a reference). To bring the comparison values up to date, the cell blank measurement has to be performed separately once a week.

#### 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

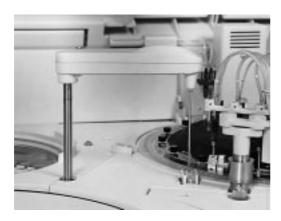
The rinse baths should be cleaned once a week. You thereby prevent contamination and bacterial development.

## **Safety Precautions**

Switch off the analyzer.

## **Necessary Material**

Sufficient sodium hypochlorite (NaOCI, 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**

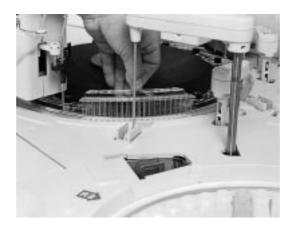
Switch off the analyzer.

## **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).

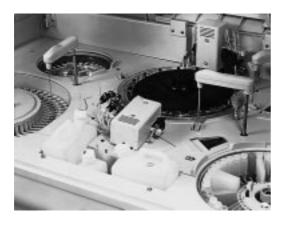
## 3.4.2 Cleaning the Incubation Bath and the Incubation Bath Drain Filter

## **Safety Precautions**

Switch off the analyzer.

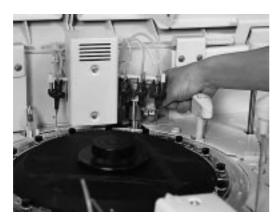
## **Necessary Material**

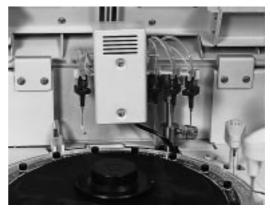
Soft lint-free towel, water.





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.

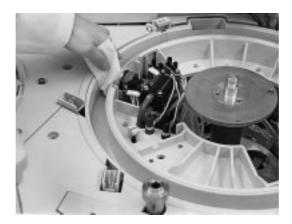
## Note

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 in 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.



- 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**

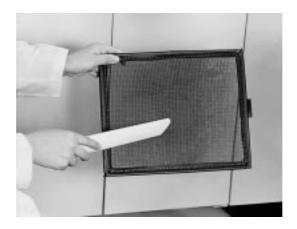
The analyzer must be in Stand-by mode or switched off.

## **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.



- 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.

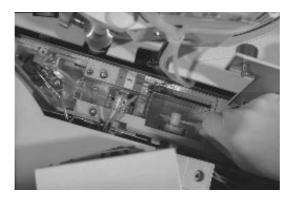
## 3.4.5 Replacing the ISE Pinch Valve Tubing

## **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

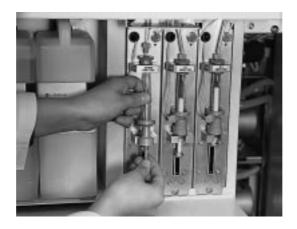


 The sample syringe is situated behind the left front door. It is the first syringe to the right of the detergent bottles. Loosen the upper and lower tube connections by turning the retaining nuts in an anti-clockwise direction. Soak up any spilt water with an absorbent cloth.

#### Note

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

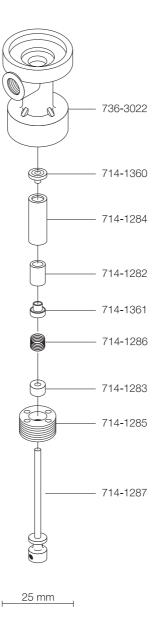
2. Loosen the knurled screw (on the top of the syringe) by turning it anti-clockwise until the syringe rests loosely in the glass body. Carefully remove the glass body with the syringe from the holder. Remove the black O-ring from the top of the glass body.





- 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.



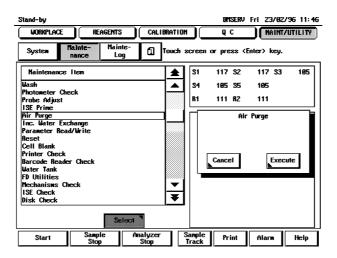


7. Refit the syringe with the glass body and the O-ring (L 456006 for sample/reagent syringes, 737-1629 for the ISE syringe) into the holder and tighten the knurled screw.

## Note

Ensure that the piston is aligned with the piston guide.

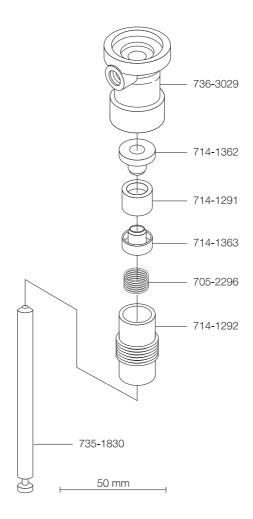
- 8. Refit the black seal washer (L 443085) on top of the glass body with the help of a pair of tweezers.
- 9. Re-connect the tube connection and switch on the analyzer.



- 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.

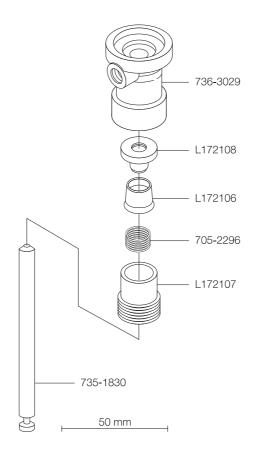
## ■ Replacing the Seals on the Reagent Syringes

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:



# $\overline{\wedge}$

## Caution

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

# $\overline{\Lambda}$

## 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

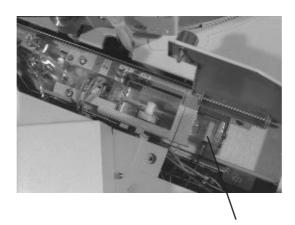
For EMF values outside the specified range, the analyzer issues the alarm code 90-1, 90-2 or 90-3.

## **Safety Precautions**

Normal laboratory safety precautions.

## **Necessary Material**

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



Reference electrode

- 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.
- 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 lockedposition.
- 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 KCI (MAINTENANCE sub menu, MAINT/UTILITY main menu, ISE PRIME, REF menu option).
- 9. Finally, calibrate the ISE unit (see chapter 3.2.9).

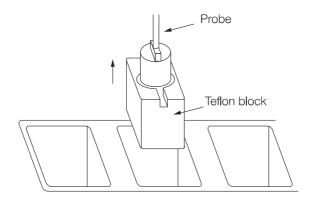
## 3.6.2 Replacing the Teflon Block (Nozzle Tip)

## **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.

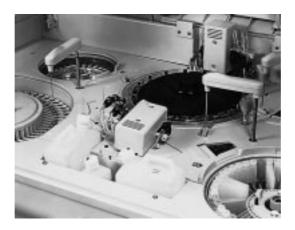
## **Necessary Material**

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

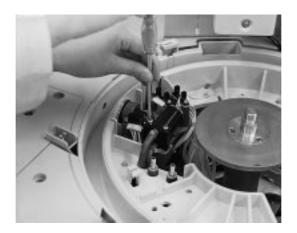
Never close the cover of the analyzer, as this could damage rinse unit 2.



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.

# $\hat{}$

# 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).

# $\overline{\Lambda}$

# 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

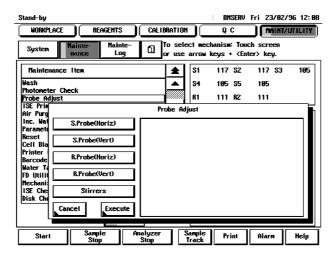
Each newly replaced probe must be realigned after installation. This applies to the horizontal as well as the vertical alignment.

## **Safety Precautions**

Normal laboratory safety precautions.

#### **Necessary Material**

Positioning aid.



 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

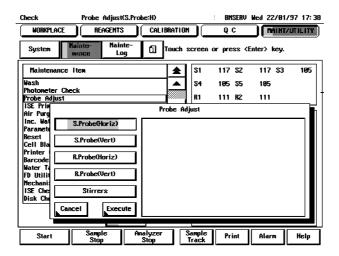
The horizontal alignment of the probe must be carried out prior to the vertical alignment. If this is not observed, correct functioning of the probe movement cannot be guaranteed.

■ Alignment of the sample probe (horizontally)

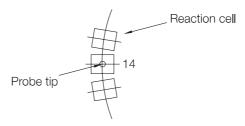
#### Note

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.



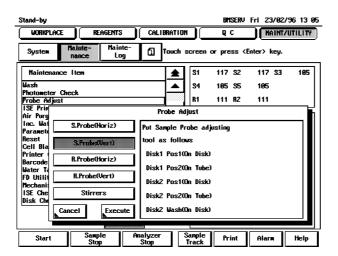
- The system will move the reagent probe into a position above reaction cell number
   Position the probe manually above the center of the reaction cell, as shown in the diagram.
- 3. To move the probe on to the next position, press SAMPLE STOP and YES. Check the centering above each respective position.
- 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

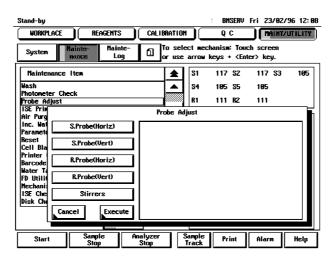
- 1. Instead of using positioning aids, place empty Hitachi cups in both of the sample disks (any position).
- 2. Program a test order so that the analyzer pipettes out of the empty cups.
- 3. Start a routine run.
- 4. Check whether the system issues the SAMPLE SHORT alarm.
- 5. If the analyzer issues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

Checking the horizontal alignment of the reagent probes

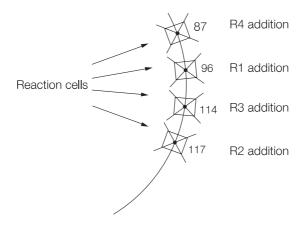
#### Note

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.



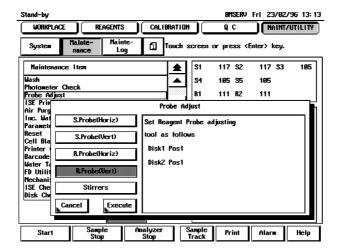
- 2. The system positions the R1 reagent probe above the reaction cell 87, in which R4 is dispensed, and the R2 probe is positioned above the reaction cell 114, in which R3 is dispensed. Manually position the probe above the center of each reaction cell, as shown in the diagram.
- 3. To move the probes 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.

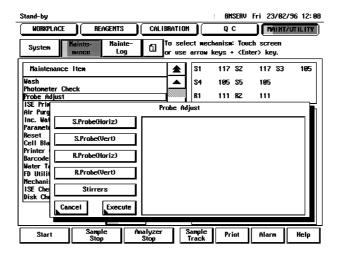


- 1. Place an alignment gauge on position 1 on the reagent disk 1 and on position 2 on the reagent disk 2.
- 2. Press the R. PROBE (VERT.) button and then EXECUTE; the system will now start the automatic vertical alignment above the center of each alignment gauge. The system will automatically adjust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

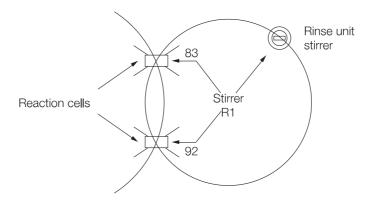
The determined adjustments are saved to calculate the correct amount of remaining reagent. The system lists the distance values which are determined during the vertical alignment in the MAINTENANCE sub menu under R1 and R2 in mm.

### ■ 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.

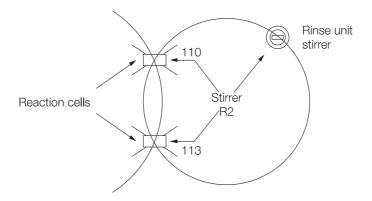


2. The system positions each stirring paddle above the appropriate reaction cell.

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.



 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.

### BM/Hitachi 917

- 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**

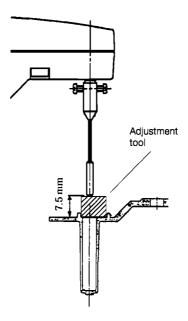
Screwdriver, new stirring paddles, alignment gauge.



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/STIR-RERS 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**

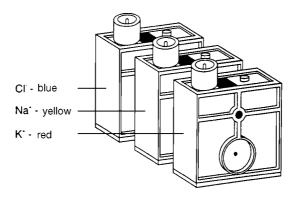
Normal laboratory safety precautions (e.g. gloves).

#### **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.

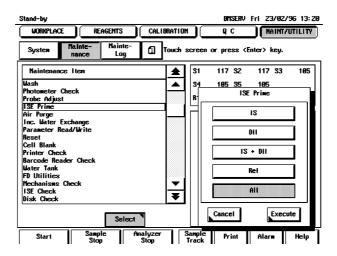


- 6. Fit the new cartridges into the ISE measuring chamber in the sequence shown above.
- 7. Push the lock/release lever to the right until the clamp lever is released. Using spring force, the lock/release lever is then pushed to the left until it engages into the locked position.

#### 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.



- 9. Select the ISE PRIME menu option in the MAINTENANCE sub 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**

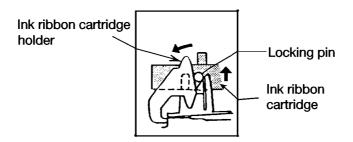
Switch the printer off, let it cool down.

# **Necessary Material**

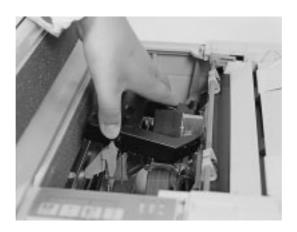
Ink ribbon cartridge.



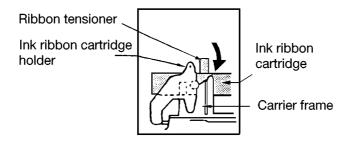
- 1. Open the front hinged access cover of the printer. With a finger, press on the cover from the inside and pull the cover upwards.
- 2. Position the print head in the center of the printer.



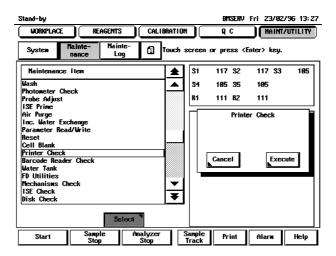
- 3. Pull the holder of the ink ribbon cartridge forwards, until it is loose. Pull the cartridge out.
- 4. Pull off the red paper strip from a new ink ribbon cartridge.



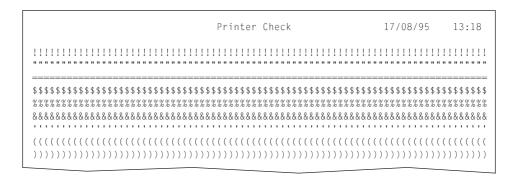
5. Fit the new ink ribbon cartridge as shown in the illustration. It must click obviously into place.



- 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.



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.



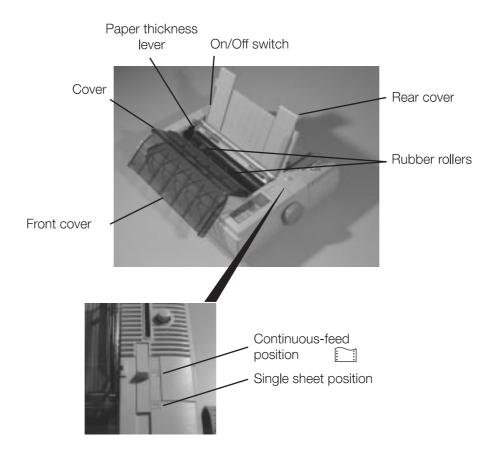
# 3.8.3 Loading Continuous-Feed Paper

# **Safety Precautions**

None.

# **Necessary Material**

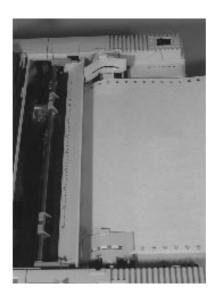
Box containing continuous-feed paper.



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

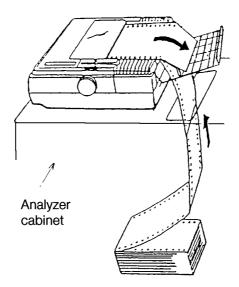


- 2. Open the cover. Take hold of the front hinged access cover with both thumbs and pull it upwards.
- 3. Switch the paper thickness to the correct setting. The lever is located inside the printer on the left. A detailed description of the procedure can be found in chapter 3.8.5.
- 4. Push the two rubber 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 evently 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
- 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.

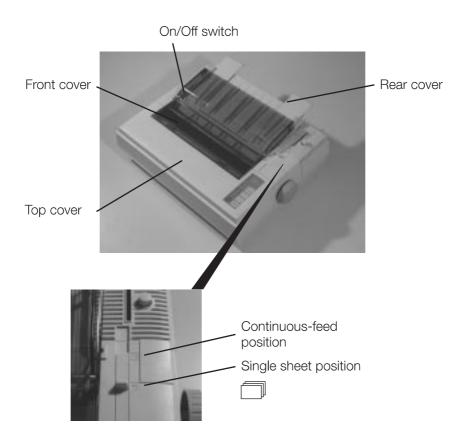
# 3.8.4 Inserting Single Sheets

# **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/m2	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.

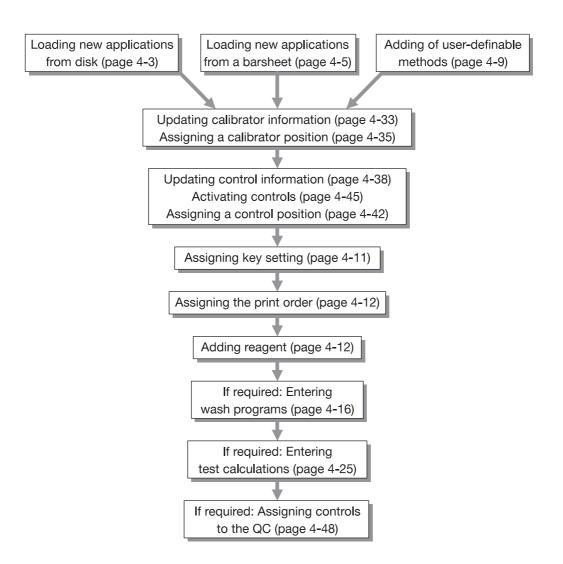
4. Operation Support

### 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.

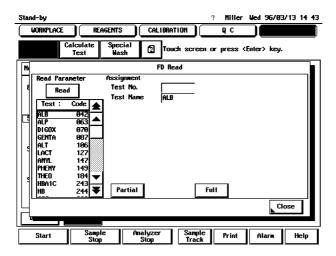
#### Sequence of steps for the adding of new applications

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.
- 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.

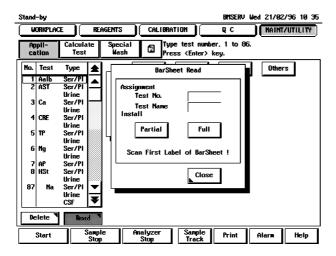
If test applications already exist for the selected test code, a warning window pops up. Touch YES to overwrite the parameters. Touch NO to cancel the parameters write.

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.

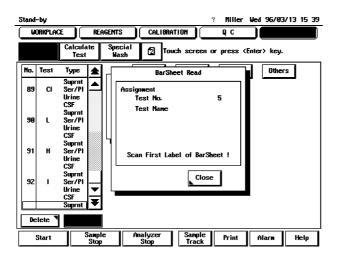
Before you install a new application, check the unit setting on the MAINT/UTILITY, RANGE screen. Changing to another unit after setting the calibration and control values deletes them.

### 4.1.2 Loading New Applications from a Barsheet

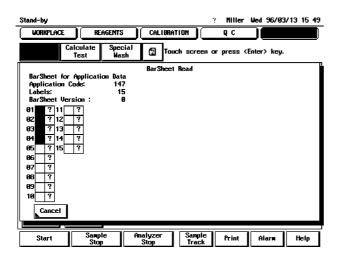
- 1. Touch MAINT/UTILITY, followed by APPLICATION on the second sub menu level to display the APPLICATION sub menu.
- 2. Determine the next vacant test number in the list.
- 3. Touch the READ button to display the corresponding window.
- 4. Touch BARSHEET READ and press ENTER to display the corresponding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



- 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 ap	plication	Partial application		
	overwritten	not overwritten	overwritten	not overwritten	
Sample Vol. (reduced)	Х		Х		
SD Limit, Duplicate Limit	Х		Х		
Sensitivity Limit, S1Abs Limit	Х		Х		
Auto Calibration	Х			Х	
Data Mode	Х		Х		
Control Interval	0			Х	
Instr. Factor	X (FD)	X (Barsheet)	X (FD)	X (Barsheet)	
Techn. Limit	0			Х	
Rerun Limit	0			X	
Expected Value Range	0			Х	
Calibrator Code	Х		Х		

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

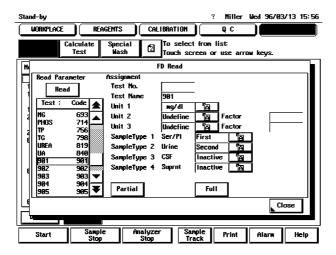
o = User-specific entries are overwritten by the original default application data which then have to defined individually by the operator.

### 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.

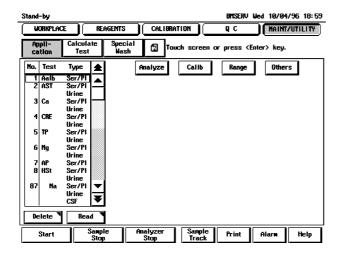


- 4. Enter the test number in the ASSIGNMENT TEST NO. assist box.
- 5. Enter the short name of the test (max. of 5 characters) in the test name field.
- 6. Select the unit for your test in the assist box list. Up to 3 different units can be selected for the test.
- 7. If more than one unit is being used, 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.

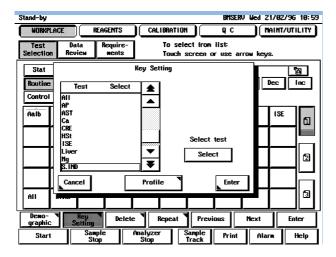


#### **CAUTION**

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.



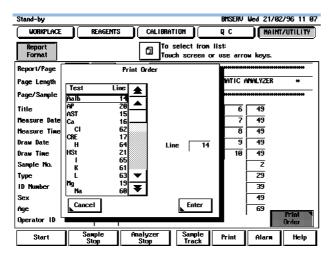
5. Touch the desired test name from the list box, followed by SELECT (a \* is displayed in the SELECT column). Touch ENTER to assign the test to the selected key.

#### 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.

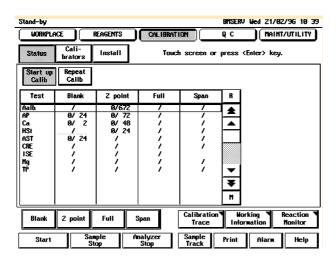
### 4.1.6 Reagent Registration

- 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.

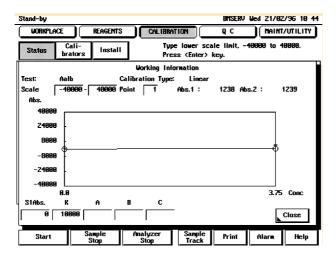
### 4.1.7 Programming Preset K Factors for Assays

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.

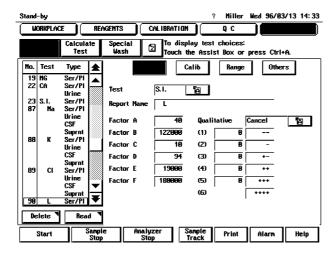
#### If the barsheet reader is activated

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.

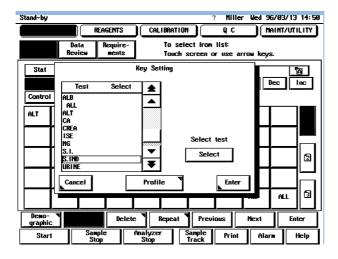
- 4. Press READ to display the new applications in the list.
- 5. Select the BM application S.I. with the application number 850 from the list and assign the vacant test number to the S.I. test in the TEST NO. field; confirm by pressing ENTER on the keyboard. Enter a test shortname in the TEST NAME field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



- 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	Α	В	С	D	Е	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.

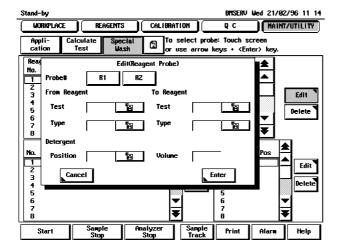
## 4.3 Special Wash Programming

## 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.

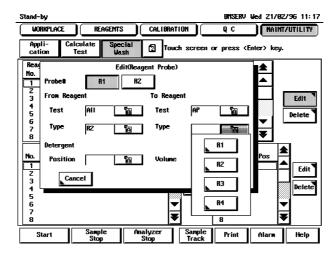


- 4. Touch the R1 or R2 button to select the desired reagent pipettor.
- 5. Touch the appropriate test name in the FROM REAGENT list box with which the wash is to begin and press the E button in the scrollbar. Touch the appropriate reagent type (e.g. R1) in the TYPE assist box.
- 6. Touch the appropriate 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 (1D1to 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:

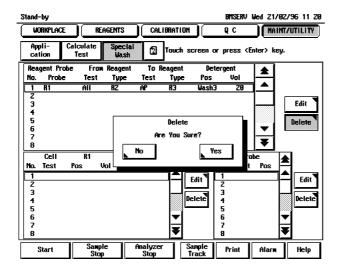
- 1. Touch MAINT/UTILITY, followed by SPECIAL WASH on the second sub menu level to display the corresponding sub menu.
- 2. Touch the number in the REAGENT PROBE wash box you want to edit.
- 3. Touch EDIT to the right-hand side of the list box to display the EDIT (REAGENT PROBE) window. Perform the steps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



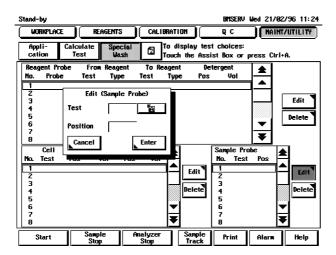
4. Touch YES to delete the wash programming.

#### 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.

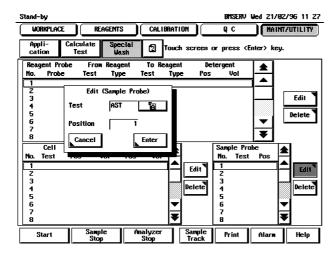


- 4. Touch the appropriate test name in the list box and press E on the scrollbar.
- 5. Select the detergent (W1 to W3) from sample disk 2 with which the sample probe is to be washed.
- 6. Touch ENTER to close the window.

## ■ To edit a sample probe wash

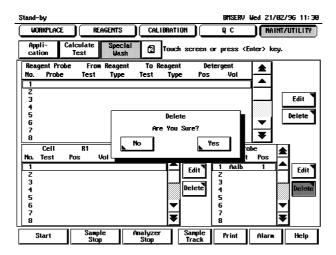
Perform the following steps in order to carry out a sample probe wash:

- 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.



## ■ 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.



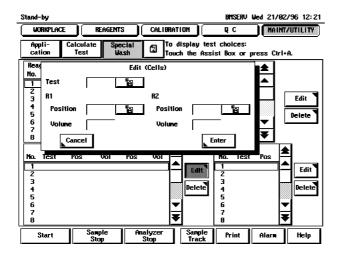
4. Touch YES to delete the wash programming.

#### 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.

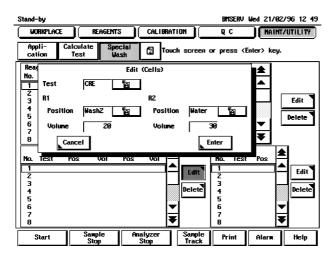


- 4. Select a test from the TEST assist box, then press E on the scrollbar.
- 5. Select the wash solution (1D2, 1D3, water) for the R1 pipettor from the R1 assist box
- 6. Enter the detergent volume (max. 270 mL) in the VOLUME text box.
- 7. Select the wash solution (2D2, 2D3, water) for the R2 pipettor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

### ■ To edit a cell wash

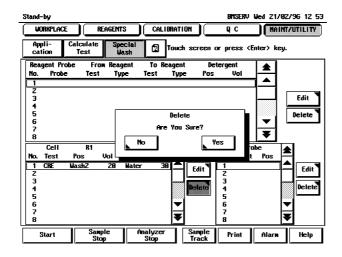
Perform the following steps in order to change a reaction cell program:

- 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

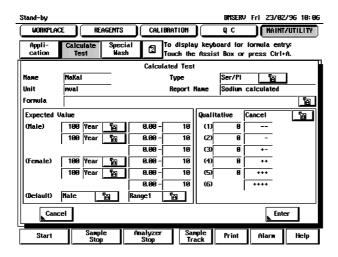
There are two different types of test calculations:

- 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

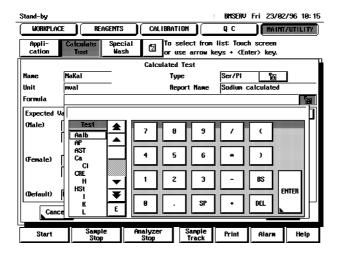
### ■ Entering a calculated test formula

- 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.

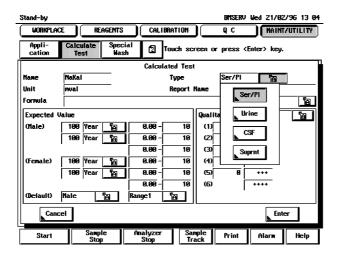
#### Note

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.

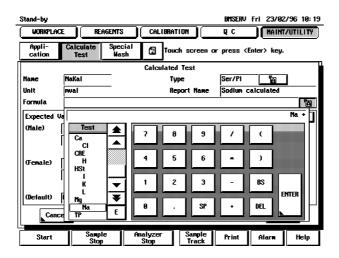
If the calculated result is to be printed out with a decimal point, this option has to be defined first in the expected value fields by entering a corresponding value beforehand.

## ■ 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).



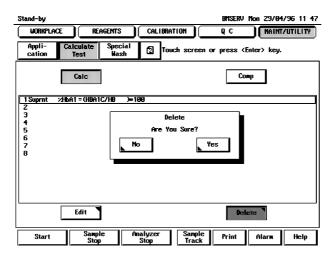
5. Touch the FORMULA assist box to display the list box and numeric key pad used to change the formula. Use the list box to select any test name that is part of the formula. Confirm it with E on the scrollbar. Use the numeric key pad to enter operands and numerals. Use DEL to delete the whole formula,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



- 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

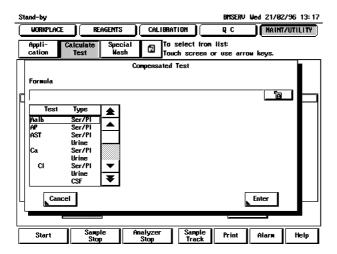
- 1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch CALC.
- 2. Touch the number of the calculated test you want to delete.
- 3. Touch DELETE to display the corresponding window. Select YES to delete the calculated test formula.



## 4.4.2 Compensated Tests

### ■ Entering a compensated test formula

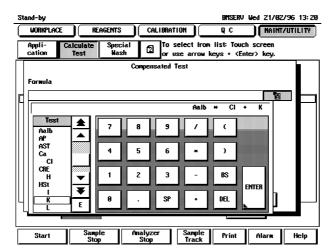
- 1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch COMP.
- 2. Touch the number you want to assign the compensated test formula to.
- 3. Touch EDIT below the list box to display the COMPENSATED TEST window.



- 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

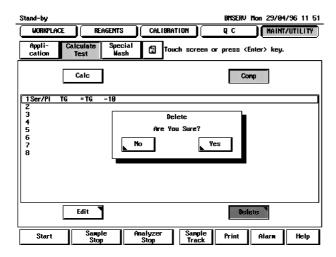
- 1. Touch MAINT/UTILITY, followed by CALCULATE TEST on the second sub menu level to display the corresponding sub menu. Then touch COMP.
- 2. Touch the number of the compensated formula you wish to edit.
- 3. Touch EDIT below the list box to display the COMPENSATED TEST window.
- 4. Perform the desired 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.

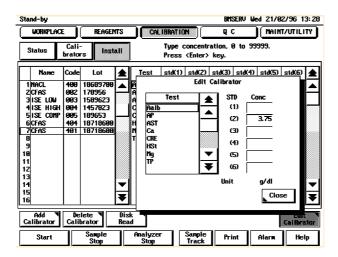


## 4.5 Loading Calibrator Information

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).



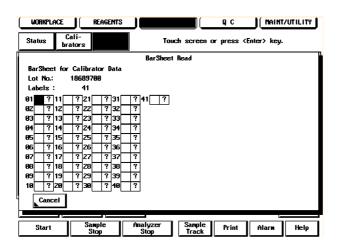
5. Touch ENTER to save the input and then CLOSE to close the window.

### 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.

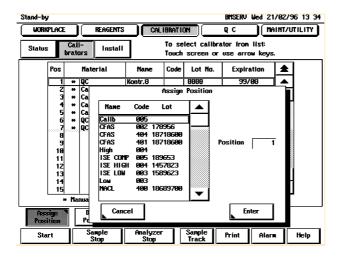
### 4.5.3 Assigning a Calibrator Position

 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.

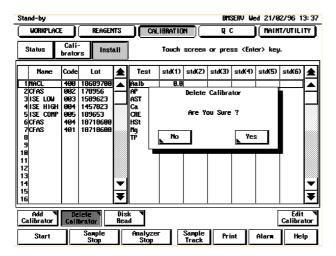
2. Touch ASSIGN POSITION to display the corresponding window. Touch the name of the calibrator from the list box. The chosen POSITION is displayed in the corresponding field. Touch ENTER to save the entry.



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

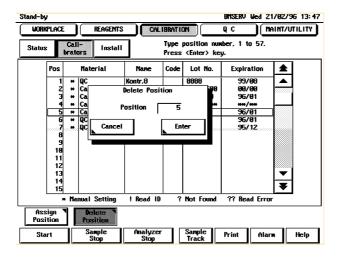
- 1. Touch CALIBRATION, followed by INSTALL, to display the corresponding sub menu.
- 2. Touch the calibrator name in the list box on the left that you want to delete. Touch DELETE CALIBRATOR to display the corresponding window.



3. Touch YES to delete the selected calibrator.

## 4.5.5 Deleting a Calibrator Position

- 2. Choose the calibrator position that you want to delete.



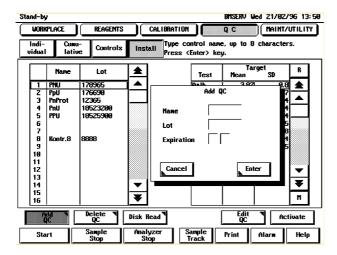
3. Touch DELETE POSITION to display the corresponding window. The chosen position is displayed in the corresponding field. Touch ENTER to delete the calibrator position.

# 4.6 Loading Control Information

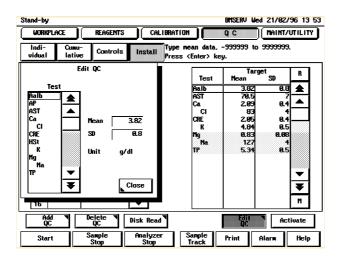
Use the following procedures to add new control setpoints, either manually or from a barsheet. The settings are to be entered in the ADD QC window of the INSTALL sub menu (QC main menu).

### 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.



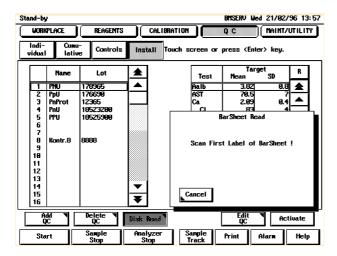
- 3. Enter the name of the control, lot number and expiration date. Press ENTER to save the entry.
- 4. Touch EDIT QC to display the corresponding window. Touch the test name you are entering control values for in the list box. Enter the Mean and 1 SD value. Repeat this procedure for all tests that need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



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

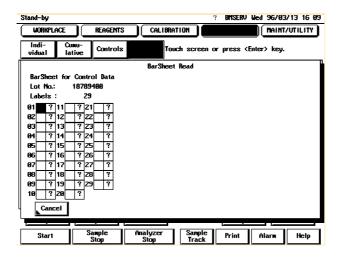
- 1. Touch QC, followed by INSTALL, to display the corresponding sub menu.
- 2. Touch the next vacant number in the list box on the left. Touch DISK READ to display the corresponding window.



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.



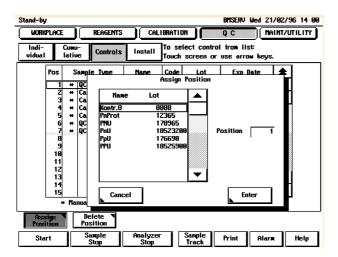
4. Scan all subsequent barcodes on the sheet. After the scanning is finished, the window closes automatically. Control name and lot number are displayed in the left box. The target mean and SD appear in the right box.

### Note

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

### 4.6.3 Assigning a Control Position

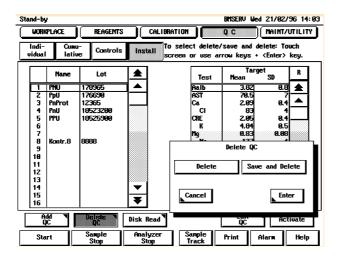
Touch QC, followed by CONTROLS, to display the corresponding sub menu. All
calibrators and controls which are assigned to a position are displayed in this screen.
Choose a position that is not currently assigned to another calibrator or control.
Activated controls appear highlighted in yellow.



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.



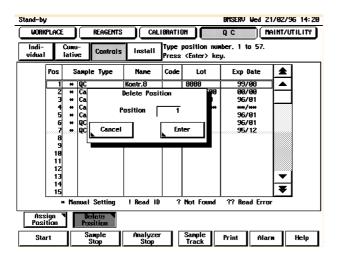
3. Touch the DELETE button or the SAVE AND DELETE button. Then touch ENTER, followed by YES to delete the entry.

### 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

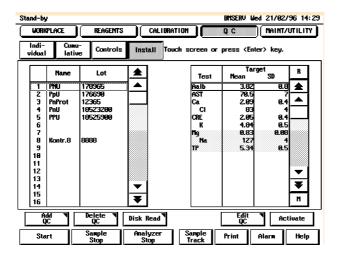
- 2. Touch the position you want to delete.



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.



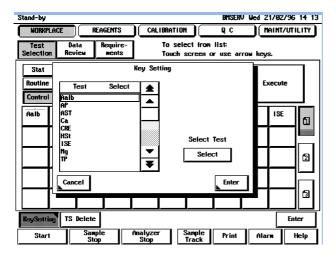
- 2. Touch the control name in the list box. Then touch ACTIVATE. The control is highlighted in yellow.
- 3. Mark all single tests of this control lot on the right list box. Touch the M button on the lower right side of the test list box. Touch the test name to be activated. Continue touching test names 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.

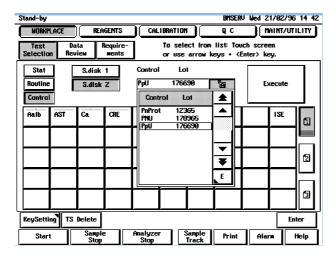


5. Touch the desired test name in the list box, followed by SELECT (a  $^{\star}$  is displayed in the SELECT column). Confirm with ENTER.

## 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.
- 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

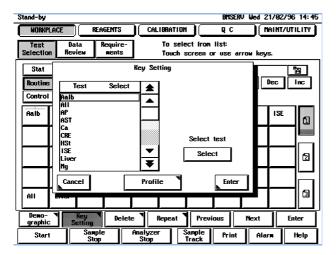
- 1. Touch QC, followed by CUMULATIVE and CHART to display the CUMULATIVE QC CHART window.
- 2. Touch the TEST assist box. Touch the test you want to review and press ENTER.
- 3. Touch SELECT to display the SELECT CONTROL window. Touch the control name followed by the PLOT button. This assigns the selected 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

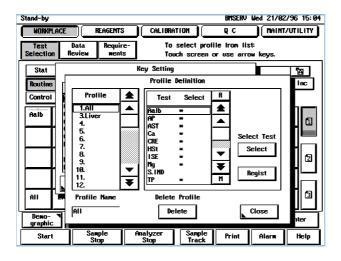
A number of different tests can be combined to a "profile". Use the following procedures to define profiles.

## 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.



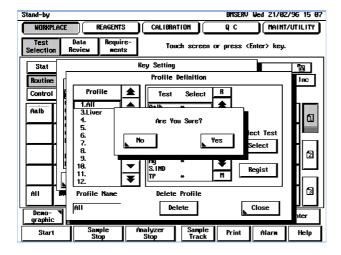
4. The KEY SETTING window is displayed. Touch PROFILE to display the PROFILE DEFINITION window.



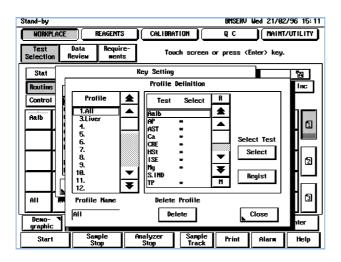
- 5. Touch the next vacant profile number in the left list box. Enter the profile name in the PROFILE NAME text box and press ENTER.
- 6. Touch a test in the list box and touch SELECT. An asterisk (\*) appears beside the test name indicating that this test is assigned to the profile. Touch SELECT again 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.

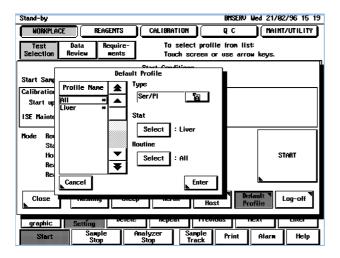


8. Touch CLOSE to close the PROFILE DEFINITION window. Then touch ENTER in the KEY SETTING window to confirm the entry.

#### 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.

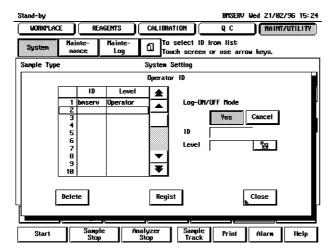
Operator IDs may consist of up to 6 characters.

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.



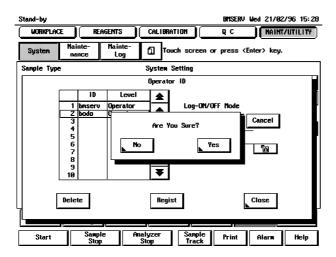
- 2. Touch the next vacant number in the list box.
- 3. Enter the operator ID in the ID text box.
- 4. Choose a security level (operator/supervisor) from the LEVEL assist box.
- 5. Touch REGIST, followed by CLOSE to save the ID.

## 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.



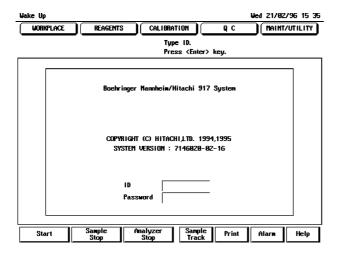
3. Touch DELETE, followed by YES to delete the operator ID.

#### 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.



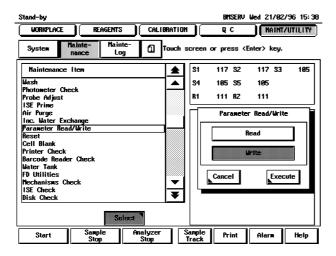
- 1. Enter your operator ID in the LOG ON screen. When you log on for the first time, enter your personal password. A row of asterisks (\*\*\*\*) is displayed on the screen. Press ENTER to complete the registration.
- 2. If you have forgotten your password, the supervisor must delete the old ID and assign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

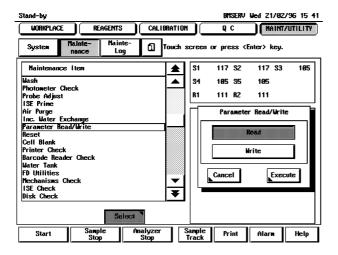
- 1. Use only formatted floppy disk to write the parameters on a disk. If the floppy disk is not formatted, use the option FD UTILITIES in the list in the MAINTENANCE sub menu.
- 2. Touch MAINT/UTILITY, followed by MAINTENANCE, to display the corresponding sub menu. Insert the floppy disk into the FD 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

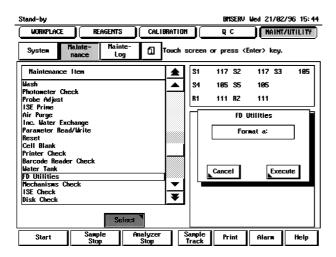
- 1. Insert the parameters floppy disk in drive a: of the analyzer.
- 2. Touch MAINT/UTILITY, followed by MAINTENANCE, to display the corresponding sub menu. Insert the floppy disk into the FD drive of the analyzer's computer. Touch PARAMETER READ/WRITE in the list box. Touch SELECT to display the PARAMETER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

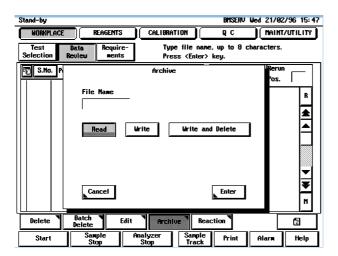
### 4.9.4 Archiving Data

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.

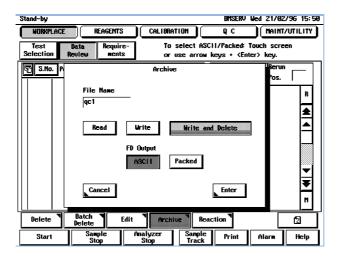
### 7. Touch the desired format.

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.



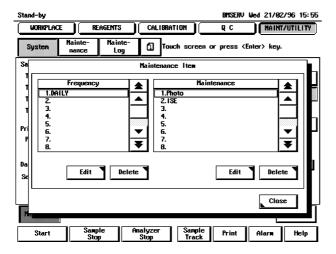
Refer to chapter 4.6.4, Deleting a Control, for further instructions.

## 4.10 Define Maintenance Frequency and Maintenance Item

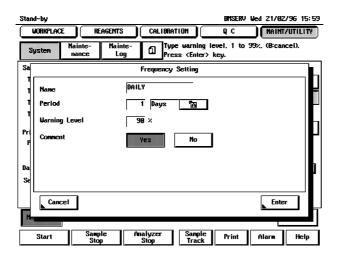
Use the following procedure to set or edit the daily, weekly, monthly, and other maintenance frequencies and to define any special frequencies needed by your laboratory.

## 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.



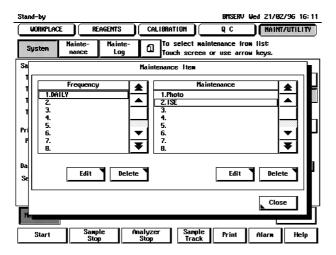
- 5. Enter the name of the frequency in the NAME text box, then press ENTER on the keyboard.
- 6. Enter the desired interval number in the PERIOD text box, then press ENTER on the keyboard.
- 7. Select the period interval (days, months) in the PERIOD assist box, then press ENTER on the keyboard.
- 8. 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

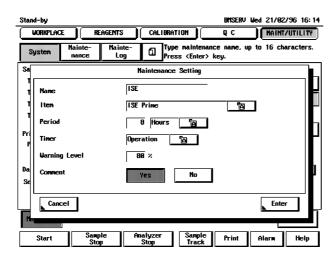
If the warning level is reached, a yellow '?' appears in the status line. If the interval is elapsed, a red '!' appears in the status line. The maintenance item ought to be performed immediately.

## 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.



- 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.
- 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

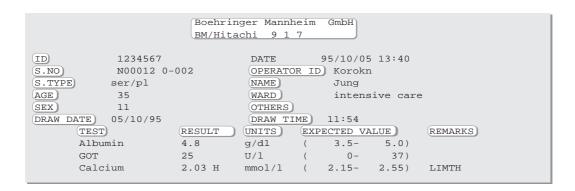
### 5.1 MEASUREMENT DATA Printout

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.

### One Report Per Page



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

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 9 1 7				Boehringer Mannheim GmbH BM/Hitachi 9 1 7			
95/10/05 N00010 ID 1234	0-001 p	12:19 Ser/Pl		95/10/05 N00012 ID 7890	0-002 p	13:40 Ser/P	1	
TEST	RESULT	UNITS	REMARKS	TEST	RESULT	UNITS	REMARKS	
Sodium		mmol/1	LIMTL	Albumin	4.8		g/dl	
Potassium	4.9 H	mmol/l		GOT	25		U/l	
Chloride	104	mmol/l		Calcium	2.83	Н	mmol/l	
				Creatinin	1.87	H	mg/dl	
				Total Prot.	5.5	L	g/dl	
				Magnesium	1.18	Н	mmol/l	
				Sodium	135		mmol/l	
				Potassium	5.2	Н	mmol/l	
				Chloride	111	Н	mmol/l	

95/10/05 12:19 Date and time of printout

N00010 0-001 p / N00012 0-002 p

Patient's sample number

RESULT Test result

UNITS Units of measure used

REMARKS Remarks, e.g. data alarms

such as LIMTL.

Ser/P1 Sample Type

TEST Test name

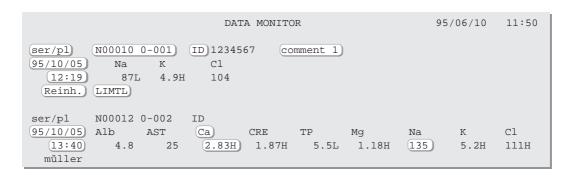
UNITS Units of measure used

ID 7890123 ID 7890123 Patient ID

numbers, if available.

#### 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

ID) Sample barcode, if available

(LIMTL) Data alarm

(ca) Test name

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

comment 1 comment 1, as entered in

the DEMOGRAPHICS window (WORKPLACE main menu)

N00010 0-001 p Patient's sample number

(Reinh.) Example of the user's operator ID

95/06/10) Draw date

(12:19) Draw time

135 Test result

#### 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 x 10<sup>4</sup>. 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.

	Ser/Pl	N00001 1 100182	1-001) CE	REACTION	N MONITOR	)	95/10/19	11:13					
	*** 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

- ID Sample barcode, e.g. 100182
- Ca Test name and test result, e.g. 2.38
- (6-10) Measurement points 6-10
- 59 Example of an absorbance

PRIMARY Absorbance x 10<sup>4</sup> of primary wavelength-cell blank

N00001 1-001 Example of a sequence number

CELL Reaction cell number, e.g. 016

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

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.

(SECONDARY) Absorbance x 10<sup>4</sup> of secondary wavelength-cell blank

#### 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.

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

Ser/Pl Sample type

(CELL) Reaction cell number, e.g. 016

ID Sample barcode, e.g. 100182

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.

3159 Example of an absorbance

N000001 1-001) Example of a sequence number

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

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

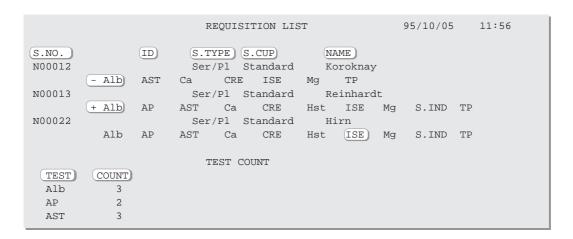
11-15 Measurement points 11 to 15

## 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.



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

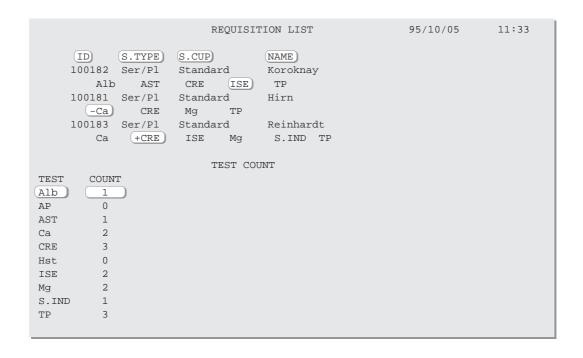
ISE Example of a requested test requested

TEST) Test name

**COUNT)** Total number of test requisitions

## 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.



ID Sample ID, if available

S.CUP Sample cup, e.g. Standard

ISE Example of a requested test

TEST Test name

COUNT) Total number of test requisitions

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

NAME Patient's name, if available

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

## 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							
	ID S.TYPE 100182 Ser/Pl		NAME Koroknay					
	100183 Ser/Pl		Reinhardt					
	100181 Ser/Pl		Hirn					
	TEST C	OUNT						
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

D Sample ID, if available

S.CUP Sample cup, e.g. Standard

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

TEST Test name

POS) Position number

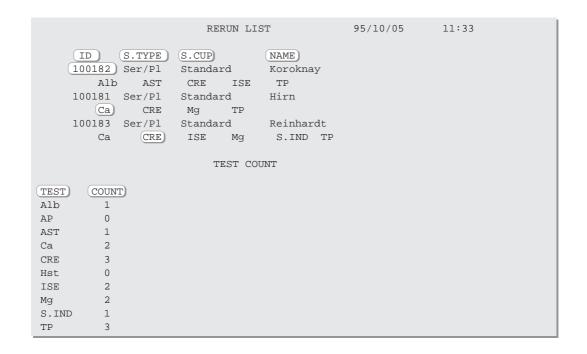
S.TYPE Sample type, e.g. serum/plasma

NAME) Patient's name, if available

**COUNT** Total number of test requisitions

## 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.



ID Sample ID, if available

Example: 100182

S.CUP Sample cup, e.g. Standard

Ca CRE Example of a test name

TEST Test name

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

NAME Patient's name, if available

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.

			PRECI	95/10/05	13:44			
TEST) Ca	<u>N</u>	MEAN 2.682	UNIT mmol/l	RANCE 0.05	MAX.) 2.71	MIN. 2.66	\$D 0.016	CV(%)
Cl	9	104.7	mmol/1	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/1	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

MEAN Mean value

RANGE Deviation (Max.-Min.)

MIN.) Minimum value

©V(%) Coefficient of variation

Number of measurements

UNIT Unit of test result

MAX.) Maximum value

SD Standard deviation

## 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 LIS	Г		95/10/05	14:10
[KEY PROFILE]	1 11 51 61		31 81	41	
*1 ALL Ser/Pl	******				
2 ALL Urine	_****		·	 	
3 LIVER Ser/Pl	_*_*_				
[STAT PROFILE]					
Ser/Pl	_*_*				
CH TEST NAME	CH.TEST NAME	CH.TEST NAME	1	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
- (ALL ) Example of a profile name
- 21 Example of a method number

TEST NAME Test name, e.g. Ca

- 1 Profile number
- Ser/Pl) Example of a sample type
- СH. Test number

# 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.

	SY	STEM REQU	IREMENTS	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	t short 50	
=== CALIBRATOR ===					
NAME	POS.	LOT	REASON		
NACL	1(0)	18689700	no calib. material		
=== QC ===					
NAME	POS.	LOT	REASON		
PNU	2-6(0)	18523200	QC error		
PPU	2- 7(0)	18525900	QC error		

REAGENT CALIBRATOR QC	TEST Test name
Material type	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

# 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	0/13 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	0 *
	R1	1 33!	220	652840	693	96/ 5	0 *
	R3	2 32	230	651063	693	96/ 5	0 *
AST	R1	1 27*	260	655652	253	96/10	7
	R2	2 10	260	655865	253	96/11	69
TP	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			60 ml				
	2D1		59 ml				

TEST Test name

Pos.) Disk number and position

LOT Lot number

EXP.Month Expiration year and month

2\*29 Reagent in incorrect disk

1 27\*) Reagent loaded twice

(barcoded and manually)

ISE WASH S. ISE and rinse solution in ml, e.g. 353 ml

TYPE Reagent type, e.g. R1; DIL stands for diluent (sample diluent)

TESTS Number of available tests, rounded down); diluent in ml

**BOTTLE** Application number

STAB. Stability on board in days

1 33!) Manually loaded reagent

Barcode was recognized, corresponding application not available, thus no assignment possible

# 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 x 10<sup>4</sup>) 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.

				CALI	BRATION MONI	TOR	95/10/13	14:0
5/10/13	13:49	Korok	nay)					
TEST	5	51	5	52	S3	S4	S5	S6
Mg	14878	22243	9040	18882				
	14903	22288	9097	18900	J			
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	J			
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.

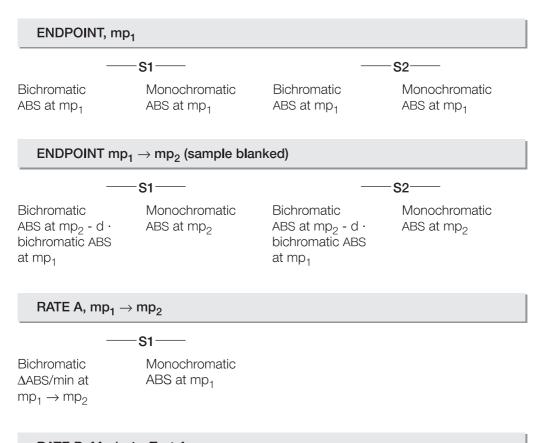
```
AST -3 13697 -361 15251
-6 14785 -363 15337
```

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  $\Delta E/\min$ , 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.

# ■ Interpretation for calibration monitor



# RATE B, Mode 1 - Test A

——S1—

Bichromatic  $\Delta ABS/min$  at  $mp_1 \rightarrow mp_2$ 

Monochromatic ABS at mp<sub>1</sub>

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

\_\_\_\_S1\_\_\_

Bichromatic  $\Delta ABS/min$  at  $mp_3 \rightarrow mp_4$ 

Monochromatic ABS at mp<sub>3</sub>

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

\_\_\_\_S1\_\_\_

Bichromatic ΔABS/min at Monochromatic ABS at mp<sub>3</sub>

 $mp_3 \rightarrow mp_4$  - d · bichromatic  $\Delta$ ABS/min at  $mp_1 \rightarrow mp_2$ 

## RATE B, Mode 2 - Test A

——S1——

Bichromatic ΔABS/min at Monochromatic ABS at mp<sub>1</sub>

 $mp_1 \to mp_2$ 

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

----S1----

 $\begin{array}{ll} \mbox{Bichromatic} & \mbox{Monochromatic} \\ \Delta \mbox{ABS/min at} & \mbox{ABS at mp}_5 \end{array}$ 

 $\begin{array}{l} \mathrm{mp_5} \rightarrow \mathrm{mp_6} \text{ -} \\ \mathrm{d} \cdot \mathrm{bichromatic} \\ \Delta \mathrm{ABS/min} \text{ at} \\ \mathrm{mp_3} \rightarrow \mathrm{mp_4} \end{array}$ 

## Legende

S1 = Standard 1

S2 = Standard 2

mp<sub>1</sub> = Photometric measurement point 1

. '

mp<sub>6</sub> = Photometric measurement point 2
 d = correction factor of liquid volume

Monochromatic ABS = Absorbance for primary waavelength

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

			CALIBR	ATION MONI	9	5/10/05	14:07	
95/10/0 TEST Na	5 13:49 (I IS EMF) -32.2	Hirn Sl EMF -35.9	S2 EMF -28.8	S3 EMF -33.7	SLOPE IS	.CONC.) (S3	CONC.	C.VALUE -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

S1 EMF Electromotive force (in mV) for Standard Low

(S2) (EMF) Electromotive force (in mV) for standard high

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

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

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

Na = 50 to 68, K = 50 to 68,

 $Na = 140 \pm 10, K = 5 \pm 1,$ 

CI = -68 to -40

 $CI = 100 \pm 10$ .

S3 CONC.) Calculated compensator concentration

(C. VALUE) Target value minus measured com pensator concentration

# Note

The EMF results must be within the defined ranges:

Na: -90 mV to -10 mV K: -90 mV to -10 mV 80 mV to 160 mV CI:

# 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  $10^4$ . 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.

			REACTIO	N MONITO	R		95/10/13	17:58
	S21	CE	LL 081) (	AST	-341	)		
(LOT. 187	/18600)							
*** PRIN	MARY ***							
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					
*** (SECC	NDARY **	*						
(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:

Standard 2, measurement 1

AST Test name

Lot number

6-10 Measurement points 6-10

PRIMARY Absorbance x 10<sup>4</sup> of the

primary wavelength minus cell blank

CELL 081 Reaction cell number, e.g. 081

<u>-341</u> Example of a measured test result (for Standard Absorbance)

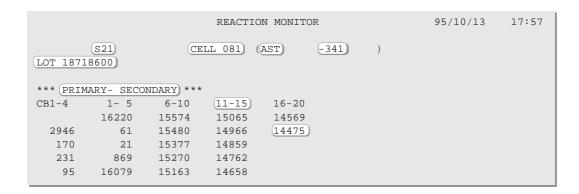
CB1-4 Reaction cell blank value 1-4

194 example of an absorbance x  $10^4$ 

SECONDARY Absorbance x 10<sup>4</sup> of the secondary wavelength minus cell blank

## 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



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 primary 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											
(1(0))	NACL	18689700	Alb	*AP	AST	Ca	CRE	*Hst	Mg	TP	
2(0)	CFAS	18718600	Alb	*AP	AST	Ca	CRE	*Hst	Mg	TP	
3(0)	ISE LOW		ISE								
4(0)	ISE HIGH		ISE								
5(0)	ISE COMP	189653	ISE								

[Start up] Chosen calibration type

(NAME) Calibrator name

**AST** Test name

(1(0)) Example of a sample on the outer ring. 36 (I) would be a sample on the inner ring.

pos.no.) Calibrator position on the sample disk 2. Example: 1 (0), indicates the outer ring. 36 (I) indicates the inner ring.

Lot number of the calibrator

\*AP Blocked test

# 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.

	CALIBI	RATION TRACE	95/01/26	10:18
AST DATE TIME OF	P.ID RESULT STD.LOT F	· ·		-R3
28/09 10:10 Kd	orokn 14088B 18689700	362 18718600	655652 03771 655865 02550	
05/10 12:10 Re	einh 13729 18689700	361 18718600	655652 03771	
09/10 14:17 KG	orokn 13528 18689700 -		655865 02550 655652 03771	
19/10 15:45 Re	einh (13604) 18689700		655865 02550 655652 03771 655865 02550	

#### AST Test name

OP.ID Operator identification, e.g. Korokn RESULT STD.LOT Result and standard lot for Std1 or Std2 to 6. Example:

Calibration was performed without this standard

02550 Bottle number of reagent 1 to 4. -341 =  $\Delta$ E/min.for rate measurement

(primary minus secondary wavelength).

Date and time of settings

LOT BOTTLE Lot and bottle number of the reagents. Example:

655865 Lot number of reagent 1 to 4.

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

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

alarm that has occurred for this calibration

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

# 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.

(TP)				CALIBRA'	TION TRAC	CE 9	5/10/20 1	0:31
DATE	TIME	OP.ID					LOT BOTTLE LOT	
							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	
COMME	NT							
Pleas	e cons	ider th	e error d	codes				

#### TP Method name

OP.ID Operator identification, e.g. Reinh
RESULT STD.LOT Result and lot number for Std1 or Std2 to 6. Example: 238
End absorbance of the Standard for primary minus secondary wavelength -1116

Please consider the error codes

Comment that has been entered in CALIBRATION TRACE window

DATE TIME Date and time of settings

LOT BOTTLE Lot and bottle number of the reagents R1-R4. Example:

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).

#### 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.

77.		CAI	JIBRATION	TRACE	95	/10/05	10:25		
(Na) (DATE	TIME	OP.ID		CALIB.LOT 3 CONC.)					
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

OP.ID Operator ID

Std 3 CONC. Compensator

concentration, e.g. 124.0 in mmol/L

DATE TIME Date and time of the settings

SLOPE Slope

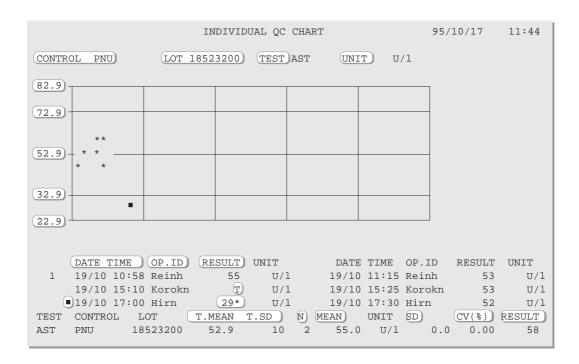
45.6R -5.6E Measured slope in mV

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 the 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.



CONTROL PNU Control name, e.g. PNU

LOT.18523200 Control lot number

TEST Test name, e.g. AST

**UNIT** Units of measure

DATE TIME Date and time of requisition 19/10 Value has already been accumulated

OP. ID) Operator ID, e.g. Reinh

RESULT) Results

T = data alarm instead of a result

29\* = Result lies outside ± 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

Number of controls, e.g. 2

MEAN Mean value, e.g. 55.0

SD Standard deviation, e.g. 0.0

(CV(%)) Variationskoeffizient, z.B. 0.00

RESULT) Last measured result, e.g. 58

#### Graph:

82.9) +3SD range

(72.9) +2SD range

52.9) Target value

32.9) -2SD range

22.9) -3SD range

• 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.

		2	0/10/95	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/	0.0	0.00	58
AST	PPU	18525900	144	26	3	147.7 U/	5.8	3.93	151
Ca	PNU	18523200	2.31	0.2	4	2.695mmol/	0.636	23.60	2.25
Ca	PPU	18525900	3.35	0	4	2.785mmol/	0.958	34.40	3.62
Cl	PNU	18523200	86	2	4	83.0mmol/	2.4	2.89	84
Cl	PPU	18525900	115	3	4	113.5mmol/	2.6	2.29	114
Mg	PNU	18523200	0.86	0.11	3	0.683mmol/	0.006	0.88	0.68
Mg	PPU	18525900	1.69	0	3	1.557mmol/	0.006	0.39	1.56

TEST Test name, e.g. AST

LOT Lot number, e.g. 18523200

T.SD Target standard deviation

MEAN Mean value

SD Standard deviation, e.g. 0.006

RESULT) Last measured value, e.g. 1.56

CONTROL Control name, e.g. PNU

Target mean value, e.g. 1.69

Number of control measurements, e.g. 3

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

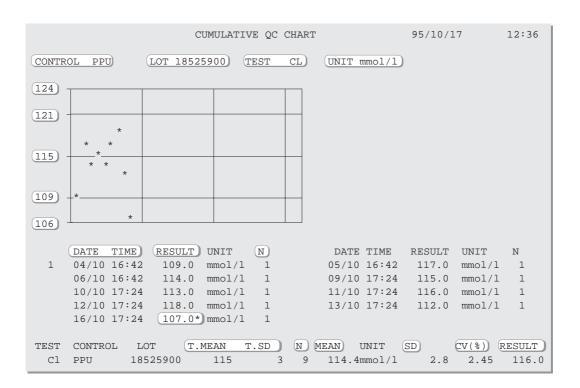
(CV(%)) Coefficient of variation, e.g. 0.39

#### 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.



CONTROL PPU Control name, e.g. PPU

LOT 18525900 Control lot number

TEST CL Test name, e.g. CL

UNIT mmol/1 Units of measure, e.g.

mmol/I

DATE TIME Date and time of calibration

RESULT Calculated mean value, example:

107.0\* = the result lies outside ± 2SD.

N Number of controls, e.g. 9

RESULT Last measured result, e.g. 116.0

T.MEAN T.SD Target mean value and target standard deviation, e.g. 115 = target mean value, 3 = target standard deviation

- Number of control measurements, e.g. 9
- MEAN Mean value, e.g. 114.4
- SD Standard deviation, e.g. 2.8
- CV(%) Coefficient of variation, e.g. 2.45

## Graph:

- (124) +3SD range
- 121 +2SD range
- 115 Target value
- 109 -2SD range
- 106 -3SD range

# 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.

				CU	OC	LIST	20/1	20/10/95		
						~				
TE	ST)	CONTROL	LOT	T.MEAN)	(T.SD)	$\overline{N}$	MEAN) UNIT	SD) C7	7(%)	RESULT
	Cl	PNU	18523200	86	2	10	83.3mmol/1	1.3	1.55	83.0
	Cl	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	127.8 mmol/1	0.7	0.52	127.0
	Na	PPU	18525900	140	2	9	138.4 mmol/l	2.2	1.58	139.0

TEST Test name, e.g. Cl

LOT Lot number, e.g. 18523200

T.SD Target standard deviation

MEAN Mean value

SD Standard deviation, e.g. 1.3

RESULT) Last measured value, e.g. 83.0

CONTROL Control name, e.g. PNU

Target mean value, e.g. 140

Number of control measurements, e.g. 9

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

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

# 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.

		95/10/17 10:28		
10/17 18:17			Cell Rinse Cleaner	
10/17 18:16	2		Cell Rinse Cleaner	
10/17 18:14			Cell Rinse Cleaner	
10/17 18:13			INCUBATION BATH WAT	
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 WAT	ER 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 WAT	ER 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			Cell Rinse Cleaner	
10/17 17:47			Cell Rinse Cleaner	

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% Chang	e	
2-084-088-003	Calibration > 20% Chang	е	
2-084-089-003	Calibration > 20% Chang	е	
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 S	HORT	
2-013-001	24V FOR DO2 PCB		
2-018-043	DISTILLED WATER SHORT		
К 001-003	START		
003-001	STOP		

5/10/95 10:07 10:29

ISE Slope Error

Date and time of the alarm message

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
                                           95/10/17
                                                    06:37
06:36:38 06:36:38 AU->HOST
274>
ETX
06:36:32 06:36:32 HOST->AU
723>
ETX
06:36:30 06:36:30 HOST->AU
                   100001
725;A1
ETX
06:36:30 06:36:30 AU->HOST
276?
ETX
06:36:29 06:36:30 HOST->AU SUM ERROR
                             100001
Comment 2
ETX
D0
CR
```

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.

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

DATE Date

LOGON Login time (Log In)

\*\*\* The analyzer was switched off

without performing a LOGOFF

OP. ID) Operator ID

LOGOFF) Logoff time (Log Off)

#### 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.

		CU	MULATIVE (	OPERATION I	LIST	95/10/	10:32
1. POW	VER ON TIME			351	HOURS		
2. OPE	RATION			133	HOURS		
3. TES	T 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	ROI	UTINE	RERUN	STAT	TOT	AL
			292	140	56	48	38

- 1. POWER OF TIME Power-on time in hours, e.g. 351
- 2. OPERATION) Operating time, e.g. 133
- $\ensuremath{\mbox{3. TEST COUNT}}\mbox{ Type}$  and number of tests performed during the switched-on time broken down into

TEST Test name, e.g. Alb

APP.CODE Test application number,

e.g. 042

ROUTINE Number of routine determin-

ations performed using this test

CALIB.

Number of calibrations performed

using this test, e.g. 66

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

CONT. Number of controls performed using this test

RERUN Number of reruns performed

using this test, e.g. 3

**STAT** Number of STAT samples

performed using this test

TOTAL Total of all test types for this

test, e.g. 113

 ${f 4.}$  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 MAINTE-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.

	MA	T NT(T) T) NT N 1	MAE DED	ODE	05/10/	18 17:33
	MA	INTENA	NCE REP	URI	95/10/	18 17.33
PARTS WEEKLY	DATE	TIME)		COMMENTS CELLS replaced		
	12/10/95	15:19	Korok	ELLIS TEPTACEU		
CELL blank measurement	12/10/95					
	05/10/95	16:47	Reinh			
Clean container	10/10/95	17:33	Korok	Condensation wi	ped away	
	12/10/95	15:13	Hirn			

PARTS Type and frequency of the maintenance

WEEKLY Example of a maintenance

cycle, that has been confirmed using the

ALL COMPLETE in sub menu MAINTE-LOG

DATE TIME Date and time when the

maintenance procedure was performed

OP.ID Operator ID

COMMENTS Comment text (optional);
e.g. Cells replaced; if the comment is selected, the text appears here in the printout

Cell blank measurement Example of a

mainte nance 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

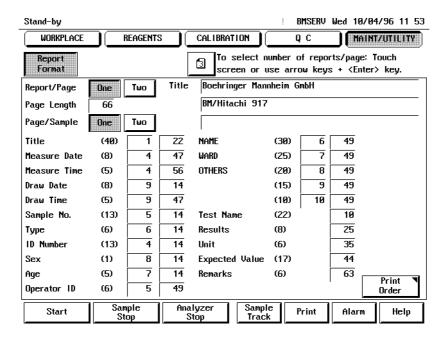
The following two examples show the different formats of a Report Example. This list is printed out according to the settings made beforehand in the main menu MAINT/UTILITY, sub menu REPORT FORMAT. The specifications for the list format in the form of line and character numbers are entered in the screen 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.

## 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.



```
Boehringer Mannheim GmbH
                                            BM/Hitachi 9 1 7
                                                       DATE 06/10/95 11:43
OPERATOR ID &&&&&
TD
                 1234567890123
                 NR00001 0-001
S.NO.
S.TYP)
                                                          NAME ##Kommentar1#####################
AGE
                  100 J
                                                           WARD
                                                                                    %%Kommentar2%%%%%%%%%%%%%%
                                                             OTHERS
SEX
                                                                                     @@Kommentar3@@@@@@@
                                                            DRAW TIME 11:43
DRAW DATE 06/10/95

        TEST
        RESULT
        UNITS
        EXPECTED VALUE
        REMARKS

        (Albumin)
        999999 H
        g/dl
        (-999999-9999999)
        *******

        GOT
        999999 H
        U/l
        (-999999-9999999)
        *******

             Calcium 999999 H mmol/l (-999999-9999999) ******

Creatinine 999999 H mg/dl (-999999-999999) ******
             Total Prot. 999999 H g/dl (-999999-999999) ******
            Magnesium 999999 H mmol/l (-999999-9999999) ******

Alk. Phos. 999999 H U/l (-999999-9999999) ******

Bun. 999999 H mg/dl (-999999-9999999) ******

Sodium 999999 H mmol/l (-999999-9999999) ******

Potassium 999999 H mmol/l (-999999-9999999) ******

Chlorid 999999 H mmol/l (-999999-9999999) ******

Lip. 999999 H *****
            Lip. 999999 H haemol. 999999 H
                                                                                                                *****
             Ict.
                                       999999 Н
```

```
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
```

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

Boehringer Mannheim GmbH Example of a report title

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

TEST) Method name, e.g. (Albumin);

EXPECTED VALUE Defined reference range

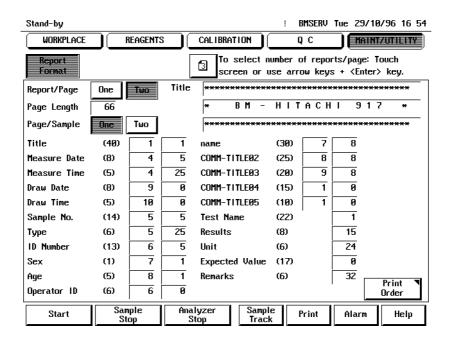
REMARKS Additional remarks

## 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.



Boehring	er Mannl	ne:	im GmbH		Во	ehringe	r Mannh	eir	n GmbH		
BM/Hitac	hi 9 1	7			BM	/Hitach	i 91'	7			
06/10/95			11:48		06/	10/95			11:48		
NR00001 0	-001 p		*****	)	NR0	0001 0-	001 p		*****		
123456789	0123				123	4567890	123				
M ##Comm	ent1###	+######	####)	M	##Comm	ent1###	###	+######	#####		
100 y) %%Comm	ent2%%%	<sub>કે</sub> ફે ફે ફે ફે ફે ફે	)	100 J	%%Comm	ent2%%%	응용	૪ <b>૨</b> ૨૨૨			
@@Comm	@@Comment3@@@@@@@						ent3@@@	@@@	@@@		
TEST	RESULT	)	UNITS	REMARKS	TEST		RESULT		UNITS	REMARKS	
Albumin	999999	Η	g/dl	*****	Albumi	n	999999	Η	g/dl	****	
GOT	999999	Η	U/l	*****	GOT		999999	Η	U/l	*****	
Calcium	999999	Η	mmol/l	*****	Calciu	m	999999	Η	mmol/1	*****	
Creatinine	999999	Η	mg/dl	*****	Creati	nine	999999	Η	mg/dl	*****	
Total Prot.	999999	Н	g/dl	*****	Total	Prot.	999999	Н	g/dl	*****	
Magnesium	999999	Н	mmol/l	*****	Magnes	ium	999999	Н	mmol/l	*****	
Alk. Phos	999999	Η	U/l	*****	Alk. P	hos	999999	Н	U/l	*****	
Bun	999999	Η	mg/dl	*****	Bun		999999	Н	mg/dl	*****	
Sodium	999999	Н	mmol/l	*****	Sodium		999999	Н	mmol/l	*****	
Potassium	999999	Η	mmol/l	*****	Potass	ium	999999	Н	mmol/l	*****	
Chlorid	999999	Η	mmol/l	*****	Chlori	d	999999	Η	mmol/l	*****	
Lip.	Lip. 999999 H *****		*****	Lip.		999999	Н		*****		
haemol.	naemol. 999999 H *****		haemol		999999	Н		*****			
Ict.	999999	н		*****	Ict.		999999	ш		*****	

06/10/95 Date of sample requisition

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

(1234567890123) Sample barcoder number

M Patient's sex

100 y Patient's age

Comment 1

according to the setting in the

"Comment 1" field, in this example: NAME

\(\frac{\circ}{\circ}\text{8Comment2\circ}\text{8\circ}\t

Comment 2

according to the setting in the

"Comment 2" field, in this example: WARD

@@Comment3@@@@@@@

Comment 3

according to the setting in the "Comment 3"field, in this example: OTHERS

\*\*\*\*\* Sample type (list header)

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 stands for HIGH (Result exceeds reference range)

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

**REMARKS** Additional remarks

## 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.

				95	/10/17	10	:25						
0 = 4 = 4	95/10/12 10:21 WAVE LENGTH(NM)												
NO.	340	376	415	450	480	AVE LEI ) 505	NGTH ( NI 546	4) 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

(in NM) Measurement wavelength

12338) and ADC2) of the first reaction cell

-317 -316 Example of absorbancedifferences 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
( PF	REVIOUS DATA -		) (			CURRENT D.	ATA	
DATE 11/10/95	00:05		DATE	12/10/	/95	11:08		
	WV1(2nd) WV	V2(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	

Data from the last measurement

800 NM Example of a wavelength (in NM)

WV1 (2nd) Absorbance of the secondary wavelength

WV2 (PRI.) Absorbance of the primary

wavelength

## 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 (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 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											
95/1	95/10/12 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	=		10407	10191	10073	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).

## 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.

PRINTER CHECK 95/10/18	11:14
!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!	######################################
	00000000000 011111111111 2222222222 3333333333
<<<<<<<<<<<<<<<<<<<><<<<<<<<<<<<<<<<<<<	.<<<<<
>>>>>>>>>>>>	>>>>>>

## 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	5 11:18
POS.NO ID RD 1001 042654052069290747 SD 1056		ID 651653080005600026		100182
RD 1002 315651307055980746 SD 1057	RD 2002	756651253026025456	SD 2002	
RD 1003 756651252005885426 SD 1058	RD 2003	693651063024283686	SD 2003	100183
RD 1004 951653228045232307 SD 1059	RD 2004	315651307050940746	SD 2004	100181
RD 1005 420651836004780747 SD 1060	RD 2005	315652499051250046	SD 2005	100184
RD 1006 693652840014013626 SD 1061	RD 2006	420651774016370077	SD 2006	100189
RD 1007 SD 1062	RD 2007	253655865025508316	SD 2007	100190

POS. NO. Identification of the disk, ----- ID ----- ID of the scanned disk number and position number barcode on the disk RD 1001 Example: RD = reagent disk; SD 1062 Example: SD = sample disk; 1001 = disk number 1 (1) and 1062 = barcode reader on inner ring (1) and position 1 (001) and position 62 (062) SD 2001 Example: SD = sample disk; 042654052069290747) Example of a reagent 2001 = barcode reader on outer ring (2) barcode and position 1 (001) 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 CI, 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

NA EMF EMF (Electromotive
force in mV) of the Na electrode

K EMF EMF of the K electrode

CL EMF EMF of the Cl electrode

(REF.EMF) EMF of the reference 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

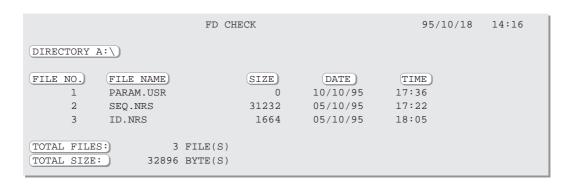
TOTAL SUM:0072 Total check sum

	H	D 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 FILE	=				
OTAL SIZE	/3343/92 BI	16(3)			
YSTEM PRO	OGRAM VERSION: 0	2-16			
CHECK SUM	)				
	FILE NAME	SUM			
	CU.EXE	F94B			
	MSGRUN	F7DC			
	MSGRUN AUPROG1	1389			
	AUPROG1	E0AD			
	TMPROG1	B685			
	TMPARM1	5C6C			
DOMAT CITY	0072				
COTAL 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.



DIRECTORY A:\ Drive identification

FILE NO. File number

FILE NAME File name

SIZE Size of the file (in bytes)

DATE TIME Date and time of installation

TOTAL FILES Total number of files on the floppy disk

TOTAL SIZE Total size of the files

(in bytes)

#### 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

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	D	0 (1)	1 (0)	Pho	otom	etry		ISE		Page	Note
Data alarm	Printout	S. (1)	I. (2)	R/S	С	Std.	R/S	С	Std.		1
Absorbance over	ABS?	Z	Z	0	0	O				6-28	
ADC abnormal	ADC?	Α	Α	О	0	0	О	0	0	6-29	
Absorbance maximum over	>AMAX	>	>	0						6-29	
Calculation test error	Calc?	%	%	0	0		0	0		6-30	
Calibration result abnormal	CalErr	!	!	0	0		0	0		6-30	
Calibration error	Calib	_	В			O				6-31	
Cell blank abnormal	Cell?	Q	Q	0	0	0				6-32	
Test-to-test comp. error	Cmp.T	С	С	0	0		0	0		6-33	
Test-to-test compensation disabled	Cmp.T!	М	М	0	0		0	0		6-34	4
Duplicate error	Dup	_	U			0				6-34	
Edited test	Edited	*	*	0	0		0	0		6-36	
Outside of reference value (high)	Н	_	_	0			0			6-36	5
Internal standard concentration abnormal	I.Std	-	D						О	6-37	

(1) Screen display

(2) Interface = Transmission to the host

	<b>.</b>	0 (1)	. (0)	Pho	otom	etry		ISE		Page	Note
Data alarm	Printout	S. (1)	I. (2)	R/S	С	Std.	R/S	С	Std.		1
Outside of reference value (low)	L	-	_	0			0		0	6-36	5
Level error	Level	L	L				0	0	0	6-38	
Reaction limit over	Limt0 Limt1 Limt2	J K	J K	0 0	0 0 0	0 0				6-41	
Technical value limit over	LIMTH LIMTL	\$ \$	\$ \$	0			0			6-40	
Linearity abnormal	Lin. Lin.8	W F	W F	0	0 0	0				6-44	
ISE prepara- tion abnormal	Margin	-	R						O	6-48	
Noise error	Noise	N	N				0	0	О	6-49	
Overflow	Over	0	0	0	0		О	0		6-50	4
Prozone error	Prozon	Р	Р	0	0	0				6-50	3
QC error 1	QCErr1	+	+		0			0		6-51	
QC error 2	QCErr2	+	+		0			0		6-52	
Random error	Random	@	@		0			0		6-53	
Reagent short	Reagn	Т	Т	0	0	0				6-54	2
Value outside repeat limit (high)	ReptH	=	=	0			0			6-55	
Value outside repeat limit (low)	ReptL	=	=	0			0			6-55	
Sample value abnormal	R.Over	&	&				0	0		6-55	
Standard 1 absorbance abnormal	S1Abs?	_	Н			0				6-67	

Data alarm	Printout	S. (1)	I. (2)	Photometry			ISE			Page	Note
				R/S	С	Std.	R/S	С	Std.		1
SD error	SD!	_	G			0				6-57	
Sample short	Sampl	V	V	0	0	0	О	0	0	6-56	2
Sensitivity error	Sens	_	Y			0				6-58	
Slope abnormal	Slope?	_	Е						0	6-59	
STD error	Std?	_	S			0				6-60	
Systematic error 2 <sub>2SA</sub> 2 <sub>2SW</sub> 4 <sub>1SA</sub> 4 <sub>1SW</sub> 10 <sub>XA</sub> 10 <sub>XW</sub>	Systm1 Systm2 Systm3 Systm4 Systm5 Systm6	# # # #	# # # #		0 0 0 0			0 0 0 0		6-61 ff.	
Calculation disabled	???	Х	Х	O	0	0	0	0		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

# PROBLEM: The instrument does not power up.

- 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.

## Remedy

- 1. Plug instrument power cord into socket.
- 2. Switch main circuit switch to the ON position.
- 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 °C  $\pm$  0.2 °C.
- 2. Poor calibration results.

Check the calibrator preparation.

Check the calibrator data; 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 °C  $\pm$  0.2 °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.

 $2. \ \, \text{Sample probe does not reach the bottom of the reaction cell when dispensing sample}.$ 

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 (MAINTE-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.
- 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 °C  $\pm$  0.2 °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:

 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 (KCI), 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.

- 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 CI.

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).

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  $\pm 2$  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  $\pm 2$  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 CI: 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 printout.

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 EXCHANGE screen.
- 5. Is the incubation bath temperature displayed on the SAMPLE TRACKING global menu 37 °C  $\pm$  0.2 °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 EXCHANGE 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: Χ

Description:

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.

Note: Result is left blank.

Remedy: 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/UTIL-ITY, 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: Ζ

Description: The absorbance value to be used for cal-

culation after cell blank correction exceed-

ed 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:

If all samples are affected:

Check reagent preparation for that test.

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 cal-

ibration)

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 sam-

ple volume.

6.3.4 ADC abnormal

Alarm: ADC abnormal

Printed Alarm: ADC? Alarm Code in DATA REVIEW screen: Α

Description: The ADC (analogue-digital converter) value

is abnormal.

a. If any other instrument alarms are pre-

Remedy: sent, correct those alarms and resume

operation.

b. Touch MAINT/UTILITY; go to the MAIN-TENANCE 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:
	- Calculation disabled (???)
	<ul> <li>Test-to-test compensation disabled (Cmpt!)</li> </ul>
	<ul> <li>Expected value limit over (H,L)</li> </ul>
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:	a. Correct the condition causing the alarm

b. Recalibrate.

er Technical Support.

c. If the alarm recurs, call the BM Custom-

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:	a. Correct any other instrument and/or data alarms.
	b. Check standards, reagents, and controls. Recalibrate, if necessary.
	c. 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) is differs more than specified (in the COMPENSATE LIMIT fields for Na, K and CI, 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:	previous value - current value
	(previous value + current value) / 2

### 6.3.8 Cell blank abnormal

Alarm: Cell blank abnormal

Printed Alarm:

Alarm Code in DATA REVIEW screen:

Description:

Remedy:

Cell?

Q

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).

- 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 MAIN-TENANCE, 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 MAINTE-NANCE 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:

1. In a test-to-test compensation calcula-

tion, 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 isoen-

zyme-P concentration:

Exceptions: - Calculation disabled (???)

- Test-to-test compensation disabled

(Cmp.T!)

- Overflow (Over)

- Random error (QC) (Random)

- Systematic error (System)

- Expected value limit over (H, L)

a. Correct the data alarm for the test that

caused the error message.

b. Rerun the sample.

Remedy:

## 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:

- 1. During test-to-test compensation calculations, the denominator became zero.
- 2. The test used for test-to-test compensation was not measured.
- 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.
- a. Correct the data alarm for the compensated test.
- b. Rerun the sample.

# 6.3.11 Duplicate error

Remedy:

Alarm: Duplicate error

Printed Alarm: Dup

Alarm Code in DATA REVIEW screen: Not Displayed (calibration data)

Description: An error message is calculated as follows:

- Each calibrator is measured twice (Abs 1 and Abs 2).
- The absorbance dup limit is firstly calculated in absolute numbers and then in percentages, if needed.

- 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.
- Is the % error < the % Dup limit?</li>
   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.

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.

Remedy:

Additional Information:

### 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 RE-

VIEW 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: H: For patient samples, the calculated con-

centration 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).

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).

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.

Note:

### 6.3.14 Internal standard concentration abnormal

Alarm: ISE Internal standard concentration abnor-

mal

Printed Alarm: I.Std

Alarm Code in DATA REVIEW screen: Not displayed

Description: The concentration of Internal Standard so-

lution was not within the following range:

Na<sup>+:</sup> 120.0 mmol/L to 160.0 mmol/L

K<sup>+</sup>: 3.0 mmol/L to 7.0 mmol/L Cl<sup>-:</sup> 80.0 mmol/L to 120.0 mmol/L

Remedy: 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 recali-

brate.

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 concentra-

tion 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 Cus-

tomer 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

CI-: 80.0 mV to 160.0 mV

Remedy:

- 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 (KCI), 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: The measured value is outside the techni-

cal limit range as entered on the MAINT/UTILITY, APPLICATION, RANGE screen.

Greater than the upper limit value (LIMTH).

Less than the lower limit value (LIMTL).

Remedy:

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  $\ensuremath{\mathsf{MAINT/}}$ 

UTILITY screen.

d. Dilute the sample (for LIMTH), if neces-

sary.

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 (Limt0)

Alarm: Reaction limit over at all points (rate assays

only, including two-point rate assays)

Printed Alarm: Limt0

Alarm Code in DATA REVIEW screen:

Description:

the reaction limit at all photometric points that are used for calculation. No photometric measurement point lies within the reaction limit.

 a. Check the stability and preparation of the reagent. Replace the reagent, if nec-

The main wavelength absorbance exceeds

essary.

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 Cus-

tomer Technical Support.

See Manual, Vol. System Description, chap-

ter 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?.

Remedy:

Additional Information:

## 6.3.18 Reaction limit over at 1 point (Limt1)

Alarm: Reaction limit over at 1 point (rate assays

only, including two-point rate assays)

Printed Alarm: Limt1

Alarm Code in DATA REVIEW screen: J

Description:

Remedy:

Additional Information:

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.

 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.

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?.

## 6.3.19 Reaction limit over(Limt2)

Alarm:

Alarm Code in DATA REVIEW screen:

Description:

Printed Alarm:

Remedy:

Additional Information:

Reaction limit over (rate assays only, including two-point rate assays)

Limt2

Κ

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.

- 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.

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:

Printed Alarm:

Alarm Code in DATA REVIEW screen:

Description:

Remedy:

Linearity abnormal (for rate assays only)

Lin.

W

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.

- 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/UTIL-ITY, SYSTEM, ALARM SETTINGS screen.
- f. If the alarm recurs, inform the BM Customer Technical Support.

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  $60 \times 10^{-4}$ , 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:

Printed Alarm:

Alarm Code in DATA REVIEW screen:

Description:

Remedy:

Linearity abnormal (for rate assays only)

Lin.8

F

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.

- 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/UTIL-ITY, SYSTEM, ALARM SETTINGS screen.
- f. Resume operation. If the alarm recurs, call the BM Customer Technical Support.

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  $60 \times 10^{-4}$ , 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 The slope lies within the following limits:

Na+, K+: between 45,0 and 49,9 mV,

or bigger than 68,0

Cl -: between -35,0 and -39,9, or

less than -68 mV.

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 The slope lies within the following range:

Na<sup>+</sup>, K<sup>+</sup>: between 50,0 and 68 mV Cl<sup>-</sup>: between -68,0 and -40 mV.

Remedy: 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. im-

mediately.

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:

Ν

Description:

IN

Remedy:

The ISE measuring signal is unstable.

- 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 0

Alarm Code in DATA REVIEW screen:

Description: The result cannot be output in the specified

number of digits. A blank space is left for

the result. Remedy: 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:

Description: In a one-point or two-point assay with pro-

zone 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 de-

tails.

Remedy: a. Repeat the measurement with the man-

ually 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, APPLICA-

TION, ANALYZE screen.

d. If the alarm recurs, inform the BM Cus-

tomer Technical Support.

## 6.3.26 QC error 1

Alarm: QC error 1

Printed Alarm: QCErr1

Alarm Code in DATA REVIEW screen:

Description:

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.

Note: This check is performed only when RULE 1-3SD is selected.

- a. Check if calibrators, controls, and reagents are properly prepared and stored.
- b. Check that calibrators and controls are properly positioned on the sample disk2.
- 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:

QCErr2

QC error 2

Printed Alarm:

ااعال

Alarm Code in DATA REVIEW screen:

Description:

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.

Note: This check is performed only when RULE 1-2.5SD is selected.

- a. Check that calibrators, controls, and reagents are properly prepared and stored.
- b. Check that calibrators and controls are properly positioned on the sample disk2.
- 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.

Remedy:

#### 6.3.28 Random error

Alarm:

Printed Alarm:

Random

Random error

Alarm Code in DATA REVIEW screen:

Description:

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

Data: Measured value of the control.

Note: The check is performed only, if RULE R-4SD is selected.

N = Control run number entered on REAL TIME QC screen.

- 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: There is insufficient or no reagent volume in

the reagent bottle (photometric).

If the alarm is associated with sodium, potassium and chloride values, it indicates

insufficient ISE reagents.

Remedy:

For photometrics:

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.
- 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.

For ISEs:

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 up-

per 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<sup>-</sup>: 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: 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 SE-

LECTION 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

Description:

Note:

Remedy:

Alarm: SD error Printed Alarm: SD!

lawa Oada in DATA DEWENA annana

Alarm Code in DATA REVIEW screen: Not displayed

bration the SD value is larger than the SD limit that was programmed on the MAINT/ UTILITY, APPLICATION, ANALYZE screen.

The calibration result is updated.

 a. Check the calibrator positions on sample disk 2 on the CALIBRATION, CALI-BRATORS screen.

During non-linear or multipoint linear cali-

- b. Check the SD limit on the MAINT/UTILI-TY, 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.

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.

Additional Information:

6.3.34 Sensitivity error	
Alarm:	Sensitivity error
Printed Alarm:	Sens
Alarm Code in DATA REVIEW screen:	Not displayed
Description:	Sensitivity is checked for linear (2 to 6 points), non-linear or isoenzyme-P calibration.
	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).
	*N =2: = two calibration points (linear 2-point calibration or isoenzyme-P). Sensitivity calculation with Standard 1 and 2.
	*N = 2-6: = Multipoint calibration, Sensitivity calculation with Standard 1 and Span point.
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:	<ul> <li>a. Check preparation and expiration dates of calibrators and reagents. Recalibrate the affected test.</li> </ul>
	b. Check the sample pipettor for leaks and recalibrate the affected test.
	c. Check the sensitivity limit (MAINT/UTILI- TY, APPLICATION, CALIB screen) and rec- alibrate.

d. If the alarm recurs, inform the BM Cus-

tomer 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 <sup>-</sup> : bigger than - 35 mV
Remedy:	a. 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).
	<ul> <li>b. If the slope decreases abruptly or shows other irregularities, check if there are leaks, contaminations or air bubbles in the ISE system.</li> </ul>
	c. Check standards and reagents.
	d. Prime all reagents and recalibrate.
	e. Perform an ISE maintenance, prime the solutions, condition and recalibrate.
	f. 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 <sup>-</sup> : between -68,0 and -40.0 mV

a. Check the control results.

b. Perform an ISE maintenance, prime the solutions, condition and recalibrate.

Description:

# 6.3.36 Standard error Alarm: Standard error Printed Alarm: Std?

Alarm Code in DATA REVIEW screen: Not displayed

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 absorb-

ance 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.

The calibration is not updated, if this alarm is issued.

- 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.

Note:

### 6.3.37 Systematic error 1

Alarm: Systematic error 1

Printed Alarm: Systm1

Alarm Code in DATA REVIEW screen: #

larger than 2SD.

2. The control X and Y data values are

2. The control X and Y data values are smaller than -2SD.

1. The control X and Y data values are

This check is performed only when RULE 2-2SD is selected.

a. Check that calibrators, controls, and reagents are properly prepared and stored.

- b. Check that calibrators and controls are properly positioned on the sample disk2.
- 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.

### Remedy:

Description:

### 6.3.38 Systematic error 2

Alarm:

Systm2

Systematic error 2

Printed Alarm:

Alarm Code in DATA REVIEW screen:

Description:

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.

This check is performed only when RULE 2-2SD is selected.

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
- 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.

Note:

### 6.3.39 Systematic error 3

Alarm:

Systematic error 3

Systm3

Printed Alarm:

Эузин

Alarm Code in DATA REVIEW screen:

#

Description:

- 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.

This check is performed only when RULE 4-1SD is selected.

- 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.

Note:

### 6.3.40 Systematic error 4

Alarm:

Systm4

Systematic error 4

Printed Alarm:

J

Alarm Code in DATA REVIEW screen:

Description:

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.

This check is performed only when RULE 4-1SD is selected.

- 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.

Note:

### 6.3.41 Systematic error 5

Alarm: Systematic error 5

Printed Alarm: Systm5

Alarm Code in DATA REVIEW screen:

Description:

 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.

This check is performed only when RULE 10X is selected.

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 disk2.
- 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:

Systm6

Printed Alarm:

Systematic error 6

Alarm Code in DATA REVIEW screen:

Description:

- 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.

This check is performed only when RULE 10X is selected.

- 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
- 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.

Note:

### 6.3.43 Standard 1 absorbance abnormal

Alarm: Standard 1 absorbance abnormal

Printed Alarm: S1Abs?

Alarm Code in DATA REVIEW screen: Not displayed

Description: During calibration, the expected absorb-

ance of Standard 1 is outside the S1Abs

Limit.

A check is performed for the following meth-

ods:

Rate assays: First measuring point (initial

absorbance) at main wavelength.

Endpoint assays: defined measurement point (endpoint) at bichromatic measurement (main wavelength minus sub wave-

length).

A Std? alarm is displayed, the calibration is

not calculated.

a. Check reagent preparation and calibra-

tion.

b. Recalibrate.

c. Check the S1Abs? Limit on the MAINT/

UTILITY, APPLICATION screen.

d. If the alarm recurs, call the BM Custom-

er Technical Support.

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

Α

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.

### В

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).

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 quantitati-

ve and qualitative determinations of a wide range of analy-

tes 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, key-

board, CPU, touchscreen and printer.

CPU (Central Processing Unit) the data processing unit of the

system.

cumulative QC The accumulated data and associated statistics of indivi-

dual 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 repli-

cate assays of the standards.

Ε

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 con-

centration.

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.

Н

Hitergent Surfactant which is added at each exchange of the incu-

bation bath water. Positions 1D1 and 2D1.

host communication Information exchange with a Laboratory Information Sy-

stem (host computer).

incubation bath Temperature-controlled (37 °C ± 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 po-

wer ON.

instrument alarms Displayed alarms that indicate unusual instrument conditi-

ons.

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 selec-

tive 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.

Κ

K Factor A factor used in conversion of absorbance values to con-

centration 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.

Ν

NaOH-D A detergent used in cell wash and probe wash

0

Operate The operational mode during which the instrument pro-

cesses 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

quantitative measurement

QC Button

Report of a test concentration in qualitative symbols.

Test report including the concentration or activity of a test.

Button used to display the QC main menu.

R

RAM (Random Access Memory) the part of a computer's me-

mory 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 reac-

tion 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 exter-

nally 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, re-

agent 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 (KCI) 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 nor-

mal 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.

	3

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 diluti-

on 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 aspira-

tion 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 pro-

blem with the sampling system. Sampling stops, but sam-

ple 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 lipe-

mia, 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 measu-

red 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 – 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.

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 con-

tain text when selected.

time out Automatic count down of calibration stability.

### W

warning - A statement called out in this manual to make the

operator aware of conditions that could cause perso-

nal injury.

- An instrument alarm level that does not interrupt ope-

ration.

wash solution - 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 window

Container that collects reaction waste.

Used to perform specific tasks on the system, displayed

by touching a command button.

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