# User Manual

**Software version V4.XX**

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# Revisions

| Date | Description | Version | Stamp |
|---|---|---|---|
| 02/21/2008 | Revision A<br><br>SECTION 1 OPERATING PRINCIPLE<br>SECTION 2 USE SECTION<br>SECTION 3 MESSAGES<br>SECTION 4 MAINTENANCE<br>SECTION 5 PROBLEMS AND CORRECTIVE ACTION<br>APPENDIX I WASTE DISPOSAL<br>APPENDIX II DISINFECTING THE DEVICE APPENDIX III DISPOSAL OF THE MEDICAL DEVICE<br>Attached document:<br>Connection Protocol, revision C | V 3.03 |  |
| 10/21/2008 | Revision B<br><br>Replacement of 3x3 with IDS-iSYS.<br>Replacement of BIOCODE-HYCEL by IDS.<br><br>SECTION 1 OPERATING PRINCIPLE<br>SECTION 2 USE<br>SECTION 3 MESSAGES<br>SECTION 4 MAINTENANCE<br>SECTION 5 PROBLEMS AND CORRECTIVE ACTION<br>APPENDIX I WASTE DISPOSAL<br>APPENDIX II DISINFECTING THE DEVICE APPENDIX III DISPOSAL OF THE MEDICAL DEVICE<br>Attached document:<br>Connection Protocol, revision D | V 3.12 |  |

# Revisions (Continued)

| Date | Description | Version | Stamp |
|---|---|---|---|
| 02/26/2009 | Revision C<br>SECTION 1 OPERATING PRINCIPLE<br>SECTION 2 USER INTERFACE SOFTWARE<br>SECTION 3 USE<br>SECTION 4 MESSAGES<br>SECTION 5 MAINTENANCE<br>SECTION 6 PROBLEMS AND CORRECTIVE ACTION<br>APPENDIX I WASTE DISPOSAL<br>APPENDIX II DISINFECTING THE DEVICE<br>APPENDIX III DISPOSAL OF THE MEDICAL DEVICE<br>APPENDIX IV IDS-iSYS CUVETTES<br>Attached document:<br>Connection Protocol, revision E | V 4.03 |  |
| 08/07/2009 | Revision C1<br>General review of the terminology in all sections and appendices of revision C.<br>SECTION 1 OPERATING PRINCIPLE<br>SECTION 2 USER INTERFACE SOFTWARE<br>SECTION 3 USE<br>SECTION 4 MESSAGES<br>SECTION 5 MAINTENANCE<br>SECTION 6 PROBLEMS AND CORRECTIVE ACTION<br>APPENDIX I WASTE DISPOSAL<br>APPENDIX II DECONTAMINATING THE ANALYSER<br>APPENDIX III DISPOSAL OF THE ANALYSER<br>APPENDIX IV IDS-iSYS CUVETTES<br>Attached document:<br>Connection Protocol, revision E | V 4.03 |  |

# Preface

## Special precautions

The safety precautions specific to certain handling procedures described throughout the user manual are indicated in the following form:

### Important notice

### Precaution which MUST be respected

### Presence of a potential risk

# Preface

This instruction manual is to be used in conjunction with the ids-isys *in vitro* diagnostic analyser and must be read before installing or using the analyser.

The ids-isys *in vitro* diagnostic analyser must only be used by personnel trained by approved IDS staff.

The purpose of the user manual is to explain:

- The way the analyser works.
- How to use it in routine working practice.
- The preventive maintenance required.

Revision C1 of the ids-isys User Manual was produced on the 8th July 2009, for the software version:

- **V 4.03**

The manual comprises the following sections and appendices:

| | | |
|---|---|---|
| **Section 1:** | **Operating Principle** | **Rev C1** |
| **Section 2:** | **User Interface Software** | **Rev C1** |
| **Section 3:** | **Use** | **Rev C1** |
| **Section 4:** | **Messages** | **Rev C1** |
| **Section 5:** | **Maintenance** | **Rev C1** |
| **Section 6:** | **Problems And Corrective Action** | **Rev C1** |
| **Appendix I:** | **Waste Disposal** | **Rev C1** |
| **Appendix II:** | **Decontaminating The Analyser** | **Rev C1** |
| **Appendix III:** | **Disposal Of The Analyser** | **Rev C1** |
| **Appendix IV:** | **IDS-iSYS Cuvettes** | **Rev C1** |

**Attached document: Protocol for connection, revision E**

If the analyser is not used in accordance with the recommendations provided in this manual, the level of performance offered by the analyser may be impaired and the results generated may be incorrect.

## List of CE symbols used on the analyser

| | |
|---|---|
|  | Manufacturer. |
|   | *In vitro* diagnostic medical device. |
|  | Consult the instructions for use. |
|  | Caution recommended: see Safety Precautions. |
|  | Risk of biological contamination. |
|  | Risk of crushing injury. |
|   | Serial number. |
|  | Electrical and electronic waste: dispose of in accordance with current country-specific laws. |
|  | High temperature. |
|  | Risk of LED radiation. |
|  | Risk of hand injury. |

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# Section 1:
# Operating Principle

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## Operating Principle 1

# Operating Principle

## 1-1 Field of Use

IDS-iSYS is an *in vitro* diagnostic analyser. It enables Immunoassay, Biochemistry and Coagulation[1] assays to be carried out on a single analytical platform:

- Immunoassay.
  - Bone and Growth.
  - Infectious Diseases.
  - Hypertension.
  - Autoimmunity.

- Biochemistry.
  - Substrates.
  - Enzymes.
  - Electrolytes.
  - Specific Proteins.

- Coagulation.
  - Chronometric tests.
  - Chromogenic substrates.
  - Immunoassays.

The IDS-iSYS must only be used by trained personnel working in compliance with the safety precautions set out in this manual (see Section 1-6-1, page 16) and good laboratory practice (GLP).

[1] Coagulation version available during 2010.

# Operating Principle

## 1-2 General Overview

ids-isys is an *in vitro* diagnostic analyser. It enables Immunoassays, Biochemistry and Coagulation assays to be carried out on a single analytical platform:

Individual assays are carried out in disposable cuvettes which are automatically loaded onto a carousel.

Asynchronous management allows each cuvette to be processed individually and transferred to the relevant reaction modules positioned around the carousel.

The cuvette is able to ensure compatibility in all three fields. The measurements specific to each discipline are carried out directly in the reaction cuvette:

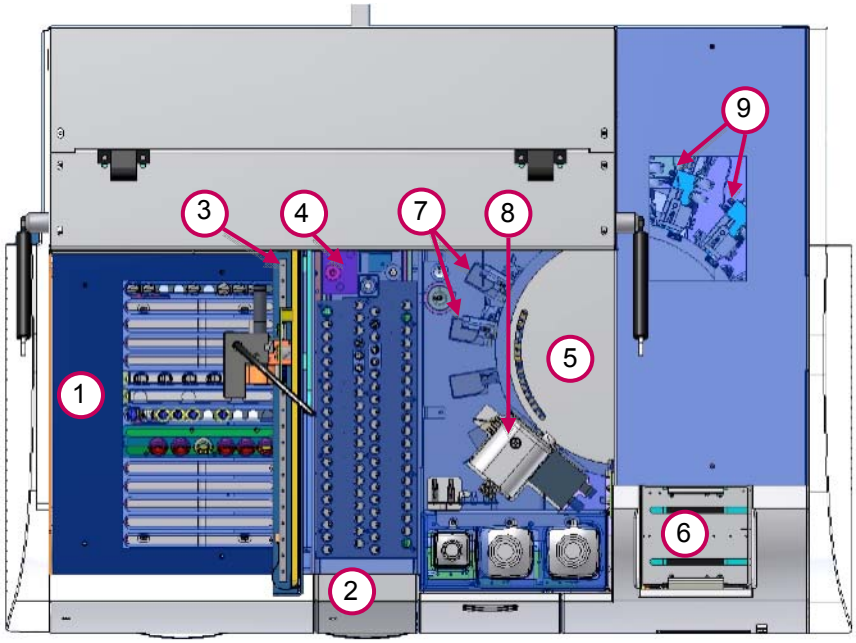
- Luminescence measurements carried out in the luminometer (Immunoassay).
- Absorbancy measurements carried out continuously by the spectrophotometer (Biochemistry).
- Optical measurements for detection of a clot in the chronometer (Coagulation).

Designed for continuous loading, the analyser works on a smaple-by-sample basis. There are several configurations available:

- Immunoassay and Biochemistry.
- Biochemistry and Coagulation.
- Immunoassay, Biochemistry and Coagulation.

For Biochemistry (as an option), the analyser can be fitted with a module using selective electrodes (ISE) to determine Sodium, Potassium and Chloride levels.

With all modules fitted the analyser comprises the following key components:




1. A refrigerated reagent compartment, consisting of 15 rails containing the Immunoassay, Biochemistry or Coagulation racks as well as a specialised rack for chronometric reagents.
2. A sample tray with 64 positions for samples, calibrators and controls.
3. A pipetting arm that pipettes both reagents and samples.
4. For Biochemistry configurations, an optional ISE module with selective electrodes for the simultaneous determination of Sodium, Potassium and Chloride levels.
5. A thermo-regulated carousel set at 37°C with 90 positions for disposable cuvettes. Incorporated into the carousel is the spectrophotometer, used for measuring absorbancy from certain Immunoassay, Biochemistry and Turbidimetry reactions.
6. An automatic cuvette loader, taking 960 cuvettes at a time (pre-formed as a cube).
7. Two modules for chronometric measurements (Coagulation version).
8. A luminometer measuring luminescence in Immunoassay reactions (Immunoassay version).
9. Two or four washers (depending on configuration) for washing magnetic particles (Immunoassay version).

Two barcode readers (one located on the front face of the analyser, the other integrated into the reagent compartment) identify samples, ancillary reagents and reagent cartridges supplied by IDS.

The reagent cartridges are stored in the refrigerated reagent compartment between 12 and 15°C while the analyser is operating, and between 8 and 10°C in standby mode.

Depending on the configuration of the analyser, up to 15 Immunoassay parameters can be programmed simultaneously or up to 36 Biochemistry parameters or a combination of both, up to the maximum number of positions available.

For Immunoassays, the analyser only uses reagents supplied by IDS and its partners. For Biochemistry, it is possible to use reagents available from suppliers other than IDS, however these reagents will not be managed using the barcode system, and the information required for traceability must be manually programmed by the operator.

If reagents other than those marketed by IDS and its partners are used IDS takes no responsibility for the validity of results obtained. It is the responsibility of the operator to ensure any non-IDS reagents are optimised and validated for use on the analyser.

Samples and reagents are aspirated using a probe equipped to detect liquid level using capacitance. The sample and reagents are pipetted in accordance with the validated parameters for each assay and transferred into a cuvette where the reaction takes place. Between each sample, the probe is rinsed internally and externally in order to eliminate any risk of contamination.

**Immunoassays:**
The cuvettes are transferred to the washer module where magnets hold the solid phase (magnetic particles) whilst washing takes place. The cuvette is then transferred to the luminometer where trigger reagents are added to produce luminescence. When measurement is complete, cuvettes are automatically ejected into a re-usable solid waste tray.

**Biochemistry assays:**
Photometric changes taking place in the reaction are measured continuously by the spectrophotometer.

The analyser is connected to a computer via an Ethernet link.

The software is able to programme the analyser workload and carry out the following functions:

- Management of lots of reagents, calibrators and controls.
- Quality controls (Levey-Jennings and Westgard).
- Management of ancillary reagents.
- Operator traceability.
- Transfer of results to a centralised computer system.
- Printing, storing and traceability of results.

# Operating Principle

## 1-3 Characteristics

### Analyser

| | |
|---|---|
| System | • Multidiscipline Biochemistry analyser (ISE as an option), Immunoassay and Coagulation.<br>• Continuous loading.<br>• Configurations:<br>  • Biochemistry (ISE) + Immunoassay (4 washers).<br>  • Biochemistry (ISE) + Immunoassay (2 washers) + Coagulation (2 chronometric modules).<br>  • Biochemistry (ISE) + Coagulation (2 or 4 chronometric modules). |
| Analyser Physical Characteristics | • Analyser dimensions: L 105 cm x H 70 cm x W 75 cm.<br>• Overall dimensions: L 124 cm x H 110 cm x W 71 cm.<br>• Weight: 103 kg.<br>• Computer System: L 60 cm x H 40 cm x W 50 cm. |
| Throughput | • According to configuration.<br>• Biochemistry + ISE 360 tests/hour.<br>• Immunoassay Up to 120 tests/hour (Assay dependent).<br>• Coagulation 60 tests/hour (2 chronometric modules).<br>• 120 tests/hour (4 chronometric modules). |
| Number of tests on line | • 50 Biochemistry + 3 tests ISE, 15 Immunoassay or10 Coagulation. |
| Biochemistry detection | • Spectrophotometer with interferential filters.<br>• Wavelengths: from 340 to 620 nm.<br>• Halogen lamp (optical fibre transmission). |
| Immunoassay detection | • Chemiluminescence.<br>• Luminometer. |
| Coagulation detection | • Optic detection of clot.<br>• Bi-chromatism. |
| Selective electrodes module (ISE) | • Determination of Sodium, Potassium, Chloride levels.<br>• Direct potentiometry on serum.<br>• Indirect potentiometry on urine (automatic pre-dilutions). |
| Samples | • Serum, plasma or urine.<br>• Primary tubes 5 mL (13 x 75 mm), 7 mL (13 x 100 mm). 10 mL (16 x 75 mm).<br>• Secondary tubes (13 x 75 mm).<br>• Paediatric tubes.<br>• 500 µL cups (ref. IS-SC105) and 1.5 mL cups (ref. IS-SC115).<br>• 64 positions for samples, calibrators and controls.<br>• Liquid level detection by capacitance.<br>• Clot detection.<br>• Dilutions and automatic pre-treatments. |
| Barcode readers | • Reader on front face for barcode identification of samples, cuvettes and ancillary reagents.<br>• Integrated reader for reagents barcode. |

| | |
|---|---|
| Reagent compartment | • 15 rails, each of which can hold:<br>  • 1 x Immunoassay cartridge.<br>  • 3 x 45 mL Biochemistry Reagent.<br>  • 6 x 20 mL (or 5 mL) Biochemistry Reagent.<br>• Storage at 12-15°C whilst operating.<br>• Internal storage between 8-10°C in standby mode. |
| Sample volume (µL) | • Immunoassay: from 4 to 300 µL.<br>• Biochemistry: from 4 to 50 µL.<br>• Programmable in steps of 0.5 µL. |
| Reagent volume (µL) | • Biochemistry: from 10 to 400 µL.<br>• Immunoassay: from 10 to 400 µL.<br>• Programmable in units of 1 µL. |
| Reaction volume (µL) | • Immunoassay and Biochemistry: from 180 to 550 µL. |
| Pipetting system | • Pipetting reagents and samples by probe.<br>• Liquid level detection by capacitance.<br>• Preheating of reagents/samples.<br>• Internal and external rinsing between each pipetting of sample. |
| Spectrophotometer | • Spectrophotometer with interferential filters.<br>• 6 wavelengths available: 340, 405, 500, 540, 580 and 620 nm.<br>• Halogen lamp. Transmission by fibre optic.<br>• Linearity: Up to 3 OD.<br>• Optic path of cuvettes: 0.7 cm. |
| Luminometer | • Wavelengths: from 300 to 500 nm.<br>• Linearity: Up to 10 Million RLU. |
| Reaction carousel | • Thermo regulated at 37°C.<br>• 90 positions for disposable cuvettes.<br>• Automatic cuvette supply by cuvette loader. |
| Cuvette loader | • Loader for cube of cuvettes.<br>• Contains 960 disposable cuvettes.<br>• Thermostatically controlled. |
| Common liquid consumables | • IDS-iSYS System Liquid (5 litre containers).<br>• IDS-iSYS Wash (10 litre containers).<br>• IDS-iSYS D-Sorb (1 litre containers).<br>• Immunoassay only: IDS-iSYS Triggers A & B (250 mL each). |
| Waste collection | • 10 litre container for liquid waste posing a biological risk.<br>• Solid waste (cuvettes) disposed of in re-usable container. |
| Power supply | • Voltage: 220 - 240 V.<br>• Frequency: 50 - 60 Hertz.<br>• Maximum power consumed: 1000 VA. |

### Selective electrodes module (ISE) (optional)

| | |
|---|---|
| Principle | • Measurement using specific electrodes for Sodium, Potassium and Chloride levels.<br>• Direct potentiometry on serum and plasma.<br>• Indirect potentiometry on urine. |
| Sample | • Serum, plasma sampled on sodium/lithium heparin or lithium (volume taken: 70 µL).<br>• Urine automatically pre-diluted to 1/10. |
| Precision | • Serum $Na^+$ CV < 1.5% (100 – 160 mmol/L).<br>• $K^+$ CV < 2% (3.0 – 6.0 mmol/L).<br>• $Cl^-$ CV < 2% (80.0 – 120.0 mmol/L). |
| Cycle time | • Serum 30 seconds.<br>• Urine 60 seconds. |

### Computer system: Minimum configuration required

| | |
|---|---|
| Operating system | • Windows XP Pro Service Pack 2.<br>• Windows Vista Service Pack 1.<br>• English. |
| Microprocessor | • Type Sempron 3100 or equivalent. |
| Live memory | • 1 Gb. |
| Hard disk | • 80 Gb. |
| Ethernet | • 2 independent Ethernet network adaptors. |
| Ports | • USB ports (min 2 one of which at front).<br>• Serial port for connection to centralised computer system. |
| Input devices | • Keyboard (country specific).<br>• Mouse. |
| Screen | • Monitor. Speakers integrated. |
| Screen resolution | • 1024 x 768 pixels. |
| Peripherals | • Reader – CD writer. |

## 1-4-1 Environment

The packaging of the IDS-iSYS has been designed to prevent any damage occurring during transportation.

The analyser can be stored in its original packaging under the following conditions:

- Storage temperature 10-40°C.
- Relative humidity 70% non condensing.
- Duration 2 months.

A satisfactory installation site is essential for the analyser to function correctly.

The user must ensure compliance with the conditions required in terms of environment and electricity supply in order to maintain the performance of the analyser and to guarantee safe use for the operator.

Environmental conditions required:

- The analyser must not be exposed to direct light.
- A clean and ventilated air environment.
- The analyser must be placed on a flat work surface, capable of supporting its weight (103 kg) without significant vibration.
- The surrounding temperature must be between 15°C and 30°C. Temperature fluctuations during analyses must not exceed ± 2°C.
- Relative humidity must be below 70% (non-condensing).
- The analyser must not be installed under an air-conditioning unit.
- Clearance of at least 15 cm must be provided at the rear, front, left and right of the analyser to allow evacuation of heat produced by the apparatus.
- The analyser must not be installed near strong sources of electromagnetic radiation and electrical interference (e.g. refrigerators).

Physical characteristics of the analyser:

- Dimensions of the analyser L 105 x H 70 x W 75 cm.
- Overall dimensions L 124 x H 110 x W 71 cm.
- Weight 103 kg.
- Computer system L 60 x H 40 x W 50 cm.

## 1-4-2 Electricity supply

The electricity supply must meet the following conditions:

- Voltage 220 - 240 V.
- Frequency 50 - 60 Hz.
- Maximum power consumed 1000 VA.

If necessary, the installation of a regulated electrical supply may be required.

In order to protect the analyser's electrical safety (in accordance with standards), it is essential to check that the associated peripheral computer equipment (external printer and computer) is earthed.

In the event of prolonged storage, the analyser performance must be checked. The unpacking, installation and initial qualification of the analyser must only be carried out by a qualified IDS representative.

## 1-4-3 Connections

### Fluidic connections

The fluidic connections are located on the right hand side of the analyser. The tubing is identified by a colour code.

| Description | Colour code | Field |
|---|---|---|
| IDS-iSYS System Liquid | White. | All. |
| IDS-iSYS Wash Solution | Blue. | Immunoassay. |
| Liquid Waste | Red. | All. |
| IDS-iSYS D-Sorb | Black. | All. |

- Connect the tubing corresponding to the colour code to the right hand side of the analyser by applying a quarter turn to the screw.
- Install the tubing into each of the respective containers.
- Connect the volume detection devices for IDS-iSYS Wash, IDS-iSYS D-Sorb Solution and Liquid Waste.

For the Biochemistry or Coagulation analyser configurations, the IDS-iSYS Wash solution is not used. Do not connect any tube to the blue connector.

### Electrical connections

For the Biochemistry analyser configurations, use only the IDS-iSYS System Liquid reference R5H135A.

The electrical connections are located on the left hand side of the analyser.

- Connect the analyser to the PC via the Ethernet cable.
- Connect the mains supply cable.

Depending on the type of analysis, the ids-isys uses the following measurement principles:

- Luminescence measurements carried out in the luminometer (Immunoassay).
- Absorbancy measurements carried out continuously by the spectrophotometer.
- Potentiometry measurements made by the selective electrodes (ISE).
- Optic detection of clot by chronometer.

### 1-5-1 Absorbancy measurements

Samples and reagents are aspirated in accordance with the validated parameters for each assay and are transferred into a cuvette where the changes in absorbancy (or optical density) will be monitored in the course of the reaction taking place.

Photometric measurements are carried out in the reaction cuvette (maximum interval between two consecutive measurements is 25 seconds).

These measurements are carried out at the wavelength specific to the analysis, defined in the parameters, by automatic selection of the appropriate interferential filter.

In monochromatic light and at constant temperature, the relationship between absorbancy (or optical density - OD) and the concentration of the analyte is provided by the BEER-LAMBERT law:

$OD = \varepsilon \, l \, C$ with $OD = \text{Log} \frac{I_0}{I}$

**Where:**

- $I_0$ Light flow at cuvette entrance.
- $I$ Light flow at cuvette exit.
- $\varepsilon$ Molar extinction coefficient of the analyte (in $L.mol^{-1}.cm^{-1}$).
- $l$ Optical pathway (cm).
- $C$ Concentration of analyte ($Mol.L^{-1}$).

Absorbancies are measured with an optical pathway of 0.7 cm and corrected for an optical pathway of 1 cm.

Depending on the type of assay defined in the analytical configuration for each set-up, the following absorbancy measurements are used in the calculations:

- Terminal Point — Uses the last absorbancy and the first absorbancy.
- Delta Terminal Point — Calculation of the difference between the first and the last absorbances.
- Kinetic — Calculation of the slope by linear regression over the absorbancies measured. Calculation of enzymatic activities using the formula:

$$\text{Activity} = \frac{V_T \times \Delta \text{ OD/min} \times 1000}{V_E \times l \times \varepsilon}$$

**Where:**

- $V_T$ = Total volume.
- $V_E$ = Sample volume.
- $l$ = Optical pathway (1 cm).
- $\varepsilon$ = Molar extinction coefficient of analyte (in $L.mol^{-1}.cm^{-1}$).

**Comment:**
In the set-up, the factor entered is equal to ε x 100.
The results are calculated either in relation to a calibration, or multiplied by a factor.
The function used for the calibration is fixed in the analytical configuration. The functions available are:

- Linear regression.
- Linear interpolation.
- Polynomial function degree 2.
- Polynomial function degree 3.
- Polynomial function degree 4.
- Cubic Spline.
-

The calibrations and controls can be programmed on demand or automatically managed in terms of frequency by the analyser.

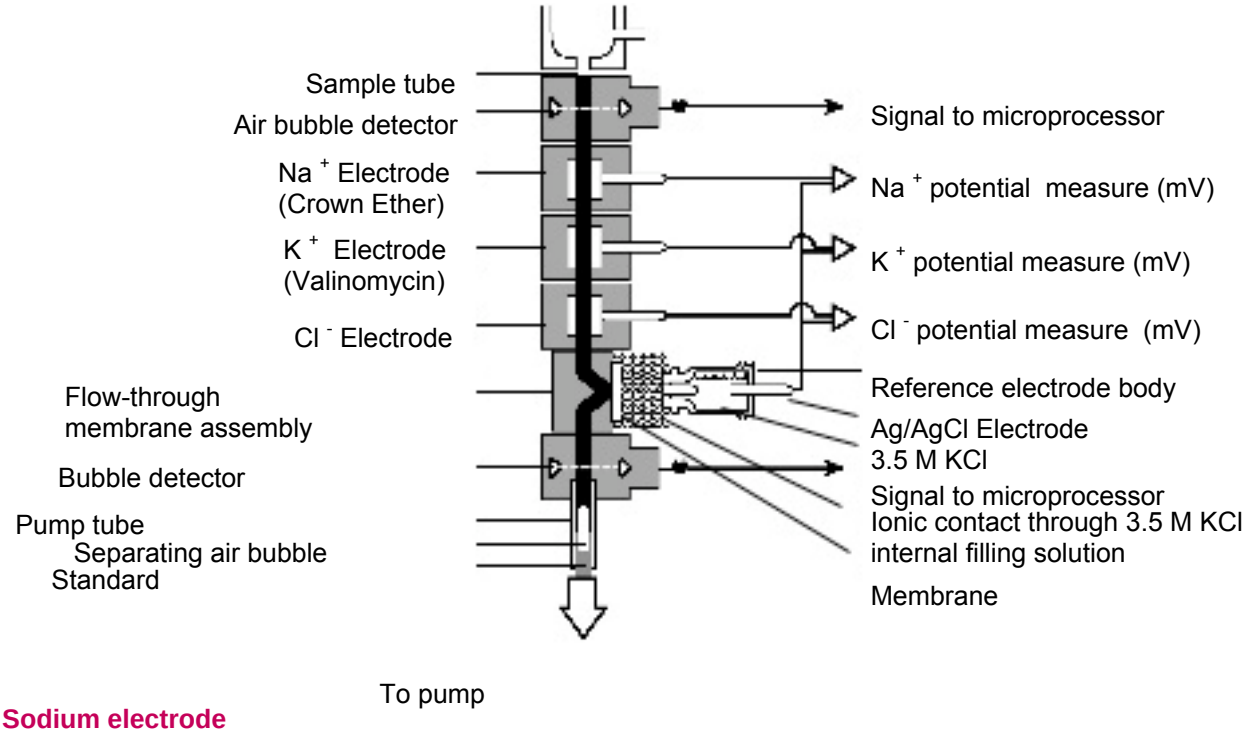
A request for calibration is automatically accompanied by a request to perform QC control.

Requests for calibrations and controls can be made at any time. If the analyser is in the process of carrying out the assay, the calibrations and controls take place prior to the analyses requested on the samples.

### 1-5-2 Potentiometry measurements

The electrolytes in blood are traditionally measured using flame photometry. In this method, the sample, diluted with a known concentration of a reference ion (usually lithium or caesium), is vaporised then passed through a flame which causes excitation of the cations. The energy is re-emitted in the form of a light with a different frequency; with the amplitude of the emission being proportional to the ion concentration in the sample. The development of organic compounds selective to sodium, potassium, chlorides and other electrolytes has led to the development of sensors capable of taking direct measurements in biological fluids.

The module for measuring sodium, potassium and chloride electrolytes in the ids-isys employs selective electrode technology, as shown in the diagram below:




#### Sodium electrode

The fluid circuit from the sodium electrode has a selective PVC tube specially formulated to be specifically permeable to sodium ions.

#### Potassium electrode

The fluid circuit for the potassium electrode has a plastic tube in which valinomycin is incorporated as the selective element.

#### Chloride electrode

The fluid circuit for the chlorides electrode has a plastic tube specially designed to recognise chloride ions.

### 1-5-2 Potentiometry measurements (continued)

The potential of each electrode is measured in comparison with a stable voltage established by the reference electrode Ag/AgCl. A selective electrode develops a voltage which varies according to the concentration of the ion to which it responds. The relationship between the voltage developed and the ionic concentration is logarithmic and is expressed by the NERNST equation:

- $E = E_0 + \frac{RT}{nF} \log(\alpha C)$

**Where:**

- E = Potential of the electrode in the sample.
- $E_0$ = Potential developed under standard conditions.
- RT/NF = Constant dependent on temperature, referred to as "slope".
- log = Decimal logarithm function.
- α = Activity coefficient of the ion measured in the solution.
- C = Concentration of the ion measured in the solution.

A comparison method is used. Firstly, the module measures the potentials developed by the sample passing in front of the electrodes. A measurement is then taken on Calibrator A. The difference between the two potentials is a logarithmic function of the concentration of the ions measured in the sample, divided by their respective concentration in the Calibrator. As the differences of potentials and concentrations in sodium, potassium and chloride ions of the Calibrator are known, the ionic concentrations of the sample can be calculated, using the NERNST equation:

Or $\frac{E - E_0}{S} = \log(C_x / C_S)$

$\frac{(E - E_0)}{S} = C_x = C_S \times 10$

**Where:**

- E = Potential of the electrode in the sample.
- $E_0$ = Potential developed by the electrode in the solution of Calibrator.
- S = Slope of the electrode calculated during calibration.
- $C_x$ = Concentration of the ion in the sample.
- $C_S$ = Concentration of the ion in the solution of Calibrator.

The slope "S" is determined during calibration with the solutions of Calibrators A and B whose concentrations are known. When a calibration is carried out, the slope is calculated from the difference between the second measurement of Calibrator A and the measurement of Calibrator B. An excessive deviation or excessive background noise measurements are indicated with error messages accompanying the printout of the results.

### 1-5-3 Luminescence measurements

By-products of luminescent acridinium esters are used as detection markers (DMAE - dimethylethanolamine). The acridinium esters emit light after reacting with hydrogen peroxide and an alkaline solution. IDS-iSYS Trigger A contains hydrogen peroxide in a dilute acid medium, and IDS-iSYS Trigger B contains a solution of dilute sodium hydroxide. The analyser automatically injects trigger solutions A and B into the reaction cuvette, which results in the oxidation of the ester into an excited form. The return to a stable state is accompanied by the emission of light which is measured and is expressed in relative light units (RLU) by the luminometer integrated in the analyser.

Assays are carried out using either a one-site or two-site method.

#### One-site (competitive) method assay

The assay is based on competition between an unknown quantity of analyte in a sample with labelled analyte in the kit.

In a sample where no analyte is present, maximum binding of the labelled analyte is possible. With the increasing analyte concentrations, decreasing binding of labelled analyte is observed. The signal generated by the labelled analyte in the luminometer is therefore *inversely proportional* to the concentration of analyte in the sample.

#### Two-site (sandwich) method assay

This technique uses two antibodies that detect and bind different portions of the analyte molecule. Incubation of these antibodies with the sample results in the formation of a ‘sandwich’ complex, where the analyte is specifically bound by both antibodies. Incubation with coated magnetic particles allows capture of these complexes. The signal generated by detection of the captured complexes is directly proportional to the concentration of analyte in the sample.

#### Generating the master curve and calculation of results

The results are calculated in comparison to a calibration curve.

The specific reference curve (master curve) for a reagent lot is in the file containing all the data for that lot, that is provided on the CD accompanying the cartridge. This information is registered in the analyser’s database when the CD is introduced on the controlling computer.

If a new reagent lot is used, this curve must be registered on the database and then adjusted by a 2 point calibration before sample results can be calculated.

#### 2 point calibration

Analyser-to-analyser variation and different reagent lots will require adjustment of the master curve (calibration). This is done by assaying two calibrators supplied with the reagent cartridge. The analyser’s software will automatically perform the data processing to generate a new curve by defining new values for two of the four parameters considered to be critical.

In practice, the 4 parameters of the reference curve specific to the reagent cartridge lot are loaded in the user’s analyser via a CD provided with the kit. Calibration of the test must then be requested prior to use. The calibration is performed and then verified by assaying one or more controls. Subsequent calibrations must be repeated regularly in accordance with each assay’s instructions for use or as prompted by the analyser.

The ids-isys is a multiparameter selective analyser for *in vitro* assays in clinical biology.

The analyser must only be used by trained personnel in compliance with the following safety precautions and good laboratory practice (GLP).

## 1-6-1 General precautions

- After start up and installation of reagents, cartridges must be left for a period of time before use. For biochemistry this should be 20 minutes to allow temperature equilibration. For Immunoassay this should be 40 minutes for temperature equilibration and magnetic particle re-suspension.
- Do not lift the lid while the analyser is running (i.e. during the run cycle). Opening the lid during the run cycle interrupts the movements of the pipetting arm. Should this occur, analyses under way may be interrupted and restarted (recycled).
- Do not place bottles of reagent on the surface of the analyser.
- While the analyser is in operation, do not touch the analyser stop/start button.
- Make sure that the reagent and sample racks are clean at all times.
- The database is automatically backed up once a week. Operators should store back-ups from the computer onto CD or USB flash drive.
- Keep documentation of the set-up programmed on the analyser.
- Only Immunoassay and ancillary reagents supplied by IDS and its partners, can be used on the analyser (catalogue available on request).
- To ensure that the cuvette loader functions correctly, only use full cubes of cuvettes. Never install isolated layers in the loader.
- In the event of maintenance or an intervention by IDS Service & Support Personnel, the analyser and its various components must first be cleaned and decontaminated as defined in the Maintenance section (see Section 5, page 84).
- Maintenance operations must be carried out at the frequency stipulated for each type of maintenance activity. As some parts of the analyser are in contact with the biological samples, they must be considered to pose a potential risk of infection.
- Validation of non-IDS biochemistry reagents is the responsibility of the user and IDS takes no responsibility for the validity of results if non-IDS products are used.
- In order to guarantee the thermo-regulation of the carousel, ambient temperature must be lower than 30°C. If necessary, provide air conditioning for the site.

## 1-6-2 Special precautions

The safety precautions specific to certain handling procedures described throughout the user manual are indicated in the format described in the Preface section.

SECTION 2:

# User Interface Software

# Section 2

## User Interface Software 17

# User Interface Software

## 2-1 Structure of the Software

The software provides access to the options and information required to run the analyser.

Various options are available via pull-down menus at the top of the screen.

Access to the software requires a password.  Multiple authorisation levels are managed by the system:

- Operator and Supervisor levels are for laboratory users while all other levels are reserved for IDS Service and Support personnel. Access to items in the menu is dependent on user level.

Passwords and authorisation levels can be modified later if required.

The user interface application software is run on an external PC using Microsoft Windows™ (XP or Vista). The PC is linked to the analyser via an Ethernet cable.

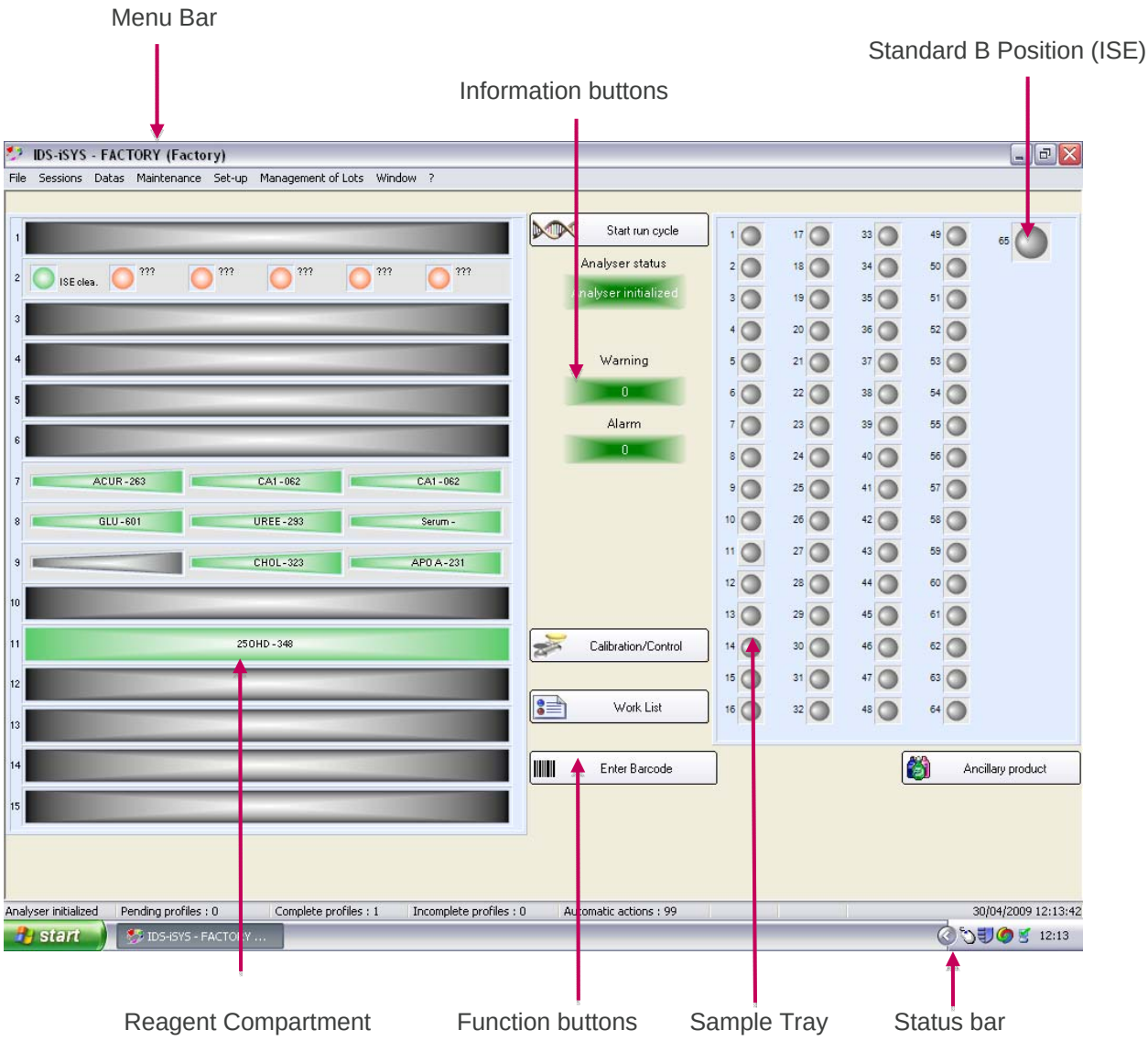
The analyser uses embedded software which interprets instructions from the user interface application software into actions to be performed by the analyser. It also records the data obtained. This data is then sent to the user interface application software for final result calculation and storage.

In the event of any interruption in the connection with the user interface, this software configuration allows the analyser to continue to carry out its workload and store the raw data produced. When the connection is restored, synchronisation will occur automatically without any data loss or interruption to the analytical process.

# User Interface Software

## 2-2 Main Screen

When the application is opened and a valid access code entered, the main screen is displayed.



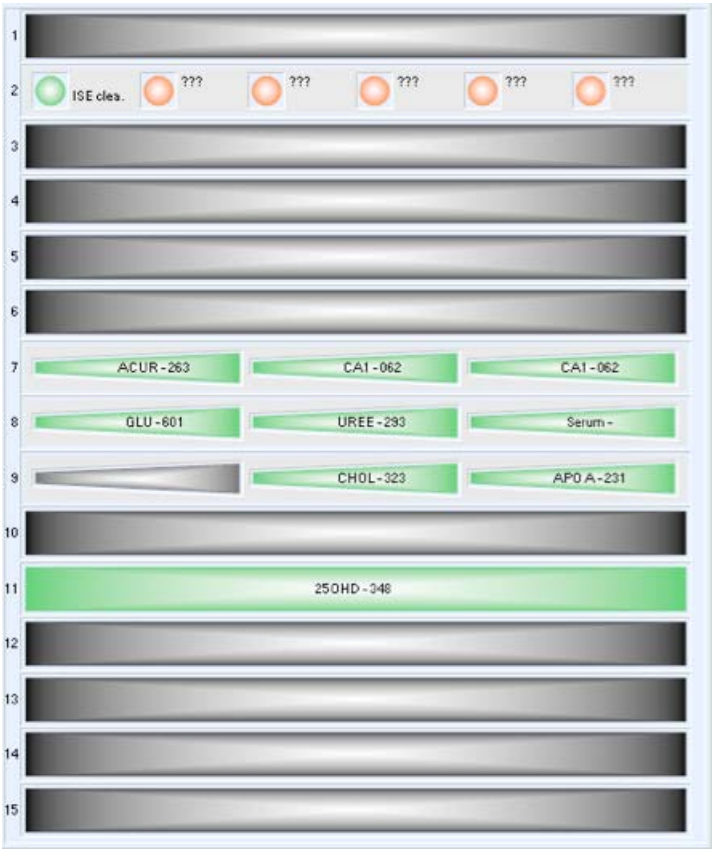

The Standard B position for ISE is present only with 80 positions drawer (diameter 13 mm). With the 64 positions drawer (diameter 16 mm), this position has been removed.

### Menu bar

Provides access to the different pull-down menus.

File Sessions Data Maintenance Set-up Management of Lots Window Help

### Reagent Compartment




The illustration above shows the reagent compartment with reagents on board.

The racks are automatically identified by the integrated barcode reader when the rack is inserted in the rail.

For each occupied position the following information is displayed:

- Test name.
- Lot number.
- Status of the reagent indicated by a colour code (see Section 3, page 38).

Detailed information for each analyte may be accessed by clicking on the cartridge, in the case of Immunology, or individual Biochemistry reagents.

Information includes:

- Test name.
- Reagent type.
- Lot number.
- Container number.
- Type of container.
- Expiry date.
- In-use stability.
- Available volume and number of tests remaining.

### Information Application Buttons


Provides access to information regarding the analyser status including :

- General status of the apparatus (initialised, standing etc.).
- Status of the various modules.
- Allowed/forbidden assays depending on the field.
- Temperatures : reagent compartment, carousel, ambient.
- Status of reagents.
- Status of reagent drawer, samples drawer, lid.

The general status is indicated by a colour code:

- Green = Operational.
- Orange = Caution: one of the elements is outside the optimal operating conditions (for example, temperature).
- Red = Error/fault.
- Yellow = Analyser not initialised (standing).


Provides information covering the workload requested including:

- Missing reagents required to perform queued assays.
- Expired reagents.
- Unavailable tests.
- Tests stopped during the cycle due to calibration failures, Westgard rules violation etc.
- Automatic requests for calibrations and controls generated by the system.

If messages affecting the current workload appear, the button is displayed in orange with the number of warning messages indicated.

If automatic requests have been generated, a flashing  icon will appear.

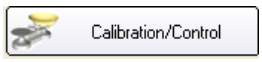

Provides access to the alarms generated by the system:

- Module errors.
- Lack of reagents.

An error message is indicated in the ALARM button which is displayed in red and contains the number of errors identified.

### Function application buttons


Starts the run cycle.




Accesses calibration and quality control requests.
Displays the current calibration for each on-board lot of reagent.


Provides access to the work list and generated results. Contains profiles sent by the Laboratory Information System (LIS). The work list contains the details of the profiles completed or in progress. When the completed profile has been stored, the results are displayed in the work list until the associated sample is removed. The results are automatically stored provided the tests complete without any errors/faults.


Allows manual entry of a barcode identifier for samples or reagents in the event of a misreading by the integrated barcode readers.


Allows access to information regarding the ancillary reagents connected to the system, and the status of the solid and liquid waste.

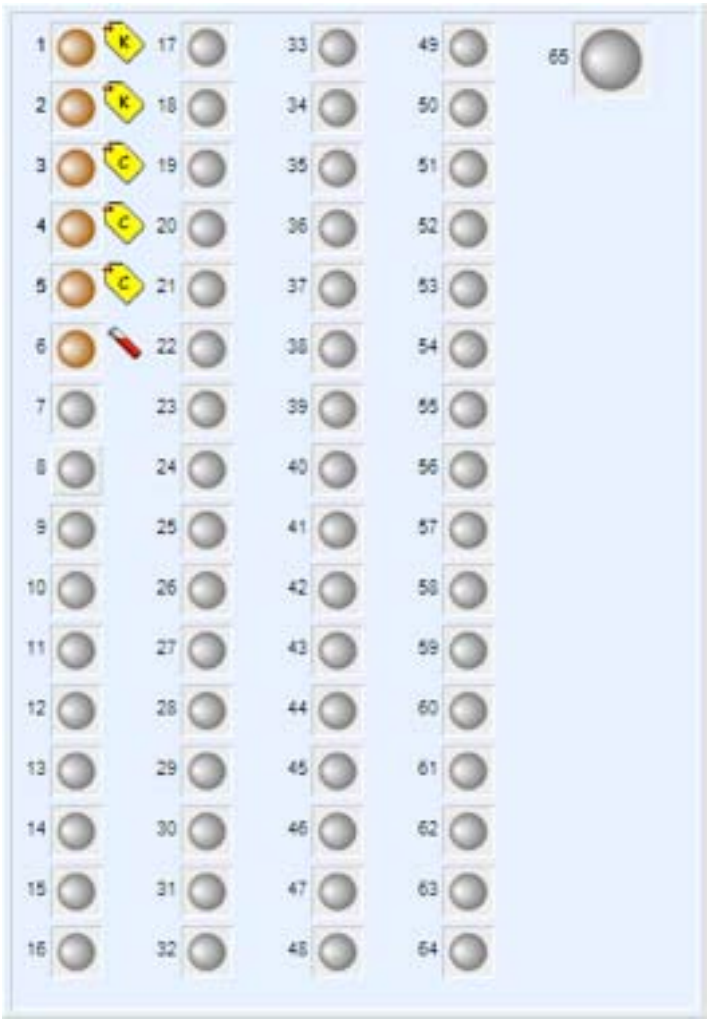
The level of each element is displayed. The following detailed information can be displayed by clicking on the reagent button:

- Identifier and name of the reagent.
- Lot number.
- Number of the container in the lot.
- Type of container.
- Expiry date.
- Status of the reagent.
- Available volume (or number of cuvettes).

This menu allows the user to manually enter a barcode identifier in the event of misreading by the integrated barcode reader.

Clicking on the liquid or solid wastes allows the user to confirm emptying.

### Sample tray




The illustration above shows the samples tray with the positions occupied by:

- Calibrators.
- Controls.
- Samples.

Each position is equipped with a detection sensor. The samples are identified by the barcode reader (on the front face) prior to loading the sample. Alternatively, barcode identifiers can be entered manually after sample loading:

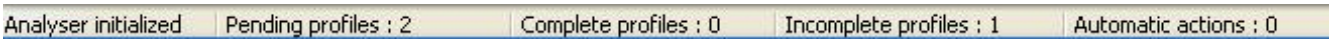
Any position of the sample compartment may be used to load a calibrator, a control or a sample.

An icon identifies the type of reagent installed (see Section 3, page 48).

For each occupied position the following options are available:

- Entry of the identifier and the type of reagent installed (without a barcode).
- Programming of the analyses to be carried out.
- Results display for controls or samples.
- Colour coded analysis status (see Section 3, page 57).

### Status bar

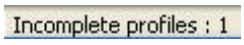



Displays the analyser status, work list and the connection status of the analyser (com flashes blue in normal activity or red when there is a break in communication).

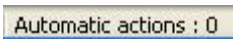

Status of the analyser.


Number of profiles without associated positions. These profiles will never be performed. The profiles will be started only when a position is assigned.


Number of completed profiles in the work list.




Number of incomplete profiles in the work list with at least one assay programmed but not completed.




Number of automatic requests generated by the system. The list can be accessed via the WARNING window.

Other functions are accessed by using the pull-down menus on the interface.


### 2-3-1 FILE menu


Save

Allows the user to save the database, in addition to the automatic save performed each week. The saved database contains:

- Analytical configuration.
- Personal library.
- Calibrations and the quality controls.
- Reagent and ancillaries traceability.
- Stored results.

The database is saved under the format used in the application.

Restore

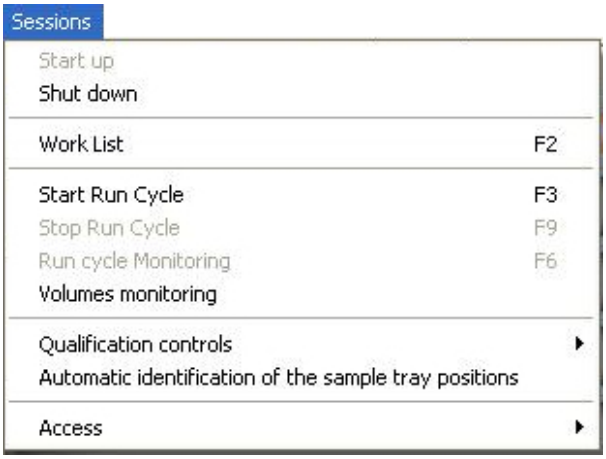
Allows the user to restore all or part of the saved database, as desired, including:

- Analytical configuration.
- Personal library.
- Calibrations and the quality controls.
- Stored results.

Exit

Allows the user to exit the software.

### 2-3-2 SESSIONS menu




**Start up**

Allows the user to start up the analyser. All modules will be initialised and automatically primed. The reading modules are automatically controlled. Once start-up is complete, the option becomes inactive (grey).

**Shut down**

Allows the user to put the analyser into standby mode. In standby mode, the reagents are stored between 8 and 10°C. For an analyser equipped with the selective electrodes module (ISE), the Standard A is periodically refreshed.

**Work List**

Access to the work list: (see Section 3-10-4, page 62).

**Start Run Cycle**

Allows the user to start the run cycle: (see Section 3-8, page 53).
Once the analyser is in assay mode, the option becomes inactive.

**Stop Run Cycle**

This option is active when the analyser is in run cycle.
Allows the user to stop the assay process.

**Run cycle Monitoring**

This option is active when the analyser is in run cycle.
Displays information concerning the tests in process. The software displays the time of processing and when each assay's results will be available.

**Volumes monitoring**

Allows the user to view the available volumes and the number of tests for each on-board reagent, before or during the run cycle.

**Qualification controls**

Programming and processing of tests for the reagent Cartridge Check System (CCS).

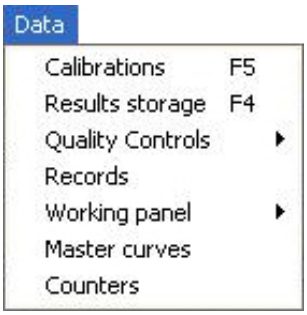
**Automatic identification of the sample tray positions**

Simplifies programming of the work list by applying the same profile to each occupied position.

**Access**

Management of user access: when an access code is entered, a specific session is opened. The user's identifier and the level of authorisation are displayed at the top of the title bar. Access codes and identifiers are programmed in the SETTINGS menu. Keep a record of your access codes. If lost, Operator sessions can be opened by using the code HELP. Each access will be recorded.

### 2-3-3 DATA menu

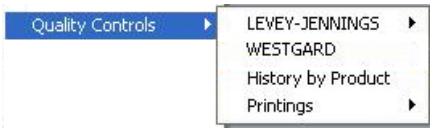



**Calibrations**

Allows access to all the calibrations currently valid for each test in the personal library. Displays the active calibration of a reagent lot for each test of the personal library.

**Results storage**

Allows access to the stored results. When opened, the results are displayed. Various filters can be applied to display results for a single date, between two dates or for the entire storage period.




Analysis of quality controls results.

- LEVEY-JENNINGS: cumulative analysis of the results obtained by test or by a control lot for a programmable period of time.
- WESTGARD: inspection of the control results with selected rules.
- History by product: record of the results obtained for each reagent and for all tests using this reagent.
- Printouts: global printouts of Levey-Jennings data.

**Records**

Records events for:

- System.
- Database.
- Access.
- Analytical.
- Laboratory Information System (LIS) transfers.
- Maintenance.
- Positive identification.

**Working panel**

For use in fail mode: failure to detect samples and reagents.
Allows user to memorise configurations of the reagent compartment, with the positions of each reagent recorded.

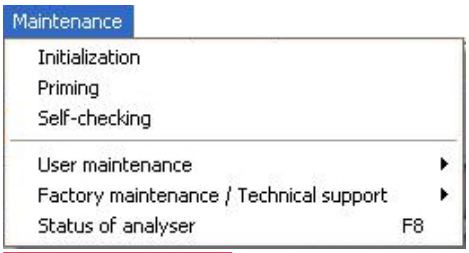
**Master curves**

Displays the master curve data recorded in the system (Immunoassay).

**Counters**

Displays the number of assays (calibrations, controls, samples) performed for each test.

### 2-3-4 MAINTENANCE menu




**Initialization** — Allows selective initialisation of modules.

**Priming** — Allows selective priming of modules.

**Self-checking** — Allows self-checking of measurement modules.

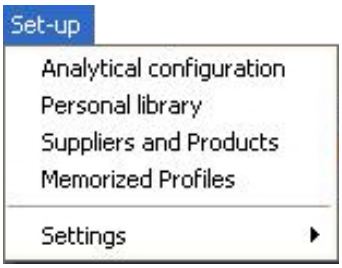

User maintenances:

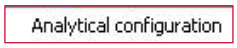
- XY adjustment: adjustment of the positions of the probe.
- Daily maintenance: table of daily maintenance.
- Weekly maintenance: table of weekly maintenance.
- Monthly maintenance: table of monthly maintenance.
- Maintenance history: allows user to display and print the maintenance carried out.

**Factory maintenance / Technical support** — Reserved for IDS Service and Support Personnel.

**Status of analyser** — Displays the analyser status (see Section 2-2, page 21).

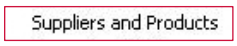
### 2-3-5 SET-UP menu



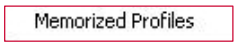




Contains a list of all the tests developed for the analyser.
Selecting one from the list displays the set-up of the test: steps of the assay, calibrators and controls, handling volumes, incubation time, etc.
Some elements can be modified by the Supervisor (such as units or controls), others can only be viewed.


Contains a list of tests that can be run on the analyser.




Allows access to the list of all products and suppliers stored in the system.




Allows the user to create an unlimited number of profiles which can be used for programming.


Allows the operator to personalise the system:

- System: selection of printing options, automatic validation of results, automatic transfers to the LIS; activation of sound alarms; programming of automatic start-up and shut-down.
- Languages: selection of user language.
- Operators: programming of access level and user authorisation (name and access code).

### 2-3-6 MANAGEMENT OF LOTS menu



Displays reagents used on the system:

- Personal library: data storage for different reagent lots for the tests in the personal library for each cartridge the identifier, the lot number, the expiry date and the remaining number of tests can be displayed.
- Preventive alert thresholds: allows programming of the minimum available number of tests for each assay. When this level is reached, a preventive alarm is generated.
- Trace: traceability of calibrations, controls and results obtained with each reagent cartridge.
- On-board volumes: displays volumes and number of tests for all on-board reagents and ancillaries.


Lists calibrators used on the system. Allows users to manually input the values for each lot of calibrator. Allows activation of the calibrator lots used for a specific assay.


Lists controls used on the system. Allows users to enter manually the values of each lot of control. Allows activation of the control lots used for a specific assay.


Displays data for the lots of ancillaries used with the system. For each ancillary, the identifier, the lot number, and the expiry date can be displayed.

### 2-3-7 HELP Menu

Displays information concerning software (for example, specific version).

# User Interface Software

## 2-4 Function Keys

The function keys can be used as a shortcut to access the following options from the main screen.

| | |
|---|---|
| **F2** | Work list. |
| **F3** | Start the run cycle. |
| **F4** | Storage. |
| **F5** | Calibrations. |
| **F6** | Run cycle monitoring. |
| **F8** | Status of analyser. |
| **F9** | Stop run cycle. |

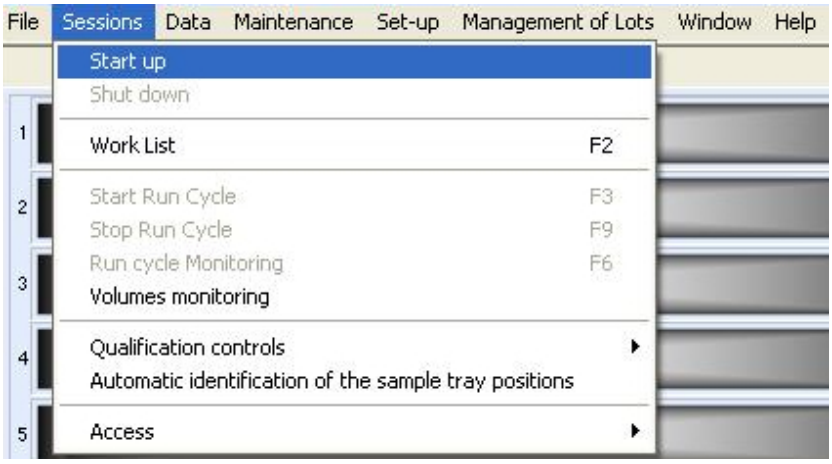
SECTION 3:

# Use

# Section 3

### 3-1-1 Initial Start up

- Switch the analyser on by pressing the switch located on the left-hand side to position “1”.
- Switch the computer on, then open the software by double-clicking on the IDS-iSYS icon.
- Once the software is open, enter your access code to open a session.
- Start the analyser by selecting Start up from the session menu:




All modules are initialised and the ancillary reagents are automatically primed.

If a new version of the software is detected on the analyser after opening, a message about downloading this new version to the analyser will appear.

### 3-1-2 Start up from standby mode

Enter your access code to open a session. The analyser can be programmed to start up automatically at a selected ‘wake-up’ time.

Take care when opening and closing the reagent compartment: rough handling when opening and closing the drawer may cause the internal reagents to spill.

| | |
|---|---|
|  | Access authorised (Drawer unlocked). |
|  | Sampling in progress. Access denied (Drawer locked). |
|  | (Flashing between red and green) Sampling in less than 2 minutes. |

During the run cycle, if a reagent is to be aspirated within 2 minutes, the drawer light flashes red and green.

When opening the reagent compartment during the run cycle, assays which are under way may be stopped if a reagent was scheduled to be added when the compartment was open. In the event of this, the rescheduled assays are automatically added to the end of the work list.

The reagent racks are loaded in the refrigerated compartment.

The reagent cartridges are placed on racks specific to each field.

An Immunoassay reagent rack is designed to hold a cartridge containing all the reagents needed for the test.


Biochemistry reagents are supplied in the form of individual reagent bottles.

Biochemistry reagent racks are designed to contain either 3 x 50 mL bottles or 6 x 20 mL bottles.

**Rack IDS1**
**3 x 50 mL**

**Rack IDS2**
**6 x 20 mL**

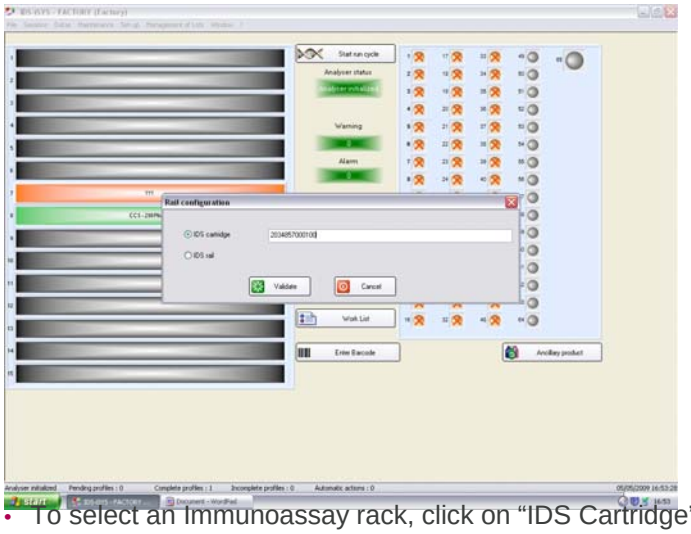
If the reagents have been stored on-board and the analyser has been put into standby mode, the identification of these reagents will be restored upon start up.

Reagent cartridges can also be installed during the run cycle:

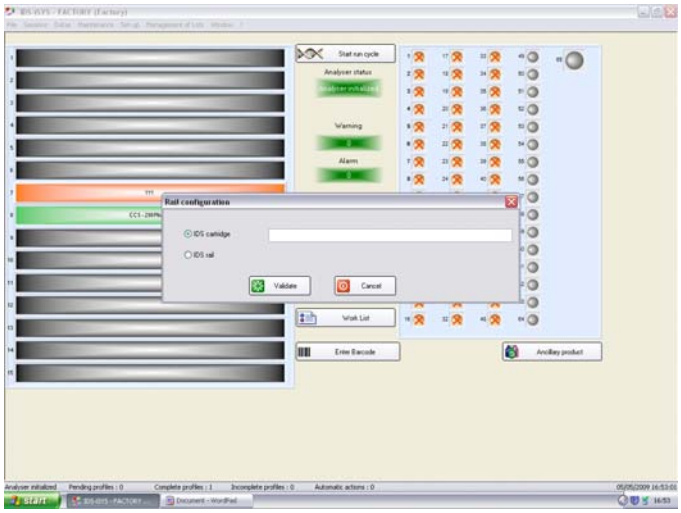
- If access is authorised, open the reagent compartment.
- Slide the reagent rack into a rail in the refrigerated reagent compartment until the positioning pin is fully inserted.
- The reagent cartridges are automatically identified by the barcode reader as the rack is inserted in the rail.
- On the interface, the reagents are identified and displayed in green with the corresponding lot number.
- Repeat for all the racks to be installed on the analyser.

If positive identification has failed, the reagent cartridge position is displayed in orange with "???" instead of the name and lot number.

- Should identification fail, repeat the procedure for putting the reagent rack in position.
- If the position is still not identified, click on the position.
- Select the type of reagent rack installed.



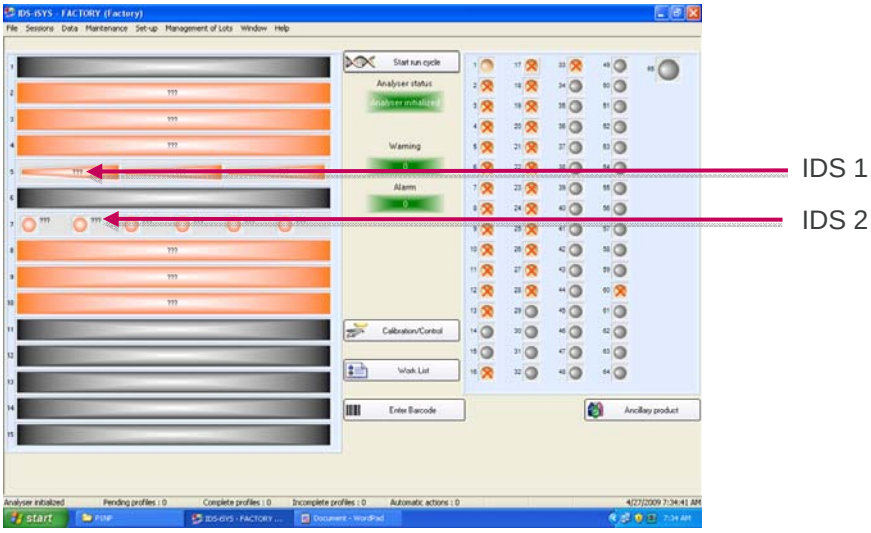

- To select an Immunoassay rack, click on "IDS Cartridge" and use the keyboard to manually enter the barcode identifier for the cartridge.



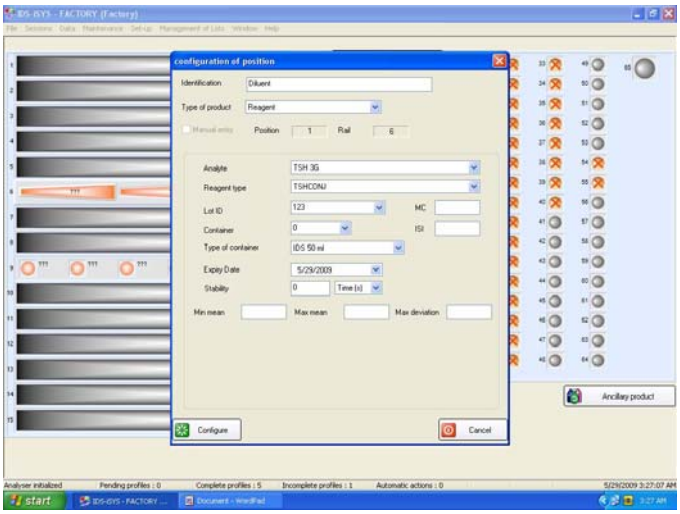

- The information relating to the Immunoassay reagent cartridge (composition, reagent lots, expiry date, master curve) is automatically associated with the barcode reading and the position is displayed in green. This information is also contained in the CD supplied with the kits.
- If this information is not available, the position of the reagent is displayed in white with red stripes.
- In this case, install the CD supplied with the kit and use the keyboard to re-enter the barcode identifier.

To select a Biochemistry rack, click on “IDS Rack”. Then select the type of rack:

- For a 3 x 50 mL rack, click on IDS 1.
- For a 6 x 20 mL rack, click on IDS 2.




- Then click on the position and use the keyboard to enter the barcode identifier for the bottle, and select the reagent installed.



- The information about the bottle (type of reagent, lot, expiry date) is automatically associated with the barcode reading. This information is also contained in the CD supplied with the reagents. If the information is not available, the position of the reagent is displayed in white with red stripes.
- In this case, install the CD supplied with the kit.

Wait for 40 minutes after installing reagent cartridges before starting assays, as the reagent cartridge temperature must be allowed to equilibrate (20 min for Biochemistry).

### 3-2-1 Colour codes associated with reagent positions in the reagent compartment.

| | |
|---|---|
| | Rail free. |
| | Reagent correct. |
| | Presence of a rack or reagent detected but not identified. |
| | A calibration will be requested in the next 24 hours. |
| | Preventive alarm threshold reached. |
| | Reagent volume inadequate or reagent expired. |
| | Information associated with the reagent not available. |

## 3-3 Installation of Ancillary Reagents

On board levels and expiry dates of ancillary reagents are managed by the analyser.

The ancillary reagents comprise:

- IDS-iSYS Cuvettes.
- Internal ancillary reagents.
- External ancillary reagents.
- Click on 

to display the level of ancillary reagents available.

For each solution the current volume is displayed.

The number of IDS-iSYS Cuvettes present in the loader is displayed.

- If an ancillary reagent is displayed as missing or volume is inadequate (colour code red), install a new ancillary reagent.

If the analyser is carrying out an assay, only the IDS-iSYS Cuvettes cube and the IDS-iSYS System Liquid can be replaced. The other ancillary reagents cannot be replaced until the analyser has completed the cycle.

Only use IDS products.

### 3-3-1 Installation of internal ancillary reagents

| Description | Field |
|---|---|
| Standard A | ISE. |
| IDS-iSYS Trigger A | Immunoassay. |
| IDS-iSYS Trigger B | Immunoassay. |

**WARNING:**
**OPENING/CLOSING THE LID**

The lid must be opened for this operation. Always handle the lid carefully during opening and closing and is fully open to ensure it is stable. When the lid is not fully open there is a risk of it falling.

Take care not to knock the lid during any analyser intervention.

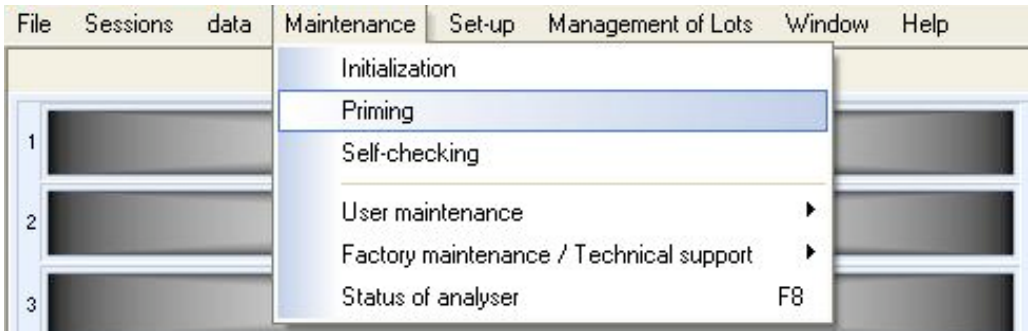
- Open the lid fully.
- Remove the cap from the new ancillary reagent container.
- If necessary, take out the bung and remove the empty container.
- Scan the ancillary with the barcode reader.
- Install the new bottle in its position identified by colour code.
- Install the supply line into the bottle.
- Standard A is automatically primed when newly installed. IDS-iSYS Trigger A and B are not automatically primed, and therefore a manual priming request is required.
- If the barcode is not read by the barcode reader, click on the ancillary reagent then use the keyboard to enter the identifier.
- Close the lid.

Refer to the catalogue for the product references of the ancillary reagents to be ordered.

### 3-3-2 Installation of external ancillary reagents

| Description | Colour code | Field |
|---|---|---|
| IDS-iSYS System Liquid (5 litres) | White. | All. |
| IDS-iSYS Wash (10 litres) | Blue. | Immunoassay. |
| IDS-iSYS D-Sorb (1 litre) | Black. | All. |

- Remove the lid and level sensor from the container to be replaced.
- Scan the new ancillary reagent with the barcode reader.
- Put the level sensor in position within the new ancillary reagent for the IDS-iSYS D-Sorb and IDS-iSYS Wash solutions.
- Priming of the IDS-iSYS System Liquid takes place automatically. For other ancillaries, request partial priming from the menu:




- If the ancillary barcode is not read by the barcode reader, click on the ancillary reagent then use the keyboard to enter the identifier.

Refer to the catalogue for the product references of the ancillary reagents to be ordered.

For Biochemistry, use only the IDS-iSYS System Liquid reference R5H135A.

### 3-3-3 Installation of IDS-iSYS cuvettes

**WARNING:**
**RISK OF INJURY**

Do not place your hand or fingers into the loader.

If necessary, remove the empty IDS-iSYS Cuvettes box.

- Scan the replacement box with the barcode reader.
- Within 10 seconds of the barcode reading, install the IDS-iSYS Cuvettes cube into the loader with the window to the front.
- Remove the protective plastic strip: pull upwards to break the seal and then forwards to remove the protective strip. Place the protective strip over the cube to protect the window from dust.


- If the barcode is not read by the barcode reader, click on the ancillary reagent then use the keyboard to enter the barcode identifier.

Follow the directions for positioning of the cube in the loader.

Do not remove the protective strip before installing the cube in the loader.

Install only full cubes. Never install individual plates. Reassembly of cuvette plates will cause the analyser to jam.

Correct positioning of the cube of cuvettes in the loader is essential for the automatic cuvette loading module to function correctly.

The cuvettes are disposable devices.

Refer to the catalogue for the product references of the ancillary reagents to be ordered.

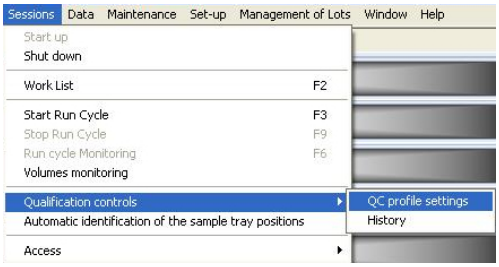
The performance of the analyser must be checked on a daily basis before performing an assay requiring calibration, controls or samples.

To achieve this, a reagent cartridge known as Cartridge Check System (CCS) is used. Different protocols are applied to this cartridge in order to determine the functional state of the various analyser modules.

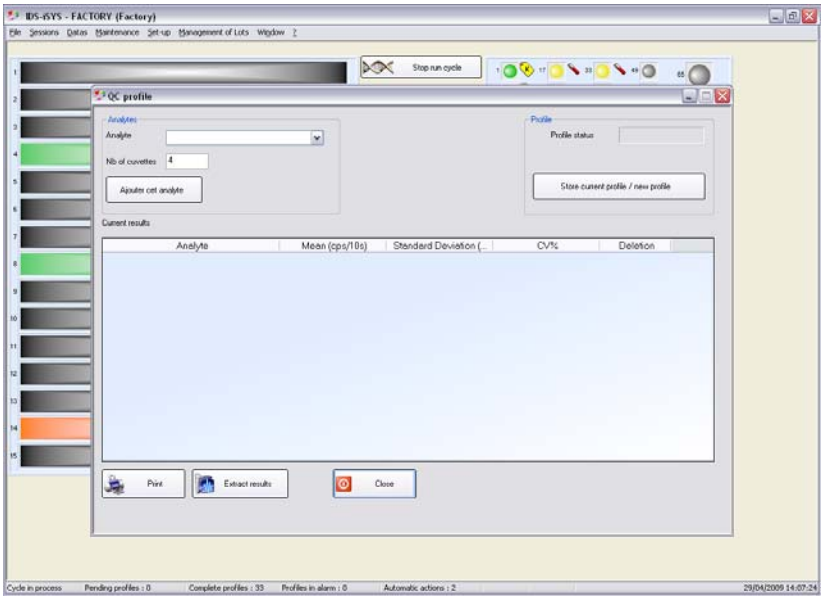
For daily use and acceptance criteria, refer to the CCS cartridge instructions for use (IFU).

## 3-4-1 Programming the qualification profile

- From the main screen, select :




The qualification profile menu is displayed.




- If results from a previous profile are present in the list of current results, click on 

. The results are sent to storage and the list is released for a new profile.
- From the drop-down list, select the necessary test and programme the required number of replicates (see CCS IFU) then click on 

.
- Repeat the operation for each test required.
- Click on 

.
- Start the profile by clicking on 

.

### 3-4-2 Programming the automatic qualification profile

The qualification profile can be programmed as part of the automatic start-up of the analyser. The automatic start-up is programmed in the set-up menu under SYSTEM SETTINGS.

In the SYSTEM SETTINGS window, select the STARTING-UP tab.

- Click on the box 'Activate wake-up'.
- Check the box 'Run a QC profile on wake-up'.
- The fields for programming the qualification profile are displayed.
- From the drop-down list, select the necessary test and programme the required number of replicates (see CCS IFU) and click 

.
- Repeat the operation for each test required.
- Click on 

.

Provided a valid CCS reagent cartridge is present, along with sufficient levels of ancillary reagents, the analyser will automatically perform the relevant priming and QC profile at the scheduled 'wake-up' time.

### 3-4-3 Management of results

- Extract the CCS raw data.
  - In the work list, choose the individual CCS results you wish to export, or select 'All profiles' when prompted. This can be done in either the Standard or Tabular views.
  - Click the 'Extract Results' button.
  - Choose the location where you would like to save your raw CCS data file, name the file and click on 'Save'.
  - This will save your raw CCS data in a text file (.txt).
- Import the data into the EXCEL file provided on the CD.
- Validate the analyser performance using this data as directed by IDS Service and Support Personnel.

Do not perform immunoassays if the analyser performance level is not satisfactory (valid).

Refer to Section 6 of this manual Troubleshooting (see Section 6, page 104).

The frequency of calibrations and controls can be programmed on demand or automatically by the analyser. Each reagent lot has its own calibration, thus allowing multiple reagent lots of the same analyte on board at the same time.

A request for calibration is automatically accompanied by a request to include QCs in the assay (QC1 for Biochemistry) or several QCs depending on the configuration.

QC4 is used only for Immunoassays.

Requests for controls can be made as soon as a validated calibration is stored.

Requests for calibrations and controls can be made regardless of calibration status. During the run cycle the calibrations and the controls take priority over all other tests requested.

From the main screen, click on 

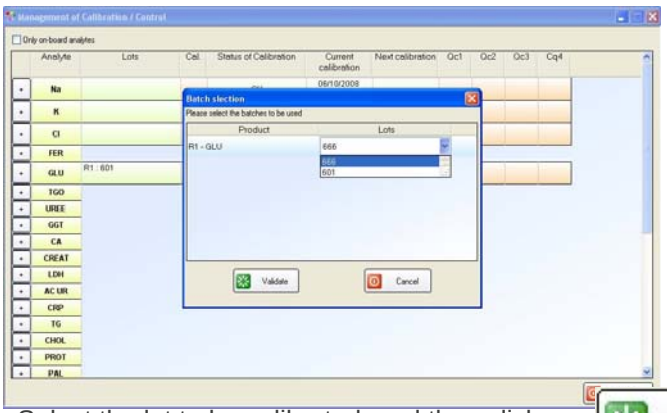
.


## Programming a Calibration of a New Reagent Lot

- Click on 

alongside the assay to be calibrated. A tick is displayed in the calibration column and in the appropriate QC column(s).
- If more than one reagent lot is on-board, when 

is clicked on a new window appears (see below).

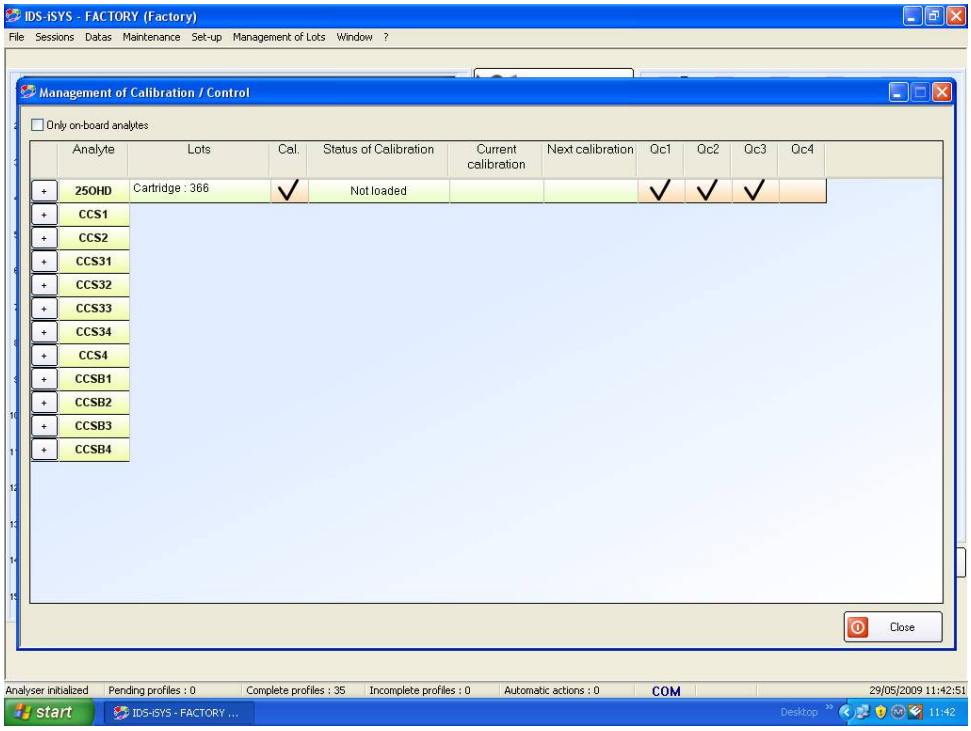



- Select the lot to be calibrated, and then click on 

. A tick is displayed in the calibration column and in the appropriate QC column(s).

### Programming a New Calibration for a Reagent

- The resulting screen (see below) shows a list of all tests in the personal library. It also includes the date and time of the last calibration for the on-board analytes.
- Click on the box in the column Cal in front of the lot to be calibrated. A tick is displayed in the calibration column and in the QC column(s).




Calibrations for several lots of the same reagent can programmed simultaneously.

### Programming Quality Controls for a Reagent Lot

Controls can be performed at any time for the on-board reagent lots provided there is a valid calibration.

- To request a QC1, QC2, QC3 or QC4 quality control, click on the box corresponding to the test to be performed.
- Load the necessary calibrators and controls onto the analyser.

If the value of a calibrator or control is not defined for the active lot, a window automatically opens allowing values to be entered.

The current calibration can be displayed for a reagent lot by double - clicking on the lot number or on the display area (light green area).

Take care when opening and closing the reagent drawer: rough handling when opening and closing the drawer may cause the internal reagents to spill.

| | |
|---|---|
| | Access authorised (Drawer unlocked). |
| | Sampling under way. Access denied (Drawer locked). |

Any position of the sample tray may be used to install samples, calibrators and controls. Each of these have an associated icon shown in the table below:

| | | | |
|---|---|---|---|
| **Calibrator** | | **Sample** | **Serum, Plasma, Other** |
| **Control** | | | **Urine** |

## 3-6-1 Installation using a barcode

- If the light is green, open the drawer.

### Calibrators and controls

- Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
- Within 5 seconds, place in a free position on the rack. If the barcode is recognised, the analyser will beep a second time. On the interface, the display will indicate that the position has been identified. If no second beep is heard, the position is considered to be occupied but not identified. In this case, re-start the barcode reading and installation process.
- If the barcode label is illegible, click on 

- Use the keyboard to enter the barcode identifier.
- Select ‘Vial association with samples tray’ and click ‘OK’.
- Click on ‘Configure’.
- The position is configured.

For the calibrators and controls supplied by IDS, enter the 12 figures from the barcode: the product, the lot number, the expiry date as well as the table of corresponding values are automatically entered.

### Samples

- Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
- Within 5 seconds, place the sample in a free position on the rack. If the barcode is recognised, the analyser will beep a second time. On the interface, the display will indicate that the position has been identified. If no second beep is heard, the position is considered to be occupied but not identified. In this case, re-start the barcode reading and installation process.
- If the barcode label is illegible, click on 

- Use the keyboard to enter the barcode identifier.
- Select ‘Vial association with samples tray’ and click ‘OK’.
- Select the appropriate Sample.
- Click on ‘Configure’.
- The position is configured.
- For tubes from patients whose profile has already been sent through via a centralised computer or manually programmed, the profile in the memory is automatically associated with the position.

### 3-6-2 Installation without barcode

- If the light is green, open the drawer.

**Calibrators and Controls**

- Place the tube(s) or sample cup(s) in a free position on the tray.
- Click on the position which is occupied but not identified.
- The software opens a window which allows the position to be configured.
- Use the keyboard to enter the identifier (1 to 10 alphanumeric characters).
- Select from the following list:
  - Calibrator.
  - Control.
- Select the name from the list.
  - The active lot number is displayed, as well as the corresponding expiry date.
- Select the bottle number and the type of container.
- Click on ‘Configure’.

**Samples**

- Place the sample in a free position on the tray.
- Click on the position which is occupied but not identified.
- The software opens a window which allows the position to be configured.
- Use the keyboard to enter the identifier (1 to 10 alphanumeric characters).
- Select “type of product” as Sample and click on ‘Configure’.
  - For samples whose profiles have already been programmed or sent through via a centralised computer, the profile in the memory is automatically associated with the sample position.

- If the profile is not in the memory, the profile programming window opens (see Section 3-7, page 52).
- When all the samples have been installed, close the drawer.
- If the analyser is in the run cycle, the drawer locks automatically and any new assays waiting to be carried out are added to the analyser’s workload.
- If the analyser is initialised but not in the run cycle, the drawer remains unlocked and the assays will be carried out as soon as the run cycle is started.

When the sample drawer is opened during the run cycle, new tests will be delayed.

The reagents will continue to be aspirated for the tests which are already running.

Once the drawer is closed, the analyser can resume the sample workload, including the new tests.

When using the 64 position sample tray, sample cups and paediatric tubes must be placed in the tube adapters provided with the system to guarantee the quality of sampling.

Take care when opening and closing the reagent drawer: rough handling when opening and closing the drawer may cause the internal reagents to spill.

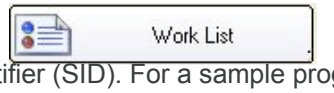
### 3-6-3 Colour codes associated with sample positions

| | |
|---|---|
|  | Position free. |
|  | Position occupied but not identified. |
|  | Position of sample identified without associated profile. |
|  | Position occupied by a serum or plasma sample, profile associated. |
|  | Position occupied by a urine, profile associated. |
|  | Position occupied by a calibrator, calibration programmed. |
|  | Position occupied by a control, calibration programmed. |
|  | Position occupied by a calibrator, no associated request. |
|  | Position occupied by a control, no associated request. |

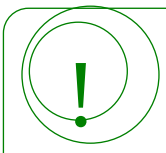
If the analyser is not connected to a centralised computer system, the profiles to be carried out must be programmed manually.

The samples are programmed either directly from their position on the sample tray or from the work list. In the latter case, the samples are programmed without an associated position.

- Click on the occupied position or click on 

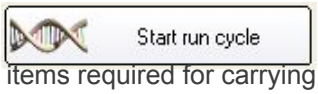
in 

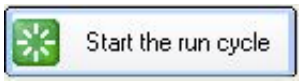
- For a sample programmed from the work list, enter the identifier (SID). For a sample programmed on the sample tray, the identifier is displayed.
- Select the container: PT (primary tube), cup, ST (secondary tube) etc.
- Select the type of sample: serum, urine, other.
- Enter the full name (optional field).
- Select the analyte(s) required by checking the box in front of the desired analyte.
- When an analyte is selected, a black tick is displayed.
- If an analyte has been selected by mistake, uncheck the box to deselect the analyte.
- Proceed in the same way with all analyses to be carried out.
- When the profile has been programmed in full, click on 

If the patient profile is programmed during the run cycle, the sample status will immediately be displayed as loaded.

Do not open the analyser lid during the run cycle, as this will cause the moving parts to stop immediately for safety purposes and all assays underway will be lost.

- Click on 

.
- If all the items required for carrying out the programmed workload are available, the analyser initialises and begins aspirating samples.
- If any of the items required to carry out the programmed workload are missing, a window is opened which lists them all.
- Install the missing items then click on 

.The analyser will begin aspirating samples.

The run cycle will start even if some items are missing.

The analyser will then carry out all the assays for which all required items are available.

The missing items can be installed at any time during the assay by following the procedures described below.

### 3-8-1 Performing assays

Assays are carried out in the following order:

- Calibrations.
- Controls.
- Emergency (STAT) samples.
- Samples.

Samples are tested in the order of the sample tray positions.

During a run cycle, a test may be terminated by the analyser as a result of certain faults, details of which can be viewed by clicking the ‘Warning’ messages button. Faults may include:

- Calibration fails to comply with the criteria for automatic validation.
- The result of the control violates one of the Westgard rules (if activated).
- One of the reagents or a diluent required for the test has been detected as missing.
- One of the reagents or a diluent is empty.

When issues preventing test completion have been resolved, the test will be automatically restarted.

### 3-8-2 Adding samples during an assay

- If the analyser is not connected to a centralised computer system, programme the profile(s) to be performed on the samples.
- If the light is green, open the drawer.
- Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
- Within 5 seconds, place the sample in a free position on the rack. If the sample is recognised, the analyser will beep a second time. On the interface, the display will indicate that the position has been identified. If no second beep is heard, the position is considered to be occupied but not identified. In this case, re-start the barcode reading and installation process.
- If the barcode label is illegible, click on 

- Use the keyboard to enter the barcode identifier.
- Select 'Vial association with samples tray' and click 'OK'.
- Select the appropriate identifier (Sample/Calibrator/Control).
- Click on 'Configure'.
- The position is now configured.
- Proceed in the same way for other samples to be added.
- Close the drawer.
- The analyser will resume sample aspiration once the drawer is locked.

### 3-8-3 Adding or replacing a reagent during an assay

- If the light is green, open the drawer.
- When replacing a reagent, remove the rack containing the reagent to be replaced.
- Slide the rack containing an Immunoassay reagent cartridge or a Biochemistry cartridge into a rail in the refrigerated compartment until the positioning pin is inserted.
- The reagents are automatically identified by the barcode reader as the rack is inserted in the rail.
- On the interface, identified reagents are displayed in green with the corresponding lot number.
- If the reagent barcode is not read, identify the reagent manually by using the keyboard (see Section 3-2, page 36).
- Repeat for all racks installed on the analyser, then close the drawer.
- The analyser will resume processing samples.

When the reagent compartment is opened, assays which are under way may be cancelled if reagent aspiration was scheduled. In this case, the assays are automatically rescheduled.

To optimise analyser function, do not leave the reagent compartment open any longer than necessary.

Do not remove reagent cartridges during the run cycle if in use.

It is essential for Immunoassay reagent cartridges to remain on the analyser until all the results are obtained.

### 3-8-4 Releasing an alarm during an assay

On the interface, a problem during an assay is indicated by a change in colour of the ALARM button from green to red. The number of alarms is indicated in the ALARM button.

Some faults do not interrupt the run cycle (for example, lack of reagent or sample) and may be resolved in the course of the run cycle.

Other faults will terminate assays (for example, lack of IDS-iSYS System Liquid, fault in a module, etc.). If a module is faulty, the analyser will carry out the assays which do not use this module.

- Click on the ALARM button.
- The software opens the faults window and indicates the fault which has occurred.
- In the case of a lack of ancillaries (for example, IDS-iSYS Cuvettes or IDS-iSYS System Liquid) installing the new ancillary and ensuring its barcode identifier is read by the barcode reader will automatically release the fault.
- If the fault involves one of the internal ancillary reagents or the IDS-iSYS Wash solution, the run cycle must be stopped before the fault can be resolved.
- For other faults, select the fault then click on 

.
- If the fault cannot be resolved during the assay, the software displays a message.
- Release this message, then either wait for the end of the current workload or request all assays to be stopped.

## 3-9 Adding an Emergency (STAT) Sample

Emergency (STAT) samples can be programmed for all the sample tray positions.

If the profiles are sent through by a centralised computer system, the category of ‘STAT’ is already associated with the profile.

The priority of any sample can be raised to ‘STAT’ as long as it has not already been incorporated into the analyser workflow (brown colour code). Otherwise, the profile must be programmed before the sample is installed on the tray.

Click on 

then click on 

.

- Enter the identifier (SID).
- Select the container: PT (primary tube), cup, ST (secondary tube).
- Select the type of sample: serum, urine, other.
- Click in front of ‘STAT’.
- Enter the full name (optional field).
- Then select the assays to be carried out by clicking in front of the desired analyte.
- When an assay is selected, a black tick is displayed.
- When all the analyses to be carried out have been selected, click on 

- If the light is green, open the drawer.
- Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
- Within 5 seconds, place the sample in a free position on the rack. If the sample is recognised, the analyser will beep a second time. On the interface, the display will indicate that the position has been identified. If no second beep is heard, the position is considered to be occupied but not identified. In this case, re-start the barcode reading and installation process.

- If the barcode label is illegible, click on 

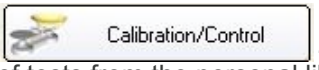
- Use the keyboard to enter the barcode identifier.
- Select ‘Vial association with samples tray’ and click ‘OK’.
- Select the appropriate Sample, Calibrator or Control.
- Click on ‘Configure’.
- The position is configured.
- Close the drawer again.
- The analyser starts initiating tests again once the drawer is locked and deals with the ‘STAT’ sample immediately after completion of calibrator control assays.

As the run cycle progresses, the status of the sample tray position changes when all the tests associated with this position have been completed.

The colour code associated with the output of results is as follows:

| | |
|---|---|
|  | Calibrators / Controls / Samples: assays in process. |
|  | Calibrator: all calibrations are correct.<br>Control: all results are within the limits defined.<br>Samples: results calculated without any message. |
|  | Calibrators: Calibrations are completed but one of the parameters is not within the criteria set for automatic validation.<br>Controls: all results are calculated but at least one of the results is outside the limits defined.<br>Samples: all results are calculated but at least one of the results has an attention message. |
|  | Calibrators / Controls / Samples: a lack of reagent/sample or another fault prevents the requested assays being carried out in full. |
|  | Only when assays are stopped.<br>Calibrators / Controls / Samples: incomplete processing of another workload. The assays programmed for this position were not completed due to a problem encountered before the end of the assays. |
|  | Samples: the results are stored in accordance with the criteria defined for automatic filing and transferred to a centralised computer system (if the connection is activated). |
|  | Only when the connection with a centralised computer system is activated.<br>Samples: the profile is completed but the results have not been sent/received by a centralised computer system. |

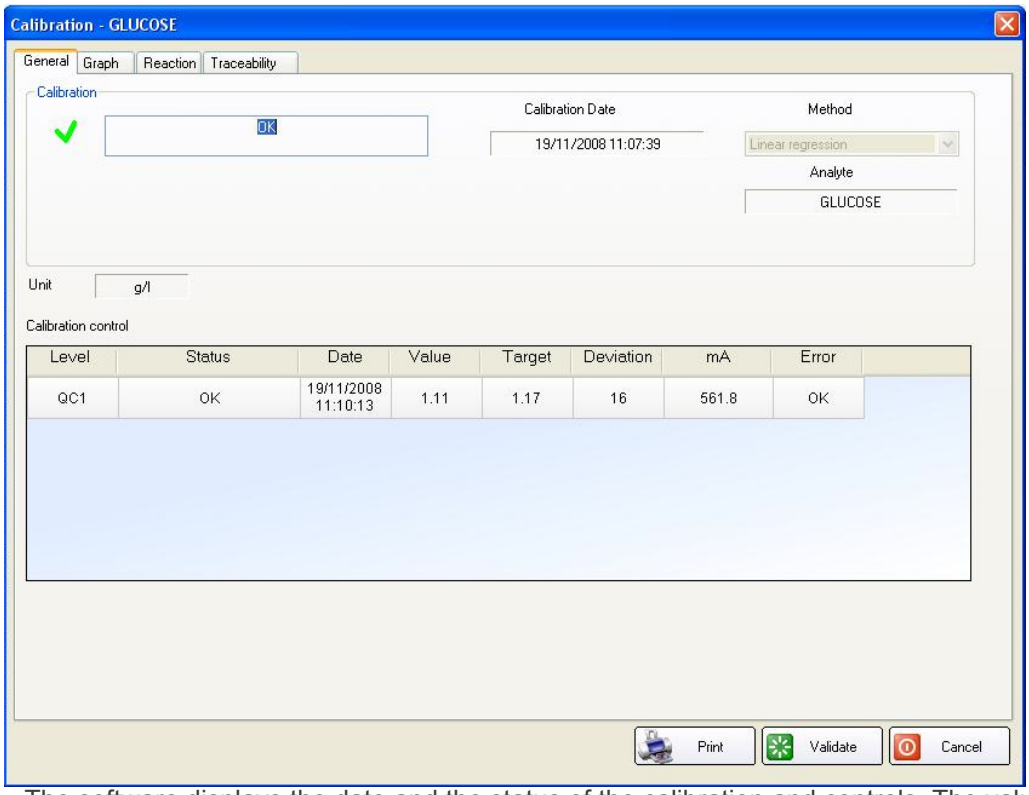
### 3-10-1 Result of a calibration

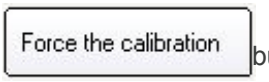
- Click on 

.
- The list of tests from the personal library is displayed with the status of the last calibration performed for each reagent lot on-board:

| | |
|---|---|
|  | Calibration validated. |
|  | Calibration not validated. |
|  | Calibration correct with control(s) out-of-range. |

- To display the calibration curve for a test, double-click on the reagent lot number.




- The software displays the date and the status of the calibration and controls. The value calculated for each control associated with the calibration (QC1 for Biochemistry; QC1 to QC4 for Immunoassay), is also given.
- If the calibration is validated, the message **OK** is displayed.
- In the event of an invalid calibration, a message is displayed at the top of the screen indicating the cause (see Section 4-1, page 75).
- When it is not possible to automatically validate a calibration, the 

button is displayed.

### 3-10-1 Result of a calibration (continued)

The following tabs display the detailed information relating to the calibration:

| | |
|---|---|
| General | The general tab shows whether a calibration has passed or not, type of curve fit used, analyte it refers to and date of calibration. It also displays data for the controls including target values, mean obtained values, CV% and status (i.e. pass/fail). |
| Graph | Displays the calibration curve and each calibrator:<br>• Raw data obtained.<br>• Target value.<br>• Value calculated using the mathematic model of the calibration.<br>• Calibrator lot.<br>Displays value of coefficient of determination (r2).<br>Allows calculation of multiple-point calibrations after removing a calibrator. |
| Reaction | Displays the RLU values for Immunoassay or reaction kinetics for Biochemistry, for each of the calibrators or controls. |
| Traceability | Displays traceability data for the modules and ancillary reagents used for each replicate of the calibrators and controls. |

**Criteria For Validating a Calibration**

- Calculated percentage of translation is lower than the programmed limit (Immunoassay).
- Percentage of the deviation on calibrator signal (RLU) is within acceptable limits provided by IDS (Immunoassay).
- CV calculated with the RLU of each calibrator is lower than the acceptable limit (Immunoassay).
- ODs of the blank and the reaction are within the programmed limits (Biochemistry).
- Slope is within the programmed limits (ISE).
- Sensitivity is higher than the programmed limit (Biochemistry).
- Coefficient of determination of the function calculated is higher than the programmed limit.
- Function corresponds to configured rules.
- Percentage transfer calculated is lower than that programmed (Immunoassay).
- Control(s) is (are) within acceptable limits.

### 3-10-1 Result of a calibration (continued)

**Invalid Calibration:**

- If the calibration is invalid, a message is displayed at the top of the screen indicating the cause (see Section 4-1, page 75).
- If the calibration cannot be automatically validated, the Force the calibration button is displayed.
- A calibration can be forced under the operator's responsibility with or without modifications of the data used for the calculation. The software allows for the exclusion of a calibrator from the calculation (Biochemistry only) or for the exclusion of a replicate (Immunoassay only).
- To exclude a calibrator, click on Reaction to display calibration.
- Then click on the corresponding red tick.
- The calibration and the control(s) are calculated with the new curve equation.
- When points have been excluded, the icon is displayed with the calibration date.
- Click on Validate to save the modification.
- For Immunoassay, individual outlying calibrator or control replicates can be excluded when the CV is above the acceptable limit. Click on Reaction to display the RLU measurements.
- To exclude one of the RLU measurements, click on the corresponding red tick.
- The calibration and the control(s) are calculated with the new curve equation.
- When points have been excluded, the icon s displayed with the calibration date.
- When the recalculated calibration is valid, wi control(s) within acceptable limits, the message OK is displayed.
- Click on Validate to save the modification.
- If the calibration is not validated, the Force the calibration button is displayed.
- An invalid calibration can be forced **under the operator's responsibility.**

  In this case, click on the Force the calibration button. The control(s) is (are) calculated, the assays which are already completed are calculated and those on standby are resumed.
- Any forcing of a calibration is recorded in the journal of events and all the results calculated with this calibration are identified by the message **FOR.**
- If a calibration is not validated, request a new calibration after having replaced failed calibrator/control.

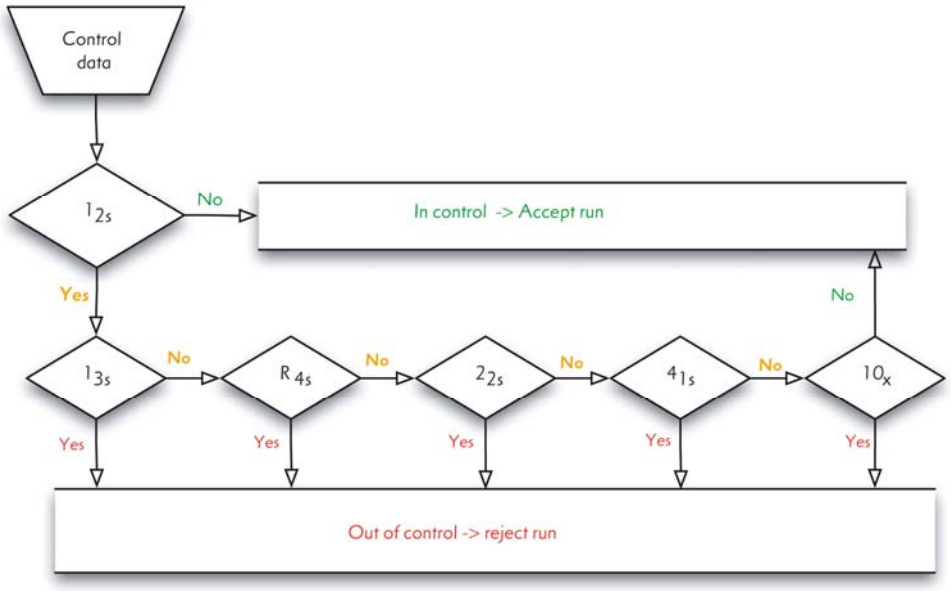
> ! If the reason for validation failure has been clearly identified and deemed to have no impact on results, the calibration may be forced at the discretion of the operator.

### 3-10-2 Results of controls

- Click on the position occupied by the control.
- The results obtained for this control are displayed along with the programmed limits of acceptance.
- A result outside the limits is displayed in red.
- The results of the controls are automatically stored and recorded in Levey-Jennings charts and inspected using the Westgard rules, if selected.
- The results of the control can be printed out from its position.
- If a control is outside the acceptable limits, the status of the calibration is displayed as **Invalid.**
- In this case, request a new calibration.

#### Westgard Rules Inspection

- If WESTGARD rules are selected for the test, the rules defined in the analytical configuration will be tested in the following order:




The violation of certain rules will generate automatic requests. In this event, the  icon flashes in the WARNING button.

- The violation of 2 2S, 4 1S, 10 X rules will automatically generate a request of calibration.
- Click on the WARNING button to open the window.
- Click on Yes to request the calibration and the controls. If necessary, install the required calibrators and controls on the analyser.
- To cancel the calibration request, click on No. This action will be detailed in the Records.
- Then release to restart the test.
- All the results are identified by the message **W!.**
- If another rule is violated, the test is stopped.
- Perform the necessary actions to correct the problem and request a calibration or a single control.
- Each time a violation occurs, a message displayed in the WARNING window allows the release of the violation, whatever rule is violated.

- To release a test, click No. This action will be detailed in the Records. All the results are identified by the message **W!.**

### 3-10-3 Sample results

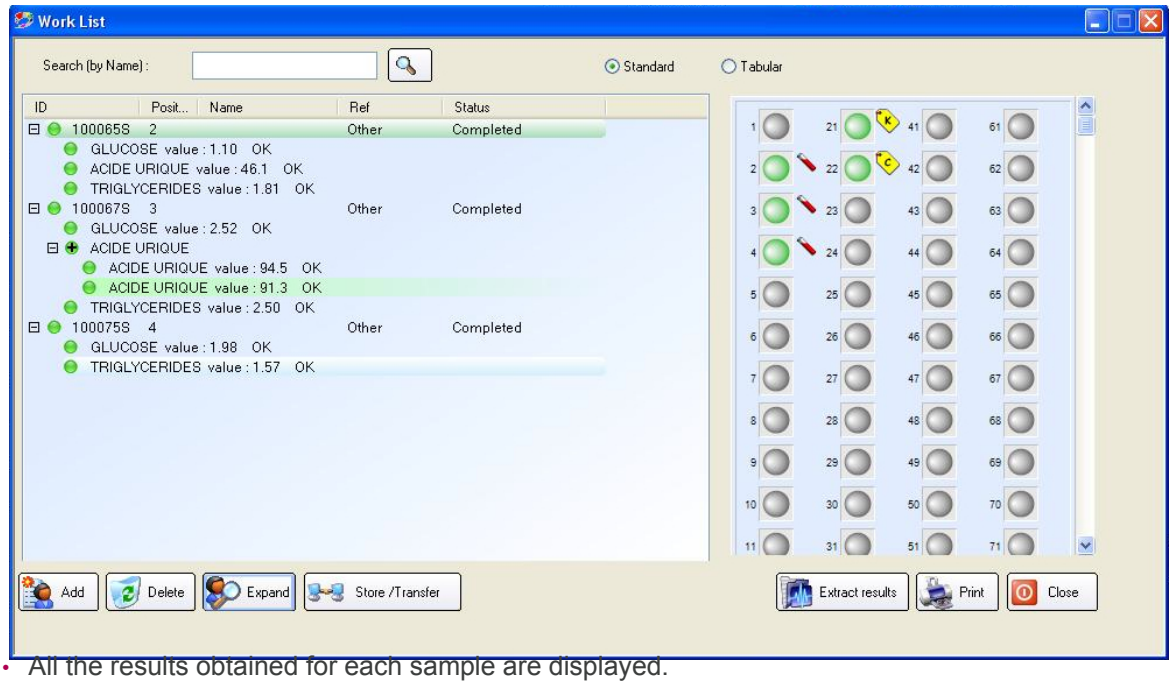
- Click on the position occupied by the sample.
- The results obtained are displayed with any associated messages.
- In the case of multiple replicates, the last result is displayed on a yellow background.
- Double-click on the result to view the results for all replicates.
- To confirm a result, an analysis can be repeated. To do this, check the box in front of the analyte to be repeated.
- The results can be printed out.

### 3-10-4 Work list results

- Click on 

then click 

.



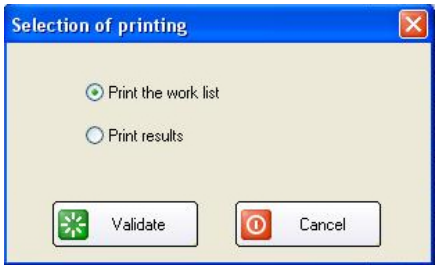

- All the results obtained for each sample are displayed.
- To display the measurements conducted in relation to an analysis, double-click on the result.

- To repeat a test, select the result and click on 

### 3-10-4 Work list results (continued)

- To print out the results, click on 

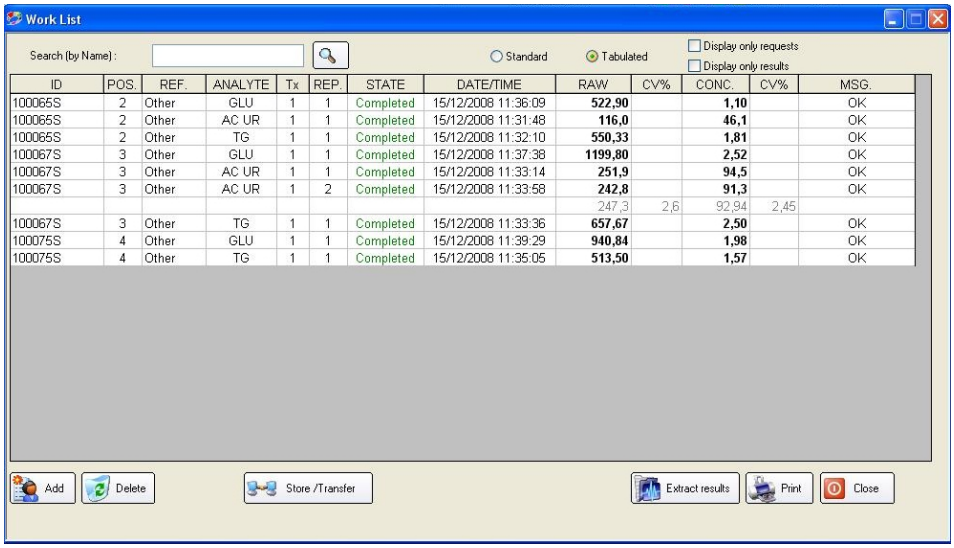
.




- Select “Print results” and click on 

.
- The results of the work list can be displayed in tabular mode.
- At the top of the screen, select 

.




| ID | POS. | REF. | ANALYTE | Tx | REP. | STATE | DATE/TIME | RAW | CV% | CONC. | CV% | MSG. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 100065S | 2 | Other | GLU | 1 | 1 | Completed | 15/12/2008 11:36:09 | **522,90** | | **1,10** | | OK |
| 100065S | 2 | Other | AC UR | 1 | 1 | Completed | 15/12/2008 11:31:48 | **116,0** | | **46,1** | | OK |
| 100065S | 2 | Other | TG | 1 | 1 | Completed | 15/12/2008 11:32:10 | **550,33** | | **1,81** | | OK |
| 100067S | 3 | Other | GLU | 1 | 1 | Completed | 15/12/2008 11:37:38 | **1199,80** | | **2,52** | | OK |
| 100067S | 3 | Other | AC UR | 1 | 1 | Completed | 15/12/2008 11:33:14 | **251,9** | | **94,5** | | OK |
| 100067S | 3 | Other | AC UR | 1 | 2 | Completed | 15/12/2008 11:33:58 | **242,8** | | **91,3** | | OK |
| | | | | | | | | 247,3 | 2,6 | 92,94 | 2,45 | |
| 100067S | 3 | Other | TG | 1 | 1 | Completed | 15/12/2008 11:33:36 | **657,67** | | **2,50** | | OK |
| 100075S | 4 | Other | GLU | 1 | 1 | Completed | 15/12/2008 11:39:29 | **940,84** | | **1,98** | | OK |
| 100075S | 4 | Other | TG | 1 | 1 | Completed | 15/12/2008 11:35:05 | **513,50** | | **1,57** | | OK |

- For each result, the display provides the raw RLU measurement ( RAW column) and the calculated result ( CONC. column). For assays performed in replicates ( REP. column), the mean of the measurements and of the results are displayed in grey; the corresponding CV is displayed in the CV% column.
- Click on 

to print the table.

## 3-11 Messages Associated with Results

The results generated for samples are accompanied by a message (displayed in the column “MSG”) associated with a colour code.

If a result does not have a message attached, OK is displayed and the result is associated with a green colour code.

If one of the messages listed below accompanies a result, an orange colour code is associated with the result (displayed in “STATE” column).

The colour code is also passed on to patient level:

- Green = No message accompanies the results.
- Orange = At least one result has a message.

| Message | Meaning |
|---|---|
| **AIRA** | Biochemistry – Selective electrodes<br>Air detected during the measurement of Calibrator A. |
| **AIRS** | Biochemistry – Selective electrodes<br>Air detected during the measurement of the sample. |
| **RDS** | Immunoassay<br>Problem with agitation of magnetic particles on the reagent rack. |
| **BLR** | Biochemistry<br>Absorbance of blank outside the limits defined in the analytical configuration. |
| **NOIS** | Biochemistry – Selective electrodes<br>Electrical noise interfering with the measurement. |
| **KIN!** | Biochemistry<br>The absorbances measured while monitoring the reaction are not strictly increasing or decreasing (non-monotony of the reaction). |
| **CDE** | Biochemistry<br>Slope of the kinetics has been calculated on a non-linear section of the reaction (for KINETIC type of assay).<br>The coefficient of determination is lower than the limit value defined in the analytical configuration. |
| **IDB** | Biochemistry – Selective electrodes<br>Error on one of the bubble detectors. |
| **DRIF** | Biochemistry – Selective electrodes<br>Deviation relating to the measurement of Calibrator A. |

| Message | Meaning |
|---|---|
| **ASU** | Biochemistry<br>An absorbance is outside the limits of reaction defined in the analytical configuration. The sample will be automatically diluted.<br>If the ASU message accompanies the message “RED”, one of the absorbances is still outside the limits of reaction defined after dilution.<br>**In this case, the sample must be re-diluted to a level higher than that programmed in the analytical configuration, then tested again.** |
| **CE** | All fields<br>Error when calculating a parameter calculated. |
| **EDE!** | All fields<br>The calibration used for calculating the result was obtained with at least one calibrator excluded. |
| **FOR** | All fields<br>The calibration used for calculating the result was forced. |
| **OMR** | All fields<br>It has not been possible to calculate the result because the calibration is not valid. |
| **OMR-** | All fields<br>The result calculated is below the lower limit of the field of measurement. |
| **OMR+** | All fields<br>The result calculated is above the upper limit of the field of measurement. The sample will be automatically diluted.<br>If the message OMR+ accompanies the message “RED”, the result is still higher than the upper limit of the field of measurement after dilution.<br>**In this case, the sample must be re-diluted to a level higher than that programmed in the analytical configuration, then tested again.** |
| **MA** | All fields<br>The assay is no longer being requested by analyser. |
| **MES** | All fields<br>Error when recovering the measurements. |
| **MRE!** | Immunoassay<br>The calibration used for calculating the result was obtained with at least one relative light unit (RLU) measurement excluded. |
| **LOW** | All fields<br>Result lower than the lower normal value. |

| Message | Meaning |
|---|---|
| **HIGH** | All fields<br>Result higher than the higher normal value. |
| **ORA-** | Immunoassay<br>The result cannot be calculated as the measurement is lower than the scope of the measurements defined by the master curve. |
| **ORA+** | Immunoassay<br>The result cannot be calculated as the measurement is higher than the scope of the measurements defined by the master curve. |
| **RDE!** | Immunoassay<br>The calibration used for calculating the result was obtained with one of the replicates for calibrator excluded. |
| **RED** | All fields<br>The result was calculated after a dilution. The value given takes into account the dilution factor. |
| **LS** | Biochemistry<br>The result was calculated from absorbances measured with an unstable lamp. |
| **PMS** | Immunoassay<br>Problem with luminometer stability. |
| **SUB** | Biochemistry<br>Detection of enzymatic hyperactivity. The change in absorbance per minute (ΔA/min) calculated between the injection of the sample and the first measurement used in the calculation exceeds the programmed limit. The sample will be automatically diluted.<br>If the SUB message accompanies the message “RED”, enzymatic hyperactivity is still detected after dilution.<br>**In this case, the sample must be re-diluted to a level higher than that programmed in the analytical configuration, then tested again.** |
| **CT** | All fields<br>Temperature of the carousel outside limits during the assay. |
| **RT** | All fields<br>Storage temperature of reagents outside limits during the assay. |
| **W!** | All fields<br>One of the Westgard rules applied for this analyte has been violated. |

When a sample is completed, it must be stored for the results to be archived in the IDS-iSYS software built in database.

If automatic storage has been programmed in the SYSTEM SETTINGS menu, the profile is stored as soon as the profile is completed.

As soon as the position occupied by this sample is released, the profile is automatically transferred to storage.

All stored results can be viewed via the DATA menu under RESULTS STORAGE.

The results can be stored individually or in multiples.

- Click on 

then click 

- Select the relevant profile option to be stored (all profiles, selection, profiles without message), then click 

.
- The stored profiles change to a yellow colour code.
- As soon as a position for which the profile has been stored is released, the profile will be available in results storage.
- It is also possible to delete all the stored profiles from the work list. To do this, click on 

then select “**Profiles stored**” and 

.
- All the stored profiles are deleted from the work list and transferred to analyser software’s database.

It is possible to request repeat analyses for a stored profile as long as the tube is still in the sample rack.

The results calculated for the controls are automatically stored for each reagent lot.

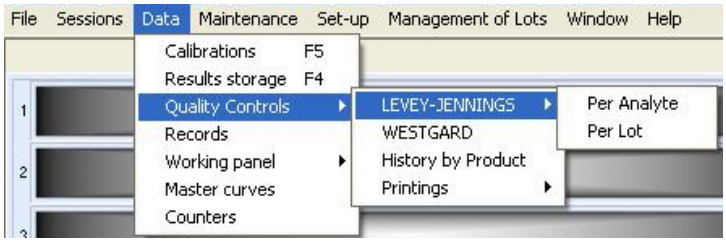
The results are recorded for each test and for each lot of reagent for cumulative analysis (Levey-Jennings) and, depending on the analytical configuration, with Westgard rules for one or two levels of control.

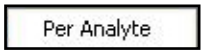
## 3-13-1 Cumulative analysis

The results calculated for the controls are stored by reagent lot with the date and time of the assay. The results are automatically recorded for cumulative examination. The results and the statistical calculations can be displayed for a selected period of time (60 days maximum) including mean, standard deviation, CV and charts (control results plotted around the mean value defined for the active lot).

The control data can be displayed by analyte or active lot. By selecting from the control lot, the data of the stored lots can be displayed.

- In the **DATA** menu, select the following pathway:

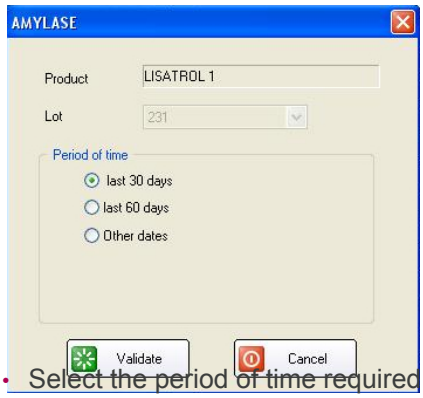




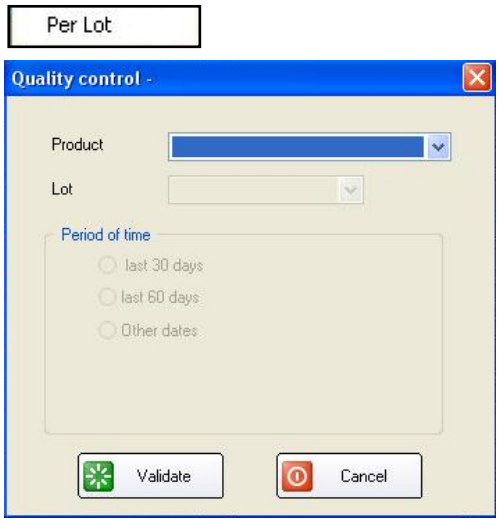
- In the pop-up menu, select the desired analyte.
- The software displays the controls associated with this analyte.

- Select the control and click on 

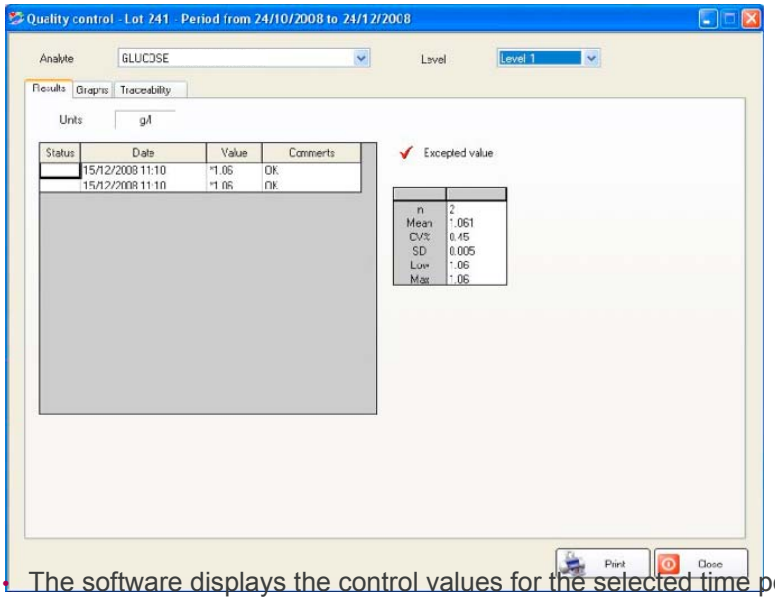

- Select the period of time required for display, then click on
- The results of the control are displayed for the selected time period.

### 3-13-1 Cumulative analysis (continued)




- Select the control. The software displays the stored lots.
- Select the lot number, the time period of interest, then click on 

- Then select the test in the pop-up menu.




- The software displays the control values for the selected time period along with the calculated mean, standard deviation and CV.

#### To Exclude a Value from Statistical Calculation

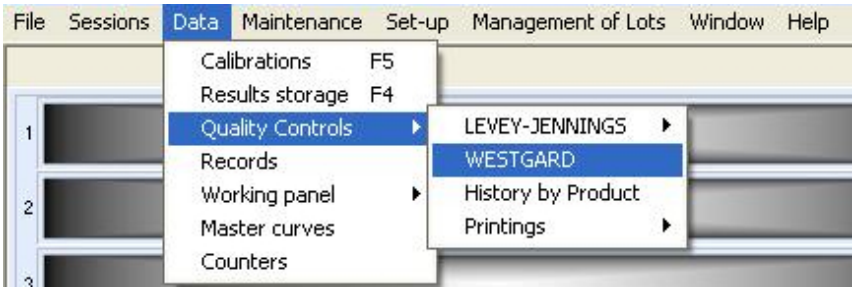
The statistics can be calculated with values removed by clicking in the box in front of the date and time of the result. The red tick indicates that this value has been removed from the calculation.

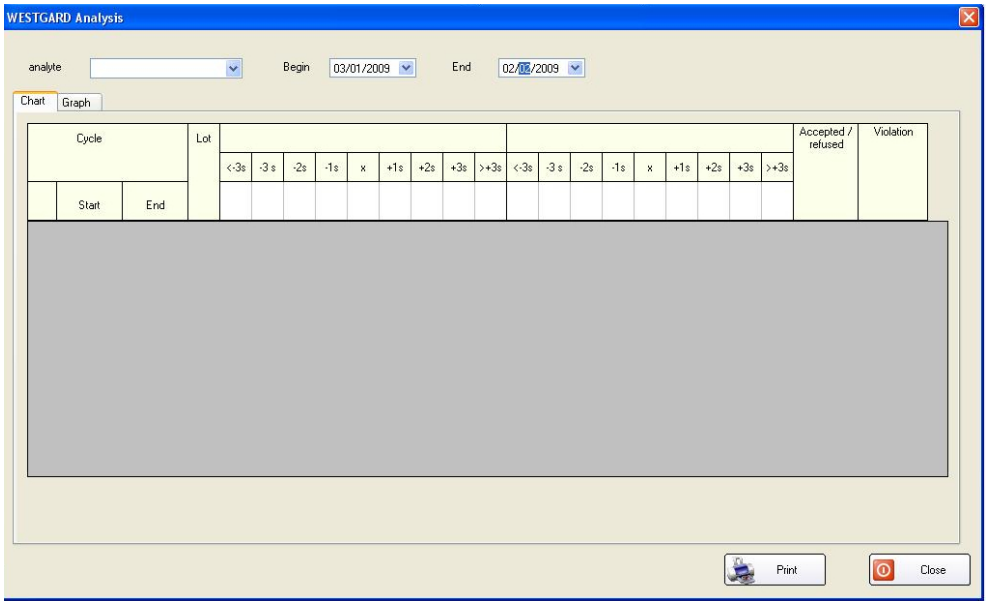
The chart is displayed by clicking on the tab.

### 3-13-2 Westgard rules

The Westgard rules are selected for each test in the QUALITY CONTROL tab of the analytical configuration, with an application of 1 or 2 levels of control.

- In the **DATA** menu, select:



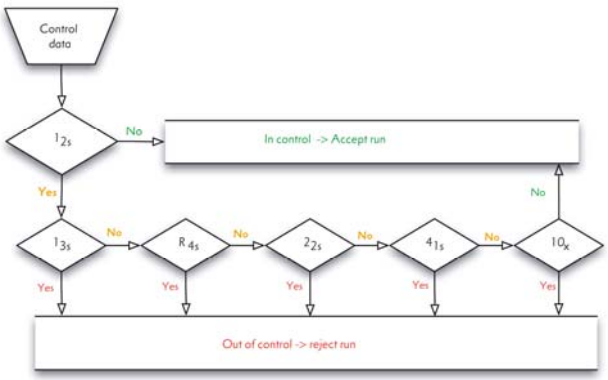

- Select the test and the time period of interest.
- For each run, the software displays the control measurement, the result of the selected Westgard rules examination (IN CONTROL, OUT OF CONTROL or WARNING) and the violated rules.
- The chart can be display by clicking the tab.

### 3-13-2 Westgard rules (continued)

| | |
|---|---|
| **1** $_{2s}$ | One control measurement exceeds the limits of x ± 2s.<br>This rule provides a WARNING and an additional inspection with the other rules. |
| **1** $_{3s}$ | One control measurement exceeds the limits of x ± 3s. This rule is sensitive to random errors.<br>The run is judged to be OUT OF CONTROL. |
| **2** $_{2s}$ | Two consecutive measurements within the run exceed the same limit either x - 2s or x + 2s.<br>This rule is sensitive to systematic errors.<br>This rule is applied to the same control lot or on different control lots:<br>one measurement of each control exceeds the same limit.<br>The run is judged to be OUT OF CONTROL. |
| **R** $_{4s}$ | The range between the high and low control measurements within a run exceeds 4s. This rule is sensitive to random errors.<br>This rule is applied on the same control lot and on different control lots: one measurement exceeds the +2s limit and the other exceeds the -2s limit.<br>The run is judged to be OUT OF CONTROL. |
| **4** $_{1s}$ | 4 consecutive control measurements within or across a run exceeds the same limit, either x - 1s or x + 1s. This rule is sensitive to systematic errors.<br>This rule is applied on the same control lot or on different control lots:<br>4 consecutive measurements across control lots exceed the same limit,<br>either x - 1s or x + 1s.<br>The run is judged to be OUT OF CONTROL. |
| **10** $_{x}$ | 10 consecutive control measurements fall on one side of the mean. This rule is sensitive to systematic errors.<br>This rule is applied on the same control lot or on different control lots<br>The run is judged to be OUT OF CONTROL. |

**Rules Inspection:**

The rules defined in the set-up test will be tested in the following order:



## 3-14 Switching The Analyser Off

The analyser remains in assay mode until the run cycle is stopped.

Assays must be stopped in order to carry out maintenance procedures.

- Click on 

.
- If assays are under way, the analyser finishes these before stopping.

- Check that all the profiles are completed and that there are no unfinished profiles.
- The latter are displayed in purple and their number is indicated on the status bar at the bottom of the screen.

- If all the profiles are completed, open the drawer and remove all samples.

- If reagent cartridges are not intended to be stored on-board, remove reagent racks and store in accordance with IFU recommendations.

- Carry out daily maintenance, then if necessary, weekly and monthly maintenance.

- Empty the liquid waste and solid waste tray if necessary.

- Waste must be disposed of in accordance with current local regulations (see APPENDIX I: Waste disposal, page 110).

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

Waste which contains, or has been in contact with, biological specimens must be considered to pose a potential risk of infection.
Wear disposable gloves when handling waste.
The waste must be disposed of in accordance with current local regulations.

- ~~Check that the work list is empty. If necessary, delete profiles that are no longer required.~~
- Check that the volume of Standard A available for the selective electrodes is adequate for the usage required in standby mode.

It is essential for an analyser equipped with the selective electrodes module to be put into standby mode in order to ensure that the selective electrodes are kept in optimum working order.
If the analyser has to be switched off, the electrodes must be rinsed in de-ionised water before being stored in their original packaging.

- Check the time and date of “wake-up” programmed in the SYSTEM SETTINGS menu if applicable.
- From the Session menu, select SHUT DOWN to put the analyser into standby mode.

In standby mode, the reagents are stored at a temperature of between 8 and 10°C.

Do not turn off the computer in standby mode.

## 3-15 Switching The Analyser Off Completely

This procedure is only applicable to analysers not equipped with a selective electrode module and to the analysers for which reagents must not be stored internally.

- Remove all the reagents installed on the reagent rack.
- From the File menu, click on EXIT, the software will close.
- Then turn off the computer following the procedure for shutting down WINDOWS.
- Finally, press the switch located on the left-hand side of the analyser into position ‘0’.

SECTION 4:

# Messages

# Section 4

## Messages 74

# Messages

## 4-1 Messages Associated with Calibrations

If a calibration fails to meet the criteria for automatic validation, the calibration status is represented by a red  half circle.

For Biochemistry, the corresponding assays will not be processed by the analyser until a new calibration is carried out and is correct, or until the calibration is forced. In the case of Immunoassays assays will be processed but values will not be calculated until an new calibration is carried out and is correct, or until the calibration is forced.

Messages associated with the calibrations are displayed with the calibration curve.

| Message | Meaning |
|---|---|
| **Abs. out of range** | Biochemistry<br>One of the calibrator replicates' absorbances is outside the limits specified in the analytical configuration for the test. |
| **Blank out of range** | Biochemistry<br>The reagent blank is outside the limits specified in the analytical configuration of the test. |
| **Fail of calibration calculation** | All fields<br>The calibration could not be calculated. |
| **Sensitivity out of range** | Biochemistry<br>The sensitivity calculated is lower than the value specified in the analytical configuration. |
| **Determination coefficient too low** | Biochemistry<br>The determination coefficient calculated for the calibration curve is lower than the value specified in the analytical configuration. |
| **Monotony Problem** | Biochemistry - Immunoassay<br>The calibration has not been calculated as the curve is not strictly increasing or decreasing. |
| **Tolerance out of range** | Immunoassay<br>The deviation between the relative light unit (RLU) obtained for one of the calibrators and the measurement of the last calibration is higher than the percentage specified in the analytical configuration. |

## 4-1 Messages Associated with Calibrations (continued)

| Message | Meaning |
|---|---|
| **Control out of range** | All fields<br>The control carried out with the calibration has not been calculated or is outside the limits of acceptability. |
| **Determination coefficient too low for one assay** | Biochemistry<br>The slope of the kinetics calculated for one of the calibrators was calculated on a non-linear section of the curve. |
| **ISE Error** | Biochemistry - ISE<br>The calibration slope of one of the electrodes was not transferred by the selective electrodes module. |
| **No control for checking** | All fields<br>The control measurements requested with the calibration have not been performed. Calibration is not considered to be valid. |
| **Out of the activity limits** | Biochemistry<br>The slope of the kinetics calculated for one of the calibrators is higher than the limit value of activity specified in the analytical configuration, or enzymatic hyperactivity was detected. |


When the controls carried out with the calibration do not meet the criteria for automatic validation, the status of each control is represented by a red circle in the appropriate column(s) (e.g. QC3) and by a red half-circle in the calibration column.

For Biochemistry assays, only QC1 is carried out with the calibration.

In this case, the corresponding assays will not be processed by the analyser until a new calibration has been carried out and is correct, or until the calibration is forced. The messages associated with the calibration control are displayed with the calibration curve in the control section.

| Message | Meaning |
|---|---|
| **Calibration out of range** | Biochemistry - Immunoassay<br>The control was not calculated as the calibration is invalid. |
| **Out-of-range** | All fields<br>The value calculated for the control is outside the limits of acceptability. These limits of acceptability are calculated from data supplied for the control lot. |
| **Calculation Error** | Biochemistry - Immunoassay<br>The control value was not calculated due to incomplete data generation. |
| **ISE Error** | Biochemistry - ISE<br>The control value for one of the electrodes was not transferred by the selective electrodes module. |

# Messages

## 4-3 Messages Associated with Results

Results calculated for samples are accompanied by a colour-coded message (displayed in the column “STATE”).

If a result does not have a message associated with it, “OK” is displayed in the “MSG” column (green colour code associated).

If a result is accompanied by one of the following messages, an orange colour code is associated.

| Message | Meaning |
|---|---|
| **AIRA** | Biochemistry – Selective electrodes<br>Air detected during the measurement of the sample. |
| **AIRS** | Biochemistry – Selective electrodes<br>Air detected during the measurement of the sample. |
| **RDS** | Immunoassay<br>Problem with agitation of magnetic particles on the reagent rack. |
| **BLR** | Biochemistry<br>Absorbance of blank outside the limits defined in the analytical configuration. |
| **NOIS** | Biochemistry – Selective electrodes<br>Electrical noise interfering with the measurement. |
| **KIN!** | Biochemistry<br>The absorbances measured while monitoring the reaction are not strictly increasing or decreasing (non-monotony of the reaction). |
| **CDE** | Biochemistry<br>Slope of the kinetics has been calculated on a non-linear section of the reaction (for KINETIC type of assay).<br>The coefficient of determination is lower than the limit value defined in the analytical configuration. |
| **IDB** | Biochemistry – Selective electrodes<br>Error on one of the bubble detectors. |
| **DRIF** | Biochemistry – Selective electrodes<br>Deviation relating to the measurement of Calibrator A. |

| Message | Meaning |
|---|---|
| **ASU** | Biochemistry<br>An absorbance is outside the limits of reaction defined in the analytical configuration. The sample will be automatically diluted.<br>If the ASU message accompanies the message “RED”, one of the absorbances is still outside the limits of reaction defined after dilution.<br>In this case, the sample must be re-diluted to a level higher than that programmed in the analytical configuration, then tested again. |
| **CE** | All fields<br>Error when performing a parameter calculation. |
| **EDE!** | All fields<br>The calibration used for calculating the result was obtained with at least one calibrator excluded. |
| **FOR** | All fields<br>The calibration used for calculating the result was forced. |
| **OMR** | All fields<br>It has not been possible to calculate the result because the calibration is not valid. |
| **OMR-** | All fields<br>The result calculated is below the lower limit of the field of measurement. |
| **OMR+** | All fields<br>The result calculated is above the upper limit of the field of measurement. The sample will be automatically diluted.<br>If the message OMR+ accompanies the message “RED”, the result is still higher than the upper limit of the field of measurement after dilution.<br>*In this case, the sample must be re-diluted to a level higher than that programmed in the analytical configuration, then tested again.* |
| **MA** | All fields<br>The assay is no longer being requested by analyser. |
| **MES** | All fields<br>Error when recovering the measurements. |
| **MRE!** | Immunoassay<br>The calibration used for calculating the result was obtained with at least one relative light unit (RLU) measurement excluded. |
| **LOW** | All fields<br>Result lower than the lower normal value. |

| Message | Meaning |
|---|---|
| **HIGH** | All fields<br>Result higher than the higher normal value. |
| **ORA-** | Immunoassay<br>The result cannot be calculated as the measurement is lower than the scope of the measurements defined by the master curve. |
| **ORA+** | Immunoassay<br>The result cannot be calculated as the measurement is higher than the scope of the measurements defined by the master curve. |
| **RDE!** | Immunoassay<br>The calibration used for calculating the result was obtained with one of the replicates for calibrator excluded. |
| **RED** | All fields<br>The result was calculated after a dilution. The value given takes into account the dilution factor. |
| **LS** | Biochemistry<br>The result was calculated from absorbances measured with an unstable lamp. |
| **PMS** | Immunoassay<br>Problem with luminometer stability. |
| **SUB** | Biochemistry<br>Detection of enzymatic hyperactivity. The change in absorbance per minute (ΔA/min) calculated between the injection of the sample and the first measurement used in the calculation exceeds the programmed limit.<br>The sample will be automatically diluted.<br>If the SUB message accompanies the message “RED”, enzymatic hyperactivity is still detected after dilution. *In this case, the sample must be re-diluted to a level higher than that programmed in the analytical configuration, then tested again.* |
| **CT** | All fields<br>Temperature of the carousel outside limits during the assay. |
| **RT** | All fields<br>Storage temperature of reagents outside limits during the assay. |
| **W!** | All fields<br>One of the Westgard rules applied for this analyte has been violated. |

# Messages

## 4-4 Warning Messages

Warning messages are displayed in the WARNING window, either before the start, or during the run cycle.

If messages affecting the operation of the current workload appear, the button is displayed in orange with the number of messages indicated.


The appearance of certain types of message is also indicated with a flashing icon:

-  A request for calibration, QC1, QC2 or QC3 has been generated automatically.
- These requests are generated in the following cases:
  - No calibration in the memory for the analytes requested.
  - Reagent lot present in the compartment is out of date.

- For Biochemistry if certain Westgard rules have been violated, a request for calibration or control is generated depending on the rule in question.

- The calibration and/or control(s) will be carried out after acceptance by the user (by clicking YES): If the user does not want to accept these actions, it is possible to cancel the request by clicking NO. This action will be detailed in the Records.

-  Daily, weekly or monthly maintenance has not been carried out.

Messages are displayed by clicking on the WARNING button. If items are missing, the installation of the item automatically deletes the message.

Depending on the nature of the message, certain tests may stop. In this case, the analyser will not be able to complete the entire workload. To carry out the entire workload without affecting the deadline for producing the results, it is important to act upon the messages as soon as possible.


The temperatures of the carousel and the reagent compartment are continually monitored. If, during operations, one of the temperatures is outside the acceptable limits, the analyser will continue to carry out assays and the icon  will be displayed in the ANALYSER STATUS button.

Error messages appear in the ALARM button which is displayed in red with the number of faults indicated.

Alarms are classified into two categories.

### Errors in modules

- These errors indicate that one of the elements of the analyser is no longer operational (for example, the diluter, transfer arm, cuvette loader, carousel, etc.).
- The analyser will continue with the workload without using this module, or if this is not possible to carry out any new assays, the samples being measured will be terminated.
- For resolution, select the error then click 

.
- If the error cannot be resolved during the run cycle, the system will display a message.
- Release this message, then either wait for the workload under way to complete, or ask for the run cycle to be stopped.
- The fault must be released again after stopping the run cycle. At the time of release, the element concerned is automatically initialised.

### Errors in drawer elements

- These errors indicate either a lack of an item or that an item loaded on the analyser is unusable.
- The analyser will continue with the workload without using this item, or, if this is not possible, the samples being measured will be terminated.
- In the event of a lack of reagents, sample, IDS-iSYS Cuvettes or IDS-iSYS System Liquid, the installation of the new item using the barcode reader will automatically release the fault.
- Please note that if the error involves one of the other ancillaries (for example, IDS-iSYS Wash Solution) the error must be resolved after stopping the run cycle.

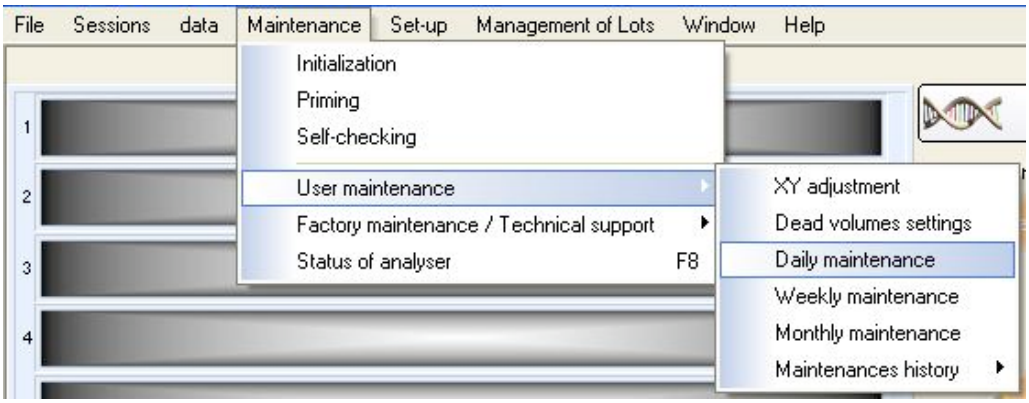
SECTION 5:

# Maintenance

# Section 5

## Section 5: Maintenance 83

In the MAINTENANCE menu, select DAILY MAINTENANCE:




Daily maintenance activities are presented under three tabs: General, Immunology and, if appropriate, Biochemistry. Certain maintenance activities are carried out automatically by the system whilst others must be carried out by the operator. In both cases, the maintenance activities are recorded.

**WARNING:**
**OPENING/CLOSING THE LID**

The lid must be opened for some maintenance procedures.

Handle the lid carefully during opening and closing, as there is a risk of it falling. Always open the lid fully before any intervention. In the maximum height position, the lid is stable and will remain open.

Take care not to knock the lid with your head.
Never open the lid partially: risk of falling back at an inappropriate time.

### 5-1-1 General Maintenance

#### 5-1-1-1 Checking the reagent compartment and Plexiglas®

Do not use any spray products on the analyser.

- Open the reagent compartment drawer.
- Check that no trace of reagent is present on the base plate of the compartment If traces of reagent are evident, use absorbent paper to clean the rails.
- Then use a disinfectant wipe/solution suitable for medical devices.
- Close the drawer.
- Open the lid and check that there are no traces of liquid on the Plexiglas® over the reagent compartment. If traces of liquid are evident, use absorbent paper to remove them.
- Close the lid.
- When maintenance is complete, click on the corresponding Execute the maintenance, then confirm the maintenance by clicking on YES.

#### 5-1-1-2 Checking the sample tray and Plexiglas®

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

These parts of the analyser are in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

Do not use any spray products on the analyser.

- Open the sample compartment drawer.
- Check that no trace of liquid is present on the surface of the sample tray. If traces of liquid are evident, use absorbent paper to clean the surface of the sample tray. Then use a disinfectant wipe/solution suitable for medical devices.
- Close the drawer.
- Open the lid and check that there are no traces of liquid on the Plexiglas® over the sample tray. If traces of liquid are evident, use absorbent paper to remove.
- Close the lid.
- When maintenance is complete, click on the corresponding Execute the maintenance, then confirm the maintenance by clicking on YES.

## 5-1-1 General Maintenance (continued)

### 5-1-1-3 External cleaning of the probe

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

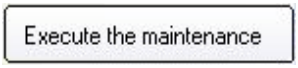
This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

- Open the lid.
- Gently clean the probe with absorbent paper soaked in alcohol.
- Close the lid.

Handle the probe with care. Do not twist or bend the probe during cleaning.

### 5-1-1-4 Decontamination of the probe

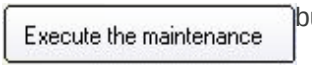
- Check that IDS-iSYS D-Sorb solution is present on the analyser.
- Click on the corresponding 

button in front of this item in the maintenance list.
- Click 

. The probe will automatically aspirate the IDS-iSYS D-Sorb solution.
- When maintenance is completed without any error, the date and time it is carried out are recorded.

## 5-1-2 Biochemistry-ISE Maintenance

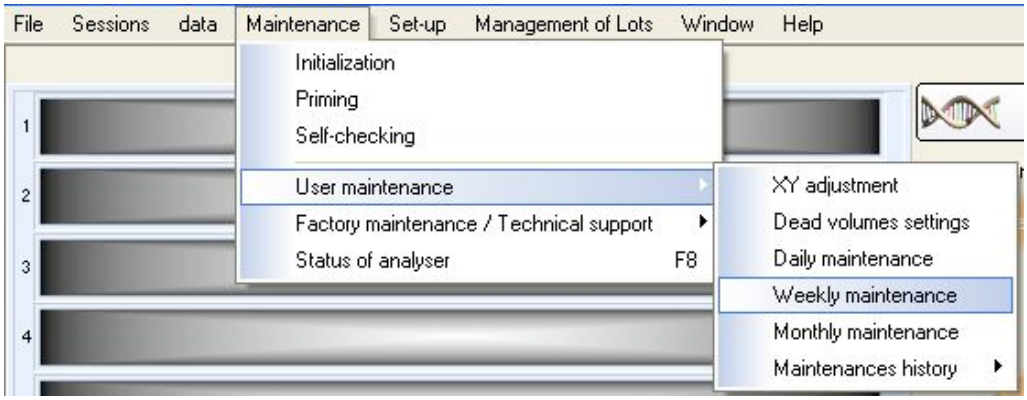
### 5-1-2-1 Cleaning cycle for selective electrodes

- Install an IDS2 rack containing the daily cleaning solution in the reagent compartment (position 1, rail 1).
- Click on the corresponding 

button in front of this item in the maintenance list.
- Then click on 

to start the maintenance procedure. The probe will aspirate the cleaning solution and inject it into the selective electrode well. The cleaning cycle lasts for approximately two minutes.
- When maintenance is completed without any error, the date and time are recorded.

- In the MAINTENANCE menu, select WEEKLY MAINTENANCE:




- The weekly maintenance procedures are presented under 3 tabs: General, Immunology and, if appropriate, Biochemistry. Certain maintenance activities are carried out automatically by the system whilst others must be carried out by the operator. In both cases, the maintenance activities are recorded.

**WARNING:**
**OPENING/CLOSING THE LID**

The lid must be opened for some maintenance procedures.

Handle the lid carefully during opening and closing, as there is a risk of it falling.

Always open the lid fully before any intervention. In the maximum height position, the lid is stable and will remain open.

Take care not to knock the lid with your head.
Never open the lid partially: risk of falling back at an inappropriate time.

### 5-2-1 General Maintenance

#### 5-2-1-1 Cleaning the reagent compartment and Plexiglas®

Do not use any spray products on the analyser.

- Open the reagent compartment drawer.
- Clean the upper lid with absorbent paper soaked in de-ionised water.
- Clean the compartment base plate with absorbent paper soaked in de-ionised water. Then use a disinfectant wipe/solution suitable for medical devices.
- Close the drawer.
- Open the lid and clean the Plexiglas® over the reagent compartment with absorbent paper soaked in de-ionised water. Then use a disinfectant wipe/solution suitable for medical devices.
- Close the lid.
- When maintenance is complete, click on the corresponding maintenance by clicking on YES. Execute the maintenance then confirm the

#### 5-2-1-2 Cleaning the sample tray and Plexiglas®

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

Do not use any spray products on the analyser.

- Open the sample drawer.
- Clean the surface of the tray with a disinfectant wipe/solution suitable for medical devices.

**WARNING:**
**RISK OF INJURY**

If a position has to be cleaned, take care not to push the wipe into the position with your finger: risk of cuts from the detection sensors.

- Close the drawer.
- Open the lid and clean the Plexiglas® over the tray with absorbent paper soaked in de-ionised water. Then use a disinfectant wipe/solution suitable for medical devices.
- Close the lid.
- When maintenance is complete, click on the corresponding maintenance by clicking on YES. Execute the maintenance then confirm the

### 5-2-1 General Maintenance (continued)

#### 5-2-1-3 Cleaning the rinsing well

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

- Open the lid.
- Pour alcohol into the rinsing well.
- Use a cotton bud soaked in alcohol to clean the well.
- When maintenance is complete, click on the corresponding maintenance by clicking on YES.

Execute the maintenance then confirm the

#### 5-2-1-4 Cleaning the reagent barcode reader mirror

Do not spray any product onto the medical device.

- Open the reagent drawer.
- Clean the mirror with absorbent paper soaked in alcohol.
- Close the reagent drawer again.
- When maintenance is complete, click on the corresponding maintenance by clicking on YES.

Execute the maintenance then confirm the

#### 5-2-1-5 Checking dilutors and IDS-iSYS System Liquid pumps

- Remove the cover from the right-hand hand side of the analyser.
- Check for any leaks on the tubing connections at the outlet of each dilutor.
- Check for any leaks on the IDS-iSYS System Liquid pumps.
- Replace the cover.
- When maintenance is complete, click on the corresponding maintenance by clicking on YES.

Execute the maintenance then confirm the

## 5-2-1 General Maintenance (continued)

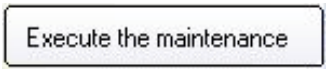
### 5-2-1-6 Cleaning the solid waste chute

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

- Switch off the analyser.
- Open the lid.
- Push the pipetting arm to the left until it is above the reagent compartment.
- Carefully remove the Plexiglas® over the sample tray.
- Clean the solid waste chute with a cotton bud soaked in alcohol.
- Without dismantling, clean the upper section of the drainage area by using a cotton bud soaked in alcohol on the interior and the exterior.
- Replace the Plexiglas®.
- Close the lid.
- Switch the analyser back on again and start it up.
- When maintenance is complete, return to the weekly maintenance menu, click on the corresponding




, then confirm the maintenance by clicking on YES.

## 5-2-2 Biochemistry-ISE Maintenance

### 5-2-2-1 Cleaning the selective electrodes injection well

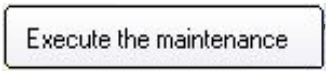
**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

- Open the lid.
- Clean the injection well with a cotton bud soaked in the daily cleaning solution.
- Close the lid.

- When maintenance is complete, click on the corresponding maintenance by clicking on YES.

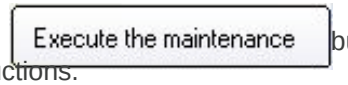



then confirm the

### 5-2-3 Immunoassay Maintenance

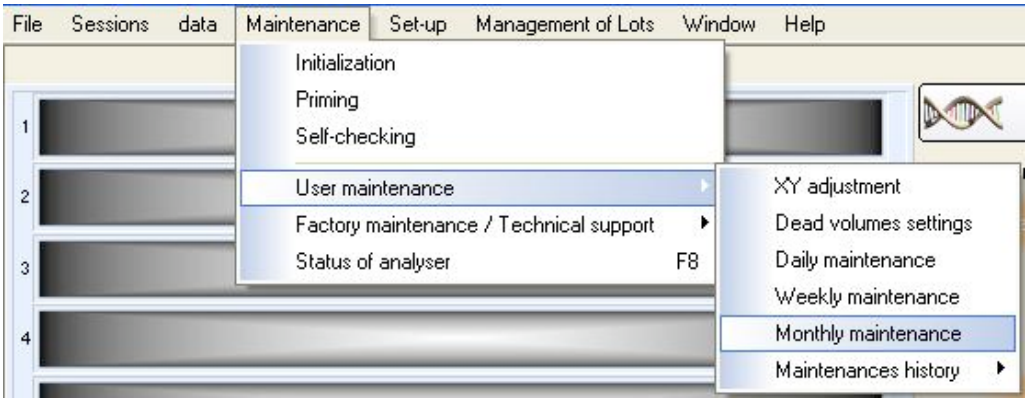
#### 5-2-3-1 Flushing the IDS-iSYS Triggers and IDS-iSYS Wash Solution tubing

- Prepare a large container (at least 10 litres) of distilled water and two 500 mL bottles containing distilled water to mimic the IDS-iSYS Wash Solution and IDS-iSYS Triggers.

- Click on the corresponding 

button in front of this item in the maintenance list.
- Follow the on-screen instructions.
- When maintenance is completed without any error, the date and time are recorded.

- In the MAINTENANCE menu, select MONTHLY MAINTENANCE :




- The monthly maintenance activities are presented under 3 tabs; General, Immunology and, if appropriate, Biochemistry. Certain maintenance activities are carried out automatically by the system whilst others must be carried out by the operator. In both cases, the maintenance activities are recorded.

## 5-3-1 General Maintenance

### 5-3-1-1 Cleaning the IDS-iSYS System Liquid pump shafts

- Remove the cover located on the right-hand side of the analyser.

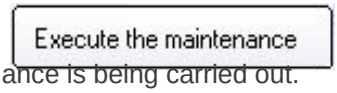
- Click on the corresponding 

button in front of each item in this maintenance list. No spindle must rotate while this maintenance is being carried out.
- Release the pump body from its shaft by pinching the two clips at either side and gently pulling, ensuring the tubes remain connected.
- Clean the pump shaft with absorbent paper soaked in alcohol.
- Return the pump body to its shaft.
- Carry out this procedure for the other pumps.

- When maintenance is completed, click 

. The date and time it is carried out are recorded.

### 5-3-1-2 Cleaning the liquid waste pump shaft

- Click on 

box located in front of this maintenance. No spindle must rotate while this maintenance is being carried out.
- Release the pump body from its shaft by pinching the two clips at either side and gently pulling, ensuring the tubes remain connected.
- Clean the pump shaft with absorbent paper soaked in alcohol.
- Return the pump body to its shaft.
- Carry out this procedure for the other pump.

- When maintenance is completed, click on 

The date and time it is carried out are recorded.

### 5-3-1 General Maintenance (continued)

#### 5-3-1-3 Cleaning the IDS-iSYS D-Sorb pump and level sensor shafts

**WARNING:**
**OPENING/CLOSING THE LID**

The lid must be opened for this maintenance procedure.

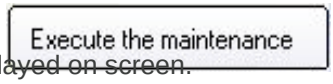
Handle the lid carefully during opening and closing, as there is a risk of it falling.

Always open the lid fully before any intervention. In the maximum height position, the lid is stable and will remain open.

Take care not to knock the lid with your head.

Never open the lid partially: risk of falling back at an inappropriate time.

- Open the lid.
- Remove the cover located at the rear.

- Click on the corresponding 

button in front of this item in the maintenance list.
- Follow the instructions displayed on screen.
- Release the pump body from its shaft by pinching the two clips at either side and gently pulling, ensuring the tubes remain connected.
- Clean the pump shaft with a cloth soaked in alcohol.
- Return the pump body to its shaft.
- Put the cover back in place and close the lid.
- To clean the level sensor, use absorbent paper soaked in de-ionised water.

- When maintenance is completed, click on 

. The date and time it is carried out are recorded.

#### 5-3-1-4 Cleaning the liquid waste level sensor

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

- Click on the corresponding 

button in front of this item in this maintenance list.
- Remove the lid from the liquid waste bottle.
- Clean the level sensor with bleach (commercial preparation).
- Rinse the level sensor with de-ionised water.
- Replace the lid.
- When maintenance is completed, click on 

. The date and time it is carried out are recorded.

## 5-3-1 General Maintenance (continued)

### 5-3-1-5 Checking lamp intensity

- At the bottom of the main screen, click on the ANALYSER STATUS button.
- Check the intensity values for each of the filters are between 900 and 3000.
- When maintenance is complete, click on the corresponding Execute the maintenance button and confirm by clicking 'YES'.

## 5-3-2 Biochemistry-ISE Maintenance

### 5-3-2-1 Cleaning the Standard A and Waste pump shafts

**WARNING:**
**OPENING/CLOSING THE LID**

The lid must be opened for this maintenance procedure.

Handle the lid carefully during opening and closing, as there is a risk of it falling.

Always open the lid fully before any intervention. In the maximum height position, the lid is stable and will remain open.

Take care not to knock the lid with your head.

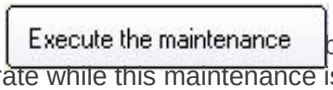
Never open the lid partially: risk of falling back at an inappropriate time.

- Click on the corresponding Execute the maintenance button in front of each item in this maintenance list.
- No spindle must rotate while this maintenance is being carried out.
- Open the lid.
- Remove the bottom partition at the rear of the rinsing well.
- Release the Standard A pump body from its shaft by pinching the two clips at either side and gently pulling, ensuring the tubes remain connected.
- Clean the shaft of the pump with a cloth soaked in alcohol.
- Return the pump body to its shaft.
- Proceed in the same manner for the Waste pump.
- Replace cover and close the lid.
- When maintenance is completed, click on Ok. The date and time it is carried out are recorded.

### 5-3-3 Immunoassay Maintenance

5-3-3-1 Cleaning the IDS-iSYS Wash Solution pump and level sensor shafts

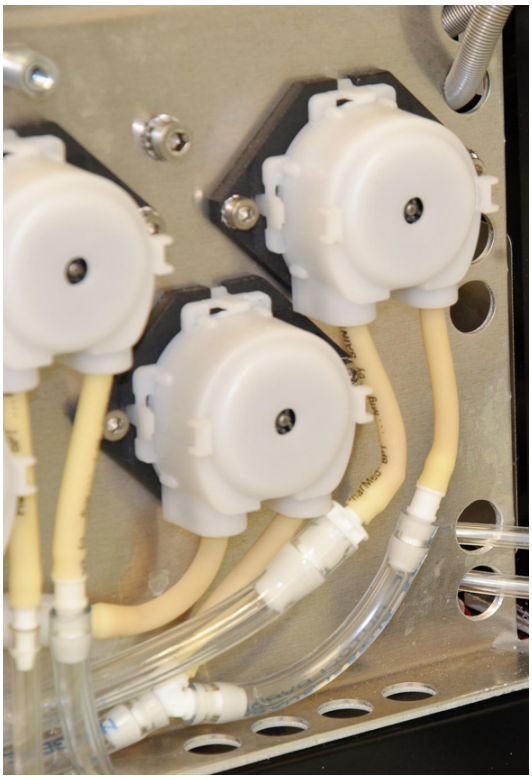
- Remove the cover located on the right-hand side of the analyser.

- Click on the corresponding 

button in front of this item in this maintenance list. No spindle must rotate/operate while this maintenance is being carried out.
- Follow the instructions displayed on the screen.
- Release the IDS-iSYS Wash pump body from its shaft by pinching the two clips at either side and gently pulling, ensuring the tubes remain connected.
- Clean the shaft of the pump with a cloth soaked in alcohol.
- Return the pump body to its shaft.
- Carry out this procedure for the other pumps.
- To clean the level sensor, use absorbent paper soaked in de-ionised water.

- When maintenance is completed, click 

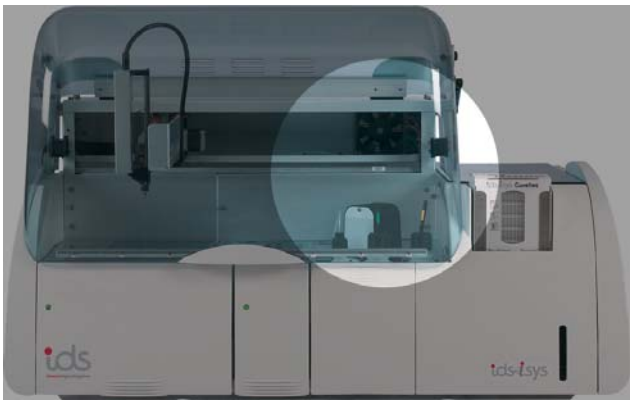
. The date and time it is carried out are recorded.
- Replace cover on the right-hand side of the analyser.



### 5-4-1 Replacement of lamp

**WARNING:**
**RISK OF BURNS**

Before handling, allow the lamp to cool for approximately 10 minutes after switching the analyser off.



- Switch the analyser off and unplug the power cable.
- Open the lid.
- Remove the bottom partition at the rear of the rinsing well.
- Disconnect the lamp from its supply.
- Unscrew the securing screws located on both sides of the lamp in order to remove the lamp-support unit.
- Remove the old lamp.

**WARNING:**
**RISK OF BURNS**

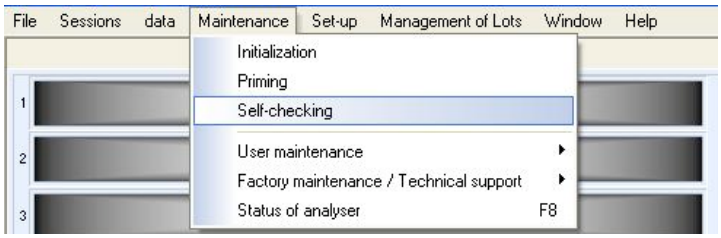
Do not touch the lamp with your fingers.

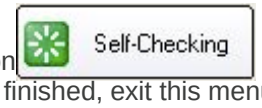
- Wipe the new lamp with a soft cloth.

Do not touch the lamp with your fingers.

### 5-4-1 Replacement of lamp (continued)

- Put the new lamp and its base in place, with the guide pin positioned downwards.
- Tighten the securing screws using a screwdriver.
- Connect the lamp to its power supply.
- Replace the partition.
- Close the lid.
- Switch the analyser back on and start it up.
- Wait for 10 minutes, then request a measurement of the intensity values by the following pathway:




- From the list of elements, select ABS READER then click on 

. The analyser carries out a measurement for each of its filters. When the procedure is finished, exit this menu.
- Click on the ANALYSER STATUS button and check the intensity values for each of the filters are between 1300 and 3000.

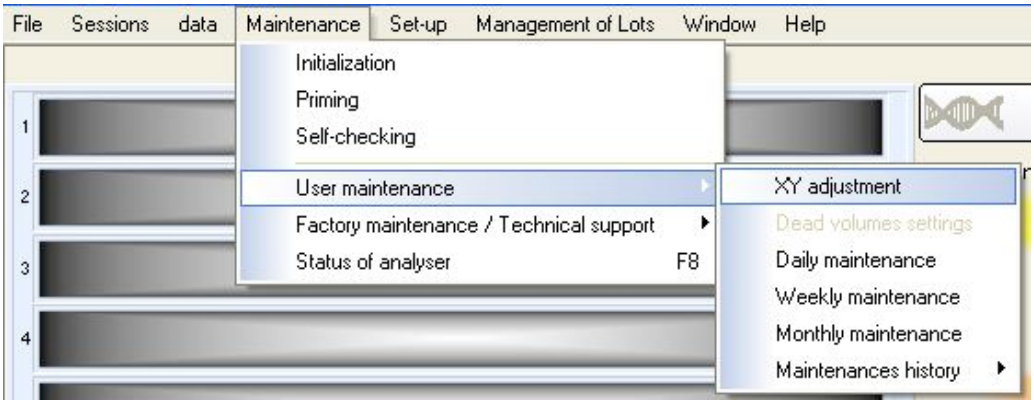
## 5-4-2 Replacement of probe

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

- Open the lid.
- Unscrew the probe requiring replacement.
- Install the new probe by screwing it in by hand as far as possible to avoid risk of leakage. Take care not to twist or bend the probe, always handling it by the threaded screw connector.
- Check the probe reference position.




- Select **Needle position calibration** then click 

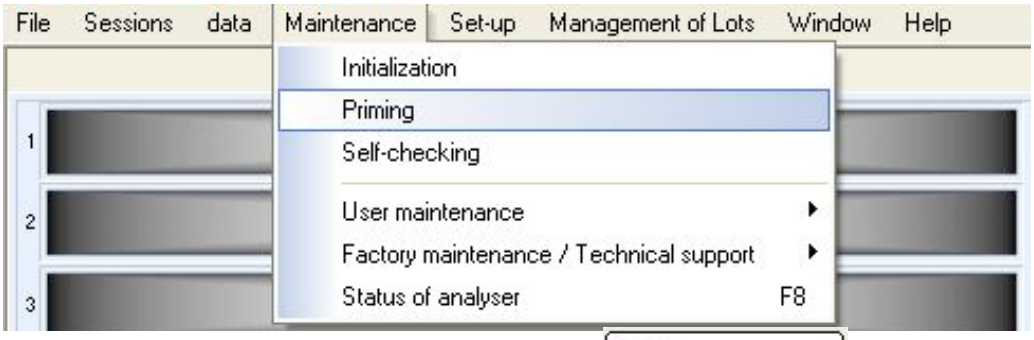
. The probe will be placed over the reference position, located to the left of the rinsing well.
- If the probe is correctly centred on the reference position, click on 

. The pipetting arm will move to the rinsing well. A message confirming cancellation of the procedure is displayed. Click on **OK** to validate this message.
- If the probe is off-centre, readjust its position using the movement arrows and click 

. The pipetting arm will move to the rinsing well before returning to a point above the reference position.
- Click 
. A message confirming completion of the procedure is displayed. Click on **OK** to validate this message.
- When the check on the reference position is completed, exit this menu.

### 5-4-2 Replacement of probe (continued)

- Prime the analyser as follows:




- Select ARM-Mixed Partial Priming, then click on 

.
- The analyser will prime the tubing circuit and rinse the probe.

### 5-4-3 Replacement of primary fuses

**WARNING:**
**RISK OF ELECTRIC SHOCK**
It is essential for the mains connection to be unplugged during replacement of fuses.

- The primary fuses are located in the mains plug located on the left-hand side of the analyser.
- Switch the analyser off and unplug the power cable.
- Using a screwdriver, remove the fuse-holder from its housing.

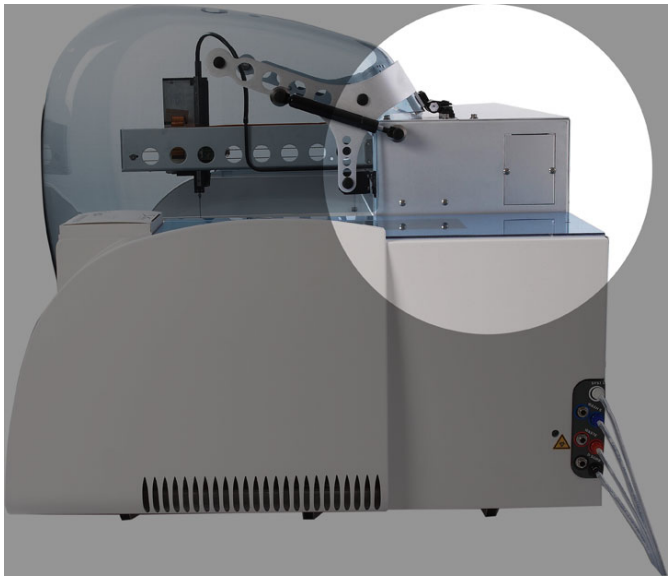

- Replace the faulty fuse, ensuring it is of the same value.
- Return the fuse holder to its housing.
- Switch the analyser back on and perform the start-up procedure.

## 5-4-4 Replacement of secondary fuses

**WARNING:**
**RISK OF ELECTRIC SHOCK**
It is essential for the mains connection to be unplugged when replacing fuses.

- Turn off the analyser and unplug the power cable.
- Remove the screws from the secondary fuse protection plate located on the right-hand side of the analyser and gently prise the plate away using a flat head screwdriver (see picture 1).

*Picture 1*



*Picture 2*


- Insert a flat head screwdriver into the fuse-holder and turn anti-clockwise to unscrew (see picture 2).
- Take out the fuse-holder and replace the faulty fuse with one of the same value (see picture 3).

*Picture 3*

- Return fuse-holder to its housing and screw firmly into place, taking care not to over-tighten.
- Replace the fuse protection plate.
- Switch the analyser back on again and perform the start-up procedure.

### 5-4-5 Replacement of IDS-iSYS Wash Solution pump (Immunoassay)

- Switch the analyser off.
- Remove the cover from the right-hand side of the analyser.
- Press on the two pins at each side of the pump to be changed and remove the pump body from its shaft.
- Disconnect the pipes from the connectors and plug into the new pump.
- Clean the shaft of the pump with absorbent paper soaked in alcohol.
- Put the pump back in place on its shaft.
- Replace the cover of the analyser.
- Switch the analyser back on again and perform the start-up procedure.
- Carry out partial priming of the washers in order to prime the tubing circuit again.

### 5-4-6 Replacement of IDS-iSYS System Liquid pump

- Switch the analyser off.
- Remove the cover from the right-hand side of the analyser.
- Press on the two pins at each side of the pump to be changed and remove the pump body from its shaft.
- Disconnect the pipes from the connectors and plug into the new pump.
- Clean the shaft of the pump with absorbent paper soaked in alcohol.
- Put the pump back in place on its shaft.
- Replace the cover of the analyser.
- Switch the analyser back on again and perform the start-up procedure.
- Carry out partial priming of the arm in order to prime the circuit again.

### 5-4-7 Replacement of liquid waste pump

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

As this part of the analyser is in contact with biological samples, it must be considered to pose a potential risk of infection.

Wear disposable gloves for handling procedures.

- Switch the analyser off.
- Remove the cover from the right-hand side of the analyser.
- Press on the two pins at each side of the pump to be changed and remove the pump body from its shaft.
- Disconnect the pipes from the connectors and plug into the new pump.
- Clean the shaft of the pump with absorbent paper soaked in alcohol.
- Put the pump back in place on its shaft.
- Replace the cover of the analyser.
- Switch the analyser back on again and perform the start-up procedure.

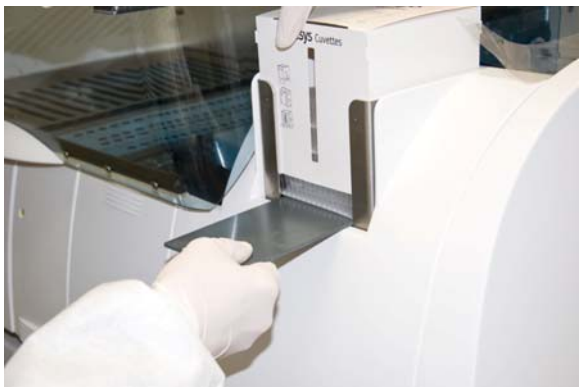
### 5-4-8 Replacement of IDS-iSYS D-Sorb pump

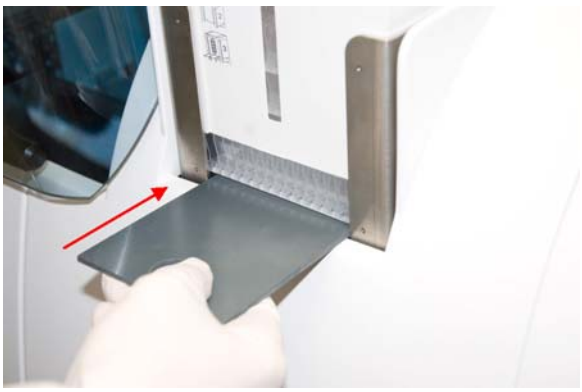
- Open the lid.
- Remove the cover located at the rear.
- Press on the two pins at each side of the pump to be changed and remove the pump body from its shaft.
- Disconnect the pipes from the connectors and plug into the new pump.
- Clean the shaft of the pump with absorbent paper soaked in alcohol.
- Put the pump back in place on its shaft.
- Replace the cover and close the lid.
- Carry out partial priming of the arm in order to prime the circuit again.

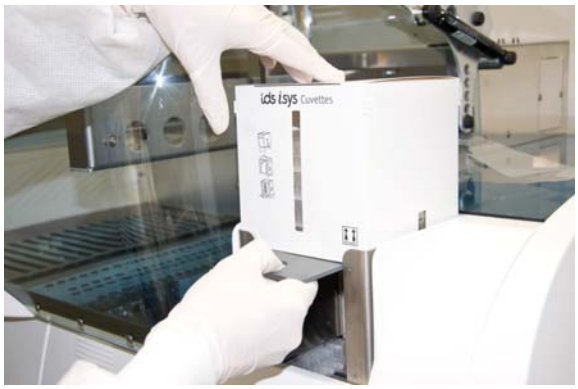
### 5-4-9 Removal of the on-board IDS-iSYS Cuvettes cube

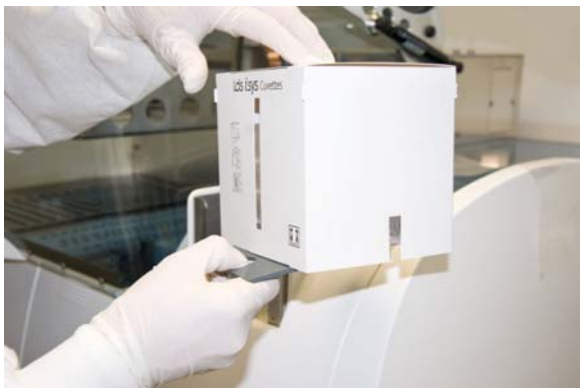
Perform this operation only at the request of IDS Technical Service & Support personnel.

Use the special plate provided with the analyser.









### 5-4-10 Replacement of Standard A or Waste pumps

- Open the lid.
- Remove the cover located at the rear.
- Release the pump body from its shaft by pinching the two clips at either side and gently pulling.
- Disconnect the pipes from the connectors and plug into the new pump.
- Clean the pump shaft with absorbent paper soaked in alcohol.
- Return the pump body to its shaft.
- Put the cover back in place and close the lid.
- If the body for the Standard A pump has been replaced, carry out one or several priming procedures of the ISE module to prime the circuit again.

SECTION 6:

# Problems & Corrective Action

# Section 6

# Problems & Corrective Action

## 6-1 Resolving Errors in Cartridge Check System (CCS)

| Problem | Possible cause & corrective action |
|---|---|
| **CCS1 %CV outside limits** | 1 - Check for air bubbles in the tubing circuit. Carry out a full priming of the arm.<br>2 - Check for the presence of bubbles in the reagents: there should be none.<br>3 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 86). If the probe is bent, replace it and check the XY reference position (see Section 5-4-2, page 98).<br>4 - Check for air bubbles on the IDS-iSYS Triggers A and B tubing circuits. Check for air bubbles in the tubing circuits.<br>5 - Repeat the CCS1 test.<br>6 - If the problem persists, contact IDS Service & Support personnel. |
| **CCS2 %CV outside limits** | 1 - Check for air bubbles in the tubing circuit. Carry out a full priming of the arm.<br>2 - Check for the presence of bubbles in the reagents: there should be none.<br>3 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 86). If the probe is bent, replace it and check the XY reference position (see Section 5-4-2, page 98).<br>4 - Check for air bubbles in the IDS-iSYS Triggers A and B tubing.<br>5 - Repeat the CCS2 test.<br>6 - If the problem persists, contact IDS Service & Support personnel. |
| **CCS3x Value outside limits** | 1 - Presence of residual IDS-iSYS Wash for the associated washer: carry out a full priming of all washers.<br>2 - Check for air bubbles in the IDS-iSYS Triggers A and B tubing.<br>3 - Check IDS-iSYS Cuvettes and IDS-iSYS Triggers by carrying out a CCS4 test.<br>4 - If CCS4 is within the limits, replace the IDS-iSYS Wash Solution in use. Carry out full priming of washers and repeat CCS3 tests.<br>5 - If the problem persists, contact IDS Service & Support personnel. |

| Problem | Possible cause & corrective action |
|---|---|
| **CCS4 Value outside limits** | 1 - Replace the IDS-iSYS Triggers and the IDS-iSYS Cuvettes cube in use. Carry out a full priming of luminometer, then repeat the CCS4 test.<br>2 - If the problem persists, contact IDS Service & Support personnel. |
| **CCSB %CV outside limits** | 1 - The magnetic particles of the CCS cartridge are not correctly mixed: manually mix the magnetic particles vial by gentle repeated inversion.<br>2 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 86). If the probe is bent, replace it and check the XY reference position (see Section 5-4-2, page 98).<br>3 - Check for air bubbles in the IDS-iSYS Wash Solution tubing. Carry out a full priming of all washers.<br>4 - Repeat the CCSB test.<br>5 - If the problem persists, contact IDS Service & Support personnel. |
| **CCS1/CCS2 Ratio outside limits** | 1 - Check for air bubbles in the tubing circuit. Carry out a full priming of the arm.<br>2 - Check for the presence of bubbles in the reagents: there should be none.<br>3 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 86). If the probe is bent, replace it and check the XY reference position (see Section 5-4-2, page 98).<br>4 - Check for air bubbles in the IDS-iSYS Triggers A and B tubing.<br>5 - Repeat the CCS1 & 2 tests.<br>6 - If the problem persists, contact IDS Service & Support personnel. |
| **CCSB / CCS1 (x10) Ratio outside limits** | 1 - Replace the IDS-iSYS Triggers A and B.<br>2 - Check the probe XY reference position (see Section 5-4-2, page 98).<br>3 - Replace the CCS cartridge.<br>4 - Repeat the CCS1 and CCSB tests.<br>5 - If the problem persists, contact IDS Service & Support personnel. |

# Problems & Corrective Action

## 6-2 Resolving Errors in Selective Electrodes

| Problem | Possible cause & corrective action |
|---|---|
| **Calibration slopes outside limits:**<br><br>Na < 45 mV/dec. or Na > 63 mV/dec.<br><br>K < 45 mV/dec. or K > 63 mV/dec.<br><br>Cl < 35 mV/dec or Cl > 63 mV/dec. | 1 - Incorrect alignment of the electrodes: remove the 4 electrodes from the module, and reinstall them in the following order (from bottom to top): Reference; Chloride; Potassium; Sodium.<br><br>2 - Deterioration in calibration solutions: first replace Standard B. If the problem persists, replace Standard A.<br><br>3 - Deterioration of an electrode: carry out a cleaning cycle. If the problem persists, replace the electrode.<br><br>4 - Air bubble on the membrane of the reference electrode: remove the reference electrode. Tap to dislodge the bubble then reinstall the electrode.<br><br>5 - Deterioration of the reference electrode: replace the electrode.<br><br>6 - Interaction between the electrodes: replace the Chloride electrode.<br><br>7 – If the problem persists, contact IDS Service & Support personnel. |
| **Message “NOIS” on a parameter** | 1 - Deterioration of an electrode: carry out a cleaning cycle. If the problem persists, replace the electrode. |
| **Message “NOIS” on the 3 parameters** | 1 - Deterioration of the reference electrode: replace the electrode.<br><br>2 - Erratic signal coming from the module environment: contact IDS Service & Support personnel. |
| **Message “DRIF” on a parameter** | 1 - If the electrode or Standard A has recently been replaced, carry out several start-up cycles of Standard A before recalibrating.<br><br>2 - Replace Standard A.<br><br>3 - Deterioration of the electrode: carry out a cleaning cycle. If the problem persists, replace the electrode. |
| **Message “DRIF” on the 3 parameters** | 1 - If the electrode or Standard A has recently been replaced, carry out several start-up cycles of Standard A before recalibrating.<br><br>2 - Replace Standard A.<br><br>3 - Incorrect alignment of the electrodes: remove the 4 electrodes from the module and reinstall them in the following order (from bottom to top): Reference; Chloride; Potassium; Sodium.<br><br>4 - Deterioration of the reference electrode: replace the electrode. |

| Problem | Possible cause & corrective action |
|---|---|
| **Message “AIRA” during calibration** | 1- Air detected during the measurement on Standards A and B: check the levels of Standards A and B.<br>• Carry out several start-up cycles for Standard A. Check the tubing circuit for Standard A.<br>• Check that the pump for Standard A is working correctly.<br>• Check the reject position of the sampler in the module well.<br>• Check that the electrodes are correctly installed (in particular, check that the toric joint of each electrode is correctly maintained).<br><br>2 - Presence of fibrin or salt in the tubing pathway of the electrodes: carry out a cleaning cycle. |
| **Message “AIRS” on the samples** | 1 - Air detected during the measurement on the sample or on Standard A: check that the volume of sample installed on the analyser is sufficient.<br>• Check the level of Standard A.<br>• Carry out several priming cycles for Standard A.<br>• Check the tubing circuit for Standard A.<br>• Check that the pump for Standard A is working correctly.<br>• Check the reject position of the extractor in the module well.<br>• Check that the electrodes are correctly installed (in particular, check that the toric joint of each electrode is correctly maintained).<br><br>2 - Presence of fibrin or salt in the tubing pathway of the electrodes: carry out a cleaning cycle. |

# Appendices

# Appendices

# Appendices

## A-1 Waste Disposal

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

Waste which contains, or which has been in contact with, biological specimens must be considered to be a potential risk of infection.

Always wear disposable gloves for all handling procedures.

Waste must be disposed of in accordance with current local regulations.

### Liquid waste

Liquid waste is collected in a 10 litre container.

Liquid waste should be considered potentially infectious and must, therefore, be processed prior to disposal in accordance with current local regulations.

- Dilute commercial bleach with water to obtain a 9% solution of active chloride.
- Put 250 mL of freshly prepared bleach into an empty container (10 litres).
- When the container is 3/4 full add 125 mL of freshly prepared bleach.
- Eliminate the processed waste in accordance with current local procedures.

Do not use bleach in tablet form.

### Solid waste

- Probes.
- Electrodes.
- IDS-iSYS Cuvettes.

Solid waste should be considered potentially infectious and must, therefore, be disposed of in accordance with current local regulations.

## A-2 Decontaminating the Analyser

**WARNING:**
**RISK OF BIOLOGICAL CONTAMINATION**

Certain parts of the analyser are routinely in contact with biological samples: there is, therefore, a potential risk of infection.

Wear disposable gloves for all handling procedures.

Waste must be disposed of in accordance with current local regulations.

The analyser must be decontaminated after carrying out the regular maintenance procedures described in Section 5 of this user manual. It is essential that decontamination is carried out:

- Prior to any intervention by the Technical Services & Support personnel.
- Prior to any transportation of the system.

A cleaning/decontaminating declaration must be completed by the user.

The declaration is printed on the following page and should be duplicated and, once completed, attached to the analyser in a prominent position.

It is essential for this declaration to accompany the analyser during any transportation (e.g. return to factory).

Cleaning/decontamination process:

- Decontaminate the probe with a wipe soaked in a decontaminating solution suitable for medical devices.
- Decontaminate the sample tray and reagent compartment with a wipe soaked in a decontaminating solution suitable for medical devices.
- Decontaminate the rinsing well and the liquid waste tubing by pouring bleach (commercial preparation) into the drainage hole in the rinsing well.
- Empty the solid waste tray and liquid waste container.
- Decontaminate the solid waste tray with a wipe soaked in a decontaminating solution suitable for medical devices.
- Decontaminate the bodywork, the keyboard and the keys of the computer with a wipe soaked in a decontaminating solution suitable for medical devices.

Do not use any spray products on the analyser.

## Cleaning/Decontaminating Declaration

**NAME OF ANALYSER:** ids-isys

SERIAL NUMBER: _____

**LABORATORY**

NAME _____

ADDRESS _____

_____

_____

**This analyser was cleaned and decontaminated on ...../...../.....**

I declare that I have carried out all stages of cleaning and disinfecting described in the user manual.

NAME _____

Position (optional) _____

**SIGNATURE** **LABORATORY SEAL**

## A-3 Disposal Of The Analyser

Once the analyser is no longer in use, the following precautions must be taken:

- Clean and decontaminate:
  - Racks.
  - Rinsing wells.
  - Selective electrodes injection well.
  - Bodywork.
  - Liquid waste containers.
  - Solid waste tray.
- Dispose of any solid waste and liquid waste tubing in compliance with current local regulations.
- Since 13/08/2005, the disposal of electrical and electronic waste has been governed by **Directive 2002/96/E.C. of 27 January 2003.**
- In application of this regulation the corresponding responsibilities are divided up in the following way for devices sold by IDS France S.A., a member of IDS group, after this date and used in France:
  - Sending the equipment to IDS for disposal is now the CUSTOMER's responsibility.
  - Dismantling of the apparatus, sorting of the parts and disposal of waste from this equipment is the responsibility of the manufacturer in accordance with current national and local laws.

In the event of resale to a third party, the first CUSTOMER must notify the manufacturer of the name and address of the new owner of the apparatus in order to guarantee traceability of the equipment and for its subsequent disposal, and must inform the new owner that it will be its responsibility to send the equipment to the manufacturer for disposal.

Failing this, the first CUSTOMER will have to pay all the costs and all the fines the government may enforce upon the manufacturer for breach of its obligation to ensure the traceability of the disposal of its equipment in accordance with regulations.

With regard to systems sold before this date, failing any specific stipulations, disposal of the device is the client's responsibility. The manufacturer will be able to arrange for this disposal: consult us for a quote.

For devices sold and used in other countries, the CUSTOMER must contact its VENDOR in order to obtain information about its responsibilities.

# Appendices (continued)

## A-4 IDS-iSYS Cuvettes

### A4-1 List of CE symbols used on the IDS-iSYS Cuvettes cube

| | |
|---|---|
|  | Manufacturer. |
|  | *In vitro* diagnostic medical device. |
|  | Store/hold the box this way up. |
|  | Keep dry. |
|  | Fragile. |
|  | Single use. |
|  | Catalogue number. |
|  | Lot number. |
|  | Expiry date. |
|  | Storage temperature. |
|  | Quantity. |

### A4-2 Storage of the IDS-iSYS Cuvettes cube

- Always store IDS-iSYS Cuvettes cube in their original packaging.
- Never store IDS-iSYS Cuvettes cube outside the original packaging.
- Always store the IDS-iSYS Cuvettes cube in the upright position as indicated by the arrows on the box.
- Keep IDS-iSYS Cuvettes cube in a clean and dry place, sheltered from dust.