User Manual

microlab 300 lx

ELITechGroup

EMPOWERING IVD

Preface

CE

This instrument conforms to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998.

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The manual describes the analyzer system Microlab 300 LX and the software version V2.0. Please call ELITechGroup B.V. if you need advice or you have any questions.

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Safety Precautions and Potential Hazards

1.1   General

Before you start installing and working with the analyzer, you should read the safety precautions and regulations shown in this chapter. Safety comes first!

The analyzer was designed and manufactured according to modern standards and with regard to international safety regulations. All possible risks that were known at the time of manufacturing were taken into account and either eliminated or reduced. Nevertheless, some sources of danger cannot be eliminated. Please note the following guidelines.

When operating the analyzer all national or international guidelines and regulations must be observed, as in the normal lab routine. Power supply accessories (cables/plugs) must be installed in such a way that sources of danger (overheating of cables, short circuit due to incorrect fuse ratings, loose cables etc.) are eliminated. The user should be aware, that if the analyzer is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. The analyzer is supplied without anti-virus software. If you connect the analyzer to a network, make sure that the network has the necessary protection.

1.1.1   Basic assumptions for risk analysis

Following assumptions are the basis for the risk analysis. It is assumed that:

- The Samples were adequately derived, prepared, handled, and labeled before being loaded into the device.
- Reagents and calibrators were adequately stored, prepared, handled, and labeled before being loaded into the device.
- Adequate quality control procedures are observed by laboratory personnel to check the performance of the analyzing system by adequate use of control material.
- Laboratory personnel involved in operation and handling of the device are adequately trained.
- Laboratory personnel involved in operation and handling of the device are aware of the risks involved in handling material of human origin (biological hazards) and that correct procedures are followed to prevent infection.
- Service personnel involved in preventive and corrective maintenance of the device are adequately trained.
- Service personnel who maintain the device know the risks of biological hazards and follow the correct precautions.
- Preventive maintenance is performed in accordance with the instructions provided by the User Manual and the Service Manual.
- Original replacement parts are used in maintenance of the device.
- Original disposables are used in operation of the device.
- Reagents and methods are validated before actual samples are measured.
- Service personnel must follow the instructions to install and check the device.
- Limit checks are correctly implemented and used in the test parameter settings. (absorbance, reagent blank absorbance, control, calibrator, etc.).
- Test results obtained from the instrument are carefully examined by an expert before any further measures are taken based on the analytical results.

1.1.2   Operator qualification

The analyzer should only be used by qualified and trained personnel, who have taken part in a special operator training course on the instrument.

For clinical tests, the instrument should be used under the management of a doctor or clinical inspector.

1.1.3 Service technician qualification

To install, maintain and repair the instrument, a service technician has to be trained on the instrument by the manufacturer or their representative. A service technician is also expected to be familiar with the normal operation of the instrument as described in the operator manual and the special operations as described in the Service manual.

1.2 Description of symbols

1.2.1 Symbols on the instrument

WARNING

Attention, consult instructions for use. This symbol appears on several parts of the analyzer and the specific meaning of each of these symbols is described below.

WARNING

Hot surface. This label is attached on or close to parts of the instrument that get hot when the instrument is switched on. Make sure to keep fingers and other body parts clear of the hot surface.

WARNING

Pinch point. Fingers and other body parts can be pinched where this label shows. Make sure to keep fingers and other body parts clear of the pinch point.

BIOHAZARD

The contents of the container marked with this symbol are a biological hazard and are potentially infectious. This symbol is shown on waste bottles.

ATTENTION

This symbol means that at the end of life, the analyzer must be separately collected in accordance to the European Directive 2012/19/EU.

1.2.2 Symbols in the manual

WARNING

Failure to follow information contained in warning messages could lead to serious personal injury and/or damage to the analyzer.

ATTENTION

Failure to follow information contained in the attention messages could lead to damage to the analyzer.

Note

Notes contain additional information corresponding to the text.

1.3 Hazards

1.3.1 Electrical hazards

WARNING

To prevent the risk of electrical shock and/or damage to the instrument, operators should not open the covers of live parts (electrical) of the instrument. Only authorized personnel, e.g. service technicians, may open the instrument to perform maintenance or repairs.

Touching the live parts when the power is on may cause severe injury or death.

To make sure the electrical power is interrupted, push the power switch in the back to the OFF position and disconnect the power cable.

1.3.2 Mechanical hazards

WARNING

DO NOT wear loose garments or jewelry that could catch in mechanisms.

DO NOT put your fingers/hands into the pathway of any part while the analyzer is in operation.

DO NOT attempt mechanical repair unless the instrument is not in operation or OFF.

1.3.3 Lamp

WARNING

During operation, the photometric lamp becomes extremely hot. DO NOT look directly into the light path of the lamp when it is on.

DO NOT touch the lamp when it is on!

If the lamp needs to be changed, wait until the lamp has cooled down. For details refer to 10.2.2 Replace and adjust the lamp in this manual.

1.3.4 Chemical hazards

The operator is responsible for taking all necessary precautions against hazards associated with the use of clinical laboratory chemicals. Specific recommendations for each reagent used with the analyzer are normally found on the manufacturer's package inserts or on product information sheets for each chemical. Wipe up any reagent spillage on the instrument immediately.

Additional precautions:

Consult the reagent manufacturer for information on the concentrations of heavy metals and other toxic constituents in each reagent.

Avoid direct body-contact with reagents and cleaning solutions. Direct body-contact may result in irritation or damage to your skin. Refer to the manufacturer's reagent kit box and package inserts, or product information sheets for specific instructions.

1.3.5 Biohazard

BIOHAZARD

Patient samples, controls, calibrators and liquid waste are potentially infectious. The handling of patient samples, control sera and liquid waste must be performed according to national and international laboratory safety regulations.

Patient samples, controls, calibrators and liquid waste should be considered potentially infectious and capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other blood borne pathogens. The handling of these substances must be performed in accordance with established laboratory safety regulations in order to minimize risk to laboratory staff. This includes wearing of gloves, splash protection, etc. Contact of skin and mucous membranes must be avoided.

This also applies to all components of the instrument that are exposed to these substances. If any specimen is spilled on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant.

In various countries there are regulations on the disposal of waste. Refer to local sources for additional information on correct waste disposal.

1.3.6 Operational requirements

WARNING

Do not place the analyzer against a wall. There must be access available at all times to the rear access panels of the analyzer. Make sure the power cord is accessible. Make sure the power switch is accessible and there is free circulation of ventilation air.

WARNING

To make sure the electrical power is interrupted, push the power switch in the back to the OFF position and disconnect the power cable.

1.3.7 Transport and storage requirement

ATTENTION

Always store the analyzer in an environment with temperatures between -10 °C and +45 °C.

ATTENTION

The analyzer should only be transported in a dry condition. All system solution and cooling liquid should be removed from the analyzer before transporting the system.

1.4 Installation

The analyzer unit, parts, and accessories are shipped in transport boxes and have to be unpacked and installed by a qualified service technician from the manufacturer or his designated representative. If these instructions are not observed, The manufacturer does not assume responsibility for occurring damage or improper operation of the analyzer. The customer is responsible for providing the necessary facilities as described in detail in 2.2.2 Installation.

1.4.1 External connections

WARNING

Only instruments that meet the relevant safety requirements may be connected to the analyzer. Only use UL-listed power supply cable and power distribution blocks.

1.4.2 Maintenance

ATTENTION

For continued protection against risk of fire only use fuses of the specified type and current ratings.

For maintenance and repair procedures (e.g. replacement of the photometer lamp) follow the instructions given by service personnel or specified in the manual.

Do not use unsuitable tools for repairs (e.g. screwdrivers which are not insulated for work performed at electrical components).

During operation and maintenance of the instrument, proceed according to the instructions and do not touch any parts of the instrument other than those specified.

Avoid touching any mechanical parts while the instrument is operating. This may cause operation to stop or damage the instrument.

Only original spare parts should be used in the maintenance of this analyzer.

Only original disposables and accessories should be used in the operation of this analyzer.

Never leave a reagent/sample mixture in the flow cell for longer than necessary. Always clean the flow cell after a batch of measurements and keep the flow cell filled with distilled water when not in use.

Make sure the front covers are closed while the instrument is in operation.

1.4.3 Instrument unused for a long time

If the instrument is not to be used for a long period of time, before you switch off the analyzer, contact ELITechGroup B.V. Technical Support for further information.

1.5 Use of materials with the analyzer

1.5.1 Specimens

This analyzer is designed for measurements of analytes in samples of serum, plasma and urine. Patient samples should be prepared and handled in accordance with the instructions from the reagent manufacturer. Refer to the reagent kit insert for detailed instructions.

ATTENTION

Make sure that the sample/reagent mixture does not contain any blood clots, dust or other insoluble contaminants. If insoluble contaminants are contained in the sample, correct measuring values may not be obtained.

1.5.2 Reagents and calibrators

The manufacturer recommends the use of ELITech reagents, calibrators and controls in combination with the analyzer. Application sheets are available for a large variety of clinical chemistry tests. Therefore contact your local reagent supplier for the application sheets required.

ATTENTION

Treat all reagents according the manufacturer's recommendations. Refer to the reagent kit box and package inserts, or product information sheets for specific instructions.

Disclaimer

The manufacturer assumes no responsibility for erroneous test results caused by reagent kits and/or test parameters that are not explicitly provided or recommended by the manufacturer.

1.5.3 Controls

The manufacturer recommends the use of quality control solutions with known values for each test in accordance with international regulations and guidelines. Results obtained should fall within the limits defined by the day to day variability of the system as determined in the user laboratory. If the results fall outside the laboratory's established limits, refer to the troubleshooting information in this manual or contact your agent.

1.5.4 Analytical results

The analytical results do not only depend upon correct operation of the analyzer but also on a variety of external influences beyond the control of the manufacturer. Therefore the test results obtained with this instrument must be carefully examined by a clinical inspector or doctor, before any diagnostic or therapeutic measures are taken based on the analytical results.

WARNING

An incorrectly measured result may lead to an error in diagnosis, thereby posing a danger to the patient.

WARNING

Component failure may cause a delay in reporting test results. The user is advised to notify their local distributor if this occurs, so that the component(s) can be replaced.
Components can fail over the course of normal usage, or from external causes that cannot be controlled for. The laboratories must define how a delay in obtaining results will affect them, and develop their own protocols for preventing harm to the patients

Introduction

2.1 The system

2.1.1 Intended use

The analyzer is a semi-automated chemistry analyzer, to be used in combination with certain reagents for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine and aqueous standard solutions. The analyzer is designed as an ´open´ system. Most clinical chemistry tests that require a photometric measurement can be adapted for the system. The analyzer is intended for use in clinical chemistry laboratories where the workload is of low quantity. The analyzer must be operated by qualified and trained personnel.

Disclaimer

Depending on the specific characteristics of the involved reagent kit, the results obtained from a clinical chemistry system may vary. The test parameters for each test (and each reagent supplier), need to be developed and validated by appropriate methods [for example using ECCLS[1] or CLSI[2] guidelines] before the system is used for actual measurements of samples.

The manufacturer recommends the use of ELITech reagents, calibrators and controls on their analyzers. The manufacturer assumes no responsibility for erroneous test results caused by reagent kits and/or test parameters that are not explicitly provided or recommended by the manufacturer.

1 ECCLS = European Committee for Clinical Laboratory Standard
2 CLSI = Clinical and Laboratory Standards Institute

2.1.2 System presentation

The instrument is small and compact and consists of an analyzer, a computer unit with an integrated screen and keyboard.

The analyzer is for bench top use to save space in the laboratory. User defined tests are entered via the integrated keyboard. An external computer keyboard can also be connected.

The software provides calibration and control measurements, results statistics and reports. A total of 80 tests can be programmed, however the number of programmable tests are dependent on your distributor. Please ask you distributor or technical service representative for information.

Data transmission is via the serial port on the instrument. A parallel port is available for connection to an external printer.

2.2 Shipping and Installation

2.2.1 Unpacking

The box should be inspected for damage and contents. In case of any damage or missing parts, please inform your supplier. The box contains the following parts:

Order No	Item
6002-310	The Analyzer
6002-478	Accessory kit

The accessory kit contains the following parts:

Order No	Item
1513-024	Tube ID 4 x OD 8 (1m)
3069-040	Dust cover
3374-066	Mains cable
4104-134	Sipper tube

2.2.2 Installation

1. Remove all inserts that hold the instrument in position.
2. Place the instrument on a level surface.

> **Note**
> The surface must be clean, free from obstructions, vibration and direct sunlight.

3. Make sure the analyzer has a space of 10 cm at the rear for a free flow of air.
4. Connect all cables and plugs when the analyzer is in place.

> **ATTENTION**
> Always connect the analyzer to an earthed wall socket.

> **ATTENTION**
> Make sure the power cord is accessible.

5. Connect the waste tubing to a waste collection facility or sink.
6. Make sure all contents are removed before discarding the packaging.

2.2.3 Warranty

If the analyzer has a defect or malfunction, please inform your distributor immediately. Your distributor will inform you about all guarantee conditions.

Theory

3.1 General information

Parameters are measured as spectral absorbance A (λ) relative to a zero-adjustment on water [A (λ) = 0]. The zero-adjustment takes place automatically at the start of each test series. The relationship between concentration and change in spectral absorbance determines the concentration.

The following measurement methods are available.

- Absorbance
- Kinetic, with or without reagent blank, with or without linearity check, with or without sample blank.
- Monochromatic endpoint, with or without reagent blank, with or without sample blank.
- Bichromatic endpoint, with or without bichromatic reagent blank, with or without bichromatic sample blank
- Two point, with or without reagent blank, with or without sample blank.
- Non-linear calibration method (Curve fittings)

In the following sub-chapters a detailed explanation, including the equations for each method is given.

3.1.1 Absorbance

The absorbance is calculated according to Lambert-Beers law:

$$A = \varepsilon \times d \times c = - \log T = 2 - \log T\%$$

3.1.2 Principle of kinetic tests

The kinetic method is usually used for enzyme activity tests. The reaction is monitored during the time programmed at intervals of 0.5 seconds. The measurements are checked for linearity. If the non-linearity is greater than the programmed limit, and the delta absorbance per minute (δAbs/min) is greater than 15 milli absorbance per minute (mAbs/min), the analyzer issues a warning message. The calculation of Kinetic methods is as follows:

$$c(U/L) = \delta Abs/\min \times \left(\frac{V_{total} \times 1000}{\varepsilon \times d \times V_{sample}} \right)^{*}$$

* Note that the second part of the formula corresponds to the enzymatic factor (F). This factor can be found in the package insert of the test.

The non-linearity is calculated as follows:

$$NonLin = \frac{\delta Abs/\min_{(1)} - \delta Abs/\min_{(2)}}{\delta Abs/\min} \times 100\%$$

3.1.3 Principle of endpoint tests

Reactions that reach an endpoint are measured using the endpoint function. The reaction is normally completed before the sample/reagent mixture is aspirated and so before measurement. An endpoint measurement is performed in 2 seconds on the analyzer. Different calculations are available.

Standard endpoint

$$c = \frac{Abs_{sample}}{Abs_{std}} c_{std}$$

To calculate the sample concentration, c, the factor F is calculated as follows:

$$F = \frac{c_{std}}{Abs_{std}}$$

The sample concentration is calculated as follows:

$$c = Abs \times F$$

Endpoint with reagent blank

$$c = \frac{Abs_{sample} - Abs_{reag}}{Abs_{std} - Abs_{reag}} c_{std}$$

$$F = \frac{c_{std}}{Abs_{std} - Abs_{reag}}$$

$$c_{sample} = (Abs_{sample} - Abs_{reag}) \times F$$

Endpoint with reagent blank and sample blank

$$c = \frac{(Abs_{sample} - Abs_{reag}) - (Abs_{sampleb} - Abs_{reagbl})}{(Abs_{std} - Abs_{reag}) - (Abs_{stdb} - Abs_{reagbl})} c_{std}$$

$$F = \frac{c_{std}}{(Abs_{std} - Abs_{reag}) - (Abs_{stdb} - Abs_{reagbl})}$$

$$c_{sample} = ((Abs_{sample} - Abs_{reag}) - (Abs_{sampleb} - Abs_{reagbl})) \times F$$

Abbreviation	Explanation
reag	The reagent blank with an active reagent.
reagbl	The reagent blank with an inactive reagent.
sampleb	The sample blank for a sample.
stdb	The sample blank of the standard.

Bichromatic endpoint

$$c = \frac{Abs_{sample,\lambda 1} - Abs_{sample,\lambda 2}}{Abs_{std,\lambda 1} - Abs_{std,\lambda 2}} c_{std}$$

The factor calculation and the formula for bichromatic endpoints with reagent blank or sample blank are identical to the standard endpoint method.

3.1.4 Principle of two-point tests

$$c = \frac{Abs_{sample,\,t1} - Abs_{sample,\,t0}}{Abs_{std,\,t1} - Abs_{std,\,t0}} c_{std}$$

The factor calculation and the formula for two point tests with reagent blank or sample blank are identical to the standard endpoint method.

3.1.5 Curve fitting algorithms

The curve of best fit for non-linear tests creates the best fit from a series of calibrator measurements. This paragraph describes the theoretical background for the available methods. The procedure to obtain the measurements is given in section 6.2.2 The Standards values.

4-point Logit-Log curve

The 4-point Logit-Log (4PLL) curve matches the following equation:

$$A = A_0 + \frac{K}{1 + e^{-a-b\,\ln C}}$$

A is the absorbance (typically dAbs/min), C is the concentration. The factors A_0, K, a and b are determined with a Non-Linear Least Squares (NLLS) curve fit method.

NLLS curve fitting

Non-Linear Least Squares (NLLS) curve fitting is performed using the Levenberg-Marquardt method. Before this method is applied, the following checks are performed:
1. All concentrations must be monotonically increasing
2. All absorbance values must be either monotonically increasing or monotonically decreasing

The Levenberg-Marquardt method is an iterative approach that modifies the factors for a curve until one of the following criteria is met:
1. Chi-square is below 1×10^{-6}
2. Chi-square changes less than 0.0001 in three successive iterations (in this case the NLLS curve fitting is in a valley and only slowly iterates toward a better result)

The approach fails if more than 100 iterations are performed without meeting either of the above criteria.

Calculation of concentration from absorbance

The following steps are performed to determine a concentration from a measured absorbance:
A_{cal0}, A_{cal1}, ..., A_{caln} are absorbances of calibrators 0, 1, ..., n.
C_{cal0}, C_{cal1}, ..., C_{caln} are concentrations of calibrators 0, 1, ..., n.
$A_{measured}$ is the measured absorbance.
C_{calc} is the calculated concentration.

1. Check the validity of measured absorbance ($A_{measured}$):
   - for increasing curves:
     if $A_{measured} < 0.99 \times A_{cal0}$ then set RL flag
     if $A_{measured} > 1.01 \times A_{caln}$ then set RH flag
   - for decreasing curves:
     if $A_{measured} < 0.99 \times A_{cal0}$ then set RH flag
     if $A_{measured} > 1.01 \times A_{caln}$ then set RL flag
2. If either the RL or RH flag is set, the calculation of the concentration is aborted.

3   For 4PLL the concentration is calculated using:

$$C_{calc} = e^{\left(\dfrac{-\ln\left(-1-\dfrac{K}{A_0 - A_{measured}}\right) - a}{b}\right)}$$

4   If the calculation did not yield a result, the absorbance is checked against the absorbances of the curve:

Note

The absorbance of the second calibrator is used. This check is performed because the curve fit is sometimes non-continuous and starts above the first calibrator (for increasing curves). For Logit-Log curves this typically occurs when $A_0 > A_{cal0}$. In this case the result is clipped to the value of the first calibrator (typically 0).

- for increasing curves:
  if $A_{measured} < A_{cal1}$ then $C_{calc} = C_{cal0}$
  if $A_{measured} > A_{cal1}$ then set RH flag
- for decreasing curves:
  if $A_{measured} < A_{cal1}$ then set RH flag
  if $A_{measured} > A_{cal1}$ then $C_{calc} = C_{caln}$

5   The calculated concentration is checked for feasibility:
    If $C_{calc} < -99999$ then set RL flag
    If $C_{calc} > 999999$ then set RH flag

Cubic spline calculation

The cubic spline fitting algorithm determines if a logarithmic axis yields a better fit. It maps the absorbance and concentration values to an x and y axis using logarithmic relations.

The value on the x axis is derived from the absorbance using any of the following possible relations:

1    $x = A$
2    $x = \ln(-A - g_x)$
3    $x = \ln(A - g_x)$

The concentration is derived from the value on the y axis, using any of the following possible relations:

1    $C = f \cdot y$
2    $C = f(-e^y - g_y)$
3    $C = f(e^y + g_y)$

The factors f, g_x and g_y are determined by the curve fitting algorithm.

The relation between x and y is given by the following formula:

$y_k(x) = a_k x^3 + b_k x^2 + c_k x + d_k$

In this formula, the factors a_k, b_k, c_k and d_k are determined using the cubic spline fitting algorithm. Which factors must be used depends on the measured values. The following must hold:

$x_k < x_{measured} < x_{k+l}$

The value for x is then determined by:

$x = x_{measured} - x_k$

Linear

Multipoint linear calibration is carried out by solve for slope and intercept by using the method of linear regression and least squares. Calculations to solve for slope and intercept are automatically performed by the instrument. The mathematical theory exceeds the scope of this manual, but can be found in every standard mathematical textbook.

$C_m = Intercept + Slope * A_m$

C_m is the calculated concentration, A_m is the measured absorbance, *Intercept* and *Slope* are calculated by the analyzer.

System description

4.1 Parts of the system

4.1.1 The cover

The cover protects the measurement unit and printer. A status LED is located on top of the cover. The cover is removed by lifting it from the front.

ATTENTION

Do not remove the cover when the analyzer is on.

If you touch parts while the instrument is on you can cause personal injury and cause damage to the analyzer.

4.1.2 The sipper unit

The sipper unit is located at the front of the analyzer. The sipper unit encloses the sipper tube used for aspirating samples, reagents and cleaning solutions. The sipper button starts the aspiration process.

To aspirate a fluid do as follows:

1. Place the bottle with the liquid under the sipper tube.

2. Make sure the tube is deep enough in the liquid to aspirate the necessary fluid. A minimum of 250 µl of liquid is necessary to ensure proper measurement or cleaning.
3. Push the sipper button to start the aspiration.
4. The LED is lit during operation.

4.1.3   The measurement unit
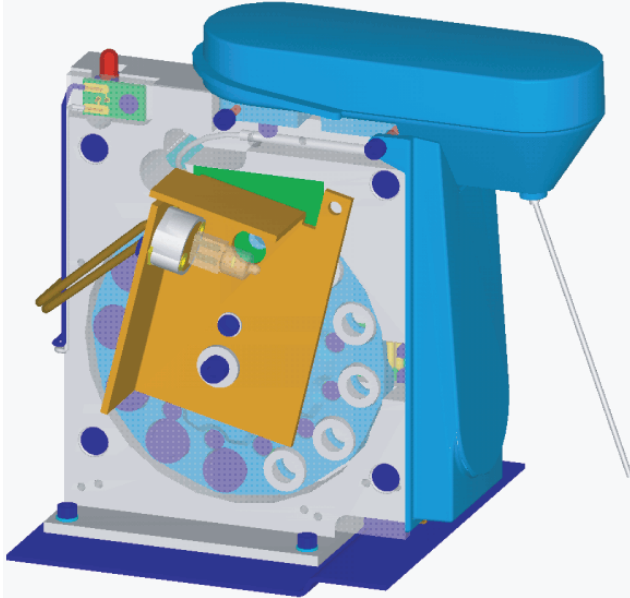
The measurement unit that measures the sample mixture is under the blue cover. It consists of: optical system, photometer lamp, and light filters.

4.1.4   The pump
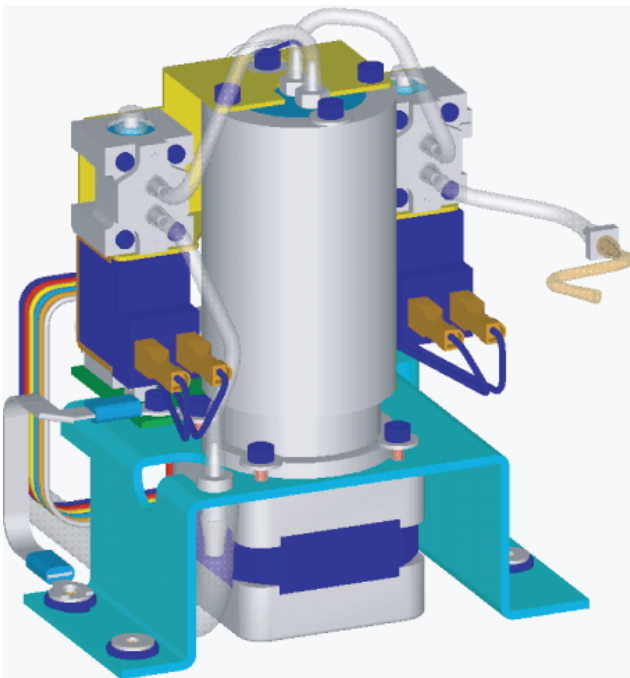
The pump is located between the measurement unit and the printer. It transports fluids from the sipper unit to the measurement unit and to the waste tube.

4.1.5 The screen

The LCD screen displays the software commands and results. To adjust the contrast, use the plus/minus keys.

4.1.6 The keyboard

The keyboard consists of hard keys with fixed functions and soft keys with screen dependant functions. Alphanumeric and cursor keys are also available.

Hard keys

Hard Keys	Description
	Contrast control of the screen.

Hard Keys	Description
	The PAPER key advances the paper one step. The FLUSH key pumps fluid through the system at a rate of 1500 µl per cycle. To stop the flushing, press the FLUSH key again. The PRIME key starts the sipper for one cycle at the programmed test volume without starting a measurement.
	The MEAS key measures the sample present in the flow-cell without aspirating.

Soft keys

The function of a soft key is shown on the screen immediately above the soft key. These functions depend on the screen that is shown and are described in the corresponding chapter.

Alphanumeric keys

The keyboard contains the arabic numbers 0 to 9 and the latin keys A to Z.

The backspace key deletes the character to the left of the cursor.

Hyphen and minus key.

The enter key confirms an entry in the screen.

The space bar has three functions; to set spaces between characters, to activate or deactivate check boxes, to activate or deactivate the PgUp / PgDn functionality in a list box.

Cursor keys
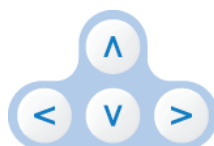
The cursor keys are used to navigate between lines, columns, and fields.

4.1.7 Software field description

Field	Description
Information field	Gives information. The user has no access to this field.
Edit Box	A value or name can be entered into this field. The field is marked with a frame and a cursor is visible. Enter the value or name and confirm with the ENTER key. Example: Name of the laboratory.
List box	A value or name that can be selected from a list that is shown by the UP and DOWN cursor keys. To see all the selection list press the UP or DOWN keys until the first selection is seen again. To confirm the selection press the ENTER key. It is also possible to select items in the list by pressing the first letter of the item. Example: Date and Time fields when programming the analyzer for the first time.
Check box	A field that can be set to ON or OFF. The field is marked with a frame and a box. If the check box is empty the function is disabled, if the check box has a small cross then the function is enabled. To enable/disable a check box, press the space bar once. Example: The external printer field when programming the analyzer for the first time.

4.2   Technical Information

4.2.1   Rear panel
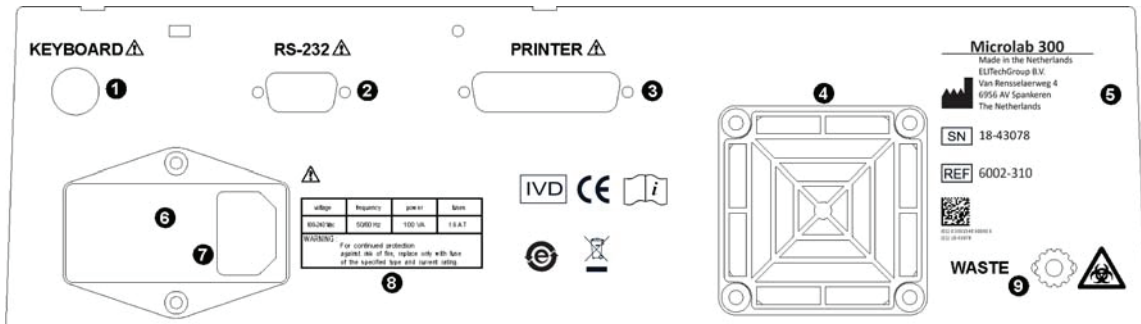
1   PS/2 socket for connection of an external keyboard.
2   RS-232 socket for a host connection.
3   Parallel connection for a printer.
4   Fan.
5   Analyzer information.
6   Fuse cover.
7   Power supply.
8   Power supply information.
9   Plug connection for the waste tube.

4.2.2   Technical data

Dimensions and weight

Width x Depth x Height	40 x 36,5 x 17 cm
Weight	8,5 kg

Power requirements

Supply voltage	100-240 V nominal
Supply frequency	50/60 Hz
Power consumption	max. 100 VA
Installation category II	In accordance to IEC 60664
Mains cable	Suitable for non-polarized outlets.

Environmental conditions

Ambient temperature	15 °C - 35 °C
Maximum relative humidity	80% at temperature up to 30 °C, decreasing linear to 65% at 35 °C.
Altitude	max. 2000 m
Pollution degree	2 (in accordance with IEC 60664)
Approvals	CE, CB

Start the system for the first time

5.1   Start the analyzer

5.1.1   Pre-start checks

Do the following checks before you start the analyzer.

WARNING

Read the safety warnings and cautions and potential hazards listed in chapter 1, before you operate the analyzer. Follow all local safety regulations.

1.   Make sure that the power cable is connected to the power supply and to the analyzer.
2.   Make sure that the waste tube from the analyzer leads to a suitable waste container.
     a   Empty the container if necessary.
     b   Do not contaminate yourself, the analyzer or the environment with bio-hazardous material.
     c   Make sure the container is no more than half a meter above or one meter below the level of the analyzer.

3.   Prepare the following solutions to clean the flow cell: The system uses 1500 µL per flush cycle of each cleaning solution.
     •   detergent solution (distilled water containint 5% non-foaming detergent)
     •   98% Methanol solution
     •   distilled water

4.   Prepare the calibrators and controls required according to the manufacturer's instructions.
5.   Prepare the reagents and samples required according to the manufacturer's instructions and to the regulations of the laboratory.

ATTENTION

Samples and reagents must not contain fibrin, dust, or any other insoluble contaminants. Insoluble contaminants lead to incorrect measurements and may endanger the patient.

5.1.2   Set the analyzer on

ATTENTION

It is advised to let the analyzer warm up for half an hour after you set the analyzer to on. The analyzer must be at operating temperature to give correct measurements.
You can use this warm-up time to clean the flow cell.

1.   Make sure all pre-start checks are complete.

2.   Set the analyzer to ON. The power circuit breaker is on the back panel of the analyzer.

3. Wait for the analyzer to initialize, do an system reset and a maintenance check. The above screen shows with the software version in the bottom right-hand corner of the screen.

5.1.3   Flush the flow cell

Note

ℹ️ Allow 12 minutes for the analyzer to flush the flow cell. 10 Minutes for the detergent flush and 2 minutes for the distilled water flush.

The analyzer makes a check for necessary actions. If no action is necessary, the Main Menu will display. If action is necessary, do as follows.

1. Fill a bottle with 5% detergent solution.
2. Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 45 ml of liquid is necessary to make sure proper cleaning.
3. Place the bottle with the liquid under the sipper tube.

4. Press the bottle against the sipper switch of the analyzer to start the cleaning process. When the analyzer is clean the following message appears: Place water and press sipper.
5. Fill a bottle with distilled water.
6. Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 9 ml of liquid is necessary to make sure proper cleaning.
7. Place the bottle with the liquid under the sipper tube.
8. Press the bottle against the sipper switch of the analyzer to complete the flush of the flow cell. When the flush of the flow cell is complete the MAIN MENU shows.

5.1.4 Start the system settings menu

Note

This chapter describes the actions necessary to start the analyzer for the first time. Pre-programmed tests are present on the system depending on the distributor. If you need to program tests refer to chapter 6.

When you start the analyzer for the first time, it is necessary to program the system parameters to make sure the analyzer works correctly. Do as follows.

1. Select PROGRAM from the MAIN menu.
   Use the cursor keys to select PROGRAM and press the ENTER key, or press the corresponding number key.
2. Select SYSTEM SETTINGS
3. Type your password.

Note

The default setting of the password is ADMIN. Change the default password to prevent unauthorized access to the system. Refer to chapter 9.
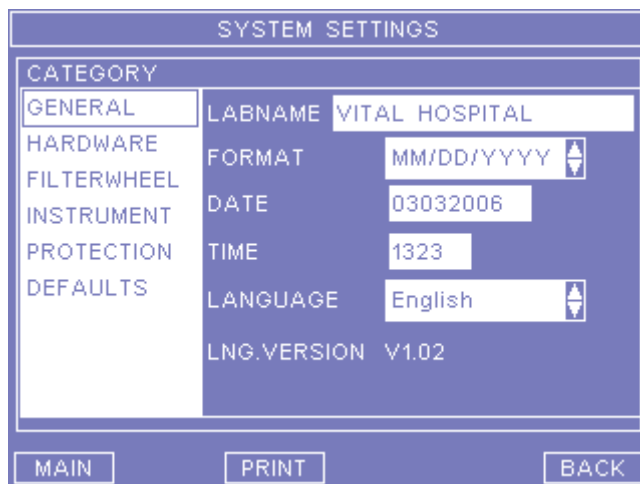
4. The above screen appears.

5.1.5 Set the General parameters

1. Make sure GENERAL is selected and press ENTER. The cursor moves to the LABNAME field.
2. Type the name of your laboratory in the LABNAME field and press ENTER. The cursor moves to the date FORMAT field.

3. Use the UP and DOWN arrows to select the date format. Press ENTER. The cursor moves to the set DATE field.

Note

The available formats are as follows:
*   MM/DD/YYYY
*   DD/MM/YYYY
*   YYYY/MM/DD

4. Type the current date in the DATE field without spaces between the numbers. The date must be in the same format as the date format you set, DD/MM/YYYY for 24th day of December 2003 is 24122003. Press ENTER. The cursor moves to the TIME field.
5. Type the current time in the 24 hour clock format with no spaces between the numbers. Example, type 1425 for 25 minutes past two o'clock in the afternoon. Press ENTER. The cursor moves to the next field.
6. Use the UP and DOWN arrows to select the LANGUAGE. The language set is used throughout the whole system. Press ENTER. The cursor moves back to the CATEGORY menu screen.
7. Press the soft key MAIN or BACK to leave the system settings or use the UP and DOWN arrows and press ENTER to select another sub menu.

Note

If the analyzer is connected to a LAB-EDP system (LABoratory Electronic Data Processing) for the transfer of results for further processing, it is possible to change the baud rate. Refer to section 5.1.6.

Parameters and keys

Parameter Fields	Parameter description
LAB NAME	The name of the user's laboratory. The name entered here will be printed with all results.
DATE FORMAT	The format of the date. Three formats available. Will be printed with all results. • MM/DD/YYYY • DD/MM/YYYY • YYYY/MM/DD
DATE	The current date. The date follows the date format set. Will be printed with all results.
TIME	The current time. Must be entered with out spaces or any characters between the numbers. Will be printed with all results.
LANGUAGE	The language used by all screens and printed results.
LNG VERSION	The software version of the language file.

Softkeys: see 5.1.10.

5.1.6   Set the Hardware parameters

To enter the baud rate to transfer the results from the analyzer to a LAB-EDP system do as follows.

```
                    SYSTEM SETTINGS

  CATEGORY
  GENERAL         EXT KEYB    United States  ⬍
  HARDWARE        EXT PRINTER   ☐
  FILTERWHEEL     INT PRINTER   ☐
  INSTRUMENT
  PROTECTION      BAUDRATE    9600           ⬍
  DEFAULTS        HW VERSION

                  SERIAL NR.


    MAIN          PRINT              BACK
```
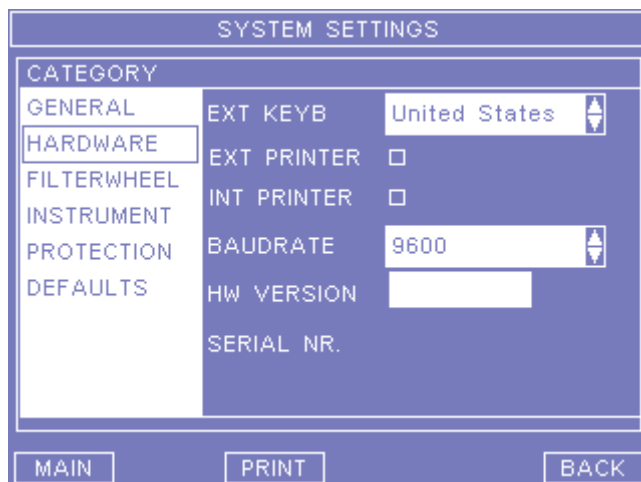
1. Make sure HARDWARE is selected and press ENTER. The cursor moves to the EXT KEYB field.

2. Use the UP and DOWN arrows to select the type of external keyboard that is used with the system. If no external keyboard is installed, select DISABLE. Press ENTER. The cursor moves to the EXT PRINTER field.

Note

ℹ️ The external keyboard will be activated after switching the analyzer off and on.

3. Press the space bar to set an external printer ON or OFF in the EXT PRINTER field. Press ENTER. The cursor moves to the INT PRINTER check box.
4. Ignore the INT PRINTER check box. Press ENTER. The cursor moves to the BAUDRATE field.
5. Use the UP and DOWN arrows to select the baudrate. Press ENTER. The cursor moves back to the CATEGORY menu screen.
6. Press the soft key MAIN or BACK to leave the system settings or use the UP and DOWN arrows and press ENTER to select another sub menu.

Parameters and keys

Parameter field	Parameters description
EXT KEYB	The type of external keyboard. The keyboard can be set to US, French, German, Spanish, Portuguese and Russian keyboard or disable.
EXT PRINT	To make an external printer connection. The printer can be selected or de-selected.
INT PRINT	Not available for the Microlab 300 LX.
BAUDRATE	The baud rate for transferring data from the analyzer to a LAB-EDP.
HW VERSION	The version of the analyzer. Not accessible by the user.
SERIAL NR	The serial number. Not accessible by the user.

Softkeys: see 5.1.10.

5.1.7 View the Filterwheel parameters

The filterwheel parameters show the filters installed. The settings can be changed by service technicians only.
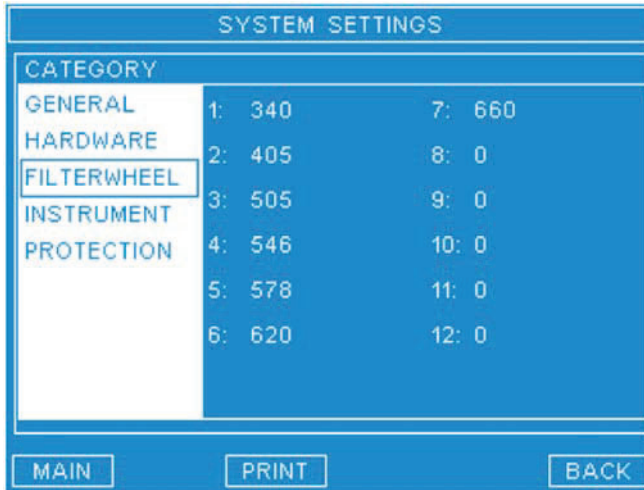
Softkeys: see 5.1.10.

5.1.8 Set the Instrument parameters

This category shows the instrument parameters. Auto Sample NR, Auto Print RES. and Results Format are accessible for the user. Transport VOL and Open Channels are not accessible for the user.
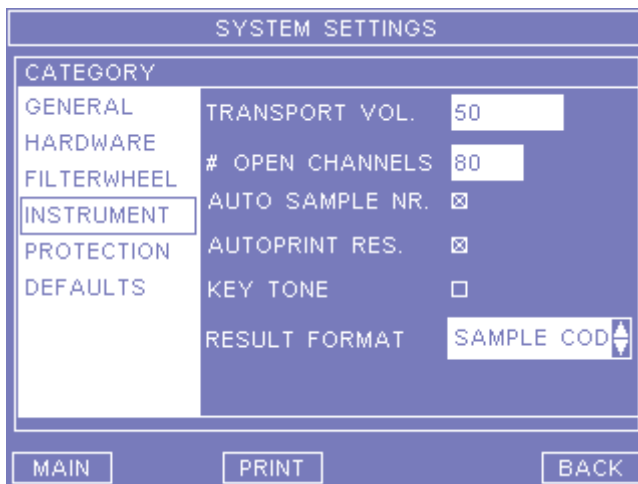
Parameter field	Parameter description
Transport Volume	Not set by the user. The extra internal transport volume that is made after aspirating a liquid. The analyzer gives an audible signal for the removal of the sample from the sipper tube after which the analyzer aspirates the set Transport Volume. The volume is used for two reasons. • To create an air gap between samples • To reduce the possibility of carryover between samples.
Open Channels	Not set by the user. The number of tests that can be defined by the user. For more information, contact your dealer.

Parameter field	Parameter description
AUTO SAMPLE NR.	Set by the user. This function automatically increments the sample code by one during each sample measurement. Set the check box to ON to enable this function.
AUTOPRINT RES	Set by the user. Set the check box to ON to automatically print the results after measurement.
KEY TONE	This can be used to switch on and off the keytone. When a key a is pressed an audible signal is heard as confirmation that the button is pressed.
RESULT FORMAT	Set by the user. Define the format of the results list. Select SAMPLE CODE to list the results as a patient number. Select PATIENT NAME to list the results by the patients name.

Softkeys: see 5.1.10.

5.1.9 Set the Default parameters

This category shows the default parameters, which determine who can store backups. The screen also allows retrieving the last backup. Backups contain all settings and test parameters.

```
                    SYSTEM SETTINGS
   ┌──────────────┬──────────────────────────┐
   │ CATEGORY     │                          │
   │ GENERAL      │  ADMIN BACKUP      ⊠      │
   │ HARDWARE     │  DEFAULTS:      Available │
   │ FILTERWHEEL  │                          │
   │ INSTRUMENT   │                          │
   │ PROTECTION   │                          │
   │ DEFAULTS     │                          │
   │              │                          │
   └──────────────┴──────────────────────────┘
   │ MAIN │      │ PRINT │BACKUP│Restore│ BACK │
```
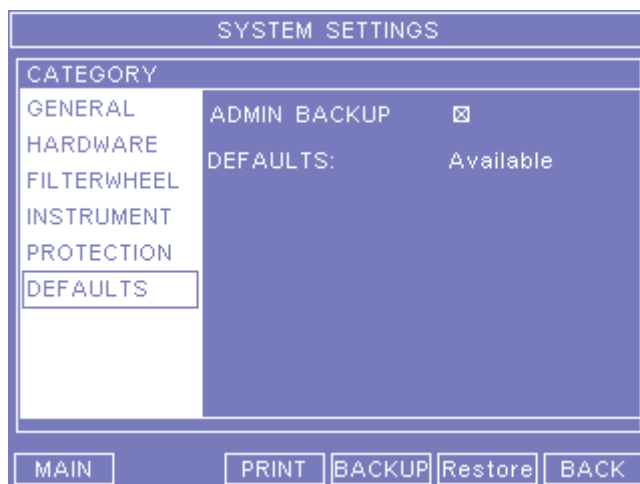
Parameter field	Parameter description
ADMIN BACKUP	Only visible when the service engineer is logged in. Set the check box to ON to allow users (using the administrator password) to store the current settings as the new default.
DEFAULTS	After the first backup is made, defaults are available.

Softkeys: see 5.1.10. This screen contains two extra softkeys:

Softkeys	Key description
BACUP	Only visible when logged on at the required level. If the ADMIN BACKUP option is switched ON, adminstrators can store backups. If the ADMIN BACKUP option is switched OFF, only service engineers can store backups.
RESTORE	Restore the settings that were backed up the last time. The analyzer screen restarts automatically when the restore process is finished.

5.1.10 Softkeys

Softkeys	Key description
MAIN	Return to the main menu.
BACK	Return to the previous screen.
PRINT	Print out the parameter settings.

5.1.11 Install the calibrators

To install the calibrators, use the test programming part of the system. If a one-point, two-point, or multi point calibration is selected in the test-parameter then you can enter names and concentrations. Refer to chapter 6.

Program tests and calibrators

6.1 Program tests

This chapter describes the programming of user defined tests and calibrators, describes how to set the controls, gives values for calibration and gives information about calibration curves.

All test parameters, including calibrator information and calibration values are stored in the Test Protocol Data in the software. The access to test parameters differ according to whether the test is user defined or pre-programmed. Pre-programmed tests (tests programmed by the distributor) may be set by the distributor so that the parameters can not be edited or deleted but only viewed. User defined tests (tests defined by the user) can be both edited and deleted.

The total number of tests able to be stored in the analyzer is 80. The total amount that can be user defined depends on how many tests are pre-programmed by the distributor and how many are left open. Ask the distributor or technical service representative for information about the number of pre-programmed tests and user defined tests.

A password is necessary to gain access to the user defined tests.

6.1.1 Program a user defined test: New, Edit, Del.

1. Select PROGRAM from the main menu.
   Use the cursor keys to select PROGRAM and press the ENTER key, or press the corresponding number key.
2. Select TESTS.
3. Type your password.

Note
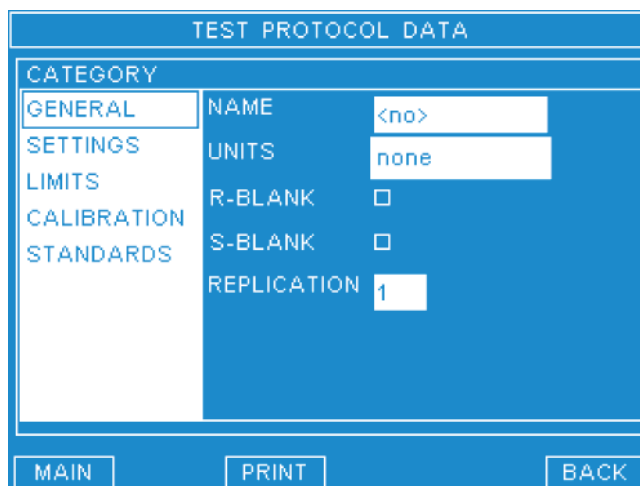
The default setting of the password is ADMIN. Change the default password to prevent unauthorized access to the system. Refer to chapter 9.

4. Press the softkey NEW to add a new test to the analyzer, or use the UP and DOWN keys to select a test and press the softkey EDIT to edit the test or DEL to delete the test.

Note

The softkey NEW is not available if the maximum number of tests (80) is reached.

5. The above screen appears.
6. Set the category GENERAL.

6.1.2 Enter the General parameters

General parameters

The following parameters are available in the GENERAL menu.

Field	Description
NAME	The name of the test.

Enter the values

Use the method sheet from the reagent manufacturer for the data for the following fields:

1. Make sure GENERAL is selected and press ENTER. The cursor moves to the NAME field.
2. Type the name of the test in the NAME field. Press ENTER. The cursor moves to the UNITS field.
3. Use the UP and DOWN arrows to select the units for the test. Press ENTER. The cursor moves to the R-BLANK field.
4. Press the SPACE BAR to select or de-select the reagent blank. Press ENTER. The cursor move to the S-BLANK field.
5. Press the SPACE BAR to select or de-select the sample blank. Press ENTER. The cursor moves to the REPLICATION field.
6. Type the number of replications for each measurement. The number is shown as default in the measurement screens. Press ENTER. The cursor moves to the DEVIATION field.
7. Type the value of the deviation in the DEVIATION field. Press ENTER. The cursor moves back to the CATEGORY menu screen.

6.1.3 Enter the Settings parameters

Field	Description
L-ABS-RB	The low absorbance limit for a reagent blank. This field shows when a default reagent blank is set in the General category. If the result for a reagent blank is less than this value, the result shows with an error flag.
H-ABS-RB	The high absorbance limit for a reagent blank. This field shows when a default reagent blank is set in the General category. If the result for a reagent blank is greater than this value, the result shows with an error flag.

6.1.4 Enter the Limits parameters

Limits parameters

The following parameters are available in the LIMITS menu. All parameters are available for all tests.

Field	Description
L-ABS	The low absorbance limit. If the result is less than this value, the result shows with an error flag.
H-ABS	The high absorbance limit. If the result is greater than this value, the result shows with an error flag.
REF-LOW	The low limit of the reference range for the sample. If the values are less than the REF-LOW limit during the measurement, the result shows with an error flag.

Field	Description
REF-HIGH	The high limit of the reference range for the sample. If the values are greater than the REF-HIGH limit during the measurement, the result shows with an error flag.
DECIMALS	The number of decimal places that shows after the decimal point. E.g. 1 means that results for controls and patients are reported to one decimal place.
L-ABS-RB	The low absorbance limit for a reagent blank. This field shows when a default reagent blank is set in the Type category. If the result for a reagent blank is less than this value, the result shows with an error flag.
H-ABS-RB	The high absorbance limit for a reagent blank. This field shows when a default reagent blank is set in the Type category. If the result for a reagent blank is greater than this value, the result shows with an error flag.

Enter the values

Use the method sheet from the reagent manufacturer for the data for the following fields.

1. Make sure LIMITS is selected and press ENTER. The cursor moves to the L-ABS field.
2. Type the low absorbance value in the L-ABS field. Press ENTER. The cursor moves to the H-ABS field.
3. Type the high absorbance in the H-ABS field. Press ENTER. The cursor moves to the REF-LOW field.
4. Type the low limit of the reference range in the REF-LOW field. Press ENTER. The cursor moves to the REF-HIGH field.
5. Type the high limit of the reference range in the REF-HIGH field. Press ENTER. The cursor moves to the DECIMALS field.
6. Type the number of decimal places in the DECIMALS field. Press ENTER. The cursor moves to the L-ABS-RB field.
7. Type the low absorbance limit in the L-ABS-RB field. Press ENTER. The cursor moves to the H-ABS-RB field.
8. Type the high absorbance limit in the H-ABS-RB field. Press ENTER. The cursor moves back to the CATEGORY menu screen.

6.2 Program calibrators

This sub-chapter describes the programming of calibrators, gives values for calibration and gives information about calibration curves. The analyzer generates a calibration curve when a non-linear test is used.

All calibrator information and calibration values are stored in the Test Protocol Data in the software. A password is necessary to gain access to the calibrator parameters.

The following calibration methods are supported by the analyzer and are described in this sub-chapter.

- 1-Point
- 2-Point
- Multi (cubic spline)
- Factor
- LinReg (linear regression)
- 4PLL (4 parameter logitlog)

6.2.1 Enter the Calibration Parameters

Enter the values

1. Select PROGRAM from the main menu.
   Use the cursor keys to select PROGRAM and press ENTER, or press the corresponding number key.
2. Select TESTS.
3. Type your password and press ENTER.

Note

The default setting of the password is ADMIN. Change the default password to prevent unauthorized access to the system. Refer to chapter 9.

4. Use the UP and DOWN arrows to select the test set to the calibrator. Press ENTER or the softkey EDIT.

5. The above screen shows.

6. Select the category CALIBRATION. Press ENTER. The curser moves to the METHOD field.

7. Use the UP and DOWN arrows to select the calibration method. Press ENTER. The cursor moves to the NAME field.

8. Type the name of the calibrator in the NAME field. Press ENTER. The cursor moves to the next field depending on the method selected.
   - 1-Point
   - 2-Point
   - Multi (cubic spline)
   - Factor
   - LinReg (linear regression)
   - 4PLL (4 parameter logitlog)

1-Point calibration parameters

The following parameters are available for 1-point calibration.

Field	Description
NAME	The name of the test. Use the keyboard to enter the name.
FACTOR	The Factor is a number that is automatically calculated during calibration and is applied to the result of the calibrated test. The factor is shown in this field and can be edited by the user.
REPLICATION	The number of times each calibration is made before it is applied to a test. This number shows default in the measurement screens.
DEVIATION	This field occurs when Replication value is greater than 1. The deviation is the allowed maximum difference of the measured absorbance between the replicate samples. The highest value measured minus the lowest value measured. If the calculated result is greater than the deviation set, the analyzer will flag the result.
L-ABS	The low absorbance limit for a calibration. If the result for a calibration is less than this value, the result shows with an error flag.
H-ABS	The high absorbance limit for a calibration. If the result for a calibration is greater than this value, the result shows with an error flag.

2-Point Calibration parameters

Note

The fields for a 2-point calibration are the same as for 1-point calibration except there is no FACTOR.

MULTI, LinReg and 4PLL calibration

Note

The fields for a MULTI, LINREG or 4PLL calibration are the same as for 1-point calibration except there is no FACTOR. Additionally the following double field #/ACCURACY is available.

Field	Description
#/ACCURACY	The first field shows the number of standards (calibrators) used. The second field only applies for MULTI calibration, and shows the curve of best fit for the calibration curve. If 0 is set the line goes through each point in turn. If 99 is set the smoothest curve of best fit is generated. Make entries in both fields and press ENTER to confirm.

FACTOR calibration

Some tests do not require calibration as the reagents used give consistent results. For tests that do not require calibration, the multiplication factor from the method sheet must be entered here.
If the reaction is decreasing, the factor must be a minus figure.

6.2.2 The Standards values

The number of standards used depends on the calibration method. Up to 10 standards can be set.
- 1-Point, 1 standard
- 2-Point, 2 standards
- Multi point, LinReg and 4PLL, up-to 10 standards
- Factor, none

In the standards screen you can enter or edit the concentration and the absorbance values of the calibrators. After an accepted calibration, the measured values are stored in these fields. Old values are overwritten. It is recommended that the values made in calibration should be accepted here. Refer to section 7.2.4.
If more than one standard is used, the analyzer generates a calibration curve. The analyzer can produce a calibration curve from a series of 10 standards. The mathematical model is based on a cubic spline fit and is a curve of best fit.

In the case of MULTI calibration, after the curve of best fit is described, smoothness factors are applied to obtain the required level of fit. Select the level of fit in percentage terms. You can change the level of fit at any time; the re-run of the standards is not necessary.
To change the curve of best fit use the field ACCURACY. See the above section Multi calibration.

Note

The standards concentration values and absorbance values (after being measured) can be printed from the testparameters. The concentration values are printed when the testparameters are printed. The measured absorbance values can be printed when the GRAPH button is pressed followed by the PRINT button. The graph will be printed together with the measured absorbance values.

6.3 Set the Controls

The use of controls is dependent on the tests used. Up to 15 controls can be set. A maximum of 2 controls can be set to each test. Two steps are necessary when a control is used for the first time.

- Program the controls
- Set the control to a test

You can set one control to many tests or set one test with a maximum of two controls.

6.3.1 Control Parameters and softkeys

All control parameters can be set by the user.

Parameter field	Parameter description
H	The high limit value for the control of the selected test.
T	The target value for the control of the selected test.
L	The low limit for the control of the selected test.

Softkeys	Key description
MAIN	Return to the main menu.
ADD	Adds a test to a control or a control to a test. No more than two controls can be assigned to a test.
DEL	Removes the assigned control from the test or a test from a control.
GRAPH	Shows a graphical representation of the selected control.
TRGT	Opens a screen to add or edit value for the control. Refer to chapter 8.
BACK	Return to the previous screen
YES	Press to confirm the deletion of either a test or a control after pressing DEL.
NO	Press to cancel the deletion of a control or test after pressing DEL.

6.3.2 Program a new control

1. Select PROGRAM from the main menu.
   Use the cursor keys to select PROGRAM and press the ENTER key, or press the corresponding number key.
2. Select CONTROLS.

```
┌─────────────────────────────────────────┐
│        PROGRAM CONTROL MENU               │
├─────────────────────────────────────────┤
│       ┌─────────────────────┐             │
│       │ ORTHO-L1-UN130      │             │
│       │ ORTHO-L2-UE078      │             │
│       │ PRECI-U-199451      │             │
│       │ QC-HSN-451          │             │
│       │ QC-HSP-452          │             │
│       │                     │             │
│       │                     │             │
│       │                     │             │
│       │                     │             │
│       └─────────────────────┘             │
├─────────────────────────────────────────┤
│ MAIN     NEW   EDIT   DEL   BACK          │
└─────────────────────────────────────────┘
```
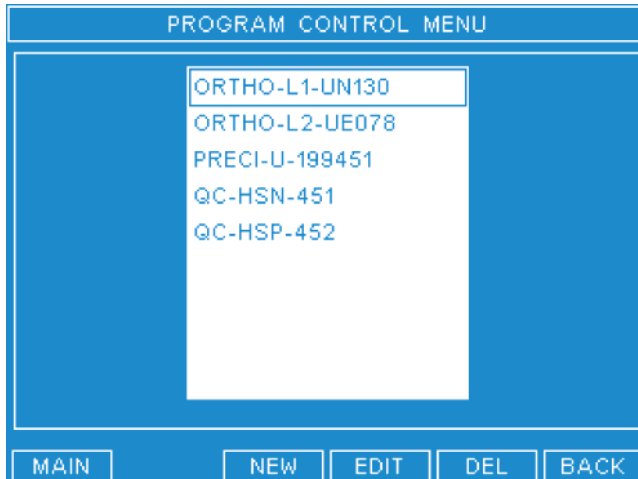
The screen shows all the available controls. If no control are set the screen is empty.

3.   Press the soft key NEW to enter a new control.
4.   Type the name of the control in the CONTROL NAME field. Press ENTER. The cursor moves to the BATCH NUMBER field.
5.   Type the manufacturer's batch number of the control in the BATCH NUMBER field. Press ENTER. The cursor moves to the EXPIRY DATE field.
6.   Type the expiry date of the control in the EXPIRY DATE field. Press ENTER. The cursor moves back to the PROGRAM CONTROL menu screen. The new control shows with the batch number.

6.3.3   Set one test with a maximum of two controls

Note

ℹ No more than two controls can be set to one test. If two controls are already set to one test, the analyzer will give an audible signal and reject the control. You must remove one of the controls set before you can set an other one.

1.   Select QUALITY CONTROL from the main menu.
     Use the cursor keys to select QUALITY CONTROL and press ENTER, or press the corresponding number key.
2.   Use the UP and DOWN arrows to select the test from the TEST menu. Press ENTER. The cursor moves to the CONTROLS AVAILABLE menu.
3.   Use the UP and DOWN arrows to select the control for the selected test. Press the softkey ADD. To add another control to the same test, select the additional control and press the softkey ADD.
4.   Press the softkey TRGT to go to the set control value screen.
5.   Use the UP and DOWN arrows to select the control.
6.   Press the RIGHT arrow key to select the value fields. The cursor moves to the H field.
7.   Type the high limit value of the control according to the data sheet in the H field. Press ENTER. The cursor moves to the T field.
8.   Type the target value of the control according to the data sheet in the T field. Press ENTER. The cursor moves to the L field.
9.   Type the low limit value of the control according to the data sheet in the L field. Press ENTER. The values are set for the control for the selected test.
10. If another control is also selected for the same test, use the UP and DOWN arrows to select the other test repeat steps 6 to 9. Use the softkey BACK to get back to the MAIN MENU.

6.3.4 Set one control to many tests

1. Select QUALITY CONTROL from the main menu.
   Use the cursor keys to select QUALITY CONTROL and press ENTER, or press the corresponding number key.
2. Press the RIGHT arrow key to move the cursor to the CONTROLS menu.
3. Use the UP and DOWN arrows to select the control from the CONTROL menu. Press ENTER. The cursor moves to the TESTS AVAILABLE menu.
4. Use the UP and DOWN arrows to select the test required for the selected control. Press the softkey ADD.
5. Repeat step 4 until all the required tests for the control are selected.
6. Press the softkey TRGT to go to the set control value screen.
7. Use the UP and DOWN arrows to select the test for the selected control.
8. Press the Right arrow key to select the value fields. The cursor moves to the H field.
9. Type the high limit value of the control according to the data sheet in the H field. Press ENTER. The cursor moves to the T field.
10. Type the target value of the control according to the data sheet in the T field. Press ENTER. The cursor moves to the L field.
11. Type the low limit value of the control according to the data sheet in the L field. Press ENTER. The values are set for the control for the selected test.
12. Repeat steps 7 to 10 until all the control values for all the tests are set.

6.3.5 Disable a control from a test

1. Select QUALITY CONTROL from the main menu.
   Use the cursor keys to select QUALITY CONTROL and press ENTER, or press the corresponding number key.
2. Press the right key to move the cursor to the CONTROLS menu.
3. Use the UP and DOWN arrows to select the control to be disabled from the test. Press ENTER.
4. Use the UP and DOWN arrows to select the test from the TEST menu. Press DEL. The message ABOUT TO DELETE, ARE YOU SURE shows on the screen. Press YES. The control is disabled from the selected test.

6.3.6 Edit an existing control

Note
If you edit a control the history of that control will be deleted.

1. Select PROGRAM from the main menu.
   Use the cursor keys to select PROGRAM and press the ENTER key, or press the corresponding number key.
2. Select CONTROLS.
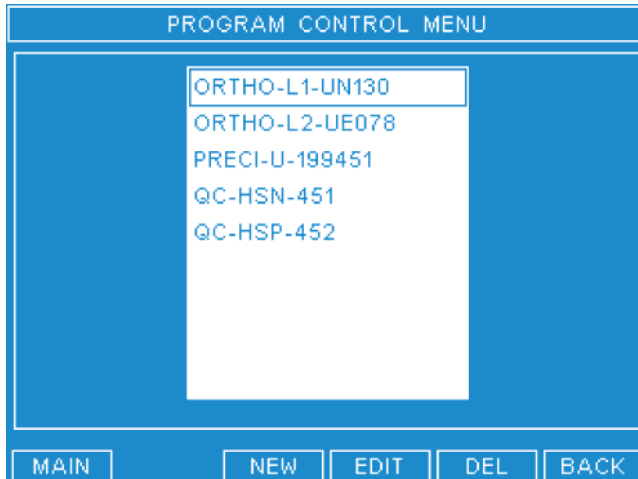
The screen shows all the available controls.

3. Press the soft key EDIT to edit an existing control.
4. Type the name of the control in the CONTROL NAME field. Press ENTER. The cursor moves to the BATCH NUMBER field.
5. Type the manufacturer's batch number of the control in the BATCH NUMBER field. Press ENTER. The cursor moves to the EXPIRY DATE field.
6. Type the expiry date of the control in the in the EXPIRY DATE field. Press ENTER. The cursor moves back to the PROGRAM CONTROL menu screen. The new control shows with the batch number.

6.4 Softkeys

The following softkeys are available in the Program test menu and Test Protocol Data menus.

6.4.1 Details

Softkey	Description
MAIN	Go back to MAIN MENU
NEW	To generate a new test. The TEST PROTOCOL DATA shows.
EDIT	Opens the test protocol of the selected test.
DEL	Deletes the selected test without confirmation. Be careful when using this key as all results from the test will also be deleted. Pre-programmed tests can not be deleted by the user.
GRAPH	Opens the CALIBRATION GRAPH screen. Visible in the STANDARDS menu or after calibrating a test. Refer to section 7.2.4. Only visible if a calibration curve exists.
PRINT	Prints out all parameters for the test with the programmed values. If the CALIBRATION GRAPH screen is open and PRINT is selected. The calibration curve is printed with the ACCURACY (only in case of MULTI).
BACK	Returns to the previous screen.

Performing tests

7.1 Introduction

7.1.1 Solutions

Sample blanks
The sample blank is made up from distilled water and the patient sample. The sample blank is used to measure the background color of the sample. Follow the reagent manufacturer's instructions as indicated in the package inserts for the reagents.

Reagent blanks
The reagent blank is made by adding the reagent to distilled water. The reagent blank is used to measure the background color of the reagent without the patient's sample.

Calibrator
The calibrator is made by adding the reagent to the calibrator sample. The calibrator is used to calibrate the analyzer for a certain test. Follow the reagent manufacturer's instructions as indicated in the package inserts for the reagents.

Control
The control is made up from reagent and the control sample. The control is used to make sure the analyzer is in operating limits. Follow the reagent manufacturer's instructions as indicated in the package inserts for the reagents.

7.1.2 Softkeys in the measurement screens

Softkey	Description
MAIN	Stops the measurement procedure. The screen shows the maintenance screen before going to Main Menu.
SKIP	Skips this action and moves to the next step.
NEW	Moves to the next sample measurement.
NEXT	Moves to the next step in the analysis sequence.
PRINT	Prints the measured result.
REPEAT	Repeats the measurement. Two choices are available: • Repeats the measurement with the same sample, but aspirating the measured sample first. Press the sipper button. • Repeats the measurement with the same sample without aspirating. Press the MEAS button.
INFO	Opens the information screen. All details of the test are available. For a kinetic test the the reactions graph
BACK	Moves back one screen.
ACCEPT	Stores the measured values for use by calibration and quality control.
DECLINE	Rejects the measured values. They will not be stored.

microlab 300 lx

7.2 Test selection

The method of each test differs depending on the test selected. The measurements that follow can be programmed for all tests, but are not always necessary. This chapter describes all measurements that are available. A sample blank, a reagent blank, calibrators and controls are not always required, however the water blank measurement always must be done. Refer to the different tests in this chapter for the procedure for each measurement.

The following measurements can be required:

- Sample blank
- Reagent blank
- Calibrator
- Control

The water blank is always necessary and must not be missed.

7.2.1 Preconditions

The following conditions must be made before you start any test.

- All Tests, controls and calibrators must be programmed.
- The flow cell must be clean
- All samples, reagents and blanks must be prepared

7.2.2 Start the test and do water blank

Start test
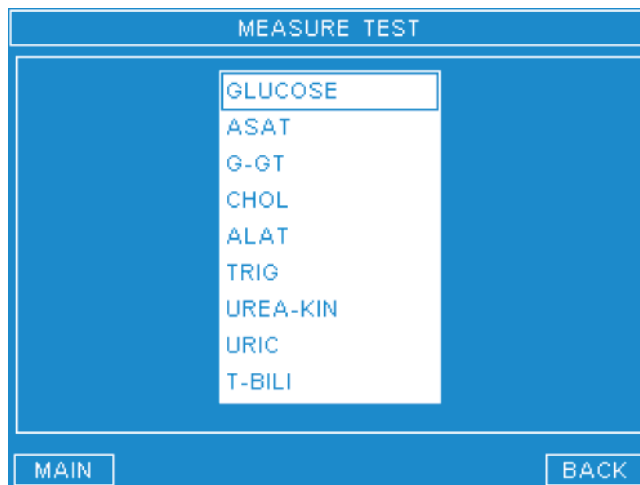
1. From the MAIN MENU, select MEASURE. Press ENTER. The above screen shows.
2. Use the UP and DOWN arrow keys to select the required test. Press ENTER.

Note

There are two options to go up and down this list faster.

1. When the spacebar is pressed the square box around the testname becomes bold, or, when it already is bold, deselects the entry. Pressing the up and down arrow key moves the selection 10 entries.
2. Pressing the first letter of the testname jumps to the next test with that letter.

Water blank

Every test requires a water blank measurement. The following screen shows.

```
           MEASURE ASAT TEST

 MEASURE WATER BLANK








      Ready to blank. Press sipper!

 MAIN                           BACK
```
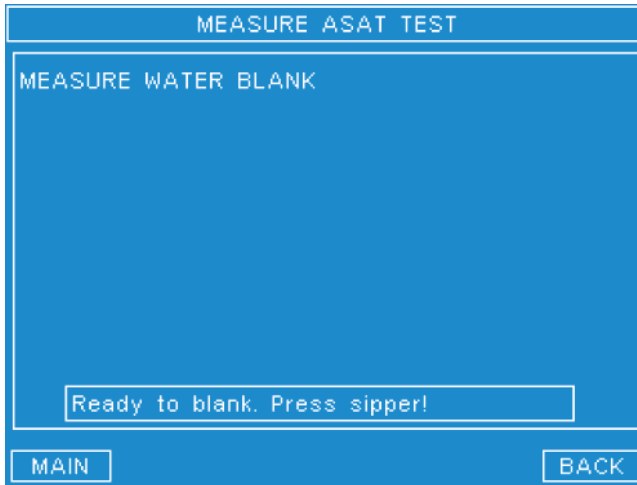
1. Fill a bottle with distilled water.
2. Place the bottle with the liquid under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.

7.2.3 Reagent blank

If a Reagent blank is necessary the following screen shows. Do as follows.

```
           MEASURE CHOL TEST

 MEASURE      REAGENT BLANK

 MEASURED         08/14/2001




 RESULT           Abs

      Press sipper to measure reagent blank

 MAIN   SKIP   PRINT  REPEAT   INFO   BACK
```
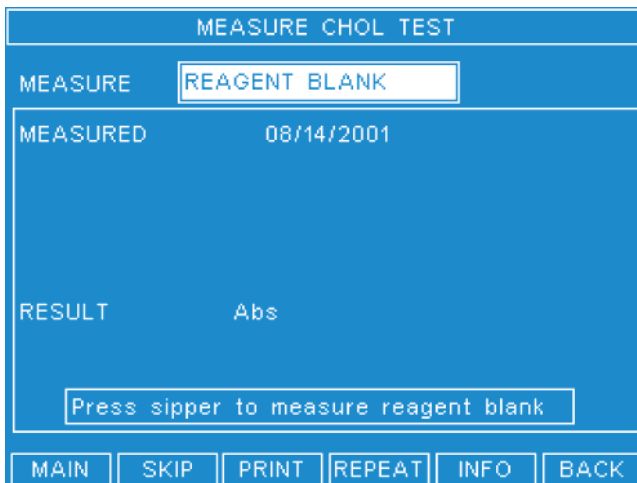
1. Place the bottle with the Reagent blank under the sipper tube.
2. Press the bottle against the sipper button to start aspiration.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
3. When the measurement is finished, the status bar will show READY, PRESS NEXT TO CONTINUE.
4. Press the softkey NEXT.

7.2.4 Calibration

A calibrator may be required, if is necessary, the following screen shows. Do as follows.

1. Read the status bar for the instructions. A sample blank may be required before calibration.
2. If a sample blank is required, place the bottle with the sample blank under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
4. Place the bottle with the calibrator under the sipper tube.
5. Press the bottle against the sipper tube.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
6. Depending on the test, more calibrations may be necessary. Repeat steps 1 to 5 until the calibration is complete.
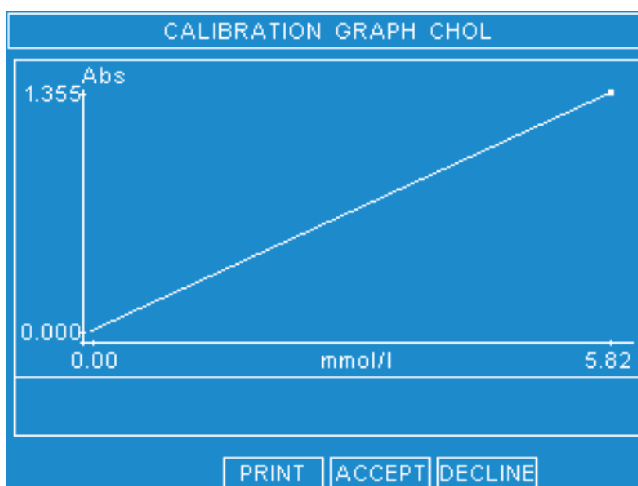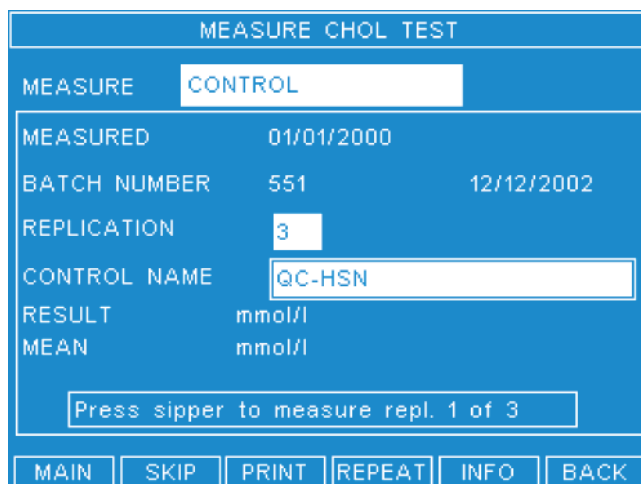
7. The screen will show the results of the calibration. The status bar will show, Press graph to validate calibration.
8. Press the softkey GRAPH.
9. Press
   - PRINT to print the graph
   - ACCEPT to accept the calibration. The measured calibration result will overwrite the previous calibration result.

- DECLINE to decline the calibration. The measured calibration will not be saved. The previous calibration will not be overwritten.

10. Press the softkey Next.

7.2.5 Control measurement

A Control may be required, if is necessary, the following screen shows. Do as follows.

```
            MEASURE CHOL TEST
   MEASURE     CONTROL
   MEASURED        01/01/2000
   BATCH NUMBER    551         12/12/2002
   REPLICATION      3
   CONTROL NAME     QC-HSN
   RESULT          mmol/l
   MEAN            mmol/l

   Press sipper to measure repl. 1 of 3

   MAIN   SKIP   PRINT  REPEAT  INFO   BACK
```

1. You can change the control if more than one control is set for a test. Press ENTER and select the control by pressing the DOWN key. Press ENTER to confirm.
2. If a sample blank is required, place the bottle with the sample blank under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
4. Place the bottle with the control under the sipper tube.
5. Press the bottle against the sipper button.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
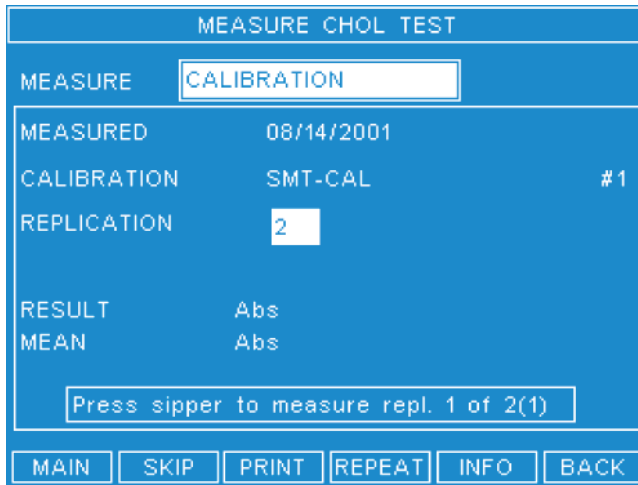6. Repeat steps 2 to 5 until the number of replications for the control is complete.
7. Press
   - ACCEPT to accept the control. The measured control value is saved and is used by the control statistics.
   - DECLINE to reject the control. The measured value is rejected and will not be used by the control statistics.

8. Press
   - NEXT to measure the sample or change the measurement type to make another measurement.
   - ENTER to save the result of the measurement for use by quality control otherwise select and measure the other control that may be programmed.

7.3 Do the test

7.3.1 Sample measurement

After the analyzer completes the reagent blank, calibration and control measurement, the analyzer is ready to make the sample measurement. Do as follows:

ℹ **Note**

If no sample code or patient name is entered before the measurement, the results will show no assignment. Make sure a correct order is maintained. Always use sample codes or patient names before measurement.

```
┌─────────────────────────────────────────┐
│          MEASURE CHOL TEST               │
│  MEASURE    ┌──────────┐                 │
│             │ SAMPLE   │                 │
│  ┌──────────┴──────────┴──────────────┐  │
│  │ PATIENT NAME   ┌─────────────────┐ │  │
│  │                └─────────────────┘ │  │
│  │ SAMPLE CODE    ┌──────────────┐    │  │
│  │                └──────────────┘    │  │
│  │ REPLICATION    ┌───┐               │  │
│  │                │ 1 │               │  │
│  │                └───┘               │  │
│  │ RESULT       mmol/l                │  │
│  │                                    │  │
│  │ ┌────────────────────────────────┐ │  │
│  │ │ Press sipper to measure repl. 1 of 1 │ │
│  │ └────────────────────────────────┘ │  │
│  └────────────────────────────────────┘  │
│ ┌────┐┌────┐┌─────┐┌──────┐┌────┐┌────┐  │
│ │MAIN││SKIP││PRINT││REPEAT││INFO││BACK│  │
│ └────┘└────┘└─────┘└──────┘└────┘└────┘  │
└─────────────────────────────────────────┘
```

1. The status bar shows, READY, PRESS NEW FOR NEXT SAMPLE.
2. Press the softkey NEW. If the sample blank is necessary, the status bar shows, PRESS SIPPER TO MEASURE SAMPLE BLANK.
3. Enter the patient's name or sample code.
4. Place the bottle with the sample blank under the sipper tube.
5. Press the bottle against the sipper tube.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
6. Place the bottle with the sample under the sipper tube.
7. Press the bottle against the sipper tube.
   When the audible sound is made, remove the bottle from the sipper unit. The analyzer will make the transport volume to make a break between solutions.
8. Repeat steps 4 to 7 until the number of replications for the sample measurements are complete.
9. When complete the status bar shows, Ready, Press new for next sample.
10. Press
    - MAIN to go to the Main Menu. The changing test maintenance to clean the flowcell will start to make the analyzer ready for a new test.
    - NEW to measure a new sample with the same test.
    - PRINT to print the results.
    - REPEAT to repeat the same sample with the same test.
    - INFO to see the test results and to print the results.
    - BACK to go back one screen. The changing test maintenance to clean the flowcell will start to make the analyzer ready for a new test

7.3.2 Sample measurement result details

Flags

The following flags could occur after measurement. The description gives the meaning for each flag. For further information refer to chapter 11.

Flag	Description
H	The result is greater than the high reference concentration limit set in the test parameters.
L	The result is less than the low reference concentration limit set in the test parameters.
A	The absorbance is outside the high or low absorbance levels set in the test parameters.
nl	The non linearity is greater than the limits set in the test parameters
>	The control result is above the high concentration limit set in the quality control.
<	The control result is below the low concentration limit set in the quality control.
D	The deviation between replicates exceeds the limit set in the test parameters.
S	The stabilization of the analyzer is not complete.
R	The results can not be calculated.
T	The temperature is out of range.

The INFO screen

After a sample or a reagent solution is measured and you press the INFO softkey the following screen shows. The details listed are shown.

```
                MEASURE CHOL TEST
   ┌──────────────────────────────────────────┐
   │  REP     Abs       mmol/l                 │
   │ ┌────────────────────────────────────────┐│
   │ │  1     1.420        6.11                ││
   │ └────────────────────────────────────────┘│
   │    2     1.420        6.11                 │
   │    3     1.420        6.11                 │
   │                                           │
   │                                           │
   │                                           │
   │                                           │
   │  MEAN        6.11 mmol/l     Flags         │
   │  SD          0.00                          │
   │  DEV         0.00 mmol/l                   │
   └──────────────────────────────────────────┘
              [ PRINT ]          [ BACK ]
```

Detail	Description
REP	The number of replicates.
ABS	The measured raw absorbance, corrected for the reagent or sample blanks.

Detail	Description
[UNIT]	The calculated result from the measured absorbance.
FLAGS	Flags that occur during the measurement show in this column.
MEAN	The mean value of the results of all replicates. If no replicate is made, then the value as in the unit column will show.
SD	The calculated standard deviation from all replicates.
DEV	The maximum deviation between the highest and lowest replication result. DEV = Result high - Result low
START	Kinetic test only. The start absorbance of the kinetic measurement.
S.BLANK	The ABS result of the sample blank.

INFO screen for kinetic tests

For a kinetic measurement, it is possible to display the reaction on screen. Press INFO twice. The following screen shows.
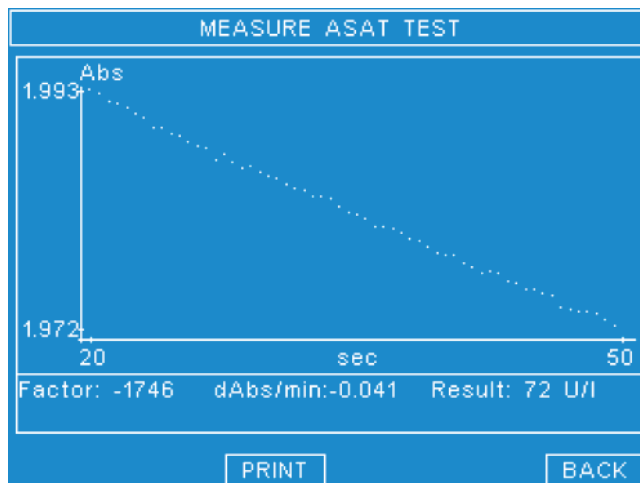
Detail	
....	All measured points on the kinetic test.
ABS	The absorbance range of the measurement. The start and end of the measured kinetic test.
SEC.	The time axis. Displays the time as programmed in test parameters.
FACTOR	The programmed kinetic factor.
DABS/MIN.	The delta absorbance factor
RESULT	The kinetic measurement result in the specified units.

7.3.3 Changing test maintenance

When changing tests the changing test maintenance to clean the flowcell will start to make the analyzer ready for a new test.

```
┌─────────────────────────────────────────┐
│        CHANGING TEST MAINTENANCE         │
│ ┌─────────────────────────────────────┐ │
│ │ Flush the flowcell                  │ │
│ │                                     │ │
│ │                                     │ │
│ │                                     │ │
│ │                                     │ │
│ │                                     │ │
│ │                                     │ │
│ │ ┌─────────────────────────────────┐ │ │
│ │ │ Place 5% detergent and press sipper │ │
│ │ └─────────────────────────────────┘ │ │
│ └─────────────────────────────────────┘ │
│            ┌──────────┐                   │
│            │   SKIP   │                   │
│            └──────────┘                   │
└─────────────────────────────────────────┘
```
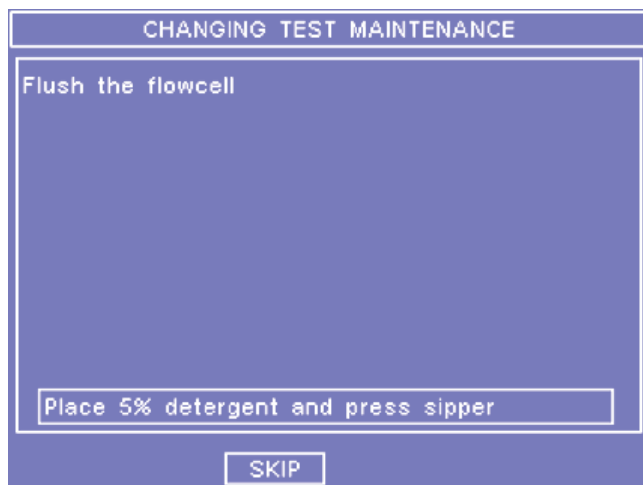
Note

Allow 3 minutes for the analyzer to flush the flow cell, 2 minutes for the detergent flush and 1 minute for the distilled water flush.

When switching tests, the analyzer makes a check for necessary actions. If no action is necessary, the MEASURE TESTS MENU will display. If action is necessary, do as follows.

1. Fill a bottle with 5% detergent solution.
2. Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 10 ml of liquid is necessary to make sure proper cleaning.
3. Place the bottle with the liquid under the sipper tube.
4. Press the bottle against the analyzer to start the cleaning process. When the analyzer is clean the following message appears: Place water and press sipper.
5. Fill a bottle with distilled water.
6. Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 5 ml of liquid is necessary to make sure proper cleaning.
7. Place the bottle with the liquid under the sipper tube.
8. Press the bottle against the analyzer to complete the flush of the flow cell.
   When the flush of the flow cell is complete either the MAIN MENU or the MEASURE TEST MENU shows, depending on which button is pressed (MAIN or BACK).

7.3.4 Evaluate the test

The evaluate test screen shows the results of the last 100 sample measurements. The oldest measurement is deleted when more measurements are added.

Note

If no sample code or patient name is entered before the measurement, the results will show no assignment. Make sure a correct order is maintained. Always use sample codes or patient names before measurement.

```
          EVALUATE TEST REQUESTS

  SAMPLE CODE  TESTNAME       RESULT

  XS206        CHOL          6.14 mmol/l
  YV641        CHOL          2.40 mmol/l
  RT456        CHOL          6.07 mmol/l
  AS121        GLUCOSE       17.7 mmol/l
  QW003        GLUCOSE        6.8 mmol/l
  AD002        GLUCOSE       17.9 mmol/l
  AB001        GLUCOSE       21.1 mmol/l
  AS121        ASAT           72 U/l

  MAIN  print all  PRINT  CLEAR        BACK
```

1. From the MAIN MENU select EVALUATE TESTS.
2. The above screen shows the results with sample code and test name.
3. To do a PgDn press the SPACE bar and then the DOWN arrow.
4. Press
    - MAIN to return to the main menu.
    - PRINT ALL to print all test results.
    - PRINT to print the selected test results.
    - CLEAR to delete all test results. A Yes/No selection is made before all test results are deleted.

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Quality control

8.1 Statistical information

8.1.1 General

Statistical information about the controls is given in the Quality Control menu. Two controls can be defined for each test that is programmed. A maximum of 15 different controls is available.

The analyzer stores the last 30 results in the form of a Levey-Jennings plot together with all the statistical information. When you add one more result, the oldest will be deleted and the statistics be re-calculated.

The statistical information can be shown by test or by control. To shown by control, select the control first; to show by test, select test first. The procedure here is to shown by test, but the logic for each test is the same.

8.1.2 Statistics

To validate control statistics do as follows.

1. Use the UP and DOWN arrow keys to select QUALITY CONTROL from the MAIN MENU. Press ENTER. The following screen shows.
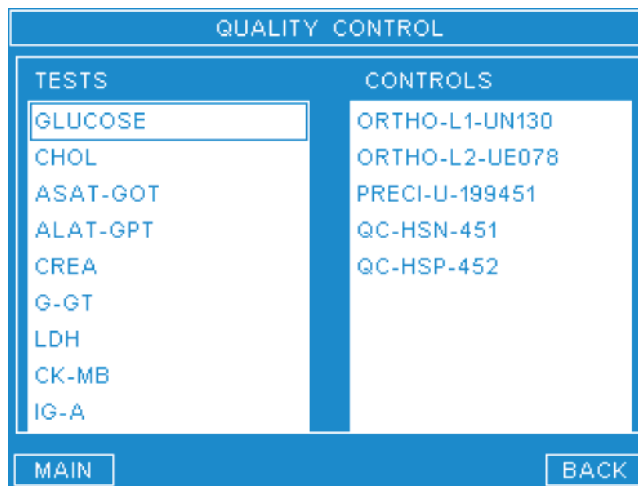
2. Use the UP and DOWN arrow keys to select the test. Press ENTER. The following screen shows.
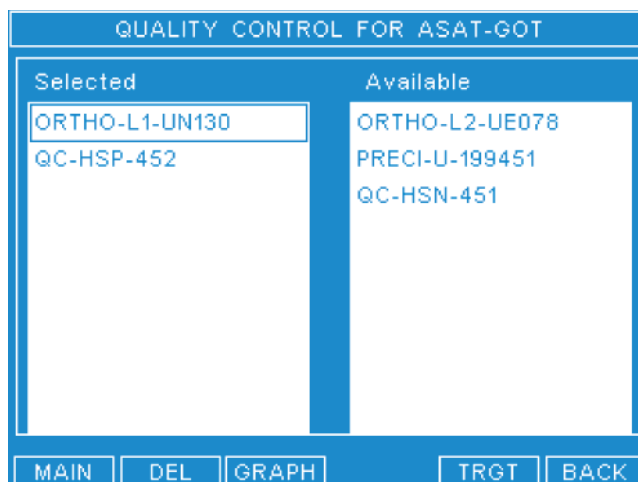
3. From the SELECTED column, select the control for validation.
4. Press the softkey Graph. The graph screen shows the stored course of the control measurements for the selected test.

5. The screen shows the measured values of the control in relation to the programmed target values and limits. Press to print the values.

8.1.3 Details of the Quality control screen

The printout and the screen contain the following information.

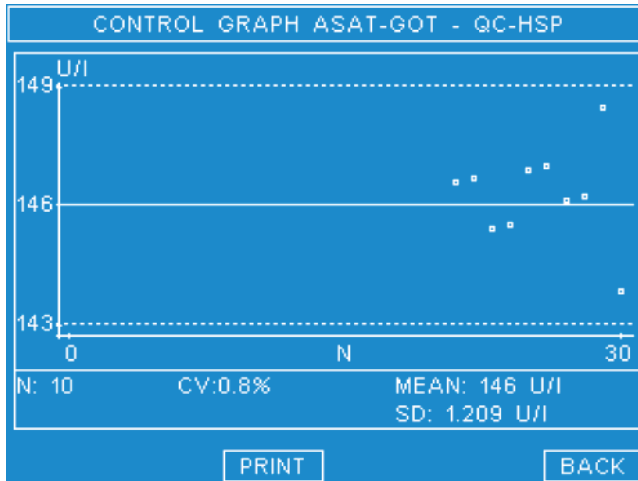| Details	Description
Control	The name of the selected control.
QC	The name of the test assigned to the control.
Batch No.	The batch number of the control. Printout only.
Exp.Date	The expiration date of the control as entered in the program control.
- - - - - - - - - -	The high limit set in quality control.
---------------------	The reference value as set in quality control.
- - - - - - - - - -	The low limit as set in quality control.
N	The number of test measurements carried out with the control.
CV	Coefficient of variation. Displayed as a % of the relationship between the mean value and the standard deviation.
MEAN	The mean value and the unit of all the displayed control values in the graph.
SD	Standard deviation of all results.

Passwords

9.1 Password information

9.1.1 General

This chapter describes the use of passwords in the analyzer. The analyzer is protected by two passwords: the user and the service password.

The software has three sections that are password protected:

- Tests in the PROGRAM Menu
- System Settings in the PROGRAM Menu
- Service in the MAINTENANCE Menu

The user has access to the Test and the System Settings parts of the software, the service engineer has access to all three parts of the software. When the user accesses the user part of the software, the service password is unavailable for use. The service technician must log in with his own password.

ATTENTION

Remember your own password. If you forget your password you have no access to the Tests or the System Settings parts of the analyzer. The service technician has no access to the Service part of the software.

9.1.2 Change passwords

To change a password, do as follows:

1. Select PROGRAM from the MAIN MENU.
   Use the cursor keys to select PROGRAM and press the ENTER key, or press the corresponding number key.
2. Select SYSTEM SETTINGS.
3. Type your password.

Note

The default setting of the password is ADMIN. Change the default password to prevent unauthorized access to the system.

4. Use the UP and DOWN arrows to select the PROTECTION in the CATEGORY menu. Press ENTER.
5. Use the BACK arrow key to delete the existing password.
6. Type the new password in the field LABORATORY PWD for the user or SERVICE ENG.PWD for the service technician.
   The use of letters and numbers up to 6 characters long is allowed.

Note

There is NO confirmation of the password. Make sure you type your password in correctly. Mistakes can not be rectified.

7. Press the softkey BACK two times to go back to the MAIN MENU.
8. Access to the different parts of the system is only possible with the use of the new password.

Note

The password is case sensitive. If the password is entered with the external keyboard and it contains lower-case letters, the password cannot be entered any more if the external keyboard is detached, because the Microlab 300 LX uses only capital letters.

Maintenance

10.1   Daily maintenance

The keep the analyzer accurate and free from micro-biological contamination of the flow path and flow cell, the daily maintenance must be adhered to. The daily maintenance schedule has two cleaning procedures; half daily and end of day maintenance. The half daily maintenance must be carried out every four hours. The end of day must be carried before the analyzer is shut down. If the analyzer has not had the end of day maintenance procedure, when the analyzer is started next time, the end of day maintenance procedure will start. The half daily maintenance and the end of day maintenance are in addition to the Change of test maintenance.

10.1.1   Half daily maintenance

The half daily maintenance consists of a flush of the flow cell with 98% methanol and a flush with distilled water. The half daily maintenance takes about 2 minutes to complete.

1. Fill a bottle with 98% methanol. At least 5 ml of methanol is is required for this step.
2. Place the bottle with the liquid under the sipper tube.
3. Select USER MAINTENANCE from the main menu.
   Use the cursor keys to select USER MAINTENANCE and press the ENTER key, or press the corresponding number key.
4. Select HALF-DAILY MAINTENANCE
5. Press the bottle against the analyzer to start the cleaning process. When the analyzer is clean the following message appears: Place water and press sipper.
6. Fill a bottle with distilled water. At least 5 ml of water is is required for this step.
7. Place the bottle with the liquid under the sipper tube.
8. Press the bottle against the analyzer to complete the flush of the flow cell.
   When the flush of the flow cell is complete the MAINTENANCE MENU shows.

ⓘ **Note**
You can permit that the half-daily maintenance is not done in urgent cases, but this is not recommended.

10.1.2   End of day maintenance

The end of day maintenance should be made before the analyzer is shut down. Do as follows.

ⓘ **Note**
Allow 12 minutes for the analyzer to flush the flow cell. 10 Minutes for the detergent flush and 2 minutes for the distilled water flush.

1. Fill a bottle with 5% detergent solution.
2. Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 45 ml of liquid is necessary to make sure proper cleaning.
3. Select USER MAINTENANCE from the main menu.
   Use the cursor keys to select USER MAINTENANCE and press the ENTER key, or press the corresponding number key.
4. Select END OF DAY MAINTENANCE.
5. Press the bottle against the analyzer to start the cleaning process. When the analyzer is clean the following message appears: Place water and press sipper.
6. Place the bottle with the liquid under the sipper tube.
7. Press the bottle against the analyzer to start the cleaning process. When the analyzer is clean the following message appears: Place water and press sipper.
8. Fill a bottle with distilled water.
9. Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 9 ml of liquid is necessary to make sure proper cleaning.

10. Place the bottle with the liquid under the sipper tube.
11. Press the bottle against the analyzer to complete the flush of the flow cell.
    When the flush of the flow cell is complete the MAINTENANCE MENU shows.

10.2 Replacements

10.2.1 Replace the fuses

The fuse holder is located between the ON/OFF switch and the power supply connector on the back panel of the analyzer. To replace the fuses do as follows:

1. Set the analyzer to OFF.
2. Use a screwdriver to pull the fuse holder from the case of the analyzer.
3. Remove the fuses from the holder.
4. Install two fuses in the holder. 250V 1.6 A.
5. Install the fuse holder in the back panel of the analyzer.

10.2.2 Replace and adjust the lamp

Replace the lamp

If the lamp has a defect or the absorbance readings are incorrect in the first instance contact your service technician or dealer. To replace the lamp do as follows:
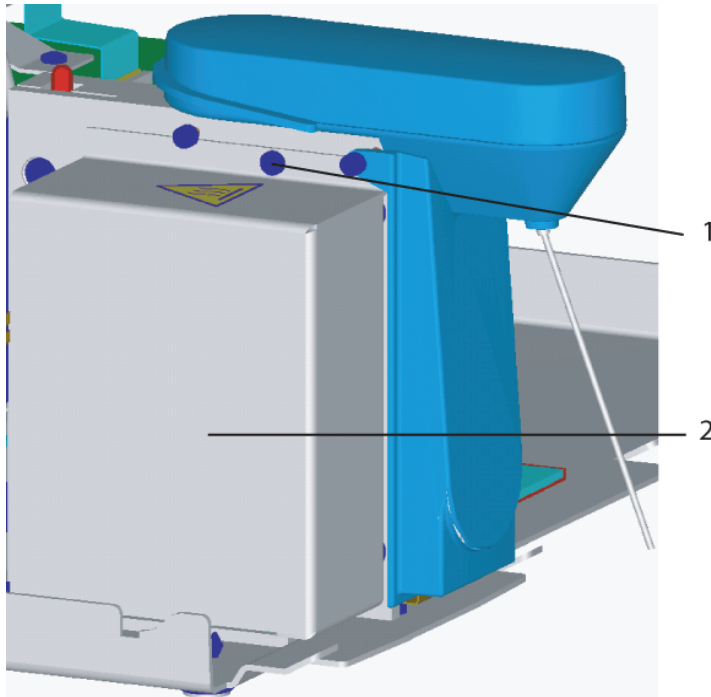
1. Select USER MAINTENANCE from the MAIN MENU.
   Use the cursor keys to select USER MAINTENANCE and press ENTER or press the corresponding number key.
2. Select ADJUST LAMP. The following screen shows.
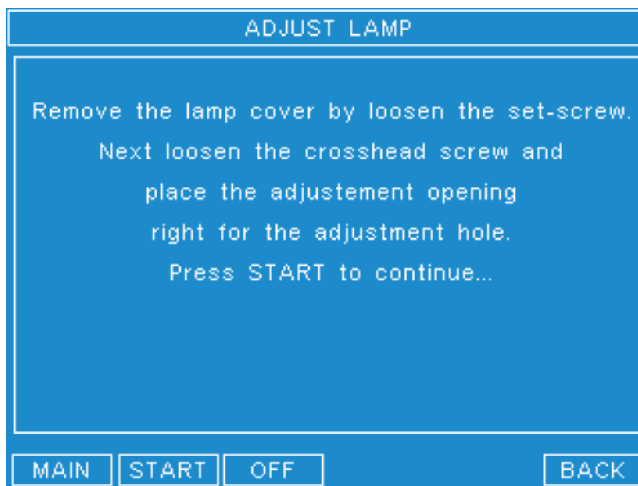
3. Press the softkey OFF to switch off the lamp.

⚠️ **WARNING**
Do not touch the lamp for five minutes after the lamp is turned off.
The lamp is very hot.

4. Remove the blue cover from the analyzer.
5. Loosen and remove the cross head screw (1).
6. Remove the metallic cover (2).
7. Wait five minutes for the lamp to cool.

8. Remove the lamp from the socket.

ATTENTION

Do no touch the new lamp with bare fingers. Salt from your fingers will reduce the life of the lamp. Wear surgical gloves when handling the new lamp.

9. Press the new lamp into the socket with care until the lamp is fully in.

Adjust the lamp
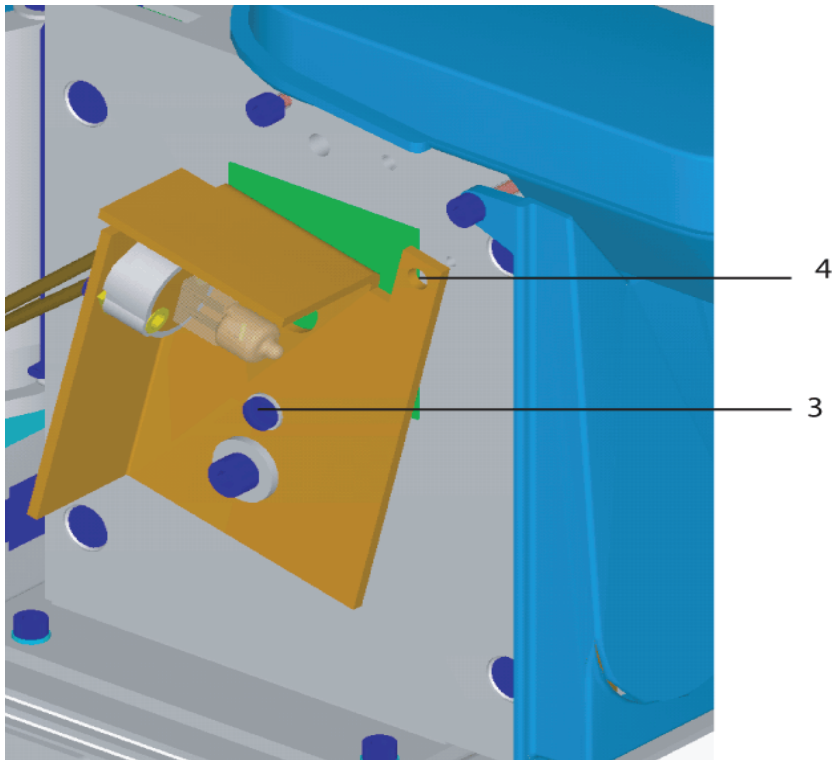
1. Loosen the screw (3).
2. Press the softkey ON to set the lamp on.
3. Press the softkey START to start the adjustment. The following screen shows.

ADJUST LAMP

Put a screwdriver in the adjustment
opening and let it fall into the
adjustment hole. Adjust the lamp
to the position with the lowest
absorbance value by means of
moving the screwdriver.
Press STOP to continue...

| 0.000 | | 0.004 | Abs |

| MAIN | STOP | | BACK |
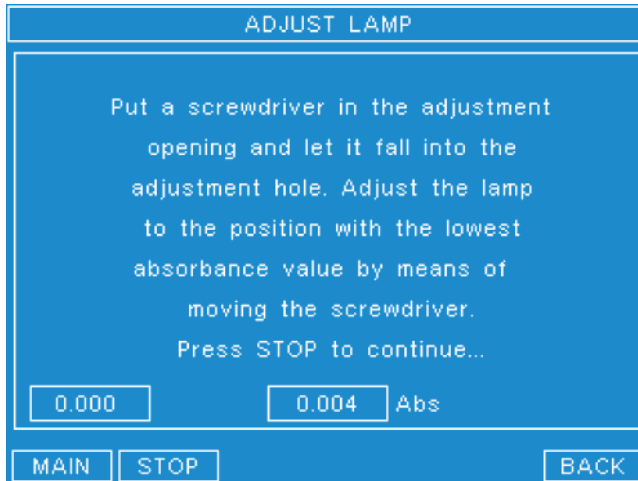
4. Insert a thin screwdriver through the hole (4) to the hole behind the opening.
5. Follow the online instructions to adjust the lamp.
6. Tighten the screw loosened in step 5 of the previous text.
7. Attach the cover and fasten the screw.
8. Press the softkey MAIN.

10.3 Maintenance list and error history

10.3.1 Maintenance list

The maintenance list function prints a list of the most recent maintenance actions including date, time and name of the maintenance procedure. To print the list do as follows:

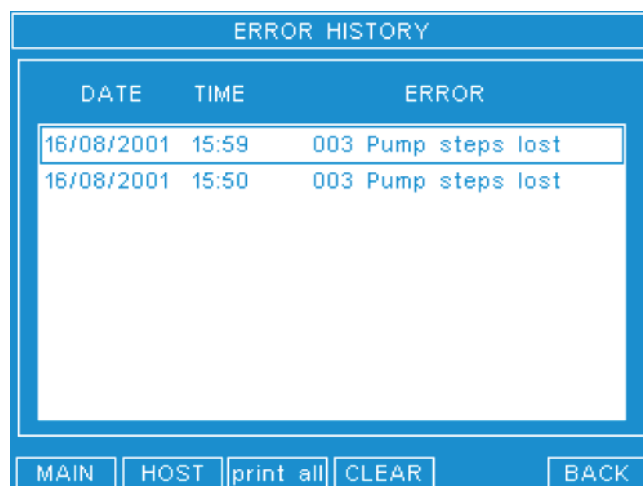1. Select USER MAINTENANCE from the main menu.
   Use the cursor keys to select USER MAINTENANCE and press the ENTER key, or press the corresponding number key.
2. Select PRINT MAINTENANCE LIST.
   The analyzer prints the list.

10.3.2 Error history

The error history stores the last 30 errors in the analyzer. The error history helps in identifying and solve possible errors. For further information please refer to chapter 11 Troubleshooting.

1. Select USER MAINTENANCE from the main menu.
   Use the cursor keys to select USER MAINTENANCE and press the ENTER key, or press the corresponding number key.


```
ERROR HISTORY

DATE        TIME        ERROR

16/08/2001  15:59       003 Pump steps lost
16/08/2001  15:50       003 Pump steps lost




MAIN    HOST  print all CLEAR            BACK
```

2. Select ERROR HISTORY.
   The screen above shows.

Field	Description
DATE	The date of the error.
TIME	The time of the error
ERROR	Short explanation of the error with the error code. Refer to chapter 11 Troubleshooting.

Softkey

MAIN	Go to the main menu
HOST	Transfers the error message to the host.
PRINT	Prints the error list

Softkey

CLEAR   Deletes the error list. This can only be done by the service technician.

BACK   Go back to the previous screen.

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Troubleshooting

11.1 General

The analyzer is error tolerant with proven accuracy and precision. This chapter describes the causes and possible solutions to errors and faults.

Indications of problems are noticeable by high or low, erratic, or unexpected results. Obvious errors are indicated by flags in the results screens and on the printouts. Hardware errors are indicated by error messages, software errors are indicated by warning messages.

WARNING

Problems that are not described in this chapter or can not be solved by the use of this chapter should be referred to your service technician. You must not alter the system without consulting the service technician.

The problems that occur are attributable to two main causes:
*   Sample and reagent problems
*   Analyzer problems

11.1.1 Sample and reagent problems

To prevent errors due to samples and reagents check the following:

Samples
*   Check that the sample is not too hemolytic, icteric or lipeamic.
*   Check that the sample material is fresh and treated according to the requirements of the manufacturer of the reagents, as listed on the package insert of the test.

Reagents, calibrators and controls
*   Check the reagent expiry date.
*   Check the reagent dilution ratio.
*   Check that the water is de-ionized or distilled and free from impurities.
*   Check the storage requirements, frozen or cooled.
*   Check the settings in the QUALITY CONTROL menu; target values, high and low limits of the control.
*   Check the settings in the TEST PARAMETER menu; reference and absorbance limits of the specific test.
*   Check the manufacturers required volume for each reagent, calibrator and control.
*   Check the correct pipette is used to prepare the solution.

11.1.2 Analyzer problems

To prevent errors due to the analyzer, check the following:
*   Check the connections of the power supply unit.
*   Check external connections to external printer keyboard of host computer.
*   Check all tube connections.
*   Check the maintenance record. Refer to chapter 10 Maintenance.

11.2 Problems, causes and solutions

This sub-chapter describes problems and possible causes and solutions. The problem, cause, solution, is divided into error codes, warning messages, data flags and physical conditions.

11.2.1 Error messages

Error messages normally indicate a hardware problem and are number coded with a short explanation. Switch the analyzer off for 10 seconds and switch back on again. Check to see if this solved the problem. If not contact your service technician.

Error code	Cause	Solution
000 Temp. Time out.	The flowcell has not reached the correct temperature within 30 seconds.	Wait for a few minutes for the flag to disappear. If the flag does not disappear, switch the analyzer off and reset the analyzer. If the problem is still present, contact you service technician.
001 Blank out of range.	No light or insufficient light.	Check lamp and lamp adjustment.
	No water in the flowcell or polluted flowcell.	Check flowcell. Flush the flowcell.
	Too much light.	No filter or defect filter. Check the filter wheel. Contact your service technician.
006 Temp. hardware failure.	Loose or wrongly connected connectors from the Peltier elements or temperature sensor. Defective Peltier element or temperature sensor.	Contact you service technician.
007 Temp. too high.	Ambient temperature is too high, >35° C or fan does not run. Defective Peltier element or temperature sensor	Check fan. Contact your service technician.
008 Temp. too low	Defective Peltier element or temperature sensor.	Contact you service technician.

11.2.2 Warning messages

Warning messages normally indicate a temporary communication problem, or a false entry. These messages show at the top of the screen. Press the softkey BACK to clear the message and make a valid entry in the test program. The following is a list of warning messages due to communication problems. If the solution can not be found, contact you service technician.

Message	Cause	Solution
Ext. Printer not online	The external printer is disconnected or not switched on.	Check the external printer to make sure it is on.
Ext. Printing error	An external problem with the printer.	Check the external printer and connections.
Int. Printer not online	The internal printer is not set as the default printer or a connection is not made.	Check the software settings for the printer in the analyzer.

Message	Cause	Solution
Int. Printing error	Problem with the internal printer.	Check the software settings. Contact your service technician.
Host connection lost.	The physical connection to the host is lost.	Check the RS 232 connection in the back of the analyzer and the host computer.
Ext.Keyboard error.	Problem with the keyboard or with the connection to the keyboard.	Check the connection to the keyboard, check the software settings, check the keyboard. Replace the keyboard.

11.2.3 Data flags

The following flags can occur after measurement.

Flag	Cause	Solution
H	The result is greater than high reference concentration limit set in the test parameters.	Check the REF-HIGH limit in the `PROGRAM TEST LIMITS` menu.
L	The result is less than the low reference concentration limit set in the test parameters.	Check the REF-LOW limit in the `PROGRAM TEST LIMITS` menu.
A	The absorbance is outside the high or low absorbance levels set in the test parameters.	Check the L-ABS and H-ABS limits in the `PROGRAM TEST LIMITS` menu.
nl	The non linearity is greater than the limits set in the test parameters	Check the NON-LIN in the `PROGRAM TEST SETTINGS` menu.
>	The control result is above the high concentration limit set in the quality control.	Check the H limit set in the `QUALITY CONTROL` menu.
<	The control result is below the low concentration limit set in the quality control.	Check the L limit set in the `QUALITY CONTROL` menu.
D	The deviation between replicates exceeds the limit set in the test parameters.	Check the deviation parameter set in the `PROGRAM TEST GENERAL` menu.
S	The stabilization of the analyzer is not complete. The analyzer needs about 30 minutes to warm up. If the stabilization period is not complete, all results will show a flag. Once skipped, all results show the S-flag until the analyzer is reset.	Switch off the analyzer, wait for ten seconds, switch the analyzer on and wait for the analyzer to stabilize.

Flag	Cause	Solution
R	• Absorbance could not be calculated: - Outside linear range of the photometer. - Measurement under range. • Concentration could not be calculated: - Concentration outside fixed concentration limits -99999 and 999999. - Measurement outside calibration values of multipoint calibration. When this occurs, an addition L or H flag is appended to indicate if the concentration is Low or High. So this takes into account if the curve is increasing or decreasing.	Go through the check list: 11.1.1 Sample and reagent problems.
T	The temperature is out of range.	Wait for a few minutes for the flag to disappear. If the flag does not disappear, switch the analyzer off and reset the analyzer. If the problem is still present, contact you service technician.

11.2.4 Physical problems

The following are problems due to physical conditions.

Problem	Cause	Solution
No sample aspiration. The analyzer does not aspirate, the prime LED shows normal operation, the pump works normally.	Insufficient cleaning or a polluted sample is used.	Check all tubes and flowcell for obstruction. Contact you service technician.
Insufficient sample aspiration.	The fluid system leaks. Air is aspirated instead of fluid. Unstable display readings is an indication.	Check all tubes and flowcell.
	The waste bottle is too high or too low relative to the analyzer.	Place the bottle no more than 0.5 m above or below the analyzer.
	The bottle is removed from the sample tube before the analyzer has given the audible signal.	Remove the sample only when the audible signal is given.
No result. The message "Measurement under range" shows.	The blank test is not made correctly.	Repeat the blank test procedure. Check the flowcell. Check the test parameters.

Problem	Cause	Solution
Drop out of measurements.	Air bubbles in the flow cell as a results of pollution in the system.	Do the end of day maintenance procedure. Flush through with methanol.
	Air bubbles in the flowcell due to leakage of the fluid system.	Check all tube connections of the fluid system especially those before the flowcell.
	Air bubbles in the flowcell due to the sample/reagent mixture is too cold. An increase of the vacuum inside the fluid system. Spontaneous formation of bubbles.	Add 0.1% neutral detergent to the reagent.
Poor reproducibility. Measurement results are not reproducible. Variation between measurements is too high.	Leakage of the sipper tube.	Check the connection of the sipper tube.
	Programmed sipper volume is too high.	Check the sipper volume.
	Air bubbles in the flowcell.	Do the end of day maintenance procedure. Flush through with methanol. Check the tube connections.
	The reagents are not stable. Pollution in the reagents.	Use fresh reagents.
Results too low. The values of the controls are too low.	Kinetic test. The delay before the kinetic test is too short.	Check the delay time in the test parameters.
	Measurements temperature is too low.	Contact you service technician.
Results too high.	The product of (factor x ΔAbs) is too great. R-Flag may also show.	Check the factor. Make sure calibration is correct. Check standard values in the test parameters.
	The absorbance value of the reagent/sample mixture is out of linear range. R-Flag may also show.	Use fresh reagent or dilute the sample.

Appendix

A.1 External keyboard

An external keyboard can be used instead of or in conjunction with the integrated keyboard. The advantages of using an external keyboard are as follows:

- All the keys of a normal keyboard are available including the special characters %,$,@ etc.
- Small letters as well as capital letters are available.
- Data entry is easier.

A.1.1 Install an external keyboard

1. Connect the PS/2 male connector of the keyboard to the PS/2 Keyboard connector in the back panel of the analyzer.
2. Switch on the analyzer.
3. Select PROGRAM from the MAIN MENU.
   Use the cursor keys to select program and press enter or press the corresponding number key.
4. Select system settings.
5. Type your password.
6. Make sure HARDWARE is selected and press ENTER. The cursor moves to the EXT KEYB field.
7. Use the UP and DOWN arrows to select the type of external keyboard that is used with the system. If no external keyboard is installed, select DISABLE. Press ENTER. The cursor moves to the EXT PRINTER field.
8. Press the soft key MAIN or BACK to leave the system settings.
9. Press the softkey SHUTDOWN to exit the analyzer.
10. Set the analyzer to OFF.
11. Set the analyzer to ON. The external keyboard is now active. When you attach the keyboard for the first time, and you press the spacebar, the analyzer will give recognition by emitting three audible signals.

A.1.2 Exceptions to the external keyboard keys.

All keys work as on a normal PC-keyboard. The shift key switches between small letters and capital letters., enter confirms selections and enteries. The following are important exceptions:

Key	Function
PgUp	Sets the screen contrast. PGUP corresponds to the + key on the internal keyboard. To use the PgUp function in a list, press the spacebar once. This function will remain active until you press the spacebar again.
PgDn	Sets the screen contrast. PGDN corresponds to the - key on the internal keyboard. To use the PGDN function in a list, press the SPACEBAR once. This function will remain active until you press the spacebar again.
F1 to F6	Corresponds to the six softkeys on the integrated keyboard from left to right.
F7	The hard key FLUSH on the integrated keyboard.
F8	The hard key PRIME on the integrated keyboard.
F9	The hard key MEAS on the integrated keyboard.
F10	The hard key PAPER on the integrated keyboard.
F11	No function
F12	The sipper button to start aspiration.

Note

For a detailed explanation of the system components and the integrated keyboard, refer to chapter 4 System description.

A.2 Order information

The following consumables and spare parts are available from your distributor.

Item	Order No.
Fuse glass 1.6 A slow blow for 250 V	3348-175
Quartz-iodine lamp 12 V / 20 W	3380-018