PREVI™ Isola

USER MANUAL

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BIOMÉRIEUX

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Revisions

The list of revisions below summarizes replacements or additional pages in your User Manual.

Version	Date of printing	Modifications	Pages modified
A	10/2008	Creation	All
B		Not used	
C	03/2009	– New software version	All
		– Deletion of Modify button	2-24
		– Addition of information for loading labels	4-16
		– Modification to Figure 4-21 : Barcode (DOB removed)	4-25
		– Correction of folder name in Instrument Log Files section	7-6
		– New Maintenance Menu screenshot	8-2
		– New order for performing maintenance operations	8-3 to 8-20
		– Deletion of Label roll length sensing procedure	8-28
		– Deletion of severity column in List of Error Messages	9-1 to 9-9
		– Addition of Event no. 20110 in List of Error Messages	9-6
		– Addition of Event no. 35026 in List of Error Messages	9-9
		– Additions to Error, Cause and Recovery table	9-11 to 9-14
		– Updated procedure for replacing the **PREVI^{TM} Isola** HEPA filter	9-18 to 9-22
		– New procedure for pipettor decontamination	9-23 to 9-24
		– New procedure for reinitializing the instrument after the pipettor descends into a plate on the process station	9-25

Warning

The contents of this manual are based on the software release V 1.1.

This manual is periodically updated. The updates shall be included in the new releases of the Software.

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Screenshots and figures are given for information purposes only.

List of Tables

2. Description

4. Using the System

1 How to use this Manual

This manual provides the appropriate instructions to install, operate and maintain the **PREVI Isola.**

CAUTION! ***The user is advised to read and understand all the instructions in this manual to be able to derive the best performance from the PREVI Isola.***

Finding topics and procedures

This manual is divided into 12 chapters.

Table of contents The Table of Contents of the manual is located on pages I-1 to I-6. It lists each chapter and the procedures and/or topics contained in the chapter.

List of figures Pages II-1 to II-4 contain a list of the figures in this manual.

Page headers and page footers Apart from the first page of every chapter, each page of this manual includes a page header and a footer.

Each page header includes the chapter title and the title of a procedure or its corresponding description.

The footers contain the name of the product, the title of the manual, and a page number.

Glossary The glossary is located in Chapter 12. It gives the definition of the main technical terms used in the manual.

Warnings

Different types of warnings are used throughout the manual:

- For safety reasons (***DANGER!***).
- To ensure that the instrument is maintained in good working condition (***CAUTION!***).
- For regulatory reasons (***WARNING!***) or,
- For optimum performance of operations, procedures, etc. (***IMPORTANT!***).

Please also read the "**General safety and regulatory information**" booklet provided with the instrument.

2 Description

Intended Use

The **PREVI Isola** is an automated device intended to perform the inoculation and streaking of Prepoured Media (PPM) with liquid microbiological samples.

System Capabilities

The **PREVI Isola** has been designed to allow the user:

- to load between 1 and 114 samples for processing,
- to load up to 150 plates.

The **PREVI Isola**:

- provides automated PPM inoculation,
- provides automated streaking of PPM,
- delivers 180 plates per hour of operation, based on a protocol of 2 plates/sample,
- ensures there is no possibility of cross-contamination during the process,
- is equipped with a **PREVI Isola** HEPA filter to avoid contamination in the laboratory during processing.

Workflow Principle

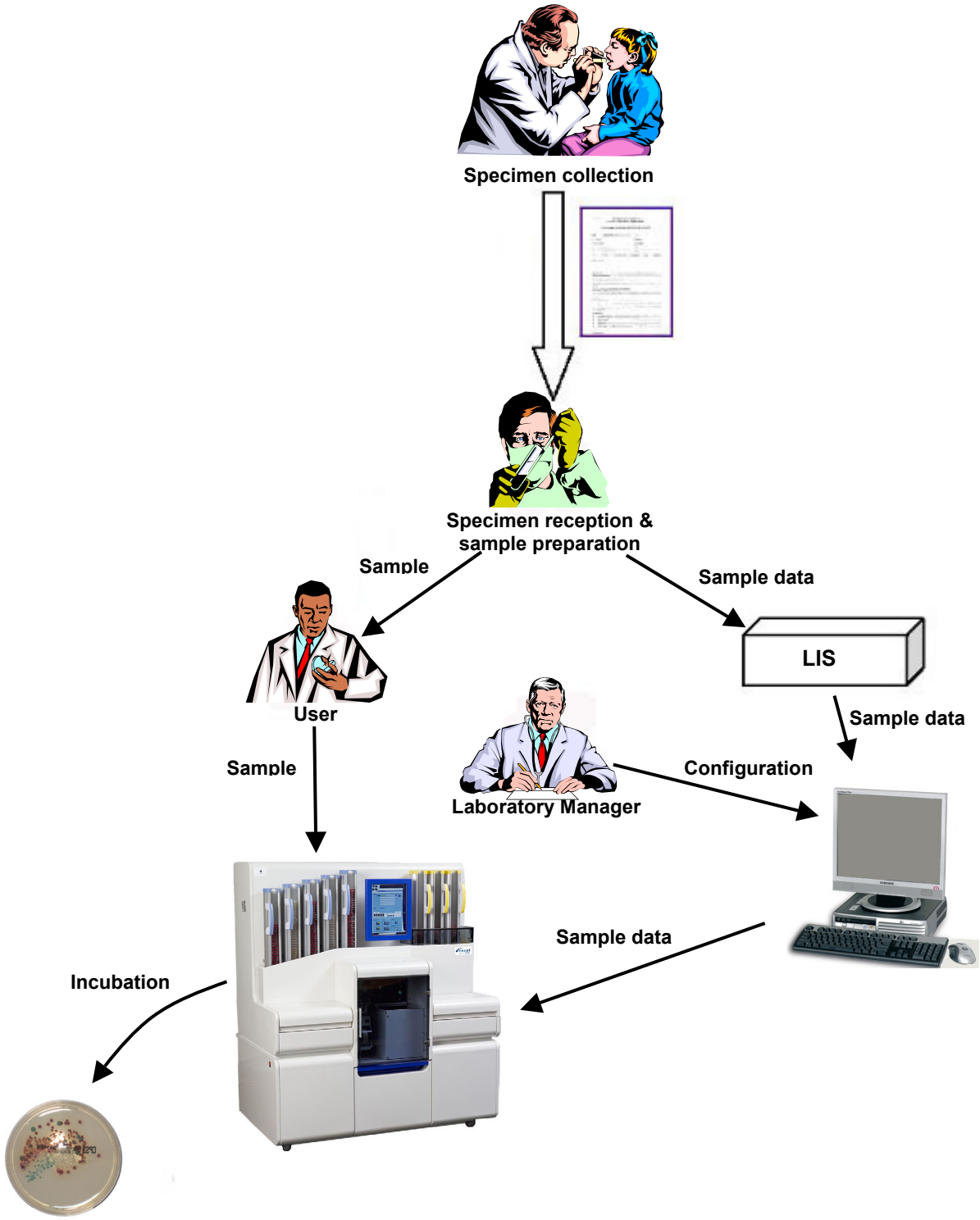


Figure 2-1 : Workflow Principle

System Architecture

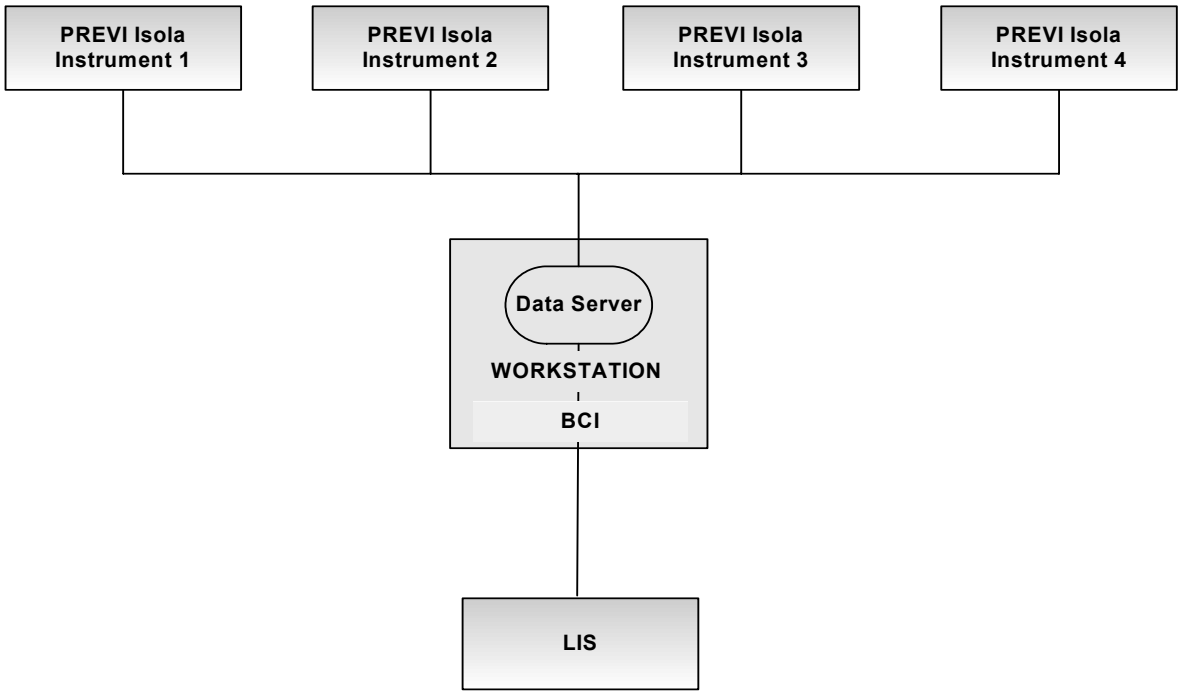


Figure 2-2 : System Architecture

LIS	Laboratory Information System.
BCI	Bi-directional Computer Interface, a bridge to LIS.
Workstation	User interface application which runs on a PC that is separate from the instrument.
Data Server	The database holding amongst other things, the plate panel definitions, and the sample assignments.
PREVI Isola	The plate processing instrument.

*Note: Four **PREVI Isola** instruments can be connected to a workstation.*

System Components

The main system components are:

- an instrument (1) with an internal computer and a touch-screen
- a standalone computer - workstation (5)
- a UPS (optional)
- two types of cassettes (input (2), output (3))
- five types of sample racks (4)
- consumables (**PREVI Isola** Applicators, **PREVI Isola** Tips, **PREVI Isola** Labels, **PREVI Isola** Waste Bins)
- a waste paper bin (for label backing) (6)

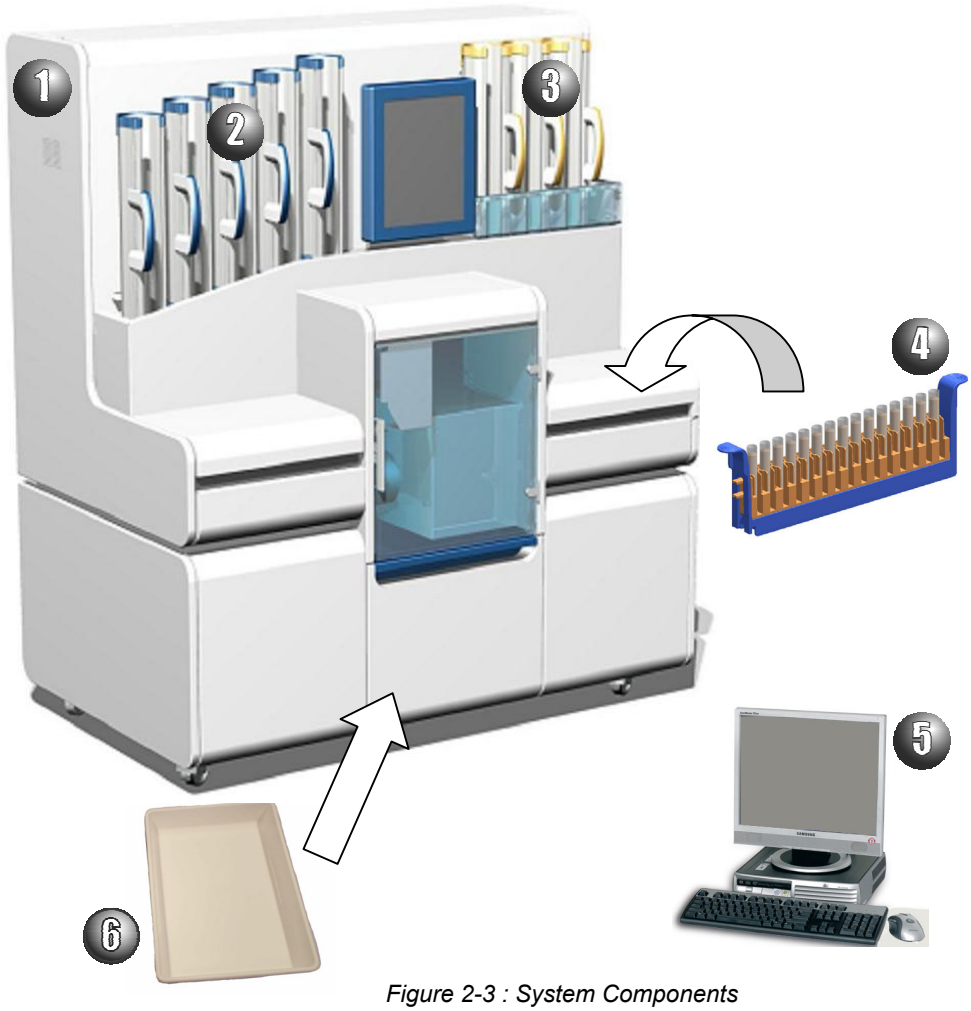


Figure 2-3 : System Components

Workstation

Description

The workstation is composed of:

- 1 computer
- 1 screen
- 1 keyboard
- 1 mouse
- 1 barcode reader
- 1 printer (optional)

*Note: Since the **PREVI Isola** system operates on a Microsoft Windows OS, it can be connected to an external printer compatible with Microsoft Windows.*

To validate this printer, please perform the Printer Verification Protocol, page 6-14.

Instrument

*Figure 2-4 : Front view of the **PREVI Isola** with covers on*

1. **Consumable lid**
   Provides access to the consumables tray for loading/unloading of tips and applicators.
2. **Process station lid** (nose cone and center cover).
   Provides access to the processing area for wiping down the process stations.
3. **Printer access door**
   Provides access for loading labels into the printer.
4. **Output cassette guard**
5. **Sample lid**
   Provides access to the sample loading bay for loading/unloading of sample racks.
6. **Waste drawer**

CAUTION! ***The PREVI Isola contains moving mechanisms. Do not remove the process station lid while the instrument is in operation.***

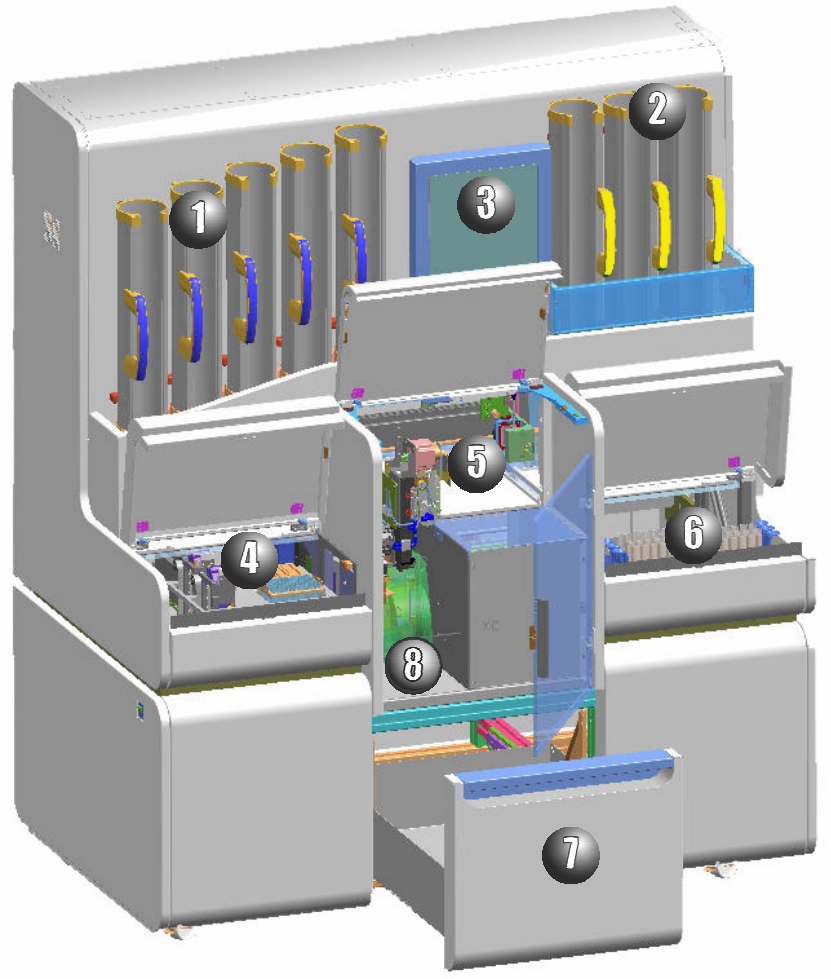


*Figure 2-5 : Front view of the **PREVI Isola** – front covers removed*

1. **Input cassette**
2. **Output cassette**
3. **LCD touch-screen and graphic user interface**
4. **Consumables tray**
5. **Plate process station**
6. **Sample loading bay with rack tray**
7. **Waste drawer**
8. **Label printer**

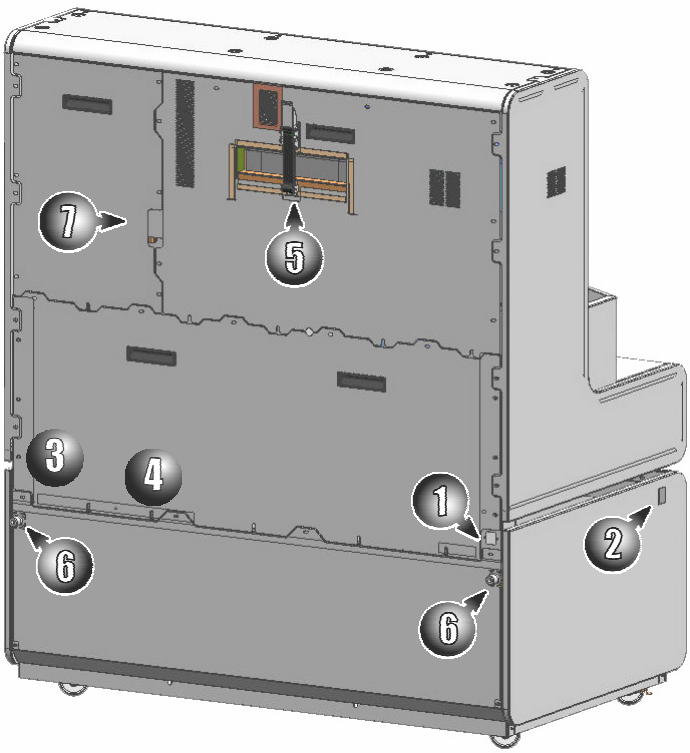


*Figure 2-6 : Back view of the **PREVI Isola** with covers on*

1 **Power connection socket**
A standard socket for power connection is located on the lower right-hand side of the rear panel for connecting to main power. The power connection socket contains two fuses.

2 **Power ON switch**
The Power ON switch is located on the left-hand side of the **PREVI Isola**.

3 **Rating plate**
The rating plate details essential regulatory information.

4 **Serial number**
This number is unique to each instrument and should be quoted when requesting technical support.

5 **PREVI Isola HEPA filter location**

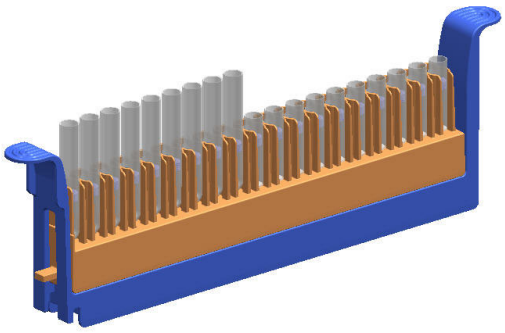
6 **Wall bumpers**
The two wall bumpers fitted to the rear of the instrument provide minimum safe spacing from the wall.

7 **USB Ports**

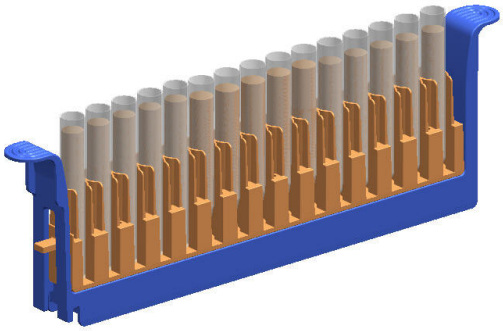
Sample racks

Test samples are loaded in racks designed to accept one of eight types of tubes, when the sample tray presents to the front right-hand side of the **PREVI Isola**.

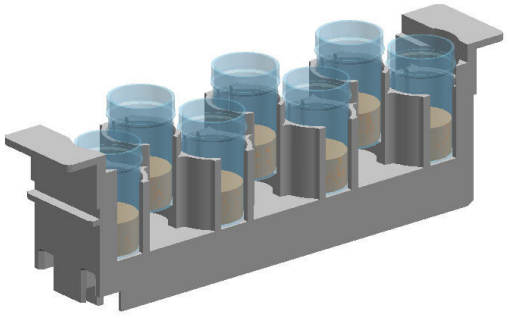
Each type of rack has an associated aspiration height.



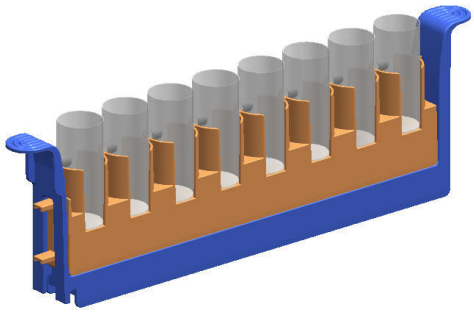
PREVI Isola *Rack 1*



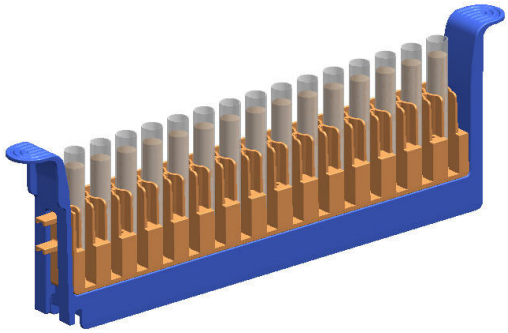
PREVI Isola *Rack 2*



PREVI Isola *Rack 4*



PREVI Isola *Rack 5*



PREVI Isola *Rack 6 (Swab)*

Figure 2-7 : Sample racks

Sample tubes

Tubes compatible for use with the PREVI Isola

Tube Description	Supplier's Part Number	Rack Name	Volume (ml)	Total Height (mm)	Min Volume µL	Min Height mm	Max Volume µL	Max Height mm	Diameter (mm)
Sterilin (Barloworld) 2mL Tube	NA2	1	2	48.5	1900	18	2500	5	11.5
Greiner VITEK® 2 tube (same dimensions as Sarstedt Haemolysis Tube)	69285	1	6	74.6	1900	48.9	2900	35.6	12.8
ESwab	480CE	6	1	80	1000	69	4000	40	13
Sarstedt Monovette Tube*	10.252 & 10.253	2	10	102	6000	50	9000	24	15
Sarstedt 10 mL tube	62.9924.283	2	10	100	5500	50	9000	21	16
Becton Dickinson Vacutainer	364948	2	10	100	6500	45	10000	20	16
Starplex Urine Container	B902.10	4	90	76	33000	50	70000	22	43
Sarstedt Pot	TP 30-001 or TP 30-004	5	40	69.2	18000	41	37000	10	29.8

**** IMPORTANT!*** ***With Sarstedt Monovette tubes, if the sample volume is small, the plunger should not be pushed up over the 6 ml mark otherwise the pipettor will collide with the plunger.***

Fill heights

The Maximum Fill Height (measured from the top of the tube) is defined so as not to pollute the pipettor body.

The Minimum Fill Height (measured from the top of the tube) is defined to enable the pipettor to aspirate 95 µL.

IMPORTANT! ***Tubes must never be filled above the maximum fill height as this would affect pipettor performance.***

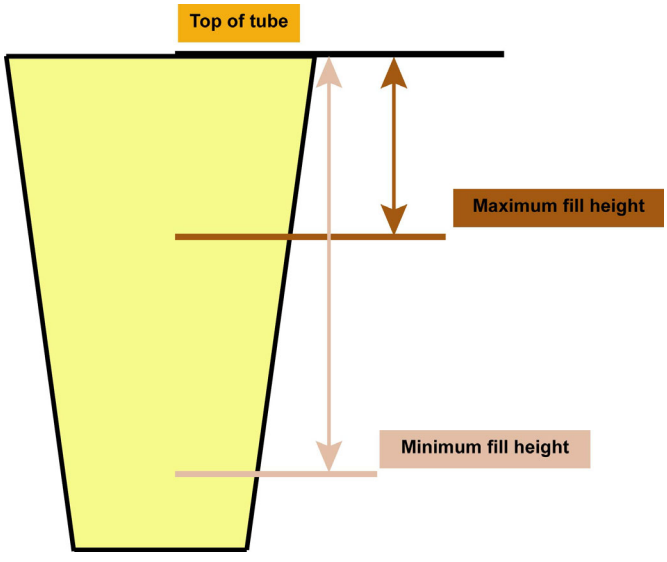


Figure 2-8 : Fill heights

Prepoured media (Plates)

Plates compatible for use with the PREVI Isola

The instrument supports round plates and bi-plates with a 90 – 94 mm outer diameter and a total plate height of between 13.6 mm and 16 mm.

For plates with a nesting feature, please contact bioMérieux S.A. or your local bioMérieux representative.

Input cassettes

The **PREVI Isola** is equipped with five input cassettes. Input cassettes are blue.

Plates are loaded into the input cassettes agar-side up.

Each cassette is designed to hold up to 30 plates and the plates are loaded into the cassettes according to the agar type. The agar type is displayed on the **PREVI Isola** touch-screen as are the details of incubation requirements for completed plates.

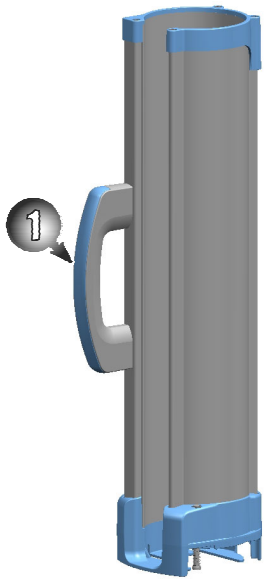


Figure 2-9 : Input cassette – front

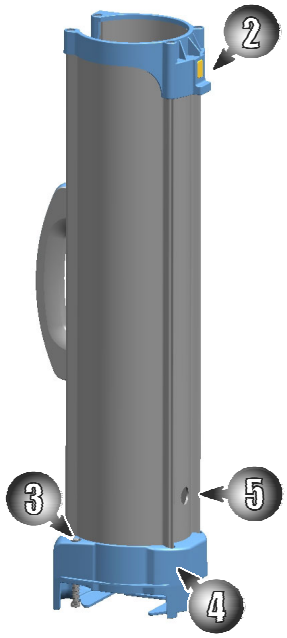


Figure 2-10 : Input cassette – back

1. **Handle**
2. **Cassette lock**
3. **Plate retention pin**
4. **Input cassette base**
5. **Plate level sensor window**

IMPORTANT! ***Input cassettes will only fit in the input-side positions and output cassettes will only fit in output-side positions.***

Output cassettes

The **PREVI Isola** is equipped with three output cassettes. Output cassettes are yellow.

On completion of processing, plates are stored, agar-side up, according to the incubation type, in the output cassettes.

Each output cassette is designed to hold up to 30 plates.

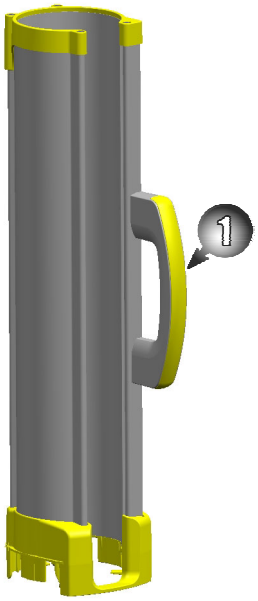


Figure 2-11 : Output cassette - front

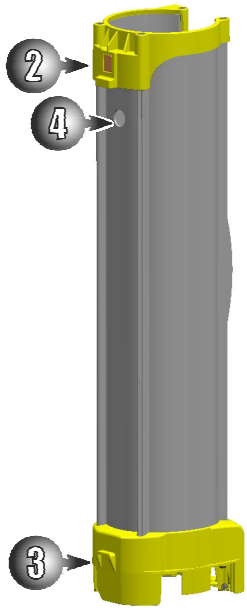


Figure 2-12 : Output cassette - back

1. **Handle**
2. **Cassette lock**
3. **Output cassette base**
4. **Plate level sensor window**

IMPORTANT! ***Input cassettes will only fit in the input-side positions and output cassettes will only fit in output-side positions.***

Touch-screen

The **PREVI Isola** touch-screen is used to operate the instrument and inform the user of the progress of streaking and the availability of consumables.

Figure 2-13: Touch-screen

PREVI Isola Waste Paper Bin

The **PREVI Isola** includes a waste paper bin for the label backing.

*Figure 2-14 : **PREVI Isola** Waste Paper Bin*

Waste drawer

The waste drawer provides access to the **PREVI Isola** Waste Bins.

The instrument includes two different types of waste bins:

- one for biohazardous waste (**PREVI Isola** Tips and **PREVI Isola** Applicators),
- one for waste paper (label backing).

Waste applicators and tips are disposed of down a waste chute which ensures that the biocontaminated tips and applicators are disposed of properly.

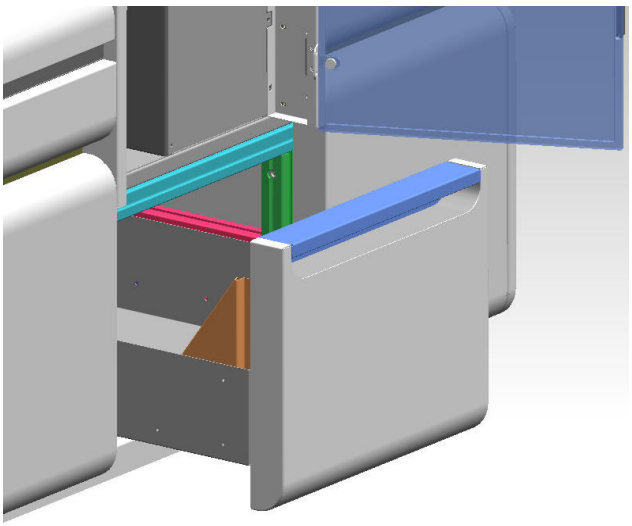


Figure 2-15 : Waste Drawer

Interlocks

The following **PREVI Isola** covers are equipped with interlocks for safety reasons:

- Consumable lid
- Process station lid
- Sample lid
- Output cassettes guard
- Printer access door
- HEPA filter latch

The process station lid should not be opened during operation.

The output cassette guard stops the instrument if it is opened during operation.

If the sample lid and consumable lid are opened during processing, a warning is generated but the instrument is not stopped.

CAUTION! ***Do not bypass interlock systems for any reason. Interlock systems are a safety feature designed to protect the user from injury and the instrument from damage.***

The waste drawer is not equipped with an interlock. Nevertheless, it should not be opened during processing.

Consumables

PREVI Isola Applicators

PREVI Isola Applicators are single use microbiological sample applicators designed to streak agar plates

*Figure 2-16 : **PREVI Isola** Applicator*

*Note: **PREVI Isola** Applicators are designed for single use. The **PREVI Isola** automatically discards used applicators to the **PREVI Isola** biohazardous Waste Bin. Discarded applicators may be biohazardous.*

PREVI Isola Applicator cartridge

PREVI Isola Applicator cartridge supplier	Part Number
bioMérieux	29509

PREVI Isola Applicator cartridges are pre-loaded with 120 **PREVI Isola** Applicators. They are designed for single-use.

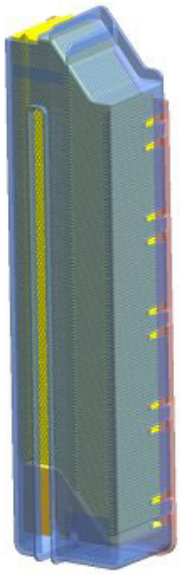


*Figure 2-17 : **PREVI Isola** Applicator cartridge*

PREVI Isola Tips

PREVI Isola Tips supplier	Part Number
bioMérieux	29508

The **PREVI Isola** Tips are designed for single use (1 tip = 1 sample).

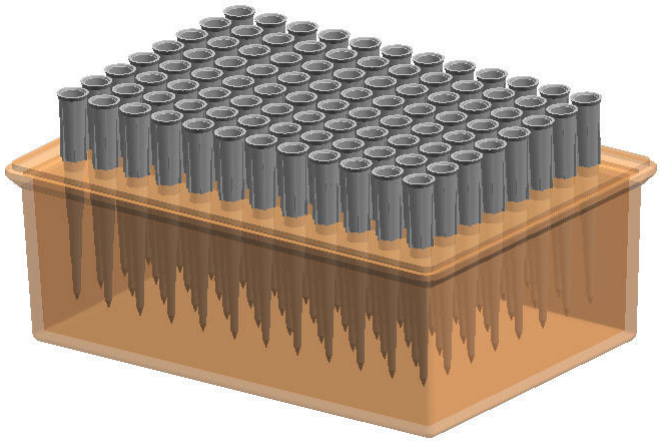


Figure 2-18 : ***PREVI Isola*** *Tips in tray*

Note: ***PREVI Isola*** *Tips are designed for single use. The* ***PREVI Isola*** *automatically discards used tips to the* ***PREVI Isola*** *biohazardous Waste Bin. Discarded tips may be biohazardous.*

IMPORTANT! ***The PREVI Isola must be used with PREVI Isola Tips only.***

PREVI Isola Labels

A barcode label (30mm x 25mm), machine and human readable, is applied to the base of each plate after completion of processing and prior to re-inversion of the base and re-application of the lid.

IMPORTANT! ***The PREVI Isola must be used with PREVI Isola Labels only.***

PREVI Isola Labels supplier	Part Number
bioMérieux	29720

PREVI Isola biohazardous Waste Bin

bioMérieux recommends the use of the following type of bin for biohazardous waste:

PREVI Isola biohazardous Waste Bin supplier	Part Number
bioMérieux	29718

PREVI Isola HEPA filter

The High Efficiency Particulate Air (HEPA) filter removes airborne particles from within the **PREVI Isola**.

PREVI Isola HEPA filter supplier	Part Number
bioMérieux	29711

Instrument Operating Principle

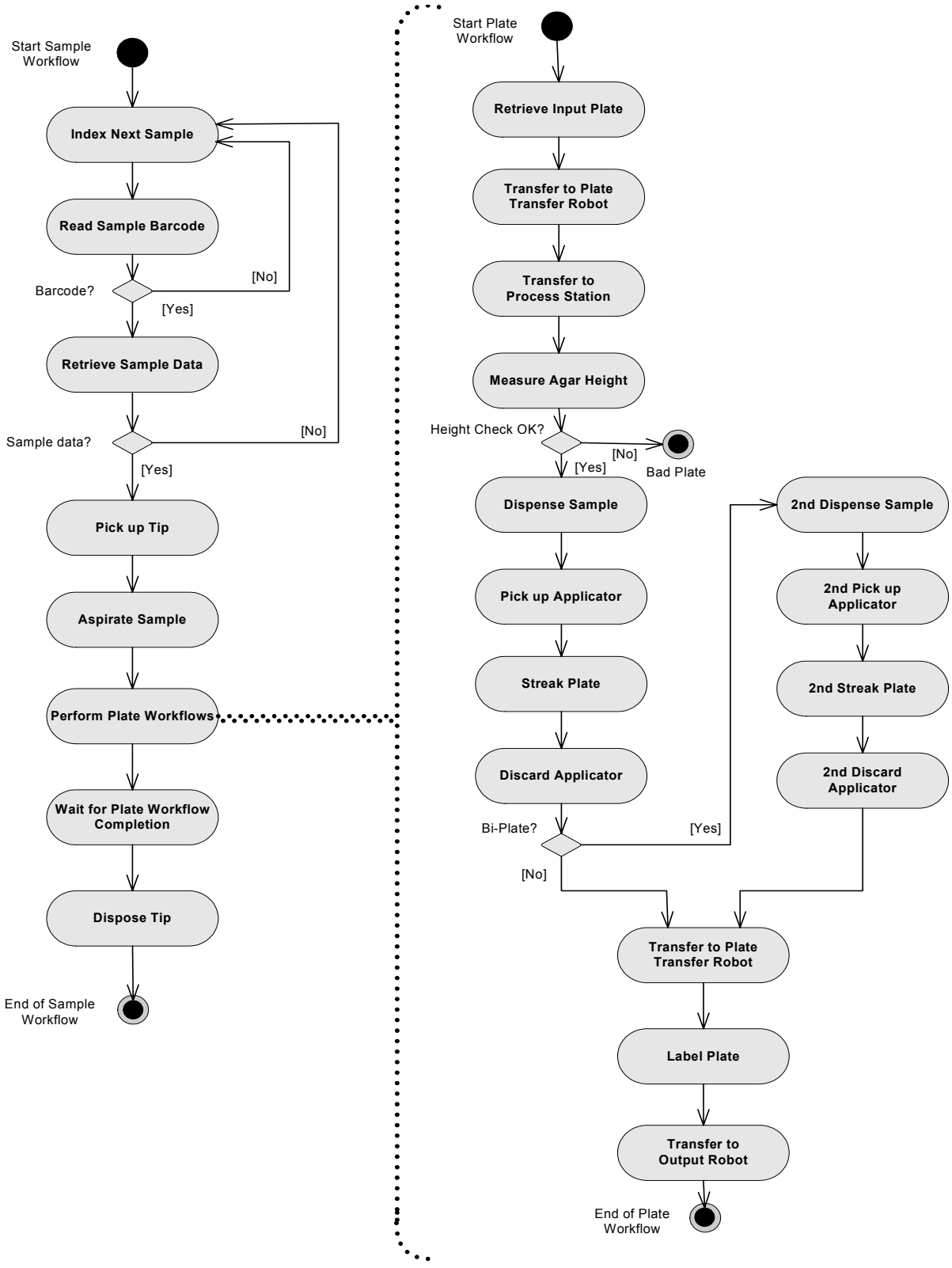


Figure 2-19 : Simplified sample workflow

Index next sample

The instrument indexes the next sample in the sample tray.

Read sample barcode

The sample tube is presented before an internal barcode reader in order to read the tube barcode and identify the sample.

The internal barcode reader can read the following barcode formats:

- UPC
- EAN
- JAN
- Code 128
- Code 39
- ITF
- Codabar
- Code 93

The quality of the barcode label can affect the scanning performance. Poor quality labels are more difficult to decode and may result in non-reads or potential misreads. The barcode label should be printed to specifications. This means that the bars are printed within spec, with the correct widths, no ink spread, crisp edges and no voids. There should be sufficient quiet zone (white space) on both ends of the barcode label. For best results, the paper or label stock should have matte finish to diffuse light. The print contrast signal (which is a comparison of the reflectance of the bars and the background stock) should be as high as practical.

The instrument is configured to work best with barcodes where the line width is between 7.5 and 10 mil. This is determined by the distance from the barcode scanner to the barcodes.

Each barcode label should be affixed vertically on an upright tube with a maximum alignment of +/- 4° in relation to the vertical axis of the tube.

The position of the label on the upright tube does not affect the reading. Preferably affix the label in the middle of the tube as indicated below.

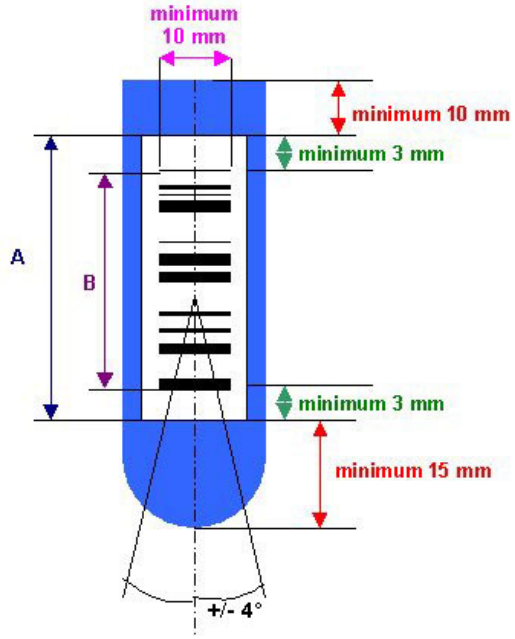


Figure 2-20 : Positioning a barcode label on a tube

A = Maximum label size which depends on the tube (see the following table).

B = Maximum barcode symbols size which depends on the tube (see the following table).

Tubes	Rack name	Tube Height (mm)	A[mm]	B[mm] for (7.5mil)	B[mm] for (10mil)
Sterelin 2mL	1	48.5	24	19.5	17.5
Greiner VITEK® 2	1	74.6	49	45.6	43.6
ESwab	6 (Swab)	80	55	51	49
Sarstedt Monovette Tube (10mL)	2	102	77	73	71
Sarstedt Tube (10mL)	2	100	75	71	69
BD Vacutainer (10mL)	2	100	75	71	69
Starplex Urine Container (90mL)	4	76	51	47	45
Sarstedt Pot (40mL)	5	69.2	44	40.2	38.2

Retrieve sample data

After reading the tube barcode, the instrument software requests the Data Server for sample Information in order to process the sample.

If the sample is identified, the Data Server returns the streaking parameters for this sample (i.e. plate panel and streaking protocol).

If the sample is not identified, it is skipped by the instrument and the instrument indexes the next sample.

Pick up tip

The electronic pipettor is mounted on the pipettor robot. The pipettor robot picks up the tip to be used for sample aspiration.

Aspirate sample

Sample aspiration is performed by the electronic pipettor.

The pipettor using the tip, aspirates samples from pre-defined depths within sample tubes.

Before aspiration, the camera detects the presence of a tip. Should the camera report the absence of a disposable tip, the pipettor continues to return to the tip tray until a disposable tip is retrieved.

After aspiration, the camera detects the sample presence.

After aspiration the workflow continues with the processing of the plates for the sample.

Perform plate workflow

Retrieve input plate

The plate input robot (left-hand side) retrieves agar plates from the input cassettes for delivery to the plate transfer robot.

Transfer to plate transfer robot

The plate transfer robot accepts agar plates retrieved from the input cassette by the plate input robot.

Transfer to process station

The plate transfer robot removes the lids by suction, maintains lid orientation, inverts the base of the plates and delivers them to the process station for inoculation and streaking.

The plate process station holds the agar plates in position for ultrasonic detection of agar height and plate orientation (whole or half-plate presence) before inoculation and streaking can occur.

Measure agar height, dispense sample

An ultrasonic measurement device reports the distance between the tip and the agar plate and the pipettor then delivers the aspirated sample to the agar plate and disposes the tip to waste. The aspirated samples are delivered to the agar surface from an internally predefined height. The total volume dispensed is no more than 95 µL and the number of plates streaked with a single sample depends on the volume per plate which can be 10 µL or 20 µL.

Pick up applicator

Applicators are retrieved from the applicator cartridge by the applicator robot and positioned over an inoculated agar plate for streaking. An applicator presence sensor reports applicator presence.

Should the presence sensor report the absence of an applicator, the applicator robot continues to return to the applicator cartridge until a disposable applicator is retrieved.

The applicator is picked up at the same time as the agar height is measured and the sample dispensed.

Streak plate

The plate process station rotates to a maximum of 330° during the streaking process. Half-plate rotation is to a maximum of 110°.

Discard applicator

After plate streaking the applicator is discarded to waste.

If Bi – plate

If the processed plate is a bi-plate, the sample is dispensed a second time on the other half of the plate.
The applicator robot picks up another applicator and the plate is streaked on the second half. When streaking is complete the applicator is discarded.

Transfer to transfer robot

On completion of inoculation and streaking, the plate transfer robot accepts the processed plate bases from the process station for barcode labeling, re-inversion of the bases and return of the lids.

The plates are then delivered to the plate output robot for stacking into the output cassettes agar side up.

Label plate

Plate barcode labeling is carried out by the barcode printer installed in the **PREVI Isola** below the plate transfer robot.

A barcode label is applied to the base of each plate after completion of processing and prior to re-inversion of the base and re-application of the lid.

Transfer to output robot

The plate output robot (right-hand side) transports processed plates from the plate transfer robot to the output cassettes.

Dispose of tip

On completion of the plate panel for a sample, the tip is disposed of by the pipettor robot into the biohazardous waste bin.

Workstation Software

Principle

The **PREVI Isola** needs to know what types of plates are to be streaked and what type of incubation atmosphere they require. This is defined by plate panels which are assigned to specimen types (see Assigning Plate Panels to Specimen Types, page 3-15) or samples (see Assigning Plate Panels to Samples, page 3-22).

If a plate panel has been assigned to a specimen type, it will automatically be assigned to all the samples of this specimen type when they are received from the LIS through BCI (see Automatically Assigning Plate Panels to Samples, page 3-18). However, this assignment can also be changed manually for individual samples (see Assigning Plate Panels to Samples, page 3-22).

The **PREVI Isola** also needs to know in which input cassette each plate type is available and which output cassette is assigned to each incubation type. This is defined by plate cassettes configurations (see Defining Plate Cassettes Configurations, page 3-19 and Selecting Plates, page 4-5).

The workstation software is an application running on the laboratory computer used to assign test panels to samples for processing by the **PREVI Isola** and to monitor sample processing status logs.

General screen layout

All the screens of the workstation software have the same general layout:

Figure 2-21 : General screen layout

Each screen is composed of four parts:

1. **Menu bar**
2. **Title and button bar**
3. **Working area**
4. **Status bar**

Menu bar

The menu bar includes three menus with submenus:

Samples	Configuration	Help
– Assign Samples	– Plate Panels	– About
– Show Worklist	– Specimen Types	
	– Plate Cassettes Configuration	
	– General Settings	

Title and button bar

The title and button bar displays the title of the submenu selected from the menu bar.

It also contains buttons to perform actions.

Button							
Name	Add a row	Delete	New	Print	Save	Validate	Undo

Table 2-1 : Workstation software buttons

Working area

The working area is different for each screen.

Status bar

The status bar displays the user's login and a button  for quitting or changing users.

Instrument Software

The instrument software allows the user to operate the instrument through a graphical interface.

Main screen and general layout

All the screens of the instrument software have the same general layout.

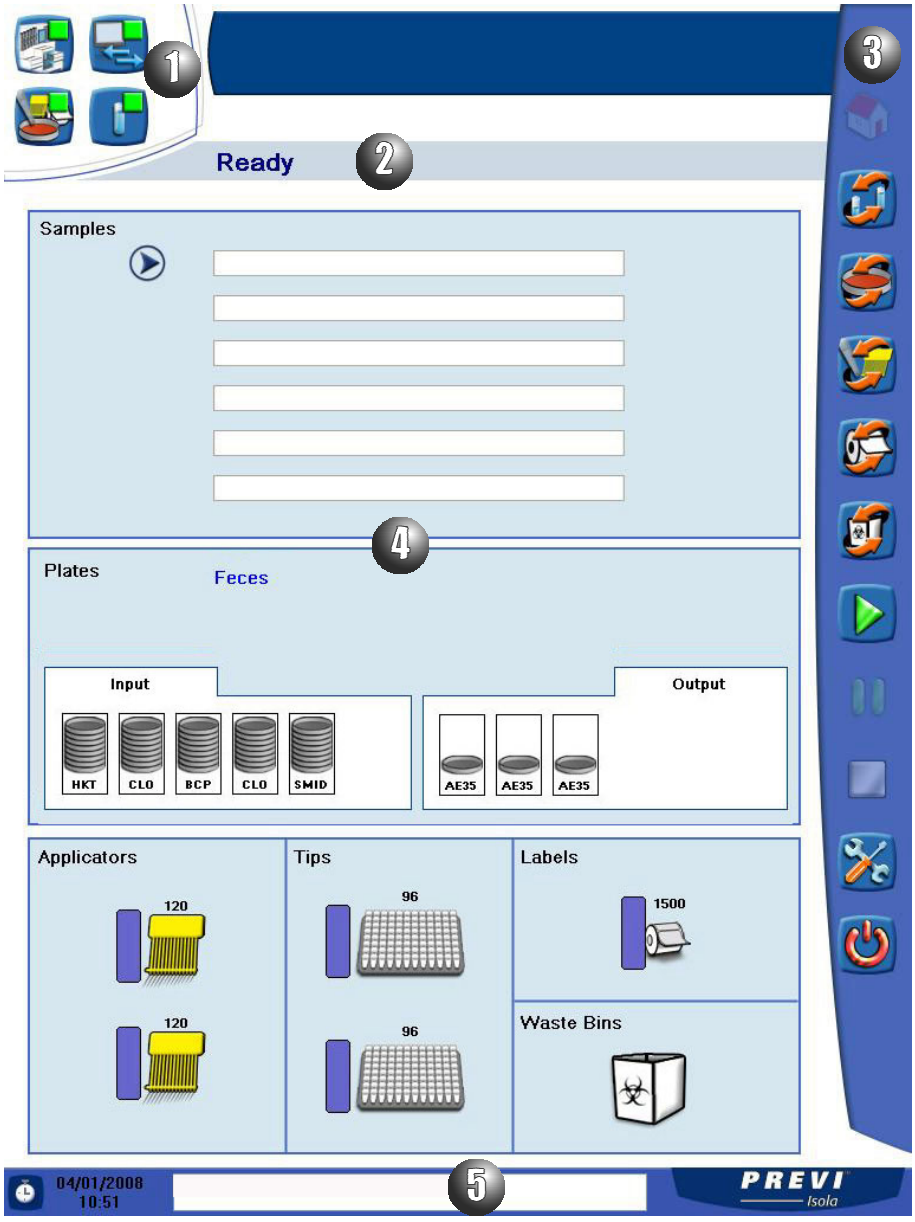


Figure 2-22 : Main screen layout

Each screen is composed of five parts:

1. **Alarm zone**
2. **Title bar**
3. **Navigation/action bar**
4. **Working area**
5. **Status bar**

Alarm zone

The alarm zone comprises four buttons, which correspond to four alarm types: Instrument, Connection, Consumables, Samples.

Alarm Type	OK	Warning	Error
Instrument			
Connection (Instrument-Workstation)			
Consumables			
Samples			

Table 2-2 : Alarm types

When there is a warning or an error, the alarm button blinks.

When it blinks, the user should touch it to display the “Event Log” screen (see Event Log, page 9-10). The button will stop blinking.

Title bar

The title bar contains either the status of the instrument (when the main screen is displayed):

- Ready
- Processing
- Pausing
- Paused
- Error
- etc.

or the purpose of the screen (when another screen is displayed).

Status bar

The two most recently generated messages are displayed in the status bar, along with the current time and date, and the instrument name (**PREVI Isola**).

Navigation/action bar

The buttons in the navigation/action bar are used either to navigate to different screens, or to perform actions, or both.

The appearance of the buttons varies according to their status.

When a button is pressed, it becomes yellow. When it is disabled, it is greyed out.

		
Disabled	Pressed	Enabled

The navigation buttons (except the Home button) are toggle buttons: when the user touches a navigation button to switch to a different screen (for example: the Samples Screen), the button remains pressed (it stays yellow), and if the user touches that button again, the software navigates back to the main screen.

Button	Name	Action
	Home	Navigates to the main screen.
	Samples	Navigates to the “Samples” screen and presents the sample tray for loading/unloading (see Loading Sample Racks, page 4-21).
	Plates	Navigates to the “Plates” screen (see Selecting Plates, page 4-5).
	Applicators & Tips	Navigates to the “Applicators and Tips” screen and presents the consumable tray for loading of applicators and tips (see Loading **PREVI Isola** Applicators, page 4-10).
	Label Roll	Navigates to the “Load Labels” screen and moves the plate transfer robot out of the way of the printer so that the user has clear access to the printer (see Loading **PREVI Isola** Labels, page 4-15).
	Empty Waste Bin	Only enabled when the main screen is displayed. The user touches this button to signal the instrument software that the waste bin has been emptied (see Removing Waste, page 4-35).
	Start/Resume Processing	Only enabled when the main screen is displayed. It starts processing, or resumes processing after pause (see Processing Samples, page 4-23).
	Pause Processing	Pauses processing after completing the current samples (see Pausing the Instrument, page 4-28).
	Stop Processing	Stops processing (see User-generated stop, page 4-31).
	Maintenance	Navigates to the “Maintenance” screen (see Presentation of the Maintenance Menu, page 8-2).
	Immediate stop/Shut down	Stops the instrument immediately and allows the user to choose whether to reinitialize it or shut it down (see Powering Down the Instrument, page 4-37).

Table 2-3 : Navigation/action bar buttons

Working area

The working area is different for each screen.

The working area of the main screen is composed of three parts.

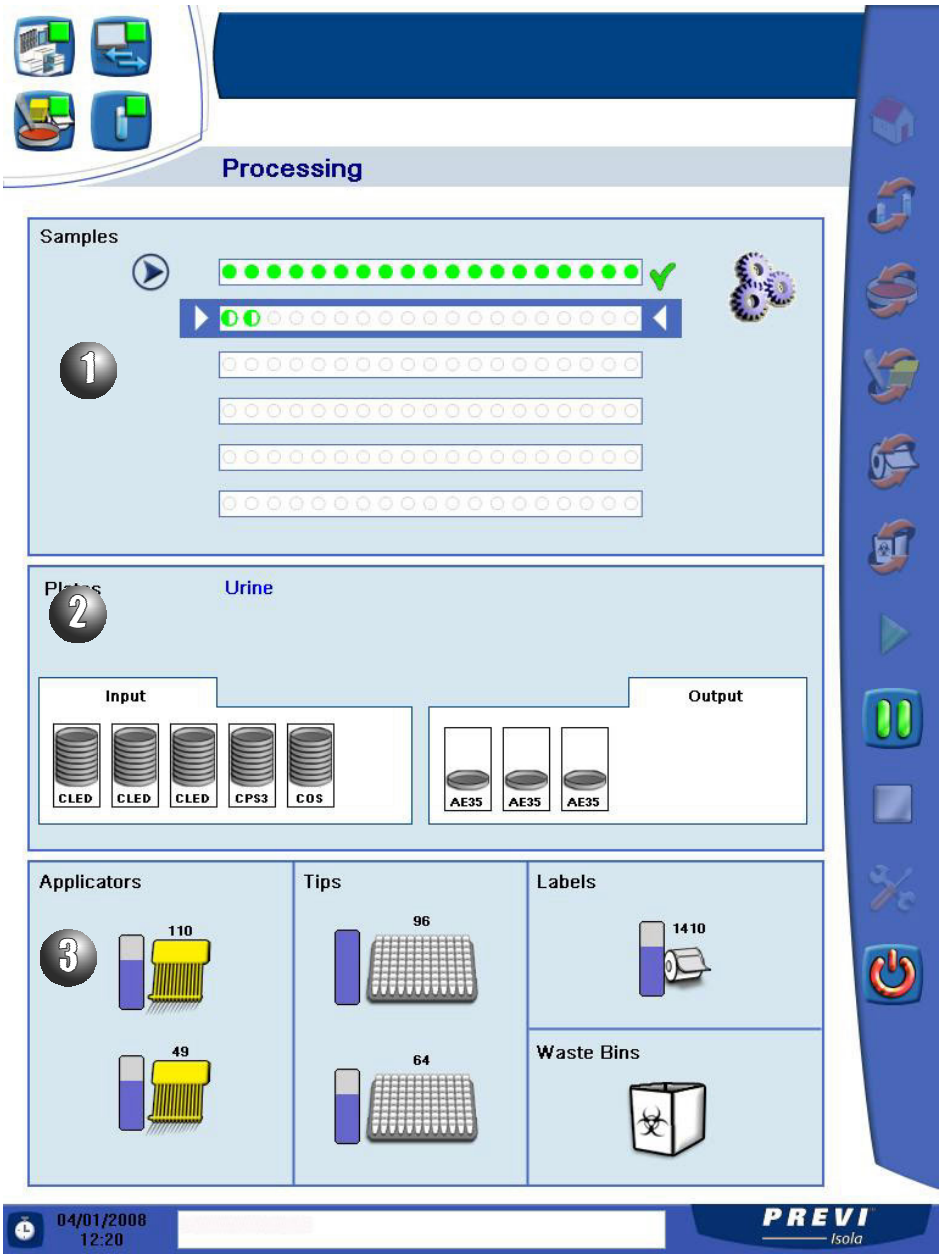


Figure 2-23 : Working area

1. **Sample processing status**
2. **Plate cassette status**
3. **Consumables status**

3 Getting Started

Assembly and Installation

DANGER! ***The PREVI Isola must be installed by bioMérieux S.A. Technical Assistance or your local bioMérieux representative.***

CAUTION! ***Before unpacking the various PREVI Isola components, it is advisable to have previously planned where they will be placed.***

Choosing a location

WARNING! ***Avoid exposing the PREVI Isola to direct sunlight, excessive heat, humidity or dust.***
Leave sufficient space around the PREVI Isola (minimum 50 cm on each side and at the rear of the instrument) to allow airflow and easy handling of the instrument. The rear of the instrument is equipped with wall bumpers to prevent impacts with the wall.
Do not obstruct the hardware ventilation apertures.

Electrical connections

CAUTION! ***Nothing should be placed on top of connection cables, whether temporarily, permanently or intermittently. Cables should not be laid across passage-ways. Computer cables must not intersect or be placed close to power supply cables. Cables should not be looped or knotted, or be rolled up near or on other electrical equipment.***

Hazardous Magnetic Fields Precautions

WARNING! ***This product contains very strong permanent magnet arrays.***

Extreme care should be taken when handling tools and other magnetic material in close proximity to the magnet arrays, as sudden high mechanical forces may be generated.

Magnetically sensitive items such as computer discs and tapes, audio and video cassettes, and credit cards should be kept well clear of the magnet arrays, as these items may be damaged by strong magnetic fields.

People wearing a pacemaker should not use this product, as the strong magnetic fields associated with this product may adversely affect or damage the pacemaker.

Moving the Instrument

WARNING! ***The instrument should be moved by personnel who are authorized to do so by bioMérieux S.A.***

Barcode Reader Installation

Sample barcodes can be entered manually or scanned using the hand-held barcode reader that is connected to the workstation.

For installation of the barcode reader, please refer to the installation procedure included in the barcode reader package.

Installation of the PREVI Isola and BCI

Installation of the **PREVI Isola** and BCI software is performed by bioMérieux or your local bioMérieux representative.

Users are trained during installation of the **PREVI Isola** so that they are able to derive the best performance from the instrument.

WARNING! ***The different equipment, software, and configuration software (especially date, time, language, keyboard type, and other formats) composing the PREVI Isola have been validated by bioMérieux S.A. to function together as an integrated unit. Any changes or additions to a configuration that do not correspond to one of the validated subunits can lead to malfunctions.***

Checking installation

After the **PREVI Isola** has been installed, bioMérieux S.A. Technical Assistance or your local bioMérieux representative will perform a test to check that the system is operating correctly.

WARNING! ***If the equipment is used in a manner not specified in the instructions for use provided by bioMérieux, the protection provided by the equipment may be impaired.***

Powering up the Workstation

IMPORTANT! ***The workstation must be running when the instrument is in use and when the LIS sends information to the PREVI Isola.***

- Power up the workstation.

  Initialization begins.

  The Windows software opens:

  The Windows loading screen is displayed,

- Enter your login and password.

  The Windows session opens.

Connecting to *BCI NET*

For further information on how to use ***BCI NET***, refer to the ***BCI NET*** User's Manual.

IMPORTANT! ***BCI NET must be running when the instrument is in use and when the LIS sends information to the PREVI Isola.***

Connecting to *BCI RS232*

For further information on how to use ***BCI RS232***, refer to the ***BCI RS232*** User's Manual.

Starting the Workstation Software

- Open a Windows session.
- Start the workstation software by double-clicking on the application icon 

The login pop-up window is displayed.

Figure 3-1 : Login pop-up window

- Enter the user name and password which is the same as for Windows.
- Click “OK”.

The user is logged on and has access to the functions that are available to his/her group.

Entry of an incorrect user name or password

If an incorrect user name or password has been entered or if a user account has been locked, the following window is displayed:

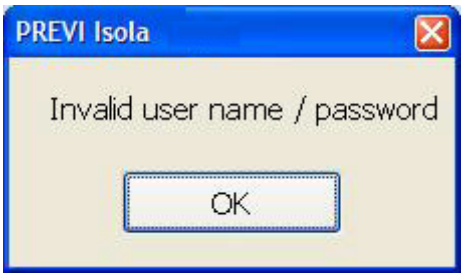


Figure 3-2 : “Invalid user name / password” window

- Click “OK” to close the window.
- Enter a new user name and password to start the application.

IMPORTANT! ***After three unsuccessful attempts to enter the password, the user will not be able to start the application as the account will have locked. It can only be unlocked by a user with Administrator or Power User privileges.***

Changing work sessions

Each user has a login and personal password which are required to open a work session on the workstation software.

If another person needs to use the instrument, they will have to open a work session on the workstation software using the login:

- Click  in the status bar.

  The workstation software shutdown window is displayed:

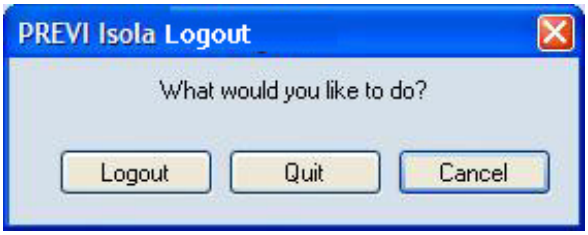


Figure 3-3 : Workstation software shutdown window

- Click “Logout” .

  The new login window is displayed.

Inactivity timeout

If the workstation software remains inactive for more than 15 minutes, it automatically logs out.

Any changes which have not been saved beforehand will be lost.

Defining Plate Panels

The **PREVI Isola** needs to know what types of plates are to be streaked. This is defined by plate panels which are assigned to specimen types or samples.

The following screen is used to create Plate Types, Incubation Types and Plate Panels.

In the “Configuration” menu,

- Select “Plate Panels” to display the “Plate Panels” screen.

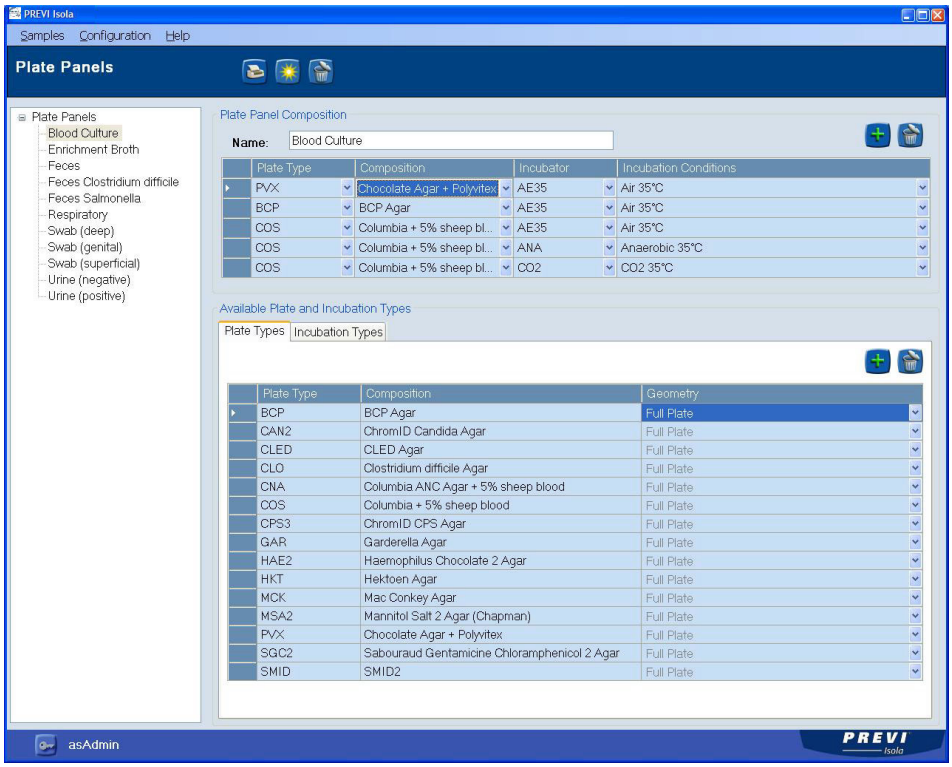


Figure 3-4 : “Plate Panels” screen

The “Plate Panels” navigation tree displays the list of all existing plate panels, sorted alphabetically.

By default, the first plate panel (if any) is selected and its composition is displayed in the table in the upper part of the screen.

The table in the lower part of the screen contains two tabs for creating plate types and incubation types.

Creating a plate panel

- Click on the  button.

  The plate panel composition part of the screen is refreshed. The field name and the composition table are empty.

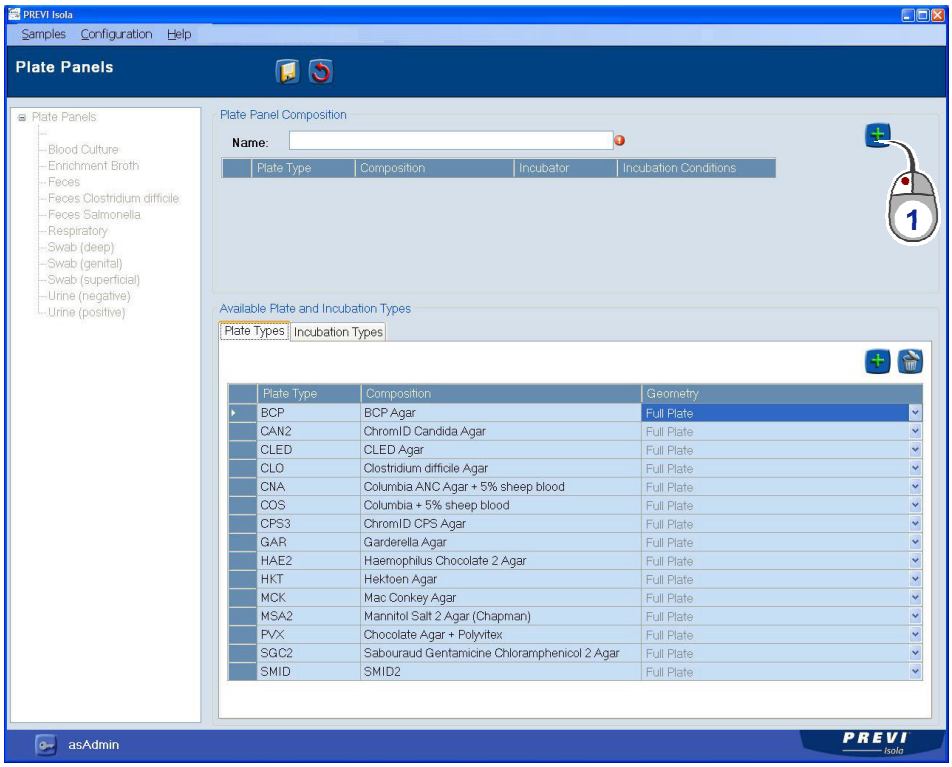


Figure 3-5 : Create a plate panel

- Enter the name of the desired plate panel.

  The plate panel name must be unique and include up to 50 characters.

Note: *It is recommended to enter names that will remind you of the types of specimens for which this plate panel will be used.*

A plate panel can only include 5 plate types.

- Fill the plate panel composition table.

  To do this,

- Click on the  button **(1)**.

  A row is added to the composition table.

  The maximum number of rows accepted in the plate panel composition table is 5.

If more than the maximum number of rows is created, an error message is displayed.

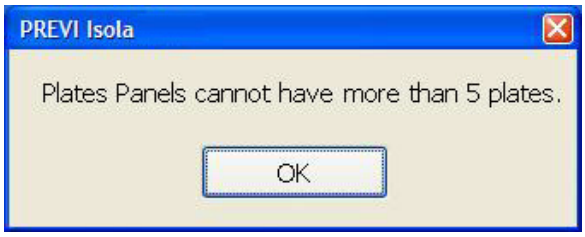


Figure 3-6 : "Plate Panel" error message

- Select a plate type and an incubation type from the drop-down lists.

Note: *A plate type or incubation type can be selected using either the full name or the abbreviated name.*

If the lists do not contain the plate types and incubation types required, they can be created using the tables in the lower part of the screen (see page 3-11).

- Click on the  button to cancel,

or

- Click  to save the new plate panel.

If a field is not adequately filled i.e. missing mandatory information, or invalid contents, an error message is displayed and the invalid field is flagged ( ). Place the pointer on the  icon to obtain more information about the error.

Figure 3-7 : "Invalid entry" error message

- Proceed in the same manner until the plate panel is complete.

Modifying a plate panel

IMPORTANT! ***Only plate panels that are not in use (i.e. not assigned to any specimen types or samples, or only to samples no longer in the database) can be modified.***

- In the "Configuration" menu, select "Plate Panels" to display the "Plate Panels" screen.
- Click on a plate panel in the navigation tree.

  The selected plate panel is displayed in the plate panel composition part of the screen.
- Modify the name and/or the composition of the plate panel: you can add rows by clicking on  and delete rows by clicking on  .

  You can also select a different plate type or incubation type for an existing row.

Note: *If you try to modify a plate panel that is in use, an error message is displayed: "This plate panel cannot be modified as it is in use" and the change is cancelled.*

- Click on the  button to cancel,

or

- Click on the  button to save the modified plate panel.

  The plate panel screen is refreshed and the name of the modified plate panel is updated in the navigation tree.

Deleting a plate panel

IMPORTANT! ***Only plate panels that are not in use (i.e. not assigned to any specimen types or samples, or only to samples no longer in the database) can be deleted.***

- In the "Configuration" menu, select "Plate Panels" to display the "Plate Panels" screen.
- Click on a plate panel in the navigation tree.

  The selected Plate Panel is displayed in the plate panel composition part of the screen.
- Click on the  button in the title and button bar to delete the plate panel.

  A confirmation message is displayed:

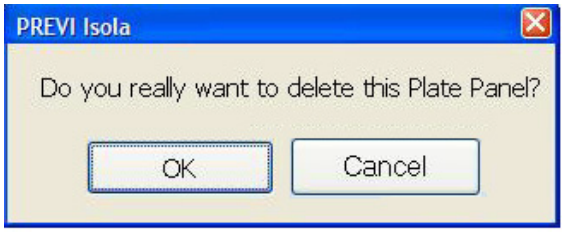


Figure 3-8 : "Delete a plate panel" confirmation message

- Click "OK" to confirm deletion of the plate panel.

  The "Plate Panel" screen is refreshed.

  The deleted plate panel is removed from the navigation tree, the first plate panel (if any) is selected and its composition is displayed in the upper part of the screen.

Printing a plate panel

To print plate panels,

- Click on the  button.

  A plate panel printing selection window is displayed:

Figure 3-9 : "Plate Panel Printing" selection window

The selected plate panels or all the plate panels depending on the choice, are displayed in a "Print Preview" window.

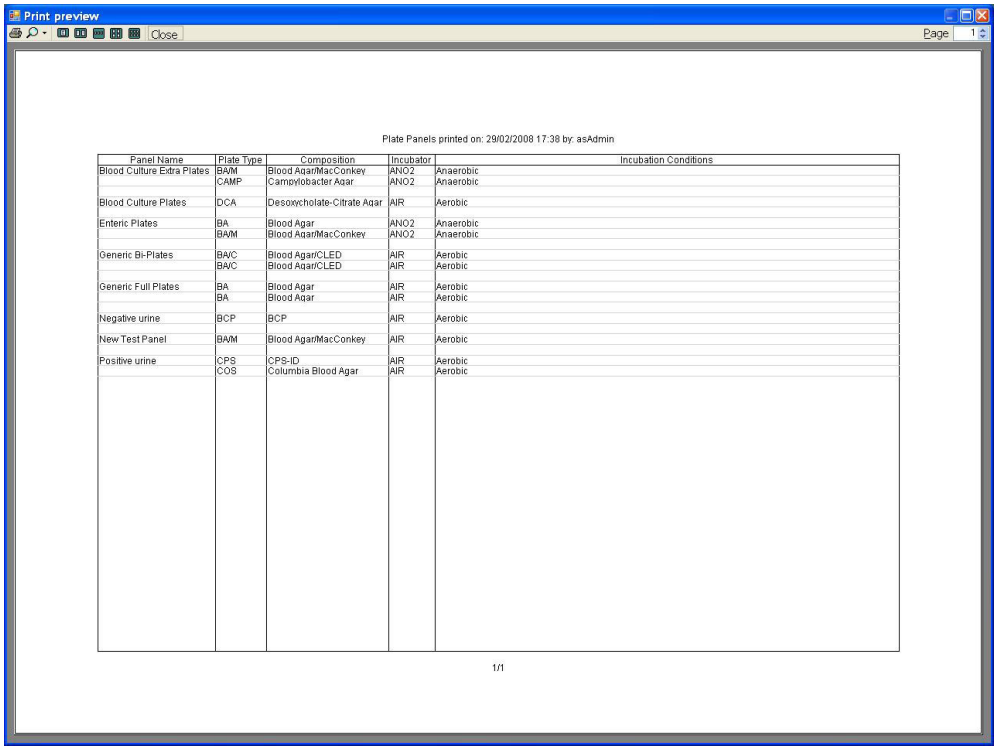


Figure 3-10 : Plate panel "Print Preview" window

- Click on the "Print" button in the "Print Preview" window.

  A printing dialog box is displayed.

- Select a printer and click "OK".

  The report is printed.

- Close the "Print Preview" window.

Defining Plate Types

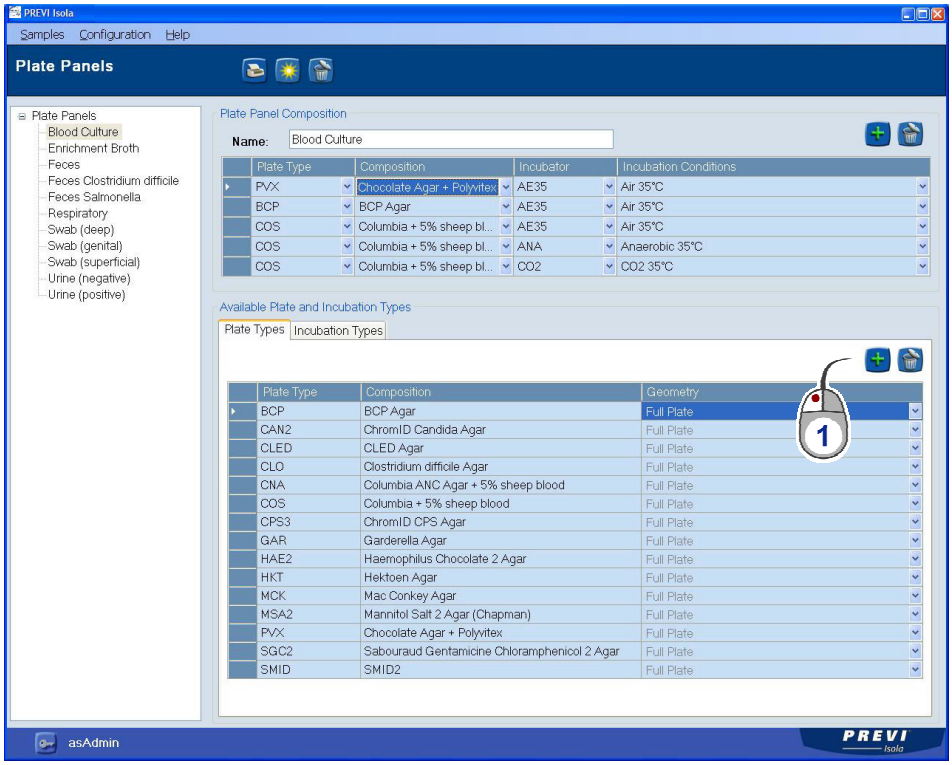


Figure 3-11 : "Plate Panels" plate types screen

In the "Configuration" menu,

- Select "Plate Panels" to display the "Plate Panels" screen.
- Click on the "Plate Types" tab.

Creating a plate type

In the "Plate Types" tab,

- Click on the  button **(1)**.

  A row is added to the end of the plate type table.

- Enter the abbreviated plate type name.

  The abbreviated plate type name must be unique and include up to 4 characters.

Note: If possible, to reduce the risk of errors, it is recommended to use the code that is printed on the plates.

- Enter the plate type composition.

  The plate type composition must be unique and include up to 50 characters.

- Select the "Geometry" from the drop-down list.

- Click on the  button to cancel,

or

- Click  to save the new plate panel.

If a field is not adequately filled i.e. missing mandatory information, or invalid contents, an error message is displayed and the invalid field is flagged ( ). Place the pointer on the icon to obtain more information about the error.

- Proceed in the same manner until the plate panel is complete.

Modifying a plate type

To modify an abbreviated plate type name and composition,

- Click in the field to modify and then enter the new name.

Modification of the geometry name is not allowed.

Deleting a plate type

Only plate types which are not used by at least one plate panel or plate cassettes configuration can be deleted.

- Select a plate type.
- Click on the  button to delete the plate type.

  The “Plate Panel” screen is refreshed. The deleted plate type is removed from the plate type table and the next plate (if any) is selected.

Defining Incubation Types

In the “Configuration” menu,

- Select “Plate Panels”.

In the “Plate Panels” screen,

- Click on the “Incubation Type” tab.

  The “Incubation Types” table contains the list of all the existing incubation types.

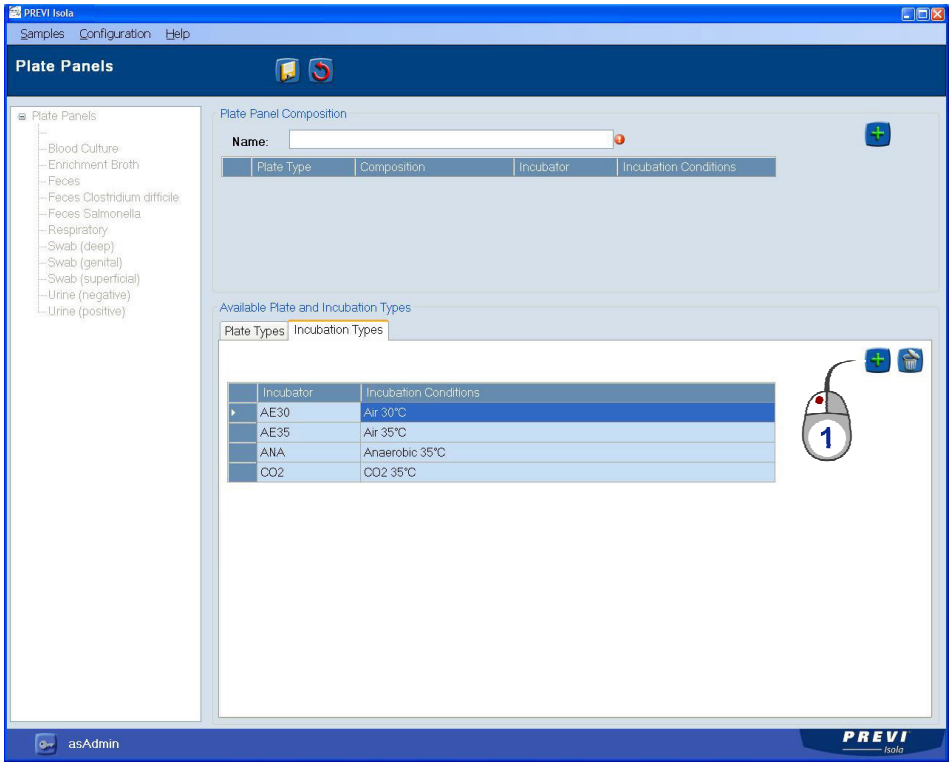


Figure 3-12 : Define incubation types

Creating an incubation type

In the “Incubation Types” tab,

- Click on the  button **(1)**.

  A row is added to the end of the incubation type table.

- Enter the abbreviated incubation type name.

  The abbreviated incubation type name must be unique and include up to 4 characters.

Note: It is recommended to use names that remind you of the incubator in which the plates will be loaded.

- Enter the full incubation type name.

  The full incubation type name must be unique and include up to 50 characters.

- Click on the  button to cancel,

or

- Click on  in the title and button bar to save the new incubation types.

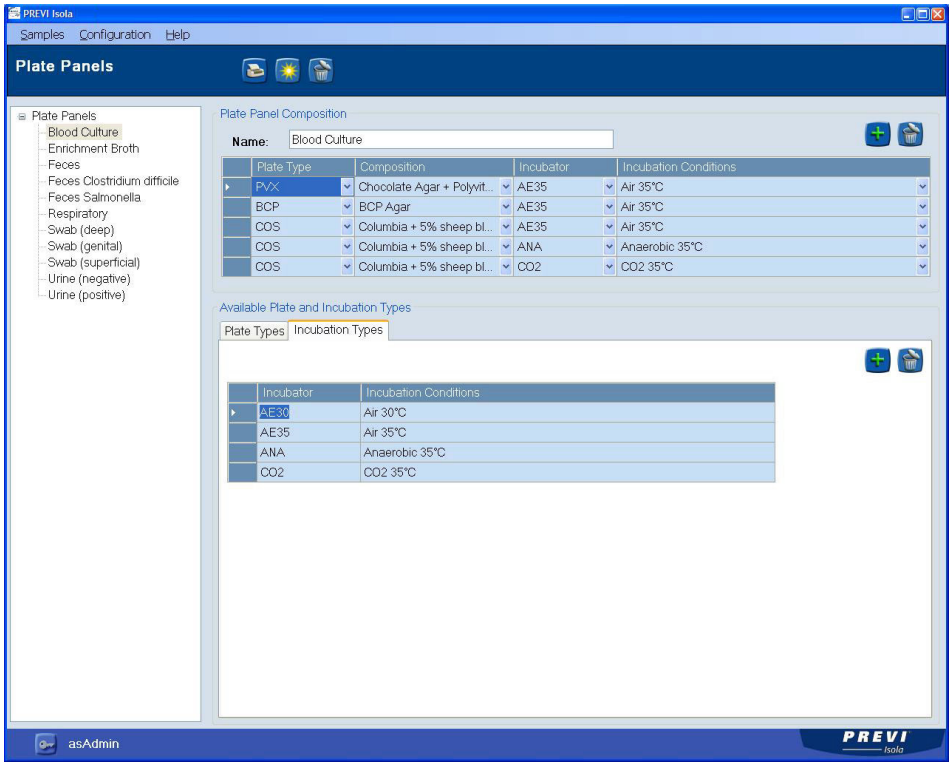


Figure 3-13 : Incubation types

- Proceed in the same manner for all the incubation types to be created.

Modifying an incubation type

IMPORTANT! ***Only incubation types that are not used by at least one plate panel or plate cassettes configuration can be modified.***

- Select the incubation type to modify.
- Modify its abbreviated name and/or its full name.
- Click on the  button to cancel,

or

- Click on the  button to save the modified incubation type.

Deleting an incubation type

IMPORTANT! ***Only incubation types that are not used by at least one plate panel or plate cassettes configuration can be deleted.***

- Select an incubation type.
- Click on the  button to delete the incubation type.
  The incubation types table is refreshed. The deleted incubation type is removed from the incubation types table and the next row (if any) is selected.

Assigning Plate Panels to Specimen Types

The **PREVI Isola** needs to know what types of plates are to be streaked. This is defined by plate panels which are assigned to specimen types or samples.

Due to the limitation of the maximum sample volume pipetted, certain streaking protocols are not compatible with certain plate panels.

In the “Configuration” menu,

- Select “Specimen Types”.

The following screen is used to assign plate panels to specimen types.

Figure 3-14 : “Specimen Types” screen

If a plate panel has been assigned to a specimen type, it will automatically be assigned to all the samples of that specimen type when they are received from the LIS. (see Automatically Assigning Plate Panels to Samples, page 3-18).

To have different plate panels for the same specimen type depending on other data, e.g. age of patient, result of another test, use the specimen details field.

A row must be created for each specimen type to process on the **PREVI Isola** (or several rows if different plate panels are required according to the specimen details).

- Click on the  button.

  A row is added to the end of the specimen type table.

  If a field is not adequately filled i.e. missing mandatory information, or invalid contents, an error message is displayed and the invalid field is flagged ( ). Place the pointer on the  icon to obtain more information about the error.

- Enter the name and LIS code of the specimen type.

  The specimen type name must be unique and include up to 40 characters and the LIS code must be unique and include up to 10 characters.

- Select a streaking protocol from the drop-down list.

  There is one streaking protocol per specimen group (urine, feces, swabs, blood, liquid respiratory, enrichment broth, quality control).

- Select a plate panel from the drop-down list (if the required plate panel is not found, it must be created: see Creating a plate panel, page 3-7).
- The composition of the selected plate panel is displayed in the plate panel composition table in the lower part of the screen.
- If specimen details are required, proceed in the same way, but fill the specimen details field. The specimen details must be unique and include up to 40 characters and the LIS code must be unique and include up to 10 characters.

To delete a specimen type and/or specimen details,

- Select the row to delete and click on the  button.

Note: *Only specimen types/specimen details which are not in use (i.e. not assigned to any samples or only to samples no longer in the database) can be deleted.*

When deleting a specimen type, all the specimen details associated with it must be deleted beforehand.

The specimen types table is refreshed.

The deleted specimen type is removed from the specimen types table and the next row (if any) is selected.

- Click on the  button to cancel,

or

- Click on the  button to save changes.

Printing plate panels assigned to specimen types

To print plate panels assigned to specimen types,

- Click on the  button.

  The report is displayed in a “Print Preview” window.

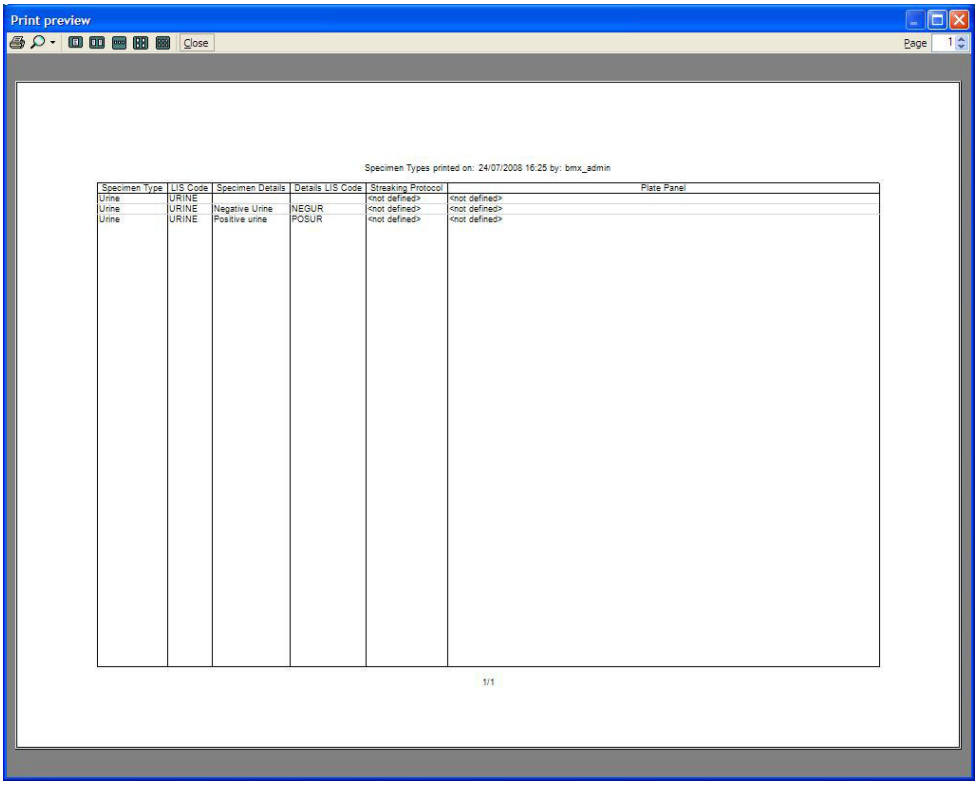


Figure 3-15 : Specimen types “Print Preview” window

- Click on the “Print” button in the “Print Preview” window.

  A printing dialog box is displayed.

- Select a printer and click “OK”.

  The report is printed.

- Close the “Print Preview” window.

Automatically Assigning Plate Panels to Samples

The software will consult the specimen types table for each sample received from the LIS (see Assigning Plate Panels to Specimen Types, page 3-15).

It will first take into account the specimen details to assign a plate panel to a sample.

If the specimen details have not been sent by the LIS, it will assign the plate panel defined for the specimen type to the sample, if any.

If no row has been created in the specimen types table for specimen details, the plate panel defined for the specimen type will be used, if any.

However, if a row has been created for specimen details with a "<not defined>" plate panel, the plate panel of the specimen type will not be used. This ensures that certain specimen details will not be taken into account by the **PREVI Isola** unless they are assigned plate panels manually.

Examples:

1. In this case:

If the Specimen Details field is not filled in for the urine sample, it will not be processed.

Specimen Type	LIS Code	Specimen Details	Details LIS	Streaking Protocol	Plate Panel
Urine	URINE			Urine	<not defined>
Urine	URINE	Negative urine	NEGUR	Urine	Negative urine
Urine	URINE	Positive urine	POSUR	Urine	Positive urine

2. In this case:

If the Specimen Details field is not filled in for the urine sample, it will be processed like a positive urine.

Specimen Type	LIS Code	Specimen Details	Details LIS	Streaking Protocol	Plate Panel
Urine	URINE			Urine	Positive urine
Urine	URINE	Negative urine	NEGUR	Urine	Negative urine
Urine	URINE	Positive urine	POSUR	Urine	Positive urine

Defining Plate Cassettes Configurations

The **PREVI Isola** needs to know in which input cassette it can find each type of plate. This is defined by plate cassettes configurations.

The plate cassette configurations are created using the workstation software and are then selected on the instrument touch-screen.

IMPORTANT! ***If a plate type is used in several plate cassettes configurations, it is recommended if possible, to always assign it to the same input cassette. This will reduce the number of manipulations and the risk of error.***

It is also recommended to assign incubation types to the same output cassettes to reduce the risk of error.

In the “Configuration” menu,

- Select “Plate Cassettes”.

  The “Plate Cassettes Configuration” screen is displayed.

Creating a plate cassettes configuration

- Click on the  button.

  The “Plate Cassettes Configuration” screen is refreshed. All the fields are empty.

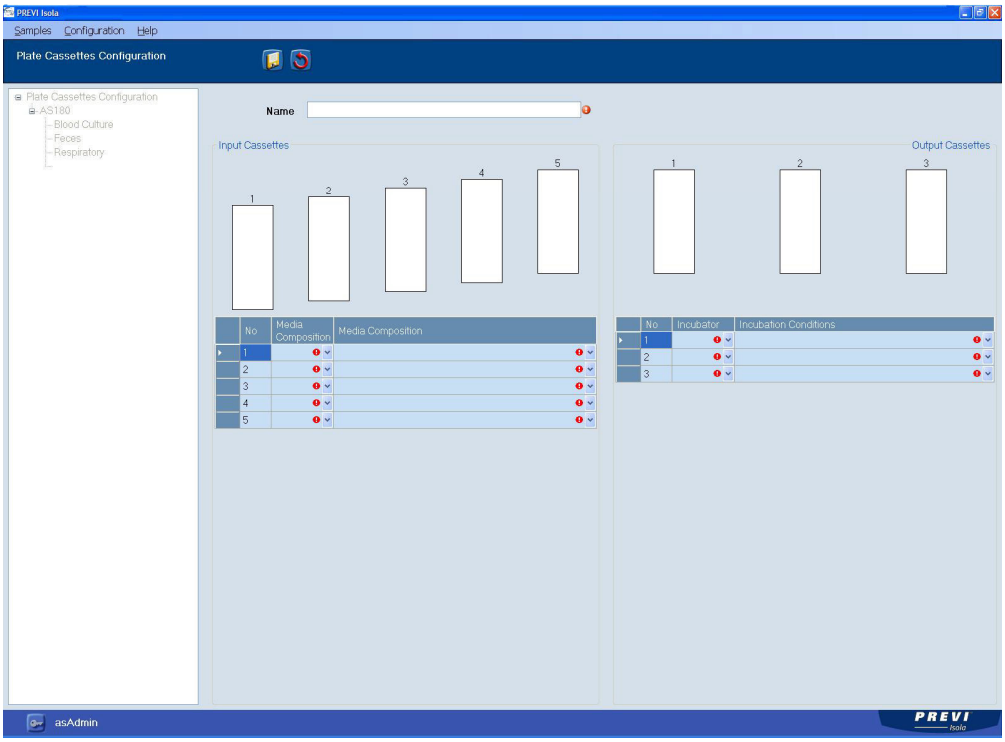


Figure 3-16 : “Plate Cassettes Configuration” screen

- Enter a name for the new plate cassettes configuration.

  The plate cassettes configuration name must be unique and include up to 50 characters.

Note: *It is recommended to use names that remind you of the types of specimens that can be processed with this plate cassettes configuration.*

- Select a plate type from the drop-down list for each input cassette.
- Select an incubation type from the drop-down list for each output cassette.

Note: A plate type or incubation type can be selected using either the full name or the abbreviated name.

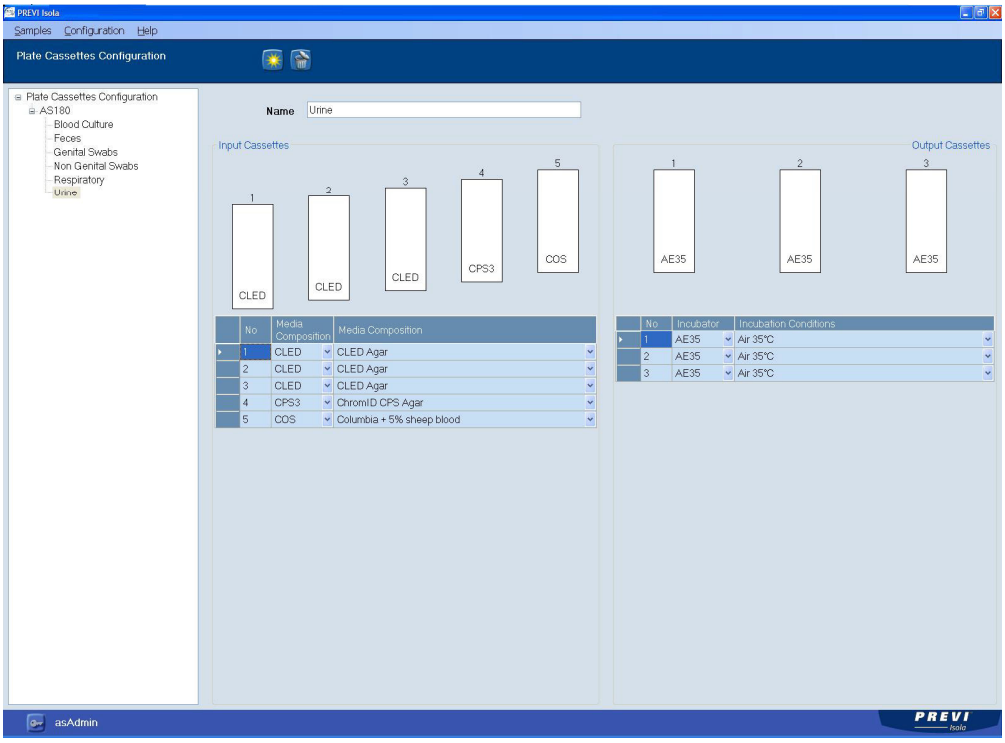


Figure 3-17 : New plate cassettes configuration

- Click  to save the new plate cassettes configuration,

or

- Click on the  button to cancel.

If a field is not adequately filled i.e. missing mandatory information, or invalid contents, an error message is displayed and the invalid field is flagged (!). Place the pointer on the ! icon to obtain more information about the error.

Figure 3-18 : "Invalid Input" error message

Modifying a plate cassettes configuration

- In the “Configuration” menu, select “Plate Cassettes” to display the “Plate Cassettes Configuration” screen.
- Click on a plate cassettes configuration in the navigation tree.

  The selected plate cassettes configuration name and composition are displayed.
- Modify the name and/or the composition of the plate cassettes configuration.
- Click on the  button to cancel,

or

- Click on the  button to save the modified plate cassettes configuration.

  The plate cassettes configuration screen is refreshed and the name of the modified plate cassettes configuration is updated in the navigation tree.

Deleting a plate cassettes configuration

- In the “Configuration” menu, select “Plate Cassettes” to display the “Plate Cassettes Configuration” screen.
- Click on a plate cassettes configuration in the navigation tree.

  The selected plate cassettes configuration name and composition are displayed.
- Click on the  button in the title and button bar to delete the plate cassettes configuration.

  A confirmation message is displayed:

Figure 3-19 : “Delete a plate cassettes configuration” confirmation message

- Click “OK” to confirm deletion of the plate cassettes configuration.

  The “Plate Cassettes Configuration” screen is refreshed.

  The deleted plate cassettes configuration is removed from the navigation tree.

Assigning Plate Panels to Samples

Plate panels are normally automatically assigned to samples when the sample data are received from the LIS (see Automatically Assigning Plate Panels to Samples, page 3-18).

This assignment is based on specimen types and details (see Assigning Plate Panels to Specimen Types, page 3-15). However, this assignment can also be changed manually for individual samples.

Manual assignment of plate panels to samples is also used for quality control.

In the “Samples” menu,

- Select “Assign Samples” to display the “Sample Assignment” screen.

  The “Sample Assignment” screen is displayed.

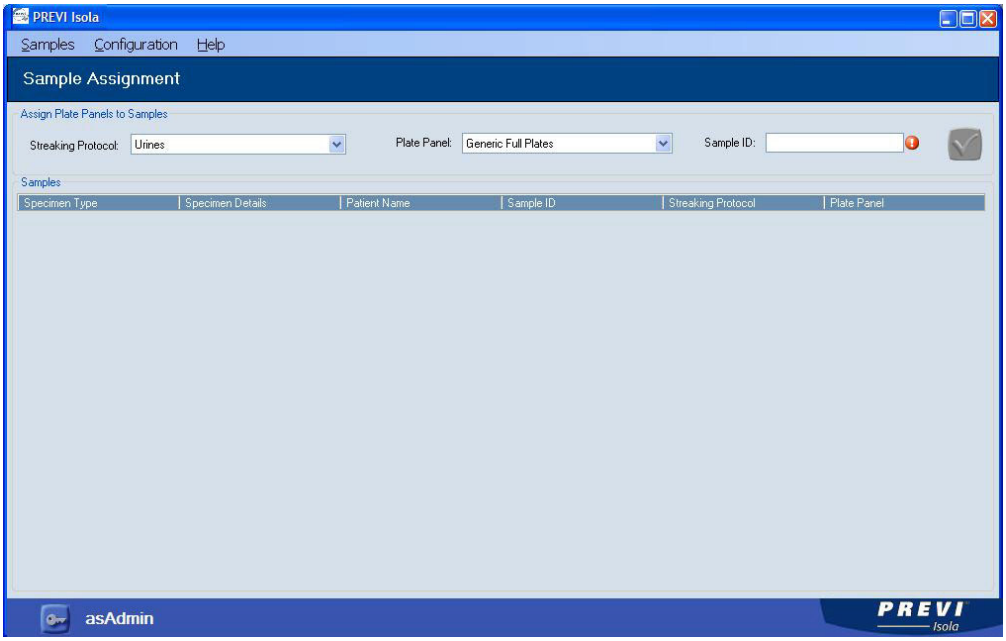


Figure 3-20 : “Sample Assignment“ screen

- Select a streaking protocol and a plate panel using the drop-down lists at the top of the screen.
- Scan the barcode on the sample tube.
- Alternatively, you can enter the barcode manually and click on the  button or the <Enter> key.

The samples will be added to the table.

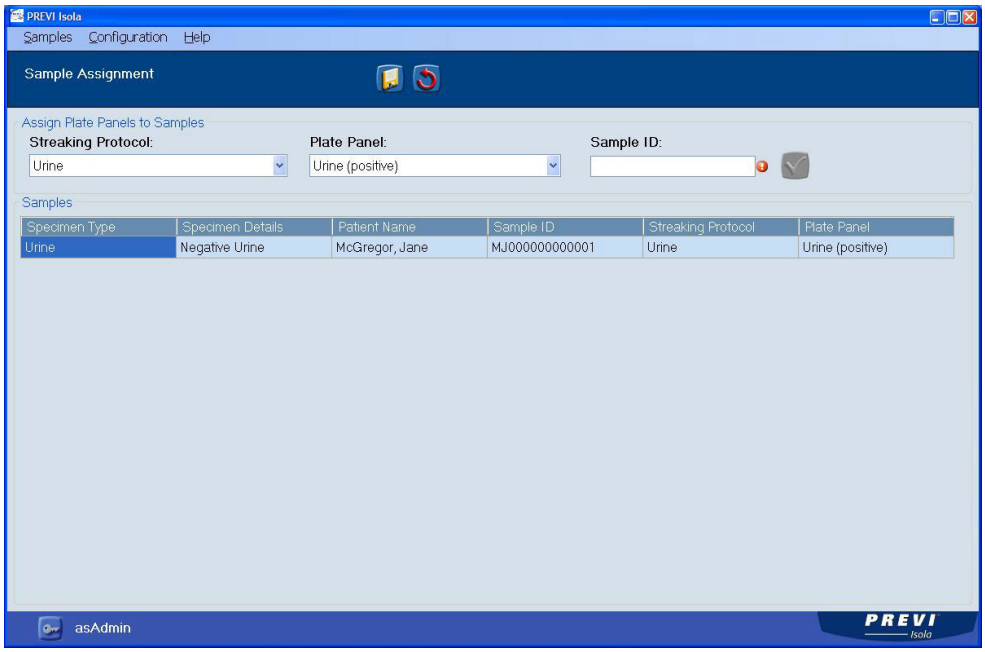


Figure 3-21 : "Sample Assignment" screen with sample

- Proceed in the same manner for each sample.
- Click on the button to cancel,

or

- Click on the button to save.

  The samples disappear from the table and can be viewed in the worklist screen (see Viewing and Printing Worklists, page 3-24).

Note: The drop-down lists include two special values: "default" and "not defined". "Default" allows you to cancel a manual assignment and revert to the default plate panel and streaking protocol of the specimen type. "Not defined" should only be used if you do not want the instrument to process a sample.

IMPORTANT! ***If an incorrect streaking protocol or plate panel is assigned to a sample which is then processed, the sample will have to be reprocessed. However, before it is reprocessed, it must be given a new sample ID. The barcode on the sample tube must be modified to include this new sample ID.***

To process the same specimen ID with different sample IDs, contact bioMérieux.

Viewing and Printing Worklists

The “Worklist” screen is used to view a list of samples with their processing state, in particular to check that all samples for which data have been received from the LIS have been processed successfully.

In the “Samples” menu,

- Select “Show Worklist”.

  The “Worklist” screen is displayed.

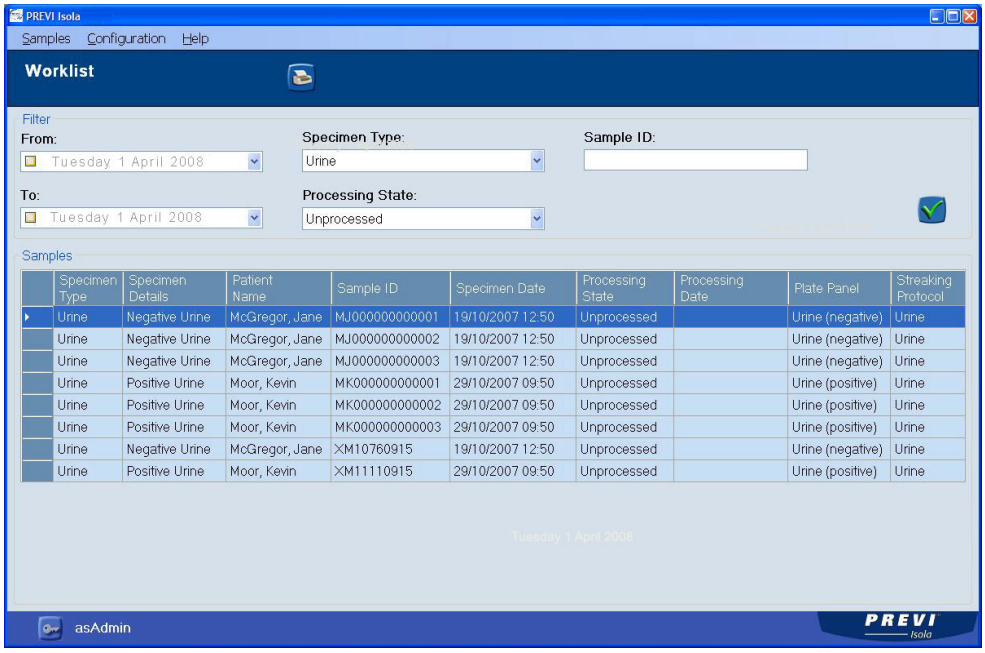


Figure 3-22 : “Worklist” screen

Data can be filtered according to the specimen collection date, specimen type, processing state or sample ID.

- Select the criteria and then,
- Click  .

Columns can be moved by dragging and dropping.

Rows can be sorted by clicking on the header of the corresponding column.

To print a worklist,

- Click on the  button.

  The report is displayed in a “Print Preview” window.

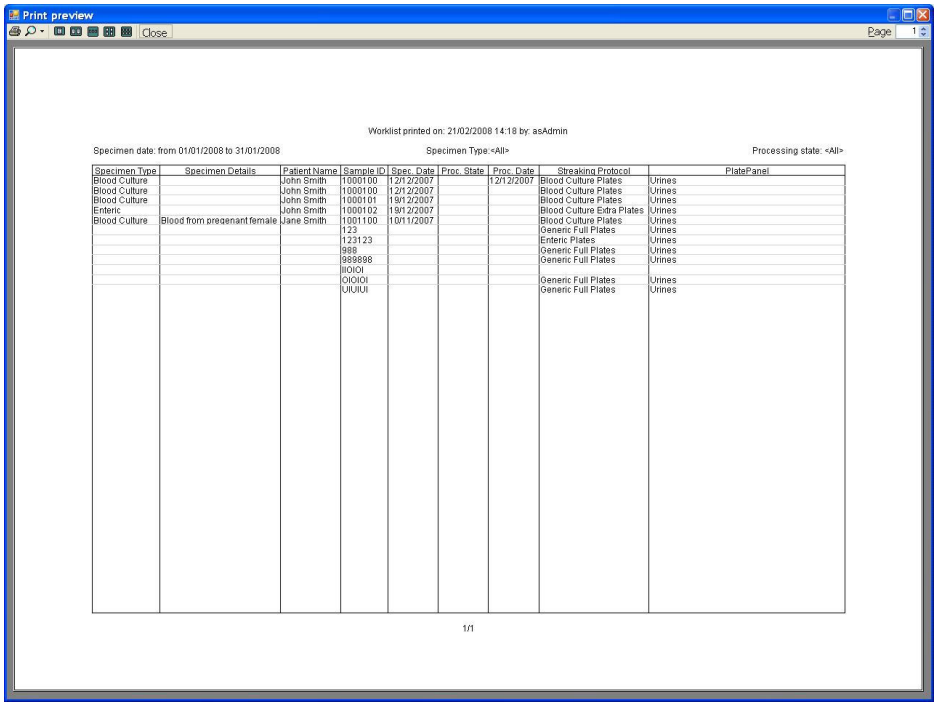


Figure 3-23 : Worklist “Print Preview” window

- Click on the “Print” button in the “Print Preview” window.

  A printing dialog box is displayed.
- Select a printer and click “OK”.
- Close the “Print Preview” window.

General Settings

In the “Configuration” menu,

- Select “General Settings”.

The “General Settings” screen is displayed.

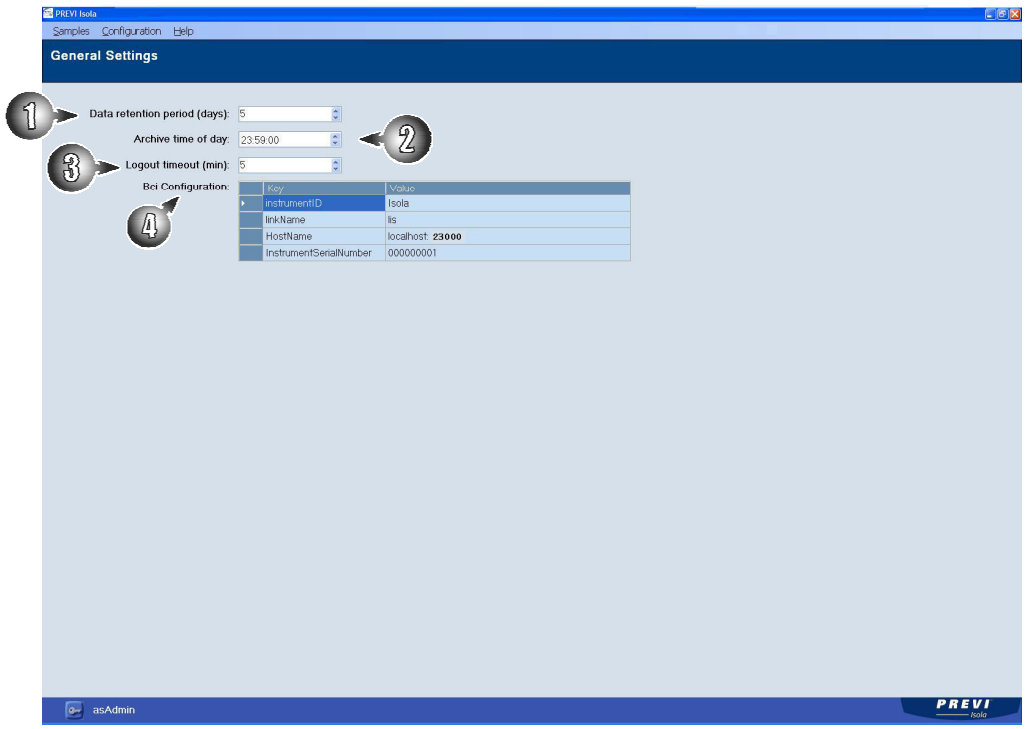


Figure 3-24 : “General Settings” screen

The following parameters can be defined in the “General Settings” screen:

Data retention period (days)

This defines the number of days that data are stored in the database after the most recent modification.

Archive time of day

This defines the time at which archiving will be performed.
Archiving should be programmed to occur when the instrument is not in use and when the antivirus full scan is not running.

Logout timeout (min)

This defines the period of inactivity (in minutes) after which the user will be logged off from the application.

BCI Configuration

The BCI configuration is done by bioMérieux at installation and should not be modified by the user.

4 Using the System

Basic Workflow

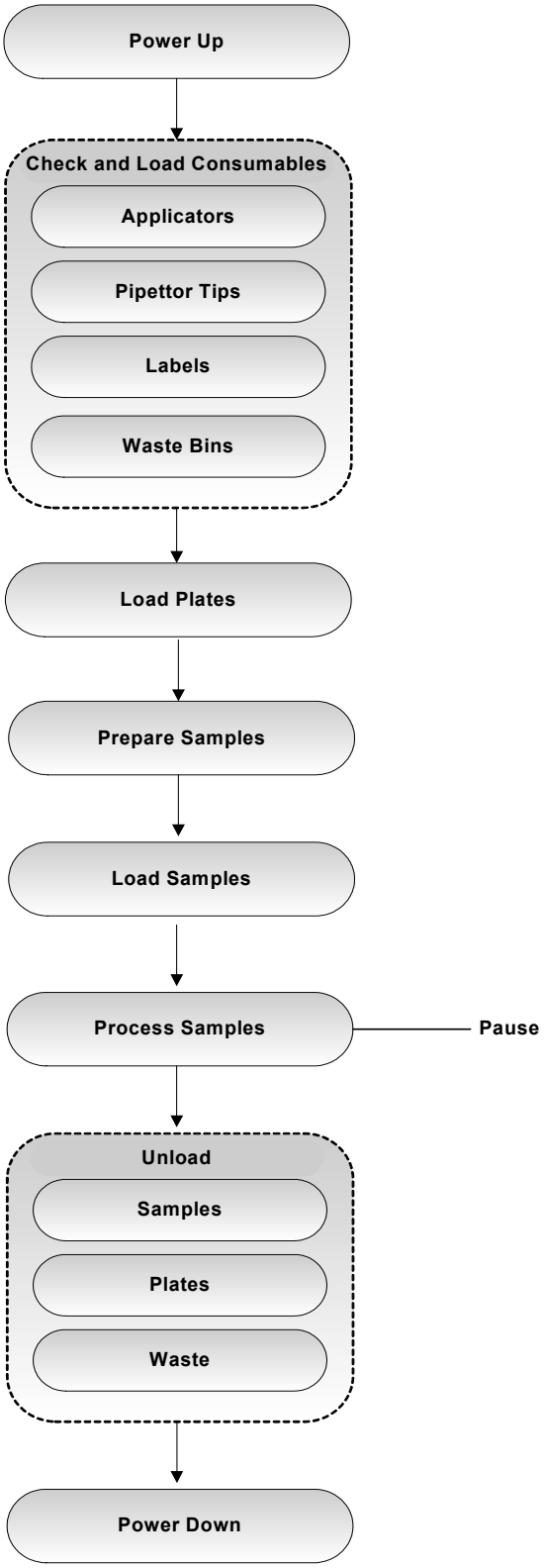


Figure 4-1 : Basic workflow diagram

Starting the System

IMPORTANT! ***The workstation must be running when the system is started (see Powering up the Workstation, page 3-3).***

The **PREVI Isola** system is started as follows:

- The UPS is powered up (optional device).
- The instrument is powered up.
- The internal computer starts up automatically.
- The instrument software starts.
- The system initializes.

Powering up the instrument

Before initialization,

- All the instrument covers must be closed.
- All the input and output cassettes must be in place on the instrument.
- The waste drawer must be closed.

CAUTION! ***Input and output cassettes must not be removed during initialization.***

- Put the power switch on the instrument in the “I” position.

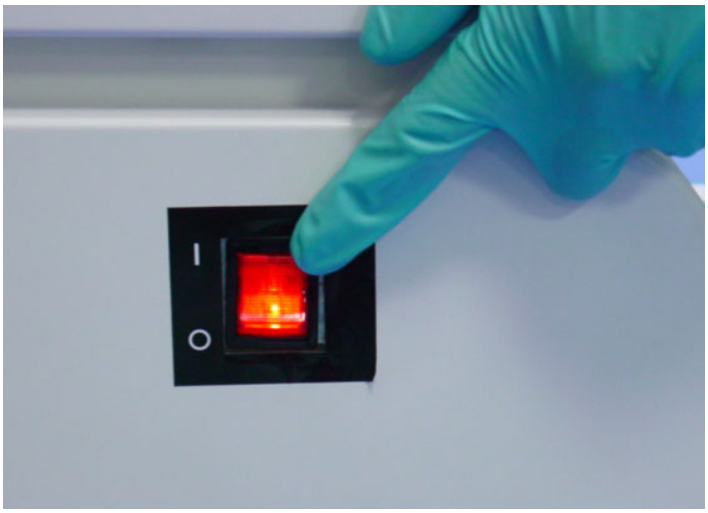


Figure 4-2 : Powering up the instrument

CAUTION! ***In case of emergency, switch off the power at the power switch.***

Screensaver

If the instrument user interface is not used for a period of time, the screen will become black.

- Simply touch the screen and the main screen will appear.

After the computer completes initialization, the main screen (see Main screen and general layout, page 2-25) appears:

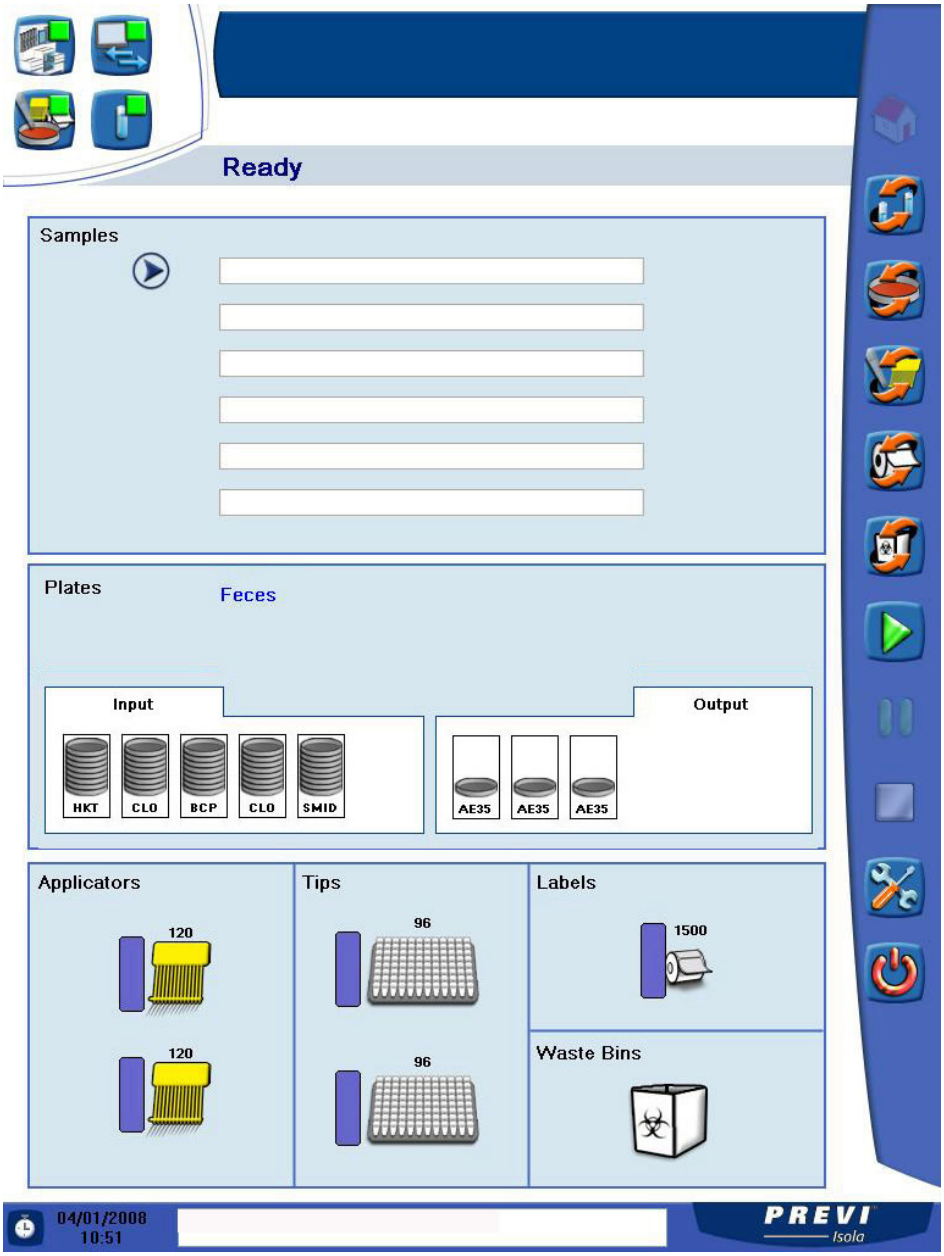


Figure 4-3 : Main screen

The instrument is now in “Ready” status.

Prerequisites for Sample Processing

Samples must be in liquid form. Samples not in liquid form must be prepared as outlined in Sample Preparation, on page 4-19.

Samples must be in compatible tubes (see Sample tubes, page 2-10). If a sample is not received in a compatible tube it must be transferred.

Samples for processing must be barcoded in a format accepted by the instrument (see Read sample barcode, page 2-19).

Pre-start Checks

- Check that the instrument is in “Ready” status.
- Make sure that there are sufficient consumables to process samples (see pages 4-5 to 4-15)
- Make sure that the **PREVI Isola** Waste Bins are in place and empty (see Removing Waste, page 4-35).
- Select the appropriate plate cassettes configuration and load the corresponding plates into the input cassettes (see Selecting Plates, page 4-5).
- Make sure that output cassettes are empty (see Unloading Processed Plates, page 4-32).

IMPORTANT! ***Please refer to the package inserts for use of the plates and consumables.***

Selecting Plates

IMPORTANT! ***Please refer to the package inserts for use of the plates.***

Note: *For information on compatible plates, refer to Plates compatible for use with the **PREVI Isola**, page 2-10.*

The instrument status should be “Ready” before changing the plate cassettes configuration.

Before loading plates, it is necessary to select the plate cassettes configuration. To do this,

- Touch the  button on the instrument touch-screen to display the “Select Plates” screen:

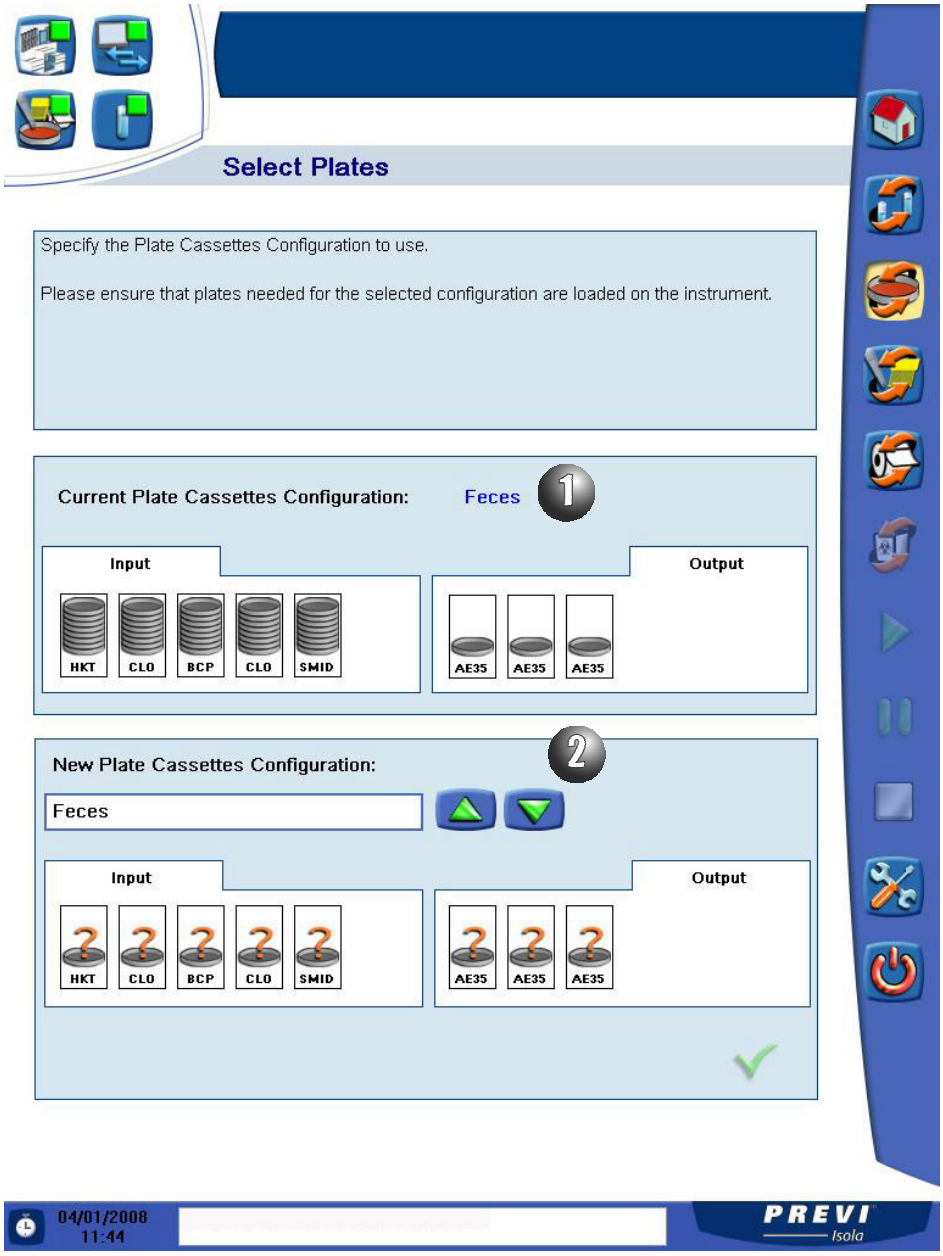


Figure 4-4 : “Select Plates” screen

The “Current Plate Cassettes Configuration” ① is displayed.

To select a different plate cassettes configuration,

- Scroll using the  and  buttons in the “New Plate Cassettes Configuration” zone ②.

- Touch the  button to accept the “New Plate Cassettes Configuration”.

The new plate cassettes configuration will now be displayed in the “Current Plate Cassettes Configuration” zone.

- Touch the  button to return to the main screen.

Loading Plates

To load plates,

- Remove the input cassette.

IMPORTANT! ***Make sure that the plates are not contaminated.***

Plates must be loaded upside down (agar side up).

The user is responsible for ensuring that the appropriate plate types are loaded into the correct input cassette.

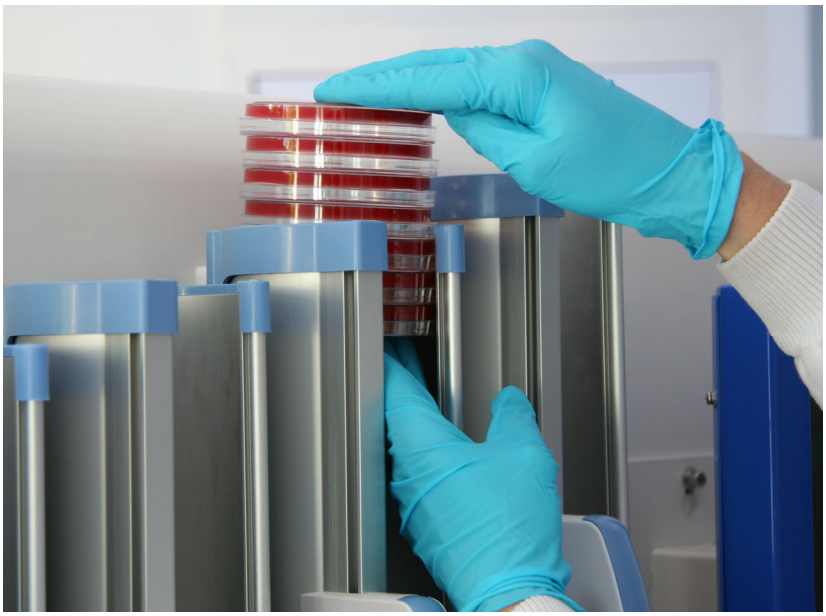


Figure 4-5 : Load plates agar-side up

- Put the input cassette back in place on the instrument.

IMPORTANT! ***Make sure the input cassettes are properly installed otherwise the instrument will not be able to start processing.***

Before starting sample processing, ensure that the output cassettes are empty and properly installed.

Loading plates during processing

During processing, the instrument monitors the plates remaining in the input cassettes. If the instrument considers there are not enough plates to process the next sample, it will display an alarm message and will pause.

- Remove the empty input cassette.
- Load plates and put the input cassette back in place.

To resume processing,

- Touch the  button on the main screen.

Loading plates without removing the input cassette

Plates can be loaded at any time without removing the input cassettes.

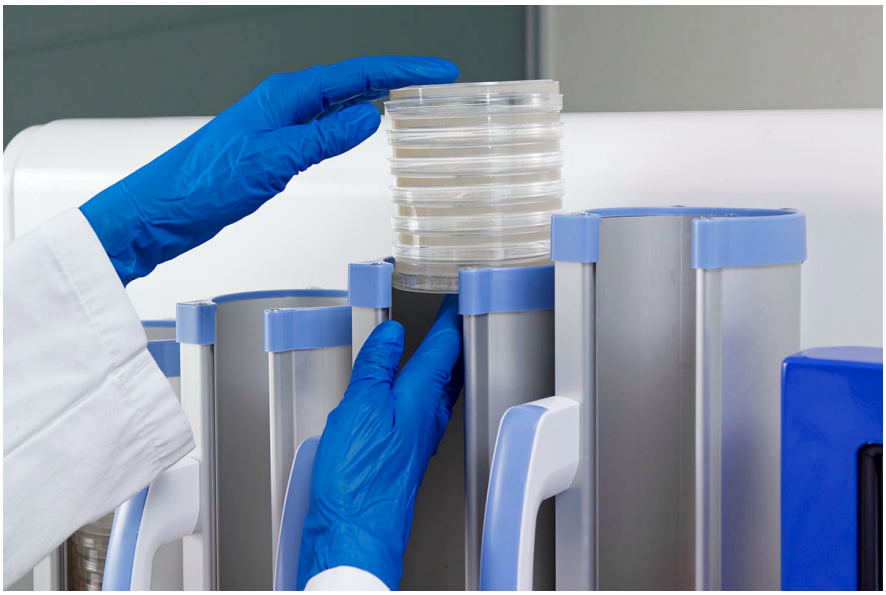


Figure 4-6 : Loading plates without removing the input cassette

> ***DANGER!*** ***Do not put your hands into the lower part of the input cassette while the instrument is operating.***

Plate cassettes status

The input and output cassettes status is displayed on the main screen.

The name of the selected plate cassettes configuration is displayed at the top.

For each input cassette, the abbreviated name of the assigned plate type is displayed.

For each output cassette, the abbreviated name of the assigned incubation type is displayed.

The cassettes status is refreshed in real-time during processing.

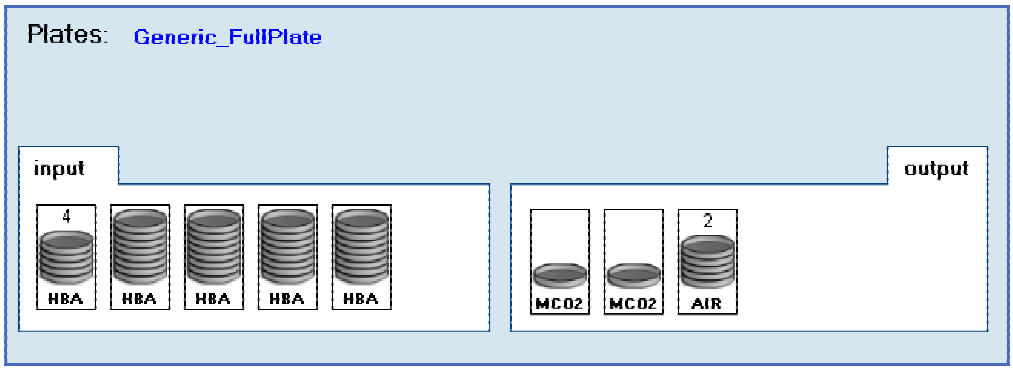


Figure 4-7 : Main screen – "Cassettes status"

An image shows the level of plates in each input or output cassette:

			
Unknown	**Empty**	**Nearly full/empty**	**Full**

Table 4-1 : Plate cassettes status icons

When an input cassette is nearly empty, the remaining number of plates is displayed above the image.

When an output cassette is nearly full, the instrument displays how many plates can still be inserted.

When an input cassette is removed, the status of all the input cassettes becomes "Empty".

When an output cassette is removed, the status of all the output cassettes becomes "Full".

During processing, when the level of plates falls below the sensor, the **PREVI Isola** considers that there are 5 plates remaining in the input cassette and starts counting down.

Note: If an error occurs, this 5-plate count is lost and the input cassette is considered to be empty.

Loading PREVI Isola Applicators

PREVI Isola Applicator cartridges should be replaced whenever they are empty.

The instrument status should be “Ready” or “Paused” before loading applicators.

To load a new applicator cartridge:

- Touch the  button on the instrument touch-screen to display the “Load Applicators and Tips” screen.

  The consumables tray is presented for loading of applicators and tips.

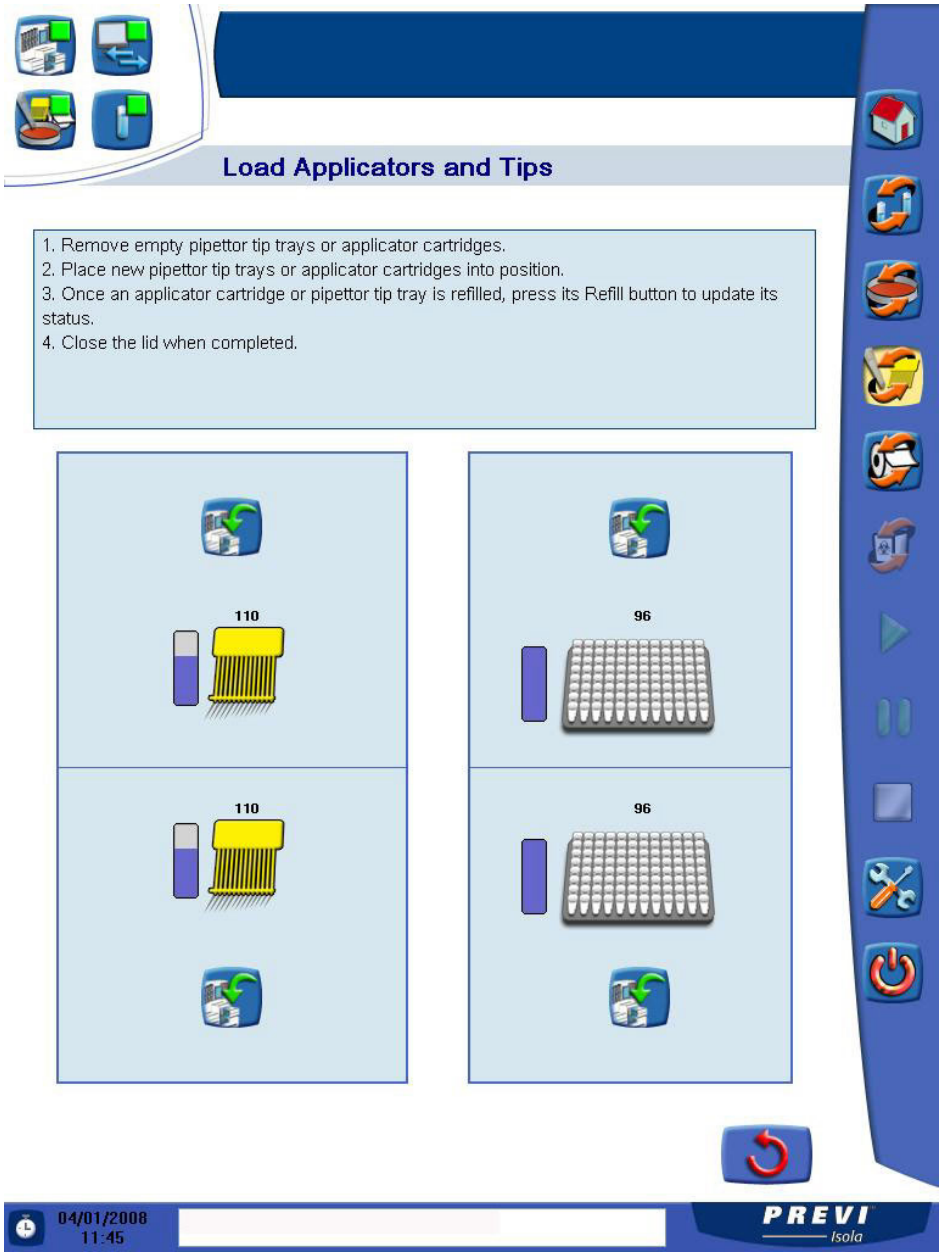


Figure 4-8 : “Load Applicators and Tips” screen

DANGER! ***Personal protective equipment must be worn when loading applicators.***

- Open the consumable lid.
- Release the top lock (1) by pulling it forward.

Figure 4-9 : Pulling the top lock

- Remove and dispose of the used applicator cartridge.
- Open the applicator cartridge packaging.
- Check that the applicator cartridge is not damaged.
- Insert a new applicator cartridge by pulling the top lock forward (2) and then pushing the cartridge down (3).

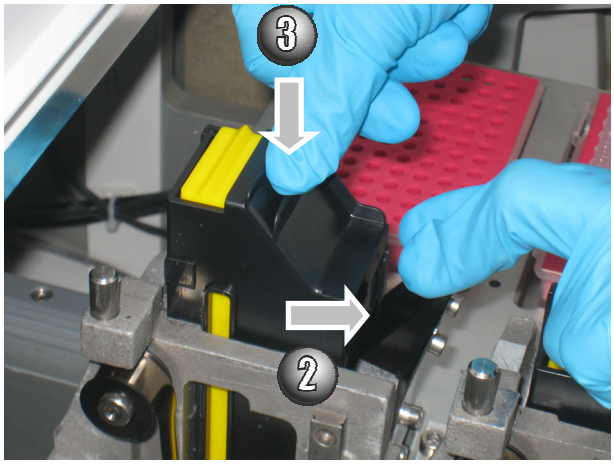


Figure 4-10 : Inserting the cartridge

When the cartridge is fully inserted,

- Release the top lock.
- Check that the top lock is holding the cartridge in place.

CAUTION! ***Do not pinch your fingers in the applicator cartridge holder.***

IMPORTANT! ***Always load FULL applicator cartridges.***

- Close the consumable lid.

IMPORTANT! ***Make sure the consumable lid is properly closed otherwise the instrument will not be able to start processing.***

- Touch the  button to indicate that the applicator cartridge has been changed,

or

- Touch the  button to go back to the previous status, in case of error.
- Touch the  button to return to the main screen.

Loading PREVI Isola Tips

PREVI Isola Tips should be replaced whenever a tip tray is empty.

The instrument status should be “Ready” or “Paused” before loading tips.

To load tips:

- Touch the  button on the instrument touch-screen to display the “Load Applicators and Tips” screen.

  The consumables tray is presented for loading of applicators and tips.

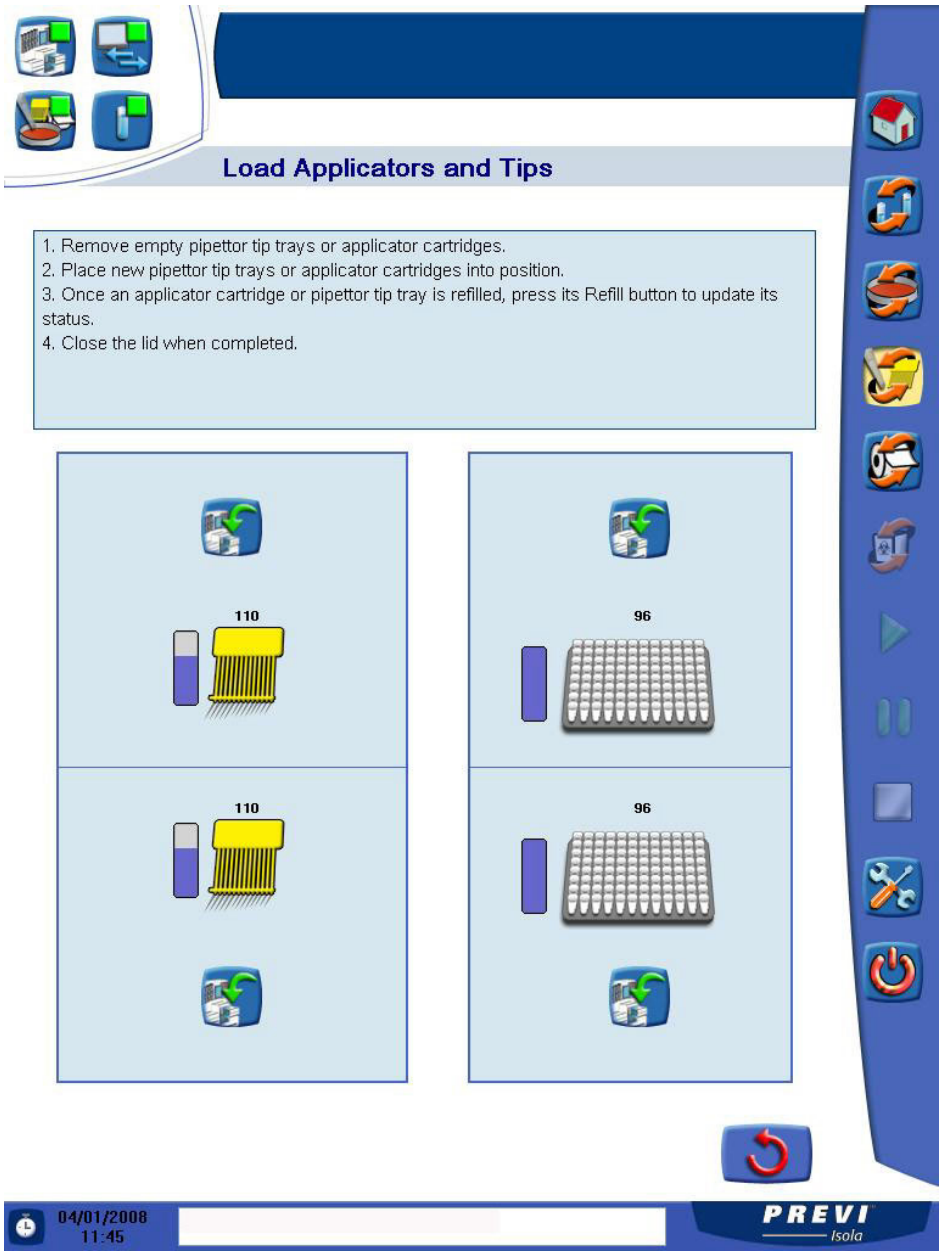


Figure 4-11 : “Load Applicators and Tips” screen

- Open the consumable lid.
- Remove the empty tip tray and discard it.
- Take the new tip tray out of its packaging.
- Remove the lid on the new tip tray.
- Load the new tip tray containing the tips.

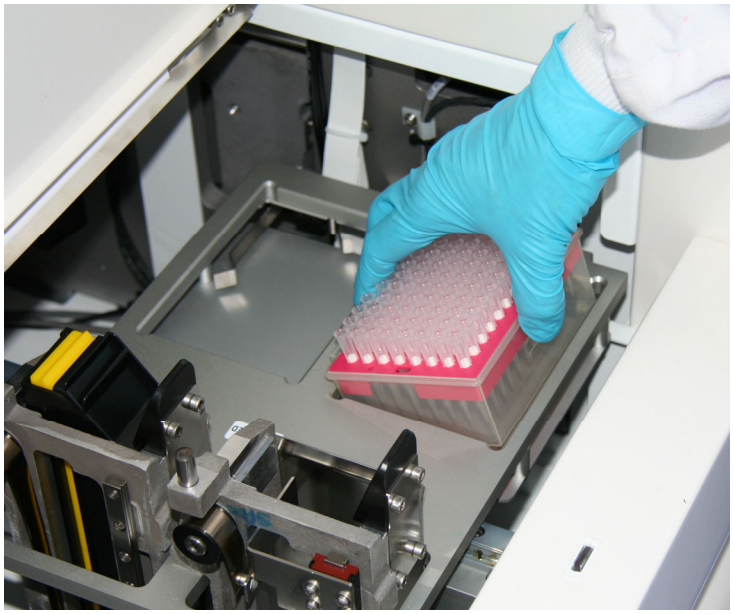


*Figure 4-12 : Inserting the **PREVI Isola** Tip tray*

IMPORTANT! ***Use of PREVI Isola Tips is mandatory.***

Always load FULL tip trays.

Make sure that the tip tray is correctly loaded.

- Close the consumable lid.

IMPORTANT! ***Make sure the consumable lid is properly closed otherwise the instrument will not be able to start processing.***

- Touch the  button to indicate that the tip tray has been changed,

or

- Touch the  button to go back to the previous status, in case of error.
- Touch the  button to return to the main screen.

Loading PREVI Isola Labels

The instrument status should be “Ready” or “Paused” before loading **PREVI Isola** Labels.

To load labels:

- Touch the  button on the instrument touch-screen to display the “Load Labels” screen.

Figure 4-13 : “Load Labels” screen

- Open the process station lid.
- Open the printer access door.
- Follow the instructions in Loading **PREVI Isola** Label Rolls, page 8-23.
- Close the printer access door and then close the process station lid.

- Touch the  button to indicate that the label roll has been changed.

The printer will print a test label.

- Open the printer access door and remove the test label.
- Press the black feed button on the printer to pull the paper through.
- Close the printer access door.

or

- Touch the  button to go back to the previous status, in case of error.

IMPORTANT! ***Do not leave any labels stuck on the printer.***

Make sure the process station lid and printer access door are properly closed otherwise the instrument will not be able to start processing.

If the printer's top cover is not properly closed and even if the green indicator light is on, blank labels will be printed. Close the cover firmly (audible click).

- Touch the  button to return to the main screen.

Monitoring Consumables and Waste Bins Status

The consumables status is displayed on the main screen.

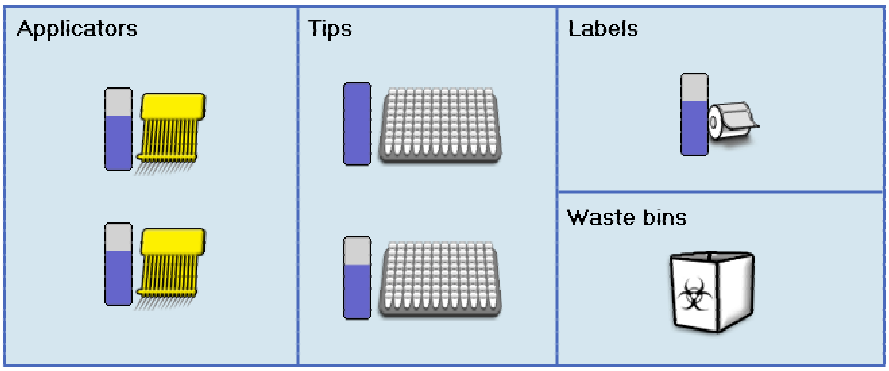


Figure 4-14 : "Main screen – consumable status"

The status area is divided into four zones which show the status of applicators, tips, labels and waste bins.

Consumables

The stock level of each type of consumable is indicated.

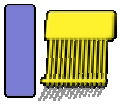
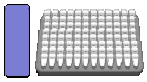
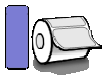
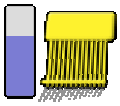
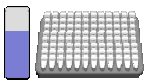
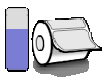
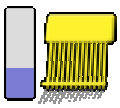
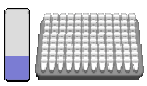
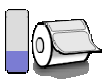
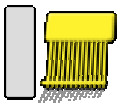
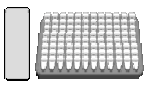
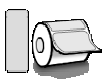
	Applicators	Tips	Label rolls
Full			
Sufficient			
Nearly Empty			
Empty			
Unknown			

Table 4-2 : Consumables status icons

PREVI Isola Waste Bins

The instrument includes two types of Waste Bins,

- one for biohazardous waste (**PREVI Isola** Tips and **PREVI Isola** Applicators)
- one for waste paper (label backing).

Only the filling level of the **PREVI Isola** biohazardous Waste Bin is monitored.

			
Empty	**Low**	**High**	**Full**

Table 4-3 : Waste bin filling level icons

If the biohazardous waste bin is full, the instrument displays a warning to tell the user to empty it. The instrument will complete processing. The user will have to remove the waste before being able to start a new run.

The determination of waste bin full is made by counting the number of tips and applicators dropped to waste and comparing this to predefined maximum levels for high and full.

Sample Preparation

DANGER! ***All organism suspensions should be considered as potentially infectious. Qualified laboratory personnel should take the usual precautions for biohazardous material.***

The **PREVI Isola** has been designed to inoculate PPM with liquid microbiological samples.

IMPORTANT! ***Samples must be thoroughly homogenized before being placed in the sample rack.***

Swabs, solid and semi-solid specimens must be prepared so that a liquid sample is presented to the instrument in the recommended types of containers (see Recommended procedures below).

The recommended sample volumes must be respected (see page 2-10).

IMPORTANT! ***Tubes must never be filled above the maximum fill height as this would affect the pipettor performance.***

Once they have been prepared, samples can be kept for up to 40 minutes before processing.

IMPORTANT! ***The instrument allows isolated colonies to be obtained for samples with a concentration of microorganisms between 10^2 and 10^8 CFU/ml.***

Recommended procedures

Urine

- bioMérieux recommends the use of **PREVI Isola** Rack 2, 4 and 5 tubes (see Sample racks, page 2-9).

Feces

- In order to obtain a liquid suspension, collect 1 to 2 g of feces and emulsify in 2.5 ml of VITEK® Saline solution (bioMérieux ref. V1204 or V1211) in a VITEK 2 tube (bioMérieux ref. 69285).

If a vortex is used,

- Place a cap on the tube beforehand.
- Leave to settle for about 3-5 minutes before processing the sample.

Dry mono swab

- Carefully rotate the swab in a VITEK 2 tube (bioMérieux ref. 69285) containing 2 ml of VITEK Saline solution (bioMérieux ref. V1204 or V1211).

Swab in a liquid transport medium

- Squeeze and rotate the swab within the fluid.
- Use the swab to prepare any microscope slides.
- Discard the swab.

Swab in gel transport medium

- Squeeze and rotate the swab in a VITEK 2 tube (bioMérieux ref. 69285) containing 2 ml of VITEK Saline solution (bioMérieux ref. V1204 or V1211).

Blood

- Carefully transfer 2.5 ml of blood culture into a VITEK 2 tube (bioMérieux ref. 69285).

IMPORTANT! ***Follow good laboratory practices when handling blood culture bottles.***

Liquid respiratory samples

- Viscosity similar to water must be obtained for liquid respiratory samples. For instance, use a digester solution.

Placing Sample Tubes in Racks

- Check that the sample volume corresponds to requirements (see Fill heights, page 2-10) and load uncapped sample tubes in the appropriate sample rack.

IMPORTANT! ***Only recommended sample tube types should be used (see Tubes compatible for use with the PREVI Isola, page 2-10).***

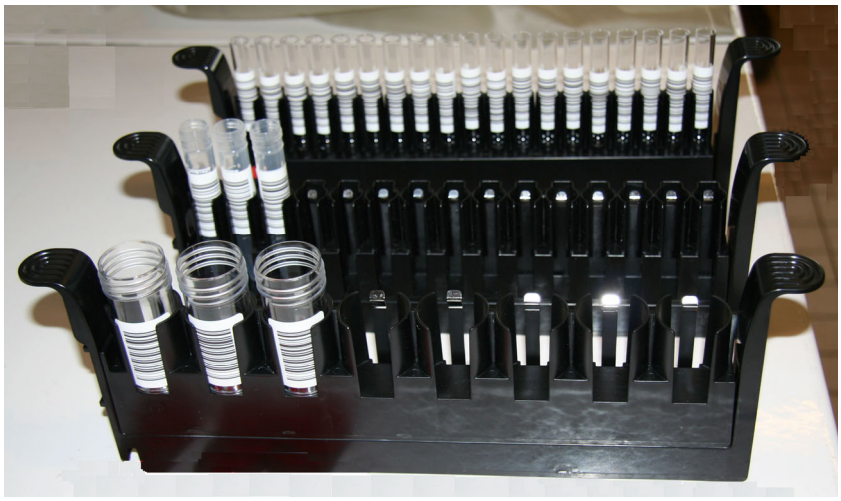


Figure 4-15 : Sample tubes in racks

- Ensure the sample tube barcode is facing the gap in the rack.

Note: *The first tube that will be processed is located in the rack closest to the back of the tray in the position furthest to the left.*

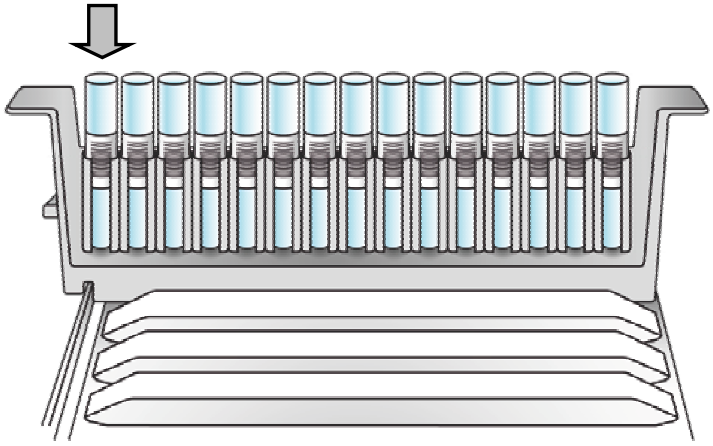


Figure 4-16 : Correct position of tubes in rack

IMPORTANT! ***Check that all the sample tubes have been labeled.***
Ensure the sample tube barcode is facing the gap in the rack. If the label is not correctly positioned, the sample will not be taken into account.

Ensure that the sample tubes are placed in the correct racks.

CAUTION! ***To avoid damage to the pipettor, ensure that the tubes are properly seated in the base of the rack.***

Check that the sample tube caps have been removed.

Loading Sample Racks

The instrument status should be “Ready” before loading sample racks.

To load sample racks:

- Touch the  button on the instrument touch-screen to display the “Load Samples” screen.

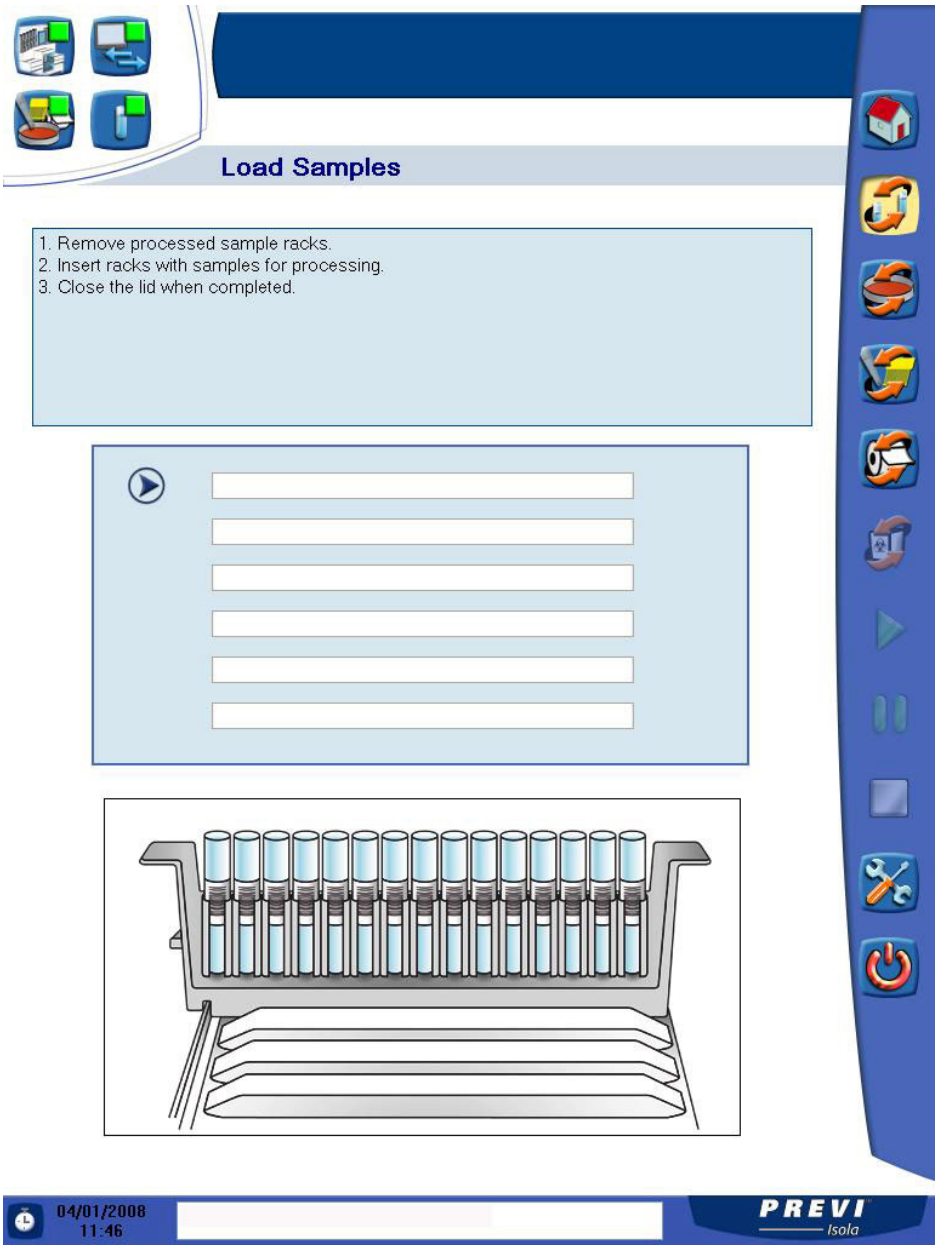


Figure 4-17 : “Load Samples” screen

The sample tray presents for loading of sample racks.

- Open the sample lid.

- Load the sample racks with barcodes facing forwards.

IMPORTANT! ***Ensure that the racks are level and seated securely on the sample tray.***

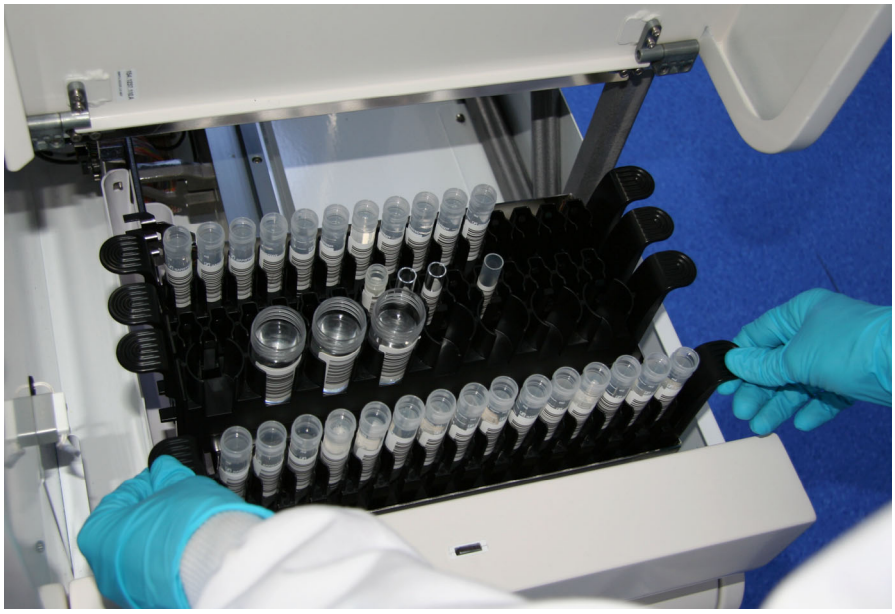


Figure 4-18 : Load sample racks

Note: *Partial filling of racks is acceptable – the instrument will determine that a sample tube location is empty as it will not read a barcode at that location.*

When the sample racks have been loaded:

- Close the sample lid.

IMPORTANT! ***Make sure the sample lid is properly closed otherwise the instrument will not be able to start processing.***

- Touch the  button to return the system to the main screen.

Processing Samples

To process samples:

- Touch the  button on the main screen.

  "Preparing to start processing ...." appears in the status bar and the instrument initializes for 10 to 30 seconds.

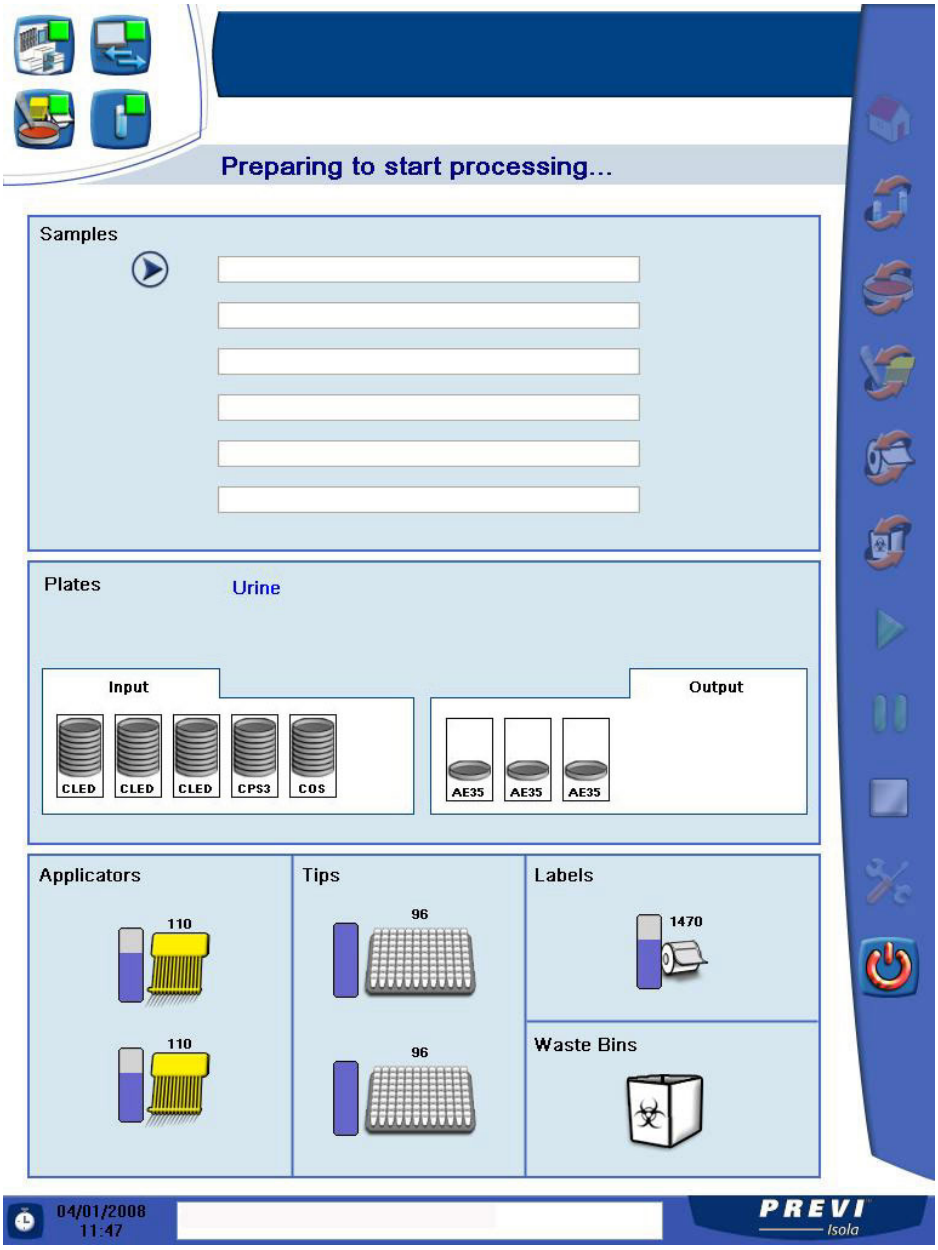


Figure 4-19 : "Preparing to start processing ..." screen

The **PREVI Isola** HEPA filter starts functioning when the  button is touched and stops after 15 minutes of instrument inactivity (see Replacing the **PREVI Isola** HEPA Filter, page 9-17).

Processing begins when the  animated icon appears on the “Processing” screen.

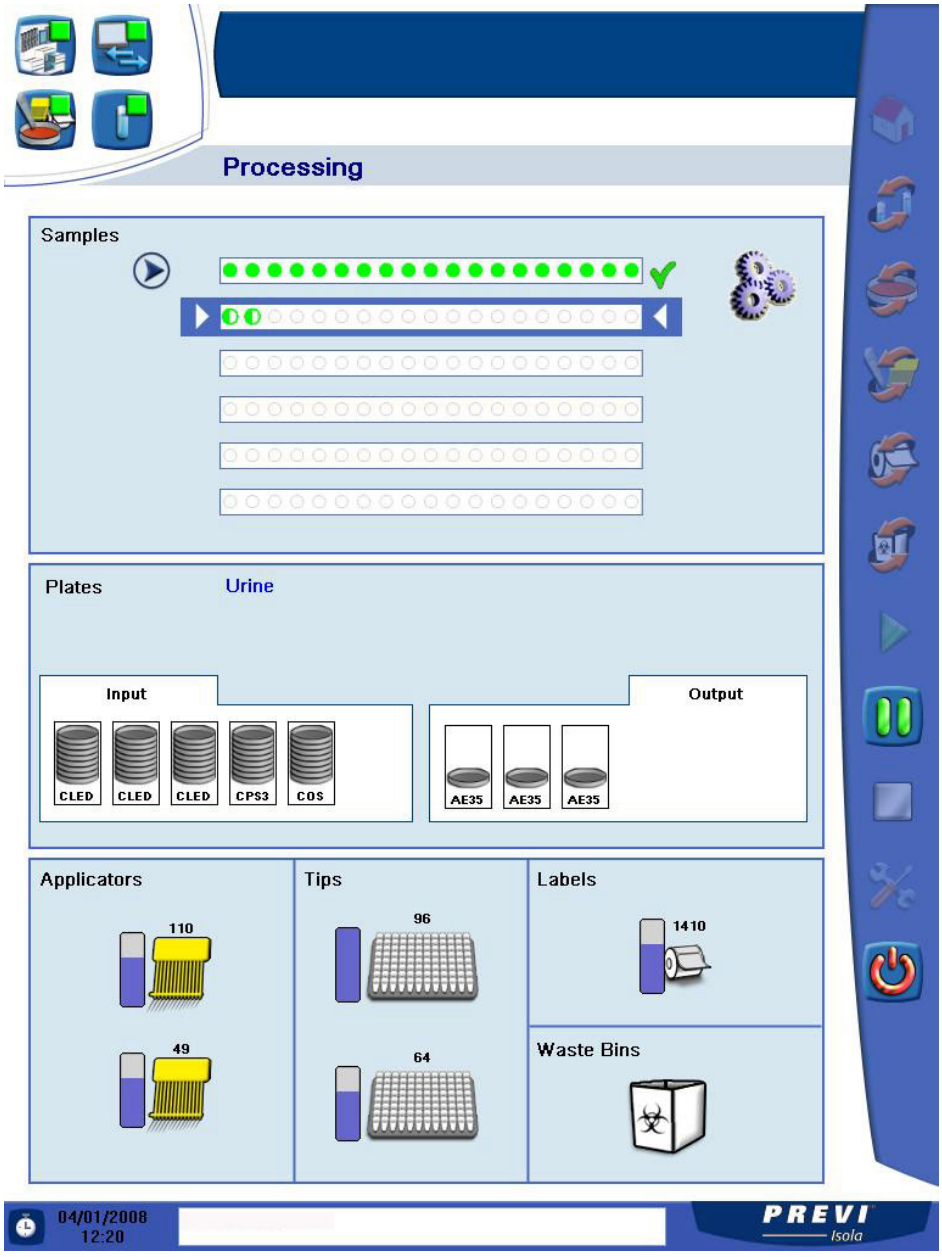


Figure 4-20 : Processing screen

The instrument begins processing the sample tubes starting from the top left of the screen. It continues until the last tube has been processed.

After streaking, each plate is labeled with a barcode containing the following information:

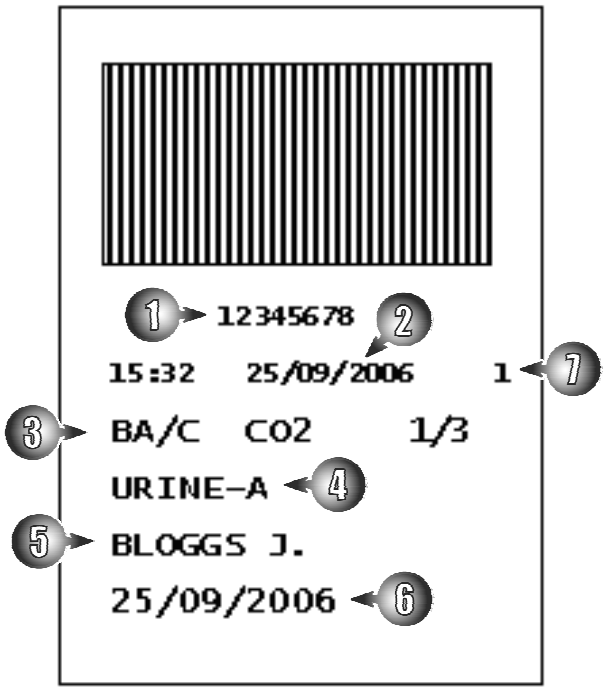
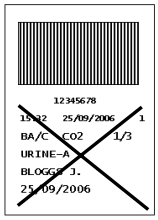


Figure 4-21 : Barcode

1. Sample ID
2. Processing time and date (hh:mm DD/MM/YYYY)
3. Agar type / Incubation atmosphere / Plate n of N
4. Plate panel (15 characters only)
5. Patient name (first 15 characters only)
6. Patient date of birth (DD/MM/YYYY)
7. **PREVI Isola** instrument number (1 to 4)

Data on the labels of failed samples are crossed out as shown below.



Processed plates are moved to the output cassette and are stacked sorted by incubation type (i.e. aerobic, anaerobic, microaerophilic, and CO_2).

Note: Processed plates are delivered to the output cassette agar-side up.

When the sample tube has been processed (i.e. all plates for this sample have been streaked and are on the output cassettes), the sample tube processing status is set to “Processed” (see Figure 4-22 : Sample processing status).

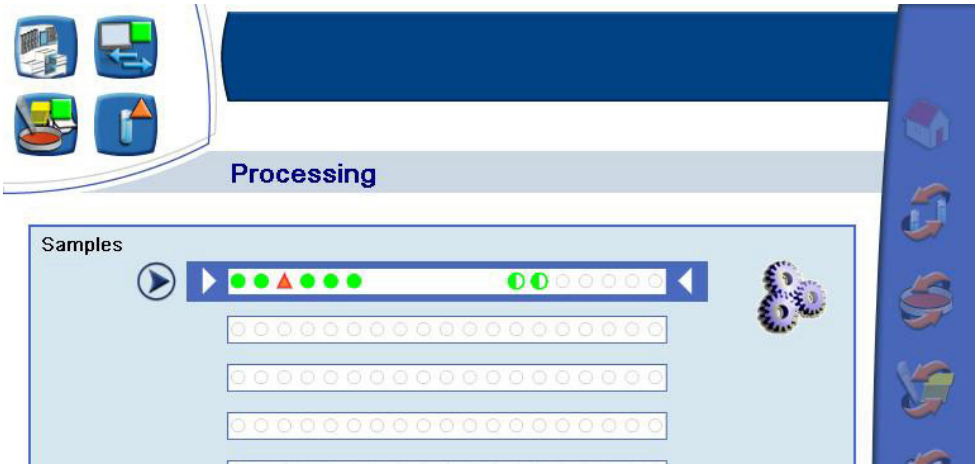


Figure 4-22 : Sample processing status

○	Status unknown The instrument has identified the type of rack but does not yet know whether a sample is present.
	No sample detected. The sample position has been processed, but the instrument has not been able to read the barcode or there is no sample in this position. The workflow resumes with the next position.
▲	Sample skipped. After reading the barcode, the instrument considers that: – the sample has already been processed, – there is no information from the Data Server enabling the sample to be processed, – the current plate cassettes configuration is not what is expected for the type of sample. Skipped sample tubes will be noted on the instrument and the user can view them using the instrument user interface when the run is complete.
◐	Sample processing.
●	Sample processed successfully.
⊗	Sample failed for the following reasons: – Incorrect sample volume The volume check ensures that there is sample in the tip. The instrument does not quantify the volume of sample. It considers that the volume is sufficient as long as it can detect some sample (at least 10 µl). However, if the sample volume is not detected as sufficient (at least 10 µl) all the plates of the plate panel will be streaked but the sample will be marked as failed. – During sample processing, a fatal error occurred which stopped the instrument.
✓	Rack processed successfully.
✗	Processing failed for at least one sample in the rack.

Table 4-4 : Sample processing status icons

When the instrument has completed processing all the loaded samples, it returns to “Ready” status.

IMPORTANT! ***At the end of a run, the failed samples can be reprocessed by touching .***

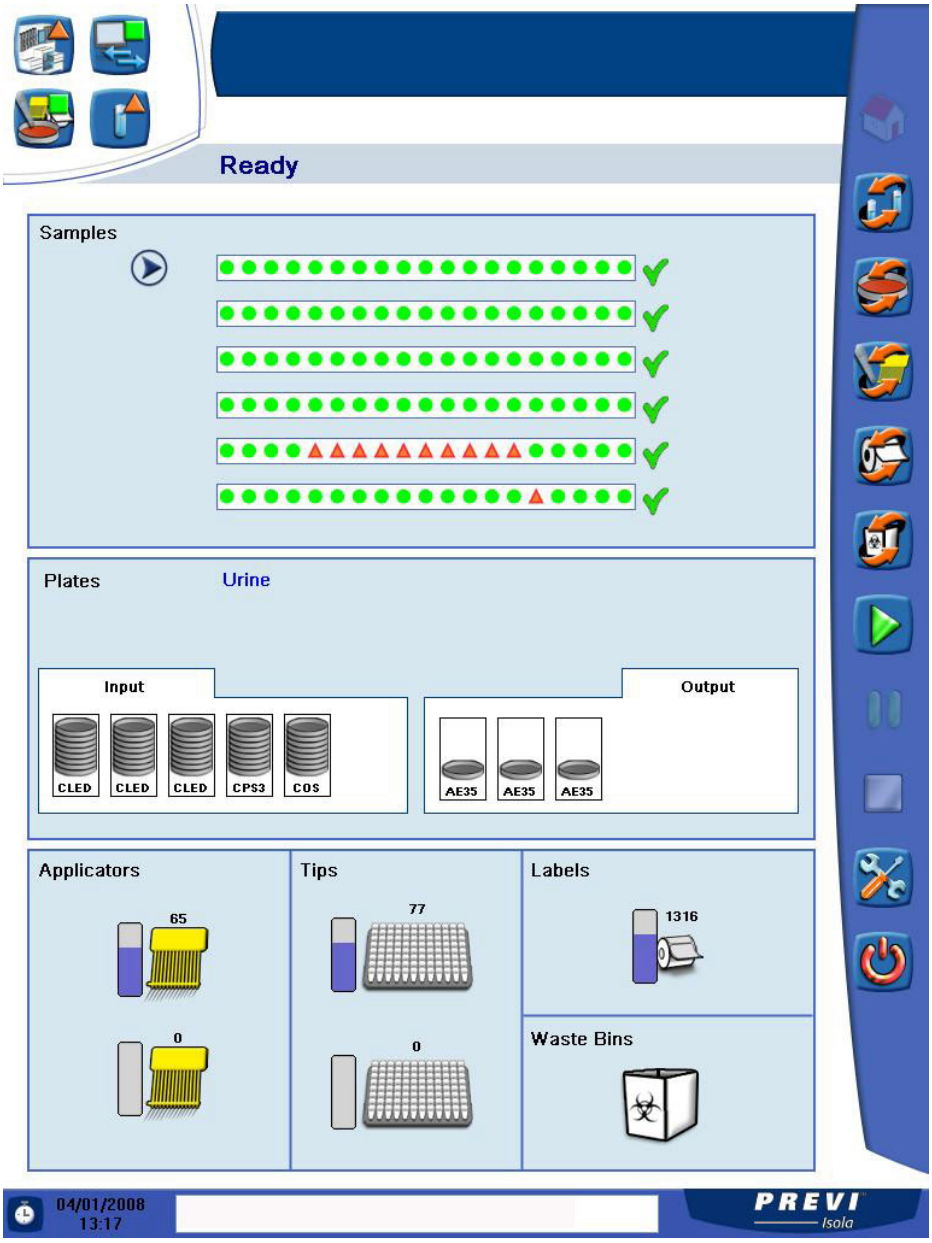


Figure 4-23 : “Processing Complete” screen

The skipped sample tubes can be located on the screen in the sample working area.

Processing hints

1. If several input cassettes contain the same type of PPM, one plate will be taken from each of these cassettes alternatively.
2. If there are several output cassettes for one incubation atmosphere, the cassettes will be filled one after another.
3. If both tip trays contain tips at the start of the streaking process, the tips are taken alternatively from each one.

DANGER! ***To avoid the risk of contamination, do not open the waste drawer during processing.***

Pausing the Instrument

Instrument-generated pause

The instrument will enter the "Paused" status:

– If it lacks consumables to process the next sample.

  If the Instrument determines that it does not have sufficient consumables (pipettor tips, plates, applicators and labels) to process the sample, it will finish processing the plates that are being processed, but will not start on the next sample. Once the last plate has been stacked in the output cassette, the instrument will enter the paused processing state and display a prompt on the instrument user interface to replenish the missing consumable(s).

- Acknowledge the message displayed.
- Perform the necessary action.

IMPORTANT! ***When the Instrument is in "Paused" mode, it is possible to load PREVI Isola Tips, PREVI Isola Applicators and PREVI Isola Labels. IT IS NOT POSSIBLE, IN THIS MODE, TO LOAD SAMPLES.***

Once the action has been performed,

- Resume processing by touching the  button in the navigation/action bar on the right-hand side of the touch-screen.

  The instrument will resume from where it paused.

User-generated pause

The user will need to pause the instrument in the following situations:

– When the instrument is close to running out of consumables – **PREVI Isola** Tips, **PREVI Isola** Applicators or **PREVI Isola** Labels – (a warning is displayed on the screen).

– When the input cassette is removed to load plates.

– When the output cassette is removed to unload processed plates.

IMPORTANT! ***When the instrument is in "Paused" mode, it is possible to load PREVI Isola Tips, PREVI Isola Applicators and PREVI Isola Labels. IT IS NOT POSSIBLE, IN THIS MODE, TO LOAD SAMPLES.***

To pause the Instrument,

- Touch the  button in the navigation/action bar on the right-hand side of the touch-screen.

The instrument will finish its cycle before pausing.

- Perform the necessary action.

To restart the instrument process,

- Touch the  button in the navigation/action bar on the right-hand side of the touch-screen.

Stopping the Instrument

Instrument-generated stop (Error case)

The instrument will stop:

- If it lacks consumables to process the current sample.
- If a fatal error occurs during processing (e.g. if a cover is opened).

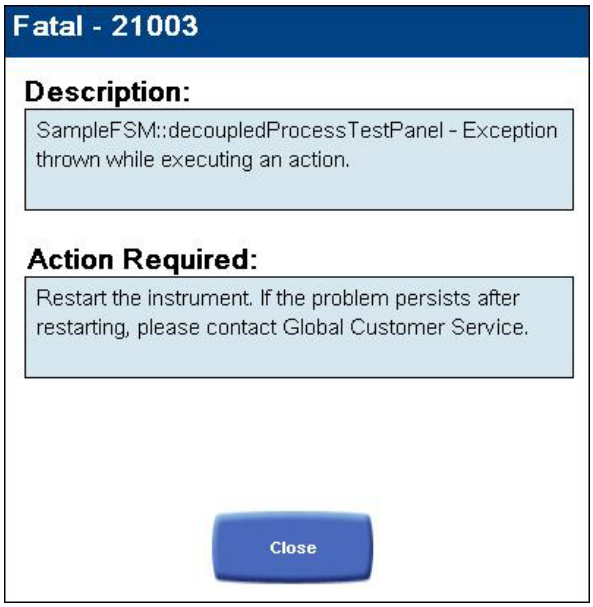


Figure 4-24 : "Fatal Error" screen

Resuming operations after stopping

Following an instrument-generated stop, only the  button is activated. Therefore,

- Acknowledge the error.
- Perform the necessary action.
- Once the action has been performed,
- Touch the  button in the navigation/action bar on the right-hand side of the touch-screen.

The “Shutdown Requested” Window is displayed.

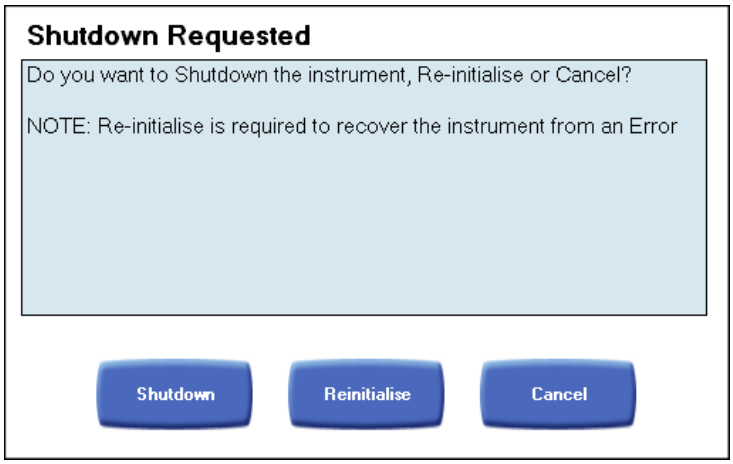


Figure 4-25 : “Shutdown Requested” window – instrument processing

- Touch the “Shutdown”, “Reinitialise” or “Cancel” button depending on what you want to do.

If the error has been caused by a missing consumable, an open lid, a cassette that has been removed or any kind of fault that can be easily remedied, perform the necessary action and reinitialize.

IMPORTANT! ***In case of Fatal error (E-stop) or power failure, do not manually move a sample rack or the sample tray. The instrument will present the sample tray after reinitializing.***

If reinitialization does not clear the error, try “shutdown” (see Restarting the Instrument Software, page 9-16).

Do not touch “Cancel” as you will return to the main screen but will not be able to continue with processing.

During reinitialization, if there are partially processed plates,

- Remove them from the instrument (see page 4-32).

Note: *Any plates on the output robot deck should be considered as processed.*

- If necessary, remove the label that has been printed and is coming out of the printer.

The instrument will reinitialize.

- Restart processing by touching the  button in the navigation/action bar on the right-hand side of the touch-screen.

  The instrument will skip any processed samples and resume processing any unprocessed samples.

User-generated stop

The user may need to stop the instrument in the following situations:

- to load additional samples.
- to change the plate cassettes configuration (the instrument was started with an incorrect plate cassettes configuration).

To stop the instrument:

If the instrument is already in the “Paused” status,

- Touch the  button in the navigation/action bar on the right-hand side of the touch-screen.

If the instrument is not paused:

- Touch the  button in the navigation/action bar on right-hand side of the touch-screen.

  The instrument finishes processing the current sample and then pauses.

CAUTION! ***Do not open any instrument covers until the instrument touch-screen returns to “Ready” status.***

Resuming operations after stopping

- Resume processing by touching the  button in the navigation/action bar on the right-hand side of the touch-screen.

  The instrument will skip any processed samples and resume processing any unprocessed samples.

Unloading Processed Plates

Unloading processed plates on completion of processing

On completion of processing, the instrument returns to the “Ready” screen and the processing status of each sample is displayed.

- Open the guard.
- Remove the output cassettes from the instrument.

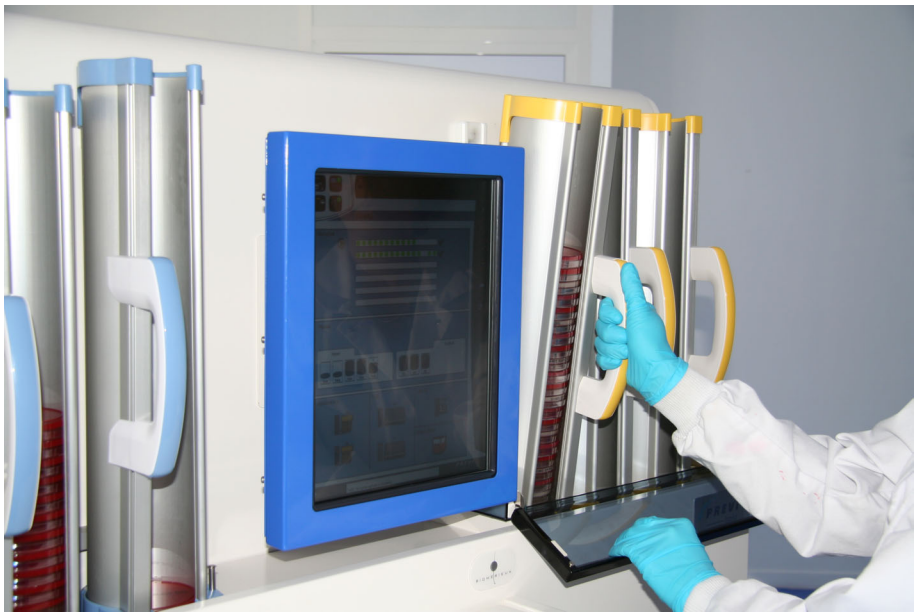


Figure 4-26 : Opening guard and removing output cassette

- Load empty output cassettes.
- Close the guard.

IMPORTANT! ***If the guard is opened during processing, or a cassette is removed without pausing the instrument, an error is generated and the instrument stops.***

Unloading processed plates during processing

Remove a full output cassette

The user may want to unload processed plates during processing if an output cassette is complete.

To do this,

- Touch the  button in the navigation/action bar on the right-hand side of the touch-screen.

  The instrument will finish its cycle before pausing and will then display the “Paused” Screen.

- Open the guard.
- Remove the output cassette from the instrument.
- Store the plates in the required incubation atmosphere, with or without the output cassette.
- Load an empty output cassette.

IMPORTANT! ***If an output cassette is missing the instrument will not operate.***

- Close the guard.

To restart the instrument process,

- Touch the  button in the navigation/action bar on the right-hand side of the touch-screen.

Remove plates from the cassettes *in situ*

It is possible to remove plates from the output cassettes while the instrument is processing without stopping the instrument.

IMPORTANT! ***Take care not to open the guard otherwise the instrument will stop.***

Unloading unprocessed plates

Unprocessed plates must be unloaded and stored according to the recommendations in the prepoured media package inserts.

Unloading Sample Tubes

When processing is complete, the instrument presents the sample tray for unloading.

To unload sample tubes:

- Touch the  button to present the sample tray for unloading of sample racks.
- Open the sample tray lid.
- Unload the sample racks.
- Store samples as per usual laboratory procedures.
- Close the sample tray lid.
- Touch the  button to return to the main screen.

Removing Waste

PREVI Isola biohazardous Waste Bin

Biohazardous waste should be removed:

– when the  or  icon is displayed,

– when recommended by the laboratory procedures.

To remove the biohazardous waste,

- Check that the instrument is not processing.
- If the instrument is working, wait for it to stop completely.
- Open the waste drawer.
- Remove the biohazardous waste bin from the instrument.
- Dispose of the biohazardous waste bin according to the usual laboratory procedures for biohazardous waste and in accordance with any applicable local regulations.
- Put a new waste bin in place.
- Close the waste drawer.
- Update the waste status by touching the  button (this button is only enabled when the main screen is displayed).

The waste bin status icon on the screen changes to 

DANGER! ***To avoid contamination of the laboratory environment, never touch the***  ***button if the biohazardous PREVI Isola Waste Bin has not actually been emptied and do not open the waste drawer during processing.***

When replacing the PREVI Isola Waste Bin, take all the necessary precautions for handling biologically hazardous products.

IMPORTANT! ***It is the responsibility of each laboratory to handle waste and effluents produced according to the nature and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.***

PREVI Isola Waste Paper Bin

The waste paper bin fill level is not monitored by the software. It should be monitored by the user.

To empty the label backing waste bin,

- Check that the instrument is not processing.
- If the instrument is working, wait for it to stop completely.
- Open the waste drawer.
- Cut the label backing. Leave about 50 cm of paper coming out of the printer.
- Remove the waste paper bin from the instrument.
- Dispose of the waste paper bin.
- Put a new waste paper bin in place.
- Make sure that the paper coming out of the printer falls into the waste bin properly.
- Close the waste drawer.

Powering Down the Instrument

The instrument status should be “Ready”.

To power down the instrument,

- Touch the  button on the instrument user interface.

The instrument user interface software puts the instrument robots into a safe state.

The following window is displayed:

- Touch “Shutdown”.
- Close the Windows application.
- Switch off the instrument.

Examples of Correct Streaking Patterns

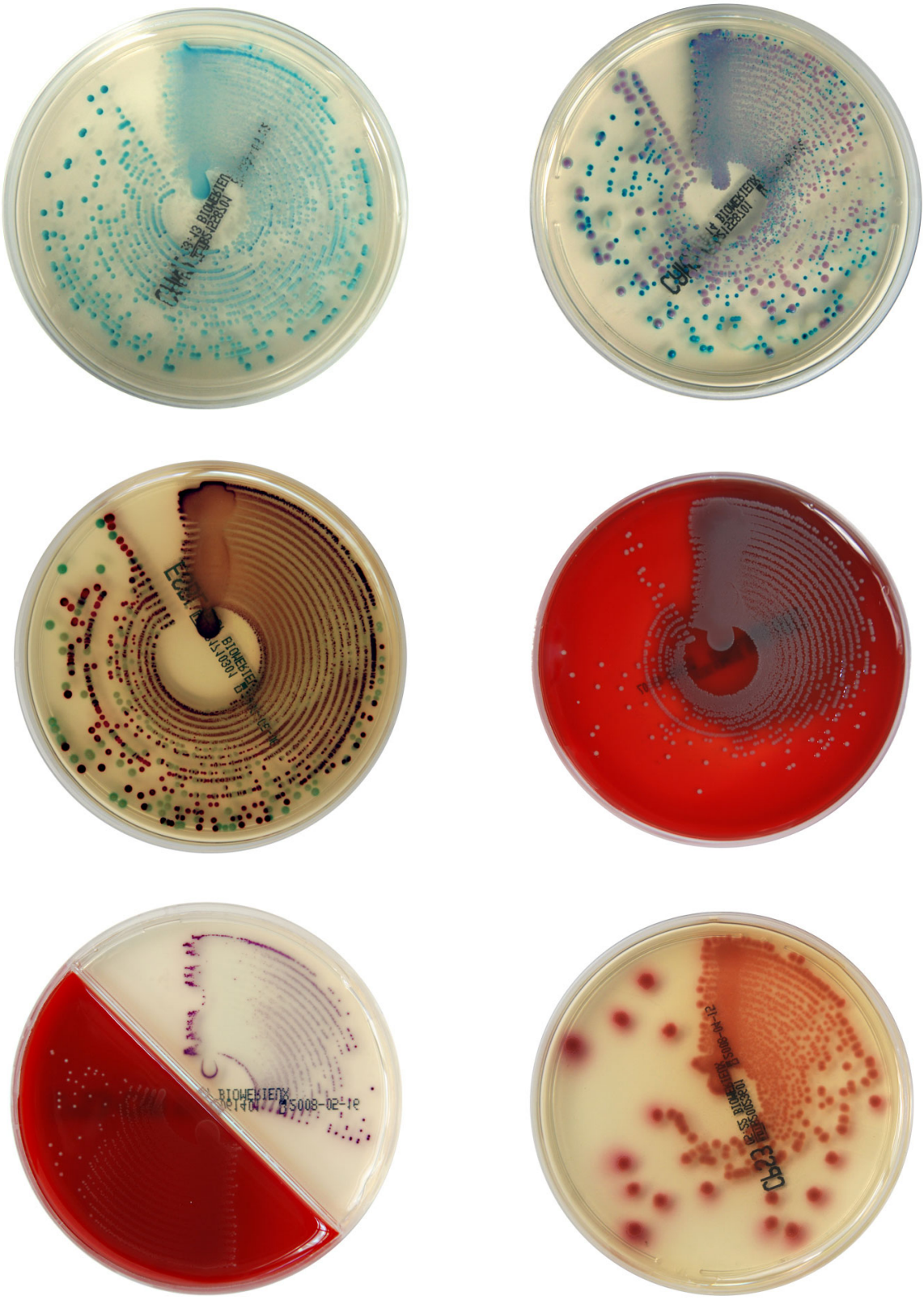


Figure 4-27 : Correct streaking patterns

5 Quality Control

Intended Use

This protocol applies to quality control of the **PREVI Isola** instruments.

It consists in testing a suspension of *E.coli* (ATCC 25922) at 10^8 CFU/ml in NaCl 0.45g/l on 2 TSA plates.

Number of isolated colonies, surface of growth and streaking anomalies are counted and compared to acceptance criteria.

Note: It is recommended to perform a weekly Quality Control.

Material

- 1 tube (VITEK® 2 - bioMérieux ref. 69285).
- *Escherichia coli* N°77 05 035, ATCC 25922
- VITEK Saline solution (bioMérieux ref. V1204 or V1211)
- a DENSICHECK™ under metrology (220 V - bioMérieux ref. 27208 / 110 V - bioMérieux ref. 27207)
- 2 TSA plates (Trypcase Soy Agar - bioMérieux ref. 43011)
- Vortex
- Psipettes (bioMérieux ref. 70250)
- **PREVI Isola** Tips (bioMérieux ref. 29508)
- **PREVI Isola** Applicators (bioMérieux ref 29509)
- Incubator under metrology
- Colony counter pen

Note: If a medium other than TSA is used, the user must establish his own criteria.

Workstation Preparation

According to the User Manual (see Chapter 4 Using the System):

- Assign to your sample a Plate Panel including two TSA plates to be incubated at 36 ± 1 °C in atmospheric air (see Assigning Plate Panels to Samples, page 3-22).
- Apply the “Quality Control” streaking protocol.

Instrument Preparation

According to the User Manual (see Chapter 4 Using the System):

- Place TSA plates (at least 7) in the Instrument input cassette.
- Load **PREVI Isola** Tips and **PREVI Isola** Applicators.
- Select the media on the screen.

Sample Tube Preparation

- Prepare 1 VITEK® 2 tube.
- Stick 1 barcode label dedicated to the QC on the tube.
- With a calibrated DENSICHECK™, prepare a 0.5 McF suspension of *E. coli* freshly cultivated on TSA agar (18-24hrs at 36°C).
- Carefully mix and adjust the suspension at 0.5 McF.
- Turn the tube several times in order to confirm the value. Mix the suspension with a Psipette or with a vortex.
- Place the tube in the corresponding rack.
- Assign the Plate Panel code: “QC” to the tube.

Sample Run and Plate Incubation

According to the User Manual (see Chapter 4 Using the System):

- Place the rack in the Instrument.
- Start the Instrument.
- Remove the plate from the Instrument once the quality control sample has been processed.
- Incubate the 2 plates at 36 ± 1 °C for 18 - 24 hours.

Results

For each plate, record:

– The **number of isolated colonies** (**IC**):
An isolated colony is defined as a colony that is separate from other colonies.

– The **score**, from 0 to 7 (**Sc**):
The score corresponds to the surface of the agar totally covered by the culture (layer or isolated colonies) (see page 5-3).

– The **Appearance** (**A**)
The expected appearance is described on page 5-3.

Score Determination

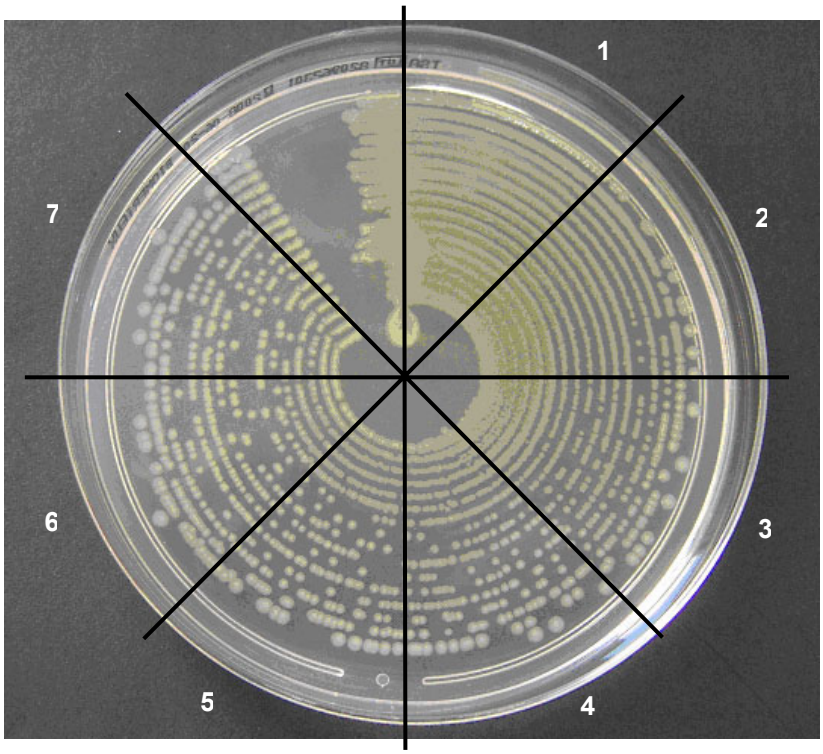


Figure 5-1 : Score determination

The plate is divided into 8 sections.

In this example the score is 7.

Reference Appearance

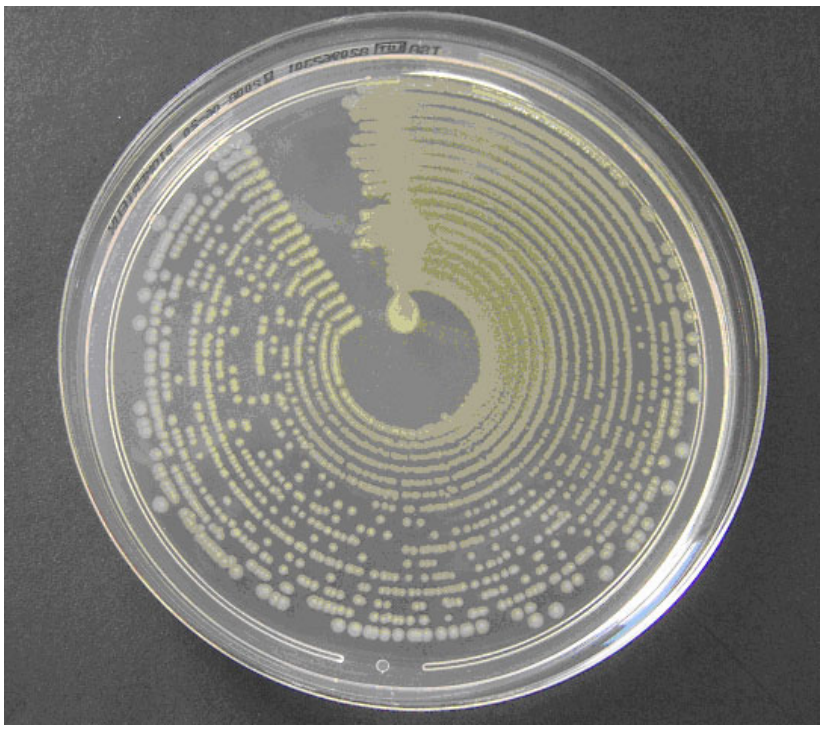


Figure 5-2 : Reference appearance

Results

The acceptance criteria are defined as follows:

Parameters	**IC**	**Sc**	**A**
Criterion	15 to 65	5 to 7	Conform to the reference
Plate 1			
Plate 2			
Conclusion			
Signature:			
Date:			

If the results are not conform, repeat the Quality Control.

If non-conformity is confirmed, contact a bioMérieux Application Specialist.

6 Information Technology Security

User Management

To use the workstation PC, a user account that belongs to specific user groups is required.

User groups

In the Windows User Management function, a user group is an account containing other accounts called members (user accounts). The permissions and rights assigned to a group are also given to its members. This enables common management of rights and permissions for sets of user accounts.

*Note: A user account contains the information which defines a user under Windows and **PREVI Isola**, in particular, the user name, password and user group membership.*

The **PREVI Isola** user groups are:

* For Windows:
  - **Users**: use of Windows.
  - **Power Users**: advanced use of Windows.
    A special **labadmin** user with **Power User** privileges has been created and provided with the system. Only this **labadmin** user is able to assign new users to the LABORATORY_SUPERVISOR, LABORATORY_TECHNICIAN, BCI_ADMIN and BCI_ROUTINE groups.
  - **Administrator**: use of Windows with administrator privileges (for bioMérieux S.A. Technical Assistance or your local bioMérieux representative only).
* For the **PREVI Isola**:
  - **LABORATORY_TECHNICIAN**: daily use of **PREVI Isola**.
    Users who want to manually assign plate panels to samples (see Assigning Plate Panels to Samples , page 3-22) or view worklists, must belong to this group.
  - **LABORATORY_SUPERVISOR**: advanced use of the **PREVI Isola** (configuration).
    Users who want to define plate panels (see Defining Plate Panels, page 3-6), assign plate panels to specimen types (see Assigning Plate Panels to Specimen Types, page 3-15), and define Plate cassettes configurations (see Defining Plate Cassettes Configurations, page 3-19), must belong to this group.
* ***BCI NET*** or ***BCI RS232*** (see the ***BCI NET*** or ***BCI RS232*** User's Manual) :
  - **BCI_ROUTINE**
    Users who want to open a Windows session on the workstation and start BCI NET must belong to the BCI_ROUTINE group.
  - **BCI_ADMIN**
    Users who want to configure BCI must belong to both the BCI_ROUTINE and BCI_ADMIN groups.

Creating a new user account

A new user account can be created by the **labadmin** user.

To access the User Management function:

- Select menu “Start / Programs / Administrative Tools / Computer Management”.

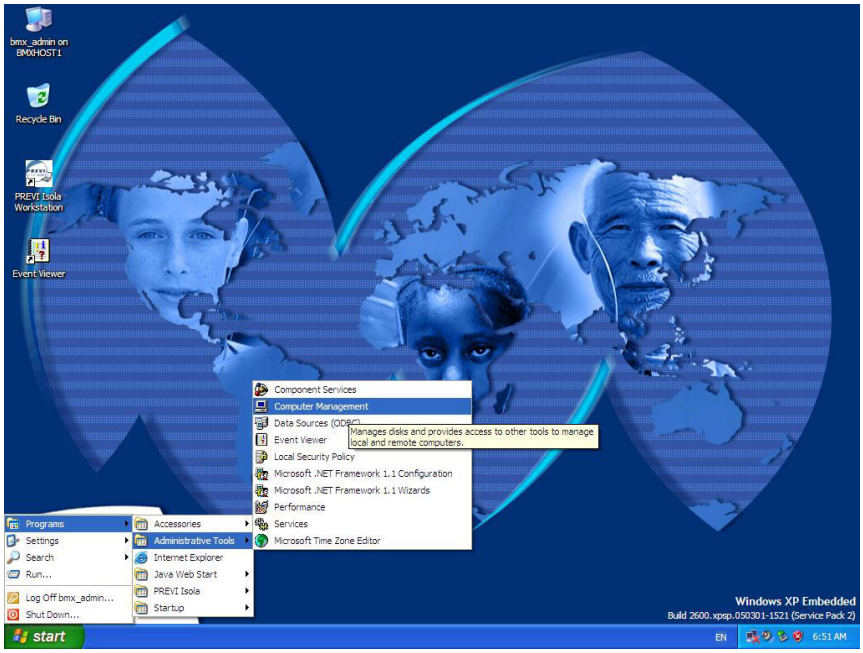


Figure 6-1 : Opening the Computer Management window

The Computer Management window is displayed.

- Click on “Local Users and Groups” **(1)** in the left-hand part of the screen.

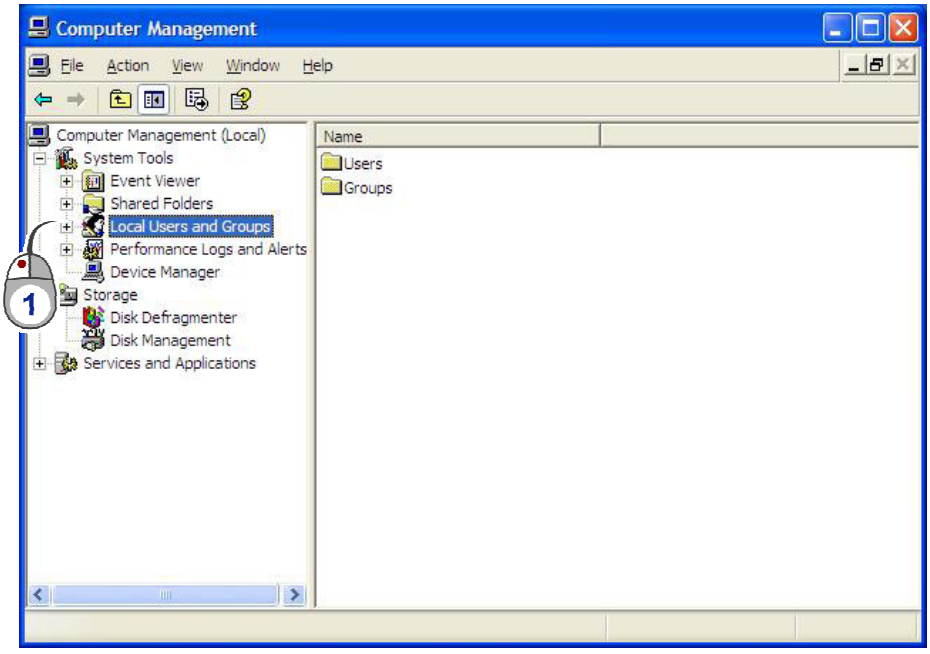


Figure 6-2 : "Computer Management" screen

To display the dialog box for creating a new user account:

- Right-click "Users" **(2)** to display the context menu.
- Click "New User…" **(3)**.

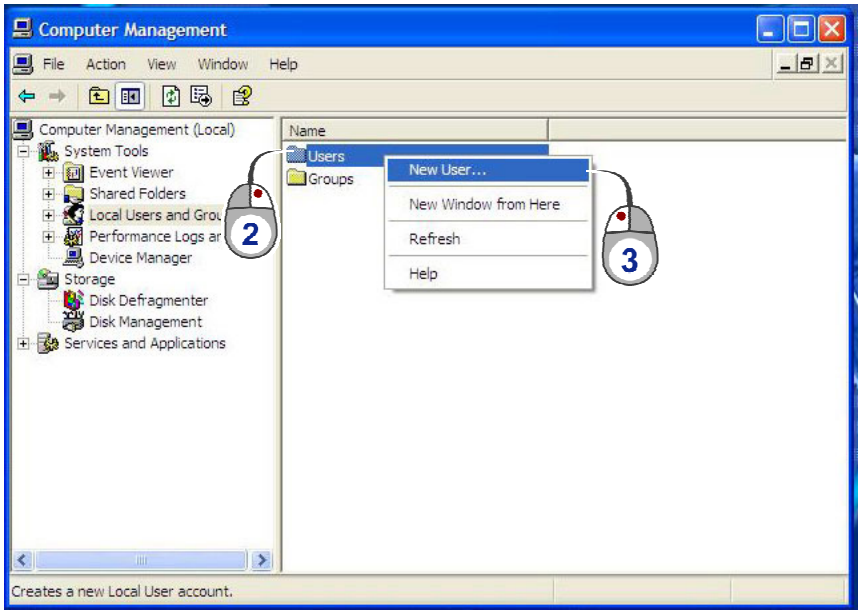


Figure 6-3 : "New User" screen

The "New User" creation box is displayed.

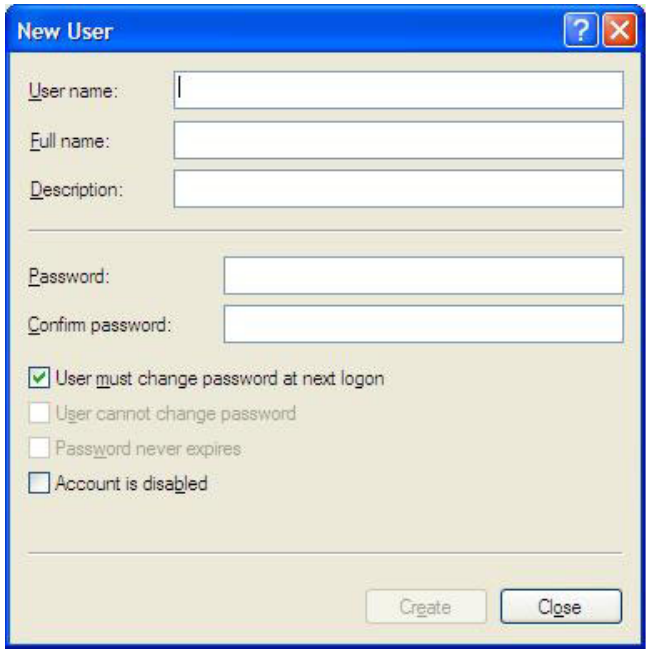


Figure 6-4 : "New User" creation box

- Enter:
  - The user name (**PREVI Isola** workstation login).
  - The user's full name.
  - The user's description (optional).
  - The user's password.

Note: The password must include at least 8 characters.

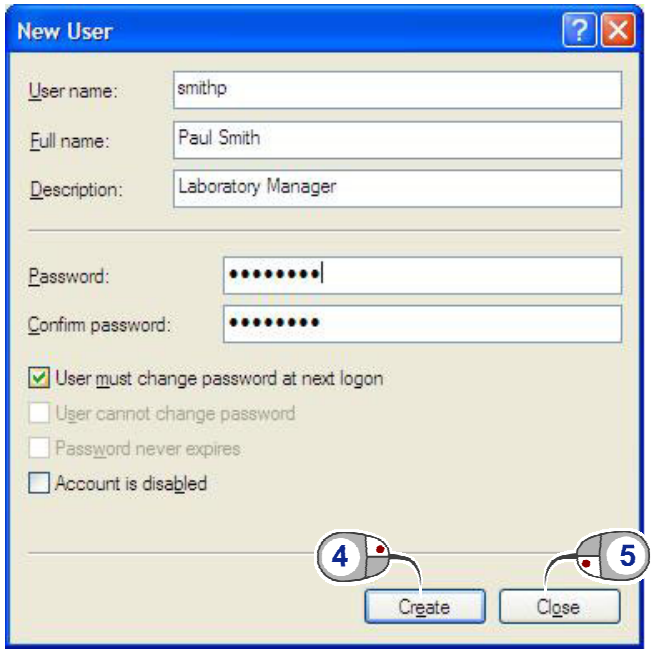


Figure 6-5 : "New User" creation box with data entered

- Click "Create" **(4)** to create the new user account.

  The information entered and the options selected disappear from the screen.

- Click "Close" **(5)** to close the window.

Assigning user permissions and rights

Permissions and rights are assigned to a user by the **labadmin** user.

User permissions and rights are assigned by attaching the user to one or more user groups.

Laboratory Managers should be assigned to the following groups:

- BCI_ADMIN
- BCI_ROUTINE
- LABORATORY_SUPERVISOR
- Power Users

Laboratory Technicians should be assigned to the following groups:

- BCI_ROUTINE
- LABORATORY_TECHNICIAN

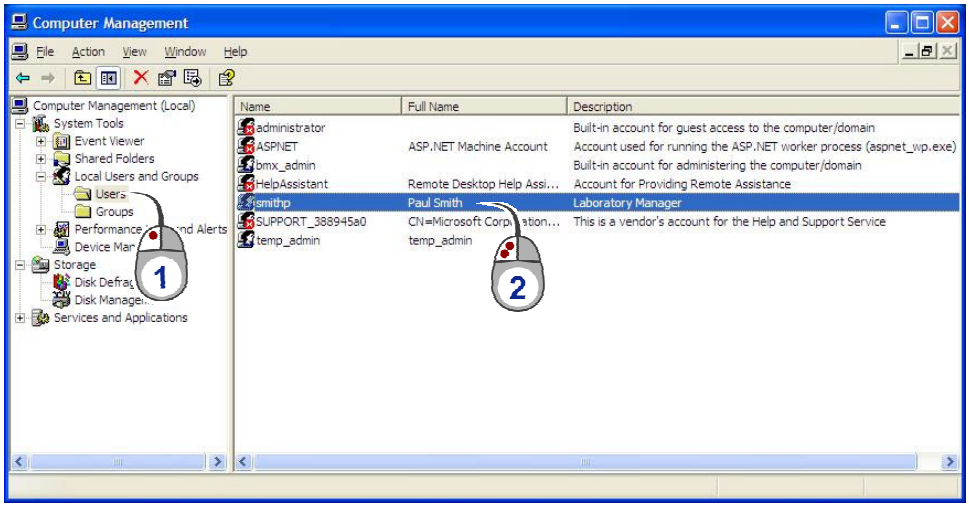


Figure 6-6 : "User Rights Management" screen

- Click "Users" **(1)** and double-click the desired user name **(2)**.

The user's "Properties" dialog box is displayed.

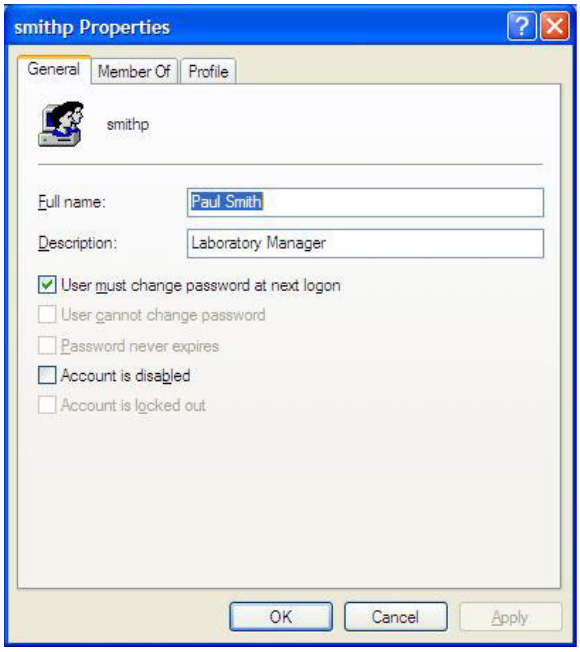


Figure 6-7 : User "Properties" screen

- Click the "Member Of" tab **(3)** to display the list of groups to which the user belongs.

Note: When a new user account is created, it is automatically a member of the "Users" group.

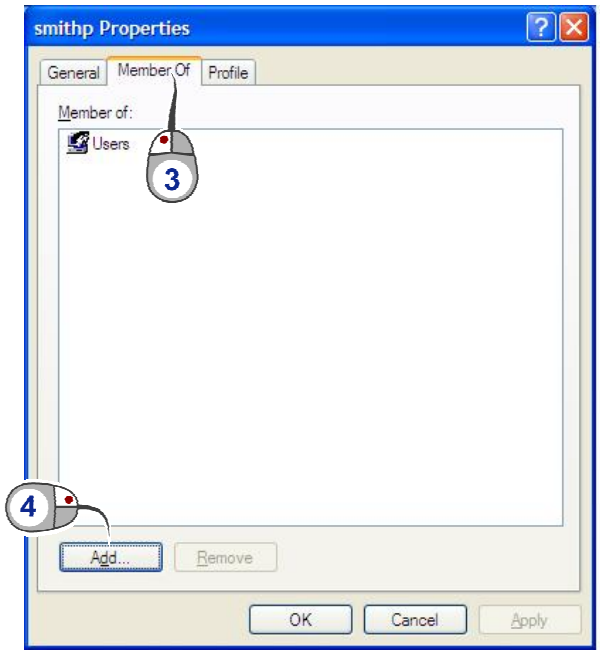


Figure 6-8 : "User properties" – " Member Of " tab screen

- Click "Add" **(4)**.

The "Select Groups" window is displayed.

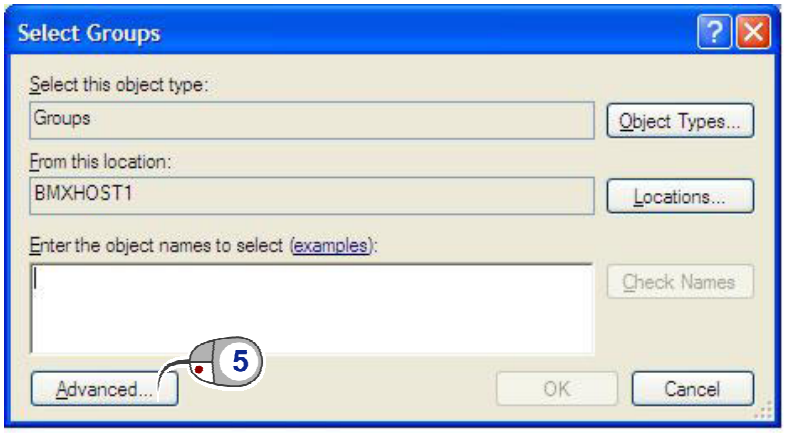


Figure 6-9 : "Select Groups" screen

- Click "Advanced…" **(5)**.

A second "Select Groups" window is displayed.

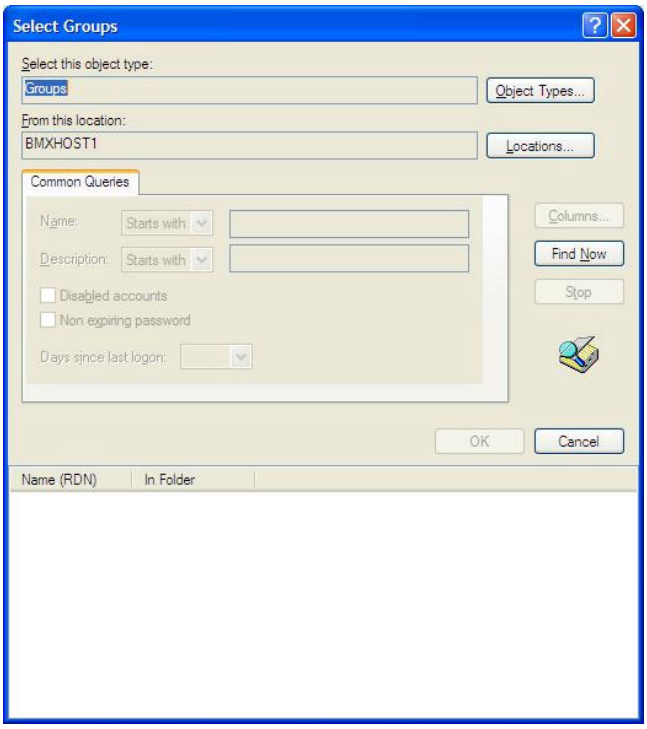


Figure 6-10 : "Select Groups" screen (cont'd)

- Click "Find Now"**(6)**.

The list of user groups is displayed at the bottom of the window.

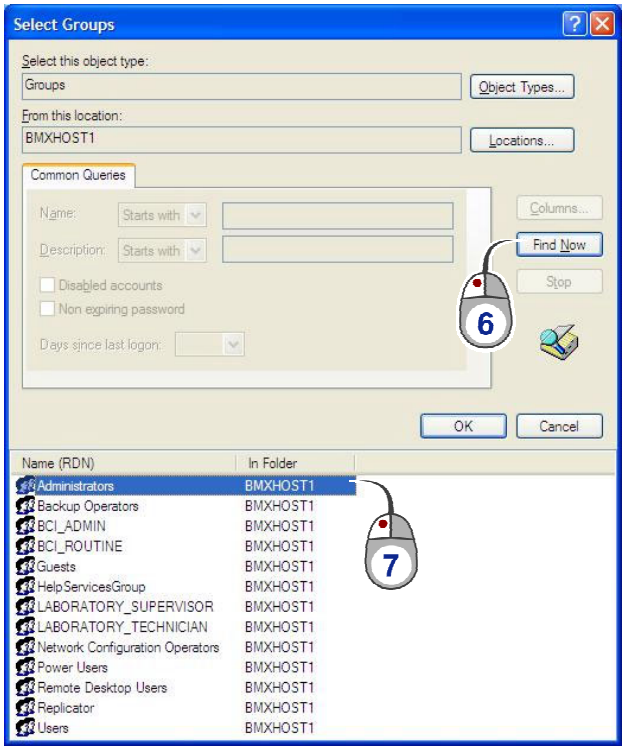


Figure 6-11 : "Select Groups" screen (cont'd)

- Select the user groups **(7)** to which the user will belong.

Note: Select the user group(s) by clicking on their name(s).

To select several groups:

*Hold down the **<Ctrl>** key and click on the names you want.*

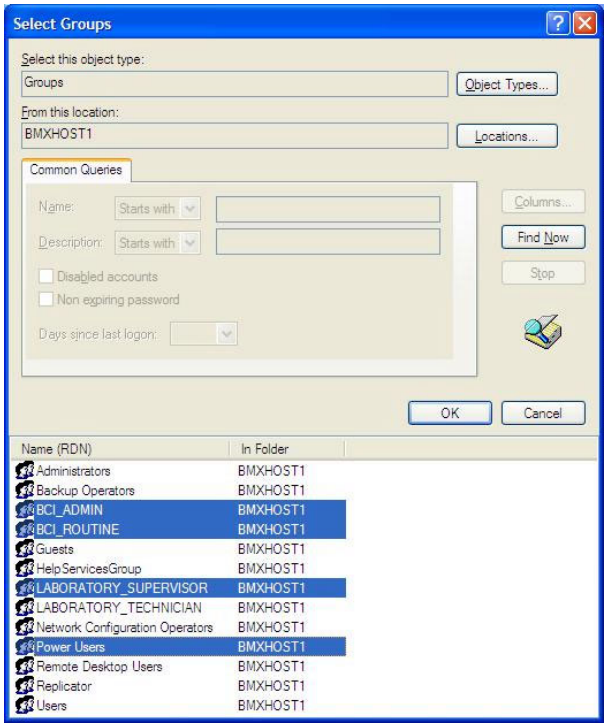


Figure 6-12 : "Select Groups" screen (cont'd)

- Click "OK" to confirm.

The "Select Groups" window is displayed with the list of user groups.

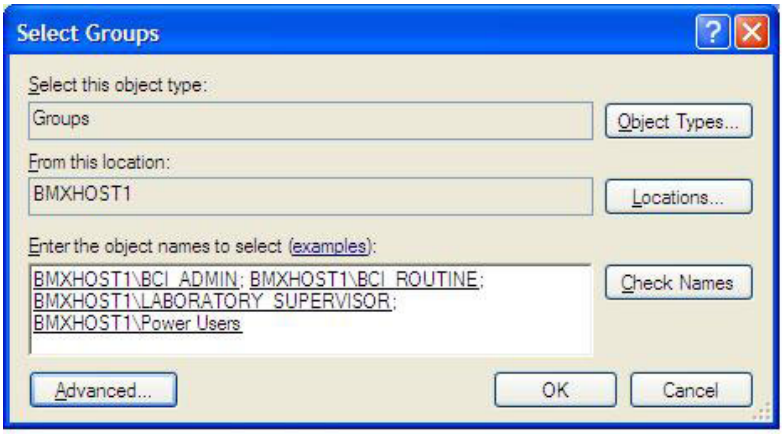


Figure 6-13 : "Select Groups" screen (cont'd)

- Click "OK" to confirm the user's group membership.

The user's "Properties" window is displayed with the list of user groups to which the user belongs.

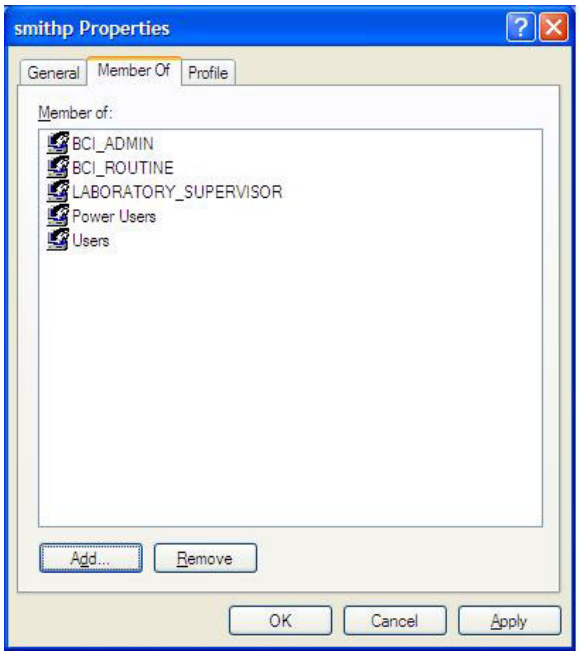


Figure 6-14 : "Properties" screen – "Member Of" tab screen

- Click "OK" to confirm.

Disabling a user account

A user account can be disabled by the **labadmin** user.

*Note: When a user no longer uses the **PREVI Isola**, the user account should be disabled.*

To disable a user account, in the “Local Users and Groups” window:

- Click "Users" **(1)** and double-click on the desired user **(2)**.

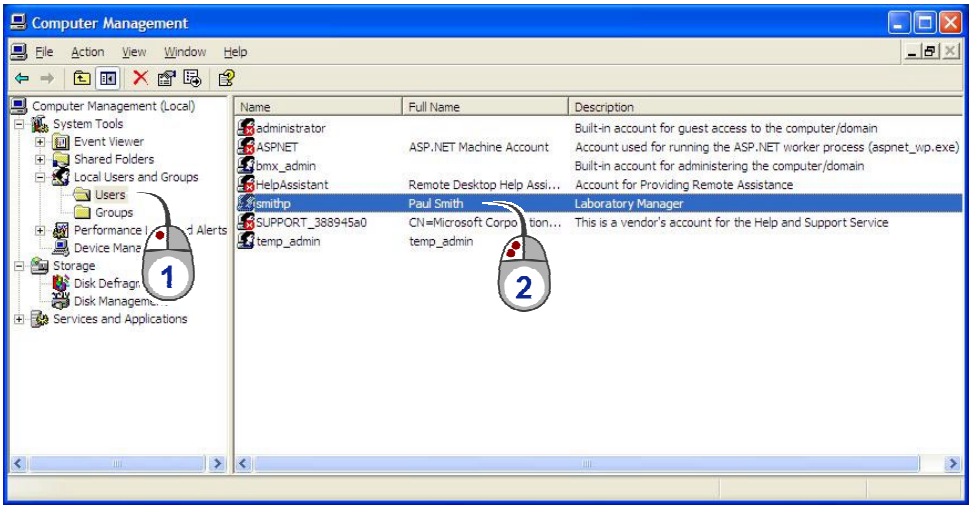


Figure 6-15 : "User Rights Management" screen

The user’s “Properties” dialog box is displayed.

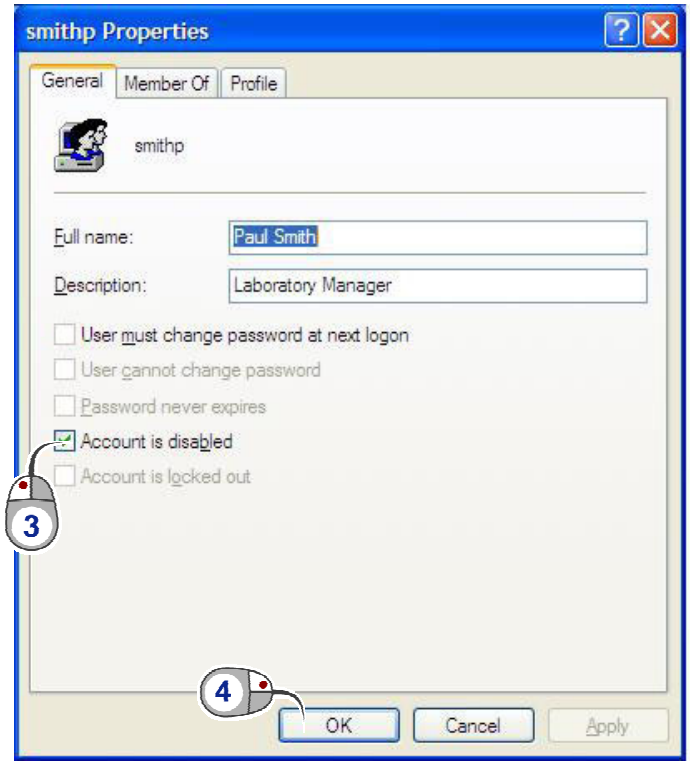


Figure 6-16 : "User Properties" - "General" tab screen

- Click on the "Account is disabled" check box **(3)**.
- Click "OK" **(4)** to confirm.

Unlocking a user account

A user account can be unlocked by the **labadmin** user.

IMPORTANT! ***After <u>five</u> unsuccessful attempts to enter the password, the user will not be able to open a work session on the PREVI Isola as the account will have locked. It can only be unlocked by a labadmin user.***

To unlock a user account, in the" Local Users and Groups" window:

- Click "Users" **(1)** and double-click on the desired user **(2)**.

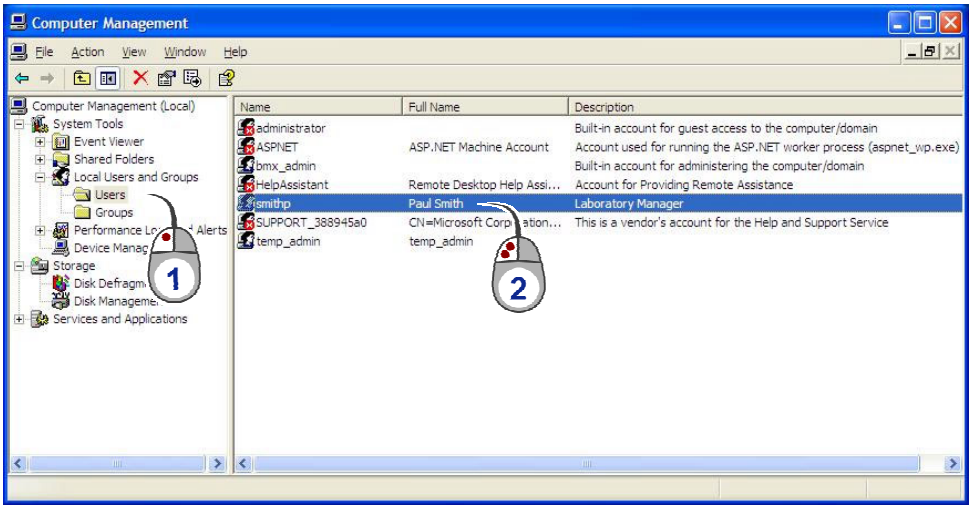
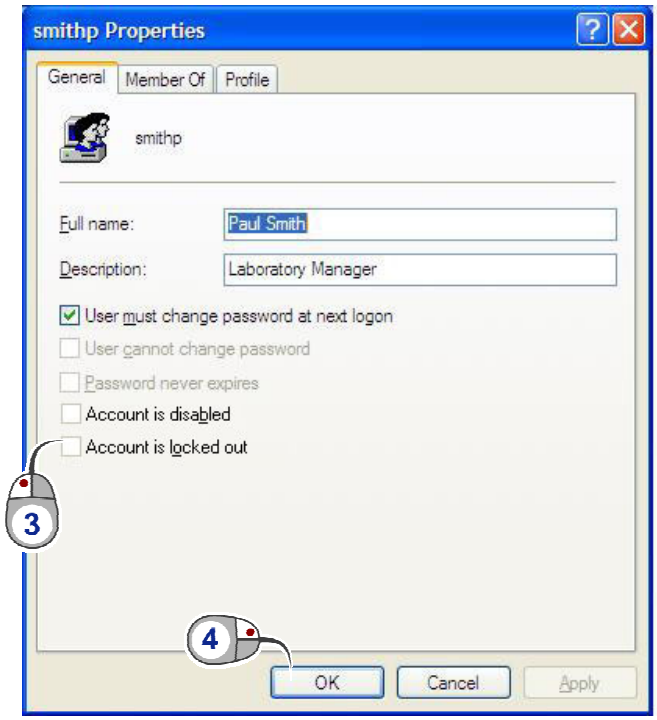


Figure 6-17 : "User Rights Management" screen

The user's "Properties" dialog box is displayed.



- Deselect the "Account is locked out" check box **(3)**.
- Click "OK" to confirm **(4)**.

Changing of a password by a user

If the **labadmin** user has given permission (see Assigning user permissions and rights, page 6-5) a user can change a password:

- Log in using the previously created user name (see Creating a new user account, page 6-2).
- Press **<Return>**.
- Press **<Ctrl>**, **<Alt>** and **<Del>** simultaneously.

The “Windows Security” window is displayed.

Figure 6-18 : " Windows Security" window

- Click "Change Password…".

The "Change Password" window is displayed.

Figure 6-19 : "Change Password" window

- Enter the user name, the old password and the new password twice.

Note: The password must include at least 8 characters (obligatory password).

- Click "OK" to confirm the change of password.

The “Windows Security” window is displayed again.

- Click "Cancel" to return to the workstation applications.

Antivirus

IMPORTANT! ***The cybersecurity maintenance plan consists, for the end-user, in applying regular antivirus and operating systems security patch updates to be qualified through the qualification protocol below.***

It is recommended to configure the antivirus so that it performs the “Full Scan” at night when the system is not being used and at a time when archiving is not running. (see General Settings, page 3-26).

- On the instrument software, the following folders must be excluded from antivirus checking:

  C:\Microstreak\bin
  C:\Microstreak\Logs
  C:\Microstreak\Archive
  C:\Microstreak\Config

- On the workstation computer, it is preferable to exclude the following folders from antivirus checking:

  D:\PREVI Isola\DataServer\bin
  D:\PREVI Isola\DataServer\Logs
  D:\PREVI Isola\DataServer\Data

Before installing a new version of antivirus, it is recommended to perform a data backup as described in Manual data backup, page 7-1.

When installing a new version of antivirus, it is recommended to follow the qualification protocol described below in order to check the system interfaces and performance.

Windows Update

When installing a Windows Security Patch, follow the qualification protocol described below.

IT Verification Protocol

The aim of the verification protocol is to ensure that the instrument and workstation are still working properly.

For this purpose,

- Process a sample from start to end:
  - Enter the sample data into the LIS.
  - Send the data to the data server through BCI.
  - Load the tube into the instrument and process it as usual.
  - After processing, unload the tube and plates and check that the plates have been labeled correctly.
  - Check that the sample is displayed correctly on the worklist screen of the workstation.

Printer Verification Protocol

The aim of the printer verification protocol is to validate the user's printer to ensure that reports are printed correctly.

For this purpose,

- Perform the IT Verification Protocol on page 6-13.

On the workstation computer,

- Print each type of report: worklist, plate panels, specimen types.
- Check that the reports have been printed correctly.

7 Data Backup, Restore and Audit Trail

Presentation

This section presents the functions of the **PREVI Isola** system which enable:

- Manual backup of data

*Note: The complete database should be backed up when the **PREVI Isola** software programs are updated.*

- Data restoration from a removable medium
- Audit trail export
- Audit trail data viewing using the event viewer
- Instrument log file retrieval
- Full system restoration

Manual data backup

The database and configuration files are automatically archived on the hard disk every day and can be copied to a removable medium using Windows Explorer.

The database is archived in the “D:\PREVI Isola\DataServer\Data\Archive” directory.

The instrument configuration files are archived in the “C:\MicroStreak\Archive” directory.

Data restoration from a removable medium

In the event of a problem affecting the database stored on the **PREVI Isola**, the restoration procedure can be used to recover the database previously saved on a removable medium.

Data restoration can be performed by a user who has administrator privileges.

To restore data,

- Shutdown the instrument (see Powering Down the Instrument, page 4-37).

On the workstation computer:

- Quit the workstation application.
- Open a Windows session as a **Power User**.
- Stop the data server (see Appendix B: Stopping and Restarting the Data Server, page 11-2).

Using the Windows Explorer,

- Copy the database file to be restored to the “D:\PREVI Isola\DataServer\Data” folder under the name “AutoStreakerDatabase.sdf”.
- Restart the data server (Appendix B: Stopping and Restarting the Data Server, page 11-2).
- Restart the Workstation application.
- Power on the instrument.

Audit trail data viewing using the event viewer

The **PREVI Isola** workstation software keeps a record of each creation, modification, and deletion of data performed by users.

This audit trail can be viewed using the Windows event viewer.

To view the audit trail,

- Double-click on the 

shortcut on the workstation desktop.

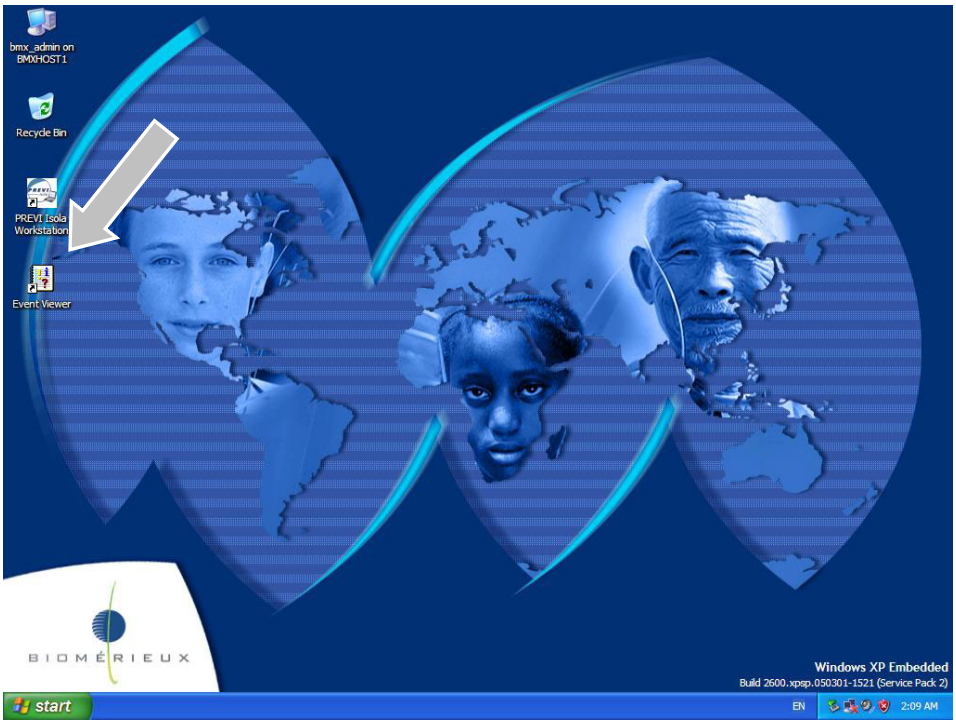


Figure 7-1 : Event viewer shortcut

The “Event Viewer” window is displayed.

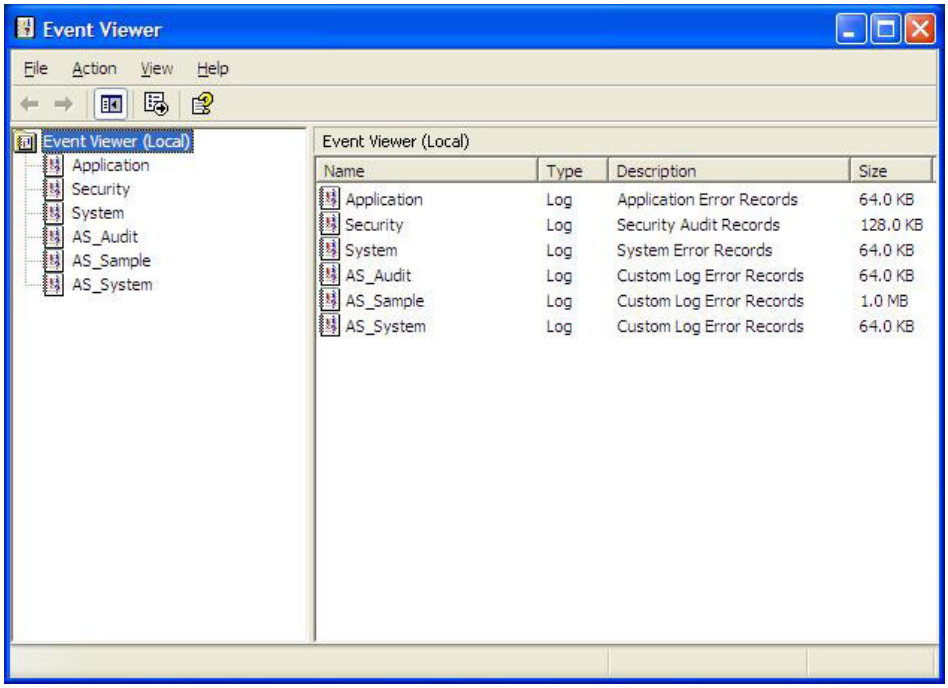


Figure 7-2 : “Event viewer” window

- Click on “AS_Audit” **(1)** on the left-hand side of the screen.

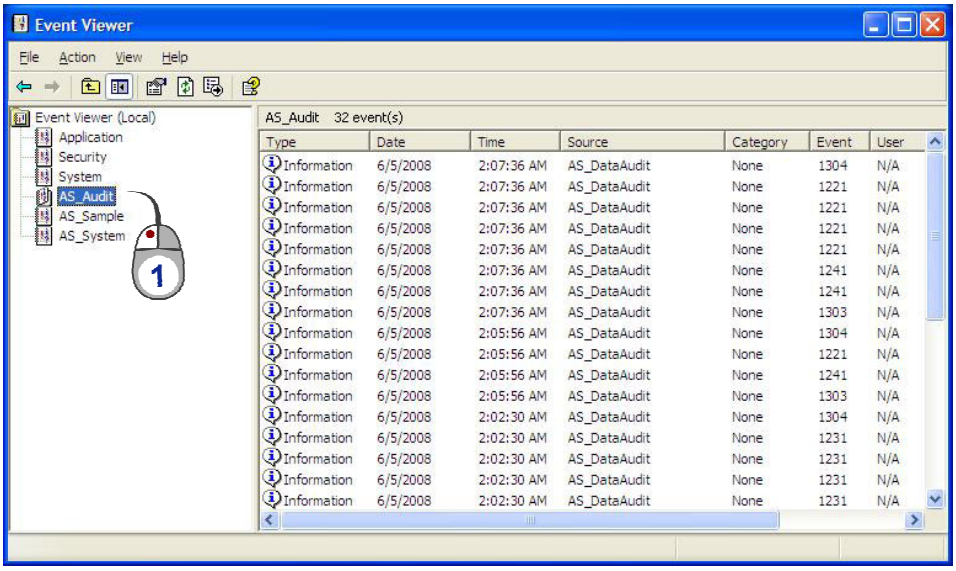


Figure 7-3 : Event viewer “AS_Audit” window

- Click on the event you want to view on the right-hand side of the screen.

The “Event Properties” window is displayed.

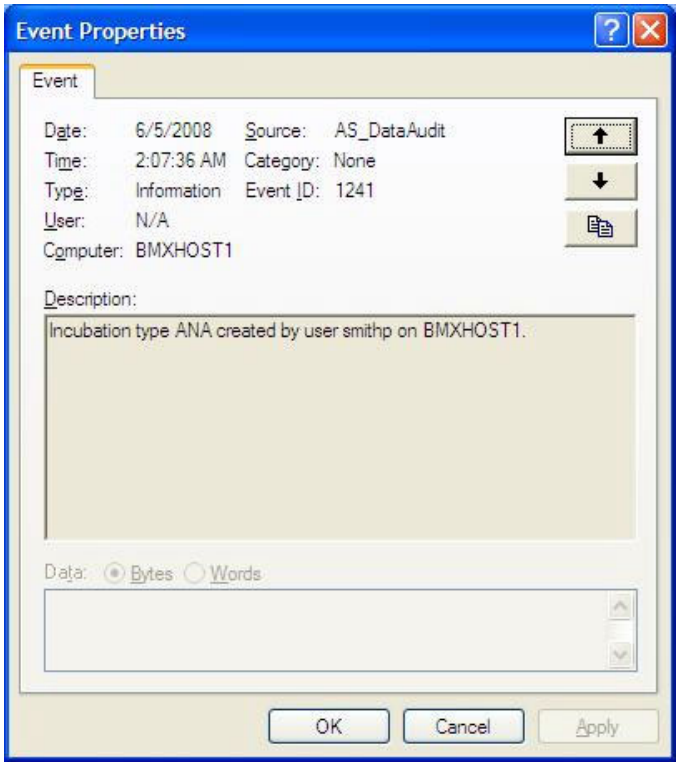


Figure 7-4 : “Event Properties” window

- View the previous or next event using the ↑ and ↓ arrows.

Saving the Audit Trail

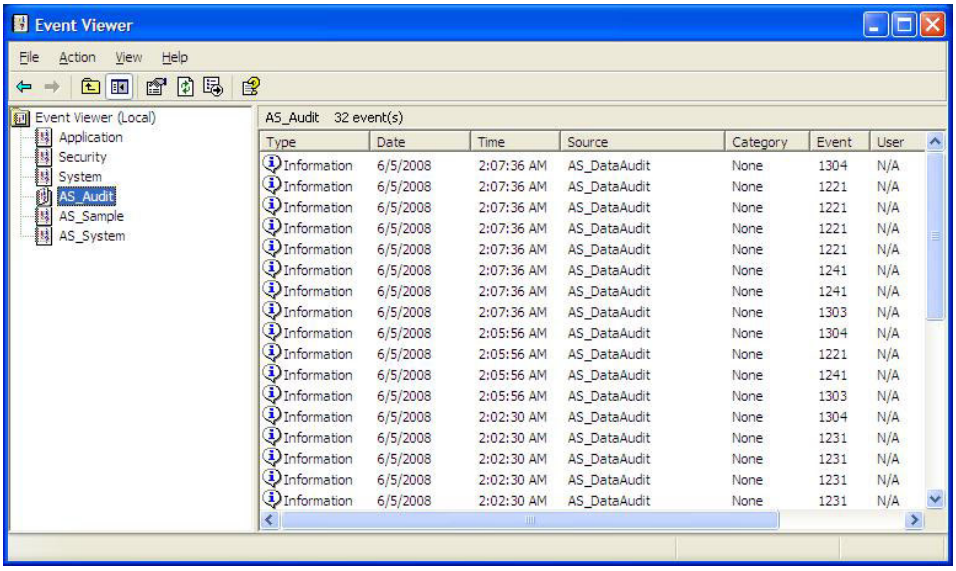
The audit trail can be saved in a file which can then be opened on a Windows PC using the event viewer.

To save the audit trail in a file:

- Double-click on the 

shortcut on the workstation desktop.

The “Event Viewer” window is displayed.



- Right-click on “AS_Audit” **(1)** on the left of the screen and select “Save Log File As …”.

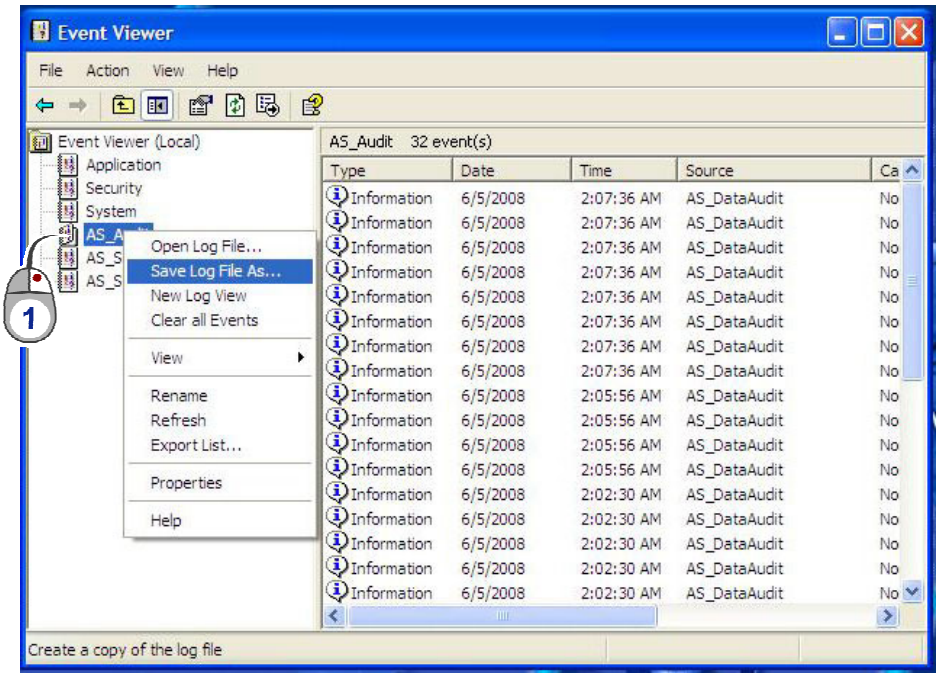


Figure 7-5 : “Save Log File AS…” window

The Save “As_Audit” as window is displayed.

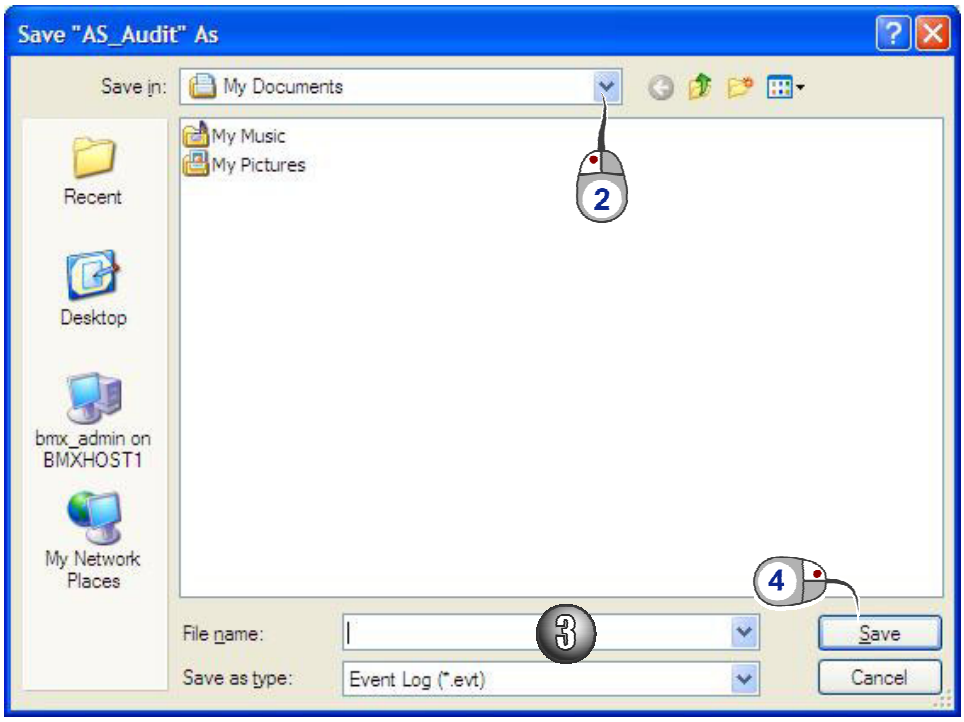


Figure 7-6 : Save “AS_Audit” As… window

- Select the folder **(2)** in which to save the audit trail.
- Enter a file name **(3)**.
- Click Save **(4)**.

Instrument and Workstation Log File Retrieval

Instrument log files

The log files for the instrument are automatically archived (zip file) whenever the software is restarted. These files are contained in the **C:\Microstreak\Archive** folder and include a copy of the configuration files and workflows as well. The active logs not yet archived are contained in the **C:\Microstreak\Logs** folder.

The **C:\Microstreak\Archive** folder on the instrument is a shared folder and is visible from the workstation computer as X:\ <instrument name> (X is given as an example, it is defined along with the instrument name, by a bioMérieux Field Service Engineer during installation).

When remotely extracting files from the instrument, care should be taken not to hinder performance of the running instrument. This means files should be copied and then viewed rather than opened remotely.

The steps to copy the logs from the instrument are:

Step 1 Log into the workstation computer using a User account with **Power User** rights (i.e. bmx_admin or tmp_admin).

Step 2 Navigate to **X:\ <instrument name>** and copy all of the required archived log files to a removable medium (e.g. USB key).

Step 3 Logout from the **Power User** account.

Workstation and data server log files

The steps to copy the logs from the workstation are:

Step 1 Stop the Data Server (see Appendix B: Stopping and Restarting the Data Server, page 11-2).

Step 2 Log into the workstation computer using a User account with **Power User** rights (i.e. bmx_admin or tmp_admin).

Step 3 Navigate to **D:\PREVI Isola\DataServer\Logs** and copy the most recent log files.

Step 4 Navigate to **D:\PREVI Isola\DataServer\data** and copy file **AutoStreakerDatabase.sdf** if a copy of the most recent database is required.

Step 5 Navigate to **D:\PREVI Isola\DataServer\Data\Archive** and copy all of the archived database files required.

Step 6 Log out from the administrator account.

Step 7 Anonymize all the database files (*.sdf files) before sending them to bioMérieux (see Anonymization of Patient Data, page 9-27.

Step 8 Restart the Data Server (see Appendix B: Stopping and Restarting the Data Server, page 11-2).

Full System Backup and Restoration

Full System Backup

The full system backup is performed at the time of installation and configuration of the workstation by bioMérieux Service Engineers.

The medium containing the Full System backup is left at the customer's site.

Full System Restoration

The full system restoration procedure is performed using the Full Backup medium created during the Full System Backup.

IMPORTANT! ***All hard drive data will be erased.***

- Switch on the computer (the computer must be able to boot on the CD Reader/Writer).
- Insert the medium containing the "Full Backup".
- Press "CTRL+ALT+DEL" (to restart the computer if necessary).

  Installation should start automatically.

The following menu appears:

1. ENGLISH
2. FRANCAIS
3. DEUTSCH
4. ITALIANO
5. ESPANOL
6. PORTUGUES

- Select the option corresponding to your language using the ↑↓ keys (English in this procedure).
- Press "Enter" to validate your choice.

The following message appears :

1. FULL BACKUP
2. FULL RESTORE

- Select "2. *FULL RESTORE*" using the ↑↓ keys.
- Press " Enter " to validate your choice.

The following message appears:

```
 "WARNING !!! FULL RESTORE. ALL DATA
ON THE HARD DRIVE WILL BE ERASED

PRESS ENTER TO CONTINUE, OR CTRL+C TO
CANCEL"
```

- Press " Enter" to confirm and to start restoration or press "CTRL+C" to cancel the restoration process.
  At the end of the restoration, the medium is ejected automatically.

The following message appears:

```
 "PROCESS COMPLETE, REMOVE CDROM AND
PRESS ANY KEY TO REBOOT"
```

At this stage, 2 are two possibilities:

1. **Do not change the SID and restart the computer:**

- Remove the medium from the drive.
- Press a key to reboot the computer.

2. **Change the Windows SID key:**

- Close the CD Reader/Writer (with the previously created medium inside).
- Wait for 20 seconds while the medium is initializing.
- Press the "CTRL+C" keys.

The following message appears:

```
"Terminer le fichier de commandes
(O/N)?"
```

"Complete the command file (Y/N) ?"

- Press the "O" key.
- Type "*ghstwalk /sure*" and then press "Enter".

IMPORTANT! ***You must confirm this step by pressing "Y" (for Yes) or "N" for "NO" if this computer is part of a network Domain.***

- Remove the medium from the CD Reader/Writer.
- Press a key to reboot the computer.

8 Maintenance

Introduction

Routine cleaning, decontamination and maintenance of the **PREVI Isola** is necessary to ensure the system performs its functions at an optimum level.

It is advisable to adopt a planned cleaning, decontamination and maintenance regime to ensure the **PREVI Isola** is maintained in a fully serviceable condition. A daily and a weekly program are advisable.

CAUTION! ***Failure to perform required routine maintenance and cleaning may reduce the performance of the PREVI Isola and cause the contamination of plates.***

Note: In this section, the cleaning procedures include decontamination.

Safety Precautions and Controls

CAUTION! ***In case of emergency, switch off the power at the power switch on the left-hand side of the instrument.***

DANGER! ***The user must only perform the maintenance operations described in this chapter and rigorously follow each of the steps.***

DANGER! ***Wear personal protective equipment when cleaning the PREVI Isola, including gloves, gown and safety glasses.***

CAUTION! ***Before carrying out the maintenance operations, switch off the instrument to avoid any damage to the system and harm to the user.***

After cleaning, wait 5 minutes before switching the instrument back on.

Biological safety requirements

Users must observe good laboratory practices when handling potentially infectious products.

Dispose of contaminated disposable materials following procedures for infectious or potentially infectious products.

IMPORTANT! ***It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.***

Recommended maintenance product

bioMérieux recommends the use of quaternary ammonium based disinfectant with the following composition:

- n-propanol (29%)
- propionate quaternary ammoniums
- polyhexanide

Note: It is not recommended to use a bleach solution when cleaning around the electronic parts.

Presentation of the Maintenance Menu

Certain maintenance operations require the use of the “Maintenance” menu.

To access this menu,

- Touch the  icon on the main screen.

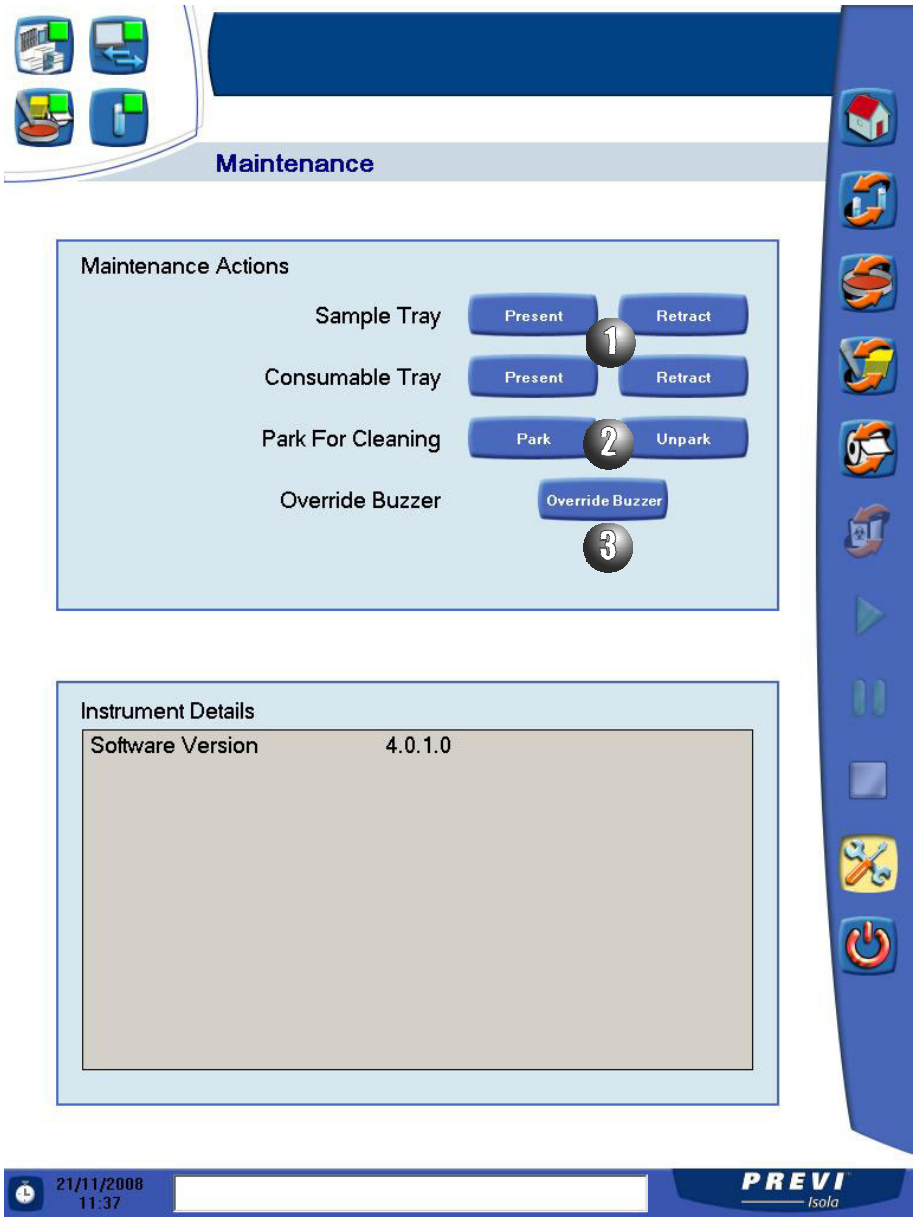


Figure 8-1 : Maintenance Menu

1. The “Present” and “Retract” buttons are used to move the sample tray and consumable tray so that they are accessible for cleaning.
2. The “Park” and “Unpark” buttons are used to move the pipettor so that it is accessible for cleaning.
3. The “Override Buzzer” button is used to deactivate the buzzer.

Maintenance Logs

The following maintenance logs are given as a guide.

			MAINTENANCE				WEEK No.: YEAR:		
			MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
Daily	Clean tray under input cassettes	Page 8-4	☐	☐	☐	☐	☐	☐	☐
	Clean waste chute top, area around waste chute top, and waste chute chimney	Page 8-5	☐	☐	☐	☐	☐	☐	☐
	Clean process station drip tray	Page 8-6	☐	☐	☐	☐	☐	☐	☐
	Clean pipettor, drip tray and area under and around the drip tray	Page 8-7	☐	☐	☐	☐	☐	☐	☐
	Clean sample racks, sample rack tray and sample spill tray	Pages 8-8 to 8-10	☐	☐	☐	☐	☐	☐	☐
	Clean tray under output cassettes	Page 8-11	☐	☐	☐	☐	☐	☐	☐
	Clean waste chute deflector	Page 8-12	☐	☐	☐	☐	☐	☐	☐
	Check, replace or empty waste bins, and clean deflector	Page 8-13	☐	☐	☐	☐	☐	☐	☐

Date: **Name and signature of person in charge of maintenance**

			MAINTENANCE		MONTH: YEAR:	
			WEEK 1	WEEK 2	WEEK 3	WEEK 4
Weekly	Clean inside input and output cassettes	Page 8-14	☐	☐	☐	☐
	Clean area around applicator cartridge and tip tray	Page 8-15	☐	☐	☐	☐
	Clean process station and reference block	Page 8-15	☐	☐	☐	☐
	Clean transfer robot suction cups	Page 8-15	☐	☐	☐	☐
	Clean agar ultrasonic sensor	Page 8-15	☐	☐	☐	☐
	Clean printer and printer platen	Page 8-18	☐	☐	☐	☐
	Clean print head	Page 8-19		☐		☐
	Clean touch-screen	Page 8-19	☐	☐	☐	☐
	Clean external surfaces of instrument	Page 8-20	☐	☐	☐	☐
	Clean waste drawer	Page 8-20	☐	☐	☐	☐

Date: **Name and signature of person in charge of maintenance**

Daily Maintenance Procedures

CAUTION! ***Before carrying out the maintenance operations, switch off the instrument to avoid any damage to the system and harm to the user.***

Clean the tray under input cassettes

Time required:	**Approx. 1 minute**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Open the consumable lid.
- Remove the tray from the instrument.

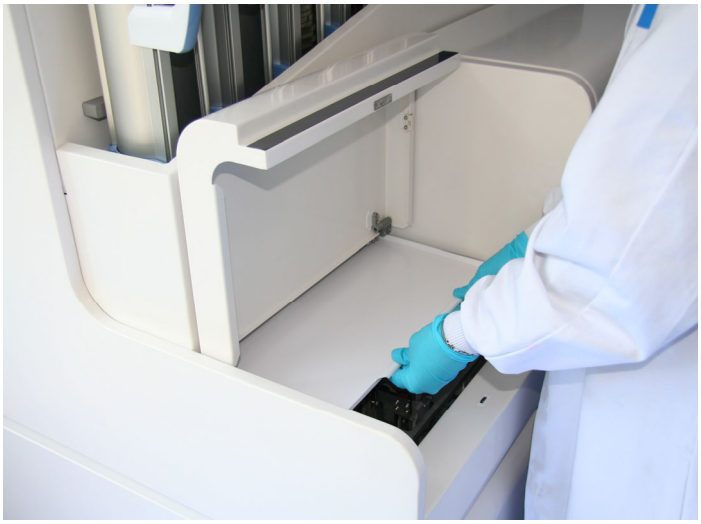


Figure 8-2 : Removing the tray under the input cassettes

- Put the tray on a clean surface.
- Spray the quaternary ammonium solution over the whole internal surface of the tray.
- Wipe the inside of the tray using lint-free paper.
- Put the tray back in place.
- Close the consumable lid.

Clean the waste chute top, the area around the waste chute top and the waste chute chimney

Operator Time required:	**Approx. 5 minutes**
Duration:	**Approx. 20 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant 70% alcohol solution (isopropanol or ethanol) Lint-free paper

- Open the process station lid.
  If the applicator robot or the pipettor prevent from reaching the waste chute top, gently push them away by hand.
- Remove the waste chute top.

Figure 8-3 : Removing the waste chute top

- Soak the waste chute top for 15 minutes in quaternary ammonium based disinfectant.

While the waste chute top is soaking:

- Make sure the consumables waste bin is in place.
- Remove the process station drip tray.
- Make sure a bin is placed under the stainless steel chimney, then spray inside the stainless steel chimney with quaternary ammonium based disinfectant.
- Clean the area around the waste chute top with lint-free paper moistened with quaternary ammonium based disinfectant.
- Clean all the visible surfaces with lint-free paper moistened with quaternary ammonium based disinfectant.

Once the waste chute top area has been cleaned,

- Take the waste chute top out of the soaking bath.
- Rinse the waste chute top using 70% alcohol solution.
- Dry the waste chute top using lint-free paper.

Note: Ensure that the waste chute top is thoroughly dry before replacing it in the instrument.

- Carefully put the waste chute top back in place, making sure it is properly positioned.
- Close the process station lid.

Clean the process station drip tray

Time required:	**Approx. 1 minute**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Open the process station lid.
- If the process station prevents from reaching the drip tray, gently push it away by hand.
- Remove the drip tray which is held in place by two pins (1).

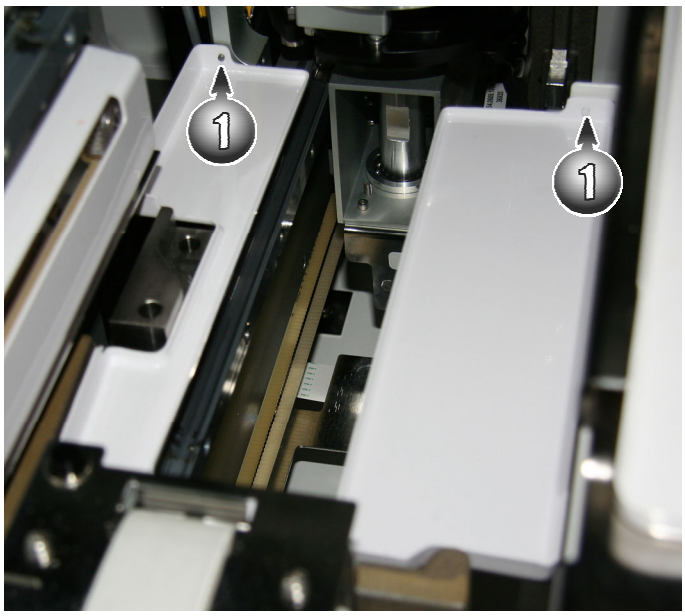


Figure 8-4 : Removing the process station drip tray

- Put the tray on a clean surface.
- Spray the quaternary ammonium solution over the whole internal surface of the tray.
- Wipe the inside of the tray using lint-free paper.
- Put the tray back in place.
- Close the process station lid.

Clean the pipettor, drip tray and area under and around the drip tray

Time required:	**Approx. 1 minute**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A.*
Maintenance products:	70% alcohol solution (isopropanol or ethanol) Quaternary ammonium based disinfectant Lint-free paper

Note: *To clean the pipettor, the instrument must be powered on.*

In the Maintenance menu,

- Touch the “Park” button to position the moving parts for cleaning.
- Open the process station lid and the printer access door.

CAUTION! ***The pipettor is a sensitive device that should be cleaned very delicately using a 70% alcohol solution.***

- Wipe the outer surfaces of the pipettor body using lint-free paper moistened with 70% alcohol solution, from the white ring to the tip of the cone.

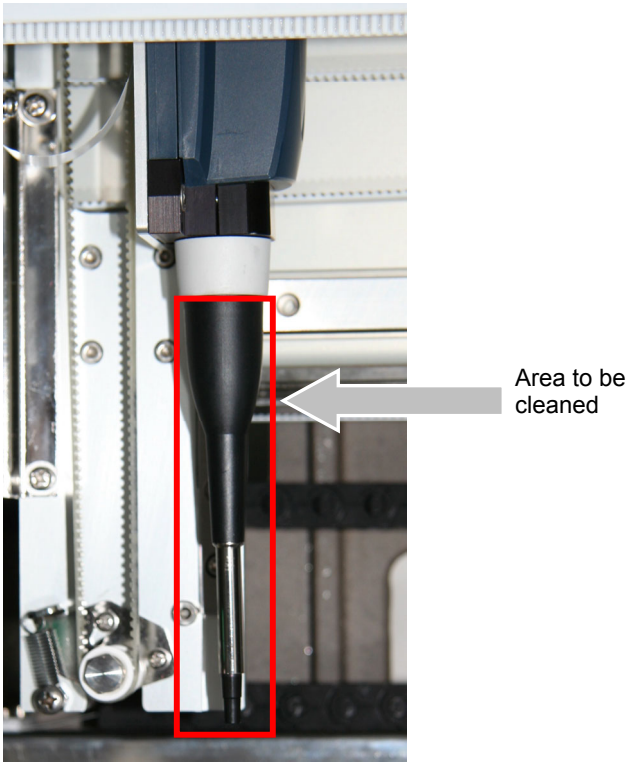


Figure 8-5 : Cleaning the pipettor

- Spray quaternary ammonium solution over the inner surface of the drip tray to the right of the process station and the area under and around the drip tray (1).

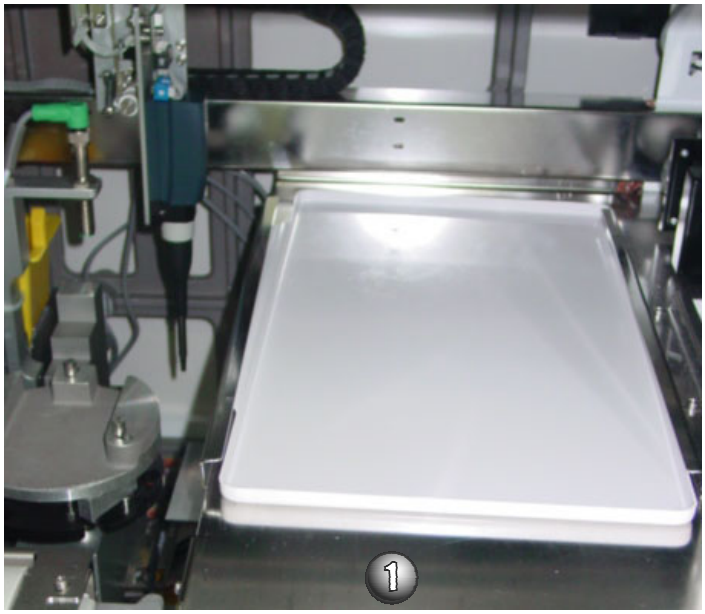


Figure 8-6 : Drip tray to the right of the process station

- Wipe using lint-free paper.
- Close the process station lid and the printer access door.
- Power off the instrument.

CAUTION! ***Wait for 10 minutes before using the instrument after cleaning the pipettor.***

Clean the sample racks

Operator Time required:	**Approx. 3 minutes**
Duration:	**Approx. 20 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant 70% alcohol solution (isopropanol or ethanol)

- Soak the sample racks for 15 minutes in quaternary ammonium based disinfectant.
- Rinse using 70% alcohol solution.
- Leave the racks to dry on absorbent paper.

Clean the sample rack tray and sample spill tray

Time required:	**Approx. 3 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Open the sample lid.
- The sample tray is presented but cannot be removed.

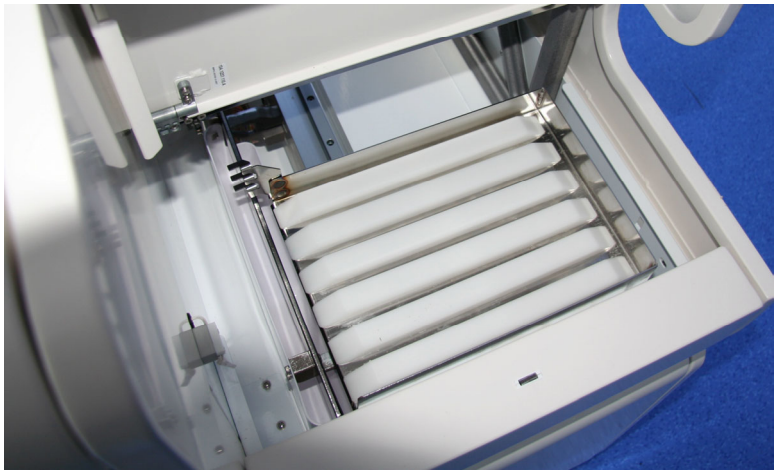


Figure 8-7 : Sample rack tray presented for cleaning

CAUTION! ***Do not spray the disinfectant directly inside the sample tray area.***

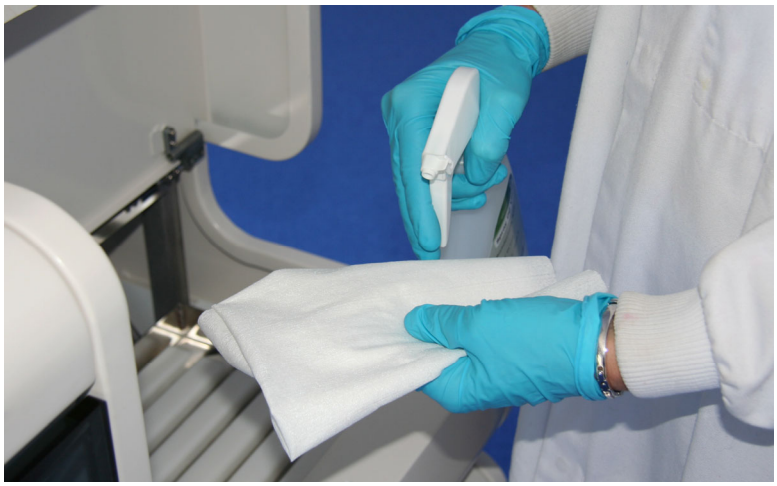


Figure 8-8 : Applying cleaning solution

- Clean using lint-free paper moistened with quaternary ammonium based disinfectant.
- Manually push the sample tray back inside the instrument.
- Remove the sample spill tray by pushing it forward slightly (1) and then sliding it to the right (2) in order to have sufficient clearance to lift it up.

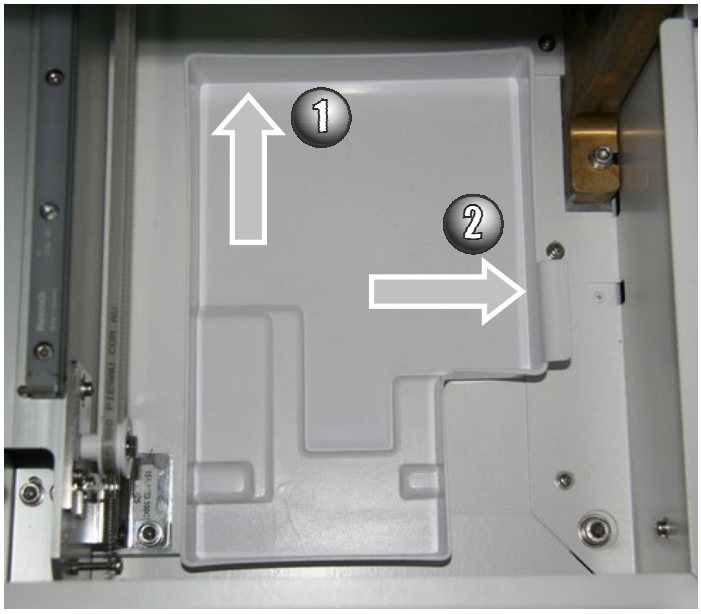


Figure 8-9 : Removing the sample spill tray

- Using two hands, lift up the spill tray and place it on a clean surface.

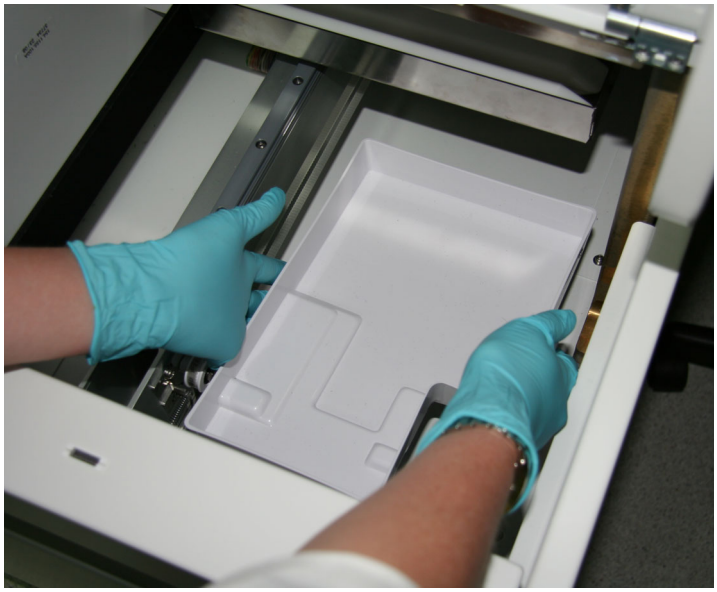


Figure 8-10 : Lifting up the sample spill tray

- Spray the quaternary ammonium solution over the whole internal surface of the tray.
- Wipe the inside of the tray using lint-free paper.
- Put the tray back in place.
- Close the sample lid.

Clean the tray under output cassettes

Time required:	**Approx. 1 minute**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Open the sample lid.
- Remove the tray.

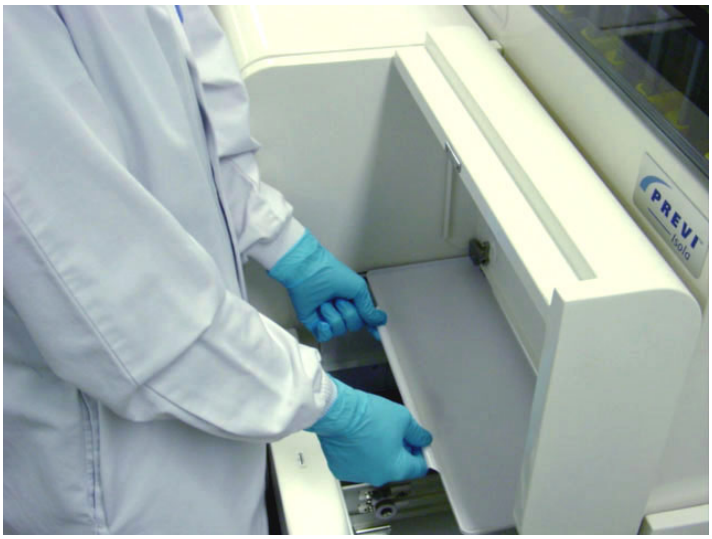


Figure 8-11 : Removing the tray under output cassettes

- Put the tray on a clean surface.
- Spray the quaternary ammonium solution over the whole internal surface of the tray.
- Wipe the inside of the tray using lint-free paper.
- Put the tray back in place.
- Close the sample lid.

Clean the waste chute deflector

- Open the waste drawer.
- First remove the label backing deflector and clean it with lint-free paper moistened with quaternary ammonium based disinfectant.
- Then remove the waste chute deflector by pulling it forward using the tab (1).

Figure 8-12 : Removing the waste chute deflector

- Clean the waste chute deflector using lint-free paper moistened with quaternary ammonium based disinfectant.
- Hold open the waste drawer.
- Place the edge of the waste chute deflector (2) on the guide inside the instrument and slide the deflector in until it is firmly held in place.

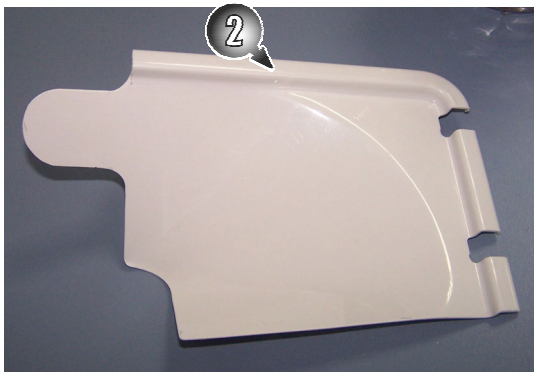


Figure 8-13 : Waste chute deflector

- Then put the label backing deflector back in place.

Check, replace or empty the waste bins, and clean the deflector

Time required:	**Approx. 3 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	***PREVI Isola*** *biohazardous Waste Bin (Part number 29718)* ***PREVI Isola*** *Waste Paper Bin (Part number 29739)*
Maintenance products:	70% alcohol solution (isopropanol or ethanol) Lint-free paper

Note: *Waste bins should be emptied when they are about 70% full.*

- Pull open the waste drawer.
- Cut the label backing without pulling.
- Remove the full waste paper bin (1) from the instrument.
- Empty the bin by discarding the label backing.
- Remove the full biohazardous waste bin (2) from the instrument.
- Dispose of the biohazardous waste bin according to the usual laboratory procedures for biohazardous waste and in accordance with any applicable local regulations.
- Clean the deflector using 70% alcohol solution.
- Dry the deflector using lint-free paper.
- Put a new biohazardous waste bin in place in the back of the waste area. The top of the bag that is folded over the edge of the bin should be pulled down as far as possible over the outside of the bin.

IMPORTANT! ***Always place two biohazardous waste bins in the drawer. If only one bin is inserted, it may move out of place and, as a consequence, applicators and tips may fall into the waste area.***

- Put the waste paper bin back into place making sure the label backing falls into the bin properly (see Figure 8-14).

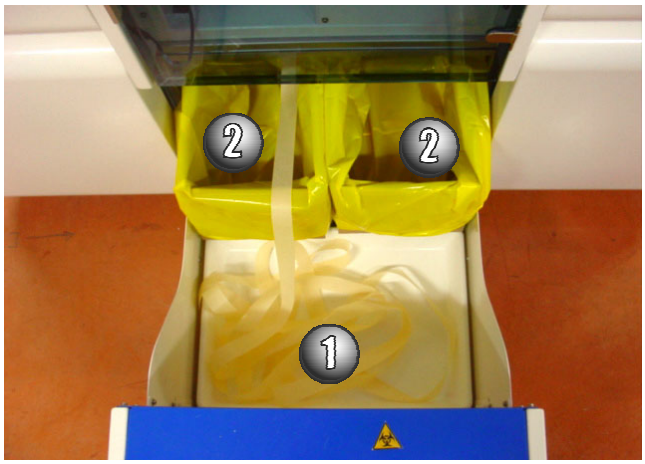


Figure 8-14 : ***PREVI Isola*** *Waste Bins in drawer*

- Close the drawer.
- Power on the instrument.
- Update the waste status by touching the button on the instrument touch-screen (this button is only enabled when the main screen is displayed).

Weekly Maintenance Procedures

Clean the inside of input and output cassettes

Time required:	**Approx. 5 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Put the input and output cassettes on a clean surface
- Spray the quaternary ammonium solution inside the cassettes.

Figure 8-15 : Cleaning inside cassettes

- Wipe with lint-free paper.

Figure 8-16 : Wiping inside cassettes

Clean the area around the applicator cartridge and the tip tray

Time required:	**Approx. 1 minute**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Lint-free paper

- Open the consumables lid.
- Manually pull the consumable tray forwards.
- Take the tip tray out of its housing.
- Clean the area using clean lint-free paper.

Note: The user may perform the Quality Control after the weekly maintenance operations (see Quality Control, page 5-1).

Clean the process station, reference block, transfer robot suction cups, and agar sensor

Time required:	**Approx. 5 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Open the process station lid and the printer access door.
- Remove the white plastic drip tray below the process station and clean it. Put it beside the process station.
- Clean the process station using lint-free paper moistened with quaternary ammonium-based disinfectant.

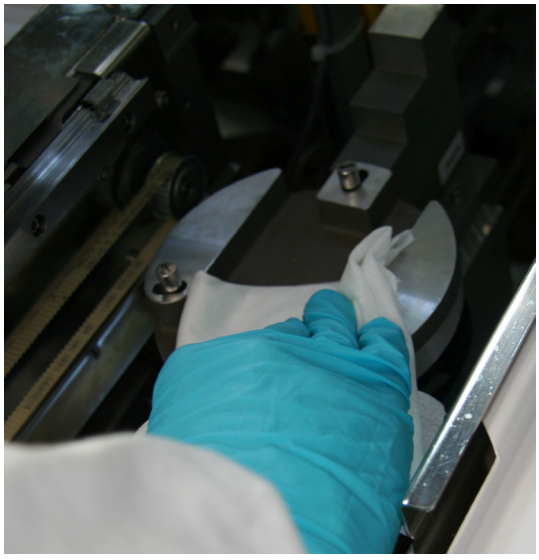


Figure 8-17 : Cleaning the process station

CAUTION! Do not spray the disinfectant directly inside the process station enclosure.

- Put the white process station drip tray back in place.
- Clean the reference block using lint-free paper moistened with quaternary ammonium based disinfectant.

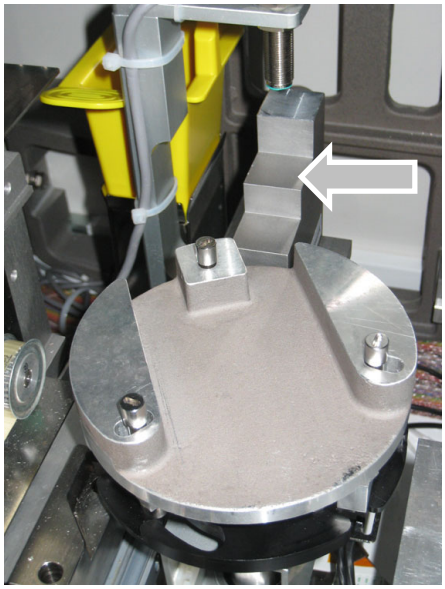


Figure 8-18 : Reference block

- Clean the robot suction cups using lint-free paper moistened with quaternary ammonium based disinfectant.

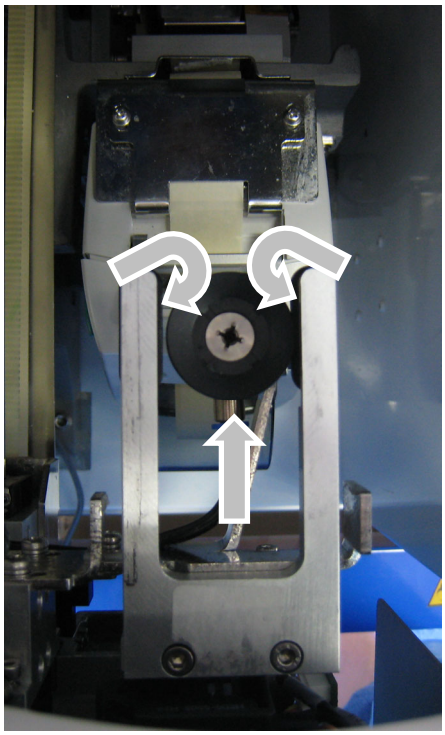


Figure 8-19 : Robot suction cups

- After cleaning, visually examine the cups for cracks. If there are any cracks, call bioMérieux S.A. or your local bioMérieux representative.

- Clean the agar sensor using lint-free paper moistened with quaternary ammonium based disinfectant.

CAUTION! ***The agar sensor is an ultrasonic device that is extremely sensitive. It should be cleaned very delicately.***

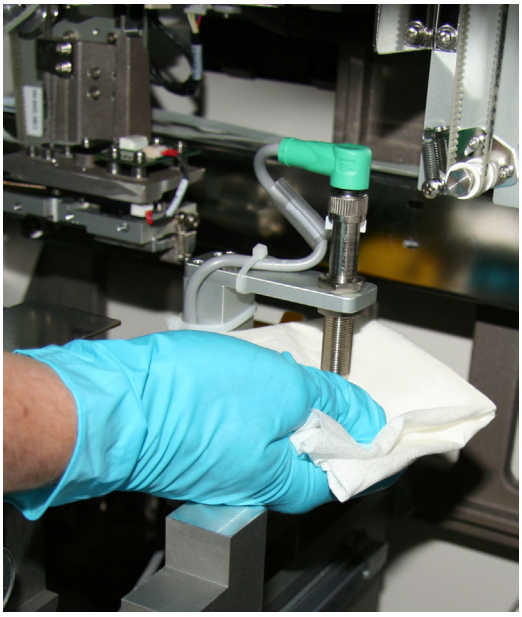


Figure 8-20 : Cleaning the agar sensor

- Close the printer access door and the process station lid.

Clean the printer and the printer platen

Time required:	**Approx. 5 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	70% isopropyl alcohol Lint-free cloth

Note: To clean the printer and the printer platen the instrument and the printer must be powered on.

- Open the process station lid and the printer access door.
- Open the printer and remove the roll of labels.
- Clean the platen surface with an alcohol-moistened cloth.
- Clean the metal parts 1, 2 and 3 with an alcohol-moistened cloth.

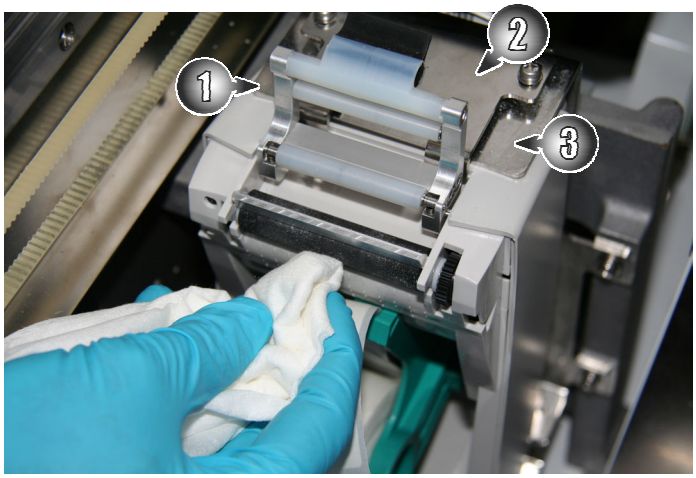


Figure 8-21 : Cleaning the platen

- Close the printer door and press the green button to advance the printer platen.
- Open the printer and clean the next portion of platen surface with an alcohol-moistened cloth.
- Repeat this process until the platen surface has been totally cleaned.
- Put the roll of labels back in place.
- Power off the printer and the instrument.

Clean the print head

- Open the process station lid and the printer access door.
- Leave the print head to cool for one minute.

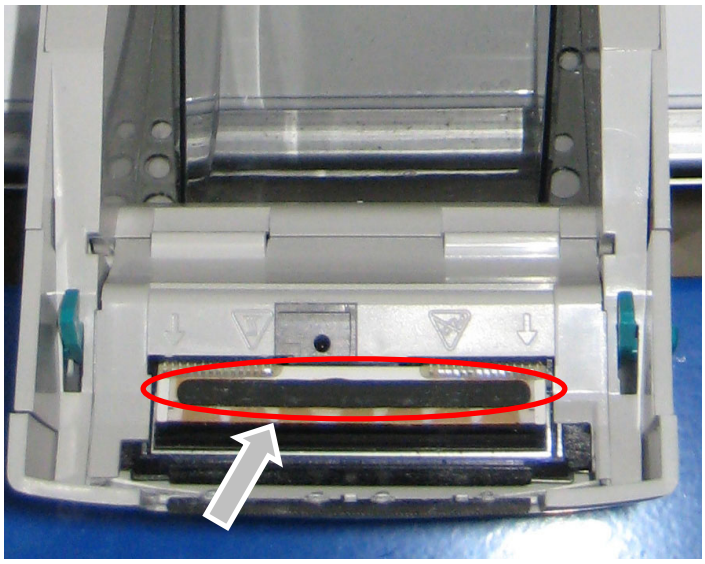


Figure 8-22 : Print head

- Use a cleaning pen to swab the print elements (thin grey line on the print head) from end to end.

Note: The printer does not have to be turned off to clean the print head.

Clean the touch-screen

Time required:	**Approx. 1 minute**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Cleaning wipes

- Clean the touch-screen with touch-screen cleaning wipes.

Clean the external surfaces of the instrument

Time required:	**Approx. 3 minutes**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Clean the external surfaces of the instrument using lint-free paper moistened with quaternary ammonium based disinfectant.

Clean the waste drawer

Time required:	**Approx. 5 minutes, to be done during daily waste bin replacement**
Performed by:	A laboratory technologist
Spare part(s) and consumables:	*N/A*
Maintenance products:	Quaternary ammonium based disinfectant Lint-free paper

- Pull open the drawer.
- Remove the waste bins.
- Remove any material or consumables that may be present in the waste drawer.
- Spray the quaternary ammonium solution on the inner bottom of the waste drawer.
- Wipe with lint-free paper.
- Replace the waste bins (new or empty) and close the waste drawer.

Maintenance Operations Performed by bioMérieux

During the warranty period, preventive maintenance operations are performed by a bioMérieux technician or a qualified person trained by bioMérieux. When the warranty period is over, these maintenance operations can be performed by a bioMérieux technician as part of a maintenance contract or on request.

Spill Management

If any biohazardous spills occur in the ***PREVI Isola*** they must be removed rapidly, observing the usual safety precautions. Should a spill occur within the process station enclosure, or the sample tray or consumables tray, perform an emergency stop before commencing the cleaning procedure.

DANGER! ***Liquid spills may present an electrical hazard! Shutdown the PREVI Isola before attempting to clean up spilled liquids.***

Wear personal protective equipment when cleaning the PREVI Isola, including gloves, gown and safety glasses.

If a spill occurs your first priority should be to the safety of yourself, others and the environment.

Materials required

- Quaternary ammonium based disinfectant
- Lint-free paper

Decontamination Procedures

CAUTION! ***It is the responsibility of the user to clean and decontaminate the PREVI Isola. The instrument must always be thoroughly cleaned and decontaminated before servicing by a bioMérieux Service Engineer.***

Environmental contamination of the instrument from biological samples will occur over time. Decontamination is necessary to protect laboratory staff and Service Engineers.

Basic decontamination

- Perform all daily and weekly cleaning operations (see pages 8-4 to 8-20).

Removal and Disposal of Materials and Waste

DANGER! ***The waste containers must be unloaded with the utmost rigor, as the user is in a potentially contaminated environment.***
Gloves, a lab coat, and protective glasses must be worn.

Treat waste material, including consumables, and any components coming into contact with waste material, as having the potential hazards of the samples used and of the reagents used in both preparing and processing the samples.

All laboratory and service personnel should be familiar with the Materials Safety Data Specifications for all materials used in the procedures relating to the instrument, and the correct procedures for handling these materials.

IMPORTANT! ***It is the responsibility of each laboratory to handle waste and effluents produced according to their type and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.***

Disposal of used consumables

It is recommended that used **PREVI Isola** Tip trays and **PREVI Isola** Applicator cartridges be disposed of before any new consumables are loaded. Dispose of used **PREVI Isola** Tip trays and **PREVI Isola** Applicator cartridges into waste containers.

Close and remove biohazard waste containers immediately after waste disposal.

DANGER! ***Do not remove waste while the instrument is in operation as doing so may cause a biohazard.***

Loading PREVI Isola Label Rolls

To load a **PREVI Isola** Label roll,

- Raise the roller arms.

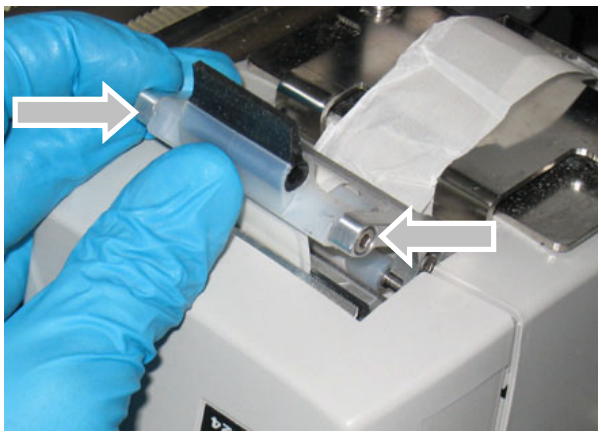


Figure 8-23 : Raising the roller arms

- Open the printer cover by raising the release latches.

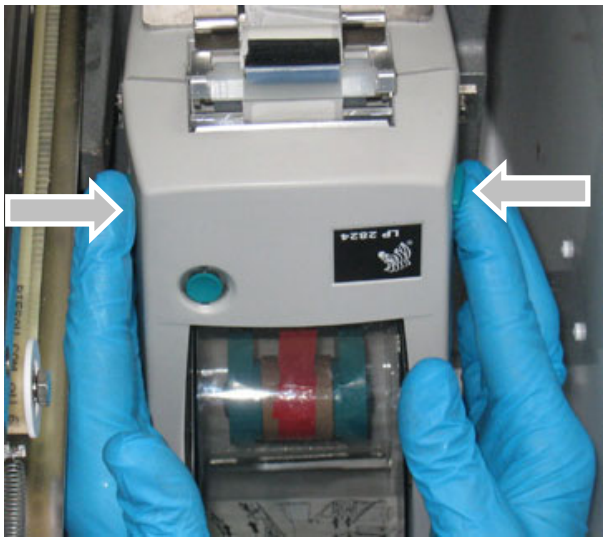


Figure 8-24 : Raising the release latches

- Separate the roll hangers and remove the empty roll.

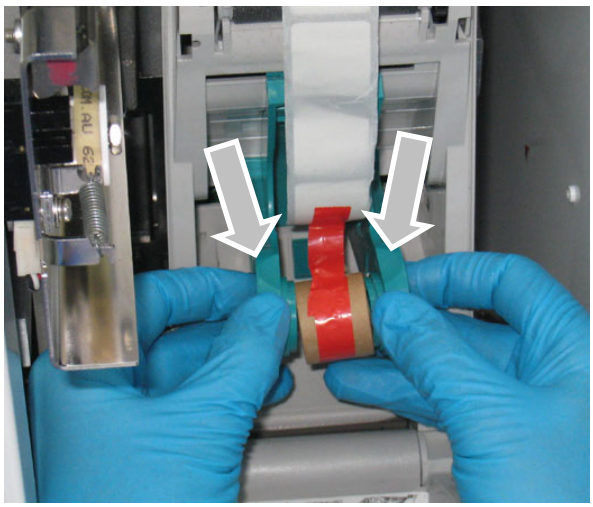


Figure 8-25 : Removing the empty roll

- Remove the labels on the first 70 cm of the new roll.
- Orient the roll so that the printing surface faces forward.

Figure 8-26 : Correct position of new roll

- Place the roll between the hangers and close them onto the core.

The guides direct the labels toward the platen and print head.

- Feed the labels through the guides which should just touch the edges of the labels.

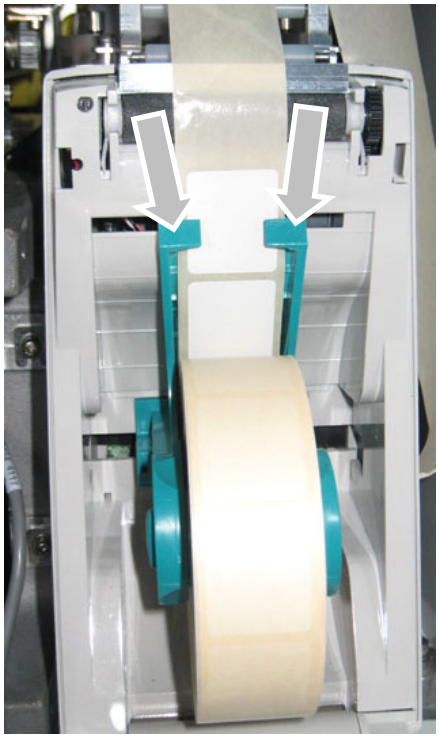


Figure 8-27 : Using the guides

- Feed the label backing through the printer as shown in the pictures below and as described on the instrument touch-screen.

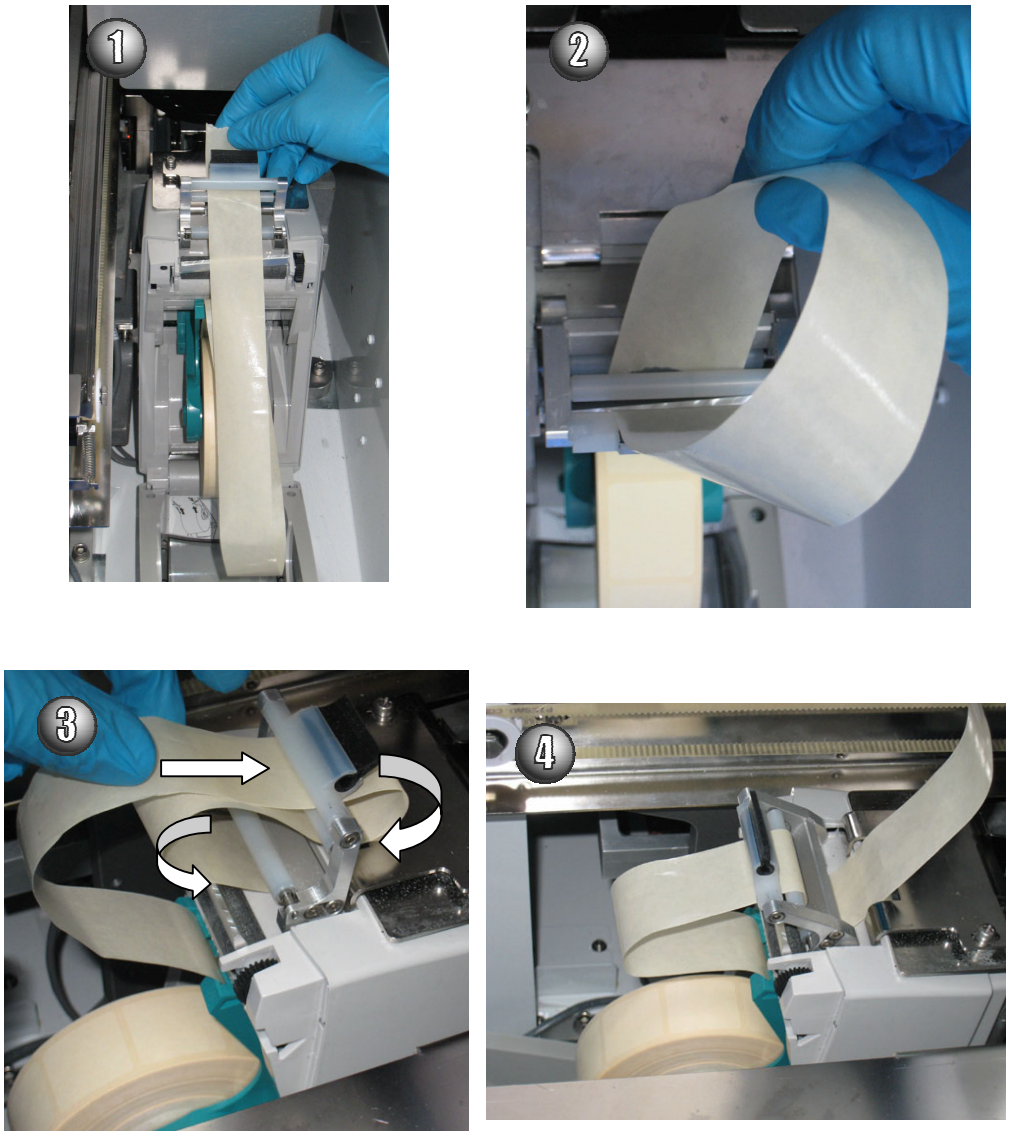


Figure 8-28 : Feeding label backing through the printer

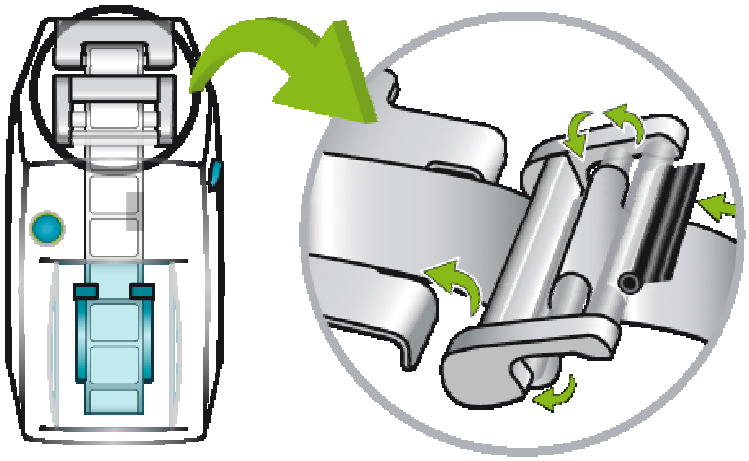


Figure 8-29 : Instructions for loading labels on instrument touch-screen

- Feed the label backing into the pull mechanism slot (1) and then press the black feed button (2).

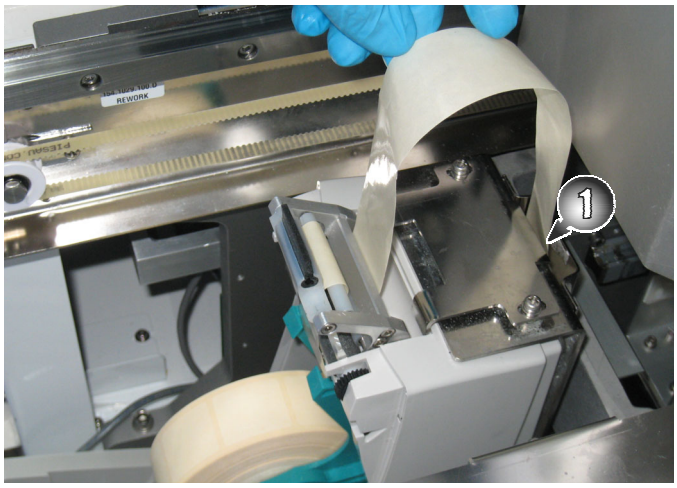


Figure 8-30 : Pull mechanism slot (top view)

The label backing will be automatically pulled into the slot .

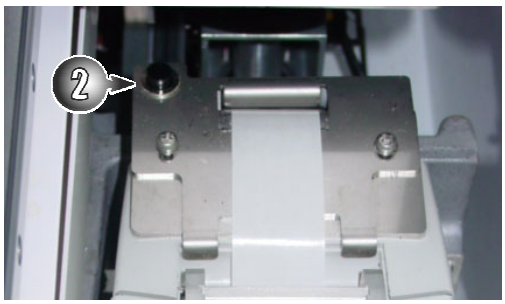


Figure 8-31 : Label backing correctly pulled into the slot (top view)

- Lower the roller arms.

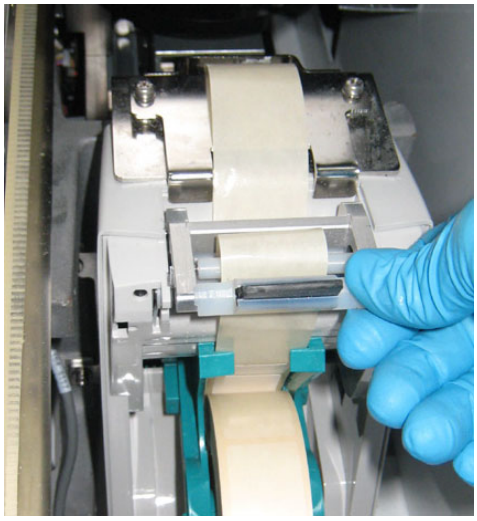


Figure 8-32 : Lowering the roller arms

- Turn the label roll slightly to avoid folds in the labels.

Figure 8-33 : Turning the label roll

CAUTION! ***When replacing the label roll, take care not to remove the metal plate indicated in the picture below.***

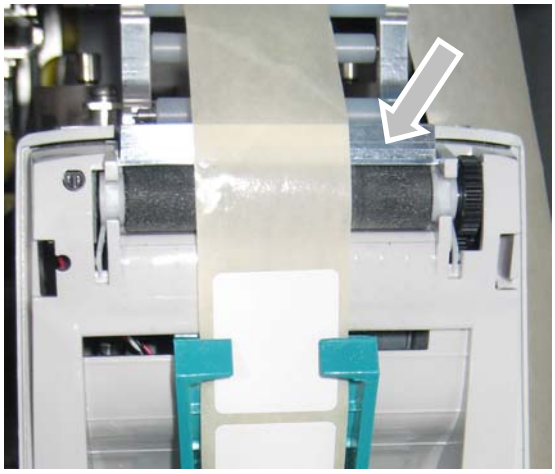


Figure 8-34 : Metal plate not to be removed

- Close the printer cover.
- Press the green button to align the labels.
- Remove the labels that are coming out of the printer.
- Press the black button to take up the slack on the label roll.

- Open the waste drawer.
- Check that the label backing (1) is coming out of the deflector (2) and is visible.

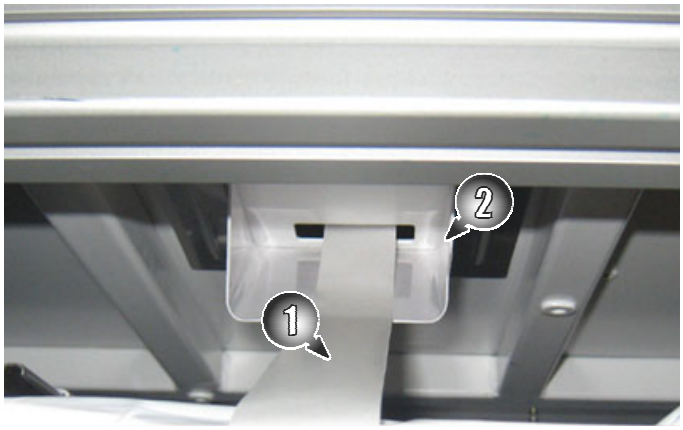


Figure 8-35 : Label backing coming out of deflector

Replacing Fuses

DANGER! ***The following maintenance operations should only be performed by a bioMérieux technician or a qualified person trained by bioMérieux.***

CAUTION! ***Before replacing fuses, shut the PREVI Isola down, turn off the main power switch and unplug the lead from the power-in socket.***

Two fuses are located in the main power inlet:

Miniature Fuses, FSF 5 x 20 mm, 5A, 250 VAC.

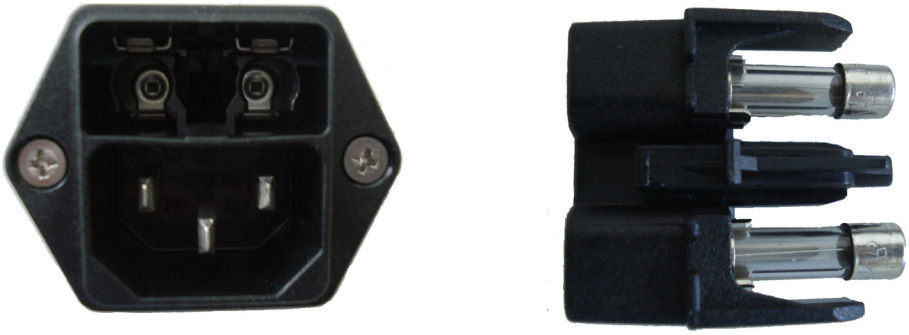


Figure 8-36 : Main power inlet fuses

CAUTION! ***Use only fuses specified or supplied by bioMérieux. Do not substitute fuses or use fuses with a higher rating.***

Replacing the PREVI Isola HEPA Filter

For replacement of the **PREVI Isola** HEPA filter, please refer to **PREVI Isola** HEPA Filter, page 9-17.

9 Troubleshooting

Introduction

This chapter provides information about troubleshooting procedures that can be performed by the **PREVI Isola** user and laboratory personnel.

When correcting errors or faults, always:

- Read the touch-screen error message before taking corrective action,
- Ensure the **PREVI Isola** is in “Pause” status before clearing any internal malfunctions,
- Wear appropriate personal protection.

List of Error Messages

Event ID	Description	Action Required
666	Unknown error code.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting: • Contact bioMérieux Technical Assistance.
10000	Consumables needed.	• Check relevant consumable types and refill as required. Remove processed plates from output cassettes or empty waste bin if required.
10001	More pipette tips needed.	• Load tips and resume processing once complete.
10002	More input plates needed.	• Load input plates at least to above the level of the sensor hole in the cassette.
10003	More applicators needed.	• Load applicator cartridges. • Remove any failed plates and resume processing.
10004	More labels needed.	• Check labels. • Replace the label roll if necessary, and resume processing.
10005	Output cassettes full.	• Remove some or all of the completed plates in the output cassettes and continue.
10006	Waste Bin is full.	• Empty the Waste Bin. • Touch the Waste button and resume processing once complete.
10007	More pipette tips needed.	• Load tips and resume processing. If the tip trays were full of tips and the user had not accidentally indicated the wrong tip tray as full then contact bioMérieux Technical Assistance.
11000	Failed to pause processing owing to instrument state.	• Restart the instrument software. If the problem persists, • Shut down and restart the instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
11001	Failed to resume processing owing to instrument state.	• Restart the instrument software. If the problem persists, • Shut down and restart the instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
11002	Unable to start workflow. There may be an incorrect version of configuration files installed.	If the problem persists, • Shut down and restart the instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
12000	A sample has reported using more than one tip and will therefore be marked as failed. This may be due to an earlier processing error.	• Please report repeated occurrences to bioMérieux Technical Assistance.
12001	A plate has reported using more than one label and will therefore be marked as failed. This may be due to an earlier processing error.	• Please report repeated occurrences to bioMérieux Technical Assistance.
12002	A plate has reported using more than one applicator and will therefore be marked as failed. This may be due to an earlier processing error.	• Please report repeated occurrences to bioMérieux Technical Assistance.

Event ID	Description	Action Required
12003	Internal software error (number of input plates used). One or more plates will be marked as failed. This may be due to an earlier processing error.	• Please report repeated occurrences to bioMérieux Technical Assistance.
12004	Internal software error (number of output cassette slots used). One or more plates will be marked as failed. This may be due to an earlier processing error.	• Please report repeated occurrences to bioMérieux Technical Assistance.
12100	Lost communications with Data Server. The Data Server may have terminated or the connection may have failed.	• Check that the Workstation application is operating correctly. If so then the problem is likely to be the connection from the instrument to the Data Server. If not, • Restart the PC on which the Data Server is running.
12112	The version of the Data Server does not match the version of the instrument.	• Please report this problem to bioMérieux Technical Assistance.
12125	The Data Server is currently undergoing maintenance. The current run will be paused until the maintenance is complete.	• Wait until the maintenance is complete and then continue the processing run.
12150	Plate Cassettes Configuration is out of date with the Data Server.	• Select a new Plate Cassettes Configuration and ensure all input and output cassettes contain the new types.
12500	The instrument was not properly shut down. This could be due to abnormal software termination or power failure. Some robots may have fallen down and therefore could become tangled, leading to initialisation problems	• Inspect the flipper robots, pipettor, sample tray and consumable tray and clean if required.
13000	Consumable lid opened during processing. The Consumable lid should not be opened while the instrument is processing.	• Please ensure that the consumable lid (left hand side) is closed properly, re-initialise the software and start processing the samples again.
13001	Sample lid is open. The Sample lid should not be opened while the instrument is processing.	• Please ensure that the sample lid (right hand side) is closed properly, re-initialise the software and start processing the samples again.
13002	Processing door or lid is open. The Processing door and lid should not be opened while the instrument is processing.	• Please ensure the door to the processing area (printers) is closed and the lid is sealed correctly. • Then re-initialise the software and start processing the samples again.
13003	Input cassette removed during processing. The plate cassettes should not be removed while the instrument is processing.	• Please ensure that all input cassettes are seated correctly, re-initialise the software and start processing the samples again.
13004	Output cassette removed during processing. The plate cassettes should not be removed while the instrument is processing.	• Please ensure that all output cassettes are seated correctly, re-initialise the software and start processing the samples again.
13005	Input cassette removed. The instrument cannot continue until all input plate cassettes are firmly in place.	• Please ensure that all input cassettes are seated correctly to continue processing.
13006	Output cassette removed. The instrument cannot continue until all output plate cassettes are firmly in place and the guard is raised.	• Please ensure that all output cassettes are seated correctly and that the guard is raised to continue processing.
13007	Fault detected with the printer motor.	• Please ensure that the labels are fed through properly. • Re-initialise the software and start processing the samples again. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.

Event ID	Description	Action Required
13010	The HEPA monitoring system detected a fault in the filtering.	• Shutdown the instrument (power off). • Then check that the HEPA filter is correctly seated and latched, and that the filter is not blocked. If the problem persists after restarting, • Please contact bioMérieux Technical Assistance.
14000	Pipette tip was not detected by camera.	• Ensure the tip tray is full before updating the status on the Applicators and Tips screen when the tray is next replaced.
14001	No further samples in this batch.	N/A
14002	No sample position found. Either a sample position is missing, the barcode failed to read or is positioned incorrectly.	• Check that all tubes have their barcode facing the front of the instrument when loading racks. • Locate unused tubes in expected positions to help distinguish between failed barcode reads and empty tube positions.
14003	Sample barcode [BarCode] has started processing.	N/A
14005	Tip tray is empty.	• Load tips.
14006	Failed to pickup applicator. No applicator detected on applicator robot.	• Check applicator cartridges for half-extracted applicators. • Check that applicator cartridge is set against clip and able to move freely in the cartridge well. • Replace empty applicator cartridges.
14007	Calculated dispense height was out of range.	• Check plates have not been loaded with agar-side down. If the problem persists, • Contact bioMérieux Technical Assistance.
14008	Calculated streak height was out of range.	• Check plates have not been loaded with agar-side down. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
14009	Calculated dispense volume was out of range.	N/A
14010	Failed to dispose applicator.	• Manually remove applicator from applicator robot, if applicator is present. If the problem persists, • Contact bioMérieux Technical Assistance.
14011	No applicator present just prior to streaking plate - applicator dropped between ejection and streaking (possible collision with pipettor robot).	• Remove dropped applicator from the instrument. • Remove plates from inside the instrument and then re-initialise the instrument. If the problem persists, • Contact bioMérieux Technical Assistance.
14012	No applicator present just after streaking plate, but it was there prior to streaking - applicator dropped during the streaking operation.	• Remove dropped applicator from the instrument. • Remove plate from Plate Process Station and then reinitialise the instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
14013	Plate lid is misaligned, unable to (de)lid plate.	• Remove plate from plate transfer robot or instrument. If the problem persists, • Contact bioMérieux Technical Assistance.
14014	Plates are within the instrument and must be removed by the operator before the instrument can initialise.	• Please remove plates present from Input, Output and Process Stations. • Touch OK to continue or touch Cancel to remain in Error state.

Event ID	Description	Action Required
14015	Pipette tip detected during initialisation indicating the camera lens or polarizing film is dirty.	• Restart the software. If the problem persists, • Contact bioMérieux Technical Assistance.
14100	Sample has been skipped. Sample may be skipped due to incorrect plate types loaded or no allocated Plate Panel for that sample barcode on the Workstation.	• Check there is an allocated Plate Panel using the Workstation application. • If defined then check that the required plate types are loaded on the instrument.
14101	Sample has been skipped. Sample was skipped due to an incorrect streaking protocol.	• Check that a streaking protocol has been allocated to that sample (using the workstation).
14102	Sample has been skipped. Sample was skipped due to no allocated Plate Panel for that sample barcode on the Workstation.	• Check there is an allocated Plate Panel for that sample (using the workstation).
14103	Sample has been skipped. The Plate Cassettes Configuration does not match the Plate Panel.	• Check that the Plate Cassettes Configuration is appropriate.
14104	Sample has been skipped. Sample was skipped due to length of the barcode exceeding the maximum length allowed.	• Check that the sample has been labelled correctly.
20000	Axis error. An error occurred on the axis that was not due to collision or unexpected movement of the axis. There could be an electronics problem with a stepper card.	• Report the failure to bioMérieux Technical Assistance. Powering off the instrument and restarting may allow processing to resume until the next service visit.
20001	Axis steploss. Attempted movement of axis resulted in collision.	Often the instrument is able to automatically recover from step loss. If this has resulted in a fatal error: then the instrument should be cleaned according to the instructions in the User Manual and restarted.
20002	Axis bumped. An axis has moved position when it was not supposed to be moving.	N/A
20100	Failed to communicate with pipettor. Connection to the pipettor failed. The COM port may be in use by another device, or the USB connections may have been reversed.	• Ensure that there is only one instance of the instrument UI application and/or Service running. • Restart the instrument PC to be certain.
20104	Failed to complete command within time limit.	• Reinitialise the instrument software. If the problem persists, • Contact bioMérieux Technical Assistance.
20105	The requested aspiration volume is invalid.	• Check plate protocols to ensure that a sample volume of no more than 95µL is aspirated. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
20106	The requested dispense volume is invalid.	• Check that a volume of less than 95µL is dispensed on all plates for a given sample.
20107	Unable to find requested Pipettor settings (speed profile).	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
20108	Unauthorised file modification detected!	If scripts have been modified, then • Check all required parameters have been added to actions. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
20109	Pipettor rejected command.	• Reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.

Event ID	Description	Action Required
20110	Unable to read Configuration files.	• Check Config directory for problems.
20200	Failed to communicate with MasterIO. Invalid serial port, serial port already in use, loose cables, bad configuration, or hardware failure.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
20201	Lost communication with a slave device. Bad configuration file, loose cabling, or hardware failure.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
20300	Comms port not available or in use by another application.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
20400	Failed to communicate with barcode scanner.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
20500	Failed to open the serial port for loopback operation.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
21000	Insufficient number of parameters passed to action.	If scripts have been modified, then • Check all required parameters have been added to actions. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
21001	Sequencer locked - error in workflow synchronisation.	If scripts have been modified, then • Check for script locking of locked sequencer. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
21002	Device name symbol cannot be dereferenced to a valid object.	If scripts have been modified, then • Check for referenced variables that do not exist. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
21003	Exception thrown while executing an action.	• Restart the instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
21004	Unregistered action name invoked.	If scripts have been modified, then • Check for unregistered action names. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
21005	Syntax error in the sequence script.	If scripts have been modified, then • Check for syntax errors. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
21006	Missing or undefined symbol used in sequence script.	If scripts have been modified, then • Check for undefined symbols. If no scripts have been modified, • Contact bioMérieux Technical Assistance.

Event ID	Description	Action Required
21007	Unknown or incorrect operand used in sequence script.	If scripts have been modified, then • Check for undefined operands. If no scripts have been modified, • Contact bioMérieux Technical Assistance.
21008	Sequencer synchronisation error detected - error in workflow synchronisation.	• Restart the instrument software. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
21009	Sequencer execution failed to complete successfully.	If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
22000	Camera Manager failed to initialise.	If the problem persists, • Contact bioMérieux Technical Assistance.
22001	Camera not found.	If the problem persists, • Contact bioMérieux Technical Assistance.
35002	Failed to communicate with agar level sensor.	• Restart the instrument software. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
35003	Raw low reading setting is greater than the raw high reading - configuration error.	The agar sensor must be recalibrated, • Contact bioMérieux Technical Assistance.
35004	Raw low reading setting is the same as the raw high reading - configuration error.	The agar sensor must be recalibrated, • Contact bioMérieux Technical Assistance.
35005	Insufficient agar height readings for half plate detection.	• Contact bioMérieux Technical Assistance.
35006	Out of range agar height reading.	• Contact bioMérieux Technical Assistance.
35007	No plate detected on the process station.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35008	Found a plate lid on the process station.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35009	Found a plate and plate lid on the process station.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35010	Expected a half plate and found a full plate.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35011	Expected a full plate and found a half plate instead.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35012	Plate base did not seal when taking plate from Plate Input Robot to Plate Transfer Robot. Possible causes: No plate present, warped plate or plate dropped transferring from Input Robot to Transfer Robot.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.

Event ID	Description	Action Required
35013	Plate lid did not seal when taking plate from Plate Input Robot to Plate Transfer Robot. Possible causes: No plate present, warped plate or plate dropped when transferring from Input Robot to Transfer Robot.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35014	Plate base lost seal after separating the base from the lid (delidding). Possible causes: Plate and lid stuck together and base still held down with lid, or cracked or warped plate.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35015	Plate lid lost seal after separating from the plate base (delidding). Possible causes: Plate and lid stuck together and lid lifted up with plate, or cracked or warped plate.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35016	Plate base lost seal after flipping ready to process.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35017	Plate lid lost seal after plate base was rotated. Plate base collision with lid during rotation.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35018	Plate base still had seal when being transferred to Plate Process Station. Collision of Input or Output Robot with the lid.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35019	Plate base failed to seal taking plate from Plate Process Station.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35020	Plate lid lost seal during processing of the plate base at the Plate Process Station.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35021	Plate base lost seal after applying label.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35022	Plate base lost seal after rotating back above the plate lid (relidding).	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35023	Plate lid lost seal after plate base was rotated back above it (relidding).	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35024	Plate base failed to release seal after relidding.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.

Event ID	Description	Action Required
35025	Plate lid failed to release seal after relidding.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
35026	Unable to find septum on the process station.	• Remove the plates from the instrument and reinitialise the software. If the problem persists, • Contact bioMérieux Technical Assistance.
36000	Unrecognised sample rack type identifier for Rack [RackNumber].	• Remove the unrecognised sample rack. • Replace it and then restart instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
36002	Sample rack detected inside instrument, without a position to move to.	• Check if a sample rack is present, remove it and restart the instrument. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
36003	Invalid rack configuration detected.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • contact bioMérieux Technical Assistance.
36500	Sample rack sensors are failing their initialisation check.	• Contact bioMérieux Technical Assistance.
37000	Failed to communicate with camera.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
37001	Failed to find fiducial marks in image.	• Contact bioMérieux Technical Assistance.
37002	No sample detected in the tip - tube not filled to required level or incorrect camera settings.	• Ensure that tubes are filled with sample to recommended levels. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
38000	Failed to communicate with vacuum pump regulator.	• Restart the instrument software. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
38001	Vacuum pump cannot maintain vacuum pressure.	• Restart the instrument software. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
39000	Barcode printer driver has generated an error.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
39001	Barcode printer is unavailable for printing due to HeadUp or OutOfPaper.	• Check that the printer is closed properly. • Press printer feed (green) button until a blank label is fed through correctly. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.
40000	An error was generated by the instrument that could not be handled.	• Shut down (power off) the instrument and then restart it. If the problem persists after restarting, • Contact bioMérieux Technical Assistance.

Event Log

The “Event Log” screen is displayed when the user touches an alarm button after a warning or an error has occurred.

- Touch a button to display or mask a type of event (Show Fatal, Show Errors, Show Warning, Show Info).

When the button is yellow the corresponding events are displayed.

- Touch the  button to acknowledge the events and return to the main screen,

or

- Touch the “Clear Log” button to clear the events and return to the main screen.

Note: If the user does not clear the events, they will be automatically cleared when the next run is started.

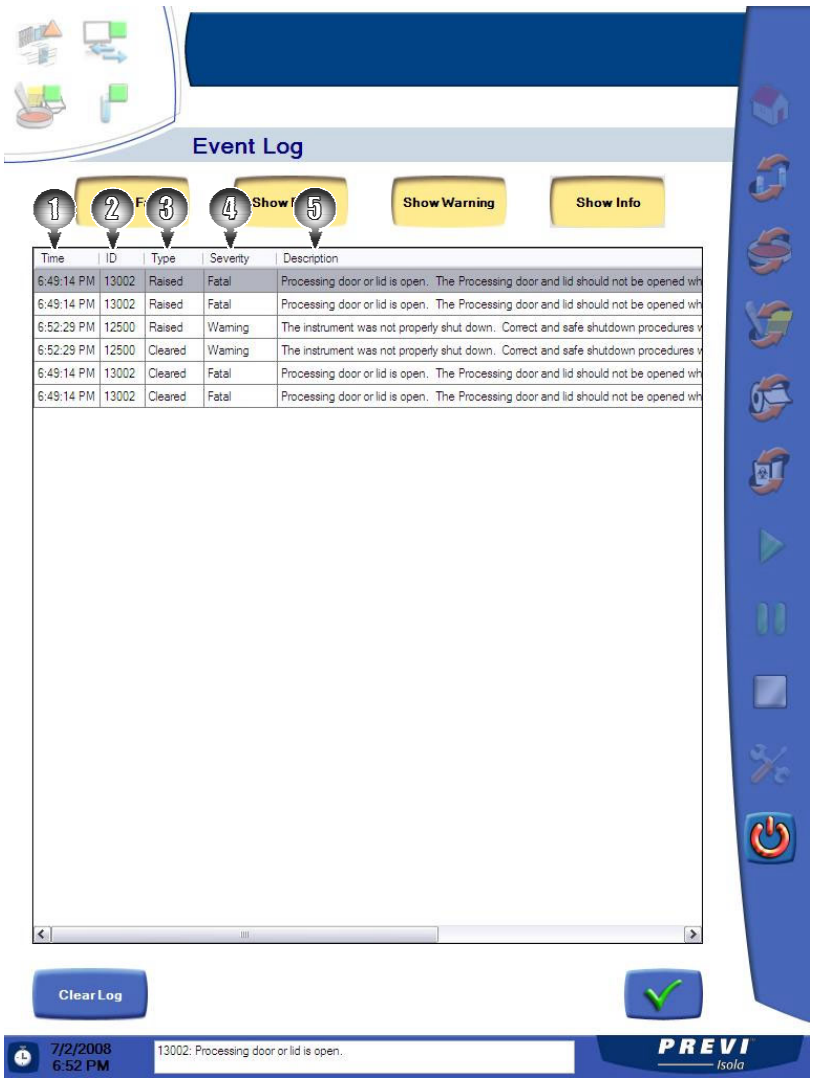
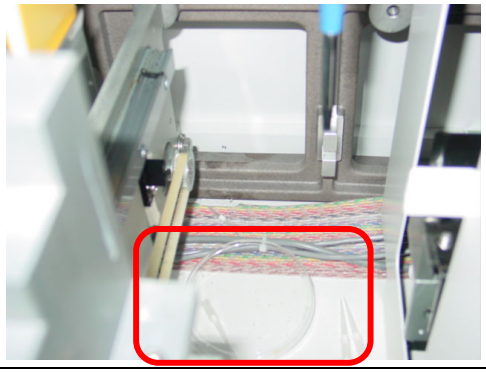


Figure 9-1 : Event Log screen

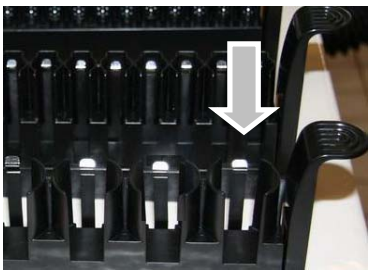
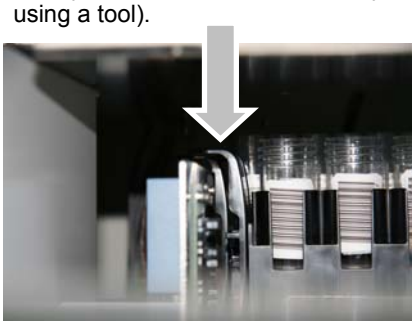
1. **Time**: Time at which the event occurred.
2. **ID**: Event identification number.
3. **Type**: Status of the event (“Raised” or “Cleared”).
4. **Severity**: Severity of the event (“Information”, “Warning”, “Fatal”).
5. **Description**: Description of the event.

Error, Cause and Recovery

Error	Cause	Recovery
Main power failure	Cable disconnected.	• Reconnect cable.
Fuse failure	Blown fuse.	• Replace fuse.
Computer failure	Power cable disconnected.	• Contact bioMérieux S.A. or your local bioMérieux representative.
Touch-screen failure	Power cable disconnected.	• Contact bioMérieux S.A. or your local bioMérieux representative.
Process fails to start	Covers open.	• Close covers.
Plate input failure	Input cassette is removed during instrument operation.	• Replace cassettes.
	Less than five plates in input cassettes.	• Load plates.
	Plates incorrectly positioned or jammed in the input cassettes.	• Pause the instrument, remove cassette and reposition plates.
	Plates loaded agar side down in the input cassettes.	• Pause the instrument, remove cassette and reload plates.
Plate output failure	Output cassette is removed during instrument operation.	• Replace cassette.
	Plates incorrectly positioned or jammed in the output cassettes.	• Pause the instrument, remove cassette and reposition plates.
	Plates overloaded or jammed in the output cassettes.	• Pause the instrument, remove cassette and incubate plates.
Plate transfer failure	Should not occur during normal operation.	• Contact bioMérieux S.A. or your local bioMérieux representative.
Plate process failure	Should not occur during normal operation.	• Contact bioMérieux S.A. or your local bioMérieux representative.
Plate jamming	Plates are incorrectly positioned during loading.	• Pause the instrument, remove cassette and reposition plates.
	Plates of incorrect size are loaded.	• Load compatible plates.
Applicator failure		• Pause the instrument if it has not already paused or stopped.
	Cartridges are empty.	• Replace cartridges see (Loading **PREVI Isola** Applicators, page 4-10).
	Applicator robot fails to dispose of used applicator.	• Remove the applicator manually and reinitialize the instrument.
Pipettor tip failure		• Pause the instrument if it has not already paused or stopped.
	Pipettor trays are empty.	• Replace pipettor trays (see Loading **PREVI Isola** Tips, page 4-13) .
	Pipettor fails to dispose of a used tip.	• Remove the tip manually and reinitialize the instrument.

Error	Cause	Recovery
Aspiration/dispense failure	Damaged or incompatible tip. Misalignment of pipettor.	• Pause the instrument, check the tip for damage and compatibility. • Contact bioMérieux S.A. or your local bioMérieux representative.
Repetitive shorter dispense line or broken dispense line	The pipettor is unable to dispense the sample correctly.	• Contact bioMérieux S.A. or your local bioMérieux representative.
Sample carryover	Damaged or incompatible tip. Misalignment of pipettor.	• Pause the instrument, check the tip for damage and compatibility. • Contact bioMérieux S.A. or your local bioMérieux representative.
Fallen plates	Plates which are defective (cracked, deformed etc.) may not be retained by the transfer robot and may fall inside the instrument.	• Remove the plates from the instrument.
Abnormal output cassette filling	If, plates fall out of an overfull output cassette, or the output robot generates repetitive errors when pushing plates up into the output cassettes and the cassette status is “empty” then an output cassette sensor failure has occurred.	• Contact bioMérieux S.A. or your local bioMérieux representative. You will be able to continue processing by regularly emptying the output cassette.
Inaccessibility of plates, tips or applicators that have fallen inside the instrument	Plates, tips or applicators that have fallen inside the instrument are not accessible or are in an area that presents an electrical hazard (visible PWA, cables, etc.). 	• Contact bioMérieux S.A. or your local bioMérieux representative.
Cap left on tube	If a cap is left on a tube, the tip will hit the cap during processing. The instrument will stop and an error will be generated.	• Reinitialize the instrument. • Check whether the tip is still on the pipettor and if it is, gently remove it. • Run a QC test on the instrument to confirm that the pipettor behavior is correct. • If the QC test is not correct, contact bioMérieux S.A. or your local bioMérieux representative.
Printer fails to print	No label roll. Labels are jammed in the printer head.	• Replace label roll (see Loading **PREVI Isola** Label Rolls, page 8-23). • Pause the instrument, and clear jammed labels.
Printer label jam	If the printer remains idle for a long period of time, labels may come off the roll and cause a jam during processing.	To avoid printer label jamming, • Advance the label roll and remove 3 or 4 labels.

Error	Cause	Recovery
Label backing jam causing error 13007	Waste paper bin too full. Label backing jammed in the deflector preventing paper falling into the bin.	• Reach into the waste bin and clear any waste paper that has backed up on the paper deflector. • Gently pull the label paper from the bottom of the printer until you meet some resistance. • Using scissors, cut the paper that is hanging into the waste bin from the printer, so that around 10 cm of paper is protruding into the waste bin. • From the top of the printer, gently pull the paper out of the paper waste chute. • If you have cleared the paper jam, then you will have the end of the label paper that is cut with scissors. If you do not have this end, then you have a paper jam that requires you to call bioMérieux S.A. or your local bioMérieux representative.
Printer status causing fatal error 39000	The printer is accidentally set in “Dump Mode”. The printer power is off or disconnected or the printer serial cable is disconnected.	• Press the feed button twice on the printer. If the problem persists, • Power cycle the instrument. • Contact bioMérieux S.A. or your local bioMérieux representative.
Printer status causing warning 39001	The printer cover is open. The printer is out of labels. The printer is missing a label.	The instrument will pause. • Check that the printer cover is closed. • Load labels if necessary. • Advance the label roll.
Printer icon displayed 	The printer is accidentally powered off when the instrument is idle.	• Check whether the printer has been powered off. If so, • Power it on again. An error message will be displayed. • Acknowledge the message. • Reinitialize the instrument.
Plate labeling errors	More than one label is stuck on a plate. Labels stuck on the bottom of the printer or on the body of the transfer robot.	• It is recommended to rerun the sample corresponding to the plate. • Perform a visual check and remove labels if necessary.
Poor label print quality	Poor quality of printing.	• Clean the print head and printer platen roller as described in Clean the print head, page 8-19, and Clean the printer and the printer platen, page 8-18.

Error	Cause	Recovery
Tube movement	There may be occasions when tubes turn freely in the racks	• Tighten the springs on the racks. 
Racks stuck in the rack loading bay	There may be occasions when racks get stuck in the rack loading bay.	• Gently replace the racks (manually or using a tool). 
Waste chute full	Waste bins overflowing.	• Clear waste chute and replace waste bins (see Removing Waste, page 4-35).
Applicator jam (waste chute top)	There may be occasions when applicators get stuck inside the waste chute top and cause a jam during processing.	• Remove the applicators using a sharp object (to be disposed of). If the applicators fell in the surrounding area, please decontaminate it (see Spill Management, page 8-21). 

DANGER! ***Do not attempt to remove jammed plates or jammed tips while the instrument is in operation. Moving parts are hazardous and present a danger to the user.***

IMPORTANT! ***Plates removed from the instrument following an error must be discarded and not put back into an input cassette.***

Before re-starting the PREVI Isola following power interruption, computer failure or touch-screen failure, the user should first check the plate transfer and process station areas for dropped or damaged plates.

In case of Fatal error (E-stop) or power failure, do not manually move a sample rack or the sample tray. The instrument will present the sample tray after reinitialization.

If the pipettor is immobilized in the sample tube after power interruption, clean it thoroughly before resuming the process to avoid any risk of contamination.

Before replacing jammed or damaged pipettor tips ensure that the tip tray and pipettor tips are instrument compatible.

Recovery from Events with “Warning” Severity

If an event is expected to occur (e.g. missing consumables), a warning message will appear on the touch-screen in the Message / Work Status Zone.

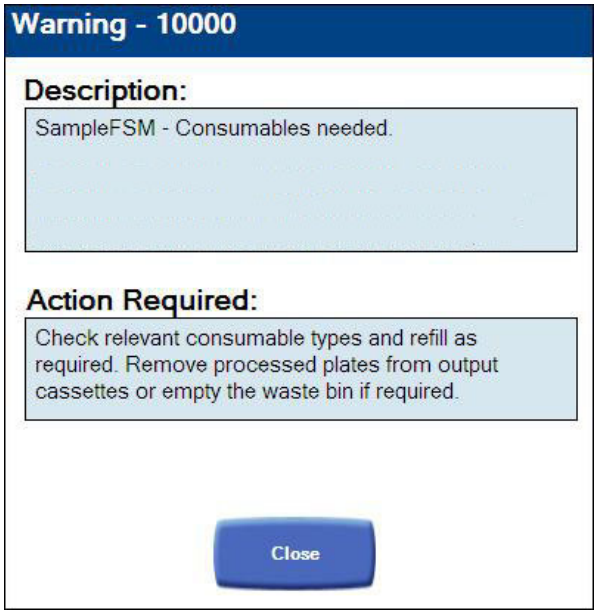


Figure 9-2 : Warning Message

To recover from displayed warnings:

- Acknowledge the message.

Recovery from Events with “Error” Severity

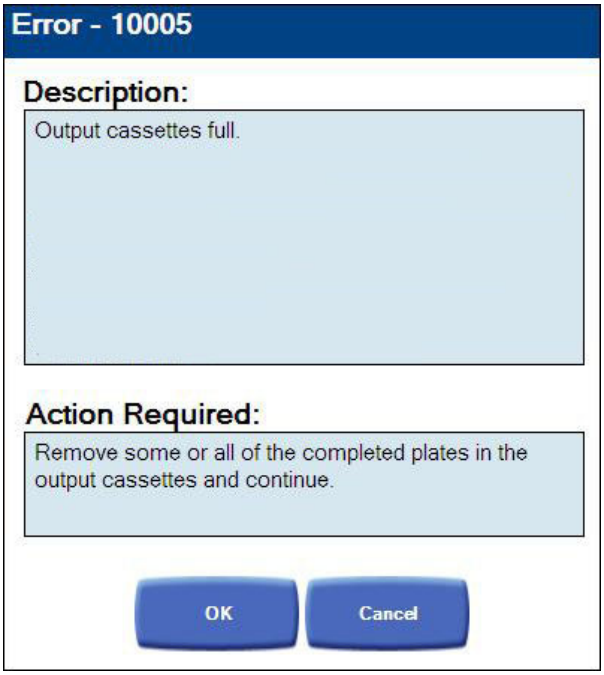


Figure 9-3 : Error Message

If the instrument has a fault at any time during the process, which it can recover from with some user assistance, it enters the processing paused state and displays a prompt on the instrument user interface.

The user will need to perform the necessary actions as prompted by the instrument user interface to clear the fault.

Once the fault is cleared, the user may resume processing via the instrument user interface.

The instrument will return to the processing state and continue processing samples.

If at the end of a run, certain samples have not been processed, the user can restart the run. All samples which have been successfully processed will be skipped and unprocessed samples will be processed.

Recovery from Events with “Fatal” Severity

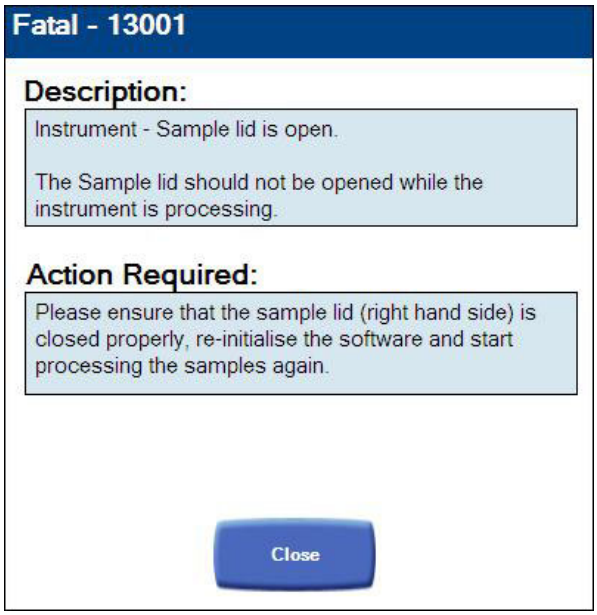


Figure 9-4 : Fatal Message

If the instrument has an unexpected fault, it will enter the fault state.

The user will be required to take some corrective action. If there are partially processed plates the user must remove these from the instrument.

When the user has cleared the fault, the instrument must be reinitialized. The user may restart processing via the instrument user interface. The instrument will skip any processed samples and resume processing any unprocessed or partially processed samples.

Restarting the Instrument Software

To restart the Instrument Software following an instrument shutdown,

- Touch the PREVI Isola icon twice.

PREVI Isola HEPA Filter

The **PREVI Isola** HEPA filter is monitored with an airflow sensor.

An error message is raised in the following events:

- the airflow sensor is triggered if the fan stops running,

or

- the HEPA filter presence sensors are triggered (if a HEPA filter is not present),

or

- the latch mechanism sensors are triggered.

The error generated is fatal and the instrument stops operating.

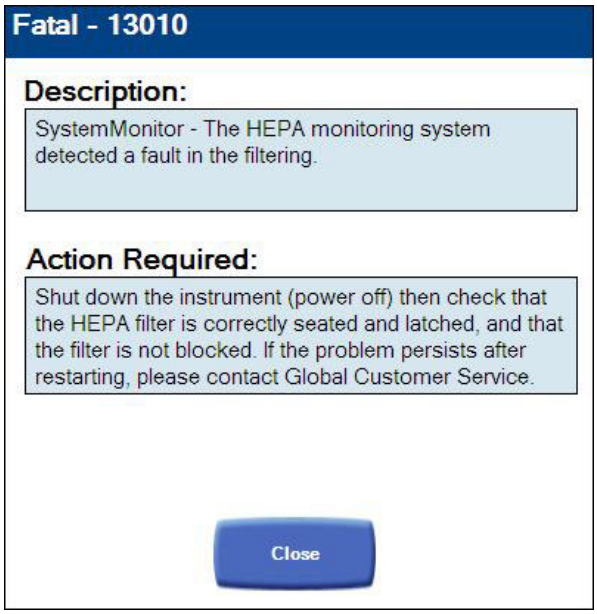


Figure 9-5 : ***PREVI Isola*** *HEPA filter error message*

Before changing the filter:

- Check that the latch is not open and the filter is in the right place.

If the latch is open,

- Close and restart.

Otherwise, if this error is raised the filter will have to be changed.

Pre-tested filters covering the following criteria should be ordered.

- arrestance efficiency : > 99.999%
- airflow capacity: 0.0472 m3 /s
- pressure drop at test airflow: 300 pa

Note: Filters other than the one recommended by bioMérieux could have invisible, non-detectable micro holes leading to micro leaks and contamination.

Replacing the PREVI Isola HEPA filter

To replace the filter,

- Unlock the latch.

Figure 9-6 : Unlocking the latch

- Unhook the latch.

Figure 9-7 : Unhooking the latch

- Gently lower the HEPA filter lever.

DANGER! ***The PREVI Isola HEPA filter must be removed with the utmost rigor as the user is in a potentially contaminated environment.***
Gloves, a lab coat, a face mask and protective glasses must be worn.

- Prepare a plastic bag and a biohazardous container in which to discard the HEPA filter.
- Position the plastic bag so that it is ready to receive the HEPA filter (see figure below).

*Figure 9-8 : Preparing to place the **PREVI Isola** HEPA filter in a plastic bag*

- Slide the HEPA filter forward until it comes out of its housing.

*Figure 9-9 : Sliding the **PREVI Isola** HEPA filter out of its housing*

- Continue removing the HEPA filter from its housing .

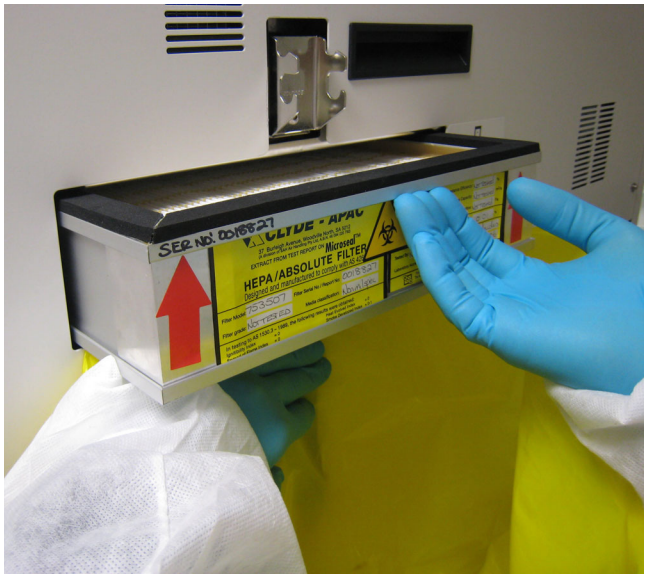


*Figure 9-10 : Removing the **PREVI Isola** HEPA filter from its housing*

- Cover the extracted part of the HEPA filter with the plastic bag.

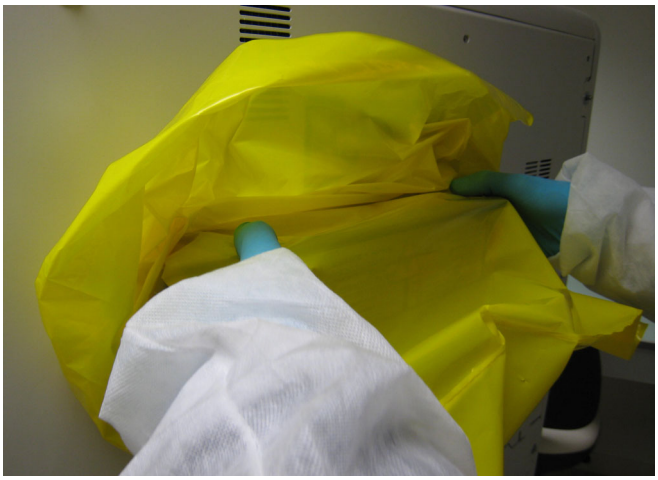


*Figure 9-11 : Covering the **PREVI Isola** HEPA filter as it comes out of its housing*

- Continue covering the HEPA filter until it has been fully extracted.

*Figure 9-12 : Covering the **PREVI Isola** HEPA filter until fully extracted*

DANGER! ***Rotating blades may be accessible when the filter is removed even though the fan is disabled.***

- Close the plastic bag as soon as the filter has been removed from its housing and is in the bag.

Figure 9-13 : ***PREVI Isola*** *HEPA filter in the plastic bag*

- Dispose of the HEPA filter according to the usual laboratory procedures for biohazardous waste and in accordance with any applicable local regulations.
- Check for old filter parts in the housing before installing a new filter (i.e. if part of the old gasket remains it may cause seal failure on the new filter).
- Check the new filter for damage before inserting it.
- Insert the new filter the correct way up (red arrows pointing upwards).
- Slide the new filter into the housing.
- Hook and lock the latch.

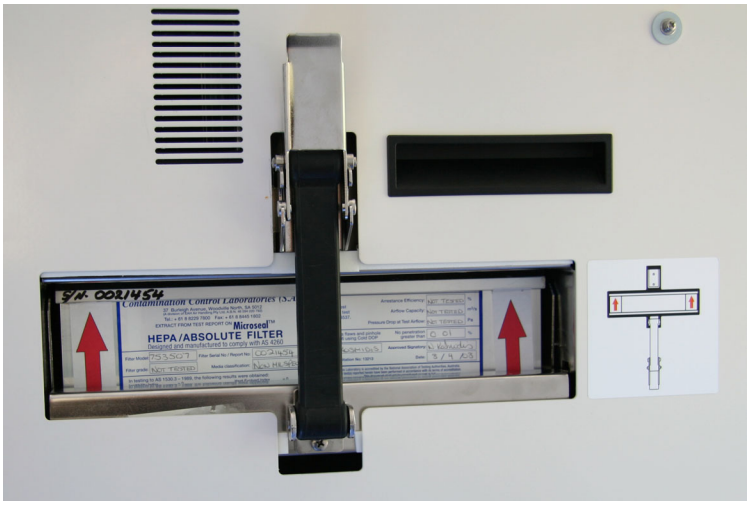


Figure 9-14 : New ***PREVI Isola*** *HEPA filter in place*

- Note the date of the filter change on the maintenance sheet.
- Order a new filter from bioMérieux.

IMPORTANT! ***It is mandatory to always have a replacement filter available.***

If the error persists after the filter has been changed,

- Verify the position of the filter and check that the latch is correctly locked.

If the error persists,

- Call bioMérieux Technical Assistance.

Pipettor

Clean and decontaminate the pipettor if it descends into a sample tube

If power supply is lost or if one of the instrument covers is opened during plate processing, the pipettor may descend into a sample tube and become contaminated.

Material required

- 70% alcohol solution (isopropanol or ethanol)
- Lint-free paper
- Swabs

Procedure

IMPORTANT! ***The pipettor cleaning procedure must be performed with the utmost care and attention as the pipettor is a very sensitive component that can easily be damaged.***

- Power down the instrument (see Powering Down the Instrument, page 4-37).
- Move the pipettor so that it is on the right-hand side of the process station.
- Unscrew the pipettor barrel. Only the blue part (1) should be unscrewed.

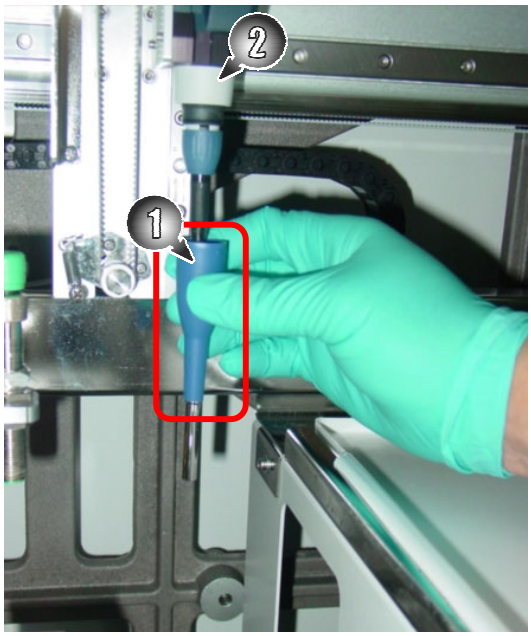


Figure 9-15 : Unscrew the pipettor barrel

- If the white ring (2) comes away with the pipettor barrel, screw the pipettor back into place and call bioMérieux Technical Assistance.

- Clean the black pipettor piston (the part of the pipettor remaining on the instrument) using lint-free paper moistened with a 70% alcohol solution.

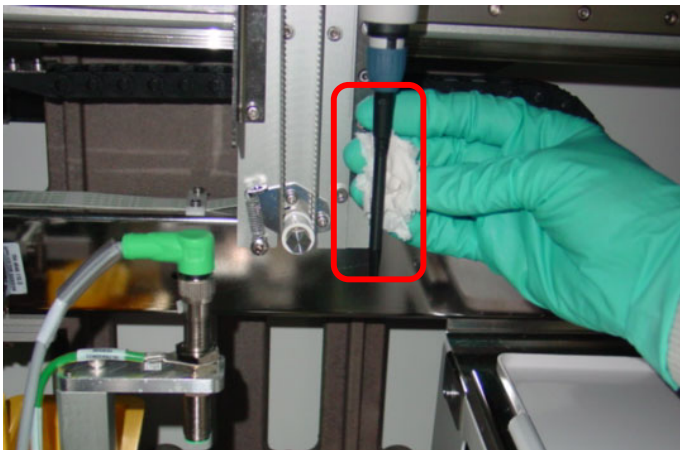
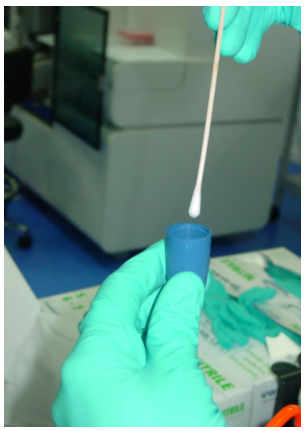
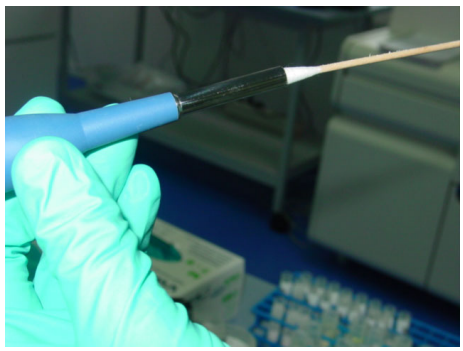


Figure 9-16 : Cleaning the black pipettor piston

- Clean the inside of the pipettor barrel using a swab moistened with a 70% alcohol solution.





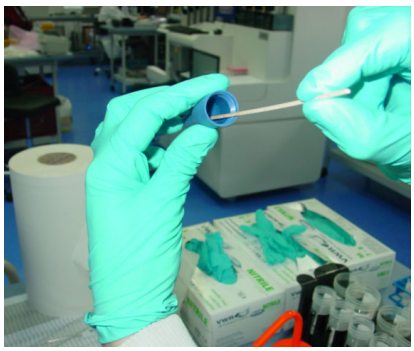


Figure 9-17 : Cleaning the inside of the pipettor barrel

- Clean the outside of the pipettor barrel using lint-free paper moistened with a 70% alcohol solution.

Figure 9-18 : Cleaning the outisde of the pipettor barrel

- Allow the barrel to dry for 5 to 10 minutes before screwing it back onto the pipettor piston.
- Gently screw the barrel back on until it is securely in place.
- Power up the instrument (see Powering up the instrument, page 4-2).

Possible issues after cleaning

Issue	Possible Cause	Recovery
The pipettor fails to take a tip.	The pipettor barrel has not been fully screwed on.	Check that the pipettor barrel is securely screwed in place.
The pipettor fails to eject a tip.	The pipettor barrel has jammed.	Contact bioMérieux S.A. or your local bioMérieux representative.

Reinitialize the instrument after the pipettor descends into a plate on the process station

If power supply is lost, or if one of the instrument covers is opened during plate processing, the pipettor may descend into the plate that is on the process station.

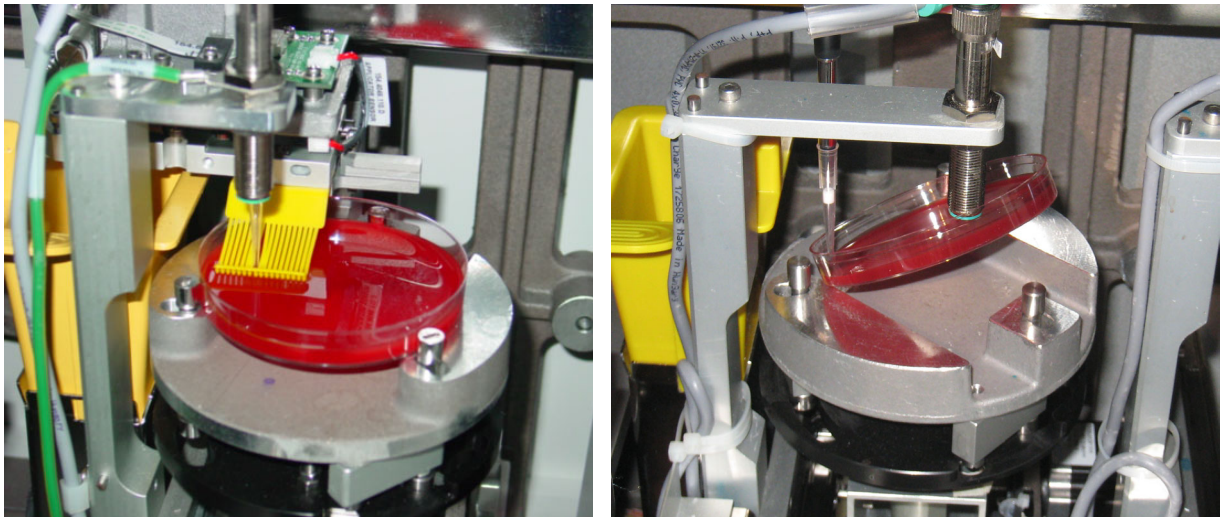


Figure 9-19 : Pipettor that has descended into a plate

Procedure

- Touch the  button.

The following message appears:

```
Warning 14014: Plates are within the
instrument and must be removed by the operator
before the instrument can initialize.
```

- Remove the plate from the input robot (if a plate is present).

CAUTION! ***Do not remove the plate from the process station, the applicator from the robot, or the tip on the pipettor.***

- Remove the plate from the output robot (if a plate is present).
- Touch the  button to complete the initialization.

Once the instrument is in “Ready” state:

- Remove the plate from the process station and discard it.

IMPORTANT! ***Please refer to the relevant package inserts for disposal of plates.***

- Remove the tip and/or applicator from the robots if they were not discarded during initialization. (See Disposal of used consumables, page 8-22).

Examples of Incorrect Inoculation and Streaking Patterns

Figure 9-20 : Incorrect inoculation and streaking patterns

Back up Instrument Log Files

For information on how to back up instrument log files, see Instrument and Workstation Log File Retrieval, page 7-6.

Anonymization of Patient Data

Should the user be required to send a copy of his database to bioMérieux for troubleshooting purposes, the patient data will need to be anonymized.

To anonymize patient data,

- Open the Windows Explorer.
- Select “Start“ / “Programs” / “PREVI Isola” / “DatabaseAnonymiser”.

The following screen is displayed:

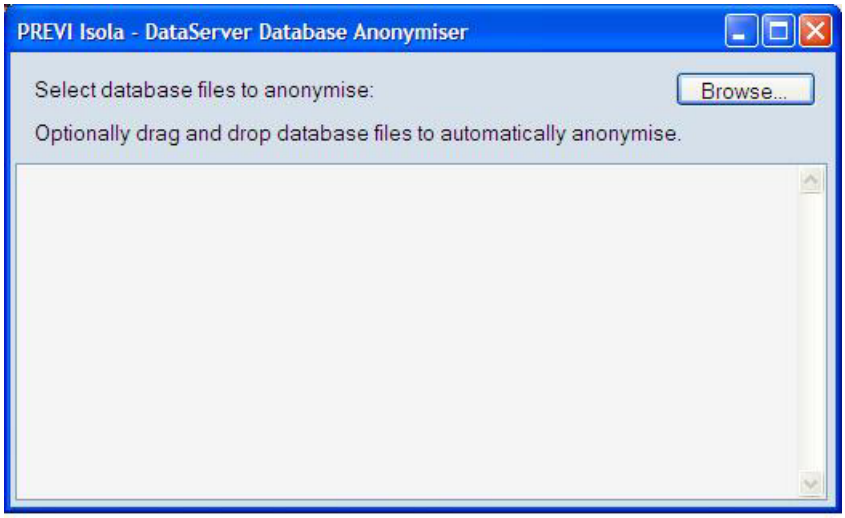


Figure 9-21 : “Database Anonymiser” screen

In D:\PREVIIsola\DataServer\Data,

- Create a copy of the file “AutoStreakerDatabase.sdf” which contains the complete database.
- Start the anonymizer by clicking on “Browse” and selecting the copy of the database (AutoStreakerDatabase.sdf), or by dragging and dropping the file into the anonymizer.

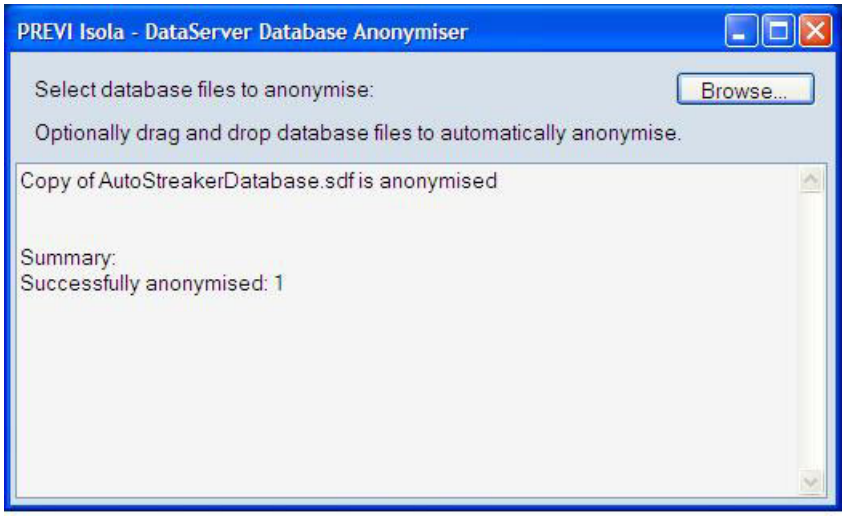


Figure 9-22 : Database successfully anonymized

10 General System Characteristics

Dimensions

	Crate + Instrument	Instrument
Height (mm)	2010	1680
Width (mm)	1700	1445
Depth (mm) (with wall bumper)	1100	920

Weight

	Crate + Instrument	Instrument
Weight (kg)	470	298

Electrical specifications

Power Supply: ..... 100 - 240 VAC, 50 / 60 Hz

Power Rating ..... 400 W

Neutral system: ..... TT or IT or TN

Approximate emission of heat ..... 1365 BTU / hr

Note: Only a mains cable rated to greater than 45°C must be used with this product.

The instrument is grounded through the mains lead.

The instrument is protected from overloads and short circuits by fuses in the mains inlet socket.

Environmental considerations

The **PREVI Isola** is intended for indoor use only.

Installation category: II.

Pollution degree: 2.

Sound level: 60.4 dB(a)

*Note: The **PREVI Isola** bar code readers (internal or external) produce class 1 radiation according to standard IEC 60825-1. Class 1 laser beams are not considered harmful and do not cause burns (skin and eyes).*

Temperature

Operating temperature: ..... 15°C to 30°C (59°F – 86 °F) (room temperature)

Storage temperature: ..... - 20°C to + 60°C (- 4°F – 140°F)

Humidity

Relative humidity: ..... 20% to 80% non-condensing

During storage and shipping ..... Maximum of 80% non-condensing

Altitude

Maximum altitude (Operating): ..... Up to 2,000 m (above sea level)

11 Appendices

Appendix A: Packing list

Instrument kit

- 1 **PREVI Isola** instrument
- 1 Rack 1
- 1 Rack 2
- 1 Rack 4
- 1 Rack 5
- 1 Rack 6 (Swab)
- 5 Input Cassette
- 3 Output Cassette
- 1 Drip Tray (Pro. Stat.)
- 3 Drip Tray (Flat Ret.)
- 1 Drip Tray (Sam. Hand.)
- 1 Waste chute (top)
- 1 Waste Paper Bin (Labels)

User Manual kit

- 1 **PREVI Isola** User Manual (EN)
- 1 **PREVI Isola** User Manual CD-ROM (Multilingual) (optional)
- 1 **BCI NET** User Manual CD-ROM (optional)
- 1 **BCI RS232** User Manual CD-ROM (optional)

Workstation PC kit

- 1 HP DC7700 Computer
- 1 RS232 Cable- USB (optional)
- 1 Philips Monitor
- 1 Visibroker License
- 1 Barcode Reader kit
- 1 Printer 220 V (optional)
- 1 Printer 110 V (optional)
- 1 Generic router/firewall kit (optional)
- 1 Generic bioMérieux 5 port Ethernet switch (optional)

Appendix B: Stopping and Restarting the Data Server

Stopping the data server

On the workstation computer:

- Select “Start Programs / Administrative Tools / Services”.

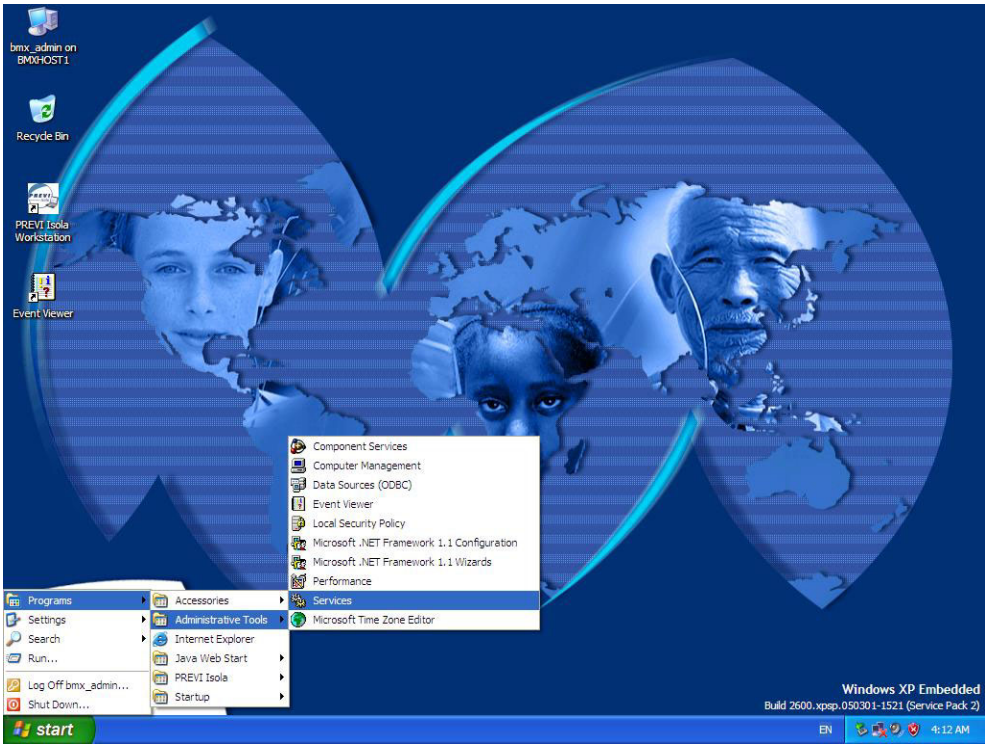


Figure 11-1 : Opening the “Services” window

The “Services “ window is displayed:

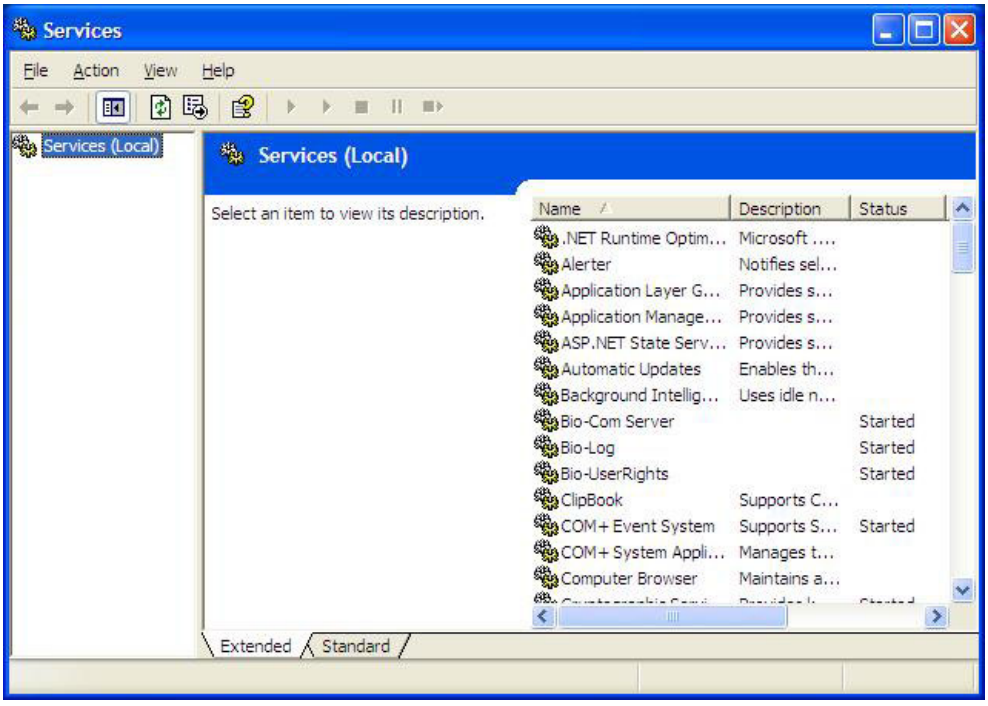


Figure 11-2 : “Services” window

- Click on “DataServer“ **(1)** in the name column.

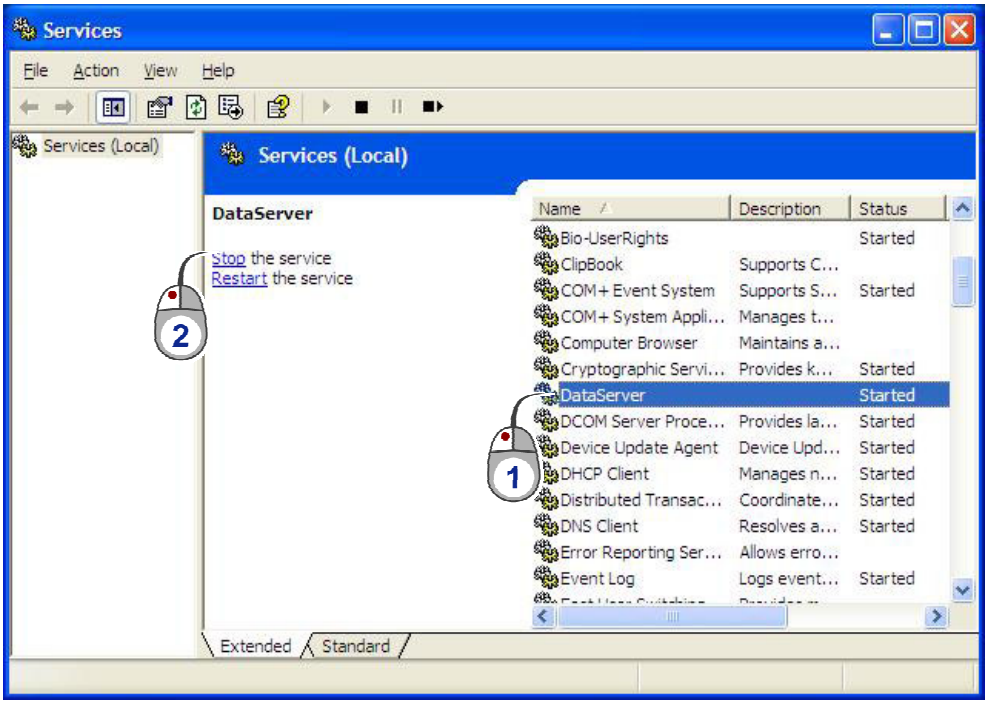


Figure 11-3 : “DataServer” selection window

- Click on the “Stop the service” link **(2)**.

The “Service Control” dialog box is displayed.

Figure 11-4 : “Service Control” dialog box

- Wait until the Service is stopped.

  The “Service Control” dialog box will close automatically.

Do not close the “Services” window.

Restarting the data server

In the “Services” window,

- Click on the “Start the service” link **(3)**.

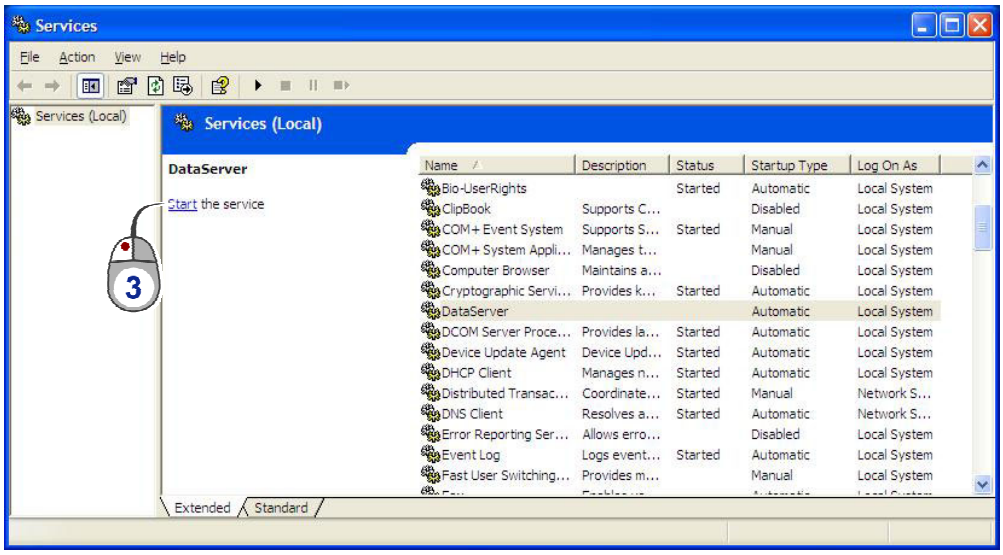
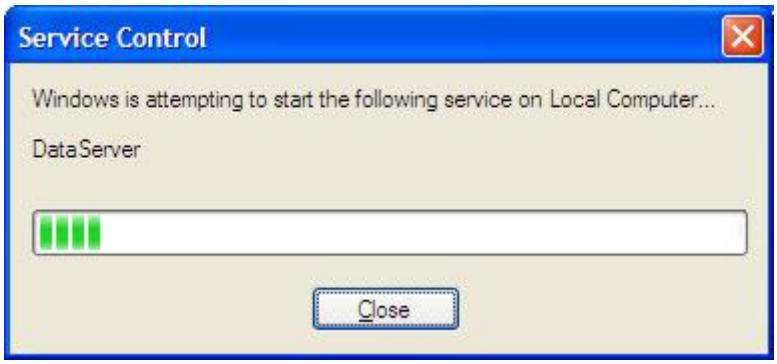


Figure 11-5 : Selecting the “Start” link

The “Service Control” dialog box is displayed.



- Wait until the data server is started.

12 Glossary

Agar Plate (PPM)	Plastic petri dish with a base containing a layer of nutrient agar, used for the growth of microbial cultures.
Applicator	A disposable plastic device for the streaking of a sample over the agar surface of a pre-inoculated agar plate.
Aspirate	The process of retrieving by pipetting prepared samples for inoculation onto agar plates.
Barcode Scanner - External	Hand-held instrument used to scan and record details of samples.
Barcode Scanner - Internal	Installed scanner used to read sample barcodes during **PREVI Isola** operation.
BCI	bioMérieux Communication Interface for communications between the **PREVI Isola** system and a LIS. Two versions of BCI are available: BCI Net, which uses an Ethernet connection, and BCI RS232, which uses an RS232 connection.
Bi-Plate	A plate divided into two halves, separated by a wall, each of them containing a different type of media (agar).
Carryover	The contamination of a sample, or agar plate, with bacteria from another source (such as a previous sample).
Cartridge	A disposable plastic cartridge holding 120 applicators.
Cartridge Holder	A holding area for the cartridges in the consumable tray of the instrument.
Cassette	A removable metal container for holding vertically stacked groups of inverted agar plates in the instrument. (Also see input cassette & output cassette).
CFU	Colony Forming Units. Any entity (usually a viable single cell) that can form a colony on an agar plate.
Clinical Specimen	A specimen collected from a patient for the purpose of diagnostic microbiology.
Colony	A clone of bacterial cells on a solid medium that is visible to the naked eye. A macroscopically visible population of cells growing on solid medium, arising from a single cell.
Colonial morphology	Refers to the form or structure of a colony.
Data Server	Software application running in the background of the **PREVI Isola** external PC and communicating with the **PREVI Isola** user interface and LIS.
Dispense	The process of dispensing (pipetting) sample preparations onto agar plates.
Full Plate	A plate containing a single agar type.
Half Plate	A plate with a divider creating two halves, containing different agar types (also referred to as a Bi-plate).

HEPA	High Efficiency Particulate Air Filter.
Incubation	The temperature and atmospheric conditions that an inoculated agar plate is exposed to to allow the growth of bacteria. Incubation is performed in atmospheric air unless otherwise noted.
Incubation Types	Incubation conditions: atmosphere and temperature at which a streaked plate must be incubated.
Inoculate	In the **PREVI Isola** context: the process of pipetting samples onto a fresh agar plate.
Inoculum	Material used to initiate a microbial culture.
Input Cassettes	Cassettes positioned in locations on the left-hand side of the **PREVI Isola** where fresh agar plates are loaded.
Instrument Covers	Safety covers installed over the consumable trays, processing stations and consumable racks.
Instrument UI	Software application running on the internal computer of the **PREVI Isola**, accessible on the touch screen on the **PREVI Isola** instrument.
Instrument Workflow	Order in which specific work is performed by the specific components in the instrument while in operation.
IT	Information Technology.
Knowledge Base	The knowledge base of the **PREVI Isola** contains the available plate cassettes configurations, specimen types, specimen details, plate types, streaking protocols, plate panels and incubation types.
Laboratory Workflow	Refers to the order in which specific work is performed in the laboratory, specifically focused on the handling of specimens and preparation of samples.
LAN	Local Area Network.
LIS	Laboratory Information System.
Navigation Button	Buttons (Icons) on the instrument user interface used to change screens or trigger instrument actions.
Output Cassettes	Cassettes positioned in some locations on the right-hand side of the **PREVI Isola** where inoculated and streaked agar plates are received and stacked.
Petri Dish	A shallow dish consisting of two round, overlapping halves, that is used to grow micro-organisms on solid culture medium; the top is larger than the bottom of the dish to prevent contamination of the culture.
Plate Barcoding Station	The internal processing station where the human and machine-readable barcode identifier is attached to the base of the plate.
Plate Cassettes Configuration	A plate cassettes configuration defines which type of plate is loaded into each input cassette and to which incubation atmosphere each output cassette is assigned.
Plate Geometry	The plate geometry contains information that tells the **PREVI Isola** how this plate should be streaked.

Plate Input Robot – (left-hand side)	Delivers fresh PPM to the plate transfer robot.
Plate Output Robot – (right-hand side)	Delivers inoculated and streaked plates to output cassettes.
Plate Panel	Set of plates to be streaked, with for each plate its type (culture media), its geometry and its incubation conditions (temperature and atmosphere). Plate panels are created by the user.
Plate Panel Assignment	Process of associating a plate panel and a streaking protocol with a sample barcode identification.
Plate Streaking Station	Internal processing station where the sample is dispensed by the pipettor for streaking.
Plate Transfer Robot	Device used to rotate and remove lids from plates, deliver plates to the process station, receive plates for lid replacement and deliver plates to the plate output robot.
Plate Type	Type of culture media on the plate. Most plates contain only one culture media, bi-plates contain two. (See “Plate geometry.)
PPM	Prepoured Media. Petri dishes that are purchased with the nutrient agar pre-poured into the dish (agar plate).
Process Station	Mechanism used to hold and rotate agar plates for inoculation and streaking.
Processing	The action of inoculation and streaking of a PPM.
Sample	Unknown volume of liquid consisting of the specimen diluted or undiluted.
Sample Identification (ID)	The identifier (normally a barcode) on the sample container that is loaded on the system for processing. The instrument will use this to look up the appropriate plate panel to use for processing this sample.
Sample Rack	Rack in which the sample tubes are placed for processing.
Sample Rack Tray	A device to hold multiple sample racks, used for transporting of Sample Racks to and from the instrument.
Sample Tube	A bar-coded container containing a sample for testing.
Specimen	Any fluid, tissue, swab or other material collected for microbiological assessment.
Specimen Details	Any refinement of the specimen type that allows the **PREVI Isola** to know which plate panel has to be used for a sample (for example “positive urine”, “negative urine”, young child’s urine’, “pregnant woman’s urine’).
Specimen Group	Group of specimen types for which a single streaking protocol can be used for each plate type. For example: urine, stool or swab.
Specimen Type	Type of specimen received from the LIS. The list of specimen types differs from one customer to another. For example: broncho-alveolar washing or urinary probe.
Stand-Alone System	Autonomous, self-sufficient system that does not require any additional feature or device to process the plates.
Streaking	Spreading of a microbial mixture over the agar surface, using an applicator.

Streaking Head	Mechanical head that retrieves and holds an applicator, streaks a sample and then ejects the applicator into the waste bin.
Streaking Protocol	Parameters that define how to streak a plate depending on the plate type and on the specimen group. These parameters are defined by bioMérieux for each combination of plate type and specimen group. The user cannot define streaking protocols.
Supervisor	Laboratory staff members responsible for defining the Plate Panels for the processing of each Specimen type or clinical situation and defining laboratory profiles.
System	Instrument, computer, software, peripherals, consumables or any additional device involved in the process of inoculating and streaking the plates.
Technologist	Laboratory staff members responsible for assessing samples and assigning Plate Panels; loading the correct agar plates (by selection of the appropriate Plate Panel from the instrument user interface); loading consumables and samples; unloading agar plates for incubation.
Throughput	Number of plates processed in a certain time (average measured in predefined condition of use).
Tip	A tip that is used by the pipettor for aspiration of sample and inoculation of sample onto the agar plate. After inoculation, the tip is discarded into the waste bin.
Tip Tray Holder	The location where the tip trays are loaded onto the **PREVI Isola**.
Touch-Screen	The Instrument Liquid Crystal Display computer screen that the user touches in order to make selections.
UPS	Uninterruptible Power Supply.
User	Any user of the instrument including the Technologist, Laboratory Manager or Supervisor.
Walk-Away	Capability of the system to process the plates without any user interaction during a certain amount of time.
Waste Station	Biohazardous waste containers for used tips and applicators. Also refers to the waste drawer below the process station used to collect barcode label backing.
Workstation	Laboratory space dedicated to a particular function in the microbiology laboratory.
Workstation Software	Software application running on the **PREVI Isola** external PC used to configure the system.

Notes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