

# respons®910VET Analyzer Operator's Manual

For software version 4

Manual revision: B

## FOREWORD

This document includes all the information intended for the authority responsible for the use of the respons<sup>®</sup>910VET analyzer.

The respons®910VET is a device dedicated to veterinarian diagnostics only. It must be used by professionals who have formal training and expertise in performing diagnostic tests and using diagnostic instrumentation, in order to ensure work efficiency, quality test results and trouble free analyzer operation and performance. The test results must always be interpreted by a veterinary healthcare professional as part of the clinical management of animals.

This manual is designed to be a reference for easy operation and general maintenance of this analyzer. The manual contains detailed descriptions of the respons®910VET analyzer's features and specifications.

The assumption is made that before making an attempt to operate the analyzer, the operator is familiar with the operation of the analyzer and has:

- 1. Been trained to use Microsoft Windows Operating system user interface.
- 2. Been trained to use Acrobat Reader user interface.
- 3. Been trained by DiaSys Diagnostic Systems GmbH's authorized personnel.
- 4. Read the Operator's Manual.
- 5. Personalized the analyzer, checked and/or modified methods, parameters, profiles, serum control values etc.

#### Analyzer Manufacturer

DiaSys Diagnostic Systems GmbH Alte Strasse 9 65558 Holzheim, Germany

#### Analyzer Field Service

Contact the manufacturer or your local DiaSys Diagnostic

representative for support.

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## A. General safety note

## A.I. Warning labels

This section provides the operator with necessary information on the warning labels. The operator is required to read this manual before the installation of the analyzer. The following warning labels are affixed on the places that are potentially hazardous.

LABEL	WARNING ABOUT	LOCATION
	CAUTION Consult accompanying documents.	On the lamp hatch. On the STAT drawer.
	WARNING - HOT SURFACE.	On the lamp hatch. On the lamp cover.
(-)	PROTECTIVE EARTH.	Inside the analyzer, near the power supply connector.
	WARNING - BIOLOGICAL HAZARD Consider all specimens, reagents, calibrators, controls etc as potentially infectious! Use established good laboratory work practices when handling specimens. Wear appropriate protective gear (gloves, lab coats, safety glasses, face shields).	Near the waste output. On the robotic arm cover.
X	WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE). Do not dispose of in household waste.	Above the main power switch and the USB
	Read instructions for use.	connectors.

LABEL	WARNING ABOUT	LOCATION
	Notes & recommendations	
	The operator must be vigilant: handling can be dangerous for him/her or the environment, cause possible damage to the analyzer or generate erroneous test results.	In the manual.

### A.II. Safety information

The respons<sup>®</sup>910VET analyzer is designed to operate safely. When the operator operates the analyzer in a safe environment, in accordance with the guidelines and procedures stipulated in this manual, there are no known operating hazards.

The operator is requested to read this instruction before using the analyzer for the first time in order to become acquainted with the way to operate the analyzer.

The main power connector must always be immediately within reach of the operator.

Do not use the analyzer for any other purpose than the one it is intended for. Otherwise the operator's safety cannot be guaranteed.

The environmental work conditions requirements must strictly be respected. (see "B.V Environmental conditions" page 18).

- The cables connected to the analyzer must be in compliance with the local regulations and must be correctly connected. The main power voltage and the effectiveness of the ground connection must be strictly assured.
- All instructions described in the package of each reagent, cleaner, control or calibrator must be strictly followed.
- If any problem (liquid being spilled inside the analyzer, leakage, damaged parts...), stop using the analyzer immediately, disconnect the power cable and contact the DiaSys Diagnostic Systems GmbH authorized service engineer for guidance and repair.

- Always make sure the lamp hatch is closed.
- When closing the dome, be careful that nothing could get pinched between the dome border and the chassis of the system. Severe injury could occur.
- For the replacement of the halogen lamp, wait for at least 30 minutes after the analyzer power switch has been switched off to allow the used lamp cooling down and to avoid the risk of burns. Do not touch any glass part of the new lamp with bare hand (use gloves). Make sure that there is no crack in the glass.
- If the probe gets damaged, do not try to re-use or to fix it. You must replace the damaged probe by a new one.
- Old appliances contain valuable materials that can be recycled. Please arrange for the proper recycling of old appliances and use appropriate collection systems.
- The respons<sup>®</sup>910VET is in conformity with the requirements of the IEC 61326-2-6:2005 standard.

Tests designation	Results satisfying?	Comments
EMISSION		
Harmonics current emission	YES	Class A
Measurement of voltage fluctuation and flicker	YES	
Radiated electric field measurement	YES	Class B
Conducted emission	YES	Class B
IMMUNITY		
Radiated, radio-frequency, electromagnetic field immunity	YES	
Immunity to conducted disturbances, induced by radio- frequency fields	YES	
Electrical fast transient/burst immunity	YES	
Electrostatic discharges immunity	YES	
Immunity to power frequency magnetic field	N.A.	No sensible parts to magnetic field
Surge immunity	YES	
Voltage dips, short interruptions and voltage variations immunity	YES	

#### A.III. Handling dangerous substances



Some reagents or cleaners are strong acids or alkaline solutions. Handle with care and avoid any contact with skin, eyes or clothing.

If your hands or clothing come into contact with either reagent or cleaner, immediately wash them off with plenty of water.

If a reagent comes into contact with your eye(s), immediately rinse with water for at least 15 minutes.

Do not touch samples, mixtures & waste liquids with bare hands. Be sure to wear protection gloves. In the event of contamination, disinfect the affected area immediately, wipe off any contaminants from the system and call a physician.

# B. Instructions for transport and installation

## B.I. Shipment

The analyzer is thoroughly tested before shipment and is packed carefully to prevent damage during shipping and handling. Keep the original packaging. No warranty can be assumed by the manufacturer if the analyzer is shipped without the original packaging.



### **B.II. Transport**

To move the analyzer:

- 1. Shut down the analyzer following the normal procedure (see "G.II Shutting down" page 58).
- 2. Ensure that the arm is in the parking station.



## Parking station

- 3. Disconnect USB and power cables.
- 4. Remove the probe (see "E.V Pipetting module" page 32).
- 5. Remove the tray.
- 6. Empty the water tank.
- 7. Disconnect and remove the waste tubing.

- 8. Close the dome.
- 9. Close the STAT drawer.
- 10. At least two persons are necessary to handle the analyzer (weight: 60kg). The analyzer does not have specific handles. It must be handled by putting one's hands below the chassis, on both sides, near its feet.



#### **B.III. Power supply conditions**

- Voltage: Automatic 100-240 Volts
- Voltage input power fluctuation
- Frequency: 47/63 Hz
- Power supply: 350 Watts
- Over-voltage tolerance in compliance with level 2 of the IEC 60364-4-443.

The respons<sup>®</sup>910VET analyzer is a single-phase device connected by cable. It is equipped with a connector which allows removal of the cable without a tool. Always use a power cable complying with the local regulations.

<±10%

#### B.IV. Emitted noise level

The emitted noise level is below 65 dB. No special precaution needs to be taken.

#### **B.V. Environmental conditions**

The respons®910VET is intended for indoor use only.

•	Altitude: < 2000 meter	
•	Room temperature:	15° to 30°C
•	Relative humidity:	10 to 80%
•	Applicable pollution degree:	2
•	Ventilation requirements:	none

Avoid any inclination, vibration, shock, etc (including during transportation).

Ensure that the analyzer is not close to a storage room for chemicals, to any gas source or to the vicinity of a source of electromagnetic interferences (such as a CRT screen, mobile phones or defective neon light bulbs).

#### B.VI. Space requirements and weight

- Analyzer dimensions: 598mm (W) x 682mm (D) x 610mm (H)
- Functional space: 900mm (W) x 682mm (D) x 1029mm (H)
- Weight: 60 kg

The front side of the analyzer must always be fully accessible.

A space of 15 centimeters must be reserved on each side of the analyzer. On the left, this space is necessary for the use of the STAT drawer.

On the right, this space is mandatory for safety purposes, so that the power supply cable can easily be disconnected.



#### **B.VII. Waste requirements**

Check that the waste tubing has no leakage and is correctly connected to a waste disposal.



Liquids going through waste tubing have very low level of contamination and can be disposed in sewers according to local regulations.



The cuvettes are intended for single use only! Do not wash or re-use them. Treat used cuvettes as infectious waste.

#### **B.VIII. Installation**

- Ensure that instructions of the previous paragraphs are followed (see "B.III Power supply conditions" page 17; "B.V Environmental conditions" page 18; "B.VI Space requirements and weight" page 18 and "B.VII Waste requirements" page 20).
- Connect the waste tubing on the respons<sup>®</sup>910VET analyzer and hook the tube up to a specific drain.
- Install the probe (see "E.V Pipetting module" page 32)



The installation of the respons®910VET analyzer must be done by a DiaSys Diagnostic Systems GmbH authorized service engineer.

#### **B.IX. Storage**

- Keep the analyzer indoors and do not splash liquids on it.
- Keep the analyzer in the required environmental conditions (see "B.V Environmental conditions" page 18).



The analyzer must be decontaminated before storage.

# C. Before starting

#### C.I. Recommendations

The operator should be trained by a DiaSys Diagnostic Systems GmbH authorized service engineer and is requested to read this manual before using the analyzer for the first time. Since all adjustments of the instrument are set at the factory, the hardware of the instrument is ready to use but its software must be customized according to user needs. This especially concerns the administrator password (see "H.I Operator management" page 60 for more details).

Moreover the following recommendations shall be considered:

- 1. Caution when using and handling samples or chemical products:
  - Samples and chemical products must be handled gently to avoid formation of bubbles.
- 2. Additional caution to be taken when using the analyzer:
  - Before use, verify all liquid volumes on the analyzer: water tank, reagent bottles, cleaners, calibrators, controls, sample tubes etc.
  - It is highly recommended to run controls for each method that could be used.
  - Be sure to have filled all requested identification fields to avoid any errors.
  - The dome is locked during operation. Do not try to open it as long as the "in operation" icon is visible in the top right corner of the screen.
  - It is recommended to use barcodes for identification of reagents and samples.
    If this is not applicable, carefully double-check the positioning of samples and reagents by verifying the numbers on the tray to prevent mismatches.
  - When processing analysis, the automatic modes are always recommended.
  - In case of software shutdown, always switch the instrument off and on again before restarting the software.

- 3. Caution to observe after the use of the analyzer:
  - Clean the analyzer and its accessories before storage. The storage area must fulfill the required environmental conditions (see "B.V Environmental conditions" page 18).
  - Keep the analyzer clean so as not to inconvenience the next operator and/or affect the next operation.
- 4. Maintenance:
  - It is necessary for the analyzer and its associated parts to be periodically checked. The attached maintenance plan must be strictly followed.
  - Use only original parts, materials and accessories distributed by DiaSys Diagnostic Systems GmbH.

#### C.II. Order information

Reagents, controls and calibrators must be ordered through a local representative of DiaSys Diagnostic Systems GmbH.

Using DiaSys system reagents is highly recommended to achieve the best respons®910VET functionality. However, additional tests can be setup on the analyzer. Contact your local representative for more details.

#### C.III. Warranty and maintenance contract

The respons®910VET analyzer is warranted against defective materials or workmanship for a period as agreed by DiaSys Diagnostic Systems GmbH. This warranty does not cover any defect, malfunction or damage due to:

- Accident, neglect or willful mistreatment of the product.
- Failures to use, operate, service or maintain the product in accordance with the applicable Operator's Manual.
- Use of reagents or chemicals of a corrosive nature.
- It is strongly recommended that a maintenance service contract is established with the local representative of DiaSys Diagnostic Systems GmbH.

# D. List of accessories

The following table lists all accessories with their respective reference number and packaging unit.



Only original accessories must be used. Contact your local representative of DiaSys Diagnostic Systems GmbH for purchase.

Description	Reference	Packaging unit
Fuse 5AT 5x20	960584	2
Fuse 3.15 AT 5x20	960582	4
Probe	960503	1
Halogen lamp	960505	1
Tray assembly	960589	1
10mL Tube Insert	960586	32
5 mL Tube Insert	960585	32
1.5 mL Sample Cup Adaptor	960587	10
2.5 mL Sample Cup Adaptors	960588	10
Cuvette segments for Respons®910VET	960502	256
Waste Connector	960583	1
Water filter	960504	5
Cleaner B	186509910923	4



For cleaning, a solution of isopropyl alcohol is necessary.

For maintenance action, the following screwdrivers are necessary:

- slot screwdriver with a blade of 3.5mm x 0.75mm
- cross-headed screwdriver with a diameter of 3mm
- cross-headed screwdriver with a diameter of 4.5mm

# E. Description of the analyzer

## E.I. Introduction

The respons®910VET analyzer is a clinical chemistry analyzer, intended for a large number of methodologies with a maximum throughput rate of 150 tests per hour for mono-reagent tests and 100 tests per hour for bi-reagent ones.



Two types of measurements can be performed:

- Colorimetric methods
- Turbidimetric methods

The respons<sup>®</sup>910VET analyzer allows different work flows and suits to any type of organization and management of patient files of your laboratory. It is equipped with an integrated bar-code reader which can recognize labels on sample containers as well as on reagent bottles and may be connected to a Laboratory Information System (LIS) via its bidirectional connection.

This manual is entirely intended for use and programming of respons<sup>®</sup>910VET analyzer in routine work, as well as for emergency maintenance of the analyzer.

#### E.II. General overview



\* Those functional units are not visible on the scheme.

## E.III. Specifications

Throughput	100 tests/hour (bi-reagent) and 150 tests/hour (mono-reagent) for a cycle
	time of 12 seconds
System type Automated random access analyzer, closed system	
Sample	Serum, plasma, whole blood, urine, CSF.
Measurement principle Photometer (Kinetic / End Point) with 12 different wavelengths from 3 to 800nm.	
Applicable analyses	Parameters according to DiaSys product catalog.
On board capacity	30 reagent positions (mono or bi-reagent).
Assay modes	End-Point, Fixed time kinetic, Linear kinetic.
Sample volume	2-30 μl (adjustable in 0.1 μl step).
Reagent volume	Reagent 1: 90µl – 250µl (1µl increment). Reagent 2: 10µl – 130µl (1µl increment).
Reaction temperature	37 °C; temperature stability: ± 0.2 °C.
Reaction time	12 seconds increment. Mono-reagent: up to 16min. Bi-reagent: up to 16min including incubation time (at least 4min 36sec).
Test selection	Selection of tests one by one or with profile for each sample. Selection from host computer via interface. Selection according to sample barcode reading.
Maintenance	Maintenance actions: Photometer auto-adjustment, needle auto- adjustment, probe cleaning, priming and bubble purging.
Barcode identification	Sample tube barcode ID (NW7, code 39, code 128, 2 of 5 interleaved, 2 of 5 standard, ISBT-code 128). Reagent barcode ID (18digit). Built-in reagent barcode scan.
Water consumption	0.9L per hour.
System Warm-up Time	10 minutes system warm-up time.
Safety mechanism	Vertical obstruction detection. Capacitance based liquid level sensing.
System interface	Analyzer <-> PC interface: USB. PC <-> Host interface: RS232, TCP/IP.

#### E.IV. Dome

To open or close the dome, manipulate it by its low border drawn in red in the image below.





When closing the dome verify that nothing is caught between the dome border and the chassis of the system. Severe injury may occur.



Avoid any bending of the dome when closing.

### E.V. Pipetting module

The pipetting module includes a robotic arm with a probe, a parking station (home position) and a wash station. It provides different features such as the pipetting of samples and reagents, the mixing and the liquid level detection.



Probe in home position

Wash station

The probe is equipped with an automatic capacitive level detection in order to limit its immersion into liquids and to minimize possible contamination. The detection occurs for each pipetting procedure. After each aspiration step, the probe is thoroughly washed internally and externally. The required water is directly pumped out of the internal water tank (see "E.VIII Water tank" page 40).

A further feature of the probe is the mixing functionality of reagent and sample inside the reaction cuvette. This is achieved by multiple aspirations and dispenses into the reaction cuvette.

The probe also provides a clot and foam detection function. If clots or foam are suspected, a warning is shown on the results (see "Q.VI Analytical flags" page 211). Additionally a crash sensor has been integrated to the probe to avoid any risk of injury and to limit the risk of damage, e.g. when a cap has been forgotten on a container.

To obtain the best performances it is highly recommended to clean the probe after daily work.

If needed, the probe can be easily removed by turning clockwise to unscrew it.



The syringe module does not need any maintenance from the operator. It is not accessible without removing the main cover.



When a probe is damaged, do not try to re-use it but use a new one.



The arm must be in home position to remove the probe. Only original probes must be used. Contact the local representative of DiaSys Diagnostic Systems GmbH for purchase.

E.VI. Rotor

#### E.VI.1. Tray handling



The probe must be in the parking station before moving the tray to avoid any damage.

The tray must be removed and stored in a refrigerated place as soon as the routine work is completed.

One tray carries both the samples (in different types of sample tubes/ cups on the "outer ring") as well as reagents (on the "inner ring"). The tray can be removed from the analyzer by pulling the blue handle for e.g. storage overnight in the refrigerator.





To place the tray on the analyzer:



1. Hold the tray by the lever, place it onto its shaft and turn clockwise.



2. Turn until it moves down by half a centimeter.



 Lower the lever to ensure that the tray is locked for operation.


4. If the tray is correctly locked, a small metallic pin becomes visible.

#### E.VI.2. Sample positions for routine work

The respons<sup>®</sup>910VET analyzer can use whole blood, plasma, serum, urine or CSF as sample material.

Samples are placed on the outer ring of the tray on 30 positions for the following kinds of containers:

- 5 mL, 7 mL and 10 mL tubes (dead volume is 500 μL).
- 1.5 mL and 2.5 mL sample cups (dead volume is 50 μL).

The samples must be loaded before closing the cover of the analyzer and launching the analysis. Two STAT positions are available for emergency (see "E.VII STAT drawer" page 39).

Before placing a container on the tray, ensure that there is enough sample and that no air bubbles or foam are present. Also check that no clot is visible at least on the surface of the sample.

Consider all materials (including calibrators and controls) as potentially infectious! Follow the good laboratory practices and wear appropriate protection gears (gloves, lab coat, safety glasses, face shield) while handling them.



Only original inserts and adaptors must be used. Contact your local representative for purchase.

The respons®910VET analyzer can be loaded with primary tubes for 5mL, 7mL or 10mL. The respective adaptors can be used.





White inserts for 5mL and 7mL tubes.

Black inserts for 10mL tubes and adaptors.

To use 1.5 and 2.5 mL cups, insert them into the correct adaptor.





1.5mL cup adaptor.

2.5mL cup adaptor.



For proper placement, the adaptors must be inserted and pushed until reaching the bottom. Poor placement of the adaptors may result in liquid detection system problems.

#### E.VI.3. Reagent positioning

The reagents must be placed on the 30 positions available on the inner ring of the tray. There are three different types of bottles:

- Mono-container (dead volume is 1700 μL).
- Small twin-container (dead volume is 500 μL for both inner and outer part).
- Large twin-container (dead volume is 1000 µL for inner part and 500 µL for outer ring).





#### E.VI.4. Reaction cuvettes

The respons®910VET uses disposable reaction cuvettes that are assembled on segments of 15 cuvettes. In total seven segments (= 105 cuvettes) can be loaded at a time. The optical path length is 0.5 cm.



#### E.VI.4.a. Loading new cuvettes



The probe must be in the parking station before moving the rotor to avoid any damage.

Only original and clean cuvette segments must be used. Contact your local representative of DiaSys Diagnostic Systems GmbH for purchase.

The cuvette segments must be kept within their packaging until use to prevent dust and/or possible humidity. Never use cuvettes whose packaging is damaged.



The cuvette segments are intended for single use only, and must be disposed of after each usage.

Do not try to wash and re-use the cuvettes.

Before insertion of the cuvette segment, visually check each segment to ensure there is no defect.

E.VI.4.b. Unloading used cuvettes



The probe must be in the parking station before moving the rotor to avoid any damage.



Use established good laboratory practices when removing used cuvettes. Treat them as infectious waste and wear appropriate protective gear (gloves, lab coats, safety glasses, face shields).

#### E.VI.5. Heating system for the reaction cuvettes



When the power switch is ON, the temperature control of the incubator starts automatically.

The reaction temperature is controlled by a metallic incubator block regulated at 37°C. The operator can check the temperature on the main screen of the operator software.

## E.VII. STAT drawer



Please see paragraph "E.VI.2 Sample positions for routine work" page 35 for description of inserts and adaptors.

The STAT drawer allows running samples in emergency (STAT samples means Short TurnAround Time samples). It is located on the left-hand side of the analyzer and offers two sample positions which are available anytime. Inserts and/or adaptors are the same as the ones used on the tray. The barcode reader is not working for STAT positions, thus the emergency samples must be manually identified.





The STAT drawer is locked when the system processes emergency samples sets on one of the STAT positions. This processing takes place with the highest priority within the current run.



Forcing the opening of the STAT drawer can damage the locking system.



The STAT drawer must be closed before the analysis is processed. Please see "I.III Emergency Entry" page 83 for detailed instructions on STAT sample entries.

### E.VIII. Water tank

#### E.VIII.1. Description

The respons<sup>®</sup>910VET analyzer uses de-ionized or distilled water stored in a water tank. This tank is equipped with a detector that informs on the water level. A corresponding symbol is displayed on the screen (refer to paragraph "F.I Software main screen" page 46).

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The water tank is located on the left front side of the analyzer. It is sitting on a sliding carriage and can easily be drawn out of the analyzer for filling.



To fill it, it is not necessary to remove the water tank from the analyzer, although this is also possible (see "O.III.3.g Cleaning of the water tank" page 194).



### E.VIII.2. Characteristics

#### E.VIII.2.a. Water tank characteristics

The following specifications describe the water tank and its filling volume:

Total volume	2.7 L
Maximum useable volume	2.47 L
Dead volume	230 mL
Maximum volume required for washing during mono-reagent tests	4 mL
Maximum volume required for washing during bi-reagent tests	6 mL



The water tank is completely empty (only dead volume left).



The water tank is completely filled.



The water tank is nearly empty. The analyzer can perform the running tests but the operator is asked to refill.

#### E.VIII.2.b. Water requirements

The respons®910VET uses the water stored in its water tank to rinse the probe. The water tank must be filled only with de-ionized or distilled water only.

There are two specifications with regard to appropriate water:

- Resistivity > 5 MΩ.cm
- Conductivity < 0.2 µS.cm<sup>-1</sup>

## E.IX. Optical module



Only original lamps must be used. Contact your local representative of DiaSys Diagnostic Systems GmbH for purchase.

To change the lamp, refer to paragraph "O.III.1.c Lamp exchange" page 190. The respons®910VET is equipped with a photometer able to measure twelve different wavelengths simultaneously. A special opening on the right of the analyzer is designed to reach the lamp and to allow its replacement easily. Following are the specifications of the photometer:

Wavelength range	340-800 nm
Wavelength bandwidth	10 nm ± 2 nm (depending on the wavelength)
Wavelength accuracy	± 3 nm
Linearity	0 – 2.5 O.D.

Before any maintenance on the lamp, switch the analyzer off and wait for at least 30 minutes in order to allow the lamp to cool down and avoid burn hazards.

## E.X. Waste output

The waste output connector is located on the left side of the analyzer.



The waste output must be connected with a flexible tubing accessory equipped with a seal and lock connector. Make sure that the waste container is placed at least below the level of the waste output connector as waste flow is passive by means of gravity.



Proper decontamination of waste water container must be ensured in accordance with applicable regulations and directives.

## E.XI. Electrical connections



Two connections are on the right hand side of the analyzer:

- Main power connector: connector type CEE22.
- USB connector: type B.

Cables are not provided with the analyzer.

# F. Screen layout



## F.I. Software main screen



Description of different icons or symbols visible on the main screen:

<administrator> Ope</administrator>	erator currently logged on.								
2015-04-30T15:42:22 tt 290001	2015-04-30T15:42:22 290001Current date and time (YYYY-MM-DDThh:mm:ss) and serial number of the analyzer.								
Live report icon. The I 24hours (see "F.VI Live	ive report shows the results of all report" page 53). To display it, click	the runs performed within the last on this icon.							
When this icon is visible on the top right of the screen, it indicates that some warnings were issued by the system. To display these warnings, click on this icon.									
Host interface status is shown on the right top edge of the main screen (see "F.VII Host interface status" page 54). The icon is blinking when data is exchanged between analyzer and server. Host interface status is displayed on the left upper field.									
•	•								
The link between the PC and the analyzer is not ready to use. The analyzer cannot process test analysis.	The link between the PC and the analyzer is established. The analyzer is not processing test analysis.	The analyzer is running and the link between the PC and the respons <sup>®</sup> 910VET is working correctly.							
Water tank ready to use.	Not enough water for a complete run.	No water tank or water tank not correctly plugged.							
Photometer lamp is switched on. Represents cuvettes. above a cuvette position	Photometer lamp is switched off. The first cuvette of each segment on displays information about its con	Photometer scan in process. t is numbered. Moving the cursor itent.							



4.0.1.0 Current software version number. A more general version number is also displayed in the middle of the screen (v 4 on the picture).

The function of the "Entries", "Results", "Configuration" and "Work list" buttons is explained in "F.II Top menu bar" page 49.

## F.II. Top menu bar

The top menu bar on the top of the screen hides further drop-down lists. To see these menus, move the cursor onto the bar.

				i i i i i i i i i i i i i i i i i i i
<administrator></administrator>		- TOP MENU BAR -		· · · ·
2015-04-30T15:42:22	~		$\frown$	

While doing so, the menu bar is enlarged and you may select one of the icons as follows:

WORK LIST	▼ ENTRIES	▼ RESULTS	▼ CONFIGURATION	▼ MAINTENANCE	HELP	▼ QUIT	

- "Work list": Gives an overview of the current work list (see "I.II Work list" page 71).
- "Entries": Allows entering the analysis (calibration, control or patient) to process.
- "Results": Shows currently available results.
- "Configuration": Allows changing the analyzer settings (see "N Software options" page 167).
- "Maintenance": Allows performing all the maintenance procedures (see "O Maintenance" page 185).
- "Help": Opens the Operator's Manual as pdf file (see "F.VIII Operator help" page 55).
- "Quit": Closes the software and switches the computer off (see "G.II Shutting down" page 58).

## F.III. Function bar

The function bar is located at the bottom of the screen (except for the main screen) and is always displayed in reduced form.

I	EXIT	REPEAT PRESCRIPTION	DELETE PROFILE	SAVE PROFILE	CLEAR SELECTION	ADD TO WORK LIST	

When the mouse is moved on this bar, it is enlarged to show all available functions.

EXIT REPEAT PRESCRIPTION P	ELETE SAVE PROFILE PROFILE	CLEAR SELECTION	ADD TO WORK LIST	
----------------------------	-------------------------------	--------------------	---------------------	--

## F.IV. Message bar

On the top of the screen, above the main menu bar, a message bar scrolls information, warnings and error messages (see "Q.II Messages during analysis run" page 205). The list of all the messages can be displayed by clicking on it.

When warnings and/or error messages are displayed, a sound can be setup to inform the user (see "N.X Appearance & sounds" page 182).

Messages				×				
Date/Time	#ID	Message						
2015-04-30T15:42:28		All tests are terminated						
2015-04-30T15:42:28	12	You may have forgotten a bottle cap on the reagent position 1						
2015-04-30T15:42:28		T:GLÜC (GLUC @1) cuv# 25-28998						
2015-04-30T15:42:28	:28 Water cuv#? 24							
2015-04-30T15:42:28		Scheduling Rotor sample position 1						
2015-04-30T15:42:28	1000	To preserve reagents && calibrators, return them to the fridge.						
2015-04-30T15:42:28		All tests are terminated						
2015-04-30T15:42:28		PAT:ALP/2 (ALP @3) cuv# 27-28997						
2015-04-30T15:42:28		PAT:AST/2 (AST @2) cuv# 26-28999						
2015-04-30T15:42:28	1005	Cancelling jobsAwaiting completion						
1								
□ View only Alerts			Clear messages list	Close				

Different colors indicate the type of message:

- White = information
- Yellow = warning
- Red = error

## F.V. Schedule management window

The schedule management window automatically appears from the main screen in case of change in the calibration status of a reagent which is on the current tray. From another screen than the main one, a message automatically appears in the message bar when needed. Clicking on it leads to the window. Finally, clicking on the button "Schedule" also opens this window.

Schedule Mana	igement				
Add	Method	Position	Reagent Lot Number	Validity	$\Delta$
	AA	1	1221	2 week(s), 1 day(s)	
	ALB	4	5216	1 week(s)	
	ALT	5	1916	2 expired days	
	CHOL	10	1546	missing definition	
	GGT	2		not performed	
	RF2	22	5671	1 month(s), 2 week(s), 3 day(s)	
	tall				Ŷ
	, com			ОК	
🗹 Displ	ay all the reager	nts loaded on the	e current tray	Invalid	
	Add to \	WorkList		Expired / Not performed / On error Nearly expired	Close

The table is divided into five columns:

- "Add": Allows selecting methods by checking the related box before adding the related calibration orders to the work list. Note that it is not possible to select a method whose calibration prescription is already in the work list or a method whose calibration cannot be performed (missing definition for instance).
- "Method": Gives the name of the methods.
- "**Position**": Gives the position of the reagent on the current tray.
- "Reagent Lot Number": Gives the lot number of each reagent (if available).
- "Validity": Gives either the time the calibration is still valid for, or the time it has been expired for. If no calibration definition or result can be found, it is written in this column as well.

Only the reagents from the current tray and with a calibration issue are displayed. Different colors are used:

- Green (if the option "Display all the reagents loaded on the current tray" is enabled only): the calibration is valid.
- Black: no calibration definition can be found for the method.
- Red: the calibration is expired (due to an expired calibration stability delay for instance), on error or has not been performed yet.
- Yellow: the calibration is nearly expired according to the warning percentage defined in the options (see "N.II Analysis" page 172).

Two check-boxes and two buttons also appear on this screen:

- "Select all": allows selecting all the listed reagents.
- "Display all the reagents loaded on the current tray": Displays all the reagents that are on the current tray, even if they do not have any calibration issue (green lines).
- "Add to Work List": Adds a calibration order to the work list for the selected reagents (checked boxes).
- "Close": Closes the schedule management window and goes back to the main screen.

# F.VI. Live report

The live report icon is displayed on the left-hand side of the message bar. The results of all the runs performed during the last 24 hours appear when clicking on it.

Report	CALIBRAT	E ION ON 2	ALL POINTS		_ <b>_</b> ×
Detailed absorbances o	of each aspin	ation			
Calibrator #Lot	Dil	Conc.	Prev.Abso.	Abso#1	Abso#2
NaCl #001 TruCal U #19846	1 1	0.0 114.0		-0.00035 OK -0.00009 OK	-0.00026 OK -0.00023 OK
Method Degree Variance	Previous  		New X 1 0.00 %		
C0 C1			233. 761591.	328 057	
✓ Page1 of 4					

This list is updated in real time as soon as the results are available.

Results can be printed or deleted from the list through the following windows which is also displayed when clicking on the live report icon.

LiveReport			
Page Selection			
⊙ All			
C Pages :			
	Enter page nun separated by co	nbers and/or a selection mmas (1,3,5-12)	
Pri	nt )	Clear	

All the results older than 24 hours are automatically deleted from the live report.

The results removed from the live report cannot be retrieved in the live report but they are still available in the result screens.

## F.VII. Host interface status

The status of the host interface is shown on the top right corner of the screen.



The icons in use are the following ones:





## F.VIII. Operator help

The operator has access to the Operator's Manual within the main software. The manual is installed and renewed with each installation of the main software.

#### From "Main menu bar" => "Help"

Work List Entries Results Configuration M	Maintenance	Help	Quit
---	-------------	------	------

The Operator's Manual is open in a fixed window which never overlaps the system message bar or the menu bar.

### F.IX. Screen overview

In all operator screens, some common rules apply:

- The top of the screen always displays the message bar, the top menu bar and the host interface status icons.
- The working area is displayed in the middle of the screen, and contains standard windows items (lists, buttons, edit controls ...).
- The bottom of the screen displays the function bar with different buttons depending on the screen.

The Operator's Manual gives the following information:

- Path to follow for entering a screen.
- Overview of the respective screen and its content.
- Description of the screen functions.
- Detailed information about the function of the buttons and/or frames.

# G. Starting and stopping process

## G.I. Starting process

Before launching a run, some preliminary steps must be followed:

- 1. Check that the waste tubing is connected to a waste disposal.
- 2. Visually inspect the analyzer to ensure there is no visible leakage.
- 3. Check the water level in the water tank.
- 4. Replace the used cuvettes by new ones.
- 5. Close the dome.
- 6. Switch the analyzer and the PC on.
- 7. Wait until "System Ready" is displayed.
- 8. Check that sufficient reagents and samples are on the tray.
- 9. Start working.

The power switch of the analyzer is on the right side. First switch the analyzer on and then start the PC.



### G.II. Shutting down

Before switching the analyzer off, you have to shut down the software first.

#### From "Main menu bar" => "Quit" => "Shutdown"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit	
						Change operator	
						Shutdown	
					-far-	Field service	
						access	

The analyzer can then be turned off.

# H. Operators

## H.I. Operator management

For security reasons, restrictions apply to access some software features.

Two operators are created by default and cannot be deleted: "**Guest**" with limited access and "**Administrator**" who can configure the respons<sup>®</sup>910VET analyzer, establish further new operators and define access rights for each of them.

At the very first starting of the software, a message appears to warn the operator that the administrator password is defined by default and has to be changed as soon as possible. From "Main screen" => "Configuration" => "Operators configuration"



This screen is used to define operator access rights to specific parts of the software as well as to add additional operators. It is divided into several parts.

On the left column all the setup "**Operators**" are listed with their identifier (User ID). "**Administrator**" and "**Guest**" (written in italic) are automatically created by the software and cannot be deleted. The one written in bold font style is setup as default. When the system starts, this user will be active until another one logs in.

On the top right part, the "**Name**" of the selected operator is displayed, as well as a field for the account "**Password**". A checkbox allows giving a user a "**Time out**". In case of inactivity, the selected account will be automatically logged out after a certain time (default is 5 minutes, see "N.I System" page 169 to change it).

On the middle and bottom right parts lists the actions that the selected operator can or cannot do:

- "ADM": The operator has access to the whole system without restrictions and can do all the actions listed below.
- "SETS": The operator can setup the software options but not the analytical configuration.
- "SAV": The operator can run maintenance tools (photometer and probe adjustment, bubble purging, etc...).
- "SET": The operator can setup methods, trays and solutions.
- "CTL": The operator can setup calibrations and controls.

On the function bar there are six buttons:

- "Exit": Goes back to the main screen. This button is the only one that can be seen by operators without administrator rights.
- "Show passwords" or "Hide passwords" (works only if the currently logged operator has administrator rights): Displays or hides the password of the selected operator.
- "Set as default": Sets the selected operator as default one. The "Administrator" stays the default operator until the password for its account is changed.
- "New": Allows the addition of a new operator.
- "Delete" (greyed if the selected operator is "Guest" or "Administrator"): Deletes the selected operator.
- "Modify": Allows the edition of the selected operator's settings. When clicking on this button, the screen switches to the edition mode. Only three buttons are then displayed: "Cancel" to leave the edition mode and go back to the view mode without changing anything (confirmation requested), "Show passwords" and "Save" to save the operator's settings.

## H.II. Operator change

#### From "Top menu bar" => "Quit" => "Change Operator"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit
						Change operator
					r	Shutdown
			Current operator is : Ad	ministrator		
		00	vrotor nomo			
		Ope				
			Password			
			Default opera	ator		
			ок	Cancel		

This screen is used to choose an operator in the drop-down list and enter the password if requested. Press "**OK**" to confirm or "**Cancel**" to return to the main screen.

# I. Entries

## I.I. Routine Entry



#### From "Main Screen" => "Entries" => "Routine entry"



<administrator> - TOP MENU BA</administrator>	IR : ROUTINE ENTRY -					
Animal Registration ID AW 34160 Animal's name Delilah Owner's Last Name Baker Species Cat Age (y.o.) 45 Date of birth 19/05/1970	Sample Sampling time Sample ID (Barcode) (yyyy-mm-dd T hh:mm:ss) 20T:_ Type of container © 5-10 mL tube © 1.5 mL cup © 2.5 mL cup					
Profiles	2 3					
Methods Please select a tray to change methods ordering <a href="https://www.alignedical.order">Alphabetical Order&gt;</a>	Please type method shortcut, and press <enter></enter>					
ALB ALT AMY AP APC diluted by 8 ALT AMY AP APC CA CHE CHOL CK-MB C	DA1     APOB     ASO     AST     C3c     C4       Crea     PAP     CRP     CRP hs     DBIL     DDI					
ETH FE FERR GGT GLUC	C GOD GLUC HK HbA1c HCY HDLC IGA					
IGE K LACT LDH LDL Lp(a) LPS MALBU MG PALB						
PAMY PO3 Dd9 RF TBIL						
Legend Keep the mouse button pressed on a method to select a predilution           Method         Method	[Profile] Invalid profile Invalid profile					
EXIT REPEAT PRESCRIPTION DELETE PR	ROFILE SAVE PROFILE CLEAR SELECTION ADD TO WORK LIST					

This screen allows ordering patient analysis and is divided into several parts:

 "Animal": Allows providing information about the animal (see "I.I.3 Animal identification" page 70).

- "Sample": Allows registering information about the sample:
  - "Sample ID (Barcode)": defines the sample and is essential to avoid any error.
     When the barcode reader is disabled for samples, an automatic numbering is done from the number entered in this field. If the field is empty, no numbering takes place.
  - "Type of container": Allows selecting what kind of sample container is used.
  - "Sampling time" (optional): Allows entering when the sample was taken.
  - "**Sample type**": Defines which sample material is used for the analysis. This field is mandatory.
- "Ordering Vet." for "Ordering Veterinarian" (optional): Specifies which veterinarian ordered the analysis; including a phone number for emergency calls.
- "Profiles": Shows all the existing profiles for animal analyses (see "I.I.2 Profile use" page 69).
- "Methods": Allows ordering the tests to run for each sample by clicking on the related button. All the useable methods that are defined on the analyzer are listed in that part and are coded by colors, shade and underlining. The drop-down list on the left allows selecting a sorting tray to display the methods in the same order (see "N.XI Method ordering" page 183). The one on the right allows selecting methods by entering their shortcut.
- "Legend": Gives more details about the color code used for the buttons.
- "Information": Allows changing the number of replicates (up to 20 per sample if enabled in the options) and shows the number of fresh cuvettes required for the prescription.

On the function bar there are six buttons:

- "Exit": Goes back to the main screen.
- **"Repeat prescription**": Repeats the previous prescription for a new entry.
- "Delete Profile": Deletes the selected profile.
- "Save profile": Saves several selected methods as a profile.
- "Clear Selection": Unselects all selected methods.
- "Add to Work List": Ends the edition of an entry and adds the prescription to the work list.

#### I.I.1. Method selection

The methods are always displayed within a green background. If a shortcut has been setup, it appears below the test name. To select a method, click on the related button. To unselect it, click again.



Shaded button with green background: unselected method.

Unshaded button with bright green background: selected method.

To request a specific dilution of the sample (only if no sample hemolysis is required by the method), keep pressing onto the method button for a few seconds until a drop-down list appears. Choose the required dilution factor or set "1" for no dilution. The dilution factor will then be displayed on the button below the name of the method.



Unshaded button with bright green background and dilution ratio: selected method with a specific dilution.



For patient tests, dilutions are only allowed for factors between 6 and 26. The following table shows the sample and diluent volumes used for each dilution factor.

Dilution	Sample	Diluent
factor	(µL)	(µL)
6	20	100
7	17	102
8	15	105
9	14	112
10	12	108
11	11	110
12	10	110

Dilution	Sample	Diluent
factor	(µL)	(µL)
13	10	120
14	9	117
15	8	112
16	8	120
17	7	112
18	7	119
19	7	126

Dilution	Sample	Diluent
factor	(µL)	(µL)
20	6	114
21	6	120
22	6	126
23	6	132
24	6	138
25	6	144
26	6	150

#### I.I.2. Profile use

Profiles are always displayed within a pink background. To select a profile, click on the related button. To unselect it, click again.



Shaded button with pink background: unselected profile.

Unshaded button with bright pink background: selected profile.

A profile allows selecting or unselecting several methods often used together (e.g. for cardiac screening). To create a profile:

- 1. Select methods to combine to a profile.
- 2. Click on "Save profile".
- 3. Enter a unique name for the new profile.
- 4. Click on "OK".

If the entered name is already used for another profile, the software will ask a confirmation before replacing the currently existing profile by the new one.

To delete a profile, select it and click on "Delete profile".

If a method is disabled (see "L.II Method configuration" page 132), all the profiles using this method are disabled as well and cannot be used anymore.

The profile use is similar for calibrations and controls. However, the defined profiles are not linked to one another. For instance, a profile created for calibrations will not be visible in the routine and control entry screens. They are all independent.

#### I.I.3. Animal identification

The "Animal" part in the top left corner of the "Routine entry" screen displays all information related to the animal file. The following fields can be left empty or be filled by the operator:

- "Registration ID": Internal number for each animal.
- "Animal's name" and "Owner's Last name".
- **"Species**": Can be defined in the options.
- "Age (y.o.)" for age (years old) and "Date of birth".
- "Reading glass" button: Leads to the animal database.

				4	c.	
<administrator> - TOP MENU BAR : ROUTINE ENTRY -</administrator>						
Search Filters				(72 found	)	
Owner's Last Name	Animal's name	Registration ID	Date of birth	Species		
Smith	Tiggy	1YB9 LYZH CLCC	24/12/1990	Dog	分	
Pitt	Tornado	2PRB G1KX RH29 UJ3	25/04/1988	Dog		
Baker	Wamba	2TWO ECR8 S1KX KOS	19/01/1989	Cat		
Jonas	Tornado	2XPA 9T8K M4XR EPX	09/08/1986	Dog		
Smith	Wamba	40KJ 2N2T PWFBA	02/09/1992	Cat		
Goodman	Skippy	4QEY YQW3 VB1W4	09/07/2002	Dog		
Baker	Delilah	4YPK EOG4	02/12/2005	Cat		
FitzPatrick	Tiggy	58B5 A26Y QP	03/05/2011	Dog		
Jonas	Wamba	5D4E M	13/08/1997	Cat		
Jonas	Skippy	513S G258 P0Y6Q	23/04/2006	Dog		
Goodman	Bagheera	50CI QC	14/02/1988	Dog		
Miller	Tiggy	60TJ AONS	22/08/2000	Dog		
Pitt	Wamba	6R4Z ZXFW JBID AJT	04/09/2011	Cat	오	
Owner's Last Name Smith	Animal's name	Tiggy	Species Dog	1	-	
Date of birth: 24/12/1990   Registration ID: 1YB9 LYZH CLCC						
BACK		NEW ANIMAL DELETE ANIMAL	MODIFY ANIMAL	SELECT ANIN	IAL	

From "Main Screen" => "Entries" => "Routine entry" => "Reading glass"

This screen displays all the animal information registered from the "**Routine entry**" screen. The animals can be filtered by name, owner's last name or registration ID. Full information related to a selected patient is displayed at the bottom of the screen.
There are five buttons in the function bar:

- "Back": Goes back to the "Routine Entry" screen.
- "New Animal": Allows the registration of a new animal file.
- "Delete Animal": Deletes the selected animal file from the list.
- "Modify Animal": Allows the modification of an animal file.
- "Select Animal": Goes back to "Routine Entry" with the selected animal file.

#### I.II. Work list

#### I.II.1. Layout

#### From "Main Screen" => "Work List"

Type         ID         Method         Status           CAL         2×14C°         BF (RS11)         M** Accounts         Sample Time           2×14C°         BF (RS11)         M** Accounts         M** Accounts         Part Status         Part Status <td< th=""><th><adminis< th=""><th>strator&gt;</th><th></th><th>- TOP MENU</th><th>BAR : WORK</th><th>LIST -</th><th></th><th></th><th></th><th></th></adminis<></th></td<>	<adminis< th=""><th>strator&gt;</th><th></th><th>- TOP MENU</th><th>BAR : WORK</th><th>LIST -</th><th></th><th></th><th></th><th></th></adminis<>	strator>		- TOP MENU	BAR : WORK	LIST -				
Type         ID         Method         Status           CAL         2x10x2         RF (R811)         With Konsta         A           2x10x2         RF (R811)         With Konsta         A         A           2x10x2         RF (R811)         With Konsta         A         A           2x10x7         RF (R811)         With Konsta         A           <	Tests	- A.				Gener	ated tra	v		
GAL         TO VALIDATE 2 × NGCH         TO VALIDATE 2 × TC RFL1         PF (R81)         N=T NG GAMAL N=T NG GAMAL         POS         Type         Reference         Exp           2 × TC RFL1         RF (R81)         N=T NG GAMAL         N=T NG G	Туре	ID	Method	Status		Sample	Tray			
2 × Nach       PF (R811)       ATTAC LONGE.       CAL       MaC1 Back       mear exp         2 × TC RF L2       PF (R811)       ATTAC LONGE.       CAL       TC RF L2 #144501       expired         2 × TC RF L3       PF (R811)       ATTAC LONGE.       CAL       TC RF L2 #144501       expired         2 × TC RF L3       PF (R811)       ATTAC LONGE.       CAL       TC RF L3 #144501       expired         2 × TC RF L3       PF (R811)       ATTAC LONGE.       CAL       TC RF L3 #144501       expired         2 × TC RF L3       PF (R811)       ATTAC LONGE.       CAL       TC RF L3 #144501       expired         2 × TC RF L3       PF (R816)       ATTAC LONGE.       CAL       TC RF L3 #144501       expired         2 × TC RF L3       PF2 (R816)       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.         2 × TC RF L3       PF2 (R816)       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.         2 × TC RF L4       PF2 (R816)       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.         CTL       STT REL4       PF2 (R816)       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE.       ATTAC LONGE. </td <td>CAL</td> <td></td> <td></td> <td>TO VALIDATE</td> <td></td> <td>Pos</td> <td>Type</td> <td>Reference</td> <td>Exp</td> <td></td>	CAL			TO VALIDATE		Pos	Type	Reference	Exp	
22 to the H_1       RF (R811)       AT ALL CONSEL       CAL       TO RF L 1 # H4500       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired         2 x TO RF L3       RF (R811)       AT ALL CONSEL       expired       expired       expired </td <td></td> <td></td> <td>RF (R811)</td> <td>R1* FAIL CANCEL</td> <td></td> <td>01</td> <td>CAL</td> <td>NaCl #xxx</td> <td>nearexo</td> <td></td>			RF (R811)	R1* FAIL CANCEL		01	CAL	NaCl #xxx	nearexo	
2 × TC RF L2       RF (R811)       AT AC. CONCL.         2 × TC RF L2       RF (R811)       AT AC. CONCL.       CAL.       TC RF L2 SH45S1       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       CAL.       TC RF L2 SH45S1       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       CAL.       TC RF L2 SH45S1       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       CAL.       TC RF L4 SH45S2       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       CAL.       TC RF L4 SH45S2       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       CAL.       TC RF L4 SH45S3       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       RF (R811)       AT AC. CONCL.       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.       RF (R811)       AT AC. CONCL.       expired         2 × TC RF L3       RF (R811)       AT AC. CONCL.			RF (R811)	R1" FAIL CANCEL		62	CAL	TC RF L1 #14560	expired	
2×TC BF L3       BF (R811)       BF (R811) <td></td> <td></td> <td>RF (R811)</td> <td>R1" FAIL CANCEL</td> <td></td> <td>03</td> <td>CAL</td> <td>TC RF L2 #14561</td> <td>expired</td> <td></td>			RF (R811)	R1" FAIL CANCEL		03	CAL	TC RF L2 #14561	expired	
2xTCRFL3       RF (R811)       RF 40, 0000000       CAL       TC RFL3#14563       expired         2xTCRFL3       RF (R811)       RF 40, 000000       RT 40, 000000       CAL       TC RFL3#14563       expired         2xTCRFL3       RF2 (R816)       RF 40, 000000       RT 40, 000000       RT 40, 000000       expired       expired         2xTCRFL3       RF2 (R816)       RF 40, 000000       RT 40, 000000       RT 40, 000000       expired         2xTCRFL3       RF2 (R816)       RF 40, 000000       RT 40, 200000       expired       0000000         2xTCRFL3       RF2 (R816)       RF 40000000000       RT 40, 200000       expired       000000000         2xTCRFL3       RF2 (R816)       RF 4000000000000000000000000000000000000			RF (R811)	R1* FAIL CANCEL		04	CAL	TC RF L3 #14562	expired	
2 × TOPL LS       PF (P811)       AT PLONGE.         2 × TOPL LS       PR2 (P816)       AT PLONGE.       expired         2 × TOPL LS       PR2 (P816)       AT PLONGE.       expired         2 × TOPL LS       PR2 (P816)       AT PLONGE.       PR2 (P816)         2 × TOPL LS       PR2 (P816)       AT PLONGE.       PR2 (P816)         2 × TOPL LS       PR2 (P816)       AT PLONGE.       PR2 (P816)         2 × TOPL LS       PR2 (P816)       AT PLONGE.       PR2 (P816)         2 × TOPL LS       PR2 (P816)       AT PLONGE.       PAT 39639635         2 × TOPL LS       PR2 (P816)       AT PLONGE.       PAT 39639635         CTL       TO VALIDATED       PR4 1 39639635       PAT 39639635         CTL       Zx TOLED P       PR4 1 99639635       PAT 39639635         CTL       Zx TOLED P       PAT 36721383       MALBs (P820)         PAT 36721383       MALBs (P820)       PAT 36721383       MALBs (P820)         Zx       MALBs (P820)       PAT 36721383       MALBs (P820)         Zx       MALBs (P820)       TO LAUNCH       PAT 36721383       MALBs (P820)         Zx       MALBs (P820)       TO LAUNCH       PAT 36721383       MALBs (P820)         Zx <td< td=""><td></td><td>2 x TC RF L4</td><td>RF (R811)</td><td>R1* FAIL CANCEL</td><td></td><td>05</td><td>CAL</td><td>TC RF L4 #14563</td><td>expired</td><td></td></td<>		2 x TC RF L4	RF (R811)	R1* FAIL CANCEL		05	CAL	TC RF L4 #14563	expired	
2 × Noci       RF2 (R816)       RF2 (R817)       RF2 (R816)       RF2 (R816)       RF2 (R817)       RF2 (R817)       RF2 (R817)       RF2 (R817)       RF2 (R816)       RF2 (R817)       RF2 (R817)       RF2 (R816)       RF2 (R817)       RF2 (R816)       RF2 (R816) <td></td> <td>2 x TC RFLS</td> <td>RF (R811)</td> <td>R1* FAIL CANCEL</td> <td></td> <td>96</td> <td>CAL</td> <td>TC RF L5 #14564</td> <td>expired</td> <td></td>		2 x TC RFLS	RF (R811)	R1* FAIL CANCEL		96	CAL	TC RF L5 #14564	expired	
2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         2 × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         CTL       S × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         CTL       S × T0 #P Lis       RF2 (R816)       ATTAL CANDEL         CTL       S × T0 #Lis P (R811)       RF2 (R816)       ATTAL CANDEL         CTL       Z × T0 Lab P (R806)       TO LAUNCH       TO LAUNCH         2 ×       MALBs (R820)       TO LAUNCH       TO LAUNCH         2 ×       MALBs (R820)       TO LAUNCH       Statistic S × S			RF2 (R816)	R11 FAIL CANCEL		07	C71	TL Protein L1 #12577		
2 × TO BP L2       PF2 (R86)       AT FAC LONGE.         2 × TO BP L3       PF2 (R86)       AT FAC LONGE.         2 × TO BP L4       PF2 (R86)       AT FAC LONGE.         2 × TO BP L4       RF2 (R86)       AT FAC LONGE.         2 × TO BP L4       RF2 (R86)       AT FAC LONGE.         2 × TO BP L4       RF2 (R86)       AT FAC LONGE.         2 × TO L8P L4       RF2 (R86)       AT FAC LONGE.         2 × TO L8P L4       RF2 (R86)       AT FAC LONGE.         CTL       S × TL Protein L1       RF (R811)         MALE POWEN L1       RF2 (R86)       VALIDATED         O'C       CHE (R806)       TO LAUNCH         TO VALIDATED       O'C         PAT       94310413       VALIDATED         O'S       MALBS (R820)       O'C         PAT       39639635       TO LAUNCH         2 ×       MALBS (R820)       O'C         PAT       95772879       TO LAUNCH         0 S       RF2 (R816) #90077       TO LAUNCH         0 S       RF2 (R816) #90077       TO LAUNCH         0 AT       35772879       TO LAUNCH         2 x       MALBs (R820)       TO LAUNCH         2 x       MALBs (R820)       TO LAU		2 x TC RF L1	RF2 (R816)	R1" FAIL CANCEL		08	CTL	TruLab P #14007	expired	
2 × TC RF-L3       RF2 (R816)       RF1 MAL CANCEL         2 × TC RF-L3       RF2 (R816)       RF1 MAL CANCEL         2 × TC RF-L3       RF2 (R816)       RF1 MAL CANCEL         2 × TC RF-L3       RF2 (R816)       RF1 MAL CANCEL         CTL       TO VALIDATE       Novel, Construction         CTL       2 × TruLab P       CHE (R806)         VALIDATED       %         PAT       39639635         2 ×       MALBs (R820)         X       MALBs (R820)         Y       TO LAUNCH         Y       MALBs (R820)         Y       TO LAUN			RF2 (R816)	R1* FAIL CANCEL		09	PAT	94310413		
2 × TC RF L4       RF2 (R816)       RF #AL-GNGEL         2 × TC RF L5       RF2 (R816)       RF #AL-GNGEL         CTL       S × TL Protein L1       RF (R811)       RMSL FOUREL         S × TL Protein L1       RF2 (R816)       RF2 (R816)       RFS AND GNGEL         CTL       S × TL Protein L1       RF2 (R816)       RFS (R810, MALE FOUREL       RMSL FOUREL         CTL       2 × TruLab P       CHE (R806)       Of       Of         CTL       2 × TruLab P       CHE (R806)       TO LAUNCH       TO LAUNCH         PAT       36721383       MALBs (R820)       Of         PAT       39639535       MALBs (R820)       TO LAUNCH         TO LAUNCH       TO LAUNCH       TO LAUNCH       3371         2 ×       MALBs (R820)       TO LAUNCH       396         2 ×       MALBs (R820)       TO LAUNCH       396         3 11			RF2 (R816)	R1" FAIL CANCEL		10	PAT	39639635		
2 × TO: RFL5       RF2 (R816)       RF (R811)         S x TL Protein L1       RF (R811)       RAVE ROWERL CANCEL         S x TL Protein L1       RF2 (R816)       RAVE ROWERL CANCEL         CTL       VALIDATED         CTL       VALIDATED         CTL       VALIDATED         CTL       VALIDATED         CTL       VALIDATED         CTL       VALIDATED         PAT       94310413         CN       MALBs (R820)         PAT       36721383         CX X       MALBs (R820)         PAT       36396355         ZX       MALBs (R820)         PAT       55772879         MALBs (R920)       TO LAUNCH         TO LAUNCH       TO LAUNCH         ZX       MALBs (R920)         Last known status : Wwind calibration       Wwind control		2 x TO REL4	RF2 (R816)	R11 FAIL CANCEL		11	PAT	55772879		
CTL       S × TL Protein L1       RF (R811)       AMOL ROUTAL CANCEL         MADE ROUTAL CANCEL       VALIDATED       OF         CTL       2 × TruLab P       CHE (R806)       OF         CTL       2 × TruLab P       CHE (R806)       OF         PAT       24310413       VALIDATED         2 ×       MALBs (R820)       OF         PAT       36721383       VALIDATED         2 ×       MALBs (R820)       OF         PAT       39639635       TO LAUNCH         2 ×       MALBs (R820)       OF         PAT       355772879       TO LAUNCH         2 ×       MALBs (R820)       TO LAUNCH         3 ×       TO LAUNCH       TO LAUNCH         3 ×       MALBs (R820)       TO LAUNCH         3 ×       MALBs (R820)       TO LAUNCH <td></td> <td></td> <td>RF2 (R816)</td> <td>R1* FAIL CANCEL</td> <td></td> <td>12</td> <td></td> <td></td> <td></td> <td></td>			RF2 (R816)	R1* FAIL CANCEL		12				
5 x TL Protein L1 5 x TL Protein L1 5 x TL Protein L1 7 x TruLab P       RF (R811) RF2 (R816)       RW06, FOM FALL ANDEL WALLDATED         CTL 2 x TruLab P       CHE (R806)       TO LAUNCH VALIDATED         PAT       94310413 2 x       VALIDATED         Ave:       MALBs (R820)       V         PAT       36721383 2 x       VALIDATED         PAT       36539635 2 x       VALIDATED         PAT       355772879 2 x       TO LAUNCH To UMADERT GR         PAT       557772879 2 x       TO LAUNCH To UMADERT GR         PAT       557772879 2 x       TO LAUNCH To UMADERT GR         PAT       557772879 2 x       TO LAUNCH To UMADERT GR         Last known status : XXX: Invalid calibration       XXX: Invalid control	CTL			TO VALIDATE		13				
S x TL Protein L1       RF2 (R816)       RAVEL ROWINGL CANCEL         CTL       VALIDATED         CTL       TO LAUNCH         PAT       94310413       VALIDATED         PAT       36721383       VALIDATED         2x       MALBS (R820)       OK         PAT       39639635       TO LAUNCH         2x       MALBS (R820)       OK         PAT       39639635       TO LAUNCH         2x       MALBS (R820)       OK         PAT       55772879       TO LAUNCH         2x       MALBS (R820)       TO LAUNCH         131       TO LAUNCH       TO LAUNCH         14       TO LAUNCH       TO LAUNCH         15 <t< td=""><td></td><td></td><td>RF (R811)</td><td>RANGL FOAM FAIL CANCEL</td><td></td><td>14</td><td></td><td></td><td></td><td></td></t<>			RF (R811)	RANGL FOAM FAIL CANCEL		14				
CTL       VALIDATED         2x TruLab N       CHE (R806)         TO LAUNCH       TO LAUNCH         PAT       94310413         VALIDATED       VALIDATED         PAT       36721383         VALBS (R820)       VALIDATED         PAT       39639635         Zx       MALBS (R820)         PAT       39639635         Zx       MALBS (R820)         PAT       355772879         TO LAUNCH       TO LAUNCH         Zx       MALBS (R820)         Last known status (WW Invalid calibration         WW Invalid calibration       WW Invalid control         Automatic Selection Selection       Select		5 x TL Protein L1	RF2 (R816)	RANGL FOAM FAIL CANCEL		15				
2 x TruLab N       CHE (R806)       CM         CTL       TO LAUNCH       TO LAUNCH         PAT       9310413       VALIDATED         PAT       36721383       VALIDATED         2.x       MALBs (R820)       CM         PAT       39639635       MALBs (R820)         PAT       39539635       TO LAUNCH         2.x       MALBs (R820)       TO LAUNCH         To JAUNCH       TO LAUNCH       Second         2.x       MALBs (R820)       TO LAUNCH         1.1       To LAUNCH       Select C         06       To LAUNCH       Select C         11       11       12         12       13       14	ст∟			VALIDATED		17				Л
CTL       TO LAUNCH         2 x TruLab P       CHE (R806)       To LAUNCH         PAT       94310413       VALIDATED         2 x       MALBs (R820)       %         PAT       36721383       VALIDATED         2 x       MALBs (R820)       %         PAT       39639635       TO LAUNCH         2 x       MALBs (R820)       %         PAT       39639635       TO LAUNCH         2 x       MALBs (R820)       TO LAUNCH         70 - MARK(100)       TO LAUNCH       89         2 x       MALBs (R820)       TO LAUNCH         3 11       11       12         12       13       14		2 x TruLab N	CHE (R806)	OK .		1 12				$\mathbf{\nabla}$
2 x TruLab P       CHE (R806)       TO JUNICH         PAI       94310413       VALIDATED         PAT       36721383       VALIDATED         2 x       MALBs (R820)       VALIDATED         PAT       3563535       TO LAUNCH         2 x       MALBs (R820)       OK         PAT       355772879       TO LAUNCH         2 x       MALBs (R820)       TO LAUNCH         11       12       13         12       13       14	CTL			TO LAUNCH		Reagen	it Tray			
PAT       94310413       VALIDATED         PAT       36721383       MALBs (R20)         PAT       36721383       VALIDATED         2.x       MALBs (R20)       %         PAT       39639635       TO LAUNCH         2.x       MALBs (R20)       %         PAT       55772879       TO LAUNCH         2.x       MALBs (R820)       #33076         3.33076       Wastable       89         0.1       To JAUNCH       11         12       13       14		2 x TruLab P	CHE (R806)	TO LAUNCH		Pas	Name	Evo	Lova	
PAT       36721383       VALIDATED         2x       MALBS (R820)       ox         PAT       39639635       TO LAUNCH         2x       MALBS (R820)       TO LAUNCH         11       12       13         12       13       14	PAT	94310413		VALIDATED		103	DE (DOA	4) #22044	Leve	<u>"</u> 'J'
PAT       36721383       VALIDATED       02       HEMIOAGENT (nemo K801)       Near exp.       70 miss         PAT       39639635       TO LAUNCH       03       RF2 (R816) #90077       94       CHE (R806) #12177       95         PAT       2x       MALBs (R820)       TO LAUNCH       TO LAUNCH       96       06       07       06       07       06       07       08       09       10       11       12       13       14       14       11       12       13       14 <td></td> <td>2 x</td> <td>MALBs (R820)</td> <td>OK.</td> <td></td> <td>101</td> <td>RF (ROT</td> <td>1) #33641</td> <td>70</td> <td>4</td>		2 x	MALBs (R820)	OK.		101	RF (ROT	1) #33641	70	4
2 x       MALBs (R820)       6x       Malbs (R820)	PAT	36721383		VALIDATED		02		16) #00077	exp 701	
PAT     39639635     TO LAUNCH       2x     MALBs (R820)       PAT     55772879       MALBs (R820)     To LAUNCH       To LAUNCH     To LAUNCH       To LAUNCH     06       07     MALBs (R820)       Walket     3076       08     09       11     12       12     13       14     14		2 x	MALBs (R820)	ox		0.3	CHE (DO	10) #90077	THE	5
2x         MALBs (R820)         To LAUNCH           2x         MALBs (R820)         To LAUNCH           2x         MALBs (R820)         To LAUNCH           Last known status : XXXX Invalid calibration         XXXX Invalid calibration         XXXX           Automatic Selection IN         Select IN         Image: Control	PAT	39639635		TO LAUNCH		04		(D920) #22076	31	
PAT       55772879       TO LAUNCH         2.x       MALBS (R820)       TO UNDERFOR         Underform       07         08       09         11       12         12       13         14       14         Colspan="2">Colspan="2"         Colspan="2"		<u>2 x</u>	MALBs (R820)	TO LAUNCH (1 OK)		05	WALDS	(R620) #33076		19
2x       MALBs (R820)       To LAudor (100)         Last known status:       Image: Control in the status in the s	PAT	55772879		TO LAUNCH		07				
Last known status : XXX Invalid calibration XXX Invalid control  Automatic Selection		<u>2 x</u>	MALBs (R820)	TO LAUNCH (1 OK)		02				
Last known status : XXXX Invalid calibration XXXX Invalid control  Automatic Selection						00				
Last known status : XXXX Invalid calibration XXXX Invalid control  Automatic Selection						10				
Last known status : XXX Invalid calibration XXX Invalid control  Automatic Selection						11				
Last known status : XXX Invalid calibration XXX Invalid control Automatic Selection X Select X Required curve						12				
Last known status : XXX Invalid calibration XXX Invalid control					Д	13				
Last known status : XXXX Invalid calibration     XXXX Invalid calibration       Automatic Selection INVAL     Select INVAL						14				Л
Automatic Selection	L	ast known status : >>>>> Inv	alid calibration	Malid control				5.0		
Required cuve		Automa	tic Selection F	N Sel	ect		1	nselect All	= 2 2	
		/ aconia		w Ock			W-O		Required o	uvette

All daily jobs (patients, controls and calibrations) are executed via the work list.

The screen is divided into three windows: "**Tests**" (left), "**Sample Tray**" (upper right) and "**Reagent Tray**" (lower right). It shows at a glance the different prescriptions and their respective status.

The "**Tests**" window shows the entries of the work list. The entries highlighted in blue are loaded (or selected), which means that they are ready to be performed. This window is divided into four columns:

- "Type": Can be an animal sample (PAT), a control (CTL), a calibrator (CAL) or an emergency animal sample (PAT-ER, not visible on the picture).
- "ID": Shows the barcode number (or an automatically allocated prescription number if there is no barcode number) for PAT or PAT-ER or the name of the control or calibrator for CTL and CAL.
- "Method": Shows the methods to run for each prescription. The ones written in red or blue are not calibrated or not controlled, according to the legend displayed at the bottom of the window.
- "Status":
  - "TO LAUNCH": This entry has been scheduled but has not been run.
  - "**RUNNING**" (not visible on the picture): This entry is currently running.
  - "TO VALIDATE": This entry has been finished with errors or has been partially finished.
  - "VALIDATED": This entry has been run and results are available.

The "**Sample Tray**" window shows the samples (PAT, CTL, CAL or PAT-ER, not visible on the picture) related to the loaded prescriptions. This window is divided into four columns:

- "Pos" for position: Shows where the sample tubes are supposed to be placed on the tray. It goes from 01 to 30. There also are two lines on the top of the list for the STAT1 and STAT2 positions (not visible on the picture). Clicking on the up or bottom arrow on the right of the window will move the selected sample to the next available position. A color code provides information about the test status: green for conducted tests, red for failed tests and white for tests to run.
- "Type": PAT, CTL, CAL or PAT-ER (not visible on the picture).

- "Reference": Gives the sample barcode number (for PAT and PAT-ER) or the name of the control or calibrator (for CTL and CAL).
- "Exp" for expiration: Shows the controls and calibrators which are expired or nearly expired (less than one month left). This column is empty on the picture.

The up and down arrows on the right of the window can be used to move the selected sample to the next position available.



# The emergency analyses (PAT-ER) can be moved from a STAT position to another position but the reverse is not possible.

The "**Reagent Tray**" window shows the status of the solutions (reagents, diluents, hemolysis agents or cleaners) of the loaded tray as known at the end of the last run. If no specific tray has been loaded (see "L.III Tray configuration" page 148), one will be automatically generated, depending on the tests to run. The name of the current tray is displayed above the "**Sample Tray**" window. The "**Reagent Tray**" window is divided into four columns:

- "Pos" for position: Shows where the bottles are supposed to be placed on the tray. It goes from 01 to 30. Clicking on the up or bottom arrow on the right of the window will move the selected solution to the next available position (only if there is no predefined tray loaded).
- "Name": Gives the name of each solution and its unique internal reference. For the reagents, the name is the same as the related method.
- "Exp" for expiration: Shows the solutions which are expired (red), nearly expired (yellow) and the unstable reagents, which means the reagents open for a too long time and whose on-board stability has expired (red as well).
- "Fill": Shows the filling level for each solution and the estimated number of tests that can be performed before the bottle is empty. If the filling bar is green there is enough liquid in the bottle. If it is orange there is less liquid than the warning level (further details about the warning level in "L.III Tray configuration" page 148) and if it is red the bottle is empty and no test can be performed.

The up and down arrows on the right of the window can be used to move the selected bottle to the next position available.

Some other buttons allow the management of the work list:

- "Automatic Selection": Loads as much tests as possible. However, when a test cannot be properly performed (e.g. due to a solution not being on the tray, a method not calibrated and/or controlled, etc...) the related entry cannot be selected using this button.
- "Select": Loads an entry.
- "Unselect All": Unloads all the previously selected entries.
- "Left arrow" button: Allows unloading the prescriptions one by one.
- "Bin" button: Empties both the sample and the reagent trays.

The number of fresh cuvettes required to perform the selected tests is displayed on the bottom right of the screen.

There also are a couple of additional buttons in the function bar:

- "Exit": Goes back to the main screen.
- "Delete": Removes the selected entries from the work list screen. The entries already loaded in the sample tray cannot be removed with this button. They must be unloaded first.
- "Modify": Allows the modification of an entry. This automatically removes the entry from the sample tray and opens the respective prescription screen.
- "Results": Shows the results for an entry (if available).
- "Clean work list": Removes the validated entries from the work list.
- "Scan & run" (greyed if the barcode reader is disabled for the samples and/or the reagents): Scans all the barcodes and automatically generates the tray.
- "Select tray" (greyed if the barcode reader is enabled for the reagents): Allows changing the tray.
- "Run": Starts the run process for the selected entries.

#### I.II.2. Run sequence

#### I.II.2.a. Tray confirmation

#### From "Main Screen" => "Work List" => "Run"

Adr	ninistrator>	- TOP MENU BA	R : W	ORKL	IST:	RUN -		
Pos	. Name	Bottle type		Pos.	Type	Sample ref		Tube type
1	NaCl (dil R800)	Diluent						
2	FE (R042)	Large twin container						
				1	CAL	NaCl #xxx		5-10 mL tube
4	HEMOAGENT (hemo R801)	Hemolysis agent		2	CAL	TC RF L1 #14560		5-10 mL tub
5	CK-MB (R030)	Small Twin container		3	CAL	TC RF L2 #14561		5-10 mL tube
				4	CAL	TC RF L3 #14562		1.5 mL cup
7	Natrium 3 (R805)	Monocontainer		5	CAL	TC RF L4 #14563		5-10 mL tube
				6	CAL	TC RF L5 #14564		5-10 mL tube
9	CHEtzt (Rtzt)	Small Twin container		7	CTL	TL Protein L1 #12577		5-10 mL tube
				8	CTL	TruLab P #14007		5-10 mL tube
	1			9	PAT	33590672		5-10 mL tube
				10	PAT	19606645		5-10 mL tube
				11	PAT	56429702		5-10 mL tube
14	Natrium 4 (R809)	Monocontainer						
15	GLUC HK (R)	Small Twin container						
16	DBIL (R018)	Small Twin container						
17	HCO3 (R017)	Monocontainer						
18	TRIG (R052)	Monocontainer						
19	CHOL (R024)	Monocontainer						
	1							
	1							
22	CLNA (cln R900)	Cleaner						
	1		V		3			
Ge	nerated tray				17 c	uvettes required	2 se	gments
	BACK						PRINT	PUN

This screen is divided into two windows: reagents (left) and samples (right).

The reagent window is a summary of the previous "**Reagent Tray**" window. It lists the position, the name and the bottle type of the solutions on the tray. The reagents can be stored in mono-containers, small twin-containers or large twin-containers, depending on the analytical method. The diluents, hemolysis agents and cleaners are stored in mono-containers. The name of the current tray is displayed below the window.

The sample window is a summary of the previous "**Sample Tray**" window. It lists the position, the type (PAT, CTL, CAL or PAT-ER, not visible on the picture) and the reference (barcode number or name of the control or calibrator) of the samples on the tray. The last column shows the type of sample container to use. It can be a 1.5 or 2.5 mL cup or a tube (5 or 10 mL). Unlike the solution bottle type, the sample container type can be modified by using the drop-down list.



When the barcode reader is enabled for reagents, the reagent window is empty. A summary of the bottle positions is displayed after the barcode scan (see "I.II.2.e Barcode confirmation" page 80).

The number of fresh cuvettes required to perform the run is reminded, as well as the respective number of cuvette segments.

Additional buttons in the function bar are:

- "Back": Goes back to the previous screen.
- "**Print**": Prints the tray configuration.
- "Run": Goes to the next step.

The launch process follows the subsequent rules:

- Calibrations are always processed first, then controls, then animals.
- Controls are processed after the related calibrations and only if these are good.
- Animals are processed after the related controls and only if these are good.

Some of these rules can be changed (see "N.II Analysis" page 172) in order to start the controls before getting the related calibration results or to start the animals before getting the related control results.

#### I.II.2.b. Operation confirmation

After the confirmation of the tray settings another screen is displayed. It lists the points that need to be checked and the bottles that will need to be replaced soon before the run can start.

From "Main Screen" => "Work List" => "Run" => "Run"

Before starting the run:         ?       Set the bottles         ?       Set the samples         ?       Check that 15 clean cuvette(s) (1 segment(s)) are available         Fill the water tank       Wait for the temperature to be stabilized (at the moment : (null) deg.)         Wait for the light to be stabilized       Close the dome
3:RF2 (R816) #90077
If you don't want to run now, press <cancel>. When you are ready, select an option below for clean cuvettes management, and press <ok>.</ok></cancel>
<ul> <li>I replaced some segments with clean ones         Used segments : S1,S2,S4,S5         Replaced segments : None</li> <li>I continue with the current used segments</li> </ul>
OK Cancel

Green squares mean that everything is fine and red ones (not visible on the picture) mean that it is not. For the temperature and the light stabilization, the only thing to do is to wait.

#### I.II.2.c. Cuvettes replacement

Before launching the tests a special attention must be paid to the cuvettes management. If all the segments of cuvettes are clean, it is displayed on the screen (not visible on the picture) and there is nothing more to do.

But depending on the situation, the operator is asked to choose between replacing used segments or continuing with the currently used segments. That means the dispensing will begin in the first clean cuvette.

When checking the option "I replaced some segments with clean ones", a screen appears. It allows informing the software about the segments that have been replaced.

From "Main Screen" => "Work List" => "Run" => "Run" => replace segments option. Or from "Main Screen" => "Replace Segments"



There is no need to replace all the segments at the same time. Click on the replaced ones. The related square must then switch from red, white or grey to green and the software will consider the replacement. Note that a segment is displayed in red if there is at least one used cuvette.

When everything is done, click on **"Ok"** to go back to the previous screen, then "**Ok**" again to launch the tests.



The cuvettes are for single-use only. It is not foreseen to re-use cuvettes under any circumstance to guarantee reliable patient results.

#### I.II.2.d. System verifications

At the very beginning of the run, the system internally checks a couple of points:

- Communication with the PC.
- Closure of the dome.
- Locking of the dome.
- Incubator temperature.
- Lamp stability.
- Scanning of tubes and reagents barcodes.

If any test fails, the run is aborted.

#### I.II.2.e. Barcode confirmation

At the end of the barcode scan, the barcode confirmation window appears (if the barcode reader is enabled).

Reagent Tray Bottles detected : 8 including manual entries : 5	Sample Tray Tubes detected : 13
More >>>	Extensive Scan OK Cancel

When pressing "More >>>", the window extends as follows:

	Bottles de including man	etected : 8 ual entries : 5		Tube	es detected : 13	
Pos	Barcode	Comment	Pos	Barcode	Comment	
5 7 3 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 7 28 9 0	Manua Manua Manua Manua Manua 103422024496022304 103421093816049254 101021114102005225	GGT (R034) GGT (R034) ALT (010)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	18468615 30647959 19606645 56429702 67158449 41063764 54207278 03002784 02760520 92650567 ? ?	Cup Cup Cup	
٩	Aerge with a preselecte	d tray Tray	2			

This screen is a summary of the position of the reagents, solutions and samples after the barcode scan and is divided into two parts.

The "**Bottles**" window (displayed only if the barcode reader is enabled for reagents) shows the position of the reagents, diluents, hemolysis agents and cleaners with their barcode (if any) and name. If a tray has been generated prior to the run (when the prescriptions are selected, a reagent tray is automatically created), the related bottles that have not been detected by the barcode reader are shown as manual. The drop down menu below the window lists all the tray setup on the analyzer and allows the merging of the barcode scan results with an existing tray.



# A bottle whose the barcode has been read always overwrites bottles from a loaded tray and cannot be replaced during a merging.

The "**Samples & Controls**" window shows the position of the samples and controls with their barcode and name. A barcode displayed as a "?" means that an adaptor for 1.5 or 2.5 mL cup has been detected. The unknown barcodes are those for which there is no prescription related to the tube.

For both parts, a click on the barcode number selects the related entry and allows its modification. When everything is ready, press "**Ok**" to start the analysis or "**Cancel**" to go back to the work list screen. The "**Extensive Scan**" button can be used for an extra reading of a given barcode.

If the option is activated (see N.IV Barcode Reader page 175) and if there is nothing wrong with the barcodes, the confirmation screen is automatically closed after 12 seconds. However, it is highly recommended to have an operator checking the positions read by the barcode reader to avoid errors.

#### I.II.2.f. Calibration and control verifications

Calibration and control status are automatically checked before the run can start. In case of failure (bad calibration data, expired calibration, control rules not filled...) a list appears on the screen. If the problem concerns a method ordered in a prescription to run, the run has to be cancelled. If it concerns other methods, the run can continue but the mentioned methods will not be available for emergency analysis (see I.III "Emergency Entry" page 83).

Calibration stability and/or control status checking can be enabled/disabled in the software options (see "N.II Analysis" page 172).

#### I.II.3. Sample barcode restrictions

The following limitations are imposed on the sample barcode identification:

- Maximum bar code length is 25 characters.
- Maximum number of consecutive digits is 17.
- No occurrence of the sequences ".%", ".\$ ", or "\$%" in the code.
- No bar code starting by "{\*}" or "{\$}".

Any barcode that does not meet the above mentioned requirements will be ignored by the software.

#### I.II.4. Bidirectionnal interface

When a run is launched with the LIS sending a prescription, a pop-up message is displayed and the prescription list is updated (see "R Bidirectional interface" page 213 for more details).

### I.III. Emergency Entry

# From "Main Screen" => "Entries" => "Emergency entry"



<administrator> - TOP MENU B</administrator>	AR : EMERGENCY ENT	RY -		
Animal Registration ID AW 34160 Animal's name Delilah Owner's Last Name Baker Species Cat Age (y.o.) 45 Date of birth 19/05/1970	Sample Sample ID (Barcode) Type of container 5-10 mL tube 1.5 mL cup 2.5 mL cup	Sampling time (yyyy-mm-dd T hh:mm:ss) 20T Sample type Serum	Ordering Vet.	<u> </u>
Profiles	2	(	3	
Methods				
Please select a tray to change methods ordering <alphabetical order=""></alphabetical>	<u> </u>	Please type method shortcut, and	press <enter></enter>	•
ALB ALT AMY AP A diluted by 8 ALT AMY AP A CA CHE CHOL CK-MB	APOA1 APOB	ASO 1117 ASO 011 011 011 011 011	r C3c	C4 DDI
ETH FE FERR GGT G		HbA1c HC		
IGE K LACT LDH	LDL Lp(a)		Bu) MG	PALB
PAMY PO3 RF TBIL				
Keep the mouse button pressed on a method to select a predilutio	n	inform	ation	
Method         Method<	[Profile] Invalid profile		Required Cuvette	es: 6
EXIT: REPEAT PRESCRIPTION DELET	TE PROFILE SAVE PROFILE	CLEAR SELECTION	REQUEST HOST	RUN on STAT

This screen is similar to the "Routine entry" screen, although some changes can be seen in the function bar:

- "Request host" (greyed if no connection to the host is setup): Sends a request to the host to find the animal prescription related to the input barcode (see "R.II.3 Emergency entry" page 215 for further information).
- "Run on STAT" (equivalent of "Add to work list" in the "Routine entry" screen): Integrates the samples in the running list.



The STAT positions are labelled ST1 and ST2. Ensure that each sample is placed on the position requested by the software.



Only methods with a valid calibration and control status and whose bottles are already on the tray can be selected as emergency entries. Such samples are processed with a higher priority than those which have already been launched through the work list.

After up to two STAT samples are loaded, the drawer is locked either until the STAT samples are pipetted, or until the whole STAT prescription is done (to setup this option, see "N.II Analysis" page 172). In both cases, the next emergency prescription could be ordered only once the results will be available for the STAT samples already in process.

# I.IV. Analysis results

#### I.IV.1. Result search

From "Main Screen" => "Results" => "Analysis results"



										(	4
<administrator></administrator>		-	TOP MEI	NU BAR : ANA	LYS	SIS RESULTS	5-		10000		
			Samp	le ID Owne	er's l	Last Name / Ar	nimal's Na	me	Date	Status	
To Launc	h		3691	5618 Jor Dog	nas	23/04/2006	Skipp 5138	y 6 G258 P0Y6C	2011-09-09 T11:17:06	TO VALIDATE	1
Running	te		92832	2588 Mill Cat	ler	11/07/1993	Wamb	a O38N E	2011-07-20 T11:33:20	VALIDATED	
Validated			23276	5941					2011-07-20 T11:33:09	VALIDATED	
Animal Sample		-1	52260	0301					2011-07-20 T11:33:04	VALIDATED	
Registration			10333	3309					2011-07-20 T11:32:58	VALIDATED	
Animal's nar	me		0309	1733					2011-07-20 T11:32:52	VALIDATED	
Owner's Last Nar	me		66770	0425 Pitt		09/01/1987	Faïka	E1W1 FFVS	2011-07-20 T11:32:45	VALIDATED	
Creation Da	ite	Ţ	55772	2879 Fitz	Pa	trick 03/05/2011	Tiggy	885 A26Y QF	2011-07-20 T11:32:00	TO VALIDATE	_
To 201	15-04-30		39639	9635 Sm Cat	ith	02/09/1992	Wamb 40k	a (J 2N2T BA	2011-07-20 T11:31:56	TO VALIDATE	
	(11 found)		3672	1383			111	1	2011-07-20 T09:39:07	TO VALIDATE	
CI	lear Filters		94310	0413					2011-07-20 T09:38:57	TO VALIDATE	
										·	
<u>s</u>	View Tests										
											ŗ
EXIT	DELETE ALL	BIDIR	2	RECALCULATE ALL		EXPORTALL	PRIN	IT ALL	VIEW TESTS	DELETE	

This screen shows all the analysis results. The files can be sorted using different options.

#### I.IV.1.a. Filtering by status

The different sorting options for the animal file status are:

- "To Launch": Ordered tests that have not been launched yet.
- "Running": Tests that are currently processed.
- "To Validate": Tests that have been partially finished or finished with errors avoiding the automatic validation (e.g. due to bubbles, missing reagent, etc...). Manual validation can be required.
- "Validated": Tests that are completed and whose results have been automatically or manually validated.

Filtering by status is also possible for calibration and control results and works exactly the same way.



A status "To Validate" or "Validated" does not mean that the result is pathological or normal. It only warns that something unusual occurred during the run.

#### I.IV.1.b. Filtering by animal details

It is possible to filter the results by typing the "Sample ID", the "Registration ID", the "Animal's name" or the "Owner's Last Name"

#### I.IV.1.c. Filtering by prescription date

It is possible to filter the results by selecting a range of dates.

Filtering by prescription date is also possible for calibration and control results and works exactly the same way.

#### I.IV.1.d. Other actions

A click on "**Clear filters**" clears the search criteria and displays all results. A click on "**View tests**" displays detailed results for the selected entry. Also works when pressing the button in the function bar and when double-clicking on the selected line.

It is possible to select several entries at a time by pressing the "shift" key while clicking on the related tests.

On the function bar there are eight more buttons:

- "Exit": Goes back to the main screen.
- "Delete all": Deletes all displayed results (confirmation requested).
- "BIDIR" (greyed if no connection to the host is setup): Sends the results to the server.
- "Recalculate all": Recalculates all the displayed results according to the most recent calibration data. This tool is only working between identical reagent lots.
- "Export all": Exports the details of all the displayed results in a text file.
- "Print All": Prints all the displayed results.
- "View tests": Same as the "View tests" button mentioned above.
- "Delete": Deletes the selected entry (confirmation requested).



The results of currently running prescriptions cannot be deleted. The run must be completed first.



The validation of the results must be done by trained professionals having the knowledge to interpret the values output by the analyzer. If any doubt, see "P Troubleshooting" page 199.

#### I.IV.2. Result view

Sample ID (barcodo)		Name	11434	
92832588		Miller War	iba	
Registration ID				
O38N B		Ordering Vet.		
Sampling date				
Test	Pre-Dil	Result Units		Status Sel.
MALBu	1	0.54 mg/L	ок	Run on :2014-07-10T03:35:07
MALBu	1	0.60 mg/L	ок	Run on :2014-02-15T21:47:39
MALBu	1	0.15 mg/L	ок	Run on :2014-04-13T14:40:10
MALBu	1	0.51 mg/L	ок	Run on :2015-01-23T07:16:55 Total calibration on 2015-01-20T05:04:54
MALBu	1	0.51 mg/L	ок	Run on :2015-04-05T18:37:14 Total calibration on 2015-04-02T16:25:13
Niew Detai	ils		😭 Delete resu	lt 📩 Edit Result

From "Main Screen" => "Results" => "Analysis results" => "View Tests"

This screen shows the detailed results for the selected prescription.

On the top of the screen, information about the animal and the sample is shown.

The "**Test**" column shows the methods that have been run. The "**Pre-Dil**" (for "**Pre-dilution**") column shows the specific dilution requested in the entry screen (1 is displayed in no specific dilution occurred). The "**Status**" column displays flags for each test (more details about the flags and their meaning in "Q.VI Analytical flags" page 211), the date and time of the test completion and the calibration data used to calculate the result. The yellow box allows the selection of the result to display on the printing if several are available for the same measurement (e.g. if a result has been manually edited the first value is still available).

There are several buttons either within the screen or on the function bar:

- "View Details": Displays the raw data for the selected test. Also works when doubleclicking on the selected line.
- "Delete result": Deletes the selected result (confirmation requested).
- "Edit Result": Allows the modification of the selected result. The new value must be set by the operator.
- "Back": Goes back to the previous screen.
- **"Export details**": Exports the details of the selected prescription in a text file.
- "Validate prescription" (greyed if the status of the prescription is already "Validated"): Validates the status of the prescription.
- "BIDIR" (greyed if no connection to the host is setup): Sends the results to the server.
- "Recalculate": Recalculates all the results of the prescription according to the most recent calibration data. This tool is only working between identical reagent lots.
- "Previous prescription": Goes back to the previous entry.
- "Next prescription": Goes to the following entry.
- "**Print**": Prints the results.

#### I.IV.3. Result edition

It is possible to manually edit a result after the tests have been performed on the analyzer. To edit a result, select the respective test and click on "Edit Result". The following window appears.

Enter the new value and click on "**Confirm**". A click on "**Cancel**" closes the window without changing anything.

All the modified results are flagged on the printout.

#### I.IV.4. Raw data

#### I.IV.4.a. Data

# From "Main Screen" => "Results" => "Analysis results" => "View Tests" => "View Details"

Reaction	cuv #60											
	340	380	405	450	480	508	546	570	600	660	700	800
CuvRef	0.10593	0.10445	0.09860	0.10604	0.10143	0.10106	0.10447	0.10416	0.09933	0.09927	0.09291	0.08907
Reagent	0.00505	0.00378	0.00315	0.00205	0.00141	0.00042	0.00052				-0.00048	-0.00035
	0.00638	0.00489	0.00415	0.00229	0.00218	0.00046	0.00141				0.00029	0.00062
Sample	0.00620	0.00448	0.00403	0.00220	0.00218	0.00076	0.00137				0.00075	0.00108
):12	0.00642	0.00485	0.00429	0.00248	0.00248	0.00066	0.00148				0.00061	0.00083
):24	0.00712	0.00522	0.00457	0.00260	0.00243		0.00161				0.00115	0.00124
0:36	0.00759	0.00565	0.00512	0.00323	0.00297	0.00152	0.00212				0.00138	0.00178
):48	0.00779	0.00590	0.00512	0.00347	0.00320	0.00152	0.00221				0.00148	0.00166
1:00	0.00751	0.00565	0.00492	0.00309	0.00290	0.00108	0.00184				88000.0	0.00114
1:12	0.00804	0.00604	0.00526	0.00326	0.00312	0.00133	0.00212				0.00119	0.00141
1:24	0.00830	0.00610	0.00542	0.00319	0.00301	0.00146	0.00208			0.00129	0.00130	0.00153
1:36	0.00859	0.00625	0.00540	0.00340	0.00312	0.00160	0.00221				0.00136	0.00162
1:48	0.00861	0.00625	0.00542	0.00338	0.00320	0.00162	0.00219			0.00139	0.00132	0.00160
2:00	0.00857	0.00631	0.00536	0.00344	0.00324	0.00150	0.00216			0.00129	0.00123	0.00141
2:12	0.00865	0.00639	0.00549	0.00330	0.00324	0.00137	0.00231				0.00117	0.00139
2:24	0.00879	0.00631	0.00555	0.00345	0.00320	0.00148	0.00219			0.00120	0.00123	0.00143
2:36	0.00885	0.00650	0.00563	0.00355	0.00324	0.00158	0.00223				0.00121	0.00139
2:48	0.00875	0.00648	0.00563	0.00332	0.00320	0.00156	0.00227			0.00131	0.00128	0.00141
3:00	0.00889	0.00639	0.00559	0.00345	0.00324	0.00150	0.00223				0.00126	0.00143
3:12	0.00892	0.00643	0.00542	0.00336	0.00316	0.00160	0.00218			0.00125	0.00121	0.00143
3:24	0.00877	0.00633	0.00551	0.00319	0.00305	0.00154	0.00210				0.00126	0.00143
3:36	0.00889	0.00637	0.00554	0.00328	0.00314	0.00152	0.00218			0.00125	0.00125	0.00137

This screen displays all data collected for each wavelength for the selected test. It is similar for analysis, calibration and control results.

On the bottom right of the screen there are three tabs:

- "Absorbances": Shows the absorbance values.
- "Measurements": Shows the signal values for the reaction cuvettes.
- "References": Shows the signal values for the reference cuvettes (water cuvettes).

Two more buttons are displayed in the function bar:

- "Back": Goes back to the previous screen.
- "Export results": Exports the details of the selected test in a text file.

#### I.IV.4.b. Graph

Clicking on the "**Graph**" tab on the bottom right corner of the raw data screen displays the following view.



This screen displays the previous data as a chart.

On the left of the screen, several buttons allow changing the scale (up and down arrows), zooming (reading glasses) and coming back to the initial view. A zoom can also be made by selecting a part of the chart with the mouse. The wavelength(s) to display can be filtered by clicking on the related buttons below the chart.

# J. Calibrations

<Admini

Calibr

# J.I. Calibrator configuration

#### From "Main Screen" => "Configuration" => "Calibrator configuration"

		Entr	ies		Method configurati	ion	
		Res	ults		Control configurati	on	
		Configu	uration		Calibrator configura	tion	
	*			r	Solution configurat	ion	
					Tray configuration	n	
					Operators configura	ition	
					Options		
strator>		- TOP MENU I	BAR : CALIBRAT	OR CONFIGURATI	ON -	<b>]</b>	<b>1</b> (N
ator				Calibrator I	Name: TC Protein L5		
P(a) L3	<del>ි බ</del>			Lot Refe	rence: 07596		
P(a) L4	<b>.</b>	Lot Expiration		Expiration	Date: 2015-08-28		
P(a) L5	<del>@</del>	07596 2016-05-09	This calibrat	or lot is usable			
otein L1		04576 2015-09-11	Method			Unit	Conc
otein L2	<b></b>	04881 2015-08-15	CHE			U/L	12
			MALDa			-11	CA 4000

TC LP(a) L3	<u>유</u> 산		Lot Re	ference: 07596	6		
TC LP(a) L4	6	Lot Expiration	Expirati	on Date: 2015	-08-28		Ŧ
TC LP(a) L5	9	07596 2016-05-09	This calibrator lot is usable				
TC Protein L1	<b>_</b>	04576 2015-09-11	Method		Unit	Conc.	
TC Protein L2	<del>Q</del>	04881 2015-08-15	CHE		U/L	12	Û
TC Protein L3	A	13865	MALBs		g/L	84.4000	
TC Protein L4	0	14759	PALB Prozone		mE	1.160	
TC Protein L 5		2015-11-02 41736	Palb 380nm		g/L	1.160	
	····	2015-01-30 01238	Transferin		mg/dL	746.0	_
TC RF L1		2015-05-03					
TC RF L2		2015-10-07					_
TC RF L3	9						
TC RF L4	9						
TC RF L5	9						-
TruCal U	•						
Ve Wasser	Ŷ	<del>₽</del>					오
EXIT	CALIBRATION	NEW CALIBRATOR	SET ACTIVE LOT	NEW LOT	DELETE LOT	MODIFY LC	т

This screen is divided into several parts.

The left part is a list of all the calibrators setup in the database. The ones with a padlock are those provided by DiaSys GmbH. When a calibrator is selected, related lot numbers and expiration dates appear in the next column. Red and yellow highlighting is used to warn the operator in case of expired or nearly expired (during the current month) lots. For the selected calibrator and lot, this information is also displayed in the top right part. A check box allows defining a lot as usable or not (unusable lots are greyed).

The right part shows the methods that are calibrated by the selected lot of calibrator and the related concentration. When in edition mode, all the useable methods setup on the analyzer are listed.

There are seven buttons on the function bar:

- "Exit": Goes back to the main screen.
- "Calibration": Allows access to the list of methods.
- "New calibrator": Creates a new calibrator.
- "Set active lot": Replaces all the calibration settings using the selected calibrator by the settings of the selected lot.
- "New lot": Duplicates the settings of the selected calibrator to setup a new lot.
- "Delete lot": Deletes the selected lot (confirmation requested).
- "Modify lot": Allows the edition of the selected calibrator. When clicking on this button, the screen switches to the edition mode. Only two buttons are then displayed: "Cancel" to leave the edition mode and go back to the view mode without changing anything (confirmation requested) and "Save" to save the calibrator.

To associate a method to a calibrator, the related concentration value must be entered. To remove it from the method list, the field must be empty.

The name, the lot reference and the expiration date of the selected calibrator can also be modified (the name cannot be edited for DiaSys calibrators though).

# J.II. List of methods

From "Main Screen" => "Configuration" => "Calibrator configuration" => "Calibration"

<administrator></administrator>	- T	OP MENU BAR :	CALIBRATION CO	NFIGURATION -		<u></u> •	<
Method Name		Reaction	Calibration Status	Calibration Type	Reagent Lot	Last calibration	
CHE		Linear kinetic	ok	Main point calibration		2014-01-21 T15:13:18	4
CHEtzt		Linear kinetic	ok	Total calibration		2014-09-14T08:04:40	
Chlorid 1		End point	not performed	not performed			
CHOL	•	End point	ok	Main point calibration		2015-09-07 T04:19:02	
CK-MB	9	Linear kinetic	on error	Total calibration			
CREA Jaffe	9	Linear kinetic	ok	Manual calibration		2014-01-18T05:33:02	
Crea PAP		End point	on error	Total calibration			
CRP	9	End point	not performed	not performed			
DBIL	9	End point	missing definition	missing definition			
FE	9	End point	ok	R2 Compensation		2015-06-03T03:26:05	
GGT	9	Linear kinetic	ok	Main point calibration		2015-04-20T04:30:20	
GLUC GOD	•	End point	ok	Total calibration		2015-04-20T00:33:08	
GLUC HK		End point	not performed	not performed			
HbA1c	9	End point	ok	Main point calibration		2014-06-06 T08:31:21	
HCO3	9	Fixed time kinetic	on error	Total calibration			
HDL	9	End point	ok	Manual calibration		2014-04-17 T00:14:33	
HEMO	9	Twin Reaction	on error	Total calibration			ſ
BACK			-	the Carl		CALIBRATION SETT	ING

This screen displays the list of all the useable methods with their current calibration status and is divided into six columns:

- "Method Name": Alphabetically lists all the methods available on the analyzer (the ones with a padlock are those provided by DiaSys GmbH).
- "Reaction": Provides information about the reaction type. It can be "End point",
   "Linear kinetic", "Fixed time kinetic" or "Twin reaction".

- "Calibration Status": Describes the current status of the selected calibration. Prior to running a test it is absolutely essential to have a valid calibration. The different status are:
  - "Missing definition": Initial state. No calibration parameters specified.
  - "Not performed": Calibration parameters specified but no calibration performed.
  - "OK": Calibration performed and valid.
  - "On error": Calibration performed but not valid.
  - "Pending" (not visible on the picture): Calibration currently running.
- "Calibration Type": Can be:
  - "Not performed": No calibration has been made.
  - "Main point calibration": Calibration on the main point only has been made.
  - "Total calibration": Calibration on all the defined points has been made.
  - "**R2 compensation**": Calibration curve has been corrected according to the absorbance of the second reagent.
  - "Manual calibration": Calibration data was manually input.
- "Reagent Lot": Shows the current reagent lot number.
- "Last Calibration": Shows the date and time of the last calibration for each method.

The buttons on the function bar give access to the following functions:

- "Exit": Goes back to the main screen.
- "Calibration settings": Allows access to the settings for the selected method.
   Double-clicking on the method works as well.

### J.III. Calibration settings

#### J.III.1. Analytical calibrations

#### J.III.1.a. View of analytical calibration settings

From "Main Screen" => "Configuration" => "Calibrator configuration" => "Calibration" => "Calibration settings"

	1.00
<administrator> - TOP MENU BAR : CALIBRATORS DETAILS -</administrator>	
[ MALBu ]	
Calibrator Lot Dil. Conc. Max delta abs	it ma/l
	ait : [0, 90 %
TC ALB U/CS 14455 1 11.40 0.10000	III. 10.00 %
TC ALB U/CS - 14456 - 1 20.90 0.10000 Model : CubicSpline -	
TC ALB U/CS 14457 1 44.50 0.10000	
TC ALBU/CSF 14459 1 310.00 0.10000	
BACK	MODIFY

This screen shows the calibrators used for the selected method and provides information about the method as well as the curve fitting.

There are two buttons on the function bar:

- "Back": Goes back to the previous screen.
- "Modify": Leads to the edition mode.

#### J.III.1.b. Edition of analytical calibration settings

From "Main Screen" => "Configuration" => "Calibrator configuration" => "Calibration" => "Calibration settings" => "Modify"

<administrator></administrator>	- TOP MENU BAR : CALIBRATORS D	ETAILS -
<administrator> Calibrator   Lot Dil   NaCl XXX   1   TC ALB U/CS 14455   TC ALB U/CS 14456   TC ALB U/CS 14457   TC ALB U/CS 14457   TC ALBU/CSF 14459   1 +</administrator>	- TOP MENU BAR : CALIBRATORS D Conc. Max delta abs 0.00 0.10000 11.40 0.10000 20.90 0.10000 44.50 0.10000 310.00 0.10000	ETAILS -
CANCEL		
		SAVE

This screen allows adding new calibrators for the selected method. It is similar to the view mode.

New calibrators can be added by clicking on the "+" icon then by using the drop down menu. Only the calibrators defined in "Calibrator configuration" can be added on this screen. The displayed concentrations are the defined ones. The field is greyed because the value cannot be changed and is automatically updated if a dilution is required. The bin icon can be used to remove a calibrator. The line highlighted in blue defines the "Main point" calibrator that will be used for main point calibrations. Other settings such as the maximum delta absorbance, the drift limit and the model of curve can be defined. The maximum delta absorbance value is the biggest difference allowed between the two absorbance measurements performed for the related calibrator and the drift limit is the biggest difference allowed between the calibration points and the calculated curve.

The k factor calibration can be used for the methods using a "X degree 1" calibration curve (only if the selected method does not require a twin reaction). In such a case, the calibration measurement is performed on one point only (the one defined as the main point, generally the zero calibration point) and the slope is defined by the operator in the calibration settings. According to what is selected in the prescription screen, a k factor calibration can be considered either as a total calibration, or as a main point calibration (see "J.IV Calibration entry" page 107).

If the selected method requires a twin reaction, two tabs are displayed: one for each reaction.

On the function bar, the buttons are now:

- "Cancel": Leaves the edition mode and goes back to the view mode without changing anything (confirmation requested).
- **"Save**": Saves the calibration data.

#### J.III.2. Manual calibrations

#### J.III.2.a. View of manual calibration settings

From "Main Screen" => "Configuration" => "Calibrator configuration" => "Calibration" => "Calibration settings"

		4
<administrator></administrator>	- TOP MENU BAR : CALIBRATORS DETAILS -	
<administrator></administrator>	- TOP MENU BAR : CALIBRATORS DETAILS-	: g/dL t: 0.80 % ree : Auto Y Change
BACK		MODIFY

This screen shows the calibration points used for the selected method and provides information about the method as well as the curve fitting.

There are two buttons on the function bar:

- "Back": Goes back to the previous screen.
- "Modify": Leads to the edition mode.

#### J.III.2.a. Edition of manual calibration settings

From "Main Screen" => "Configuration" => "Calibrator configuration" => "Calibration" => "Calibration settings" => "Modify"



This screen is divided into two parts: the upper window (similar to the view mode) allows adding up to six calibration points for the selected method and the lower window displays the calibration curve (only after its calculation).

Next to the curve, the "**Calc. Conc.**" (for calculate concentration) button can be used to calculate the concentration for a given absorbance according to the calibration curve.

New calibration point can be added by clicking on the "+" icon then by entering a concentration (field "Conc.") and an absorbance (field "Absorbancies"). The bin icon can be used to remove a calibration point. Other settings such as the reagent blanks (if requested by the method), the drift limit and the model of curve can be defined.

If the selected method requires a twin reaction, two tabs are displayed: one for each reaction.

On the function bar, the buttons are now:

- "Cancel": Leaves the edition mode and goes back to the view mode without changing anything (confirmation requested).
- "Calculate": Displays the calibration curve calculated with the data input for each calibration point. This curve will also be available in the calibration results (only if the calibration is saved).
- "Save": Saves the calibration data (it is not mandatory to calculate the curve first).

#### J.III.3. Calibration curve types

A brief description on mathematical curve models follows below.

For all subsequent formulas:

*A* = Absorbance of a measured point.

 $K_{0...}K_{N}$  = Coefficients of a polynomial.

Res = Result obtained from the absorbance measurement.

The software can automatically choose the best calibration curve type by choosing **"Automatic"** on the field "Model" when in edit mode.

When the respective formula is based on a polynomial, the degree of development must be given or at least set to **"Auto"** in order to allow the software to choose automatically. The model defines the type of curve to use among different choices.

• X: Simple development

$$Res = K_N \times A^N + K_{N-2} \times A^{N-2} + \dots + K_2 \times A^2 + K_1 \times A + K_0$$

1/X: Inverse development

$$Res = \frac{1}{K_N \times \left(\frac{1}{A}\right)^N + K_{N-1} \times \left(\frac{1}{A}\right)^{N-1} + \dots + K_2 \times \left(\frac{1}{A}\right)^2 + K_1 \times \left(\frac{1}{A}\right) + K_0}$$

#### LOGIT(X): Logit development

With  $A_0$  = Absorbance of the first calibration point.  $A_n$  = Absorbance of the last calibration point.

And  $LNA = ln \frac{A - A_0}{A_m - A}$ 

 $Res = \exp(K_N \times LNA^N + K_{N-1} \times LNA^{N-1} + \dots + K_1 \times LNA + K_0)$ 

LOGIT(X) curve requires at least four calibration points. The calculated curve can be used from the second to the last point only, which means that the measured values must be inside this interval. When the slope is negative,  $A_0$  and  $A_n$  values are reversed.

LOG4P, LOG5P: Four or five parameters Logistic

For 4 parameters logistic:

$$A = R_0 + \frac{K_c}{1 + \frac{1}{\exp[a + b \times \ln(Res)]}}$$

For 5 parameters logistic:

$$A = R_0 + \frac{K_c}{1 + \frac{1}{\exp[a + b \times \ln(Res) + c \times Res]}}$$

In both cases the curve fitting will determine  $R_{0}$ ,  $K_{c}$ , a, b and c.

The four and five parameters logistic curves respectively require at least four and five calibration points. The calculated calibration curve can be used from the first to the last point of calibration, which means that the measured values must be inside this interval.

#### Cubic Spline & Akima Spline

The cubic spline deals with all calibration points without any drift and the akima spline minimizes the occurrence of oscillations. At least three calibrations points are required to use spline calibrations.

However, the mathematical description of splines is beyond the scope of this manual. Suitable mathematics textbooks can be referred to get more information.

#### R2 compensation

The software can also use the R2 compensation mode. In this case, the absorbance of reagent 1 plus reagent 2 (R1+R2) is measured in order to determine the absorbance of R2. The calibration curve is then corrected according to the following rules.

With  $A_{new}$  = Absorbance of the new calibration point.  $A_{old}$  = Absorbance of the previous calibration point.  $A_{R2old}$  = Previous absorbance of reagent 2 (R2).  $A_{R2new}$  = New absorbance of R2.  $V_{R1}$  = Volume of reagent 1 (R1).  $V_{R2}$  = Volume of R2.  $V_t$  = Volume of R1+R2.

$$R2blank_{old} = A_{R2old} \times \frac{V_{R1} + V_{R2}}{V_{t}}$$

And

$$R2blank_{new} = A_{R2new} \times \frac{V_{R1} + V_{R2}}{V_{c}}$$

Then  $A_{new} = A_{old} + R2blank_{old} - R2blank_{new}$ 

This kind of calibration can be used for end-point bi-reagent methods only. It allows correcting the increasing R2 absorbance over time.

#### J.III.4. Validity of the calibration curves

During calibration curve evaluation, the system compares the difference between measured and theoretical values by application of the chosen model and calculates the linear regression line thereof.

With N = Number of defined calibration points, including the implicit (0; 0) when only one point is defined.

 $\{P_i\}$  with *i* in [1 to *N*] = Target concentrations of the calibration points.

 $\{C_i\}$  with *i* in [1 to *M*] = Concentration calculated from the measured absorbances for the calibration points.

 $\overline{P}$  and  $\overline{C}$  = Respective mean values of  $\{P_i\}$  and  $\{C_i\}$ .

$$\Delta_{1} = \frac{\sum_{i=1}^{N} [(P_{i} - \bar{P}) \times (C_{i} - \bar{C})]}{\sqrt{\sum_{i=1}^{N} [(P_{i} - \bar{P})^{2}] \times \sum_{i=1}^{N} [(C_{i} - \bar{C})^{2}]}}$$

And

$$\Delta_2 = 1 - \frac{\sqrt{\sum_{i=1}^{N} [(C_i - P_i)^2]}}{N \times \bar{P}}$$

Then 
$$drift\% = 100 \times [1 - (\Delta_1 \times \Delta_2)]$$

If the calibration curve fits well with the calibration points, the drift% is low. If the drift is higher than the limit specified, the system keeps the previous calibration coefficients and a flag is reported each time this method is run until a successful calibration is achieved.
## J.IV. Calibration entry

#### From "Main Screen" => "Entries" => "Calibration entry"



<administrator> - TOP ME</administrator>	NU BAR : CALIBRATION ENTRY -		
Methods			
Please select a tray to change methods ordering <alphabetical order=""></alphabetical>	Please type m	ethod shortcut, and press <enter></enter>	<u>•</u>
			AST 011 1501-27 (MANUALI
C3c C4 CA D09 Detropher Manual	AL CHE BOG 20160330 (TOTAL) 20160745 MANUAL		
Crea PAP 2011-06-527 (TOTAL) CRP 802 2016-06-527 (TOTAL) CRP hs 2026 2016-06-527 (TOTAL) CRP hs 2016-07 CRP hs 20			FE 042 DETTS MANUALI
FERR GGT GLUC G	GOD GLUC HK MANUAL SOTISFIESD (1974)		HDLC 025 POT-13 MANUALI
	LACT		Lp(a) 814 11-96-50 (TOTAL)
LPS BOTTOPHER MANUALI BOTTOPHER MONITORIAL BOTTOPHER MONITORIAL BOTTOPHER MONITORIAL	AL PALB STOTOTOS MANUAL DOTTOTOS MANUAL		RF
TBIL TP 813 sorecist rotate 050 (rotate	DECEMBER OF ALL		
Profiles	Calibrators Lot Volume Expira	ation Date Requiring methods	
2 NaCl TruCa TruCa	xxx         60.0 μL         201           10         10929         36.0 μL         201           10         10929         36.0 μL         201           10         10929         24.0 μL         201	5-04-22 ALT, TRIG, LPS, AST 5-04-22 ALT, TRIG, LPS 5-05-29 AST	
	x •		
Legend	Type of container	Calibration type	Description
(Methods) (Profile) (Methods ) (Methods )	C 1.5 mL cup	Total     O Main point	Cuvettes
Reagent on the tray Invalid profile Calibration error Calibration	expired Calibration OK C 2.5 mL cup	○ R2 Compensation	16
EXIT	DELETE PROFILE SAVE PROFILE CLEA	R SELECTION	DD TO WORK LIST

This screen allows ordering calibrations and is divided into several parts:

 "Methods": Allows choosing the methods to calibrate by clicking on the related button (specific dilutions are not permitted in this screen). The tests without specified calibration data are greyed and cannot be selected. The drop-down list on the left allows selecting a sorting tray to display the methods in the same order (see "N.XI Method ordering" page 183). The one on the right allows selecting methods by entering their shortcut. Once a method is selected, the required calibrators are automatically added in the window below where their lot number can be chosen (if applicable). The volume of each calibrator needed is displayed as well.

- "Profiles": Shows all the existing profiles for calibrations (see "I.I.2 Profile use" page 69 for more details about profiles).
- "Legend": Gives more details about the color code used for the buttons.
- "Type of container": Allows selecting what kind of sample container is used for the calibrator.
- "Calibration type": Allows choosing between total calibration, main point calibration and R2 compensation.

The number of fresh cuvettes required for the run is displayed on the bottom right corner of the screen. For calibration runs, there are always two replicates performed for each calibration point.

# The software updates the list of calibrators, the estimated volumes and the number of required cuvettes in real time.

The R2 compensation calibration type requires two cuvettes (one per replicate) but no calibrator.

There are five more buttons on the function bar:

- "Exit": Goes back to the main screen.
- "Delete profile": Deletes the selected profile.
- "Save profile": Saves several selected methods as a profile.
- "Clear selection": Unselects all methods.
- "Add to Work list": Adds the calibration to the work list.

## J.V. Calibration results

#### J.V.1. Calibration curve

From "Main Screen" => "Results" => "Calibration results"





This screen lists all the calibration results for each method and related reagent lot numbers. It is divided into five parts.

The "**Method**" column (left) shows all the methods available on the analyzer. The date and the status of the last calibration are also displayed. The colors are used as follows: green if the last calibration was good, red if it was not and grey if the method has never been calibrated.

The "Lot" column (middle) lists all the reagent lots associated to the selected method. The date and the status of the last calibration are displayed according to the following color code: green if the last calibration was good and red if it was not (not visible on the picture).

The "**Calibrators**", "**Factors**", "**Reagents blanks**" and "**Calibration curve**" parts (right) show the calibration data for the selected method and lot. As there always are two replicates for each calibrator, the absorbance which is displayed here is the mean of the two measurements.

There are two buttons on the function bar:

- "Exit": Goes back to the main screen.
- "**Print**": Prints the last calibration report for the selected method and lot.

#### J.V.2. Calibration data

#### From "Main Screen" => "Results" => "Calibration raw data"

	Entrie Result Configura	s s ation		Analys Contr Calibra Control Calibratio	sis result ol result tion result raw data on raw data		
<administrator></administrator>						<u> </u>	4
		TOT MENO BAR					
Running ✓ To Validate ✓ Validated Creation Date From 2015-04-30 To 2015-04-30 Clear Filters	ALT (Ne 2011 MALES 2011 MALES 2011 MALES 2011 Path 38 2011 Path 39 2011 Path 30 2011 Path 30 201	C, TWCal U)  O7-20T14:12:23 (NaCd, TC Protein L1, TC Prote  O7-20T11:28:06 (NaCd, TC Protein L1, TC Prote  O7-20T09:37:45 MALEw (NaCd, TC ALE WCSF  O7-19T10:45:17 Imm (NaC, TC Protein L1, TC F  O7-19T10:29:27 Imm (NaCd, TC Protein L1, TC F  O7-19T10:59:13 Imm (NaCd, TC Protein L1, TC F  O7-18T11:21:17:44 Imm (NaCd, TC Protein L1, TC F  O7-18T11:21:17:44 Imm (NaCd, TC Protein L1, TC F  O7-18T11:28:30 Imm (NaCd, TC Protein L1, TC F  O7-18T11:28:30 Imm (NaCd, TC Protein L1, TC F  O7-18T11:11:34 Imm (NaCd, TC Protein L1, TC F  O7-14T08:39:48 Imm (NaCd, TC Protein L1, TC F  O7-14T08:48:48 Imm (NaCd, TC Protein L1, TC F  O7-14T08:48:4	ein L2, TC Protein L3, TC Protein L4, T ein L2, TC Protein L3, TC Protein L4, T E L1, TC ALB U/CSF L2, TC ALB U/CS Protein L2, TC Protein L3, TC Protein Protein L2, TC Protein L3, TC Protein	IC Protein L5) IC Protein L5) SF L3, TC ALBU/OSF L4, TC A L4, TC Protein L5) L4, TC Protein L5)	11435 11421 11421 11414 11370 11368 11368 11344 11342 11341 11340 11334	VALIDATED VALIDATED VALIDATED TO VALIDATED TO VALIDATED TO VALIDATE TO VALIDATE TO VALIDATE TO VALIDATE TO VALIDATE TO VALIDATE	_
	2011 Paib 38 2011 Paib 38 2011 Paib 38	-07-13T09:53:37 Dam (NaC, TC Protein 1, TC f -07-13T09:39:48 Dam (NaC, TC Protein 1, TC f -07-07T14:07:31 Dam (NaC, TC Protein 1, TC f	Protein L2, TC Protein L3, TC Protein Protein L2, TC Protein L3, TC Protein Protein L2, TC Protein L3, TC Protein	L4, TC Protein L5) L4, TC Protein L5) L4, TC Protein L5)	11299 11298 11297	VALIDATED TO VALIDATE VALIDATED	Ŷ
EXIT	DELETE ALL	VIEW TESTS		PRINT	PRINT ALL	DELETE	2

This screen displays all the calibration results. The last calibration performed is on the top of the list.

On the left side of the screen there is a filtering tool to sort the results by status or by date (see "I.IV.1 Result search" page 85). A click on "**Clear filters**" clears the search criteria and displays all calibration results.

There are six more buttons on the function bar:

- "Exit": Goes back to the main screen.
- "Delete all": Deletes all displayed calibration results (confirmation requested). Be sure to have archived data you want to keep for quality management.
- "View tests": Displays detailed results for the selected calibration.
- "Print": Prints the selected calibration result.
- "Print all": Prints all displayed calibration results.
- "Delete": Removes the selected calibration result from the list (confirmation requested).

When clicking on "View tests" or double-clicking on a calibration result, the following screen appears.

Fact / Calibrator // at		Dil	Desult Unit		Ctatua
	#2		Result Offic	OK	Status
laCl #0023xxx		1	0.0000 g/L		
IALBs C Protein L1 #002314922	#2	1	0.2600 g/L	OK	
IALBs C Protein L2 #002314923	#2	1	0.5300 g/L	ОК	
IALBs C Protein L3 #002314924	#2	1	1.0600 g/L	ок	
MALBs TC Protein L4 #002314925	#2	1	2.1100 g/L	ОК	
HALBs C Protein L5 #002314926	#2	1	4.2200 g/L	ОК	
IALBs IaCl #0023xxx	#1	1	0.0000 g/L	ОК	
MALBs TC Protein L1 #002314922	#1	1	0.2600 g/L	ОК	
IALBs C Protein L2 #002314923	#1	1	0.5300 g/L	ОК	
IALBs C Protein L3 #002314924	#1	1	1.0600 g/L	ОК	
IALBs C Protein L4 #002314925	#1	1	2.1100 g/L	ок	
IALBs C Protein L5 #002314926	#1	1	4.2200 g/L	ОК	

This screen displays all data for the selected calibration. The "**Test/Calibrator #Lot**" column displays the name of the method, the calibrator used, its lot number and the replicate number. The dilution ratio and the result with its unit are also shown. In the "**Status**" column are the flags for each result (more details about the flags and their meaning in "Q.VI Analytical flags" page 211).

There are five buttons on the function bar:

- **"Back**": Goes back to the previous screen.
- "Delete": Delete the selected calibration data.
- "Export details": Exports the details of the selected calibration point in a text file.
- "Print": Prints the calibration results.
- "Tests details": Gives access to raw data (See "I.IV.4 Raw data" page 91).

## K. Controls

## K.I. Control configuration

From "Main Screen" => "Configuration" => "Control configuration"



<administrator></administrator>			NS			•
	- TOP MENO B		- 			
Control	NI	Control	Name: TLA	ALB U/CS	F L1	
	J	Lot Refer	rence: 150	12		
TL ALB U/C SF L2	Lot Expiration	Expiration	Date: 201	5-07-27		*
TL Lp(a) L1	15012 2015-09-16	Control	Type: CSF	<b>.</b>		*
TL Lp(a) L2	15456 2015-12-09	This control lot is usable				
TL Protein L1	2015-09-12	Method Unit	low	high	target	drift%
TL Protein L2	108561 2016-01-20	MALBs g/L	18.2000	32.4000	25.3000	10 分
TL Urine L1	11265 2015-10-13	MALBu mg/L	18.20	32.40	25.30	10
TL Urine L2	05263 2015-03-01					
TruLab N Serum	09799 2015-05-03					
TruLab P						
٤	भ रु					Ţ,
<u> </u>						
EXIT NEW CONTRO	DL		NEW LOT	DELETE L	от м	DDIFY LOT

This screen is divided into several parts.

The left part is a list of all the controls setup in the database. The ones with a padlock are those provided by Diasys GmbH. When a control is selected, related lot numbers and expiration dates appear in the next column. Red and yellow highlighting is used to warn the operator in case of expired or nearly expired (during the current month) lots. For the selected control and lot, this information is also displayed in the top right part, as well as the type of sample the control is made for. A check box allows defining a lot as useable or not (unusable lots are greyed).

The right part shows the methods that are controlled by the selected lot of control and the related data (lowest and highest acceptable values, target value and acceptable drift between a control result and the current mean for the same control). When in edition mode, all the useable methods setup on the analyzer are listed.

There are five buttons on the function bar:

- "Exit": Goes back to the main screen.
- "New control": Creates a new control.
- "New lot": Duplicates the settings of the selected control to setup a new lot.
- "Delete lot": Deletes the selected lot (confirmation requested).
- "Modify lot": Allows the edition of the selected control. When clicking on this button, the screen switches to the edition mode. Only two buttons are then displayed:
   "Cancel" to leave the edition mode and go back to the view mode without changing anything (confirmation requested) and "Save" to save the control.

To associate a method to a control all the fields must be filled and coherent (e.g. the low value cannot be higher than the high value). To remove it from the list, they must be empty.

The name, the lot reference, the expiration date and the type of the selected control can also be modified (the name cannot be edited for DiaSys controls though).



Before processing any analysis, you should have run controls for each method that could be used.

### K.II. Control entry

#### From "Main Screen" => "Entries" => "Control entry"



<administrator></administrator>		- TOP MENU BAR : CONT	ROL ENTRY -	🗐 📲 🔫
Methods				
Please select a tray	y to change methods ordering <alphabet< td=""><td>ical Order&gt;</td><td>Please type method shortc</td><td>ut and press <enter></enter></td></alphabet<>	ical Order>	Please type method shortc	ut and press <enter></enter>
				APOB ASO
AST		C4 CA		CHOL CK-MB
CI				DDI ETH
FE		GGT GLUC		HbA1c HCY
HDLC				
Lp(a)		MALBU MG		PAMY PO3
RF 2011-0E-10				
Profiles		Controle	Type Lot Volumo Ex	nization Data Mathada
		Trul ab N Serum	14006 7.0	
( 1		TLALBU/CSFL1 CSF	15012 V 2011	2015-04-15 K
~		TL Protein L1 Serum	12577 19.0 µL	2015-05-29 K, PALB, LACT
3	$\supset$	TL Protein L2 Serum	12579 19.0 μL 2	2015-11-26 K, PALB, LACT
Legend			Type of container	Information
(Mathead)	Methods		• 5-10 mL tube	Replicates : 1 +
Wethods			1.5 mL cup	Dequired Currettee : C
Reagent on the tray	Calibration error		© 2.5 mL cup	Required Cuvettes : 9
EXIT		DELETE PROFILE	SAVE PROFILE CLEAR SELECTIO	ADD TO WORK LIST

This screen allows ordering controls and is divided into several parts:

 "Methods": Allows selecting the methods to control by clicking on the related button (specific dilutions are not permitted in this screen). The methods without specified control data are greyed and cannot be selected. The drop-down list on the left allows selecting a sorting tray to display the methods in the same order (see "N.XI Method ordering" page 183). The one on the right allows selecting methods by entering their shortcut. Once a method is selected, it is automatically added in the window below where the lot number of the controls to use can be chosen (if applicable). To remove a control from the list, click on the bin button on the left of the control name. The selected tests will be then controlled only with the remaining controls. The volume of each control needed is displayed as well.

- "Profiles": Shows all the existing profiles for controls (see "I.I.2 Profile use" page 69 for more details about profiles).
- "Legend": Gives more details about the color code used for the buttons.
- "Type of container": Allows selecting what kind of sample container is used for the control.
- "Information": Allows changing the number of replicates up to 20 per method (the setup number will be the same for all the tests of the prescription). This part also shows the number of fresh cuvettes required.



# The software updates the list of controls, the estimated volumes and the number of required cuvettes in real time.

There are five more buttons on the function bar:

- "Exit": Goes back to the main screen.
- "Delete profile": Deletes the selected profile.
- "Save profile": Saves several selected methods as a profile.
- "Clear selection": Unselects all selected methods and the related control.
- "Add to Work list": Adds the control run to the work list.

To run a control:

- 1. Select the method(s) to control.
- 2. If needed, remove some control and choose the lot number(s) to use.
- 3. Define the type of sample container to use.
- 4. Define the number of replicates.
- 5. Add to work list.

## K.III. Control results

#### K.III.1. Out of limit controls

A control point is out of limit when at least one of the following conditions is applicable:

- Result outside the interval [low value; high value] as defined in the "Control configuration" screen.
- Result outside the interval [m drift%; m + drift%] with "m" being the mean value for the previous runs of the control. The "drift%" value is the one defined in the "Control configuration" screen.
- Result which does not fill the Westgard rules (see details next page).

#### K.III.2. Westgard rules

Rule	Printed symbol	Meaning
1 <sub>2S</sub>	pt > 2 SD	Control result exceeding the value: mean ± 2 SD.
1 <sub>3S</sub>	pt > 3 SD	Control result exceeding the value: mean ± 3 SD.
2 <sub>2S</sub>	2 pts > 2 SD	2 consecutive results on the same side of the mean and exceeding the value: mean ± 2 SD.
R <sub>4S</sub>	Delta sd > 4 SD	Difference between 2 successive control results exceeding 4 SD.
<b>4</b> 1S	4 pts > 1 SD	Four consecutive control results on the same side of the mean and exceeding the value: mean $\pm$ 1 SD.
10x	10 pts same side of mean	10 consecutive control results on the same side of the mean.

With "SD" being the standard deviation of the serie.

The Westgard rules can be summarized by the following scheme. "**Yes**" means that there is a violation of the related rule and "**No**" means there is not.



#### K.III.3. Statistical results

#### From "Main Screen" => "Results" => "Control result"



This screen lists all the control results for each method. It is divided into four parts.

The "**Method**" column (left) shows all the methods available on the analyzer with the last controlled ones being on the top of the list. The date of the last control and the status of the method are also displayed. The colors are used as follows: green if the method is considered as controlled (if all the performed controls are good), red if it is not (if at least

one control is on error, not visible on the picture) and grey if no control has been performed for the method or if the last control has been performed more than 180 days ago.

When the control status of a method is not valid, the related patient tests will be cancelled as no results will be available. The prescription will be considered as incompletely done. However, it is possible to disable the control status check in the options (see "N.II Analysis" page 172).

The "**Control/Lot**" column (middle) lists all the controls associated to the selected method with their respective lot number. The date and the status of the last control are displayed as well. This status depends on the validity of the most recent control point. The square is green if the last control was good and red if it was not (not visible on the picture).

The upper right part displays the limits, the target and the drift% as setup in "Control configuration". Below are some statistics calculated for all results and for the ones included in the period of time chosen via the filter buttons in the top left corner of the screen ("**Today**", "**Last 30 days**" and "**Last 180 days**"). The number of control points, the mean, the standard deviation (SD) and the coefficient of variation (CV%) are shown. Then information concerning each control point is given: date and time, control point result, status (can be different from the control status mentioned above as in the current case it only concerns one point) and daily CV%, SD and mean. When a control point is out of limit due to one of the reasons mentioned in "K.III.1 Out of limit controls" page 120, the related column is red. Otherwise it is green.

The lower right part is a chart showing the distribution of all the selected control points. When clicking on a point on the chart, the related result is automatically selected in the table above. It is possible to have three different types of diagram:

"Levey Jennings": The reference line is the mean value and ±1SD, ±2SD and ±3SD lines are used to check the Westgard rules. Lines have also been added for the low and high limits as well as for the target value.

- "Mode 1": The reference line is the mean value. ±1S, ±2S and ±3S have been added with +2S being the difference between the high limit and the target value and -2S being the difference between the target value and the low limit.
- "Mode 2": same as "Mode 1" but the reference line is the target value.

On the function bar there are six buttons:

- "Exit": Goes back to the main screen.
- "Remove control point": Removes the selected control point (confirmation requested). It is highly recommended to input the reason of the removal, even if the field can also be left empty, before clicking on "Ok". The removed points appear in dark red (if previously red) or dark green (if previously green) and are not used in the calculations anymore. The reason of the removal (if any) is displayed above the date and time. When a removed point is selected, the "Remove control point" button is changed into "Restore control point". Clicking onto restore the selected point and switches its color back to red (if dark red) or green (if dark green).
- "Delete all results": Deletes all the control points of the selected method for the selected control (confirmation requested).
- "Print history": Prints the results displayed on the screen (last 30 days, today or last 180 days).
- "Print last control": Prints the results of the last run with the selected control and method. If other methods have been controlled during the same run, additional results will be printed.
- "Validate control": Validates the status of the selected control for the selected method despite the good or bad results. The square in the "Control/Lot" column switches to green but all the control points keep their current status.

#### K.III.4. Control data

#### From "Main Screen" => "Results" => "Control raw data"

				Anal	ysis result		
-			-	Con	trol result		
	E	ntries		Calibr	Calibration result		
the second se	Re	Results		Contr	ol raw data		
	Configuration			Calibra	tion raw data		
<administrator></administrator>			RAW DATA -			<u></u>	÷
							2
To Launch	<b>201</b> ALT (	1-11-15T10:04:18 TruLab N			11483	TO VALIDATE	分
Running	201 MALE	1-07-21T14:18:49 Is (TL Protein L2)			11456	VALIDATED	
Validated	201 MALE	1-07-21 T14:18:48 Is (TL Protein L1)			11455	VALIDATED	
Creation Date	201 MALE	1-07-21T11:33:20 Ss (TL Protein L2)			11454	VALIDATED	
From 2015-04-30	- 201 MALE	1-07-21T11:33:14 Is (TL Protein L1)			11453	TO VALIDATE	
10  2015-04-50	201 MALE	1-07-20T14:12:46 Is (TL Protein L2)			11437	TO VALIDATE	
Clear Filters	201	1-07-20T14:12:40			11436	TO VALIDATE	
	201	1-07-20T09:38:27			11418	VALIDATED	
	201	1-07-20T09:38:23			11417	TO VALIDATE	
	201	1-07-20T09:38:16			11416	VALIDATED	
	201	1-07-20T09:38:12			11415	VALIDATED	
	201 Path	1-07-19T13:58:49			11396	TO VALIDATE	
	201	1-07-19T13:58:49			11395	VALIDATED	
	201	1-07-19T13:08:30			11388	TO VALIDATE	
	201	1-07-19T13:08:30			11387		
	Palb	380nm (TL Protein L1)				VALIDATED	5
EXIT	DELETE ALL	VIEW TESTS	EXPORT ALL	PRINT	PRINT ALL	DELETE	

This screen displays all the control results. The last control performed is on the top of the list.

On the left side of the screen there is a filtering tool to sort the results by status or by date (see "I.IV.1 Result search" page 85). A click on "**Clear filters**" clears the search criteria and displays all control results.

There are seven more buttons on the function bar:

- "Exit": Goes back to the main screen.
- "Delete all": Deletes all displayed control results (confirmation requested). Be sure to have archived data you want to keep for quality management.
- "View tests": Displays detailed results for the selected control.
- **"Export all**": Exports the details of all the displayed results in a text file.
- "Print": Prints the selected control result.
- "Print all": Prints all displayed control results.
- "Delete": Removes the selected control result from the list (confirmation requested).

When clicking on "View tests" or double-clicking on a control result, the following screen appears.

		- TOP MENU BA	R . RAW CONTROL P	RESULIS-
014-07-12T14:15:02				(20 te
Test / Control #Lot	Dil	Result Units		Status
MALBs #20 TL Protein L2 #002312579	1	2.4700 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #19 TL Protein L2 #002312579	1	2.4800 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #18 TL Protein L2 #002312579	1	2.4600 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #17 TL Protein L2 #002312579	1	2.3900 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #16 TL Protein L2 #002312579	1	2.3800 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #15 TL Protein L2 #002312579	1	2.4800 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #14 TL Protein L2 #002312579	1	2.3800 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #13 TL Protein L2 #002312579	1	2.4100 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #12 TL Protein L2 #002312579	1	2.4300 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #11 TL Protein L2 #002312579	1	2.3400 g/L	OK	Total calibration on 2014-07-02T14:24:12
MALBs #10 TL Protein L2 #002312579	1	2.5400 g/L	ОК	Total calibration on 2014-07-02T14:24:12
MALBs #9 TL Protein L2 #002312579	1	2.4700 g/L	ОК	Total calibration on 2014-07-02T14:24-12
MALBs #8 TL Protein L2 #002312579	1	2.3600 g/L	ОК	Total calibration on 2014-07-02T14:24:12
MALBs #7 TL Protein L2 #002312579	1	2.1700 g/L	OK	Total calibration on 2014-07-02T14:24:12

This screen displays all data of the selected control and each line matches with a single control point. The "Test/Control #Lot" column displays the name of the method, the control used, its lot number and the replicate number. The dilution ratio and the result

with its unit are also shown. In the "Status" column are the flags for each result (more details about the flags and their meaning in "Q.VI Analytical flags" page 211) and the details of the calibration data used to calculate the result.

There are five buttons on the function bar:

- "Back": Goes back to the previous screen.
- "Delete": Delete the selected control result.
- **"Export details**": Exports the details of the selected control result in a text file.
- "**Print**": Prints the control results.
- "Tests details": Gives access to raw data (See "I.IV.4 Raw data" page 91).

## L. Reagent and method configuration

## L.I. Solution configuration

#### From "Main Screen" => "Configuration" => "Solution configuration"

• OP MENU BAR : SOLUTION CONFIGURATION -           CLEANER         900           CLEANER         801           NaCL         800           DULSAY         800           Solution settings         Type CLEANER           Name CLNA         000           Solution barcode reference 900         Solution barcode reference 900           Solution barcode reference 900         Solution barcode reference 900	_	Entries Results Configuration		Method c Control c Calibrator Solution c Tray co Operators Op	configuration configuration configuration configuration nfiguration configuration otions	
	<administrator></administrator>	- TOP MENU BAR : SOLUTIO	N CONFIGURATION	N -		

This screen allows the creation and the management of the solutions (diluents, cleaners and hemolysis agents) which can be used during an analysis.

The column on the left side lists all the solutions setup on the analyzer with their "**Type**" (diluent, cleaner or hemolysis agent), "**Name**" and "**Unique internal reference**". The ones with a padlock are those provided by DiaSys GmbH.

DiaSys cleaners have a reference from 900 to 949 while DiaSys diluents and hemolysis agents have one going from 950 to 998 (999 is automatically used for system water). The solutions that are not provided by DiaSys GmbH have a reference going from 800 to 899.

The right part of the screen shows the same information for the selected solution.

The "**Solution barcode reference**" is the barcode identifier of the container. It allows the detection of the bottle during the barcode scan.

On the function bar there are four different buttons:

- "Exit": Goes back to the main screen.
- "New": Creates a new solution.
- "Delete" (greyed if the selected solution is a DiaSys product): Deletes the selected solution.
- "Modify" (greyed if the selected solution is a DiaSys product): Allows the edition of the name of the selected solution. When clicking on this button, the screen switches to the edition mode. The two buttons that are then displayed are "Cancel" to leave the edition mode and go back to the view mode without changing anything and "Save" to save the solution. A name already used is displayed in red while in the edition mode.

## L.II. Method configuration

#### From "Main screen" => "Configuration" => "Method configuration"



Administrator>		- TOP MENU BAR : METHO	D CONFIGURATION -	A
	AI	Identification Reaction Sam	ple Results Contaminants	Calibration
LT	010	This method is useable	e for analysis	
MY -REAGENT/LIN KIN		This method is calculate	ed from others results	
P		Twin reaction		
POA1		Name	ALT	
POB -REAGENT/END POINT		Unique internal reference	010	
SO -REAGENT/LIN KIN	111	Host reference		
ST	011	Shortcut	010	
C-REAGENT/END POINT		Bottle		
4 ONO-REAGENT/END POINT		Reagent barcode reference	010	
RA-REAGENT/LIN KIN		Calibration stability	-	days - days
HE -REAGENT/LIN KIN				
		Capacity of new bottle		
K-MB	030	Large container	298 tests	Bottle is Small Twin only
	029	Small Container	liva tests	
REAGENT/END POINT				
		4		

This screen allows the management of the methods which can be performed on the analyzer.

The left part of the screen lists all the registered methods and their shortcut if one has been defined. The unusable methods are greyed, the ones with a padlock are those provided by DiaSys GmbH.

On the right part of the screen, information about the selected method is displayed. Several tabs allow switching between different characteristics.

On the function bar there are three buttons:

- "Exit": Goes back to the main screen.
- "Print Settings": Prints the configuration details of the selected method, including calibration data (if applicable).
- "Modify": Allows the edition of the selected method. When clicking on this button, the screen switches to the edition mode. Only two buttons are then displayed:
   "Cancel" to leave the edition mode and go back to the view mode without changing anything (confirmation requested) and "Save" to save the method.

Only a few fields can be edited by the operators, including administrators. Distributors can create up to five new methods upon request and more if an agreement with DiaSys GmbH has been made. Contact your local representative for more information.

#### L.II.1. Identification

From "Main screen" => "Configuration" => "Method configuration" => "Identification"

- TOP MENU BAR : METHOD	CONFIGURATION -		÷
Properties [Identification] Reaction Sam	ple Results Contaminants	Calibration	
This method is useable	for analysis		
This method is calculate	d from others results		
Twin reaction			
Name	ALT		
Unique internal reference	010		
Host reference			
Shortcut	010		
Bottle			_
Reagent barcode reference	010		
Onboard stability		days	
Calibration stability		days	
Capacity of new bottle			
Large container	298 tests	_	
Small container	179 tests	Bottle is Small Twin only	

This tab displays information about the identification of the selected method and is divided into three parts.

On the top, three check boxes give more details about the status of the selected method:

- "Useable for analysis": Unchecked if the method is unusable. It will be still visible in the "Method configuration" screen but not in the prescription (routine, calibration and control) screens. The parameters are stored but the method cannot be used anymore, unless this box is checked again.
- "Calculated": Checked if the result for the method must be calculated from results of other methods. No specific prescription is required for a calculated method; the result of the calculation is automatically added to the patient file when all the other

methods are in the prescription. No calibration or control can be performed on a calculated method.

 "Twin reaction": Checked if the method is a twin test. That means two different reactions occur, each of them according to its own settings and having its own calibration and control data.

In the middle, the references of the method are shown:

- "Name": Is the name of the method.
- "Unique internal reference": Unique identifier of the method. No reference can be used twice, even if one is for a method and the other one for a solution. The methods created by distributors must have a reference between 800 and 899.
- "Host reference" (mandatory if the bidirectional interface is set): Identifier of the method for the host interface.
- "Shortcut" (optional): Shortcut of the method. It can be used in the routine, calibration and control entry screens.



A field written in red while in the edition mode means that the name or reference number is already used somewhere else in the software. On the bottom, information about the reagent bottle is displayed:

- "Reagent barcode reference": Barcode identifier of the reagent bottle used with the method. Barcode references starting by 9 are for solutions (diluents, hemolysis agents and cleaners) only. The methods created by distributors must have a barcode reference between 800 and 899.
- "On-board stability": Time after which the reagent in an opened bottle is considered as expired.
- "Calibration stability": Time after which the calibration is considered as not valid.
- "Large container" and "Small container": Maximum number of tests which can be performed using new bottles, respectively a mono-container / large twin-container and a small twin-container.
- "Bottle is small twin only" check box: Only small twin bottles are used for this method when this option is checked.



A new bottle is not necessarily a full bottle. Some reagents are provided by DiaSys Diagnostic Systems GmbH in partially filled containers.

#### L.II.2. Reaction

From	"Main	screen"	=> "Co	onfiguration	' =>	"Method	configu	uration"	=>	"Reaction"	"
------	-------	---------	--------	--------------	------	---------	---------	----------	----	------------	---

Type Linear kinetic ✓ Reagents Volume First reagent Second reagent Temperature sensitive reagent	nt Blank stability +/- 10.0000 abs.
Linear kinetic Reagents Volume Blank reagent First reagent Second reagent 40 µL Temperature sensitive reagent	nt Blank stability +/- 10.0000 abs.
Reagents Volume Blank reagent First reagent 160 µL ✓ Second reagent 40 µL ↓ Temperature sensitive reagent	nt Blank stability +/- 10.0000 abs.
Volume Blank reager First reagent 160 µL ✓ Second reagent 40 µL	nt Blank stability +/- 10.0000 abs.
Second reagent 40 µL	+/- 10.0000 abs.
Second reagent 40 µL Temperature sensitive reagent	
Temperature sensitive reagent	
Wavelengths	
Main 340 nm 👻	Secondary 405 nm -
	Polychromatic factor : 1.0000
Timings (minutes:seconds)	
First reading time 06:24 - +	Last reading time 10:00 - +
Verificat	tions
Substrate depletion	
	Absorbance limit :
	Empty field to disable verification
Linearity	



If the selected method is a twin test, two tabs named "Reaction 1" and "Reaction 2" are displayed, one for each reaction involved in the test.

This tab displays the technical specifications of the selected method and is divided into several parts.

The "**Type**" window shows the type of reaction. It can be "**End point**" (not visible on the picture), "**Linear kinetic**" or "**Fixed time kinetic**" (not visible on the picture).

The "**Reaction way**" window shows if the reaction is decreasing or increasing. This information is used to verify the result at the end of the analysis.

The "Reagents" window shows information about the reagent(s) used for this method:

- Reagent volumes setup for the method. The "First reagent" volume must be between 90 and 250 µL and the "Second reagent" volume (if applicable) must be between 10 and 130 µL. However, the total volume in the cuvette (reagents + sample) cannot exceed 260 µL. If a reagent blank correction is required by the method, the related boxes are checked and the allowed drift is defined.
- Temperature sensitive reagent checkbox. If this box is checked, extra care is taken while performing tests using this reagent.

The "Wavelengths" window shows the wavelengths used for the absorbance measurements. The selection is made among 12 values (from 340 nm to 800 nm). The "Main" wavelength must be the most sensitive one. The "Secondary" wavelength and the "Polychromatic factor" are used when a polychromatic correction is needed (see "M.III Bichromatic correction" page 154).

The "**Timings**" window shows the reading times. The "**First reading time**" (for kinetics only) is the first time used for the calculation after the sample and the second reagent (if applicable) have been dispensed and the "**Last reading time**" is the last one. A couple of rules apply to the reading times:

- In all cases, the time origin is the time of the sample dispensing into the cuvette.
- The setup times must be coherent (the first reading time must be before the last one).
- The first reading time cannot be more than 15 minutes 48 seconds (15:48) and the last reading time cannot be more than 16:00.
- For mono-reagent methods, the first reading time cannot be less than 00:12 and the last reading time cannot be less than 00:24 (00:12 for end point reactions).
- For bi-reagent methods, the delay used by the analyzer between the sample dispensing and the second reagent dispensing is always 04:36. That means the first reading time cannot be less than 04:48 and the last reading time cannot be less than 05:00.

The "**Verifications**" window shows the value of the parameters used in the verification of the results. Those parameters are different for each type of reaction:

- For end point reactions: The "Stability" and the "Prozone" can be checked as some end points may be unstable. The largest remaining slope is the highest allowed ratio of variation per minute between the second last and the last measurement points. Its value must be between 0 and 30 %. The prozone limit is the highest allowed ratio of variation during the two last thirds of the reaction.
- For linear kinetics: The absorbance limit and the maximum deviation used for the "Substrate depletion" and the "Linearity" can be defined. For more details about the linearity verification, see "M.VI Linear kinetic" page 159.
- For fixed time kinetics: The absorbance limit used for the "Substrate depletion" can be defined. As a fixed time kinetic is not necessarily linear, no maximum linearity deviation can be setup.

#### L.II.3. Sample

#### From "Main screen" => "Configuration" => "Method configuration" => "Sample"

ntification Reactio	on Sample R	esults C	ontaminants	Calibratio	n	
iluent System water		emolysis Agent No Hem Sample	olysis	Clean	volume	μL
oncentration techni	ical limits					
				_		
Lo	ower 2.2300			Upper 7	33.0000	
Lo	wer 2.2300			Upper 7	33.0000	
Lo	wer 2.2300	al	Below N	Upper 7	33.0000	ormal
Lo	Norm Volume (µL)	al	Below No	Upper 7	33.0000 Above Ν Volume (μL)	ormal
onditions SERUM	wer 2.2300 Νοιτικά Volume (μL) 12.0	al Dilution	Below Να Volume (μL) 20.0	Ormal Dilution	Above Ν Volume (μL) 5.0	ormal Dilution 1
onditions SERUM URINE	Norm           Volume (μL)           12.0           12.0	al Dilution 1	Below Ν Volume (μL) 20.0 20.0	Upper 7	Above Ν Volume (μL) 5.0 5.0	ormal Dilution 1 1
onditions SERUM URINE PLASMA	Norm Volume (μL) 12.0 12.0 12.0	al Dilution 1 1 1	Below Ν Volume (μL) 20.0 20.0 20.0	Upper 7: ormal Dilution 1 1 1	Above Ν Volume (μL) 5.0 5.0 5.0	ormal Dilution 1 1 1
onditions SERUM URINE PLASMA CSF	Norm           Volume (μL)           12.0           12.0           12.0           12.0           12.0           12.0           12.0	al Dilution 1 1 1 1 1	Below Να Volume (μL) 20.0 20.0 20.0 20.0 20.0	Upper 7: ormal Dilution 1 1 1 1	Above Ν Volume (μL) 5.0 5.0 5.0 5.0 5.0	ormal Dilution 1 1 1 1

This tab displays information about the sample for the selected method and is divided into four parts.

The "**Diluent**" window shows the diluent used during the test (in case a dilution is required during the run).

The "**Hemolysis**" window shows details regarding the hemolysis process (in case a sample hemolysis is required by the method). The hemolysis agent and the cleaner to use are specified, as well as the volumes of sample and hemolysis agent.



If a sample hemolysis is requested, it will apply to samples only. Calibrators and control solutions will be processed without hemolysis and will have to be manually hemolyzed (if needed) before the run. The "**Concentration technical limits**" window (available only when no sample hemolysis is required by the method) shows the lower and upper limits of the method. When the run conditions are normal, an absorbance related to a concentration being outside this interval would not be reliable due to the technical limits of the photometer.

The "**Conditions**" window shows the sample volumes and the dilution factors that have to be used. The volume must be between 2 and 30  $\mu$ L and dilutions are only allowed for factors between 6 and 26. For each type of sample there are three different cases:

- "Normal" conditions: These values are the ones used during a normal run. For serum samples, the dilution factor is always 1 because the parameters are used during the calibration and the control of the method.
- "Below Normal" conditions: These values are the ones used if the result of a test is below the lower technical limit. A rerun is then automatically performed using the values specified in this column.
- "Above Normal" conditions: These values are the ones used if the result of a test is above the upper technical limit. A rerun is then automatically performed using the values specified in this column.



Between the normal and the rerun (below or above normal) conditions either the sample volume or the dilution factor can change but not both.

#### L.II.4. Results

From "Main screen" => "Configuration" => "Method configuration" => "Results"

				_ <u>_</u> N	•
Properties	THOD CONFIGURATION -				
Identification Reaction	Sample Results Contamina	ants Calibratio	n]		
Value	Correlation factor				
Desimala	Offeet 0.00	000			
Decimais.	Oliset. Jo. of				
Units : U/L	Slope : 1.00	000			
SERUM URINE PLA	SMA CSF WHOLE BLOO	DD			
Normal ranges					
	de range	Value	range		
Species >=	<=	Minimum	Maximum	- 1	
Cat 1	5 Years -	3	16		
	Add	Del			

This tab displays information about the results for the selected method and is divided into three parts.

The "Value" window shows the number of decimals and the unit which must be displayed with the results.

For the twin reactions, those settings can be defined three times: for the first reaction, for the second one and for the final result (additional fields not visible on the picture).

The "**Correlation factor**" window shows the "**Offset**" and the "**Slope**". Both are used to minimize the differences between the results obtained with the current analyzer and those obtained with a reference one.
The "**Normal ranges**" window shows the normal values for each type of sample regarding the animal species and age. Several parameters can be specified:

- "Species": Can be selected via the drop down menu which lists all the setup species (See the part "N.IX Species" page 181 to add new species). "All" can be used to setup ranges valid for all the species. Such range (if defined) is used when no other setup range is applicable.
- "Age range": Can be in days, months or years. 0 setup in the two columns (>= and
   =) means that the range is valid for all ages. If defined, it is used when no other setup age range is applicable.
- "Value range": Interval of values considered as normal for the specified species and age. The defined ranges are informative. A result out of the range will be flagged but without any change on the result itself.



The precision of the results is limited by the reagent characteristics and the analyzer specifications.

### L.II.5. Contaminants

From "Main screen" => "Configuration" => "Method configuration" => "Contaminants"

700 1151					CN	•
- TOP MENU	J BAR : METHOD C	ONFIGURATION -				
Identification	Reaction Sample	Results Contaminants	Calibra	tion		
Contamina	ants for this method ar	e listed below :				
	Contaminant	Wash with	Cycles	Volume (µL)		
	UREA (054)	syst.water (R999)	1	2000		
	UA (R055)	CLNA (R900)	1	250		

This tab displays information about possible contaminations between the selected method and other tests setup on the analyzer.

As far as possible the software tries to avoid running methods right after their contaminants but sometimes it is not possible and washing cycles must be considered.

The table is divided into four columns:

- "Contaminants": Shows the tests whose reagents could contaminate the selected method.
- "Wash with": Shows the washing solution to use in case of contamination. It can be a cleaner or system water.

- "Cycles": Shows the number of washing cycles to perform in case of contamination.
   With system water this number can be between 1 and 4 but with cleaners it has to be 1.
- "Volume": Shows the volume used for each washing cycle in case of contamination.
   With system water the volume is 2000 µL and with cleaners it is 250 µL.



The contaminations rules provided by DiaSys GmbH cannot be modified but the operator can add as much new rules as needed.

### L.II.6. Calibration

From "Main screen" => "Configuration" => "Method configuration" => "Calibration"

- TOP MENU BAR : METHOD CONFIGURATION -	÷
Properties Identification Reaction Sample Results Contaminants Calibration	
Manual calibration	
KFactor	
Drift limit : 0.50 %	
Manual calibration KFactor Drift limit : 0.50 % Model : Automatic  Degree : Auto	

This tab displays information about the calibration of the selected method and is divided into two parts.

The upper area allows the activation/inactivation of the manual calibration. This choice can be made in this screen only.



A method whose calibration is defined as manual will not be available in the calibration entry because no analytical calibration is possible.

For methods that do not require a twin reaction, it also allows the activation/inactivation of the k factor calibration (see "J.III.1.b Edition of analytical calibration settings" page 99 for more details). This choice can also be made in the calibration settings screen.

The lower area allows defining the drift limit as well as the model of curve. If the selected method requires a twin reaction, two tabs are displayed: one for each reaction.

### L.II.7. Calculation

When the selected method is a calculated one, the tabs "**Technic**", "**Sample**" and "**Contaminants**" are no longer useful. They are then replaced by a "**Calculation**" tab.

#### From "Main screen" => "Configuration" => "Method configuration" => "Calculation"

- TOP MENU BAR : METHOD CONFIG	URATION -
Identification Calculation Results	
Select formula to use for calculations :	(A/B)*100 <u>-</u>
A AST (011) B ALT (010)	Constants
([AS	;T] / [ALT]) × 100

This tab displays information about the way of calculation of the selected method and is divided into several parts:

- "Formula": Shows which calculation must be done. Ten different formulas are setup on the analyzer.
- "Methods": Shows the tests whose result is used for the calculation.
- "Constants": Shows the value of the constants defined for the calculation (if applicable).

A summary of the formula with the chosen methods and the related constants (if any) is displayed on the bottom.



A calculated method is added to the results report if all the methods involved in the calculation are requested in the prescription.

# L.III. Tray configuration

#### From "Main Screen" => "Configuration" => "Tray configuration"



NEWTRAY 1		Tray name NEWTR	AY 3					
NEWTO AV O					Test	8	D	ates
NEW IRAY 2	Posi	tion Bottle	Container	Lot	Remaining	Warning	Expiration	Openin
NEWTRAY 3	1	MALBu (R821)	Twin/Small	33336	326	81	2023-12	
NEWTRAY 4	3	CLNA (cin R900)	Cleaner	25130	57 mL	14 mL	2005-01	
NEWTRAY 5	5							
NEWINALS	6	UA (R055)	Twin/Small	84280	19	4	2006-11	
	7	Natrium 4 (R809)	Mono	98176	225	56	2008-12	
	8	HEMO (R221)	Twin/Large	89238	48	12	2024-10	
	9	LDL (026)	Twin/Large	89516	85	21	2015-01	
	11							
	12	NaCl (dil R800)	Diluent	87315	51 mL	12 mL	2001-05	
	14	Crea PAP (R807)	Twin/Large	18765	268	67	2009-01	
	15	CHEtzt (Rtzt)	Twin/Large	23500	345	86	2010-03	
	16	HEMOAGENT (hemo R801)	Hemolysis Agent	61396	61 mL	15 mL	2028-12	
	17	TP (050)	Twin/Large	51402	395	98	2024-12	
	18	TBIL (R019)	Twin/Large	66388	115	28	2022-08	
	20	PAMY (R815)	Twin/Large	82415	76	19	2022-05	
	21	_						
	23	ALT + p5p (R)	Twin/Large	35796	307	76	2010-01	
	24	CRP (706)	Twin/Large	98958	121	30	2010-03	
	26							
	27							
	29	Natrium 2 (R812)	Twin/Small	47675	234	58	2024-08	

This screen allows the creation and the management of trays with reagents, diluents, hemolysis agents and cleaners.

The column on the left side shows the name of all the defined trays. The name of the selected tray is also displayed on the top of the screen. If a tray is setup as active, its name is displayed in red in the column.

The right part of the screen is divided into eight columns:

- "Position": Shows where the bottles are supposed to be placed on the tray.
- "Bottle": Allows choosing a bottle to setup for each position via a drop-down list. The name of the bottle and its unique internal reference are displayed too.
- "Container": Shows the type of the bottles and can be "Mono", "Small Twin", "Large Twin", "Diluent", "Hemolysis agent" or "Cleaner". Diluents, hemolysis agents and cleaners are in mono-containers.
- "Lot": Shows the lot number of each bottle.
- "Tests/Remaining": Shows the remaining amount of liquid in the bottles (number of tests for reagents and volume for diluents, hemolysis agents and cleaners). In case of a new bottle, the number of tests is first displayed according to what has been specified in the method configuration before being updated at the end of the runs. For diluents, hemolysis agents and cleaners, a new bottle is supposed to be full.
- "Tests/Warning": Allows the edition of the warning level. This parameter allows the operator to be warned that a bottle is nearly empty and should be replaced or refilled. Its default value is:
  - For the reagents: 35 tests or 10% of the number of tests performed with a new bottle (see "L.II.1 Identification" page 134) if this value is lower than 35.
  - For diluents: 20% of the full bottle volume.
  - For hemolysis agents: 20% of the full bottle volume.
  - For cleaners: 30% of the full bottle volume.
- "Dates/Expiration": Allows the input of the expiration date (format YYYY-MM).
- "Dates/Opening": Allows the input of the opening date of the bottle. This date is used to check the reagent on-board stability. If no date is specified, the one of the first use of the bottle will be setup. If the on-board stability is not good, the reagent is considered as expired.

There are six buttons on the function bar:

- "Exit": Goes back to the main screen.
- "**Print**": Prints the configuration of the selected tray.
- "Set as active tray" (greyed if the barcode reader is enabled for reagents): Loads the selected tray as current "Reagent Tray".
- "New": Creates a new empty tray.
- "Delete" (greyed if the selected tray is set as active): Deletes the selected tray.
- "Modify": Allows the edition of the selected tray (if it is not setup as active). When clicking on this button, the screen switches to the edition mode. Only two buttons are then displayed: "Cancel" to leave the edition mode and go back to the view mode without changing anything (confirmation requested) and "Save" to save the tray configuration.

# M. Method calculations

# **M.I. Introduction**

### M.I.1. Beer's law

Beer's law is the basic principle of measurement used by the system. The law states that there is a logarithmic dependence between the transmittance of the light through a substance and the absorption coefficient of the substance multiplied by the distance the light travels through the material (path length). The absorbance can be written as the product of the wavelength-dependent molar extinction coefficient by the concentration of the substance.



- With T = Transmittance of the light.
  - $I_0$  = Intensity of the incident light.
  - $I_1$  = Intensity of the transmitted light.
  - $\alpha$  = Absorption coefficient.

*I* = Path length.

- $\varepsilon_{\lambda}$  = Molar extinction coefficient.
- c = Concentration of the solution.
- A = Absorbance.

$$T = \frac{I_1}{I_0} = 10^{-\alpha l} = 10^{-\varepsilon_\lambda lc}$$

And

$$A = \log_{10} \frac{I_0}{I_1} = \alpha l = \epsilon_{\lambda} lc$$



For the respons<sup>®</sup>910VET analyzer, the optical path length of the reaction cuvettes is 0.5 cm.

Beer's law is considered as the basic principle of the concentration calculation. The concentration is then given by:

$$c = \frac{A}{\varepsilon_{\lambda} l}$$

Details concerning the derivatives and corrections to apply are given in the following paragraphs.

### M.I.2. Types of reaction

The three types of method are described, and, for each of them, the measurement principles and the calculations which are applied by the system are explained.



### M.II. Volume correction factor

With:  $V_{R1}$  = Volume of reagent 1 (R1).

 $V_{R2}$  = Volume of reagent 2 (R2).

 $V_S$  = Volume of sample.

 $VCF_{RI}$  = Volume Correction Factor applied to mono-reagent methods (R1 absorbance is measured but must be corrected because of the dilution due to the addition of the sample).

 $VCF_{R2-1}$  = Volume Correction Factor applied to bi-reagent methods (R1+Sample absorbance is measured but must corrected because of the dilution due to the addition of R2).

 $VCF_{R2}$  = Volume correction Factor applied to bi-reagent end point methods (R1+R2 absorbance is measured during the calibration, R2 absorbance is then calculated but must be corrected because of the dilution due to the addition of sample).

The volume correction factors used in all the calculations are expressed as follows:

$$VCF_{R1} = \frac{V_{R1}}{V_{R1} + V_S}$$
$$VCF_{R2-1} = \frac{V_{R1} + V_S}{V_{R1} + V_{R2} + V_S}$$

$$VCF_{R2} = \frac{V_{R1} + V_{R2}}{V_{R1} + V_{R2} + V_{S}}$$

### M.III. Bichromatic correction

With: *PF* = Polychromatic Factor.

 $A_i$  = Absorbance at time  $t_i$  (with bichromatic correction when enabled).

 $A_{i,M}$  = Raw absorbance at time  $t_i$  for the main wavelength.

 $A_{i,\lambda 2}$  = Raw absorbance at time  $t_i$  for the secondary wavelength.

The corrected absorbance is  $A_i = A_{i,\lambda 1} - PF \times A_{i,\lambda 2}$ 

### M.IV. Variation of absorbance

#### M.IV.1. Mono-reagent method

With:  $A_i$  = Absorbance at time  $t_i$  (with bichromatic correction when enabled).  $A_{RI}$  = Absorbance of R1 (with bichromatic correction when enabled).  $VCF_{RI}$  = Volume Correction Factor applied to mono-reagent methods (see "M.II Volume correction factor" page 154).

The variation of the absorbance is given by  $\Delta A_i = A_i - A_{R1} \times VCF_{R1}$ 

### M.IV.2. Bi-reagent method

With: A<sub>i</sub> = Absorbance at time t<sub>i</sub> (with bichromatic correction when enabled).
A<sub>R2-1</sub> = Absorbance of R1+Sample (with bichromatic correction when enabled).
A<sub>R2</sub> = Absorbance of R2 measured during the calibration (with bichromatic correction when enabled).
VCF<sub>R2-1</sub> = Volume Correction Factor applied to bi-reagent methods (see "M.II Volume correction factor" page 154).
VCF<sub>R2</sub> = Volume correction Factor applied to bi-reagent method calibrations (see "M.II Volume correction factor" page 154).

The variation of absorbance is given by:  $\Delta A_{l} = A_{l} - A_{R2-1} \times VCF_{R2-1} - A_{R2} \times VCF_{R2}$ 

### M.V. End point method

### M.V.1. Sequence

- 1. Dispensing of R1.
- 2. Absorbance measurement (reagent blank).
- 3. Dispensing of sample.

- 4. Absorbance measurement.
- 5. Dispensing of R2 4 min 36 s after the dispensing of sample (bi-reagent methods).
- 6. Reaction end point.
- 7. Absorbance measurement.

After the dispensing of R1 into the cuvette, the system takes a first measurement to get the reagent blank. This value will be compared to the one defined in "Method configuration".

After the addition of the sample into the cuvette, the reaction starts and the system performs absorbance measurements every 12 seconds. At the same time, the measured values are compared to the ones obtained with a reference cuvette filled with deionized water.

### M.V.2. Calculations



\* Incubation period automatically added before the dispensing of the second reagent.

For bi-reagent end point methods, the absorbance of R2 is automatically estimated during the calibration. The system dispenses both reagents into a cuvette without sample and in the same proportions as those defined in the method.

With  $\Delta A_{EP}$  = Variation of the absorbance at the end point (see "M.IV Variation of absorbance" page 155). *f* = Calibration function determined during the calibration process (see "J.III.3 Calibration curve types" page 103).

The result is defined by the following equation:  $Res = f(\Delta A_{EP})$ 





\* Incubation period automatically added before the dispensing of the second reagent.

At the end of the reaction, the system compares the absorbance measured for the two last points: the last reading point and the one 12 seconds before.

With:  $\Delta A_{EP}$  = Variation of the absorbance at the end point (see "M.IV Variation of absorbance" page 155).  $\Delta A_{EP-1}$  = Variation of the absorbance 12 seconds before the end point. *% stability limit* = Highest variation per minute allowed at the end point. *t* = 12 s = 0.2 min

Stable end point if:

$$100 \times \left| \frac{\frac{\Delta A_{EP} - \Delta A_{EP-1}}{\Delta A_{EP}}}{t} \right| < \% \text{ stability limit}$$

If the difference is higher than the stability rate limit defined in the method, an "EP" flag appears on the test result, meaning that the end point is not stable enough. As a consequence, the patient prescription is considered as incomplete.

#### M.V.4. Verification of the prozone effect

It is considered that after one third of the time the reaction is developed up to approximately 80% and a plateau is reached. To ensure that it is, the system calculates the difference between the absorbance measured at the first third of the reaction and the one measured at the end. This variation is then compared to the value calculated for the calibration point with the highest concentration. The calculation can be done during the calibration and it is better to let the analyzer do it. This verification can be enabled in method configuration ("L.II.2 Reaction" page 137).

With:  $\Delta A_{EP}$  = Variation of the absorbance at the end point (see "M.IV Variation of absorbance" page 155).  $\Delta A_{EP/3}$  = Variation of the absorbance at one third of the reaction time. % prozone limit = Highest variation allowed during the last two thirds of the reaction. For increasing reactions:

$$100 \times \left| \frac{\Delta A_{EP/3} - \Delta A_{EP}}{\frac{\Delta A_{EP/3} + \Delta A_{EP}}{2}} \right| \le \% \text{ prozone limit}$$

For decreasing reactions:

$$100 \times \left| \frac{\Delta A_{EP/3} - \Delta A_{EP}}{\frac{\Delta A_{EP/3} + \Delta A_{EP}}{2}} \right| \ge \% \text{ prozone limit}$$

If the difference is higher than the prozone rate limit defined in the method, a "**P**\*" flag appears on the test result, meaning that a prozone issue has been detected. As a consequence, the prescription is considered as incomplete and the sample is automatically rerun using the "Above normal" result configuration.

# M.VI. Linear kinetic

### M.VI.1. Sequence

- 1. Dispensing of R1.
- 2. Absorbance measurement (reagent blank).
- 3. Dispensing of sample.
- 4. Absorbance measurement.
- 5. Dispensing of R2 4 min 36 s after the dispensing of sample (bi-reagent methods).
- 6. First reading time.
- 7. Absorbance measurement every 12 seconds until the last reading time.

Thus, the number of measurement depends on the delay setup between the first and the last reading points.

### M.VI.2. Calculations



\* Incubation period automatically added before the dispensing of the second reagent.

With:  $\Delta A / \Delta t$  = Slope of the reaction.

 $t_i$  = Time at point *i*.

 $\Delta A_i$  = Variation of the absorbance at time  $t_i$  (see "M.IV Variation of absorbance" page 155).

N = Number of measurements from first to last reading time (both included).

f = Calibration function determined during the calibration process (see "J.III.3 Calibration curve types" page 103).

$$\frac{\Delta A}{\Delta t} = \frac{\sum \left(\Delta A_i \times \frac{t_i}{N}\right) - \overline{\Delta A} \times \overline{t}}{\frac{\sum (t_i)^2}{N} - (\overline{t})^2}$$

The result is defined by the following equation:  $Res = f(\Delta A / \Delta t)$ 

### M.VI.3. Verification of the substrate depletion

The substrate depletion is checked when a limit of absorbance is defined in the method configuration. This limit is usually reached in case of very high analyte concentration but also if the reagent is outdated or improperly prepared.

With: $A_i$  = Absorbance at time  $t_i$  (see "M.IV Variation of absorbance" page 155). $t_i$  = Time at point i. $A_{lim}$  = Absorbance beyond which the substrate depletion is too low to have a linear and reliable reaction.

For increasing reactions:  $A_i \leq A_{lim}$ For decreasing reactions:  $A_i \geq A_{lim}$ 

If one measured absorbance is higher or lower (depending on the reaction way) than the limit defined in the method at least for one point from the first to the last reading point, an "**ABSLIM**" flag appears on the test result. As a consequence, the prescription is considered as incomplete and the sample is automatically rerun using the "Above normal" result configuration.

### M.VI.4. Verification of the linearity

The variation of absorbance during the last minute of the reading period is subtracted from the variation of absorbance during the first minute. This difference is divided by the total absorbance variation.



\* Incubation period automatically added before the dispensing of the second reagent.

With:  $\Delta A_{f}/\Delta t$  = Variation of absorbance over the minute after the first reading.  $\Delta A_{l}/\Delta t$  = Variation of absorbance over the minute before the last reading.  $\Delta A_{f}$  = Difference of absorbance between the first reading time absorbance and the initial absorbance (see "M.IV Variation of absorbance" page 155).  $\Delta A_{l}$  = Difference of absorbance between the last reading time absorbance and the initial absorbance (see "M.IV Variation of absorbance" page 155).  $\Delta A_{l}$  = Difference of absorbance between the last reading time absorbance and the initial absorbance (see "M.IV Variation of absorbance" page 155). *Maximum deviation* = Highest change rate allowed between the first and last reading periods.



If the time between first and last reading is less than 2 minutes, the system calculates each  $\Delta A$  on half of the setup time.

Correct linearity if:

$$100 \times \frac{\frac{\Delta A_{l}}{\Delta t} - \frac{\Delta A_{f}}{\Delta t}}{\frac{\Delta A_{l}}{\Delta A_{l}} - \Delta A_{f}} \leq \% \text{ maximum deviation}$$

If the deviation is higher than the limit defined in the method, an "LIN" flag appears on the test result, meaning that the reaction exceeds the linearity limit. As a consequence, the prescription is considered as incomplete.

### M.VII. Fixed time kinetic

### M.VII.1. Sequence

- 1. Dispensing of R1.
- 2. Absorbance measurement (reagent blank).
- 3. Dispensing of sample.
- 4. Absorbance measurement.
- 5. Dispensing of R2 4 min 36 s after the dispensing of sample (bi-reagent methods).
- 6. First reading time.
- 7. Absorbance measurement.
- 8. Last reading time.
- 9. Absorbance measurement.

### M.VII.2. Calculations



\* Incubation period automatically added before the dispensing of the second reagent.

With:  $\Delta A_1$  = Variation of the absorbance at the first reading time (see "M.IV Variation of absorbance" page 155).  $\Delta A_2$  = Variation of the absorbance at the last reading time (see "M.IV Variation of absorbance" page 155). *f* = Calibration function determined during the calibration process (see "J.III.3 Calibration curve types" page 103).

The result is defined by the following equation:  $Res = f(\Delta A_2 - \Delta A_1)$ 

### M.VII.3. Verification of the substrate depletion

This verification is the same as the one explained for linear kinetic reactions (see "M.VI.3 Verification of the substrate depletion" page 161).

### M.VIII. Twin reaction

### M.VIII.1. Séquence

- 1. Dispensing of R1.
- 2. Absorbance measurement (reagent blank).
- 3. Dispensing of sample.
- 4. First reaction (end point or kinetic).
- 5. Absorbance measurements at required reading times.
- 6. First intermediate result.
- 7. Dispensing of R2.
- 8. Second reaction (end point or kinetic)
- 9. Absorbance measurements at required reading times.
- 10. Second intermediate result.
- 11. Calculation formula involving intermediate results.
- 12. Final test result.

### M.VIII.2. Calculations and verifications

The calculation and the verification of the intermediate results entirely depend on the type (end point, linear kinetic or fixed time kinetic) that has been setup for the two related reactions. For more details, refer to "M.V End point method" page 155, "M.VI Linear kinetic" page 159 and "M.VII Fixed time kinetic" page 163.

With:  $Res_1$  = Result of the first reaction.

*Res*<sup>2</sup> =Result of the second reaction.

The final test result for twin reactions is:  $Res = \frac{Res_2}{Res_4} \times 1000$ 

# N. Software options

#### From "Main screen" => "Configuration" => "Options"



This screen is made to change the main settings and to customize the respons®910VET analyzer software. Several tabs allow switching between different characteristics of the software.

Two buttons are displayed on the function bar:

- "Exit": Goes back to the main screen.
- "Save changes": Saves the modifications made to the software settings.

## N.I. System

### From "Main screen" => "Configuration" => "Options" => "System"

ninistrator>	- TOP MENU BAR : OPTIONS -
vstem Analysis Printer Barc Language English Operator access TimeOut	de Reader       Backups       LIS       Information       Field Service       Species       Appearance & Sounds       Method Orderin         Image: Species       Automatic screen adaptation       Automatic lamp switch on at system start-up       Automatic cuvettes scan enabled         Image: Species       Automatic cuvettes scan enabled       Foam Detector enabled       Foam Detector enabled
System Time Current time Current Date format ISO Compliant T Cu I Use [Time] in Sampling tir	one : (UTC+01:00) Bruxelles, Copenhague, Madrid, Paris date : 2015-04-30 Current time : 15:43:19 rent Date/Time : 2015-04-30T15:43:19 estamp
Upgrade Diasys da	abase

This tab allows changing settings related to the system:

- Choice of the language for the entire software.
- Activation/inactivation of the 16/9 ratio screen adaptation.
- Activation/inactivation of the automatic power on of the lamp at the startup of the system.



It is not recommended to disable the automatic lamp switching as the system will not be ready for analysis straight after the start-up. The lamp needs a few minutes to heat-up.

- Activation/inactivation of the automatic cuvettes scan prior to the launch of the work list to find the clean cuvette segments.
- Activation/inactivation of the bubbles and foam detectors.
- Choice of the operator access time-out (time of inactivity before the system logs the operator out).
- Choice of the current time zone, date and time and of the date format used in the entire software.
- Upgrade of the database provided by DiaSys GmbH (for operators with administrator rights only).

To import the most recent DiaSys database, press "**Upgrade Diasys database**". The following screen appears.

						· · ·
<admini< th=""><th>strator&gt;</th><th>- TOP MENU</th><th>BAR : Databa</th><th>se import -</th><th></th><th></th></admini<>	strator>	- TOP MENU	BAR : Databa	se import -		
	Sel	ect an option below			2	<u>.</u>
	Impo	nt new Diasys methods using a USB stick				
	Imp	oort Diasys methods (2011-09-03)				
	Online	import Diasys methods				
	☐ Don't import the da	tabase. Do a simulation.			<u>-</u>	-
1	EXIT				PRIN	г

There are three ways to upgrade the database:

- "Import new Diasys methods using a USB stick": Imports the new database from a file stored on a USB stick.
- "Import Diasys methods (YYYY-MM-DD)": Imports the new database from a file stored in the software itself. The date of the last software update is displayed.
- "Online import Diasys methods (YYYY-MM-DD)" (greyed if no database is available online): Imports the new database from a file that is available on internet. The date of the last software update is displayed.

The right part of the screen lists all the modifications that have been made to update the database (empty list on the picture). To display it without overwriting the current database, check the option "Don't import database. Do a simulation". If the list seems correct, uncheck the option and import the new database for real.

There are two buttons on the function bar:

- "Exit": Goes back to the main screen.
- "Print": Prints the list of modifications.

# N.II. Analysis

### From "Main screen" => "Configuration" => "Options" => "Analysis"

	4 🔤 🏑
ministrator> - TOP MENU BAR : OPTIONS -	
System Analysis Printer Barcode Reader Backups LIS Information Field Service Species Appearance & Sounds Method	Ordering
<ul> <li>Wait for calibration completion before starting related controls</li> <li>Wait for control completion before starting related patient analysis</li> </ul>	
Display age instead of date of birth on patient results	
<ul> <li>Control results are checked according to Westgard rules</li> <li>Control Results are checked according to provided drift</li> </ul>	
Allow replicates for patient tests WARNING : Reruns & calculated methods will be disabled for tests with replicates	
V Use additional Control Results diagrams	
✓ Use +3S/-3S instead of High/Low limits for control result checking WARNING : This is different from +3SD/-3SD	
✓ Schedule Management activated Near expiration factor 50 % of calibration stability	
<ul> <li>Don't check calibration stability status of methods when running control &amp; patient analysis WARNING : Checking this option will disable internal validations (results will be flagged CAL_WARN)</li> <li>Don't check control status of methods when running patient analysis WARNING : Checking this option will disable internal validations (results will be flagged QC_WARN)</li> <li>Allow ReRuns on STATs (this will lead STAT drawer to remain closed until analysis completion)</li> </ul>	
Special mode for low patient samples volume aspiration.	
The 2 pictograms of the mode will be displayed on the main screen. The liquid sensor is disabled for aspiration in the patient samples, only low volumes must be on the rotor. This is for patient samples only. Controls and calibrators aspiration are not modified by this mode.	

This tab allows changing settings related to the software behavior during analysis:

- Launching of the controls before getting the related calibration results.
- Launching of the animal analysis before getting the related control results.
- Choice to display the animals' age or date of birth on results.
- Verification of the control results according to the Westgard rules.
- Verification of the control results according to the provided drift.
- Activation/inactivation of replicates for animal analysis.
- Use of extra control results diagrams.
- Use of different control verifications.
- Activation/inactivation of the schedule management window (see "F.V Schedule management window" page 51) and definition of the delay after which the

calibration is considered as nearly expired (in percentage of the whole calibration stability time).

- Activation/inactivation of the verification of the calibration stability status before running controls and/or animal prescriptions ("System Validation OFF" will be displayed on printings in case of activation). Only the calibration stability checking can be inactivated. The other ones (on-board stability, lot numbers, etc...) cannot. Moreover, if no calibration data is available at all for a method, the related prescriptions could not be run.
- Activation/inactivation of the verification of the control status before running animal prescriptions ("System Validation OFF" will be displayed on printings in case of activation).
- Activation/inactivation of the reruns for analyses run from a STAT position.
- Activation/inactivation of the "low sample volume" mode used if only a very few amount of sample is available.



When the "low sample volume" mode is enabled, the system is unable to detect the liquid level and the probe is going deep into the sample container, even if this one is full.

# N.III. Printer

### From "Main screen" => "Configuration" => "Options" => "Printer"

Stem       Analysis       Printer       Barcode Reader       Backuton         Automatic Printing       Calibration results       Control results       Printer Type         Printer Type       Dot Matrix Printer       I order per page         Clear print spooler       Clicking on this button cancels all the pending printings	ups       LIS       Information       Field Service       Species       Appearance & Sounds       Method Ordering         Select printer to use :       PDF Creator       Microsoft XPS Document Writer       Imprimante d'image PaperPort         Fax       Envoyer à OneNote 2010       Brother QL-570         Brother MFC-J6910DW Printer (Copie 1)       Brother MFC-J6910DW

This tab allows changing settings related to printers:

- Activation/inactivation of the automatic printing for calibrations, controls and analysis results.
- Activation/inactivation of a dot matrix printer use.
- If using a dot matrix printer, selection of the mode (continuous or one order per page).
- Cancellation of all the pending printings.

### N.IV. Barcode Reader

### From "Main screen" => "Configuration" => "Options" => "Barcode Reader"

ministrator>	- TOP MENU BAR : OPTIONS -
ystem Analysis Printer Barcode Re	der Backups LIS Information Field Service Species Appearance & Sounds Method Ordering
Enabled for reagents	
Enabled for samples	
Checksum Digit	
Fixed length barcodes :	
Number of scanning passes	3 💌
Estimated scannin	time: 1m 00s
Barcoded controls	
E Barcode starts with	004225037
<ul> <li>Barcode starts with</li> <li>Skip barcodes confirmation screen Notice that activating this option could</li> </ul>	004225037 (The screen will disappear after a small delay) cause barcode reading problems if no Checksum digit is available.
<ul> <li>Barcode starts with</li> <li>Skip barcodes confirmation screen Notice that activating this option could</li> </ul>	004225037 (The screen will disappear after a small delay) cause barcode reading problems if no Checksum digit is available.
<ul> <li>Barcode starts with</li> <li>Skip barcodes confirmation screer Notice that activating this option could</li> </ul>	004225037 (The screen will disappear after a small delay) cause barcode reading problems if no Checksum digit is available.

This tab allows changing settings related to the barcode reader:

- Activation/inactivation of the barcode reading for reagents. When enabled, a reagent tray is automatically generated according to the bottles detected.
- Activation/inactivation of the barcode reading for samples.
- Choice of the number of scanning passes (to make sure that the barcodes have been correctly identified).
- Activation/inactivation of the checksum digit.
- Activation/inactivation and choice of a fixed length barcode.

- Activation/inactivation of barcodes on control tubes. When enabled, the checkbox "barcode starts with" allows choosing which barcode header will be used for controls (optional).
- Activation/inactivation of the automatic closing (after 12s) of the barcode confirmation screen before starting a run.



To limit the risk of reading errors, it is recommended to enable at least one of the two options "checksum digit" or "fixed length barcodes".

### N.V. Backups

### From "Main screen" => "Configuration" => "Options" => "Backups"

<administrator> - TOF</administrator>	MENU BAR :	OPTIONS -		
<administrator>     - TOF System Analysis Printer Barcode Reader Backups Database backup frequency Cleanup raw data entries older than Cleanup prescriptions and results older than Compress database if gain is more than Number of backup files to keep on hard disk</administrator>	MENU BAR : LIS Information 7 days 14 days 60 days 100 Mbyte: 5	OPTIONS - n Field Service Species (maximum value is 3 (maximum value is 7 s (maximum value is 7 s (maximum value is 7	Appearance & Sounds 15 days) 30 days) days) 1000 Mbytes)	Method Ordering
EXIT				SAVE CHANGES

This tab allows changing settings related to the database backup management. The database contains everything that is visible in the software (results, method configurations, solutions...) except the settings defined in the Configuration/Options screen.

The database backup (every 7 days on the picture) requires several steps:

- Database cleaning:
  - Deletion of the raw data older than "x" days (14 on the picture).
  - Deletion of prescriptions and results older than "x" days (60 on the picture). For the calibration results, the last one is always kept in the database, even if it is older than the specified value.
  - Deletion of the expired reagent bottles (automatically the same value as for the raw data).
- Database compression: only if it allows a gain of at least "x" Mbytes (100 on the picture). The purpose of this step is to shrink the database size on the hard disk.
- Database backup: the whole database is copied on the hard disk without exceeding "x" backup files (5 on the picture). The oldest backups are deleted.
- Database archiving: the database can be saved on an external media device (during the next startup of the software).

# N.VI. LIS

### From "Main screen" => "Configuration" => "Options" => "LIS"

Protocol	Protocol Settings	opecies / opeciaties a counts   method	ordening
		IA 0010	
<no datalink=""></no>		SIL DO10	
RAXT	Default Eramo Sizo		
ASTM/ISO	Allow 7 Frame	true	
MIRA	Control Name is in frame 9.1.6	true	
	Control Lot is in frame 0.4.4.2	true	
Hitachi	Loguacious Protocol / closer to ASTM than ISO 18	3812) true	
	Linknow Sex Code ( " or "!")	1	
Server 127.0.0.1	Debug Mode Allow partial analysis	false	
	Urine Code	U	
Port : 1111	Blood Code		
Sec. 10	Plasma Code		
This PC is	Whole Right Code	C	
C Server Client	System Automatically Queries Host for Worklist	true	
	System Automatically Sends Results	true	
	Use UTF8 Encoding for non ANSI characters	false	
	BIDIR local testing	true	
	TimeOut for ACK (s)	15	
	TimeOut for Frame (s)	15	

This tab allows changing settings related to the bidirectional interface (see part "R.IV.1 BIDIR Settings main screen" page 217 for further details). The respons®910VET analyzer can be connected to a LIS (Laboratory Information System), thus the type of protocol to use can be selected.
# N.VII. Information

#### From "Main screen" => "Configuration" => "Options" => "Information"

Versions			U	sage counters		
Modulo	Eirmwar		— <sub>т</sub>   [	Method	Usage	Ī.
Hydro Arm Rotor Syringe Colo Restriction 5 Spe	H221013 S160610 S160610 C070808	BH MM MM BD ds		CHE (R806) Crea PAP (R807) Natrium 4 (R809) RF2 (R816) Natrium 2 (R812) Chlorid 1 (R808) RF (R811) PAMY (R815) CHOL (R024) UREA (054) ALT (010) DBIL (R018) Ca P (R804) AP (R014) FE (R042) Ritis (R817) CREA Jaffe (R032) Natrium 1 (R810) GGT (R034) CHEtzt (Rtzt)	56 50 49 44 41 33 27 19 14 14 14 10 9 5 5 4 3 2 1	

This tab displays miscellaneous information:

- Analyzer serial number.
- Firmware version for the different modules.
- Number of specific methods (non DiaSys methods) allowed.



When purchasing the analyzer, the restriction is five. Contact your local representative if you need more specific methods.

Number of tests performed for each method.

# N.VIII. Field Service

#### From "Main screen" => "Configuration" => "Options" => "Field Service"

<administrator></administrator>	- TOP MENU BAR : OPTIONS -	
System Anal	ysis   Printer   Barcode Reader   Backups   LIS   Information   Field Service   Species   Appearance & Sounds   Metho	d Ordering
R	emote Assistance	
	Prepare Logs	
	Enter code	
EXIT		SAVE CHANGES

This tab is intended to be used upon request of a maintenance team member only. The log preparation and the remote assistance are protected by a specific password. The code that can be entered is used to specify the number of specific methods allowed. This can only be done by a distributor.

## N.IX. Species

#### From "Main screen" => "Configuration" => "Options" => "Species"

	<u></u>
System Analysis Printer Barcode Reader Backups   LIS   Information Field Service Species   Appearance & Sounds   Method	d Ordering
List of Species   Hostcode     Cat Male   CTM     Cat Female   CTF     Dog Male   DGF     Bird   BRD     Fish   FSH     Gorilla Male   GM	
EXIT	SAVE CHANGES

This tab allows the management of the species and of their related host code used for the animal prescriptions. The host code is the identifier of the species for the host interface. Its definition is recommended if the bidirectional interface is set. Three buttons can be used:

- "Add": Adds a new species to the list. A name and its host code must be entered in the field on the left before clicking on this button.
- "Delete": Deletes the selected species.
- "Change": Allows changing the name or the host code of the selected species.

# N.X. Appearance & sounds

#### From "Main screen" => "Configuration" => "Options" => "Appearance & sounds"

dministrator>			- TO	P MEN	U BAR : OI	PTIONS -			
System Analysis	Printer	Barcode Reade	r   Backups	LIS	Information	Field Service	Species	Appearance & Sounds	Method Ordering
Click to select th	e backgro	und color of the	Main Screen	1	1				
Click on the squa	are button.	s to select sour	d tone						
I Enable on e	rrors		I Enable	on warn	ings		Enable or	n error boxes	
1	Play			Play	<u>ta</u>			Play	

This tab allows changing settings related to the background of the main screen and the sounds:

- Selection of the background color of the main screen.
- Activation/inactivation of sounds on errors, warnings and error boxes.
- Personalization of the sounds played on errors, warnings and error boxes.

# N.XI. Method ordering

#### From "Main screen" => "Configuration" => "Options" => "Method ordering"

lame : Sorting tray	•	New		)elete	pecies   Appear		
Method Type AST AST + p5p Ca P Ca P 2 TZT Ca P 3 TZT CHE CHEtzt Chlorid 1 CHOL CK-MB CK-NAC CREA Jaffe CREA Jaffe CREA Jaffe GGT CREA Jaffe		ALB	ALT	ALT + p5p	AMY	AP	Image: red order   Imag
Default ordering	Entry screens	Alphabetical (	Order>		I	Results <a>Alphab</a>	etical Order>

This tab allows creating lists according to which the methods can be sorted in entry and result screens. The icon displayed for each method depends on the type of method (mono-reagent, bi-reagent or calculated).

# O. Maintenance

# O.I. Maintenance notebook

#### From "Top menu bar" => "Maintenance" => "Maintenance notebook"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit
				Maintenance		
			1000 100 100 100 100 100 100 100 100 10	notebook		
				Turn lamp off		
				Photometer		
				adjustment		
				Probe exchange		
				Cleaning		
				Priming &		
				purging		

	operator		
Maintenance operations performed	Administrator	2015-04-30 T15:42:10	$\overline{0}$
Reagents to replace by next month	Administrator	2015-04-30 T15:42:10	
			_
			ெப
Decontamination.			
Decontamination.			
Decontamination.			

This tool allows any operator with appropriate rights to record a short message in a dedicated notebook.

There are three buttons on the function bar:

- "Back": Goes back to the main screen.
- "Delete": Deletes the selected note.
- "New": Allows the creation of a new note. When clicking on this button, the screen switches to the edition mode. Only two buttons are then displayed: "Cancel" to go back to the main screen without adding anything and "Save" to save the note.

## O.II. Maintenance calendar



# Rigorously following this table reduces the risk of contamination and increases the lifetime of the respons®910VET analyzer.

FREQUENCE	INTERVENTION	CHAPTER
	1. Install new cuvettes.	-
	2. Check level in the water tank and drain.	-
End of Day	1. Quick probe cleaning at the end of the day (with cleaner B).	O.III.3.h
End of Day	2. Remove used cuvettes.	-
	1. Complete probe cleaning with cleaner B and alcohol.	O.III.3.h
WEEKIY	2. Clean the water tank.	O.III.3.g
	3. Wipe the surfaces.	O.III.3.b
	4. Change or clean diluent and cleaner bottles.	O.III.3.c
	1. Decontaminate hydraulic circuit.	O.III.3.h
MONTHLY	2. Decontaminate the wash station.	O.III.3.f
	3. Clean removable tray.	O.III.3.d
	1. Check lamp emission level.	O.III.1.b
BIMONTHET	2. Replace lamp if necessary.	O.III.1.c
	1. Purge bubbles if the analyzer has been inactive for a long time.	O.III.4
	2. Replace probe if it seems bent, scratched or if droplets are	O.III.2.a
	projected.	
OCCASIONALLY	4. Change or clean diluent and cleaner bottles.	O.III.3.c
	3. Perform probe cleaning if system stops by error.	O.III.3.h
	4. Replace power switch fuses.	O.III.5
	5. Clean cuvette holders.	O.III.3.e

#### O.III. Maintenance procedures

#### O.III.1. Lamp maintenance

#### O.III.1.a. Lamp turning off

#### From "Top menu bar" => "Maintenance" => "Turn lamp off"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit
				Maintenance		
				notebook		
			was not soon one toos one of the	Turn lamp off		
			,	Photometer		
				adjustment		
				Probe exchange		
				Cleaning		
				Priming &		
				purging		

This function switches the lamp off to allow its replacement. "Turn lamp off" is then replaced by "Turn lamp on" to allow switching the lamp on again.

From "Top menu bar" => "Maintenance" => "Turn lamp on"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit
				Maintenance		
				notebook		
				Turn lamp on		
			,	Photometer		
				adjustment		
				Probe exchange		
				Cleaning		
				Priming &		
				purging		



Before any maintenance on the lamp, switch the analyzer off and wait for at least 30 minutes in order to allow the lamp to cool down.

#### O.III.1.b. Checking of the lamp intensity

From "Top menu bar" => "Maintenance" => "Photometer adjustment"





This tool allows a recalibration of the photometer. Prior to the adjustment, all the cuvette segments must be removed.

The vertical colored bars display the output level for each channel of the photometer. The number below is the gain level for each of them. After the heating time, when the lamp temperature is stabilized, the bars are green if the adjustment is good. If they are not, an adjustment must be done by clicking on "**Adjust**" (the button is greyed until the end of the heating) to maintain an optimal gain on every channel of the photometer.

Once the photometer has been adjusted, all channels must be green. In case of adjustment error, the lamp shall be replaced.

#### O.III.1.c. Lamp exchange

To replace the lamp:

- Switch the analyzer off and wait at least 30 minutes to allow the lamp to cool down.
- 2. Unscrew the opening on the right of the analyzer with a flat screwdriver.





4. Remove the lamp by pulling the wire.





 Hold the new lamp by the wires and insert it (only one valid position).

- 6. Screw the lamp, the electrical connections and the opening.
- 7. Turn the light on and wait for two hours (stabilization time).

#### O.III.2. Probe maintenance

From "Top menu bar" => "Maintenance" => "Probe exchange"



This tool is used for probe exchange and adjustment.

#### O.III.2.a. Probe exchange



- 1. Click on "Replace Probe" to home the robotic arm.
- 2. Completely unscrew the probe and remove it.
- 3. Completely screw the new probe.
- 4. Click on "Adjust Probe".

#### O.III.2.b. Probe adjustment

Click on "Adjust probe" to start the adjustment. Once it is done, the boxes next to "Probe length adjustment" and "Wash station positioning" are shown in green. The position of the probe above one of the three holes of the wash station appears on a picture and must be checked (at this stage, the dome is unlocked to allow it). The red arrow gives information about the quality of the probe detection which is more reliable when the arrow gets closer to the green middle part. On the top right of the screen, a scheme shows the estimated probe tip position. The blue cross in the middle of the triangle means that the probe is straight. If the probe looks bent or if it is not well positioned above one of the holes in a way that would allow it to enter the hole, then it must be replaced.

#### O.III.3. Cleaning

#### O.III.3.a. Cleaning agents

The recommended surface cleaning solutions are water and isopropyl alcohol.

#### O.III.3.b. Cleaning of the surfaces

The cuvette cover should remain closed during cleaning. Use water, wipe and dry all surfaces.



Never clean the dome with dry material. Use a wet soft sponge, cloth or washleather and light duty-detergent.

#### O.III.3.c. Cleaning of the bottles

For diluents and cleaners only. Reagent bottles must not be refilled. Rinse the bottles with de-ionized or distilled water and dry them.

#### O.III.3.d. Cleaning of the removable tray

The tray can be cleaned in a dishwasher with regular detergent. All adaptors must be removed before cleaning.

#### O.III.3.e. Cleaning of the cuvette holders

In case of cuvette holder contamination, use a vacuum cleaner to remove any fiber or dust. Do not use water.

Manually rotate the tray, remove the cuvettes and aspirate the dust from the sockets.

#### O.III.3.f. Cleaning of the wash station

Pour some 10% sodium hypochlorite solution in the three cavities, rinse the wash station seven times and perform a probe cleaning.

It is strongly recommended to measure the pH of the liquid system before and after the cleaning procedure to ensure that the rinsing removed all traces of sodium hypochlorite. This measurement can be done during the priming procedure (see "O.III.4 Priming and purging" page 197).

#### O.III.3.g. Cleaning of the water tank

Wash the water tank in a dish washer then rinse it several times with distilled water and dry it before filling it again.



To remove the water tank, pull it out of the analyzer as to fill it then press the button on the right hand side (as shown on the picture).

#### O.III.3.h. Probe cleaning and decontamination of the hydraulic circuit

## From "Top menu bar" => "Maintenance" => "Cleaning"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit
				Maintenance		
				notebook		
				Turn lamp off		
				Photometer		
				adjustment		
				Probe exchange		
				Cleaning		
				Priming &		
				purging		
			Clean Probe			
		Г	Decontaminati	ion		
EXIT						

This tool is used to clean the probe and decontaminate the hydraulic circuit.

Place a bottle filled with a cleaner (e.g. cleaner B provided by DiaSys Diagnostics Systems GmbH) on the first position of the reagent tray and click on "**Clean Probe**" to perform a quick probe cleaning. The software is then providing full guidance all along this process.

For a complete procedure, wash the lower 3 cm of the probe external surface with alcohol. Special precautions must be taken:

- Wear protection gloves to avoid any injury.
- Do not bend the probe.
- Do not leave fibers or dust on the probe extremity.

To perform a decontamination of the hydraulic circuit, follow the steps below:

- 1. Prepare about 1L of 10% sodium hypochlorite solution.
- 2. Empty the water tank and fill it with the sodium hypochlorite solution.
- 3. Click on "Decontamination" and wait until the water tank is empty.
- 4. Thoroughly rinse the water tank.
- 5. Completely fill the water tank with distilled water.
- 6. Repeat the decontamination process.
- 7. Run a priming process.



On the function bar, the button "Exit" goes back to the main screen.

#### O.III.4. Priming and purging

#### From "Top menu bar" => "Maintenance" => "Priming & purging"

Work List	Entries	Results	Configuration	Maintenance	Help	Quit
				Maintenance		
				notebook		
				Turn lamp off		
				Photometer		
				adjustment		
				Probe exchange		
				Cleaning		
				Priming &		
				purging		
			Prime			
			Purge bubble	s		
			•			
EXIT						

This tool is used to purge the bubbles that may appear within the tubing and to fill the hydraulic system with fresh distilled water.

Click on "**Purge bubbles**" to remove unexpected bubbles that were detected by the system and that can disturb the measurements. The software is then providing full guidance all along this process.

Place a bottle filled with deionized water on the first position of the reagent tray and click on "**Prime**". The analyzer then pumps water from this bottle to fill the hydraulics. The software is providing full guidance throughout this process.

#### O.III.5. Power switch fuse replacement

- 1. Disconnect the power cable from the analyzer.
- 2. Remove the fuse box located just above the power plug by pulling the plug on its low border.



- 3. Replace the fuses (SPT 5AT 5x20 fuses).
- 4. Put the fuse box back into its location.
- 5. Reconnect the power cable to the analyzer.

# P. Troubleshooting



Most of the following problems can create erroneous results. This list should be checked in case of any doubt concerning the results.

Problem	Corrective action
No connection between PC and	Switch the analyzer off and then on again. Check the USB cable.
analyzer	Exit and re-launch the software.
Motor problem on rotor, arm or suringe	During analysis check whether "abnormal noise" occurs. In such
	case, contact your local DiaSys representative.
	Remove the probe. Insert a fine nylon wire (Ø 0.5 mm max.) in
Clogged probe	the large hole of the probe and push it until it goes through the
	small hole. Remove it and put the probe back on the robotic arm.
	If the probe is frequently clogged you may have to replace it.
Wrong probe adjustment	Use the "Probe adjustment" tool to check and adjust the probe.
	Check that the tray is perfectly flat and can be inserted and
Wrong roton odiustment	removed without excessive backlash. Use the "Probe
wrong rotor adjustment	adjustment" tool as this will also adjust the functional parameters
	of the rotor.
Contaminated water	Refer to chapter "O Maintenance" page 185.
When a shot proton a division and	Use the "Photometer adjustment" tool ("O.III.1.b Checking of the
wrong photometer adjustment	lamp intensity" page 189) to check and adjust the photometer.
Contaminated waste tubing or probe	Refer to chapter "O Maintenance" page 185.
Contaminated wash station	Refer to chapter "O Maintenance" page 185.

# Q. Messages and analytical flags

# Q.I. Messages when starting the work list

 $``\mathsf{ID"}$  is the number displayed on the screen next to the message.

"---" replaces variable data.

ID	Error message	Meaning
2020	Sample is not located at position Sample at position is not detected as the correct type of container. Bottle () is not found.	According to the barcodes, some bottles or samples are not at the correct position on the tray. Check the positions and the type of sample tubes and reagent containers.
2082	The analyzer is not correctly connected to the PC or is not powered on. Check the status and try again	The communication between the PC and the analyzer is not working. Try to switch the analyzer off then on again, check the USB cable, exit and restart the software.
2083	The analyzer is busy or switched off.	Switch the analyzer on or restart the whole system (analyzer and PC).
2084	Air detected in hydraulic system. Purge is needed.	Run the purge bubbles maintenance tool prior to start the analysis (see "O.III.4 Priming and purging" page 197).
2085	Not enough valid cuvettes detected. valid cuvettes are needed. Please add new segments or replace the used segments by clean ones.	More cuvettes than detected are required to process the current work list. Please set new cuvettes in the rotor.
2091	Communication problem	Communication was lost: check that the cable still connects the instrument to the PC.
2092	Error: Problem with the communication.	The communication between the PC and the analyzer is not functioning. Try to switch the analyzer off then on again, check the USB cable, exit and restart the software.
2093	Error: Problem with the settings.	Some important settings are invalid. Please contact your local representative.
2094	Error: Dome not locked.	The dome is not closed or a hardware error occurred. In the latter case, contact your local representative.

ID	Error message	Meaning
2095	Error: Problem with the robot initialization.	Error during the initialization of the mechanics. Start again and give this information to your local representative.
2096	Error: Problem with the lamp testing.	Problem with the level or the stability of the lamp. Run the photometer adjustment tool (see "O.III.1.b Checking of the lamp intensity" page 189) to check the lamp signal. If needed, replace the lamp (see "O.III.1.c Lamp exchange" page 190).
2097	Error while purging tubing. Water Tank may be empty.	Fill the water tank, run the purge bubbles maintenance tool (see "O.III.4 Priming and purging" page 197) then start again.
2099	Liquid Level Detector: Noise on readings >4 in air (missing arm cover?).	The LLD readings are not stable. The arm cover may be missing.
2100	Liquid Level Detector: all readings >240 (probe missing?).	The probe may be missing.
2101	Liquid Level Detector: all readings = 0 in air (hardware problem?).	May be due to a hardware failure. Contact your local representative.
2102	Lamp: the maximum amplification 255 is reached. The lamp must be replaced.	Adjust the photometer (see "O.III.1.b Checking of the lamp intensity" page 189) or replace the lamp (see "O.III.1.c Lamp exchange" page 190).
2103	Error: Problem with the temperature.	The analyzer cannot accurately regulate the temperature of the reactions. Switch the instrument off for 2 minutes then start again. Contact your local representative.
2104	Water tank not connected.	The water tank is not or badly installed.
2105	Not enough water in tank.	A minimum amount of water is necessary to start working. Fill the water tank.
2106	Mechanical problem: step-loss on the syringe module.	The analyzer syringe module is not working properly, or the probe is obstructed. Try to replace the probe (see "O.III.2.a Probe exchange" page 192) and start again. Contact your local representative.
2107	Mechanical problem: step-loss on the arm module.	The analyzer robotic arm is not working properly. Contact your local representative.

ID	Error message	Meaning
2108	Incorrect reading in cuvettes. (Mainly cuvette). Please check cuvettes and the photometer adjustment.	Inspect the given position, replace the cuvette segment and start again. If the problem is not on the given position or cuvette, proceed to a photometer adjustment (see "O.III.1.b Checking of the lamp intensity" page 189).
2110	Stagnant waste in wash station.	The waste tubing may be obstructed.
2112	The tray is not positioned correctly. Please check the locking.	See "E.VI.1 Tray handling" page 33.
2113	Some cuvettes do not seem to have been replaced. Replace them all and try again.	New cuvettes may not be read correctly. Used cuvettes are set instead of new ones, cuvettes are not properly set in the holder or there is a foreign material in one of the holders. Inspect the cuvette holder, replace the cuvette segment(s) or proceed to a photometer adjustment (see "O.III.1.b Checking of the lamp intensity" page 189).
2114	Unable to connect to LIS.	The communication with the laboratory information management system (LIMS or HOST or LIS) is not established. This can be due to a disconnected wire, a network failure in the lab or a configuration mismatch. Contact your local representative.
2115	Some needed cleaners are not available on the current tray. Please correct this before starting an analysis. List of missing cleaners:	One or more cleaning solutions are missing on the tray. Add the requested solutions on the tray then start again.
2119	Unstable optical reading through the cuvette [noise =] (ensure that the cuvette is new or that the holder is empty).	The photometer does not measure stable values. Check that there is no used cuvette in the mentioned position, run the photometer adjustment tool (see "O.III.1.b Checking of the lamp intensity" page 189) or replace the lamp (see "O.III.1.c Lamp exchange" page 190). If the lamp has been replaced, it needs about 2h to heat.
2128	Position is not empty on the tray. Please free this position.	Remove the sample or the reagent bottle from the mentioned position.
2140	Liquid Level Detector: Some readings = 0 in air (hardware problem?).	May be due to a hardware failure. Contact your local representative.

ID	Error message	Meaning
2141	Liquid Level Detector: Peak values >240 in air (missing arm cover?).	The LLD readings are not stable. The arm cover may be missing.
2142	Can't get optical reading higher than 5000 through the cuvette (Ensure that the cuvette is new or that the holder is empty).	Check that there is no used cuvette in the mentioned position, run the photometer adjustment tool (see "O.III.1.b Checking of the lamp intensity" page 189) or replace the lamp (see "O.III.1.c Lamp exchange" page 190).
2143	Liquid Level Detector: value in air is too low.	Bad LLD values. No pipetting can take place. Flag on results.

# Q.II. Messages during analysis run

"ID" is the number displayed on the screen along the message in the message list (see "F.IV Message bar" page 50).

"---" replaces variable data.

ID	Error message	Meaning
1	The sample position can't be run on this tray.	No reagent on the tray for the required sample.
2	CarryOver due to lack of	Lack of cleaner. Flag on results.
3	Too CPU intensive softwares are currently running on this computer.	Other softwares have probably been launched. Only the respons®910VET analyzer software can be used on the analyzer PC. Inform your local representative.
4	Lack of reagent position	The liquid level detector did not detect anything in the reagent bottle. Flag on results.
5	Lack of diluent position	The liquid level detector did not detect anything in the diluent bottle. Flag on results.
7	Lack of sample position	The liquid level detector did not detect anything in the sample tube. Flag on results.
8	Not enough cuvettes available for a re- run.	Not enough clean cuvettes available to perform a required re-run. Flag on results.
9	Unavoidable carryover (>,).	The system could not avoid two consecutive tests with the first one contaminating the second. Flag on results.

ID	Error message	Meaning
12	You may have forgotten a bottle cap on the reagent position	The probe was blocked while going down to the reagent bottle. This bottle is ignored for the rest of the run. Flag on results.
13	You may have forgotten to remove tube cap on sample position	The probe was blocked while going down to the sample tube. The sample is ignored for the rest of the run. Flag on results.
14	You may have forgotten to remove tube cap on sample position STAT	The probe was blocked while going down to a sample tube on a STAT position. This sample cannot be analyzed. Flag on results.
15	Bubbles detected. Check Water Tank.	Air has been detected in the hydraulic circuit. Run the purge bubbles maintenance tool (see "O.III.4 Priming and purging" page 197). Flag on results.
17	Foam/Clot detected.	Liquid level in the cuvette is lower/higher than expected after the dispensing. Ensure the cuvettes are clean and that there is no foam on the reagent. Flag on results.
18	Reagent pipetting problem (Foam/Clot?)	A liquid detection occurred after a reagent pipetting. If the problem persists, contact your local representative. Flag on results.
19	Sample pipetting problem (Foam/Clot?)	A liquid detection occurred after a sample pipetting. If the problem persists, contact your local representative. Flag on results.
20	Pickup error of reagent position	A liquid detection was missing during a reagent pipetting. If the problem persists, contact your local representative. Flag on results.
21	Pickup error of sample position	A liquid detection was missing during a sample pipetting. If the problem persists, contact your local representative. Flag on results.
22	Pickup error of sample position STAT	A liquid detection was missing during a sample pipetting on a STAT position. If the problem persists, contact your local representative. Flag on results.
23	WARNING: detection of dust between cuvette position and	The analyzer measured some light where dark is expected. This could be some dust on the cuvette holders. Inspect the given positions after the run.

ID	Error message	Meaning
24	Bubbles detector out of order. Disabling bubbles detection.	A hardware failure is avoiding potential bubble detection. The detection is disabled. No flag but not the optimal conditions for the analysis.
25	Reference water cuvette not stable.	The reference changed during the analysis. Flag on results.
26	Unable to detect correct bottle:	Issue with a reagent bottle during the run. An analysis was cancelled.
27	Tray temperature not stabilized.	Target tray temperature was not reached. Wait a few more minutes. Flag on results.
29	Remote Assistance disconnected due to inactivity.	Too much time was elapsed since requesting Remote Assistance and no connection was made. Remote Assistance is cancelled. Try again.
30	Failure in bubbles flushing. Proceed to bubbles purge.	The system is unable to flush bubbles. Run the purge bubbles maintenance tool (see "O.III.4 Priming and purging" page 197).
31	Lack of cleaner position	The liquid level detector did not detect anything in the cleaner bottle. Flag on results.
32	Pickup error of reagent position	A liquid detection was missing during a reagent pipetting. If the problem persists, contact your local representative. Flag on results.
1002	One or more analysis were cancelled.	At least one analysis has been aborted.
1003	The STAT drawer is not closed properly.	Close the drawer immediately so the analyzer can process the STAT samples.
1004	No Answer From Host For Barcode, Position	The host has no prescription for the required sample. The analyzer will not process it.
1005	Cancelling jobs… Awaiting completion	The analyzer stopped the dispensing and is completing the photometry on the started analysis.
1006	Liquid level detector: value in air is too low.	The LLD calibration failed because of a low signal in air. The current pipetting is cancelled. Flag on results.
1008	Awaiting completion	An error occurred and led to analysis cancellation.
1010	calibration failed. Related analysis cancelled.	A calibration failed. All the analyses of the current run using this method are cancelled.
1011	control failed. Related analysis cancelled.	A control failed. All the analyses of the current run using this method are cancelled.

ID	Error message	Meaning
1012	Method wavelengths are not coherent. Please check method configuration.	The method wavelengths are not consistent with the photometer. Contact your local representative.
1014	Some analysis were cancelled due to lack of cuvettes.	Some results are missing due to a lack of cuvettes. Can happen when some results require reruns or if STAT analysis were added during the run.
1015	Some analysis were cancelled due to carry-over.	Some orders were skipped due to carry-over rules.
1016	Some analysis were cancelled due to STAT problem.	Some STAT orders were skipped due to a STAT drawer not closed.
1017	Light problem: total dark reading during photometry.	The photometer does not measure stable values. This can occur with a new lamp during the first hours or with one which must be replaced.
1018	Reference water cuvette parasite.	There is a photometer problem or dirty cuvettes are on the tray.
1019	Detection of a mechanical limitation of the piston.	The syringe module is not working properly but the analyzer can still work. Contact your local representative.
1020	Detection of a mechanical limitation of the arm.	The robotic arm is not working optimally but the analyzer can still work. Contact your local representative.
1022	Liquid Level Detector: Noise on readings >4 in air (missing arm cover?).	The LLD readings are not stable. The arm cover may be missing.
1023	Liquid Level Detector: peak value 255 in air.	Bad LLD signal. Flag on results.
1024	The probe hasn't been cleaned. Use the maintenance tool.	No cleaner could be use after a sample hemolysis. There could be a contamination. Clean the probe before starting working again.
1025	Something has changed, check the schedule management.	The calibration status of one or several reagents has changed. Check the schedule management window.

# Q.III. Messages related to calibrations

"ID" is the number displayed on the screen and/or on printings.

ID	Error message	Meaning
90001 90004 90005 90006	At least 2 calibrations points are similar Calibration calculation error	Gauss pivot resolution not possible or Gauss pivot used for the polynomials. Try another model or a higher degree.
90007	At least 2 absorbances lead to the same concentration	The model is not monotonous. Increase the drift limit to fit a less precise but more simply model or use a different model.
90008	Negative concentration	The model returns a negative concentration for one of the absorbances. Bad fitting with this type of curve, use a different one.
90009	Infinite concentration	The model returns NaN or infinite. It is not possible to use this curve with these calibration points, use a different calibration curve.
90010	1/X model: concentration is zero	Polynomial of 1/X does not handle 0 as definition for concentration. Do not use polynomial of 1/X when a concentration is 0.
90011 90012	Not enough calibration points	The model is not applicable due to a lack of defined calibration points. Polynomial degree N requires at least N+1 points, log4p requires at least 4 points and log5p requires at least 5 points.
90013	1/X model: concentration is zero	Polynomial of 1/X does not handle 0 as definition for concentration. Do not use polynomial of 1/X when a concentration is 0.
90014	1/X model: absorbance is zero	Polynomial of 1/X does not handle 0 as definition for absorbance. Do not use polynomial of 1/X when an absorbance is 0.
90015	Standard deviation higher than limit	The model does not fit the requested drift%. Increase the drift limit %.

ID	Error message	Meaning
90016	Invalid curve	Impossible to determine a curve: either the requested type of curve is wrong or the fitting is not as requested. Increase the drift limit % or change the type of curve.
90017	2 calibration points with the same absorbance	2 calibration points have the same absorbance. During a run, perform a rerun. During a manual calibration, change the absorbance.
90018	Regression calculation error	The drift is not calculable. Mathematical error that should not happen in the field of biochemistry. Report the calibration values and configuration to your local representative.
90019	No model available	The model cannot fit the given calibration points for one of these 2 reasons: a log4p or log5p curve cannot be calculated or there is an inconsistency between the number of given calibration points and the type of curve. Report the calibration values and configuration to your local representative.
90022	The difference between the two absorbances is too high.	The 2 replicates of the calibration points are different and this difference is higher than the maximum delta absorbance allowed.

# Q.IV. Messages on an idle analyzer

"ID" is the number displayed on the screen along the message in the message list (see "F.IV Message bar" page 50).

ID	Error message	Meaning
1000	To preserve reagents & calibrators, return them to the fridge.	Appears after one hour of inactivity to remind that it is better to store the reagents in the fridge.
1001	Air detected in hydraulic system. Purge is needed.	Air detected in the tubing. Run the purge bubbles maintenance tool (see "O.III.4 Priming and purging" page 197).

## Q.V. System crash error messages

In case of system error message having a code between 50000 and 89999, contact your local representative.

# Q.VI. Analytical flags

FLAG	MEANING	RELATED
		PARAMETERS
@D_LLD <sup>(1)</sup>	Discontinuity of the liquid level sensing during pipetting.	n/a
@R_LLD <sup>(1)</sup>		
@S_LLD <sup>(1)</sup>		
@R_CRASH <sup>(1)</sup>	Attempt to probe in a closed reagent container.	n/a
@S_CRASH <sup>(1)</sup>	Attempt to pipette in a closed sample tube or cup.	n/a
#PD	A rerun occurred, the sample was diluted.	n/a
#VD	A rerun occurred, the sample volume was decreased.	n/a
#VI	A rerun occurred, the sample volume was increased.	n/a
<b>???_1</b> <sup>(1)</sup>	A problem occurred while converting the absorbance into a	Calibration points,
<b>???_2</b> <sup>(1)</sup>	concentration or an absorbance could not be measured.	calibration curve
ABSLIM <sup>(1)(2)</sup>	Substrate depletion.	Limit of absorbance
BUB	Detection of air bubbles in the circuit, or the dispensing of a	n/a
	component was replaced by a bubble purging process.	
CALC1 <sup>(1)</sup>	Calculation of a calculated method impossible due to a	n/a
	dependent method failure.	
<b>CALC2</b> <sup>(1)</sup>	The calculation of a calculated method generated an error.	n/a
CALCULATED	Calculated method.	n/a
	The process was interrupted and one of the components was	n/a
	not dispensed.	
CARRYOVER	Detection of potential cross-contamination with reagents.	n/a
CLOT	Detection of potential clot in sample.	n/a
<b>CUV</b> <sup>(1)(</sup>	A re-run was needed but no available cuvette was found.	n/a
<b>CUV*</b> (1)	Not enough cuvettes available to run the analysis.	n/a
<b>DIL*</b> (1)	The diluent bottle was empty (or missing).	n/a
EDIT	The result was manually edited.	n/a
EP	End point is not stable.	Stability limit
FAIL	Calibration and/or control validation has failed.	Control or calibration
		settinas

FLAG	MEANING	RELATED PARAMETERS
FOAM	Detection of potential foam in reagent.	n/a
Н	Result higher than the normal range.	Normal range, age
L	Result lower than the normal range.	and species.
LAMP	Anomaly of the light source detected in the water reference	n/a
	cuvette (empty cuvettes and/or air) during the cuvette scan.	
LIN	The linearity test for linear kinetics failed.	Linearity limit.
LLDCAL <sup>(1)</sup>	The liquid level sensor detected a poor signal. Pipetting and	n/a
	dispensing are interrupted.	
NEG <sup>(1)</sup>	The calculation of the result gives a negative value.	Calibration settings
NEWCAL	The result has been recalculated.	n/a
NOCAL <sup>(1)</sup>	The method is not calibrated.	Calibration settings
ОК	No analytical error.	n/a
<b>P*</b> (1)(2)	Pro-zone.	Pro-zone limit
QC_CANCEL <sup>(1)</sup>	The test was skipped because of a failed control.	Control parameters
<b>D1</b> (1)	Instability of the reagent blank.	First reagent
		absorbance tolerance
<b>R1*</b> <sup>(1)</sup>	The first reagent container was empty (or missing).	n/a
<b>R2*</b> (1)	The second reagent container was empty (or missing).	n/a
<b>R2!</b> <sup>(1)</sup>	The second reagent aspiration could not take place because	n/a
	of another problem (probe crash for instance).	
RANGH <sup>(1)(2)</sup>	The final absorbance is greater than the maximum	n/a
	absorbance defined by the calibration curve.	
RANGL <sup>(1)(2)</sup>	The final absorbance is lower than the minimum absorbance	n/a
	defined by the calibration curve.	
RUNNING <sup>(1)</sup>	In process.	n/a
<b>S*</b> (1)	The sample tube or cup was empty (or missing).	n/a
<b>ST</b> <sup>(1)(</sup>	A re-run was needed but re-runs are disabled for samples	n/a
	taken from the STAT drawer.	
STERR <sup>(1)</sup>	The sample could not be pipetted from the STAT position.	n/a
<b>TEC-H</b> <sup>(1)(2)</sup>	Result above the high technical limit.	High technical limit
<b>TEC-L</b> <sup>(1)(2)</sup>	Result below the low technical limit.	Low technical limit
WARMUP	The system has not reached a workable temperature	n/a
WASHFULL <sup>(1)</sup>	Detection of stagnant waste in the wash-station's drain.	n/a

<sup>(1)</sup> No result available.

 $^{\mbox{(2)}}$  If possible, a rerun will occur.

# R. Bidirectional interface

## **R.I.** Purpose

The Bidirectional interface is used to exchange patients' information, prescriptions and results with a centralized mainframe computer (LIS = Laboratory Information System). The communication between the respons®910VET analyzer and a LIS consists in receiving the test requests from the LIS and reporting the results back to it. This is done via an RS232 connection or a TCP/IP connection and can follow several

standards:

- ASTM 1394 (high level) and 1381 (low level) standards for communication.
- ISO 18812:2003 protocol.
- Hitachi 911 analyzer protocol.
- Cobas Mira Plus protocol.
- RAXT protocol.

ISO, ASTM and RAXT protocols are recommended. Hitachi 911 and Cobas Mira protocols are provided but are not covered by the technical assistance.

#### **R.II.** Locations

#### R.II.1. Main screen

When the operator press the button "**IDEE**", a query is posted to the LIS, sending all the sample barcodes and waiting for the related prescriptions. The analysis starts on the instrument and the results are sent back to the LIS.

The sample must be known by the LIS to avoid any error reply from the LIS (Q record with X value).
#### R.II.2. Work list

If the protocol configuration is ASTM/ISO, the LIS has two ways to send the test order:

- Barcode in 9.4.3.1
- Position in 9.4.3.3 and container reference in 9.4.3.4. The container reference (tube, 1.5mL cup, 2.5mL cup) must be set in the LIS options (see "N.VI LIS" page 178).

In the work list, generated IDs are as follows: "YYYYMMDDhhmmss\_position.

When the work list is launched with the LIS sending a prescription, a pop-up message is displayed. That means that the prescription list will be updated. The order is placed in the test window. The user can select it and move it to the sample window in the same way as for a "normal" order. If the order is sent by its position, it will be placed on the correct position in the sample window. An error message is displayed if this position is not free.

#### R.II.3. Emergency entry

As there is no barcode reader reaching the STAT positions, the field "Sample ID (Barcode)" must be filled. Pressing the "Request host" button posts a query to the LIS in order to get the related prescription. The analysis starts on the instrument and the results are sent back to the LIS.

#### R.II.4. Analysis results

Pressing the "**BIDIR**" button sends the selected validated results to the LIS.

### R.II.5. Method configuration

The field "**Host reference**" cannot be empty if the bidirectional interface is used. It is the only way to identify a method on a heterogeneous system.

### **R.III. Physical connection**

To use the respons<sup>®</sup>910VET analyzer's bidirectional interface, the computer running the respons<sup>®</sup>910VET software must have one of the following serial links dedicated to this purpose:

- RS232 port: any hardware implementation following the EIA RS-232C standard. The computer must be setup to make such an implementation available for software with COM<x> port. (I.e. COM1:). It is also possible to connect a "USB to RS232" adaptor plugged into a USB port.
- Network port: any hardware implementation that can follow the TCP/IP protocol.

## **R.IV.** Configuration

#### **R.IV.1. BIDIR Settings main screen**

#### From "Main screen" => "Configuration" => "Options" => "LIS"

Protocol	Protocol Settings	
<no datalink=""></no>	- Instrument identifier	IA R910
	LIS identifier	SIL R910
RAXI	Default Frame Size	230
ASTM/ISO	Allow Z Frame	true
MIRA	Control Name is in frame 8.1.6	true
Hitachi	Control Lot is in frame 9.4.4.2	true
11100011	Loquacious Protocol ( closer to ASTM than ISO 18	3812) true
	Unknow Sex Code ( 'I' or 'U' )	1
address	Urine Code Blood Code	U
Dort : 11111	Blood Code	B
	Plasma Code	P
TI: 00:	CSF Code	C
T I NIS PC IS	Whole Blood Code	W
C Server C Client		and the second se
C Server Client	System Automatically Queries Host for Worklist	true
C Server Client	System Automatically Queries Host for Worklist System Automatically Sends Results	true true
C Server Client	System Automatically Queries Host for Worklist System Automatically Sends Results Use UTF8 Encoding for non ANSI characters	true true false
C Server Client	System Automatically Queries Host for Worklist System Automatically Sends Results Use UTF8 Encoding for non ANSI characters BIDIR local testing	true true false true
C Server Client	System Automatically Queries Host for Worklist System Automatically Sends Results Use UTF8 Encoding for non ANSI characters BIDIR local testing TimeOut for ACK (s)	true true false true 15

This screen allows the configuration of the bidirectional interface and is divided into four parts.

The "Protocol" window lists the different protocols which can be used.

When the ASTM/ISO protocol is selected, all the methods are checked and a warning message listing the methods without host reference (if any) appears. The host reference is a fundamental data in an environment using the bidirectional interface and the logical link between the LIS and the respons<sup>®</sup>910VET analyzer to identify a method.

The "Physical layer" window allows the configuration of the LIS connection type:

- "TCP/IP" connection:
  - This PC is "Server": The PC will act as the server and wait for a connection request from the LIS. The address specified in the "R910VET Address" field is the address of the PC.
  - This PC is "Client": The PC will ask the LIS for a connection. The address specified in the "R910VET Address" field is the address of the LIS.
  - "**Port**": TCP/IP port used for communication.
- "RS-232" connection (not visible on the picture):
  - "Byte Length", "Stop Bits", "Parity" and "Speed": RS232 communication settings.
  - "COMx": Combo-box which allows choosing the COM port on which the communication will occur.

The "**Protocol Settings**" window displays the specific configuration setup for the selected protocol.

The "**Common settings**" window allows the definition of bidirectional communication settings.

#### R.IV.2. Common settings

"True" means that an option is enabled and "False" means that it is disabled.

- "Debug Mode": Sets the respons®910VET analyzer's software to work in debug mode. In this mode the entries are not processed when the LIS sends them to the respons®910VET analyzer. This mode is for a testing purpose only.
- "Allow partial analysis": If disabled, the respons®910VET will process only entries which can be completely processed (example: patient prescription with glucose and calcium. Calcium analysis cannot be performed on the analyzer so no test is processed at all for this animal). If enabled, the analyzer will process any possible part of an entry (example: prescription with glucose and calcium. Calcium analysis

cannot be performed on the analyzer so only glucose test is processed for this animal).

- "Urine", "Blood", "Plasma", "CSF" and "WHOLE BLOOD" codes: Represent the respective internal codes for urine, serum, plasma and CSF sample types. For instance, those five fields are used in conjunction with ASTM field 9.4.16.
- "System automatically queries host for work list": If enabled, a request is sent to the LIS to get the related work list when the samples barcodes are read.
- "System automatically sends results": If enabled, this result is automatically sent to the LIS when a result is available.
- "Use UTF8 encoding for non ANSI characters": If enabled, all non ANSI characters are treated as UTF8 encoded. UTF8 allowed fields are the animal's name and owner's last name, the sample ID, the method name and the veterinarian name.
- **"BIDIR local testing**": Used to test bidirectional communication without connection to a host. This option checks data processing even if no host is available.
- "TimeOut for ACK (s)": Defines the timeout before sending ACK or NAK, or before receiving ACK or NAK. After the defined timeout the connection is reset.
- "TimeOut for Frame (s)": Defines the timeout before cancelling the reception of a frame. After the defined timeout the connection is reset.
- "Type Tube 5-10 ml Code": Defines the code used by the LIS to specify that the type of tube is 5-10mL. Used when the LIS sends the sample order by position instead of barcode.
- "Type Tube 1.5 ml Code": Defines the code used by the LIS to specify that the type of tube is 1.5mL. Used when the LIS sends the sample order by position instead of barcode.
- "Type Tube 2.5 ml Code": Defines the code used by the LIS to specify that the type of tube is 2.5mL. Used when the LIS sends the sample order by position instead of barcode.
- "Z Record Code ('Z' or 'M')": Defines the code used by the LIS to specify the Z record. Z Record is used to send controls and calibrators. The default value is 'Z'.

#### **R.IV.3. Protocol settings**

#### R.IV.3.a. ASTM / ISO protocol

- "Instrument identifier": Name of the respons®910VET analyzer PC. Used in ASTM field 7.1.10.
- "LIS identifier": Name of the LIS. Used in ASTM field 7.1.5.
- "Default Frame Size": Default size of the frame. 230 is the normal default value.
- "Allow Z Frame": When this option is selected as true, the bottle status are specified in a special frame named Z Frame or Z Record.
- "Control Name is in frame 8.1.6": In case the prescription is a control, the control name is stored into the owner and animal name fields.
- "Control Lot is in frame 9.4.4.2": In case the prescription is a control, the control lot number is added to the barcode in 9.4.4 with a delimiter between both.
- "Loquacious Protocol": In this mode, the frame sent to the LIS has more detailed data and is closer to ASTM protocol than ISO 18812. The default value is 'true'.
- "Unknown Sex Code": When the analyzer sends animal data to the LIS, if the species is unknown, the two enable values are 'U' and 'I'. The default value is 'U'.

#### R.IV.3.b. Hitachi protocol

Not visible on the picture:

- **"End Packet Type**": Used to define the end of a data frame:
  - 0: ETX+BCC
  - 1: CR+LF+ETX
  - 2: ETX
  - 3: ETX+CR+LF
  - 4: ETX+CKSH+CKSL+CR

- Other specifications:
  - The method host code must use the format "Sxx" where "S" is the uppercase letter and "xx" a number between 01 and 46 (i.e. S17). The number must correspond to the "channel" definition of the original Hitachi protocol.
  - Only routine entries can be processed. Controls and calibrations are not possible.

#### R.IV.3.c. RAXT protocol

Not visible on the picture:

- "Instrument number": Identification number of the analyzer.
- "Chem. code length": Number of digits (2 or 3) used to code the methods. Depending on the code length, N°99 or N°999 are forbidden. The coherence between the method configurations on the analyzer and on the LIS must be checked.
- "Maximum of retries": In case of transmission error, the analyzer is authorized to retry within the limits fixed by this field. If the analyzer exceeds this number, it will disconnect itself and switch to idle mode.
- "Delay between frames": Period (in seconds) between two frames emitted by the analyzer. Allows the adaptation to the cycle of the LIS. During this time, the instrument is in sleep mode.
- "Freeze delay when host full": When the LIS is busy, the analyzer stops sending further data up to the time setup in this field.
- "Barcode length": Length of the barcodes used on the tubes (7 is recommended).
- "Barcode left-completed with 0's": If the barcode is shorter than required and if this option is activated, the barcode is supplemented by zeros (spaces are used if the option is disabled).
- "Send the sample position": If this option is activated, the analyzer sends the position of the tube to LIS. These data include relative position on the sample tray and number of turns. If this option is not activated, then 00-00 is sent.
- "Name record enabled" (option specific to the respons®910VET analyzer and not compatible with other analyzers): If this option is enabled the LIS can send details about the animal. The respons®910VET will record those details. Either

"Registration ID" alone or "Registration ID ^name^firstname^date of birth^gender" with date of birth format "YYYY-MM-DD" and "Gender: M or F".

- "Urine / sample field enabled" (option specific to the respons®910VET analyzer and not compatible with other analyzers): If this option is enabled, the LIS can specify if the sample is urine or serum (specific field) as follows:
  - If the analyzer sends a result frame, the type of sample material is added in a field just behind the space character located after the barcode field. The value of the field is a letter as defined in the settings.
  - If the analyzer sends an entry frame, then the type of sample material is added just before the list of the methods by a single character. If this character is 'U', the sample is considered as urine, otherwise it is considered as serum.

If this option is not activated, it is possible to indicate that the sample is urine by adding the code #99 at the end of the list of methods (if the length of the code is 3, then add #999).

#### R.IV.3.d. Mira protocol

Not visible on the picture:

- Only routine entries can be processed. Controls and calibrations are not possible.
- Units used by the analyzer must be selected ONLY from the units included in the following list, applying the exact syntax listed below:

mol/L	%	U/L	IU/L	g/L	g/dL	mg/mL	µkat/L	dA
mmol/L	d%	mU/L	mIU/L	mg/L	mg/dL	µg/mL	nkat/L	dA/min
µmol/L	meq/L	kU/L	kIU/L	µg/L	µg/dL	ng/mL		
nmol/L	mval/L	U/mL	IU/mL	ng/L	ng/dL	pg/mL		
pmol/L	S	mU/mL	mIU/mL					

#### R.IV.3.e. Dataflow viewer

From "Main screen" => click onto "Host interface" icon (see "F.VII Host interface status" page 54).

DATA TRANSFER L	INK -DIASY	S TECHNOLOGIES-			- 8 - IX
27/05/2010 09:17:	17 - Closi	ing Port			
27/05/2010 09:17:	18 - Openi	ing TCPIP 10.1.103.174			
27/05/2010 09:17:	23 - <crea< th=""><th>ATE REQUEST:0042250371</th><th>&gt;</th><th></th><th></th></crea<>	ATE REQUEST:0042250371	>		
27/05/2010 09:17:	24 - <seni< th=""><th>D FRAME: QUERY: 00422503</th><th>71&gt;</th><th></th><th></th></seni<>	D FRAME: QUERY: 00422503	71>		
27/05/2010 09:17:	24 - Send:	ENQ>			
27/05/2010 09:17:	24 - Recv:	<ack></ack>			
27/05/2010 09:17:	24 - Send:	<stx>1H \^&amp;   DiasysT</stx>	ech^R910^280001	P E1394-97 201005270917	23 <cr><etx>43</etx></cr>
		<cr></cr>			
27/05/2010 09:17:	24 - Recv:	<ack></ack>			
27/05/2010 09:17:	25 - Send:	<stx>2Q 1 ^0042250371</stx>	0 <cr><etx>39&lt;</etx></cr>	<cr></cr>	
27/05/2010 09:17:	25 - Recv:	<ack></ack>			
27/05/2010 09:17:	25 - Send:	<stx>3L 1 N<cr><etx>0</etx></cr></stx>	6 <cr></cr>		
27/05/2010 09:17:	25 - Recv:	<ack></ack>			
27/05/2010 09:17:	26 - Send:	<eot></eot>			
27/05/2010 09:17:	28 - <new_< th=""><th>PACKET&gt;</th><th></th><th></th><th></th></new_<>	PACKET>			
27/05/2010 09:17:	28 - Recv:	<enq></enq>			
27/05/2010 09:17:	28 - Send:	CACK>			4 001001005000
27/05/2010 09:17:	28 - Recv:	91727 <cr><etx>11<cr></cr></etx></cr>	ecu.Kain.i!!!!nisääie	5CU~K3I0~580001  F F133	4-9/12010052/0
27/05/2010 09:17:	28 - Send:	<ack></ack>			
27/05/2010 09:17:	29 - Recv:	<stx>2P 1  1168  Math</stx>	ieu^MARCIACQ  19680311	M                  <cr></cr>	<etx>05<cr></cr></etx>
27/05/2010 09:17:	29 - Send:	<ack></ack>			
27/05/2010 09:17:	29 - Recv:	<stx>30 1 0042250371 </stx>	^^^CK\^^^UREAU\		X>22 <cr></cr>
27/05/2010 09:17:	29 - Send:	<ack></ack>			
27/05/2010 09:17:	30 - Recv:	<stx>4L 1 N<cr><etx>0</etx></cr></stx>	7 <cr></cr>		
27/05/2010 09:17:	30 - Send:	<ack></ack>			
27/05/2010 09:17:	30 - Recv:	<eot></eot>			
2515					Clear Lag
2010					Clear Log
0042250371		DEE REQUEST			MAITING CONNECTION
1					WenningConningEntox

This screen shows the dataflow exchanged between the respons®910VET analyzer and the LIS during the run. All incoming / outgoing messages are displayed in real-time. It is also possible to simulate a LIS request or enforce results to send to the LIS.

There are three different buttons:

- "Send Results": Sends the results of the selected entry to the LIS.
- "IDEE Request": Requests the entry for the selected ID.
- "Clear Log": Clears the log window.

#### R.IV.3.f. BIDIR software log frame

The log frame displays time stamped dataflow, following color formatting:

10/06/2009 14:52:18 - Send:<ENQ><LF> => Outgoing message. 10/06/2009 14:52:18 - Recv:<ACK><LF> => Incoming message. 10/06/2009 14:52:17 - <CREATE\_REQUEST:0001> => Comment.

## R.V. Implementation of ASTM/ISO protocol

### R.V.1. [H]eader record

Field Number	Field Name	Mandatory	Direction	Value
7.1.1	Record Type ID	Yes		'H'
	Delimiter		Outgoing	' \^&'
7.1.2	7.1.2 Definition	Yes	Incoming	Recommended to use ' \^&', but any four of the ASCII characters are allowed.
7.1.5 Sender Nam	Sender Name	No	Outgoing	'Diasys' and 'r910VET' followed the serial number of the analyzer.
			Incoming	Stored as future receiver ID.
		No	Outgoing	LIS name as defined in BIDIR settings.
7.1.10	Receiver ID		Incoming	Name used to verify that transmission is intended for the respons910VET PC. If sent, it must match the analyzer's name in the BIDIR

Field Number	Field Name	Mandatory	Direction	Value
		Outgoing	Either 'P' (Production) or 'D' (Debug). Debug mode is used for testing the ASTM protocol. Debug mode can be set in BIDIR settings. Either 'P' (Production), 'D' (Debug), 'Q' (QC) or	
7.1.12	Processing ID	No	Incoming	nothing. Default value is 'P'. In this case, the incoming application message is parsed and processed. If processing ID is 'D', the incoming application message is parsed, but data is not processed. Debug mode is used for testing the ASTM protocol. If processing ID is 'Q', the incoming application message will be considered as a Control.
H13	Version Number	No	Outgoing	'E1394-17'
H14	Date and Time of Message	No	Outgoing	Date/Time stamp

## R.V.2. [P]atient Information Record

Field Number	Field Name	Mandatory	Direction	Value
8.1.1	Record Type ID	Yes		'P'
			Outgoing	Formatted number with a range from '1' through '65535'. Equal to nth occurrence of a patient record within the current outgoing application message. Used for integrity validation of the application by ensuring that message contains all records.
8.1.2	Sequence Number	Yes	Incoming	One to any character, with a default value of zero which is always an invalid Sequence Number. Formatted as a string of ASCII numeric characters. Equal to the nth occurrence of a patient record within the current incoming application message. If the current Sequence Number does not equal the Sequence Number of the expected record, an error is reported.
8.1.4	Laboratory Assigned Patient ID	No		Patient ID (PID).
8.1.6	8.1.6 Patient Name No	No	Outgoing	If not processing controls, this field is set to the patient name field of the result. Components are separated by component delimiter character ('^') e.g. 'Smith^John'. Trailing empty name components and component delimiter characters are not included; e.g. patient name set to 'Smith' for a patient work list entry with the last name 'Smith'. If processing controls, this field is the control name.
			Incoming	Zero to three components (further components are ignored). Written to the patient name field of the work list entry.
9161	Owner Last	No	Outgoing	Owner Last Name if available.
0.1.0.1	Name	NO	Incoming	Owner Last Name.

Field Number	Field Name	Mandatory	Direction	Value
9160	Animal Nama	Ne	Outgoing	Animal Name if available
0.1.0.2	Animai Name	INO	Incoming	Animal Name
8.1.6.3	Middle Initial	No	Incoming	Added to the Animal Name after a space character.
8.1.8	Birthdate	No	Outgoing	Set to ANSI X3.30 format of patient date of birth (DOB) in result entry (e.g. 19721005 = October 5, 1972). If patient DOB field is not specified in work list or result entry, this field is empty. The allowed range is 10010101 through 21001231 (January 1, 1001 through December 31, 2100). ANSI X3.30 date format. Written to date of birth (DOB) field in the work list entry.
8.1.9 Animal S		No	Outgoing	Value set by Animal Species field in result entry.
	Animal Species		Incoming	Written to the Animal Species field in work list entry. This field is used for establishing normal ranges for the sample.

# R.V.3. [C]omment Record

Field Number	Field Name	Mandatory	Direction	Value
11.1.1	Record Type ID	No		'C'
11.1.2	Sequence Number	No	Outgoing	One character ranging from 1 to 3. Used for validating the integrity of the application message by ensuring that the message contains all records.
11.1.3	Comment Source	No	Outgoing	Ч
11.1.4	Comment	No	Outgoing	Comment field.
11.1.5	Comment type	No	Outgoing	т

## R.V.4. Test [O]rder Record

Field Number	Field Name	Mandatory	Direction	Value
9.4.1	Record Type ID	Yes		'O'
		Yes	Outgoing	One to any number. Used for validating the integrity of the application message by ensuring that message contains all records.
9.4.2	Sequence Number		Incoming	One to any number of characters, (default value '0)', which is always an invalid sequence number. Formatted as string of ASCII characters. Equal to the nth occurrence of an entry record since the last patient record, which is considered the current patient record. If the current Sequence Number is not equal to the Sequence Number of the expected record, an error is reported.
9.4.3	Specimen ID	Yes	Outgoing	Set to Sample ID (SID) field of result entry. (If bar-codes are used this field must be set to the bar-code of the sample)
			Incoming	Sample ID (SID) field of imported work list entry.
9.4.4	Specimen ID	n ID Yes	Outgoing	Set to Sample ID (SID) field of result entry (barcode).
	Specimen ID		Incoming	If processing a QC, the second subfield is the control lot number.

Field Number	Field Name	Mandatory	Direction	Value
		Yes	Outgoing	List of tests, where each test is described by a multi-component field, separated by a Component Delimiter character ('^'). Each group of components is separated by a Repeat Delimiter character ('\'). If current entry record is submitting a work list request for a specific sample, this field describes the list of requested tests. If current entry record is for reporting single/multiple result values, this field describes the list of tests whose result values are reported subsequently. Refer to individual components (field components 9.4.5.1 through 9.4.5.4) for data format information.
9.4.5	Universal Test ID		Incoming	List of tests where each test is described by a multi-component field, separated by a Component Delimiter character ('^'). Each group of components is separated by a Repeat Delimiter character ('\'). If a test is unknown to r910VET, the test is rejected to LIS and processing continues on the list of tests. If "AllowPartialAnalysis" is false, the whole entry is rejected to LIS. The list of tests can contain any number of names. Refer to field 9.4.12 "Action Code" for updating and cancelling of tests specified in this field. Refer to individual components (field components 9.4.5.1 through 9.4.5.4) for data format information.
9.4.5.1	Universal Test	No	Outgoing	Always empty.
	U		Incoming	This component is always ignored.
9.4.5.2	Universal Test	No	Uutgoing	Always empty.
			Outgoing	Always empty
9.4.5.3	ID Type	No	Incoming	This component is always ignored.

Field Number	Field Name	Mandatory	Direction	Value
			Outgoing	Three characters. The code is corresponding to the chemistry.
9.4.5.4	Manufacturer Code	Yes	Incoming	Three characters. If a value exists, this value is used to search into the r910VET method database. If code corresponds to a method, the test is selected for this sample. If no match is found, the test entry is rejected to LIS.
9.4.6	Priority	No	Outgoing	One character. Value determined by STAT flag in result entry. If STAT flag is Yes, Priority field is set to 'S' (STAT). If flag is No, Priority field is set to 'R' (Routine). One character. If Priority is 'S', STAT flag is set
				to Yes (STAT), otherwise to No (No STAT).
9.4.12	Action Code	No	Incoming	One character. If entry record is for an incoming work list entry (refer to field 9.4.26, Report Type), this field is processed as following: If action code is 'C' (Cancel Request), tests specified in Universal Test ID field 9.4.5 are canceled for sample specified in field 9.4.3. If action code is 'Q', means that the order is a QC. If action code does not specify Cancel Request or is empty/invalid, Action Code is interpreted as New Request or Add Request, depending whether the Sample ID (field 9.4.3) already exists in the r910VET database.
9.4.16	Sample Type	No	Incoming	One character. Sets the sample type as defined in BIDIR Settings (Blood/CSF)
9.4.26	Report Types	Yes	Outgoing	One character. If the outgoing message contains rejected incoming work list data, the Report Type field contains 'X' (Work Cannot Be Done). If outgoing message is a reply with tests that can't be done, field contains 'P' (Preliminary results). If outgoing message contains result data, Report Type field contains 'F' (Final Results). If outgoing message contains data in response to a query, Report Type field contains 'Q' (Response to a Query).

# R.V.5. [R]esult Record

Field Number	Field Name	Mandatory	Direction	Value
10.1.1	Record Type ID	No	Outgoing	'R'
10.1.2	Sequence Number	No	Outgoing	Up to 5 characters, formatted as left justified number with a range from 1 through 65535. Equal to the number of occurrence of a result record since the last entry record. Verifies integrity of an application message by checking all records.
10.1.3	Universal Test ID	No	Outgoing	A single test name described by 4 components, where each component is separated by a component delimiter character ('^'). The Universal Test ID specifies test name associated with the result. Refer to the individual components (field components 10.1.3.1 through 10.1.3.4) for data format information.
10.1.3.1	Universal Test ID	No	Outgoing	No characters; always empty.
10.1.3.2	Universal Test ID Name	No	Outgoing	No characters; always empty.
10.1.3.3	Universal Test ID type	No	Outgoing	No characters; always empty.
10.1.3.4	Manufacturer Code	No	Outgoing	Three characters. r910VET code of the method.
10.1.4	Data or measurement Value	No	Outgoing	Depending on result aspect, several result formats are available at the Data Value field: number - concentration value - qualitative - text string - alphanumeric such as '< value', or '> value', or Interpretation text, or numeric value 1234565
10.1.5	Units	No	Outgoing	If Data Value field (10.1.4) represents a quantitative result, this field is set to Units field of the definition of the associated test. If Data Value field represents a qualitative result, Units field is empty.

Field Number	Field Name	Mandatory	Direction	Value
10.1.7	Result Abnormal Flags	No	Outgoing	The repetitions represent some of the r910VET system result flags and are as follows: If result is flagged under range, this field contains '<', if result is flagged over range, this field contains '>'.
10.1.9	Result Status	No	Outgoing	If entry can't be processed 'X'; if still in analysis 'I'; if test is in error 'W'; if test has been validated manually 'V'; if response from a query 'Q' and for any other case 'F'.
10.1.11	Operator ID	No	Outgoing	Operator identification that started analysis. This number is the UserID as visible in User management screen.
10.1.13	Date/Time Test Completed	No	Outgoing	Set to ANSI X3.43 format of date and time values. ACCP system does not keep time in seconds; transmits a 12-character-string (YYYYMMDDHHMM). Hours are in military (24-hour) form; e.g. '199808051403' stands for August 5, 1998, 14:03 (2:03 p.m.).

# R.V.6. [Q]uery Record

Field Number	Field Name	Mandatory	Direction	Value
12.1.1	Record Type ID	Yes		'Q'
			Outgoing	Always '1'.
12.1.2	Sequence Number	Yes	Incoming	One to any number of characters, with a default value of '0', which is always an invalid sequence number. Formatted as a string of ASCII numeric characters. Equal to the number of occurrence of an entry record since the last patient record, which is considered the current query record. If the current Sequence Number does not equal the Sequence Number of the expected record, an error is reported.

Field Number	Field Name	Mandatory	Direction	Value
	Starting Range		Outgoing	Field has 2 components. First is Patient ID, which is always empty and separated by the component delimiter ('^') from the Sample ID. Refer to the individual components (field components 12.1.3.1 and 12.1.3.2) for data format information.
12.1.3	1.3 ID	Yes	Incoming	0 or two components. If field is empty or 'ALL', no restrictions are made on Patient ID or Sample ID. Otherwise the field has two components separated by the component delimiter ('^') and is a single value. Refer to individual components (field components 12.1.3.1 and 12.1.3.2) for data format information.
		No	Outgoing	Always empty.
12.1.3.1	Patient ID		Incoming	Patient ID is used as a criterion for matching PID field in result entries.
			Outgoing	Sample ID is selected from work list SID field.
12.1.3.2	12.1.3.2 Sample ID	Yes	Incoming	Sample ID is used as criterion matching SID field in result entries.
12.1.5	Universal Test ID	No	Incoming	0 or 1 or 4 components. If empty, or 'ALL', no restrictions of record selection based on test. Otherwise field is a single value or list of test names. Each test is 4 components and each group of 4 components is separated by a repeat delimiter character. If a name is unknown to r910VET, test name is ignored and processing continues on the work list. The list of test names can contain any number of names. Refer to individual components (field components 12.1.5.1 through 12.1.5.4) for data format information.
12.1.5.1	Universal Test ID	No	Outgoing Incoming	No character; always empty. 0 to any number of characters. This component is always ignored.

Field Number	Field Name	Mandatory	Direction	Value
	Liniversal Test	No	Outgoing	No character; always empty.
12.1.5.2	ID Name		Incoming	0 to any number of characters. This component is always ignored.
	Universal Test ID Type		Outgoing	No character; always empty.
12.1.5.3		No	Incoming	0 to any number of characters. This component is always ignored.
12.1.5.4	Manufacturer Code	lanufacturer Code	Outgoing	No character; always empty.
			Incoming	Three characters. If a value exists, this value is used to search the R910VET chemistry database. The R910VET analyzer searches the test definition database for the matching LIS
Request	Request		Outgoing	'O'
12.1.13	I.13 Information No Status Code	Incoming	'P', 'F', 'I', or 'N': New entry, X for Error	

## R.V.7. [L] Message Terminator Record

Field Number	Field Name	Mandatory	Direction	Value
13.1.1	Record Type ID	Yes	Outgoing	'L'
13.1.2	Sequence Number	Yes	Outgoing	'1'
13.1.3	Termination Code	No	Outgoing	'N'

### R.V.8. [Z] Containers Records

This part is an extension of the standard and has been written by DiaSys GmbH.

Field Number	Field Name	Mandatory	Direction	Value
20.1.1	Record Type ID	No		'Z' or 'M' according the setup in LIS options
20.1.2	Sequence Number	No	Outgoing	One to any number of characters. Used for validating the integrity of the application message by ensuring that the message contains all records.
20.1.3.1	Object Type	No	Outgoing	Could be R1, R2, CTLx or CALx. R1/R2: information about reagents. CTL1 to CTL4: information about controls. CAL1 to CAL6: information about calibrators.
20.1.3.2	Name	No	Outgoing	Product name.
20.1.4	Lot Number	No	Outgoing	Ŧ
20.1.5	Lot Expirat	No	Outgoing	Expiration Date (format 20110331).
20.1.6	Bottle Number	No	Outgoing	Т
20.1.7	Remaining Tests	No	Outgoing	For R1/R2 only. Number of remaining tests.

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