Sediment Terminal

Operator's Manual

for the use with **cobas u** *411 system or Urisys 1800*

Revision history

Manual version	Software version	Revision date	Amendments
1.0	1.0 / 2.0 related to Urisys 1800	August 2005	Initial version Urisys 1800 ST
1.1	1.0 / 2.0 related to Urisys 1800	December 2005	COBAS branding Urisys 1800 ST
1.0	3.0 related to cobas u 411	December 2006	Initial version Sediment Terminal
2.0	3.0 related to cobas u 411 4.0 related to Urisys 1800	August 2007	Common version of Urisys 1800 ST and Sediment Terminal
2.1	3.0 related to cobas u 411 4.0 related to Urisys 1800	Mai 2010	Generalizing text for both analyzers, minor corrections
2.2	3.0-3.2 related to cobas u 411 4.0 related to Urisys 1800	December 2010	Additional item (15-meter serial cable) deleted

Edition notice

Sediment Terminal Operator's Manual

Every effort has been made to ensure that all the information contained in this manual is correct. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void.

Intended use

The Sediment Terminal is used to enter microscopic results for the sample of corresponding test strip obtained with the **cobas u** 411 or the Urisys 1800 analyzer. Only trained personnel working in a professional laboratory environment may operate the Sediment Terminal.

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Type approval

Our devices meet the protection requirements of the IVD directive 98/79/EC and the European standard EN 591. Furthermore, our devices are manufactured and tested in accordance with the international standards EN/IEC 61010-1 and EN/IEC 61010-2-101.

The conformity of the devices with these standards is certified by the following symbols:

CE Complies with the IVD directive 98/79/EC.

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Preface

The Sediment Terminal is used to enter microscopic results for the sample of corresponding test strip obtained with the **cobas u** 411 or the Urisys 1800 analyzer.

It is important that the operator reads this manual thoroughly before using the Sediment Terminal.

How to use this manual

- *Keep this manual in a safe place where it will not be damaged and is available for reference.*
- *This Operator's Manual should be accessible at all times.*

Table of contents

The table of contents at the start of the manual and of every chapter makes it easy to find the subject you are looking for. You will also find a comprehensive index of key words at the end of the manual.

The manual is divided into the following parts:

Part A – System Description

The System Description provides an overview of the system. This section also explains the hardware components and gives an overview of the software.

Part B – Operation

This section defines the installation procedure as well as the daily operation of the Sediment Terminal analyzer in a step-by-step guide.

Symbols

Symbols are used to help quickly locate and interpret information in this manual. This section explains the formatting conventions used in this manual.

Symbols The following symbols are used:

Symbol	Definition
►	Instruction
•	Bullet point
👁	Cross-reference
☞	Commands used to call up a screen or a specific function
	Note
	Caution
	Warning
	Risk of infection

System description A

System description

This chapter contains a description of the system hardware.

In this chapter *Chapter* 1

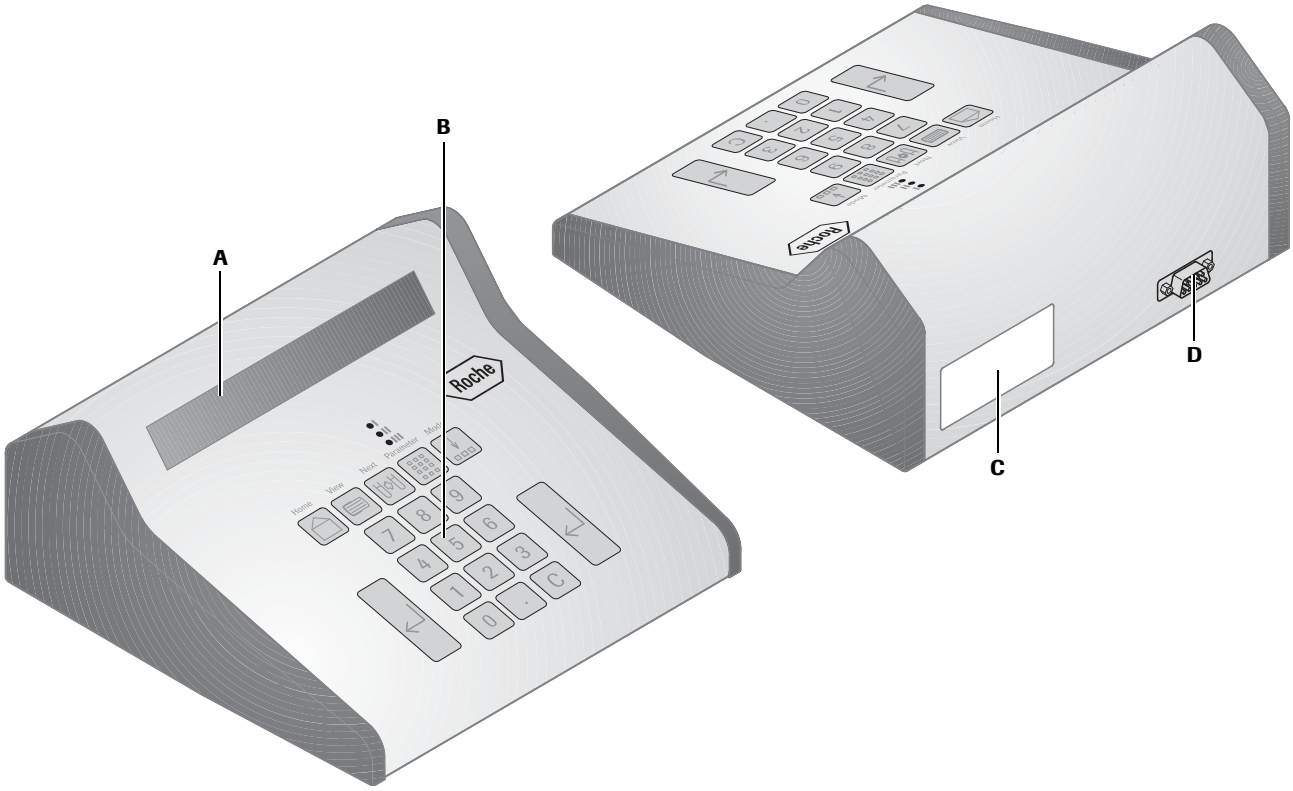
Table of contents

System overview

The Sediment Terminal consists of the following components:

- Two-line LC display
- Membrane keypad for configuration of the Sediment Terminal and for entering microscopic parameters

On the rear of the Sediment Terminal is a serial interface for connecting the Sediment Terminal to the analyzer.



A Display
B Membrane keypad
C Type plate
D Serial interface

Figure A-1 The Sediment Terminal

Functions

Automatic identification

- The analyzer automatically identifies a Sediment Terminal that is connected via the serial interface.

Sediment parameters

- The sediment parameters are defined on the analyzer.
- Up to 30 parameters can be defined on the analyzer.
  - Up to 5 ranges can be defined per parameter.
  - For technical reasons, the 30 sediment parameters on the Sediment Terminal are divided into 3 groups of 10 parameters.

For more information, see *Sediment parameters* on page B-17.

Sample selection

The Sediment Terminal can be set to select one of the following types of samples:

- All Samples

  All samples are selected except samples with a test strip error (T flag).

- Only samples with sieve positive results are displayed. They are marked with the S-flag on the analyzer.

  Refer to the Operator's Manual of the analyzer: *Sieve and abnormal values*.

For more information, see *Sample selection* on page B-19.

Sediment entry mode

The first step when entering microscopic parameters is to select a sample. On the Sediment Terminal the sample selection can be set to one of the following sediment entry modes:

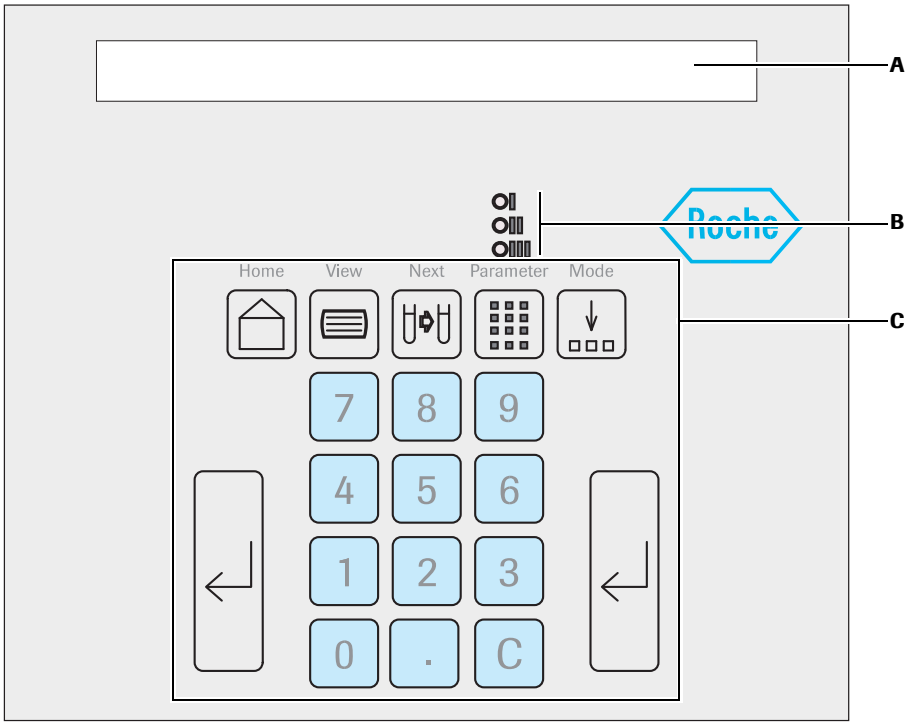
- Sample ID
- Sequence number
- Work list

In the Sample ID or Sequence number modes, the sample is selected by the sample ID or sequence number, respectively. In the Work list mode, the sample is selected in the result list order of the analyzer.

For more information, see *Sediment entry mode* on page B-20.

User Interface

The operator interacts with the terminal by means of a two-line LC display and a membrane keypad:



A Display **B** LED for selected parameter group **C** Keypad

Figure A-2 Sediment Terminal keypad

The functions of the individual keys are described below:

Home

<Home> calls up the main menu, and toggles between <Home> and <View>.

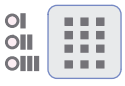
View

<View> displays the test strip results of the sample.

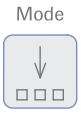
Next

<Next> completes and stores the entry of the microscopic test results, if at least one parameter was entered. Depending on the selected entry mode the next sample will be displayed or can be entered via sample ID or sequence number.

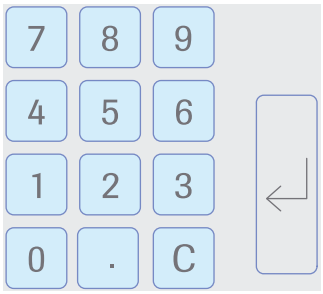
Parameter



<Parameter> : The sediment parameters (max. 30) are assigned to 3 parameter classes of 10 parameters each. The LED displays the last parameter class selected. It toggles from class I to class II to class III, then back to class I.



Use <Mode> to change the way in which results are entered. The operator determines the preferred test format (based on sequence or sample numbers, testing only of samples recognized as sieve, etc.). <Mode> is active only in the main menu.



Use the numerical keyboard to enter patient or sample numbers and select the sediment parameter.

<Clear>: In the view mode only the microscopic results can be skipped by pressing the <Clear> button. Delete entered but not yet confirmed items with this key.

<Enter>:

- Completes all entries of patient or sample numbers made on the numerical keypad.
- Can be used to select the next higher concentration range after a sediment parameter has been selected.

Software Overview

The illustration on the next page gives an overview of the software functions.

For detailed descriptions of the tasks that are performed during routine operation, see Chapter 3 *Daily operation*.

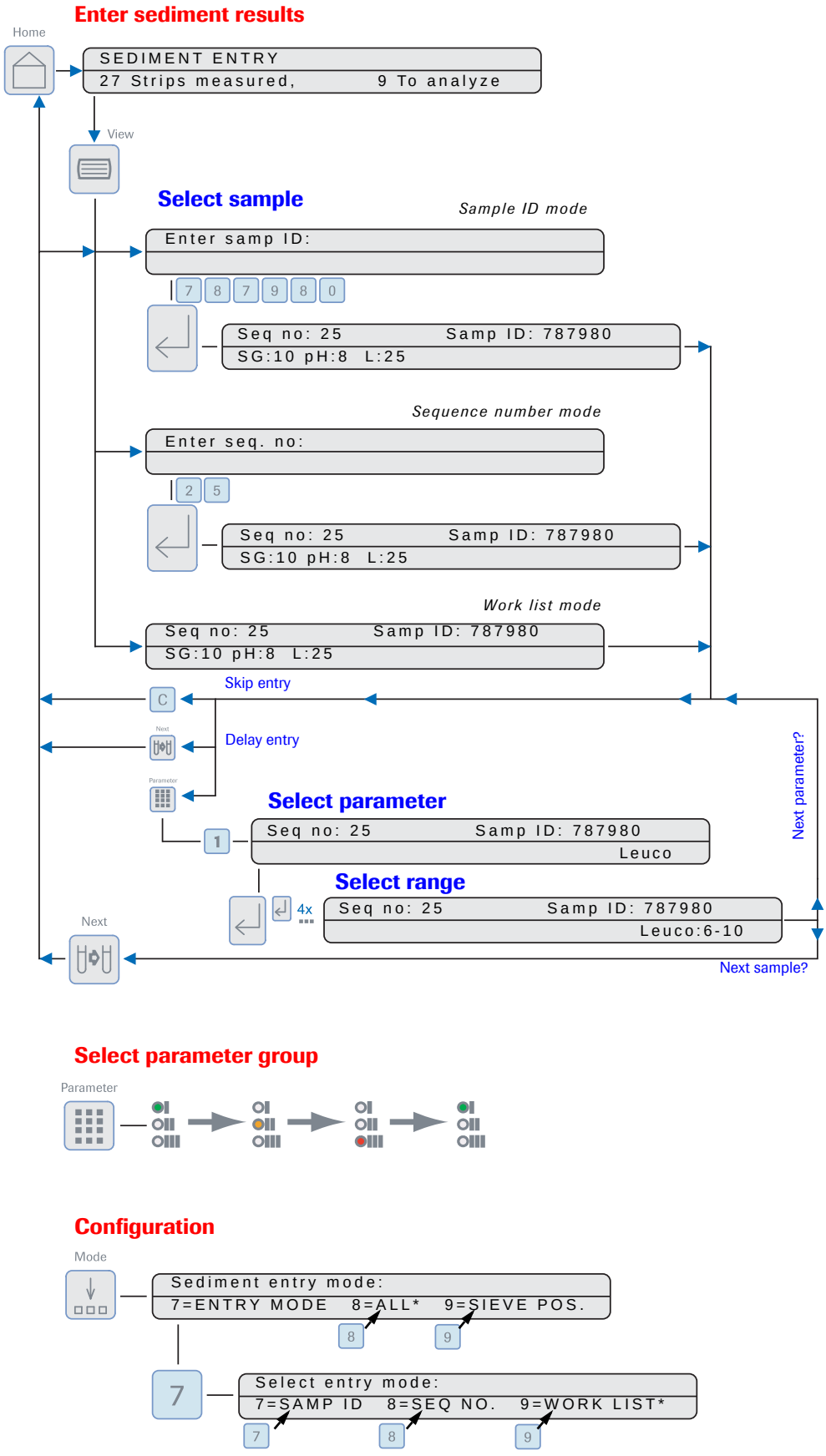


Figure A-3 Software overview

Technical specifications

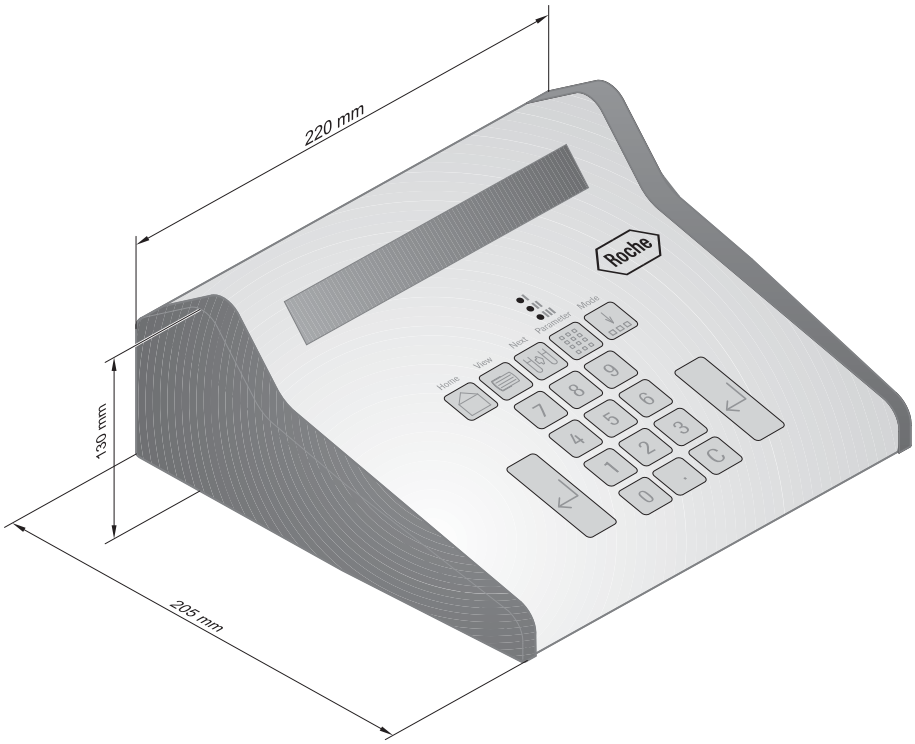
Physical dimensions (max.)		
	Weight	approx. 0.8 kg
Power requirements	Line voltage	24 Vdc / 100 mA (supplied by the analyzer)
Environmental conditions	Temperature	
	• Running conditions	15 – 32 °C (59 – 89,6 °F)
	• Storage	-25 – 60 °C (-13 – 140 °F)
	Humidity	10% – 95% no condensation
	• Running conditions	30% - 80%, non condensing
	• Transportation and storage	10% - 95%, non condensing
	Pollution	Pollution degree 2 (EN/IEC 61010-1)
	Altitude	0 – 2000 m, airpressure 80 to 106 kPa
Display / Interface	Interfaces	1 x RS232 (for connecting to the analyzer)
	Display	2-line passive matrix display, monochrome.

Table A-1 Technical specifications

Operation B

Installation

This chapter provides information on the installation of the Sediment Terminal.

In this chapter *Chapter* 2

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As-delivered condition and accessories

As-delivered condition

The Sediment Terminal is delivered with a 1.5-meter serial cable for connecting to the analyzer.

Environmental conditions

The Sediment Terminal must be used in an environment that meets the following conditions:

- Relative humidity according to technical specifications, without moisture condensation
- Well-distanced from any machine generating a high frequency voltage (for example, a centrifuge)
- Free from electromagnetic wave interference

Installing the Sediment Terminal

Installation of the Sediment Terminal consists of just a few steps:

- Unpacking
- Connecting the Sediment Terminal to the analyzer

Unpacking

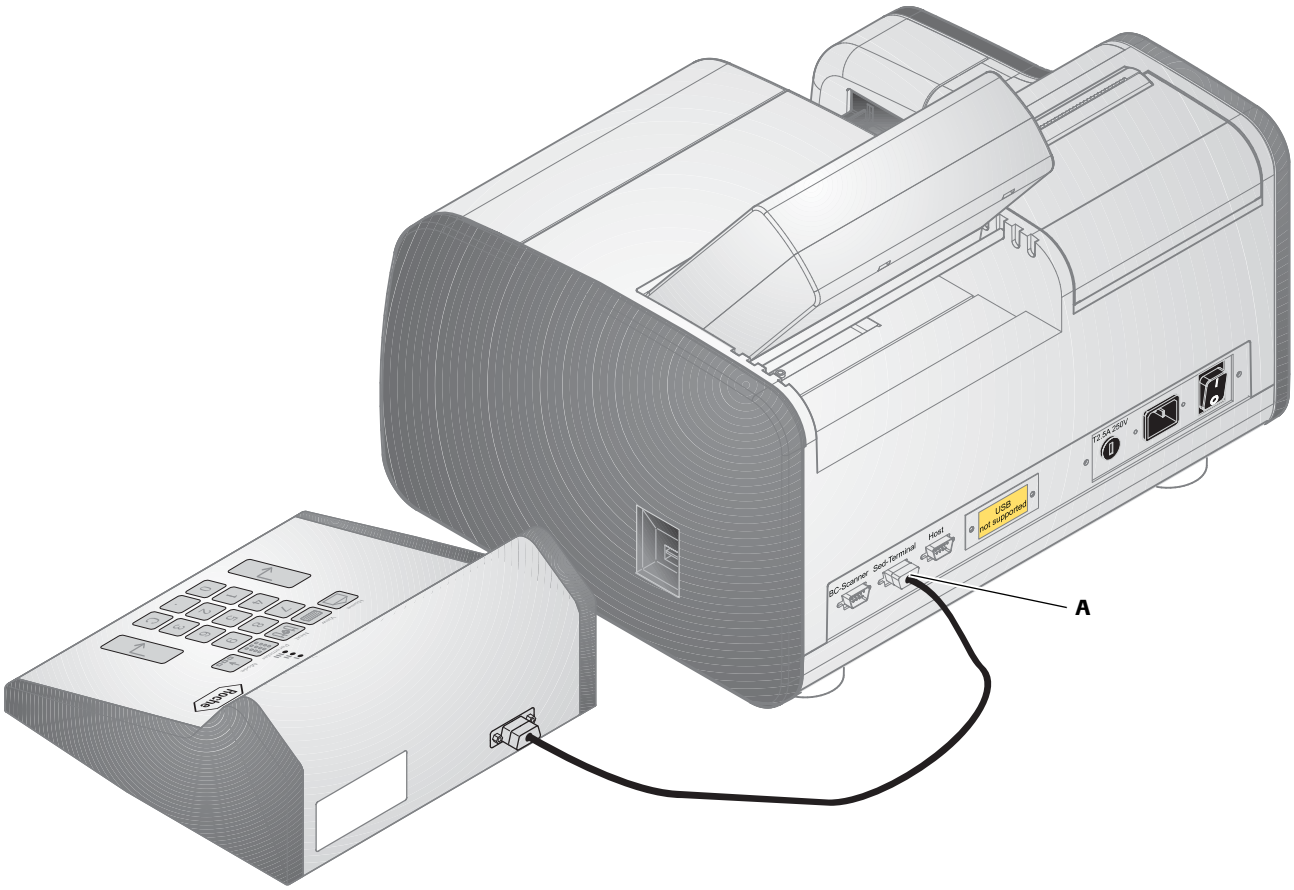
► **To unpack the analyzer**

1 Open the box and unpack.

Connecting the Sediment Terminal to the analyzer

After unpacking the Sediment Terminal, you can connect it to the analyzer.

The following figure shows the ports and switches on the rear of the analyzer:



A Sediment Terminal interface

Figure B-1 Connecting the Sediment Terminal to the analyzer

► To connect the Sediment Terminal to the analyzer

The analyzer features a serial interface (**A**) for connecting the Sediment Terminal.

1 Connect the serial cable of the Sediment Terminal to the corresponding interface connector (**A**) of the analyzer, labelled with Sed-Terminal.

The analyzer needs to be configured for operation with a Sediment Terminal.

For further information, see *Activating Sediment Terminal* of the Operator's Manual of the analyzer.

Using the Sediment Terminal for the first time

The analyzer identifies a Sediment Terminal that is connected via the serial interface automatically. No further set-up is required. You only have to activate the Sediment Terminal.

- *If no sediment parameters are defined on the analyzer, an error is displayed on the analyzer and a message is displayed on the Sediment Terminal.*
- *If the Sediment Terminal is not activated within the analyzer software, the message "Sediment terminal deactivated" is displayed.*

For more information, see *Sediment parameters* on page B-17.

If you wish to change the configuration for entering sediment results, you may edit the following settings:

- Sample selection
  Sample selection on page B-19.
- Sediment entry mode
  Sediment entry mode on page B-20.

Disposal of the instrument

Disposal

The instrument must be treated as biologically contaminated-hazardous waste. Final disposal must be organised in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed on for final disposal.

For more information contact your local Roche Support personnel.

Daily operation

This chapter describes the procedures that are necessary for the daily operation of the Sediment Terminal.

In this chapter *Chapter* 3

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Starting the system

The Sediment Terminal is supplied with power through the serial interface of the analyzer.

The main menu of the Sediment Terminal is displayed after the analyzer is switched on.

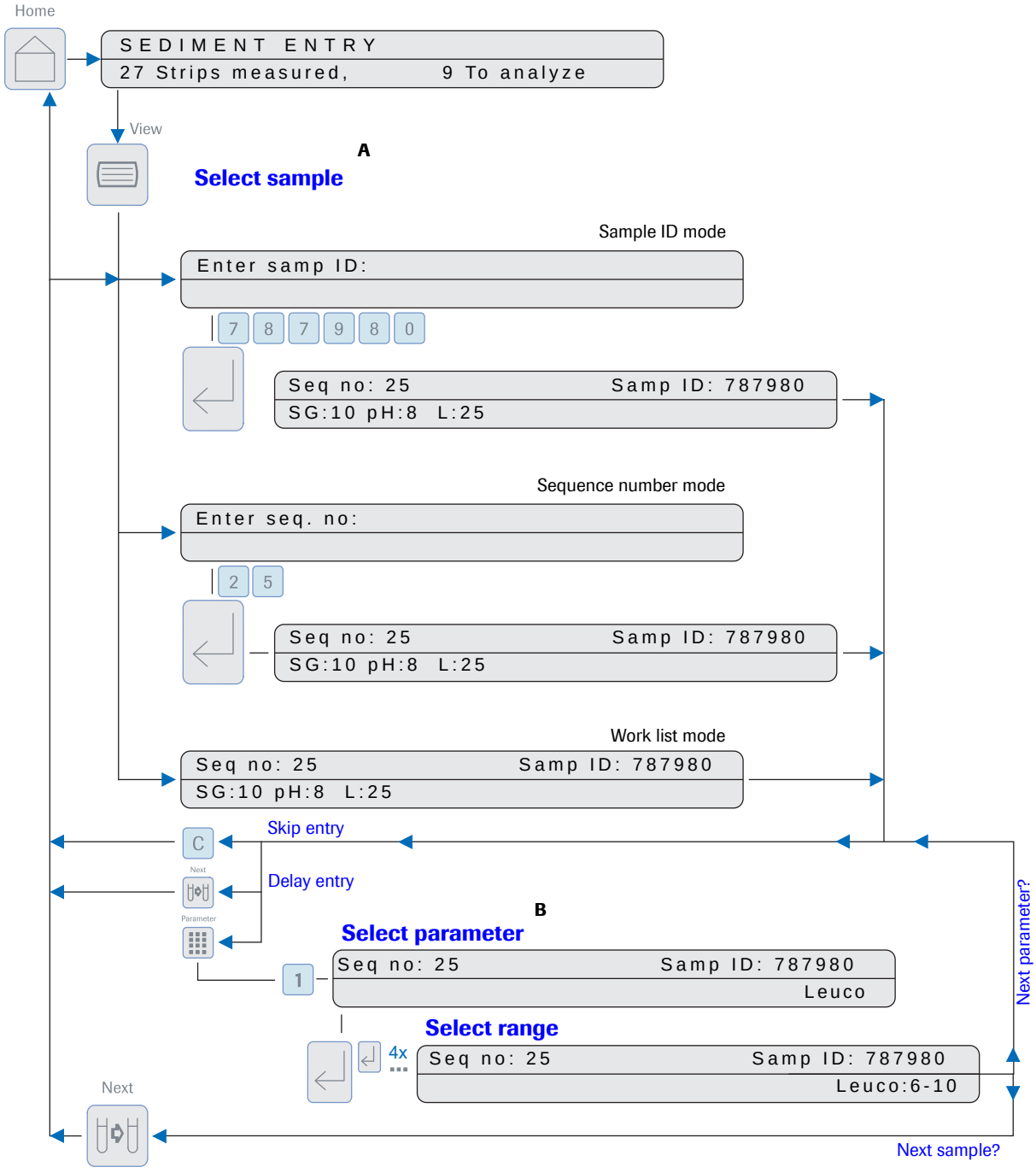
The number of measured strips and the number of strips which still have to be examined and analyzed are shown in the lower line of the display.

- *If no sediment parameters are defined on the analyzer, an error is displayed on the analyzer and a message is displayed on the Sediment Terminal.*
- *If the Sediment Terminal is not activated within the analyzer software, the message "Sediment terminal deactivated" is displayed.*

For more information, see *Configuration* on page B-17.

Entering sediment parameters

The following illustration gives an overview of the process of entering sediment parameters:



A The Sediment Terminal offers 3 different modes for sample selection: Sample ID, Sequence number and Work list (see *Sediment entry mode* on page B-20)

B Before selecting a parameter *number* (0-9), you have to preselect a parameter *group* (I, II, III), (see *Selecting a sediment parameter* on page B-14)

Figure B-2 Overview of the procedure for entering sediment parameters

Overview

To be able to enter sediment results using the Sediment Terminal you first have to define the sediment parameters.

- *If no sediment parameters are defined on the analyzer, an error is displayed on the analyzer and a message is displayed on the Sediment Terminal.*
- *If the Sediment Terminal is not activated within the analyzer software, the message "Sediment terminal deactivated" is displayed.*

For more information, see *Configuration* on page B-17.

The process of entering sediment parameters consists of the following steps:

- Selecting a sample
- Selecting a sediment parameter
- Selecting a result range for the sediment parameter
- Completing sample processing

The next section provides important information. If you are already familiar with the Sediment Terminal, you may skip this section and proceed with:

Sediment parameter input on page B-15

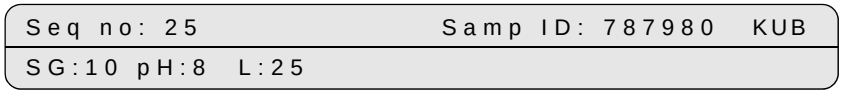
Selecting a sample

The first step when entering sediment parameters is to select a sample. On the Sediment Terminal you can configure the sample selection and the sediment entry mode.

- Sample selection
  - All results
  - Sieve positive results

  For more information, see *Sample selection* on page B-19
- Sediment entry mode
  - Sample ID
  - Sequence number
  - Work list

  For more information, see *Sediment entry mode* on page B-20



This display shows the following information:

- Upper line
  - Sequence number
  - Sample ID (if defined)
  - K (Ketone), U (Urobilinogen), B (Bilirubin)
    If the result for one of these parameters falls into the abnormal range, the corresponding character is displayed.

- Lower line
  - Results for SG and pH (are always displayed)
    For SG only the last 2 digits are displayed.
    For example, SG:00 means 1.000, SG:05 means 1.005, …
    pH:6+ means 6.5
  - Results of sieve parameters
    Only results of parameters that fall into the sieve range are displayed. Sieve positive results are marked with the S-flag on the analyzer.

  Refer to the Operator's Manual of the analyzer.
  Sediment parameters on page B-17

Selecting a sediment parameter

The sediment parameters are defined on the analyzer. Up to 30 parameters can be defined. You can define up to 5 ranges per parameter.

For technical reasons, the 30 sediment parameters on the Sediment Terminal are divided into 3 groups of 10 parameters. Within each group, the parameters are numbered from 1-9, 0 (0 selects the parameter no. 10, 20 or 30, depending on the selected group). Thus, you have to know the number under which the desired parameter is defined.

Desired parameter Parameter number on **cobas u** 411	**Parameter group**	**Parameter number to enter** Parameter number on Sediment Terminal
Parameter 4	Group I	4
Parameter 16	Group II	6
Parameter 23	Group III	3

Table B-1 Selecting a sediment parameter (examples)

If you do not know the numbers of the sediment parameters, you can print out the configuration report on the analyzer.

See *To print out the configuration report* on page B-18

Selecting a result range for the sediment parameter

The ranges for the selected parameter are selected by pressing <Enter>. Pressing <Enter> switches from range 1 to range 5. If range 5 is displayed and you want to select another range, clear the entry by pressing C and then press <Enter> repeatedly until the desired range is displayed.

By selecting one of the numeric fields the corresponding sediment parameter will be displayed and the last entry is automatically stored.

Completing sample processing

<Next> selects the next sample and completes the sediment entry for the current sample. If the end of the sample list is obtained in the worklist mode, the system returns to the home menu. If the sediment entry for the current sample is not completed and you select <Next>, the sample will stay in the worklist and the entry is delayed.

<Home> returns to the home menu and completes the sediment entry for the current sample.

<View> changes to the output of test strip results.

You can call up a sample again if you are in sample ID mode or sequence mode. If automatic results printout is selected on the analyzer, the results of the current sample are printed and uploaded to the host, provided at least one sediment parameter is stored for the sample and sample processing is completed.

The following section provides a step-by-step description of the actions that are necessary for entering sediment parameters.

Sediment parameter input

► To enter sediment parameters

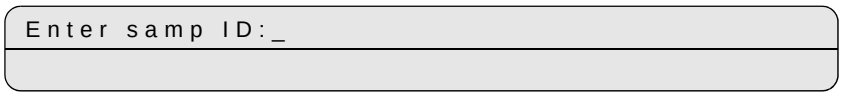
Selecting a sample

1 On the home menu press <View> to display the next sample.

Depending on the sediment entry mode, one of the following displays is shown:

Sample ID mode

The following display is shown in sample ID mode:



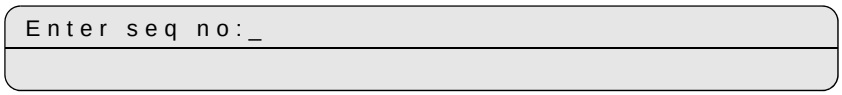
- Enter the sample ID and confirm with <Enter> or scan the sample ID with barcode scanner of the analyzer.

  The results of the selected sample are displayed.

  See *Work list mode* on page B-15.

Sequence number mode

The following display is shown in sequence number mode:



- Enter the sequence number and confirm with <Enter>.

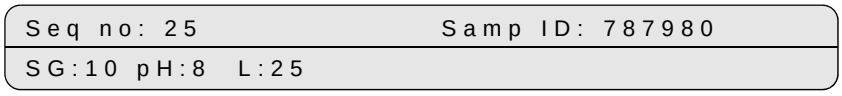
  The results of the selected sample are displayed.

  See *Work list mode* on page B-15

- *If the sample ID or the sequence number that you entered does not exist, a message is displayed.*
- *If the results for the selected sample are normal, the message "All results are neg!" is displayed.*
- *In sample ID mode and Sequence number mode reediting of sediment results is possible.*

Work list mode

The following display is shown in Work list mode:



The results of the next sample in the work list are displayed directly. The upper line displays the sequence number and the sample ID. If no sample ID has been defined for the sample, only the sequence number is displayed. The lower line

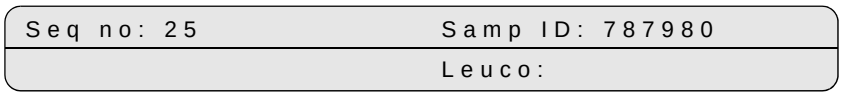
displays the results for SG and pH and the sieve positive results of the other parameters.

- Press <Next> to display the next sample of the work list or proceed with the selection of a sediment parameter.
- If you do not need to enter a sediment parameter for the selected sample, press C. The documented flag is assigned to the sample. In this case, it is only possible to enter sediment parameters for the sample in sample ID or sequence number mode. Only results with a documented flag can be printed and uploaded to the host.

Selecting a sediment parameter

2 Press <Parameter> to select the parameter group I, II, or III of the desired parameter.

3 Press the number <0-9> of the desired parameter.

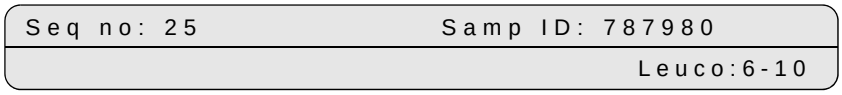


If the parameter you entered is not defined on the analyzer, the message *Parameter?:* is displayed.

Selecting a result range for the sediment parameter

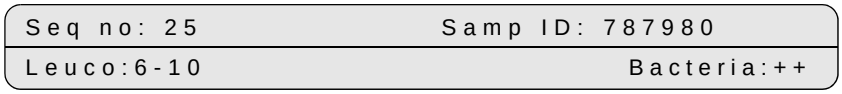
4 Press <Enter> repeatedly to select a range for the selected parameter.

- Pressing <Enter> repeatedly displays the defined ranges from range 1 to range 5.
- If range 5 is displayed and you wish to select range 3 for example, clear the entry by pressing C and then press <Enter> repeatedly until range 3 is displayed.



5 If the selected range is correct, repeat steps 2 to 4.

When you select the next sediment parameter, the result of the last sediment parameter is moved to the left. You can enter up to 30 sediment parameters for one sample.



Editing a sediment parameter result

- If you want to edit a sediment parameter result, press the number of the sediment parameter again. The sediment parameter is moved to the right.
- Clear the entry by pressing C and then press <Enter> repeatedly until the desired range is displayed.

Completing sample processing

6 Press <Next> to display the next sample.

If automatic printout is selected on the analyzer, the results of the sample are printed and uploaded to the host.

7 Repeat steps 1 to 6 to enter sediment parameter for other samples.

8 Press <Home> to display the Home menu when you have entered sediment results for all samples.

If a Sediment Terminal is connected to your analyzer, results are printed and uploaded to the host only if a sediment parameter has been entered or if the sample was skipped by pressing C .

Configuration

The following section contains a description of those configuration items that must be adjusted individually by the user.

- Sediment parameters
- Sample selection
- Sediment entry mode

Sediment parameters

To be able to enter sediment parameters using the Sediment Terminal, you first have to define the sediment parameters.

The sediment parameters are defined on the analyzer. Up to 30 parameters can be defined. You can define up to 5 ranges per parameter.

For technical reasons, the 30 sediment parameters on the Sediment Terminal are divided into 3 groups of 10 parameters.

► To set sediment parameters

1 Call up the [Sediment Parameters] screen from the [Utilities] tab.

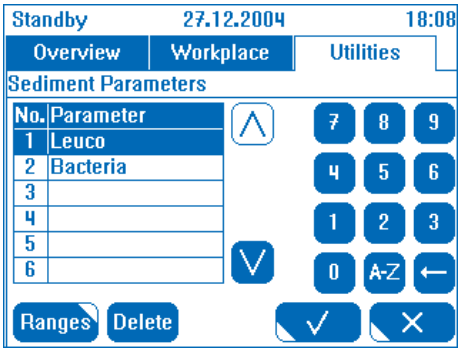


Figure B-3 [Sediment Parameters] screen

This screen lists the defined sediment parameters.

2 Use or to select an empty row or the required sediment parameter.

3 If you define a new sediment parameter, use the touch screen keyboard to enter the name of the sediment parameter (max. 10 characters).

4 Press <Ranges> to define the ranges for the selected sediment parameter.

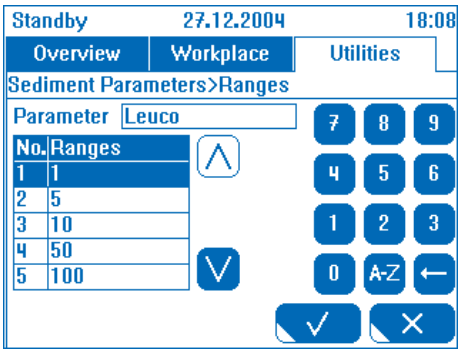


Figure B-4 [Sediment Parameters > Ranges] screen

5 Use ⋁ or ⋀ to select a range that you wish to edit.

6 Use the touch screen keyboard to enter the value of the selected range (max. 8 characters).

Using the touch screen keyboard, you can enter numerical values (1, 10, 15, …), ranges (1-10, 11-20, …) or alphanumerical values (low, high, …, +, ++, +++, …) as ranges for the sediment parameters.

7 Apply the changes for the ranges by pressing √.

8 Repeat steps 2 through 6 for the next parameters.

9 Apply the changes for the sediment parameters by pressing √.

This closes the screen.

If you need more than 5 ranges for a sediment parameter, allocate the ranges to 2 or more sediment parameters, e.g. Cylinder small, Cylinder large.

To enter sediment parameters you need to know their numbers. It may be helpful to print out the configuration report, which contains the sediment parameters.

► To print out the configuration report

1 Call up the [Tools1 > Data Exchange] screen from the [Utilities] tab.

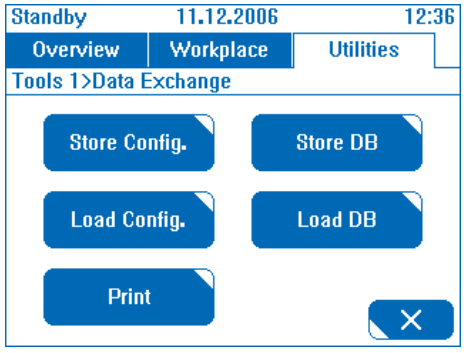


Figure B-5 [Tools1 > Data Exchange] screen

From this screen system, test and sediment parameters can be printed, loaded from diskette or stored on diskette.

2 Press <Print> to print the configuration report. This report includes the sediment parameters at the end of the report.

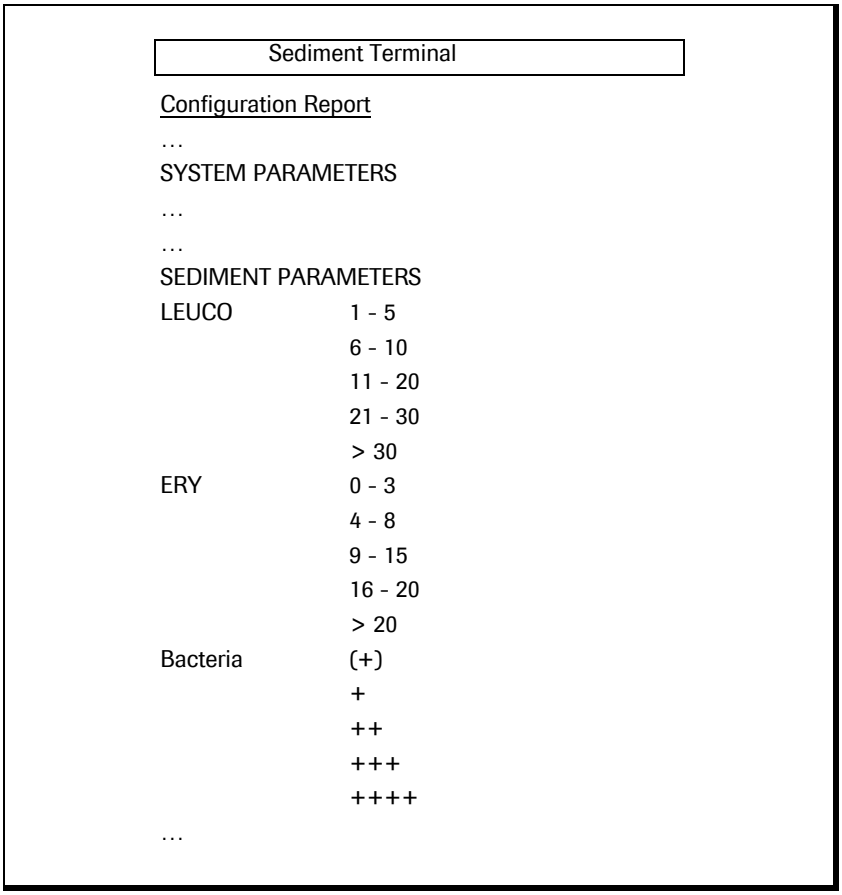


Figure B-6 Example of a configuration report

Sample selection

The Sediment Terminal can be set to select one of the following kind of samples:

- Samples with all kind of results

  All kind of samples are selected except for samples with a test strip error (T flag).

- Samples with sieve positive results

  Only samples with sieve positive results are displayed. Sieve positive results are marked with the S-flag on the analyzer.

  👁 Refer to the Operator's Manual of the analyzer.
  Sediment parameters on page B-17

► To set the result selection for samples

1 Press <Mode>. The following display is shown:

```
Sediment entry mode: Work List
7=ENTRY MODE | 8=ALL*. | 9=To analyze
```

2 Set the result selection:

- To select all results, press <8>.
- To select sieve positive results only, press <9>.

The selected option is marked by an asterisk (*).

3 Press <Home> to return to the home menu.

Sediment entry mode

The first step when entering sediment parameters is to select a sample. On the Sediment Terminal the sample selection can be set to one of the following sediment entry modes:

- Sample ID

  The sample is selected by sample ID. Before entering sediment results, you have to select the sample by entering the sample ID.

You can use the sample ID mode only with numeric sample IDs. The Sediment Terminal can display alphanumeric characters, but it is not possible to enter alphanumeric characters via the keyboard.

- Sequence number

  The sample is selected by the sequence number. Before entering sediment results, you have to select the sample by entering the sequence number.

- Work list

  The sample is selected in the result list order of the analyzer. Press <Next> while entering sediment results to display the next sample in the work list.

► To set the sediment entry mode

1 Press <Mode> and then <7>. The following display is shown:

```
Sediment entry mode: Work List
7=SAMP ID | 8=SEQ. NO. | 9=WORK LIST*
```

The active sediment entry mode is displayed in the first line and marked by an asterisk (*) in the second line.

2 To change the sediment entry mode:

- Press <7> to select samples according to the sample ID.
- Press <8> to select samples according to the sequence number.

- Press <9> to select samples according to the work list of the analyzer.

The selected option is marked by an asterisk (*).

3 Press <Home> to return to the home menu.

Cleaning the surface of the Sediment Terminal

► To clean the surface of the Sediment Terminal

1 Before cleaning, turn off the power switch on the rear of the analyzer.

2 Wipe down all exterior parts of the analyzer except for the touch screen with a damp cloth.

Use a cloth moistened with water or with a liquid cleaning agent to clean the outer surface. Use a disinfectant when necessary.

Cleaning the surface of the Sediment Terminal