IH-500

User Manual

BIO-RAD

Identification

IH-500 User Manual

Version 3.1 - 12/2022

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Manufacturer

DiaMed GmbH

Pra Rond 23
1785 Cressier FR
Switzerland

Technical Information Contacts

Tel. +41 (0)26 67 45 111

Fax +41 (0)26 67 45 145

web: www.bio-rad.com

EC REP Bio-Rad

3 Boulevard Raymond Poincaré
92430 Marnes-la-Coquette
France

Tel. +33 1 47 95 60 00

Version History

Document version	Software version	Date	Changes
1.0	1.0	06/2015	First edition
2.0	2.0	05/2016	New page layout Revised: • the content of the manual in accordance with the software version; • the general safety instructions; • the typographical conventions.
2.1	2.2	05/2017	Updated: • the Identification Plate on page 54; • the Software Overview on page 63; • the Weekly Hydraulic Maintenance Reminder on page 75; • the Resources on Board on page 96; • the Ordering Tests on page 134; • the Quality Control on page 166; • the Options (Main Screen) on page 168. Added: • the Quality Control Reminder on page 76; • the Configure Separate HC/Serum Sample Tubes on page 119; • the Sample Barcode Manual Input on page 122; • the list of Assays for Titration on page 251.
2.2	2.2	11/2018	Revised: • the number of gel cards to be stored; • the use of pediatric and low volume tubes; • the user management. Added complementary information.
2.3	2.2	04/2021	Updated the picture of the identification plate. Added: • a statement about cybersecurity; • the new solid waste bin assembly; • the drawer lockers. Added complementary information.
3.0	2.2	03/2022	User Manual fully revised in accordance to the new European regulation (EU) 2017/746 (IVDR).
3.1	3.1	12/2022	Updated the manual in accordance with the software version. Added the description of the System Liquid Container 6.3L

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Table of Contents

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← Generalities

This chapter describes the intended use and contains basic information on the instrument and the document structure.

1.1 Intended Use

The IH-500 is a fully automated instrument intended for the ID-System used in immunohematology testing for ABO blood grouping (forward and reverse), antigen typing, antibody screening, antibody identification and titration, Direct Antiglobulin Testing (DAT) and compatibility tests in human blood samples.

For in vitro diagnostic use, by trained laboratory personnel. Device for professional user in a laboratory environment only.

Use of the IH-500 is only permitted in conjunction with the corresponding software or in a configuration which is authorized by Bio-Rad.

Only use IH-500 with gel cards and reagent authorized by Bio-Rad.

The use of any material not specified in the User Manual (e.g. non-authorized substances) is forbidden.

b The instructions. instructions contained in this User Manual must be followed, in particular the safety

Reliability of results is dependent upon compliance with good laboratory practices.

The User Manager module is required to define the IH-500 users and the related appropriate access rights. The IH-500 cannot be operated without registered users.

Refer to the appendix User Manager Module on page 257 for more details.

1.2 Warranty Limitation

Bio-Rad denies any responsibility in case of:

- ← wrong use of the instrument;
- ← unauthorized modification (willingly or unwillingly);
- ← not complying to the instructions contained in the manuals provided with the instruments and software;
- ← non-compliance with the safety instructions contained in the manuals;
- ← damages linked with the use of the instrument, in particular any data loss or any financial loss which could possibly be attached to the use of the software;
- ← if the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

When the instrument is connected to a host, the user takes the entire responsibility for an error-less transmission of the results (e.g. hardware, software and firmware) to this system.

← Any warranty will, be deemed void if fault is found to have been caused by maltreatment, misuse, unauthorized maintenance of service or negligence of regular maintenance and service, accidental damage, incorrect storage or use of the products for operations outside their specified limitations, outside their specifications, contrary to the instructions given in this manual (or with other than the manufacturer's original tips).

Each Bio-Rad IH-500 is tested by the manufacturer before shipping.

1.3 Glossary

The following terms, among others, are used in this manual.

APF	Assay Protocol File.
DMS	Data Management Software
GUI	Graphical User Interface
LAN	Local-Area Network
OBT	On-Board Time
QC	Quality Control
RBC	Red Blood Cell
RF	Radio frequency
UDI	Unique Device Identifier
UPS	Uninterruptible Power Supply
USB	Universal Serial Bus

1.3.1 Persons

Manufacturer

The manufacturer of the IH-500 is:

DiaMed GmbH

Pra Rond 23
1785 Cressier FR
Switzerland

Operator

The operator is the owner of a IH-500 both when using it as its owner and when transferring it to a third-party.

Personnel

The personnel gathers persons who have any kind of activity with the IH-500 and who are qualified in accordance with the manufacturer's requirements and who are consequently authorized.

Technical Personnel

The term «technical personnel» designates the duly trained persons, who are permitted to perform specific tasks on the IH-500.

For instance, an electrician is designated as technical personnel for the activities linked to wiring the IH-500 to the electrical network.

Minor Injury

A Reversible injury that does not require medical treatment.

Moderate Injury

A Reversible injury that does require medical treatment.

Major Injury

The damage that is irreversible, causes handicap or death.

1.3.2 Product (Definitions, Acronyms and Abbreviations)

Instrument

This is the IH-500 distributed by the manufacturer.

Bio-Rad authorized gel card

Gel Card based on column agglutination technique including a Micro-Tube-System consumable where the antigen-antibody binding is fixed in the gel-matrix.

- Only gel cards manufactured by Bio-Rad may be used in the instrument.

  Assure that any operations performed by the user are in compliance with the instructions for use of the gel card.

Sample

Content of any sample tube.

Bio-Rad authorized reagent

A **Consumable** substance or compound that is added to a system in order to get a chemical reaction. Such a reaction is used to confirm the presence of another substance.

b Only reagents authorized by Bio-Rad may be used in the instrument. Assure that any operations performed by the user are in compliance with the instruction for use of the reagents.

Diluent

A **Consumable** dilution solution used to produce a suspension with RBCs from **Samples**.

Consumable (Resources)

All items placed inside the **System** by a user except **Sample** tubes.

Barcode

A **Barcode** based data tag (an identification tag attached to a **Consumable** or **Sample** that can be automatically read by the **System**).

System

The complete Fully Integrated System hardware (PC integrated), software, **Consumables** and operating procedures.

STAT Samples

Sample with high priority to be integrated in the current work-flow of **SAMPLE** processing.

1.4 Typographical Conventions

The following styles are used in this manual.

Content of software screens and buttons remain in English printed in bold italic type and are followed by their translation in brackets (e.g. click the **VALIDATE** button to confirm).

1.4.1 Warning

bTo designate:

an imminent and dangerous situation which, if not avoided, may lead to major injury of the user;

or a potentially dangerous situation which, if not avoided, may lead to:

← moderate injury of user or in the tests being false;

← injury of user or in important delay in delivery of the test results.

1.4.2 Note

kIndicates:

•apreferred procedure or recommended use,

← a general or informative remark.

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← Safety and Handling

This chapter sets out instructions to ensure safe and trouble-free operation of the IH-500 and associated software. It also describes the handling and storage conditions.

2.1 Introduction

2.1.1 Principles

Before carrying out any operation on the IH-500, it is imperative to read this chapter and fully understand it.

In case of any doubt, consult your Bio-Rad Technical Service representative.

2.1.2 Importance of the Safety Instructions

All the safety instructions in this User Manual and on the instrument must be complied with in order to prevent accidents to persons, damage to equipment or pollution of the environment.

In a similar manner, the legal bylaws and the recognized technical rules which apply in the country of use of the IH-500 must be adhered to.

If during the use of this device or as a result of its use, a serious incident occurs, please report it to Bio-Rad Laboratories and/or its authorized representative and to your national Competent Authority.

2.1.3 Disregarding the Safety Rules

Disregarding the safety rules, as well as existing legal and technical regulations, may lead to accidents, property damages or environmental pollution.

Disregarding the instructions for use given by the manufacturer may reduce the level of protection offered by the instrument.

2.2 Environmental Conditions

Electro-medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

- The IH-500 must be kept away from potential sources of interference.

  The IH-500 may not be exposed to direct sunlight, heat, dust or excessive humidity (use only in a clean laboratory environment).

- The instrument must not be located near sources of high electromagnetic radiation which may interfere with proper operation.

  The use of the instrument in a dry environment especially if synthetic materials are present (clothes, synthetic carpets, etc.) may cause electrostatic discharges and lead to false results.

- Assess the electromagnetic environment of the site in which the IH-500 is located before switching it on.
- The recommended maximum length for the power cord is 2 meters.

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bio-Rad as replacement parts for internal components, may result in increased emissions or decreased immunity of IH-500.

IH-500 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, IH-500 should be monitored to verify normal operation in the configuration in which it will be used.

IH-500 complies with the EMC requirements according to IEC 61326-2-6.

It should be considered to perform an electromagnetic survey before putting the IH-500 into operation. IH-500 is intended for use in the electromagnetic environment specified below. The customer or the user of IH-500 should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	IH-500 uses RF energy only for 26its internal function.
CISPR 11		CISPR 11 Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	IH-500 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
CISPR 11		
Harmonic emissions	Compliant	
IEC 61000-3-2		
Voltage fluctuations/ flicker emissions	Compliant	
IEC 61000-3-3		

IH-500 is intended for use in the electromagnetic environment specified below. The customer or the user of IH-500 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air ±2 kV for power supply lines	±6 kV contact ±8 kV air ±2 kV for power supply lines	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±1 kV for lines no input/output ±1 kV line to line	±1 kV for lines no input/output ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Shock waves IEC 61000-4-5	±2 kV line to earth	±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and outages IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of IH-500 requires continued operation during power mains interruptions, it is recommended that IH-500 be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

IH-500 is intended for use in the electromagnetic environment specified below. The customer or the user of IH-500 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of IH-500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: ← $d = 1.2\sqrt{P}$: 150 kHz to 80 MHz ← $d = 1.2\sqrt{P}$: 80 MHz to 800 MHz ← $d = 2.3\sqrt{P}$: 800 MHz to 2.5 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

← Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IH-500 is used exceeds the applicable RF compliance level above, the IH-500 should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IH-500.

← Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The IH-500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IH-500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IH-500 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m] 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.3 General Safety Instructions

- Reagents, gel cards, samples, liquid and solid wastes should be considered potentially infectious. Therefore all parts of IH-500 should be considered as potentially infectious. When performing any operation on IH-500 local safety regulations and good laboratory practice must be followed. It is imperative to wear protective gloves when working with potentially infectious materials. The keyboard should be always covered by the provided silicon protection.

  For any other materials referred to in this manual (e.g NaOH, Wash Solution A) corresponding safety data sheets should be consulted before the first use, adequate protective measures should be applied and any applicable regulations should be followed.

- Repair and service operations must only be performed by a qualified service engineer appointed by the manufacturer.

  The IH-500 may only be connected to the electrical power sources specified.

  It is imperative to use only the liquids, reagents, gel cards, accessories, spare parts, software specified in this manual.

  The IH-500 may only be operated with the software supplied by the manufacturer. Anti-virus software can be installed following the Bio-Rad recommendations.

  Always scan USB devices (USB key, camera...) with updated anti-virus software prior to connecting to the instrument, if no anti-virus is installed on IH-500 PC.

  Make sure that the LIS is equipped with the necessary protection to ensure no virus nor access is transmitted to the IH-500.

  Any infringement of this rule will be considered by the manufacturer as guilty negligence.

bDo not place anything on top or above IH-500.

← This class (B) apparatus complies with Canadian ICES-003.

← The instrument is designed to be safe when temporary overvoltages that may occur between the line conductor and earth in electrical installations.

2.4 Special Safety Instructions and Signs

Appropriate safety instructions are mentioned in the specific chapters. They should be observed in the same way as the general safety instructions contained in this chapter.

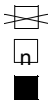
2.4.1 Signs

The following signs can be found on the IH-500. Associated warnings are explained in the table.

Sign	Description	Explanation
	Caution, consult accompanying documents	-
	Biological hazard	INFECTION All blood samples should be considered potentially infectious. Contact with skin/mucous membranes must be avoided. Always wear protective gloves when working with gel cards, sample tubes, waste bin and with any instrument, in accordance with laboratory safety regulations. All biological waste must be handled and treated by the user before disposal in accordance with local procedures and directives.
	High voltage danger	ELECTROCUTION During maintenance work, use extreme caution at all times when the IH-500 is powered and uncovered; the instrument must not be left unmonitored. Avoid using non-isolated metallic parts to work inside the instrument such as screwdrivers.
	Burning danger	HOT SURFACE Contact may cause burns. Do not touch.
	Corrosive product	CORROSIVE Causes severe burns. Avoid contact with skin and eyes.
	Main switch	Power ON

Sign	Description	Explanation
	Main switch	Power OFF
	Protective earthing	-

2.4.2 Packaging Signs

Symbol	Description
	Fragile, handle with care.
	Keep dry.
	Keep upright.
	Maximum and minimum humidity limitation.
	Maximum and minimum temperature limit.
	Stacking limit by number. Not to be vertically stacked higher than the specified number of items.
	Phytosanitary treatment of the pallet.
	Serial Number.

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← Instrument Overview

This chapter is a general presentation of the instrument.

3.1 Introduction

The IH-500 is a fully automated system for use in immunohematology testing. IH-500 automates the entire process of sample pipetting, addition of reagents, incubation, centrifugation and image capture.

IH-500 is a random access analyzer. There is no pre-sorting or batching of samples required before loading onto the system. Red blood cell reagents can be stored continually on board for 7 days. An internal inventory of up to 92 gel cards, 34 reagents vials and 4 diluent racks is possible.

IH-500 has capacity to load up to 50 samples. When additional routine samples are loaded onto the system, IH-500 automatically schedules the processing for optimum throughput. When priority samples are included into the work flow, IH-500 will interrupt less important processes in order to provide the result in the most efficient way possible.

All parameters involved in the testing of patient samples are continually monitored and recorded. Interaction with IH-500 is via a Graphical User Interface.

3.1.1 Main Features

- ← Fully automated system
- ← Continuous loading of samples and reagents
- ← Walk-away system (autonomy)
- ← Priority (STAT) sample handling
- ← 7 days reagent red blood cell on board storage
- ← 24/7 ready to start availability
- ← Well by Well management
- ← Single card tracking
- ← Titration testing

3.1.2 Data Management Software

The IH-Com data management software is required to analyze results.

3.1.3 Computer Protection

An application has been implemented to protect the computer.

It prevents any software installation from an external drive or local drive when logged in as **Standard user**. The installation of software such as Microsoft Office will be blocked.

An **Administrator** user level allows the installation of any software but the software must be copied on the desktop to be able to launch it.

A new component installation may require a patch to update the authorized application deployment.

At the end of the installation, the Field Service Engineer must inform the customer about the cybersecurity risks. He must define with the customer a new access login and password to forbid the free access to the computer.

3.2 Instrument Overview

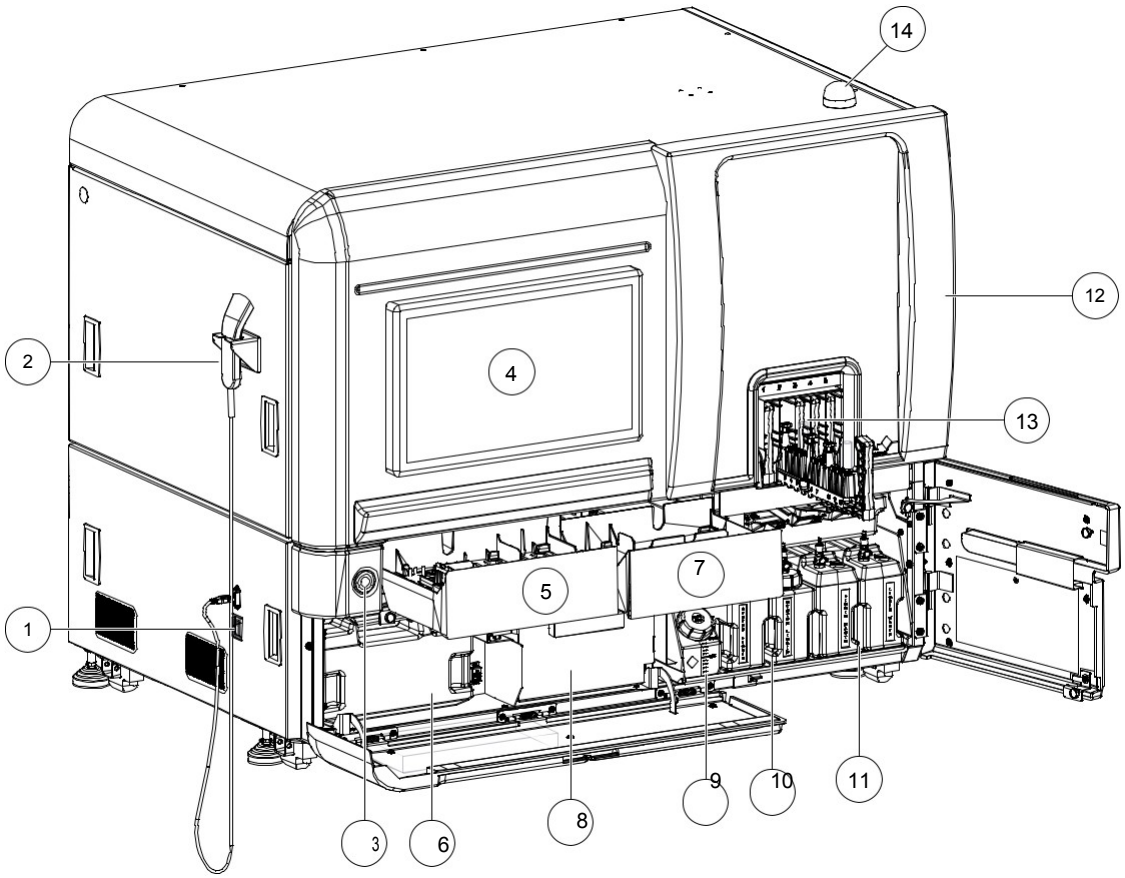


Figure 1. Front view

← Main power switch

← Hand-held barcode scanner

3Power button

4Touch-screen monitor

5Left drawer (gel cards, reagents and diluent loading and unloading)

If the option **Return Gel Cards** is active for this drawer, it is not possible to load gel card. See chapter Return Gel Cards on page 172.

← Cleaning liquid container storage area ***(for weekly maintenance)***

7Right drawer

The right drawer contains only gel card trays.

If the option **Return Gel Cards** is active for this drawer, it is not possible to load gel card. See chapter Return Gel Cards on page 172.

← Solid waste bin

← Decontamination liquid container (NaOH)

10 System liquid containers

11 Liquid waste containers

← Pipetting area door

← Samples loading area

← Operating status light

See chapter Operating Status Light on page 30.

b It is forbidden to physically force the opening of the pipetting area door.

← Only a qualified Bio-Rad service engineer is allowed to open the maintenance door.

3.2.1 Operating Status Light

Green	Instrument ready and waiting for new samples.
Blue	Instrument processing samples.
Orange	Instrument continues to work but indicates a minor problem (GUI displays an orange warning), e.g. if one liquid waste container is full. Perform a corrective action as soon as possible.
Red	Instrument has stopped (GUI displays a red error) and requires a user intervention, e.g. solid waste bin full.

3.2.2 Internal Storage and Pipetting Area

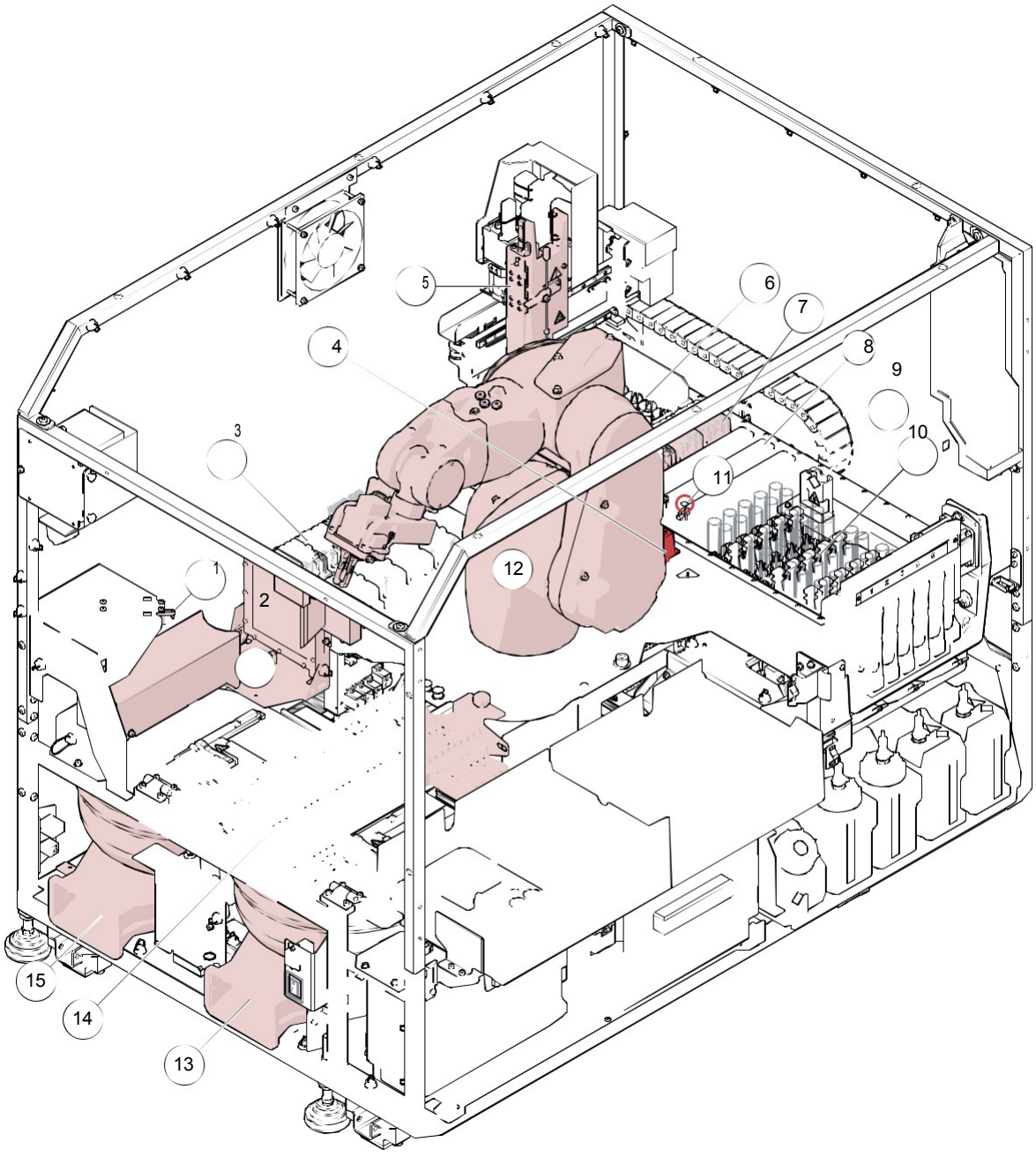


Figure 2. IH-500 - Top view - Internal storage and pipetting area

← Gel cards piercer module

2Imaging station

3Gel card preparation area

4Incubator 37°C

← Pipettor

← Reagents pipetting, cooling and storage module

7Gel cards pipetting module

8Diluent piercing, pipetting and storage module

9Washing module

← Sample racks loading and pipetting area
← Needle reference position
← Transport arm (robot)
← Front centrifuge
← Gel cards internal storage
← Rear centrifuge

3.2.3 Left Drawer

The left drawer offers multiple loading options for reagent vials, diluent racks and gel card trays (input and output).

It is possible to load up to:

← 3 gel card trays, 5 reagent vials;

← or 17 reagent vials and 4 diluent or titration racks.

Markings indicate where to load the resources in the left drawer. The resources loaded in the left drawer have priority over resources loaded in the right drawer.

See chapter Loading Options on page 34.

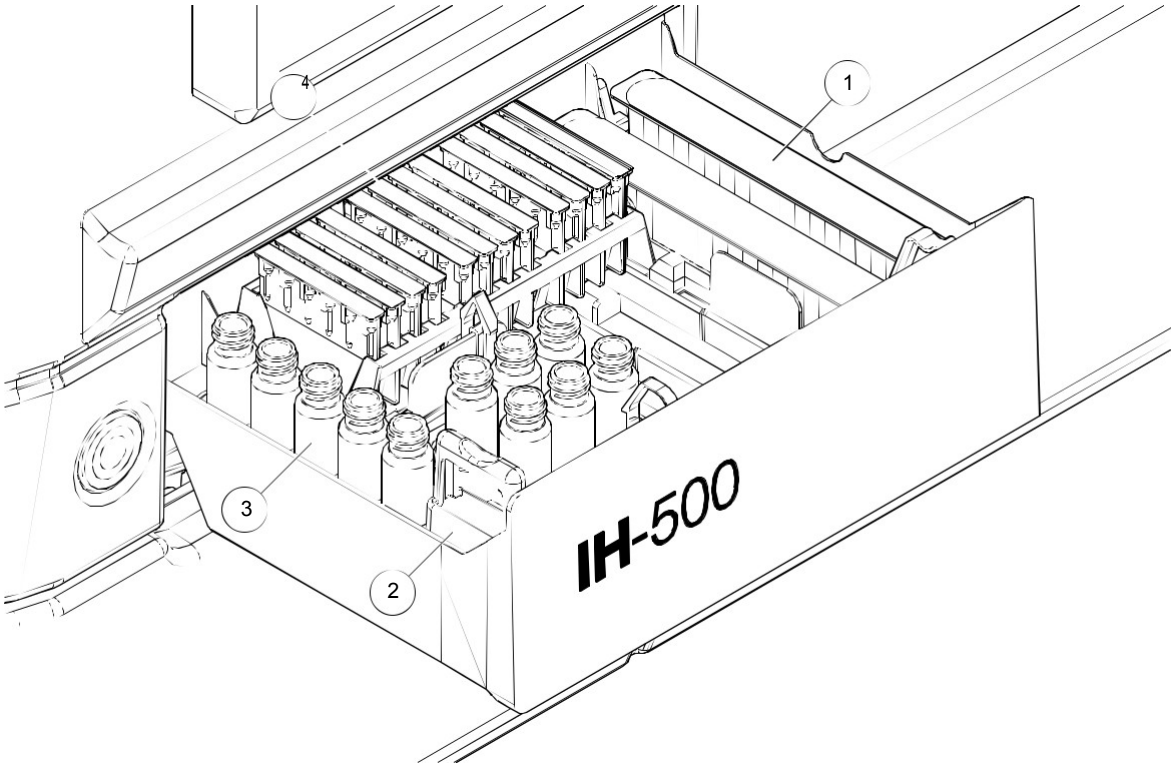


Figure 3.

← Diluent rack or ID-Titration rack

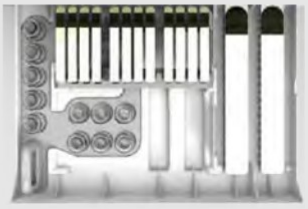
2Reagent tray

3Reagent vial or ID-Titration Solution vial

4Gel card tray

For help regarding preparation of the resources refer to chapter Preparing Resources and Samples on page 91.

3.2.3.1 Loading Options

Gel card tray	Diluent or ID-Titration rack	Reagent vials	Configuration
0	4	17	
1 x 12	2	17	
1 x 12	2	11	 
2 x 12	2	5	
2 x 12	0	11	 
3 x 12	0	5	

3.2.4 Rear View

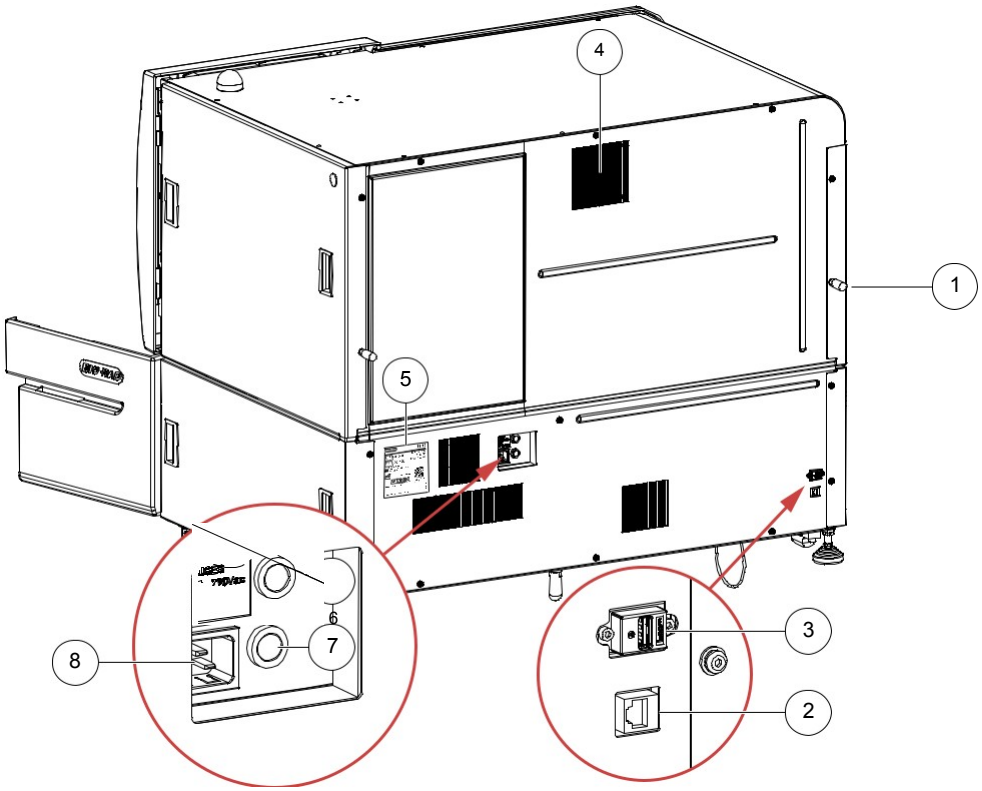


Figure 4.

← Wall spacer

← RJ45 port to connect the LAN network cable

3USB port for UPS

4Fan and filter

5Identification Plate (see page 54)

6AC (L): Alternative Current Live fuse connection

7AC (N): Alternative Current Neutral fuse connection

8Main power supply plug

Fuses

- 2x8AT 230 VAC
- 2x20AT 120 VAC

bOnly connect low voltage devices to the USB and RJ45 ports.

← Only a qualified Bio-Rad technical representative is allowed to remove the protection panels.

← Only a qualified Bio-Rad technical representative is permitted to change the fuses.

3.3 IH-500 Components

3.3.1 Gel Card and Gel Card Tray

There are different types of gel cards available:

- ← Gel cards which contains specific antibodies and reagents to determine erythrocyte antigens (blood groups antigens and other rare antigens);
- ← Gel cards which contains the anti-human globulin (mono-/polyspecific for performing antibody screening tests, antibody identification, tolerance test and to determine the direct Coomb tests;
- ← Neutral gel cards to determine the serum check, NaCl and the enzyme test.

bOnly gel cards manufactured by Bio-Rad may be used.

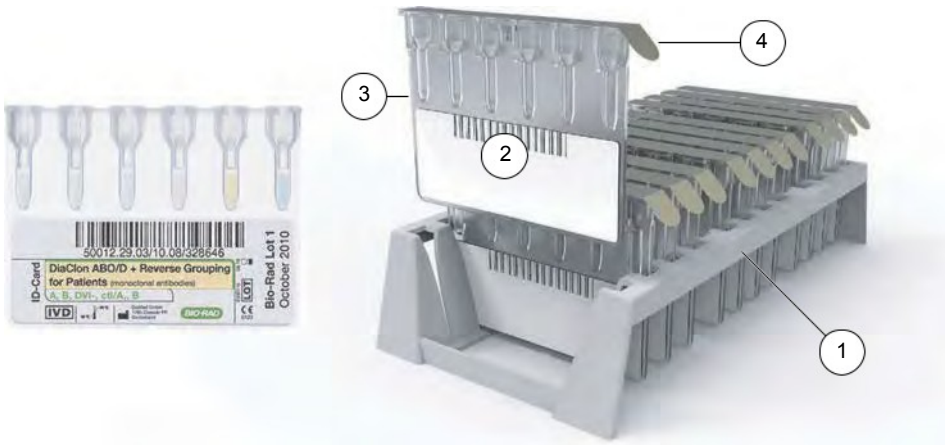


Figure 5. Gel card and gel card tray

← Gel card tray

← Gel card identification barcode

3Gel card

4Foil strip

Gel cards are delivered in trays which can be loaded directly on the instrument. Each tray can hold up to 12 gel cards.

It is possible to load 3 trays in the right drawer (gel cards input only) and 3 trays in the left drawer (gel cards input / output), if the return of gel cards is not activated.

The instrument internal storage can contain up to 92 gel cards.

The instrument unloads gel cards to the left or right drawer according to the option **Gel Cards Release Drawer** (for visual inspection).

Used gel cards (all wells pierced) are sent to the solid waste bin.

3.3.2 Reagent or ID-Titration Solution Tray

Only reagents or ID-Titration Solution authorized by Bio-Rad may be used. Make sure that any operations performed are in compliance with the instructions for use.

Figure 6. Reagent vials and ID-Titration Solution vial (example)

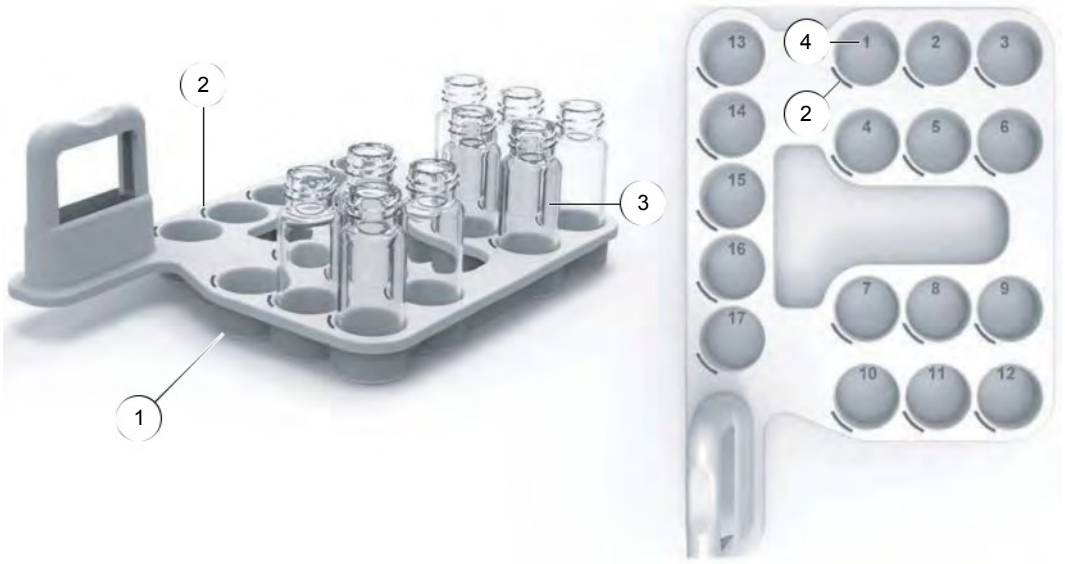


Figure 7. Reagent tray

← Reagent tray

← Barcode alignment mark

← Reagent or titration solution vial

4Reagent vial position number

A reagent tray can contain up to 17 vials.

Alignment marks indicate which way to orientate the vial barcodes.

It is possible to load 34 reagent or titration solution vials in the instrument.

b Only load vials in the reagent tray delivered with the instrument and in the left drawer A area. vial placed in a other area can lead to spillage and contamination.

3.3.3 Diluent or ID-Titration Solution Rack

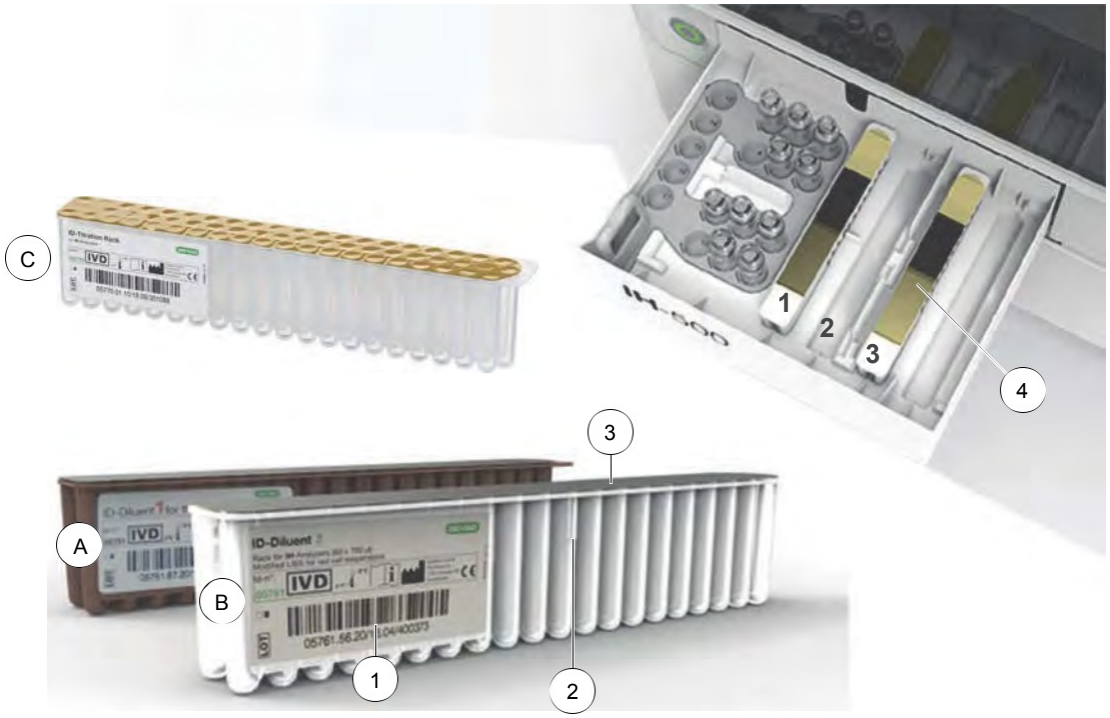


Figure 8. IH-500 Diluent rack

← Identification barcode

2Positioning support

← Foil

← Left drawer entry positions (1 to 4)

It is possible to load 3 diluent racks in the instrument internal storage.

Four entry positions (1 to 4) clearly indicate where to place the diluent racks in the left drawer. It is possible to load multiple resources in the left drawer.

Non-pierced diluent racks are brought back to the left drawer. Pierced diluent racks are sent to the solid waste bin.

⟵ Only use racks (with positioning support):

- ← **ID-Diluent 1** (**A** - brown plastic);
- ← **ID-Diluent 2** (**B** - translucent plastic);
- ← **ID-Titration Rack** (**C** - translucent plastic).

⟵ Only load unused (non-pierced) racks.

3.3.4 Sample Specifications

- Use only samples which are correctly centrifuged (refer to Good Laboratory Practice). It is recommended to centrifuge samples from blood bag segments prior to their use. The use of non-centrifuged samples from blood bag segments might lead to an increased number of doubtful reactions.
- Samples should be centrifuged before retesting on the instrument in order to ensure complete separation of red cells from plasma/serum.
- Reliability of results is dependent upon compliance with good laboratory practices for reagents and samples as well as with the corresponding box inserts.
- Do not use samples which are older than 5 days (older samples can degrade the results).
- Make sure that the sample tube barcode specifications comply with chapters Type of Barcodes read by the Instrument on page 41 and Sample Tube Barcode Specifications on page 42.
- Verify that the quantity of plasma/serum and red blood cells is conform with the need of the tests to be processed. Refer to tables of chapter Quantity of Plasma/Serum and Red Blood Cells on page 43 containing the specifications for each diameter of tube. An incorrect estimation can degrade the result.
- The barcodes of the sample tube holders must be clean and not scratched. If necessary, clean the barcodes with a lint free cloth or replace the sticker set.

3.3.4.1 Sample Requirements ABO/Rh Testing

Centrifuged blood samples are required for tests which involves red cells. EDTA is considered an acceptable anticoagulant for patient and donor samples.

Clotted samples (no anti coagulant in the sample) cannot be used when red cell testing is being performed. Clotted, grossly hemolyzed or grossly lipemic or grossly icteric samples may result in inaccurate typing or increased “not interpretable” results.

Anti-coagulated blood samples can be tested for up to 5 days after collection. If the samples are not tested within 24 hours of collection, samples should be stored at 2 to 8°C.

The samples must return to room temperature prior to analysis. The use of cold samples may cause dispensing errors or non-specific reactions.

Prior testing, samples must be centrifuged according to the local Good Laboratory Practices, e.g. 10 minutes at 1500g, in order to obtain a distinct separation between cells and plasma/serum.

3.3.4.2 Antibody Screen Testing

Plasma or serum can be used for the antibody screening, antibody identification, reverse grouping and crossmatch on the IH-500.

3.3.4.3 Type of compatible Samples Tubes

The following glass, PET or polyethylene tubes are compatible with the instrument:

Refer to section Samples Tubes Specifications on page 252 for more details.

Sample Tubes Shapes

Figure 9. Sample tubes shapes

← Spherical bottom tube

2Pediatric tubes

To be used with spherical bottom tube.

3Conical tube

4Plunger tube (flat bottom tube)

5Special flat bottom tube

6Customer defined tube *(not illustrated)*

← During the commissioning of the instrument, Bio-Rad personnel can set up specific adjustment of the aspiration position for:

- ← pediatric patient tubes (sample tubes block type 02 and 12);
- ← sample tubes block “low volume” (sample tubes block type 06 and 16).

However, the customer is responsible for the validation of these specific tube types after the adjustment. The customer must use only the validated types of sample tube on the rack 2 and/ or 6. If no specific adjustment is performed, the rack number 2 and/or 6 cannot be used.

Sample Tube Dimensions

←	10 to 17 mm
←	8 to 15 mm
←	66 to 100 mm

Figure 10. Sample tubes dimensions

3.3.4.4 Type of Barcodes read by the Instrument

1D sample tube barcode

← It is recommended to use secured barcode types. For non-secured types (Codabar, Code 39, Code 93, Interleaved 2 of 5), the barcode must have at least 4 characters in order to prevent confusions.

Barcode types
Code 39, 93, 128
Interleaved 2 of 5
EAN-8
CODABAR with control character suppressed
UCC-EAN 128 with control character suppressed
ISBT 128 with specific characters
EAN13 (equal to UPC-A 13)

Characters ASCII allowed
a b c d e f g h I j k l m n o p q r s t u v w x y z A B C D E F G H I J K L M N O P Q R S T U V W X
Y Z 0123456789
[Space] ! “ # $ % & ’ ( ) * + , - . / : ; < = > ? @ [\ ] ^ { | } ~

3.3.4.5 Sample Tube Barcode Specifications

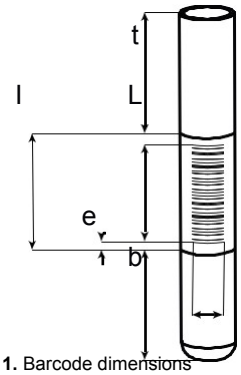


Figure 11. Barcode dimensions

Ref	Designation	Description	Comments
b	Barcode position: bottom	min. 10 mm for rounded end tubes min. 13 mm for flat end tubes (plunger tubes)	-
e	Blank space	Min. 5x Module size x Ratio For code 128 only: 7 mm with a «Module» of 0.35 (0.35x4x5) (Code incl. Up to 4 different bar widths)	e.g.: 4.5 mm for a Module of 0.3 mm with a Ratio of 3
H	Height of code	min. 5 mm	-
L	Length of code	min. 35 mm	-
l	Total length	max. 70 mm	-
t	Barcode position: top	min. 15 mm	-
-	Color	Black with white background	-
-	Number of characters	max. 30	-
-	Grade	B min. recommended	Print quality
-	Module	0.2 to 0.35 mm	Width of single bars
-	Ratio	from 2.2 to 3	Relation between small and wide bars

3.3.4.6 Dead Volumes

Model	Volume
Standard tube 13*75 Terumo	150 µl
Plunger tube 11*66 Sarstedt	100 µl
Low volume tubes 1,5 ml Sarstedt	50 µl

3.3.4.7 Quantity of Plasma/Serum and Red Blood Cells

bBefore loading, ensure that there is a sufficient quantity of sample for the required tests to be processed.

IH-500 Centrifuged Sample Tubes Minimum Plasma Height

Example: When using 11mm diameter tubes and 400µl plasma, height must be at least 12mm (see example below in the green cell).

	Tube exterior diameter (mm)						
	11	12	13	14	15	16	17
25	7	6	6	6	6	6	6
50	7	7	6	6	6	6	6
75	7	7	7	6	6	6	6
100	8	7	7	7	6	6	6
125	8	8	7	7	7	6	6
150	8	8	7	7	7	7	6
175	9	8	8	7	7	7	7
200	9	8	8	7	7	7	7
225	9	9	8	8	7	7	7
250	10	9	8	8	7	7	7
275	10	9	8	8	8	7	7
300	10	9	9	8	8	7	7
325	11	10	9	8	8	8	7
350	11	10	9	9	8	8	7
375	11	10	9	9	8	8	8
400	12	10	10	9	8	8	8
425	12	11	10	9	9	8	8
450	12	11	10	9	9	8	8
475	12	11	10	9	9	8	8
500	13	11	10	10	9	9	8
525	13	12	11	10	9	9	8
550	13	12	11	10	9	9	8

Distributed volume (µl)

Red blood Cells Minimal Height

Dimension (mm)	Standard tube		Plunger tubes				Low volume tubes
Diameter	13	16	11	13	15	16	-
Red Blood cells height	6	6	9	10	9	9	5

The values are valid for the tubes of type:

- ← BD diagnosis;
- ← Terumo and Greiner for standard tubes;
- ← Sarstedt for plunger tubes;
- ← Sarstedt ref: 72.703 for low volume tubes.

3.3.5 Sample Rack and Sample Tube Holder

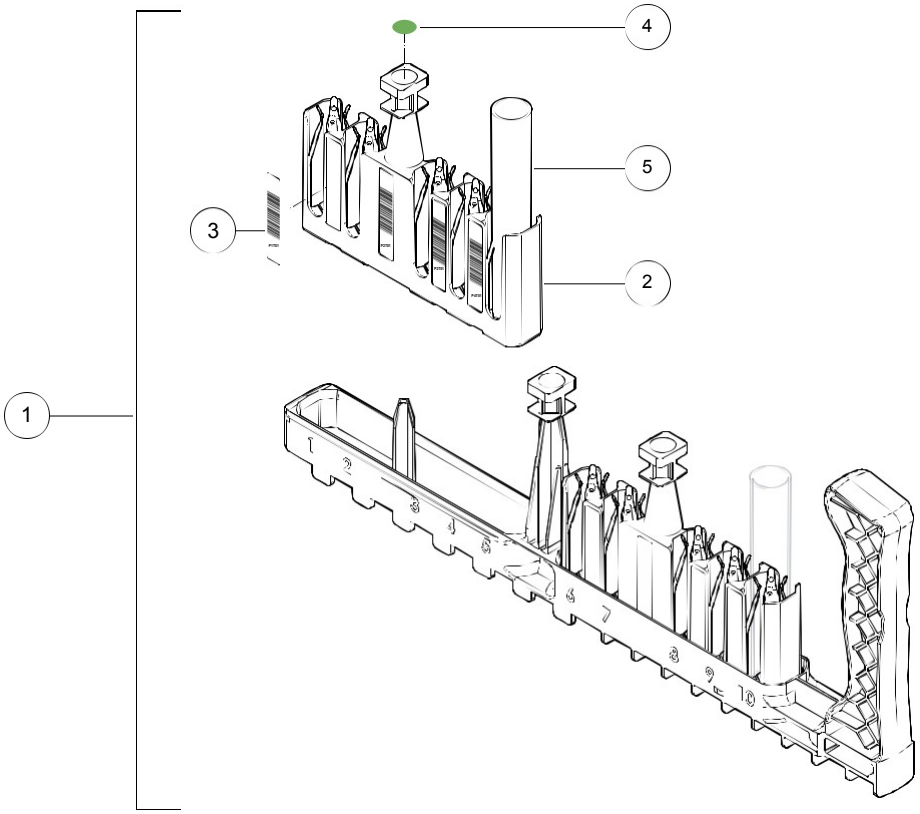


Figure 12. IH-500 sample rack

← Sample rack

← Sample tube holder

3Barcode stickers

4Tube type stickers

5Sample tube

A sample rack can contain up to 10 sample tubes.

Each sample rack can contain two sample tube holders (2 x 5 sample tubes - positions 1 to 5 and 6 to 10) which are handled by the transport arm.

The barcode of the tube has to be visible on the left side. If the barcode of a sample cannot be read, the instrument will give an unreadable or non detected barcode error.

The position of the sample in the rack defines which sample will be processed first; the samples are processed in numerical order.

Sample racks can be introduced from position 1 to 5 in the samples loading area.

50 samples can be loaded onto the instrument.

3.3.5.1 Using Barcode Stickers on Sample Tube Holders

Barcodes (3) must be used on sample tubes holders in order for them to be used on the instrument.

Stickers with barcodes must be put on a new sample tube holder so that it can be used in the instrument.

For details, see chapter Standard and STAT Sample Barcode Sticker Sheets on page 46.

3.3.5.2 Priority Sample Tube Holder

A priority sample tubes holder is identified by a specific barcode.

If the required resources are available, all the samples of the priority tubes holder will be processed before the samples of a standard rack.

See chapter STAT Sample Tube Holders Barcode Sticker Sheet on page 46.

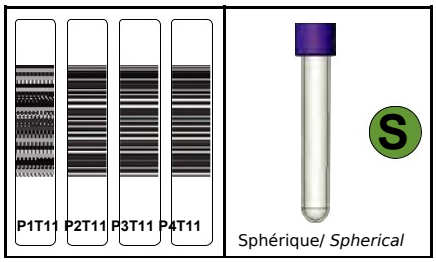


Figure 13. STAT sample barcode sticker sheet (example)

3.3.5.3 Standard and STAT Sample Barcode Sticker Sheets

STAT Sample Tube Holders Barcode Sticker Sheet

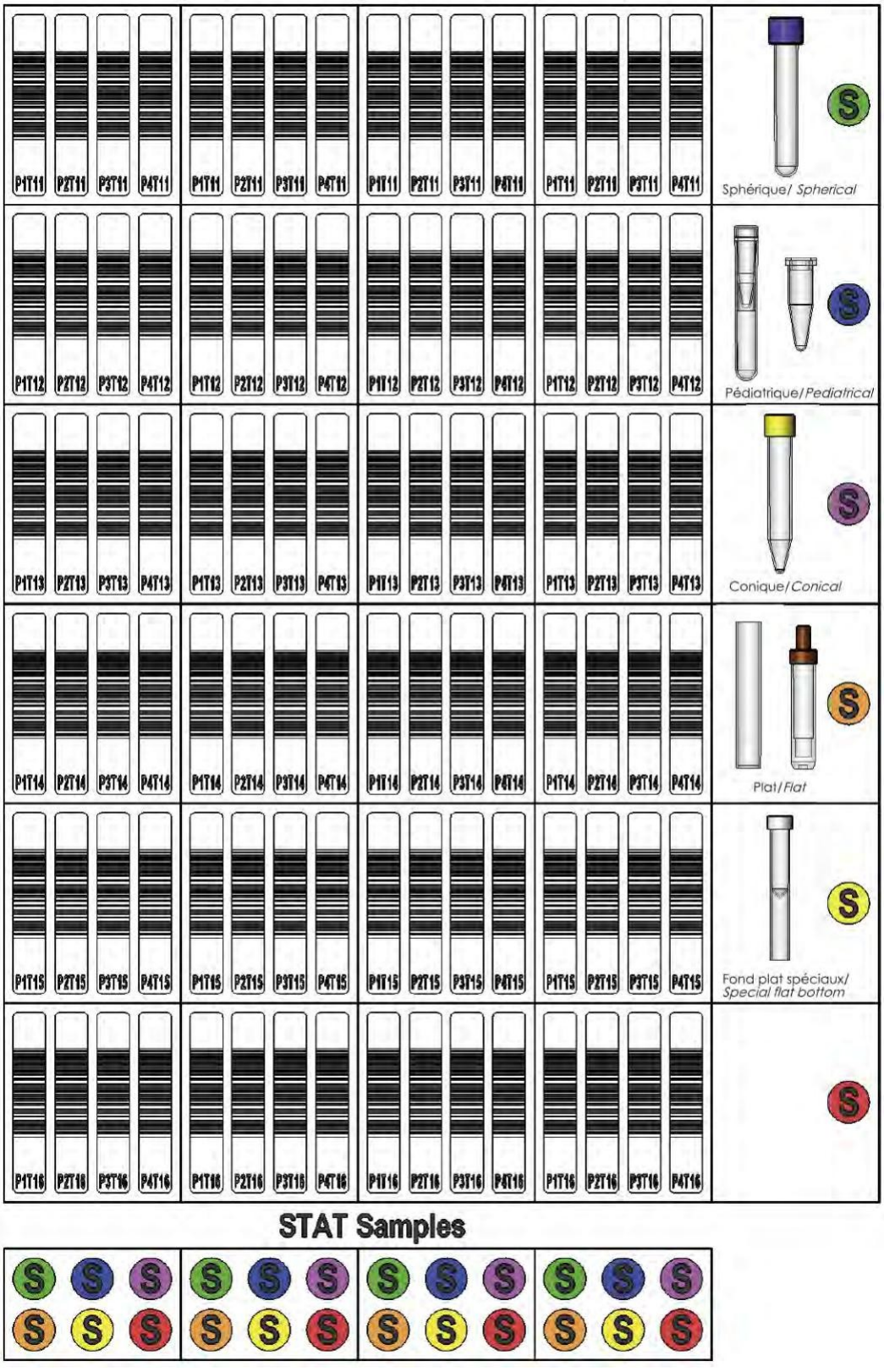


Figure 14. Description - STAT sample barcode sticker sheet

Sample Tube Holders Barcode Sticker Sheet

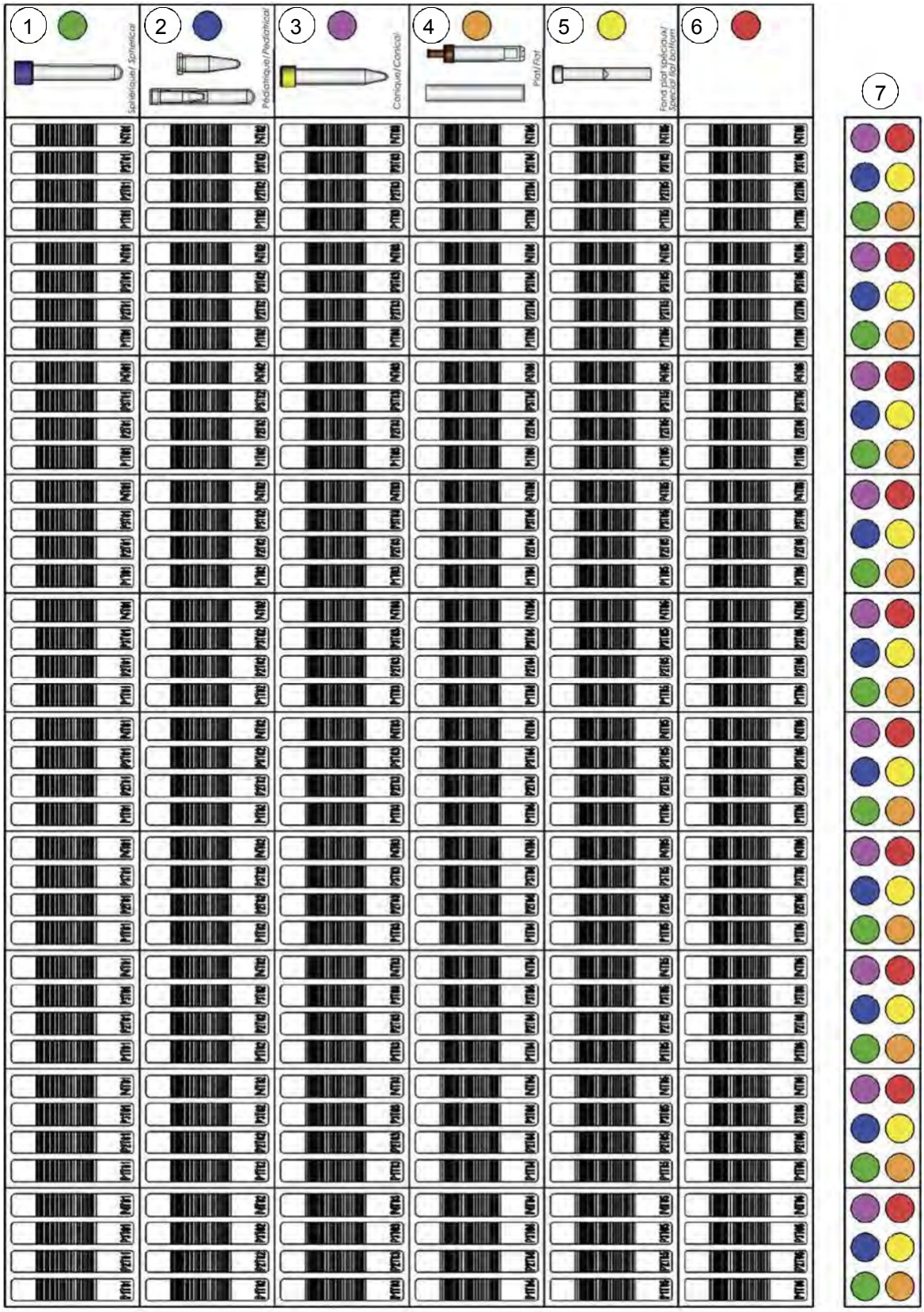
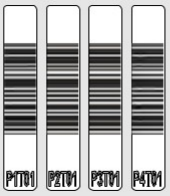
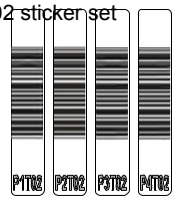
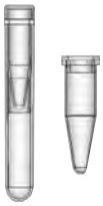
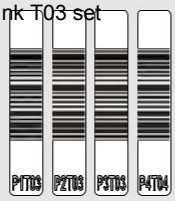
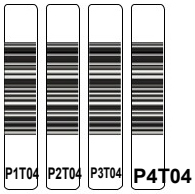
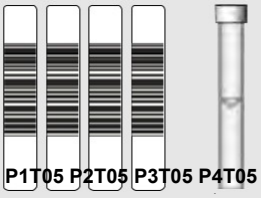
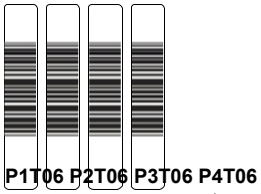
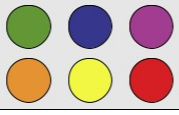


Figure 15. Barcode sticker sheet

Barcode Sticker Sheet (Description)

#	Description	sticker	Tube type barcode Figure	color sticker (7)	Tube type Color	Tube type (#)
1	**Spherical** tube barcode sticker set (standard spherical bottom tube)				Green	T01
2	**Pediatric** tube barcode Blue T02 sticker set (low volume tube)					
3	**Conical** tube barcode sticker Pink T03 set (standard conical bottom tube)					
4	**Flat** tube barcode sticker set (plunger tube)				Orange	T04
5	**Special flat bottom** tube barcode sticker set				Yellow	T05
6	Customizable				Red	T06
7	Tube type color sticker set			-	-	-

Barcode Sticker Set (Identification)

Each set is composed of four barcode stickers to be used on a sample tube holder. Each set is identified as follows:

Px**T**yy

← «**x**» is the sample separator barcode Position (**P1** to **P4**);

← «**yy**» is the tube type (**T01** to **T06**)

The first number defines the priority of sample tube holder:

← **T01** to **T06**: routine sample loading;

← **T11** to **T16**: STAT (priority) sample loading (see Priority Sample Tube Holder on page 45).

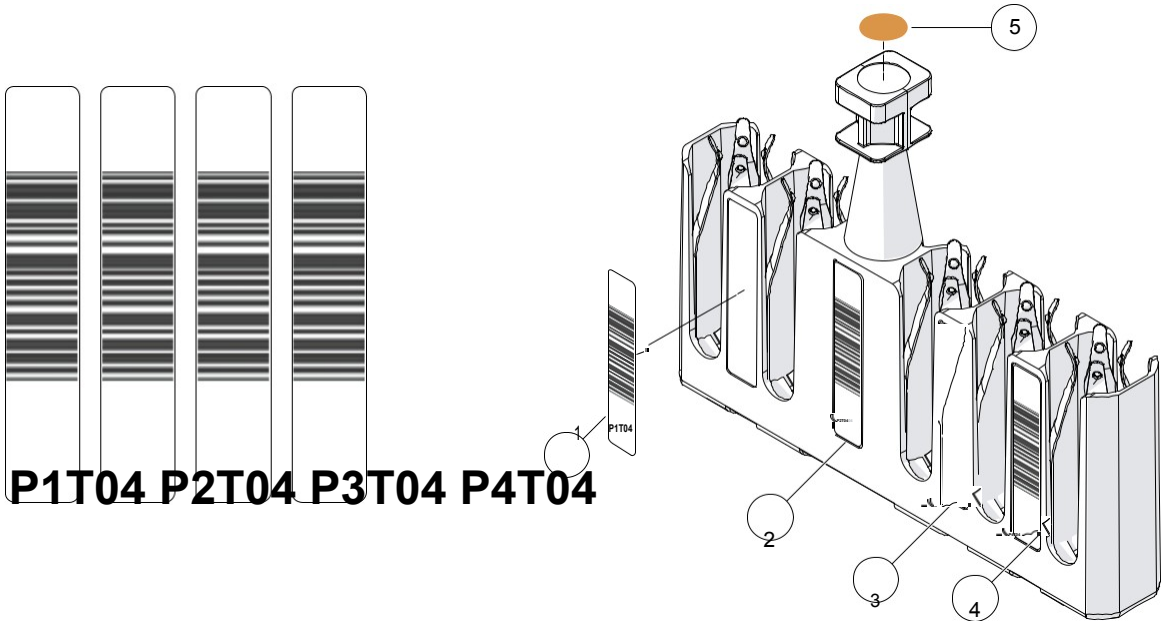


Figure 16. Example using a sample tube holder with flat bottom tubes (**T04**)

← **P1T04**

← **P2T04**

← **P3T04**

← **P4T04**

← Tube type orange sticker

STAT (priority) sample is identified with an S (see STAT Sample Tube Holders Barcode Sticker Sheet on page 46).

⟵ The barcodes of a sticker set must only be used on the same sample tube holder, with the corresponding color sticker.

3.3.6 Solid Waste Area Door

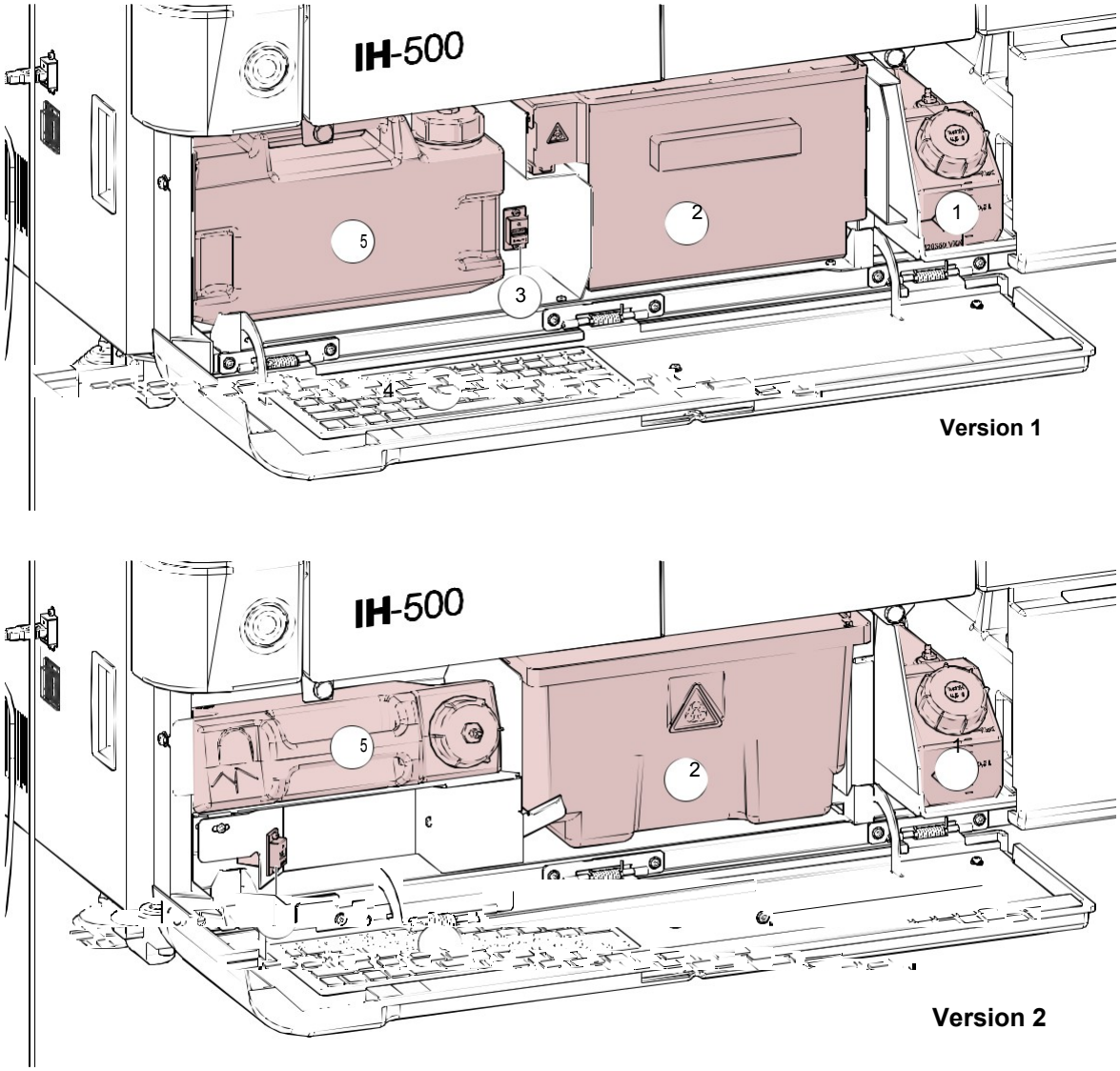


Figure 17. IH-500 Solid waste area door

← Decontamination liquid container (NaOH 0.5 M)

2Solid waste bin

3USB port

4USB Keyboard

5Cleaning liquid container storage area

Empty or expired reagent vials (except some 5 ml vials, see chapter Used 5 ml Vials brought back (Left Drawer) on page 251) are sent to:

- ← the solid waste bin, if the option **Do Not Trash Any Reagent** is disabled;
- ← the left drawer, if the option **Do Not Trash Any Reagent** is

enabled. See chapter Do Not Trash Any Reagents on page 173.

Used diluent racks and gel cards are sent to the solid waste bin.

Always empty the solid waste bin on startup and shutdown.

A keyboard according to country specifications (e.g. QWERTZ or QWERTY) is available.

The solid waste area door also allows access to the cleaning liquid container (storage only) and the decontamination liquid container (NaOH 0.5 M).

3.4 Technical Data

3.4.1 Performance

Throughput	Depending on the profile, up to 70 gel cards per hour
Loading capacity	• Up to 50 sample tubes; • up to 34 reagent vials; • up to 92 gel cards internally or 164 gel cards with the 2 drawers; • up to 4 diluent racks; • 2 x 2L container for system liquid; • 2 x 2L container for liquid waste; • 1 x 1L container for decontamination liquid (NaOH 0.5 M); • 1 x 2L container for cleaning liquid • 1 x solid waste bin, capacity for 50 gel cards, 2 ID-Diluent and 8 reagents vials.
Identification	Full positive identification (by barcode) of primary sample tubes, reagent vials, diluent products and gel cards including lot number and expiry date control

3.4.2 Order information

IH-500	001500
Stand-alone table (optional)	0595002

3.4.3 Dimensions of instrument

Width	115 cm
Height	98 cm
Depth	85 cm
Depth (pipetting door open)	141 cm
Weight	213 kg

3.4.4 Electrical Data

Voltage	100-230 VAC
Frequency	50/60 Hz
Power consumption	1,350 VA maximum

b The power cord must be in accordance with local regulations.
Voltage/Current specifications are: 230V/10A or 110V/15A.

3.4.5 Environmental Conditions

bDo not use the instrument outside the defined ranges of environmental conditions.

Operating room temperature	18°C to 28°C
Storage & transport temperature	-20°C to 55°C
Relative humidity, no condensing	5 to 80% rh (storage, transport and operating)
Power fluctuation	± 10%
Transient over-voltage	Category II
Altitude (above sea level)	2000 m maximum

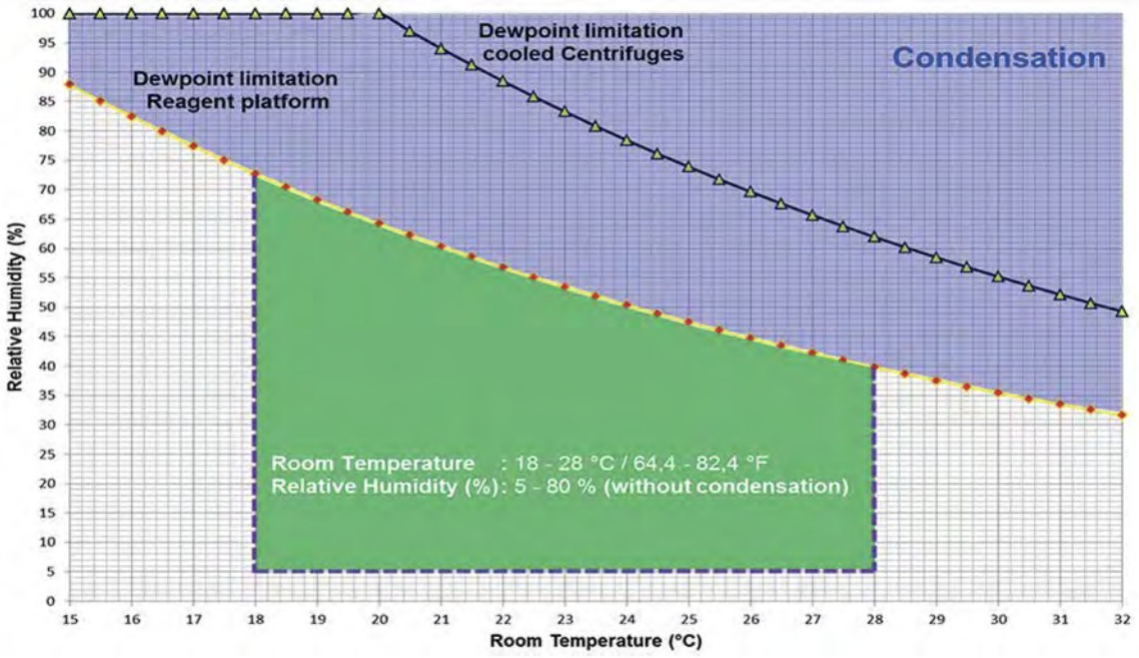


Figure 18.

3.4.6 Emissions

Heat emission	1000 W maximum
Noise	65 dB (A) maximum
Pollution level	2

3.4.7 Identification Plate

The identification plate is located at the rear of the instrument.

Please copy the following information from the identification plate in the fields below:

Type

Serial number (SN)

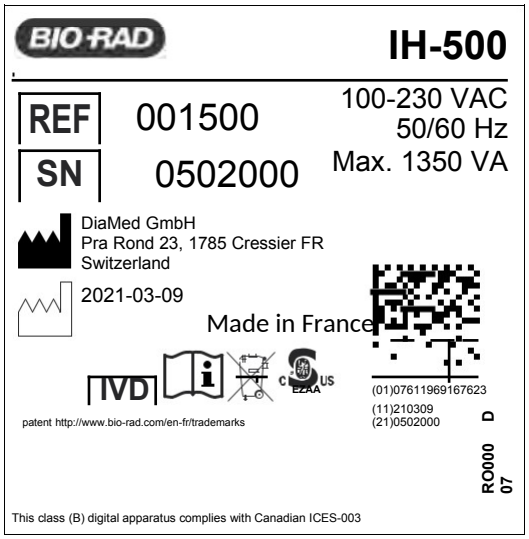


Figure 19. Identification plate

Sign	Description
←	Manufacturer reference (order number)
←	Serial number
	Manufacturer
	Date of manufacture (yyyy-mm)
	CE mark See chapter CE Compliance on page 248.
←	In Vitro Diagnostic medical device
	See documentation
	WEEE mark See chapter CE Compliance on page 248.
	Curtis-Straus marking - Canadian & US
	2D barcode (SN + UDI)

3.5 Theory of Operations

3.5.1 Reaction Process

The ID-System is based on a process concerned with the determination of antigen-antibody complexes. The agglutinated particles are separated from non-agglomerated particles by the means of an inner gel. The gel cards used contain 6 microtubes.

The reaction occurs on the gel-filled microtubes. The gel contains specific antibodies or reagents in accordance with the desired reaction.

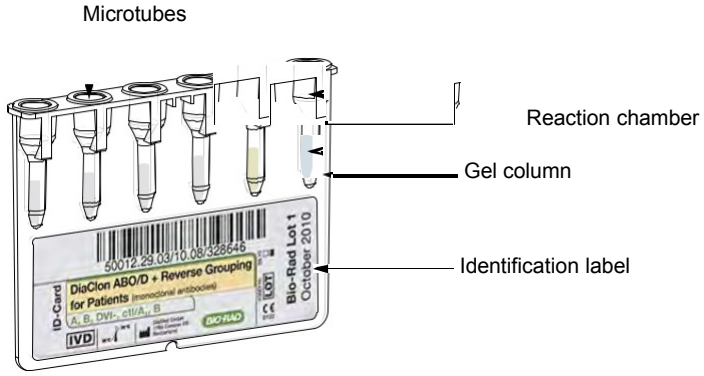


Figure 20. Gel card description

After adding the sample to test, it is possible to visually observe in the gel column the separation between the agglomerated and non-agglomerated red blood cells after a centrifugation.

Depending on the intensity of the reaction, red blood cells penetrate the gel to a different extend. It is thus possible to classify the reaction into 6 steps: ++++, +++, ++, +, +/-, -, as follows:

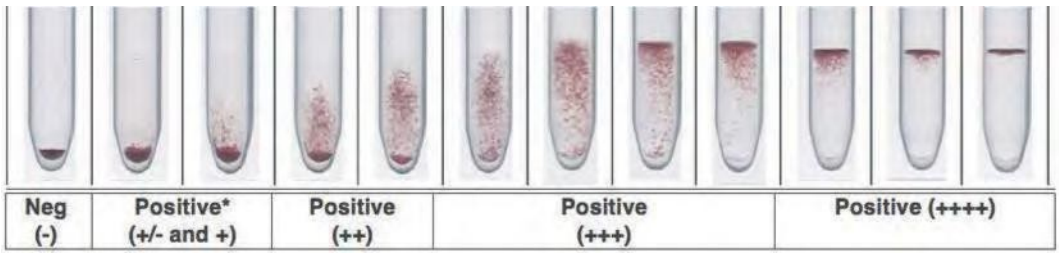


Figure 21. Gel card - Degrees of reaction

3.5.2 Test, Interpretation and Result

The imaging station captures an image of the gel card reaction. The image is divided into search windows, which are then analyzed by the instrument.

Search windows are divided into 6 zones: the lower part for a negative result, the upper part for the positive ++++ results and four intermediate zones for the +/-, +, ++, and +++ results.

The instrument analyzes the image and determines the reaction result for each microtube.

A test result is based on the results of the corresponding microtubes. That result must then be validated by the user on the basis of the digital image provided. Refer to IH-Com User Manual for detailed information on reaction results.

Manual corrections are marked with an asterisk “*”.

3.6 Process Flow

Depending on the process, the pipettor will take suitable quantities of sample, diluent and reagent. It will then supply them to the appropriate gel cards. The pipette needle is then automatically sent to the washing module. IH-500 allows continuous sample and resources loading.

- As soon as the right drawer is closed the entire drawer is scanned and each gel card is transported individually to the imaging station for identification. If valid they are loaded on board otherwise they are brought back to the right drawer. If the option **Gel cards control** is set, the system checks the integrity of each gel card.
- As soon the left drawer is closed the entire drawer is scanned and each resource (reagents, diluents or gel cards) is transported individually to the imaging station for identification. If valid they are loaded on board otherwise they are brought back to the left drawer. The left drawer has priority over the right drawer. If the option **Gel cards control** is set, the system checks the integrity of each gel card.
- The reagent vials are cooled and set into motion to keep the cells in suspension. On board stability is 7 days for Red cells and Antiserum.
- As soon as the sample holders are loaded, these ones are detected by the transport arm. The sample tube holders are carried to the imaging station:
  - for identification (samples and separators barcodes);
  - to check the presence or absence of caps on each tube;
  - to measure the dimensions of each tube (external diameter and height).

  The sample tube holders are then brought back to the pipetting area.
- According to the process, the transport arm grabs a diluent piercer and required diluent wells are pierced in the diluent piercing, pipetting and storage module.

← According to process the transport arm sends the necessary gel cards to the piercing module and transports them to the gel cards preparation area to prepare blocks up to four gel cards which are sent to the pipetting area.

The gel cards preparation area allows to:

- ← prepare gel cards before pipetting operations;
- ← incubate at ambient temperature after pipetting;
- ← prepare gel cards before incubation at 37°C;
- ← prepare gel cards before transport to the centrifuge.

← The pipettor supplies the sample and the reagents in the appropriate well of the gel card.

8 If necessary, the transport arm brings the gel card to the 37°C incubator module.

← The transport arm loads the gel cards into an available centrifuge. If necessary, a balance gel card is loaded.

← The transport arm takes the centrifuged gel card to the imaging station and reads the result. The result is sent to the data management software to be interpreted.

← According to the setting of the option **Return Gel Cards**, all or some gel cards are returned to the gel card release drawer (left or right drawer) or sent to the solid waste bin. See chapter Return Gel Cards on page 172.

The other used resources are sent to the solid waste bin (except some used 5 ml vials are brought back to the left drawer). It is possible to unload unused resources to the left drawer.

3.7 Features

3.7.1 Full Positive Identification

IH-500 allows single gel card tracking for flexibility during loading.

IH-500 automatically identifies the resources required by reading the barcodes when they are first placed on the instrument and compares them with the ones required for the selected test program.

It also checks the lot number and the expiry date of the resources used in the system.

3.7.2 Liquid Level Detection

The IH-500 is designed to permanently check the availability of reagent, diluent and liquid containers in order to avoid any failure.

3.7.3 Clot Detection

To prevent any obstruction of the fluid circuit by red cells or serum during the pipetting process, a sensor detects the presence of clot.

In case a clot is detected, refer to chapter Pipettor in Error on page 154.

3.7.4 Priming and Washing of the Fluidic Circuit

During operational processes the pipetting needle is decontaminated with any NaOH (0.5 M) present in the decontamination liquid container.

The weekly maintenance command primes the hydraulic circuit with cleaning liquid and system liquid.

3.8 Cap Detection for Reagents and Samples

3.8.1 Reagents Vial Caps

All Bio-Rad reagent vial caps are detected by the IH-500.

3.8.2 Sample Tube Caps

← Residual blood at the top of the sample tube maybe wrongly detected as a cap. Visually check the sample tube before proceeding the test.

3.8.2.1 Types of Caps detected on Standard Tubes

These types of tubes must be loaded only on sample tube holders labeled with code 01 or 11.

bIf these conditions are not met, there is a risk of causing a needle to crash.

The following types of caps are detected by the IH-500.

Figure 22. Cylindrical tubes cap detection

Ref	Brand	Manufacturer Ref. (1)	Color	Size (2)
BD1	BD diagnostic	367-704	Opaque blue	13*75
BD2	BD diagnostic	367-862	Opaque purple	13*75

Ref	Brand	Manufacturer Ref. (1)	Color	Cap Detection for Reagents and Samples Size (2)
BD3	BD diagnostic	367-614	Opaque red	13*75
Ter1	Terumo	VF-054-SBCS	Opaque blue	13*75
Ter2	Terumo	VF-054 SDK	Opaque purple	13*75
Ter3	Terumo	VF054SAS	Opaque red	13*75
Gr1	Greiner	GR02CCNV (454322)	Opaque light blue	13*75
Gr2	Greiner	GR01CC (454320)	Opaque dark blue	13*75
Gr3	Greiner	GR05K3 (454036)	Opaque dark purple	13*75
Gr4	Greiner	GR05K3NV (454021)	Opaque light purple	13*75
Gr5	Greiner	GR05P (454 027)	Opaque red	13*75

← All tubes with the same cap type are detectable.
← All tubes higher than 100mm with a cap must not be loaded on the IH-500.

3.8.2.2 Types of Caps that are not detected

Translucent caps that are red, blue and purple will not be detected. All other colors will be detected.

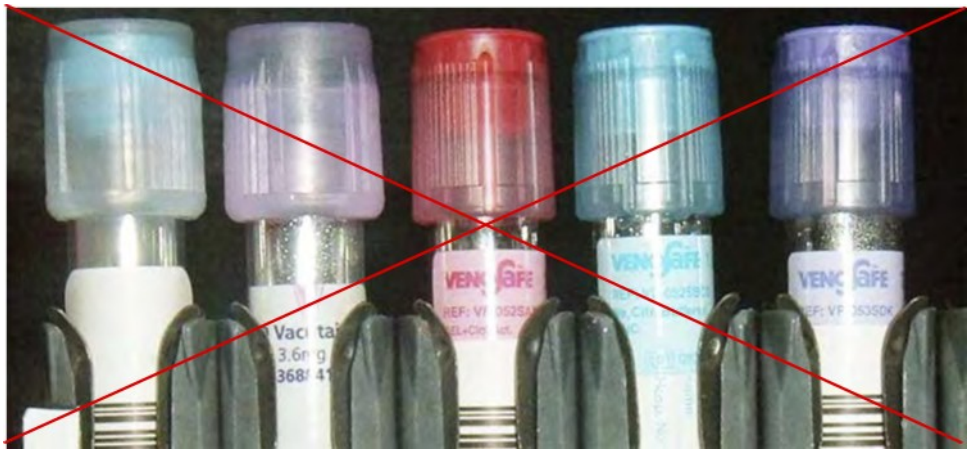


Figure 23. Cylindrical tubes cap detection

3.8.2.3 Cap Detection on Low Volume Tubes

Remove caps from low volume tubes before loading on the IH-500.

Caps on low volume tubes may not be detected by the instrument.

Low volume tubes must be loaded on racks labeled with code 02 or 12.

bIf this condition is not met, there is a risk of causing the needle to crash.

3.8.2.4 Cap Detection on Plunger Tubes

This is not a valid function as the reliability is less than 100%.

Plunger tubes must be loaded only on racks labeled with code 03 or 13.

bIf this condition is not met, there is a risk of causing the needle to crash.

3.9 IH-500 Optional Table (Overview)

An optional table to support IH-500 and to offer an additional volume to store accessories and resources is also available.

The workstation can be installed to the left and/or the right of the optional table and can support a weight of 20 kg.

A second optional workstation can be ordered and installed.

The external solid waste bin replaces the solid waste bin of the IH-500 and increases capacity.

Dimensions

Width - with workstation	120 cm 177 cm
Height	69 cm
- with workstation	97 cm
Depth	82 cm
- with open doors	137 cm

Front View

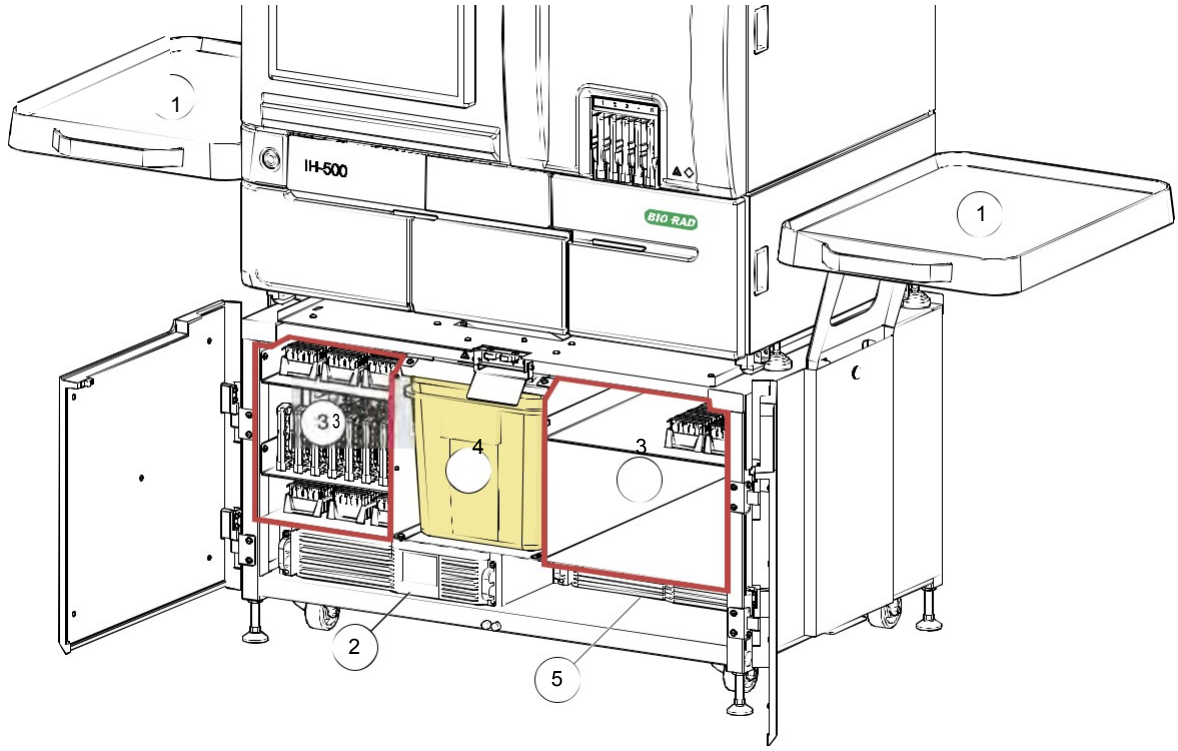


Figure 24. IH-500 optional table - front view

← Workstation

← UPS (Uninterrupted Power Supply)

3Storage area

4External solid waste bin

5Battery pack

3.10 System Liquid Container 6.3L (Option)

This container is available as an option. It increases the capacity to distribute the system liquid into the instrument.

It is installed in place of the right system liquid container and the 2 liquid waste containers.

Due to the absence of the liquid waste canisters, the **(0595142) IH-500 External Liquid Waste Kit** is required. Contact your Bio-Rad representative for more information.

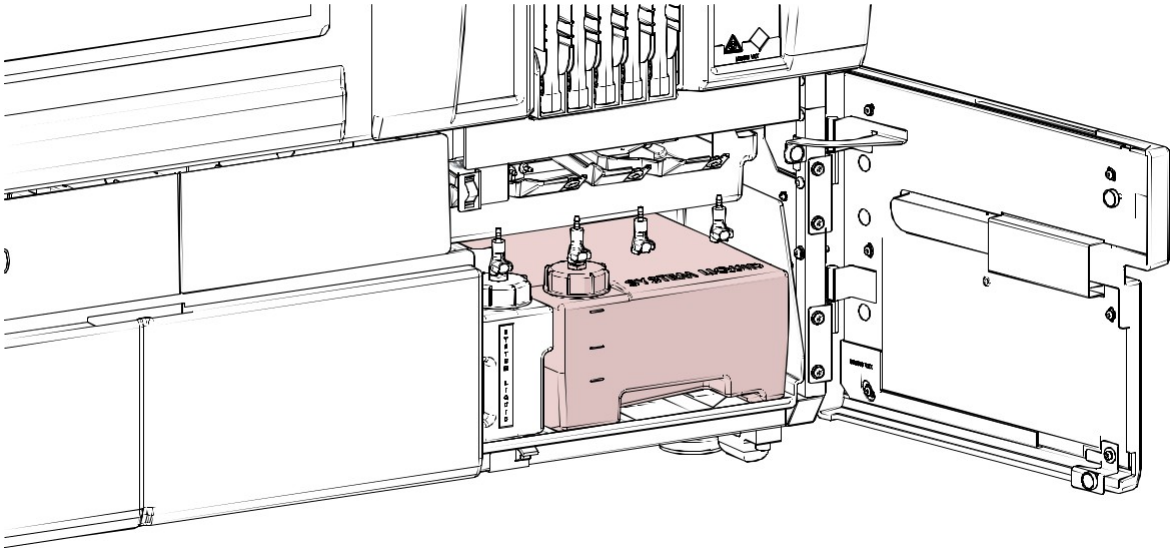


Figure 25.

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← Software Overview

This chapter describes the IH-500 software at a glance and the use of the touch-screen monitor. The software manages the tests and the resources status of the instrument.

4.1 Working with the Software

The software can be operated with the touch-screen monitor and/or the keyboard (accessible by opening the solid waste area door).

4.1.1 Touch-screen and on-screen Keyboard

Touching the screen with fingers (or stylus pen) has the same effect as a mouse tap:

- ← Select a button to execute the command;
- ← Select a text box to activate this box for input. A mini keyboard cursor appears above the text box, touch the mini keyboard and enter data via the on-screen keyboard displayed.
- ← Select a row in a selection list to select this row.
- ← To select a consecutive group of items in a list, select the first item, activate the <**Shift**> key, and select last item.
- ← To select non-consecutive items, activate the <**Ctrl**> key, and select each item.
- ← It is possible to operate the touch screen with laboratory gloves.

- ← Select an input field to access the on-screen keyboard.
- ← Close the on-screen keyboard when done.

Figure 26. On-screen Keyboard

4.1.2 USB Keyboard

Text entries are made via keyboard after selection of the text field.

Most program features can also be selected via keyboard (with the <**Tab**> key).

4.2 Main Screen

The main screen allows to access most of the instrument functions.

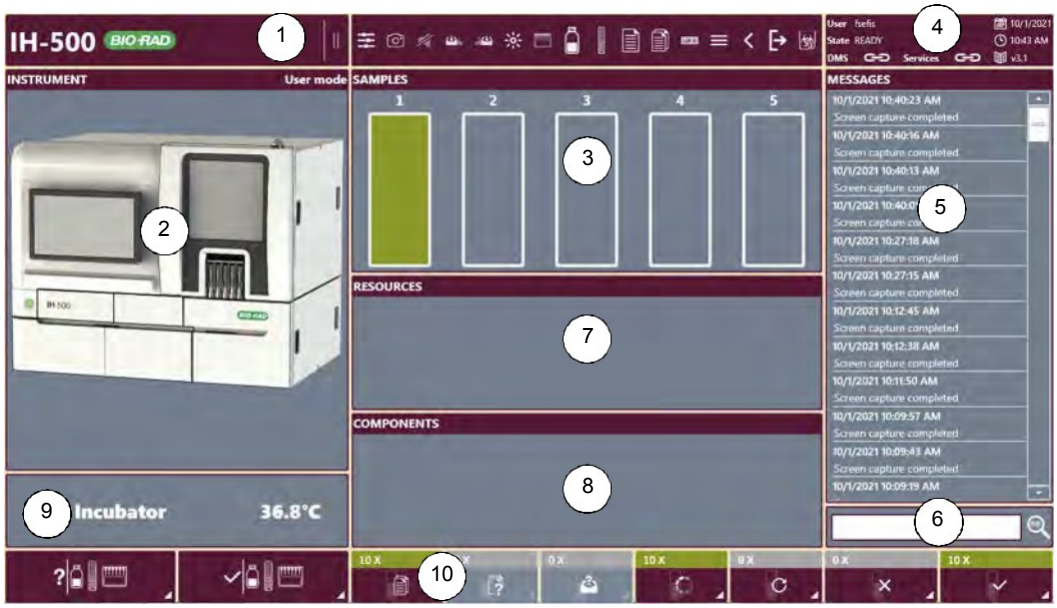


Figure 27. Main screen

← Header

See chapter Header on page 66.

← Instrument interactive area

See chapter Instrument Area (Interactive Image) on page 68.

← Samples

See chapter Samples Screen on page 116.

← Instrument status area

See chapter Instrument Status Area on page 72.

← Messages list

6Search area

See chapter Search Area on page 69.

7Resources area

See chapter Resources Area (Error or Warning) on page 78.

8Components area

See chapter Components Area (Error or Warning) on page 79.

9Temperature display and access to **TEMPERATURES** screen

See chapter Components Screen on page 148.

10 Footer strip

See chapter Footer Strip on page 70.

The instrument interactive image (2) allows access to all instrument areas (open doors and drawers and access areas in error).

The **COMPONENTS / RESOURCES** area (7/8) displays missing resources or components in error.

4.2.1 Header

The header is always visible. Pressing the expanding button let display the shortcut bar or the header strip.

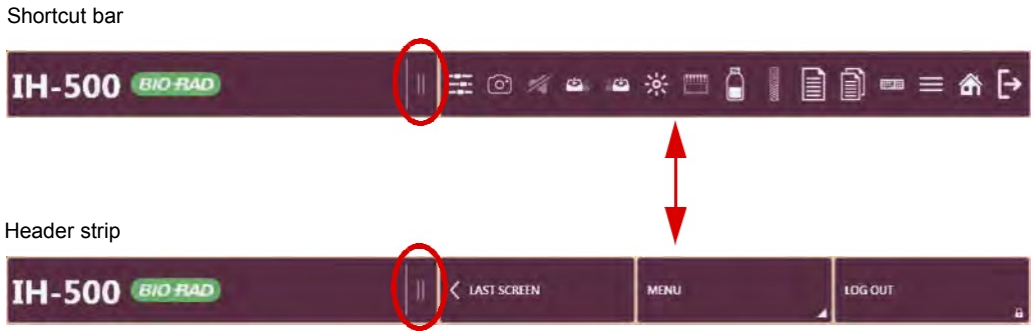


Figure 28.

4.2.1.1 Shortcut Bar

The shortcut bar is configurable through the software options. See chapter Shortcut Menu and Icons Test on page 189.

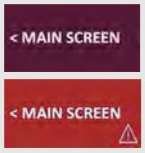
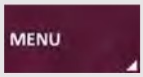
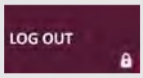
Based on the options, shortcuts may not be visible on the bar. The keyboard, capture and log in/off icons are always visible.

Disabled commands are grayed.

	To display the GUI Customization screen. See chapter GUI Customization on page 183.
	To capture a screen shot of the graphic user interface (GUI). Captures are saved in **C:/Users/Public/IH-500/Images/Screenshots**.
	To turn off sound and audible alarms. See chapter Stop Sound and Audible Alarms on page 81.
	To open the left drawer.
	To open the right drawer.
	To turn ON/OFF the internal light.
	To display the gel cards on board. See chapter Gel Card Details on page 98.
	To display the reagent on board. See chapter Reagent Details on page 100.
	To display the diluents on board. See chapter Diluent Details on page 102.
	To display the list of imported APF. See chapter APF Profiles Management on page 177.
	To display the test profile management. See chapter Profile Management on page 179.

	To display the on-screen keyboard. See chapter Touch-screen and on-screen Keyboard on page 64.
	To display the **MENU** screen. See chapter Menu Screen on page 80.
	To display the main screen from any screen (at any time). If an error occurred while not on the main screen (e.g loading error), the icon turns red.
	To display the previous screen from the main screen.
	To log in.
	To log out. An open drawer disables the logout button (grayed). It is not possible to logout, exit or shutdown the instrument.
	To release the solid waste bin.

4.2.1.2 Header Strip

	To display the main screen from any screen (at any time). If an error occurred while not on the main screen (e.g loading error), a caution sign flashes on the **MAIN SCREEN** button.
	To display the previous screen from the main screen.
	To display the **MENU** screen. See chapter Menu Screen on page 80.
	To log in.
	To log out.
	An open drawer disables the logout button (grayed). It is not possible to logout, exit or shutdown the instrument.

4.2.2 Instrument Area (Interactive Image)

The interactive image is divided into 7 main areas. Select an area to access specific screens, functionalities and information.

If an error occurred, the area is highlighted red and the specific components or resources icons are displayed. See chapter Main Screen in Error (Red/Orange) on page 77.

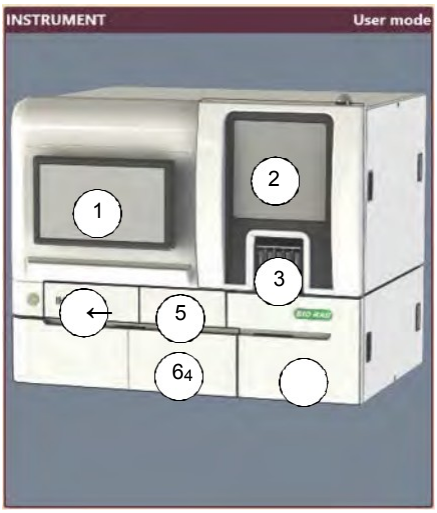


Figure 29. Main screen - Interactive image area

← Access to **RESOURCES ON BOARD** screen

← Access to **Components** screen and opening of the pipetting area door

3Access to **SAMPLES** screen

4Access to **SOLUTIONS / WASTES** screen (liquid containers door)

5Access to **Right Drawer / Details** screen and opening button

6Access to **SOLUTIONS / WASTES** screen (solid waste area door)

7Access to **Left Drawer / Details** screen and opening button

4.2.3 Samples Area

The **SAMPLES** area displays the status of all loaded sample racks.

To view all loaded samples, remove racks or manage samples with an error, select the samples area to access the **SAMPLES** screen.

It is also possible to access the SAMPLES screen from the instrument interactive image.

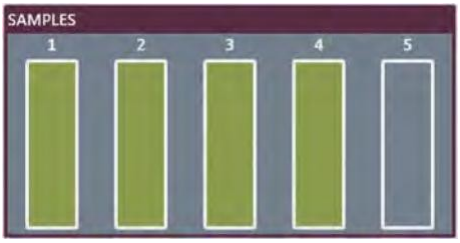


Figure 30.

4.2.4 Search Area

To view the history of a particular sample, type the sample barcode with the keyboard or scan it with the hand-held barcode scanner.

In this example, the sample barcode is **58585296**.

Figure 31.

A list of test related to the sample is displayed.

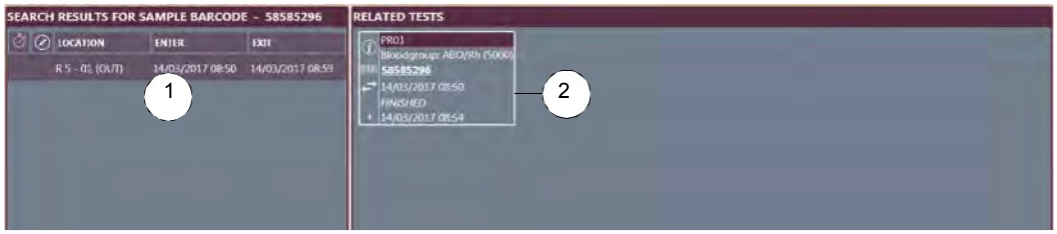


Figure 32.

← Result of the search according to the sample barcode

2Detailed information about the selected test including:

- ← type and description of the test;
- ← sample barcode (1 click on the barcode displays the screen **TESTS COMPLETED**);
- ← date and time of start of the test;
- ← test status
- ← date and time of the end of test.

4.2.5 Components Temperature Area

The components temperature area cycles each component temperature (°C) display:

- ← **INCUBATOR**;
- ← **EXTERNAL** (laboratory room);
- ← **INTERNAL** (instrument internal storage);
- ← **COOLING** (reagents module);
- ← **FRONT CENTRIFUGE**;
- ← **REAR CENTRIFUGE**.

Select this area to access the **COMPONENTS** screen.

See chapter Components Screen on page 148.

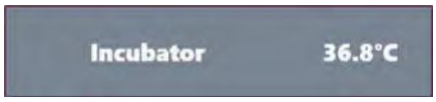


Figure 33.

4.2.6 Footer Strip

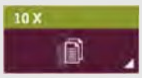
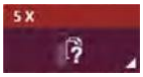
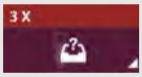
The footer strip is only visible from the main screen. It may have seven or nine buttons to manage resources and tests.

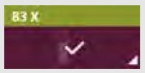
The sample management and tests screens are accessible only if the corresponding button displays a non-zero number. Otherwise, the buttons are disabled.

The option **Icons Test Buttons** defines the appearance of the footer strip (text or pictogram).
See chapter Shortcut Menu and Icons Test on page 189.

With the option ON

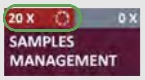
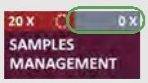
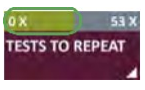
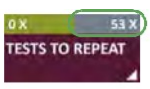
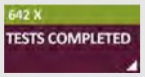
Figure 34.

Button	Description
	To display all missing resources. Resources missing for a specific test are accessible only from the **TESTS WITHOUT RESOURCES** screen. See chapter Missing Resources Screen on page 139.
	To display all resources on board. See chapter Resources on Board on page 96.
	To display samples with requests. See chapter Ordering Tests on page 134.
	To display samples without requests: See chapter Ordering Tests on page 134.
	To display all tests without resources. This symbol appears when the system is defining the requested resources. See chapter Tests without Resources on page 138.

Button	Description
	To display: • all test in progress; • the operating status of the instrument for each test (e.g. pipetting, transport, centrifugation, ready to start). See chapter Tests In Progress on page 141.
	To display all tests to repeat (flagged). See chapter Tests Canceled / to Repeat (flagged Tests) on page 145.
	To display all canceled tests. See chapter Tests Canceled / to Repeat (flagged Tests) on page 145.
	Displays all tests completed. See chapter Tests Completed on page 143.

With the option OFF

Figure 35.

Button	Description
	To display all missing resources. Resources missing for a specific test are accessible only from the **TESTS WITHOUT RESOURCES** screen. See chapter Missing Resources Screen on page 139.
	To display all resources on board. See chapter Resources on Board on page 96.
	To display: ← all samples on board; ← assigned tests in progress; ← samples without requests (e.g. rack number, position, assays, profiles). See chapter Ordering Tests on page 134. ← Sample(s) without request counter. This symbol displays while calculating;
	• Sample(s) with request counter.
	To display all tests without resources. This symbol displays while calculating. See chapter Tests without Resources on page 138.
	Displays all test in progress and operating status of the instrument (e.g. pipetting, centrifugation, ready to start). See chapter Tests In Progress on page 141.
	Displays all tests to repeat (flagged) and canceled tests. See chapter Tests Canceled / to Repeat (flagged Tests) on page 145. • Tests to repeat counter;
	• Cancelled tests counter (e.g following stop all).
	Displays all tests completed. See chapter Tests Completed on page 143.

4.2.7 Instrument Status Area

This area displays the system information:

- ← the name of the connected user;
- ← the instrument status;
- ← the Data Management Software (**DMS**) status;
- ← the launcher status;
- ← the date, time and software version.

Figure 36.

Select the book to display information about software installed in the IH-500.

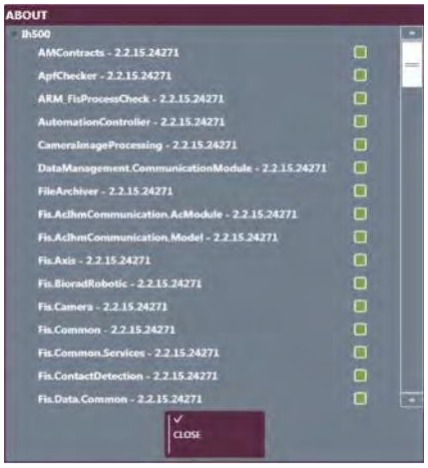


Figure 37.

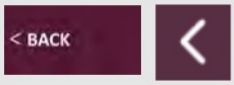
Select the chain next to **Services** to display information about the software backup and user management services status.

Figure 38.

4.3 Common Functions and Screens

Depending on the current operation, the following functions, areas or screens may appear.

4.3.1 BACK Button

	The **BACK** button is available on all the software screens (except main screen). It allows to return to the previous screen.

4.3.2 Column Sorting

Select one or more column title(s) to sort by ascending or descending.

	Single column sorting enabled Data can be sorted only according to one column
	Multiple column sorting enabled Data can be sorted according to one or more columns.

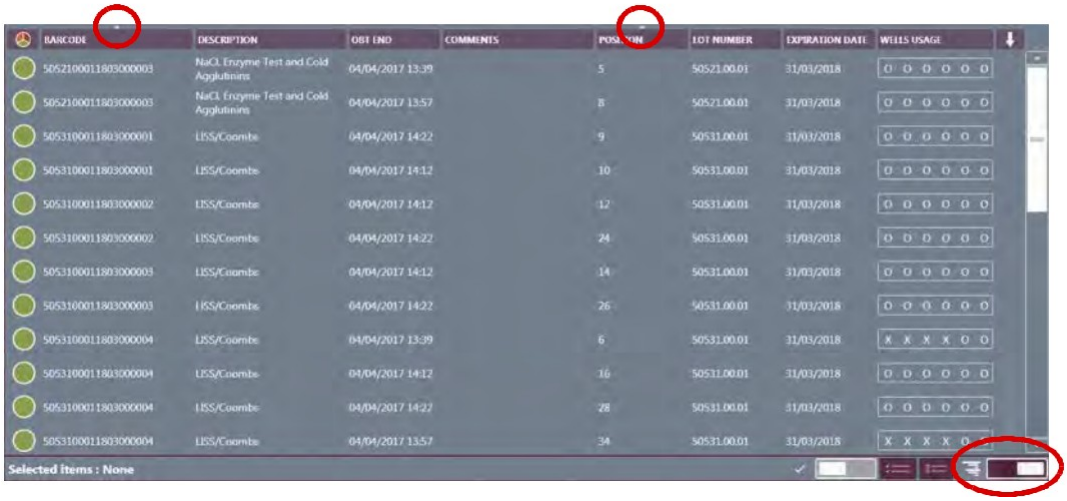


Figure 39. Column sorting

4.3.3 List Filtering

A list of data can be filtered according to one or more specific criteria. A popup menu is displayed for the selection of filtering criteria. When set, the defined filtering criteria is used to display the list of data.

The value (1) indicates the number of items displayed in the list.

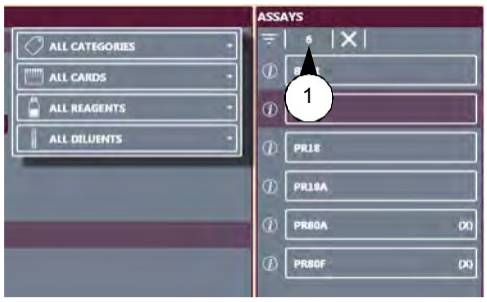


Figure 40. Filtering a list

	No filter is applied. All items of the list are displayed. Press the icon to display the popup menu for criteria selection.

	A filter is applied, according to the criteria selected in the popup menu.
	The filter is canceled. Pressing the icon displays all items of the list.
	To activate a filter on a specific assay category. *For example: blood group, crossmatch or antigen.*
	To activate a filter on a specific gel card type.
	To activate a filter on a specific reagent type.
	To activate a filter on a specific diluent type.

4.3.4 List Selection

Figure 41. List selection

Selected line (3) is highlighted.

A	Enable or disable the multiple selection (1). ← **OFF**: single selection ← **ON**: multiple selection.
← 	Press to select all.
C 	Press to un-select all ← *The number of **Selected Items**: # (2) is displayed.*

4.3.5 Warning Screen

Warning screens have a red triangular sign and are displayed when an error occurred or if an action is requested.

An appropriate message informs the user in each case.

In some cases it is required to input the word «**YES**» to confirm the action or «**NO**» to cancel.

Figure 42. Warning screen

4.3.6 Weekly Hydraulic Maintenance Reminder

The weekly hydraulic maintenance has to be done once a week.

	This reminder appears on the main screen when the weekly maintenance has not been performed on duly scheduled time. Normal operations are not possible.
	It turns orange when the user press the reminder to override the weekly maintenance and start new tests. The option **Override Maintenance Locking** must be set to ON. See chapter General, Profiles and Samples on page 169. Normal operations are possible. All tests results are tagged “**Date of Hydraulic Maintenance expired**”.
	This reminder appears when the weekly maintenance is soon expired. Pressing the icon displays the remaining time before to perform a weekly maintenance (see Figure 43). The option **Maintenance Warning Delai** defines when the reminder is displayed (by default, 2 hours). See chapter General, Profiles and Samples on page 169.

See chapter Weekly Maintenance Procedure on page 197.

Figure 43. Example of message

4.3.7 Quality Control Reminder

The quality control has to be done once a week.

	This reminder appears on the main screen when the quality control has not been performed on duly scheduled time. The option **Instrument qc** and/or **Reagent qc** must be set to ON. See chapter QC Management on page 175. Normal operations are not possible.
	It turns orange when the user press the reminder to override the quality control and start new tests. The option **Override** must be set to ON. See chapter QC Management on page 175. Normal operations are possible. All tests results are tagged “**Date of Quality Control expired**”.

4.3.8 Service in Progress

If a service engineer is working with the service software the interactive image border is highlighted orange and **Service** is written instead of **Routine**.

Figure 44.

4.4 Main Screen in Error (Red/Orange)

When an error or a warning occurs, the concerned area is highlighted in red or orange. The system also generates an audible alarm and the status light is red or orange.

Warning (Orange)	The instrument continues to work but informs about a minor problem, e.g. one full liquid waste container. A user action is recommended.
Error (Red)	The instrument has stopped. A user action is required.

Detailed information on errors are given by selecting:

← the interactive image;

← the **SAMPLES** (6) or **RESOURCES** (9) or **COMPONENTS** (10) areas.

After a stop, it is necessary to initialize the instrument to continue testing. The system removes sample racks and unloads reagents vials (canceled tests are displayed in the test to repeat screen). Diluent racks are re-identified.

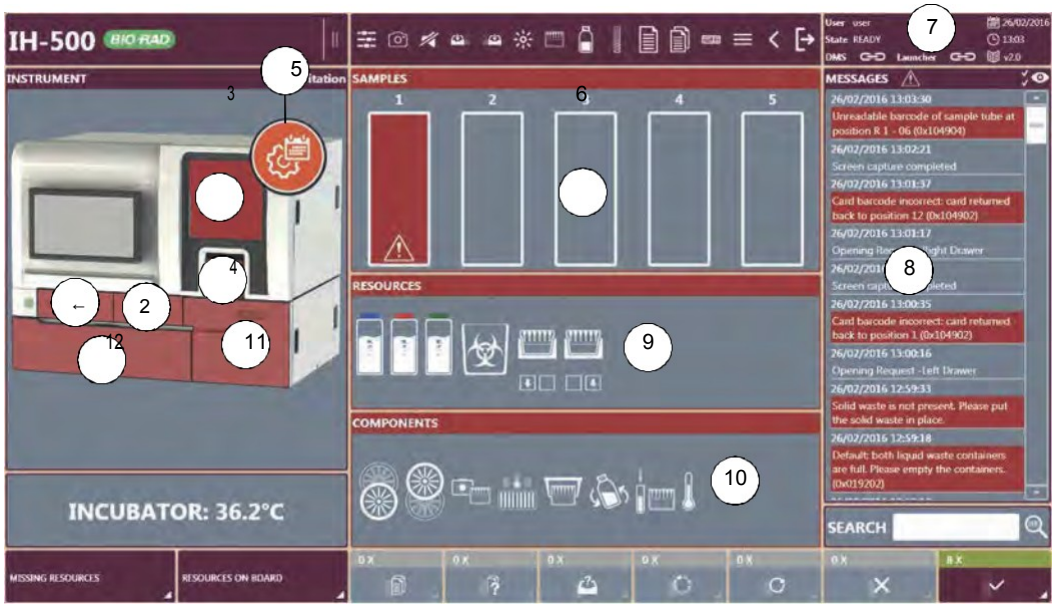


Figure 45. Main screen in error

← Error in left drawer

2Error in right drawer

3Error in the components area

4Error in the samples area

5Weekly maintenance reminder icon (red if option is set to blocking)

6SAMPLES area in error

7Instrument state

See Instrument State on page 79.

8MESSAGES area (error information is highlighted in red or orange)

← **RESOURCES** area in error

See Resources Area (Error or Warning) on page 78.

← **COMPONENTS** area in error

See Components Area (Error or Warning) on page 79.

← Error in the liquid containers door

← Error in the solid waste area door

4.4.1 Resources Area (Error or Warning)

	System liquid container (blue cap) **Red**: both containers are empty or disconnected. **Orange:** only one container needs to be refilled or is disconnected. See chapter Refilling a System Liquid Container on page 125.
	Liquid waste container (red cap) **Red**: both containers are full or disconnected. **Orange**: only one container needs to be emptied or is disconnected. See chapter Emptying a Liquid Waste Container on page 127.
	Decontamination liquid container (green cap) (NaOH 0.5 M) **Red**: container level empty. **Orange**: container level low. See chapter Refilling a Decontamination Liquid Container (NaOH 0.5 M) on page 129.
	Solid waste bin **Red**: solid waste bin full or almost full (over 80%) or disconnected. **Orange**: solid waste bin almost full (over 60%). See chapter Emptying the Solid Waste Bin on page 130.
	Diluent rack **Red**: not possible to identify the diluent rack. See chapter Left Drawer Details on page 108.
	Reagent vials **Red**: On board reagent vials in error. See chapter Removing Reagents on page 112.
	Reagent vials **Red**: not possible to identify a reagent vial. See chapter Left Drawer Details on page 108.
 	Gel cards **Red**: not possible to identify a gel card. See chapter Right Drawer Details on page 105 or Left Drawer Details on page 108.

4.4.2 Components Area (Error or Warning)

Refer to section To acknowledge a Component in Error on page 149 for more details.

	Front centrifuge		Pipetting area
	Rear centrifuge		Incubator at 37°C
	Imaging station		Reagent area
	Transport arm gripper		Ambient temperature

4.4.3 Instrument State

If IH-500 displays one of the following states, it is not possible to perform any tests.

OUT OF SERVICE	Try to restart the system or contact a service engineer.
STOPPED	Acknowledge error or Initialize. See chapter Initialize Instrument on page 162.
INITIALIZATION	Wait for system initialization to finish.
PREPROCESSING	Wait until complete or if the left drawer is in error; access it to acknowledge the error message. If it was not possible to restore resources (e.g remove reagents after initialization), see chapter Removing Reagents on page 112. If the option **Return Gel Cards** is set, it is always necessary to have at least one empty gel card tray in the left drawer. Otherwise the instrument will remain in **Preprocessing** state. See chapter Return Gel Cards on page 172 for help.
WAITING	All functions are disabled. Select **LOG IN** (header strip) and enter user name and password.

4.5 Menu Screen

← 

Select **MENU** (header strip).

Functions may be disabled (gray), if not logged in with the required user rights or if the instrument is in the state: «**READY**». Either **LOG IN** with required rights or **STOP ALL** (e.g. to launch the weekly maintenance IH-500 must be in the state «**STOPPED**»).

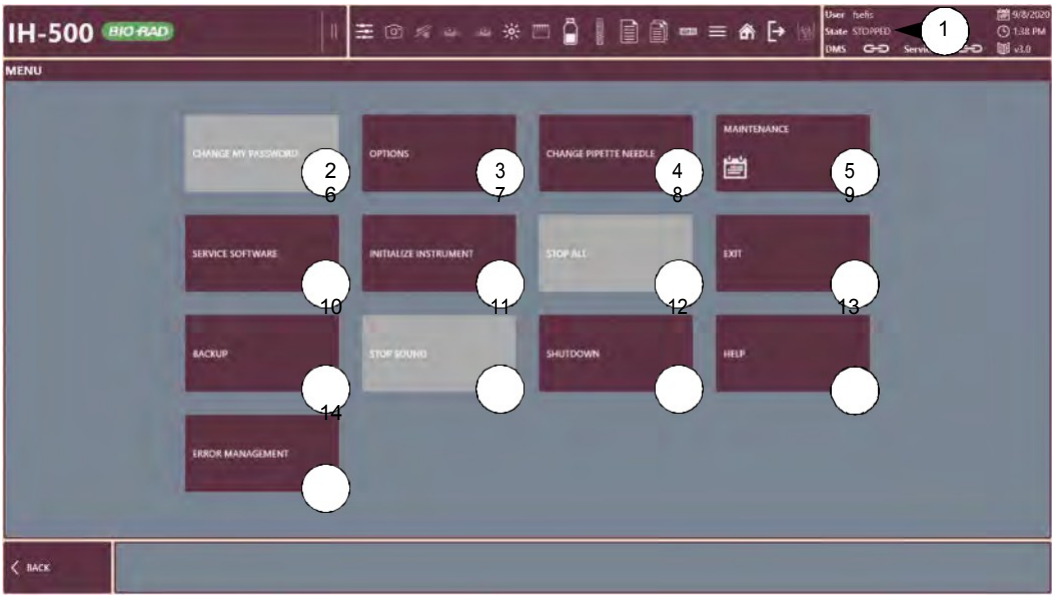


Figure 46. Menu screen

← Instrument status

← **CHANGE MY PASSWORD** (user level > 1)

See chapter Change Password on page 165.

← **OPTIONS** (user level > 1)

See chapter Options (Main Screen) on page 168.

← **CHANGE PIPETTE NEEDLE** (user level > 1)

See chapter Pipette Needle Replacement / Cleaning on page 201.

← **MAINTENANCE** (user level > 1)

See chapter Maintenance on page 191.

← **SERVICE SOFTWARE** (service engineer restricted user rights only)

7INITIALIZE INSTRUMENT

See chapter Initialize Instrument on page 162.

8STOP ALL

See chapter Stop All on page 160.

9EXIT (user level > 1)

See chapter Exit on page 159.

← **BACKUP**

See chapter Backup Database on page 163.

← **STOP SOUND**

See chapter Stop Sound and Audible Alarms on page 81.

← **SHUTDOWN**

See chapter Shutdown on page 160.

← **HELP**

Display informations about the meaning of the pictogram used in the GUI.

← **ERROR MANAGEMENT**

See chapter Error Management on page 152.

4.6 Stop Sound and Audible Alarms

← 

Select **MENU** (header strip).

← 

Select **STOP SOUND** to mute the audible alarms.

Audible alarm table

Alarm	Description
Low-pitched tone	Error occurred (red), user action is required.
High-pitched tone	Error occurred (orange warning), user action is recommended.

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← Emergency Stop

This chapter explains how to perform an emergency stop of the IH-500.

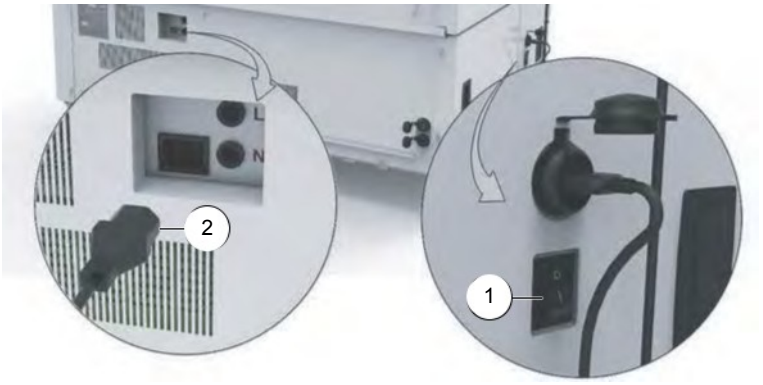

Figure 47. IH-500 - Emergency stop

b Perform an emergency stop ONLY if the instrument is completely stalled and does not respond to any issued command.

To stop all mechanical movement of the instrument either:

← switch OFF «**O**» the main power switch (1) on the left side of the IH-500;

← unplug the power cord from the rear of the instrument (2) or from the mains power socket.

← The IH-500 must be located in such a manner that operating its disconnecting devices (the ON/ OFF switch and the power cord) is possible at all times. In the latter case, the mains power socket must be located near the instrument and must be easily accessible by the operator.

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← Getting Started

This chapter explains how to start up and prepare the instrument for routine operation.

6.1 Preliminary Checks before Startup

Before starting routine work, the following checklist must be performed.

← Room temperature between 18 °C and 28 °C

Do not use the instrument outside the defined ranges of environmental conditions.

← Liquid waste containers empty and connected

See chapter Emptying a Liquid Waste Container on page 127.

← System liquid containers full and connected

See chapter Refilling a System Liquid Container on page 125.

← Decontamination liquid container (NaOH 0.5 M) full

See chapter Refilling a Decontamination Liquid Container (NaOH 0.5 M) on page 129.

Solid waste bin empty and in place

See chapter Emptying the Solid Waste Bin on page 130.

Pipetting area door correctly closed. At

start up:

if sample racks are detected in the pipetting area, they are automatically removed;

if reagent vials are restored, check their integrity before use;

any reagent on board is removed.

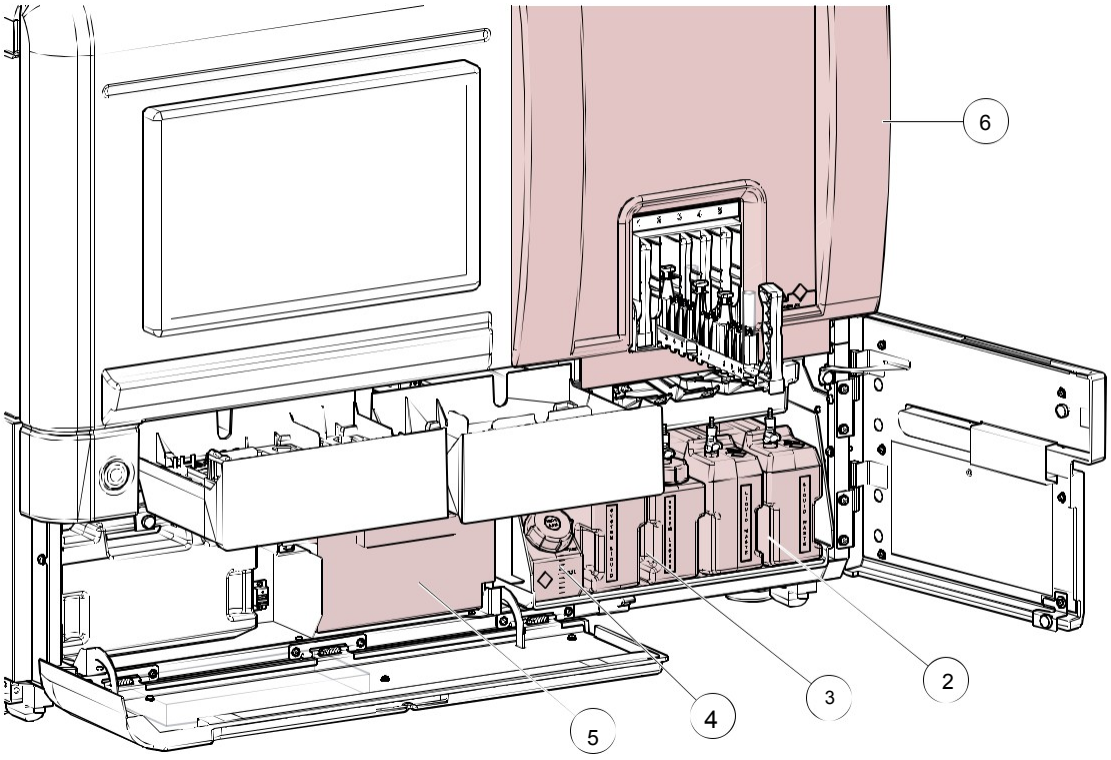
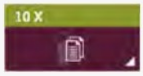
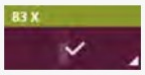
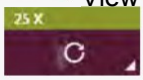


Figure 48.

6.2 Guidelines for Routine Operations

	Step	Section
	Start the instrument.	8.2 on page 133
	If necessary, acknowledge errors.	4.4 on page 77
	Prepare the instrument for routine operation.	7.5 on page 123
	Prepare required resources.	7.1 on page 91
	Load required resources.	7.2 on page 96
	Load samples racks.	7.4 on page 114
G	 Create a test order and associate profiles to samples without requests.	8.3 on page 134
	 The **TESTS WITHOUT RESOURCES** button is active if one or more resources are missing to start the test.	8.3.4 on page 138
I	 View which resources are needed to start the tests. Load required resources.	8.3.5 on page 139
	 View the tests in progress.	8.4.1 on page 141
	 View the completed tests.	8.4.2 on page 143
L	 If an error occurred during a test, the test is flagged and displayed in the **TESTS TO REPEAT** or **CANCELED** screen.	8.4.4 on page 145
M	From the IH-Com Data Management Software, go to the **Results** screen area to verify and validate the result.	Refer to the IH-Com Data Management User Manual.
N	Shutdown the instrument. *When all the tests are processed.*	8.8.3 on page 160

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Managing Resources, Samples and Waste

This chapter describes the type of resources and samples which can be used, how to prepare and how to load and remove them.

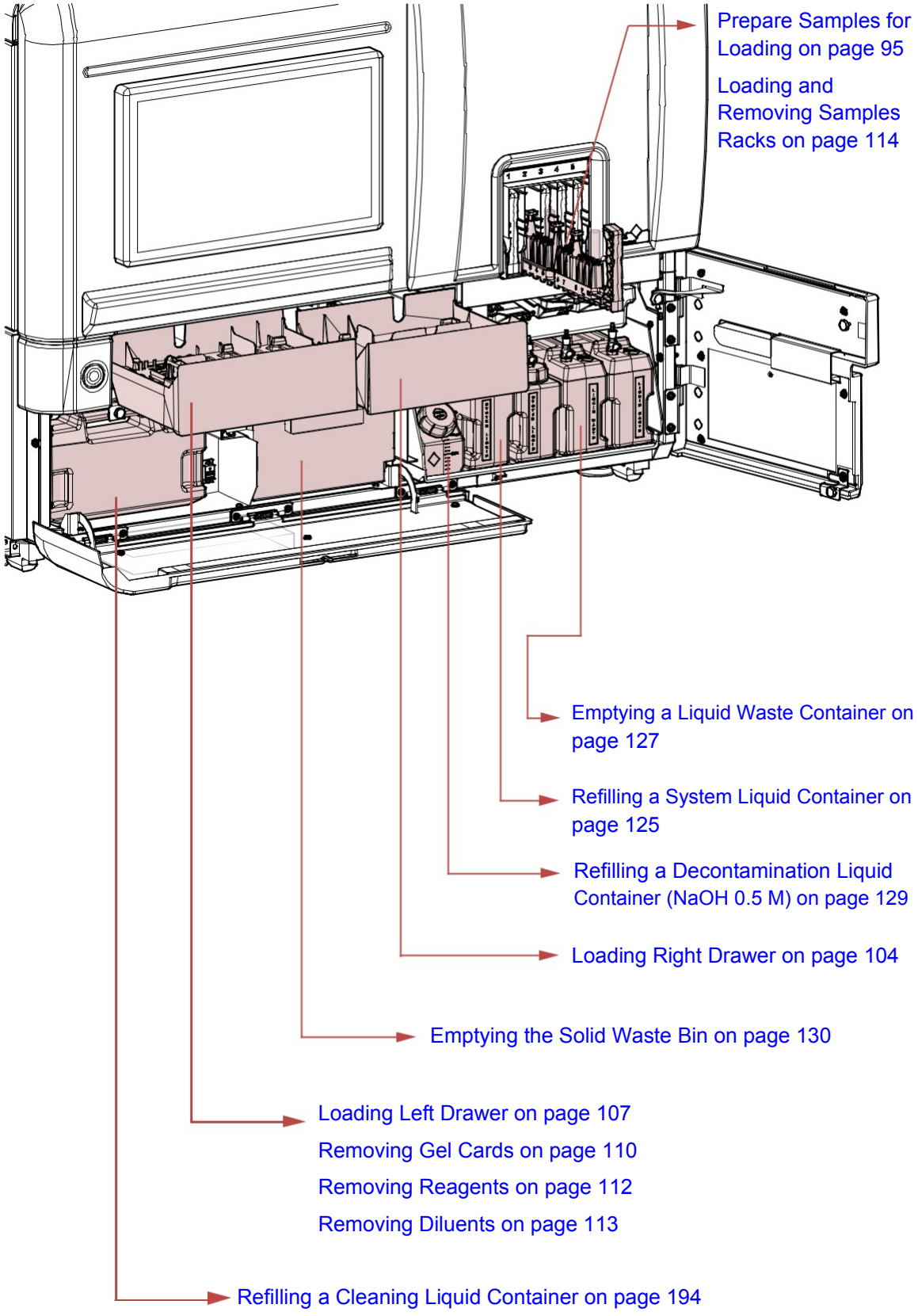


Figure 49. Synoptic

7.1 Preparing Resources and Samples

7.1.1 Gel Cards

A Insert all gel cards with the barcode facing in the same direction.

If barcodes are facing different directions, the system will recognize them but working will take longer.

B Verify that:

the foil strip of each gel card is not damaged;

the foil strip is NOT folded upwards;

the gel of the card is in good condition (no spilling of supernatant inside the well);

there are no air bubbles present in the gel;

the expiry date of the gel card is valid (also checked by the instrument).

Do not load opened or partially used gel cards.

All gel cards can be kept on-board for a maximum of 504 hours (21 days). After that time, it is imperative to remove the gel cards from the instrument and dispose of it.

7.1.2 Diluent Rack

- Only use unused (non-pierced) diluent racks.

  The protective foil of the diluent rack product must not be pierced or damaged before loading; each well will be pierced automatically by the instrument.

- Handle the diluent rack with care in order to avoid damage to the barcode. If the IH-500 detects unreadable barcode, the error message appears and the diluent rack is rejected. It is possible to print a new label using the IH-Com software. For further instructions refer to the IH-Com User Manual.

- On-board stability is 720 hours (30 days) for diluent rack. After that time, it is imperative to remove the diluent rack(s) from the instrument and dispose of it.

7.1.3 Reagents on Tray

When loading the reagents, user must check their integrity: a blurred liquid (1) can reveal a bacterial contamination. No foam or bubble should be present (1).

The cells of the reagents (2) must be in suspension before the vial is loaded on the rack (gently swirl the vials).

Gently swirl the vial (3) in order that the cells of the reagents are in suspension.

Remove the caps and place the vials in the reagent tray.

C Orientate all reagent vials with the barcodes (4) facing towards the barcode alignment marks (5).

If a reagent vial barcode is not correctly aligned, the system will not identify the reagent and it will be returned to the left drawer.

Handle the reagent vials with care in order to avoid damage to the barcode. If the IH-500 detects unreadable barcode, an error message appears and the vial is rejected. It is possible to print a new label using the IH-Com software. For further instructions refer to the IH-Com User Manual.

On-board stability is 168 hours (7 days) for red blood cell reagents, Titration Solution and for Antisera. After that time, it is imperative to remove the reagent(s) from the instrument and dispose of it.

If the **On Board Time Management** option is turned on, after spending 168 hours on board, the system automatically removes the vials and will not accept them anymore on board of the instrument.

Only load reagent vials in the reagent tray delivered with the instrument and only in the dedicated left drawer area.

A reagent vial placed in an other area can lead to spilling and contamination.

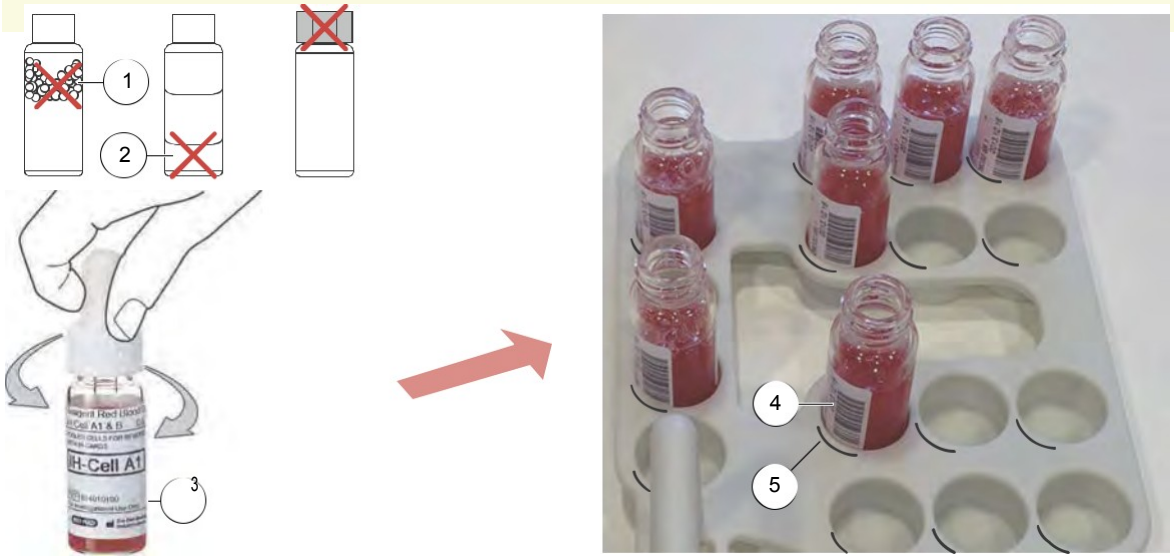


Figure 50.

7.1.4 Samples

b If these conditions are not respected, there is a risk to crash the pipette needle.

7.1.4.1 Using Spherical Tubes

Spherical tubes must be used only with sample tube holders of type T01 (green) or T03 (pink sticker) (or T11 or T13 for priority racks).

See chapter Standard and STAT Sample Barcode Sticker Sheets on page 46.

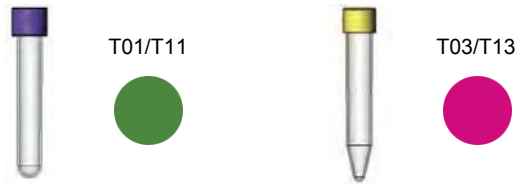


Figure 51.

7.1.4.2 Using Pediatric Tubes

The low volume tubes must be used for small quantity sample. Use SARSTEDT products.

Micro tube 1.5mL ref. 72.703

Rounded end tube 5mL ref. 55.475.005

The micro tube must be completely inserted into the tube.

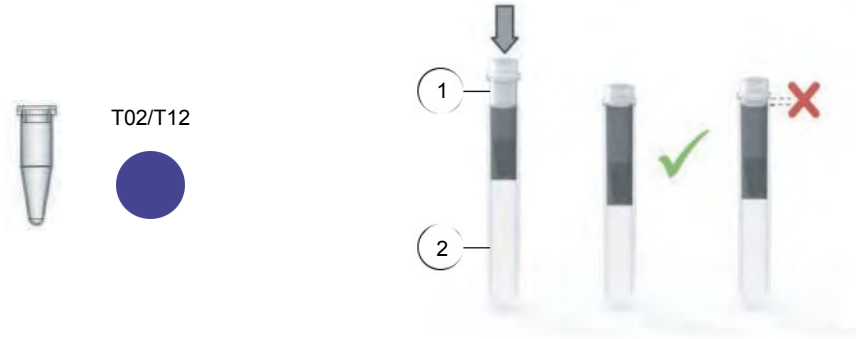


Figure 52.

Low volume tubes must be used only with sample tube holders of type T02 (blue sticker) (or T12 for priority racks).

See chapter Standard and STAT Sample Barcode Sticker Sheets on page 46.

7.1.4.3 Using Flat Tubes

Flat tubes must be used only with sample tube holders of type T04 (orange sticker) (or T14 for priority racks).

See chapter Standard and STAT Sample Barcode Sticker Sheets on page 46.

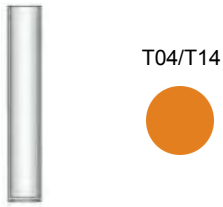


Figure 53.

b When using this type of tubes, the plunger must be always on the lowest possible position (all the way down) to avoid a risk of needle crash.

7.1.4.4 Using Special Flat Bottom Tubes

Special flat bottom tubes must be used only with sample tube holders of type T05 (yellow sticker) (or T15 for priority racks).

See chapter Standard and STAT Sample Barcode Sticker Sheets on page 46.

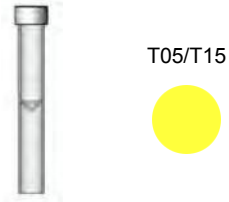


Figure 54.

7.1.5 Prepare Samples for Loading

To prevent level detection errors, no foam or bubbles (5) must be present on the surface of the liquid and no presence of fibrin clot.

To prevent overflow when pipetting, take care of the maximum filling level of the sample tube (6) (13 mm min. from the top of tube).

Pay attention not to tilt the sample tubes holders and subsequently the racks.

Before loading the sample tube holders (3), check the absence of foreign objects in the sample rack (4). Risk to crash the pipette needle.

Remove the sample tube caps.

Insert the sample tubes (1).

Orientate the barcode of the tubes (2) to be visible on the left side of the rack.

Check that the tube is vertical and completely inserted into the sample rack (7).

Gently insert the sample tube holder (3) in the rack (4).

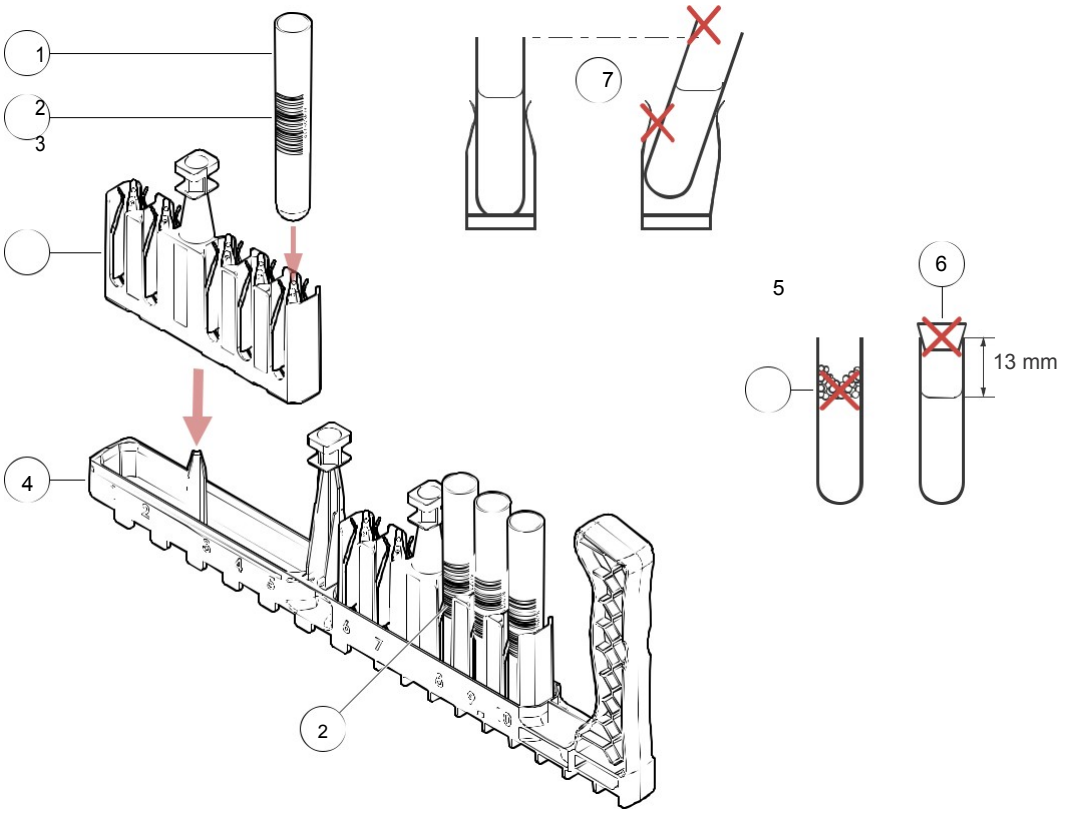


Figure 55.

7.2 Loading and Removing Resources

7.2.1 Resources on Board

The **RESOURCES ON BOARD** screen:

displays all resources loaded on the instrument (gel cards, reagents and diluents);

allows opening of the left and right drawers;

allows access to the **GEL CARDS**, **DILUENT**, **REAGENT DETAILS** and **MISSING RESOURCES** screens.

It is possible to remove resources or return partially used gel cards for second reading from the **RESOURCES ON BOARD** screen. It is only possible to return resources to the left drawer.

It is not possible to remove resources if the release drawer (left or right drawer) is open, full, no empty gel card tray or reagent tray or if the resource is in use.

 Select to display the **RESOURCES ON BOARD** screen.

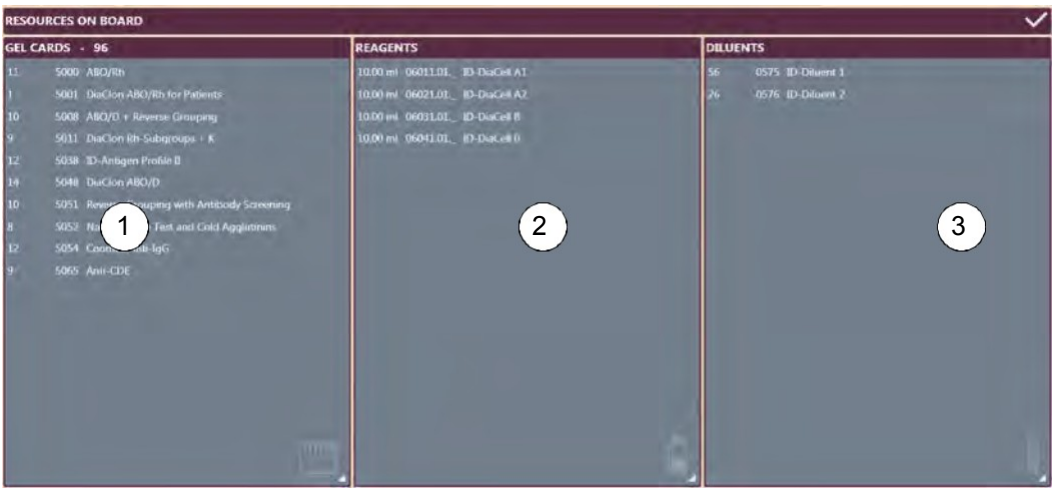


Figure 56. Resources on board screen

The area describes the gel cards present by displaying:

the number of available gel cards for the next tests;

the gel card product code

the gel card type.

Clicking on the title displays the **GEL CARD DETAILS** screen. See chapter Gel Card Details on page 98.

The area describes the reagents which are available for tests by displaying:

the available volume (ml) per vial;

the reagent lot number;

the reagent type.

The reagents assigned to tests in progress are not taken in account. The list of reagents in this screen can be different to the list of reagents from the **REAGENT DETAILS** screen.

Clicking on the title displays the **REAGENT DETAILS** screen. See chapter Reagent Details on page 100.

The area describes the diluents present by displaying:

the number of available diluent wells per item;

the diluent product code;

the type of diluent (ID-Diluent 1 or 2).

Clicking on the title displays the **DILUENT DETAILS** screen. See chapter Diluent Details on page 102.

7.2.1.1 Gel Card Details

The **GEL CARD DETAILS** screen:

gives detailed information on gel cards loaded in the instrument;

allows the gel cards removal.

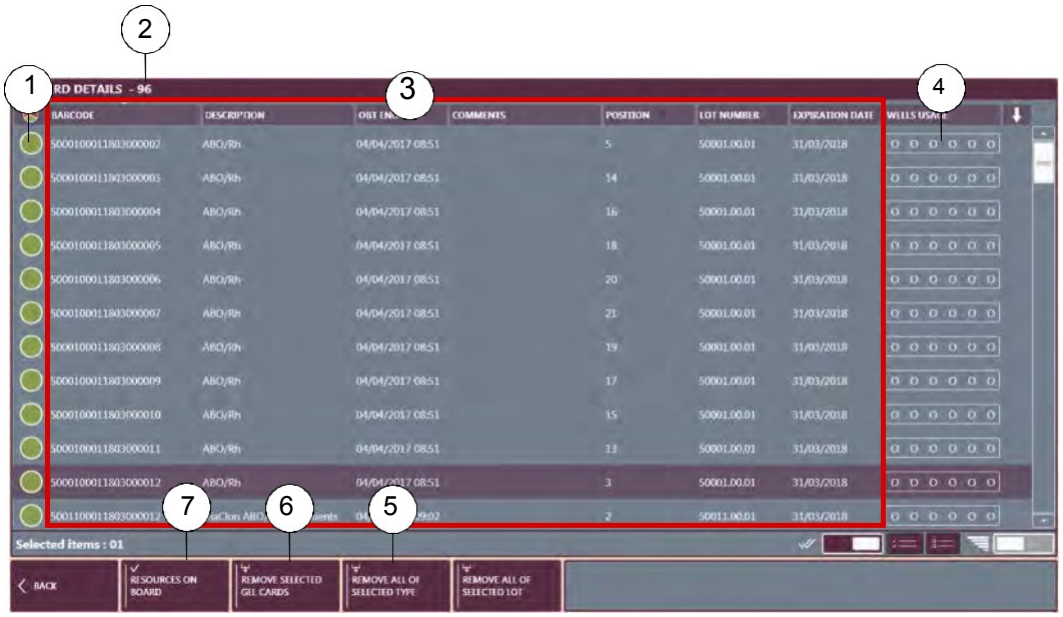


Figure 57. Gel card details screen

Gel card detection status

See Gel Card Detection Status on page 99.

Total gel cards on board

Detailed information of the gel cards loaded in the instrument including:

- gel card identification barcode;
- description of the gel card (type);
- remaining time on board allowed before removal, if the option **OBT Management** is enabled. See chapter General, Profiles and Samples on page 169.
- position on the internal storage;
- lot number and expiration date.

Status of use for the wells (gel card column)

- **X**: used;
- **O**: not used.

Function to remove all gel cards of the same type of the one selected in the list (disabled if no gel card is selected)

In the example, a gel card type 5065 is selected (line highlighted). Activating the function removes all gel cards type 5065 present in the instrument.

Function to remove the gel card selected in the list (disabled if no gel cards are selected)

See chapter Removing Gel Cards on page 110.

Display the Resources on board screen.

See chapter Resources on Board on page 96.

b All gel cards can be kept on-board for a maximum of 504 hours (21 days). After that time, it is imperative to remove the gel cards from the instrument and dispose of it.

Gel Card Detection Status

	The gel card is correctly detected.	-
	The gel card is detected with a warning.	Refer to the message displayed on screen.
	The gel card is detected with an error.	Remove and check the gel card.
	The gel card is expired according to OBT management.	Remove the gel card.

7.2.1.2 Reagent Details

The **REAGENT DETAILS** screen:

provides detailed information on loaded reagent vials;

allows the removal of reagent vials;

allows the opening of the left drawer.

Figure 58. Reagent details screen

Reagent detection status

See Reagent Detection Status on page 101.

Detailed information of the reagents loaded in the instrument including:

barcode of the vial;

description of the reagent (type);

remaining time on board allowed before removal, if the option **OBT Management** is enabled. See chapter General, Profiles and Samples on page 169.

position on the shelf;

remaining volume of reagent (ml);

lot number and expiration date of the reagent.

Function to remove the reagent selected in the list (disabled if no reagents are selected)

See chapter Removing Reagents on page 112.

To open the left drawer

To display the **RESOURCES ON BOARD** screen See

chapter Resources on Board on page 96.

The list includes reagents available for future tests and reagents already assigned for programmed tests. This list may be different to the list from the **RESOURCES ON BOARD** screen.

When a **STOP ALL** command is issued, the instrument returns all reagents to the left drawer just after initialization. Therefore, the allowed remaining time on shelf is kept.

If the 2D barcode scan is enabled, when re-inserting these reagents, the OBT countdown restarts from the remaining time before expiration. Otherwise, the allowed remaining time on shelf is lost. See chapter Barcode 2D on page 173.

Reagent Detection Status

	The vial is correctly detected.	-
	The vial is detected with a warning.	Refer to the message displayed on screen.
	The vial is detected with an error.	Remove and check the vial.
	The vial is detected with cooling defect error	Remove the vial.
	The barcode can not be read.	Enter manually the barcode.
	The vial is detected with a cap.	Remove the vial and the cap.
	No OBT data has been sent from the DMS for the vial.	Remove the vial.
	No OBT data has been sent from the DMS for the vial, but the user overrides the OBT management (Advanced or Admin user level required).	-
	The reagent is expired according to OBT management.	Remove the vial.
	The reagent is expired, but the user overrides the OBT management (Advanced or Admin user level required).	-
	The reagent quality control vial is not valid.	Remove the vial.
	The reagent quality control vial is not valid, but the user overrides the vial use.	-
	The user overrides the use of an invalid quality control reagent vial or a vial that remained too long on board.	-

7.2.1.3 Diluent Details

The **DILUENT / DETAILS** screen:

provides detailed information on loaded diluents;

allows the removal of diluent racks;

allows the opening of the left drawer.

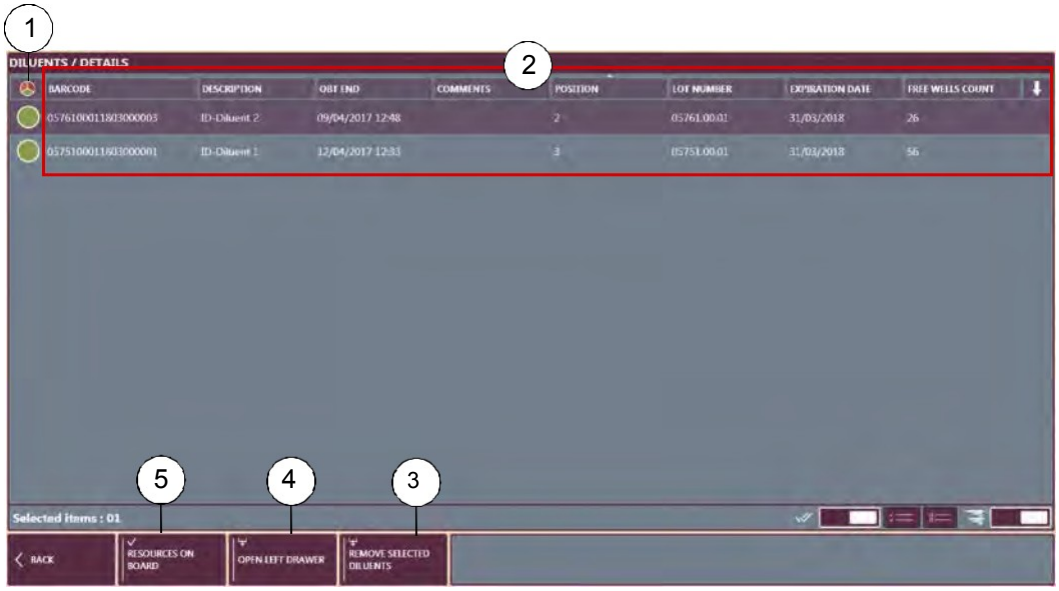


Figure 59. Diluent details screen

Diluent detection status

See chapter Diluent Detection Status on page 103.

Detailed information of the diluents loaded in the instrument including:

barcode of the item;

description of the diluent (type);

remaining time on board allowed before removal, if the option **OBT Management** is enabled. See chapter General, Profiles and Samples on page 169.

position on the shelf;

lot number and expiration date.

Function to remove the diluent selected in the list (disabled if no diluent is selected)

See chapter Removing Diluents on page 113.

To open the left drawer

To display the **RESOURCES ON BOARD** screen See

chapter Resources on Board on page 96.

Diluent Detection Status

	The diluent is correctly detected.	-
	The diluent is detected with a warning.	Refer to the message displayed on screen.
	The diluent is detected with an error.	Remove and check the diluent.
	The diluent is expired according to OBT management.	Remove the diluent.

7.2.2 Loading Right Drawer

The right drawer is dedicated to gel cards only. It can contain up to 3 trays, indicated by markings.
Ensure that empty trays are removed before loading.

See chapter Gel Cards on page 91 for on how to insert the gel cards in the tray.

A  Unlock the drawer (3).

From the shortcut bar, for example.

Open the drawer (3) and remove the empty gel card trays.

C Load the trays (1) in the right drawer with the barcodes facing towards the right (4)

or the front (2) of the instrument.

The trays must be perfectly inserted and secured by the drawer lockers (5).

D Gently close the drawer (3) until it locks.

The instrument will scan the entire drawer and then identify individually all gel cards when placing in the internal storage.

If identifying error occurred, see Right Drawer Details on page 105.

To view loaded gel cards, see chapter Resources on Board on page 96.

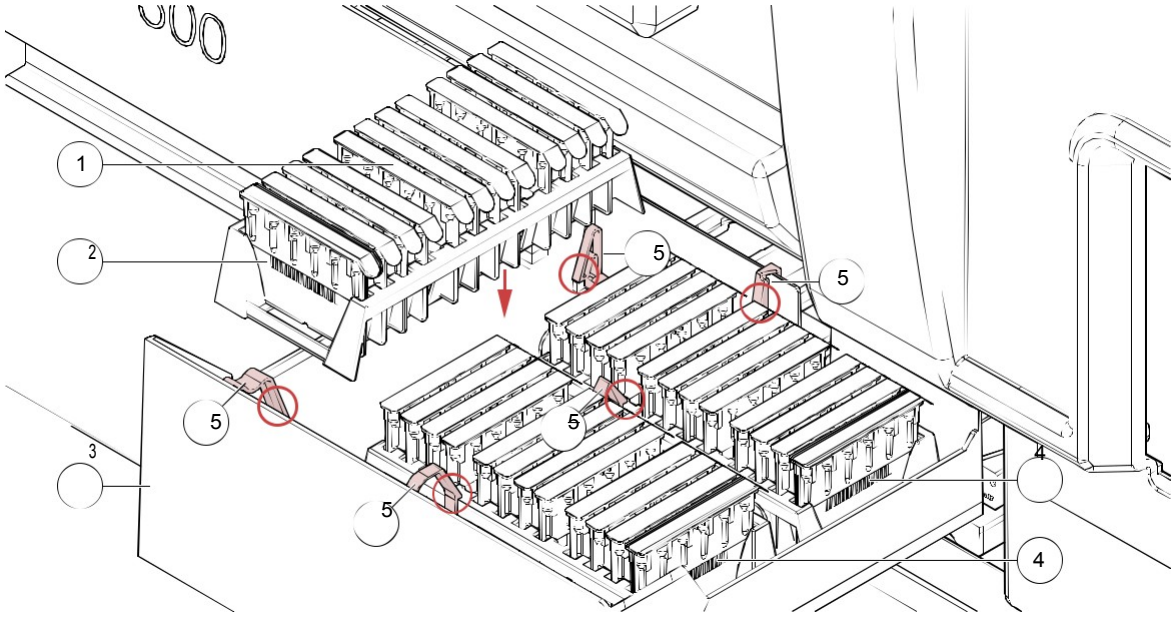


Figure 60.

7.2.2.1 Right Drawer Details

The screen describes the content of the right drawer.

A 

Select the right drawer to display the **Right drawer / Details** screen.

On the interactive image of the instrument area.

If the internal storage is full, identified gel cards remain in the drawer. They are displayed in green if the drawer is closed or in orange if opened.

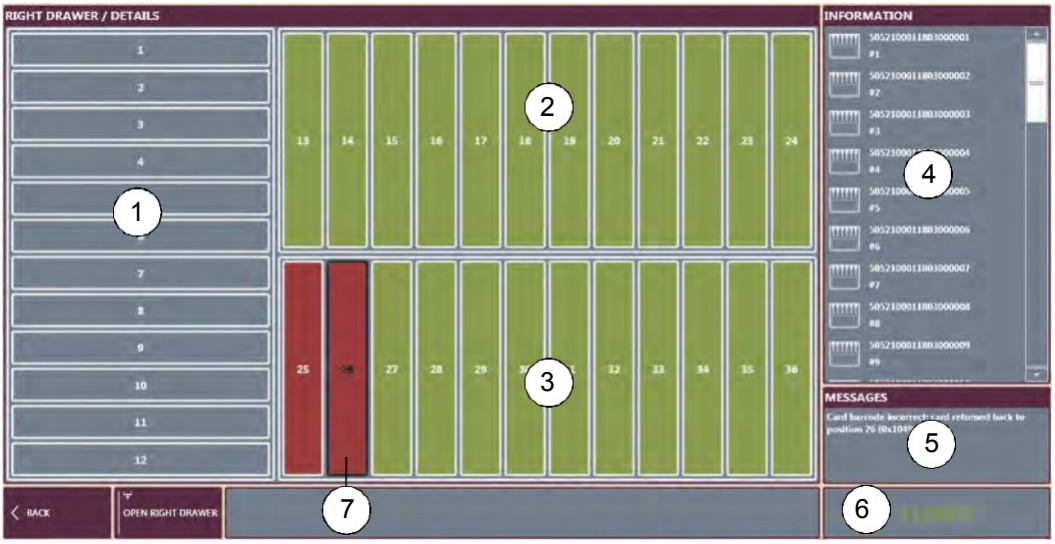


Figure 61. Loading gel cards - Right Drawer Details screen

Tray 1 (gel cards 1 to 12)

Gray: position not used (this tray is empty, in this example)

2Tray 2 (gel cards 13 to 24)

Green: gel card detected waiting for identification or unloading

3Tray 3 (gel cards 25 to 36)

Green: gel card detected waiting for identification or unloading

Red: gel card in error

Gel card information area

Messages related to the gel card selected in the list (4)

6Drawer status (**OPEN** or **CLOSED**)

7Selected gel card (black border) and in error (highlighted red)

7.2.2.2 Removing a Gel Card in Error

If an error occurred, the drawer (9) is highlighted red. It is also possible to select the right drawer icon (8) in the **RESOURCES** area.

Figure 62.

A		Select the right drawer to display the **Right drawer / Details** screen. *On the interactive image of the instrument area.*
		Select a gel card to view detailed information in the **MESSAGES** (5) area.
C		Open the drawer to remove the gel card in error.
D		Dispose the damaged gel cards in accordance with internal rules. Add new ones, if necessary.
E		Close the right drawer. *To view loaded gel cards, see chapter Resources on Board on page 96.*

7.2.3 Loading Left Drawer

The following procedure shows an example with 1 gel card tray, 2 diluent rack products and 11 reagent vials.

Gel cards and diluent racks loaded in the instrument must be unused (non-pierced).

Take care to load only one gel card tray by location. Loading more than one tray (pile-up) can lead to instrument damage.

A Unlock the drawer (1).

From the shortcut bar.

Open the drawer (1) and remove the empty gel card trays.

C Load the reagent tray (2) and the diluent racks (5).

The barcode for the diluent rack (6) must face towards the right of the instrument. The barcode for the reagent vials must face the alignment marks.

D Load the gel card tray (3) in the available place with the barcodes (4) facing towards the right of the instrument.

The trays must be perfectly inserted and secured by the drawer lockers (7).

E Gently close the drawer (1) until it locks.

The instrument will scan the entire drawer and then identify individually all the loaded resources.

If an error occurred, see *Left Drawer Details on page 108**.*

To view loaded resources, see chapter *Resources on Board on page 96**.*

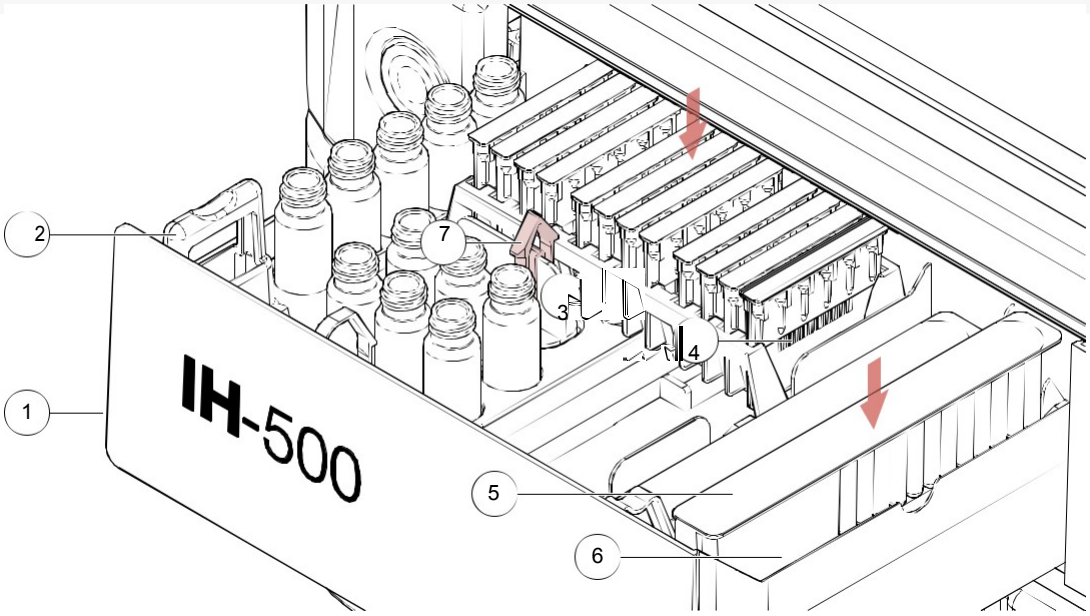


Figure 63.

7.2.3.1 Left Drawer Details

A Select the left drawer to display the **LEFT DRAWER DETAILS** screen.

On the interactive image of the instrument area.

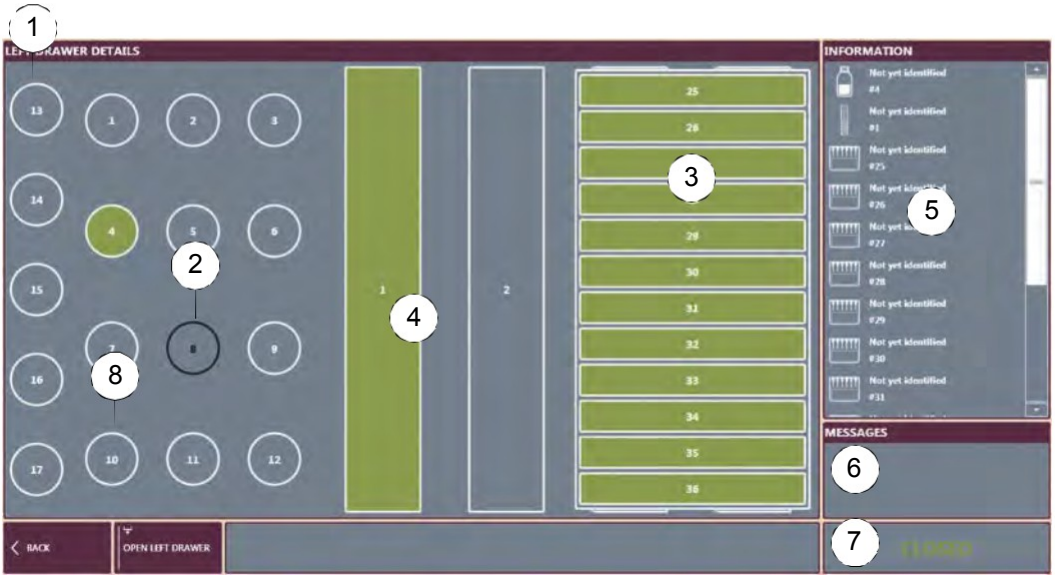


Figure 64. Loading resources - Left drawer details screen

Reagent positions (1 to 17)

Green: reagent detected waiting for identification;

Red: reagent in error.

Selected resource (black border)

The **INFORMATION** area (5) describes the type of resources.

If a selected resource is in error (red), the **MESSAGES** area (6) describes the type of error.

Gel card positions (25 to 36)

Green: gel card detected waiting for identification or unloading;

Red: gel card in error.

Diluent rack positions (1 to 4)

Green: diluent rack detected waiting for identification or unloading;

Red: diluent rack in error.

Information about the loaded resources (product barcode and position)

6Messages related to a selected resource

7Drawer state (**OPEN** or **OPENING REQUEST SENT** or **CLOSED**)

8Empty position (gray background)

7.2.3.2 Removing a Resource in Error

If an error occurred, the drawer (10) is highlighted red. It is also possible to select the left drawer icon (9) in the **RESOURCES** area.

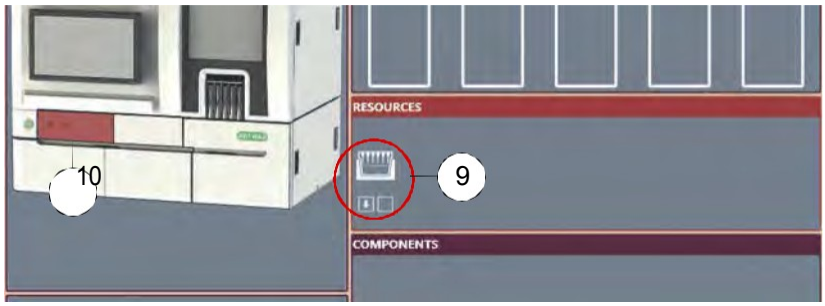


Figure 65.

A  Select the left drawer to display the **LEFT DRAWER DETAILS** screen.

If it is not possible to load a reagent vial (maximum capacity on board is reached), an alarm is generated. Unload the corresponding vials and store them in a fridge.

Select the resource to view detailed information in the **MESSAGES** area.

C  Open the drawer to remove the resource(s) in error.

➔ *Verify that the expiry date of the resource is valid, that the barcode is correctly orientated and that it is clean and not scratched. If necessary, clean the barcode with a lint free cloth or print a new one.*

D Dispose the damaged resource(s) in accordance with internal rules and add new ones, if necessary.

E Gently close the left drawer.

To view all resources loaded in the instrument, see chapter Resources on Board on page 96.

7.3 Resources Removal

7.3.1 Removing Gel Cards

If an unused gel card is returned to the drawer and the drawer is opened and closed without removing the gel card from the instrument, this card is automatically loaded on board and the countdown (OBT) starts from the beginning.

An used gel card is sent to the waste bin.

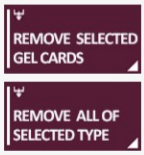
Take care to load a single empty tray in each location.

A  Display the screen **GEL CARD DETAILS**.

Refer to chapter Gel Card Details on page 98 for detailed description.

B Select the gel card(s) to remove.

Use the list selection buttons to remove more than one gel card.

C 

Remove the gel cards.

Refer to chapter Gel Card Details on page 98 for detailed description.

D 

Select **YES** to confirm action or **NO** to cancel.

➔ *If the action is confirmed and no error occurred, the selected gel card(s) is sent to the left or right drawer (go to step J).*

If it is not possible to remove a gel card, a warning screen is displayed. Close drawer and retry.

*If there is no tray in the left or right drawer, a caution symbol flashes on the **MAIN SCREEN** button and the removal symbol  remains active.*

E  Display the main screen.

F  Display the screen of the drawer in error (the left drawer, in this example).

*A red error message displays: **No available places to remove gel cards**.*

G  Open the drawer.

The left drawer, in this example.

Add one or more empty tray.

I Gently close the drawer.

Gel cards previously selected are unloaded in the left or right drawer. A message displays that resources are ready to be discharged.

J  Request the opening of the left drawer. Then remove the gel cards.

Unloaded resources are displayed in orange and with this symbol.

Remarks when removing gel cards:

For the trays facing towards the right of the instrument, squeeze gently the tray to release from the lockers.

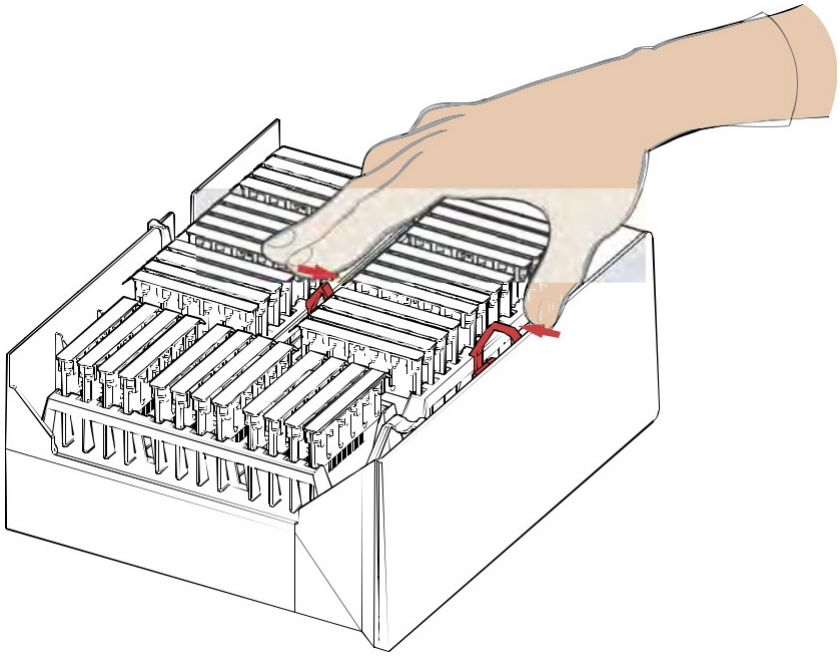


Figure 66.

For the tray facing towards the front of the instrument, press the locker to release the tray, then tilt and extract it.

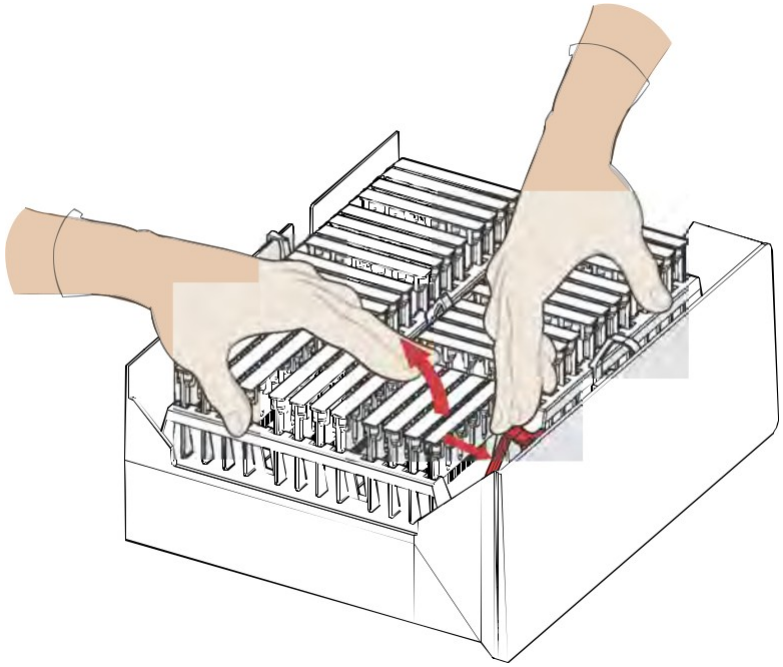


Figure 67.

7.3.2 Removing Reagents

When the OBT management is enabled, if a reagent vial is returned to the drawer and the drawer is opened and closed without removing the vial from the instrument, the reagent vial is automatically loaded on board and the countdown (OBT) starts from the remaining time before the OBT end.

Always close the reagents and assure not to mix the caps between reagents vials.

A		Display the screen **REAGENT DETAILS**. *Refer to chapter Reagent Details on page 100 for detailed description.*
B		Select the reagent(s) to remove. *Use the list selection buttons to remove more than one reagent.*
C		Remove the reagent(s). *Refer to chapter Reagent Details on page 100 for a detailed description.*
D		Select **YES** to confirm action or **NO** to cancel. ➔ *If confirmed and no error occurred, selected reagent vials are sent to the left drawer.* *If an error occurred, a warning screen is displayed (e.g open the left drawer, add a reagent tray and try again).*
E		Open the drawer.
F		Remove the reagent(s) from the drawer. *Unloaded resources are displayed in orange and with this symbol.*

7.3.3 Removing Diluents

If an unused diluent rack is returned to the drawer and the drawer is opened and closed without removing the rack from the instrument, the diluent rack is automatically loaded on board and the countdown (OBT) starts from the remaining time before the OBT end.

A 

Display the screen **REAGENT DETAILS**.

Refer to chapter Diluent Details on page 102 for detailed description.

B Select the diluent(s) to remove.

Use the list selection buttons to remove more than one diluent.

C 

Remove the diluent(s).

Refer to chapter Diluent Details on page 102 for a detailed description of this screen.

Confirm the remove the diluent rack(s).

E 

Confirm to discard the used diluent rack.

➔ *If the actions are confirmed and no error occurred, selected not used diluents are sent to the left drawer.*

Used diluent racks are sent to the solid waste bin.

F 

Open the drawer.

G 

Remove the diluent(s) from the drawer and place them in the fridge.

Unloaded resources are displayed in orange and with this symbol.

Remarks

If the left drawer is full (due to 4 diluent racks not yet identified or empty gel card and reagents trays), the removal symbol remains active.

The message **No available places to remove diluents** is displayed on the screen **LEFT DRAWER DETAILS**.

7.4 Loading and Removing Samples Racks

bRead carefully the instructions given in chapters Sample Specifications on page 39 and Samples on page 93.

Sample racks can be loaded in any available lane of the samples area (position 1 to 5).

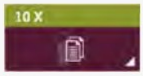
The position of the sample rack in the samples area defines which rack is processed first. For example, the rack in position 1 is processed before the rack in position 2.

Each lane is numbered and a led (1) indicates the status of each lane:

a green light indicates that the lane is available;

a blinking red light indicates that a rack is moving (unloading);

a red light indicates that a rack is already loaded in the lane.

		Prepare a rack with sample tubes (3).
B		Fully engage and lock the sample rack into the samples loading area (2). *The instrument automatically identifies the samples.*
C		Display the screen **SAMPLES DETAILS** to see detailed information of the loaded samples. *See chapter Samples Screen on page 116.*
D		Display the screen **SAMPLES MANAGEMENT** to associate profiles. *See chapter Samples Management (displays all Samples on Board) on page 134.*

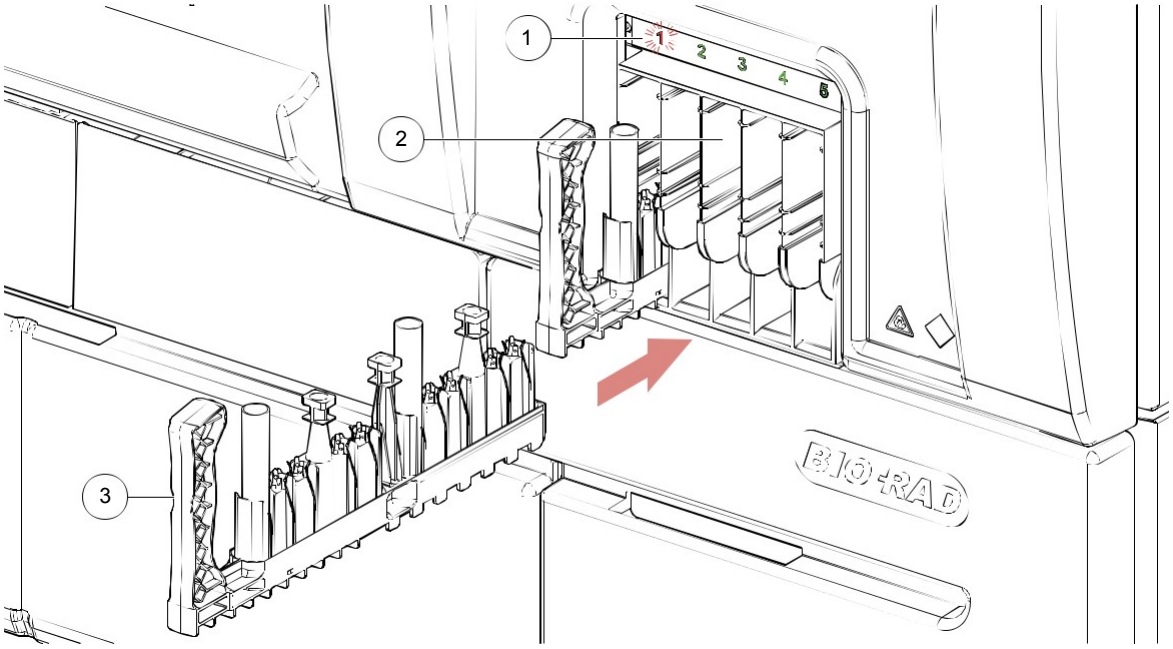


Figure 68. Loading samples rack

Remarks

If the identification fails or an error occurred (e.g. unreadable barcode or cap detected), the **SAMPLES** area (5) and samples loading area (4) of the interactive image are highlighted in red.

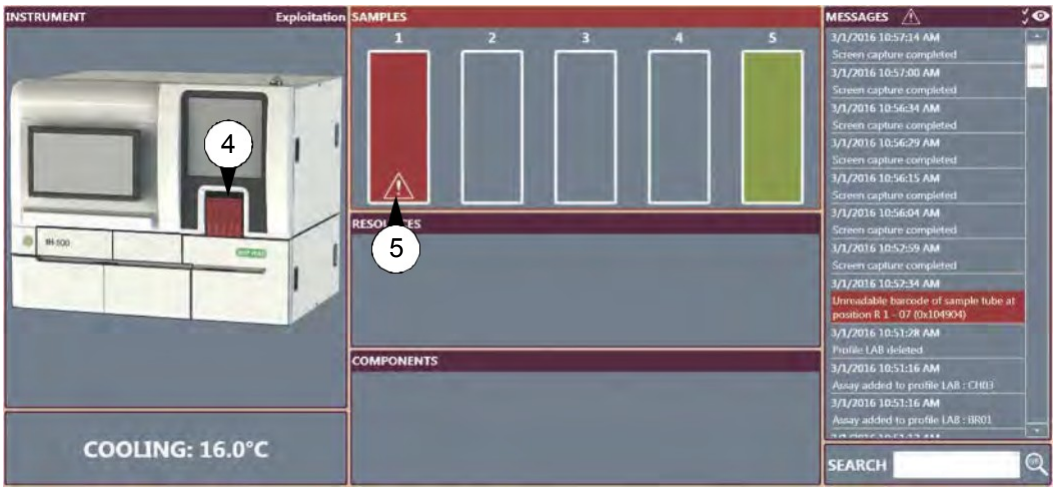


Figure 69.

The rack can be unloaded and identified manually using the barcode reader or by typing the barcode.

See chapter Sample Barcode Manual Input on page 122.

7.4.1 Samples Screen

A  Display the screen **SAMPLES**.

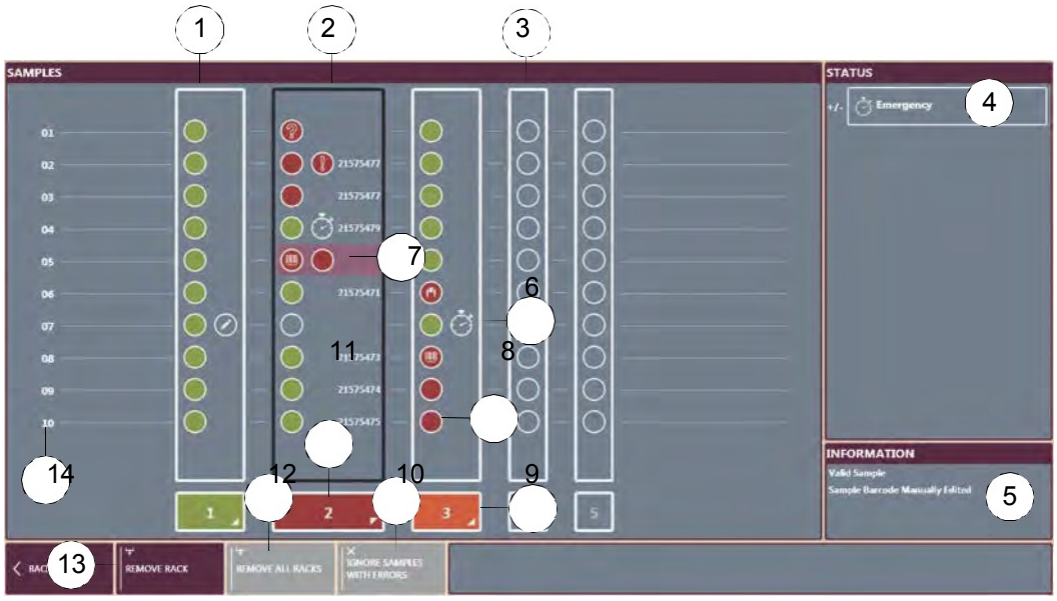


Figure 70. Samples screen

Valid sample rack (green)

2Sample rack in error (red)

3Empty sample rack lane (white)

4Status area (Priority)

5Area to display information of the selected sample tube

6Sample tube with **Priority** status

7Selected sample tube (highlighted)

8Sample tube in error (red symbol)

See chapter Sample Detection Symbols on page 117.

9Rack removed for re-identification (orange)

10 Function to ignore samples with errors

11 Sample rack selected

12 To remove all racks

13 To remove the selected rack

14 Sample tube position in the rack

Sample Detection Symbols

Symbol	Description	What to do?
	The removal is in progress or the removal request is recorded.	Wait for process completion.
	Valid sample rack	View details or select **REMOVE RACK**.
	Small lane number # color: green	
	Valid selected sample rack	View details or select **REMOVE RACK**.
	Large lane number # color: green	
	Selected sample rack in error	View details, select **IGNORE SAMPLE WITH ERRORS** or
	Large lane number # color: red	**REMOVE RACK**.
	Sample rack removed for re-identification	Fix the error(s) and re-load rack.
	Empty sample position	-
	Valid sample detected.	-
	Sample invalid (duplicated or mismatch)	View details, select **IGNORE SAMPLE WITH ERRORS** or
		**REMOVE RACK**.
	Manually edited barcode	See chapter Sample Barcode Manual Input on page 122.
	Sample with a warning.	Refer to the message displayed on screen.
	Sample barcode unreadable	See chapter Sample Barcode Manual Input on page 122.
	Sample detected with a cap.	Select the symbol to confirm absence of the cap (a warning
		screen is displayed) or **REMOVE RACK** and remove the cap.
		See chapter Confirm Absence of a Cap on page 118.
	Sample detected with a cap. The user confirms that there is no cap present.	-
	Sample with Priority status	See chapter Assign a Priority Status to a Sample on page 118.
	Sample position was empty before re-identification	View details, select **IGNORE SAMPLE WITH ERRORS** or **REMOVE RACK**.
	Sample missing, was present before re-identification	View details, select **IGNORE SAMPLE WITH ERRORS** or **REMOVE RACK**.
	Sample barcode unreadable + mismatch after re-identification	View details, select **IGNORE SAMPLE WITH ERRORS** or **REMOVE RACK**.
	Sample duplicate + empty before re-identification	View details, select **IGNORE SAMPLE WITH ERRORS** or **REMOVE RACK**.

Symbol	Description	What to do?
	Sample with red blood cells only.	-
	Sample with serum only.	-
	Sample configured as Quality Control tube.	-

7.4.2 Assign a Priority Status to a Sample

A sample can be loaded with a priority status when:

it is loaded with a priority sample rack;

the status of the samples is set to “Emergency” in the Samples screen;

the priority status is sent with the test request from the DMS.

See chapter Priority Sample Tube Holder on page 45.

7.4.3 Confirm Absence of a Cap

A		Select the sample with a cap detected symbol. *The following message is displayed:* ***Do you confirm absence of cap on the sample “xxxxxxxx” at location “Rx - yy”****.*
B		Confirm the absence of the cap on the sample tube. *The valid sample tube symbol is displayed.*

7.4.4 Ignore Samples with Errors

The button is disabled (gray) if no rack is selected or if removed for re-identification.

Samples in error are automatically ignored according to time set in the **GENERAL CONFIGURATION** area of the option screen (see chapter Timeout before ignoring Sample Errors on page 170 for details).

		Select the rack lane with samples in error.
B		Ignore the rack lane. *The sample rack switches to green and is ready for pipetting.*

7.4.5 Configure Separate HC/Serum Sample Tubes

2 samples tubes with the same barcode (one containing only RBC and the other containing serum) are required to proceed a test with separate RBC / serum.

The red blood cell sample should have a maximum height of 20 mm, to ensure a 1% red blood cell suspension. Otherwise, the dilution rate will be too high and may cause erroneous interpretation of results.

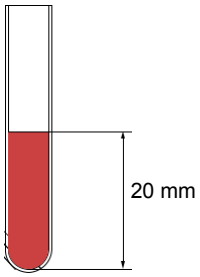


Figure 71.

A Load the 2 sample tubes on the same rack.

See chapter Loading and Removing Samples Racks on page 114.

A warning appears on the screen.

Figure 72.

B  Select one of the sample tubes.

A message prompts to define the type of selected sample.

C 


Indicate which tube contains:

Red Blood Cell;

- Serum.

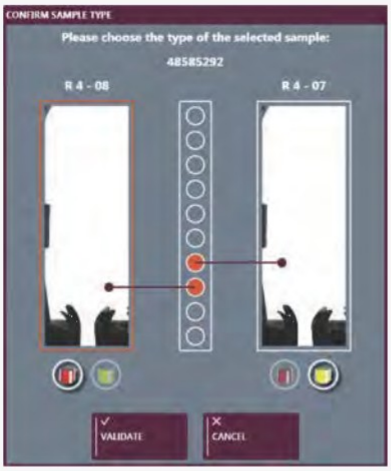


Figure 73.

D 

Validate the selection.

The tubes are indicated with RBC or serum.

Figure 74.

7.4.6 Remove all Racks

It is only possible to remove racks which are not in use.

Wait until all the rack lane lights are green (no longer blinking red) to remove the racks. Samples should be centrifuged before retesting on the instrument in order to ensure complete separation of red cells from plasma/serum.

A 

Remove all racks.

The removal symbol is displayed and all racks are removed.

7.4.7 Remove Rack

This button is disabled (gray) if no rack is selected.

Wait until all the rack lane lights are green (no longer blinking red) to remove the rack(s). Samples should be centrifuged before retesting on the instrument in order to ensure complete separation of red cells from plasma/serum.

Select a rack.

B 

Remove the selected rack.

The removal symbol is displayed and the transport arm pushes the rack out.

Remarks

If the selected rack is in use, a warning message prompts that the system is unable to remove the rack.

Acknowledge the message.

Wait for the end of the test.

If a rack is detected with an unreadable sample barcode, a warning message prompts that the rack has a barcode error.

A 

Acknowledge the message to remove the rack for re-identification. See chapter Sample Barcode Manual Input on page 122.

Cancel the message to not remove the rack (without re-identification).

7.4.8 Remove a Sample Rack manually

Only when the IH-500 is shut down.

A Shutdown the instrument.

See chapter Shutdown on page 160.

B Gently remove the sample rack.

For example, use pliers to grab the rack handle.

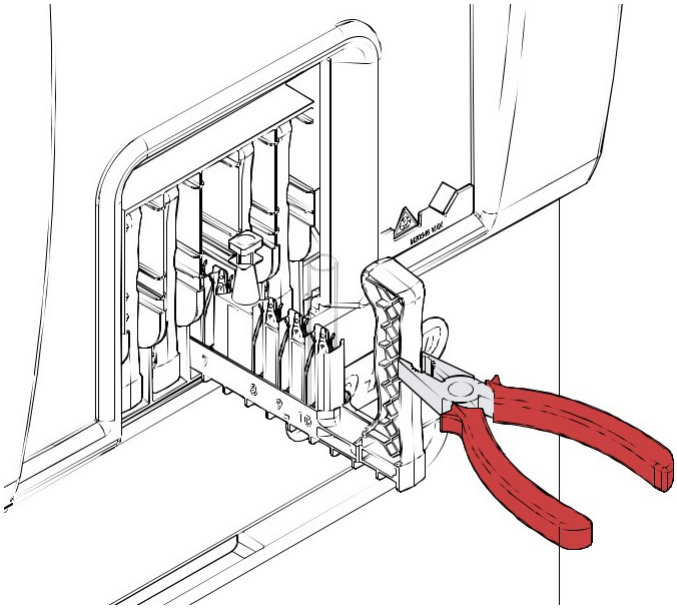


Figure 75.

7.4.9 Sample Barcode Manual Input

To avoid re-identification errors, ensure that the sample is placed in its original position.

A  Select the sample with the barcode unreadable symbol.

*The screen **MANUAL BARCODE INPUT** is displayed.*

Remove the rack to take the sample.

Input the barcode or scan with the barcode reader.

D Confirm barcode input to check it matches the first input.

Figure 76.

The screen displays if the entry is incorrect:

Mismatch between first and second input or;

Barcode duplication with another sample.

E 

Confirm the entry.

The sample tube displays a green valid symbol and the manually edited barcode symbol.

Repeat manual input for each unreadable sample barcode.

G Once done, re-load the rack in its original position.

If a re-identification error occurred, see chapter Sample Detection Symbols on page 117 for details.

7.5 Managing Solutions and Waste

7.5.1 Solutions/Wastes Screen

If a container is full or empty during a run, it is highlighted orange or red.

Orange (Warning)	• 1 system liquid container empty or disconnected; 1 liquid waste container full or disconnected; solid waste almost full (over 60%); decontamination liquid almost empty.
Red (Error)	• solid waste full (over 80%); decontamination liquid container empty; both system liquid containers empty or disconnected; both liquid waste containers full or disconnected.

A  Display the screen **SOLUTIONS/WASTES**.

Select an area to display details in the **Information** area.

Refill or empty the container according to specifications.

Connect the container.

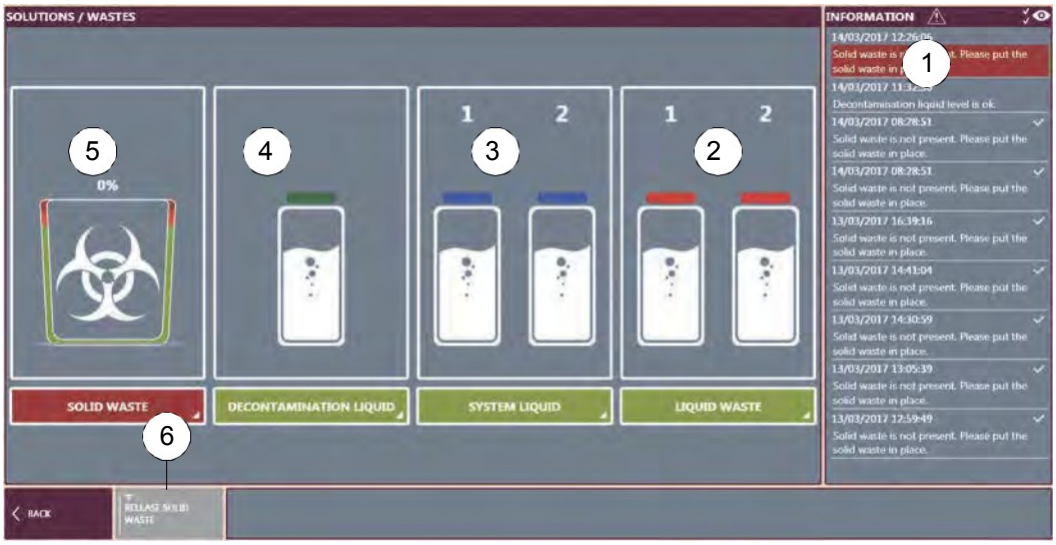


Figure 77. Solutions/Wastes screen

Information area

Liquid waste containers status

See chapter Emptying a Liquid Waste Container on page 127.

System liquid containers status

See chapter Refilling a System Liquid Container on page 125.

Decontamination liquid container status

See chapter Refilling a Decontamination Liquid Container (NaOH 0.5 M) on page 129.

Solid waste bin status

See chapter Emptying the Solid Waste Bin on page 130.

To open the solid waste bin.

If the liquid waste is connected to a laboratory drain (optional kit), no action is required. The external waste connection is displayed instead of the liquid waste containers.

Figure 78.

7.5.2 Refilling a System Liquid Container

b If the tubing appears dirty (visually), the container must be replaced.
System liquid is stable for 7 days.

Status	Description
	An empty liquid container appears in orange (left in this example), refer to the **Information** area for details. If disconnected, the liquid container appears with a plug symbol. The status light is orange.
	If both system liquid containers are empty or disconnected, the **SYSTEM LIQUID** button is red. The status light is red. The **Information** area indicates that the system is in error (red message). It is not possible to run a test. The following message is displayed: "**Both system liquid containers are empty. Please fill the containers".**

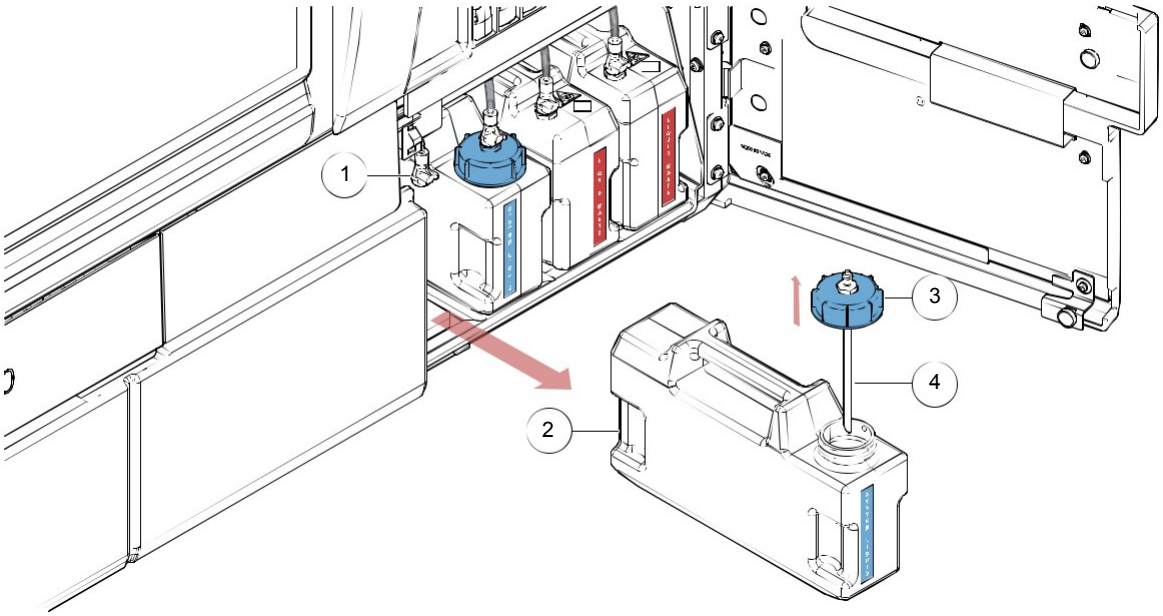


Figure 79.

A Display the screen **SOLUTIONS / WASTE**.

See chapter Solutions/Wastes Screen on page 123.

Open the liquid containers door.

Verify that the container (2) is empty.

Press the quick coupling thumb latch (1) to disconnect the container.

Remove the empty system liquid container (2).

		Unscrew and remove the blue cap (3).
		Empty completely the container (2).
H		Rinse the container and tubing (4) with deionized water. *Deionized water must meet a minimum standard of Grade 2 - ISO 3696 or Type II - ASTM D1193-91.*
I		Fill the container with system liquid. The solution must contain: **100 ml** of Wash Solution A Concentrate bottle (1 bottle of 100 ml) and **2 liters** of deionized water for a standard container, **300 ml** of Wash Solution A Concentrate bottle (3 bottles of 100 ml) and **6 liters** of deionized water for the System Liquid Container 6.3L (Option). *Deionized water must meet a minimum standard of Grade 2 (ISO 3696) or Type II (ASTM D1193-91). Use of water not conforming to the specified requirements may affect the results.*
		Tighten the equipped blue cap assembly (3) on the container.
K		Place the refilled system liquid container. *A sensor detects the container type is correct.*
L		Connect the tubing to the container. *Press the quick coupling thumb latch (2)*
M		Acknowledge the message of the information area. ***Information** area displays: **System liquid container #1 (or #2) is usable**.*

7.5.3 Emptying a Liquid Waste Container

Status	Description
	The full or disconnected liquid waste container appears in orange, refer to the warning of the **Information** area for details. If disconnected a plug symbol appears.
	If both liquid waste containers are full or disconnected, the **LIQUID WASTE** button is red. The **Information** area indicates that the system is in error (red message). It is not possible to run a test. The following message is displayed: "**Both liquid waste containers are full. Please empty the containers.**".

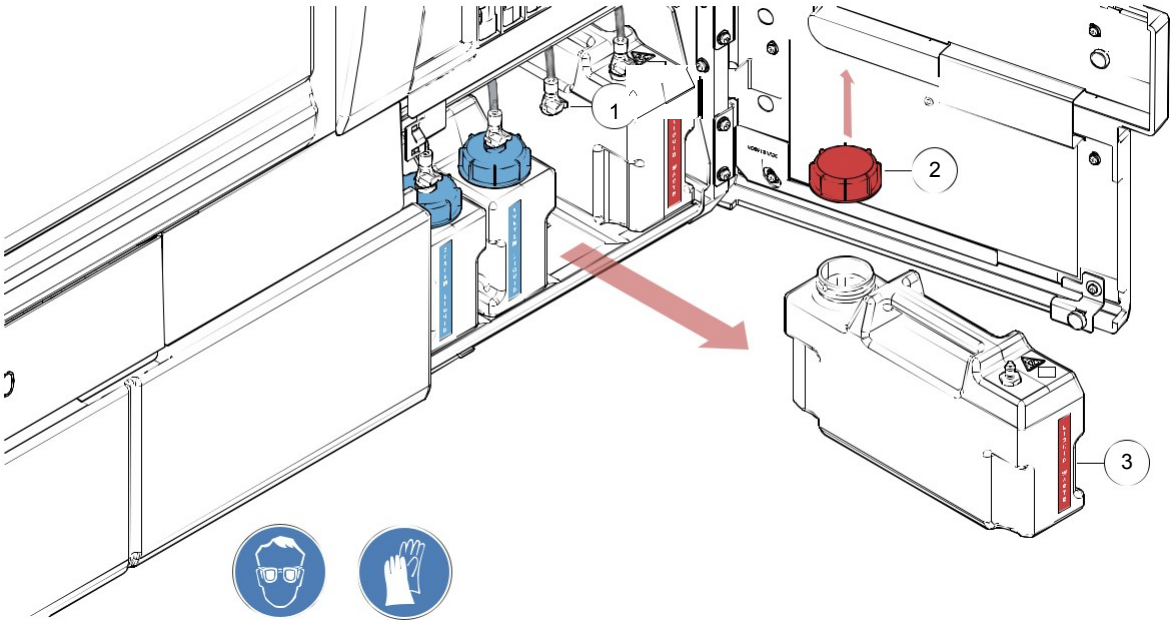


Figure 80.

A Display the screen **SOLUTIONS / WASTE**.

See chapter Solutions/Wastes Screen on page 123.

Open the liquid containers door.

Press the quick coupling thumb latch (1) to disconnect the full container.

Remove the full liquid waste container (3).

Unscrew the red cap (2).

Dispose the liquid waste in accordance with the local regulations.

Rinse the container with demineralized water.

Replace the red cap (2).

I	Place the empty liquid waste container in the instrument. *A sensor detects the container type is correct.*
J	Press the quick coupling thumb latch (3) to connect the tubing to the container. ***Information** area displays: **Liquid waste container #2 (or #1) is usable**.*

7.5.3.1 External Waste (Laboratory Drain)

If the liquid waste is connected to a laboratory drain (optional kit), make sure that both liquid waste containers are empty, rinsed and connected inside the instrument.

b Only a service engineer is allowed to connect the instrument to an external laboratory drain.

7.5.4 Refilling a Decontamination Liquid Container (NaOH 0.5 M)

Status	Description
	The **DECONTAMINATION LIQUID** button appears in orange if the liquid level is low. Refer to the **Information** area for details.

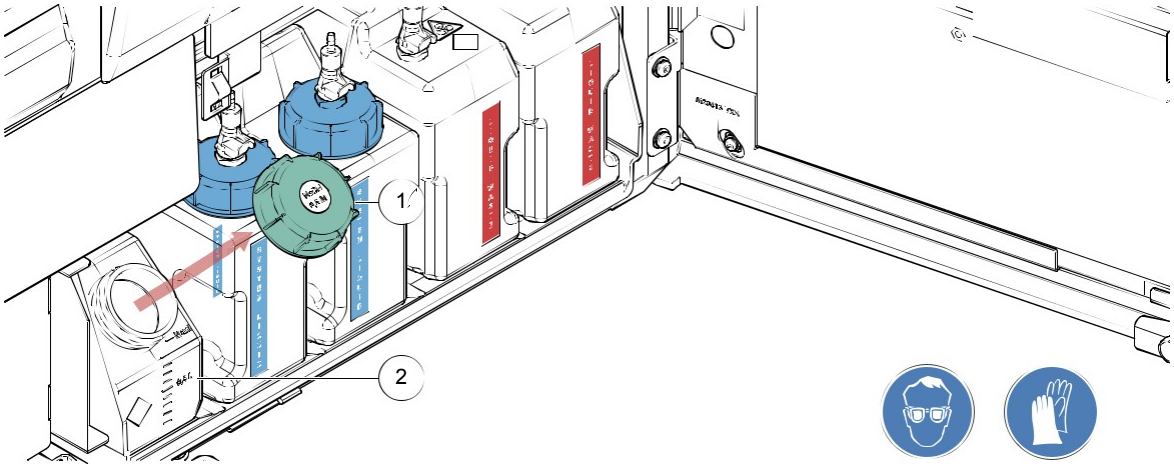


Figure 81.

A	Display the screen **SOLUTIONS / WASTE**. *See chapter Solutions/Wastes Screen on page 123.*
	Open the solid waste area door.
C	Check the liquid level. ***Maxi** = 1 liter (see graduation on the container) (2).* ***Mini** = 0.5 liter (see graduation on the container).*
	Unscrew the green cap (1).
	Fill the container with decontamination liquid (NaOH 0.5 M).
	Tighten the cap and close the solid waste area door.
G	Acknowledge message of the information area. ***Information** area displays: **Decontamination liquid level is ok**.*

7.5.5 Emptying the Solid Waste Bin

Status	Description
	The **SOLID WASTE** button appears in orange if level reaches high limit, or in red if full or disconnected. Refer to the **Information** area for details.

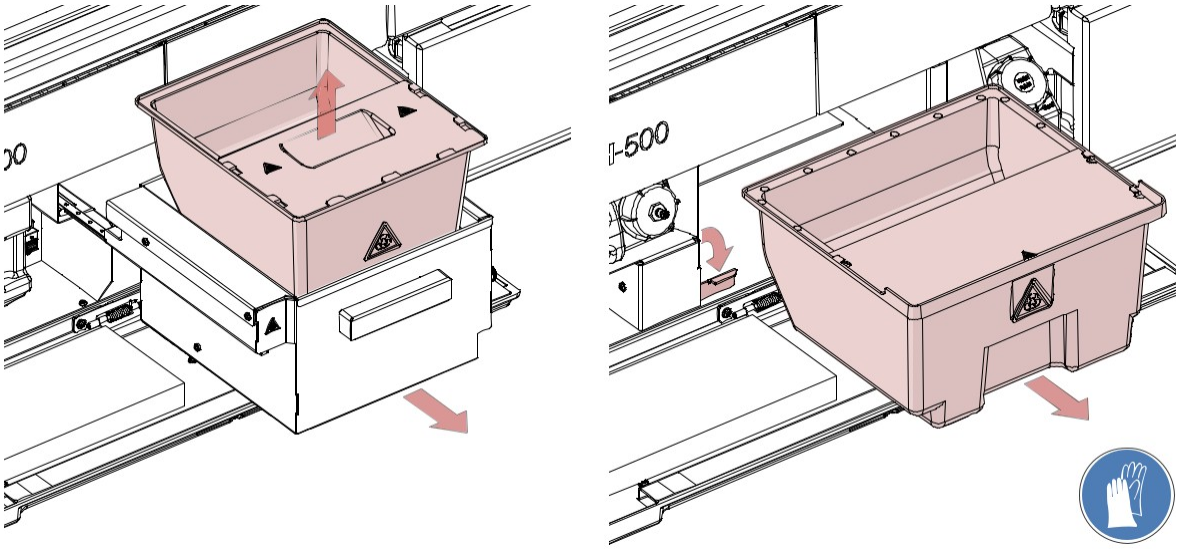


Figure 82.

Risk of hand pinching.

Do not put an hand into the solid waste bin location. It can be injured by a moving part nearby.

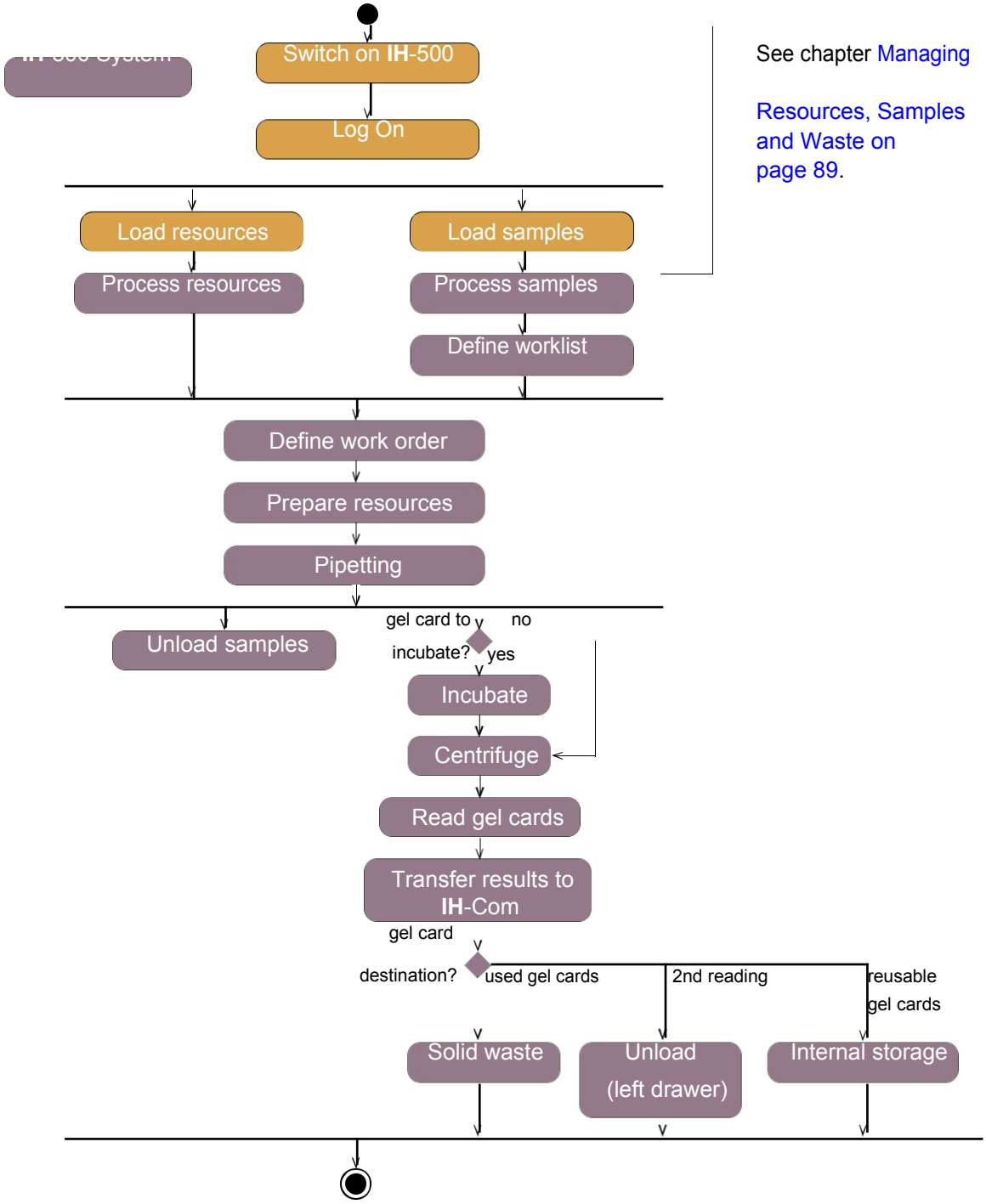
A	Display the screen **SOLUTIONS / WASTE**. *See chapter Solutions/Wastes Screen on page 123.*
	Open the solid waste area door.
	Select **RELEASE SOLID WASTE** to unlock the solid waste bin.
	Pull out the solid waste bin.
	Dispose the content of the solid waste in accordance with the local rules.
	Replace the solid waste.
	Lock the solid waste bin.

Operation

This chapter presents how to operate IH-500, run a test, manage test screens, operating errors (such as clot detected) and shutdown. User level rights are described in User Manager Module on page 257.

b Reliability of results is dependent upon compliance with good laboratory practices for reagents and samples.

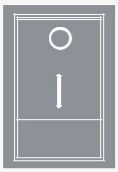
8.1 Standard Process Flow Chart



See chapter Managing Resources, Samples and Waste on page 89.

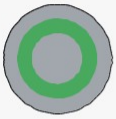
Figure 83. Process flow chart

8.2 Startup Procedure

A 

Start the instrument.

*Main power switch to "**I**" (ON).*

B 

Press and hold the instrument power button (until a sound is generated).

The computer starts, the touch-screen monitor switches on and the main screen is displayed with the login popup (Figure 84). A green light around the power button indicates that the computer is powered on.

C

Enter the **USER NAME** and **PASSWORD**.

Figure 84. Login

If the password is entered incorrectly five times in a row, the user account is blocked. A password reset will be required by the User Manager Module.

See chapter How to reset a Password on page 261.

D 

Select **VALIDATE** to confirm.

*The **LOG IN** screens closes and all IH-500 functions are initialized and checked.*

*Errors are displayed in the **MESSAGES** area.*

*It is possible to operate when the instrument **State** displays **READY**.*

Figure 85.

*If the instrument state displays **STOPPED**, an error occurred during initialization and an action is required (see chapter Main Screen in Error (Red/ Orange) on page 77).*

8.3 Ordering Tests

8.3.1 Ordering Tests from the LIS

Refer to the IH-Com Software User Manual.

8.3.2 Ordering Tests manually through IH-Com

Refer to the IH-Com Software User Manual.

8.3.3 Ordering Test through IH-500

8.3.3.1 Samples Management (displays all Samples on Board)

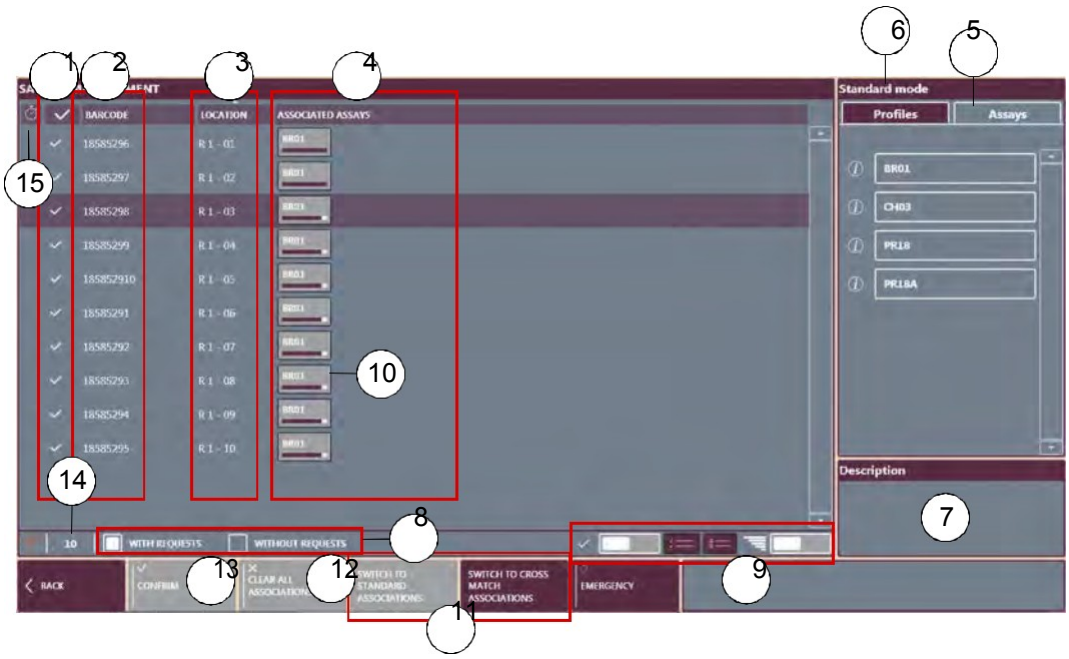


Figure 86. Samples management screen (standard mode)

Status (tick = sample with request)

2Barcode (sample tubes)

3Location (rack # and position of the sample tube in the rack, e.g. **R1 - 01**)

4Associated Assays area

5Select a tab to displays the list of **Profiles** or **Assays** available

6Displays the selected mode:

Standard mode or

Cross match mode

Assay(s) **Description** area

Function to filter the samples list

By checking the options, only samples with and/or without requests are displayed

Selection buttons

For details see chapter List Selection on page 74

10 Associated assay
When the assay is gray, the associated test is in progress.

11 Buttons to display the selected mode (Standard or Crossmatch) in area (6).

If no crossmatch profile is configured, these buttons are not visible.

12 **CLEAR ALL ASSOCIATIONS** button

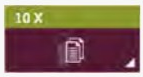
13 **CONFIRM** button

14 **Selected items: #**

15 **Priority** sample

8.3.3.2 Ordering a Test

A Select to display the **SAMPLES MANAGEMENT** screen.



➔ *This screen displays all samples on board and allows tests to be ordered manually at any time.*

B Select a sample line or press the **Select All** button.

*Activate **Extended** to select more than one lines (9).*

C From the **Profiles** or **Assays** tab (6), select the profile or assay to associate.

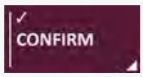
Select **i** to display a **Description** (8) of the assay(s).
➔ *Selected assays are displayed in the **Associated Assays** area (4).*

The «Assays» tab displays a list of available assays according to profiles created in the instrument or in IH-Com.
To create new profiles, see chapter Profile Management on page 179 (user level rights > 1 required) or refer to IH-Com User Manual.

D Select the associated assay button (11) or select **CLEAR ALL ASSOCIATIONS**

(12) to cancel an assay association.

If necessary to cancel an assay association.

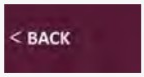
E 

Select **CONFIRM** (13) to validate associated assays.

Confirmed assays are displayed in blue grey (11).

*If no resources are missing, the run starts after a few seconds and it is possible to monitor the progress state of each test, in the **TEST IN PROGRESS** screen.*

See chapter Tests In Progress on page 141.

F 

Select **BACK** to return to the main screen.

*If resources are missing, go to the **TESTS WITHOUT RESOURCES** screen.*

See chapter Tests without Resources on page 138.

8.3.3.3 Ordering a Cross Match Test

Before performing a cross match test, make sure that there are sufficient gel cards on board.

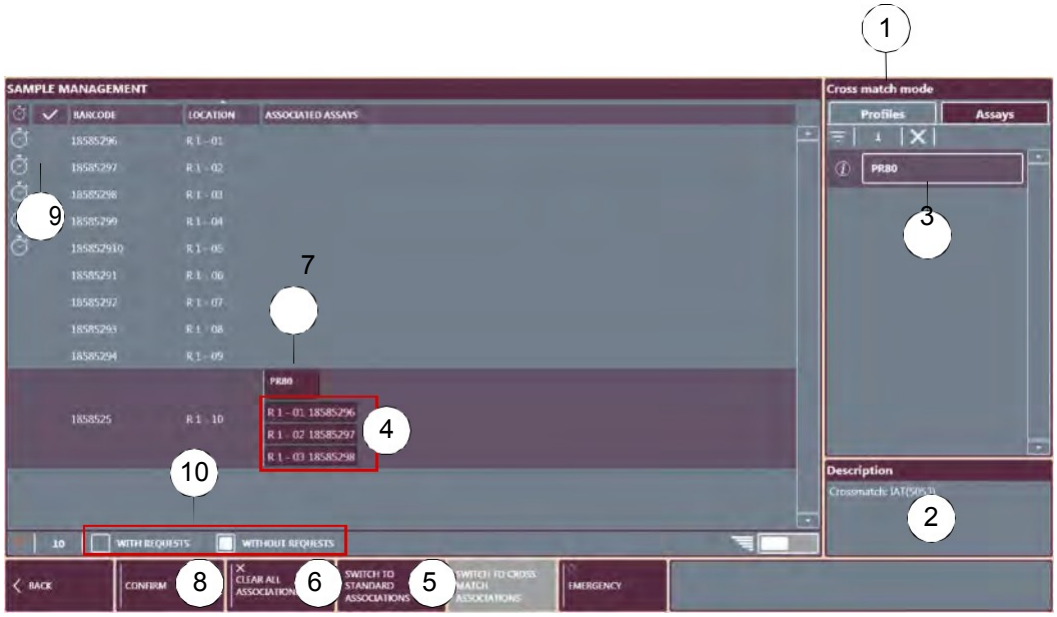


Figure 87. Samples management screen (Cross match mode)

Cross match mode

Assay(s) **Description** area

List of available Cross match **Profiles** and **Assays**

Associated Donors (Barcode - Position - Assays) area

Select **SWITCH TO STANDARD ASSOCIATIONS** to switch back to **Standard mode**

6CLEAR ALL ASSOCIATIONS button

7Associated Assays

8CONFIRM button

9Status column (tick = sample with request)

10 Function to filter the samples list

By checking the options, only samples with and/or without requests are displayed

A SWITCH TO CROSS MATCH ASSOCIATIONS Select **SWITCH TO CROSS MATCH ASSOCIATION** (from **Standard mode** - Figure 86).

*The **Cross match mode** is displayed with its related **Profiles** and **Assays**.*

Select the sample for a cross match test.

C From the list of **Profiles** or **Assays** tab (3), select the cross match profile or assay to associate (select **i** to display a **Description** (2) of the assay(s)).

The «Assays» tab displays a list of available assays according to profiles created in the instrument or in IH-Com.

To create new profiles, see chapter Profile Management on page 179 (user level rights > 1 required) or refer to IH-Com User Manual.

*The **DONOR SAMPLES ASSOCIATION** screen appears.*

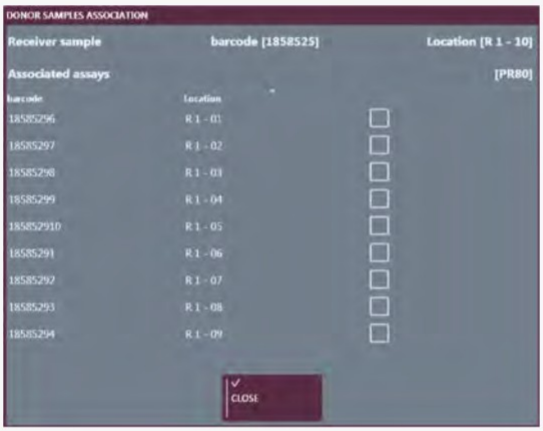


Figure 88.

Select the donor(s) to associate by checking the boxes.

E ✓ CLOSE Select **CLOSE**.

***Associated donors** (4) and **Associated Assays** (7) are displayed (Figure 87).*

F ✓ CONFIRM Select **CONFIRM** to validate cross match associations.

The confirmed assays are displayed grey.

*If no resources are missing, the run starts after a few seconds and it is possible to monitor the progress state of each test, in the **TEST IN PROGRESS** screen.*

See chapter Tests In Progress on page 141.

G < BACK Select **BACK** to return to the main screen.

*If resources are missing go to the **TESTS WITHOUT RESOURCES** screen.*

See chapter Tests without Resources on page 138.

8.3.4 Tests without Resources

This screen displays tests which cannot be performed due to missing resources.

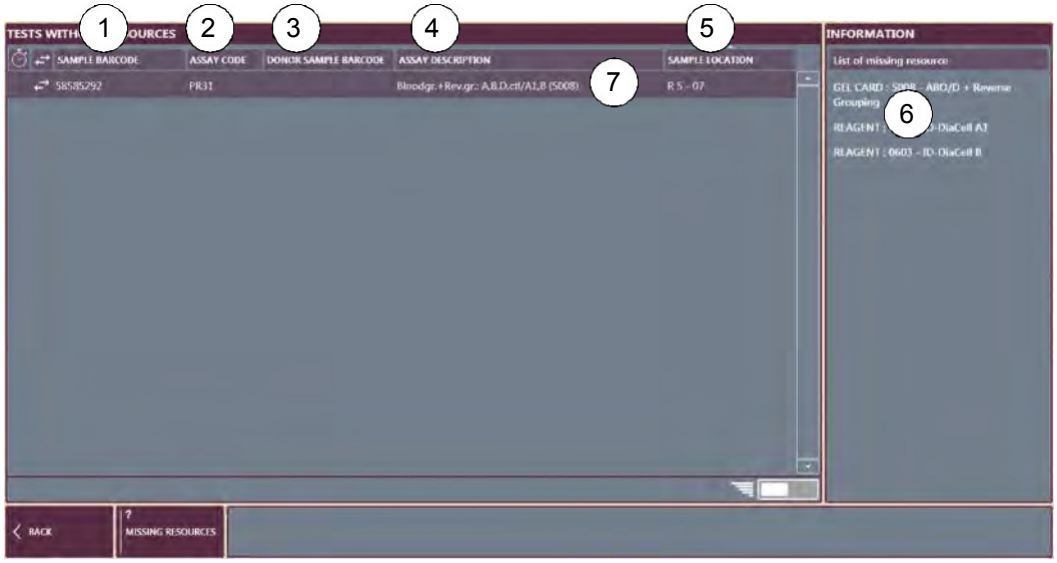


Figure 89. Tests without resources screen

Sample barcode

2Assay code

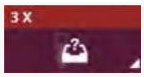
3Donor Sample Barcode (cross match)

4Assay description

5Sample location (rack # and position of the sample tube in the rack)

6INFORMATION area (missing resources for a selected sample test)

7Selected sample test



Select to display the **TESTS WITHOUT RESOURCES** screen.

B Select a sample (7) to display an associated list of missing resources for the test in the **INFORMATION** (6) area.

C  Select **MISSING RESOURCES** to display a list of all missing resources.

See chapter Missing Resources Screen on page 139.

8.3.5 Missing Resources Screen

This screen displays all missing resources associated to ordered tests. It is also possible to open the right and left drawers from this screen.

Figure 90. Missing resources screen

Missing **GEL CARDS** area

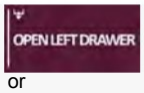
2Missing **REAGENT** area

3Missing **DILUENT** area

4OTHER area (missing donor/recipient, balance cards or reused cards in process of test)

A  Select **MISSING RESOURCES** to access this screen.

*Either from the main screen or from the **TESTS WITHOUT RESOURCES** screen.*

B 

or


To load the missing resources, select **OPEN LEFT DRAWER** or **OPEN RIGHT DRAWER** according to missing resources.

The right drawer is dedicated to gel cards only.

Load the required resources.

Comply with all instructions of chapter Managing Resources, Samples and Waste on page 89 and follow Good Laboratory Practice.

Close the drawer(s).

E Resources are automatically identified.

If all resources are on board, the IH-500 system automatically starts the run.

8.4 Starting a Run

If all resources and samples have been loaded and the appropriate test ordered, the IH-500 system automatically starts the run.

The **TESTS IN PROGRESS** screen allows the monitoring of all tests in progress. See chapter Tests In Progress on page 141.

If an error occurred during a run, go to chapter **TESTS TO REPEAT**. See chapter Tests Canceled / to Repeat (flagged Tests) on page 145.

If an error occurred on a container, the interactive image and **RESOURCES** area are highlighted red or orange on the main screen. Detailed information is displayed in the **SOLUTION / WASTES** screen. This screen also has the option to unlock the solid waste bin. See chapter Managing Solutions and Waste on page 123.

If an error occurred on a component, the interactive image and components area are highlighted red on the main screen (e.g. pipette needle detected with a clot). Detailed information is displayed in the **COMPONENTS** screen. This screen also has the option to open the pipetting door and switch ON or OFF the pipetting area light.

See chapter Components Screen on page 148.

To enter patient data, verify and validate results, refer to the IH-Com Data Management Software User Manual.

8.4.1 Tests In Progress

This screen displays all ordered tests which are in progress, the state of each IH-500 operating module and the remaining time to complete the assay.

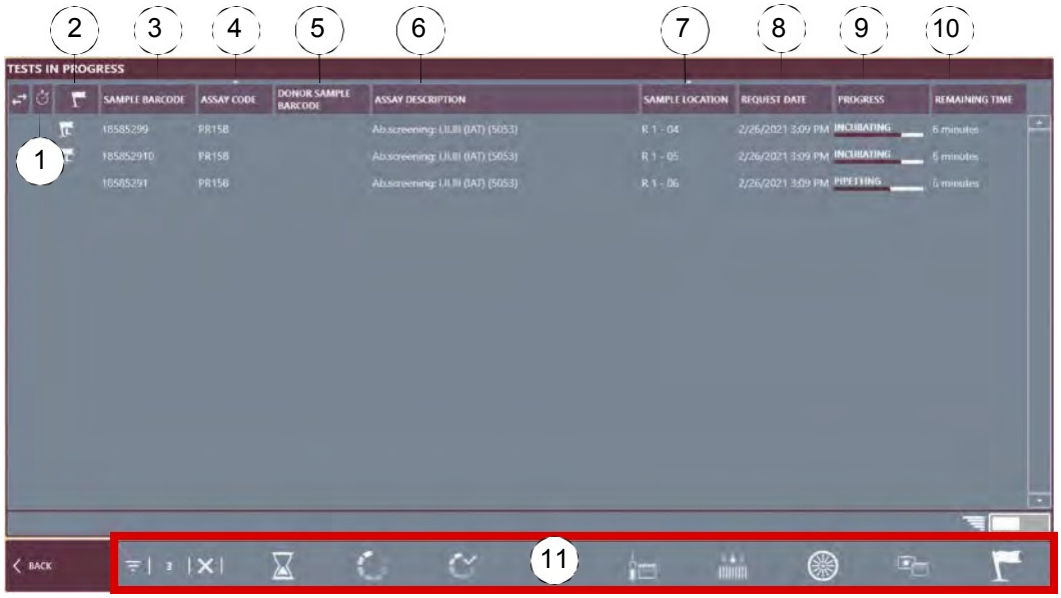


Figure 91. Tests in progress screen

Priority sample

Notification related to air-gap or LIQ failure occurring during the test, with specific icons (L for LIQ, A for air-gap).

Sample barcode

4Assay code

5Donor Barcode (cross match)

6Assay description

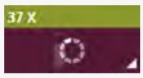
7Sample location (rack number and position of the sample tube in the rack)

8Request date

9Progress state

10 Remaining Time

11 Filter by area

A 

Select **TESTS IN PROGRESS** to access the screen.

From the main screen (footer strip)

It is possible:

to filter tests according to the progress state (8); *See chapter Filtering Options on page 142.*

to monitor completed tests, in the **TESTS COMPLETED** screen.

See chapter Tests Completed on page 143.

8.4.1.1 Filtering Options

Select one or more pictogram to filter the list of tests.

Pict.	Status
	WAITING
	CALCULATING
	READY TO START
	PREPARATION
	PIPETTING
	INCUBATING
	CENTRIFUGING
	READING
	AIR-GAP OR LIQ FAILURES When an air-gap or LIQ failure occurs, the main screen displays the button for tests in progress or completed with the warning color as long as similar tests with are in progress.

8.4.2 Tests Completed

This screen allows to monitor all completed tests.

Figure 92. Tests completed screen

Notification related to air-gap or LIQ failure occurring during the test, with specific icons (L for LIQ, A for air-gap).

Sample barcode

3Assay code

4Donor Barcode

5Assay description

6End date

7Sample location (rack number and position of the sample tube in the rack)

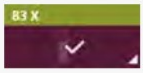
8Detailed information for a selected test

9SEND RESULT TO DMS button

See chapter Send Result to DMS on page 144.

10 To acknowledge the selected results.

Any accepted test is removed from the list.

A		Select **TESTS COMPLETED** to access the screen. *From the main screen (footer strip).* *The button is green when a test is completed.*
B		Select a test to display associated details in the **INFORMATION** area (8). *The information area displays the card and wells used to perform the selected assay.*

If weekly maintenance was not launched in the last 7 days, tests are flagged «Date of hydraulic maintenance expired». This may lead to false results.

8.4.3 Send Result to DMS

Results are sent automatically to the DMS. The procedure below describes how to transfer manually results to the DMS.

Select a test.

B 

Select **SEND RESULT TO DMS**.

The following screen is displayed.

Figure 93.

C 

Close the screen.

To verify results, refer to the IH-Com Data Management Software User Manual.

8.4.4 Tests Canceled / to Repeat (flagged Tests)

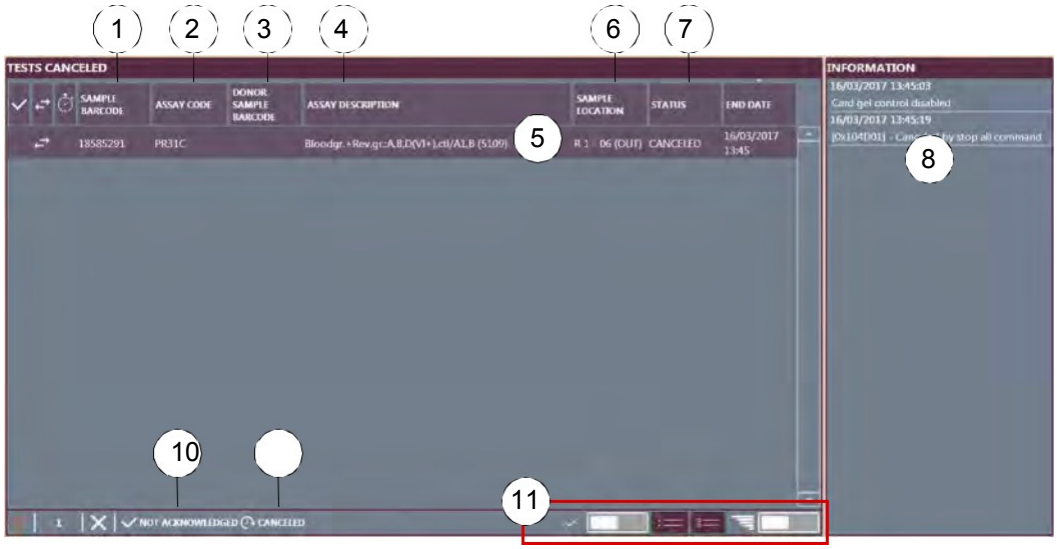


Figure 94. Tests to repeat screen

Sample barcode

2Assay code (profile)

3Donor Barcode

4Assay description

5Selected test

6Sample location column (rack number and position of the sample tube in the rack)

7Status of the test and the date of cancellation

8INFORMATION area (select a test to display details)

9Options to filter the samples list

ALL: The list displays all samples;

NOT ACKOWNLEDGED: The list displays only samples which have not been acknowledged.

Options to filter the samples list

ALL STATUS: The list displays samples with the **CANCELED** and **TO REPEAT** status;

CANCELED: The list displays samples which are canceled.

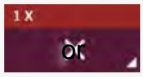
TO REPEAT: The list displays samples which must be repeated.

*The title of the screen is updated according to the filtering criteria (for example: if the filtering criteria is **CANCELED**, the title of the screen is **TESTS CANCELED**.*

Selection buttons

For details see chapter List Selection on page 74

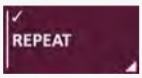
A



or

Select **TESTS CANCELED** or **TO REPEAT** to access the screen.

*If tests encounter errors during a run (for example, clot detected on a sample), they are moved to the **TEST TO REPEAT** screen. The **INFORMATIONS** area (8) provides details of when the error occurred.*
*If a **STOP ALL** command is issued, tests are moved to **TESTS CANCELED**.*
The corresponding button turns to RED when a test is moved.

B		Select a test to repeat or select the **Select All** button. *Activate the slider to select more than one test (11).*
C		Select **REPEAT**, to repeat the test(s). *Sample may need to be re-loaded if already ejected from the system.*

8.4.5 Second Reading

If the option **Return Gel Cards** is set to **Return All Cards**, all gel cards are returned to the drawer defined by the option **Gel Cards Release Drawer** for second reading.

To activate these options (user level 3 required), see chapter General, Profiles and Samples on page 169.

An empty gel card tray should be available in the drawer to empty the centrifuge. If this is not the case, the drawer on the interactive image is highlighted red.

Take care to load single empty trays only and no piled up trays.

If the drawer is open or if the gel card trays are full after card reading, the cards will be discarded automatically.

A Display the screen of the drawer used for returned gel cards.

A warning message displays: ***No available card positions to empty a full centrifuge****.*

See Right Drawer Details on page 105 or Left Drawer Details on page 108.

Open the drawer used for returned gel cards.

or

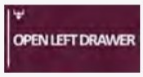
Add an empty gel card tray.

Gently close the drawer.

Run the tests.

F Open the drawer used for returned gel cards.

or *Unloaded resources are displayed in orange and with this symbol .*



Visually read the gel card reaction.

Dispose of the gel card in accordance with internal rules.

Remove all gel cards.

Gently close the drawer.

8.5 Results

Completed results are automatically sent to the IH-Com Data Management Software.

bReturned results with question mark “?” must be checked manually during validation.

Refer to the IH-Com Data Management Software User Manual.

8.6 Components Screen

The instrument monitors and displays:

the temperature of each module as well the internal and external ambient temperatures when available;

the status of the main components of the IH-500.

It is also possible to switch ON or OFF the internal light.

A To access the screen, select:

the **COMPONENTS** area (1) or;

the pipetting area (2) or;

the temperature area (3).

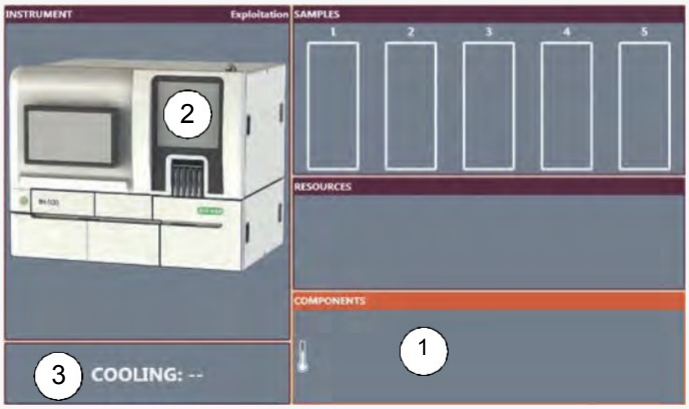


Figure 95.

Figure 96. Components screen

INFORMATION area or **Acknowledge information** (if a component is selected)

2OPEN PIPETTING AREA button

3SWITCH INTERNAL LIGHT ON/OFF

4Component in error

8.6.1 To acknowledge a Component in Error

If a component encounters an error during a run, the interactive image, the components area (main screen) and the components of this screen (4) are displayed in red or orange.

If the temperature of a module is exceeded, the system generates an audible alarm and a warning screen is displayed (in progress tests are flagged, see chapter Tests Canceled / to Repeat (flagged Tests) on page 145).

A	Select the component in error to display associated information in the **Acknowledge information** area.

Figure 97.

B	Follow the instructions on screen. *Refer to the table on next page for instructions on addressing the error specific to each component.*

	Front Centrifuge Select the button and acknowledge the error displayed in the **Acknowledge information** area. See chapter Troubleshooting on page 207.
	Rear Centrifuge Select the button and acknowledge the error displayed in the **Acknowledge information** area. See chapter Troubleshooting on page 207.
	Transport Arm Select the button and acknowledge the error displayed in the **Acknowledge information** area. See chapter Troubleshooting on page 207.
	Pipettor Select the button and acknowledge the error displayed in the **Acknowledge information** area. If a clot is detected, refer to section Pipettor in Error on page 154; to replace a pipette needle, refer to section Maintenance on page 191.
	Reagent Area Select the button and acknowledge the error displayed in the **Acknowledge information** area. See chapter Troubleshooting on page 207.
	Imaging Station Select the button and acknowledge the error displayed in the **Acknowledge information** area. See chapter Troubleshooting on page 207.
	Incubator Select the button and acknowledge the error displayed in the **Acknowledge information** area. See chapter Troubleshooting on page 207. If the incubator temperature is outside the tolerance range (37°C ± 2°C): a warning message is displayed and the status light is activated (red); sample processing of the related gel card is canceled; the instrument is in error and it is not possible to start a test using a heated temperature incubation until the temperature is within the range.

Ambient Temperatures

Select the button and acknowledge the error displayed in the **Acknowledge information** area.

See chapter Troubleshooting on page 207.

If the external or internal temperatures are exceeded, the system generates an audible alarm and a warning screen is displayed (in progress tests are finished and flagged, see chapter Tests Canceled / to Repeat (flagged Tests) on page 145).

Two levels for **INTERNAL** room temperature are defined (See chapter Internal Temperature in Error on page 156.):

1: Warning level (28°C to 31°C):

a warning message is displayed and the status light is activated (orange);

tests in progress are finished and flagged;

acknowledge the error to start new tests.

2: Stop level (> 31°C):

a warning message is displayed and the status light is activated (red);

tests in progress are finished and flagged;

it is not possible to start a new test until internal temperature is within the operating range.

One level for **EXTERNAL** room temperature is defined:

1: If temperature is above 28°C, a warning screen is displayed and the status light is activated (red):

tests in progress are finished;

it is not possible to start a new test;

the shutdown procedure is automatically launched.

8.7 Error Management

This menu displays the current status of the different modules. It allows the user:

to initialize individually each module or all modules;

to display the nature of an error;

to acknowledge an error which occurred on a module;

to prime the fluidic circuit in order to remove air bubbles. The instrument must be stopped to access the menu.

Figure 98.

	Module not initialized
	Module initialized
	Module in error The code indicates the nature of the error. Refer to section Troubleshooting on page 207 for more details.

To initialize a module

A		Initialize the module. *After a successful initialization, the status indicator turns green and displays **Functional** for the module.*

To initialize all modules

A		Initialize all modules. *After a successful initialization, the status indicators turn green and display **Functional** for all modules.*

To acknowledge an error on a module other than the transport arm

 Acknowledge the fault.

B		Initialize the module. *After a successful initialization, the status indicator turns green and display **Functional** for the module.*

To acknowledge an error on the transport arm

See chapter Transport Arm in Error on page 157.

8.7.1 Pipettor in Error

If a clot is detected, the pipettor is in error, and respective areas are highlighted red, the instrument stops and a user action is required.

If the time between the occurrence of the error and the user action is too long (2 min), the error **0x018E2E** (see page 228) is displayed. The needle is no longer usable (dried blood inside the needle). Clean or replace the needle. See chapter Pipette Needle Replacement / Cleaning on page 201.

e **HOT SPOT**
Be careful when accessing the pipetting area (1). Particular attention should be directed to the pipette needle and sample racks.

d **INFECTION**
There is a risk of infection from skin contact with blood. Always wear protective gloves, in accordance with laboratory safety regulations.

b Do not move, load, unload or mix any resources, samples or elements in the instrument.

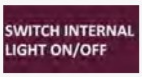
A Display the **COMPONENTS** screen.

See chapter Components Screen on page 148.

B 

Select **PIPETTOR** to display the error in the **Acknowledge Information** area.

The warning message is displayed: ***Embedded clot detected. Click next to start acknowledgment procedure****.*

C 

Select **SWITCH INTERNAL LIGHT ON/OFF**.

If the internal light is off.

D 

Select **NEXT** to start acknowledgment procedure.

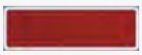
This message is displayed: ***Move the pipettor needle upwards and tap next****.*

Open the pipetting area door.

F Gently lift the pipette needle support (2).

Pipettor vertical Z-axis.

Be careful not to move the pipettor in any other direction.

G 

Select **NEXT**.

This message is displayed: ***Check the clot, clean the needle if clot is confirmed and tap next****.*

H		Verify if there is a clot present on the pipette needle (if there is a clot go to step I). *If there is no clot present, lift the support until the pipette needle is in it's highest position.* *If a clot detection message still appears even if there is no clot present, contact the Bio-Rad Technical Service representative.*
I		If there is a clot, lift the support (4) until the pipette needle is in its highest position (Z-axis).
J		Remove the clot and wipe the pipette needle. *Use non-woven wipes or a lint-free cloth soaked in 70% ethanol.*
K	NEXT	Select **NEXT**. *This message is displayed: **Close the door and click next**.*
		Close the pipetting area door.
M	NEXT	Select **NEXT**. *This message is displayed: **Tap acknowledge to validate the procedure**.*
	LEDGE	Select **ACKNOWLEDGE**. *All resources of the pipetting area are identified again.* *IH-500 system automatically continues the run ignoring the sample detected with a clot. The test for the sample detected with a clot is placed in **TEST TO REPEAT** list.* *The pipettor performs a decontamination cycle.*

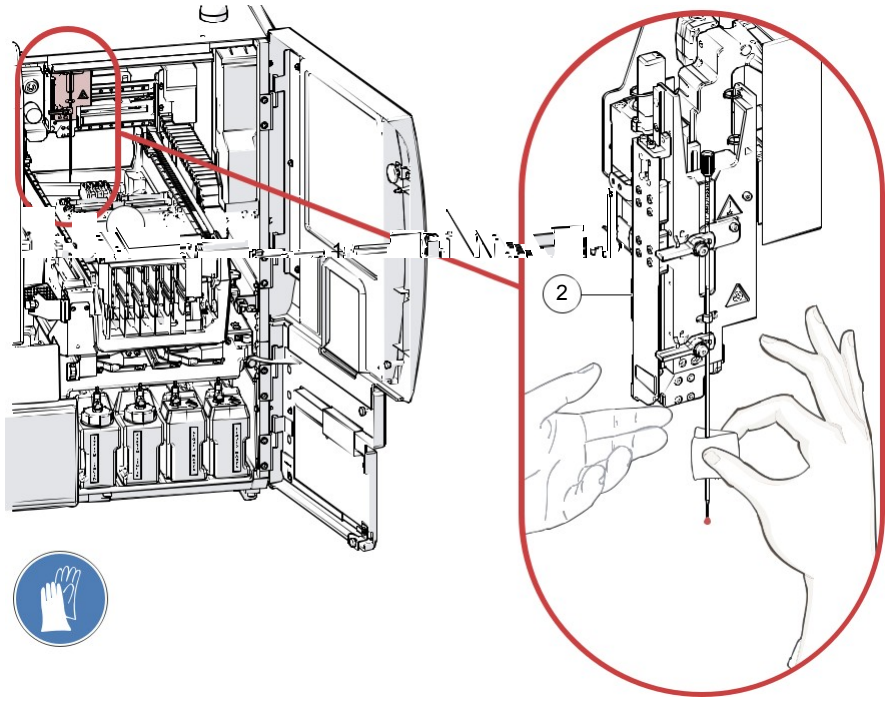


Figure 99.

8.7.2 Internal Temperature in Error

8.7.2.1 Internal Temperature between 28°C and 31°C

If the internal temperature is between 28°C and 31°C, the tests in progress are completed. The tests ready to be performed can not be launched.

A Display the **COMPONENTS** screen.

See chapter Components Screen on page 148.

B 

Select **AMBIANT TEMPERATURE** to display the error in the **Acknowledge Information** area.

➔ *The warning message is displayed:* ***Internal temperature too high (warning)****.*

Select **ACKNOWLEDGE**.

The temperature status is set to green.

The tests ready to be processed are automatically started.

8.7.2.2 Internal Temperature over 31°C

If the internal temperature exceeds 31°C, the tests in progress are completed but no test can be started.

It is not possible to acknowledge the error message until the temperature drops below 31°C (see above).

A Display the **COMPONENTS** screen.

See chapter Components Screen on page 148.

B 

Select **AMBIANT TEMPERATURE** to display the error in the **Acknowledge Information** area.

➔ *The warning message is displayed:* ***Internal temperature too high (alert). Fault's acknowledge is possible only if temperature values are acceptable again.***

C Wait until the temperature is below 31°C and acknowledge the error message (see above).

Or re-initialize the instrument.

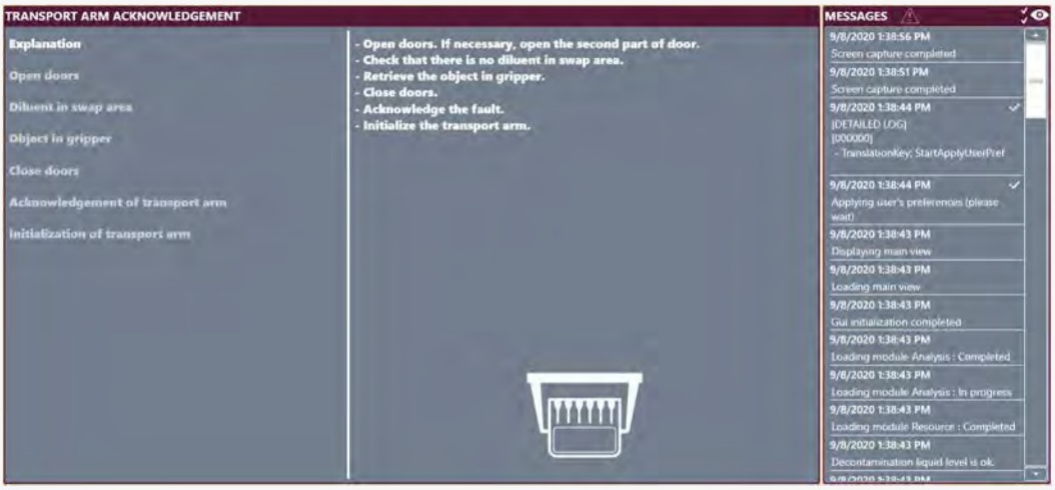
8.7.3 Transport Arm in Error

When an error occurred in the transport arm, the instrument stops and an user action is required. As resources can be present on the gripper or onto the swap area, visual check may be requested to avoid any crash or damage.

The example below shows how to reinitialize the transport arm after the error **0x18B19** - Incorrect positioning of the transport during a movement with a resource.

A ACKNOWLEDGE BLOCKING FAULT Acknowledge the error to reinitialize the transport arm.

The following screen appears. It describes the steps to perform for a proper recovery. Follow the instructions displayed on screen.



Next Press the button to execute the next step.

Open the doors of the instrument.

D Next Press the button to execute the next step.

The software asks to check the presence of diluent rack on the swap area.

E Check for the presence of diluent rack on the swap area.

If it is the case, remove it.

F Next Press the button to execute the next step.

The software asks to check the presence of object on the gripper.

Check for the presence of an object on the gripper.

H ✓ YES If an object is present, proceed to the next step.

A message informs the user to hold the object before proceeding to the next step.

X NO If no object is present, proceed to step M.

I Next Release the gripper.

A countdown of 5s starts before the release of the gripper. Then the gripper is set in freewheel.

Remove the object from the gripper.

	Next	Press the button to execute the next step.
		Close the doors of the instrument.
M	Next	Acknowledge the message. *The instrument reinitializes the transport arm. Wait for the end of the process.*
N	Finish	Close the screen.

8.8 Exit, Stop All and Shutdown

8.8.1 Exit

This function closes the software and allows access to the LAUNCHER.

A 

Login with the required rights (user level > 1) and select **MENU** (header strip).

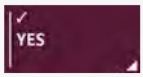
*The **MENU** screen is displayed.*

B 

Select **EXIT**.

A confirmation message is displayed.

Figure 100. Exit warning screen

C 

Confirm.

The User Interface closes immediately but the instrument continues to process tests in progress.

D 

To restart the User Interface, select the **IH-500 software** button.

The software loads and the main screen is displayed.

Figure 101. Launcher screen

Shutdown (1) (requires specific user rights) to access Windows Operating System.

8.8.2 Stop All

This function stops all tests in progress as soon as possible.

After a **STOP ALL**, it is necessary to initialize the instrument to continue testing. The system removes sample racks and unloads reagents vials (canceled tests are displayed in the test to repeat screen). Diluent racks are re-identified.

The **STOP ALL** function is also necessary to:

launch the maintenance;

change the pipette needle;

set options.

A MENU Login with the required rights (user level > 1) and select **MENU** (header strip).

*The **MENU** screen is displayed.*

B STOP ALL Select **STOP ALL**.

A confirmation message is displayed.

Figure 102. Stop all warning screen

C YES Select **YES** to confirm.

All tests in progress are lost.

*Tests in progress are canceled and flagged in the **TEST TO REPEAT** screen. The instrument state displays **STOPPED**.*

8.8.3 Shutdown

This function allows complete shutdown of the IH-500 system.

b Always shutdown IH-500 with the **SHUTDOWN** function.
Only use the main power switch in case of an emergency. Using the main power switch of the instrument leads to an immediate stop and may lead to damage of the instrument.

k The shutdown of the instrument may take a certain time.

A MENU Login with the required rights (user level > 1) and select **MENU** (header strip).

*The **MENU** screen is displayed.*

B 

Select **SHUTDOWN**.

*It is not possible to shutdown if tests are in progress or if the drawers are open. Use **STOP ALL** function first (refer to chapter Stop All on page 160 for help).*

The following warning screen is displayed.

Figure 103.

C 

Select **YES** to confirm.

Reagent vials are unloaded and placed in the left drawer. Then the left drawer opens automatically.

*If there is no reagent tray in the left drawer, the following warning screen is displayed: "**Can't Process to Shutdown: The reagent cage is needed to remove stored reagents.**"*

Add empty reagent tray to the left drawer and start procedure again.

D Remove returned reagents from the drawer by selecting the main screen button.

The interactive image will show red for the left drawer.

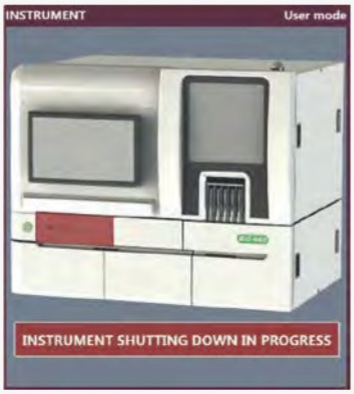


Figure 104. Shutdown warning screen

E Select the left drawer on the interactive image to display the **LEFT DRAWER DETAILS** screen.

Figure 105. Shutdown warning screen

OPEN LEFT DRAWER Remove the reagent tray.

G Store reagent vials in the fridge. Close the left drawer.

The solid waste bin is released and the touchscreen computer power switches OFF.

Empty solid waste and return bin to closed position.

For further instructions see chapter Emptying the Solid Waste Bin on page 130.

Wait until the instrument is shut down.

8.8.4 Initialize Instrument

After a **STOP ALL** command (instrument state **STOPPED**) or if an error occurred on a component, it is possible to initialize the instrument.

A MENU Select **MENU** (header strip).

*The **MENU** screen is displayed.*

B INITIALIZE INSTRUMENT Select **INITIALIZE INSTRUMENT**.

*The instrument initializes and state switches to **INITIALIZING**, **PREPROCESSING** and **READY**.*

Sample racks are removed and all reagent vials are unloaded to the left drawer. On-board diluent racks are identified again.

If necessary load an empty reagent tray in the left drawer.

If reagent vials and samples are on-board, they will be removed. Check the integrity of reagent and samples before use.

8.9 Backup Database

This function allows to:

backup the database;

create the weekly maintenance reports.

8.9.1 Database Backup

A MENU Select **MENU** (header strip).

*The **MENU** screen is displayed.*

B BACKUP Select **BACKUP**.

The following screen is displayed.

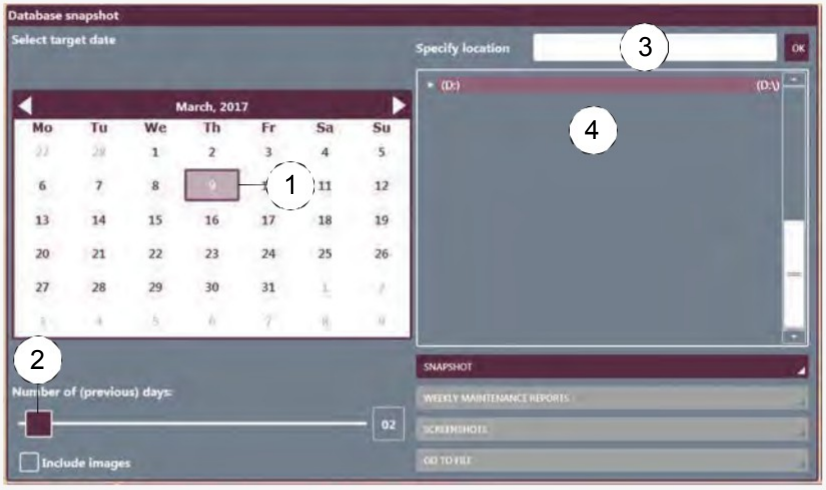


Figure 106. Backup screen

Select the date (1) in the calendar.

D Enter the number of previous days by moving the slider (2).

Max 60 days.

E Enable **Include images and curves**.

If desired.

F Specify the backup folder path.

Network or removable drives only (3).

G Select the folder (4).

H SNAPSHOT Start the database backup.

A confirmation message is displayed (See example below).

Figure 107.

I ✓ VALIDATE Validate.

The in progress screen is displayed. Depending upon the size of the database, the backup may take several minutes.

A folder is created in the backup path previously selected.
For example: 2014-08-20_182616_IH-500_SNxxxxxx_SNAPSHOT.

GO TO FILE Select **Go To File** to view destination of the database file.

8.9.2 Weekly Maintenance Report

Connect a USB key memory.

B MENU Select **MENU** (header strip).

*The **MENU** screen is displayed.*

C BACKUP Select **BACKUP**.

The following screen is displayed.

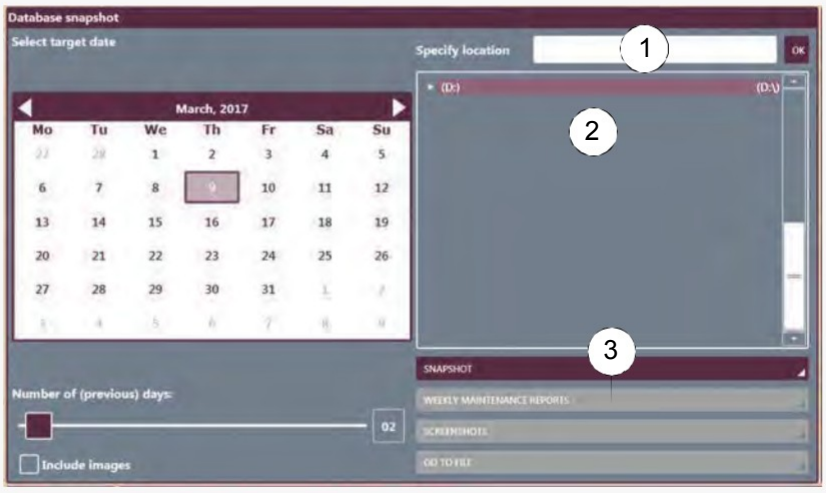


Figure 108. Backup screen

D Specify the backup folder path.

Network or removable drives only (1).

E Select the folder (2).

F WEEKLY MAINTENANCE REPORTS Create the weekly maintenance report.

*A file is created on the folder **D:||MaintenanceReports**.*
For example: WeeklyMaintenanceReport_20160406_152152.xps.

8.10 Change Password

This function allows to change the password.

A MENU Login with the required rights (user level > 1) and select **MENU**.

*The **MENU** screen is displayed.*

B CHANGE MY PASSWORD Select **CHANGE MY PASSWORD**.

The following screen is displayed.

Figure 109.

Enter **OLD PASSWORD** and **NEW PASSWORD**.

CONFIRM NEW PASSWORD.

E VALIDATE Select **VALIDATE** to confirm password change (or **CANCEL** to close the screen).

8.11 Quality Control

A Quality Control check (QC) must be performed:

after any maintenance operation;

when it is notified by the Quality Control Reminder on page 76.

Refer to QC Management and Maintenance on page 175 for more details.

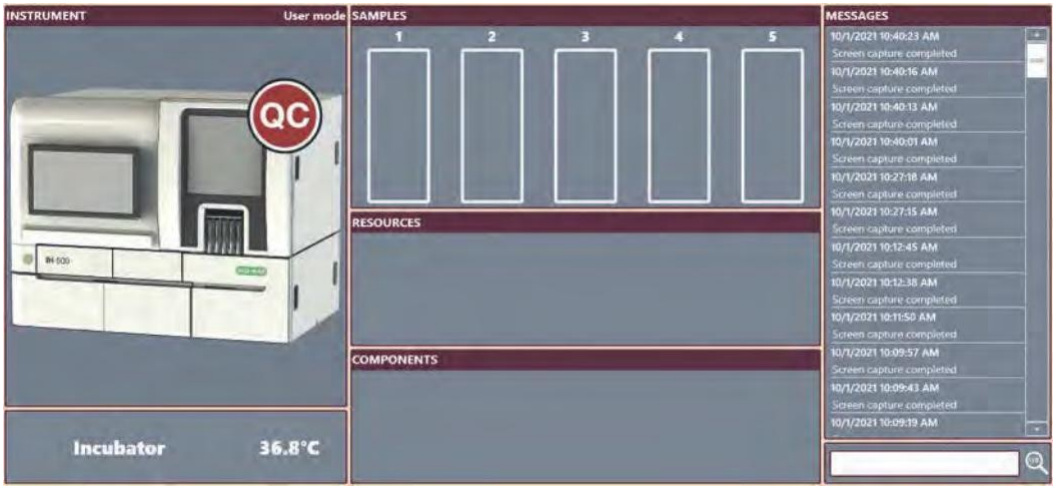


Figure 110.

Refer to the IH-Com Data Management Software User Manual.

Options and Customization

This chapter describes how to:

configure the instrument settings;

configure the sample barcode filtering;

connect with DMS;

manage profiles and assays;

customize the GUI theme.

Minimum Advanced user level right is required otherwise it is not possible to access the following screens and commands.

9.1 Options (Main Screen)

Login with the required rights.

MENU Select **MENU.**

C OPTIONS Select **OPTIONS**.

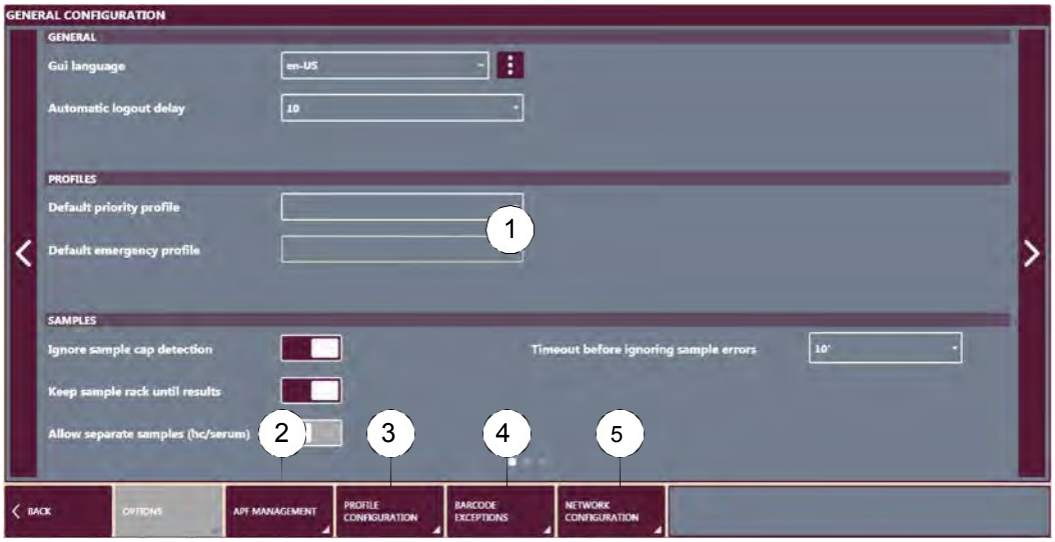


Figure 111. Options screen

General configuration

The general configuration area contains all parameters grouped by topic. They are located on 3 screens accessible with the lateral buttons:

General, Profiles and Samples on page 169;

Gel Cards, Reagents and Diluents on page 171;

QC Management and Maintenance on page 175.

See chapter APF Profiles Management on page 177.

3See chapter Profile Management on page 179.

4See chapter Barcode Exceptions Configuration on page 181.

5See chapter Data Management Configuration on page 182.

9.1.1 General, Profiles and Samples

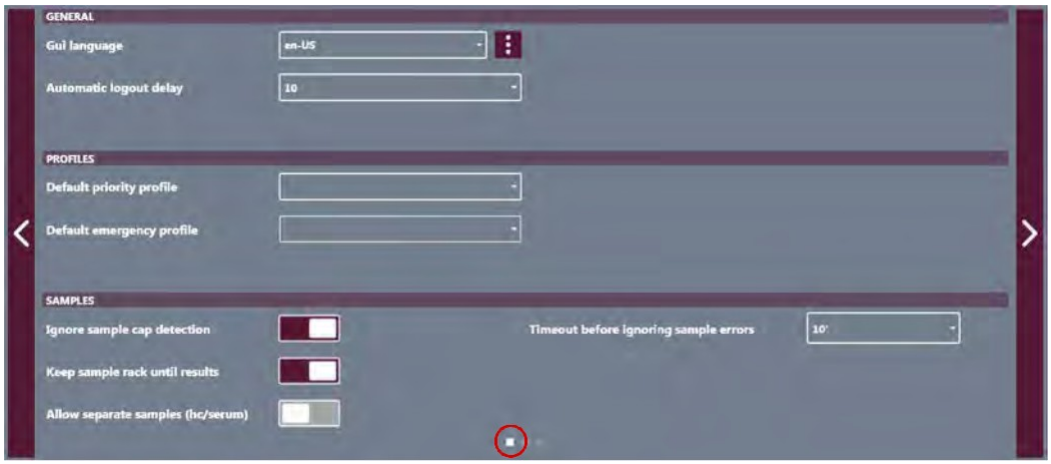


Figure 112.

9.1.1.1 General

GUI Language

Select the drop down list and select the required **GUI Language**.

Press the ⋮ button to import a new language package.

Exit and restart GUI interface to change the language.

Automatic Logout Delay

Option to automatically log out a user which did not intervene on the instrument during a defined duration (in minutes).

It is possible to define the duration from 0 to 60 minutes (0 = no automatic logout).

9.1.1.2 Profiles

Default Priority Profile

If a **Default Priority Profile** is set, all samples loaded with no specific test request, the configured profile will automatically run.

If the **Default Priority Profile** is set to **BLANK**, a profile must be assigned for each sample.

Select the drop down list and select the **Default Priority Profile**.

Only configured profiles are available.

To configure a new profile, see chapter Profile Management on page 179.

The default profile is associated to each correct identified sample at time expiration defined in section Timeout (in seconds) before returning Samples for Manual Input on page 182.

Default Emergency Profile

If a default emergency profile is set, all samples loaded with the priority status will be automatically tested with the configured profile.

If the **Default Emergency Profile** is set to **BLANK**, a profile must be assigned for each priority sample.

Select the drop down list to select the **Default Emergency Profile**.

Only configured profiles are available.

To configure a new profile, see chapter Profile Management on page 179.

The **Default Emergency Profile** is associated to each correct identified emergency sample at time expiration defined in section Timeout (in seconds) before returning Samples for Manual Input on page 182.

9.1.1.3 Samples

Ignore Sample Cap Detection

This option enables/disables the sample cap detection.

To activate this option, the instrument must be in state **STOPPED**. The user level 3 rights are required. See chapter Instrument State on page 79.

Flag	Description
ON	Enabled
OFF	Disabled

Timeout before ignoring Sample Errors

User level 3 rights are required to configure this option.

By default, the timeout is set to 10 minutes.

Select the drop down list and select the **Timeout before ignoring sample errors**.

It is possible to set time-out between 15 seconds to 60 minutes.

The timeout is disabled as soon as the option **Allow Separate Samples (HC/Serum)** is activated.

Keep Sample Rack Until Results

This option enables the instrument to keep or discard the samples until the results is transmitted to the DMS.

Flag	Description
ON	The samples are kept until the results are transmitted to the DMS.
OFF	The samples are discarded when the pipetting is performed.

Allow Separate Samples (HC/Serum)

The option allows to determine the presence of RBC or serum in a sample tube in case of duplicate sample.

9.1.2 Gel Cards, Reagents and Diluents

Figure 113.

9.1.2.1 Gel Cards

Gel Card Control

b Activating this option is recommended otherwise there in an increased risk of using non-conforming gel cards (as defined in the gel card box insert). By default, this function is not enabled.

To change this option, an Administrator user level is required. It is possible to deactivate the option by un-checking the corresponding box.

OBT Activate

The OBT Management (On Board Time) is an option to manage the shelf life of the loaded resources. It defines:

how long a resource may stay in the instrument before removal;

how is a resource is removed (returned or trashed).

Resources	Shelf life
Gel card	504 hours (21 days)

When the resources are expired, the system returns or discards the loaded resources according to the resources status.

Resources status	Description
Not used	Resources returned to the drawer.
Used	Resources discarded and sent to the solid waste bin.

Return Gel Cards

b If the release drawer is open, the gel card trays are full during the card reading or if there are no empty trays, the cards will be discarded automatically. The release drawer appears in red in the GUI and the LEFT/RIGHT DRAWER DETAILS screen displays «No available card positions to empty a full centrifuge».

To set this option, the instrument must be in state **STOPPED**. The user level 3 rights are required. See chapter Instrument State on page 79.

Select the popup menu to activate, deactivate or customize the **Return Gel Cards** option:

Trash all cards	All gel cards are sent to the waste bin.
Return all cards	All gel cards will be returned to the drawer selected in **Gel cards release drawer** (see below) for second reading. Read the gel card results without any delay according to the instruction for use. See chapter Second Reading on page 147.
Configure returned cards	It is possible to define how to return the gel cards in accordance with the interpretation results for specific assay. See next page.

To configure the returned gel cards

A Select **Configure returned cards**.

From the popup menu.

B  Display the list of assays.

C Select one or more assays to customize.

*In this example, the assays **CH03**, **PR16A** and **PR70** (1) are selected.*

Only APF included in configured profiles are available. To configure a new profile, see chapter Profile Management on page 179.

D Select the reactions (2) which defines a gel card return.

*In this example, if a gel card gets a DP reaction, this one is returned to the drawer. The column **RETURN IF** describes the defined reactions.*

Otherwise the gel card is discarded.

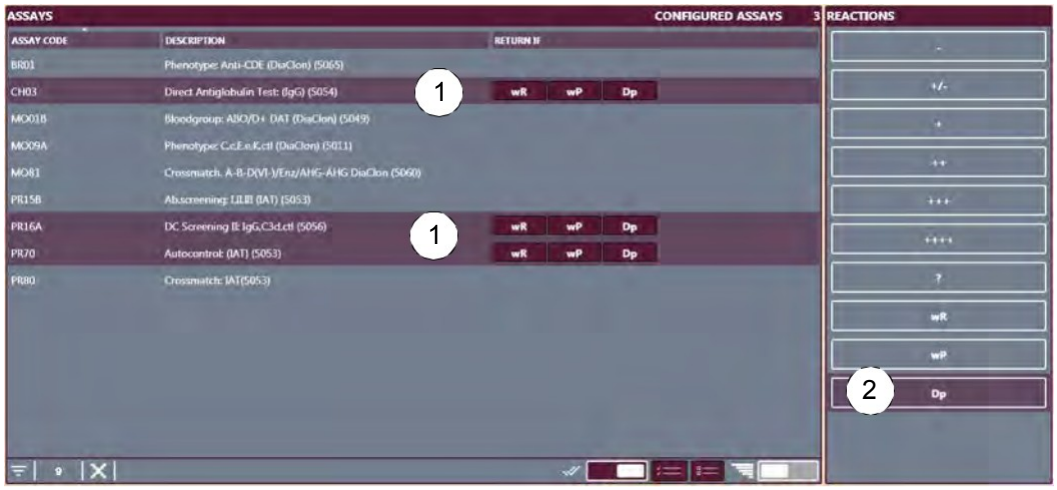


Figure 114.

Gel Cards Release Drawer

This option indicates which drawer for the option **Return Gel Cards** (Left Drawer or Right Drawer). It is also valid for the manual removal of gel cards.

To activate this option, the instrument must be in state **STOPPED**. The user level 3 rights are required.

9.1.2.2 Reagents

Do Not Trash Any Reagents

This option indicates if the expired or empty reagents are discarded in the waste bin or sent back to left drawer.

To activate this option, the instrument must be in state **STOPPED**. The user level 3 rights are required. See chapter Instrument State on page 79.

Flag	Description
ON	Expired or empty reagents sent back to the left drawer.
OFF	Expired or empty reagents discarded in the waste bin.

Barcode 2D

This option enables the reagent 2D barcode scan for identification.

OBT Activate

The OBT Management (On Board Time) is an option to manage the shelf life of the loaded resources. It defines:

how long a resource may stay in the instrument before removal;

how is a resource is removed (returned or trashed).

Resources	Shelf life
Reagent	168 hours (7 days)

When the resources are expired, the system returns or discards the loaded resources according to the resources status.

Resources status	Description
Not used	Resources returned to the drawer.
Used	Resources discarded and sent to the solid waste bin.

The OBT can be enabled only if the Barcode 2D option is active.

9.1.2.3 Diluents

OBT Activate

The OBT Management (On Board Time) is an option to manage the shelf life of the loaded resources. It defines:

how long a resource may stay in the instrument before removal;

how is a resource is removed (returned or trashed).

Resources	Shelf life
Diluent rack	720 hours (30 days)

When the resources are expired, the system returns or discards the loaded resources according to the resources status.

Resources status	Description
Not used	Resources returned to the drawer.
Used	Resources discarded and sent to the solid waste bin.

9.1.3 QC Management and Maintenance

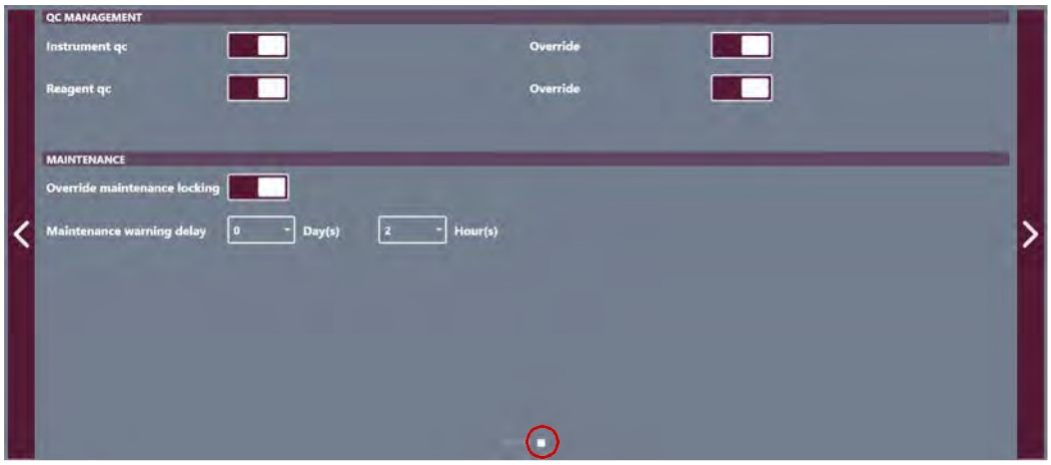


Figure 115.

9.1.3.1 QC Management

The options enable/disable the quality control for the instrument and the reagents used by the instrument. The QC control status is managed by IH-Com.

If the options are disabled, all test results are flagged.

Refer to the IH-Com Data Management Software User Manual.

Instrument qc	The instrument processes the control tests listed by IH-Com for the instrument. The **Instrument qc** is considered valid if all control tests to be processed have a valid status.
Reagent qc	The instrument checks the validity of the QC control status for each new reagent lot introduced in the instrument.

The QC can be overridden if the option **Override** is enabled (ON). All test results are tagged “Date of Quality Control expired”. The icon turns to orange.

Otherwise, it is not possible to run a test.

9.1.3.2 Maintenance

Override Maintenance Locking

The weekly maintenance must be done every 7 days.

If activated, pressing the weekly maintenance reminder overrides the weekly maintenance request and tests can be started. All tests results are tagged “**Date of Hydraulic Maintenance expired**”. The icon turns to orange. These results are flagged **as maintenance overdue** in IH-Com.

Otherwise it is not possible to run a test.

bResults generated by an instrument without valid maintenance can be false.

Bio-Rad declines any responsibility if the instrument is used out of the intended use (no valid maintenance).

To change this option, user level 3 is required. Check the box to activate the option.

Maintenance Warning Delay

This option sets a time limit of notification before a weekly maintenance request. The user can use the instrument but he is informed that the weekly maintenance is soon expired.

The time limit can be adjusted from **0 days - 0 hours** to **6 days - 23 hours** (by default, it is set to **2 hours)**.

9.1.4 APF Profiles Management

This screen manages and imports the Assay Protocol Files.

To configure the DMS communication, the instrument must be in state **STOPPED**. The user level 3 rights are required. See chapter Instrument State on page 79.

The APF designed for software v1.0 are not compatible with software v2.0.

Figure 116. APF management screen

List of APF imported in the system

2Assay code

3Assay description

4Assay version

5Version of the file containing the assay

6Option to enable/disable the second cells suspension

See chapter Enable a second Cells Suspension on page 178.

7Indicates if the assay is configured in assay oriented mode

See chapter Assay Oriented Mode on page 178.

8Logs containing events related to the assay.

This list includes the date and a description of the event.

9Command to import APF in the system

10 To delete the selected APF from the list.

9.1.4.1 Enable a second Cells Suspension

If this option is enabled, IH-500 prepares a separate cell suspension for each single ABO assay.

A	In the **SEPARATE DILUTION** column (6), tick the box of the related assay. *The **LOGS** (7) area displays the **Date** and if the second cell suspension is enabled or disabled under the **Information** column.*
< BACK	Select ***BACK*** to return to the options screen.

9.1.4.2 Assay Oriented Mode

By default, when a or more sample racks are inserted, the instrument processes all samples related to a patient. Then it continues with the next patient until all patients are processed.

If the assay is set to **Oriented Mode**, the user inserts one or more sample racks to set a batch of tests. All samples rack inserted within 50 seconds are considered in one batch. An icon indicates the order of insertion of the sample racks as shown next ( ).

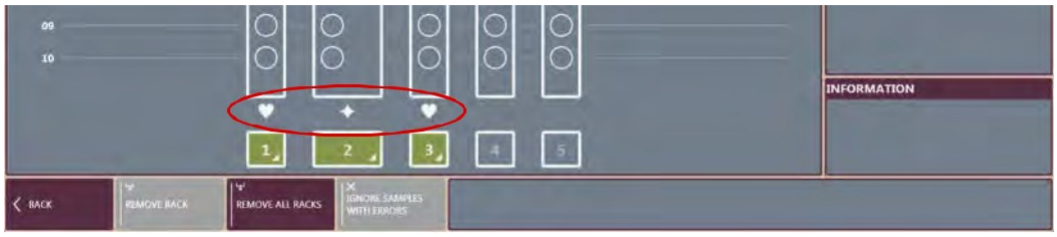


Figure 117.

Then the instrument processes all samples related to an assay present on sample racks according to the order of insertion. Then, it continues with the next assay until all assays are processed.

Once done, the instrument processes the next batch of test.

All assays can be set to **Oriented Mode**, except the ones designed for titration testing.

The **Oriented Mode** may have an impact of the performance of instrument (ex. time of tests, consumption of reagents).

9.1.5 Profile Management

This screen allows the configuration of profiles.

A profile should not contain a standard test and a crossmatch test simultaneously.

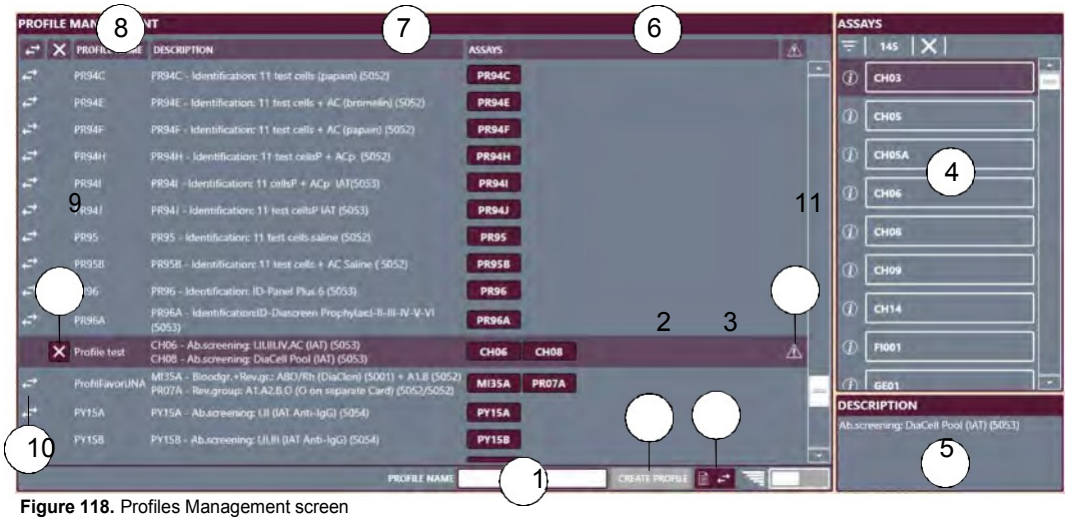


Figure 118. Profiles Management screen

New **Profile name** field

2Create Profile button

3Profile synchronization with DMS

4List of **Assays** available according to imported **APF**

5Assay **Description**

Select to display information.

6Associated Assays button (select to remove)

7Description of associated assays

8Created **Profile name**

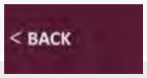
9Delete Profile button

10 Transmitted by DMS symbol

11 Indicates that one or more APF have been removed from this profile.

This profile can no longer be modified or updated. If the user wants to update it, he has to create a new one.

9.1.5.1 Create a new Profile (user-defined)

	Enter a new profile in the **Profile name** field (1).
	Select **Create profile**.
C them	Select the new profile line and select on the required assays (4) to associate with new profile. *A detailed list of assays is available in chapter List of Assays on page 251. Select an assay on the profile to delete it.*
	Select **BACK** to close screen.

k It this is recommended screen. to select the **Back** button to take into account all modifications and to exit

9.1.5.2 Modify an existing (user-defined) Profile

It is only possible to modify user-defined profiles.

	Select the existing profile line.
B (4)	Select an associated assay button to remove it or select an assay from the list to add a new one to the selected profile.

9.1.5.3 Delete an existing (user-defined) Profile

It is only possible to modify user-defined profiles.

	Select the existing profile line.
	Select the associated delete button to remove it.

9.1.6 Barcode Exceptions Configuration

bMake sure that the filtering does not remove digits used by IH-Com and/or LIS for a proper sample identification. Otherwise, IH-Com may detect a discrepancy.

When the sample tubes are identified, the digits from the barcode are removed in accordance with the settings (1).

The digits of the sample barcodes which meet the exception criteria (2) are not deleted.

For example (with the settings above):

Samples Barcode before Filtering		Samples Barcode after Filtering
P0256010		560
LAB025009		**LAB**025009 (exception, not filtered)
UP00AB10QC	→	UP00AB10**QC** (exception, not filtered)
XP0002698		XP0002698
LAB006605QC		**LAB**006605**QC** (exception, not filtered)

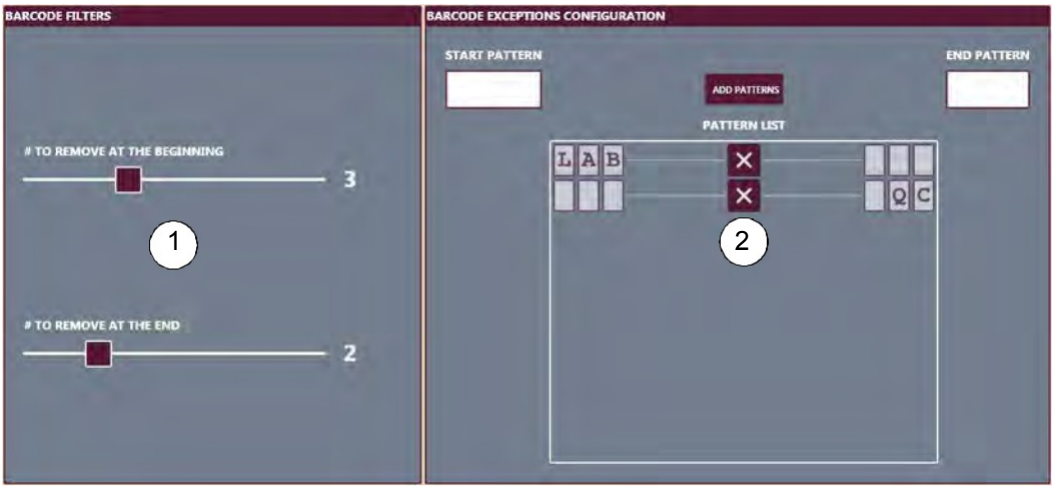


Figure 119.

9.1.7 Data Management Configuration

This area allows configure of communication with the Data Management Software (DMS).

To configure the DMS communication, the instrument must be in state **STOPPED**. The user level 3 rights are required. See chapter Instrument State on page 79.

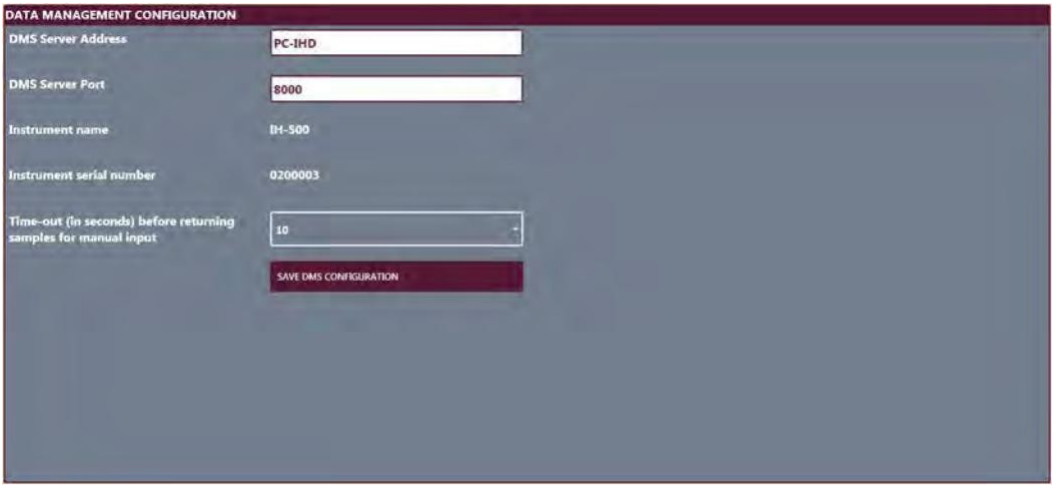


Figure 120. Data Management Configuration

Configure the following settings.

DMS Server Address	PC-IHD (default)
DMS Server Port	8000 (default)

The name and the serial number of the instrument can not be edited.

Save the **SAVE DMS CONFIGURATION** when done.

*The instrument status area of the header strip should display **DMS Connected**.*

Timeout (in seconds) before returning Samples for Manual Input

During this time lapse, the instrument waits for working order until it receives assay assignation from Data Management Software. This period begins just after a complete identification of a sample rack without error. If no work order have been received during this period, it is possible after expiration to assign manually a profile for each sample.

By default, the timeout is set to 70 seconds.

It is possible to set the timeout between 5 seconds to 100 minutes.

To change this option, user level 3 is required. Select the drop down list and select the **Timeout (in seconds) before returning samples for Manual input**.

9.2 GUI Customization

The Graphical User Interface is user-specific configurable.

Each user can define for the interface:

the colors;

the layout;

the theme;

the shortcut to include in the menu;

the sound volume.

A		Expand the shortcut menu. *If necessary.*
		Display the GUI customization screen.
C		Define the interface.

The GUI customization screen can be fixed or modal by clicking on the pin.

	The screen is fixed and can not be moved.
	The screen is modal and can be moved along the screen.

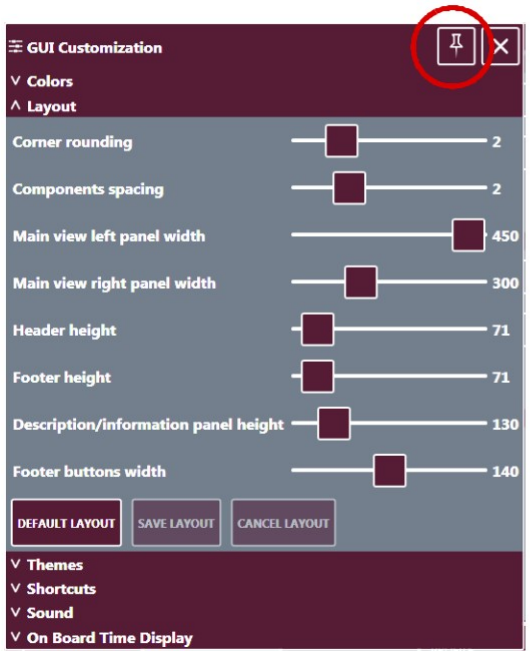
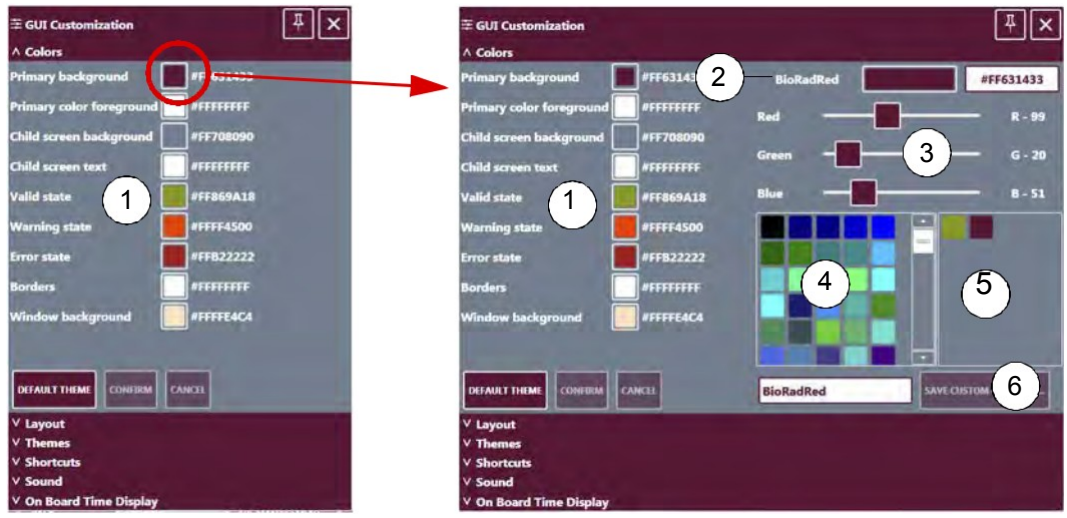


Figure 121. Modal screen

9.2.1 Colors

This screen allows to define the colors of the Graphic User Interface. It displays the color setting (screen expanded) when an item is selected.

All screens described in this manual use the default theme colors.



Retracted Expanded

Figure 122. Color selection screen (retracted and expanded)

List of item to customized

Selecting an item expands/retracts the screen

Name and hexadecimal value of the selected item

*In this example, the **Primary Background** is selected and the color is set to **BioRadRed**.*

Sliders to adjust the RGB component of the selected color in (2). The

interface is automatically updated.

Pre-defined color picker

5User-defined color picker

See chapter How to create a Customized Color on page 185.

6Entry field for a name when creating a custom color

9.2.1.1 How to configure the Interface Colors

A Select an item in the list (1).

*In this example, the item **Primary Background** is selected.*

The screen is expanded and displays the color definition.

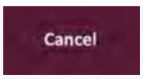
B Set or adjust the color:

- with the sliders (3);
- by selecting a color in the pre-defined (4) or user-defined (5) color picker;
- by entering the hexadecimal value of the color in the field (2).

The interface is automatically updated.

Repeat these steps for all items to be updated.

Confirm to save the new interface color definition.

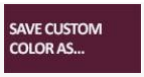


Cancel to discard the color changes.

9.2.1.2 How to create a Customized Color

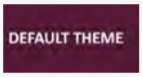
Select an item in the list (1).

Set or adjust the color (See above).



Save the newly created color in the user-defined color picker.

9.2.1.3 How to restore the Default Color

A 

Select to restore the default configuration.

All colors of the Graphical User Interface switch back to defaults.

9.2.2 Layout

The layout screen allows to reshape the interface. All dimensions are given in pixels.

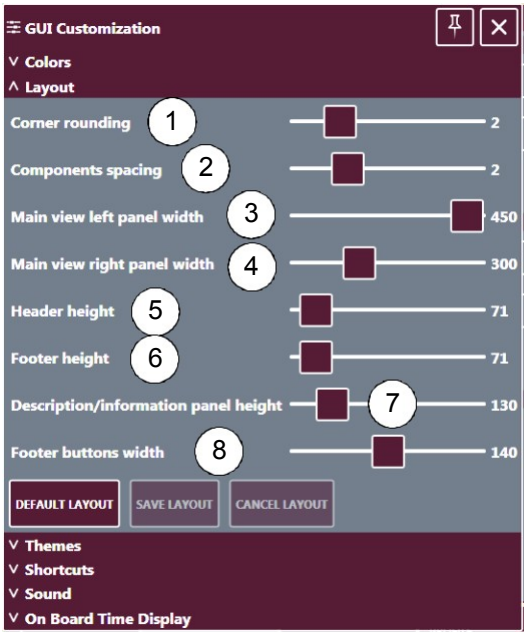


Figure 123.

To set the radius of the corner

To set the space between the items

3To set the left panel width

The central pane is automatically adapted.

4To set the right panel width

The central pane is automatically adapted.

5To set the header strip height

6To set the footer strip height

7To set the description pane height *The information pane is adapted.*

8To set the function buttons width on the footer strip

9.2.2.1 How to configure the Layout

A Use the sliders to adjust the shape, the dimensions or the spacing of the items on the interface.
See figures below.

B Save the layout.

SAVE LAYOUT

CANCEL LAYOUT Discard the changes.

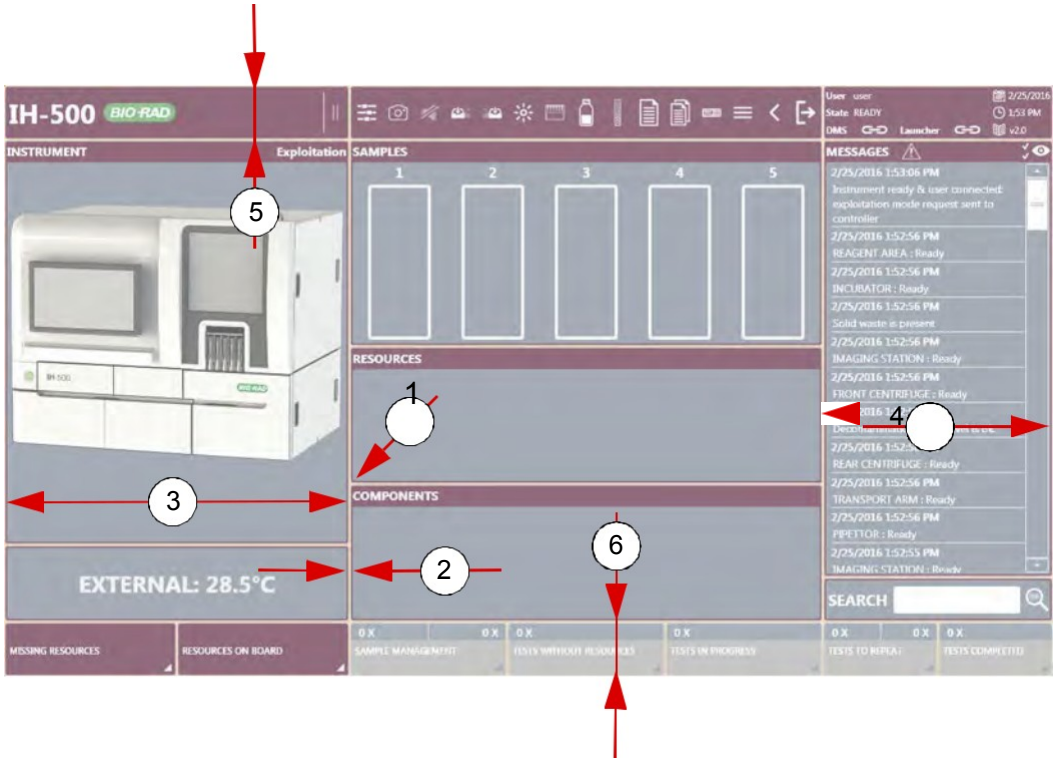


Figure 124. Reshaping the interface

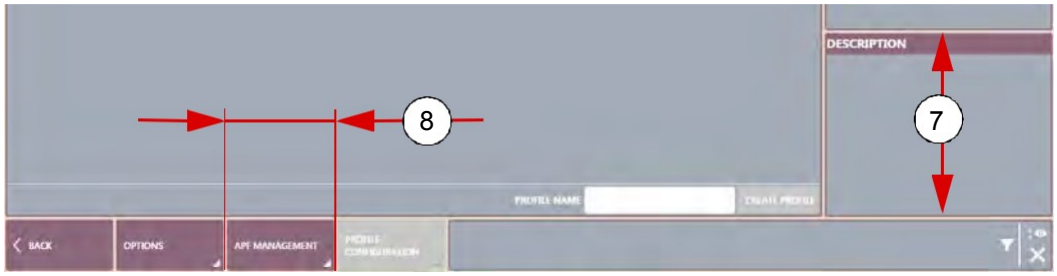


Figure 125.

9.2.2.2 How to restore the Layout

A DEFAULT LAYOUT Select to restore the default layout.

9.2.3 Theme

This screen manages the theme used by the instrument.

A theme is a collection of color and layout settings defined by a user. A theme created by a user does not apply to a other user.

The instrument applies the theme assigned to the user which is logged.

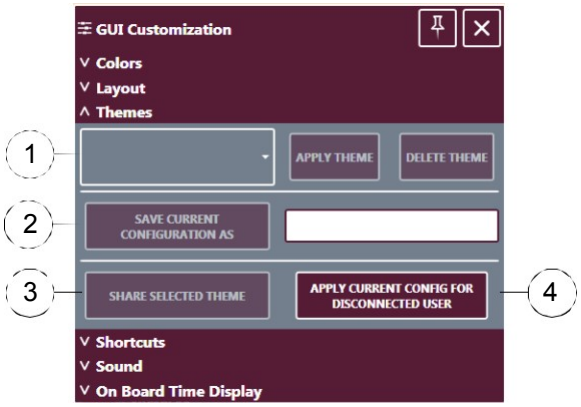


Figure 126.

List of registered themes for one user

Function to save the current configuration (color and layout) as new theme

Command to share the theme selected in the list (1) to other users registered in the instrument

4Command to apply the current configuration when no user is logged on the system.

9.2.3.1 How to create a Theme

A	Configure the layout and the colors of the interface. *Refer to Colors on page 184 and Layout on page 186.*
	Enter a name for the theme in the field (2).
SAVE CURRENT CONFIGURATION AS	Save the current configuration as a theme.

9.2.3.2 How to apply a Theme

	Select the theme from the popup menu (1).
APPLY THEME	Apply the theme.

9.2.3.3 How to delete a Theme

		Select the theme from the popup menu (1).
B	DELETE THEME	Delete the theme. *It is removed from the popup menu (1).*

9.2.3.4 How to share/un-share a Theme

Select the theme from the popup menu (1).

B SHARE SELECTED THEME Share the theme.

This theme is now available for all users registered in the instrument.

9.2.4 Shortcut Menu and Icons Test

This screen allows to:

define which shortcut to include in the shortcut menu;

configure the behavior of the shortcut menu;

show/hide the icon tests in the footer strip.

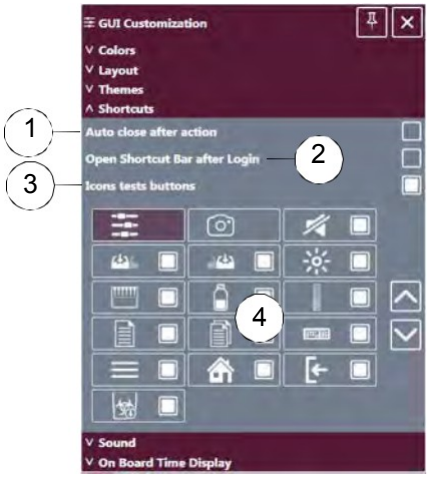


Figure 127. Shortcut configuration

Auto Close After Action

Option to hide automatically the shortcut menu when an user selected a shortcut.

Open Shortcut Bar After Login

Option to show automatically the shortcut menu when an user is logged in. **ON**: enabled

OFF: disabled

Icons Test Buttons

Option to change the appearance (text or pictogram) of the footer strip buttons. Refer to Footer Strip on page 70 for more details.

List of buttons which can be displayed and reordered in the shortcut menu. **ON**: button enabled

OFF: button hidden

9.2.4.1 How to reorder the Buttons in the Shortcut Menu

A		Select the action button. *The selected button is highlighted.*
B		Move the selected action button to the desired position. *The shortcut menu is automatically updated.*

9.2.5 Sound

This screen defines the sound volume for a user.

Move the slider to adjust the volume.

When no user is connected, the sound volume is decreased by 50% compared to the sound volume of the last connected user.

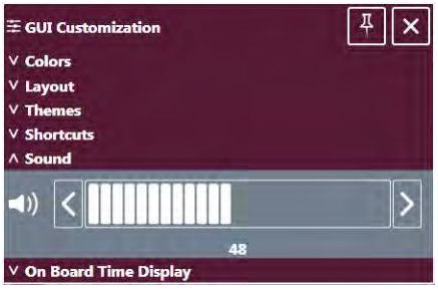


Figure 128.

9.2.6 Miscellaneous

This screen defines how to display the OBT Management.

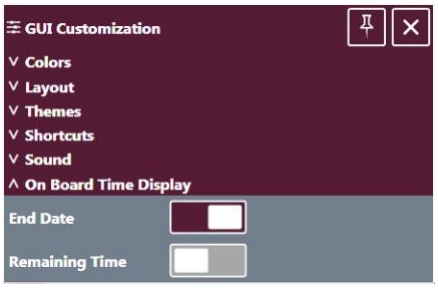


Figure 129.

State	Function
End Date	When active, the expiry date and hour of the resources is displayed.
Remaining Time	When active, the remaining time of the resources is displayed (countdown).

10 Maintenance

This chapter explains in detail the periodic maintenance of the IH-500, how to replace or clean the pipette needle, and how to decontaminate and store the instrument.

10.1 Maintenance Operations

Log all maintenance operations in the maintenance record.

See chapter Maintenance Record on page 250.

If any variation of performance of the instrument is observed or suspected even after maintenance operations, contact your service engineer.

10.2 QC Check

bA Quality Control check (QC) must be performed after any maintenance operation.

Refer to the Data Management software on running QC.

10.3 Decontamination

b Before a Field Service Engineering (FSE) intervention, decontaminate the instrument in accordance with Good Laboratory Practices.

In the case of spillage and contamination in or around the pipetting area or internal storage.

A	Remove all contaminated resources and samples and dispose of them in accordance with internal rules.
B	Empty the solid waste bin. *See chapter Emptying the Solid Waste Bin on page 130.*
C	Shutdown the instrument. *See chapter Shutdown on page 160.* ➔ *Call a service engineer and stop using the instrument.*
D	Clean the doors, covers, racks and trays with a lint-free cloth soaked in 70% ethanol.
E	Fill in the official decontamination certificate (an example is available in chapter Decontamination Certificate on page 248).

Suitable Decontamination Solution

Use the following disinfection solution or a suitable disinfectant with a lint-free cloth to perform the decontamination of parts:

70% ethanol.

Never use acetone as it will damage the instrument.

10.4 Periodic Maintenance

10.4.1 As Required Cleaning

Clean:

the outer surfaces of the instrument, the hand-held barcode scanner, and the touch-screen with a lint-free cloth soaked in 70% ethanol;

the pipette needle reference position with a lint-free cloth soaked in 70% ethanol. See chapter Pipette Needle Reference Position on page 196.

10.4.2 Visual Check

Visually check that the drawer lockers are not broken or unsticked. If it is the case, call a qualified Bio-Rad service engineer for the damaged lockers replacement.

10.4.3 Weekly Maintenance

When the weekly maintenance alarm appears on the main screen, launch the maintenance procedure as soon as possible as it may lead to false results.

See chapter Weekly Maintenance Procedure on page 197.

If the option **Override Maintenance Locking** is activated, pressing the weekly maintenance reminder overrides the weekly maintenance request and tests can be started. All tests results are tagged “**Date of Hydraulic Maintenance expired**”.

Otherwise it is not possible to run a test.

Refer to Override Maintenance Locking on page 175.

This alarm appears when the weekly maintenance is soon expired.

10.4.4 6 Monthly Maintenance

The 6 monthly maintenance has to be performed by a qualified Bio-Rad service engineer.

10.5 Refilling a Cleaning Liquid Container

If the tubing (4) appears dirty (visually), replace the container.

Open the solid waste area door (1).

Remove the cleaning liquid container from its storage area (2).

Unscrew the cap and remove the black cap assembly (3).

D Empty any remaining solution present following local waste procedures. Rinse container.

See chapter Rinsing a Container on page 195.

E Fill the container with cleaning liquid solution. This solution must contain 8 ml of Microcide SQ™ and 2 liters of deionized water. This solution is stable for 7 days.

Tighten the cap on the container.

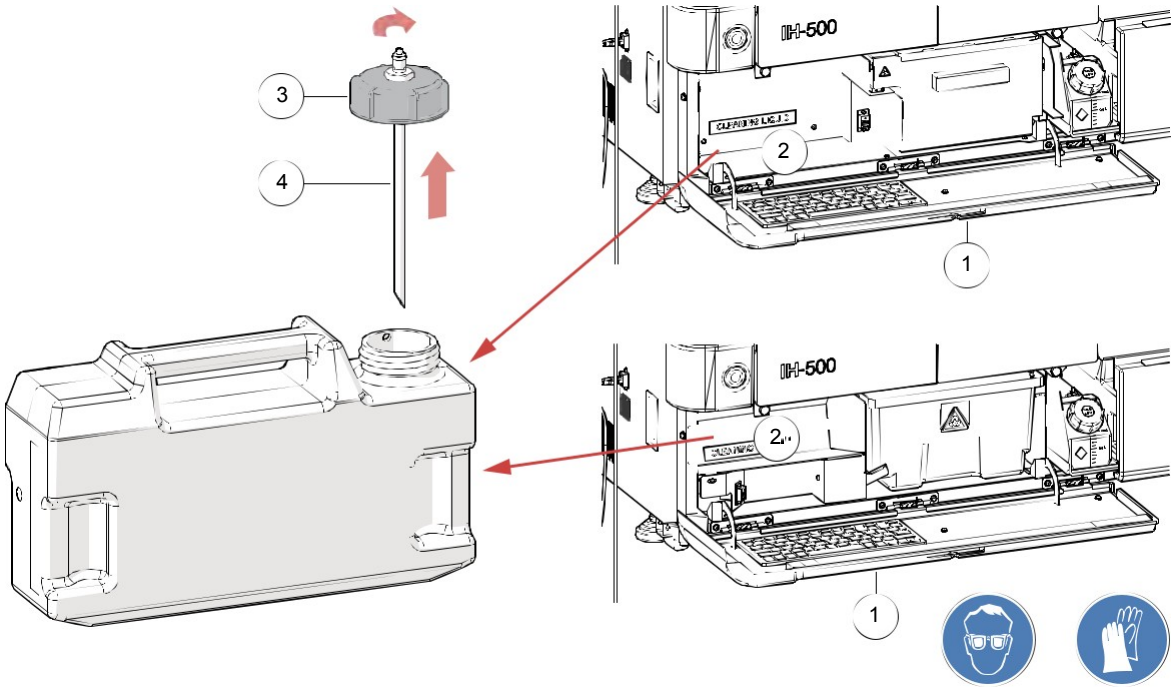


Figure 130.

10.6 Rinsing a Container

The following procedure explains how to rinse a container.

It is to rinse a container during the weekly maintenance, during the refilling process or when a container has not been used for a prolonged period (e.g. after storage).

Disconnect the container and remove it.

Unscrew the cap.

Empty the container and dispose of the liquid in accordance with internal rules

Fill the container with about 1 liter of cleaning liquid and tighten the cap.

Whirl the cleaning liquid to clean the container.

Remove the cap and empty the container in accordance with internal rules.

Rinse the container with demineralized water.

Wipe the cap and aspiration hose with 70% ethanol.

I Refill the container. For further instructions refer to the following chapters:

Refilling a System Liquid Container on page 125;

Refilling a Cleaning Liquid Container on page 194;

Refilling a Decontamination Liquid Container (NaOH 0.5 M) on page 129.

Tighten the cap and connect the container to IH-500.

10.7 Cleaning

10.7.1 Pipette Needle Reference Position

The needle reference position needs to be cleaned every 6-months or during the **CHANGE PIPETTE NEEDLE** command.

e **HOT SPOT**
Be careful when accessing the pipetting area, with particular attention to the pipette needle, sample racks and heat of incubator.

d **INFECTION**
There is a risk of infection from skin contact with blood. Always wear protective gloves when working, in accordance with laboratory safety regulations.

Do not move, load, unload or mix any resources, samples or elements in the instrument (except to following).

A Select **OPEN PIPETTING AREA**.

*From the **COMPONENTS** screen*

B OPEN PIPETTING AREA Completely open the pipetting area door.

Be careful that the sample racks are not to far out.

C Clean the needle reference position (1) with a lint-free cloth soaked in 70% ethanol.
Then dry the needle reference position.

Close the pipetting area door.

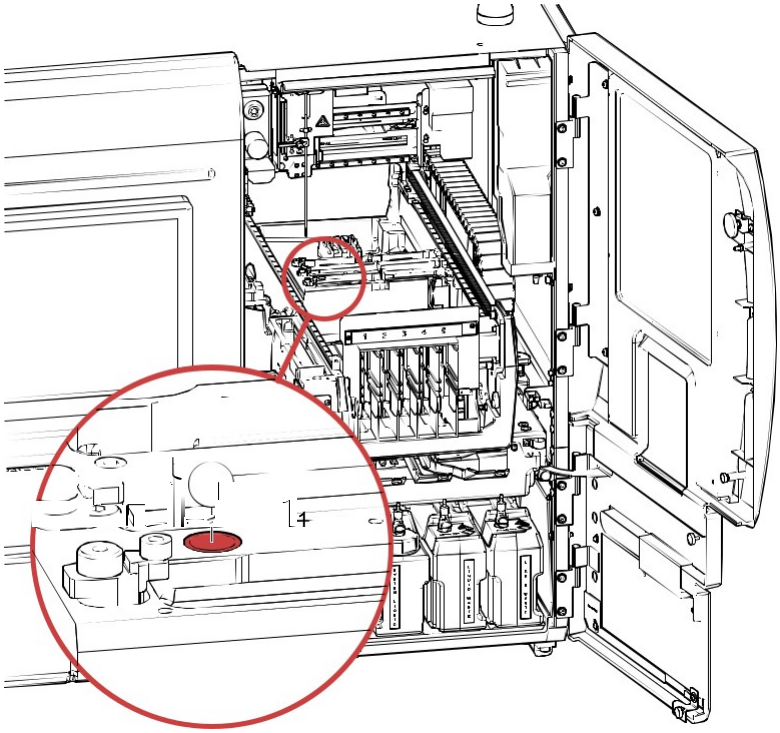


Figure 131.

10.8 Weekly Maintenance Procedure

The automated hydraulic weekly maintenance procedure allows to prime the hydraulics with cleaning liquid.

A weekly maintenance report is automatically generated on a USB memory key connected to the instrument. If no memory key is present, the report is saved in the folder C:/User/Public/IH-500/ MaintenanceReports.

Refer to Weekly Maintenance Report on page 164 to manually create a weekly maintenance report.

10.8.1 Total estimated Times and Liquid Volumes for Weekly Maintenance

Estimated time IH-500 system	20 minutes
Estimated liquid waste volume	0.9 l
Estimated cleaning liquid volume	0.9 l
Estimated decontamination liquid volume	0.9 l

10.8.2 Perform before Weekly Maintenance

Verify the expiry date of the cleaning liquid (the solution is stable for 1 week). If necessary fill the container with cleaning liquid, see chapter Refilling a Cleaning Liquid Container on page 194.

Verify that there is no leakage around liquid containers.

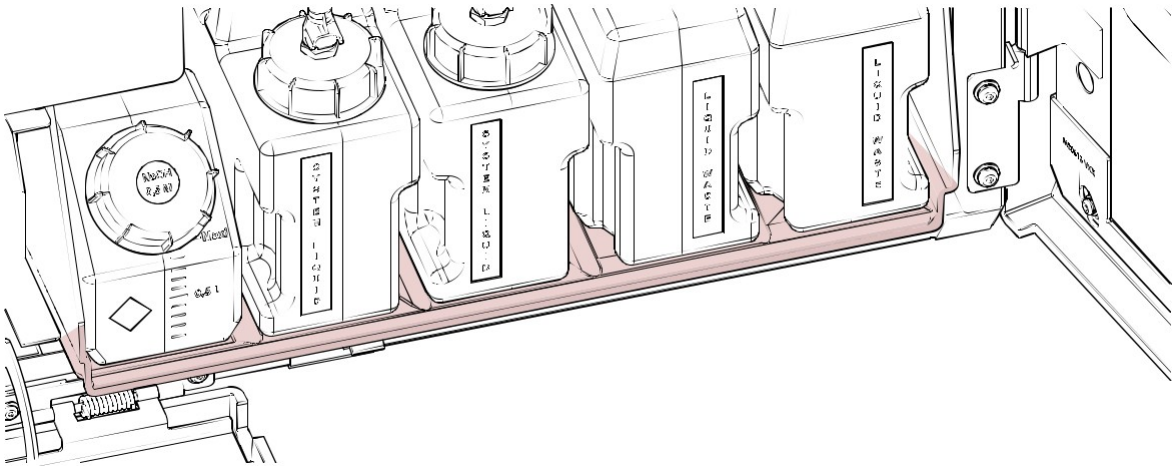


Figure 132.

10.8.3 Procedure

A Connect a USB memory key (optional).

To save the weekly maintenance report, if required.

B Login with the required user rights.

User level > 1.

C Select **MENU** (header strip).

MENU

➔ *The menu screen is displayed.*

D Stop all processes running in the instrument.

STOP ALL

➔ *All tests in progress are cancelled.*

E Select **MAINTENANCE**.

MAINTENANCE

➔ *The following screen is displayed. The left pane displays the estimated time to finish the weekly maintenance procedure.*

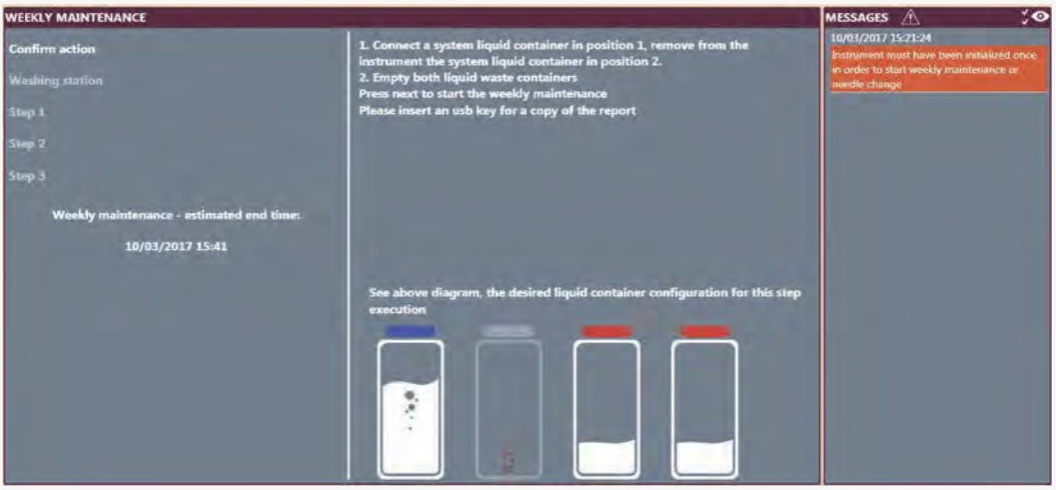


Figure 133.

F Follow on screen instructions:

connect a system liquid container in position 1;

disconnect the system liquid container in position 2;

empty both liquid waste containers.

G Next

Select **Next** to start weekly maintenance.

H Follow on screen instructions:

open the solid waste area door (5) and containers door (1);

disconnect and remove both **SYSTEM LIQUID** containers (4) (blue caps);

empty both **LIQUID WASTE** containers (2) (red caps), rinse them with cleaning liquid and reconnect them;

For further instructions refer to chapter Emptying a Liquid Waste Container on page 127.

remove the **CLEANING LIQUID** container (black cap) from its storage area (3) and fill it with cleaning liquid;

For further instructions refer to Refilling a Cleaning Liquid Container on page 194.

connect the **CLEANING LIQUID** container (3) in position #1 of the system liquid container (see schematics on the door (1)).

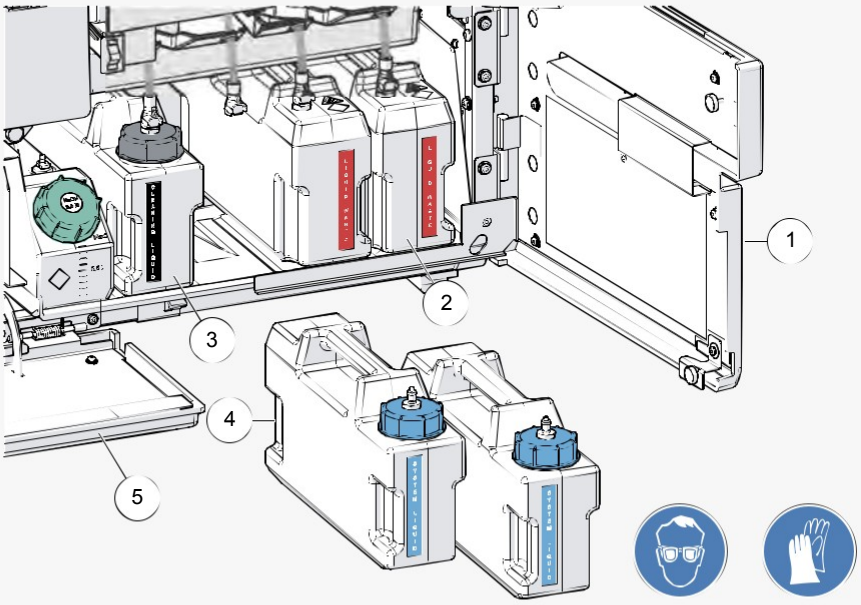


Figure 134. Connect cleaning liquid container #1

I Next Select **Next** when done.

➔ *The screen indicates that the **Step 1** is completed.*

J Follow on screen instructions:

disconnect the cleaning liquid container and connect it in position #2 of the system liquid container (see schematics on the door (1)).

K Next Select **Next** when done.

*The screen indicates that the **Step 2** is completed.*

L		Follow on screen instructions: disconnect the **CLEANING LIQUID** container and move to the storing area (5). ensure both **SYSTEM LIQUID** containers (4) are full. *If necessary see chapter Refilling a System Liquid Container on page 125.* connect both **SYSTEM LIQUID** containers.
M		Select **NEXT** when done. *The screen indicates that the **Step 3** is completed.*
		Select **Finish** to close the screen.
		Select **MENU**.
P		Select **INITIALIZE INTRUMENT**. *IH-500 unloads all reagent vials and sample racks.*
Q		Shut down the instrument. *See chapter Shutdown on page 160.*
R		Restart the instrument. *See chapter Startup Procedure on page 133.* If reagent vials are reloaded, check their integrity before to reuse them.
S		Perform a Quality Control run (QC). *Refer to the Data Management software for detailed information on running QC.*

10.9 Pipette Needle Replacement / Cleaning

Required Material

Dry sampling needle (REF 0595004) provided with a cork;

Non-woven wipes or a lint-free cloth soaked in 70% ethanol.

Procedure

e **HOT SPOT**
Be careful when accessing the pipetting area, with particular attention to the pipette needle, sample racks and heat of incubator.

d **INFECTION**
There is a risk of infection from skin contact with blood. Always wear protective gloves when working, in accordance with laboratory safety regulations.

b Do not move, load, unload or mix any resources or samples in the instrument.

Ensure the pipette needle is correctly positioned to avoid instrument damage. The ring must fully inserted in the guide (Figure 139 - 5) of the pipettor Z-axis support.
If reagent vials are reloaded, check their integrity before use.

If the needle replacement was interrupted by a forced shut down, on the next start-up of the system, perform the **CHANGE PIPETTE NEEDLE** procedure again (without changing the needle).
This is to make sure that the needle is correctly localized.

Login with User level > 1.

B Select **MENU** (header strip).

The Menu Screen is displayed.

MENU

C Select **STOP ALL**, then **YES** to confirm.

STOP ALL

All tests in progress are canceled.

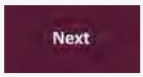
Refer to chapter Stop All on page 160 for details.

D Select **CHANGE PIPETTE NEEDLE**.

CHANGE PIPETTE NEEDLE

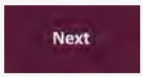
The screen below is displayed.

Figure 135.

E 

Select **Next** to confirm change of the needle.

The following screen warns the user to wear gloves.

F 

Select **Next**.

The pipetting area door unlocks.

Check sample racks are removed or in the locked position prior to opening.

H Open the pipetting area door.

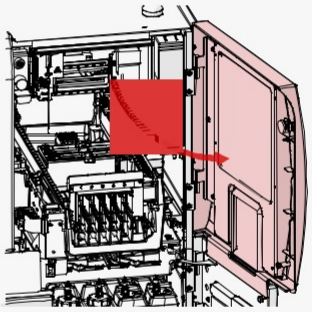


Figure 136.

I Place a tissue under the pipette needle tip before disconnecting the tubing as it drips.

J Disconnect the pipette needle (1) from the tubing by unscrewing the red connector (2).

Open both locks (3) by turning counter clockwise (90°).

Remove the pipette needle from the housing.

M Perform an internal rinse of the needle using a deionized water wash bottle to detect if the needle is clogged. If it is the case, replace the needle.

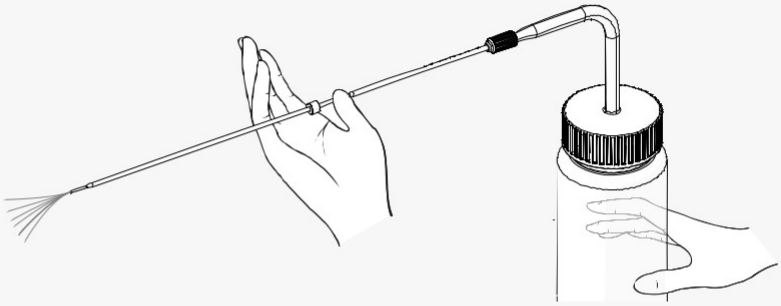


Figure 137.

N Clean the external part of the needle with a non-woven wipe or a lint-free cloth soaked in 70% ethanol.

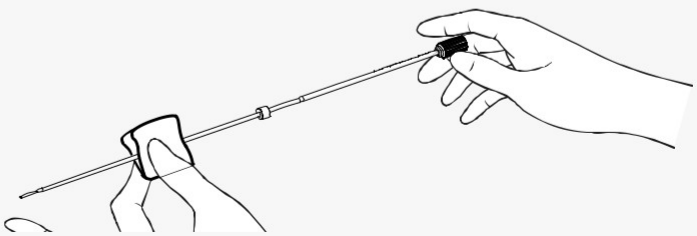


Figure 138.

O	Dry the external part of the needle with a clean dry non-woven wipe or a lint-free cloth.
P	Position the new or cleaned pipette needle (1) in its housing. *The collar on the needle (4), when properly inserted, prevents the needle from moving independent of the mechanism.*
Q	Lock the needle by turning the two locks clockwise (3). *With the locks closed, the pipette needle is locked on the pipettor Z-axis support.*
R	Tighten the tubing connector (red) (2) on the pipette needle (1). Turn it gently clockwise till you hear a click.
S	Clean the pipette needle reference position with non-woven wipes or a lint-free cloth soaked in 70% ethanol. Then dry the pipette needle reference position. *For further instructions see chapter Pipette Needle Reference Position on page 196.*

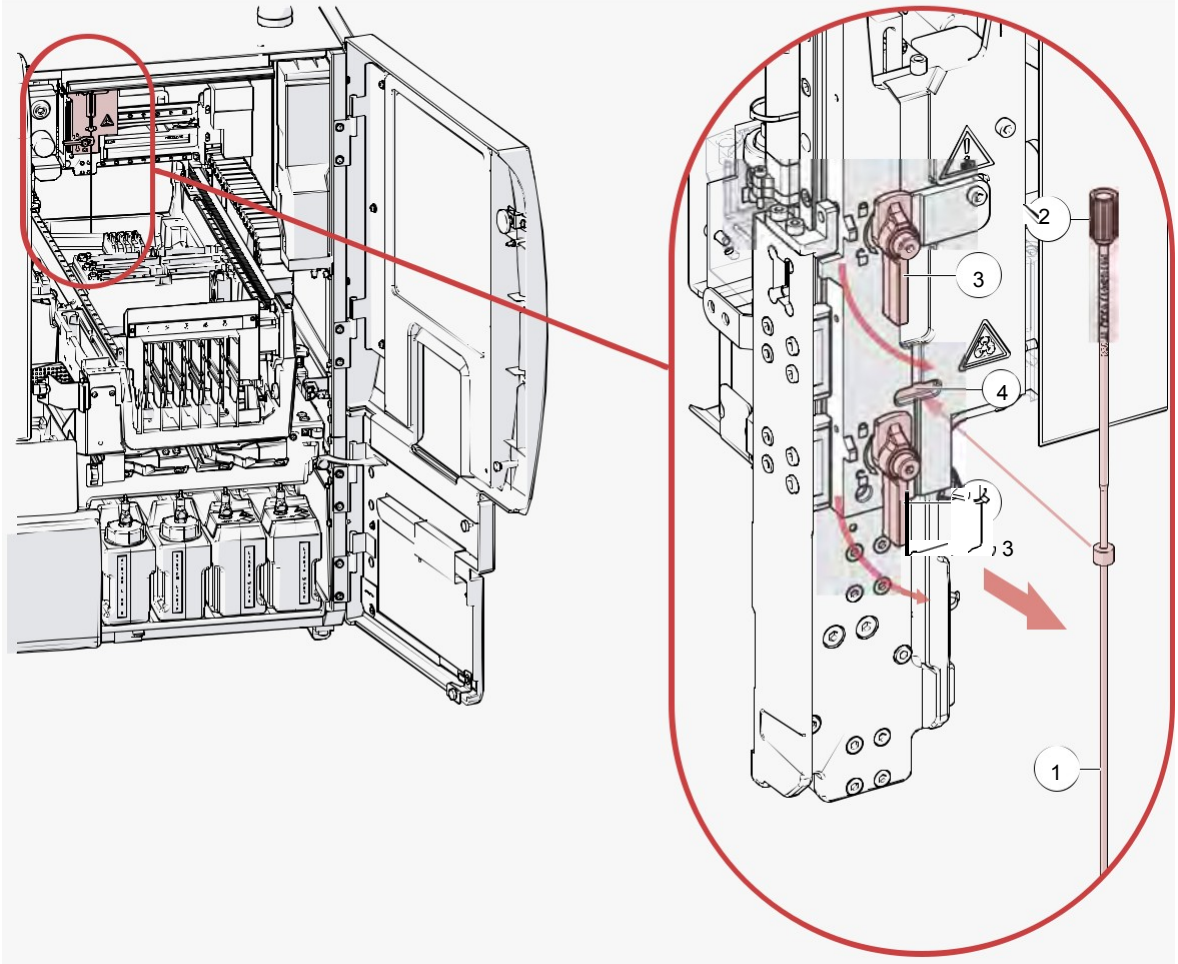


Figure 139.

T Close the pipetting area door. The **Next** button is enabled.

Push on the top left of the door to make sure that the pipetting door is properly closed (area marked with red circle).

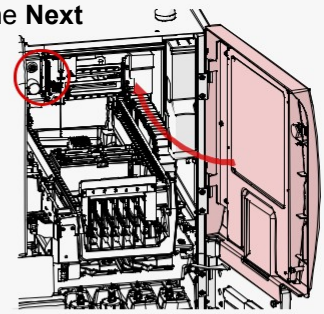


Figure 140.

U Next — Select **Next**.

The following screen prompts to validate the replacement.

Next — Select **Next** to validate the needle replacement.

Finish — Select **Finish** to close the screen.

MENU — Select **MENU**.

Y INITIALIZE INSTRUMENT — Select **INITIALIZE INSTRUMENT**.

IH-500 unloads all reagent vials and sample racks and the system initializes.

Z Repeat the procedure to improve the accuracy of the needle localization. Do not disconnect the needle (Skip steps I to R).

When the needle is installed and initialized, it is filled with system liquid. This improves the needle localization.

AA Perform a QC run after a change pipette needle.

Refer to the Data Management software for detailed information on running QC.

10.10 Storage

When it is planned not to use the instrument for a prolonged period (over several days), specific operations must be considered.

10.10.1 Short Term Storage in Laboratory Conditions

If the instrument is not to be used for several weeks but will remain in a laboratory environment, no wrapping or packing is required.

Weekly maintenance operations must be performed every week even if the instrument is not used.

10.10.2 Other Storage Conditions

When the instrument is stored outside laboratory conditions or if it is stored for a long term storage, special procedures must be performed by a service engineer.

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11 Troubleshooting

It is imperative to read and understand this user manual before carrying out any troubleshooting on the IH-500. In case of unclear information, contact the Bio-Rad Technical Support.

11.1 Alarms and Error Management

When an error message appears on the screen, read it and check whether an explanation is given in the following list. Then select the **OK** button and execute the required procedure to solve the problem.

11.2 Software Error Messages

For any error messages not listed in the following tables (mainly module and software errors), contact a Bio-Rad service engineer.

11.2.1 All Modules

ALL MODULES

Error code	Error description	Possible cause	Corrective actions
0x018B2F	Access door open during initialization.	1. Front door open. 2. Sensor malfunction.	Check to make sure that the front door is correctly closed In case of sensor malfunction, see error 0x018B43 on page 221.
0x018B38	Presence of a canister of solution for maintenance and/or status of the fluidic circuit.	Interruption of weekly maintenance followed by power switch-off.	After correcting the fault, repeat the weekly maintenance with the IHM or the service software
0x018B3C	Change of needle is in progress during initialization of the instrument.	Interruption of the needle changing procedure followed by power switch-off.	After correcting the fault, repeat the needle change with the IHM or the service software
0x018B3F	Failure of presence detection auto-test during initialization of the instrument.	Sensor defect, maladjustment.	1. Check function of sensor (LED at the level of the sensor). 2. Contact your Bio-Rad technical representative.
0x018E2A	At initialization of the instrument: a fault due to an embedded clot is present.	Power switched off during a clot procedure.	1. Check to make sure that there is no clot on the needle. 2. Clear fault and perform fluidic priming. 3. If the needle is clogged, change it.
0x019003	The internal ambient temperature has reached the pre-warning threshold (30°C).	1. High external temperature. 2. Malfunction of the temperature sensor.	1. Internal temperature above 30°C. 2. Contact your Bio-Rad technical representative.
0x019004	The internal ambient temperature has reached the warning threshold (31°C).	1. High external temperature. 2. Malfunction of the temperature sensor.	1. Internal temperature above 31°C. 2. Contact your Bio-Rad technical representative.

ALL MODULES Error code	Error description	Possible cause	Corrective actions
0x019005	The external ambient temperature has reached the warning threshold (28°C).	1. High external temperature. 2. Malfunction of the temperature sensor.	1. External temperature above 28°C, or check to make sure that there is no heat source near the temperature sensor. 2. Contact your Bio-Rad technical representative.
0x019006	Discrepancy between the sensor for internal temperature and the sensor for external temperature (difference greater than 10°C).	Malfunction of a temperature sensor.	1. Check external temperature and environmental conditions of the device (open window, heating, air current, etc...). 2. Contact your Bio-Rad technical representative.
0x019007	Internal ambient temperature too low (18°C).	1. External temperature too low. 2. Malfunction of a temperature sensor.	1. Check external temperature and environmental conditions of the device (open window, heating, air current, etc...). 2. Contact your Bio-Rad technical representative.
0x104B03	Card block detected as missing during the instrument initialization.	1. Card block missing. 2. Mapping sensor failure.	1. Check that all card blocks are correctly installed. 2. Contact your Bio-Rad technical representative.
0x104C01	APF Checker failure. Error during the check between the APF and the dispense set used.	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x104D06	Expiry date of the reagent reached.	Reagent vial expired.	1. Check the expiry date of the product. 2. Check the date of the computer.
0x104D07	Expiry date of the diluent reached.	Diluent rack expired.	1. Check the expiry date of the product. 2. Check the date of the computer.
0x104D08	Expiry date of the gel card reached.	Gel card expired.	1. Check the expiry date of the product. 2. Check the date of the computer.

ALL MODULES Error code	Error description	Possible cause	Corrective actions
0x104D09	On board time of the reagent reached.	OBT of the reagent vial expired.	Remove the product.
0x104D10	On board time of the gel card reached.	OBT of the gel card expired.	Remove the product.
0x104D11	On board time of the diluent rack reached.	OBT of the diluent rack expired.	Remove the product.
0x104D22	Test performed when the instrument is not in exploitation mode.	Test performed in service mode.	Switch to exploitation mode.
0x104F02	The maximum duration (10min) between the pipetting and the incubation is reached.	The card did not go to the incubator (following an other error).	Check for failure on transport arm, pipettor and incubator. Contact your Bio-Rad technical representative.
0x104F05	The maximum duration between 2 dispenses is reached.	Pipetting issue.	Check for failure on pipettor. Contact your Bio-Rad technical representative.
0x104F06	The maximum duration (60min) between the end of the centrifugation and the reading is reached.	Instrument issue.	Check for failure on the system. Contact your Bio-Rad technical representative.
0x108B16	Diluent piercing pin found missing during the instrument initialization.	Piercing pin removed by the user. Gripper failure.	Check the presence of the piercing pin. Contact your Bio-Rad technical representative.

ALL MODULES

Error code	Error description	Possible cause	Corrective actions
0x108B41	Software version are not correct after a check during the instrument initialization.	Server, application or files not compliant with the current software version.	1. Check the version on the service software. 2. Check the firmware and all applications. 3. Contact your Bio-Rad technical representative.
0x108C07	Adjustment status found missing after a check during the instrument initialization.	Adjustment status not present.	Contact your Bio-Rad technical representative.
0xmm0101	Error on electronic boards.	Electronic boards failure.	"**mm**" linked to the module:
0xmm0102			• **02**: X pipettor axis;
0xmm0103			• **03**: Y pipettor axis;
0xmm0104			• **04**: Z pipettor axis;
0xmm0105			• **05**: Front centrifuge;
0xmm0106			• **06**: Rear centrifuge;
0xmm0107			• **07**: I/O fluidic board;
0xmm0108			
0xmm0109			Contact your Bio-Rad technical representative.
0xmm010A			
0xmm010B			
0xmm010C			
0xmm010D			
0xmm010E			
0xmm010F			
0xmm0110			
0xmm0111			
0xmm0112			
0xmm0113			
0xmm0114			
0xmm0115			
0xmm0309			
0xmm030D			
0xmm030F			
0x0B8904			

11.2.2 Transport Arm

TRANSPORT ARM

Error code	Error description	Possible cause	Corrective actions
0x018010 0x018011	Failure of communication with the transport arm controller.	Connection malfunction (TCP/IP).	1. Start again the instrument. 2. If the problem persists, contact a service engineer.
0x018106	The transport arm does not position itself correctly during its empty movements.	1. Hardware failure. 2. Clash with a resource. 3. Clash with the pipettor.	1. Check there is no contact with an object which could block moves. 2. Contact your Bio-Rad technical representative.
0x018110 0x018B1A			
0x018106	The transport arm does not position itself correctly while being initialized.	1. Hardware failure. 2. Clash with a resource. 3. Clash with the pipettor.	1. Check there is no contact with an object which could block moves. 2. Contact your Bio-Rad technical representative.
0x018110 0x018B1B			
0x018106	The transport arm does not position itself correctly during detection of the resources.	1. Hardware failure. 2. Clash with a resource. 3. Clash with the pipettor.	1. Check to make sure that there is no contact with an object which could block moves. 2. Contact your Bio-Rad technical representative.
0x018110 0x018B1F			
0x018116	Transport arm power failure.	1. Emergency stop. 2. Safety chain: transport arm cannot be powered.	1. Check that instrument access are correctly closed (electromagnetic latch and security sensor of the left door and LED board connector). 2. Contact your Bio-Rad technical representative.
0x018119	The transport arm does not position itself correctly during its movements with an element.	1. Hardware failure. 2. Clash with a resource. 3. Clash with the pipettor.	1. Check there is no contact with an object which could block moves. 2. Contact your Bio-Rad technical representative.
0x01811A 0x018B19			
0x01811B	Error during the positioning of the diluent lock.	1. Contact with an object. 2. Positioning fault of the diluent rack. 3. Drag overshoot of transport arm.	1. Check that there is no contact with an object which could block moves. 2. Contact your Bio-Rad technical representative.
0x01811D	Position error of the transport arm while moving a resource.	1. Contact with an object. 2. Drag overshoot of transport arm.	1. Check that there is no contact with an object which could block moves. 2. Contact your Bio-Rad technical representative.

TRANSPORT ARM Error code	Error description	Possible cause	Corrective actions
0x01811D	Position error of the transport arm while piercing a diluent rack.	Contact with an object. Drag overshoot of transport arm.	Check that there is no contact with an object which could block moves. Contact your Bio-Rad technical representative.
0x01811F	Position error of the transport arm when unloading the sample rack.	Contact with an object. Drag overshoot of transport arm.	Check that there is no contact with an object which could block moves. Contact your Bio-Rad technical representative.
0x018120	Position error of the transfer robot when performing a centrifuge to trap operation.	Contact with an object. Position error of the centrifuge trap. Drag overshoot of transport arm.	Check that there is no contact with an object which could block moves. Check the position of the centrifuge trap. Contact your Bio-Rad technical representative.
0x018121	Unable to open the gripper after a gripper control position/torque check failure.	Hardware failure.	Contact your Bio-Rad technical representative.
0x018417 0x018B34			
0x018130	Position error of the transport arm while piercing a gel card.	Contact with an object. Position error of the piercing pin. Drag overshoot of transport arm.	Check that there is no contact with an object which could block moves. Contact your Bio-Rad technical representative.
0x018210	Timeout error during the access to the shared area (with no resources on the gripper).	Module failure in the shared area.	Contact your Bio-Rad technical representative.
0x018212	Unexpected object detected in the gripper during the transport arm initialization.	The system previously saved the state of the gripper.	Contact your Bio-Rad technical representative.
0x018213	Timeout error during the access to the shared area (with resources on the gripper).	Module failure in the shared area.	Contact your Bio-Rad technical representative.

TRANSPORT ARM Error code	Error description	Possible cause	Corrective actions
0x018220	An unexpected diluent rack is detected in the intermediate diluent position during the transport arm initialization.	Transport arm failure.	Contact your Bio-Rad technical representative.
0x018224	The gripper does not close correctly when picking a consumable.	1. Hardware failure. 2. Wrong picking position of the consumable. 3. Bad calibration.	1. Check the position of the consumable. 2. Contact your Bio-Rad technical representative.
0x018226	Error sent by the transport arm controller during the power calibration of the transport arm motor.	Communication failure.	Contact your Bio-Rad technical representative.
0x018227			
0x018410	Communication error between the transport arm controller and the gripper.	Communication failure.	1. Check the connection of the gripper spiral cable on the arm. 2. Contact your Bio-Rad technical representative.
0x018411			
0x01841B			
0x018412	The gripper does not open correctly when placing a consumable.	Hardware failure.	Contact your Bio-Rad technical representative.
0x018412	The gripper does not open correctly when placing a consumable in the solid waste.	Hardware failure.	Contact your Bio-Rad technical representative.
0x018412	Position error of the gripper when opening/ closing a centrifuge trapdoor or diluent lock.	Hardware failure.	Contact your Bio-Rad technical representative.
0x018413	Inserted diluent rack not detected during a pickup for identification.	1. Diluent rack removed by the user. 2. Gripper failure.	1. Check the presence of the diluent rack. 2. Contact your Bio-Rad technical representative.

TRANSPORT ARM Error code	Error description	Possible cause	Corrective actions
0x018413 0x018B16	Piercing tip not detected when picked by the gripper (clamping force).	Piercing tip removed by the user. Gripper failure.	Check the presence of the piercing tip. Contact your Bio-Rad technical representative.
0x018413 0x018B18	Resource (sample rack excluded) not detected when picked by the transport arm.	Resource removed by the user. Gripper failure.	Check the presence of the resource. Contact your Bio-Rad technical representative.
0x018413 0x018B1D	Sample rack not detected when picked by the transport arm.	Resource removed by the user. Gripper failure.	Check the presence of the resource. Contact your Bio-Rad technical representative.
0x018413 0x018B36	Resource (sample rack excluded) not detected when picked by the transport arm, but detected by the mapping sensor.	1. Resource not detected. 2. Gripper failure.	Contact your Bio-Rad technical representative.
0x018413 0x018B37	Card block detected by the mapping sensor but not detected by the gripper when picked by the gripper.	1. Resource not detected. 2. Gripper failure.	Contact your Bio-Rad technical representative.
0x018414	Excessive torque for the gripper to pick up a resource (value out of range). Not applicable for the drawers.	1. Resource not correctly installed in the instrument. 2. Gripper failure.	Check that the resource is correctly placed. Contact your Bio-Rad technical representative.
0x018414 0x01841C	Excessive torque for the gripper to pick up a resource from the drawers (value out of range).	1. Resource not correctly installed in the instrument. 2. Gripper failure.	Check that the resource is correctly placed. Contact your Bio-Rad technical representative.
0x018415 0x018B20	Resource lost during the transfer.	1. Resource not correctly picked by the gripper. 2. Gripper failure.	Check the resource and the gripper. Contact your Bio-Rad technical representative.

TRANSPORT ARM			
Error code	Error description	Possible cause	Corrective actions
0x018416	Gripper initialization failure (home position not detected).	1. Effort not detected. 2. Motor control board failure.	Contact your Bio-Rad technical representative.
0x018418	Unable to open the gripper after a gripper failure to pick resources.	Gripper failure.	Contact your Bio-Rad technical representative.
0x018B32	Transport arm failure after placing a reagent vial.	Hardware failure.	Contact your Bio-Rad technical representative.

11.2.3 Centrifuge

CENTRIFUGE			
Error code	Error description	Possible cause	Corrective actions
0x014B04 0x018B30	The presence of a card in a centrifuge has been detected during initialization of the instrument. A card has been detected as missing in a	1. Resource left in the instrument. 2. Mapping sensor detection fault. 1. Resources were manipulated during	Contact your Bio-Rad technical representative.
0x014B05 0x018B30	centrifuge during initialization of the instrument.	stoppage of the instrument. 2. Mapping sensor detection fault.	Contact your Bio-Rad technical representative.
0x018217 0x058217	During a closure check, it has been detected that the trapdoor is NOT CLOSED.	1. Trapdoor absent - white strip on the trapdoor absent. 2. Gripper damaged. 3. Malfunction of the resource detection sensor.	Check the integrity of the centrifuge trapdoor. Check the integrity of the gripper. Contact your Bio-Rad technical representative.
0x01821E 0x05821E	During an opening check, it has been detected that the trapdoor is NOT OPEN.	1. Trapdoor absent - white strip on the trapdoor absent. 2. Gripper damaged. 3. Malfunction of the resource detection sensor.	Check the integrity of the centrifuge trapdoor. Check the integrity of the gripper. Contact your Bio-Rad technical representative.

CENTRIFUGE			
Error code	Error description	Possible cause	Corrective actions
0x019008	The centrifuge temperature has reached the pre-warning threshold.	Control malfunction.	Contact your Bio-Rad technical representative.
0x019009	The temperature has reached the warning threshold.	Control malfunction.	Contact your Bio-Rad technical representative.
0x050404 0x050411 0x050413 0x05FD07 0x05FD12	Error during the search for the origin of the centrifuge axis.	Axis fault (obstacle). An object is interfering with the centrifuge head. Centrifuge head missing or misplaced. Malfunction of motor, encoder or electronic board. Damaged or missing hub O-ring.	Contact your Bio-Rad technical representative.
0x050411 0x050413 0x05FD07 0x05FD12	Positioning error of the centrifuge (static or dynamic) during movement before placing a gel card.	Axis fault (obstacle). An object is interfering with the centrifuge head. Malfunction of motor, encoder or electronic board.	Contact your Bio-Rad technical representative.
0x050411 0x050413 0x05FD07 0x05FD12 0x060411 0x060413 0x06FD07 0x06FD12	Positioning error of the centrifuge (static or dynamic) during movement before picking a gel card.	Axis fault (obstacle). An object is interfering with the centrifuge head. Malfunction of motor, encoder or electronic board.	Contact your Bio-Rad technical representative.
0x050411 0x050413 0x05FD07 0x05FD12 0x060411 0x060413 0x06FD07 0x06FD12	Positioning failure (static or dynamic) at end of centrifugation.	Axis fault (obstacle). An object is interfering with the centrifuge head. Malfunction of motor, encoder or electronic board. Damaged or missing hub O-ring.	Contact your Bio-Rad technical representative.

CENTRIFUGE Error code	Error description	Possible cause	Corrective actions
0x050411 0x050413 0x05FD11 0x05FD12 0x060411 0x060413 0x06FD11 0x06FD12	A positioning error (static or dynamic) has occurred at initialization, during resource detection.	1. Axis fault (obstacle). An object is interfering with the centrifuge head. Malfunction of motor, encoder or electronic board.	Contact your Bio-Rad technical representative.
0x05FD04 0x05FD09 0x06FD04 0x06FD09	Speed error during centrifugation (possibly due to an axis drag error, a speed control error or a current limitation error).	1. Axis fault (obstacle). 2. An object is interfering with the centrifuge head. Malfunction of motor, encoder or electronic board. Damaged or missing hub O-ring. Instrument has sustained a shock which can cause a centrifuge disturbance.	1. Acknowledge the error. 2. If the problem persists, contact your Bio-Rad technical representative.

11.2.4 Incubator

INCUBATOR Error code	Error description	Possible cause	Corrective actions
0x014301	The temperature of the incubator is out of range (37°C±2.7°C).	Normal message during start-up of the instrument (wait for 5 to 10 min).	Normal message during start-up of instrument (wait for 5-10 min). If the problem persists, contact your Bio-Rad technical representative.
0x014B04 0x014B05	The presence of a gel card in the incubator has been detected during initialization of the instrument. A gel card has been detected as missing in the	Resources were manipulated during stoppage of the instrument. Mapping sensor detection fault.	Check to make sure that there is no card in the incubator. Contact your Bio-Rad technical representative.
	incubator during initialization of the instrument.	Resources were manipulated during stoppage of the instrument. Mapping sensor detection fault.	User error. Contact your Bio-Rad technical representative.

INCUBATOR

Error code	Error description	Possible cause	Corrective actions
0x019001	Discrepancy between the temperature sensors of the incubator (deviation of more than 5.4°C between the 2 sensors).	Malfunction of the measuring chain (sensor, card, etc.).	Contact your Bio-Rad technical representative.
0x104F03	The maximum incubation period at 37°C of a well of a gel card has been exceeded (incubation period at 37°C 10 min longer compared to the test definitions).	1. Module not available with the result that the card cannot be transferred into the centrifuge. 2. Incubation management fault.	1. Restart the test. 2. Contact your Bio-Rad technical representative.
0x104F03	The maximum incubation period of 5 min of a well of a gel card has been exceeded (incubation period 5 min longer compared to the test definitions).	1. Module not available with the result that the card cannot be transferred into the centrifuge. 2. Incubation management fault.	1. Restart the test. 2. Contact your Bio-Rad technical representative.
0x104F03	The maximum incubation period of a well of a gel card without incubation has been exceeded (waiting period before the start of centrifugation longer than 10 min).	1. Module not available with the result that the card cannot be transferred into the centrifuge. 2. Incubation management fault.	1. Restart the test. 2. Contact your Bio-Rad technical representative.

11.2.5 Pipettor

PIPETTOR

Error code	Error description	Possible cause	Corrective actions
0x018B21	Shared zone occupied by defective transport arm, or lost element in shared zone.	Transport arm error in shared zone.	Analyze previous default.
0x018B32	Pipettor X, Y or Z position error while the transport arm is in the reagents protective position in the shared area.	1. Mechanical failure. Driving failure. Position control chain failure.	Contact your Bio-Rad technical representative.
0x018E01	Following a fault, the Z axis of the pipettor fails to reach its disengagement position (drag error or static error of Z axis).	1. Mechanical obstacle. 2. Control fault.	Contact your Bio-Rad technical representative.

PIPETTOR			
Error code	Error description	Possible cause	Corrective actions
0x018E14	Invalid location of needle, sensing of target (pipettor outside of limit).	Faulty contact between needle and target.	Contact your Bio-Rad technical representative.
0x018E1E	Drag error or static error of the Z axis during liquid detection or during positioning on the withdrawal side.	1. Cap present. 2. Tube does not conform to the type identified.	1. Check to make sure that there is no obstacle on the pipettor axis and no play in the rack-and-pinion mechanism. 2. Check to make sure that there is no cap on the tube. 3. Check to make sure that the tube conforms to the rack type. 4. Contact your Bio-Rad technical representative.
0x018E25	The consecutive sensing number for a point has exceeded the set limit during location of the needle.	Faulty contact between needle and target.	Contact your Bio-Rad technical representative.
0x018E26	Location of the needle, defect of capacitive detection signal (non-conforming reference signal).	Material defect.	Contact your Bio-Rad technical representative.
0x020404 0x020411 0x020413 0x028E28 0x040404 0x040411 0x040413 0X048E28	The transport arm fails to reach its position during X, Y or Z initialization: drag error of the X and/or Y and/or Z axes; or static error of the X and/or Y and/or Z axes; or error of the home position sensor of the X and/or Y and/or Z axes.	Mechanical obstacle. Control fault.	1. Check to make sure that there is no obstacle on the pipettor axis and no play in the rack-and-pinion mechanism. Contact a service engineer. 2. Contact your Bio-Rad technical representative.
0x020411 0x020413 0x028E28	The transport arm fails to reach its position during movement in X or Y direction: drag error; or static error of the X and/or Y axes.	Mechanical obstacle. Control fault.	1. Check there is no hard spot on pipetor axis. Contact a service engineer. 2. Contact your Bio-Rad technical representative.
0x020411 0x020413 0x030411 0x040411 0x040413	Location of the needle, drag or static error of the pipetting robot during location process.	Mechanical obstacle. Control fault.	1. Check there is no hard spot on pipetor axis and no play in rack-and-pinion mechanism. Contact a service engineer. 2. Contact your Bio-Rad technical representative.

PIPETTOR Error code	Error description	Possible cause	Corrective actions
0x040411 0x040413 0x048E28	The Z axis fails to reach its position during vial bottom detection. • drag error; • or static error of the Z axis outside of the bottom detection zone.	Mechanical obstacle. Control fault.	Check there is no hard spot on pipetor axis and no play in rack-and-pinion mechanism. Contact your Bio-Rad technical representative.
0x040411 0x040413 0x048E28	The Z axis fails to reach its position during a Z axis movement: • drag error; • or static error of the Z axis.	Mechanical obstacle. Control fault.	Check there is no hard spot on pipetor axis and no play in rack-and-pinion mechanism. Contact your Bio-Rad technical representative.

11.2.6 Access to the Drawer / Pipetting Area

ACCESS TO THE DRAWER / PIPETTING AREA

Error code	Error description	Possible cause	Corrective actions
0x018B31	The pause of maintenance of the reagent vials in suspension has exceeded the maximum time limit.	Malfunction of the agitation system.	Analyze the previous fault. Reagent tray fault possible: 0x040411, 0x040413, 0x048E28 on page 221.
0x018B43	The right-hand door of the pipetting area does not appear to open at the opening command for this door.	1. Blocked door. 2. Control system out of order. 3. Sensor out of order.	Check that the door is not blocked and has not been re-closed too quickly (opening is monitored 1s after opening request). Check that the electromagnetic latch is guided correctly (disabling of the magnet). Contact your Bio-Rad technical representative.
0x080404	Failure of initialization of the reagent tray.	Malfunction of the agitation system:	Contact your Bio-Rad technical representative.
0x080411 0x080413 0x088B22		1. Mechanical defect. 2. Electrical defect.	Contact your Bio-Rad technical representative.
0x080411 0x080413 0x088B2A 0x088B51	During maintenance in suspension, the reagent tray does not position itself correctly, or its speed is non-conforming.	Malfunction of the agitation system.	Contact your Bio-Rad technical representative.
0x104B04	The presence of a sample rack has been detected during initialization of the instrument.	1. Operator error (insertion of a rack while the software has not started up). 2. Defect of the rack detection card.	1. Operator error. 2. Contact your Bio-Rad technical representative.

ACCESS TO THE DRAWER / PIPETTING AREA

Error code	Error description	Possible cause	Corrective actions
0x104B04	The presence of a gel card in the preparation area or the pipetting area has been detected during initialization of the instrument.	After abnormal stoppage: Mapping fault. Manipulation during stoppage.	Operator error. Rack detection board failure. Contact your Bio-Rad technical representative. See error code 0x018B35 on page 234
0x104B04	A gel card has been detected as newly present during mapping of the pipetting area after an access.	Manipulation during access to the instrument (withdrawal of a card by the user). Detection error.	1. User error. 2. Contact your Bio-Rad technical representative.
0x104B04	The presence of a reagent vial has been detected in the pipetting area during initialization of the instrument.	After abnormal stoppage: 1. Mapping fault. 2. Manipulation during stoppage.	1. User error. 2. Contact your Bio-Rad technical representative.
0x104B04	A diluent rack has been detected as newly present during initialization of the instrument.	Manipulation during stoppage.	User error. Contact your Bio-Rad technical representative.
0x104B04	A diluent rack has been detected as newly present during mapping after an access.	Manipulation during access to the instrument.	User error. Contact your Bio-Rad technical representative.
0x104B05	A gel card has been detected as newly absent during mapping of the pipetting area after an access.	1. Manipulation during access to the instrument (withdrawal of a card by the user). 2. Detection error.	User error. Contact your Bio-Rad technical representative.
0x104B05	A diluent rack has been detected as newly absent during mapping after an access.	Manipulation during access to the instrument.	User error. Contact your Bio-Rad technical representative.
0x104B05	A diluent rack has been detected as newly absent during initialization of the instrument.	Manipulation during stoppage.	User error. Contact your Bio-Rad technical representative.

ACCESS TO THE DRAWER / PIPETTING AREA

Error code	Error description	Possible cause	Corrective actions
0x104B05	A gel card has been detected as newly absent in the preparation or pipetting area during initialization of the instrument.	After abnormal stoppage: 1. Mapping fault. 2. Manipulation during stoppage.	User error. Contact your Bio-Rad technical representative.
0x104B05	A reagent vial has been detected as newly absent in the pipetting area during initialization of the instrument.	After abnormal stoppage: 1. Mapping fault. 2. Manipulation during stoppage.	User error. Contact your Bio-Rad technical representative.
0x108B2E	The right-hand door of the pipetting area has been detected as being open during the process.	Forced opening of the door (malicious act).	Door opened by user. Defect of the plunger of the front door. If OK, see error code 0x018B43 on page 221.
0x108B42	While dealing with an embedded clot, the right-hand door of the pipetting area has been detected as being open upon clicking on **Next**.	The operator validates closure of the door whereas it is detected as being open.	Close the front door. If OK, see error code 0x018B43 on page 221.

11.2.7 Ionizer

IONIZER

Error code	Error description	Possible cause	Corrective actions
0x018B28	Ionizer is faulty prior to the piercing of a gel card.	Malfunction of the ionizer.	Contact your Bio-Rad technical representative.

11.2.8 Consumable Drawer

CONSUMABLE DRAWER

Error code	Error description	Possible cause	Corrective actions
0x018221	Inconsistency check during mapping: detection of absent gel card and tray.	1. Background fault. 2. Misplacement of a consumable. 3. Mapping sensor fault.	1. Clean the left-hand drawer. 2. Check the positioning of the drawer (no play or maladjustment of the drawer). 3. Contact your Bio-Rad technical representative.
0x018222	Inconsistency check during mapping: detection of a diluent rack and a gel card tray.	1. Background fault. 2. Misplacement of a consumable. 3. Mapping sensor fault.	1. Clean the left-hand drawer. 2. Check the positioning of the drawer (no play or maladjustment of the drawer). 3. Contact your Bio-Rad technical representative.
0x018223	Inconsistency check during mapping: detection of a diluent rack and gel card.	1. Background fault. 2. Misplacement of a consumable. 3. Mapping sensor fault.	1. Clean the left-hand drawer. 2. Check the positioning of the drawer (no play or maladjustment of the drawer). 3. Contact your Bio-Rad technical representative.
0x018B45	The depot drawer (left or right) does not open upon opening request (no change of status of the sensor following the opening command).	1. Consumable drawer blocked or closed too fast after opening (1s). 2. Pilotage damaged. 3. Electromagnetic latch damaged.	1. Clean the left-hand drawer. 2. Check to make sure that the depot is not blocked and has not been re-closed too quickly (opening is monitored 1s after opening request). 3. Contact your Bio-Rad technical representative.
0x104108	The reagent plate is full.	The reagent plate is full.	1. Check the reagent plate. 2. If necessary, remove the not used vials.
0x104922	The maximum time allowed for the reagent vial to be inside the drawer is reached.	The reagent stayed too long in the drawer without to be used. The cells of the reagents are no longer in suspension.	1. Open the drawer. 2. Whirl the reagent vial. 3. Close the drawer to validate the reagent.
0x104F06	No free space in the left depot at return of the cards after interpretation.	Maximum capacity of gel cards to be re-read reached.	Empty the left input depot and place empty trays in position.

11.2.9 Fluidic

FLUIDIC

Error code	Error description	Possible cause	Corrective actions
0x0182C	Detection of a volume of liquid less than 1 dose.	Vial virtually empty. Level detection fault.	1. Check the presence of liquid in the bottle. 2. Verify the absence of hard spot on the Z axis. 3. Contact your Bio-Rad technical representative.
0x018E06	Failure during level detection signal check	Level detection fault.	Contact your Bio-Rad technical representative.
0x018E07	(before submersion of the needle). Level detection error (failure to detect loss of	1. Foam present.	1. Check there is no foam or bubble in the reagent.
	level during level detection) in spite of several attempts.	2. Level detection fault.	2. Contact your Bio-Rad technical representative.
0x018E0A	Failure to detect liquid during assessment of the	1. Vial is empty.	1. Check there is liquid in the sample tube.
	reagent vials (drag error during liquid detection or low mark reached).	2. Level detection fault.	2. Contact your Bio-Rad technical representative.
0x018E0C	Defect of filling of the decontamination well	1. Decontamination circuit empty.	Contact your Bio-Rad technical representative.
0x018E0E	(level detection height below the threshold). Non-conforming sampling set: extra volume not	2. Level detection fault. 1. APF definition error.	APF definition default. If it is not OK, send LOG files and pictures to instrument
	zero.	2. Software bug.	support to perform complete expertise.
0x018E0F	Non-conforming sampling set: drying volume	1. APF definition error.	APF definition default. If it is not OK, send LOG files and pictures to instrument
	not zero.	2. Software bug.	support to perform complete expertise.
0x018E10	Failure at non un-priming check at end of	1. Bubble present in the vial during	1. Check reagent quality.
	withdrawal (un-priming in a reagent vial).	withdrawal. 2. Level detection fault.	2. Contact your Bio-Rad technical representative.

FLUIDIC Error code	Error description	Possible cause	Corrective actions
0x018E12 0x104B06 0x018E13	Insufficient volume of liquid in a reagent vial during a withdrawal, no dose can be withdrawn (volume calculated during level detection insufficient). Insufficient volume of liquid in a reagent vial during a withdrawal, at least one dose can be withdrawn (volume calculated during level detection insufficient).	There is not enough liquid in the vial. Level detection fault. There is not enough liquid in the vial. Level detection fault.	Check if there is liquid in the reagent. Check there is no hard spot on pipetor axis and no backlash in rack-and-pinion mechanism. Contact your Bio-Rad technical representative. Check if there is liquid in the reagent. Check there is no hard spot on pipetor axis and no play in rack-and-pinion mechanism. Contact your Bio-Rad technical representative.
0x018E15	Detection of clogging of the hydraulic circuit (not resorbed) for the samples.	1. Clot present. 2. Viscosity of liquid out of range.	Check blood quality (less than 5 days). Clean or replace the needle. See sections Pipettor in Error on page 154 or Pipette Needle Replacement / Cleaning on page 201. Contact your Bio-Rad technical representative.
0x018E16 0x018E17	Failure during non un-priming check at end of withdrawal (embedded filament). Failure during non un-priming check at end of withdrawal (loss of level in high range detected - broken filament).	1. Level detection fault. 2. Embedded filament. Thread embedded, then broken during a sample withdrawal.	1. Check blood quality (less than 5 days). 2. Contact your Bio-Rad technical representative. 1. Check blood quality (less than 5 days). 2. Contact your Bio-Rad technical representative.
0x018E18	Insufficient volume of liquid in a sample tube during a withdrawal (volume calculated during level detection insufficient).	1. There is not enough liquid in the tube. 2. Level detection fault.	1. Check there is liquid in the sample tube. 2. Contact your Bio-Rad technical representative.
0x018E19	Emptying fault of an overflow or collection well (liquid present in the collection well at periodic check by level detection).	1. Defect of emptying pump, solenoid valve. 2. Emptying circuit clogged.	Contact your Bio-Rad technical representative.
0x018E1B	Loss of level outside of the anticipated range, or no loss of level, in the overflow well at the end of rinsing or pre- washing.	1. Defect of washing pump. 2. Solenoid valve blocked in emptying position.	Contact your Bio-Rad technical representative.

FLUIDIC Error code	Error description	Possible cause	Corrective actions
0x018E1D	Loss-of-level detection error following failed attempts in the case of the decontamination well.	Level detection fault.	Contact your Bio-Rad technical representative.
0x018E23	Filling fault of the collection well (level detection height in the collection well below the threshold at periodic check).	Defect of washing pump. Solenoid valve blocked in emptying position.	Contact your Bio-Rad technical representative.
0x018E24	Failure of emptying of the decontamination well (by level detection).	Pump defect. Solenoid valve, emptying circuit clogged.	Contact your Bio-Rad technical representative.
0x018E29	Failure at volume check of a delivered dose.	Dispensing error (withdrawal of air).	In case of more than 3% of failed dispense: Check needle position in gel card (drop under foil detected or contact between needle and foil). Check there is no foam in the sample tubes (detection of foam dispense). Deviation of the PDS calibration. Contact your Bio-Rad technical representative.
0x018E2B	At **weekly maintenance**: prior to distribution in the washing station, the presence of a liquid is detected in the retaining container.	1. Leakage of the fluidic circuit. 2. Leakage of a canister. 3. Undetected overflows of the washing station.	Fluidic leak / bottle leak / washing station overflow / intermediate tank overflow. Washing station overflow due to waste circuit clogged. Bottle overflow (system or NaOH solution) during filling. Remove the canisters, clean and restart.
0x018E2C	Not enough liquid in the reagent vial.	1. The reagent vial is empty. 2. Level detection failure.	Contact your Bio-Rad technical representative. (A) Check that there is liquid in the reagent vial. (B) Check the reagent bottom level and adjust it if necessary.
0x018E2D	The state of the intermediate tank sensor did not change during the washing process.	Washing pump failure.	Contact your Bio-Rad technical representative.

FLUIDIC			
Error code	Error description	Possible cause	Corrective actions
0x018E2E	Time between the error occurrence and the acknowledgment of this error too long. The needle is no longer usable (blood dried inside the needle).	Response of the user too long.	Clean or replace the needle. See sections Pipettor in Error on page 154 or Pipette Needle Replacement / Cleaning on page 201.
0x018E2C	Not enough liquid in the pediatric or low volume tube (for sampling).	1. The tube is empty or the sample volume is insufficient. 2. Level detection failure.	1. Check that there is liquid in the tube. 2. Contact your Bio-Rad technical representative.
0x019101	Time-out for filling of the intermediate reservoir (for complete filling, during priming, in the scope of **weekly maintenance**,…)	1. Malfunction of the pump. 2. Malfunction of the level sensor.	Contact your Bio-Rad technical representative.
0x019102	Time-out for filling of the intermediate reservoir (for continuous filling).	1. Malfunction of supply of the intermediate reservoir. 2. Malfunction of the level sensor.	Contact your Bio-Rad technical representative.
0x019103	1 system solution canister is not operational (not connected, or empty, or maintenance canister present).	Status OK if the canister is: 1. not connected, or 2. empty, or 3. not the correct one.	1. Check the system solution bottle (it has no magnet on the rear). 2. Contact your Bio-Rad technical representative.
0x019104	2 system solution canisters are not operational (not connected, or empty, or maintenance canister present).	Status OK if the canister is: 1. not connected, or 2. empty, or 3. not the correct one.	1. Check the system solution bottle (it has no magnet on the rear). 2. Contact your Bio-Rad technical representative.
0x019105	The bottom level of the decontamination solution reservoir was reached when priming the decontamination well during initialization of the instrument.	Status OK is the volume is less than 0.5 liter .	1. Check the filling of the decontamination bottle. 2. Contact your Bio-Rad technical representative.
0x019107	No maintenance solution canister is operational during weekly maintenance.	Status OK if the bottle is: 1. not connected, or 2. empty, or 3. not the correct one.	1. Check the maintenance bottle (it has a magnet on the rear). 2. Contact your Bio-Rad technical representative.

FLUIDIC

Error code	Error description	Possible cause	Corrective actions
0x019110	Before starting a pipetting operation, the presence of a liquid is detected in the retaining container.	Leakage of the fluidic circuit. Leakage of a canister. Undetected overflows of the washing station.	Fluidic leak / bottle leak / washing station overflow / intermediate tank overflow. Washing station overflow due to waste circuit clogged. Bottle overflow (system or NaOH solution) during filling. Remove the canisters, clean and restart. Contact your Bio-Rad technical representative.
0x019201	1 waste canister is not operational (not connected or not present or full).	Canister is being replaced.	Check the waste bottle (it has a magnet on the rear). Contact your Bio-Rad technical representative.
0x019202	2 waste canisters are not operational (not connected or not present or full).	Malfunction of collecting circuit, 2 canisters are being replaced.	Check the waste bottle (it has a magnet on the rear). Contact your Bio-Rad technical representative.
0x019203	One waste canister is not operational during the purge (not connected or not present or full).	One waste container is full, canister is being replaced.	1. Check the waste bottle (it has a magnet on the rear). 2. Contact your Bio-Rad technical representative.
0x0C0411 0x018E0A	Liquid not detected during reagent evaluation (drag overshoot during liquid detection or bottom level reached).	1. Vial is empty. 2. Detection of the bottom before liquid detection. 3. Level detection fault.	1. Check that there is liquid in the reagent vial. 2. Check that there is no obstacle on the pipettor axis and no play in the rack-and-pinion mechanism. 3. Contact your Bio-Rad technical representative.
0x0C0411	Liquid not detected during first reagent sampling (drag overshoot during liquid detection or bottom level reached).	1. Vial is empty. 2. Detection of the bottom before liquid detection. 3. Level detection fault.	1. Check that there is liquid in the reagent. 2. Check that there is no hard spot on pipetor axis and no play in rack- and-pinion mechanism. 3. Contact your Bio-Rad technical representative.
0x0C0411 0x0C0413	During a withdrawal, except for washing (liquid or air bubble), the pump of the PDS module fails to reach its position (static or dynamic positioning error).	Wiring defect of the pump or the solenoid valve of the PDS module. Particle in the pump.	Contact your Bio-Rad technical representative.
0x0C0411 0x0C0413	During a delivery, except for washing and priming, the pump of the PDS module fails to reach its position (static or dynamic positioning error).	Wiring defect of the pump or the solenoid valve of the PDS module. Particle in the pump.	Contact your Bio-Rad technical representative.

FLUIDIC			
Error code	Error description	Possible cause	Corrective actions
0x0C0411 0x0C0413	During a withdrawal or delivery for washing, the pump of the PDS module fails to reach its position (static or dynamic positioning error).	1. Wiring defect of the pump or the solenoid valve of the PDS module. 2. Particle in the pump.	Contact your Bio-Rad technical representative.
0x0C0411 0x0C0413	During a delivery for priming, for purging or for flushing, the pump of the PDS module fails to reach its position (static or dynamic positioning error).	1. Wiring defect of the pump or the solenoid valve of the PDS module. 2. Particle in the pump.	Contact your Bio-Rad technical representative.
0x0C0411 0x0C0413	During weekly maintenance: During a delivery for filling of the washing station, the pump of the PDS module fails to reach its position (static or dynamic positioning error).	Wiring defect of the pump or the solenoid valve of the PDS module. Particle in the pump.	Contact your Bio-Rad technical representative.
0x0C0411 0x0C0413 0x018E0A	Failure to detect liquid in a reagent vial prior to a withdrawal (drag error during liquid detection or low mark reached).	Vial is empty. Level detection fault.	Check there is liquid in the reagent. Check there is no hard spot on pipetor axis and no play in rack-and-pinion mechanism. Contact your Bio-Rad technical representative.
0x0C0411 0x0C0413 0x018E22	During the unblocking sequence of the pump, the pump fails to reach its position (static or dynamic positioning error).	Wiring defect of the pump or the solenoid valve of the PDS module. Particle in the pump.	Contact your Bio-Rad technical representative.
0x0C0416	Overpressure fault of the pump of the PDS module during a delivery to gel card or diluent rack.	Liquid used is too viscous. The needle is clogged. Malfunction of the pressure sensor.	Check blood quality (less than 5 days). Check that needle is not clogged. Change it if necessary. Contact your Bio-Rad technical representative.
0x0C0416 0x018E1F	During weekly maintenance: Overpressure fault of the pump of the PDS module during a delivery for filling the washing station, for priming or for purging.	Liquid used is too viscous. The needle is clogged. Malfunction of the pressure sensor.	Check liquid: no foreign object. Check that needle is not clogged. Change it if necessary. Contact your Bio-Rad technical representative.
0x0C0416 0x018E20	Overpressure fault of the pump of the PDS module during a delivery for priming, for flushing or for purging.	1. Liquid used is too viscous. 2. The needle is clogged. 3. Malfunction of the pressure sensor.	Check liquid: no foreign object. Check that needle is not clogged. Change it if necessary. Contact your Bio-Rad technical representative.

FLUIDIC

Error code	Error description	Possible cause	Corrective actions
0x0C0416 0x018E21	Overpressure fault of the pump of the PDS module during a purging process with service software.	1. Liquid used is too viscous. 2. The needle is clogged. 3. Malfunction of the pressure sensor.	1. Check liquid: no foreign object. 2. Check that needle is not clogged. Change it if necessary. 3. Control and/or change PDS module.
0x0C0416 0x018E31	Pressure sensor failure or pressure out of range during a sampling process.	1. Liquid used is too viscous. 2. The needle is clogged. 3. Malfunction of the pressure sensor.	1. Check liquid: no foreign object. 2. Check that needle is not clogged. Change it if necessary. 3. Control and/or change PDS module.
0x0C0416 0x0C8E1A	Overpressure fault of the pump of the PDS module during a washing process.	1. Liquid used is too viscous. 2. The needle is clogged. 3. Malfunction of the pressure sensor.	1. Check there is no sediment in the washing fluidic circuit (change tubings and intermediate tank if necessary). 2. Check that needle is not clogged. Change it if necessary. 3. Contact your Bio-Rad technical representative.
0x0C4011 0x0C4013 0x018E2F	Position error of the PDS pump (during titration).	1. Wiring issue of the PDS module. 2. Dust in the pump.	1. Check the wiring. 2. Control and/or change PDS module.
0x0CED07	Excessive negative pressure when withdrawing liquid, except for washing (air or liquid).	1. Viscosity of liquid out of range (blood over 5 days). Needle too close to the bottom of the sample tubes.	1. Check blood quality (less than 5 days). 2. Contact your Bio-Rad technical representative.
0x0CED07 0x0CED08 0x018E1C	Excessive negative pressure when withdrawing decontamination solution during washing (air or liquid).	Pressure sensor failure. 2. Circuit clogged. 1. Viscosity of liquid out of range. 2. The needle is too close to bottom of the decontamination well.	1. Check liquid: no foreign object. 2. Check needle position in the tube. 3. Check that needle is not clogged. Change it if necessary. 4. Contact your Bio-Rad technical representative. 1. Check that needle is not clogged. Change it if necessary. 2. Contact your Bio-Rad technical representative.
	0x0CED08	1. Viscosity of liquid out of range. 2. Circuit clogged. 3. Pressure sensor failure.	1. Check that needle is not clogged. Change it if necessary. 2. Contact your Bio-Rad technical representative.
	0x0CED08		

Detection of clogging of the hydraulic circuit (not resorbed), except for samples.	Hydraulic ci	rcuit for the samples clogged (not resorbed).
Viscosity of liquid out of range.		

FLUIDIC			
Error code	Error description	Possible cause	Corrective actions
0x0CED0B	Malfunction of pressure sensor (static pressure outside of tolerance at start of withdrawal or no signal variation at start of withdrawal).	Sensor disconnected. Sensor damaged.	Contact your Bio-Rad technical representative.
0x104D12	After a sampling of a reagent vial, there is no enough volume to process the next batch.	Insufficient volume of reagent.	Insert a new reagent vial.
0x109109	The presence of a liquid is detected in the retaining container during initialization of the instrument.	Leakage of a canister. Leakage of the intermediate tank. Leakage of the fluidic circuit. Undetected overflows of the washing station. Sensor malfunction	Fluidic leak / bottle leak / washing station overflow / intermediate tank overflow. Washing station overflow due to waste circuit clogged. Bottle overflow (system or NaOH solution) during filling. Remove the canisters, clean and restart. Contact your Bio-Rad technical representative.

11.2.10 Internal Storage

INTERNAL STORAGE			
Error code	Error description	Possible cause	Corrective actions
0x018B2D	The internal depot is detected as not being locked during initialization of the instrument.	Error during an intervention. Detection error.	Check to make sure that the internal depot is locked (screw of depot completely locked). In case of a problem with detection by the gripper: Contact your Bio-Rad technical representative. If the transport arm is malpositioned: Contact your Bio-Rad technical representative.
0x104B05	Expected gel card not detected during the instrument initialization.	1. Gel card removed by the user. 2. Mapping sensor failure.	Check the presence of the gel card. Contact your Bio-Rad technical representative.

11.2.11 Reagent Cooling

REAGENT COOLING Error code	Error description	Possible cause	Corrective actions
0x014302	The temperature of the reagent vials is above 25°C (reagent too warm).	1. The instrument is being started up. 2. Malfunction of cooling system: • Lack of liquid in the reservoir, • The fan is not rotating and/or the air emitted is not warm. 3. Malfunction of the measuring chain.	Message at start-up of the system (the cooling system reaches its set temperature within approx. 30 min). Contact your Bio-Rad technical representative.
0x014303	The temperature of the reagent vials is between 18°C and 25°C (outside of tolerance, but reagent usable).	1. The instrument is being started up. 2. Malfunction of cooling system: • Lack of liquid in the reservoir, • The fan is not rotating and/or the air emitted is not warm. 3. Malfunction of the measuring chain.	Message at start-up of the system (the cooling system reaches its set temperature within approx. 30 min). Contact your Bio-Rad technical representative.
0x019002	Discrepancy between the temperature sensors of the reagent tray (deviation of more than 2°C between the 2 sensors).	Malfunction of the measuring chain (sensor, card, etc.).	Malfunction of one of the temperature sensors. Contact your Bio-Rad technical representative.
0x01900A	The temperature of the reagent vials is below 14°C (reagent unusable).	1. Malfunction of the measuring chain (sensor, card, etc.). 2. Malfunction of cooling system.	Contact your Bio-Rad technical representative.
0x01900B	The reagent cooling compressor is defective.	Compressor defect (fault output of reagent cooling system activated).	Cooling compressor defect due to overpressure or temperature fault: wait for the second fault.
0x01900C	Reagent cooling compressor: second fault within the defined time.	Compressor defect (fault output of reagent cooling system activated in spite of re-start-up).	Contact your Bio-Rad technical representative..
0x10900D	Reagent cooling function is deactivated.	Reagent cooling function is deactivated by ParamManager (Cooling.IsDeactivated on True).	Reagent cooling function is deactivated by FSE. Reactivate this function to correct the default. Contact a service engineer.

11.2.12 Sample Rack

SAMPLE RACK

Error code	Error description	Possible cause	Corrective actions
0x018413 0x018B1D	A sample block has been detected as newly absent after an access to the instrument.	Withdrawal of a block during the access.	1. User error. 2. If the rack is present, defect on the rack detection card See error code 0x018B35 on page 234.
0x018413 0x018B36	During return, the gripper closes without detecting a rack, which is nevertheless present (fault of gripper closure).	Breakage of the gripping button of the rack.	1. Check sample rack integrity. 2. Check transport arm position during rack return and if necessary perform sample area teaching. 3. Contact your Bio-Rad technical representative.
0x018B35	A rack is detected as still present following its return.	1. Reinsertion of the rack by the user. 2. Malfunction of the lane sensor.	1. The sample rack must not be reinserted immediately into the instrument after its return. You must wait for at least 5s. 2. Contact your Bio-Rad technical representative.
0x104905	A code that has been automatically read or manually entered is identical to a code already present in the instrument on another rack (duplicate).	1. Input error. 2. Real duplicate.	1. Re-enter the barcode of the sample tube. 2. Check to make sure that there is no duplicate in the instrument. The instrument will not accept several tubes with the same barcode.
0x108B3E	A sample rack previously present is detected as missing.	Manual withdrawal of the rack by the operator (malicious act).	1. Manipulation of the rack (deliberate withdrawal while the instrument is operating). 2. If the rack is present, defect on the rack detection card. See error code 0x018B35 on page 234.

11.2.13 Software

SOFTWARE

Error code	Error description	Possible cause	Corrective actions
0x103001	APF checker error. The system detects an error between the APF and the process performed on the instrument.	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103002	APF Checker. The maximum duration between the dispense and the incubation is reached.	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.

SOFTWARE Error code	Error description	Possible cause	Corrective actions
0x103003	APF Checker. The minimal duration of the incubation is not reached (checked at the end of the process).	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103004	APF Checker. The maximum duration between the incubation and the centrifugation is reached (checked at the end of the process).	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103005	APF Checker. The maximum duration between the dispense and the centrifugation is reached (checked at the end of the process).	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103006	APF Checker. The maximum waiting time on the centrifuge is reached (checked at the end of the process).	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103007	APF Checker. The minimal duration of the centrifugation is not reached (checked at the end of the process).	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103008	The maximum time for an open well is reached.	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103009	APF Checker. An expired reagent vial was used during the test.	Process issue.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x103010	APF Checker. An expired gel card was used during the test.	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
		APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.

SOFTWARE Error code	Error description	Possible cause	Corrective actions
0x103011	APF Checker. An expired diluent rack was used during the test.	APF Checker error. Process not compliant with the APF folder.	Contact your Bio-Rad technical representative. Send the snapshot for investigation.
0x104921	The length of the sample barcode is greater than the set length (30 digits).	Barcode too long.	Use a conforming barcode (below 30 digits).
0x104923	Image not found when picture of the well is sent.	Image corrupted..	1. Check the integrity of the archive folder. 2. Contact your Bio-Rad technical representative.
0x104D01	Test deleted.	1. Test deleted with **Stop all**.	Test deleted done by user.
0x104D02 0x104D03 0x104D04		2. Test to repeat launch (first test deleted with 4D02 and new test created). 3. Test deleted by DMS. 4. Test with missing resources deleted by sample rack removing.	
0x104D13	QC flag disabled.	QC flag disabled by the user.	Enable the QC flag and start a new test.
0x104D14	The user sent the interpretation with the function “Send result to DMS”.	No issue.	-
0x104D15	The user disables the QC flag for QC.	No issue.	-

SOFTWARE Error code	Error description	Possible cause	Corrective actions
0x104D16	On board time option disabled for gel cards.	No issue.	-
0x104D17	On board time option disabled for diluent racks.	No issue.	-
0x104D18	On board time option disabled for reagents.	No issue.	-
0x104D19	On board time status for the reagent not sent by	No issue.	-
0x104D20	the DMS, but validated by the user. On board time allowed for the reagent is	No issue.	-
0x104D21	reached, but validated by the user. On board time status for the reagent not sent by	No issue.	-
0x105001	the DMS, but validated by the user. Incorrect file name.	Non-compliant APF.	Non-compliant file.
0x105002	Error during APF file import. The file does not	Non-compliant APF.	Contact your Bio-Rad technical representative. Non-compliant file.
	pertain to the IH-500.		Contact your Bio-Rad technical representative.

SOFTWARE Error code	Error description	Possible cause	Corrective actions
0x105003	Error during APF file import. The file version is incorrect.	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105004	Error during APF file import. The file does not pertain to the range used on the instrument,	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105005	Error during APF file import. APF with a version identical to or lower than the version imported into the instrument.	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105006	Error during APF file import. Invalid XML file (corrupted file).	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105007	Error during APF file import. Invalid data (corrupted file).	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105009	Error during APF file import. Invalid checksum (corrupted file).	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105010	Error during APF file import. Data insertion failed.	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105010	Error during APF file import. Weighting of pipetting not compatible with the data of the instrument.	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105011		Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.

SOFTWARE Error code	Error description	Possible cause	Corrective actions
0x105012	Error during APF file import. NPAC incompatible with generic cards.	Non-compliant APF.	Non-compliant file. Contact your Bio-Rad technical representative.
0x105014	Error during vision files import.	Corrupted file.	Non-compliant file.
0x105015	Error during flag files import.	Corrupted file.	Contact your Bio-Rad technical representative. Non-compliant file.
0x105016	Error during APF files import. Vision parameters not found.	Non-compliant APF.	Contact your Bio-Rad technical representative. Non-compliant file.
0x105017	Error during APF files import.	Non-compliant APF.	Contact your Bio-Rad technical representative. Non-compliant file.
0x105018	External media used for a snapshot full.	Media full.	Contact your Bio-Rad technical representative. Use another media.
0x105019	External media used for a snapshot not found.	Name of the external media not found.	Check the connection of the media.
0x105200	Error during translation files import.	Corrupted file.	Non-compliant file.
			Contact your Bio-Rad technical representative.

SOFTWARE

Error code	Error description	Possible cause	Corrective actions
0x105201	Error during translation files import	The file does not contain translation data	Non-compliant file Contact your Bio-Rad technical representative.
0x105202	Error during translation files import.	Incorrect file version.	Non-compliant file.
0x108B01	Exception software. Unmanaged fault	1. Unmanaged error. 2. Software bug.	Contact your Bio-Rad technical representative. Contact your Bio-Rad technical representative.

11.2.14 Solid Waste

SOLID WASTE

Error code	Error description	Possible cause	Corrective actions
0x018B23	The solid waste bin is missing.	Unloading in progress.	Re-close the solid waste bin and check to make sure that the plunger is in contact with the electromagnet. If not, see error code 0x018B24 on page 240.
0x018B24	The solid waste bin is still present after being unlocked.	1. Waste bin drawer blocked. 2. Plunger defective.	Check to make sure that the waste bin is not blocked and has not been re-closed too quickly (opening is monitored 1s after opening request).
0x018B25	The solid waste bin has reached its filling safety threshold (maximum filling threshold reached, or overflow detected by the waste bin sensor). The software prohibits the starting of a new test and no longer discards the used consumables.	Waste bin in state of overflow.	Contact your Bio-Rad technical representative. Empty the solid waste bin. Check whether the overflow sensor has been activated. Contact your Bio-Rad technical representative.
0x104801	The solid waste bin has reached its pre-warning threshold (normal operating situation). Informative message, no impact on the operation of the instrument.	The counter has reached its pre-warning threshold.	Empty the solid waste bin.

SOLID WASTE

Error code	Error description	Possible cause	Corrective actions
0x104802	The solid waste bin has reached its warning threshold. The software prohibits the starting of a new test, but continues to discard the used consumables.	Waste bin full.	Empty the solid waste bin.

11.2.15 Vision Station

VISION STATION

Error code	Error description	Possible cause	Corrective actions
0x018504	At first identification of a gel card, the type or	Loaded card is non-conforming (not supported	Check to make sure that the card corresponds to an APF recognized by the
0x104902	format of the barcode is incorrect (format not recognized by the instrument).	by the instrument).	instrument.
0x01880B	When taking an image, the camera is unable to	Capturing fault at camera level.	Contact your Bio-Rad technical representative.
0x018901	take the image (black image or camera fault) in spite of several attempts and a camera reset. Several different codes are read at the same	1. Barcode not correctly oriented.	1. Check sample tube orientation in the bloc.
0x018902	tube location during an identification sequence for a block of tubes. During an identification sequence for a block of	2. Label damaged. 1. Barcode reader defective.	2. Check integrity and quality of the barcode used. 3. Contact your Bio-Rad technical representative. 1. Check presence, order and integrity of the separation stickers on the sample
	tubes, the type of tube supported by the block is illegible or unknown.	2. Use of an unknown barcode type. 3. All the separation stickers are damaged or missing.	bloc. 2. Check that used barcode is conform to user manual specification. 3. Contact your Bio-Rad technical representative.
0x018903	During an identification sequence for a block of tubes, the presence or order of the separators is non-conforming.	1. Separation sticker damaged or missing. 2. Barcode reader defective.	Check presence, order and integrity of the separation stickers on the sample bloc.
0x018B52	Can not perform the sample identification on	Settings for low volume or pediatric tubes not	Contact your Bio-Rad technical representative.
	rack type 2 or 6.	defined.	Contact your Bio-Rad technical representative.

VISION STATION Error	Error description	Possible cause	Corrective actions
code 0x018F04	During the air gap check, the barcode does not correspond to the one expected.	1. Card was moved manually during the process. 2. Software bug.	User error. Request expert assessment from technical support. Send the logs along with the images.
	During interpretation of the wells, the barcode does not correspond to the one expected.	1. Card was moved manually during the process. 2. Software bug.	
0x018F04	During adjustment, a lighting anomaly is detected (background average brightness or CV outside of tolerance or reference brightness outside of tolerance).	1. An object is present. 2. Lighting fault. 3. Fault of lens or camera.	User error. Request expert assessment from technical support. Send the logs along with the images.
0x018F0C 0x018F0E	During first identification of a gel card, the barcode is illegible.	1. Labeling faulty. 2. Fault of camera focus adjustment.	Check there is no dust or spot on the backlight or the lens of the camera. Check backlight homogeneity (LED out of order). Contact your Bio-Rad technical representative.
0x018F0D	During the air gap control, the barcode of the gel card is illegible (even after the second attempt).	1. Labeling faulty. 2. Fault of camera focus adjustment.	Check the label of the card. Contact your Bio-Rad technical representative.
0x018F0D	During the interpretation of the wells, the barcode of the gel card is illegible (even after the second attempt).	1. Labeling faulty. 2. Fault of camera focus adjustment. 3. Significant vibration during identification.	Check the label of the card. Contact your Bio-Rad technical representative. If the gel card vibrates, it could be a bad gel card taking into the store (the card slides into the legs of the gripper). Contact your Bio-Rad technical representative.
0x018F0D	During an adjustment, a lighting defect is detected (exposure calculated on object outside of tolerance or deviation of brightness of one of the color channels or management of the background impossible).	1. Lighting defective. 2. Camera defective. 3. Lens or lighting system dirty.	Check there is no dust or spot on the backlight or the lens of the camera. Check backlight homogeneity (LED out of order). Contact your Bio-Rad technical representative.
0x018F10 0x018F14 0x018803 0x018804			
0x018F11 0x018805 0x018806	When adjusting the vision station, white balance adjustment is impossible (exposure determined outside of tolerance or management of white balance impossible).	1. Camera too badly out of adjustment. 2. Lighting defective. 3. Fault of lens or camera.	Restart the instrument. Check there is no external lighting source which could disturb the vision station. Check backlight homogeneity (LED out of order). Contact your Bio-Rad technical representative.

VISION STATION

Error code	Error description	Possible cause	Corrective actions
0x018F12 0x018808 0x018809	When adjusting the vision station, exposure time adjustment is impossible (exposure determined outside of tolerance or management of white balance impossible).	1. Camera too badly out of adjustment. 2. Lighting defective. 3. Fault of lens or camera.	Restart the instrument.
0x018F13 0x018F15 0x0B8807	When adjusting the vision station, the lighting control fails (background brightness outside of tolerance or exposure calculated on object outside of tolerance).	1. Camera too badly out of adjustment. 2. Lighting defective. 3. Fault of lens or camera.	
0x104901	Camera communication failure during the initialization or the normal operation.	Communication failure.	
0x104903	At first identification of a gel card, the expiry date has been reached.	Expired card.	
0x104904	The presence of a cap is detected on a reagent vial.	1. Cap present on the vial. 2. Defect of the cap detection function.	
0x104905			
0x104906	During sample rack identification, a sample tube barcode is unreadable (while the tube is really present).	1. Barcode not correctly oriented. 2. Label damaged. 3. Barcode not supported by the reader. 4. Barcode reader defective	
0x104907	A barcode read or entered manually is identical to one barcode of a sample present in the instrument.	1. Input error. 2. Real duplicates.	
	The presence of a cap is detected on a reagent vial.	1. Cap present on the vial. 2. Defect of the cap detection function.	

Check there is no external lighting source which could disturb the vision station.
Check backlight homogeneity (LED out of order).
Contact your Bio-Rad technical representative.
Restart the instrument.
Check there is no external lighting source which could disturb the vision station.
Check backlight homogeneity (LED out of order).
Contact your Bio-Rad technical representative.
Contact your Bio-Rad technical representative.

Check to make sure that the expiry date of the card is consistent. If OK, check the date configuration of the PC.

Check to make sure that there is no cap on the sample tube. Confirm that there is no cap when prompted by the software.
Contact your Bio-Rad technical representative.

Check sample tube orientation in the bloc.
Check integrity and quality of the barcode used.
Check that barcode is supported by the reader.
Contact your Bio-Rad technical representative.

Input again the sample barcode.
Check for duplicates. The instrument does not work with tubes with same barcode.

Check there is no cap on the reagent vial.
Check the reagent vial neck (no default).
Contact your Bio-Rad technical representative.

0x104909	During identification of a diluent rack, the barcode of the rack is unreadable (even after the second attempt).	Check vial sticker integrity. Contact your Bio-Rad technical representative. External vibration.
0x104910	At identification of a diluent rack, the expiry date of the rack has been reached.	Check that the expiry date is coherent. Check date configuration of the computer.
0x104910	During the instrument initialization, the expiry date of a diluent rack has been reached.	Check that the expiry date is coherent. Check date configuration of the computer.
0x104911	During first identification the reagent is out of date.	Check that the expiry date is coherent. If yes, check date configuration of the computer.
0x104912	At the check of the gel of the cards, a well is detected as not being new and unused.	Check that the well is empty. Check there is no foreign object (dust in or out of the well).
0x104913	At identification of a reagent vial, the type of reagent is unknown (format not recognized by the instrument).	Check that the reagent corresponds to an APF managed by the instrument.
0x104914	At identification of a diluent rack, its type is unknown (format not recognized by the instrument).	Check to make sure that the diluent rack corresponds to an APF supported by the instrument.

VISION STATION Error code	Error description	Possible cause	Corrective actions
0x104915	At start-up, the vision station is not calibrated.	Calibration not performed or expired.	Contact your Bio-Rad technical representative.
0x104917	During identification after an access, a sample block is detected as being different from the identification prior to the access.	Blocks exchanged by the operator.	Forbidden action during access to the pipetting area.
0x104918	When identifying a gel card, this one is detected as already used in the instrument (This case includes balancing cards. The software must return the gel card if this one has already been used as a balancing card in the instrument.).	Gel card already used.	1. Check the gel card barcode. 2. Discard the gel card if it was used,
0x104918	When identifying a gel card, this one is detected as already used in the system.	Gel card already used.	1. Check the gel card barcode. 2. Discard the gel card if it was used,
0x104919	During diluent rack first identification, the rack is detected still used in the instrument.	Still used diluent rack.	User error. Still used diluent rack insertion forbidden.
0x104920	During identification after an access, a diluent rack is detected as being different from the identification prior to the access.	Racks exchanged by the operator.	Forbidden action during access to the pipetting area.
0x104920	At identification during initialization of the instrument, a diluent rack is detected as being different from the identification prior to the stoppage.	1. Manipulation during stoppage.	Forbidden action when the instrument is stopped.
0x104920	At identification of a diluent rack while going into operating mode, the barcode of the rack is illegible (even after the second attempt).	1. Label damaged. 2. Vision station reading fault.	1. Check integrity of the barcode used. 2. Contact your Bio-Rad technical representative.

VISION STATION Error	Error description	Possible cause	Corrective actions
code 0x104925	Gel control not activated.	Gel control disabled by the user.	-
	Structure of the reagent vial barcode incorrect.	Incorrect or unknown barcode.	1. Check the vial barcode.
0x104926			2. Check if the corresponding APF is correctly loaded.
	During identification after an access, a sample	Tubes exchanged, added or withdrawn by the	Forbidden action during access to the pipetting area
0x104B05 0x104B04 0x104917	tube is detected as being different from the identification prior to the access, or as being missing or newly present.	operator.	
	Communication with the barcode reader failed	Barcode reader defective.	Contact your Bio-Rad technical representative.
0xmm030F 0x018904	during an identification sequence for a block of tubes.		

Appendix

This chapter contains additional content and forms such as the equipment and document list, decontamination certificate, tests executions and more.

A.1 Equipment List

Description	Quantity
IH-500	1
Fuse 6.3x32 time lag T 250v	2
Power cord 220 V	1
Keyboard	1
Keyboard fixing kit (Velcro fastener)	4
External barcode reader	1
Barcode scanner holder	1
Sample rack	5
Sample block with spring	10
Barcode label set	1
Reagent tray	1
Piercing tip	2
Gel cards block	8
Cleaning liquid container	1
Decontamination liquid container	1
System liquid container	2
Liquid waste container	2
Bin cover	1
Bottom of the solid wastes bin	1
Solid waste box	1
User Manual	1

A.2 Accessories

Description	Quantity
IH-500 optional table (with workstation and solid waste bin)	1
Battery pack	1
UPS (Uninterrupted Power Supply)	1

A.3 CE Compliance

This instrument is and in-vitro diagnostic medical device and complies with all applicable European Community Directives and associated harmonized standards, including but not limited to the standards pertaining to the electrical safety as well as the emission and immunity requirements as specified in IEC 61326-2-6.

A.4 Documents / Forms

A.4.1 Decontamination Certificate

The official decontamination certificate is available on Bio-Rad website, section «**distributors - secret area - official forms**».

IH-500 and its accessories must be cleaned and decontaminated before any of the following interventions:

- periodic maintenance;
- hardware upgrades or replacements;
- removing the instrument from service (long term storage);
- transportation;
- decommissioning.

Fill in the official electronic document of the decontamination certificate and place it on the instrument, in a conspicuous place.

The absence of the decontamination certificate may extend the time needed for revision and maintenance.

BIO-RAD

A.4.2 Maintenance Record

When a maintenance record is required (e.g. needle replacement), make a copy of this page and fill in the table.

Type

Page

Serial number

Maintenance / Defect	Action	Operator	Date

A.5 Spare Parts Ordering

Please contact the Bio-Rad Technical Support.

A.6 Device Disposal

- To protect the persons and the environment, any instrument and its accessories must be disposed of in an appropriate way. Its is mandatory to strictly apply laws and local bylaws relative to an appropriate disposal procedure.

- An instrument may only be dismounted and divided into its basic components by a qualified technician.

  Parts and sub-parts removed from an instrument may not be reused unless after having been approved in writing by the manufacturer. Any future application has to be precisely described in the request.

- Decontaminate the instrument before disposal.

Once the instrument is cleaned and decontaminated it should be disposed of according to locally binding regulations and guidelines. For more information and assistance, contact the Bio-Rad Technical Support.

A.7 List of Assays

A.7.1 Standard Assays

Refer to the appropriate Instruction for Use of gel cards for more details.

A.7.2 Assays for Titration

Refer to IH-Com User Manual for Titration testing.

A.8 Used 5 ml Vials brought back (Left Drawer)

DiaClon Anti-D for Dweak confirmation (09410)

Test serum M, N, S, s, Fya, Fyb for antigen profile III (set 45460)

Test serum Anti-S for ID-card (09010)

Test serum Anti-s for ID-card (09110)

Test serum Anti-Fya for ID-card (09210)

Test serum for Anti-Fyb for ID-card (09310)

Set of 6 vials for DiaScreen Prophylax (45660)

A.9 Samples Tubes Specifications

Any sample tube can be used with the appropriate sample rack. It must comply with the specifications mentioned in section Type of compatible Samples Tubes on page 40. The dimensions of the sample tube must meet the specifications described below.

A.9.1 ID n°1 - 11 (STAT) - Spherical Bottom Tubes

Sampling liquid: Serum-Plasma & Red Blood Cells

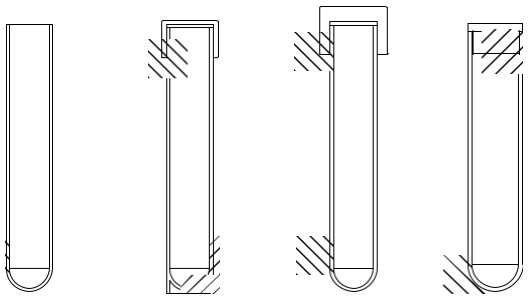

Figure 141.

Manufacturer	Reference	Nature Additive	Volume tube (ml)
TERUMO	VF-054SDK	EDTA K2	5.0
TERUMO	VF-052SDK	EDTA K2	5.0
TERUMO	VF-076SDK	EDTA K2	7.0
TERUMO	VF-109SDK	EDTA K2	10.0
TERUMO	VF-053SP	Clot activator	5.0
TERUMO	VF-076SP	Clot activator	7.0
TERUMO	VF-109SP	Clot activator	10.0
TERUMO	VP-109SURI	-	10.0
BD Diagnostics	367614	None	5.0
BD Diagnostics	368841	EDTA K2	5.0
BD Diagnostics	367864	EDTA K2	7.0
BD Diagnostics	367525	EDTA K2	10.0
BD Diagnostics	367862	EDTA K2	4.0
GREINER	454021	EDTA K3	5.0
GREINER	455036	EDTA K3	10.0
GREINER	454036	EDTA K3	5.0
GREINER	456038	EDTA K3	7.0
GREINER	TH5	None	5.0
GREINER	TH5PV	None	5.0
GREINER	TH5V	None	5.0
GREINER	VH1275E080	None	5.0
GREINER	TH5S	None	5.0
GREINER	TH5VS	None	5.0
GREINER	TCR10P	None	10.0
GREINER	LES004000	None	10.0
GREINER	TCR10S	None	10.0
GREINER	TCR10	None	10.0
GREINER	456003	EDTA K3	7.0
GREINER	454208	EDTA K2	5.0

Manufacturer	Reference	Nature Additive	Samples Tubes Specifications Volume tube (ml)
GREINER	456067	EDTA K3	7.0
GREINER	456074	EDTA K3	7.0
GREINER	456085	None	7.0
GREINER	454241	None	5.0
DIAMED	F000117 + D000171	None	5.0
DIAMED	F000117 + D000177	None	5.0
SARSTEDT	55.463	None	15.2
SARSTEDT	55.459 + cap 65.816	None	13.1
SARSTEDT	55.468	None	14.2
SARSTEDT	55.520 + cap 65.521	None	13.2
SARSTEDT	55.466 + cap 65.802	None	12.5
SARSTEDT	55.474	None	10.0
SARSTEDT	55.495	None	10.0
SARSTEDT	55.467	None	10.0
SARSTEDT	55.473	None	10.0
SARSTEDT	55.472 + cap 65818	None	6.8
SARSTEDT	55.475	None	5.0
SARSTEDT	55.468.001	None	14.2
SARSTEDT	60.541.003	None	15.1
SARSTEDT	60.541.545	None	15.1
SARSTEDT	60.514.014	None	15.1
SARSTEDT	60.540.052	None	15.1
SARSTEDT	60.610	None	10.0
SARSTEDT	60.506.001	None	10.0
SARSTEDT	60.550.109	None	7.0
SARSTEDT	60.540.686	None	14.8
SARSTEDT	62.551.201	None	10.0

A.9.2 ID n°2 - 12 (STAT) - Pediatric Tubes

Sampling liquid: Serum-Plasma & Red Blood Cells

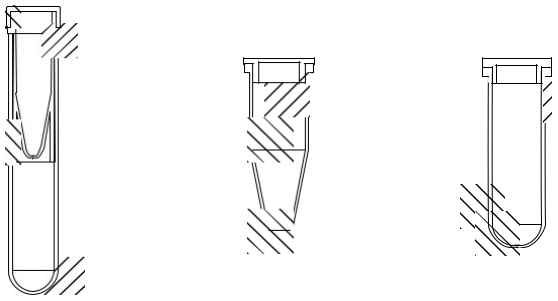

Figure 142.

Manufacturer	Reference	Nature Additive	Volume tube (ml)
SARSTEDT	72.703 + 55.475.005	None	0.62
EPPENDORF	0030 120.086	None	0.71
EPPENDORF	0030 120.094	None	1.29

A.9.3 ID n°3 - 13 (STAT) - Conical Tubes

Sampling liquid: Serum-Plasma & Red Blood Cells

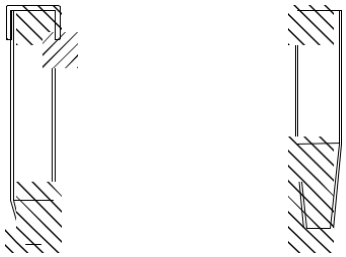

Figure 143.

Manufacturer	Reference	Nature Additive	Volume tube (ml)
GREINER	TCC16	None	9.2
GREINER	TC7512	None	7.1
SARSTEDT	57.462	None	12.0
SARSTEDT	57.469	None	10.0
SARSTEDT	62.9924.284	None	10.0

A.9.4 ID n°4 - 14 (STAT) - Flat Tubes (Plunger)

Sampling liquid: Serum-Plasma & Red Blood Cells

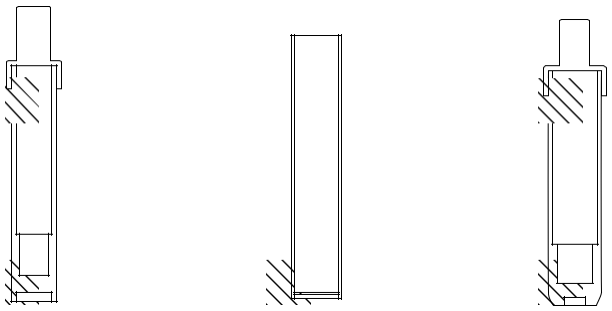

Figure 144.

Manufacturer	Reference	Nature Additive	Volume tube (ml)
SARSTEDT	04.1931.100	EDTA K3	4.9
SARSTEDT	04.1901.100	EDTA K3	2.6
SARSTEDT	03.1397.100	Serum bille	5.5
SARSTEDT	02.1063.100	Serum bille	9.0
SARSTEDT	05.1167	EDTA	2.7
SARSTEDT	03.1524	Serum bille	5.5
SARSTEDT	03.1397.001	Serum Z	5.5
SARSTEDT	04.1917	EDTA k	2.7
SARSTEDT	04.1904.001	Serum Z	2.6
SARSTEDT	04.1904.100	Serum bille	2.6
SARSTEDT	05.1167.100	EDTA KE	2.7
SARSTEDT	58.505	None	12.0

A.9.5 ID n°5 - 15 (STAT) - Special Flat Bottom Tubes

Sampling liquid: Serum-Plasma & Red Blood Cells

Figure 145.

Manufacturer	Reference	Nature Additive	Volume tube (ml)
SARSTEDT	60.9921.829	None	9.0
SARSTEDT	60.9921.821	None	9.0
SARSTEDT	62.617	None	3.0
SARSTEDT	60.613	None	3.0
SARSTEDT	62.612	None	4.0
SARSTEDT	62.611	None	4.0

A.9.6 ID n°6 - 16 (STAT) - Customizable “Low Volume” Tubes

Sampling liquid: Serum-Plasma & Red Blood Cells

1 sample tube of the previous list.

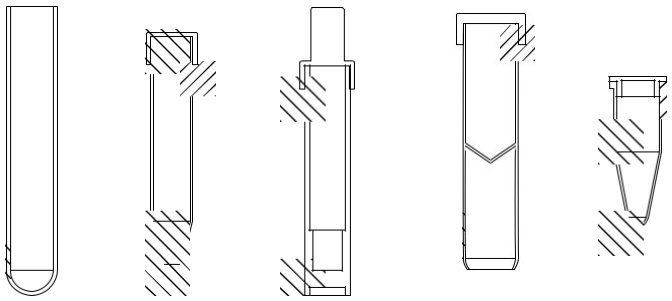

Figure 146.

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User Manager Module

This appendix describes:

the user manager module;

the user rights level configuration for the IH-500.

The User Manager module is required to define the IH-500 users and the related appropriate access rights. The IH-500 cannot be operated without registered users.

B.1 User Manager Module Overview

The User Manager Module is part of the IH-500 Software System. It is designed to:

- create, edit and delete users;
- define the user rights access for each user;
- set or reset the user password;
- define a password expiration date.

The user level description in this manual is according to the user management tables (manufacturer default settings) described in section User Rights Configuration on page 262:

- Level 1 = Basic;
- Level 2 = Advanced;
- Level 3 = Admin.

B.1.1 User Manager Startup

A Exit the IH-500 user interface to display the **Launcher**.

See chapter Exit on page 159.

B Start the **User manager**.

Figure 147. Launcher

The software initializes.

C Enter the username and the password.

***Administrator** or **Advanced** access level required.*

Save Validate.

The main screen is displayed. Refer to User Interface on page 259.

B.1.2 User Interface

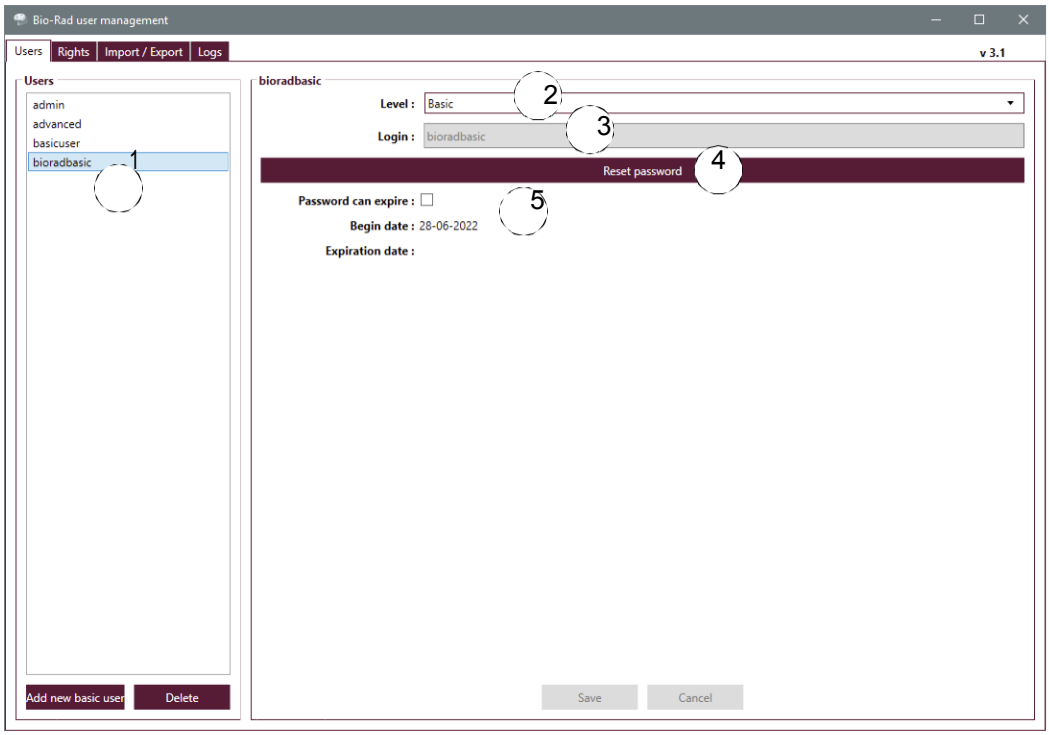

Figure 148.

Users list

The list displays only the users with the access level which can be managed by the logged user. For example, the list displays the users with:

advanced and **basic** access level for an administrator;

basic access level for an advanced user.

A basic user is not allowed to log in to the user manager software. An administrator can not see the other administrators registered in the user database.

Access **Level** of the selected user which are defined by:

Administrator

Advanced

Basic

Username for login

Once created, can not be changed.

Password reset for the selected user

When reset, the password is identical to the username. The user is requested to change it at the next login.

See chapter How to reset a Password on page 261.

Password expiration time

B.1.2.1 How to create a User

Add new... Create a user.

B Define the access level.

Advanced *or* ***Basic****.*

Enter an username in the field ***Login***.

D Check **Password can expire** to set a password expiration date.

Optional.

E Enter a expiration date.

If ***Password can expire*** *is active.*

Save Validate.

OK Confirm.

The new user is registered in the database. The password of the newly created user is identical to the username.

B.1.2.2 How to edit a User

Select the user from the **Users** list.

B Edit or change the user settings.

Access level or password settings.

The username can not be changed.

Save Validate.

The user settings are updated.

Cancel Cancel the changes.

The user settings are not updated.

B.1.2.3 How to delete a User

System users **advanced** and **basicuser** can not be deleted.

Select the user from the **Users** list.

Delete Delete the user.

A confirmation message is displayed.

OK Confirm.

The user is removed from the database.

B.1.3 How to reset a Password

Select the user from the **Users** list.

Reset

Reset the password.

OK

Confirm.

The user password is reset and identical to the username. The system will request the user to change the password at the next login.

B.1.4 User List Export/Import

The list of the users registered in one instrument can be copied or transferred to another instrument by exporting and importing the database.

A zip file is created when exporting the users data (File syntax: IH-500_yyyymmddhhmm.zip).

B.1.4.1 How to export the Users List

Export datas

Export the users list. *From the main screen.*

Select the folder to save the exported data.

OK

Confirm.

The zip file is created.

B.1.4.2 How to import an Users List

Import datas

Import the users list.

A file dialog appears.

Locate the zip file to import.

OK

Confirm.

The Users list is imported into the instrument database.

B.2 User Rights Configuration

The tables below describe the factory user rights configuration when the IH-500 is shipped.

Field service engineer access level required for any changes in the IH-500 user rights configuration.

B.2.1 Diagnostics

Right (description)	Admin	Advanced	Basic	Refer to chapter
Capture screen	x	x	x	4.2.1 on page 66
Login / logout	x	x	x	4.2.1 on page 66
Display backup options screen	x	x	x	8.9 on page 163
Use Acronis functions in backup screen	-	-	-	-
Exit software	x	x	-	8.8.1 on page 159
Launch service software	-	-	-	-
Execute weekly maintenance	x	x	-	10.8.3 on page 198
Execute change pipette needle	x	x	-	10.9 on page 201
Acknowledge robotic and components errors	x	x	x	8.6 on page 148
Initialize instrument	x	x	x	8.8.4 on page 162
Shutdown instrument	x	x	x	8.8.3 on page 160

B.2.2 Navigation

Right (description)	Admin	Advanced	Basic	Refer to chapter
Display software about screen	x	x	x	4.2.1 on page 66
Display Menu screen	x	x	x	4.5 on page 80
Display Resources on board screen	x	x	x	7.2.1 on page 96
Display Missing resources screen	x	x	x	8.3.5 on page 139
Display Tests without resources screen	x	x	x	8.3.4 on page 138
Display Tests in progress screen	x	x	x	8.4.1 on page 141
Display Tests to repeat screen	x	x	x	8.4.4 on page 145
Display Tests completed screen	x	x	x	8.4.2 on page 143
Display Gel card details screen	x	x	x	7.2.1.1 on page 98
Display Reagent details screen	x	x	x	7.2.1.2 on page 100
Display Diluent details screen	x	x	x	7.2.1.3 on page 102
Display Components screen	x	x	x	8.6 on page 148
Display Solutions / wastes screen	x	x	x	7.5.1 on page 123
Display Left drawer details screen	x	x	x	7.2.3.1 on page 108
Display Right drawer details screen	x	x	x	7.2.2.1 on page 105
Display Samples screen	x	x	x	7.4.1 on page 116
Display Options screen	x	x	-	9 on page 167
Display Profiles management screen	x	x	-	9.1.5 on page 179
Display last screen	x	x	x	4.2.1 on page 66
Display main screen	x	x	x	4.2.1 on page 66
Display APF management screen	x	-	-	9.1.4 on page 177
Display Samples management screen	x	x	x	8.3.3.1 on page 134

B.2.3 Profile Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Save profiles	x	x	-	9.1.5 on page 179

B.2.4 I/O Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Release solid waste	x	x	x	7.5.1 on page 123
Open left drawer	x	x	x	7.2.3 on page 107
Open right drawer	x	x	x	7.2.2 on page 104
Remove sample rack	x	x	x	7.4.7 on page 120
Remove all sample racks	x	x	x	7.4.6 on page 120
Switch internal light ON / OFF	x	x	x	8.6 on page 148
Open pipetting area	x	x	x	8.6 on page 148

B.2.5 Log

Right (description)	Admin	Advanced	Basic	Refer to chapter
Display full log information	-	-	-	-

B.2.6 DMS APF Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Import APF	x	-	-	9.1.4 on page 177
Set APF separate dilution setting	x	-	-	9.1.4 on page 177
Change DMS connection parameters	x	-	-	9.1.7 on page 182
Remove APF	x			9.1.4 on page 177

B.2.7 Samples Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Search sample barcode	x	x	x	4.2 on page 65
Ignore samples with errors	x	x	x	7.4.1 on page 116
Manual sample barcode input	x	x	x	7.4.1 on page 116
Flag / Unflag a priority sample	x	x	x	7.4.1 on page 116
Confirm absence of sample cap	x	x	x	7.4.1 on page 116
Associate a profile to a sample	x	x	x	8.3.3.1 on page 134

B.2.8 Tests Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Repeat tests	x	x	x	8.4.4 on page 145
Send results of a selected tests to DMS	x	x	x	8.4.2 on page 143
Stop all	x	x	x	8.8.2 on page 160

B.2.9 Resources Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Remove selected gel cards	x	x	x	7.2.1.1 on page 98
Remove all of selected type	x	x	x	7.2.1.1 on page 98
Remove selected diluent rack	x	x	x	7.2.1.3 on page 102
Remove selected reagents	x	x	x	7.2.1.2 on page 100

B.2.10 Options

Right (description)	Admin	Advanced	Basic	Refer to chapter
Change default profile to associate to samples	x	x	-	9.1.1.2 on page 169
Change default profile to associate to priority samples	x	x	-	9.1.1.2 on page 169
Change gel card control flag	x	-	-	9.1.2.1 on page 171
Change return gel cards flag	x	-	-	9.1.2.1 on page 171
Change timeout before ignoring samples errors (automatically)	x	-	-	9.1.1.3 on page 170
Change weekly hydraulic maintenance blocking flag	x	-	-	9.1.3.2 on page 175
Timeout in seconds before returning samples for manual input	x	-	-	9.1.7 on page 182

B.2.11 Error Management

Right (description)	Admin	Advanced	Basic	Refer to chapter
Error management view	x	x	-	8.7 on page 152
Transport Arm Acknowledgement View	x	-	-	8.7.3 on page 157
Transport Arm Acknowledgement with object in gripper	x	-	-	8.7.3 on page 157
Acknowledge or Initialize robotic module	x	-	-	8.7 on page 152
Initialize all robotic module	x	-	-	8.7 on page 152
Allow priming in Error management view	x	-	-	8.7.1 on page 154

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Notes

Bio-Rad Laboratories

Clinical Diagnostics Group

Website *www.bio-rad.com/diagnostics* ***Australia*** *61-2-9914-2800* ***Austria*** *43-1-877-8901* ***Belgium*** *+32 (3)710-53-00* ***Brazil*** *+55 (31)3689-6600* ***Canada*** *1-514-334-4372* ***China*** *86-21-61698500* ***Czech Republic*** *420-241-430-532* ***Denmark*** *+45-4452-1000* ***Finland*** *358-9-804-22-00* ***France*** *33-1-47-95-60-00* ***Germany*** *+49 (0)89-318-840* ***Greece*** *30-210-7774396* ***Hong Kong*** *852-2789-3300* ***Hungary*** *+36-1-459-6100* ***India*** *1800-180-1224* ***Israel*** *972-3-9636050* ***Italy*** *+39-02-216091* ***Japan*** *81-3-6361-7070* ***Korea*** *82-2-3473-4460* ***Mexico*** *+52 (55)5488-7670* ***The Netherlands*** *+31-318-540666* ***New Zealand*** *64-9-415-2280* ***Norway*** *+47-23-38-41-30* ***Poland*** *48-22-3319999* ***Portugal*** *351-21-472-7700* ***Russia*** *+7-495-721-1404* ***Singapore*** *65-6415-3170* ***South Africa*** *27-11-442-85-08* ***Spain*** *34-91-590-5200* ***Sweden*** *+46-8-555-127-00* ***Switzerland*** *+41 (0)26-674-55-05/06* ***Taiwan*** *886-2-2578-7189* ***Thailand*** *662-651-8311* ***United Kingdom*** *+44 (0)20-8328-2000*