ids·isys

IS-310400 IDS-iSYS
(Multi-Discipline Automated System)

User Manual

Software version V 14

ids

immunodiagnosticsystems

For further assistance,
please contact IDS Technical Support:
Tel: 0191 519 6153
Fax: 0191 519 0760
Email: techsupport.uk@idsplc.com

CE ▲ IDS France , 42, rue Stéphane Mazeau, 21320 POUILLY-EN-AUXOIS, FRANCE

IDS Ltd 10 Didcot Way, Boldon Business Park,
Boldon, Tyne and Wear, NE35 9PD
Tel: 0191 519 0660

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.**

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 M1 of the ids·isys User Manual was produced on the 21st December 2015, for the software version:

V 14.04

The information contained in this document is applicable to any subsequent software version identified as «V 14.XX». Changes with the decimals of the version identifier are used to account for minor software enhancements, concerning neither the features nor the use of the system.

The manual comprises the following sections and appendices:

> **Section 1:** **Operating Principle**
> **Section 2:** **User Interface Software**
> **Section 3:** **Use**
> **Section 4:** **Messages**
> **Section 5:** **Maintenance**
> **Section 6:** **Problems And Corrective Action**
> **Section 7:** **System Configuration**
> **Appendix I:** **Waste Disposal**
> **Appendix II:** **Decontaminating The Analyser**
> **Appendix III: Disposal Of The Analyser**
> **Appendix IV: IDS-iSYS Cuvettes**
> **Appendix V: Sample barcode symbology managed by the system**
> **Appendix VI: Analyser long stoppage period**
>
> *Attached document: Protocol for connection, revision N1*

> **!** If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
> If the recommendations contained in this manual are not respected, the level of performance offered by the analyser may be impaired and the results generated may be incorrect.

Preface

New in the manual Revision M1

Section 1

· Modification in **Characteristics**, pages 7 to 9.
· Modification in **1-1-6-Precautions for use,** page 15: use of the sample type «Other» in immunoassays.

Section 2

· Modification in **2-3-1-FILE Menu,** page 25: adding of a new feature accessible from this menu.
· Modification in **2-3-4-MAINTENANCE Menu,** page 28: adding of a new automatic maintenance accessible from this menu
· Modification in **2-3-5-SETUP Menu,** page 30: adding of a new feature accessible from this menu.

Section 3

· Modification in **3-3-1-Installation of internal ancillary reagents,** page 47 and in **3-3-2-Installation of external ancillary reagents**, page 48: adding of automatic priming of ancillary reagents.
· Modification in **3-4-System Performance Checks,** pages 42 and following: programming the automatic qualification profile now in section 7.
· Adding of **3-5-1-Programming calibrations**, page 55: new display options in the calibrations/controls window.
· Modification in **3-7-Programming Samples,** pages 69 and following: use of the sample type «Other» in immunoassays.
· Adding of **3-8-6-Performing reflex tests,** page 76.
· Adding of **3-8-7-Performing dilutions,** page 77: post dilutions carried out on user request.
· Modification in **3-10-1-Result of a calibration,** page 84: the validation criteria «calibrator CV in RLU» is modified.
· Modification in **3-10-3-Sample results,** page 87: change in the reporting of results outside the measuring range; adding of reflex test launch.
· Modification in **3-10-4-Work list results,** pages 87 and 88: adding of reflex test launch.
· Modification in **3-11-Messages associated with results,** pages 89 and following: adding of the messages RFX and AIN; modification of messages OMR- and OMR+.
· Modification in **3-12-Results Storage,** pages 93 and 94: storage of incomplete profiles and removal of stored profiles
· Modification in **3-13-1-Cumulative analysis,** pages 95 and following: modification in Levey-Jennings access.
· Modification in **3-14-1-Emptying the solid waste,** page 101: use of disposable container.

Section 4

· Modification in **4-3-Messages associated with results,** pages 108 and following: adding of the messages RFX and AIN; modification of messages OMR- and OMR+.

Section 5

· Adding of **5-4-13-2-Cleaning the probe**, page 145.

Section 7

· Adding of **Section 7**: System Configuration, pages 151 and following.

Appendices

· Modification in **A-6- Analyser long stoppage period,** pages A-8 and following.

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New features in the software version V 14.04

- The system allows reflex testing: tests can be defined with a Supervisor level of access and can be carried out either automatically or on request.
- Ancillary solutions IDS-iSYS TRIGGER A & B, IDS-iSYS WASH S and IDS-iSYS DSORB are now automatically primed when installed in the system.
- Incomplete patient profiles can now be stored together with the completed profiles. In this case, the analysis requests that have not been performed are automatically removed.
- The results calculated outside the measuring range are now interpreted in relation to the limits of the measuring range.
- The number of available tests is now indicated on Immunology cartridges common to several analytes (eg CCS cartridge). The minimum and the maximum numbers of available tests are displayed next to the $\sum$ icon.
- The pubertal development stage (Tanner stage) can now be defined in the patient identification tab. This data is transferred using the connection protocol «ASTM Compatible V3».
- The qualification profile tests are no longer displayed in the calibrations/controls window.
- New display options are available in the calibrations/controls window.
- The criteria for automatic validation of Immunoassay calibrations are modified: a specific limit can now be applied to the CV calculated on the RLU of each calibrator. This CV may also be excluded from the calibration validation criteria.
- A new criteria is now applied to Immunoassays calibrated without master curve: it allows verifying the difference between the target and the calculated value of each calibrator.
- The validity of an expired calibration can be extended one day.
- CV calculated with raw data of each control is now displayed on the first tab of calibration for immunoassays measured by spectrophotometer.
- An identifier entered for a calibrator or control is recorded by the system. When this ID is used again, the lot data are automatically associated.
- In the **CONSUMABLES** menu, the filling of the solid waste is now displayed proportional to a maximal capacity of 400 cuvettes.
- Post-dilutions can be performed either automatically or on request.
- An automatic maintenance, requested by infectious disease assays, is automatically performed when the system is placed in standby mode.
- In the reference tables of analytical configuration, it is no longer mandatory to define an interval that does not generate a message.
- The connection protocol « ASTM Compatible V3» is added:
    - transfer the identifier of the operator who validates the profile.
    - transfer the Tanner stage.
- The system can now be connected to the centralised computer via an Ethernet link.
- Access to the Levey-Jennings menu is simplified.
- The function for updating the analytical configuration is now integrated to the user's interface.
- Biochemistry assay setup is modified: modification in step configuration (compatible with previous versions without modifying the analytical process).

Issues in software package V14.04

- Using Westgard Rules, when a calibration has failed, a normal WE! Error message is attached to the results. When the calibration is then restarted and been successful, normally the WE! error message should disappear. That is not the case in this software version, the flag is still wrongly displayed on control results but not on patient profile results
- Using Westgard Rules, in the case of a calibration with two levels of controls violating a rule (WE! Error message), only the first control level is displayed on the Westgard graph and in the table of values.
- When a calibration curve is displayed, only the control level 1 is shown on the curve. Other control levels must be selected each time to be displayed.
- An error message displays each time a Levey-Jennings graph is displayed for a control that does not have a target value defined. This error message must be accepted prior to select the appropriate graphic representation (mean/deviation).
- When restoring a high volume database, the option «Stored results» for a partial restoring cannot be used. Full restoring or the other options for partial restoring can be used.

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- In the Storage menu displayed in standard mode, when the transfer to the LIS of a patient profile is requested while one of multiple replicate results is selected, this selected result is not sent with the profile results. The relevant profile must be selected to ensure sending of the complete profile.
- In certain cases, assays schedule to a first cartridge but not complete, may remain in error (red tick) despite a second cartridge of the same lot being on-board. The first cartridge may also not be fully used. In this case, the run cycle must be stopped and the relevant assays must be deselected (uncheck the box) prior to be selected again.
- Rounding at 0.1 mAbs may be different for the same result.
- When two analytes use the same cartridge, the number of available tests can be incorrect. In this case, all assays requested for the two analytes will be carried out.
- The blue contour is applied only to removable racks in the sample compartment.
- A countdown before use may not resume when the cartridge is removed less than 5 minutes. In this case, a new countdown begins.
- The status of a faulty calibration is not updated when excluding one of the calibrator replicates during a run. Patient results and controls are calculated. The calibration status will be updated once the run cycle is stopped.

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List of C E **symbols used on the analyser**

⚒	Manufacturer.
IVD	In vitro diagnostic medical device.
📖	Consult the instructions for use.
⚠	Caution recommended: see Safety Precautions.
☣	Risk of biological contamination.
⚠	Risk of crushing injury.
♲	Electrical and electronic waste. Dispose of in accordance with current country-specific laws.
♨	High temperature.
✋	Risk of hand injury.

DECLARATION DE CONFORMITE CE
EC DECLARATION OF CONFORMITY

Je, soussigné Alain ROUSSEAU, Président Directeur Général de IDS France, déclare que le :
Undersigned Alain ROUSSEAU, IDS France CEO, declares the:

Dispositif
Device

> **IDS-iSYS**
>
> Système automatisé de multi discipline
> *Multi Discipline Automated System*
> Référence produit/*Product Reference:* IS-310400
> GMDN code: 35742 / 42823

est conforme aux exigences essentielles des Directives suivantes :
complies with the essential requirements of the following Directives : :

Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
Directive 98/79/EC in vitro diagnostic medical device
Directive 2014/35/UE Directive relative au matériel électrique destiné à être employé dans certaines limites de tension
The Low-Voltage Directive 2014/35/EU

depuis le 11 décembre 2008.
since December the 11th of 2008.

Classification : générale selon la Directive 98/79/CE
Classification: general pursuant to the Directive 98/79/EC

Procédure d'évaluation de conformité et Documentation Technique : Annexe III de la Directive 98/79/CE
Conformity Assessment Procedure and Technical Documentation: Annex III of the Directive 98/79/EC

Cette conformité est basée sur l'application (entre autres) des normes harmonisées suivantes :
This conformity is based on the application (between others) of the following harmonized standards:

- Normes de sécurité électrique CEI 61010-2-101et CEI 61010-1
  Electrical safety standards IEC 61010-2-101and IEC 61010-1
- Normes de compatibilité électromagnétique CEI 61326-2-6 et CEI 61326-1
  Electro-magnetic compatibility standards IEC 61326-2-6 and IEC 61326-1
- Norme assurance qualité EN ISO 13485
  Quality management standard EN ISO 13485

Fait le/*done the* : 10-07-2014

Alain ROUSSEAU

IDS FRANCE
42 rue Stéphane Mazeau
21320 POUILLY EN AUXOIS
FRANCE

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SECTION 1:
Operating principle

Section 1

Operating principle   1

ids·isys is an in vitro diagnostic analyser. It enables Immunoassay and Biochemistry assays to be carried out on a single analytical platform:

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

· Biochemistry.
  · Substrates.
  · Enzymes.
  · Electrolytes.
  · Specific Proteins.

The **ids·isys** analyser is intended for professional use and must only be used by trained personnel working in compliance with the precautions for use set out in this manual (see Section 1-6-1, page 15) and good laboratory practice (GLP).

Operating principle

ids·isys is an in vitro diagnostic analyser. It enables assays using different systems of detection to be carried out on a single analytical platform: luminescence and spectrophotometry, applied to the different fields of clinical biology, Immunoassays and Biochemistry.

The analyser can support Immunoassays based on the principle of chemiluminescence as well as assays using an enzymatic detection.

The analyser enables the complete automation for Immunoassays and Biochemistry tests.

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 both fields. The measurements specific to each principle are carried out directly in the reaction cuvette:

· Luminescence measurements carried out in the luminometer.
· Absorbency measurements carried out continuously by the spectrophotometer.

Designed for continuous loading, the analyser works on a sample-by-sample basis.

With all modules fitted the analyser comprises the following key components:
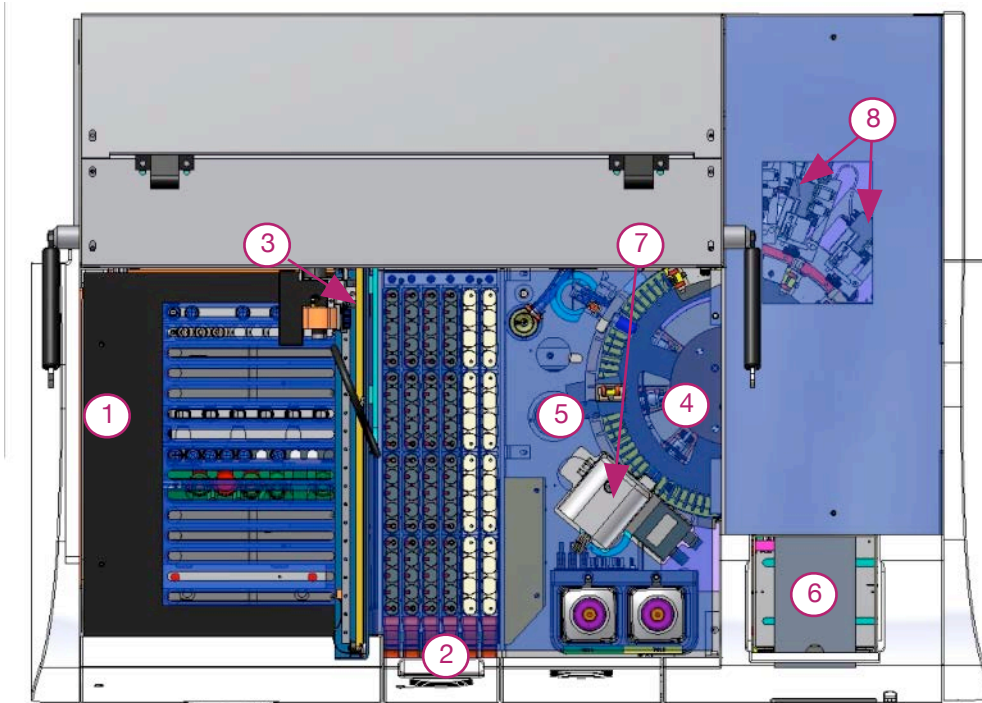
1. A refrigerated reagent compartment, consisting of 15 rails containing the Immunoassay or Biochemistry racks as well as a specialised rack for chronometric reagents.

2. A compartment for samples , calibrators and controls with, depending on the analyser configuration, a fixed sample tray with 64 positions , or a rack containing 6 removable trays each with 20 positions.

3. A pipetting arm that pipettes both reagents and samples.

4. 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.

5. A sedimentation module for magnetic particles.

6. An automatic cuvette loader, holding 960 cuvettes at a time (pre-formed as a cube).

7. A luminometer measuring luminescence in Immunoassay reactions (Immunoassay version).

8. Four washers for washing magnetic particles.

The barcode reader integrated into the reagent compartment identifies reagent cartridges supplied by IDS.

A second barcode reader, located on the front of the analyser identifies ancillary reagents.

Samples, calibrators and controls are identified or by the reader located on the front for analysers with a fixed sample tray, either by a reader integrated into the sample compartment for analysers with removable sample trays.

Operating principle

For the fixed-tray configuration, each position is equipped with a detection sensor. Samples are identified by the barcode reader (on the front) prior to loading the sample, or manually programmed after sample loading.

For the removable-tray configuration, the tray and each of its positions are identified when loading by the integrated barcode reader.

Configuration with removable sample trays
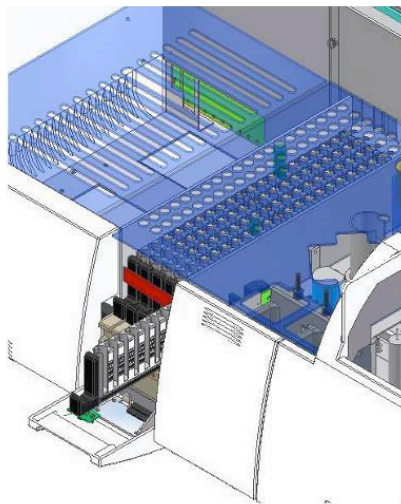
The reagent cartridges are stored in the refrigerated reagent compartment between 12 and 15°C while the analyser is operating and between either 8 and 10°C or 12 and 15°C in standby mode (depending on the analyser configuration).

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.

When Biochemistry regents available from third-party suppliers 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.

When the reaction is over, depending on the type of the assay, the cuvette is either transferred to the luminometer for chemiluminescence assays or kept in the carousel for enzymatic assays.

For chemiluminescence assays, trigger reagents are added to produce luminescence.

For enzymatic assays, substrate is added and the photometric changes are measured continuously by the spectrophotometer.

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 program 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

Analyser

System	• Multidiscipline Immunoassay and Biochemistry analyser. • Continuous loading. • Configuration: • Immunoassay (4 washers) + Biochemistry.
Analyser Physical Characteristics	• Analyser dimensions: L 105 cm x H 70 cm x W 75 cm. • Overall dimensions: L 124 cm x H 110 cm x W 71 cm. • Weight: 103 kg. • Basis weight: 130 kg/m^2 • Sound level: 55 dB (average in run cycle); up to 66 dB • Emitted heat: up to 530 W (1808 BTU/h or 16,5 cal/s) • Computer System: L 60 cm x H 40 cm x W 50 cm.
Throughput	• Immunoassay Up to 120 tests/hour (Assay dependent)*. • Biochemistry 240 tests/hour. * According to configuration.
Number of tests on board	• 15 Immunoassay. • Up to 50 Biochemistry.
Immunoassay detection	• Chemiluminescence (luminometer). • Enzymatic assays (spectrophotometer)
Biochemistry detection	• Colorimetric and enzymatic assays. • Turbidimetric assays.

Samples	• Serum, plasma or urine.
	• Primary tubes 5 mL (13 x 75 mm), 7 mL (13 x 100 mm).
	  10 mL (16 x 75 mm).
	• Secondary tubes (13 x 75 mm).
	• Cups (ref. IS-CSC105 and ref. IS-CSC115).
	• Depending on the configuration, positions for samples, calibrators and controls:
	  • Fixed tray : 64 positions
	  • Removable trays : 20 positions per tray. Up to 6 trays on board. Possibility of special tray for calibrator and control vials (16 positions for 2ml vials, diameter 18 mm).
	• Liquid level detection by capacitance.
	• Clot detection.
	• Dilutions and automatic pre-treatments.

Barcode readers	• Reader on front face for barcode identification of cuvettes and ancillary reagents. Used for sample identification in fixed tray configuration. • Integrated reader for reagents barcode • For configuration with removable trays, reader integrated into the sample compartment.

Reagent compartment	• 15 rails, each of which can hold:
	  • 1 x Immunoassay cartridge.
	  • 3 x 50 mL Biochemistry Reagent.
	  • 6 x 20 mL (or 5 mL) Biochemistry Reagent.
	• Storage at 12-15°C whilst operating.
	• Internal storage between 12-15°C or 8-10°C* in standby mode.
	* Depending on the analyser configuration

Sample volume (µL)	• Immunoassay: from 4 to 300 µL. • Biochemistry: from 4 to 50 µL. • Programmable in steps of 0.5 µL.
Reagent volume (µL)	• Immunoassay: from 10 to 400 µL. • Biochemistry: from 10 to 400 µL. • Programmable in units of 1 µL.
Reaction volume (µL)	• Immunoassay : up to 500 µl • Biochemistry: from 180 to 550 µL.
Pipetting system	• Pipetting reagents and samples by probe. • Liquid level detection by capacitance. • Preheating of reagents/samples. • Internal and external rinsing between each pipetting of sample.

Spectrophotometer	• Linearity: Up to 3 Abs.
	• Optic path of cuvettes: 0.8 cm.
	• Spectrophotometer with interferential filter wheel:
	  • 6 wavelengths available: 340, 405, 500, 540, 580 and 620 nm.
	  • Light source: Halogen lamp.
	• Spectrophotometer with LEDs:
	  • 12 wavelengths interferential filters: 340, 405, 450, 500, 540, 550, 580, 620, 650, 700, 720 and 750 nm.
	  • Light sources: multiple LEDs.

Luminometer	• Wavelengths: from 300 to 500 nm. • Linearity: Up to 10 Million RLU.
Reaction carousel	• Thermo regulated at 37°C. • 90 positions for disposable cuvettes. • Automatic cuvette supply by cuvette loader.
Cuvette loader	• Loader for cube of cuvettes. • Contains 960 disposable cuvettes. • Preheated loader.

Common liquid consumables	• IDS-iSYS System Liquid (5 litre containers).
	• IDS-iSYS Wash (10 litre containers).
	• IDS-iSYS D-Sorb (1 litre containers).
	• Immunoassay only:
	  • IDS-iSYS Triggers A & B (250 mL each).
	  • AP Substrate Chemiluminescence substrate (500 mL) *
	* Depending on the analyser configuration

Waste collection	• 10 liters container for liquid waste posing a biological risk. • Solid waste (cuvettes) disposed of in re-usable container.
Power supply	• Voltage: 100 - 240 V. • Frequency: 50 - 60 Hertz. • Maximum power consumed: 750 VA.

Computer system: Minimum configuration required

Operating system	• Windows XP Pro Service Pack 2. • Windows Vista Service Pack 1. • Windows 7. • Windows 8.
Microprocessor	• Type Sempron 3100 or equivalent. • Windows 7: 1 gigahertz (GHz) or faster 32-bit (x86) or 64 bits (x64) processor
Live memory	• 4 Gb. • Windows 7: 4 gigabyte (GB) RAM (32-bit) or 4 GB RAM (64-bit).
Hard disk	• 80 Gb. • Windows 7: 16 GB available hard disk space (32-bit) or 20 GB (64-bit).
Ethernet	• 2 independent Ethernet network adaptors.
Ports	• USB ports (min 2 one of which at front). • Serial port for connection to centralised computer system.
Input devices	• Keyboard (country specific). • Mouse.
Screen	• Monitor. Speakers integrated.
Screen resolution	• 1024 x 768 pixels.
Peripherals	• Reader – CD writer. • Windows 7: DirectX 9 graphics device with WDDM 1.0 or higher driver.

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   80% non condensing.

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.

> **!** After installation by Technical Services or an IDS representative, do not handle or move the analyser.
> If the analyser must be moved, contact Technical Services or IDS representative.

1-4-1- Environment

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.
· Relative humidity must be within 20 and 80% (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 be installed in such as way as to allow the user to easily access the ON/OFF button and the main cable inlet.
· The analyser must not be installed near strong sources of electromagnetic radiation and electrical interference (e.g. refrigerators).

The IVD medical device complies with the emission and immunity requirements described in the standard IEC61326-2-6.

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.
· Basis weight   130 kg/m^2 *
· Computer system   L 60 x H 40 x W 50 cm.

* Analyser only. Basis weight of analyser and its special table: 278 kg/m^2

1-4-2- Electricity supply

The electricity supply must meet the following conditions:

- Voltage   100 - 240 V.
- Frequency   50 - 60 Hz.
- Maximum power consumed 750 VA.

If necessary, the installation of a regulated electrical supply may be required by IDS Technical Services.

> **!** In order to ensure the analyser's electrical safety (in accordance with standards), it is essential to check that the analyser and its associated peripheral computer equipment (external printer and computer) are properly earthed.

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.
AP Substrate	Green	Immunoassay*.

* Depending on the analyser configuration
- 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, Liquid Waste and, if relevant, for AP substrate.

Electrical connections

The electrical connections are located on the left hand side of the analyser.
- Connect the Ethernet cable (RJ 45, 8 pins) between the analyser and the PC (local network).
- 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.
· Absorbancy measurements carried out continuously by the spectrophotometer.

Depending on the type of the assay, Immunoassays using the chemiluminescence method are measured by the luminometer and by the spectrophotometer for enzymatic detection assays.

BIochemistry assays are measured by the spectrophometer.

1-5-1- 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.

1-5-2- Absorbancy measurements

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.

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:

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

Where:
· I_0 Light flow at cuvette entrance.
· I Light flow at cuvette exit.
· ε 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 0.8 cm and corrected for an optical pathway of 1 cm.

1-5-3- Immunoassays

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 the 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.

For chemilumescence assays, after washing, the cuvette is transferred to luminometer where trigger solutions are injected into the reaction cuvette. For enzyme-luminescence detection assays, after washing, the substrate is added into the cuvette then transferred to the luminometer.

For enzymatic assays, after washing, the substrate is added into the reaction cuvette where the reaction takes place. Increases in absorbancy are monitored by the spectrophotometer.

The signal generated by detection of the captured complexes is directly proportional to the concentration of analyte in the sample.

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.

1-5-4- Biochemistry assays

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.

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.
- **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:

$$\text{Activity} = \frac{V_T \times \Delta \, DO/mn \times 1000}{V_E \times l \times \varepsilon}$$

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

Comment: In the set-up, the factor entered is equal to $\varepsilon \times 100$

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.

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

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

1-6-1- General precautions

- When installing Immunoassay cartridges into the reagent compartment, each reagent rack must be properly inserted as shown on the sticker displayed on the reagent compartment cover (see 3-2- Installation of reagents, page 38). Incorrect positioning of the rack onto its rail may cause either an insufficient mixing of magnetic particles in their vial or incorrect pipetting of reagents.
- After start up or installation of a new reagent, a waiting period is necessary before using the reagent in an assay. For Immunoassay cartridges this should be 40 minutes for temperature equilibration and magnetic particle re-suspension (for biochemistry this should be 20 minutes to allow temperature equilibration). The waiting period is automatically managed by the system through a count-down displayed on each reagent position. Interrupting a count-down may impair the quality of analytical results.
- When the lid of the analyser is not equipped with a locking system, 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).
- An activation key is provided with the accessories for analysers equipped with a locking system. The use of the activation key is strictly restricted to the adjustment of probe position described in Section 5, **5-4-10-2- Adjustment procedure for analyser with lid locking system**, page 136.
- 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, do not remove the solid waste. The solid waste tray must be present to enable the analyser to function.
- The solid waste can contain 400 cuvettes. The waste can be emptied during operation. It is recommended to empty the solid waste before starting the run cycle
- Make sure that the reagent and sample racks are clean at all times.
- During sample programming (either from the interface software or via the centralised computer system), verify that the appropriate sample type is selected. The type «**Serum/Plasma»** must be selected for each blood sample, whether collected in a dry tube (serum) or collected in a tube containing anticoagulants (plasma). The type «**Urine»** must be used only when defined in the assay setup (refer to the reagent IFU). The type «**Other»** must be used when specified in the reagent IFU.
- The validity of results obtained depends on the correct programming of the sample type.
- Verify that the barcode reader can recognize the barcode symbology used for sample tubes (see Appendix A-5, page A7). The character «%» is not recognized and must not be used. It is recommended to use a symbology containing a check character.
- When installing a sample tube, check that the barcode number corresponds to the sample identification.
- Do not expose the eyes to the beam of barcode readers.
- The database is automatically backed up once a week when opening the application. Operators should store back-ups from the computer onto CD or USB flash drive.
- To ensure confidentiality of results, patient demographic information (name, birth date, ...) are encrypted in the database. An encryption key is generated in the first installation of the software. A copy is kept on the Windows desktop. Keep a backup of the encryption key, outside the computer.
- 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).

- 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 biochemistry reagents is the responsibility of the user and IDS takes no responsibility for the validity of results.
- 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 precautions for use specific to certain handling procedures described throughout the user manual are indicated in the following format:

· **Important notice**

· **Precaution which MUST be respected**

1-6-3- Safety precautions

The safety precautions specific to certain handling procedures are described throughout the user manual in the relevant paragraph and are associated with a symbol specific to the potential risk, in the following format :

WARNING:

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.

Menu Bar   Information buttons

Reagent   Status bar   Function   Unlock lid   Sample Compartment[2]
Compartment   buttons   button[1]
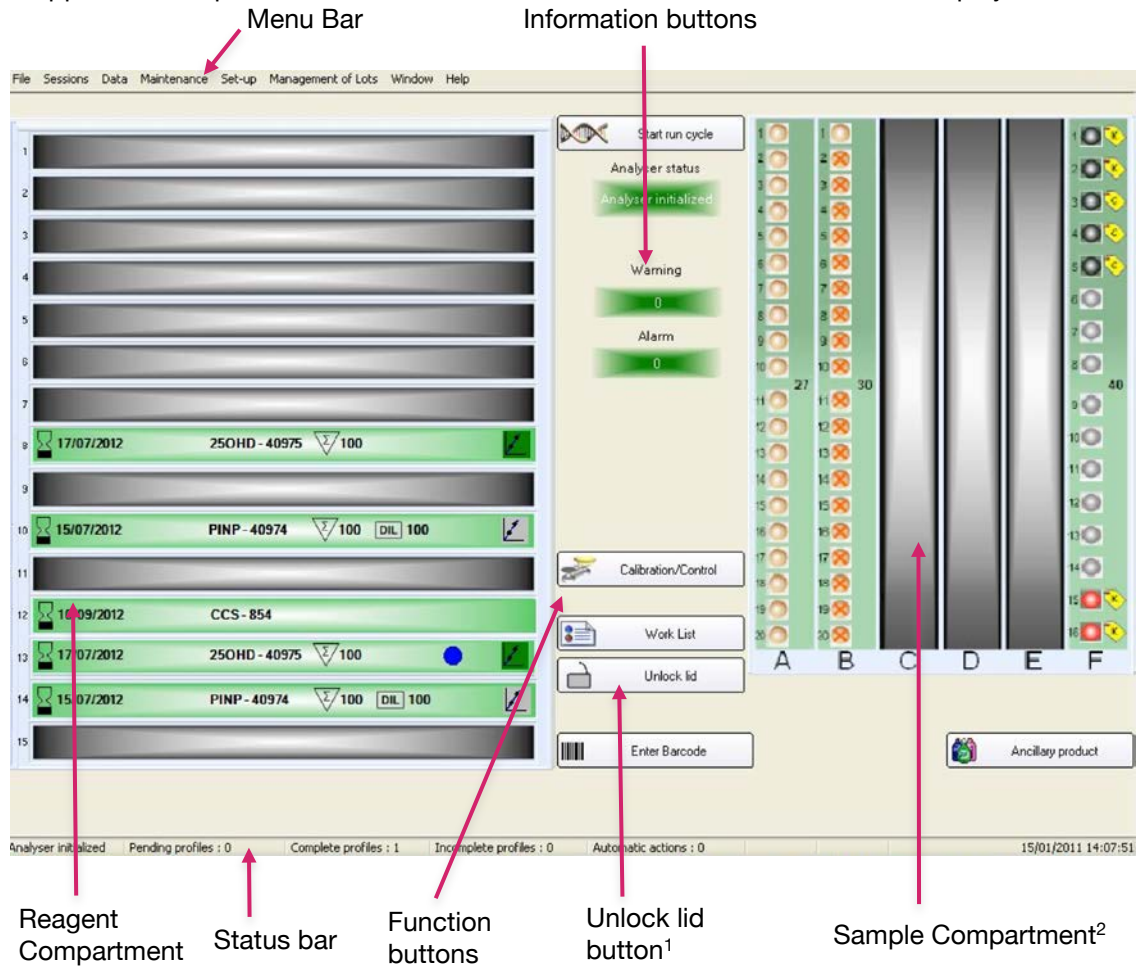
[1] Only for analyser equipped with a lid locking system

**[2] Configurations of
Sample compartment**
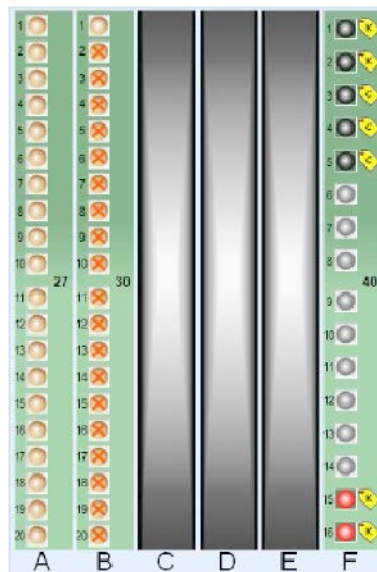
Removable trays   Fixed tray
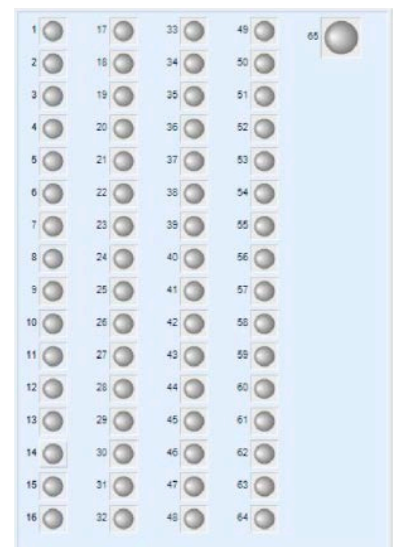
User Interface Software

2-2- Main Screen (continued)

Menu bar
Provides access to the different pull-down menus.

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

The illustration 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.
· On-board expiry date.
· Number of tests remaining.
· Status of the reagent indicated by a colour code (see Section 3, page 43).
· Status of the current calibration (see Section 3, page 44).
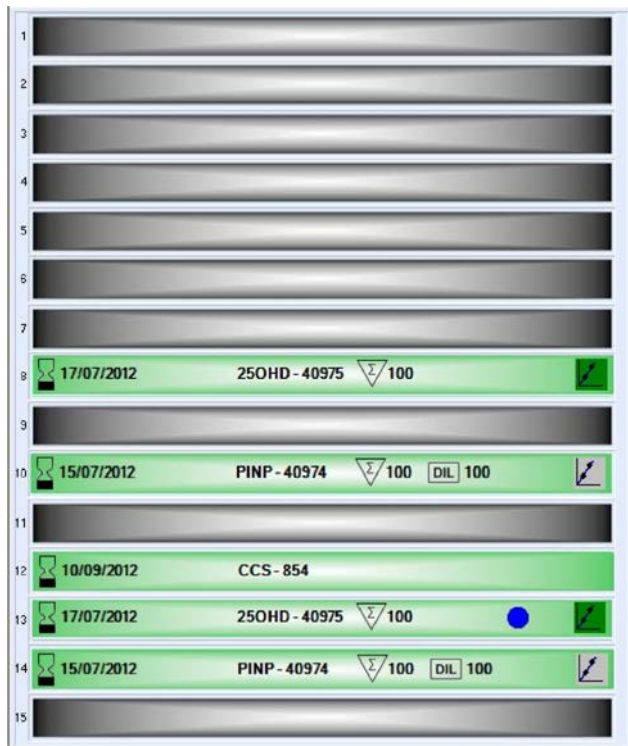
Detailed information for each analyte may be accessed by clicking on the cartridge, in the case of Immunology, or individual Biochemistry reagents.

Information includes:
· Test name.
· Reagent type.
· Lot number.
· Container number.
· Type of container.
· Lot expiry date.
· Master curve number.
· In-use stability.
· On-board stability.
· Cumulative time on-board.
· On-board expiry date.
· For Immunology cartridges, the number of remaining tests available after completion of the programmed workload.
· For Biochemistry reagents, the available volume and number of tests remaining.

User Interface Software

2-2- Main Screen (continued)

Information Application Buttons

System status
System initialized
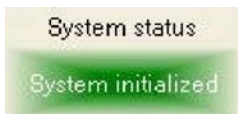
Provides access to information regarding the analyser status including :
- General status of the apparatus (initialised, standing etc.).
- Status of the various modules.
- Allowed/forbidden assays depending on the field.
- Temperatures : reagent compartment, carousel, ambient.
- Status of reagents.
- 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).

Warning
0

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.

Alarm
0

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.

User Interface Software

Function application buttons

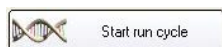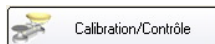|	
Start run cycle	Starts the run cycle.
Calibration/Contrôle	Accesses calibration and quality control requests. Displays the current calibration for each on-board lot of reagent.
Work List	Provides access to the work list and generated results. Contains profiles sent by the Laboratory Information System (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.
Enter Barcode	Allows manual entry of a barcode identifier for samples or reagents in the event of a misreading by the integrated barcode readers.
Ancillary product	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.
- Lot expiry date.
- In-use stability*.
- Cumulative time on-board*.
- On-board 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.

* not managed for cuvettes

Unlock lid button
(only for analyser equipped with a lid locking system)

Unlock lid	This button is displayed only when the analyser is equipped with a lid locking system. In this case, the lid is continuously locked. As the lid must be opened for maintenance tasks or interventions, access to the lid is authorised when the analyser is not in cycle mode. The button, when displayed, allows the user to unlock the lid before opening.

User Interface Software

Sample compartment

The illustration of the sample compartment depends on the analyser configuration. For the two configurations (fixed sample tray or removable trays), the occupied positions are shown.
Each position can be occupied by:

- Calibrators.
- Controls.
- Samples.
- Stat.

An icon identifies the type of sample installed in a position (see Section 3, page 67).
For each occupied position the following options are available:

- Entry of the identifier and the type of product installed (without a barcode).
- Programming of the sample analyses to be carried out.
- Results display for controls or samples.

A colour coded analysis status is associated with the center of the position (see Section 3, page 80).
A colour code is associated to the contour of the positions, to inform whether the system is using the installed product (see Section 3, page 68). During a run cycle:

- a blue contour colour indicates that the installed product is scheduled in the workload and can still be removed; remove this product and the planned workload will be modified.
- a green contour colour indicates that all the tests programmed for the sample are completed. It is possible to configure the software in **LOCAL SYSTEM SETTINGS** menu to change the contour colour at the end of sampling rather than completion of assays. The same colour code is applied on each tray for the removable-tray configuration.

Removable trays
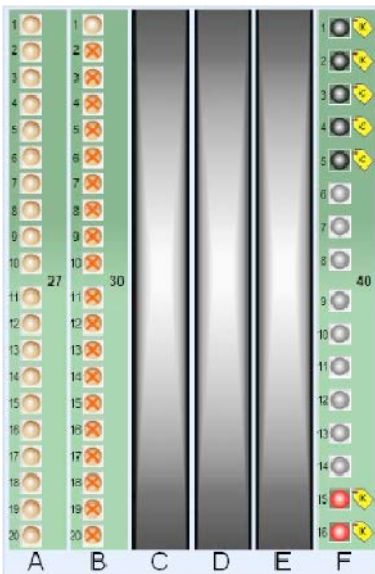
The illustration to the left shows the sample compartment with the on-board trays
The tray and its samples are identified by the integrated barcode reader when loading the tray in the compartment.
Each tray is numbered.
For each tray, the free and occupied positions are displayed. Each position can be occupied by :

- calibrators,
- controls,
- samples

The positions occupied but not identified by barcode reading are programmed after loading the tray in the sample compartment.
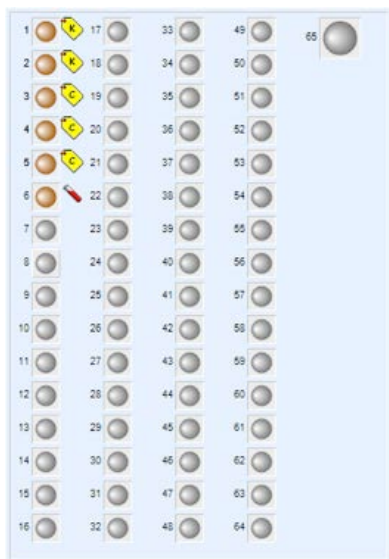Any position of a 20 position-tray may be used to load a calibrator, a sample or a stat sample.
A colour code is associated with the removable-tray configuration (see Section 3, page 67).

User Interface Software

Fixed 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, a sample or a stat sample.

Status bar

Displays information regarding:
· the analyser status,
· the work list status,
· the connection activity of the analyser (**COM** flashes blue in normal activity;   fixed when there is a break in communication),
· the connection activity with the centralised computer system (**LIS** flashes blue in normal activity;   fixed 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.

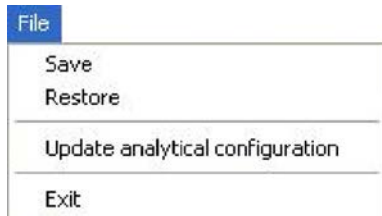Other functions are accessed by using the pull-down menus on the interface.

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

2-3-1- FILE Menu

File
Save
Restore
Update analytical configuration
Exit

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.

Update analytical configuration

Allows the user to update the analytical configuration from the CD-ROM Master Database provided by Immunodiagnostic Systems.

Exit

Allows the user to exit the software.

2-3-2- SESSIONS menu

Sessions	
Start up	
Shut down	
Work List	F2
Start Run Cycle	F3
Stop Run Cycle	F9
Run cycle Monitoring	F6
Volumes monitoring	
CCS Management	▶
Automatic identification of the sample tray positions	
Manual identification table	
Access	▶

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.

Work List — Access to the work list: (see page 22).

Start Run Cycle — Allows the user to start the run cycle: (see page 22).
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.

CCS Management — 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.

Manual identification table — *Active only when removable-tray configuration (use in fail mode)*
Simplifies programming of the work list by applying the same profile to each occupied position of a removable sample tray.

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.

User Interface Software

2-3-3- DATA menu

```
Data
  Calibrations      F5
  Results storage   F4
  Quality Controls  ▶
  Records
  Working panel     ▶
  Master curves
  Counters
```

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.

Quality Controls ▶ LEVEY-JENNINGS ▶
WESTGARD
History by Product
Printings ▶
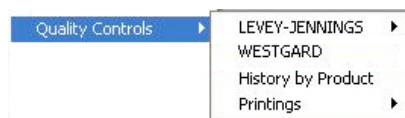
Analysis of quality controls results.
· LEVEY-JENNINGS: cumulative analysis of the results obtained by test or by a control lot for a programmable period of time.
· WESTGARD: inspection of the control results with selected rules.
· History by product: record of the results obtained for each reagent and 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
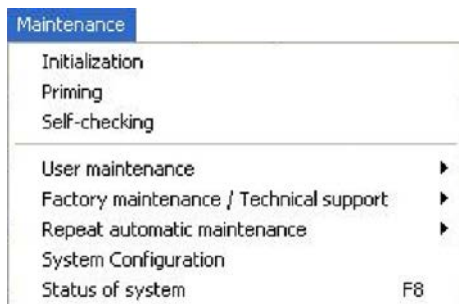
Reserved for IDS Service and Support Personnel.

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:
- XYZ adjustment: adjustment of the probe reference position.
- 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.
- Trace machine: used at the request of IDS Technical Services & Support; allows the exporting of data from the device for Service diagnostics.

Factory maintenance / Technical support

Reserved for IDS Service and Support Personnel.

Allows the user to carry out on demand one of the maintenance activities automatically managed by the system.
- Washer needle cleaning: washer needles are cleaned by aspirating IDS-iSYS D-SORB solution. The relevant volume is pipetted by the sampling needle and distributed into four cuvettes. The cuvettes are transferred to the washer module. After washing, these cuvettes are eliminated into the solid waste. This automatic maintenance takes place when the system is placed in standby mode.
- Cleaning sample needle: certain categories of assays (infectious diseases, auto-immunity) require an additional cleaning of the sampling needle. This automatic maintenance activity is displayed when the personal library contains a such assay. The cleaning solution (Immunocleaner) is placed into the reagent compartment. 0.9 mL of solution are sampled by the needle, followed by a full rinsing of the needle using D-Sorb solution. This automatic maintenance takes place when the system is placed in standby mode.

2-3-4- MAINTENANCE menu (continued)

System Configuration

Used only at the request of IDS Technical Services & Support: allows the user to deactivate a washer module or a specific wavelength in case of failure.

Status of system

Displays the analyser status (see Section 2-2, page 21).

2-3-5- SETUP 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.

Analytical configuration

Personal library

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

Reflex tests

Allows the user to program reflex tests. Depending upon defined conditions, the result of an analyte obtained for a sample can trigger additional assays on the same sample (see page 156).

Suppliers and Products

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

Memorized Profiles

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

Rack configuration

For removable-tray configuration:
Allows the operator to define for each removable rack:
· the type of rack:
    - M (mixed): for samples, calibrators and controls
    - 1.25D ME: dedicated for 1,25 D immunopurified samples (manual extraction)
· the default sample container for the rack: tube, cup, ….
· the start option : automatic or on demand start.

**Settings**

Allows the operator to personalise the system:
· Local 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).

User Interface Software

2-3-6- MANAGEMENT OF LOTS menu
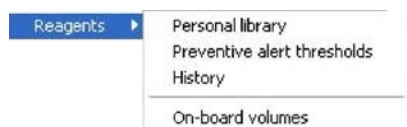
Displays reagents used on the system:
· Personal library: data storage for different reagent lots for the tests in the personal library. For each cartridge the identifier, the lot number, the lot expiry date, the in-use and on-board stabilities, the records of loading/unloading operations, the dates of first and last uses 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.
· History: 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.
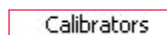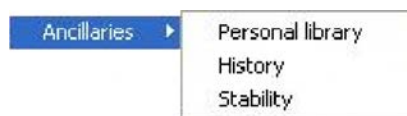

Lists calibrators used on the system.
Allows users to manually input the values for each lot of calibrator.
Allows activation of the calibrator lots used for a specific assay.

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 ancillaries used with the system.
· Personal library: information regarding the different lots of ancillaries used with the system.
  Allows display of the identifier, the lot number and its expiry date, the in-use stability (cuvettes excepted), the dates of first and last use and the remaining quantity (volume or number of cuvettes) for each individual product.
· History: traceability of calibrations, controls and results obtained with each ancillary.
· Stability: displays the in-use stability value for the relevant ancillaries.

2-3-7- HELP menu
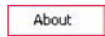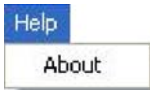
   Displays information concerning software (for example, specific version).

User Interface Software

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

Use	**34**

The purpose of the analyser lid is to protect the user when the pipetting arm moves.

Opening the lid during use stops any movement of the pipetting arm in order to guarantee the user's safety during operation.

All analysers are equipped with sensors to detect the opening or closing of the lid.

To increase the level of security, the latest analysers are now equipped with an electro-magnetic lid locking system, managed by software.

The locker is located under the lid, at the rear, right side. The lid is continuously locked, even when the analyser is off. The lid can be opened only after sending the unlock command from the user interface.

Access to the lid's opening is controlled and authorised only when the analyser is not in cycle mode. In this case, the unlock lid button is displayed on the main screen.

Certain operations described from this section require the lid to be opened e.g. installation of TRIGGER A and TRIGGER B, maintenances, etc. Depending on the presence or absence of the locking system, the procedure for the lid's opening is different.

The lid must always be fully opened and the lid support tool provided with the analyser must always be installed in order to ensure the user's safety.

When the lid support tool is fully inserted onto the piston rod, the lid can not accidentally fall down.

Analysers without locking system

The lid can be opened directly. The sensors on the analyser will detect that he lid has been opened and prevent any movement of the pipetting. The only exception to this is during the adjustment procedure for the reference position of the sampling needle.

When the lid is opened, the pipetting arm is powered but remains in its last position and any movement is stopped. An accidental opening during the run cycle interrupts sampling and may result in recycling.

Analysers fitted with locking system

The lid can only be opened if unlocked. Lid unlocking is requested by using a function button on the main screen, displayed only if the analyser is not in cycle mode. Before final unlocking, the pipetting arm moves to its home position, located at the left side of the reagent compartment, with the sampling system on its bracket. The pipetting arm is then turned off and the lid can be opened to perform the required operations. The lid is locked as soon as closed. The pipetting arm will remain in home position until the next use (run cycle, priming,..).

- From the main screen, click on .

  The command for unlocking is sent to the analyser
- The message displays:

  The sampling arm moves to its home position.
- When the lid is unlocked, the message and the unlock button are no longer displayed.
- The lid can then be opened.

Opening the lid

· When access is authorised, open the lid up to its maximal position.

· Insert the lid support tool onto the piston rod until the clips is fully inserted.
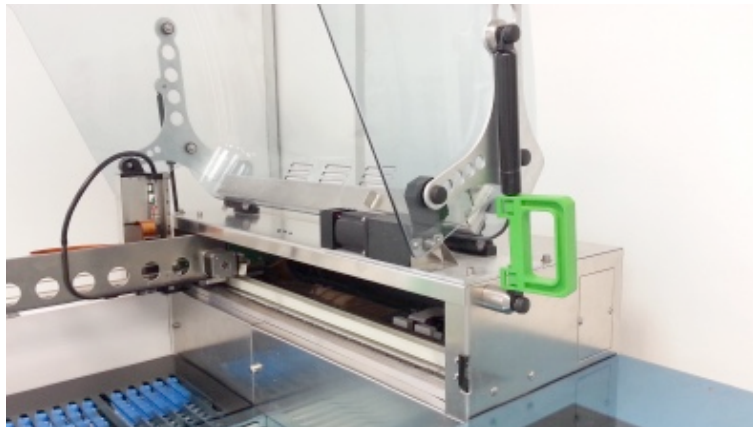
Closing the lid

· Hold the lid in upper position using its handle.
· Remove the lid support tool.
· Gently lower the lid until closing.

Use
3-1- Start up

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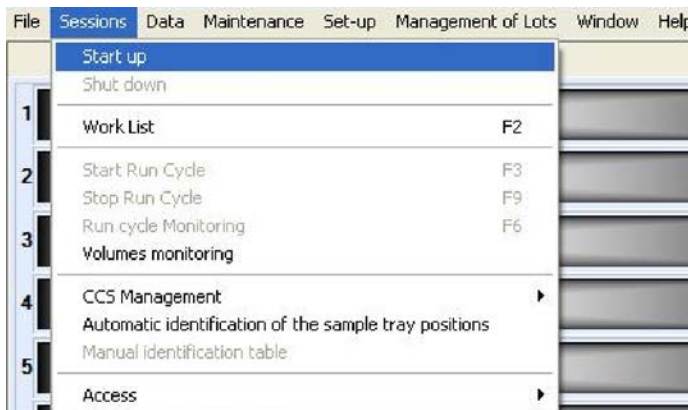
All modules are initialised and the ancillary reagents are automatically primed.

> ⚠ 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.
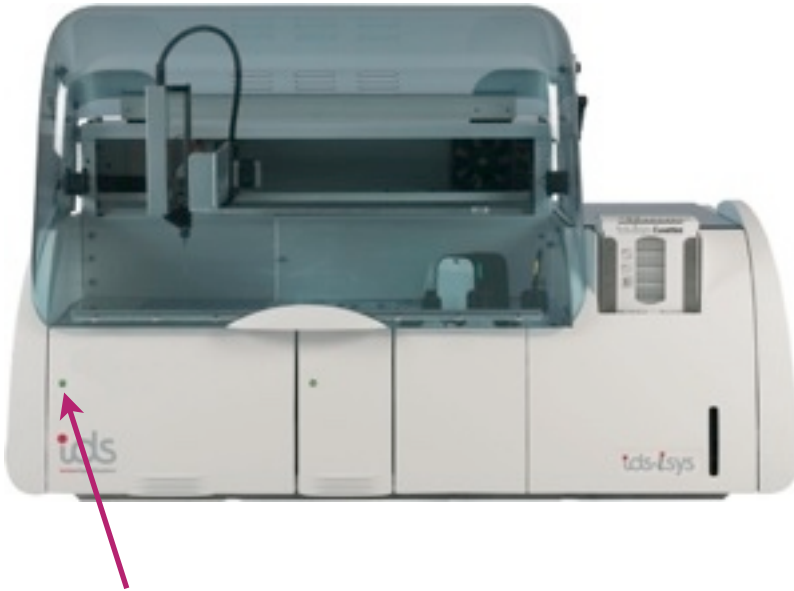
🟢	Access authorised (Drawer unlocked).
🔴	Sampling in progress. Access denied (Drawer locked).
🟡	(Flashing between red and green) Sampling in less than 2 minutes.

> ⚠ 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.

Access to the reagent compartment is controlled. The light located on the front face of the drawer indicates whether access is authorised (green indicator) or if the drawer is locked (red indicator).

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.

> ! For cartridge handling, refer to the reagent instructions for use (IFU).
> Magnetic particles in certain Immunoassay cartridges require a particular mixing step before loading the cartridge into the rack. Follow the instructions for mixing described in the reagent instructions for use.

Biochemistry reagents are supplied in the form of individual reagent bottles.
Biochemistry reagent racks are designed to contain either 6 x 20 mL bottles or 3 x 50 mL bottles.

Rack 6 x 20 ml

Rack 3 x 50 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.
The magnetic particle vial of Immunoassay cartridges is continuously stirred when in the reagent compartment.

The pictogram below appears on the reagent cover, and describes the precautions to be taken when loading a reagent rack:

Installation of reagents in the refrigerated compartment

- 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.
- Push down the rack handle to ensure the reagent rack is firmly positioned at the bottom of the compartment. The reagent rack should be firmly locked and should not move during the stirring of magnetic particle vial.
- Visually check the magnetic particle vial of Immunoassay cartridges is stirring in a smooth motion.
- Repeat for all the racks to be installed on the analyser.

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.
The countdown sequence until use begins automatically.

> ⚠ Each time a cartridge (or a reagent bottle) *already stabilized on-board* is removed then installed again in the compartment, a countdown before use begins, even for an immediate reloading.
> Handle the reagent racks only when necessary.

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

> ⚠ It is imperative, when installing a cartridge or a reagent bottle, that each occupied position of the reagent compartment should be immediately identified.
> Otherwise, the management of reagents provided by the system (see **3-2-3 Management of on board reagents**, page 44) may be impaired and the results generated may be incorrect.

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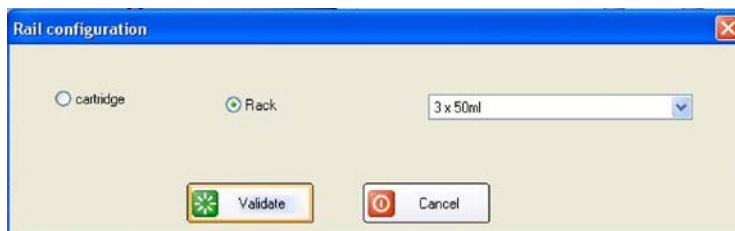
- To select an Immunoassay rack, click on "Cartridge" and use the keyboard to manually enter the barcode identifier for the cartridge.

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.
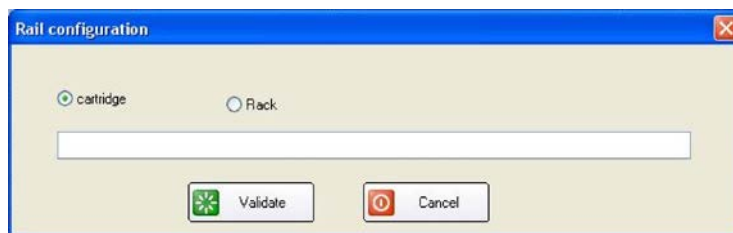- In this case, install the CD supplied with the kit and use the keyboard to re-enter the barcode identifier.

- To select another type of rack, click on "Rack".
- Then select the type of rack installed:
  - 3 x 50 mL, for Biochemistry reagents.
  - 6 x 20 mL, for Biochemistry reagents.

3 x 50 ml rack

6 x 20 ml rack

- 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.

Management of waiting period before reagent use

As soon as a reagent loaded in the reagent compartment is identified by the system, the countdown until use begins.

The remaining time before use, expressed in minutes and second, is displayed inside the cartridge icon 18:58 .

This delay before use allows the reagent temperature to stabilize to the compartment temperature, and the magnetic particles to be sufficiently stirred in Immunoassay cartridges.

This time is managed specifically per analyte and individually for each on-board reagent.

A cartridge can be removed during this waiting period. If the time removing is under 5 minutes, the current countdown continues.

If a cartridge is removed with more than 5 minutes left, the countdown is stopped and a new countdown begins.

A countdown may be stopped in certain clearly identified cases (e.g., quick unloading of a reagent previously on board):

· Click on the relevant cartridge or reagent.

· In the detailed information window, click on Stop :
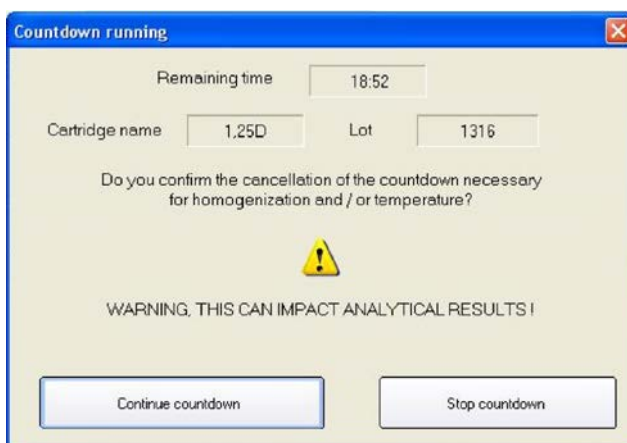
· To stop the countdown, click on Stop countdown .

The cartridge will be used for running assays as soon as the countdown has been stopped.

· To continue the current countdown, click on Continue countdown .

Reagent will be used in assays when the countdown ends.
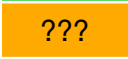
> The reagents must be stabilised at the temperature of the refrigerated compartment before use. Magnetic particles in Immunoassay cartridges must be sufficiently stirred.
> Wait for 40 minutes after installing reagent cartridges before starting assays (20 min for Biochemistry).
> Any interruption of countdown before use may impair the analytical quality of results.

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.
	Preventive alarm threshold reached.
	Reagent volume inadequate or deadline for using over.
	Information associated with the reagent not available.
	Reagent detected higher than the maximum filling level.

3-2-2- Information displayed with reagents

The main information regarding on-board reagents is directly displayed via its graphic representation. Detailed information is displayed by clicking on the relevant reagent.

Immunoassay cartridges

17/07/2012	Deadline for using the cartridge on the system. Date is replaced by expiry time when the day of expiry date begins.
18:58	Countdown before use (after reagent loading).
PINP - 40975	Test name and lot number.
Σ 100	Number of remaining tests.
DIL 100	Number of available dilutions (only for tests using a diluent).
(blue circle)	A calibration will be requested in the next 24 hours for tests using a calibration frequency managed by the system.
	The calibration was recalculated after excluding at least one calibrator replicate
	Status of the current calibration for the reagent lot (see page 44).

Calibration status

The icon on the cartridge shows the status of the current calibration.

	Not calibrated
	Valid Calibration
	Calibration accepted by the user
	Expired or not valid Calibration

Biochemistry reagents
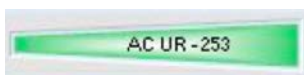
The following information is displayed for Biochemistry reagents:
· test name,
· lot number.

3-2-3- Management of on board reagents

Reagents are managed by the system in terms of:
· available on board quantity (number of tests for Immunoassay cartridges and volume for Biochemistry reagents),
· expiry date,
· in-use stability,
· on board stability.
The expiry date is managed for the reagent lot. Other data are individually managed per cartridge or per bottle of the lot.
When loading a new cartridge or a new reagent bottle the system records the date and time of installation.
All operations of loading / unloading are recorded for each cartridge or each reagent bottle.
Cumulative on board time is calculated from these data (displayed in the format: Days \ Hours : Minutes : Seconds)
All this information can be displayed by clicking on the position occupied by the reagent and is stored in the menu **MANAGEMENT OF LOTS / REAGENTS**.
The two following stabilities, included in the lot data, are applied to each cartridge or reagent bottle:
· in-use stability: period of time during which a cartridge or a reagent bottle can be used after opening and storage in conditions defined in reagent IFU. In-use stability is defined by the system from the date and time of first installation of the cartridge or reagent bottle into the reagent compartment.
· on board stability: period of time during which a cartridge or a reagent bottle can be used after opening when stored on-board. On-board stability is defined by the system from the date and time of first installation of the cartridge or reagent bottle and takes into account the cumulative on board time of the cartridge or reagent bottle.
According to the nature of the reagents, these stabilities are expressed in days or in hours.

By using these stability data, the system manages the expiry of each individual cartridge or reagent bottle installed in the refrigerated compartment. This expiry date is established with the two following dates:
- lot expiry date,
- on board expiry date, defined as the use-by date for using the cartridge or the reagent bottle.

The on board expiry date d'expiration is established by a dynamic calculation based on the following data:
- cumulative on board time,
- on board stability,
- in-use stability,
- lot expiry date.

The on board expiry date (in days and hours) is initially calculated from the first installation date of the reagent and from the on board stability supplied with the lot data. The expiry time is set at 23:59 for all reagents.

Then this date is constantly updated taking into account the cumulative on board time. This date is finally compared with the in-use expiry date and with the lot expiry date.

The cartridge or bottle can be used up to the date and time displayed as its on board expiry date.

The date is replaced by expiry time (23:59) when the day of expiry date begins.

The ancillary reagents comprise:
- IDS-iSYS Cuvettes.
- Internal ancillary reagents.
- External ancillary reagents.

Ancillary reagents are managed by the analyser:
- for available on-board quantities,
- for expiry date,

and, except for cuvettes:
- for in-use stability.

The expiry date is managed for each lot.

When identifying a new ancillary reagent is identified, the system records the date and time of installation.

All operations of loading / unloading are recorded. Cumulative on-board time is calculated from this data (displayed in the format Number of: Days \ Hours : Minutes : Seconds).

The expiry date of each individual ancillary reagent is established from the first on board installation date and from its in-use stability, except for cuvettes. The on board expiry date of each cuvette cube is the lot expiry date. The expiry time is set at 23:59 for all ancillary reagents.

A message displayed in the WARNING window the last day of use for a consumable indicates that expiry will occur later that day.

Detailed information can be displayed by clicking on the icon of each consumable and is recorded in the menu **MANAGEMENT OF LOTS / ANCILLARIES**.

. Click on [Ancillary product] 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, either volume is inadequate or expiry date is exceeded (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
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.
> The lid must always be fully open and the lid support tool must always be installed.
> Take care not to knock the lid during any analyser intervention.
> When the lid is not fully open there is a risk of it falling.
> During closing, maintain the lid open when removing the lid support tool, to avoid any risk of accidental falling.

- Open the lid and insert the lid support tool (see pages 35 and 36).
- 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.
  The analyser will beep for the first time.
- Within 10 seconds, install the new bottle in its position identified by colour code.
- Install the supply line into the bottle.
  The analyser will beep a second time.
- If the barcode is not read by the barcode reader, click on the ancillary reagent then use the keyboard to enter the identifier.
- Remove the lid support tool and close the lid (see page 36).
- Once the new bottles are installed, a message proposing an automatic priming is displayed:

- Click on [Yes] to confirm the priming of the product(s).
  The analyser starts the priming sequence.

  Comment: The automatic priming can be cancelled by clicking on [No]. In this case, the priming will take place automatically when starting a run cycle.

> ! 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.
AP Substrate	Green	Immunoassay*.

*Depending on the analyser configuration

Installation of IDS-iSYS System Liquid, Wash S and D-Sorb
· Remove the lid and level sensor from the container to be replaced.
· Remove the adhesive barcode label for SYST L and WASH container.
· Scan the new ancillary reagent barcode label with the reader located on the front of the machine.
  The analyser will beep for the first time.
· Within 10 seconds, put the level sensor in position within the new ancillary reagent for the IDS-iSYS D-Sorb and IDS-iSYS Wash solutions.
  The analyser will beep a second time.
  Replace the lid and the plunger of the IDS-iSYS System Liquid.
· Priming of the IDS-iSYS System Liquid takes place automatically.
· For other ancillaries, a message proposing an automatic priming is displayed:

· Click on [Yes] to confirm the priming of the product(s).
  The analyser starts the priming sequence.

  Comment: The automatic priming can be cancelled by clicking on [No]. In this case, the priming will take place automatically when starting a run cycle.
· 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.

Installation of AP Substrate
· Remove the cap from the new ancillary reagent bottle.
· If necessary, take out the bung and remove the empty bottle.
· Scan the ancillary with the barcode reader.
  The analyser will beep for the first time.
· Within 10 seconds, install the new bottle in its position.
  The analyser will beep a second time.
· Install the supply line into the bottle.
· If the barcode is not read by the barcode reader, click on the ancillary reagent then use the keyboard to enter the identifier.
· Once a new bottle is installed, a message is displayed:

· Click on [Yes] to confirm the priming of the AP substrate.
  The analyser starts the AP Substrate priming sequence.

  <u>Comment:</u> The automatic priming of the AP Substrate circuit can be cancelled by clicking on [No]. In this case, the priming will take place automatically when starting a run cycle.

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

> **WARNING:**
> **RISK OF INJURY**
>
> Do not place your hand or fingers into the loader.
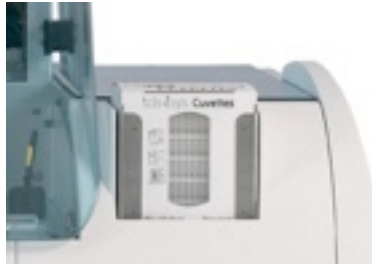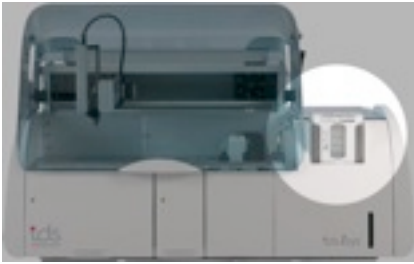
If necessary, remove the empty IDS-iSYS Cuvettes box.
- Scan the replacement box with the barcode reader.
- Within 10 seconds of the barcode reading, install the IDS-iSYS Cuvettes cube into the loader with the window to the front.

- Remove the protective plastic strip: pull forwards to break the seal. Gently pull upwards 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).
The qualification profile can be programmed as part of the automatic start-up of the analyser (see Section 7, **7-1- Programming the automatic qualification profile**, page 152).
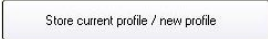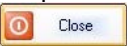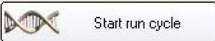
3-4-1- Programming the qualification profile

· From the main screen, select:
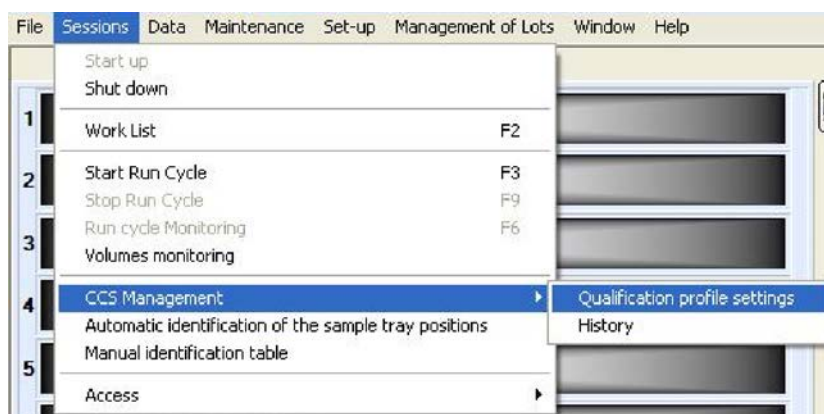
The qualification profile menu is displayed.
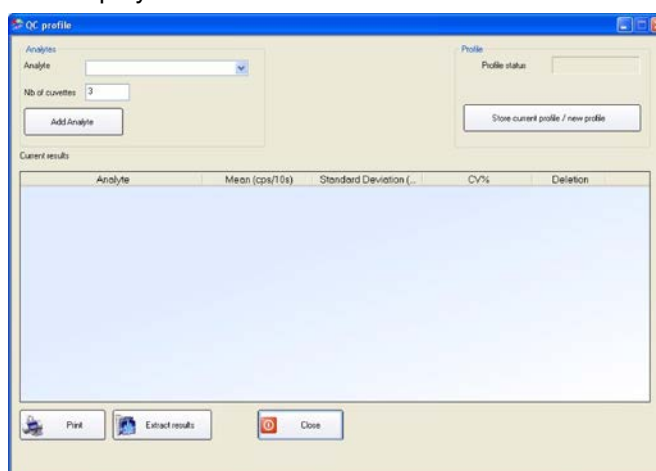
. If results from a previous profile are present in the list of current results, click on [Store current profile / new profile] .

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 [Add Analyte] .
· Repeat the operation for each test required.
· Click on [ⓞ Close] .
· Start the profile by clicking on [▷▨▨ Start run cycle] .

3-4-2- Management of results

. From the QC profile settings menu, click on [Store current profile / new profile] to store the current results.

· The CCS raw data are extracted in the STORAGE menu. From the main screen, select:

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

Calibrations   F5
Results storage   F4
Quality Controls   ▸
Records
Working panel   ▸
Master curves
Counters

. In Results storage menu select the CCS results you wish to export, then click on [Extract] .

· Validate the selection corresponding to the results you wish to export.
· Enter the file name [Date CCS] and save the txt file in the assigned folder.
  This will save the raw CCS data in a text file (.txt).
· Minimize GUI software then open assigned CCS folder.
· Right click on desired .txt file. Choose "Open With".
· Select «OpenOffice Scalc».
· On the "Text Import" screen, click on "OK".
· In the OpenOffice Scalc worksheet, highlight line 1 to line 18 (results for CCS).

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V W X Y Z A A A A A A A A A A A A A A A A A A A A A A A A A A B B B B B	BF	BG	BH	BI	BJ
1	13/12/2010 10:06	5	QUALIFICATION					CCS1	1		RLU	64	1	19532	0	P	CCSCONJ	667					69429	69427	72012		41101
2	13/12/2010 10:06	5	QUALIFICATION					CCS1	2		RLU	64	1	19256	0	P	CCSCONJ	667					69429	69427	72012		41101
3	13/12/2010 10:06	5	QUALIFICATION					CCS1	3		RLU	64	1	18937	0	P	CCSCONJ	667					69429	69427	72012		41101
4	13/12/2010 10:06	5	QUALIFICATION					CCS2	1		RLU	64	1	5001	0	P	CCSDIL	667	P	CCSCONJ	667		69429	69427	72012		41101
5	13/12/2010 10:06	5	QUALIFICATION					CCS2	2		RLU	64	1	4959	0	P	CCSDIL	667	P	CCSCONJ	667		69429	69427	72012		41101
6	13/12/2010 10:06	5	QUALIFICATION					CCS2	3		RLU	64	1	4957	0	P	CCSDIL	667	P	CCSCONJ	667		69429	69427	72012		41101
7	13/12/2010 10:06	5	QUALIFICATION					CCS31	1		RLU	64	1	130	0								69429	69427		71970	41101
8	13/12/2010 10:06	5	QUALIFICATION					CCS31	2		RLU	64	1	114	0								69429	69427		71970	41101
9	13/12/2010 10:06	5	QUALIFICATION					CCS31	3		RLU	64	1	123	0								69429	69427		71970	41101
10	13/12/2010 10:06	5	QUALIFICATION					CCS32	1		RLU	64	1	121	0								69429	69427		71970	41101
11	13/12/2010 10:06	5	QUALIFICATION					CCS32	2		RLU	64	1	119	0								69429	69427		71970	41101
12	13/12/2010 10:06	5	QUALIFICATION					CCS32	3		RLU	64	1	85	0								69429	69427		71970	41101
13	13/12/2010 10:06	5	QUALIFICATION					CCS33	1		RLU	64	1	118	0								69429	69427		71970	41101
14	13/12/2010 10:06	5	QUALIFICATION					CCS33	2		RLU	64	1	119	0								69429	69427		71970	41101
15	13/12/2010 10:06	5	QUALIFICATION					CCS33	3		RLU	64	1	103	0								69429	69427		71970	41101
16	13/12/2010 10:06	5	QUALIFICATION					CCS34	1		RLU	64	1	116	0								69429	69427		71970	41101
17	13/12/2010 10:06	5	QUALIFICATION					CCS34	2		RLU	64	1	114	0								69429	69427		71970	41101
18	13/12/2010 10:06	5	QUALIFICATION					CCS34	3		RLU	64	1	115	0								69429	69427		71970	41101

| ! | Many important data are not visible on the screen as some columns in the file are not used and the ancillary lot numbers are hidden on the right side of the file (See sign in red).
All data including those not visible on the screen should be copied and pasted into the "QC outil client CCS" file
All complete lines should be highlighted to be copied. |

· With arrow on highlighted area, right click mouse and choose "Copy" (or press CTR+C).
· Minimize OpenOffice Scalc worksheet.
· Open the "QC outil client CCS" (EXL-CQR-001V2) with OpenOffice 'Scalc' from CD drive (CCS mini CD-ROM).

Use

- Click on "Ready Only" in the Password window.

- Select the "Raw data" sheet.

- Select the cell A2 then Right click on mouse with the arrow on the cell A2 and choose "Paste" (or press CTR +V) to paste data into template.
- Verify that the data are paste in the correct order and all in triplicates.
- The data are automatically calculated and all necessary information is transmitted into the CCS result form.
- 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 143).

- Complete the form with the laboratory name, the Operator name, the instrument S/N and GUI version. (time can be saved by saving this information in a template file in the assigned folder).
- Select File (from the toolbar) "Save As" (from the drop down menu) and rename the file using "date CCS» to save in the assigned folder, then click on "Save".
- Select "Keep current format.
- If a printed copy is required, print the CCS results.

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

ManagIng the frequency will automatically generate a demand if the relevant calibration and/or control is not yet programmed in the menu Calibration/Control.

Each reagent lot has its own calibration and controls, 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.

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

Requests for calibrations and controls can be made at any time for the reagent lots on board. During the run cycle the calibrations and the controls take priority over all other tests requested.

3-5-1- Programming calibrations

Accepting an automatic action

Automatic requests for calibration are generated only for the reagent lots on board, either when a new lot of a Biochemistry reagent is detected, or when the calibration has expired (as defined in the assay set-up).

An automatic request must be confirmed in order to be performed.
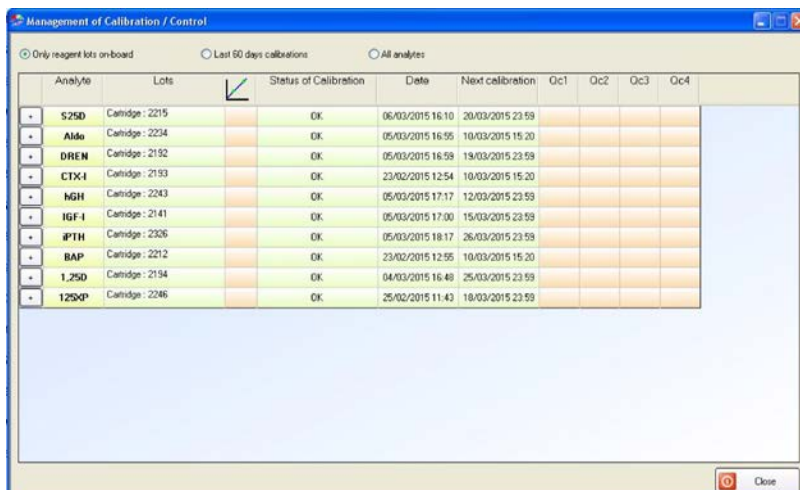
The appearance of automatic actions are indicated with the icon flashing in the WARNING button.

· From the main screen, click on the **WARNING** button.

· All the automatic requests for calibration generated by the system are shown in the lower part of the window, under the label «Automatic Action». The reagent lot is displayed along with the demand.

· A calibration request is accepted by clicking on Yes .

Comment: an automatically generated request for calibration can be cancelled by clicking on No . In this case, a record is made in the event log. If the current calibration has expired, results will not be calculated.

Programming a calibration

. From the main screen, click on Calibration/Control

The list of calibrations for each reagent lot is shown according to the selected display option:

⊙ Only reagent lots on-board   Displays the last calibration for each on-board lot of reagent.

⊙ Last 60 days calibrations   Displays all the calibrations performed in the last 60 days.

⊙ All analytes   Displays the calibrations of all unexpired reagent lots for all
                                             analytes of the private library.

Only the last calibration is diplayed for each lot of reagent.

Comment: The display option selected is kept after closing the window.

Programming a Calibration of a New Reagent Lot

> (!) When calibrating a new Immunoassay reagent lot, the calibrators associated with this lot must
>   be placed into the sample rack before programming the request.

. Click on [+] alongside the assay to be calibrated.

A message confirming the request displays:
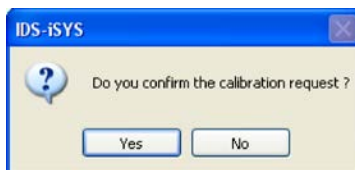
IDS-iSYS

? Do you confirm the calibration request ?

[Yes] [No]

· Click on [Yes] .

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

Comment: The request can be cancelled by clicking on [No] .

If more than one reagent lot is on-board, when [+] is clicked on a new window appears (see below).

Batch selection

Please select the batches to be used

Product	Lots	
R1 - GLUBC	1022596	˅

[✳ Validate] [Ⓞ Cancel]

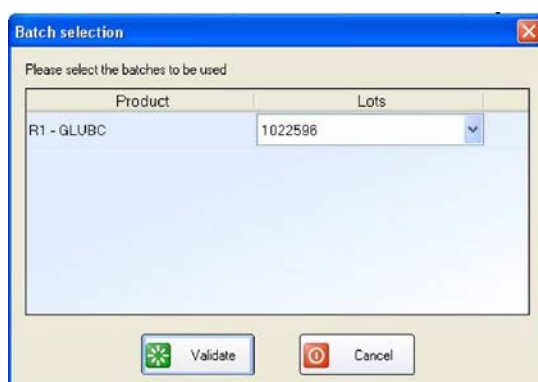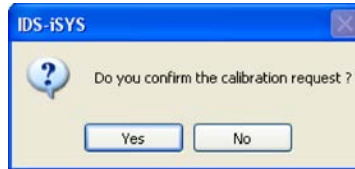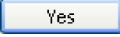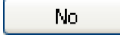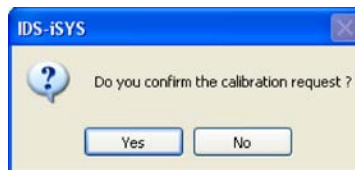. Select the new lot to be calibrated, and then click on [🟢 Validate] .

A message confirming the request displays:

- Click on [Yes] .
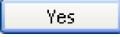 A tick is displayed in the calibration column and in the appropriate QC column(s).

  Comment: The request can be cancelled by clicking on [No] .

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 [📈] in front of the lot to be calibrated.

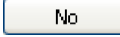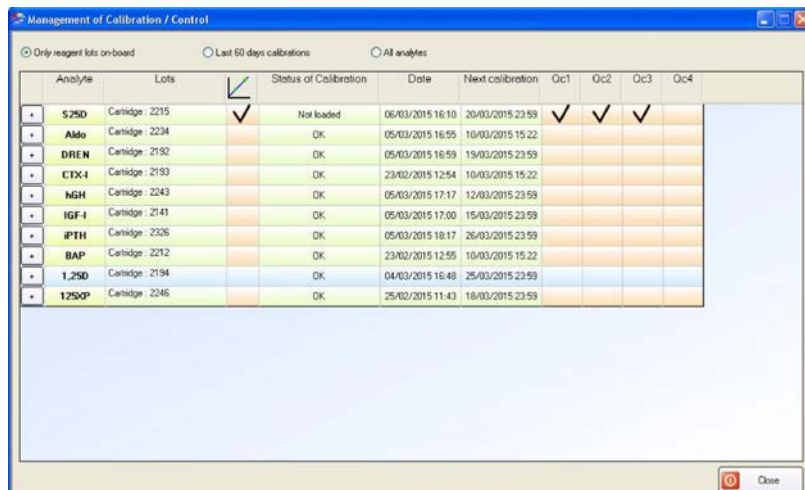 A message confirming the request displays:

- Click on [Yes] .
  A tick is displayed in the calibration column and in the appropriate QC column(s).

  Comment: The request can be cancelled by clicking on [No] .

> ! Calibrations for several lots of the same Biochemistry reagent can be programmed simultaneously.

> ! 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).

3-5-2- Programming Quality Controls

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

An automatic frequency can also be defined for each control in the assay setup.

Control levels validating the calibration and defined in the assay setup with an automatic frequency (once or twice per day) are run in the number of replicates required by the frequency (singlicate or duplicate) at the first programming of the day. When 2 runs per day are required, the same rule is applied for the first control run of the afternoon. In the case of an automatic request, controls are run in the number of replicates defined in the assay setup.

Accepting an automatic action

Automatic requests for controls are generated for each level, and only for reagent lots on board.

An automatic request must be confirmed in order to be performed.

The appearance of automatic actions are indicated with the icon [i] flashing in the **WARNING** button.

· From the main screen, click on the **WARNING** button.
  All the automatic requests for controls generated by the system are shown in the lower part of the window, under the label «Automatic Action». The reagent lot is displayed with the request.

· A control request is accepted by clicking on Yes .

Comment: a request for control generated automatically can be cancelled by clicking on No . In this case, a record is made in the event log.

> ! Controls programmed by accepting automatic actions are always run in the number of replicates defined in the assay setup.

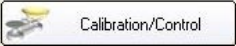### Programming Quality Controls for a Reagent Lot

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

The number of replicates can be defined for each control level at the programming step, except when set by the system.

If an automatic action generated for a control level validating the calibration was cancelled or not yet accepted, the number of replicates is set by the system. Control runs required by the frequency (1 or 2 assays per day) must be assayed in the number of replicates defined in the assay setup. In this case, the system will not allow any selection in the programming window (radio buttons in grey).
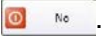
The number of replicates can be selected for each supplementary run.

In case of a control level not validating the calibration and managed in frequency, the number of replicates can be selected for each run.

. From the main screen, click on [🖱 Calibration/Control] .

· To request a QC1, QC2, QC3 or QC4 quality control, click on the box corresponding to the test and to the reagent lot to be performed.

· Select the relevant number of replicates for the control when applicable.
  When appropriate, the number of replicates programmed is shown in grey.
· Click on [🖱 Yes] to confirm the control programming.

  Comment : Control request can be cancelled by clicking on [🖱 No] .
· 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.
> Entering values of calibrators and controls requires a Supervisor level of access (or above).

🟢	Access authorised (Drawer unlocked).
🔴	Sampling under way. Access denied (Drawer locked).

Access to the sample compartment is controlled. if the light is green, access is available. When assays are under way, the sample compartment is locked (red light).

> **!** When the sample compartment 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.
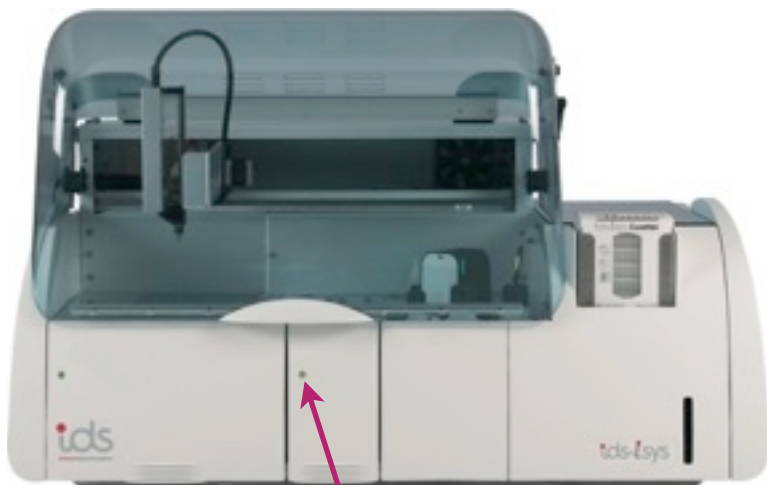> Once the compartment is closed, the analyser can resume the sample workload, including the new tests.
> Close the sample compartment as soon as the loading is finished in order to maintain the performance of the analyser.

Any position of the sample compartment 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
Control				Urine

> **!** Sample identifiers (barcodes or manual entries) must not contain the character «%». This character is not recognized by the system.
> Avoid the use of identifiers solely containing 12 numbers, similar to the barcode structure of calibrators and controls provided by IDS.

> **!** 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.

3-6-1- Removable trays

> **!** When not on-board, removable trays should be placed on a flat solid surface, to avoid any risk of spillage.
> During loading/unloading operations in the sample compartment, handle the removable trays with care.
> Rough handling may cause the samples to spill.

· Prepare the trays containing the samples to be assayed.
· Place the calibrators and controls in cups with an adapter on the tray.
· Place the tubes with the barcode label facing outward.
  Each position may be used to load a calibrator, a control or a sample, placed in a tube or in a cup (with adapter).
  When all the products are installed, the tray can be loaded.
· If the light is green, open the sample compartment.
· Slide the removable tray into a rail in the sample compartment until the positioning pin is fully inserted.
· As the tray is inserted in the rail, the positions and the barcoded tubes are automatically identified by the integrated barcode reader.
· On the interface, the tray is displayed with the free and occupied positions. Each identified position is labelled with the corresponding icon.
  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.
· If the profile is not in the memory, the profile programming window opens (see Section 3-7, page 69).
· If the barcode is not read by the barcode reader or is missing for a position, the software opens a window which allows the position to be identified.
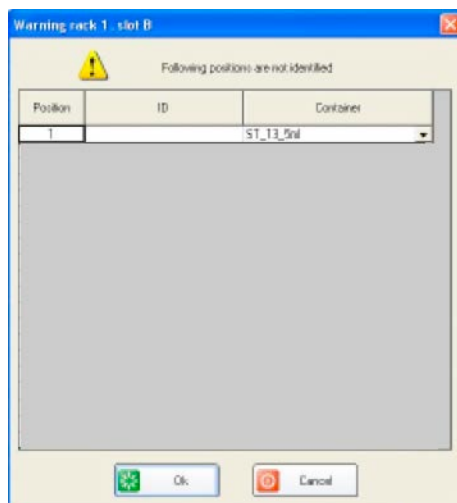
· Then identify the position(s) not identified by the barcode reader (see **Identify the positions of the tray without barcode reading**, page 63).

> **!** If positive identification has failed, the rail position is displayed in orange with "???" instead of the removable tray representation.

- Should identification fail, repeat the procedure for putting the sample tray in position.
- If the rail is still not identified, the tray must be identified via the user interface.

> **!** If a barcode of one of the samples installed on the removable tray contains a **%**character the tray is not identified and the rail position is displayed in orange with «???».
> In this case, remove the relevant sample from the tray, then place it again at its position with its barcode label facing inwards. Once the removable tray is installed into the compartment, this sample must be identified using the keyboard.

Configure a tray

- Click on the tray position:

Rail configuration

○ Cartridge	⊙ Rack	20 x sample
	1	

| ⊛ Validate | | ⊙ Cancel |

- Select in the corresponding dialog boxes the type and number of the tray.
- Click on ⊛ Validate .

The corresponding tray is displayed on the interface, with each position considered to be occupied but not identified. The software opens a window which allows the positions to be identified:

Warning rack 1 , slot B

⚠ Following positions are not identified

Position	ID	Container	
1		ST_13_5ml	▾
2		ST_13_5ml	▾
3		ST_13_5ml	▾
4		ST_13_5ml	▾
5		ST_13_5ml	▾
6		ST_13_5ml	▾
7		ST_13_5ml	▾
8		ST_13_5ml	▾
9		ST_13_5ml	▾
10		ST_13_5ml	▾
11		ST_13_5ml	▾
12		ST_13_5ml	▾
13		ST_13_5ml	▾
14		ST_13_5ml	▾
15		ST_13_5ml	▾
16		ST_13_5ml	▾
17		ST_13_5ml	▾
18		ST_13_5ml	▾
19		ST_13_5ml	▾
20		ST_13_5ml	▾

| ⊛ Ok | | ⊙ Cancel |

- Next, identify the occupied positions (see **Identify the positions of the tray without barcode reading**, page 63).

**Identify the positions of the tray without barcode reading**

If the barcode identification fails for at least one position, or if the tray has been configured, a window is displayed with the list of the positions occupied but not identified.

If the tray has been configured from the interface, each position is considered as occupied but not identified.

This window allows the positions to be identified by programming the identifier and the container type.
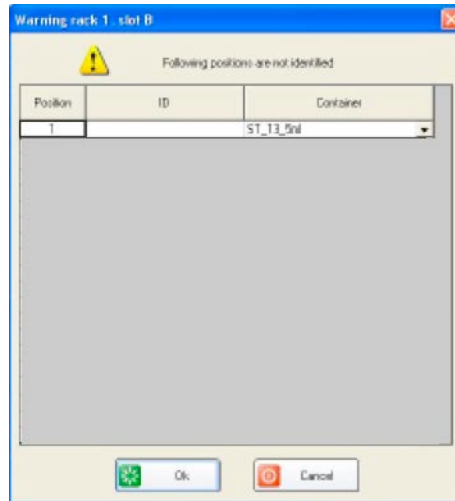
- Click on the box corresponding to the identifier to program.
- Use the keyboard to enter the identifier.
- Select the container type from the list.
- Use the keyboard to enter the barcode identifier.
- Repeat for each position of the list.
- When all the positions are identified, click on [Ok] .

  By default, the positions are identified as «specimen» .

  A position may be identified as occupied by a calibrator or a control (see **3-6-3- Configure a position without barcode**, page 65).

- 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.
- If the profile is not in the memory, the profile programming window opens (see Section 3-7, page 69).

When the tray has been identified by the barcode reader, and when the window is displayed, the tray can be removed to check identifier(s).

In this case, information can be entered, but can only be validated only after replacing the tray in the same position, with a new automatic identification.

Should automatic identification fail, the information will not be saved.
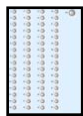
In this case, click on [Cancel] .

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.

3-6-2- Fixed tray

> **!** Take care when opening and closing the sample drawer: rough handling when opening and closing the drawer may cause the internal samples to spill.

· If the light is green, open the sample compartment.

Installation using a barcode

· Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
· Within 10 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,remove the tube and click on `|||||  Enter Barcode` .

· Use the keyboard to enter the barcode identifier.
· Select 'Vial association with samples tray' and click 'OK'.
· Click on `✳ Configure`.

· Within 10 seconds, place in a free position on the rack.
  If the association process is correct, the analyser will beep .
  On the interface, the display will indicate that the position has been identified.
  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.
· If the profile is not in the memory, the profile programming window opens (see Section 3-7, page 69).

> **!** 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.

Installation without barcode

· 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.
· Then configure the position (see **3-6-3- Configure a position without barcode**, page 65).

3-6-3- Configure a position without barcode

· Click on the position which is occupied but not identified (colour code:) or on the position which is identified (colour code:).

The software opens a window which allows the position to be configured.

Calibrators and Controls

· Use the keyboard to enter the identifier (1 to 32 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 .

Samples

· Use the keyboard to enter the identifier (1 to 32 alphanumeric characters).
· Select "type of product" as Sample and click on .

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 69).

> **!**
> Sample identifiers (barcodes or manual entries) must contain only alpha-numeric and blank characters.
> Only these characters are recognized by the system.
> Avoid the use of identifiers solely containing 12 numbers, similar to the barcode structure of calibrators and controls provided by IDS.

3-6-4- End of loading

· When all the samples have been installed, close the drawer.

Removable trays

If the analyser is initialised but not in the run cycle, the compartment remains unlocked and the assays will be carried out as soon as the run cycle is started. Each on-board tray will be assayed whether defined for automatic start or not.

If the analyser is in the run cycle, the compartment locks automatically.

For the trays defined for automatic start (in **Rack Configuration** menu), any new assays waiting to be carried out are added to the analyser's workload.

For the others, the new assays will be added to the analyser's workload after clicking on the corresponding Start button.

Fixed tray

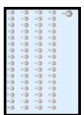If the analyser is initialised but not in the run cycle, the drawer remains unlocked and the assays will be carried out as soon as the run cycle is started.

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.

3-6-5- Colour codes associated with sample positions

	Position free.
	Position occupied but not identified.
	Position identified.
	Placement error: the product identified by barcode cannot be placed in the sample tray.
	Position occupied by a serum or plasma sample, profile associated.
	Position occupied by a urine sample, profile associated.
	Position occupied by a calibrator, calibration programmed.
	Position occupied by a control, control programmed.
	Position occupied by a calibrator, no associated request.
	Position occupied by a control, no associated request.

3-6-6- Colour codes associated with removable trays

	Rail free
	Tray not used by the analyser
???	Tray detected but not identified

During the run cycle, the tray displays in green when all corresponding assays are completed, or if the option is selected in **SETTINGS LOCAL SYSTEM**, when all corresponding assays are pipetted.
Lights are placed in front of each rail of the compartment:

	Tray not used by the analyser
	Tray in-use

3-6-7- Colour codes associated with position contour

	The installed product is not or is no longer used in assay. The product can be removed.
	The installed product is scheduled in a list of assays which will be progressively sent to the analyser. The relevant assays are not yet taken into account by the analyser: the programming can still be modified and, if necessary, the product can still be removed.

A green colour code is displayed on the contour of a position whether the analyser is in pending mode or in assay mode. During a run cycle, this code indicates that all the tests programmed for the sample are completed or, when the option is selected in the menu **SETTINGS LOCAL SYSTEM**, that all the samplings have been performed.

A blue colour code is shown only during a run cycle. The tests associated with this position have been included in a predictive list of assays. This list is established according to test priority and according to the order of the sample tray positions. As the tests have not yet been sent to the analyser, the sample programming can still be modified.

This product can also be removed from the sample compartment. In this case, the predictive list of assays is modified after excluding the relevant tests.

If this product is reloaded onto the sample compartment, the relevant assays are included at the end of the list of assays. In this case, a new predictive list is established, following the same criteria. This product will be processed after all the products with the same priority level, even if the product returned at its original position.

The blue colour code of the contour disappears when the tests are sent to the analyzer, at the moment when the center of position turns to blue (assays in process).

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 compartment 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 [Add] in [Work List] .

· For a sample programmed from the work list, enter the identifier (SID). For a sample programmed on the sample tray, the identifier is displayed.

> (!) Sample identifiers (barcodes or manual entries) must not contain the character «%». This character is not recognized by the system.
> Avoid the use of identifiers solely containing 12 numbers, similar to the barcode structure of calibrators and controls provided by IDS.

· Select the container: PT (primary tube), cup, ST (secondary tube) etc.
· Select the type of sample: Serum/Plasma, Urine, Other.
  - **Serum/Plasma** must be selected for each blood sample, whether collected in a dry tube (serum) or collected in a tube containing anticoagulants (plasma),
  - **Urine** must be used only when defined in the assay setup (refer to the reagent IFU),
  - **Other** must be used when specified in the reagent IFU.

> (!) The validity of results obtained depends on the correct programming of the sample type.
> When samples other than serum, plasma or urine must be assayed, refer to the reagent IFU or contact Technical Services.

· 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 [Validate] .
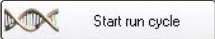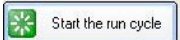
> (!) If the patient profile is programmed during the run cycle, the sample status may immediately be displayed as loaded.

> **!** 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.
> The solid waste can contain 400 cuvettes. Empty the solid waste before to start the run cycle.

- Click on [🧬 Start run cycle] .
- 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 [❄ Start the run cycle] . The analyser will begin aspirating samples.
- The run cycle monitoring window displays. After 30 seconds an estimated time for the end of processing all the on-board samples is displayed.

> **!** 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.

Comment:
For the removable-tray configuration, each on-board tray will be carried out, whether or not defined for automatic start.

3-8-1- Performing assays

Assays are carried out in the following order:
- Calibrations.
- Controls.
- Emergency (STAT) samples.
- Samples.

At the run start, samples are tested in the order of the sample compartment positions.
A predictive list including all the tests that will be sent to the analyser is established when starting the run for all the products installed onto the sample compartment, according to the priority order mentioned above. The contour colour of each relevant position turns to blue.
Tests are sent to the analyser 5 at a time, up to a maximum of 90.
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 sample compartment.

Removable trays

- Slide the removable tray containing the new samples into a rail in the sample compartment until the positioning pin is fully inserted.
- The positions and the barcoded tubes are automatically identified by the integrated barcode reader as the tray is inserted in the rail.
- On the interface, the tray is displayed with the free and occupied positions. Each identified position is labelled with the corresponding icon.
  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.
- If the barcode is not read by the barcode reader or is missing for a position, identify the products installed (see page 63).
- Proceed in the same way for other trays to be added.
- Close the compartment.
- The trays defined for automatic start are automatically added to the analyser's workload.
- For the others, the new assays will be added to the analyser's workload after clicking on the corresponding

  | Start | button.

Fixed tray

- Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
- Within 10 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 | ‖‖‖ Enter Barcode |.
- Use the keyboard to enter the barcode identifier.
- Select 'Vial association with samples tray' and click 'OK'.
- Select the appropriate identifier (Sample).
- Click on | ✳ Configure |.
- Within 10 seconds, place the sample in a free position on the tray.
- 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 40).
· Repeat for all racks installed on the analyser, then close the drawer.
· The analyser will resume processing samples.

> After loading a reagent into the compartment, the lag time before use is automatically managed by the system.
> The reagents must be stabilised at the temperature of the refrigerated compartment before use. Magnetic particles in Immunoassay cartridges must be sufficiently stirred.
> Wait for 40 minutes after installing reagent cartridges before starting assays (20 min for Biochemistry).
> Any interruption of countdown before use may impair the analytical quality of results.

> 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 🔆 Release .
· 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.

Option «Clot detection»: releasing specific alarms

When a system is equipped with the option «Clot detection», two different alarms may occur during a run cycle, either when a clot is detected during sampling, or if the probe is clogged. User intervention is required after releasing one of these two alarms.
The message indicating that a clot is detected under the sampling needle can be resolved during the run cycle. If the sampling probe is clogged, the cycle must be stopped and the message released.

WARNING:
RISK OF BIOLOGICAL CONTAMINATION

The probe is in contact with biological samples. There is, therefore, a potential risk of infection.
Wear disposable gloves for all handling procedures.

Clot detected

When a clot is detected during sample pipetting, the arm stops over the position where the fault is detected and the probe waits over the sample concerned.

· Select the fault then click on 🔆 Release . The sampling probe moves up.

The following message displays:
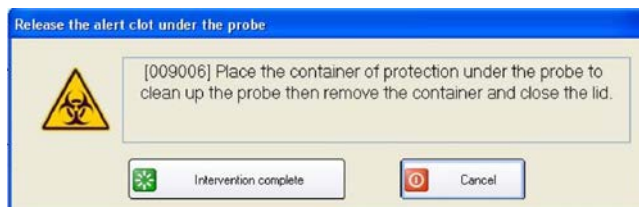
- Open the lid and insert the lid support tool (see pages 35 and 36). The sampling arm stays at its position.
- Install the specific protective tray under the probe while holding the sampling head.
- Remove the clot under the probe.
- Then clean the probe with an absorbent paper soaked in alcohol at 70% v/v (ethyl or isopropyl).
- Remove the protective tray.
- Remove the lid support tool and close the lid (see page 36), then click on [❄ Intervention complete] . The cycle resumes at the end of the rinse.
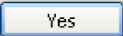
Probe blockage alarm

If the probe becomes clogged when dispensing into a cuvette or when rinsing, the arm stops at the position where the fault is detected.

- Click on [⫝̸ Stop run cycle] .
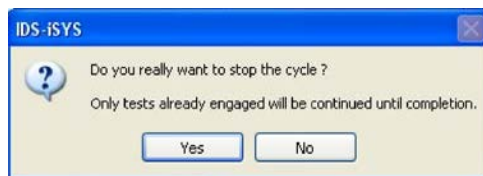
  A message confirming the request displays:

  IDS-iSYS
  ? Do you really want to stop the cycle ?
  Only tests already engaged will be continued until completion.
  [Yes] [No]

- To stop the cycle, click on [Yes] .
  If assays are under way, the analyser finishes these before stopping.
- Then, select the fault and click on [❄ Release] .

  The following message displays:

  Release probe blockage
  ⚠ [009003] Place the container of protection under the probe. Disassemble, unblock and clean up the probe with the provided mandrel.
  [❄ Intervention complete]
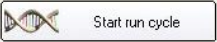
- Open the lid and insert the lid support tool (see pages 35 and 36).
- Install the specific protective tray under the probe while holding the sampling head.
- Unscrew the probe.
- Unclog the probe (see Section 5, **5-4-11- Unclogging the sample probe**, page 141).
- Then clean the probe with an absorbent paper soaked in alcohol at 70% v/v (ethyl or isopropyl).
- Click on [❄ Intervention complete] . The following message displays:
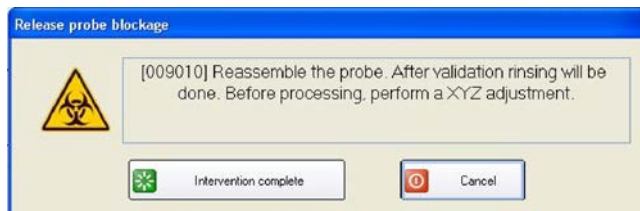
  Release probe blockage
  ⚠ [009010] Reassemble the probe. After validation rinsing will be done. Before processing, perform a XYZ adjustment.
  [❄ Intervention complete] [⭘ Cancel]

- Reassemble the probe by screwing it in by hand as far as possible to avoid risk of leakage.
- Remove the protective tray.
- Remove the lid support tool and close the lid (see page 36), then click on [✳ Intervention complete] .
- Then, adjust the probe reference position (see Section 5, **5-4-10- Adjustment of probe reference position, page 132**).
- Click on [⋈ Start run cycle] to continue the run cycle.

3-8-5- Unloading samples during an assay

The contour colour of a position changes when all the tests associated with this position have been processed. During the run cycle, a green contour indicates that all the tests have been completed. If the option is selected in **SETTINGS LOCAL SYSTEM**, a green contour indicates the end of sampling for this position.
For the fixed-tray configuration, each position is individually managed.
For the removable-tray configuration, the entire tray is managed. The tray can be removed when all the positions have been completed.

> **(!)** The option indicating the end of sampling does not take into account the dilution, if applicable, when a result is outside the field of measurement.
> If a sample cannot be diluted, the corresponding identifier will be displayed as in error in the work list.
> The number of incomplete profiles is indicated in the status bar.

- If the light is green, open the sample compartment.

Removable trays

- Check that the light of the corresponding rail is green.
- Remove the tray(s).
- If necessary, install new tray(s).
- Close the sample compartment.

> **(!)** A completed tray can contain one or more positions in error (position code 🔴).
>
> Each corresponding identifier will be displayed as in error in the work list.
> The number of incomplete profiles is indicated in the status bar.

Fixed tray
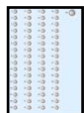
- Remove each completed sample.
- If necessary, install new sample(s).
- Close the sample compartment.

3-8-6- Performing reflex tests

When reflex tests have been programmed for an analyte (see Section 7, **7-2- Defining reflex tests**, page 156), and when a patient result meets the defined conditions, depending on the option in the **REFLEX TESTS** menu**,** additional assays can be:

- automatically added to the relevant profile,
- added to the profile either after accepting an automatic action or after using a specific button in the profile edition.

Once the requests of the new assays are added to the profile, assays are carried out in the worklist after calibrations, controls and STAT samples.

Any result of a reflex test is accompanied by the message **RFX**.

When the same assay is requested by several reflex tests, this assay is carried out once only.

Similarly, in the case of an analyte assayed in several replicates, a single request is programmed for each of the reflex tests associated to this analyte.

Only a calculated result of a patient profile can generate reflex tests. A result of a reflex test (with message **RFX**) will not generate reflex testing.

Option ☑ Automatic launch of tests

As soon as the result of the analyte concerned by a reflex test meets the defined conditions, additional assays are automatically added to the profile. The relevant assays are included in the list of assays and scheduled after calibrations, controls and STAT samples according to the order of the sample compartment positions.

Option ☐ Automatic launch of tests

An automatic action is generated by the system as soon as reflex tests must be carried out for a patient. The appearance of this automatic action is indicated with the icon 🛈 flashing in the **WARNING** button.

Reflex tests can be requested either by accepting the automatic action or from the relevant profile edition.

Accepting the automatic action

· From the main screen, click on the **WARNING** button.
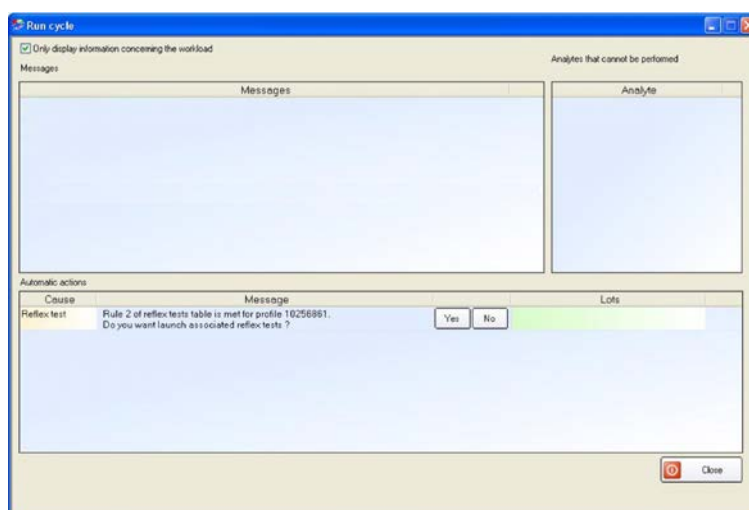
- A reflex test request is accepted by clicking on [Yes].

  Comment: the request generated automatically can be cancelled by clicking on [No]. In this case, reflex tests can be requested from the profile edition.

Programming from the profile edition

- Display the relevant profile from its position in the sample compartment (see page 86) or from the worklist (see page 87).
- Click on [Launch reflex tests] to program the reflex tests.
- Then click on [ⓞ Close].

3-8-7- Performing dilutions

Depending on the option selected in the analytical configuration, a post dilution can be performed either:
- automatically,
- or after accepting an automatic une action or programming from the profile edition.

Option   ⦿ Automatic post dilution

Post dilution is automatically performed.

Option   ⦿ Post dilution on user request

When a patient must be diluted, an automatic action is generated by the system. The appearance of this automatic action is indicated with the icon 🛈 flashing in the **WARNING** button. A dilution can be requested either by accepting the automatic action or by programming in the profile edition.

Accepting the automatic action

- From the main screen, click on the **WARNING** button.
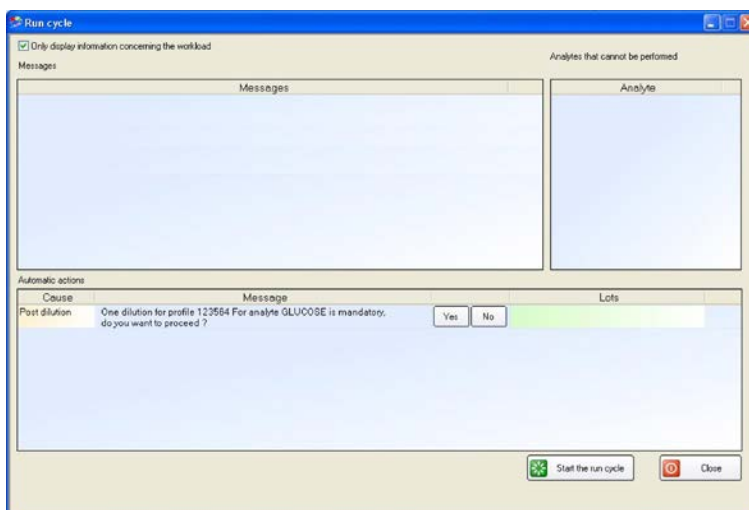
Programming in the profile edition
· Click on the position occupied by the sample.
· Click in the box in front of the analyte for which a dilution must be performed:

· The post dilution is requested by selecting:
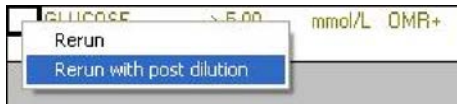
. Then click on [⊘ Close].

Programming in the worklist
· Click on [Work List] then select the relevant result.
. Click on [ReRun] :

· The post dilution is requested by selecting:

. Then click on [⊘ Close].

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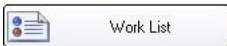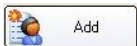
Emergency (STAT) samples can be programmed for all the sample tray positions.

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.

> **!** Sample identifiers (barcodes or manual entries) must not contain the character «%». This character is not recognized by the system.
> Avoid the use of identifiers solely containing 12 numbers, similar to the barcode structure of calibrators and controls provided by IDS.

- Click on | Work List | then click on | Add | .
- Enter the identifier (SID).
- Select the container: PT (primary tube), cup, ST (secondary tube).
- Select the type of sample: Serum/Plasma, Urine, Other (see page 69).
- 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 | Validate | .
- If the light is green, open the sample compartment.

Removable trays

- Install the tube on a removable tray. Slide the tray into a rail in the sample compartment until the positioning pin is fully inserted.
- The positions and the barcoded tubes are automatically identified by the integrated barcode reader as the tray is inserted in the rail.
- On the interface, the tray is displayed with the free and occupied positions. Each identified position is labelled with the corresponding icon.
- If the barcode label is illegible, identify the products installed (see page 69).
- Proceed in the same way for other trays to be added.
- Close the compartment.
- The trays defined for automatic start are automatically added to the analyser's workload.
- For the others, the new assays will be added to the analyser's workload after clicking on the corresponding | Start | button.

Fixed tray

- Scan the barcode with the reader located on the front face. The analyser will beep when the barcode has been correctly read.
- Within 10 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 | Enter Barcode | , then select 'Vial association with samples tray'.
- Use the keyboard to enter the barcode identifier, then select the appropriate identifier (Sample).
- Click on | Configure | .
- Within 10 seconds, place the sample in a free position on the tray. 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.

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. Control: all results are within the limits defined. Samples: results calculated without any message.
🟠	Calibrators: Calibrations are completed but one of the parameters is not within the criteria set for automatic validation. Controls: all results are calculated but at least one of the results is outside the limits defined. 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. 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 received by a centralised computer system (if the connection is activated).
🟣	Only when the connection with a centralised computer system is activated. 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 [Calibration/Control] .
- 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.
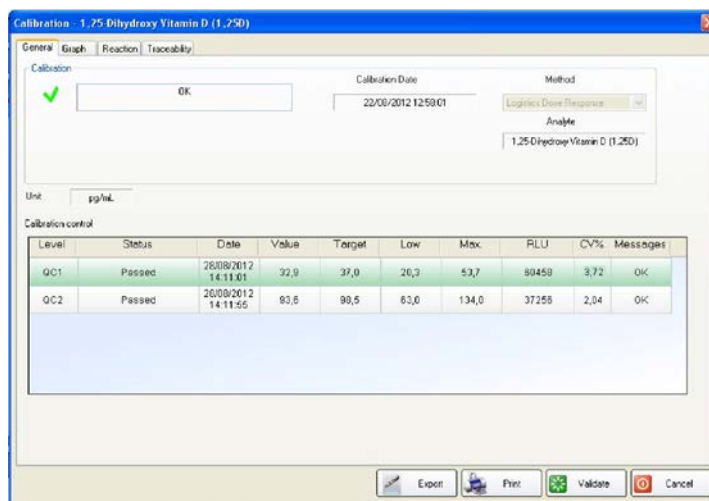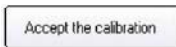
- To display the calibration curve for a test, double-click on the reagent lot number.

- 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 105).
- When it is not possible to automatically validate a calibration, the [Accept the calibration] button is displayed when the user has a Supervisor level of access (or above).

> ⚠️ When a calibration is displayed before each associated control has been calculated, [Print] and [Validate] buttons are not displayed.

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: · Raw data obtained. · Target value. · Value calculated using the mathematic model of the calibration. · Calibrator lot. Displays value of coefficient of determination (r2). Allows calculation of multiple-point calibrations after removing a calibrator.
Reaction	Displays the RLU values for Immunoassays using the chemiluminescence method or absorbancy values for methods using enzymatic detection. For Biochemistry, reaction kinetics for each of the calibrators and controls are displayed.
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 defined for each calibrator; when a limit is set at 0 or when the relevant option is selected (Calibration tab of the analytical configuration), the CV is not verified (Immunoassay).
· Difference between the calculated and the target value (in %) is within the acceptable limit of curve fitting defined for each calibrator. This criteria is not applied to calibrations with a master curve (Immunoassay).
· ODs of the blank and the reaction are within the programmed limits (Biochemistry).
· 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.
· Control(s) is (are) within acceptable limits.

Invalid Calibration:
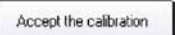
If the calibration is invalid, a message is displayed at the top of the screen indicating the cause (see Section 4-1, page 105).

· Request a new calibration after having replaced failed calibrator/control.

The software allows the user to validate a calibration when not automatically validated.

> (!) The validation or modification of an invalid calibration requires a Supervisor level of access (or above).
> The [Accept the calibration] button is not displayed when user has an Operator level of access.

If the calibration is not valid, the [Accept the calibration] button is displayed.

A calibration can be accepted **under the user'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).

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

· Accepting a calibration without modification

· In this case, click on the [Accept the calibration] button.

  The control(s) is (are) calculated,
· 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 **ACP.**
· Click on [Validate] to save the modification.
· The assays which are already completed are calculated and those on standby are resumed.

· Possible modifications of a calibration

  · Excluding a calibrator (Biochemistry only)

· To exclude a calibrator, click on [Graph] 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.

· When the recalculated calibration is valid, with the control(s) within acceptable limits, the message **OK** is displayed.
· Click on [Validate] to save the modification.

· If the calibration is not validated, the [Accept the calibration] button is displayed.

· In this case, request a new calibration after having replaced failed calibrator/control.

• Excluding one of the replicates

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 measurements (RLU or mAbs.).
- To exclude one of the 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 [icon] is displayed with the calibration date.
- When the recalculated calibration is valid, with the control(s) within acceptable limits, the message **OK** is displayed.
- Click on [Validate] to save the modification.
- If the calibration is not validated, the [Accept the calibration] button is displayed.
- In this case, request a new calibration after having replaced failed calibrator/control.

3-10-2- Result 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.
- A result which is not calculated is replaced by * * * * *.
- 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:
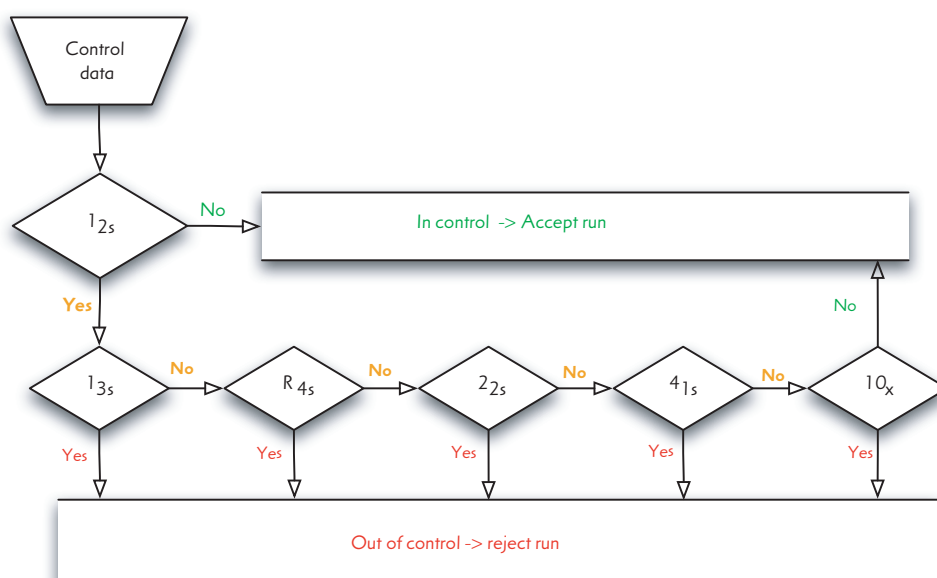
The violation of certain rules will generate automatic requests. In this event, the ⓘ icon flashes in the **WARNING** button.

- 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 **WE!.**
- 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 **WE!.**

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 contour.
- 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.

If the value cannot be calculated or is outside the field of measurement, the result is replaced by * * * * * .

* * * * * is always accompanied by a message (see **3-11- Messages Associated with Results** , page 89).

If the value is outside the field of measurement, the following information is displayed:

- value below the field of measurement: the message OMR- is accompanied by «< Low limit of the sample measurement range». When the field of measurement starts at 0, the result is replaced by * * * * * .
- value above the field of measurement: the message OMR+ is accompanied by «> High limit of the sample measurement range».

Limits are expressed in working units.

Comment:

When the message ORA accompanies the messages OMR- or OMR+, the result is not calculated and is replaced by * * * * * .

> If the analyser is connected to a centralised computer system, the information sent for results outside the field of measurement depends on the selected connection protocol:
> - ASTM Compatible: results are always sent in the format * * * * * ..
> - ASTM V2 Compatible and ASTM V3 Compatible: results are sent in the following format:
>   - **OMR-**: < Low limit of the sample measurement range, even when the measuring range starts at 0.
>   - **OMR+**: > High limit of the sample measurement range.
>
> Limits are expressed in working units.

Programming reflex tests

When reflex tests can be launched for a sample, the button | Launch reflex tests | is displayed.

- Click on | Launch reflex tests | to program the reflex tests.

  The new analyse requests are added to the profile.

  Comment: an analysis requested by a reflex test can be removed by unchecking the analysis.

- Then click on | ⓪ Close |.

Use

3-10-4- Work list results

- Click on [🔖 Work List] then click [👤 Expand].
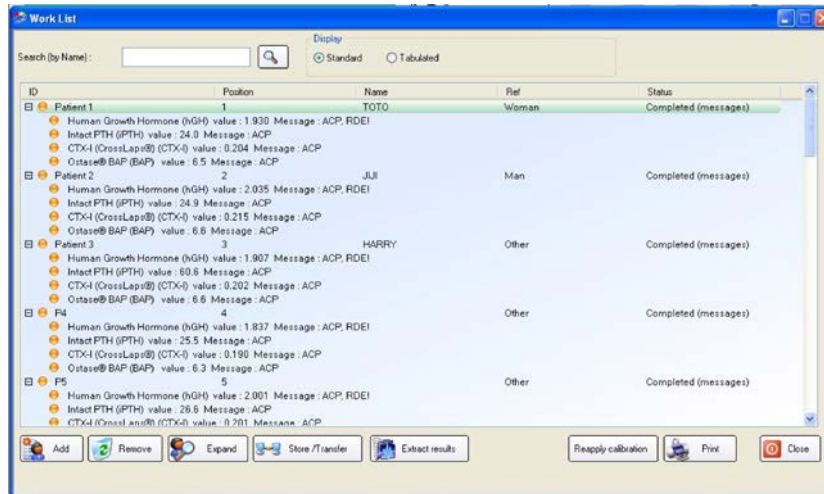
- All the results obtained for each sample are displayed.
- To display the measurements conducted in relation to an analysis, double-click on the result.
- To repeat a test, select the result and click on [⭐ ReRun].
- To print out the results, click on [🖨 Print].

- To print out all the results of the work list, select "**Print results**" and click on [✳ Validate].

Programming reflex tests

- Select the relevant profile.
- Double-click on the line to display the profile.
- Click on [Launch reflex tests] to program the reflex tests.

  The new analyse requests are added to the profile.
  Comment: an analysis requested by a reflex test can be removed by unchecking the analysis.
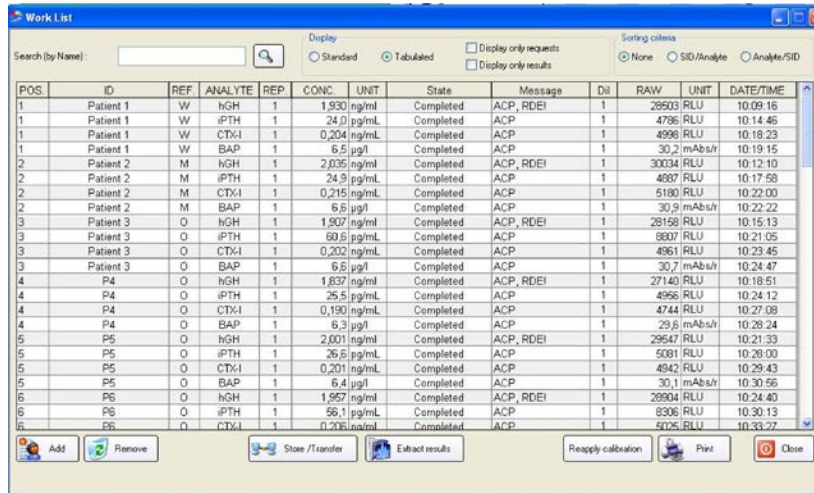
- Then click on [⓪ Close].

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

For each result, the display provides the calculated result (CONC. column), the raw RLU measurement (RAW column), with their relevant units and the messages. A comma displayed after the last message indicates that all the messages cannot be shown in the column. A double-click on the line will open a window containing the full list of messages. For assays performed in replicates (REP. column), the mean of the measurements and of the results are displayed in bold, accompanied by each corresponding CV.

Results are displayed in the order of positions in the sample compartment. Other sorting criteria may be selected for the display by using one of the following options:

The selected option is retained for printing also.
- Click on [Print] to print the table.

- To print out all the results of the work list, select "**Print results**" and click on [Validate] .

Programming reflex tests

- Open the relevant profile by double-clicking on the left part of the line, up to the «Analyte» column.
- Click on [Launch reflex tests] to program the reflex tests.

The new analyse requests are added to the profile.

Comment: an analysis requested by a reflex test can be removed by unchecking the analysis.

- Then click on [Close] .

The results generated for samples are accompanied by a message (displayed in the column "MESSAGE") 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
ACP	All fields The calibration used for calculating the result was accepted with a Supervisor level of access.
AIN	Spectrophotometry An absorbance is below the limit of reaction defined in the analytical configuration. * * * * * is displayed instead of the result.
ASU	Spectrophotometry An absorbance exceeds the limit of reaction defined in the analytical configuration. * * * * * is displayed instead of the result. The sample will be automatically diluted if a dilution rate is defined in the analytical configuration. If the ASU message accompanies the message "RED", one of the absorbances is still outside the limits of reaction defined 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.**
BLR	Biochemistry Absorbance of blank outside the limits defined in the analytical configuration.
CDE	Spectrophotometry Slope of the kinetics has been calculated on a non-linear section of the reaction (for KINETIC type of assay). The coefficient of determination is lower than the limit value defined in the analytical configuration.
CDI	For the Clot Detection option Clot detection is not active for this test. The sample volume defined for the test is below the lower sample volume required by the clot detection process.
CE	All fields Error when calculating a parameter calculated.
CLU	Luminescence The RLU measurement was corrected. One measurement of the integrated signal, out of the scope of the luminometer, was excluded and replaced by a point calculated by smoothing.
CT	All fields Temperature of the carousel outside limits or not stable during the assay.

Message	Meaning
EDE!	The calibration used for calculating the result was obtained with at least one calibrator excluded.
FIB	For the Clot Detection option A clot was detected when pipetting on the sample. All the calculated results must be verified.
HIGH	Result higher than the higher normal value.
KIN!	Spectrophotometry The absorbances measured while monitoring the reaction are not strictly increasing or decreasing (non-monotony of the reaction). * * * * * is displayed instead of the result.
LOW	Result lower than the lower normal value.
LS	Spectrophotometry The result was calculated from absorbencies measured with an unstable lamp.
MA	The assay is no longer being requested by analyser.
MAR	Luminescence This message is applicable to semi-quantitative assays. The luminescence signal measured is below the minimal acceptable signal. In this case, the sample must be tested again. * * * * * is displayed instead of the result.
MES	Luminescence Error when recovering the measurements. Spectrophotometry Error when recovering the measurements, or the result can not be calculated because the number of measurements insufficient.
MRE!	Luminescence The calibration used for calculating the result was obtained with at least one relative light unit (RLU) measurement excluded.
OMR	It has not been possible to calculate the result because the calibration is not valid. * * * * * is displayed instead of the result.
OMR-	The result calculated is below the lower limit of the field of measurement. «< Low limit of the sample measurement range» is displayed instead of the result.
0 with OMR-	Luminescence This message is applicable to semi-quantitative assays. The result calculated is below the lower limit of the field of measurement and forced to 0: the sample result can be reported as Negative.

Message	Meaning
OMR+	The result calculated is above the upper limit of the field of measurement. The sample will be automatically diluted if a dilution rate is defined in the analytical configuration. «> High limit of the sample measurement range» is displayed instead of the result. If the message OMR+ accompanies the message "RED", the result is still higher than the upper limit of the field of measurement 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.**
ORA	Luminescence The result cannot be calculated as the measurement is outside the scope of the measurements defined by the master curve. * * * * * is displayed instead of the result.
PMS	Luminescence Problem with luminometer stability.
RDE!	Luminescence The calibration used for calculating the result was obtained with one of the replicates for calibrator excluded.
RDS	Immunoassay Problem with agitation of magnetic particles on the reagent rack.
REC	The result was recalculated after modifying the calibration.
RED	The result was calculated after a dilution. The value given takes into account the dilution factor.
RFX	Result obtained for a reflex test.
RT	Storage temperature of reagents outside limits during the assay.
SUB	Spectrophotometry 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. * * * * * is displayed instead of the result. The sample will be automatically diluted if a dilution rate is defined in the analytical configuration. 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.**
SLU	Luminescence At least two measurements of the integrated signal are out of the scope of the luminometer, * * * * * is displayed instead of the result.
TAM-	Luminescence (if thermal compensation activated) Ambient temperature lower than the acceptable limit.
TAM+	Luminescence (if thermal compensation activated) Ambient temperature higher than the acceptable limit.
WE!	One of the Westgard rules applied for this analyte has been violated.

Messages associated with semi-quantitative assays

Message	Meaning
NEG	The result is negative (below the defined threshold)
NORM	The result is normal (within the defined thresholds)
POS	The result is positive (above the defined threshold)
(+++)	The result is positive (above the defined threshold)
(++)	The result is positive (above the defined threshold).
(+)	The result is positive (above the defined threshold).
(+/-)	The result is uncertain.

Use

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 **LOCAL 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 [Work List] then click [Store /Transfer] .

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

  The incomplete profiles can be stored when the analyser is not carrying out an assay.
  This option automatically removes the analysis requests remaining in the profiles when storing the profiles.
- 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 possible to request repeat analyses for a stored profile as long as the tube is still in the sample compartment.

> (!) In the **STORAGE** menu, results can be dispayed either in standard mode or in tabular mode.
> The sorting options available in the work list menu can be applied to stored results.

- It is also possible to delete all the stored profiles from the work list.
- To do this, click on ⟨ Remove ⟩ :
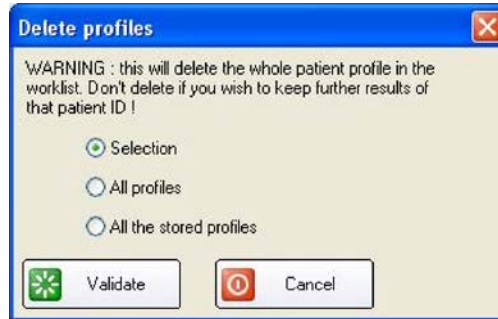
- Select "**Profiles stored**" and ⟨ Validate ⟩ .
- All the stored profiles are deleted from the work list and transferred to analyser software's database.

⚠️ ⟨ Remove ⟩ button is intended to remove profiles.

All the stored profiles deleted from the work list are transferred to analyser software's database.
When using the options «Selection» or «All results», always verify that the relevant profiles have been stored prior to remove them (display the work list in «standard mode», stored profiles are with a yellow colour code).
Otherwise, profiles that have not been previously stored are deleted from the work list and definitively lost.
In tabular mode display, when a result is selected, all the profile is removed.

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:
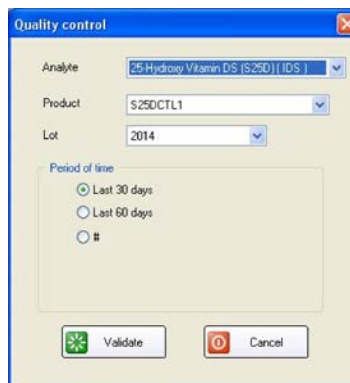
• In the dropdown list «Analytes», select the desired analyte.
• The software displays the controls associated with this analyte. Then select the control in the relevant dropdown list:

Use

- The system displays the active lot of the selected control. Another lot can be selected in the relevant dropdown list:
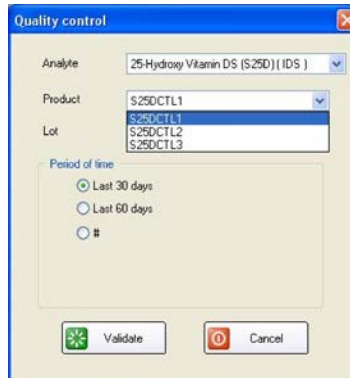
- Select the period of time required for display, then click on ![Validate] .

  The results of the control are displayed for the selected time period.
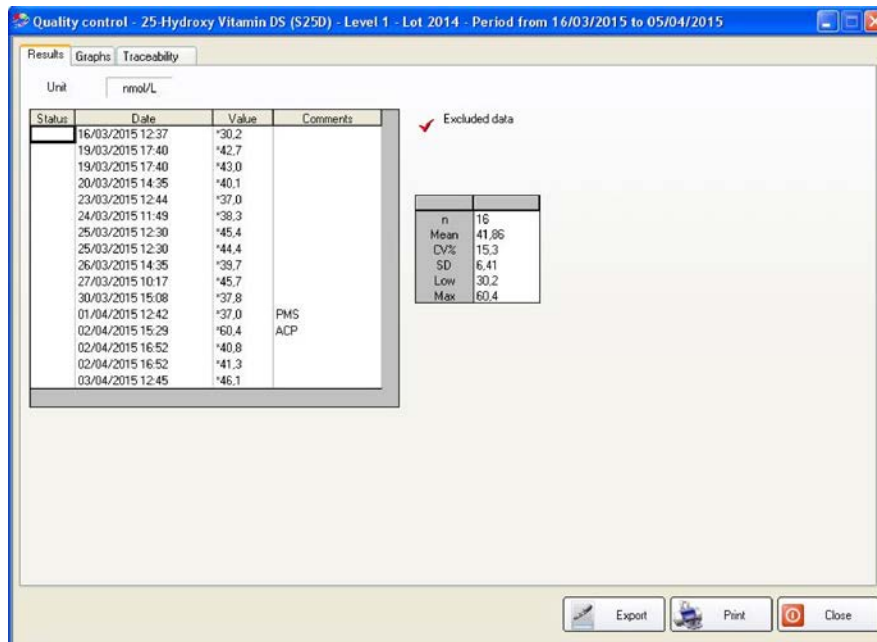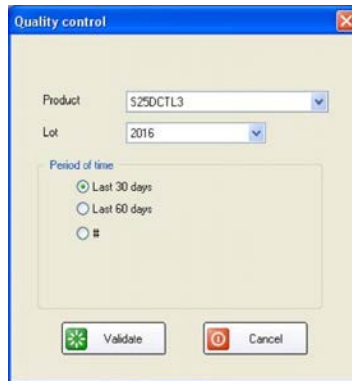
Per Lot

- Select the control.
- The system displays the active lot of the selected control. Another lot can be selected in the relevant dropdown list:

- Select the time period of interest, then click on Validate .

- Then select the test in the relevant dropdown list.

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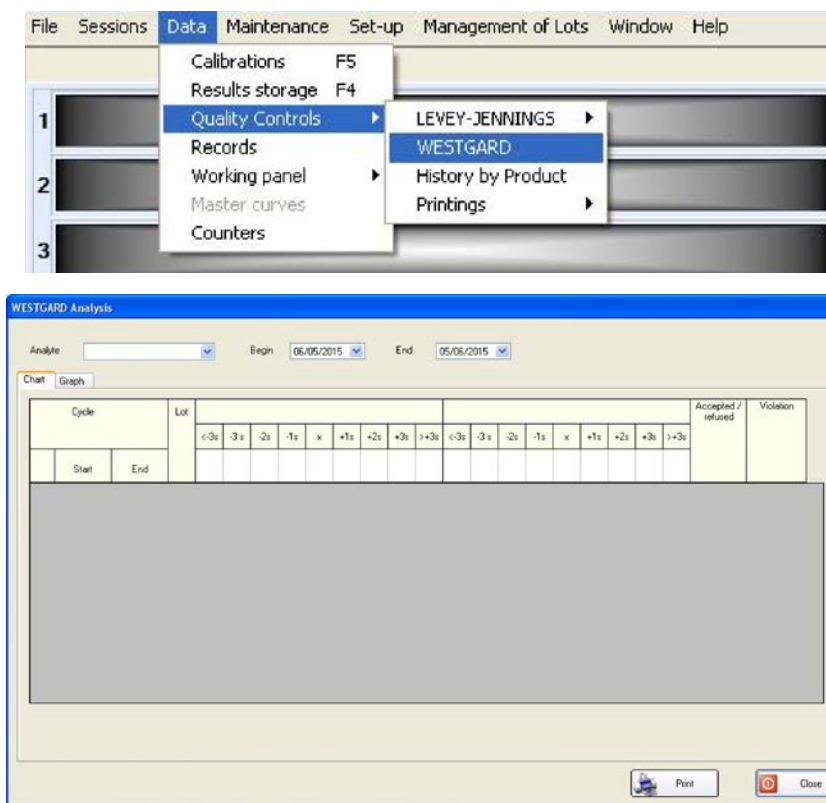
- Select the test and the time period of interest.
- For each run, the software displays the control measurement, the result of the selected Westgard rules examination (IN CONTROL, OUT OF CONTROL or WARNING) and the violated rules.
- The chart can be display by clicking the Graph tab.

The rules to apply are selected for each test in the 6 rules defined as follows:

1 $_{2s}$	One control measurement exceeds the limits of x ± 2s. 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. 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. This rule is sensitive to systematic errors. This rule is applied to the same control level or on different control levels: one measurement of each control exceeds the same limit. 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. This rule is applied on the same control level and on different control levels: one measurement exceeds the +2s limit and the other exceeds the -2s limit. 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. This rule is applied on the same control level or on different control levels: 4 consecutive measurements across control levels exceed the same limit, either x - 1s or x + 1s. 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. This rule is applied on the same control level or on different control levels 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:
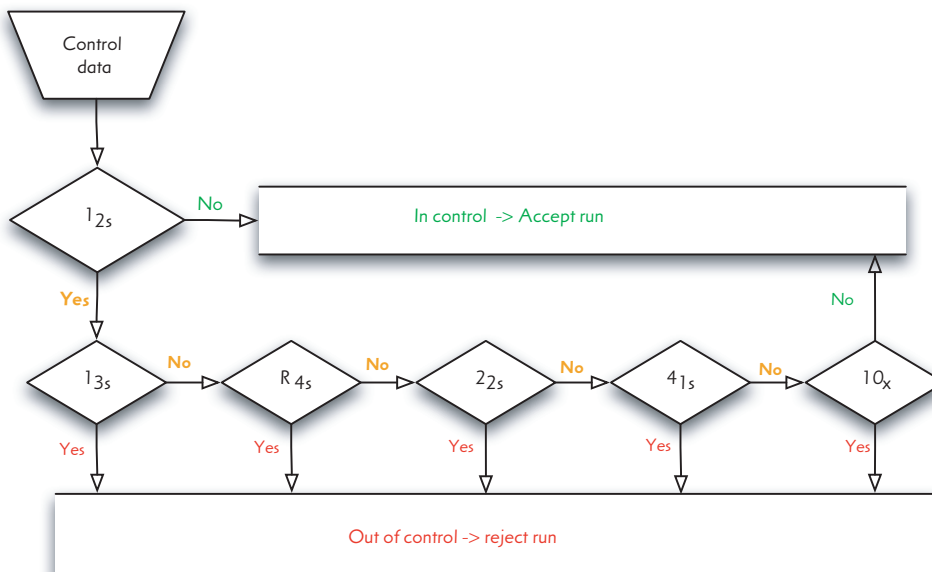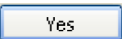
The analyser remains in assay mode until the run cycle is stopped.
Assays must be stopped in order to carry out maintenance procedures.
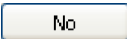
- Click on [⦻ Stop run cycle] .
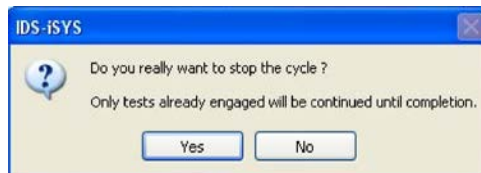
  A message confirming the request displays:

  IDS-iSYS

  ? Do you really want to stop the cycle ?

  Only tests already engaged will be continued until completion.

  [Yes]   [No]

- To stop the cycle, click on [Yes] .
  If assays are under way, the analyser finishes these before stopping.

  Comment: The request to stop the run cycle can be cancelled by clicking on [No] .
- 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.
- If the reagent drawer is equipped with a condensation waste, empty the drip tray if necessary.
- Empty the solid waste tray (see **3-14-1- Emptying the solid waste**, page 101) and the liquid waste if necessary (see **3-14-2- Emptying the liquid waste**, page 102).
- Waste must be disposed of in accordance with current local regulations (see APPENDIX I: Waste disposal, page A2).

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 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.

! For systems using DSORB solution, a maintenance procedure for the four washers will take place automatically during the SHUT DOWN procedure.

! Do not turn off the computer in standby mode.

3-14-1- Emptying the solid waste

> **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.

· Open the compartment by pushing on the cover, then remove the waste tray.

With re-usable solid waste

· Empty the content of the solid waste tray into a container reserved for disposal of biological waste.
  Waste must be disposed of in accordance with current local regulations (see APPENDIX I: Waste disposal, page A2).
· Decontaminate the solid waste tray (see Section 5, **5-5-1- Decontaminating the containers of solid and liquid wastes**, page 147).

With disposable solid waste container

· Remove the disposable container from the solid waste tray.
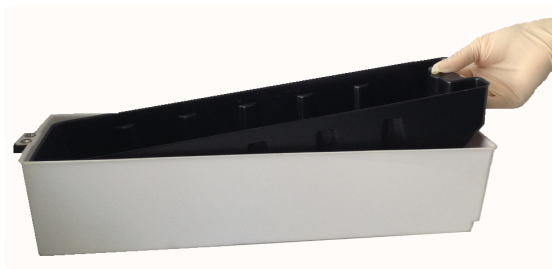
· Discard the disposable solid waste container and its content into a container reserved for disposal of biological waste.
  Waste must be disposed of in accordance with current local regulations (see APPENDIX I: Waste disposal, page A2).
· Install a new disposable container into the solid waste tray.

· Return the waste tray inside its compartment.
· Close the cover by pushing on it until it remains locked.
· Then release the solid waste alarm by clicking on [Ancillary product].
· Click on the solid waste icon.
  A confirmation message displays.
· Click on [Yes] to confirm the emptying of the waste.
· Exit the ancillaries management window.

3-14-2- Emptying the liquid waste

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.

· Remove the level sensor from the container collecting the liquid waste.
· Treat liquid waste prior to disposal in accordance with current local regulations (see APPENDIX I: Waste disposal, page A2).
· Decontaminate the liquid waste container (see Section 5, **5-5-1- Decontaminating the containers of solid and liquid wastes**, page 147).
· Replace the level sensor in the empty waste container.
· Then release the solid waste alarm by clicking on [Ancillary product] .
· Click on the liquid waste icon.
  A confirmation message displays.
· Click on [Yes] to confirm the emptying of the waste.
· Exit the ancillary management window.

The container provided by IDS is intended to be used for liquid waste collection and is not suitable either for storage, or for transport of liquid waste.
The responsibility for checking when to replace this reusable container lies entirely with the user.

Use 3-15

- 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'.

> **!** In order to maintain the performance of the operating system, the computer must be turned off one time per week.

> **!** When the analyser has been inactive for more than two days, a specific procedure must be applied depending on duration of the stoppage (see Appendix A-6- Analyser long stop period, page A-8).

SECTION 4:
Messages

Section 4

Messages 104

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	Spectrophotometry One of the calibrator replicates' absorbances is outside the limits specified in the analytical configuration for the test.
Blank out of range	Biochemistry The reagent blank is outside the limits specified in the analytical configuration of the test.
Fail of calibration calculation	All fields The calibration could not be calculated.
Sensitivity out of range	Biochemistry The sensitivity calculated is lower than the value specified in the analytical configuration.
Determination coefficient too low	Biochemistry The determination coefficient calculated for the calibration curve is lower than the value specified in the analytical configuration.
Monotony Problem	Biochemistry - Immunoassay The calibration has not been calculated as the curve is not strictly increasing or decreasing.
Tolerance out of range	Immunoassay 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. The **ETO** message is displayed with the corresponding calibrator in the ⬛Graph tab.

Messages

Message	Meaning
CV tolerance has failed on at least one of the calibrators	Immunoassay The CV calculated for one of the calibrators replicates is higher than the percentage specified in the analytical configuration. The **CVM** message is displayed with the corresponding calibrator in the `Graph` tab.
Control out of range	All fields 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 The slope of the kinetics calculated for one of the calibrators was calculated on a non-linear section of the curve.
No control for checking	All fields The control measurements requested with the calibration have not been performed. Calibration is not considered to be valid.
Out of the activity limits	Biochemistry 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.

Messages

4-2- Messages Associated with Calibration Controls

| + | QC2B2 | Cartridge : QC2MB2 | 🔴 | Invalid | 3/26/2009 11:37 | 3/27/2009 11:37 | 🟢 | 🟢 | 🔴 | |

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
Failed: calibration!	Biochemistry - Immunoassay The control was not calculated as the calibration is invalid.
Failed: range! or CV	All fields 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.
Failed: calculation!	Biochemistry - Immunoassay The control value was not calculated due to incomplete data generation.
Failed: system!	All fields The control value was calculated while the system was on alert (lamp or luminometer not stabilized, temperatures outside the limits)

Messages

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 "Message" column (green colour code associated).

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

Message	Meaning
ACP	All fields The calibration used for calculating the result was accepted with a Supervisor level of access.
AIN	Spectrophotometry An absorbance is below the limit of reaction defined in the analytical configuration. * * * * * is displayed instead of the result.
ASU	Spectrophotometry An absorbance exceeds the limit of reaction defined in the analytical configuration. * * * * * is displayed instead of the result. The sample will be automatically diluted if a dilution rate is defined in the analytical configuration. If the ASU message accompanies the message "RED", one of the absorbances is still outside the limits of reaction defined 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.**
BLR	Biochemistry Absorbance of blank outside the limits defined in the analytical configuration.
CDE	Spectrophotometry Slope of the kinetics has been calculated on a non-linear section of the reaction (for KINETIC type of assay). The coefficient of determination is lower than the limit value defined in the analytical configuration.
CDI	For the Clot Detection option Clot detection is not active for this test. The sample volume defined for the test is below the lower sample volume required by the clot detection process.
CE	All fields Error when calculating a parameter calculated.
CLU	Luminescence The RLU measurement was corrected. One measurement of the integrated signal, out of the scope of the luminometer, was excluded and replaced by a point calculated by smoothing.
CT	All fields Temperature of the carousel outside limits or not stable during the assay.

Messages

Message	Meaning
EDE!	The calibration used for calculating the result was obtained with at least one calibrator excluded.
FIB	For the Clot Detection option A clot was detected when pipetting on the sample. All the calculated results must be verified.
HIGH	Result higher than the higher normal value.
KIN!	Spectrophotometry The absorbances measured while monitoring the reaction are not strictly increasing or decreasing (non-monotony of the reaction). * * * * * is displayed instead of the result.
LOW	Result lower than the lower normal value.
LS	Spectrophotometry The result was calculated from absorbencies measured with an unstable lamp.
MA	The assay is no longer being requested by analyser.
MAR	Luminescence This message is applicable to semi-quantitative assays. The luminescence signal measured is below the minimal acceptable signal. In this case, the sample must be tested again. * * * * * is displayed instead of the result.
MES	Luminescence Error when recovering the measurements. Spectrophotometry Error when recovering the measurements, or the result can not be calculated because the number of measurements insufficient.
MRE!	Luminescence The calibration used for calculating the result was obtained with at least one relative light unit (RLU) measurement excluded.
OMR	It has not been possible to calculate the result because the calibration is not valid. «> High limit of the sample measurement range» is displayed instead of the result.
OMR-	The result calculated is below the lower limit of the field of measurement. «< Low limit of the sample measurement range» is displayed instead of the result.
0 with OMR-	Luminescence This message is applicable to semi-quantitative assays. The result calculated is below the lower limit of the field of measurement and forced to 0: the sample result can be reported as Negative.

Messages

Message	Meaning
OMR+	The result calculated is above the upper limit of the field of measurement. The sample will be automatically diluted if a dilution rate is defined in the analytical configuration. «> High limit of the sample measurement range» is displayed instead of the result. If the message OMR+ accompanies the message "RED", the result is still higher than the upper limit of the field of measurement 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.**
ORA	Luminescence The result cannot be calculated as the measurement is outside the scope of the measurements defined by the master curve. * * * * * is displayed instead of the result.
PMS	Luminescence Problem with luminometer stability.
RDE!	Luminescence The calibration used for calculating the result was obtained with one of the replicates for calibrator excluded.
RDS	Immunoassay Problem with agitation of magnetic particles on the reagent rack.
REC	The result was recalculated after modifying the calibration.
RED	The result was calculated after a dilution. The value given takes into account the dilution factor.
RFX	Result obtained for a reflex test.
RT	Storage temperature of reagents outside limits during the assay.
SUB	Spectrophotometry 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. * * * * * is displayed instead of the result. The sample will be automatically diluted if a dilution rate is defined in the analytical configuration. 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.**
SLU	Luminescence At least two measurements of the integrated signal are out of the scope of the luminometer, * * * * * is displayed instead of the result.
TAM-	Luminescence (if thermal compensation activated) Ambient temperature lower than the acceptable limit.
TAM+	Luminescence (if thermal compensation activated) Ambient temperature higher than the acceptable limit.
WE!	One of the Westgard rules applied for this analyte has been violated.

Messages

Messages associated with semi-quantitative assays

Message	Meaning
NEG	The result is negative (below the defined threshold)
NORM	The result is normal (within the defined thresholds)
POS	The result is positive (above the defined threshold)
(+++)	The result is positive (above the defined threshold)
(++)	The result is positive (above the defined threshold).
(+)	The result is positive (above the defined threshold).
(+/-)	The result is uncertain.

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 SYSTEM STATUS button.

Messages

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

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Maintenance

5-1- Daily Maintenance

In the MAINTENANCE menu, select **DAILY MAINTENANCE**:
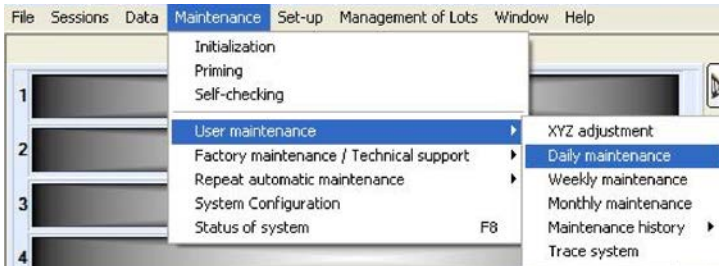
Daily maintenance activities are presented under a single tab. Certain maintenance activities are carried out automatically by the system whilst others must be carried out by the operator. In both cases, the maintenance activities are recorded.

> **WARNING:**
> **OPENING/CLOSING THE LID**
> The lid must be opened for this operation.
> Always handle the lid carefully during opening and closing.
> The lid must always be fully open and the lid support tool must always be installed.
> Take care not to knock the lid during any analyser intervention.
> When the lid is not fully open there is a risk of it falling.
> During closing, maintain the lid open when removing the lid support tool, to avoid any risk of accidental falling.

> If the analyser is equipped with a locking system, unlock lid before selecting the MAINTENANCE menu (see page 35).
> Close the lid when all maintenance procedures are complete (see page 36).

5-1-1- General Maintenance

5-1-1-1- Checking reagent drawer 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.
- 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 drawer.
- When maintenance is complete, click on the corresponding [Execute the maintenance] , then confirm the maintenance by clicking on YES.

5-1-1-2- Checking sample drawer 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 fixed or removable 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 (see page 35) 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.
- Remove the lid support tool and close the lid (see page 36).
- When maintenance is complete, click on the corresponding [Execute the maintenance] , then confirm the maintenance by clicking on YES.

Maintenance

5-1-1-3- Cleaning needle exterior

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 and insert the lid support tool (see pages 35 and 36).
· Gently clean the probe with a cloth soaked in deionized water to remove traced on the needle.
· Then use absorbent paper soaked in alcohol at 70% v/v (ethyl or isopropyl) to decontaminate the needle.
· When the cleaning procedure is finished, verify the tightness of the needle.
· Remove the lid support tool and close the lid (see page 36).
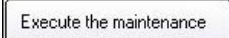
Handle the probe with care. Do not twist or bend the probe during cleaning.

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

This maintenance activity is managed only for systems using DSORB solution.
For other systems, this maintenance activity is not required.

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

· Click on the corresponding | Execute the maintenance | button in front of this item in the maintenance list.

· Click | Start | . 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.

Maintenance

In the MAINTENANCE menu, select **WEEKLY MAINTENANCE**:
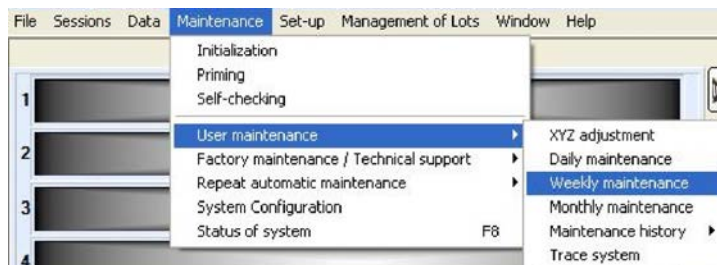
The weekly maintenance procedures are presented under two tabs: General and Immunology. Certain maintenance activities are carried out automatically by the system whilst others must be carried out by the operator. In both cases, the maintenance activities are recorded.

WARNING:
OPENING/CLOSING THE LID

The lid must be opened for this operation.
Always handle the lid carefully during opening and closing.
The lid must always be fully open and the lid support tool must always be installed.
Take care not to knock the lid during any analyser intervention.
When the lid is not fully open there is a risk of it falling.
During closing, maintain the lid open when removing the lid support tool, to avoid any risk of accidental falling.

If the analyser is equipped with a locking system, unlock lid before selecting the MAINTENANCE menu (see page 35).
Close the lid when all maintenance procedures are complete (see page 36).

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 insert the lid support tool (see pages 35 and 36).
- 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.
- Remove the lid support tool and close the lid (see page 36).
- When maintenance is complete, click on the corresponding [Execute the maintenance] , then confirm the maintenance by clicking on YES.

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 fixed or removable tray with a disinfectant wipe/solution suitable for medical devices.

> **WARNING:**
> **RISK OF INJURY**
>
> If a position of the fixed tray 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 insert the lid support tool (see pages 35 and 36).
- Clean the Plexiglas® over the tray with absorbent paper soaked in de-ionised water. Then use a disinfectant wipe/solution suitable for medical devices.
- Remove the lid support tool and close the lid (see page 36).
- When maintenance is complete, click on the corresponding [Execute the maintenance] , then confirm the maintenance by clicking on YES.

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 and insert the lid support tool (see pages 35 and 36).
- Pour alcohol at 70% v/v (ethyl or isopropyl) into the rinsing well.
- Use a cotton bud soaked in alcohol at 70% v/v (ethyl or isopropyl) to clean the well.
- When maintenance is complete, click on the corresponding [Execute the maintenance] , then confirm the maintenance by clicking on YES.

5-2-1-4- 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 [Execute the maintenance] , then confirm the maintenance by clicking on YES.
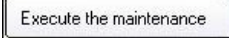
> (!) This maintenance activity can be carried out with the lid opened.

5-2-2- Immunoassay Maintenance

5-2-2-1- Rinsing of the IDS-iSYS Triggers tubing

- Open the lid and insert the lid support tool (see pages 35 and 36).
- Prepare two 250 mL bottles containing de-ionised water to mimic the IDS-iSYS Triggers.
- Click on the corresponding | Execute the maintenance | 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.

> ⚠ This procedure can be carried out with the lid opened.

When this maintenance is completed, proceed to the weekly shutdown of the computer:
- From the File menu, click on EXIT, the software will close.
- Then turn off the computer following the procedure for shutting down WINDOWS.
- 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.

Maintenance

In the MAINTENANCE menu, select **MONTHLY MAINTENANCE** :
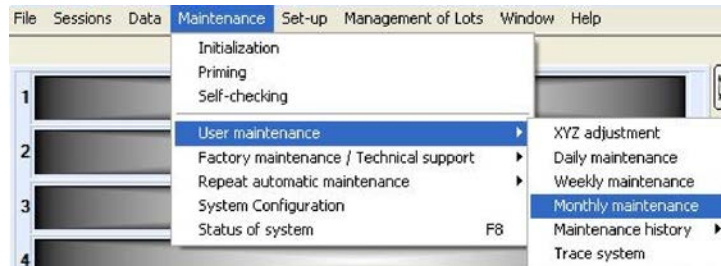
The monthly maintenance activities are presented under two tabs: General and Immunology. Certain maintenance activities are carried out automatically by the system whilst others must be carried out by the operator. In both cases, the maintenance activities are recorded.

! If the analyser is equipped with a locking system, unlock lid before selecting the MAINTENANCE menu (see page 35).

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 [Execute the maintenance] button in front of this item in the 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 at 70% v/v (ethyl or isopropyl).
· Return the pump body to its shaft.
· Carry out this procedure for the other pumps.
· When maintenance is completed, click [Validate] . The date and time it is carried out are recorded.

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

· Click on [Execute the maintenance] 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 at 70% v/v (ethyl or isopropyl).
· Return the pump body to its shaft.
· Carry out this procedure for the other pump.
· When maintenance is completed, click on [Validate] . The date and time it is carried out are recorded.

Maintenance

## 5-3-1-3- Cleaning the IDS-iSYS D-Sorb pump and level sensor shafts
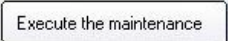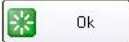
> (!) This maintenance activity is managed only for systems using DSORB solution.
> For other systems, this maintenance activity is not required.

> ⚠️ **WARNING:**
> **OPENING/CLOSING THE LID**
> The lid must be opened for this operation.
> Always handle the lid carefully during opening and closing.
> The lid must always be fully open and the lid support tool must always be installed.
> Take care not to knock the lid during any analyser intervention.
> When the lid is not fully open there is a risk of it falling.
> During closing, maintain the lid open when removing the lid support tool, to avoid any risk of accidental falling.

- Open the lid and insert the lid support tool (see pages 35 and 36).
- Remove the cover located at the rear.
- Click on the corresponding [Execute the maintenance] 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 at 70% v/v (ethyl or isopropyl).
- Return the pump body to its shaft.
- Put the cover back in place.
- Remove the lid support tool and close the lid (see page 36).
- To clean the level sensor, use absorbent paper soaked in de-ionised water.
- When maintenance is completed, click on [Ok]. The date and time it is carried out are recorded.
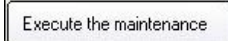
5-3-1-4- Cleaning the liquid waste level sensor
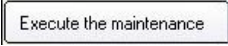
> ⚠️ **WARNING:**
> **RISK OF BIOLOGICAL CONTAMINATION**
> This part of the analyser is in contact with biological samples. There is, therefore, a potential risk of infection.
>
> Wear disposable gloves for all handling procedures.

- Click on the corresponding [Execute the maintenance] 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 [Validate]. The date and time it is carried out are recorded.

5-3-1-5- Checking lamp references
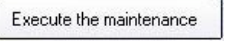
- From the main screen, click on the SYSTEM STATUS button.
- Check the intensity values for each of the filters are between 900 and 3100.
- When maintenance is complete, click on the corresponding [Execute the maintenance] button and confirm by clicking 'YES'.

5-3-1-6- Switch off the instrument

- Switch off the analyser by pressing the switch located on the left-hand side to position "0".
- Wait for few minutes, then switch the analyser on by pressing the switch to position "1".
- Click on the corresponding [Effectuer la maintenance] button and confirm by clicking 'YES'.
- Then perform the start-up procedure.
- Once the start-up procedure is complete, open the reagent compartment
- Remove then reload all the racks in the compartment.
- Should identification fail, identify the reagent(s).

5-3-2- Immunoassay Maintenance

5-3-2-1- 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 [Execute the maintenance] 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 at 70% v/v (ethyl or isopropyl).
- 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 [Ok] . The date and time it is carried out are recorded.
- Replace cover on the right-hand side of the analyser.
- Prime the circuit as follows:
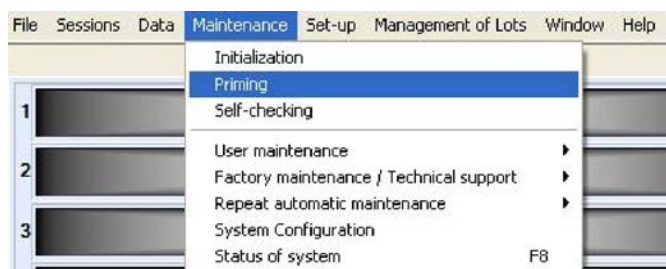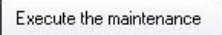
- Select **ALL WASHERS-FULL PRIMING,** then click on [Priming] .

  The analyser starts up the priming.
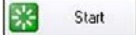
Maintenance
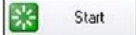
5-3-2-2- Rinsing of the AP Substrate tubing

- Prepare a 500 mL bottle containing de-ionised water to mimic the AP Substrate.
- Click on the corresponding [Execute the maintenance] button in front of this item in the maintenance list:

Rinsing of the AP Substrate fluid line

Automatic maintenance | Rinsing of the AP Substrate fluid line.
Replace AP substrate bottle with distilled water bottle.

[Start]   [Cancel]
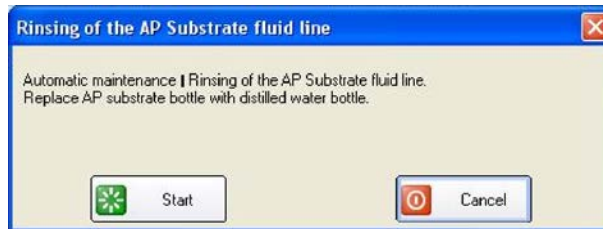
- Replace the AP Substrate bottle with the de-ionised water bottle.
- Click on [Start].
- When the rinsing is complete, the following message displays:

Rinsing of the AP Substrate fluid line

Automatic maintenance | Rinsing of the AP Substrate fluid line.
Replace AP substrate bottle.

[Start]   [Cancel]
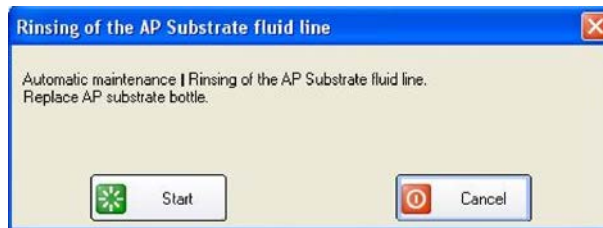
- Remove the de-ionised water bottle and replace the original AP Substrate bottle.
- Click on [Start].
- When maintenance is completed without any error, the date and time are recorded.

5-4-1- Replacement of lamp

(only for systems using a spectrophotometer with an halogen lamp)

> **WARNING:**
> **RISK OF BURNS**
>
> Do not handle the lamp to be replaced immediately after turning off the analyser. Before handling, allow the lamp to cool for approximately 10 minutes after switching the analyser off.
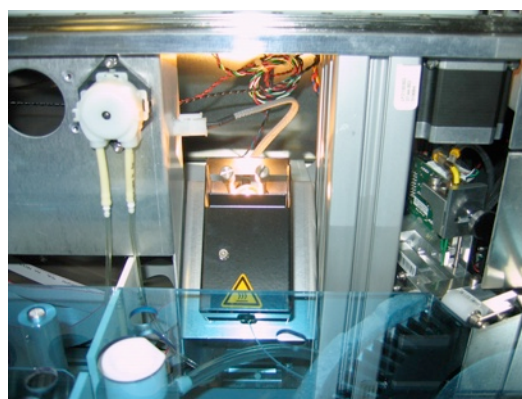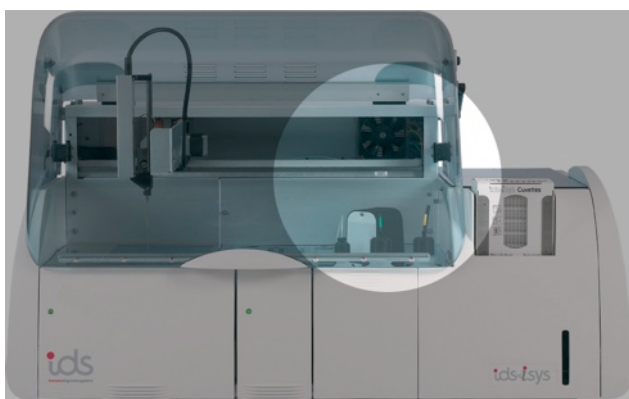
- Open the lid and insert the lid support tool (see pages 35 and 36).
- Switch the analyser off and unplug the power cable.
- Remove the bottom partition at the rear of the rinsing well.
- Disconnect the lamp from its supply.
- Unscrew the securing screws located on both sides of the lamp in order to 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.

- 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.
- Remove the lid support tool and close the lid (see page 36).
- Switch the analyser back on and start it up.

Maintenance

- Wait for 10 minutes, then request a measurement of the intensity values by the following pathway:
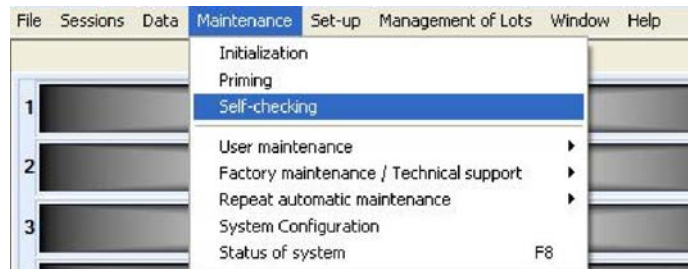
- From the list of elements, select ABS READER then click on . The analyser carries out a measurement for each of its filters. When the procedure is finished, exit this menu.
- Click on the SYSTEM STATUS button and check the intensity values for each of the filters are between 900 and 3100.

5-4-2- Replacement of probe

WARNING:
RISK OF BIOLOGICAL CONTAMINATION

The probe is in contact with biological samples. There is, therefore, a potential risk of infection.
Wear disposable gloves for all handling procedures.
The probe must be disposed of in accordance with current local regulations.

- Open the lid and insert the lid support tool (see pages 35 and 36).
- When the lid of the analyser is equipped with a locking system, the sampling arm moved to its home position.
- Install the specific protective tray under the probe.
- 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.
- Remove the protective tray.
- Remove the lid support tool and close the lid (see page 36).
- Adjust the probe reference position (see page 132).
- When the adjustment on the reference position is completed, exit this menu.
- Prime the fluidics circuit as follows:
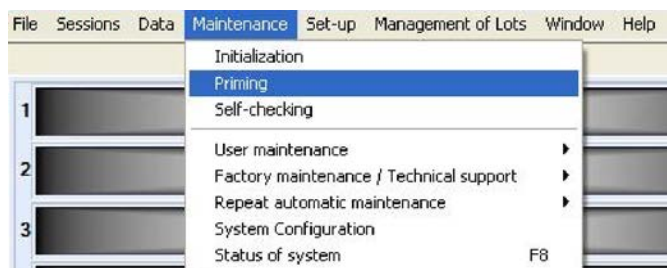
- Select **ARM-Mixed Partial Priming**, then click on .

  The analyser starts up the fluidics circuit and rinses the sampling needle.

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 and the same type (time-delay fuse).
· 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 during replacement of 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 prize the plate away using a flat head screwdriver.
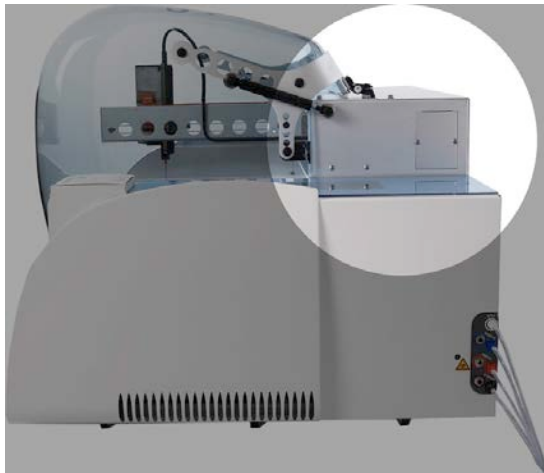
- Insert a flat head screwdriver into the fuse-holder and turn anti-clockwise to unscrew.

- Take out the fuse-holder and replace the faulty fuse with one of the same value and the same type (time-delay fuse).

- 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 at 70% v/v (ethyl or isopropyl).
· 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 at 70% v/v (ethyl or isopropyl).
· 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**
>
> 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 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 at 70% v/v (ethyl or isopropyl).
· 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 and insert the lid support tool (see pages 35 and 36).
· 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 at 70% v/v (ethyl or isopropyl).
· Put the pump back in place on its shaft.
· Replace the cover.
· Remove the lid support tool and close the lid (see page 36).
· 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.
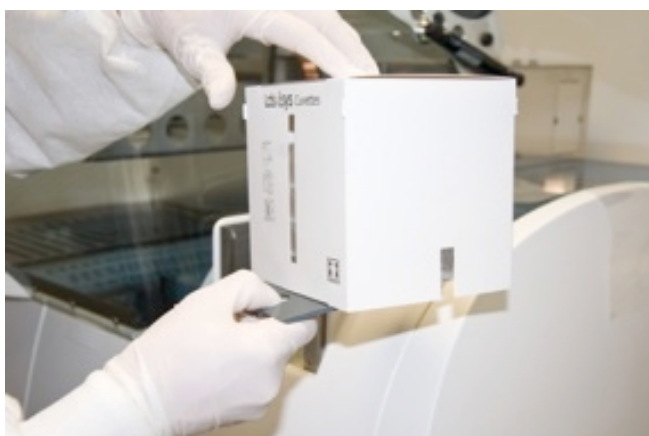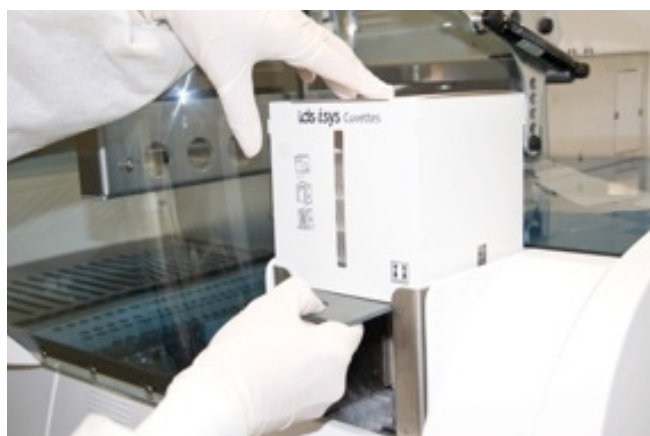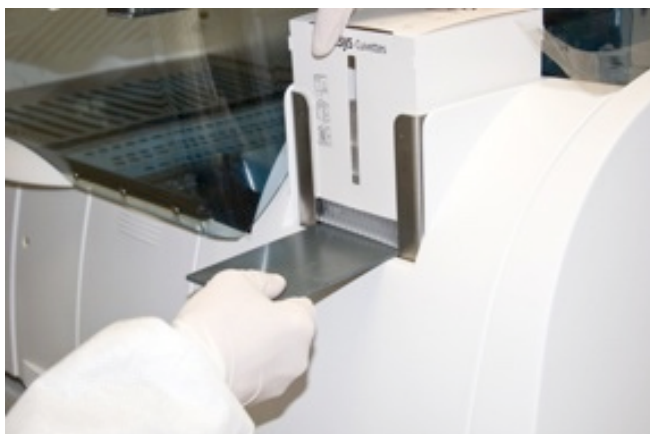
> ! Slightly lift the box to introduce the plate and then put if back before lifting the cube.

5-4-10- Adjustment of probe reference position

> **WARNING:**
> **RISK DUE TO ARM MOVEMENT**
>
> This operation must only be performed by a user specially trained by Technical Services.
> The pipetting arm will move with the lid open during this operation.
> Contact with the moving pipetting arm may cause severe injuries.

The reference position of the probe must be adjusted each time the needle is replaced, or when requested by the Technical Services.

This operation is considered as a particular use of the analyser and must be performed only by a user specially trained to this process.

The different probe positions are defined in relation to this reference position , located to the left of the rinsing well.

Adjustment must be defined for the three dimensions of the analyser's functional plane (XYZ adjustments).

> It is essential that each position be adjusted for the three dimensions.
> Inappropriate adjustments may decrease the level of analytical performance.
> Perform this procedure only at the request of IDS Technical Service & Support personnel.

Depending on whether the locking system is present or not, the procedure is different. The operations to be performed in each case are described in two different procedures.

If the lid is not equipped with a locking system, refer to the procedure described in chapter **5-4-10-1- Adjustment procedure for analyser without lid locking system**, page 133.

If the lid is equipped with the locking system, the activation key provided with the analyser's accessories will be used in this procedure. Refer to the procedure described in chapter **5-4-10-2- Adjustment procedure for analyser with lid locking system**, page 136.

> **WARNING:**
> **USE OF THE ACTIVATION KEY**
>
> The activation key allows a particular use of the analyser, without user's protection against the pipetting arm movements. The pipetting arm will move with the lid opened.
> Contact with the moving pipetting arm may cause severe injuries.
> The use of the activation key is strictly restricted to this adjustment procedure.

Maintenance

- In the MAINTENANCE menu, select **XYZ ADJUSTMENT**:
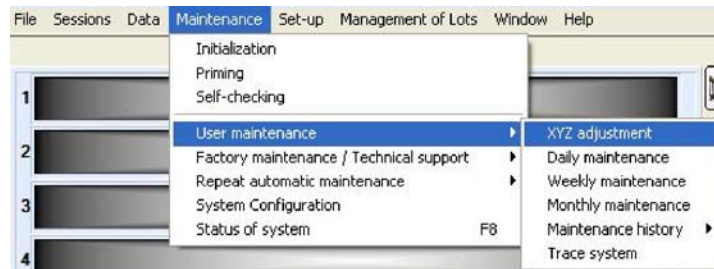
> **WARNING:**
> **OPENING/CLOSING THE LID**
>
> The lid must be opened for this operation.
> Always handle the lid carefully during opening and closing.
> The lid must always be fully open and the lid support tool must always be installed.
> Take care not to knock the lid during any analyser intervention.
> When the lid is not fully open there is a risk of it falling.
> During closing, maintain the lid open when removing the lid support tool, to avoid any risk of accidental falling.

5-4-10-1- Adjustment procedure for analyser without lid locking system
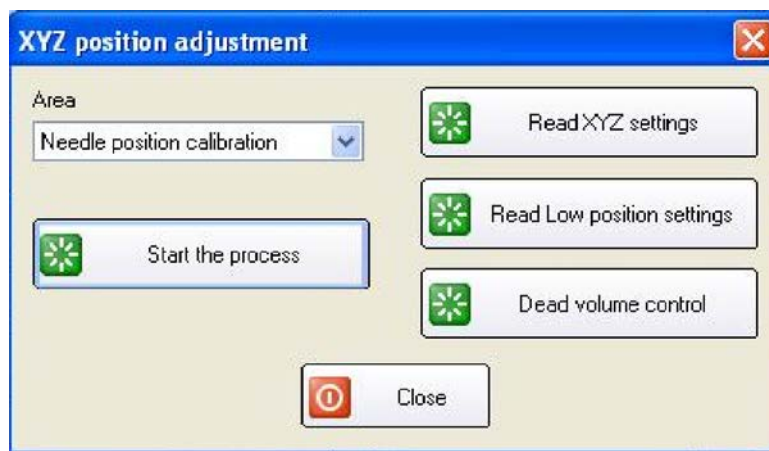
- Click on [Start the process] .

Maintenance

· The probe will be placed over the reference position, located to the left of the rinsing well.
  The probe is moved using the arrow buttons on the screen :
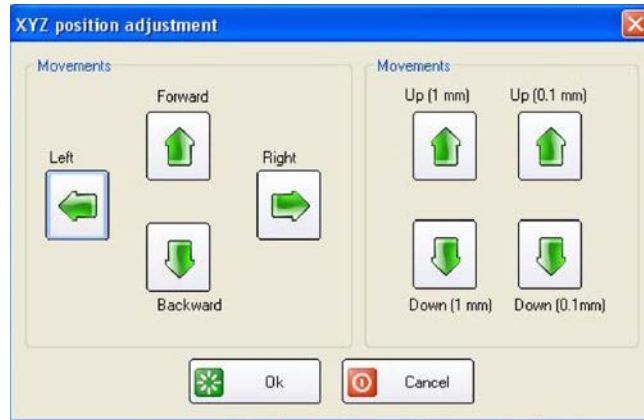
· Adjust first the XY positions of the probe, using the corresponding movement arrows (**Left**, **Right**, **Forward**, **Backward**). The probe must be centered on the pin of the target.
· Then adjust the Z position: click on the **Down (1 mm)** button twice.
· Adjust the probe position using repeatedly the **Down (0,1 mm)** button. The probe must be adjusted just above the center pin of the target.
· Open the lid and insert the lid support tool (see pages 35 and 36).
· Gently touch the probe: the probe must slightly resist to the lateral movement.

WARNING:
RISK OF BIOLOGICAL CONTAMINATION

The probe is in contact with biological samples. There is, therefore, a potential risk of infection.
Wear disposable gloves for all handling procedures.

The probe can be moved using **Up** and **Down** buttons when the lid is open.
The **Left**, **Right**, **Forward**, **Backward** buttons can only move once to each direction when the lid is open.
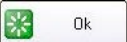
· When the adjustment is completed, remove the lid support tool and close the lid (see page 36).
· Click on [Ok] .

· The pipetting arm will move to the rinsing well before returning to the new adjusted position :
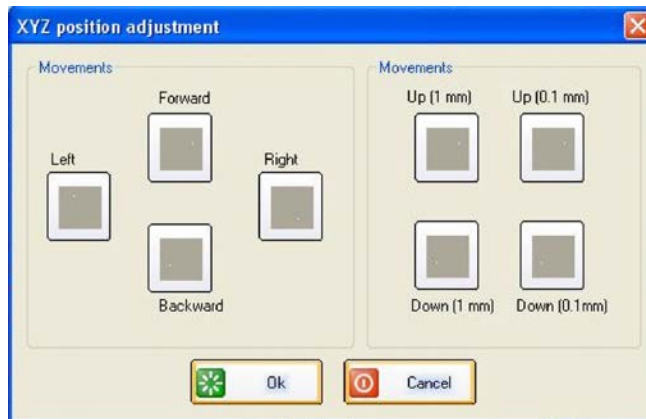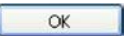
· Check the probe position, then remove the lid support tool and close the lid (see page 36).
· Click on ⬛ Ok .
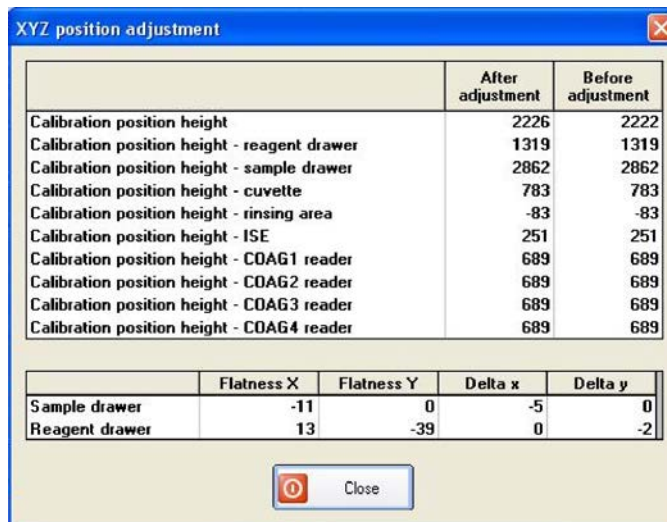
The pipetting arm will move to the rinsing well.
A message confirming completion of the procedure is displayed :

· Click on OK to validate this message.

A window containing the settings values is displayed :

XYZ position adjustment	After adjustment	Before adjustment
Calibration position height	2226	2222
Calibration position height - reagent drawer	1319	1319
Calibration position height - sample drawer	2862	2862
Calibration position height - cuvette	783	783
Calibration position height - rinsing area	-83	-83
Calibration position height - ISE	251	251
Calibration position height - COAG1 reader	689	689
Calibration position height - COAG2 reader	689	689
Calibration position height - COAG3 reader	689	689
Calibration position height - COAG4 reader	689	689

	Flatness X	Flatness Y	Delta x	Delta y
Sample drawer	-11	0	-5	0
Reagent drawer	13	-39	0	-2

· Click on ⬛ Close .

The main position adjustment window is displayed.

· Click on ⬛ Close to exit this menu

Comment:

The [⊙ Cancel] button is active in two windows. Clicking on this button will cancel changes in the position adjustment and the current adjustment will be kept.

To keep the previous adjustment :

• Click on [⊙ Cancel] .

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.
The main position adjustment window is displayed.

5-4-10-2- Adjustment procedure for analyser with lid locking system
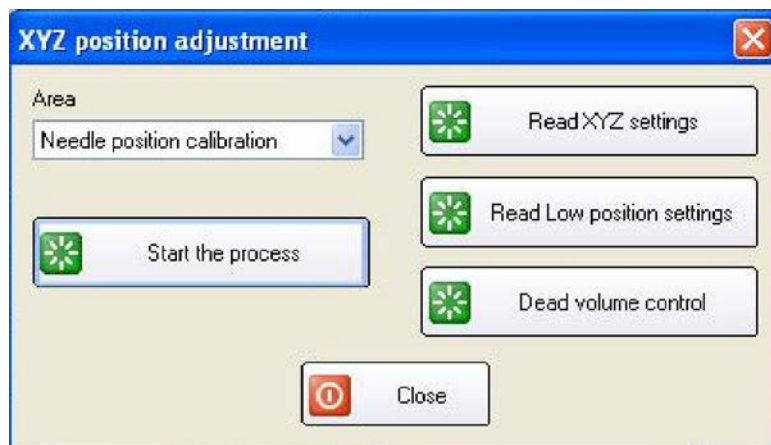
• Click on [Start the process] . The message displays:
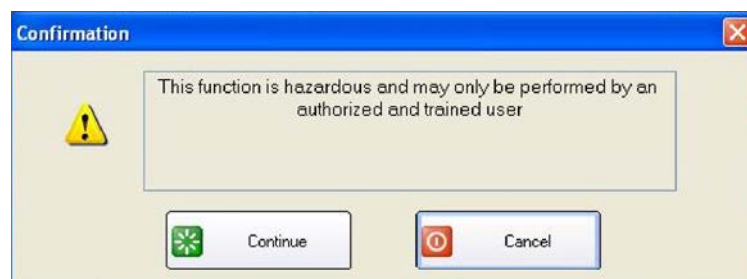
Maintenance

- Click on [✳ Continue].

  The pipetting arm moves to its home position and the lid is unlocked.
  The message displays:

  Activation key ✕

  Please open lid and insert ACTIVATION KEY

  [✳ Continue]   [⊙ Cancel]

- Open the lid and insert the lid support tool (see pages 35 and 36).
- Insert firmly the activation key into place.
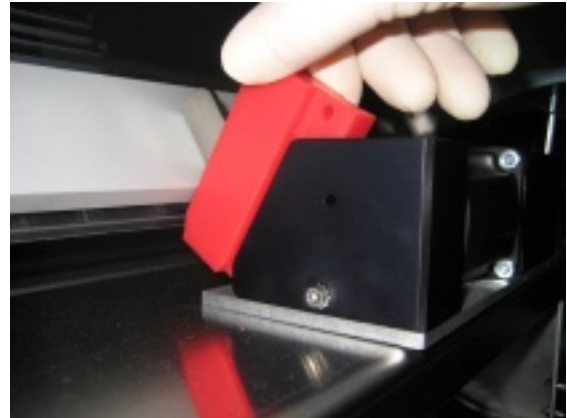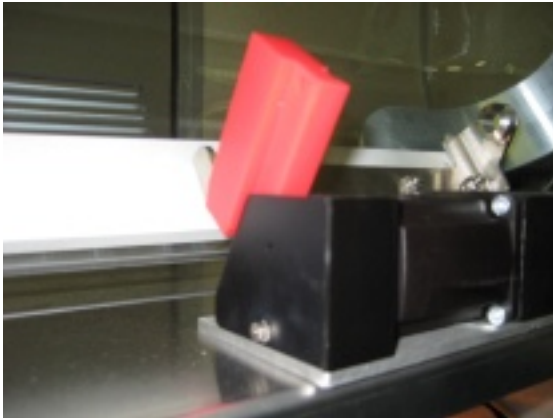
WARNING:
USE OF THE ACTIVATION KEY

⚠ The activation key allows a particular use of the analyser, without user's protection against the pipetting arm movements. The pipetting arm will move with the lid opened.
Contact with the moving pipetting arm may cause severe injuries.
The use of the activation key is strictly restricted to this adjustment procedure.

- When the activation key is detected, the message displays:

  Confirmation ✕

  ⚠ Warning : During the whole teaching process, arm is allowed to move while lid is open. Please press CONTINUE to move arm and start teaching function or CANCEL to stop

  [✳ Continue]   [⊙ Cancel]
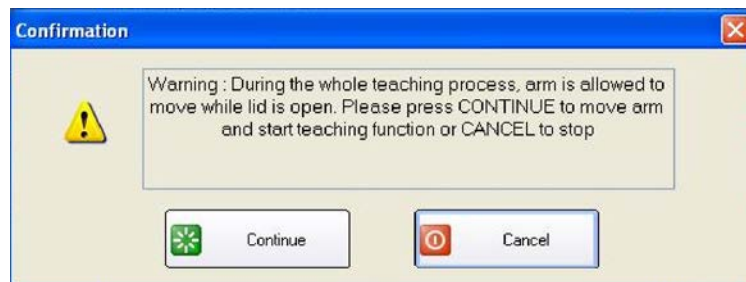
Maintenance

- Click on [Continue].

   The pipetting arm moves to the probe reference position, located to the left of the rinsing well.

> **WARNING:**
> **PIPETTING ARM MOVEMENT**
>
> During this operation, the pipetting arm will move with the lid opened.
> Contact with the moving pipetting arm may cause severe injuries.

- The probe will be placed over the reference position, located to the left of the rinsing well.
   The probe is moved using the arrow buttons on the screen :
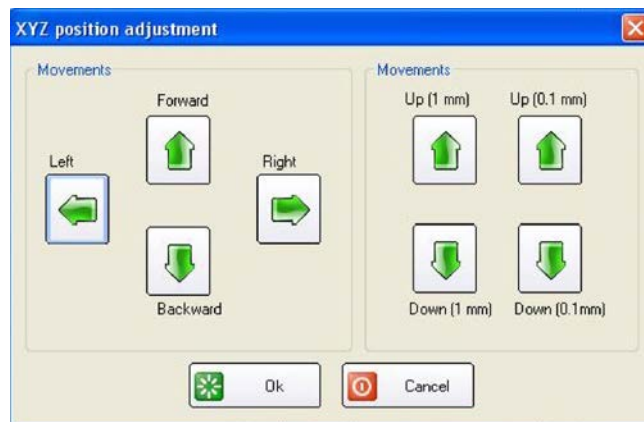
- Adjust first the XY positions of the probe, using the corresponding movement arrows (**Left**, **Right**, **Forward**, **Backward**). The probe must be centered on the pin of the target.
- Then adjust the Z position: click on the **Down (1 mm)** button twice.
- Adjust the probe position using repeatedly the **Down (0,1 mm)** button. The probe must be adjusted just above the center pin of the target.
- Gently touch the probe: the probe must slightly resist to the lateral movement.

> **WARNING:**
> **RISK OF BIOLOGICAL CONTAMINATION**
>
> The probe is in contact with biological samples. There is, therefore, a potential risk of infection.
> Wear disposable gloves for all handling procedures.

- When the adjustment is completed click on [Ok].

· The pipetting arm will move to the rinsing well before returning to the new adjusted position :
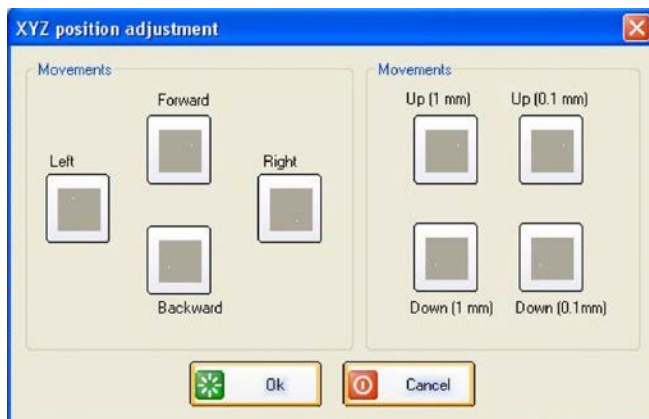
· Check the probe position.
· Click on [Ok] .

The pipetting arm will move to the rinsing well.
A message confirming completion of the procedure is displayed :
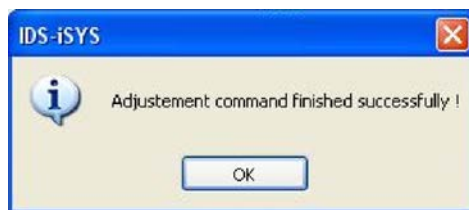
· Click on [OK] to validate this message. The message displays:
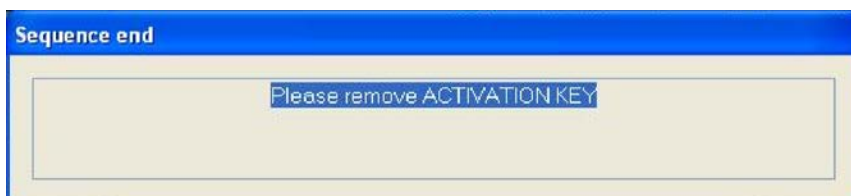
· Remove the activation key. The removal is detected by the analyser and the message is displayed:
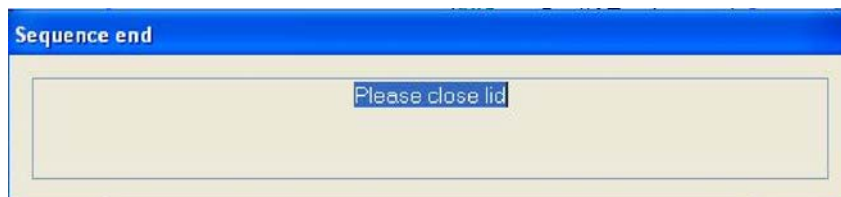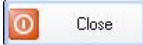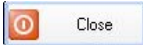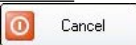
- Remove the lid support tool and close the lid (see page 36). The lid closing is detected by the analyser and a window containing the settings values is displayed:

XYZ position adjustment	After adjustment	Before adjustment
Calibration position height	2226	2222
Calibration position height - reagent drawer	1319	1319
Calibration position height - sample drawer	2862	2862
Calibration position height - cuvette	783	783
Calibration position height - rinsing area	-83	-83
Calibration position height - ISE	251	251
Calibration position height - COAG1 reader	689	689
Calibration position height - COAG2 reader	689	689
Calibration position height - COAG3 reader	689	689
Calibration position height - COAG4 reader	689	689

	Flatness X	Flatness Y	Delta x	Delta y
Sample drawer	-11	0	-5	0
Reagent drawer	13	-39	0	-2

- Click on [ⓞ Close] .

   The main position adjustment window is displayed.
- Click on [ⓞ Close] to exit this menu.

Comment:

The [ⓞ Cancel] button is active in two windows. Clicking on this button will cancel changes in the position adjustment and the current adjustment will be kept.

To keep the previous adjustment :

- Click on [ⓞ Cancel] .

   The pipetting arm will move to the rinsing well.
   A message confirming cancellation of the procedure is displayed:

IDS-iSYS

⚠ Adjustment command canceled !

OK

- Click on [OK] to validate this message. The message displays:

Sequence end

Please remove ACTIVATION KEY

Maintenance

- Remove the activation key. The removal is detected by the analyser and the message is displayed:

Sequence end

Please close lid

- Remove the lid support tool and close the lid (see page 36). The lid closing is detected by the analyser and the main position adjustment window is displayed.

5-4-11- Unclogging the sampling probe

> **WARNING:**
> **RISK OF BIOLOGICAL CONTAMINATION**
>
> The probe is in contact with biological samples. There is, therefore, a potential risk of infection.
> Wear disposable gloves for all handling procedures.
> The probe must be disposed of in accordance with current local regulations.

> Use only the nylon mandrel provided for this purpose with the analyser.
> Do not use a metallic mandrel that will damage the internal surface of the probe.

- Open the lid and insert the lid support tool (see pages 35 and 36).
- If the lid of the analyser is equipped with a locking system, the sampling arm moves to its home position.
- Install the specific protective tray under the probe.
- Unscrew the sampling probe.
- Insert the mandrel into the bottom of the probe, and pass it through the entire length of the probe, until the probe becomes unblocked.
- Outside of the analyser, verify that the probe is fully unblocked by passing deionized water through the top of the probe with a syringe:
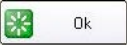
> **WARNING:**
> **RISK OF BIOLOGICAL CONTAMINATION**
>
> The probe is in contact with biological samples. There is, therefore, a potential risk of infection.
> Wear disposable gloves for all handling procedures.
> The probe must be disposed of in accordance with current local regulations.

- If the probe is properly unblocked, the water will exit the probe in a straight jet and the syringe plunger can be pushed freely.
- If the syringe plunger must be strongly pushed and if water drips when exiting the probe, repeat this procedure.
- Then clean the probe with an absorbent paper soaked in alcohol at 70% v/v (ethyl or isopropyl).
- Reassemble the probe by screwing it in by hand as far as possible to avoid risk of leakage.
- Remove the protective tray.
- Remove the lid support tool and close the lid (see page 36).

When the analyser is not in cycle mode:
- Adjust the probe reference position (see page 132 and following).
- Prime the fluidics circuit as follows:

- Select ARM-Mixed Partial Priming, then click on .
  The analyser starts up the fluidics circuit and rinses the sampling needle.

Maintenance

5-4-12- Intervention in System Configuration menu

> **!** Perform this procedure only at the request of IDS Technical Service & Support personnel.

If a module remains unusable once the error message is released, the faulty element is no longer operational and the error message will remain. When this fault involves either one of the washers or a particular wavelength of the spectrophotometer, the relevant element can be temporarily deactivated using the SYSTEM CONFIGURATION menu. This should only be used when following guidance by IDS Technical Service & Support personnel.

This operation requires a Supervisor level of access.

· In the MAINTENANCE menu, select **SYSTEM CONFIGURATION**:
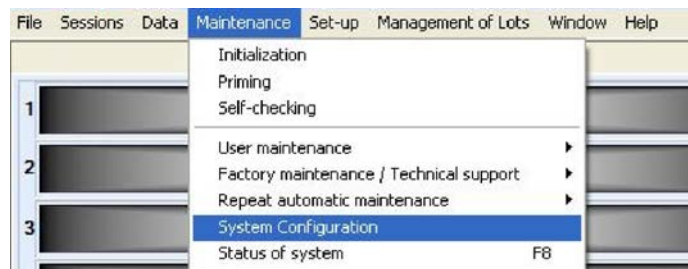
The configuration system menu is displayed.
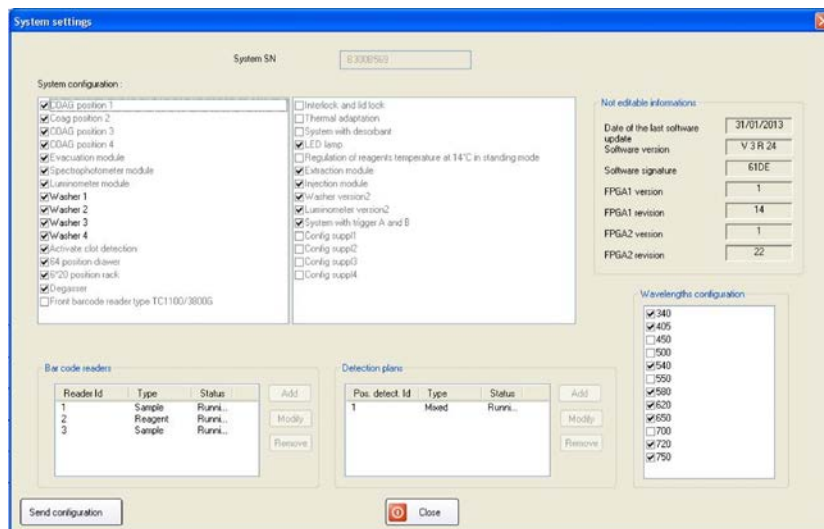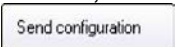
Deactivate a washer

System configuration :

☑ COAG position 1
☑ Coag position 2
☑ COAG position 3
☑ COAG position 4
☑ Evacuation module
☑ Spectrophotometer module
☑ Luminometer module
☑ Washer 1
☑ Washer 2
☑ Washer 3
☑ Washer 4
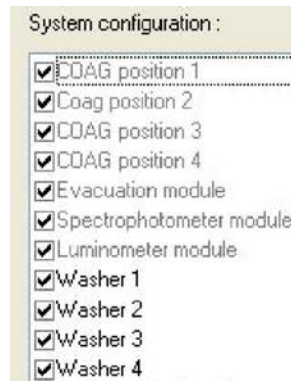
- · To deactivate a washer, uncheck the relevant box to deselect the washer.
- · Then click on [Send configuration] .
- · When the modification is completed, click on [⊙ Close] to exit the menu.
- · Perform the start-up procedure.

> ⚠ Washer deselection may impair the Immunoassay analytical throughput.

Deactivate a wavelength

Wavelengths configuration

☑ 340
☑ 405
☐ 450
☐ 500
☑ 540
☐ 550
☑ 580
☑ 620
☑ 650
☐ 700
☑ 720
☑ 750
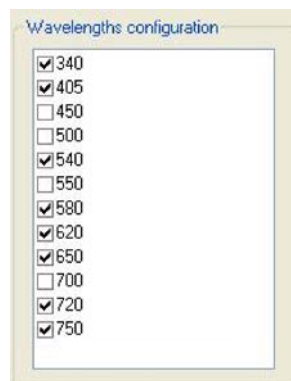
- · To deactivate a wavelength, uncheck the relevant box to deselect the wavelength.
- · Then click on [Send configuration] .
- · When the modification is completed, click on [⊙ Close] to exit the menu.
- · Perform the start-up procedure.

5-4-13- Repeat an automatic maintenance

Certain maintenance activities are carried out automatically by the system, without user's intervention.
If a fault prevents the automatic maintenance being carried out in full, an error message is displayed. A Warning message remains in the **WARNING** window until a new maintenance is complete without any error.
When this maintenance cannot be carried out automatically by the system, a new maintenance can be requested by the user.

5-4-13-1- Washer needle cleaning

This automatic maintenance takes place when the system is placed in standby mode.
After cleaning the sampling probe using D-SORB solution, four cuvettes are prepared, each filled with 500 µl of this solution (injected in two steps). The cuvettes are then transferred to the four washers: the aspiration needle of the washer is cleaned when aspirating the D-SORB solution. This step is followed by a washing step. This maintenance takes around 3 minutes et uses 3 ml de solution D-SORB.
· Check that D-SORB and WASH S solutions are present on the system, both with sufficient volumes..
· From the MAINTENANCE menu, select **REPEAT AN AUTOMATIC MAINTENANCE,** then select:
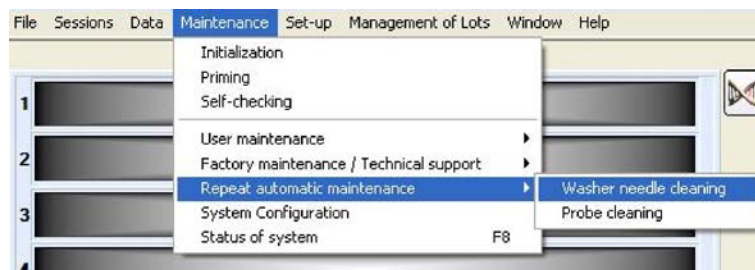
As soon as the menu option is selected, the maintenance is carried out by the system.
· When maintenance is completed without any error, the date and time are recorded in the journal of events (in the SYSTEM RECORDS tab).

5-4-13-2- Cleaning the probe

This automatic maintenance takes place when the system is placed in standby mode.
Certain assays performed on the system require a daily cleaning of the sampling probe with the Immunocleaner solution. This product is supplied in the form of a reagent cartridge and must be installed in the reagent compartment.
During this maintenance, the probe performs three times the following cycle : pipetting 300 µl of Immunocleaner solution, waiting for 30 seconds above the rinsing well, rinsing. The final rinsing uses D-Sorb solution.
· Check that IDS-iSYS D-Sorb and Immunocleaner solutions are present in sufficient quantities on the analyser.
· From the MAINTENANCE menu, select **REPEAT AN AUTOMATIC MAINTENANCE,** then select:

As soon as the menu option is selected, the maintenance is carried out by the system.

Maintenance

! Do not use any spray products on the analyser.

The cleaning and decontamination process for the parts of the analyser protected by the lid is described in **5-2- Weekly Maintenance**, page 118 and following.

The analyser bodywork can be cleaned with absorbent paper soaked in de-ionised water. If necessary, use a neutral, phosphate free detergent suitable for medical devices, diluted as recommended by the supplier, to clean traces on the bodywork.

The external side of the lid can be cleaned with absorbent paper soaked in de-ionised water.

! Do not clean the internal side of the lid.

Decontaminate the bodywork and the lid (internal and external sides) with a disinfectant wipe/solution suitable for medical devices.

For the internal side of the lid:
· Open the lid and insert the lid support tool (see pages 35 and 36).
· Switch off the analyser.
· Decontaminate the internal side of the lid with a disinfectant wipe/solution suitable for medical devices.

! Do not touch the lock spring.
A slight touch on this spring releases the locking mechanism and prevents the lid closing.
In this case, switch off the analyser and push the lock axis back into its housing.

In case of hazardous material accidental spillage into or onto the analyser, decontaminate with a disinfectant wipe/solution suitable for medical devices.

The following products cannot be used for cleaning or decontamination of the analyser:
· Strong or weak acids
· Bases
· Pure alcohol
· Solvents (ether, White Spirit, gasoline)
· Ammonia
· Chlorine
· Bleach
· Benzene

! If there is any doubt about using a particular product, contact Technical Services.

5-5-1- Decontaminating the containers of solid and liquid waste

> **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.

Solid waste tray

· Empty and decontaminate the waste tray once emptied with a disinfectant solution suitable for medical devices.
· Rinse it with water, then decontaminate again with a disinfectant solution suitable for medical devices.
· Dry the tray prior to replacing in its compartment.

Liquid waste container

· Rinse the container with freshly prepared bleach once the liquid waste has been disposed of.
· Then rinse with tap water.
· Add the appropriate volume of bleach prior to reusing the container with the analyser (see Section Appendices, **A-1- Waste Disposal,** page A2).

SECTION 6:

Problems & Corrective Action

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Problems & Corrective Action 148

Problem	Possible cause & corrective action
CCS1 %CV outside limits	1 - Presence of air bubbles in the sampling fluidic circuit. Check for air bubbles in the tubing circuit. Carry out a full priming of the arm.
	2 - Check for the presence of bubbles in the reagents: there should be none.
	3 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 117), if applicable. If the probe is bent, replace it and adjust the XYZ reference position (see Section 5-4-2, page 127).
	4 - Check for air bubbles on the IDS-iSYS Triggers A and B tubing circuits. Check for air bubbles in the tubing circuits.
	5 - Repeat the CCS1 test.
	6 - If the problem persists, contact IDS Service & Support personnel.
CCS2 %CV outside limits	1 - Presence of air bubbles in the sampling fluidic circuit. Check for air bubbles in the tubing circuit. Carry out a full priming of the arm.
	2 - Check for the presence of bubbles in the reagents: there should be none.
	3 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 117), if applicable. If the probe is bent, replace it and adjust the XYZ reference position (see Section 5-4-2, page 127).
	4 - Check for air bubbles in the IDS-iSYS Triggers A and B tubing.
	5 - Repeat the CCS2 test.
	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.
	2 - Check for air bubbles in the IDS-iSYS Triggers A and B tubing.
	3 - Check IDS-iSYS Cuvettes and IDS-iSYS Triggers by carrying out a CCS4 test.
	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.
	5- If CCS4 exceeds the limits, replace the IDS-iSYS Cuvettes and IDS-iSYS Triggers in use.
	5 - If the problem persists, contact IDS Service & Support personnel.

Problem	Possible cause & corrective action
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.
	2 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 117), if applicable. If the probe is bent, replace it and adjust the XYZ reference position (see Section 5-4-2, page 127).
	3 - Check for air bubbles in the IDS-iSYS Wash Solution tubing. Carry out a full priming of all washers.
	4 - Repeat the CCSB test.
	5 - If the problem persists, contact IDS Service & Support personnel.
CCS1/CCS2 Ratio outside limits	1 - Presence of air bubbles in the sampling fluidic circuit. Check for air bubbles in the tubing circuit. Carry out a full priming of the arm.
	2 - Check for the presence of bubbles in the reagents: there should be none.
	3 - Check that the probe is not blocked or bent. Carry out a decontamination of the probe (see Section 5-1-1-4, page 117, if applicable. If the probe is bent, replace it and adjust the XYZ reference position (see Section 5-4-2, page 127).
	4 - Check for air bubbles in the IDS-iSYS Triggers A and B tubing.
	5 - Repeat the CCS1 & 2 tests.
	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.
	2 - Adjust the probe XYZ reference position (see 5-4-10- Adjustment of probe reference position, page 132).
	3 - Replace the CCS cartridge.
	4 - Repeat the CCS1 and CCSB tests.
	5 - If the problem persists, contact IDS Service & Support personnel.

SECTION 7:
System Configuration

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System Configuration 151

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 **SET-UP** menu, select the **LOCAL SYSTEM** menu:

- In the **LOCAL SYSTEM** menu, select the **STARTING-UP** tab:
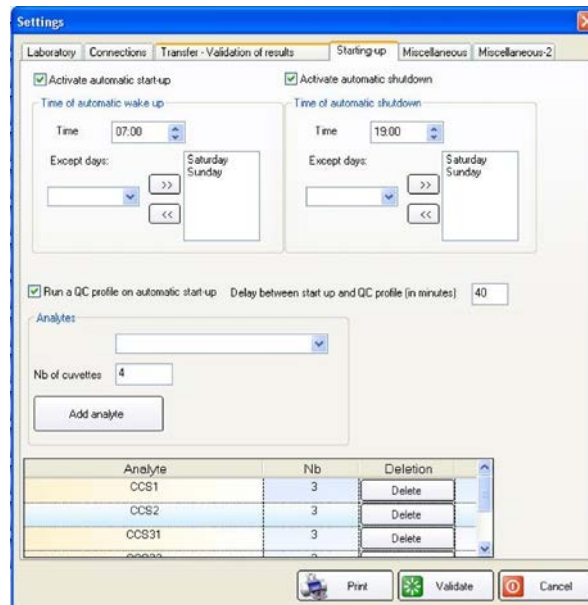
- Click on the box 'Activate wake-up'.
- Check the box 'Run a QC profile on wake-up'.
- The fields for programming the qualification profile are displayed.
- From the drop-down list, select the necessary test and programme the required number of replicates (see CCS IFU) and click [Add Analyte] .

- Repeat the operation for each test required.
- Click on [Validate] .

> ! 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.

System Configuration

The reflex tests are automatically scheduled for a given patient when a result previously obtained for one, two or three tests meets defined conditions.

Depending upon the selected option, tests to be scheduled are either automatically added or added on user's request.

The system can thus manage one, two or three conditions related to the assay result of one, two or three tests. These conditions are defined in rules.

Reflex tests can be created with a Supervisor level of access when the system is not in cycle mode. These tests can be created or imported from a file.

The existing reflex tests can be displayed by any level of access, even during a run cycle.

Tests to launch when the defined conditions are met must target the same type of sample (serum / plasma, urine, Other) than the triggering test.

If the same test is requested several times by different reflex tests, this assay is performed once.

Similarly, when an analyte is assayed in several replicates, a single request is programmed for each of the reflex test associated with that analyte .

· In the **SETUP** menu, select:
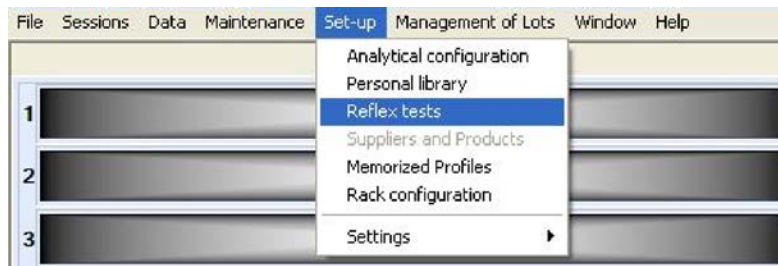
· The table of the reflex tests is displayed:
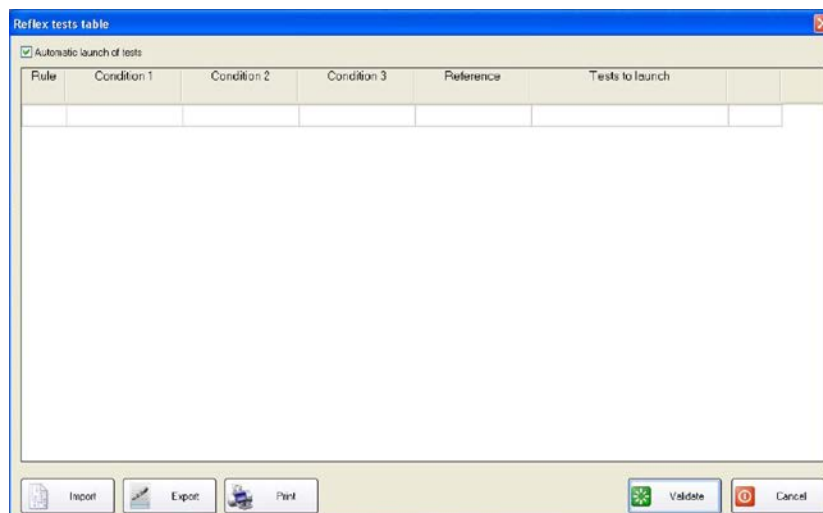
7-2-1- Creating a new rule

- Click on an empty cell of the «Condition 1» column in order to create a new rule of reflex tests:
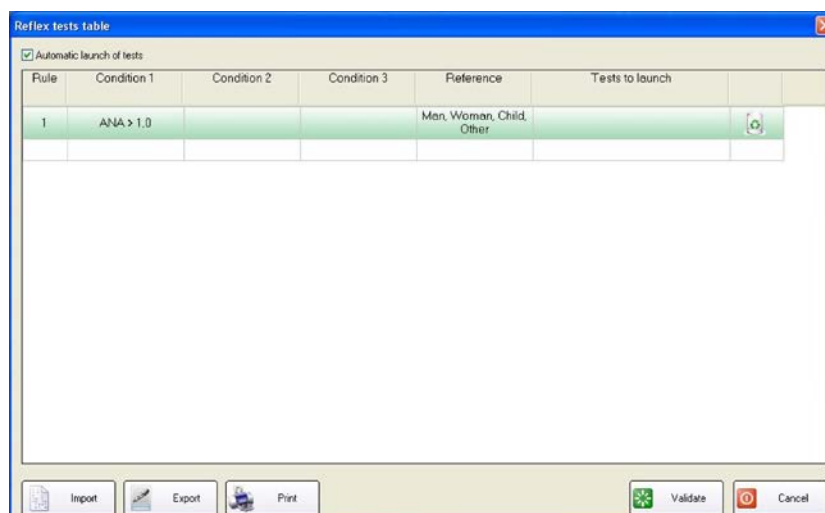
- Select the target analyte from the dropdown list.
- Then enter the value (in working units) triggering the condition.
- Then select the relation of order between the condition and the programmed value (lower, lower or equal, higher, higher or equal by clicking the appropriate radio button:

- Click on .

  The rule is created with its number in the list and is immediately applied to the references Man, Woman, Child and Other:

- Two other conditions can be defined as described above by clicking in the relevant column.

System Configuration

• The application can be restricted to certain patient categories by clicking in the cell of the Reference column:

• Click on the relevant tick to deselect a reference.
• Then click on [Validate].
• Click in the cell of the «Test to launch» column:
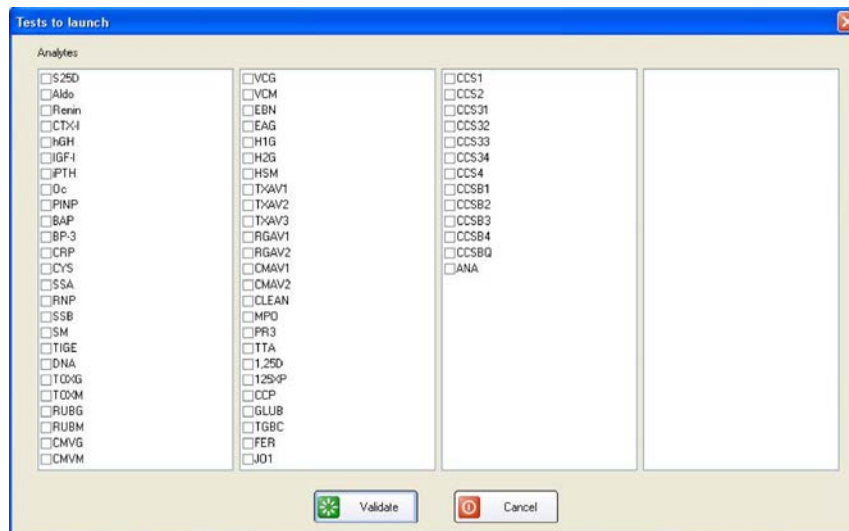
The tests of the personal library are displayed.
• Select the additional test(s) to launch by clicking in the relevant box.
• Then click on [Validate]:
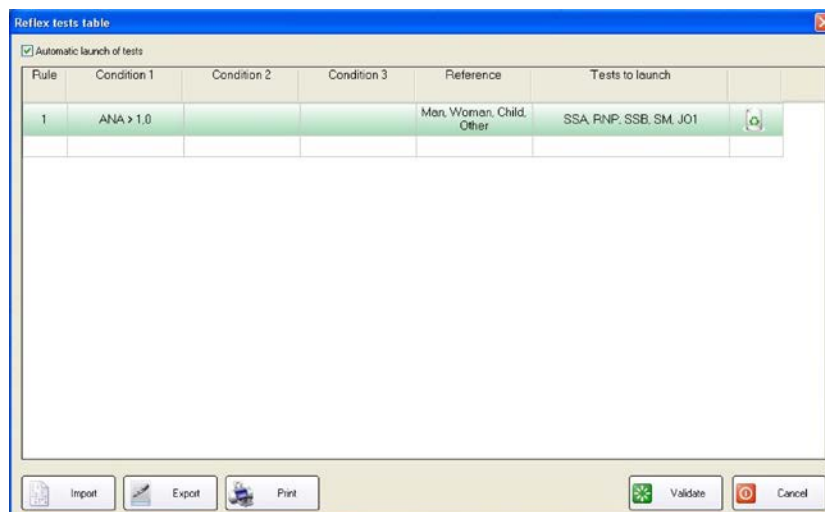
- Proceed in the same way for other rules to be created.
- Click on [✳ Validate] to exit the menu and save the created rules.

7-2-2- Launch option of reflex tests

Depending upon the selected option, additional tests to perform can be:
- automatically added to the relevant profile,
- added to the profile after accepting the automatic action or by using a specific button in the profile edition.

| ☑ Automatic launch of tests | Tests are automatically added to the profile. |

| ☐ Automatic launch of tests | Tests are added to the profile after user's indication. |
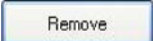
- Tick or untick the launch option of tests according to the desired behavior.
- Exit the menu by clicking on [✳ Validate] to save the modification.

7-2-3- Modifying an existing rule

· Select the desired rule and click in the cell to modify.

· Enter the modification and click on the [⊛ Validate] button in the window.

· Conditions 2 and 3 can be removed. To do this, click in the relevant cell to display the programming window of condition 2 or condition 3, then click on [Remove].

· Exit the menu by clicking on [⊛ Validate] to save the modification.
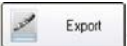
> **!** Condition 1 cannot be removed.

7-2-4- Importing/exporting rules

The table containing the rules defining the reflex test can be exported. When exporting, the system generates a specific format file (extension .rfx) that can then be imported into the software interface.

Exporting the rules

· Click on [✎ Export].

· Select the assigned folder and enter the file name.

· Click on **SAVE**.

Importing the rules

· Click on [⊡ Import].

· Select the source file (file format .rfx) by specifying the appropriate pathway and click on **OPEN**.

· The rules contained in the file are added to the existing rules.

· Exit the menu by clicking on [⊛ Validate] to save the modification.

7-2-5- Removing a rule

An existing rule can be removed.

· Click on the icon [♺] of the rule to remove.

· The rule is removed from the table and the numbering of the rules is consequently modified.

· Exit the menu by clicking on [⊛ Validate] to save the modification.

System Configuration
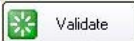
- In the **SET-UP** menu, select the **LOCAL SYSTEM** menu:

- Printing parameters are defined in the **LABORATORY** tab:
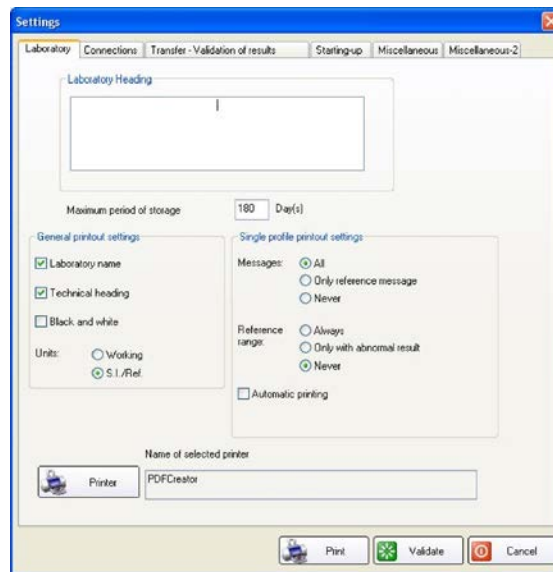
- Use the keyboard to enter the header text.
  To insert a line break, use CTRL + ENTER.
- Select the desired printing options by clicking the appropriate radio button.
- Select the printer if necessary.
- Exit the menu by clicking on [Validate] to save the modifications.

- In the **SET-UP** menu, select the **LOCAL SYSTEM** menu:

- The options of validating and transferring the results are defined in the **TRANSFER/VALIDATION OF RESULTS** tab:
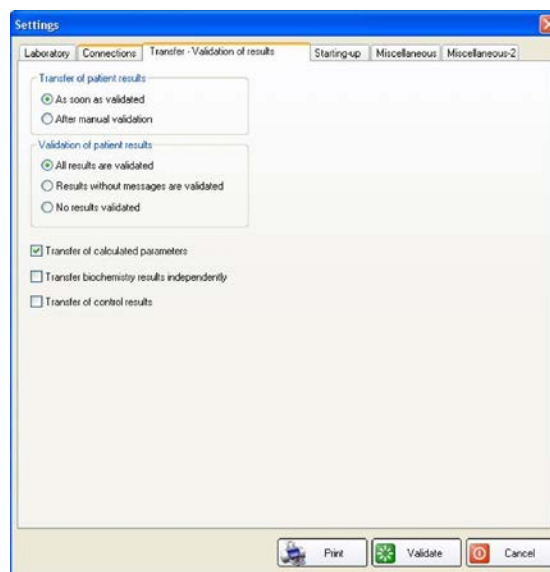
- Select the option of result transfer by clicking in the appropriate radio-button:
    - **As soon as validated**: as soon as available, the result is sent to the centralised computer
    - **After manual validation**: all results of patient profile are sent after using the [Store /Transfer] button in the worklist or in profile edition.
- Select the option of result validation by clicking in the appropriate radio-button:
    - **All results are validated**: as soon as available, the result is validated and sent to the centralised computer. The completed profile is automatically stored.
    - **Results without messages are validated**: only the results accompanied with the message **OK** are validated. [Store /Transfer] button must be used to store the other results and transfer the relevant patient profiles.
    - **No results validated**: [Store /Transfer] button must be used to store and transfer each patient profile.
- Then select the transfer option(s) of calculated parameters and biochemistry profiles (applicable when a profile contains both biochemistry and immunology tests).
- Exit the menu by clicking on [Validate] to save the modifications.

System Configuration

Access to the application is controlled by access code. Several levels of authorization are managed by the system, which for users, Supervisor and Operator levels. The upper levels are reserved to Technical Services.

The codes and access levels are declared in the system and can be modified later.

Access to the various menu is dependent on user level. Certain menus can be not accessible for certain levels or can only be displayed, but cannot be modified.

Adding new users is allowed from the Supervisor level.

Each user is defined by a name and a password. The name and the access code must be unique in the system.

· In the **SET-UP** menu, select:
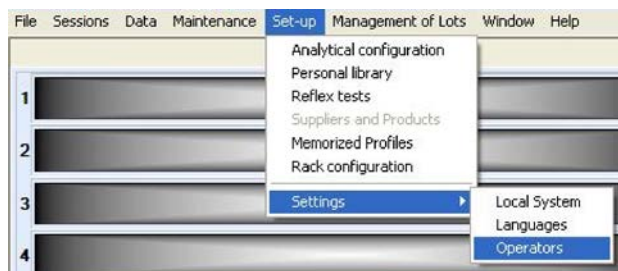
The list of the users defined for the system is displayed:
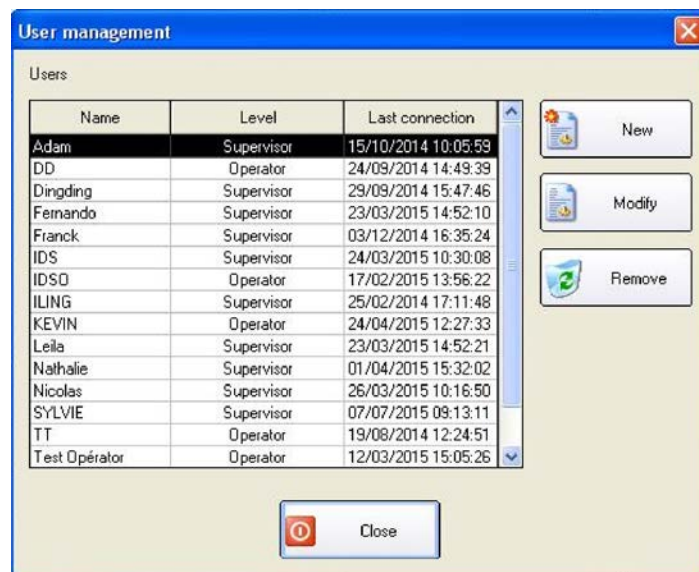
Declare a new user

· To declare a new user, click on :
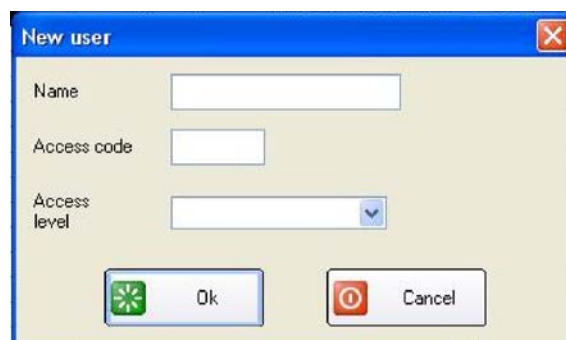
System Configuration

- Click in the entry field of the name then enter the name using the keyboard (maximal length: 20 alphanumeric characters).
- Click in the entry field of the access code then enter the password sing the keyboard (maximal length:8 alphanumeric characters).

> (!) Remember the defined password and its cases (combination of characters in capital and lower cases).

- Then select in the list the level of access.
- Click on [OK] to record the new user.

Modify a user

- Select the user to modified then click on [Modify] .
- Enter the relevant modification(s) then click on [OK] .

Remove a user

- Select the user to remove then click on [Remove] .
- The user is removed from the list.

When the analytical configurations must be updated, a "Master Database & Update Tool" CD is provided by IDS.

The update is done from the user interface.

· Insert the CD provided by IDS in the CD drive.
· In the **FILE** menu, select:
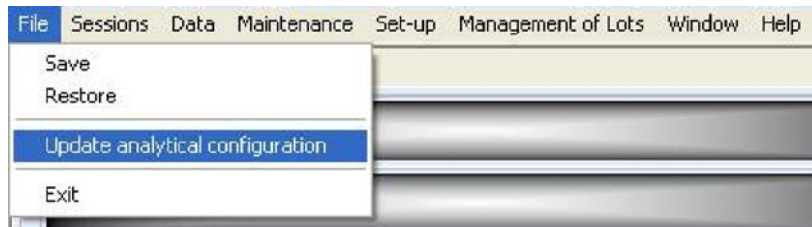
· Open the file «config.acu» from the CD by indicating the relevant pathway.
· When the update starts, a window is displayed with the list of the modified analytes and with the result of each modification:
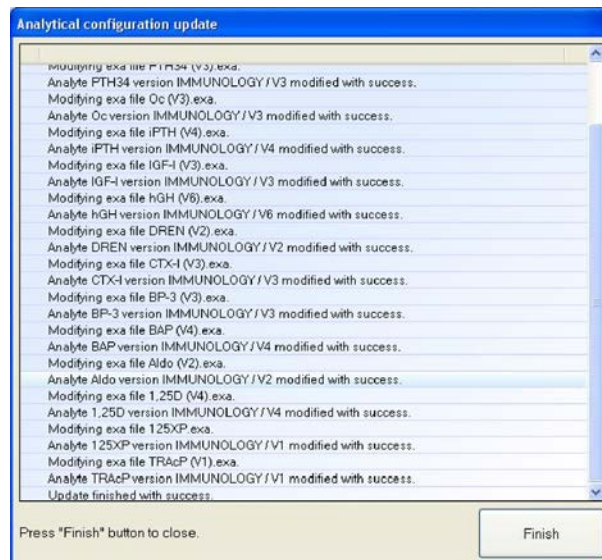
! In case of error message or failure when updating one or several analytes, contact IDS Technical Services.

· Click on [Finish] . During the software initialisation, the following message is displayed:
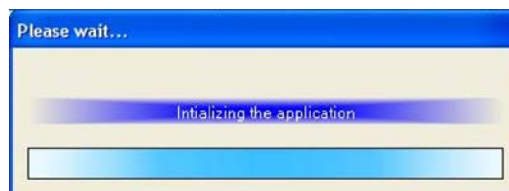
Appendices

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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 liters container.

· Before installing the liquid waste container container, put 250 mL of commercial bleach ready-to-use (2,6% of active Chloride) into the empty container.

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

Except when an automated system of liquid waste treatment is used, liquid waste must be processed prior to disposal in order to eliminate a biological risk. This procedure must be carried out outside of the analyser:

· When the container is full, remove the plunger and remove the container from the analyser.

· Add 500 mL of concentrated bleach (9,6% of active Chloride).

· Leave on overnight.

· Eliminate the processed waste in accordance with current local procedures.

This process does not eliminate chemical risk.

Do not use bleach in tablet form.

Solid waste
· Probes.
· IDS-iSYS Cuvettes.

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

Appendices

A-2- Decontaminating the Analyser

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.

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.

Appendices

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**

Appendices

A-3- Disposal Of The Analyser

Since 13/08/2005, the disposal of electrical and electronic waste has been governed by **Directive 2002/96/E.C. of 27 January 2003,** revised by **Directive 2012/19/UE of 4th July 2012**.
This Regulation is applied in each European country. The OWNER of the equipment must contact its VENDOR in order to obtain information about current national and local laws.

In case where the equipment is removed from the OWNER's site, the OWNER must return the device decontaminated, and must apply the disinfection procedure described in Appendix 2.
Furthermore, containers that have been in contact with solid waste must be disinfected. Solid and liquid waste, as well as liquid waste tubing must be disposed of according to the current local laws.

In the event of resale to a third party, the first OWNER must notify the VENDOR of the name and address of the new OWNER of the device in order to guarantee traceability of the equipment and for its subsequent disposal, and must inform the new OWNER that the equipment must be disposed of according to the current local laws.

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

Appendices

A-4- IDS-iSYS Cuvettes

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

	Manufacturer.
IVD	In vitro diagnostic medical device.
	Store/hold the box this way up.
	Keep dry.
	Fragile
	Single use.
REF	Catalogue number.
LOT	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.

Appendices

A-5- Sample barcode symbology managed by the system

> ! It is recommended to use a symbology containing a check character.

> ! Calibrators and controls are automatically identified using a 12 digit barcode.
> When possible, avoid 12 digit identification for samples.

Barcode symbology recognized by the reader

- Code 128
- Code 39
- Codabar
- EAN/UPC
- Interleaved 2 of 5

Reader programming possibilities

Depending of the barcode symbology, the following elements can be programmed.
This programming can be done on demand by Technical Service.

	Check digit	Min number of characters	Max number of characters
Interleaved 2 of 5	yes	yes	yes
Code 128	no	yes	yes
Code 39	yes	yes	yes
Codabar	no	yes	yes
EAN/UPC	yes	no	no

Recommendations

- The barcode should contain at least 5 digits for the removable rack configuration (sample tubes identified by the barcode reader integrated into the sample compartment) or at least 4 digits (except if Interleaved 2of 5) for the fixed tray configuration (sample tubes identified by the barcode reader in the front of the analyser).
- The barcode must not contain more than 32 digits. The character «%» must not be used .
- The height of the barcode should not be less than 10 mm
- The barcode symbol should be placed at the center of the area between 20 mm above the bottom of the tube and 14 mm below the top of the tube, excluding the cap.
- The label should be placed with the bars perpendicular to the axis of the tube.

Appendices

A-6- Analyser long stoppage period

When the analyser has been inactive for more than 2 days, a specific procedure for stopping the analyser must be applied. The procedure will depend on the duration of the stoppage.

- Less than 14 days: the analyser will be placed in standby mode, with a daily automatic wake-up. A startup procedure will be automatically performed every day. Ancillary reagents will be kept on-board, except AP Substrate.
- Between 15 and 30 days: the analyser will be switched off completely, after a decontamination of the TRIGGERS A and B fluidic circuits.

If the analyser must be stopped for a period longer than one month, contact the Technical Services.

> ⚠ TRIGGER A and TRIGGER B solutions must not be kept on-board during long periods of inactivity (more than two weeks).
> TRIGGER B solution may damage the fluidic circuit pump and may have an impact on CCS results.

A6-1-Less than 14 days

The analyser is placed in standby mode, with a daily automatic wake-up. Ancillary reagents are kept on-board, except AP Substrate. A startup procedure is automatically performed every day.
For systems using AP Substrate, a cleaning procedure of the AP Substrate fluidic circuit must be carried out. The AP Substrate tubing rising maintenance, included in the monthly maintenance, will be used to carry out this procedure.

Each startup procedure will use the following products:

Description	Quantity
IDS-iSYS Trigger A	4.8 mL
IDS-iSYS Trigger B	4.8 mL
IDS-iSYS SYST L	3.4 mL
IDS-iSYS WASH S	35 mL
IDS-iSYS Cuvettes	28 cuvettes
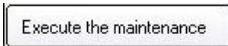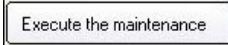
> ⚠ As the solid waste will be full after 14 days, the automatic startup will no longer be performed. When the spectrophotometer is deactivated, the solid waste will be full after 3 days and the automatic startup will no longer be performed.

Appendices

For systems using DSORB solution, a maintenance procedure for the four washers will take place automatically during the SHUT DOWN procedure. Each shutdown procedure will use the following products:

Description	Quantity
IDS-iSYS WASH S	24 mL
IDS-iSYS D-SORB	3 mL
IDS-iSYS Cuvettes	4 cuvettes

- Remove all samples.
- Remove reagent racks and store in accordance with IFU recommendations.
- Carry out daily maintenance, then if necessary, weekly and monthly maintenance.
- For systems using AP Substrate, from the MONTHLY MAINTENANCE menu, perform the « Rinsing of the AP Substrate tubing» maintenance twice to rinse the fluidic circuit following the below steps:
    - Replace the AP Substrate bottle by a 500 mL bottle containing de-ionised water to mimic the AP Substrate.
    - Click on the corresponding [Execute the maintenance] button in front of this item in the maintenance list.
    - Click on [Start].When the first step is completed, a message is displayed.
    - Keep *the distilled water bottle in the AP Substrate position*, continue the maintenance by clicking on [Start].
    - Repeat this procedure a second time.
- After the two rinsing procedures are completed, perform the « Rinsing of the AP Substrate tubing» maintenance for a third time to compete the rinse and to empty the fluidic circuit:
    - Keep *the distilled water bottle in the AP Substrate position*.
    - Click on the corresponding [Execute the maintenance] button in front of this item in the maintenance list.
    - Click on [Start].When the first step is completed, a message is displayed.
    - Replace the bottle containing distilled water with an *empty bottle*. Continue the maintenance by clicking on [Start].
- Empty the liquid waste
- Empty the solid waste.
- Waste must be disposed of in accordance with current local regulations (see APPENDIX I: Waste disposal, page A2).

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.

- Click on [Ancillary product].
- Click on the liquid waste icon.
Then validate the message confirming the liquid waste emptying.

Appendices

- Click on the solid waste icon.
  Then validate the message confirming the solid waste emptying.
- Check the current volume of each ancillary reagent is sufficient to cover the stoppage period.
  If necessary, install a new ancillary reagent.
- Exit the menu.
- In SETUP menu, select the **SETTINGS LOCAL SYSTEM** menu:
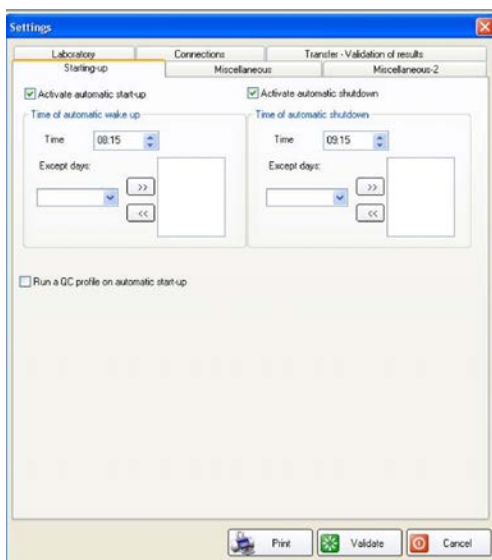
- Program a daily automatic wake-up, without exception days .
- Program a daily automatic shut down, without exception days . One hour time delay between wake-up and shut-down is required.
- If necessary, unselect the automatic QC profile option.
- Click on [Validate] to save the modification.
- From the Session menu, select **SHUT DOWN** to put the analyser into standby mode.
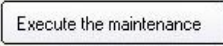
> (!) For systems using DSORB solution, a maintenance procedure for the four washers will take place automatically during the SHUT DOWN procedure.

Appendices

A6-2-Between 15 and 30 days

The analyser can be completely stopped after a decontamination of the IDS-iSYS TRIGGER B fluidic circuit followed by the emptying of the two TRIGGER and of the D-SORB fluidic circuits. The TRIGGER tubing cleaning maintenance, included in the weekly maintenance, will be used to carry out this procedure.
- Remove all samples.
- Remove reagent racks and store in accordance with IFU recommendations.
- Carry out daily maintenance.
- Carry out the general steps of the weekly maintenance.
- Perform the «Rinsing of the Trigger A and Trigger B fluid lines» maintenance <u>a first time</u> for rinsing the fluidic circuits:
    - Replace the two Trigger bottles by *two 250 mL bottles containing distilled water*.
    - *When the first step of the maintenance is completed*, continue the maintenance with the two bottles containing distilled water.
- When the rinsing is over, perform the «Rinsing of the Trigger A and Trigger B fluid lines» maintenance <u>a second time</u> for decontamination of the fluidic circuits:
    - Keep *the distilled water bottle in the TRIGGER A position*. Install *the TRIGGER A bottle at the TRIGGER B position*.
    - *When the first step of the maintenance is completed*, continue the maintenance with the same bottles installed.
- When the decontamination is over, perform the «Rinsing of the Trigger A and Trigger B fluid lines» maintenance <u>a third time</u> for rinsing and emptying the fluidic circuits:
    - Replace the two Trigger bottles by *two 250 mL bottles containing distilled water*.
    - *When the first step of the maintenance is completed*, replace the two bottles containing distilled water with *empty bottles*. Continue the maintenance.
- Carry out the general steps of the monthly maintenance.
- For systems using AP Substrate, perform the « Rinsing of the AP Substrate tubing» maintenance <u>twice</u> to rinse the fluidic circuit following the below steps:
    - Replace the AP Substrate bottle by a 500 mL bottle containing de-ionised water to mimic the AP Substrate.
    - Click on the corresponding | Execute the maintenance | button in front of this item in the maintenance list.
    - Click on | Start |.When the first step is completed, a message is displayed.
    - Keep *the distilled water bottle in the AP Substrate position*, continue the maintenance by clicking on | Start |.
    - Repeat this procedure a second time.
- After the two rinsing procedures are completed, perform the « Rinsing of the AP Substrate tubing» maintenance for <u>a third time</u> to complete the rinse and to empty the fluidic circuit:
    - Keep *the distilled water bottle in the AP Substrate position*.
    - Click on the corresponding | Execute the maintenance | button in front of this item in the maintenance list.
    - Click on | Start |.When the first step is completed, a message is displayed.
    - Replace the bottle containing distilled water with an *empty bottle*. Continue the maintenance by clicking on | Start |.
- Remove the bottle in the AP Substrate position.

Appendices

- For rinsing the D-SORB fluidic circuit, replace the D-SORB bottle with a bottle containing de-ionised water.
- Identify the position by using the barcode label of the D-SORB bottle that just has been removed from the system.
- Request three times the priming **SPECIFIC DECONTAMINATING SOLUTION,** from the menu
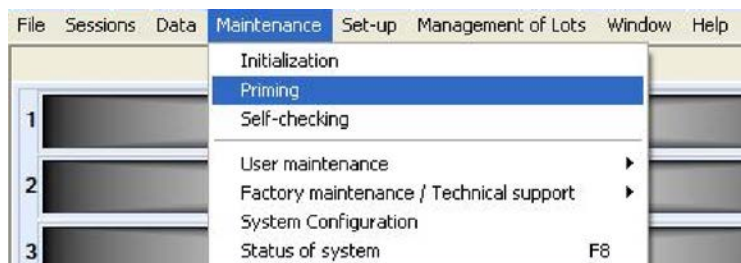
- For emptying the D-SORB fluidic circuit, remove the D-SORB level sensor from the bottle and wipe it.
- Invert the D-SORB level sensor and keep it in the air.
- Identify the position by using the barcode label of the D-SORB bottle that just has been removed from the system.
- Request three times the priming **SPECIFIC DECONTAMINATING SOLUTION,** from the menu

- Empty the liquid waste
- Empty the solid waste.
- Waste must be disposed of in accordance with current local regulations (see APPENDIX I: Waste disposal, page A2).

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.

- Click on [Ancillary product] .
- Click on the liquid waste icon.
  Then validate the message confirming the liquid waste emptying.
- Click on the solid waste icon.
  Then validate the message confirming the solid waste emptying.
- Check the current volume of each ancillary reagent is adequate with the stop period.
- 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'.

Appendices

A6-3-Analyser start up after a long stoppage period

- Perform the initial start up.
- Install new ancillary reagents

Description
IDS-iSYS Trigger A
IDS-iSYS Trigger B
IDS-iSYS SYST L
IDS-iSYS WASH S
IDS-iSYS D-SORB

- For systems using AP Substrate, install a new bottle of AP Substrate in its corresponding position.
- Once the new bottles are installed, a message proposing an automatic priming is displayed:

- Click on [Yes] to confirm the priming of the product(s).

  The analyser starts the priming sequence.
- Request twice **ALL SYSTEM-FULL PRIMING** from the menu:
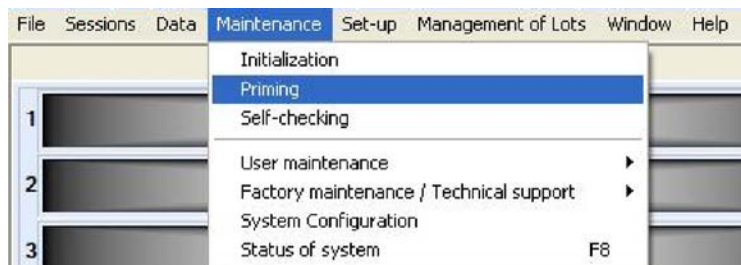
- Install a CCS reagent cartridge.
- Then perform the qualification profile.

> ! Wait for 40 minutes after installing CCS reagent cartridge before starting qualification profile, as the CCS reagent cartridge temperature must be allowed to equilibrate.

Connection
Protocol

For further assistance,
please contact IDS Technical Support:
Tel: 0191 519 6153
Fax: 0191 519 0760
Email: techsupport.uk@idsplc.com

CE IDS France , 42, rue Stéphane Mazeau, 21320 POUILLY-EN-AUXOIS, FRANCE

IDS Ltd 10 Didcot Way, Boldon Business Park,
Boldon, Tyne and Wear, NE35 9PD
Tel: 0191 519 0660

Connection Protocol

Contents	1

Connection Protocol

Contents (continued)

1– Versions of ASTM Protocol

The low level connection protocol uses the standard ASTM E 1381-95 "Standard Specification for Low-Level protocol to transfer messages between clinical laboratory Instruments and computer systems" and the high level connection protocol uses the standard ASTM E1394-91 "Standard Specification for transferring information between clinical instruments and computer systems".

Three versions are available in the software and can be selected from the IDS-iSYS interface:
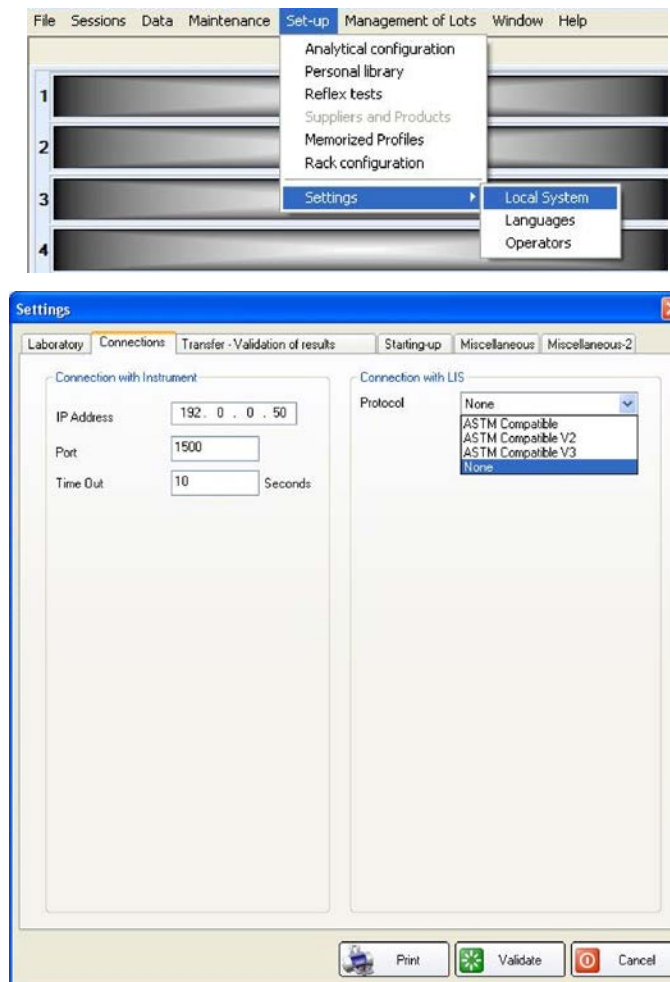
The **ASTM Compatible** version is the original connection protocol version, existing in the IDS-iSYS software versions prior to V10.00.

The **ASTM Compatible V2** version offers additional functionalities for the transfers to the LIS:
- transfer of the traceability associated with a result,
- transfer of messages associated with a result in a Comment block,
- transfer of quality control results (if the option is selected).

The **ASTM Compatible V3** version offers, in addition to the features of ASTM Compatible V2 version:
- transfer of the operator identifiers,
- transfer of the traceability associated with a result including information about AP Substrate and pretreatment washer,
- results are resent when a clot is detected on a sample,
- transfer of Tanner stage.

This document describes the structure and construction of ASTM messages used in each version of the connection protocol.

2- ASTM Compatible Version
2-1- General information
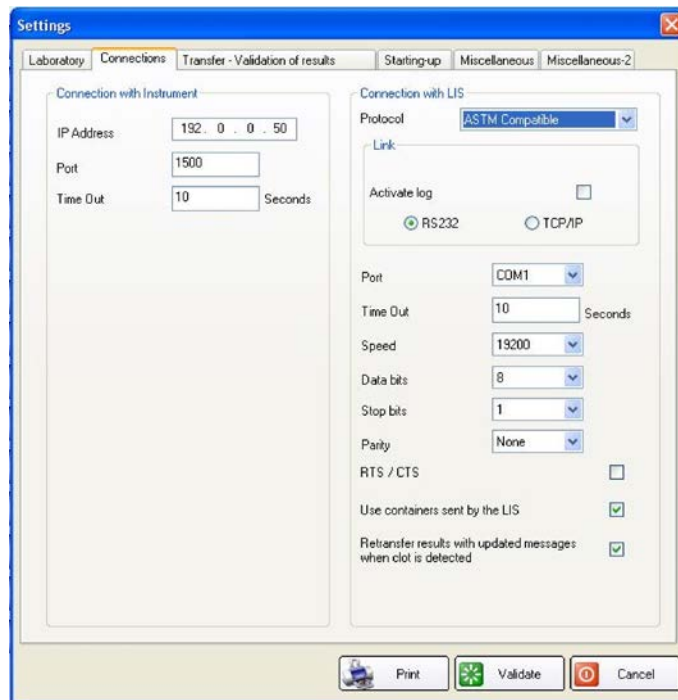
The ASTM protocol allows an ASTM message to be sent.

The **ASTM Compatible** version uses the sections defined as follows:

- The Header block: this block is the first one found in an ASTM frame, it defines the characteristics of the messages as well as the characters separating the fields and components which will be used
- The Patient block: this block contains all the information about the patient such as his or her last name, first name, PID, etc
- The Test Order block: this block defines a test, so it contains the data relating to a test carried out on one or several analytes. This block is always preceded by a patient block
- The Result block: this block contains the result of one analyte and one alone. It is always preceded by a Test Order block or by another Result block. If several results are sent through for one test, there will then be several Result blocks following a Test Order block (typically if a test has been carried out on several analytes, the result of each of these will be provided in one single message but in several Result blocks)
- The Request Information block: This block allows information to be requested in both directions Analyser to LIS and vice versa. Results or information can be requested about a patient
- The Message Terminator block: This block indicates that the message is ended

The ASTM message has a hierarchical structure, each block from the lower level refers to the block from the level immediately above, except for the comments blocks.

2- ASTM Compatible Version

2-1- General information (continued)

The structure of the ASTM message is the following for this version of protocol:

Header
> **Patient 1**
>> **Order 1**
>>> **Result 1**
>>> **…….**
>>> **Result n**
>> **……..**
>> **Order n**
>>> **Result 1**
>>> **…….**
>>> **Result 2**

Message Terminator

Example of an ASTM message:

H|\^_|||IDS-iSYS B300B0378|||||||P|2|20111124135800
   P|1||20105863||BONTEMPS^Robert||19500226|M|||||DUPONT|||||Comment||||||||||||||
   Radiology
      O|1|01^7148345||^^^25OHD|R||||||A||||S||||||||||O
         R|1|^^^25OHD|25,2|ng/mL|10,0 to 100,0|N||F||||20111124133726|IDS-iSYS
         B300B0378|
L|1|N

2- ASTM Compatible Version

2-2- The Header Block

H|\^_|||IDS-iSYS B300B0378|||||||P|2|20111124135800

This block is the first in the message, and is the one which defines its characteristics.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type	H	Fixed value H to indicate a Header block.
Delimiters Definition	|\^_	Definitions of the delimiters that will be used in the message. These are the 4 characters which follow the H, with the following being initialized: · The field delimiter (|) which separates the various fields. · The repeat delimiter (\ ) which separates a repetition in a field. · The component delimiter (^) which separates the various components of the field. · The escape delimiter (_) which indicates an escape sequence for dealing with special characters. N.B. The record delimiter is fixed and is always the character ASCII 13 (carriage return).
Message Control ID		**Not used.**
Access Password		**Not used.**
Sender Name or ID	IDS-iSYS B300B0378	Name or identifier of the issuer: · Not used in the direction LIS => analyser. · Fixed at IDS-iSYS + Serial number in the direction device to LIS.
Sender Street Address		**Not used.**
Reserved Field		
Sender Telephone Number		**Not used.**
Characteristics of Sender		**Not used.**
Receiver ID		**Not used.**
Comment or Special Instruction		**Not used.**
Processing ID	P	Type of message fixed at P for Production.
Version No.	2	Version of the protocol, always equal to 2 (in the direction analyser => LIS).
Date and Time of Message	20111124135800	Date of message in the format YYYYMMDDHHmmss.

2- ASTM Compatible Version

2-3- The Patient Block

**P|1||20105863||BONTEMPS^Robert||19500226|M|||||DUPONT|||||Comment||||||||||||||
Radiology**

This block represents the information relating to a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type	P	Fixed value P to indicate a Patient block.
Sequence Number	1	Number of the Patient block in the message starts at 1 and is increased for each block in the message.
Practice Assigned Patient ID		**Not used.**
Laboratory Assigned Patient ID	20105863	PID.
Patient ID #		**Not used.**
Patient Name	BONTEMPS^Robert	Field consisting of 5 components last name, first name, initials, suffix and title. Only the first 2 fields are used.
Mother's Maiden Name		Not used.
Birth Date	19500226	Date of birth in format YYYYMMDD.
Patient Sex	M	Reference of patient values: • M for Man. • F for Woman. • E for Child. • U for others. In the direction LIS=>IDS-iSYS: • M for Man. • F for Woman. • U for Child. • U for others.
Patient Race		**Not used.**
Patient Address		**Not used.**
Reserved Field		**Not used.**

2- ASTM Compatible Version

2-3- The Patient Block (continued)

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Patient Telephone Number		**Not used.**
Attending Physician ID	DUPONT	Name of doctor associated with profile.
Special Field 1		**Not used.**
Special Field 2		**Not used.**
Patient Height		**Not used.**
Patient Weight		**Not used.**
Patient Known or Suspected Diagnosis	Comment	Comment associated with profile.
Patient Active Medication		**Not used.**
Patient Diet		**Not used.**
Practice Field 1		**Not used.**
Practice Field 2		**Not used.**
Admission and Discharge Dates		**Not used.**
Admission Status		**Not used.**
Location		**Not used.**
Nature of Alternative Diagnostic Code		**Not used.**
Alternative Diagnostic Code		**Not used.**
Patient Religion		**Not used.**
Marital Status		**Not used.**
Isolation Status		**Not used.**
Language		**Not used.**
Hospital Service	Radiology	Department associated with the profile.
Hospital Institution		**Not used.**
Dosage Category		**Not used.**

2- ASTM Compatible Version

2-4- The Order Block

O|1|01^7148345||^^^25OHD|R||||||A||||S|||||||||||O

This block represents the information about one or several test requests for a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	O	Fixed value O for indicating an Order block.
Sequence Number	1	Number of the order within the Patient block starts at 1 and is increased for each Order block in the message.
Container and Specimen ID	01^7148345	This field consists of 2 components: · The type of container used for the sample (2 digits). · 01 PT_11_4.5 mL. · 02 PT_13_6 mL. · 03 ST_13_5 mL H. · 05 Cup 500 µL. · 06 Cup 2 mL. · 07 PT_16_10 ml. · 08 to 17 for configurable containers. PT for Primary Tube; ST for Secondary Tube For correct functioning of the apparatus, it is important to allocate the correct type of container used for the sample. If this component is null, the default container type defined for the tray will be used. · The SID of the profile concerned by the request.
Instrument Specimen ID		**Not used.**
Universal Test ID	^^^25OHD	This ASTM field consists of 4 components: · Universal test ID. · Universal test ID Name. · Universal test ID Type. · Manufacturer's Code. Only the last component is used and will be entered with the unique IDS-iSYS identifier of the analyte. In one single order it is possible to specify several tests by adding a repeat delimiter and by then adding one or several UTI thus obtaining a chain of the type ^^^25OHD\^^^BAP. Multiple requests of the same test can also be made: ^^^25OHD\^^^25OHD

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Priority	R	This field may contain the values: · S = STAT. · A = ASAP. · R = Routine. · C = Callback. · P = Preoperative. For the device, only S has any influence, the passage of the associated profile into Urgent, and the other values are ignored.
Requested/Ordered Date and Time		**Not used.**
Specimen Collection Date and Time		**Not used.**
Collection End Time		**Not used.**
Collection Volume		**Not used.**
Collector ID		**Not used.**
Action Code	A	Action to be carried out on the block test or tests. This field may contain the values: · **A** for Add. · C for Cancel. · **N** for New. · P for Pending. · Q for QC. For the device, A and N are managed in the same way (new request or new rerun), C (cancellation of a request) can be managed if the test is not in progress. P and Q are not managed.
Danger Code		**Not used.**
Relevant Clinical Information		**Not used.**
Date and Time Specimen Received		**Not used.**

ASTM Name of the field	Value*	Description and use in IDS-iSYS system

Specimen Descriptor	S	This field consists of two sections:
		
		· The sample type which can take for the IDS-iSYS the following values:
		  · U = Urine.
		  · S = Serum.
		  · O = Other.
		· The sample source (place where the sample was taken) is not used.

Ordering Physician		Doctor
Physician Telephone Number		**Not used.**
User Field 1		**Not used.**
User Field 2		**Not used.**
Laboratory Field 1		**Not used.**
Laboratory Field 2		**Not used.**
Date and Time Result Reported or Last Modified		**Not used.**
Instrument Charge to Computer System		**Not used.**
Instrument Section ID		**Not used.**
Report Type	O	This field may take the values: · **O** = Order. · C = Correction. · P = Preliminary results. · F = Final results. · X = Cancel. · I = Instrument pending (in response to a request). · Y = No order on record for this test (in response to a request). · **Z** = No record for this patient (in response to a request). · **Q** = Response to a request. In the device, C is managed when a clot is detected on a sample (see page 67).
Reserved Field		**Not used.**
Location or Ward of Specimen Collection		**Not used.**
Nosocomial Infection Flag		**Not used.**
Specimen Service		**Not used.**
Specimen Institution		**Not used.**

2- ASTM Compatible Version

2-5- The Result Block

R|1|^^^25OHD|25,2|ng/mL|10,0 to 100,0|N||F||||20111124133726|IDS-iSYS B300B0378|

This block represents the information sent through by the IDS-iSYS to the LIS after a test has been carried out for a patient.

Here are the various fields of this block used in the protocol version:
* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	R	Fixed value R for indicating a Result block.
Sequence Number	1	The number of the result within the Patient block begins at 1 and is increased for each Result block in the message.
Universal Test ID	^^^25OHD	This ASTM field consists of 4 components: · Universal test ID. · Universal test ID name. · Universal test ID type. · Manufacturer's code. Only the last component is used and will be provided with information with the unique IDS-iSYS identifier of the analyte.
Data or Measurement Value	25,2	The value in the form of ASCII chain. Results which cannot be calculated are sent in the format * * * * * . Each character * is separated by a space.If the value is outside the measuring range, is transmitted in this field: · * * * * * when the result is below the measuring range · * * * * * when the result is above the measuring range (For 25OHD: <5 or >140)
Units	ng/mL	Blocks used
Reference Range	10,0 to 100,0	Normal reference values used for the patient sent through in the form of an ASCII chain.
Result abnormal Flags	N	This field may take the values: · L = Below low normal. · H = Above high normal. · LL = Below alarm low. · HH = Above alarm high. · < of absolute low (Field of measurement). · > of absolute high (Field of measurement). · **N** = Normal. · **A** = Abnormal. · U = Significant change Up. · D = Significant change Down. · B = Better. · W = Worse. Only A and N are managed by IDS-iSYS.

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Nature of Abnormality Testing	S	This field forces S or A for the IDS-iSYS can take the values: · **A** = Age. · **S** = Sex. · R = Race. And is able to provide an indication about the bases on which the values of normality were determined.
Result Status	F	This field forces to F or P (replicate) on the IDS-iSYS can take the following values: · C = Correction. · **P** = Preliminary results. · **F** = Final results. · X = Request not honored. · I = Results pending. · S = Partial results.
Date of change in Instrument Normative Values		**Not used.**
Operator ID		**Not used.**
Date and Time Test Started		**Not used.**
Date and Time Test Completed	20111124133726	Date and time of result of test on the GUI.
Instrument Identification	IDS-iSYS B300B0378	Name of device + Serial number.

Q|1|^7148344||ALL|||||||||O

This block represents a request for information whose origin now can only be the IDS-iSYS.

This request will be used by the IDS-iSYS after discovering a tube for a patient whose profile is known on the work list in order to request the tests to be carried out on this tube.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	Q	Fixed value Q to indicate a Request Information block.
Sequence Number	1	The request number starts at 1 and is increased for each request block in the message.
Starting Range ID Number	^7148344	This field consists of 3 elements; only the first 2 are used by the IDS-iSYS in order to specify the PID (optional) and the SID (obligatory) allowing the profile quoted to be identified.
Ending Range ID Number		*Not used*
Universal Test ID	ALL	This field can either indicate 1 particular test (in the identifier via its ID cf Test Order block) or request all the tests via the code ALL.
Nature of request Time Limit		***Not used in the direction IDS-iSYS=>LIS.*** Useful if LIS => IDS-iSYS with the value R to say that the date to be taken into account in the event of filter is the date of the test results and the date of arrival of the profile (code S).
Beginning request Results Date and Time		***Not used*** Useful in the direction LIS=>IDS-iSYS.
Ending request Results Date and Time		***Not used*** Useful in the direction LIS=>IDS-iSYS.
Requesting Physician Name		***Not used***
Requesting Physician Telephone Number		***Not used***
User Field 1		***Not used***
User Field 2		***Not used***

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Request Information Status Code	O	Potential values: · C · P · F · X · I · S · M · R · **A** · N · **O** · D Only the values O and A are managed in the direction IDS-iSYS to LIS. A is used when the LIS does not respond to a request. In such cases, the request is cancelled (this field takes the value A). The request is transmitted 3 times, after which the transmission is aborted.

L|1|N

This block is used in order to indicate the end of an ASTM block. It consists of the following fields:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	L	Fixed value L for indicating a Terminator block.
Sequence Number	1	Always at 1 as there is only one sequence per message.
Termination code	N	This code designates of end of the message with the following values, depending on the situation: · **N** = Normal. · T = Abandon issuer. · R = Abandon receiver. · E = Unknown Error. · Q = Error in last request. · I = No Information available for last query. · F = Last request for information processed. of comment.

2-8-1-Equipment configuration

Communication with the centralized computer system is connected to the PC associated with the analyser and can be made by:
· RS232C link. DB9 standard pinouts.
· TCP/IP link. Ethernet cable (RJ45,8 pins)

2-8-2- Change to connection setup

The connection set-up for the interface can be found under SET-UP/SETTINGS/LOCAL SYSTEM:

· With RS232C selected:
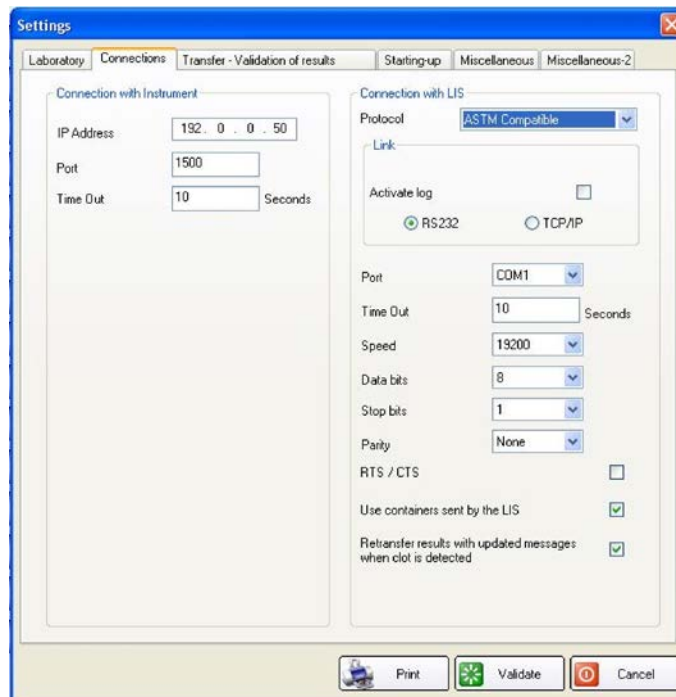
2- ASTM Compatible Version
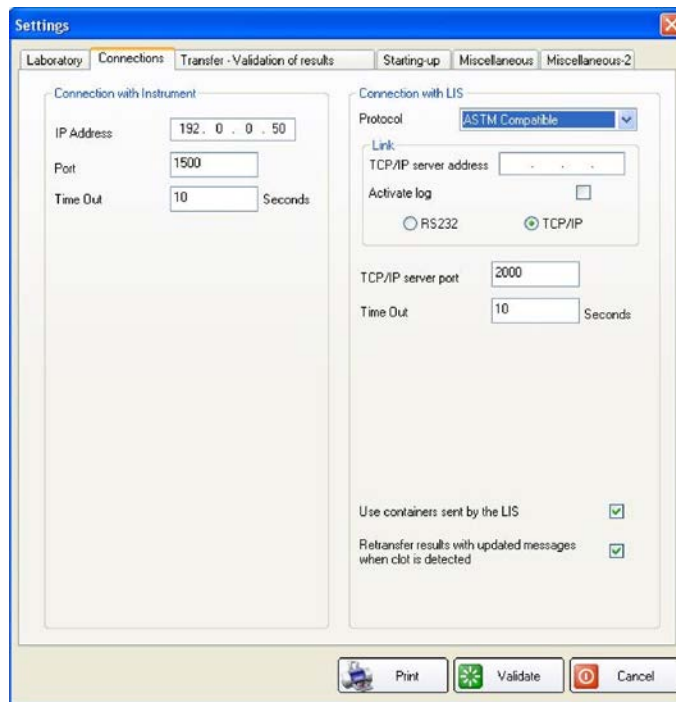
- With TCP/IP selected:

- Configurable options:

	The sample container is set with the type sent in the field «Container and Specimen ID» (see Order Block, page 9). The user can modify this container type until the sample is processed by the analyser (blue colour code).
	The sample container sent by the LIS is ignored and is set with the container type defined for the removable rack or for the fixed tray. The user can modify this container type until the sample is processed by the analyser (blue colour code).

- Configurable options (continued):

	Active for the option «Clot Detection» When a clot is detected in a sample, results from this sample's profile that have already been transferred to the LIS will be resent (see **7- Important notes, page 67**).
	Active for the option «Clot Detection» Results that have already been transferred to the LIS are not resent when a clot is detected in a sample.

3- ASTM Compatible V2 Version

3-1- General information
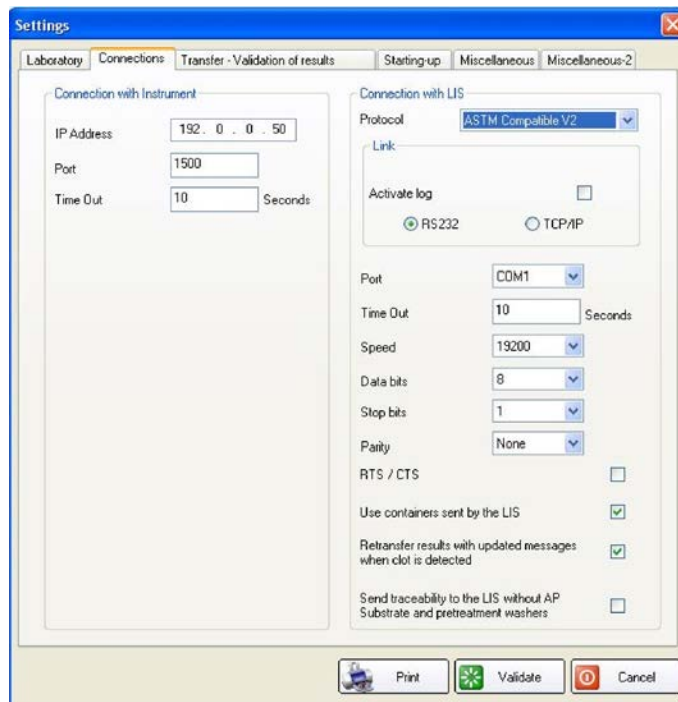
The **ASTM Compatible V2** version uses the sections defined as follows:

- The Header block: this block is the first one found in an ASTM frame, it defines the characteristics of the messages as well as the characters separating the fields and components which will be used
- The Patient block: this block contains all the information about the patient such as his or her last name, first name, PID, etc, and, in case of control transfer, the name of the control.
- The Test Order block: this block defines a test, so it contains the data relating to a test carried out on one or several analytes. This block is always preceded by a patient block
- The Result block: this block contains the result of one analyte and one alone. It is always preceded by a Test Order block or by another Result block. If several results are sent through for one test, there will then be several Result blocks following a Test Order block (typically if a test has been carried out on several analytes, the result of each of these will be provided in one single message but in several Result blocks)
- The Manufacturer Information block: this block contains the information about the traceability of the result.
- The Request Information block: This block allows information to be requested in both directions Analyser to LIS and vice versa. Results or information can be requested about a patient
- The Comment block: this block contains comments. It can be located anywhere in the message before the end block
- The Message Terminator block: This block indicates that the message is ended

The quality control results are transferred to the LIS when the option is selected (see **3-10-3- Transferring quality control results**, page 37).

The ASTM message has a hierarchical structure, each block from the lower level refers to the block from the level immediately above, except for the comments blocks.

The structure of the ASTM message is the following for this version of protocol:

Header
    Patient 1
        Order 1
            Result 1
                Comment 1
                Manufacturer 1
            ....
            Result n
                Comment 1
                Manufacturer 1
        ....
        Order n
            Result 1
                Comment 1
                Manufacturer 1
            ....
            Result n
                Comment 1
                Manufacturer 1
    Message Terminator

Example of an ASTM message:

H|\^_||||IDS-iSYS B300B0378||||||||P|4|20111124135800
   P|1||20105863||BONTEMPS^Robert||19500226|M|||||DUPONT|||||Comment|||||||||||||
   Radiology
     O|1|01^7148345||^^^25OHD|R||||||A|||||S|||||||||||O
     R|1|^^^25OHD^04^F^1|63,9|ng/mL|10,0 to 100,0|N||F||||20111123171733|IDS-
     iSYS B300B0378
       C|1|I|FOR, MRE!|N
       M|1|^^^25OHD^04^F^1|51||25OHD^0952^209525602987^20120229|System
       Liquid^72634^00162^20121209\Cuvettes^18121^02177^20120506|
       TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash
       S^72508^00322^20121104\Wash1^2\Wash2\Wash3\DSORB

L|1|N

> ⚠ A blue italic font identifies the differences with Compatible ASTM in the description of the various fields of each block.

3- ASTM Compatible V2 Version

3-2- The Header Block

H|\^_|||IDS-iSYS B300B0378||||||P|4|20111124135800

This block is the first in the message, and is the one which defines its characteristics.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type	H	Fixed value H to indicate a Header block.
Delimiters Definition	|\^_	Definitions of the delimiters that will be used in the message. These are the 4 characters which follow the H, with the following being initialized: • The field delimiter (|) which separates the various fields. • The repeat delimiter (\ ) which separates a repetition in a field. • The component delimiter (^) which separates the various components of the field. • The escape delimiter (_) which indicates an escape sequence for dealing with special characters. N.B. The record delimiter is fixed and is always the character ASCII 13 (carriage return).
Message Control ID		**Not used.**
Access Password		**Not used.**
Sender Name or ID	IDS-iSYS B300B0378	Name or identifier of the issuer: • Not used in the direction LIS => analyser. • Fixed at IDS-iSYS + Serial number in the direction device to LIS.
Sender Street Address		**Not used.**
Reserved Field		
Sender Telephone Number		**Not used.**
Characteristics of Sender		**Not used.**
Receiver ID		**Not used.**
Comment or Special Instruction		**Not used.**
Processing ID	P	Type of message fixed at P for Production.
Version No.	4	Version of the protocol, *always equal to 4 (in the direction IDS-iSYS to LIS)*.
Date and Time of Message	20111124135800	Date of message in the format YYYYMMDDHHmmss.

3- ASTM Compatible V2 Version

3-3- The Patient Block

**P|1||20105863||BONTEMPS^Robert||19500226|M|||||DUPONT||||||Comment|||||||||||||
Radiology**

This block represents the information relating to a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type	P	Fixed value P to indicate a Patient block.
Sequence Number	1	Number of the Patient block in the message starts at 1 and is increased for each block in the message.
Practice Assigned Patient ID		**Not used.**
Laboratory Assigned Patient ID	20105863	PID.
Patient ID #		**Not used.**
Patient Name	BONTEMPS^Robert	Field consisting of 5 components last name, first name, initials, suffix and title. Only the first 2 fields are used. *When sending a control from IDS-iSYS to LIS, the first component in the field will be used for the name of control.*
Mother's Maiden Name		Not used.
Birth Date	19500226	Date of birth in format YYYYMMDD.
Patient Sex	M	Reference of patient values: · M for Man. · F for Woman. · E for Child. · U for others. In the direction LIS=>IDS-iSYS: · M for Man. · F for Woman. · U for Child. · U for others.
Patient Race		**Not used.**
Patient Address		**Not used.**
Reserved Field		**Not used.**

3- ASTM Compatible V2 Version

3-3- The Patient Block (continued)

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Patient Telephone Number		**Not used.**
Attending Physician ID	DUPONT	Name of doctor associated with profile.
Special Field 1		*This field allows to define the profile type sent. This field can take the values:* • *NULL for a patient* • *02 for a control*
Special Field 2		**Not used.**
Patient Height		**Not used.**
Patient Weight		**Not used.**
Patient Known or Suspected Diagnosis	Comment	Comment associated with profile.
Patient Active Medication		**Not used.**
Patient Diet		**Not used.**
Practice Field 1		**Not used.**
Practice Field 2		**Not used.**
Admission and Discharge Dates		**Not used.**
Admission Status		**Not used.**
Location		**Not used.**
Nature of Alternative Diagnostic Code		**Not used.**
Alternative Diagnostic Code		**Not used.**
Patient Religion		**Not used.**
Marital Status		**Not used.**
Isolation Status		**Not used.**
Language		**Not used.**
Hospital Service	Radiology	Department associated with the profile.
Hospital Institution		**Not used.**
Dosage Category		**Not used.**

3- ASTM Compatible V2 Version

3-4- The Order Block

O|1|01^7148345||^^^25OHD|R||||||A||||S|||||||||||O

This block represents the information about one or several test requests for a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	O	Fixed value O for indicating an Order block.
Sequence Number	1	Number of the order within the Patient block starts at 1 and is increased for each Order block in the message.
Container and Specimen ID	01^7148345	This field consists of 2 components: • The type of container used for the sample (2 digits). • 01 PT_11_4.5 mL. • 02 PT_13_6 mL. • 03 ST_13_5 mL H. • 05 Cup 500 µL. • 06 Cup 2 mL. • 07 PT_16_10 ml. • 08 to 17 for configurable containers. PT for Primary Tube; ST for Secondary Tube For correct functioning of the apparatus, it is important to allocate the correct type of container used for the sample. If this component is null, the default container type defined for the tray will be used. • The SID of the profile concerned by the request.
Instrument Specimen ID		**Not used.**
Universal Test ID	^^^25OHD	This ASTM field consists of 5 components: • Universal test ID. • Universal test ID Name. • Universal test ID Type. • Manufacturer's Code. • *Sample type (patient or control)* *In the direction LIS => IDS-ISYS, only the Manufacturer's code is used and this last component will be entered with the unique IDS-iSYS identifier of the analyte.* In one single order it is possible to specify several tests by adding a repeat delimiter and by then adding one or several UTI thus obtaining a chain of the type ^^^25OHD\^^^BAP. Multiple requests of the same test can also be made: ^^^25OHD\^^^25OHD *In the direction IDS-ISYS => LIS, the last component will be NULL for a patient or equal to 02 for a control.*

3- ASTM Compatible V2 Version

3-4- The Order Block (continued)

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Priority	R	This field may contain the values: • **S** = STAT. • A = ASAP. • **R** = Routine. • C = Callback. • P = Preoperative. For the device, only S has any influence, the passage of the associated profile into Urgent, and the other values are ignored.
Requested/Ordered Date and Time		**Not used.**
Specimen Collection Date and Time		**Not used.**
Collection End Time		**Not used.**
Collection Volume		**Not used.**
Collector ID		**Not used.**
Action Code	A	Action to be carried out on the block test or tests. This field may contain the values: • **A** for Add. • C for Cancel. • **N** for New. • P for Pending. • Q for QC. For the device, A and N are managed in the same way (new request or new rerun), C (cancellation of a request) can be managed if the test is not in progress. P and Q are not managed.
Danger Code		**Not used.**
Relevant Clinical Information		**Not used.**
Date and Time Specimen Received		**Not used.**

ASTM Name of the field	Value*	Description and use in IDS-iSYS system

Specimen Descriptor	S	This field consists of two sections:
		
		· The sample type which can take for the IDS-iSYS the following values:
		  · U = Urine.
		  · S = Serum.
		  · O = Other.
		· The sample source (place where the sample was taken) is not used.

Ordering Physician		Doctor
Physician Telephone Number		**Not used.**
User Field 1		**Not used.**
User Field 2		**Not used.**
Laboratory Field 1		**Not used.**
Laboratory Field 2		**Not used.**
Date and Time Result Reported or Last Modified		**Not used.**
Instrument Charge to Computer System		**Not used.**
Instrument Section ID		**Not used.**
Report Type	O	This field may take the values: · **O** = Order. · C = Correction. · P = Preliminary results. · F = Final results. · X = Cancel. · I = Instrument pending (in response to a request). · Y = No order on record for this test (in response to a request). · **Z** = No record for this patient (in response to a request). · **Q** = Response to a request. In the device, C is managed when a clot is detected on a sample (see page 66).
Reserved Field		**Not used.**
Location or Ward of Specimen Collection		**Not used.**
Nosocomial Infection Flag		**Not used.**
Specimen Service		**Not used.**
Specimen Institution		**Not used.**

3- ASTM Compatible V2 Version

3-5- The Result Block

R|1|^^^25OHD^04^F^1|63,9|ng/mL|10,0 to 100,0|N||F||||20111123171733|IDS-iSYS B300B0378

This block represents the information sent through by the IDS-iSYS to the LIS after a test has been carried out for a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	R	Fixed value R for indicating a Result block.
Sequence Number	1	The number of the result within the Patient block begins at 1 and is increased for each Result block in the message.

Universal Test ID	^^^25OHD^04^F^1	*This ASTM field consists of 8 components:*
		- Universal test Id : forces NULL
		- Universal test Id Name: forces NULL.
		- Universal test Id Type: forces NULL.
		-Manufacturer's Code: contains the unique IDS-iSYS identifier for the analyte.
		-Test type: 02 for a control, 04 for a patient
		-Result type: F for final, P for partial.
		-Replicate number: 1, 2,up to 10
		-Control identifier, defined as follow:
		   • *21 for a control Level 1*
		   • *22 for a control Level 2*
		   • *23 for a control Level 3*
		   • *24 for a control Level 4*
		For a patient,this component is NULL.
		-Dilution rate: NULL if not applicable.

Data or Measurement Value	63,9	The value in the form of ASCII chain. Results which cannot be calculated are sent in the format * * * * * . Each character * is separated by a space.If the value is outside the measuring range, is transmitted in this field: • < Low limit of the sample measurement range, when the result is below the measuring range • > High limit of the sample measurement range, when the result is above the measuring range (For 25OHD: <5 or >140)
Units	ng/mL	Blocks used
Reference Range	10,0 to 100,0	Normal reference values used for the patient sent through in the form of an ASCII chain.

3- ASTM Compatible V2 Version

3-5- The Result Block (continued)

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Result abnormal Flags	N	This field may take the values: • **L** = Below low normal. • **H** = Above high normal. • LL = Below alarm low. • HH = Above alarm high. • **<** of absolute low (Field of measurement). • **>** of absolute high (Field of measurement). • **N** = Normal. • **A** = Abnormal. • U = Significant change Up. • D = Significant change Down. • B = Better. • W = Worse. *L, H, <, >, A and N are managed by IDS-iSYS. All associated messages are sent in a Comment block.*
Nature of Abnormality Testing	S	This field forces S or A for the IDS-iSYS can take the values: • **A** = Age. • **S** = Sex. • R = Race. And is able to provide an indication about the bases on which the values of normality were determined.
Result Status	F	This field forces to F or P (replicate) on the IDS-iSYS can take the following values: • C = Correction. • **P** = Preliminary results. • **F** = Final results. • X = Request not honored. • I = Results pending. • S = Partial results.
Date of change in Instrument Normative Values		**Not used.**
Operator ID		**Not used.**
Date and Time Test Started		**Not used.**
Date and Time Test Completed	20111123171733	Date and time of result of test on the GUI.
Instrument Identification	IDS-iSYS B300B0378	Name of device + Serial number.

C|1|I|FOR, MRE!|N

This block represents a comment.

This type of block can be inserted after a Result Block. Depending on configuration, several Comment blocks can be sent.

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	C	Fixed value C for indicating a Comment block.
Sequence Number	1	Number of the comment begins at 1 and is increased for each comment block in the message.
Comment Source	I	Issuer can take the following values: • P = Practice. • L = computer system in the direction LIS. • **I** = Instrument.
Comment Text	FOR, MRE!	If the field Comment Type takes the value N, this field contains the message associated with a result.
Comment Type	N	Type of comment. This field can take the values: • **G** = Generic comment (any permitted). • T = Test name comment. • P = Positive test comment. • **N** = Negative test comment. • I = Instrument flags comment.

M|1|^^^25OHD^04^F^1|51||25OHD^0952^209525602987^20120229|System Liquid^72634^00162^20121209\Cuvettes^18121^02177^20120506| TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash S^72508^00322^20121104\Wash1^2\Wash2\Wash3\DSORB

This block contains traceability information sent by IDS-iSYS to the LIS, and follows a Result block.

Here are the various fields of this block used in the protocol version:

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	M	Fixed value M for indicating a Manufacturer Information block.
Sequence Number	1	Number of the block associated with a result, begins at 1 and is increased for each Manufacturer Information block in the message.

Universal Test ID	^^^25OHD^04^F^1	• Universal test ID: NULL.
		• Universal test ID name: NULL.
		• Universal test ID type: NULL
		• Manufacturer's code
		• Test type: **02** for a control, **04** for a patient.
		• Result type: always **F** for final. Depending on the test, a final result can be a mean value.
		• *Replicate number: **1, 2**, up to **10***
		• *Control identifier, defined as follow:*
		  • ***21** for a control Level 1*
		  • ***22** for a control Level 2*
		  • ***23** for a control Level 3*
		  • ***24** for a control Level 4*
		For a patient, this component is NULL.
		• *Dilution rate: NULL if not applicable.*

Assay type	51	*This field can take the values:* • *51 for Immunoassays,* • *52 for Biochemistry.*
Component information		This field will be used only for control transfers. For a patient, this field is NULL. For a control, this field consists of: · target value, · low value of acceptable range, · high value of acceptable range · lot number · bottle number, · expiry date.

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Reagent traceability	25OHD^0952^209525602987^20120229	*This field contains infomation for each reagent used in the assay:* *Reagent 1^Lot^Bottle Number ^Expiry date* *Reagent 2^Lot^Bottle Number ^Expiry date\......*
Common ancillaries	System Liquid^72634^00162^20121209\ Cuvettes^18121^02177^20120506	*This field consists of:* *System Liquid^Lot^Bottle Number ^Expiry date* *Cuvettes ^Lot^Cube Number^Expiry Date.*
Specific ancillaries	TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash S^72508^00322^20121104\Wash1^2\Wash2\Wash3\DSORB	*If the field «Assay type» takes the value 51 (Immunoassay), the information contained in this field depends on the option selected in the CONNECTIONS tab (LOCAL SYTEM SETTINGS menu):* Send traceability to the LIS without AP Substrate and pretreatment washers ☐ *When this option is not checked, this field consists of:* *NaOH^Lot^Bottle Number ^Expiry date* *H2O2^Lot^Bottle Number ^Expiry date\ Wash S^Lot^Bottle Number ^Expiry date* *Wash1^Number of the washer\ Wash2^Number of the washer\ Wash3^Number of the washer* *DSORB^Lot^Bottle Number ^Expiry date.* Send traceability to the LIS without AP Substrate and pretreatment washers ☑ *When this option is checked, this field consists of:* *NaOH^Lot^Bottle Number ^Expiry date* *H2O2^Lot^Bottle Number ^Expiry date\ Wash S^Lot^Bottle Number ^Expiry date* *Wash1^Number of the washer\ Wash2^Number of the washer\ Wash3^Number of the washer* *DSORB^Lot^Bottle Number ^Expiry date* *APSUB^Lot^Bottle Number ^Expiry date* *WashPT1^Number of the washer for pretratment* *WashPT2^Number of the washer for pretratment.* *If the field «Assay type» takes the value 52 (Biochemistry), this field consists of:* *Saline Solution^Bottle Number ^Expiry date.*

3- ASTM Compatible V2 Version

3-8- The Request Information Block

Q|1|^7148344||ALL|||||||O

This block represents a request for information whose origin now can only be the IDS-iSYS.

This request will be used by the IDS-iSYS after discovering a tube for a patient whose profile is known on the work list in order to request the tests to be carried out on this tube.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	Q	Fixed value Q to indicate a Request Information block.
Sequence Number	1	The request number starts at 1 and is increased for each request block in the message.
Starting Range ID Number	^7148344	This field consists of 3 elements; only the first 2 are used by the IDS-iSYS in order to specify the PID (optional) and the SID (obligatory) allowing the profile quoted to be identified.
Ending Range ID Number		*Not used*
Universal Test ID	ALL	This field can either indicate 1 particular test (in the identifier via its ID cf Test Order block) or request all the tests via the code ALL.
Nature of request Time Limit		***Not used in the direction IDS-iSYS=>LIS.*** Useful if LIS => IDS-iSYS with the value R to say that the date to be taken into account in the event of filter is the date of the test results and the date of arrival of the profile (code S).
Beginning request Results Date and Time		***Not used*** Useful in the direction LIS=>IDS-iSYS.
Ending request Results Date and Time		***Not used*** Useful in the direction LIS=>IDS-iSYS.
Requesting Physician Name		***Not used***
Requesting Physician Telephone Number		***Not used***
User Field 1		***Not used***
User Field 2		***Not used***

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Request Information Status Code	O	Potential values: • C • P • F • X • I • S • M • R • **A** • N • **O** • D Only the values O and X are managed in the direction IDS-iSYS to LIS. A is used when the LIS does not respond to a request. In such cases, the request is cancelled (this field takes the value A). The request is transmitted 3 times, after which the transmission is aborted.

L|1|N

This block is used in order to indicate the end of an ASTM block. It consists of the following fields:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	L	Fixed value L for indicating a Terminator block.
Sequence Number	1	Always at 1 as there is only one sequence per message.
Termination code	N	This code designates of end of the message with the following values, depending on the situation: · **N** = Normal. · T = Abandon issuer. · R = Abandon receiver. · E = Unknown Error. · Q = Error in last request. · I = No Information available for last query. · F = Last request for information processed. of comment.

3- ASTM Compatible V2 Version

3-10-1-Equipment configuration

Communication with the centralized computer system is connected to the PC associated with the analyser and can be made by:
· RS232C link. DB9 standard pinouts.
· TCP/IP link. Ethernet cable (RJ45,8 pins)

3-10-2- Change to connection setup

The connection set-up for the interface can be found under SET-UP/SETTINGS/SYSTEM:
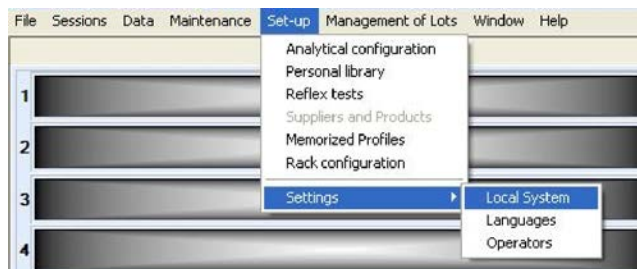
· With RS232C selected:
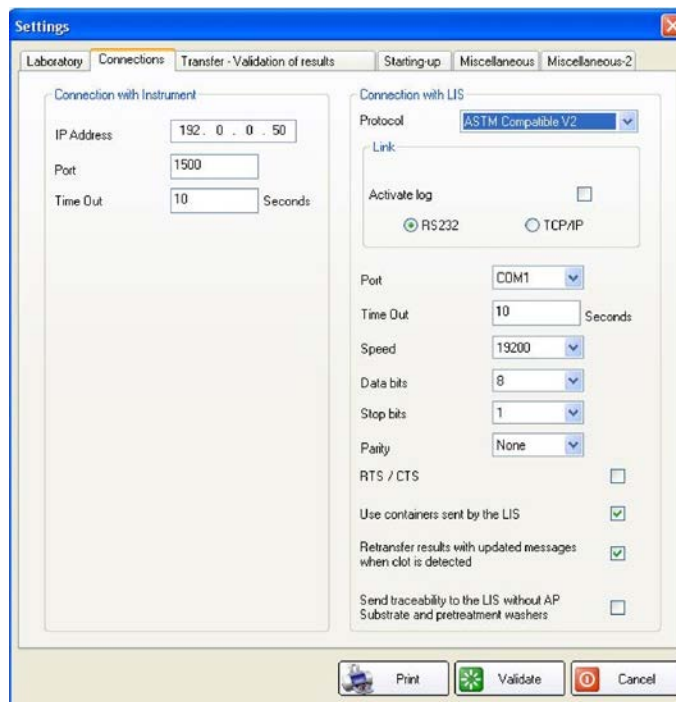
- With TCP/IP selected:
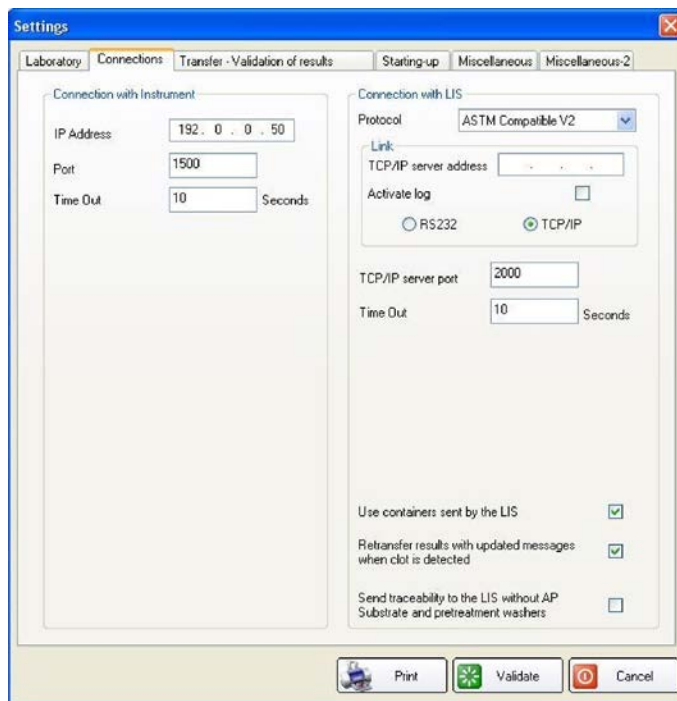
- Configurable options:

The sample container is set with the type sent in the field «Container and Specimen ID» (see Order Block, page 24).
The user can modify this container type until the sample is processed by the analyser (blue colour code).

The sample container sent by the LIS is ignored and is set with the container type defined for the removable rack or for the fixed tray.
The user can modify this container type until the sample is processed by the analyser (blue colour code).

· Configurable options (continued):

Active for the option «Clot Detection»
When a clot is detected in a sample, results from this sample's profile that have already been transferred to the LIS will be resent (see **7- Important notes, page 67**).

Active for the option «Clot Detection»
Results that have already been transferred to the LIS are not resent when a clot is detected in a sample.

The field «Specific ancillaries» in the Manufacturer block will not contain the components corresponding to the traceability of AP SUBSTRATE and washer(s) used in the pretreatment step.
The relevant field is described in page 31.

The field «Specific ancillaries» in the Manufacturer block will contain the components corresponding to the traceability of AP SUBSTRATE and washer(s) used in the pretreatment step.
The relevant field is described in page 31.

3-10-3- Transferring quality control results

To transfer the quality control results, select the corresponding option, in the tab Transfer - Validation of results under **SET-UP/SETTINGS/SYSTEM** menu:
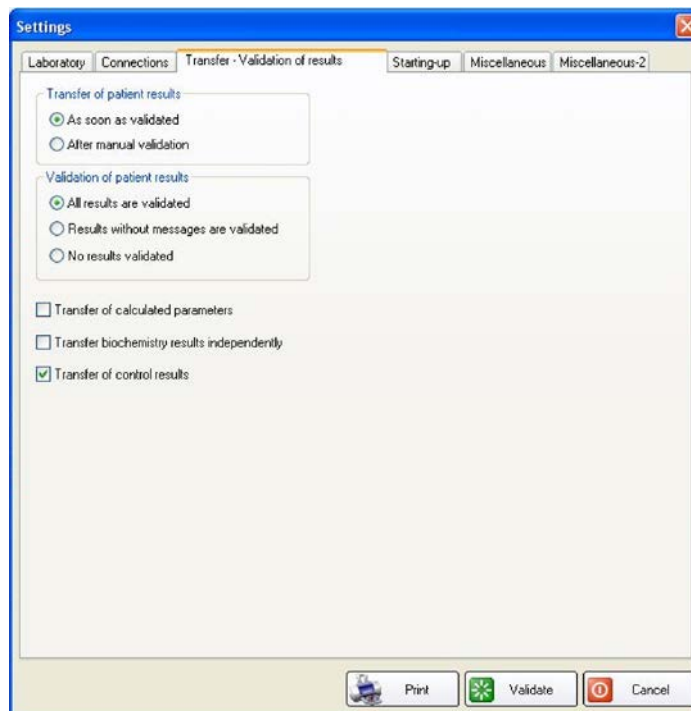
4- ASTM Compatible V3 Version

4-1- General information
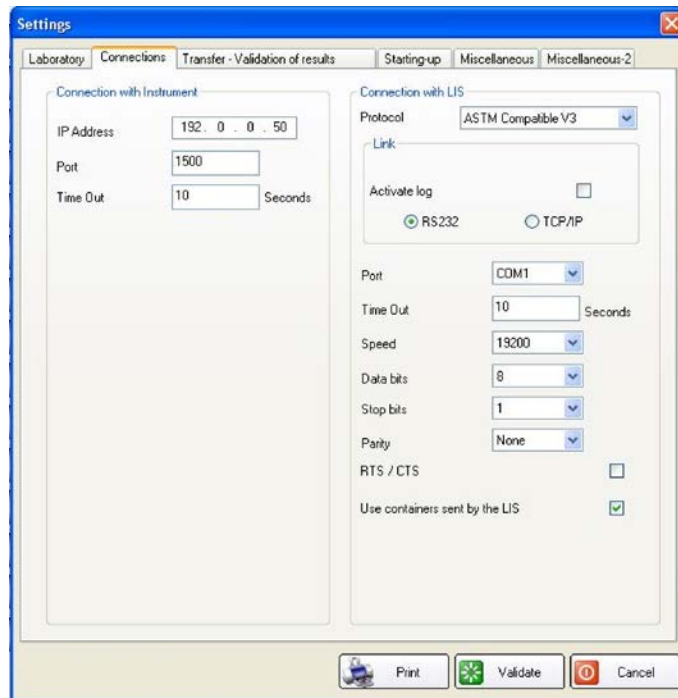
The **ASTM Compatible V3** version uses the sections defined as follows:

- The Header block: this block is the first one found in an ASTM frame, it defines the characteristics of the messages as well as the characters separating the fields and components which will be used
- The Patient block: this block contains all the information about the patient such as his or her last name, first name, PID, etc, and, in case of control transfer, the name of the control.
- The Test Order block: this block defines a test, so it contains the data relating to a test carried out on one or several analytes. This block is always preceded by a patient block
- The Result block: this block contains the result of one analyte and one alone. It is always preceded by a Test Order block or by another Result block. If several results are sent through for one test, there will then be several Result blocks following a Test Order block (typically if a test has been carried out on several analytes, the result of each of these will be provided in one single message but in several Result blocks)
- The Manufacturer Information block: this block contains the information about the traceability of the result.
- The Request Information block: This block allows information to be requested in both directions Analyser to LIS and vice versa. Results or information can be requested about a patient
- The Comment block: this block contains comments. It can be located anywhere in the message before the end block
- The Message Terminator block: This block indicates that the message is ended

The quality control results are transferred to the LIS when the option is selected (see **4-10-3- Transferring quality control results**, page 56).

The ASTM message has a hierarchical structure, each block from the lower level refers to the block from the level immediately above, except for the comments blocks.

4- ASTM Compatible V3 Version

The structure of the ASTM message is the following for this version of protocol:

Header
 Patient 1
  Order 1
   Result 1
    Comment 1
    Manufacturer 1
   …….
   Result n
    Comment 1
    Manufacturer 1
  ……..
  Order n
   Result 1
    Comment 1
    Manufacturer 1
   …….
   Result n
    Comment 1
    Manufacturer 1
 Message Terminator

Example of an ASTM message:

H|\^_|||IDS-iSYS B300B0378||||||||P|5|20111124135800
 P|1||20105863||BONTEMPS^Robert||19500226|M|||||DUPONT|||||Comment|||||||||||||| Radiology
  O|1|01^7148345||^^^25OHD|R||||||A||||S|||||||||||O
  R|1|^^^25OHD^04^F^1|63,9|ng/mL|10,0 to 100,0|N||F||||20111123171733|IDS-iSYS B300B0378
   C|1|I|FOR, MRE!|N
   M|1|^^^25OHD^04^F^1|51||25OHD^0952^209525602987^20120229|System Liquid^72634^00162^20121209\Cuvettes^18121^02177^20120506| TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash S^72508^00322^20121104\Wash1^2\Wash2\Wash3\DSORB

L|1|N

> ⚠ A blue italic font identifies the differences with Compatible ASTM V2 in the description of the various fields of each block.

4- ASTM Compatible V3 Version

4-2- The Header Block

H|\^_|||IDS-iSYS B300B0378||||||P|5|20111124135800

This block is the first in the message, and is the one which defines its characteristics.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type	H	Fixed value H to indicate a Header block.
Delimiters Definition	|\^_	Definitions of the delimiters that will be used in the message. These are the 4 characters which follow the H, with the following being initialized: • The field delimiter (|) which separates the various fields. • The repeat delimiter (\ ) which separates a repetition in a field. • The component delimiter (^) which separates the various components of the field. • The escape delimiter (_) which indicates an escape sequence for dealing with special characters. N.B. The record delimiter is fixed and is always the character ASCII 13 (carriage return).
Message Control ID		**Not used.**
Access Password		**Not used.**
Sender Name or ID	IDS-iSYS B300B0378	Name or identifier of the issuer: • Not used in the direction LIS => analyser. • Fixed at IDS-iSYS + Serial number in the direction device to LIS.
Sender Street Address		**Not used.**
Reserved Field		
Sender Telephone Number		**Not used.**
Characteristics of Sender		**Not used.**
Receiver ID		**Not used.**
Comment or Special Instruction		**Not used.**
Processing ID	P	Type of message fixed at P for Production.
Version No.	5	Version of the protocol, *always equal to 5 (in the direction IDS-iSYS to LIS)*.
Date and Time of Message	20111124135800	Date of message in the format YYYYMMDDHHmmss.

4- ASTM Compatible V3 Version

4-3- The Patient Block

**P|1||20105863||BONTEMPS^Robert||19500226|M|||||DUPONT|||||Comment||||||||||||||
Radiology||TANNER STAGE^5**

This block represents the information relating to a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type	P	Fixed value P to indicate a Patient block.
Sequence Number	1	Number of the Patient block in the message starts at 1 and is increased for each block in the message.
Practice Assigned Patient ID		**Not used.**
Laboratory Assigned Patient ID	20105863	PID.
Patient ID #		**Not used.**
Patient Name	BONTEMPS^Robert	Field consisting of 5 components last name, first name, initials, suffix and title. Only the first 2 fields are used. When sending a control from IDS-iSYS to LIS, the first component in the field will be used for the name of control.
Mother's Maiden Name		Not used.
Birth Date	19500226	Date of birth in format YYYYMMDD.
Patient Sex	M	Reference of patient values: • M for Man. • F for Woman. • E for Child. • U for others. In the direction LIS=>IDS-iSYS: • M for Man. • F for Woman. • U for Child. • U for others.
Patient Race		**Not used.**
Patient Address		**Not used.**
Reserved Field		**Not used.**

4- ASTM Compatible V3 Version

4-3- The Patient Block (continued)

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Patient Telephone Number		**Not used.**
Attending Physician ID	DUPONT	Name of doctor associated with profile.
Special Field 1		This field allows to define the profile type sent. This field can take the values: • NULL for a patient • 02 for a control
Special Field 2		**Not used.**
Patient Height		**Not used.**
Patient Weight		**Not used.**
Patient Known or Suspected Diagnosis	Comment	Comment associated with profile.
Patient Active Medication		**Not used.**
Patient Diet		**Not used.**
Practice Field 1		**Not used.**
Practice Field 2		**Not used.**
Admission and Discharge Dates		**Not used.**
Admission Status		**Not used.**
Location		**Not used.**
Nature of Alternative Diagnostic Code		**Not used.**
Alternative Diagnostic Code		**Not used.**
Patient Religion		**Not used.**
Marital Status		**Not used.**
Isolation Status		**Not used.**
Language		**Not used.**
Hospital Service	Radiology	Department associated with the profile.
Hospital Institution		**Not used.**
Dosage Category	TANNER STAGE^5	*Allows defining the Tanner stage.* *The second component of the field can take the values from 1 to 5 (integral values).*

4- ASTM Compatible V3 Version

4-4- The Order Block

O|1|01^7148345||^^^25OHD|R||||||A||||S|||||||||||O

This block represents the information about one or several test requests for a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	O	Fixed value O for indicating an Order block.
Sequence Number	1	Number of the order within the Patient block starts at 1 and is increased for each Order block in the message.
Container and Specimen ID	01^7148345	This field consists of 2 components: · The type of container used for the sample (2 digits). · 01 PT_11_4.5 mL. · 02 PT_13_6 mL. · 03 ST_13_5 mL H. · 05 Cup 500 µL. · 06 Cup 2 mL. · 07 PT_16_10 ml. · 08 to 17 for configurable containers. PT for Primary Tube; ST for Secondary Tube For correct functioning of the apparatus, it is important to allocate the correct type of container used for the sample. If this component is null, the default container type defined for the tray will be used. · The SID of the profile concerned by the request.
Instrument Specimen ID		**Not used.**
Universal Test ID	^^^25OHD	This ASTM field consists of 5 components: · Universal test ID. · Universal test ID Name. · Universal test ID Type. · Manufacturer's Code. · Sample type (patient or control) In the direction LIS => IDS-ISYS, only the Manufacturer's code is used and this last component will be entered with the unique IDS-iSYS identifier of the analyte. In one single order it is possible to specify several tests by adding a repeat delimiter and by then adding one or several UTI thus obtaining a chain of the type ^^^25OHD\^^^BAP. Multiple requests of the same test can also be made: ^^^25OHD\^^^25OHD In the direction IDS-ISYS => LIS, the last component will be NULL for a patient or equal to 02 for a control.

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Priority	R	This field may contain the values: · **S** = STAT. · A = ASAP. · **R** = Routine. · C = Callback. · P = Preoperative. For the device, only S has any influence, the passage of the associated profile into Urgent, and the other values are ignored.
Requested/Ordered Date and Time		**Not used.**
Specimen Collection Date and Time		**Not used.**
Collection End Time		**Not used.**
Collection Volume		**Not used.**
Collector ID		**Not used.**
Action Code	A	Action to be carried out on the block test or tests. This field may contain the values: · **A** for Add. · C for Cancel. · **N** for New. · P for Pending. · Q for QC. For the device, A and N are managed in the same way (new request or new rerun), C (cancellation of a request) can be managed if the test is not in progress. P and Q are not managed.
Danger Code		**Not used.**
Relevant Clinical Information		**Not used.**
Date and Time Specimen Received		**Not used.**

ASTM Name of the field	Value*	Description and use in IDS-iSYS system

Specimen Descriptor	S	This field consists of two sections:
		
		· The sample type which can take for the IDS-iSYS the following values:
		  · U = Urine.
		  · S = Serum.
		  · O = Other.
		· The sample source (place where the sample was taken) is not used.

Ordering Physician		Doctor
Physician Telephone Number		**Not used.**
User Field 1		**Not used.**
User Field 2		**Not used.**
Laboratory Field 1		**Not used.**
Laboratory Field 2		**Not used.**
Date and Time Result Reported or Last Modified		**Not used.**
Instrument Charge to Computer System		**Not used.**
Instrument Section ID		**Not used.**
Report Type	O	This field may take the values: · **O** = Order. · C = Correction. · P = Preliminary results. · F = Final results. · X = Cancel. · I = Instrument pending (in response to a request). · Y = No order on record for this test (in response to a request). · **Z** = No record for this patient (in response to a request). · **Q** = Response to a request. In the device, C is managed when a clot is detected on a sample (see page 67).
Reserved Field		**Not used.**
Location or Ward of Specimen Collection		**Not used.**
Nosocomial Infection Flag		**Not used.**
Specimen Service		**Not used.**
Specimen Institution		**Not used.**

4- ASTM Compatible V3 Version

4-5- The Result Block

R|1|^^^25OHD^04^F^1|63,9|ng/mL|10,0 to 100,0|N||F|||SYSTEM^SYSTEM|
20111123171733|IDS-iSYS B300B0378

This block represents the information sent through by the IDS-iSYS to the LIS after a test has been carried out for a patient.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	R	Fixed value R for indicating a Result block.
Sequence Number	1	The number of the result within the Patient block begins at 1 and is increased for each Result block in the message.

Universal Test ID	^^^25OHD^04^F^1	This ASTM field consists of 8 components:
		- Universal test Id : forces NULL
		- Universal test Id Name: forces NULL.
		- Universal test Id Type: forces NULL.
		-Manufacturer's Code: contains the unique IDS-iSYS identifier for the analyte.
		-Test type: **02** for a control, **04** for a patient
		-Result type: **F** for final, **P** for partial.
		-Replicate number: 1, 2,up to 10
		-Control identifier, defined as follow:
		   · **21** for a control Level 1
		   · **22** for a control Level 2
		   · **23** for a control Level 3
		   · **24** for a control Level 4
		For a patient,this component is NULL.
		-Dilution rate: NULL if not applicable.

Data or Measurement Value	63,9	The value in the form of ASCII chain. Results which cannot be calculated are sent in the format * * * * * . Each character * is separated by a space.If the value is outside the measuring range, is transmitted in this field: · < Low limit of the sample measurement range, when the result is below the measuring range · > High limit of the sample measurement range, when the result is above the measuring range (For 25OHD: <5 or >140)
Units	ng/mL	Blocks used
Reference Range	10,0 to 100,0	Normal reference values used for the patient sent through in the form of an ASCII chain.

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Result abnormal Flags	N	This field may take the values: · **L** = Below low normal. · **H** = Above high normal. · LL = Below alarm low. · HH = Above alarm high. · **<** of absolute low (Field of measurement). · **>** of absolute high (Field of measurement). · **N** = Normal. · **A** = Abnormal. · U = Significant change Up. · D = Significant change Down. · B = Better. · W = Worse. *L, H, <, >, A and N are managed by IDS-iSYS.* *All associated messages are sent in a Comment block.*
Nature of Abnormality Testing	S	This field forces S or A for the IDS-iSYS can take the values: · **A** = Age. · **S** = Sex. · R = Race. And is able to provide an indication about the bases on which the values of normality were determined.
Result Status	F	This field forces to F or P (replicate) on the IDS-iSYS can take the following values: · C = Correction. · **P** = Preliminary results. · **F** = Final results. · X = Request not honored. · I = Results pending. · S = Partial results.
Date of change in Instrument Normative Values		**Not used.**
Operator ID	SYSTEM^SYSTEM	Identifying the operators who handled the profile. This field consists of 2 components: - Identifier of the operator who creates the profile; if the profile was transferred by the LIS, the identifier **SYSTEM** is sent. - Identifier of the operator who stores/tranfers the profile; if the profile was automatically stored/transferred, the identifier **SYSTEM** is sent.
Date and Time Test Started		**Not used.**
Date and Time Test Completed	20111123171733	Date and time of result of test on the GUI.
Instrument Identification	IDS-iSYS B300B0378	Name of device + Serial number.

C|1|I|FOR, MRE!|N

This block represents a comment.

This type of block can be inserted after a Result Block. Depending on configuration, several Comment blocks can be sent.

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	C	Fixed value C for indicating a Comment block.
Sequence Number	1	Number of the comment begins at 1 and is increased for each comment block in the message.
Comment Source	I	Issuer can take the following values: · P = Practice. · L = computer system in the direction LIS. · **I** = Instrument.
Comment Text	FOR, MRE!	If the field Comment Type takes the value N, this field contains the message associated with a result.
Comment Type	N	Type of comment. This field can take the values: · **G** = Generic comment (any permitted). · T = Test name comment. · P = Positive test comment. · **N** = Negative test comment. · I = Instrument flags comment.

4- ASTM Compatible V3 Version

4-7- The Manufacturer Information Block

M|1|^^^25OHD^04^F^1|51||25OHD^0952^209525602987^20120229|System Liquid^72634^00162^20121209\Cuvettes^18121^02177^20120506| TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash S^72508^00322^20121104\Wash1^2\Wash2\Wash3\DSORB

This block contains traceability information sent by IDS-iSYS to the LIS, and follows a Result block.

Here are the various fields of this block used in the protocol version:

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	M	Fixed value M for indicating a Manufacturer Information block.
Sequence Number	1	Number of the block associated with a result, begins at 1 and is increased for each Manufacturer Information block in the message.

Universal Test ID	^^^25OHD^04^F^1	· Universal test ID: NULL.
		· Universal test ID name: NULL.
		· Universal test ID type: NULL
		· Manufacturer's code
		· Test type: **02** for a control, **04** for a patient.
		· Result type: always **F** for final. Depending on the test, a final result can be a mean value.
		· Replicate number: **1**, **2**, up to **10**
		· Control identifier, defined as follow:
		  · **21** for a control Level 1
		  · **22** for a control Level 2
		  · **23** for a control Level 3
		  · **24** for a control Level 4
		For a patient, this component is NULL.
		· Dilution rate: NULL if not applicable.

Assay type	51	This field can take the values: · 51 for Immunoassays, · 52 for Biochemistry.
Component information		This field will be used only for control transfers. For a patient, this field is NULL. For a control, this field consists of: · target value, · low value of acceptable range, · high value of acceptable range · lot number · bottle number, · expiry date.

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Reagent traceability	25OHD^0952^209525602987^20120229	This field contains infomation for each reagent used in the assay: Reagent 1^Lot^Bottle Number ^Expiry date\ Reagent 2^Lot^Bottle Number ^Expiry date\…….
Common ancillaries	System Liquid^72634^00162^20121209\ Cuvettes^18121^02177^20120506	This field consists of: System Liquid^Lot^Bottle Number ^Expiry date\ Cuvettes ^Lot^Cube Number^Expiry Date.
Specific ancillaries	TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash S^72508^00322^20121104\Wash1^2\Wash2\Wash3\DSORB	If the field «Assay type» takes the value 51 , this field consists of: *NaOH^Lot^Bottle Number ^Expiry date\ H2O2^Lot^Bottle Number ^Expiry date\ Wash S^Lot^Bottle Number ^Expiry date\ Wash1^Number of the washer\ Wash2^Number of the washer\ Wash3^Number of the washer\ DSORB^Lot^Bottle Number ^Expiry date\ APSUB^Lot^Bottle Number ^Expiry date\ WashPT1^Number of the washer for pretratment\ WashPT2^Number of the washer for pretratment.* If the field «Assay type» takes the value 52 (Biochemistry), this field consists of: Saline Solution^Bottle Number ^Expiry date.

Q|1|^7148344||ALL|||||||||O

This block represents a request for information whose origin now can only be the IDS-iSYS.

This request will be used by the IDS-iSYS after discovering a tube for a patient whose profile is known on the work list in order to request the tests to be carried out on this tube.

Here are the various fields of this block used in the protocol version:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	Q	Fixed value Q to indicate a Request Information block.
Sequence Number	1	The request number starts at 1 and is increased for each request block in the message.
Starting Range ID Number	^7148344	This field consists of 3 elements; only the first 2 are used by the IDS-iSYS in order to specify the PID (optional) and the SID (obligatory) allowing the profile quoted to be identified.
Ending Range ID Number		*Not used*
Universal Test ID	ALL	This field can either indicate 1 particular test (in the identifier via its ID cf Test Order block) or request all the tests via the code ALL.
Nature of request Time Limit		*Not used in the direction IDS-iSYS=>LIS.* Useful if LIS => IDS-iSYS with the value R to say that the date to be taken into account in the event of filter is the date of the test results and the date of arrival of the profile (code S).
Beginning request Results Date and Time		*Not used* Useful in the direction LIS=>IDS-iSYS.
Ending request Results Date and Time		*Not used* Useful in the direction LIS=>IDS-iSYS.
Requesting Physician Name		*Not used*
Requesting Physician Telephone Number		*Not used*
User Field 1		*Not used*
User Field 2		*Not used*

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Request Information Status Code	O	Potential values: • C • P • F • X • I • S • M • R • **A** • N • **O** • D Only the values O and X are managed in the direction IDS-iSYS to LIS. A is used when the LIS does not respond to a request. In such cases, the request is cancelled (this field takes the value A). The request is transmitted 3 times, after which the transmission is aborted.

4- ASTM Compatible V3 Version

4-9- The Message Terminator Block

L|1|N

This block is used in order to indicate the end of an ASTM block. It consists of the following fields:

* The field value corresponds to the above block

ASTM Name of the field	Value*	Description and use in IDS-iSYS system
Record Type ID	L	Fixed value L for indicating a Terminator block.
Sequence Number	1	Always at 1 as there is only one sequence per message.
Termination code	N	This code designates of end of the message with the following values, depending on the situation: • **N** = Normal. • T = Abandon issuer. • R = Abandon receiver. • E = Unknown Error. • Q = Error in last request. • I = No Information available for last query. • F = Last request for information processed. of comment.

4- ASTM Compatible V3 Version

4-10- Line of Communication
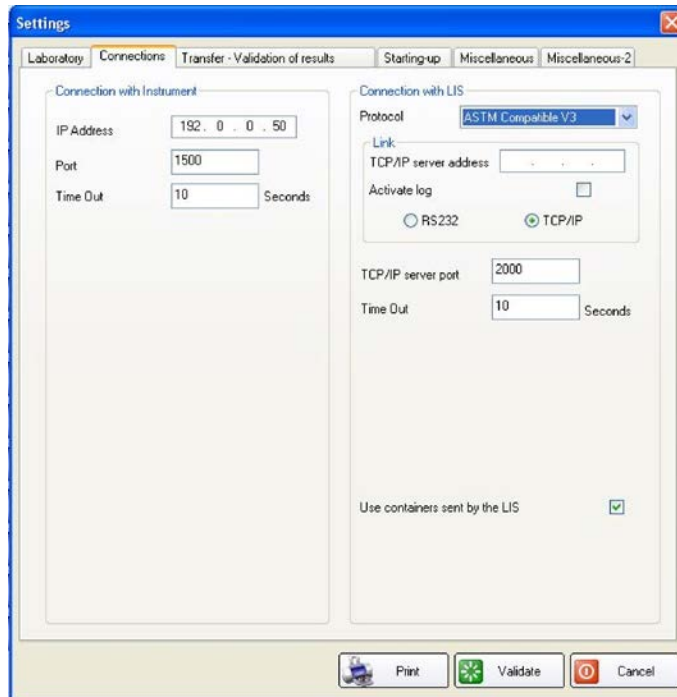
4-10-1-Equipment configuration

Communication with the centralized computer system is connected to the PC associated with the analyser and can be made by:

· RS232C link. DB9 standard pinouts.
· TCP/IP link. Ethernet cable (RJ45,8 pins)

4-10-2- Change to connection setup

The connection set-up for the interface can be found under SET-UP/SETTINGS/SYSTEM:

· With RS232C selected:

- With TCP/IP selected:

- Configurable options:

The sample container is set with the type sent in the field «Container and Specimen ID» (see Order Block, page 43). The user can modify this container type until the sample is processed by the analyser (blue colour code).

The sample container sent by the LIS is ignored and is set with the container type defined for the removable rack or for the fixed tray. The user can modify this container type until the sample is processed by the analyser (blue colour code).

4-10-3- Transferring quality control results

To transfer the quality control results, select the corresponding option, in the tab

Transfer - Validation of results   under **SET-UP/SETTINGS/SYSTEM** menu:

5-List of assay identifiers

The list of assay identifiers is obtained in the SET-UP/PERSONAL LIBRARY menu.
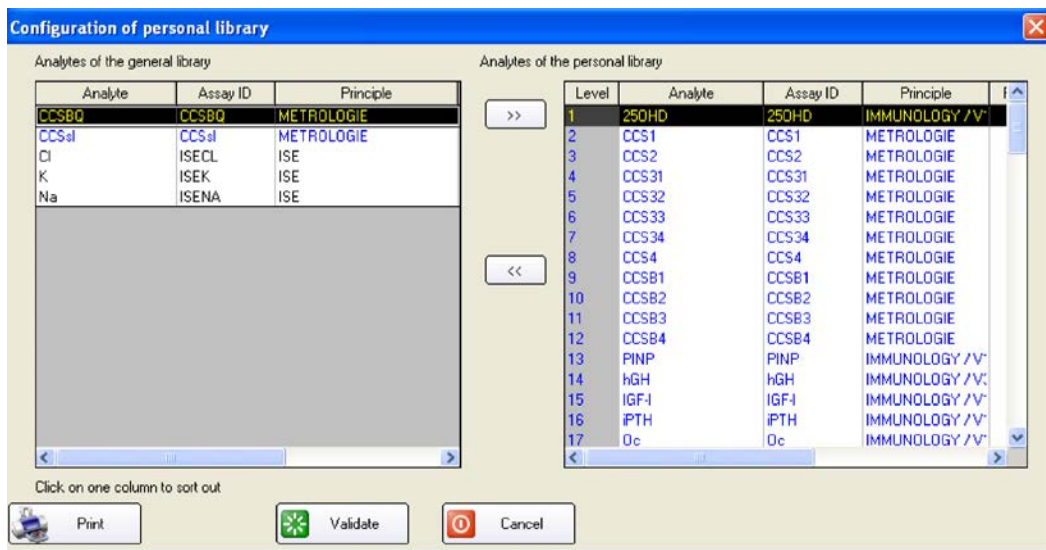
The list of assay identifiers can also be printed.

6- Examples of Data Transfer

6-1- Data transferred by the LIS

> ! Data sent by the LIS to IDS-iSYS are the same for the protocol versions **ASTM Compatible** and **ASTM Compatible V2**.

Request sent by IDS-iSYS and profile sent by LIS

==> : IDS-iSYS to LIS
<== LIS to IDS-iSYS

05 12 2011 à 15:46:39 ==> \<ENQ>
05 12 2011 à 15:46:39 <== \<ACK>
05 12 2011 à 15:46:40 ==> \<STX>1H|\^_|||IDS-iSYS B300B0378|||||||P|4|
20111205154639\<CR>\<ETX>B8\<CR>\<LF>
05 12 2011 à 15:46:40 <== \<ACK>
05 12 2011 à 15:46:40 ==> \<STX>2Q|1|^7148344||ALL||||||||O\<CR>\<ETX>89\<CR>\<LF>
05 12 2011 à 15:46:40 <== \<ACK>
05 12 2011 à 15:46:40 ==> \<STX>3L|1|N\<CR>\<ETX>06\<CR>\<LF>
05 12 2011 à 15:46:40 <== \<ACK>
05 12 2011 à 15:46:40 ==> \<EOT>
05 12 2011 à 15:46:40 <== \<ENQ>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:40 <== \<STX>
05 12 2011 à 15:46:40 <== 1H|\^&|||IDS iSYS Simulator^^2|||||||D|1|20111205154639\<CR>\<ETX>28\<CR>\<LF>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:40 <== \<STX>
05 12 2011 à 15:46:40 <== 2P|1|20105863||BONTEMPS^Robert||19500226|M|||||DUPONT|||||
Comment|||||||||||||Radiology\<CR>\<ETX>4D\<CR>\<LF>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:40 <== \<STX>
05 12 2011 à 15:46:40 <== 3O|1|01^7148344||^^^25OHD|R||||||A||||S|||||||||||Q\<CR>\<ETX>A0\<CR>\<LF>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:40 <== \<STX>
05 12 2011 à 15:46:40 <== 4L|1|N\<CR>\<ETX>07\<CR>\<LF>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:40 <== \<STX>
05 12 2011 à 15:46:40 <== 5H|\^&|||IDS iSYS Simulator^^2|||||||D|1|
20111205154639\<CR>\<ETX>2C\<CR>\<LF>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:40 <== \<STX>
05 12 2011 à 15:46:40 <== 6P|1|||||||U\<CR>\<ETX>FC\<CR>\<LF>
05 12 2011 à 15:46:40 ==> \<ACK>
05 12 2011 à 15:46:41 <== \<STX>
05 12 2011 à 15:46:41 <== 7O|1|01^7148344||^^^hGH|R||||||A||||S|||||||||||Q\<CR>\<ETX>59\<CR>\<LF>
05 12 2011 à 15:46:41 ==> \<ACK>
05 12 2011 à 15:46:41 <== \<STX>
05 12 2011 à 15:46:41 <== 0L|1|N\<CR>\<ETX>03\<CR>\<LF>
05 12 2011 à 15:46:41 ==> \<ACK>
05 12 2011 à 15:46:41 <== \<EOT>

6-1- Data transferred by the LIS (continued)

Request sent by IDS-iSYS without profile sent by LIS

==> :   IDS-iSYS to LIS
<==   LIS to IDS-iSYS

05 12 2011 à 11:25:20 ==> <ENQ>
05 12 2011 à 11:25:20 <== <ACK>
05 12 2011 à 11:25:20 ==> <STX>1H|\^_|||IDS-iSYS B300B0378||||||||P|4|
20111205112520<CR><ETX>A7<CR><LF>
05 12 2011 à 11:25:20 <== <ACK>
05 12 2011 à 11:25:20 ==> <STX>2Q|1|^7148344||ALL|||||||||O<CR><ETX>89<CR><LF>
05 12 2011 à 11:25:20 <== <ACK>
05 12 2011 à 11:25:20 ==> <STX>3L|1|N<CR><ETX>06<CR><LF>
05 12 2011 à 11:25:20 <== <ACK>
05 12 2011 à 11:25:20 ==> <EOT>
05 12 2011 à 11:25:20 <== <ENQ>
05 12 2011 à 11:25:20 ==> <ACK>
05 12 2011 à 11:25:20 <== <STX>
05 12 2011 à 11:25:20 <== 1H|\^&|||IDS iSYS Simulator^^2|||||||D|1|20111205112519<CR><ETX>1F<CR><LF>
05 12 2011 à 11:25:20 ==> <ACK>
05 12 2011 à 11:25:20 <== <STX>
05 12 2011 à 11:25:20 <== 2P|1|||||||||U<CR><ETX>F8<CR><LF>
05 12 2011 à 11:25:20 ==> <ACK>
05 12 2011 à 11:25:20 <== <STX>
05 12 2011 à 11:25:20 <== 3O|1|01^7148344|||R||||||||||||||||||||||||Z<CR><ETX>B9<CR><LF>
05 12 2011 à 11:25:20 ==> <ACK>
05 12 2011 à 11:25:20 <== <STX>
05 12 2011 à 11:25:21 <== 4L|1|N<CR><ETX>07<CR><LF>
05 12 2011 à 11:25:21 ==> <ACK>
05 12 2011 à 11:25:21 <== <EOT>

Worklist downloaded by LIS

==> :   *IDS-iSYS to LIS*
<==   *LIS to IDS-iSYS*

23 11 2011 à 10:22:15 <== <ENQ>
23 11 2011 à 10:22:15 ==> <ACK>
23 11 2011 à 10:22:15 <== <STX>
23 11 2011 à 10:22:15 <== 1HI\^&IIIIDS iSYS Simulator^^2IIIIIIIDI1I20111123102214<CR><ETX>15<CR><LF>
23 11 2011 à 10:22:15 ==> <ACK>
23 11 2011 à 10:22:15 <== <STX>
23 11 2011 à 10:22:15 <== 2PI1II20105863IIROBERT^BONTEMPSII19500226IMIIIII
DUPONT<CR><ETX>FC<CR><LF>
23 11 2011 à 10:22:15 ==> <ACK>
23 11 2011 à 10:22:15 <== <STX>
23 11 2011 à 10:22:16 <== 3OI1I05^7148345II^^^25OHDIRIIIIIIAIIIISIIIIIIIIIIO<CR><ETX>A3<CR><LF>
23 11 2011 à 10:22:16 ==> <ACK>
23 11 2011 à 10:22:16 <== <STX>
23 11 2011 à 10:22:16 <== 4LI1IN<CR><ETX>07<CR><LF>
23 11 2011 à 10:22:16 ==> <ACK>
23 11 2011 à 10:22:16 <== <STX>
23 11 2011 à 10:22:16 <== 5HI\^&IIIIDS iSYS Simulator^^2IIIIIIIDI1I20111123102214<CR><ETX>19<CR><LF>
23 11 2011 à 10:22:16 ==> <ACK>
23 11 2011 à 10:22:16 <== <STX>
23 11 2011 à 10:22:16 <== 6PI1II2011223IIDESOILLE^FLORENCEII19800926IF<CR><ETX>E8<CR><LF>
23 11 2011 à 10:22:16 ==> <ACK>
23 11 2011 à 10:22:16 <== <STX>
23 11 2011 à 10:22:16 <== 7OI1I05^7148346II^^^25OHDIRIIIIIIAIIIISIIIIIIIIIIO<CR><ETX>A8<CR><LF>
23 11 2011 à 10:22:16 ==> <ACK>
23 11 2011 à 10:22:16 <== <STX>
23 11 2011 à 10:22:16 <== 0LI1IN<CR><ETX>03<CR><LF>
23 11 2011 à 10:22:16 ==> <ACK>
23 11 2011 à 10:22:16 <== <EOT>

6- Examples of Data Transfer

6-2- Data transferred to the LIS with ASTM Compatible Version

Results sent by IDS-iSYS

==> :   IDS-iSYS to LIS
<==   LIS to IDS-iSYS

24 11 2011 à 13:37:26 ==> <ENQ>
24 11 2011 à 13:37:26 <== <ACK>
24 11 2011 à 13:37:26 ==> <STX>1H|\^_|||IDS-iSYS B300B0378|||||||||2|
20111124133726<CR><ETX>60<CR><LF>
24 11 2011 à 13:37:26 <== <ACK>
24 11 2011 à 13:37:26 ==> <STX>2P|1||20105863||BONTEMPS^ROBERT||19500226|M|||||
DUPONT<CR><ETX>FC<CR><LF>
24 11 2011 à 13:37:26 <== <ACK>
24 11 2011 à 13:37:26 ==> <STX>3O|1|7148345||^^^25OHD|R|||||||||||S<CR><ETX>78<CR><LF>
24 11 2011 à 13:37:26 <== <ACK>
24 11 2011 à 13:37:27 ==> <STX>4R|1|^^^25OHD|25,2|ng/mL|10,0 to 100,0|N|||F||||20111124133726||IDS-iSYS
B300B0378<CR><ETX>92<CR><LF>
24 11 2011 à 13:37:27 <== <ACK>
24 11 2011 à 13:37:27 ==> <STX>5L|1|N<CR><ETX>08<CR><LF>
24 11 2011 à 13:37:27 <== <ACK>
24 11 2011 à 13:37:27 ==> <EOT>

6- Examples of Data Transfer
6-3- Data transferred to the LIS with ASTM Compatible V2 Version

Results sent by IDS-iSYS

==> : IDS-iSYS to LIS
<==   LIS to IDS-iSYS

23 11 2011 à 15:23:10 ==> <ENQ>
23 11 2011 à 15:23:10 <== <ACK>
23 11 2011 à 15:23:10 ==> <STX>1H|\^_|||IDS-iSYS B300B0378|||||||P|4|
20111123152310<CR><ETX>A7<CR><LF>
23 11 2011 à 15:23:10 <== <ACK>
23 11 2011 à 15:23:10 ==> <STX>2P|1||20105863|||||19500226|M<CR><ETX>22<CR><LF>
23 11 2011 à 15:23:11 <== <ACK>
23 11 2011 à 15:23:11 ==> <STX>3O|1|7148345||^^^25OHD|R||||||||||S<CR><ETX>78<CR><LF>
23 11 2011 à 15:23:11 <== <ACK>
23 11 2011 à 15:23:11 ==> <STX>4R|1|^^^25OHD^04^F^1|16,3|ng/mL|10,0 to 100,0|N||F||||20111123152310|
IDS-iSYS B300B0378<CR><ETX>7D<CR><LF>
23 11 2011 à 15:23:11 <== <ACK>
23 11 2011 à 15:23:11 ==> <STX>5M|1|^^^25OHD^04^F^1|51||25OHD^0952^209525602987^20120229|
System Liquid^72634^00162^20121209\Cuvettes|
TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash
S^72508^00322^20121104\Wash1^1\Wash2\Wash3\DSORB<CR><ETX>CC<CR><LF>
23 11 2011 à 15:23:11 <== <ACK>
23 11 2011 à 15:23:11 ==> <STX>6L|1|N<CR><ETX>09<CR><LF>
23 11 2011 à 15:23:11 <== <ACK>
23 11 2011 à 15:23:11 ==> <EOT>

6- Examples of Data Transfer

6-3- Data transferred to the LIS with ASTM Compatible V2 Version (continued)

Results with messages sent by IDS-iSYS

==> : *IDS-iSYS to LIS*
<==   *LIS to IDS-iSYS*

05 12 2011 à 12:02:49 ==> <ENQ>
05 12 2011 à 12:02:49 <== <ACK>
05 12 2011 à 12:02:49 ==> <STX>1HI\^_IIIDS-iSYS B300B0378IIIIIIIPI4I
20111205120249<CR><ETX>AE<CR><LF>
05 12 2011 à 12:02:49 <== <ACK>
05 12 2011 à 12:02:49 ==> <STX>2PI1IIIIIIIU<CR><ETX>F8<CR><LF>
05 12 2011 à 12:02:49 <== <ACK>
05 12 2011 à 12:02:49 ==> <STX>3OI1I2II^^^25OHDIRIIIIIIIIIIS<CR><ETX>3A<CR><LF>
05 12 2011 à 12:02:49 <== <ACK>
05 12 2011 à 12:02:50 ==> <STX>4RI1I^^^25OHD^04^F^1I<5,0Ing/mLII<IIFIIII20111125141601IIDS-iSYS
B300B0378<CR><ETX>A8<CR><LF>
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 == Réception ACK (Etat_Waiting_2)
05 12 2011 à 12:02:50 ==> <STX>5CI1IIIHDM-, FORIN<CR><ETX>79<CR><LF>
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 ==> <STX>6MI1I^^^25OHD^04^F^1I51II25OHD^894^208944900848^20111231ISystem
Liquid^72634^00162^20121209\Cuvettes^18121^02177^20120506I
TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash
S^72508^00322^20121104\Wash1^3\Wash2\Wash3\DSORB<CR><ETX>46<CR><LF>
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 ==> <STX>7RI2I^^^25OHD^04^F^2I<5,0Ing/mLII<IIFIIII20111125141652IIDS-iSYS
B300B0378<CR><ETX>B3<CR><LF>
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 ==> <STX>0CI1IIIHDM-, FORIN<CR><ETX>74<CR><LF>
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 ==> <STX>1MI1I^^^25OHD^04^F^2I51II25OHD^894^208944900848^20111231ISystem
Liquid^72634^00162^20121209\Cuvettes^18121^02177^20120506I
TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash
S^72508^00322^20121104\Wash1^1\Wash2\Wash3\DSORB<CR><ETX>40<CR><LF>
05 12 2011 à 12:02:50 == Thread Emission Attente 0 pdt 15000
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 ==> <STX>2LI1IN<CR><ETX>05<CR><LF>
05 12 2011 à 12:02:50 <== <ACK>
05 12 2011 à 12:02:50 ==> <EOT>

Quality Control Results sent by IDS-iSYS

==> : IDS-iSYS to LIS
<== LIS to IDS-iSYS

23 11 2011 à 11:59:54 ==> <ENQ>
23 11 2011 à 11:59:54 <== <ACK>
23 11 2011 à 11:59:54 ==> <STX>1HI\^_IIIIDS-iSYS B300B0378IIIIIIIPI4I
20111123115954<CR><ETX>B4<CR><LF>
23 11 2011 à 11:59:54 <== <ACK>
23 11 2011 à 11:59:54 ==> <STX>2PI1IIII25DCTL1IIIIIIIIII02<CR><ETX>AC<CR><LF>
23 11 2011 à 11:59:54 <== <ACK>
23 11 2011 à 11:59:54 ==> <STX>3OI1I207284703325II^^^25OHD^02ISIIIIIIIIIIIS<CR><ETX>34<CR><LF>
23 11 2011 à 11:59:54 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>4RI1I^^^25OHD^02^F^1^21I13,6Ing/mLIIINIIFIIII20111123115953IIDS-iSYS
B300B0378<CR><ETX>7B<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>5MI1I^^^25OHD^02^F^1^21I51I12,30^7,87^16,73^728^^20111130I
25OHD^0952^209525602987^20120229ISystem
Liquid^72634^00162^20121209\Cuvettes^18121^02208^20120506I
TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash
S^72508^00322^20121104\Was<ETB>B5<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>6h1^3\Wash2\Wash3\DSORB<CR><ETX>89<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>7PI2IIII25DCTL1IIIIIIIIII02<CR><ETX>B2<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>0OI1I207284703325II^^^25OHD^02ISIIIIIIIIIIIS<CR><ETX>31<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>1RI1I^^^25OHD^02^F^1^21I11,4Ing/mLIIINIIFIIII20111123115954IIDS-iSYS
B300B0378<CR><ETX>75<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:55 ==> <STX>2MI1I^^^25OHD^02^F^1^21I51I12,30^7,87^16,73^728^^20111130I
25OHD^0952^209525602987^20120229ISystem
Liquid^72634^00162^20121209\Cuvettes^18121^02208^20120506I
TRIGB^70245^00049^20130203\TRIGA^70244^00200^20130203\Wash
S^72508^00322^20121104\Was<ETB>B2<CR><LF>
23 11 2011 à 11:59:55 <== <ACK>
23 11 2011 à 11:59:56 ==> <STX>3h1^1\Wash2\Wash3\DSORB<CR><ETX>84<CR><LF>
23 11 2011 à 11:59:56 <== <ACK>
23 11 2011 à 11:59:56 ==> <STX>4LI1IN<CR><ETX>07<CR><LF>
23 11 2011 à 11:59:56 <== <ACK>
23 11 2011 à 11:59:56 ==> <EOT>

6- Examples of Data Transfer

6-4- Data transferred to the LIS with ASTM Compatible V3 Version

Request sent by IDS-iSYS and profile sent by LIS

==> : IDS-iSYS to LIS
<==   LIS to IDS-iSYS

07 05 2015 ‡ 15:30:38 ==> <ENQ>
07 05 2015 ‡ 15:30:38 <== <ACK>
07 05 2015 ‡ 15:30:38 ==> <STX>1H|\^_|||IDS-iSYS0000000001|||||||P|5|
20150507153038<CR><ETX>91<CR><LF>
07 05 2015 ‡ 15:30:38 <== <ACK>
07 05 2015 ‡ 15:30:38 ==> <STX>2Q|1|^E1S0001||ALL|||||||||O<CR><ETX>A4<CR><LF>
07 05 2015 ‡ 15:30:38 <== <ACK>
07 05 2015 ‡ 15:30:38 ==> <STX>3L|1|N<CR><ETX>06<CR><LF>
07 05 2015 ‡ 15:30:38 <== <ACK>
07 05 2015 ‡ 15:30:39 ==> <EOT>
07 05 2015 ‡ 15:30:39 <== <ENQ>
07 05 2015 ‡ 15:30:39 ==> <ACK>
07 05 2015 ‡ 15:30:39 <== <STX>
07 05 2015 ‡ 15:30:39 <== 1H|\^&|||IDS iSYS Simulator^^2|||||||D|1|
20150507153038<CR><ETX>28<CR><LF>
07 05 2015 ‡ 15:30:39 ==> <ACK>
07 05 2015 ‡ 15:30:39 <== <STX>
07 05 2015 ‡ 15:30:39 <== 2P|1||007||FRANCKY^JEAN||19900107|U|||||WHO |||||||||||||||||||||TANNER
STAGE^5<CR><ETX>49<CR><LF>
07 05 2015 ‡ 15:30:39 ==> <ACK>
07 05 2015 ‡ 15:30:39 <== <STX>
07 05 2015 ‡ 15:30:39 <== 3O|1|01^E1S0001||^^^25OHD\^^^hGH\^^^IGFBP-3|S|||||||A|||||S|||||||||||
Q<CR><ETX>67<CR><LF>
07 05 2015 ‡ 15:30:39 ==> <ACK>
07 05 2015 ‡ 15:30:39 <== <STX>
07 05 2015 ‡ 15:30:39 <== 4L|1|N<CR><ETX>07<CR><LF>
07 05 2015 ‡ 15:30:39 ==> <ACK>
07 05 2015 ‡ 15:30:39 <== <EOT>

Results sent by IDS-iSYS

==> : IDS-iSYS to LIS
<==   LIS to IDS-iSYS

07 05 2015 ‡ 15:53:04 ==> <ENQ>
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <STX>1H|\^_|||IDS-iSYS0000000001|||||||P|5|
20150507155304<CR><ETX>8F<CR><LF>
07 05 2015 ‡ 15:53:04 == Thread Emission Attente 0 pdt 15000
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <STX>2P|1||0008||RABBIT^ROGER||19980507|M|||||HOUSE|||||NONE|||||||||||||
ROME||TANNER STAGE^4<CR><ETX>5D<CR><LF>
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <STX>3O|1|E1S0002||^^^00000|S||||||||||||S<CR><ETX>42<CR><LF>
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <STX>4R|1|^^^00000^04^F^1|0,03|mDO|0,75 to 1,15|N||F||SYSTEM^SYSTEM||
20150507155304||IDS-iSYS0000000001<CR><ETX>57<CR><LF>
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <STX>5M|1|^^^00000^04^F^1|52||R1^123456^6^20160505|System
Liquid^80408^00265^20161030\Cuvettes^10511^01038^20171224|Saline Solution<CR><ETX>06<CR><LF>
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <STX>6L|1|N<CR><ETX>09<CR><LF>
07 05 2015 ‡ 15:53:04 <== <ACK>
07 05 2015 ‡ 15:53:04 ==> <EOT>

7- Important notes

- The connection with the LIS is initialised when opening the IDS-iSYS application.

- Profiles can be sent by the LIS by downloading of the work list and/or in answer to a request sent by IDS-iSYS (the two modes are managed interchangeably).

- When a new SID is detected on IDS-iSYS (barcode reading or keyboard entry), IDS-iSYS examines the work list first of all.

- If the associated profile is not in the work list, IDS-iSYS sends a request to the LIS. The LIS must send a message in answer to each request.

- If the LIS does not answer to a request, IDS-iSYS will not send or accept a new message.

- When no profile is associated to a request sent by IDS-iSYS, the LIS must send a message containing a Test Order block with the Report Type field fixed at the value Z.

- In answer to a request, the LIS must send a message containing a Test Order block with the profile and with the Report Type field imperatively fixed at the value Q.

- The «Specimen type» in the field «Specimen Descriptor» (see Order Block, page 9) must be sent with the value corresponding to the sample type: S for Serum, U for Urine (in this case, verify that the assay protocol is defined for this sample type). The type «Other» (value =O) must not be used for Immunoassays.

- In the case of a field containing multiple components, if the last component(s) takes a NULL value, the last component delimiter(s) can be not sent.

- The exchanges between IDS-iSYS and LIS can be recorded by selecting the option available in the tab `Connections` under **SET-UP/SETTINGS/SYSTEM** menu:
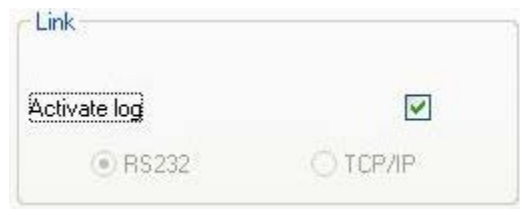
The transfers between both systems will be recorded in a log file, in the interface software folder (folder GUI). The log must be activated only for a sort period of time, to solve transfer problems.
Activating the log permanently may cause interface software dysfunctions.

- The barcode should contain at least 5 digits for the removable rack configuration (sample tubes identified by the barcode reader integrated into the sample compartment) or at least 4 digits (except if Interleaved 2/5) for the fixed tray configuration (sample tubes identified by the barcode reader in the front of the analyser).

- If data sent by the LIS cannot be processed, the message is accepted but the corresponding profile will not be created in the worklist.

- For system equipped with the option «Clot detection», when a clot is detected in a sample, all the results previously transferred to the LIS will be resent with a field Report Type set at the value C (correction) in the Test Order block.
In the Result block, the field Result abnormal Flags is then forced to A.
With the versions **ASTM Compatible V2** and **ASTM Compatible V3**, a message FIB is sent in the Comment block.