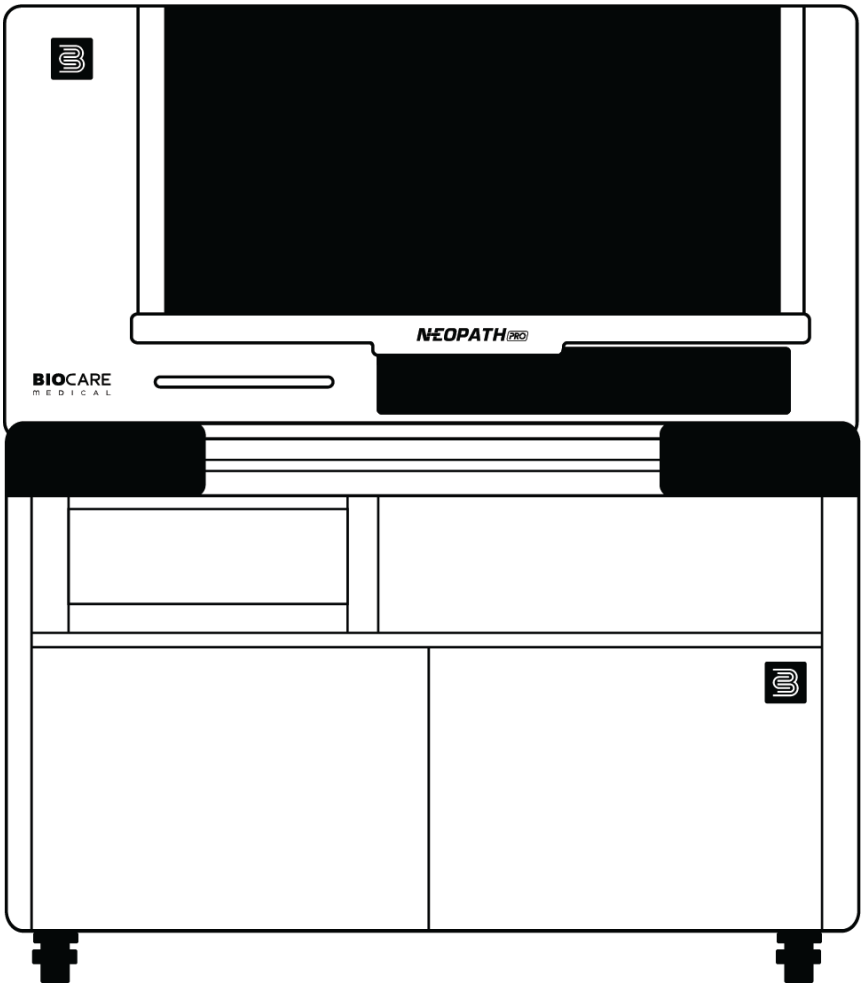
NEOPATH PRO
User Manual



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1 Intended Use

For *in vitro* diagnostics. Instrument for automated histological staining of formalin-fixed, paraffin-embedded tissue sections (FFPE). The instrument is designed for use in clinicopathological and physiological situations requiring the analysis of associated biomarkers. This platform is designed to be operated by qualified professionals trained in immunohistochemistry (IHC) techniques in histopathology-related laboratories.

2 Principle Method

Immunohistochemistry is a procedure that aims to detect, amplify and visualize the presence of an antigen by binding to a specific antibody and revealed through a colorimetric enzyme-linked immunosorbent reaction, allowing the presence and localization of the antigen in the tissue to be observed by microscopy. The NeoPATH Pro performs the protocol in an automated way, focusing on four main steps:

- Tissue deparaffinization: First, paraffin is removed from FFPE tissue sections.

- Antigen retrieval induced by heat or enzyme digestion: Once the sample is deparaffinized, an antigen retrieval step is performed to expose the antigen by high temperature or enzymatic treatment. This can be done at different pH values with Low-AR or High-AR reagents depending on the antibody used.

- Detection and Development: Once the antigens have been unmasked, the primary antibody is added, which will bind specifically to the antigen under evaluation. Subsequently, a secondary antibody bound to an enzyme allows visualization of the binding site through an enzymatic reaction that generates a colored product.

- Counterstaining: Finally, the nuclei are stained with hematoxylin to contrast the tissue and identify tissue and cellular structures. Once finished, the stained tissue section is covered with a coverslip and permanent mounting medium for microscopic visualization.

3 System Specifications

3.1 General specifications

The NeoPATH Pro consists of the following parts:

Slide Rack. It contains 42 reaction chambers to place the slides and perform the techniques. Each of them has an LED to indicate its status.

Slides: slides treated for use in immunohistochemistry or hybridization techniques should be used, preferably positively charged slides or silanized slides, whose recommended dimensions are 25 mm x 75 mm x 1 mm.

Reagent Vial Rack. It contains space for 7 reagent racks. Each of them contains a capacity of 8 reagent vials. There is a cold table under the rack in order to keep the reagents at a lower temperature. Temperatures are controlled and parameterizable.

Bulk Flask Containers The instrument has 6 flasks with a maximum capacity of 2 liters, with the reagents required for the different processes. The layout is as follows from left to right:

- Flask 1: contains COVER.
- Flask 2: contains DEWAX.
- Flask 3: contains DAB ENHANCER.
- Flask 4: contains HIGH-AR.

- Flask 5: contains DEWAX-2.
- Flask 6: contains HEMATOXYLIN.

Large Bulk Containers The instrument has 2 bottles with a maximum capacity of 25 liters, with the reagents required for the different washing processes. The layout is as follows:

- Bulk 1: contains WASH BUFFER.
- Bulk 2: contains CLEANING SOLUTION.

Waste Containers. The instrument has 2 containers with a maximum capacity of 25 l. to store the waste generated during run and maintenance. The layout is as follows:

- Waste 1: Hazardous Waste.
- Waste 2: Non-hazardous Waste.

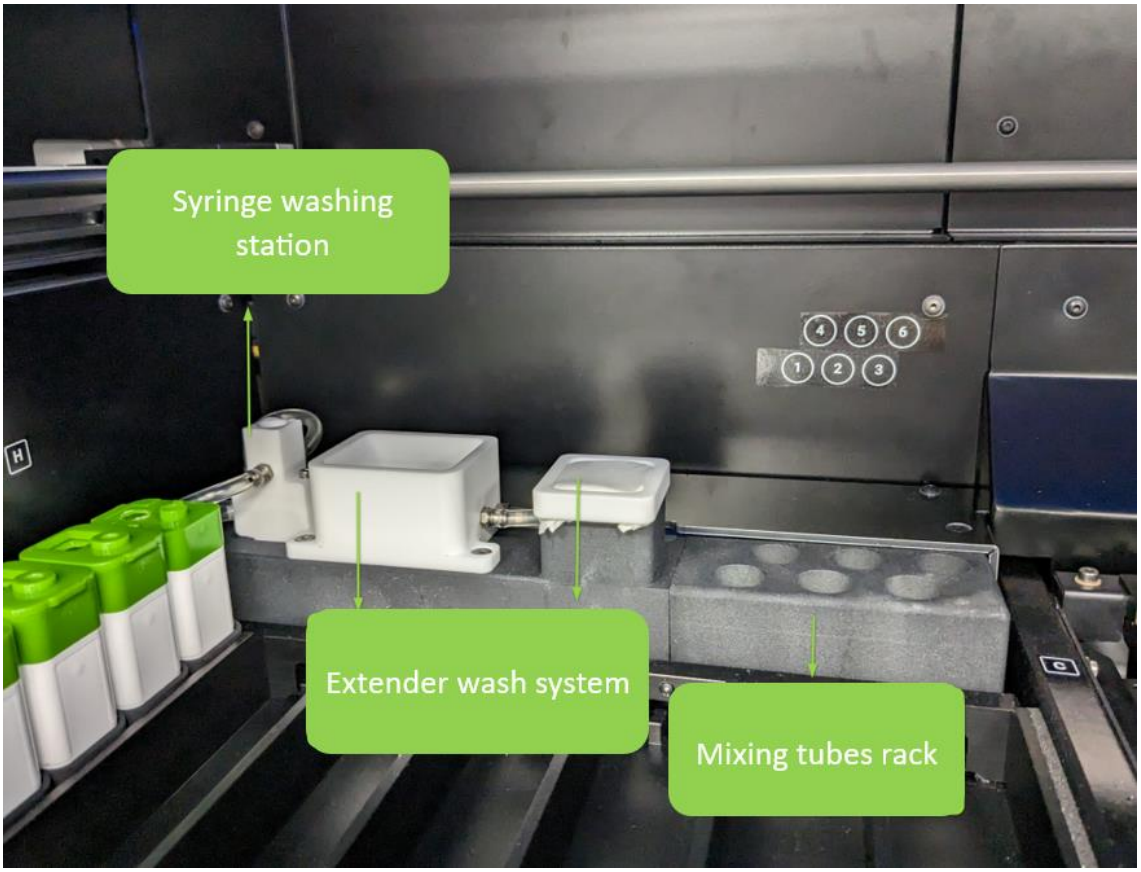
NeoPATH Pro generates 5-6 liters of waste per run of 42 immunohistochemistry tests. This represents approximately 130 milliliters of waste per test. Of the total waste, approximately 60% is non-hazardous waste and the remaining 40% is hazardous waste.

Handling of this waste must be carried out in accordance with current legislation and local regulations and with the involvement of an authorized waste manager if necessary. The waste containers are not designed for the transport of hazardous waste (**DO NOT hand over** to the authorized waste handler). An approved hazardous waste container must be used to store and transport hazardous waste.

Syringe Wash Station. The instrument will simultaneously wash the inside and outside of the reagent probe. It has an anti-overflow safety system due to blockages in the hydraulic waste circuit.

Spreader Washing Station. This is a bathtub style wash station for complete washing of the spreader roll with a drying area for the spreader roll and an anti-overflow safety system due to blockages in the hydraulic waste circuit.

Mixing Vial Rack. It contains space to place up to 6 mixing vials where the system will automatically perform the DAB and AP mix.

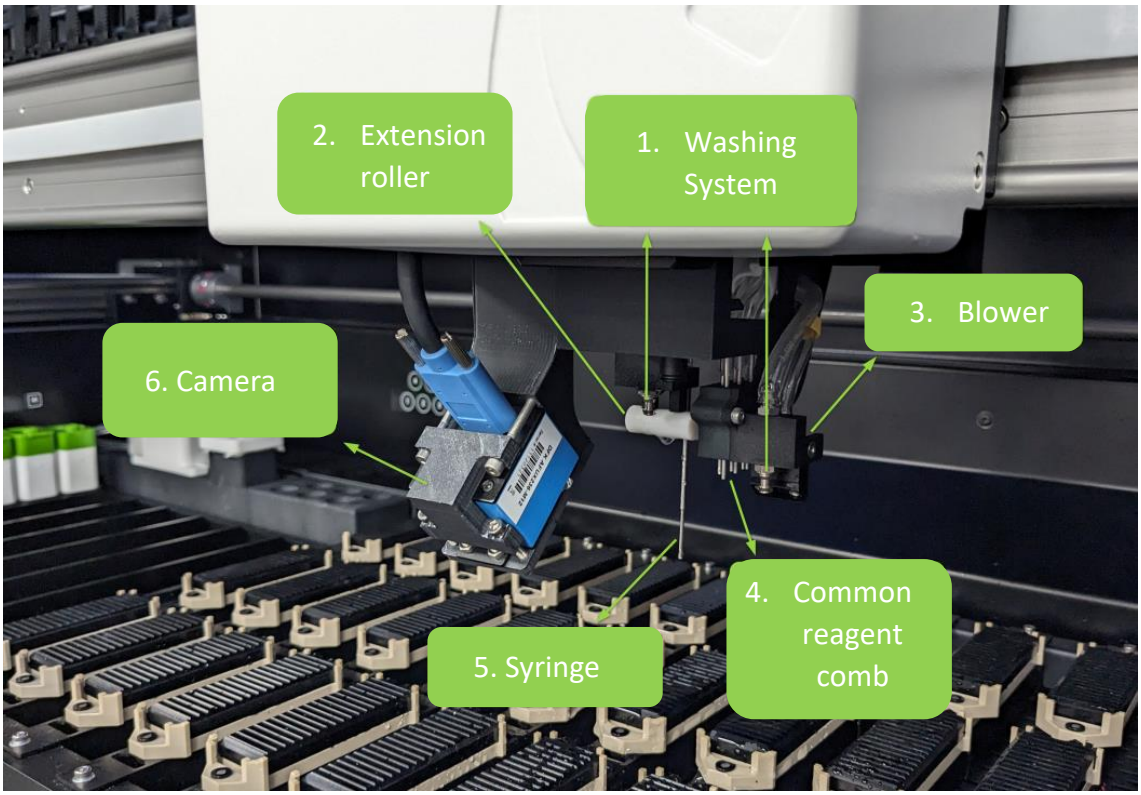


Waste Tray. It receives all reagent waste and has a drainage system that allows for the separate removal of hazardous and non-hazardous wastes into the corresponding waste. It has an anti-overflow safety system due to blockages in the hydraulic waste circuit.

Robotic Arm. The arm will move in the XYZ axis and will have the following components:

1. Spreader roller. Allows to spread very viscous reagents on the preparation. Intended for ISH testing
2. Slide washing system with Washing Solution or Buffer.
3. Air Blow Head to remove reagents located on the slide.

4. Reagent Comb. A cluster of 6 probes connected to the bulk flask containers whose purpose is to take the reagents from the flasks and dispense them onto the samples.
5. Reagent probe. Its purpose is to collect the individual reagents from the vials and dispense them onto the slides.
6. Camera. The camera has the following functions.
    - Determine the position of each element read.
    - Detect the correct positioning of the slides.
    - Scan labels on slides and vials.
    - Register slides and vials if the code contains all the necessary information.
    - Detect the existence or absence of the vials and whether they are open or closed.
    - Detect mixing tubes

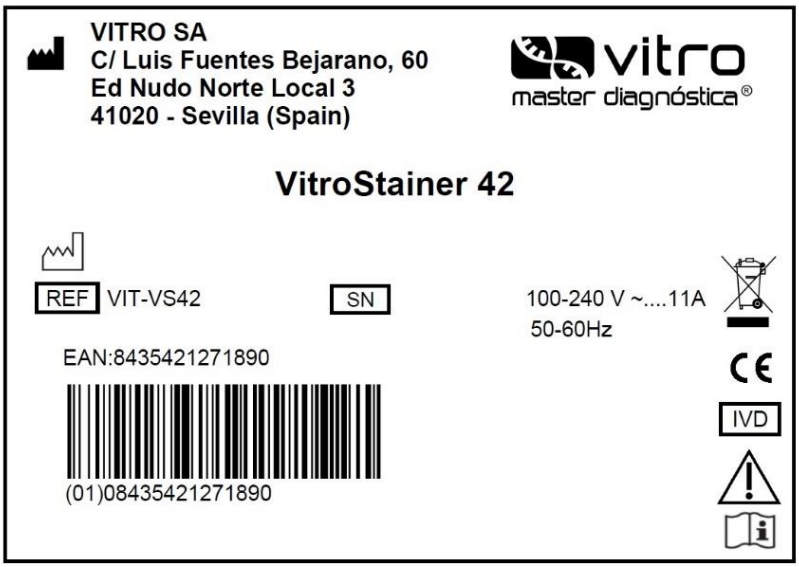


Printer. The instrument includes a ZEBRA printer with all the accessories to print slide labels.


LDPE

3.2 Technical specifications

Equipment labeling for Legal Manufacturer label



Labeling for NEOPATH PRO to be Provided by Purchaser (dimensions: 3” x 5”):

New Instrument Label: RMNPP30001 REV A

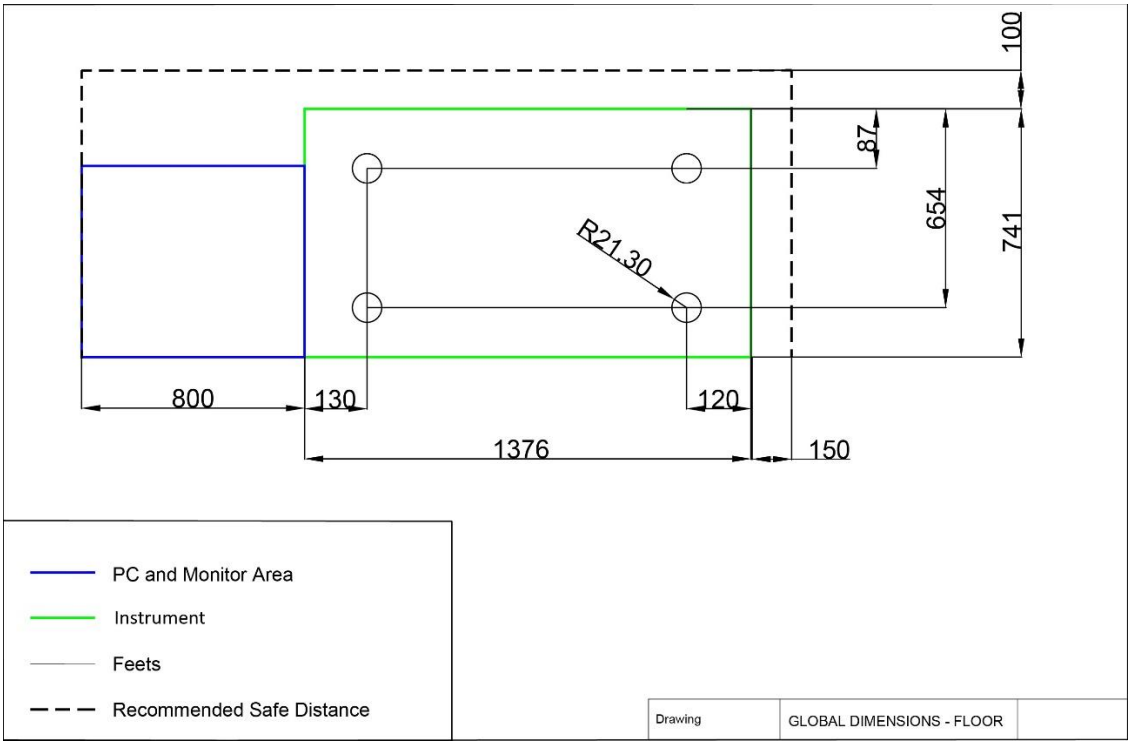
Refurbished Instrument Label: RMNPP30002 REV A

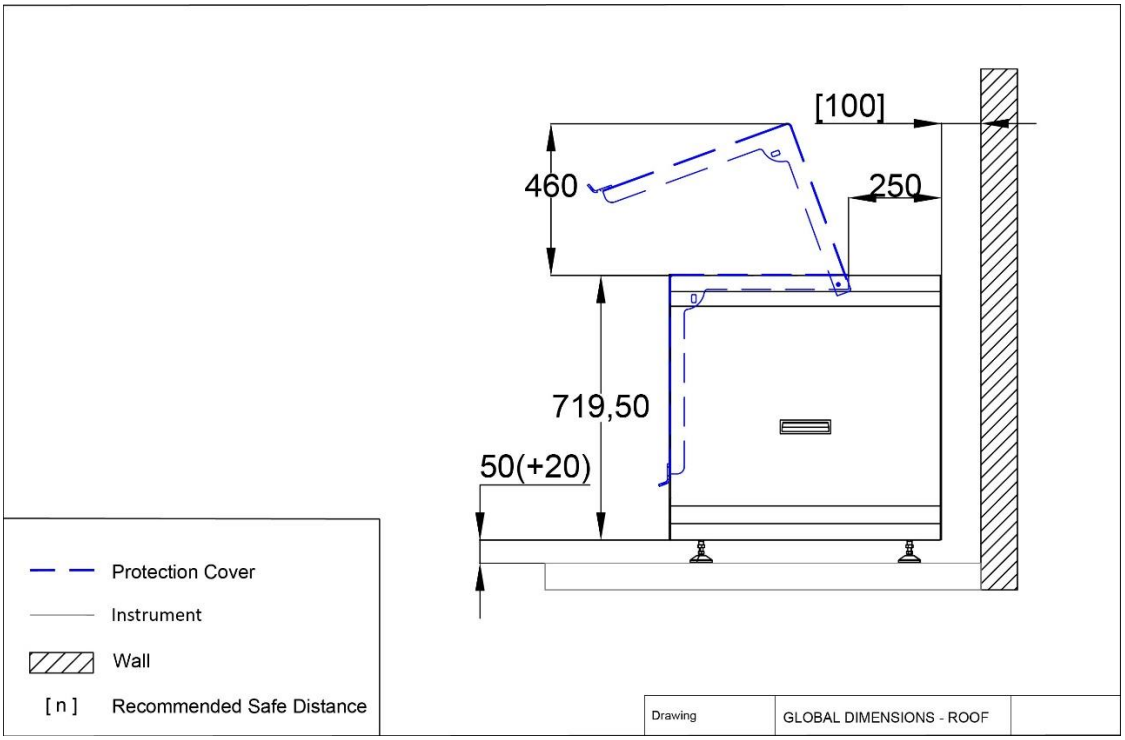
Label symbols

IVD	Medical device for in vitro diagnostics		Date of manufacture
	Manufacturer	SN	Serial number
	Waste electrical and electronic equipment (WEEE)	REF	Catalog number
	Caution (contains hazardous waste)		Please refer to the instructions for use
~	Alternating current		Distributor

Space Requirements

The following spaces must be available around the equipment:





Item	Width	Depth	Height
NeoPATH Pro	1376 mm (54.17”)	741 mm (29.17”)	1229.5 mm (48.41”)
PC & Computer	800 mm (31.50”)	-	-
Recommended Safe Distance	100 mm (3.94”)	100 mm (3.94”)	-

Weight

- 150kg (331lbs) - Benchtop model
- 260kg (574lbs) - Floor model with Dock Accessory

Electrical requirements

- Frequency: 50 to 60 Hz
- Voltage: 100-240 V (Universal input)
- Current rating: 5.5 A for 220-240 V
- Current rating: 12 A for 100-110 V
- Power consumption: 1100W maximum
- Standby power consumption: 0,06 kWh

Storage Conditions

- Temperature requirement: -20º - 50ºC

Operating Conditions

- Temperature requirement: 5º - 32º C
- Operating Altitude: Up to 2000 m
- Humidity: 40% - 80%

Warranty

The NeoPATH Pro warranty is for one year (12 months) from receipt of purchase and covers all parts and labor when performed solely by Biocare Medical, LLC. Warranty is invalidated if equipment is abused, damaged, or improperly maintained by customer. Warranty is not transferable to any other party should the equipment be resold or transferred by the customer to another party. To the extent permitted by law, Biocare Medical, LLC disclaims any liability for any incidental or consequential damages related to this equipment or for any warranty-related services it performs.

Safety Warning Labels

Warning labels posted on the NeoPATH Pro and in this manual warn you about sources of potential injury or harm. A key for each safety warning label is referenced in the Table.

Icon	Meaning

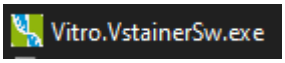
	**CAUTION**: contains hazardous waste
	**CAUTION**: Risk of electric shock! This symbol identifies components of the instrument that pose a risk of electric shock if mishandled.
	**CAUTION**: Hot surface! This symbol identifies instrument components that pose a risk of personal injury due to excessively high temperature if handled improperly.
	**CAUTION**: biohazard
	***CAUTION**: Pinch/Catch Point! This symbol identifies instrument components that may pose a risk of personal injury when moved.*

4 INSTRUCTIONS FOR USE

4.1 Turn on and start the system

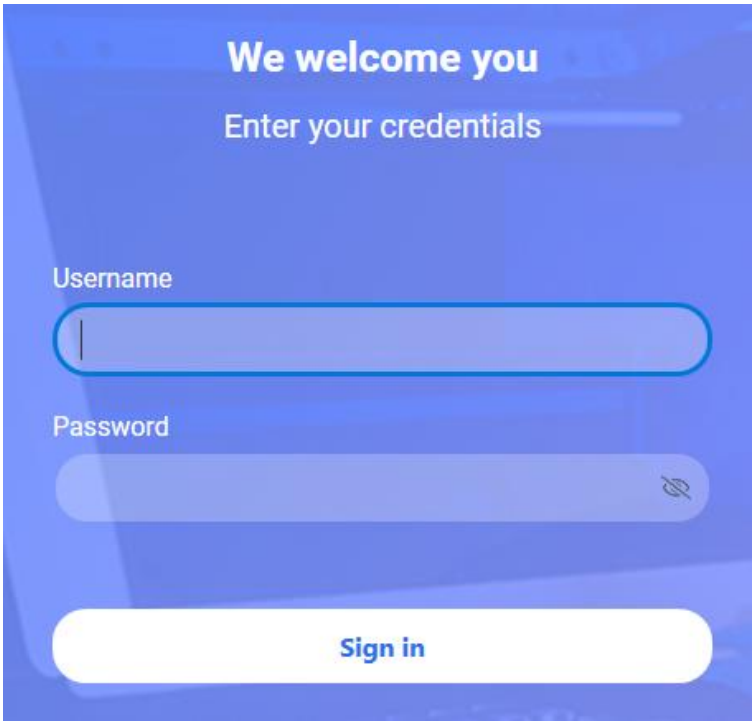
Turn on the system. To do this, press the power button located at the bottom right front of the instrument.

Turn on the label printer.

Turn on the computer and log on to the system. From Windows, double-clicking on the icon 

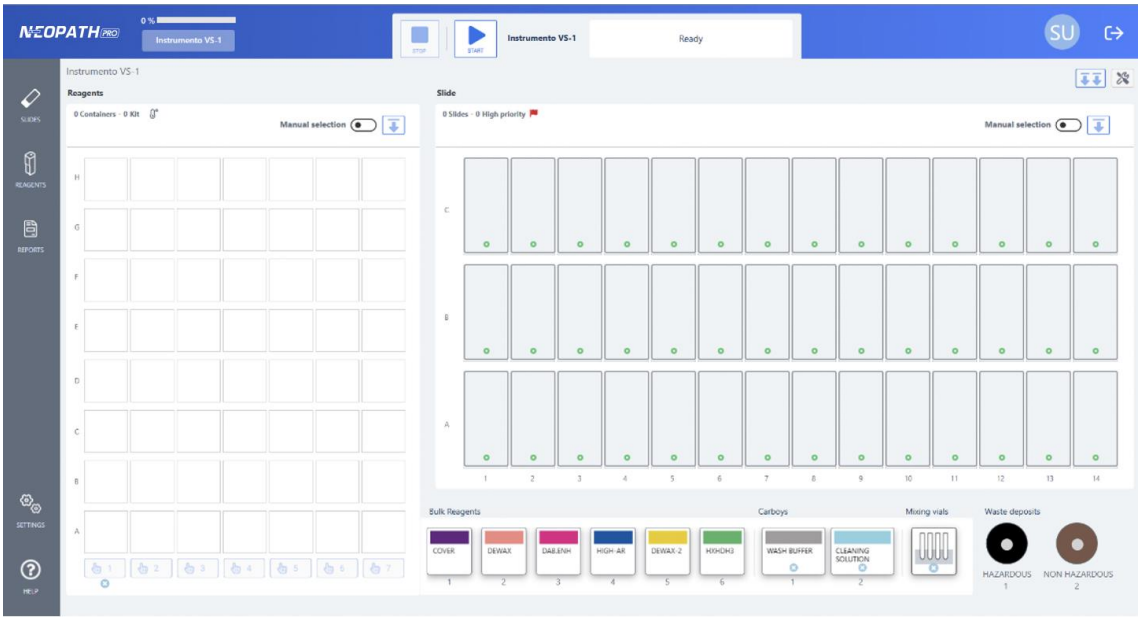
the VStainerSW application access window opens, where the user and password fields must be filled in and the "Log in" button must be clicked to open the application.

Before logging in, you have the option to configure the home screen, rather than the application itself, in either English or Spanish. To do so, you'll need to select the language in which the home screen will be displayed from the drop-down menu.



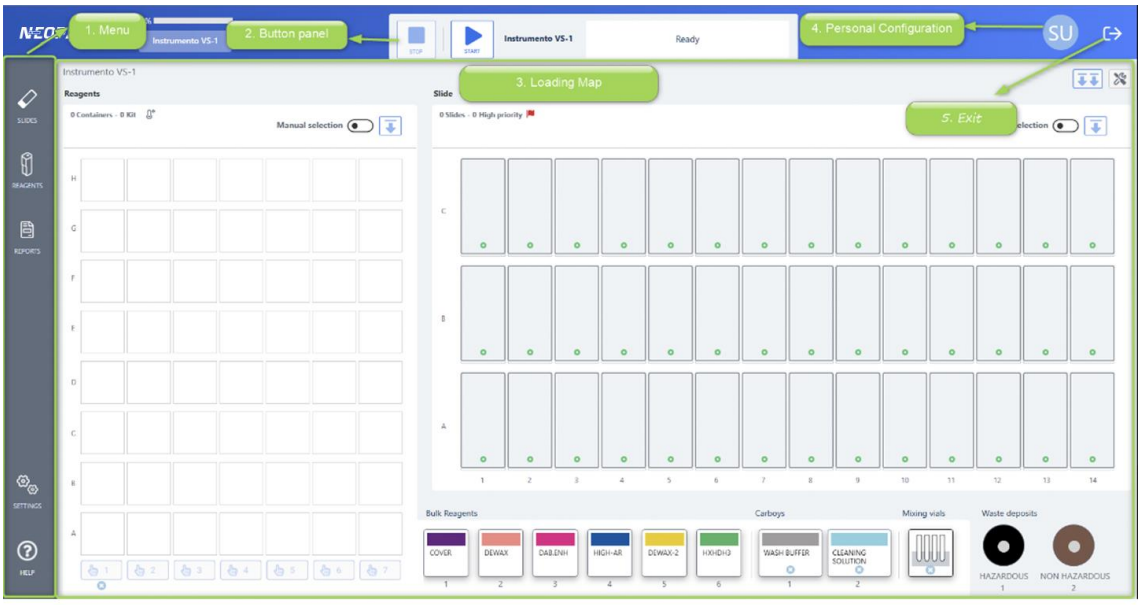
When the application is opened, after entering the appropriate login credentials, it will connect to the instrument and initialize it.

Certain permissions will be available depending on the role of the user accessing the application.



4.2 Screen Layout

The following is a brief description of the elements that make up the main screen that is displayed when the application is opened:

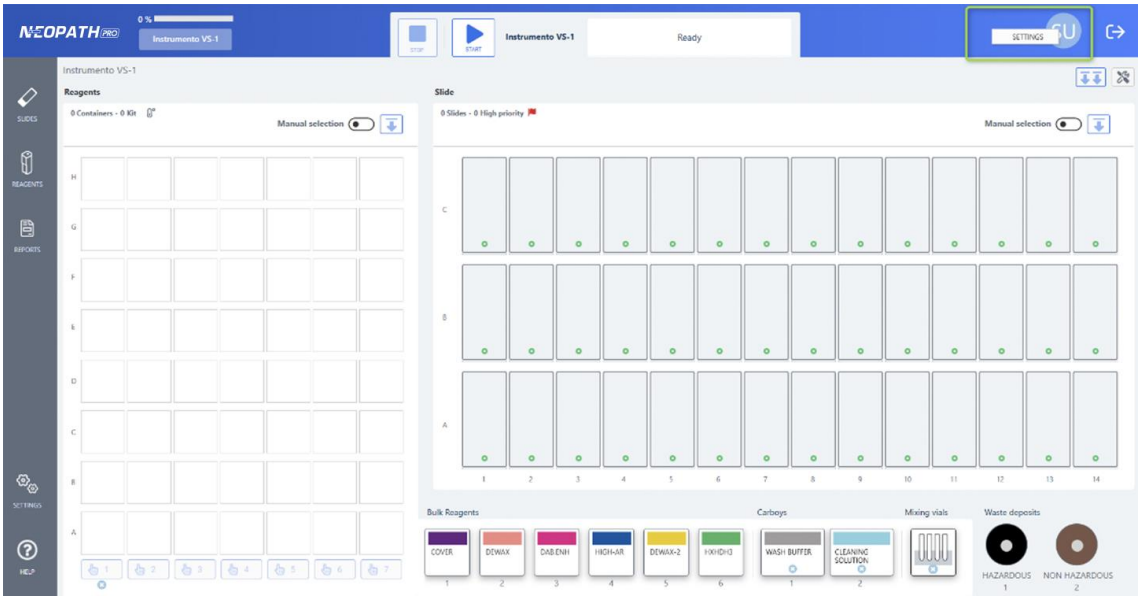


1. **MAIN MENU**. Gives access to each of the essential actions:
    - **SLIDE**: manages pending work and allows the user to create or print labels for lab testing.
    - **REAGENTS:**
        - Inventory management of reagents.

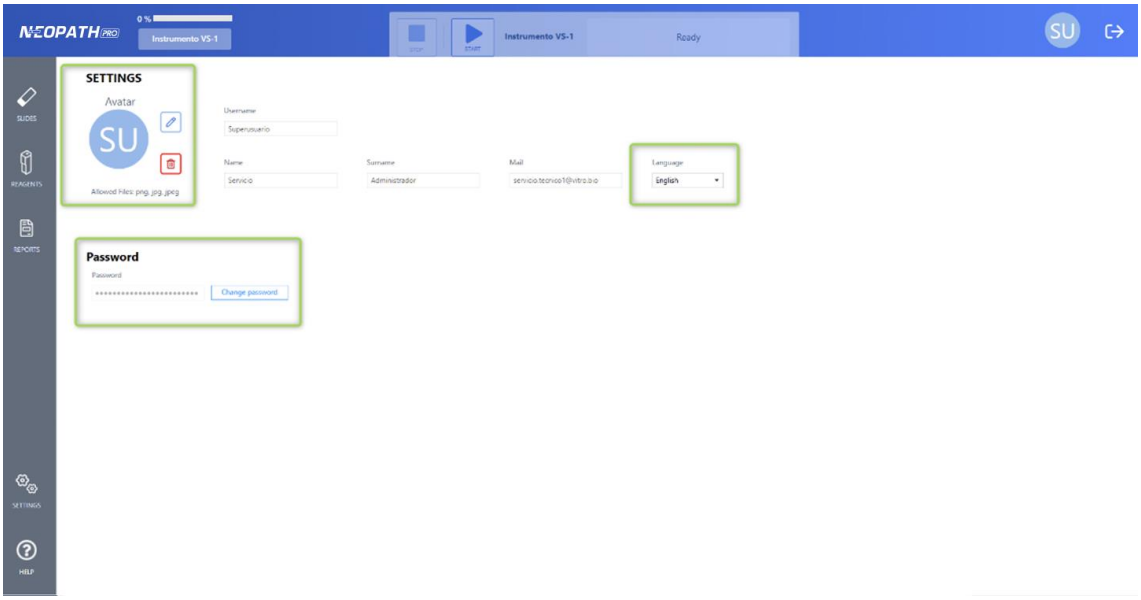
        - Management and configuration of the reagents that can be used in the instrument and their characteristics.
    - **REPORTS:** Access to view and export reports generated by the application. The reports include results from series executions, detailed information about slides and reagents, as well as a log of user activity.
    - **SETTINGS:**
        - Management of the different configuration options at instrument level.
        - Management and configuration of application users.
        - Management and configuration of protocols and techniques.
    - **HELP**: Provides access to a quick start guide and a complete manual for consulting and answering questions about the application's operation and use.
        - Quick Start Guide: Simplified instructions for quick reference of key aspects.
        - Complete Manual: Detailed manual covering all the application's features and settings.
2. **BUTTON PANELS**: control the instrument and initiate the reading and verification of the slides and reagent racks before allowing the start of a run.
   Report on the status of the instrument at any given moment.
3. **MAP.** Presents each physical component of the instrument and its status.
    - Slide rack.
    - Reagent rack.
    - Bulk Flasks.
    - Large Bulk Containers
    - Mixing vials.
    - Waste.
4. **PERSONAL CONFIGURATION**: Manage language, password and personalized avatar.
5. **EXIT**: the "Exit" icon closes the application.

4.3 Personal configuration

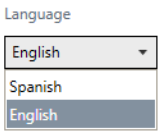
Personal Settings can be accessed from any screen you are on from the profile icon of the user who has accessed the application, by clicking on PERSONAL SETTINGS.



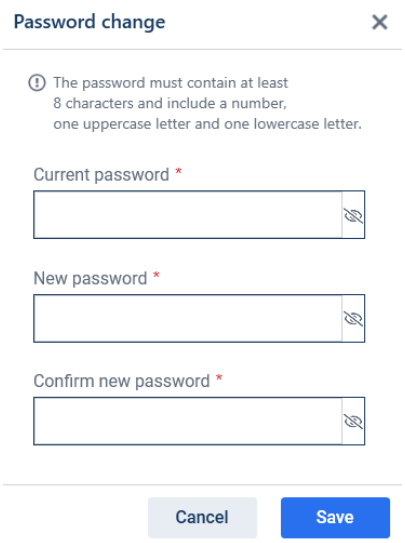
In the Personal Settings window, the user data is displayed. The actions that can be carried out are as follows:



- Change or delete avatar.
  - By clicking on the icon , you will be able to choose the path of the desired image to change the avatar.
  - From the icon , you can delete the currently configured avatar.
- Change language. A selectable list of available languages is displayed. The selected language is the language that is set by default for the user who configures it.

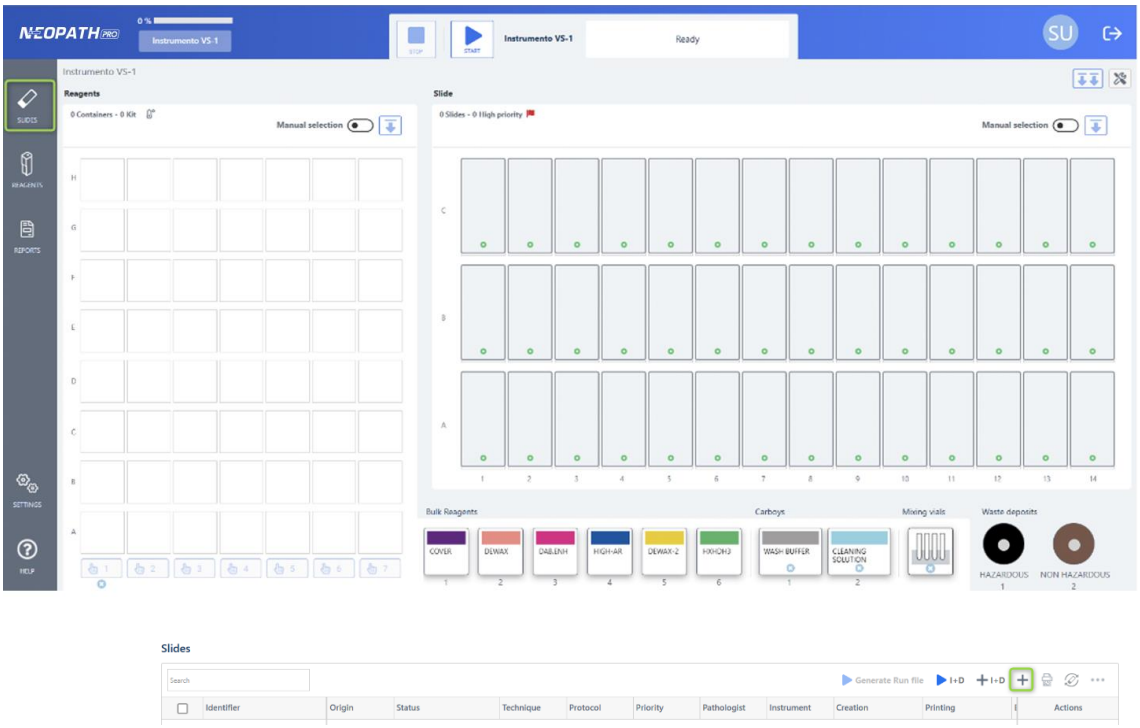


- Change password. When you click on the Change Password button, the following window opens with information about the password requirements and the necessary fields to be filled in to change the password.



4.4 Prepare slides and print labels

Click on the "Slides" button in the main menu to open the slide management module.



The list of slides created in the system will open. To create a new one from this section, click on the "+" button.

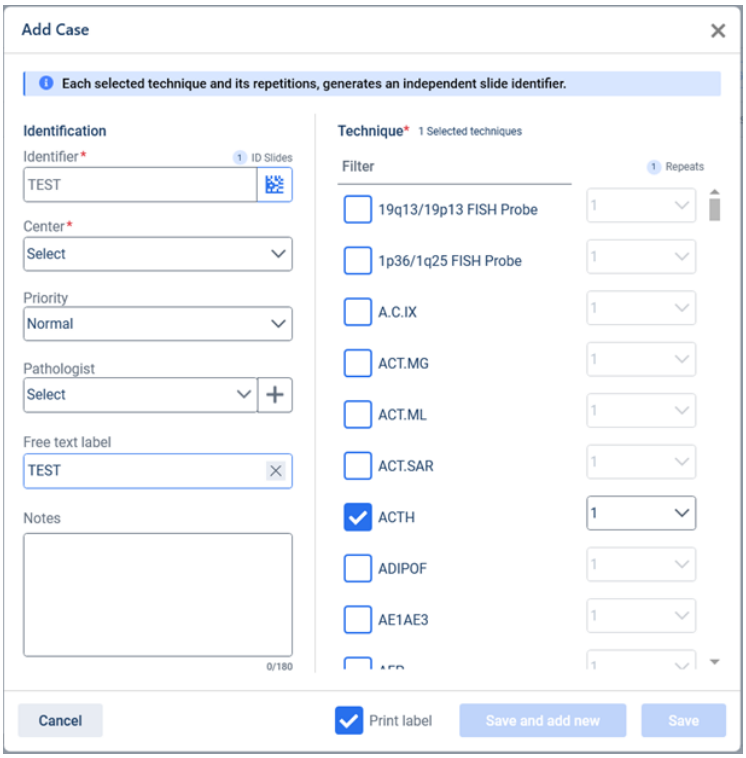
The following fields are available for registering a slide in the system:

- **Identifier:** This field appears blank by default, allowing customization of the slide identification.
- **Priority:** Defaults to "Normal" priority but can be edited to "Urgent."
- **Pathologist:** A pathologist can be created or directly assigned to be responsible for the sample.
- **Technique:** The user must select one or more techniques from the available list, specifying how many times each technique should be performed for the same ID.
- **Center:** This is a mandatory field. If the installation is in single center, the field will not be visible. In multi-center installations, the different centers configured in the system will be displayed.
- **Notes:**
- **Print Labels Checkbox:** Checked by default.

Once the data entry is complete, the user will have the following options:

- **Save:** Saves the created slide and closes the window.

- **Save and Add Another:** Saves the current slide and allows you to continue creating more slides without leaving the window. This makes it easy to quickly enter multiple consecutive slides with similar identifiers.



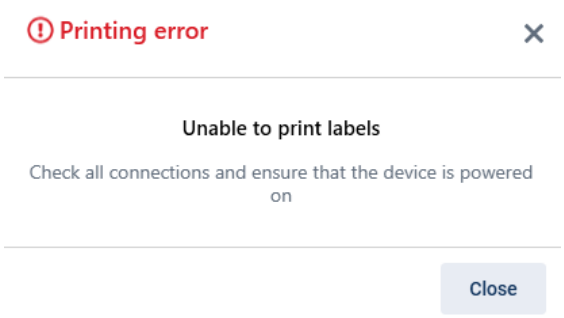
When the user clicks "Save and Add Another," the functionality is similar to the "Save" button, but with one key difference: the modal window does not close, allowing the user to continue entering more slides without having to reopen the window.

The following fields are NOT reset when the button is clicked.

- **Identifier:** The previously entered identifier is retained, making it easier to create consecutive slides.
- **Center:** If the center field is enabled, the entered information will be retained.
- **Pathologist:** The previously assigned pathologist is retained.
- **Print Check:** If the user selected the print option, it is retained.

The following fields ARE reset when the button is clicked.

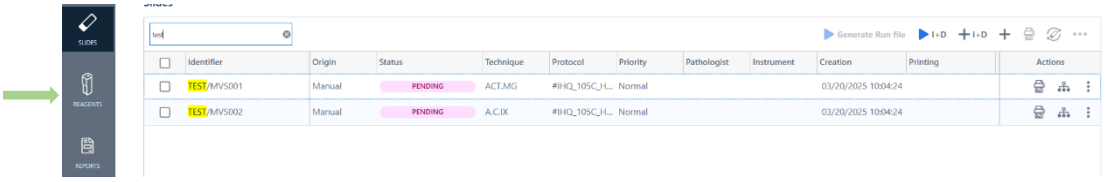
- **Priority:** Resets to its default value, which is "Normal."
- **Technique:** The field is cleared to allow new technique selections.
- **Number of Repeats:** The field is reset to allow new repeats to be entered if needed.
- **Notes Field and Free text label:** The notes field is cleared to be filled again if necessary.



If the label cannot be printed due to a problem with the printer, this message will be displayed. Please ensure that the device is turned on and connected to the computer.

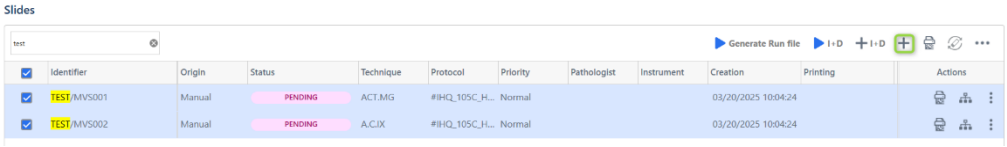
Once the slide has been created, it will appear in the list with the status "Pending" and the following information will be provided:

- Identification.
- Site (only for multi-site installations).
- Origin.
- Status.
- Technique.
- Protocol.
- Priority.
- Pathologist (if the field has been filled out).
- Instrument Name/Serial. This field is only filled out when the camera has read the label.
- Creation date.
- Print date.
- End of staining run.

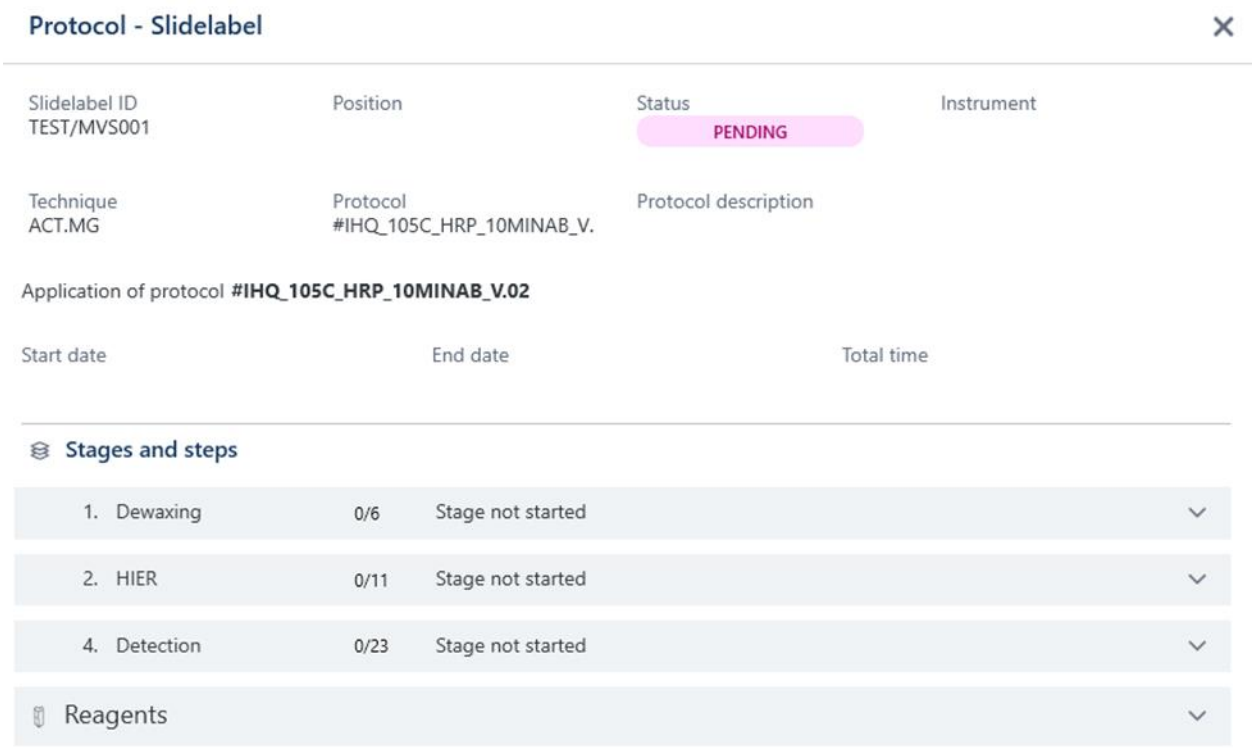


Actions on a pending slide

At the slide level there are different types of actions that can be performed:

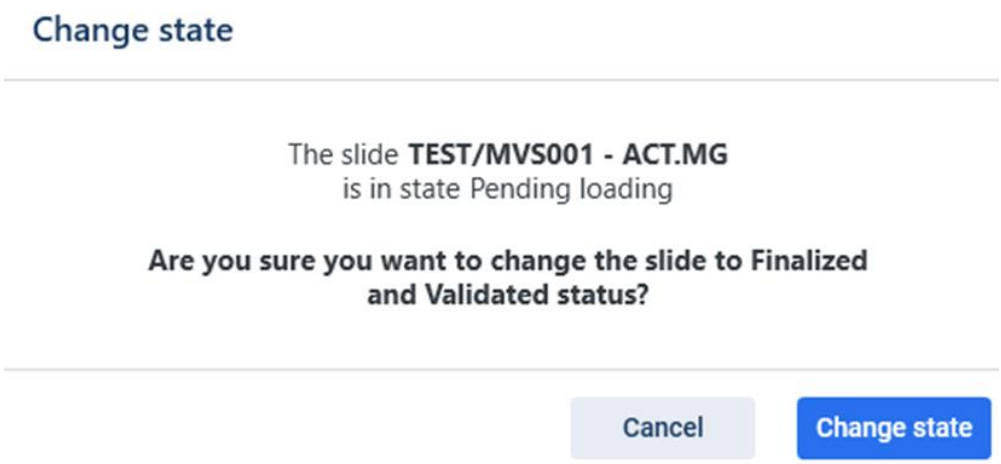


Print the label. The label will be printed individually for only one specific slide. With multiple selection, activate the top print button, and pressing it will print the labels for all the selected slides. Once the label printing is complete, a confirmation message will appear.



- **Review** the steps to be performed on that sample. The following screen will open, displaying the phases and steps to be performed.

- **Change the status** of a pending slide to completed or validated. Click the three dots, Change Slide Status > Completed and Validated > Change Status. With multiple selection, the same operation can be performed on different slides.



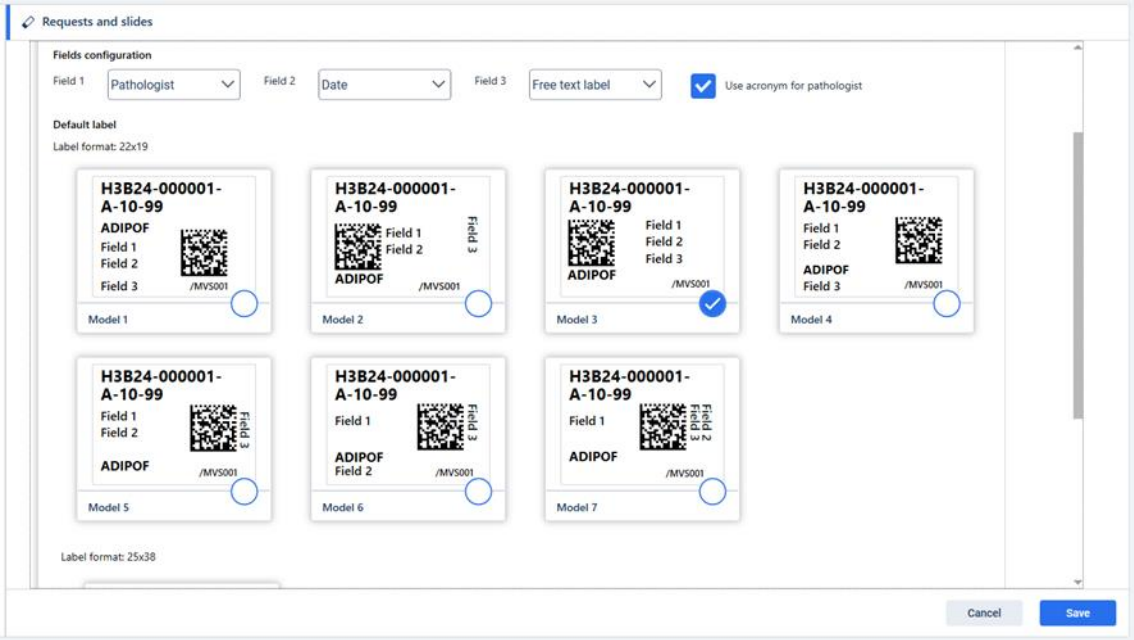
Preconfigured Label Selection

From the menu **Settings > General > Requests and Slides**, you can access the list of preconfigured slide labels.

From here, you can choose the label size and model you want for the installation, and even configure the information you want to display in each of fields 1, 2, and 3. You can choose from the following fields, without the possibility of repetition:

- Pathologist
- Center
- Request date
- Free label text (new field)

You can also select "(Empty)" if you don't want to display anything in any of the fields. Additionally, there is an option to configure whether you want to display the pathologist with the acronym instead of the full first and last name. This option will only be enabled if "Pathologist" has been selected in any of the fields.



4.5 Physically load slides into the instrument

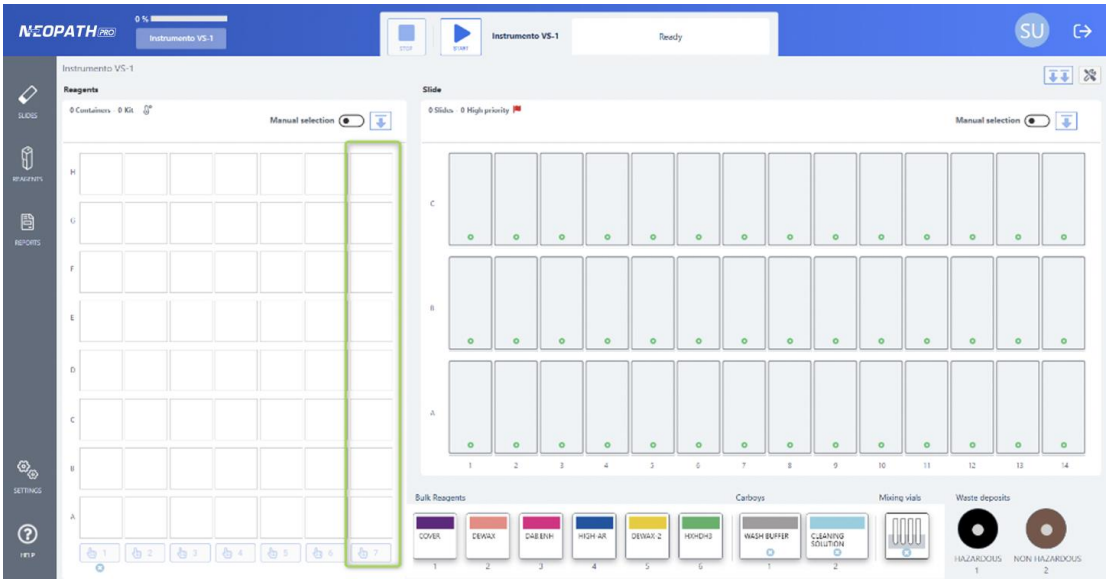
Slides should be loaded into the instrument preferably from 1-A to 14-C position. That is, from left to right and starting with the row closest to the user, row A.

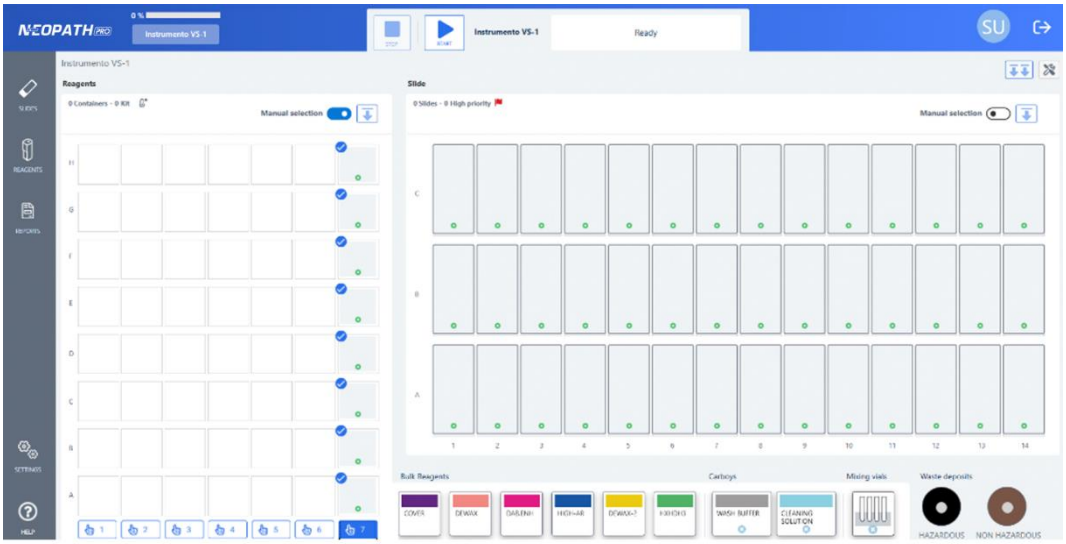
They should be placed with the label facing up and towards the front of the instrument.

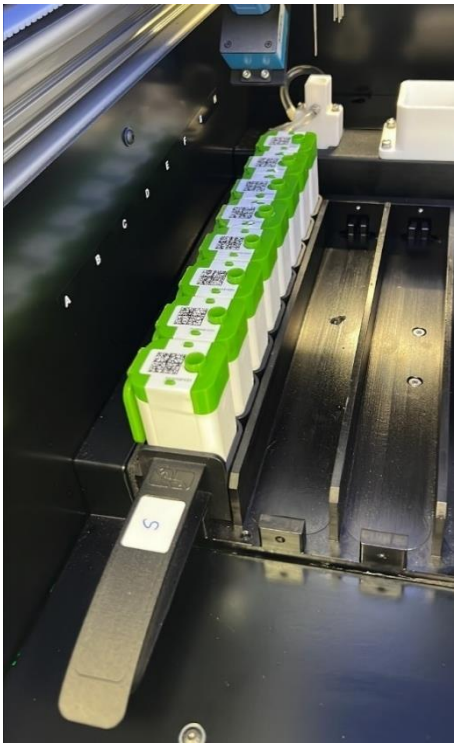
4.6 Physically load reagent vials into the instrument

Prepare the reagents following the instructions provided by Biocare Medical, LLC and detailed in the data sheet of each vial.

The reagent vials should be loaded with the rack removed and the lid should be open. Once the vials have been placed, the rack must be inserted in the corresponding position of the instrument. At that time, the system will detect the rack and display it on the screen automatically marked for reading.







4.7 Place the mixing vials

The instrument has space for 6 mixing vials. Before starting a run, check that they are all in place and clean. If this is not the case, the missing ones must be installed and/or unsuitable ones must be replaced.

4.8 Refill bulk flasks

It is very important to record each replacement of the bulk flask in the system to maintain traceability of the slides made with that batch. The flasks should be removed and replaced with the appropriate reagent. Once replaced, screw the cap back on and place it in the corresponding position.

If there isn't enough volume to start a set, the device will report a shortage. To resolve this issue, replace the flask and you need to go to the **"Troubleshooting Flask Problems"** section to address it at the application level

Note: If the device hasn't been used for several days, the system integrates a purge of the flasks that will be used at the beginning of the cycle.

4.9 Refill large bulk containers

It is very important to record each filling of the bulk carboy in the system to maintain traceability of the slides made with that batch.

The cap should be unscrewed, and the bottle filled with the appropriate reagent. Once filled, the cap must be screwed back on and placed in the corresponding position.

The instrument checks the connection and volume of the bottles before starting a run; if it is not sufficient, an “Insufficient Volume” error is displayed, and if it is not connected, a “Bottle Disconnected” error is displayed. To resolve these issues, you need to connect or replace the large bulk container and go to the **"Troubleshoot Containers"** section to resolve the issue at the application level.

Note: If the device hasn't been used for several days, the system integrates a purge of the carboys that will be used at the beginning of the cycle.

4.10 Emptying waste containers

Unscrew the cap and empty the waste container. Dispose of waste in accordance with federal and local regulations.

The connector of the tube will be disconnected from the stopper using the metal tab and the waste will be disposed of properly. The cap will then be screwed on again and the tubing will then be reconnected to the container.

The instrument checks that the waste containers are connected and are not full before starting a run; otherwise, the system will display a "Container disconnected" or "Container Full" error. If the waste container is detected to be full, the final circuit of the container will be automatically emptied to avoid liquid spillage when emptying it. To resolve these issues, connect/replace the container and go to the "**Troubleshoot Containers**" section for application-level troubleshooting.

4.11 Starting a run

Disable slide rack positions

There is the possibility of disabling positions, if a problem is detected in one of the reaction chambers. This prevents any slides from being placed in this position.

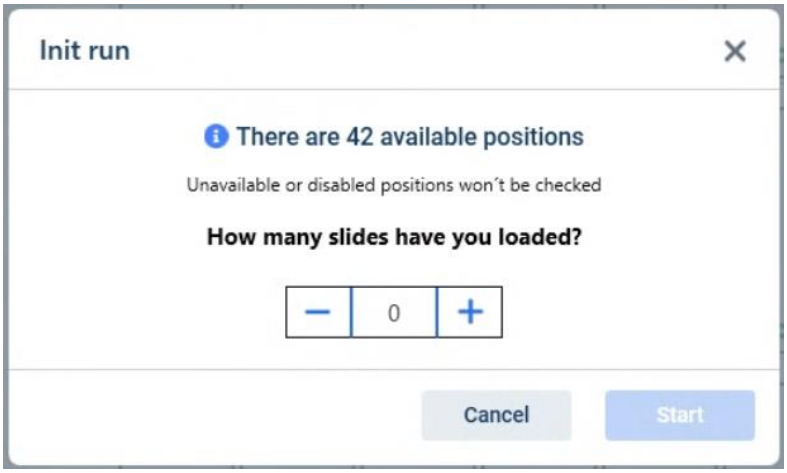
By right-clicking on a position in the slide rack, the **Disable Position** option appears.

A disabled position will not be considered in the execution of a run and will be represented as shown below. On the instrument the position led will be off.

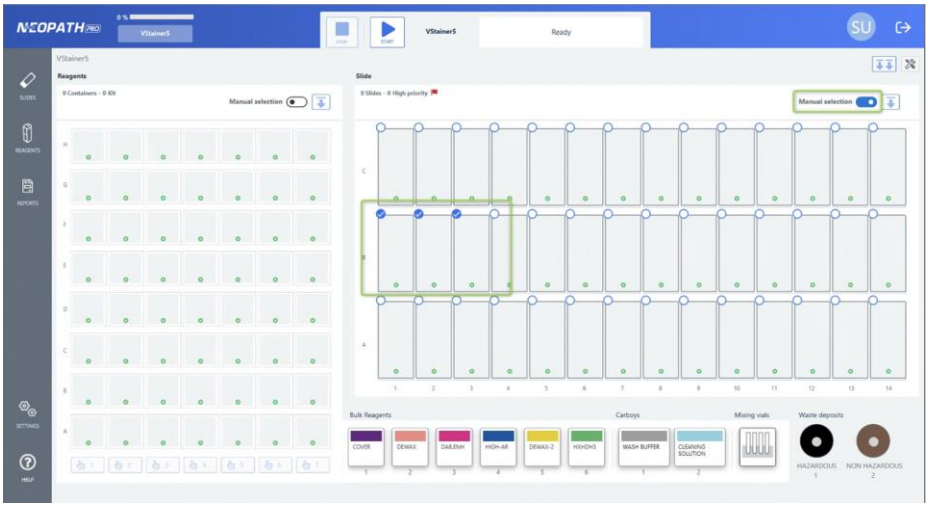
Scanning of the slide rack

Scanning of the slide rack can be done in two ways:

- **Automatic mode:** the instrument will scan from position 1-A to position 14-C, as many positions as slides have been indicated to be loaded in the instrument in the next window.



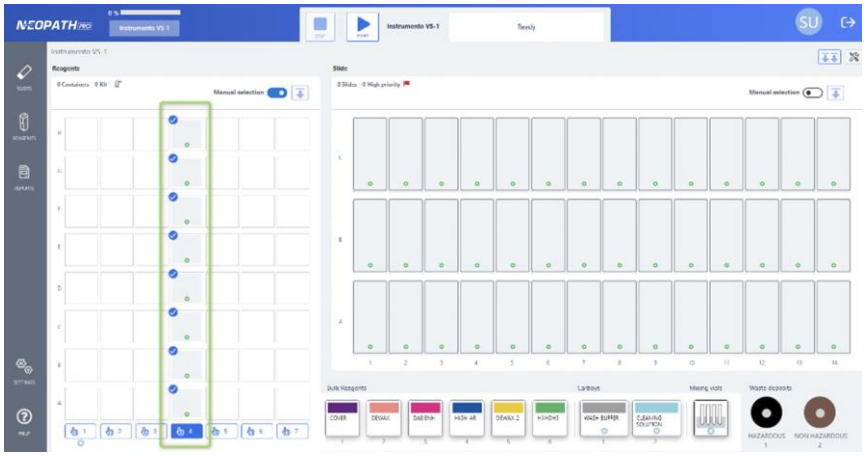
- **Manual mode:** Selection of the specific positions to be scanned.
    - The manual mode is activated from the *Manual selection* activation button, and the positions to be scanned must be selected on the position of the slide rack.



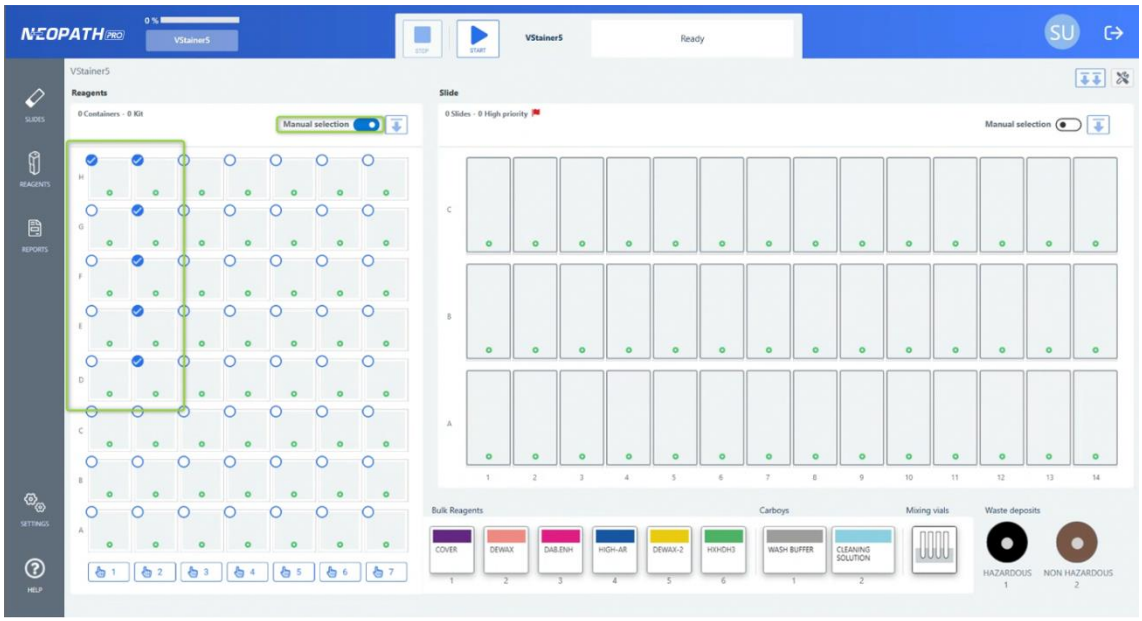
Scanning of the reagent rack

Scanning of the reagent rack can be done in two ways:

- **Automatic mode:** the instrument will scan the positions according to the situation in which the reagent rack was previously located:
    - If racks are loaded or there are manually marked positions, only those racks or positions will be read.
    - If no new rack has been loaded and there are previously detected vials, all racks in the rack will be reread and a check will be made to see if there is sufficient volume for the run.
    - If no rack or position is selected and no previously detected vial is present, all loaded racks will be read.



- **Manual mode:** Selection of the positions of the reagent rack to be scanned.
    - The manual mode is activated from the Manual selection activation button, and the positions to be scanned must be selected on the position of the reagent vial rack.



1. Automatic Volume Detection in Reagent Vials (LLD)

Before starting a run, a resumption, or hydraulic circuit maintenance, an automatic volume detection process is carried out on the reagent vials to verify they contain the required amount of reagent.

- The actual volume of the reagent vials to be used in the run or maintenance is automatically checked, provided that the system has the Liquid Level Detection (LLD) sensor activated.
- Detects volume changes due to possible evaporation, prior to use, or handling issues.
- Displays warnings if a lower-than-expected volume is detected or if no volume is detected at all.

Functionality.

- Pre-wash of the probe: Before detecting each reagent vial, the system performs an automatic probe cleaning to prevent reagent cross-contamination.
- Vial grouping: Vials containing the same reagent and batch are grouped to allow consecutive detection, minimizing intermediate washes.
- Automatic detection:
    - The probe is lowered into each reagent vial that meets the requirements, and the actual volume is detected. Requirements include:
        - Being detectable by the LLD.
        - The reagent is used by one of the run protocols.
        - The vial has no errors.
    - If the volume is sufficient, the process continues.
    - If the volume is lower than expected, the system adjusts it and flags it with a warning.
    - If no volume is detected, the vial is flagged with a warning and considered empty.

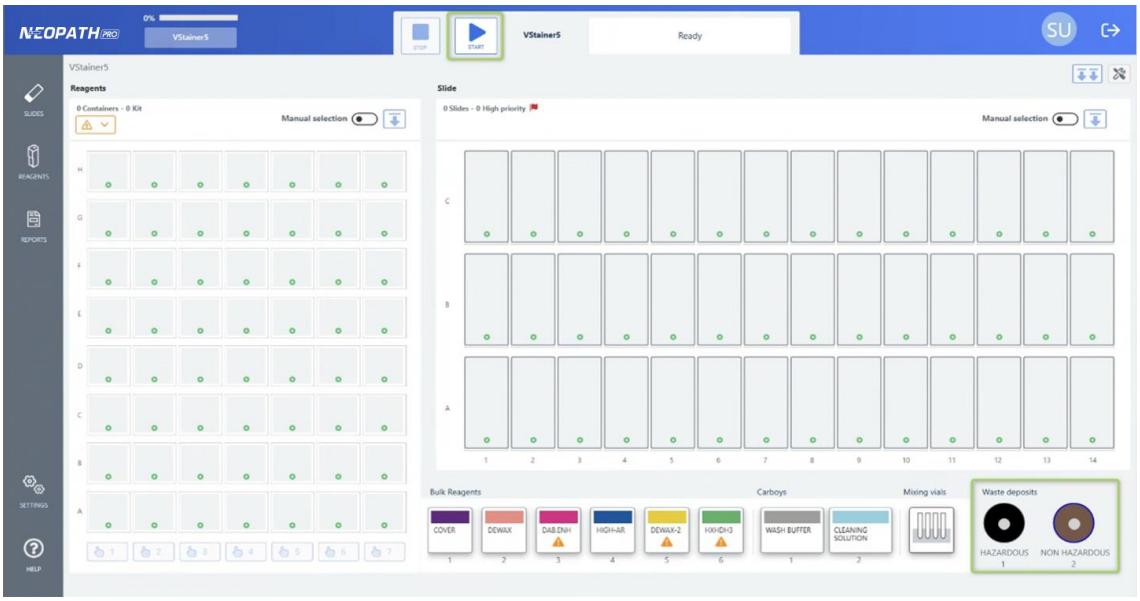
Warning Summary.

- “Detected volume is less than expected” → The reagent vial contains less volume than estimated.
- “No volume was detected in this vial” → No detectable volume is present.
- “LLD did not perform detection; system volume is used” → The estimated value is used because the sensor did not respond.

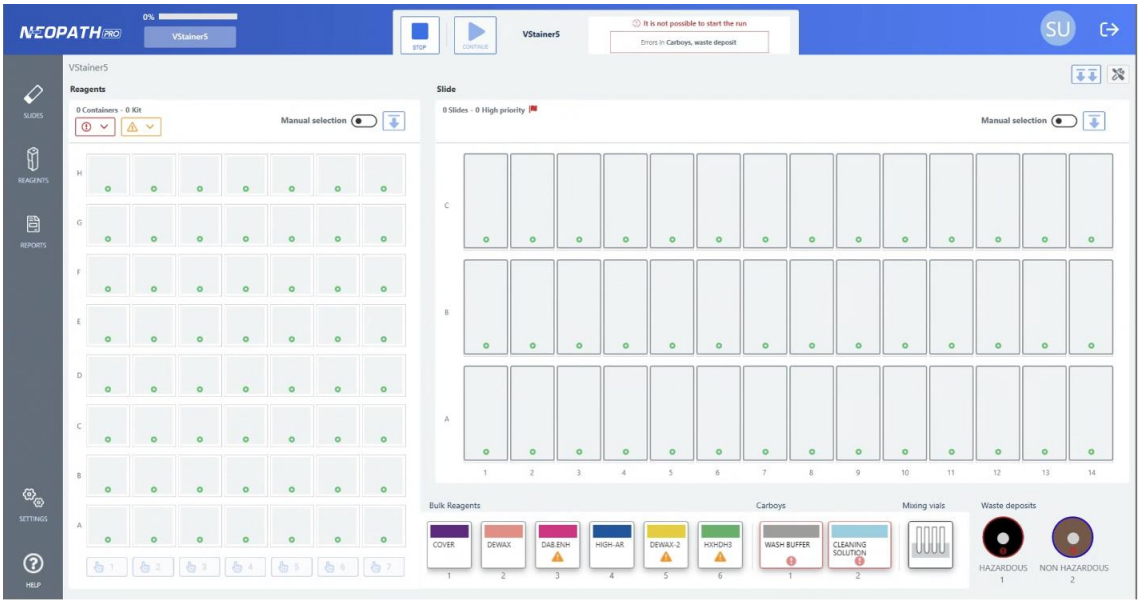
Begin a run

Once the instrument is prepared with all slides and containers, to run a series, close the hood and click the **"START"** button on the Work in Progress screen.

Before starting the run, if the equipment has not been used for several days, a priming of the flasks must be performed before starting the cycle.



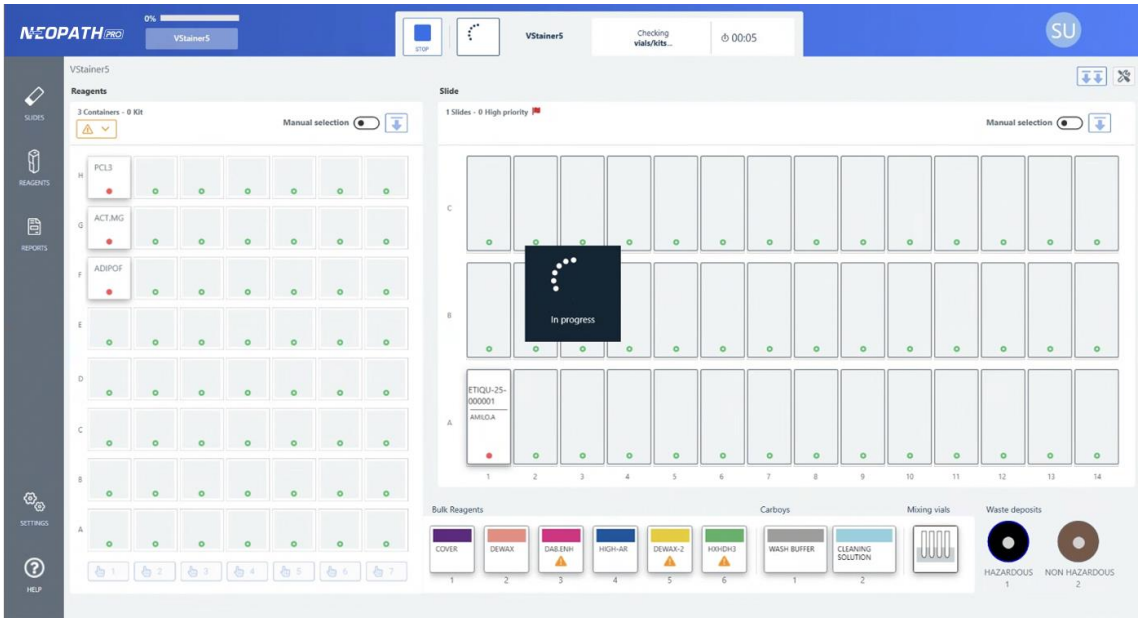
The system will first check that the containers (bulk flasks, large bulks and waste containers) are correctly prepared for the execution of a run.



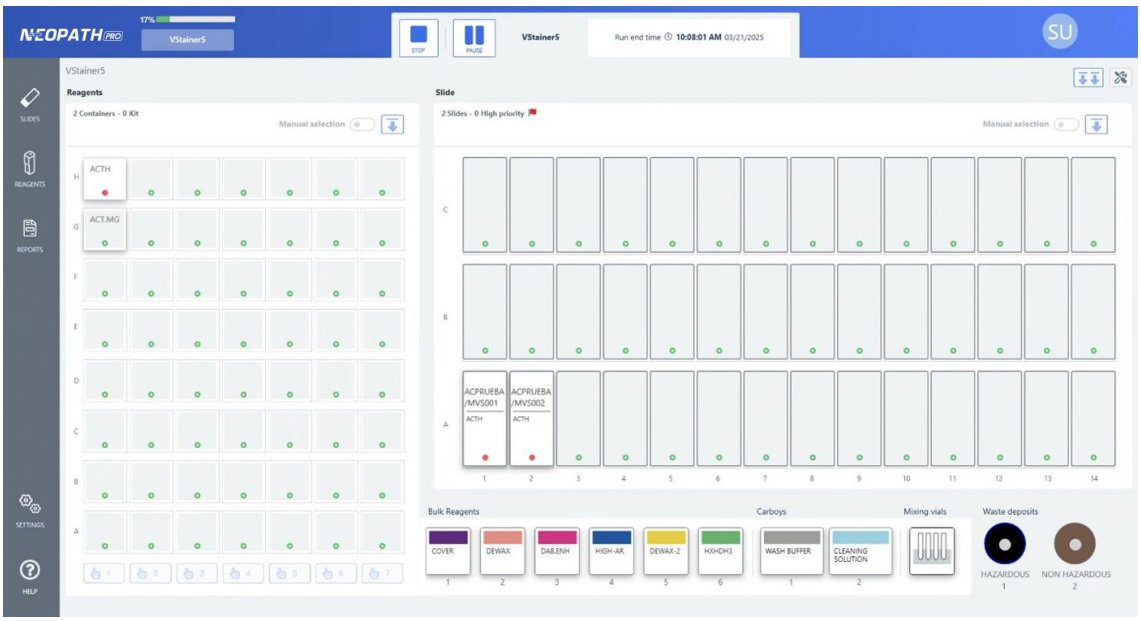
After the verification of the bulks, the instrument proceeds to the scanning of the slide rack, the reagent vial tier, flasks and mixing vials. As indicated above, scanning will be performed in automatic mode or will be performed in manual mode if Manual selection has been activated.

After scanning the slide and reagent vial rack, the scanned positions are displayed as the instrument performs the reading.

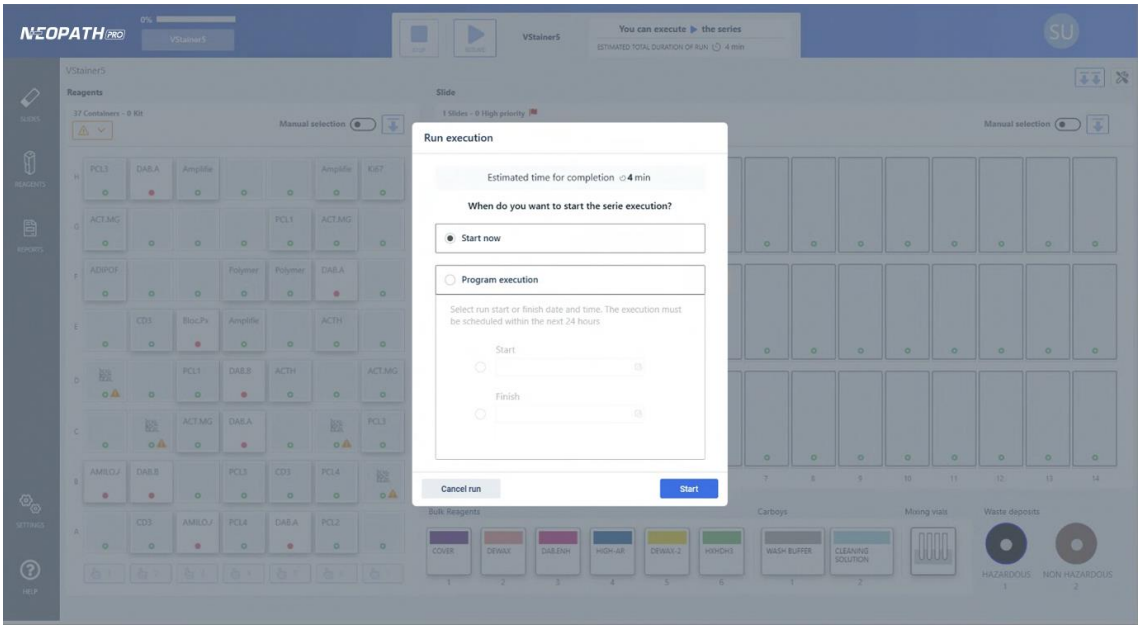
- **Slide rack:** the information displayed on each scanned position is the identification and technique of each slide in the rack.



- **Reagent Vial rack:** the information displayed on each scanned position is the acronym of the reagent contained in the vial of each position.



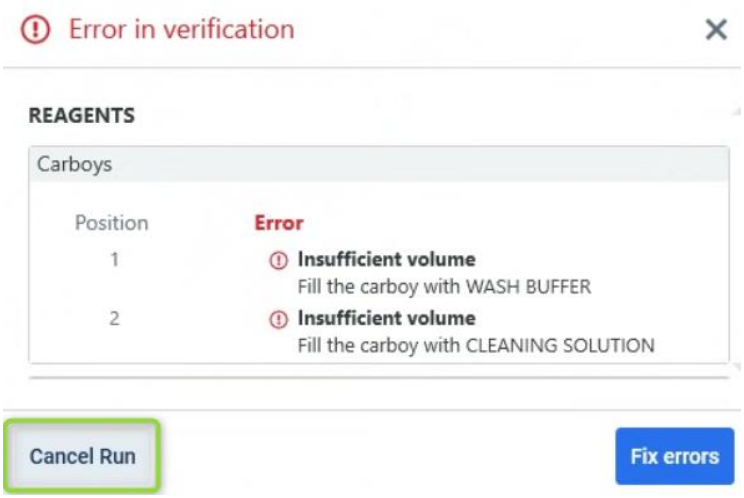
Once all checks are successfully completed, the estimated duration of the run will be displayed. With this information, the user can immediately start the run or schedule its start or end time. At this point it is also possible to cancel the run by unloading the slides to be able to start it again.



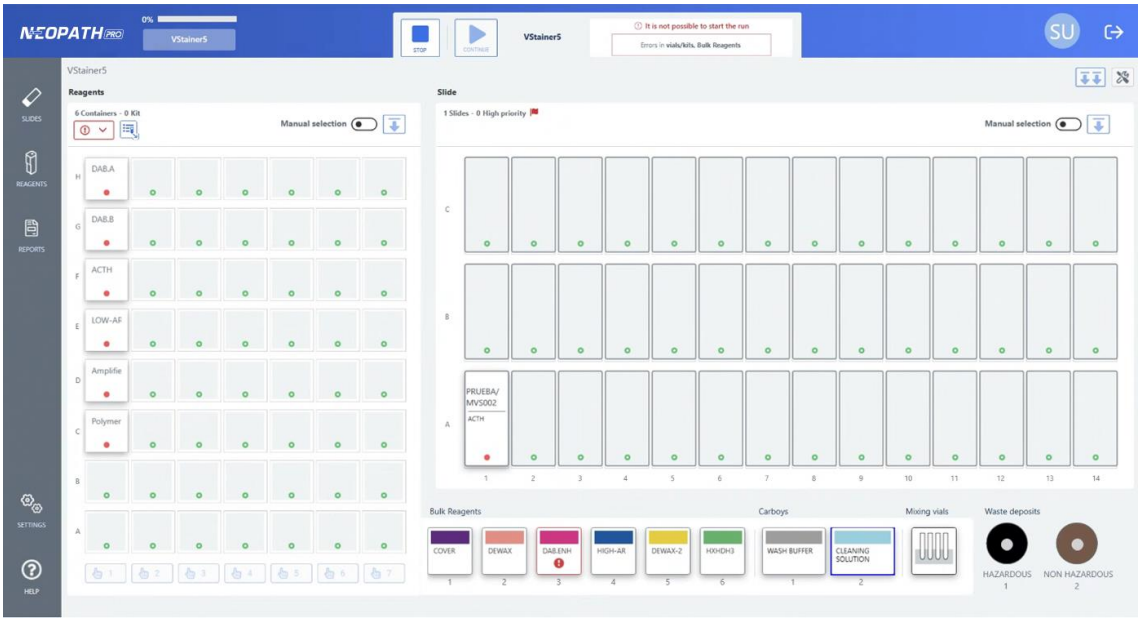
1. Troubleshooting bulk reagent problems (bulk flasks, large bulks and waste)

If during the verification of bulk flasks, large bottle containers and wastes, a problem of insufficient volume or full waste tank is detected, a warning will be displayed, and the run cannot be executed until the problems are solved.

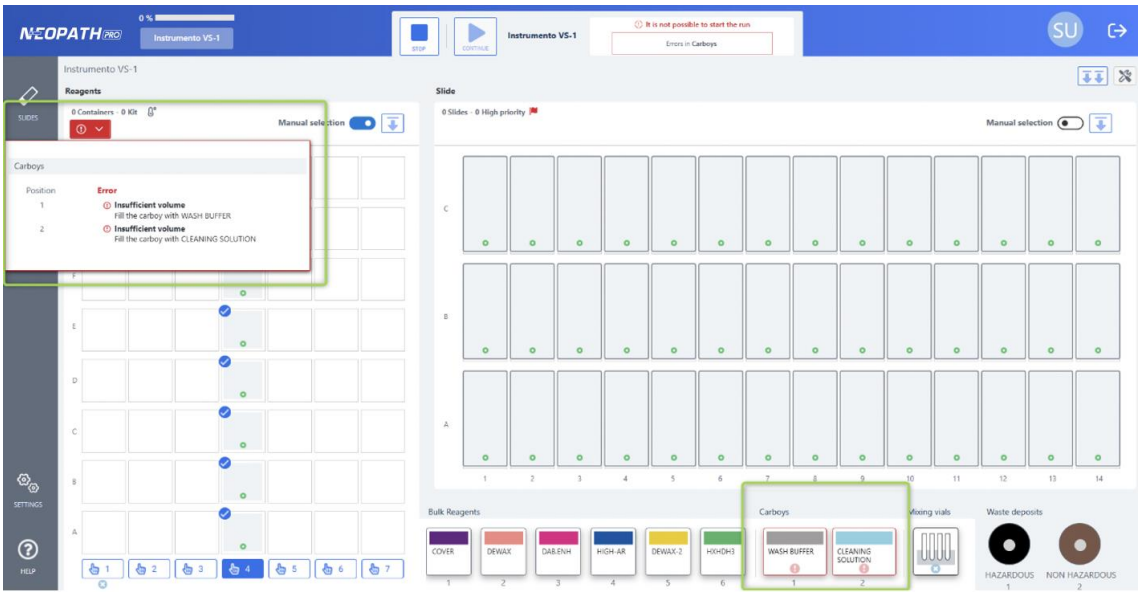
To correct the errors, click on the ***"Correct errors"*** button and proceed to refill the corresponding carafes, or empty the full waste tank, as appropriate. If you do not wish to continue with the run at this point, you have the option to Cancel the run by pressing the ***"Cancel Run"*** button.



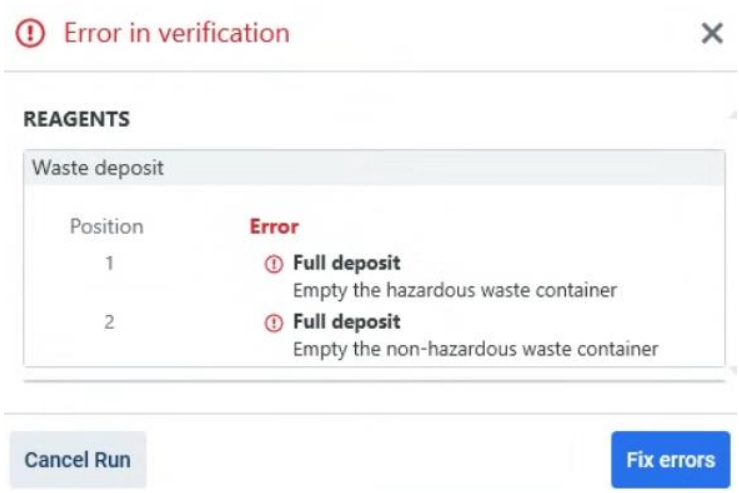
The error in the corresponding containers is represented with the icon . And, in addition, the button panel informs the user about the elements that have errors.



The error summary can also be accessed from the icon shown in the reagent rack.



Once the problems are resolved, physically on the instrument, click on each position with error and click on the "***Fix errors*** " button.



The error then disappears from the position.

To refill bottles, you can do so directly from the main screen when the instrument is in the Ready state. You can also refill a run when it is stopped due to errors during testing.

By right-clicking on the bottle you want to fill and clicking Record Fill, the Record Fill window will automatically open, allowing you to manually enter the filling data. Since the run started when the refill was requested, the purging will be integrated into the run when it begins.

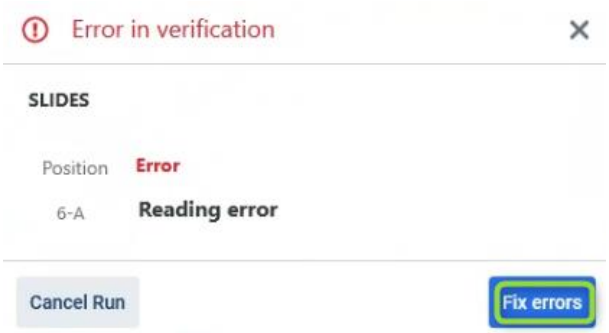
Once the bottle has been filled, the complete refill history can be accessed from the context menu of each bottle by clicking on Refills.

Once all errors have been corrected, the "Continue" button is enabled to continue with the rest of the checks, and the widget displays the error resolution.

2. Slide troubleshooting

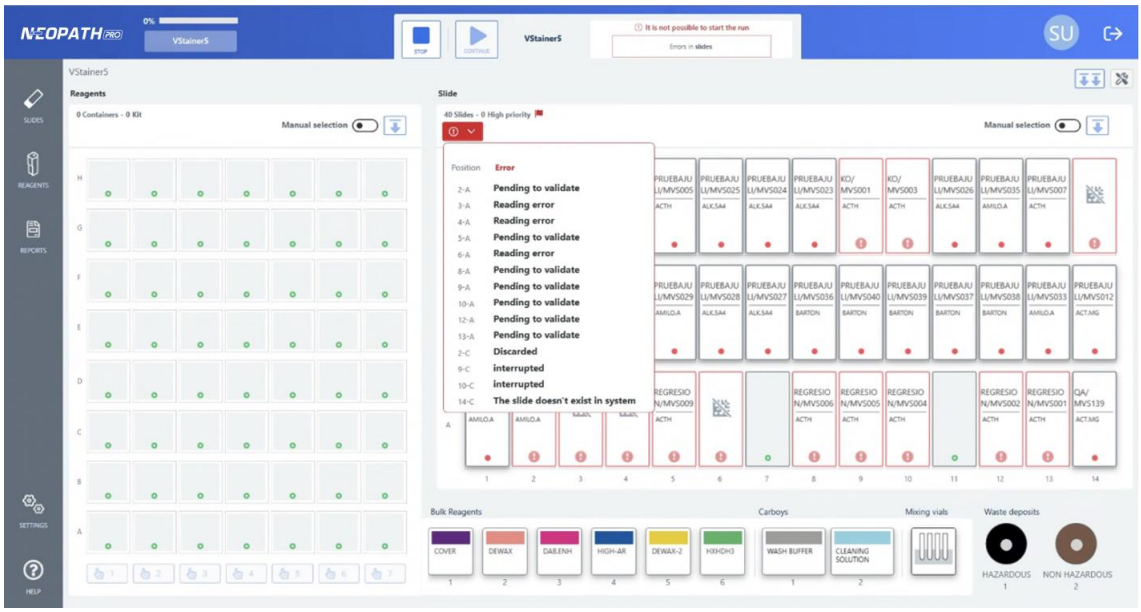
During slide scanning, a number of problems may occur with the reading of loaded slides. When a slide error occurs, an information window is displayed with the position and the error that occurred on each position.

To fix the errors, click on the ***"Fix errors"*** button. If you do not wish to continue with the run at this point, you have the option to Cancel the run by pressing the ***"Cancel Run"*** button.



The error in the slide rack is represented by the following icon  . By clicking on the position the user can see all the information necessary to detect the error occurred

In addition, the error summary can be accessed via the icon at the top.



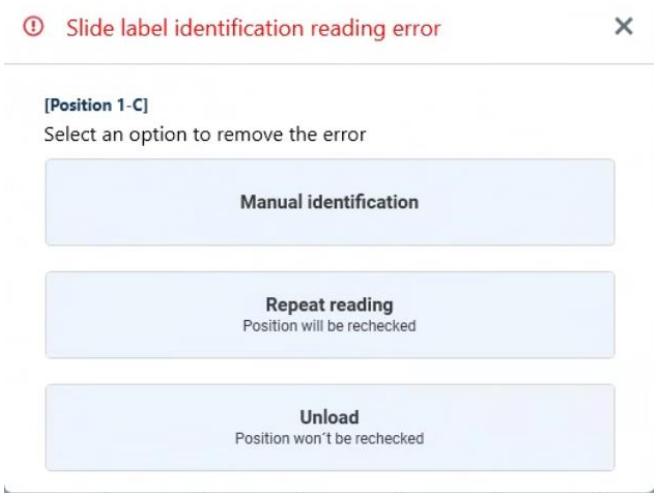
To eliminate the problems that appear during the run, the user must click on the error itself.

Possible problems that may occur in the slide rack reading are as follows:

- **Not detected**

  This error occurs when the camera's image sensor is disabled. Corrective actions are the same as for a reading error (see next point).

- **Reading error**

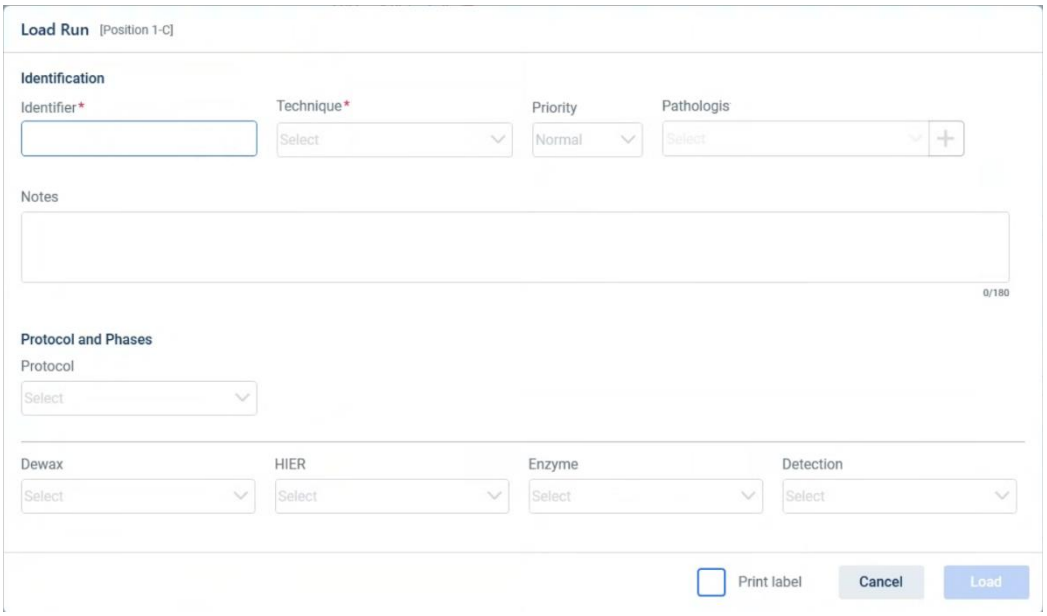


The solution options are:

  - **Manual Identification:** the slide loading window will be displayed where all the necessary data for the creation of the slide must be entered:
    - Identifier
    - Priority
    - Technique
    - Pathologist

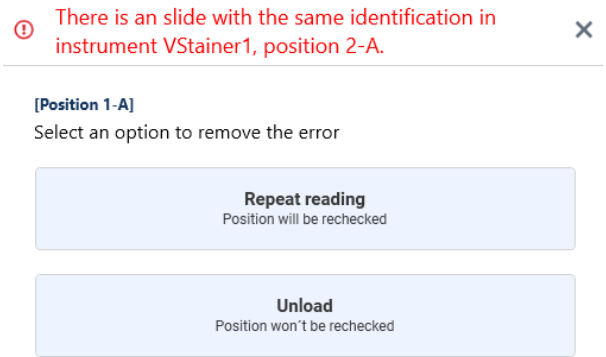
- Center (only in multi-center facilities)
- Notes (optional)
- Protocol and phases (once the technique is selected, the protocol and phases are completed with the default value for each of them).
    - Protocol
    - Priority
    - Phases (once the protocol is selected, the phases are completed with the default value for each one of them).
    - Notes (optional)

- **Repeat reading:** perform the slide reading again
- **Unload:** The slide in the position is unloaded and shown as available.

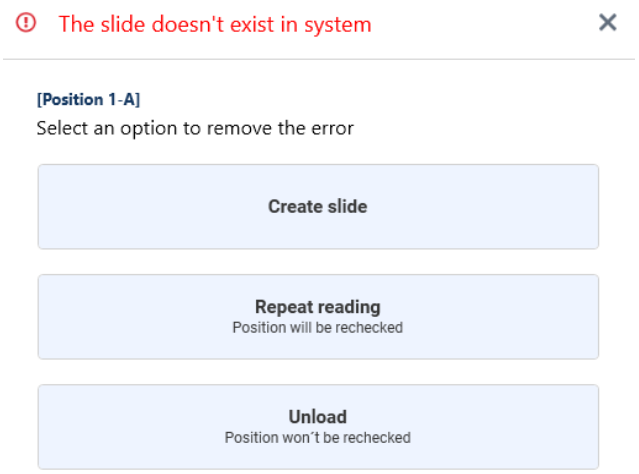


Once all the necessary data have been entered correctly, the **Save and Load** action is activated, so that the slide is registered in the system and therefore appears loaded in the rack.

- **Slide identifier already loaded in the same or another instrument.**
    - Repeat Reading: The slide will be read again.
    - Download: The position is downloaded and displayed as available.

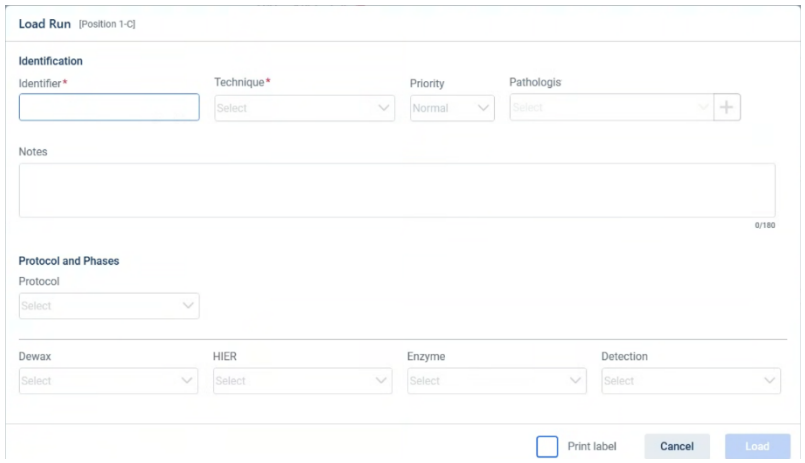


- **The slide identifier read does not exist in the system**



The solution options are:

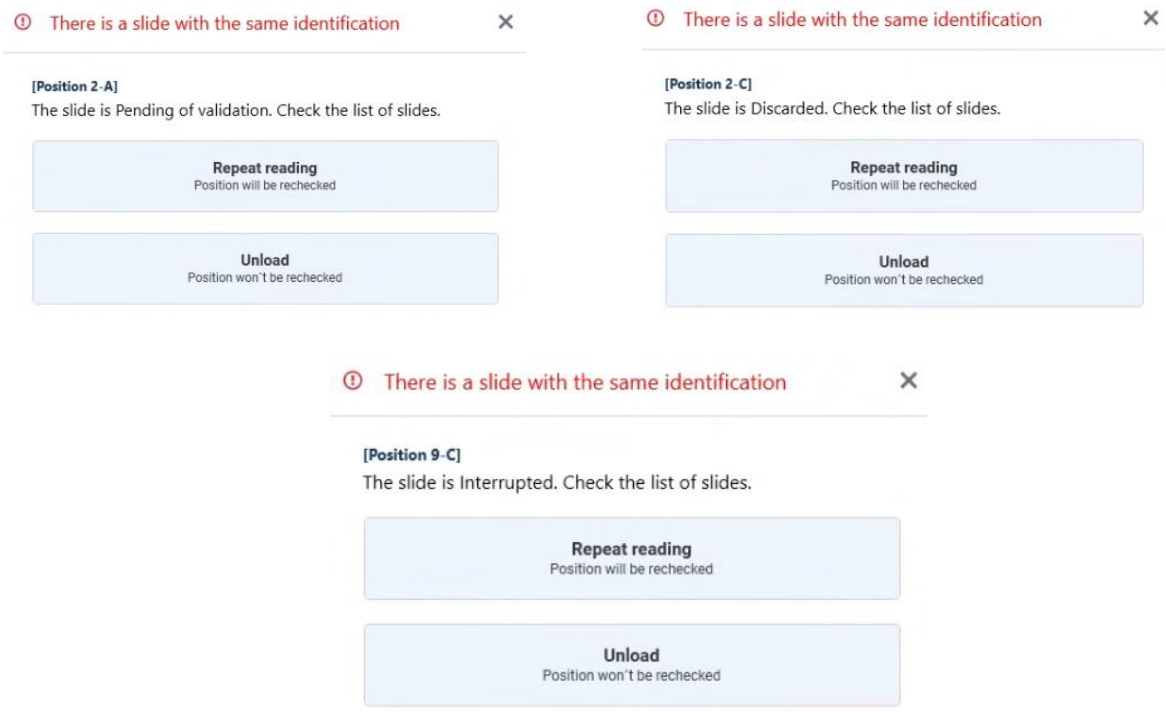
  - **Create slide:** the slide loading window will be displayed where all the necessary data for the creation of the slide must be entered:
    - Identifier
    - Priority
    - Technique
    - Pathologist
    - Center (for multi-center facilities)
    - Notes (optional)
    - Protocol and phases



  - **Repeat reading:** The position will be reread on the next scan after the remaining errors have been resolved. The position is displayed as available.
  - **Unload:** the slide position is unloaded and shown as available.

- **Slide states other than pending**
  After a slide rack reading, it may happen that there are slides loaded in the rack that are in a state other than pending. In this case, the application will flag the position where one of the following states is detected as an error and allow you to perform the following actions depending on the slide status

- **Pending validation, Completed and validated, Discarded, Interrupted:**
  - **Repeat Reading:** The slide will be read again.
  - **Download:** The position is downloaded and displayed as available.



3. Reagent Vial troubleshooting

During scanning of the reagent vial racks, a number of problems can occur with the reading of loaded vials. This error is represented by an information window in each of the positions.

To fix the errors, click on the **"Solve errors"** button. However, if the user decides not to continue with the execution of the run, he/she has the option to cancel the run by clicking on the *"Cancel Run"* button.

The error in the reagent vial rack is represented with the icon . Additionally, the information section indicates where the error has occurred.

Each position is represented on the rack according to the error shown. The error summary can also be accessed from this icon located at the top left of the screen.

To resolve the errors, click on each position with the error where. Depending on the error, possible solutions will be offered. A vial can also be added manually by tapping on an available position after performing an initial reading of the vial tier. When this occurs, the system will display the message "Unselected vials must be placed and opened," to alert the user of the action they should take.

2.5mL, 15mL and 50mL Empty Vials are “user-fillable” vials that are designed for the utilization of alternate primary antibodies or probes not offered within the NeoPATH Pro reagent line on the NeoPATH Pro. 2.5mL Empty Vials have a dead volume of 100uL. 15mL and 50mL Empty Vials have a dead volume of 400uL.

The possible problems and their options, which can occur in the reading of the vial rack, are as follows:

- **Vial with closed cap**

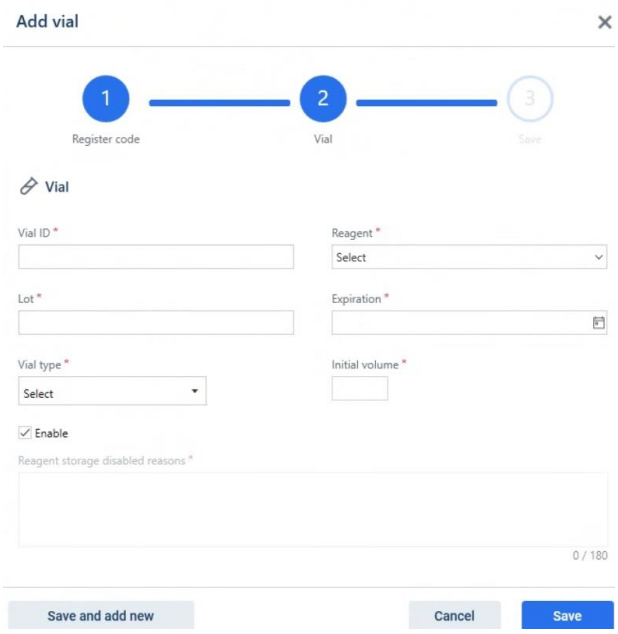
To solve the error, the reagent vial cap located in the reagent vial position must be physically opened. When closing the displayed prompt, the position is represented as available.

- **Reading error**

The identification code of the reagent vial must be entered, either manually or with a label reader.

When accepting, if the reagent vial already exists in the system, the position with error is updated with the reagent information of that reagent vial.

If the reagent vial does not exist in the system, the reagent vial registration window will open. If it is recognized by the label reader, the reagent vial data will appear on the registration form, otherwise it must be entered manually to complete the registration.



- **Expired vial**

The reagent vial must be unloaded to solve the error. The position with the error remains as an available position.

- **Insufficient volume**

The reagent vial must be unloaded to solve the error. The position with the error remains as available position.

- **Disabled vial**

If a user that has an access level that allows editing and enabling a reagent vial is logged in, they may do so in a way that is represented by the acronym of the reagent in the reagent vial. If the user does not have this access level, the user must unload the reagent vial so that the position with the respective error becomes available again.

- **Vial loaded in another position or instrument**

The vial must be unloaded to solve the error. The position with error remains as an available position.

4. Troubleshooting Flask Problems

Flask errors will only be reported for those that don't have enough volume to complete the set in question. This means that flasks that aren't going to be used in the set won't display any errors.

When you select the flask with the error, the following window will appear:

When replacing a reagent, it is necessary to record its replacement for proper traceability. By clicking Replace, you can identify the new reagent by reading the barcode on the label, or you can also record it manually. The replaced reagent will be purged at the start of the run.

- **Replace**: To replace a reagent that failed due to insufficient volume during the run checks, you must click on it. The application will present the following solutions:
- **Continue:** By clicking this button, the pouch error will disappear, the system will not recheck the pouch, and the run will begin.

Once the pouch replacement is complete, the complete replacement history can be accessed from the context menu for each pouch by clicking on Replacements.

5. Troubleshooting mixing tubes

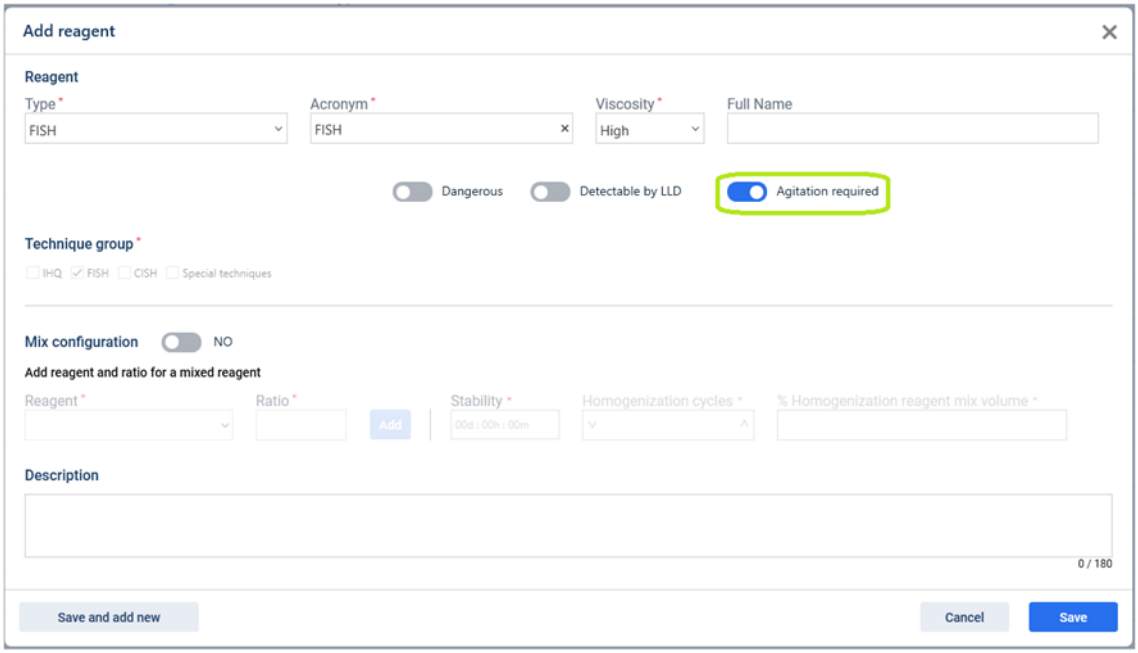
During scanning mixing tubes, problems may occur with the reading of the mixing tubes. When an error occurs in the mixing tubes, an information window appears with the position and the error in the application step.

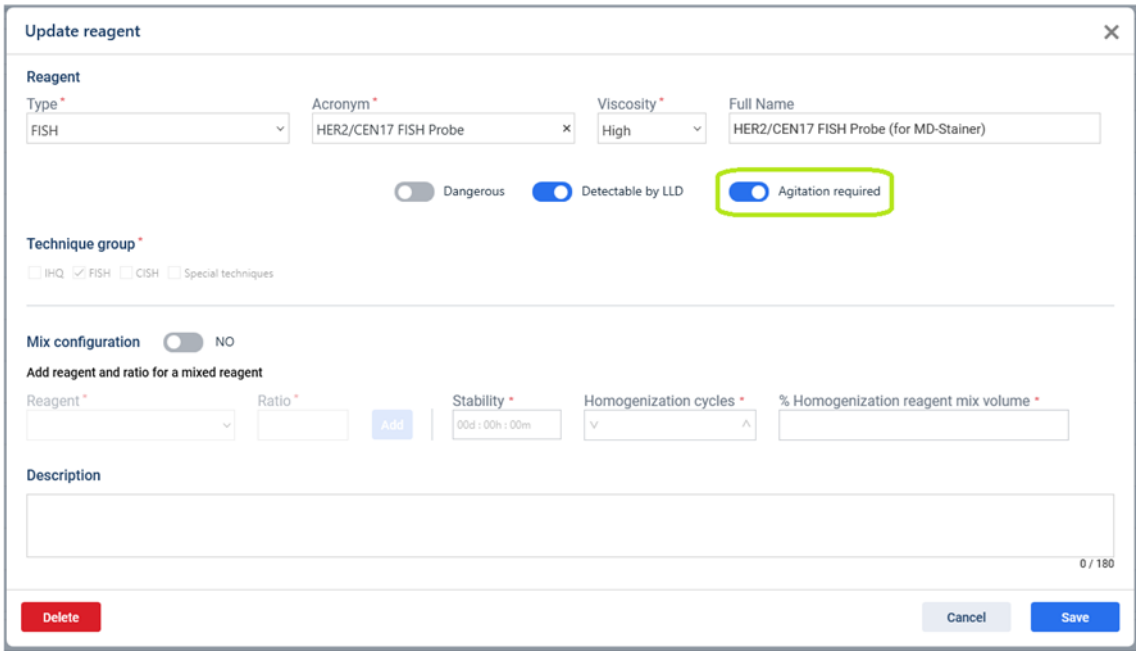
To resolve errors, click the "Correct Errors" button. If you do not wish to continue the run at this time, you have the option to cancel the run by clicking the "Cancel Run" button.

Alternatively, if you wish to continue the run, you must click on the element with the error and click the "Resolved" button. At the same time, all mixing tubes must be placed in the instrument so that no errors are returned when a second reading is taken.

4.11.4.6 Reagent Homogenization

Users with permission can configure reagents (especially FISH probes) to be agitated (homogenized) prior to their first dispensing during a series. These can be configured by accessing the reagent list when adding a new reagent or editing an existing one.

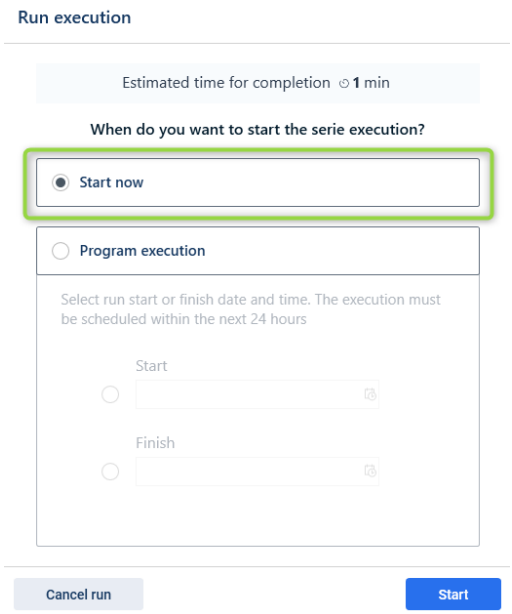




Vials with this reagent checked must be agitated as required before dispensing onto a slide. All identical reagents from the same batch must be agitated without having to wash between each vial.

If there are multiple vials with the same reagent and batch, only those that will be aspirated must be agitated.

Immediate start

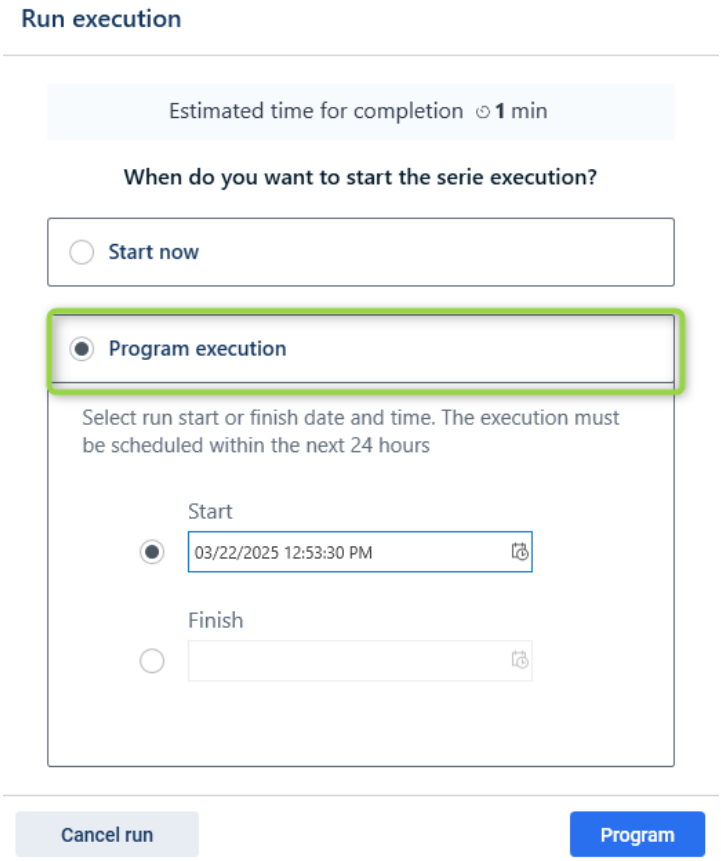


If you decide to start the run immediately, you must select the Start now option and click on the **Start** button.

Schedule run

For scheduling a run, the ***"Schedule Run"*** option must be selected. This is where a run can be scheduled by start or end date and time. To schedule the start of the run, the user must click on the **Schedule** button.

By default, the run schedule is configured to limit its execution to within the next 24 hours, although this may vary depending on the parameter value. This will be indicated in the previous modal.

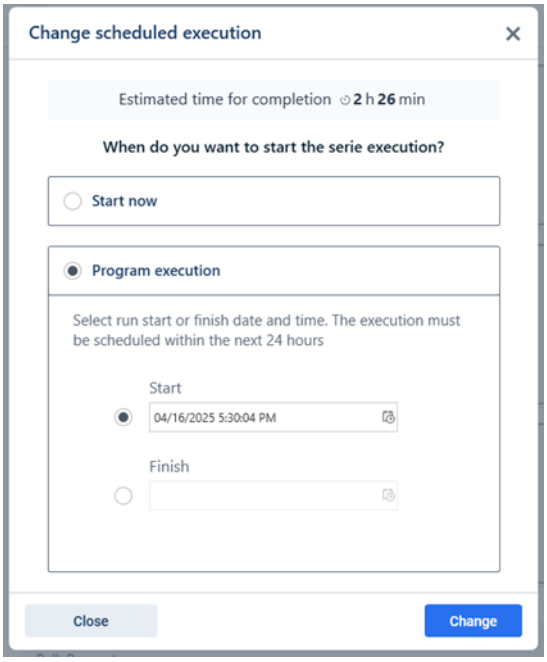


In the information part of the button panel, it informs that the run is scheduled, how much time is left for the start, the duration of the run, and the start and end time and date.

1. Change scheduling date and time

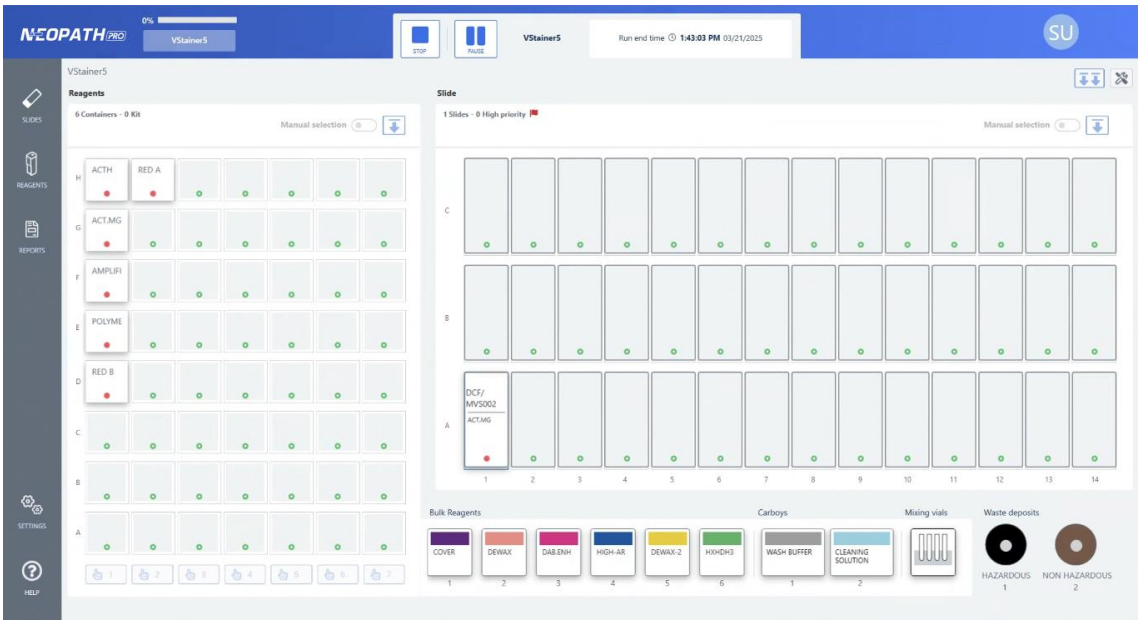
Clicking the SCHEDULED button will open a new window where you can:

- Change the date/time with the start or end option, as long as it meets the usual criteria.
- Start the series now. If you click the "Start" option, the "Confirm" button changes to "Start."
- Close to return to the previous settings.

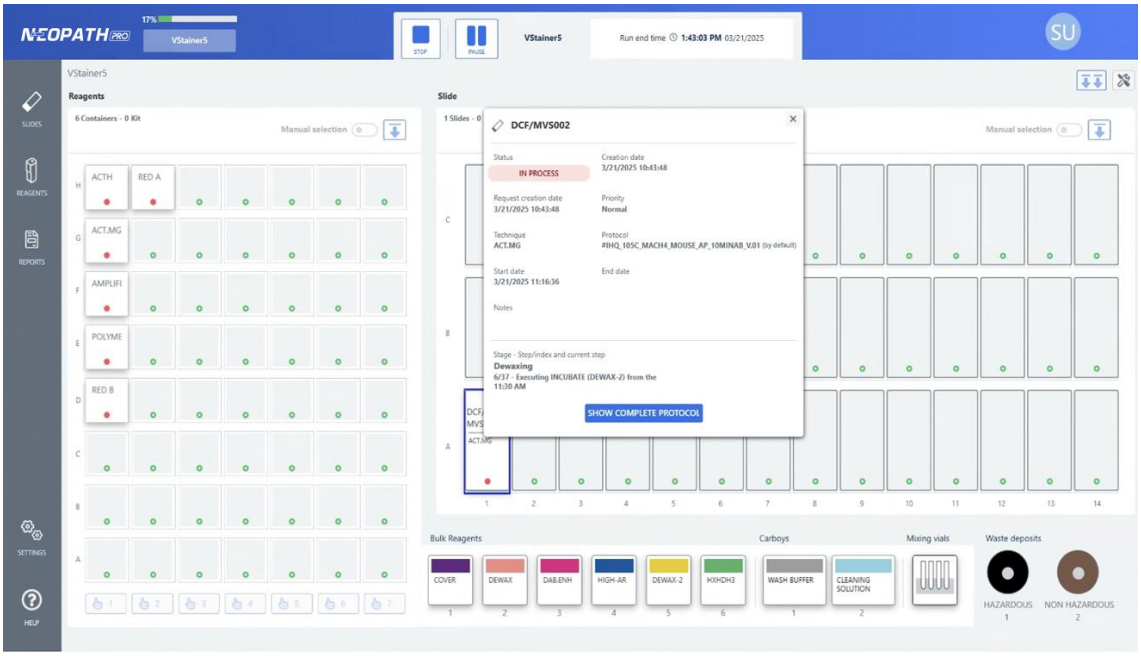


Execution Information

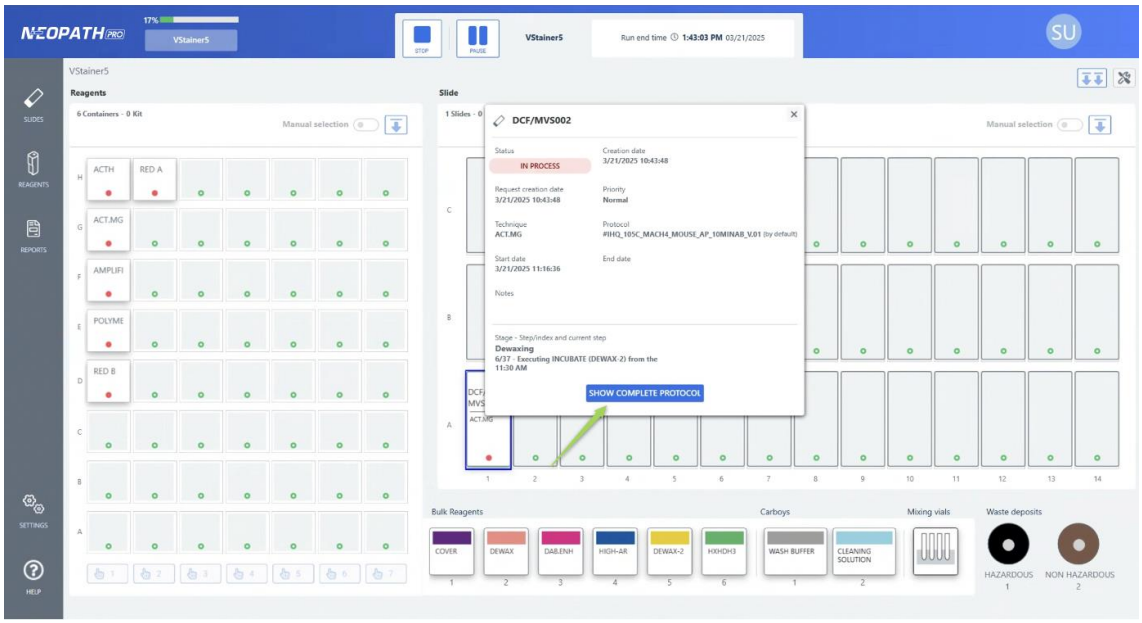
Once the run has started, in the button panel information section, the end date of the run is indicated, along with the option to stop it.



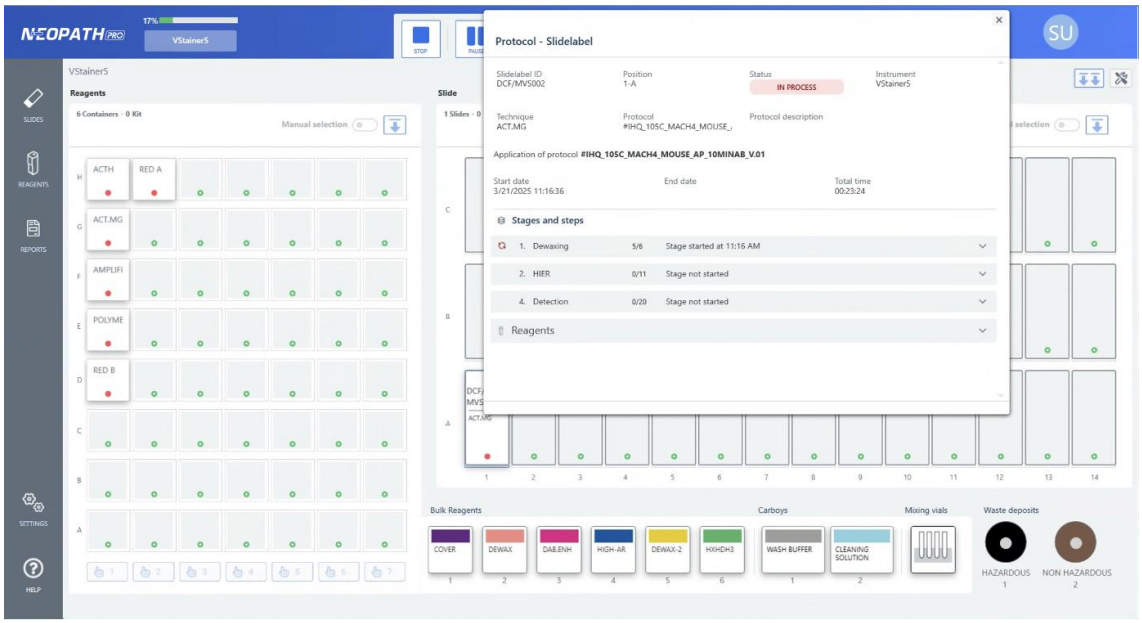
The progress of the run is indicated by a percentage bar, which fills to 100% as the cycle progresses. In addition, as the different slides are completed, the positions of the slides change to flashing green.



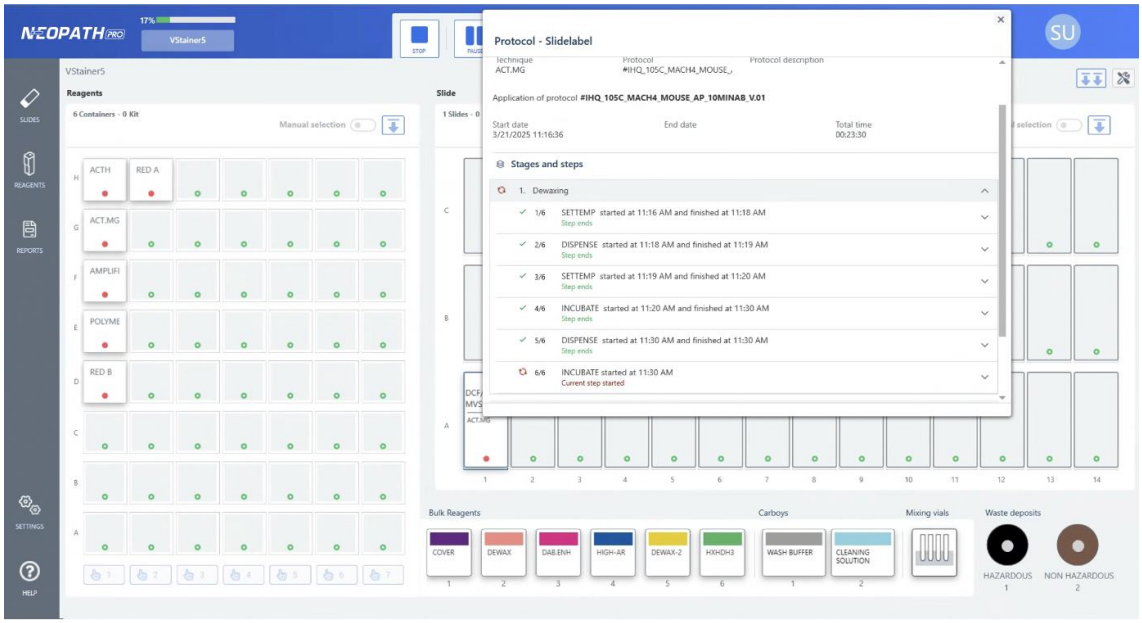
Clicking on each position displays a new window with all of the information corresponding to the status and execution of the slide, so that the user can track the protocol in real time.



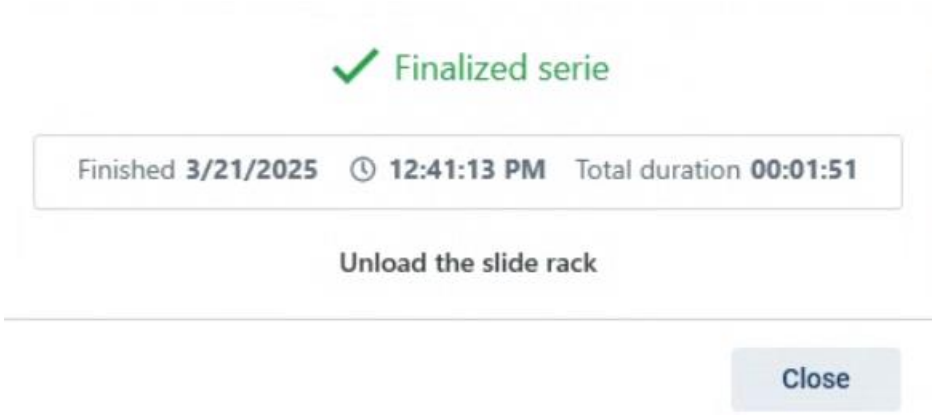
Additionally, the complete protocol can be accessed in detail by pressing the button SHOW COMPLETE PROTOCOL



Additionally, it is possible to know which phase and step is being executed.



At the end of a run, the following warning appears.



To restart a new run, the slide rack must be unloaded. All slides and reagent vials can be unloaded from the interface using the double arrow button, as well as only reagents or slides using the single arrow buttons located on each side of the interface (indicated in the image with arrows).

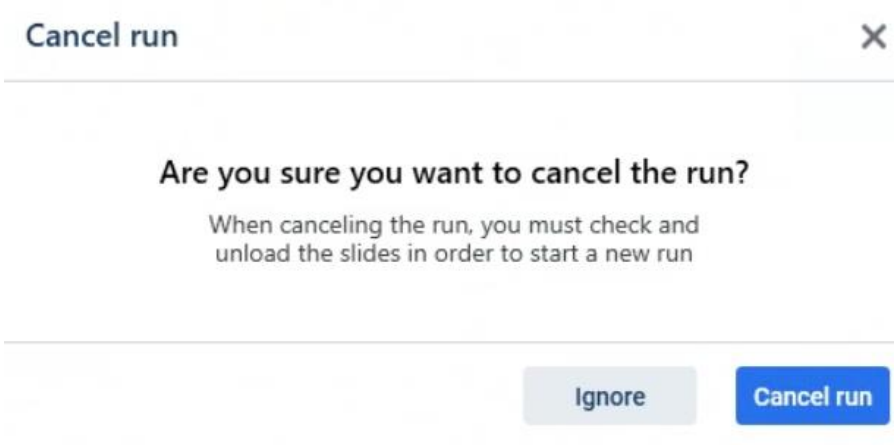
Run cancellation

The run can be canceled in various ways.

1. **Cancellation by pressing the Stop button**

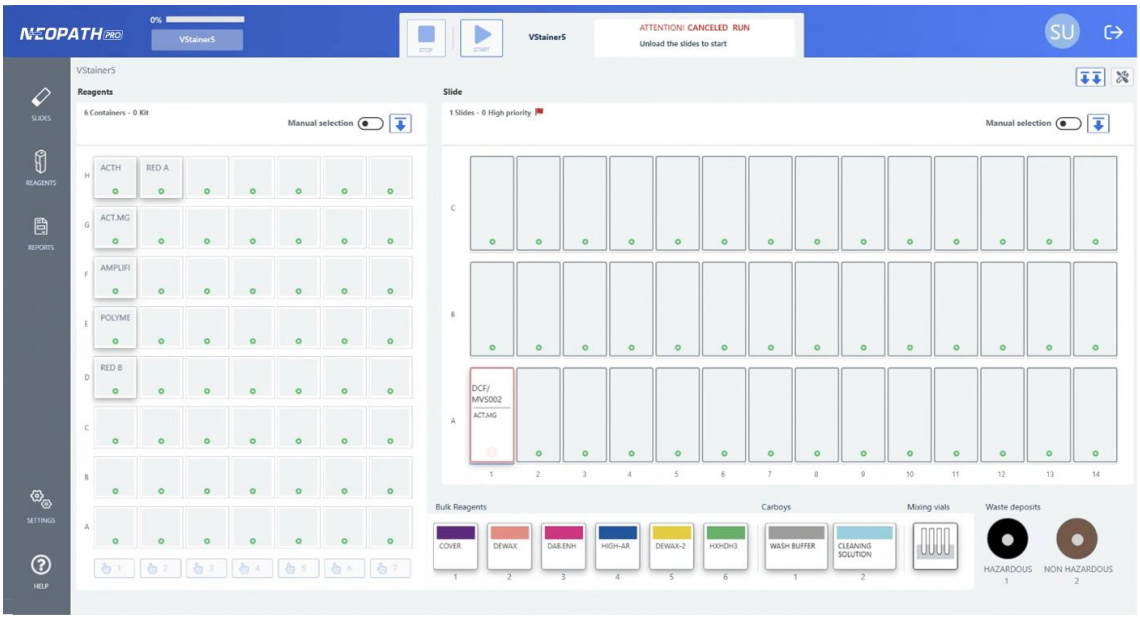
As soon as a run is started, the "STOP" button is enabled.

By using this action the run can be canceled. When the "STOP" button is pressed, a confirmation window is displayed. At whatever stage the run is in when the "STOP" button is pressed, to start a new run, the slide must be unloaded, if any slides have already been read.



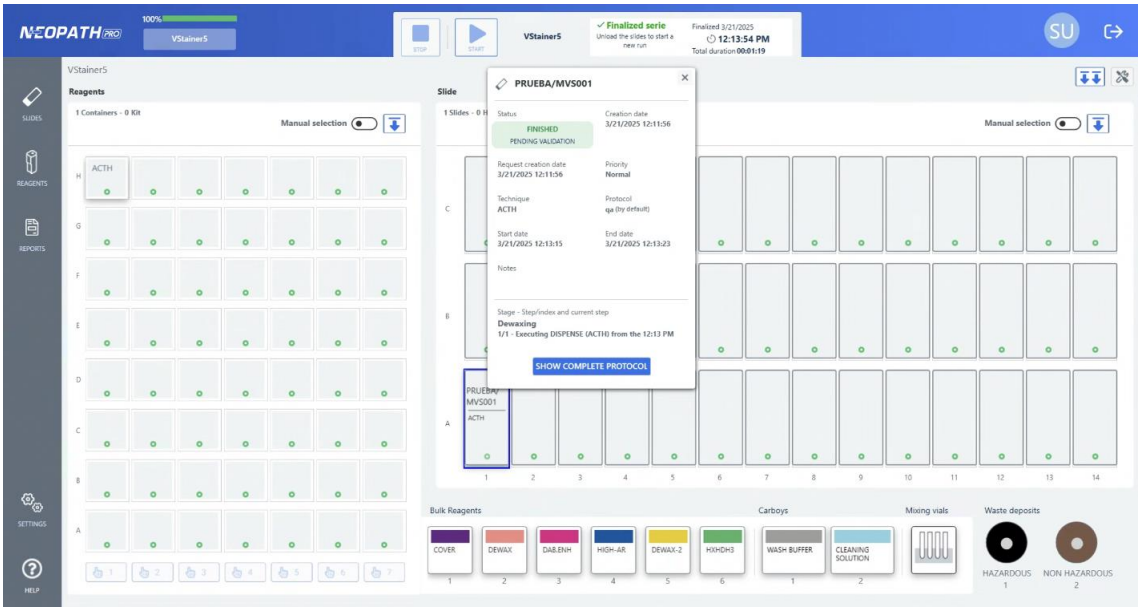
When the cancellation of the run is confirmed, the information section displays a message indicating that the run has been canceled and that the slide rack must be reviewed and unloaded in order to start a new run.

If any position in reagent vials has an error when a run is canceled, it will be represented as a warning.

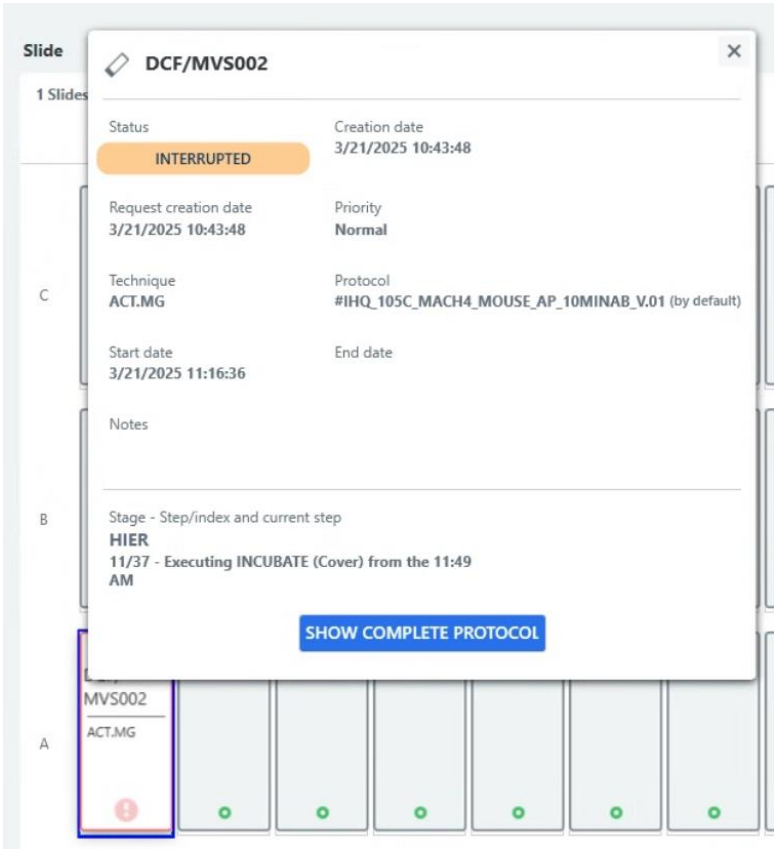


When the cancellation occurs during a run, the slides may be in multiple different statuses:

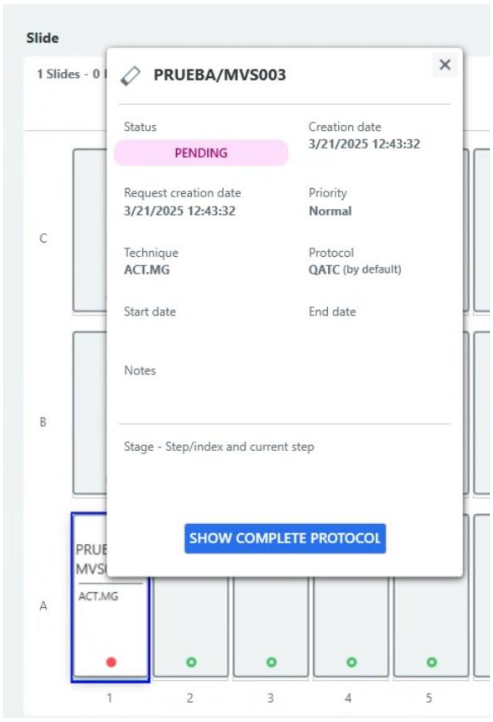
- **FINISHED** (Pending validation/Validated): The staining has correctly come to an end on the slide.



- **INTERRUPTED**: Staining on that slide was in progress and had not yet been completed. By clicking on the information card, you can see in detail where you were in the execution.

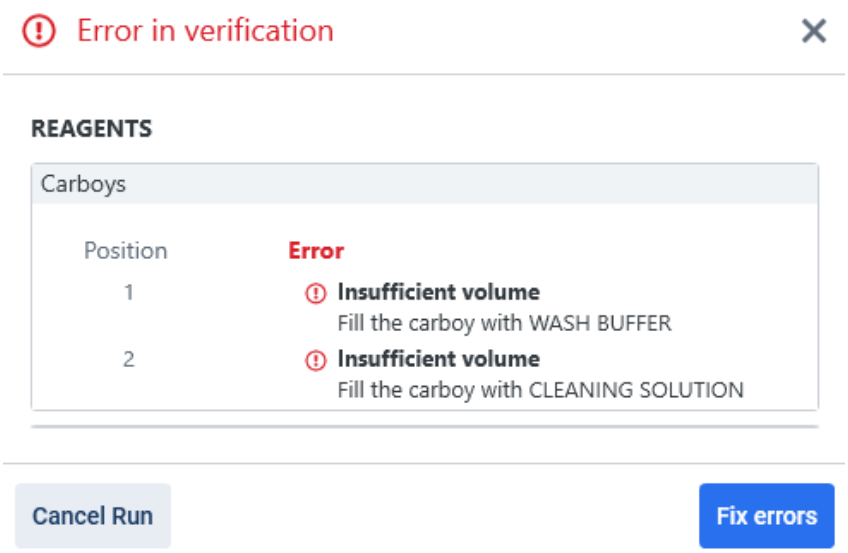


- PENDING: Staining has not started on these slides.



2. Canceling by pressing Cancel Run from the troubleshooting windows

The option to cancel a run is available as soon as the run is started and a problem occurs in reagents or slides. In case of errors, a summary window is displayed. By pressing the **Cancel Run** button, the behavior is the same as described in the previous section, when the Stop button is pressed.



3. Unload slide and reagent vial rack

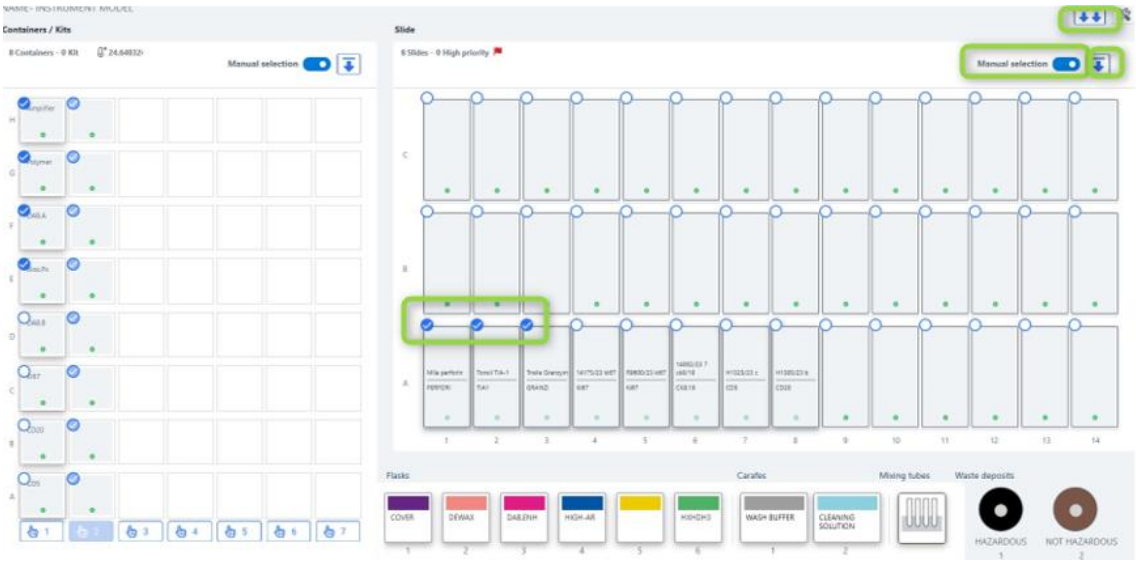
To empty the slide or reagent vial rack, click on the "Unload" button of each rack, or, alternatively, the "Unload all" button, which will empty the slides and reagent vials (if any are read).

It is also possible to unload only manually selected items, both in the slide rack and in the reagent vial rack.

Unloading slides after calculating required volumes

If pending slides are unloaded after the required volumes for running the run have been calculated, all reagent volumes in the protocol associated with the unloaded slide will be subtracted from the calculations already performed. In addition, the system will subsequently recalculate all required volumes before running the run to ensure there is sufficient volume to run it.

This will be reflected in the volumes of the required reagent modes:

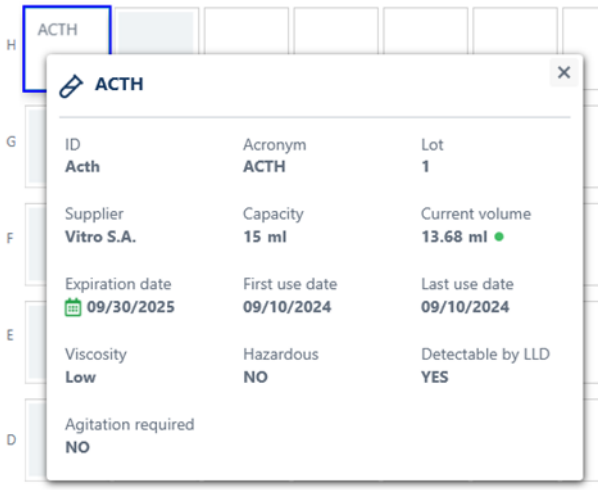


Reagent information card

Clicking on each of the positions of the vial, flask, bottles or tanks racks displays a window with the relevant information for each container.

1. Reagent Vial rack

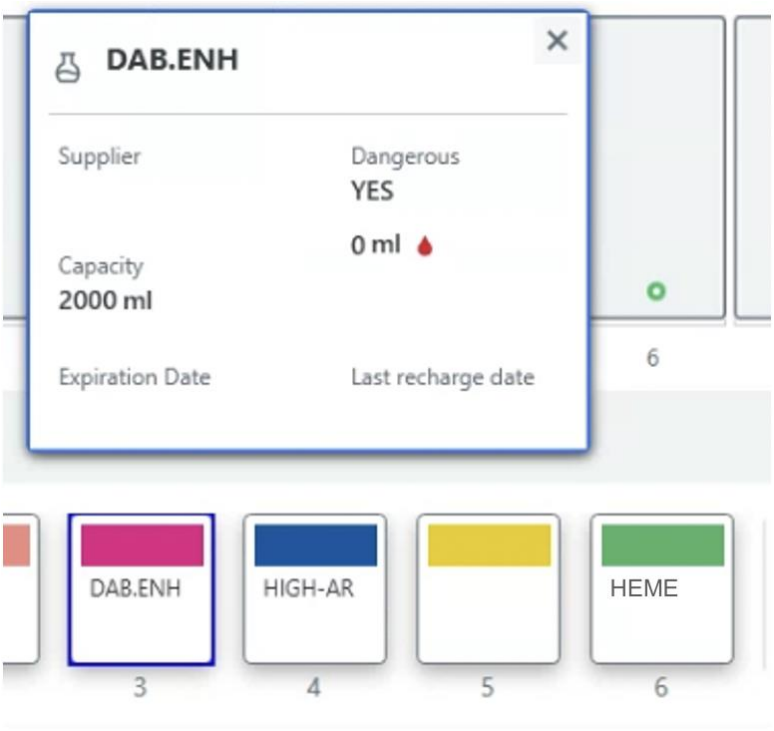
- Once the vial rack has been entered, the title with the acronym of the reagent contained in the vial is displayed and any warning or error it may have is indicated. When the information card is displayed in the header, the following data are shown in addition to the acronym of the vial content:
- Information on the error or warning
- Vial identifier
- Acronym
- Lot
- Supplier
- Vial capacity
- Current volume
- Expiration date
- First use date
- Last use date
- Viscosity
- Danger
- Air filter
- Detectable by LLD
- Agitation required

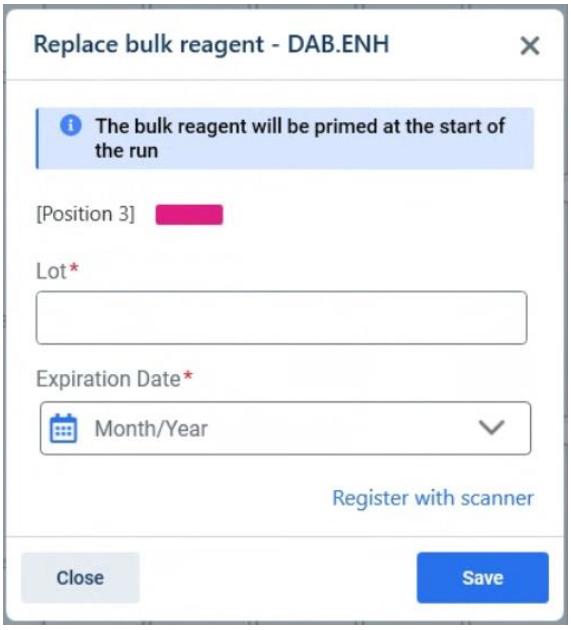


2. Bulk Flask Containers

Any warnings or errors will be shown on the map of the bulk flasks. By opening the information card of a bulk flask, the header shows the title with the acronym of the reagent contained in the flask. In addition, the following bulk flask data are displayed:

- Information on errors or warning
- Supplier
- Danger
- Capacity
- Current volume
- Expiration date
- Last refill date

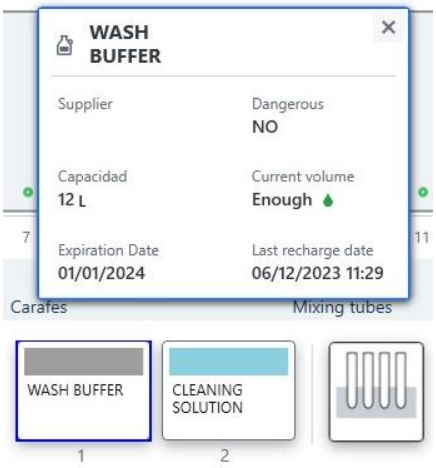


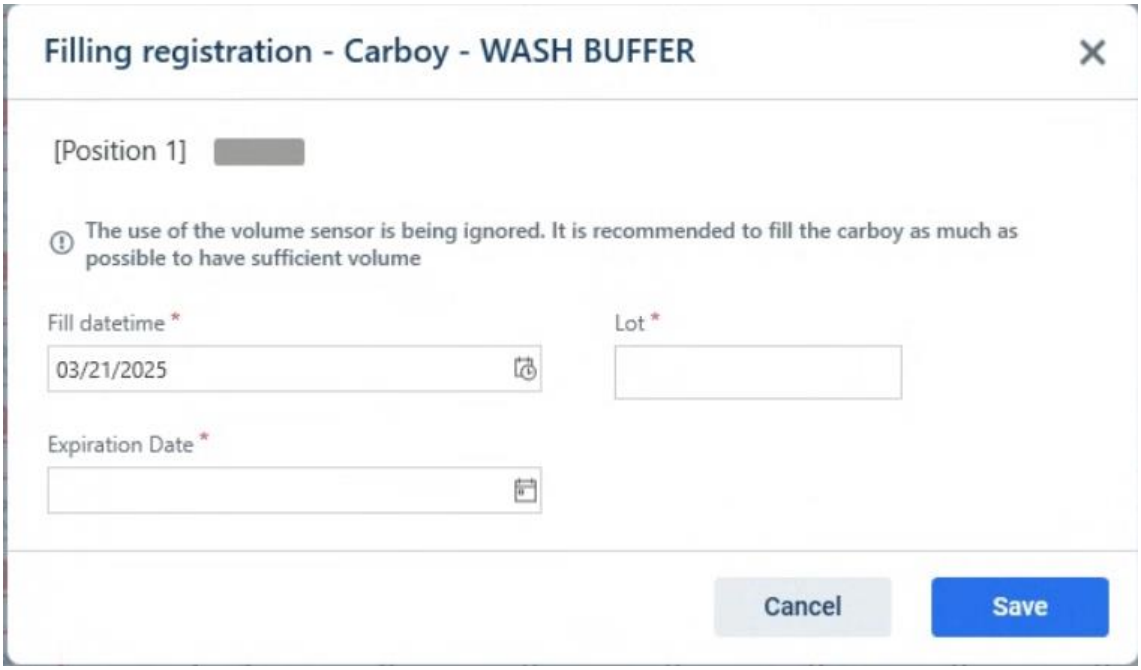


3. Bulk Carboys rack

The header of the information card of a carboy shows the title with the acronym of the reagent contained in the bottle and indicates first the warning or error it may have. In addition, the following bottle data are displayed:

- Supplier
- Danger
- Capacity of the carboy
- Current volume
- Expiration date
- Last refill date

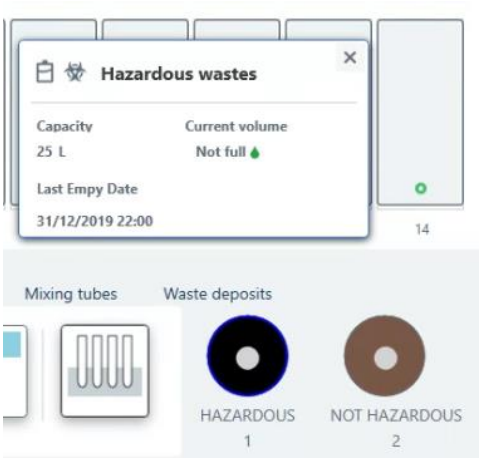




4. Waste tank rack

The header of the information card of a waste container shows the title and icon representing whether the container is a hazardous or non-hazardous waste container and first indicates the warning or error it may have. In addition, the following container data are displayed:

- Capacity
- Current volume: Full or Not full
- Last emptying date

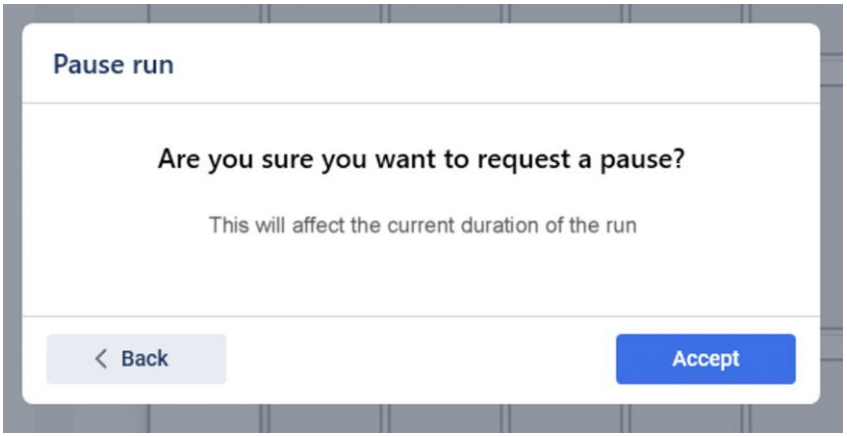


4.12 Pausing a Run

Once the run has started, the user can request a pause from the system interface (the appearance of the pause button will be parameterized). The Pause point will be based on protocol status (i.e. antibody incubation requires completion before the instrument will pause).

The NeoPATH Pro has Continuous Random-Access capability, for slides that require immediate processing and need to be added to an existing run. This feature can be accessed by clicking the Pause button, The user can also unload completed slides when the instrument is Paused. Once the Pause button is selected, the screen will display a countdown of when the instrument will reach a Pause point to allow the addition of new slides. Once new slides have been added, the instrument will scan new slides and calculate new reagent volume requirements. The instrument will automatically prime if reagent vials were re-filled or new reagent vials were added to meet new required volumes. A new completion time will appear on the screen with the addition of new slides.

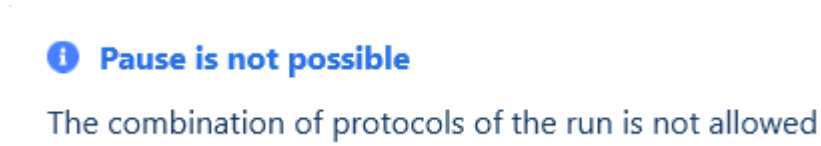
Once requested, the following confirmation window will appear:



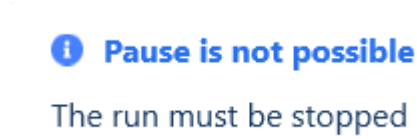
Initial Checks

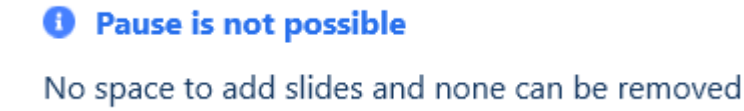
Once a pause is requested, the system will check the following conditions before allowing the pause:

- Mixes on Slides: The pause is allowed if all slides contain HRP reagents or all are AP reagents, but not both together.



- Slide Status: The pause is allowed if at least one slide has a pending step that can be paused.



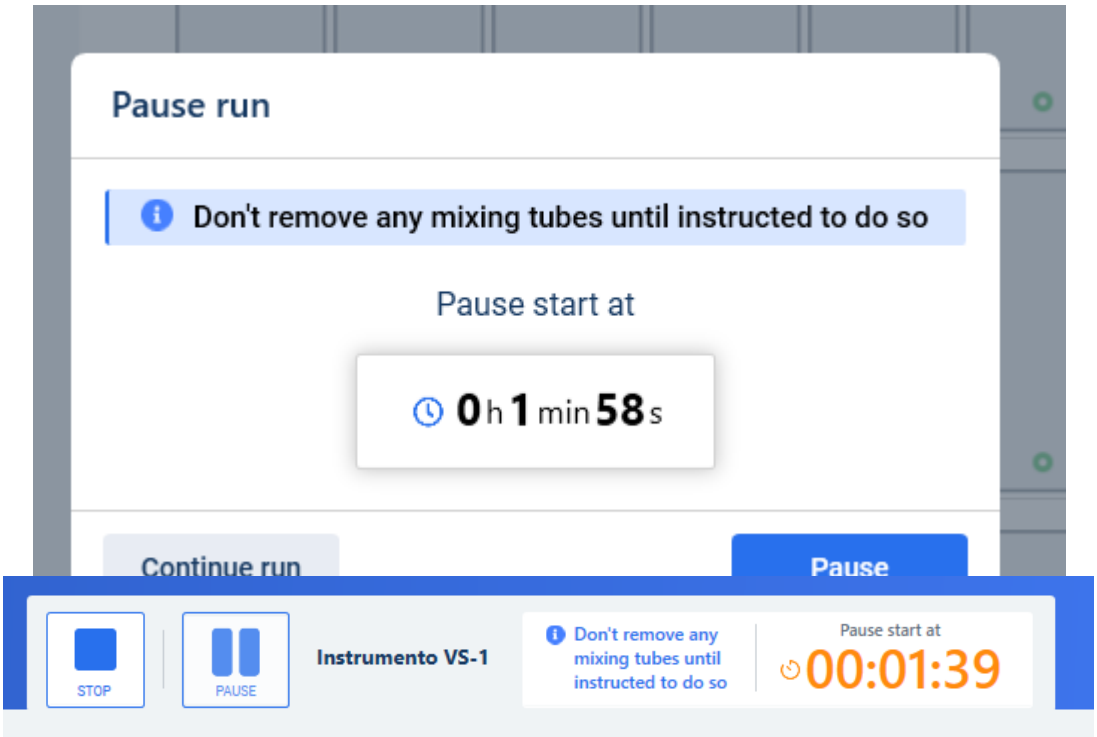


- Position Availability: The pause is allowed if there is at least one empty position for inserting a new slide or a position with a completed slide for removing it.

Calculating the Estimated Time to Pause

If all conditions are met, the system will calculate the estimated time to complete the pause. This information will be displayed in a pop-up modal window that will include the estimated time to complete the pause.

Actions on the Pause Series Modal Window

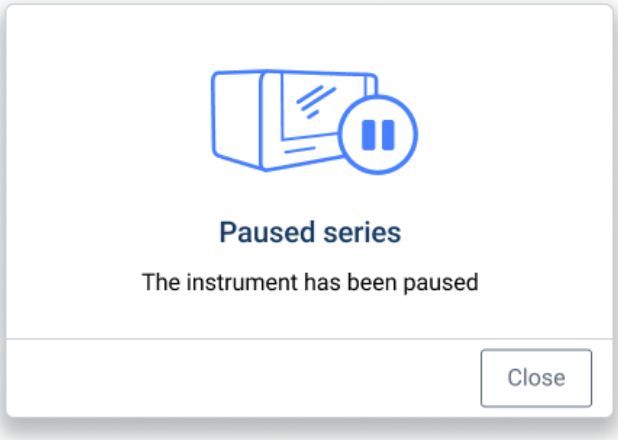


The user can decide what to do from the Pause Series modal window:

- Cancel the Pause
    - If the user cancels the pause request before the process is complete, the run will continue as normal.
    - If canceled after 5 minutes, there is a risk of causing delays in the run.
- Continue the Pause
    - If the user confirms that they want to continue the pause, the process will continue.
    - Once the pause is confirmed, it will not be possible to reverse this action.
    - If the user does not take any action, the modal window will close automatically once the system has completed the pause.

Actions During Pause

The user will be notified that the system has completed the pause by an on-screen message accompanied by an audible alert.



At this point, the user can perform the following actions:

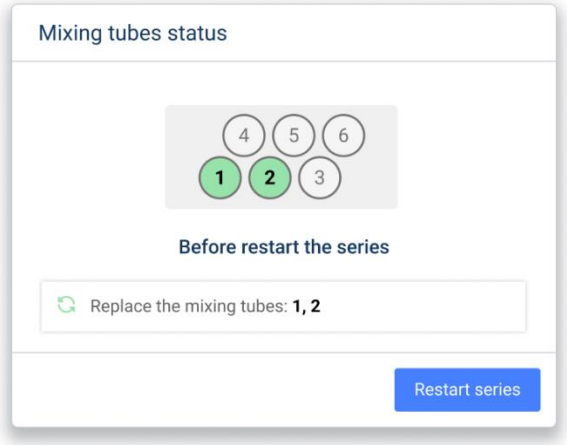
- Slide Management:
    - Remove completed slides.
    - Place new slides in the available positions.
- Rack and vial management:
    - Remove or place racks to replace or refill vials
- System maintenance:
    - Replace vials.
    - Refill reagent bottles.
    - Empty waste.

- Priming of vials and bottles are integrated into the run resumption process. Unloading slides:
    - Only slides that are not in progress can be unloaded (pending and completed slides can be unloaded).
- Continuous Random Access:
    - Place new slides in the available positions.
    - Replace vials.
    - Refill reagent bottles.
    - Empty waste.
    - Remove completed slides.
    - Priming of vials and bottles are integrated into the run resumption process.

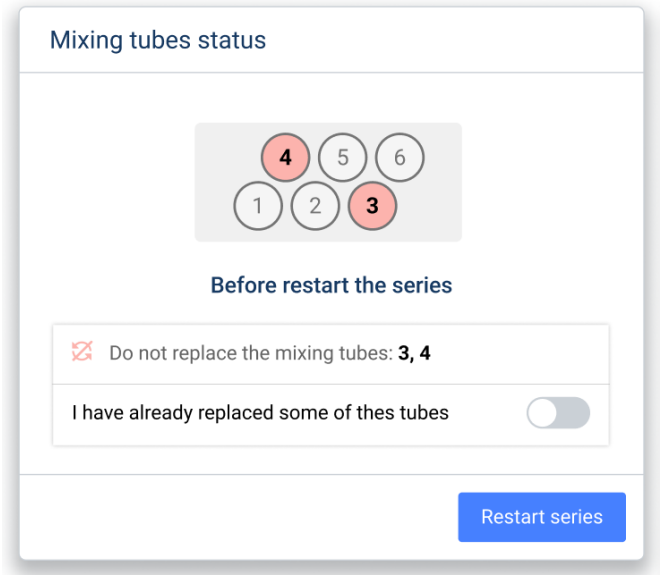
4.13 Resuming a run

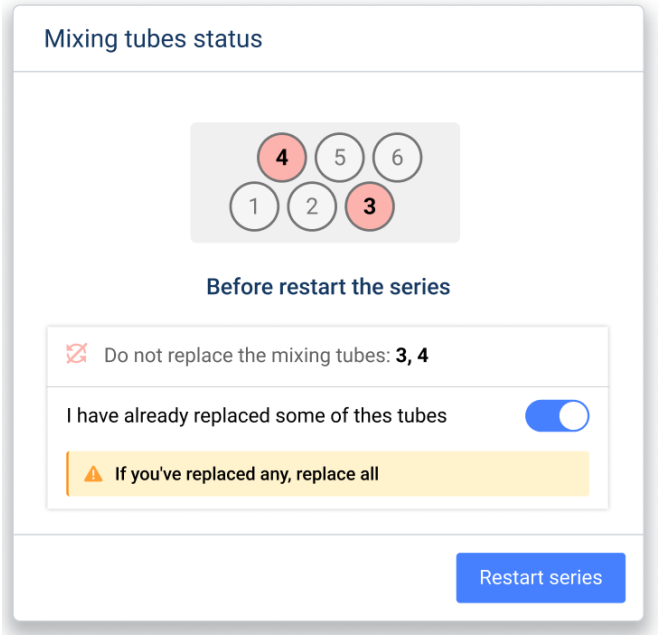
At the end of the pause, the system will perform the same checks it performs at the start of a run:

- Slide check: Any problems detected with the slides will be reported.
- Vial and reagent check: The reagents and consumables will be validated to ensure they are sufficient to continue.
- Mixing Tube Management:
    - The system will inform you if any mixing tubes that have already been used during the process can be replaced (highlighted in green).

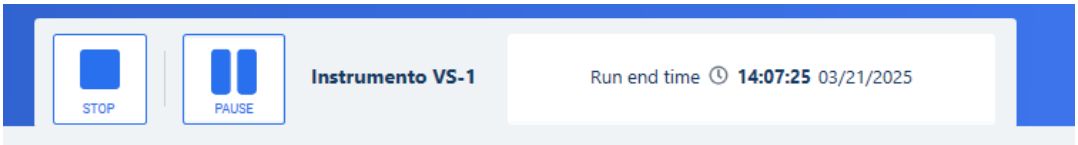


    - It will also notify you if there are any mixing tubes that should not be removed because they will be needed when resuming the run (highlighted in red).
        - If the user has already removed any mixing tubes at that time, they will all need to be replaced so the planner knows how to perform the mixes again and must have sufficient volume.





If all checks are correct, the run will automatically resume, and the system will update the estimated completion time.



4.14 List of slides

From this module, slides can be created and managed regardless of their status.

The possible statuses are:

- Pending execution.
- In process.

- Finished.
- Interrupted.
- Discarded.
- Canceled.
- Completed (Pending validation).
- Completed (Validated).

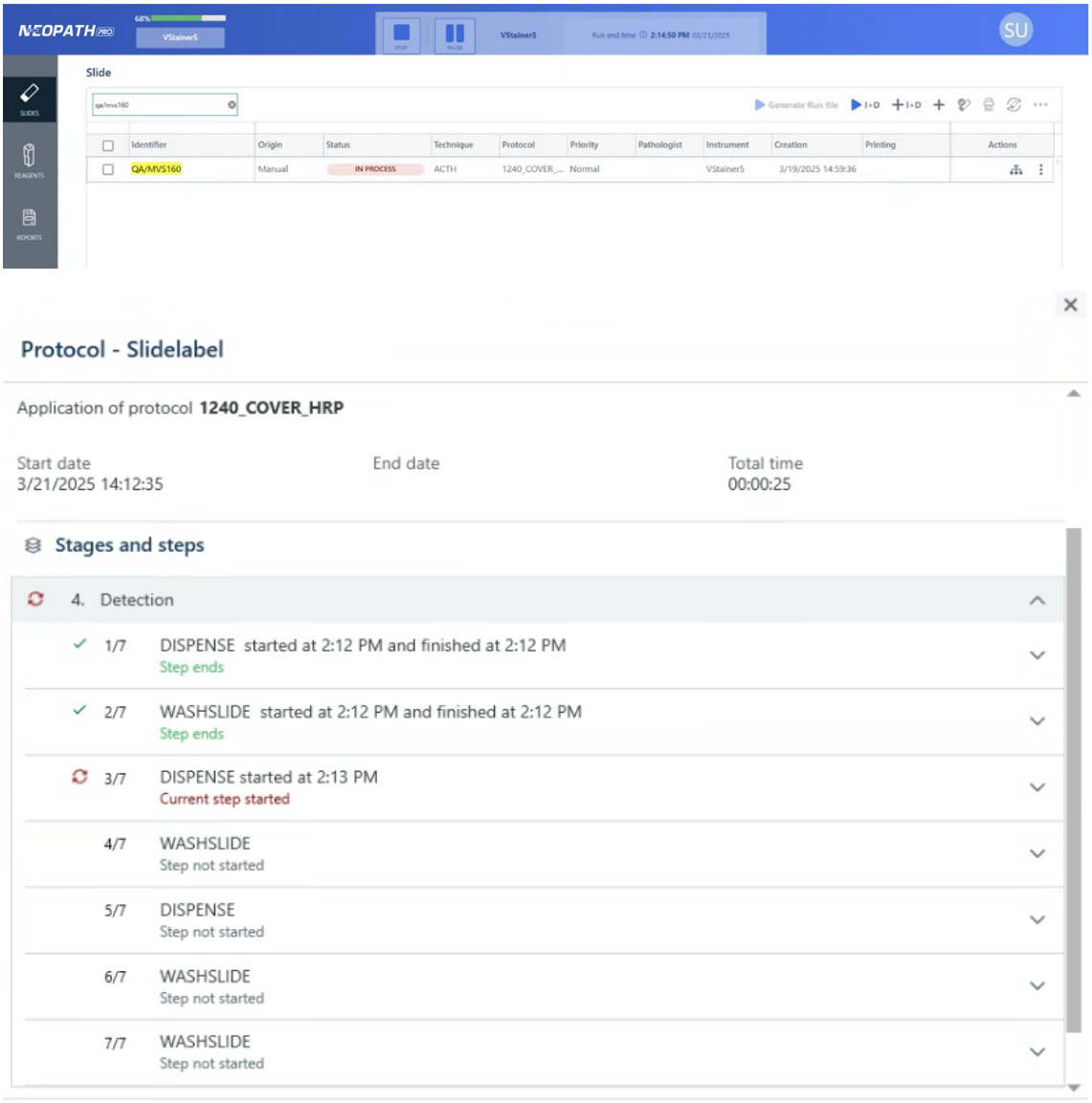
The various slide list configuration options may be affected depending on the application's settings.

If there is integration with a LIS (the LIS Integration parameter is enabled), the changes will be as follows:

  - “Origin” column, to be able to differentiate the origin of the request to which the slide corresponds (LIS or Manual).

View the steps of a slide and the reagents used

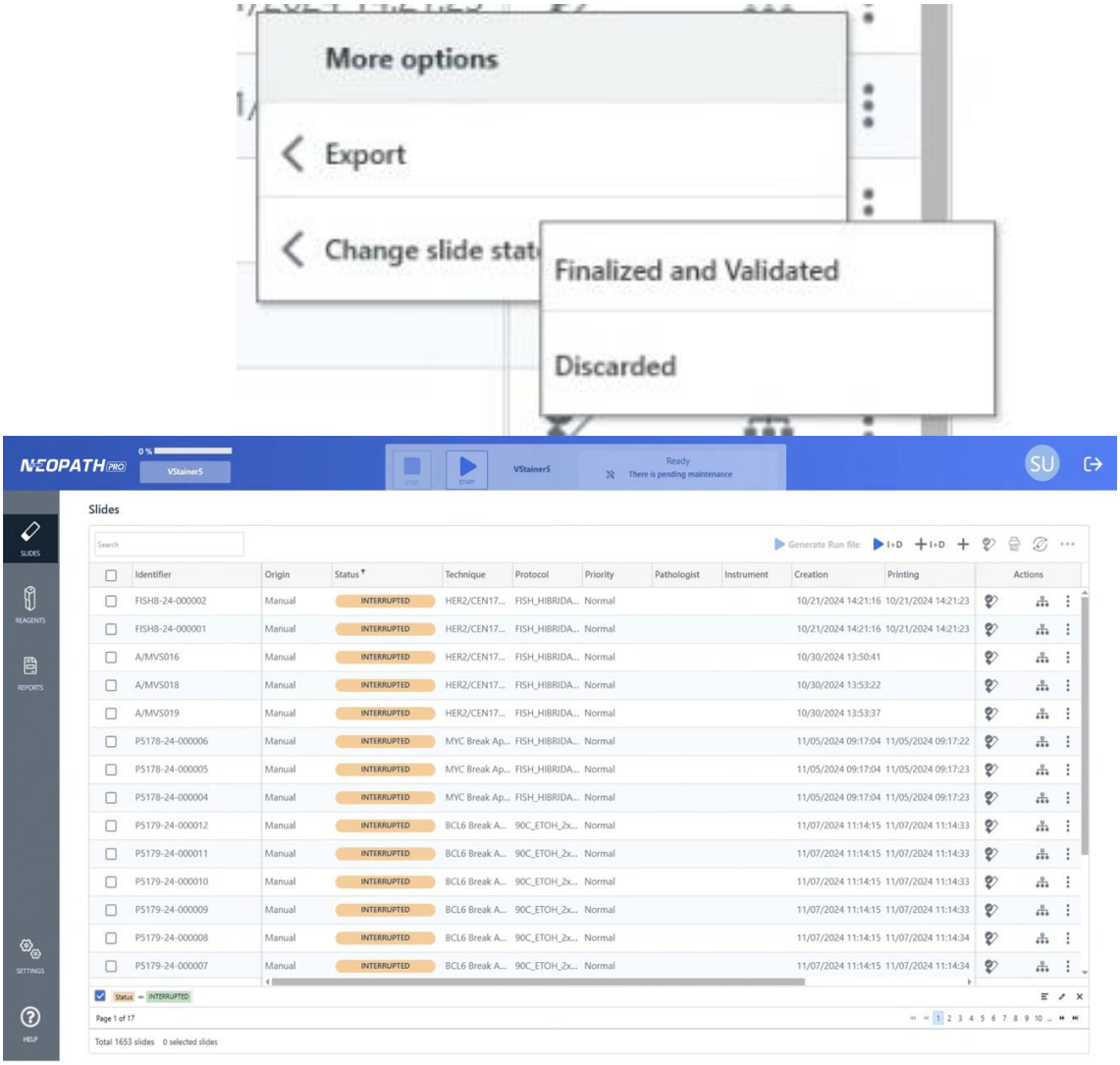
For all of them you can see the status of each phase and step, as well as its duration.



From this same window the reagents used during staining can be viewed.

End or discard a slide

Once the user has decided whether the slide has remained at a valid point or whether it should be discarded, the user can change its status from the more actions button and select the final status. The user may also finish it manually if it is recoverable and then change its status to finished and validated.



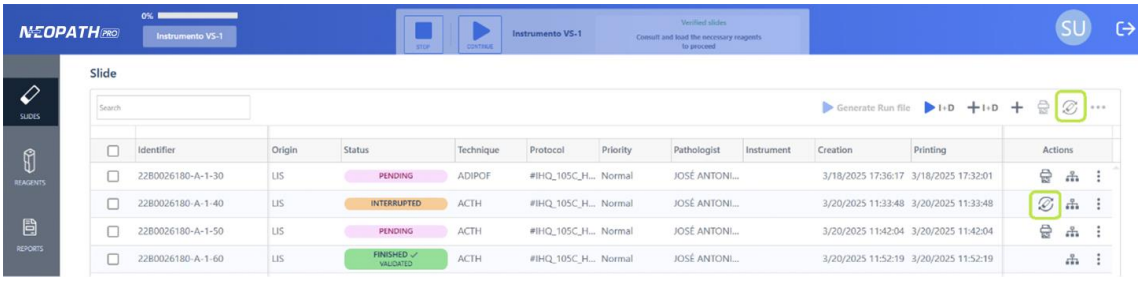
The status of these slides can be changed depending on their current status:

- Interrupted Slides: A slide changes to interrupted status if the procedure was started and the run has been canceled, either by user decision, an instrument failure, or a disconnection. The new statuses the user can choose are: Completed and validated or discarded.
- Slides pending loading: The new status the user can choose is: Completed and validated.
- Completed slides pending validation: The new statuses the user can choose are: Completed and validated or discarded.

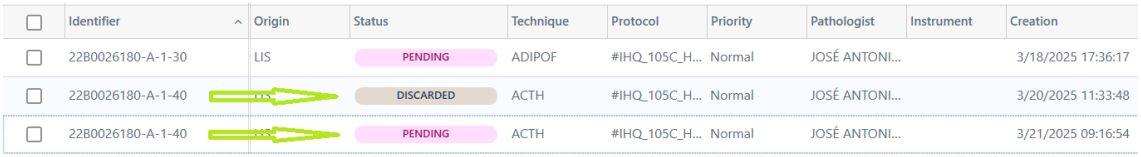
Repeat and print label for slides from the LIS

For slides from the LIS, there is the option to repeat slides from the LIS, ensuring that this can only be done under certain conditions. This way, a slide may be discarded, but the user will be able to repeat the slide associated with the same LIS origin request and maintain traceability.

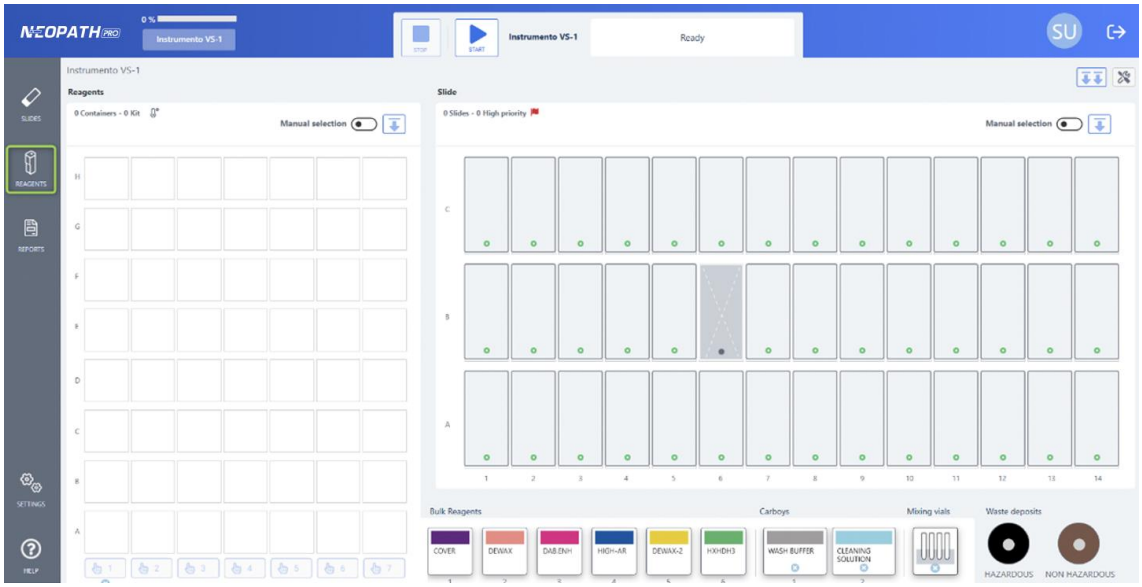
This action will only be available for slides from the LIS that are not loaded in the slide rack and are in the Interrupted, Discarded, and Completed pending validation statuses.



After repeating and printing a slide, a new slide is recorded in the Pending status, equal to the original. The original slide's status changes to Discarded.



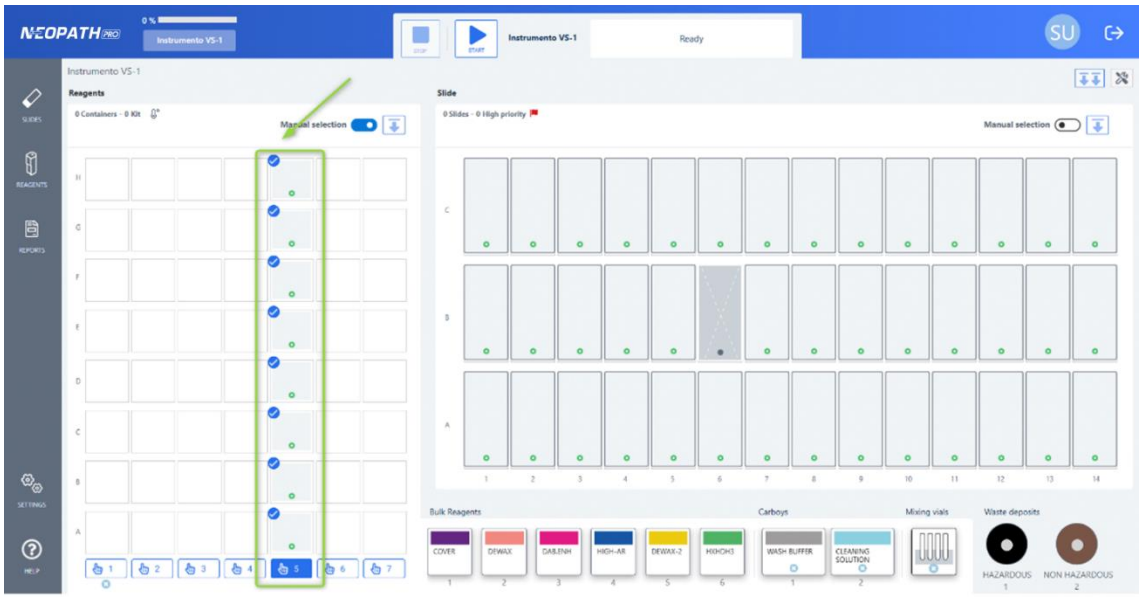
4.15 Vial inventory



The Inventory is accessed through the REAGENTS button in the vertical menu on the left side of the main screen.

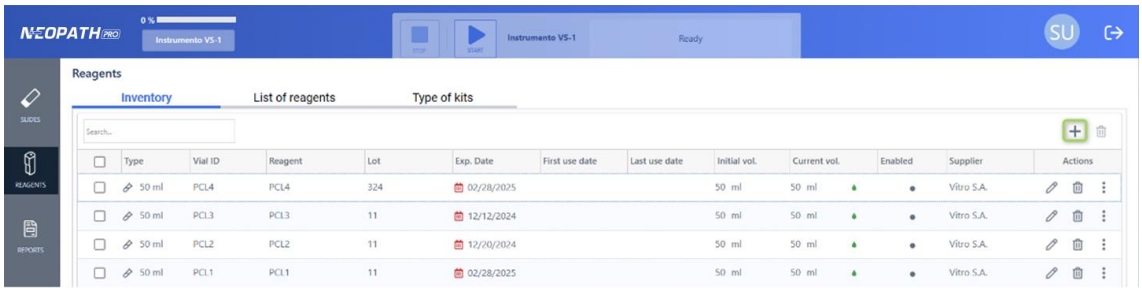
Register reagent vials

Vials can be deregistered in two ways:



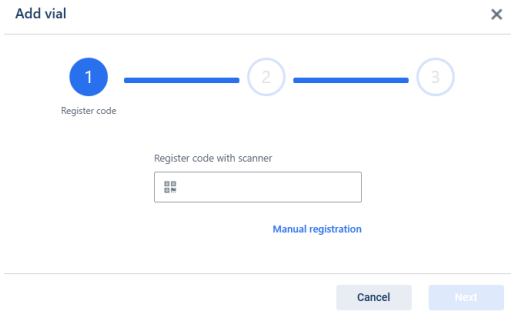
- **Automatically:** when the reagent vial rack is scanned at the start of a run, the instrument will read the positions of the racks that have been inserted and detected by the instrument.

  All vials will be added to the Inventory automatically by reading the labels on the vials.

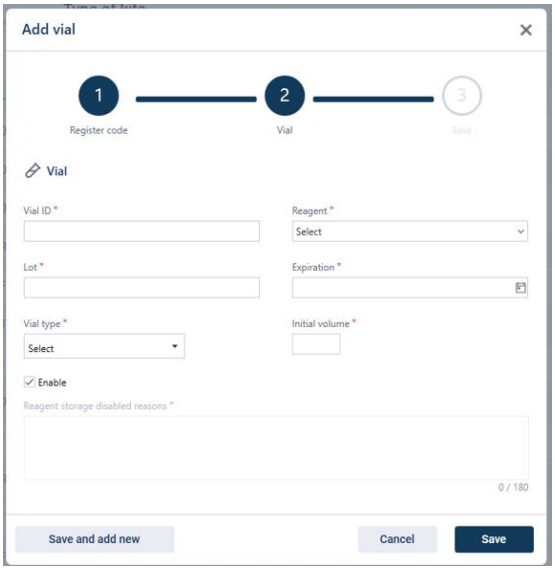


- **Manually:** from the Inventory screen, click on the button to access the form for adding new vials to the Inventory.

  It can be registered manually or with a label reader.



In one way or another, the vial registration form opens. All data will be reported if the code reading of the vial label has been performed correctly. Or enter the vial data manually.



The data to be reported to register vials are as follows:

- Vial ID
- Reagent
- Lot
- Expiration

- Vial type (2.5mL; 15mL; 50mL).
  Note: This information is shown at the bottom of the vial label.
- Initial volume
- The vial will be enabled by default when it is registered.

The options available from this window are:

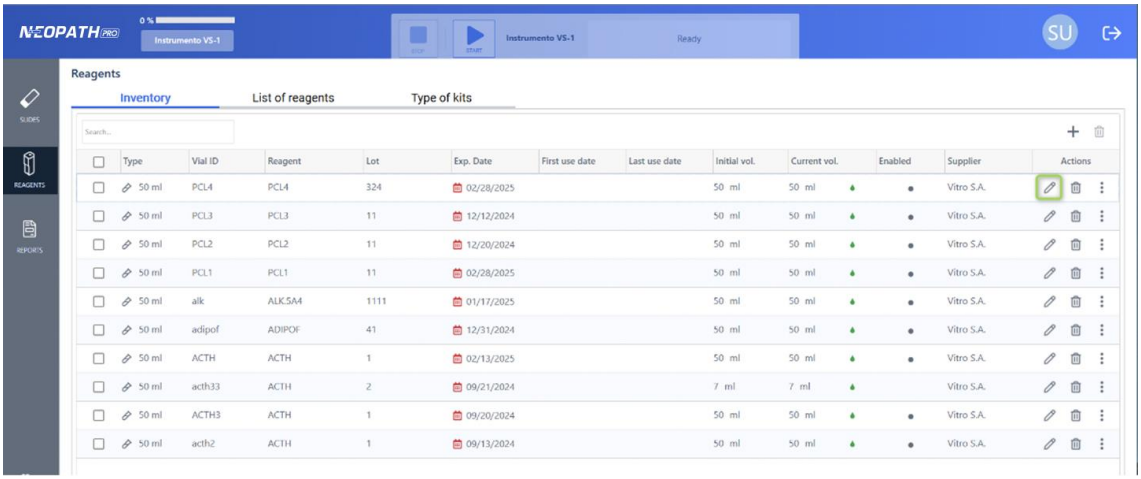
- **Save**: if all the data entered are validated correctly, the form is closed, and it appears in the inventory list.
- **Cancel** or cross in the upper right corner to close the registration form.
- **Save and add new,** it validates that all the data entered are correct and, after closing the form and updating the inventory with the vial created, the window opens again to report the barcode or register manually and continue with the registration.

Edit vials

For each vial record, by accessing the icon from the Inventory list.

The vial editing window opens. The editing window is similar to that of the vial registration, with the added fields of Current volume and date of first and last use.

- **If the vial has not been used.** All data can be updated, except current volume, and date of first and last use.
- **If the vial has not been used.** All data will be displayed in read mode, but will not be editable, except for the Enable field, and only if the user has permissions, and the vial meets the criteria to be enabled.

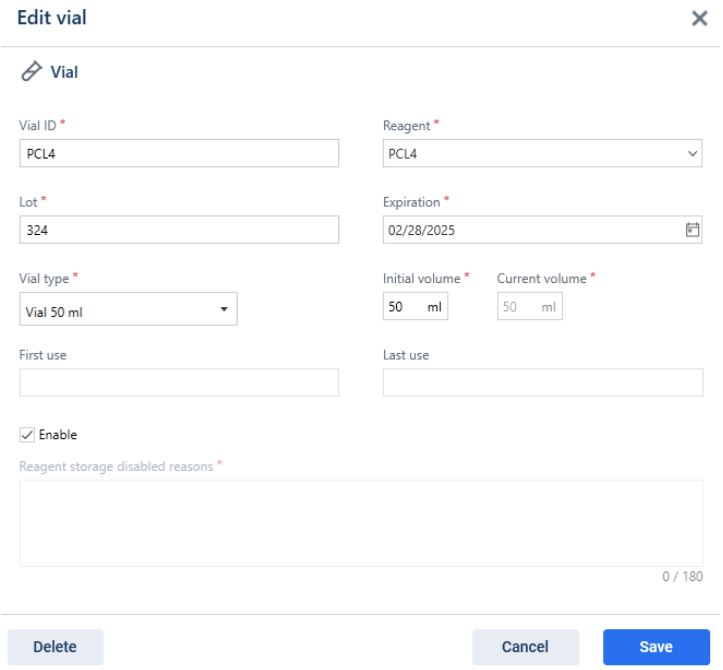


The options available from this window are:

- **Save**: if all the data entered are validated correctly, the form is closed and appears updated in the inventory list.
- **Cancel** or cross in the upper right corner to close the registration

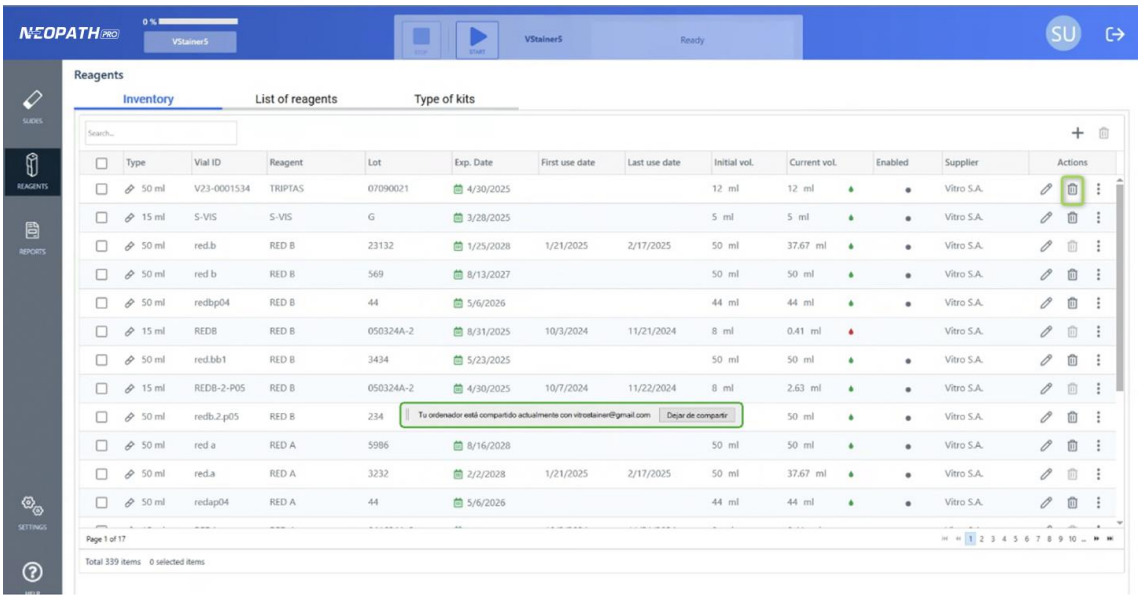
In addition, if the vial can be removed, the following option is available:

- **Delete:** The Delete button will only be available if the vial has not been used and will display a confirmation dialog after pressing it. After confirmation, the corresponding record will be deleted, the window will close, and the inventory list will be updated.



Delete vials

You can delete a vial individually by clicking on the icon at the record level in the list.

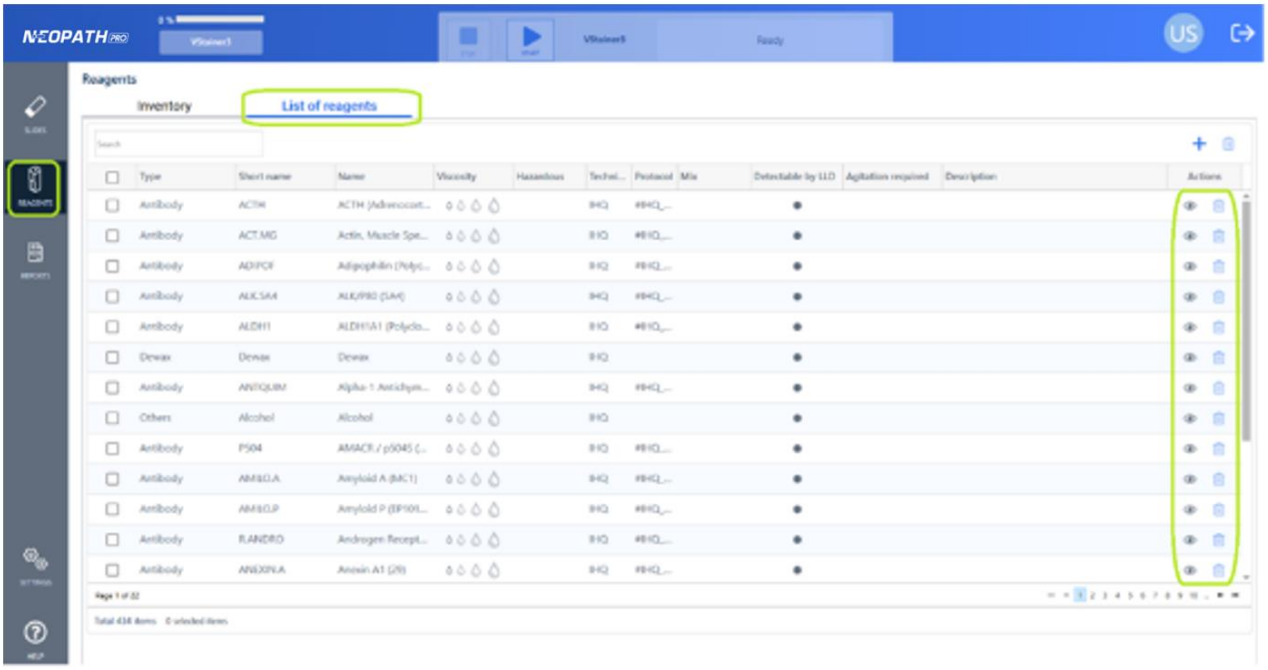


The Delete button will only be enabled if the vial has not been used and will display a confirmation dialog after pressing it. After confirmation, the corresponding record will be deleted, the window will close, and the inventory list will be updated.

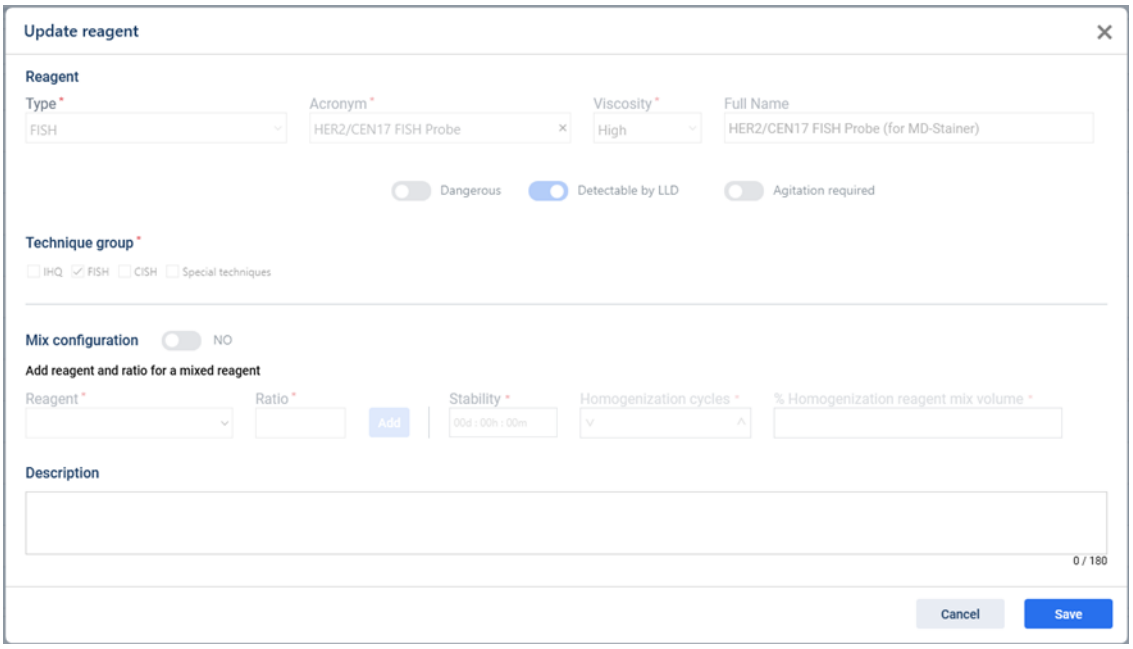
The table level button will be enabled only if you select one or more rows in the list that have the row level delete button visible, and none of them have previous uses. After pressing it, a confirmation dialog is displayed. After confirmation, the corresponding records are deleted, the window is closed, and the inventory list is updated.

4.16 List of reagents

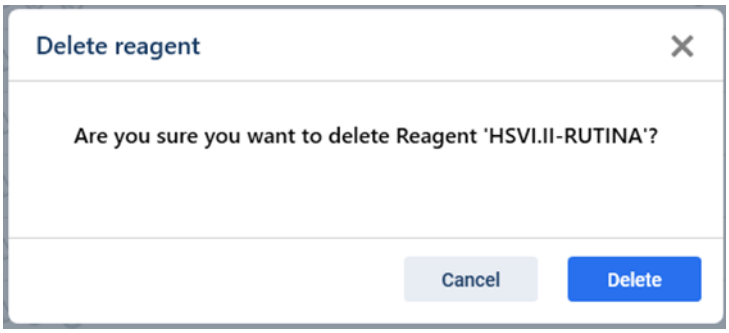
Access to the List of reagents is through the REAGENTS button in the vertical menu on the left side of the main screen.



The data of each reagent can be accessed, but only in read mode, from the icon . It can also be accessed by selecting a single record and clicking on the icon at the table level.

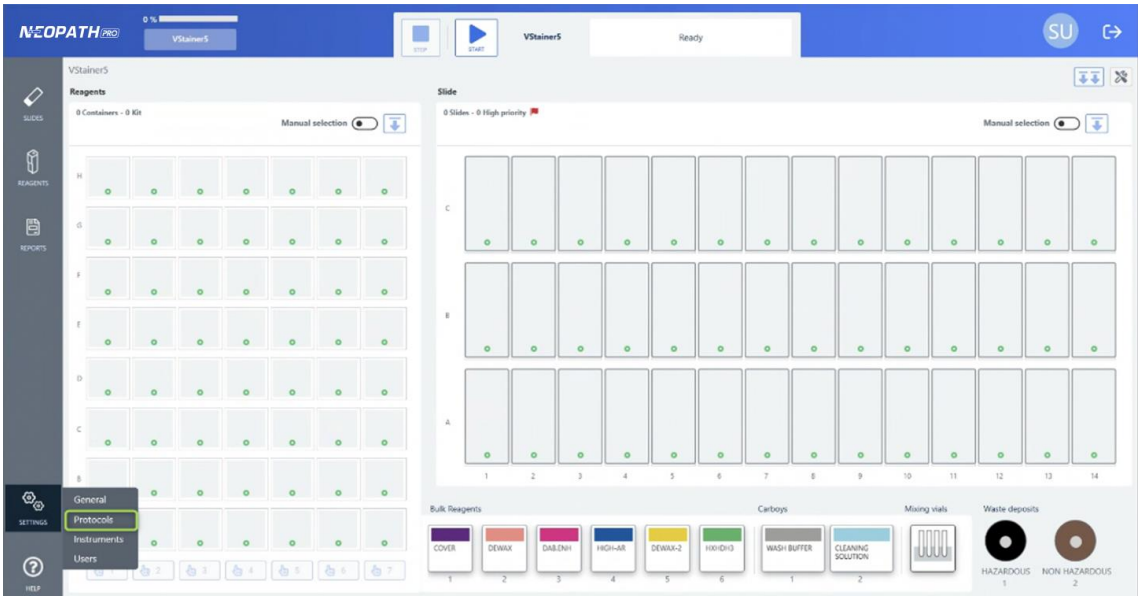


The reagent that meets the criteria will have the icon enabled and can be deleted. When the icon is clicked, a window is displayed to confirm or cancel the action of deleting a reagent. The same icon will also be enabled at the table level for the mass deletion of reagents, if they all meet the conditions for deletion.



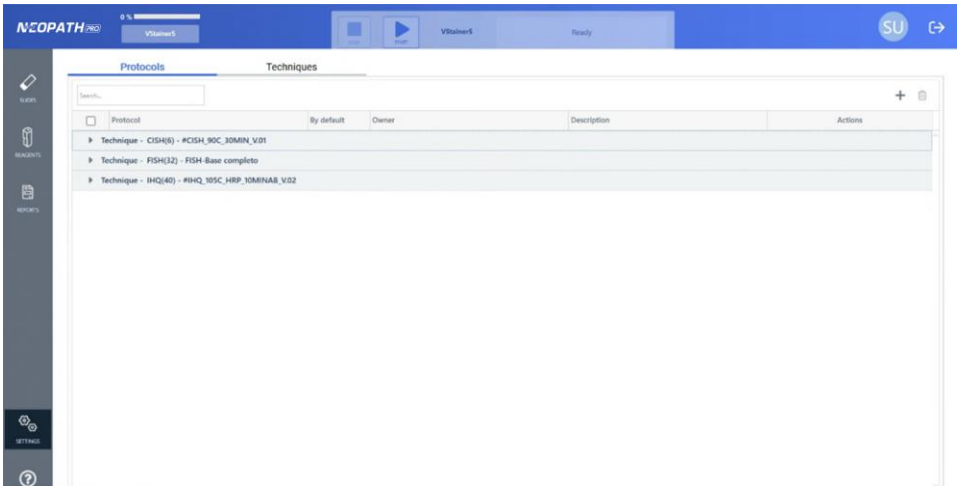
4.17 Protocols and techniques

To access the management of protocols and techniques, click on Settings/Protocols.



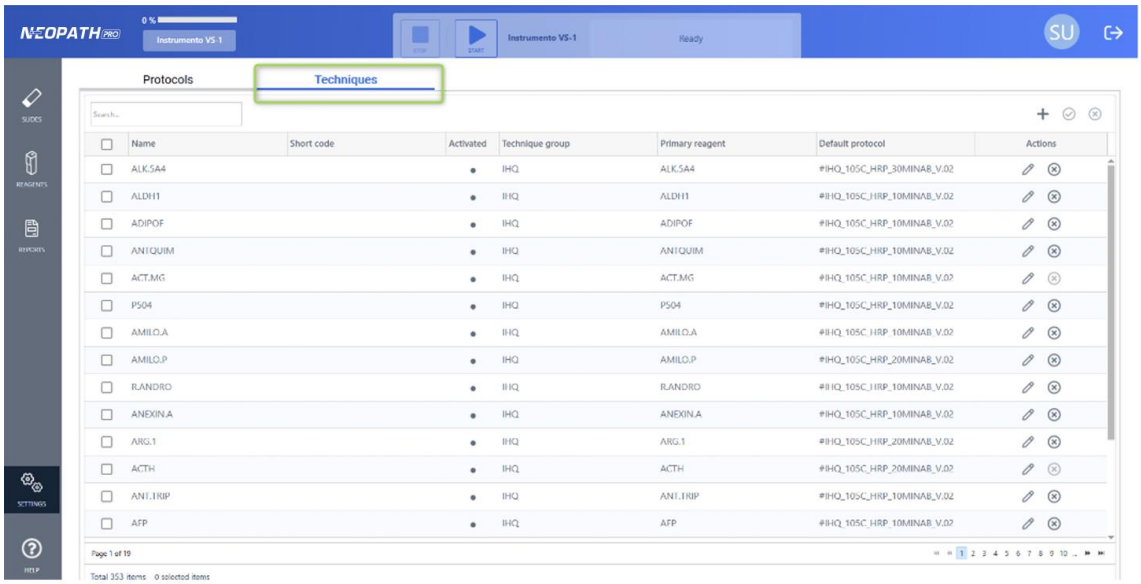
Protocols

From this module you can view the protocols assigned to each group of techniques and see which is the default protocol.



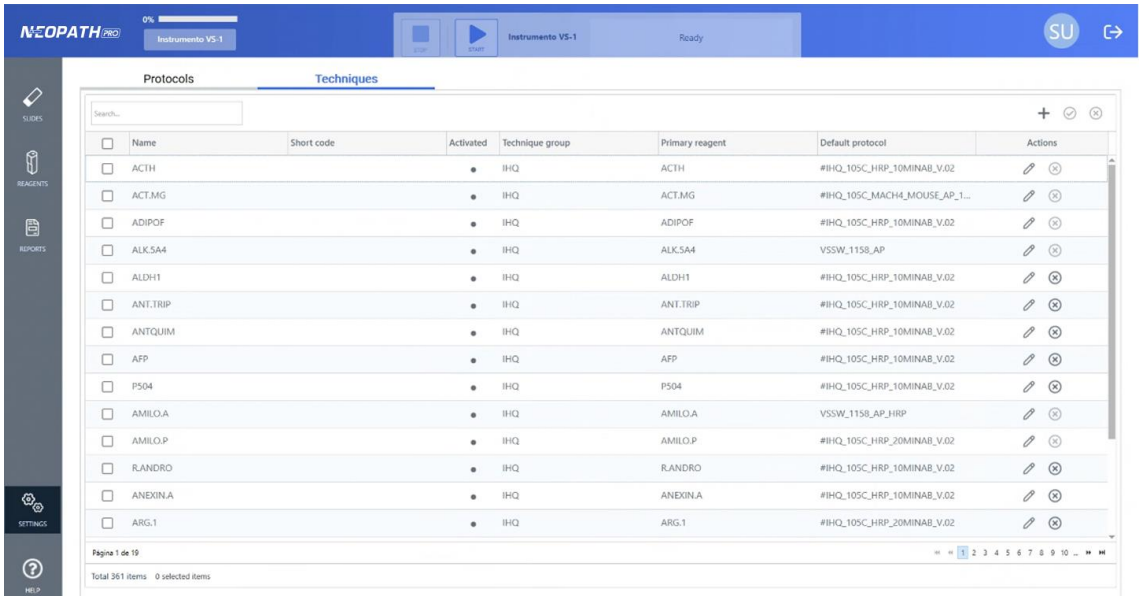
Techniques

To access the techniques, click on the Techniques tab.

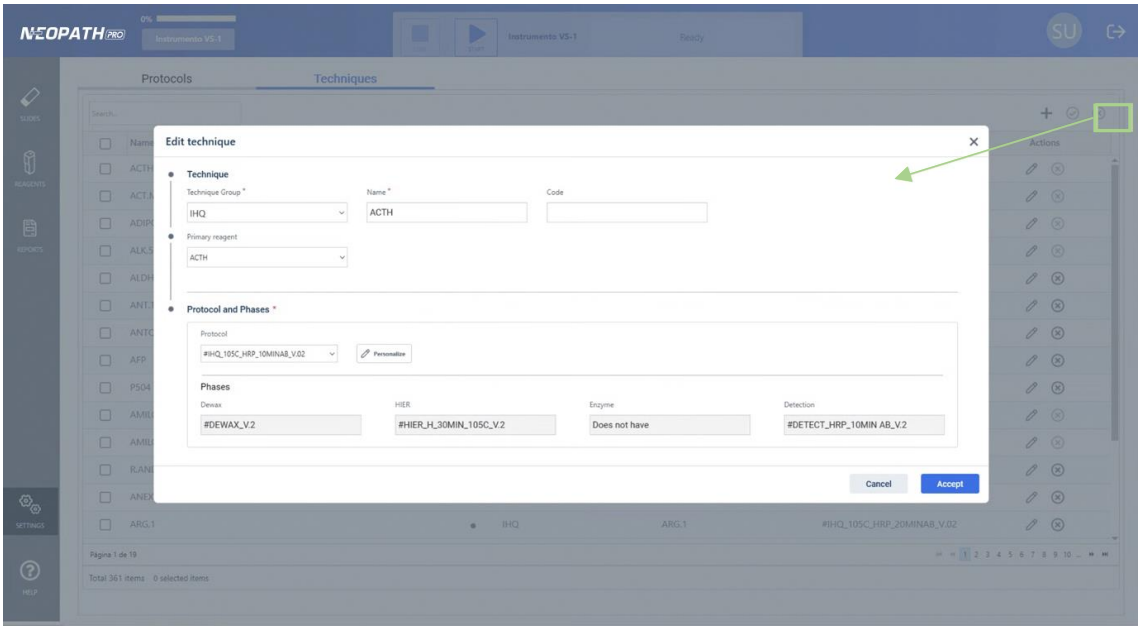


From this module you can see the list of techniques and their configuration.

- Technique activated or not.
- Group of techniques to which it belongs.
- Primary reagent associated with the technique.
- Protocol associated with the technique.



To edit the technique, click the icon . From here, you can access the technique editing window.

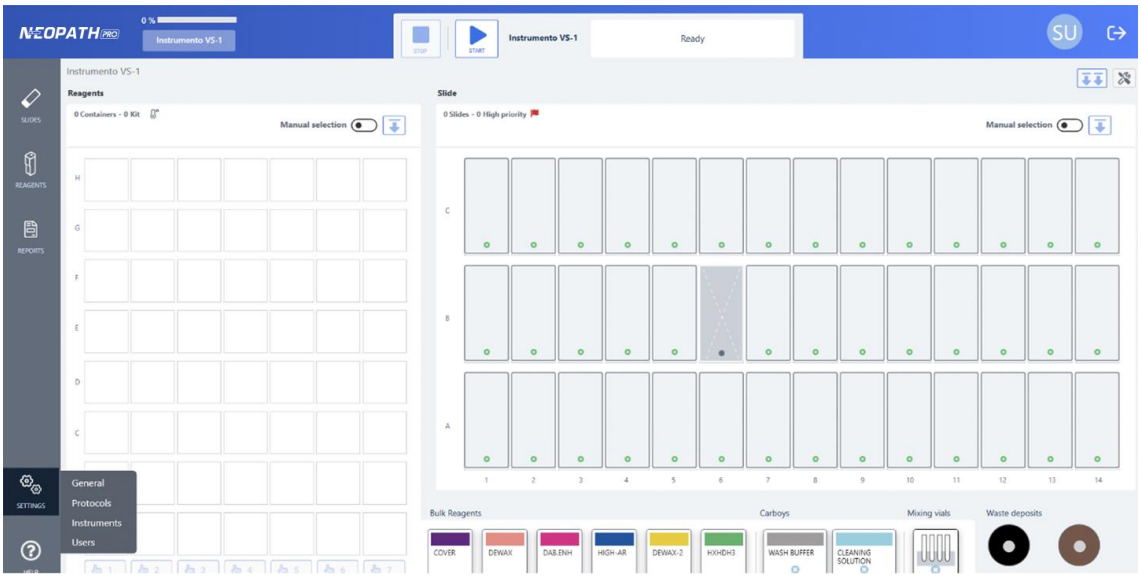


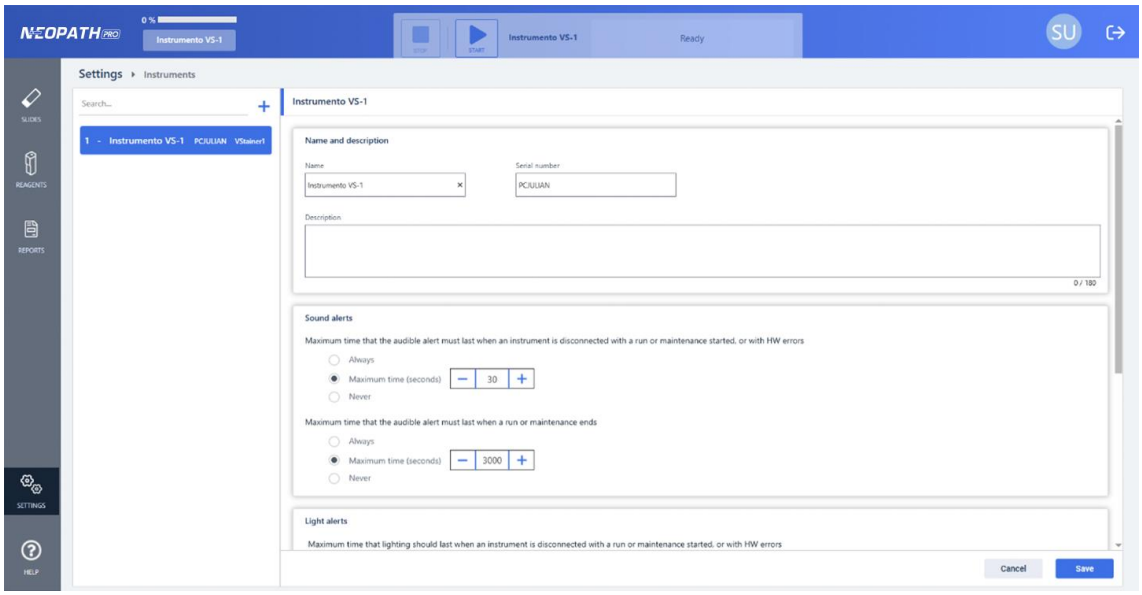
The window contains the following options:

- Technique group.
- Name.
- Code.
- Primary reagent: The system will allow a reagent to have multiple associated techniques. This means that, when creating or editing a technique, the user can select any reagent from the system, even if it is already linked to another technique.
- Protocols and phases.

4.18 Instruments

To access instrument management, click on Settings/Instruments. From this module you can view and change the configuration of the instruments.



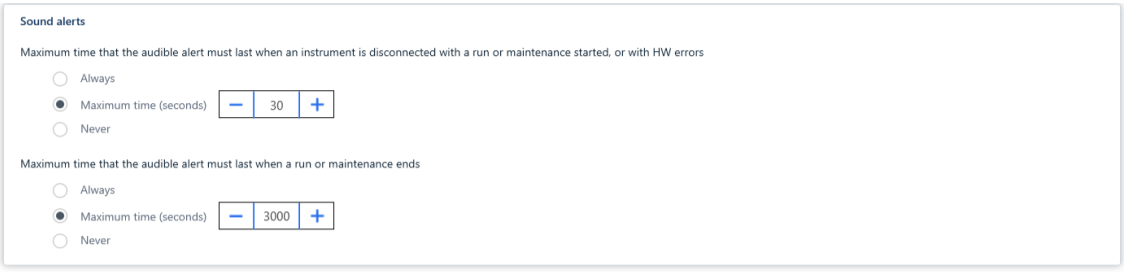


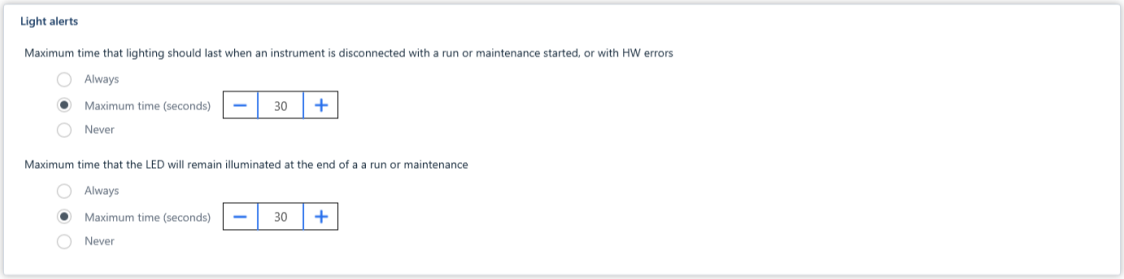
Alert configuration

At the end of a run, maintenance or when a problem occurs, the system activates sound and light alerts to inform of the event.

These alerts can be configured to work as follows:

- **Always.** (option by default). They will be activated until the window informing about the event is closed.
- **Maximum time.** They will be activated until the maximum time set is reached or the window informing of the event is closed.
- **Never.** They will not be activated at any time.





Cold table configuration

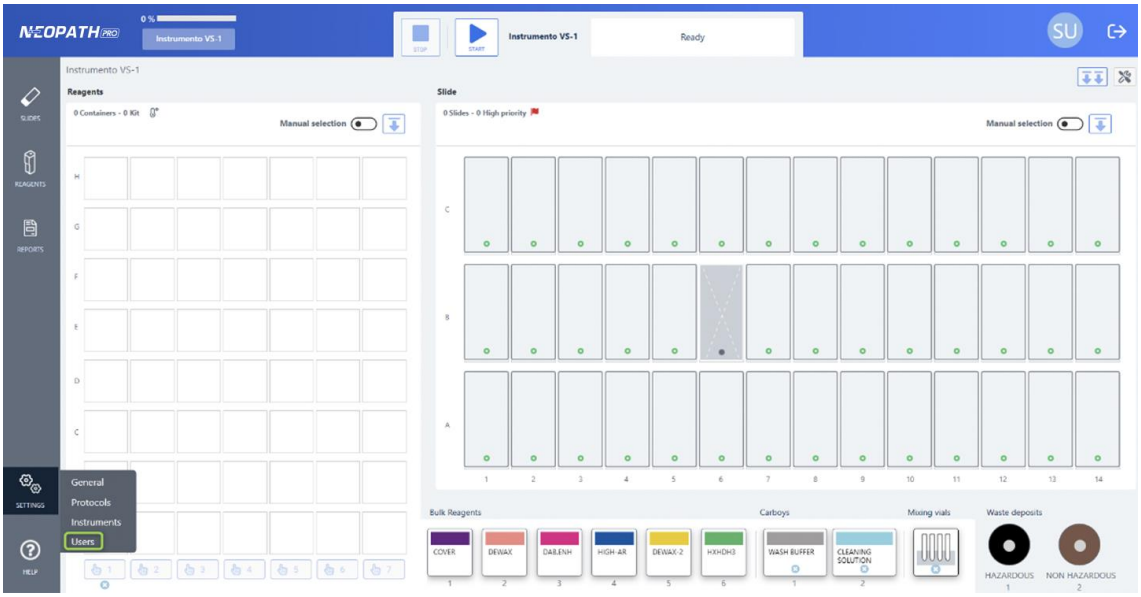
The cold table is internally configured with the following values:

- Storage temperature: 18°.
- Temperature during the run: 20°.

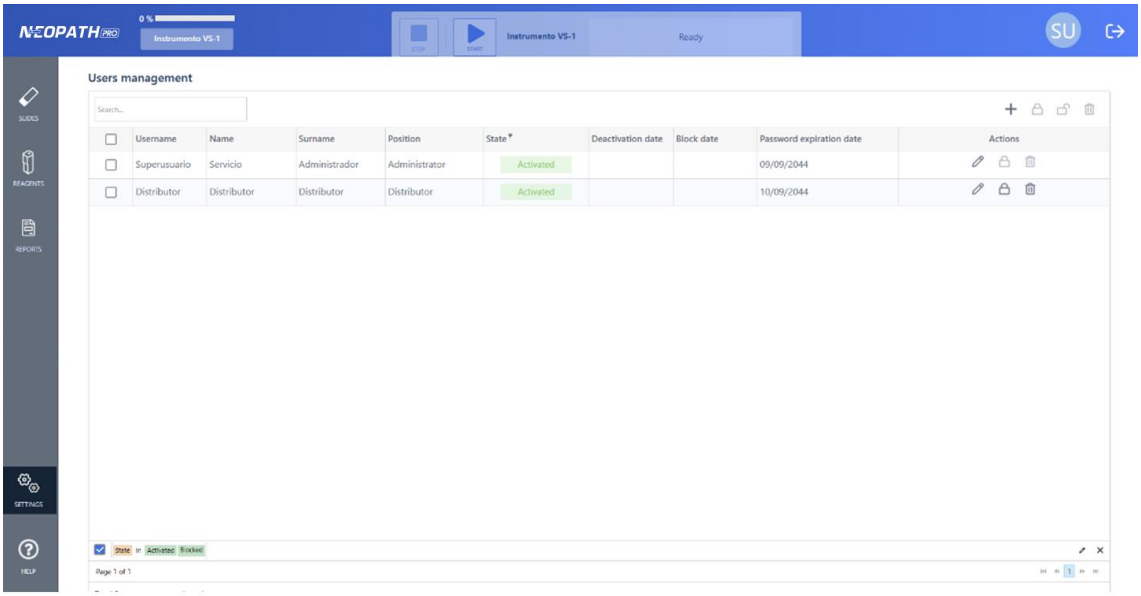
These values can be changed if necessary.

4.19 Users management

To access user management, click on Settings/Users. From this module the system users can be managed.

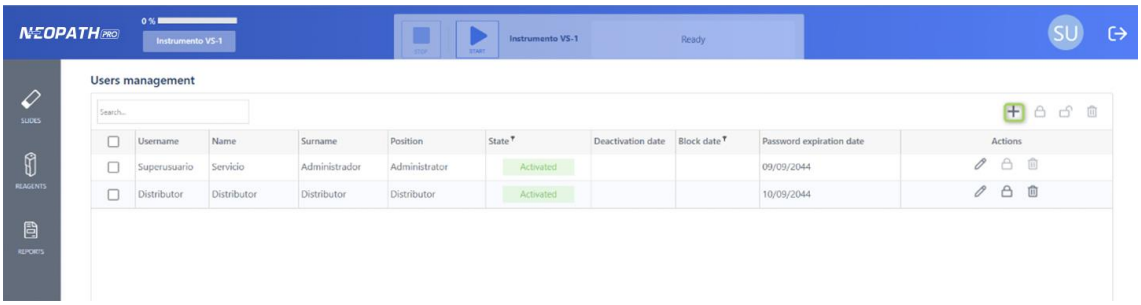


When logging in, the list of users will be displayed.



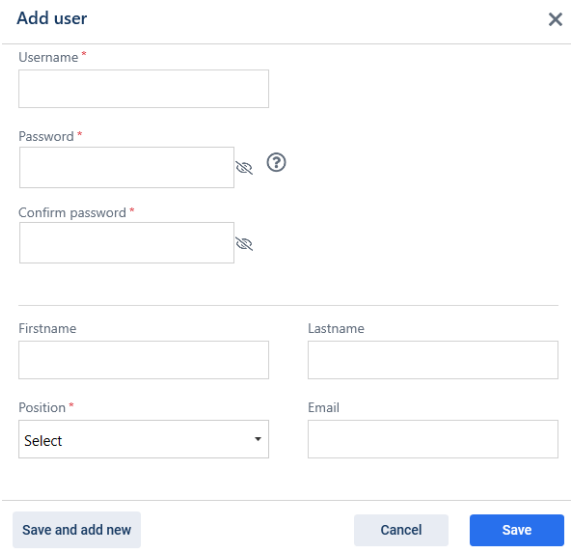
Register users

To create a new user in the system, click on the "+" button.



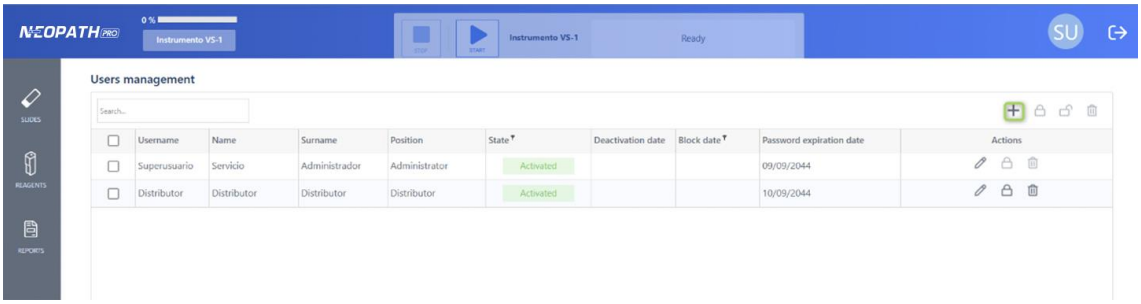
Then, in the creation window, the following fields must be filled in:

- User.
- Password. Clicking (?) displays a window indicating what's needed for a secure password.
- Position. The user can choose between the role of Lab Administrator or Lab Technician.



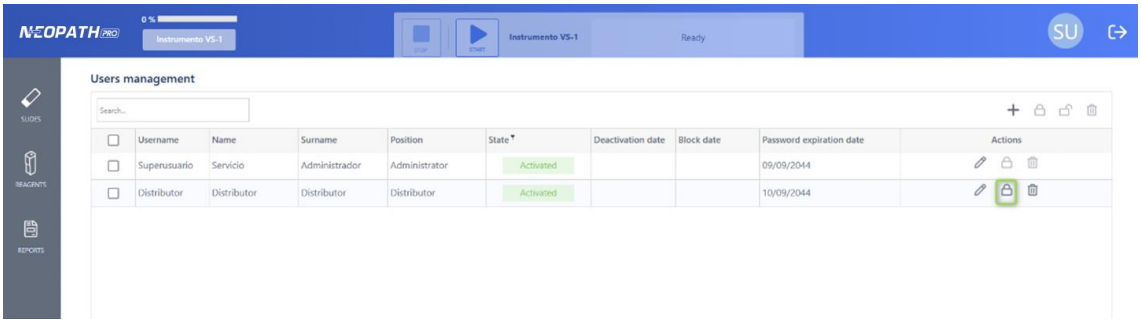
Edit users

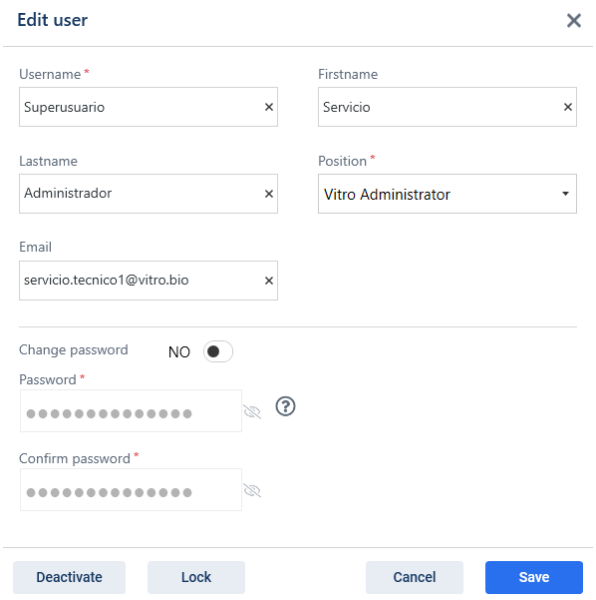
Clicking on the edit icon will open a window where you can edit the information and change the user's password.



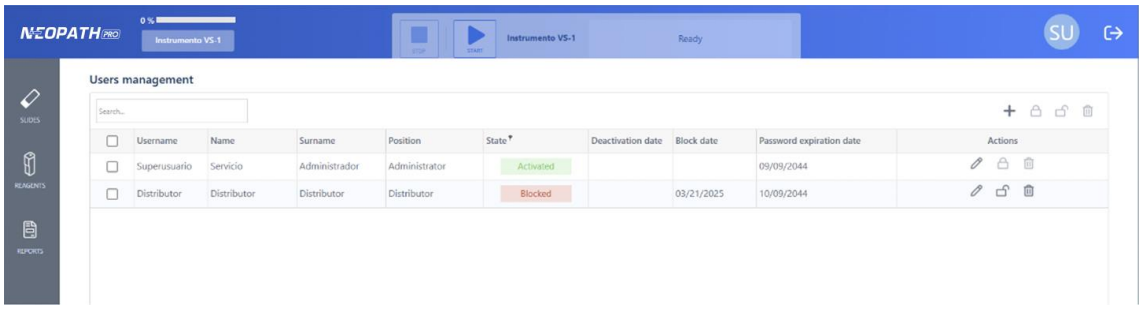
Block user

To block a user, press the button . In this way, access to the system can be blocked from the date indicated in the block.

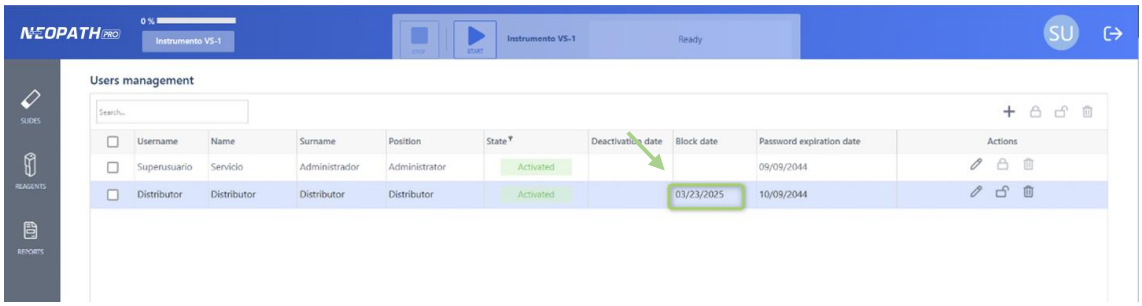




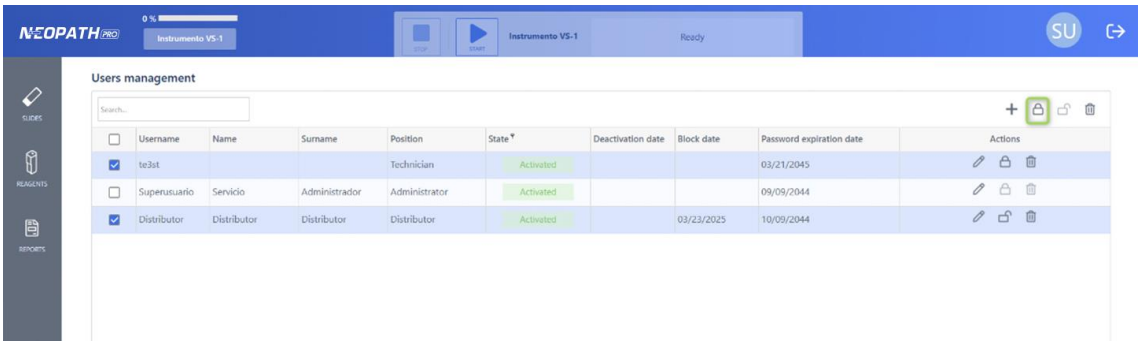
- If we block with current date the user will be immediately blocked.



- If we block with a future date. The user will be able to work normally until the indicated date arrives, which will be reflected in the blocking date section, once the date arrives the user will be blocked.

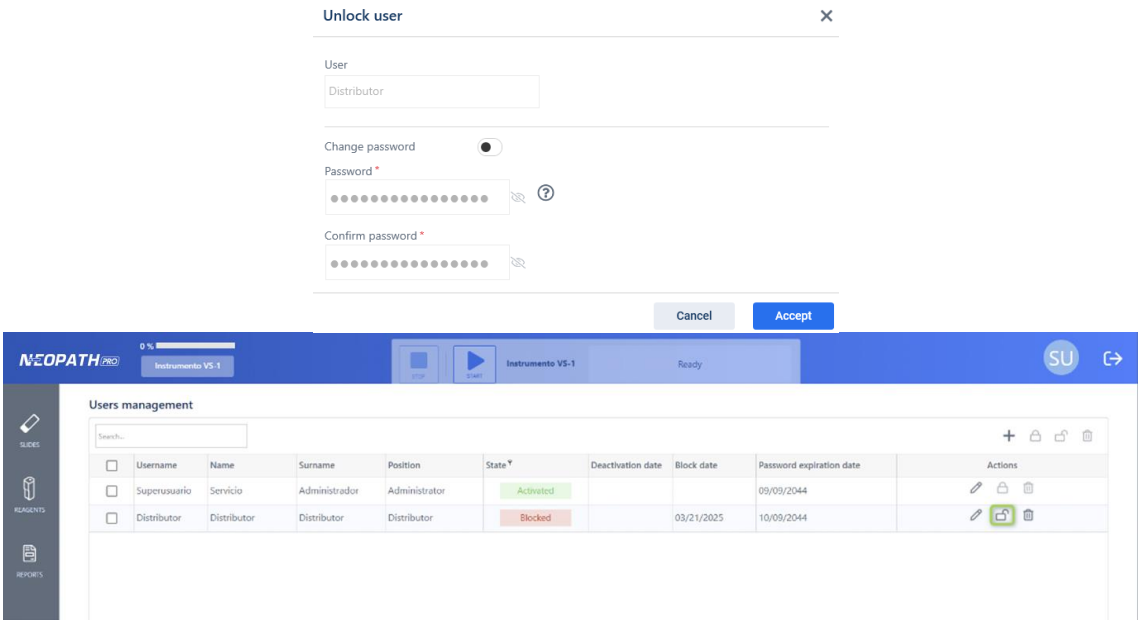


This blocking can be done massively by selecting different users from the list and pressing the button at the top.

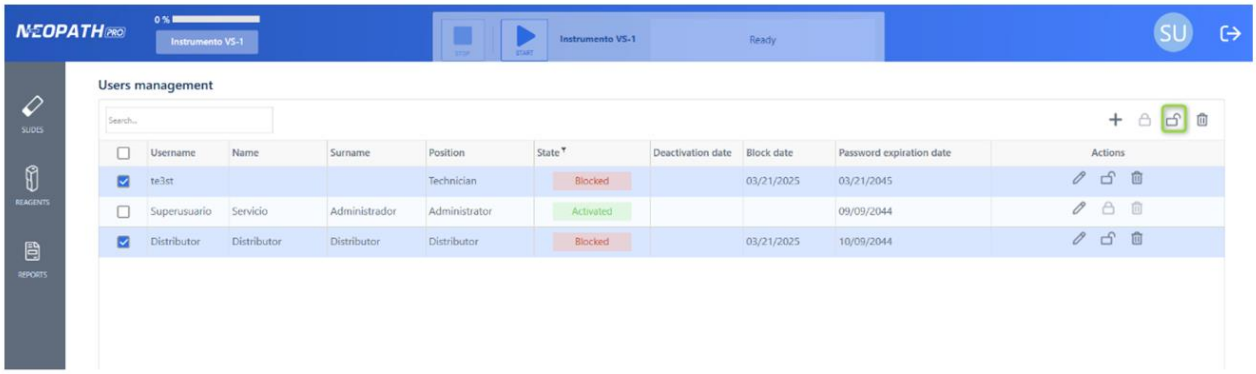


Unblock user

To unlock a user, press the button . In addition, the user's password can be changed from the unlock window

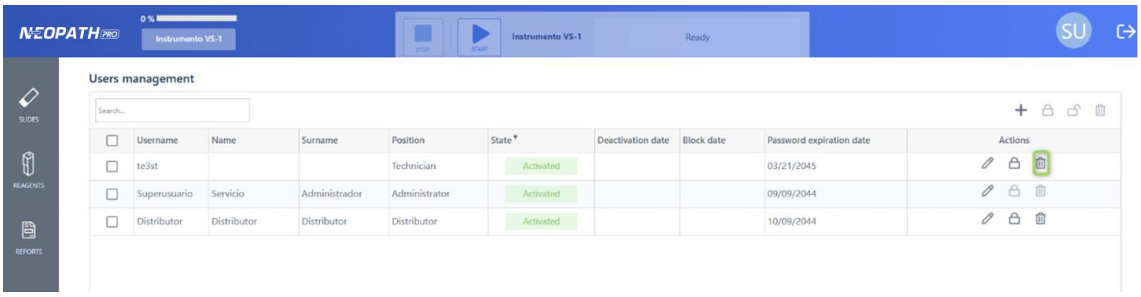


This unblocking can be done in bulk by selecting different users from the list and pressing the button at the top.

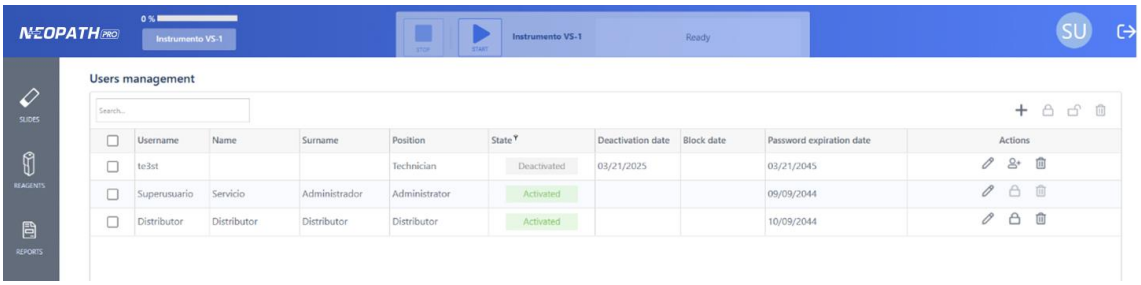


Deactivate user

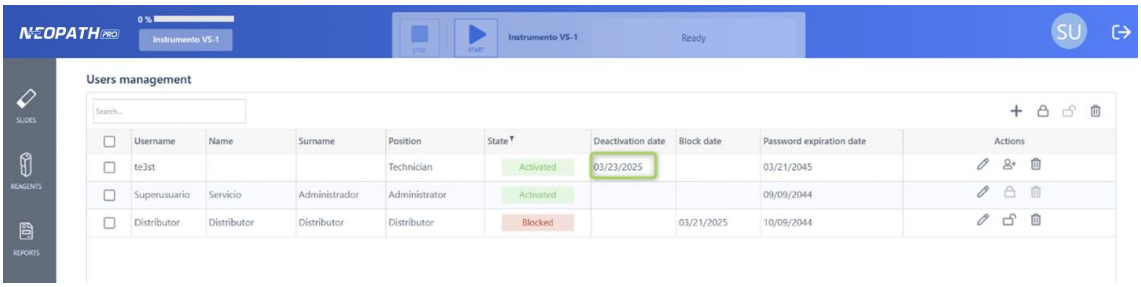
To deactivate a user, press the button . In this way, the user can be deactivated and prevented from accessing the system from the date indicated in the blocking.



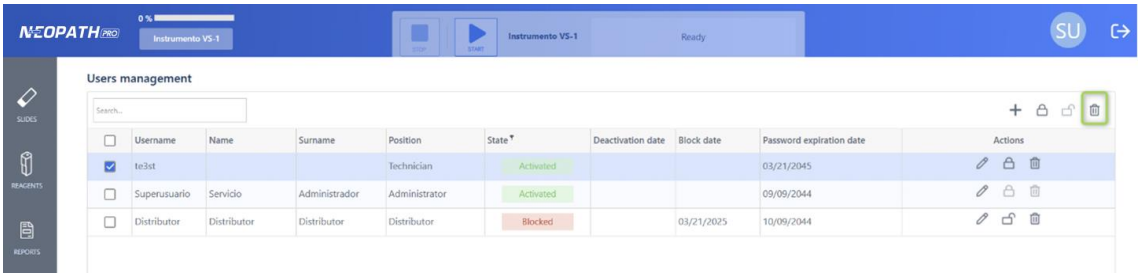
- If we deactivate the current date the user will be immediately blocked.



- If we deactivate with a future date. The user will be able to work normally until the indicated date arrives, which will be reflected in the blocking date section, once the date arrives the user will be blocked.

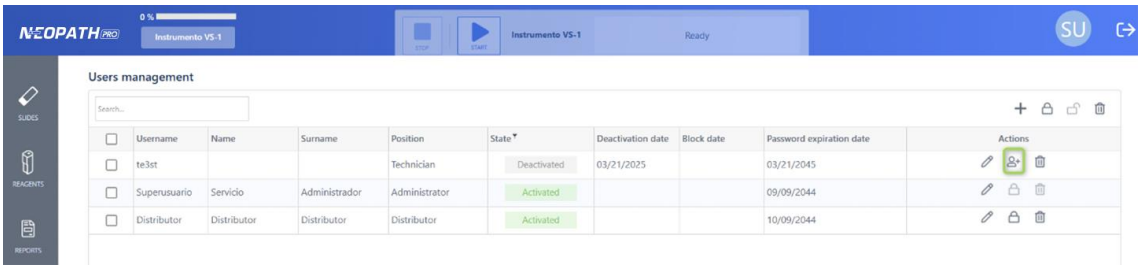


This deactivation can be done massively by selecting different users from the list and clicking on the button at the top.



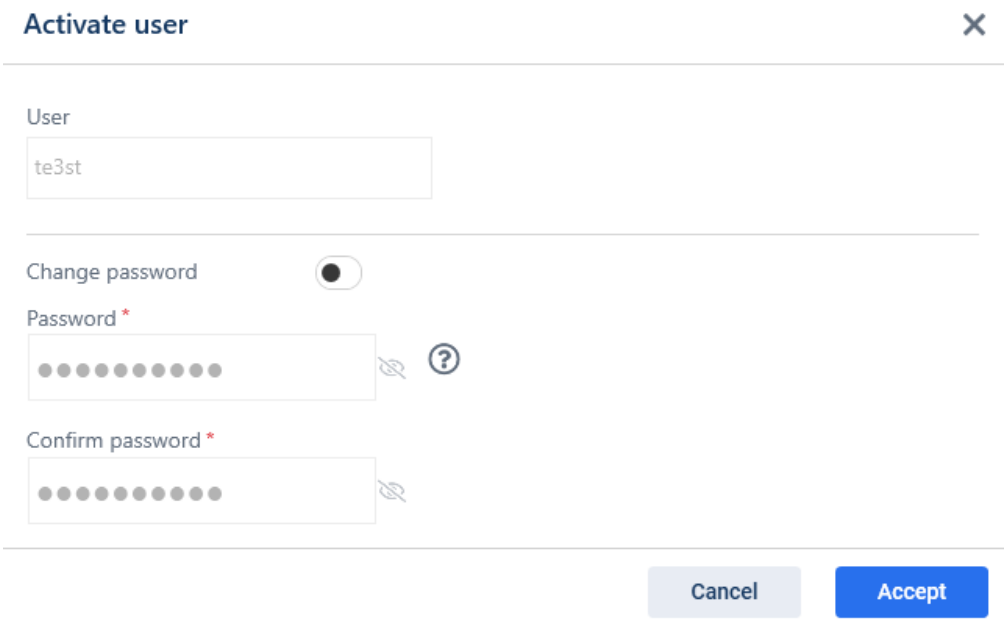
Activate user.

To activate a user, press the button . In addition, the user's password can be changed from the activation window.



User accessibility: permissions and roles

There are four levels of user access in NeopathPro . The options available for each profile are described below:



Permission / Role	NeoPATH Pro Administrator	Distributor	Laboratory Supervisor	Laboratory Technician
Slide Option	Not applicable			
See R&D button	X			
Change or create evalutions				
View Reagents Options	X	X	X	X
View inventory option	X	X	X	X
Register a vial	X	X	X	X
Edit a vial	X	X	X	X
Delete a vial	X	X	X	X
Enable/disable vials	X	X	X	X
View Reagents' list option	X	X	X	X
Edit a NeoPATH Pro reagent	X	X		
Delete a NeoPATH Pro reagent	X	X		
Register a custom reagent	X	X	X	X

Edit a custom reagent	X	X	X	X
Delete a custom reagent	X	X	X	X
View options for types of kits	X			
Register a type of kit	X			
View Settings Options	X	X	X	X
View General option	X	X	X	
Access to Configure Alerts	X	X	X	
Access to Configure Notifications	X			
Access to configure requests and slides	X	X	Reading only	
Login to set up Password security	X			
Access to configure Reagents	X			
Access to configure Sites	X	X	X	
View Protocols options	X	X	X	X
Protocols tab	Not applicable			
Create protocols	X	X	X	
Edit protocols	X	X	X	
Delete protocols	X	X	X	
View Techniques tab	X	X	X	
Create and edit techniques	X	X	X	
Deactivate / actívate techniques	X	X	X	
Change Technique protocol	X	X	X	
Change phases of the protocol	X	X	X	
View instruments options	X	X		
View users options	X	X	X	
User registration	X	X	X	
User edit	X	X	X	
User deregistration	X	X	X	
User blocking	X	X	X	

**The breakdown of permissions and roles is incorporated based on the information in the table from NeoPATH Pro Soft version 80 onwards.*

4.20 Reports

To access the reports module, click the Reports option in the sidebar. From this module, you can view and manage all reports.

Run Report

1. Detailed Run Report

The purpose of this report is to obtain a document with the most relevant information about the slides and reagents used. It focuses on allowing the user to access records of completed, stopped, or interrupted run within a defined date range.

The report structure allows for managing information on run and executed processes, optimizing their traceability, analysis, and documentation for audits or technical reviews.

The entire slide execution process is included.

The configuration parameters for displaying records in this report are:

- Parameter to limit the date range to a maximum number of days. By default, it is limited to 365 days.
- Parameter to establish which predefined date range values will exist for this type of report. The following types are available for this report:
    - Today
    - Yesterday
    - Last week
    - Last month
    - Last year

    - The default value will be Today.
- Parameter to limit the number of records to select in the grid. Initially, this will be limited to 1 by default.

Filters

The filters that can be applied in this report are based on the 'Date Range' field. The options are:

- Predefined date and time range. By default, Today will be selected, and it will be displayed in the Start Date and End Date fields.
- Custom date range. When selecting this option, the 'Start Date' and 'End Date' fields must be enabled. These dates must meet the following criteria:
    - Start date and time: Must be less than or equal to the current date. Otherwise, an error message will be displayed. The message will be "Must be current or earlier."
    - End date and time: Must be greater than or equal to the start date and less than the start date + the parameter value to limit the date range to a maximum number of days, and always less than or equal to the current date. If the date range is not within the range, an error message will be displayed below the field.
        - If it is less than the Start date, "Must be the start date or later."
        - If it exceeds the maximum number of days, "Date outside the maximum range of days: value of the _Parameter to limit the date range to a maximum number of days."
    - The results grid will only be updated when both the start and end dates have a correct date, that is, within the limits.

Results Grid

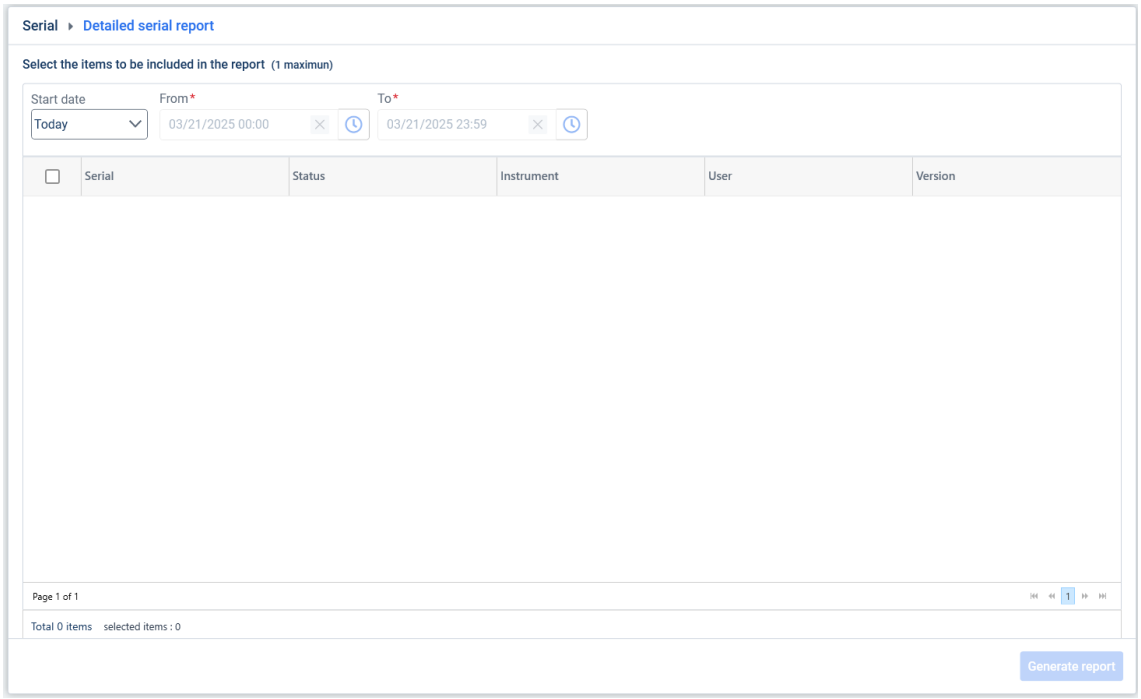
By default, the results grid displays records corresponding to the run whose execution start date falls within the previously selected date range. This report will only display records from run that are in the finished, stopped, or interrupted status, and will not display records from series that are running. These records will also be sorted by run date.

The columns that should be displayed are:

- Selector
- Series
- Status
- Instrument
- User

- Version

Additionally, a button appears at the bottom of the grid with the value 'Generate report.' This button will only be enabled when a series ID has been selected.



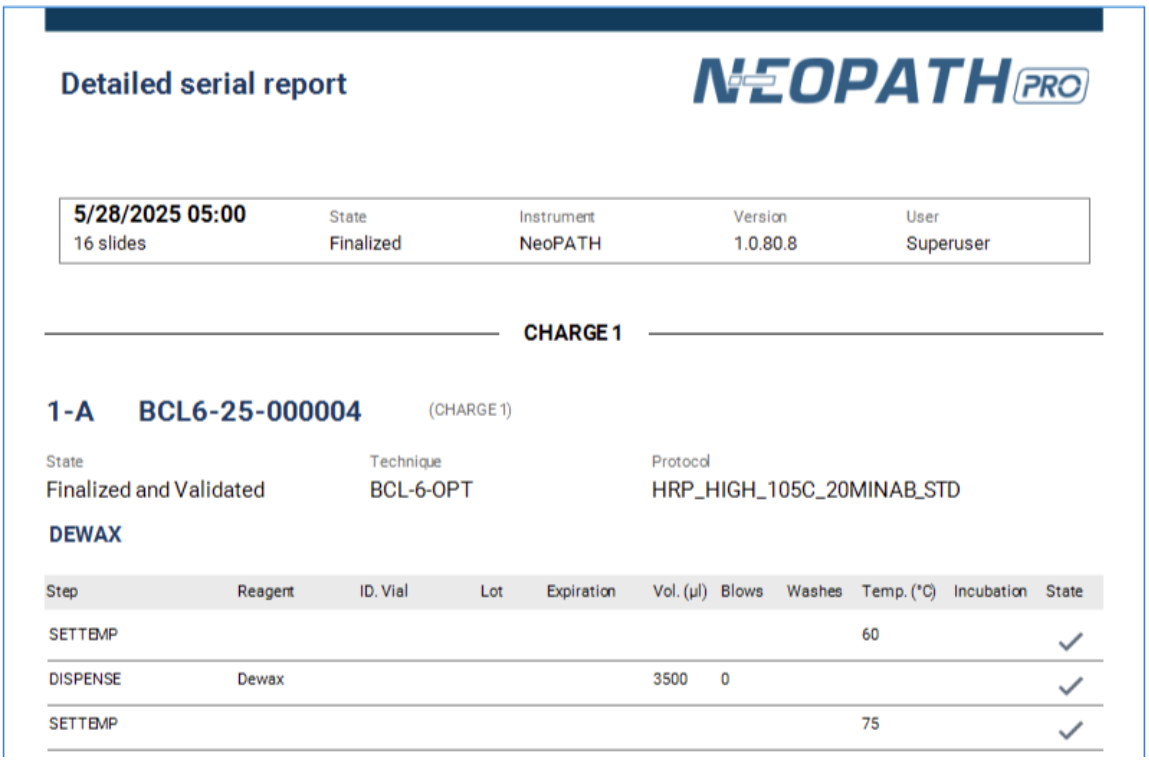
Report Layout

- Header
  - Logo
  - Report Title
- For each series:
  - Date and time of the series
  - Series status
  - Number of slides
  - Instrument name
  - Version in which the series was run
  - User who ran it
  - For each Load in the series, a subheader will be displayed with the slide information:
  - Reaction chamber
  - Slide ID
  - Technique
  - Protocol
  - Slide status
- Information on the protocol steps and reagents in columns.
  - Group the phases by the following data:
  - Step name
    - Dispensed reagent
    - Vial ID
    - For dispensing a mixture, information must be provided for each vial used for the mixture.

        - Batch
        - Expiration date
    - Volume dispensed in microliters
    - Number of blows
    - Number of washes
    - Step status
    - Temperature for SETTEMP
    - Incubation time
- Reagent section used in the run. This section must be shown for each run. The data will be grouped as follows:
    - Section title: Reagent Use
        - Header
        - Reagent
    - Data by reagent
        - Vial ID
        - Batch
        - Expiration date
        - Volume dispensed
        - Number of slides made
        - List of slide IDs
- Series observations section, where data for each slide in the run related to warnings, errors, or notes will be reported. The columns will be divided into the following data:
    - Slide ID
    - Reaction chamber
    - Type
        - If the field is not null in the Type column, the value 'Warning' will be displayed
        - If the field is not null in the Type column, the value 'Notes' will be displayed
        - If both fields are null, no information will be reported for each slide.

    - Observation
        - If the field is not null, the Observation column will display the value of the field itself.
        - If the field is not null, the value of the field itself will be displayed in the Type column.
        - If both fields are null, no information will be reported on each slide.

- Footer: This will be repeated on each page of the report.
    - User - Date and time of printing
    - Software version from which the print is made
    - Total page number



Detailed serial report

NEOPATH PRO

5/28/2025 05:00	State	Instrument	Version	User
16 slides	Finalized	NeoPATH	1.0.80.8	Superuser

CHARGE 1

1-A BCL6-25-000004 (CHARGE 1)

State	Technique	Protocol
Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_20MINAB_STD

DEWAX

Step	Reagent	ID. Vial	Lot	Expiration	Vol. (µl)	Blows	Washes	Temp. (°C)	Incubation	State
SETTEMP								60		✓
DISPENSE	Dewax				3500	0				✓
SETTEMP								75		✓

2. Summary series report

This report allows users to view, analyze, and export relevant details about the run, including the final status of the slides, reagents used, and any observations recorded during the run, without going into the details of the run process.

The configuration parameters for viewing logs in this report are:

-Parameter to limit the date range to a maximum number of days. By default, it is limited to 365 days.

- Parameter to establish which predefined date range values will exist for this report type. The following types are available for this report:

  - Today
  - Yesterday
  - Last Week
  - Last Month
  - Last Year
  - The default value will be Today.

- Parameter to limit the number of records to select in the grid. By default, this value will be limited to 1.

Filters

The filters that can be applied in this report are based on the 'Date Range' field. The options are:

- Predefined date and time range. By default, Today will be selected, and it will be displayed in the Start Date and End Date fields.

- Custom date range. When selecting this option, the 'Start Date' and 'End Date' fields must be enabled. These dates must meet the following criteria:

  - Start date and time: Must be less than or equal to the current date. Otherwise, an error message will be displayed. The message will be "Must be current or earlier."
  - End date and time: Must be greater than or equal to the start date and less than the start date + the parameter value to limit the date range to a maximum number of days, and always less than or equal to the current date. If the date range is not within the range, an error message will be displayed below the field.
    - If it is less than the Start date, "Must be start date or later."
    - If it exceeds the maximum number of days, "Date outside the maximum number of days: _Parameter value to limit the date range to a maximum number of days."

-The results grid will only be updated when both the start date and the end date have a correct date, that is, within the limits.

Results Grid

By default, the results grid displays records corresponding to the run whose execution start date falls within the previously selected date range. This report will only display records from series that are in the completed, stopped, or interrupted status, and will not display records from series that are running. These records will also be sorted by the series date.

The columns to be displayed are:

- Selector

- Series: The date of the first record in the run with a started status will be displayed.

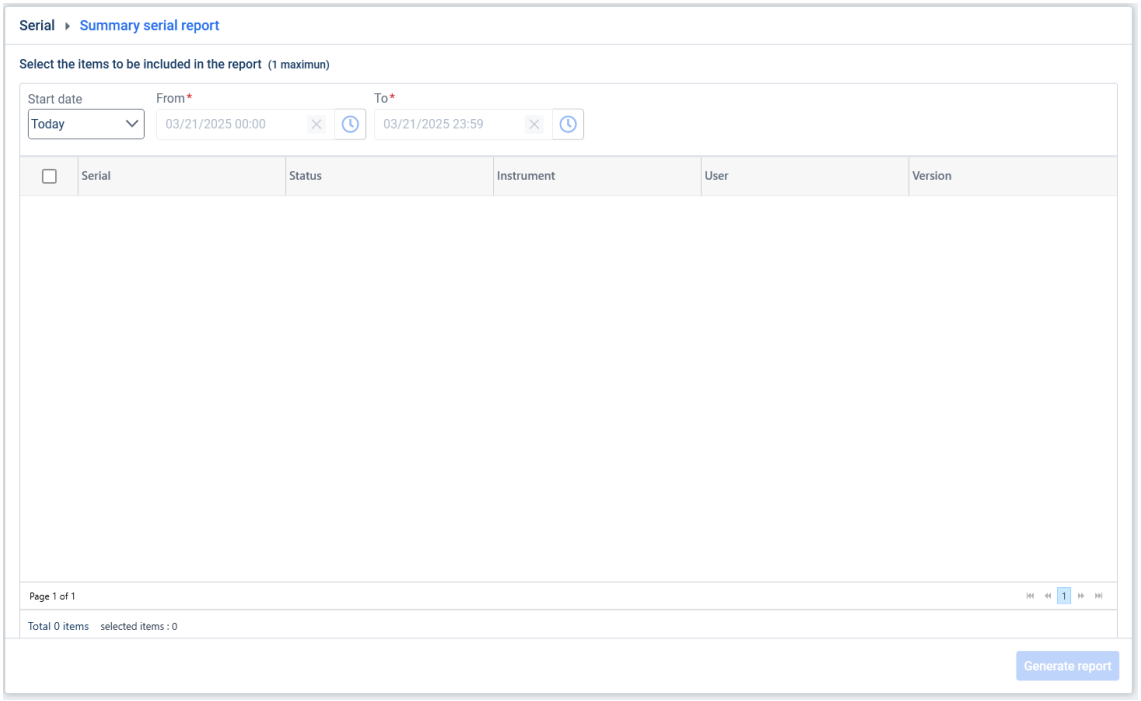
- Status: The name of the status corresponding to the last record in the run will be displayed.

- Instrument: Name of the instrument associated with the run.

- User: The user registered in the final status of the run will be displayed.

- Version: The version registered in the final status (completed, stopped, or interrupted) of the run will be displayed.

Additionally, a button with the value 'Generate report' appears at the bottom of the grid. This button will only be enabled when a series ID has been selected.



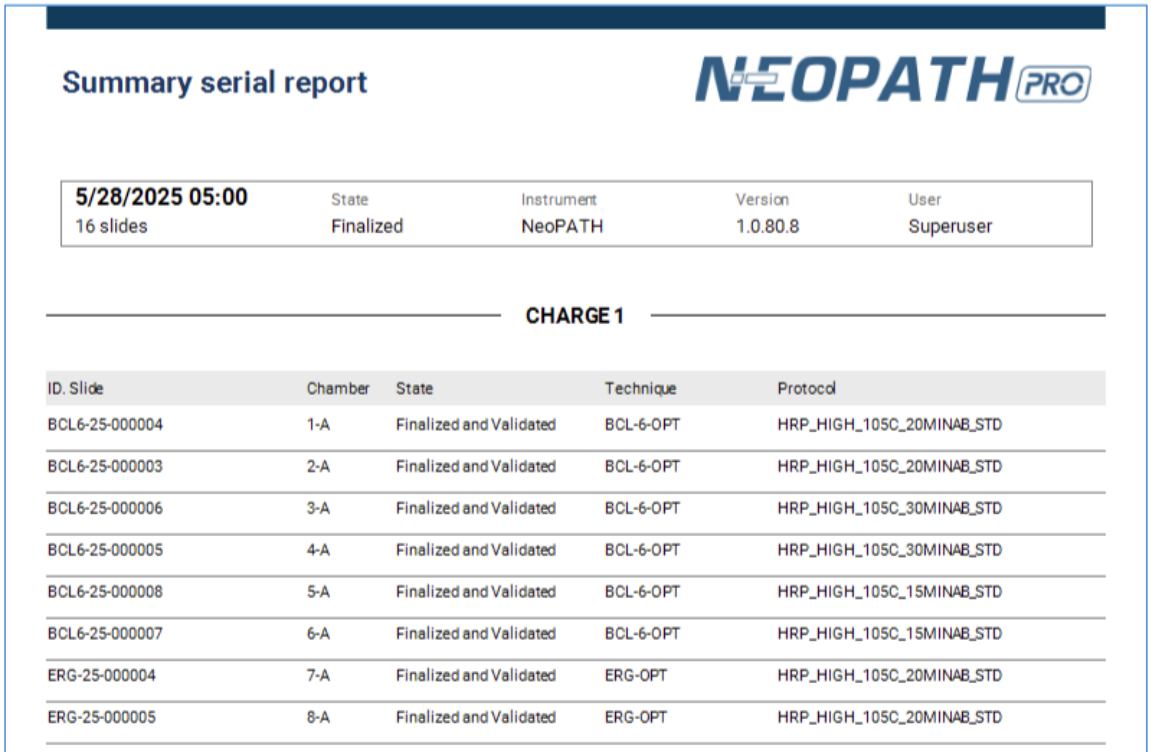
Report Layout

- Header
    - Logo
    - Report Title
- For each run, a subheader will be displayed with the following information:
    - Date and time of the run
    - Run status. It can be Finished, Stopped, or Interrupted.
    - Number of slides
    - Instrument name
    - Version in which the run was run
    - User who ran it
- For each load in the run, a subheader will be displayed with the slide information. This information includes:
    - Reaction chamber
    - Slide ID
    - Technique
    - Protocol
    - Slide status

- Information on the protocol steps and reagents in columns.
    - Reagents used in the series section. This section must be displayed for each run. The data will be grouped as follows:
        - Section title: Reagent Use
            - Header
            - Reagent
    - Data by reagent

        - Vial ID
        - Batch
        - Expiration date
        - Volume dispensed
        - Number of slides made
        - List of slide IDs
    - Series observations section, where data related to warnings, errors, or notes will be reported for each slide in the run. The columns will be divided into the following data:
        - Slide ID
        - Reaction chamber
        - Type
            - If the field is not null in the Type column, the value 'Warning' will be displayed
            - If the field is not null in the Type column, the value 'Notes' will be displayed
            - If both fields are null, no information will be reported for each slide.
    - Observation
        - If the field is not null, the field value will be displayed in the Observation column.
        - If the field is not null, the field value will be displayed in the Type column.
        - If both fields are null, no information will be reported on each slide.

- Footer: This will be repeated on each page of the report.
    - User - Date and time of printing
    - Software version from which the report is printed
    - Total page number



Summary serial report

NEOPATH PRO

5/28/2025 05:00	State	Instrument	Version	User
16 slides	Finalized	NeoPATH	1.0.80.8	Superuser

CHARGE 1

ID. Slide	Chamber	State	Technique	Protocol
BCL6-25-000004	1-A	Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_20MINAB_STD
BCL6-25-000003	2-A	Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_20MINAB_STD
BCL6-25-000006	3-A	Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_30MINAB_STD
BCL6-25-000005	4-A	Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_30MINAB_STD
BCL6-25-000008	5-A	Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_15MINAB_STD
BCL6-25-000007	6-A	Finalized and Validated	BCL-6-OPT	HRP_HIGH_105C_15MINAB_STD
ERG-25-000004	7-A	Finalized and Validated	ERG-OPT	HRP_HIGH_105C_20MINAB_STD
ERG-25-000005	8-A	Finalized and Validated	ERG-OPT	HRP_HIGH_105C_20MINAB_STD

Slides Report

1. Processed slides

The purpose of this report is to provide a structured and filterable breakdown of the slides processed in a run. It allows users to view key information about the status, run, and configuration of each slide, including instrument, user, protocol, reagents used, and observations. It also facilitates process traceability and assists in the validation and quality control of the results obtained.

Parameter settings

- Parameter to limit the custom date range to a maximum number of days. By default, this will be set to 31 days.
- Parameter to define which predefined date range values will exist for this report type. The following types are available for this report:
    - Today
    - Yesterday
    - Last week
    - Last month
    - The default value will be Today.
- Parameter to limit the number of records to select in the grid. By default, this will be limited to 100.

Filters

The filters that can be applied to this report are related to the following fields. The options are:

- Porta Id: Text field where you can enter a search string that filters matching results in the system.
- Status: Only portal statuses with a specified execution date should be displayed. By default, 'All' should be selected.
- Slide run date: You can select one of these options directly and slides whose run date falls within the selected dates will be filtered.
- Predefined date and time range. By default, Today will be selected, and it will be displayed in the Start Date and End Date fields.
- Custom date range. When selecting this option, the 'Start Date' and 'End Date' fields must be enabled. These dates must meet the following criteria:
    - Start date and time: Must be less than or equal to the current date. Otherwise, an error message will appear. The message will be "Must be current or earlier."
    - End date and time: Must be greater than or equal to the start date and less than the start date + the *parameter value to limit the date range to a maximum number of days,* and always less than or equal to the current date. If it is not within the range, an error message must be displayed below the field.
        - If it is less than the Start date “Must be Start date or later”
        - If it exceeds the maximum number of days “Date outside the maximum range of days: _Parameter value to limit the date range to a maximum number of days”

The results grid will only be updated when both the start date and end date are within the correct date range, that is, within the limits.

Filter results grid

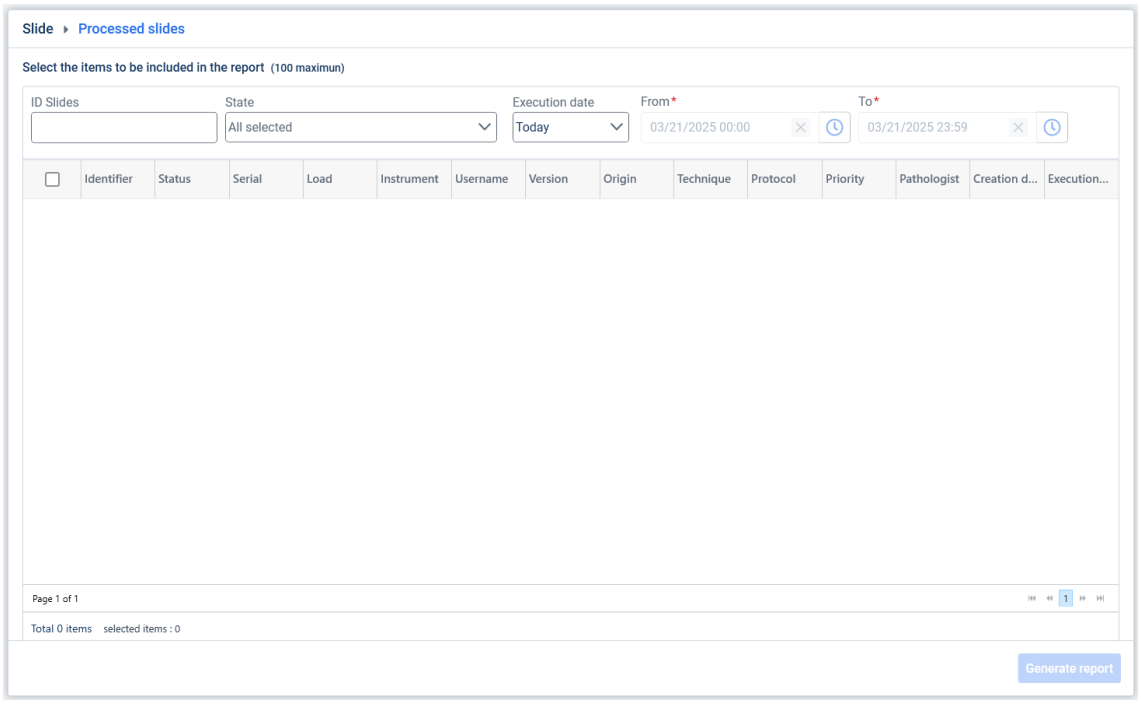
The columns to be displayed sorted by portal id are as follows:

- Selector
- Id portal

- State
- Series: the start date of the run to which the slide is associated will be displayed.
- Load: the run of the series to which the slide is associated will be displayed
- Instrument: name of the instrument where the slide was processed
- User: The registered user will be displayed in the final status.
- Version: The version recorded in the final state will be displayed
- Center: This field will only be displayed if the multi-centre option is enabled.
- Origin: This field will only be displayed if you have LIS integration
- Technique
- Protocol
- Priority
- Pathologist
- Creation date
- Execution date.
- Warning
- Grades

By default, records corresponding to portals whose execution date falls within the selected date range should be displayed, and only those portals that have an execution date reported.

Additionally, a button appears at the bottom of the grid with the value 'Generate Report'. This button will only be enabled when a serial ID has been selected.

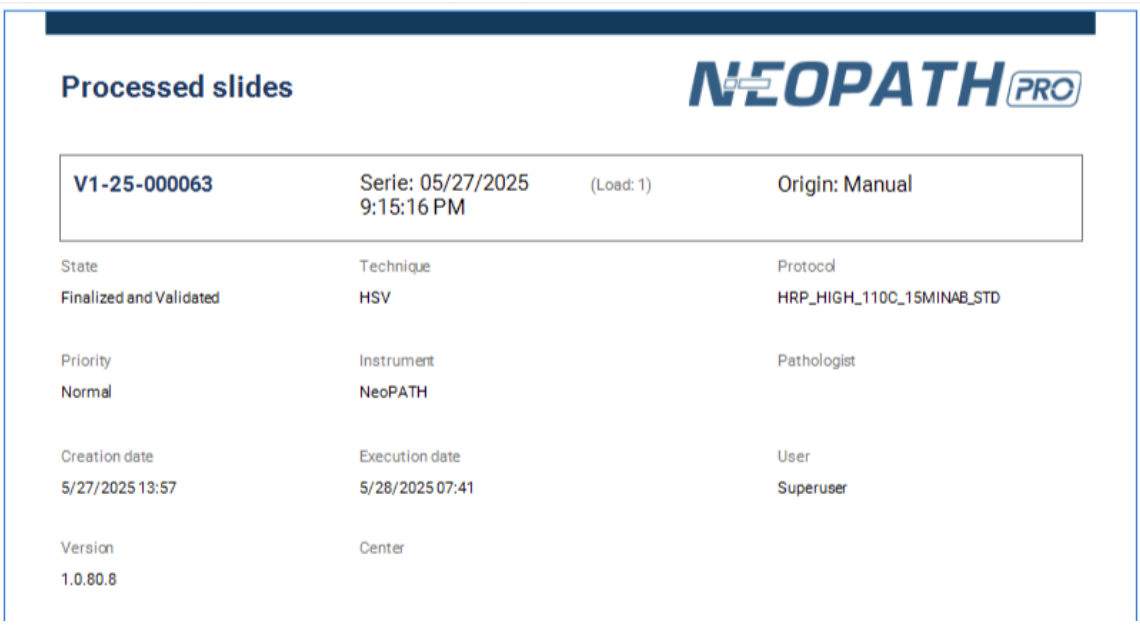


Composition of the report

- Head
  - Logo
  - Title of the report
- Sub header with the data for each of the slides in the selection.
  - Id portal

- State
- Series: The start date of the run to which the portal is associated will be displayed. Only if the portal has been executed will be reported.
- Load: The execution of the series to which the portal is associated will be displayed. Only if the portal has been executed will be reported.
- the portal has been made.
- User: The registered user will be displayed in the final status.
- Version: The version recorded in the final state will be displayed
- Center: only if it is multicenter
- Origin: only if LIS Integration exists
- Technique
- Protocol
- Priority
- Pathologist
- Creation Date
- Execution Date. Only if the contract has been executed will be reported.
- Information about the protocol steps and reagents in columns. Since there are many columns, it would be important to determine whether the report is displayed horizontally or vertically.
    - Only the steps taken should be shown.
        - Finished. All because all are done.
        - Interrupted, discarded, and canceled: all that has been done.
    - Group the following data by phase:
        - Step name
        - Dispensed reagent (only reported in the case of DISPENSE and WASHSLIDE)
            - Vial ID (will only be reported in the case of a DISPENSE of vials).
            - In the case of dispensing a mixture, the information for each vial used for the mixture must be reported.
            - Batch (only reported in the case of DISPENSE and WASHSLIDE)
            - Expiration date (only reported in the case of DISPENSE and WASHSLIDE)
        - Volume dispensed in microliters (only reported in the case of DISPENSE and WASHSLIDE)
        - Number of blows (only reported in the case of a DISPENSE and WASHSLIDE)
        - Number of washes (only reported in the case of a WASHSLIDE)
        - Step status: Completed or not, indicated with a check.
        - Temperature for the SETTEMP
        - Incubation time (only reported in the case of an INCUBATE)
    - Observations section for each page, where any warnings, errors, or notes will be reported. If there are no warnings, errors, or notes, they will not be displayed. The following data will be shown in columns:
        - Id portal
        - Reaction chamber
        - Type. For each port, a record will be created for each of the following fields:
            - If the field is not null in the Type column the value “Warning” will be displayed.

        - If the field is not null in the Type column the value “Notes” will be displayed.
        - If both fields are null on each page, nothing will be reported.
    - Note: For each portal, a record will be created for each of the following fields:
        - If the field is not null, the value of the field itself will be displayed in the Observation column.
        - If the field is not null in the Type column, the value of the field itself will be displayed.
        - If both fields are null on each page, nothing will be reported.
- Foot:
    - User - Print date and time
    - Version of the SW from which printing is made
    - Total page number



2. Pending Slides

This report provides a detailed overview of slides in the "Pending" status, i.e., those that have not yet been processed. It allows users to filter, view, and generate a report with key information for each slide, including its origin, technique, protocol, priority, and assigned pathologist. In addition, any associated warnings or notes are included, facilitating the management and planning of pending samples.

Parameter settings

- Parameter to limit the custom date range to a maximum number of days. By default, this will be set to 31 days.
- Parameter to define which predefined date range values will exist for this report type. The following types are available for this report:
    - Today
    - Yesterday
    - Last week
    - Last month

    - The default value will be Today.
- Parameter to limit the number of records to select in the grid. By default, this will be limited to 100.

Filters

The filters that can be applied to this report are related to the following fields. The options are:

- Portal Id: Text field where you can enter a search string that filters matching results in the system.
- Slide creation date. You can select it directly from any of the options. Slides whose creation date falls within the selected dates will be filtered, only for slides with a 'Pending Upload' status.
    - Predefined date and time range. By default, Today will be selected, and it will be displayed in the Start Date and End Date fields.
    - Custom date range. When selecting this option, the 'Start Date' and 'End Date' fields must be enabled. These dates must meet the following criteria:
        - Start date and time: Must be less than or equal to the current date. Otherwise, an error message will appear. The message will be "Must be current or earlier."
        - End date and time: Must be greater than or equal to the start date and less than the start date + the *parameter value to limit the date range to a maximum number of days,* and always less than or equal to the current date. If it is not within the range, an error message must be displayed below the field.
            - If it is less than the Start date “Must be Start date or later”
            - If it exceeds the maximum number of days “Date outside the maximum range of days: _Parameter value to limit the date range to a maximum number of days”
- The results grid will only be updated when both the start date and end date are within the correct date range, that is, within the limits.

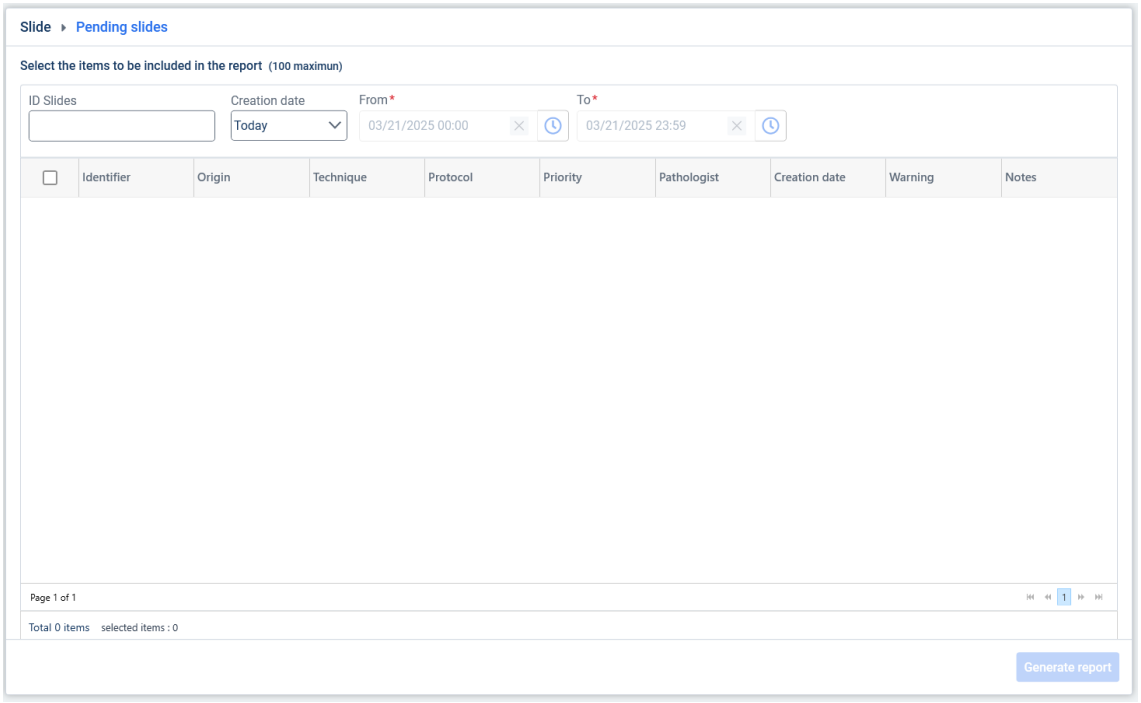
Filter results grid

The columns to be displayed sorted by portal id are as follows:

- Selector
- Id portal
- Center: This field will only be displayed if the multi-center option is enabled.
- Origin: This field will only be displayed if you have LIS integration
- Technique
- Protocol
- Priority
- Pathologist
- Creation date
- Warning
- Grades

By default, records corresponding to portals whose execution date falls within the selected date range should be displayed, and only those portals that have an execution date reported.

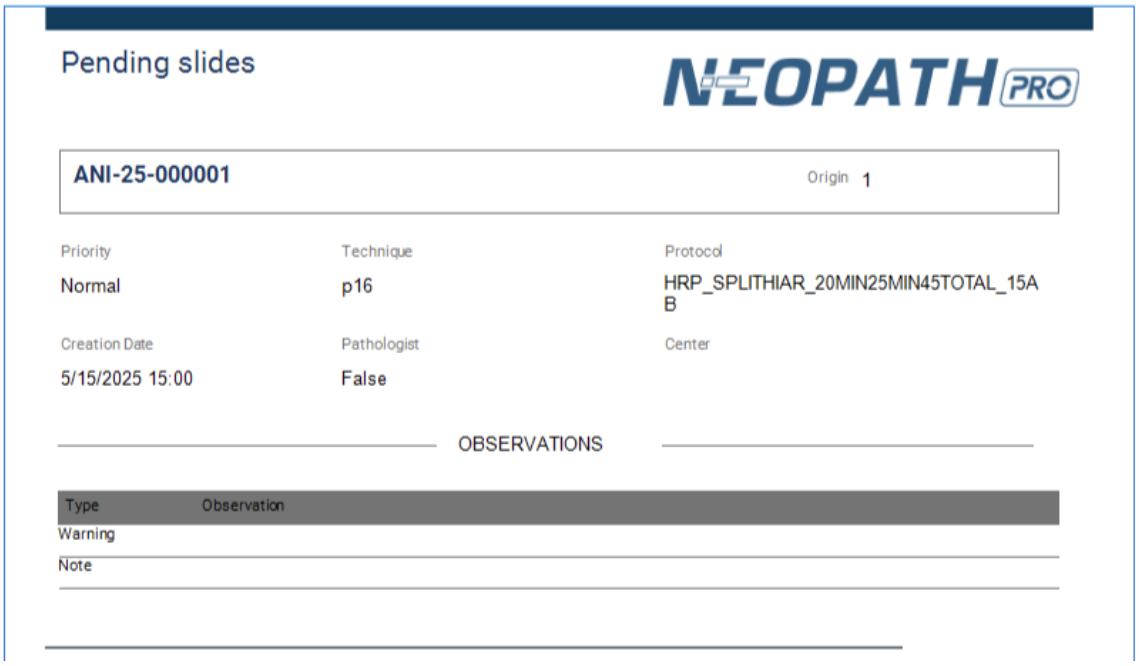
Additionally, a button appears at the bottom of the grid with the value 'Generate Report'. This button will only be enabled when a serial ID has been selected.



Composition of the report

- Header: It will be repeated on each page of the report
  - Logo
  - Report Title: Pending Slides
- Data for each of the selection's portals:
  - Id portal
  - Center: only if it is multi-center
  - Origin
  - Technique
  - Protocol
  - Priority
  - Pathologist
  - Creation Date
  - Execution Date. Only if the contract has been executed will be reported.
- Observations section for each page, where any warnings, errors, or notes will be reported. If there are no warnings, errors, or notes, they will not be displayed. The following data will be shown in columns:
  - Id portal
  - Type. For each port, a record will be created for each of the following fields:
    - If the field is not null in the Type column the value “Warning” will be displayed.
    - If the field is not null in the Type column the value “Notes” will be displayed.
    - If both fields are null on each page, nothing will be reported.
  - Note: For each portal, a record will be created for each of the following fields:
    - If the field is not null, the value of the field itself will be displayed in the Observation column.
    - If the field is not null in the Type column, the value of the field itself will be displayed.
    - If both fields are null on each page, nothing will be reported.
- Foot:

- User - Print date and time
- Version of the SW from which printing is made
- Total page number



Reagent reports

1. General reagent report

This report provides a detailed list of the reagents available in the system, allowing their identification through key attributes such as acronym, name, technique group, and specific characteristics (hazard, viscosity, and whether they are part of a mixture). Its purpose is to facilitate the management and control of reagents in the laboratory, ensuring rapid reference and monitoring of them.

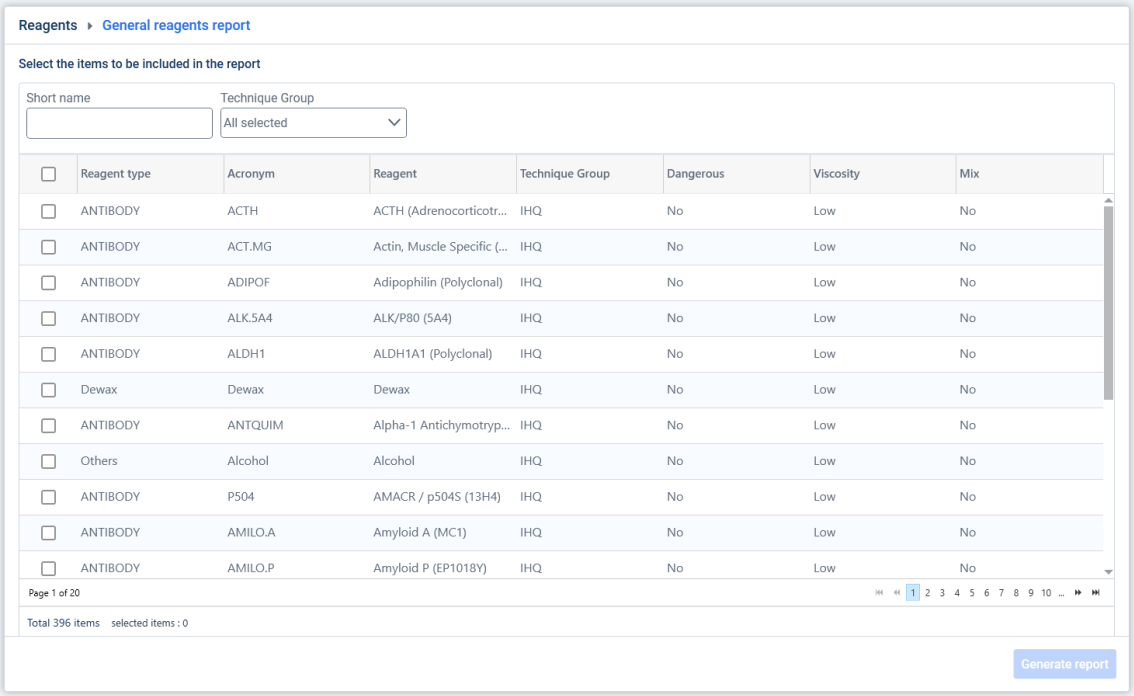
Filters

- Acronym: Text field where you enter a search string that filters the system's matching results.
- There are currently no advanced filters, so the button should remain hidden.

Filter results grid

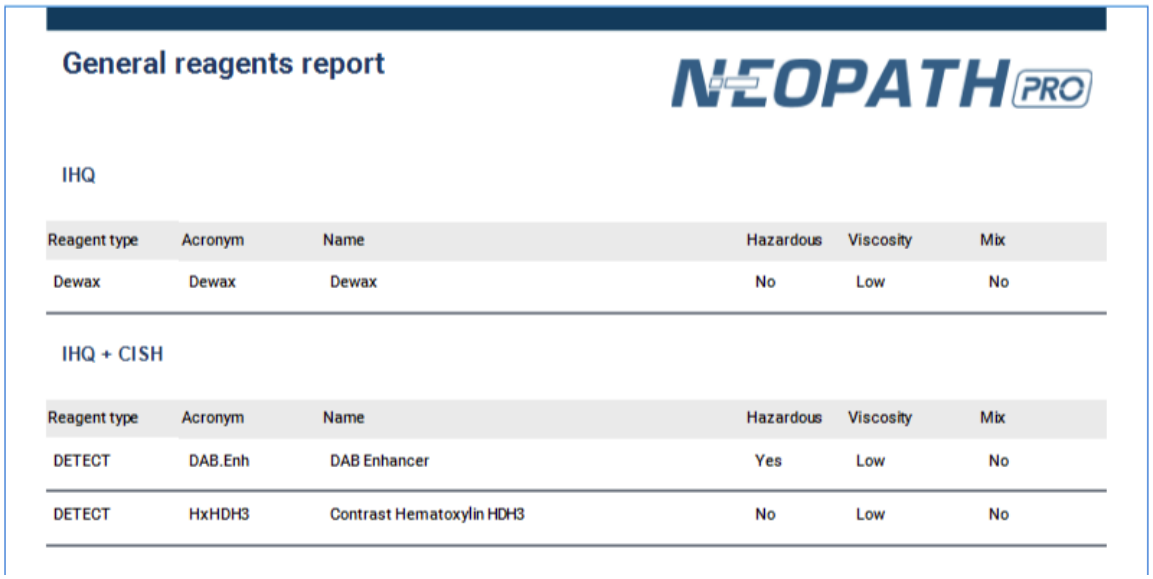
- The columns to be displayed are the following, and it should be possible to filter by each of them.
    - Type of reagent
    - Acronym
    - Name
    - Group of techniques
    - Dangerous
    - Goo
    - Mix

- By default, all reagents should be displayed.
- Currently, changing any filter will require refreshment of the results. If a record was already selected, the previous selection will be lost.
- Generate Report Button:
    - The Generate Report button will only be enabled when you have selected at least one record.
    - The report must be generated in the same language configured for the application.
    - Clicking the button changes the view to the report preview.



Composition of the report

- Header: It will be repeated on each page of the report
    - Logo
    - Report Title: Reagents
- Information for each reagent
    - Type of reagent
    - Acronym
    - Name
    - Group of techniques
    - Dangerous
    - Goo
    - Mix
- Foot:
    - Date and time of printing
    - User - Version of the SW from which printing is made
    - Total page number



General reagents report

NEOPATH PRO

IHQ

Reagent type	Acronym	Name	Hazardous	Viscosity	Mix
Dewax	Dewax	Dewax	No	Low	No

IHQ + CISH

Reagent type	Acronym	Name	Hazardous	Viscosity	Mix
DETECT	DAB.Enh	DAB Enhancer	Yes	Low	No
DETECT	HxHDH3	Contrast Hematoxylin HDH3	No	Low	No

2. Slides processed by Id vial

This report records and details the use of vials in slide processing within a selected date range, including the lot identifier. It allows you to identify key reagent inventory information, such as the vial ID, type, lot, expiration date, and volume, as well as their use on the different slides processed. It also provides a detailed view of the usage history of each vial, facilitating the control, traceability, and auditing of reagent consumption in the laboratory.

Parameter settings

- Parameter to limit the custom date range to a maximum number of days. By default, it will be limited to 31 days.
- Parameter to define which predefined date range values will exist for this report type. The following types are available for this report:
    - Today
    - Yesterday
    - Last week
    - Last month
    - The default value will be Today.
- Parameter to limit the number of records to select in the grid. By default, this will be limited to 100.

Filters

The filters that can be applied to this report are related to the following fields. The options are:

- Road ID: Text field where you can enter a search string that filters the system's matching results.
- Reactive: multi-selector or text.
- Last use date. You can select one of these options directly and slides whose last use date falls within the selected dates will be filtered.
    - Predefined date and time range (the *parameter to limit the date range to a maximum number of days does not apply to predefined ranges*)
        - Today, yesterday, last week, last month. Those defined in the *Parameter to establish which predefined date range values will exist for this type of report.*

        - By default, the Today option will be selected (*Parameter to set which predefined date range should appear selected by default from those existing in the previous parameter*) and will be shown selected in the Start Date and End Date fields.
    - Custom date range. When clicked, the Start Date and End Date fields should be enabled with the predefined range. The Start Date and End Date fields should be limited.
        - Start date: Must be less than or equal to the current date. If it is not within the range, an-error message will appear below the field ("Must be current or earlier").
        - End date: Must be greater than or equal to the start date and less than the start date + the *parameter value to limit the date range to a maximum number of days and* must always be less than or equal to the current date. If it is not within the range, an error message must be displayed below the field.
            - If it is less than the Start date "Must be Start date or later"
            - If it exceeds the maximum number of days "Date outside the maximum range of days: _Parameter value to limit the date range to a maximum number of days"
        - The results grid will only be updated when both the start date and end date are within the correct date range, that is, within the limits.
- There are currently no advanced filters, so the button should remain hidden.

Grid of filter results.

The columns to be displayed are as follows, in ascending order by Last Used Date, and it should be possible to filter by each of them.

- Selector.
- Road identifier.
- Reagent.
- User or Technician
- Batch.
- Expiration
- First use
- Last use
- Initial volume
- Current volume
- Enabled
- Supplier

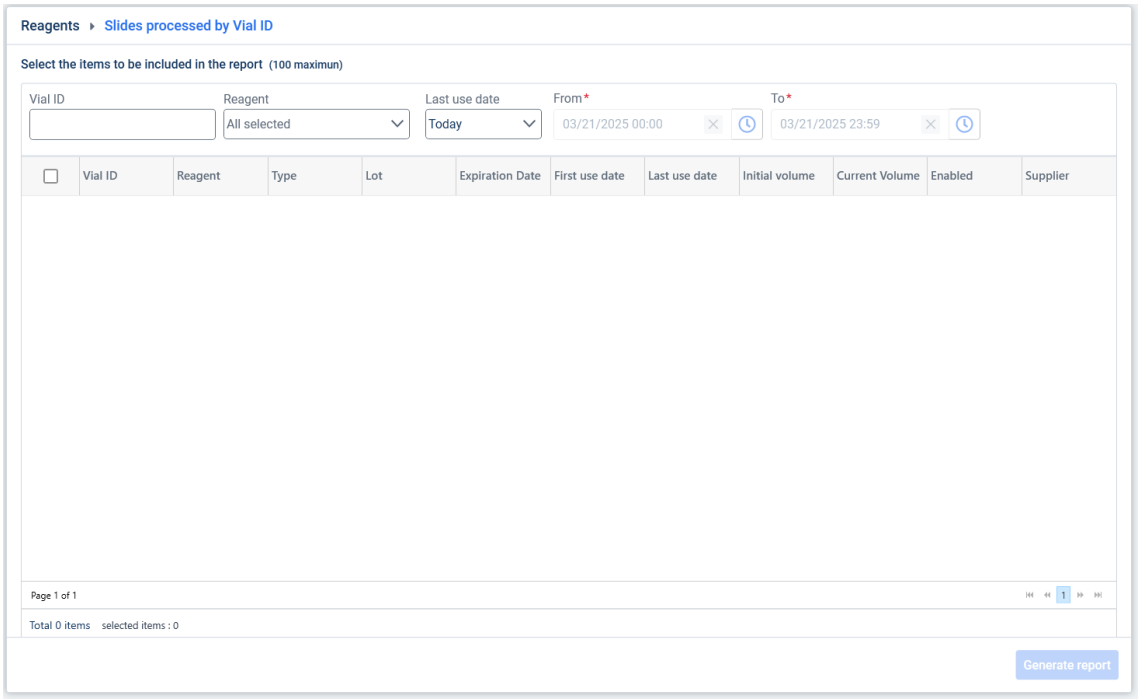
By default, the corresponding inventory records whose last use date falls within the selected date range should be displayed.

Currently, changing any filter will require a refreshment of the results. If a record was already selected, the previous selection will be lost.

Generate Report Button:

- The Generate Report button will only be enabled when you have selected at least one record.
    - Currently, only a maximum of 100 records can be selected, and the user must be informed of this limitation. Furthermore, the user must be informed if they exceed the limit of 100 without deselecting the current selection.
- The report must be generated in the same language configured for the application.

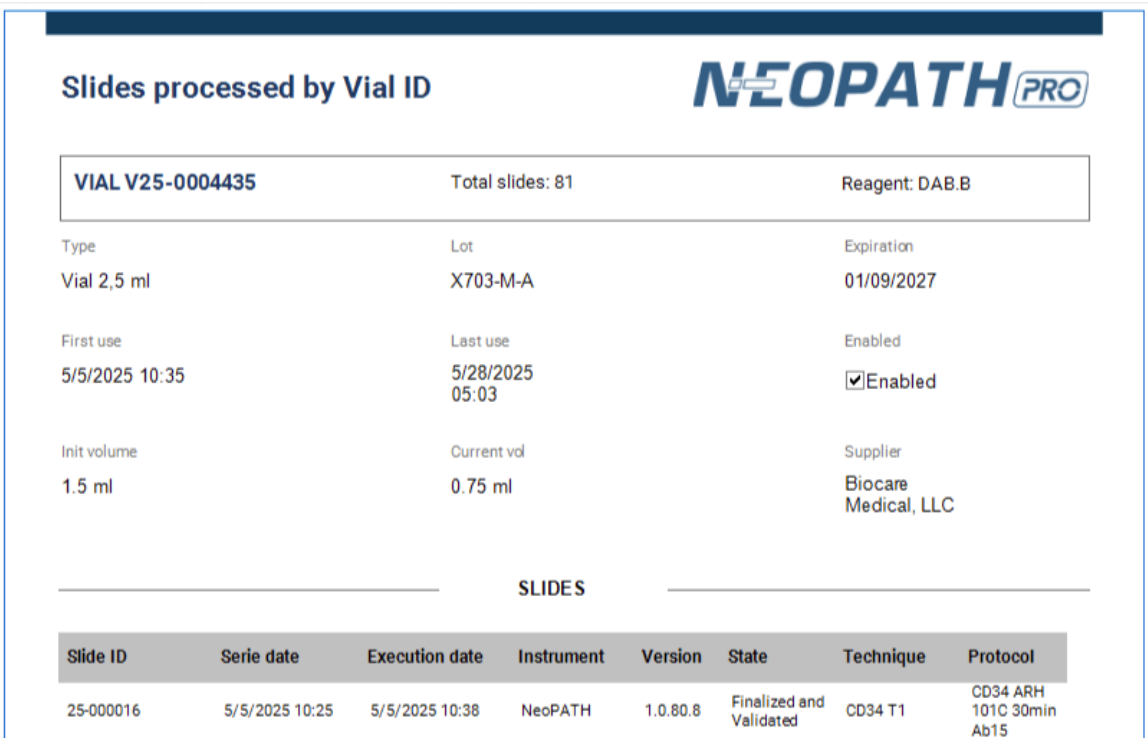
- Clicking the button changes the view to the report preview.



Composition of the report

- Header: It will be repeated on each page of the report.
  - Logo
  - Report Title: Slides processed by Id Vial
  - Subheader: Vial information (there is only one) if grouped by Vial ID
    - Total number of portals made with that vial.
    - Road identifier.
    - Reagent.
    - User or Technician
    - Batch.
    - Expiration
    - First use
    - Last use
    - Initial volume
    - Current volume
    - Enabled
    - Supplier
    - Information about each slide where the vial has been used, in columns. To do this, retrieve information about all slides where that vial has been used.
      - Serial date
      - Instrument
      - Version
      - Slide identifier
      - State

    - Date of execution
    - Technique
    - Protocol
- Foot:
    - Date and time of printing
    - User - Version of the SW from which printing is made
    - Total page number



Slides processed by Vial ID

NEOPATH PRO

VIAL V25-0004435	Total slides: 81	Reagent: DAB.B

Type	Lot	Expiration
Vial 2,5 ml	X703-M-A	01/09/2027
First use	**Last use**	**Enabled**
5/5/2025 10:35	5/28/2025 05:03	☑Enabled
Init volume	**Current vol**	**Supplier**
1.5 ml	0.75 ml	Biocare Medical, LLC

SLIDES

Slide ID	Serie date	Execution date	Instrument	Version	State	Technique	Protocol
25-000016	5/5/2025 10:25	5/5/2025 10:38	NeoPATH	1.0.80.8	Finalized and Validated	CD34 T1	CD34 ARH 101C 30min Ab15

3. Slides processed by batch Id

This report records and details the use of vials in slide processing within a selected date range, including the lot identifier. It allows you to identify key reagent inventory information, such as the vial ID, type, lot, expiration date, and volume, as well as their use on the different slides processed. It also provides a detailed view of the usage history of each vial, facilitating the control, traceability, and auditing of reagent consumption in the laboratory.

Parameter settings

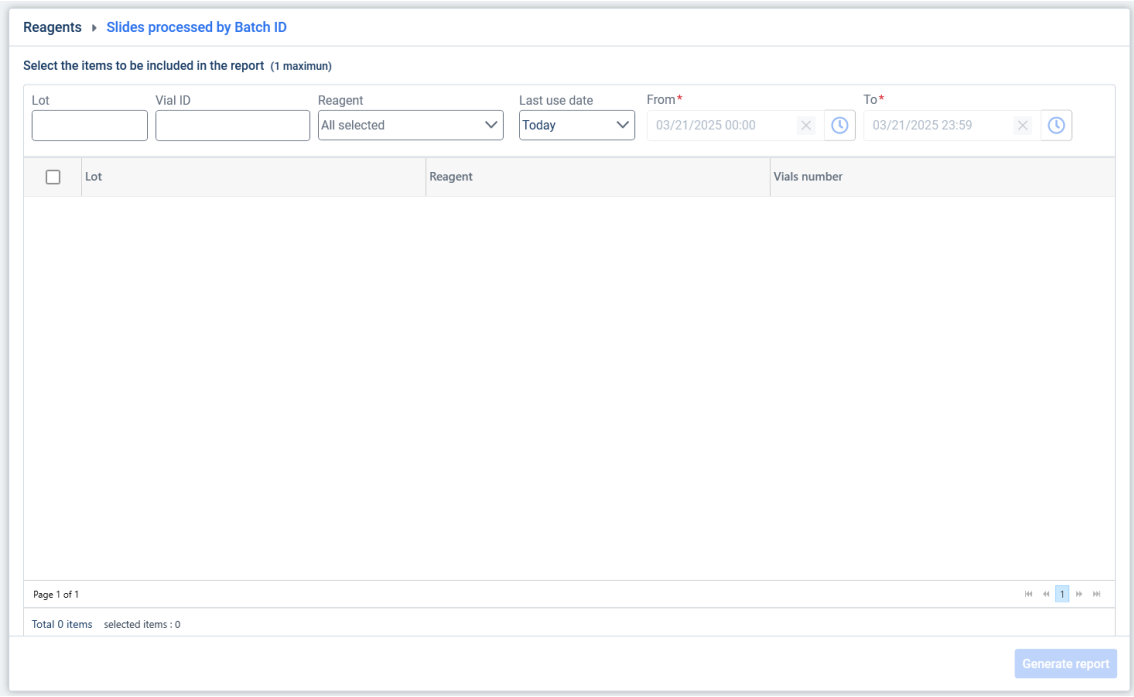
- Parameter to limit the custom date range to a maximum number of days. By default, it will be limited to 31 days.
- Parameter to define which predefined date range values will exist for this report type. The following types are available for this report:
    - Today
    - Yesterday
    - Last week
    - Last month
    - The default value will be Today.
- Parameter to limit the number of records to select in the grid . By default, this will be limited to a value of 1.

-

Filters

The filters that can be applied to this report are related to the following fields. The options are:

- Batch: Text field where you enter a search string that filters the system's matching results.
- Road ID: Text field where you can enter a search string that filters the system's matching results.
- Reactive: multi-selector or text.
- Last use date. You can select one of these options directly, and slides whose last use date falls within the selected dates will be filtered.
    - Predefined date and time range (the *parameter to limit the date range to a maximum number of days does not apply to predefined ranges)*
        - Today, yesterday, last week, last month. Those defined in the *Parameter to establish which predefined date range values will exist for this type of report.*
        - By default, the Today option will be selected (Parameter *to set which predefined date range should appear selected by default from those existing in the previous parameter)* and will be shown selected in the Start Date and End Date fields.
    - Custom date range. When clicked, the Start Date and End Date fields should be enabled with the predefined range. The Start Date and End Date fields should be limited.
        - Start date: Must be less than or equal to the current date. If it is not within the range, an-error message will appear below the field ("Must be current or earlier").
        - End date: Must be greater than or equal to the start date and less than the start date + the *parameter value to limit the date range to a maximum number of days,* and must always be less than or equal to the current date. If it is not within the range, an error message must be displayed below the field.
            - If it is less than the Start date “Must be Start date or later”
            - If it exceeds the maximum number of days “Date outside the maximum range of days: _Parameter value to limit the date range to a maximum number of days”
        - The results grid will only be updated when both the start date and end date are within the correct date range, that is, within the limits.
- There are currently no advanced filters, so the button should remain hidden.



Grid of filter results.

The columns to be displayed are as follows, in ascending order by Last Used Date, and it should be possible to filter by each of them.

- Batch
- Reagent
- Number of vials

By default, the corresponding inventory records whose last use date falls within the selected date range should be displayed.

Currently, changing any filter will require the results to be refreshed. If a record was already selected, the previous selection will be lost.

Generate Report Button:

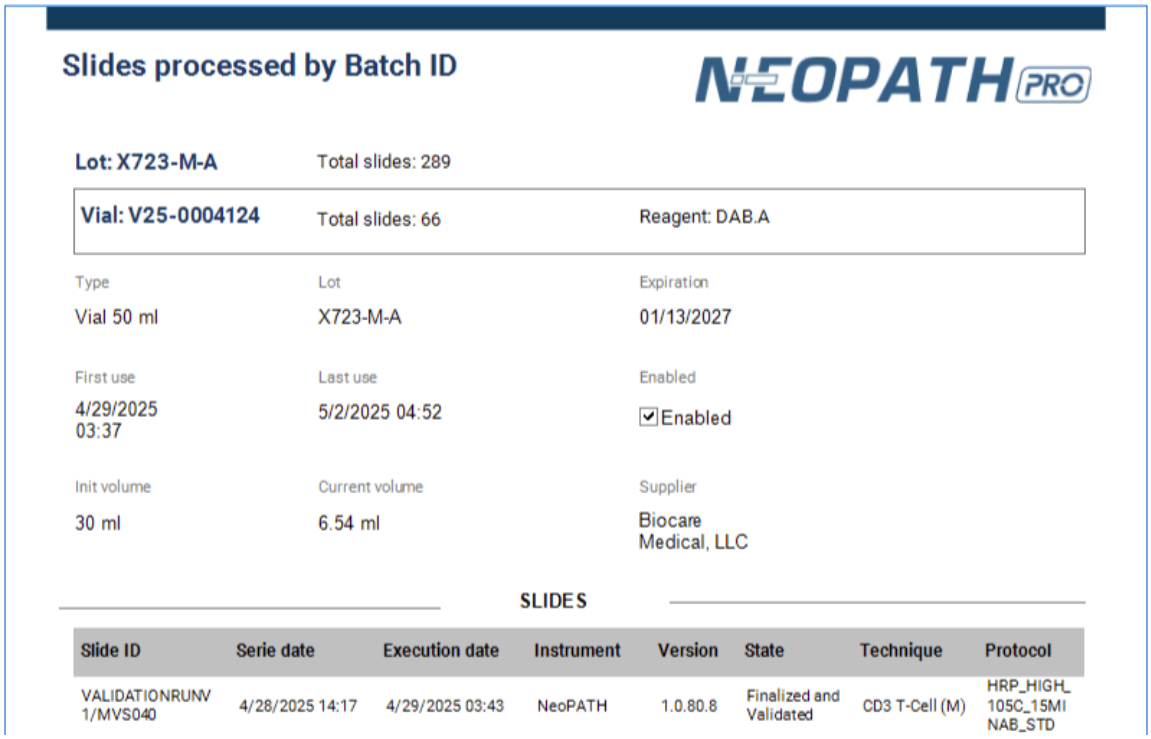
- The Generate Report button will only be enabled when you have selected at least one record.
  - Currently, only a maximum of 100 records can be selected, and the user must be informed of this limitation. Furthermore, the user must be informed if they exceed the limit of 100 without deselecting the current selection.
- The report must be generated in the same language configured for the application.
- Clicking the button changes the view to the report preview.

Composition of the report

- Header: It will be repeated on each page of the report.
  - Logo
  - Report title: Slides processed by Id Vial

- Subheader: Vial information (there is only one) if grouped by Vial ID
    - Total number of slides made with that batch.
    - Road identifier.
    - Reagent.
    - User or Technician
    - Expiration
    - First use
    - Last use
    - Initial volume
    - Current volume
    - Enabled
    - Supplier
    - Information about each slide where the vial has been used, in columns. To do this, retrieve information about all slides where that vial has been used.
        - Serial date
        - Instrument
        - Version
        - Slide identifier
        - State
        - Date of execution
        - Technique
        - Protocol

- Foot:
    - Date and time of printing
    - User - Version of the SW from which printing is made
    - Total page number



Slides processed by Batch ID

NEOPATH PRO

Lot: X723-M-A Total slides: 289

Vial: V25-0004124 Total slides: 66 Reagent: DAB.A

Type	Lot	Expiration
Vial 50 ml	X723-M-A	01/13/2027
First use	**Last use**	**Enabled**
4/29/2025 03:37	5/2/2025 04:52	☑ Enabled
Init volume	**Current volume**	**Supplier**
30 ml	6.54 ml	Biocare Medical, LLC

SLIDES

Slide ID	Serie date	Execution date	Instrument	Version	State	Technique	Protocol
VALIDATIONRUNV 1/MVS040	4/28/2025 14:17	4/29/2025 03:43	NeoPATH	1.0.80.8	Finalized and Validated	CD3 T-Cell (M)	HRP_HIGH_ 105C_15MI NAB_STD

User Activity Report

The purpose of this report is to record and detail user activity in the system within a selected date range. It allows you to monitor actions performed, identifying the type of activity, the user who performed it, the date and time of the event, and the device from which it was executed. Its use is key for monitoring operations, internal audits, and access control on the platform.

Parameter settings

- Parameter to limit the custom date range to a maximum number of days. By default, it will be limited to 365 days.
- Parameter to define which predefined date range values will exist for this report type. The following types are available for this report:
    - Today
    - Yesterday
    - Last week
    - Last month
    - Last year
    - The default value will be Today.
- Parameter to limit the number of records to select in the grid. By default, this will be limited to a value of 1.

Filters

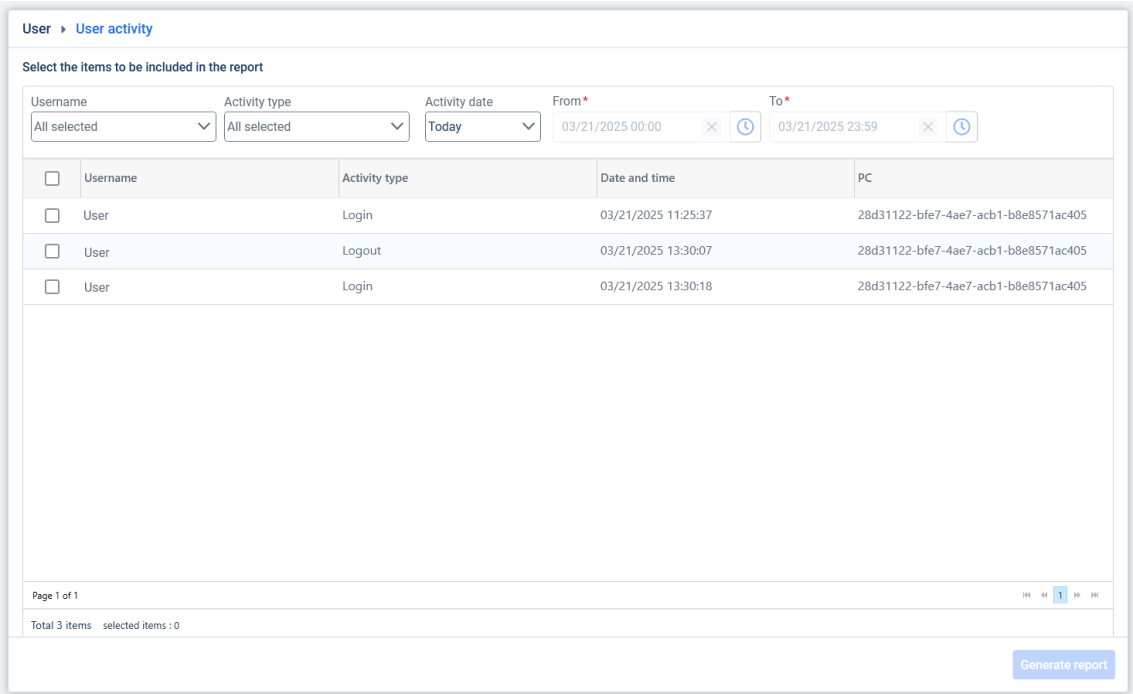
The filters that can be applied to this report are related to the following fields. The options are:

- User: Text field where you enter a search string that filters the system's matching results.
- Activity Type: Selector with available values Login or Logout .
- Access date range: You can select one of these options directly. This will filter the activity of users whose access date falls within the selected dates.
    - *parameter to limit the date range to a maximum number of days* does not apply to predefined ranges.)
        - Today, yesterday, last week, last month, last year. Those defined in the *Parameter to establish which predefined date range values will exist for this type of report.*
        - By default, the Today option will be selected (*Parameter to set which predefined date range should appear selected by default from those existing in the previous parameter*) and will be shown selected in the Start Date and End Date fields.
    - Custom date range. When clicked, the Start Date and End Date fields should be enabled with the predefined range. The Start Date and End Date fields should be limited.
        - Start date: Must be less than or equal to the current date. If it is not within the range, an error message will appear below the field ("Must be current or earlier").
        - End date: Must be greater than or equal to the start date and less than the start date + the *parameter value to limit the date range to a maximum number of days* and must always be less than or equal to the current date. If it is not within the range, an error message must be displayed below the field.
            - If it is less than the Start date “Must be Start date or later”
            - If it exceeds the maximum number of days “Date outside the maximum range of days: *Parameter value to limit the date range to a maximum number of days*

- The results grid will only be updated when both the start date and end date are within the correct date range, that is, within the limits.
- There are currently no advanced filters, so the button should remain hidden.

Grid of filter results.

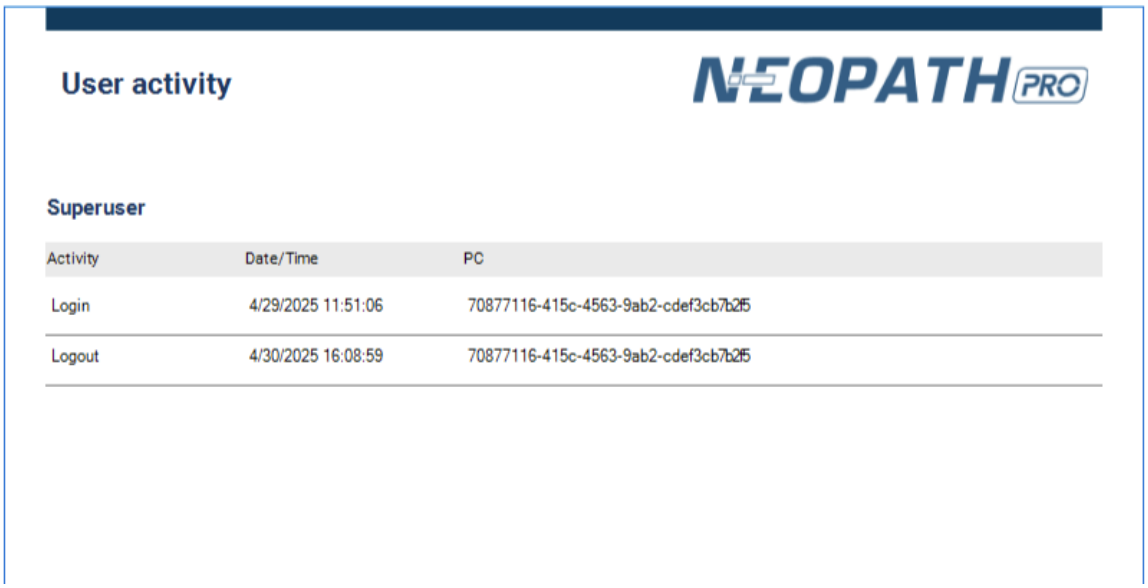
- The columns to be displayed are the following, and it should be possible to filter by each of them.
    - Selector
    - User
    - Type of activity
    - Date
    - PC
- By default, records corresponding to user activity whose date falls within the selected date range should be displayed.
- Currently, changing any filter will require the results to be refreshed. If a record was already selected, the previous selection will be lost.
- Generate Report Button:
    - The Generate Report button will only be enabled when you have selected at least one record.
    - **The report must be generated in the same language configured for the application.**
    - Clicking the button changes the view to the report preview.



Composition of the report

- Header: It will be repeated on each page of the report
    - Logo

    - Report Title: User Activity
- The data to be reported are the following, grouped by user; each grouping will be displayed as a subheader.
    - Activity
    - Date and time
    - PC
- Foot:
    - User - Print date and time
    - Version of the SW from which printing is made
    - Total page number

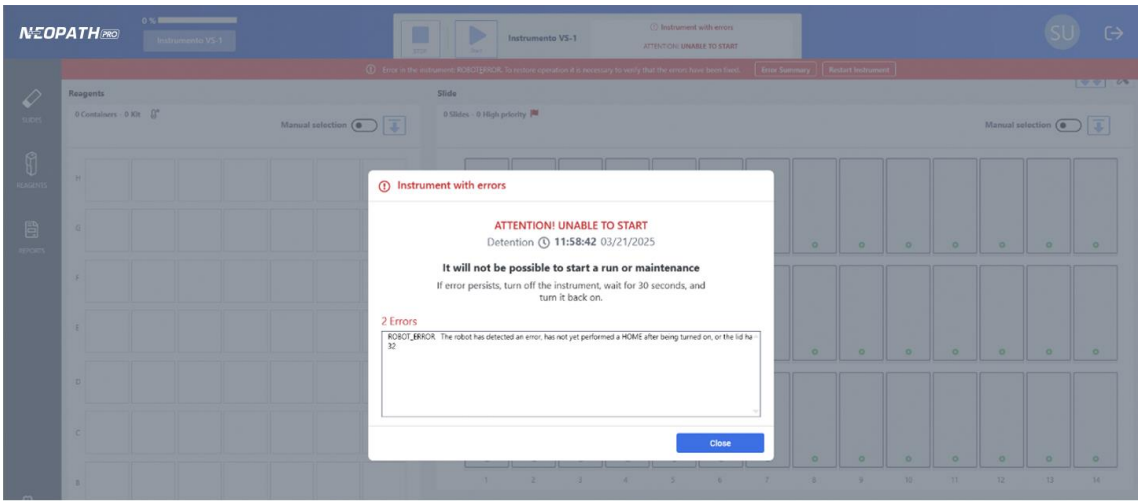


5 HW OR DISCONNECTION ERRORS

At any time, the system can detect an error in the robot or a disconnection of the robot, because the USB cable has been disconnected or because the protective case has been opened while the instrument is running (the latter case does not apply when the instrument is in standby mode).

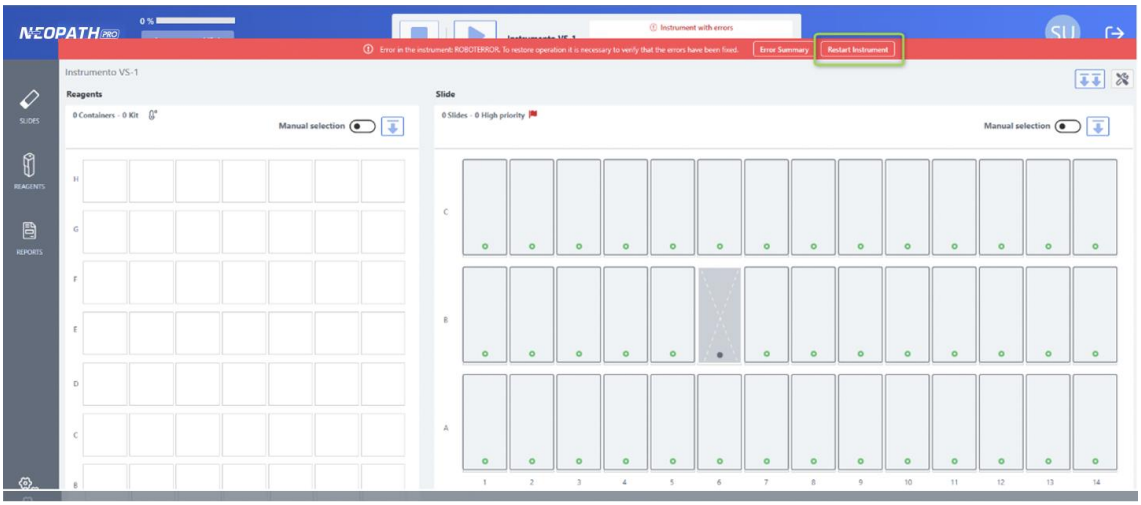
In these cases, run or maintenance cannot be started and, if any of them had been started, they will be automatically canceled and the behavior on them will be as described in the cancellation point.

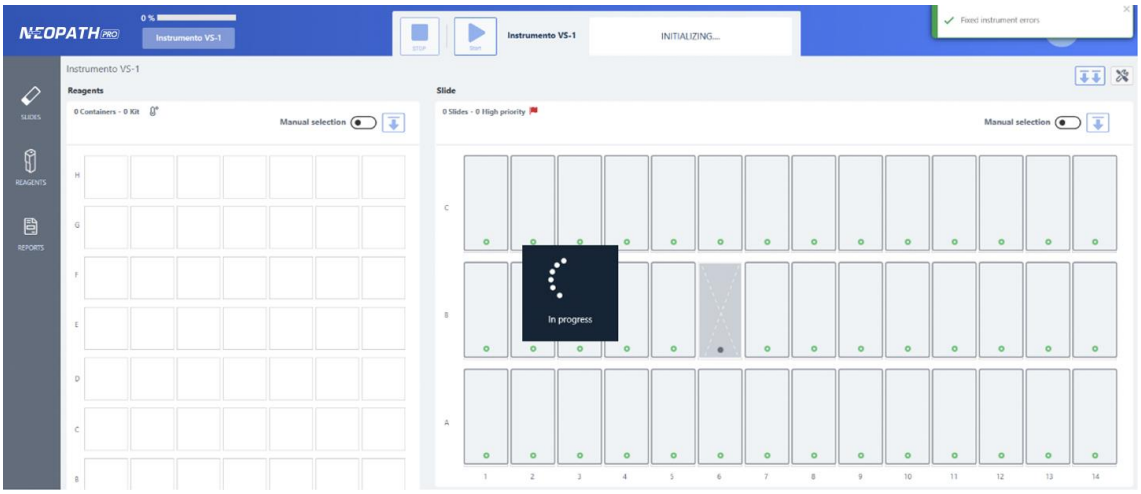
To inform the user of the problem, it is indicated by a red stripe in the work in progress window.



To view the error(s) that have occurred, click on the "Check errors" button.

To solve the error(s) and restart the robot, click on the "Restart robot" button.

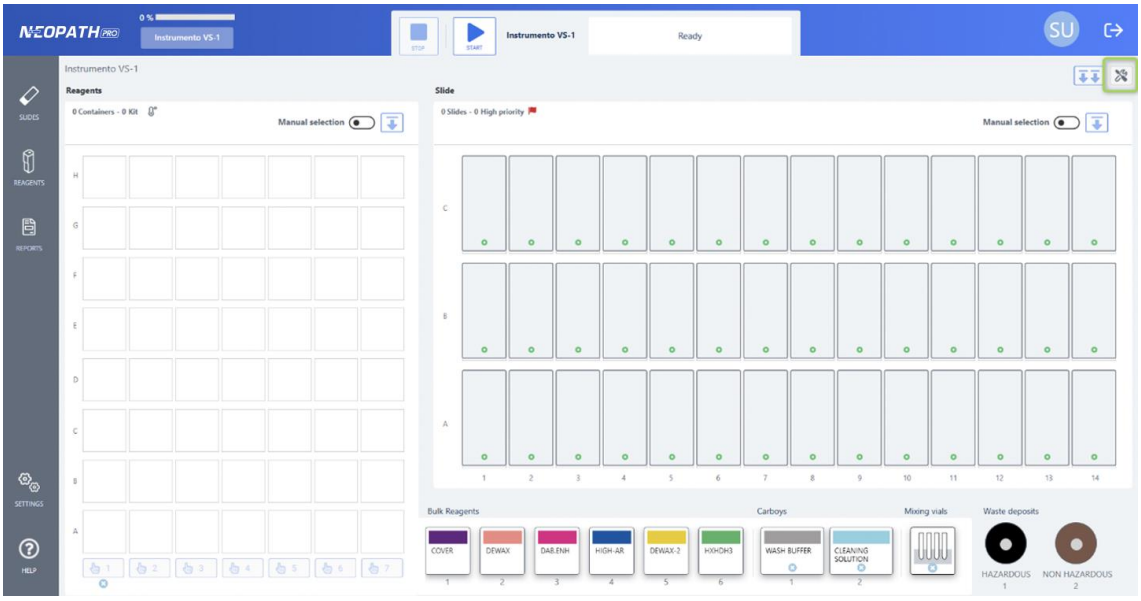




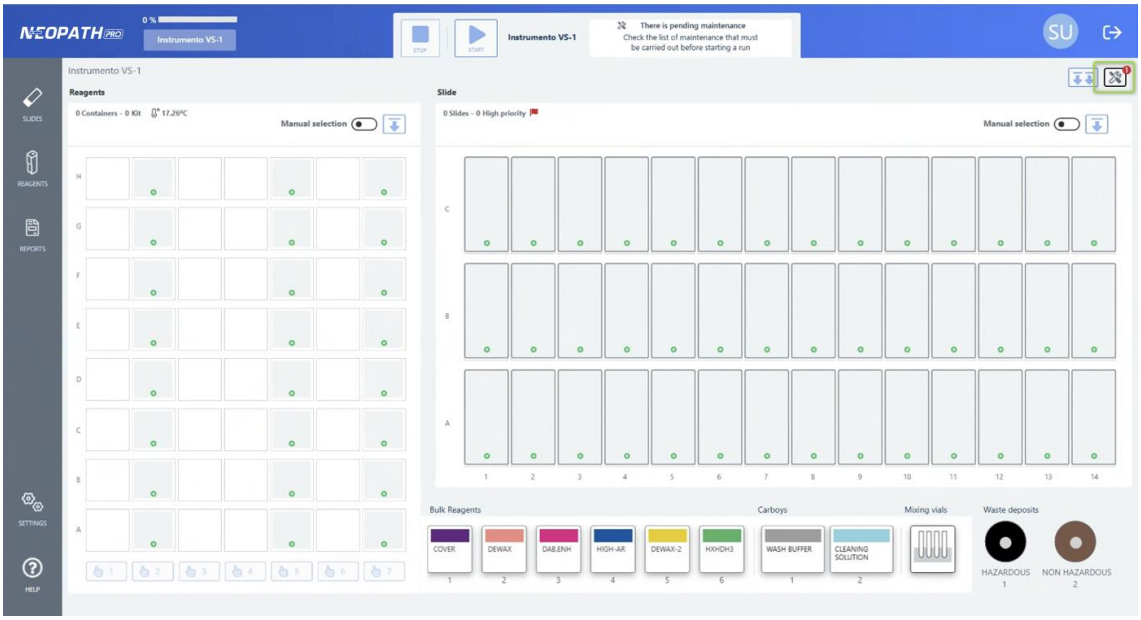
To start a new run or maintenance, the user must unload the slides, if any, and start the run or maintenance again.

6 Maintenance And Configuration Of Sensors And Devices

In the Work in progress screen there is a button  that gives access to maintenance programs and to the configuration of sensors and devices.

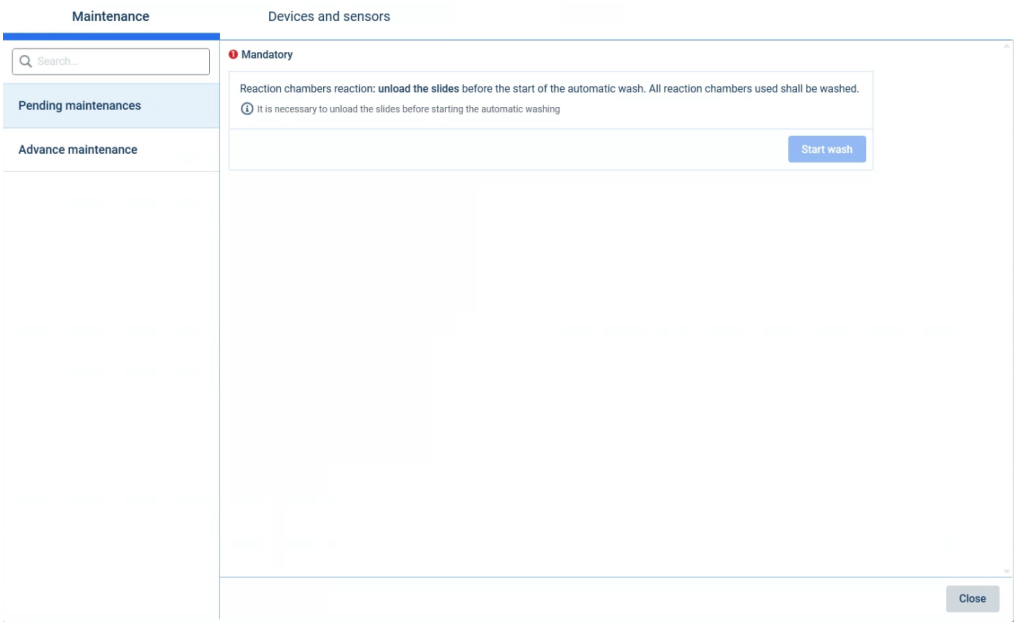


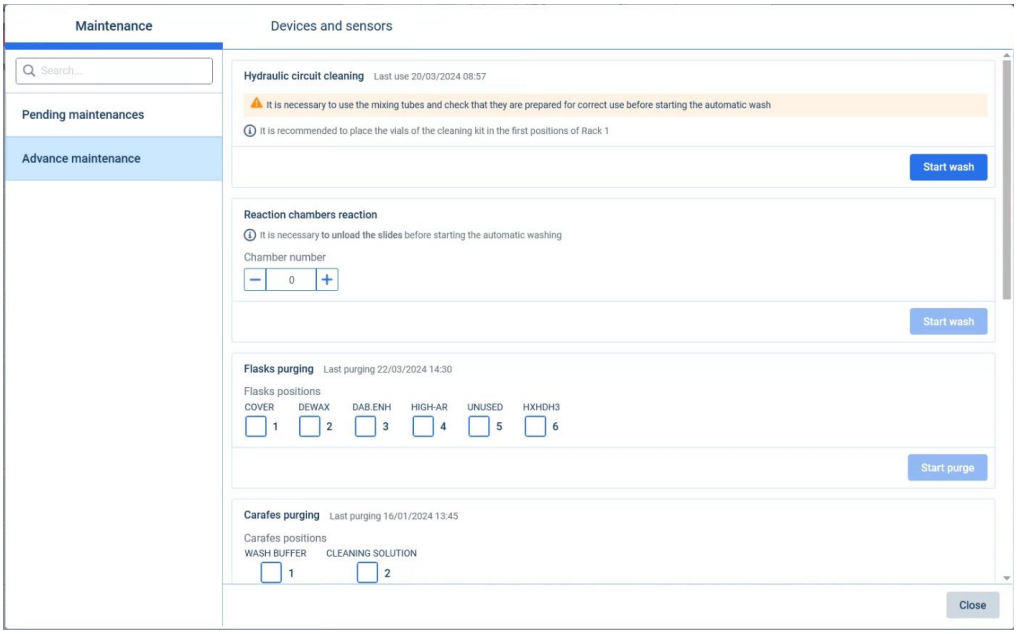
When maintenance is required, a red warning will appear on the maintenance icon indicating that maintenance is needed.

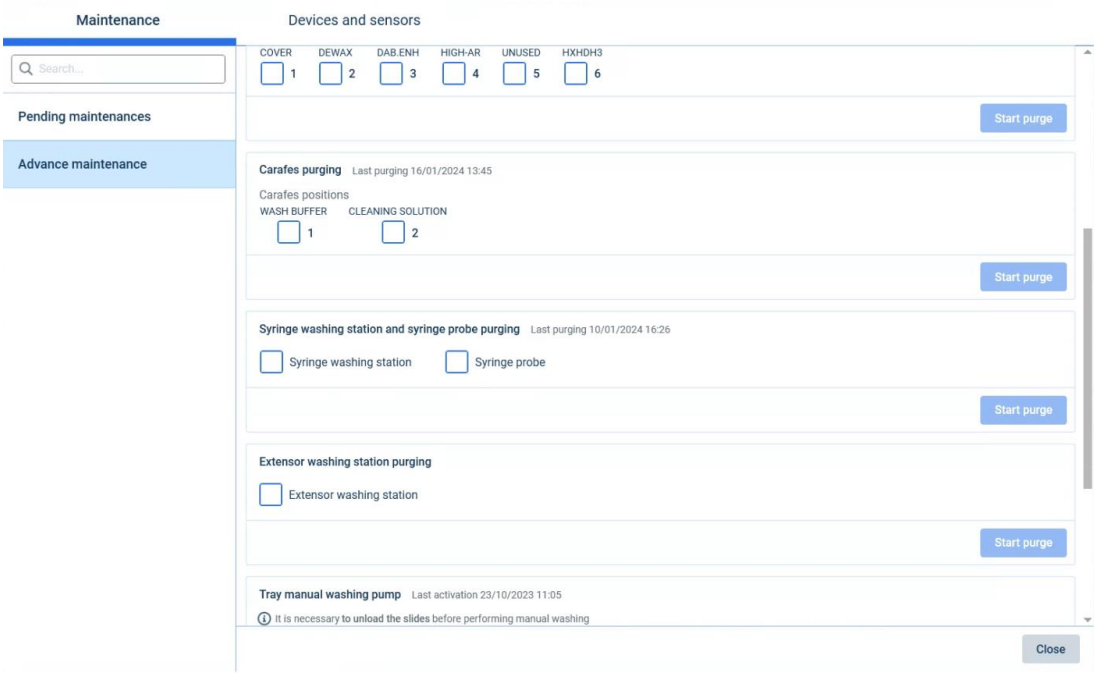


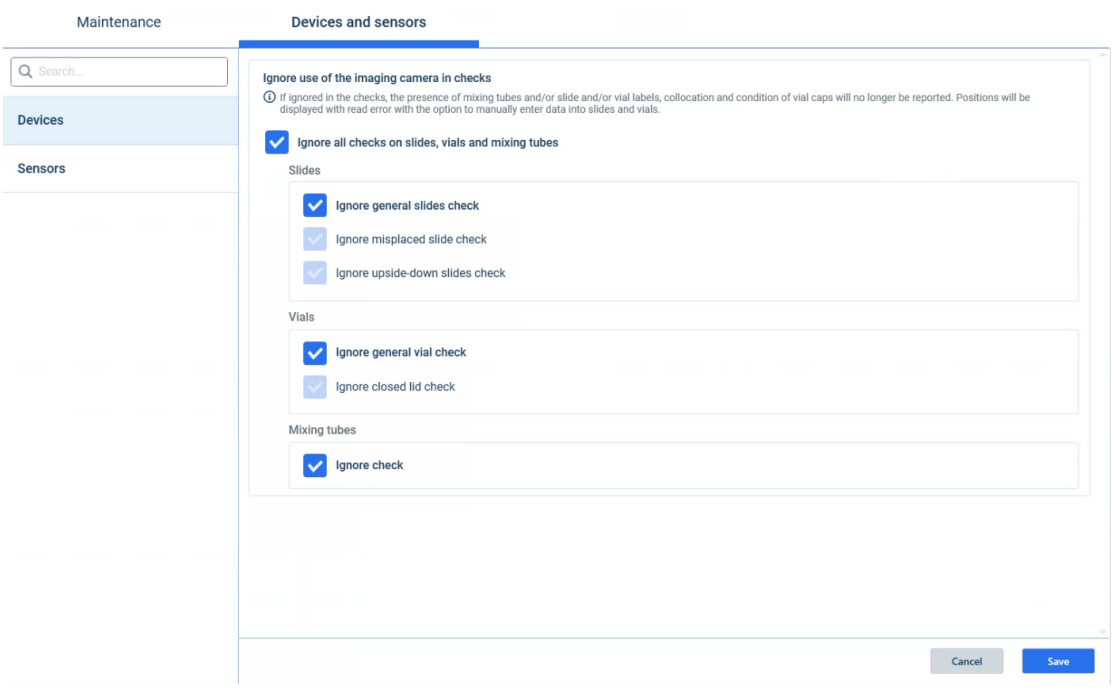
Pressing the icon will open the maintenance and sensors tab. In the maintenance section, you will find two parts:

- **Pending Maintenance:** This section lists all maintenance tasks that need to be performed at that moment but have not been done yet.
- **Advanced Maintenance:** This section lists all maintenance tasks that can be performed on the equipment:


Maintenance
Devices and sensors
Search...
Pending maintenances
Advance maintenance
Mandatory
Reaction chambers reaction: unload the slides before the start of the automatic wash. All reaction chambers used shall be washed.
It is necessary to unload the slides before starting the automatic washing
Start wash
Close


Maintenance
Devices and sensors
Search...
Pending maintenances
Advance maintenance
Hydraulic circuit cleaning Last use 20/03/2024 08:57
It is necessary to use the mixing tubes and check that they are prepared for correct use before starting the automatic wash
It is recommended to place the vials of the cleaning kit in the first positions of Rack 1
Start wash
Reaction chambers reaction
It is necessary to unload the slides before starting the automatic washing
Chamber number
0
Start wash
Flasks purging Last purging 22/03/2024 14:30
Flasks positions
COVER 1
DEWAX 2
DAB.ENH 3
HIGH-AR 4
UNUSED 5
HXHDH3 6
Start purge
Carafes purging Last purging 16/01/2024 13:45
Carafes positions
WASH BUFFER 1
CLEANING SOLUTION 2
Close





In Neopath Pro only two maintenances are mandatory:

- Washing of the hydraulic circuit, which is compulsory after every 230 preparations.
- Washing of the reaction chambers is optional after each cycle and mandatory after 2 cycles performed in the same positions.

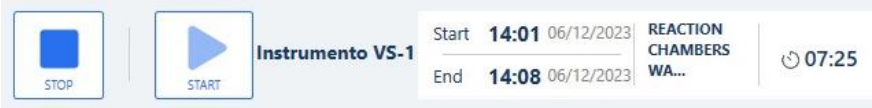
Maintenance programs

This screen shows different sections corresponding to all the maintenance tasks of the instrument.

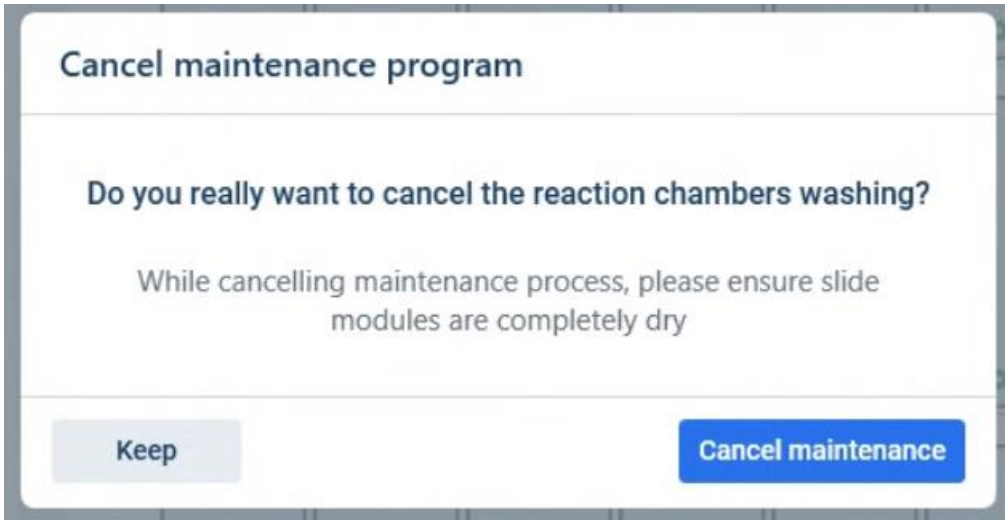
In order to start maintenance, it is necessary that a run or other maintenance is not being executed.

When one of the maintenances is started, the screen closes and the maintenance is started in the instrument and displayed in the Work in Progress window, except for the manual recording of the extensor drying towel change, which does not require any action by the instrument. Each maintenance has its own verifications of the elements that are required for its execution. In this way, as with a run, if an error occurs, it will be displayed in the information section of the keypad.

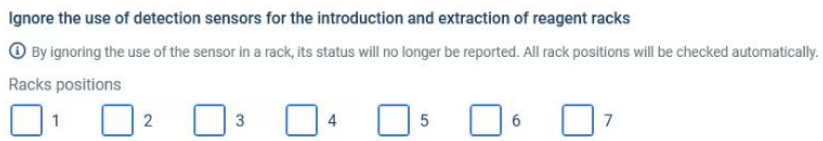
Once it has been verified that all the elements required for the execution of a maintenance are correct, the instrument executes the corresponding maintenance program. The information section of the keypad shows a countdown with the remaining maintenance time, as well as the start and end date.



As in a run, the maintenance can also be stopped, informing at any time from the keypad that the maintenance has been canceled, after the confirmation of definitive cancellation.

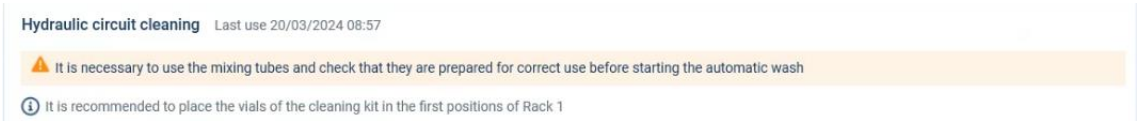


When maintenance is completed, an acoustic alert is activated and a wash completion message is displayed. The information section of the control panel will indicate the end of the washing process. In turn, in the Maintenance window, next to each of the available maintenances, the date of the last washing, purging or corresponding maintenance will appear.



1. Hydraulic circuit washing

It started by clicking on the **Start Washing button.** It is recommended that the cleaning kit be placed in the first position (position 1-A) to save time when scanning the vial tier.



2. Reaction chamber washing

The number of reaction chamber positions in which the washing is to be performed must be indicated. When a number greater than 0 is selected, the **Start washing** button is enabled, which washes the number of positions indicated starting from the 1-A position.

In this maintenance, an initial camera reading is performed at the selected positions to detect whether there are slides. If the camera sensor is disabled for slides, this check will not be performed, and the maintenance will proceed directly.

If we are not ignoring the slides, slide detection will be performed at the positions, giving the following options:

- No slides detected: Maintenance begins immediately.
- A slide is detected: The lower modal appears, giving us the option to repeat the reading or continue the maintenance directly.

3. Purging of flask probes

To enable this maintenance, you must first select the flask probe positions to be purged. Once all the positions to be purged have been selected, the **Start purge** button will be enabled, which starts this maintenance.

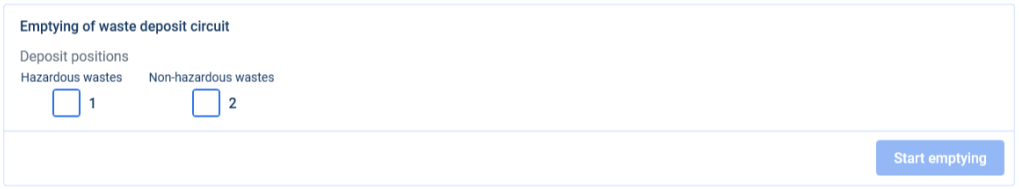
4. Purging of bottle probes

To enable this maintenance, you must first select the cylinder probe positions to be purged. Once the positions to be purged have been selected, the **Start purge** button will be enabled, which starts this maintenance.

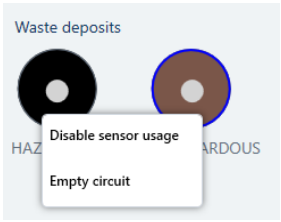
5. Emptying of waste deposit circuit

This maintenance is useful for removing residual liquids from the final circuit of waste tanks. This prevents liquid spills when emptying the deposit.

To enable this maintenance, you must first select the tank whose circuit you want to empty. Once you select the position you want to empty, the **Start Emptying** button will be enabled, which begins this maintenance.



It can also be activated from the current work window using the context menu for deposit positions.



6. Syringe wash station and syringe probe purging

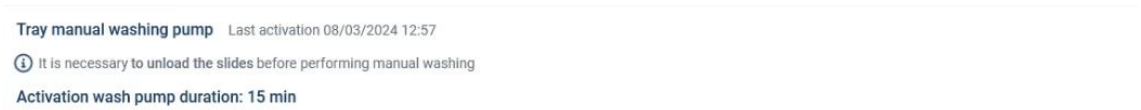
To enable this maintenance, you must first select whether you want to purge the Syringe Wash Station, the Syringe Probe, or both. Once the selection has been made, the **Start purge** button will be enabled, which starts this maintenance.

7. Extender wash station purging

In order to **Start purging**, it is necessary to select the Enable station purging option and press the start button.

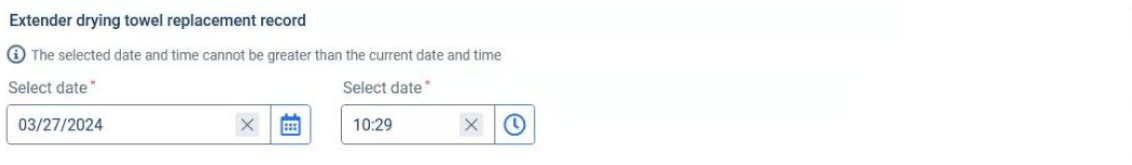
8. Activate pump for manual washing of the tray

Before starting maintenance, please be informed that all slides must be removed so that manual washing of the slide tray can be performed. In this way, when pressing the **Activate button to perform manual washing**, if it is verified that there are no slides in the rack, the pump is activated for washing during the set time.

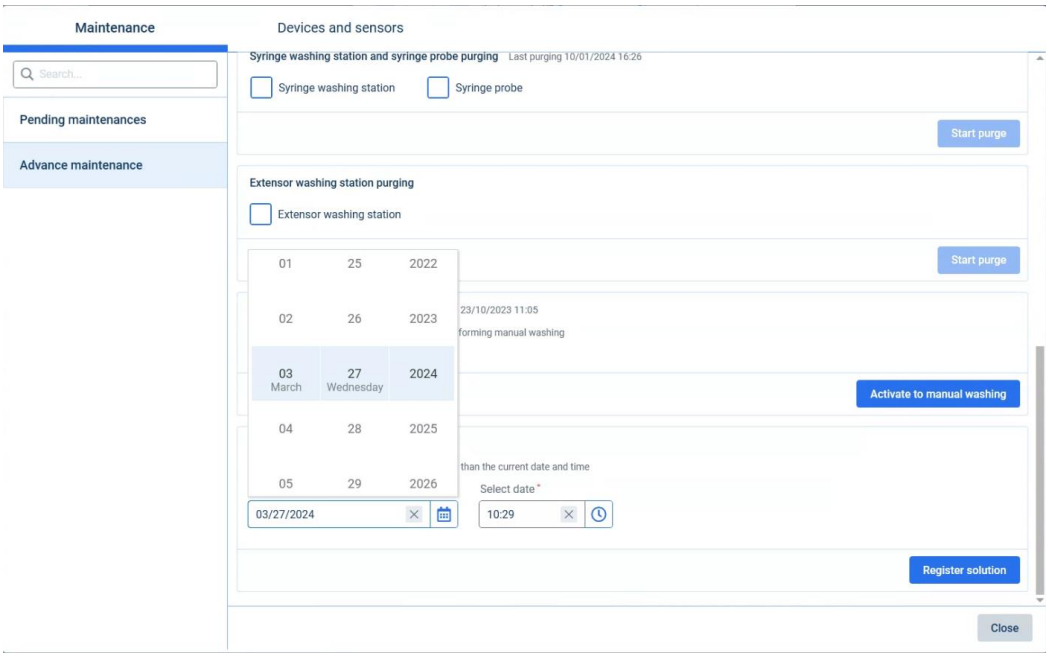


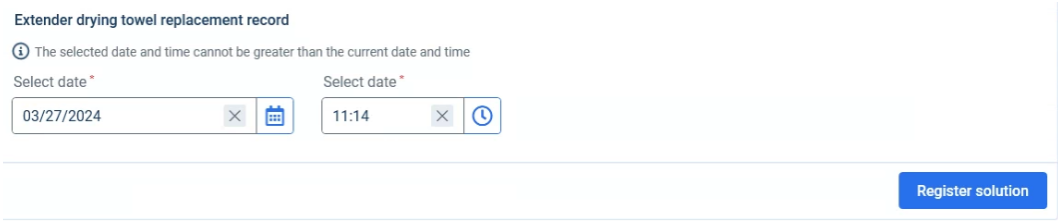
9. Change of drying towel of the spreader

The drying towel of the spreader will be changed manually, so that the date of the last change is recorded in the system, the record must be made in this section.



To do this, the date and time must be selected in the box for the date the change was recorded. The following window opens to set a date and time.



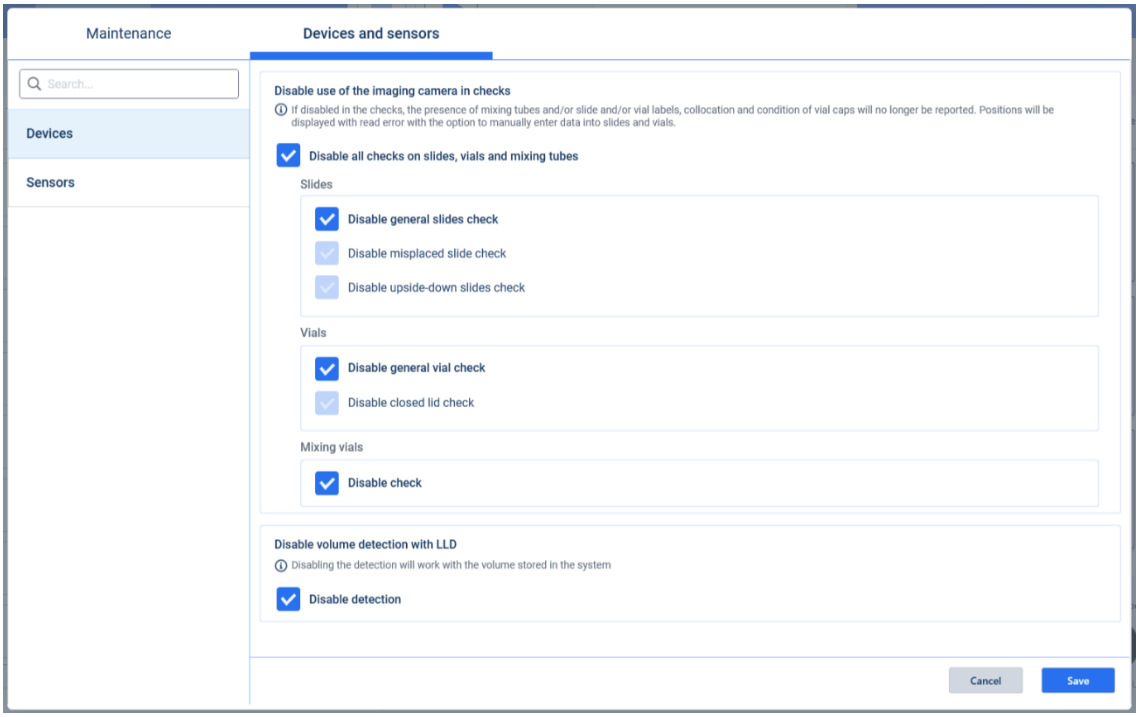


By clicking on the **Register solution** button, the date of the last change is displayed next to the maintenance section.

Devices and sensors

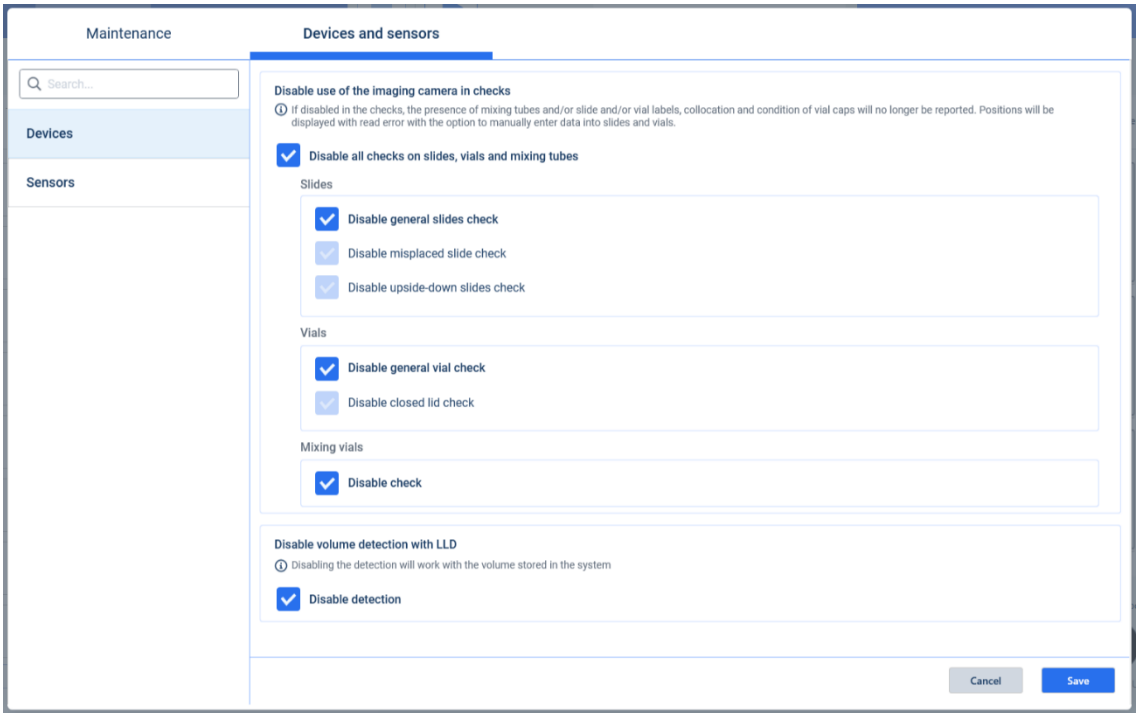
This screen shows different sections corresponding to all the devices and sensors of the instrument. These devices and sensors can be configured to disable if a specific problem is detected in any of them, so as not to prevent the use of the instrument while they are being solved.

In addition, for each sensor and device, the consequences of disabling them when performing a run or maintenance are briefly reported.



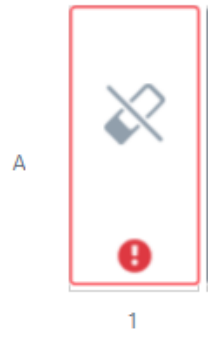
1. Imaging camera

To disable the imaging camera, you mark it to be disabled and save the settings.

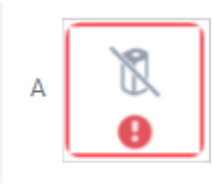


When running a series or maintenance, and the use of the imaging camera is being disabled, the scanning of the port and reagent vial racks is not performed in the port and vial verification, and all positions that were to be read with the imaging camera are represented with not detected error for manual data entry.

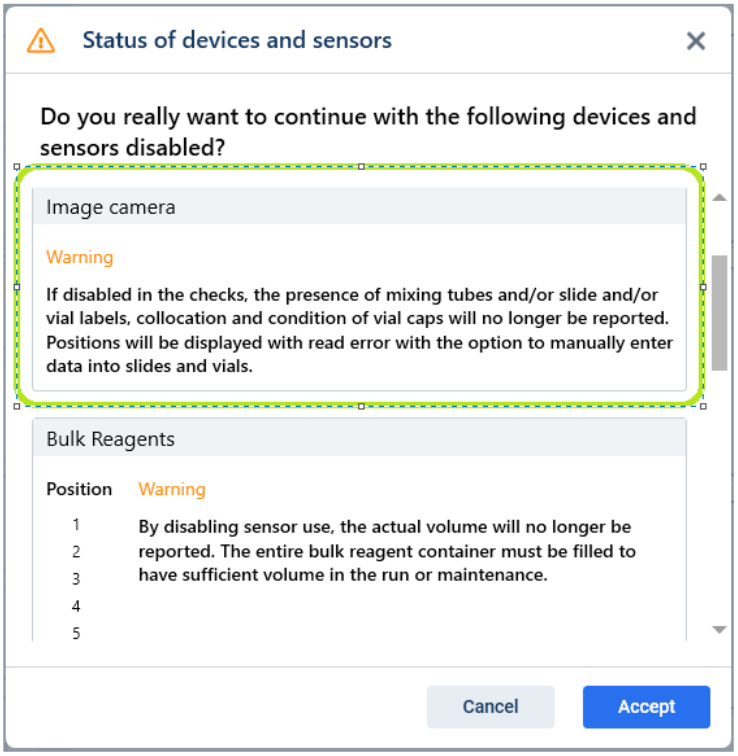
- Slides:



- Vials:

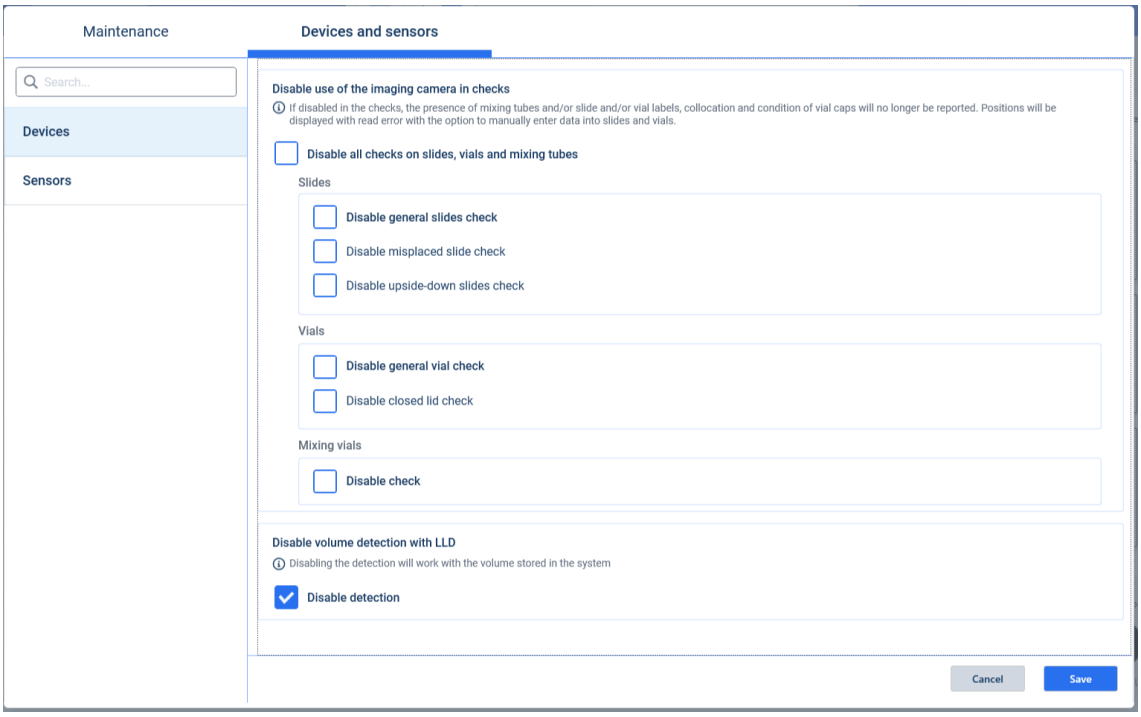


When starting a run or maintenance, and this device is being disabled, the behavior and consequences of disabling the imaging camera are reported in a window.

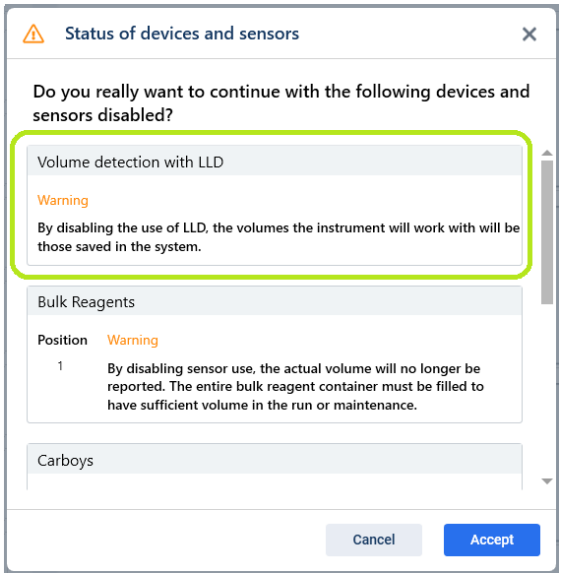


2. Automatic Volume Detection in Vials (LLD)

To disable the volume detection sensor, select and save the setting.

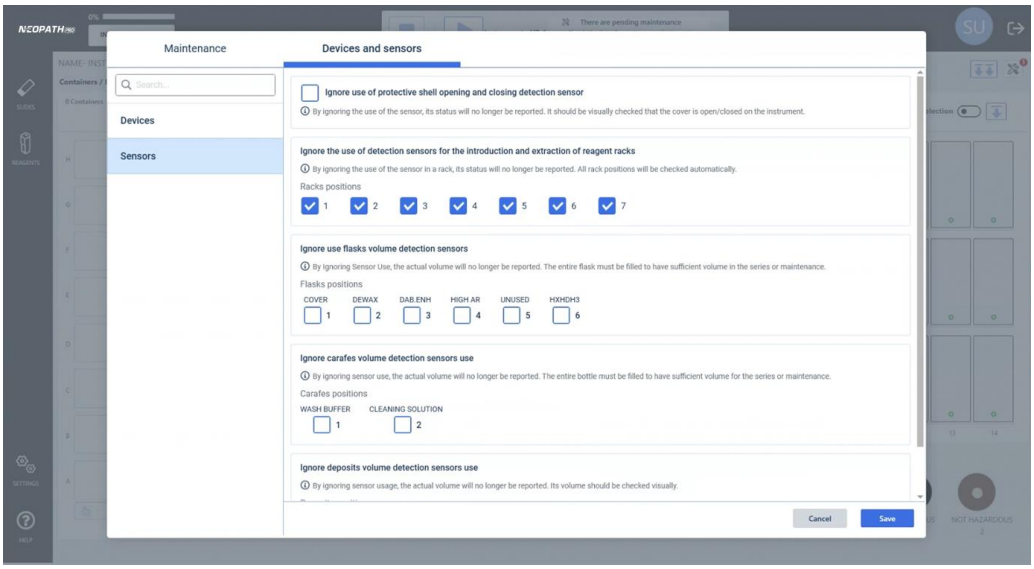


When starting a series or a maintenance with this configuration, a window informs about the consequences of running a series with the disabled sensor.



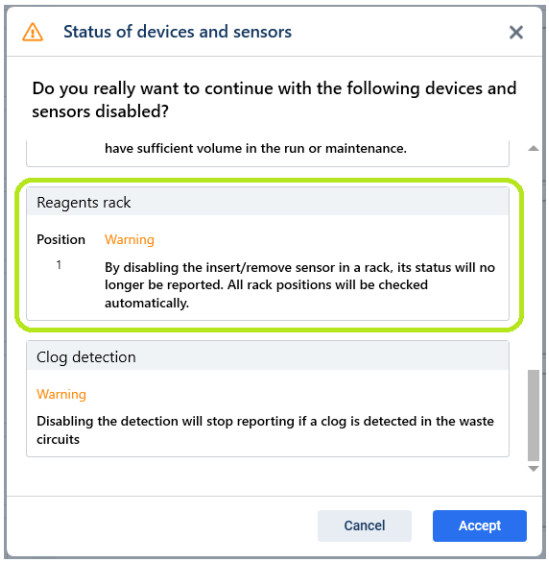
3. Reagent rack

To ignore the sensor that detects the insertion or removal of reagent vial racks, the position of the corresponding rack(s) to be disabled is marked and the configuration is saved.



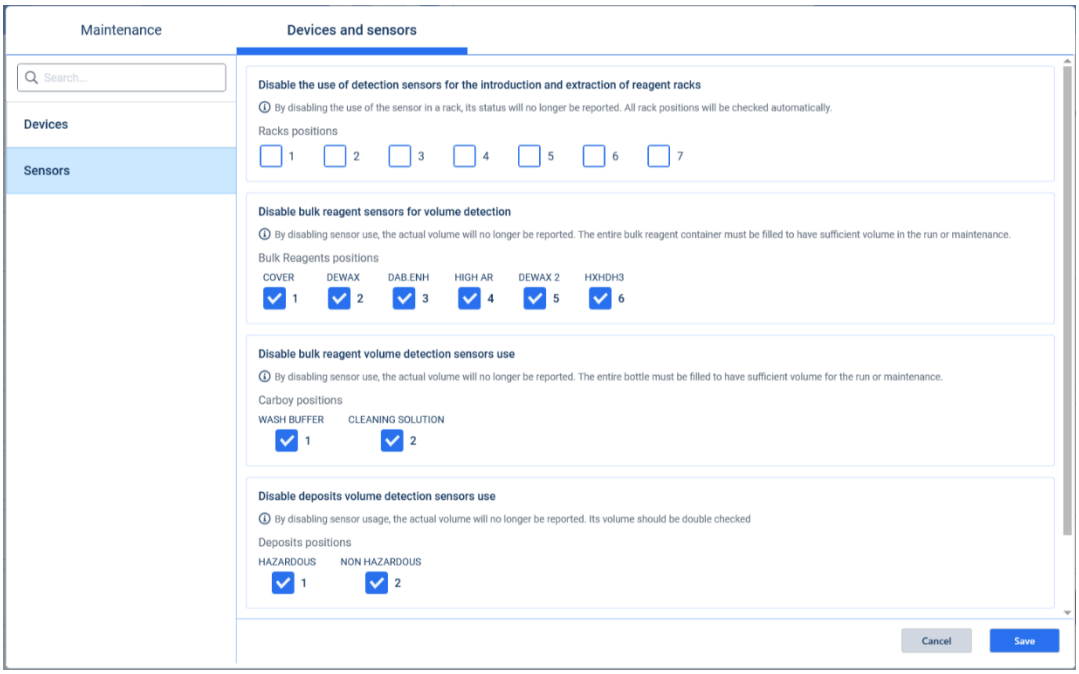
When running a series or maintenance, and the use of the sensor is disabled, it is not reported if a rack is inserted or removed, and all disabled rack positions will be scanned in the reagent vial rack check.

When starting a run or a maintenance with this configuration, a window informs about the consequences of running a series with the disabled sensor.



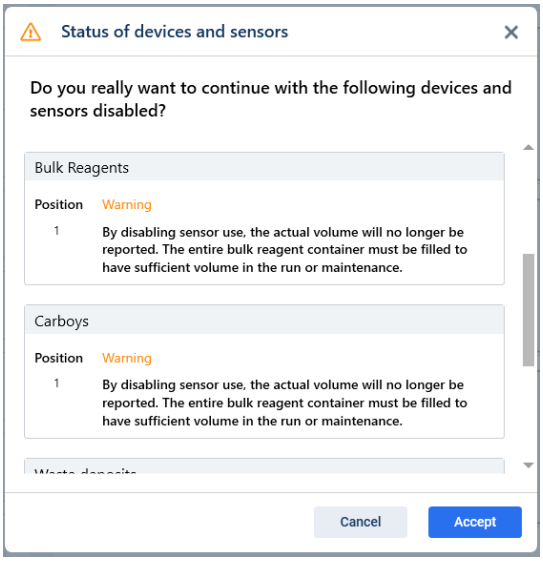
4. Sensors for flasks, bottles and waste

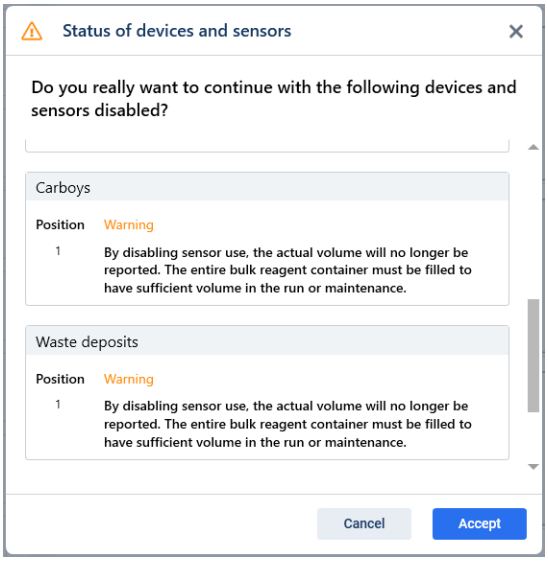
To disable the flasks, bottles and waste container sensors, the positions of the corresponding flasks, bottles or waste to be disabled are marked and the configuration is saved.



When running a series or maintenance, and the use of the sensor is being ignored, the volume or capacity will not be reported, and should be checked visually, to avoid running a run without sufficient reagent volume or capacity.

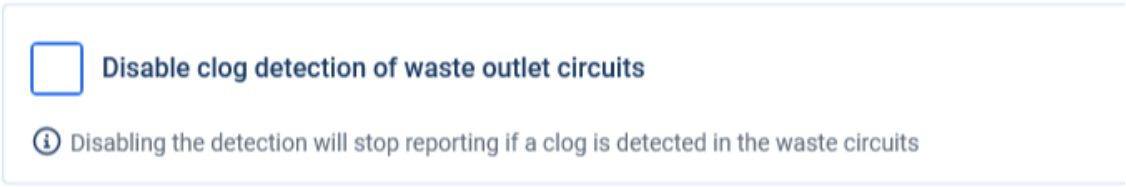
When starting a series or a maintenance with this configuration, a window informs about the consequences of running a series with one of these ignored sensors.



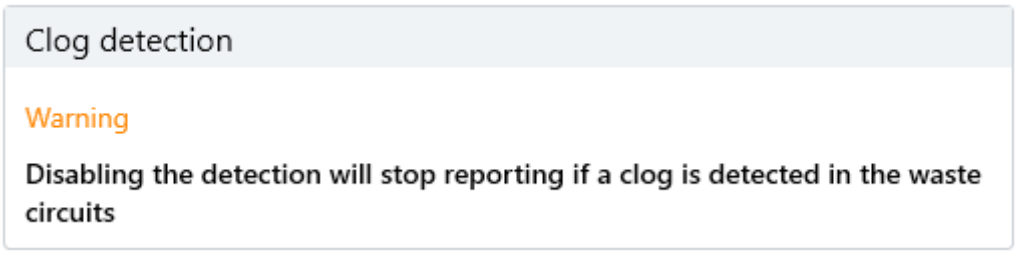


5. Clog detection sensor in waste outlet circuits

To deactivate the clog detection of the waste outlet circuits, the check box must be selected for this option.



When a run or maintenance is running, and this sensor is disabled, a message will not be sent if a blockage in the waste outlet circuits is detected. A window will inform you of the consequences of having this sensor disabled.



If a blockage is detected in the circuits and the sensor is not deactivated, the warning icon on the storage rack will indicate this.

Manual preventive maintenance

1. **Cleaning of Containers: Cleaning Solution and Wash Buffer**

- **Frequency:** Every month
- **Procedure:**
  1. Empty both the Cleaning Solution and Wash Buffer containers.
  2. Fill each container with 80 mL of bleach and 2 L of distilled water.
  3. Secure the lids on the containers.
  4. Shake the containers gently to ensure the bleach solution reaches all internal surfaces.
  5. Let the containers stand upright for 20 minutes to allow adequate contact time.
  6. Discard the bleach solution.
  7. Rinse the containers thoroughly with 2 liters of distilled water, repeating the rinse 3 to 5 times to ensure complete removal of any bleach residue.
  Make sure to rinse:
  The inner walls of the containers
  The lids
  The inner and outer surfaces around the container openings
  8. After rinsing, prepare fresh Cleaning and TBS (Tris-Buffered Saline) solutions.
  9. Perform a washing probe priming to ensure proper operation.

7 SUPPORT FILE GENERATION

When the application detects an error not related to hardware, it automatically generates files that gather the necessary information to analyze the issue. Additionally, users can manually generate these reports if they notice any abnormal behavior.

To do so, go to **Help > Support**. From there, you can:

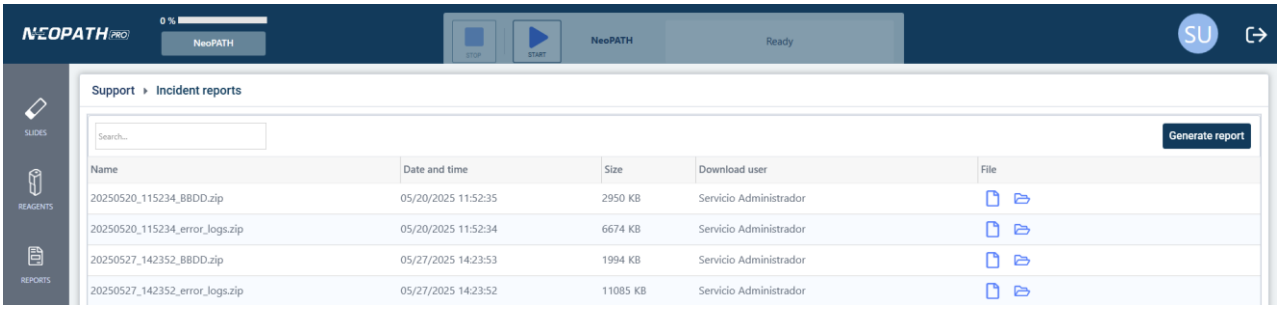
- View already generated reports.
- Open a file directly or the folder containing it.
- Generate a new report by selecting a date range (maximum 30 days).

The system will automatically include two ZIP files:

- Application logs.
- A copy of the database.

Once generated, these files will be available to share with technical support to help expedite problem resolution.

When the user manually generates the files, the system adds the word “manual” to the file name to distinguish it from those created automatically when the system detects an error.



8 States Of The Elements

8.1 Microscope slide

The different states on the slides are:

- Unloaded position:

- Disabled position:

- Pending or in process:

- Finalized:

- Not detected:

- Reading error:

- Other errors:

- Poorly placed:

- In process with warnings:

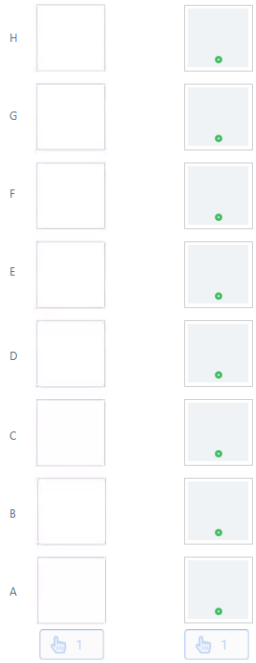
- Finished with warnings:

Disabled position

8.2 Racks

Positioning of the racks in the rack.

Without Rack With Rack



8.3 Vials

The different states on the roads are:

- Unloaded position:

- Vial loaded and required in the series:

- Vial with warning:

- Not detected:

- Reading error:

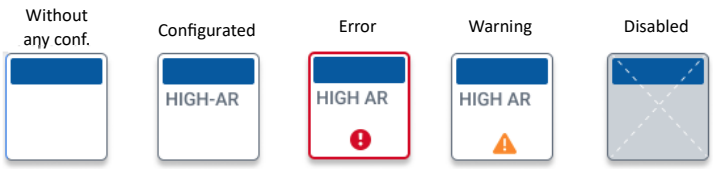
- Closed lid error:

- Other types of errors:

- Not used in the series:

- Not used in the series and with a warning:

8.4 Flasks



8.5 Big bottles

8.6 Waste containers

9 MEANING OF LEDS

9.1 Slide LEDs

The instrument has an LED in each chamber to indicate different situations. This representation is also done from the application.

SLIDES And POSITIONS	LEDS
Disabled position	No light
Empty position and machine without HW errors	Fixed green
Empty position and machine with HW errors	No light
Position occupied (Slide on the rack in pending execution state or in process) and machine with series started	Fixed red
Slide/position with Error (Check error or interrupted)	Flashing red
If there are still some slides to be placed in the rack	Flashing green
Slide finished	Flashing green
Position occupied (carrier in the rack in a pending execution state) and machine stopped by the user, due to errors or disconnection.	Fixed green

9.2 Front LED

The instrument has illumination on the chassis to indicate its status in different situations.

INSTRUMENT	LEDS
Disconnected	No light
Ready	Green
In process	Fixed red
Set	Fixed red
Waiting for the pause	Flashing orange
Paused	Fixed orange
Completed	Flashing green
Check error	Flashing red
HW or disconnection error	Flashing red
Stopped	Flashing red

10 LANGUAGE COMBINATIONS FOR THE SYSTEM

These are the combinations between the operating system language, barcode reader, keyboard, and application that have been either accepted or rejected due to potential conflicts.

Accepted.

Not Accepted.

11 Warnings And Precautions

- Verify at the end of each cycle that all tissues are stained correctly by checking that the internal or external positive controls included in each slide are correct.
- Ensure that none of the vials are empty at the end of a cycle; at least the dead volume must remain within the vials.
- Do not interchange reagent vials between different instruments.
- Store vials are not to be used in a cycle with the cap closed at the temperature indicated by the manufacturer on the label. Do not use the instrument to store unused reagents.
- Ensure that reagent vials are stored closed and in an upright position with minimal risk of tipping.
- It is not recommended to run the cycles on weekends.

12 Change Log

Date	Description
V.1	– Creation of new document
V.1	– Expansion of the section “Intended use”
V.1	– Redefinition of the intended use – Addition of the section “Principle of the method”
V.1	– Slides are included in section 4.1 “General specifications” – Included in section 4.2 “Technical specifications”: label of the equipment, symbols, electrical requirements, and operating conditions.
V.1	– Section 1. “Revision history” is deleted – Relevant information on waste production, management and handling is included in section 3.1 “General specifications” – New version of the instrument label, symbols and storage conditions included in section 3.2 “Technical specifications” – Addition of section 4.17.7 “Users accessibility: permissions and roles” – Information on maintenance and periodicity is included in section 6. “Maintenance and configuration of sensors and devices” – Addition of section 9. “Warnings and Precautions” and section 10. “Change Log”

V.1	– The setting to allow working with the hood open has been removed – A reports section has been added. – A continuous charging section has been added.
V.2	– Section 4.4.2 Preconfigured Label Selection has been added. – Section 4.10 Emptying waste containers have been updated to include error identification for disconnected waste carboys. – Section 4.11.3.1 Automatic Volume Detection in Reagent Vials (LLD) has been added. – Information is added to section 4.15.1 Register reagent vials. – Information added to section 4.15.2 Edit vials. – Subsection 5.1.2.3.1 Rack Removal/Placement, which stated that the series would stop upon rack removal detection, has been removed. – It has been added that an audible alert is triggered when a pause is initiated. – Section 6.1.2.5 Clog Detection Sensor in the waste outlet circuits has been added. – Section 6.1.2 Devices and Sensors have been updated to replace the term “ignore” with “disable,” and the images representing ignored elements have been updated accordingly. – Section 6.1.1.5 Emptying the Waste deposit circuit has been added. – Section 6.1.3 Manual preventive maintenance – Section 7 Support File Generation has been added. – Section 10 Language combinations accepted for the system is added. – New images added for Section 4.5 Physically load slides into the instrument and for Section 4.20 Reports.
V.3	– The distributor label symbol has been added to Section 3.2 Technical Specifications. – Operating altitude has been added to Section 3.2 Technical Specifications. – Permission/Role table has been updated in Section 4.19.7 User accessibility: permissions and roles
V.4	– Section 4.4 has been updated to add the new field for slides: "Free text label," and to update the screenshots with this field. – Section 4.4.2 for label selection has been updated, as some of the fields for pre-configured models are now configurable. – Section 4.11.4.6 has been added, as a new behavior has been added during the execution of homogenization runs prior to the first dispensing of highly viscous reagents (especially FISH reagents). – The screenshots in section 4.11.10 have been updated to display the "Detectable by LLD" and "Stirring Required" fields in the vial information card. – The screenshots in section 4.16 have been updated to display the windows with the "Detectable by LLD" and "Stirring Required" fields.