

# User Manual



SELECTRA *PRO M*



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This document is valid for the standard model of the Selectra ProM. Vital Scientific cannot be held responsible for any damage resulting from changes made to the Selectra ProM after it was supplied to you. Vital Scientific cannot be held responsible from any damage resulting from not complying to the specifications supplied with the Selectra ProM.

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## Preface



**This instrument (excluding the computer) 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.**

The declaration of conformity is supplied with each device in a separate file.



This manual was written and produced with the utmost care. However, errors can never be fully excluded. Vital Scientific does not take any responsibilities and accepts no liabilities for incidents of any kind that may occur because of errors in the manual. When you have doubts about information given in this manual, please contact your supplier.



This manual describes the Selectra ProM with software version 4.2.x. To find the version number of the software installed on your analyzer, see par. 6.7.1.



The Selectra ProM may contain optional software and/or hardware components. These may or may not be included in your analyzer. This user manual describes the analyzer with all optional components. If optional components are not included in your analyzer, this does not affect the behavior of other components.



**Read this manual carefully before you use the analyzer. Observe the safety guidelines listed in the Safety chapter. Observe safety procedures that may be defined in your laboratory. When you are in doubt about any information in this manual, consult your superior or contact your supplier.**

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**C. INDEX**



## Introduction

## 1.1 About this manual

### 1.1.1 Scope and contents

This manual is written for all users of the Selectra ProM chemistry analyzer. It contains all information required to start, use and shut down the analyzer. It also contains information about maintenance and troubleshooting. Detailed servicing information is only available to trained and authorized service personnel.



#### Note

If you need information that is not included in this manual, or if you are in doubt about the information included in this manual, contact the technical support department of the supplier of your analyzer. Make sure to have the serial number of your Selectra ProM and the article number of this document available when contacting the technical support department. Contact details for the supplier of your analyzer are listed in the *Preface*.

The manual contains the following chapters:

#### 1 Introduction

- Symbols and typographic conventions used in this manual.
- Description of the analyzer and the modules contained in it.

#### 2 Safety

- Guidelines for working safely.
- Potential hazards for your personal health.
- Risks of damage to the analyzer and the environment.
- Warning symbols on the analyzer.

#### 3 Theoretical foundations

- Theoretical models used for measurements.
- Calibration algorithms.
- Automatic evaluation methods

#### 4 User Interface

- Description of the main screens, menus and buttons.

#### 5 Everyday usage

- Procedures for everyday operation of the analyzer.

#### 6 Configuration

- Configuration options for the analyzer.
- Programming tests and calculated tests.
- Defining calibrator and control values.
- Defining reagent positions.
- Defining printer and LIS host connections.
- Defining custom result formats.

#### 7 Maintenance and servicing

- Maintenance schedule and procedures.
- Error messages and troubleshooting guide.

The appendices contain various information (technical specifications, descriptions of optional modules, spare parts list, checklists, index). For a complete list, see the *Table of Contents*.

## 1.1.2 Conventions used in this manual

### Symbol



#### **WARNING**

Failure to follow information contained in warning messages could lead to serious personal injury.

In some cases, the generic warning symbol is replaced with a specific symbol. This points out a particular danger, e.g. hot surface or biohazard. All warning symbols have the same yellow triangle shape and they are identical to the symbols that may be placed on the analyzer. A full list of possible warning symbols is shown in par. 2.1.5.



#### **ATTENTION**

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



#### **Note**

Information that may be helpful to the user.

### Typographic

When the text refers to items on the screen, the words that appear on the screen are shown in ***bold italics***. These words may appear on buttons, in the menu tree, in the status bar, or anywhere else on the screen. The words in the manual are spelled exactly as they are on the screen.



#### **Note**

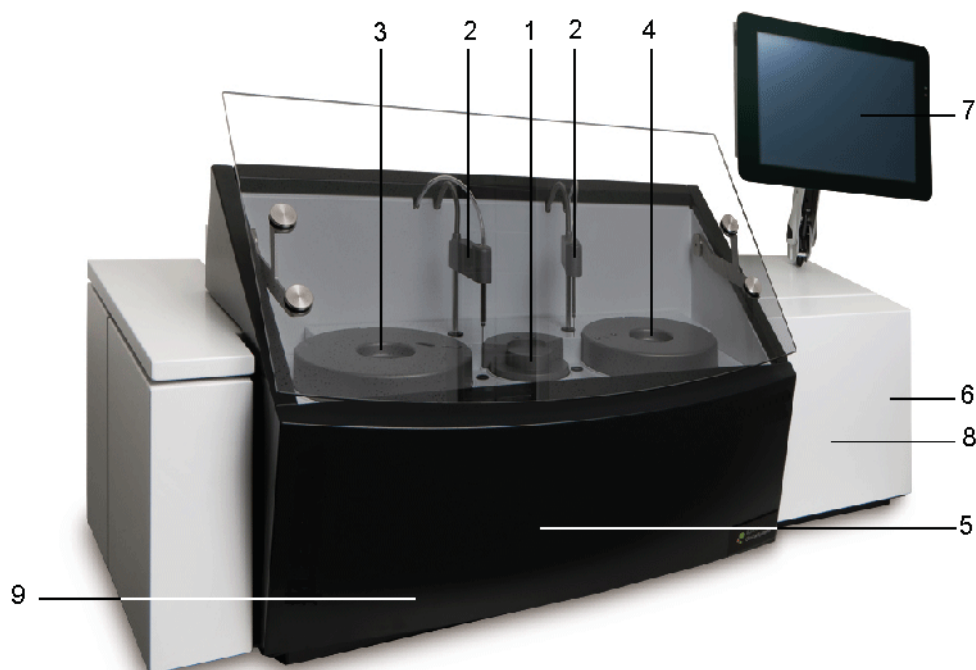
Not all texts on the screen are translated to all languages that are available in the user interface of the analyzer. If the screen texts remain in English when switching to another language, they also remain English in translations of this manual.

References to chapter titles are shown in *italics*.

## 1.2 The Selectra ProM analyzer

### 1.2.1 Overview

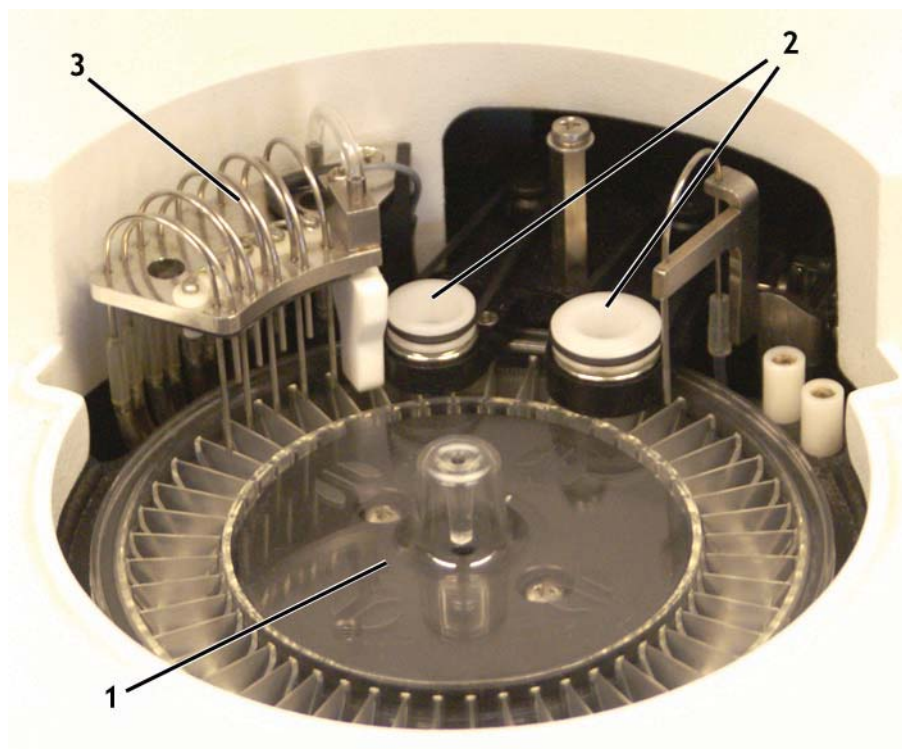
The Selectra ProM is an automatic chemistry analyzer, used in combination with reagents for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine and aqueous standard solutions. The Selectra ProM is designed as a table-top system with all standard components fitted in one unit. Optional modules are external. A detailed description is given in the subsections below.



Nr	Description	See:
1	Cuvette rotor	par. 1.2.2
2	Pipettor arms	par. 1.2.3
3	Reagent rotor	par. 1.2.4
4	Sample rotor	par. 1.2.5
5	Lamp unit (inside cabinet)	par. 1.2.6
6	Syringes (inside cabinet)	par. 1.2.3
7	Touch panel PC running the analyzer software	par. 1.2.11
8	Water / waste containers (inside cabinet)	par. 1.2.8
9	Cooling unit (inside cabinet)	par. 1.2.7

Keyboard, mouse and optional hand-held barcode reader are not shown in the above picture.

### 1.2.2 Cuvette rotor



The cuvette rotor [1] contains 48 cuvettes. The measuring volume is 220 to 400  $\mu\text{l}$ . The cuvette rotor has a heated cover. The cuvettes are kept at 37°C. The stirrer [2] ensures that the reaction mixture is mixed well before being measured. The pipettor arm is pushed through the excentric hole in the stirrer and into the cuvette. The rotation of the stirrer makes the pipettor needle move around in the mixture.

After the last measurement, the rotor is washed and dried. The reagent probe automatically fills the cuvettes with water to avoid drying-in of the rotor.



#### ATTENTION

Make sure the cover is closed while the instrument is in operation. Only open the cover when access is needed.

#### Washing unit

The washing unit [3] aspirates the reaction mixture after analysis and washes the cuvettes with 4 x 500  $\mu\text{l}$  water. The waste is disposed in a waste container. The washing unit is equipped with sensors to avoid flooding the system with water.

### 1.2.3 Pipettor arm and syringes



The Selectra ProM has two pipettor arms. The pipettor arms are operated by separate control boards in the analyzer. The water, reagent and sample fluids are pipetted by precision syringes. These are mounted in the side cabinet.



### 1.2.4 Reagent rotor



In the Selectra ProM, the left rotor holds reagent bottles. Bottles of 10 ml, 25 ml and 50 ml can be placed. The entire rotor can easily be replaced. This may be useful when different sets of reagents are needed. During normal operation, the rotor is covered. The base of the rotor is cooled.

**Note**

Optimal cooling can only be reached when the cover is kept closed as much as possible. Only open the cover when access is needed.

**Note**

It is possible to use multiple rotors for the same Selectra ProM. Each rotor may hold a different set of reagents. Switching rotors can be done without shutting down the analyzer. See par. 5.2.4. For details on configuring multiple rotors, see par. 6.3.2.



### 1.2.5 Sample rotor



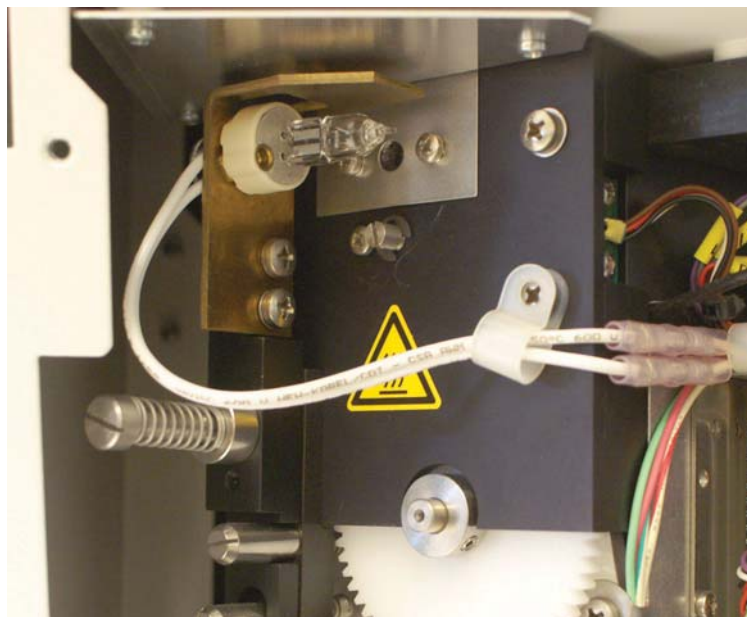
The sample rotor of the Selectra ProM has 75 positions, divided over three rings. Routine sample tubes are placed in the two outer rings. The inner ring is used for special samples, such as calibrators and controls. The entire rotor can easily be removed and/or replaced.

**Note**

The cover protects sample material from contamination. Always keep the rotor covered, except when loading or unloading.



## 1.2.6 Lamp unit



The lamp unit is fitted inside the main cabinet of the Selectra ProM. The light passes through one of eight filters before it reaches the cuvette. Each test uses light of a specific wavelength to measure the absorbance. The wavelengths installed on your Selectra ProM are shown in the **System Configuration** screen. See par. 6.5.2.

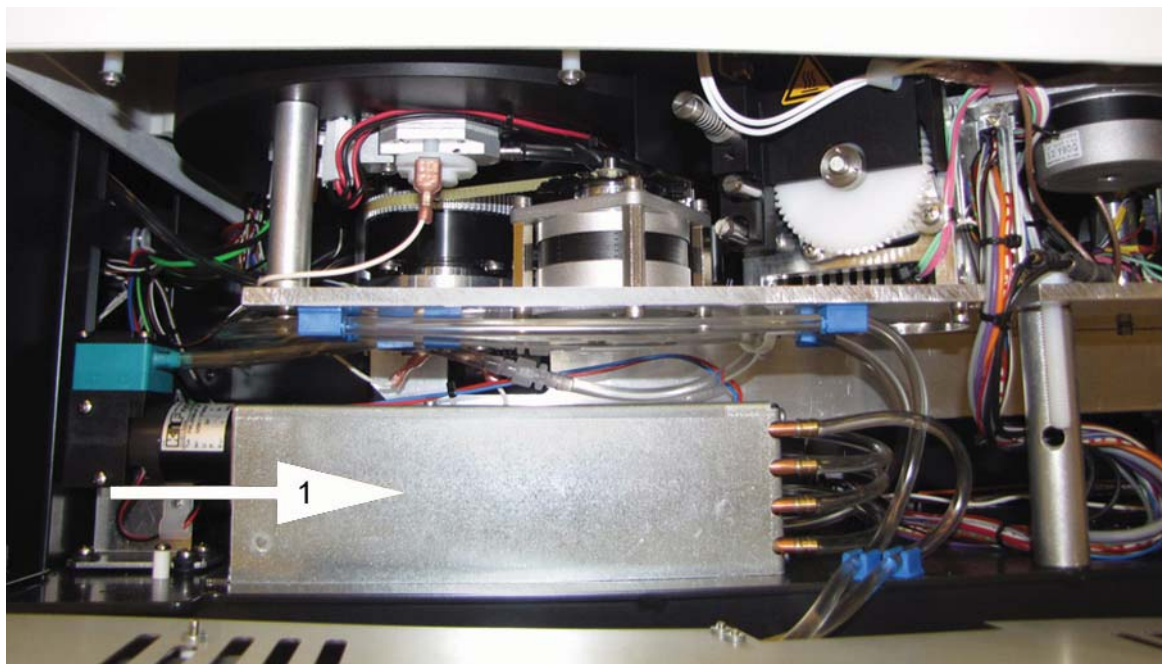
When the analyzer detects that the lamp is not fit for use anymore, an error message appears on the screen. For instructions on replacing the lamp, see par. 7.3.3.



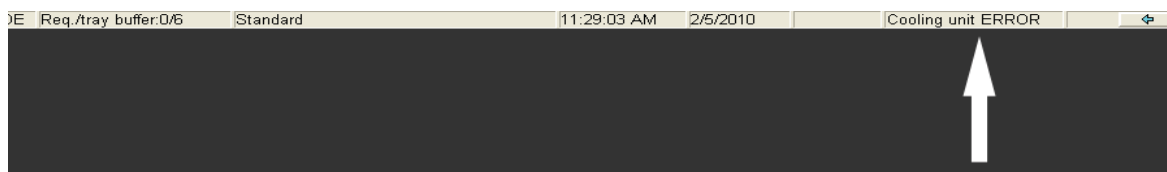
### **HOT SURFACE**

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

### 1.2.7 Cooling unit



The Selectra ProM is fitted with an internal cooling unit. The cooling unit [1] is mounted on the base plate of the analyzer. The cooling unit provides a constant temperature of the reagents, keeping them fresh (as required). The cooling unit guarantees absolute cooling (8 - 12 °C) up to an ambient temperature of 25 °C. Above 25 °C the temperature of the reagent cooling starts to increase relative to ambient temperature. The user cannot change the temperature setting of the cooling unit. If the cooling temperature is not ok, this is shown in the status bar on the screen.



**Note**

If the cooling temperature is not ok, even after the Selectra ProM has been running for an hour, contact your supplier for technical support.

### 1.2.8 Water and waste containers



The water and waste containers are positioned in the right-side compartment of the Selectra ProM. The water is used to wash the cuvettes between measurements. The water and waste containers can easily be exchanged.



#### **BIOHAZARD**

Fluids in the waste container are potentially infectious. These fluids must be handled with great care. Clean up spills immediately. Use applicable procedures to discard the fluids from the waste container.

### 1.2.9 Dry Electrode ISE unit (optional)



The Dry Electrode ISE unit is an optional module for the Selectra ProM analyzer. When installed, it is mounted in the cabinet on the left side of the analyzer, as shown in the above picture. The samples for the Dry Electrode ISE unit are taken from the cuvette rotor. This is done by the ISE sipper arm [1]. This is only available when the Dry Electrode ISE unit is installed. The Dry Electrode ISE unit is described in appendix B.



### 1.2.10 External barcode reader (optional)



A hand-held barcode reader can be connected to a USB port of the computer. The reader can be used to request tests, program reagents and load barcoded samples. Most of the existing barcode fonts can be read. The Codabar barcode is used to request tests. The barcode reader has a separate instruction manual. Please read the barcode reader manual for more information and user instruction.



#### ATTENTION

Vital Scientific cannot guarantee correct functioning of a barcode reader if it was not purchased from Vital Scientific or one of their distributors. Barcode readers must be programmed to correctly recognize the labels on a Codabar chart before they can be used. Barcode readers purchased from Vital Scientific or one of their distributors are shipped with the correct programming instructions.

### 1.2.11 Computer

A touch panel PC provides the user interface for the analyzer. A height adjustable monitor arm allows adjusting the viewing angle individually.

The operating system is Microsoft® Windows® XP Embedded. The computer is dedicated to run only the user interface software for the Selectra ProM. The control of the mechanical components in the analyzer is handled by a separate microprocessor in the instrument. All mechanical devices are driven and checked by slave processors. The state of the analyzer is continuously communicated to the user interface software and shown on the screen.

**ATTENTION**

Do not use the computer for anything other than running the pre-installed control software. The use of any other software might cause failures in the analyzer.

**ATTENTION**

Make sure that no liquid gets into the computer. Liquids will do serious damage.

With the touch panel the analyzer can be operated by simply touching the display screen. A mouse and keyboard are available for navigation through the user interface and for entering data where needed. It is possible to connect the analyzer to a laboratory information system (LIS). In that case, test requests can be retrieved from the host computer and results are transferred back automatically when the tests are completed. See par. 6.6.2 for details on this setup.

## Safety

## 2.1 General

### 2.1.1 Intended use

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



#### **Disclaimer**

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

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

<sup>1</sup> ECCLS = European Committee for Clinical Laboratory Standard

<sup>2</sup> CLSI = Clinical and Laboratory Standards Institute



### 2.1.2 Safety guidelines

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 guidelines listed in this chapter.

When operating the analyzer all national or international guidelines and regulations must be observed, as in the normal laboratory 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.

### 2.1.3 Safety requirements

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

## 2.1.4 User qualifications

### Operators

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.

### Service technicians

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

### 2.1.5 Symbols on the analyzer

**WARNING**

This label indicates potential danger. It may be placed on various parts of the analyzer. The specific meaning that applies is described in "Specific safety aspects" on page 2-7.

**HOT SURFACE**

This label is placed on or near parts that get hot when the analyzer is switched on. Make sure to keep fingers and other body parts clear of the hot surface.

**PINCH POINT**

This label is placed on or near areas where fingers or other body parts can get pinched. Make sure to keep fingers and other body parts clear of the pinch point.

**BIOHAZARD**

This symbol is shown on or near areas where potentially infectious liquids are present, such as the cuvette rotor and the waste container. The contents of the areas marked with this symbol may present a biological hazard and are potentially infectious.

**ATTENTION**

This label is attached to the back of the analyzer. The symbol indicates that at the end of its lifetime, the analyzer must be separately collected in accordance with the European Directive 2002/96/EC.

## 2.2 Specific safety aspects

### 2.2.1 Hazards

#### Electrical hazards

**WARNING**

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

#### 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 switched off.

#### Pipettor arm and rotors

**WARNING**

Do not touch movable parts of the system (rotors, arm, 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, except when loading or unloading. Covering protects sample material and reagents from contamination.

#### Lamp

**HOT SURFACE**

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 must be changed, wait until the lamp has cooled down.

#### 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. Consult local sources for additional information on correct waste disposal.

**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.

For correct use of reagents in combination with the instrument consult package inserts in the reagent kit box of the reagent manufacturer, or reagents application sheets.

## 2.2.2 Transport and installation

### Transport and storage requirements

**ATTENTION**

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

**ATTENTION**

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

Always contact technical support for the best procedure to transport when the analyzer is to be transported from one building to another. The manufacturer recommends that only qualified service personnel of the supplier prepares the analyzer for transport.

At the arrival at the new location, the analyzer has to be installed by a service technician.

When the analyzer is at the end of its lifetime, contact the support department of your supplier for removal instructions.

### Installation site requirements

The customer is responsible for providing the necessary facilities as described in par. A.1.3.

**WARNING**

The analyzer and optional additional 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.

**ATTENTION**

The analyzer has to be installed on a level surface.

**ATTENTION**

Always connect the analyzer to an earthed wall socket.

**ATTENTION**

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

Adequate ventilation of the room is recommended to prevent condensation occurring at the analyzer parts.

**ATTENTION**

The analyzer shall not be exposed to direct sunlight or vibrations.

**WARNING**

Do not use the analyzer in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

**Note**

It is recommended to use an uninterruptible power supply (UPS), supplying power from a separate source when utility power is not available.

**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.

**Operational requirements****ATTENTION**

The cooling unit must be filled with liquid. Check liquid level every 3 months. For details on the cooling liquid to use, see par. A.2.1.



### 2.2.3 Operational requirements

#### Maintenance

**ATTENTION**

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

For maintenance and repair procedures follow the instructions given by service personnel of your supplier or procedures specified in the manual.

Use suitable tools for repairs (e.g. insulated screwdrivers for work on 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 covers are closed while the instrument is in operation.

#### Instrument not used for a long time

**ATTENTION**

If the instrument is not to be used for a long time, contact the support department of your supplier for further information and assistance.

## 2.2.4 Use of materials with the analyzer

### Specimens

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



#### **ATTENTION**

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

### Reagents and calibrators

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



#### **ATTENTION**

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



#### **Disclaimer**

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

### 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.

### 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. A clinical technician must carefully examine the test results obtained with this instrument 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.

## Theoretical foundations

### 3.1 Absorbance measurements

#### 3.1.1 Types of measurements

##### Measuring concentrations via absorbance

Parameters are measured as spectral absorbance relative to a zero-adjustment on water. The zero-adjustment takes place automatically at the start of each test series. The relationship between concentration and change in spectral absorbance determines the concentration. The absorbance is calculated according to Lambert-Beers law:

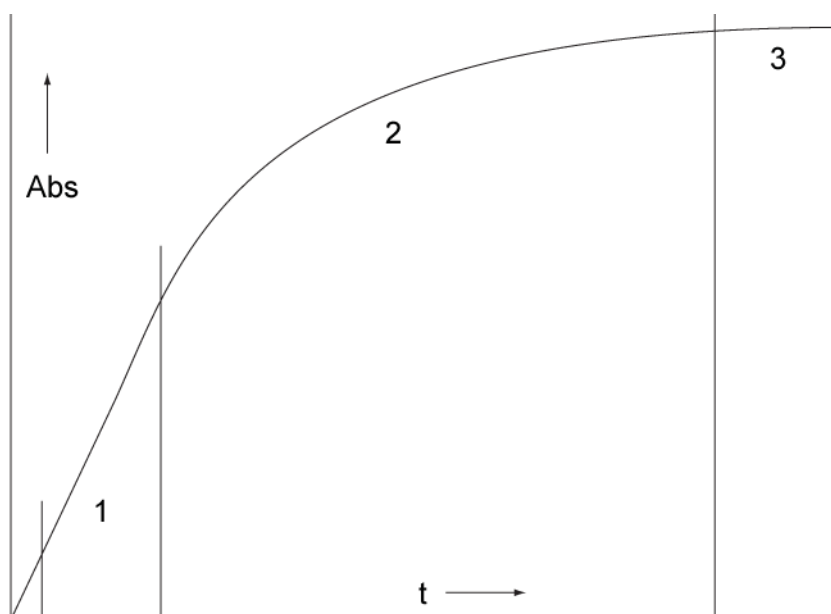
$$\text{Abs} = \varepsilon \times d \times c = -\log T = 2 - \log T\%$$

Abs =	Absorbance
$\varepsilon$ =	Molar extinction coefficient
d =	Length of the light path
c =	Concentration
T =	Transmission

##### Measurement types

When samples and reagents are mixed, a reaction takes place. The concentration of the products of the reaction is determined via the absorbance measurements. As the behavior of the reagents are well defined, this gives a clear indication for the concentration of a particular substance in the sample.

Reaction speeds differ greatly between test methods. The time frame for measurements on the analyzer is limited (both for mechanical and usability reasons). The time to reach an endpoint in the reaction may be anything between a few seconds and more than an hour. To determine the substance concentration for all possible methods within the same time frame, three basic types of measurement are available.



1. Kinetic tests. The measurement time frame lies in the first section of the curve, which is checked for a linearity.
2. Two point tests. The measurement time frame lies in the second section of the curve.
3. Endpoint tests. The measurement time frame lies in the last section of the curve, where the reaction has reached a stable endpoint.

The following sections give a detailed explanation, including available variants for each of the basic measurement types and the algorithms used in the calculations. The measurements are checked against the available calibration curves. See par. 3.2 for calibration algorithms.

### 3.1.2 Kinetic tests

The kinetic method is normally used for enzyme activity tests. The reaction is monitored at intervals of 27 seconds. The measurements are checked for linearity. If the alinearity exceeds the specified limit and the delta absorbance is greater than 15 mAbs/min, a warning is given. Kinetic tests can be performed with linearity checks, sample blanks and/or reagent blanks.



#### Note

In all formulas shown in this chapter, the following abbreviations are used:

- reag - reagent blank with an active reagent
- reagbl - reagent blank with an inactive reagent
- samplebl - sample blank
- stdb - sample blank of the standard

The calculation for kinetic tests is as follows:

$$c(U/L) = \delta Abs/min \times \frac{V_{total} \times 1000}{\epsilon \times d \times V_{sample}}$$

The second part of the formula corresponds to the enzymatic factor (F). This factor can be found in the package insert of the method.

The alinearity is calculated as follows:

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

c =	Concentration
$\delta Abs/min$ =	Delta absorbance per minute
$\epsilon$ =	Molar extinction coefficient
d =	Length of the light path
$V_{sample}$ =	Sample volume
$V_{total}$ =	Total volume (reagents plus sample)

### 3.1.3 Endpoint tests

Reactions that reach an endpoint quickly are measured using the endpoint method. The reaction is normally completed before measurement takes place. Various calculation methods are available.

#### Standard endpoint

$$c = \frac{\text{Abs}_{\text{sample}}}{\text{Abs}_{\text{std}}} C_{\text{std}}$$

The factor F is calculated as follows:

$$F = \frac{C_{\text{std}}}{\text{Abs}_{\text{std}}}$$

The sample concentration c is calculated as follows:

$$c = \text{Abs} \times F$$

#### Endpoint with reagent blank

$$c = \frac{\text{Abs}_{\text{sample}} - \text{Abs}_{\text{reag}}}{\text{Abs}_{\text{std}} - \text{Abs}_{\text{reag}}} C_{\text{std}}$$

$$F = \frac{C_{\text{std}}}{\text{Abs}_{\text{std}} - \text{Abs}_{\text{reag}}}$$

$$c_{\text{sample}} = (\text{Abs}_{\text{sample}} - \text{Abs}_{\text{reag}}) \times F$$

#### Endpoint with reagent blank and sample blank

$$c = \frac{(\text{Abs}_{\text{sample}} - \text{Abs}_{\text{reag}}) - (\text{Abs}_{\text{samplebl}} - \text{Abs}_{\text{reagbl}})}{(\text{Abs}_{\text{std}} - \text{Abs}_{\text{reag}}) - (\text{Abs}_{\text{stdbl}} - \text{Abs}_{\text{reagbl}})} C_{\text{std}}$$

$$F = \frac{C_{\text{std}}}{(\text{Abs}_{\text{std}} - \text{Abs}_{\text{reag}}) - (\text{Abs}_{\text{stdbl}} - \text{Abs}_{\text{reagbl}})}$$

$$c_{\text{sample}} = ((\text{Abs}_{\text{sample}} - \text{Abs}_{\text{reag}}) - (\text{Abs}_{\text{samplebl}} - \text{Abs}_{\text{reagbl}})) \times F$$

**Bichromatic endpoint**

$$c = \frac{Abs_{\text{sample}, \lambda_1} - Abs_{\text{sample}, \lambda_2}}{Abs_{\text{std}, \lambda_1} - Abs_{\text{std}, \lambda_2}} c_{\text{std}}$$

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



### 3.1.4 Two point tests

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

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

## 3.2 Calibration algorithms

### 3.2.1 Introduction - calibrators

Calibrators must be programmed before you define the parameters for the various tests. You can change the parameters for a calibrator or add new calibrators later.

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
  - Standard cubic spline
  - Smooth cubic spline
  - Linear regression
  - Point to point
  - 4-parameter Logit-Log (4 or more standards)
  - 5-parameter Logit-Log (5 or more standards)
  - 5-parameter exponential (5 or more standards)
- Multi point calibration of different dilution levels made from one (parent) calibrator.

All these methods give quantitative results. Where a qualitative result is required (either positive or negative) cut-off calibration must be used. With a cut-off calibration, a "close to cut-off" or "grey" area can be defined.

**Note**

Possibly, not all of the algorithms described in this section are available on your analyzer. This depends on configuration settings defined by your supplier.

### 3.2.2 Standard cubic spline

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

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

$$c_m = p c_i + q c_{i+1} + \frac{1}{6} (p^3 - p) (A_{i+1} - A_i)^2 a_i + \frac{1}{6} (q^3 - q) (A_{i+1} - A_i)^2 a_{i+1}$$

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:

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

### 3.2.3 Smoothed cubic spline

The cubic spline curve fitting algorithm determines if a logarithmic axis would yield a better fit (i.e. a smoother curve). The following formula is used:

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

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 by:

$$x_m = A_m$$

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

The curve-fit algorithm determines the best relation. When  $x_m$  is calculated,  $x$  is derived by:

$$x = x_m - A_i$$

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.

$A_i$	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

### 3.2.4 NLLS algorithms

#### 4 parameter logit-log (NLLS)

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

$A_m$	Measured absorbance value for the sample
$C_m$	Calculated concentration
$x_0, K, a, b$	Factors determined by the curve-fit algorithm

#### 5 parameter logit-log (NLLS)

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

$A_m$	Measured absorbance value for the sample
$C_m$	Calculated concentration
$x_0, K, a, b, c$	Factors determined by the curve-fit algorithm

#### 5 parameter exponential (NLLS)

$$A_m = x_0 + K e^{a \ln C_m + b \ln^2 C_m + c \ln^3 C_m}$$

$A_m$	Measured absorbance value for the sample
$C_m$	Calculated concentration
$x_0, K, a, b, c$	Factors determined by the curve-fit algorithm

### 3.2.5 Other calibration algorithms

#### Linear regression and point-to-point

$$C_m = \text{Intercept} + (\text{Slope} \times A_m)$$

$A_m$  = Measured absorbance value for the sample

$C_m$  = Calculated concentration

Slope, Intercept = Factors determined by the algorithm

### 3.3 Explanation of analyzer features

#### 3.3.1 Integrity checking

The Selectra ProM can perform a number of checks on the integrity of the measurements. Some optional methods are explained in this paragraph. When an integrity check fails, an error flag is set for the measurement result. The error flags are shown in the **Evaluate Results** screen. An example is shown below. The error flags are also printed with the results.

Test name	Value	Flags
<input type="checkbox"/> <b>Cholesterol</b>	<b>REJECT</b>	<b>m</b>
<input type="checkbox"/> Point#1	*INFO* Abs	m
Measurement	*INFO* Abs	m
Measurement	REJECT Abs	
Measurement	REJECT Abs	

Apart from the optional integrity checks explained in this chapter, a number of standard checks are always performed. These may also lead to error flags. A full list of error flags in the Selectra ProM is available in par. 5.6.2.

#### Substrate depletion check

This is used for methods where the reaction rate is measured rather than the concentration of the end product of the reaction (kinetic tests). When the substrate starts running out before measurements are completed, the reaction is not linear anymore. This can be checked by setting a substrate depletion limit. The analyzer uses a minimum of four measurement points to check against this limit. If one of the values falls below the limit, the D flag is set. The test can be repeated with a more appropriate sample and/or reagent volumes. This more appropriate volume is set in the **rerun volume**: test parameters.

#### Prozone check

The prozone check can be used in methods that are based on the formation of antigen-antibody complexes (agglutination). Samples with an extremely high antigen content can reverse the reaction direction and cause incorrect results. This reverse in the reaction is called the prozone or hook effect. To recognize incorrect results, a prozone check can be performed for:

- **Min. dAbs ratio** - minimum delta absorbance ratio
- **Max. dAbs ratio** - maximum delta absorbance ratio
- **Min. Abs ratio** - minimum absorbance ratio
- **Max. Abs ratio** - maximum absorbance ratio

The analyzer calculates the absorbances or delta absorbances at two times (prozone points 1 and 2). When delta absorbance ratios are selected, three measurement points around both prozone points are used. The ratio is then calculated by one of these formulas:

$$\text{ratio} = \frac{\text{Abs}_{\text{proz. point 1}}}{\text{Abs}_{\text{proz. point 2}}} \times 100$$

$$\text{ratio} = \frac{\delta\text{Abs}/\text{min}_{\text{proz. point 1}}}{\delta\text{Abs}/\text{min}_{\text{proz. point 2}}} \times 100$$

If the calculated percentage exceeds the applicable limit, the P flag is set. When the prozone check is enabled, the **Result Details** screen shows a separate **Prozone graph** and **Prozone table**. See par. 4.2.6.

### 3.3.2 Absorbance check for calibrated tests

After a calibration, an automatic rate check is initiated. The following limits are set:  
(the percentage mentioned is adaptable)

- Low rate limit = Lowest calibrator rate - 1% (highest calibrator rate - lowest calibrator rate)
- High rate limit = Highest calibrator rate + 1% (highest calibrator rate - lowest calibrator rate)

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 k or K 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 (m or M)

**Note**

We recommend setting concentration limits when a test is calibrated. When a high concentration limit is set at 300 mg/dl, all results above this limit (also 9999.0) are presented in the form "> 300 mg/dl".



### 3.3.3 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 set 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.

### 3.3.4 Predilution

Predilution is used in samples that would normally fall outside the measurable absorbance or calibration range. The sample is prediluted by the analyzer, using diluent available on the rotor.

**Note**

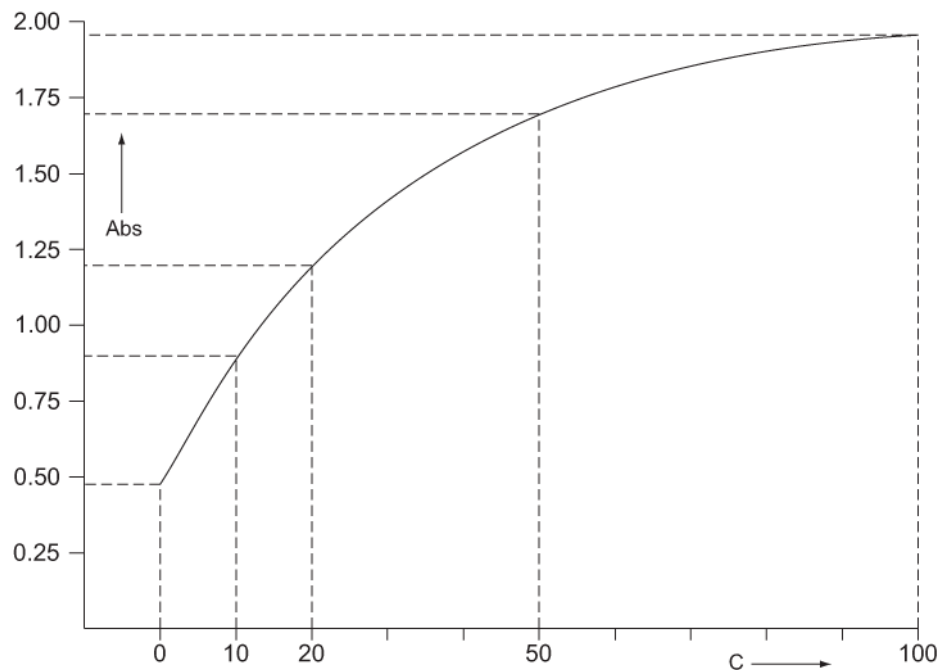
In this manual and in the analyzer software, the dilution ratios are given as parts of the sample to parts of the resulting solution. Thus, a dilution ratio of 1:5 means 1 part of the sample diluted with 4 parts of diluent, resulting in 5 parts of solution.

**ATTENTION**

When using predilution, the analyzer measures lower concentrations than the sample contains. To check the measured absorbances against calibrators, the same predilution factor must be used on the calibrators and the samples. Otherwise, the test results will not be valid.

**Example**

A test uses a calibrator with 5 standards, for concentrations 0, 10, 20, 50 and 100. Because these concentrations are higher than can be measured, a predilution factor of 1:5 is used for the calibrator standards. The absorbances measured for the standards are really those for concentrations 0, 2, 4, 10 and 20. The graph can still be used to find concentrations in samples because the sample is prediluted with the same factor of 1:5.



## User Interface

## 4.1 Overview

### 4.1.1 Screen, keyboard and mouse

The Selectra ProM is supplied with a touch panel PC. The screen shows the current state of the analyzer. You control the analyzer with the touch panel or keyboard. The Selectra ProM comes with the US-International mini keyboard with built-in trackball as shown here:



#### Note

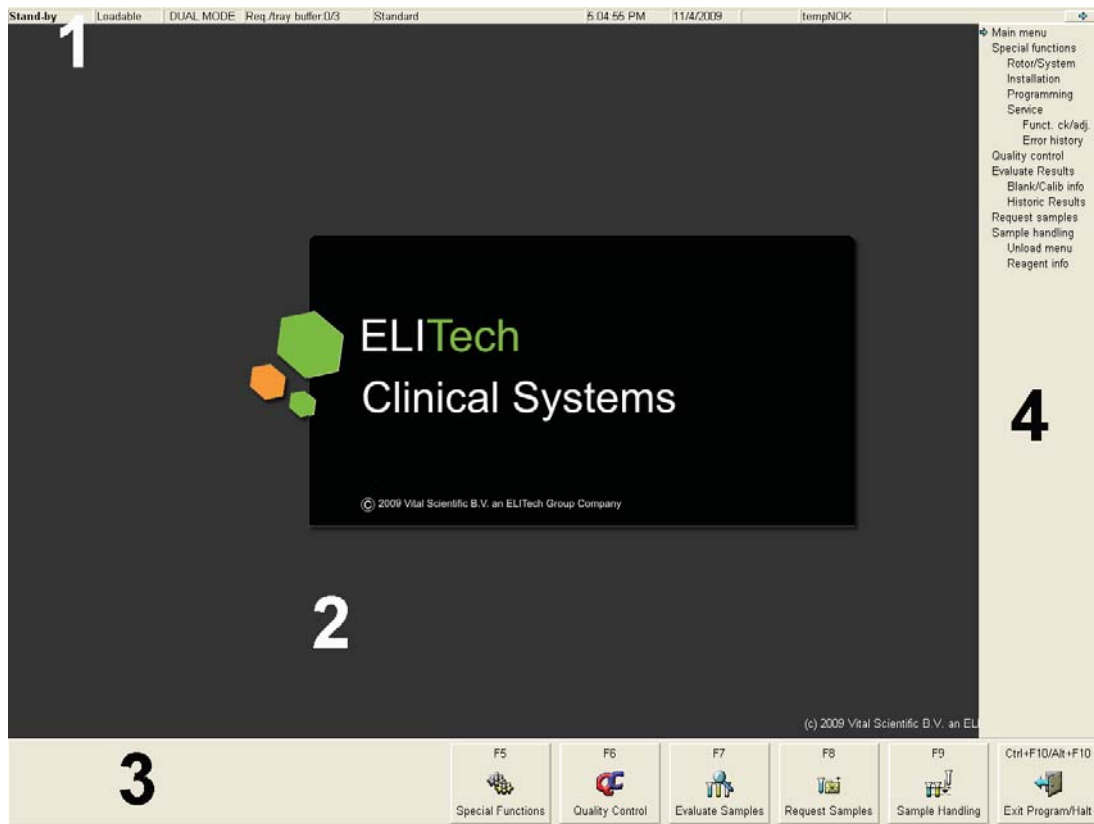
It is possible to replace the supplied keyboard with a localized USB keyboard. Make sure to change the keyboard settings in the Windows control panel when installing a keyboard with another keyboard layout.

#### Keyboard functions

A number of keys on the keyboard have defined functions, as listed in the table below.

Arrow keys	Move to another field
Tab	Switch between left and right sections on the screen
Page Up, Page Down	Move one position up or down in a list
Home, End	Move to the first or last position in a list
Enter	Confirm entered data
Function keys	Functions as shown on the screen
Alt+F10	Emergency halt
Spacebar	Select or deselect a checkbox

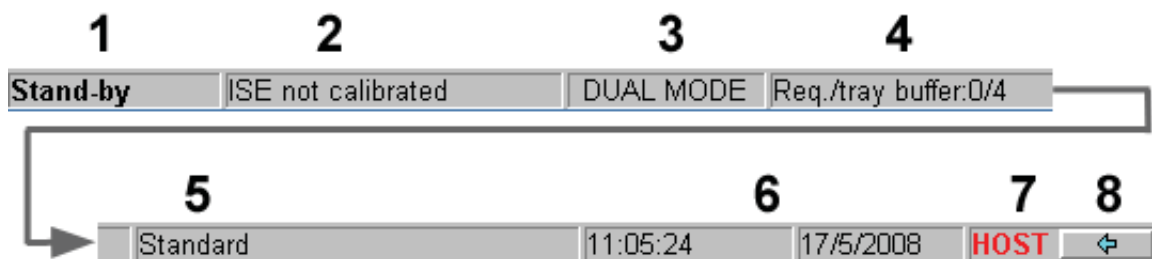
4.1.2 Parts of the screen



1. Status bar
2. Main screen area
3. Function keys
4. Menu tree (may be hidden)

**Status bar**

The narrow section at the top of the screen shows the current status of the analyzer. The images below show the left and right half of the status bar enlarged.



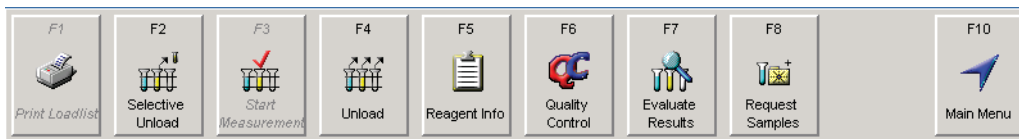
1. State of the analyzer. See par. 5.2.1.
2. State of the Dry Electrode ISE unit (when installed), not shown for the Selectra ProM. See par. 5.2.1.
3. Mono or Dual mode selected. See par. 6.5.2.
4. Number of samples in the request buffer (not yet loaded) and in the tray buffer (loaded).
5. Name of the selected rotor configuration. See par. 5.2.4.
6. Current date and time.

- 7. State of the LIS host computer (when activated). See par. 5.2.1.
- 8. Button to open or close the menu tree. See page 4-5.

**Main screen area**

This part of the screen changes with the functions chosen in the analyzer software. The right-hand part of the main screen is covered by the menu tree when it is opened. The main screens are described in chapter 5. Screens that are used for configuration and servicing of the analyzer are listed in chapter 6 and chapter 7.

**Function keys**



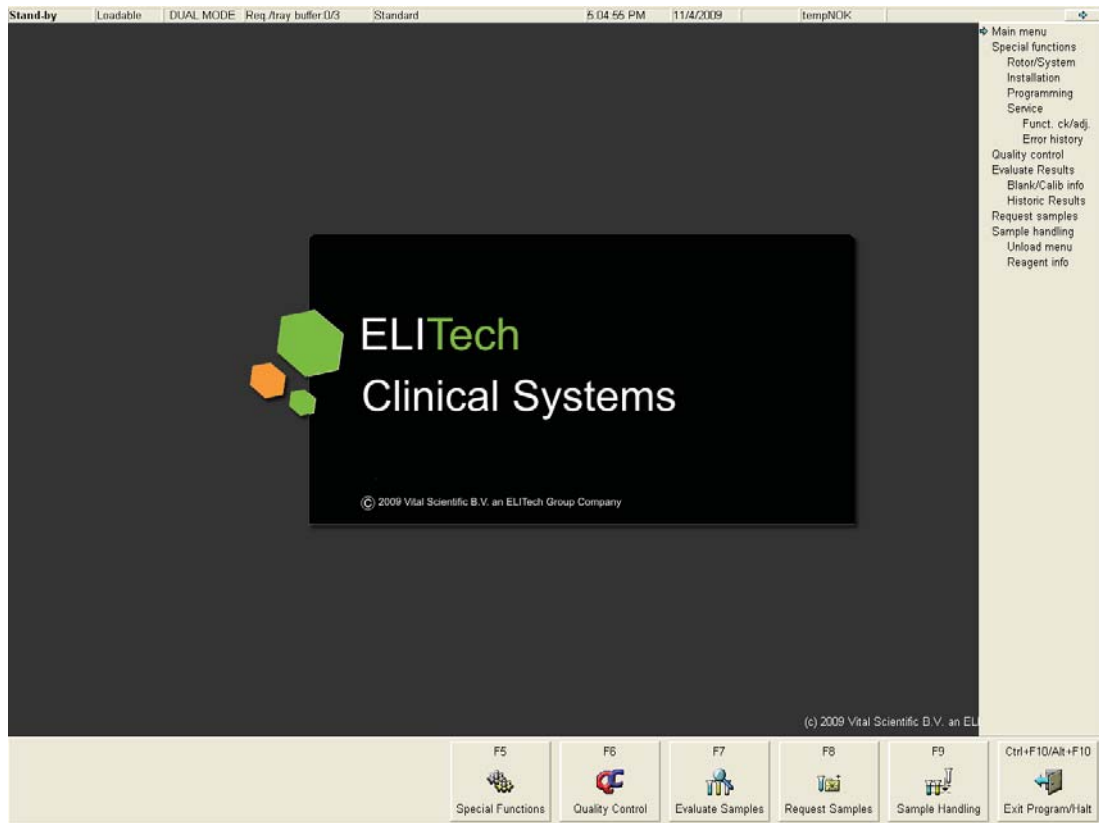
To activate a function, click on the function key with the mouse or press the corresponding function key on the keyboard. The available function keys and the functions linked to them change according to the main screen that is shown. Some functions remain the same on various screens. When the text on a function key is shown in grey and italics, the function is not available.



On some screens, several related functions are linked to the same function key. In this case, clicking the function key on the screen makes a short list of options appear, from which you can choose one using mouse or keyboard. These functions can also be chosen directly by using the modifier keys that are shown on the screen. Press the modifier key and the function key simultaneously on the keyboard.

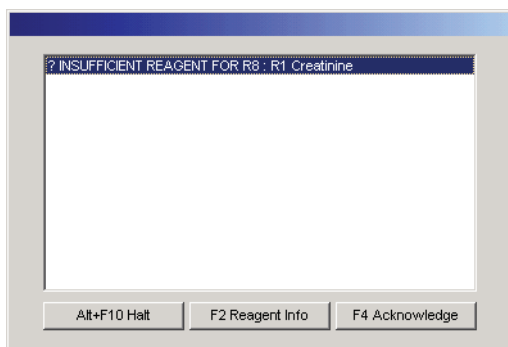
**Menu tree**

The menu tree can be opened and closed by clicking on the blue arrow on the far right of the status bar. When the menu tree is opened, it blocks part of the main screen area from view. The menu tree shows the available functions in the analyzer software. The current function is highlighted. Clicking on any of the functions in the menu tree makes the corresponding screen show up and the menu tree close again. Functions listed in grey cannot be selected.



### 4.1.3 Messages

If an error occurs in the analyzer an error message is shown. The message is accompanied by an acoustic signal. To switch off the acoustic signal press the spacebar.



All possible error messages and the actions to be taken are described in par. 5.6 and par. 7.2.2.



#### Note

The error message must be handled before you can continue working with the analyzer. Select one of the buttons to perform an action. Possible error messages and available buttons are listed in par. 5.6.



## 4.2 Screens, buttons and parameters

### 4.2.1 Overview of main screens

This paragraph contains a roadmap to the main screens in the user interface of the Selectra ProM. Some screens listed below are described as part of the procedures in chapter 5.

**Note**

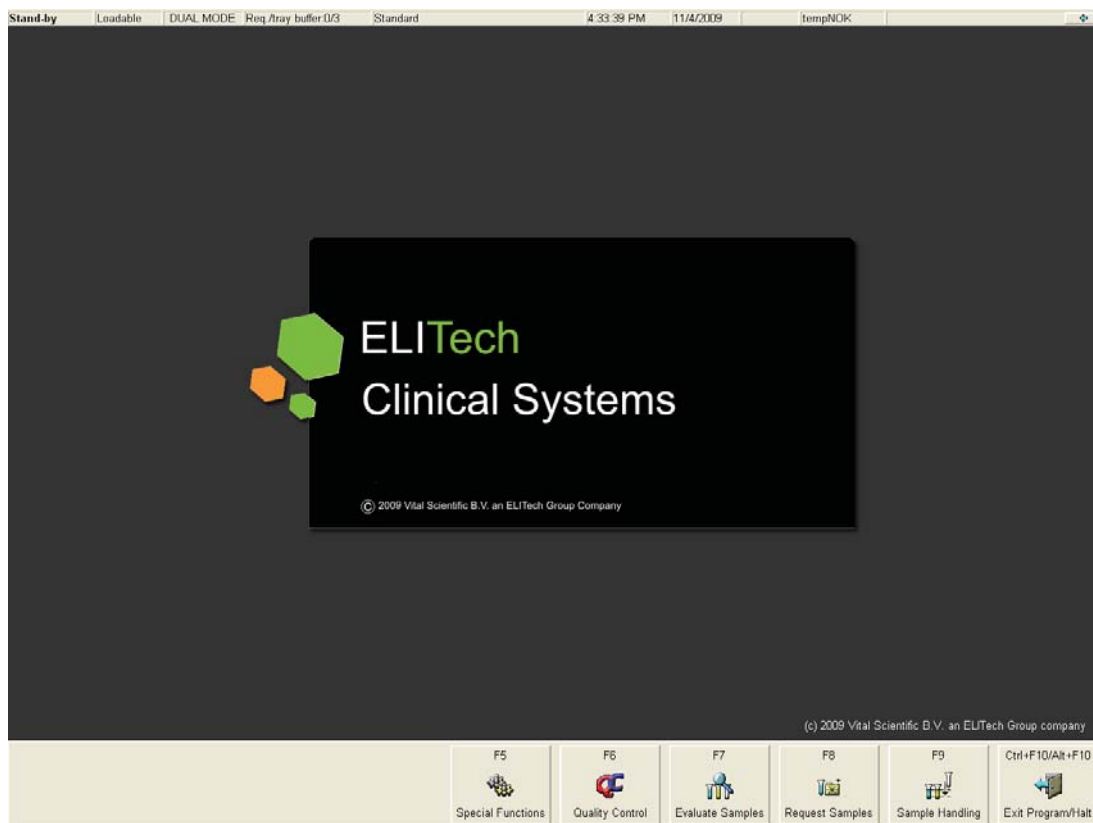
Some screens listed in this chapter may not be available to all users. This depends on security settings that may be defined in your analyzer. It is also possible that values on the screen can be viewed, but not changed without authorisation. If authorisation is required, a password dialog appears. See par. 6.5.7 for details on setting passwords.

**Note**

Some screens listed in this chapter show optional modules and functions that may not be available on your analyzer.

Screen	Description / actions to perform	See:
<i>Main menu</i>	Startup screen.	par. 4.2.2
<i>Request samples</i>	Identify samples and request tests.	par. 4.2.3
<i>Sample Handling</i>	Position samples and start measurements.	par. 4.2.4
<i>Selective Unload</i>	Unload some, but not all finished samples.	par. 5.3.6
<i>Reagent Info</i>	Check and refill reagents.	par. 4.2.7
<i>Evaluate Results</i>	View and archive measurement results.	par. 4.2.5
<i>Search Results</i>	Search and reload archived measurement results.	par. 5.5.2
<i>Result Details</i>	View and accept or reject individual test results.	par. 4.2.6
<i>Quality Control</i>	View results of control measurements.	par. 4.2.8
<i>Blank/Calib info</i>	View the status of reagent blanks and calibrations.	par. 4.2.9
<i>Display Calibration</i>	View and accept or reject calibration results.	par. 4.2.10

## 4.2.2 Main menu screen

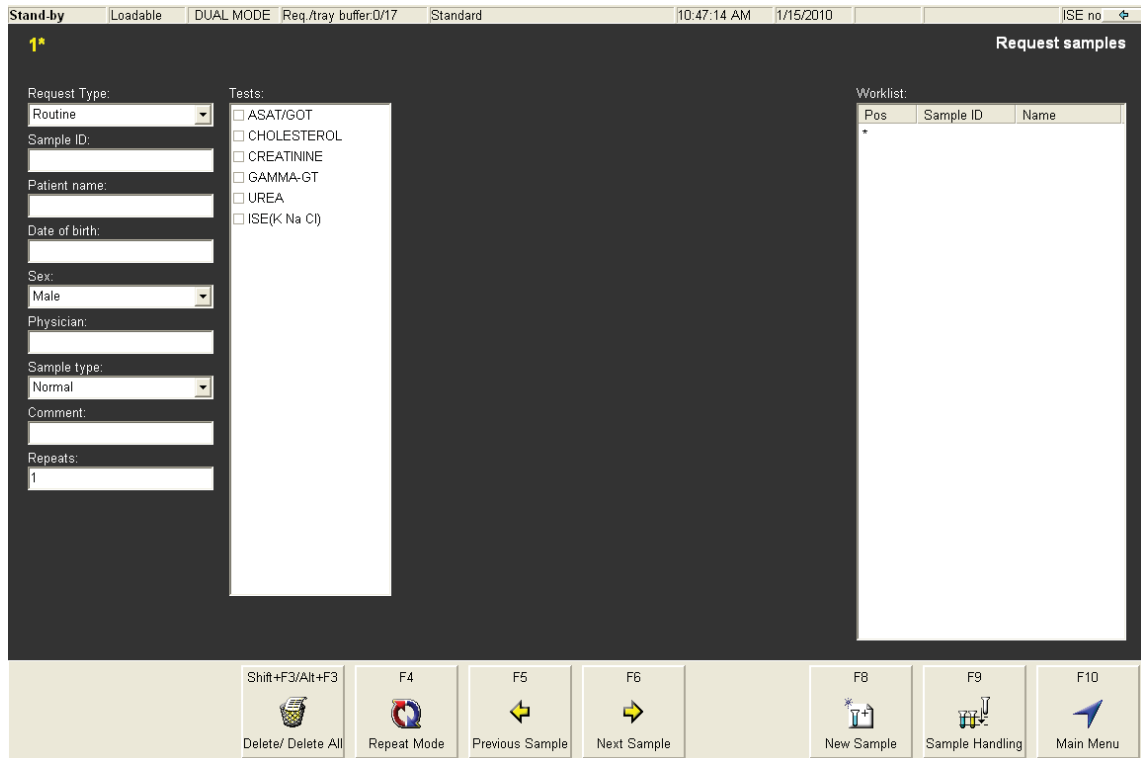


This screen is shown after start up of the Selectra ProM. You can always return to this screen by selecting the **Main menu** option in the menu tree. See par. 4.1.2.

### Function keys

Keys	Description	See also:
F5	Open the <b>Special Functions</b> screen.	par. 6.1.1
F6	Open the <b>Quality Control</b> screen.	par. 4.2.8
F7	Open the <b>Evaluate Results</b> screen.	par. 4.2.5
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Open the <b>Sample Handling</b> screen.	par. 4.2.4
Ctrl + F10	Exit the analyzer program.	par. 5.1.4
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

### 4.2.3 Request samples screen



This screen is used to define new samples, enter sample data and request tests for the samples. Sample data can be edited or deleted before the tests have started. For detailed procedures, see section 5.3.

#### Function keys

Keys	Description	See also:
F1	Print the worklist.	
Alt+F3	Delete all samples from the worklist.	
Shift+F3	Delete the selected sample from the worklist.	
F4	Switch <b>Repeat Mode</b> on or off.	
F5	Select the previous sample in the worklist.	
F6	Select the next sample in the worklist.	
F8	Save the current sample in the worklist.	
F9	Open the <b>Sample Handling</b> screen.	page 4-11
F10	Open the <b>Main menu</b> screen.	page 4-8
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

## Parameters

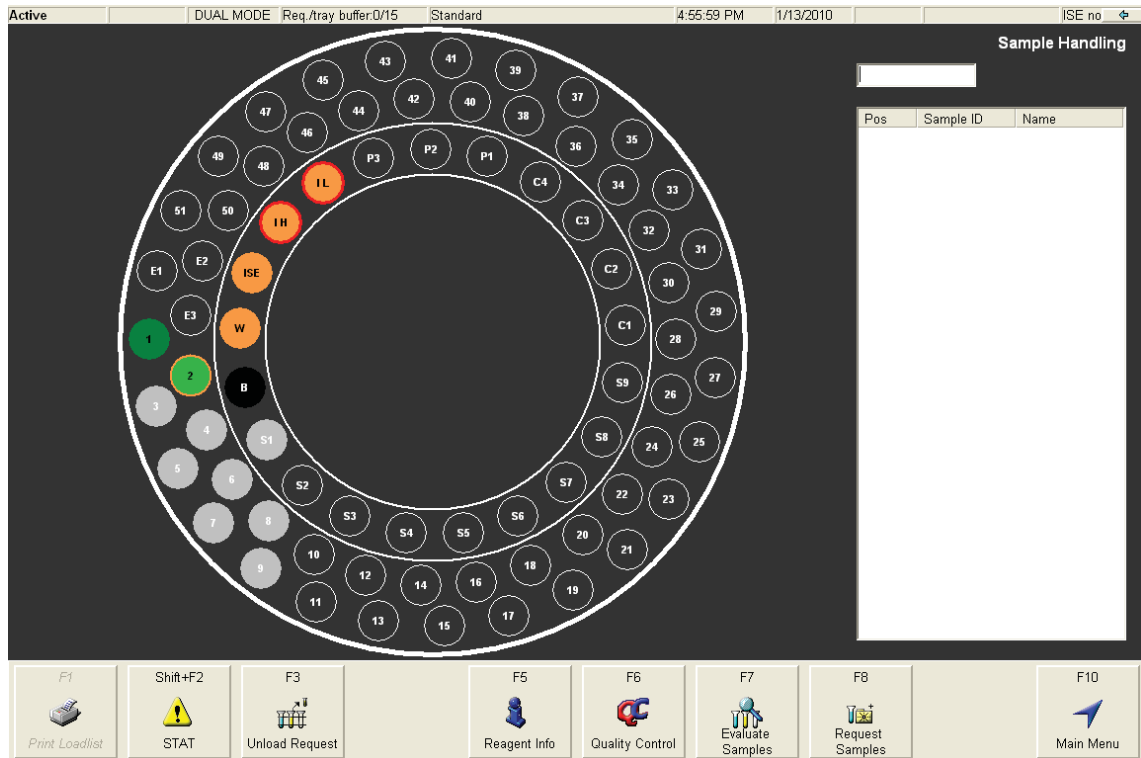
<b>Request Type:</b>	<ul style="list-style-type: none"> <li>• <b>Routine</b> - Normal samples.</li> <li>• <b>ASAP</b> - Priority samples, measured before <b>Routine</b> requests.</li> <li>• <b>STAT</b> - Emergency samples, measured immediately. See par. 5.4.1.</li> <li>• <b>Control</b> - Control measurements. See par. 5.4.3.</li> <li>• <b>Calibrate</b> - Calibrator measurements. See par. 5.4.2.</li> <li>• <b>Blank</b> - Blank measurements. See par. 5.4.2.</li> </ul>
<b>Sample ID:</b>	Unique identifier, 12 characters maximum (letters and numbers). The analyzer can automatically increment the Sample ID. See par. 6.5.1. The <b>Sample ID:</b> of a barcoded sample can also be read with the external barcode reader.
<b>Patient name: *</b>	Patient name or other identification for the sample.
<b>Date of birth: *</b>	Date format is defined in Windows regional settings.
<b>Sex:</b>	This choice determines which reference values are used to check the test results. See par. 6.2.2.
<b>Physician: *</b>	Default is the last entered name.
<b>Sample type:</b>	The sample types are defined in the <b>System Configuration</b> screen. They are used to set separate reference parameters for each type of sample (e.g. serum, urine, etc.). See par. 6.2.2.
<b>Comment:</b>	The comment appears on printed test reports for this sample.
<b>Repeats:</b>	Tests can be measured more than once. The average of all measurements is reported.
<b>Tests:</b>	Select tests, profiles and/or calculated tests to be performed on the sample. See par. 5.3.2.
<b>Sample blank</b>	Only appears if the <b>Sample blank:</b> option is set to <b>On request</b> in the test parameters.
<b>Worklist:</b>	List of requested samples. The position column will be filled when the samples are loaded (see par. 5.3.3).

\* Optional. It is not necessary to enter data in these fields to process a sample. Also, it is possible to redefine the labels for these fields, e.g. for use of the analyzer in a veterinarian laboratory. See chapter 6.5.2.

**ATTENTION**

Do not use a semi-colon (;) symbol in any of the fields. This causes failures in the communication with the LIS host.

### 4.2.4 Sample Handling screen



This screen is used to load samples, start measurements and unload samples. The rotor image on the screen shows the positions of samples. The colors show the state of the samples. The color codes are listed on the next page. The list shows all samples in the worklist. The background colors in the list show the status of the samples. The color codes are listed on the next page. For detailed sample handling procedures, see par. 5.3.3.

#### Function keys

Keys	Description	See also:
F1	Print the loadlist. This list contains all loaded samples.	
Shift + F2	Pause measurements to load a <b>STAT</b> sample.	par. 5.4.1
F3	Start measurements or continue after interruptions.	
F3	Pause measurements for loading or unloading of samples.	
F4	Confirm that all finished samples were unloaded. *	
F5	Open the <b>Reagent Loadlist</b> screen.	par. 4.2.7
F6	Open the <b>Quality Control</b> screen.	par. 4.2.8
F7	Open the <b>Evaluate Results</b> screen.	par. 4.2.5
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Unload specific finished samples. *	par. 5.4.1
F10	Open the <b>Main menu</b> screen.	par. 4.2.2
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

(\*) Only finished samples can be unloaded. Finished samples are shown as solid green circles on the rotor. Removing other samples will lead to errors.

### Parameters

<b>Pos</b>	Position assigned to the sample on the rotor.
<b>Sample ID</b>	Identifier of the sample. A letter in front of the sample ID shows the type of sample. Special sample types are always listed first. <ul style="list-style-type: none"> <li>• B: <b>Blank</b></li> <li>• S: <b>Calibrate</b></li> <li>• C: <b>Control</b></li> <li>• E: <b>STAT</b></li> <li>• P: <b>ASAP</b></li> </ul>
<b>Name</b>	The patient name as set in the <b>Request Samples</b> menu.

### Sample rotor positions

<b>1 - 51</b>	These positions are used for routine samples.
<b>B</b>	This position is reserved for reagent blank measurements. Place a sample tube with distilled water or saline solution.
<b>S1 - S9</b>	These positions are reserved for calibrators. If more positions are needed, the analyzer shows the positions to use.
<b>P1 - P6</b> (without ISE) <b>P1 - P3</b> (with ISE)	These positions are reserved for pediatric samples. The analyzer processes these samples before routine samples.
<b>E1 - E3</b>	These positions are reserved for <b>STAT</b> samples. The analyzer processes these samples with highest priority.
<b>C1 - C4</b>	These positions are reserved for controls. If more positions are needed, the analyzer shows the positions to use.
<b>W</b>	This position is reserved for the system cleaning solution. Place a sample tube with fresh system cleaning solution. A hypochlorite solution is recommended.
<b>ISE</b>	This position is reserved for the ISE activator. See the separate ISE documentation for details.

### Color codes for rotor positions

transparent, white border	The position is free and available for a new sample.
orange	The position is reserved, but not in use.
yellow	The sample is loaded but measurements have not started yet.
light grey	Measurements have started but the sample is not yet in process.
black	The sample is in process.
green	The sample is processed and the results are accepted.

green, green border	The result is available but the sample is still in process.
green, red border	The sample is processed but some results are not accepted.
green, white border	The position is selected to be unloaded.
yellow, green border *	The position is registered and the ID of the sample is recognized by the LIS host.
yellow, red border *	The position is registered but the ID of the sample is unknown to the LIS host.
light blue	The reagent bottle is full.
dark blue	The reagent bottle is empty.
grey	The position is free and available for a reagent bottle.

(\*) These color codes only occur when bi-directional communication with a LIS host computer is available and using the CLSI host protocol.

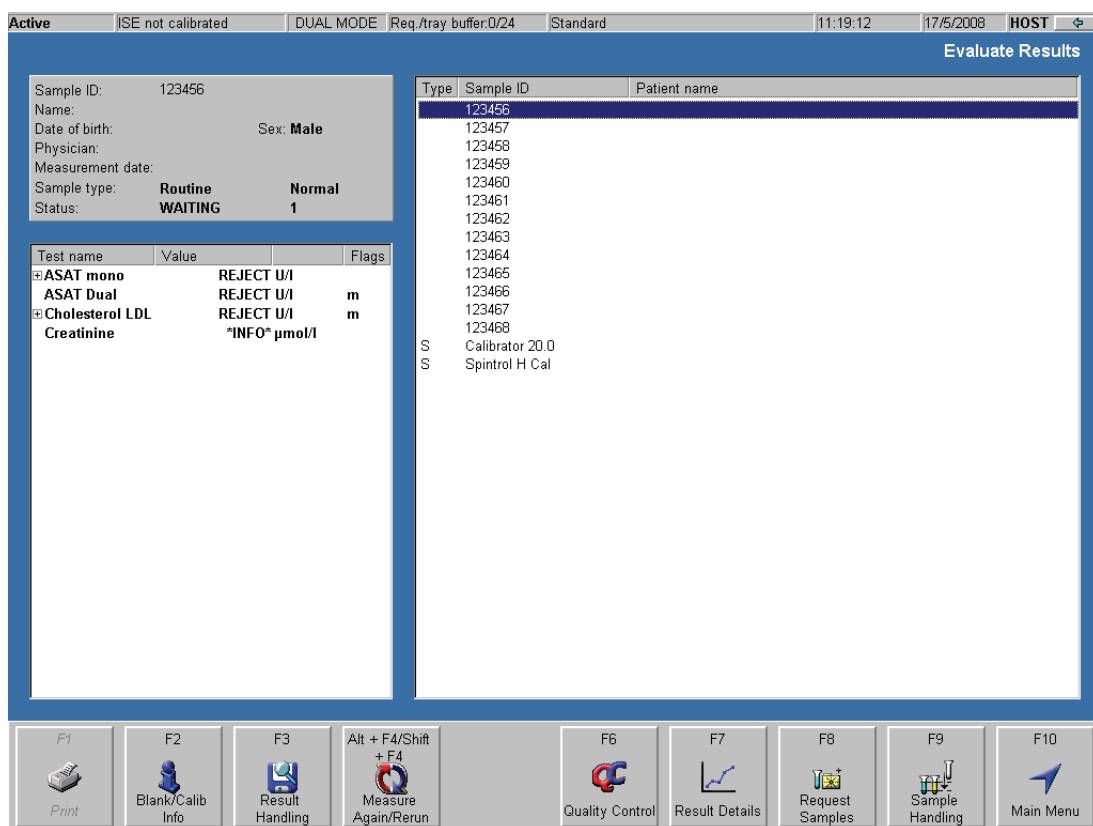
**Note**

Messages with status information show up when the mouse is moved over the sample and reagent positions on the screen.

**Color codes in the worklist**

white	The sample is not yet loaded.
yellow	The test is requested, but not yet started.
dark blue	The sample is selected but not yet assigned to a position. Pressing <b>Enter</b> assigns the position. If a calibrator consists of multiple standards, multiple lines are selected and assigned as if they were one sample.

## 4.2.5 Evaluate Results screen



The **Evaluate Results** screen shows test results. The list to the right shows all samples. The two sections to the left show details of the currently selected sample.

## Function keys

Keys	Description	See also:
F1	Print a report for the selected sample.	par. 6.6.1
Shift + F1	Print a custom report for the selected sample.	par. 6.5.5
F2	Open the <b>Blank/Calib info</b> screen.	par. 4.2.9
Ctrl + F3	Search and load results from the archives.	par. 5.5.2
Shift + F3	Save all results to an archive and empty the list.	par. 5.5.2
Alt + F3	Export all results to a file. The list is not changed.	par. 5.5.3
Shift + F4	Rerun all tests for the selected sample, using the rerun volumes as specified in the test parameters.	
Alt + F4	Rerun all tests for the selected sample, using the original volumes as specified in the test parameters.	
F6	Open the <b>Quality Control</b> screen.	par. 4.2.8
F7	Open the <b>Result Details</b> screen for the selected sample.	par. 4.2.3
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Open the <b>Sample Handling</b> screen.	par. 4.2.3
F10	Open the <b>Main menu</b> screen.	par. 4.2.2



Keys	Description	See also:
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

**Parameters - samples list**

<b>Type</b>	Type of sample: E ( <b>STAT</b> ), P ( <b>ASAP</b> ), B ( <b>Blank</b> ), C ( <b>Control</b> ) or S ( <b>Calibrate</b> ). For <b>Routine</b> samples, no type is listed.
<b>Sample ID</b>	Identifier of the sample. For controls and calibrators, the name of the control or calibrator is listed.
<b>Patient name</b>	Name of the patient.

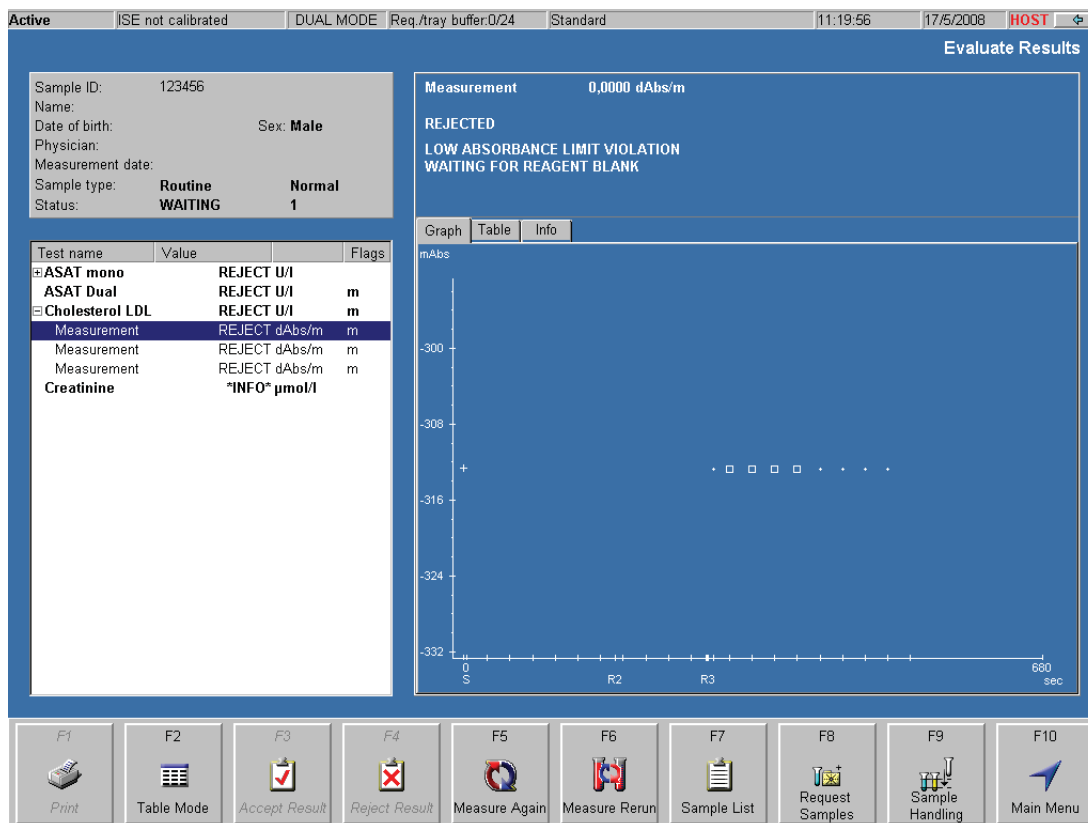
**Parameters - sample details**

<b>Sample ID:</b>	Identifier of the sample. For controls and calibrators, the name of the control or calibrator is listed.
<b>Name:</b>	Copied from the sample data.
<b>Date of birth:</b>	Copied from the sample data.
<b>Sex:</b>	Copied from the sample data.
<b>Physician:</b>	Copied from the sample data.
<b>Measurement date:</b>	Date and time when the sample was measured.
<b>Sample type:</b>	Type of sample that was measured.
<b>Status:</b>	Status of the sample. This can be one of the following: <ul style="list-style-type: none"> <li>• <b>IN PROCESS</b> - The sample is being processed. The result of at least one test is pending.</li> <li>• <b>CANCELLED</b> - The sample is loaded, but the test request is cancelled. The sample will not be processed and results will not be calculated.</li> <li>• <b>READY</b> - The sample was fully processed. All results are available.</li> <li>• <b>UNLOADED</b> - The sample was unloaded.</li> <li>• <b>WAITING</b> - The test cannot be performed. The reason for waiting is shown in the result details. See par. 4.2.6.</li> </ul>
Position (on the right of <b>Status</b> )	Position on the rotor. If the sample was unloaded, the position field is empty.

**Parameters - test details**

<b>Test name</b>	Names of the tests that were performed for the sample.
<b>Value</b>	Result of the measurement. When the word <b>*INFO*</b> is shown next to the result, it must be validated. See par. 5.3.5.
<b>Flags</b>	Possible error flags for the result. See par. 5.6.2.

4.2.6 **Result Details** screen



The **Result Details** screen shows detailed test results. The section to the right shows all measurement points in a graph or a table.

**Function keys**

Keys	Description	See also:
F1	Print a report for the selected sample.	par. 6.6.1
F2	Toggle between graphic, table and info views.	
F3	(Only for <b>*INFO*</b> results) Accept the test result.	par. 5.3.5
F4	(Only for <b>*INFO*</b> results) Reject the test result.	par. 5.3.5
F5	Rerun the test, using the original volumes as specified in the test parameters.	par. 5.3.5
Shift+F5	View the test parameters.	par. 6.2.2
F6	Rerun the test, using the rerun volumes as specified in the test parameters.	par. 5.3.5
F7	Return to the <b>Evaluate Results</b> screen.	par. 4.2.5
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Open the <b>Sample Handling</b> screen.	par. 4.2.4
F10	Open the <b>Main menu</b> screen.	par. 4.2.2
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4



## Table

The table shows the test results for all measurement points. Arrows in front of the measurements show that they are used in the calculation of the test result. In the prozone table, the arrows show the measurements used in the prozone check. The last column of the table shows additional information which is shown only in case of a reagent absorbance deviation error or a substrate depletion error.

2 points used		-0.1009 dAbs					
Point[sec]	Value	Point[sec]	Value	Point[sec]	Value	Point	Value
-4	↔ 1.4353	209	1.2875	386	1.1457	RAD	0.500
-4	1.4354	236	1.2631	413	1.1265	+	1.4353
24	1.4591	262	1.2407	439	1.1097	X	1.4328
50	1.4344	280	1.2247	466	1.0929	RAD limit	0.9353
77	1.4086	280	1.2243	492	1.0763		
103	1.3835	289	1.2183	519	1.0598		
130	1.3594	307	1.2045	680	0.9737		
156	↔ 1.3344	333	1.1851	680	0.9735		
183	1.3089	360	1.1657				

Measurement date: 08/03/2010 08:51:39

<b>RAD</b>	Reagent absorbance deviation. This parameter is set in the <b>Absorbance limits</b> section of the <b>Test programming</b> screen, on the second page. See par. 6.2.2.
<b>SD</b>	Substrate depletion. This parameter is set in the <b>Absorbance limits</b> section of the <b>Test programming</b> screen, on the second page. See par. 6.2.2.
<b>+</b>	Measurement of the first reagent.
<b>×</b>	Extrapolated value.
<b>RAD limit</b>	Reagent absorbance deviation limit. Calculated reagent absorbance limit based on the reagent absorbance deviation and the measured reagent absorbance.
<b>SD limit</b>	Substrate depletion limit. Calculated substrate depletion limit based on the substrate depletion and the measured substrate depletion.

## Info

Depending on the type of test, the info shows the following details:

- Tests with reagents: used reagents with positions, batch numbers and expiry dates.
- ISE tests: details of the measurements.
- Calculated tests: formula used to calculate the test result.

## Prozone graph

The graph shows the points used for the prozone check calculations. See the description of the graph section for details. For details on the prozone check, see par. 3.3.1.

**Prozone table**

The table shows the measurements used for the prozone check calculations. See the description of the table section for details. For details on the prozone check, see par. 3.3.1.

## 4.2.7 Reagent Info screen

Pos name	description	batch no.	expiry date	ml	tests	tray	fill
1	R1 ASAT/GOT			25.0	96	0	
2	R2 ASAT/GOT			25.0	378	0	
3	R CHOLESTEROL			25.0	78	0	
4	R1 CREATININE			25.0	108	0	
5	R2 CREATININE			25.0	324	0	
6	R1 GAMMA-GT			25.0	96	0	
7	R2 GAMMA-GT			25.0	378	0	
8	R1 UREA			25.0	96	0	
9	R2 UREA			25.0	378	0	
10							
11							
12							
13							
14							
15							
16	NEEDLE RINSE			25.0			
17	HCL			25.0			
18							
19							
20							
21							
22	ISE CLEANER			25.0			
23	ISE CONDITIONER			25.0			
24	ISE DILUENT			25.0	72	0	
25							
26							
27							
28							
29							
30							
31							
32							

F1	Ctrl+F2/Shift+F2	F3	F4	F5	F6	F7	F8	F9	F10
	Confirm Refill					Counter Mode	Calibrators and controls		
Print		Unload Request	10 ml	25 ml	50 ml			Sample Handling	Return

This screen shows the loaded reagents with their batch numbers, expiry dates and estimated remaining volumes. See par. 5.2.2 for detailed procedures.

**Note**

In counter mode, the four columns to the right are replaced with one column showing the total number of tests performed since the last time the counters were reset.

**Function keys**

Keys	Description	See also:
F1	Print the list with reagent information.	
Ctrl + F2	Confirm that the selected reagent is filled.	
Shift + F2	Confirm that all reagents are filled.	
Alt + F3	Set all values in the <b>total test count</b> column to zero.	
F3	Pause measurements for loading or unloading of samples. Wait until the state of the analyzer is <b>Loadable</b> . Do not open the cover before the <b>Loadable</b> state has been reached.	
F4	Set the bottle size of the selected reagent to 10 ml.	
F5	Set the bottle size of the selected reagent to 25 ml.	
F6	Set the bottle size of the selected reagent to 50 ml. *	par. 6.3.1
F7	Switch between <b>Counter Mode</b> and <b>Normal Mode</b> .	
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Open the <b>Sample Handling</b> screen.	par. 4.2.4

Keys	Description	See also:
F10	Open the <i>Main menu</i> screen.	par. 4.2.2
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

\* This is only possible in certain rotor positions, as the bottle takes up two positions in the rotor.

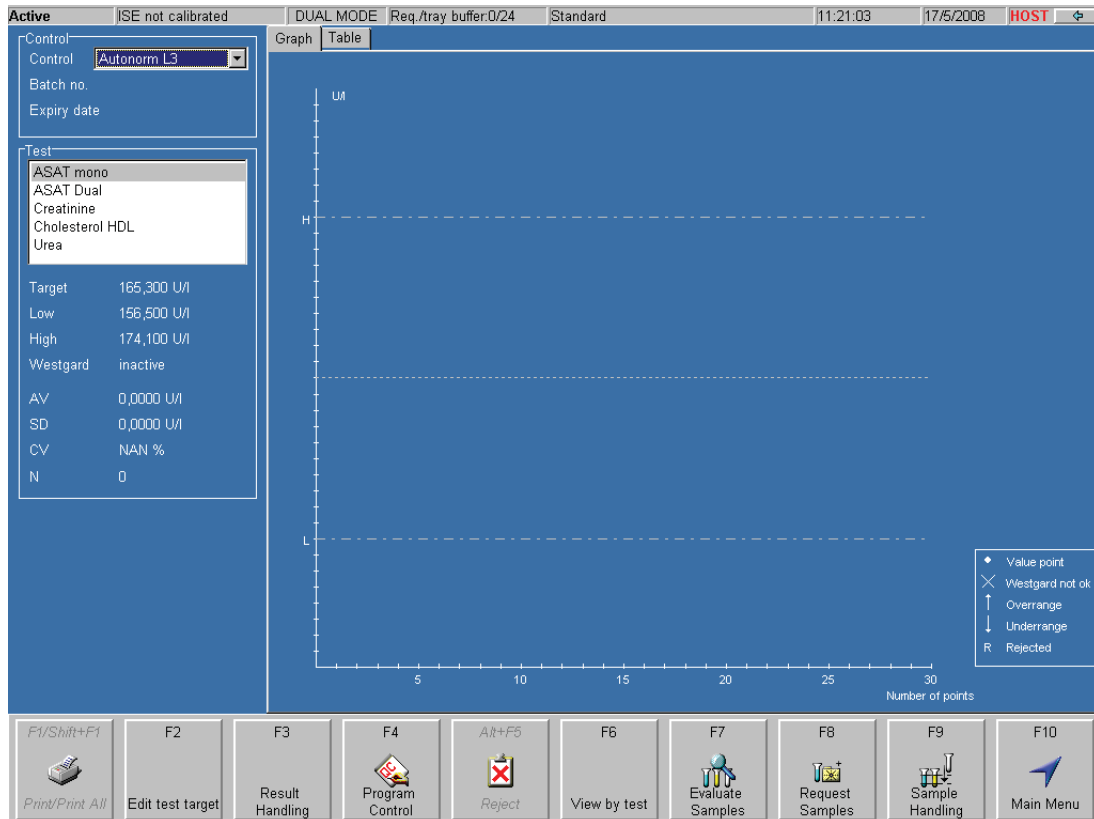
### Parameters

<i>Pos</i>	Position on the rotor.
<i>name</i>	Name of the reagent. R2 is the second reagent. R3 is the third reagent.
<i>description</i>	Comment text.
<i>batch no.</i>	Batch number of the reagent.
<i>expiry date</i>	Expiry date of the reagent.
<i>ml</i>	Calculated remaining reagent volumes.
<i>tests</i> *	Number of tests that can be performed with the calculated remaining reagent volume.
<i>tray</i> *	Number of tests currently requested with this reagent.
<i>fill</i> *	A red dot shows a shortage of the reagent and a refill is necessary to perform the current test. A yellow dot shows there is not enough reagent to perform all the requested tests.
<i>total test count</i> **	Number of tests performed with the reagent since the last time the counters were reset.

\* Only visible in normal mode.

\*\* Only visible in counter mode.

### 4.2.8 Quality Control screen



This screen shows the status of control measurements. The information should be checked after performing control measurements. See chapter 5.4.3.

#### Function keys

Keys	Description	See also:
F1	Print the measurement results of the currently selected control/test combination.	
Shift + F1	Print all measurement results of the selected test/control. *	
F2	Edit the target values for the control/test combination.	par. 6.2.4
Shift + F3	Clear all results for the control/test combination.	
Ctrl + F3	Export all results for the control/test combination.	
F4	Open the <b>Program control</b> screen.	par. 6.2.4
Alt + F5	Reject the currently selected measurement results.	
F6	Switch between viewing all tests for a selected control or viewing all controls for a selected test.	
F7	Return to the <b>Evaluate Results</b> screen.	par. 4.2.5
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Open the <b>Sample Handling</b> screen.	par. 4.2.4
F10	Open the <b>Main menu</b> screen.	par. 4.2.2
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4



\* Depending on the choice to view results by test or by control.

### Parameters

<b>Control</b>	Control for which test measurements are shown. The control is either selected from a list box (viewing results by control) or from the list below the test name (viewing results by test).
<b>Name</b>	Test for which control measurements are shown. The test is either selected from a list box (viewing results by test) or from the list below the control name (viewing results by control).
<b>Batch no.</b>	Batch number of the control.
<b>Expiry date</b>	Expiry date of the control.
<b>Target</b>	Target for measurement of this control/test combination.
<b>Low</b>	Lower limit for this measurement.
<b>High</b>	Upper limit for this measurement.
<b>Westgard</b>	Whether or not the <b>Westgard</b> rules were active. This option is set in the control parameters. For an explanation of these rules, see par. 3.3.3.
<b>AV</b>	Mean of all measured values.
<b>SD</b>	Standard deviation over the measured values.
<b>CV</b>	Coefficient of variation of the measured values in %.
<b>N</b>	Number of control measurements performed.

Details about the test results are given in par. 5.3.5.

4.2.9 *Blank/Calib info* screen

Checking status   SE Param Sync   DUAL MODE   Req./tray buffer:0/13   Standard   12:39:05   18/5/2008   HOST						
Blank/Calib info						
Test name	Reagent blank		Calibrator			
	Value	Meas. date	Accepted	Meas. date	Valid for(days)	Calibration type
ASAT mono			Yes	17/5/2008	Not valid	Multi point-Smoothed cubic spline
ASAT Dual						
Cholesterol LDL		Not measured				
Creatinine		Not measured	No			One point
Cholesterol HDL		Not measured	No			One point
Cocaine			No			One point - Cut-off
HDL chol						
LDL CHOL						

F1 Print	F2 Display Calibration	F6 Quality Control	F7 Evaluate Samples	F8 Request Samples	F9 Sample Handling	F10 Main Menu
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This screen shows the status of reagent blank and calibration measurements. The information on this screen should be checked as part of the start-of-day procedure. See par. 5.2.3.

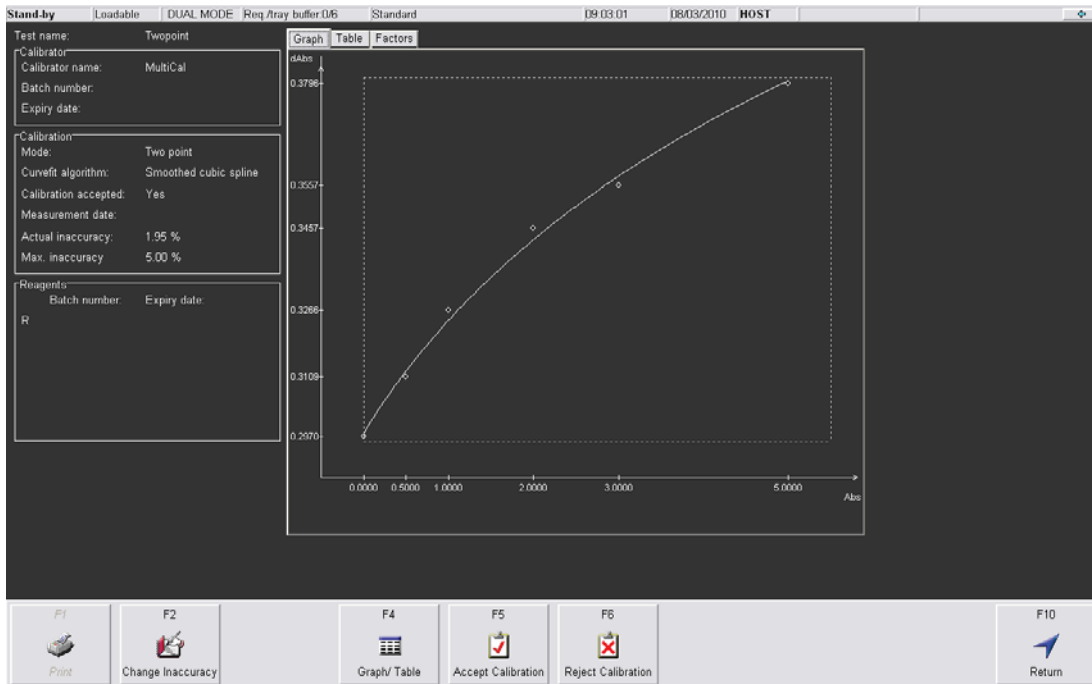
## Function keys

Keys	Description	See also:
F1	Print the list with reagent blank and calibration information.	
F6	Open the <b>Quality Control</b> screen.	par. 4.2.8
F7	Return to the <b>Evaluate Results</b> screen.	par. 4.2.5
F8	Open the <b>Request samples</b> screen.	par. 4.2.3
F9	Open the <b>Sample Handling</b> screen.	par. 4.2.4
F10	Open the <b>Main menu</b> screen.	par. 4.2.2
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

**Parameters**

<b><i>Test name</i></b>	The name of the test as defined in the test parameters.
<b><i>Reagent blank</i></b>	The last measured reagent blank:
• <b><i>Value</i></b>	• Value of the reagent blank.
• <b><i>Meas. date</i></b>	• Date of measurement.
<b><i>Calibrator</i></b>	The last measured calibration:
• <b><i>Accepted</i></b>	• Calibrator is accepted or rejected.
• <b><i>Meas. date</i></b>	• Date of measurement.
• <b><i>Valid for(days)</i></b>	• Calibrator is still valid for this number of days.
• <b><i>Calibration type</i></b>	• Kinetic, endpoint, cut-off, two point or multi-point. This also shows the calibration method used, if applicable.

4.2.10 Accept Calibration screen



This screen shows the result of calibration measurements. The screen is shown when a calibration is performed and the result requires your attention. See par. 5.2.3.

Function keys

Keys	Description	See also:
F1	Print the calibration details.	
F4	Toggle between graphic and table views.	
F5	Accept the calibration.	
F6	Reject the calibration.	
F10	Return to the previous screen.	
Alt + F10	Halt the analyzer program immediately (emergency stop).	par. 5.1.4

Parameters

The parameters shown are for information only. The settings for the calibration can be changed in the test parameters. See par. 6.2.5.

- Test name:** The test for which the calibration was done.
- Calibrator name:** Name of the calibrator that was used.
- Batch number:** Batch number of the calibrator that was used.
- Expiry date:** Exiry date of the calibrator that was used.
- Mode:** Type of the test for which the calibration was done.
- Curvefit algorithm:** Algorithm used to determine the calibration result.

<b>Calibration accepted:</b>	Calibration may be accepted automatically or manually.
<b>Measurement date:</b>	Date and time of the calibration measurement.
<b>Reagents</b>	Batch numbers and expiry dates of reagents and diluents for this test.

### **Graph**

The graph shows the calibration measurement points. The X-axis shows the timing of measurements. The Y-axis shows the measured absorbances.

### **Table**

The table shows the test results for the calibration measurement. Arrows in front of the measurements show that they are used in the calculation of the test result.

### **Factors**

This table shows the factors calculated for the calibration.



## Everyday usage

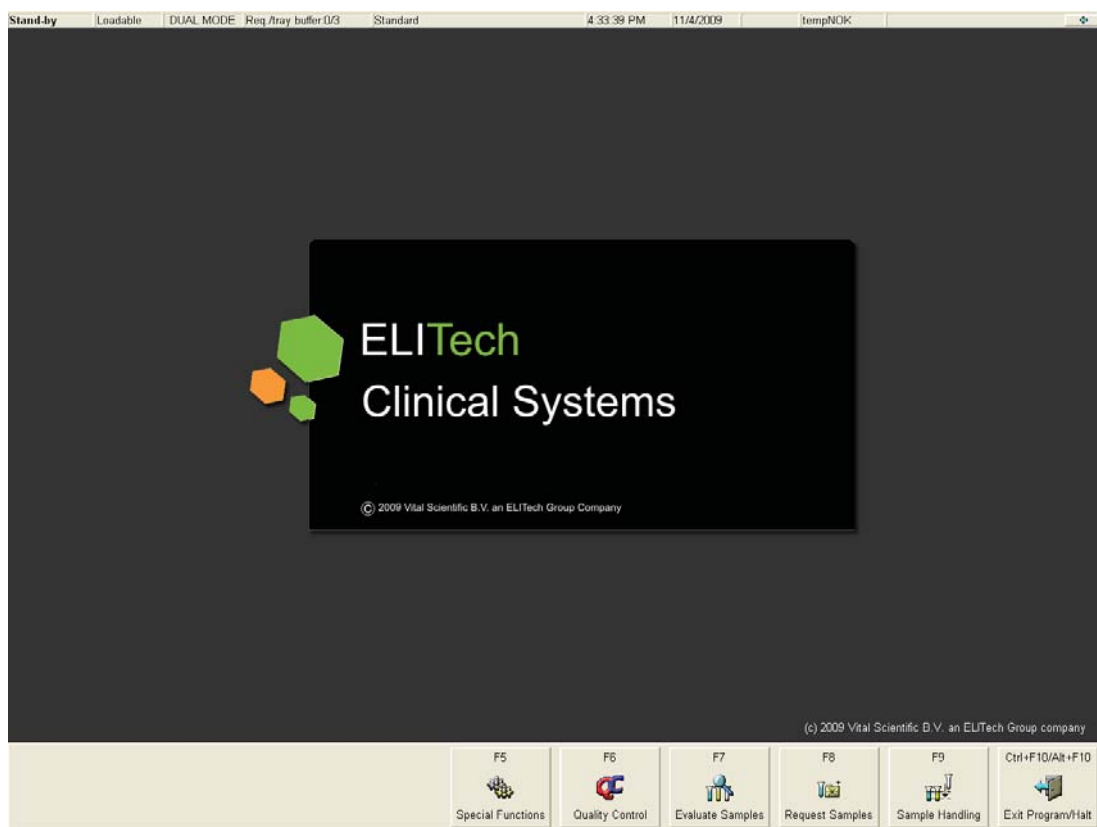
## 5.1 Startup and shutdown procedures

### 5.1.1 Switching the analyzer on

**Note**

Vital Scientific recommends that the analyzer is kept switched on always. A number of automatic procedures are performed every day outside working hours, see par. 7.1.2.

1. Make sure it is safe to switch on the analyzer. The analyzer must be clean and dry. All cabinet doors and covers must be closed.
2. Push the power switch at the back to the ON position.
3. Switch on the computer of the analyzer. When the operating system has started, double-click the Analyzer symbol on the desktop. After initialization of the software, the main screen is shown.

**Note**

The screen may look different on your screen, depending on the display settings, the type of analyzer and the software version installed. For a description of the main sections of the screen, see par. 4.1.2.



### 5.1.2 Start-of-day procedure

**Note**

Vital Scientific recommends using the following start-of-day procedure. Your laboratory may have defined its own procedure. When in doubt about the following procedure, please consult your superior.

1. Make sure the waste container is emptied.

**BIOHAZARD**

Fluids in the waste container are potentially infectious. These fluids must be handled with great care. Clean up spills immediately. Use applicable procedures to discard the fluids from the waste container.

2. Make sure the water container is filled. Fill if needed.

**Note**

Use 400 parts water with 1 part system solution. Use distilled or purified water (at least ASTM type II grade water).

3. Check the syringes for air bubbles. Replace syringes if needed. See par. 7.3.4.
4. Remove the cover from the cuvette rotor. Visually inspect the cuvette rotor and stirrer belts. Replace stirrer belts if needed, see par. 7.1.6. Reposition the cover.
5. Open the **Rotor/System** screen of the **Special Functions** menu. Run the **Fill System** procedure.
6. Check if cuvette blanks were performed. Check results. See par. 7.1.4.

**Note**

It is recommended to print a maintenance report as part of the start-of-day procedure. The report gives an overview of the cuvette blank status and of the expiry dates for calibration measurements, reagents, calibrators and controls. The button to print the maintenance report is shown in the **Blank rotor** screen. See par. 7.1.3.

7. Check if reagents are filled and not expired. See par. 5.2.2.
8. Check reagent blanks and calibrators. Perform reagent blanks and calibrations when required. See par. 5.2.3.
9. Perform daily routine controls as required.

### 5.1.3 End-of-day procedure

**Note**

Vital Scientific recommends using the following end-of-day procedure. Your laboratory may have defined its own procedure. When in doubt about the following procedure, please consult your superior.

1. Make sure all measurements are performed.
2. Archive measurement results. See par. 5.5.2.
3. Make sure all samples are ready to be unloaded. Unload all samples.
4. Depending on your laboratory standard operating procedures, it may be required to unload and store all reagents.
5. Make sure the water container is filled. Fill if needed.

**Note**

Use 400 parts water with 1 part system solution. Use distilled or purified water (at least ASTM type II grade water).

6. Empty the waste container.

**BIOHAZARD**

Fluids in the waste container are potentially infectious. These fluids must be handled with great care. Clean up spills immediately. Use applicable procedures to discard the fluids from the waste container.

### 5.1.4 Switching the analyzer off

**Note**

Vital Scientific recommends that the analyzer is kept switched on always. A number of automatic procedures are performed every day outside working hours, see appendix 7.1.2.

There may be various reasons for switching the analyzer off. The following sections describe the recommended procedures in standard cases.

**Note**

The procedures listed here are recommendations by Vital Scientific. There may be other procedures that must be used, as defined by your laboratory.

#### Switching off without emergency

1. Wait until all measurements are finished.
2. Unload all samples.
3. Unload all reagents and store them, according to the laboratory procedures.
4. Open the **Main menu** screen. This screen is available in the menu tree.
5. Click **Ctrl+F10 Shut Down**.
6. Wait until the message "it is now safe to switch off the computer" appears on the screen.
7. Switch off the computer.
8. Push the power switch in the back of the analyzer to the OFF position.

**ATTENTION**

If you are planning on storing or moving the analyzer, special precautions must be taken. See par. 7.3.6.

#### Performing an emergency stop

Press **Alt+F10** on the keyboard. The analyzer immediately stops any actions. This works from any screen in analyzer software.

**WARNING**

The power supply to the analyzer is NOT switched off when an emergency stop is performed. To make sure the electric power is interrupted, remove the power cable from the back of the analyzer.

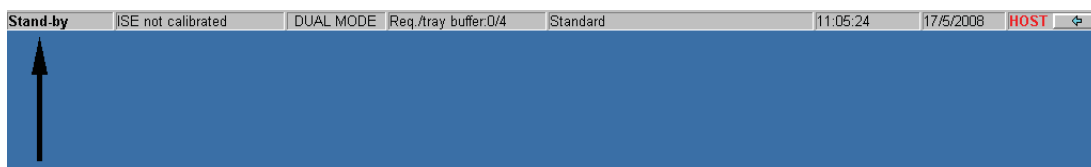
After performing an emergency stop, the following procedure must be followed to restore the analyzer to normal working condition.

1. Make sure the dangerous situation (the reason for the emergency stop) is resolved.
2. Open the **Rotor/System** screen. This screen is listed in the menu tree.
3. Click **F1 Reset System**. The analyzer performs the reset procedure.
4. Wait until the analyzer status in the top left of the screen shows **Stand-by**.
5. Rerun or abort interrupted tests.

## 5.2 Routine checks and procedures

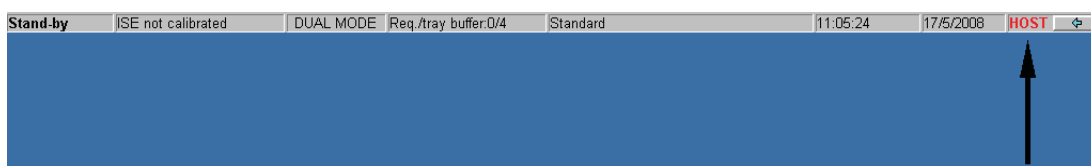
### 5.2.1 Checking the state of the analyzer and optional modules

#### Analyzer state



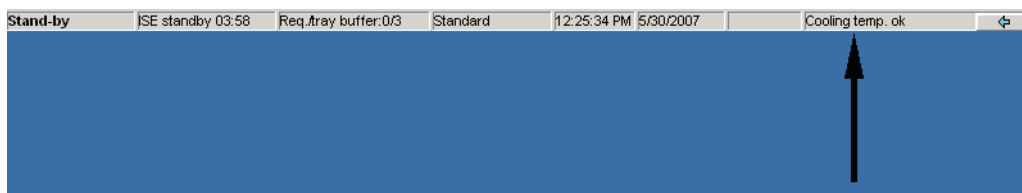
State	Description / action to perform	See:
<b>Active</b>	Measurements are being performed. Wait until the <b>Stand-by</b> state is reached.	
<b>Blanking</b>	A cuvette blank is being performed. Wait until the <b>Stand-by</b> state is reached.	
<b>Cleaning</b>	A clean system command was given. Do not interfere.	par. 7.1.5
<b>Emptying</b>	An empty system command was given. Do not interfere.	
<b>Filling</b>	A fill system command was given. Do not interfere.	
<b>Inactive</b>	An emergency stop was performed. Reset the analyzer.	par. 5.1.4
<b>Loadable</b>	Measurements are finished. The cuvette rotor is being washed. It is OK to load samples and unload finished samples. (This is a substate of the <b>Active</b> or <b>Stand-by</b> state.)	par. 5.3.6
<b>Resetting</b>	A reset command was given. Wait until the <b>Stand-by</b> state is reached.	
<b>Stand-by</b>	Ready to accept commands.	
<b>Stopping</b>	A load/unload command was given during measurements.	par. 5.4.1

#### LIS host connection



State	Description / action to perform	See:
<b>HOST</b> (in black)	Host connection is OK.	
<b>HOST</b> (in red)	Host connection is lost. Contact your technical support department.	par. 6.6.2
(empty)	Host connection is not configured. If required, the host connection must be configured.	par. 6.6.2

**Cooling unit temperature**



State	Description / action to perform	See:
<b>Cooling unit Error</b>	The cooling unit on the reagent rotor is <ul style="list-style-type: none"> <li>• not installed, or</li> <li>• not working OK.</li> </ul> Contact your technical support department.	
(empty)	The cooling unit on the reagent rotor is working OK. No further action is required.	

## 5.2.2 Checking and refilling reagents

1. Open the **Reagent Loadlist** screen. This screen is listed in the menu tree. The screen shows all reagents that are currently placed on the analyzer. See par. 4.2.7 for details.

Pos	name	description	batch no.	expiry date	ml	tests	tray	fill
R1	R1 Cocaine				25.0	130	0	
R2					25.0			
R3					25.0			
R4	R1 ASAT				25.0	96	3	
R5								
R6	R1 Cholesterol				25.0	78	10	
R7								
R8	R1 Creatinine				25.0	133	11	
R9								
R10	R1 Ureum				10.0	31	11	
R11								

2. Check the expiry date for each reagent. Program if not present. If the expiry date for a reagent is in the past, perform the following procedure:
  - 2.1. Discard the reagent. Place a fresh bottle with new reagent in the same position.
  - 2.2. Change the expiry date for the replaced reagent. Click in the expiry date field. Enter the new expiry date. The expiry date is available on the package insert of the reagent.



### Note

By scanning the barcode on the reagent bottle that will be placed, the expiry date and batch number of the fresh reagent will be automatically updated.

3. Check the available reagent volumes. Reagents that are running low have a yellow or red dot in the **fill** column to the far right. The **tray** column shows how many tests can be performed with the remaining reagent volume.
4. Refill reagents as required:
  - 4.1. Select the reagent you want to refill. Click on the row in the table. The selected row is marked by a dark blue background.
  - 4.2. Refill the reagent to the bottle volume.
  - 4.3. Click **Ctrl+F2 Confirm Refill**. The volume is changed to the bottle volume. The number of tests that can be performed is calculated and shown in the **tray** column.
5. (Option) Refill all reagents:
  - 5.1. Refill all reagents to the bottle volume.
  - 5.2. Click **Shift+F2 Confirm Refill All**. The volume for all reagents is changed to the bottle volume. The number of tests that can be performed is calculated and shown in the **tray** column.



### Note

The analyzer assumes that reagents are filled to the bottle volume. The available volume of reagent is not measured but calculated.



### ATTENTION

Do not overfill the reagent bottles. If there is too much reagent in the bottle, the analyzer cannot correctly determine the volume that is aspirated. Pipetting of the reagent will stop. An error message will be shown.

### 5.2.3 Checking reagent blanks and calibrators

1. Open the **Blank/Calib info** screen. This screen is listed in the menu tree. The screen shows the last reagent blank and calibrator measurements that were performed by the analyzer. See par. 4.2.9.

Test name	Reagent blank		Calibrator			
	Value	Meas. date	Accepted	Meas. date	Valid for(days)	Calibration type
ASAT						
Cholesterol	0.7137 [Abs]	5/30/2007	Yes	5/30/2007	1	One point
Creatinine		Not measured	Yes	5/30/2007	1	One point
UR						
Gamma-GT						
Cocaine			No			Multi point-Standard cubic spline
HDL						
Triglyceride						

2. (Optional) Click **F1 Print** to send a report to the printer. The report contains the same information that is shown on the screen.
3. Perform reagent blank and/or calibration measurements as required. See par. 5.4.2.

### 5.2.4 Replacing rotors

The reagent rotor of the Selectra ProM has 32 reagent positions: 24 for large bottles (25 ml) and 8 for small bottles (10 ml). If the number of reagents to be used in tests exceeds the available positions, more than one rotor can be used. If this option is used by your laboratory, you may have to replace the rotor before certain tests can be performed.



#### ATTENTION

The rotors do not have any physical marks or labels that identify them to the analyzer. When replacing rotors, make sure you are placing the correct rotor. Perform every step of the following procedure very carefully.

1. Wait until all current measurements are finished.
2. Unscrew the cover flange from the center of the rotor.
3. Carefully lift the rotor out of the analyzer. Store the rotor in a safe location.
4. Carefully lower the new rotor into the analyzer. Make sure that the white dot on the rotor lines up with the white dot on the driving axle [1]. When the rotor is in position, a notch on the rotor base [2] fits into a hole in the bottom of the rotor. Screw on the cover flange.



5. Open the **Installation** screen. This screen is listed in the menu tree.
6. Click **Change Reagent Disk** in the menu to the left. The screen shows the list of rotors that were defined for your analyzer.
7. Click on the new rotor in the list. The selected rotor is shown on a dark blue background. Make absolutely sure that this is the rotor you have just placed on the analyzer.
8. Click **F4 Change Reagent Disk**.  
The rotor configuration with all its reagent positions is activated. Tests for which the reagents are no longer available are disabled. Tests for which the reagents have now become available are enabled. This is also true for profiles. The name of the new rotor appears in the status bar.
9. Open the **Reagent info** screen. This screen is listed in the menu tree.
10. Check that all reagents are present. Check whether reagents require refilling.
11. You can now request tests that use reagents from the new rotor.



## 5.3 Performing measurements

### 5.3.1 Preparing samples

The analyzer needs more sample material than what is required for the measurements. A small amount of sample is aspirated before each test. This buffer sample removes any water that may line the interior wall of the sample probe. The buffer sample is discarded after every pipetting step. Also, a dead volume is left in the sample cups. This dead volume cannot be used, as the volume is not sufficient to accurately aspirate the remaining sample. When preparing samples, the oversampling and dead volume must be taken into account. Assuming that the analyzer is properly configured and the original tubes and sample cups are used, these are the required volumes:

Sample volume per test *	Buffer volume per test	Dead volume per tube **
2 - 10 µl	5 µl	250 µl
10 - 20 µl	10 µl	250 µl
20 - 30 µl	15 µl	250 µl

\* This is the total volume required for all tests to be performed on the sample.

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

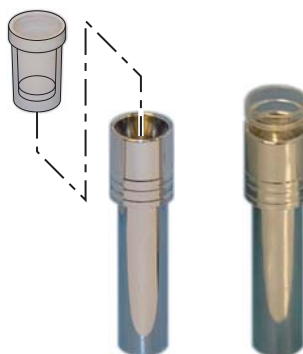
#### Using pediatric sample cups



#### ATTENTION

Only use pediatric sample cups with the silver pediatric adapter shown below. Do not use adapters other than described below.

Insert the pediatric cup into the silver pediatric adapter. The pediatric adapter can now be loaded in the same way as normal sample tubes.



#### Using gel tubes



#### ATTENTION

Gel tubes can only be used when the layer of liquid above the gel layer is at least 1 cm, otherwise the needle can get clogged (no error message is given). If the layer of liquid is less than 1 cm, use a secondary tube or pediatric sample cup.

### 5.3.2 Identifying samples and requesting tests



**Note**

If the analyzer is connected to a LIS host computer, the sample data is normally retrieved from that computer. In that case, the steps of identifying samples and requesting tests for the samples can be skipped.

1. Open the **Request samples** screen. The left part of the screen shows fields that are used to identify the sample.

2. Select the **Request Type:** from the list box:
  - **Routine** - This is the default sample type.
  - **ASAP** - The tests on the sample are done before all **Routine** samples.
  - **STAT** - The tests on the sample are done immediately. See par. 5.4.1.
  - **Blank** - A reagent blank measurement is performed. See par. 5.4.2.
  - **Control** - A control measurement is performed. See par. 5.4.3.
  - **Calibrate** - A calibrator measurement is performed. See par. 5.4.2.

3. Enter the **Sample ID:**.



**Note**

If the sample tubes have barcode labels, you can use the barcode reader to identify the sample. Click in the **Sample ID:** field. Scan the barcode. The number will appear on the screen.

4. Select the **Sample type:** from the list box.



**Note**

Further sample data are optional. They are not described here. See par. 4.2.3 for details.

5. (Optional) Choose the number of **Repeats:**. All tests for the sample will be repeated this number of times. The results of all tests are averaged.

6. Select the tests required for the sample from the **Tests:** list. Select a profile (shown in bold at the top of the list) to select all the tests in that profile. See par. 6.5.3. Click on a selected test to deselect it.

**Note**

You can use the barcode reader to select tests and/or profiles. The barcodes for these are listed on a chart with Codabar labels. See par. 1.2.10.

7. Click **F8 New Sample**. The sample is entered into the worklist. The fields are cleared for the next sample.

**Note**

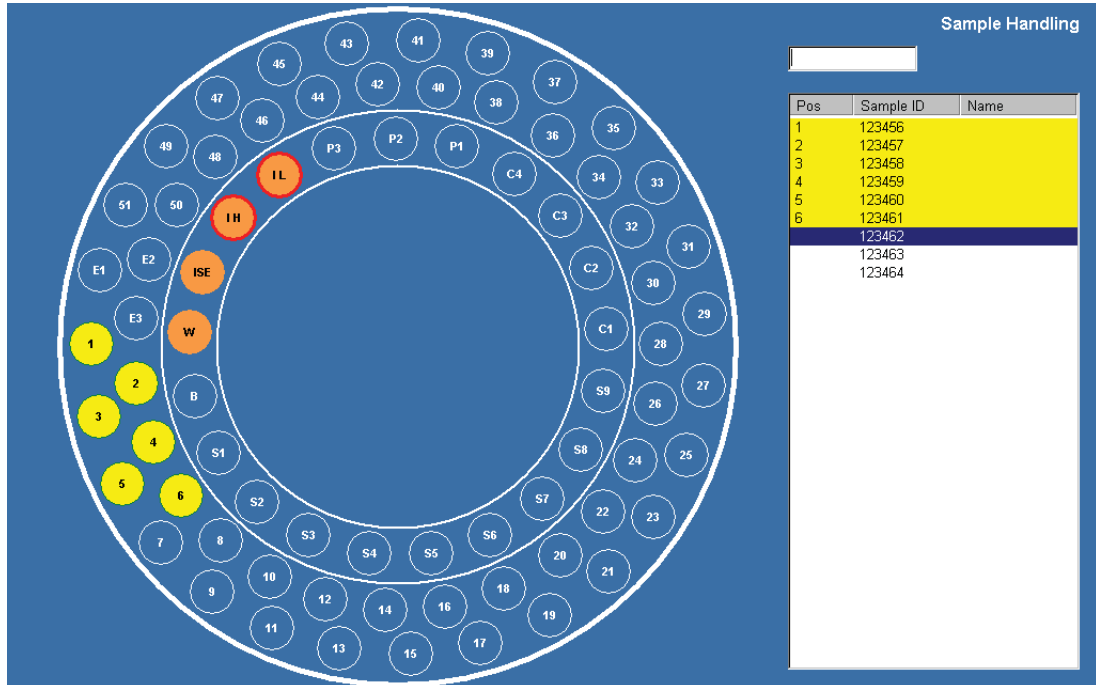
If **Repeat Mode** is switched on, the test selection is not cleared. This is useful when requesting the same selection of tests for a number of samples.

**Note**

The analyzer can automatically increment the **Sample ID**. This option is set in the **System parameters** screen. See par. 6.5.1.

### 5.3.3 Loading samples

1. Open the **Sample Handling** screen. The screen shows the sample rotor of the Selectra ProM. The list to the right shows the loadlist. The samples with a white background color are not yet loaded in the rotor.



2. Select the sample in the worklist. There are various ways to do this:
  - A Click on the sample in the list.
  - B Click in the empty field above the list. Enter the **Sample ID**: via the keyboard. The sample with matching ID is selected in the list.
  - C Scan the label on the sample tube. The sample with matching ID is selected in the list.
3. Select a position for the selected sample in the rotor. There are various ways to do this:
  - A Press the **Enter** key. The first available rotor position is selected for the sample.
  - B Right-click on the selected sample. A small dialog window opens. Enter the desired rotor position. Click **OK** to assign the position to the sample.



#### Note

When a rotor position is assigned to the sample, the next sample in the worklist is automatically selected.

4. Place the sample tube in the assigned rotor position.

**ATTENTION**

Once a sample is identified and its rotor position is selected, it should be placed in that position immediately. This avoids mistakes that would lead to mix-ups in the test results.

**Note**

Make sure no foam is formed on top of the samples. If foam is present, then remove it carefully using a disposable pipette.

5. Continue loading samples until all samples in the worklist are loaded, or until there are no more empty rotor positions.



### 5.3.5 Evaluating results

1. Open the **Evaluate Results** screen. This screen is listed in the menu tree. The screen shows all measured samples in the list to the right.

Type	Sample ID	Patient name
B	Blank	
C	Vitalab Ctrl 1	
C	Vitalab Ctrl 2	
	111111	Patient 1
	111111	Patient 1



**Note**

The list shows all samples for which tests are requested. This includes samples that are being processed, samples with **\*INFO\*** states, finished samples and unloaded samples. Samples are listed until the results are archived.



**Note**

By scanning the sample barcode the analyzer automatically displays the sample results of the sample that was scanned.

2. Check samples with **\*INFO\*** states. Select a sample in the list. The tests performed for the sample appear in the list to the left. The results of the tests are also listed.

Test name	Value	Flags
ASAT	392.0 U/l	
Cholesterol	< 0.13 mmol/l	x
UR	13.9 mmol/l	
Gamma-GT	258.1 U/l	

3. Check the status of the test results. If the test results were not automatically accepted, the status is shown in the **Value** column.

**Accepted** (not shown)      The test result falls within all defined limits.

**REJECT**      The test result is rejected automatically or manually. Automatic rejection is based on limits in the test parameters and settings for automatic evaluation by the analyzer. See par. 6.5.4.

**\*INFO\***      The test result cannot automatically be accepted or rejected. The analyzer waits for your decision. See the steps below.

4. Check the test flags. See par. 5.6.2.
5. (Optional) Click **F3 Accept Result**. The result is accepted. The **\*INFO\*** status is cleared.
6. (Optional) Click **F4 Reject Result**. The result is rejected.
7. (Optional) Click **F5 Measure Again**. The test is repeated, using the original volumes.

- (Optional) Click **F6 Measure Rerun**. The test is repeated, using the rerun volumes.

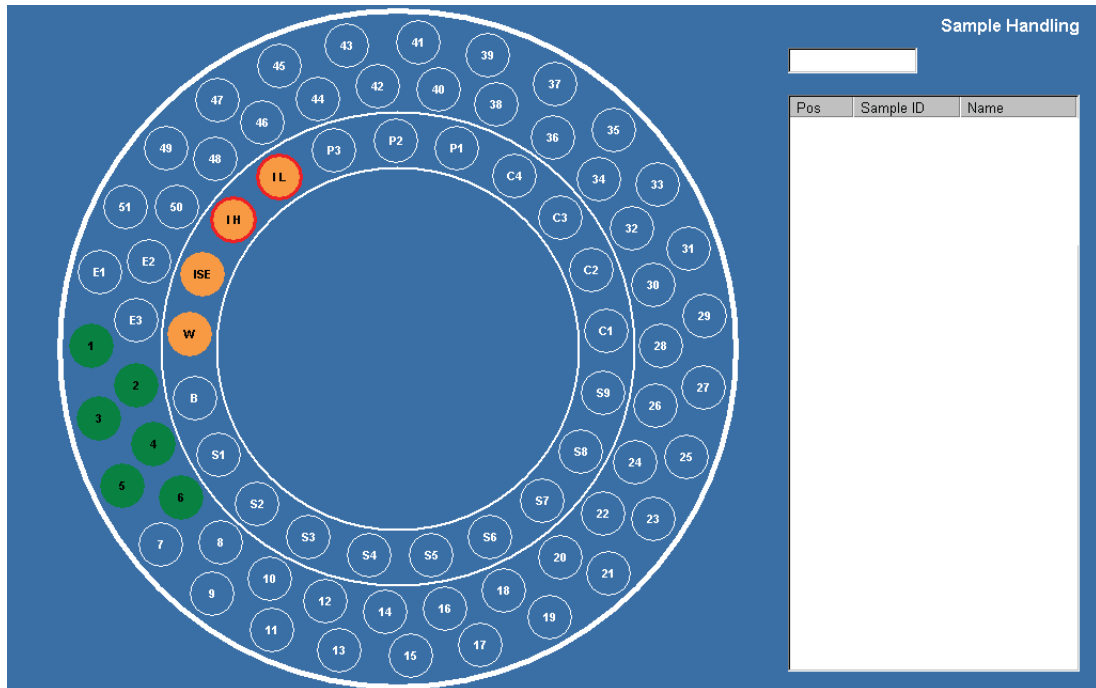
**Note**

The rerun volumes to be used for sample and reagents are defined in the test parameters. See par. 6.2.2.



### 5.3.6 Unloading samples

1. Open the **Sample Handling** screen.



2. Wait until all current measurements are finished. The analyzer state in the top left corner of the screen is set to **Stand-by**.
3. To unload specific samples, but leave other finished samples on the rotor:
  - 3.1. Click **F9 Unload Menu**.
  - 3.2. Click on a finished sample on the rotor image. Selected samples are shown with a white border. Continue to select finished samples until all required samples are selected.
  - 3.3. Click **F3 Confirm Unload**. The selected samples are unloaded.
  - 3.4. Remove the selected samples from the rotor.



#### Note

Click **F5 Select Series** to quickly select a range of samples. This method can be combined with selecting or deselecting single samples.

4. To unload ALL finished samples:
  - 4.1. Click **F4 Unload**. All finished samples are removed from the rotor image.
  - 4.2. Remove all unloaded samples from the rotor.



#### ATTENTION

Only finished samples can be unloaded. These samples are indicated by a solid green circle on the rotor image. Samples for which an error flag is set are not finished. They are not removed from the rotor image. They should not be removed from the rotor. See par. 4.2.4 for the meanings of color codes on the sample rotor.

## 5.4 Performing special measurements

### 5.4.1 Running priority (*STAT*) tests during a measurement run

1. Open the **Request samples** screen.
2. Enter the sample data and test requests.
3. Click **F2 STAT**. The test request is marked as an emergency sample. This is shown by the letter “e” in the worklist.
4. Click **F8 New Sample** to save the request. The sample is marked with the letter “e” in the worklist. The sample identification fields and test requests are emptied for the next sample.
5. (Optional) Repeat the previous 3 steps for all emergency samples to be measured.
6. Open the **Sample Handling** screen.
7. (Optional) Open the cover. The pipettor arm moves away from the sample rotor.



#### ATTENTION

Opening the cover before the analyzer state is **Loadable** causes all current pipetting to stop. This leads to loss of reagent and sample materials. Use the next step to prevent this.

8. Click **F3 Load/Unload Request**.  
The analyzer finishes pipetting and then interrupts the work. Wait until the analyzer state (in the top left of the screen) changes to **Loadable**.
9. Click on the emergency sample in the worklist.
10. Press **Enter** or double-click with the mouse to position the sample. The sample is allocated a position.
11. Place the sample in the allocated position on the sample rotor.
12. (Optional) Repeat the previous 3 steps for all emergency samples in the worklist.
13. Close the cover.
14. Click **F3 Continue Measurement**. The emergency samples will be measured first. Then other measurements are resumed.

### 5.4.2 Performing reagent blanks and calibrations

1. Open the **Request samples** screen.
2. Select **Blank** from the **Request Type:** listbox.

The screenshot shows a software interface with three main sections. On the left, a 'Request Type:' dropdown menu is set to 'Blank'. In the center, a 'Tests:' section contains a list of test options with checkboxes: Kinetic profile, Heart profile, ASAT, Cholesterol, Creatinine, Ureum, Gamma-GT, Cocaine, and HDL. On the right, a 'Worklist:' table is visible with columns for 'Pos', 'Sample ID', and 'Name'. The table currently contains a single asterisk (\*) in the 'Pos' column.

3. Select the required tests or profiles from the **Tests:** list.
4. Click **F8 New Sample** to save the request. The sample is marked with the letter “b” in the worklist. The sample identification fields and test requests are emptied for the next sample.
5. Select **Calibrate** from the **Request Type:** listbox.
6. Select the required tests or profiles from the **Tests:** list.
7. Click **F8 New Sample** to save the request. The sample is marked with the letter “s” in the worklist.
8. Open the **Sample Handling** screen.
9. Place a sample tube with distilled water in the position marked **B** on the inner ring of the sample rotor.
10. Select the calibrator in the loadlist. Calibrators are listed immediately below the blanks. Press **Enter** to position the calibrator. Place a sample tube with the calibrator in that position.

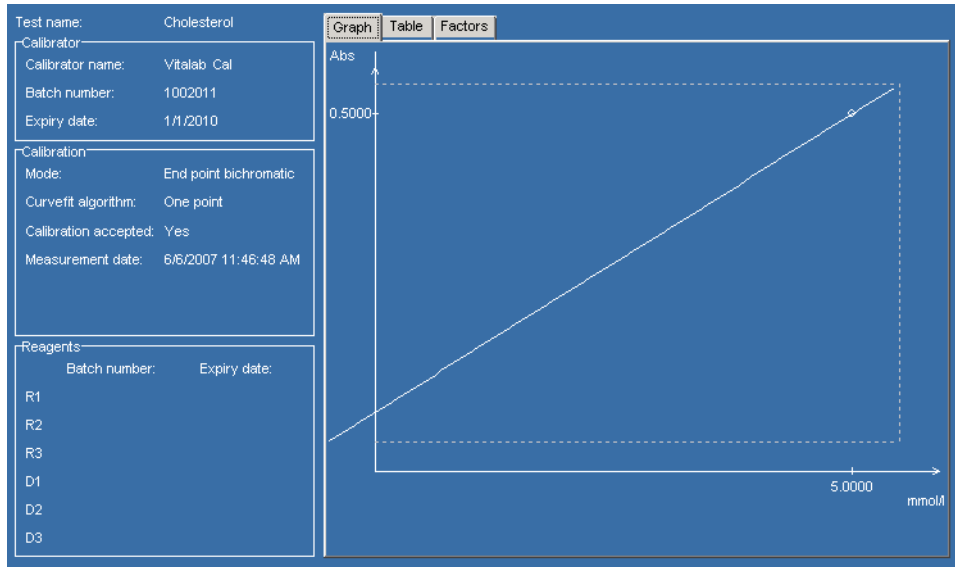


#### ATTENTION

When a multi-standard calibrator was requested, multiple positions are reserved for the calibrator tubes. Make sure they are loaded in the right positions: this is the order in which the standards were defined.

11. Make sure all required blanks and calibrators are positioned and placed on the rotor.
12. Click **F3 Start Measurement**. Blanks and calibrators are measured.

- Possibly, the **Display Calibration** screen is shown. This depends on the measurement results and on settings for automatic acceptance of the calibration (see par. 6.2.5).



- Check the calibration results. See par. 4.2.10 for details about this screen.
- Click **F5 Accept Calibration** or **F6 Reject Calibration**.

### 5.4.3 Performing control measurements



#### Note

Vital Scientific recommends that you run control measurements daily. It is also recommended to perform a calibration and a control measurement after a refill of installed fresh reagent. The frequency required in your laboratory depends on the test method, as well as on legislative regulations valid in your country and in the organization that oversees your laboratory.



#### Note

After a calibration measurement you need to run a control measurement.

1. Open the **Request samples** screen.
2. Select **Control** from the **Request Type:** listbox.

The screenshot shows the 'Request samples' interface. On the left, a dropdown menu for 'Request Type:' is set to 'Control'. In the center, a list of 'Tests:' is displayed under the 'Autonorm L3' category, which is selected with a checkmark and has a 'Repeats:' value of 1. The tests listed are ASAT mono (checked), ASAT Dual (checked), cutoff (unchecked), and Cholesterol (checked). Below this, the 'Autonorm L2' category is also visible but not selected. On the right, a 'Worklist:' table shows the current sample configuration:

Pos	Sample ID	Name
b		Blank test
s	587946312	Elitrol H Cal
*		Control

3. The list of available controls is shown. This list contains all controls that are defined on your analyzer.
4. Select the required control. Tests that can be ordered for each control are listed under the control name. Click in the checkbox to select or deselect tests.
5. Press the + button on the numeric keypad to increase the number of repeats for the test. (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. Click **F8 New Sample** to save the request. The sample is marked with the letter "c" in the worklist. The sample identification fields and test requests are emptied for the next sample.
7. Open the **Sample Handling** screen.
8. Select the control in the loadlist. Press **Enter** to position the control. Place a sample tube with the control in that position.
9. Make sure all required controls are positioned and placed on the rotor.
10. Click **F3 Start Measurement**.
11. Check the control measurement results in the **Quality Control** screen. This screen is listed in the menu tree. See par. 4.2.8.

## 5.5 Handling test results

### 5.5.1 Automatic results processing



#### Note

If the analyzer is connected to a LIS host computer, the results for each sample are sent to host computer as soon as all tests for that sample were performed, except when an **\*INFO\*** state is set for one of the measurements of that sample. In that case, the results are only sent when the **\*INFO\*** state is solved.

#### Printing of results

When all tests for a sample are ready, the analyzer automatically prints the results. The report layout can be chosen in the **Report setup** screen. A custom report layout can be defined via the same screen. See par. 6.5.5.



#### Note

Printing of test results is only done if a printer is available. Also, the option to print test results must be switched on. See par. 6.6.1.

#### Communication of results to the LIS

If the analyzer is connected to a LIS, it also sends the results to the host. The results are held if one or more of them have an **\*INFO\*** state.



#### Note

The host communication can be configured so that individual test results are transmitted to the host as soon as they become available. See par. 6.6.2.

#### Custom evaluation

The analyzer has an option to perform an automatic custom evaluation. When this option is set, the test results are compared to the limits defined in the test parameters. Depending on the outcome and the options set, one of three actions is automatically performed: accept result, reject result or ask the operator. In the latter case, the state is set to **WAITING FOR YOUR DECISION** and further processing of the sample is held until the operator has either accepted or rejected the result. For more details on the custom evaluation option, see par. 6.5.4.

#### Custom automatic rerun

The analyzer has an option to perform an automatic rerun. When this option is set, the test results are compared to the limits defined in the test parameters. Depending on the outcome and the options set, the test is automatically repeated with the rerun parameters defined for the test. For more details on the automatic rerun option, see par. 6.5.4.

## 5.5.2 Archiving and retrieving results

### Archiving to the standard archive directory

1. Open the **Evaluate Results** screen. This screen is listed in the menu tree.
2. Click **Shift+F3 Archive Results**. All samples are stored in the archive. They are removed from the list.

**Note**  
The location for result archives is set in the system parameters. See par. 6.5.1.

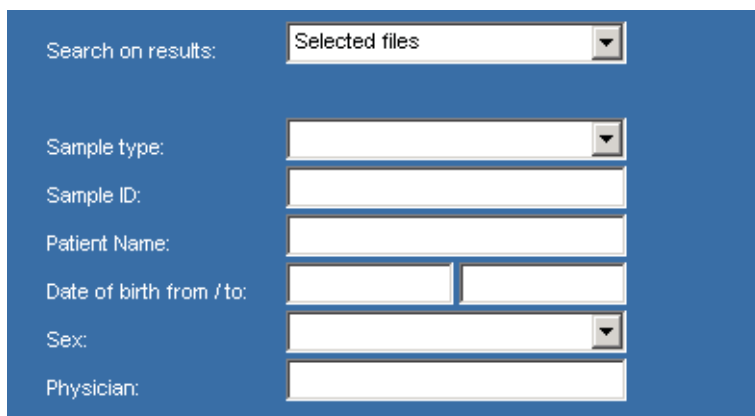
**Note**  
Clean up your hddisk on a regular basis. This will increase free disk space and prevents running out of space.

### Retrieving results from the archives

1. Open the **Evaluate Results** screen. This screen is listed in the menu tree.
2. Click **Ctrl+F3 Search Results**. The screen shows the search criteria.
3. In the list of archives to the left, select the archive(s) from which you want to view test results. The archives are identified by the date and time when they were created. To select a range of archives, click on the first one in the list and hold the **Shift** key while clicking on the last one. Add individual archives to the selection by holding the **Ctrl** key while clicking on an archive. Remove archives from the selection by holding the **Ctrl** key while clicking on a selected archive.

**Note**  
The **Search on results:** list box offers a number of standard selections.

4. Set the search criteria in the selection fields to the right. All fields are optional.



The screenshot shows a search criteria form with the following fields:

- Search on results: Selected files (dropdown menu)
- Sample type: (dropdown menu)
- Sample ID: (text input field)
- Patient Name: (text input field)
- Date of birth from / to: (two text input fields)
- Sex: (dropdown menu)
- Physician: (text input field)

**Note**  
When no search criteria are set, all test results in the selected archive(s) will be included.

- (Optional) Define conditions on test results to restrict the search results.

The screenshot shows a search filter interface with a blue background. At the top, there are four column headers: "Test", "Abbr.", "Result", and "Flags". Below each header is a white input field. The "Result" field has a small downward arrow on its right side, indicating it is a dropdown menu. The rest of the interface is a large empty blue area.

Define conditions based on test names, test results and/or flags. Click **F4 Add Condition** to add another condition. Click **Shift+F4 Remove Condition** to remove the last condition. All listed conditions are combined: test results must meet all conditions to be included.

- Click **F5 Search**. The tests that match the search criteria are shown in the sample list. All other result are suppressed.



**Note**

When viewing archived results, test results cannot be validated or rejected anymore. 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.

- Exit this screen to unload the archived test results. When you open the **Evaluate Results** screen again, the current test results will reappear.



### 5.5.3 Exporting results



#### Note

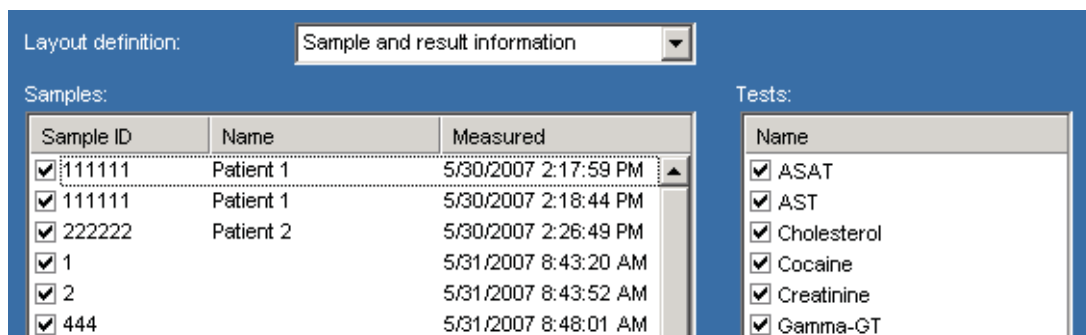
Exporting test results does not remove them from the sample list.



#### Note

It is still possible to export archived data. First, retrieve the data from the archives. See par. 5.5.2. You can then export the data to a file.

1. Open the **Evaluate Results** screen. This screen is listed in the menu tree.
2. Click **Alt+F3 Export Results**. The screen shows two selection lists.



3. Select the layout for the data to be exported. The **Layout definition:** list box offers the following options:
  - **Sample and result information**
  - **Result information only**
  - **Raw result information**



#### Note

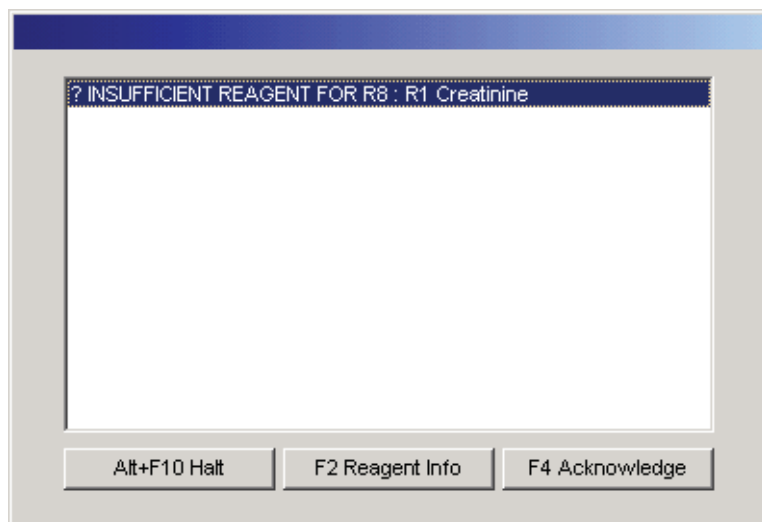
The data is exported to a text file using the comma-separated variable (CSV) format. This file type can be imported into many data processing programs, such as Excel or statistical software products.

4. Select the samples to be included in the export file. Click on the checkboxes in front of the sample IDs to select or deselect them.
5. Select the tests to be included in the export file. Click on the checkboxes in front of the test names to select or deselect them.
6. Click **F4 Export** to write the selected results to the text file. A dialog opens in which you enter the name and location for the exported file.
7. (Optional) Click **F5 Copy to Clipboard** to copy the selected data to the Windows clipboard. The clipboard contents can then be pasted into another program - if that program can accept the CSV data format.

## 5.6 Troubleshooting

### 5.6.1 Handling error messages

If the analyzer detects an error or malfunction, a dialog window is shown on the screen. The window contains buttons that lead to further actions.



Some messages are accompanied by an acoustic signal. Press the spacebar to stop the signal. The sound and duration of the signal are defined in the system parameters. See par. 6.5.1.

#### Function keys in the message windows



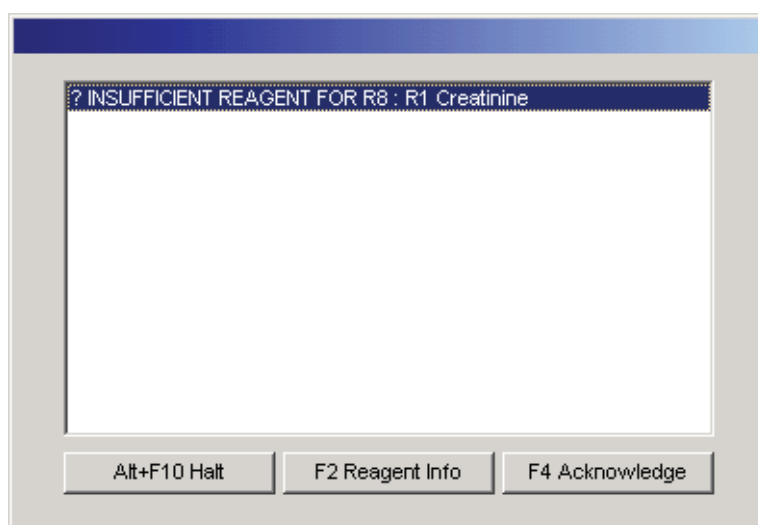
#### Note

The error messages are accompanied by different buttons, depending on the error condition. The list below shows all possible buttons and the actions associated with them.

Command	Description
<b>F1 Check Again</b>	Repeat the procedure that led to the error message. This can be used if the importance of the message is unclear.
<b>F2 Reagent Info</b>	Open the <b>Reagent Loadlist</b> screen. That screen shows which reagents need to be filled. See par. 5.2.2.
<b>F4 Acknowledge</b>	Acknowledge the message and close the window. No further action is taken.
<b>F4 Abort</b>	Abort the action that caused the error message. This option is only shown when aborting the action is possible.
<b>F5 Request calibration</b>	Enter a new request for the required calibration. The calibrator request is added to the worklist and selected. Press <b>Enter</b> to assign a rotor position.
<b>F5 Hard Reset</b>	Reset a subsystem of the analyzer. If the error condition is cleared by this, the analyzer continues.
<b>F6 Soft Reset</b>	Reset a component of the analyzer. If the error condition is cleared by this, the analyzer continues.
<b>F5 Measure</b>	Measure all pending tests.
<b>F6 Reject</b>	Rejects all pending tests.

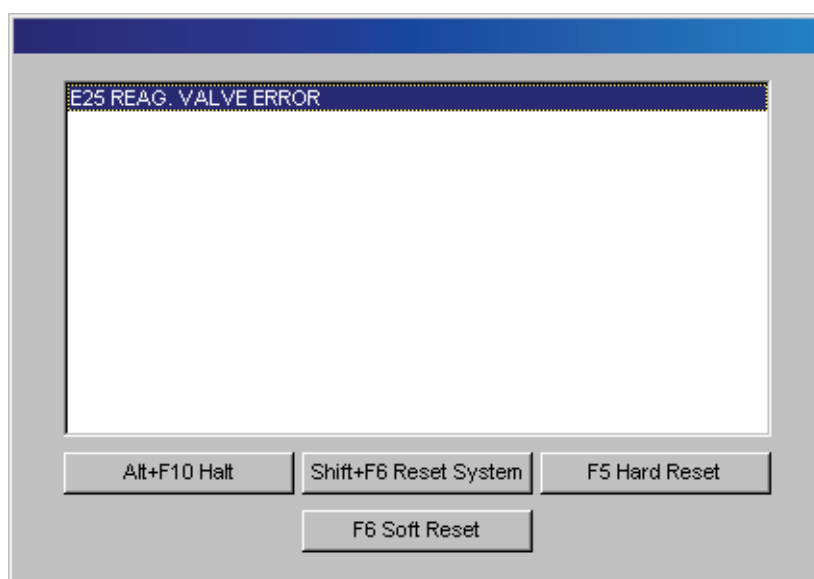
Command	Description
<b>Shift+F6 Continue</b>	Continue the measurements. This button is available when a warning is shown that not all tests can be performed with the remaining reagent volume.
<b>Shift+F6 Reset System</b>	Reset the analyzer. Only use this option if the message cannot be cleared by using the other keys.
<b>Shift+F7 Remain Inactive</b>	Close the error window without further action. The analyzer status remains inactive.
<b>Alt+F10 Halt</b>	Halt the analyzer program immediately (emergency stop).

### Test-related error messages



Messages that relate to reagents, samples, calibrations, test parameters and other software items are often fairly easy to solve. A full list of possible test-related error messages is given in par. 5.6.3.

### Hardware-related error messages



When the hardware of the analyzer runs into an error condition, the error message shown starts with the capital E, followed by an error message index. These error messages, with possible remedies, are listed in par. 7.2.2.

### 5.6.2 Understanding test flags

For certain errors the test results are marked with a flag. The flags are listed in the **Flags** column on the **Evaluate Results** screen. See par. 4.2.6. All possible flags, their meanings and actions to take are described in the following table.

Flag	Meaning	Description / Action
a	Reagent absorbance limit violation.	One of the reagent absorbance limits defined in the test parameters was exceeded. Prepare fresh reagent if needed.
A	Calibrator limit violation.	Compare the test parameters with the data given in the package insert of the test. Prepare fresh calibrator or reagent if needed.
C	Control limit violation.	Compare the test parameters with the data given in the package insert of the test. Prepare fresh control or reagent if needed.
D	Reagent absorbance deviation error. Substrate depletion error.	The limit for the reagent absorbance deviation set in the test parameters was exceeded. Click <b>F6 Measure Rerun</b> in the <b>Result Details</b> screen. The test is repeated with a smaller amount of sample (defined as rerun volume).
E	Result near cut-off.	The result lies within the set cut-off deviation defined in the test parameters.
G	General hardware error.	Use the error list in the <b>Error history</b> screen to find the cause of this error. Reset the analyzer.
k	Result exceeds calibration limits.	The rate of a test is lower than the rate of the lowest standard. The result is set to 0.00. This is only valid for tests using calibration curves with 3 standards or more.
K	Result exceeds calibration limits.	The rate of a test is higher than the rate of the highest standard. The result is set to 9999.00. This is only valid for tests using calibration curves with 3 standards or more.
L	Cuvette blank error.	Check the results of the last cuvette blank measurement. Repeat the blank measurement if required. See par. 7.1.4.
	Lamp error.	Adjust or replace photometer lamp. See par. 7.3.3.
m	Low absorbance limit violation.	The lower absorbance limit set in the test parameters was exceeded.
M	High absorbance limit violation.	The upper absorbance limit set in the test parameters was exceeded.
N+	Reference limit violation.	The applicable upper reference limit set for male, female or pediatric in the test parameters was exceeded.
N-	Reference limit violation.	The applicable lower reference limit set for male, female or pediatric in the test parameters was exceeded.
o	Cuvette blank error.	Check the results of the last cuvette blank measurement. Repeat the blank measurement if required. See par. 7.1.4.
	Overrange reference detector.	Error in the electronics. Contact the support department of your supplier.
O	Cuvette blank error.	Check the results of the last cuvette blank measurement. Repeat the blank measurement if required. See par. 7.1.4.
	Overrange	Adjust or replace photometer lamp. See par. 7.3.3.
P	Prozone error.	Repeat the measurement with pre-diluted sample.

Flag	Meaning	Description / Action
r	Rerun.	The test was repeated with the rerun parameters.
R	Insufficient reagent.	Fill the system with reagent. See par. 5.2.2.
T	Cuvette temperature error.	Contact the support department of your supplier.
u	Cuvette blank error.	Check the results of the last cuvette blank measurement. Repeat the blank measurement if required. See par. 7.1.4.
	Underrange reference detector	Error in electronics. Inform service.
U	Cuvette blank error.	Check the results of the last cuvette blank measurement. Repeat the blank measurement if required. See par. 7.1.4.
	Underrange.	Adjust or replace photometer lamp.
V	Positive (for cut-off tests).	The result is positive relative to the cut-off border. Both the flag and the result are shown.
v	Negative (for cut-off tests).	The result is negative relative to the cut-off border. Both the flag and the result are indicated.
W	Westgard rules limit violation.	Compare the results of the quality control of all controls set for this test. Prepare fresh control or reagent solution or calibrate the test, if needed.
x	Concentration limit error.	The concentration is below the analytical sensitivity.
X	Concentration limit error.	The concentration limit set in the test parameters was exceeded.
*	Non-linearity error (kinetic tests).	Linearity is outside the alinearity range defined in the test parameters.
#	Insufficient sample.	Make sure the sample is of sufficient volume, not coagulated, no foam is formed, and no air bubbles block the sample aspiration.

### 5.6.3 Test-related error messages

**Note**

All possible test-related error messages are listed below, with their probable causes and remedies. If you are in doubt about the actions to take, contact your superior.

***INSUFFICIENT REAGENT***

- The reagent bottle is empty or missing.  
Fill the reagent bottle.

***INSUFFICIENT SAMPLE***

- The sample tube is empty or missing.  
Prepare and position a new sample.

***REAGENT NOT TAKEN FOR ..***

- The fill level of the reagent is too high.  
Remove some reagent. The level should be below the neck of the bottle.
- Foam is formed in the bottle. If foam is present, then remove it carefully using a disposable pipette.  
Remove reagent and refill the bottle.

***Test sending stopped***

- The reagent needle could not be cleaned. Pipetting was stopped.  
Make sure acid solution (HCL solution) is installed on the rotor. Check the fill level.

***LAMP OVERRANGE ERROR***

- A counter overrange is detected.  
Look up ***E13 LAMP FAILURE*** in the hardware-related error messages. See par. 7.2.2.

***LAMP UNDERRANGE ERROR***

- A counter underrange is detected.  
Look up ***E13 LAMP FAILURE*** in the hardware-related error messages. See par. 7.2.2.

***LAMP REFERENCE OVERRANGE ERROR***

- A counter overrange is detected for the reference detector.  
Look up ***E13 LAMP FAILURE*** in the hardware-related error messages. See par. 7.2.2.

***LAMP REFERENCE UNDERRANGE ERROR***

- A counter underrange is detected for the reference detector.  
Look up ***E13 LAMP FAILURE*** in the hardware-related error messages. See par. 7.2.2.





## Configuration

## 6.1 Chapter overview

### 6.1.1 *Special Functions* menu



The list below shows all screens available via the ***Special Functions*** menu. The numbers between brackets indicate the paragraphs that describe the screens in detail. Some screens are described in chapter 7, as they are used in maintenance and troubleshooting, rather than configuration work.



#### Note

Some screens listed below may not be available to all users. This depends on security settings that may be defined in your analyzer. If required, a password dialog appears. Setting or clearing the password is explained in par. 6.5.7.



#### Note

Some screens listed below show optional modules and functions that may not be available on your analyzer.

- ***Rotor/ System/ISE***
  - ***Reset system*** (par. 5.2.1)
  - ***Change cuvette rotor*** (par. 7.3.2)
  - ***Change syringes*** (par. 7.3.4)
  - ***Fill/Empty system***
  - ***Clean system*** (par. 7.1.5)
  - ***Rotor/Needle rinse*** (par. 7.1.5)
  - ***Blank rotor*** (par. 7.1.5)
  - ***ISE*** (par. B.4.1)
- ***Installation***
  - ***Reagent positions*** (par. 6.3.1)
  - ***System parameters*** (par. 6.5.1)
  - ***Custom evaluation*** (par. 6.5.4)
  - ***Communication*** (par. 6.6)
  - ***Report setup*** (par. 6.5.5)
  - ***Release*** (par. 6.7.1)
  - ***Change rotor*** (par. 6.3.2)
  - ***Export / Import data*** (par. 6.4.4)
  - ***Test name order*** (par. 6.2.3)
  - ***Restore point*** (par. 6.4.3)
  - ***Passwords*** (par. 6.5.7)
- ***Programming***
  - ***Test programming*** (par. 6.2.2)
  - ***ISE test programming*** (par. B.4.2)
  - ***Calibrators*** (par. 6.2.1)
  - ***Controls*** (par. 6.2.4)
  - ***Profile programming*** (par. 6.5.3)
  - ***Calculated tests*** (par. 6.2.6)

- **Cuvette incompatibility** (par. 6.2.7)
- **Service**
  - **Functional check/adjustments** (par. 7.3.5)
  - **Needle rinse history** (par. 7.1.5)
  - **Error history** (par. 7.2.3)
  - **Changes Log** (par. 6.7.2)
  - **System configuration** (par. 6.5.2)

## 6.1.2 Suggested work order

If you are configuring the Selectra ProM yourself, the following work order is suggested. When you follow this order, configuration settings that are required in each of the steps have already been set in previous steps.

**Note**

In most analyzers, the controls, calibrators and tests are loaded from predefined data, provided by the supplier of the analyzer. These data sets can be imported from a USB memory stick. See par. 6.4.5.

1. (Optional) Define custom sample types. See par. 6.5.2.
2. Define calibrator names. See par. 6.2.1.
3. Define control names. See par. 6.2.4.

**Note**

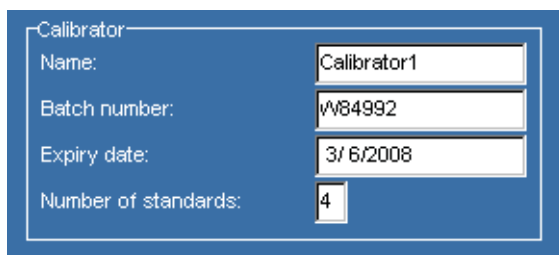
Only define the control names. As tests are not programmed yet, you cannot define the target values for the controls yet. This is done as part of the test programming procedure.

4. Program tests. See par. 6.2.2.
5. (Optional) Program calculated tests. See par. 6.2.6.
6. (Optional) Program incompatible and/or linked tests. See par. 6.2.7.
7. (Optional) Program profiles. See par. 6.5.3.
8. Program reagent positions. See par. 6.3.1.
9. Create a restore point. See par. 6.4.1.
10. (Optional) Export test parameters to a file. See par. 6.4.4.

## 6.2 Tests, calibrators and controls

### 6.2.1 Programming calibrators

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Calibrators** in the menu to the left. The screen shows the list of calibrators that is defined on your analyzer.
3. Select the calibrator you want to program:
  - Click on an empty position to define a new calibrator.
  - Click on an existing calibrator to make changes to the parameters.
4. Press **Enter**. The **Program calibrator** screen opens.
5. (Optional) Click **Shift+F3 Delete** to remove the calibrator from the list.
6. Set the parameters in the **Calibrator** section.



Calibrator	
Name:	Calibrator1
Batch number:	W84992
Expiry date:	3/ 6/2008
Number of standards:	4

- Name:** Name to identify the calibrator. The name appears in list boxes where a choice of calibrator must be made.
- Batch number:** Batch number of the calibrator, as supplied by the supplier on the package insert.
- Expiry date:** Expiry date of the calibrator, as supplied by the supplier on the package insert.
- Number of standards:** Number of standards to use when measuring the calibrator. The maximum number of standards is 9.

7. Click **F10 Return**. The parameters are saved. The calibrator is added to the list.



#### Note

Concentrations, target absorbances and deviation limits for the calibrators are set separately for each test. This is done when programming the tests. See par. 6.2.2.

## 6.2.2 Programming tests



### Note

It is possible to import tests from a file, see par. 6.4.5. This file is normally available from the supplier of your Selectra ProM. The ELITech test parameters can be found on the USB memory stick supplied with the Selectra ProM.



### Note

The Selectra ProM is supplied as closed system (designed for ELITech Clinical System reagents) or open system (designed for generic reagents). In closed systems, the test parameters are preprogrammed and 10 open channels can be fully configured. Only parameters that do not influence the measurements may be editable. In open systems, some or all tests can be fully configured.



### ATTENTION

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.

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Test programming** in the menu to the left. The screen shows the list of tests that is defined on your analyzer.
3. Select the test you want to program:
  - Click on an empty position to define a new test.
  - Click on an existing test to make changes to the test parameters.
4. Press **Enter**. The **Test programming** screen opens. This screen contains two pages with test parameters. The first page is shown.
5. (Optional) Click **Shift+F3 Delete Test** to remove the test from the list.
6. If the button **F2 Modify Test** is enabled, the test settings are password-protected. Click the button to open the password dialog. Enter the correct password to get access to the settings.

7. Set the parameters in the **General** section.

General

Name: test1

Abbreviated name: tst1

Code:

Mode: End point bichromatic

Wavelength: 340 nm ---- 415 nm

Units: mmol/l

Decimals: 2

Test repeats: 2

Dup-diff: 0,000 Abs

Concentration limits: 0,00 - 0,00 mmol/l

Calibrator name: Calibrator1

Prozone check: Min. Abs ratio

Minimum ratio: 0 %

- Name:** Name to identify the test. The name appears in reports.
- Abbreviated name:** Abbreviated name to identify the test. This must be a unique name in this analyzer. Maximum length is 4 characters.
- Code** Code to identify the test. The code is contained in the barcode of reagents (only available in specific configurations).
- Mode:** Select one of the available test methods from the list.
- Wavelength:** Filter to be used. The list contains the wavelengths of the filters in the filterwheel of your analyzer. If the **End point bichromatic** method is selected, two wavelengths must be chosen.
- Units:** Units in which the test results are reported.
- Decimals:** Number of decimals used for the measurements. This is also the number of decimals used for control reference and target values.
- Test repeats:** Number of times the test is repeated for the same sample. The results of these repeated measurements is averaged.
- Dup-diff:** The maximum allowed difference between repeated measurements of the same assay on the same sample. If the difference exceeds this, an error message is shown.
- Concentration limits:** The minimum (analytical sensitivity) and maximum (assay linearity) concentration limits defined in the package insert of the test. If these values are exceeded in a measurement, an error message is shown.

- Calibrator name:** Calibrator used for this test. Click on the button next to the calibrator name. The screen with calibrator settings opens. Set the calibration parameters for this test. See par. 6.2.5.
- Prozone check:** Select one of the options from the list. See par. 3.3.1.
- Minimum ratio:** This field only shows when a minimum prozone check method was chosen. Enter the minimum deviation percentage.
- Maximum ratio:** This field only shows when a maximum prozone check method was chosen. Enter the maximum deviation percentage.

8. Set the parameters in the **Sample types** section.

Sample types can be defined for your analyzer. This is done in the **System configuration**. See par. 6.5.2. For each sample type, separate settings can be defined here. Click on the tab for the required sample type to see and change the parameters.

- Allowed:** Select **Yes** to allow this test for the sample type. When this sample type is chosen in the **Request samples** screen, the test is included in the selection list.
- Predilution:** Select **Yes** to switch on predilution for this sample type in this test. For details on predilution, see par. 3.3.4.
- Male:** Limits to be used for samples of male patients.
- Female:** Limits to be used for samples of female patients.
- Pediatric:** Limits to be used for samples of pediatric patients.
- Panic:** Limits to be used as absolute limits for all samples.

**Note**  
 The **Sex:** field in the sample data determines the reference values that are used to check the measurement results. If the results exceed the applicable limits, the appropriate error flag is set for the result. Results that exceed the **Panic:** limits are always flagged.



9. Set the parameters in the **Controls** section.

Up to three controls can be selected for the test. Click on the button next to the field to open the **Test control programming** screen. See par. 6.2.4.

10. Set the parameters in the **Correlation** section.

**Correlation factor:** Normally set to 1.000. This factor is used to correct for small differences between analyzers in a setting where multiple analyzers are used in the same laboratory.

**Correlation offset:** Normally set to 0. This offset is used to correct for small differences between analyzers in a setting where multiple analyzers are used in the same laboratory.



**ATTENTION**

Consult the technical support department of your supplier before making any changes to the **Correlation** parameters.

11. Click the **Test parameters 2** tab. The second page of test parameters is shown.

12. Set the parameters in the **General** section.

**Name:** This is set on the **Test parameters 1** page. It cannot be changed here.

**Predilution:** Select **Yes** to switch on predilution. Then set the predilution factor. See par. 3.3.4.

13. Set the parameters in the **Sample** section.

- Sample blank:**
  - **Yes** - Sample blank measurement is done for all samples. Now the **Sample blank absorbance limits** section is shown and the parameters can be set.
  - **On request** - Sample blank measurement can be chosen per sample in the **Request samples** screen. The **Sample blank absorbance limits** section is shown and the parameters can be set.
  - **No** - Sample blank measurement is not done.
- normal volume:** The sample volume used for normal measurements. Enter any value between 2 µl and 30 µl in 0.1 µl steps.
- rerun volume:** The sample volume used for rerun measurements. Enter any value between 2 µl and 30 µl in 0.1 µl steps.

14. Set the parameters in the **Reagents** section.

Reagent blank:	normal volume:	rerun volume:
Yes (dropdown) Not measured Repeats: 2		
Reagent addition at -2,25 minutes (R1)	220 µl	220 µl
Reagent addition at 2,90 minutes (R2)	70 µl	70 µl
Reagent addition at 4,70 minutes (R3)	100 µl	100 µl

- Reagent blank:** Select **Yes** to switch on reagent blanking.
- normal volume: (R1)** The R1 volume used for normal measurements. If no R2 and/or R3 are used, enter a volume between 220 µl and 399 µl in steps of 1 µl. Otherwise, the minimum volume for R1 can be set to 110 µl.
- rerun volume: (R1)** The R1 volume used for rerun measurements.
- normal volume: (R2/R3)** The R2 and R3 volumes used for normal measurements. Enter a volume between 0 µl and 289 µl in steps of 1 µl. Entering a value of 0 µl means the reagent is not used.
- rerun volume: (R2/R3)** The R2 and R3 volumes used for rerun measurements.



**Note**

The total volume of the sample and all used reagents must be between 220 µl and 400 µl. Numbers are automatically changed by the analyzer to remain within these limits.

15. Set the parameters in the **Measurement** section.

- Slope blank:** Select **Yes** to switch on slope blanking.
- Delay, min. time:** Only for **Kinetic** tests. To the left, select the delay between addition of the sample (or the last reagent for multi-reagent tests) and the first used measurement point. To the right, select the minimum measurement time. This determines how many measurements are used.
- Incubation time:** Only for **End point monochromatic** or **End point bichromatic** tests. Select the delay between addition of the sample (or the last reagent for multi-reagent tests) and the measurement.
- Point one,two:** Only for **Two point** tests. Select the delay between addition of the sample (or the last reagent for multi-reagent tests) and the first and second measurements. If a negative value is set for point one, the measurement is performed just before addition of the sample (or the last reagent for multi-reagent tests).
- Alinearity limit:** Limit to detect a linearity error on the first 4 measurement points. Default is 10%. Use 25% for low rate assays (lower than 0.150 dAbs/m).
- Proz.pt.one,two:** Only if **Prozone check:** is switched on. Select the delay between addition of the sample (or the last reagent for multi-reagent tests) and the first and second measurements used for the prozone check.
- Prozone H.Limit:** Only if **Prozone check:** is switched on. If the prozone check results in a value higher than this limit, the analyzer signals a prozone error.
- Factor:** For tests that do not require calibration, the multiplication or enzymatic factor from the method sheet must be entered here. For tests that use one-point calibration, the factor is calculated and shown here. If the factor is exactly 1.000, the analyzer assumes calibration has not taken place.

16. Set the parameters in the **Absorbance limits** section.

- Absorbance:** Absorbance limits to be used. If a result exceeds these limits, an error flag is set for the result. If the two limits are identical, the check is not done.
- R.Absorbance:** Reagent absorbance limits as given in the test sheet. If the measured value exceeds these limits, an error flag is set for the result. If the two limits are identical, the check is not done.
- R.Abs. deviation:** This parameter is only shown when no R2 or R3 is used. It is only used for decreasing reactions. Enter the maximum deviation of the calculated (extrapolated) reagent absorbance. If the calculated reagent absorbance is below the measured reagent absorbance minus the programmed reagent absorbance deviation, an error flag is set for the result. If the **R.Abs. deviation** is set to 0,000 Abs, the RAD check will not be performed.
- Substrate depletion:** This parameter is only shown when R2 and/or R3 is used. Enter the value from the method sheet. See par. 3.3.1. If the **Substrate depletion** is set to 0,000 Abs, the SD check will not be performed.

17. Set the parameters in the **Sample blank absorbance limits** section.

Sample blank absorbance limits		
Absorbance:	-0.100	3.000 Abs
R.Absorbance:	-0.100	3.000 Abs
R.Abs. deviation	0.100	Abs

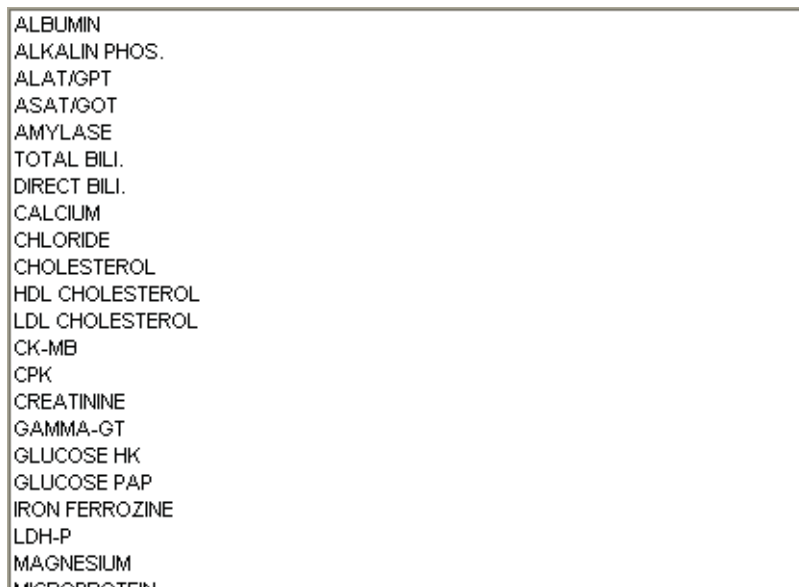
- Absorbance:** Absorbance limits to be used for sample blank measurements. If a result exceeds these limits, an error flag is set for the result. If the two limits are identical, the check is not done.
- R.Absorbance:** Reagent absorbance limits as given in the test sheet. If the measured value exceeds these limits, an error flag is set for the result. If the two limits are identical, the check is not done.
- R.Abs. deviation** This parameter is only shown when no R2 or R3 is used. It is only used for decreasing reactions. Enter the maximum deviation of the calculated (extrapolated) reagent absorbance. If the calculated reagent absorbance is below the measured reagent absorbance minus the programmed reagent absorbance deviation, an error flag is set for the result. If the **R.Abs. deviation** is set to 0,000 Abs, the RAD check will not be performed.
- Substrate depletion:** This parameter is only shown when R2 and/or R3 is used. Enter the value from the method sheet. See par. 3.3.1. If the **Substrate depletion** is set to 0,000 Abs, the SD check will not be performed.

18. Click **F10 Return**. When changes were made, a confirmation dialog is shown.

19. Click **Yes** to save the changes and close the **Test programming** screen.

### 6.2.3 Changing the test name order

1. Open the *Installation* screen. This screen is listed in the menu tree.
2. Click **Test name order** in the menu to the left. The list of programmed tests appears.



3. Click on the test you want to move.
4. Click **F5 Move Test Up** or **F6 Move Test Down** until the test is at the required position.
5. Repeat this for other tests until you are satisfied with the order. The tests will appear in this order in any screen where all tests are listed, as well as in drop-down list boxes.

#### Note



Not all tests are shown in all screens. In some screens, only tests that can be performed are shown. Tests cannot be performed when the required reagents are not available on the rotor.

### 6.2.4 Programming controls



**Note**

It is recommended that controls are programmed before the first time of operation. The test parameters must be defined before programming the controls. 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.

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Controls** in the menu to the left. The screen shows the list of controls that is defined on your analyzer.
3. Select the control you want to program:
  - Click on an empty position to define a new control.
  - Click on an existing control to make changes to the parameters.



**ATTENTION**

The results of quality control are removed when a control is changed or deleted.

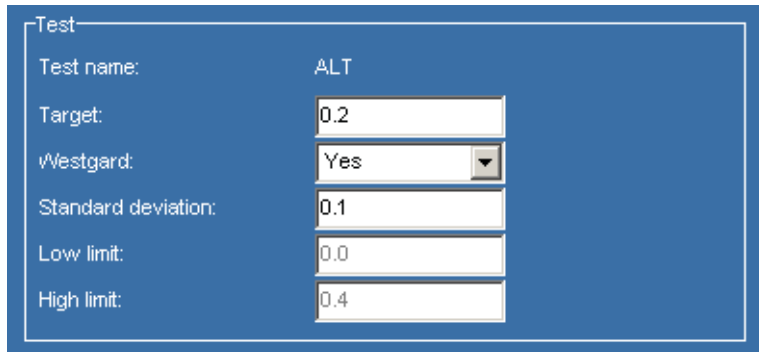
4. Press **Enter** or double click on the selected position. The **Program control** screen opens.
5. (Optional) Click **Shift+F3 Delete Control** to remove the control from the list.
6. Enter the **Control** data in the top left section of the screen.

- Name:** Name to identify the control. The name appears in list boxes where a choice of control must be made.
- Batch number:** Batch number of the control, as supplied by the supplier on the package insert.
- Expiry date:** Expiry date of the control, as supplied by the supplier on the package insert.
- Points:** Number of control points kept in the history.

7. Select a test for which you want to set the target values.

Test Name	Target	Low Limit	H.Limit	Westgard
AST	0.340 [ ]	0.120 [ ]	0.420 [ ]	No
ALT	0.2 [ ]	0.0 [ ]	0.4 [ ]	Yes
LDH	1.2 [ ]	1.0 [ ]	1.4 [ ]	No
Sodium	0.8 [ ]	0.6 [ ]	1.0 [ ]	Yes
Chloride				

- (Optional) Click **Shift+F4 Delete Test** to remove the target values for the selected test.
- Click **F5 Edit Test Target**. The **Test control programming** screen opens.
- Enter the target values for the control on this test.



Test name:	ALT
Target:	0.2
Westgard:	Yes
Standard deviation:	0.1
Low limit:	0.0
High limit:	0.4

<b>Test name:</b>	Test for which control targets are being defined.
<b>Target:</b>	Value that should be measured on the control.
<b>Westgard:</b>	Select <b>Yes</b> if <b>Westgard:</b> rules must be used to evaluate the measurement. See par. 3.3.3.
<b>Standard deviation:</b>	If <b>Westgard:</b> rules are used, this value defines the upper and lower acceptance limits.
<b>Low limit:</b>	Lower acceptance limit if <b>Westgard:</b> rules are not used.
<b>High limit:</b>	Upper acceptance limit if <b>Westgard:</b> rules are not used.

- Click **F10 Return**. The settings are saved. The screen closes. The list of tests for this control now shows the target settings.
- (Optional) Select another test to set the targets. Continue until all applicable test targets are defined for this control.

### 6.2.5 Programming calibrator values for a test

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Test programming** in the menu to the left. The screen shows the list of tests that is defined on your analyzer.
3. Select the test for which you want to program the calibration values.
4. Press **Enter** or double-click on the selected position. The **Test programming** screen opens.
5. If the button **F2 Modify Test** is enabled, the test settings are password-protected. Click the button to open the password dialog. Enter the correct password to get access to the settings.
6. Click on the button next to the **Calibrator name:**. The calibrator values screen opens. This screen is used to select a calibrator and set target values for calibration.
7. (Optional) Click **Shift+F3 Delete Calibrator** to remove the calibrator from the test.



**Note**

Some parameters listed in the steps below only show up with specific types of calibrators. All possible parameters are listed.

8. Set the parameters in the **Calibrator** section.

- Name:** Select the required calibrator from the list. The list shows the abbreviated calibrator names. See par. 6.2.1.
- Number of standards:** Number of standards defined for the calibrator. See par. 6.2.1.
- Calibration accepted:** Shows whether the last calibration values were accepted.
- Repeats:** Number of times the test is repeated for the same calibrator. The results of these repeated measurements is averaged.
- Interval:** Number of days before the test must be calibrated again. When the interval has passed, a warning message appears on the screen. The interval can be set to any number between 0 and 99. Setting the interval to 0 makes the analyzer ignore this feature. No messages will appear on the screen.

9. Set the parameters in the **Curvefit** section.



- Algorithm** Select one of the available curvefit algorithms from the list. For a description of the algorithms, see section 3.2.
- Auto accept calibration:**
  - **Yes** - The analyzer automatically accepts results from calibrator measurements.
  - **No** - After a calibrator measurement the results are shown on the screen and the operator must accept or decline the calibration.
- Last measured:** Date and time of the last calibrator measurement.

10. Set the parameters in the **Predilution** section.

- Auto predilution: \***
  - **Yes** - Automatic predilution is used. Two extra parameters appear when this option is chosen.
  - **No** - Automatic predilution is not used.
- Number of points: \*** Number of points to be used for the auto predilution.
- Sample Predilution: \***
  - **Yes** - Sample predilution is used.
  - **No** - Sample predilution is not used.

\* An explanation of sample and calibrator predilution is available in par. 3.3.4.

11. Set the parameters in the **Cut-off** section.

- Cut-off:**
  - **Yes** - Define a cut-off value for the calibrator.
  - **No** - Do not use a cut-off value for the calibrator.
- Cut-off mode:**
  - **Increase** - When the measured result is higher than the cut-off value, a positive result is returned; otherwise a negative result is returned.
  - **Decrease** - When the measured result is lower than the cut-off value, a positive result is returned; otherwise a negative result is returned.
- Deviation:** Range around the cut-off value. When the measured result is within this range of the cut-off value, an E flag is shown with the result.

- Set the measurement values for the calibrator. Enter all calibrator values in the table as they appear on the package insert for the test.



**Note**

The number of rows in the table changes with the number of standards defined for the calibrator. This number is shown in the top of the screen. It can only be changed in the calibrator programming screen. See par. 6.2.1.



**Note**

Some parameters listed below only show up with specific types of calibrators.

No.	Used	Concentration (mmol/l)			Absorbance (Abs)	Absorbance limit (Abs)		Dup-diff (Abs)
						Low	High	
#1	<input checked="" type="checkbox"/>	4.0100			0.3191	0.0000	0.0000	0.0000

- Used** Enable or disable standards in the table.
- Standard** Identifiers for the standards.
- Concentration** Concentration for the calibration standard.
- Predilution** Predilution factor for the calibrator standards. Select **DIL** to perform a zero (diluent only) measurement.
- Diluted conc.** Concentration that will be used in the calibration curve. The concentration is calculated with the sample and standard predilutions. See par. 3.3.4.
- Absorbance** Set by the analyzer after calibration is performed.
- Low** Enter the absorbance limits for each standard. If the limits are exceeded during measurement, an error message is shown. If the same value is entered for both limits of a standard, the check on absorbance limit violation is suppressed.
- High**
- Dup-diff** Enter the maximum allowed difference between repeated measurements of the same calibrator point. If the difference exceeds this, an error message is shown.
- Slope** Set by the analyzer after calibration is performed.
- Intercept**



**ATTENTION**

Some values are set by the analyzer after performing a calibration measurement. It is possible to enter values manually. Note that results based on manual entry of calibration values may be incorrect.

13. (Optional) Check the calibration curve. Click **F2 Display Calibration**. The calibration curve is shown on the screen. See par. 5.2.3.
14. Click **F10 Return**. Settings are saved. The **Test programming** screen is shown again. The chosen calibrator now appears in the list box.

### 6.2.6 Programming calculated tests

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Calculated tests** in the menu to the left. The screen shows the list of calculated tests that is defined on your analyzer.
3. Select the calculated test you want to program:
  - Select an empty position to define a new calculated test.
  - Select an existing calculated test to make changes to the parameters.



**Note**

A maximum of 20 calculated tests can be defined.

4. Press **Enter** or double-click on the selected position. The **Calculated test programming** screen opens.
5. (Optional) Click **Shift+F3 Delete** to remove the calculated test from the list.
6. Enter the **General** data in the top left section of the screen.

**Name:** Name to identify the calculated test. The name appears in list boxes where a choice of calculated test must be made.

**Abbreviated name:** Abbreviated name of the calculated test. If nothing is entered here, the calculated test will not be stored.

**Units:** Units to use for the calculated test.

**Decimals:** Number of decimals used for the results.

7. Enter the **Reference values** in the top right section of the screen.

**Male:** Limits to be used for samples of male patients.

**Female:** Limits to be used for samples of female patients.

**Pediatric:** Limits to be used for samples of pediatric patients.

**Panic:** Limits to be used as absolute limits for all samples.



**Note**

The **Sex:** field in the sample data determines the reference values that are used to check the feasibility of the measurement results. If the results exceed the applicable limits, the appropriate error flag is set for the result. Results that exceed the **Panic:** limits are always flagged.

- Define the **Formula** to use for the calculated test.

Click in the formula field in the top. Click **F7 Insert Test**. The list of available tests opens. Select a test in the list. Click inside the formula field to insert the test. Enter operators via the keyboard. Continue to insert tests and operators until the formula is complete.



**Note**

Press **Enter** to update the graphic representation of the formula. All tests and operators (except the division operator) are shown in list boxes. Select other items from the list boxes to make changes to the formula. Press **Enter** to update the formula field in the top.

- (Optional) Define a **Condition**. The test result will only be calculated when the condition is true.

Click in the condition field in the top. Click **F7 Insert Test**. The list of available tests opens. Select a test in the list. Click inside the condition field to insert the test. Enter an operator and a value via the keyboard.



**Note**

Press **Enter** to update the graphic representation of the condition. The elements of the condition are shown in list boxes. Select other items from the list boxes to make changes to the condition. Press **Enter** to update the condition field.



**Note**

The condition can compare two test results or compare one test result against a value. If the test result is not available, the condition is not used.

- (Optional) Enter a **Related Text:**. This text is used to document the calculated test. It will be printed on the test report with the calculated test result.
- Click **F10 Return** to save changes and return to the list of calculated tests.

### 6.2.7 Defining incompatible and/or linked tests



**Note**

This procedure is used to relate tests to each other in two different ways:

- Prevent that a test immediately follows another test (incompatible tests).
- Force a test to immediately follow another test (linked tests).

The latter option can also be used to enforce automatic needle rinsing after a test.

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Cuvette incompatibility** in the menu to the left.
3. Press **Enter** to open the **Program cuvette incompatibility** screen.



**Note**

It is also possible to define needle incompatibility. This is done via the **Needle incompatibility** function in the menu. The procedure is identical to the cuvette incompatibility function and not described separately in this manual.

4. Select the test for which you want to define an incompatible or linked test. Click in the first empty column behind the test.

ASAT mono	:				
ASAT Dual	:				
Cholesterol LDL	:				
Creatinine	:				
Cholesterol HDL	:				
Cocaine	:				
Urea	:				

5. (Optional) Click **Shift+F3 Delete** to remove the content of the selected cell.
6. Press **Enter** or click on the button next to the selected cell. A screen opens with all the tests defined on your analyzer.
7. Select the test to define as incompatible or linked to the first test.
8. Click **F4 Link test**. The test selection screen closes. The selected test is entered into the cell on the **Program cuvette incompatibility** screen.
9. Continue to add tests in the same row. Up to 5 tests can be listed per row.

ASAT mono	:	Cholesterol LDL	Glucose		
ASAT Dual	:				
Cholesterol LDL	:				
Creatinine	:				

10. (Optional) Click **F5 Link <<** to mark the tests as linked. A double arrow shows behind the first test name. The analyzer searches for the linked tests in the loadlist. The first linked test that is found is performed first. After that, the normal test order is resumed.

ASAT mono	<<	HCL	NEEDLE RINSE		
ASAT Dual	:				
Cholesterol LDL	:				
Creatinine	:				

11. (Optional) Click **F6 Incompatible** : to make the selected test(s) incompatible. None of the tests in the row will be executed immediately after the test to the left.

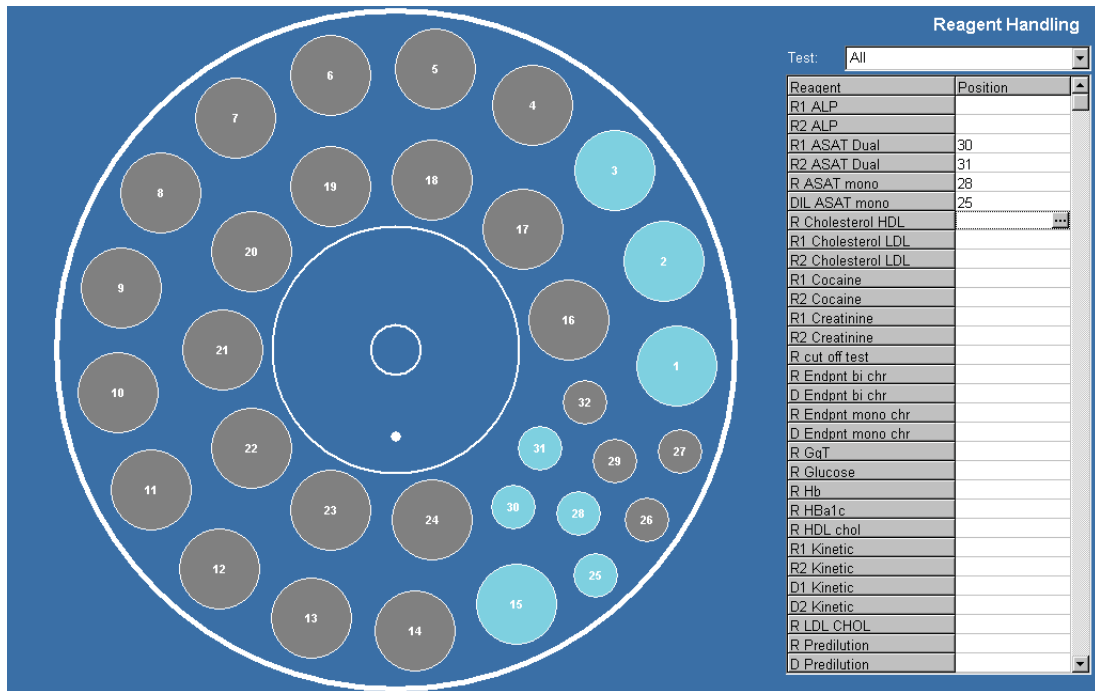
**Note**

Setting many incompatibilities has a negative influence on the throughput of the analyzer. If you have complex requirements for your analyzer, contact your supplier for support.

## 6.3 Reagents

### 6.3.1 Programming reagent positions

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Select **Reagent positions** from the list of functions to the left.
3. Press **Enter**. The screen shows the reagent rotor with the currently programmed reagent positions. The reagents for all tests are listed to the right.



4. Select the reagent you want to position on the rotor.
5. Click on an available position on the rotor image. Positions R1 through R30 are available for reagents.



**Note**

The small circles are for 10 ml bottles; the large circles are for 25 ml bottles. If you want to use 50 ml bottles, select a large circle and leave the adjacent large circle empty. The bottle uses two positions. The size of the reagent bottles is set in the **Reagent Info** screen.

6. Place reagents on the rotor.



**Note**

Depending on normal procedures in your laboratory, placing reagents may be the task of the operator as part of the start-of-day procedure.



**Note**

Make sure no foam is formed on top of the reagents. If foam is present, then remove it carefully using a disposable pipette.



**Note**

To increase the on-board stability of the reagents it is recommended to place a cap and store reagents in a refrigerator overnight.



**Note**

It is recommended to let reagents stored in a refrigerator equilibrate to instrument temperature before use.

7. Continue defining reagent positions as required.
8. To delete a reagent position, select the position in the list and press delete on the keyboard.
9. (Optional) Program expiry dates and batch numbers. See par. 5.2.2.

### 6.3.2 Defining multiple reagent rotors



#### WARNING

Using multiple reagent rotors requires strict handling procedures. The analyzer has no way of checking whether the correct reagent rotor is placed. If multiple reagent rotors are used in your laboratory, checking the current rotor configuration should be made part of standard operating procedures. See par. 5.2.4.

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Change reagent disk** in the menu to the left.
3. Press **Enter**. The screen shows the list of rotor definitions on your analyzer.
4. (Optional) Click **Shift+F3 Delete Reagent Disk** to remove the selected rotor.



#### ATTENTION

Only remove the rotor if you are sure that it will not be used anymore. All definitions of reagent positions for this rotor will be deleted with the rotor configuration.

5. Create a new rotor by one of these options:
  - Click **F5 Copy Reagent Disk** to copy the selected rotor configuration.
  - Click **F2 New Reagent Disk** to create an empty rotor configuration.

The new rotor is automatically selected as the current one.

6. Define reagent positions for the new rotor. See par. 6.3.1.

## 6.4 Back-up and restore points

### 6.4.1 Creating backup files

**Note**

It is recommended to perform backups regularly. Backup information should not be stored on the analyzer but on external storage media (e.g. a USB memory stick).

1. (Option) Create a restore point file. See par. 6.4.3.

**Note**

The Selectra ProM can make restore point files automatically. This is a recommended option. See par. 6.4.3.

2. Insert a USB memory stick into a free USB port of the built-in computer.
3. Open the Windows Explorer window.
4. Copy the newest restore point file to the USB memory stick.

**Note**

The restore point files are normally located in this directory:

***C:\Program Files\ELITech Clinical System\RestorePoints***

It is possible to change the restore point directory. See par. 6.4.3.

5. (Optional) Copy archived results to the USB memory stick.

**Note**

The archived results are normally located in this directory:

***C:\Program Files\ELITech Clinical System.***

It is possible to change the archived results directory. See par. 6.5.1.

6. Close the Windows Explorer window when the file is copied.

**ATTENTION**

It is usually not a good idea to unplug the USB memory stick without first stopping the device. Use the Windows Explorer to safely remove the USB memory stick: right-click the USB device and choose the Eject option.

**Note**

Most USB memory sticks have a light that blinks during data transfer. Wait until there is no activity on the USB memory stick for some time. It is also possible to leave the USB memory stick in the computer.

## 6.4.2 Restoring backup files

1. Insert the USB memory stick with the back-up files into a free USB port of the built-in computer.
2. (Optional) Copy the file to the harddisk of the built-in computer.
  - 2.1. Open the Windows Explorer window.
  - 2.2. Copy the restore point file from the USB memory stick to the computer.
  - 2.3. Close the Windows Explorer window when the file is copied.



### Note

The restore point files are normally located in this directory:

**C:\Program Files\ELITech Clinical System\RestorePoints.**

It is possible to change the restore point directory. See par. 6.4.3.

3. Click **Restore point** in the menu to the left.
4. Click **Shift+F8 Restore from File**. A dialog window opens.
5. Find and select the file. Click **OK** to restore the file.



### ATTENTION

It is usually not a good idea to unplug the USB memory stick without first stopping the device. Use the Windows Explorer to safely remove the USB memory stick: right-click the USB device and choose the Eject option.

### 6.4.3 Handling automatic restore points

**Note**

The restore point file contains all information required to restore the Selectra ProM to the same configuration as when the restore point file was created.

**Creating restore point files**

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Select **Restore point** from the list of functions to the left. The screen with parameters for the restore point feature opens.
3. Set the timepoint to create daily restore points.

Create daily restore point at: 0 : 0

Monday:	Not available
Tuesday:	Not available
Wednesday:	Not available
Thursday:	Not available
Friday:	Not available
Saturday:	Not available
Sunday:	Not available
Day to restore:	No restore points available

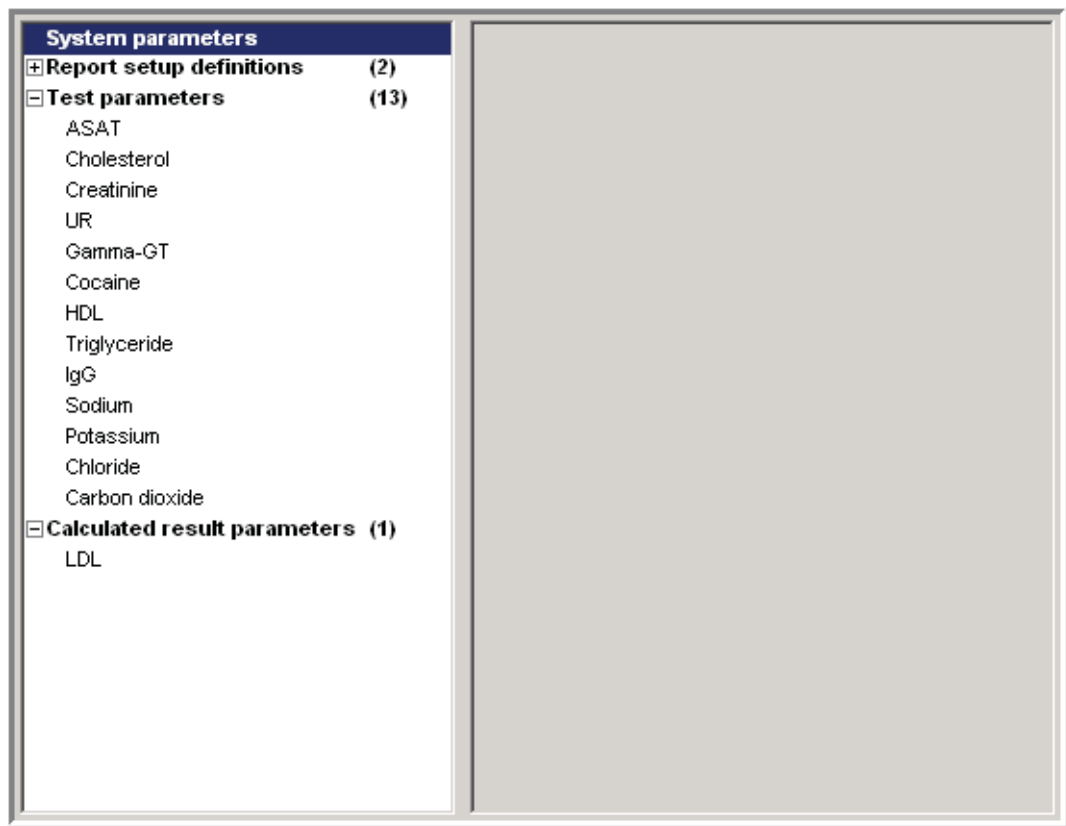
4. (Optional) Click **F6 Make Restore Point Now**. A restore point file is created immediately.

**Retrieving restore point files**

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Restore point** in the menu to the left. The screen with parameters for the restore point feature opens.
3. Select the **Day to restore:** from the list. The weekday fields show the latest available restore point files for those days.
4. Click **Shift+F7 Restore**. When the configuration is restored, the analyzer restarts.
5. (Optional) Click **Shift+F8 Restore from File**. A dialog window opens.
6. Find and select the file. Click **OK** to restore the file.

### 6.4.4 Exporting data

1. Open the *Installation* screen. This screen is listed in the menu tree.
2. Click **Export / Import data** in the menu to the left. The screen with options for exporting and importing opens.
3. 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. Click on a data set to select it. Press **Ctrl** and click on a data set to add it to or remove it from the selection. Click on the category to export all data sets in that category.

4. Click **Shift+F4 Export**.
5. 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.

### 6.4.5 Importing data

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Export / Import data** in the menu to the left. The screen with options for exporting and importing opens.
3. Click **Shift+F5 Import**.
4. The open file dialog opens. Locate the file to be imported. The required format of the data file is **XML**.
5. 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.

6. If the file contains test parameters or calculated tests, two lists are shown on the screen:

The screenshot shows a dialog box titled "C:\Program Files\Junior\exchange\Test group.XML". It displays the "Remained number of free open channels after import of selected tests: 111". The dialog is divided into four quadrants:

- Top Left:** "Delete open tests" with a list of tests: Check S, Volume 30, Check R, Test zonder R, Glucose, Creatinine, Urea, Cholesterol, and ASAT. Each test has a checkbox, with Glucose through ASAT checked.
- Top Right:** "Import open tests (5 selected)" with a list of tests: Glucose, Creatinine, Urea, Cholesterol, and ASAT. Each test has a checked checkbox.
- Bottom Left:** "Delete closed tests" with an empty list.
- Bottom Right:** "Import closed tests (0 selected)" with an empty list.

At the bottom of the dialog, it shows "Remained number of free closed channels after import of selected tests: 111".

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 tests, they are shown above the tests.

7. 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.
8. Click **F3 Confirm**.

## 6.5 Customization

### 6.5.1 Setting system parameters

1. Open the *Installation* screen. This screen is listed in the menu tree.
2. Click *System parameters* in the menu to the left. The screen shows the current settings.
3. Choose settings as required. Changes are saved immediately.

The screenshot shows a configuration window with the following fields and values:

- Language: English
- Laboratory name: (empty)
- Sample ID auto incr.: Yes
- Automatic blank time: 4 : 0
- Max. cuvette blank SD: 0.0200
- Needle rinse interval: 7 days
- Error sound: Sound 1
- Error sound duration: Constant
- Archived results folder: c:\Program Files\

**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** screen 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** screen when pressing the **New Sample** button.

When using barcoded samples, select **No**.

**Automatic blank time:** The time (hh:mm using a 24-hour clock) at which the analyzer performs a daily blank measurement of the cuvette rotor. It is recommended to do this before the daily routine. This is only possible when the analyzer is **Stand-by** at the indicated time.

**Max. cuvette blank SD:** The maximum standard deviation for a blank measurement of the cuvette rotor. The recommended value is 0.0200. If this value is exceeded, an error message is printed together with the rotor blank results.

**Needle rinse interval:** The interval in days, after which you do a needle rinsing.  
 0: No needle rinsing  
 1: The rinsing must be done every day  
 2-7: The number of days after which rinsing must be done

**Error sound:** A selection of five sounds is available for the analyzer. Click **Play Error Sound** to hear the error sound. The default sound is **Sound 1**.

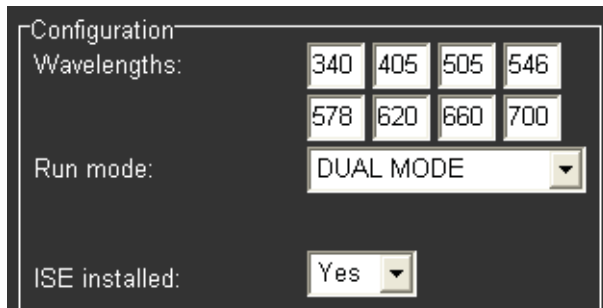


**Error sound duration:** Four error sound durations are available.

**Archived results folder:** Location where result archives must be stored. Click on the button next to the field to change the folder.

6.5.2 System configuration

1. Open the **Service** screen. This screen is listed in the menu tree.
2. Click **System configuration** in the menu to the left. The screen shows the current settings.
3. Set parameters in the **Configuration** section.



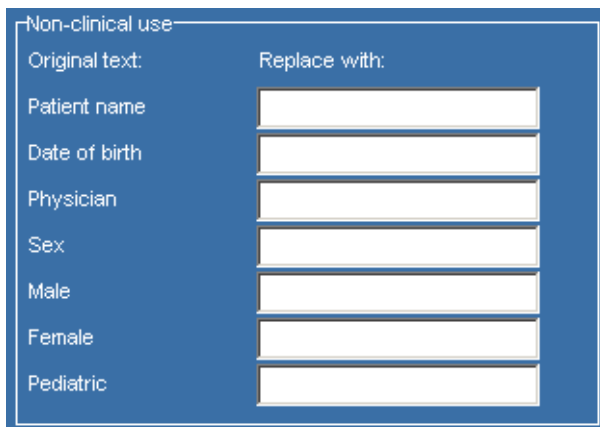
**Wavelengths:** These 8 fields contain the wavelengths of the filters that are installed in the filter wheel. All wavelengths are in nanometers.

**Run mode:**

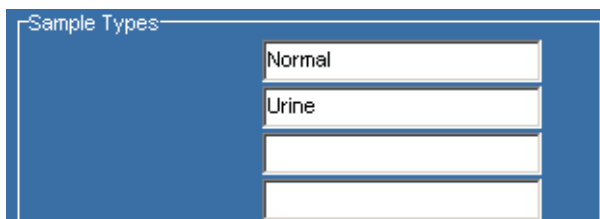
- **MONO MODE** - Only single reagent methods can be used. The cycle time is 20 seconds.
- **DUAL MODE** - All methods, including multiple reagent methods, can be used. The cycle time is 27 seconds.

**ISE installed:** Select **Yes** if the optional Dry Electrode ISE unit is installed.

4. (Optional) Redefine labels in the **Non-clinical use** section. The labels are used in all screens that list the sample details identified here. They are also used on printed reports.



5. (Optional) Define labels in the **Sample Types** section. Up to 10 labels can be defined.



These labels are used to set different test parameters for each sample type. Tests can be allowed or disallowed for each sample type. Also, reference values can be set separately for each sample type. All non-empty labels appear as separate sections in the **Test parameters 1** page. The sample type is selected in the **Request samples** screen.

Sample types

Normal **Urine**

Allowed: Yes

Predilution: Yes  1 : 5

Reference values

Male:	<input type="text" value="15.0"/>	-	<input type="text" value="200.0"/>
Female:	<input type="text" value="0.0"/>	-	<input type="text" value="0.0"/>
Pediatric:	<input type="text" value="0.0"/>	-	<input type="text" value="0.0"/>
Panic:	<input type="text" value="0.0"/>	-	<input type="text" value="0.0"/>

### 6.5.3 Programming profiles

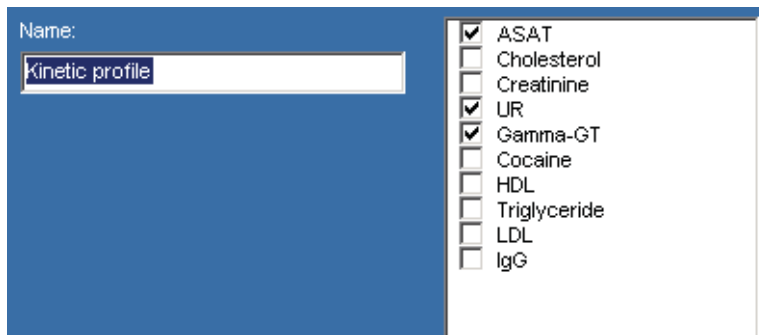
1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **Profile programming** in the menu to the left. The screen shows the current settings.
3. Select the profile you want to program:
  - Select an empty position to define a new profile.
  - Select an existing profile to make changes to it.

**Note**



A maximum of 20 profiles can be defined.

4. Press **Enter** or double-click on the selected position. The **Program profile** screen opens.
5. (Optional) Click **Shift+F3 Delete** to remove the profile from the list.
6. Set the name for the profile in the field to the left.



7. Select the tests for the profile. Click in the checkboxes in front of the test names.

**Note**



A maximum of 20 tests can be included in one profile.

**Note**

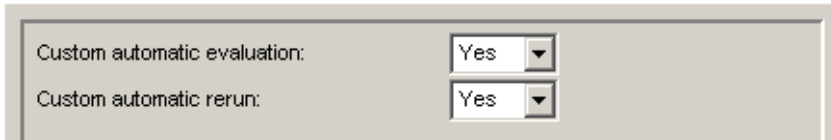


Some tests may be shown in grey in the list. These tests can be included in the profile, but the reagents for these tests are currently not available on the rotor.

8. Click **F10 Return** to save the changes and return to the list of profiles.

### 6.5.4 Setting automatic evaluation and rerun

1. Open the *Installation* screen. This screen is listed in the menu tree.
2. Click **Custom evaluation** in the menu to the left. The screen shows the current settings.
3. (Optional) Click **F2 Restore Defaults** to restore the factory settings.
4. Switch the automatic evaluation and rerun options on or off.



**Custom automatic evaluation:** Select **Yes** to make the analyzer automatically perform the actions as listed in the **Evaluation** column in the table.

**Custom automatic rerun:** Select **Yes** to make the analyzer automatically rerun measurements as listed in the **Rerun** column in the table.



**Note**

It is possible to combine the **Custom automatic evaluation:** and the **Custom automatic rerun:** options. In this case, the **Custom automatic rerun:** is performed first. If limits are still violated after the rerun the results are automatically evaluated according to the settings for the **Custom automatic evaluation:** option.

5. Select the test-specific options. Click in the cells to open a list box with available options.

Flag	Description	Evaluation	Rerun
M	HIGH ABSORBANCE LIMIT VIOLATION	Reject	No
m	LOW ABSORBANCE LIMIT VIOLATION	Reject	No
V	RESULT POSITIVE	Accept	No
v	RESULT NEGATIVE	Accept	Yes
*	LINEARITY ERROR	Reject	No
#	INSUFFICIENT SAMPLE	Reject	No
a	REAGENT ABSORBANCE ERROR	Accept	No
D	SUBSTRATE DEPLETION ERROR	Reject	No
D	REAGENT ABSORBANCE DEVIATION ERROR	Reject	No

**Flag** Error flag for which automatic actions are defined.

**Description** Error description. See par. 5.6.2.

**Evaluation**

- **Accept** - accepts the test results.
- **Reject** - rejects the test results.
- **Operator** - sets the **\*INFO\*** status to ask the operator.
- **Error** - sets the **\*INFO\*** status and shows an error message (only available for **INSUFFICIENT SAMPLE**).

**Rerun**

- **Yes** - The rerun option is switched on for this error.
- **No** - The rerun option is switched off for this error.

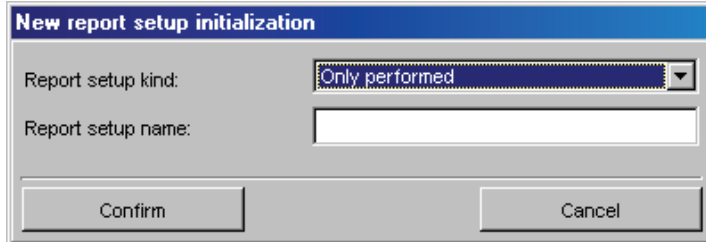


**Note**

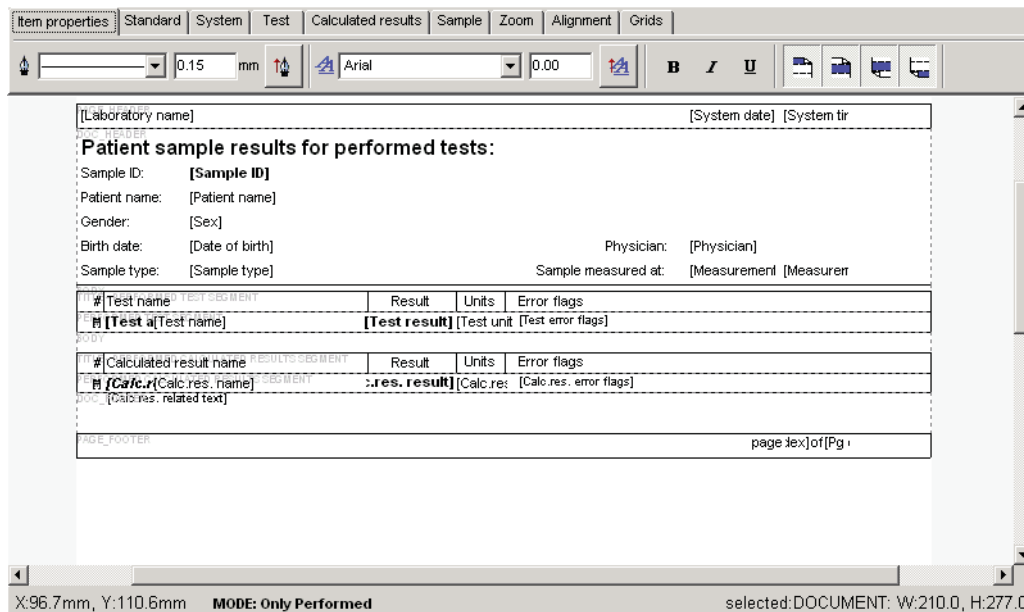
For some test flags, a rerun is not possible. The listbox is disabled in those cases.

6.5.5 Creating custom reports

1. Open the *Installation* screen. This screen is listed in the menu tree.
2. Click **Report setup** in the menu to the left. The list of report setups is shown.
3. (Optional) To create a new report setup:
  - 3.1. Select an empty position.
  - 3.2. Press **Enter** or double-click on the selected position. A dialog window opens.



- 3.3. Select **Only performed** to include only tests for which measurements were made. Select **Fixed** to include all tests, regardless whether measurements were made.
  - 3.4. Type a name for the report in the bottom field of the dialog window.
  - 3.5. Click **Confirm** to close the dialog.
4. (Optional) To change an existing report setup:
  - 4.1. Select an existing report from the list to change its layout
  - 4.2. Press **Enter** or double-click on the selected position.
5. The custom report design screen opens.



6. (Optional) Click **Shift+F3 Delete Report** to remove the report from the list.
7. Define which segments will be included in the report. Some segments are mandatory. The four buttons to the right in the Item properties tab allow switching the document and page headers and footers on or off for the report.

- 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.

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

- Use the menu items at the top of the screen to edit the standard form. 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. When an item is selected, 4 handles show at the boundaries of the item. A yellow handle is a fixed position and cannot be moved. Green handles can be moved and resized. The tab at the top of the screen will automatically show the definable properties for each item. All tabs and their options are listed in par. 6.5.6.

**Note**

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 (e.g. test parameters can only be placed in a performed test segment).

**Note**

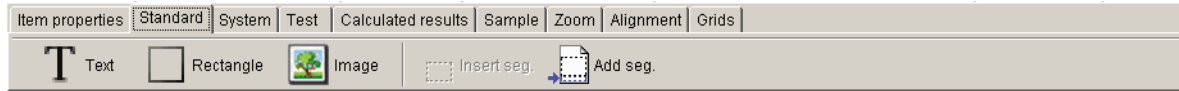
Items must be positioned completely inside the segment. It is not possible for items to be printed partially outside the segment.

- Click **F1 Render Report** to preview the layout.
- (Optional) Click **Alt+F8 Return Without Saving** to exit the custom report designer without saving any changes.
- Click **F10 Return** to exit the custom report designer after saving the new layout.
- Click on the new custom report in the list.
- (Optional) Click **F4 Scroll Mode** to make the selected custom report the default.

### 6.5.6 Report setup tabs and data fields

#### Standard tab data fields

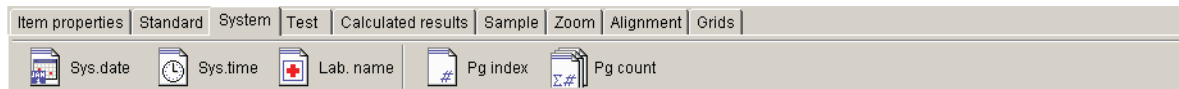
These data fields can be used in every segment.



- Text** Adds text to the report.
- Rectangle** Place a rectangle in the report. Click the location of the first corner. Then click the location of the opposite corner to define the position and size of the rectangle.
- Image** Place an image in the report. Click the location of the first corner. Then click the location of the opposite corner to define the position and size of the rectangle.
- Insert seg.** Inserts a **BODY** segment before the selected segment
- Add seg.** Inserts a **BODY** segment after the selected segment.

#### System tab data fields

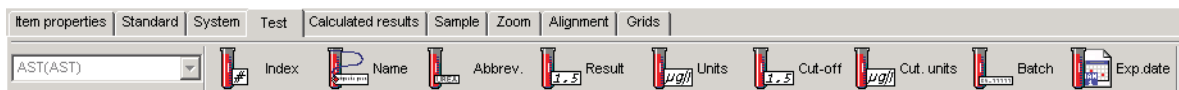
These data fields can be used in every segment.



- Sys.date** Add system date.
- Sys.time** Add 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.



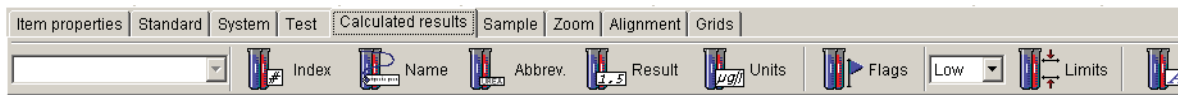
- Test** For **Fixed** reports, select the test and data fields to be placed on the report. For **Only performed** reports this field is disabled; all tests are printed with the same test data fields.
- Index** Only available for **Only performed** reports. The index number for the completed test is printed.
- Name** Test name.



<b>Abbrev.</b>	Abbreviated name.
<b>Result</b>	Measured result.
<b>Units</b>	Measurement units.
<b>Batch</b>	Batch number of the first reagent.
<b>Flags</b>	For <b>Fixed</b> reports, the 1st, 2nd, 3rd, 4th, or 5th flag of the selected test is printed depending on the selected flag. For <b>Only performed</b> reports, all flags of the test result are printed.
<b>Limits</b>	Adds low reference limit, high reference limit for the sample, or the word <b>Panic</b> if the result is outside panic limits.

**Calculated tests tab data fields**

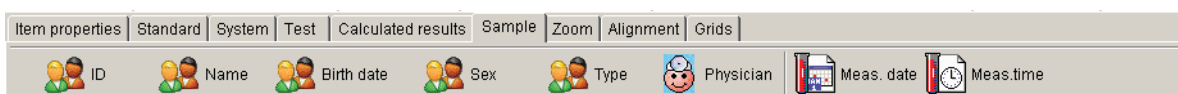
For an **Only performed** report, these data fields must be used in the performed test segment.



<b>Calculated tests</b>	For <b>Fixed</b> reports, select the calculated test and data fields to be placed on the report. For <b>Only performed</b> reports this field is disabled; all calculated tests are printed with the same results data fields.
<b>Calculated test index</b>	Place a rectangle on the report. Click the location of the first corner. Then click the location of the opposite corner to define the position and size of the rectangle.
<b>Calculated test name</b>	Test name.
<b>Calculated test short name</b>	Abbreviated name.
<b>Calculated test result</b>	Measured result.
<b>Calculated test units</b>	Measurement units.
<b>Flags</b>	For <b>Fixed</b> reports, the 1st, 2nd, 3rd, 4th, or 5th flag of the selected test is printed depending on the selected flag. For <b>Only performed</b> reports, all flags of the test result are printed.
<b>Place calculated test reference limits</b>	Adds low reference limit, high reference limit for the sample, or the word <b>Panic</b> if the result is outside panic limits.
<b>Text</b>	Adds text to the report.

**Sample tab data fields**

These data fields can be used every segment.

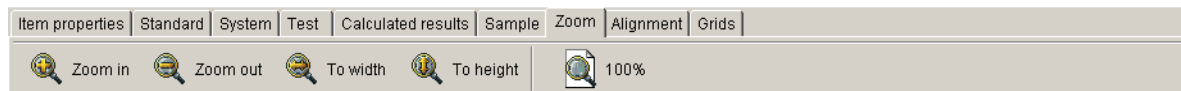


<b>ID</b>	Sample ID.
<b>Name</b>	Patient name.

<b>Birth date</b>	Date of birth.
<b>Sex</b>	Sex of the patient.
<b>Type</b>	Type of sample: ASAP, STAT or normal.
<b>Physician</b>	Name of the physician.
<b>Meas. date</b>	Date when the sample was measured.
<b>Meas.time</b>	Time when the sample was measured.

**Zoom tab effects**

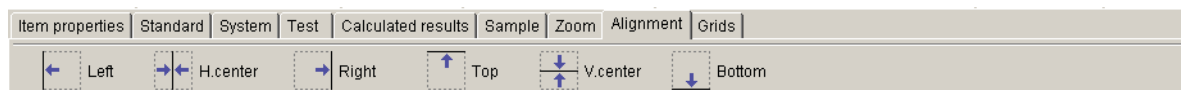
These effects are for on-screen viewing.



<b>Zoom in</b>	Zoom in.
<b>Zoom out</b>	Zoom out.
<b>To width</b>	Fits the width of the page to the width of the screen.
<b>To height</b>	Fits the height of the page to the height of the screen.
100%	Zooms to the default size.

**Alignment tab effects**

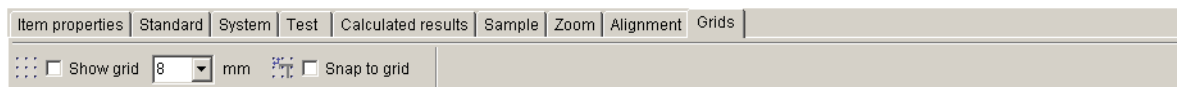
These buttons align data fields in the report layout. Select the data field to align to (this field always remains in the same position). Press the **Shift** key and select the items to align.



<b>Left</b>	Aligns the data field to the left boundary of the first selected field.
<b>H.center</b>	Aligns the data field to the horizontal center of the first selected field.
<b>Right</b>	Aligns the data field to the right boundary of the first selected field.
<b>Top</b>	Aligns the data field to the top boundary of the first selected field.
<b>V.center</b>	Aligns the data field to the vertical center of the first selected field.
<b>Bottom</b>	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**

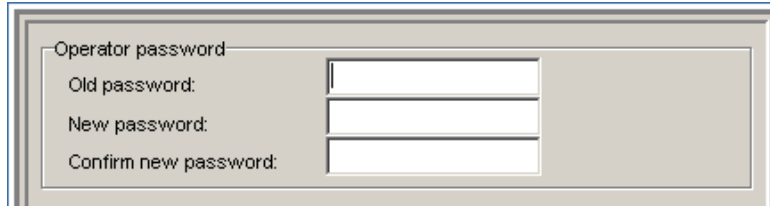
Switch the grid on. The grid size can be set from 1 to 10 mm.

**Snap to grids**

Align the data field to the horizontal and vertical lines of the grid.

### 6.5.7 Setting the password

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Passwords** in the menu to the left. The screen shows the current settings.



3. Enter the **Old password:**.



**Note**

If no password was set on your Selectra ProM, leave this field empty.

4. Enter the **New password:**. Retype the same new password in the **Confirm new password:** field.



**Note**

To disable the password on your Selectra ProM, leave both fields empty.

5. Click **Shift+F4 Change Operator Password**.
6. Open the **Main menu** from the menu tree.
7. Click **F4 Log Off**.



**ATTENTION**

Do not forget this step. The system is not protected unless you log off.

## 6.6 External connections

### 6.6.1 Configuring the printer

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Communication** in the menu to the left. The screen shows the current settings.
3. Set the **Printer** parameters in the top section of the screen.

Printer

Printing enabled: Yes

Printer name: Brother HL-5250DN series

System printouts: No Page Format: A4

Result printouts: No

Use report setup: No

Calibration printouts: No

Control printouts: No

Blank printouts: No

Page margins:

Units: cm

Left margin: 0.6

Right margin: 0.7

**Printing enabled:** Select **Yes** to enable printing.

**Printer name:** Selected printer for the printouts. Changing the printer is done via **F2 Printer Setup**.

**System printouts:** Select **Yes** to have all non-patient data printed, such as graphs, blank data, calibration curves, etc.

**Result printouts:** Select **Yes** to have all patient data printed.

**Use report setup:** Select **Yes** to activate the user defined report layout instead of the default report. See par. 6.5.5.

**Calibration printouts:** Select **Yes** to have all calibration data printed.

**Control printouts:** Select **Yes** to have all control data printed.

**Blank printouts:** Select **Yes** to have all blanks data printed.

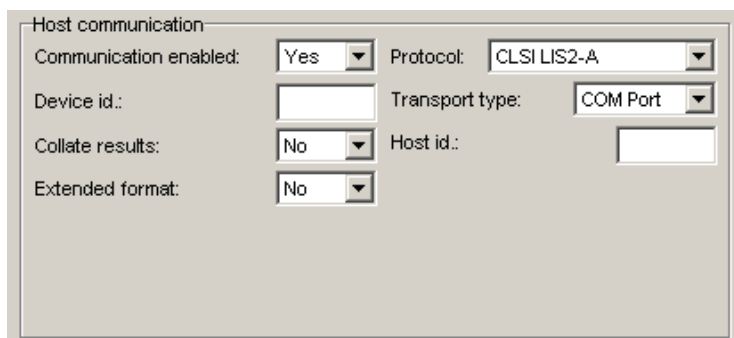
**Page Format:** Shows the currently selected page format. This setting can only be changed in the printer setup.

**Page margins:** Select the **Units:** and sizes of the page margins.

4. (Optional) Click **F2 Printer Setup** to select a printer and set the printer properties.
5. (Optional) Open the Windows printer installation section. Install the printer that will be used to print reports from the Selectra ProM. Then select the printer and printer properties.

### 6.6.2 Configuring the LIS host connection

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Communication** in the menu to the left. The screen shows the current settings.
3. Set the **Host communication** parameters in the bottom section of the screen.



**Communication enabled:** Select **Yes** to enable communication with the LIS host.

**Protocol:** Name of the protocol. A document describing the **CLSI LIS2-A** protocol can be provided on request.

**Device id.:** Six-digit code for identification purposes. All information sent to the host computer will be identified by this code.

**Host id.:** Four-digit code to identify the host computer to communicate with. This can be used in situations where multiple host systems are connected in the same LIS.

**Transport type:** Select **COM Port** or **TCP/IP**.

**Collate results:** Select **Yes** to keep test results until all tests for a sample are ready, before the whole set of test results is sent to the host. Select **No** to have the analyzer send test results as soon as they become available.

**Extended format:** Select **Yes** to use an extended format in the communications with the host computer (absorbance values are transmitted to the host along with the results).

4. (Optional) If the **Transport type:** is **COM Port**, Click **F3 Port Settings** to change the serial communication port settings. Contact your supplier for details.
5. (Optional) If the **Transport type:** is **TCP/IP**, Click **F3 TCP/IP connection settings** to change the communication settings. If required, click **F9 Network Connections** to open the Windows network configuration section.

## 6.7 Analyzer software

### 6.7.1 Checking the release

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Release** in the menu to the left. The screen shows the release information.

Release information	
Release	ELITech Clinical System 4.2.0
Version:	4.2.0
PC Software	
Version:	4.2.0
Version date:	3/1/2010 10:33:44 AM

3. Click anywhere in the right part of the screen or press **Enter**. The **Prom Software** section shows detailed information about the firmware on the processor boards in the analyzer.

Prom Software	
Master:	PRM_V1.1.2 (DUAL)
Date:	11-jan-2010 06:53
Pipettor:	PIP_V1.0.0
Meas. unit:	MDF_V1.0.0
Sample arm:	SAM_V1.0.0
Reagent arm:	RAM_V1.0.0
Reagent disk:	DIS_V1.0.0
Wash arm:	WAB_V1.0.0
ISE unit:	VB1.4.6

**Note**

The information on this screen cannot be changed. You may need it when contacting the technical support department of your supplier.

### 6.7.2 Checking configuration changes

1. Open the **Service** screen. This screen is listed in the menu tree.
2. Double-click **Changes Log** in the menu to the left. The screen shows the logged changes.

11-Mar-2008	4:02:58 PM		Modified	Test parameters for ASAT Dual
10-Mar-2008	3:32:14 PM	Operator	Modified	Test parameters for rerun
10-Mar-2008	3:26:49 PM	Operator	Modified	Test parameters for cutoff
10-Mar-2008	3:24:17 PM	Operator	Added	Test parameters for abs limit
10-Mar-2008	3:23:43 PM	Operator	Added	Test parameters for rerun
10-Mar-2008	3:23:09 PM	Operator	Added	Test parameters for reference panic
10-Mar-2008	3:22:41 PM	Operator	Added	Test parameters for reference low I
10-Mar-2008	2:29:43 PM	Operator	Modified	Test parameters for test1
10-Mar-2008	2:29:35 PM	Operator	Modified	Test parameters for test3
10-Mar-2008	2:28:04 PM	Operator	Modified	Test parameters for test3
10-Mar-2008	2:27:37 PM	Operator	Modified	Test parameters for Test 1
10-Mar-2008	2:19:36 PM	Operator	Modified	System parameters
10-Mar-2008	11:09:00 AM	Operator	Modified	Test parameters for Cholesterol
10-Mar-2008	10:14:00 AM	Operator	Modified	Test parameters for ASAT Dual
10-Mar-2008	10:09:04 AM	Operator	Modified	Test parameters for test4
10-Mar-2008	10:08:55 AM	Operator	Modified	Test parameters for test3
7-Mar-2008	2:18:45 PM	Operator	Modified	Test parameters for Bichromaat
7-Mar-2008	2:18:21 PM	Operator	Modified	Test parameters for Test 1
7-Mar-2008	9:34:18 AM	Operator	Added	Test parameters for AAA
6-Mar-2008	3:56:25 PM	Operator	Modified	System parameters
6-Mar-2008	11:50:53 AM	Operator	Modified	Test parameters for Potassium
6-Mar-2008	11:50:29 AM	Operator	Modified	Test parameters for Urea
6-Mar-2008	11:50:21 AM	Operator	Modified	Test parameters for Creatinine
6-Mar-2008	11:44:21 AM	Operator	Modified	Test parameters for Volume-3
6-Mar-2008	11:44:15 AM	Operator	Modified	Test parameters for Volume-3
6-Mar-2008	11:44:08 AM	Operator	Modified	Test parameters for Volume-30
6-Mar-2008	11:42:22 AM		Modified	Test parameters for cut off test
6-Mar-2008	11:35:33 AM		Modified	Test parameters for test1
6-Mar-2008	11:35:33 AM		Modified	Calibration for test1

3. (Optional) Click **F2 Save And Clear** to save the current change log to a file. After saving the file the current list is cleared.



### 6.7.3 Upgrading

**Note**

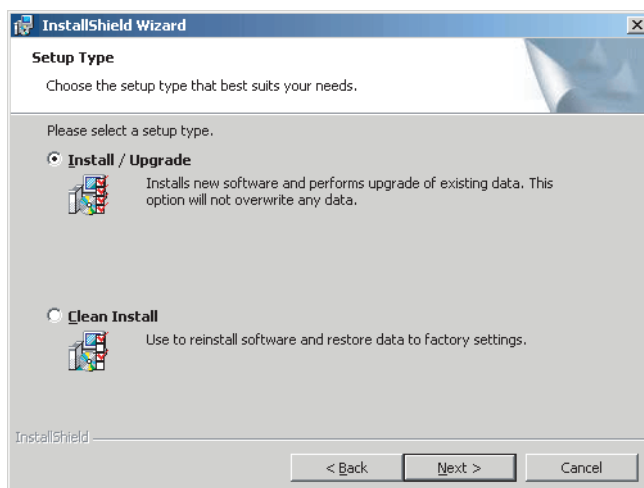
New releases of the analyzer software are normally supplied on a USB memory stick. It is possible that your supplier sends a support technician to install upgrades.

1. Make sure there are no pending measurements. The analyzer must be in **Stand-by** state and all samples must be unloaded.
2. Archive all measurement results. See par. 5.5.2.
3. Create a restore point file and a back-up. See par. 6.4.1.
4. Insert the USB memory stick with the upgrade into a free USB port. The analyzer software shuts down and the installation program is started.

**ATTENTION**

Do not insert the USB memory stick before the previous steps are finished. The software on the USB memory stick forces the analyzer software to shut down and does not give you the opportunity to perform any other steps.

5. The screen shows the setup options.



6. Select the **Install/Upgrade** option. Click **Next**.
7. Click **Finish** to start the installation process.



## Maintenance and servicing

## 7.1 Maintenance procedures

### 7.1.1 Maintenance schedule



**Note**

Some maintenance work may be done by service personnel of your supplier. When in doubt about the work that you need to do, contact your superior.



**ATTENTION**

Maintenance should only be performed by qualified personnel. The level of training that is required may differ between procedures. When in doubt, contact your superior.



**BIOHAZARD**

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 must be strictly followed, since contamination with infectious materials can never be fully excluded.

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

Frequency	Maintenance task	See also:
Every day	Fill water container.	par. 5.1.2
	Empty waste container.	par. 5.1.2
	Check cuvette blank results.	par. 7.1.4
	Fill rinse bottle with acid solution.	par. A.1.4
	Fill tube in W-position of sample rotor with system cleaning solution.	par. A.1.4
	Fill tube in B-position of sample rotor with distilled water.	
	Check wash arm, stirrer belt and cuvette rotor visually.	
	Check syringes for air bubbles and leaks.	par. 7.3.4
	Check if the cooling unit is working properly.	
Every week	Clean the needle with diluted system cleaning solution (1/10).	
Every two weeks	Check the performance with the SR3 and SR75 tests.	par. A.1.6
Every month	Clean water and waste containers with system cleaning solution. Afterwards rinse at least 3 times with distilled water.	par. A.1.4
Every quarter	Replace stirrer belts.	par. 7.1.6
	Replace drying block on wash arm.	par. 7.1.8
Twice per year	Replace water filter.	par. 7.1.7
	Run the system clean procedure (normally performed by the service engineer during preventive maintenance). Use the system cleaning solution undiluted.	par. 7.1.5

Frequency	Maintenance task	See also:
Every year	Replace the photometer lamp.	par. 7.3.3
10 000 tests	Replace the cuvette rotor.	par. 7.3.2

**Note**

Your laboratory may have additional maintenance requirements for the analyzer. The list shows the minimal tasks and frequencies recommended by Vital Scientific.

## 7.1.2 Automatic procedures

The Selectra ProM can automatically perform some maintenance procedures. These must be switched on via parameters in various configuration screens. This section lists all automatic options that can be used to keep the Selectra ProM in optimal shape.

### Cuvette blank

Setting the **Automatic blank time:** parameter makes the analyzer perform a cuvette blank every day at the specified time. This parameter is shown on the **System parameters** screen. See par. 6.5.1.

**Note**

The analyzer must be **Stand-by** at the specified time. Vital Scientific recommends keeping the analyzer switched on at all times.

**Note**

After the cuvette blank procedure, the analyzer prints a maintenance report. The printer must be switched on and have sufficient paper. Details on the report are listed in par. 7.1.3.

### Restore point

Setting the **Create daily restore point at:** parameter makes the analyzer create a restore point every day at the specified time. This parameter is shown on the **Restore point** screen. See par. 6.4.3.

**Note**

The analyzer must be **Stand-by** at the specified time. Vital Scientific recommends keeping the analyzer switched on at all times.

**Note**

It is recommended to save the latest restore point file to external storage media on a regular basis. This is not done automatically.

### 7.1.3 Printing a maintenance report

1. Open the **Rotor/System** screen. This screen is listed in the menu tree.
2. Click **Blank rotor** in the menu to the left.
3. Click **F8 Maintenance Report**. The maintenance report is sent to the printer.  
The report indicates when maintenance tasks must be performed. A section of a sample report is shown here:  
The maintenance report contains the following sections:
  - **BLANK ROTOR RESULTS** - Averages and deviations of all cuvette blank measurements for each filter. When an SD.ERR is shown, details must be checked. See par. 7.1.4.
  - **CALIBRATION PLANNING** - Shows how long calibrations are still valid. Calibrations with an asterisk in the 0 column must be done before normal tests can be performed.
  - **MAINTENANCE PLANNING** - Shows when specific maintenance tasks must be performed. Tasks with an asterisk in the 0 column must be done as soon as possible.
  - **EXPIRING REAGENTS** - Shows when reagents reach their expiry dates. Reagents with an asterisk in the 0 column must be replaced.
  - **EXPIRING CONTROLS** - Shows when controls reach their expiry dates. Controls with an asterisk in the 0 column must be replaced.
  - **EXPIRING CALIBRATORS** - Shows when calibrators reach their expiry dates. Calibrators with an asterisk in the 0 column must be replaced.

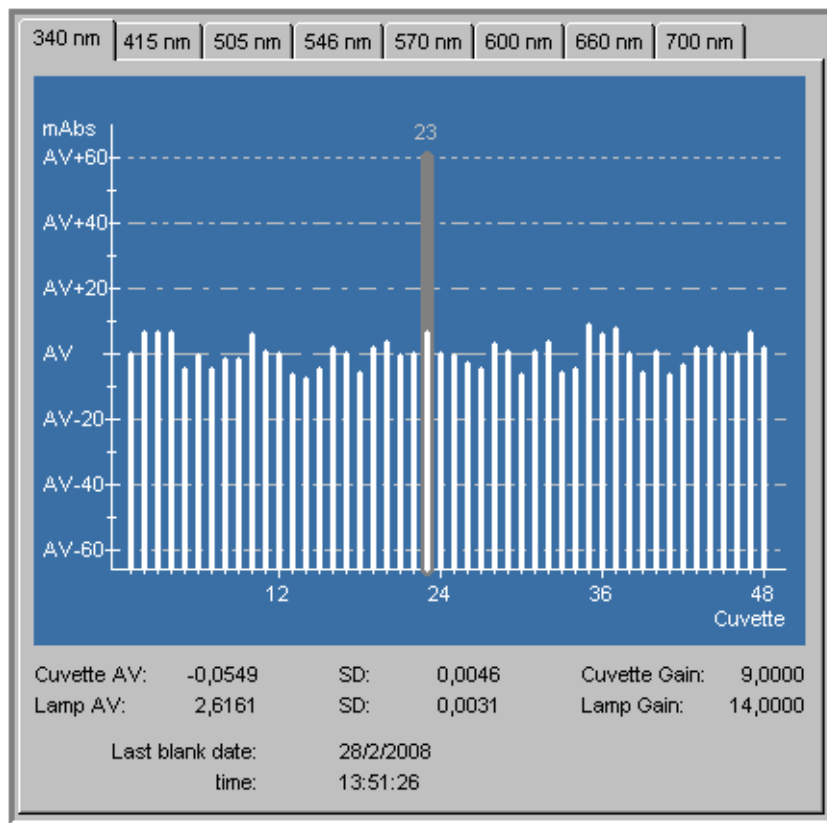
### 7.1.4 Blanking the cuvette rotor



**Note**

The analyzer can perform a daily cuvette blank automatically. See par. 7.1.2.

1. Open the **Rotor/System** screen. This screen is listed in the menu tree.
- 2.
3. (Optional) Click **F7 Graph** to see a graph of the measurement results. The numbers below the graph are identical to the numbers below the table.



4. When the last blank date and time are more than 24 hours ago, a new cuvette blank must be performed. Click **F2 Blank Rotor** to start a cuvette blank measurement manually.



**Note**

The cuvette blank measurement takes about 15 minutes to complete.

5. (Optional) Exclude cuvettes for which the results are too far off from the average.
  - 5.1. Click on the bar in the histogram to select the cuvette. The selected cuvette is indicated by a grey bar. The number of the cuvette is shown above the grey bar.
  - 5.2. Click **F5 Previous** or **F6 Next** to select another cuvette, if needed.



5.3. Click **F4 Exclude/ Include** to exclude or include the selected cuvette.



**Note**

Exclusion of cuvettes slows down the analyzer. It is recommended to keep the number of exclusions low, i.e. a maximum of three. After this, the cuvette rotor should be replaced. See par. 7.3.2.



**Note**

When the cuvette rotor is replaced, all cuvettes are automatically included again.

6. (Optional) Click **F1 Print** to send a detailed report to the printer. The report includes the table and the graphic view, but only for the selected filter.

### 7.1.5 Cleaning system parts

These procedures are normally done as part of regular maintenance. Before the procedures are started, all measurements must be finished. Make sure the water container is filled.

#### Cleaning the cuvette rotor

In this procedure, all cuvettes are filled with water and emptied four times. The procedure takes about 7 minutes.

1. Open the **Rotor/System** screen. This screen is listed in the menu tree.
2. Click **Rotor/Needle rinse** in the menu to the left.
3. Click **F1 Wash Rotor**. The analyzer performs the washing procedure. When the procedure is finished, the analyzer switches to **Stand-by**.

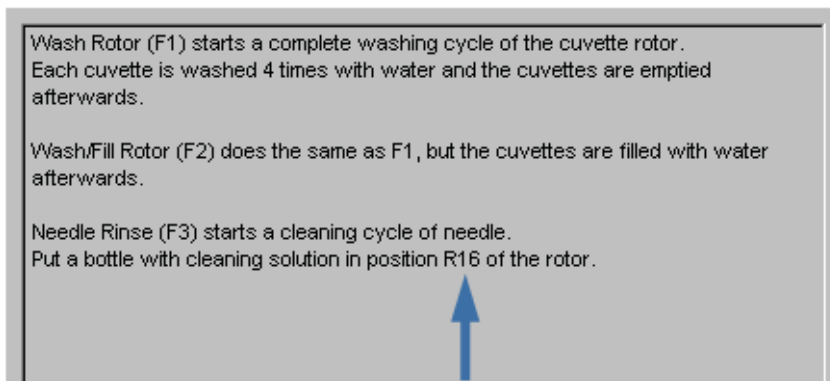
**Note**

Click **F2 Wash/Fill Rotor** to let the analyzer fill the cuvettes with water after finishing the cleaning cycle.

#### Cleaning the needle

In this procedure, the needle of the analyzer is washed with diluted system cleaning solution. See par. A.1.4.

1. Open the **Rotor/System** screen. This screen is listed in the menu tree.
2. Click **Rotor/Needle rinse** in the menu to the left.
3. Place a 50 ml bottle with at least 30 ml of diluted system cleaning solution in the rotor (a hypochlorite solution is recommended). The position for the system cleaning solution is indicated in the text on the screen.

**Note**

If the position xx is shown, you must first set the rotor position for the system cleaning solution. This is done in the **Reagent positions** screen. See par. 6.3.1.

4. Click **Needle Rinse**. The analyzer performs the needle rinsing procedure. When the procedure is finished, the analyzer switches to **Stand-by**.

### Cleaning the system

In this procedure, the entire system is washed with undiluted system cleaning solution. See par. A.1.4. After this, the system is flushed with water a couple of times. The procedure takes about 45 minutes.



#### Note

Your assistance is needed during the entire procedure. The analyzer waits for confirmation at each step.

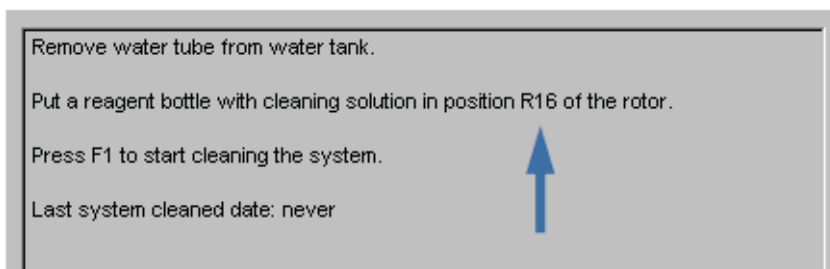
1. Open the **Rotor/System** screen. This screen is listed in the menu tree.
2. Click **Clean system** in the menu to the left.
3. Remove the tube from the water container.
4. Empty the waste container.



#### BIOHAZARD

Fluids in the waste container are potentially infectious. These fluids must be handled with great care. Clean up spills immediately. Use applicable procedures to discard the fluids from the waste container.

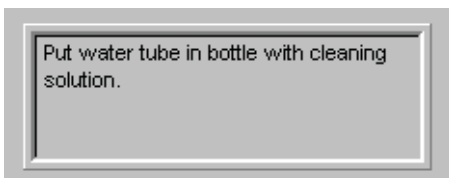
5. Place the system cleaning solution in the rotor. The position for the system cleaning solution is indicated in the text on the screen.



#### Note

If the position xx is shown, you must first set the rotor position for the system cleaning solution. This is done in the **Reagent positions** screen. See par. 6.3.1.

6. Click **F1 Clean System**. The analyzer starts the system cleaning procedure.
7. The following message is shown on the screen.



Follow the instruction on the screen. Click **F1 Ok** or **F1 Continue** after each step.

8. When the cleaning procedure is finished, the analyzer switches to **Stand-by**.

**Note**

At the end of the procedure, the first screen is shown again. The **Last system cleaned date: %s** now shows the current date.

After this procedure you have to run all programmed tests on a control serum. If the results are out of limits, do the **Fill/Empty system** procedure to remove the remaining cleaning solution.

**Cleaning the outside of the analyzer**

Keep the outside of the analyzer clean and dry. You can wipe the surfaces with a damp cloth and a mild detergent solution. To clean the display screen, wipe it gently with a soft, nonabrasive cloth. Make sure that no liquid gets into the computer.

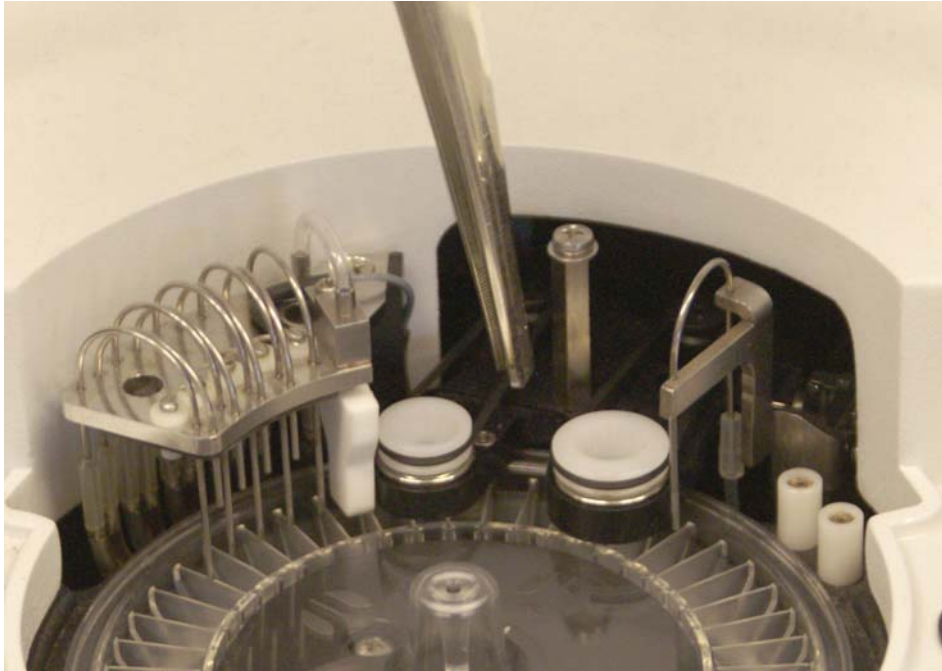
**BIOHAZARD**

Patient samples, controls, calibrators and liquid waste are potentially infectious.

Wipe up any spillage on the analyzer immediately and clean the contaminated surface with a disinfectant.

### 7.1.6 Replacing the stirrer belt

1. Make sure the state of the analyzer is **Stand-by**.
2. Carefully remove the cover from the cuvette rotor.
3. Use tweezers to take the old belt off the pulleys.

**Note**

Pull the stirrer belt off the pulley in the back first. In this way, if the belt slips out of the tweezers, it is not catapulted into the analyzer.

4. Place a new stirrer belt over the pulleys.

**Note**

Pull the stirrer belt around the pulley in the front first. In this way, if the belt slips out of the tweezers, it is not catapulted into the analyzer.

5. Carefully place the cover over the cuvette rotor.

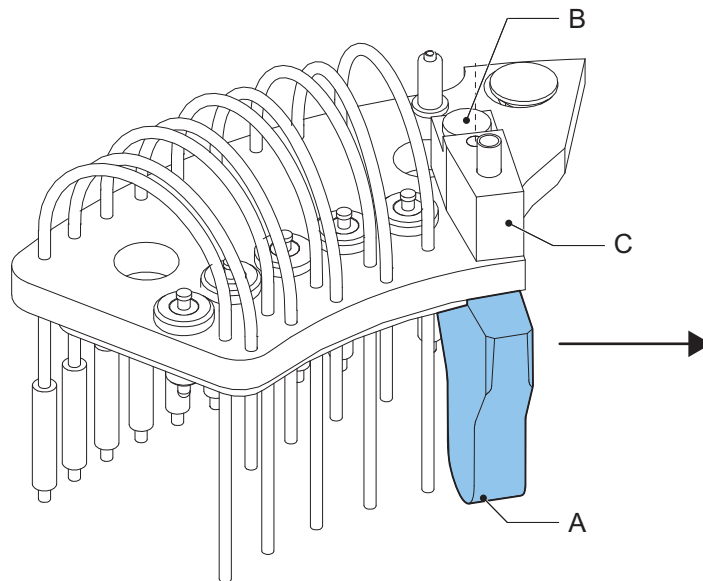
### 7.1.7 Replacing the water filter



1. Make sure the state of the analyzer is **Stand-by**.
2. Unscrew the cap of the water container.
3. Pull the tube out of the water container.
4. Unscrew the filter from the water tube.
5. Screw a new filter on the water tube.
6. Place the water tube into the water container
7. Screw the cap on the water container.

### 7.1.8 Replacing the drying block

1. Make sure the state of the analyzer is **Stand-by**.
2. Carefully remove the cover from the cuvette rotor.
3. Open the **Funct. ck/adj.** screen. This screen is listed in the menu tree.
4. Double-click **Wash arm** in the menu on the left.
5. Click **F1 Reset Wash Arm**.
6. Press the arrow up key. The wash arm moves to its highest position.
7. Disconnect the tube from the drying block.
8. Loosen the screw [B] and remove the metal block [C].



#### ATTENTION

Be careful not to drop the loose screw into the analyzer. Use a screwdriver with a magnetic tip.

9. Remove the drying block [A] by sliding it out to the right. Place a new drying block.
10. Place the metal block [C] and place screw [B]. Do not tighten the screw yet.
11. Press the arrow down key. The wash arm is lowered.
12. Press the arrow down key again. The wash arm moves to its lowest position.
13. Tighten screw [B].
14. Connect the tube to the drying block.
15. Open the **Rotor/System** screen. This screen is listed in the menu tree.
16. Click **F1 Reset System**. The analyzer performs a full system reset. When the reset procedure is finished, the analyzer switches to **Stand-by**.
17. Carefully place the cover over the cuvette rotor.

## 7.2 Troubleshooting

### 7.2.1 Introduction

The analyzer constantly monitors all functions and informs the user about operating errors and system malfunctions. The most frequent malfunctions can be solved without assistance from the service department of your supplier.



#### **ATTENTION**

Maintenance and repair procedures must be performed only by qualified personnel. Make sure you have the required procedure available before starting any servicing work.



#### **BIOHAZARD**

Materials in the analyzer may be infectious. Make sure to take all required protective measures (such as wearing gloves) before starting any servicing work. Discard any components that may be infected in the appropriate manner, as prescribed by locally valid regulations for waste disposal.



#### **ATTENTION**

If you cannot solve problems with your analyzer with the information given in this manual, contact the service department of your supplier. Do not try to solve problems yourself in such cases.



#### **Note**

Check the error history before you contact the service department of your supplier. See par. 7.2.3.



## 7.2.2 Hardware-error messages



### Note

In general, many errors cause secondary errors to occur. For example, a wash arm error (E122) also causes a system emergency halt (E02). When the first error is solved, secondary errors usually also disappear.



### Note

Error messages that do not start with a letter and two digits are not hardware-related. They are listed in par. 5.6.3.



### Note

The list below is ordered by the error codes. Error codes that do not appear in the list cannot be solved by the operator. Contact the service department of your supplier and inform them of the error code.

### ***E02 SYSTEM EMERGENCY HALT***

The pipettor arm was touched during measurement. The analyzer immediately halts.

- Check if anything is blocking the pipettor arm. Reset the system.

### ***E05 NO CLEAN CUVETTE***

The wash arm does not move down to the bottom of the cuvette. Therefore cleaning of the cuvette cannot be guaranteed.

- Check if anything is blocking the wash arm. Reset the system.
- If the error reappears after reset, contact the service department of your supplier.

### ***E07 SYSTEM RESET INCOMPLETE***

The system reset procedure could not be completed. This is normally due to other errors.

- Check other error messages. Remove the causes of those errors. Reset the system.
- If the error reappears after reset, contact the service department of your supplier.

### ***E10 NO VACUUM***

The vacuum is insufficient for longer than 2.5 seconds. There may be various causes for this error: defective vacuum pump, vacuum tubing defect, clamped or blocked, vacuum sensor defective or not adjusted. It may also be a minor communication problem.

- Check whether the tubing in the analyzer is free and not bent.
- Check the vacuum tubing for any leakage.
- If nothing seems to be wrong, click ***F1 Check Again***.
- If the error reappears after reset, contact the service department of your supplier.

### ***E12 RUNNING OUT OF WATER***

The upper level detector does not detect water in the water container for longer than 25 seconds, even though the pump is switched on.

- Fill the water container.
- Check if the water tubing is leaking or blocked. Replace defective tubes.
- Check if the filter in the water container is blocked. Replace a blocked filter.

### ***E13 LAMP FAILURE***

The signal from the photocell is too low.

- Click ***F1 Check Again***.
- Check if the lamp is working correctly. Replace the lamp if needed.

### ***E17 INSUFFICIENT WATER***

The upper level detector does not detect water in the water container.

- Fill the water container.
- Check if the water tubing is leaking or blocked. Replace defective tubes.
- Check if the filter in the water container is blocked. Replace a blocked filter.

***E124 WATER OVERFLOW MEASUREMENT DISK***

If all cuvettes under the wash arm overflow: the wash arm uses too much water.

If only some cuvettes under the wash arm overflow: the wash arm does not aspirate well.

If nothing seems to be wrong with the cuvette rotor: the sensors have a short circuit.

- Check the vacuum.
- Check the tubing between the pump unit and the main unit.
- Check the tubing between the pump unit and the water container.
- Replace tubing where needed.
- Check if any suction tubes are blocked.
- Lift the wash arm. Clean it with the needle cleaning pin.
- Lift the wash arm. Clean the underside, especially around the overflow sensors.

***All Other Exx Error Codes***

The error may be caused by a small disturbance in signals between the microcontroller and one of the slave boards. Errors may also be caused by dust particles fooling sensors. Resetting part of the analyzer may remove the error.

- Click ***F6 Soft Reset*** (if available).
- Click ***F5 Hard Reset*** (if available).
- Perform a full system reset.
- If the error reappears after reset, contact the service department of your supplier.

### 7.2.3 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). Check the **Needle rinse history** in the **Service** screen.

1. Open the **Service** menu. This screen is listed in the menu tree.
2. Click **Error history** in the menu to the left. The error history is shown on the screen.

	Error text	User action	End time
12/1/2006 7:24:24 AM			
12/1/2006 7:10:14 AM	E112 DISKS INIT FAILED	Hard Reset	12/1/2006 7:24:35 AM
11/30/2006 10:06:06 AM	E102 REAGENT DISK ERROR	Hard Reset	12/1/2006 7:24:35 AM

3. Click on the date and time in the list to the left. The list of errors that were logged at that time is shown to the right. The user actions show what the operator has done to solve the error. The end time shows when the error condition ended.
4. (Optional) Click **F2 Print All** to print out the error history.

## 7.3 Servicing procedures

### 7.3.1 Unblocking the needle



#### ATTENTION

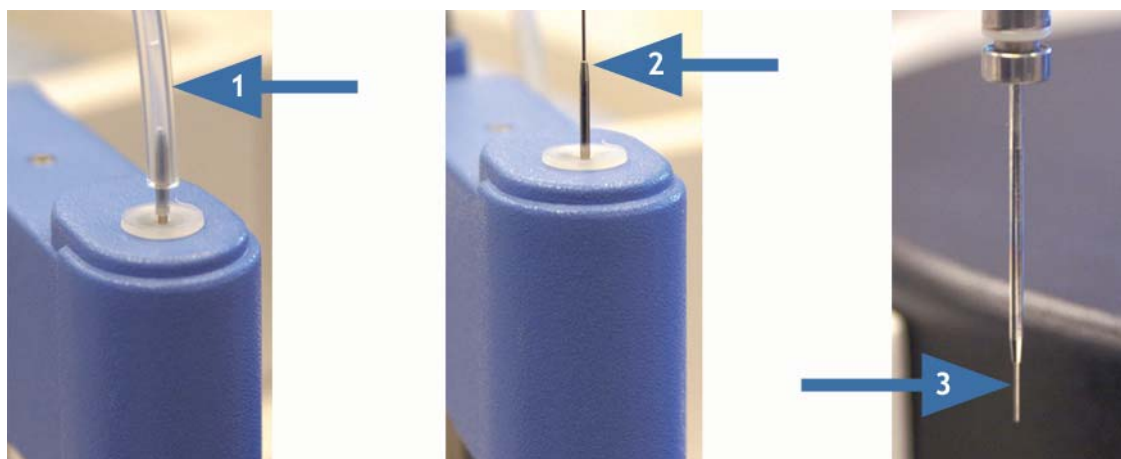
This procedure must be done with great care. The pipettor arm and its parts are fragile and vital components of the analyzer.



#### Note

For this procedure you need the piercing rod from the standard accessories kit.

1. Pull the tube off the pipettor arm [1]. The tube contains an outer and inner tube.
2. Push the piercing rod into the inner needle tube [2]. Push the piercing rod down until it comes out at the tip of the needle [3].



3. Move the piercing rod up and down several times.



#### ATTENTION

Do not dispose of the piercing rod. It should be cleaned and kept for another occasion.

4. Push the tube on the pipettor arm [1]. Make sure that both the outer and inner tube just touch the silicon seal. The tube should not be pushed into the opening of the needle cover.
5. Reset the analyzer.

### 7.3.2 Replacing the cuvette rotor

The cuvette rotor must be replaced when:

- 10 000 tests were performed with it. The counter is available in the **Change cuvette rotor** screen. See step 3 below.
- Too many cuvettes are excluded. A cuvette must be excluded when SD.ERR messages appear after performing a cuvette rotor blank. See par. 7.1.4. Vital Scientific recommends replacing the cuvette rotor when more than 3 cuvettes are excluded.



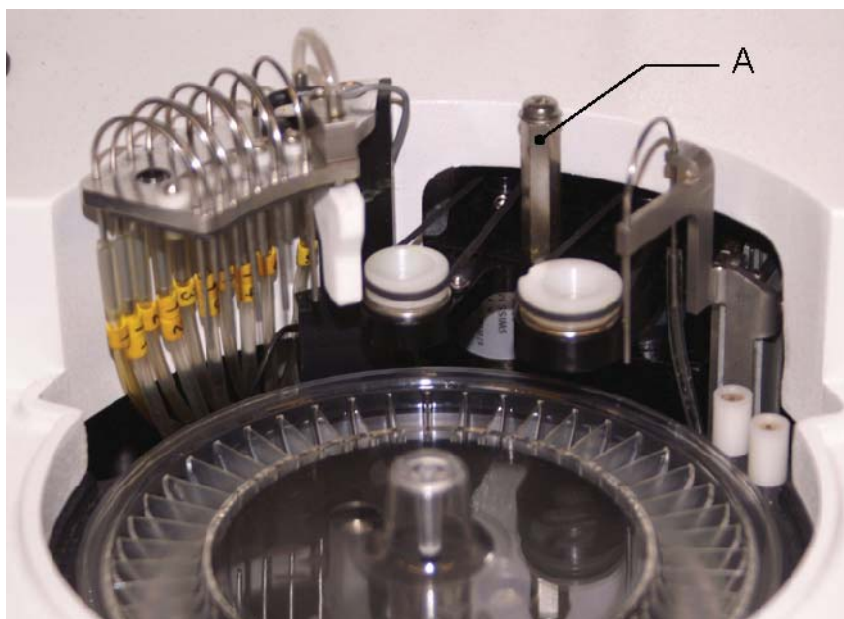
#### BIOHAZARD

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

1. Make sure the analyzer is **Stand-by**.
2. Open the **Rotor/System** screen. This screen is listed in the menu tree.
3. Click **Change cuvette rotor** in the menu to the left. The screen shows two counters. The top counter shows how many tests were performed on the current rotor. The bottom counter shows how many tests were performed on the analyzer.

Tests on this rotor:	798
Total test count:	798

4. Remove cover from the cuvette rotor.
5. Click **F1 Lift WashArm**. The wash arm moves to the highest position.
6. The analyzer asks if the counter should be reset. Click **Yes** to zero the cuvette counter.
7. Gently pull the stirrer unit up with the metal pin [A]. It remains in this position.



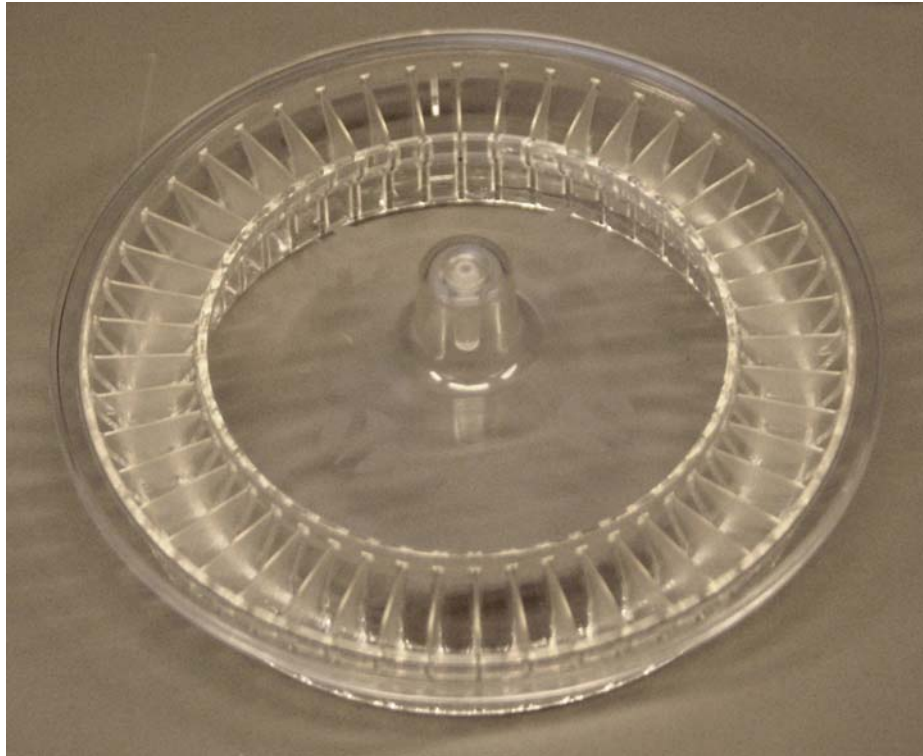
8. Carefully remove the cuvette rotor.

9. Unpack a new rotor.



**ATTENTION**

Do not touch the sides of the rotor, but hold it by its center.



10. Carefully place the new cuvette rotor. Make sure that the notches of the rotor fit into the slits of the rotor holder.
11. Gently push the stirrer unit down.
12. Click **F2 Reset System**. The analyzer lowers the wash arm and performs a system reset.
13. Carefully place the cover over the cuvette rotor.
14. Perform a cuvette blank measurement. See par. 7.1.4.

### 7.3.3 Replacing the lamp

The lamp must be replaced after about 2 000 operating hours (approximately one year under normal operating conditions) or earlier if a mechanical or technical defect is found. If the analyzer behaves in an unusual manner, check the intensity of the lamp. It is possible that the lamp deteriorates before it reaches 2 000 operating hours.

**WARNING**

Make sure the analyzer is switched off before replacing the lamp.

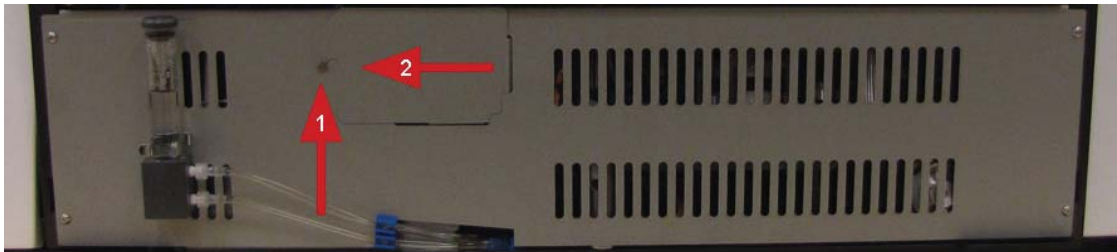
**HOT SURFACE**

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

1. Open the cover.
2. Lift the front panel and remove it from the analyzer.
3. A small sliding panel is held in position by one screw [1] on the left. Loosen the screw. Slide the panel to the left [2], then tilt and lift it out. The lamp support is now exposed.

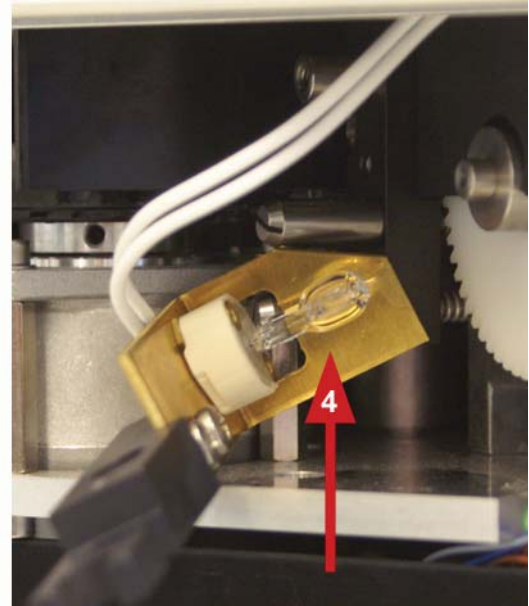
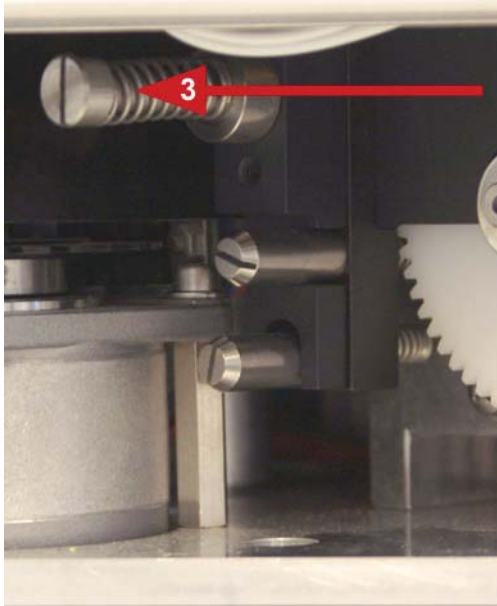
**Note**

To get better access to the lamp unit, you can remove the entire front panel. Remove the four screws around the sides to do this.





4. Remove the top screw [3]. Carefully pull the support out of the analyzer. Remove the lamp [4] from the lamp support.



5. Carefully take the new lamp by its top using a clean cloth. Push the lamp into the support. Make sure the lamp is fully inserted.

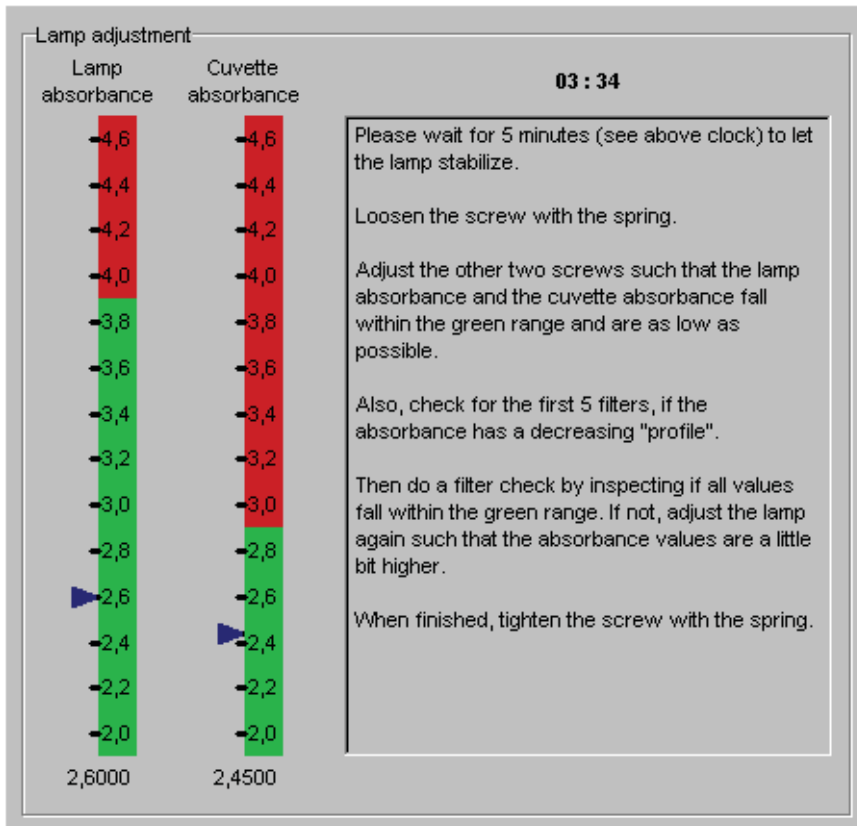
**ATTENTION**

Do not touch the glass of the new lamp with your fingers. Dust and humidity shorten the lifetime of a lamp.

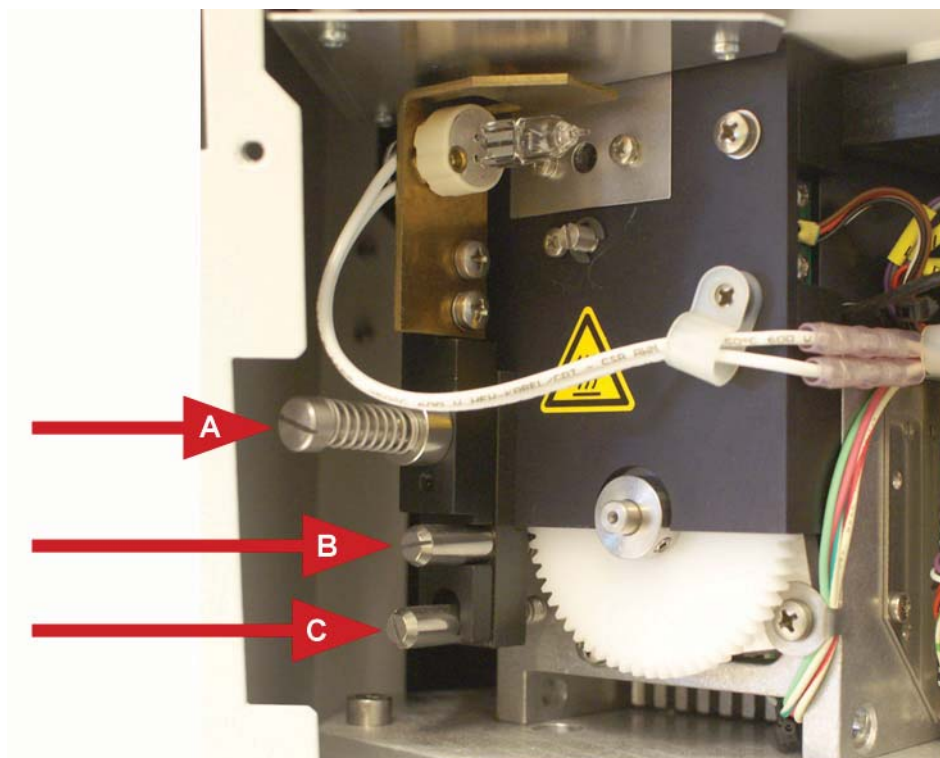
6. Place the support into the analyzer.
7. Place the screw [3] (indicated step 4 above). Do not tighten the screw yet.
8. Switch the analyzer on. Wait until the software has initialized.
9. Open the **Funct. ck/adj.** screen. This screen is listed in the menu tree.



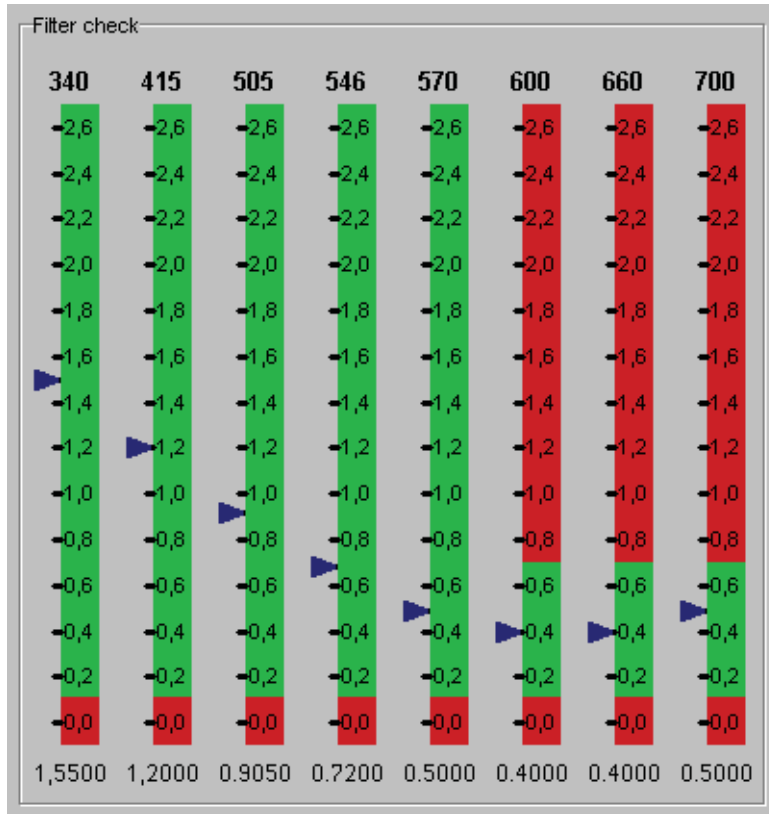
- Double-click **Adjust lamp** in the menu to the left. The lamp adjustment screen is shown. The top of the screen shows a timer counting down. Wait until the timer reaches 00:00.



- Loosen the top screw [A] on the lamp support. Adjust the lamp position until the blue arrows on both bars reach their minimum values. This is done by adjusting screws B (vertical position) and C (horizontal position) by small amounts.



- Click **F1 Filter check**. The system measures the cuvette absorbance for each filter and displays the values graphically on screen.



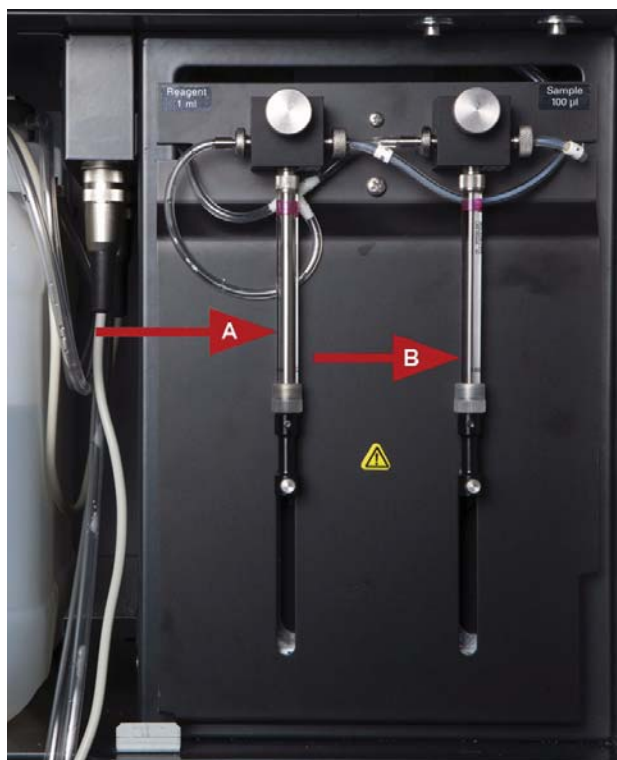
- Check the positions of the blue indicators. They should all be within the green areas. The first five bars should show a decreasing slope (as shown in the picture above).
- Adjust the lamp position if needed.
- Tighten the top screw [A].
- Place the small sliding panel in front of the lamp unit. Fasten it with the screw.
- Place the front panel on the analyzer.
- Perform a cuvette blank measurement. See par. 7.1.4.

### 7.3.4 Replacing syringes

The syringes are mounted in the side cabinet on the right-hand side of the analyzer.

There are two clear indicators for defective syringes:

- Imprecise results with no clear cause (like dirt, bad reagents, bad samples, worn lamp).
- Air bubbles in the syringes and water leaking along the syringe plunger.

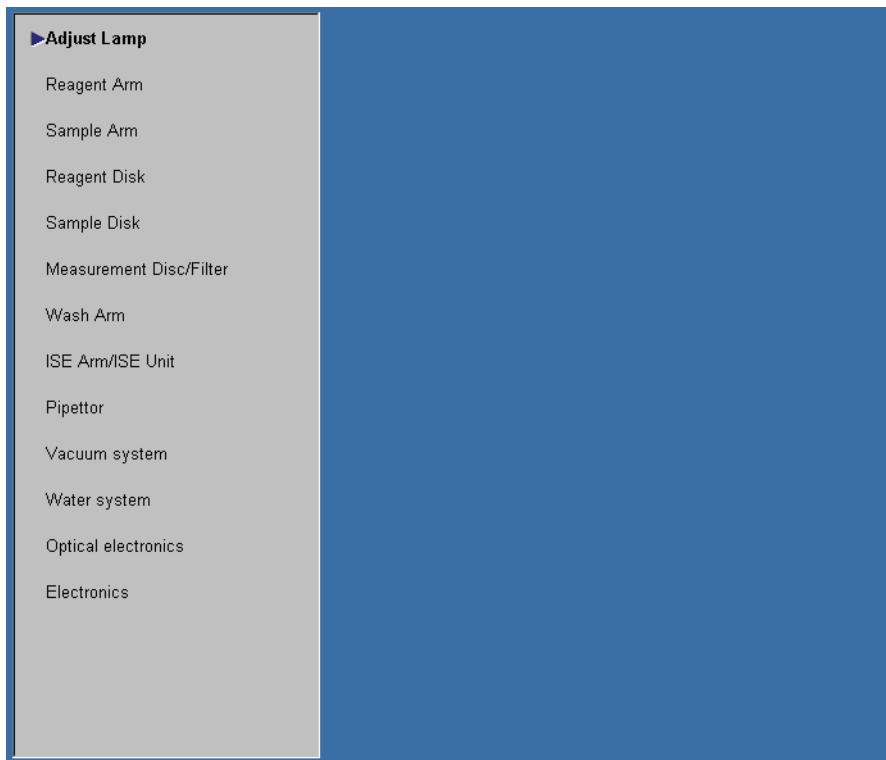


#### Removing the syringes

1. Make sure the analyzer is **Stand-by**.
2. Open the **Rotor/System** screen. This screen is listed in the menu tree.
3. Click **Change syringes** in the menu to the left.
4. Click **F1 Lower Syringe**. Both syringes move to their lowest position.
5. Remove the screws of the drive pins through the plunger.
6. Carefully unscrew the syringe from the valve. Push the syringe down a little. Remove it from the analyzer.
7. Moisten the inner side of the glass tube with water.
8. Hold the syringe in a cup of water with the plunger part up.
9. Pull water into the tube.
10. There should be no air bubbles in the syringe. In case of the reagent syringe [A] the air bubble can be removed by ticking your finger against the syringe. In case of the sample syringe [B] the previous steps of the procedure must be repeated. Make sure there is at least 2 centimeters of water in the syringe.
11. Mount the plunger over the drive pin of the pipettor. Hold the syringe vertically and pull the syringe out until it reaches the pipettor valve.
12. Screw the syringe in the pipettor valve. Make sure the syringe can be screwed in easily. Tighten well with your fingers.
13. Click **F2 Reset System**. The analyzer resets the pipettor.

14. Click ***Fill/Empty system*** in the menu to the left.
15. Click ***F1 Fill System***.
16. After refilling the system the analyzer is ready for use again. If there are still air bubbles visible in the tubing repeat the refilling procedure.

### 7.3.5 Functional checks and adjustments

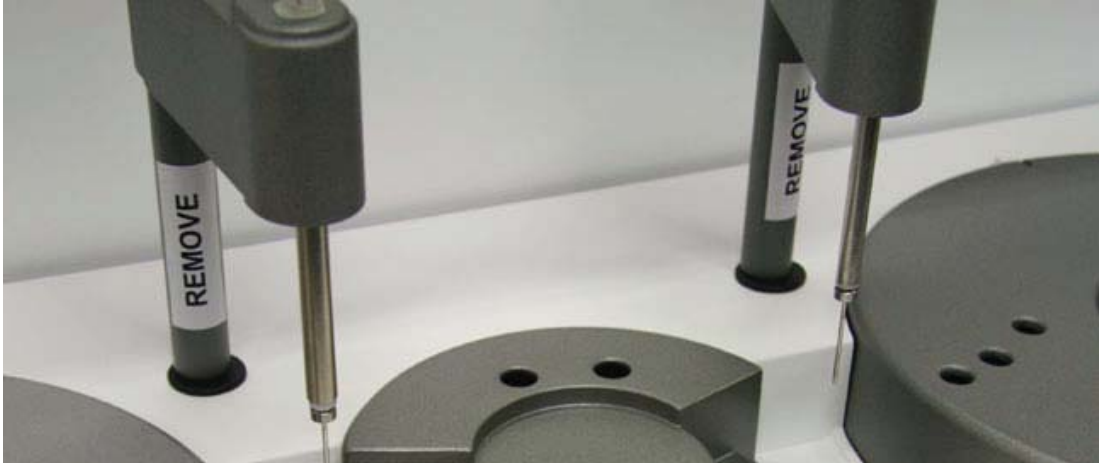


Apart from the first item in the menu, this screen is only used by service personnel. The first item is used when replacing a lamp. See par. 7.3.3. The other screens are not described in this manual.

### 7.3.6 Preparing for transport or storage

**ATTENTION**

When transporting the Selectra ProM, make sure to fit the protection sleeve over the mounting shaft, as shown in the picture below. This keeps the pipettor arm in the upper position and prevents the needle from getting damaged.



## Technical specifications

## A.1 Performance and technical data

### A.1.1 Selectra ProM

#### Performance

Maximum throughput	Mono mode: 180 tests/hour (360 with Dry Electrode ISE unit) Dual mode: 133 tests/hour (333 with Dry Electrode ISE unit)
Accuracy	See par. A.1.5
Precision	See par. A.1.5
Programmable tests	120 per reagent disk configuration unlimited number of reagent disk configurations possible
Load test capacity	32 per reagent disk
Quality control	3 per parameter, 120 controls programmable per rotor configuration
Sample processing	Random access

#### Sample system

Sample positions	51 positions
Emergency samples	3 positions
Pediatric samples	6 positions (3 positions, with ISE)
Calibrators	9 positions plus 51 sample positions
Controls	4 positions plus 51 sample positions
Blank	1 position
Acid solution	1 position
ISE positions	1 activator plus 2 calibrator positions
Sample tubes	Diameter: 13 mm Height: 75 mm Pediatric tubes: see par. 5.3.1.
Needle	Pre-heated, with level detector and integrated stirrer
Pipetting capacity	2-30 µl (steps of 0.1 µl)
Syringe	100 µl

#### Reagent system

Reagent disk	32 positions: 8 × 10 ml, 24 × 25 ml 10 x 25 ml positions can be used for 5 x 50 ml bottles
Volumes per test	Reagent 1: 110 – 399 µl Reagent 2: 10 – 289 µl Reagent 3: 10 – 289 µl



Refrigeration	8 - 12 °C (Absolute up to 25 °C ambient temperature)
Needle	Pre-heated, with level detector and integrated stirrer
Pipetting capacity	400 µl (steps of 1 µl)
Syringe	1000 µl

**Measurement station**

Cuvette rotor	Disposable rotor with 48 positions
Path length	6.8 mm
Volume range	220 µl to 400 µl (total volume of sample and reagents)
Wash station	Fully automatic with overflow-level detector
Cuvette rinsing	4 × 500 µl system solution
Light source	Quartz-iodine lamp 12V 20W
Wavelengths (2 options)	Option 1: 340, 405, 505, 546, 578, 620, 660 and 700 nm Option 2: customized
Wavelength uncertainty	± 2 nm
Spectral half-width value	10 ± 2 nm
Measuring range	-0.1 to 3.0 Abs.
Temperature	37 °C ± 0.2 °C
Cycle time	20 sec. (mono mode) 27 sec. (dual mode)

**Approvals**

CE  
CB  
UL

IEC 61326-2-6	The analyzer complies with the emission and immunity requirements described in the IEC 61326-2-6.
CISPR 11 Class A	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.



**Note**

The approvals listed here refer only to the instrument and operator console, not to additional devices. For the approvals for these devices, see the corresponding manuals.

**A.1.2 User interface****Computer system (minimal requirements)**

CPU	Intel Celeron M 575 2 GHz
RAM	DDR-RAM / SO-DIMM 2 GB
Hard disk	Flash drive 4 GB
Monitor	Touch screen monitor 15,6 inch, resolution 1366x768
Operating system	Windows XP embedded standard (WES)
Serial ports	2 x RS232 (one for analyzer, one for host connection or printer)
USB ports	4 (USB2.0)
Ethernet	1 x 100 Mbps

**Barcode reader (optional)**

Version	Hand-held device
Technology	CCD
Barcodes	Code 39 Code 128 Codabar Code 2 of 5

**Note**

Other barcodes can be configured when required. See the configuration manual that came with the hand-held barcode reader. Contact the service department of your supplier if you need more information.

### A.1.3 Physical data

#### Dimensions and weight (benchtop, without computer)

Width	125 cm
Depth	62 cm
Height	75 cm (height adjustable monitor arm)
Weight	approx. 93 kg (excl. monitor arm and panel PC)

#### Power requirements

Line Voltage	110-240 V
Line Frequency	50/60 Hz
Max. Power Consumption	400 VA (including panel PC)
Installation category	II (in accordance with IEC664)
Main fuses	2 x 5 A slow-blow

#### Environmental requirements

Ambient temperature	15 to 32 °C
Max. relative humidity	85 % RH max.
Maximum altitude	2000 meter
Pollution degree	2 (in accordance with IEC 664)
Degree of protection	IP 20



#### **WARNING**

Do not use the analyzer in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.



#### **Note**

We advise the user to evaluate the electromagnetic environment prior to operation of the Selectra ProM.

### A.1.4 Cleaning solutions

#### Introduction

CLEANING SOLUTIONS, EC marked according to the directive 98/79/EC.  
 In vitro diagnostic device, for professional use only

#### Reference

SLSY-5900	SYSTEM SOLUTION
SLNA-5900	SYSTEM CLEANING SOLUTION
SLHC-5900	ACID SOLUTION

#### Preparation and use

System solution:	Solution used diluted at 1/400 (25 ml in 10 liters of distilled water for XL and E series). It washes continuously the rotor and the needles and is also used for the pipetting system (wetting effect for fluidified system).
System cleaning solution:	Solution used diluted at 1/10 for the needle rinse. See par. 7.1.5. It cleans the sample and reagent needles. Solution used undiluted for the system clean procedure. See par. 7.1.5.
Acid solution:	Solution ready-to-use. It is used for cleaning the reagent needle and is also used in the incompatibility procedure of tests.

#### Storage and stability

Not diluted solutions are stable between 15-25°C until the expiry date stated on the label.  
 Diluted solutions are stable at least 2 weeks, on board of the analyzer.

#### Composition of the solutions

System solution:	Aqueous solution with a detergent containing sodium azide (< 0.1%).
System cleaning solution:	Aqueous solution of Sodium hypochlorite (< 2% of active chlorite) and Sodium hydroxide (< 5.4 %).
Acid solution:	Aqueous solution of hydrochloric acid (< 0.5%).

#### Precautions

System cleaning solution is **corrosive (C)**.

R 35:	Causes severe burns.
S 26:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 28: After contact with skin, wash immediately with plenty of water.

S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S 45: In case of accident or if you feel unwell, seek medical advice immediately (if possible show the label).

Acid solution is **irritant (Xi)**.

R 36/37/38: Irritating to eyes, respiratory system and skin.

S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Discard any cloudy solution.

Waste disposal: respect the legal requirements.

### A.1.5 Accuracy and precision

The chemical performance of clinical chemistry analyzers, in terms of accuracy and precision, depends on 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 manufactured by Vital Scientific may be supplied with open channels. '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. Vital Scientific recommends the use of ELITech reagents, calibrators and/or controls on their analyzers, see par. 6.2.2. Obtain information on the performance characteristics from the selected reagent distributor and/or manufacturer. Various reagent manufacturers have performed performance studies on the analyzers from Vital Scientific 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 analyzers from Vital Scientific.



#### **Disclaimer**

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

### A.1.6 Performance check for Selectra ProM

#### Introduction

With the following two tests the performance of the Selectra ProM can be checked.

- SR3                      Test with Potassium Dichromate solution on a sample position to validate sample pipetting reproducibility.
- SR75                    Test with Potassium Dichromate solution on a reagent position to validate reagent pipetting reproducibility

By performing these tests the pipetting / liquid system as well as the optical analyzer quality is checked. Furthermore SR3 tests the mixing function on the sample side whereas SR75 does so on the reagent side.

The following two products are available and can be ordered via Vital Scientific for performing the performance check:

Part number	Description	Units
3201-001	Dichromate 80 Abs. (25 ml)	1
3201-002	Dichromate 8 Abs. (25 ml)	1

Dichromate 80 Abs needs to be diluted 1:10 before use. Also keep in mind not to expose the solutions to direct sunlight, e.g. place a cap and store in a dark place when not in use.

#### Procedure

The procedure described below should be carried out once every two weeks at a minimum, after a (preventive) maintenance procedure, after a Service call or when there are problems with imprecise results.

1. Program or load (if not already done) the test parameters for the check as indicated in the table hereafter. To prevent reprogramming we suggest to program a special performance reagent disk for the Selectra ProM. See par. 6.3.2
2. Program the controls (named e.g. Water and 8-Abs) as indicated in the table hereafter.
3. Install all reagents in the reagent rotor:

Test	R1	Sample	R2
SR3; Check-S	Water	Dichromate 8 Abs	-
SR75; Check-R	Water	Water	Dichromate 8 Abs

All water bottles must be full and the dichromate bottle must contain about 5 ml.

4. Request the following samples as controls in the Request Samples menu.
  - 20 x the 8-Abs control for the SR3 (Check-S) test
  - 20 x the Water control for the SR75 (Check-R) test
5. Load the following samples in the **Sample Handling** menu and sample rotor and start the performance check by means of **F3 Start Measurement**.
  - 1 Tube containing ~ 1 ml distilled water (SR75 test; Check-R)
  - 1 Tube containing ~ 1 ml 8-Abs. Dichromate (SR3 test; Check-S)
6. Check in the Quality Control menu the results and the CV values:

**Technical specifications**

- Drop-outs on the Levy-Jennings plot indicate air-bubbles
- A high CV on the SR3 test indicates a poor sample syringe or a mixing problem on the sample side
- A high CV on the SR75 test indicates a poor reagent syringe or a mixing problem on the reagent side.

If necessary perform a Fill System to remove airbubbles. Replace the stirrer belts or the tip of the respective syringe (or the complete syringe) when necessary. Don't forget to perform a Fill System afterwards. Repeat the check and take corrective actions accordingly until the results are satisfactory.

**VALIDATION CRITERIA**

	CV	Target value	Low limit	High limit
SR3 test:	< 2 %	0.08 Abs	0.060 Abs	0.100 Abs
SR75 test:	< 2 %	1.75 Abs	1.500 Abs	2.000 Abs

The target values can vary from batch to batch and between instruments. The values are based on a Potassium Dichromate solution of ~8 Abs.

**Programming SR3 / SR75**

Name	Check-R	Check-S
Abbr. Name	SR75	SR3
Mode	Twopoint	Endpoint
Wavelength	340 nm	340nm
Units	None	None
Decimals	3	3
Low / High conc.	0.000	0.000
Calibrator name	none	none
Prozone check	No	No
Ref. Low	0.000 Abs	0.000 Abs
Ref. High	0.000 Abs	0.000 Abs
Control 1	Water	8-Abs
Target	1.750	0.080
Low Limit	1.500	0.060
High Limit	2.000	0.100
Westgard	No	No
Control 2 / 3	None	None
Correlat. factor	1.000	1.000
Correlat. offset	0.000	0.000
DUAL MODE		
Sample blank	No	No
R1 bottle	25 ml	25 ml
Normal / rerun	224 µl	297 µl



Name	Check-R	Check-S
Sample		
Normal / rerun	1.0 µl	3.0 µl
R2 bottle	25 ml	25 ml
Normal / rerun	75 µl	0 µl
Predilution	No	No
Incubation time	-	4.5 min
Slope blank	No	-
Point one, two	-3,6 sec	-
Low / High Absorbance	-0.100/3.000 Abs	-0.100/3.000 Abs
R.Abs.L / H Limit	-0.100/3.000 Abs	-0.100/3.000 Abs
Substr. Depletion	3.000 Abs	-
Reagent blank	No	No
Factor	1.000	1.000

## A.2 Spare parts

### A.2.1 Individual parts

This section lists individual part numbers for the Selectra ProM.



#### ATTENTION

When ordering parts, please include the type and serial number of your analyzer.

#### Consumables (Vital Scientific part number)

Part number	Description
3062-021	Sample cups 2 ml (1000 pieces)
3062-031	Reagent bottles 25 ml (30 pieces)
3062-042	Reagent bottle 10 ml glass with cap
3062-049	Reagent bottle 50 ml with cap
3066-083	Water filter
3066-155	Syringe long life 100 µl
3066-156	Syringe long life 1 ml
3066-157	Plunger assembly long life 100 µl
3066-158	Plunger assembly long life 1 ml
6002-706	Cuvette rotors (3 pieces)
2206-007	Cooling liquid 1 liter
3064-041	Driving belt stirrer

#### Consumables (SEPPIM part number)

Part number	Description
SLSY-5900	System solution 1 liter
SLNA-5900	System cleaning solution 1 liter
SLHC-5900	Acid solution 1 liter

#### System options

Part number	Description
6003-442	Hand-held barcode reader (with USB connector)

## Dry Electrode ISE

## B.1 System overview

### B.1.1 Introduction

The Dry Electrode ISE (Ion Selective Electrode) measures potassium ( $K^+$ ), sodium ( $Na^+$ ), chloride ( $Cl^-$ ) and  $CO_2$  levels using a patented dry electrode technology. The Dry Electrode ISE is an option for ELITech Clinical Systems. Unlike conventional systems, the ISE electrodes are shipped and maintained in a “dry” state when not in use. This avoids wasting reagents and calibrators. It also limits the chance of damage to the system. A metal shield protects the electrodes against electromagnetic influence. The photo below shows the Dry Electrode ISE unit built into the analyzer.



#### Note

The measurements used in this manual are expressed in mmol/L. For countries that use meq/L (equivalence units), 1 meq/L = 1 mmol/L.

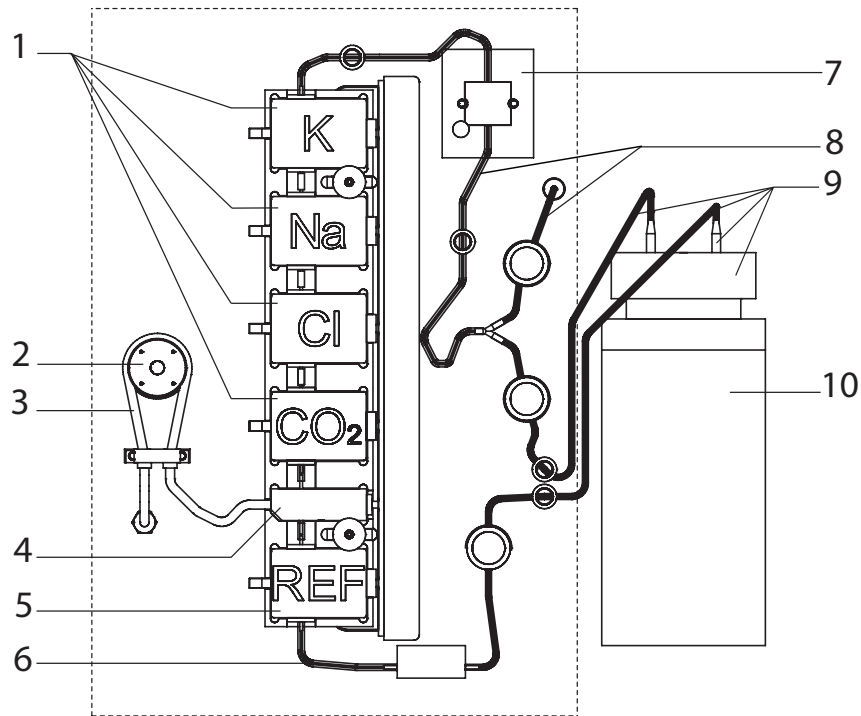


#### ATTENTION

Do not open the side door during use. Only open the side door for maintenance purposes.

**B.1.2 Functional components**

The functional components that make up the Dry Electrode ISE unit are identified in the drawing below and described in the list.



**1. Ion selective electrodes**

The Dry Electrode ISE unit contains up to 4 ion selective electrodes ( $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $CO_2$ ). Together with the ground and reference electrodes, these are placed in the electrode cradle. The electrodes have finite lifetimes and are disposable. A bypass electrode is available for systems that do not require all electrodes.

**2. Peristaltic pump**

The peristaltic pump makes the fluids flow through the tubing in exact volumes.

**3. Peristaltic pump tube**

The peristaltic pump tube leads the waste fluids to the waste container.

**4. Ground electrode**

The ground electrode provides the return path to ground for electrons generated by the other electrodes. The ground electrode is a permanent part of the system and stays when the other electrodes are replaced. Great care must be taken in the handling of the ground electrode.

**5. Reference electrode**

The reference electrode performs measurements on the reference solution. This is used to set the baseline value for measurements performed by the electrodes.

**6. Reference tube**

The tubing in the Dry Electrode ISE unit connects the various components in the unit to each other and to the analyzer. The tubes are made from materials that maximize system performance and operational lifetime.

The reference tube leads the reference fluids to the reference electrode.

A full set of tubes is available in the Dry Electrode ISE Starter Kit, supplied with each unit. They are also available in the spare tubing set. See par. B.6.4.

**7. Bubble detector**

The bubble detector detects the presence or absence of liquid.

A red warning light on the bubble detector is on when no liquid is present in the tubes.

**8. Y-connector tubing**

The Y-connector tubing leads the sample and reference fluids to the electrodes.

**9. Cap assembly**

The assembly of cap, straws and tubing allows easy replacement of the reference solution bottle with a new one. The tubing leads the reference fluids to the electrodes.

**10. Reference solution**

The reference solution forms a salt bridge between the reference electrode and the sample. The reference solution is also used to wash the electrodes during calibration and for reference measurements. The reference solution is supplied in a 500 ml bottle.

**11. Electromagnetic shield (not shown in the diagram)**

The Dry Electrode ISE unit is very sensitive to stray electromagnetic radiation within the laboratory. Any electromagnetic radiation may degrade the operation of the unit, especially the high impedance ion-selective electrodes. The electromagnetic shield prevents radiation that can affect the operation of the unit. The shield must be in place when the instrument is used.

### B.1.3 Operation specification

Dry electrodes	K <sup>+</sup> , Na <sup>+</sup> , Cl <sup>-</sup> , CO <sub>2</sub>
Sample type	Serum or plasma
Sample volume per measurement	25 µl
Diluent volume	325 µl
Cleaner volume	400 µl
Conditioner volume	400 µl
Reference volume	1000 µl
Dilution factor	1:14
Measurement cycle time	52 sec
Calibration cycle time	680-890 sec
Cleaning cycle time	2000 sec
ISE start-up time	< 1 min (< 10 min cold boot up time)

#### Performance

Maximum throughput	333 tests/hour (with ISE)
--------------------	---------------------------

For all information relative to performances of the Dry Electrode ISE unit, consult the Instructions for use of the ISE reagents.

#### Optimizing performance

To get the best performance from the Dry Electrode ISE:

- Make sure you understand the contents of this manual and know the correct operation of the analyzer.
- Check the fluid levels (activator, low calibrator, high calibrator, reference solution, diluent) before each calibration.
- Perform the maintenance tasks as listed in par. B.6.2.
- Replace worn or damaged parts by following the procedures exactly as described in this document.

## B.2 Installation

### B.2.1 Introduction

The Dry Electrode ISE unit is shipped with the electrode cradle installed. The electrodes and tubing must be installed when the unit is delivered. This is done to minimize the risk of damage during shipment of the unit.

**ATTENTION**

Installation should be done by qualified service technicians.

**Note**

This section gives installation procedures for the electrodes and tubing. To define the positions of diluent, cleaner and conditioner, see par. B.4.1.

**ATTENTION**

Do not twist or kink the tubes during installation. This can cause blockages in the tubes.

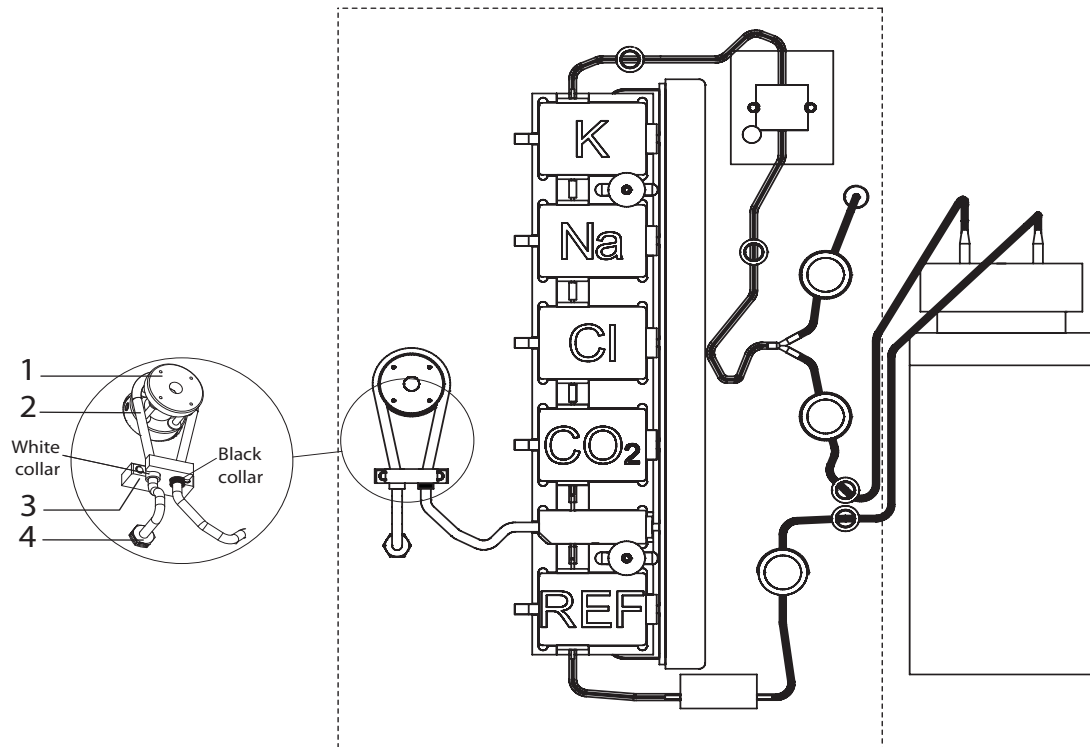
**Note**

To remove any contamination in the tubes, the manufacturer recommends to make and discard at least one measurement after any tubes are replaced.

The electrodes are sensitive and handling can cause damage. Therefore install the tubing before installing the electrodes. Install the components in the order:

- Peristaltic pump tube
- Y-connector tubing
- Cap assembly
- Electrodes



**B.2.2 Install the peristaltic pump tube**

1. Attach the white collar end of the peristaltic pump tube to the connector (4) on the base plate.
2. Install the white collar of the peristaltic pump tube (2) in the pump bracket (3). The white collar must be on the left side of the bracket.
3. Stretch the peristaltic pump tube (2) around the pump wheel (1).
4. Install the black collar of the peristaltic pump tube (2) to the other side of the pump bracket (3).

**ATTENTION**

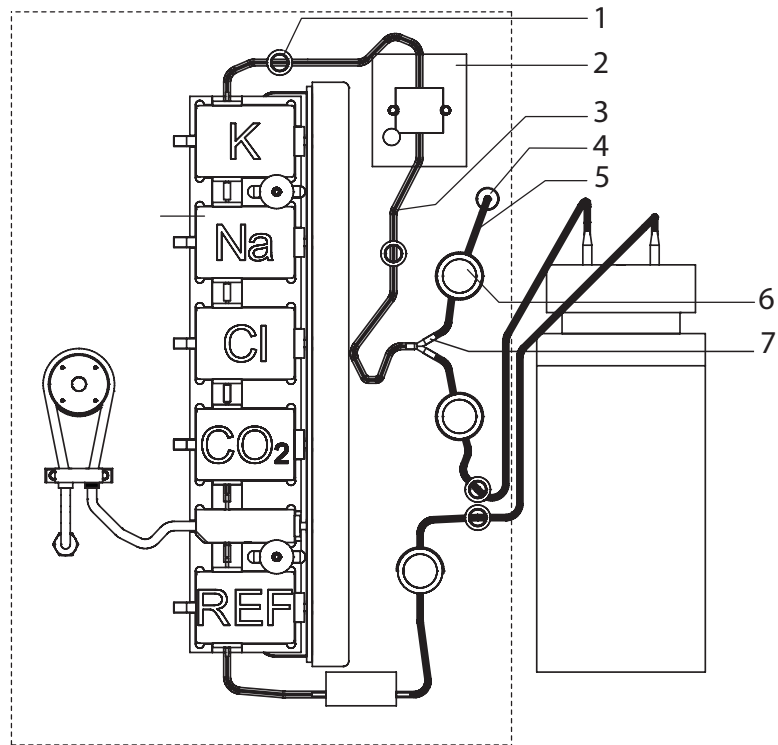
Do not overstretch the tubes. Stretch to attach the collar correctly.

**B.2.3 Install the Y-connector tubing**



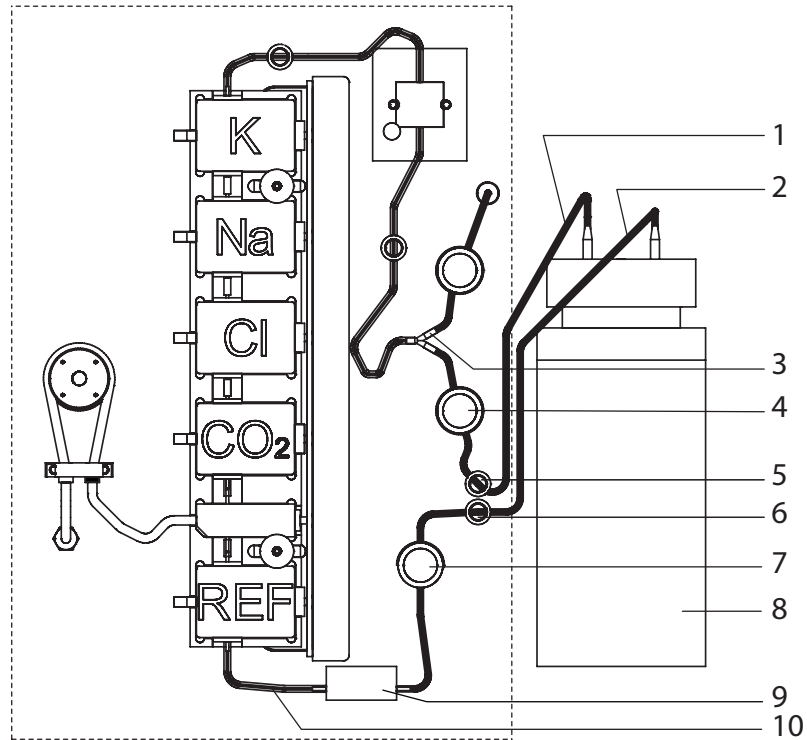
**ATTENTION**

Do not replace individual tube sections. Always replace the complete tubes assembly.



1. Push the long detector leg (3) of the Y-connector tubing through the tube constraint, through the bubble detector (2) and through the tube constraint (1).
2. Push the short sample leg (5) of the Y-connector tubing through the sample valve (6).
3. Attach the end of the sample leg to the connector (4) on the base plate.

**B.2.4 Install the cap assembly and reference tube**



1. Push the short reference feed tube (1) of the cap assembly through the tube constraint (5) and through the reference valve (4).
2. Attach the end of the short reference feed tube to the Y-connector (3).
3. Push the long reference feed tube (2) of the cap assembly through the lower tube constraint (6) and through the reference electrode valve (7).
4. Attach the end of the long reference feed tube to the restriction pipe (9).
5. Attach the single short reference tube (10) to the left side of the restriction pipe (9).
6. Remove the cap from the new reference container.
7. Attach the cap assembly to the reference container (8).

### B.2.5 Electrodes

The electrode pack for the Dry Electrode ISE unit contains 4 electrodes and the reference electrode. If an electrode is not used, it must be replaced by a by-pass electrode. The electrodes have a limited life after installation (see the table below). The lifetime is independent of use. See the manufacturers information about the shelf life. Each electrode must be marked with an install date when placed in the cradle.



**Note**

The ground electrode is permanent and does not need to be replaced during normal maintenance.

Electrode	Part No.	On-board lifetime
K <sup>+</sup>	3918-005	3 months
Na <sup>+</sup>	3918-004	12 months
Cl <sup>-</sup>	3918-006	3 months
CO <sub>2</sub>	3918-003	3 months
Reference	3918-002	12 months
By-pass	3918-007	24 months



**ATTENTION**

Do not handle the electrodes more than necessary. The electrodes are sensitive and handling can cause damage.



**ATTENTION**

When the electrode cradle is removed from the unit for maintenance or troubleshooting, keep the cradle in a vertical position to avoid any liquid flowing back to the K<sup>+</sup> electrode. The manufacturer recommends that the K<sup>+</sup> electrode is removed from the cradle first.

#### Installing the electrodes

1. Make sure the analyzer is switched off.
2. Open the side door.
3. Remove the two knurled screws. Remove the electromagnetic shield.
4. Slide the electrode cradle to the left. Pull it off the base plate of the unit.
5. Remove the electrodes from the packing material.



**ATTENTION**

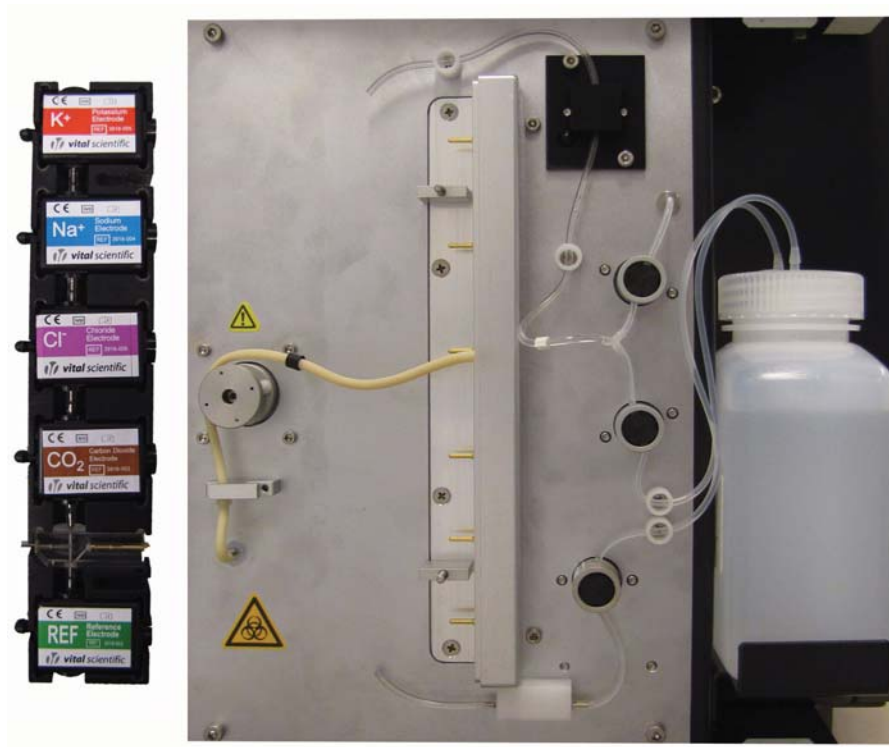
Make sure you have an earth contact when you touch the electrodes or the cradle. Follow ESD (electrostatic discharge) rules. Electrostatic discharge can damage the electrodes.



6. Assemble the electrodes in the order:  
 $K^+$ ,  $Na^+$ ,  $Cl^-$ ,  $CO_2$ , Ground electrode, Reference electrode
7. Connect the electrodes to each other with the short interconnection tubes.

**ATTENTION**

Be careful when assembling the electrodes. The electrodes are easily damaged.



8. Install the assembled electrodes into the electrode cradle.
9. Place the electrode cradle on the base plate of the Dry Electrode ISE unit. Slide the cradle to the right and into position.

**Note**

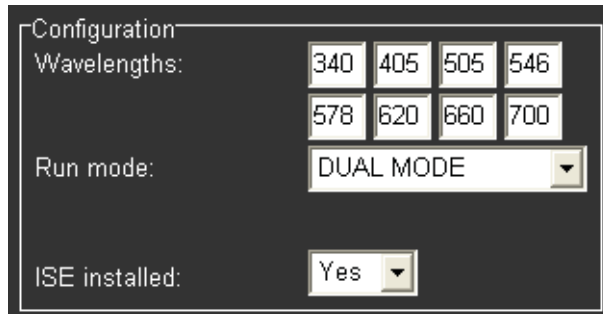


The pins in the PCB must align with the mounting holes in each electrode.

10. Attach the end of the detector leg of the Y-connector tubing to the tube connector on the K electrode.
11. Attach the end of the single short reference tube to the tube connector on the reference electrode.
12. Attach the peristaltic pump tube to the tube connector on the ground electrode.
13. Mount the electromagnetic shield. Place and fasten the knurled screws.

### B.2.6 Activate the ISE unit

1. Open the **Service** screen. This screen is listed in the menu tree.
2. Click **System configuration** in the menu to the left. The screen shows the current settings.



The screenshot shows a configuration window with a dark background. At the top left, it says "Configuration". Below that, "Wavelengths:" is followed by a 2x4 grid of input fields containing the values 340, 405, 505, 546 in the first row and 578, 620, 660, 700 in the second row. Below the grid, "Run mode:" is followed by a dropdown menu showing "DUAL MODE". At the bottom, "ISE installed:" is followed by a dropdown menu showing "Yes".

3. Select **Yes** for the option **ISE installed**.



**Note**

After activating the ISE option, you can set the parameters for the ISE unit. See par. B.4.1.

**B.2.7 Finishing the installation**

When the electrodes and tubing are installed and the ISE option is activated in the analyzer software, installation must be finished to make the Dry Electrode ISE unit operational.

1. Close the side door.

**ATTENTION**

Leave the instrument to rest for at least 10 minutes after installing electrodes and/or new tubing.

2. Reset the Dry Electrode ISE unit twice. See par. B.6.1.
3. Check whether the tubing in the unit is filled with reference fluid. If not, reset the Dry Electrode ISE unit again.



### B.3 ISE reagents and solutions

Reagents and cleaning solutions must be placed on the reagent rotor in designated positions. See par. B.3.2. The functions of the ISE fluids are listed here:

ISE Diluent	Used to dilute the samples before they are measured.
ISE Reference	Used as washing solution and to set the measurement baseline value.
ISE Cleaner	Used to clean the tubes and electrodes. The cleaning cycle is carried out automatically as defined in the ISE parameters. See par. B.4.1.
ISE Conditioner	Used to restore the surface membranes of the electrodes after the cleaning procedure.
ISE Calibrators	Used to calibrate the Dry Electrode ISE unit. High and low calibrators are used. The analyzer uses pre-programmed calibrator values. After use, the discarded low calibrator is used again as ISE Activator (see below).
ISE Activator	Used for an initial unreported measurement when the unit has been stand-by for a certain time. This measurement guarantees a higher precision of the Dry Electrode ISE unit on subsequent sample measurements. The stand-by time after which the activator measurement is needed is defined in the ISE parameters. See par. B.4.1. Also used as dummy when an ISE cleaning procedure is performed.

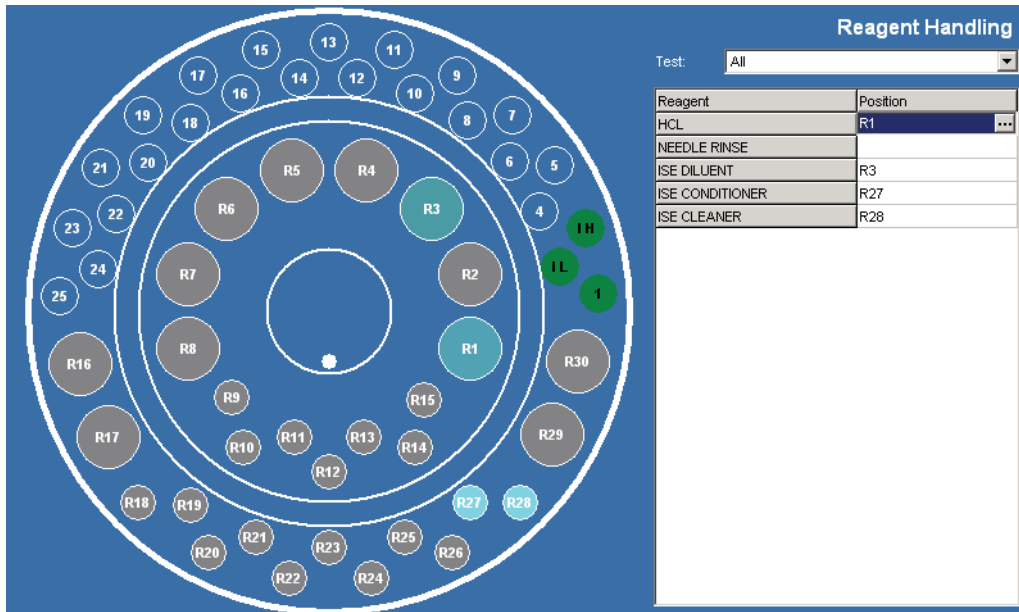
**B.3.1 General reagent handling instructions**

General information on reagent handling is given in the table below. The last column gives the reagent handling instructions during normal operation on the analyzer. This information must be followed closely. Failure to follow the recommended reagent handling procedures may lead to a decrease in overall system performance. Check the package label for detailed reagent specifications and recommended storage and handling procedures.

Reagent	Life	Storage	On-board stability
ISE Diluent	See package label	10 to 30 °C. Do not freeze.	3 days on the system. 30 min. on system to equilibrate. Agitate before every calibration or every 4 hours
ISE Reference	See package label	10 to 30 °C. Do not freeze.	30 days on the system
ISE Cleaner	See package label	2 to 8 °C. Do not freeze.	14 days on the system. Close between cleaning cycles.
ISE Conditioner	See package label	2 to 30 °C. Do not freeze.	30 days on the system. Close between cleaning cycles.
ISE Calibrators	See package label	2 to 30 °C. Do not freeze.	15 min. on the system
ISE Activator (use discarded low calibrator)		2 to 30 °C. Do not freeze.	1 day on the system

**B.3.2 Placing the ISE fluids**

1. Open the *Installation* screen. This screen is listed in the menu tree.
2. Click *Reagent positions*. The *Reagent Handling* screen is shown.



3. Click in the white field next to the *ISE DILUENT* cell.
4. Place the *ISE DILUENT* bottle in the rotor and click on the selected position on the screen.



**ATTENTION**

Before use the diluent needs to be agitated to get a homogeneous solution. Leave the diluent to acclimate for 30 min.

5. Repeat steps 4 and 5 for the *ISE CONDITIONER* and the *ISE CLEANER* fluids.



**Note**

The *ISE CONDITIONER* and *ISE CLEANER* bottles should be kept closed when not in use. Normally, they are opened as part of the end-of-day procedure and closed as part of the start-of-day procedure. The automatic cleaning cycle should be timed accordingly. See par. B.4.1.



**Note**

For optimum performance use a 10 ml bottle for the *ISE CONDITIONER*.

Placing the ISE Calibrators and ISE Activator is done before calibrating the Dry Electrode ISE unit. See par. B.5.2. Placing the ISE Controls is done in the control procedure. See the description of running controls in the analyzer manual.



**BIOHAZARD**

None of the fluids used in the Dry Electrode ISE unit are fit for consumption.

## B.4 Software settings

### B.4.1 Changing ISE Parameters



**Note**

Some settings affect the behavior of the Dry Electrode ISE unit. These are set in the software of the analyzer and need to be copied into the EEPROM in the Dry Electrode ISE unit. Other settings only affect the processing of measurement results by the analyzer. In some cases, the Dry Electrode ISE unit and/or the analyzer need to be reset to synchronize their parameter settings. Make sure to follow the procedures and recommendations listed below.

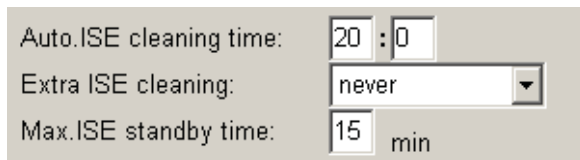
1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **ISE Parameters** in the menu on the left.



**Note**

This screen shows the parameters as they are stored in the memory of the analyzer PC. To read the parameters from the EEPROM, click **F7 ISE EEPROM Verify**.

3. Set the parameters in the upper section.



**Auto.ISE cleaning time:** Time for the automatic cleaning cycle on the Dry Electrode ISE unit. This parameter uses a 24-hour clock. The manufacturer recommends a clocktime that is guaranteed to be after the operational times of the analyzer, e.g. 20:00.

**Extra ISE cleaning:** Sets extra automatic cleaning cycles if the Dry Electrode ISE unit has not been used longer than one day. Cleaning is always done when the unit was used during the day.

- **Never** - no extra cleaning cycles are performed.
- **After X days** - if the unit has not been used for X days, a cleaning cycle is performed. All days are counted.

The recommended setting is **Never**.

**Max.ISE standby time:** Maximum stand-by time. If this time is expired, an ISE Activator sample will automatically be measured and discarded before the next measurement.

4. Set the parameters in the lower section.

	K	Na	Cl	CO2
<b>Set 1</b>				
Electrodes:	Yes ▾	Yes ▾	Yes ▾	Yes ▾
Offset:	0.00	0.00	25.00	10.00
Flush interval:	30		min	
Ref. flush time:	8		sec	
Analog:	1			
<b>Set 2</b>				
LO CAL:	3.00	91.00	78.00	11.00
HI CAL:	10.00	161.00	126.00	34.50
<b>Set 3</b>				
SLOPE MIN:	40.00	50.00	-70.00	-40.00
SLOPE MAX:	70.00	80.00	-25.00	-15.00
<b>Set 4</b>				
dCO:	3.10	4.20	6.70	7.40
dFS:	0.00	0.00	-6.00	16.00

<b>Electrodes:</b>	These options define which electrodes are installed in the Dry Electrode ISE unit. Non-installed electrodes must be replaced by a by-pass electrode.
<b>Offset:</b>	Factor in calculations of concentrations. Only to be changed by service engineers with specific instructions of the manufacturer.
<b>Flush interval:</b>	The valves in the Dry Electrode ISE unit are alternately open and flushed in the interim. The flush interval is measured in minutes.
<b>Ref. flush time:</b>	Determines how long the reference fluid is pumped through the electrodes after each measurement.
<b>Analog:</b>	System parameter. This value should not be changed by the user.
<b>LO CAL:</b>	Target values for the low calibrator. These values should only be changed when a new batch of calibrators is used.
<b>HI CAL:</b>	Target values for the high calibrator. These values should only be changed when a new batch of calibrators is used.
<b>SLOPE MIN: *</b>	Minimum slopes that should result from the measurements of the low and high calibrators.
<b>SLOPE MAX: *</b>	Maximum slopes that should result from the measurements of the low and high calibrators.
<b>dCO *</b>	Factor in calculations of concentrations.
<b>dFS *</b>	Factor in calculations of concentrations.

\* Only to be changed by service engineers with specific instructions of the manufacturer

5. Synchronize the parameter sets in the Dry Electrode ISE unit. This is only needed if parameters in set 1, 2, 3 and/or 4 are changed. Press the **F1**, **F2**, **F3** and/or **F4** button as required.

## B.4.2 Changing ISE test parameters

1. Open the **Programming** screen. This screen is listed in the menu tree.
2. Click **ISE test programming** in the menu on the left. The screen shows the parameters for the tests on the Dry Electrode ISE unit.



### Note

The screen shows one set of parameters per electrode. Click on one of other tabs to see the settings for the other electrodes.

3. Set the parameters in the **General** section.

General

Electrode: CO2

Name: Carbon dioxide

Abbreviated name: CO2

Units: mmol/l

Decimals: 1

Repeats: 1

Concentration limits: 0.0 - 0.0 mmol/l

Factor: 1.000

<b>Name:</b>	Name to identify the test. The name appears in reports.
<b>Abbreviated name:</b>	Abbreviated name. This cannot be modified.
<b>Units:</b>	Units in which the test results are reported.
<b>Decimals:</b>	Number of decimals used for the measurements. This is also the number of decimals used for reference and target values.
<b>Repeats:</b>	Number of times the test is repeated for the same sample. The results of these repeated measurements is averaged.
<b>Concentration limits:</b>	The minimum and maximum accepted values. If these values are exceeded in a measurement, an error message is shown.
<b>Factor:</b>	Used to finetune the measurement results.

4. Set the parameters in the other sections. These parameters are the same as those used for other tests on the analyzer. See par. 6.2.2.

## B.5 Normal usage

### B.5.1 Start-of-day and pre-calibration procedure

The start-of-day and pre-calibration procedure must be done at the start of every working day. This procedure checks that all the reagents are ready for normal usage. It is not part of the regular maintenance checks that are listed in the maintenance chapter.

1. Check if cleaning was performed.

Cleaning is done automatically at a preset time outside working hours (this is defined in the ISE parameters - see par. B.4.1). Check the last performed cleaning in the **ISE 2 point calibration** screen (see par. B.5.2). The last performed cleaning cycle is shown in that screen.

2. Check the ISE Diluent.

If an overnight diluent is used, replace the overnight diluent with the active diluent. Check the level of the active diluent. If the bottle is less than 1/4 full, replace it with a full bottle. Agitate, remove the cap and leave on the system for 30 minutes before calibration.



#### Note

For an overnight diluent the on-board stability time, see par. B.3.1, can be disregarded. An overnight diluent can be used until the expiry date stated on the label.

3. Check the ISE Reference fluid.

If the bottle is less than 1/8 full, replace the bottle with a full bottle. The remaining fluid from the replaced bottle can be added to the new bottle before calibration. Agitate the contents of the bottle after adding the remaining fluid from the replaced bottle. Perform a reset of the Dry Electrode ISE unit after the bottle is replaced (see par. B.6.1).

4. Check the ISE Activator.

Check the level every 4 hours and fill with the discarded low calibrator.

5. Place a cap over the ISE Conditioner.

6. Place a cap over the ISE Cleaner.



**B.5.2 Calibration procedure**

The Dry Electrode ISE unit must be calibrated every 4 hours. Also, calibration must be performed after each cleaning cycle.



**Note**

If the CO<sub>2</sub> electrode is not used (if it is replaced with a by-pass electrode), calibration only needs to be done every 8 hours.

1. Place the ISE Calibrators in the designated positions on the rotor. They are indicated on the **Sample Handling** screen of the analyzer as **IH** (ISE high calibrator) and **IL** (ISE low calibrator).



**Note**

Calibrators must not be placed in the rotor more than 10 minutes before they are measured. Always use fresh samples for the calibrators.



**Note**

If the calibrators run out or the available batch is expired, a new batch of calibrators must be used. In this case, the calibration targets must be checked and changed if needed. For the procedure to change the parameters and synchronize the EEPROM in the Dry Electrode ISE unit, see par. B.4.1.

2. Open the **ISE** screen. This screen is listed in the menu tree.
3. Click **ISE 2 point calibration** in the menu on the left. The screen shows the result of the last calibration cycle.

Last ISE calibration date: 5/31/2007		Last ISE cleaning date: 5/31/2007	
Last ISE calibration time: 2:06:18 PM		Last ISE cleaning time: 2:03:36 PM	
	Low calibration	High calibration	Slope
K	13.07 mV	41.39 mV	54.15
Na	-5.4 mV	7.83 mV	54.45
Cl	4.1 mV	-4.23 mV	-50.56
CO2	7.64 mV	-2.27 mV	-30.39

4. Click **F2 Calibrate ISE**. The calibration is performed. The results are shown on the screen. Details about the shown values are given in the table below. If calibration fails, an error message is shown on the screen. See par. B.7.3.



**Note**

Top up the ISE Diluent, agitate and leave on the system for 30 minutes before starting calibration.

5. (Optional) Click **F1 Printout Calib.Res.**. A calibration report is printed.
6. Place the ISE low calibrator in the designated position for the ISE Activator. This is indicated on the **Sample Handling** screen of the analyzer.
7. Perform measurements on normal and abnormal controls. See par. 5.4.3.

**B.5.3 Sample measurements and handling**

Loading samples and requesting tests for the Dry Electrode ISE unit is identical to loading samples and requesting tests for tests performed by the analyzer itself. The ISE tests are listed in the tests available for samples. When ISE tests are requested, the Dry Electrode ISE unit is automatically activated to perform them. For information on sample handling, see par. 5.3.

### B.5.4 End-of-day procedure

The end-of-day procedure must be done at the end of every working day. This procedure checks that all the reagents are ready for use during the night. It is not part of the regular maintenance checks that are listed in the maintenance chapter.

1. Check the ISE Diluent.

If an overnight diluent is used, replace the active diluent with the overnight diluent. Check the level of the overnight diluent. If the bottle is less than 1/6 full, replace it with a full bottle. Put a cap on the active diluent and place it in an unused position of the rotor.



**Note**

For an overnight diluent the on-board stability time, see par. B.3.1, can be disregarded. An overnight diluent can be used until the expiry date stated on the label.

2. Check the ISE Reference fluid.

If the bottle is less than 1/8 full, replace the bottle with a full bottle. The remaining fluid from the replaced bottle can be added to the new bottle before calibration. Agitate the contents of the bottle after adding the remaining fluid from the replaced bottle. Perform a reset of the Dry Electrode ISE unit after the bottle is replaced (see par. B.6.1).

3. Check the ISE Activator.

Fill the activator with the discarded low calibrator if needed. If discarded low calibrator is not available, fill with unused low calibrator.

4. Remove the cap from the ISE Conditioner.

5. Remove the cap from the ISE Cleaner.



**Note**

Calibrators and controls are not needed overnight.

### B.5.5 Shut-down procedure

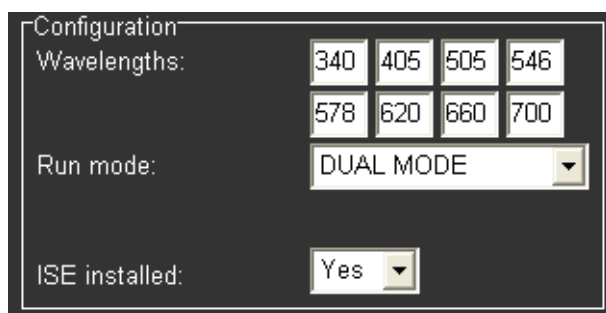
If the Dry Electrode ISE unit is to be switched off for a longer period, the manufacturer recommends to perform a shut-down procedure.



#### ATTENTION

Never just switch off the Dry Electrode ISE unit. Leaving the unit switched off without preparing it properly first will lead to damages to the components.

1. Remove the cap from the ISE Conditioner.
2. Remove the cap from the ISE Cleaner.
3. Place the (overnight) ISE diluent and ISE activator on the rotor. See par. B.3.2.
4. Open the **ISE** screen. This screen is listed in the menu tree.
5. Click **ISE electrode maintenance** in the menu on the left. The screen shows the state of the electrodes. The last performed calibration and cleaning cycles are shown at the top of the screen.
6. Click **F1 Clean Cycle**.
7. Wait until the cleaning cycle is finished.
8. Reset the Dry Electrode ISE unit twice. See par. B.6.1.
9. Disconnect or remove the ISE reference solution bottle.
10. Reset the Dry Electrode ISE unit twice. See par. B.6.1. Ignore the error message shown on the screen.
11. Check if the ISE reference solution is removed from the tubes. If there is still reference solution in the tubes, press together the Y-connector tubing and reset the Dry Electrode ISE unit again.
12. Open the **Service** screen. This screen is listed in the menu tree.
13. Click **System configuration** in the menu to the left. The screen shows the current settings.



14. Select **No** for the option **ISE installed**.
15. Place caps on all bottles.
16. Take the tubes off the peristaltic pump and off the electrode stack.
17. Close the door of the Dry Electrode ISE unit.

## B.6 Servicing

### B.6.1 Resetting the Dry Electrode ISE unit

Either a full system reset or a Dry Electrode ISE unit reset can be done.

#### Full system reset

1. Open the **Rotor/System** screen. This screen is listed in the menu tree.
2. Click **F1 Reset System**.

#### Reset the Dry Electrode ISE unit only

1. Check the level in the ISE Reference solution bottle. Top up or replace if necessary.
2. Open the **ISE** screen. This screen is listed in the menu tree.
3. Click **F1 Reset ISE**.

**B.6.2 Minimum maintenance checks**

Interval	Check	Description
Daily before use	All cables	Check all voltage and communication cables.
	Main tube connections	Check the sample, reference and peristaltic pump tube connections.
	System ON	Check that the analyzer and computer are ON.
	All fluids	Check the fluids levels and expiry dates.
	All fluids	Run the start-of-day procedure.
Every four hours	Calibration	Run the calibration procedure.
After use	All fluids	Run the end-of-day procedure.
Every 3 months	Tubes	Replace ISE tubing.
	Electrodes	Replace the K <sup>+</sup> , Cl <sup>-</sup> and CO <sub>2</sub> electrodes.
Every 12 months	Electrodes	Replace the Na <sup>+</sup> and reference electrodes.
Every 24 months	Electrodes	Replace the bypass electrodes.

### B.6.3 Checking the system behavior

#### Bubble detector

The bubble detector indicates whether the fluid flows correctly. It is one of the most important indicators to check normal operation of the Dry Electrode ISE unit. The bubble detector light shows when there is no fluid present in the detector cell.

Light status	Cause	Action
Light is on	No liquid is in the tube.	Make sure fluid levels are correct. Make sure that there are no blockages in the tubes.
No light	Liquid is present in the tube.	No action necessary.

#### The start-up and reset cycle

The start up and reset cycle runs as follows:

Step	Medium	Duration (s)	Pump	Comment
1	Air	20	ON	The pump starts to pump air through the sample tube. Any fluid still in the tube is removed. The bubble detector is not calibrated.
2	Reference	20	ON	The electrodes are flushed with reference solution. The bubble detector is calibrated.
3	Air	6	ON	The electrodes are emptied.
4	Reference	2	ON	Reference fill. A column of fluid remains between the sample valve and the bubble detector.
5			OFF	The unit remains with both valves closed with a column of fluid remaining between the reference valve and the bubble detector.

Problems that occur during the startup cycle produce the error 291 ISE Startup error. The durations listed are not precise and can vary between systems. The total time should not exceed 52 seconds.

#### Measurement and calibration cycle

The measurement and calibration cycle runs as follows:

Step	Medium	Duration (s)	Motor	Light	Comment
1	Sample	5	ON	ON	The sipper takes up a sample from the cuvette.
2	Sample	20	ON	ON	The sipper retracts with the pump still working.
3	Sample/Air	4	ON	OFF	The sample passes the bubble detector and stops 5 -10 mm from the bubble detector.
4	Sample/Air	3	Very slow	ON	Sample measurement.
5	Reference	6	ON	OFF	Reference solution is pumped.
6	Reference	3	Very slow	ON	Reference measurement.
7	Air	6	ON	ON	The electrodes are emptied.

Step	Medium	Duration (s)	Motor	Light	Comment
8	Reference	2	ON	OFF	Reference fill. A column of fluid remains between the sample valve and the bubble detector.
9			OFF	OFF	The unit remains with one valve open. A column of fluid remains between the reference valve and the bubble detector.

The durations listed are not precise and can vary between systems. The total time should not exceed 52 seconds.

### Cleaning cycle

The cleaning function consists of 5 cleaning cycles:

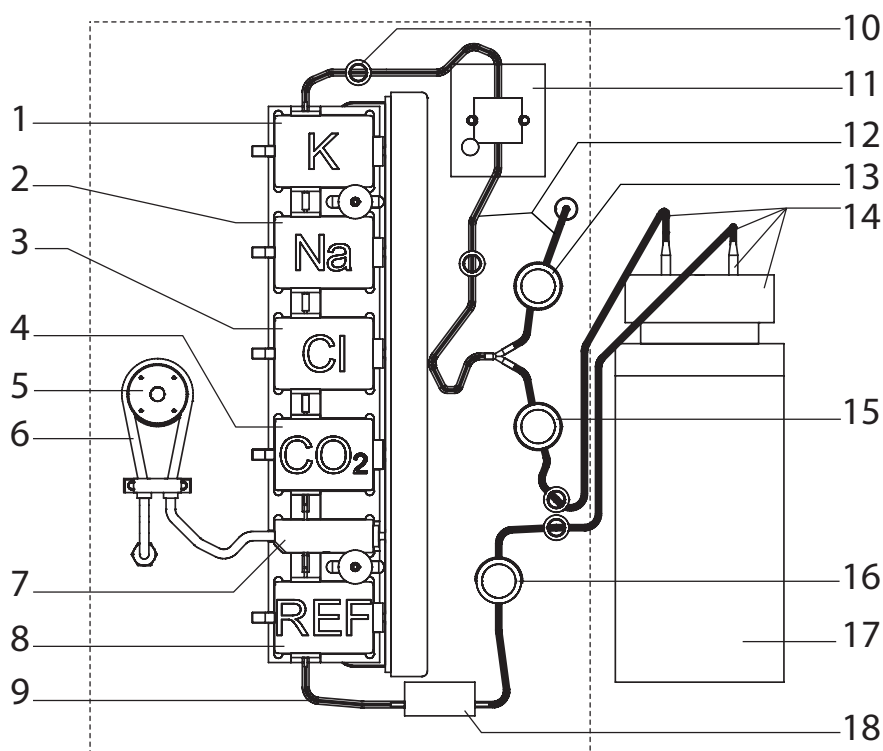
- a long cycle with ISE Cleaner
- a long cycle with ISE Conditioner
- three short cycles with a diluted ISE activator.

The cleaning cycle runs as follows:

Step	Medium	Duration (s)	Motor	Light	Comment
1	Cleaning fluid	5	ON	ON	The sipper takes up fluid from the cuvette.
2	Fluid/Air	20	ON	ON	The sipper retracts. The fluid is transported to the bubble detector.
3	Fluid/Air	4	ON	OFF	The cleaning fluid passes the bubble detector and stops 10 mm from the bubble detector.
4	Soak	10 / 300	OFF	ON	The electrodes are soaked for 10 seconds (short cycle) or 300 seconds (long cycle).
5	Air	4	ON	ON	The cleaning fluid is removed from the electrodes.
6	Reference	6	ON	OFF	The electrodes are flushed with reference solution.
7	Air	6	ON	ON	The reference solution is removed from the electrodes.
8	Reference	2	ON	OFF	Reference fill. A column of reference solution remains between the reference valve and the bubble detector.



B.6.4 Parts identification



The following table lists the parts shown in the above schematic diagram. Parts not visible in the diagram, as well as optional parts and kits, are listed at the end of the table without position numbers.

No.	Description	Part No.	Remarks
1	K <sup>+</sup> electrode	3918-005	3 months on-board lifetime
2	Na <sup>+</sup> electrode	3918-004	12 months on-board lifetime
3	Cl <sup>-</sup> electrode	3918-006	3 months on-board lifetime
4	CO <sub>2</sub> electrode	3918-003	3 months on-board lifetime
	By-pass electrode	3918-007	24 months on-board lifetime
5	Peristaltic pump assembly	6002-553	
6	Peristaltic pump tube		contained in tubing set
7	Ground electrode / check valve	3900-049	
8	Reference electrode	3918-002	12 months on-board lifetime
9	Reference tube		contained in tubing set
10	Tubing constraints		
11	Bubble detector	6002-558	
12	Y-connector tubing		contained in tubing set
13	Sample valve	3366-923	
14	Cap assembly (cap/straws/tubing)		contained in tubing set
15	Reference valve	3366-923	
16	Reference electrode valve	3366-924	
17	Reference solution container	3203-085	

No.	Description	Part No.	Remarks
18	Restriction pipe assembly	8003-376	
	Dry ISE tubing set	6003-382	

Description	Part No. SEPPIM	Volume
ISE Diluent solution	ISDI-0250	12 x 25 ml
ISE Reference solution	ISRS-0800	1 x 500 ml
ISE Cleaner/Conditioner	ISCC-0280	6 x 8 ml cleaner 3 x 25 ml conditioner
ISE Calibrator	ISCA-0250	6 x 20 ml low calibrator 6 x 20 ml high calibrator
ISE Activator		Use discarded low calibrator

## B.7 Troubleshooting

This section provides general guidelines on how to proceed in case of a failure. The following symptoms, with probable causes and actions to take, are described:

- error messages, see par. B.7.1
- error flags, see par. B.7.3
- calibration failures, see par. B.7.3
- sample measurement problems or electrode failures, see par. B.7.4.

Additionally, an inspection procedure is described to check the unit (see par. B.7.5). If the inspection does not solve the cause of the problem, the table in par. B.7.6 can be useful.

Some actions are described in more detail:

- removing blockages, see par. B.7.7, and
- reviving the Na<sup>+</sup> electrode, see par. B.7.8.

### B.7.1 Handling error messages

The system uses 2 levels of error messages.

- Information messages
- Hardware error messages

The information message shows when the error does not cause incorrect test results. The current test stops and the next test starts. A hardware error message shows when the error causes incorrect test results. The faults need immediate attention from the user.

#### ***ISE NOT PRESENT***

The connection between the Dry electrode ISE unit and the analyzer is not complete.

- Reset the analyzer. If the error does not clear, contact the technical support department of your supplier.

#### ***ISE COMMUNICATION ERROR***

The communication link between the ISE unit and the analyzer is not working properly.

- Ask a service engineer to check the communication link. Contact the manufacturer if needed.

#### ***ISE BUSY***

The ISE unit is being reset.

#### ***ISE ARM ERROR***

The ISE arm is in the wrong position during a status check.

- Reset the analyzer. Make sure there is no mechanical interference. Do not touch the ISE arm.

#### ***ISE NOT READY***

The analyzer starts during the start-up procedure of the Dry electrode ISE unit.

- Click **F4** when the Dry Electrode ISE unit is ready for operation. The result will show the flag "1". Make sure the Dry Electrode ISE unit is ready before you start a measurement.

#### ***ISE DATA ERROR***

An error occurs during the auto calibration at startup.

- Click **F4**. Do a system halt and reset the complete system.
- Check if there is enough reference solution.
- Check if the feed tube is not blocked.
- Check if the sipper is not blocked.
- Check if the pump works correctly.
- Check if the reference and sample valves work correctly.

#### ***ISE STARTUP ERROR***

A command is in the incorrect step in a sequence of commands.

- Reset the analyzer. Check the levels and positions of all fluids.

#### ***ISE INSUFFICIENT SAMPLE***

Sample fluid is not present in the system.

- Reset the analyzer.
- Examine the tubes.
- Make sure the tubes are not blocked.
- Make sure there is enough sample fluid.
- Make sure the sample cup is in the correct position.

#### ***ISE BUBBLE DETECTION ERROR***

The system pump does not work correctly.

- Reset the analyzer.
- Examine the tubes.
- Make sure the tubes are not blocked.
- Make sure that the reagents solutions and samples are in the correct positions.

- Make sure that the black and white collars of the peristaltic pump tube are installed correctly in the pump bracket.

***ISE PARAMETERS UNAVAILABLE***

The parameters are not available for the ISE unit.

- Reset the analyzer.
- Load the ISE parameters into the Dry Electrode ISE unit.

***ISE CALIBRATION UNAVAILABLE***

A measurement is started before calibrating the unit.

- Reset the analyzer.
- Calibrate the system.

***ISE INSUFFICIENT REFERENCE***

There is not enough ISE Reference solution.

- Reset the analyzer.
- Check the level in the ISE Reference solution container. Top up or replace if necessary.
- Make sure the tubes are not blocked.

**B.7.2 Understanding error flags**

For certain errors the test results are marked with a flag. The flags are listed in the **Flags** column on the **Evaluate Results** screen. The flags are also printed with the results. See par. 4.2.6. The possible flags, their meanings and actions to take are described in the following table.

Flag	Meaning	Description / Action
O	ISE measurement overrange.	The calibration slope is overrange.
o	ISE reference overrange.	ISE result out of analytical range. Repeat measurement.
U	ISE measurement underrange.	The calibration slope is underrange. See par. B.7.3.
u	ISE reference underrange.	Reference measurement not in line with previous measurements. Repeat measurement.
P	Percentage deviation	The calibration slopes differ more than the allowed percentage. See par. B.7.3.
E	EEPROM error	Call a service engineer to check the cause of this problem. The Dry Electrode ISE unit cannot be used until the problem is resolved.

### B.7.3 Calibration failures

**Note**

If a calibration fails, the analyzer starts a new ISE calibration cycle. If the calibration fails again, the analyzer shows an error message.

Check the result details to see which electrode failed and which error flags are set.

**General calibration failures (P flags)**

1. Check the ISE diluent. Replace if the bottle is less than 1/4 full.
2. Check the ISE reference solution. Replace if the bottle is less than 1/8 full.
3. Check if the ISE cleaner and ISE conditioner are still valid. Replace if needed.
4. Place fresh calibrator.
5. Start a new ISE calibration.
6. If the calibration fails again, perform the ISE cleaning procedure (described as part of the preparation to shut down the unit - see par. B.5.5). Then repeat the calibration procedure.

**CO<sub>2</sub> calibration failed with a P flag**

1. Swirl the ISE Diluent.
2. Place fresh calibrator.
3. Start a new ISE calibration.
4. If the calibration fails again, perform the ISE cleaning procedure (described as part of the preparation to shut down the unit - see par. B.5.5). Then repeat the calibration procedure.

**K<sup>+</sup> and Cl<sup>-</sup> calibration failures (U or UP flags)**

1. Check if the ISE cleaner and ISE conditioner are still valid. Replace if needed.
2. Perform the ISE cleaning procedure.
3. Leave the instrument to acclimate for 30 minutes.
4. Start a new ISE calibration.
5. If the calibration fails again, replace the electrode.

**Na<sup>+</sup> calibration failures (U or UP flags)**

1. Perform the ISE cleaning procedure.
2. Leave the instrument to acclimate for 30 minutes.
3. Start a new ISE calibration.
4. If the calibration fails again, try reviving the Na<sup>+</sup> electrode. See par. B.7.8.
5. If the calibration fails again, replace the Na<sup>+</sup> electrode.

**Note**

If the above information is not sufficient to solve the problem, contact the service department of your supplier.

**B.7.4 Sample measurement problems or electrode failures**

Problem	Cause	Action
The results from the Na <sup>+</sup> electrode are unstable.	A blockage or leak in the reference feed tubing.	Replace the reference feed tubing (cap assembly, reference tube). Replace the restriction pipe assembly. Make sure there are no leaks in the reference feed tubing (cap assembly, reference tube).
The results from the Na <sup>+</sup> electrode are too high.	Na not conditioned.	Clean and condition Na <sup>+</sup> electrode. Revive Na <sup>+</sup> electrode, see par. B.7.8.
The K <sup>+</sup> electrode fails before the expiry date.	Poisoning caused by Cl <sup>-</sup> /CO <sub>2</sub> backflow.	Replace K <sup>+</sup> electrode. See par. B.2.5.
The K <sup>+</sup> results have too low slope.	The solution flows back through the electrode housing.	Check for blockages in: <ul style="list-style-type: none"> <li>• The sipper, see par. B.7.7</li> <li>• The reference/sample tubing, see par. B.7.7</li> <li>• The vent hole in the reference bottle cap.</li> </ul> Replace the K <sup>+</sup> electrode if it is damaged by back flowing fluid.
CO <sub>2</sub> calibration fails. The slope is > -15.	CO <sub>2</sub> from the air is absorbed into the ISE Diluent.	Replace the ISE Diluent. Replace the tubes of the peristaltic pump.
Calibration fails for all electrodes.	<ul style="list-style-type: none"> <li>• Connections between the electrodes are not correct.</li> <li>• The ISE Diluent or the ISE Reference solution is contaminated.</li> <li>• Expired calibrators.</li> <li>• Reference electrode.</li> <li>• A blockage in the tubing.</li> </ul>	<ul style="list-style-type: none"> <li>• Check all the connections between the electrodes.</li> <li>• Replace the ISE Reference solution. Replace the ISE Diluent.</li> <li>• Place fresh calibrators.</li> <li>• Replace the reference electrode.</li> <li>• Remove blockages, see par. B.7.7</li> </ul>



### B.7.5 Inspecting the ISE unit

These steps are simple procedures to check the Dry Electrode ISE unit when it is not working according to specifications.

1. Check the fluid system for leaks.
2. Check the level of the fluid in the ISE Reference solution bottle.
3. Make sure the ISE Reference solution bottle is connected correctly.
4. Make sure the ISE Reference solution straws have no blockage.
5. Make sure the tubes from the ISE reference solution bottle have no blockage in the unit recess panel.
6. Make sure ISE Diluent is in the rotor. Check expiry and on-board stability.
7. Make sure ISE Cleaner is in the rotor. Check expiry and on-board stability.
8. Make sure ISE Conditioner is in the rotor. Check expiry and on-board stability.
9. Check the unit to analyzer connections.
10. Make sure the unit pinch valve tube has no holes and is correctly installed.
11. Check the tube connection between the electrodes.
12. Check if the tubing is pushed into the valve correctly.
13. Check the tube connections on the Y-connector of the bifurcated assembly.
14. Make sure the tubes have no blockage. See par. B.7.7 for removing blockages.
15. Inspect the connections for the peristaltic pump tubes. Make sure there are no leaks.
16. Check the peristaltic pump for blockages.
17. Make sure there are no blockages in the pinch valves. Make sure the correct tubes are used. The use of incorrect tubes in the pinch valves permanently reduces the system performance.

**B.7.6 Flow related problems**

Problem	Cause	Action
An absence of sample fluid in the tubes.	The system has a blockage.  The collars of the peristaltic pump tube have come loose from the pump bracket.	Check for blockages in: <ul style="list-style-type: none"> <li>• The sipper, see par. B.7.7</li> <li>• The sample tubes, see par. B.7.7</li> <li>• The vent hole in the reference bottle cap.</li> </ul> Install both collars of the peristaltic pump tube correctly in the pump bracket. See par. B.2.2.
Slow moving sample fluid.		
The sample does not reach the electrodes within 20 seconds.		
The flow of sample fluid is not smooth.		
The sample flows backwards.		
The flow of waste is not smooth.		
An absence of fluid in the system during the second period of 20 seconds.	No ISE Reference solution in the system.	Check for: <ul style="list-style-type: none"> <li>• ISE Reference solution in the bottle</li> <li>• Tubes are correctly fitted to the reference bottle cap.</li> <li>• Blockages in the reference tubing. See par. B.7.7.</li> </ul>
Air bubbles are not visible in the ground electrode when air is pumped through the sample tube.	ISE Reference solution is not pumped correctly through the reference tubes.	Check for blockages in the reference tubing. See par. B.7.7.
The test results are not consistent.	Bubbles in the reference tubes.	Reset the unit 3 times to make sure that the reference tubes are primed correctly.
No flow in the tube in the correct sequence.	Reference valve or sample valve failure.	Check for blockage. See par. B.7.7. Contact technical service.
ISE Reference solution does not flow.	The ISE reference solution has run out.	Replace the ISE Reference solution bottle with a new one.
The waste fluid flows back from the analyzer.	There is back pressure from the analyzer.	Remove the cap from the waste container and put the cap back. Make sure the cap is slightly loose.
The pump does not turn or does not turn for almost the complete reset cycle.	System fault.	Contact technical support.

### B.7.7 Removing blockages

#### Blocked sipper

1. Remove the sample tube from the analyzer.
2. Retract the plunger of a 20 ml syringe.
3. Connect the syringe to the sample line of the analyzer with an appropriate tube.
4. Gently push the plunger in to force air down the sample tube.  
The blockage should clear and a small quantity of fluid will show at the end of the sipper.
5. If this fails, gently pull the plunger to suck air into the sipper.
6. If both fail, wet the end of the sipper and repeat step 5.
7. Replace the tube if necessary.

#### Blocked reference/sample tube at the valve

1. Set the Dry electrode ISE unit to OFF.
2. Remove the tube from the valve.
3. Inspect the tube. An obvious signs of blockage or line fusion is the presence of a thin white band across the tube at the position of the valve.
4. Gently roll the tube between the fingers to relax the tube. The tube returns to the normal state.
5. Connect the tube to the valve.
6. Replace the tube if necessary.

**B.7.8 Reviving the Na<sup>+</sup> electrode****Note**

If the Na<sup>+</sup> electrode is 'shocked' there is a good chance it can be revived. This is not true for the other electrodes.

1. Remove the Na<sup>+</sup> electrode from the stack.
2. Connect 10 cm tubing to one pin of the electrode.
3. Use a syringe to fill the tubing and electrode with 0,1N NaOH.
4. Connect the open end of the tubing to the other pin of the electrode. The NaOH must remain in the tubing and electrode.
5. Let the electrode rest for 24 hours.
6. Disconnect the tubing.
7. Use a syringe to flush the electrode with reference solution.
8. Reinstall the Na<sup>+</sup> electrode. See par. B.2.5.

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