Operator's Manual



Viva·E®

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Preface

CE

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

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The 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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[1] Until December 1, 2013 ELITechGroup B.V. was known as Vital Scientific B.V.
Any reference in this manual to Vital Scientific B.V. or Vital should be read as ELITechGroup B.V. or ELITechGroup Clinical Systems.

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Safety Precautions and Potential Hazards

1.1 General

Before you start installing and working with the analyzer, you should read the safety precautions and regulations shown in this chapter. Safety comes first!
The analyzer was designed and manufactured according to modern standards and with regard to international safety regulations. All possible risks that were known at the time of manufacturing were taken into account and either eliminated or reduced. Nevertheless, some sources of danger cannot be eliminated. Please note the following guidelines.
When operating the analyzer all national or international guidelines and regulations must be observed, as in the normal lab routine. Power supply accessories (cables/plugs) must be installed in such a way that sources of danger (overheating of cables, short circuit due to incorrect fuse ratings, loose cables etc.) are eliminated. The user should be aware, that if the analyzer is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. The analyzer is supplied without anti-virus software. If you connect the analyzer to a network, make sure that the network has the necessary protection.

1.1.1 Basic assumptions for risk analysis

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

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

1.2 Description of symbols

1.2.1 Symbols on the instrument



WARNING
Attention, consult instructions for use. This symbol appears on several parts of the analyzer. The specific meaning that applies for those parts is described in 1.3 Hazards.



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



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



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



ATTENTION
This symbol means that at the end of life, the analyzer must be separately collected in accordance to the European Directive 2002/96/EC.

1.2.2 Symbols in the manual



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



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



Note
Notes contain additional information corresponding to the text.

1.3 Hazards

1.3.1 Electrical hazards



WARNING
To prevent the risk of electrical shock and/or damage to the instrument, operators should not open the covers of live parts (electrical) of the instrument. Only authorized personnel, e.g. service technicians, may open the instrument to perform maintenance or repairs.
Touching the live parts when the power is on may cause severe injury or death.

1.3.2 Mechanical hazards



WARNING
DO NOT wear loose garments or jewelry that could catch in mechanisms.
DO NOT put your fingers/hands into the pathway of any part while the analyzer is in operation.
DO NOT attempt mechanical repair unless the instrument is not in operation or OFF.

1.3.3 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.

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



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

Patient samples, controls, calibrators and liquid waste should be considered potentially infectious and capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other blood borne pathogens. The handling of these substances must be performed in accordance with established laboratory safety regulations in order to minimize risk to laboratory staff. This includes wearing of gloves, splash protection, etc. Contact of skin and mucous membranes must be avoided. This also applies to all components of the instrument that are exposed to these substances. If any specimen is spilled on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant.
In various countries there are regulations on the disposal of waste. Refer to local sources for additional information on correct waste disposal.

1.3.7 Operational requirements



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



ATTENTION
The cooling unit must be filled with liquid. The level should be visible and between a minimum and a maximum level. Check liquid level every 3 months. For details on the liquid to be used, see 2.3 Cooling unit.

1.3.8 Transport and storage requirement



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

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 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 any mechanical parts while the instrument is operating. This may cause operation to stop or damage the instrument.
Only original spare parts should be used in the maintenance of this analyzer.
Only original disposables and accessories should be used in the operation of this analyzer.
Make sure the front covers are closed while the instrument is in operation.

1.4.3 Instrument unused for one month or longer

If the instrument is not to be used for one month or longer, contact Siemens Healthcare Diagnostics Technical Support for further information before you switch off the analyzer.

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 or extract solutions from the Siemens immunosuppressant assays. Patient samples should be prepared and handled in accordance with the instructions from the reagent manufacturer. Refer to the reagent kit insert for detailed instructions.



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

1.5.2 Reagents and calibrators

The manufacturer recommends the use of Syva®/Siemens reagents and calibrators in combination with this analyzer.



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



WARNING
Vital Scientific B.V. assumes no responsibility for erroneous test results caused by reagent kits, calibrators and test parameters that are not provided by Vital Scientific B.V.



WARNING
Siemens assumes no responsibility for erroneous test results caused by reagent kits, calibrators and test parameters that are not provided by Siemens.

1.5.3 Controls

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

1.5.4 Analytical results

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



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

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. Most clinical chemistry tests that require a photometric measurement can be adapted for the system. The analyzer is intended for use in laboratories. The analyzer has to be operated by trained operators.

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´ reagents. 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.

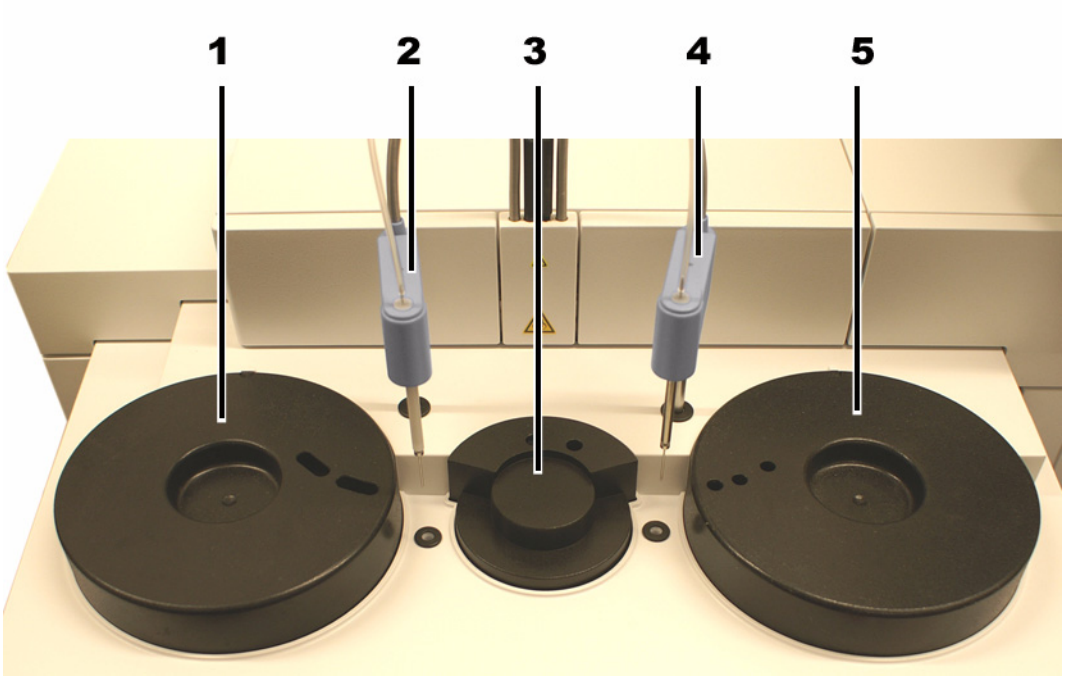
An external computer and a monitor provide the user interface for the analyzer. The operating system is Microsoft® Windows®. A keyboard or a barcode reader is necessary to enter data. The test results are saved on the computer. The software provides a standard way of output on a printer, but the operator 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 this is the case, it is possible to enter test requests directly from the host computer. Also, the test results can be transferred to the host 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 directed and monitored by dedicated processors. The operator has a constant view on the hardware status and performance of the chemistries. When errors or flagged results occur for open channel assays, 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 printed as the analysis sequence is completed. 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.



1 Reagent rotor
2 Reagent pipette
3 Cuvette rotor
4 Sample pipette
5 Sample rotor

2.2.2 Rotors

Sample rotor
The sample rotor is designed to accept a variety of sample tubes and cups. The sample rotor is covered. Emergency (STAT) samples and samples in pediatric cups can be tested without interference of the routine workload.

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

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 and is incubated at 37°C. The cuvette rotor, made for the manufacturer, is covered by a heated cover.
The maximum incubation time after sample addition is 11.5 minutes with a single reagent and 11.25 minutes with two or more reagents. 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. 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 is equipped with a level detector and can aspirate volumes between 2µl 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 internally and externally afterwards.

Reagent pipette mechanism
The reagent probe is equipped with a level detector and can aspirate volumes between 10 µl and 399 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 transfers the aspirated volume of reagent into the cuvette rotor, the probe is washed internally and externally. 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 that guarantees cooling for loaded reagents. The cooling unit operates as a sealed unit and needs little maintenance. The cooling unit is placed behind the liquid waste and water bottles and provides a constant temperature for the reagents located on the rotor, as required by the application protocol. When an acoustic signal sounds, the cooling liquid must be refilled.

Note

Use a mixture of 1 part EUROL® to 1 part water.

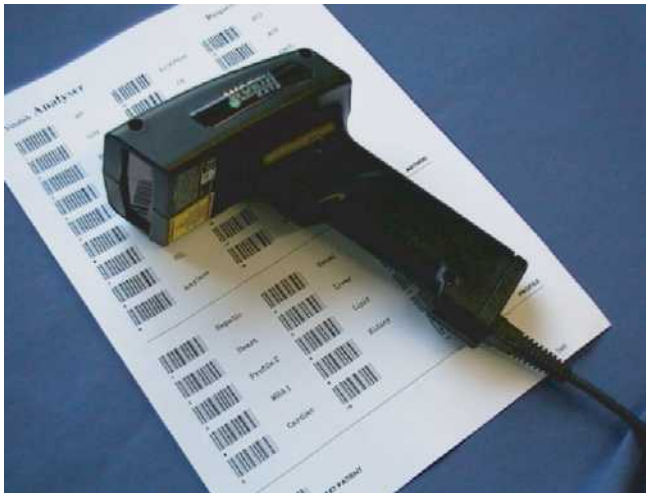
The control display shows the temperature of the cooling liquid. The actual temperature of the reagents will be slightly higher. The user cannot change the temperature setting of the cooling unit. The unit and coolant are free from chlorofluorocarbons.
The installation is made by the service engineer and is not described in this manual.



2.4 External barcode reader

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

You can shorten the operator time with an optional external barcode reader. This hand held barcode reader can be connected to the keyboard of the PC. When requesting tests, you can enter sample ID numbers from barcodes on the sample tubes. You can then assign tests with the use of the barcode request menu card.
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 can also be used to identify the samples when loading them or when viewing the test results.

Note
The external barcode reader has a separate instruction manual. Please read the barcode reader manual for information and user instruction.

Note
The manufacturer recommends that a fault safe barcode reader is used. Barcode readers that do not use a checksum can give improper or false readings.

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. Pull up the arm and place the arm protection tube over the shaft. This prevents the arm from moving down.
4. Move the analyzer with at least 2 persons. Hold the instrument only by the metal frame on the bottom.



ATTENTION
Do not lift the instrument by the door that covers the syringes. The door might come off the hinges, causing the instrument to drop.

5. Connect all cables and tubes again when the analyzer is in place.

2.6 Performance and technical data

2.6.1 Performance

Maximum throughput	One reagent: 180 tests per hour
	Two reagents: 133 tests per hour
	Three reagents: 65 tests per hour
Accuracy	Refer to 2.6.8 Accuracy and precision
Precision	Refer to 2.6.8 Accuracy and precision
Programmable tests	5 per programmed reagent disc
Preprogrammed tests	Up to 115
Quality control	1-3 per parameter, 120 controls programmable per reagent rotor
Sample processing	Prioritized: STAT, Pediatric, Normal, in that order

2.6.2 Sample system

Sample positions	51 patient samples
Emergency samples	3 positions
Calibrators	9 positions plus maximum 51 patient positions
Pediatric samples	6 positions, overflow goes to sample positions 1 - 51
Blank position	1
Controls	4 positions plus maximum 51 patient 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	2-30 µl (steps of 0.1 µl)
Syringe	100 µl
Adapter	6 (pediatric, sample rotor)

2.6.3 Reagent system

Reagent rotor (Emit)	26 positions: 13 x 14 ml, 13 x 28 ml bottles
Volume/test	Reagent 1: 110 – 399 µl, reagent 2: 0 – 180 µl, reagent 3: 0 – 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
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	27 sec. (DUAL MODE)

2.6.5 Minimum PC requirements

CPU	Intel® Pentium® 800 MHz
RAM	128 MB
Monitor	VGA monitor 1024 x 768 pixels
Hard Disk	2 GB
Additional drive	CD-ROM drive
Operating system	Windows® 2000 or Windows® XP
Serial ports	1 required for analyzer, 1 optional for host connection (a LAN connection can be used instead)
LAN connection	Optional for host connection (a serial port can be used instead)
USB Ports	One optional for printer
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 liter, glycol-based
System	Closed circulation
Connection	Mains electrical connector
Power consumption	340 VA max.
At operating voltage	110 or 230 VAC (device-dependent)
Line frequency	50/60 Hz

2.6.7 External barcode reader

Version	Hand device
Technology	CCD
Barcodes (standard)	Codabar
Barcodes (optional)	UPC-A +2, +5
	UPC-E +2, +5
	EAN-13 +2, +5
	EAN-8 +2, +5
	Code 39
	Code 93
	Code 128
	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 CLSI 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.

2.7 Analyzer technical data (without washing unit or computer)

2.7.1 Dimensions and weight

Width	115 cm
Height	49 cm
Depth	56 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	1000VA
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 (cooling). For the approvals for these devices please refer to the corresponding manuals.

System Handling Basics

3.1 Work Preparation



WARNING

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.

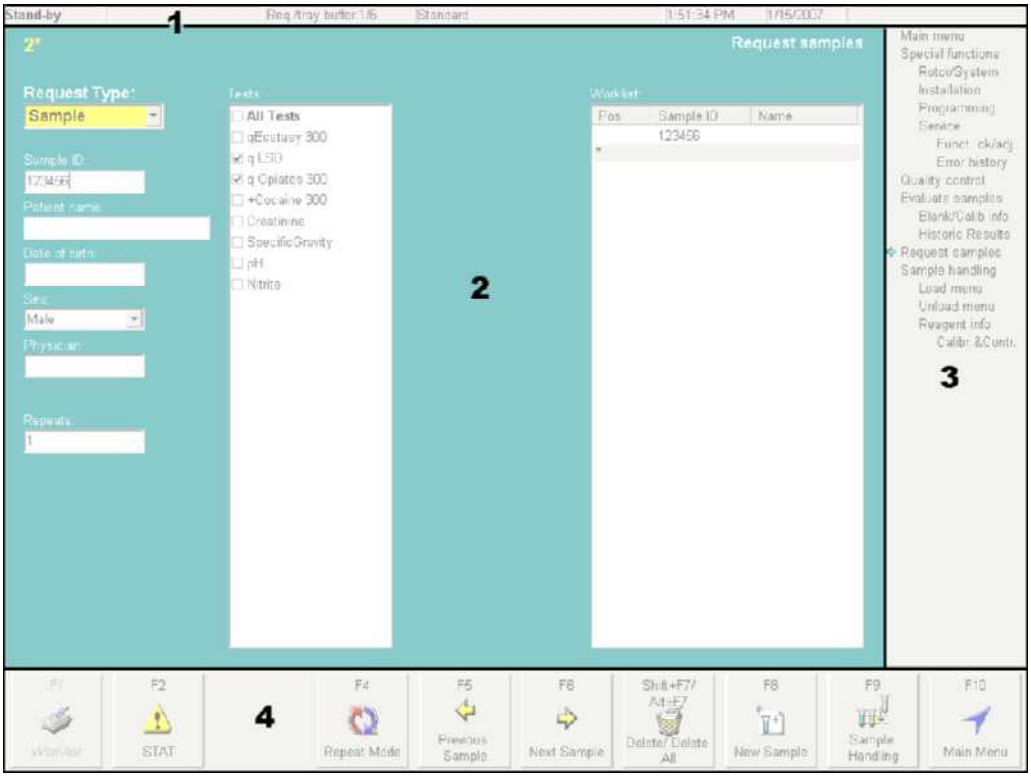
3.1.1 Use of the manual

The *Introduction* chapter describes the analyzer and its functional modules. The *Basic Routine* chapter describes the daily work procedures. The *Extended Routine* chapter describes less often used screens, with the parameters and their possible values. Step-by-step procedures are given for all basic and extended routine operations. Names and values that appear on the screen are shown in specific fonts and styles to indicate `MENU NAMES`, `FUNCTION KEYS` and `PARAMETER NAMES`.

Example: manually enter sample data and request tests

1. Select `F8 REQUEST SAMPLES` from the `MAIN MENU`.
2. Enter the `SAMPLE ID:`.
3. Enter the other parameters as required or press `TAB` to go to the tests selection.
4. Select the required tests, profiles and/or calculated results from the `TESTS:` list.
5. Select `F8 NEW SAMPLE` to save the sample in the worklist and start the definition of a new sample.
6. If no more samples are needed, you can proceed to loading samples by pressing `F9 SAMPLE HANDLING`.

3.1.2 Parts of the screen



1. Status line
2. Main screen area
3. Menu Tree
4. Function keys F1 to F10

Status line

The status line shows following information:

- Status of the analyzer, e.g. `STAND-BY`.
- 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.
- Time and Date.
- The state of the external interface (if connected), e.g. `HOST`.

Main screen area

This area is specific for the menus that can be selected via the menu tree or function keys. The screens are explained in subsequent chapters.

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 Navigation keys

Arrow Keys	Go to another field
TAB	Switch between left and right fields
PAGE UP/DOWN, HOME, END	Scroll through a list
ENTER	Select the next field
F1 - F10, SHIFT, CTRL, ALT	Go to the associated screen or execute the associated function. Function keys can be combined with the Shift, Ctrl and/or Alt keys to associate more functions to the same function key.
Spacebar	Select or deselect a checkbox and go from left to right side tab fields.

3.1.4 Emergency halt

To halt the analyzer

1. To immediately halt the analyzer, press ALT+F10.
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.

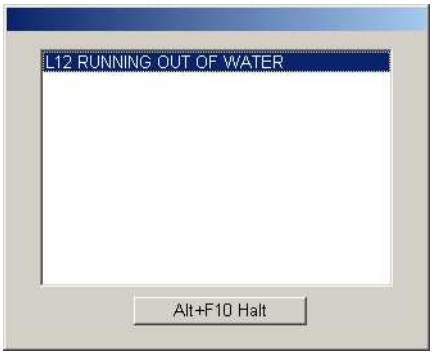
To reset the analyzer

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F1 ROTOR/SYSTEM.
3. 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 condition and, if possible, instructions on how to solve the problem. The message is accompanied by an acoustic signal. To turn off the acoustic signal press the spacebar.

Example:



This message shows when the analyzer liquid is low. You must fill the water container. See the list of error messages in 6.2 Troubleshooting.

3.2 Start the analyzer for the first time

WARNING
Do not install the analyzer yourself. The analyzer must be installed by qualified service technician.

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. Connect the cooling unit. See 3.2.3 Install the cooling unit.
2. Switch the analyzer on. See 3.2.2 Start the analyzer.
3. Install the password. See 3.2.5 Passwords.
4. Fill the system with system liquid. See 3.2.6 System liquid.
5. Set up the system parameters. See 3.2.7 System parameters.
6. Program the calibrators. See 5.2 Calibrator programming.
7. Load or program the test parameters. See 5.3 Test programming.
8. Program the controls. See 5.1 Program controls.
9. Define the incompatible tests. See 5.5 Cuvette incompatibility.
10. Program the profiles. See 5.6 Profiles.
11. Position the reagents. See 5.7 Reagent position.

3.2.2 Start the analyzer



1. Set the main switch to ON. It is 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 starts with a system reset. The analyzer is now ready for operation.

The manufacturer recommends that the analyzer and the user software are switched on at all times. This makes sure that a cuvette blank is done daily. If the analyzer is switched off, a manual cuvette blank measurement must be done when you switch on the analyzer again. See 3.2.7 System parameters.

3.2.3 Install the cooling unit

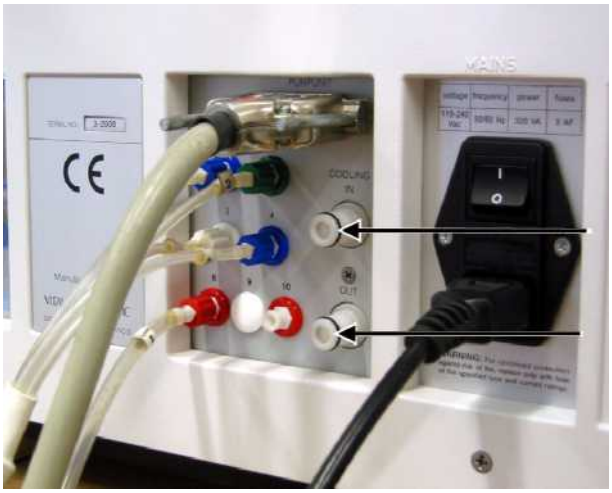


The additional external cooling unit of the analyzer guarantees necessary cooling for loaded reagents. The cooling unit operates with a sealed cycle technology. The cooling unit requires virtually no maintenance. Unit and coolant are free from CFC.

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.

Note
Use a mixture of 1 part EUROL® to 1 part water.

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 from the cooling unit to the snap-on connectors of the analyzer, as indicated 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 to `EMIT`. This is the default. To use tests from other manufacturers the reagent rotor type must be set to `CLASSIC`. An EMIT® rotor has 26 positions for reagent bottles; a classic rotor has 32 positions.

1. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
2. Select `F2 INSTALL`
3. Select `CHANGE REAGENT DISK`.
4. Select `F2 NEW REAGENT DISK`.
5. Select rotor type `EMIT` or `CLASSIC`.
6. Confirm.

3.2.5 Passwords

An operator level 1 password is used to keep unauthorized persons from altering or deleting important data. The password is required to delete historic data files, perform functional adjustments and to restrict access to the INSTALLATION, PROGRAMMING and QUALITY CONTROL menus. A level 2 password is used to restrict access to servicing functions.

Note

If the operator level 1 password is entered incorrectly, the user can still make adjustments to the lamp.

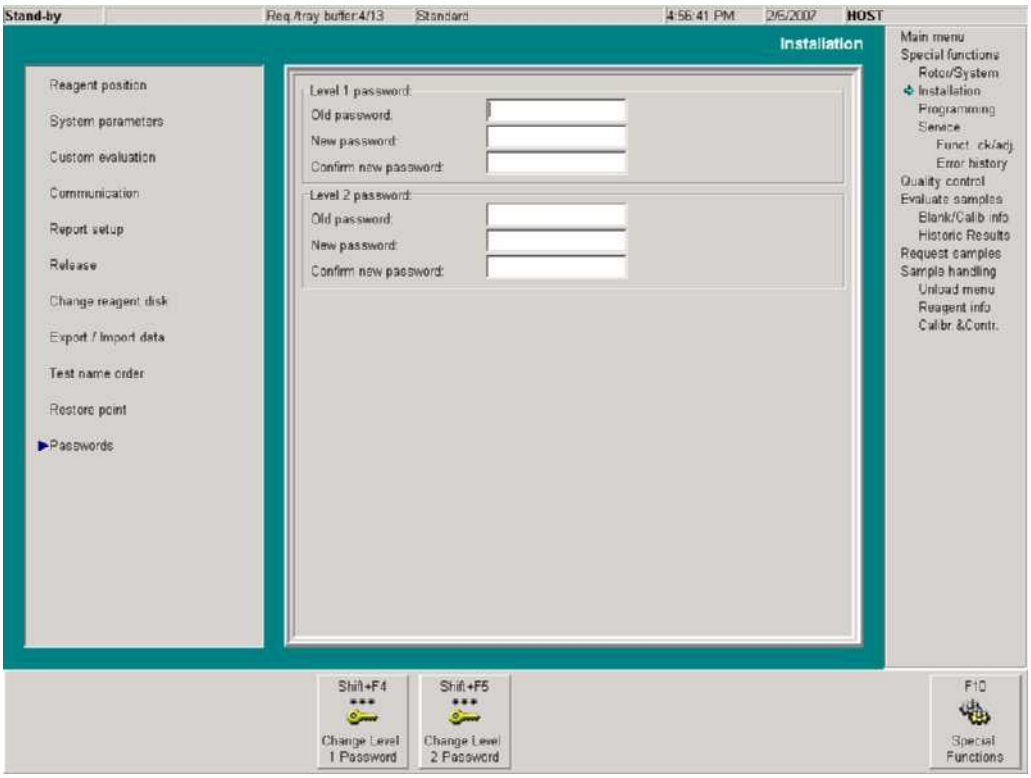
Note

The level 2 password is only available to Siemens Healthcare Diagnostics personnel.

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

Changing the level 1 password

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL
3. Select PASSWORDS from the list of functions to the left.



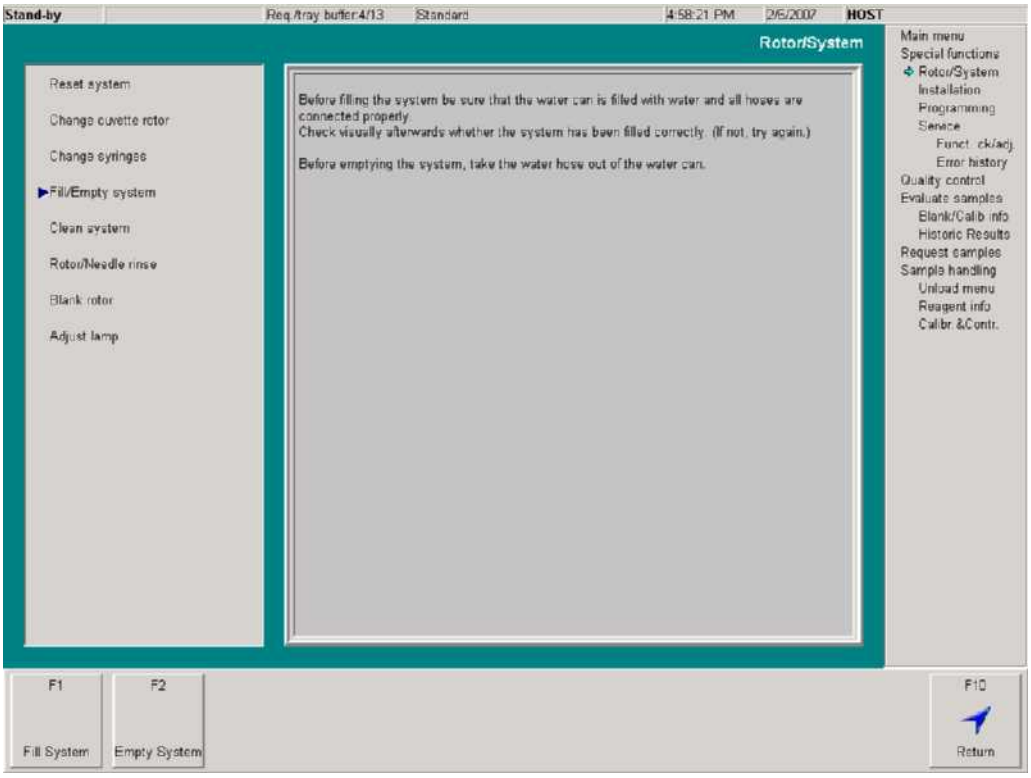
4. If the level 1 password was already defined, type it in the OLD PASSWORD: field.
5. Type the desired level 1 password in the NEW PASSWORD: and CONFIRM NEW PASSWORD: fields.
6. Press SHIFT+F4 CHANGE LEVEL 1 PASSWORD.
7. Press F10 SPECIAL FUNCTIONS to return to the SPECIAL FUNCTIONS menu.
8. Press F10 MAIN MENU to return to the MAIN MENU.
9. Select F4 LOG OFF.

3.2.6 System liquid

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

Filling system liquid

1. Fill the water container with 25 ml of system solution and 10 liters 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 FUNCTIONS` from the `MAIN MENU`.
3. Select `F1 ROTOR/SYSTEM`.
4. Select `FILL/EMPTY SYSTEM` from the list of functions to the left.



5. Press `F1 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 large air gaps.
7. If you detect any large air gaps, press `F1` to perform another fill system cycle.

Emptying system liquid

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

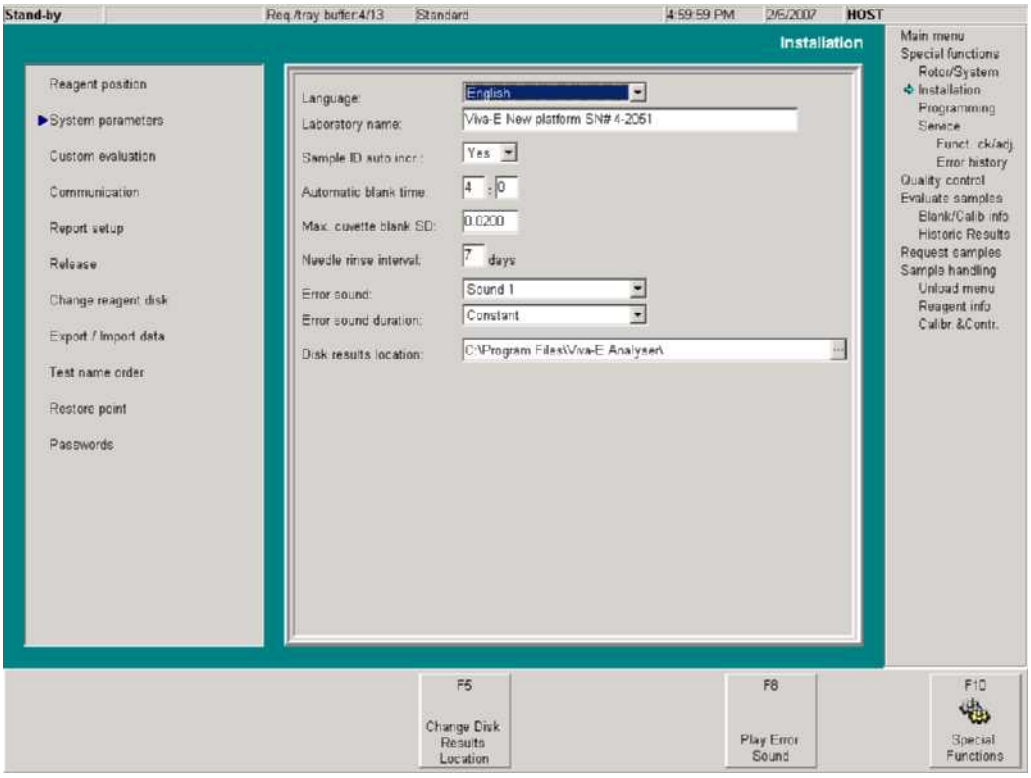
1. Remove the system liquid hose from the container.
2. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
3. Select `F1 ROTOR/SYSTEM`.
4. Select `FILL/EMPTY SYSTEM` from the list of functions to the left.
5. Select `F2 EMPTY SYSTEM` to empty the analyzer for transport.
6. Make sure that there is no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

3.2.7 System parameters

Normally the system parameters are defined once, before the analyzer goes into operation. However, you can change the parameters whenever necessary.

Viewing and changing system parameters

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL
3. Select SYSTEM PARAMETERS from the list of functions to the left.



4. To change a parameter, use the cursor keys or the mouse to select it. Enter the new value or choose another value from the listbox. Pressing ENTER selects the next parameter.

Parameters

LANGUAGE:	Language used for all screen texts. Changes are effective as soon as you leave this field.
LABORATORY NAME:	The laboratory name is shown on every result printout. The name can be 32 characters long.
SAMPLE ID AUTO INCR.:	• YES - Automatically increases the SAMPLE ID: in the REQUEST SAMPLES menu when pressing the NEW SAMPLE button. Alphanumeric data is always counted up. The analyzer counts the sequence e.g. from Az99 up to Ba00. • NO - Empties the SAMPLE ID: in the REQUEST SAMPLES menu when pressing the NEW SAMPLE button. . When using barcoded samples, select NO.

AUTOMATIC BLANK TIME:	The time (hh:mm) at which the analyzer will do a daily automatic blank measurement of the cuvette rotor. Enter the hours, press ENTER, enter the minutes and press ENTER again. It is recommended to do this measurement before the daily routine. This measurement is only possible when the analyzer is in stand-by mode at the indicated time. Otherwise, you must perform this measurement manually. 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 expiry date for reagents, controls and calibrators. If you do not perform 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 performed.
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.
ERROR SOUND:	A selection of five sounds is available for the analyzer. Press F8 PLAY ERROR SOUND to hear the error sound. The default sound is SOUND 1.
ERROR SOUND DURATION:	Three error sound duration are available. • CONSTANT - The error sound plays constantly • 5 MINUTES - The error sound plays for 5 minutes. • 20 SECONDS - The error sound plays for 20 seconds.
DISK RESULTS LOCATION:	Change the location where historic data files are stored.

Fuction keys

F5 CHANGE DISK RESULTS LOCATION	Change the location where historic data files are saved.
F8 PLAY ERROR SOUND	Plays the selected sound.
F10 SPECIAL FUNCTIONS	Go to the SPECIAL FUNCTIONS menu.

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?**	Power cables, tubing to cooling unit, communication cables, etc. are all connected.
✓	**Is the system switched on?**	Analyzer unit, computer and cooling unit are all switched 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 temperature on the cooling unit.
✓	**Are all necessary parameters defined?**	Check the following parameters and settings. • 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 function in the ROTOR/SYSTEM menu. Check the water container and syringes.
✓	**Are all work helps set as required?**	Increase of sample number, automatic rerun, custom 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 PROGRAMMING function in the PROGRAMMING 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 to make measurements 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. To avoid delays in routine operation, check the volumes of the loaded reagents before each run (REAGENT INFO 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 via the NEEDLE INCOMPATIBILITY and CUVETTE INCOMPATIBILITY functions in the PROGRAMMING menu.
✓	**Are the profiles programmed?**	Select the profiles via the PROFILE PROGRAMMING function in the PROGRAMMING menu, if you want to use profiles for the ordering of patient samples.

✓	**Has the cuvette rotor blank been done?**	Perform 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 function in the ROTOR/SYSTEM menu for a manual start of the analyzer blank.
✓	**Has the waste container been emptied?**	Empty the waste container before you start the daily 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 water container been filled?**	Fill the water container before you start the daily work. This avoids the interruption of the routine work.
✓	**Has the formation of foam been avoided during reagent preparation?**	Inspect reagent bottles.
✓	**Has the formation of foam been avoided during sample preparation?**	Inspect sample tubes.

Basic Routine

4.1 Preparing tests

4.1.1 Methods to enter sample information and select tests

The analyzer can receive sample information by three methods:

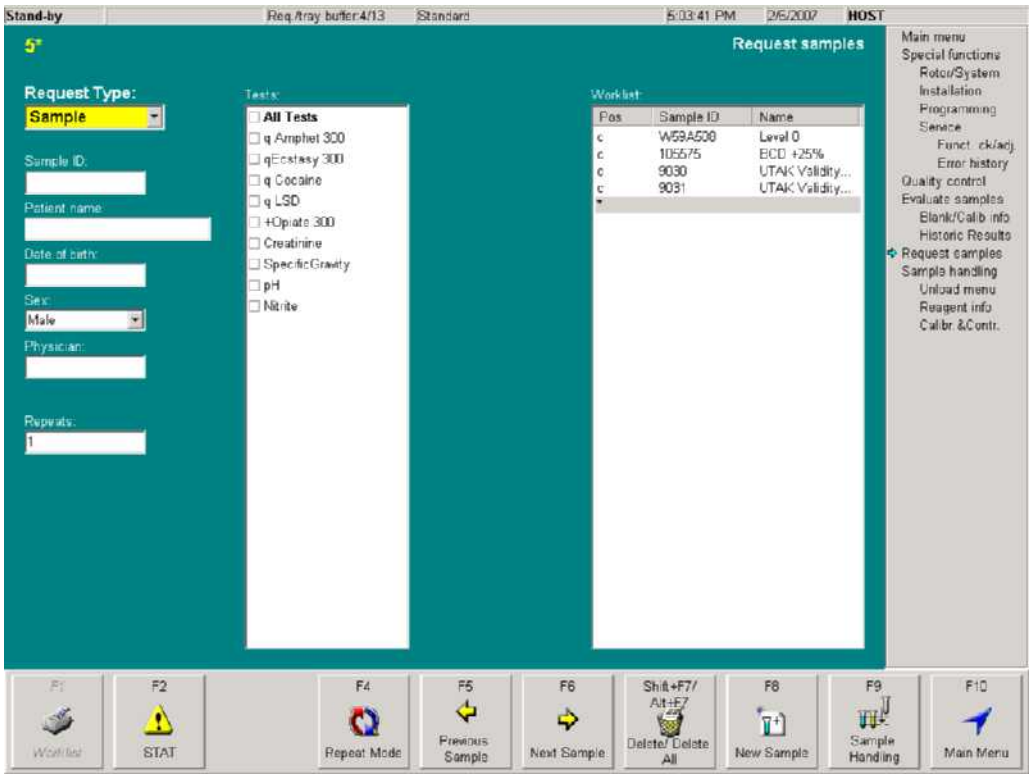
- All test information (sample identification and test requests) can be sent from the host computer to the analyzer. Refer to your LIS host software supplier for the method to send test information to the analyzer. The sample tubes must have barcode labels for identification.
  The sample tubes loaded with this method can make use of the external barcode reader. No request list needs to be defined in this case and samples can be loaded immediately. This is described in 4.3.7 Load barcoded samples (with external barcode reader).

- Sample information can be recorded by an external handheld barcode reader. Barcodes are read from the sample tubes and/or from a barcodes card that is used to identify samples and select tests or profiles. This is described in 4.2.4 Request samples and assign tests with an external barcode reader.
  When the worklist is filled, samples must be identified when they are placed in the sample rotor. This can also be done using the external barcode reader. This is described in 4.3.7 Load barcoded samples (with external barcode reader).

- Sample information can be manually entered by the user. The samples do not need barcode labels in this case. Sample IDs and associated test requests are selected via a mouse and/or the keyboard. This is described in 4.2.5 Manually request samples and assign tests.
  When samples do not have barcodes, the position in which they are placed in the sample rotor is determined by the analyzer software. The method to load the samples is described in 4.3.8 Load samples (without barcodes).

4.2 Enter sample data and test requests

4.2.1 REQUEST SAMPLES screen



The REQUEST SAMPLES screen allows requesting new samples, entering sample data and assigning tests to the samples. Samples can later be edited or deleted. If needed, the operator can print a worklist.

Note

The REQUEST SAMPLES screen is also used as a starting point to request priority samples, reagent blanks, control tests and calibrations. This is done by selecting options in the REQUEST TYPE: listbox. Procedures for requesting special samples types are described in the following subsections:

- STAT and PEDIATRIC - See 4.2.7 Requesting priority samples.
- BLANK - See 4.2.8 Request a test for a reagent blank.
- CONTROL - See 4.2.9 Request a control test.
- CALIBRATE - See 4.2.10 Request a test for calibration.

4.2.2 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.
REQUEST TYPE:	The type of sample that is requested: • SAMPLE Patient samples are positioned 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 STAT samples have priority over all other samples. The analyzer has three positions for emergency samples (E1...E3). If more than three emergency samples are requested in the same run, the analyzer positions these samples on the normal sample positions. • PEDIATRIC Pediatric samples have priority over all Normal samples. Pediatric samples must be placed in one of the positions P1 to P5. Request type Pediatric is used to assign priority to samples in pediatric cups and is not related to the age of the patient. When the results must be evaluated against the pediatric reference limits, you must select PEDIATRIC for the SEX: field also. • 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.
SAMPLE ID:	Enter the sample ID. Twelve characters are available (letters and numbers). If the option SAMPLE ID AUTO INCR.: in the SYSTEM PARAMETERS menu was selected, the analyzer automatically increments the sample ID for each new sample request. Alphanumeric data is always counted up. If the previous sample ID was 001, the next will be 002. If the previous sample ID was Az99, the next will be Ba00. You can also read the sample ID with the external barcode reader (either from the label on the sample tube, from a request form or from a barcode card). **If no ID is entered for a sample, it will not be accepted.**
PATIENT 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 date format is defined in the regional settings in the Windows® control panel.

Parameter	Description
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 ranges defined in the TEST PROGRAMMING menu. Pediatric is normally used for samples of children.
PHYSICIAN:*	Enter the name of the physician who ordered the sample. The default is the last entered name. Maximum length 20 characters.
REPEATS:	Select the number of times that the sample must be measured.
TESTS:	The REQUEST SAMPLES screen shows a variable number of tests, profiles and calculated results. The number depends on the tests loaded in the REAGENT POSITIONS fuctions in the INSTALLATION menu. Select the tests, profiles and/or calculated results required for the sample. This can be done by pressing the ARROW UP, ARROW DOWN and ENTER keys, clicking on the checkboxes, or reading a barcode from the Codabar card with the external barcode reader.
WORKLIST:	The worklist shows the requested samples with their sample ID and patient name. The position column will be filled when the samples are loaded (as described in 4.3 Load the sample rotor and start the tests). The highlighted sample is the one for which the request data are listed to the left. These data can be edited at any time before the tests are performed.

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

ATTENTION
Do not use a semi-colon (;) symbol in any of the fields. Use of the semi-colon will cause failures in the communication with the host.

4.2.3 REQUEST SAMPLES function 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 sample fields and tests list.
ENTER	• Select or deselect a test from the test display. • Moves the cursor from one field to the next.
F1 WORKLIST	Prints the worklist (not shown if the worklist is empty).
F2 STAT	Mark the currently selected sample as an emergency sample.
F4 REPEAT MODE	Switch repeat mode on or off. When repeat mode is on, the text REPEAT MODE is shown on the screen below the sample fields. • **On**: pressing F8 NEW SAMPLE creates a new sample request with the same test selections. • **Off**: pressing F8 NEW SAMPLE creates a new sample request with all tests cleared.
F5 PREVIOUS SAMPLE	Selects the previous sample in the worklist (if available).
F6 NEXT SAMPLE	Selects the next sample in the worklist (if available).

Keys	Description
SHIFT+F7 DELETE ONE	Delete the selected sample from the worklist. The numbers of the following samples in the worklist are changed accordingly.
ALT+F7 DELETE ALL	Delete all samples from the worklist.
F8 NEW SAMPLE	Store the current sample in the worklist and clear the screen for a new sample. If the option SAMPLE ID AUTO INCR.: in the SYSTEM PARAMETERS is switched on, the sample ID will increment automatically. Otherwise, the sample ID is cleared.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu (loading of the sample rotor).
F10 MAIN MENU	Return to the MAIN MENU.

4.2.4 Request samples and assign tests with an external barcode reader

The barcode label identifies the sample ID, so a manual entry of the sample ID is not necessary when you use an external barcode reader. To use the external barcode reader, the following conditions must be met:

- The primary tubes or the sample cups must have barcode labels.
- The desired tests must be marked on the request menu card 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. Scan the barcodes of the desired tests from the barcode request menu card. The recorded test requests are highlighted and the checkboxes are marked.
4. Scan the field NEXT SAMPLE to save the sample and clear the fields for the new sample request.



Note

The barcode on the request chart is of the type Codabar. Do not use the same type Codabar for labels on samples. The analyzer will not know if you are entering sample data or test requests.

4.2.5 Manually request samples and assign tests



Note

Always enter a sample ID. Sample requests without a sample ID are not accepted. Sample requests without a test are also not accepted.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Enter the SAMPLE ID:.
3. Enter the other parameters as required or press TAB to go to the tests selection.
4. Select the required tests, profiles and/or calculated results from the TESTS: list.
5. Select F8 NEW SAMPLE to save the sample in the worklist and start the definition of a new sample.
6. If no more samples are needed, you can proceed to loading samples by pressing F9 SAMPLE HANDLING.

4.2.6 Request (multiple) samples efficiently

When requesting (multiple) samples, several options are available to speed up the process. These are explained separately below. All methods can be combined. The basic procedure for requesting samples does not change when using these methods.

Automatic Sample ID numbering
When the option SAMPLE ID AUTO INCR.: in the SYSTEM PARAMETERS is switched on, the sample ID is automatically incremented when F8 NEW SAMPLE is selected. Alphanumeric data is always counted up. If the previous sample ID was 001, the next will be 002. If the previous sample ID was Az99, the next will be Ba00.

Using profiles
A set of tests can be combined into a test profile. These are listed in **bold** in the top of the TESTS: list. When a profile is selected, all tests belonging to that profile are selected in the TESTS: list. Defining profiles is done via the PROFILE PROGRAMMING function in the PROGRAMMING menu.

Using repeat mode
When the repeat mode is switched on, the test selections from the previous sample are copied to the new sample when F8 NEW SAMPLE is selected. The repeat mode can be switched on by selecting F4 REPEAT MODE in the REQUEST SAMPLES menu.

4.2.7 Requesting priority samples



Note
The PEDIATRIC and STAT samples have higher priority over all normal samples. Request type PEDIATRIC is used to assign priority to samples in pediatric cups and is not related to the age of the patient.

Requesting STAT samples
Setting the status of a sample to STAT is done by selecting F2 STAT while entering the sample data and test requests. You can also select the STAT option from the REQUEST TYPE: listbox.

Requesting pediatric samples
Select the PEDIATRIC option from the REQUEST TYPE: listbox. Also select the PEDIATRIC option from the SEX: listbox.



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

4.2.8 Request a test for a reagent blank

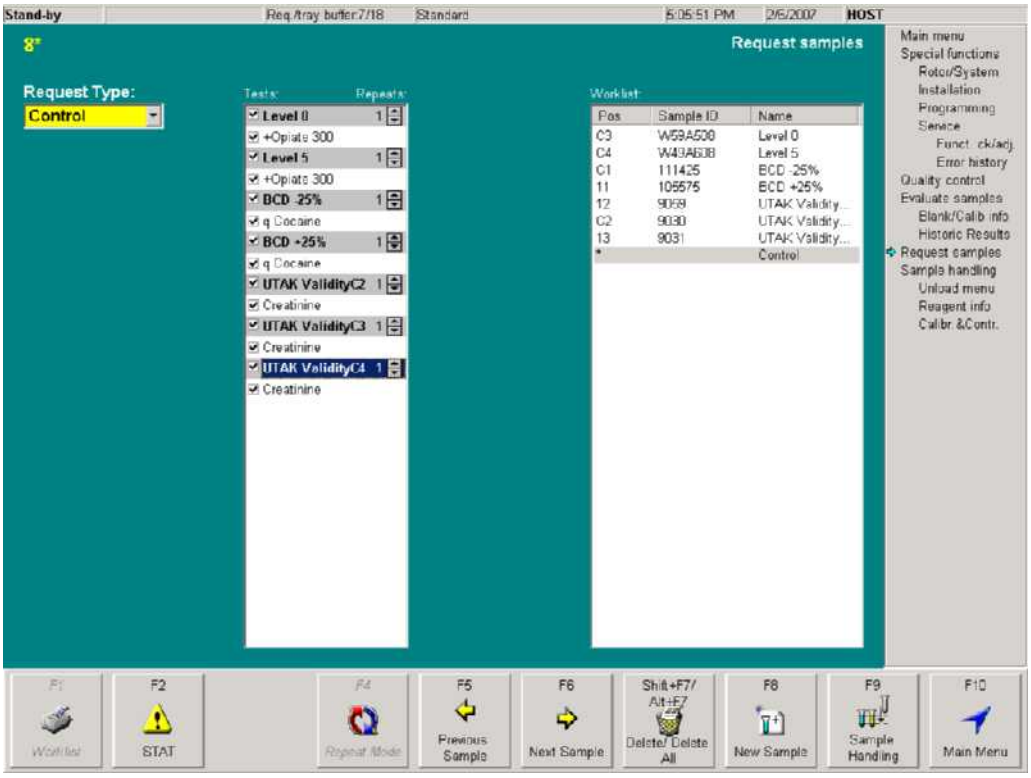
1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select BLANK from the REQUEST TYPE: listbox.
3. The list of available tests is shown. This list contains all tests that are defined with a reagent blank via the TEST PROGRAMMING function in the PROGRAMMING menu. Select the required tests.
4. Select F8 NEW SAMPLE to save the request in the worklist and start the definition of a new request or select F9 SAMPLE HANDLING to proceed with loading the reagent blank.

4.2.9 Request a control test

Note

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

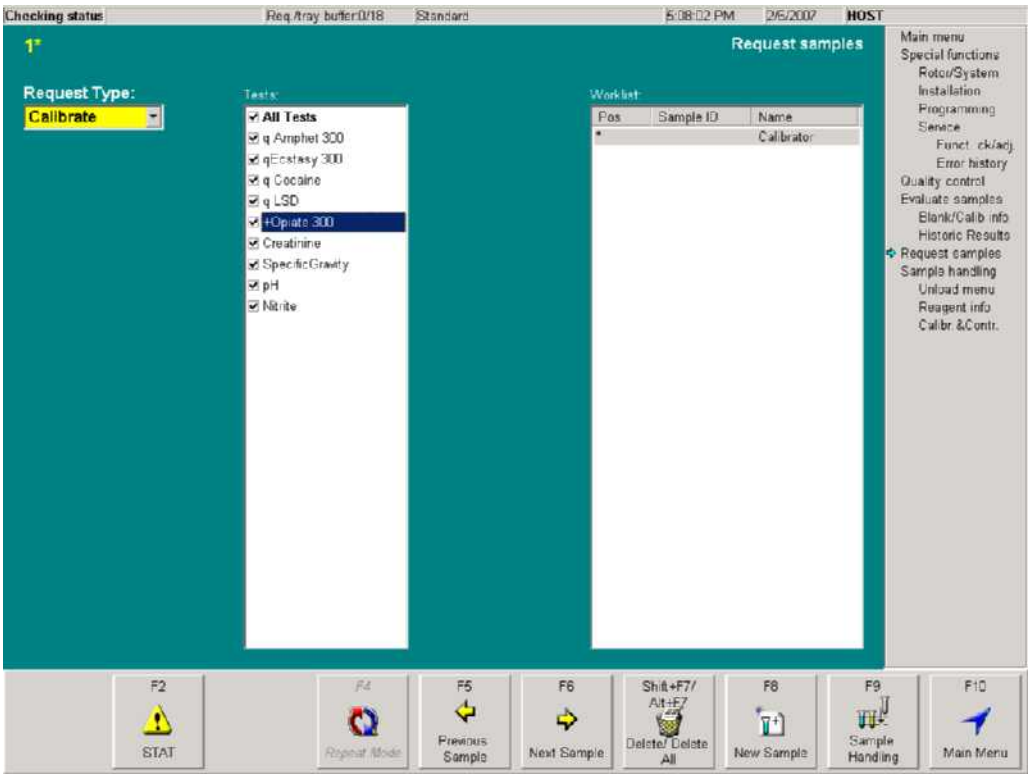
1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select CONTROL from the REQUEST TYPE: listbox.



3. The list of available controls is shown. This list contains all controls that are defined via the CONTROLS function in the PROGRAMMING menu.
4. Select the required control. Tests that can be ordered for each control are listed under the control name. Use the mouse or the arrow and ENTER keys to select or deselect tests.
5. When a control is highlighted, pressing the + button on the numeric keypad (or clicking the arrow up symbol with the mouse) increases the number of repeats to be performed for the selected test(s). Pressing the - button (or clicking the arrow down symbol) decreases the number of repeats.
6. Select F8 NEW SAMPLE to save the request in the worklist and start the definition of a new request or select F9 SAMPLE HANDLING to proceed with loading the controls.

4.2.10 Request a test for calibration

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select CALIBRATE from the REQUEST TYPE: listbox.



3. The list of available tests is shown. This list contains all tests that are defined in the REAGENT POSITIONS menu.
4. Select the required tests.
5. Select F8 NEW SAMPLE to save the request. The worklist shows the calibrators that will be tested.
6. (Optional) Select F5 PREVIOUS SAMPLE or F6 NEXT SAMPLE to check which calibrators are allocated to which individual tests.
7. Select F9 SAMPLE HANDLING to proceed to loading the calibrators.

4.2.11 View, edit or delete sample requests

Note
Samples in the worklist can only be edited or deleted if the measurements are not yet started.

1. Select F8 REQUEST SAMPLES from the MAIN MENU.
2. Select F5 PREVIOUS SAMPLE or F6 NEXT SAMPLE to scroll through the worklist. You can also select a sample directly by clicking on its line in the worklist with the mouse.
3. Select the required sample to view and edit the sample.
4. Select another sample to save the changes.
5. To delete the selected sample, select SHIFT+F7 DELETE ONE. When the sample is deleted from the worklist, all following samples are moved up and the next sample in the worklist is selected automatically. To empty the worklist completely, select ALT+F7 DELETE ALL.

4.2.12 Print a worklist

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

1. Select F9 SAMPLE HANDLING from the MAIN MENU.
2. Assign sample positions.
3. Select SHIFT+F1 WORKLIST to print the current worklist. The printout shows these data:

- Laboratory name, time and date.
- Sample type: CALIBRATE (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 special sample type designation are normal samples.

4.3 Load the sample rotor and start the tests

4.3.1 Preparation of samples, 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:

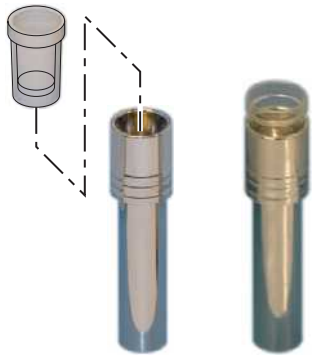
- Sample volume is 2 - 10 µl: excess volume is 5 µl
- Sample volume is 10 - 20 µl: excess volume is 10 µl
- Sample volume is 20 - 30 µl: excess volume is 15 µl

When using pediatric cups with the prescribed pediatric adaptors, the dead volume in these cups is ~100 µl. 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.

4.3.2 Loading pediatric sample cups

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

To ensure correct functioning of the liquid level sensor, pediatric cups must be loaded in the sample rotor as follows:

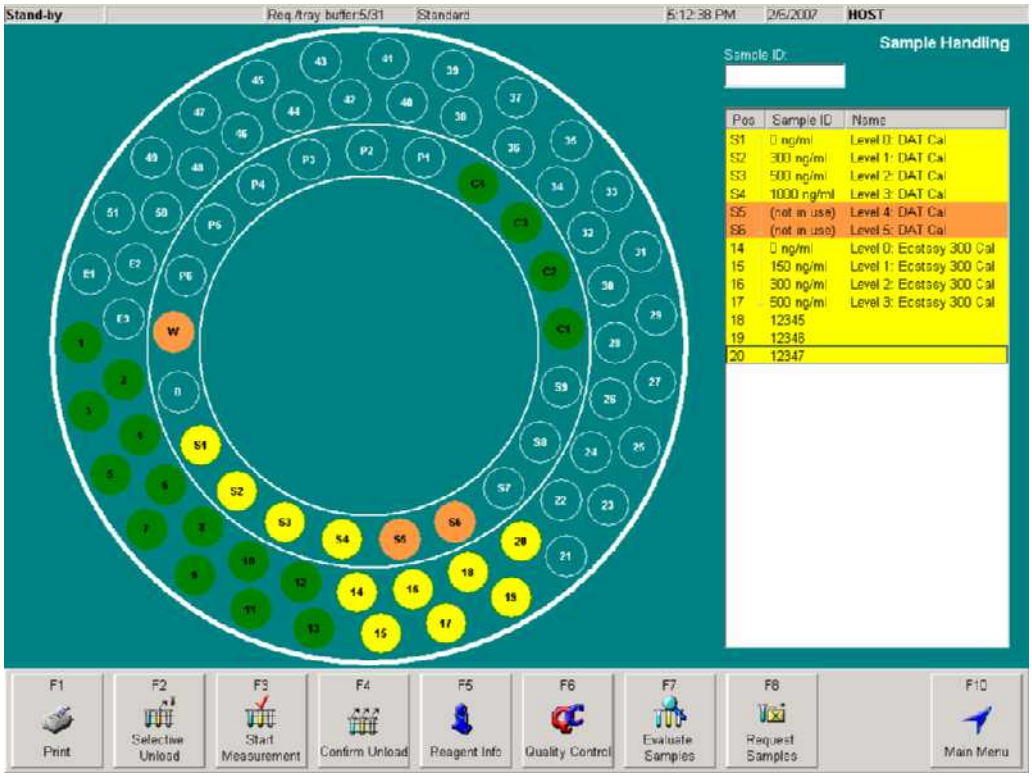


1. Insert the pediatric cup into the silver pediatric adapter.
2. Insert the pediatric adaptor with the pediatric cup into the 13 mm sample rotor.

Note
The 13 mm sample rotor may be loaded with:

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

4.3.3 SAMPLE HANDLING screen



The SAMPLE HANDLING menu has all functions to load the sample rotor and start to process the measurement. 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 current 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 use the REAGENT INFO menu to check the volume in the bottles of the loaded reagents, check the test counter and refill liquids if necessary.

4.3.4 Sample rotor positions and color codes

The SAMPLE HANDLING menu shows the sample rotor with all positions. A color code shows the current process status. The right side of the screen shows the worklist.

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 positions are used for 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 analyzer will indicate the positions to use.

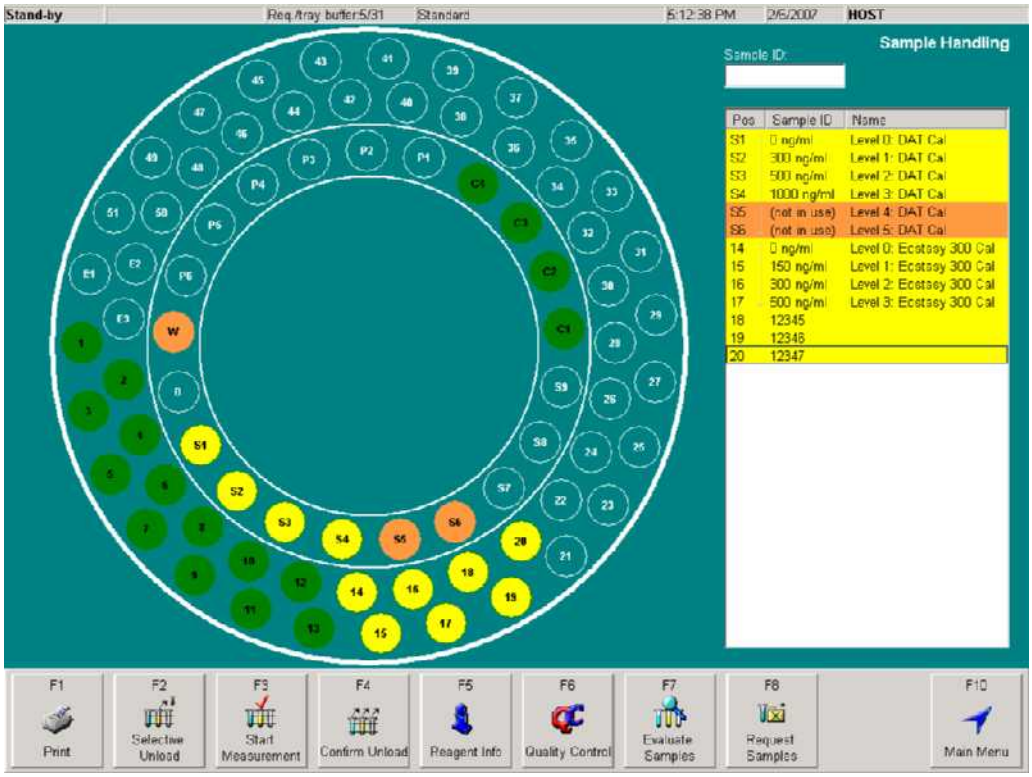
Position	Description
P1 - P6	These positions are primarily reserved for pediatric samples. The analyzer processes these samples with higher priority.
E1 - E3	These positions are reserved for STAT samples. The analyzer processes these samples with highest priority.
C1 - C4	These positions are reserved for the controls. If more positions are needed, the analyzer will indicate the positions to use.
W	This position is reserved for the needle rinse solution. The wash position must contain a sample tube filled with a sufficient amount of fresh needle rinse solution. We recommend to use hypochlorite solution. The needle rinse solution cleans the sample needle after every measurement batch.

Color codes

The following colors are used for sample rotor positions:

Color	Description
empty with white border	The position is free.
gray	The position has not been measured.
orange	These positions are reserved for standard solutions. You do not have to place any calibrators in these positions.
green	The sample on this position is processed and the results are accepted or rejected by the operator.
green with light green border	The result is given, but the test request is not finished.
green with orange border	The sample on this position is processed but has one of these faults: • An error occured during measurement. Test results with *INFO* exists for this sample. • A reagent blank is not available. Test results with *INFO*: WAITING FOR REAGENT BLANK exist for this sample. • A calibration curve is not available. Test results with *INFO*: TEST NOT CALIBRATED exist for this sample.
green with white border	The position is selected to unload.
black	The sample in this position is in process.
yellow	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.
yellow with green border	A host query for the sample in this position is pending.
yellow with red border	A host query for the sample in this position has not been answered within the defined timeout period.

4.3.5 Worklist and color codes



The request list shows the order of samples and control requests, as they have been entered via the host computer or manually 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: (above the worklist)	Use this field to search and assign a position to a sample with either the external 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 is reserved for the sample and shown here.
SAMPLE ID (in the worklist)	The analyzer shows all samples in the worklist. The requests for special sample types are listed first. • B: Blank (1 position) • S: Standard (9 positions) • C: Control (4 positions) • E: Emergency (3 positions) • P: Pediatric (6 positions) Subsequently all normal samples and controls are listed in the order in which they were requested.
NAME	The patient name or form of identification for the sample as set in the REQUEST SAMPLES menu.

Color codes

The following background colors for samples in the worklist are used:

Color	Description
white	The sample is not yet loaded.
yellow	The test is requested, but not yet started.
orange	This position is reserved (for multilevel calibrations).
dark blue	The sample is selected but not yet assigned to a position. Pressing ENTER assigns the position. In some cases, multiple lines are selected and assigned as if they were one sample.

4.3.6 SAMPLE HANDLING function keys

Key	Description
CTRL+F1 PRINT LOADLIST	Prints what is in every rotor position, regardless of status.
SHIFT+F1 WORKLIST	Prints a summary of pending test requests.
F2 SELECTIVE UNLOAD	Opens the selective unload menu. See 4.5.2 Unload samples.
F3 START MEASUREMENT	Starts to analyze the samples after you have placed all samples in the sample rotor.
F3 CONTINUE MEASUREMENT	Starts newly loaded requests or resumes a run that was interrupted.
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. See also 4.5.2 Unload samples.
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 results.
F8 REQUEST SAMPLES	Go to the REQUEST SAMPLES menu.
F10 MAIN MENU	Go back to the MAIN MENU.

4.3.7 Load barcoded samples (with external barcode reader)

If a communication link to a LIS host computer is not available, an external barcode reader provides an easy, quick and safe alternative to load samples. See 2.4 External barcode reader.

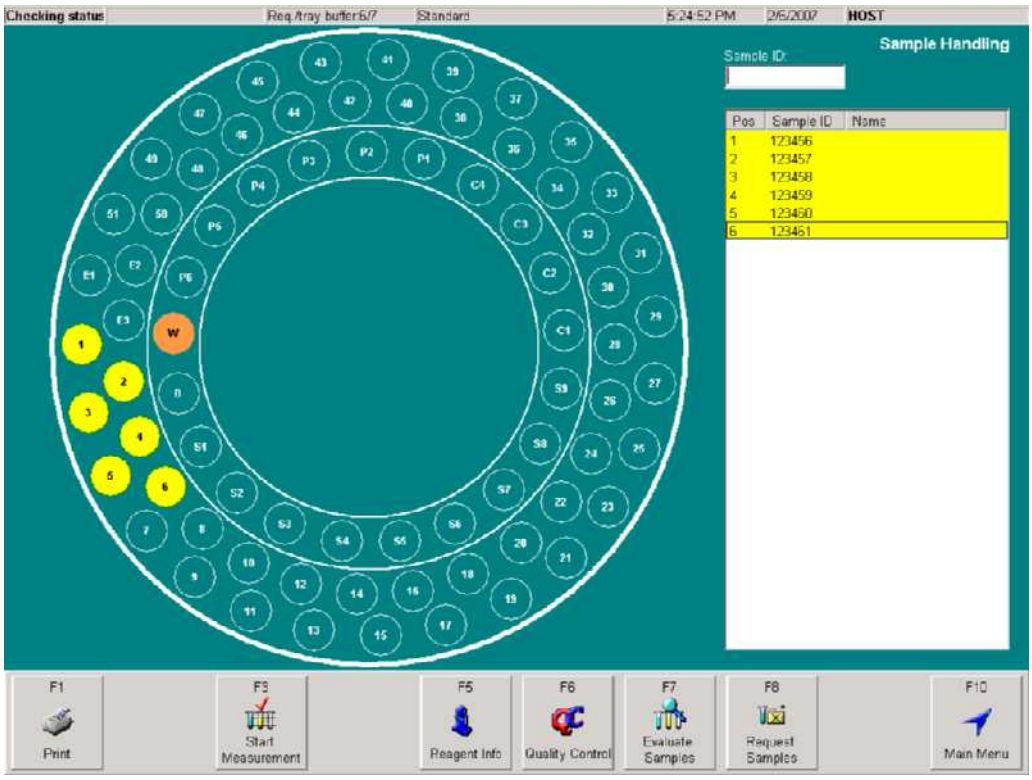
1. Select F9 SAMPLE HANDLING.
2. Scan the label on the sample. Each scanned sample will be shown on the screen. The sample is labeled with the relevant position number.
3. Place the sample on the rotor position shown on the screen.

ATTENTION

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

4. Repeat steps 2 and 3 for all samples.
5. Select F3 START MEASUREMENT to perform the requested tests.

4.3.8 Load samples (without barcodes)



Note

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

1. Select F9 SAMPLE HANDLING.
2. Select the required sample from the worklist. Samples with a white background have not been loaded yet.
3. Press ENTER or double-click with the mouse to position the sample. The sample is allocated a number. The background color for the sample in the worklist changes to yellow to show that the sample is loaded.
4. Place the sample on the allocated position on the sample rotor.
5. Repeat steps 3 and 4 for all samples.
6. Select F3 START MEASUREMENTto perform the requested tests.

4.3.9 Load samples with mouse

1. Select F9 SAMPLE HANDLING.
2. Select the required sample from the worklist.
3. Right-click the sample in the worklist or press the right arrow key.
4. Type the desired position in the SAMPLE POSITION: field. Press the OK button to accept the position, or press the CANCEL button to cancel positioning the sample.
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 entered the sample information.

6. Repeat steps 3 to 5 for all samples.
7. Select F3 START MEASUREMENTto perform the requested tests.

4.3.10 Load samples during a sample run

Samples can be loaded during a sample run in an emergency. If the sample is a STAT sample, it will be measured immediately.

1. Select F8 REQUEST SAMPLES.
2. Select request type STAT.
3. Enter the sample data and request the tests for the new sample.
4. Select F9 SAMPLE HANDLING.
5. Select the new sample in the worklist.
6. Press ENTER or double click with the mouse to position the sample. The sample is allocated a number. Alternatively, you can right-click the sample or press the arrow right key and enter the desired position number in the dialog that opens.
7. Place the patient sample in the allocated position on the sample rotor.



ATTENTION
Make sure that the sample pipetting arm is not touched when placing the sample. The best moment to load a sample during the run is when pipetting has just taken place.

4.3.11 Load a reagent blank



Note
If reagent blanks are required, they should be performed before testing a calibrator.



Note
The reagent blank must first be requested in the REQUEST SAMPLES menu. See 4.2.8 Request a test for a reagent blank.

1. Select F9 SAMPLE HANDLING.
2. Select BLANK from the worklist.
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.

4.3.12 Load a control

Note
The control must first be requested in the REQUEST SAMPLES menu. See 4.2.9 Request a control test.

1. Select F9 SAMPLE HANDLING.
2. Select the required control from the worklist.
3. Press ENTER or double click with the mouse to position the control. The small c changes to a capital C + number. If more positions are needed, the analyzer uses any available position.
4. Place the control in the position indicated on the sample rotor.
5. Select F3 START MEASUREMENT.

4.3.13 Load a calibrator

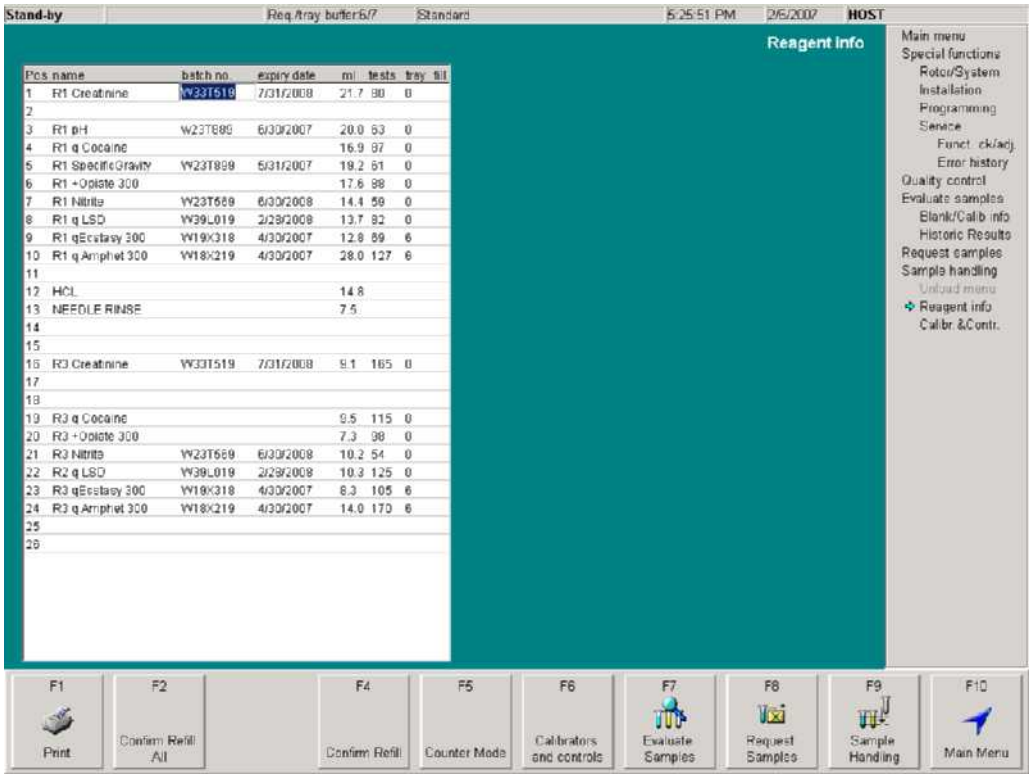
Note
The calibrator must first be requested in the REQUEST SAMPLES menu. See 4.2.10 Request a test for calibration.

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. If more positions are needed, the analyzer uses any available position.
4. Place the calibrator in the position indicated on the sample rotor.
5. Select F3 START MEASUREMENT.

4.4 REAGENT INFO screen

The REAGENT INFO menu shows the loaded reagents, estimated 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.



4.4.1 REAGENT INFO parameters

Parameter	Description
POS	The position of the reagent on the reagent rotor.
NAME	The name of the reagent. The field also shows the order of the reagent. R2 shows the reagent is the second reagent. R3 shows the reagent is the third reagent.
BATCH NO.	The batch number of the reagent.
EXPIRY DATE	The expiry date of the reagent. The expiry date is the last day of on-board stability.
ML	The available reagent volumes in the bottles.
TESTS (only in normal mode)	The number of tests, which can still be processed with the available volume of the reagent.

Parameter	Description
TRAY (only in normal mode)	The number of tests that is currently requested.
FILL (only in normal mode)	A red dot shows a shortage of the reagent and a refill is necessary. A yellow dot shows there is not enough reagent to perform all the requested tests. Refill the reagent bottle or delete the test requests as necessary.
TOTAL TEST COUNT (only in counter mode)	The number of tests that have been performed with the reagent since the last time the count was reset. Resetting all counters is done by selecting ALT+F3 CLEAR ALL COUNTERS.

4.4.2 REAGENT INFO function keys

Key	Description
F1 PRINT	Prints a list with the reagent information.
F2 CONFIRM REFILL ALL	Confirm that you have refilled all the reagents.
ALT+F3 CLEAR ALL COUNTERS (only in counter mode)	Sets all values in the total test counts to zero.
F4 CONFIRM REFILL	Confirm that you have refilled selected reagents.
F5 COUNTER MODE (only in normal mode)	Switch to counter mode.
F5 NORMAL MODE (only in counter mode)	Switch to normal mode.
F6 CALIBRATORS AND CONTROLS	Shows the loaded calibrators and controls with their names, batch numbers and expiry dates.
F7 EVALUATE SAMPLES	Go to the EVALUATE RESULTS menu.
F8 REQUEST SAMPLES	Go to the REQUEST SAMPLES menu.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING menu.
F10 MAIN MENU	Go to the MAIN MENU.

4.4.3 Check and refill reagents

1. Select F9 SAMPLE HANDLING.
2. Select F5 REAGENT INFO.
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

The volume of the reagent is measured at the moment the reagent is pipetted. The volume and test estimates are a guideline to assist the operator and should not be considered an accurate measurement.

4. Refill reagents if required. You can either refill only the insufficient reagents or refill all reagents:
   A Refill insufficient reagents: these are the ones showing the red dots. Select F4 CONFIRM REFILL after refilling.
   B Refill all reagents. Select F2 CONFIRM REFILL ALL after refilling.

Note

The analyzer assumes that reagents are filled to the bottle volume. The calculation of the number of tests that can be performed with the remaining reagent is based on this.

5. Select F6 CALIBRATORS AND CONTROLS. to check the batch number and expiry dates of the calibrators and control samples.

4.5 Start and stop the sample run

4.5.1 Start the analysis run

The analysis run must start from stand-by mode.

1. If the F3 START MEASUREMENT button is not present, the analyzer is in an inactive or halted state. To change to stand-by mode do as follows:
   A Select F5 SPECIAL FUNCTIONS from the MAIN MENU
   B Select F1 ROTOR/SYSTEM
   C Select F1 RESET SYSTEM

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. Optionally select CTRL+F1 PRINT LOADLIST.
3. Select F3 START MEASUREMENT.

Note
Messages will inform you if the measurements cannot be performed or completed. The most common messages are explained in 4.5.3 Error and warning messages.

4.5.2 Unload samples

Note
Only finished samples can be unloaded. They are shown on the rotor image by a solid green color. When moving the mouse over these samples, the status READY FOR UNLOAD appears.

Select F2 SELECTIVE UNLOAD from the SAMPLE HANDLING menu. The SELECTIVE UNLOAD menu is where you can select samples to be unloaded. Selection is done by the mouse or the keyboard.

Note
If you want to unload all samples that have status READY FOR UNLOAD, you can do this immediately from the SAMPLE HANDLING screen. Remove the samples from all positions that are shown as solid green on the sample rotor and select F4 CONFIRM UNLOAD.

Note
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.

You have different options to unload one or more samples:

1. Unload one sample at a time.
   A Type a sample number in the SAMPLE POSITION: field inside the rotor image and press ENTER to select the sample for uloading. Instead of this, you can use the mouse to click on a sample on the rotor image. A white colored ring appears around the green sample.
   B Remove the sample tube from the rotor.
   C Repeat steps A and B for all individual samples you want to unload.
   D Select F3 CONFIRM UNLOAD to confirm that the samples were unloaded. The rotor positions for the selected samples are emptied.
2. Unload a range of samples.
   A Select F5 SELECT SERIES.

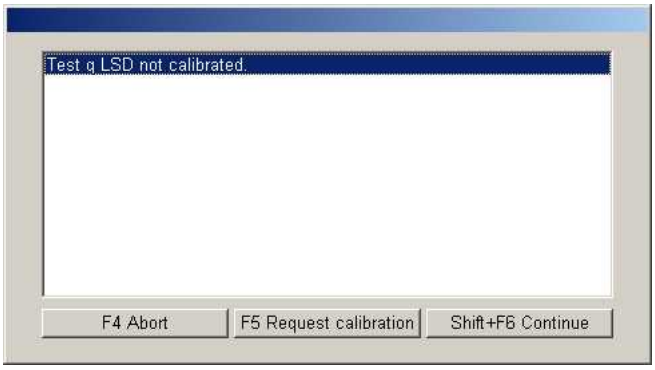
B Type the start position in the START POSITION: field.
C Type the end position in the END POSITION: field. Press ENTER. The samples that are ready to unload (solid green) in the selected range are marked with a white border.
D Remove the sample tubes from the rotor. Only remove the samples from positions that are marked with a white border.
E Select F3 CONFIRM UNLOAD to confirm that the samples were unloaded. The rotor positions for the selected samples are emptied.

3. Unload all samples
A Select F4 SELECT ALL. The samples that are ready to unload (solid green) in the entire rotor are marked with a white border.
B Remove the sample tubes from the rotor. Only remove the samples from positions that are marked with a white border.
C Select F3 CONFIRM UNLOAD to confirm that the samples were unloaded. The rotor positions for the selected samples are emptied.

4.5.3 Error and warning messages

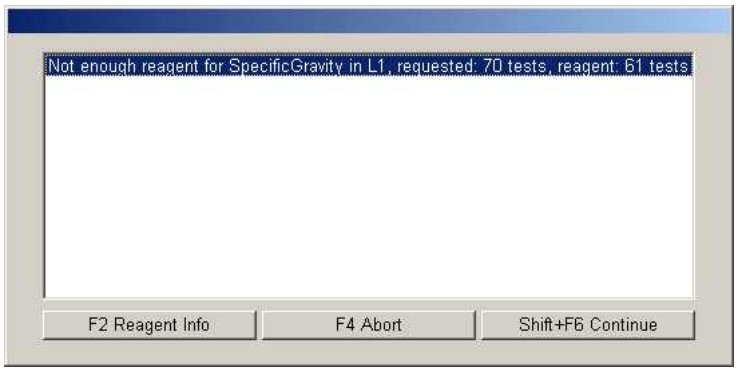
If the requested tests cannot be performed, due to insufficient reagent volumes or invalid controls or calibrations, a dialog window is shown on the screen. The window contains buttons that lead to further actions. Some of the warnings are described below. A list of all test-related messages is given in 6.2.6 Error messages.

Test(s) not calibrated



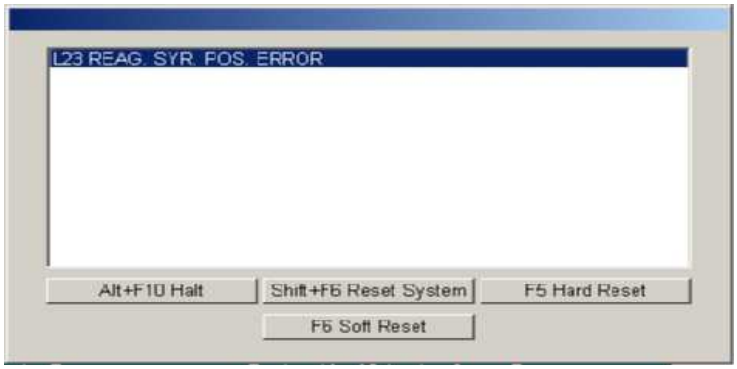
Key	Description
F4 ABORT	The measurement is not started. You can return to the F5 REQUEST CALIBRATION menu to change test assignments.
F5 REQUEST CALIBRATION	The required calibrations are added to the worklist and selected automatically. Press the ENTER key to assign positions to the calibrators and load them in the designated positions on the rotor. When measurement is continued, the calibrators are measured first.
SHIFT+F6 CONTINUE	The tests are performed and the samples for which non-calibrated tests are requested will receive an *INFO* status. This can be viewed via the EVALUATE RESULTS menu.

Insufficient reagent(s)



Key	Description
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 when all other tests are complete.
F4 ABORT	The measurement is not started. You can return to the REQUEST SAMPLES menu to change test assignments.
SHIFT+F6 CONTINUE	The tests are performed and the samples for which non-calibrated tests are requested will end with an Info status. This can be viewed in the EVALUATE RESULTS menu.

Various hardware-related errors

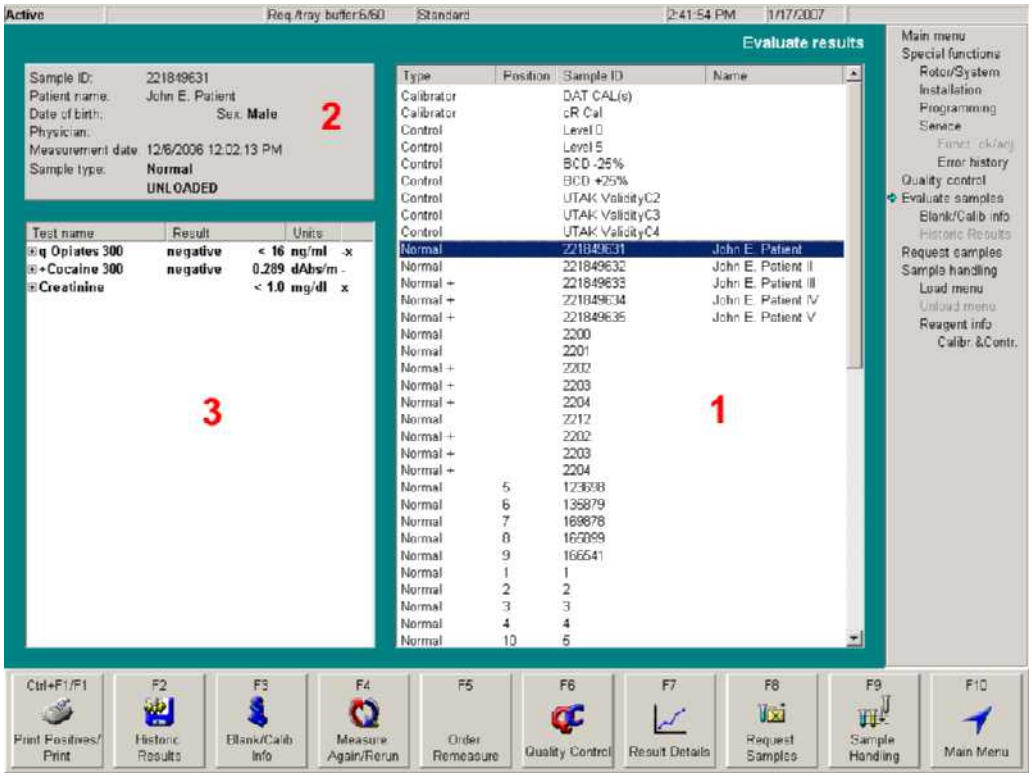


Key	Description
F6 SOFT RESET	The low-level component that is in an error condition is reset. If the problem is solved by this, the error message will disappear.
F5 HARD RESET	A higher-level component is reset. This also resets the lower-level components that are contained in it. If the problem is solved by this, the error message will disappear.
SHIFT+F6 RESET SYSTEM	The entire system is reset. If the problem is solved by this, the error message will disappear.
ALT+F10 HALT	The system is halted. Have a service engineer check the cause of the error condition. See 6.2.7 Hardware-error messages.

4.6 Check and validate the results

4.6.1 EVALUATE RESULTS screen

The results of each test can be viewed in the EVALUATE RESULTS screen. The screen contains three areas of information about the samples and test results. These are described in detail in separate subsections.



1. Shows all available samples - see 4.6.2 Sample list.
2. Shows information about the selected sample - see 4.6.3 Sample details.
3. Shows results for the selectd sample - see 4.6.4 Test results.

Depending on the type of test, you can view the calculated absorbances in tabular or graphic format. This is done in the RESULT DETAILS screen. See 4.6.8 Result details.

4.6.2 Sample list

Column	Description
TYPE	Type of the sample: Normal, STAT, Pediatric, Blank, Control or Calibrator.
POSITION	Position of the sample on the rotor.
SAMPLE ID	The ID of the sample.
NAME	The name of the patient (if available).

4.6.3 Sample details

Item	Description
SAMPLE ID:	The ID of the sample.
PATIENT NAME:	The name of the patient (if available).
DATE OF BIRTH:	The patient's date of birth (if available).
SEX:	The sex of the patient: MALE , FEMALE or PEDIATRIC.
PHYSICIAN:	The name of the physician in charge (if available).
MEASUREMENT DATE:	The date and time of the test.
SAMPLE TYPE:	Type of the sample: Normal, STAT, Pediatric, Blank, Control or Calibrator.
STATUS	The current processing status of the sample is shown in the status field directly under 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. • UNLOADED The sample is unloaded. • READY The sample has been processed. The results are available. • WAITING (List reason for waiting)e.g. Sample is waiting for a valid calibration.
Rotor position	The rotor position of the sample (shows next to the status field, if the sample is still loaded).

4.6.4 Test results

The tests performed for the selected sample are listed together with the measurement results and units.

Column	Description
TEST NAME	The name of the test as defined in the test parameters.
RESULT	The word *INFO* next to test name indicates that 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. A + sign indicates a tree view of the data.
UNITS	The units of measure (e.g., mg/dL, U/L) as defined in the test parameters.

4.6.5 EVALUATE RESULTS function keys

Key	Description
F1 PRINT	Print a report for the currently selected sample.
SHIFT+F1 PRINT WITH R.S.	Print a report for the currently selected sample using a custom report setup. See 5.10 Set up a report.
SHIFT+F2 ARCHIVE RESULTS	Saves the results to the historic data location defined in the system parameters..
ALT+F2 VIEW HISTORIC RESULTS	Displays archived results located in the historic data location.
F3 BLANK/CALIB INFO	Go to the BLANK/CALIB INFO menu.
SHIFT+F4 MEASURE RERUN	Rerun all measurements for the selected sample. The volumes that are used for the repeated measurement are the volumes that were defined in the field RERUN VOLUME: of the test parameters. Remeasurements start immediately.
ALT+F4 MEASURE AGAIN	Repeat all measurements for the selected sample. The volumes that are used for the repeated measurement are identical to those that were originally used. Remeasurements start immediately.
F5 ORDER REMEASURE	Remeasure all available samples with a specific condition: • REMEASURE INFOS - all samples with *INFO* status. • REMEASURE REJECTS - all samples with REJECT status. • REMEASURE POSITIVES - all samples with POSITIVE status. When the analyzer is connected to a LIS: • use F5 ORDER REMEASURE to remeasure all samples with *INFO* status. • samples with REJECT or POSITIVE status must be reordered using the LIS.
F6 QUALITY CONTROL	Go to the QUALITY CONTROL screen.
F7 RESULT DETAILS	Shows results details screen for the selected sample. See 4.6.8 Result details.
F8 REQUEST SAMPLES	Go to the REQUEST SAMPLES screen.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING screen.
F10 MAIN MENU	Go to the MAIN MENU.

4.6.6 Validation of a result

If the parameter CUSTOM AUTOMATIC EVALUATION: was selected in the CUSTOM EVALUATION menu, the results are automatically accepted or rejected. If you did not select this parameter, only results that are outside the limits of the test have to be manually evaluated. Subsequent samples are printed after one minute when the previous sample needs manual evaluation.
In the EVALUATE RESULTS screen 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 absorbances. Click on the list and type the ID or use the external 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. The sample will not be released and the analyzer does not print its measurement report.
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 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 PROGRAMMING menu. Currently Siemens Healthcare Diagnostics closed channel tests do not support reduced sample/reagent volumes or measure rerun.

4.6.7 Evaluate historic results

To view the results from archived tests, do as follows:

1. Select F7 EVALUATE SAMPLES from the MAIN MENU.
2. Select ALT+F2 VIEW HISTORIC RESULTS.
3. Select the test results to be viewed. The archives are identified by the date and time when they were created.
4. To view the historic results press ENTER or double-click on the file name.



Note

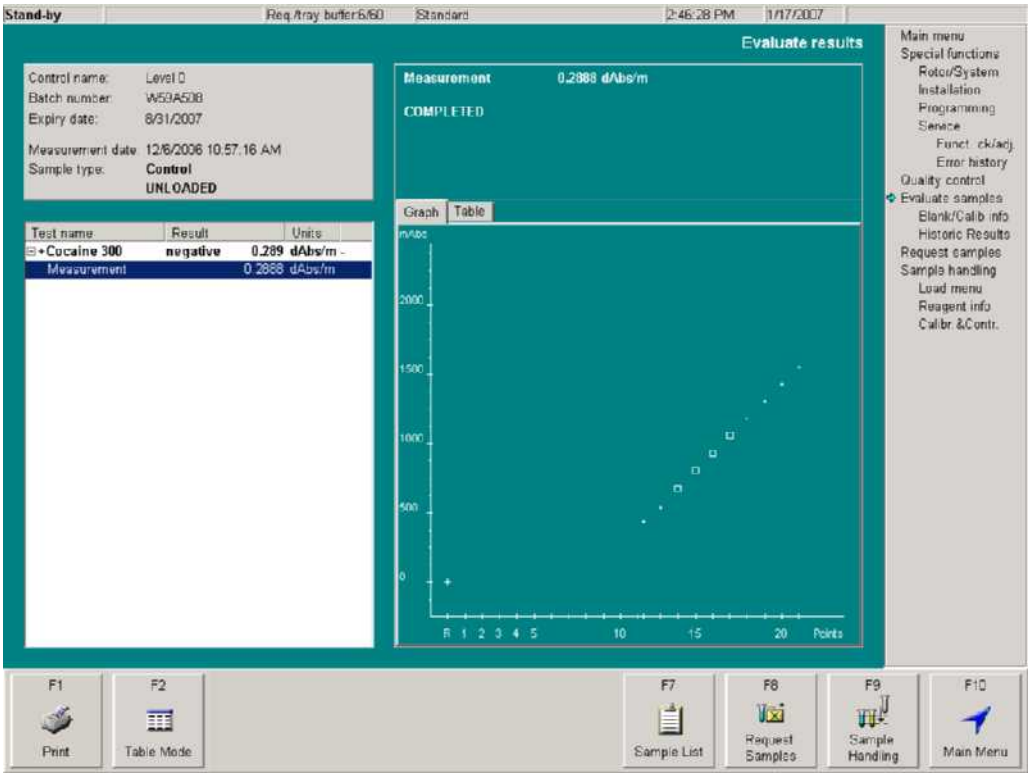
When viewing historic results, test results cannot be validated or rejected anymore. Also, samples are not available for remeasurement or reruns. It is still possible to print reports, view the result details and see the parameters that were used in the tests for the archived samples.

5. Select F10 RETURN to return to the list of archives.
6. To delete the selected file, select SHIFT+F3 DELETE. A dialog box opens to confirm.
7. Possibly, you will have to supply a valid password before the file is deleted.
8. Select F7 EVALUATE SAMPLES to return to the current sample list and test results.

4.6.8 Result details

To view result details for an individual measurement, do as follows:

1. Select F7 EVALUATE SAMPLES from the MAIN MENU.
2. Select the sample in the samples list.
3. Select F7 RESULT DETAILS.
4. On the left side of the screen, click on the + in front of the test name to show the individual measurements that were performed for this test. Then select the measurement for which you want to view the details.



5. Select F2 GRAPH MODE (or F2 TABLE MODE) to show the measurement details in graphical or tabular format. You can also click on the GRAPH or TABLE tabs to switch between these formats. 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:

- MEASURABLE
- IN PROCESS
- READY
- WAITING
- REJECTED
- COMPLETED

WAITING is shown if the word *INFO* shows next as the 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.

GRAPH 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 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 is 21. In endpoint tests (monochromatic or bichromatic), the measurement points are shown on the screen 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 absorbances 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.

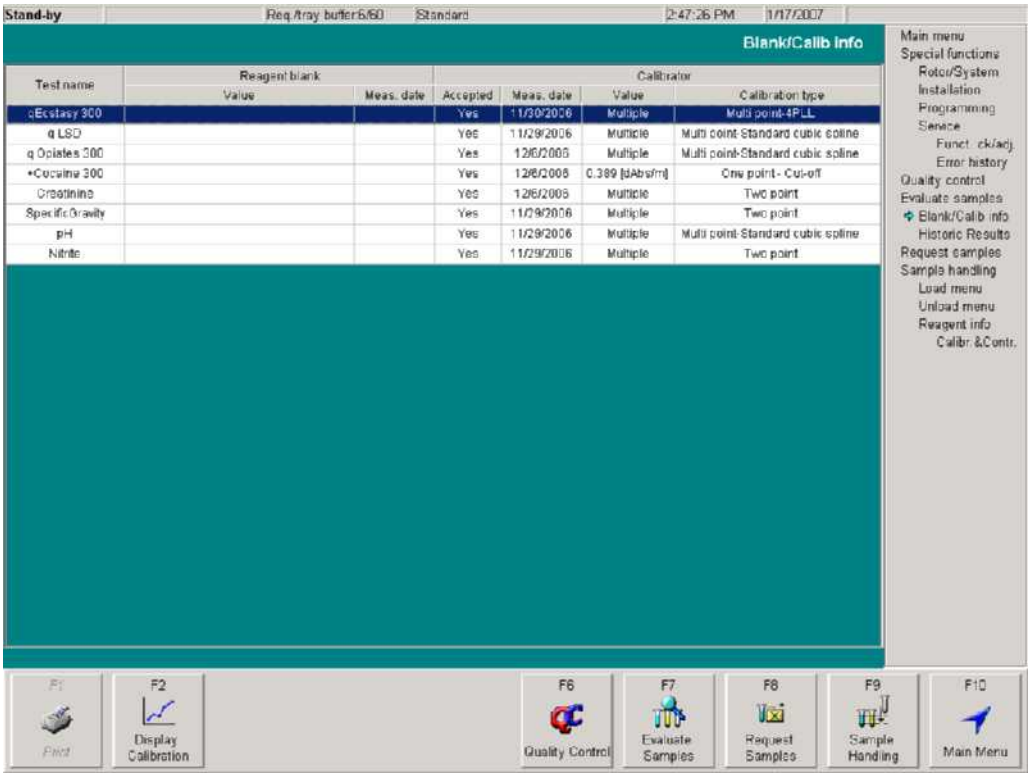
4.6.9 Result details function keys

F1 PRINT	Prints the current results display.
F2 TABLE MODE F2 GRAPH MODE	Switch between graphic and table mode. The measurement must be selected first. If the measurement is not visible, click on the + in front of the test name.
F3 ACCEPT RESULT	Validates the currently selected measurement. This button is only enabled when a measurement marked *INFO* is selected.
F4 REJECT RESULT	Reject the currently shown result. This button is only enabled when a test or measurement marked *INFO* is selected. The rejected result is marked REJECT.
F5 MEASURE AGAIN	Repeat the test. The volumes that are used for the repeated measurement are identical to those that were originally used.
SHIFT+F5 VIEW TEST PARAMETERS	Available when a test parameter is changed. The test parameters can be viewed.
F6 MEASURE RERUN	Repeat the test. The volumes that are used for the repeated measurement are the volumes that were defined in the field RERUN VOL. of the test parameters.
F7 SAMPLE LIST	Shows the sample list instead of the result details. See 4.6.2 Sample list.
F8 REQUEST SAMPLES	Go to the REQUEST SAMPLES screen.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING screen.
F10 MAIN MENU	Go to the MAIN MENU.

4.6.10 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 `F7 EVALUATE SAMPLES` from the `MAIN MENU`.
2. Select `F3 BLANK/CALIB INFO`.

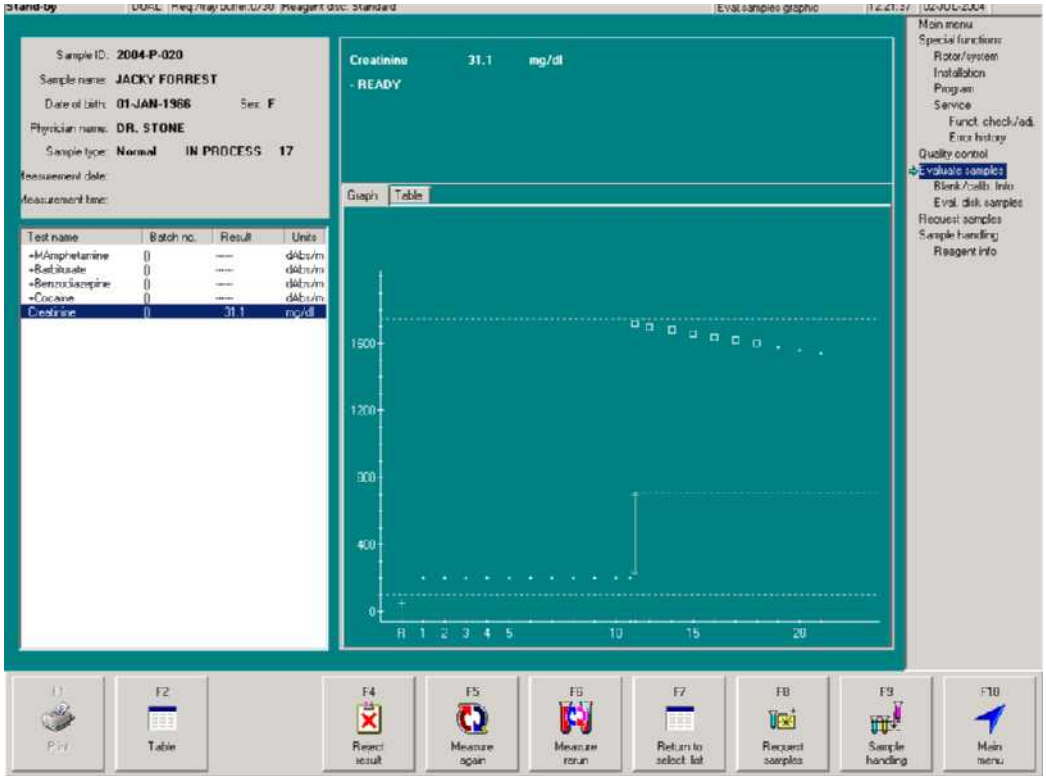


Parameter	Description
`TEST NAME`	The name of the test as defined in the test parameters.
`REAGENT BLANK` • `VALUE` • `MEAS. DATE`	The last measured reagent blank. • Value of the reagent blank with the unit • Date of measurement
`CALIBRATOR` • `ACCEPTED` • `MEAS. DATE` • `VALUE` • `CALIBRATION TYPE`	The last measured calibration. • Shows accepted if the calibration is valid. • Date of measurement. • Value of the calibrator with the unit. • Shows the type of calibration.

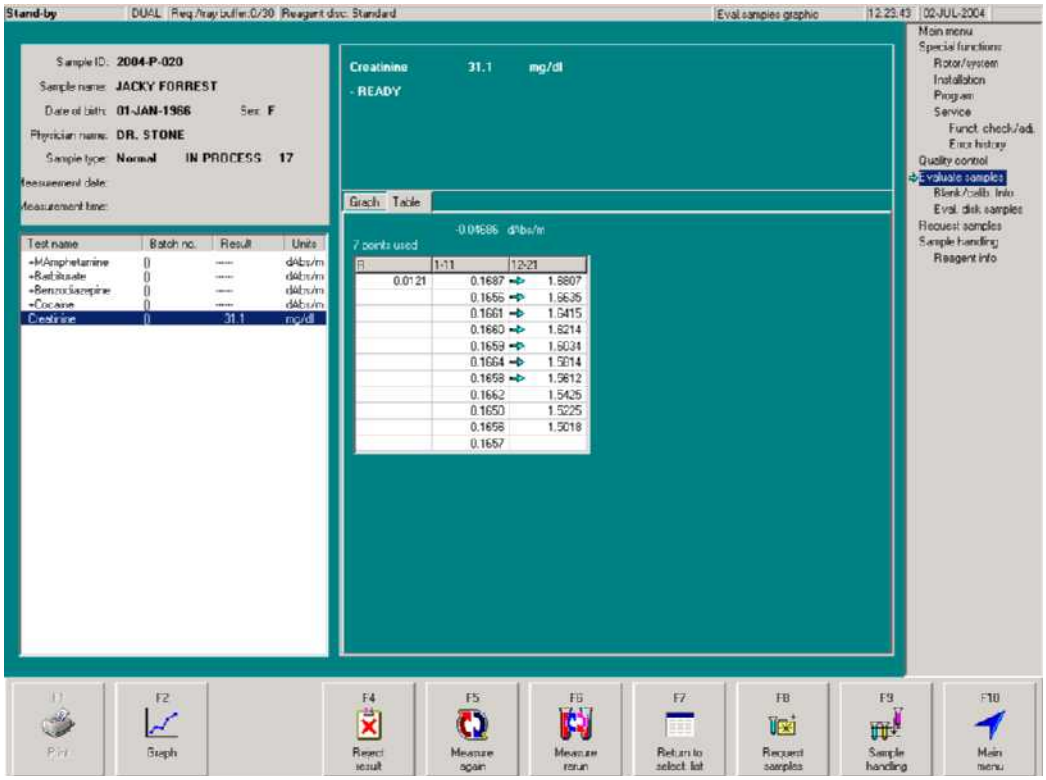
Keys	Description
`F1 PRINT`	Print a list of all shown results for blank measurements or calibrations.
`F2 DISPLAY CALIBRATION`	Shows the calibration information in graphic and tabular formats.
`F6 QUALITY CONTROL`	Go to the `QUALITY CONTROL` screen.
`F7 EVALUATE SAMPLES`	Go to the `EVALUATE RESULTS` screen.
`F8 REQUEST SAMPLES`	Go to the `REQUEST SAMPLES` screen.

Keys	Description
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING screen.
F10 MAIN MENU	Go to the MAIN MENU.

4.6.11 Result details for a two reagent kinetic test

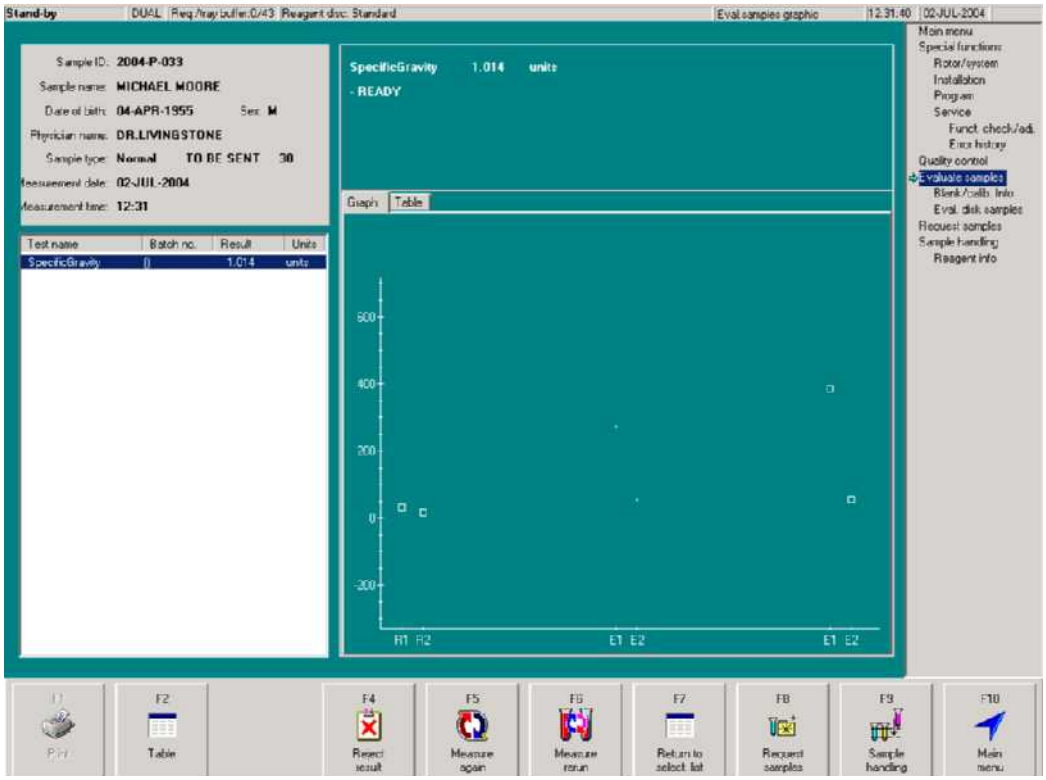


The graph shows all points on the X axis. The analyzer uses the measured points marked with a square to calculate the rate of delta absorbance per minute. The measured points marked with dots are not used for the calculation.
The level at which the substrate depletion occurs is shown by the arrow just 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, the warning message "Substrate depletion" appears. In this case, 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” appears.

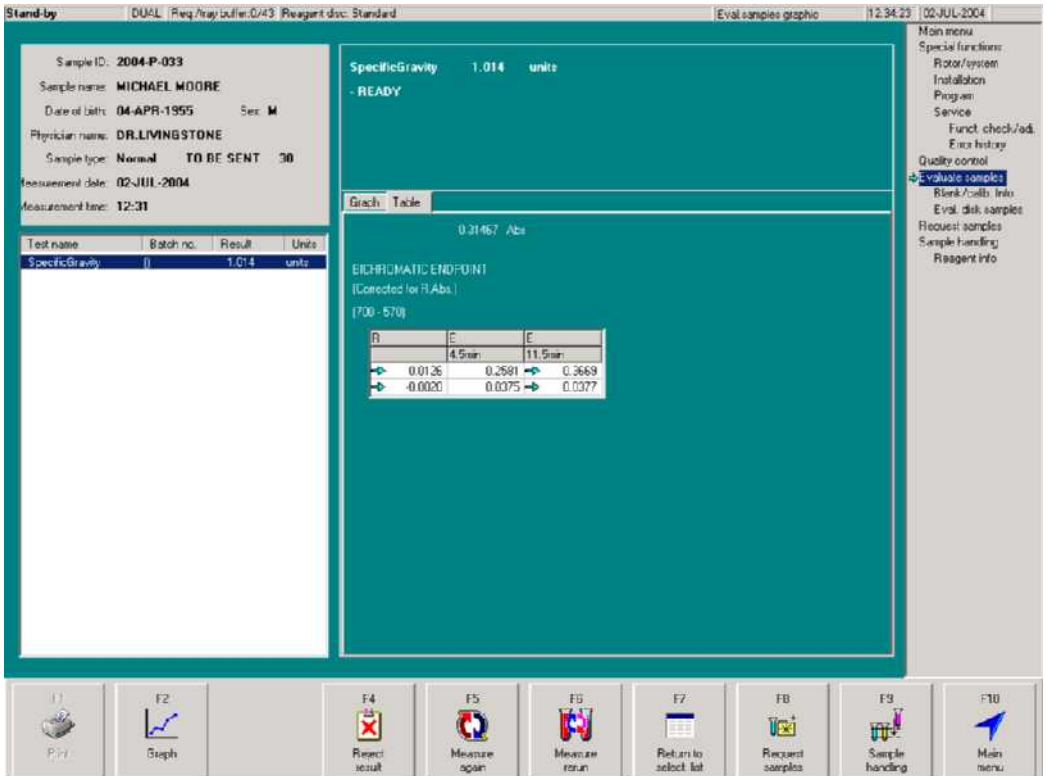


In table mode the screen shows a table with the absorbances measured during the measurement. The column R shows the absorbance value of the first reagent without the sample added. The other two columns show the points measured when sample, second and third reagent have been added (if programmed).
The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

4.6.12 Result details for an endpoint test with a reagent blank

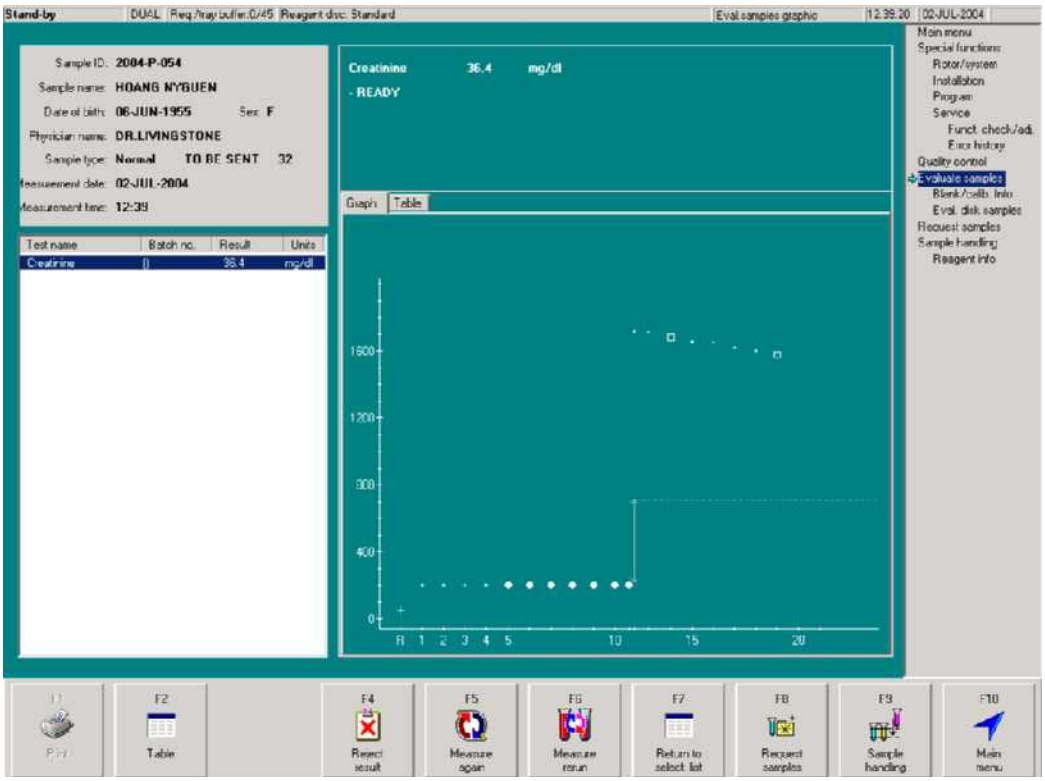


The graph shows six points on the X axis. The analyzer uses the measured points marked with a square to calculate the delta absorbance. The measured points marked with dots are not used for the calculation.

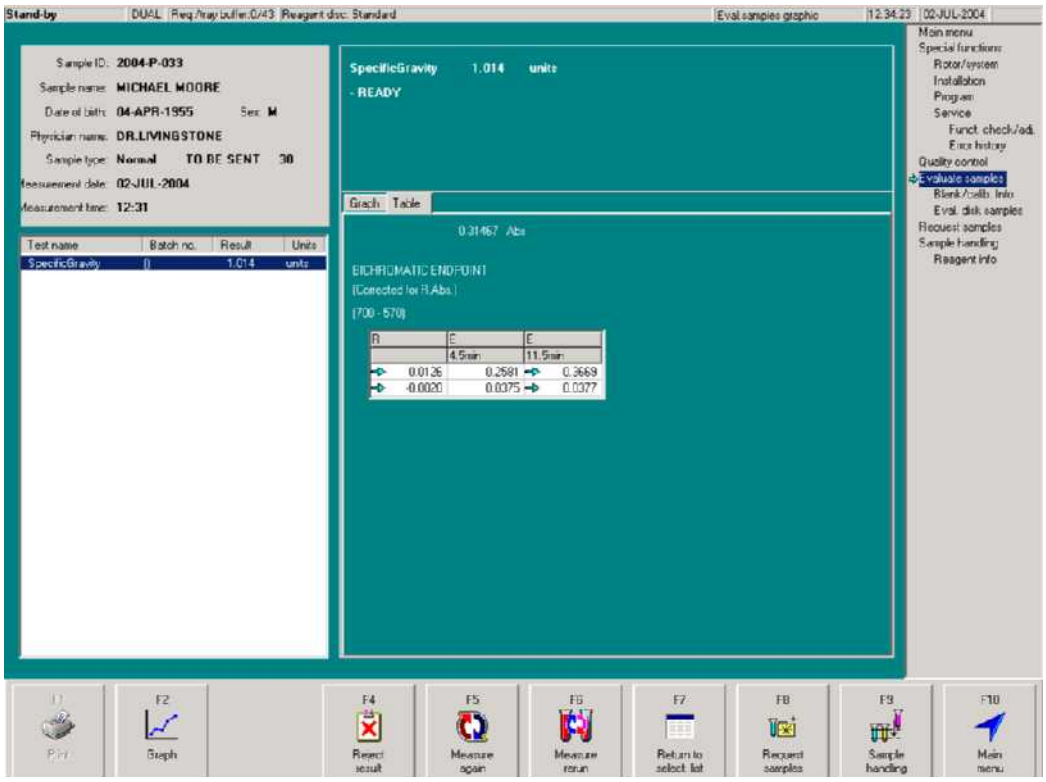


In table mode the screen shows a table with the absorbances measured during the measurement.
The column R shows the absorbance value of the first reagent without the sample added. The other two columns show the points measured when sample, and second reagents have been added.
The result of the calculation 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. An arrow indicates the points used.
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.

4.6.13 Result details for a two point test



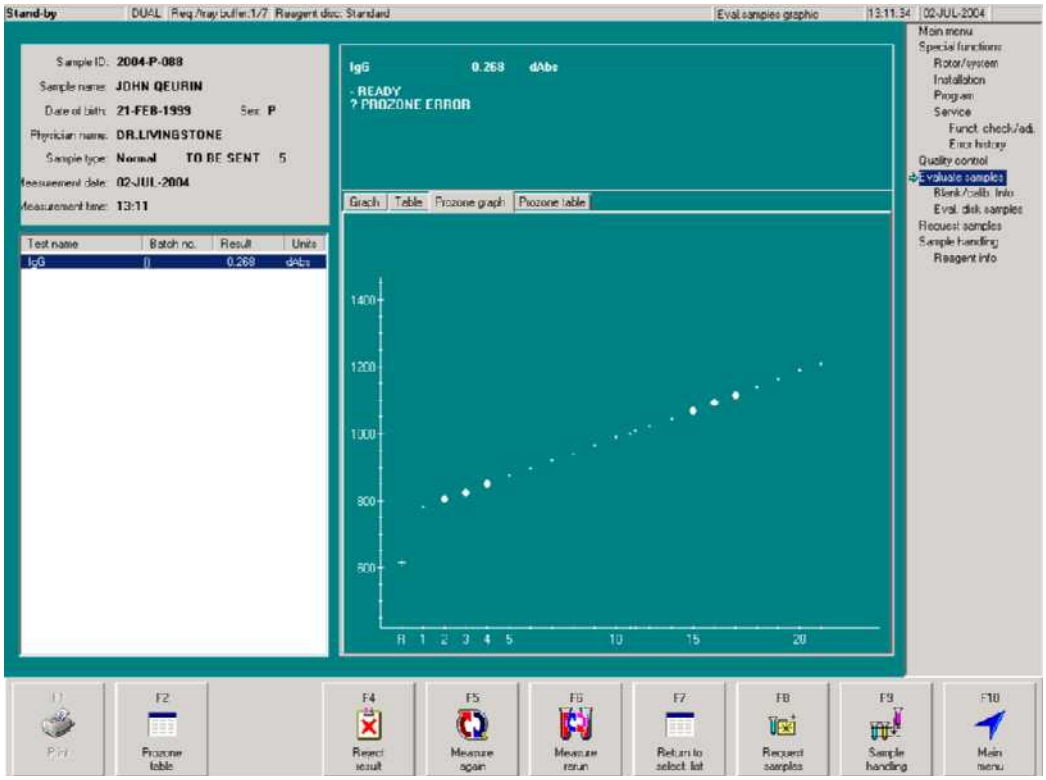
The graph shows all points on the X axis. The analyzer uses the measured points marked with a square to calculate the difference between the two points. The measured points marked with dots are not used for the calculation.
The arrow just before the addition of the last reagent shows the level at which the substrate depletion occurs.
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 are shown as white circles.



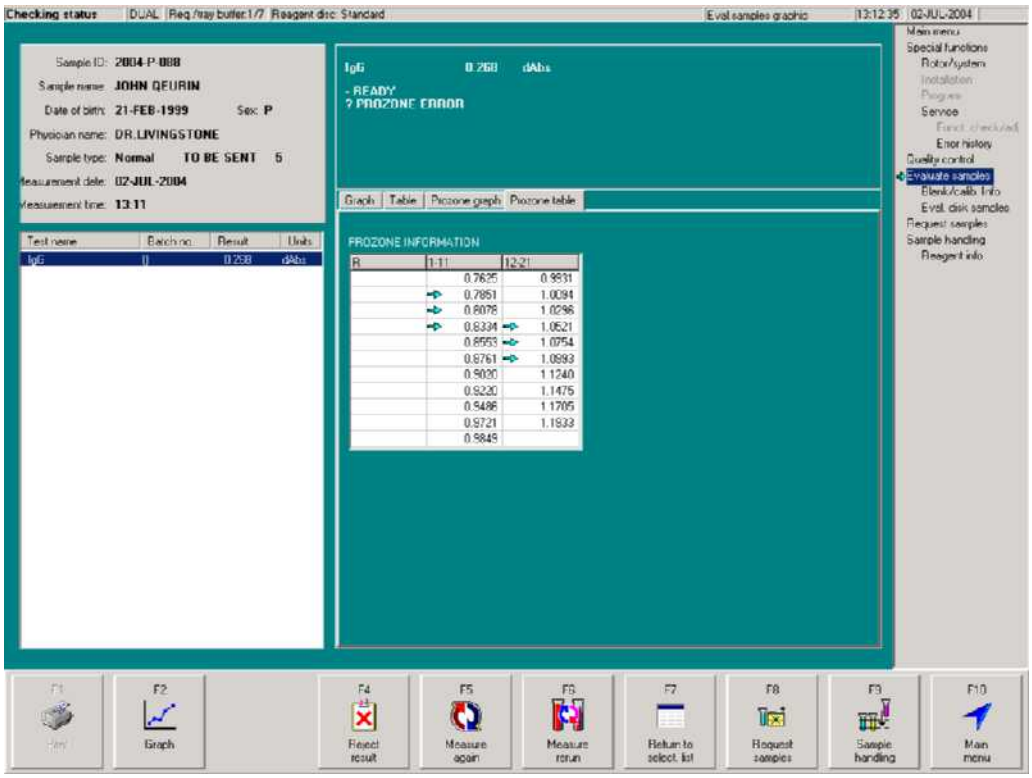
In table mode the screen shows a table with the absorbances measured during the measurement. The column R shows the absorbance value of the first reagent without the sample added. The other two columns show the points measured when sample, second and third reagent have been added (if programmed). The results of the calculation is a delta absorbance shown at the top of the table. The points used for the calculation are marked with an arrow in the table.
When slope blank is set in the `TEST PROGRAMMING` menu 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.

4.6.14 Result 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). 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 the prozone effect. The prozone check is defined in the TEST PROGRAMMING menu.



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 TEST PROGRAMMING menu, the analyzer uses two times 3 points to identify the prozone effect. If absorbance ratio is selected as minimum or maximum in the TEST PROGRAMMING menu, 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 TEST PROGRAMMING menu.



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

4.6.15 Automatic results printout

When the processing of a sample with all its requested tests is ready, the analyzer automatically prints out the results. If the analyzer is online, it also sends the results to the host through the LIS. Both multiple tests and single tests can be printed. When no report layout is programmed, the analyzer prints multiple sample results on one page to save paper.

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 `OPERATOR` in the `CUSTOM EVALUATION` menu was selected and one of the tests exceeds or falls below the limits that were defined in the `TEST PROGRAMMING` menu, the sample result will not be printed out until a manual validation of the measuring results has been done. The analyzer waits for a user response for an interval of 1 minute. If after 1 minute there is no input from the user, the analyzer will go to print out the next test. If the test with status `*INFO*` is accepted, then the test is printed.

The result will also not be printed, if error messages such as `INSUFFICIENT SAMPLE` were shown.

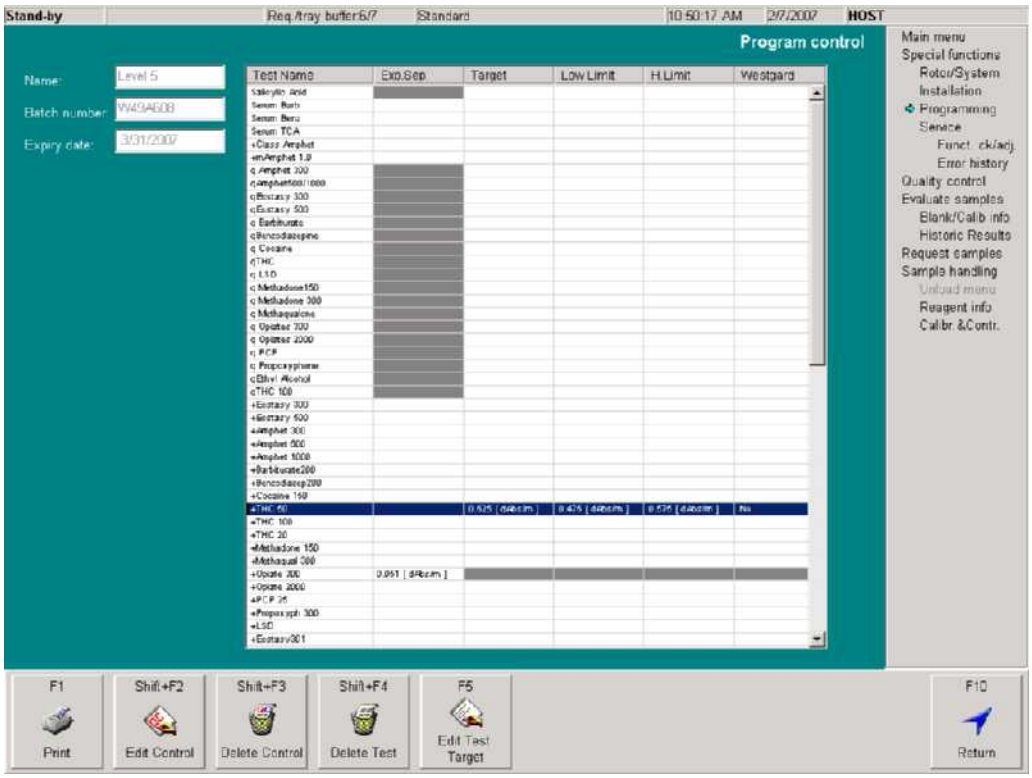
Extended Routine

5.1 Program controls

5.1.1 Introduction

It is recommended that the controls are programmed before the first time of operation. The method of the test must be defined before programming the controls, however you can program controls during a measurement. The controls that are in use cannot be changed. The batch number and expiry date are optional. A maximum of 3 controls can be set per test.

5.1.2 PROGRAM CONTROL screen



Controls are defined and assigned to tests in the PROGRAM CONTROL screen. Opening this screen is described as part of the procedures at the end of this subchaper. In the PROGRAM CONTROL screen, you can set the batch number and expiry date for the control, assign the control to tests and define the control values for the test results. To the right of the control data, a table of all tests is shown. The tests for which values are visible in the table, are currently assigned to the control.

5.1.3 PROGRAM CONTROL parameters

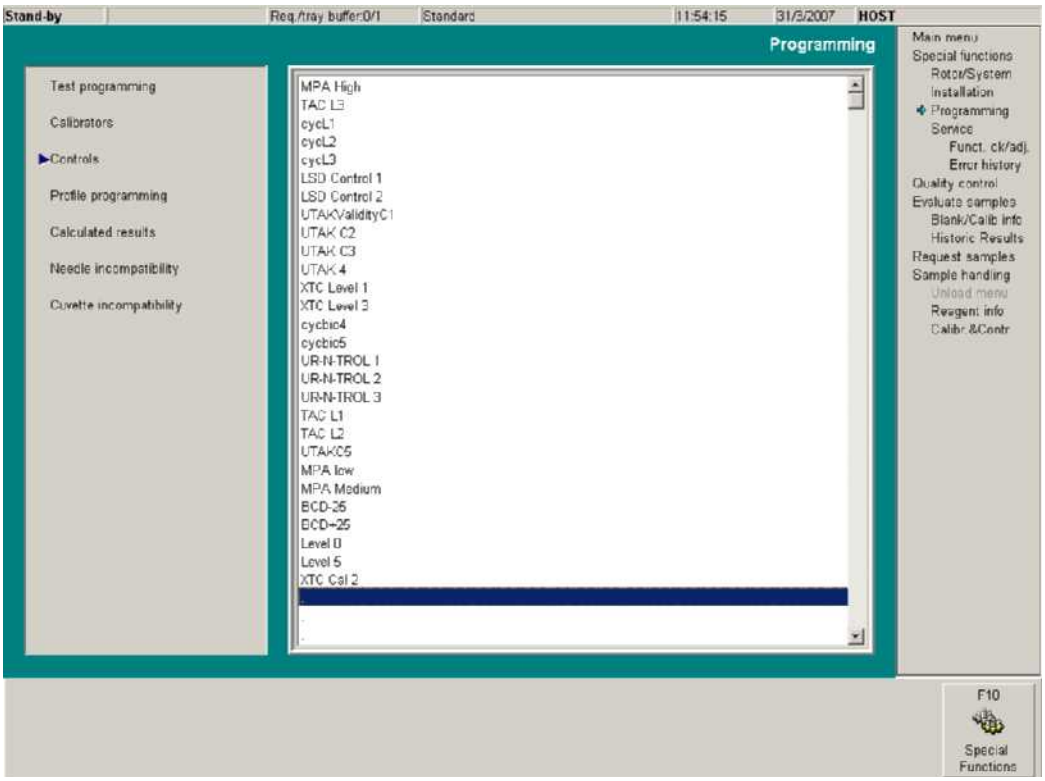
NAME:	The name of the control as provided by the insert sheet.
BATCH NUMBER:	The batch number as provided by the insert sheet.
EXPIRY DATE:	The expiry date as provided by the insert sheet.

5.1.4 PROGRAM CONTROL function keys

F1 PRINT	Prints a list of all tests assigned to the current control.
SHIFT+F2 EDIT CONTROL	Make the control data editable. You may now enter a new name, batch number and/or expiry date for the control.
SHIFT+F3 DELETE CONTROL	Deletes the selected control. The PROGRAM CONTROL screen is closed and the list of remaining controls is shown instead.
SHIFT+F4 DELETE TEST	Deletes the data for the selected test.
F5 EDIT TEST TARGET	Go to the TEST CONTROL PROGRAMMING screen. See 5.1.7 Program a control.
F10 RETURN	Go to the list of controls in the PROGRAMMING menu. All changes are saved.

5.1.5 Enter a new control

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM.
3. Type a password if necessary.
4. Select CONTROLS in the menu to the left. The list of controls is shown.



5. Select the next free entry in the list.
6. Press ENTER or double-click to open the PROGRAM CONTROL screen.
7. Type the name of the control and confirm with ENTER.
8. Type the batch number of the control and press ENTER.

9. Type the expiry date of the control and press ENTER.

Note
The control name, batch number and expiry date can be found on the insert sheet of the control.

10. Press ENTER to move to the test selection list. Programming tests for the control is described in 5.1.7 Program a control.

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

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM.
3. Type a password if necessary.
4. Select CONTROLS in the menu to the left. The list of controls is shown.
5. Double-click on a control name. The PROGRAM CONTROL screen is shown.
6. Select SHIFT+F2 EDIT CONTROL to edit the control. A confirmation dialog is shown before you can edit the control data.

Note
To delete the control, select SHIFT+F3 DELETE CONTROL. A confirmation dialog is shown before the control is deleted. When you confirm, the PROGRAM CONTROL screen is closed and the list of controls is shown, with an empty line where the deleted control was.

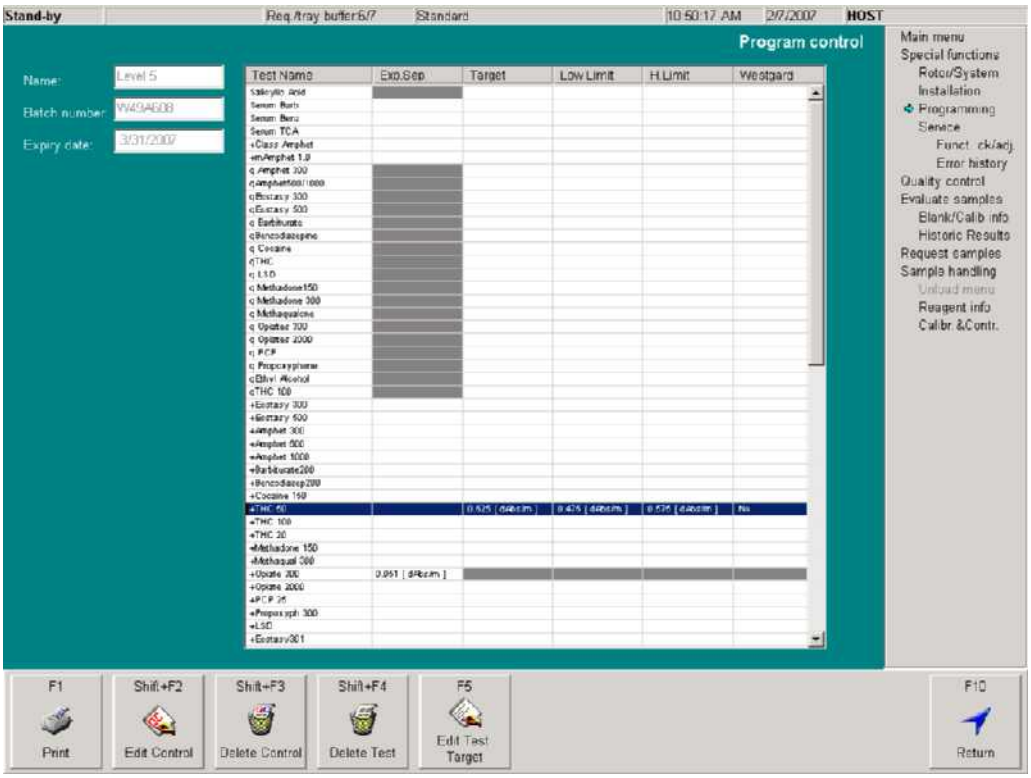
7. Type the name of the control and confirm with ENTER.
8. Type the batch number of the control and press ENTER.
9. Type the expiry date of the control and press ENTER.

Note
The control name, batch number and expiry date can be found on the insert sheet of the control.

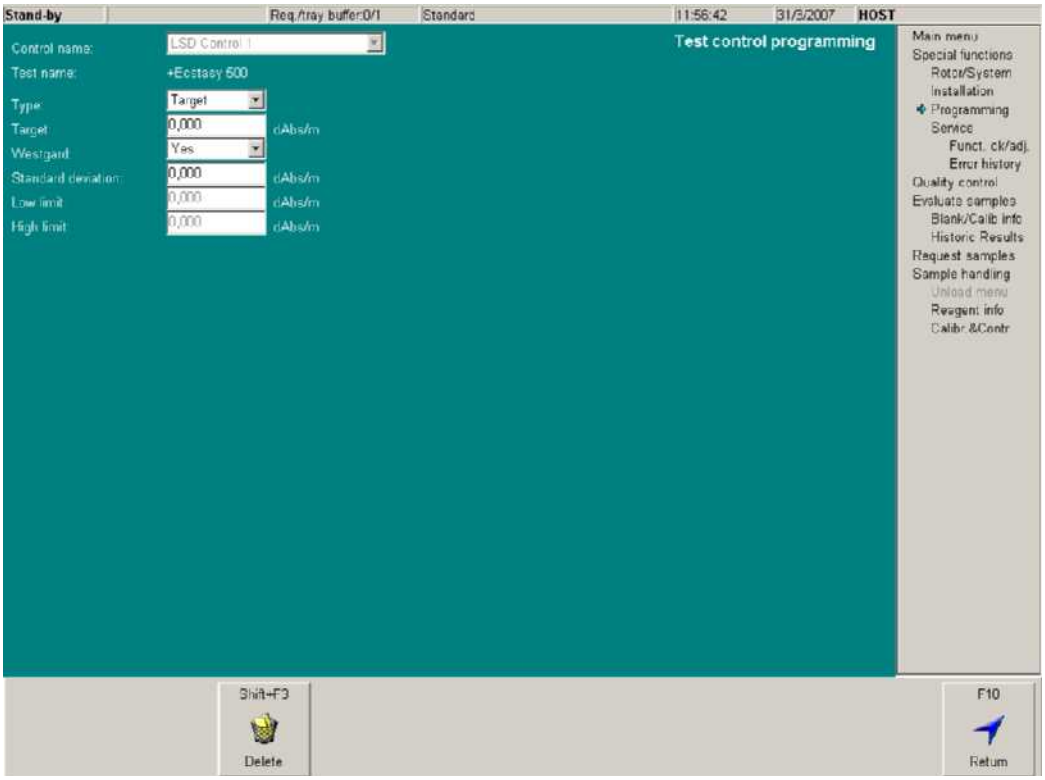
ATTENTION
The existing results of the quality control are lost if the control is changed or deleted.

5.1.7 Program a control

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM.
3. Type a password if necessary.
4. Select CONTROLS in the menu to the left. The list of controls is shown.
5. Double-click on the control name. The PROGRAM CONTROL screen is shown.



6. Tests to which the control is assigned show values for either EXP.SEP. (expected separation) or the four other columns. A control can be assigned to more than one test. Use the arrow keys or the scrollbar to move through the list.
7. Select the test for which you want to enter or change the values. Press the ENTER key, select F5 EDIT TEST TARGET, or double-click on the test in the list.
8. The TEST CONTROL PROGRAMMING screen for the selected test is shown.



9. Select the TYPE: (TARGET or SEPARATION).

Note

For some tests, the type selection is not available. These tests can only be used with the type that is preselected.

10. For SEPARATION tests: enter the EXPECTED SEPARATION:.
11. For TARGET tests: enter the TARGET:. Select YES or NO for the WESTGARD: option. For more information on the rules defined by this option, see 5.1.8 Westgard rules. Depending on this option, the following values must be entered:
    A WESTGARD: option selected: enter the STANDARD DEVIATION:. This automatically defines the LOW LIMIT: and HIGH LIMIT: values.
    B WESTGARD: option not selected: enter the LOW LIMIT: and HIGH LIMIT: values.
12. Press F10 RETURN to return to the PROGRAM CONTROL screen.

Note

When you return to the PROGRAM CONTROL screen, the test definition is entered into the list, even if no values were changed (0,000 dAbs/m is preset). If you want to abort setting the test values, select SHIFT+F3 DELETE to return to the PROGRAM CONTROL screen. This removes all values for the current test selection.

5.1.8 Westgard rules

The Westgard rules can only be used for single controls. When the Westgard option is selected, the high and low limits are automatically from the standard deviation that is entered by the user.
The Westgard rules are violated if one or more of the following conditions apply:

- 1 control result is more than 3 standard deviations from the target.
- The last 2 control results are more than 2 standard deviations from the target in the same direction (+ or –).
- The last 4 control results are more than 1 standard deviation from the target in the same direction (+ or –).
- The last 10 control results are all located either on the '+' or the '–' side to the target.

The Westgard rules are not violated in any other case.

5.2 Calibrator programming

5.2.1 Calibrators

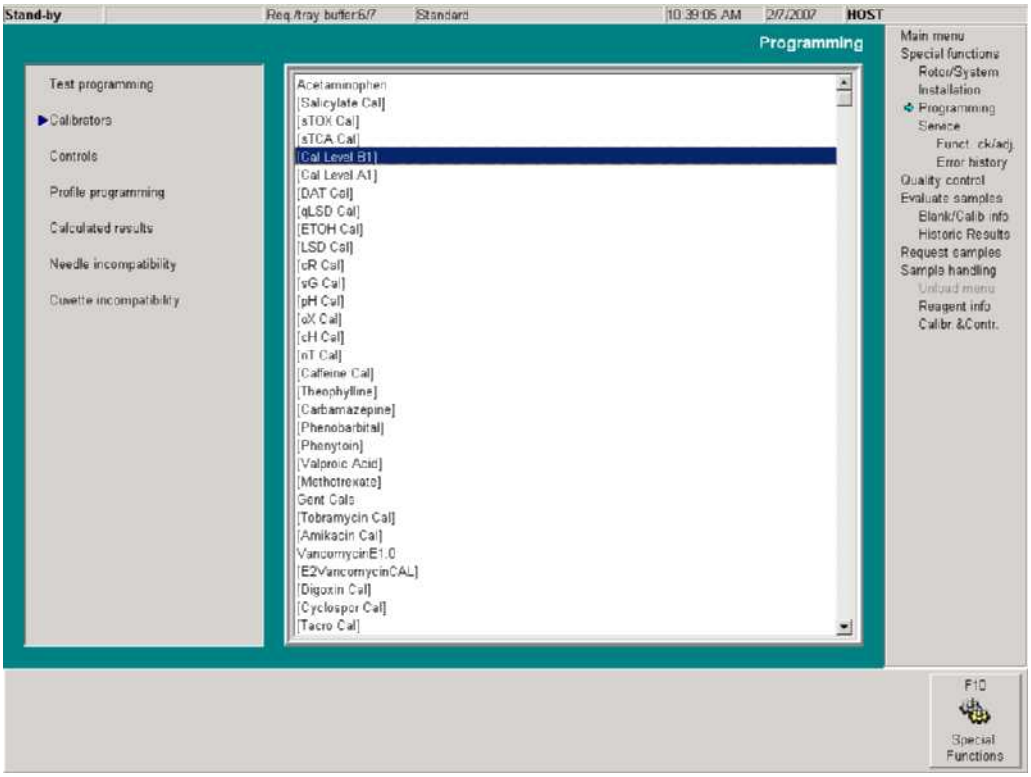
Calibrators must be programmed before you define the test parameters for the various tests. You can change the parameters for a calibrator or add new calibrators later. A total of 120 calibrators can be set. Loading predefined tests from a parameters file will load the correct calibrator.
The analyzer supports the following calibration methods:

- Qualitative cutoff calibration with 1 standard.
- Linear calibration with 1 standard
- Linear calibration with 2 standards
- Calibration with 3 to 9 standards
  - Std cubic spline
  - Smooth cubic slpine
  - 4 parameter logit log
  - Linear regression
  - Point to point
- Multi point calibration of different dilution levels made from one (parent) calibrator.

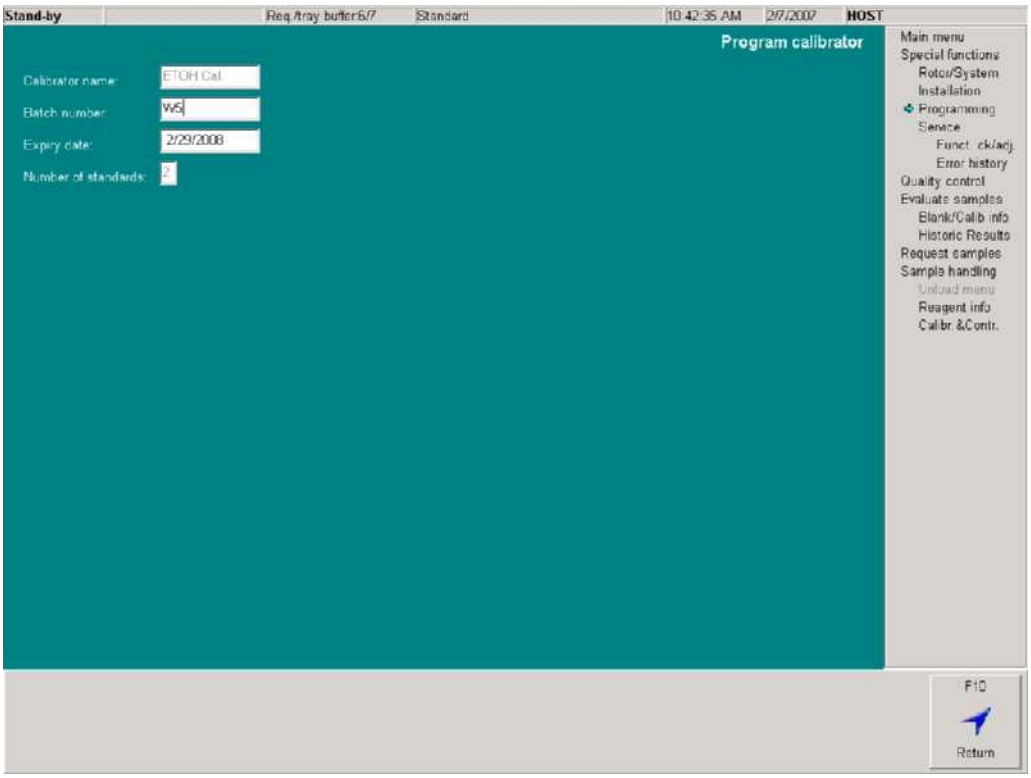
With a cut-off calibration you can also define a "close to cut-off" or "grey"-area. Cut-off grey area is a feature of this analyzer that is not supported by Siemens Healthcare Diagnostics. Results should be equal to or greater than the cut-off calibrator to be considered positive.

5.2.2 Program a calibrator

1. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
2. Select `F3 PROGRAM`.
3. Type a password if necessary.
4. Select `CALIBRATORS` in the menu to the left. The list of programmed calibrators is shown.



5. Select the name of a calibrator to be modified or an empty position for defining a new calibrator.
6. Press `ENTER` or double click on the selected position to open the `PROGRAM CALIBRATOR` screen.



7. Type the calibrator name in the CALIBRATOR NAME: field.

Note
Some calibrators are preprogrammed and protected against being deleted or renamed. You can still set the batch number and expiry date for these calibrators.

8. Type the batch number of the calibrator in the BATCH NUMBER: field.
9. Type the expiry date or the calibrator in the EXPIRY DATE: field.
10. Type the number of calibrator standards in the NUMBER OF STANDARDS: field.

Note
If you want to perform a dilution series using a one parent calibrator, please specify the number of calibration points here. Auto Predilution is specified in the test programming menu and only available in open channels.

5.2.3 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.
NUMBER OF STANDARDS:	The number of standards (1-9) for this calibrator.

5.2.4 PROGRAM CALIBRATOR function keys

SHIFT+F3 DELETE	Delete the current calibrator from the list of calibrators. This is not possible for preprogrammed calibrators.
F10 RETURN	Go to the PROGRAMMING menu.

5.3 Test programming

5.3.1 Introduction

All entries for each method are recorded in the TEST PROGRAMMING menu. The analyzer can give correct results only if the correct test parameters from the method sheets are entered. To modify a test or to add a new test, use the TEST PROGRAMMING menu and the parameters given in the method sheets. See 5.3.3 Program a new test or modify an existing test.

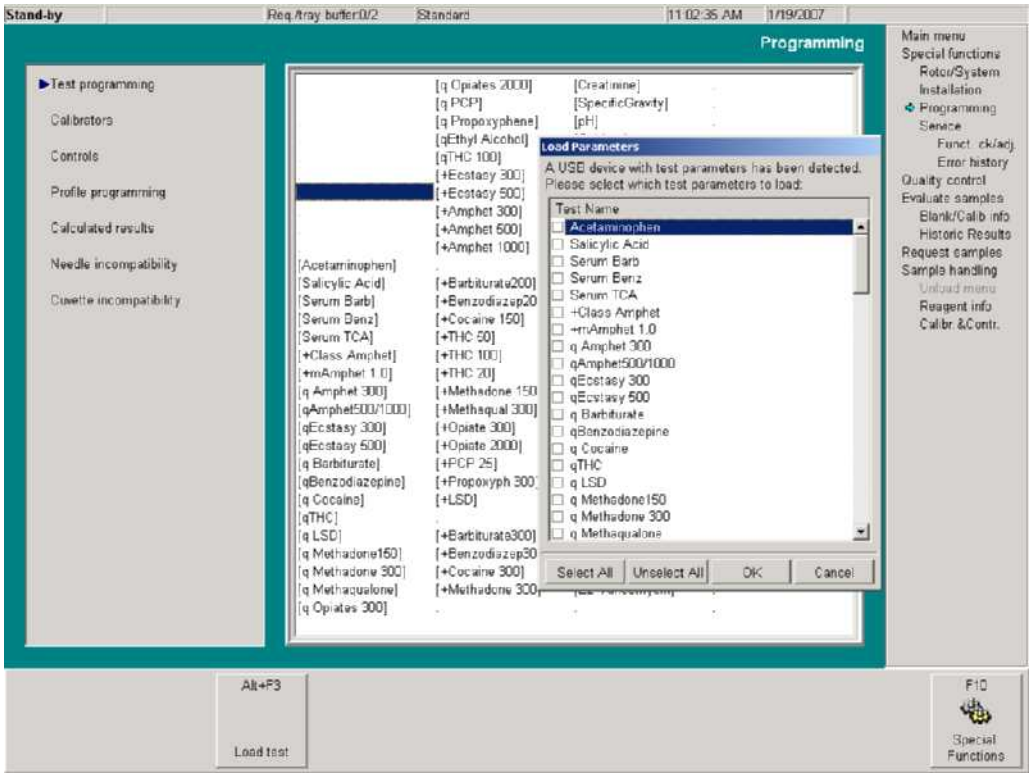
Disclaimer

All parameters must be entered exactly as given in the method sheets. The manufacturer accepts no liability for performance issues related to reagents and parameters from open channel reagents or test systems.

Predefined test parameters are available from Siemens. These do not need to be programmed manually, but can be loaded or imported. See 5.3.2 Load the test parameters.

5.3.2 Load the test parameters

Predefined test parameters are available from Siemens.



Autostart loading of test parameters

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM (TEST PROGRAMMING is the Default).
3. Press TAB.
4. Insert the storage medium (CD, USB drive) into the PC and wait for the load parameters box to appear.
5. Select All or individual tests. You can also deselect in this box.
6. Select OK.

Manual loading of test parameters

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM (TEST PROGRAMMING is the Default).
3. Press TAB.
4. Select ALT+F3 LOAD TEST.
5. Select YES in the dialog box.
6. Use the drop down arrow to browse the file system and locate the file.
7. Double-click ALLTESTS.XML.
8. The LOAD PARAMETERS dialog box opens. Select All or individual tests. You can also deselect in this box.
9. Select OK.

Note

The EXPORT / IMPORT DATA function can also be used to import test parameters from a file. See 7.6.2 Importing data.

5.3.3 Program a new test or modify an existing test

Note

The programming of open channel test parameters is level 1 password protected. This is set by the user. If you use reagents for one or more open channels contact your reagent supplier for parameters applicable for their reagents.

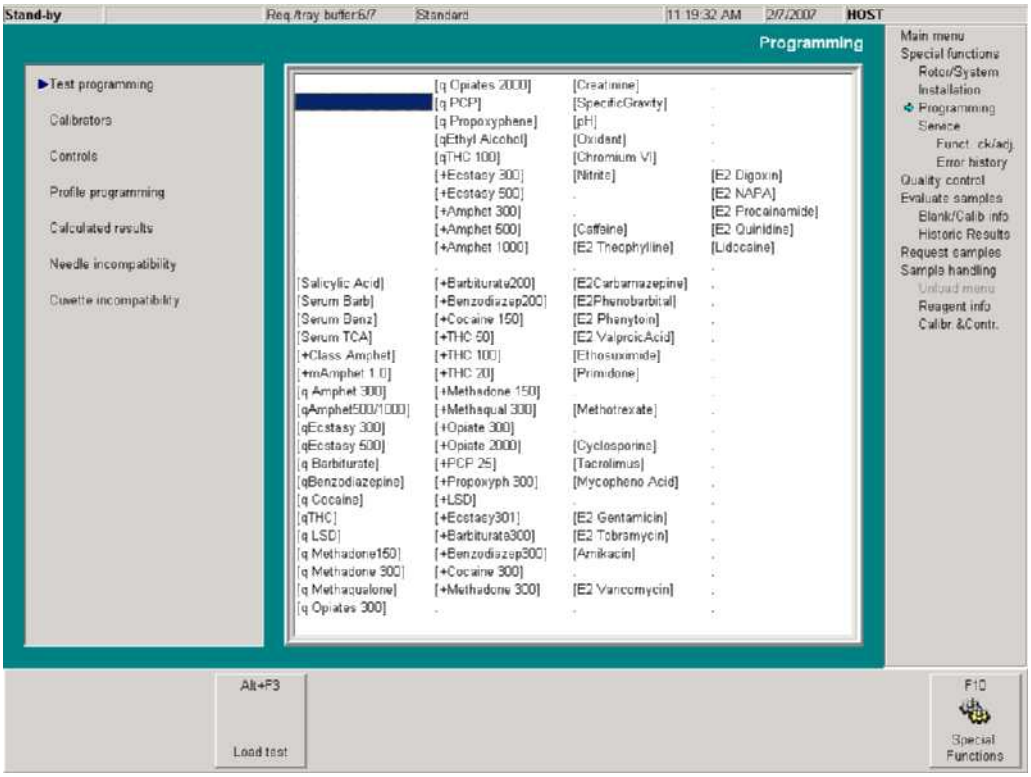
WARNING

Parameter values are saved to hard disk. Changes to the values will overwrite existing values without confirmation. The retrieval of the “old “ parameter values is not possible unless a back up of the test parameters has been made.

Note

The TEST PROGRAMMING screen consists of two pages, TEST PARAMETERS 1 and TEST PARAMETERS 2. The values on both pages must be set to the values given in the applicable method sheet.

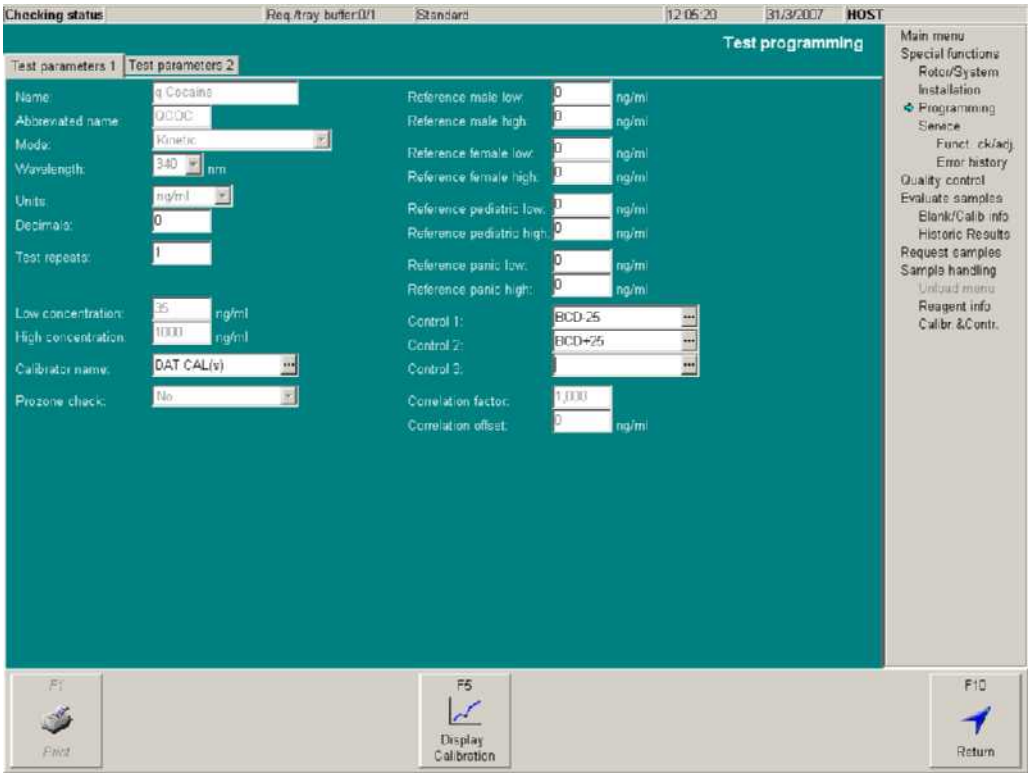
1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM.
3. Type a password if necessary.
4. TEST PROGRAMMING is the first entry in the menu and is automatically selected. A list of programmed tests appears. Empty spots are available for the definition of new tests.



5. Press TAB or ENTER to move the cursor to the list of tests.
6. Select the test you want to program:
   - Select an empty position to define a new test
   - Select an existing test to make changes to the test parameters
7. Press ENTER or double click on the selected position to call up the TEST PROGRAMMING screen.
8. The TEST PARAMETERS 1 page of the TEST PROGRAMMING screen is shown. Enter the values as required. See 5.3.4 Test programming - Test parameters 1.
9. Select the TEST PARAMETERS 2 page of the TEST PROGRAMMING screen. Enter the values as required. See 5.3.5 Test programming - Test parameters 2.
10. Select F10 RETURN to return to the PROGRAMMING menu.

Note
Enter the parameters exactly as in the method sheets.

5.3.4 TEST PROGRAMMING - TEST PARAMETERS 1



The programming of two point and end point tests is identical to kinetic test for most parameters . However, depending on the selected measurement mode (Kinetic, two point, end point), some fields are not applicable and therefore are not shown.

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 saved.

ABBREVIATED NAME: The abbreviated form of the test name. You must enter text to this field to a maximum of 4 characters. If no name is entered, the test parameters will not be stored. The abbreviated name can be used in the LIS communication.

MODE: Select the measurement mode from the drop down list. KINETIC, END POINT MONOCHROMATIC, END POINT BICHROMATIC, TWO POINT.

WAVELENGTH: Select the wavelength as given in the method sheet from the drop down list. The drop down list contains all available wavelengths. If END POINT BICHROMATIC is chosen at the parameter Mode, two drop down lists appear. Select both wavelengths 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.

TEST REPEATS:

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.

LOW CONCENTRATION:

The value for the low limit of the measuring range from the method sheet. If the result falls below of the set limit, the sample is flagged for being below the analytical sensitivity of the assay.

HIGH CONCENTRATION:

The value for the high limit of the measuring range from the method sheet. If the limit is exceeded, the sample is flagged for being above the assay range.

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 screen with calibrator settings for the test appears. See 5.3.6 Program test calibrator parameters.

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. ABS RATIO
- MAX. DABS RATIO.

If either MIN. DABS RATIO or MAX. ABS 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. ABS 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. DABS 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 by 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 page 2.

REFERENCE 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.

REFERENCE 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.

REFERENCE 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.

REFERENCE 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.

REFERENCE PEDIATRIC LOW:

The low limit of the reference range for pediatric samples. If a measured value is below this limit, the analyzer flags the result.

REFERENCE PEDIATRIC HIGH:

The high limit of the reference range for pediatric samples. If a measured value is above this limit, the analyzer flags the result.

REFERENCE 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.

REFERENCE 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.

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. See 5.1.7 Program a control.

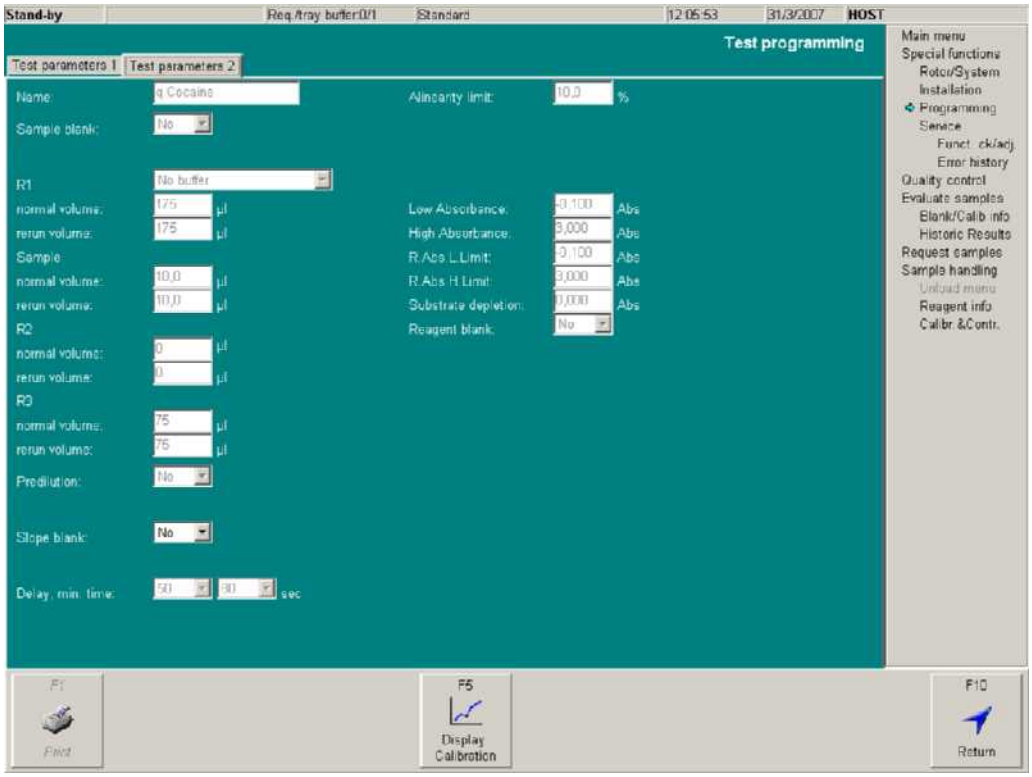
CORRELATION FACTOR	The correlation factor is a calculation factor used internally by the system. The system multiplies the result of the measurement with the value entered in this field. The standard setting is1.000; it is also the normal value for all methods with a quantitative evaluation. No correlation factor is required, if a qualitative evaluation (cut-off) was selected for the corresponding test.
CORRELATATION 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.

5.3.5 TEST PROGRAMMING - TEST PARAMETERS 2

Note

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. One of 3 different buffer solutions can be chosen. Do not forget to position the buffer solution in the REAGENT POSITIONS menu, otherwise the corresponding test cannot be requested in the REQUEST SAMPLES menu.



NAME: The test name as set on page 1.

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. For a description of these parameters see later in this chapter.
When sample blank is set to YES, the user can select a sample blank reagent SHARED BLANK 1, SHARED BLANK 2 or SHARED BLANK 3. The sample blank reagent must be placed in the reagent rotor as any other reagent. When a sample blank measurement takes place, the analyzer pipettes the sample blank instead of the normal reagent for the test.

SAMPLE	NORMAL VOLUME: Enter the normal sample volume in 0.1 µl steps between 2 and 30 µl. It is recommended not to enter a sample volume less than 3 µl. RERUN VOLUME: Enter the sample rerun volume in 0.1 µl steps between 2 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.
R1	Press ENTER to show a drop down list of the available buffers. Select a buffer for reagent 1 bottle. The different buffers that can be used are: SHARED BUFFER 1; SHARED BUFFER 2; SHARED BUFFER 3. 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 R3 110 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.
R2	The R2 is selected in the reagent position screen. NORMAL VOLUME: Enter a volume between 0 and 289 µl. RERUN VOLUME: Enter a rerun volume between 0 and 289 µl
R3	The R3 is selected in the reagent position screen. NORMAL VOLUME: Enter a volume between 0 and 289 µl. RERUN VOLUME: Enter a rerun volume between 0 and 289 µl

PREDILUTION:

The sample can be prediluted. 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 (SHARED DILUENT 1, SHARED DILUENT 2, SHARED DILUENT 3), select one diluent from the list and press ENTER again to confirm your selection.

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 volumes set at the parameters NORMAL VOLUME: and RERUN VOLUME: refer 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.
When predilution is selected here only patient and control samples will be prediluted with the specified ratio. Predilution of the calibrators has to be defined separately as part of the calibator settings for this test. See 5.3.6 Program test calibrator parameters.

SLOPE BLANK:

Kinetic and two point modes. 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 R3 was added. The slope blank can also correct for a side reaction between sample and the first reagent.

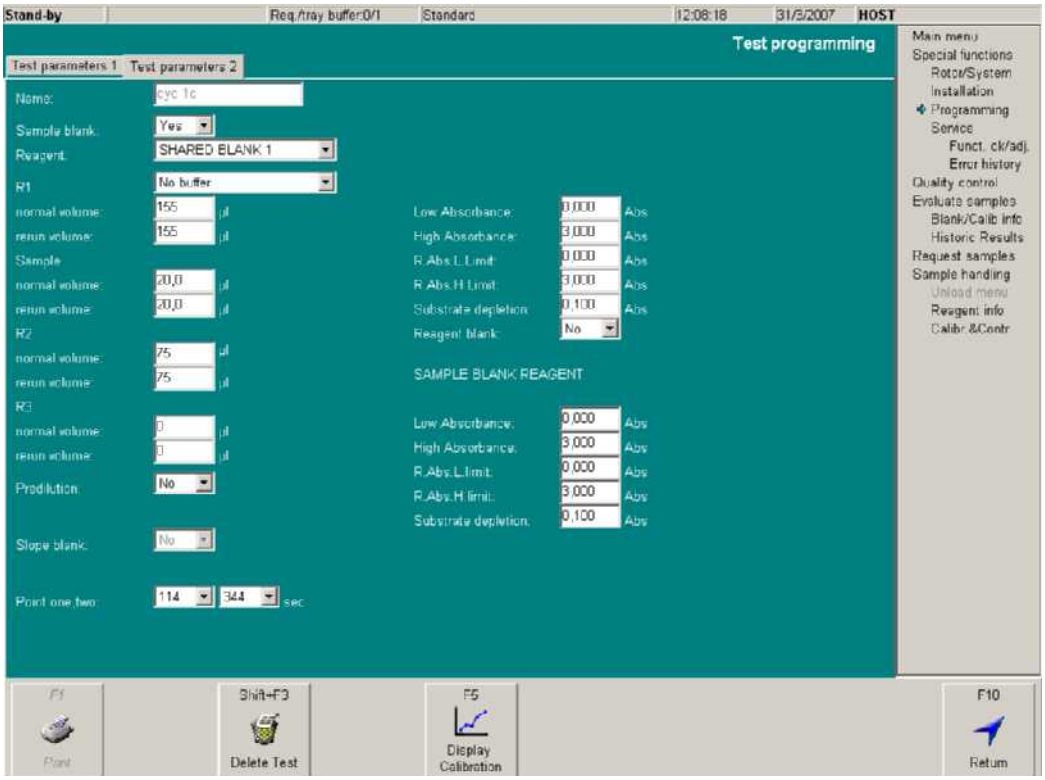
If no linearity error has been detected on the first four measurement points after the beginning of incubation, the analyzer uses the measurement points which lie between the incubation plus the minimum time entered here. E.g. 50 seconds is entered as delay and 186 seconds for the minimum time, the analyzer 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.

SLOPE BLANK DELAY:	Kinetic and two point modes 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 R3, when the results are calculated.
"POINT ONE,TWO:"	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.
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.
"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: (TEST PARAMETERS 1 page), the field "PROZ.PT.ONE,TWO:" 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.
PROZONE H.LIMIT:	If an absorbance ratio or delta absorbance ratio were selected in the field PROZONE CHECK: (TEST PARAMETERS 1 page), the field PROZONE 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

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



ALINEARITY 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%. Use 25% for low rate assays (< 0.150 dAbs/m).
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 one or more absorbance values are below this limit, the analyzer flags the result. An automatic rerun of the test starts if the CUSTOM AUTOMATIC RERUN: option was selected in the CUSTOM EVALUATION menu.
HIGH ABSORBANCE:	The high absorbance limit to be used. If one or more absorbance values are above this limit, the analyzer flags the result. An automatic rerun of the test starts if the CUSTOM AUTOMATIC RERUN: option was selected in the CUSTOM EVALUATION menu.
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.



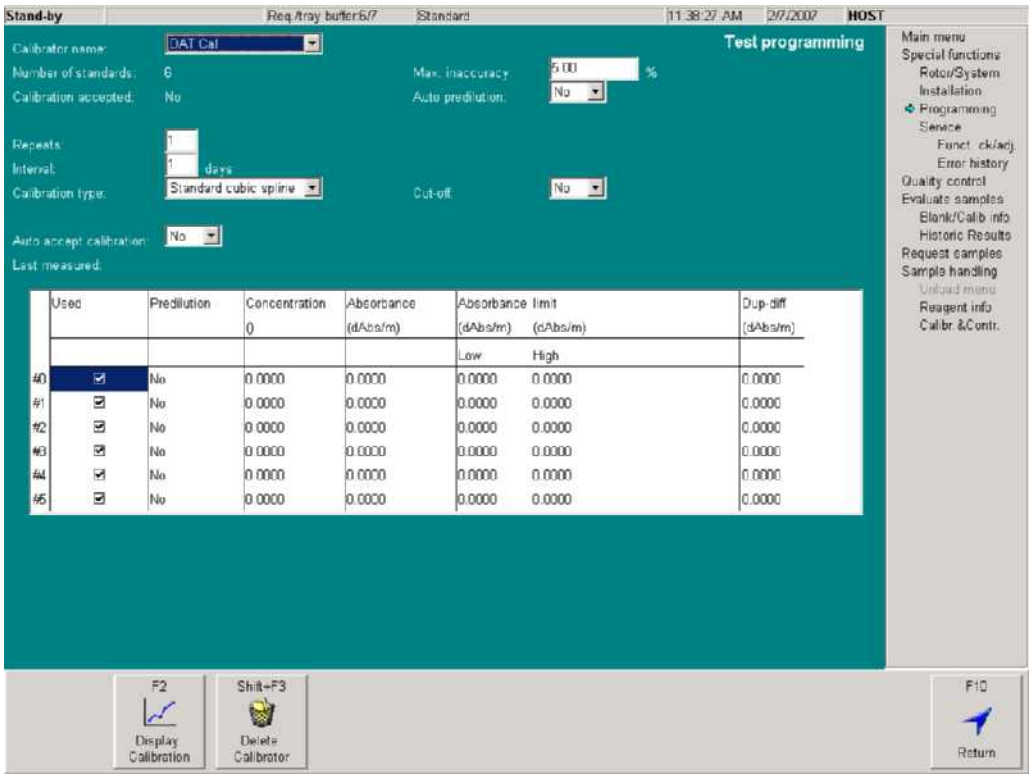
Note

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.

5.3.6 Program test calibrator parameters

After a calibrator name has been selected in the TEST PARAMETERS 1 page of the TEST PROGRAMMING screen all parameters that apply to this test must be programmed. The following screen appears:



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

CALIBRATOR NAME:	Select the calibrator that is needed. All calibrators that are programmed in the CALIBRATORS menu can be selected.
NUMBER OF STANDARDS:	The number of standards defined in the PROGRAM CALIBRATOR menu.
MAX. INACCURACY:	Any value is indicated as a percentage. This value is a measure for the maximum inaccuracy of only the fit of the smoothed 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%.
CALIBRATION ACCEPTED:	YES or NO. The parameter cannot be edited, but has to be accepted in the F2 DISPLAY CALIBRATION menu
AUTO PREDILUTION:	YES or NO. If YES then the number of points, diluent and concentration parameters are available.

REPEATS:	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.
DILUENT:	Select the diluent which is to be used for the automatic dilution. Press ENTER to open the list of diluents (SHARED DILUENT 1, SHARED DILUENT 2, SHARED DILUENT 3), select one diluent from the list and press ENTER to confirm your selection. This field is only indicated if AUTO PREDILUTION: is selected.
INTERVAL:	Enter the calibration interval in days (0 to 99) from 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.
CONCENTRATION:	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 PREDILUTION: is selected.
CUT-OFF:	YES or NO. Set to YES to flag a result negative or positive.
CUT-OFF VALUE:	Results equal to or greater than the cut-off value are flagged positive for increasing rate calibrations.
DEVIATION:	This value defines the area uncertainty before a cut-off limit. Measurements in the area of uncertainty receive a “result near cut-off” flag. Example: The result of a cut-off calibration was calculated to **0.120 delta abs/m**. The cut-off was programmed as: YES; Positive: 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 as the deviation is **-0.008 delta abs/m** and is in the range of **0.120 +/- 0.010 delta abs/m**.
DIRECTION:	Direction of the calibration rate reaction, INCREASE or DECREASE. If INCREASE is selected and the measured (delta) absorbance is higher than the value of the cut-off calibrator, the result is positive. If DECREASE is selected and the measured (delta) absorbance is lower than the value of the cut-off calibrator, the result is positive.

Note

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

CALIBRATION TYPE:	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 4.3.13 Load a calibrator.
AUTO ACCEPT CALIBRATION:	YES or NO. A calibration must be accepted before it can be used to calculate results. Select YES for the analyzer to accept the calibration after it is complete. Select NO for the operator to accept the calibration when it is complete.



Note
The act of accepting a calibration does not make the calibration acceptable. The operator should evaluate the calibration results against the appropriate criteria and the previous calibration.

LAST MEASURED:	Gives the date and time of the last measured calibration.
NUMBER OF POINTS:	The number of different pre-diluted tests that are carried out for a calibration. The number of points has no effect on the number of standards that are programmed.
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.
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, two point or endpoint.

ABSORBANCE-LIMIT	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.

5.3.7 Program calibrator function keys

F2 DISPLAY CALIBRATION	Displays a graphical representation and detailed information of the calibration curve.
SHIFT+F3 DELETE CALIBRATOR	Delete the current calibrator from the list of calibrators.
F10 RETURN	Return to the TEST PARAMETERS 1 menu.

5.3.8 Calibration curves algorithms

The analyzer provides the following different curve methods:

- Standard cubic spline
- Modified Cubic Spline
- 4 Par. logit (NLLS)

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

Standard cubic spline

Applicable formulas:

$$p = \frac{A_{i+1} - A_m}{A_{i+1} - A_i}$$

$$q = \frac{A_m - A_i}{A_{i+1} - A_i}$$

$$C_m = {}_pC_i + {}_qC_{i+1} + \frac{1}{6}(p^3 - p)(A_{i+1} - A_i)^2 a_i + \frac{1}{6}(q^3 - q)(A_{i+1} - A_i)^2 a_{i+1}$$

Where:

A_i =	Measured absorbance value for calibration point i
C_i =	Concentration for calibration point i
A_m =	Measured absorbance value for the sample
C_m =	Calculated concentration
a_i	Factor determined by the curve-fit algorithm

The value of A_i and A_{i+1} is given by:

$$A_i \leq A_m < A_{i+1}$$

Smooth cubic spline

Applicable formulas:

$$y_i(x) = a_i x^3 + b_i x^2 + c_i x + d_i$$

Where:

A_i =	Measured absorbance value for calibration point i
A_m =	Measured absorbance value for the sample
x	Input variable based on measured absorbance

y_i	Output variable for concentration
C_m =	Calculated concentration
a_i, b_i c_i d_i	Factors determined by the curve-fit algorithm
g_x	Factor determined by the curve-fit algorithm

The value of A_i and A_{i+1} is given by:

$$A_i \leq A_m < A_{i+1}$$

The value for x is given determined by

$$x_m = A_m$$

$$x_m = \ln(-A_m - g_x)$$

The curve-fit algorithm determines the best relation and displays this on the screen. When x_m is calculated, x is derived by:

$$x = x_{measured} - A_i$$

The value for y is calculated by the basic formula above. From y the concentration C is calculated as follows:

$$c = f\, y$$

$$c = f\, (-e^{y} - g_y)$$

$$c = f\, (e^{y} + g_y)$$

The curve-fit algorithm determines the best relation and displays this on the screen.

4 Parameter logit (NLLS)

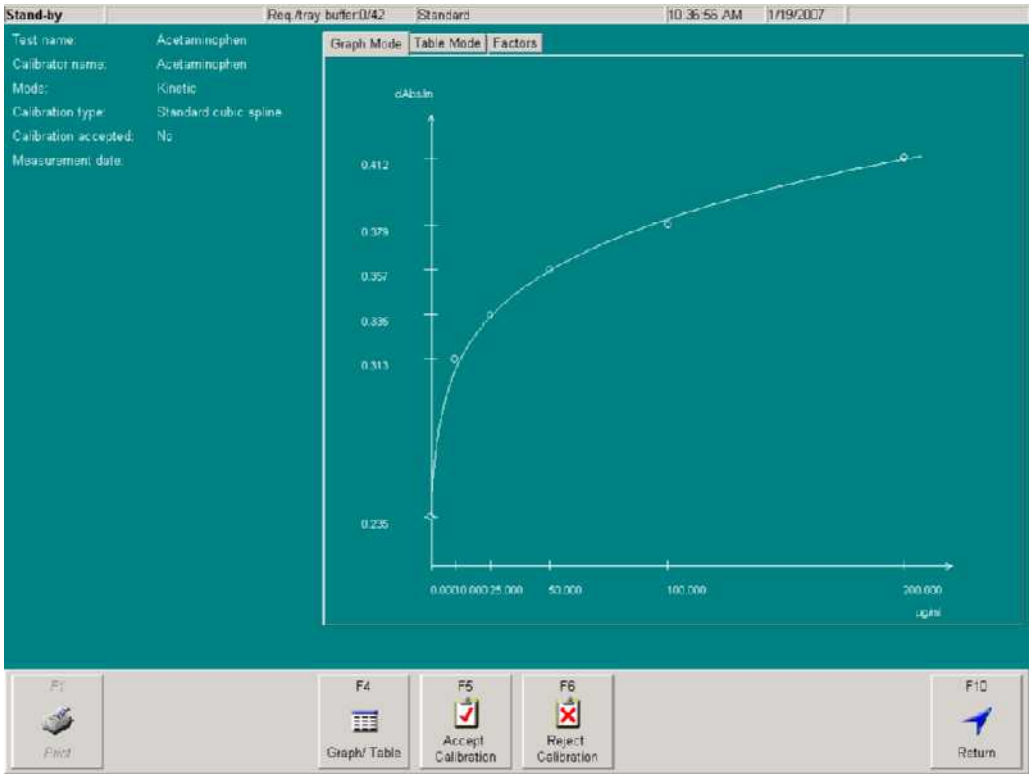
$$A_m = x_0 + \frac{K}{1 + e^{-a - b \ln C_m}}$$

Where:

A_m =	Measured absorbance value for the sample
C_m =	Calculated concentration
X_0, K, a, b	Factors determined by the curve-fit algorithm

5.3.9 Accept calibration curve parameters

The accept calibration curve parameter screen appears after a calibration is complete and the auto-accept calibration is set to NO.



1. Select F2 DISPLAY CALIBRATION.
2. Select F4 GRAPH/ TABLE to open either GRAPH MODE, TABLE MODE or FACTORS.
3. Select F5 ACCEPT CALIBRATIONor F6 REJECT CALIBRATION.
4. Select F10 RETURN to return to the TEST PROGRAMMING menu.

5.3.10 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 details will show as 0.00 and 9999.0, the result will be reported as less than or greater than the low or high concentration parameters, and displayed with the v or V flag respectively. 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

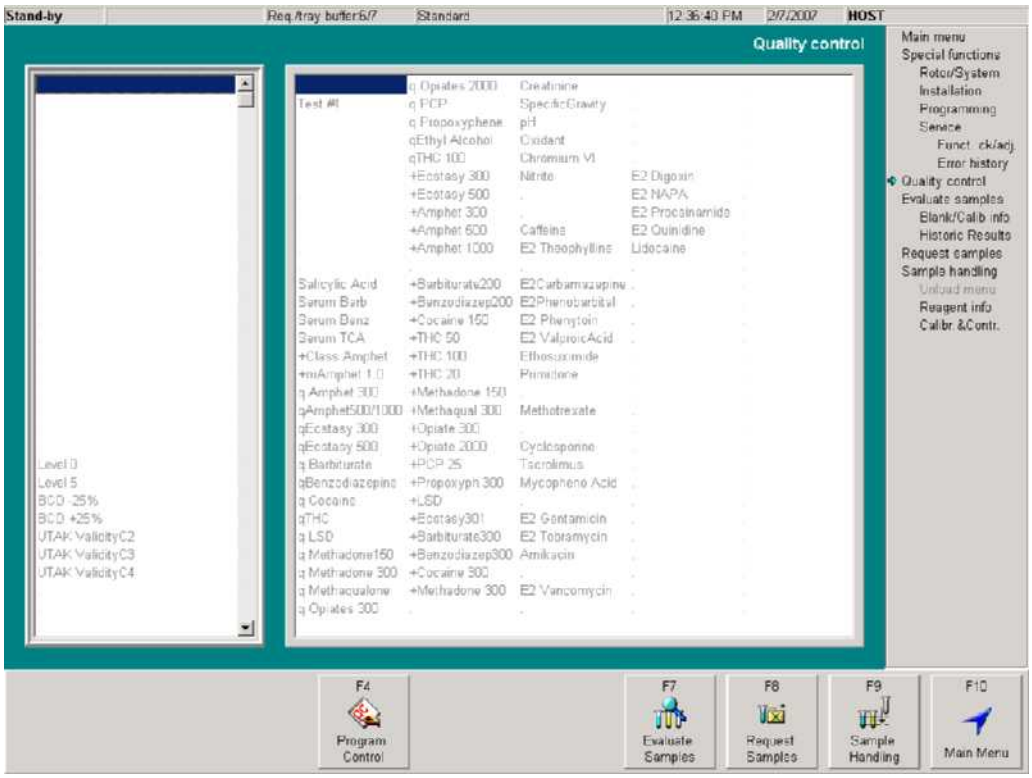
These limits are calibrator related and do not appear in the test parameters. Do not mix them with the general absorbance limits which are method related and are displayed as flagged results (< or >)

5.4 Quality control

5.4.1 Introduction

The QUALITY CONTROL screen gives an overview of all measured control data. Any one of three controls previously assigned to a test in CONTROLS 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 QUALITY CONTROL screen



5.4.3 QUALITY CONTROL parameters

Control field (left side of the screen)	All controls in CONTROLS are displayed. All controls connected to a selected test are displayed in black.
Display field (right side of the screen)	All programmed tests 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 side of the screen.

5.4.4 QUALITY CONTROL function keys

F4 PROGRAM CONTROL	Activates the program control menu to change the assignments of test and controls.
F6 GRAPH MODE	Shows the results from selected control/test combination 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	Go to the EVALUATE RESULTS screen.

F8 REQUEST SAMPLES	Go to the REQUEST SAMPLES screen.
F9 SAMPLE HANDLING	Go to the SAMPLE HANDLING screen.
F10 MAIN MENU	Go to the MAIN MENU.

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 oldest 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 linked test. Press ENTER.
5. Press F6 GRAPH MODE
6. Press F2 GRAPH/ TABLE to view the table
7. Press F2 GRAPH/ TABLE again 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:

TEST NAME	Displays the name of the test assigned to this control.
CONTROL	Displays the name of the control.
BATCH NO.	Displays the control manufacturers batch number.
EXPIRY DATE	The expiry date of the control.
TARGET	The reference value set in PROGRAM CONTROL.
LOW	The low limit as set in PROGRAM CONTROL.
HIGH	The high limit as set in PROGRAM CONTROL.
WESTGARD	Displays the status of the 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.

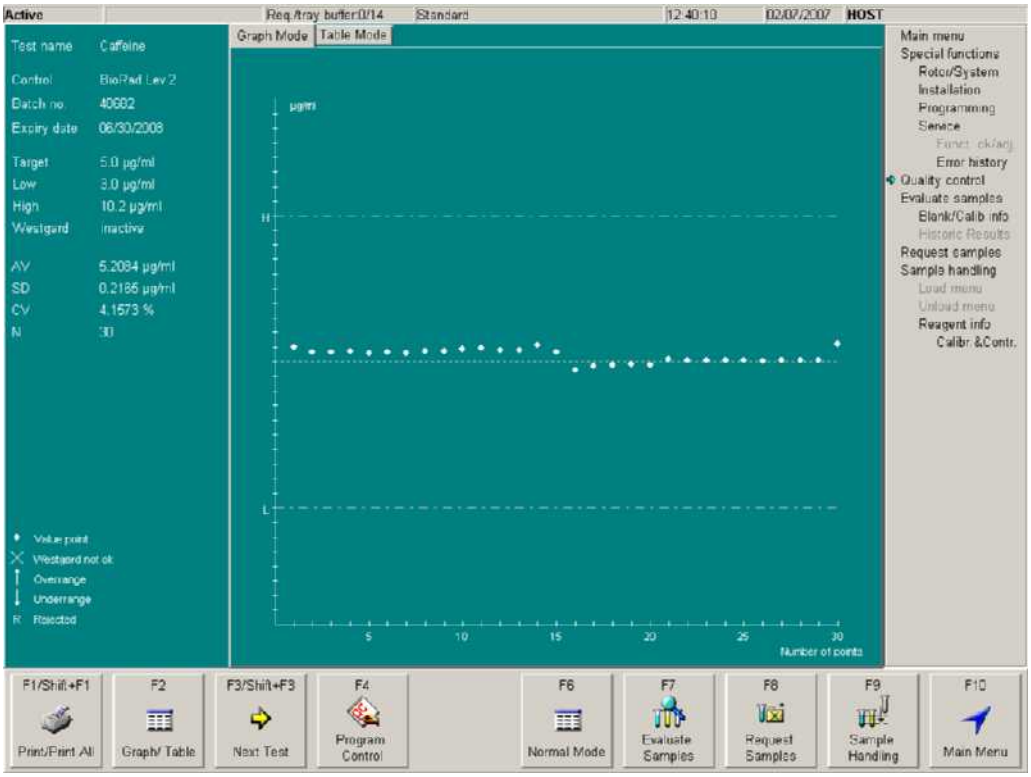
Legend

♦	Value point
╳	Westgard rule broken. Not OK.
↑	Value overrange. The result is outside the range of the graphic display. The result must be checked in table mode and marked REJECT if necessary.
↓	Value underrange. The result is outside the range of the graphic display. The result must be checked in table mode and marked REJECT if necessary.

R	Value rejected. The result has been rejected by the operator in table mode .

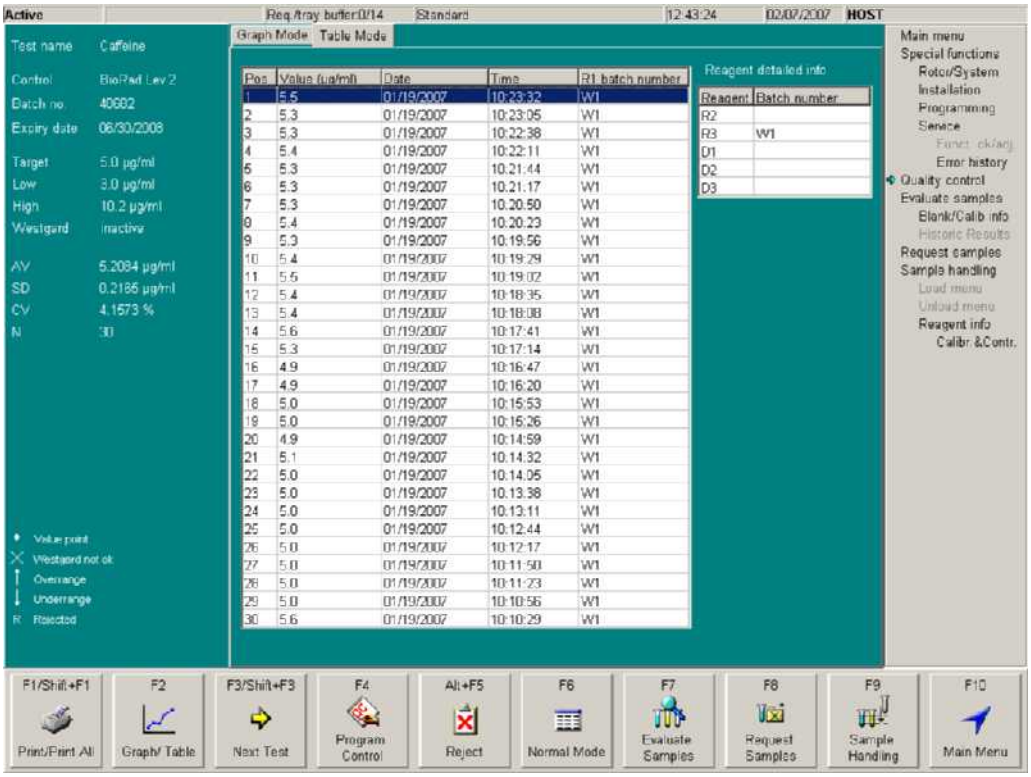
5.4.7 Description of the graphic display

Each point represents one control measurement with the corresponding test. The quality of the test can be monitored from the spread of the points.



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.

5.4.8 Description of the table mode



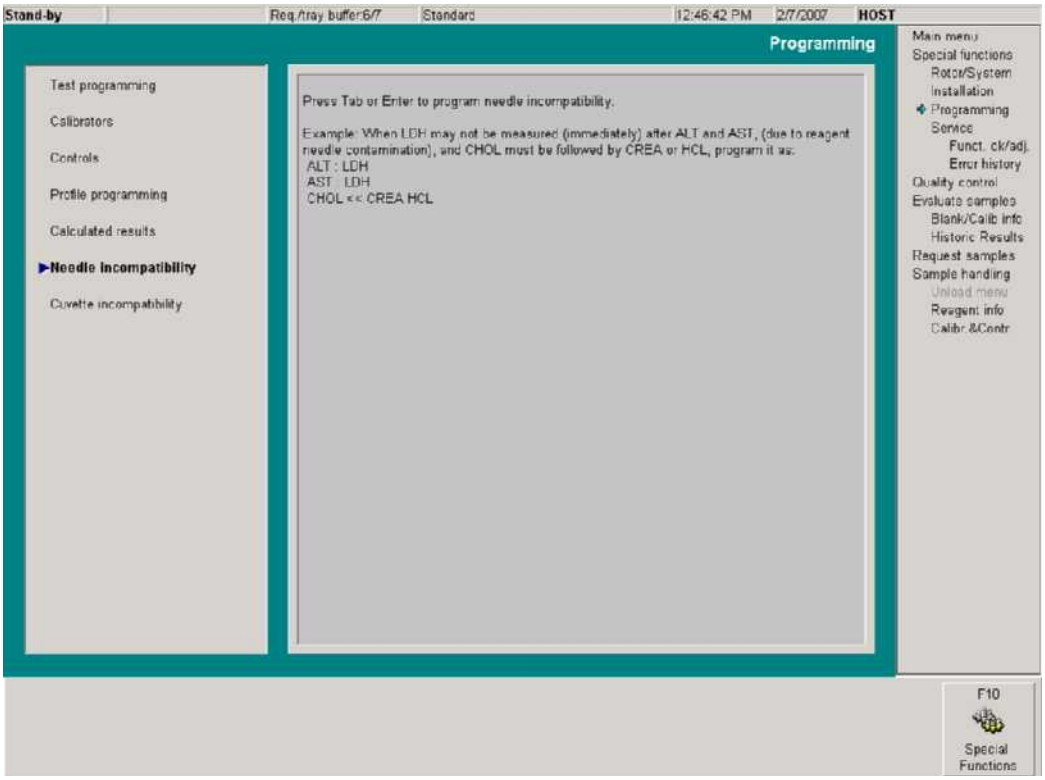
Press `F2 GRAPH/ TABLE` to change the analyzer from graphic mode to table mode. The rows display the results of the last 30 control measurements with position, value, date, time of the control measurement and the R1 batch number used.
To reject a control result, select the result using the arrow keys or the mouse and select `ALT+F5 REJECT`.

5.5 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



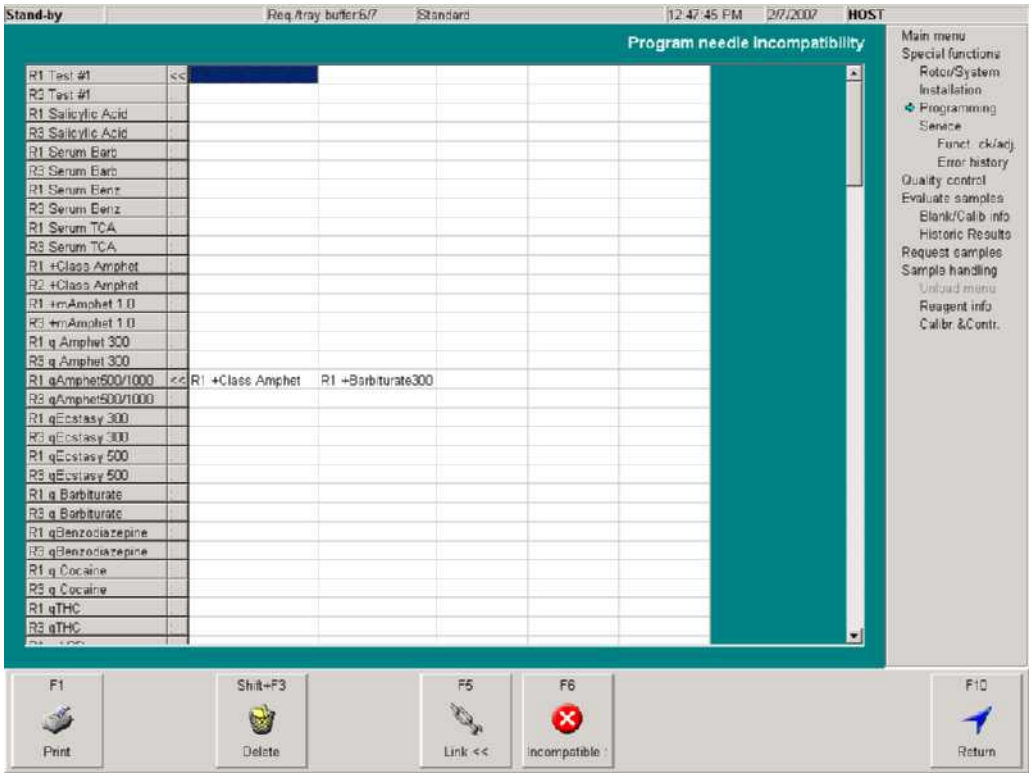
1. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
2. Select `F3 PROGRAM`.
3. Type a password if necessary.
4. Select `NEEDLE INCOMPATIBILITY` or `CUVETTE INCOMPATIBILITY`.

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 no other reagent is available, 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 no other reagent is available, HCl will be dispensed as an extra cleaning step.

5.5.4 Incompatibility screen

The program procedure and screen are identical for needle and cuvette incompatibility. All tests programmed in the analyzer are displayed on two pages. Incompatible reagents are listed behind the respective parameter. A maximum of 21 reagents can be set for each parameter.



CURSOR KEYS	Display the reagent list.
ENTER	Select a reagent row.
PAGE UP/PAGE DOWN	Scroll through the reagent list page by page.
F1 PRINT	Print out the displayed screen.
SHIFT+F3 DELETE	Delete the selected link.
F5 LINK <<	Link the selected reagent. If possible the second reagent is processed directly after the first.
F6 INCOMPATIBLE :	Make the reagents incompatible. The second reagent is not processed directly after the first.
F10 RETURN	Return to the NEEDLE INCOMPATIBILITY or CUVETTE INCOMPATIBILITY display.

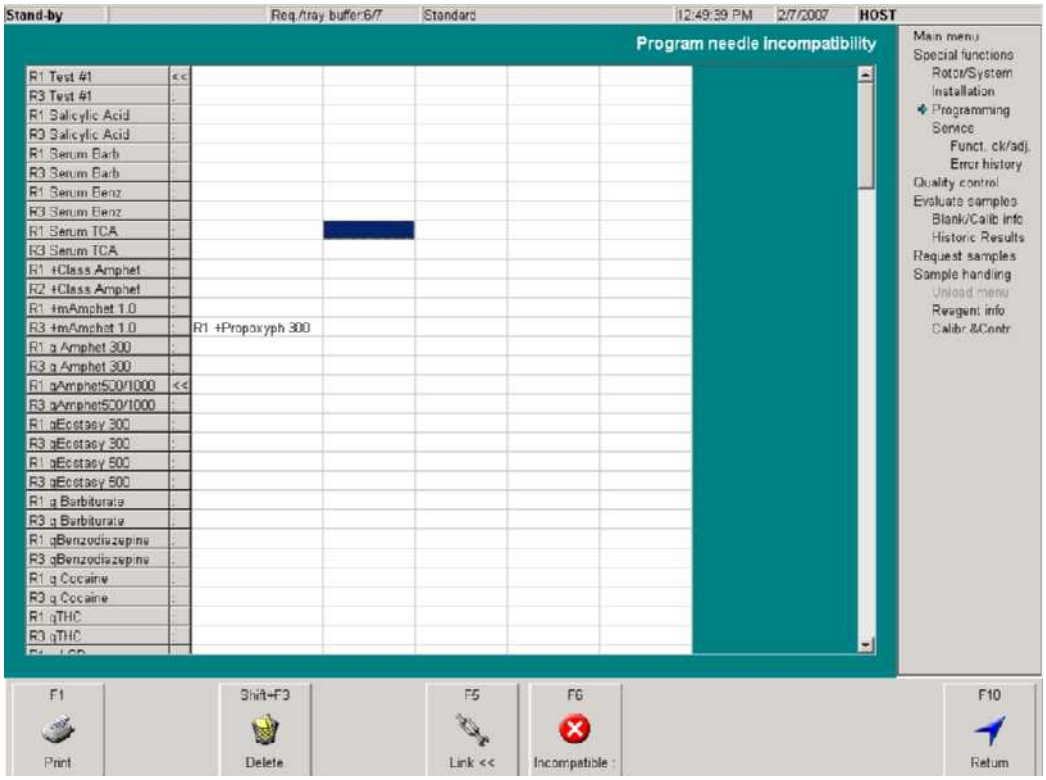
Note

A blank or dummy test has the name SHARED BLANK 1, SHARED BLANK 2 or SHARED BLANK 3.

5.5.5 Define incompatible 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.
3. Type a password if necessary.
4. Select NEEDLE INCOMPATIBILITY.
5. Press ENTER to activate the needle incompatibility overview. The information on the reagent definition is found in the data method sheets for the reagents.
6. Place the cursor in the first column behind the reagent A.
7. Press ENTER to show a list of reagents.
8. Select the reagent B that must never go after reagent A.
9. Select F4 LINK REAGENT 1.
10. Press F10 RETURN to return to the programming screen.

The default setting is that the reagent B is incompatible with the reagent 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.



Note

If test B has to be processed after test A and test B is not available, then the analyzer will process HCI as a default. If HCI is not available the analyzer will process system solution.

1. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
2. Select `F3 PROGRAM`.
3. Type a password if necessary.
4. Select `NEEDLE INCOMPATIBILITY`.
5. Press `ENTER` to activate the incompatibility overview. Information on the reagent definition is found in the method sheets for the reagents.
6. Place the cursor in the first column behind the reagent A.
7. Press `ENTER` to show a list of reagents.
8. Select the test that must go after reagent A.
9. Select `F4 LINK REAGENT 1`.
10. Select `F5 LINK <<`. The colon changes to a link sign («).

The analyzer will now process reagent B immediately after a reagent A, if possible.

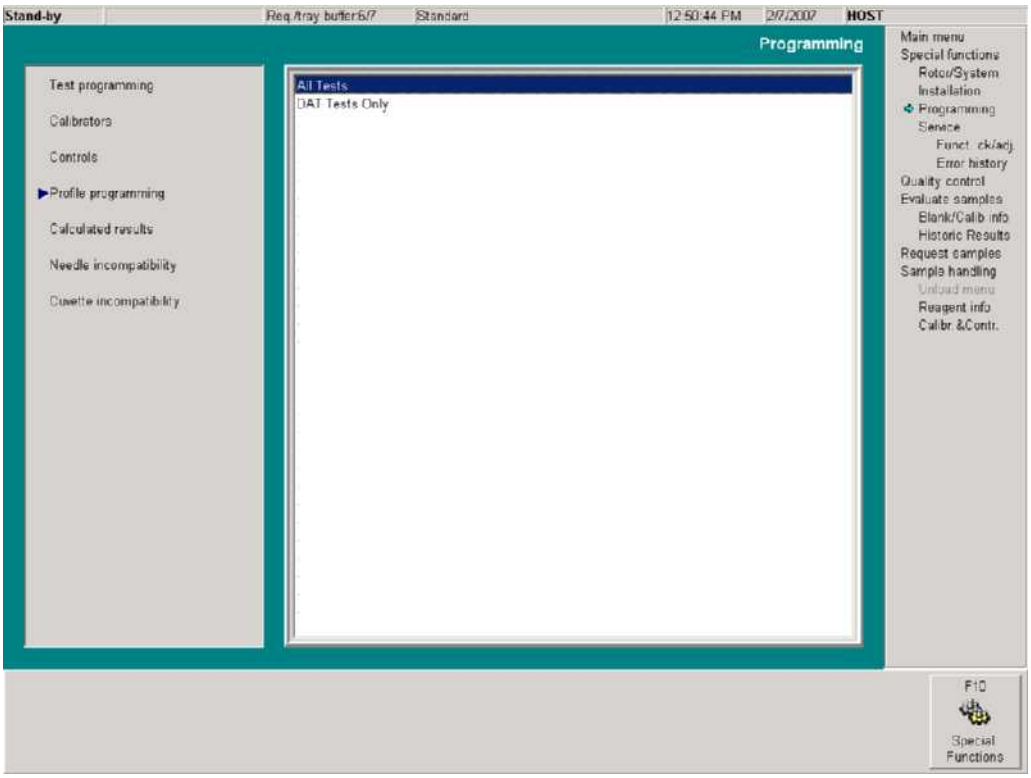
5.6 Profiles

5.6.1 Introduction

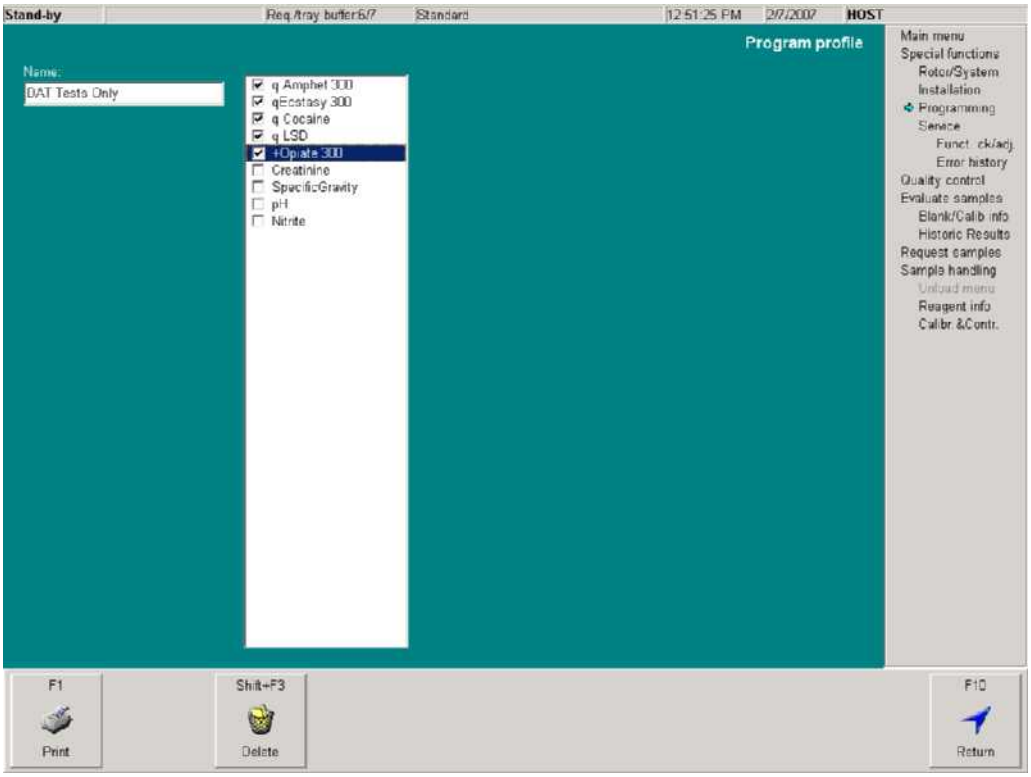
Several tests can be combined to form profiles. This increases analyzer productivity. Once profiles are programmed, they are available to record test requests. Profiles can be programmed and changed when needed in the PROFILE PROGRAMMING menu.

5.6.2 Program profiles

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F3 PROGRAM.
3. Type a password if necessary.
4. Select PROFILE PROGRAMMING. A list of programmed profiles appears.



5. Press ENTER to move the curser to the list of profiles.
6. Select a profile name or an open position and press ENTER. The PROGRAM PROFILE screen appears.



7. Change the name of the profile or type a new name and press ENTER.
8. Select the tests necessary for the profile. These tests can be changed later.
9. Select F10 RETURN to return to the list of profiles.

A maximum of 30 profiles can be programmed. Each profile name may consist of up to 20 characters.

5.6.3 PROGRAM PROFILE function keys

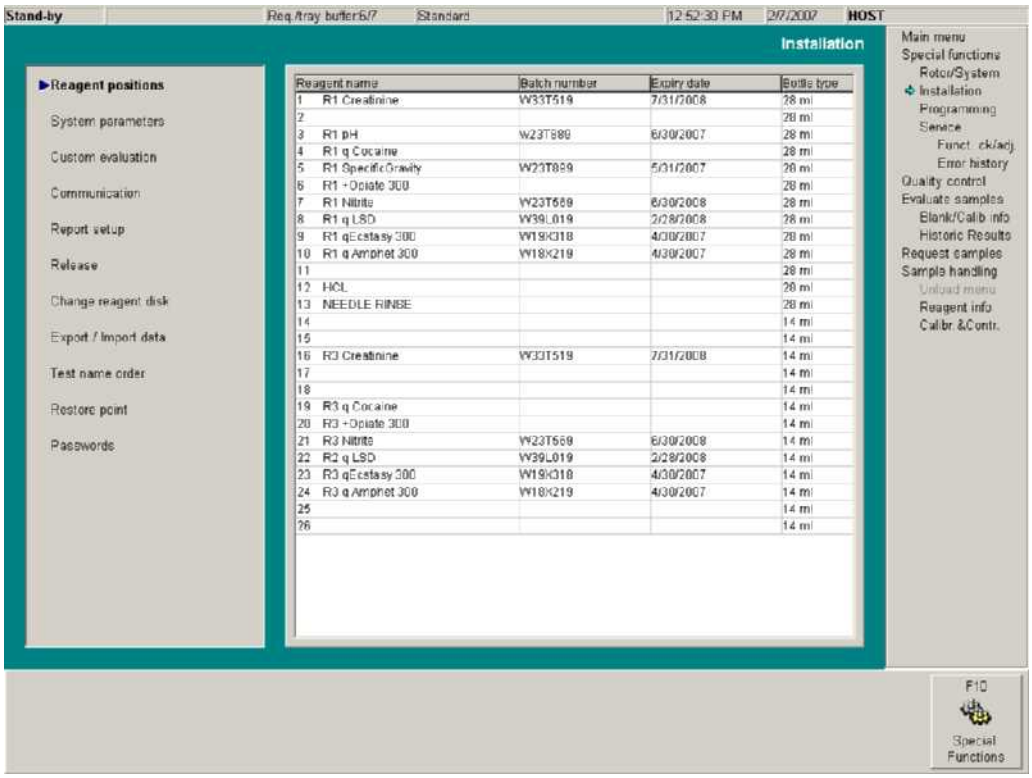
F1 PRINT	Print.
SHIFT+F3 DELETE	Delete the selected profile.
F10 RETURN	Return to the PROGRAMMING menu.
TAB	Change between the profiles list and the menu.
CURSOR KEYS	Move within the list and select different profiles.
ENTER	From the menu, moves to the profiles list. From a specific position in the profiles list, change to the next screen with the list of tests.

Note
While requesting tests 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 to reagent position

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.
A table represents the positions of the reagent rotor. When reagents are assigned, the test names are displayed on the corresponding positions. An R1, R2 or R3 in front of the reagent position indicates a starter, second or third reagent. It is common to have two reagents, R1 and R3, because of analyzer timing considerations.
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 thetest is requested in the REQUEST SAMPLES menu.

5.7.2 Program a reagent position

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL
3. Type the level one password in the dialog box and press ENTER.
4. Select REAGENT POSITIONS.
5. Press ENTER. The cursor moves to the selection field for the reagent positions.
6. Select an empty rotor position, and press ENTER.



7. Select reagent 1 for that position from the list, and press `F4 SELECT REAGENT 1`.
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 SELECT REAGENT 2`
    - `F6 SELECT REAGENT 3`
11. Place the bottles for each reagent and dummy reagent in the correct position on the rotor.

5.7.3 `REAGENT POSITION` function keys

`TAB`	From the menu, moves to the position list.
`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.
`SHIFT+F3 DELETE POSITION`	Deletes the selected reagent from the respective position. Remove the reagent from the rotor.
`F4 SELECT REAGENT 1`	Assigns the selected test to the current position. An R1 is displayed between position number and test name in the previous screen.
`F5 SELECT REAGENT 2`	Assign R2 bottle of the selected test to the current position. An R2 is displayed between position number and test name in the previous screen.
`F6 SELECT REAGENT 3`	Assign R3 bottle of the selected test to the current position. An R3 is displayed between position number and test name in the previous screen.

F10 RETURN	Return to the previous menu.
	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.

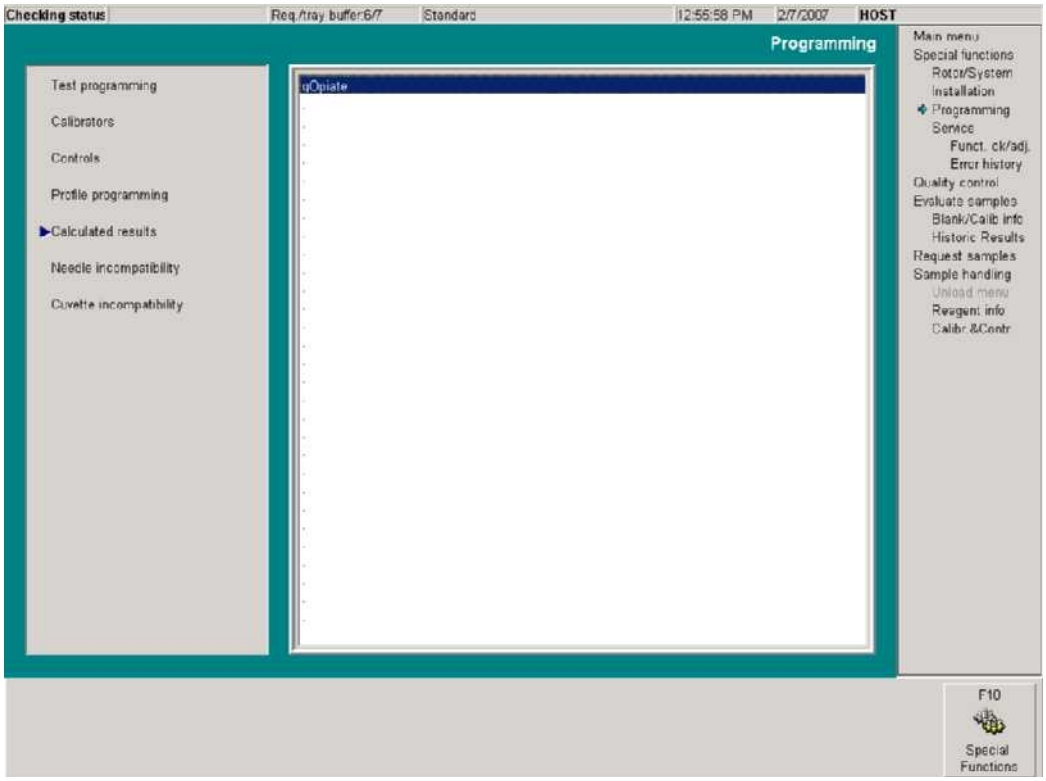
Note

Due to analyzer timing, it is common for assays that require two reagents to be loaded R1 with R3.

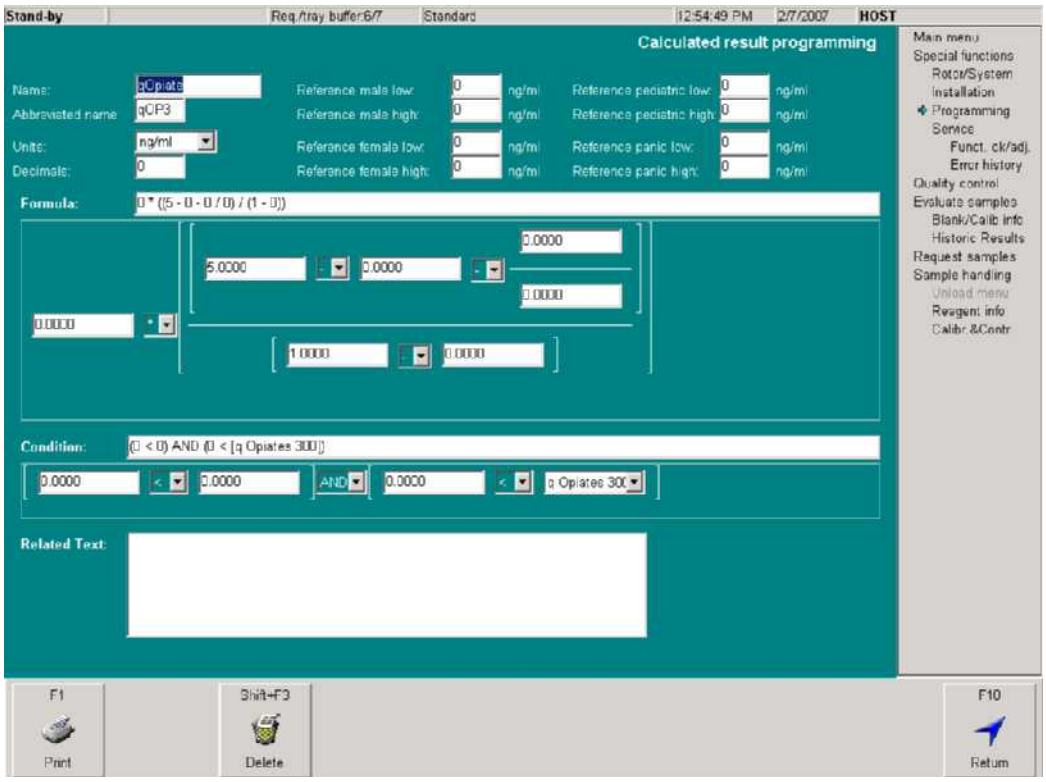
5.8 Calculated results

5.8.1 Introduction to calculated results

Formulate an expression for a formula. Use the formula to derive a calculated result from the test data. The formula is set in the CALCULATED RESULTS menu. Use the formula define the relationship between different tests. The formula is defined before the tests are carried out. Up to 30 formulas can be set. The calculated results are not used for quality control.



5.8.2 CALCULATED RESULT PROGRAMMING screen



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 the FORMULA: field or press F7 INSERT TEST and select a programmed test for the drop down menu and press ENTER two times.

Note
Combinations of values and tests are possible.

8. The formula can be edited in the formula field.
9. Set the conditions for each test in the Condition field.
10. Type any further information in the Related Text field.

Note
All information entered in the RELATED TEXT: field is available in the EVALUATE RESULTS screen.

5.8.3 CALCULATED RESULT PROGRAMMING parameters

NAME:	Name of the test. If no name is entered here, the calculated result will not be stored.
ABBREVIATED NAME:	The abbreviated name of the test. 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.
REFERENCE 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.
REFERENCE 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.
REFERENCE 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
REFERENCE 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
REFERENCE PEDIATRIC LOW:	The low limit of the reference range for pediatric samples. If a measured value is below this limit, the analyzer flags the result.
REFERENCE PEDIATRIC HIGH:	The high limit of the reference range for pediatric samples. If a measured value is above this limit, the analyzer flags the result
REFERENCE 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.
REFERENCE 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. Button 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.
CONDITION:	The programmed formula is always calculated. If the conditional statement is not valid then an error message appears. Refer to 5.9.3 Test flags.
RELATED TEXT:	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 RESULT PROGRAMMING function keys

F1 PRINT	Prints the definition of the calculated test.
SHIFT+F3 DELETE	Deletes the definition of the calculated test.
F7 INSERT TEST	Moves between value or test in a field in the formula.

Note

Printing of calculated results is done when 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 SETUP: option is set to YES in the COMMUNICATION 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. See 4.5.3 Error and warning 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 also described.
For a limited number of flagged test results, the analyzer can perform automatic actions (reject, accept, ask the operator or rerun). These actions can be programmed in the `CUSTOM EVALUATION` screen. See 5.9.4 Custom automatic evaluation and rerun.

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.

`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 REAGENT INFO` and select `CONFIRM REFILL`.
`F4 ACKNOWLEDGE`	This key is only available if the message displayed on screen requires no immediate action.
`F5 HARD 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 `CTRL+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.
`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.
`F6 SOFT RESET`	The low-level component that is in an error condition is reset. If the problem is solved by this, the error message disappears.
`SHIFT+F6 RESET SYSTEM`	Resets 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!
`ALT+F10 HALT`	The analyzer stops all current operations. The line analyzer status (upper left side of screen) displays the word `INACTIVE`.



Note
Check the error history, before you call the technical service. See 6.2.5 Error history.

5.9.3 Test flags

For certain errors or to provide additional information, the test results may be marked with a flag. The causes and necessary actions are described below.

Test flags	Cause	Action
A	Calibrator point absorbance 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.
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.
B	Barcode not matching	
b	Barcode not scanned	
C	Control limit violation.	Compare the values set in the CONTROLS menu with the data given in the insert sheet of the test. Prepare fresh control or reagent solution if necessary.
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 MEASURE RERUN in the EVALUATE RESULTS menu.
E	Cut-off result near limit.	The result lies within the set cut-off deviation programmed in the TEST PROGRAMMING menu.
F	Test not performed because of disabled analyzer part	
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 ROTOR/SYSTEM menu to clear this error. Otherwise inform service.
H	Calculated result division by zero	
h	Calculated result condition not satisfied	
V	Calibration out of high range	If the rate of a test is higher than the rate of the highest standard the result will be 9999.00 and the result will be reported as greater than the high concentration parameter value. It will get the V flag. This is only valid for tests with calibration curves with 3 standards or more. The V flag is not printed with results.

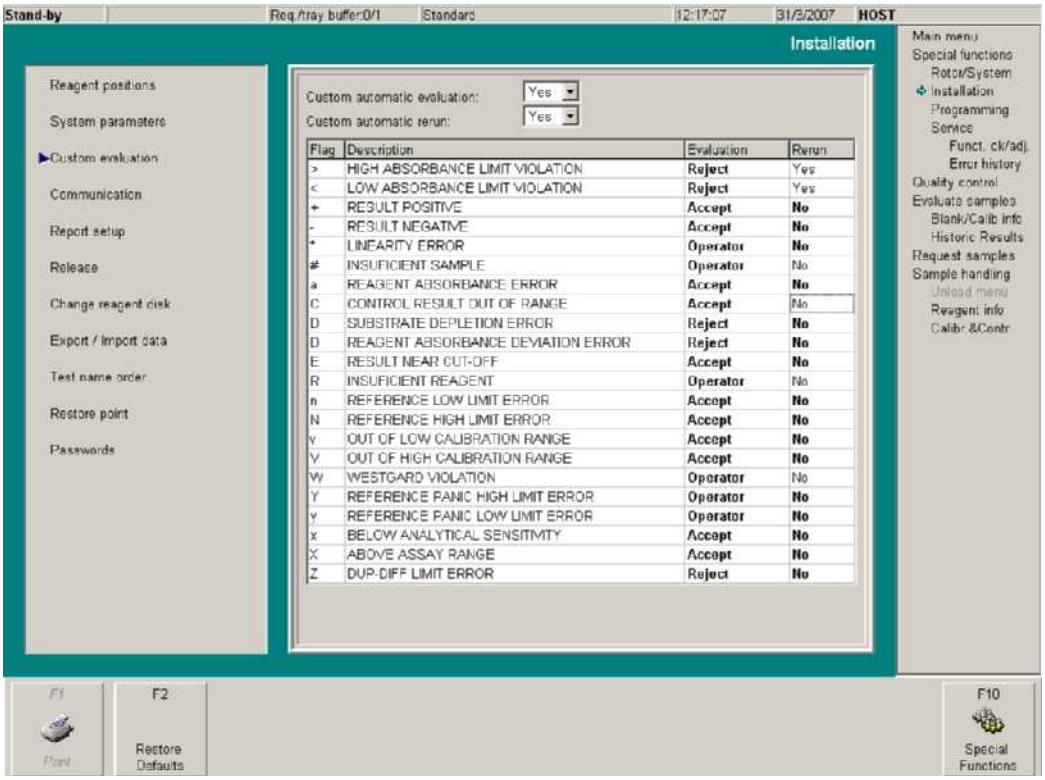
Test flags	Cause	Action
v	Calibration out of low range	If the rate of a test is lower than the rate of the lowest standard the result will be 0.00 and the result will be reported as less than the low concentration parameter value. It will get the v flag. This is only valid for tests with calibration curves with 3 standards or more. The v flag is not printed with results.
L	Lamp error.	Adjust or replace photometer lamp.
M	Absorbance high limit error.	The high limits set in the TEST PROGRAMMING menu are exceeded.
m	Absorbance low limit error	The low limits set in the TEST PROGRAMMING menu are exceeded.
N	Reference limit violation.	One of the reference limits set for male, female or pediatric in the TEST PROGRAMMING menu was exceeded.
O	Overrange	Adjust or replace photometer lamp.
o	Overrange reference detector.	Error in electronics. Inform service.
P	Prozone error.	Repeat the measurement with pre-diluted sample.
R	Insufficient reagent.	Fill the system with reagent.
r	Rerun.	A test was re-run with the re-run parameters.
T	Cuvette temperature error.	Inform service.
U	Underrange.	Adjust or replace photometer lamp.
u	Underrange reference counter	Error in electronics. Inform service.
W	Westgard 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.
X	Above assay range.	The result is above the limit set in the TEST PROGRAMMING menu. The X flag is not printed with the result. Results show a greater than (>) symbol.
x	Below analytical sensitivity	The result is below the limit set in the TEST PROGRAMMING menu. The x flag is not printed with the result. Results show a less than (<) symbol.
Y	Reference panic high error	
y	Reference panic low error	
Z	Dup-Diff error	
*	A-linearity error.	A non-linear reaction of kinetic tests on the first four measurement points.
#	Insufficient sample.	Make sure the sample is of sufficient volume, not coagulated, and no air bubbles block the sample aspiration.

Test flags	Cause	Action
+	Cut-off positive	For cut-off tests. If the result is positive relative to the cut-off value, it is flagged as +. Both the flag and the result are indicated
-	Cut-off negative	For cut-off tests. If the result is negative relative to the cut-off value, it is flagged as -. Both the flag and the result are indicated.
No reagent taken	Level of reagent too high or foam present	Check the level of reagent and replace the reagent if needed.
Reagent pipetting stopped	Reagent needle cannot be cleaned	Make sure HCI is installed on the reagent rotor and the bottle is not empty.

5.9.4 Custom automatic evaluation and rerun

The CUSTOM EVALUATION screen allows programming automatic actions for the analyzer. These are performed when specific test flags are set. To switch automatic actions on or off and to define the actions to be performed, do as follows:

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL.
3. Type a password if necessary.
4. Select CUSTOM EVALUATION in the menu to the left. The CUSTOM EVALUATION screen is shown.



5. Select YES for the CUSTOM AUTOMATIC EVALUATION: option in the top of the screen.
6. For each test flag, select the automatic action from the list box in the EVALUATION column:
   - ACCEPT - accepts the test results.
   - REJECT - rejects the test results.
   - OPERATOR - sets the *INFO* status to ask the operator.
7. Optionally, you can request automatic reruns for the tests:
   A Select YES for the CUSTOM AUTOMATIC RERUN: option in the top of the screen.
   B For each test flag, select YES or NO from the listbox in the RERUN column. When the automatic rerun is activated, the test is repeated. The volumes that are used for the repeated measurement are the volumes that were defined in the field RERUN VOLUME: of the test parameters.

Note

For some test flags, a rerun is not possible. The listbox is disabled in those cases.

5.10 Set up a report

5.10.1 Introduction

If a special result printer is to be used for result printouts, the printout format has to be defined in the REPORT SETUP 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.

5.10.2 REPORT SETUP segments

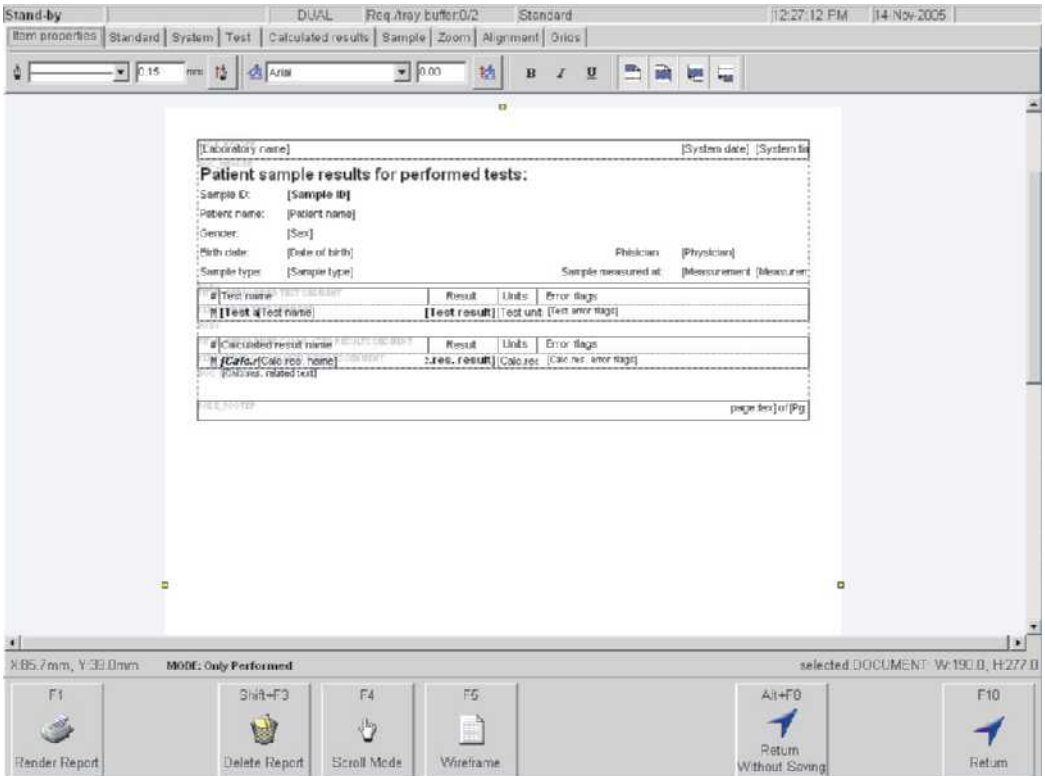
You can put items in each segment in the report and define their properties. When defining a report with the option ONLY PERFORMED, most items can only be placed in dedicated segments. (Eg., test parameters can only be placed in a PERFORMED TEST SEGMENT).

Notes:

Items must be positioned completely inside the segment. It is not possible for items to be printed partially outside the segment.

To place an item, select a tab at the top of the screen and press the item. Then move the item to a segment and position it. The tab at the top of the screen will automatically show the definable properties for each item.

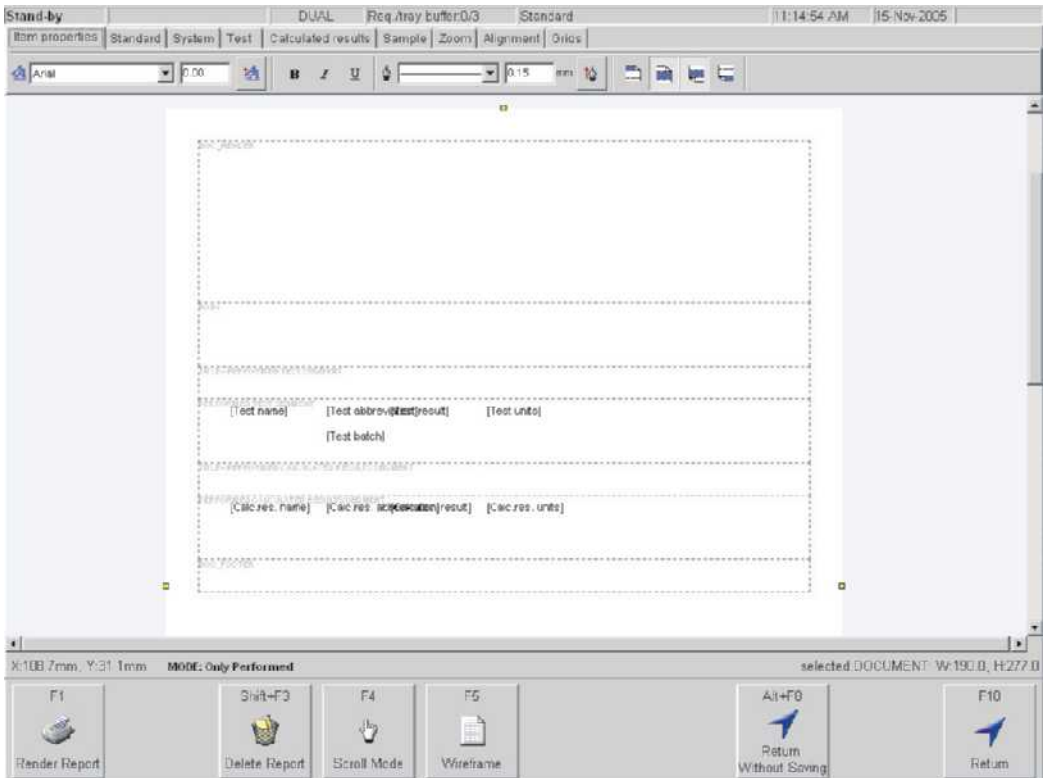
If an item is selected, there are 4 handles shown either yellow or green at the boundaries of the item. A yellow handle is a fixed position and cannot be moved. Green handles can be moved and resized.



PAGE_HEADER	This segment is printed at the top of each page.
DOC_HEADER	This segment is printed once for every sample.
BODY	This segment is printed once for every sample.
TITLE - PERFORMED TEST SEGMENT	This segment is printed once for every sample.

PERFORMED TEST SEGMENT	This segment is printed once for every test.
TITLE - PERFORMED CALCULATED RESULTS SEGMENT	This segment is printed once for every sample.
PERFORMED CALCULATED RESULTS SEGMENT	This segment is printed once for every test.
DOC_FOOTER	This segment is printed once for every sample.
PAGE_FOOTER	This segment is printed at the bottom of each page.

5.10.3 Define a report set-up

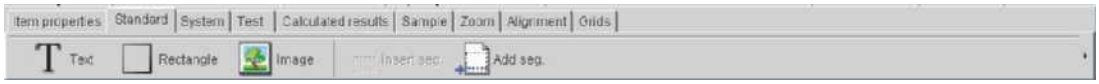


1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL.
3. Type the level one password in the dialog box and press ENTER.
4. Select REPORT SETUP.
5. Press TAB or ENTER.
6. Select an empty space to define a new report. The New Report Setup Initialization dialog box opens.
7. Select:
   - ONLY PERFORMED to print those tests for which measurements were made. Select CONFIRM.
   - FIXED to print all installed tests independant of whether a measurement was made for that test. Select CONFIRM.
8. Use the menu items at the top of the screen to edit the standard form.
9. Select F10 RETURN to save the new layout and return to the previous menu.
   The analyzer will layout the printouts.

5.10.4 REPORT SETUP tabs and data fields

STANDARD tab data fields

These data fields can be used in every segment.



TEXT	Adds text to the report.
RECTANGLE	Place a rectangle on the report. Click the location of the first corner and then the location of the opposite corner to define the position and size of the rectangle.
IMAGE	Place an image on the report. Click the location of the first corner and then the location of the opposite corner to define the position and size of the rectangle.
INSERT SEG.	Inserts a BODY segment before the currently selected segment
ADD SEG.	Inserts a BODY segment after the currently selected segment.
ALT+F8 RETURN WITHOUT SAVING	The report setup is not saved. A dialog box requests confirmation to return to the Installation screen.
F10 RETURN	Save the current layout and return to the previous screen.
CURSOR KEYS	Position the cursor on the screen.

SYSTEM tab data fields

These data fields can be used in every segment.



SYS.DATE	Add current system date.
SYS.TIME	Add current system time.
LAB. NAME	Add laboratory name
PG INDEX	Add Page index
PG COUNT	Add page count.

TEST tab data fields

For an ONLY PERFORMED report, these data fields must be used in the performed test segment.



TEST	For FIXED reports, select the test and data fields to be placed on the report. For ONLY PERFORMED reports this field is disabled, all tests are printed with the same test data fields.
INDEX	Only available for ONLY PERFORMED reports. The index number for the completed test is printed.
NAME	The name of the test.
ABBREV.	The abbreviation of the test.
RESULT	The measured result of the test.
UNITS	The units of the test.
BATCH	The batch number for the first reagent of the test.
FLAGS	For FIXED reports, the 1st, 2nd, 3rd, 4th, or 5th flag of the selected test is printed depending on the selected flag. For Only performed reports, the all flags of the test result are printed.
LIMITS	Adds Low reference limit, High reference limit for the current sample, or the word Panic if the result is outside panic limts.

CALCULATED RESULTS tab data fields

For an ONLY PERFORMED report, these data fields must be used in the performed test segment.



CALCULATED RESULTS	For FIXED reports, select the calculated result and data fields to be placed on the report. For ONLY PERFORMED reports this field is disabled, all calculated results are printed with the same results data fields.
INDEX	Place a rectangle on the report. Click the location of the first corner and then the location of the opposite corner to define the position and size of the rectangle.
NAME	The name of the test.
ABBREV.	The abbreviation of the test.
RESULT	The measured result of the test.
UNITS	The units of the test.
FLAGS	For Fixed reports, the 1st, 2nd, 3rd, 4th, or 5th flag of the selected test is printed depending on the selected flag. For ONLY PERFORMED reports, the flags of the test result are printed.
LIMITS	Adds Low reference limit, High reference limit for the current sample, or the word Panic if the result is outside panic limits.

TEXT	Adds text to the report.

SAMPLE tab data fields

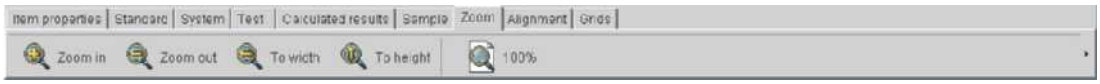
These data fields can be used every segment.



ID	Sample ID.
NAME	The name of the patient.
BIRTH DATE	The date of birth of the patient.
SEX	The sex of the patient.
TYPE	The type of sample, pediatric, STAT or normal.
PHYSICIAN	The name of the physician.
MEAS. DATE	The last date that the sample is measured.
MEAS.TIME	The time of the last measurement.

ZOOM tab effects

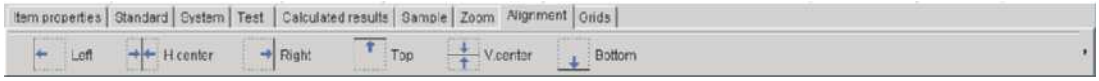
These effects are for on screen viewing.



ZOOM IN	Zoom in.
ZOOM OUT	Zoom out.
TO WIDTH	Fits the width of the page to the width of the screen.
TO HEIGHT	Fits the height of the page to the height of the screen.
100%	Goes to the default size.

ALIGNMENT tab effects

These buttons align data fields in the report layout. Select the data field to align to (this field always remains in the same position) Press the shift key and select the items to align.



LEFT	Aligns the data field to the left boundary of the first selected field.
H.CENTER	Aligns the data field to the horizontal center of the first selected field.
RIGHT	Aligns the data field to the right boundary of the first selected field.
TOP	Aligns the data field to the top boundary of the first selected field.
V.CENTER	Aligns the data field to the vertical center of the first selected field.
BOTTOM	Aligns the data field to the bottom boundary of the first selected field.

GRIDS tab effects

A grid is available on screen to make it easier to place fields correctly on the report. The grid is not printed.



SHOW GRIDS	Turns on the grid. The grid can be set from 1 mm to 10 mm.
SNAP TO GRIDS	Aligns the data field to the horizontal and vertical lines of the grid.

5.10.5 REPORT SETUP function keys

F1 RENDER REPORT	Shows a preview of the report.
SHIFT+F3 DELETE REPORT	Deletes the report layout.
F4 SCROLL MODE	Sets the report to read only.
F5 WIREFRAME	Replaces images by a wireframe placeholder - use this if you use many images and the design process slows down
ALT+F8 RETURN WITHOUT SAVING	Returns to report setup menu without saving changes.
F10 RETURN	Returns to report setup menu with saving changes.

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 for large air gaps and leakage; clean or replace syringes if necessary. • Press `CTRL+F10 EXIT PROGRAM` to exit the analyzer program and then restart the computer.
Monthly	• Clean water and waste container(s) with 0.1 mol/l NaOH. Afterwards rinse several times with water. • Press `CTRL+F10 EXIT PROGRAM` to exit the analyzer program. Shut down the computer and turn the instrument off. Switch the instrument and the computer on to restart the analyzer.
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	• Semi-annual maintenance is performed by Siemens Healthcare Diagnostics service personnel. • Set the System Clean date.
As needed	• Replace cuvette rotor (after 10,000 tests or after SD-error after cuvette blank). • Replace lamp. • If a new control or test is defined, exit the analyzer program (press `CTRL+F10 EXIT PROGRAM`) and relaunch the program by double-clicking the icon on the screen.

6.1.2 Replace cuvette rotor

The 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 CUVETTE ROTOR menu. Ignoring this message may result in incorrect results.
To replace the measurement disk do as follows:

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select: F1 ROTOR/SYSTEM .
3. Select CHANGE CUVETTE ROTOR.
4. Remove the rotor cover from the cuvette rotor.
5. Select: F1 LIFT WASHARM.
   The system will lift the wash arm. A RESET COUNTER? dialog box opens. Select YES or NO.
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 hole.
9. Place the new rotor while assuring that the notches of the rotor fit in the slits of the rotor holder.
   It is important not to twist the rotor into place, as this will scratch the cuvettes.
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 blank 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. The analyzer has to be in the stand-by mode.
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.
4. Press F2 BLANK ROTOR to start the blanking of the Cuvettes.

6.1.4 Exclude a stained cuvette

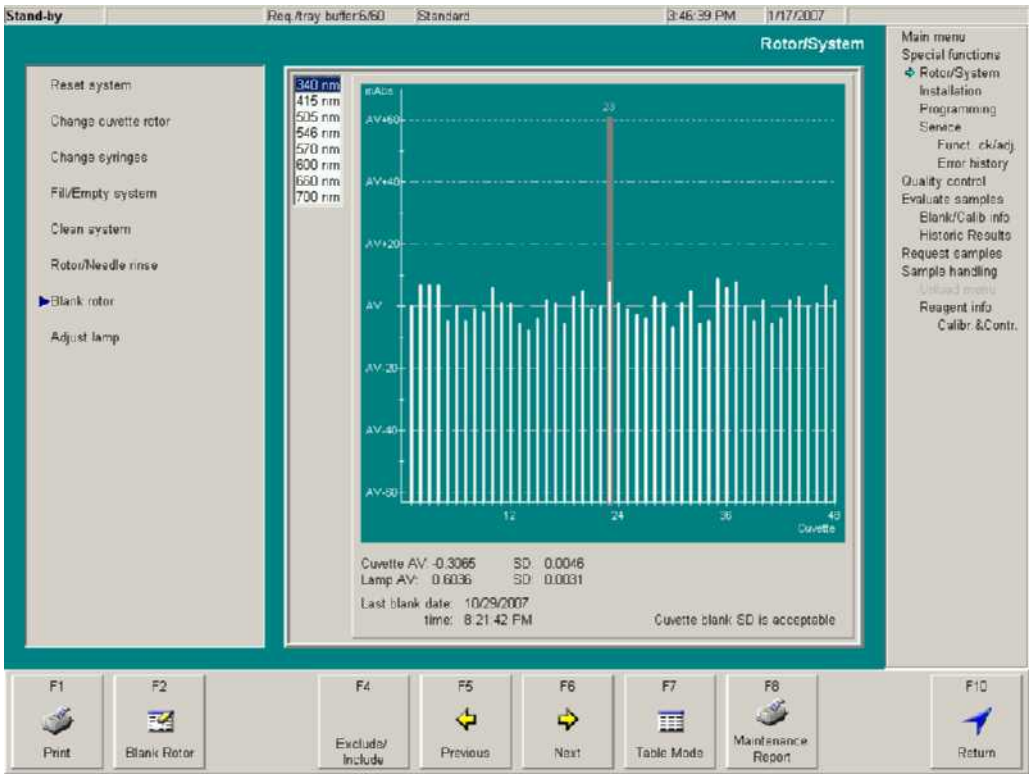
After the rotor blank measurement is complete, if there is an anomalous reading for one cuvette, it shows that the cuvette is stained and the cuvette rotor should be replaced. To exclude the use of the cuvette until the cuvette rotor is replaced, do as follows:

Note

When you change the cuvette rotor in the `CHANGE CUVETTE ROTOR` menu, the stained cuvette is included.

Note

Run a Blank after changing the cuvette rotor.



1. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
2. Select `F1 ROTOR/SYSTEM` .
3. Select `BLANK ROTOR`.
4. Press `F7 GRAPH MODE` to view the readings in graphic mode.
5. Press `F5 PREVIOUS` or `F6 NEXT` to scroll through the cuvette rotor and select the cuvette with the anomalous reading.
6. Press `F4 EXCLUDE/ INCLUDE` 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 ROTOR	Start the cuvette blank measurement. This is only possible when the system is not processing samples. A blank takes about 13 minutes.
F4 EXCLUDE/ INCLUDE.	Press the F4 key to exclude or include a selected cuvette (indicated by the selection cursor) from use. A dotted bar indicates an excluded cuvette.
F5 PREVIOUS	Selects the cuvette with the anomalous reading.
F6 NEXT	Selects the cuvette with the anomalous reading.
F7 GRAPH 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.
F8 MAINTENANCE REPORT	Prints a maintenance report.
F10 SPECIAL FUNCTIONS	Return to the SPECIAL FUNCTIONS menu.

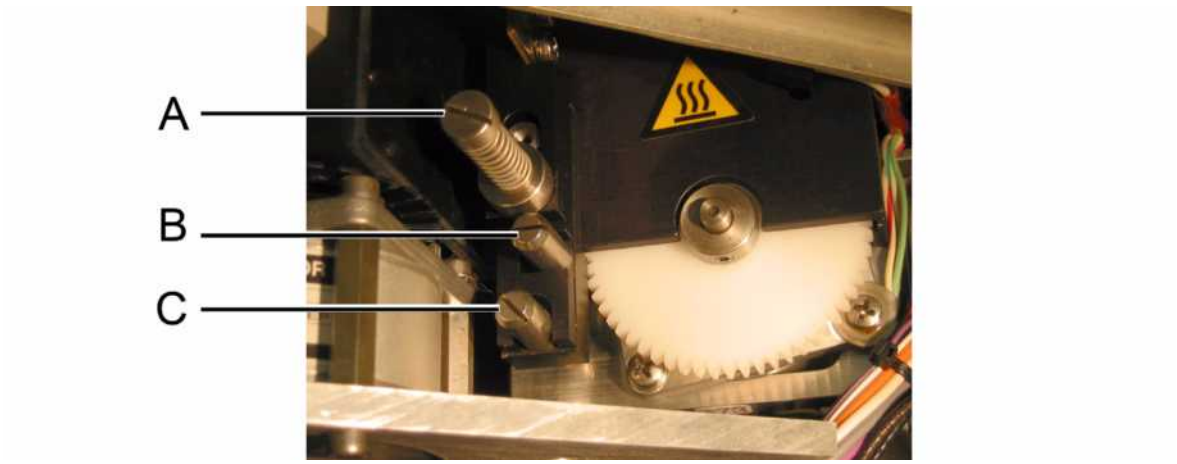
6.1.6 Replace the photometer lamp

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 ADJUST LAMP menu.
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.
2. Open the front doors of the analyzer cabinet. The lamp can be reached from the front.

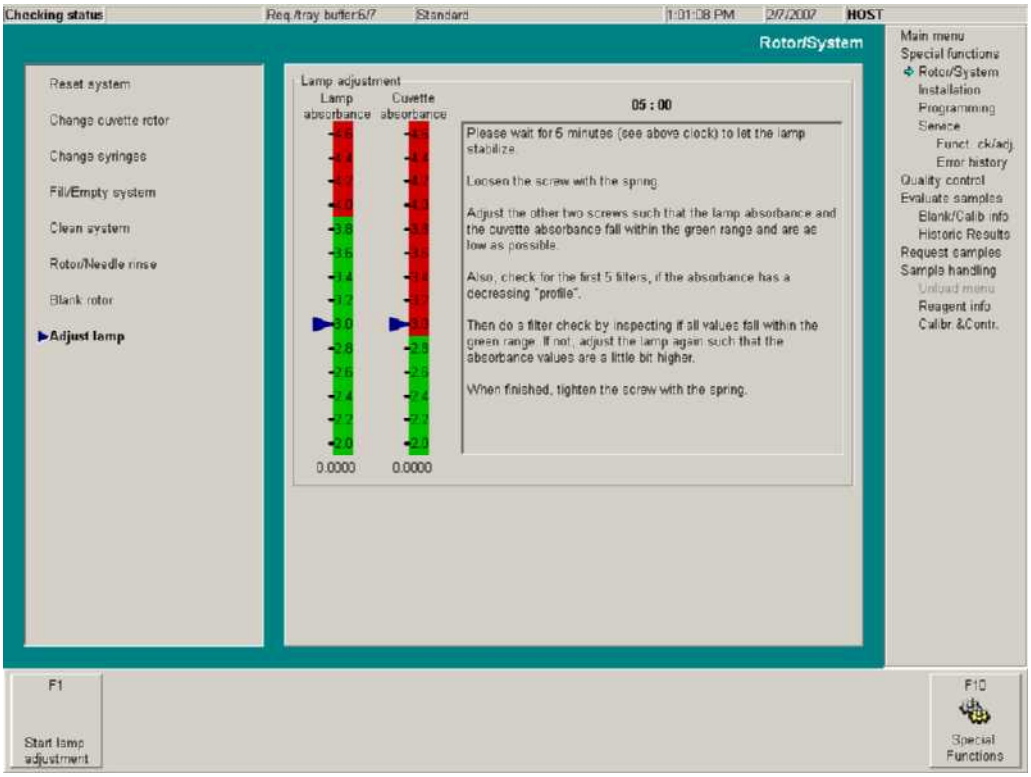
ATTENTION
Do not touch the lamp immediately after turning off the analyzer. The lamp is hot and will cause burns. Allow at least 10 minutes after turning off the analyzer for the lamp to cool before you touch the lamp.



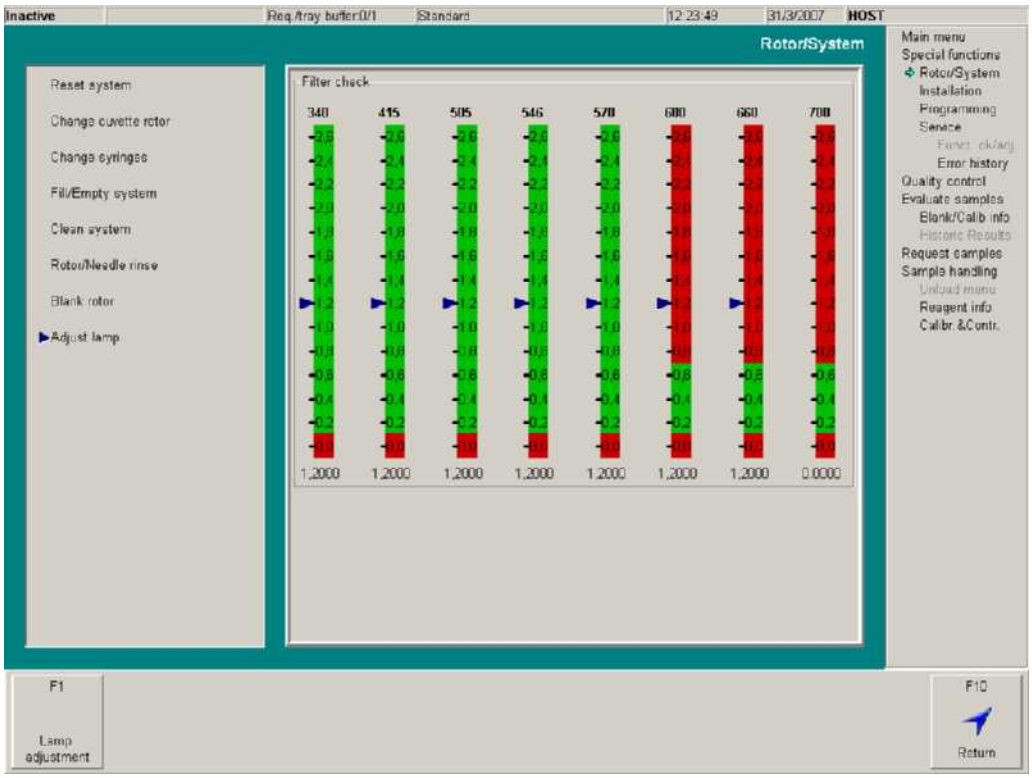
3. Loosen the top screw A with a screwdriver and remove it.
4. Carefully pull the support out towards you.
5. Remove and dispose of the lamp.
6. Carefully take the new lamp (part of the spare parts kit) by its top using a clean cloth. The new lamp must carefully be placed into the support and fastened.
7. Reinstall the support and fasten screw A.

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 of moving parts when the instrument is switched on again!



8. Adjust the lamp:
   A Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
   B Select F1 ROTOR/SYSTEM.
   C Select ADJUST LAMP.
   D Select F1 START LAMP ADJUSTMENT.
   E Wait for 5 minutes as indicated by the timer in the software.
   F Loosen screw A.
   G Adjust screws B and C so that the arrows on the bars LAMP ABSORBANCE and CUVETTE ABSORBANCE both reach their minimum values. Normally both absorbance signals reach the minimum at the same lamp position. Screw B moves the lamp up and down; screw C moves the lamp left and right.
   H Fasten screw A when the setting is correct.



9. Check whether the lamp intensity is too high for each filter:
   A Select F1 FILTER CHECK. The system measures the cuvette absorbance for each filter and displays the values graphically on screen. The value must be in the green area.
   B Reduce the lamp intensity by turning the middle and bottom screw if each bar is not in the green area.
   C Repeat the procedure as often as necessary, until all filter values are in the green area.
10. Tighten the support screw.
11. Close the front door.
12. Reinsert the safety screw.
13. Select F10 RETURN.
14. Select F10 SPECIAL FUNCTIONS to quit the ADJUST LAMP menu.

6.1.7 Replace syringes

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 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.
- Large air gaps 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 `CHANGE 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.

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 SPECIAL FUNCTIONS` 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 FILL 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 `STAND-BY` state.
3. Check the water supply and fill up the 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 WASH/FILL 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 cuvette 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.

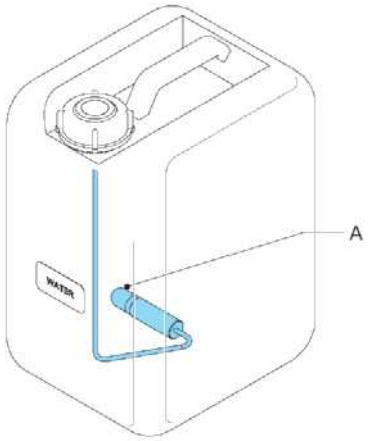
Note

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 in position W of the sample rotor.
8. Select `F3 NEEDLE RINSE`.

6.1.10 Replace the water filter

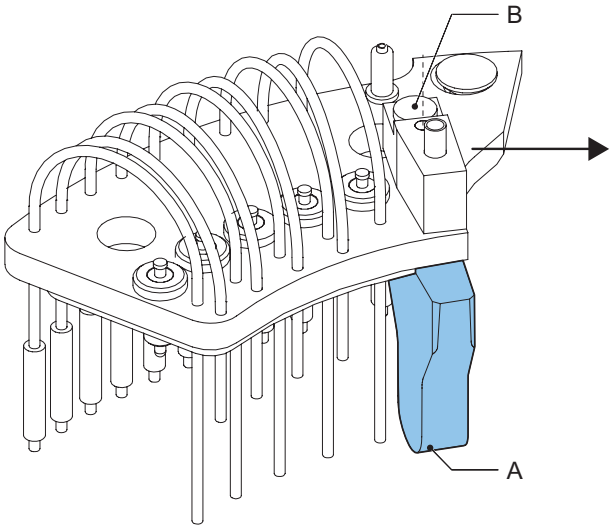
Do as follows to replace the water filter:



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 CHECK/ADJUSTMENTS`.
5. Double click `WASH ARM`.
6. Select `F1 - RESET WASH ARM`.
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 with a new one, but do not tighten screw B yet. Be careful not to drop the loose screw into the analyzer. Use a screwdriver with a magnetic tip.
10. Press arrow down key on your keyboard to lower the wash arm.
11. Wait for the wash arm to go to the correct location.
12. Press arrow down key on your keyboard 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. Select `F1 RESET SYSTEM`.
19. 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 support personnel.

Note

Check the error history, before you call the technical support. 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 you operate the analyzer. Replace the mixer belt if it looks worn or if it is broken:

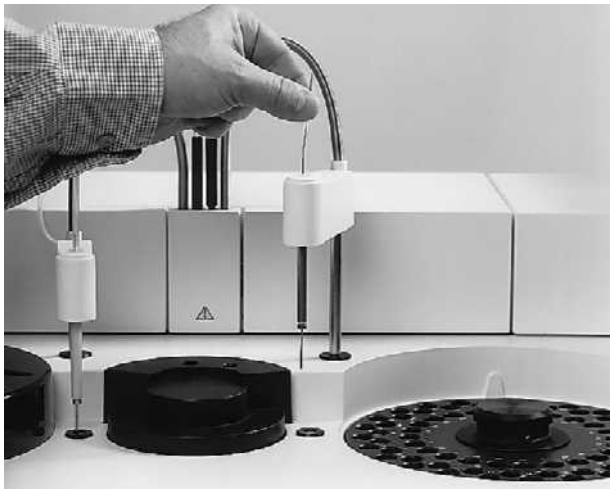


1. Lift the cover of the cuvette rotor.

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 cover back in its place.

6.2.3 Sample needle clogged

Take following actions if the sample needle is clogged:



1. Press `ALT+F10 HALT`.
2. Carefully pull the tube assembly, consisting of an outer and an inner tube, 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 of 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.

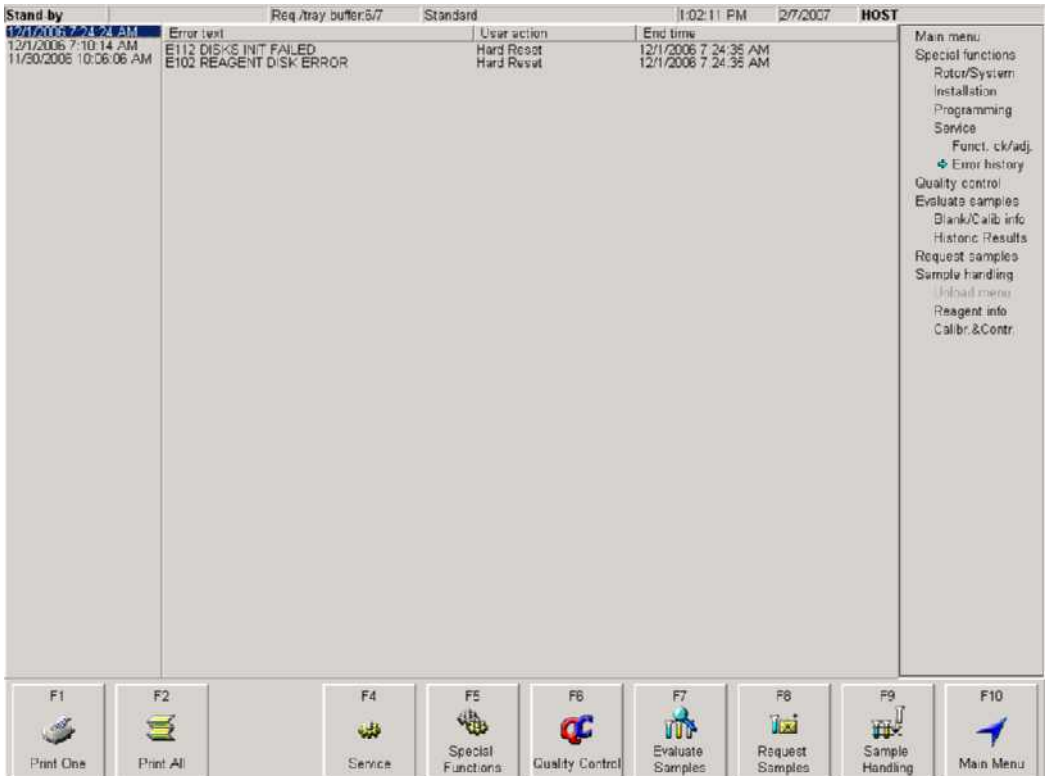
1. Press `ALT+F10 HALT`.
2. Turn the screw cap counter clockwise until it can be removed.
3. Remove the tray.
4. Clean the bottom of the rotor tray or remove the object from the rotor tray.
5. Replace the rotor. Make sure that the white dot on the rotor aligns with the white line on the rotor shaft, 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 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.

Review of the Error history can be very useful in troubleshooting instrument problems. Use this function in case of problems to inform the technical support personnel on what type of error (and error number) has occurred.



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.

Function keys

`F1 PRINT ONE`	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 EVALUATE SAMPLES`	Switch to the `EVALUATE RESULTS` 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. Hardware-error messages are described in the next subsection. 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. See 5.9.2 Test messages function keys.

Error message	Cause	Action
LINEARITY ERROR ABSORBANCE ERROR REAGENT ABSORBANCE DEVIATION ERROR OUT OF CALIBRATION RANGE CONTROL RESULT OUT OF RANGE REFERENCE HIGH 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 or remove bottle cap). Liquid detection of the reagent needle is not detecting any liquid (bottle missing or empty). Liquid detection is not working.	
* REAGENT NOT TAKEN	Filling level of the reagent bottle is too high (e.g. filling level is near screw-cap). Foam is being produced.	
* TEST SENDING 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.
* LAMP OVERRANGE ERROR	A counter overrange (> 29 000) is detected during a measurement.	Refer to hardware error E13 LAMP FAILURE.
* LAMP UNDERRANGE ERROR	A counter underrange (< 10) is detected during a measurement.	Refer to hardware error E13 LAMP FAILURE.
* LAMP REFERENCE OVERRANGE ERROR	A counter overrange (> 29 000) for the reference detector is measured during a measurement.	Refer to hardware error E13 LAMP FAILURE.
* LAMP REFERENCE UNDERRANGE ERROR	A counter underrange (< 10) for the reference detector is measured during a measurement.	Refer to hardware error E13 LAMP FAILURE.

Error message	Cause	Action
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 SHIFT+F6 RESET SYSTEM. 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 SHIFT+F6 RESET SYSTEM. If the error occurs again, inform the Technical Support.
E07 SYSTEM RESET INCOMPLETE	Due to further errors the system reset was incomplete.	Eliminate the error if possible and select SHIFT+F6 RESET SYSTEM to repeat a reset. If the error occurs again, inform the Technical Support.

Error message	Cause	Action
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.
E12 RUNNING OUT OF WATER	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.

Error message	Cause	Action
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 Support. 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 Support if the error occurs again.
E15 REAGENT NEEDLE TEMP ERROR		Select F1 CHECK AGAIN. Inform the Technical Support 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.
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		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E21 SAMPLE SYR. POS. ERROR		

Error message	Cause	Action
E22 SAMPLE VALVE ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E23 REAG. SYR. POS. ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E24 REAG. SYR. POS. ERROR		
E25 REAG. VALVE ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E30 PIPETTOR 14V FAILED		Inform the Technical Support.
E31 PIPETTOR 30V FAILED		
E32 PIPETTOR INIT FAILED		Inform the Technical Support.
E35 SAMPLE SYR RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E36 REAGENT SYR RESET FAILED		
E37 PIPETTOR COMMUNICATION ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E40 MEAS.DISK 14V FAILED		Inform the Technical Support
E41 MEAS.DISK 30V FAILED		
E42 MEASUREMENT DISK ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E43 FILTER ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E52 MEAS.DISK INIT FAILED		Inform the Technical Support.
E55 MEAS. DISK RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E56 FILTER RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Inform the Technical Support if the error occurs again.
E57 MEAS. DISK COMMUNICATION ERROR		Inform the Technical Support.
E60 SAMPLE ARM 14V FAILED		Inform the Technical Support.
E61 SAMPLE ARM 30V FAILED		

Error message	Cause	Action
E62 SAMPLE ARM HORIZONTAL ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E63 SAMPLE ARM VERTICAL ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E72 SAMPLE ARM INIT FAILED		Inform the Technical Support.
E75 SAMPLE ARM RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E76 SAMPLE ARM RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E77 SAMPLE ARM COMMUNICATION ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E80 REAGENT ARM 14V FAILED		Inform the Technical Support.
E81 REAGENT ARM 30V FAILED		
E82 REAGENT ARM HORIZONTAL ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E83 REAGENT ARM VERTICAL ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E92 REAGENT ARM INIT FAILED		Inform the Technical Support.
E95 REAGENT ARM RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E96 REAGENT ARM RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E97 REAGENT ARM COMMUNICATION ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E100 DISKS 14V FAILED		Inform the Technical Support.
E101 DISKS 30V FAILED		
E102 REAGENT DISK ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E103 SAMPLE DISK ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E112 DISKS INIT FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E115 REAGENT DISK RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.

Error message	Cause	Action
E116 SAMPLE DISK RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E117 REAG./SAMP. DISKS COMMUN. ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E120 WASHARM/BELLOWS PUMP 14V FAILED		Inform the Technical Support.
E121 WASHARM/BELLOWS PUMP 30V FAILED		
E122 WASHARM ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. Make sure the cuvette rotor is placed correctly.
E123 BELLOWS PUMP ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. 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 DISK	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.

Error message	Cause	Action
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/ BELLOWSPUMP INIT FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E135 WASHARM RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM. See also E122 washarm error.
E136 BELLOWS PUMP RESET FAILED		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.
E137 WASHARM/BELLOWS PUMP COMM.ERROR		Press either F5 (Specific Reset) or select SHIFT+F6 RESET SYSTEM.

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.



ATTENTION

Do not connect the analyzer's computer to the Internet or your Intranet.

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

7.2 Software installation

7.2.1 General

Install the software only by someone who is familiar with Windows®. The software is installed by the manufacturer. The software installation is only necessary if a replacement PC is installed.

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:

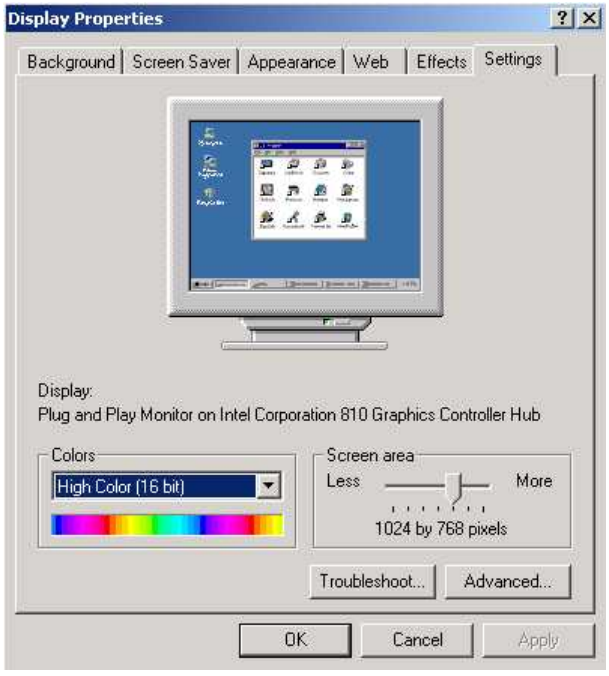
- PC as specified in section 2.9 of the manual
- Analyzer installation disk

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 size

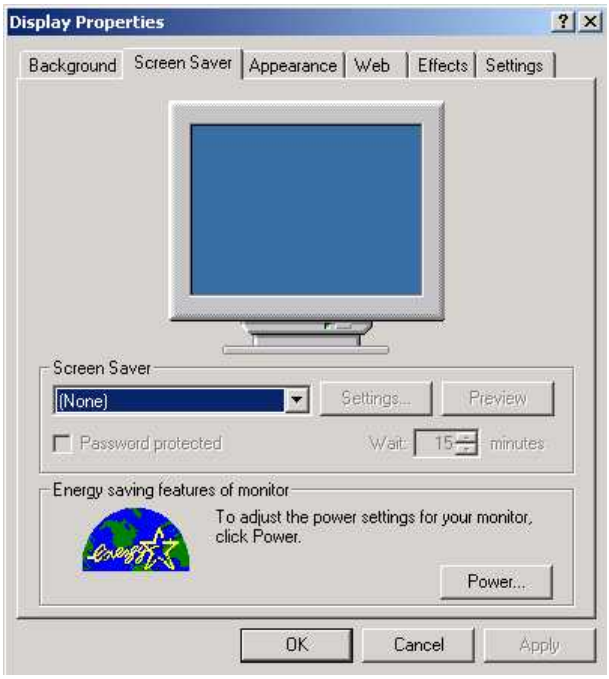
Set the screen area to 1024 x768 pixels.



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`

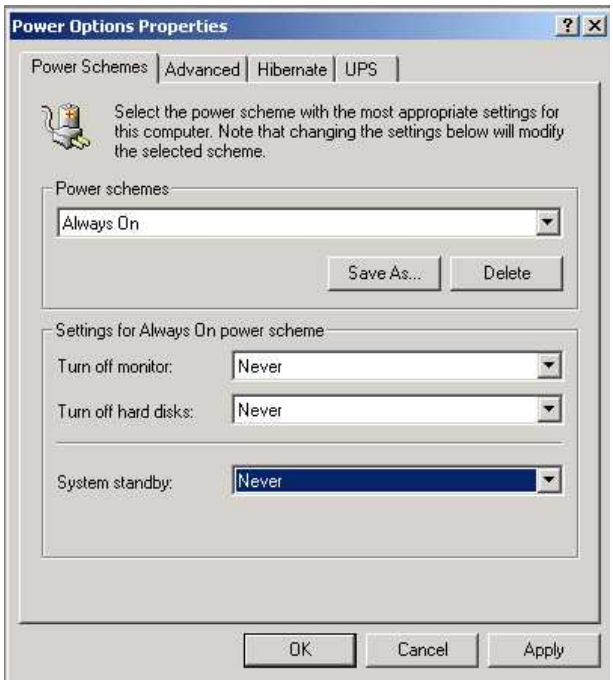
Disable the screen saver

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`

Set the 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.

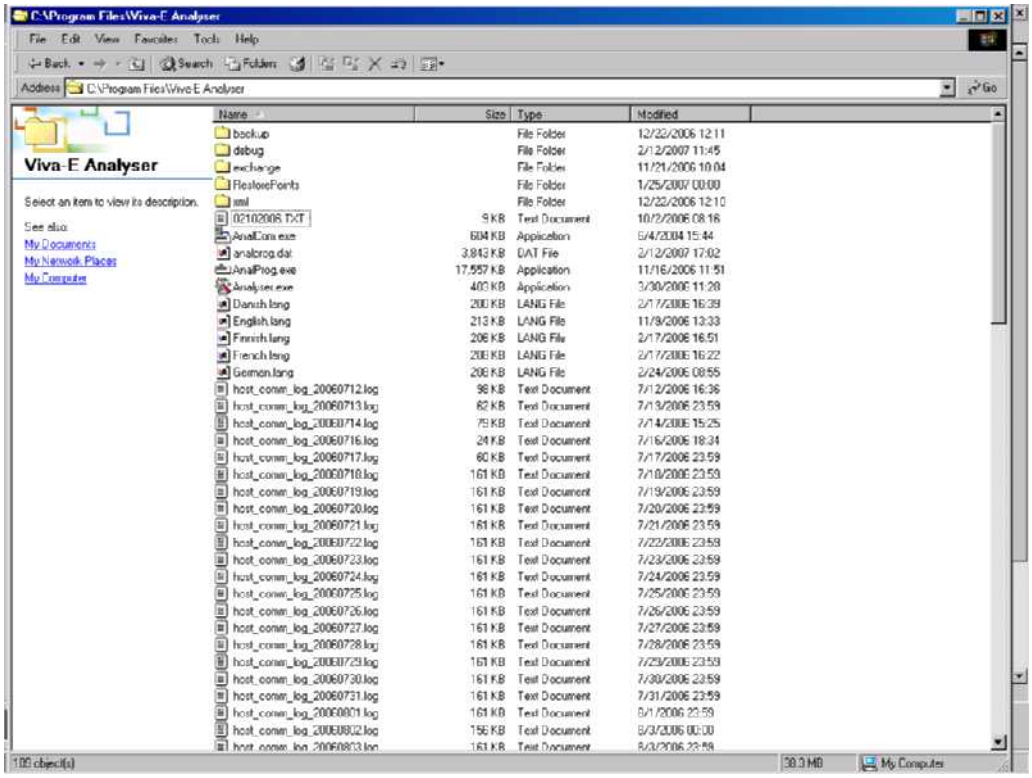
1. Exit all programs
2. Put the installation CD with the analyzer software in the CD-ROM drive of the PC.
3. If the installation program does not open automatically, proceed with step 4. If the installation program opens automatically, proceed with step 6.
4. Select:
   `START` from the Windows® desktop.
   `RUN`
5. Click Browse and search for the `SETUP.EXE` file on the CD.
6. Click the `NEXT` button to accept copyright. The following window is displayed.



7. Select:
   `INSTALL / UPGRADE`
8. Press:
   `NEXT`
9. Wait for the software to install.
10. Press in the Installation Program screen:
    `FINISH`

7.2.4 Files

The installation creates following directory:
`C:\PROGRAM FILES\VIVA-E ANALYSER`. The directory contains the files as shown below.



7.3 Configure software

7.3.1 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.
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. They are available via the `COMMUNICATION` screen in the `INSTALL` menu.



ATTENTION
Do not connect the analyzer's computer to the Internet or your Intranet.



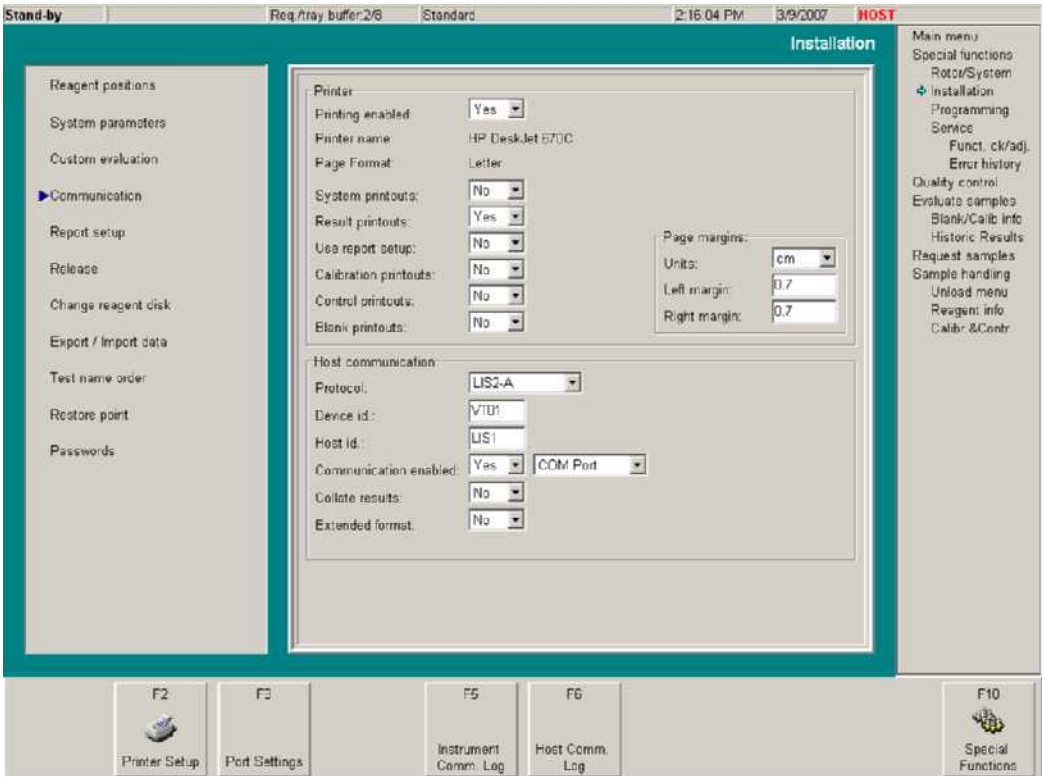
Note
Contact the Siemens Healthcare Diagnostics Technical Assistance Center to obtain a copy of the Host to PC (LIS) communication specifications document.



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 Start communication selection

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



5. Set the parameters for the printer connection in the top section of the screen.
6. Set the parameters for the host connection in the bottom section of the screen.See 7.3.7 Configure host port settings.
7. Select F10 SPECIAL FUNCTIONS to return to the main screen.

7.3.3 Printer parameters

PRINTING ENABLED:	Select YES to enable printing. Select NO to disable printing.
PRINTER NAME:	The current printer. You can change the printer via F2 PRINTER SETUP.
PAGE FORMAT:	The current page set-up. You can change the page set-up via F2 PRINTER SETUP.
SYSTEM PRINTOUTS:	Prints cuvette blank and maintenance actions when they are performed.
RESULT PRINTOUTS:	Prints the patient reports when they become available.
USE REPORT SETUP:	Select YES to use a custom report instead of the default printouts.
CALIBRATION PRINTOUTS:	Print the calibration report when a new calibration is measured.
CONTROL PRINTOUTS:	Print the control report every time a new control is measured.
BLANK PRINTOUTS:	Print the blank report every time a new blank is measured.
PAGE MARGINS:	Set the left and right margins so that printouts can be assembled into binders.

7.3.4 Host communication parameters

PROTOCOL:	CLSI Standard LIS2-A (preferred) or proprietary code v2.3.
DEVICE ID.:	Enter a 6-letter/number code for instrument identification purposes. All information sent to the host computer will be identified by this code.
HOST ID.:	Enter a 6-letter/number code for LIS identification.
COMMUNICATION ENABLED:	Option to enable or disable communication with a host computer.
COLLATE RESULTS:	NO: test results are sent to the host as soon as they are available (preferred setting). YES: all test results for the sample are sent in a single message.
EXTENDED FORMAT:	The results are sent with all the results details, including raw measurement data. The preferred setting is NO.

7.3.5 Communication function keys

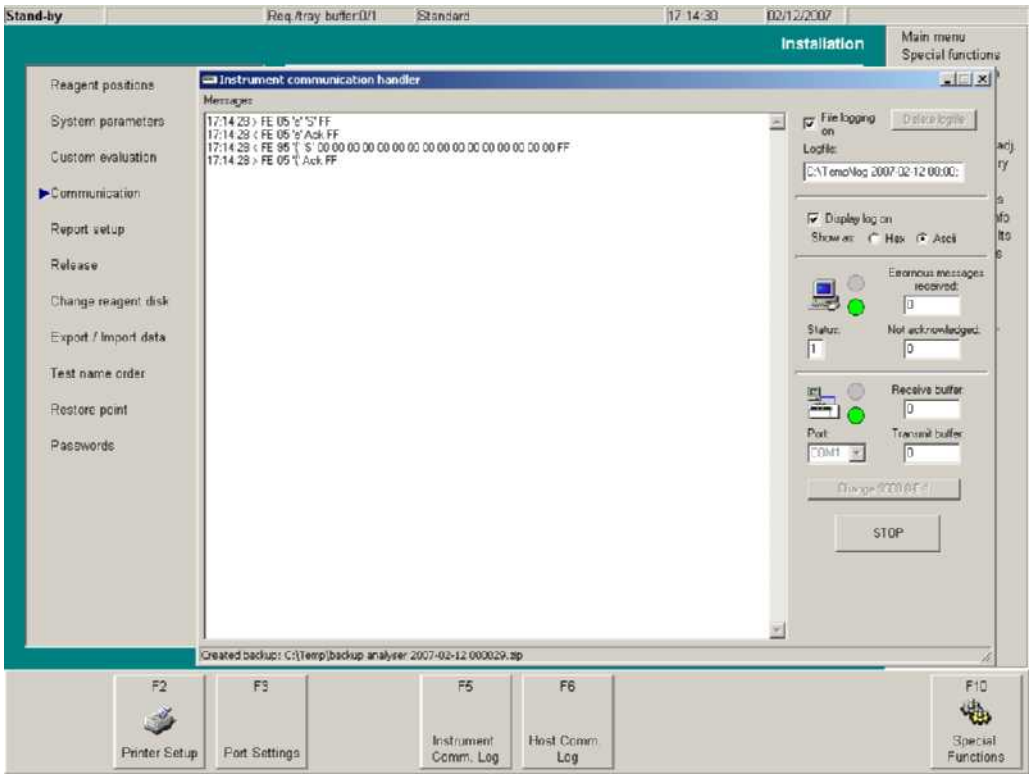
F2 PRINTER SETUP	The Windows® printer selection dialog opens. The printer and the page set-up can be defined.
F3 PORT SETTINGS	Set the LIS Host communication properties. See 7.3.7 Configure host port settings.
F5 INSTRUMENT COMM. LOG	Analyzer communication with its own PC.
F6 HOST COMM. LOG	Lists the communications to the host.

7.3.6 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
COM PORT:	COM 1
BITS PER SECOND:	9600
DATABITS:	8
PARITY:	Even
STOPBITS:	1
FLOW CONTROL:	None

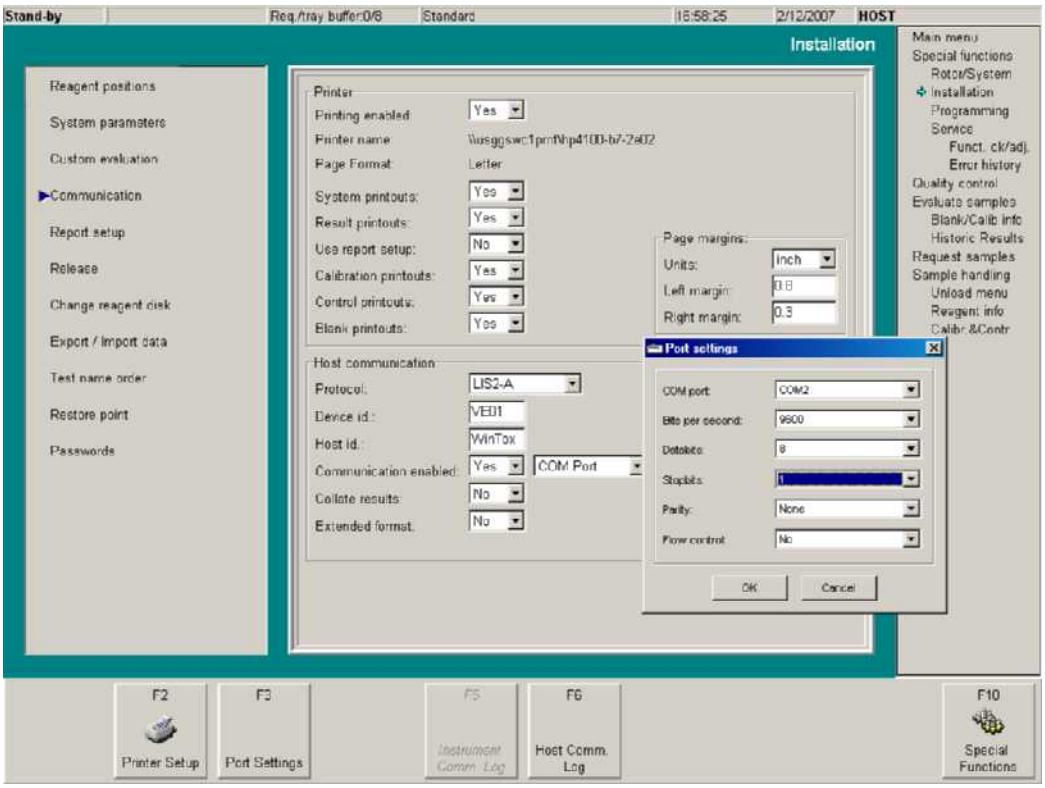
FUNCTION	DESCRIPTION
STOP/START	Starts or stops the communication between the PC and the analyzer. Stop the communication to change the port number.
PORT	Select the port number for the communication between the analyzer and the PC.



7.3.7 Configure host port settings

The recommended settings are:

Parameter	Value
COM PORT:	COM2
BITS PER SECOND:	9600
DATABITS:	8
PARITY:	None
STOPBITS:	1
FLOW CONTROL:	None



Note

Instead of the COM Port, a TCP/IP connection can be chosen. In this case, a dialog opens in which the host name or IP address and the port number can be defined. To set the connection, the communication on the host computer must be running and listening to the indicated port address. Also, the PC on which the analyzer runs must be connected to the host via the intranet.

ATTENTION

The analyzer is not protected with antivirus software. It is the customer's responsibility to install antivirus software and load and maintain updates.

7.3.8 Host - PC communication

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

7.4 System backup procedure

7.4.1 Backup files

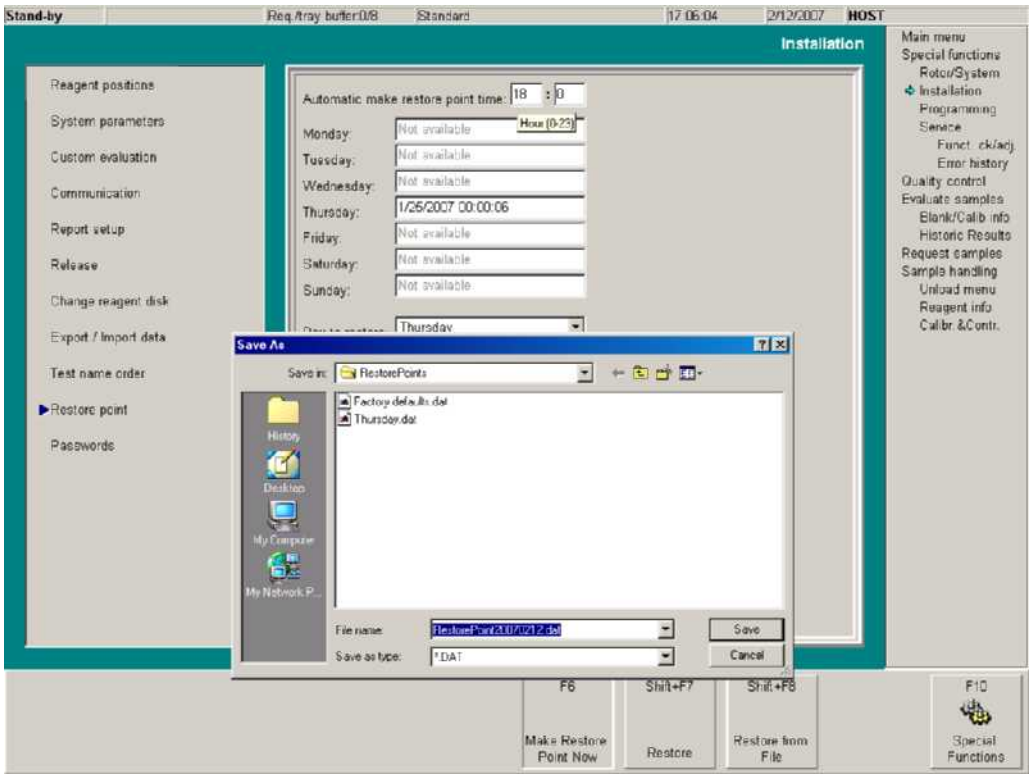
It is recommended to backup files every day or week. Both automatic and manual back-ups can be made. The back-up information is saved in the default location:

- `C:\PROGRAM FILES\VIVA-E ANALYSER\RESTOREPOINTS`.

Note
The default location can be changed to a user selected path if necessary.

This file can easily be backed up using the Restore Point in the analyzer software.
If necessary, e.g., after a PC-crash the Windows® and analyzer programs are re-installed, you need only go to restore points to restore the analyzer's current configuration.

7.4.2 Start `RESTORE POINT`



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

7.4.3 `RESTORE POINT` parameters

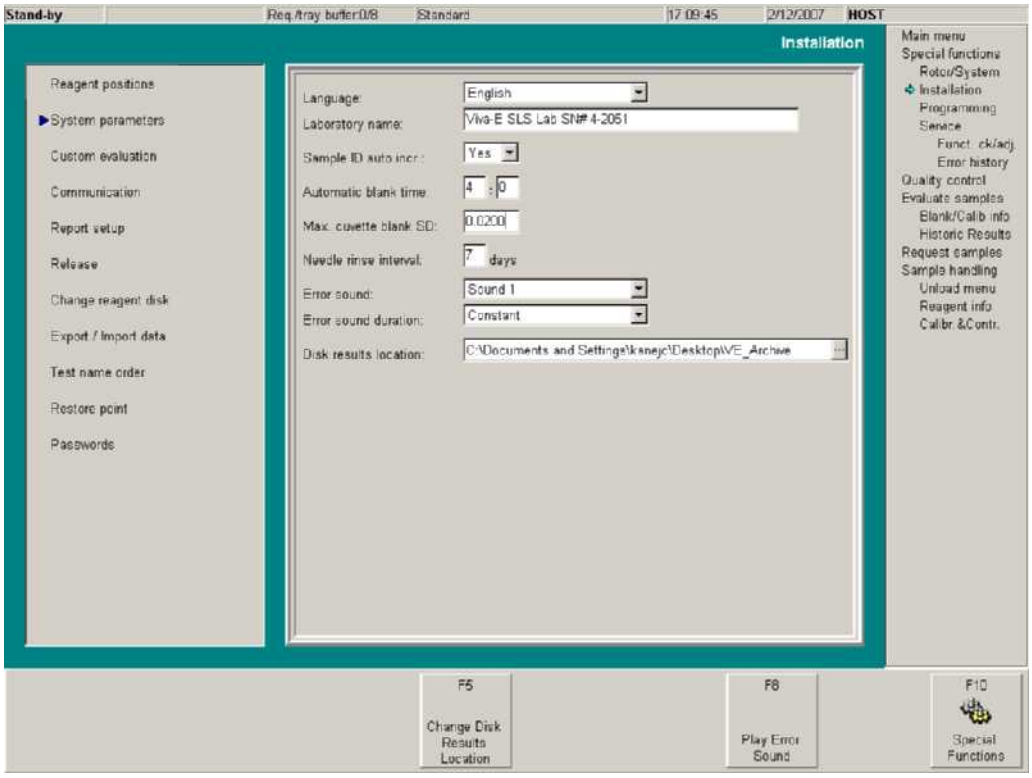
`AUTOMATIC MAKE RESTORE POINT TIME:`	Select the time to make a restore file.
`MONDAY:` to `SUNDAY:`	Shows the available files that were automatically saved on those days.
`DAY TO RESTORE:`	The files that are available to be restored.

7.4.4 RESTORE POINT function keys

F6 MAKE RESTORE POINT NOW	Creates a restore point file.
SHIFT+F7 RESTORE	Restores the automatically created restore point.
SHIFT+F8 RESTORE FROM FILE	Allows you to browse for the restore point file created with F6 MAKE RESTORE POINT NOW. The analyzer will restart.

7.5 Data backup procedure

7.5.1 Setup



1. On your analyzer's computer desktop, create a new folder named **VE_Archive**.
2. Select `F5 SPECIAL FUNCTIONS` from the `MAIN MENU`.
3. Select `F2 INSTALL`
4. Select `SYSTEM PARAMETERS`.
5. Click on the ellipsis (...) at the end of the `DISK RESULTS LOCATION:` field (see the figure above) or select `F5 CHANGE DISK RESULTS LOCATION`.
6. Browse to the desktop, select your **VE_Archive** folder and click on `OK`.

When results are archived, a Historic Results file (e.g. DiskResult12312007.evl) is written to the `DISK RESULTS LOCATION:` selected in the `SYSTEM PARAMETERS` menu.

Note
Data Backup is the customer's responsibility.

7.5.2 Data backup

1. Use a USB Removable Drive for your Data Backup. Keep this drive in an accessible location.
2. Insert the drive into a free USB port of the analyzer's computer.
3. Press `CTRL+F10 EXIT PROGRAM` to end the analyzer program.
4. Right-click on the **VE_Archive** folder on your desktop and Select Copy.
5. Double-click on My Computer.
6. Right-click on the USB Removable Drive and select Paste.
7. Select "Yes to All".
8. Properly eject the USB Removable Drive.

The USB Drive is now your backup of all data from the analyzer. Store it in a safe location.

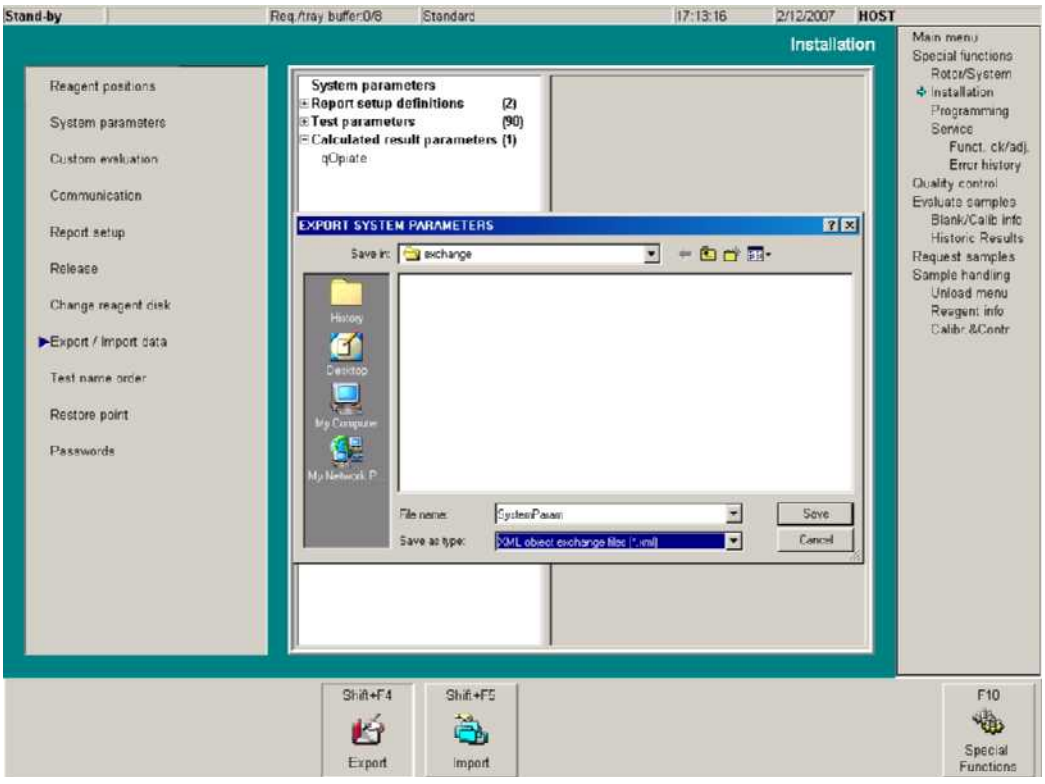
7.6 Importing and exporting data

It is possible to export certain sets of parameters to XML files. Data can also be imported into the analyzer. This enables the exchange of parameter sets between analyzers. It is also possible that supplier of reagents deliver appropriate data sets for their materials to be imported. The data that can be exported and imported include the following:

- System parameters.
- Report setup parameters.
- Test programming parameters.
- Calculated results parameters.

7.6.1 Exporting data

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL
3. Select EXPORT / IMPORT DATA.



4. Select the item(s) to export

Note

For all data except the SYSTEM PARAMETERS, multiple sets of data may be available. Double-click the + symbol in front of a category to open the list of data sets in that category. Double-click on the - symbol to close the list. Click on a data set to select it. Press Ctrl and click on a data set to add it to the selection. Press Ctrl and click on a selected data set to remove it from the selection. Click on the category to export all data sets in that category.

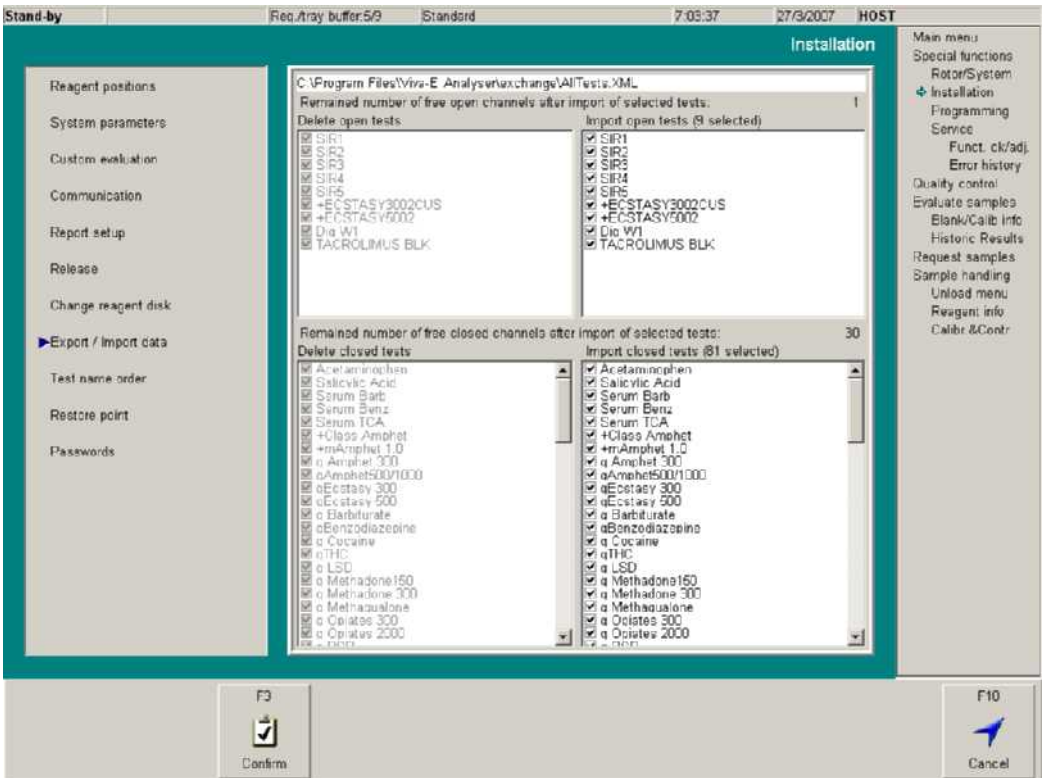
5. Select SHIFT+F4 EXPORT.
6. Select YES in the dialog box.
7. The save file dialog opens. Define the name and location for the export file. The format of the data file is XML. Click Save to export the data to the file.

7.6.2 Importing data

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL
3. Select EXPORT / IMPORT DATA.
4. Select SHIFT+F5 IMPORT.
5. Select YES in the dialog box.
6. The open file dialog opens. Locate the import file. The required format of the data file is XML.
7. Click Open to start importing the data from the file.

Note
If the data file contains system parameters or report setup definitions, the import process starts immediately. No further action is required.

8. If the file contains test parameters or calculated results, two lists are shown on the screen. To the left, the existing tests are listed, grouped in tests for open and closed channels. To the right, the tests in the import file are listed. If the import file contains calculated results, they are shown above the tests.



9. Items to the left will be deleted. Items to the right will be imported. Click on the checkboxes in front of the items to change the selections.
10. Select F3 CONFIRM or F10 CANCEL.

Results Export File

8.1 General

8.1.1 Introduction

A new feature has been added to the Viva-E® starting with software release v 2.0.12 and contained in future versions. This chapter defines and provides instructions related to software changes resulting from the addition of this new feature only. Refer to previous chapters for information not explained in this chapter. The new export feature does not change current procedures related to ordering, processing, reviewing and reporting results as defined by previous chapters. The export file software upgrade adds an additional result output option. Results for samples in the active EVALUATE SAMPLES screen and results previously archived can be exported to an electronic column separated values file (.CSV file).

There are two primary advantages of the new results export feature:

1 The results export file can be copied to a computer either over a network or by USB memory drive to a computer that contains a CSV compatible spreadsheet program like MS-Excel and can be saved as an Excel file. This eliminates the need to type results into your computer from a stack of paper printouts.
2 Depending on your level of need and available resources for laboratory information management, the results export file provides an alternative for your data management company. Instead of writing a costly and time consuming interface communication program your data management provider can write a simple CSV file import routine.

8.1.2 Summary of new features

1 Automatically create archive and export sample results files.
2 Create a column separated values results export file that is compatible with MS Excel.
3 CSV file can be imported into data management system without the need to write an interface program.
4 All information contained in the results export file is selectable and optional providing flexibility to meet your unique needs.
5 Search function in EVALUATE SAMPLES screen whether you are searching through current sample IDs or archived results files has been significantly improved.
6 A DATE COLLECTED: field was added to F8 REQUEST SAMPLES.
7 Function keys were added to allow access to the underlying computer and computer files.



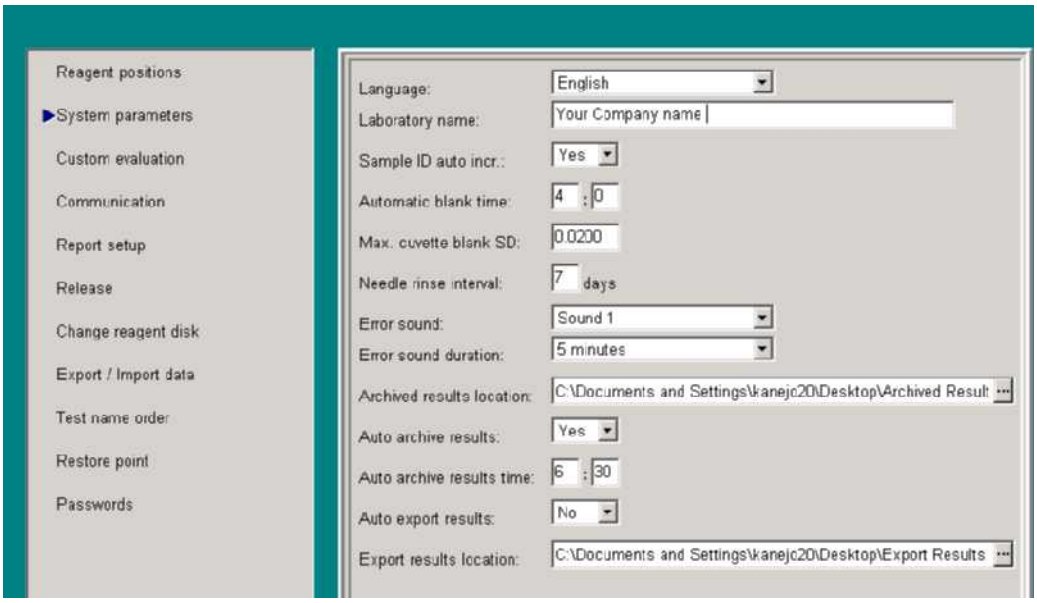
Note

Instruction provided in Results Export File chapter 8 has precedence over similar instruction from previous chapters written before the upgrade to v2.0.12.

8.2 View or change system parameters (additions)

The settings for archiving and exporting results can be viewed or changed in the SYSTEM PARAMETERS screen. Refer to 3.2.7 System parameters.

1. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
2. Select F2 INSTALL.



3. Select SYSTEM PARAMETERS from the list of functions to the left.

New parameters

ARCHIVED RESULTS LOCATION:	Displays storage location of result files archived from F7 EVALUATE SAMPLES. Archived files can only be read by the instrument program. Default location is the computer desktop. File location can be changed by selecting the 3 dot ellipse at the end of the field or by selecting F4 CHANGE ARCHIVED RESULTS LOCATION.
AUTO ARCHIVE RESULTS:	• YES - Automatically archives results listed in F7 EVALUATE SAMPLES. Prevents computer crashes. • NO - Operator will manually and daily archive results to prevent subpar computer performance.
AUTO ARCHIVE RESULTS TIME:	Enter a time on a 0-23 hour and 0-59 minute scale. Set a time after a days testing is complete. Example 19:00. This time will also be used for auto export results.
AUTO EXPORT RESULTS:	• YES - will create an export file from all completed results listed in F7 EVALUATE SAMPLES at the AUTO ARCHIVE RESULTS TIME:. • NO - Operator will create a results export file at a time and with the information of his or her choosing.
EXPORT RESULTS LOCATION:	Displays storage location of results export files. Default location is the computer desktop. File location can be changed by clicking on the 3 dot ellipse at the end of the field or by selecting F5 CHANGE EXPORT RESULTS LOCATION.

Function keys

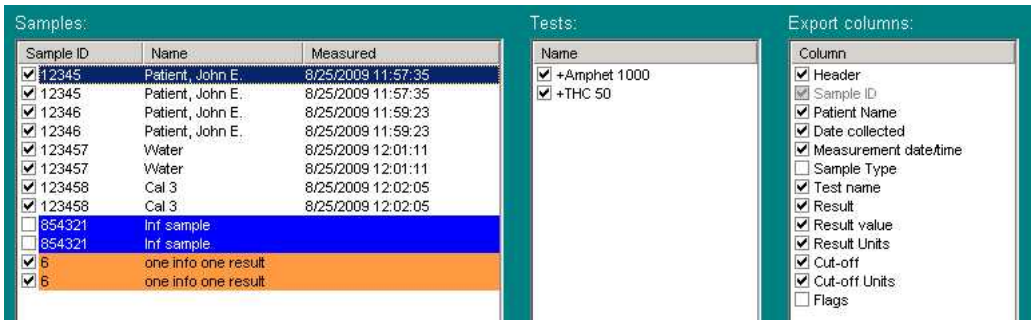


F1 EXPLORER	Default set to open the Viva-E analyzer folder. Moving or deleting files from this folder could result in harm to the instrument program. Opens Windows explorer so that users can access underlying computer files and storage drives without having to minimize or shutdown the instrument program.
F2 CONTROL PANEL	Opens MS Windows based control panel. Read computer operating systems manual for more information.
F3 RUN	Start programs by typing the program's executable name. For example mspaint or wordpad.
F4 CHANGE ARCHIVED RESULTS LOCATION	Allows operator to select a different location for archived results.
F5 CHANGE EXPORT RESULTS LOCATION	Allows operator to select a different location for the results export file. For example - a shared network drive on the company intranet.
F6 ARCHIVED RESULTS FOLDER	Opens the Archived Result folder. The operator can copy the files to a USB drive for file backup purposes.
F7 EXPORT RESULTS FOLDER	Opens the Export Results Folder. The operator can copy files to a USB drive and transfer these files to a different computer. Files can be viewed onboard with wordpad or notepad. Files are best viewed with MS Excel. Excel is not provided by Siemens.
F8 PLAY ERROR SOUND	Briefly plays the error sound selected.
F10 SPECIAL FUNCTIONS	Return to the SPECIAL FUNCTIONS menu (not shown).

8.3 Export results

8.3.1 Select information and create export files

1. Select F7 EVALUATE SAMPLES.
2. Select F2 RESULT HANDLING, replaces historic results.
3. Select EXPORT RESULTS CTRL+F2.



4. Select the SAMPLE IDs you want to export results for.

Note

Only tests within the sample ID that have completed results will write to the export file. This means the file might only contain results for 3 of the 5 assays ordered for a specific sample ID.
Tests flagged INFO or REJECTED are excluded from the export file. Tests marked INFO require operator evaluation in F7 EVALUATE SAMPLES to complete. The program assumes that REJECTED results were reviewed and are final.

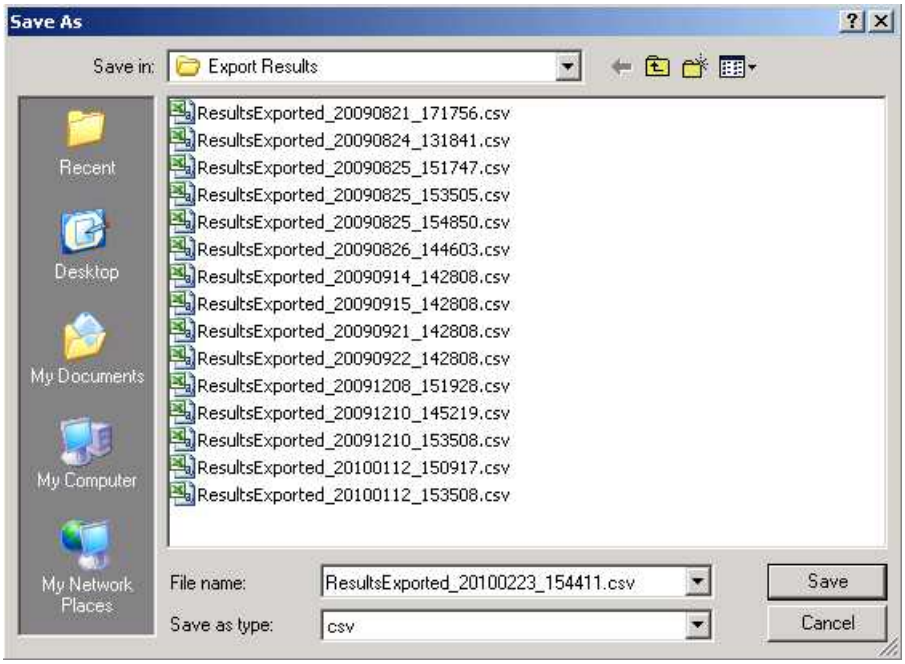
Note

Samples IDs marked in blue cannot be selected because they do not contain completed results for any tests.
Sample IDs marked orange contain completed tests and tests that are marked INFO. Trying to export sample IDs when some tests are marked INFO will result in a pop up message box. The operator can chose to resolve the INFO in EVALUATE SAMPLES or CONTINUE to create the export file without the tests marked INFO.



5. Select in the middle of the screen which TESTS: to include in the export file.
6. Select which EXPORT COLUMNS: to include in the export file.
   Changes to these selections are saved and used when auto export is activated. Only the SAMPLE ID is required. Refer to section 4.2 Enter sample data and test requests for additional information.

Export colums	Description
HEADER	Writes information typed into system parameters LABORATORY NAME: field to the export file.
SAMPLE ID	Refer to 4.6.3 Sample details.
PATIENT NAME	Refer to 4.6.3 Sample details.
DATE COLLECTED	Date the sample was collected. Entered into REQUEST SAMPLES screen.
MEASUREMENT DATE/TIME	Refer to 4.6.3 Sample details.
SAMPLE TYPE	Refer to 4.6.3 Sample details.
TEST NAME	For example +Cocaine 150
RESULT	For tests defined with a cut-off the result will be the word POSITIVE or NEGATIVE.
RESULT VALUE	The numerical result value. For example 0.301 or 80.
RESULT UNITS	Displays units selected in the test's parameters.
CUT-OFF	Numerical cut-off value.
CUT-OFF UNITS	Displays units selected in the test's parameters.
FLAGS	Refer to 5.9 Test messages and flags.



7. Select function key F4 EXPORT. The SAVE AS window appears.

Note

The default SAVE IN: location is defined in the SYSTEM PARAMETERS. The default FILE NAME: format is: RESULTSEXPORTED_YYYYMMDD_HHMMSS.CSV. Select the SAVE IN: drop down arrow to change the file destination to another storage drive. For example save directly to a USB removable drive.

8. Select SAVE.
   Example of information that can be included within the Export file:



Viva-E SN 7-2314

Sample ID	Patient Name	Date collected:	Measurement date	Test name	Result:	Result val	Units:	Cut-off:	Units:	Flags:
12345	Patient, John E	8/24/2009	8/25/2009 11:57	q Opiates 300		< 16	ng/ml			x
12345	Patient, John E	8/24/2009	8/26/2009 11:57	+Cocaine 300	POSITIVE	0.393	dAbs/m	0.389	dAbs/m	+
12345	Patient, John E	8/24/2009	8/25/2009 11:57	Creatinine		82.9	mg/dl			

8.3.2 Automatically create archive and export files

1. Select SYSTEM PARAMETERS.
2. Set AUTO ARCHIVE RESULTS: to YES.
3. Set the AUTO ARCHIVE RESULTS TIME: as preferred.
4. Set AUTO EXPORT RESULTS: to YES.

Note
Both files will be created and sent to the location defined for each file in the SYSTEM PARAMETERS.

Note
If the instrument is not in STAND-BY status at the set time the files will be created when the instrument reaches STAND-BY status.

Note
Auto export assumes sample results were reviewed by a trained operator. The export file is created excluding tests marked INFO or REJECTED.

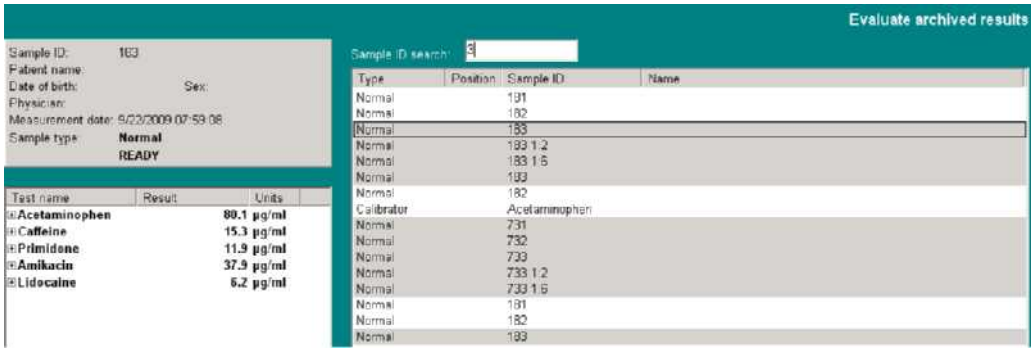
8.4 Archive and search results

8.4.1 Archive results

1. Select F7 EVALUATE SAMPLES.
2. Select F2 RESULT HANDLING.
3. Select ARCHIVE RESULTS SHIFT+F2.
4. To archive tests marked INFO, select EVALUATE SAMPLES or CONTINUE.

8.4.2 Search results

1. Select F7 EVALUATE SAMPLES.
2. Select F2 RESULT HANDLING.
3. Select SEARCH RESULTS ALT+F2.
4. Double click on the DISKRESULTMDDYYYY.EVL file. The file is loaded and is displayed in the EVALUATE ARCHIVED RESULTS screen.



5. Type the SAMPLE ID or any alphanumeric character contained in the SAMPLE ID and all matches will highlight in gray.
6. Press ENTER to page through and review the search matches.
7. Optional: create export file. Refer to 8.3.1 Select information and create export files.

Note

Previous archived files (EVL History files) stored in VE_Archive folder located on the desktop can be transferred to the new archive results folder. However, we recommend that only the most recent files be transferred or transfer files only when needed. Files created by previous software will go through an update process the first time they are used. If the file is too large, because it contains more than one day's results the program may crash and need to be rebooted. Results should be archived daily.

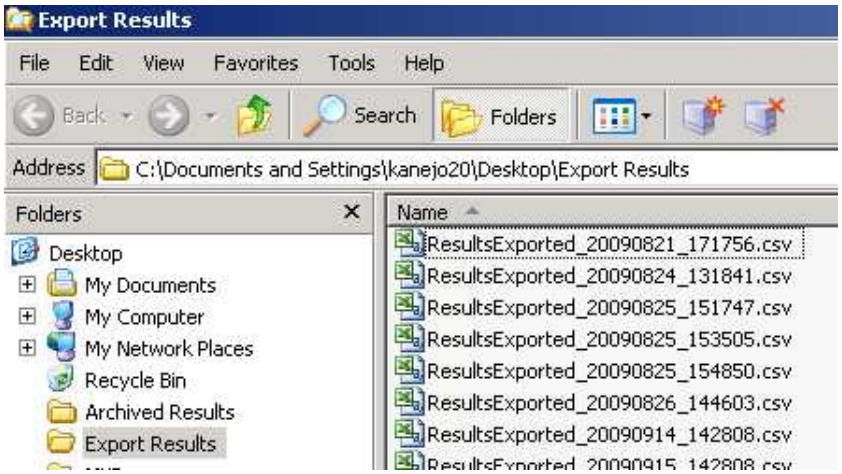
Note

Data archive text files generated with software versions below V2.0 are not compatible. These files can be viewed with Notepad.

8.5 Copy export files or archived results files to a USB drive

The result export files and archived results files can be copied using the SYSTEM PARAMETERS function keys.

1. Insert the USB drive into the instrument computer.
2. Select F5 SPECIAL FUNCTIONS from the MAIN MENU.
3. Select F2 INSTALL.
4. Select SYSTEM PARAMETERS from the list of functions to the left.
5. Select F7 EXPORT RESULTS FOLDER or select F6 ARCHIVED RESULTS FOLDER.



6. Select and copy the results export file.
7. Select My Computer.
8. Select Removable Drive.
9. Paste file to the USB drive.
10. Properly remove the USB drive.
11. Insert the USB drive into the destination computer and transfer files.

8.6 Networking

Note

The instrument has a network interface card and can be connected to the company intranet or directly to another computer with a cross over cable. The results export file can be saved directly to a shared network drive.

WARNING

The instrument does **NOT** have anti-virus, firewall, or any other type of security software loaded. Protection of the network or devices connected to the instrument is our customers' and or their network providers' responsibility.
Do NOT access the internet from the instrument.
Do NOT download computer updates from the internet.

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