



User's Manual



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MD-Stainer User Manual V4_EN (2020/01/17)

This manual can be used for the version 2.5.16077.8002

Consult your distributor for compatibility with other versions.

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SECCIÓN 1 INTRODUCTION

1.1 Theory and Intended Use

The MD-Stainer is designed to be used by laboratory professionals with the right training in immunohistochemistry techniques. The aim of the MD-Stainer is to facilitate the procedures used in such techniques: applications of immune-reagents (Deparaffining and antigenic recovery, antibodies, detection systems, etc.) to sections of tissue, cell cultures, liquid cytology samples or smear on slides. This system is designed to automatize the manual staining methods used routinely in Immunohistochemistry and “in situ” hybridization.

1.2 Flexible Programing

The MD-Stainer includes the possibility of creating protocols defined by techniques and also the programming of each slide individually.

The system provides intuitive programming routines, reagents, slide maps and information on screen regarding the time of start/end of each technique. The user will be able to create and save an unlimited number of protocols with the desired number of reagents and washings.

From 1 to 36 slides can be processed. With the possibility of each one having different protocols, reagents and dispensation volumes.

1.3 Economic Use

The MD-Stainer maximized the efficiency by using very low volumes of reagents and washing buffer, reducing costs. The system allows the flexibility of optimizing the volume of the reagents, up to a minimal volume of 85ul by each step of the technique.

1.4 Data Management and Report Generation

The MD-Stainer is designed to track a wide variety of data. You can generate reports by the patient; reactive information used or performed cycles.

1.5 Reagents controlled with RFID labels

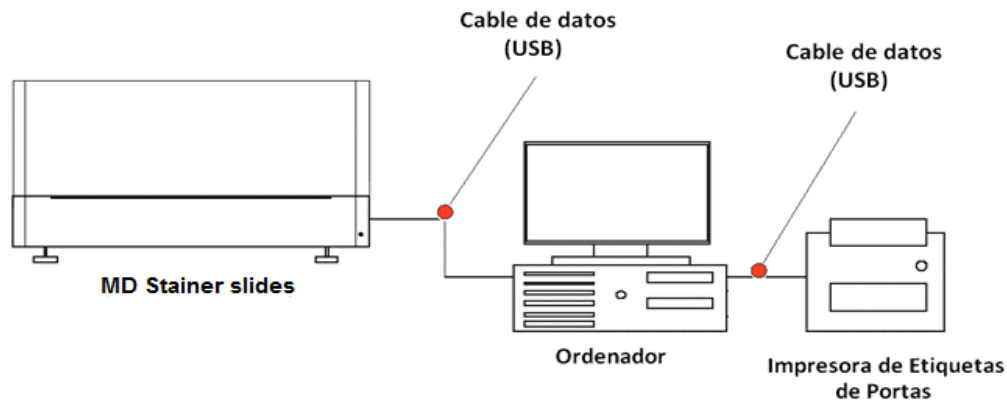
The reagents are programmed by RFID labels storing the programmable information such as the name of the reagent, lot number, number of available tests, date of expiration and supplier. The RFID scanner incorporated into the team identifies the reagent vials to automatically determine if there are enough resources to complete the selected staining protocol.

1.6 The 2D bar code labels for the slides

The software of the MD-Stainer provides an interface of simple user to generate and print labels of 2D bar codes for the preparations. The reading of the 2D bar codes is performed through a reader incorporated in the equipment identifying the labels and it automatically programes the staining cycle allowing tracking them. All labels are printed by heat and they are

resistant to chemical products, which allows the users to apply the labels in the preparations from before starting the staining procedure.

1.7 Instrument-connection Diagram:



SECCIÓN 2 SYSTEM SPECIFICATIONS

2.1 General Specifications

The MD-Stainer is a combination between Software and Hardware integrated with the appropriate reagents to perform the Immunohistochemistry techniques totally automatized. This chapter describes the hardware, Software and all the accessories provided with the system.

Work tray: holds 36 modules of slides, the reagents rack and the probe-washing stations.

Module of portal: holds 1 slide for Immunohistochemistry.

Slides, they must be used treated for use in Immunohistochemistry or hybridization techniques, whose dimensions must be of 25 mm x 75 mm x 1 mm.

Rack of Reagents: has capacity for 40 different reagents. The RFID reader scans the reagents and thus determines its position in the rack. In the immunohistochemistry techniques, the position 40 corresponds to the empty vial where the DAB will be prepared by default.

Reagents-pipette washing station, is made of black plastic, placed in the left edge of the end of the equipment, and it serves to clean the Teflon™ pipette on the inside and outside each time a new reagent is used, and in order to prime the piping corresponding to that pipette.

Hazardous waste station: is a second washing station (the one placed more to the left side) for the hazardous reagents. The hazardous reagents will be provided separately in the station of hazardous wastes and they will be collected in the hazardous waste container.

Container for the washing buffer: has capacity for 2L and it provides buffer for all the staining process.

Non-hazardous waste container: has capacity for 2L and it maintains and stores the non-hazardous reagents wastes generated during the staining process.

Hazardous wasted container: has capacity for 2L and it maintains and stores the hazardous reagents wastes generated during the staining process.

Axis X - allows the arm to move to the left and right through all the equipment.

Axis Y - allows the head of the arm containing the pipettes to move forward and backwards.

Axis Z - contains 2 independent Z axes:

- Z1 controls the pipette extracting the vial reagents and inject them inside the camera, on the porta. It also provides the circuit-washing buffer.
- Z2 controls the pipette extracting the liquid from the incubation cameras and the RFID reader.

RFID Reader: it scans the reagents vials to determine the positions of the reagents in the rack, and it updates the reagent's information of use in the RFID labels present in each vial during the staining process.

Bar-code reader: it scans the labels of the slides to assign the corresponding technique/protocol to that preparation and track it.

2.2 Technical Specifications

Dimensions:

36" W x 24" D x 21" H

(91.44 cm W x 60.96 cm D x 53.34 cm H)

Weight:

110 lb. *(49.9 kg)*

Electrical Requirements:

120V 110/120V ($\pm 10\%$) 60Hz ($\pm 2\text{Hz}$) 850 watts

220V 220/240V ($\pm 10\%$) 50Hz ($\pm 2\text{Hz}$) 850 watts

Network connector: IEC320

Standard operating temperature:

18°C – 26°C (64°F-79°F)

Slides capacity:

1 – 36 glass slides treated for immunohistochemistry.

Reagents capacity:

40 different reagents (15ml/reagent vial)

Reagent dispensing volume:

85ul – 400ul

Pipette capacity:

85ul minimum, 4500ul maximum

2.3 Computer Requirements

The supplier reserves the right to change the specifications of the computer in any moment.

Intel Core i5-2410M de 2,3 GHz CPU

4 GB of RAM

Hard drive of 500GB

4 slides USB 2.0

Computer / Monitor

Laptop or desktop computer

Operative system: Windows 7 or equivalent

Printer: Zebra TLP 3844-Z or Zebra GX430t

Operation logic

It is designed to calculate the most efficient sequence over time in order to complete a programmed staining cycle.

Protocol logic

Flexible selection of steps. Unlimited number of steps per protocol (including washing steps).

Accessories included in the MD-Stainer:

- 2 reagents rack each one with maximum capacity for 40 vials of reagents.
- Buffer containing with capacity for 2L.
- Waste container with capacity for 2L.
- Printers of 2D bar-codes labels, through heat transfer.
- Labels Size 19,05 mm (0.75in) x 25,4 mm (1 inch).
- Ribbon for printer ink.
- Cables to connect the printer.
- USB cable to connect the instrument and the computer.
- Supply cable for the instrument and the computer.
- Pre-configured computer for its use with the instrument.
- Mouse
- User Manual

SECCIÓN 3 INSTALLATION REQUIREMENTS AND INSTRUCTIONS

3.1 Requirements

Location, place the system in an area in which it is easy to operate and to connect the instrument.

Before unpacking MD-Stainer, make sure the working area for the instrument is a solid and levelled surface able to stand its weight. +- 110 pounds (49,9 kg) of the instrument plus the computer.

The size and the minimal dimensions for the working area are of 60 inches (152, 4 cm) wide x 24 inches (60.96 cm) deep x 21 inches (53, 34 cm) high.

The working area must be at a room temperature between 18 ° C-26 ° C (64 ° F-79 ° F). The area must be well ventilated, with a maximum relative humidity of the 80% for temperatures up to 31 ° C; the contamination degree II or less.

Noise, the equipment will produce less than 85 decibels in the maximum functioning.

The power supply, the MD-Stainer and its computer need an electronic delivery of 120V / 15A 240 with ground connection (3 terminals) to be connected. The supplier recommends a power supply dedicated for the MD-Stainer to avoid interferences of other instruments or equipments. Also, a UPS (1500 VA minimum) is also recommended if there are voltage peaks.

3.2 Instructions

The equipment installation must be done by an Authorized Technical Service according to the instructions included in the Service Manual of the equipment. For this, contact with the authorized distributor in your country:

Exclusive Distributor in Spain: VITRO SA

Vía de los Poblados 17 Floor 5ª, Nave 13

Building Indubuilding 28033 Madrid

www.vitro.bio

T: +34 91 382 16 20

F: +34 954 92 28 92

Technical Support: hotline@vitro.bio

Orders for consumables or other necessary materials: pedidos@vitro.bio

SECCIÓN 4 Instructions for use

The **slides** can be directly placed on the instrument for its immediate processing; although the deparaffining/adherence of the tissue can be carried out inside the equipment, it is recommended to do it in a heater at **60°C for 1 hour**. The equipment will have a standard collection of protocols optimized by the supplier. Alternatively, some protocols with specific instructions can be provided by the equipment's supplier.

4.1 Turn on and start the equipment:

Turn on and start the computer. Check all the necessary requirements before using it.

The **preparations** are loaded (one on each module) and, subsequently, processed with the instructions for the required staining protocols.

The slides are mounted typically with the tissues embedded in paraffin (FFPE) fixed in buffered formalin, therefore, **it is recommended to adhere/deparaffin in heat for at least 1 hour at 60°C** prior its introduction in the instrument. The MD-Stainer also allows this previous adhesion/deparaffining step inside the instrument.


The **reagents** are supplied by the provider in a "ready to use" format, and it is the user the one who needs to place them in the reagents rack before starting each staining cycle.

The **jar of the washing buffer** needs to be filled with an adequate volume of buffer to complete the staining cycle. The user needs to make sure before starting each cycle that they have an adequate volume to complete it.

The **waste containers** must be empty, or have enough capacity to receive the reagent wastes produced during the cycle.

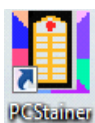
The **safety lock** prevents the user from opening the door of the instrument while this is functioning.


Firstly, we need to turn on the MD-Stainer. For this, we have 2 buttons:

- Electric power button (right rear part of the equipment)
-  Power button (rear front part)

Then we turn on the label printer and, finally, the computer

Note: *it is always recommended to turn on **first the equipment and logo and, then, the computer.***



Once we are on the Windows, double click on  to start.

Once we have double-clicked in the previous button, the following screen will appear:

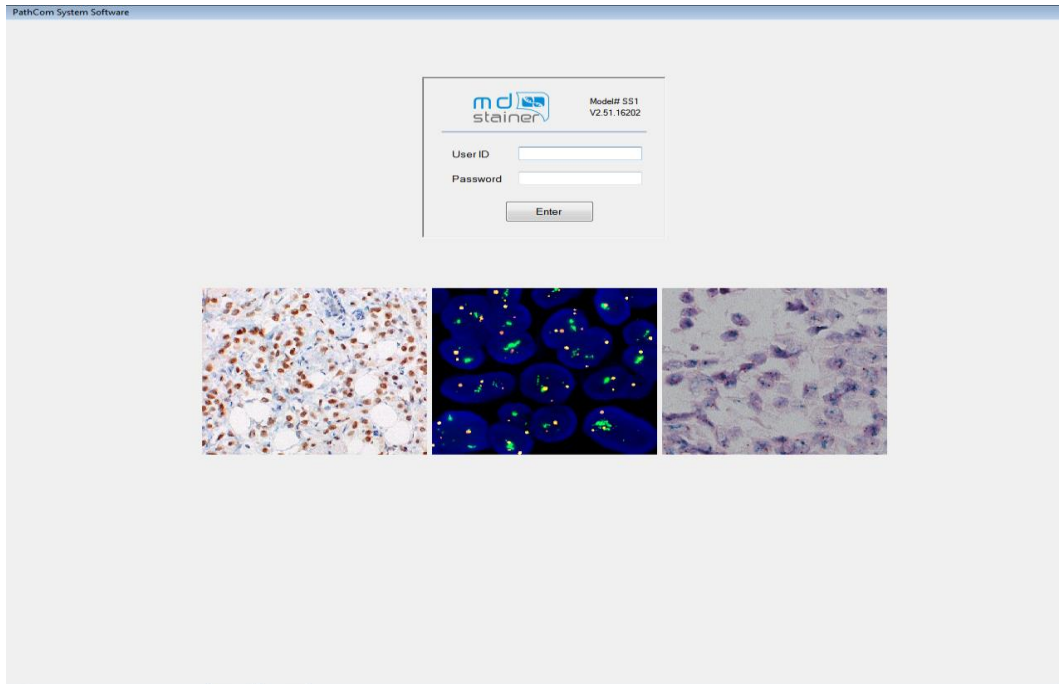


Image 1

We must write our username and password here (*These data are provided by the equipment supplier*).

Once we click on “**Enter**”, the equipment is initialized automatically.

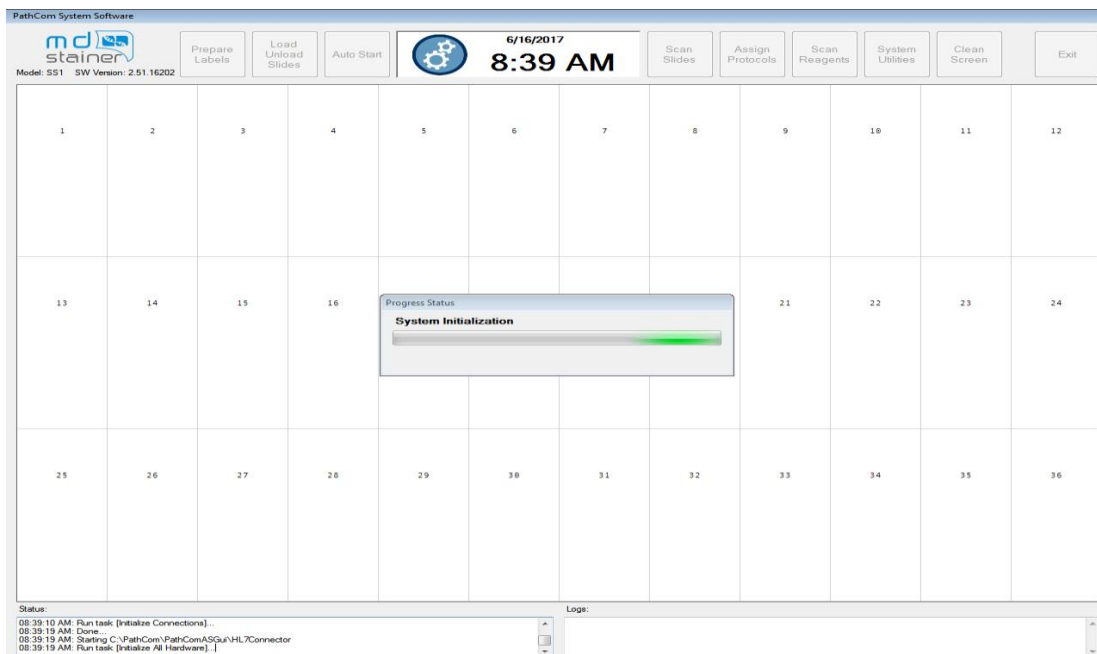


Image 2

Note: During the initialization, the equipment must upload the incubation modules as well as prime both circuits (*dispension and suction*).

Once inside the equipment software, we can easily access all the essential functions from the main screen. The **slides map** corresponding to the 36 available positions is showed in the screen, corresponding each number (from 1 to 36) to the position inside the equipment. To perform the routine execution, click on:

Prepare labels to create or print labels for the preparations. Each label is printed with a 2D bar code needed to identify the preparation.

Load / Download the preparations to upload or download the incubation modules.

Automatic start to automatically initiate a cycle after preparing the labels and loading the preparations and reagents.

Scan slides to scan the bar codes for each porta.

Assign protocols to manually assign a protocol to a preparation.

Scan Reagents to scan the RFID labels in the reagents vials.

System to access additional functions and utilities of the system.

Clean screen to delete the preparations map.

Exit to close the application.

4.2 Prepare and print labels

In order to create labels, the first step is to double-click on **“Prepare Labels”** to open the labels editor.

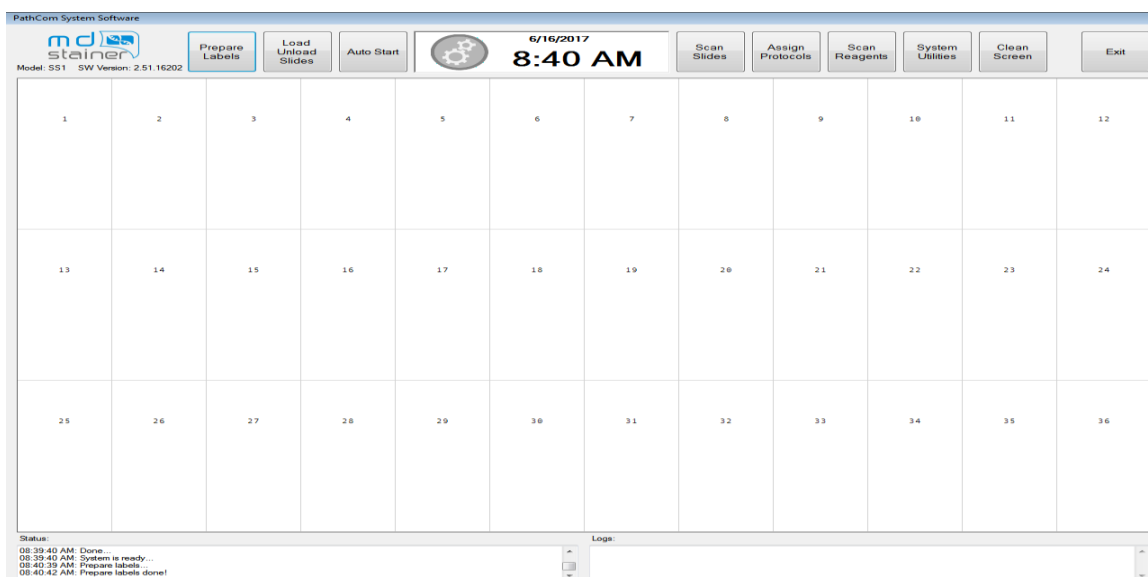


Image 3

In the **Slide Labels Editor**, we have different options:

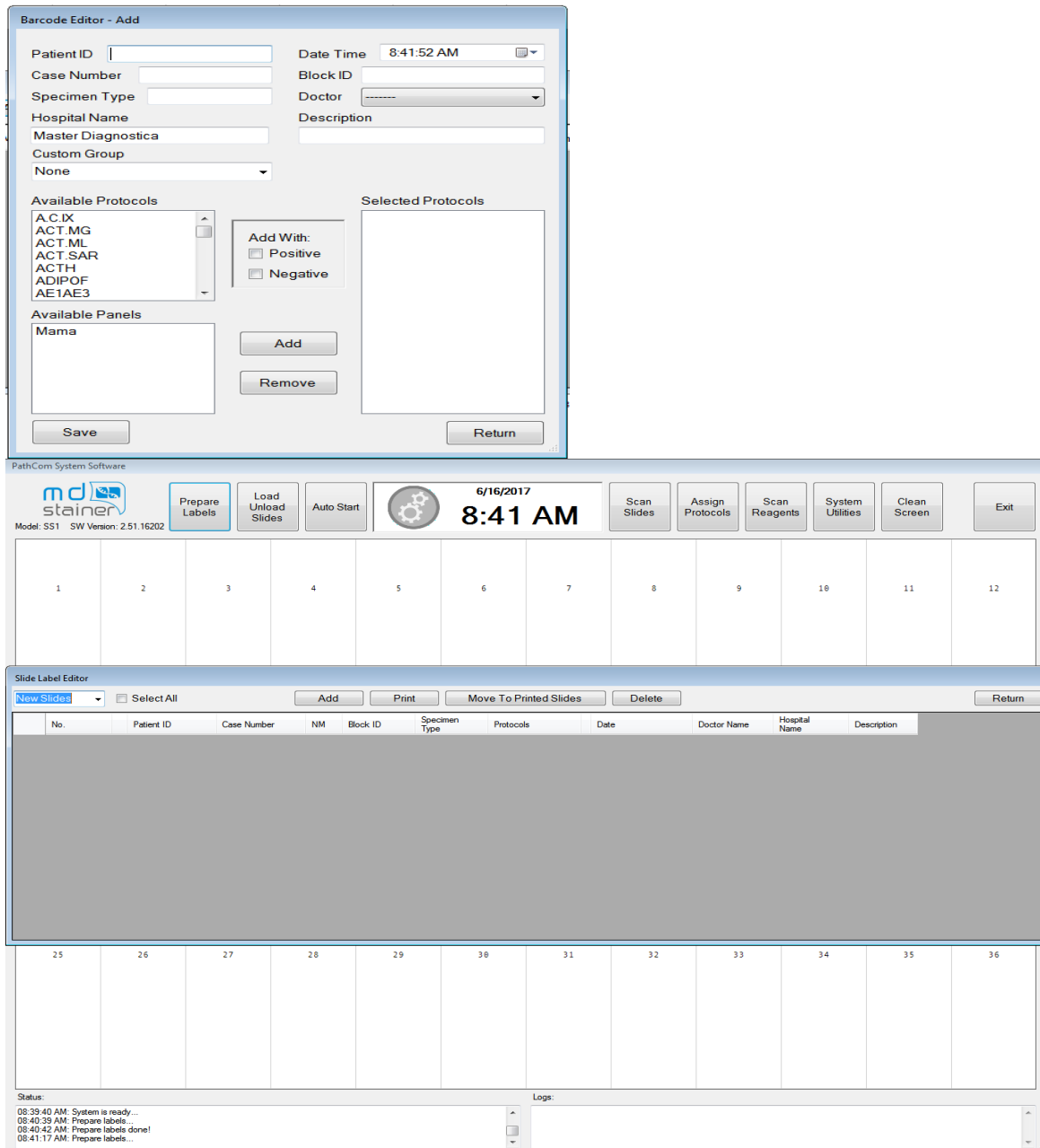


Image 4

Add to create a new case.

Print to print the techniques already created.

Move to printed slides to send the labels already printed in another platform (VTS or VitroPath) and sent to the equipment for the section of printed labels.

Delete to delete any label created.

Back to go back to the main screen.

Note: *If the client has any of the management software of Vitro SA (VTS or Vitropath), the requests can be made from there and send them to the equipment or print them in these platforms, send them to the equipment and use them as such.*

Add new labels in the bar-codes editor

In order to add new labels in the porta label editor, click on **"Add"** to open the Bar-code editor.

Insert the patient's identification, case number and other required information in the label through the designed fields.

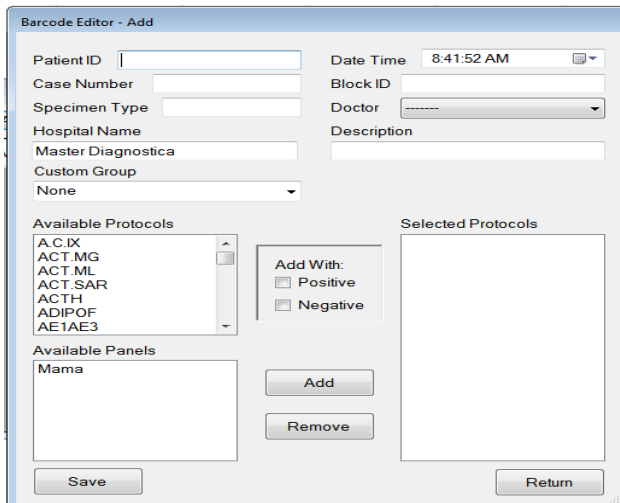


Image 5

(Optional) Select the date and time of the label.

(Optional) Select the name of the doctor from the pull-down list. To add new names to the list, check the section 5.5.2 Bar code format for more information.

Note: *The patient's identification, date, case number, hospital name and description are printed in the label by default. In order to change this configuration, check the section 5.5.2 Bar code format for more information.*

Then, add techniques from the protocol list:

To add techniques from the available Techniques list, select the available technique from the list and click **"Add"**.

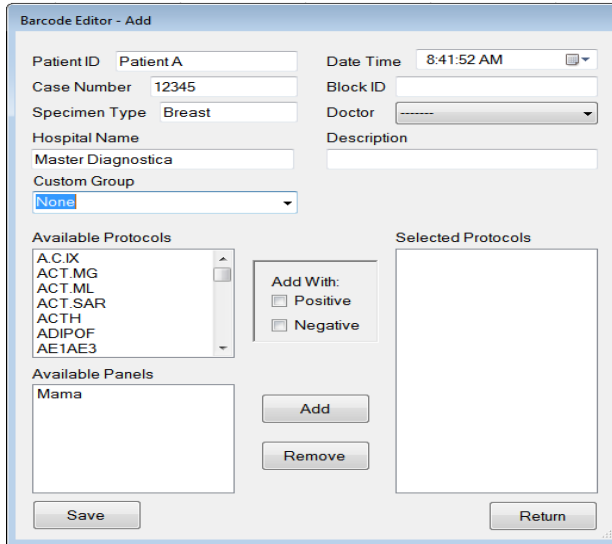


Image 6

Alternatively, the user can select a personalized list of available techniques through the **selection of a personalized group** in the pull-down menu of the personalized group.

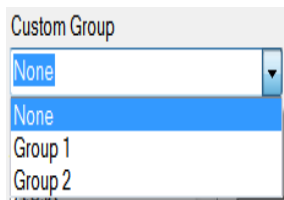
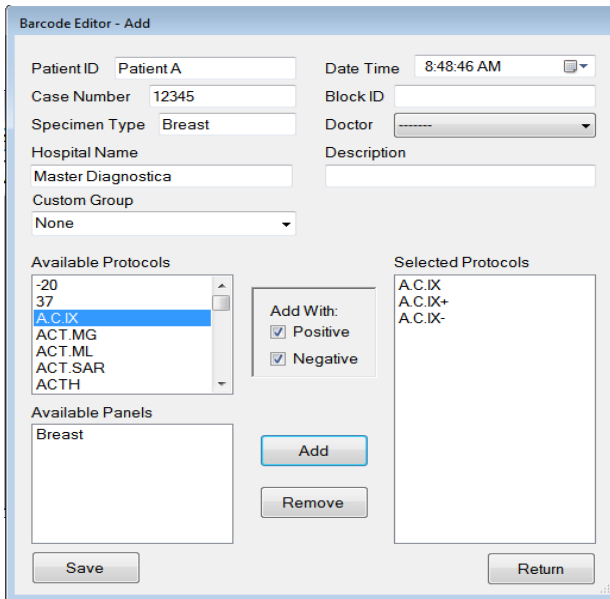


Image 7

Check the section 5.3.8 Personalized Groups Editor for more information on how to create personalized groups

To add a positive and/or negative control to the selected techniques, select the technique and select in the check box "Add" with: positive and/or negative, and click on "Add". A positive and/or negative control will be added to the selected techniques.

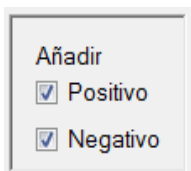


The image shows a software window titled "Barcode Editor - Add". It contains several input fields and lists:

- Patient ID:** Patient A
- Date Time:** 8:48:46 AM
- Case Number:** 12345
- Block ID:** (empty)
- Specimen Type:** Breast
- Doctor:** (empty)
- Hospital Name:** Master Diagnostica
- Description:** (empty)
- Custom Group:** None
- Available Protocols:** A list with items: -20, 37, A.C.IX (highlighted), ACT.MG, ACT.ML, ACT.SAR, ACT.H
- Selected Protocols:** A.C.IX, A.C.IX+, A.C.IX-
- Add With:** Positive, Negative
- Available Panels:** Breast
- Buttons:** Add, Remove, Save, Return

Image 8

Check the section 5.3.5 Assigning Negative Controls for more information on the assignation of negative controls to the techniques.



The image shows a small dialog box titled "Añadir" (Add) with two checked options:

- Positivo
- Negativo

Image 9

To add a complete panel of techniques to the sample or case selected, we mark the personalized panel in the list of available panels and click on "Add". All the protocols assigned to the panel will be added to the panel (included the positive and negative controls if they correspond).

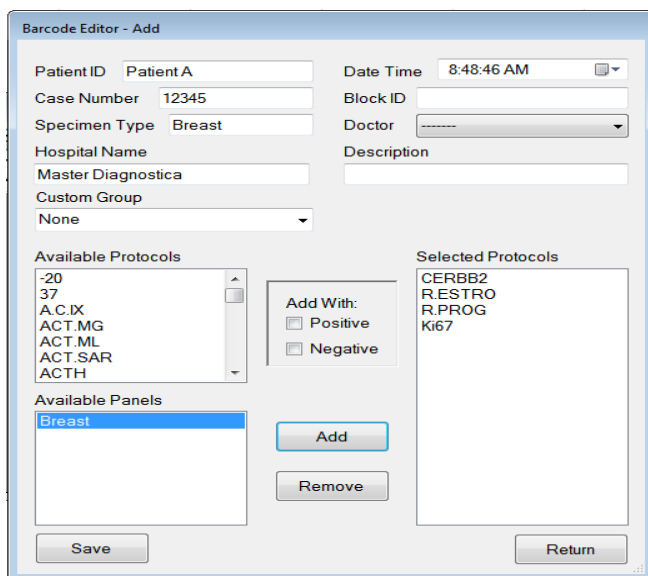


Image 10

Note: The user must create, first, a personalized panel for it to be available on the bar-codes editor. Check the section 0 To take the **protocol(s)** out from a personalized group, select the protocol(s) counted in the selected Protocols, click in "**Remove Protocol**" and click in "**Save**".

To delete a personalized group, select the group name from the drop-down list and click in "**Delete This Custom Group**".

Editor of Panels *for more information on how to create personalized panels.*

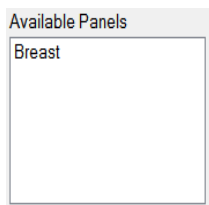


Image 11

To delete the techniques from the list of Selected Techniques, select the technique(s) of the list and click on "Remove".

Then, click on "Save" to save the information regarding that/those label(s) and to be able to generate new labels for new cases. After saving, the editor is ready to create the following set of labels by default. The patient's information will be kept in the entry fields for the following set of labels.

Click on "Return" to close the bar-code editor and go back to the label editor screen. All the selected protocols will be added as new labels in the porta labels editor.

Print labels in this label editor

The label editor will show a line for each label, included the patient's identification, case number, protocol, date and additional information related to the label. **Each label will have a validity of 30 days after the date assigned in the label.**

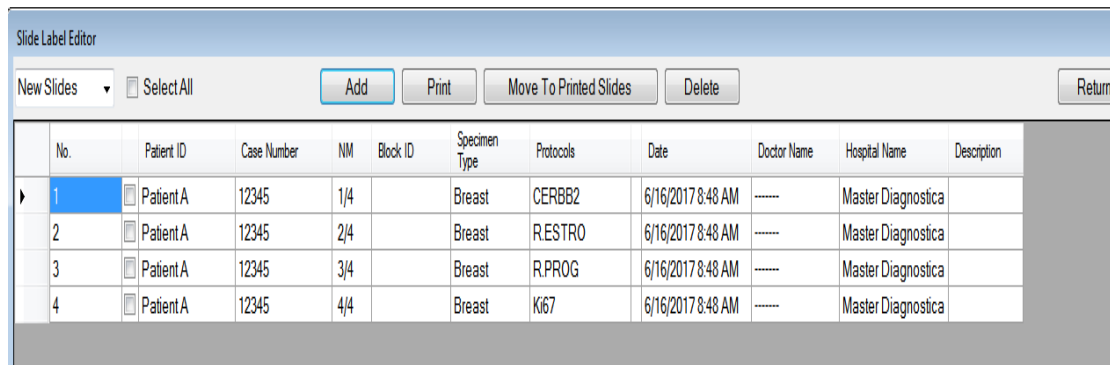


Image 12

In order to print labels, from this labels editor, select the label(s) using the verification box and click on **"Print"**. The user can click on **"All"** to select all the labels. Check the section 5.5.2 Bar code format for more information on how to adjust the printer settings and label format.

In order to delete a label from this labels editor, select the verification box and click on **"Delete"**.

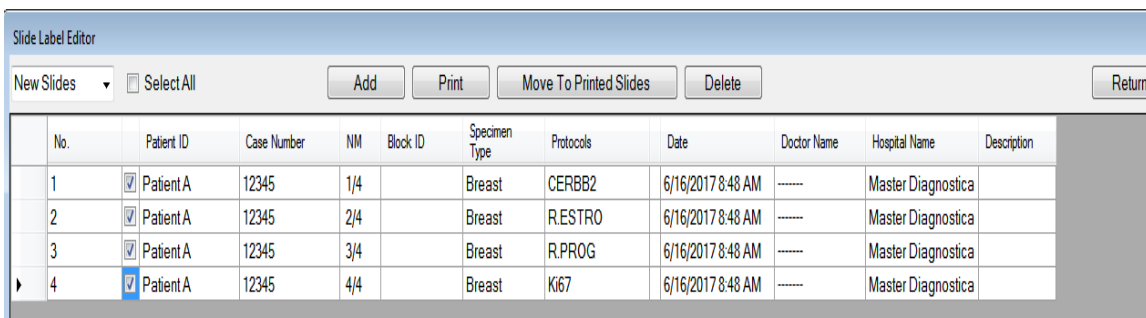


Image 13

Once printed, take the labels printed of the roll and stick them to the slides.

Labels managed in software of Vitro SA.

If the user has any of the laboratory management software of Vitro SA (VTS or VitroPath), they can proceed in two ways:

- **Send the required techniques from the application to the equipment MD-Stainer.** These will appear (with all the complemented data) in **"Porta Labels Editor"** in the section **"News"**, there, the user can print them and start using them.
- **Print the labels of the required techniques in the application**, and then, send them to the equipment MD-Stainer through communication and internal messaging systems, they will appear in the same section as in the previous option, but in this case, as these were already printed in another platform, the user will only need to select them in the corresponding box and **click in "Move to Printed Slides"**, from then, they can start using it.
- In both options, once the request has been made in the application, the technique will appear as in process and once processed in the equipment MD-Stainer, a finalized date will be automatically assigned to it.

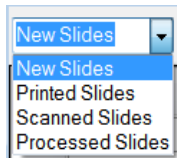


Image 14

After the printing, the labels will move into printed labels. They are accessible from the pull-down menu of the left upper corner of this label editor.

- Select **Printed Slides** to review or print a label again.
- Select **New Slides** to create or see new labels.
- Select **Scanned Slides** to review the labels that have already been scanned.
- Select **Processed Slides** to review the labels that have already been processed.

4.3 Load Slides

From the main screen, click on "**Load/Download Slides**" to raise all the modules' lids.

Carefully insert the slides. Center the slides and push them against the rear springs so that they are fixed between the springs and the two white clips placed in the front part of the module.

Click on "**Load/Download slides**" to download all the modules' lids.

Check the SECCIÓN 7 Staining Area to get more information on the localization recommendations of tissue in the slides.

4.4 Protocols: Slides Scanning and Manual Assignment of Protocols

To scan the previously printed labels, click on "Scan Slides" in the main screen. The system will automatically search in all the 36 positions. To avoid the automatic scanning of all the positions, you can select with the mouse the positions where the slides are placed and the system will only scan these selected.

Once scanned, the software will assign the technique coded in the label in the position corresponding to that porta.

PathCom System Software

md stainer Modelo: SS1 SW Version: 2.51.1620

11/7/2016 1:08 PM

Preparar Etiquetas Cargar / Descargar Portas Inicio Automático Escanear Portas Asignar Protocolos Escanear Reactivos Sistema Limpiar pantalla Salir

1	2	3	4	5	6	7	8	9	10	11	12
13	14	15	16	17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32	33	34 Bc16	35 Bc16	36 Bc16

Estado

13:05:44 PM: Prepare labels...
 13:07:42 PM: Prepare labels done!
 13:07:45 PM: Assign Protocols...
 13:07:50 PM: System is ready...

Registros

Image 15

To manually assign the protocols, click and pull down in the map of slides to select the position(s). The position(s) selected will stand out and will be visualized as "????????":

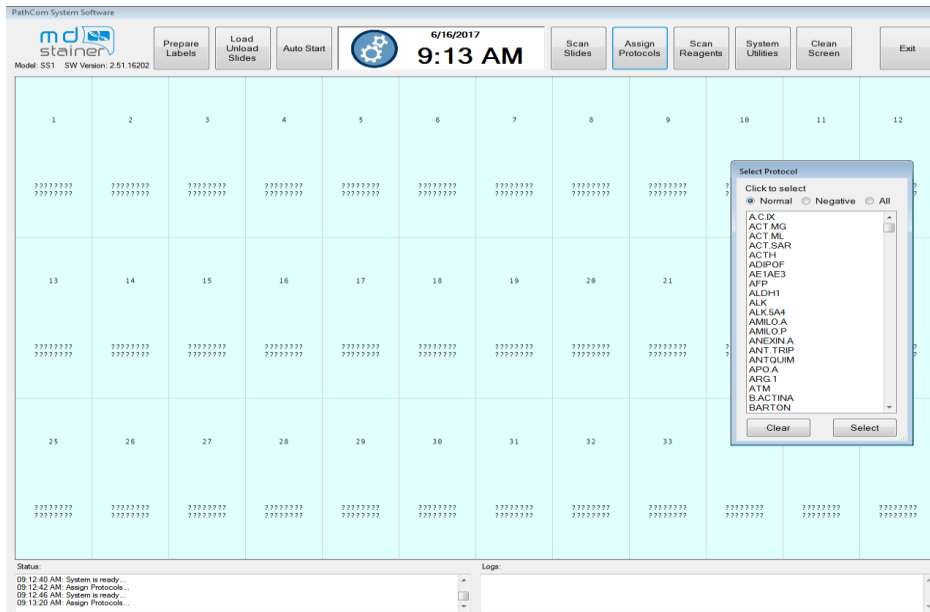


Image 16

Click in "Assign Protocols" to open the screen and select the technique/ protocol. Move around the protocol list and click on "Select" to select the desired technique. Click "Clear" to cancel the selection or close the windows.

- Select "Normal" to access the normal protocol list.
- Select "Negative" to access the negative control list.
- Select "All" to access the list of all protocols (normal and negative controls).

The selected protocol is assigned to all the selected slides/positions.

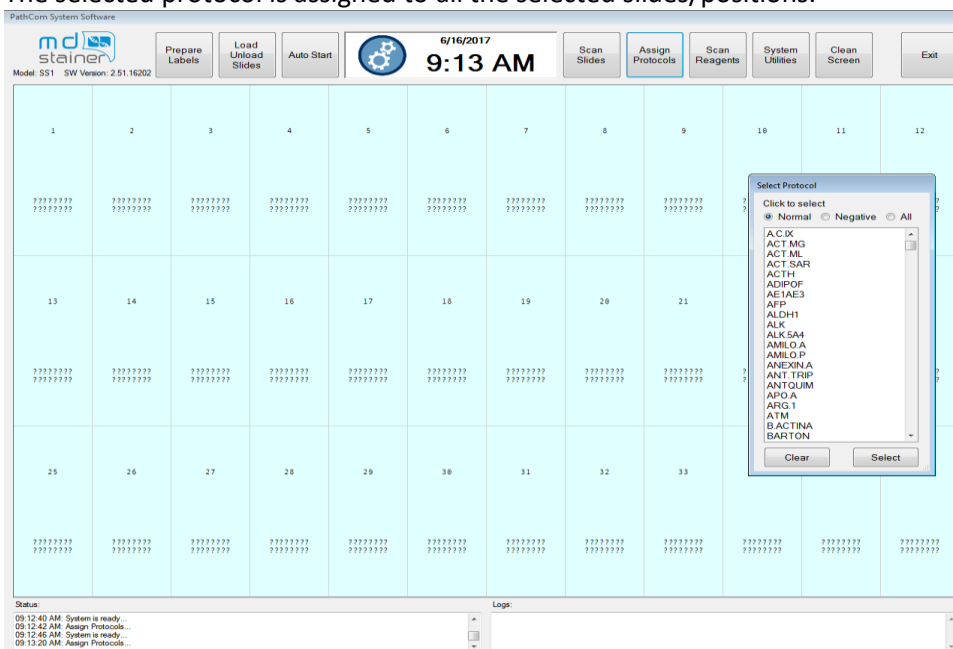


Image 17

To delete all the assigned protocols, select the desired positions dragging them with the mouse and then click again and drag once more to delete the assignment.

To delete all the slides map, click on "Clean Screen".

4.5 Reagents Load

Prepare the reagents following the instructions provided by the supplier. The requirements for the general use are detailed in the data sheet of each kit or reagent.

Place the reagents' vials in the reagents' rack, place the rack in the position designed in the system.

Make sure the rack is placed in the right orientation and it is placed flatly on the metallic plaque.



Image 18

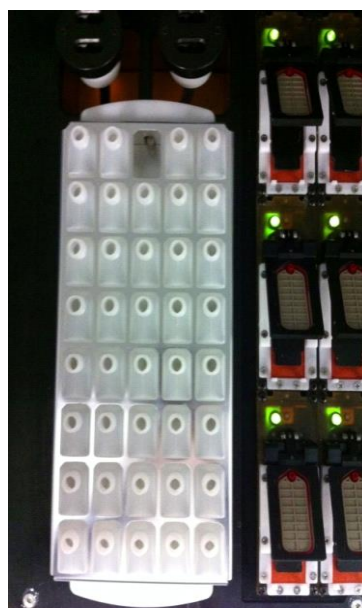


Image 19

Remove all the caps of the reagent vials, and check that all the reagent vials are completely inserted in its position


Note: *Only the reagent vials provided by the supplier are compatible with the system.*

4.6 Washing buffer and replacement of cleaning wastes

Fill in the washing buffer container and empty the waste containers as needed.

Verify the liquid level of each container before starting the cycle.

The washing buffer container has a maximum capacity of 2000 ml.

1. Unscrew the container's cap from the washing buffer.
2. Fill in with buffer prepared as per the supplier's specifications, place it back in the cap and screw it to fix it.  **Warning, do not overtighten the lid too much so that it doesn't vacuum when aspirating and it prevents the right aspiration.**

The waste container has a maximum capacity of 2000 ml.

1. Loosen the cap and empty the waste container. Delete the wastes according to the local regulation.

4.7 Reagents verification: Reagents scanning

  **Withdraw all the reagent vials' caps before scanning.**

From the main screen, click on **“Scan Reagents”** to open the Reagent Check screen. The reagents map appears on the left and all the necessary reagents for the performance of the technique(s) appear on the right.

Reagent Name	Reagent Position	Number of Tests Required	Volume Required (L) x10B%	Number of Tests Scanned	Expiration (YYYYMM)	Remarks
D55	0	36	8928	0	0	
D55	0	36	19440	0	0	
TR1, High pH	0	36	19440	0	0	
Peroxidase Blocking	0	36	5040	0	0	
A.C.D.X	0	36	5040	0	0	
Polymer Enhancer	0	36	5040	0	0	
HRP 2-Step Polymer	0	36	5040	0	0	
DAB	40	36	5040	36	201706	On Rack, Missing
DAB Substrate	0	39	2730	0	0	Reagent A for mixing DAB
DAB Chromogen	0	39	2730	0	0	Reagent B for mixing DAB
DAB Enhancer	0	36	2520	0	0	
Hematoxylin	0	36	5040	0	0	

Table Legend: Not Used Insufficient Volume Reagent Missing Reagent Expired Assigned Reagent Reagent OK

Reagent File Name:

Please check the volume in the buffer and waste bottle:
 Maximum 2094.17 ml of buffer is needed.
 Maximum 2169.79 ml of waste can be disposed.

Image 20

To scan all the reagents with the RFID reader, click in "Scan Reagents", and the scanning of all reagents displayed in the reagents rack starts immediately to read all the information of the RFID label. The system will continue the exploration until all the necessary reagents have been detected in any of the 40 available positions.

If all the reagents needed to complete the staining cycle are scanned in the first positions of the rack, the system will finish the scanning one the last reagent needed has been detected and it goes back to the "Home" position.

Note: in the Immunohistochemistry techniques requiring DAB, the empty vial where this reagent's mix will be made is in the position number 40 of the reagents rack by default.

Reagent Name	Reagent Position	Number of Tests Required	Volume Required (µl) x105%	Number of Tests Scanned	Expiration (YYYYMM)	Remarks
D55	1	36	8928	50	201803	MASTER DIAGNOSTICA, MAD-004079R5
D56	9, 8, 7	36	19440	39	201712	MASTER DIAGNOSTICA,
TR1, High pH	6	36	19440	0	201803	MASTER DIAGNOSTICA, MAD-004079R7
Peroxidase Blocking	10	36	5040	19	201805	MASTER DIAGNOSTICA, MAD-0215400-100
HRP	16	36	5040	8	201612	MASTER DIAGNOSTICA,
Polymer Enhancer	20	36	5040	83	201802	MASTER DIAGNOSTICA,
HRP 2-Step Polymer	19	36	5040	83	201802	MASTER DIAGNOSTICA,
DAB	40	36	5040	36	201706	On Risk Menu
DAB Substrate	24	39	2730	18	201806	MASTER DIAGNOSTICA, MAD-00181305-100
DAB Chromogen	25	39	2730	18	201806	MASTER DIAGNOSTICA, MAD-0018130C-100
DAB Enhancer	0	36	2520	0	0	
Hematoxylin	0	36	5040	0	0	

Image 21

The scanned reagents appear in the reagents' map to the left. Each vial of scanned reagent showed in its corresponding position in the reagents' rack (position from 1-40), with the name of the reagent, and the currently number of tests, expiration date and identification of the RFID labels. The identification of the RFID label is a single number of identification programmed on each vial. It can be used to track the reagents' vials individually used in different cycles.

After completing the scanning, the system will show the current status of the reagents:

- Expired reagents are highlighted in red.
- All the missing reagents are highlighted in pink.
- All the reagents with inadequate volume are highlighted in yellow.
- All the reagents ready for the staining process are highlighted in light green.
- All the unused reagents will be in white.

The user can then replace all the expired / inadequate reagents and make another scanning, or manually assign a position for each missing reagent.

Note: The user can add additional jars when the reagent volume of a vial is inadequate. Up to 5 vials of the same reagent can be placed simultaneously in the rack. The reagent vial with the lowest number of sample is used selectively in first place.

In order to manually assign a reagent missing in the reagents' map, select the missing reagent in the table to the right, then the line is highlighted in blue. Click in a position in the reagents' map to assign the respective reagent. In this case, the exact number of samples required for this reagent in position of the reagents' rack will be reflected in the reagents' map.

Note: The expired reagents cannot be assigned manually and must be replaced and re-scanned.

Reagent Check

Reagent Name	Reagent Position	Number of Tests Required	Volume Required (μl)x100%	Number of Tests Scanned	Expiration (YYYYMM)	Remarks
DS5	1	36	8928	50	201803	MASTER DIAGNOSTICA, MAD-004079R5
DS6	9, 8, 7	36	19440	39	201712	MASTER DIAGNOSTICA,
TR1, high pH	6	36	19440	0	201803	MASTER DIAGNOSTICA, MAD-004075RT
Peroxidase Blocking	10	36	5040	19	201805	MASTER DIAGNOSTICA, MAD-021540Q-100
HCG	15	36	5040	5	201612	MASTER DIAGNOSTICA,
Polymer Enhancer	20	36	5040	83	201802	MASTER DIAGNOSTICA,
HRP 2-Step Polymer	19	36	5040	83	201802	MASTER DIAGNOSTICA,
DAB	40	36	5040	36	201706	On Rack Mixing
DAB Substrate	24	39	2730	18	201806	MASTER DIAGNOSTICA, MAD-001813QS-100
DAB Chromogen	25	39	2730	18	201806	MASTER DIAGNOSTICA, MAD-001813QC-100
DAB Enhancer	34	36	2520	36	201706	N/A, Manually Assigned
Hematolina	33	36	5040	36	201706	N/A, Manually Assigned

Table Legend: Not Used Insufficient Volume Reagent Missing Reagent Expired Assigned Reagent Reagent OK

Reagent File Name:

Please check the volume in the buffer and waste bottle:
 Maximum 2094.17 ml of buffer is needed.
 Maximum 2169.79 ml of waste can be disposed.

Image 22

All the reagents added manually are highlighted in dark green.

Make sure that the reagent manually assigned is placed physically in its corresponding position in the reagents' rack before proceeding and that it has an adequate volume/nº of test to execute the predefined techniques.

Do not manually assign the reagents programmed with RFID because the system will use the reagent, but will not shut the number of tests used down, which will lead to an imbalance between the reagent volume and the number of tests programmed which could compromise the results of the technique(s) performed a posteriori.

Reagent Check

Reagent Name	Reagent Position	Number of Tests Required	Volume Required (μl)x100%	Number of Tests Scanned	Expiration (YYYYMM)	Remarks
DS5	1	36	8928	50	201803	MASTER DIAGNOSTICA, MAD-004079R5
DS6	9, 8, 7	36	19440	39	201712	MASTER DIAGNOSTICA,
TR1, High pH	6	36	19440	0	201803	MASTER DIAGNOSTICA, MAD-004075RT
Peroxidase Blocking	10	36	5040	19	201805	MASTER DIAGNOSTICA, MAD-021540Q-100
HCG	15	36	5040	5	201612	MASTER DIAGNOSTICA,
Polymer Enhancer	20	36	5040	83	201802	MASTER DIAGNOSTICA,
HRP 2-Step Polymer	19	36	5040	83	201802	MASTER DIAGNOSTICA,
DAB	40	36	5040	36	201706	On Rack Mixing
DAB Substrate	24	39	2730	18	201806	MASTER DIAGNOSTICA, MAD-001813QS-100
DAB Chromogen	25	39	2730	18	201806	MASTER DIAGNOSTICA, MAD-001813QC-100
DAB Enhancers	34	36	2520	36	201708	N/A, Manually Assigned
Hematolins	33	36	5040	36	201706	N/A, Manually Assigned

Table Legend: Not Used Insufficient Volume Reagent Missing Reagent Expired Assigned Reagent Reagent OK

Reagent File Name: ReagentTagData.xml Load Reagent Map File Print Required Reagents

Please check the volume in the buffer and waste bottle:
 Maximum 2094.17 ml of buffer is needed.
 Maximum 2169.79 ml of waste can be disposed.

Scan Reagents Start Staining Process Delay Start Staining Process Return to Main Screen

Image 23

Once all the reagents have been assigned, the user must check both boxes (below) to proceed, confirming that there is enough buffer volume and enough space in the waste container to complete the staining process.

Note: once both boxes (below) have been selected the process will be able to continue.

Please check the volume in the buffer and waste bottle:

Maximum 133.34 ml of buffer is needed.

Maximum 137.55 ml of waste can be disposed.

Image 24

To obtain more information on the reading and writing of the RFID labels, check the section 5.3.7 Preparation of reagents with RFID labels with the RFID editor.

In order to review the reagents map previously executed click in "Open Reagents Map File" and select the file (by date) of the list of records of the reagents' map.

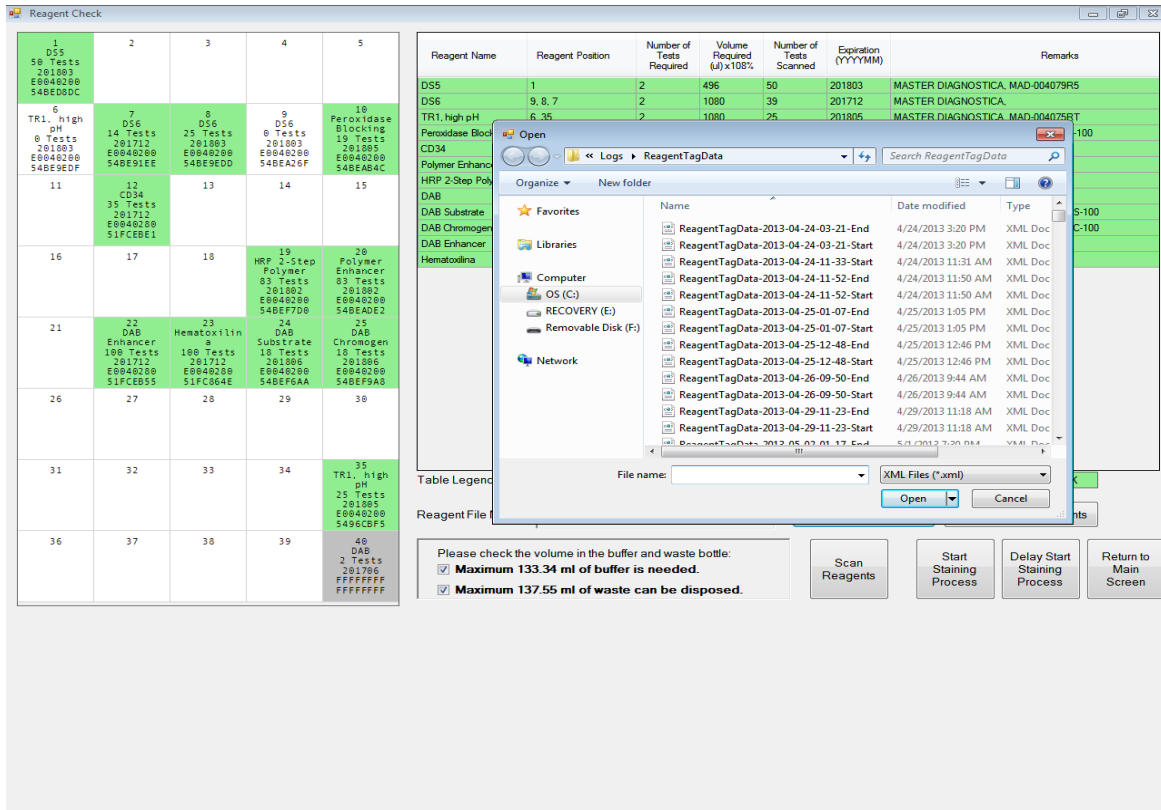


Image 25

Each record is saved with the date and time of the execution. Open the record and it is showed to the left of the reagents' map.

4.8 Start Staining Process

4.8.1 Immediate Start

In order to immediately start the staining process, close the door and click in **"Start Staining Process"** in the Check Reagents screen.

⚠ Check all the lids have been withdrawn from the reagents' vials before starting the staining process.

⚠ Close the door before starting the process. The door will be locked and will lock the access to the instrument whilst working. The staining cycle will not start until the door is open.

The system will initialize and will close the door. Then, the system calculates the most effective scheme to complete the cycle. Once the calculations have been completed, the staining process will initiate and a timer will appear in the upper part of the screen, in which you can see the countdown of the process time left until the end of the cycle.

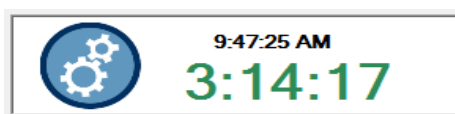


Image 26

Note: The duration will vary depending on the type of protocol(s) used and on the complexity of the execution (number of samples and types of protocols selected). A maximum number of 36 protocols can be selected, corresponding to each one of the 36 positions. The selection of different protocols of a different type will lead to a longer execution time.

4.8.2 Delayed Start

To start the staining process in a delayed way, which is, with a later date or time, click in "Delay Start" in the "Check Reagents" screen:

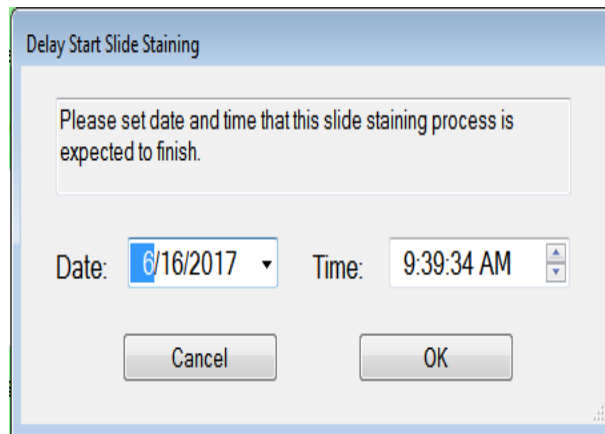


Image 27

Enter the date and time you wish the staining cycle to finish.

The system will calculate the time of delay and will start a countdown. When the time to the left (or time to start) reaches 0:00:00, the system will automatically start the staining process.

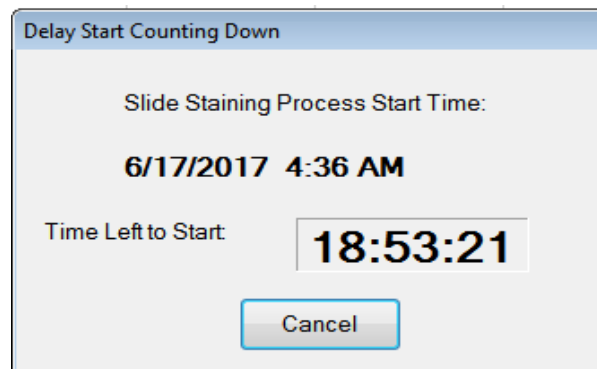


Image 28

Advice: For over-night cycles, use a delayed start to avoid the tissues to be dried once the cycle has finished.

4.9 Automatic Start

Alternatively, the user can also **start the staining process from the main screen.**

The **instrument will automatically search** for all the slides to assign protocols and will scan the reagents' vials to make the reagent verification.

To use the automatic start, close the door and click in "Automatic Start" in the main screen.

All the preparations must be labelled and loaded in the instrument.

All the required reagents must be labelled loaded in the reagent's rack placed in the instrument.

The user will be asked to insert the expected number of samples/slides that will scan.

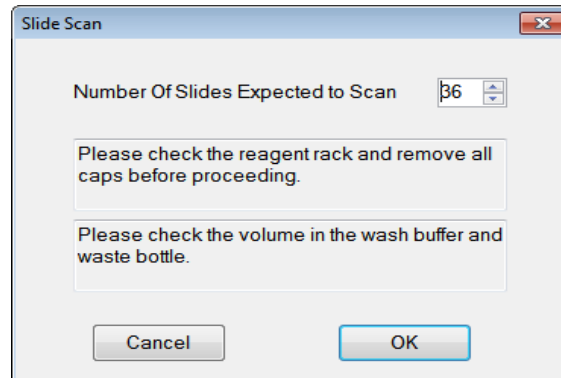




Image 29

After finishing the scanning of the slides, the system will automatically verify the real number of cases scanned with the expected number of slides.

After completing the scanning of the reagents, the system will initiate automatically the staining process. If the system does not detect enough reagents, the user can chose to start a new scanning or go back to the main screen / cancel.

4.10 Finalization of a cycle

 Do not try to enter / exit Windows or change user, while the instrument is functioning. This will cause a serious error in the system and will cause the system to lock.

 Do not try to execute other applications in a second level when the instrument is functioning, which means: updates of Windows, Internet Explorer, Antivirus, etc., or itself can lead to an unexpected accident of the system.


 Other applications such as **Automatic Autostainer Server, Robot and Slide Processor Terminals** will also be open and working while the instrument is executing the staining cycle. Do not try to close these applications while the instrument is functioning because it can lead to an unexpected accident of the system.



Image 30

While the instrument is working, **the user can follow up the staining progress in the main screen.** The slides map show all the 36 preparations, in each one the protocol, the time and


the current step are registered. An additional record is shown in the right lower corner of the screen.

If the system **finds an error** during the normal functioning, it will try to recover it. Then, the system continues with the following step and registers the error. Any position(s) in which the error was generated will be marked in **yellow** and it will be marked in the protocol step in which the first error was produced.

The system will automatically check the heaters during the course of the staining process. If a heater does not heat up at the reference temperature during the time range assigned, the corresponding position in the slides map will be marked in yellow and will show a warning message due to **"Low Temperature"** or a warning due to **"High Temperature"**.



Image 31

 After finding a temperature warning, it is recommended that the user checks the heater to verify its functioning. Check the section 5.1.10 Check if there is any bad functioning of a heater for more information.

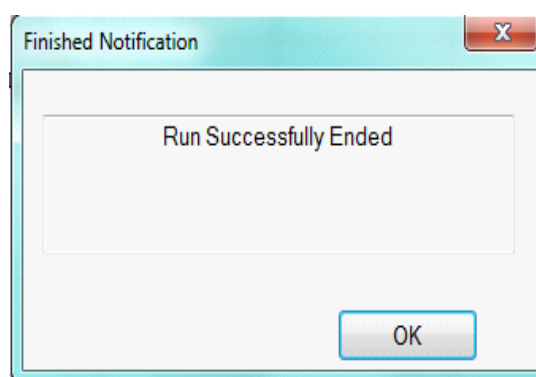


Image 32

The system will put the slides that have been successfully completed in a light green colour and will mark them as **"Finished"**. After completing the last step of the process, the system will open the door and send a notification for the user: **"Run successfully finished"**.

If an error or warning has been found during the functioning, the system will send a notification for the user: "Run Ended with warnings".

The user can review the slides map and/or the reported data to identify the preparations that may have been affected by the error. Check the section 5.1.7 Generate Reports for more information.



Image 33

⚠ Do not close or turn off the MD-Stainer user's interface applications before the final notification message is sent. The instrument can still be functioning. The incubation cameras are filled in with washing buffer after the last step to prevent the preparations from drying before they are withdrawn from the equipment.

Once the staining process is finished and the notification of finished cycle appears click in "OK" to close the screen to go back to the main screen.

From the main screen, click in "Load/Unload slides" to raise all the modules' lids. Open the door and withdraw all the preparations of the modules.

Clean any residual buffer that is left in the surface of the modules and the camera with absorbent paper and towels with alcohol. Check the SECCIÓN 8 Preventive Cleaning and Maintenance debajo de for more information.

4.11 Turn off the MD-Stainer

Advice: Do not turn off the equipment without cleaning the surfaces of the modules with a cloth / absorbent paper and the cameras with a cloth with alcohol to eliminate any waste / disposal that may adhere to the incubation camera while the equipment is off.

From the main screen, double click in "Exit" to close the program. Then click in "Yes" to confirm.

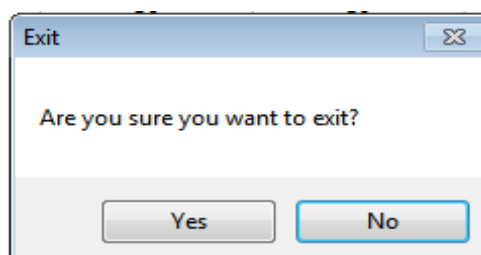


Image 34

This process can take a few minutes, as the system waits for all the modules' lids to go to the extraction position and for all the applications to be closed. Wait for the application to be completely closed; the main screen must be closed and go back to the Log-in screen. **Press and keep pressed** the On button in the right lower part of the MD-Stainer until it turns off.

Once back in the **Log-in screen** “click” on **ALT+F4 to close** it and go back to the main screen of Windows.

⚠ Do not leave the modules completely open or closed during a prolonged period of time (for instance, long weekends, public holidays, etc.). The modules must rest in the extraction position when the equipment is inactive.

4.12 Continuous Load

The user can load additional preparations in the system during the execution of a staining process.

This allows the user to load more slides after a group of preparations have finished or after receiving an additional order to process more preparations.

Note: *The use of this function can increase significantly the total functioning time of the equipment to process all the preparations.*

Stop the current process

In order to initiate the continuous load function, click in "**Load New Slides**". The system will continue processing the existing slides and will stop the process once it has arrived at a safe point in the staining protocol. This will minimize the risk of compromising the results of the staining of the active preparations.

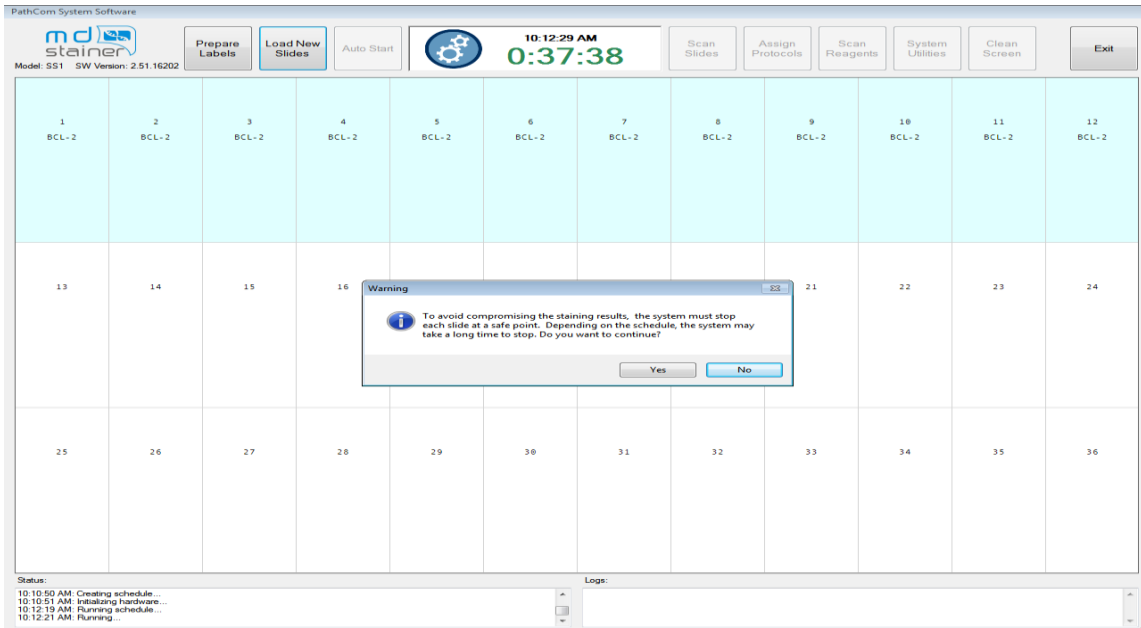


Image 35

⚠ The system won't stop until all the preparations are on a safe step (example: a washing), therefore, the waiting time can vary depending on the combination and on the type of preparations active in the current execution.

Once the system has stopped the progress of all the preparations, the door will open and a pop-up message will warn the user "Run Successfully Stopped".

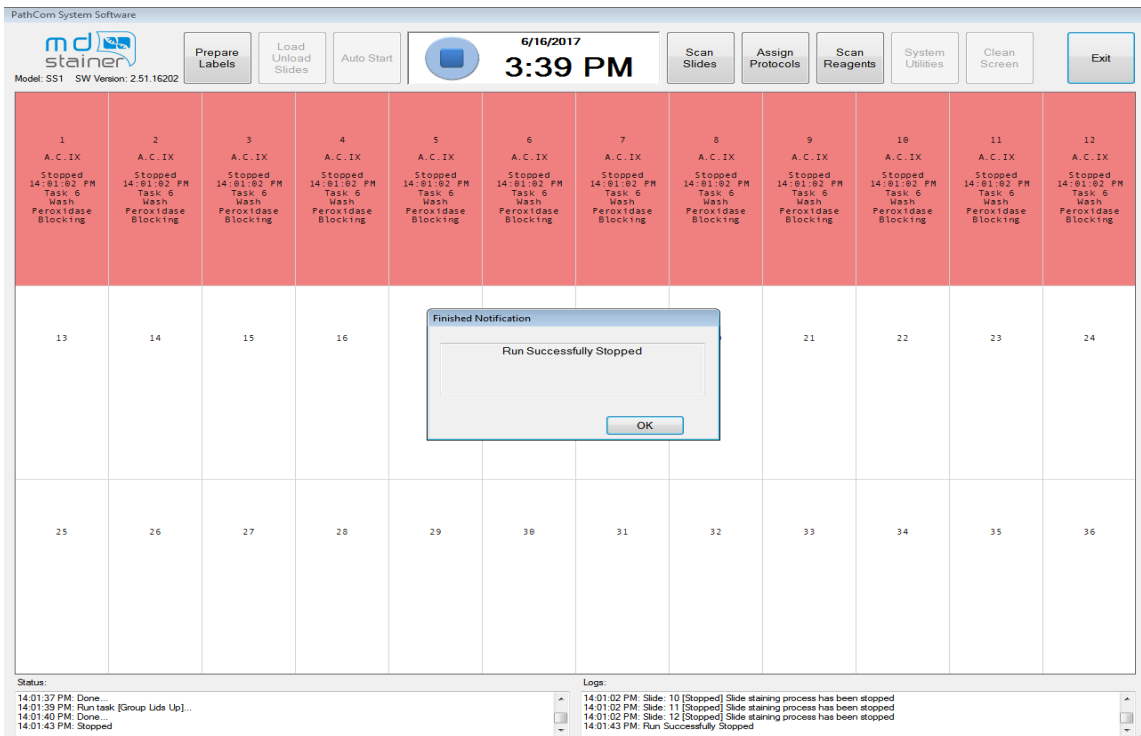



Image 36

Unload the finished slides

After stopping the process, the system will automatically lift the lids from all the available positions, included the empty positions and the positions marked as "Finished".

If the equipment is stopped once the staining process of all slides is finished, the user can remove them and load them again.

For the preparations that have been stopped (without the process being finished), they will be marked in red colour and marked with the message "Stopped". These preparations will be kept in the respective washing solution (buffer or other) with the incubation chamber closed so that they are not dried and they cannot be downloaded or extracted from the instrument. 

Prepare labels

Prepare labels for the new preparations. This function is available once the process has been finished correctly.

Scan the slides

The system scans the new slides to automatically assign the protocols, or can they can be manually assigned in the available positions. The slides marked as "Stopped" are blocked and in this position a new protocol cannot be assigned.

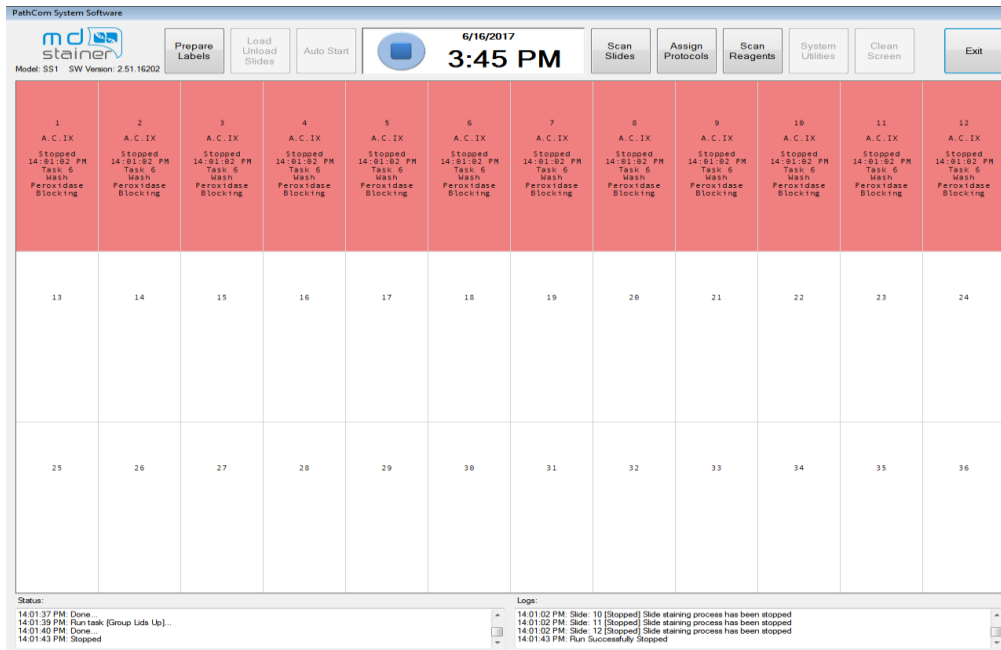


Image 37

Scanning of reagents

Load all the additional reagents that can be required by the new preparations and scan again the reagents' rack. The screen of reagent verification will be updated with the new required reagents.

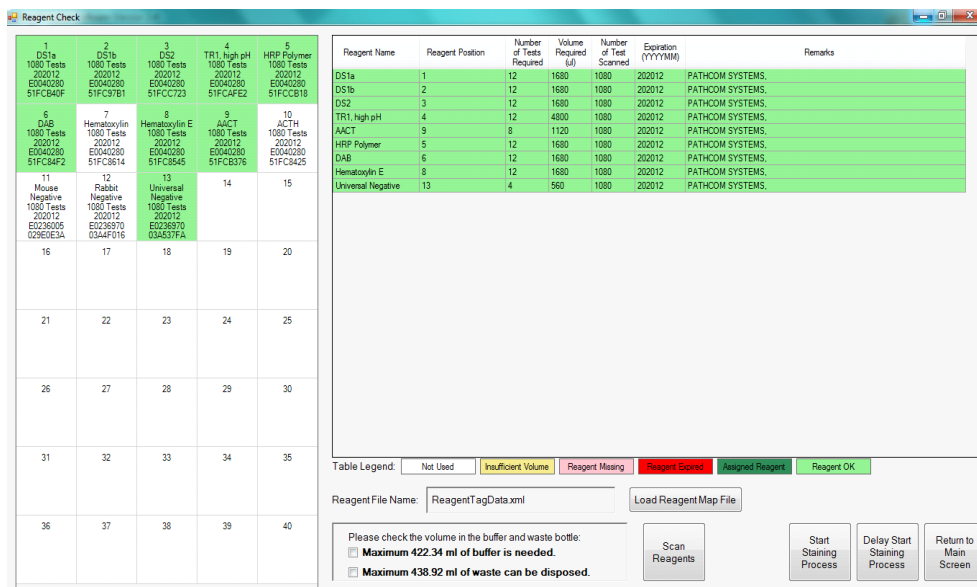


Image 38

Start the staining process

Start again the staining process. The system will organize again all the steps in order to incorporate the new preparations. The new preparations will have priority, and will be executed separately until they arrive at the step in which the already existing preparations have been stopped. The preparations that were stopped will be restarted when the new ones arrive at the same step or at the corresponding one. From there, the other common steps will be gathered between the new preparations and the already existing ones.

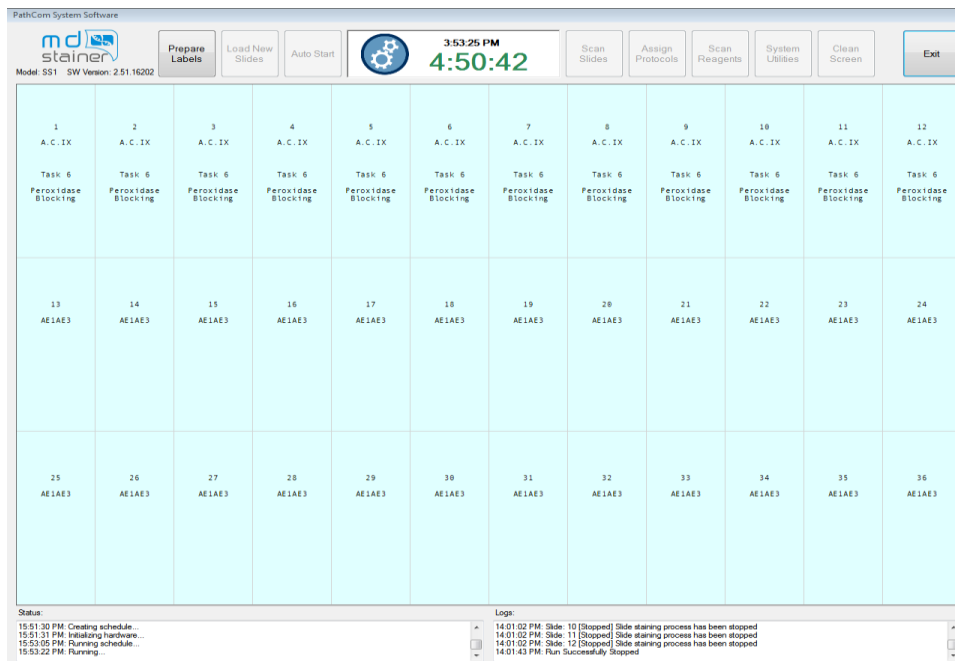


Image 39

The continuous load can share steps of the process. However, the total execution time will increase with each addition load of preparations.

SECCIÓN 5 System Utilities

From the main screen, click in "System" to access additional functions and the advanced characteristics of the system.

Note: *The users at a technical level will have limited access to these characteristics. Check the section 5.4.2 Administration of users for more information.*

5.1 Tools

Perform manual operations with the system using the functions that are found under the tab "Tools".

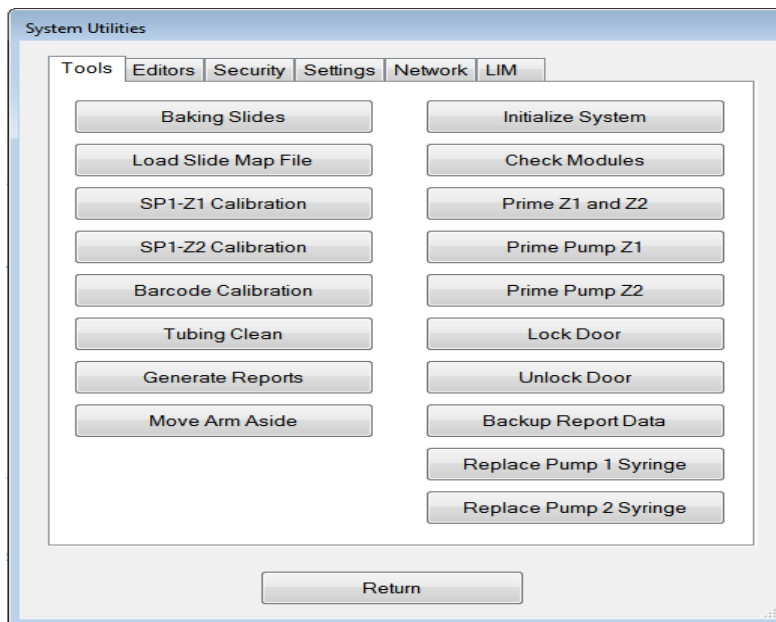


Image 40

Perform basic operations:

1. Heat up slides
2. Load SlidesMaps
3. Calibrate SP1-Z1
4. Calibrate SP1-Z2
5. Calibrate Bar code
6. Tubes Cleaning
7. It generates reports ratio
8. Move arm
9. Start System
10. Check Modules
11. Prime Z1 and Z2
12. Prime Pump Z1
13. Prime Pump Z2
14. Close door (only Supervisor)
15. Unlock door (only Supervisor)
16. Make Back-up copy
17. Change Pipette 1
18. Change Pipette 2

Note: *The user can need to click "Start System" to start the system before using any other tool.*

5.1.1 Prepare the slides using the heater system

Click in **"Baking Slides"** to select the preparations or heat. Mark the boxed to select a complete file or select the preparations individually as per the module's position.

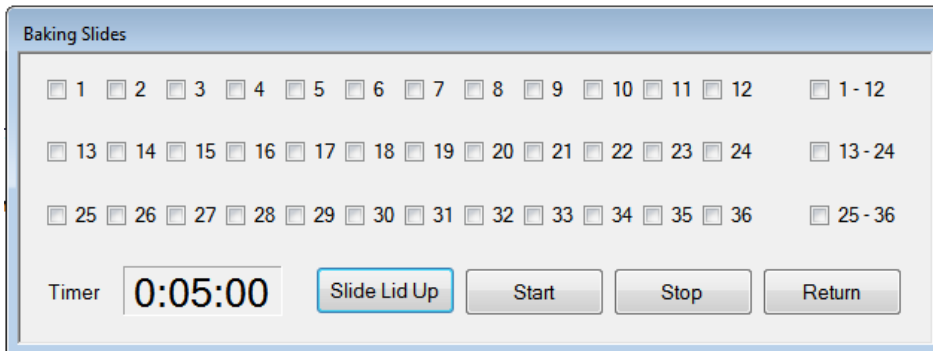


Image 41

Click in **"Start"** to start heating. The timer to the left will start the countdown and will automatically close the heaters once the timer reaches 0:00:00. Check the section 5.5.1 Setting of the slides' heater for more information.

Lick in **"Stop"** to manually stop the process.

5.1.2 Load Slides Map

Click in **"Load Slides Map"** to select a slides map previously saved to lead and see it in the main screen. The file of slides map for each execution is automatically saved by the system.

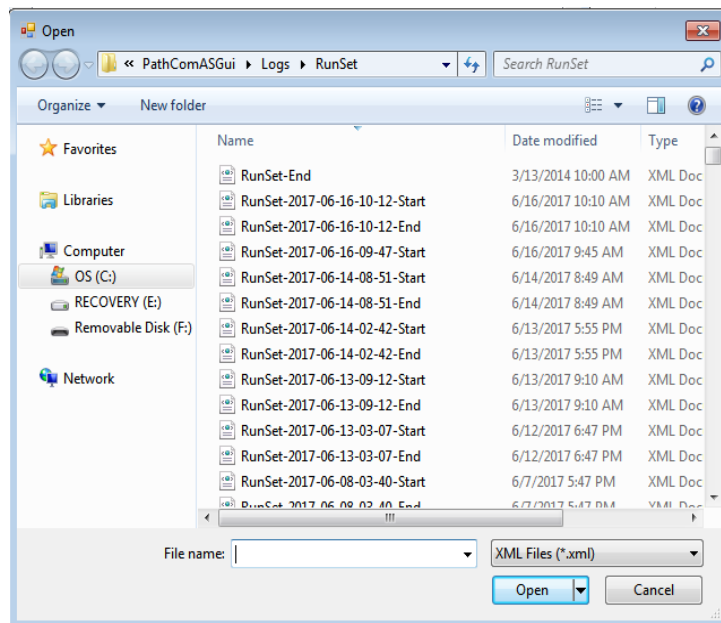


Image 42

5.1.3 Verify the calibration of the SP1-Z1

Click on **"SP1-Z1 Calibration"** to move the probe Z1 to the slot 1 and verify the position XY-Z of SP1-Z1.

5.1.4 Verify the calibration of the SP1-Z2

Click on "SP1-Z2 Calibration" to move the probe Z2 to the slot 1 and verify the position XY-Z of SP1-Z2.

5.1.5 Verify the reader calibration of the bar code

Click on "Bar Code Calibration" to move the bar-code reader to the slot 1 and verify the position XY of the bar code-SP1.

5.1.6 Clean Z1 / Z2

Click on "Tubing Clean" to open the function of tubes cleaning. Fill in two vials of 15 ml with the appropriate cleaning solution.

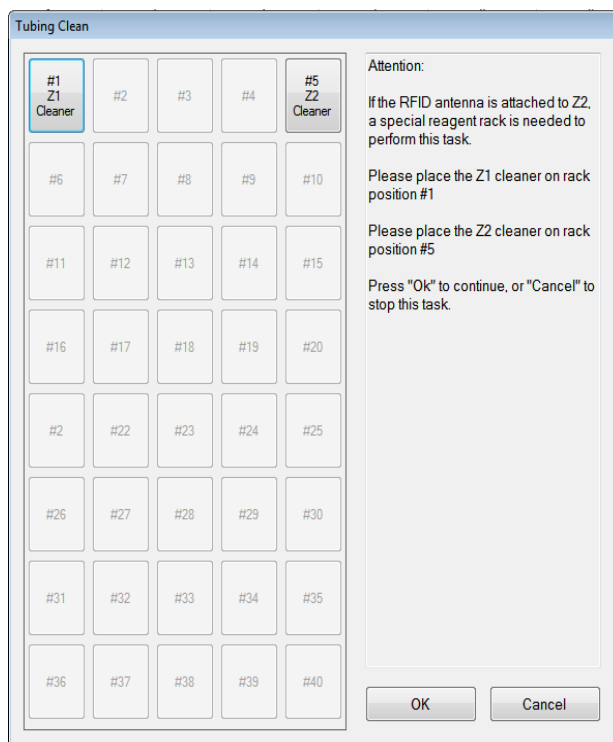


Image 43

Place the cleaning solution Z1 in the position # 1 reagents' rack as indicated in the map to the left.

Place the cleaning solution Z2 in the position # 5 reagents' rack as indicated in the map to the left.

Click in "OK" to start the tubes cleaning.

Recommendations: Use the solutions recommended by the provider to make the cleaning cycle. Check the SECCIÓN 8 - Preventive Cleaning and Maintenance for more information.

The probes Z1 and Z2, both aspire 5 ml of cleaning solution for each one of the vials placed in their respective positions of the reagents' rack. Then, the system will start a countdown of **20 minutes**.

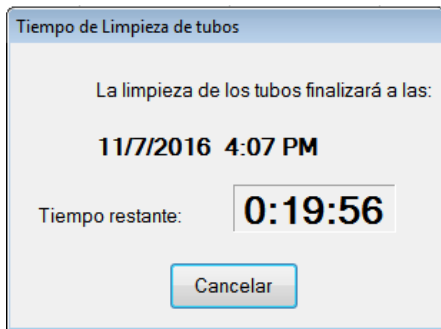


Image 44

Once 20 minutes have passed, **the system will automatically make an initialization** of the system and will purge the wastes of the cleaning solutions. Click in "Cancel" in any moment to immediately purge the pipe wastes.

5.1.7 Generate Reports

Click in "Reports Generation" to open the utility of the report generator.

5.1.7.1 By bar code of the slides

To follow up the slides proceed by bard code 2D, select the option Slide Barcode and click on "Start".

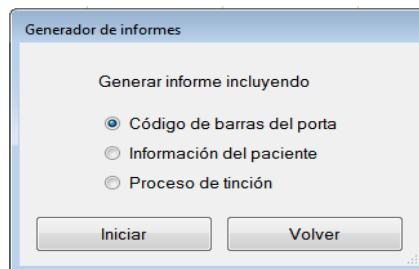


Image 45

When requested, place the slides you want to track in the selected position 1-36 in the instrument. The 2D bar code reader will scan the label and look for the information of the slides in the data records.

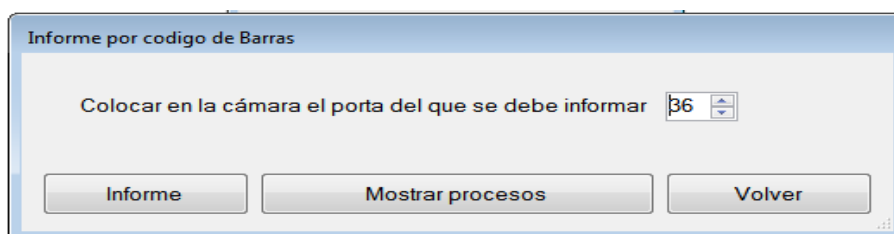


Image 46

A. Click in "Report" to generate the report for the scanned preparation.

B. Click on "Show All Runs for This Slide" to generate an Execution List of all the actions included in the scanned slide.

Note: the execution list can associate 2 or more cycles with a determined porta if their execution process was interrupted by any continuous load. Each time the instrument is stopped to load more preparations, the system generates a new execution calendar and starts a new staining process.

C. Click in "Return" to go back to the previous screen aiming at exploring a new porta or select a different option.

From the execution list, the user can choose from:

Choose a cycle by clicking on the empty box on the left column (the row will be highlighted in blue). Click on "Show All Slides in Selected Run" to generate a list of all the slides of the selected cycle.

ii. Click in "Reagent Usage Report" to generate a summary of the total use of reagents for all the staining cycles appearing in the execution list.

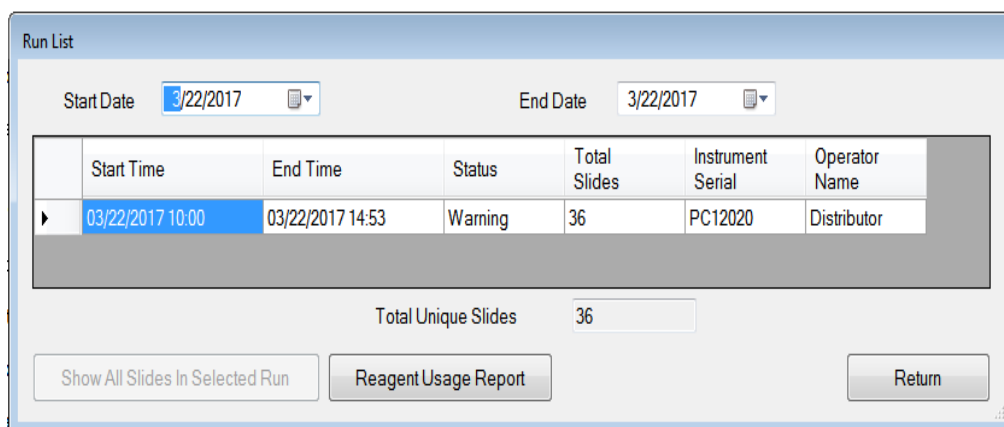


Image 47

In the Slides List, the user can opt for:

i. Select other porta in the same test clicking in the empty box in the left column (the row will be highlighted in blue). Click in "Report of Slide" to generate the porta report selected.

ii. Click in "Reagent Usage in Run Report" to generate the report for the use of reagents in the previous period.

Slide List

	Start Time	End Time	Protocol Name	Slide Position	Detection	Status	Control	Manual	LIS Slide
▶	03/22/2017 10:01	03/22/2017 14:53	VIMENT	1	2016-04-15 co...	[Module Maifu...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:01	03/22/2017 14:53	VIMENT	2	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:01	03/22/2017 14:53	VIMENT	3	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:01	03/22/2017 14:53	VIMENT	4	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	5	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	6	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	7	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	8	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	9	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	10	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	11	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:02	03/22/2017 14:53	VIMENT	12	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:03	03/22/2017 14:53	VIMENT	13	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:03	03/22/2017 14:53	VIMENT	14	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:03	03/22/2017 14:53	VIMENT	15	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:03	03/22/2017 14:53	VIMENT	16	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>
	03/22/2017 10:03	03/22/2017 14:53	VIMENT	17	2016-04-15 co...	[5. Insufficient ...	1	<input type="checkbox"/>	<input type="checkbox"/>

Slide Report Reagent Usage in Run Report Return

Image 48

5.1.7.2 Patient's information

In order to manually follow up a slide processed by the patient's information, select the option "Patient's information" and click "Start".

Report Generator

Generate Report By Using

- Slide Barcode
- Patient Information
- Staining Runs

Start Return

Image 49

The system will show all the processed slides on the patient's information list. Search in the list inserting the patient's ID in the search box for the patient identification search. Order the list by any column clicking in the column heading.

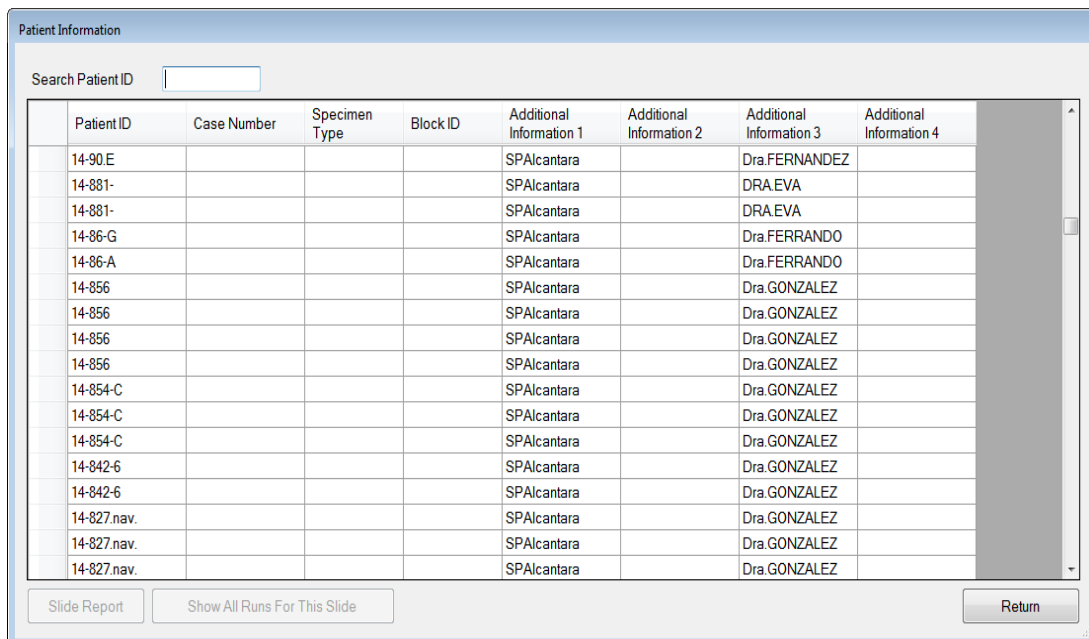


Image 50

In the patient's information list, the user can opt for:

- Select a Slide clicking on the empty box in the left column (the row will be highlighted in blue). Click on "Slide Report" to generate the selected report.
- Select a Slide clicking in the empty box of the left column (the row will be highlighted in blue). Click on "Show all Runs For This Slide" to generate an execution list of all the tests that include the staining cycles selected.

5.1.7.3 By staining process

In order to manually follow up a porta in the execution session, select the option "Staining process" and click on "Start".

Note: This is the only method for the follow-up of a porta assigned manually..

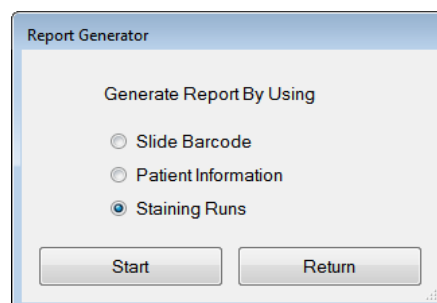


Image 51

The system will generate an execution list of all the executed cycles. The total number of slides processed in the system appear in the lower part of the list.

Select a start and an ending date to show all the slides of a given period of time.

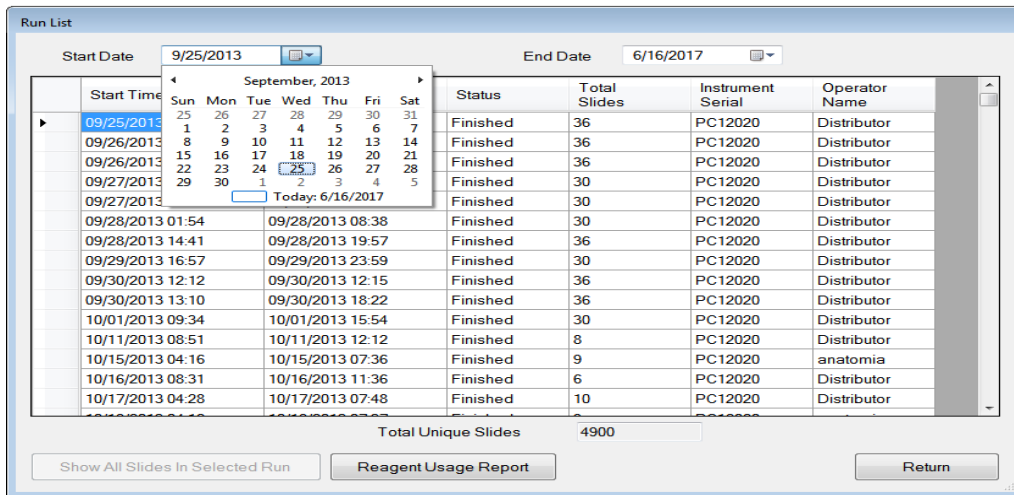


Image 52

From the execution list, the user can opt for:

- i. i. Choose a cycle clicking in the empty box in the left column (the row will be highlighted in blue). Click in "Show slides" to generate a list of slides of all the cycle slides.
- ii. ii. Click in "Report on Reagent Use" to generate a summary of the total use of reagents for all the series appearing in the execution list for the period of time selected.

5.1.8 Types of reports

Reports of slides

The Report of slides (show slides) provides the execution summary for a slide individually. The report can be generated through the scanning of a slide with the bar code option or through the selection of a slide of a preparations list or in the patient's information list.

6/16/2017 11:07:46 AM

Instrument	Operator	Run ID	Slide ID
PC12020	anatomia	ipH8Hn-QzEq7np18VmHpLw	1fSPgBfAJU2wNG1tPrbXyg

Patient ID	Case Number	Block ID	Specimen	Additional Information 1	Additional Information 2
14-3792				SPAcantara	

Protocol Name	Detection	Position	Ctrl	LIS	Start	End
SINAPT	Master Protocolo	9	1	N	5/16/2014 12:07:58 AM	5/16/2014 6:13:01 AM

Status
[Finished]

Reagent Name	Time (hh:mm:ss)	Temperature (C°)	Volume (ul)	Lot Number	Catalog Number	Expiry Date
DS1a	0:10:00	72	170	111111	Manually Assigned	2014-05
DS1b	0:08:00	72	170	0101-03		2015-05
TR1, high pH	0:32:00	102	370	140220-04		2016-02
System Fluid	0:04:00	37	130			2014-05
System Fluid	0:04:00	25	130			2014-05
Peroxidase Blocking	0:04:00	25	130	140103AF-04		2015-07
SINAPT	0:10:00	25	130	0170-02		2015-03
System Fluid	0:06:00	25	130			2014-05
Polymer Enhancer	0:10:00	25	130	H1304-03		2014-09

Image 53

The first line shows the date and time in which the report was generated.

The first table shows the instrument's serial number, the username, the cycle ID and the porta ID.

Instrument	Operator	Run ID	Slide ID
PC12020	anatomia	ipH8Hn-QzEq7np18VmHpLw	1fSPgBfAJU2wNG1tPrbXyg

Image 54

Note: Each cycle can be associated with 2 or more single identifiers if their execution process was interrupted by the continuous load.

The second table shows the patient's ID, case number, block identification, sample type, addition information 1 and additional information 2.

The third table shows the protocol name, the type of detection system, the porta position in the equipment, type control type (normal, positive or negative), LIS (yes / no), starting time and ending time.

Status
[Finished]

Image 55

Note: The table will show 2 or more groups of starting/ending times, if the execution process was interrupted by the continuous load.

The fourth table shows the real status, recording of all the warning / errors produced during the cycle and final situation [Finished].

Estado
[Finished]

Image 56

Note: The status [Stopped] indicates that the execution process was interrupted by the continuous load.

The fifth table show a summary of the protocol steps performed (name of the reagent, incubation time and temperature, volume) and the reagents used (lot number, catalogue number, expiration date) in the porta.

Note: For the fluid system (which corresponds to the washing buffer) and reagents manually assigned, an expiration date with the current month will be shown by default.

Report of reagents' use by staining cycle

The report of reagents' use offers a detailed summary of the reagents used in an individual cycle.

The reagents used in the cycle correspond to the individual reagents' vials programmed with RFID label. The report can be generated through the selection of any porta in the list.

Reagent Report

6/16/2017 11:10:05 AM

Instrument	Operator Name	Start Time	End Time	Status	Total Slides	Run UID
PC12020	anatomia	5/16/2014 12:06:31 AM	5/16/2014 7:13:15 AM	Finished	36	ipH8Hn-QzEq7np18VmHpLw

Reagent Name	Tag ID	Test Contained	Test Used	Position	Catalog Number	Lot Number	Expiry	Vendor
DS1a	FFFFFFFFFFFFFFFF		36	36	1 Manually Assigned	111111	2014-05	Unknown
DS1b	E023697003A216F4		80	36	2	0101-03	2015-05	MASTER DIAGNOSTICA
TR1, high pH	E004028051FCC643		36	36	7	140220-04	2016-02	MASTER DIAGNOSTICA
Enzima 2	FFFFFFFFFFFFFFFF		2	2	40 Manually Assigned	111111	2014-05	Unknown
Peroxidase Blocking	E004028051FCAE0C		45	36	3	140103AF-04	2015-07	MASTER DIAGNOSTICA
BER EP4	E0236815016B1507		18	2	23	23556	2014-06	VITRO
Polymer Enhancer	E004028051FCD9CE		45	36	4	H1304-03	2014-09	MASTER DIAGNOSTICA
HRP 2-Step Polymer	E004028051FCAESB		45	36	5	H1304-03	2014-09	MASTER DIAGNOSTICA
DAB	E004028051FC83BB		72	36	9	H1401-05	2014-11	MASTER DIAGNOSTICA
Hematoxilina	E004028051FC9CA3		45	36	8	CN2056-04	2015-03	MASTER DIAGNOSTICA
HMB 45	E004028051FCDC06		41	6	12	0197-04	2015-06	MASTER DIAGNOSTICA
MELANA	FFFFFFFFFFFFFFFF		8	8	37 Manually	111111	2014-05	Unknown

Image 57

The first line shows the date and time in which the report was generated.

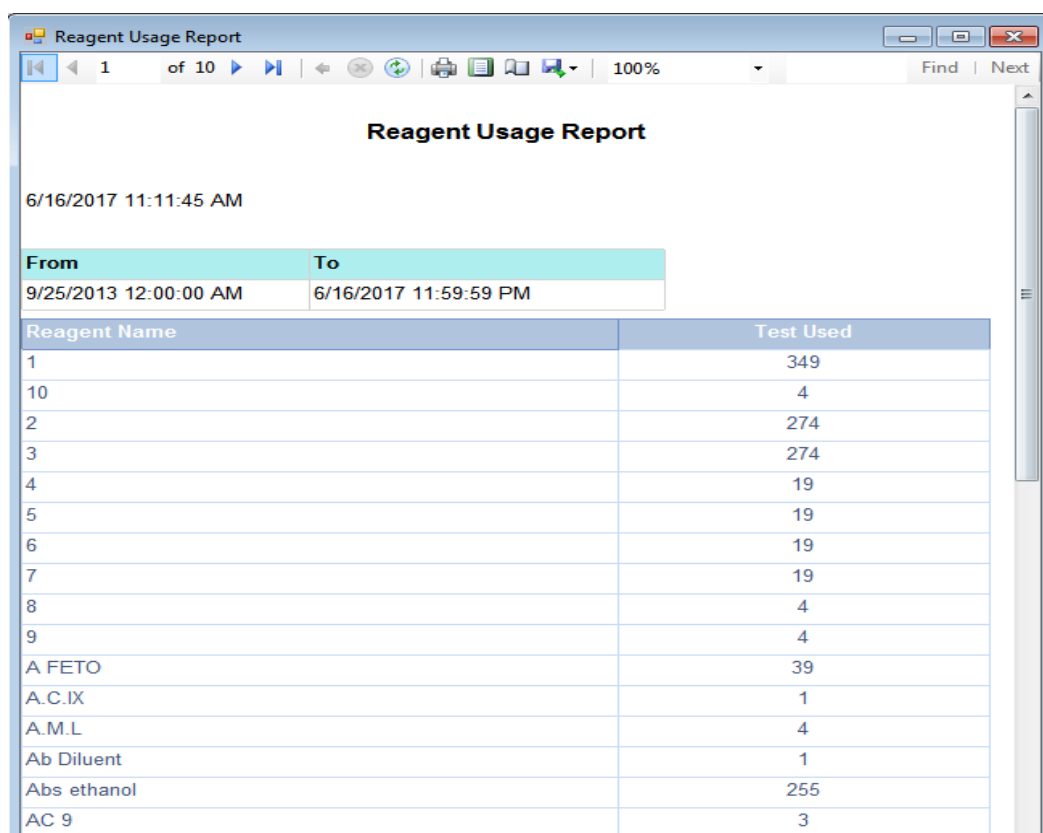
The first table shows the serial number of the instrument, the user name, the starting/ending time of the cycle, the cycle status, the total slides and the cycle ID.

The second table shows a summary of all the reagents used in the previous period (Reagent Name, ID RFID, Number of the test it contains, Used Tests, Positions in the rack, Catalogue Number, Lot number, Expiration date and Supplier).

Report on the reagents' use

The report on the reagents' use provides a global summary of the total use of reagents for a period of time specified by the user.

these data can be useful for the order and the follow-up of the reagents' use. The report can be generated from any execution list.



Reagent Name	Test Used
1	349
10	4
2	274
3	274
4	19
5	19
6	19
7	19
8	4
9	4
A FETO	39
A.C.IX	1
A.M.L	4
Ab Diluent	1
Abs ethanol	255
AC 9	3

Image 58

The first line shows the date and time in which the report was generated.

The first table shows the period of time specified by the user which is used to generate the report.

Note: *The report can also be generated using a cycle list for an individual porta.*


The second table show a list of all the reagents and the number of tests that will be used of each one. The last line of the table shows the total number of tests used in the period of time specified by the user.

Print and save a report

The system can generate different types of reports. Surf around each report through the number box in the page, arrows and searches placed in the tools bar.




Image 59

In order to print a report, click in the Print icon  in the tools bar and select an available printer.



Do not select the bar-code printer.

In order to save a report, click in the Export icon  in the tools bar and select the application: Excel, PDF or Word.

Data back-up

From the main screen, click in "System" and select the tools tab to access the utility.

Click in "**Back-up copy**" to access the function of back-up..

Select / Insert a back-up date of the data report and click in "Copy".

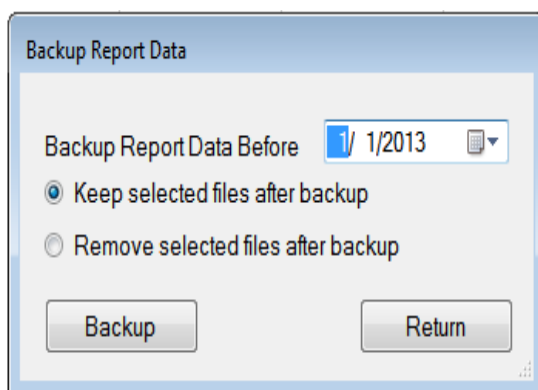


Image 60

To keep the data selected after doing the back up, select the option: "**Keep the files**".

To delete the selected data after doing the back up, select the option: "**Remove the files**".

Select a location folder where the back-up will be stored, i.e.,: local disk or external disk entity. Alternatively, the user can create a new location of the folder clicking in "Make New Folder" and click in "OK" to continue.

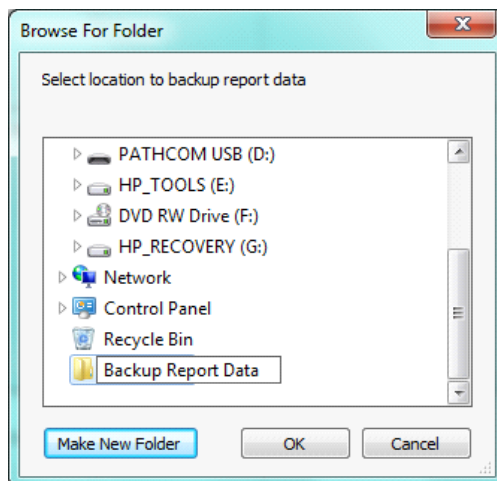


Image 61

All the files of the data report created before the selected fate are copied in a new folder with the name "**Backup Report Data**" and the current date.

5.1.9 Starting the system

Click in "**Start System**" to start the system. The robot will move backwards to the initial position and the 36 modules will move upwards and downwards. At the same time as the modules are moving, each pipette will prime in the washing station to clean pipes corresponding to Z1 and Z2.

5.1.10 Check if there is any bad functioning of a heater

Click in "**Check Modules**" to check the functioning of the 36 heaters. There is also the option to check the individual functioning or in groups of 12 modules. We just need to click in "Start".

There is also the option to check the modules individually or simultaneously in relation to movement and/or temperature. We only need to select the desired option selecting "Heater", "Motion and Heater" or "Motion".

The countdown timer will show the time left and the ending time. Click in "Cancel" if you wish to cancel the process.

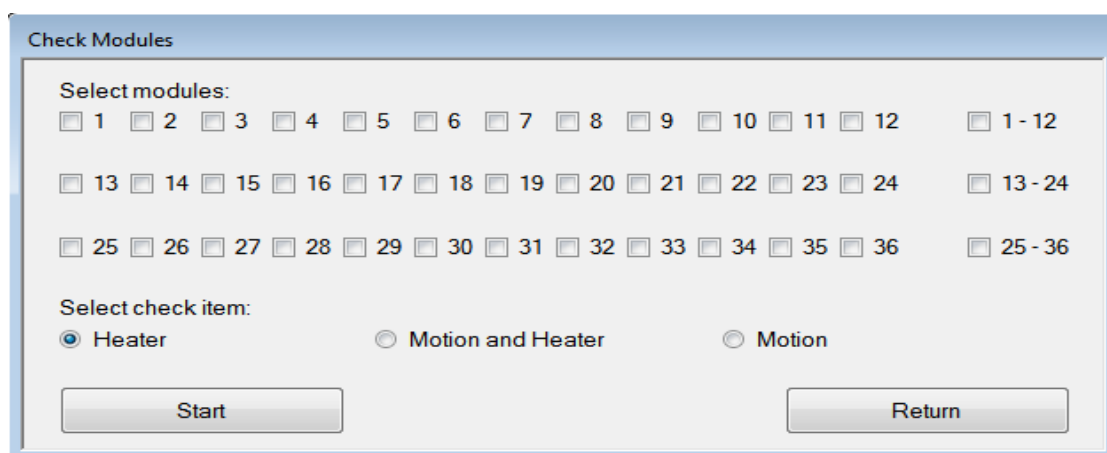


Image 62

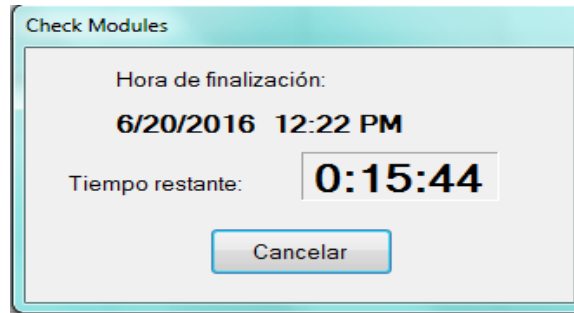


Image 63

⚠ The heaters need a few minutes to heat up the higher temperatures during the comprobation of the heater. To avoid burns/injuries, do not touch the heaters during the process until the heaters have been cooled down enough.

If all the modules have passed the verification correctly, the system will return the message: **"All heaters are functioning properly."**

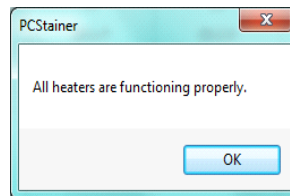


Image 64

On the contrary, if the system detects any heater with a wrong functioning, it will make it in red in the slides map with the message: "Low Temperature", "High Temperature" or "Over Heating".



Image 65

If during the verification of the heater functioning regarding movement, any abnormality is detected, the system places the corresponding module in **"red"** with the message of "Module Malfunction"

In both cases, **once the verification has been done and the wrong functioning of a module has been confirmed**, whether it's due to temperature or movement, the user must contact the provider to communicate the incidence.

⚠ **The protocols cannot be assigned to a position for whose heater a wrong functioning was detected until the heater is substituted and a new verification is performed.**

5.1.11 Pump Z1 Priming

Click in " Prime Pump Z1 " to check the functioning of the pump 1. The pump 1 is connected to the pipeline Z1. The pipette Z1 will be moved into the washing station and will dispense washing buffer.

5.1.12 Pump Z2 Priming

Click in "Prime Pump Z2" to check the functioning of the pump 2. The pump 2 is connected to the pipe line Z2. T probe Z2 will be moved into the washing station and will dispense the washing buffer.

5.1.13 Close door

Click in "**Close door**" to manually lock the door. Only the level of supervisors gives access to this function.

5.1.14 Unlock door

Click in "**Unlock door**" to manually unlock the door. Only the level of supervisors gives access to this function.

5.3 Editors

Access the **protocol and reagents editor and the RFID editor.**

Note: *The users with the technical security level don't have access to this function.*

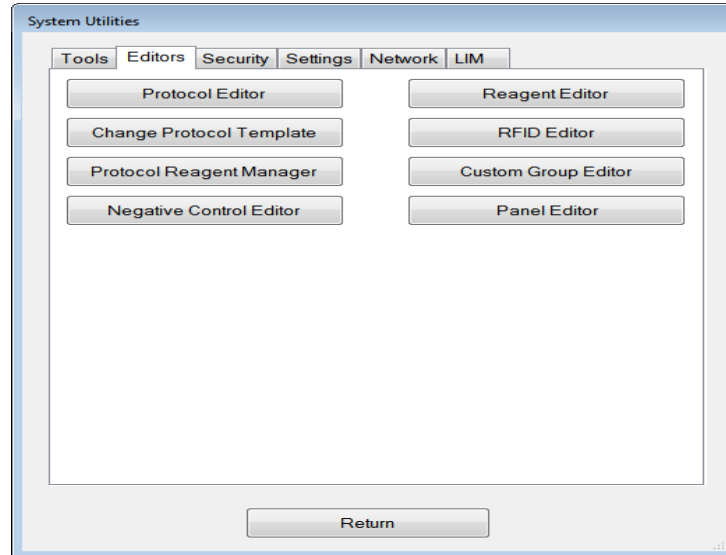


Image 66

5.3.1 Protocol Edition

Click on **"Protocol Editor"** to make personalized modifications in the protocols. The user can access the different protocol templates inside this editor. These include HRP, HRP Super, AP, AP Super, double Stain, FISH, CISH, Cyto, CISH + IHC, and the protocols of special kind. The new protocols are added through the addition of new primary antibodies or reagents in Edit Reagent. Consult "Edit Reagent" (page 67 for more information).

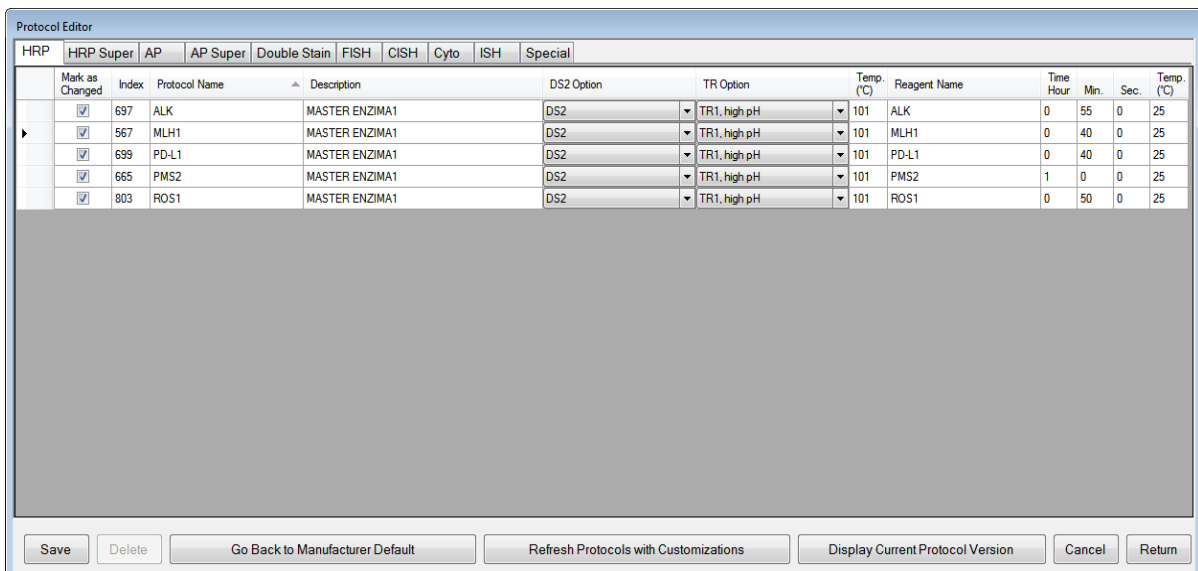
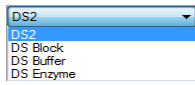
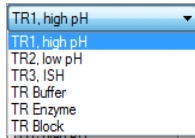


Image 67

In this section **you can edit the incubation time and temperature of the primary antibody** (hours, minutes, seconds). The incubation time must be adjusted between 5-120.




To **modify the reagent DS2** for a IHC protocol, select an option of the drop-down list in the option DS2.




To **modify the reagent of antigenic recovery TR** for a IHC protocol, select an option of the drop-down list in the TR. There is also the possibility of modifying the temperature of the antigenic recovery in the section **"Temp (°C)"** right after the TR.

Note: *It is not recommended to modify the TR conditions without the support of a specialist.*


Click in **"Save"** to apply the new modifications to the protocol(s) selected. On the left edge column of the editor, all the protocols that have been modified will have the box **"Marked to change"** marked.



 This action can be used to: 1) apply modifications to the protocol.


 2) Permanently save all the modifications of the current protocol, the user must go to System Utilities > Settings and click in **"Save all the personalizations"**. Check the section 5.5.3 Save all the personalizations for more information.

Click on **"Cancel"** to cancel the changes.

Click on **"Refresh protocols with Customizations"** to update the protocol(s) selected using the protocol model by default and apply the personalizations saved by the user.

 This action can be used for 1) regenerate all the protocols after modifying the protocol template, or 2) restore the protocols for the personalizations saved by the user, or 3) load the imported protocols.

  Any modification of the current protocol that has not been permanently saved will be over-written with the personalizations saved by the user. Check the section 5.5.3 Save all the personalizations for more information.

 Click on **"Go back to the manufacturer's default"** to load the protocol(s) selected using the protocol model by default and apply the provider's personalizations by default.

This action can be used to 1) restore the protocols for the provider's personalizations by default.

Advice: *The user can select all the protocols clicking in the box of the left upper corner of each tab. The user can select different protocols by keeping the "Ctrl" key pressed.*

The version number of the current protocol can be seen by clicking on "**Display Current Protocol Version**". The version number is updated each time the provider edits a new group of protocols and reagents different from the ones that are by default. Protocols and templates added by the user do not affect the number of version.


Click on "**Return**" to close the Protocol Editor and go back to the Editors screen.


5.3.2 Special Protocols

Special protocols can be created for applications requiring more personalizations, which are not available in the Protocol Editor or in the general templates. The special protocols cannot be created or edited in the Protocol Editor, **but they need to be generated in an external application. Contact your provider to get assistance with the special protocols.** The new protocols can be imported to the system using the option "Protocols and Reagents Manager". Check the section 5.3.4 Protocol Import for more information.

Note: *It is not recommended to modify the TR conditions without the support of a specialist.*


Click in "**Save**" to apply the new modifications to the protocol(s) selected. On the left edge column of the editor, all the protocols that have been modified will have the box "**Marked to change**" marked.



 This action can be used to: 1) apply modifications to the protocol.


 2) Permanently save all the modifications of the current protocol, the user must go to System Utilities > Settings and click in "**Save all the personalizations**". Check the section 5.5.3 Save all the personalizations for more information.

Click on "**Cancel**" to cancel the changes.

Click on "**Refresh protocols with Customizations**" to update the protocol(s) selected using the protocol model by default and apply the personalizations saved by the user.

 This action can be used for 1) regenerate all the protocols after modifying the protocol template, or 2) restore the protocols for the personalizations saved by the user, or 3) load the imported protocols.

  Any modification of the current protocol that has not been permanently saved will be over-written with the personalizations saved by the user. Check the section 5.5.3 Save all the personalizations for more information.

 Click on "**Go back to the manufacturer's default**" to load the protocol(s) selected using the protocol model by default and apply the provider's personalizations by default.

This action can be used to 1) restore the protocols for the provider's personalizations by default.


Advice: *The user can select all the protocols clicking in the box of the left upper corner of each tab. The user can select different protocols by keeping the "Ctrl" key pressed.*


The version number of the current protocol can be seen by clicking on "**Display Current Protocol Version**". The version number is updated each time the provider edits a new group of protocols and reagents different from the ones that are by default. Protocols and templates added by the user do not affect the number of version.

Click on "**Return**" to close the Protocol Editor and go back to the Editors screen.

Note: *It is not recommended to modify the TR conditions without the support of a specialist.*


Click in "**Save**" to apply the new modifications to the protocol(s) selected. On the left edge column of the editor, all the protocols that have been modified will have the box "**Marked to change**" marked.



 This action can be used to: 1) apply modifications to the protocol.


 2) Permanently save all the modifications of the current protocol, the user must go to System Utilities > Settings and click in "**Save all the personalizations**". Check the section 5.5.3 Save all the personalizations for more information.

Click on "**Cancel**" to cancel the changes.

Click on "**Refresh protocols with Customizations**" to update the protocol(s) selected using the protocol model by default and apply the personalizations saved by the user.

 This action can be used for 1) regenerate all the protocols after modifying the protocol template, or 2) restore the protocols for the personalizations saved by the user, or 3) load the imported protocols.

  Any modification of the current protocol that has not been permanently saved will be over-written with the personalizations saved by the user. Check the section 5.5.3 Save all the personalizations for more information.

 Click on "**Go back to the manufacturer's default**" to load the protocol(s) selected using the protocol model by default and apply the provider's personalizations by default.

This action can be used to 1) restore the protocols for the provider's personalizations by default.

Advice: *The user can select all the protocols clicking in the box of the left upper corner of each tab. The user can select different protocols by keeping the "Ctrl" key pressed.*

The version number of the current protocol can be seen by clicking on "**Display Current Protocol Version**". The version number is updated each time the provider edits a new group of protocols and reagents different from the ones that are by default. Protocols and templates added by the user do not affect the number of version.

Click on "**Return**" to close the Protocol Editor and go back to the Editors screen.

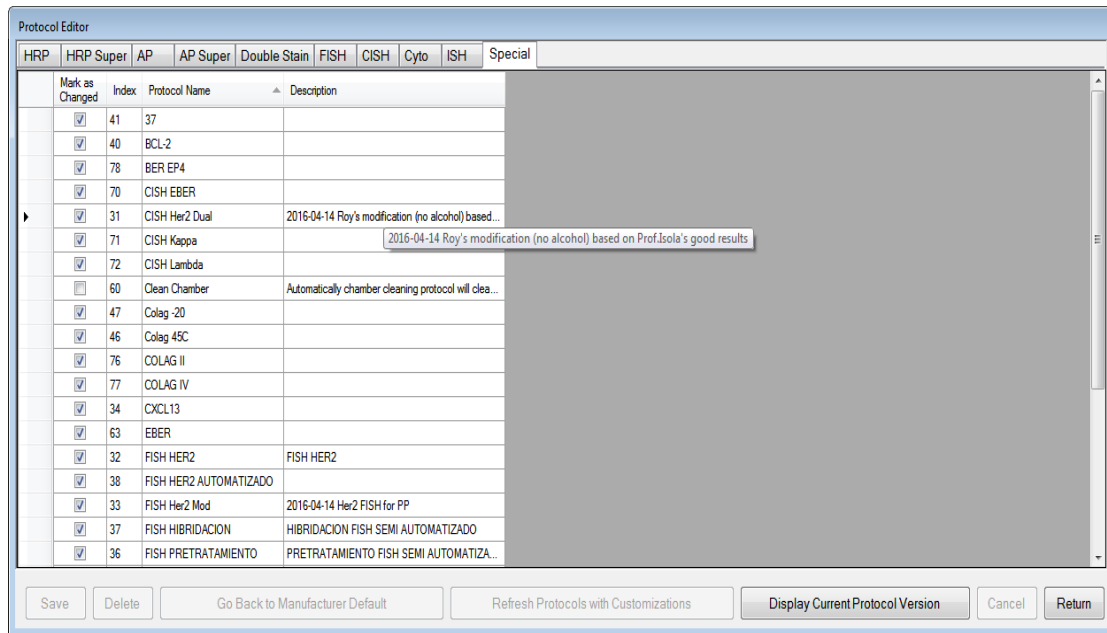



Image 68

Once generated, imported the new special protocol or updated an already-existing one, the user must select all the protocols clicking in the box of the left upper corner.

Once all the protocols have been selected, click in **"Save"** to generate/update the new special protocol(s) selected.

5.3.3 Change the protocol mode

Click in **"Change the protocol template"** to open the protocol templates. Each type of the protocol has a template selected that is used to generate all the protocols belonging to this type. Check the Image 70 to see the list of templates predetermined by the provider.

 The change into a different protocol model can update all the protocols using the new template as predetermined. The protocol personalizations will be restored using the protocol personalizations saved by the user.

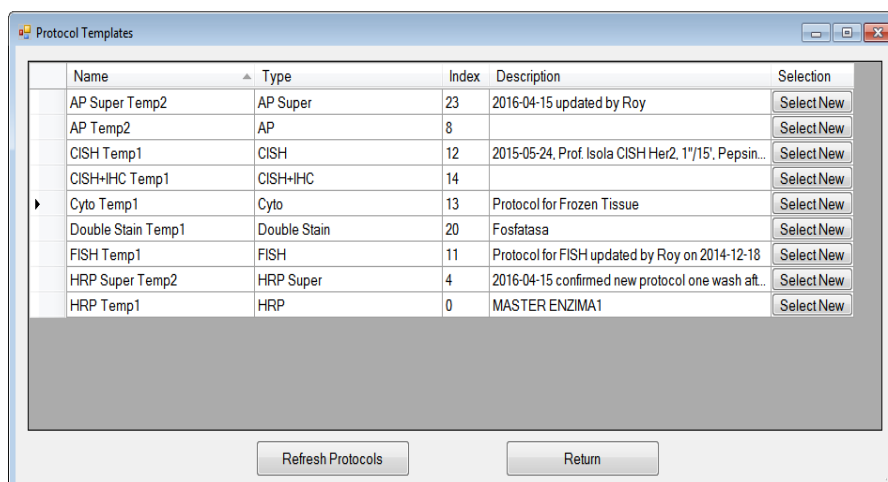


Image 69

 Do not change protocol templates without the assistance of a specialist.

To change into a new protocol template model, select the type of protocol appropriate and click in "Select New".

The screen "Select template" will open:

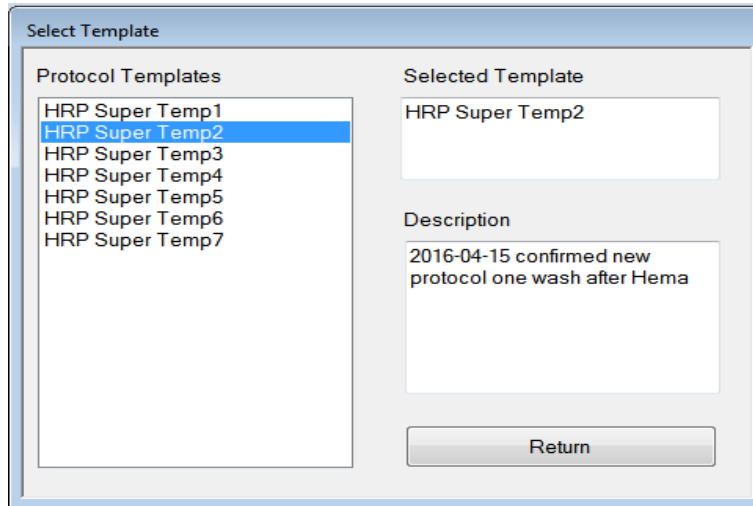



Image 70

Select a new template model from the list "Protocol Template" and click in "Back" to close the screen.

In the Protocol Templates screen, click in "Save" to automatically update all the protocols using the new template and apply the personalizations saved.

 The system will take a few minutes to update all the protocols.

Click in "Back" to close the screen of the protocol templates.

Note: Contact your provider to get assistance with the modification of the existing protocol template.

5.3.4 Protocol Import

Click in "Protocol Reagent Manager" to open the utility.

Log in with an user ID and password.

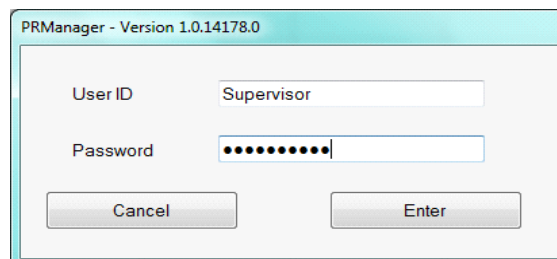


Image 71

Select the option **"Export"** or **"Import"** for the import or export of files. Click in **"Import"** or **"Export"** for the import/export of files and select the desired export/import file (compressed zip folder). Contact your provider to get more information.

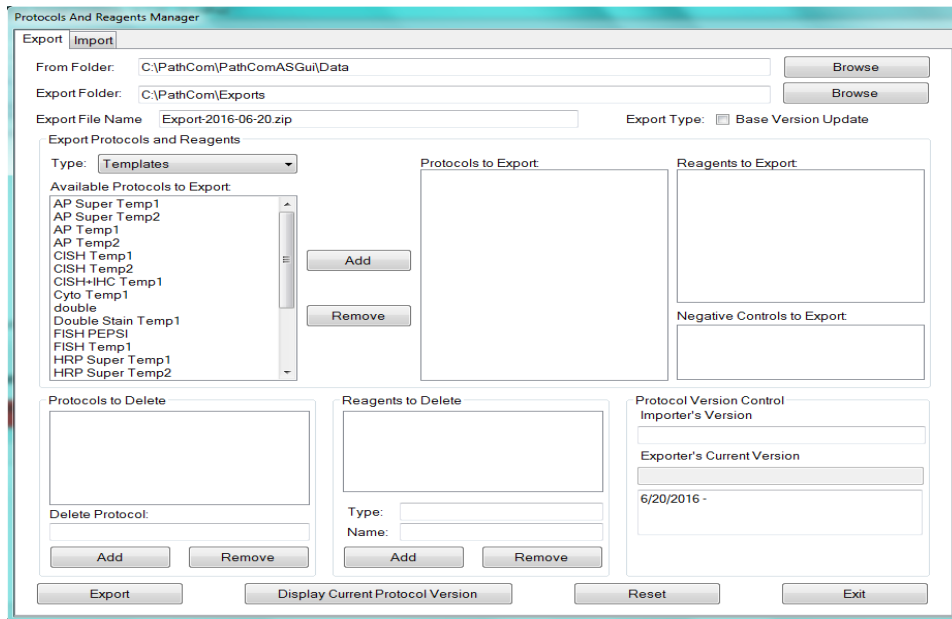


Image 72

Option of importing template (it is applied only to the protocol templates). Protocol templates are stored in index positions 1-30. By fault, the system selects the option **"Over-write already-existing template"**. The imported template will always over-write the existing template in the same index position. If needed, the user can cancel the selection of the default option to import the template to the following available index position.

Click on **"Import"** to import the new protocol(s), associated reagent(s) and negative control(s) and save the data.

Update the protocol(s) in the Protocol Editor immediately after the protocols' import.

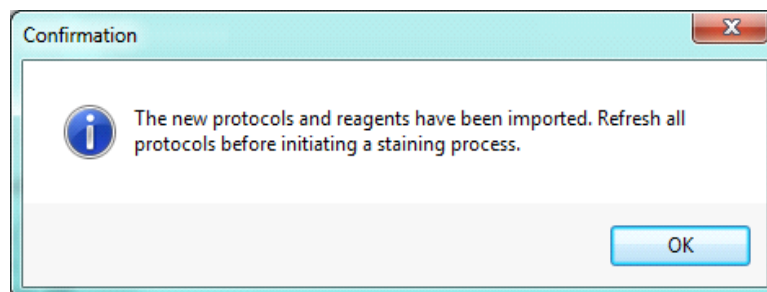


Image 73

The protocols sharing the same name as an existing protocol cannot be imported. The user can delete the existing protocol in the Protocol Editor before the new protocol can be imported.

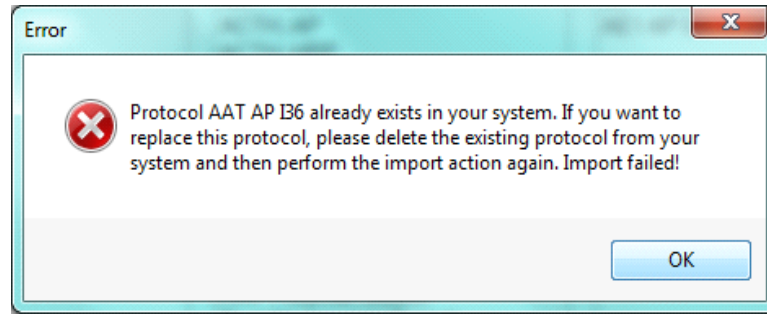


Image 74

Click in "Display Current Protocol Version" to see the version number of the current protocol. The version number will be updated automatically after importing the update of the provider's protocol

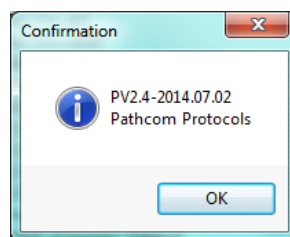


Image 75

Click in "Exit" to close the utility.

5.3.5 Assigning Negative Controls

Click on "Editor of negative controls" to manage and assign the negative controls. A negative control can be assigned to each protocol; the predetermined value is universal negative.

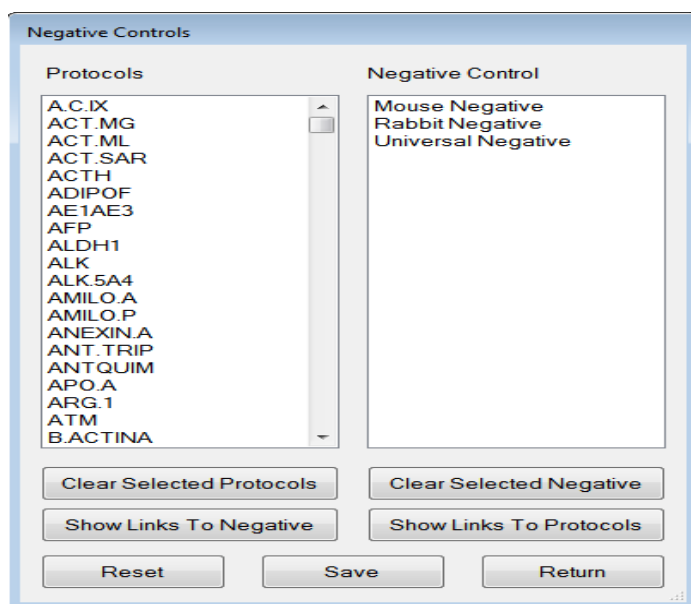


Image 76

To see all the protocols assigned to a negative control, select the negative control in the list of negative controls and click in **"Links to protocol"**.

To see the negative control assigned to a protocol, select the protocol mentioned under the list of Protocols and click in **"Links to Negative"**.

To delete the selection(s), click in **"Delete Protocol"** and/or **"Delete Negative"**.

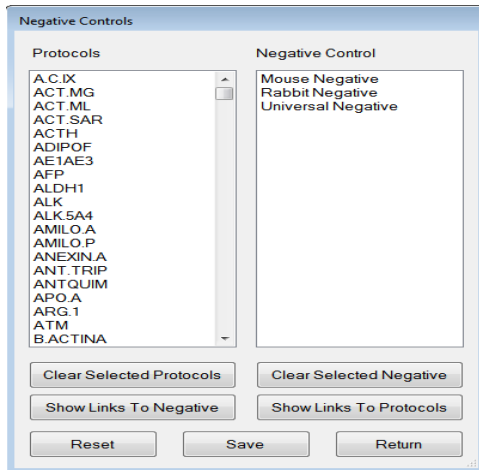


Image 77

To assign a negative control a protocol, select the protocol(s) under the Protocol list and select a negative control.

Click in **"Save"** to link the protocol(s) with the negative control.

Note: *The additional negative controls can be added to the Editor of reagents in negative type. Check the section 0 To go back to the predetermined configuration, click on "Reset". All the protocols will be assigned to the predetermined negative control, Universal negative.*


Editor of Reagents *for more information.*

To go back to the predetermined configuration, click on **"Reset"**. All the protocols will be assigned to the predetermined negative control, Universal negative.


5.3.6 Editor of Reagents

Click in **"Edit Reagents"** to administer the list of antibodies, negative controls and reagents of special use of the system.

To **add a new antibody**, select the **type of reagent** of the list and click in **"Add new"**. Insert the name of the antibody in the name field. When adding the new antibody, a new protocol for the antibody will be automatically generated.

 Each antibody is unique and only a single name can exist.

The protocol name is established automatically in the antibody's name by default. You can modify the protocol name in the corresponding field, if needed.

 Each protocol needs to have a single name. On the contrary, different protocols can share the same antibody.

When creating a new reagent, the user must select the box **“Hazardous”** when the new reagent is dangerous and needs its wastes to be placed in the container enabled for so. If the referred box is not selected, the disposals from this reagent will be placed in the container for non-hazardous wastes.

Viscosity levels, there are 4 viscosity levels influencing when aspirating and dispensing that reagent. The level one is used for the reagents without viscosity and the level four for reagents with maximum viscosity. The user can select a viscosity level for the new reagent that is being created according to its viscosity level.

In the section **“This reagent is”** the user must keep the option **“Ready to use”**, if the reagent is ready to be used. If the reagent that is being created needs a mixture before being used, please contact its provider.

Click in **“Save”** to add the new antibody. The new protocol will appear in the Editor of Protocols.

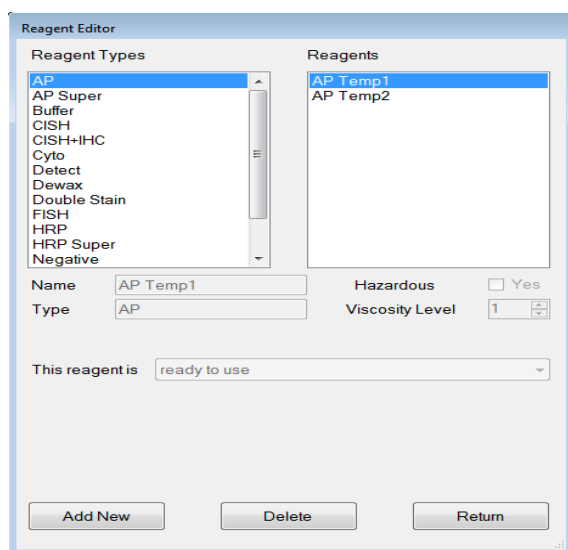


Image 78

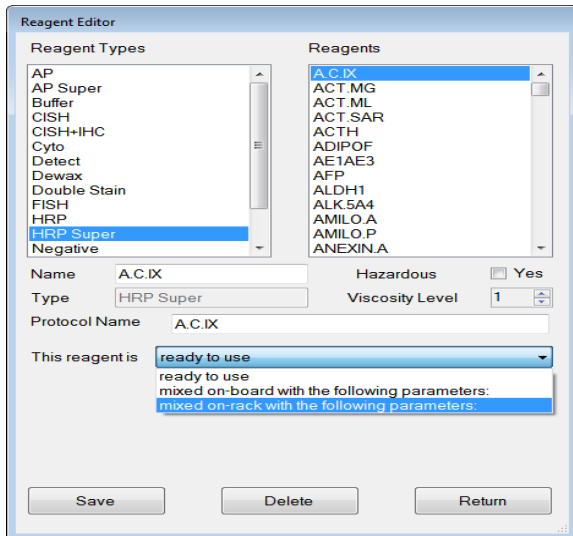


Image 79

To **add special reagents** or negative controls, select the type of reagents of the list and introduce the new name.

Click in **"Save"** to add the new reagent.

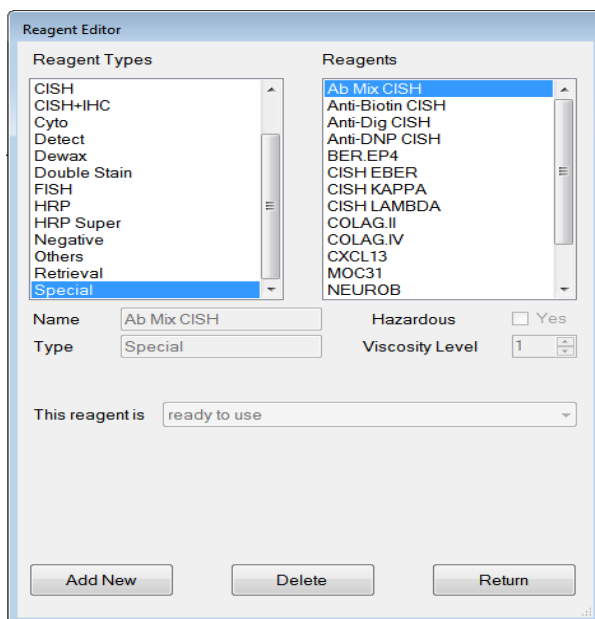



Image 80

 To reclassify an existing reagent, first take out the reagent from the list of reagents and then, add it to the list again as a hazardous reagent.

To **delete an existing reagent** from the system, select a reagent from the list and click in **"Delete"**.

Note: *The user can only delete the reagents added by the user from the list of reagents. The reagents added by the provider cannot be deleted.*

5.3.7 Preparation of reagents with RFID labels with the RFID editor


Click in **"Edit RFID"** to start editing RFID labels. The robotic arm moves the RFID antenna to the front part of the instrument. Place a reagent vial with the RFID label under the antenna.

To **write information in the RFID label**, complete the entry fields to the right and click in **"Write"**.

Select the reagent type and then the reagent name of the drop-down lists.

Note: *The user can only select the reagents added by the user to the list of reagents.*

Select the appropriate type of vial (15 or 7 ml) and insert the storing temperature. Insert the number of tests, lot number (up to 12 characters) and the expiration date (aa/aa/mm). Select the provider name and write the catalogue number.

 The system will immediately write after writing the RFID label to verify that the data have been correctly recorded. Do not take back the vial until the left RFID label ID turns in green relief to indicate that the label has been correctly read.

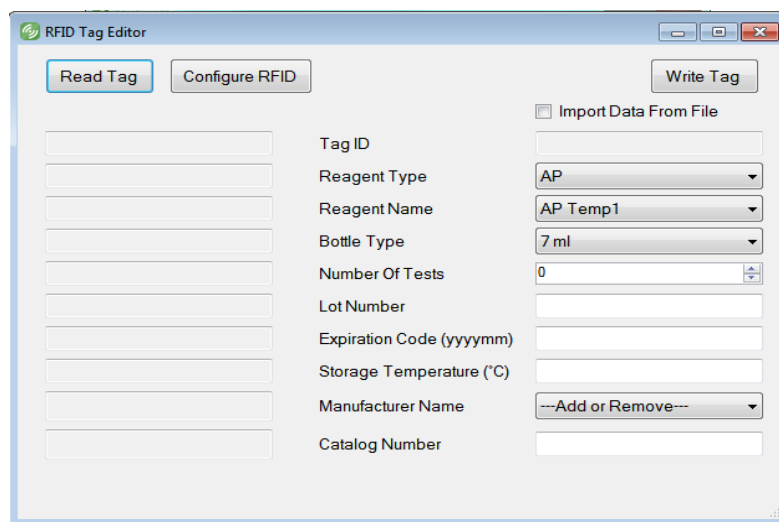


Image 81

To manually read the information of the RFID label, click in **"Read RFID"**. The programmed information will be showed in the empty fields to the left.

Note: *The new RFID labels will only contain the identification generated randomly. The other information is to be programmed by the provider or user.*

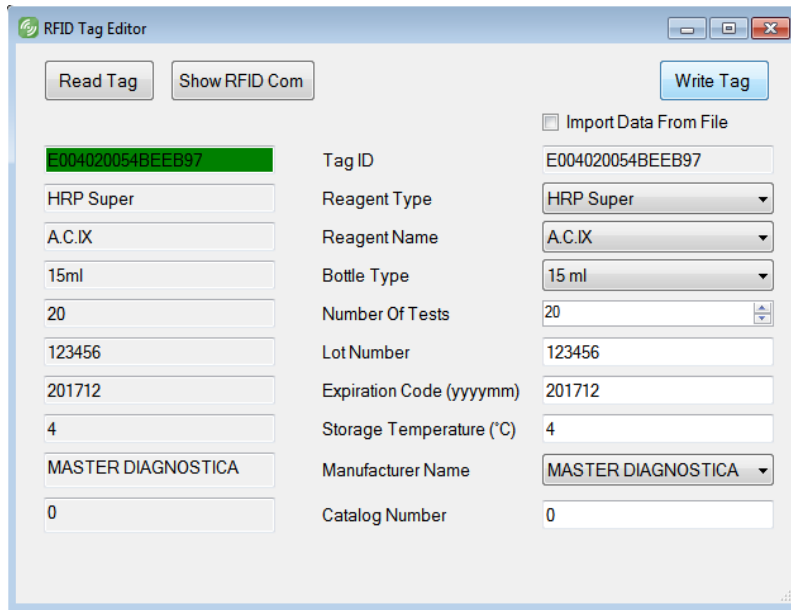


Image 82

5.3.8 Editor of personalized groups

Click in **"Edit Custom groups"** to edit / create personalized lists of protocols for the quick access to protocols in the editor of slides' labs.

Select a **personalized group** in the drop-down list **"Available protocols"**. The Protocols in the personalized group are shown in selected protocols.

To add a **personalized group**, click in **"Add group"**, insert a new name and click in **"Add"**.

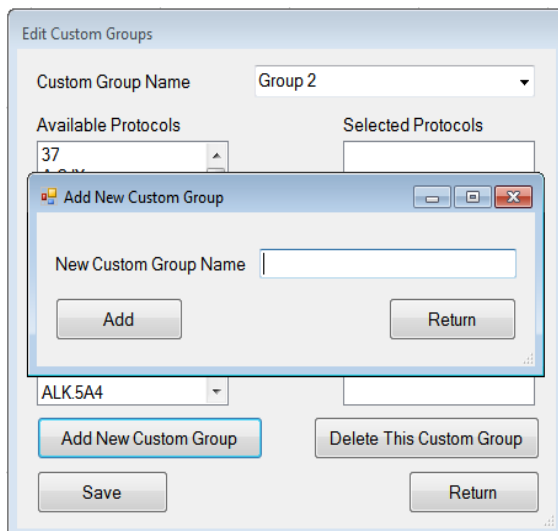


Image 83

To add the **protocol(s)** to a **personalized group**, select the protocol(s) counted in the available protocols, click in **"Add protocol"** and click in **"Save"**.

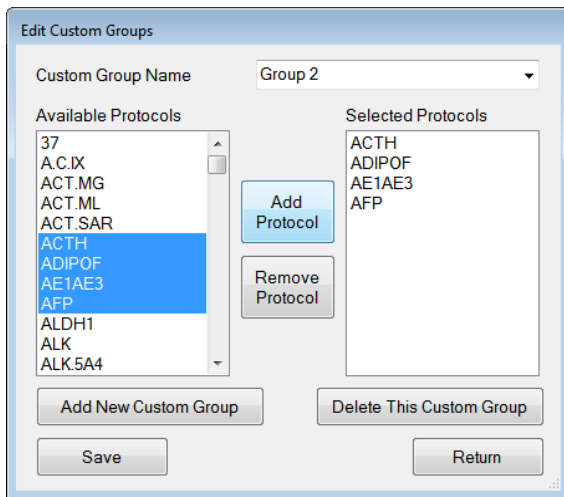


Image 84

To take the protocol(s) out from a personalized group, select the protocol(s) counted in the selected Protocols, click in "Remove Protocol" and click in "Save".

To delete a personalized group, select the group name from the drop-down list and click in "Delete This Custom Group".

5.3.9 Editor of Panels

Click in "Edit panels" to edit / create personalized panels of protocols from them to be accessible in the editor of slides labels.

Select a name from the drop-down list panel. The panel protocols will be shown in selected protocols.

To add a new panel, click on "Add New panel", insert a new name and click on "Add".

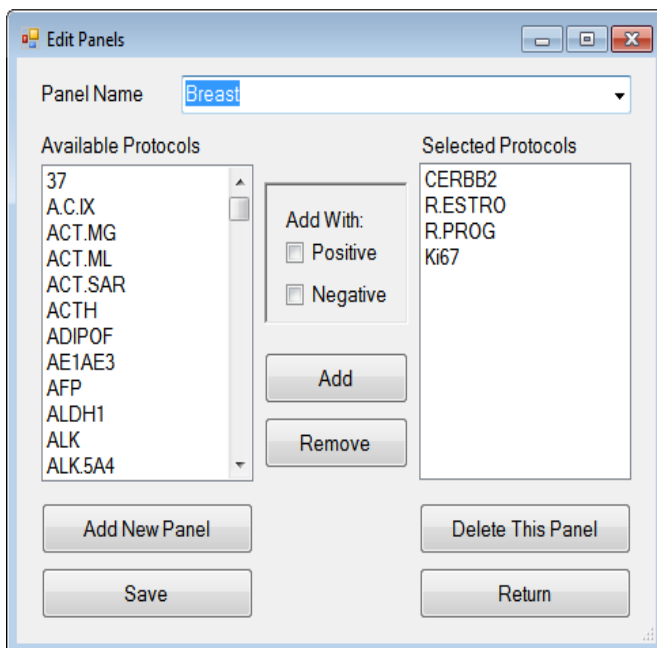


Image 85

In order to add the protocol(s) to a panel, select the protocol(s) counted in the available protocols, click in "Add" and click in "Save".

Note: The user can include a positive control and / or negative one with each protocol if they wish to do so.

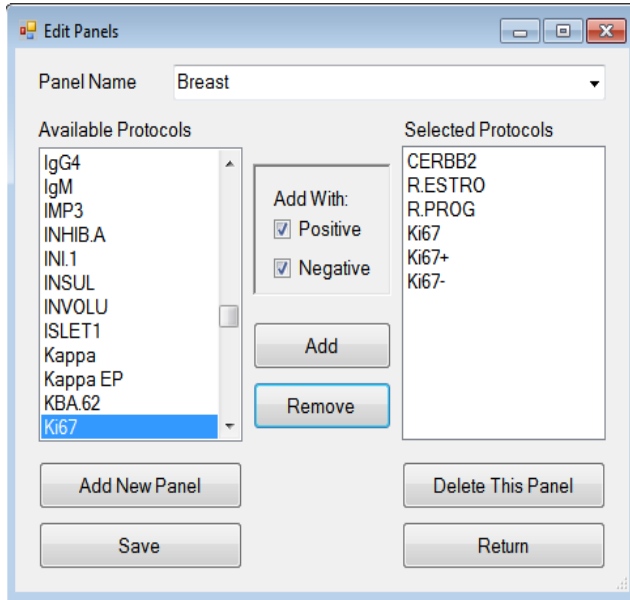


Image 86

To download the protocol(s) of a panel, select the protocol(s) counted in the selected protocols, click in "Delete" and click in "Save".

To delete a panel, select the panel from the drop-down list "Panel name" and click in "Delete protocol".

5.4 Security

The security in the access and administration systems can be managed in the "Security" tab.

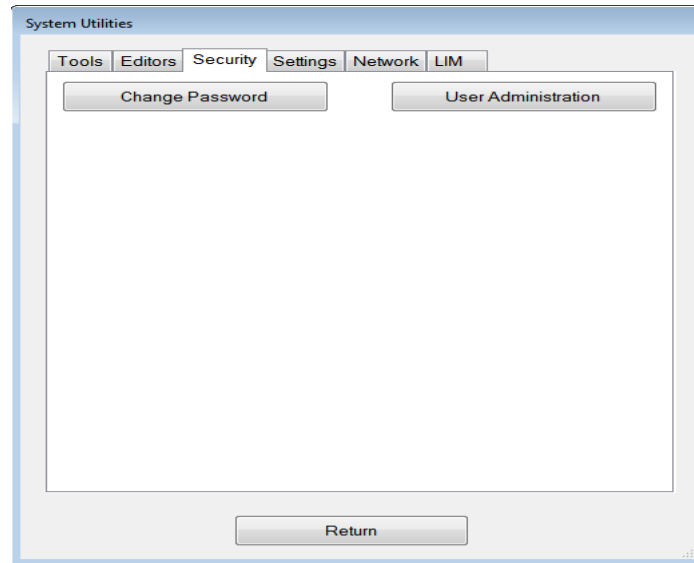


Image 87

5.4.1 Change password

Click in "Change password" to change the log-in password of the current user.

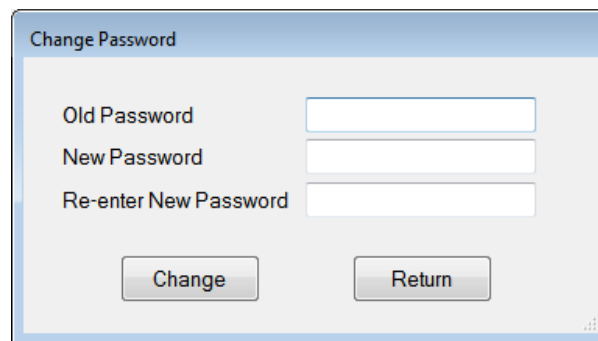


Image 88

5.4.2 Administration of users

Click in "Users Administration" to see the list of users:

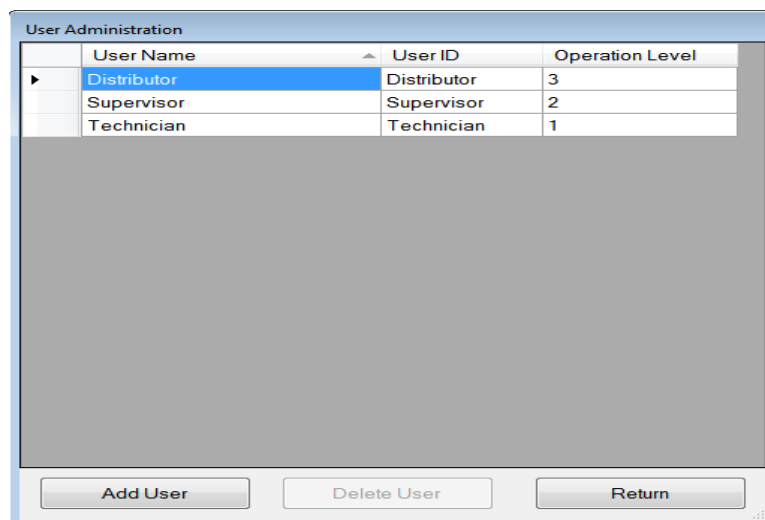


Image 89

There are different user levels:

Distributor (access to all tools, functions and settings)

Supervisor (full access to tools and editors, and intermediate access for the Security and configuration)

Technician (limited access to Tools, Security, Configuration and Editors)

To add a new user, click in "**Add user**" to open the window "Add user".

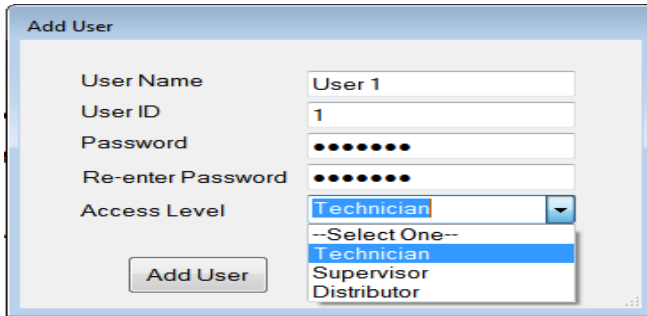


Image 90

Insert the name, user ID and password to establish the access level.

Note: *Only the users with a supervisor access level can create additional user accounts.*

To **delete an user**, select the user in the list and click in "**Delete User**".

5.5 Settings

See system information and adjust the system settings in the "**Settings**" tab.

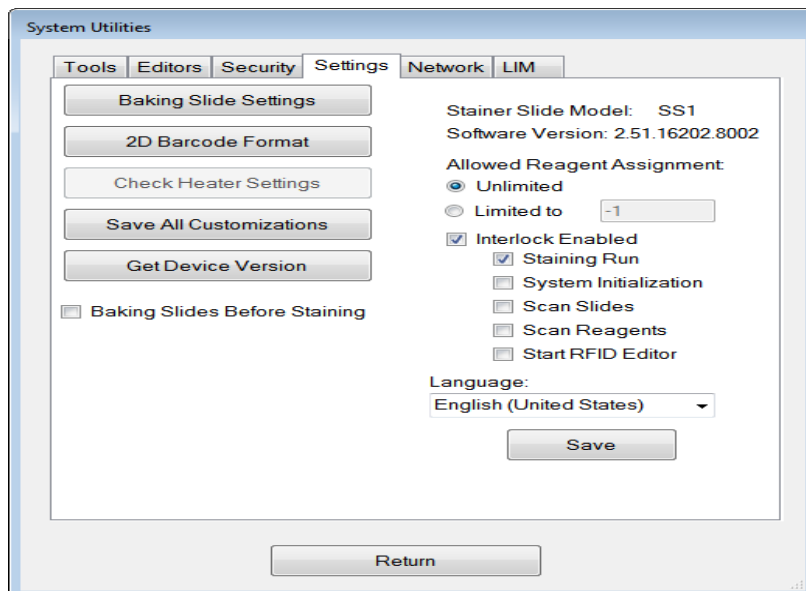


Image 91

See the version of the system software and the model number in the model in the right upper corner of the screen.

To change the working language, select a language from the languages drop-down list.

To see the information of the version of the different devices of the system, click in "Hardware Version".

5.5.1 Setting of the slides' heater

Click on "**Baking Slide Settings**" to adjust the temperature (C) and the heating time (minutes). Click on "**Save**" and "**Return**" when you have finished.

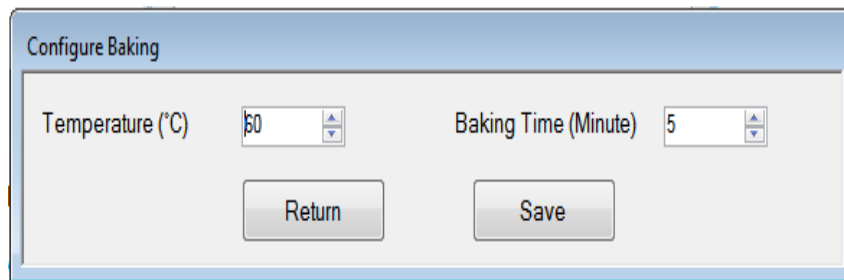


Image 92

To configure **the slides' hearing before the staining**, mark the box **for hearing the slides before the staining** and select the time assigned for the cooling down after the heating. Click in "**Save**" in the Settings tab. The system will automatically start the heating of the slides before starting the cycles.

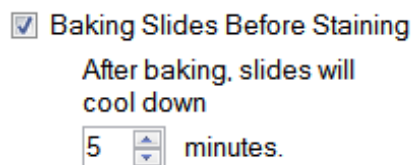
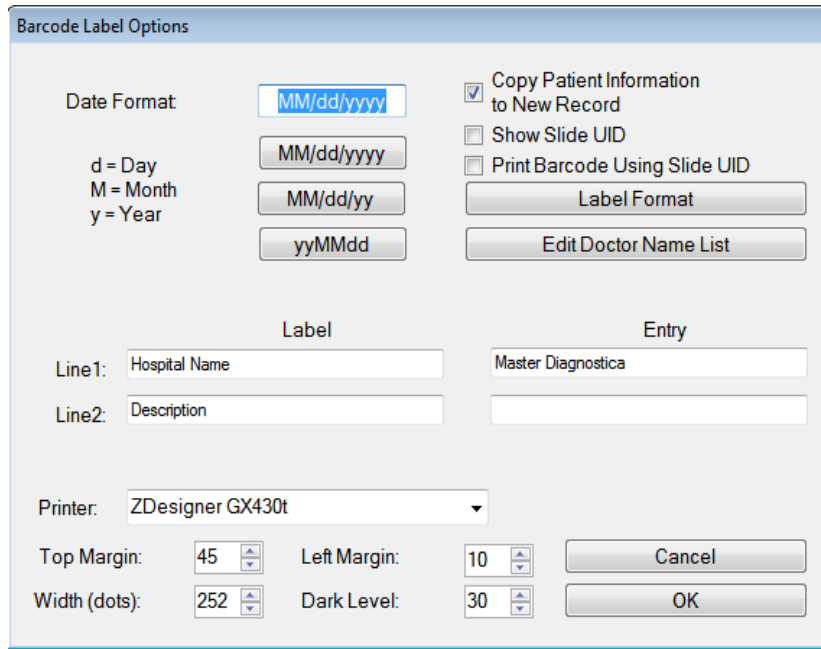


Image 93

5.5.2 Bar code format

Click in "**Bar-code Format**" to open the section "Options of bar-code" and edit the setting for the bar-code labels editor.



The dialog box titled "Barcode Label Options" contains the following elements:


- Date Format:** A text field with "MM/dd/yyyy" selected. Below it are four buttons: "MM/dd/yyyy", "MM/dd/yy", and "yyMMdd". A legend indicates: d = Day, M = Month, y = Year.
- Checkboxes:**
 - Copy Patient Information to New Record
 - Show Slide UID
 - Print Barcode Using Slide UID
- Buttons:** "Label Format" and "Edit Doctor Name List".
- Text Fields:**
 - Label:** Line1: "Hospital Name", Line2: "Description".
 - Entry:** "Master Diagnostica".
- Printer:** A drop-down menu showing "ZDesigner GX430t".
- Print Settings:**
 - Top Margin: 45 (spinners)
 - Left Margin: 10 (spinners)
 - Width (dots): 252 (spinners)
 - Dark Level: 30 (spinners)
- Buttons:** "Cancel" and "OK".

Image 94

Select the **date format**.

Insert the names of the label fields by default for the text line 1 and text line 2 of the label. Insert an entry by default if you want to.

Select the printer from the drop-down menu and adjust the printing edges and darkness level as needed.

 Make sure the label printer is connected (currently compatible with Zebra TLP 3844-Z or Zebra GX430t) and it is selected in the drop-down list of the printers.

Select the option of copying the patient's identification and the protocol name. This option will keep the patient's information from the previous label series for the following group of barcodes labels in the labels Editor. Deactivate this option to delete all the patient's information after saving a group of labels.

Click in **"Label format"** and you can edit the printable data in the label. The user can change the label line order or select new types of data that will be printed in each line of the label.

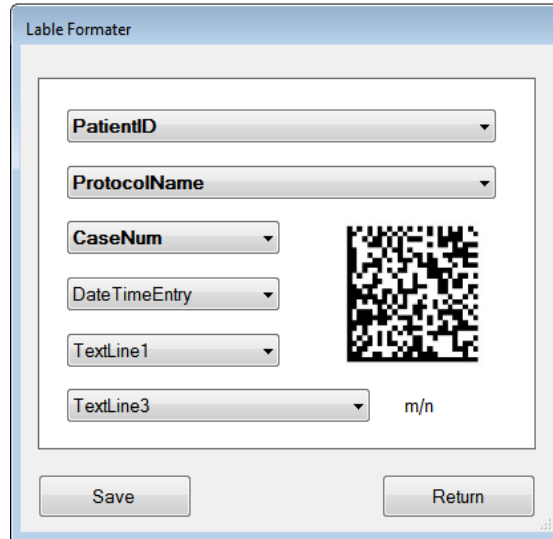


Image 95

Select the types of data in the drop-down list for each line. Click on **"Save"** to save the changes for the label format.

Note: Please, check that the printed data will not be overlapped with the 2D bar-code label.

Click on **"Edit Doctor Name List"** to add new doctors to the drop-down list in the label bar-code editor.

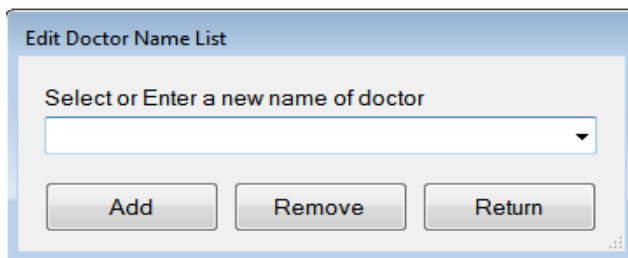


Image 96

To add a new doctor, insert the new name and click on **"Add"**.

To take out an existing doctor, select the name of the drop-down list and click on **"Remove"**.

Click on "Accept" when you have finished editing the label in the format option. The label format by default is shown below.

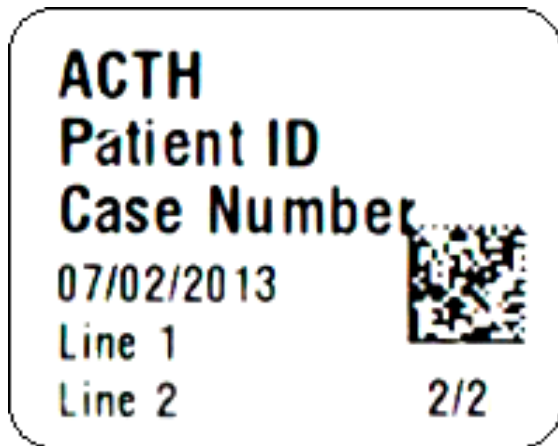


Image 97

Protocol Name

Patient Identification

Case Number

2D Bar-Code

Date


Text line 1

Text line 2

5.5.3 Save all the personalizations

Click in **"Save all the personalizations"** so permanently save all the modifications of the current protocol in the Protocol Editor.

This action will keep all the modifications of the protocol for all the protocols of each type, including: HRP, HRP Super, AP, AP Super, double staining, FISH, CISH, CISH + IHC.

 The personalizations previously saved will be overwritten. Therefore, the user must verify all the modifications of the current protocol in the Editor of Protocol before proceeding.

The user can restore the protocols and the protocols' personalizations saved clicking in **"Update protocol"** in the Protocol Editor.

5.6 Network

Connect different systems to a PC / main server in the "Red" tab.

The systems connected through the local read can print with a specialized printer in the PC / main server and share records of 2D bar-code labels. The labels printed in a system / PC in the red can be used equally in all the other systems of the Network.

Contact your provider to set up the Network and connect the existing systems to the Network.

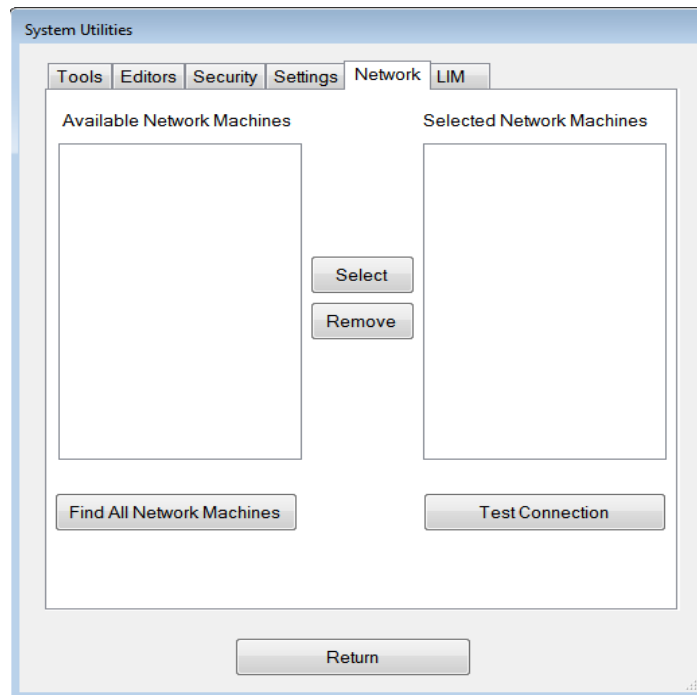



Image 98

All the systems connected to the Network are shown in Available network machines.

The network system(s) connected to the current system will appear in the Network Machines selected.

 To avoid unexpected errors, please, make sure that all the machines in the network are connected to the network during the instrument functioning.

To check the connection to the network, click in "Test Connection" to verify whether the system is correctly connected to the selected network / PC of the main server.

If no connection is detected, verify that all the systems are connected to the read and they have been joined to the group in the local network. Check the configuration of Windows in Control Panel > Network and Internet.

To print from a network printer, go to the tab "Settings" and click in "Bar-code Format".

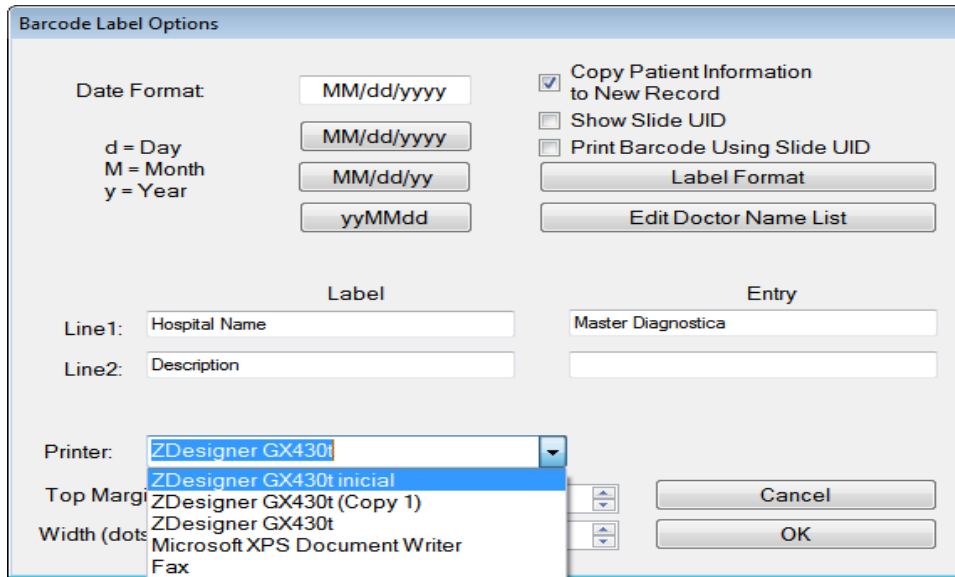


Image 99

Select the network printer in the drop-down list of the printers. The printer name will be preceded by the name of the system in the network. Change the format options of the label, if needed.

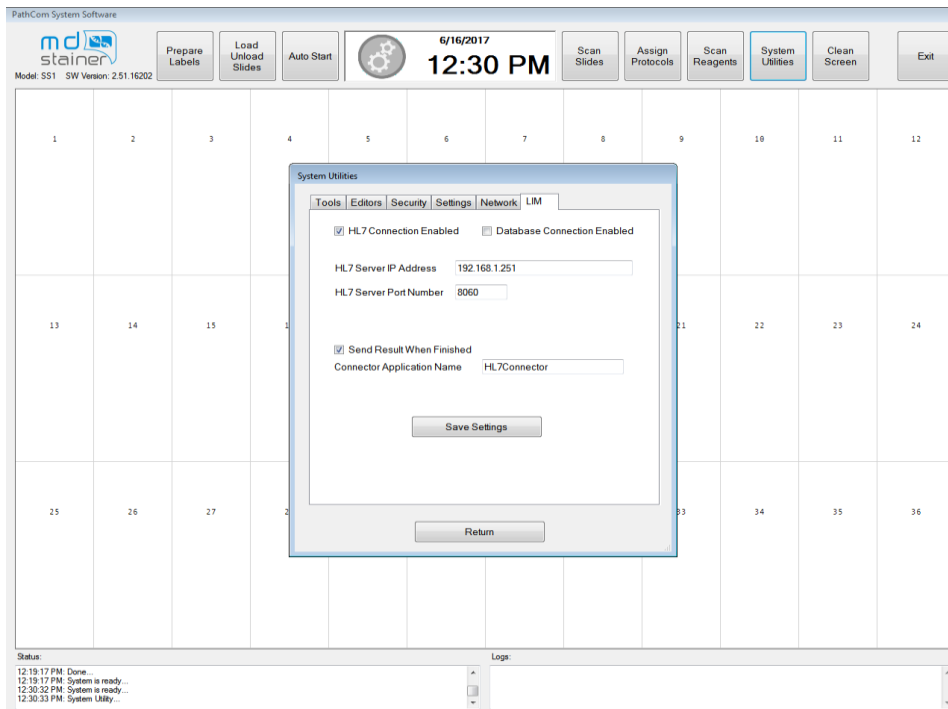
! If the network printer does not appear in the printers' drop-down list, add the network printer to the system in devices of Windows / printers and share the printer.

! Do not share more than one printer in the network. Deactivate the other shared printers, as many of them cause unexpected errors.

Note: If a printed label is not recognized, make sure that all the systems are connected to the network, as this will guarantee that the recording of the printed labels is up-to-date in all the systems.

5.7 LIM

The system supports the SS1 connection with the server HL7 and the connection of MSS database.



If you need to connect the MD-Stainer with any other laboratory management software or other type of platform, contact your provider.

SECCIÓN 6 Reagents Vials

All the reagents are provided in a "ready to use" format in vials of 15 ml, and appropriately labelled with all the necessary information.

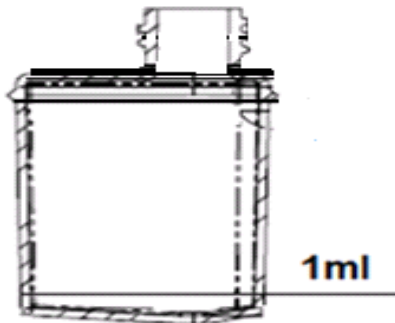


Image 100

The dead volume of a vial of 15 ml is ~ 400uL.

The standard volume for each test is 130uL

The minimum volume for a test is 530uL (volume for the test plus the dead volume)

Note: *If you need any new reagent or you need to do any other type of tests, check the equipment provider.*

SECCIÓN 7 Staining Area

In order to guarantee the quality and reliability of staining, the slides must be prepared with its respective tissues following the guidelines of the staining area of the system MD-Stainer.

Refer to the diagram of a slide of 1 mm series in the Image 47. The area highlighted in yellow is the staining area. The circle area is the placing area recommended for the tissue.

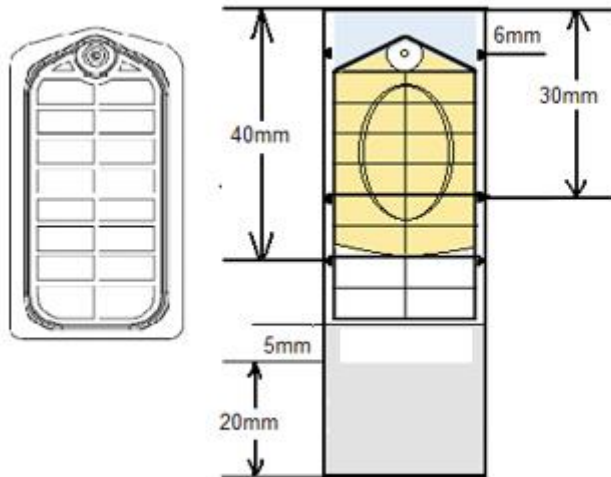


Image 101

SECCIÓN 8 Preventive Cleaning and Maintenance

8.1 Cleaning Recommendations

8.1.1 Modules and modules' plate

The modules must be cleaned on a daily basis to delete the rests of reagents and/or avoid the accumulation of salt (specially important for ISH).

1. Download all the slides of the system.
2. **It is recommended to use absorbing**, soft, paper cleaning the excess of liquid that is left after the Staining cycle both on the modules as well as around them.

8.1.2 The washing station and probe Z1 / Z2

In the upper surface of the **washing stations** and in the **probes Z1/Z2** rests of salt and reagents can be also accumulated with the functioning of the equipment. Clean the wastes with a cotton wool / towel damped with alcohol.

8.1.3 Pipette

The pipette corresponding to Z2 can accumulate wastes of DAB, Hematoxylin and other reagents with the functioning of the equipment. Regularly the visual inspection of the pipettes, both Z1 and Z2, is recommended, as well as cleaning them as needed.

Routine cleaning procedure:

1. Load the reagents' rack especially with the cleaning solutions for Z1 and Z2.
2. Place the rack in the system.
3. Connect the fluid system (Washing buffer).
4. Access from the main screen to the "System", click in "Tubes Cleaning".
5. Follow the instructions below:
 - Place the cleaning solution Z1 in the position # 1 of the reagents' rack as indicated in the image.
 - Place the cleaning solution Z2 in the position # 5 of the reagents' rack as indicated in the image.
 - Click in "OK" to start the cleaning of the tubes.

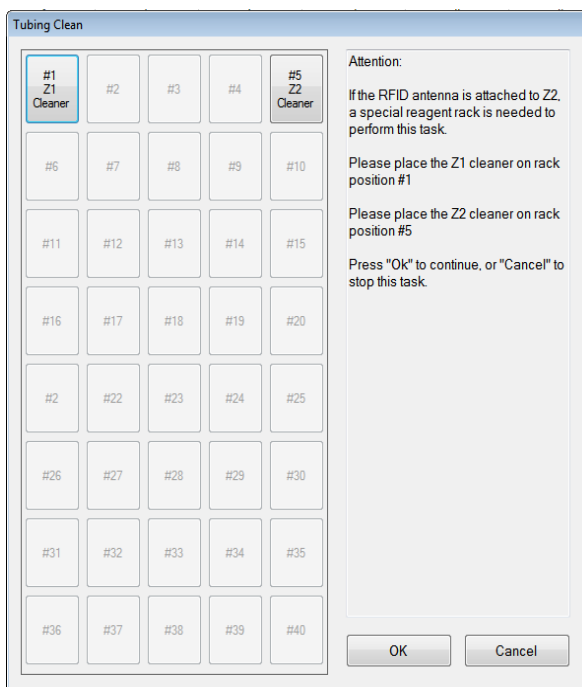


Image 102

The probes Z1 and Z2, both aspire 5 ml of cleaning solution for each one of the vials placed in their respective positions of the reagents' rack. Then, the system will start a countdown of **20 minutes**.

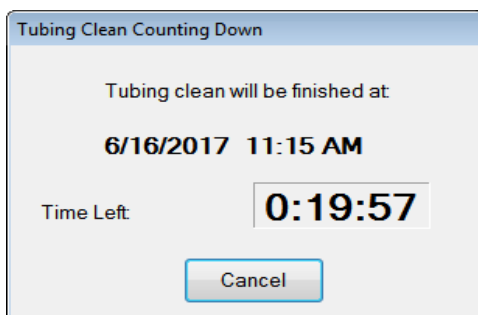


Image 103

After 20 minutes, **the system will automatically make an initialization** of the system and will purge the wastes of the cleaning solutions. Click in "Cancel" in any moment to immediately purge the pipe wastes.

8.1.4 Chamber

The chambers must be regularly cleaned to eliminate the residual stains accumulated during the staining cycle.

Routine cleaning procedure (it is recommended after each staining cycle):

To avoid the accumulation of salts and wastes of reagents, clean the surfaces of the cameras with a cotton wool/towel dampened with alcohol after each staining cycle.

Note: The user does not have to take the cameras off the modules to carry out this cleaning procedure.

Deep cleaning procedure (it is recommended after each 3-5 staining cycles):

Carry out a deep cleaning of the cameras using 1/10 diluted bleach:

1. Prepare the solution of 1/10 diluted bleach in a cuvette.
2. Take out all the incubation cameras of the modules and place them in the diluted bleach solution. Maintain for 30 minutes.

Note: *If after 30 minutes you can see that any of them is not completely clean, keep it for a longer period.*

3. Withdraw the cameras from the bleach solution and clean/dilute 3 times in distilled water.
4. Dry with absorbing paper.

Note: *While the cameras are being dried with absorbing paper, the user must check the status of these. In case of detecting any anomaly, replace the camera for a new one.*

5. Once all the previous steps have been finished, place the cameras in the modules again.

Note: *There is no need to place the cameras in the position in which they were before.*



Image 104

8.2 Routine Preventive Maintenance

It is necessary to carry out the routine preventive maintenance, to maintain reliability, the shelf life of the equipment and the quality of the staining.

A routine preventive maintenance programme includes:

1. Cleaning of the Modules and Modules' plate (Daily), following the recommendations of the provider previously mentioned.
2. The regular inspection of the cameras (Weekly) looking for cracks, leaks, the degradation of the camera's surface.
3. The visual inspection of the modules and robot and the verification of their right functioning (Monthly).
4. The visual inspection of aspiring/dispensing pipes and wastes aiming at detection anomalies, as precipitates, breaks (monthly).
5. Check the wrong functioning of the heaters after receiving a temperature warning (High Temperature/ Low Temperature). Check page 54 "Check if there is wrong functioning of a heater".

Note: Contact your provider of MD-Stainer for any detected anomaly or for the supply of replacement parts and consumable materials.

8.3 Annual Preventive Maintenance.

The annual report must be performed in all the system by a qualified technician. Contact your provider of MD-Stainer to program such annual maintenance.

SECCIÓN 9 General Precautions

Make sure that the slides are placed in safe way in the module – the slide must be pressed against the spring in the rear part and held in the front part by the contact clamps.

Place the reagents' rack firmly in its position before initiating a staining cycle.

Withdraw the buffers of the reagents' vials before initiating a staining cycle.

Keep the door closed during the functioning. The robotic arm moves unexpectedly during the operation - remain away. Do not put the movement of the robotic arm in danger in any way.

Contact your provider of MD-Stainer before using reagents and solutions provided by other suppliers. Some dissolvents, acids and other solutions, can cause damages to the internal components of the MD-Stainer and affect the performance and guarantee of its instrument.

Use disposable gloves and protection laboratory clothes when handling reagents.. The reagents can be harmful and irritating to the eyes, the airways and the skin. They can be harmful to the lungs and stomach if ingested. The data sheet will be provided by the reagents' provider.

The wastes of hazardous reagents must be eliminated according to the local and governmental regulations. Use the appropriate personal protection equipment to avoid the exposure.

Do not perform different tasks whilst the instrument is working. The multi-task is defined as executing other software applications, which are not necessary for the functioning of the equipment (including CD players and screen protectors). This may block the instrument.

Deactivate the automatic updating of Windows and other programs in a second level while the instrument is working.

Deactivate the connection to local Internet / Wireless while the instrument is working.

Do not modify the energy options of Windows or install a screen protector. The equipment may turn off unexpectedly while the instrument is still functioning or it may block the instrument.

Do not install any software or hardware products of third parties. The installation of products of third parties may block the instrument and cancel the guarantee.

Do not make any hardware or software changes before checking with your MD-Stainer provider.

Do not use an USB cable of 3-meter length.

Restart the equipment if:

- 1) The USB is disconnected. Always connect the USB cable to the USB designed port.
- 2) The power supply for the instrument is on / off or disconnected.
- 3) The equipment is in suspension or hibernation mode.
- 4) The user finds an unexpected error.

Do not try to fix the MD-Stainer, unless your MD-Stainer provider indicates it. If you do so, the guarantee will be voided.

Do not relocate the MD-Stainer system inside its installations before contacting your MD-Stainer provider to obtain information. This may affect the guarantee.

SECCIÓN 10 Translation of Warnings in screen or reports

The MD-Stainer software can show warning messages in the screen. These messages will appear in English below, you can find their translations into Spanish.

Warning / Aviso [TaskNumber.Error]	Meaning	Translation
TaskNumber.Agitation Up	Error occurred during module agitation at the specified task number.	Problema detectado durante agitación del módulo en el paso especificado
TaskNumber.Aspirate	Error on Pump2 during aspiration of waste from module at the specified task number.	Problema en la bomba 2 durante la aspiración para eliminación en la tarea especificada
TaskNumber.Aspirate Gap	Error on Pump2 during aspiration of air gap at the specified task number.	Problema en bomba 2 durante la aspiración de aire
TaskNumber. Deliver	Error occurred during reagent delivery to the slide at the specified task number.	Problema detectado durante la dispensación de reactivo en el porta
TaskNumber. Extract	Error occurred during reagent extraction from the slide at the specified task number.	Problema detectado durante la extracción del reactivo del porta
TaskNumber.Get Reagent	Error occurred while getting reagent from the vial at the specified task number.	Problema detectado durante la obtención de reactivo desde el vial
TaskNumber. High Temperature	The module temperature is higher than expected at the specified task number.	La temperatura del módulo es más alta de lo esperado
TaskNumber. Incubation Start	Timeout error occurred while waiting for the incubation to start at the specified task number.	Tiempo excedido detectado en el inicio de la incubación
TaskNumber. Incubation Stop	Timeout error occurred while waiting for the incubation to stop at the specified task number.	Tiempo excedido detectado en la detención de la incubación
TaskNumber.Insufficient {ReagentName}	The liquid detection system detected an insufficient volume of reagent in the vial at the specified task number.	Reactivo insuficiente detectado en el vial indicado
TaskNumber. Low Temperature	The module temperature is lower than expected at the specified task number.	La temperatura del módulo indicado es menor de la esperada
TaskNumber.Not Detected	The liquid detection system did not detect reagent in the vial at	Reactivo no detectado en el vial indicado

	the specified task number.	
TaskNumber.Pump1 Air Gap	Error on Pump1 during aspiration of air gap at the specified task number.	Problema en la bomba 1 durante la aspiración en el Gap en la tarea especificada
TaskNumber.Pump1 Dispense	Error on Pump1 during reagent dispensation at the specified task number.	Problema en la bomba 1 durante la dispensación en la tarea especificada
TaskNumber.Pump1 Set Speed	Error occurred while setting the speed parameter on Pump1 at the specified task number.	Problema en el ajuste del parámetro de la velocidad en la bomba 1 en la tarea especificada
TaskNumber.Pump Speed	Error occurred while setting the speed parameter on the Pump at the specified task number	Problema en el ajuste del parámetro de la velocidad en la bomba en la tarea especificada
TaskNumber.Robot HV Position	Error on the Robot while moving to a horizontal and vertical position at the specified task number.	Problema en el robot durante el movimiento a una posición horizontal y vertical en la tarea especificada
TaskNumber.Robot Position	Error on the Robot while moving to a position at the specified task number.	Problema en el robot durante el movimiento a una posición en la tarea especificada
TaskNumber. Robot V Position	Error on Robot while moving to a vertical position at the specified task number.	Problema en el robot durante el movimiento a una posición vertical en la tarea especificada
TaskNumber.SP Extract Position	Error on Module while moving to the Extract position at the specified task number.	Problema en Módulo durante el movimiento a la posición de extracción en la tarea especificada
TaskNumber.SP Position	Error on Module while moving to the required position at the specified task number.	Problema en el Módulo durante el movimiento a la posición requerida en la tarea especificada
TaskNumber. Special Agitation	Error occurred during module special agitation at the specified task number.	Problema detectado durante la agitación especial del módulo en la tarea especificada