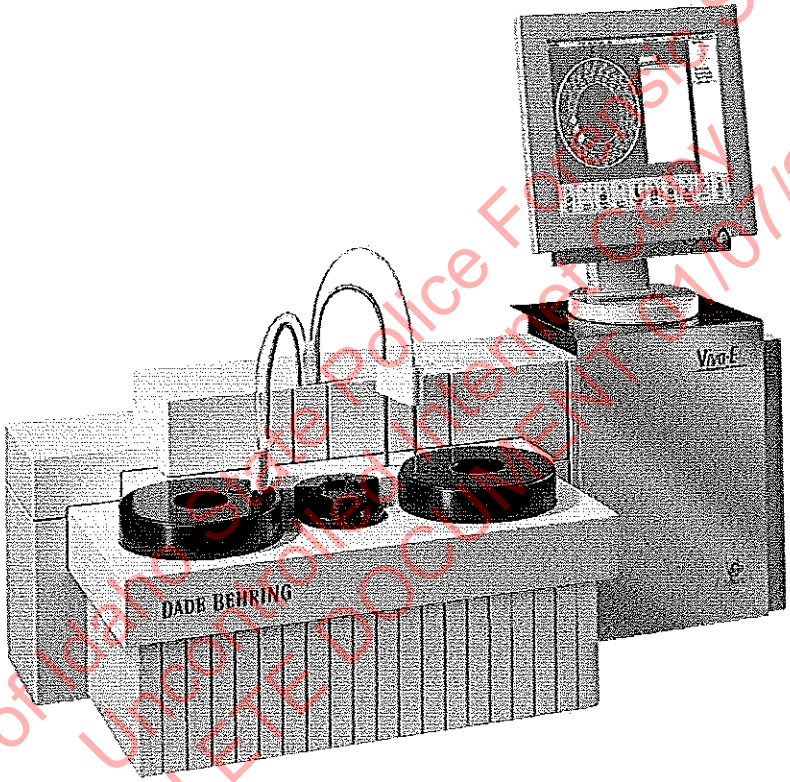
Operator's Manual



Viva·E™

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This manual tested with OS software 1.0

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.

This manual was written and produced with the utmost care. However, errors cannot be fully excluded. Vital Scientific do not take any responsibilities and accepts no liabilities for incidents of any kind that may occur because of errors in the manual.
All product names are mentioned in this manual are registered trademarks. The manual describes the analyzer system Viva E and the software version 1.0.
The Viva E has been conceptualized, manufactured and tested in accordance with the declaration of conformity. This declaration is supplied with each device in a separate file.
Please call Technical Support if you need advice or you have any questions.

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Contents.

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.

Disclaimer

The manufacturer does not recommend any specific reagent kit or reagent supplier to be used in combination with this analyzing system. This instrument is designed as a 'open' system allowing for a wide range of clinical chemistry tests to be adapted to the system. As results obtained from a clinical chemistry system may vary depending upon the specific characteristics of the reagent kit involved, the test parameters for each test (and each reagent supplier), needs to be established by appropriate methods, before the system is used for actual measurements of patient samples. The manufacturer assumes no responsibility for erroneous test results caused neither by the reagents and/or calibrators nor for inadequate use and determination of test parameters.

1.1.1 Basic assumptions for risk analysis

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

- The patient 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 sera.
- 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 involved in preventive and corrective maintenance of the device are aware of the risks involved (biological hazards) and that proper precautions are taken to prevent infection.
- 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 patient samples are measured.
- Installation and checking of the device is performed in accordance with the instructions provided.
- Limit checks are correctly implemented and used in the test parameter settings. (absorbance, reagent blank absorbance, control, calibrator, etc.).
- A rotor blank run is performed once every day before measurements are performed.

- 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 User's manual and the special operations as described in the Service manual.

1.2 Description of symbols

1.2.1 Symbols on the instrument

WARNING
This symbol means that the labelled item is hot while the instrument is in use. Don't touch the labelled item as you could be burnt!

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

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 authorised personnel, for example, service technicians, may open the instrument to perform maintenance or repair.
Touching the live parts when the power is on may cause severe injury or death.

1.3.2 Mechanical hazards

WARNING
DO NOT wear loose garments or jewellery 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 Sample and Reagent arms

WARNING
Do not touch movable parts of the system (rotors, arms, etc.) while they are in motion.
Particular attention and caution must be paid to sample and reagent needles. Although the greatest possible safety precautions were taken, these parts still are potentially hazardous. However, the system automatically interrupts the procedure if the needles are touched. Always keep rotors covered with the supplied caps, except when loading or unloading. Covering protects sample material and reagents from contamination.

1.3.4 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 6.1.6 Replace the Photometer Lamp in this manual.

1.3.5 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.

1.3.6 Biohazard

WARNING

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 spilt 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.

1.4 Installation

The analyzer, cooling unit and other devices, 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 chapter 2.6 Performance and technical data.

1.4.1 External connections

ATTENTION
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 cuvette rotor, 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 all mechanisms, i.e. sample needle, 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.

1.4.3 Instrument unused for a long time

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

1.4.4 Coolant liquid

The cooling unit of the analyzer is filled with ethylene glycol. Any spills during maintenance should be disposed of according to local regulations.

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 does not recommend the use of specific reagents or calibrators in combinations with this analyzer. Several reagent manufacturers have application sheets 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, calibrators and /or test parameters that are not provided 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 an expert, before any 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.

Introduction

2.1 The system

2.1.1 Intended use

The analyzer is an automatic chemistry analyzer, 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 to medium quantity. The analyzer has to be operated by trained professionals.

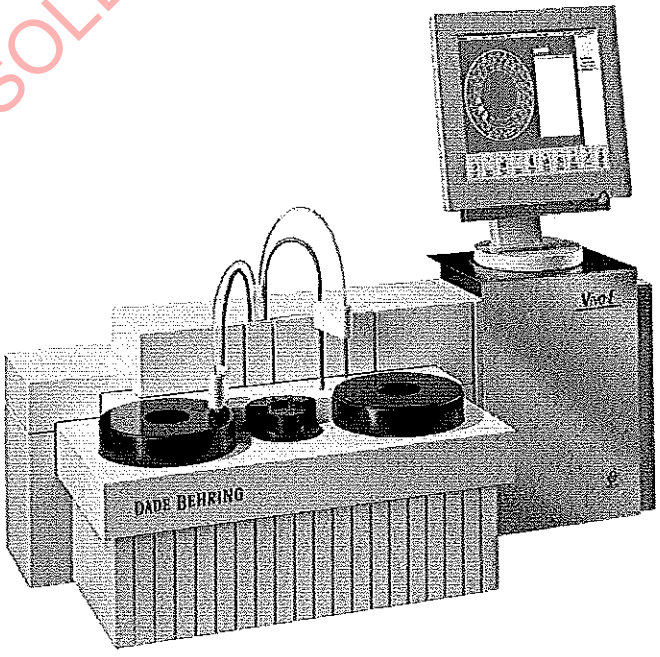
Disclaimer

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 NCCLS[2] guidelines] before the system is used for actual measurements of patient samples. The manuufacturer is not responsible for erroneous test results caused by reagent kits, calibration and controls and incorrect test parameters.

1 ECCLS = European Committee for Clinical Laboratory Standard
2 NCCLS = National Committee for Clinical Laboratory Standards (USA)

2.1.2 System presentation

The analyzer is a universal system. The price-performance-relation is optimized for small and medium workload; up to 180 tests per hour. It is easy to adapt the analyzer in any kind of laboratory. In the main unit of the system, the actual analyzer, all liquid handling and measurements take place. A separate computer controls the analyzer unit, collects the raw data and provides the user interface. A cooling unit enables the system to ensure the precision of all ´on-board´ parameters. Environmental compatibility and economic efficiency are guaranteed. Easy operation (menu and message control by display), short training time as well as recording of sample and test data with barcode scanner reduce personnel assignment and save a maximum of time.



2.1.3 Computer control

ATTENTION
Only run the software in order to operate the analyzer. The use of other software might cause failure in the communication between the analyzer and the computer.

An external computer provides the user interface for the analyzer. The software is MicroSoft ™ Windows based. A keyboard or a barcode reader is necessary to enter data. The test results are saved on the computer. The software provides a standard way of output on a printer, but the operator can change the format of the result report. Test parameters, control results and calibration results are also saved on the computer and are ready for access.
It is possible to connect the analyzer to a lab data processing system (central processor/host computer). If so, it is possible to enter test requests directly from the host computer. Also the test results can be transferred to the host computer. Please refer to 2.6 Performance and technical data for the minimum requirements for the computer.

2.2 Modules

2.2.1 General

Note
In the screen texts system liquid is replaced by water.

The analyzer is microprocessor controlled. All mechanical functions are driven and checked by slave-processors. The operator has a constant view on the hardware status and performance of the chemistries. When errors or flagged results occur, the analyzer offers an automatic re-run facility. The re-run facility includes automatic pre-dilution by sample reduction for high results. The results are patient-oriented printed in the analysis sequence. The print is held when a test is in evaluation or re-run. This prevents mixing-up the analysis sequence. The operator can change the format of the result report. Prints of calibration curves, reaction curves, Levey-Jennings plots, test methods, etc. are possible.

2.2.2 Rotors

Sample rotor
Replace highlighted with the sentence: The sample rotor is designed to accept a variety of sample tubes and cups (refer to sections 2.6.2 Sample system, 3.2.8 Set the Run Mode and 5.2.6 Delete the assignment between a control and a test).
The sample rotor is covered.
Emergency and pediatric samples can be tested without interference of the routine workload.

Reagent rotor
The reagent rotor compartment is cooled to approximately 12°C below ambient temperature. The rotor is covered to protect light sensitive reagents and to isolate from ambient temperature.

Note
For optimum cooling and to avoid waste of energy, cover unused positions during a test with caps. The caps also prevent evaporation of the reagents.

Cuvette rotor

Note
Replace the cuvette rotor when one of the eight wavelengths shows the message SD.ERR after the rotor blank measurement. The quality and reliability is not guaranteed when the cuvette rotor is not replaced.

The multi-use cuvette rotor contains 48 cuvettes, incubated at 37°C. The path length is 6.8 mm, the minimum measuring volume is 220 µl and the maximum volume is 400 µl. The cuvette rotor, special made for the manufacturer, is covered by a heated cover.
The cycle-time in the mono-reagent mode is 20 seconds, in which the analyzer can do up to 180 tests/hour. The cycle-time in the dual-reagent mode is 27 seconds, in which the analyzer can do up to 133 tests/hour.
The cuvette rotor makes in the mono mode a complete revolution plus one extra step every 20 seconds. The analyzer can measure 22 kinetic points, an endpoint and a reagent blank at any of the 8 available wavelengths during a revolution.
The rotor makes in the dual mode a complete revolution plus one extra step in 27 seconds. The analyzer can measure 21 kinetic points, an endpoint and a reagent blank at any of the 8 available wavelengths during one revolution.

In both modes, the measurement of the endpoint methods can be bichromatic. The absorbance values are corrected for a path length of one cm.
The maximum incubation time after sample addition is 11.5 minutes in mono mode and 11.25 minutes in dual mode. The first kinetic point in the mono mode can be measured after 12 seconds, the last after 422 seconds. In the dual mode the first kinetic point can be measured after 24 seconds, the last after 519 seconds. After the last measurement, the rotor is washed and dried. To avoid drying-in of the rotor, the reagent pipette automatically fills the rotor with water.

Washing unit
The washing unit aspirates the reaction mixture after analysis and washes the cuvettes with 4 x 500 µl water. The waste is disposed in a waste container. Separated waste, concentrated and diluted in two containers, is available, but must be specified on order. The washing unit is equipped with liquid sensors to avoid the flooding of the system with water.

2.2.3 Pipette system

Pipettes
Two syringes, a 1000 µl and a 100 µl, are used in combination with a valve block to pipette reagents and samples. The pipette mechanisms are water-filled. Pipetting takes place by means of positive water displacement with air bubble separation.

Sample pipette mechanism
The sample probe, equipped with a level detector, aspirates volumes between 1µl and 30 µl (in steps of 0.1 µl). The level detector in the sample probe detects if sufficient sample is present. The probe dispenses the sample into the cuvette rotor and also mixes the reaction mixture. When a sample is needed, the probe senses the liquid to take up an air bubble first before taking up the sample. The probe is washed in- and outside afterwards.

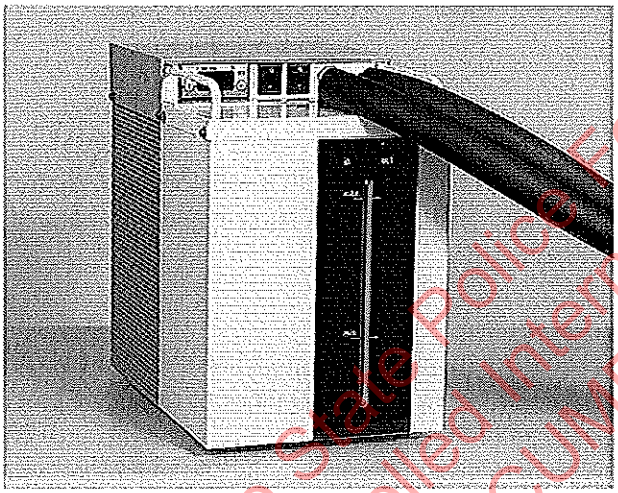
Reagent pipette mechanism
The reagent probe, equipped with a level detector, aspirates volumes between 10 µl and 400 µl (in steps of 1.0 µl). The level detector in the reagent probe detects if sufficient reagent is present. A heating element in the probe pre-heats the cooled reagents. Reagents must be prepared outside the analyzer. After the probe transferred the aspirated volume of reagent into the cuvette rotor, the probe is washed in- and outside. After a 2nd or 3rd reagent is dispensed, the reagent probe mixes the reaction mixture before it goes to the wash.

2.3 Cooling unit

WARNING

The cooling unit with the analyzer is filled with ethylene glycol. Any spills during maintenance should be disposed of according to local regulations.

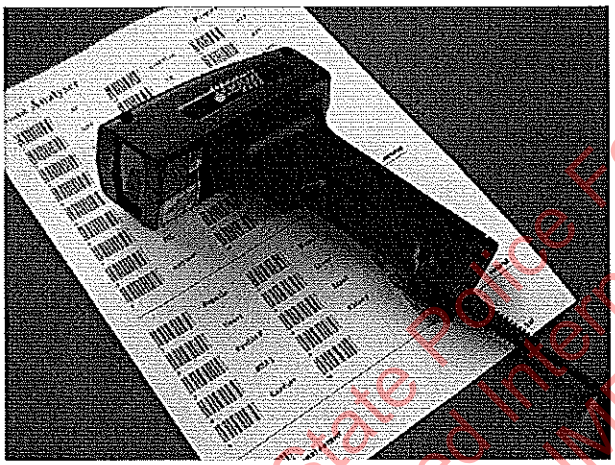
The analyzer is equipped with an external cooling unit. The cooling unit provides a constant temperature for the reagents located on the rotor, keeping them fresh (as required by the application protocol). When an acoustic signal sounds, the cooling liquid must be refilled. The control display shows the temperature of the cooling liquid. The actual temperature of the reagents will be slightly higher. The user cannot change the temperature setting of the cooling unit.



2.4 Barcode reader

ATTENTION
Switch off the computer before you install the barcode reader.

A barcode reader, as an optional extra, can be connected to the keyboard of the external PC. The reader is used for test requisition and randomized loading of the samples. Most of the available barcodes can be read. The Codabar barcode is used for test requisitions. The Codabar start character is used to differentiate between tests and profiles. The barcode reader has a separate instruction manual. Please refer to the barcode reader manual for information and user instruction.



2.5 Installation

2.5.1 Installation requirements

Only a qualified service technician may unpack the analyzer, cooling unit and other devices. The manufacturer does not take responsibility for damage or improper operation of the analyzer, when these instructions are not observed. The analyzer is inspected and ready for use when it is handed over to the user.

Use the analyzer in closed rooms. It must be placed on a flat, horizontal surface that is not subject to vibrations. Avoid exposure to direct sunlight.

The electrical connection has to be grounded according to common regulations to ensure proper operation of the analyzer.

The analyzer is compliant with the requirements of the applicable EMC standards. Electronic equipment that exceed the radiation limits defined in the EMC standards, like GSM and other handheld mobile equipment, may affect proper operation of the equipment.

Note

This is a class A product. This product may cause interference in a domestic environment. In this case the user may be required to take adequate arrangements.

2.5.2 Move the analyzer

Please follow the instructions below when the instrument needs to be moved.

1. Switch off the analyzer, the computer and the cooling unit.
2. Disconnect all cables and tubes.
3. Remove the door of the syringe compartment by lifting it when fully opened.
4. Pull up the arms and place the arm protection tubes over the shafts. The arms are prevented from going down.
5. Move the analyzer with at least 2 persons. Hold the instrument only by the metal frame on the bottom.
6. Connect all cables and tubes again when the analyzer is in place.

2.6 Performance and technical data

2.6.1 Performance

Maximum throughput	MONO MODE: 180 tests per hour
	DUAL MODE: 133 test per hour
Accuracy	Refer to 2.6.8 Accuracy and precision
Precision	Refer to 2.6.8 Accuracy and precision
Programmable tests	120 per programmed reagent disc
Quality control	3 per parameter, 15 controls programmable per reagent disc
Sample processing	Patient oriented

2.6.2 Sample system

Sample positions	51 patient samples
Emergency samples	3 positions
Calibrators	9 positions plus max. 51 patient sample positions
Pediatric samples	5 positions
ISE position	1
Blank position	1
Controls	4 positions plus max. 51 patient sample positions
Rinsing position	1
Sample tubes	primary/secondary tubes
	Diameter: 13 mm
	Height: max. 78 mm
Sample needle	with level detector and integrated mixer
Pipetting capacity	1-30 µl (steps of 0.1 µl)
Syringe	100 µl
Adapter	6 (pediatric, sample rotor)

2.6.3 Reagent system

Reagent rotor (classic)	32 positions: 24 × 25 ml, 8 × 5 ml (10 x 25 ml positions can be used for 5 x 50 ml)
Reagent rotor (Emit)	26 positions: 13 x 14 ml, 13 x 28 ml bottles
Volume/test	Reagent 1: 110 – 399 µl, reagent 2: 10 – 180 µl, reagent 3: 10 – 180 µl
Cooling	Up to 12 °C below ambient temperature
Needle	Pre-heated, with level detector
Pipetting capacity	400 µl (steps of 1 µl)

Syringe	1000 µl
Adapters (classic)	8 for 5 ml bottle in 25 ml position
Adaptors (Emit)	10 in total: 5 for 6 ml bottle, 5 for 3 ml bottle

2.6.4 Measurement Station

Cuvette rotor	Multi use disposable rotor with 48 cuvettes
Path length	6.8 mm
Minimum volume	220 µl
Maximum volume	400 µl
Wash station	fully automatic with overflow-level detector
Cuvette rinsing	4 × 500 µl system liquid
Light source	Halogen lamp 12V 20W
Wavelength	340, 415, 505, 546, 570, 600, 660 and 700 nm
Wavelength uncertainty	+/- 2 nm
Spectral half-width value	10 +/- 2 nm
Measuring range	-0.1 to 3.0 Abs.
Temperature	37 °C ± 0.2 °C
Cycle time	20 sec. (MONO MODE)
	27 sec. (DUAL MODE)

2.6.5 Minimum PC Requirements

CPU	Intel Pentium 800 MHz
RAM	128 MB
Monitor	VGA Monitor 1024 x 768 pixel
Hard Disk	2 GB
Floppy Disk drive	3.5" (1.44 MB)
Additional drive	CD-ROM drive
Operating system	Windows 2000
Serial ports	1 for analyzer
Serial ports	Optional for printer or host
USB Ports	Optional for printer or host
Parallel Ports	Optional for printer

2.6.6 Cooling unit

Weight (empty)	19.6 kg
Weight (filled)	approx. 23 kg

Required space	84 cm²
Dimensions (cm)	24W × 37H × 35L
Coolant	3.5 l, glycol-based
System	Closed circulation
Connection	Mains connector
Power consumption	340 VA max.
At operating voltage	110 or 230 VAC (device-dependent)
Line frequency	50/60 Hz

2.6.7 Barcode reader

Version	Hand device
Technology	CCD
Barcodes	UPC-A +2, +5
	UPC-E +2, +5
	EAN-13 +2, +5
	EAN-8 +2, +5
	Code 39
	Code 93
	Code 128
	Codabar
	Code 2 out of 5
	Code 2 of 5 interleaved
	MSI/Plessey

2.6.8 Accuracy and precision

The chemical performance of clinical chemistry analyzers, in terms of accuracy and precision, depend on the following: the characteristics of the instrument; the measurement techniques and the materials used. Therefore, the chemical performance characteristics of a clinical chemistry analyzer can only be established and postulated in terms of: the analyte; the specific reagent kit and calibrator(s) used; the type and constitution of the specimens involved; etc.
The analyzers are designed as open systems. ´Open´ implies that most clinical chemistry tests and techniques that require photometric measurement, can be adapted on the system. Only the test parameters for a specific test need to be adjusted. The user needs to establish the required test parameter settings to achieve satisfactory results, utilizing appropriate methods. The methods are preferably based on international guidance documents, for example ECCLS or NCCLS guidelines. The manufacturer does not suggest or propose any particular reagents, calibrators and/or controls on their analyzers from a specific manufacturer. Obtain information on the performance characteristics from the selected reagent distributor and/or manufacturer. Various reagent manufacturers have performed performance studies on these series of analyzers in combination with their reagent kits. Therefore, they have application sheets available for various analytes. The

required information usually can be obtained from the reagent package inserts. Please contact your local representative and/or reagent manufacturer for further information on the chemical performance of their reagents on these analyzers.

Disclaimer

The manufacturer assumes no responsibility for erroneous test results caused either by the reagent kits and/or calibrators or for inadequate use and determination of test parameters.

2.7 Analyzer technical data (without washing unit or computer)

2.7.1 Dimensions and weight

Width	115 cm
Depth	56 cm
Height	49 cm
Weight	approx. 85 kg

2.7.2 Power requirements

Line Voltage	110/240 V nominal, tolerance 10%
Line Frequency	50/60 Hz
Power Consumption	320VA
Installation category	II (in accordance with IEC 664)

2.7.3 Environmental requirements

Ambient temperature	15 to 32 °C
Max. relative humidity	85% @ 32 °C
Pollution degree	2 (in accordance with IEC 664)

2.7.4 Approvals

CE

CB

UL

Note
The approvals listed here refer only to the instrument and operator console, not to additional devices (optional cooling). For the approvals for these devices please refer to the corresponding manual.

System Handling Basics

3.1 Work Preparation

Read this chapter carefully before you start to work with the analyzer. Always observe the safety instructions in order to prevent accidents.

Note

In this manual, the dilution ratios are given as parts of the sample to parts of the resultant solution. Thus, a dilution ratio of 1:5 means 1 part of the sample diluted with 4 parts of diluent that results in 5 parts of solution.

3.1.1 Use of the Manual

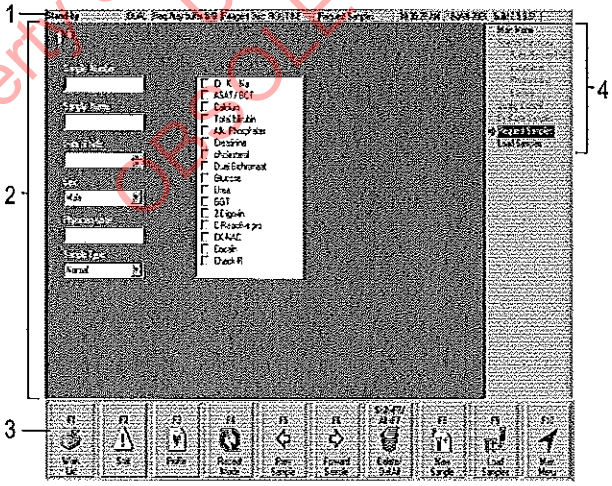
An introduction to each chapter describes the operation of the analyzer. The introduction is followed by a list of parameters and functions available in the menu structure.
The manual gives clear instruction to do the necessary steps.
Example for a function section "Manually request tests and sample data".

Example: Manually request tests and enter sample data

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the SAMPLE ID.
3. If the laboratory needs personal patient information, type the name of the patient in the SAMPLE NAME field and enter the DATE OF BIRTH. This data is printed on each result report. To change the date format go to the SYSTEM PARAMETERS menu.
4. Enter the other parameters, if required.
   Or: Press TAB to go directly to the test selection area.
5. Select the required tests.
6. Select F8 NEW SAMPLES to store the request.
   An empty screen is shown for adding the next request.

The number of requests waiting for analysis in the request buffer is shown at the top of the screen (REQ./TRAY BUFFER:). You can now select the SAMPLE HANDLING menu.

3.1.2 Parts of the screen



1. Status line
2. Input and output area with functions
3. Function keys F1 to F10
4. Menu Tree

Status line

The status line shows following information:

- Status of the analyzer, e.g. STAND-BY.
- Run Mode: MONO MODE or DUAL MODE.
- Request Buffer: information about the number of samples that is requested but not yet loaded.
- Tray Buffer: information about the current number of sample tubes loaded into the analyzer.
- Reagent disc: name of the selected reagent disc.
- Display mode: the menu in which you are currently working, e.g. MAIN MENU.
- Time and Date.
- The state of the external interface (RS 232), e.g. ON-LINE.

Input and output area with functions

To input data and to select the functions and menus use the keyboard or mouse. To read bar-coded samples and to request tests from the request chart, use the barcode reader.

Function Keys

Information of the specific function of the function keys is on constant display on the monitor.
All displays have a common structure with the Function Keys at the bottom of the monitor. You can press the function keys on the keyboard, or you can click on the button with the mouse.

3.1.3 Keys

ARROW KEYS	Go to another field
TAB	Switch between left and right fields
PAGE UP/DOWN, HOME, END	Scroll through a list
ENTER	Confirm entry
F1 - F10	Function keys
ALT+F10	Emergency halt
SPACEBAR	Select or deselect a checkbox

3.1.4 Emergency stop

To stop the analyzer

1. To stop the whole analyzer or operation routine, press ALT+F10 simultaneously.
2. The analyzer goes to the inactive state and all in-process measurements are lost.
3. You can repeat these measurements once the analyzer is reset.

To reset the analyzer

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F1 ROTOR/SYSTEM/ISE.
3. Select RESET SYSTEM and press ENTER.
4. Select F1 RESET SYSTEM to reset the analyzer.

3.1.5 Messages

If an error occurs in the analyzer or the operation routine, the analyzer displays an error message on the monitor. The message gives information about the error and, where possible, instructions how to solve it. The message is accompanied by an acoustic signal. To turn off the acoustic signal press the spacebar.

Example:

E12 WATER RUNNING OUT shows when the analyzer liquid is low. You must fill the water container. The analyzer will continue the interrupted operation without further consequences. Refer to the messages in 6.2.7 Hardware-error messages.

3.2 Start the analyzer for the first time

WARNING
Do not install the analyzer yourself.
The analyzer must be installed by trained personnel.

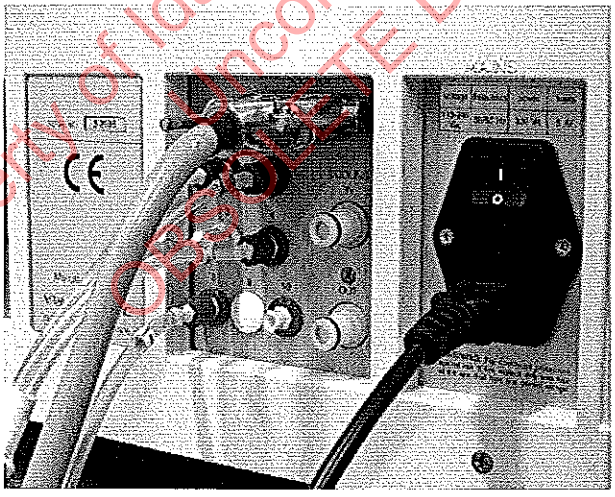
After installation and before you can use the analyzer in normal routine operation, several system adjustments must be made.

3.2.1 Prepare the analyzer

Do following operations in this sequence:

1. Install PC and analyzer software. Refer to 7.2.2 Prepare PC.
2. Start the analyzer. Refer to 3.2.2 Start the analyzer.
3. Connect the cooling unit. Refer to 3.2.3 Install the Cooling Unit.
4. Install the passwords. Refer to 3.2.5 Define passwords.
5. Set the reagent rotor type. Refer to 3.2.4 Set the reagent rotor type.
6. Fill the system with system liquid. Refer to 3.2.6 Fill/Remove System Liquid.
7. Set up the system parameters. Refer to 3.2.7 Set the System Parameters.
8. Set the system run mode. Refer to 3.2.8 Set the Run Mode
9. Program the calibrators. Refer to 5.1 Program Calibrators.
10. Load or program the test parameters. Refer to 5.3 Program Test.
11. Program the controls. Refer to 5.4 Quality Control.
12. Define the incompatible tests. Refer to 5.5 Needle/Cuvette Incompatibility.
13. Program the profiles. Refer to 5.6 Profiles.
14. Position the reagents. Refer to 5.7 Reagent Position.

3.2.2 Start the analyzer



1. Set the main switch to ON, located on the rear panel of the analyzer.
2. Set the PC to ON.
3. Start the analyzer software. The MAIN MENU appears on the monitor. When the analyzer remains on, but is not active carrying out processes, the analyzer goes to STAND-BY MODE.
   The analyzer is now ready for operation.

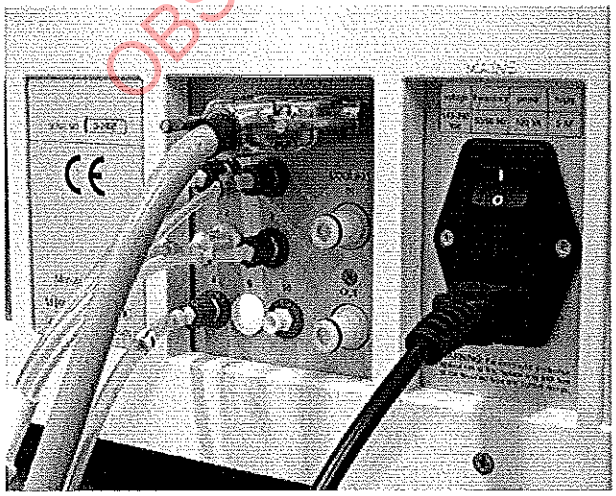
The manufacturer recommends that the analyzer and the user software is switched on at all times. This makes sure that a cuvette blank is done once every day.
Should the analyzer be switched off after the last routine is finished, you must start a manual cuvette blank measurement when you switch on the analyzer again. Refer to 3.2.7 Set the System Parameters for details about the cuvette blank.

3.2.3 Install the Cooling Unit

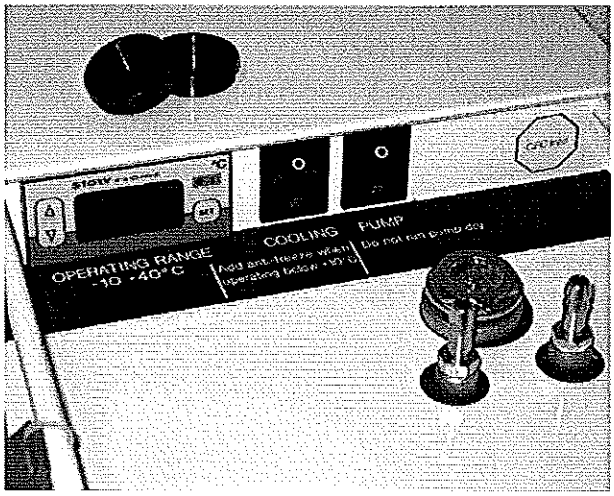
The additional external cooling unit of the analyzer guarantees necessary cooling for loaded reagents. The cooling unit operates with a sealed cycle technology. The cooling unit requires virtually no maintenance. Unit and coolant are free from CFC.

Fill the unit with coolant and demineralized or distilled water before you put the analyzer in operation. Only refill the coolant in large intervals, since the coolant circulates in a closed liquid cycle. Refill the liquid if the LED flashes and/or an acoustic signal is heard.

ATTENTION
Check the cooling unit for the correct voltage before you connect the cooling unit.
Never let the cooling unit pump run dry, because this will damage the pump.



1. Attach the connection tubing to the cooling unit and analyzer as shown in the figure.
2. Install the power cable to the back of the unit. The unit can run with either 110 or 230 V (device-dependent).



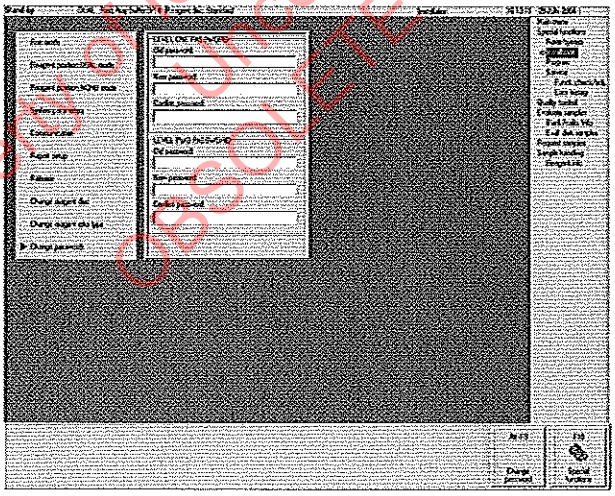
3. Switch on both switches on the front of the cooling unit before you switch on the analyzer.
   Recommendations to ensure a steady cooling of the reagent rotor:
   - Constantly keep the unit in stand-by mode.
   - Cover the unloaded rotor positions with the supplied caps.

3.2.4 Set the reagent rotor type

To use EMIT® tests the reagent rotor type must be set on Emit. This is the default. To use tests from other manufacturers the reagent rotor type must be set on classic. An Emit rotor has 26 positions for reagent bottles a classic rotor has 32 positions.

1. Select F5 SPECIAL FUNCTION from the MAIN MENU.
2. Select F2 INSTALLATION
3. Select CHANGE REAGENT ROTOR TYPE.

3.2.5 Define passwords



A two level password system is used to prevent non-qualified persons altering or deleting important data. The level 1 password is required to enter the following menus:

- F2 INSTALLATION
- F3 PROGRAMMING
- F6 QUALITY CONTROL

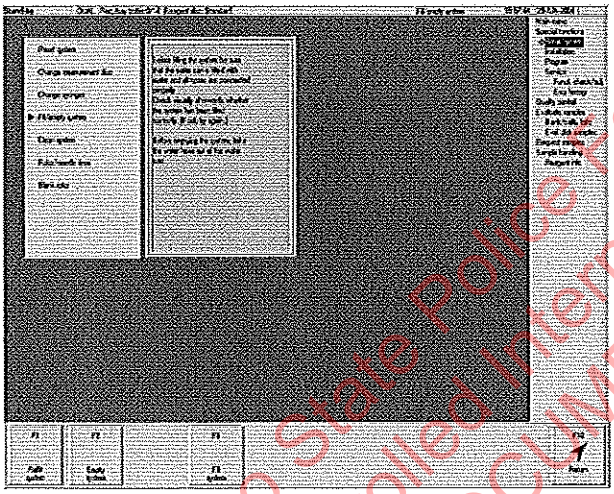
The level 2 password is available to authorized personnel only (Technical Support) to change the test parameters of the "closed channels".

No password is required to request tests, load samples or start the measurement.

To enter a password

1. Select F5 SPECIAL FUNCTION from the MAIN MENU.
2. Select F2 INSTALLATION
3. Select CHANGE PASSWORDS.
4. If you enter a password for the first time, type a password in the NEW PASSWORD and CONFIRM PASSWORD fields.
5. If you change the password, type the old password in the OLD PASSWORD field.
6. Press ALT+F9 CHANGE PASSWORD.

3.2.6 Fill/Remove System Liquid



To prepare the analyzer for operation, make sure the analyzer has system liquid.

Fill System

1. Fill the water container with 25 ml of system solution and 10 l of distilled or de-ionized water. Use water with a conductivity of less than 30 µS and a microbial count of less than 10 CFU/ml. For transport preparation empty the analyzer liquid container and the waste container(s).
2. Select F5 SPECIAL FUNCTION from the MAIN MENU.
3. Select F1 ROTOR SYSTEM.
4. Select FILL/EMPTY SYSTEM.
5. Press F4 FILL SYSTEM, to start filling the analyzer with system liquid.
6. When the filling is complete, make sure that the tubing (e.g. tubing of sample probe or reagent probe) is filled with system liquid without air bubbles.
7. If you detect any air bubbles, press F1 to repeat the software commands.

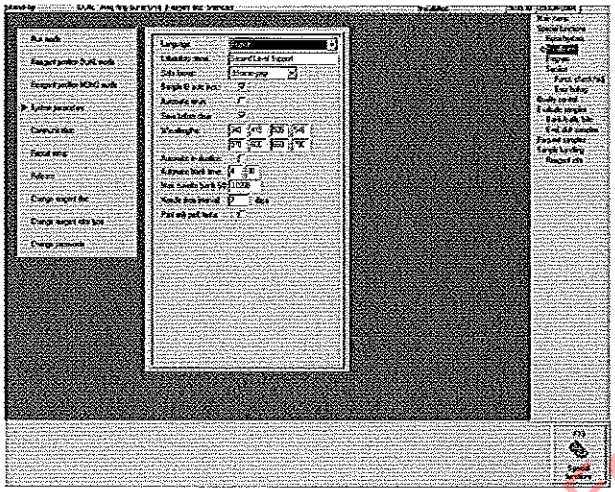
Empty System

Use this menu when you must remove water from the analyzer, e.g. for transport purposes.

1. Remove the system liquid hose from the container.
2. Select F5 SPECIAL FUNCTION from the MAIN MENU.
3. Select F1 ROTOR SYSTEM.
4. Select FILL/EMPTY SYSTEM.
5. Select F2 EMPTY SYSTEM to empty the analyzer for transport.
6. Make sure that there is no system liquid left in the tubing.
7. If necessary, select F2 EMPTY SYSTEM to restart the emptying. The remaining waste must be removed after the procedure has been completed.134*40

3.2.7 Set the System Parameters

Normally enter these parameters once, before the analyzer goes into operation. However you can change the parameters whenever necessary e.g. the date format.



1. Select F5 SPECIAL FUNCTION from the MAIN MENU.
2. Select F2 INSTALLATION. If you set a password, the password dialog box appears.
3. Select SYSTEM PARAMETERS.
4. Enter the system parameters. Use the cursor keys or the mouse to select the following parameters. Enter the value and confirm with ENTER.

Parameters

LANGUAGE	Select the language.
LAB. NAME	Type the name of the laboratory. The field is 32 characters in size. The name is shown on every result printout.
DATE FORMAT	Select the date format. The date is shown on the monitor and on every printout: DD-MMM-YYYY e.g. 13-JUN-2000 MMM-DD-YYYY e.g. JUN-13-2000 DD-MM-YYYY e.g. 13-06-2000 MM-DD-YYYY e.g. 06-13-2000
SAMPLE ID. AUTO INCR.	☒ Select the sample counter to automatically increase the sample number in the REQUEST SAMPLES menu, when patient samples are recorded. Alphanumeric data is always counted up. The analyzer counts the sequence e.g. from Az99 up to Ba00.
AUTOMATIC RERUN	☒ Select the automatic rerun to automatically schedule a test with the rerun parameters of the respective test when the defined limits are exceeded. The rerun applies to the following cases: • Linearity error • Absorbance limit error • Reagent deviation error • Substrate depletion error • Prozone error • Concentrated error limit The rerun is done with the defined rerun parameters. Limits and volumes of each parameter are set in the PROGRAM TESTS menu.

SAVE BEFORE CLEAR

☒ The analyzer automatically saves the result data on hard disk when the results buffer is cleared.
☐ All result data will be lost and replaced by new data.
You can also manually delete the results buffer with ALT+F2 (CLEAR RESULT BUFFER) in the EVALUATE SAMPLES menu.

Note
Data in the main memory is automatically deleted if the storage capacity is exceeded or when reagents have been positioned on the reagent rotor.

WAVELENGTHS

The eight wavelengths of the interference filters, displayed as nanometer values.
Only change this parameter if new filters have been installed.

AUTOMATIC EVALUATION

☒ The analyzer automatically prints out, and sends to the host if enabled, all results. Invalid results are marked as REJECT.
☐ The analyzer blocks the patient results with one or more error messages, until you accept or reject these results in the EVALUATE SAMPLES menu. The results are then printed out.

AUTOMATIC BLANK TIME

The time (hh:mm) at which the analyzer will do every day an automatic blank measurement of the cuvette rotor. Enter the hours, press ENTER, enter the minutes and press ENTER again.
This measurement is only possible when the analyzer is in stand-by mode. If the analyzer is switched off, you must start this measurement manually each day.
It is recommended to do this measurement before the daily routine.
After the measurement the analyzer prints a list with the following information:

- Blank date/time.
- Blank results.
- Number of days left before you must calibrate the respective method.
- Number of days left before you must do the next needle rinse in the maintenance schedule.
- Number of days left before you must do the next system clean.
- The date of expiry for reagents, controls and calibrators.

If you do not do the cuvette blank measurement, the analyzer can continue to run but the results can be affected and incorrect. In case of an expired calibration, the analyzer will use the last calibration data until a new calibration is executed.

MAX. CUVETTE BLANK SD

The maximum standard deviation tolerated by the analyzer in a blank measurement of the cuvette rotor. The recommended value is 0.0200. If this deviation is exceeded, an error message is printed out together with the rotor blank results.

NEEDLE RINSE INTERVAL

The interval in days, at which you do a needle rinsing.
0: No needle rinsing
1: The rinsing must be done each day
2: The number of days after which rinsing must be done
It is recommended to enter 7 days and to perform the rinsing at the end of the working week. Activate the NEEDLE RINSE function in the ROTOR/SYSTEM menu.

PRINT ONLY PERF. TESTS

Only applicable when using report set-up. It selected, reports the only tests that are requested. All other tests are not printed.

Keys

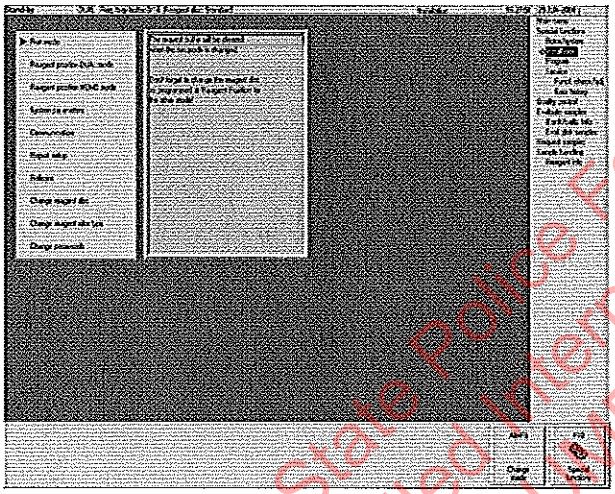
F10 Go to the SPECIAL FUNCTIONS menu.

3.2.8 Set the Run Mode

The analyzer can be set in two modes, mono and dual. In mono mode you can only do single reagent tests, in dual mode you can do both single and multi reagent tests. When only single reagent tests are made, it is better to set the analyzer to mono mode as the throughput is better.

Note

All existing requests are cancelled when you change the run mode. The reagent positions must be defined separately for both modes. Also the result memory is cleared when changing modes.



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALLATION. If you set a password, the password dialog box appears.
3. Select RUN MODE.
4. Press ENTER or TAB.
5. Press ALT+F9 to change the mode.

Keys

ALT+FF9 CHANGE MODE	Toggles between Dual Mode and Mono Mode.
F10 SPECIAL FUNCTIONS	Go to the SPECIAL FUNCTIONS menu.

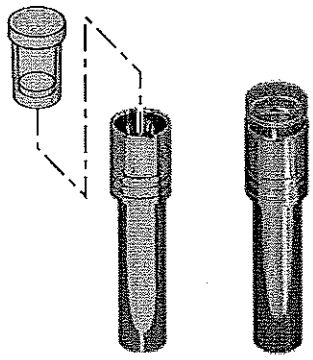
3.2.9 Load pediatric sample cups

The level sensor on an analyzer is based on capacitance. The sample containers must make contact with the rotor base plate.

ATTENTION

Do not use pediatric sample cups without the silver pediatric adapter shown below. Do not use the adapters other than described below.

To make sure the correct function of the liquid level sensor, pediatric cups must be loaded to the sample rotor as follows:



1. Insert the pediatric cup into the silver pediatric adapter.
2. Insert the pediatric adaptor with the pediatric cup into the 13 mm sample rotor.

Note

The 13 mm sample rotor may be loaded with:

- Pediatric cup + pediatric adapter.
- 13 x 75 mm sample tube.

3.3 Checklist

3.3.1 Checklist for Routine Operation

WARNING
Always observe the common safety precautions (rubber gloves, splash-protection).

✓	**Are all cables correctly connected to the System?**	Voltage cables, tubing to cooling unit, communication cables, etc.
✓	**Is the system switched on?**	Analyzer unit, computer and cooling unit: all switches "On".
✓	**Is the cooling unit working correctly?**	Fill the cooling unit correctly with coolant. Install the tubing of the analyzer unit correctly. Regularly check the liquid level visually.
✓	**Are all necessary parameters defined?**	Check the following parameters and settings. • Run Mode • System Parameters • Printer Settings • Host Communications
✓	**Is the liquid system filled with system liquid?**	Fill the liquid system of the analyzer with system liquid, when the system is put into operation for the first time. Use the FILL/EMPTY SYSTEM menu. Check the water container and syringes.
✓	**Are all work helps set as required?**	Increase of sample number, automatic rerun, automatic result evaluation, automatic cuvette rotor blank, profiles.
✓	**Are all necessary test parameters programmed?**	Load or program all parameters that are regularly used by the analyzer Use the TEST PARAMETERS menu. This also applies to new tests that must be added. The programming instructions (e.g. test method, volumes, units etc.) are explained in the method sheets of the reagents.
✓	**Is HCL installed?**	HCL must always be present on the reagent rotor otherwise no measurement is possible.
✓	**Are all reagents correctly positioned?**	Reagent positions on the reagent rotor that are currently used must be programmed in the analyzer. Use the INSTALLATION menu. In order to avoid delays in routine operation, check the volumes of the loaded reagents daily (REAGENT INFO). If the analyzer operates both in the MONO MODE and in the DUAL MODE, the required reagent positions must be programmed separately for both modes (REAGENT POSITION MONO MODE menu and REAGENT POSITION DUAL MODE menu).
✓	**Are all required calibrators defined?**	Program the calibrators to be used by the system in the CALIBRATORS menu.
✓	**Are all required test controls defined?**	Program the controls in the CONTROLS menu.
✓	**Are the incompatible tests defined?**	Certain tests must not be run in succession, since the danger of carry-over is very high. Select the tests not to be run in succession in the TEST INCOMPATIBILITY menu.

✓	**Are the profiles programmed?**	Select the profiles in the PROFILES menu, if you want to use profiles for the recording of patient samples. If the analyzer operates both in the MONO MODE and in the DUAL MODE, the required profiles must be programmed separately for both modes (REAGENT POSITION MONO MODE menu and REAGENT POSITION DUAL MODE menu).
✓	**Has the cuvette rotor blank been done?**	Do a cuvette rotor blank measurement once every day. This measurement is carried out automatically, if the respective settings have been made in the SYSTEM PARAMETERS menu. For this purpose, the system has to be in stand-by mode. Use the BLANK ROTOR menu for a manual start of the analyzer.
✓	**Has the waste container been emptied?**	Empty the waste container and fill the water container before you start the daily work. You avoid the interruption to the routine work. The analyzer stops the operation if the water level is too low or the waste water too high. The analyzer continues again when the required liquids are filled up or emptied.
✓	**Has the formation of foam been avoided during reagent preparation?**	Reagent bottles.
✓	**Has the formation of foam been avoided during sample preparation?**	Sample tubes.

Basic Routine

4.1 Enter sample data and test requests

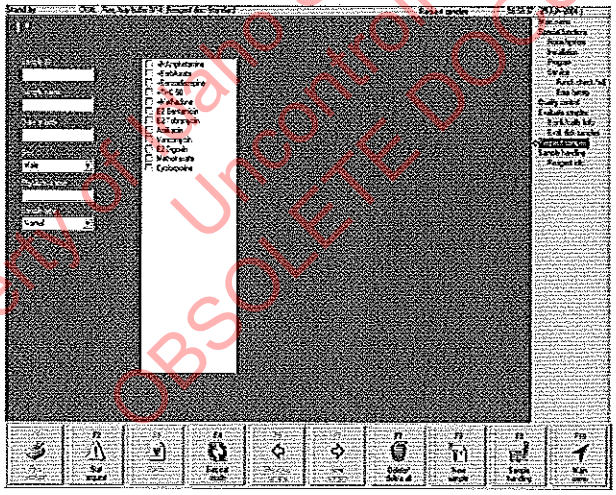
4.1.1 Preparation of sample, dead volume and over sampling

To guarantee accurate and precise addition of sample, more sample is used than programmed. A small volume of extra buffer sample is aspirated before each test and each sample. This buffer sample removes any water that may line the interior wall of the sample probe. The buffer is discarded to the waste after every pipetting step.
In addition to the sampling buffer there is also a safety residue (dead volume) left in the sample cups and secondary tubes that cannot be aspirated because the volume is insufficient for the probe to accurately aspirate the remaining sample. While preparing samples, take this over sampling and dead volume into account to avoid insufficient sample and interruption to the routine.
The following specifies the over sampling and dead volume specifications that are expected when the original tubes and cups are used with this analyzer and when the analyzer is properly adjusted.
Over sampling depends on the programmed sample volume. When:

- Sample volume is 2 - 10 µl: excess volume is 5 µl
- Sample volume is 10 - 20 µl: excess volume is 10 µl
- Sample volume is 20 - 30 µl: excess volume is 15 µl

When using pediatric cups with the prescribed pediatric adaptors, the dead volume in these cups is ~100 µl. Refer to chapter 3.2.9, Load pediatric sample cups.
When using secondary 13 x 75 mm tubes the dead volume in these tubes is ~350 µl.
When using primary tubes no statement can be made about the dead volume because of the residue of blood cells after centrifugation.

4.1.2 Request Samples menu



The REQUEST SAMPLES menu contains the parameters to request (patients) samples, to make a record of patient and sample data and to assign tests to the samples. The record of the patient and sample data is made simply and quickly. Recorded samples can later be edited or deleted. If needed, the operator can print a work list.
You can shorten the operator time with an optional hand held barcode reader. In the REQUEST SAMPLES menu you can make a record of the patient sample ID number and assign test to the sample with the use of the barcode request menu card. In the SAMPLE HANDLING menu you can select and assign the sample ID from the list shown. In the EVALUATE SAMPLES menu, you can use the barcode reader to do a sample ID search and view the graphical data of the sample.

4.1.3 Request Samples Parameters

Parameter	Description
REQUEST NUMBER	A request number is automatically assigned to each sample that is requested. The request number is shown on the top left. The request number indicates the place of the sample in the request buffer. An asterisk indicates a new request that is not saved yet.

Note
To request a calibrator, a control or a blank sample, go directly to SAMPLE TYPE. Use the Arrow Down key or the mouse.

Parameter	Description
SAMPLE ID	Enter the sample ID. Twelve characters are available (letters and numbers). If the checkbox SAMPLE NO. AUTOM. INCR. of the SYSTEM PARAMETERS menu was selected, the analyzer automatically increases the number entered here by one for each following test request. You can also record the sample ID with the barcode on the request form. **If no number is entered for a patient sample the request will not be accepted.** To request a calibrator, a control or a blank sample, go directly to SAMPLE TYPE. Use the Arrow Down key or the mouse.
SAMPLE NAME*	Enter the patient name or any other form of identification for the sample. Maximum length: 20 characters.
DATE OF BIRTH*	Enter the date of birth of the patient. The entry form depends on the definition in the SYSTEM PARAMETERS menu.
SEX	Select the sex of the patient. Use the drop-down list or press M (Male), F (Female) or P (Pediatric). The analyzer uses the specified sex to compare the results to the respective reference values in the TEST PROGRAMMING menu. Usually select Pediatric for samples of children.
PHYSICIAN NAME*	Enter the name of the physician who ordered the sample. The default of PHYSICIAN NAME is the last entered name. Maximum length 20 characters.

Parameter	Description
SAMPLE TYPE	Select the type of sample that is needed: • NORMAL The analyzer automatically positions patient samples on the outer two rings of the sample rotor. The analyzer can process a maximum of 51 patient samples at one time, without having to reload the sample rotor. • STAT Emergency sample. The analyzer has three positions for emergency samples (E1 ... E3). The analyzer positions these samples on the dedicated positions on the sample rotor. The STAT samples have higher priority over all other samples. If more then three emergency samples are requested in the same run, the analyzer positions these samples on the normal samples positions. • PEDIATRIC Samples of children and teenagers. Pediatric samples have the same priority as STAT samples. If you select pediatric in this field, you must place the corresponding sample in one of the positions P1 to P5 after confirmation in the SAMPLE HANDLING menu. When the results must be evaluated against the pediatric reference limits as set in the test program menu, you must select PEDIATRIC at SEX. • CONTROL Requests that are recognized by the analyzer as controls. You can place controls in the positions C1 to C4 and in any position available for patient samples. • CALIBRATE Calibrate tests, as described in the respective method sheets. You can place Calibrators in the positions S1 to S9 and in any position available for patient samples. • BLANK One position on the inner ring of the rotor is reserved for the reagent blank measurement. It is recommended to carry out a daily blank measurement for methods that require a reagent blank. You must place a tube that is filled with distilled water or saline solution at this position.
TEST PANEL	The screen shows a variable number of tests. The number depends on the programming made in the PROGRAM TEST menu. The maximum number of tests is 32. You can program the tests in the TEST PARAMETERS menu. In the REAGENT POSITION menu, you can define the test for the current reagent rotor.

* Optional. It is not necessary to enter data to these fields to process a sample.

Note
Do not use a semi-colon (;) symbol in these fields. Use of the (;) will result in failure to the communication with the host.

4.1.4 Request Samples Keys

Keys	Description
ARROW LEFT/RIGHT	Move inside an entry field from one position to the next.
ARROW UP/DOWN	Move the cursor to the next or previous field.
TAB	Switch between left and right fields.

Keys	Description
ENTER	• Select or deselect a test from the test display. • Moves the cursor from one field to the next.
F1 WORK LIST	Print a list of all data in the request buffer.
F2 STAT	Mark the sample request currently shown on the screen as an emergency sample.
F3 PROFILE	A window with all profiles for the current run mode appears. Select a profile from the list and press ENTER. All tests defined in that profile will be added to the current list of tests. You can program the profiles in the PROGRAM PROFILES menu.
F4 REPEAT MODE	Subsequent requests use the same set of test selections as default as the current one.
F5 PREV SAMPLE	Show the previous request in the request buffer.
F6 FORWARD SAMPLE	Show the next request in the request buffer.
SHIFT+F7 DELETE	Delete the request that is currently shown on the screen. The numbers of the following requests in the request buffer are changed accordingly.
ALT+F7 DELETE ALL	Delete all requests from the request buffer.
F8 NEW SAMPLE	Store the current request in the request buffer and clear the screen for a new request. If you selected the parameter SAMPLE NO. AUTOM. INCR. in the SYSTEM PARAMETERS menu, the sample ID will increase automatically. If F4 REPEAT MODE is on, tests selected at the previous patient will automatically be selected at current request.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu (loading of the sample rotor).

4.1.5 Manually request (patient) samples and assign tests

Note

Always enter a sample ID. The analyzer rejects requests without a sample ID.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the SAMPLE ID.
3. Enter the other parameters, if required. These data are printed on each result report.
   Or, press TAB to go directly to the test panel.
4. Select the required tests.
5. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.

The number of requests waiting for analysis in the request buffer is shown at the top of the screen (REQ./TRAY BUFFER:). You can now select the F9 SAMPLE HANDLING menu.

4.1.6 Request (patient) samples and assign tests with the barcode reader

A barcode reader is the easiest, quickest and safest way to request samples and tests and to load samples. The barcode label encodes the sample ID, so a manual entry of the sample ID is not necessary when you use a barcode reader.
To use the barcode reader, following preconditions must be met:

- The primary tubes or the sample cups must have barcode labels.
- The requested tests must be marked on the request chart that is provided by the manufacturer.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Scan the code on the sample label. The sample ID is shown on the screen.
3. Use the barcode request menu card.
4. Scan the barcodes of the necessary tests from the barcode request menu card. The recorded test requests are highlighted. The checkbox is marked.
5. Scan the field NEXT PATIENT to save the request and to clear the screen for the new request.

Note

The barcode on the request chart is of the type codabar. Do no use the same type codabar for labels on patient samples. The analyzer will not know if you are entering sample data or data from the chart.

4.1.7 Request multiple (patient) samples with the same test selection

Use the repeat mode to request tests for a number of samples with the same test selections.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the SAMPLE ID.
3. Enter the other parameters, if required. These data are printed on each result report.
   Or, press TAB to go directly to the test panel.
4. Manually select the required tests.
5. Select F4 REPEAT MODE.
6. Select F8 NEW SAMPLE to save the request.

Note

If you selected the parameter SAMPLE NO. AUTOM. INCR. in the SYSTEM PARAMETERS menu, the sample ID will increase automatically. If the first sample ID was 001, the next number will be 002. If the last number is A-z-99, the next number will be B-a-00.

7. Enter the other parameters, if required. Select F8 NEW SAMPLE. Every new request that you created with F8 NEW SAMPLE will now have the test selection for that sample.
8. Repeat steps 6 and 7 until all requests are made.
9. Select F4 REPEAT MODE to stop the repeat mode. A new request starts with a test list with no tests selected.

4.1.8 Request a patient sample using a predefined profile

Use the profiles to request a predefined set of tests for a sample. You can define the profiles for the current run mode in the SPECIAL FUNCTIONS menu. Program the profiles in the PROGRAM PROFILES menu.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the SAMPLE ID.
3. Enter the other parameters, if required. These data are printed on each result report.
   Or, press TAB to go directly to the test panel.
4. Select F3 PROFILE to show the list of profiles.
5. Select the desired profile.
   The test list for the current sample will show all the tests that belong to the selected profile.
6. Select additional tests or deselect tests, if necessary.
7. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.

4.1.9 Request multiple patient samples using the same predefined profile

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the sample ID.
3. Select F3 PROFILE to show the list of profiles.
4. Select the desired profile.

5. Select F4 REPEAT MODE.
6. Select F8 NEW SAMPLE to save the request.
7. Enter the other parameters, if required. Select F8 NEW SAMPLE. Every new request that you created with F8 NEW SAMPLE will now have the same profile for that sample.
8. Repeat steps 6 and 7 until all requests are made.
9. Select F4 REPEAT MODE to stop the repeat mode. A new request starts with a test list with no tests selected.

4.1.10 Request STAT (patient) sample with the barcode reader

To use the barcode reader, following preconditions must be met:

- The primary tubes or the sample cups must have barcode labels.
- The requested tests must be marked on the request chart that is provided by the manufacturer.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Scan the code on the sample label. The sample ID is shown on the screen.
3. Use the barcode request menu card.
4. Scan the barcodes of the necessary tests from the barcode request menu card. The recorded test requests are highlighted. The checkbox is marked.
5. Select F2 STAT or STAT from the parameter SAMPLE TYPE to change to STAT.
6. Scan the field NEXT PATIENT to save the request and to clear the screen for the new request.

Note
Place all STAT-samples to the assigned (STAT-) positions.

4.1.11 Request a pediatric sample

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the SAMPLE ID.
3. Select PEDIATRIC at the parameter SEX.

Note
The analyzer requires the entry PEDIATRIC at the parameter SEX for correct result evaluations. Results of this sample type are compared to the reference values in the defined pediatric samples in PROGRAM TESTS.

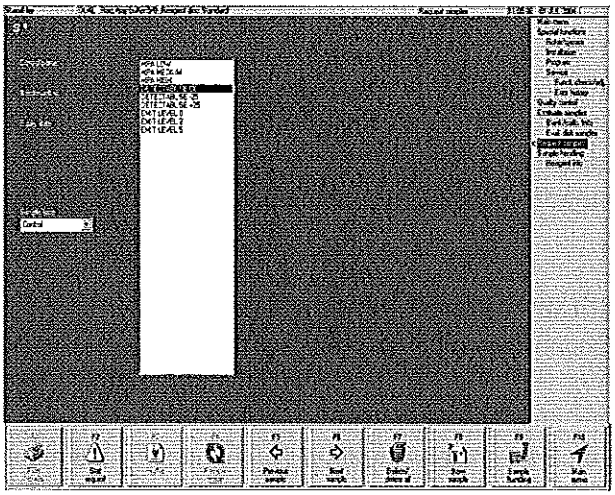
4. Select PEDIATRIC at the parameter SAMPLE TYPE.

Note
When you select PEDIATRIC at the parameter SAMPLE TYPE, the analyzer positions these samples on the dedicated positions on the sample rotor (P1 to P5). The Pediatric and STAT samples have higher priority over all other samples.

5. Enter the other parameters, if required. These data are printed on each result report. Or, press TAB to go directly to the test panel.
6. Select the required tests.
7. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.

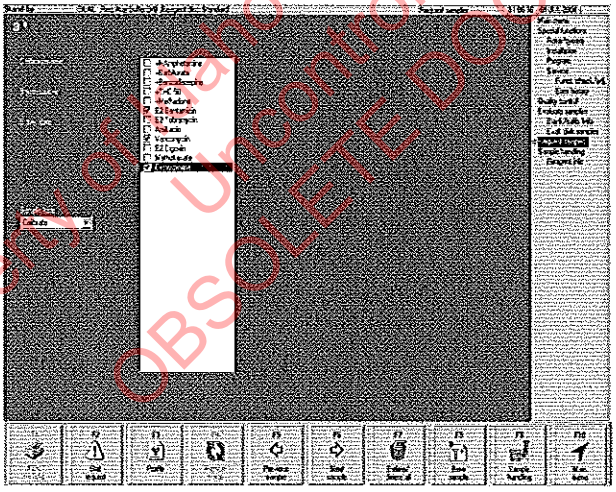
4.1.12 Request a control test

Note
We recommend that you run controls regularly. The frequency depends on the respective method, legislative regulations of each country and the organization of your laboratory.



1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select CONTROL from the parameter SAMPLE TYPE.
   The list of available controls shows. These controls have been defined in the CONTROLS menu.
3. Select the required control.
   The parameter CONTROL NAME shows the name of the control. The BATCH NUMBER shows the lot number. On the right, a list is shown with all tests that can be tested with this control. These tests have been defined in the CONTROLS menu.
4. Select the required tests.
5. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.

4.1.13 Request a test for calibration



1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select CALIBRATE from the parameter SAMPLE TYPE.
   The list of available tests shows. This list contains all tests that are defined in the PROGRAM TEST menu with a calibrator.
3. Select the required tests.

Note

During the selection of the tests, no name is shown at the parameter CALIBRATOR NAME. The analyzer cannot assign the calibrators until the request is completed.

4. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.
5. Select F5 PREV SAMPLE or F6 FORWARD SAMPLE to check which calibrators are allocated to individual tests.
   The name and details of the calibrator for this test shows.
6. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.

4.1.14 Request a test for a reagent blank

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select BLANK from the parameter SAMPLE TYPE.
   The list of available tests shows. This list contains all tests that are defined in the PROGRAM TEST menu with a reagent blank.
3. Select the required tests.
4. Select F8 NEW SAMPLE to save the request and to clear the screen for the new request.

4.1.15 View and Edit a saved request

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select F5 PREV SAMPLE or F6 FORWARD SAMPLE to scroll through and view the list of stored samples and requests.
3. Select the required sample to view or edit the sample.
4. Select F8 NEW SAMPLE to save the changes and close the screen for a new request. Repeat steps 2 and 3 if needed.

4.1.16 Delete a request

You can delete any saved request. A request can only be deleted if it is not started with F3 START MEASUREMENT in the SAMPLE HANDLING menu.

1. Select F8 NEW SAMPLE from the MAIN MENU.
2. Select F5 PREV SAMPLE or F6 FORWARD SAMPLE to scroll through and view the list of stored samples and requests. The position of the actual sample in the request buffer is shown at the top left
3. Select the required sample to delete the request.
4. Select SHIFT+F7 DELETE to delete the selected request or select ALT+F7 DELETE ALL to delete all requests.
   When the request is deleted, all following request numbers are moved up by 1. The screen shows the new request with the current number. If you deleted the last request, the screen jumps to the first request.

4.1.17 Print a work list

```
27-MAR-2001  18:06

WORK LIST
  Number       Name                Tests requested
-------------------------------------------------------------------------
B Blank                           AST  CREA GGTS UREA
S SMT-Calibrator                  CREA UREA
S ISE-Calibrator                  Na   K    Cl
S Cal, Digoxine                   DIGO
C Qualitrol HSN   451             AST  CHOL CREA Na   K    Cl   UREA DIGO
C Qualitrol HSP   452             Na   K    Cl   UREA DIGO
  27032001-003 Eliza Scott        AST  CREA GGTS TBIL UREA
  27032001-004 Peter Oakfield     DIGO
  27032001-005 Randolph Smith     AST  GGTS
  27032001-006 Yvette van Lier    GLUC
  27032001-007 Jean Austin        Na   K    Cl
  27032001-008 Patrick O'Donald   CHOL
```

A work list can be helpful to prepare samples, calibrators and controls.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select F1 WORK LIST to print the current work list. The work list shows these data:

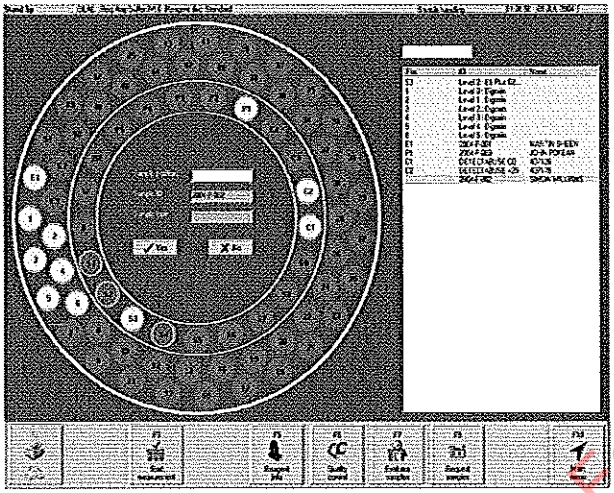
- Lab. Name, Time and date
- Sample type: Calibration (S), Reagent Blank (B), STAT sample (E), Pediatric sample (P) or Control (C).
- Sample ID
- Patient name
- List of requested tests

Note

Requests that do not have a sample type designation are patient samples.

4.2 Load the sample rotor and start the tests

4.2.1 Sample handling menu



The SAMPLE HANDLING menu contains all functions to load the sample rotor and start to process the sample. You can place the programmed samples in any position on the outer two rings of the sample rotor. You can also load and start STAT samples, controls, calibrators and pediatric samples. The analyzer shows the present status of the samples.
You can place a new sample in the sample rotor, as soon as the processed sample has been removed. The analyzer will automatically process the new sample. You can also use the SAMPLE HANDLING menu to check the volume in the bottles of the loaded reagents, check the test counter and refill liquids if necessary.

4.2.2 Sample rotor positions and color codes

The SAMPLE HANDLING menu shows the sample rotor with all positions and the present process status. A color code shows the process status. The right side of the screen shows the request list.

Note
A hint message with sample information shows if the mouse is moved over the sample position on the screen.

Sample rotor positions

Position	Description
1 - 51	These position are used for patient samples.
B	This position is reserved for the reagent blank measurement. You must place a sample tube filled with distilled water or saline solution in this position if you request a reagent blank.
S1 - S9	These positions are reserved for calibrators. If more positions are needed, the screen will show the positions to use (1-51).
P1 - P5	These positions are primarily reserved for pediatric samples. The analyzer gives these samples a higher priority.
E1 - E3	These positions are reserved for STAT samples. The analyzer gives these samples a higher priority.

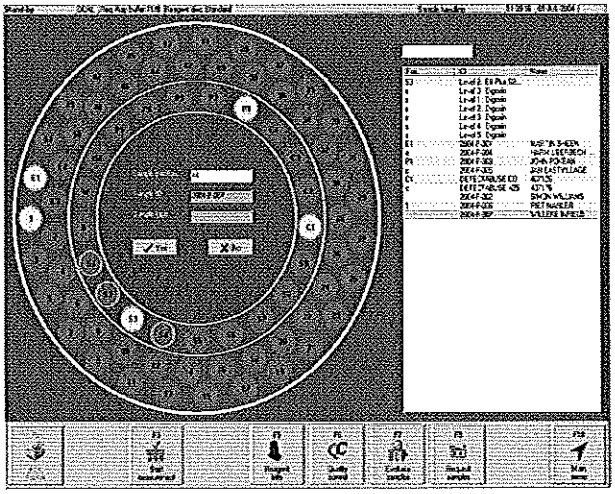
Position	Description
C1 - C4	These positions are reserved for the controls. If more positions are needed, the screen will show the positions to use (1-51).
W	This position is reserved for the wash solution. The wash position must contain a sample tube filled with a sufficient amount of fresh wash solution. We recommend to use hypochlorite solution. The wash solution cleans the sample needle after every measurement batch.

Color codes

The following colors for sample rotor positions can occur.

Color	Description
gray	The position is free and available for a new cup or tube.
gray with green border	These positions are reserved for calibrator points of a multi test calibrator set. These calibrator points are not needed for the test that is requested for calibration. The positions are reserved, but not used at this time. You do not have to place any calibrators in these positions.
green	The sample on this position is processed and the results are accepted.
green with red border	The sample on this position is processed but some results are not accepted. Test results with INFO exists for this sample.
green with white border	The position is selected to unload.
black	The sample in this position is in process.
yellow with green border	The position is registered and the ID of the sample is recognized by the system. You must make sure that the positions are loaded with the samples indicated on screen.
red	The same sample ID is already loaded to another position but the patient information is different. The analyzer sees changes made to patient information as a new sample and therefore incorrect. Sample IDs are unique.

Request list



The request list shows the order that patient and control requests are entered in the REQUEST SAMPLES menu. The list shows all other sample types at the top of the list. You can identify these samples by the corresponding letter.

SAMPLE ID SEARCH AND ASSIGN	Use this field to search and assign a position to a sample with either the barcode reader or type the sample ID and press the enter key.
POS	Select the sample with the up and down arrow key or the left hand mouse button, press ENTER. The next available position on the sample rotor shows.

Note
You can also load the position by the use of the mouse. Refer to 4.2.9, Load samples with mouse.

ID	The analyzer shows all samples in the request buffer. The requests of special sample types are listed first. • B: Blank (1 position) • S: Standard (9 positions) • C: Control (4 positions) • E: Emergency (3 positions) • P: Pediatric (5 positions) Subsequently all patient samples and controls are listed in the order in which these were requested.
NAME	The patient name or form of identification for the sample set in the REQUEST SAMPLE menu.

4.2.3 Keys available in Sample Handling menu

Key	Description
F1 PRINT LOADLIST	Prints a load list when the loading is ready and the analysis run was started with F3 START MEASUREMENT.
F2 SELECTIVE UNLOAD	Unloads specific samples that are ready, e.g. all controls or all normal samples. Ready samples show full green on the screen. You can place a new sample on the emptied positions. Here you can select the samples that must be unloaded. Samples that have an INFO can not be unloaded.
F3 CONTINUE MEASUREMENT	Starts to analyze the samples after you have placed all samples in the sample rotor.
F4 CONFIRM UNLOAD	When samples are ready and show as full green, you can remove them from the sample rotor. Select F4 CONFIRM UNLOAD before you load a new sample. Samples that have an INFO can not be unloaded.
F5 REAGENT INFO	This menu is used to check the volume in the bottles of the loaded reagents, to check the test counter and refill liquids. Do this check before each run to make sure that there is sufficient reagent for all requests. This menu is also used to look up the batch number and expiry dates of calibrators and controls.
F6 QUALITY CONTROL	This menu is used to check the results of the quality control.
F7 EVALUATE SAMPLES	This menu is used to check and evaluate the results to accept of reject the measurements.
F8 REQUEST SAMPLES	Go to the REQUESTS SAMPLES menu.
F10 MAIN MENU	Go back to the MAIN MENU.

4.2.4 Load a reagent blank

Note
Start a reagent blank before you start a calibrator.

Prerequisite
The reagent blank must first be requested in the Sample Request menu. Refer to 4.1.14, Request a test for a reagent blank.

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select BLANK from the request list.
3. Press ENTER or double click with the mouse to position the blank. The small b changes to a capital B.
4. Place a sample tube with distilled water or saline solution on position B on the sample rotor.
5. Select F3 START MEASUREMENT or continue to load samples.

4.2.5 Load a calibrator

Prerequisite
The calibrator must first be requested in the Sample Request menu. Refer to 4.1.13, Request a test for calibration.

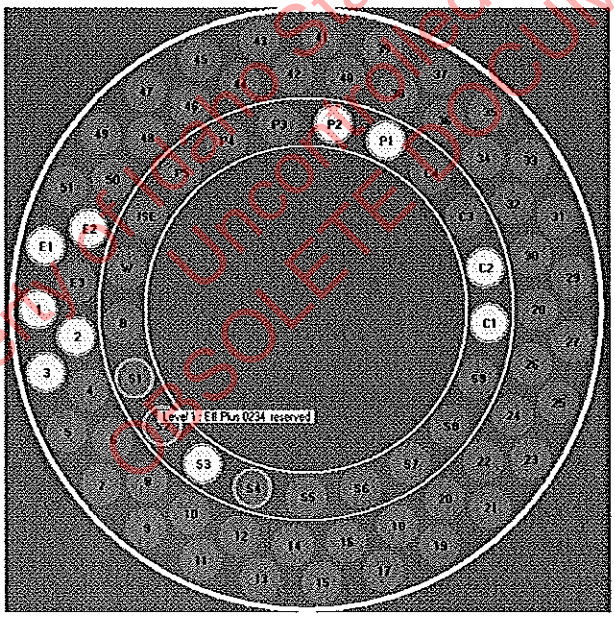
1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select the required calibrator from the request list.
3. Press ENTER or double click with the mouse to position the calibrator. The small s changes to a capital S + number (S1 to S9). If more positions are needed, the analyzer uses any available patient sample position.
4. Place the calibrator to the position indicated by the list and sample rotor on the screen.
5. Select F3 START MEASUREMENT or continue to load samples.

4.2.6 Load a control

Prerequisite
The control must first be requested in the Sample Request menu. Refer to 4.1.12, Request a control test.

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select the required control from the request list.
3. Press ENTER or double click with the mouse to position the control. The small c changes to a capital C + number (C1 to C4). If more positions are needed, the analyzer uses any available position.
4. Place the control to the position indicated by the list and sample rotor on the screen.
5. Select F3 START MEASUREMENT or continue to load samples.

4.2.7 Load a patient sample



Note
You do not have to place the samples in the rotor in the same sequence as defined in the REQUEST SAMPLES menu.

Prerequisite
The sample must first be requested in the Sample Request menu. Refer to 4.1.5, Manually request (patient) samples and assign tests.

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select the required patient sample from the request list.
3. Press ENTER or double click with the mouse to position the sample. The sample is allocated a number.
4. Place the patient sample to the allocated position on the sample rotor.
5. Select F3 START MEASUREMENT or continue to load samples.

Note
There are three types of patient sample; normal, STAT and pediatric. STAT samples are assigned to position E1 to E3; pediatric samples are assigned to position P1 to P5 on the sample rotor. If more positions are needed, the analyzer uses any available patient sample position.

4.2.8 Load samples with barcode reader

A barcode reader is the easiest, quickest and safest way to request samples and tests and to load samples. Refer to 2.4, Barcode reader.

Prerequisite
The sample must first be requested in the Sample Request menu. Refer to 4.1.6, Request (patient) samples and assign tests with the barcode reader. The samples must have barcode labels.

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Scan the label for the required sample. Each scanned sample will be shown on the screen. The sample is labeled with the relevant position number.
3.

ATTENTION
To avoid mistakes, place the sample on the indicated position on the sample rotor as soon as you have scanned the sample.

   Place the sample on the rotor position shown by the screen.
4. Select F3 START MEASUREMENT or continue to load samples.

4.2.9 Load samples with mouse

Prerequisite
The samples must first be requested in the Sample Request menu. Refer to 4.1.5, Manually request (patient) samples and assign tests.

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select the required patient sample from the request list.
3. Right mouse click the patient sample.
4. Type the position of the sample in the sample number field. Press the YES button to accept the position, or press the NO button to cancel the position.
5. Place the sample on the rotor position.

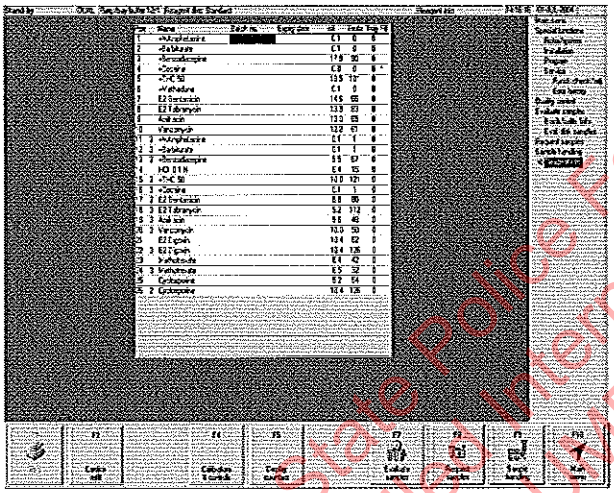
ATTENTION
To avoid mistakes, place the sample on the indicated position on the sample rotor as soon as you have scanned the sample.

6. Place the sample on the rotor position shown by the screen.

4.3 Reagent Info Menu

The REAGENTS INFO menu shows the loaded reagents, volumes, batch no and expiry date. Use this menu to check the reagent inventory before you start the analysis run. We recommend to check the reagent before the start of each run. When there is not enough reagent present to finish the request, the analyzer shows there is insufficient reagent. You can refill the bottles without interruption of the routine during the analysis run.

Note
When a classic rotor is used, the screen shows 32 positions, when an EMIT rotor is used the screen shows 26 positions.



4.3.1 Reagent Info parameters

Parameter	Description
POS.	The positions of the reagents on the reagent rotor.
NAME	The name of the reagent. The field also shows the order of the reagent. 2 shows the reagent is the second reagent. 3 shows the reagent is the third reagent. D shows the reagent is a dummy reagent.
BATCH NO.	The batch no. of the reagent.
EXPIRY DATE	The expiry date of the reagent.
ML	The available reagent volumes in the bottles.
TESTS	The number of tests, which can still be processed with the available volume of the reagent.
TRAY	The number of tests that is currently requested.
FILL	*: Shows a shortage of the reagent and a refill is necessary.

4.3.2 Keys available in Reagent Info menu

Key	Description
F1 PRINT	Prints a list with the reagent information.
F2 CONFIRM REFILL	Confirm that you have refilled the reagents.

Key	Description
ALT+F3 CLR. ALL COUNTER	Sets all values in the total test counts to zero. Check under Counter mode and normal mode.
F4 CALIBRATORS AND CONTROLS	Lists all calibrators and controls with batch number and Expiry date
F5 DISPLAY COUNTERS / RETURN TO SELECT LIST	Toggle switch between counter and list selection.
F7 EVALUATE SAMPLES	Go to the Evaluate Samples menu to check all results and do validations, if necessary.
F8 REQUEST SAMPLES	Go to the REQUESTS SAMPLES menu.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu.
F10 MAIN MENU	Go to the MAIN MENU.

4.3.3 Check the inventory of the reagents

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select F5 REAGENT INFO to go to the REAGENT INFO menu.
3. Check the following information:
   - The batch in the BATCH NO column.
   - The expiry date in the EXPIRY DATE column.
   - The available reagent volume in the ML column.
   - Number of the test that can be processed in the TESTS column.
   - Number of tests requested in the TRAY column.

Note

Check the loaded reagents and their volumes before you start the analysis run.
If you have already assigned positions to the requested samples, you can only go to the REAGENT INFO menu. If you go to other menus, the information of the assignment is lost and the assignment must be repeated.

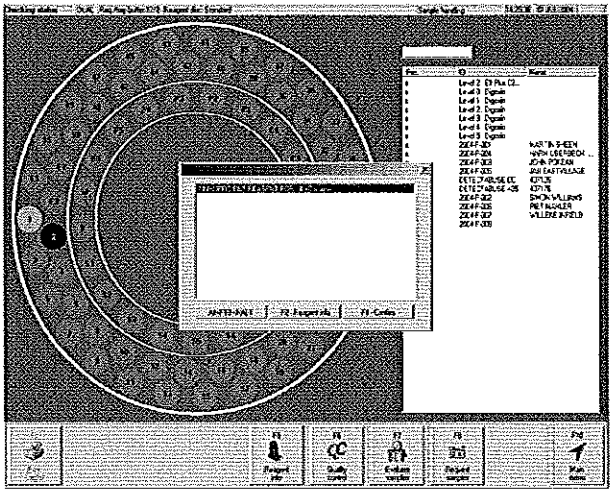
4.3.4 Refill the reagents

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select F5 REAGENT INFO to go to the REAGENT INFO menu.
3. Refill the reagents that are marked with an asterisk (*) in the FILL column.
4. Select F2 CONFIRM REFILL. The analyzer assumes that all the reagents are refilled. The screen is updated.

Note

Check the loaded reagents and their volumes before you start the analysis run.
If you have already assigned positions to the requested samples, you can only go to the REAGENT INFO menu. If you go to other menus, the information of the assignment is lost and the assignment must be repeated.

4.3.5 Insufficient reagent



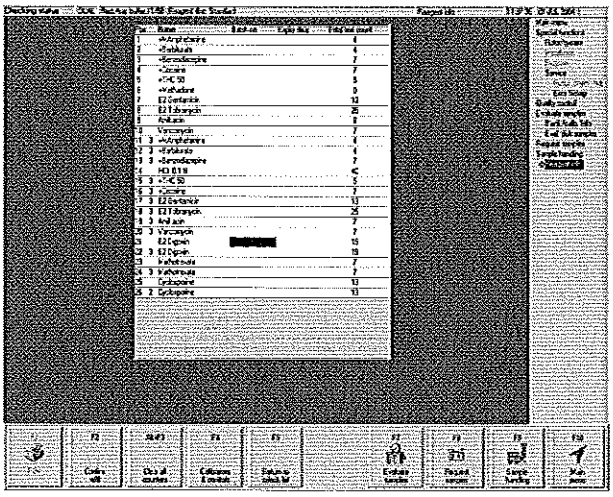
If a reagent volume becomes insufficient for a test during a sample analysis, the instrument issues a INSUFFICIENT REAGENT DURING SAMPLE ANALYSIS warning message.
This warning message gives information on the test and the position that has insufficient reagent.

1. Press one of the keys below to acknowledge the message.
2. Select F9 SAMPLE HANDLING from the MAIN MENU.
3. Select F5 REAGENT INFO to go to the REAGENT INFO menu.
4. Refill the reagents that are marked with an asterisk (*) in the FILL column.
5. Select F2 CONFIRM REFILL. The analyzer assumes that all the reagents are refilled. The screen is updated.
6. Confirmed the refill, select F2 CONFIRM REFILL in the REAGENT INFO menu.
7. The analyzer shows a message: Calibration still valid for [test name] [batch no.]
   1. Select F5 YES if the calibration is still valid. The analyzer continues with the measurement of patient samples.
   2. Select F6 NO if the calibration is not valid anymore. The tests are flagged with NO CALIBRATION CURVE. You must now do a calibration of the test. After calibration the analyzer automatically starts with the test that are flagged with NO CALIBRATION CURVE.

Key	Description
ALT+F10 HALT	The instrument will stop immediately. All actions and all tests in process are lost. After this action a system reset must be initiated.
F4 ACKNOW MESSAGE	The instrument stops pipetting reagent for the test with insufficient reagent. All other tests continue as normal. The system goes to stand-by mode the moment all other tests are complete. A refill can be performed at any time (Go to REAGENT INFO menu and select CONFIRM REFILL).
F2 REAGENT INFO	The instrument goes to the REAGENT INFO screen. The instrument stops pipetting the reagent for the test with insufficient reagent. All other tests continue as normal. The system goes to stand-by mode the moment all other tests are complete. A refill can be performed at any time.

4.3.6 Counter mode and Normal mode

The analyzer gives support for the analyzer statistics. To show or delete the statistics do as follows:



1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select F5 REAGENT INFO to go to the REAGENT INFO menu.
3. Select F5 DISPLAY COUNTERS to show the analyzer statistics. The counters shows the total number of processed measurements per method in both run modes. After changing from one mode to the other, also the test count changes.

Note

In DISPLAY COUNTERS you can change the expiry date and batch number.

4. Select F5 NORMAL MODE to return to the Normal mode.
5. Check and if necessary, select ALT+F3 CLR ALL COUNTS to delete the statistics and to reset all counters to 0.

4.3.7 Calibrators and Controls

To make a record of the batch number and expiry date of the calibrators and control samples, do as follows:

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Select F5 REAGENT INFO to go to the REAGENT INFO menu.
3. Select F4 CALIBRATORS AND CONTROLS.

Note

In CALIBRATORS AND CONTROLS you can change the expiry date and batch number.

4. Check and if necessary, type the appropriate data for calibrators and control samples.
5. Select F10 RETURN to go back to the MAIN MENU.

4.4 Start and stop the sample run

4.4.1 Start the analysis run

The analysis run must start from Standby mode.

1. If the Start Measurement button is not present, the analyzer is in an inactive or halted state. To change to Standby mode do as follows:
   1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU
   2. Select F1 ROTOR/SYSTEM
   3. Select F1 SYSTEM RESET
   4. Select SYSTEM RESET

Note

When the analyzer starts from Stand-by mode, the analyzer will switch on the lamp and the vacuum pump, and rinse the cuvettes. Messages will inform you if there are any unusual incidents.

2. Start the measurement.
   1. Select F9 SAMPLE HANDLING from the MAIN MENU.
   2. Place all samples, standards, controls, etc. in their correct position on the sample rotor as previously described in 4.2, Load the sample rotor and start the tests.
   3. Make sure there is a sufficient amount of reagents available for all requests. Select F5 REAGENT Info to make sure of expiry dates and quantities.
   4. Select F1 PRINT LOADLIST to obtain a printout of the load list.
   5. Select F3 START MEASUREMENT

Note

Do not change to another menu except F5 REAGENT INFO before pressing F3, otherwise all position definitions for the sample rotor are lost.

4.4.2 Unload the samples

Selective unload where you can select the ones to be unloaded.

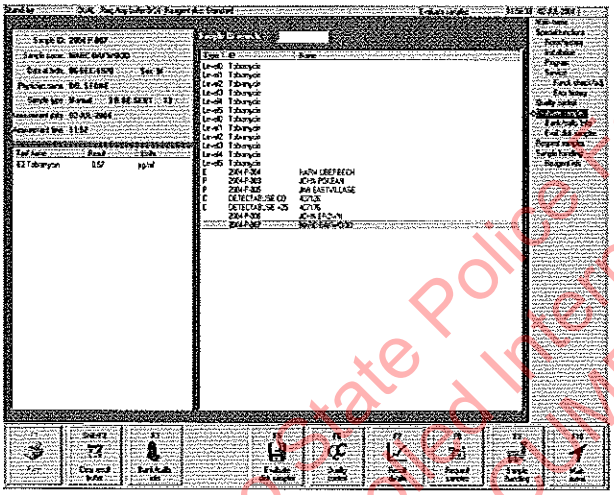
1. Unload one or a selection of samples.
   1. Select F2 SELECTIVE UNLOAD from the SAMPLE HANDLING menu.
   2. Type a sample number or sample numbers in the Sample position field.
   3. Remove the sample tubes from the rotor.
   4. Select F4 CONFIRM UNLOAD to confirm that the sample was unloaded.
   5. After unloading a sample, you can immediately load a new sample at that position on the sample rotor. If you Select F3 START MEASUREMENT, the new sample is integrated into the current run and will be processed.
2. Unload a range of samples.
   1. Select F2 SELECTIVE UNLOAD from the SAMPLE HANDLING menu.
   2. Select F5 SELECT RANGE.
   3. Type the start position in the START POSITION field.
   4. Type the end position in the END POSITION field.
   5. Remove the sample tubes from the rotor.
   6. Select F4 CONFIRM UNLOAD to confirm that the samples were unloaded.
   7. After unloading a sample, you can immediately load a new sample at that position on the sample rotor. If you Select F3 START MEASUREMENT, the new sample is integrated into the current run and will be processed.
3. Unload all samples
   1. Select F4 CONFIRM UNLOAD from the SAMPLE HANDLING menu.
   2. Remove all the sample tubes from the rotor.

4.5 Check and validate the results

4.5.1 Evaluate Samples menu

The results of each sample and test can be evaluated in the EVALUATE SAMPLES menu.
If the parameter AUTOMATIC EVALUATION was selected in the SYSTEM PARAMETERS menu, the results are automatically accepted or rejected and a printout of results is generated. If you did not select this parameter, only results that are outside the limits of the test have to be manually validated.
Subsequent samples will not be printed until the previous samples have all been validated.
Depending on the type of test, you can choose between a screen of the calculated absorbencies in tabular or graphic form.

4.5.2 Validation of a Result



1. Refer to 4.5.3, Personal and Status Details of the Sample
2. Refer to 4.5.4, Test Display fields (Normal Mode)
3. Refer to 4.5.5, Display fields right side of screen (Normal Mode)

In the SAMPLE HANDLING menu go to the EVALUATE SAMPLES menu. In the EVALUATE SAMPLES menu, you can check and, if necessary, validate results of a sample that is currently being processed.
You can check the test results of a sample, view the points in the graph or compare the individual values of the absorbencies. You can also enter the sample ID in the entry field above the sample list to select the sample, or use the barcode reader.
The left screen shows all sample data, the position of the sample on the sample rotor and the status. You can also view in graphic mode. Select one of the processed tests on the left with the cursor keys. A graphic of the corresponding test is shown.
When *INFO* is shown next to the test you must validate the results. This only applies if AUTOMATIC EVALUATION in the SYSTEM PARAMETERS menu was not selected. The sample will not be released and the analyzer does not print it.
Sample information (number, name, etc.), test name and unit are shown above the table or the graphic. A message indicates why the test was not released. Due to this message (e.g. REAGENT ABSORBANCE LIMIT ERROR), you are required to make a decision (WAITING FOR YOUR DECISION).
You can accept or reject the result, repeat the measurement (measure again), or run the test again with different sample and reagent volumes (measure re-run). If measure re-run is used, the analyzer measures the test again with the sample and reagent volumes as they were entered when the method was programmed in the TEST PARAMETERS menu.

4.5.3 Personal and Status Details of the Sample

Detail	Description
SAMPLE ID	The sample ID as defined in the REQUEST SAMPLES menu.
SAMPLE NAME	The sample name as defined in the REQUEST SAMPLES menu.
DATE OF BIRTH	The patient's date of birth if defined in the REQUEST SAMPLES menu.
PHYSICIAN NAME	The name of the physician in charge if defined in the REQUEST SAMPLES menu.
SAMPLE TYPE	The sample type (Normal, Pediatric, Control, etc.).
MEASURED DATE	The date of the test
MEASURED TIME	The time of the test
ROTOR POSITION	The rotor position of the sample (shows behind the status field directly behind SAMPLE TYPE.
SEX	The sex of the patient: M (male), F (female), or P (pediatric).
STATUS	The current processing status of the sample is shown in the status field directly behind SAMPLE TYPE. The status field shows the position and the status of the samples on the sample rotor. The following status indications are possible: • IN PROCESS The sample or one of its allocated tests is currently being processed. The result of at least one test is pending. • CANCELLED The sample is loaded, but the request is cancelled. The sample will not be processed and results will not be calculated. • READY The sample has been processed. The results are available. • LOADED The sample is loaded, but not yet started to be processed. • TO BE SENT This message appears only if the analyzer is connected to a Laboratory Information System (LIS). The results can be sent to the host-computer. • PRINTED The result is printed. • DELETED The result is rejected.

4.5.4 Test Display fields (Normal Mode)

All tests measured for a sample are shown together with the measurement results and units. The screen shows up to 28 test results (without sample blanks) per patient in the normal mode. In the graphic mode, a maximum of 32 tests including sample blanks are shown.

Display fields	Description
TEST NAME	The name of the test as defined in the test parameters.
RESULTS	If the word *INFO* is shown next to test name, you must validate the result. Press F3 to accept the result, F4 to reject the result, F5 to repeat the measurement or F6 to re-run the test with specific re-run volumes.
BATCH NO.	Select F7 RESULTS DETAILS to see the Batch No. graphic and table displays.
UNITS	The units as defined in the test parameters.

4.5.5 Display fields right side of screen (Normal Mode)

Display fields	Description
SAMPLE ID SEARCH	Type the sample ID to show the results of the sample in the test display on the left side. Or use the barcode scanner.
TYPE	All samples that have been or are currently being processed, are shown. Stat samples, controls, etc. are labeled with their respective type letter. If you did not select the parameter AUTOMATIC EVALUATION in the SYSTEM PARAMETERS menu, the samples, which require manual validation of at least one test, are listed first. The left side shows the results of the currently selected sample.
ID	The ID of the sample.
NAME	The name of the sample.

4.5.6 Evaluate Samples Keys (Normal Mode)

Key	Description
F1 PRINT	Make a printout of the currently selected patient.
SHIFT+F2 CLEAR RESULT BUFFER	Delete all results that are currently shown. If you selected SAVE BEFORE CLEAR in the SYSTEM PARAMETERS menu, the results will first be copied to hard disc.
F3 BLK/CAL. INFO	Go to the BLANK/CALIBRATION INFORMATION menu.
SHIFT+F4 CANCEL REQUEST	Cancel the selected sample any time during sample processing. All the tests for the sample is cancelled and a corresponding message is shown and printed out. The results are not calculated. Note that as the instrument is in fact already busy with this sample it might still pick up reagent for it.
F5 EV.DISK SAMPLES	Load the results that are stored on hard disk. A file list is shown. The file list shows the date and time of storage and the file size. Select a file with the arrow keys and press ENTER. When evaluating results from disk, only the final result is available, not the reaction curve.
F6 QUALITY CONTROL	Go to the QUALITY CONTROL menu.

Key	Description
F7 RESULTS DETAILS	Show the results of saved samples that are shown on the left side of the screen, in graphic mode. Select F7 again to go back to the normal mode.
F8 REQUEST SAMPLES	Go to the REQUESTS SAMPLES menu.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu. Further samples can be loaded here.
F10 MAIN MENU	Go back to the MAIN MENU.

4.5.7 Evaluate Disk Samples

To view the results from a saved test, do as follows:

1. Select F7 EVALUATE SAMPLES from the MAIN MENU.
2. Select F5 EV. DISK SAMPLES menu.
3. Select the date of the test results to be viewed or deleted.
4. To view the file press ENTER.
   The following test data shows:
   - Test name.Units
   - Batch no.
   - Result
   - Units
   - Flags for cut-off tests. See Flags for cut-off tests.
5. To delete the file, select SHIFT F2 DELETE FILE. A dialog box opens to confirm Delete file? Yes or No.
6. Select YES.

4.5.8 Evaluate Samples Keys (Graphic and table mode)

F1 PRINT	Prints the current results display (Graphic or Table).
F2 TABLE / GRAPHIC	Switch between graphic and table mode. Pressing F7 or ENTER to return to the normal mode.
F3 ACCEPT RESULT	Validates the tests marked *INFO* so that it can transfer the results to the results printer. WAITING FOR YOUR DECISION is shown on the right-hand side on the screen. The result will only be transferred if this is enabled by the error that has caused the mark *INFO*; i.e. F3 is not available for serious errors such as INSUFFICIENT SAMPLE.
F4 REJECT RESULT	Reject the currently shown result. The rejected result is marked REJECT.
F5 MEASURE AGAIN	Repeat the test. The volumes that are used for the repeated measurement are identical with those that were originally used.
F6 MEASURE RERUN	Repeat the test. Unlike F5 MEASURE AGAIN the defined volumes that are used here for the repeated test are the volumes that were defined in the field RERUN VOL. of the test parameters.

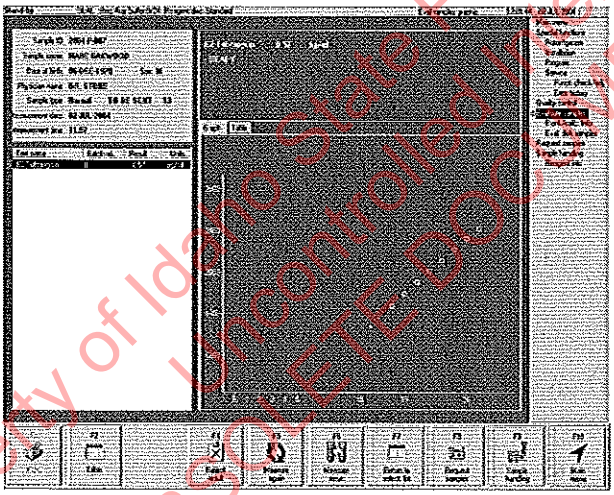
Note

F5 MEASURE AGAIN and F6 MEASURE RERUN use two different parameter settings in Program test.

SHIFT+F6 MEASURE ALL AGAIN	If a calibrator has been run in duplicate or in triplicate, the option MEASURE ALL AGAIN appears. If selected, the instrument will measure this single standard again in duplicate or triplicate. Do not use this function if a calibration fails, but repeat the request of the entire calibration.
CRTL+F2 DISPLAY CURVE	If the test is a calibration, the calibration curve together with concentrations, measurement values and limit values are shown after pressing CRTL+F2.
F7 NORMAL MODE	Return to the normal mode.
F8 REQUEST SAMPLES	Go to the REQUESTS SAMPLES menu.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu.
F10 MAIN MENU	Go to the MAIN MENU.

4.5.9 Results details: Graphic mode and Table mode

A maximum of 32 results including blanks are shown for each sample (left-hand side of screen). The current test and the respective unit are shown above the table or the graphic.



1. Select F7 EVALUATE SAMPLES from the MAIN MENU.
2. Select F7 RESULT DETAILS.
3. Select F2 GRAPHIC/TABLE MODE to show the results in detail. You can also select the Graphic and Table tabs to view the same information.

A separate prozone graphic and a prozone table can be called up if a prozone check was defined for a method in the TEST PROGRAMMING menu.

STATUS

Shows the status, name and results of the test. The following states apply:

- READY
- BEING REMEASURED
- BEING MEASURED
- WAITING FOR YOUR ATTENTION
- NO CALIBRATION CURVE
- REJECTED
- WAITING FOR OTHER RESULTS

WAITING FOR YOUR DECISION is shown if the word *INFO* shows next to a result. Depending on the shown error message (e.g. INSUFFICIENT SAMPLE or ABSORBANCE LIMIT ERROR), the user may now either accept the result, reject the result, repeat the measurement or rerun the test with a specific rerun volume. Chapter 5 contains a list of possible error messages.

GRAPHIC MODE

The x axis represents time. The x axis shows the measurement points in relation to the time function. Kinetic and two point methods have 22 points (1 to 22) available in the MONO MODE and 21 points (1 to 21) in the DUAL MODE. The y axis represents the absorbance values.
If the cuvette (reagents plus sample) contains less than 220 µl during the measurement of a point, e.g. before the sample or reagent 2 is added, these measurement points will not be shown on screen. The measurement points in the coordinate system have following functions:

☐ Used measurement point.
· Unused measurement point.
● The used slope point for the slope blank calculation or the used prozone point, depending on the display mode.
+ Measured absorbance of the first reagent.
X Extrapolated value (used for the reagent absorbance deviation check), only used for sample start methods with falling kinetics.

Results monochromatic mode

R_1 Measured absorbance of the first reagent at the primary wavelength.
R_2 Second measured absorbance of the first reagent at the primary wavelength.
E_1 Measurement point in endpoint tests for the primary wavelength.
E_2 Second Measured point in endpoint tests for the primary wavelength.
Measurement point = $(R_1+R_2)/2$= result
Measurement point = $(E_1+E_2)/2$ = result

Results bichromatic mode

R_1 Measured absorbance of the first reagent at the primary wavelength.

R_2 Measured absorbance of the first reagent at the secondary wavelength.

E_1 Measurement point in endpoint tests for the primary wavelength.

E_2 Measurement point in endpoint tests for the secondary wavelength.

Measurement point = (R_1-R_2)= result

Measurement point = (E_1-E_2) = result

TABLE MODE

Depending on the type of test method the following absorbance is shown:

- Calculated absorbance (endpoint)
- Delta absorbance (two point)
- Delta absorbance per minute (kinetic)

The number of measurements for kinetic or two point measurements depends on the mode:

- Mono mode: 22 measurements
- Dual mode: 21 measurements

In endpoint tests (monochromatic or bichromatic), the measurement points are shown on the screen:

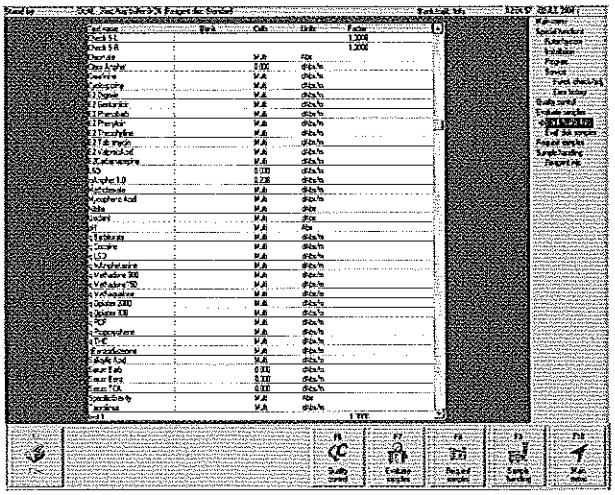
- Mono mode: after 11.5 minutes of sample addition
- Dual mode: after 2.0, 4.5, 6.5, 8.0 or 11.5 minutes of sample addition

The measurement points marked with an arrow were used for calculation purposes by the analyzer.
The first column R shows the measured reagent absorbance for all methods of the first reagent (only if the volume of the first reagent is larger than 220 µl).
The second column (1-11 of the first reagent or $E_{1,2}$) shows the points measured before the second reagent was added.
The third column shows the results of the tests run with the second reagent for the individual measurement points (below 12-21 or E 11.5 MIN.). The shown absorbencies are already corrected to meet the respective value of the total volume of the tests in the cuvette and are corrected for a 1 cm light path.

4.5.10 Information screen for blank/calibration

All programmed tests together with last blank measurement, last calibration result and the programmed or calculated factor are shown.

1. Select F9 SAMPLE HANDLING from the Main Menu.
2. Select F7 EVALUATE SAMPLES.
3. Select F3 BLANK CAL INFO.

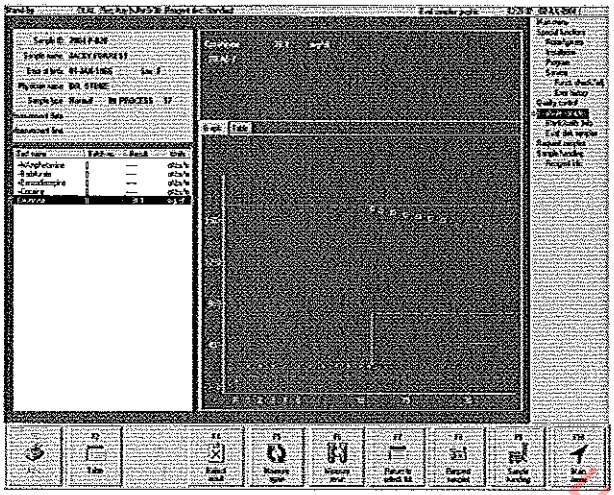


Parameter	Description
TEST NAME	The name of the test as defined in the test parameters.
BLANK	The last measured reagent blank.
CALIB	The last measured calibration. If Multi shows, the calibration is a multi point calibration.
UNITS	The units used for the measured calibration value.
FACTOR	The calculated or programmed calibration value.

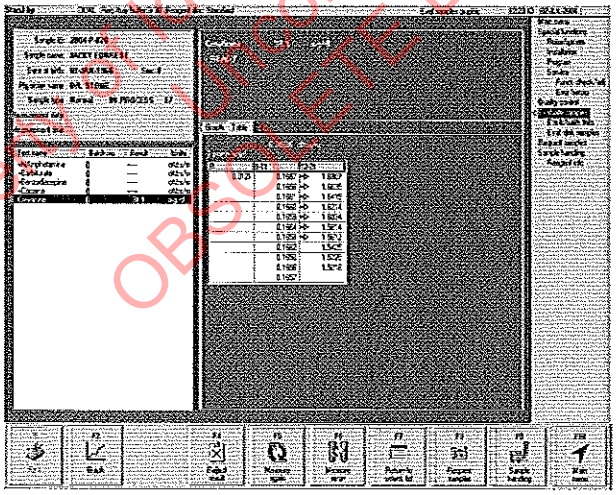
Keys	Description
F1 PRINT	Print a list of all shown results for blank measurements or calibrations.
F6 QUALITY CONTROL	Go to the QUALITY CONTROL menu.
F7 EVALUATE SAMPLES	Go to the EVALUATE SAMPLES menu.
F8 REQUEST SAMPLES	Go to the REQUESTS SAMPLES menu.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu.
F10 MAIN MENU	Go to the MAIN MENU.

4.5.11 Results details for kinetic tests

The results details for a kinetic test show as graphic and table.



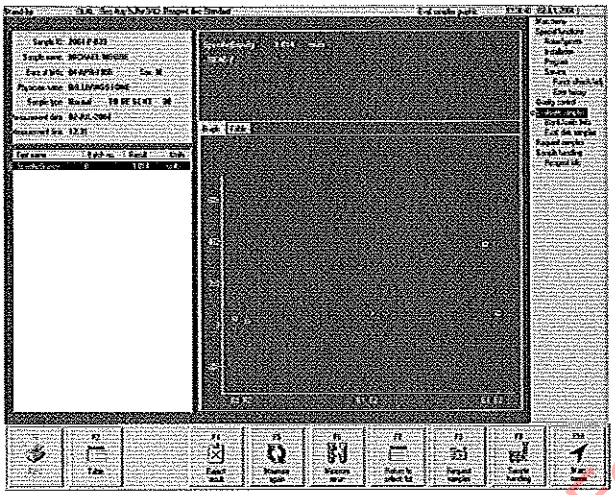
The graph shows all points on the X axis. The analyzer uses the measured points that are marked with a square to calculate the rate of delta absorbance per minute. The other measured points not used for the calculation show as a dot.
The level at which the substrate depletion occurs is shown by the arrow just before the addition of the last reagent. This is the substrate depletion limit for kinetic tests with two or more reagents.
The software needs four points to calculate a rate of absorbance. If one of the first four decreasing measured values falls below this line, then the substrate starts to deplete and a warning message shows. The operator must re-measure with a diluted sample.
The low and high absorbance limits show as two dotted parallel lines. If a measured value is outside these limits, the error message High or Low absorbance limit violation shows.



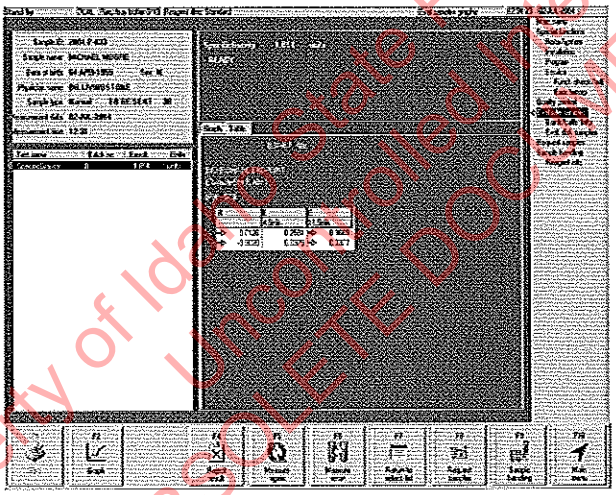
If you go to the table mode the screen shows a table with the absorbencies measured during the measurement.
The column R shows the absorbance value of the first reagent without the sample added. The other two columns show the points measured when sample, second and third reagent have been added (if programmed).
The results of the calculation is a delta absorbance per minute, shown at the top of the table.
The table indicates the points used for the calculation with an arrow.

4.5.12 Results details for a endpoint test

The results details for an endpoint test show as graphic and table.



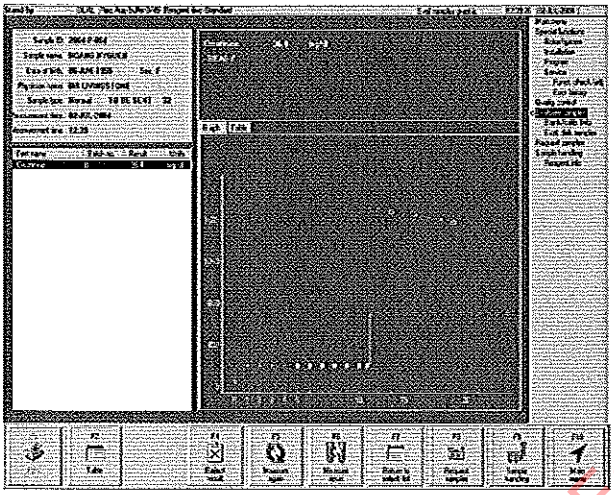
The graph shows six points on the X axis. The analyzer uses the measured points that are marked with a square to calculate the delta absorbance. The other measured points not used for the calculation show as a dot.



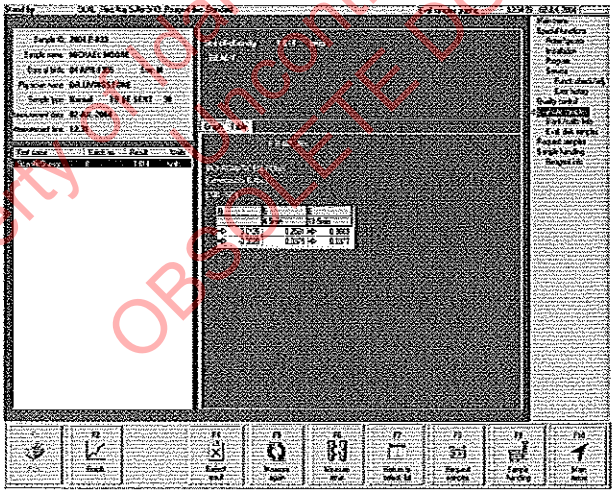
If you go to the table mode the screen shows a table with the absorbencies measured during the measurement.
The column R shows the absorbance value of the first reagent without the sample added. The other two columns show the points measured when sample, second and third reagent have been added (if programmed).
The result of the calculation is an absorbance value, shown at the top of the table.
Depending on the programming of the tests, the analyzer selects the columns that are used for the calculation. The points used are indicated by an arrow.
Monochromatic tests uses the average of each set of values in each column.
Bichromatic tests uses the difference between each set of values in each column.

4.5.13 Results details for a two point test

The results details for a two point test show as a graphic and table.



The graph shows all points on the X axis. The analyzer uses the measured points that are marked with a square to calculate the difference between the two points. The other measured points not used for the calculation show as a dot.
The level at which the substrate depletion occurs is shown by the arrow just before the addition of the last reagent.
There may be a side reaction between the first reagent and the sample. This is measured as rate of Delta absorbance per minute and can continue after the addition of the second reagent. A slope blank corrects for this side reaction. The measured points used to calculate a slope blank show as white circles.



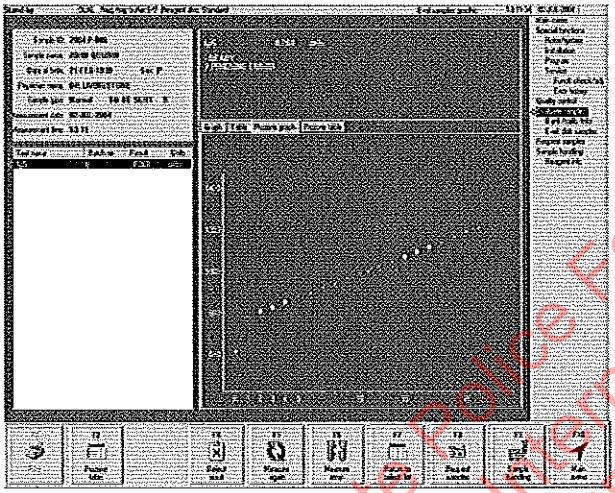
If you go to the table mode the screen shows a table with the absorbencies measured during the measurement.
The column R shows the absorbance value of the first reagent without the sample added. The other two columns show the points measured when sample, second and third reagent have been added (if programmed).
The results of the calculation is a delta absorbance shown at the top of the table.
The table indicates the points used for the calculation with an arrow.
When slope blank is set in the PROGRAM TEST, then an additional value shows. This is the first value at the top of the table; the slope blank value is measured as delta absorbance per minute.
The second value is the delta absorbance of the two point test, not yet corrected by the slope blank.

4.5.14 Results details for a measurement with a prozone check

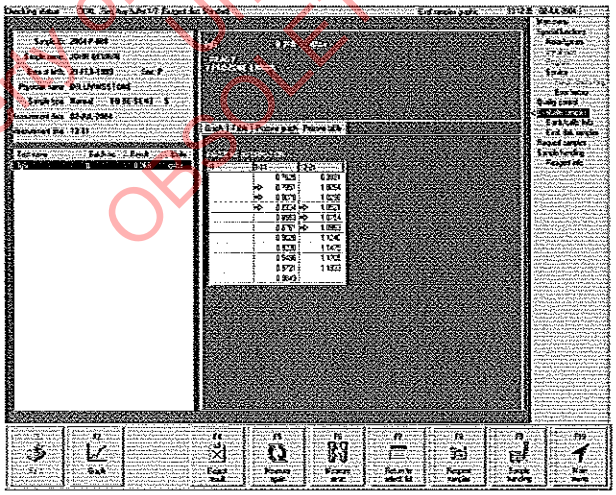
The prozone check is only used in tests that are based on the formation of antigen-antibody complexes (agglutination). Patient samples with an extremely high antigen content can reverse the reaction direction to cause incorrect results. This reverse in the reaction is called the prozone or hook effect.

To recognize incorrect results, the analyzer offers a check function to detect for the prozone effect. You define the prozone check in the PROGRAM TEST menu.

The results details for a test with a prozone check show as a prozone graph and prozone table.



If the prozone graph is selected, points that are used to identify the prozone effect show as white circles. If delta absorbance ratio is selected as minimum or maximum in the program test menu, then the analyzer uses two times 3 points to identify the prozone effect. If Absorbance ratio is selected as minimum or maximum in the program test menu, then the analyzer uses two times a single value to identify the prozone effect. The points used to calculate for the effect are set in the parameters PROZ.PT.ONE,TWO in the PROGRAM TEST menu.



If the prozone table is selected, points that are used to identify the prozone effect show as with an arrow.

4.5.15 Automatic Results Printout

When the processing of a sample with all its requested tests is ready, the analyzer automatically prints out the results and sends the results to the Host through the LIS, if the analyzer is ON-LINE.

The printout includes the sample ID, patient name, date of birth, sex, sample type, sample status and the tests that are done for that sample. The test results are shown with their respective units (mg/dl, mmol/l etc.).
If the parameter AUTOMATIC EVALUATION in the SYSTEM PARAMETERS menu was not selected and one of the tests exceeds or falls below the limits that were defined in the test parameters (TEST PARAMETERS menu), the patient result will not be printed out, until a manual validation of the measuring results has been done.
The result will also not be printed, if error messages such as INSUFFICIENT SAMPLE were shown.

Extended Routine

5.1 Program Calibrators

5.1.1 Introduction

Calibrators must be programmed before you define the test parameters for the various tests. You can change the parameters for a calibrator or add new calibrators later. A total of 50 calibrators can be set.

The analyzer supports the following calibration methods:

- linear calibration with 1 standard, where a concentration of 0 shows no reaction
- linear calibration with 2 standards
- non-linear calibration with 3 to 9 standards
  - Cubic spline
  - Modified cubic spline
  - 4 parameter logit log
  - 5 parameter logit log
  - 5 parameter exponential
- Multi test calibration of different dilution levels made from one (parent) calibrator.

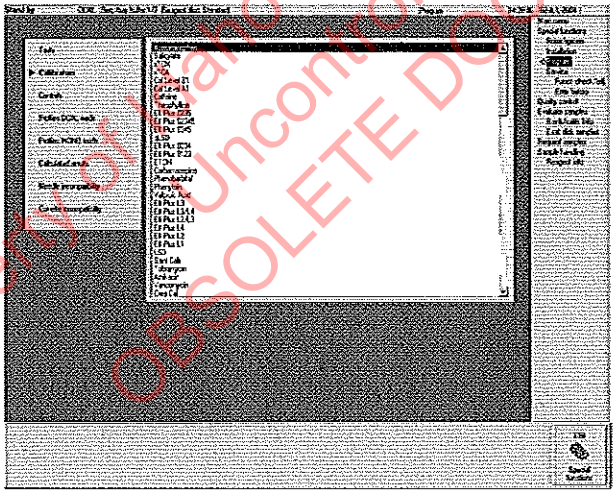
All these methods will give quantitative results.

Where a qualitative result is required (either positive or negative) cut-off calibration must be used. With a cut-off calibration you can also define a "close to cut-off" or "grey"-area.

Note

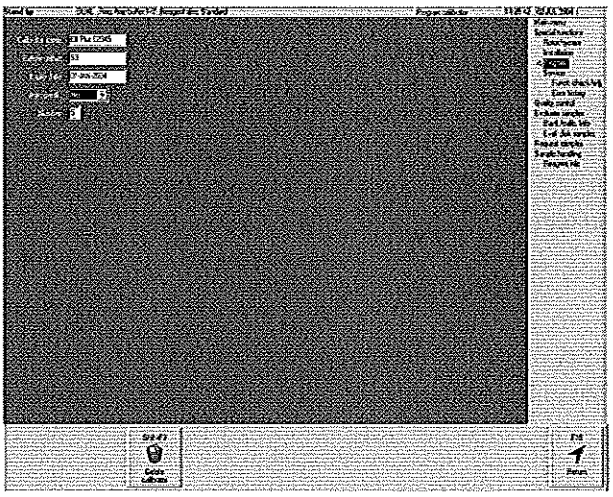
This menu is protected by the level 1 password, if it has been programmed in the SPECIAL FUNCTIONS/INSTALLATION menu. For detailed information refer to chapter 3.2.5, Define passwords.

5.1.2 Program a Calibrator



Note

If you want to perform a dilution series using a one parent calibrator, please specify the number of calibration points here. The specific dilution ratios can be specified later on in the test programming menu (if 'Yes' was selected at Auto Predilution).



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select CALIBRATORS from the menu and press ENTER. A list of programmed calibrators appears.
4. Press TAB or ENTER to move the cursor to the list of calibrators.
5. Select the name of a calibrator to be modified or an empty position for defining a new calibrator using the cursor keys or the mouse.
6. Press ENTER or double click on the selected position to call up the PROGRAM CALIBRATOR screen.
7. Type the calibrator name in the CALIBRATOR NAME field
8. Type the batch number of the calibrator in the BATCH NO. field.
9. Type the expiry date or the calibrator in the EXPIRY DATE field.
10. Select AUTO PREDILUTION in the drop down menu AUTO PREDL: Yes or No.
11. Type the number of calibrator standards in the NUMBER field.

5.1.3 Program Calibrator Parameters

CALIBRATOR NAME	The name of the Calibrator.
BATCH NUMBER	The batch number of the calibrator as provided by the insert sheet.
EXPIRY DATE	The expiry date of the calibrator as provided by the insert sheet.
AUTO PREDIL.	Select "Yes" to automatically dilute the calibrator. The required dilution ratio is selected in the TEST PROGRAMMING menu for the test that uses this calibrator. Select 'No' if this calibrator does not have to be (pre)diluted.
NUMBER	The number of standards (1-9) for this calibrator.

5.1.4 Program Calibrator Function Keys

SHIFT+F3 DELETE CALIBRATOR	Delete the current calibrator from the list of calibrators.
F10 RETURN	Return to the PROGRAMMING menu.

5.2 Program Controls

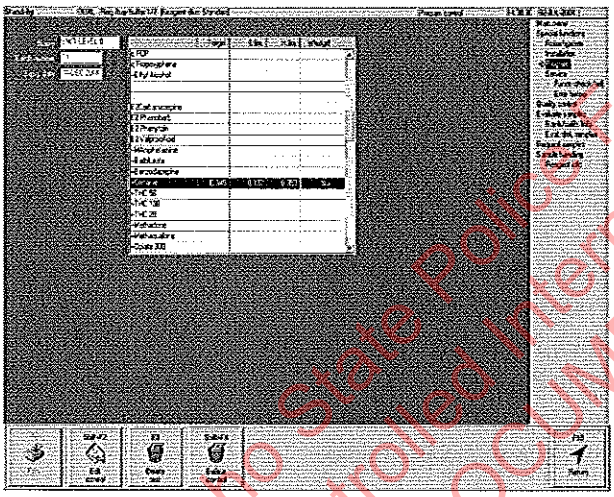
5.2.1 Introduction

The controls are programmed before the first time of operation. The method of the test must be defined before programming the controls. You can change method assignments and program new controls later; only the name of the control has to be entered. The batch number and expiry date are optional. A total of 15 controls can be set with a maximum of 3 controls per test.

Note

This menu is protected by the level 1 password, if it has been programmed in the SPECIAL FUNCTIONS/INSTALLATION menu. For detailed information refer to chapter 3.2.5, Define passwords.

5.2.2 Program a Control



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select CONTROLS from the menu and press ENTER. A list of programmed controls appears. The analyzer displays the programmed tests that can be assigned to the control NAME displayed on the left. Use the PAGE UP and PAGE DOWN keys or the SCROLLBAR to scroll through the list. All values set to the test are displayed: the target value, the low limit, the high limit and information whether Westgard rules apply to control results. When no values are shown, the test is not assigned to the control.
4. Select the test from the list that will use the selected control.
5. Press the ENTER key.
6. The values set in the PROGRAM CONTROL screen are displayed.
7. Enter the values for Target, Low Limit, High Limit, Westgard Active.
8. Press F10 RETURN to return to the PROGRAM CONTROL screen.

To activate the same screen from the MAIN MENU. Press F6 QUALITY CONTROL, F4 PROGRAM CONTROL. However, this should only be done if a name and batch number have already been assigned to the control.

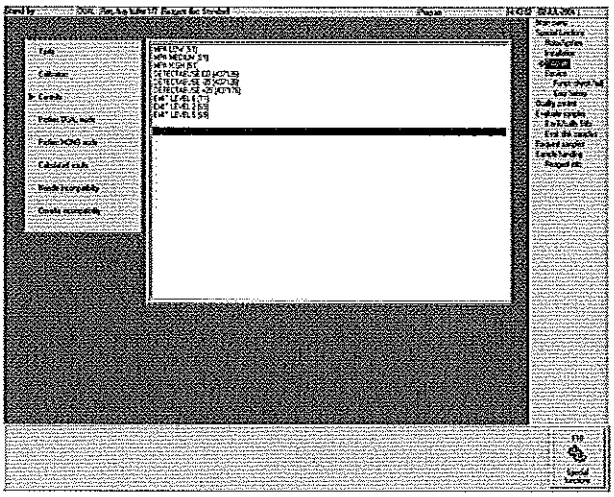
5.2.3 Program Control Parameters

NAME	The name of the control as provided by the insert sheet. Enter the name to program a new control.
BATCH NUMBER	Enter the batch number as provided by the insert sheet.
EXPIRY DATE	Enter the expiry date as provided by the insert sheet.

5.2.4 Program Controls Function Keys

F1 PRINT	Print out a list of all tests assigned to the current control.
SHIFT+F2 EDIT CONTROL	Place the cursor in the field NAME. You may now enter a new name and/or batch number for that control. All test assignments to the current control are deleted.
F3 DELETE TEST	Deletes the assignment of the test to the current control without confirmation. All values are lost.
SHIFT+F4 DELETE CONTROL	To delete the current control. There is no confirmation and all the related quality control test results are also deleted.
F10 RETURN	Goes back one screen to either QUALITY CONTROL, or PROGRAMMING. All changes made are saved.

5.2.5 Enter a control and assign the control to a number of tests.



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU,
2. Select F3 PROGRAMMING. If you set a password, the password dialog box appears.
3. Select CONTROLS from the menu and press ENTER. A list of programmed controls appears.
4. Select the next free entry.
5. Press ENTER or double click to call up the screen for programming a new control.
6. The cursor is in the field NAME.
7. Type the name of the control and confirm with ENTER.
8. Type the batch number of the control in the BATCH NUMBER field and press ENTER. The batch number can be found on the insert sheet of the control.
9. Type the expiry date of the control in the EXPIRY DATE field and press ENTER. The expiry date can be found on the insert sheet of the control.
10. Press ENTER to move to the test selection list.
11. Select the test to be assigned using the CURSOR keys or the mouse.
12. Press ENTER or double-click on it to assign it to the control.
13. Enter the TARGET VALUE, the LOW LIMIT and HIGH LIMIT, and select WESTGARD ACTIVE, if necessary.
14. Press F10 RETURN to return to the test list.
15. To assign other tests to the control, place the cursor on the test name and press ENTER or double click. Repeat these steps.

5.2.6 Delete the assignment between a control and a test

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAMMING. If you set a password, the password dialog box appears.
3. Select CONTROLS from the menu and press ENTER. A list of programmed controls appears.
4. Select the test from the test list of the PROGRAM CONTROL screen.
5. Press F3 DELETE TEST.

5.2.7 Change or delete a control (e.g. when the batch/lot number has changed)

To change the details of a control when the batch or lot number of the control changes.

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU,
2. Select F3 PROGRAMMING. If you set a password, the password dialog box appears.
3. Select CONTROLS from the menu and press ENTER. A list of programmed controls appears.
4. Select the test from the test list of the PROGRAM CONTROL screen.

5. Select SHIFT+F2 EDIT CONTROL to edit the displayed control, or SHIFT+F4 DELETE CONTROL to delete it without confirmation.

ATTENTION
The existing results of the quality control are lost if the control is changed or deleted.

5.2.8 Westgard Rules

The Westgard rules used on the analyzer are valid only for single controls. They evaluate the quality controls according to the following rules:

- If 1 result of the control is outside 3 standard deviations, the Westgard rules are broken.
- If the last 2 control results exceed 2 standard deviations in the same direction (+ or –), the Westgard rules are broken.
- If the last 4 control results exceed 1 standard deviation in the same direction (+ or –), the Westgard rules are broken.
- If the last 10 control results are all located either on the '+' or the '–' side to the mean, the Westgard rules are broken.
- If one test result of the control is within 2 standard deviations, the Westgard rules are not broken.

The Westgard rules are not violated in all other cases.

5.3 Program Test

5.3.1 Introduction

All entries for each method are recorded in the PROGRAM TEST menu. The analyzer can give correct results only if the correct test parameters from the method sheets are entered. The analyzer is delivered with a set of pre-programmed parameters. Please contact your reagent supplier to confirm that these parameters are applicable for their reagents. To modify a test or to add a new test, use the PROGRAM TEST menu and the parameters given in the method sheets.

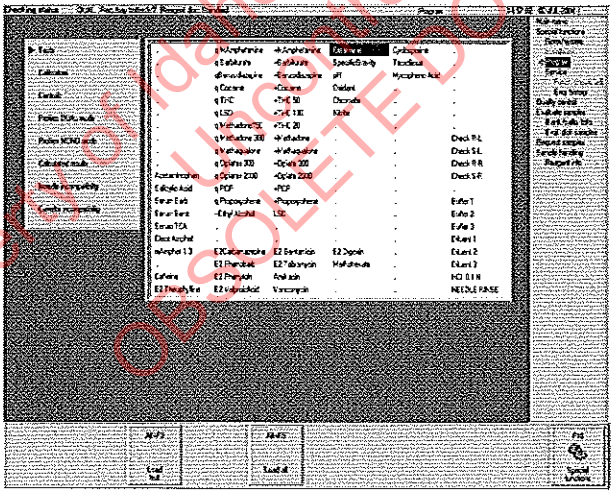
Note

The programming of test parameters is password protected. Please contact the Technical Assistance Center for information or guidance.

The PROGRAM TEST screen consists of three pages. Page 1 contains the global values that are independent of the mode. These values must be set to the values given in the respective method sheet. Page 2 is for values that are required for DUAL MODE. Page 3 is for values that are required for MONO MODE. Complete the pages as required for either dual or mono mode applications. Parameters values are saved to hard disk. Changes to the values will overwrite existing values without confirmation. The retrieval of the "old " parameters values is not possible unless a back up of the test parameters has been made.

5.3.2 Open and protected channels

In the programming menu there are 112 positions available for programming tests. The last 8 positions cannot be used for test programming. They are reserved for liquids such as diluents, buffer solutions or cleaning liquid in the reagent rotor. Displayed is an example of how the list of tests in PROGRAMMING menu may be displayed.



The first 10 positions are so-called "open channels". You can choose which tests to program on these positions and edit all parameters.
The remaining positions are so-called "closed channels'. The tests on these positions are pre-configured and cannot be deleted or moved. However, some of the parameters for these tests, for example reagent volume, absorbance limits, etc. can be changed This is only possible after entering level 2 password (refer to chapter 3.2.5, Define passwords).

5.3.3 Load or save Parameters

It is possible to either load and save the parameters for all tests at once or for individual tests.

The analyzer is delivered with a test parameter data set on CD-ROM. On this medium the parameters are stored in a file with the extension DAT. These files are binary files that cannot be modified. You can copy them to and from any DOS or Windows compatible computer.
When loading or saving all parameters the following information is loaded or stored:

- All test parameters.
- All calibrators (including the programmed concentrations for each parameter).

Note
When loading test parameters the calibration curve is no longer valid. You must perform a new calibration for each loaded test.

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU,
2. Select F3 PROGRAMMING. If you set a password, the password dialog box appears.
3. Select TEST PROGRAMMING from the menu and press ENTER. The load and save key functions appear.
4. Select one of the following:

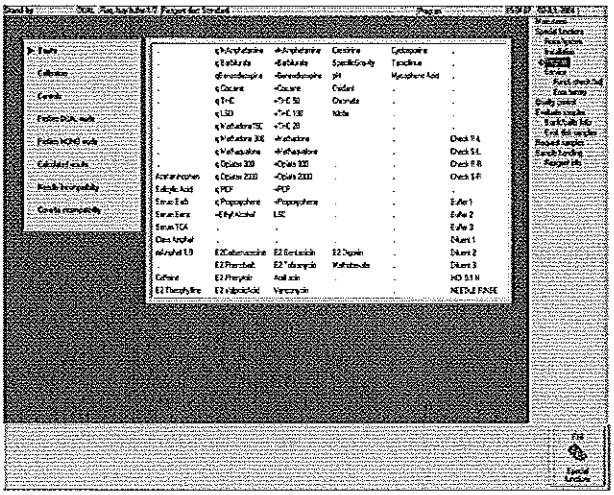
Note
If a test already exists at the same position, it will be overwritten without notice upon loading.

- SHIFT+F4 SAVE CURRENT TEST PARAMETERS
- SHIFT+F6 SAVE ALL PARAMETERS
- ALT+F3 LOAD CURRENT TEST PARAMETERS
- ALT+F5 LOAD ALL PARAMETERS

5.3.4 Parameter load and save function keys

ALT+F5 LOAD ALL PARAMETERS	This key combination loads all parameters from the data set. Existing parameters in the parameter directory will be overwritten.
SHIFT+F6 SAVE ALL PARAMETERS	This key combination saves all parameters from the directory on your hard disk to the selected data medium. This key combination is hidden and means the function is not visible on the screen. Press Shift+F6 from the keyboard.
ALT+F3 LOAD CURRENT TEST PARAMETERS	This key combination loads the selected parameters from the data medium. Existing parameters on the parameter directory will be overwritten.
SHIFT+F4SAVE CURRENT TEST PARAMETERS	This key combination saves the selected parameters from the directory on your hard disk to the selected data medium. This key combination is hidden and means the function is not visible on the screen. It is only possible from the key-board, press Shift+F4.

5.3.5 Program a test



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAMMING. If you set a password, the password dialog box appears.
3. Select TESTS from the menu and press ENTER. A list of programmed tests appears.
4. Press TAB or ENTER to move the cursor to the list of tests.
5. Select an empty position to define a new test using the cursor keys or the mouse.
6. Press ENTER or double click on the selected position to call up the PROGRAM TEST screen.
7. The first page of the PROGRAM TEST screen is shown.
8. Enter the test parameters in all three pages according to the respective method sheet here.
9. Select F10 RETURN to return to the PROGRAM menu.
   Repeat these steps to program additional tests.

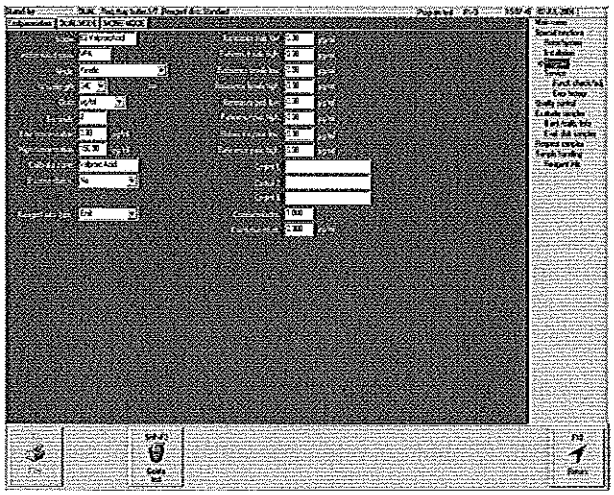
Note
Enter the parameters exactly as in the method sheets.

5.3.6 Modify an existing text

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAMMING. If you set a password, the password dialog box appears.
3. Select TESTS from the menu and press ENTER. A list of programmed tests appears.
4. Press TAB or ENTER to move the cursor to the list of tests.
5. Select the position to modify a test using the cursor keys or the mouse.
6. The first page of the PROGRAM TEST screen is shown.
7. Move the cursor to the corresponding field.
8. Make the necessary changes to the parameters.
9. Select F10 RETURN to return to the PROGRAM menu
10. Select F10 SPECIAL FUNCTIONS to return to the SPECIAL FUNCTIONS menu
    Repeat these steps to modify additional tests.

Note
Enter the parameters exactly as in the method sheets.

5.3.7 Test programming parameters



The programming of twopoint and endpoint tests is for the most parameters identical to kinetic test. However, depending on the selected measurement mode (Kinetic, Two-point, end-point) some fields are not applicable and therefore are not displayed.
Differences are described in the following section.

NAME	The name of the test. You must enter text to this field to a maximum of 15 characters. If no name is entered, the test parameters will not be stored.
ABBR. NAME	The abbreviated form of the test name. You must enter text to this field to a maximum of four characters. If no name is entered, the test parameters will not be stored.
MODE	Select the measurement mode from the drop down list. KINETIC, ENDPOINT - MONOCHROMATIC, ENDPOINT - BICHROMATIC, TWOPOINT.
WAVELENGTHS	Select the wavelength as given in the method sheet from the drop down list. The drop down list contains all available wavelengths. If ENDPOINT - BICHROMATIC is chosen at the parameter Mode, two drop down lists appear. Select both wavelenghts as indicated in the method sheet.
UNITS	Select the desired unit from the drop down list. All test results will be displayed and printed using this unit.
DECIMALS	Select the number of decimal places for patient or control data used in display and printout. If the test has not been calibrated or if the factor is exactly 1, the analyzer automatically selects 3 decimal places. In this case the unit is selected in accordance with the selected test method: absorption for endpoint tests, delta absorption for twopoint tests, delta absorption per minute for kinetic tests.
LOW CONC.	The value for the low limit of the measuring range from the method sheet. If the result falls below of the set limit, an error message is given.

HIGH CONC.

The value for the high limit of the measuring range from the method sheet. If the set limit is exceeded, an error message is given and the analyzer will do a re-test depending if Automatic Rerun is selected in the System Parameters menu an automatic re-test with the rerun parameters will be performed.

CALIBRATOR NAME

If the test has to be calibrated, a calibrator must be selected from the list of pre-programmed calibrators. Press ENTER and a drop down list with all calibrators appears. Press ENTER again and select the appropriate calibrator using the cursor keys or the mouse. After a calibrator has been selected the PROGRAM CALIBRATOR screen appears. Refer to 1.5.2, Reagents and calibrators.

PROZONE CHECK

The prozone effect can occur in tests based on the principle of the formation of an antigen-antibody complex (agglutination), e.g. in Ig tests. The effect often occurs in patient samples with a very high antigen content. The surplus of antigen inverts the reaction direction (de-agglutination) and causes incorrect measurement values for the sample. To avoid this, the analyzer offers a prozone check function.
Press ENTER and a drop down list with all prozone options appears:

- No
- Min. dAbs ratio
- Min. Abs ratio
- Max. dAbs ratio
- Max. Abs ratio.

If either MIN. DABS RATIO or MAX. DABS RATIO (dAbs = Delta Absorbance) is selected, the analyzer calculates the respective delta absorbencies of 2 x 3 measurement points at two different points in time (Prozone points 1 and 2). Both delta absorbance values are divided and then multiplied with the factor: 100 ((delta absorbance proz. point 1/delta absorbance proz. point 2) x 100).
The result percentage is called DELTA ABSORBANCE RATIO. If MIN. DABS ratio is selected and the result falls below the set minimum rate (e.g. 80%) or if the MAX. DABS ratio is selected and the result exceeds the set maximum ratio, the analyzer detects a PROZONE ERROR and marks the corresponding result with a prozone flag.
If the MIN. ABS RATIO or MAX. ABS RATIO is selected, the analyzer calculates the respective absorbance of 2 x 1 measurement points at two different points in time (Prozone points 1 and 2). Again both values are divided and then multiplied with 100. The further calculation operations are identical with those of the delta ABSORBANCE ratio. If a prozone error is detected by the system, the corresponding result will be marked with a flag.

MINIMUM RATIO
MAXIMUM RATIO

The percentage minimum or maximum ratio – depending on the selection in Prozone check – of the two absorbance values (or delta absorbencies) calculated by the system. If this value is exceeded, the analyzer detects a prozone error and marks the corresponding result with a prozone flag. The default setting is 80%.

The other prozone parameters are entered on pages 2 (DUAL MODE) and 3 (MONO MODE) and are described there.

REAGENT ROTOR TYPE	Select the type of rotor. **Emit** and **classic** are available. An Emit rotor has 26 positions for reagent bottles, a classic rotor has 32 positions. Information about the different bottle sizes are given in the field description for the R1 BOTTLE in 5.3.8, Dual mode and mono mode parameters.
REF. MALE LOW	The low limit of the reference range for male samples. If a measured value is below this limit, the analyzer flags the result.
REF. MALE HIGH	The high limit of the reference range for male samples. If a measured value is above this limit, the analyzer flags the result.
REF. FEMALE LOW	The low limit of the reference range for female samples. If a measured value is below this limit, the analyzer flags the result.
REF. FEMALE HIGH	The high limit of the reference range for female samples. If a measured value is above this limit, the analyzer flags the result.
REF. PED. LOW	The low limit of the reference range for pediatric samples. If a measured value is below this limit, the analyzer flags the result.
REF. PED. HIGH	The high limit of the reference range for pediatric samples. If a measured value is above this limit, the analyzer flags the result.
REF. PANIC LOW	The low panic limit of the reference ranges for all types of samples. If a measured value is below this limit, the analyzer flags the result only on the printout if the report set-up is enabled.
REF. PANIC HIGH	The high panic limit of the reference ranges for all types of samples. If a measured value is above this limit, the analyzer flags the result only on the print-out if the report set-up is enabled. Note The respective Ref. high value must always be greater than the corresponding Ref. low value! If a low and a high limit are identical the analyzer will not check these limits and will not flag the results.

Note
The respective Ref. high value must always be greater than the corresponding Ref. low value! If a low and a high limit are identical the analyzer will not check these limits and will not flag the results.

CONTROL 1 CONTROL 2 CONTROL 3	A maximum of three controls can be assigned to one test. Press ENTER or double-click in one of the fields, the analyzer displays the PROGRAM CONTROL screen. Refer to 5.3.11, Program Test Control Parameters.
CORRELAT. FACTOR	The correlation factor is a calculation factor used internally by the system. The system multiplies the result of the measurement with the value entered in this field. The standard setting is 1.000; it is also the normal value for all methods with a quantitative evaluation. No correlation factor is required, if a qualitative evaluation (cut-off) was selected for the corresponding test.

CORRELAT. OFFSET

The value entered in this field is a calculation value used internally
by the system. The system adds the correlation offset as a constant value to the result of the multiplication of measuring result and correlation factor:

MEASURED RESULT X CORRELATION FACTOR + CORRELATION OFFSET
=
FINAL RESULT

The default setting and the normal value for all methods is 0.000. The correlation factor is not used for cut-off tests.

Note

The difference (Bias) between individual methods on different analyzers can be balanced out by means of the correlation factor and correlation offset.

5.3.8 Dual mode and mono mode parameters

The functions of the individual parameters for DUAL MODE and MONO MODE are identical. Only the fields for the second and third reagent and the field Substrate depletion are missing on the MONO MODE screen.

Note

In the DUAL MODE screen up to 3 reagents can be programmed for each test. The order of dispensing is as follows.
Reagent 1 or buffer
Sample
Reagent 2 (optional)
Reagent 3 (optional)
Instead of Reagent 1, a buffer solution can be used. 1 of 3 different buffer solutions can be chosen. Do not forget to position the buffer solution in the REAGENT POSITION menu, otherwise the corresponding test cannot be requested in the REQUEST SAMPLES menu

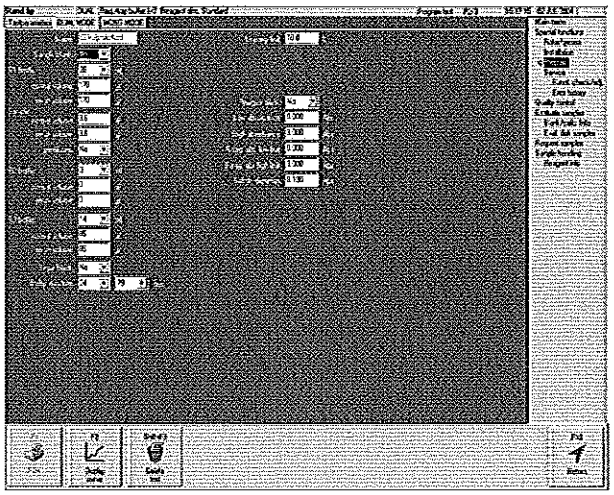
This chapter explains the parameters that need to be programmed in the MONO MODE and DUAL MODE screens. The programming depends on the modes selected and used. When the analyzer is used in dual mode, complete the parameters in the DUAL MODE screen. When in mono mode, complete the parameters in the MONO MODE screen.

NAME

The test name as set on Screen Page, 1 TEST PARAMETERS.

SAMPLE BLANK

Select whether to measure a sample blank in a separate cuvette for the corresponding test. Obtain the information from the test method sheet if a sample blank measurement is needed.
Press ENTER in this field, select Yes or No from the drop down list and press ENTER again to confirm. If you select Yes, DUAL MODE screen pages and the MONO MODE screen page show fields for parameters regarding the sample blank. For a description of these parameters see later in this chapter.
The sample blank reagent (or dummy reagent) is treated as a normal reagent regarding placement on the reagent rotor and incompatibilities. The dummy reagent is distinguished from the normal reagent by superscripted ^{D} in front of the reagent name, e.g.
TBIL= normal reagent for Bilirubin
^{D}TBIL= dummy reagent for Bilirubin



R1 BOTTLE

Press ENTER to show a drop down list of the available bottle sizes and buffers.
Select a buffer or one size for reagent 1 bottle.
If EMIT was selected at the parameter reagent rotor type in Testparameters screen, the different bottle sizes and buffers that can be used are: BUF1; BUF2; BUF3; 28 ml; 14 ml; 6 ml; 3 ml.
If classic was selected at the parameter reagent rotor type in Testparameters screen, the different bottle sizes and buffers that can be used are:BUF1; BUF2; BUF3; 50 ml; 25 ml; 5 ml.

NORMAL VOLUME

Enter a reagent volume between 220 µl (or with R2 110 µl) and 399 µl.
Enter the volume in steps of 1 µl. The total of the normal reagent volume (R1, R2 and R3) and normal sample volume may not be less than the cuvette's minimum volume (220 µl), otherwise the entry in this field is automatically increased to a total volume of 220 µl. The maximum volume is 400 µl.

RERUN VOLUME

The reagent volume for a rerun. Enter a reagent volume between 220 µl (or with R2 and R3110 µl) and 399 µl. The analyzer needs this to perform an automatic rerun, if necessary. Enter the volume in steps of 1 µl. The total of the normal reagent volume (R1, R2 and R3) and normal sample volume may not be less than the cuvette's minimum volume (220 µl), otherwise the entry in this field is automatically increased to a total volume of 220 µl. The maximum cuvette volume is 400 µl.

SAMPLE NORMAL VOLUME

Enter the normal sample volume in 0.1 µl steps between 1 and 30 µl. It is recommended not to enter a sample volume less than 3 µl.

SAMPLE RERUN VOLUME

Enter the sample rerun volume in 0.1 µl steps between 1 and 30 µl. Do not enter a sample rerun volume less than 2 µl. The analyzer needs this value to perform an automatic rerun, if necessary. The analyzer corrects the rerun results according to the reduced sample ratio.

R2 BOTTLE

As with R1, depending on the rotor type selection, a choice can be made between 3 or 4 bottle sizes. Every test that has the reagent volumes programmed at this parameter Reagent 2, requires an extra instrument cycle, thus decreasing the throughput. It is advised, that if a test needs two reagents to program the reagent volumes, to use R1 Bottle and R3 Bottle reagent volume parameters.

Note

A bottle size must always be selected. If a reagent is not used, select a bottle size and enter 0 µl for the normal and the rerun volume.

NORMAL VOLUME

Enter a volume between 0 and 180 µl.

RERUN VOLUME

Enter a rerun volume between 0 and 180 µl

R3 BOTTLE

As with R1 and R2, a choice can be made between 3 or 4 bottle sizes. If you only program R1 Bottle reagent volumes and R3 Bottle reagent volumes, on the bottles it can say "Reagent 1" and "Reagent 2" or something similar.

NORMAL VOLUME

Enter a volume between 0 and 180 µl.

RERUN VOLUME

Enter a rerun volume between 0 and 180 µl

PREDILUTION

The sample can be prediluted in the DUAL MODE only. Press ENTER in this field and select a pre-dilution ratio (1:5, 1:10, 1:20, 1:30, 1:40, 1:50, 1:100 or NO for no pre-dilution) from the dropdown list. E.g. A dilution ratio of 1:5 means 1 part of the sample diluted with 4 parts of diluent that results in 5 parts of solution. Confirm with ENTER. If you selected a ratio, a field appears, from which you have to select the diluent. Press ENTER to open the list of diluents (DIL 1, DIL 2, DIL 3), select one diluent from the list and press ENTER again to confirm your selection.

Note

The selected diluent must be positioned in the REAGENT POSITION DUAL MODE menu. A bottle with the diluent has to be placed in the corresponding position on the reagent rotor.

When predilution is used, the instrument uses an extra cycle for preparation of the diluted sample. In the first cuvette diluent is dispensed and sample is added and mixed. In a second cuvette the reagent is dispensed. The sample needle will pick up the diluted sample from the first cuvette and add it to the reagent in the second cuvette.
The sample volume set at the parameter SAMPLE NORMAL VOLUME and SAMPLE RERUN VOLUME refers to the volume of the diluted sample with a maximum of 15 µl. The instrument itself determines how much concentrated sample and diluent will be picked up.

DELAY, MIN.TIME

Kinetic Measurement Mode. Press ENTER to open a drop down list with incubation times (values in seconds).
If only one reagent is used, the incubation time is the time interval between the addition of the sample and the measurement of the first point that is used for calculation.
If two or more reagents are used, the incubation time is the time interval between the addition of the last reagent and the measurement of the first point that is used for calculation. Select a minimum incubation time from the second drop down list. The minimum incubation time is amount of seconds the measurement takes place after the delay time (incubation time). It defines how many measurement points are used for the calculation.

If no linearity error has been detected on the first four measurement points after the beginning of incubation, the analyzer uses the measurement points which lie between the incubation plus the minimum time entered here. E.g. 50 seconds is entered as delay and 186 seconds for the minimum time, the analyzer measures the first point that will be used for the calculation 50 seconds after the last reagent addition, and the last point at 236 seconds.

If, the instrument detects a linearity error on the first measurement points, the analyzer uses as many points as possible for the calculation (even after the minimum time). In both cases, (linearity error or no linearity error detected for the first four measurement points), the analyzer uses as many measurement points as possible (min. 4) until either the curve decreases, the absorbance limits are exceeded or the substrate is depleted.

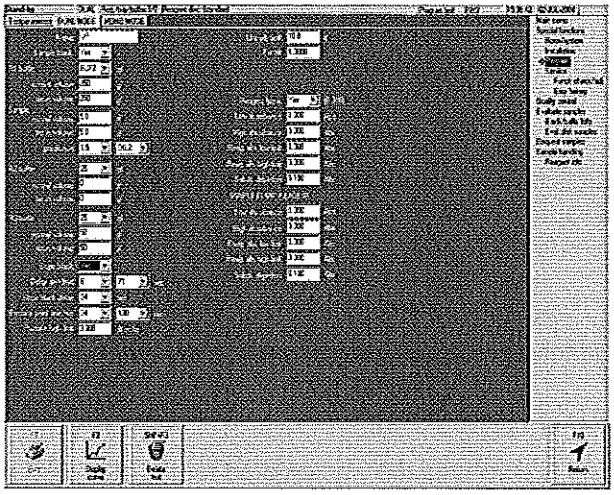
INCUBATION TIME

Endpoint Mode. If only R1 bottle reagent volumes are programmed, you can select between 11.5 min. and 4.5 min. If R3 bottle reagent volumes are programmed, the incubation time is fixed to 6.5 min. The incubation time refers to the time from addition of the last reagent for dual and triple reagent tests, or sample for mono reagent tests, to the endpoint measurement.

SLOPE BLANK	If R3 bottle reagent volumes are programmed and the R2 bottle reagent volumes are set to 0 (so not programmed), you can select whether to use a SLOPE BLANK. Press ENTER, select Yes or No from the drop down list and press ENTER to confirm. If Yes is selected, the analyzer subtracts the slope, calculated before the second reagent was added, from the slope that was calculated after R2 was added. The slope blank can also correct for a side reaction between sample and the first reagent.
SLOPE BL. DELAY	Appears if SLOPE BLANK was selected with Yes. Press ENTER and select a time in seconds. Press ENTER to confirm. E.g. 50 is selected, the analyzer will use all the measurement points after 50 seconds from the addition of the sample for the calculation of the blank slope. The result of the blank slope is subtracted from the reaction slope (after addition of R2), when the results are calculated.
POINT ONE, TWO	Twopoint Mode. Point one is the delay to the start of the first measurement. Point two is the time to the second measurement point. For both Point 1 and Point 2, press ENTER, select a value and press ENTER again to confirm. The times listed represent the time after sample addition (for mono-reagent tests) or the time after the addition of the last reagent (for dual and triple reagent tests). A negative value at point 1 describes a measurement point just before the addition of the sample or reagent. If > 0 was entered for the reagent 2 bottle in the field normal volume the values refer to the time after reagent 2 was added. If not, then the values refer to the time after the sample was added.
PROZ. PT ONE,TWO	If an absorbance ratio or delta absorbance ratio were selected in the field PROZONE CHECK (page 1, Test Parameters), the field PROZ. POINT 1,2 is displayed here. Press ENTER to open a drop down list, select the time in seconds for the measurement of the first prozone point and confirm with ENTER. Repeat for the second point in the other field.
PROZ. H. LIMIT	If an absorbance ratio or delta absorbance ratio were selected in the field PROZONE CHECK (page 1, Test Parameters), the field PROZ. H.LIMIT is displayed here. Enter a high limit in form of an absorption or delta absorption per minute and confirm with ENTER. If this limit is exceeded, the analyzer displays a prozone error.

Note

When predilution is selected here only patient and/or control samples will be prediluted with the specified ratio. Predilution of the calibrators has to be defined separately in the Calibrator selection window.



LINEARITY LIMIT

The limit is used to detect a linearity error on the first four measurement points and to evaluate those measurement points of a kinetic test that can be accepted for evaluation. The default value is 10%.

FACTOR

For methods that do not require calibration, the multiplication or enzymatic factor from the method sheet must be entered here. The factor is negative for a decreasing reaction. If a method uses a one-point-calibrator, the factor is automatically calculated and displayed in this field. If the factor is exactly 1.000, the analyzer concludes that the test was never calibrated. The results of this test are printed out with 3 decimal places and the unit abs, dabs or dabs/m (depending on the type of test, endpoint, twopoint, kinetic).

REAGENT BLANK

Select whether or not a reagent blank measurement is to be used. Press ENTER, select YES or NO from the drop down list and press ENTER again to confirm. If you selected to carry out a blank measurement, a number after YES appears that will contain the result of the reagent blank after the measurement.
The reagent blank is the unspecific change in absorbance in the reagent solution if water is used as the sample. The result is subtracted from the absorbance change of the reaction with the sample.

Note

Do not confuse the reagent blank with the absolute absorbance measurement of the first reagent just before the addition of the sample, which automatically takes place for every test provided R1 volume > 220µl.

LOW ABSORBANCE

The low absorbance limit to be used. If the measured value is below this limit, the analyzer flags the result. An automatic rerun of the test starts if the Automatic Rerun option was selected in SYSTEM PARAMETERS.

HIGH ABSORBANCE

The high absorbance limit to be used. If the measured value is above this limit, the analyzer flags the result. An automatic rerun of the test starts if the Automatic Rerun option was selected in SYSTEM PARAMETERS.

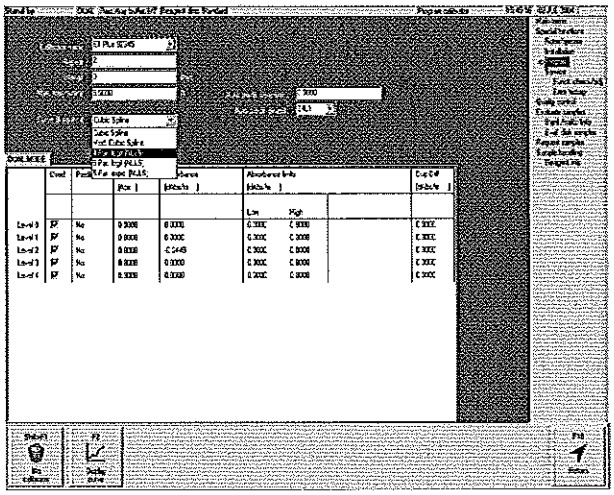
R. Abs. L. Limit	The Reagent absorbance low limit that is given in the method sheet. It is used to check the absorbance of the first reagent. If the measured value is below this limit, the analyzer flags the result.
R. Abs. H. Limit	The Reagent absorbance high limit that is given in the method sheet. It is used to check the absorbance of the first reagent. If the measured value is above this limit, the analyzer flags the result.

Note
If the respective low and high limits are identical, no check will be performed by the system.

R. Abs. Deviation	This field is displayed if 0 was entered for the R2 or R3 bottle in the field normal volume. The value is only used for decreasing reactions. Here, the maximum deviation of the calculated (extrapolated) reagent absorbance value from the measured reagent absorbance value (point measured before the sample is added) is entered. The set value ensures detection of substrate consumption. If the extrapolated reagent absorbance falls below the measured reagent absorbance minus the programmed reagent absorbance deviation, the result is marked with an error flag. If the reaction increases, it is recommended to enter 3.000 abs.
Substrate depletion	If a value > 0 was entered for the R2 or R3 bottle in the field normal volume, this field will be displayed instead of R. Abs. Deviation. Enter the value given in the respective method sheet. If the reaction increases, the analyzer adds this value to the point measured before the last reagent was added; the resulting absorbance is the substrate depletion limit for this measurement. If the reaction decreases, the analyzer subtracts this value from the last point measured before the last reagent was added; the resulting absorbance is the substrate depletion limit for this measurement. If this value is exceeded while the analyzer measures the first four kinetic points, the error message Substrate depletion will be displayed in the results report. The analyzer uses all absorbance values to calculate a result that has not exceeded the programmed limit value.

5.3.9 Program Test Calibrator Parameters

After a calibrator has been selected in page 1 of the test parameter-programming screen all parameters that apply to this test must be programmed. The following screen appears:



1. Select CALIBRATOR NAME from the PROGRAM TEST screen.
2. Press ENTER to open the PROGRAM CALIBRATOR screen.
3. Select the calibrator from the CALIBRATOR NAME drop down menu.
4. Enter the calibrator parameters according to the respective method sheet here.
5. Select F10 RETURN to return to the PROGRAM TEST screen.

CALIBRATOR NAME	Select the calibrator that is needed. All calibrators that are programmed in the PROGRAM CALIBRATOR menu can be selected.
REPEAT	Type the number of repeats 1 for a single measurement, 2 for a duplicate measurement, or 3 for a triplicate measurement. If duplicate or triplicate measurements are defined, the average value from the measurements will be used for the calculations. The number entered here will also define if the reagent blank is run in duplicate or triplicate. Enter a value and confirm with ENTER.
INTERVAL	Enter the calibration interval in days (0 to 99) as shown in the method sheet. This number is the period in days when the method has to be re-calibrated. The analyzer includes the remaining days to the next calibration on the list with the daily blank measurement results. If 0 has been entered here, the analyzer only prints the test name without a mark on the list above and does not check the calibration interval.

Note
If the calibration interval has exceeded, the analyzer will use the old calibration factor or curve.

MAX INACCURACY	Any value is indicated as a percentage. This value is a measure for the maximum inaccuracy of only the fit of the cubic spline curve. The lower the value the more the curve will be forced to go through the calibrator points. The value defaults to 5%.

AUTO PREDIL. CONCENTR.	Enter the concentration of the parent calibrator, so the concentration matches that of the calibrator before the actual dilution. The instrument will automatically calculate the concentration when a dilution ratio is selected at the PREDILUTION parameter for the individual calibrator points. This field is only indicated if AUTO PREDIL is selected in the PROGRAM CALIBRATOR menu.
AUTO PREDIL. DILUENT.	Select the diluent which is to be used for the automatic dilution. Press Enter to open the list of diluents (DIL 1, DIL 2, DIL 3), select one diluent from the list and press ENTER to confirm your selection. This field is only indicated if AUTO PREDIL is selected in the PROGRAM CALIBRATOR menu.
CURVE FIT MENTHOD	Press ENTER in this field and select the calibration algorithm from the drop down list. Confirm with ENTER. This field is only available if three or more calibrators are used. Refer to 4.3.7, Calibrators and Controls.
USED	The user can use one multi analyte, multipoint calibrator set for different tests to calibrate a range of tests. Calibrator levels that are not needed to calibrate a test can be excluded from the calibrator set. Select the checkboxes to specify the levels to be used for a certain test.

Note

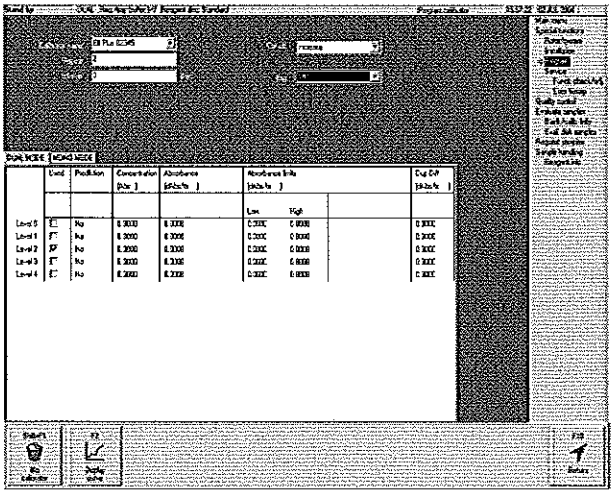
Calibrators for some methods have more than one analyte. Each calibrator level may contain three or four analytes in each sample bottle. With the multiple test calibration, a set of calibrators are loaded to the analyzer and used to calibrate a number of methods without the need to load more calibrators.
The user needs to load all the calibrator standards once. The Used column lists all the calibrator standards that are with a particular calibrator.

PREDILUTION	Press ENTER in this field and select a pre-dilution ratio from the drop down list. (for example: 1:5 means one part sample and four parts diluent). Confirm with ENTER.
CONCENTRATION	Enter the concentration of the calibrator standards (1 to 9 standards). These are the same units as selected in page 1 (Test Parameters)
ABSORBANCE	The analyzer automatically sets the values in this column after calibration. It is possible to fill in values copied from a previous calibration or another system manually. Results based on manually entered values may be invalid. The units here depend on the test; kinetic, twopoint or endpoint.
ABSORBANCE LIMITS LOW/HIGH	Enter the absorbance limit for each individual standard. If a measurement exceeds the specified limits, the analyzer displays an error message (calibration limits violated). This is used to check if a standard has expired or if standards accidentally are exchanged. If the same value is entered in both fields (e.g. 0.000), the calibration limits will not be checked.

DUP-DIFF	Enter the maximum allowable difference between replicate measurements of one calibrator point. When the value is greater than the maximum allowed difference, the calibration is not accepted and one or all the replicates must be re-measured. If a value of 0.000 is entered, then the Dup./Diff limit will not be checked.
SLOPE/INTERCEPT	TwoPoint calibration. These values represent the slope and the offset of the calibration line for a 2-point calibrator. The analyzer will automatically set the values in this column after calibration. It is possible to fill in values copied from a previous calibration or another system manually. Results based on manually entered values may be invalid.
F2 DISPLAY CURVE	Displays a graphical representation of the calibration curve. Refer to 5.3.12, Calibration curves algorithms.
SHIFT+F1 NO CALIBRATOR	Deletes the assignment of the current calibrator to the test. You may select a different calibrator in the TEST PARAMETERS screen
F10 RETURN	Goes back one screen to PROGRAMMING. All changes made are saved.

5.3.10 Program cut-off tests

The Cut-off tests option becomes available when the number of standards defined in the calibrator programming is one. The CUT-OFF parameter must be selected in PROGRAM CALIBRATOR to define that the results are either qualitative or quantitative.
The result for a cut-off test is always the measured absorbance value (or delta absorbance or delta absorbance per minute, depending on the type of test) and, as a flag, a positive or negative result.



1. Press ENTER in the field TARGET.
2. Select either NO, (No cut-off test) INCREASE or DECREASE from the drop down list.
3. Press ENTER to confirm.
   When Increase or Decrease is selected, the measured (delta) absorbance is given as a **positive** or **negative** result.

   1. If Increase is selected and the measured (delta) absorbance is higher than the value of the cut-off calibrator, the result is a **positive** one.
   2. If Increase is selected and the measured (delta) absorbance is lower than the value of the cut-off calibrator, the result is a **negative** one.

   The opposite occurs if Decrease is selected.

Note
When the cut-off parameter for a single calibrator is set to Increase or Decrease, then the further parameter field shows; flag.

4. If the parameter flag shows, do as follows:
   1. Press ENTER in the field FLAG.
   2. Select YES or NO from the drop down list.
   3. Press ENTER to confirm.

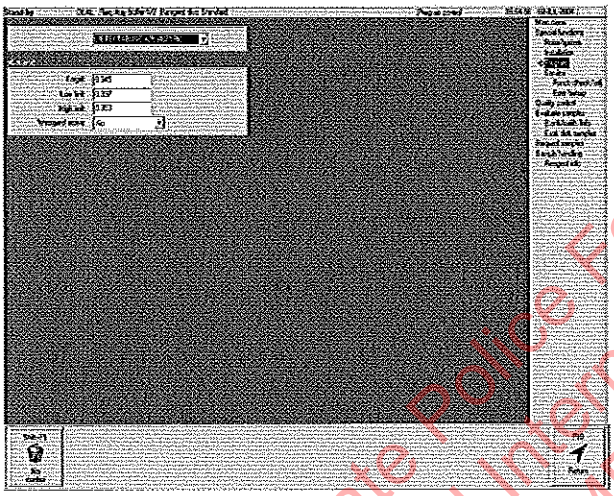
   If YES is selected, you have the option to define a grey area parameter called the CUT-OFF DEVIATION in PROGRAM TEST - DUAL MODE and MONO MODE.
   When the difference between the result and the measured value of the calibrator is within the cut-off deviation, the flag E is printed in the results report.
5. Confirm your selection and return to the previous menu with F10 RETURN
6. Set remaining controls if necessary.

The following parameters apply on pages 2 and 3 of the TEST PROGRAMMING screen if cut-off and flag has been selected in the program calibrator screen.

CUT-OFF VALUE	The result of the calibration. The analyzer displays the value after the cut-off calibration. It is possible to fill in values copied from a previous calibration or another system manually. Results based on manually entered values may be invalid.

CUT-OFF DEV	Enter the Cut-off deviation that causes a flag. Example: The result of a cut-off calibration was calculated to **0.120 delta abs/m**. The cut-off was programmed as: Yes; Increasing; flag: Yes; cut-off deviation: **+/- 0.010 delta abs/m**. The result of the sample is: **0.112 delta abs/m** Negative, since 0.112 is lower than 0.120. The result flagged with an E as the deviation is **-0.008 delta abs/m** and is in the range of **0.120 +/- 0.010 delta abs/m**.

5.3.11 Program Test Control Parameters



1. Select CONTROL 1 2 or 3 from the PROGRAM TEST screen.
2. Press ENTER to open the drop down list.
3. Select one control and press ENTER again.
4. Enter the Target value and the Low and High Limit. The respective values are given in the insert sheet for the control.
5. Select YES from the Westgard active drop down list to evaluate the control results to Westgard rules.
6. Confirm your entry and return to the TEST PARAMETERS screen by pressing F10 RETURN.

Additional controls can be programmed as described above. To delete a selected control, press SHIFT+F1 NO CONTROL in the PROGRAM CONTROL screen.

5.3.12 Calibration curves algorithms

The analyzer provides the following different curve methods:

- Cubic Spline
- Modified Cubic Spline
- 4 Par. logit (NLLS)
- 5 Par. logit (NLLS)
- 5 Par. expo. (NLLS)

In the following, the mathematical model for each of the calibrations curves methods is given.

Cubic spline and modified cubic spline

$$A = a(I) + b(I)(C - C(I)) + c(I)(C - C(I))^2 + B(I)(C - C(I))^3$$

Where:

A =	Measured absorbance value or absorbance variation rate of standard solution (except Std 1 solution)
B =	Calibration curve parameter (measured absorbance value or absorbance variation rate of Std 1)
a,b,c =	Calibration curve parameters
a(I), b(I), c(I), d(I)	Calibration curve parameters used only in spline. These parameters are determined according to the standard solution numbers I and I + 1. (1 = I = 5)

The difference between the two cubic spline methods is found in the absorbance units. The modified cubic spline is calculated with milli-Absorbance units and the cubic spline is calculated with Absorbance units.

4 Par. logit (NLLS)

$$R=Ro+K*(1/(1+\exp[-(a+b*\ln C)]))$$

5 Par. logit (NLLS)

$$R=Ro+K*(1/(1+\exp[-(a+b\ln C+cC)]))$$

5 Par. expo. (NLLS)

$$R=Ro+K*\exp[a*(\ln C)+b(\ln C)^2+c*(\ln C)^3]$$

Where:

a,b,c =	Calibration curve parameters
R =	The rate of change of absorbance (measured rate)
Ro =	The predicted rate for a calibrator with zero concentration
C =	The actual concentration for a calibrator or a sample

5.3.13 Absorbance check for calibrated tests

After a method calibration, an automatic rate check is initiated. The following limits are set:

- Low rate limit = Lowest calibrator rate - 1%
- High rate limit = Highest calibrator rate + 1%

When a test violates these limits after the calibration, then the results will show as 0.00 and 9999.0 and displayed with the OVFL flag. The results 0.00 and 9999.0 defined as

- 0.00 = result is lower than the lowest standard
- 9999.0 = results is higher than the highest standard

Note

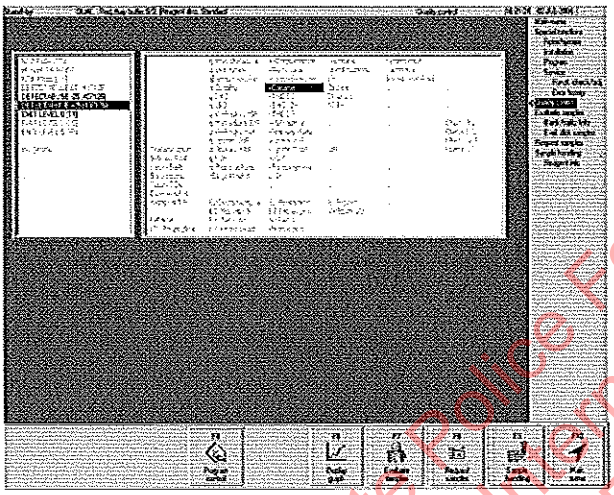
These limits are calibrator related and do not appear in the test parameters. Do not mix them with the general absorbance limits which are method related and are displayed as flagged results (< or >)

5.4 Quality Control

5.4.1 Introduction

The QUALITY CONTROL menu gives an overview of all measured control data. Any one of three controls previously assigned to a test in PROGRAM CONTROL can be selected to view the test statistics in GRAPHIC MODE, and can be printed. Quality control is not available for incomplete tests. Quality control is available during measurement.

5.4.2 Start Quality Control



1. Select F6 QUALITY CONTROL from the MAIN MENU.

5.4.3 Quality Control Parameters

CONTROL FIELD (LEFT-HAND SIDE OF SCREEN)	All controls in PROGRAM CONTROL (max. 15) are displayed in grey. All controls connected to a selected test are displayed in black.
DISPLAY FIELD (RIGHT-HAND SIDE OF SCREEN)	All programmed tests (max. 55) are displayed. All tests connected to the selected control are displayed in black. All controls connected to a selected test are shown in black on the left-hand side of the screen.

5.4.4 Quality Control Function Keys

F1 PRINT	Prints the current display. This function is available in graphic or table mode.
F2 TABLE/GRAPHIC MODE	The analyzer moves from the GRAPHIC to the TABLE mode and back.
F3 NXT.TEST SHIFT F3 PRV.TEST	Selects the graphic representation of the next (F3) or the previous (SHIFT + F3) test of the current control.
F4 PROGRAM CONTROL	Activates the program control menu to change the assignments of test and controls.
F6 GRAPHIC/NORMAL MODE	When in QUALITY CONTROL, the results from selected control/test combination are displayed in graphic format. This function is available for valid control/test combinations. When in GRAPHIC MODE, F6 returns to NORMAL MODE. The last 30 measurements are available.

F7 EVALUATE SAMPLES	Goes to the EVALUATE SAMPLES menu.
F8 REQUEST SAMPLES	Goes to the REQUEST SAMPLES menu.
F9 SAMPLE HANDLING	Goes to the SAMPLE HANDLING menu.
F10 MAIN MENU	Returns to MAIN MENU.
TAB	Move between the controls list and tests list.
ENTER	The same as F6 GRAPHIC MODE. If an invalid control/test combination is selected, the message "Illegal combination" will be displayed.
CURSOR KEYS	Move within a list of controls or tests.

5.4.5 Graphic Representation of Quality Control

The analyzer displays a graphic representation of valid control/test combination measurements. A maximum of 30 results per control and test are stored. If more than 30 tests are run, the earliest results are deleted (First In First Out).

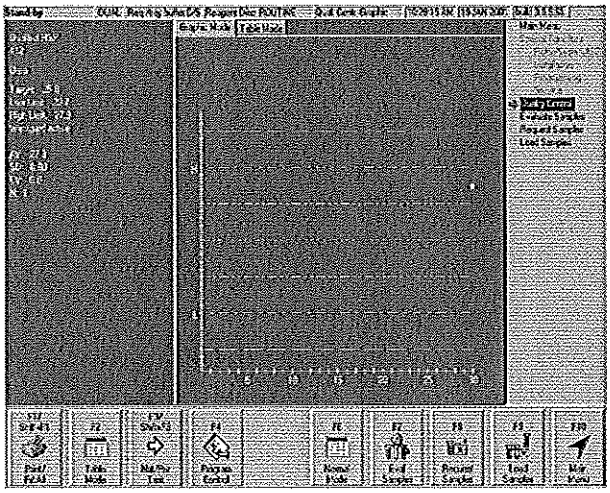
1. Select F6 QUALITY CONTROL from the MAIN MENU. If you set a password, the password dialog box appears.
2. Select the control name.
3. Press TAB
4. Select the test required. Press ENTER.
5. Press F6 GRAPHIC MODE
6. Press F2 TABLE MODE to view the table
7. Press F2 GRAPHIC MODE to view the graph

5.4.6 Fields visible in Graphic and Table Modes (Left Hand Side)

The parameters shown to the left of the graph are as follows:

CONTROL NAME	Displays the name of the control.
BATCH NUMBER	Displays the reagent manufacturers batch number.
TEST NAME	Displays the name of the test assigned to this control.
TARGET	The reference value set in PROGRAM CONTROL.
LOW LIMIT	The low limit as set in PROGRAM CONTROL.
HIGH LIMIT	The high limit as set in PROGRAM CONTROL.
WESTGARD	Displays the status of WESTGARD option.
AV	Displays the mean value of all measured values.
SD	Displays the standard deviation of the measured values.
CV	Displays the coefficient of variation of the measured values as %.
N	Displays the number of control measurements.

5.4.7 Description of the Graphic display (Right Hand Side)

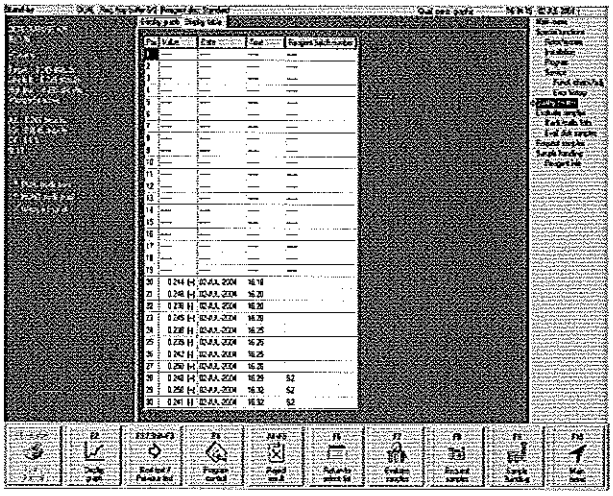


Note

To offer more detailed information about each measuring point, the system provides the following function: move the mouse pointer to the appropriate measuring point (do not click!).
A hint text appears at that position indicating the following: date and time when this measurement point was taken; the reagent batch number and information on which reagent rotor the corresponding assay was positioned (L for left, R for right).

Points on the graph	Each point represents one control measurement with the corresponding test. The quality of the test can be monitored from the spread of the points. The display of the points depends on the mode (DUAL/MONO MODE) that the control was run and whether the measurements meet the evaluation rules (Westgard rules): • = measurement DUAL MODE o = measurement MONO MODE X = does not meet the Westgard rules.
H	The line H indicates the set high limit
L	The line L indicates the set low limit
Arrow	An arrow (pointing up or down) indicates that a result is outside the range of the graphic display. The result must be checked in TABLE MODE and marked REJECT if necessary.
R	An R at the top or lower edge of the display indicates that the result has been rejected by the operator in TABLE MODE.

5.4.8 Description of the Table Mode.



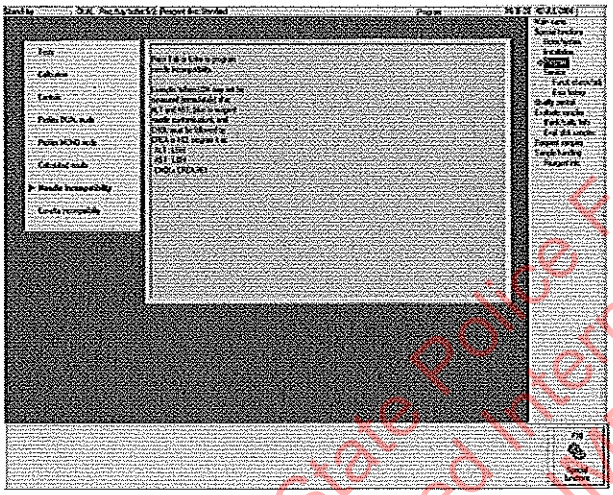
Press F2 TABLE MODE to change the analyzer from graphic mode to table mode. The rows display the results of the last 30 control measurements with date, time of the control measurement and the reagent batch number used.
To reject a control result, select the result using the cursor keys or the mouse and select ALT+ F5 REJECT RESULT.

5.5 Needle/Cuvette Incompatibility

5.5.1 Introduction

To avoid cross contamination, the analyzer can be programmed that certain tests will never follow each other.
This programming of incompatibilities can be performed for both the reagent needle and cuvettes. The user sets the analyzer for compatible and incompatible tests. Information on incompatibility can be found on the respective data sheets. The incompatibility of tests must be checked and re-set when new test parameters are programmed.

5.5.2 Start needle and cuvette incompatibility



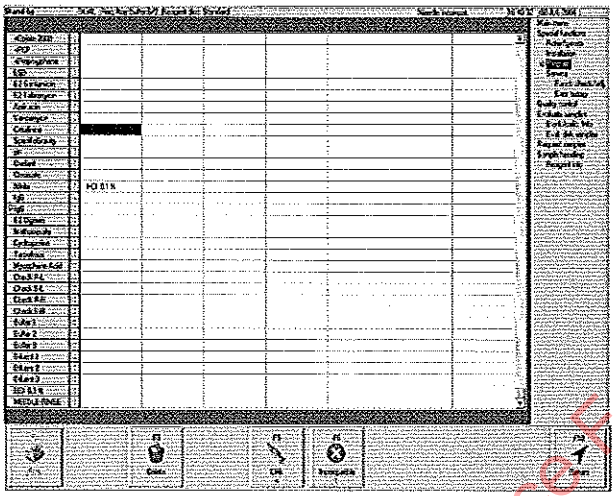
1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select NEEDLE INCOMPATIBILITY or CUVETTE INCOMPATIBILITY.

5.5.3 Incompatibility parameters

NEEDLE INCOMPATIBILITY ALT: LDH	The reagent needle will not aspirate the LDH reagent immediately after the ALT reagent. The analyzer selects another test to be aspirated. If not HCl will be aspirated as an extra cleaning step.
CUVETTE INCOMPATIBILITY ALT: LDH	A cuvette will not be used for the LDH test after ALT test. The analyzer selects another test for this cuvette. If not HCl will be dispensed as an extra cleaning step. This is after 48 cycles later.

5.5.4 Incompatibility function keys

The program procedure and display screen are identical for needle and Cuvette incompatibility. All tests programmed in the analyzer are displayed on two pages. Incompatible tests are listed behind the respective parameter. A maximum of seven tests can be set for each parameter.



ENTER	Select a test row
CURSOR KEYS	Display the test list
PAGE UP/PAGE DOWN	Scroll through the test list page by page
F1 PRINT	Print out the displayed screen
F3 DELETE	Delete the selected parameter
F5 LINK	Link the selected tests. The second test is processed directly after the first.
F6 INCOMP	Make the test incompatible. The second test is not processed directly after the first.
F10 RETURN	Return to the NEEDLE INCOMPATIBILITY or CUVETTE INCOMPATIBILITY display

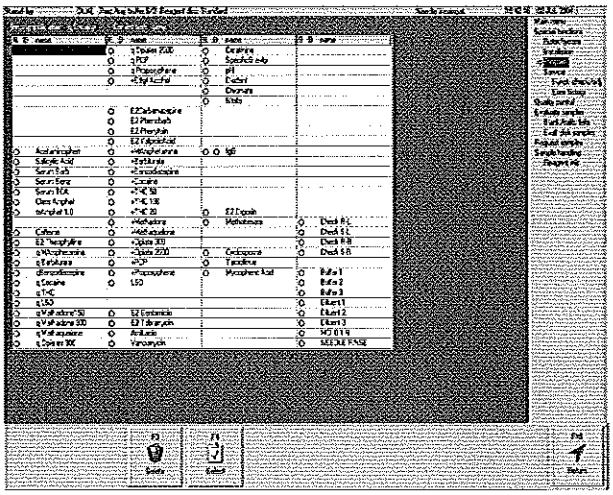
Note

A test with a superscripted ^{D} refers to the sample blank or "dummy" test, whereas a test without a ^{D} refers to a normal test.

5.5.5 Define Incompatibile tests

The following refers to the NEEDLE INCOMPATIBILITY menu. To define cuvette incompatibilities, use the same procedure. The analyzer can hold up to seven incompatible and compatible tests for each test.

In this example, the test B must never be processed after test A.



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select NEEDLE INCOMPATIBILITY.
4. Press ENTER to activate the Needle incompatibility overview. The information on the test definition is found in the data method sheets for the reagents.
5. Place the cursor in the first column behind the test A.
6. Press ENTER to show a list of tests.
7. Select the test B that must never go after test A.
8. Press ENTER to confirm. The analyzer will return to the incompatibility overview.

The default setting is that the test B is incompatible with the test A. This setting is indicated by the colon (:) behind the test A. Select F10 RETURN to return to the test A list without selecting a test B. If test A is very contaminating and no other reagent should be picked up by the reagent needle after test A then HCl must be linked to test A. Refer to 5.5.6, Define compatible tests.

5.5.6 Define compatible tests

In this example, the test B must be processed after test A when possible.

1. Select F5 SPECIAL FUNCTIONS from the Main Menu.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select NEEDLE INCOMPATIBILITY.
4. Press ENTER to activate the incompatibility overview. Information on the test definition is found in the method sheets for the reagents.
5. Place the cursor in the first column behind the test A.
6. Press ENTER to show a list of tests.
7. Select the test that must go after test A.
8. Press ENTER to confirm. The analyzer will return to the incompatibility overview.
9. Select F5 LINK. The colon changes to a link sign («).

The analyzer will now process test B directly after a test A, if possible.

Note

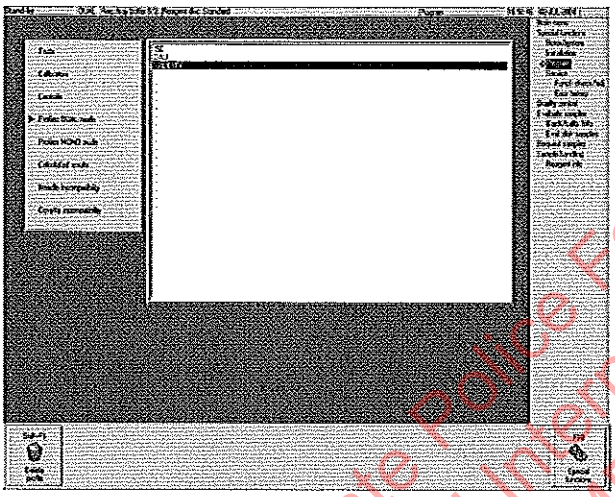
An o in front of a test name in column D in the incompatibility screen indicates that this test has a sample blank (dummy reagent). This dummy reagent can be selected by pressing F7 SELECT DUMMY instead of ENTER.

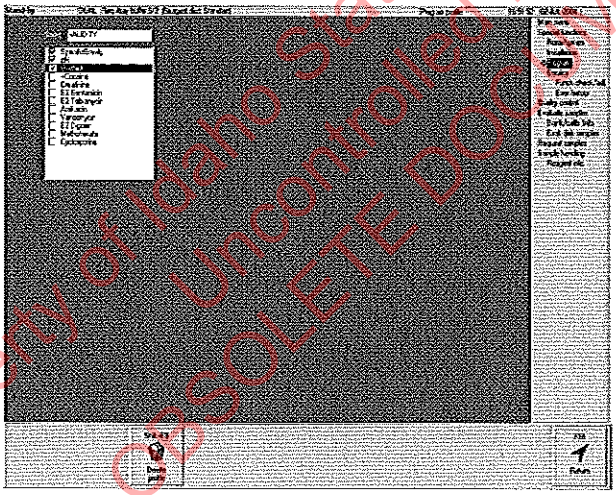
5.6 Profiles

5.6.1 Introduction

Several tests can be combined to form profiles. This increases analyzer productivity. Once profiles are programmed, they are available to record test requests. Profiles can be programmed and changed when needed in the PROFILES menu. Profiles have to be set for DUAL and MONO MODE separately. The procedure is identical for both modes.

5.6.2 Program Profiles





1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select either PROFILES DUAL MODE or PROFILES MONO MODE. A list of programmed profiles appears.
4. Press ENTER to move the curser to the list of profiles.
5. Select a profile name or an open position and press ENTER.
6. Change the name of the profile or program a new name and press ENTER.
7. Select the tests necessary for the profile. These tests can be changed later.
8. Select F10 RETURN to return to the list of profiles.

A maximum of 15 profiles can be programmed. Each profile name may consist of up to 20 characters.

5.6.3 Profile function keys

SHIFT+F1 DELETE PROFILE	Delete the selected profile without confirmation
F10 SPECIAL FUNCTIONS	Return to the SPECIAL FUNCTIONS menu
TAB	Change between the profiles list and the menu
CURSOR KEYS	Move within the list and select different profiles.
ENTER	From the menu, moves to the profiles list. From a specific position in the profiles list, change to the next screen with the list of tests

Note
While requesting patients you can also use the barcode reader with the tests request chart instead of a manual profile selection.

5.7 Reagent Position

5.7.1 Introduction

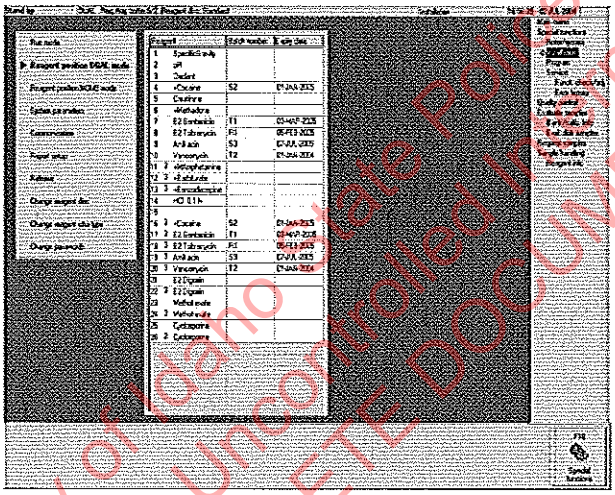
After the test parameters are set the necessary reagents must be assigned to positions on the reagent rotor. This is done in the INSTALLATION menu.

Please note the difference between the DUAL MODE and the MONO MODE. If you move between both modes, program each reagent position separately. It is recommended to use separate reagent rotors with separate bottle positioning for the two modes. If the mode is changed, it is then only necessary to replace the respective reagent rotor.

A table represents the positions of the reagent rotor. When reagents are assigned, the test names are displayed on the corresponding positions. A superscript capital D in front of the reagent name indicates a sample blank reagent. A superscript ^{2} or ^{3} in front of the reagent position indicates a second, third or starter reagent.

If you wish to change a reagent position, the analyzer will automatically delete all results that are currently stored on the main memory. Use the SAVE BEFORE CLEAR option in SYSTEM PARAMETERS if you want all results to be saved to disk.

Only tests programmed in the TEST PROGRAMMING menu can be assigned a reagent position.



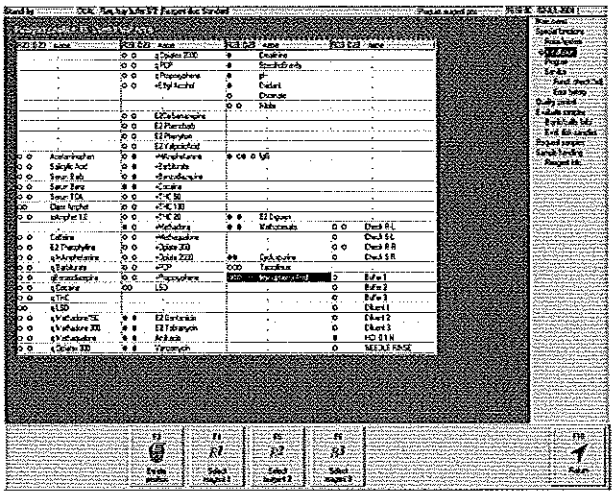
Note

When the expiry date of a reagent is overdue, the instrument issues a warning when the test is requested in the Request Samples menu.

Check the windows date and time settings for correctness, otherwise invalid reagent expiry warnings will be generated.

The default setting is the Emit rotor, 26 positions for reagent bottles are available. An EMIT® test can only be used on the Emit rotor, not on the classic rotor.

5.7.2 Program a REAGENT POSITION



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALLATION
3. Type the level one password in the dialog box and press ENTER.
4. Select REAGENT POSITION DUAL MODE or REAGENT POSITION MONO MODE
5. Press ENTER. The cursor moves to the selection field for the reagent positions. All test results stored in the main memory are deleted. The message ALL RESULTS HAVE BEEN CLEARED! is displayed.
6. Select an empty rotor position, and press ENTER.
7. Select reagent 1 for that position from the list, and press F4 SELECT REAGENT.
8. Place the bottle with the reagent 1 in the rotor at that position.
9. Select the next empty rotor position, and press ENTER.
10. Select the next required reagent and press:
    - F5 to select Reagent 2
    - F6 to select Reagent 3
    - F7 to select Dummy 1
    - F8 to select Dummy 2
    - F9 to select Dummy 3
11. Place the bottles for each reagent and dummy reagent in the correct position on the rotor.

Note

When you change reagent positions, the analyzer deletes all results from the main memory without confirmation. They will only be saved to disk if option SAVE BEFORE CLEAR was selected in SYSTEM PARAMETERS.

5.7.3 Reagent position function keys

TAB	From the menu, moves to the position list. All results are deleted from the main memory.
CURSOR KEYS	Move within the list/select a reagent position.
ENTER	Change to the list of programmed tests.
F1 PRINT	Print out a list of reagents and their respective positions on the reagent rotor.

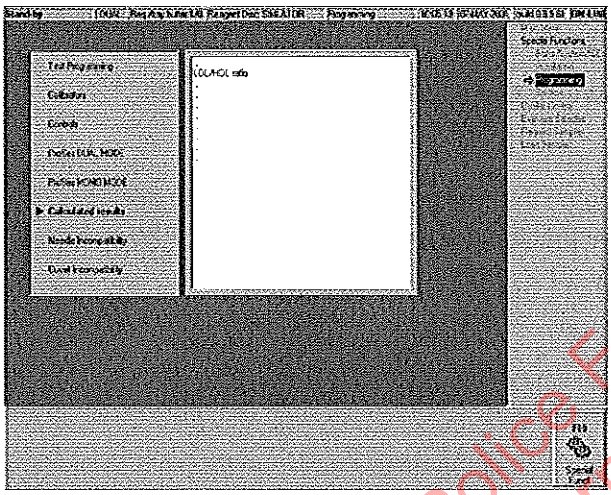
F3 DELETE POSITION	Deletes the selected reagent from the respective position. Remove the reagent from the rotor.
F10 SPECIAL FUNCTIONS	Return to the previous menu.
F4 SELECT REAG 1	Assigns the selected test to the current position. This applies to both modes (MONO and DUAL) for reagent 1.
F5 SELECT REAG 2	Assign R2 bottle of the selected test to the current position. This only applies to the DUAL MODE. A superscript ^{2} is displayed between position number and test name in the previous screen.
F6 SELECT REAG 3	Assign R3 bottle of the selected test to the current position. This only applies to the DUAL MODE. A superscript ^{3} is displayed between position number and test name in the previous screen
F7 SELECT DUMM.1	Assigns a dummy reagent (reagent blank) to the current position. This only applies to tests with reagent blanks defined. The superscript D in front of the test name is displayed in the previous screen to indicate the dummy reagent.
F8 SELECT DUMM.2	Assign dummy reagent 2 to the current position.
F9 SELECT DUMM.3	Assign dummy reagent 3 to the current position.
	The columns contain a graphic representation that indicates whether the reagents exist and are installed (empty) = reagent not defined in test parameters for this test o = reagent not installed ● = Black point means the reagent installed, red point means reagent 1 is one of three buffers. In the MONO MODE no reagent 2 or 3 can be installed.

5.8 Calculated Results

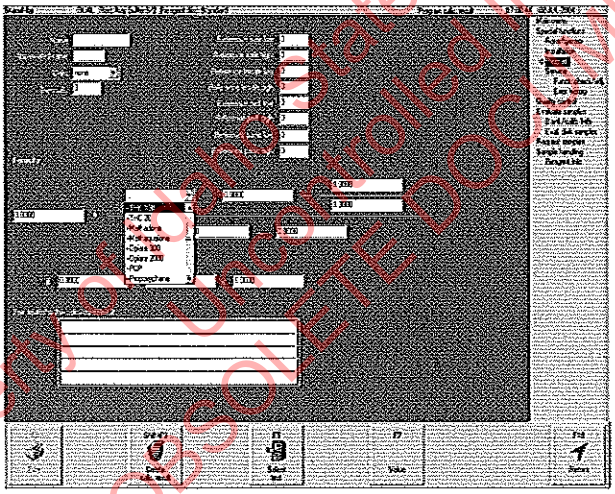
5.8.1 Introduction

Use a formula to derive a calculated result from the test data. The formula is set in the CALCULATED RESULTS menu.

Up to 20 formulas can be set. The calculated results are not used for quality control.



5.8.2 Program Calculated Results



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM. If you set a password, the password dialog box appears.
3. Select CALCULATED RESULTS menu.
4. Press ENTER to go to the list with the programmed calculated tests.
5. Select a calculated test or an open position and press ENTER.
6. Type in the parameter fields.
7. To create a new formula type a value in each FORMULA field or press F7 TEST and press F5 SELECT TEST select a programmed test for the drop down menu and press ENTER.

Note

Combinations of values and tests are possible.

5.8.3 Calculated results parameters

NAME	Name of the calculated result. If no name is entered here, the calculated result will not be stored.
ABBR. NAME	The abbreviated name of the calculated result. Otherwise, the calculated result will not be stored.
UNITS	The unit for the calculated result. By pressing ENTER a drop down menu shows the available units.
DECIMALS	The number of places after the decimal point.

Note

The screen contents changes depending on the type of units and number of decimals chosen. Enter the reference range values. Notice that the low limit values have to be lower than the high limit values.

REF. MALE LOW	The low limit of the reference range for male samples. If a measured value is below this limit, the analyzer flags the result.
REF. MALE HIGH	The high limit of the reference range for male samples. If a measured value is above this limit, the analyzer flags the result.
REF. FEMALE LOW	The low limit of the reference range for female samples. If a measured value is below this limit, the analyzer flags the result
REF. FEMALE HIGH	The high limit of the reference range for female samples. If a measured value is above this limit, the analyzer flags the result
REF. PED. LOW	The low limit of the reference range for pediatric samples. If a measured value is below this limit, the analyzer flags the result.
REF. PED. HIGH	The high limit of the reference range for pediatric samples. If a measured value is above this limit, the analyzer flags the result
REF. PANIC LOW	The low panic limit of the reference ranges for all samples. If a measured value is below this limit the analyzer flags the results on the print-out if the report set-up is enabled.
REF. PANIC HIGH	The high panic limit of the reference ranges for all samples. If a measured value is above this limit the analyzer flags the results on the print-out if the report set-up is enabled.
FORMULA	Here you can enter the formula for the calculated result at the cursor position. Buttons F5 and F7 become active when editing the formula. You can set a value in each of the formula fields or you can choose a pre-programmed test.
IF	The programmed formula will only be calculated if the 'if' statement is valid. For example, if the following is entered: if 0.00 <1.00 < 2.00 the formula will always be calculated, but if the following is entered: if 0.00 < TRIG < 400 the formula will only be calculated if the result for Triglycerides lies between 0 and 400.
TEXT RELATED TO THIS CALCULATED RESULT	You can create a text to the calculated result. This will be printed on the result´s list only when the calculated results can be derived.

5.8.4 Calculated results function keys

F1 PRINT	Prints the definition of the calculated test.
SHIFT+F3 DELETE CLC.RES	Deletes the definition of the calculated test.
F5 SELECT TEST	When the cursor is focused on a field in the formula that is selected as a test, pressing F5 opens a drop down menu allowing you to choose between the available tests.
F7 VALUE OR TEST	Moves between value or test in a field in the formula.

Note

Printing of all calculated results is only performed if all data needed for the calculation is available, if the calculated test is programmed in the user defined report set-up and if the USE REPORT LAY-OUT check box is checked in the SPECIAL FUNCTIONS menu. If a result cannot be calculated then the text containing fields related to this calculated result will not be printed.

5.9 Test Messages and Flags

5.9.1 Introduction

The analyzer constantly checks its settings, even during sample processing, test programming or in the stand-by mode. Each deviation from the set reference values is immediately displayed on the screen in form of messages.

A test message informs the user about operating errors, system errors and faults with the corresponding action to take. For example: insufficient liquids in the system and errors in the system setting.

In this chapter, the test messages, causes and actions to take are described. Some of the functions related to test messages and the action required are described too.

5.9.2 Test messages function keys

Some messages are accompanied by acoustic signals. Press the spacebar to stop the signal.

There are several ways for the user to react if a message is displayed. For each alternative a key or key combination has to be pressed. The analyzer displays the respective keys and their function on the monitor.

F1 CHECK AGAIN	Repeats the procedure that led to the error message if the importance of the message is unclear. Take action if the message is displayed again.
F2 REAGENT INFO	This key is only available if a message is displayed for insufficient amounts of reagent. In this case, replace or refill the reagent bottle on the reagent rotor and then press F2. The error message will be cleared from the screen.
F4 CONFIRM	This key is only available if the message displayed on screen requires no immediate action.
F5 RESET	Partly resets a component of the analyzer. This key is only available if the message is related to a specific component of the analyzer. The reset is carried out for the respective displayed component. If the measure is successful, the analyzer continues. Press SHIFT+F6 if pressing F5 was not successful (system does not work).
F5 MEASURE	Measures all tests still to be measured. This button will be displayed after a complete reset of the instrument and test were still in process.
CTRL+F5 RESET INSTRUMENT SIDE	Resets the complete right or left side of the instrument depending on the message (left or right).
F6 REJECT	Rejects all tests still to be measured. This button will be displayed after a complete reset of the instrument and test were still in process.
CTRL+F6 RESET SYSTEM	Restarts the analyzer. Only use SHIFT+F6 if the message cannot be cleared from the screen using the other keys. Inform the service technician if the message is displayed again after a reset!
SHIFT+F7 REMAIN INACTIVE	The analyzer status remains inactive. The analyzer cannot continue with the operation. It can only be brought back to the stand-by mode by triggering reset. Inform the service technician.
ALT+F10 INACTIVE	The analyzer stops all current operations. The line analyzer status (upper left side of screen) displays the word HALTED.

Note
Check the error history, before you call the technical service. See chapter 6.

5.9.3 Test flags

For certain errors the test results are marked with a flag. The cause and necessary action are described below. Further information about troubleshooting is given in chapter 4.3.

Error flag	Cause	Action
G	General hardware error. A hardware error is ignored.	Use the error list in the ERROR HISTORY menu to find the cause of this error. Select F1 RESET SYSTEM in the RESET SYSTEM menu to clear this error. Otherwise inform service.
R	Insufficient reagent.	Fill the system with reagent. Press F2 (Refill) to confirm.

Error flag	Cause	Action
#	Insufficient sample.	Make sure the sample is of sufficient volume, not coagulated, and no air bubbles block the sample aspiration.
L	Cuvette blank error.	Check the results of the last cuvette blank measurement in the BLANK ROTOR menu. Repeat the blank measurement if required.
	Lamp error.	Adjust or replace photometer lamp.
U	Cuvette blank error.	Check the results of the last cuvette blank measurement in the BLANK ROTOR menu. Repeat the blank measurement, if required.
	Underrange.	Adjust or replace photometer lamp.
O	Cuvette blank error.	Check the results of the last cuvette blank measurement in the BLANK ROTOR menu. Repeat the blank measurement, if required.
	Overrange	Adjust or replace photometer lamp.
u	Cuvette blank error.	Check the results of the last cuvette blank measurement in the BLANK ROTOR menu. Repeat the blank measurement, if required.
	Underrange reference detector	Error in electronics. Inform service.
o	Cuvette blank error.	Check the results of the last cuvette blank measurement in the BLANK ROTOR menu. Repeat the blank measurement, if required.
	Overrange reference detector.	Error in electronics. Inform service.
T	Cuvette temperature error.	Inform service.
r	Rerun.	A test was re-run with the re-run parameters.
*	Non-linearity error.	A non-linear reaction of kinetic tests on the first four measurement points.
X	Concentration limit error.	The limit set in the TEST PROGRAMMING menu was exceeded.
D	Reagent absorbance deviation error. Substrate depletion error (dual or triple reagent tests).	The limit for the reagent absorbance deviation set in the test programming menu was exceeded. Select F6 RERUN MEASUREMENT in the EVALUATE SAMPLES menu.
a	Reagent absorbance limit violation.	One of the reagent absorbance limits set in the test programming menu was exceeded. Prepare fresh reagent solution if necessary.
A	Calibrator limit violation.	Compare the values set in the TEST PROGRAMMING menu with the data given in the insert sheet of the test. Prepare fresh calibrator or reagent solution if necessary.

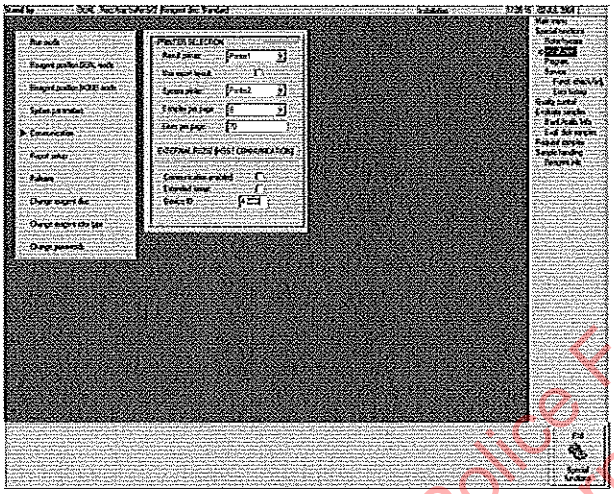
Error flag	Cause	Action
C	Control limit violation.	Compare the values set in the TEST PROGRAMMING menu with the data given in the insert sheet of the test. Prepare fresh control or reagent solution if necessary.
N	Reference limit violation.	One of the reference limits set for male, female or pediatric in the test programming menu was exceeded.
W	Westgard rules limit violation.	Compare the results of the quality control of all controls set for this test. Prepare fresh control or reagent solution or calibrate the test, if necessary.
P	Prozone error.	Repeat the measurement with pre-diluted sample.
E	Result near cut-off.	The result lies within the set cut-off deviation programmed in the TEST PROGRAMMING menu.
<	Low absorbance limit violation.	The low limits set in the TEST PROGRAMMING menu are exceeded.
>	High absorbance limit violation.	The high limits set in the TEST PROGRAMMING menu are exceeded.
	No reagent taken.	This error message is displayed when the level of reagent in the reagent bottle is too high (e.g. filling level is near screw-cap) or when foam is present.
	Reagent pipetting stopped	The reagent needle can not be cleaned and so has stopped pipetting. Make sure HCl is installed on the reagent rotor and the bottle is not empty.
OVFL	Overflow result for calibrated test.	If the rate of a test is higher than the rate of the highest standard or lower than the rate of the lowest standard the result will be respectively 9999.00 or 0.00 and it will get the OVFL flag. This is only valid for tests with calib. curves with 3 standards or more.
POSIT	Positive	For cut-off tests. If the result is positive relative to the cut-off border, it is flagged as POSIT. Both the flag and the result are indicated.
NEGAT	Negative	For cut-off tests. If the result is negative relative to the cut-off border, it is flagged as NEGAT. Both the flag and the result are indicated.

5.10 Select printers and set host connection

5.10.1 Introduction

If the analyzer is to be connected to a Lab-EDP System, or if a printer is to be installed, connections and specifications of these devices must be defined.

5.10.2 Start communication selection



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALLATION
3. Type the level one password in the dialog box and press ENTER.
4. Select COMMUNICATION and press ENTER.

5.10.3 Communication parameters

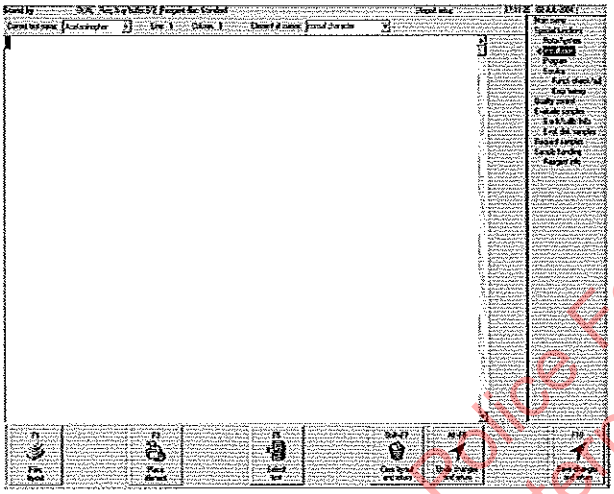
RESULT PRINTER	Select a printer for all patients. Select Off to disable the printer. Any printer supported by Windows can be selected.
USE REPORT LAYOUT	Select to have the result printer use the user defined report set-up. De-select to have the result printer use the default report set-up.
SYSTEM PRINTER	Select a printer for all non-patient result data like graphs, blank data, calibration curves, etc. Any printer supported by Windows can be selected.If both printers are set to Off no data will be printed.
SAMPLES PER PAGE	Select the number of patient samples the printer should print on one page. The software will organize, together with the entered value at the LINES PER PAGE field, that results of one single sample will not be separated.
LINES PER PAGE	Enter the total number of lines that fit on one single page(70). The software will organize, together with the selected number at the Samples per page field, that results of one single sample will not be separated.
COMMUNICATION ENABLED	Select to enable communication with a host computer. De-select to disable communication with a host computer. (Default)
EXTENDED FORMAT	Use an extended format (absorbance values are transmitted to the host along with the results).
DEVICE ID.	Enter a four-digit code for identification purposes. All information sent to the host computer will be identified by this code.

5.11 Set up a report

5.11.1 Introduction

If a special result printer is to be used for result printouts, the printout format has to be defined in the Report Set Up menu. The layout of the reports can be individually defined. You can define which information is to be printed out, and also its appearance on the page.

5.11.2 Define a report set-up



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALLATION.
3. Type the level one password in the dialog box and press ENTER.
4. Select REPORT SET-UP.
5. Press TAB or ENTER.
   In the report set-up, it is possible to write text like you would do with a normal word processor, but you can also add parameter fields with a variable content.
   The words between the brackets «and» in the figure above are the parameter fields, that are replaced by the actual contents of the parameters at the time of printing.
6. Select F3 PLACE ELEMENT to define and position field elements e.g. abbreviations and units of measurement.
7. Select F5 SELECT TEST to define the tests and their corresponding attributes, e.g. abbreviations and units of measurement.

Note

If a test is not positioned (i.e. not displayed in the layout), the results are not printed out in the result report, even if the test was requested and measured. Therefore, make sure that the required test is positioned when setting up a report.

8. Select F10 STORE & RETURN to save the new layout and return to the previous menu.
   The analyzer will layout the printouts.

5.11.3 Report setup function keys

F1 PRINT LAYOUT	Print out the report layout. This is only possible if a result printer is activated in the COMMUNICATION menu.

F3 PLACE ELEMENT	After pressing F3, select an element from the drop down list and press ENTER to place the element for the current selected test name at the cursor's current position. Position the cursor on the desired place first to position an element
F5 SELECT TEST	Select a test from the drop down list and confirm with ENTER. Test-specific elements, placed with F3, refer to this test.
SHIFT+F7 CLEAR LAYOUT AND RETURN	Clear the layout completely without confirmation!
ALT F8 UNDO CHANGE AND RETURN	The change made previously is ignored. The software goes back to the last screen.
F10 STORE AND RETURN	Save the current layout and return to the previous screen.
CURSOR KEYS	Position the cursor on the screen.

5.11.4 Example for printouts

Vital Scientific N.V. MEDICAL CENTER
7000 G. 13TH, SUITE 3B58
McALLEN, TEXAS 78504
(956) 700-7777

CLIA# 45D0990259 TECH:

PATIENT: Jan van Gend PATIENT ID:2004_0304_014 MAR-03-2004
DOB: 07-07-1962 SEX:M TIME 12:03
Physician: C.M. Brunsweijk, M.D.

COMMENTS:

TEST NAME	RESULTS	UNITS	FLAG	REFERENCE RANGE LOW	HIGH
UREA	4	mmol/l		3	- 7
CREATININE	85	µmol/l		70	- 105
B/C RATIO	0.05	ratio			
GLUCOSE	4.5	mmol/l		3	- 6
CALCIUM	2.25	mmol/l		2.10	- 2.55
CHOLESTEROL	5.2	mmol/l		3	- 7.85
		Men Women			
	1/2 Average Risk	3.4 3.3			
	Average Risk	5.0 4.4			
	2x Average Risk	9.6 7.1			
	3x Average Risk	15.0 11.0			
TRIGLYCERIDES	1	mmol/l		0.8	- 1.70
HDL-DIRECT	1	mmol/l		0.78	- 2.20
LDL	4.01	mmol/l		1.68	- 4.53
LDL/HDL RATIO	0.64	ratio			
VLDL	0.8	mmol/l		0.4	- 1.1
CHOL/HDL RATIO	5.2	ratio			
%HDL	19	%			
TOTAL PROTEIN	70	g/l		60	- 80
ALBUMIN	41	g/l		35	- 50
GLOBULIN	13.1	g/l		6.6	- 14.1
A/G RATIO	1.4	ratio			
BILIRUBIN TOTAL	17.1	µmol/l	High	3	- 17
GAMMA GT	30	U/l			< 50
ALKALINE PHOS	150	U/l	High		< 120
ALT/SGPT	20	U/l			< 50
AST/SGOT	22	U/l			< 40
AMYLASE	200	U/l			< 220
URIC ACID	3.1	mmol/l		0.35	- 3.2
LDH-L	26.5	U/l			< 450
MAGNESIUM	0.8	mmol/l		0.65	- 1.05
C-REACTIVE PROT	5	mg/l		0	- 9
SODIUM	140	mmol/l		133	- 144
POTASSIUM	4	mmol/l		3.6	- 4.8
CHLORITE	100	mmol/l		98	- 106
CARBON DIOXIDE	24	mmol/l		21	- 28

Maintenance

6.1 Maintenance procedures

The analyzer has very low maintenance requirements. However, it is important that the maintenance procedures are strictly followed. All maintenance steps are described in the following table.

WARNING

Liquid waste is potentially infectious and can be hazardous to health. It must be disposed of according to national and international instructions for the safe disposal of biohazardous waste. All laboratory-specific safety precautions have to be strictly followed for the cleaning of the analyzer, since contamination with infectious materials can never be fully excluded.

6.1.1 User Maintenance

Do the daily maintenance before you start to test samples or controls.

There is no end-of-day procedure that must be followed. Just before going into standby mode the instrument will automatically clean the reagent needle with the HCl-solution that is on the reagent wheel and the sample needle with the sodium hypoclorite solution that is on the W position on the sample wheel.

Do the weekly maintenance at the end of the week.

Daily	• Fill water container with system liquid and distilled water (25 ml system liquid on a full 10 liter container). • Empty the waste container (follow the safety instructions for working with potentially infectious material!). • Check cuvette rotor blank results. Replace cuvette rotor if necessary. • Check printer paper. • Fill HCl-bottle in the reagent rotor with 0.1 mol/l HCl. • Fill tube in W-position of sample rotor with hypochlorite solution. • Fill tube in B-position of sample rotor with distilled water. • Remove cuvette cover and check wash arm, mixers and cuvette rotor visually. • Make sure that the cooling unit is on and operating correctly
Weekly	• Perform needle rinse procedure: clean the sample and reagent needle with hypochlorite solution. • Check syringes and Teflon tips on air bubbles and leakage; clean syringes or replace tips if necessary.
Monthly	• Clean water and waste container(s) with 0.1 mol/l NaOH. Afterwards rinse several times with water.
Quarterly	• Replace mixer belts. If not done by the service technician during preventive maintenance: • Replace water filter. • Replace drying block on wash arm.
Semi-annual	• Run the clean system procedure. This procedure is done by the field service engineer. • During the clean system procedure the instrument is completely rinsed with a concentrated hypochlorite solution.
As needed	• Replace cuvette rotor (after 10 000 tests or after SD-error after cuvette blank). • Replace lamp.

6.1.2 Replace measurement disk

The measurement disk (cuvette rotor) must be replaced after 10 000 tests or when an SD-ERR appears on the print-out after the cuvette blank. If the counter of the system has recorded more than 10 000 tests, an error message is displayed on the screen.

You can reset the counter to zero and cancel the error message by pressing SHIFT+F3 RESET COUNTER in CHANGE MEASUREMENT DISK menu. Ignoring this message may result in incorrect results. To replace the measurement disk do as follows:

1. Remove all samples.
   Check that the analyzer is in standby.
2. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
3. Select: Change Rotor in the ROTOR/SYSTEM menu.
4. Remove the rotor cover from the cuvette rotor.
5. Select: F1 LIFT WASHARM.
   The system will lift the wash arm.
6. Lift the mixer tray manually.
7. Remove the rotor.

ATTENTION
Observe all common safety precautions (e.g. wear gloves), since this part of the system is potentially infectious. Also make sure that no liquids leak into the analyzer system.

8. Unpack a new rotor.
   Do not to touch the sides of the rotor, but hold it by its center hold.
9. Place the new rotor while assuring that the notches of the rotor fit in the slits of the rotor holder.
10. Answer the question displayed on the screen.
    After selecting Yes the system will reset the counter to zero.
11. Press the mixer tray down.
12. Select F2 RESET SYSTEM to lower the wash arm.
13. Place the cover.
14. Perform a cuvette rotor blank measurement.

6.1.3 Manual Cuvette Rotor Measurement

Once a day a cuvette rotor blank measurement must be performed. The analyzer can carry this out automatically, if the Automatic Blank Time was set in the SYSTEM PARAMETERS menu. For an automatic blank measurement the analyzer has to be in the stand-by mode. Cuvette rotor blank measurements can also be performed manually. It has to be carried out manually after the first installation of the system and after replacement of the cuvette rotor (see previous section). A manual cuvette rotor blank measurement is started in the BLANK ROTOR menu.
After the menu is called up the system displays all absorbance values for the 48 cuvettes. The values for the cuvette AV and the lamp AV are displayed together with the respective standard deviations SD.
The graphic mode shows a graphic representation of the blank measurement results.

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F1 ROTOR/SYSTEM.
3. Select BLANK ROTOR and press ENTER.
4. Press F2 BLANK to start the blanking of the Cuvettes.

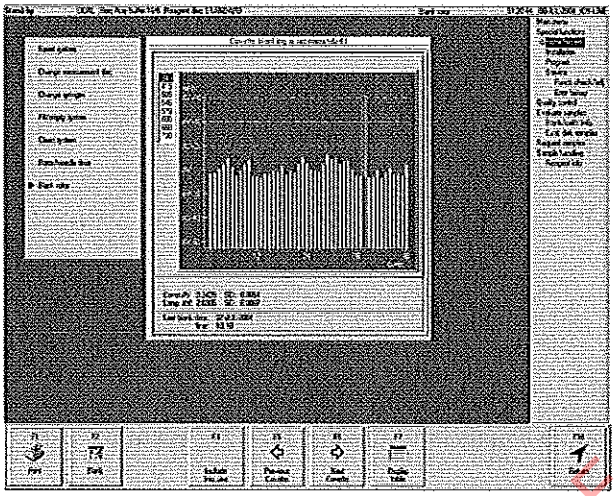
6.1.4 Exclude a stained cuvette

After the rotor blank measurement is complete, if there is an anomalous reading for one cuvette, it shows that the cuvette is stained and should be replaced. To stop the use of the cuvette until the cuvette is replaced, do as follows:

Note
When you change the cuvette in the rotor in CHANGE MEASUREMENT DISK, the excluded cuvette is included.

Note

When you include the cuvette after being excluded, you should do a Blank. Press F2 BLANK.



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F1 ROTOR/SYSTEM.
3. Select BLANK ROTOR.
4. Press ENTER to access the blank rotor function keys.
5. Press F7 GRAPHIC MODE to view the readings in graphic mode.
6. Press F5 PREVIOUS CUVETTE or F6 NEXT CUVETTE to scroll through the cuvette rotor and select the cuvette with the anomalous reading.
7. Press F4 EXCLUDE FROM USE to stop a cuvette from being used.

6.1.5 Blank rotor function keys

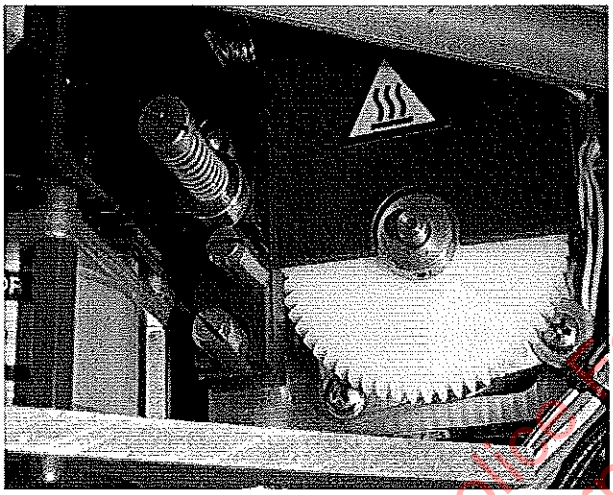
Key	Description
Cursor keys	Selects the wavelength.
F1 PRINT	Prints the current display.
F2 BLANK	Start the cuvette blank measurement. This is only possible when the system is not processing samples. A blank takes about 13 minutes.
F4 EXCLUDE FOR USE.	Press the F4 key to exclude or include a selected cuvette (indicated by the selection cursor) from use. A red bar indicates an excluded cuvette.
ENTER or F7 GRAPHIC MODE/ TABLE MODE	View a graphic representation of the measuring results. Press F7 TABLE MODE or ENTER within the graphic mode changes to the table mode again.
F10 RETURN	Return to the previous screen (ROTOR/SYSTEM menu).

6.1.6 Replace the Photometer Lamp

The photometer lamp has to be replaced after about 2,000 operating hours. Indications for a necessary replacement of the lamp are unusual measured results that cannot be explained. In all cases that unusual measuring results occur, check the intensity of the lamp. This is done via the FUNCTIONAL CHECK/ADJUSTMENTS menu (menu SERVICE).

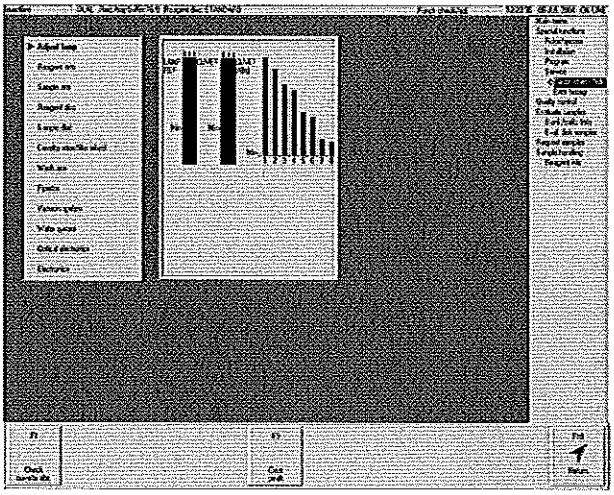
Should the photometer lamp have any mechanical/ technical defects, an error message is displayed on the screen. However, normal wear of the lamp is not detected by the system.

ATTENTION
Be sure to switch off the instrument before replacing the lamp. Make sure that no samples are currently being processed.



1. Switch off the analyzer and remove the safety screw in the middle of the device (the screw can only be seen from below).
2. Open the front of the analyzer by simply pulling at the sides of the cover. Warning! The lamp may be hot.
3. Loosen the top screw (of a total of three screws) with a screwdriver and remove it.
4. Carefully pull the support out towards you. Attention! Cable connections!
5. Remove and dispose of the lamp.
6. Carefully take the new lamp (part of the spare parts kit) by its top using a clean cloth. The new lamp must carefully be placed into the support and fastened.
7. Reinstall the support and fasten the screw. The lamp must be adjusted with the two screws below the top screw.

ATTENTION
Do not touch the glass part of the lamp with your fingers. Fingerprints, dust and humidity shorten the life of a lamp and limit its function. Be careful for movable parts when the instrument is switched on again!



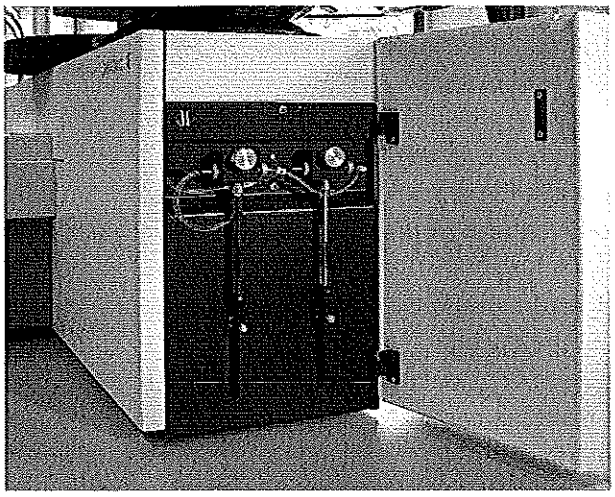
8. Adjust the lamp:
   1. Select: F5 SPECIAL FUNCTIONS from the MAIN MENU.
   2. Select F4 SERVICE.
   3. Select FUNCTIONAL CHECK/ADJUSTMENTS.
   4. Select ADJUST LAMP.
   5. Press TAB or ENTER. A screen is displayed showing two bars representing the lamp intensity that is measured by the reference detector (Lamp) and the actual detector (Cuvette).
   6. Loosen the support screw a small amount.
   7. Adjust the lamp by screwing the middle and bottom screw with the two screwdrivers in such a way that the Cuvette bar on the screen is on Max. If you turn the screws carefully, you can see the bars in the display move up and down. Turn the screws until the bars reach maximum height. They should not show infinity signs however. The values must be at least equal to the minimum.
9. Check whether the lamp intensity is too high for each filter:
10. Select: F1 CHECK CUV. ABS. The system measures the cuvette absorbance for each filter and displays the values graphically on screen. The value must be equal to or higher than the minimum value, i.e. each bar on the screen has to be at or above Min.
11. Select F1 CHECK CUV. ABS again and compare the heights of the bars.
12. Reduce the lamp intensity by turning the middle and bottom screw if each bar is not at or above Min.
13. Repeat the procedure as often as necessary, until all filter values are equal to or higher than Min.
14. Tighten the support screw.
15. Close the front door.
16. Place the safety screw.
17. Select F10 RETURN to quit the ADJUST LAMP menu.

6.1.7 Replace syringes and syringe tips

The accuracy of the system highly depends of the state of the syringes, especially the sample syringe. It is therefore necessary to check their state regularly and replace the Teflon tips (sealing) or the complete syringes, if required. There are two clear indications for defective syringes:

- Imprecise results, with no clearly definable cause like dirt, reagents, other liquids or the photometer.
- Air bubbles in the syringes and water leaking along the syringe plunger.

Remove the syringes:



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F1 ROTOR/SYSTEM.
3. Select CHANGES SYRINGES.
4. Press ENTER.
5. Select F1 LOWER SYRINGE to bring both syringes to their low position.
6. Remove the screws of the drive pins through the plunger.
7. Carefully unscrew the syringe from the valve and push it down a little, then remove it from the instrument.

A new Teflon tip or a complete new syringe must be installed. If the last Teflon tip only lasted for a short period of time it is likely that the syringe itself is worn and must be replaced completely.

Install the Teflon tips:

1. Pull the plunger out of the glass barrel.
2. Remove the old tip from the plunger. The small tip (sample syringe) can easily be removed with the finger nail. The large tip (reagent syringe) can be removed with a bull-nose pliers.
3. If the O-ring under the tip is damaged, replace it as well.
4. Place the new tip upside down in the tip holder from the accessory box.
5. Hold the plunger vertical and press the top into the Teflon tip.

Install the syringes

1. Moisten the inner side of the glass barrel with water.
2. Hold the glass barrel in a cup of water with the plunger part up.
3. Take the barrel out of the water.
4. Insert the plunger in the glass barrel. There should be no air bubbles on top of the plunger now. In case of the reagent syringe the air bubble can be removed by ticking with your finger against the syringe. In case of the sample syringe the procedure must be repeated.
5. Mount the plunger over the drive pin of the pipettor, hold the syringe vertically and pull it straight up.
6. Screw the syringe in the pipettor valve. Make sure the syringe can be screwed in easily. Tighten well with your hands.
7. Select F2 RESET SYSTEM in order to reset the pipettor and F10 RETURN to leave the menu. If the analyzer is now in the Halted state, reset the complete analyzer.
8. Select the FILL/EMPTY SYSTEM menu (from the MAIN MENU, press F5 SPECIAL FUNCTIONS, F1 ROTOR/SYSTEM) and press F1 REFILL SYSTEM. After refilling the system the instrument is ready for use again. If there are still air bubbles visible in the tubing repeat the refilling procedure.

6.1.8 Washing/filling cuvette rotor

Wash and fill the cuvette rotor as follows:

1. Stop any processing of samples.
2. Make sure the analyzer is in the standby state.
3. Check the water supply and fill up the 10 l container, if required.
4. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
5. Select F1 ROTOR/SYSTEM.
6. Select ROTOR/NEEDLE RINSE.
7. Press TAB or ENTER.
8. Select F2 WSH/FIL ROTOR.

As soon as washing/filling of the cuvette rotor is finished, the system switches to the stand-by mode. The analyzer also offers the possibility of washing the rotor only by selecting F1 WASH ROTOR. After finishing the routine all cuvettes are washed automatically; there is usually no need to perform this function manually.

The manual rotor washing procedure is only necessary, if, for any reason, the analyzer may be stopped (ALT+F10) while there was still reagent and/or sample in the cuvette rotor. If no new tests are performed immediately after stopping the instrument the rotor wash must be performed, otherwise the cuvette rotor will dry up and residues will stick to the rotor wall.

6.1.9 Needle rinse

During the needle rinse procedure both needles will be cleaned more intensely with the hypochlorite solution. The needle rinse procedure will take about 30 minutes.

1. Stop any processing of samples.
2. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
3. Select F1 ROTOR/SYSTEM.
4. Select ROTOR/NEEDLE RINSE.
5. Press TAB or ENTER.

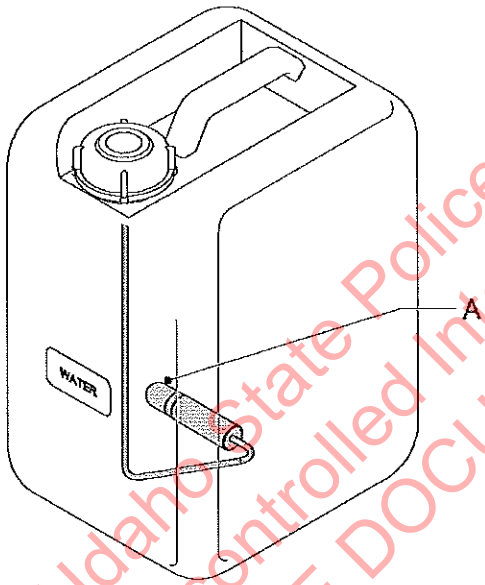
6. Place a 28 ml bottle with hypochlorite solution on the reagent wheel at the position shown on the screen.

Note
If the position of the needle rinse on the reagent rotor is not displayed on screen (displaying xx instead of a number) you must install and assign a position for the needle rinse on the reagent rotor in the reagent installation menu.

7. Place a full sample tube with hypochlorite solution on position no. 1 of the sample rotor.
8. Select F3 NEEDLE RINSE.

6.1.10 Replace the water filter

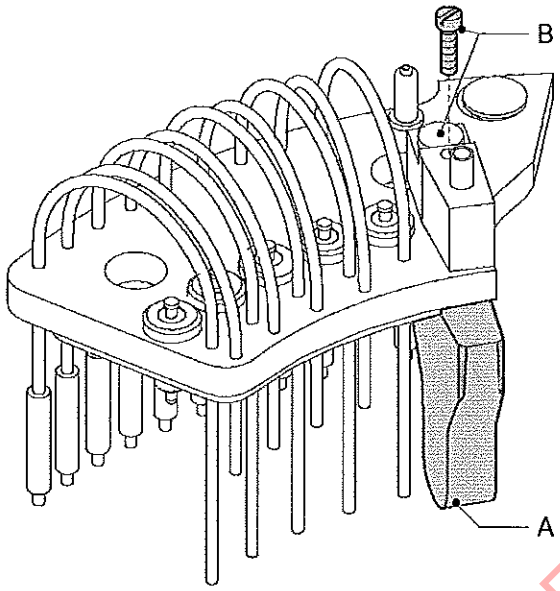
Do as follows to replace the water filter:



1. Unscrew the cap of the water container and pull out the water filter A that is connected to the tube.
2. Unscrew the filter and replace the filter by a new one.
3. Put the filter back into the water container and screw the cap back on the container.

6.1.11 Replace the drying block

Do as follows to replace the drying block:



1. Remove the cover of the measurement disk of which the drying block needs to be replaced.

2. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
3. Select F4 SERVICE.
4. Double click Functional checks/adjustments.
5. Double click Wash arm.
6. Select F1 - RESET WASHARM.
7. Press arrow up key on your key-board to lift the wash-arm.
8. Disconnect the tube from the drying block.
9. Loosen screw B and replace the drying block of the wash arm by a new one, but do not tighten screw B yet.
10. Press arrow down key on your key-board to lower the wash-arm.
11. Wait for the wash-arm to go to the correct location.
12. Press arrow down key on your key-board to put the drying block in the correct position.
13. Tighten the screw B of the drying block.
14. Connect the tube to the drying block.
15. Select F10 RETURN.
16. Select F10 SPECIAL FUNCTIONS.
17. Select F1 ROTOR/SYSTEM.
18. Double click RESET SYSTEM.
19. Select F1 RESET SYSTEM.
20. Replace the measurement disk covers.

6.2 Troubleshooting

6.2.1 Introduction

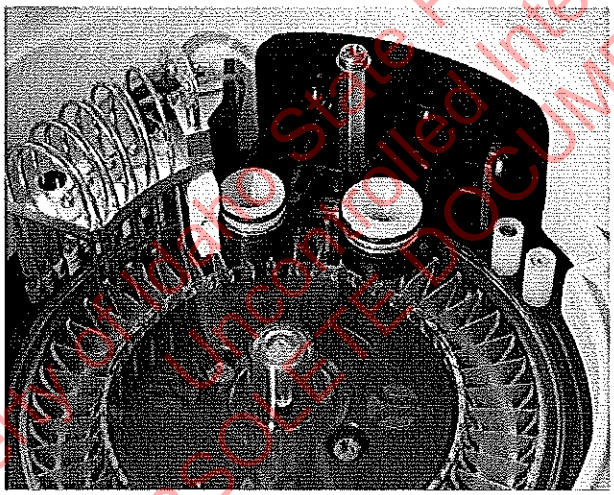
The analyzer reflects the most up-to-date technological standards and was designed to be as user-friendly as possible. It constantly monitors all functions and informs the user about operating errors and system malfunctions. However, in technical systems operating errors and certain system malfunctions can never be fully excluded, especially since mechanical components are always subject to wear. The most frequent malfunctions caused by wear are described in the following chapter. A great number of these can be solved without assistance from the technical service personnel.

Note

Check the error history, before you call the technical service. See 6.2.6 Error messages.

6.2.2 Defective mixer belt

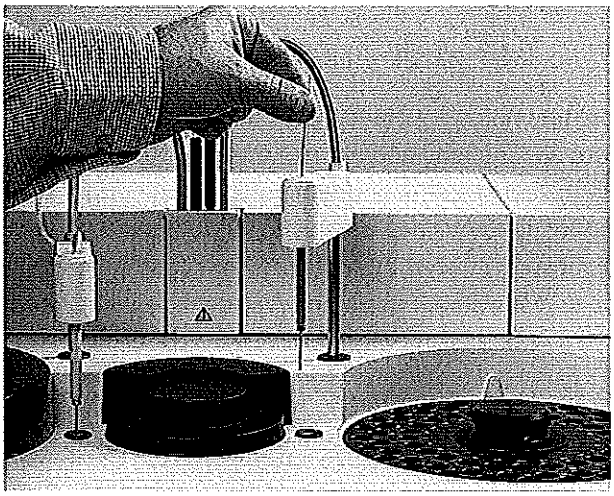
If you notice invalid measuring results marked with a flag, the cause of which is unclear, the reason could be a defective mixer belt. It can be acoustically detected: the typical mixing sound is missing. Moreover, neither the sample needle nor the reagent needle rotates during mixing (the reagent needle only rotates if the second or third reagent was added).
The mixer belts must be checked daily before running the routine. Replace the mixer belt if it looks worn or if it is broken:



1. Lift the cover of the cuvette rotor.
2. Remove the old belt from the support. If the belt is destroyed, remove the parts from the area around the cuvette rotor.
3. Pull the new mixer belt (part of the spare parts kit) over the support until it is correctly positioned.
4. Put the cuvette rotor lid back in its place.

6.2.3 Sample needle clogged

Take following actions if the sample needle is clogged:



1. Press ALT+F10 EMERGENCY HALT.
2. Carefully pull the tube, consisting of an outer and an inner part, off the sample arm.
3. Take the stylet that is part of the spare parts kit and carefully push it into the inner needle from above until it comes out at the end of the needle.
4. Carefully move the stylet up and down several times to remove all substances that block the needle. Do not dispose the stylet afterwards.
5. When the tube is put back into its place, ensure that both the outer protective tube and the inner tube are not pushed into the opening of the needle cover. They should just touch the silicon seal.
6. Reset the analyzer and continue operation.

6.2.4 Removal of the rotor tray

Should you detect any liquids or objects on the bottom of the rotor trays (sample and reagent tray), the respective tray must be removed and cleaned.

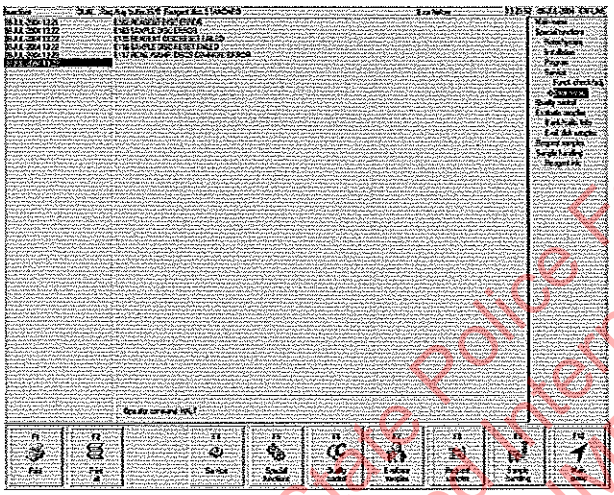
1. Press ALT+F10 EMERGENCY HALT.
2. Turn the screw cap counter clockwise until it can be removed.
3. Remove the tray.
4. Clean the bottom of the rotor tray or remove the object from the rotor tray.
5. Replace the rotor. Make sure that the white dot on the rotor aligns with the white line on the rotor shaft, otherwise the rotor does not lock.
6. Make sure the screw cap is in place, turn the screw cap clockwise.

6.2.5 Error history

Note

Malfunctions are often caused by the fact that the mentioned cleaning procedures were not performed often enough (i.e. not in accordance with the maintenance plan). You can check the needle rinse history by activating the corresponding item in the SERVICE menu.

Use this function in case of problems to inform the technical service personnel on what type of error (and error number) has occurred.
The easiest and fastest way to inform the technical service about the detected malfunctions is to send the printout to the respective Technical Assistance Center per fax.



1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F4 SERVICE
3. Select ERROR HISTORY
4. Press TAB or ENTER.
   Each error message displayed by the analyzer is documented here.
   On the left side of the display date and time of an error is displayed. The right-hand side shows the corresponding error number and an error description. The analyzer also documents which measures the user took, i.e. which keys were used. Use the cursor keys to scroll through the list of messages.
5. Select F2 PRINT ALL to print out the entire error history.

Keys

F1 PRINT	Print out the selected error message including date and time of occurrence.
F2 PRINT ALL	Print out the complete list of error messages including last needle rinsing and last system cleaning data. Make sure, there is enough paper in the printer!
F4 SERVICE	Switch to the SERVICE menu.
F5 SPECIAL FUNCTIONS	Switch to the SPECIAL FUNCTIONS menu.
F6 QUALITY CONTROL	Switch to the QUALITY CONTROL menu.
F7 EVAL SAMPLES	Switch to the EVALUATE SAMPLES menu.
F8 REQUEST SAMPLES	Switch to the REQUEST SAMPLES menu.

F9 SAMPLE HANDLING	Switch to the SAMPLE HANDLING menu.
F10 MAIN MENU	Return to the MAIN menu.

6.2.6 Error messages

The error messages displayed by the analyzer can be divided into two groups: test messages and hardware-error messages.
Test Messages (Flags). Refer to 5.9 Test Messages and Flags.
Flag messages are printed behind a test result. Error messages that are marked with an asterisk (*) in the list below are also displayed on screen and can be recognized by an acoustic signal, which can be stopped by pressing the space bar. Refer to 5.9.2 Test messages function keys.

Error message	Cause	Action
LINEARITY ERROR ABSORBANCE LIMIT ERROR REAGENT ABSORBANCE DEVIATION ERROR REAGENT BLANK LIMIT ERROR CALIBRATION LIMIT ERROR CONTROL LIMIT ERROR REFERENCE LIMIT ERROR REAGENT ABSORBANCE ERROR	Violation of setting in test parameters	Check the sample, the reagent and the test parameters.
* INSUFFICIENT REAGENT	Safety switch of the reagent needle is activated (bottle empty). Liquid detection of the reagent needle is not detecting any liquid (bottle missing or empty). Liquid detection is not working.	
* NO REAGENT TAKEN	Filling level of the reagent bottle is too high (e.g. filling level is near screw-cap). Foam is being produced.	
* REAGENT PIPETTING STOPPED	The reagent needle could not be cleaned and therefore stopped pipetting.	Make sure HCl is installed on the reagent rotor and its bottle is not empty.

Error message	Cause	Action
* LAMP UNDERRANGE	A counter overrange (> 29 000) is detected during a measurement.	Refer to hardware error LAMP FAILURE.
* LAMP OVERRANGE	A counter underrange (< 10) is detected during a measurement.	Refer to hardware error LAMP FAILURE.
* LAMP UNDERRANGE REF CHANNEL	A counter overrange (> 29 000) for the reference detector is measured during a measurement.	Refer to hardware error LAMP FAILURE.
* LAMP OVERRANGE REF CHANNEL	A counter underrange (< 10) for the reference detector is measured during a measurement.	Refer to hardware error LAMP FAILURE.
INSUFFICIENT SAMPLE	The safety switch of the sample needle is activated (sample cup empty). Liquid detection of the sample needle is not detecting any liquid after aspirating the sample (detection of air bubbles).	

6.2.7 Hardware-error messages

Hardware-error messages are displayed on screen and can be recognized by an acoustic signal, which can be stopped by pressing the space bar. The most important hardware-error messages will be explained below. Errors that can be eliminated by the user himself, will be described in detail. In general, many errors cause other errors at the same time. For example, a wash arm error (E122) also causes a system emergency halt (E02). When the most obvious error is solved, usually also the other error disappears.

Error message	Cause	Action
E02 system emergency halt	Sample or reagent arm, for example, were accidentally touched during measurement. The analyzer immediately interrupts all operations.	Eliminate the error if possible and select CTRL+F6 SYSTEM RESET. The analyzer then asks you on the screen, whether the interrupted measurements, the results of which were cancelled, should be repeated.
E05 no clean cuvette	If no clean cuvette is available on the cuvette rotor, (e.g. caused by a vacuum error), the wash arm with the dry block does not move down to the bottom of the cuvette to prevent contamination of the dry block. Thus no clean cuvette is available in the analyzer.	Eliminate the error if possible (for example, clean and dry the rotor manually, install a new one or refill it) and select CTRL+F6 SYSTEM RESET. If the error occurs again, inform the Technical Assistance Center.
E07 system reset incomplete	Due to further errors the system reset was incomplete.	Eliminate the error if possible and select CTRL+F6 SYSTEM RESET to repeat a reset. If the error occurs again, inform the Technical Assistance Center.
E10 no vacuum	Vacuum pump defective. Vacuum tubing defect or clamped. Vacuum sensor defective or not well adjusted.The vacuum is not sufficient for a period longer than 2.5 seconds.	Select F1 CHECK AGAIN and inform the service personnel. Check that the tubing that connects the analyzer with the pump unit or the analyzer with the bottles is not kinked or clogged. Service personnel only: Check if the vacuum pump is working properly and replace the membrane or the complete vacuum pump, if necessary. Check the vacuum tubing for leakage. Check the vacuum sensor and re-adjust it, if necessary.
E11 waste full	The WASTE FULL signal is "high" for 1 second (or longer).	Empty the waste container. Check if the waste container floating switch is working properly and replace/repair it, if necessary. Check the wiring. Service personnel only: Check if the waste full signal detection signal is present on the system board. When the signal is present, malfunctioning of the system board may cause the problem.

Error message	Cause	Action
E12 water running out	The upper level detector detects "No water" in the water container, although the pump is switched on for a period longer than 25 seconds.	Check if there is enough system liquid in the water container and refill, if necessary. Check if the water tubing is leaking or blocked and repair or replace defective tubes, if necessary. Check if the filter in the system liquid container is blocked and replace it, if necessary. If the waste container has been empty, hold the water container and the pump unit at a higher level, to assure that the water can reach the analyzer more easily. Service personnel only: Check if the liquid level detection circuit is working correctly and repair it, if necessary.
E13 lamp failure	A counter over range signal is detected during a measurement. The signal counter over range signal is generated when the photocell signal is too low. When the blank data values are incorrect too, the gain setting of an input amplifier is wrong or an input amplifier is defective (on the photometer board).	Select F1 CHECK AGAIN. If the error occurs again, check if the lamp is working and replace it, if necessary. Inform the Technical Assistance Center. Service personnel only: Check if the lamp voltage is present and well adjusted. Adjust or repair the voltage supply, if necessary. Check if the selected filter is in the filament of the lamp. If not, check if the transport of the filter wheel is working correctly. Find the failure by following the adjustment procedure (submenu ELECTRONICS) in the SERVICE menu if a defective or incorrect set input amplifier causes the problem. Check that the lamp intensity is not too high (infinity signs on the intensity bars in the LAMP ADJUSTMENT menu).
E14 cuvettes temp error		Select F1 CHECK AGAIN. Inform the Technical Assistance Center if the error occurs again.
E15 reagent needle temp error		Select F1 CHECK AGAIN. Inform the Technical Assistance Center if the error occurs again.
E16 concentrated waste full (only if the optional container is installed)		Empty the optional concentrated waste container. Check if the concentrated waste container floating switch is working properly. Check the wiring.

Error message	Cause	Action
E17 insufficient water	The lower level detector detects "No water" in the water container.	Check if there is enough system liquid in the container and refill if necessary. Check if the liquid tubing is leaking or if it is blocked and repair if necessary. Check if the filter in the container is blocked and replace if necessary. Service personnel only: Check if the system liquid level detection circuit is working correctly and repair if necessary.
E20 sample syr. pos. error E21 sample syr. pos. error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E22 sample valve error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E23 reag. syr. pos. error E24 reag. syr. pos. error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E25 reag. valve error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E30 pipettor 14V failed E31 pipettor 30V failed		Inform the Technical Assistance Center.
E32 pipettor init failed		Inform the Technical Assistance Center.
E35 sample syr. reset failed E36 reagent syr. reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E37 pipettor communication error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E40 meas. disc 14V failed E41 meas. disc 30V failed		Inform the Technical Assistance Center.
E42 measurement disc error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E43 filter error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E52 meas. disc init failed		Inform the Technical Assistance Center.
E55 meas. disc reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.

Error message	Cause	Action
E56 filter reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Inform the Technical Assistance Center if the error occurs again.
E57 meas. disc communication error		Inform the Technical Assistance Center.
E60 sample arm 14V failed		Inform the Technical Assistance Center.
E61 sample arm 30V failed		
E62 sample arm horizontal error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E63 sample arm vertical error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E72 sample arm init failed		Inform the Technical Assistance Center.
E75 sample arm reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E76 sample arm reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E77 sample arm communication error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E80 reagent arm 14V failed		Inform the Technical Assistance Center.
E81 reagent arm 30V failed		
E82 reagent arm horizontal error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E83 reagent arm vertical error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E92 reagent arm init failed		Inform the Technical Assistance Center.
E95 reagent arm reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E96 reagent arm reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E97 reagent arm communication error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E100 discs 14V failed		Inform the Technical Assistance Center.
E101 discs 30V failed		
E102 reagent disc error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E103 sample disc error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E112 discs init failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E115 reagent disc reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E116 sample disc reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E117 reag. /samp. discs commun. error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E120 washarm/bellows pump 14V failed		Inform the Technical Assistance Center.
E121 washarm/bellows pump 30V failed		

Error message	Cause	Action
E122 washarm error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Make sure the cuvette rotor is placed correctly.
E123 bellows pump error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. Note that this error often occurs with other errors. First try to solve the other errors. This error might also disappear then.
E124 water overflow measurement disc	The wash arm detects that liquid reaches its overflow sensors.	In the halted or inactive state remove the cuvette cover, and then continue running. Determine which of the causes 1, 2 or 3 is the case and take the respective action.
	1.The wash arm dispenses too much water. Probably all cuvettes under the wash arm show a water overflow.	1.Check that the tubing between pump unit and main unit and the tubing between pump unit and the bottles is not bent or clogged.
	2.Some or all needles of the wash arms do not aspirate correctly. Probably only a few cuvettes show water overflow.	2.In the CHANGE ROTOR menu lift the wash arm and clean with the cleaning rod the aspiration needles (long needles). Also see 1. Service personnel only: Check the vacuum and valve 2 and 4.
	3.The message looks erroneous. There is no clear overflow. There is a cause for conductance between the overflow sensors on the wash arm and the plate of the wash arm.	3.Lift the wash arm and clean the underside of the wash arm, especially around the overflow sensors. Service personnel only: Check the overflow signal; replace wash arm if necessary.
E125 no cuvettes	There is no cuvette rotor installed At resetting the wash arm can reach a too low position according to the opto read-out.	Check if a cuvette rotor is present and place one, if necessary. Then press F5 (Specific Reset). Service personnel only: Check if the wash arm adjustment is correct. Check if the opto-couplers are malfunctioning and repair them, if necessary. Check if the wash arm is well tightened.
E132 washarm/bellows pump Init failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E135 washarm reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET. See also E122 washarm error.
E136 bellows pump reset failed		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.
E137 washarm/bellows pump comm. error		Press either F5 (Specific Reset) or select CTRL+F6 SYSTEM RESET.

Installation

7.1 Hardware installation

To operate the analyzer with a PC, the analyzer must be connected to the PC with the supplied serial cable.

ATTENTION

Do not make the connection when either the PC or the analyzer is on. You can cause damage to both the PC and the analyzer.

1. Switch the PC and the Analyzer off.
2. Connect one end of the serial cable with COM1 on the PC.
3. Connect the other end of the serial cable with the RS232 connector on the rear side of the Analyzer.

7.2 Software installation

7.2.1 General

Install the software only by someone who is familiar with Windows™.

Note

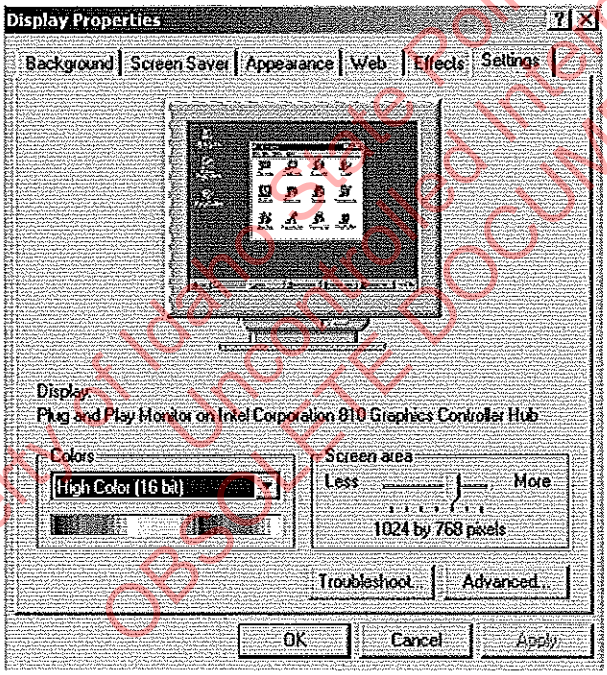
Vital Scientific N.V. does not guarantee that the program functions properly when third party programs are installed and/or active on the PC. Do not run other programs during the use of the Analyzer program.

Requirements:

- PC as specified in section 2.9 of the manual
- Analyzer installation disk

7.2.2 Prepare PC

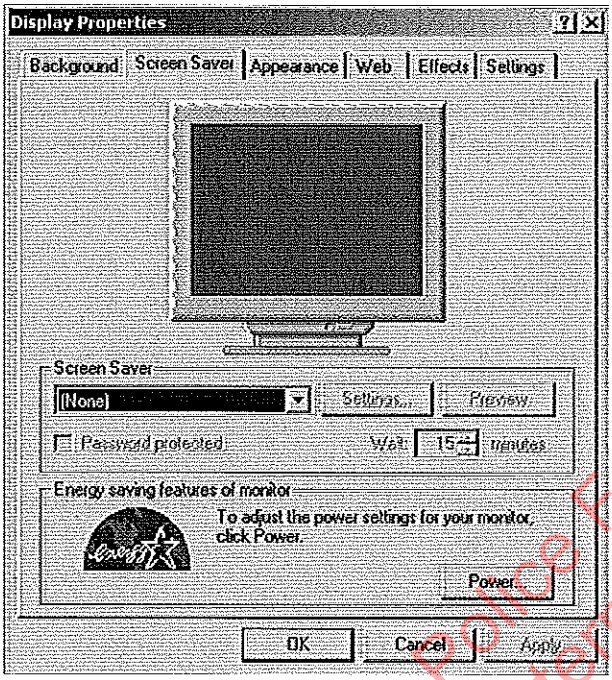
Some adjustments are necessary for optimum operation. It is strongly recommended to carry out the settings as described below:
Set the screen area to 1024 x768 pixels.



1. Select:
   START from the Windows™ operating system.
   SETTINGS
   CONTROL PANEL
   DISPLAY
2. Select:
   SETTINGS TAB
3. Move the slider in the SCREEN AREA field to
   1024 x 768
4. Press:
   OK

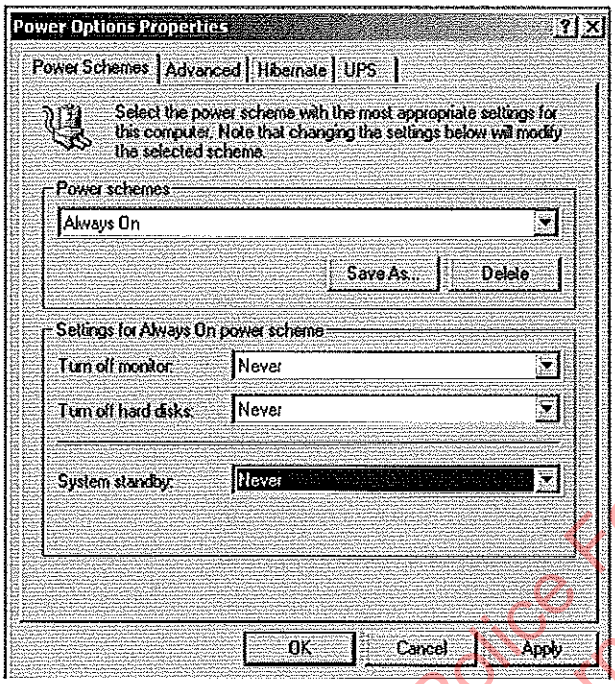
Disable the Screen saver

The screen saver must be disabled to guarantee the most stable performance.



1. Select:
   START from the Windows™ desktop.
   SETTINGS
   CONTROL PANEL
   DISPLAY
2. Select:
   SCREEN SAVER tab
3. Select in the SCREEN SAVER field:
   (None)
4. Press:
   OK

Power management



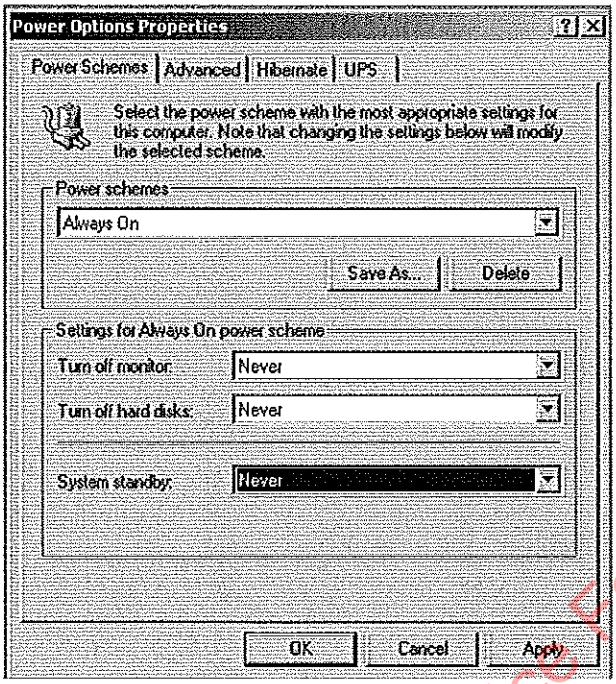
1. Select:
   START from the Windows™ desktop.
   SETTINGS
   CONTROL PANEL
   POWER OPTIONS
2. Select:
   POWER SCHEMES tab
3. Select in the Power schemes field:
   ALWAYS ON
4. Select in the Turn off monitor field:
   NEVER
5. Select in the Turn off hard disks field:
   NEVER
6. Press:
   OK

Note
If your system has provisions for Power Saving supported by the BIOS, then these features should also be turned off in the CMOS-Setup (see your PC manual for further instructions).

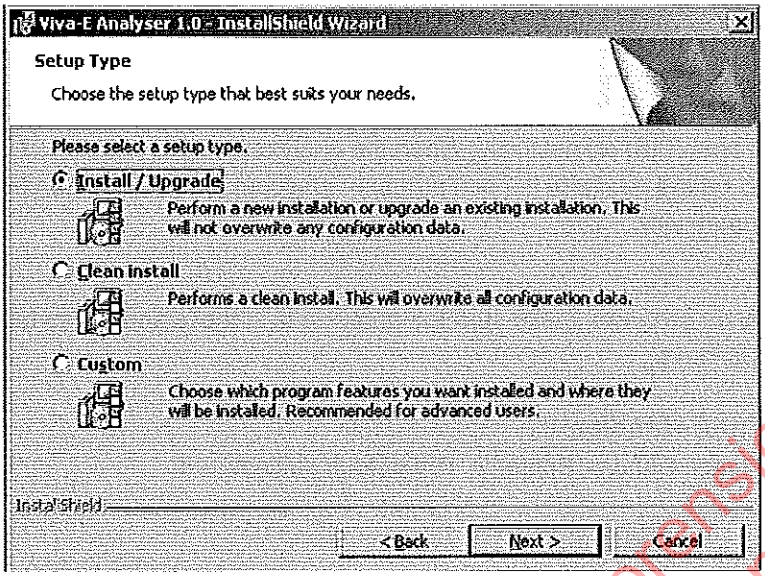
7.2.3 Install software

Preparation

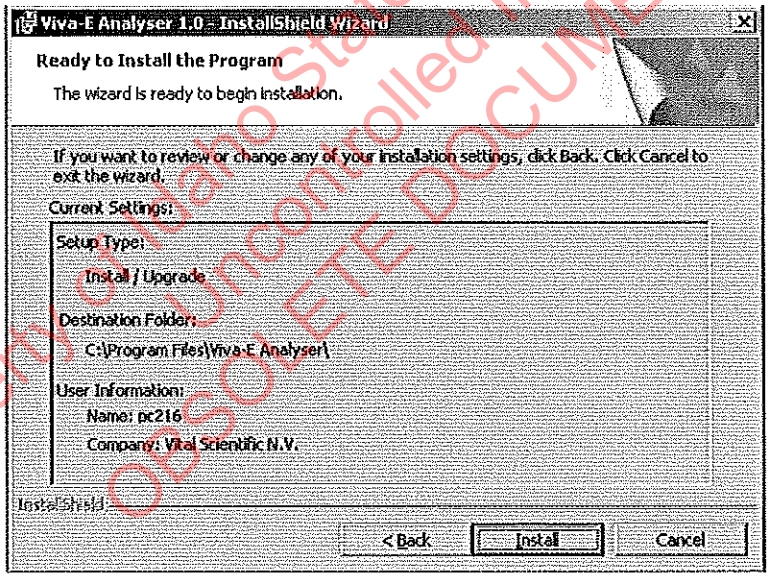
ATTENTION
Do not install software on the PC if there are other programs open. Make sure all programs are closed.



1. Exit all programs
2. Put the installation CD or floppy with the analyzer software in the CD-ROM drive or the floppy drive of the PC.
3. If the installation program does not open automatically, proceed with step 4. If the installation program opens automatically, proceed with step 6.
4. Select:
   START from the Windows™ desktop.
   RUN
5. From the drop-down menu select the setup.exe file and confirm with OK. If the disk drive is not the indicated drive in the Run window you have to browse by using the Browse button.
6. If the window above is indicated, click the Next button to accept copyright. The following window is displayed.



7. Select:
   TYPICAL
8. Press:
   NEXT
   The following window opens.



9. Check the current settings.
10. Click INSTALL to install the software or click BACK to change settings.
11. Wait for the software to install.
12. Press in the Installation Program screen:
    FINISH

7.2.4 Files

The installation creates following directories:

C:\PROGRAM FILES\ANALYSER. The directory contains the files as shown in the figure.

C:\PROGRAM FILES\ANALYSER\STANDARD. The directory contains the files as shown in the figure.

7.3 Configure software

7.3.1 Introduction

The analyzer program on the PC uses three additional programs (handlers) to communicate with the analyzer, printer(s) and host (LIS) respectively. When the analyzer program is started by means of clicking the analyzer icon on the desktop, the analprnt.exe, analcom.exe and the analhost.exe handlers are activated automatically.

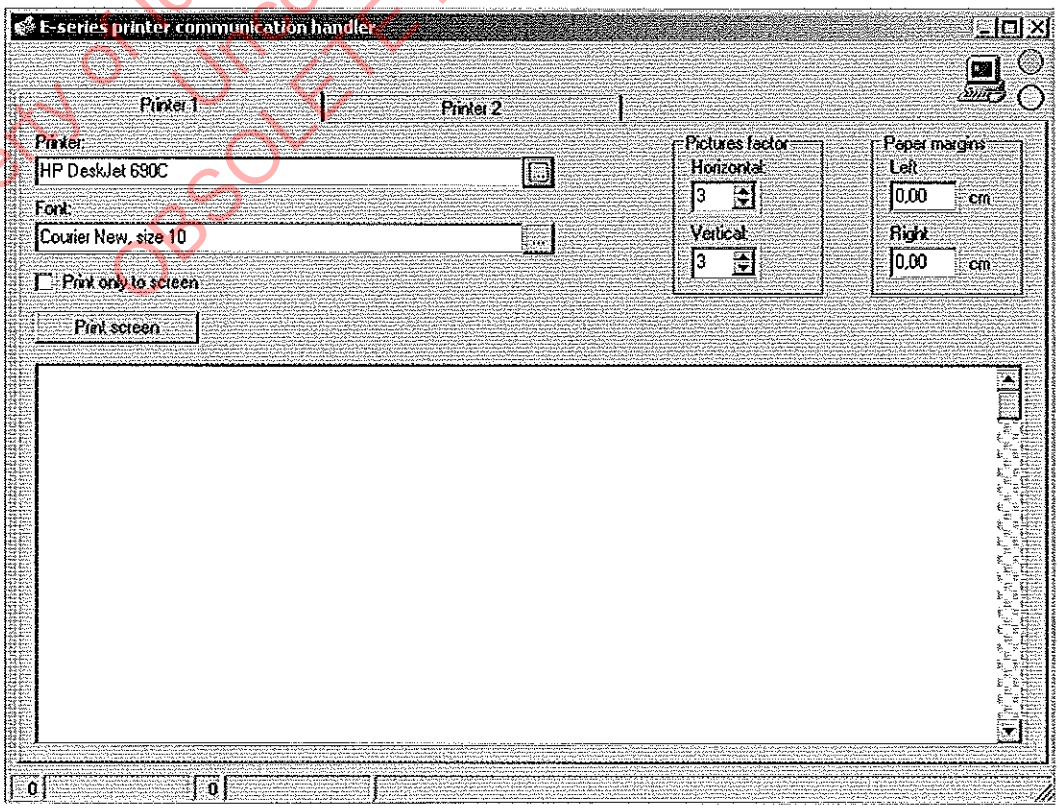
Note

To guarantee a stable analyzer program, make sure the analyzer is in the 'stand-by' status before you make changes to the handlers.

7.3.2 Configure Analyzer Printer Handler

Configure the settings of Printer 1 and/or Printer 2. The default settings are:

Parameter	Value
PRINT ONLY TO SCREEN	Default Off. Data is printed to the white preview screen and not to the selected printer.
SELECTED PRINTER	Default Windows printer. Press the Ellipses button [...] to select a different printer.
FONT	Courier New; 10 pt Press the Ellipses button [...] to select a different font and font size.
PICTURE MULTIPLYING FACTOR	Horizontal:3 Vertical:3 Change the value to increase or decrease the horizontal size of the printer illustrations.



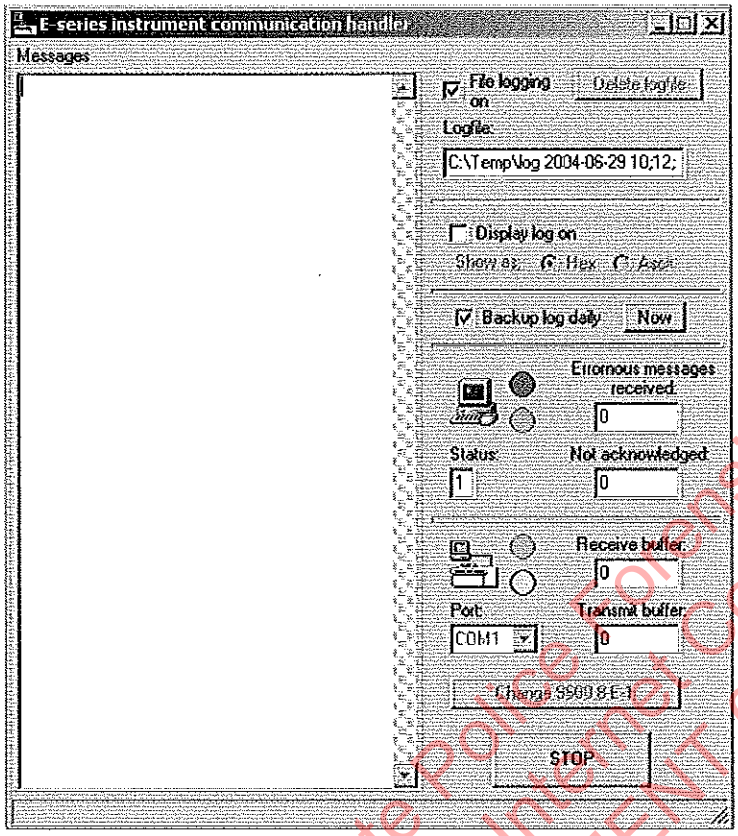
Function	Description
PAPER MARGINS LEFT	0,00 cm Change the value to increase or decrease the left hand margin.
PAPER MARGINS RIGHT	0,00 cm Change the value to increase or decrease the right hand margin.
PRINT SCREEN	When clicked, the information previously sent to the white preview screen of the Analyzer Printer Communication Handler is sent to the selected printer.

7.3.3 Configure Analyzer Communication Handler

Configure the communication port between the PC and the Analyzer. The other parameters are fixed. The default settings are:

Parameter	Value
PORT	COM 1
BITS PER SECOND	9600
DATA BITS	8
PARITY	None
STOP BITS	1
FLOW CONTROL	None

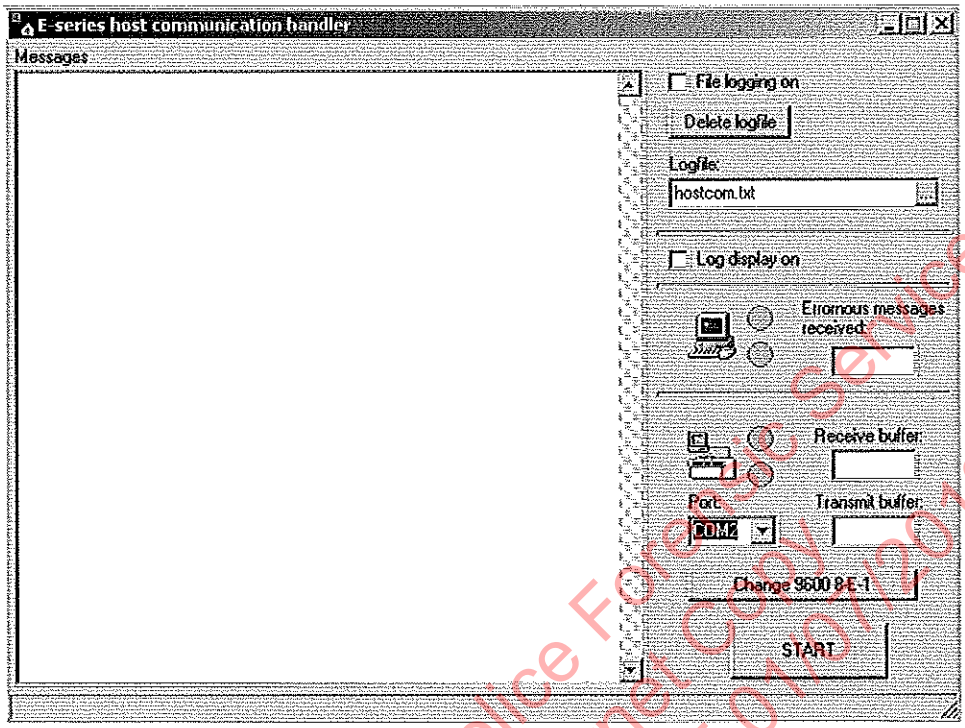
Function	Description
STOP/START	Starts or stops the communication between the PC and the Analyzer. Stop the communication to change the port number.
PORT	Select the port number for the communication between Analyzer and PC.



7.3.4 Configure Host Communication Handler

It is possible to start the Host Communication Handler manually from the START menu. Switch on and off the communication. With the communication switched on, the parameters can be changed. The default settings are:

Parameter	Value
PORT	OFF
BITS PER SECOND	9600
DATA BITS	8
PARITY	None
STOP BITS	1
FLOW CONTROL	None
PORT	Select a port (1 – 8) to switch on the communication. Here it is possible to select whether the analyzer/host communication is active and, if it is to be activated, through which port number. When a port is selected (1 to 8), the communication parameters such as baud rate, parity etc., can be set.



7.4 Backup procedure

7.4.1 Backup files

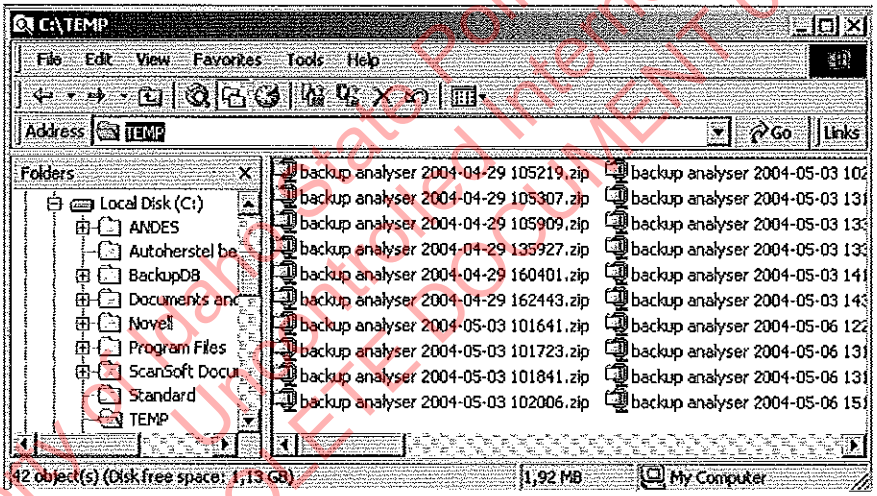
It is recommended to backup files every day or week. For backup, save the following files on a disk:

- The system information *.dat in: C:\PROGRAM FILES\ANALYSER.
- The patient results *.txt in: C:\PROGRAM FILES\ANALYSER.
- The test parameters, QC AND BLANKS *.dat in: C:\PROGRAM FILES\ANALYSER\STANDARD.

These files can easily be backed up using the Windows™ 'drag-and-drop' feature or 'copy-paste' operation to store the files on a floppy. Of course, the automatic backup functionality offered by the various Windows™ operating systems can also be used.
If necessary, e.g., after a PC-crash the Windows™ and analyzer programs are re-installed, you need only copy the backup data to its original location. These are respectively: C:\Program Files\Viva-E Analyzer\ and C:\Program Files\Viva-E Analyzer\Standard\ folders.

7.4.2 Automatic backup

Use the Analyzer communication handler to make an automatic backup file of the analyzer and communication logs. This back-up file is automatically compressed for ease of use and to save drive space. The backup files will stay for 30 days on the computer.
To activate this feature:



1. Maximize the Analyzer communication handler
2. Make sure that the backup log daily checkbox is selected
   The backup files will be saved in C:\TEMP and saved as follows: backupanalyser[date][time].zip (e.g. backup analyzer 2004-04-29 000047.zip).
3. Press the NOW button to make a real time back-up of all files and communication logs.

7.5 Host - PC communication

Please contact your local Technical Assistance Center for the most recent version of the Host-PC communication protocol.