Advancing Cancer Diagnostics
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HistoCore PELORIS 3 Quick Tips

45.7538.500 Rev A04

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Contact Details

For sales, service and support, please contact your local Leica Biosystems representative. Contact details for all regions can be found on our website:

LeicaBiosystems.com

For more detailed information please refer to the HistoCore PELORIS 3 User Manual located under the Leica Bioysystems symbol on the function bar.

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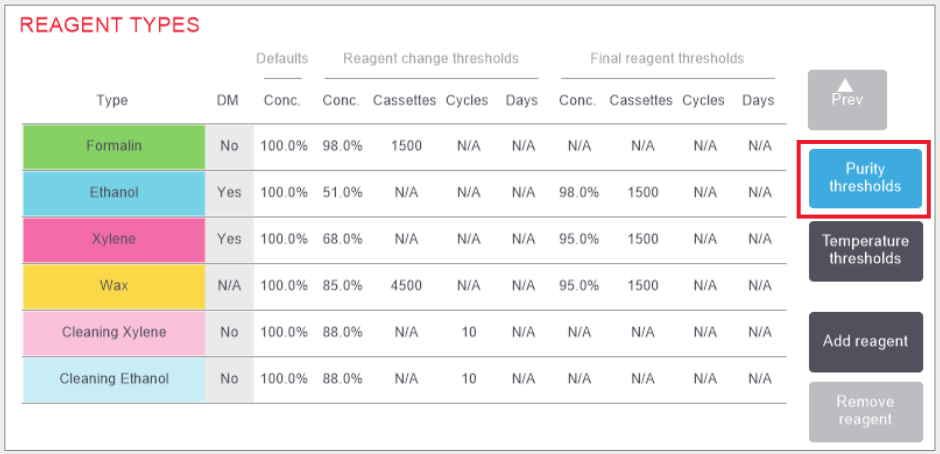
Xylene Mode – Recommended Setup

We recommend the setup shown in the images below. Setup must be validated by the laboratory prior to use, according to local or regional accreditation requirements.

Concentration Defaults and Change Thresholds

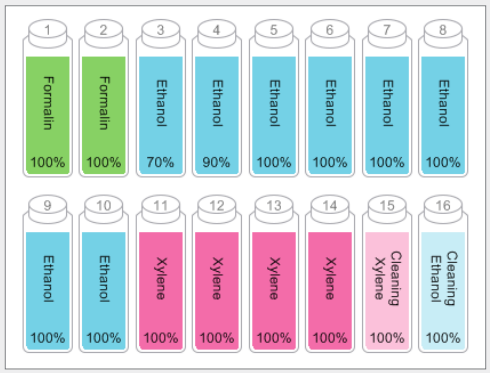


Admin > Reagent Types > Purity Thresholds

Temperature Thresholds

Admin > Reagent Types > Temperature Thresholds

Recommended Bottle Setup

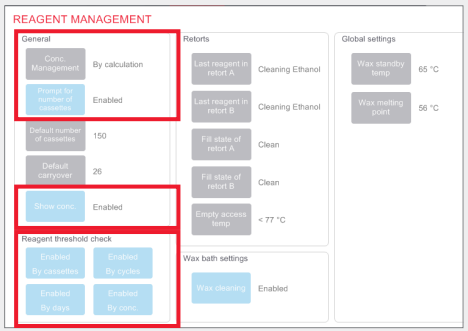


Configure the bottles as shown.

Note: Put 70% and 90% Ethanol in bottles 3 and 4 for **initial setup** or if replacing all Ethanol reagent bottles.

When replacing Ethanol as part of ongoing operation, always replace with 100% Ethanol.

Reagent Management Method



Confirm reagent management is correctly configured, on the **Reagent management screen.**

General:

- Conc. Management – By calculation
- Prompt for number of cassettes – Enabled
- Show conc. – Enabled

Reagent threshold check

All four check methods – by cassettes, cycles, days and concentration – Enabled.

Contact your local technical support to change any of the settings.

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Recommended Xylene Protocols

1 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	18	45	Ambient	Med	10
Xylene	1	Ambient	Ambient	Med	10
Xylene	1	Ambient	Ambient	Med	10
Xylene	14	45	Ambient	Med	10
Wax	2	65	Vacuum	Med	10
Wax	1	65	Vacuum	Med	10
Wax	14	65	Vacuum	Med	10

2 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	11	45	Ambient	Med	10
Ethanol	30	45	Ambient	Med	10
Xylene	1	Ambient	Ambient	Med	10
Xylene	1	Ambient	Ambient	Med	10
Xylene	28	45	Ambient	Med	10
Wax	5	65	Vacuum	Med	10
Wax	5	65	Vacuum	Med	10
Wax	20	65	Vacuum	Med	10

4 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	10	45	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	1	Ambient	Ambient	Med	10
Ethanol	20	45	Ambient	Med	10
Ethanol	20	45	Ambient	Med	10
Ethanol	45	45	Ambient	Med	10
Xylene	1	Ambient	Ambient	Med	10
Xylene	10	45	Ambient	Med	10
Xylene	45	45	Ambient	Med	10
Wax	10	65	Vacuum	Med	10
Wax	10	65	Vacuum	Med	10
Wax	40	65	Vacuum	Med	10

6 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	15	45	Ambient	Med	10
Ethanol	15	45	Ambient	Med	10
Ethanol	15	45	Ambient	Med	10
Ethanol	15	45	Ambient	Med	10
Ethanol	15	45	Ambient	Med	10
Ethanol	30	45	Ambient	Med	10
Ethanol	45	45	Ambient	Med	10
Xylene	20	45	Ambient	Med	10
Xylene	20	45	Ambient	Med	10
Xylene	45	45	Ambient	Med	10
Wax	30	65	Vacuum	Med	10
Wax	30	65	Vacuum	Med	10
Wax	45	65	Vacuum	Med	10

8 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	20	45	Ambient	Med	10
Ethanol	20	45	Ambient	Med	10
Ethanol	20	45	Ambient	Med	10
Ethanol	20	45	Ambient	Med	10
Ethanol	20	45	Ambient	Med	10
Ethanol	40	45	Ambient	Med	10
Ethanol	60	45	Ambient	Med	10
Xylene	30	45	Ambient	Med	10
Xylene	30	45	Ambient	Med	10
Xylene	60	45	Ambient	Med	10
Wax	40	65	Vacuum	Med	10
Wax	40	65	Vacuum	Med	10
Wax	60	65	Vacuum	Med	10

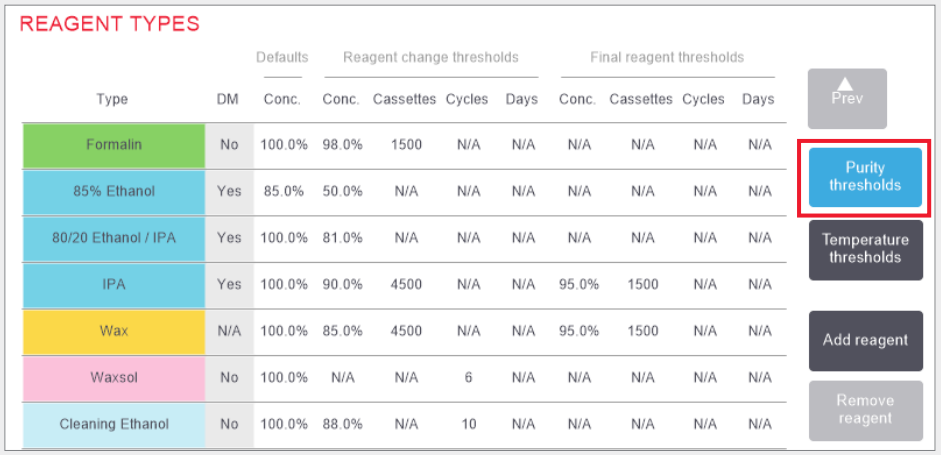
12 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	44	45	Ambient	Med	10
Ethanol	30	45	Ambient	Med	10
Ethanol	30	45	Ambient	Med	10
Ethanol	30	45	Ambient	Med	10
Ethanol	30	45	Ambient	Med	10
Ethanol	60	45	Ambient	Med	10
Ethanol	90	45	Ambient	Med	10
Xylene	45	45	Ambient	Med	10
Xylene	45	45	Ambient	Med	10
Xylene	90	45	Ambient	Med	10
Wax	60	65	Vacuum	Med	10
Wax	60	65	Vacuum	Med	10
Wax	80	65	Vacuum	Med	10

Xylene-Free Mode – Recommended Setup

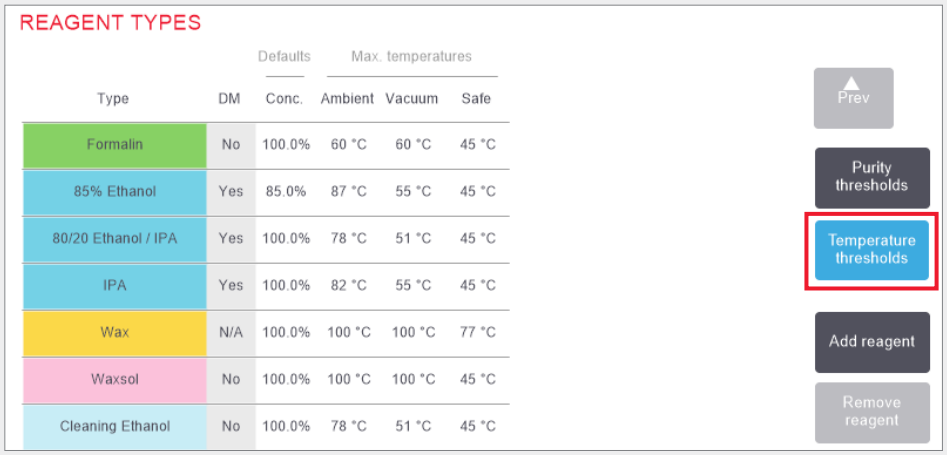
We recommend the setup shown in the images below. Setup must be validated by the laboratory prior to use, according to local or regional accreditation requirements.

Concentration Defaults and Change Thresholds



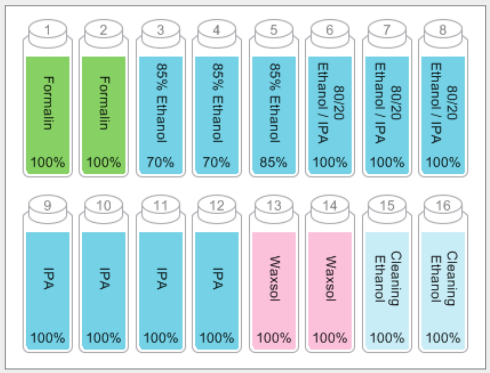
Admin > Reagent Types > Purity Thresholds

Temperature Thresholds



Admin > Reagent Types > Temperature Thresholds

Recommended Bottle Setup

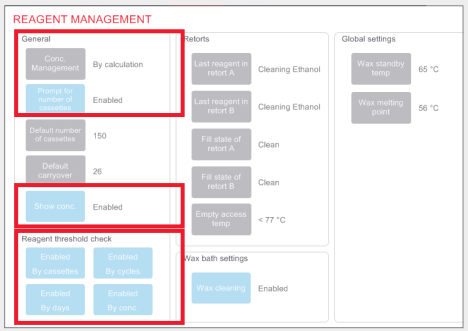


Configure the bottles as shown.

Note: Put 70% Ethanol in bottles 3 and 4 for **initial setup** or if replacing all 85% Ethanol reagent bottles.

When replacing the 85% Ethanol as part of ongoing operation, always replace with 85% Ethanol.

Reagent Management Method



Confirm reagent management is correctly configured, on the **Reagent management screen.**

General:

- Conc. Management – By calculation
- Prompt for number of cassettes – Enabled
- Show conc. – Enabled

Reagent threshold check

All four check methods – by cassettes, cycles, days and concentration – Enabled.

Contact your local technical support to change any of the settings.

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Recommended Xylene-Free Protocols

1 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	1	Ambient	Ambient	Med	10
85% Ethanol	1	Ambient	Ambient	Med	10
85% Ethanol	6	55	Ambient	Med	10
80/20	1	Ambient	Ambient	Med	10
80/20	6	55	Ambient	Med	10
IPA	1	Ambient	Ambient	Med	10
IPA	1	Ambient	Ambient	Med	10
IPA	12	55	Ambient	Med	10
Wax	20	85	Vacuum	Med	10
Wax	5	85	Vacuum	Med	10
Wax	1	65	Vacuum	Med	10

2 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	1	Ambient	Ambient	Med	10
85% Ethanol	1	Ambient	Ambient	Med	10
85% Ethanol	12	55	Ambient	Med	10
80/20	1	Ambient	Ambient	Med	10
80/20	25	55	Ambient	Med	10
IPA	1	Ambient	Ambient	Med	10
IPA	1	Ambient	Ambient	Med	10
IPA	25	55	Ambient	Med	10
Wax	25	85	Vacuum	Med	10
Wax	10	85	Vacuum	Med	10
Wax	5	65	Vacuum	Med	10

4 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	10	55	Ambient	Med	10
85% Ethanol	3	Ambient	Ambient	Med	10
85% Ethanol	22	55	Ambient	Med	10
80/20	10	Ambient	Ambient	Med	10
80/20	40	55	Ambient	Med	10
IPA	3	Ambient	Ambient	Med	10
IPA	10	55	Ambient	Med	10
IPA	45	55	Ambient	Med	10
Wax	45	85	Vacuum	Med	10
Wax	20	85	Vacuum	Med	10
Wax	10	65	Vacuum	Med	10

6 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	20	55	Ambient	Med	10
85% Ethanol	15	55	Ambient	Med	10
85% Ethanol	20	55	Ambient	Med	10
80/20	20	55	Ambient	Med	10
80/20	45	55	Ambient	Med	10
IPA	15	55	Ambient	Med	10
IPA	30	55	Ambient	Med	10
IPA	60	55	Ambient	Med	10
Wax	45	85	Vacuum	Med	10
Wax	40	85	Vacuum	Med	10
Wax	30	65	Vacuum	Med	10

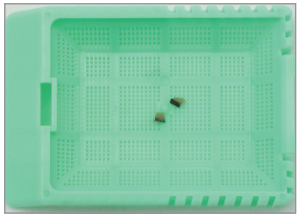
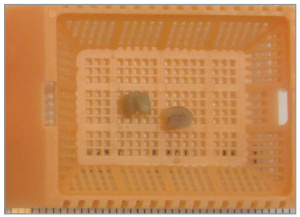
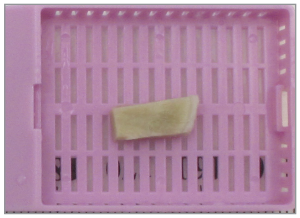
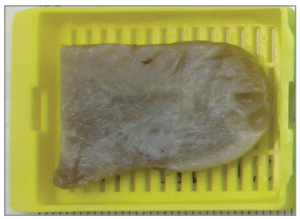
8 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	30	55	Ambient	Med	10
85% Ethanol	20	55	Ambient	Med	10
85% Ethanol	30	55	Ambient	Med	10
80/20	30	55	Ambient	Med	10
80/20	60	55	Ambient	Med	10
IPA	20	55	Ambient	Med	10
IPA	40	55	Ambient	Med	10
IPA	80	55	Ambient	Med	10
Wax	60	85	Vacuum	Med	10
Wax	50	85	Vacuum	Med	10
Wax	40	65	Vacuum	Med	10

12 hour

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	68	55	Ambient	Med	10
85% Ethanol	30	55	Ambient	Med	10
85% Ethanol	40	55	Ambient	Med	10
80/20	50	55	Ambient	Med	10
80/20	90	55	Ambient	Med	10
IPA	30	55	Ambient	Med	10
IPA	60	55	Ambient	Med	10
IPA	120	55	Ambient	Med	10
Wax	80	85	Vacuum	Med	10
Wax	70	85	Vacuum	Med	10
Wax	60	65	Vacuum	Med	10

Tissue Size Recommendations – Xylene and Xylene-Free

Protocol	Example	Maximum Thickness	Specimen Type (Example)
1hr		1.5 mm diameter	Endoscopies and needle biopsies of breast and prostate.
2hr		<3 mm diameter	All biopsies up to 3 mm diameter: GI biopsies, renal, prostatic, hepatic and breast cores, punch biopsies of skin, small colonic polyps.
4hr		3 mm diameter	Small specimens of non-dense tissues (kidney, liver, bowel etc), excisional and incisional skin biopsies, skin ellipses.
6 – 8hr		15 x 10 x 4 mm	All routine tissues up to maximum dimensions (excluding brain specimens).
12hr		20 x 10 x 5 mm	All routine tissues up to maximum dimensions. Very thick fatty specimens may require a longer protocol.

*Images not to scale.

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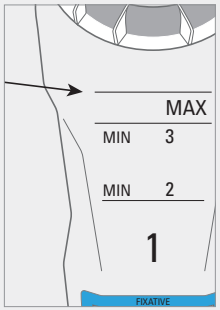
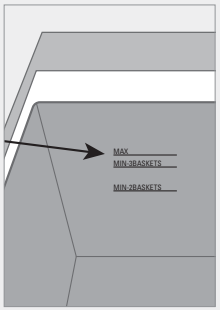
Running a Protocol

1. Conduct Pre-Run Checks

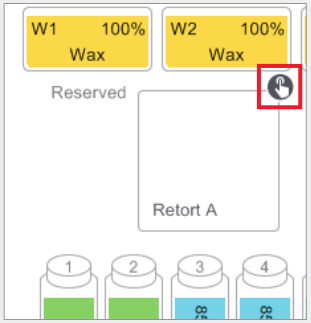




Check system status:

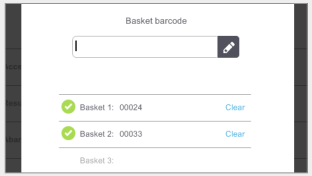
- Ensure retort is clean.
- Ensure no expired reagents.
- Check reagent and wax levels are between “MAX” and “MIN 3” (3 baskets) or “MIN 2” (2 baskets).

2. Scan Baskets (Optional Step)



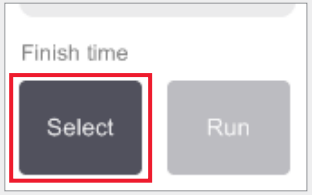
Tap on the retort scanning icon for the retort that is to be used for the protocol run. This opens the retort baskets dialog box.

Using the attached hand-held scanner, scan the barcode located on the basket tab. Alternatively, the barcode can be manually entered by tapping on the pen icon.



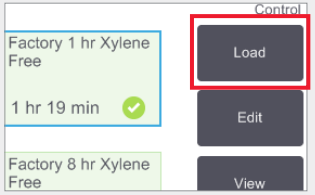
When entered, the barcode is displayed with a green tick and the cursor is ready for the next barcode in the text box. When all baskets entered, tap **OK**.

3. Load the Protocol



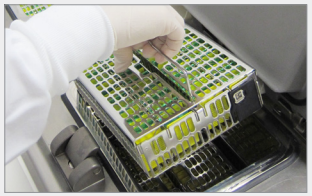
Tap **Select** on the Status screen.

Tap the required validated protocol.

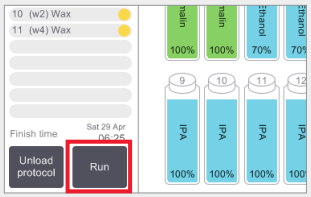


Tap **Load**.

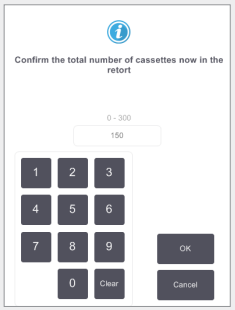
4. Start the Run



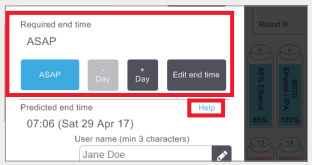
Place the baskets (1, 2 or 3) into the retort.



Tap **Run**.



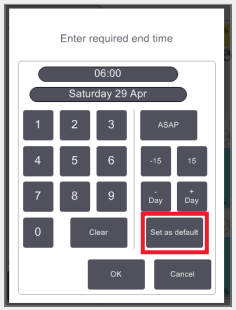
Enter the number of cassettes.



Set the end time:

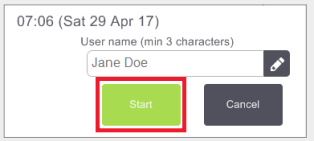
ASAP – for immediate start.

Set end time – for delayed start.



If required, accept the default time set for that protocol.

The **Help** link provides information on scheduling runs.



Scan or enter user name to enable Start button.

Tap **Start**.

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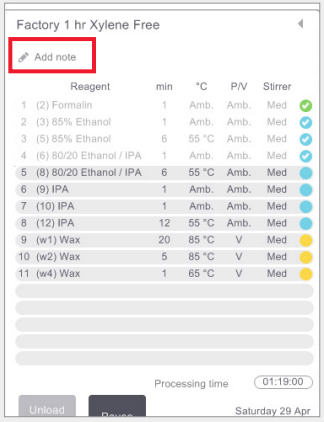
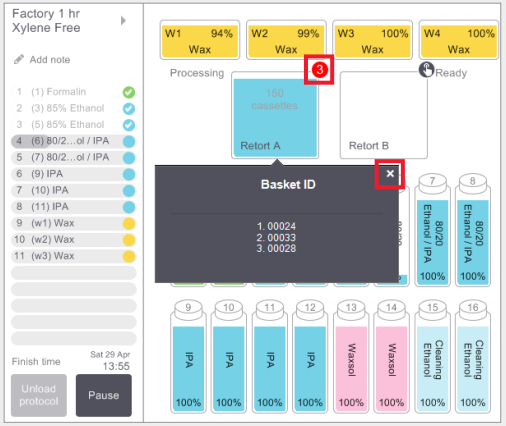
Running a Protocol

5. Monitor the Progress



From the **Status screen**, view the progress of each step (expanded view shown).

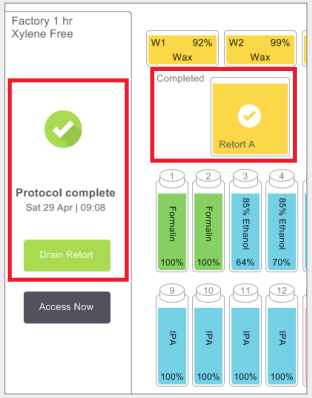
Protocol notes for a single run can be added prior to starting, or at any time during the protocol, by tapping **Add note**. This will display a keyboard.



The number of scanned baskets is displayed on the retort icon and, if you tap the icon, the basket ID (s) are displayed.

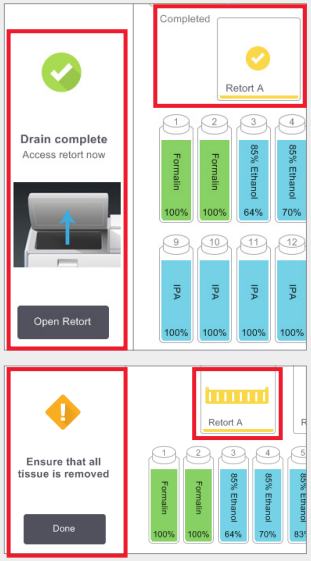
Tap the **X** to hide the basket ID box.

6. Complete the Run

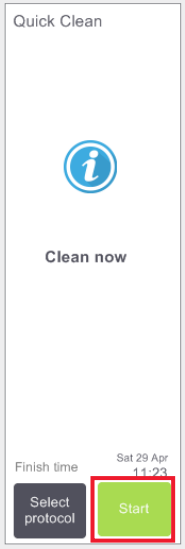


Protocol complete.

Drain the retort.



Drain complete, open the retort. When all tissue has been removed, tap **Done**.

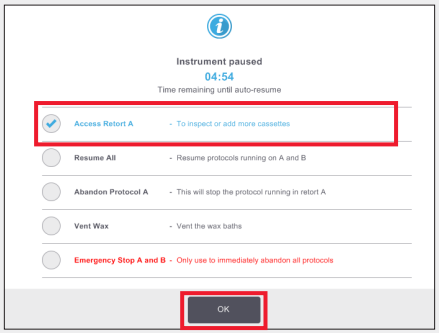


Tap **Start** to begin cleaning protocol.

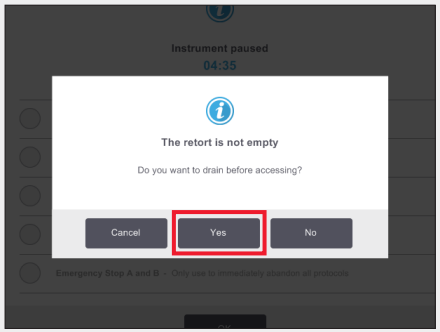
Adding Baskets and Cassettes to a Running Protocol

1. Pause the Protocol

On the **Status** screen, tap **Pause** for the retort to which you want to add the new basket or cassettes.

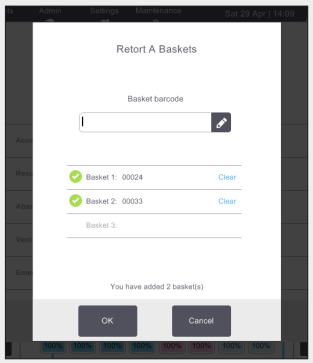


On the **Instrument paused** dialog box, tap **Access Retort**. A blue tick is displayed next to the tapped option. Tap **OK**.



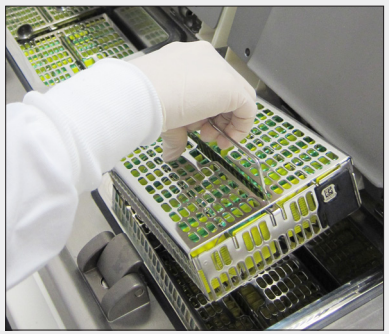
Wait for the above dialog box to appear. If you would like to drain the retort before accessing, tap **Yes**.

2. Add New Baskets/Cassettes and Restart the Protocol



Scan the basket to be added and tap **OK**.

OR To add cassettes to an existing basket, tap **Cancel**.

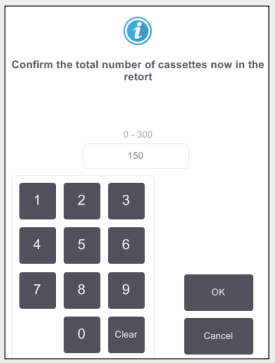


Add the scanned basket

OR Remove the cassette basket from the retort and add the new cassettes.

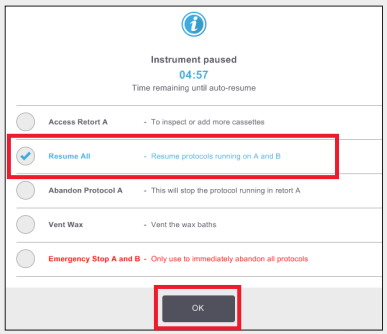
Place the basket into the retort.

Close the retort lid and tap **OK** on the **Retort accessible** dialog box.



Enter the total number of cassettes in the retort and tap **OK**.

Enter your User ID when prompted.



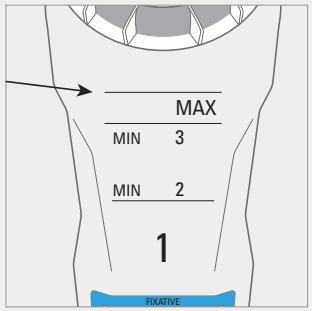
Wait for the **Instrument Paused** dialog to appear and tap **Resume All**.

Tap **OK** to refill and resume protocol.

Leica BIOSYSTEMS

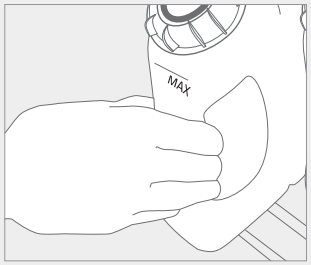
PELORIS 3 Reagent Top off/Top up

1. Check the Bottle Contents and Remove if Necessary

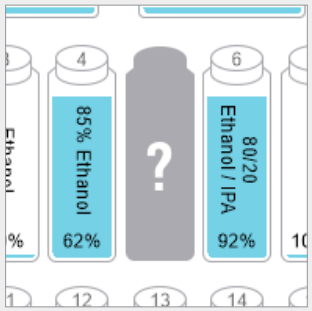


Top off/up the bottle when the reagent is below the minimum level.

This is MIN 2 for a two-basket setup or MIN 3 for a three-basket setup.

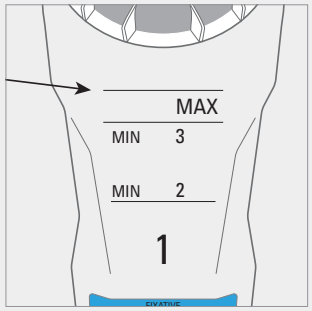


Important! Ensure no protocol is running then remove the bottle from the instrument.

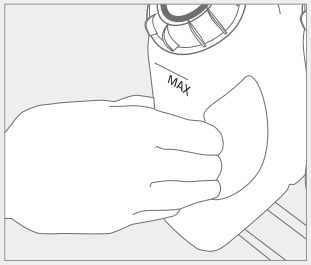


The software will indicate that the bottle is missing.

2. Fill the Bottle with the SAME Contents as on the Bottle Label

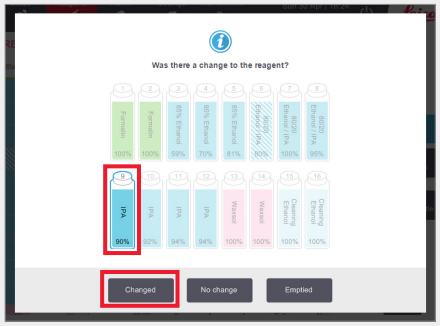


Fill the bottle to the maximum level and tighten the cap by hand.



Return the bottle to the cabinet – push firmly into the rear connectors.

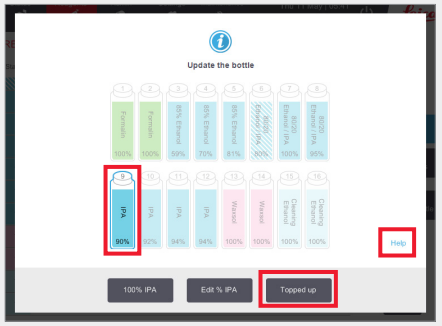
3. Update the Bottle Details



Select the bottle to update.

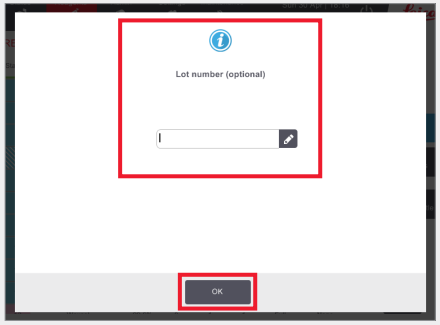
This enables the action options.

Tap **Changed**.



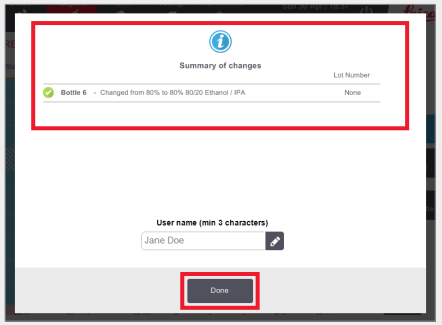
Tap **Topped Up**.

The **Help** link provides information on bottle changes.



Lot number entry is optional.

Tap **OK** to continue.

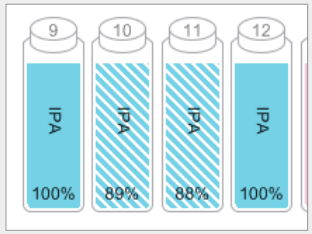


The summary of changes dialog is displayed. Enter your user ID and tap **Done** to complete.

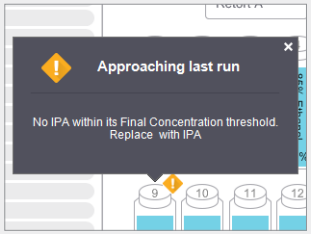
Leica BIOSYSTEMS

PELORIS 3 Reagent Replacement – Manual

1. When to Replace Reagent



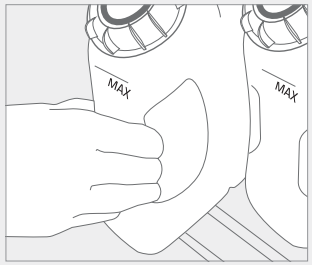
Replace reagent when bottles appear hatched on the **Status** screen.



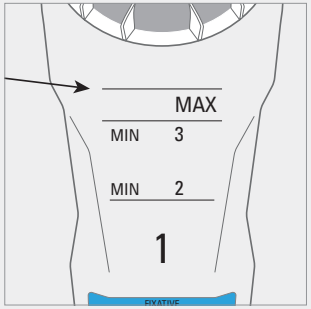
OR When warned at protocol start (final threshold exceeded).

Ensure no protocols are loaded or running.

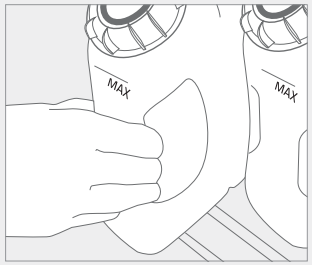
2. Empty and Replace the Reagent



Remove the bottle and safely dispose of the used reagent.

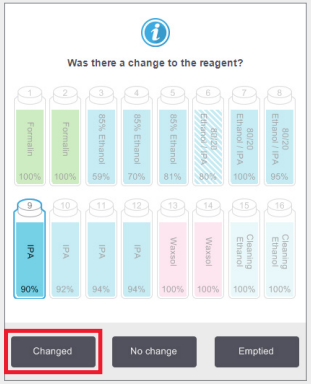


Fill the bottle to the maximum level and tighten the cap by hand.

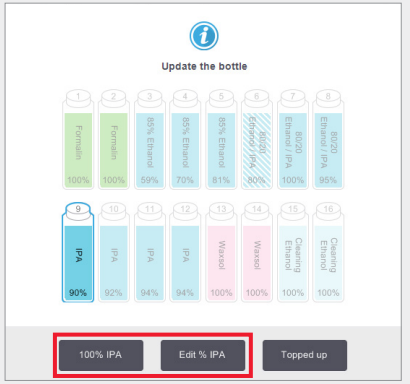


Return the bottle to the cabinet – push firmly into the rear connectors.

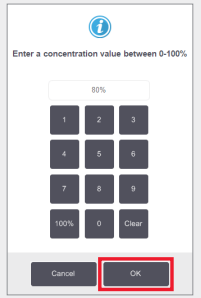
3. Update the Bottle Details

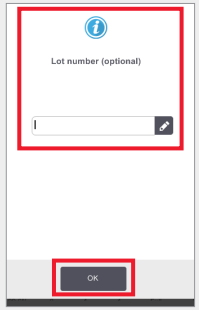


Select the bottle you replaced by tapping it on the screen. Tap **Changed**.



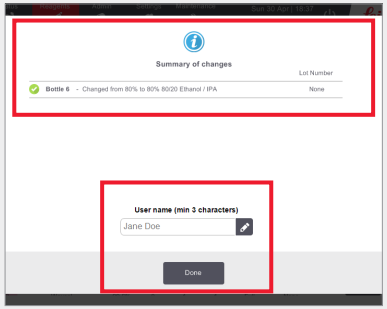
For the example shown, use the **100% IPA** option unless you need to change the concentration, in which case use **Edit % IPA** using the keypad. Tap **OK** when you are done.





Lot number entry is optional.

Tap **OK** to continue.



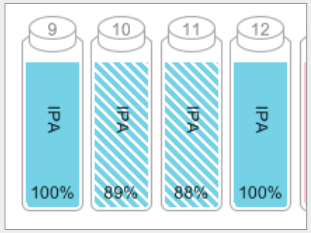
The summary of changes dialog is displayed. Enter your user ID and tap **Done** to complete.

Note: You can find information on bottle changes in the help link on the "Update the bottle" dialog box.

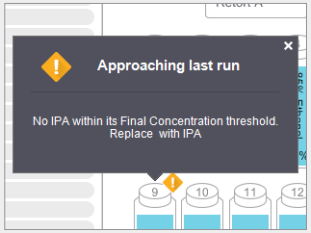
If you receive warnings that an out-of-threshold reagent has been selected for a protocol, do not proceed with the protocol run. Out-of-threshold reagents will result in poor-quality processing.

PELORIS 3 Reagent Replacement – Remote Fill and Drain

1. When to Replace

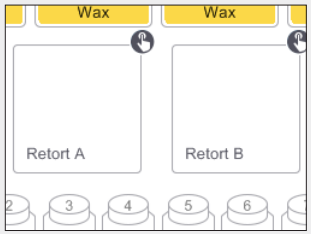


Replace reagent when bottles appear hatched on the **Status** screen.



OR When warned at protocol start (final threshold exceeded).

2. Drain Preparation

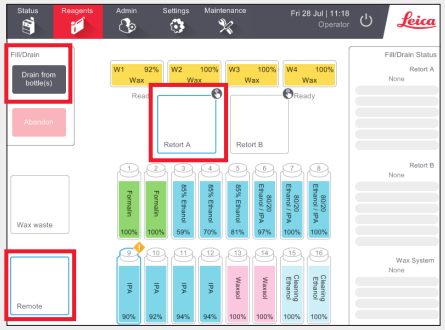


Ensure a clean retort is available.

Connect the remote fill/drain hose.

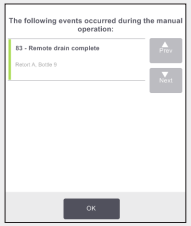
Insert the hose into a stable container with sufficient capacity to avoid overflow.

3. Drain



Go to Reagents > Remote Fill/Drain.

Tap **Remote**, a retort and the bottles to drain, then tap **Drain from bottle(s)**. Enter your user ID to continue.



An Action Queue item is displayed when the drain is complete.

Tap **OK**.

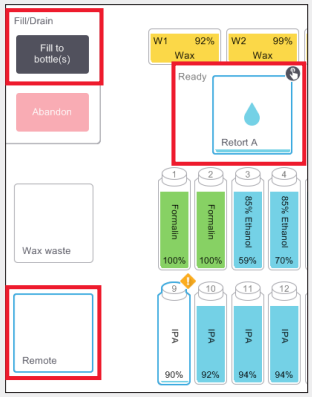
4. Fill Preparation

Connect the remote fill/drain hose.

Insert into reagent container.

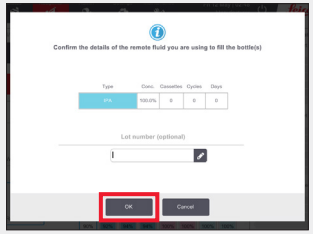
Ensure empty bottles are securely in position and the caps are not loose.

5. Fill



Go to Reagents> Remote Fill/Drain.

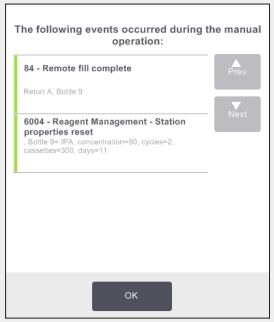
Tap **Remote**, a retort and the bottles to fill, and then tap **Fill to bottle(s)** and follow the instructions.



Confirm or change new reagent details when prompted.

Optional: Enter lot number when prompted.

Enter your User ID when prompted.



An Action Queue item is displayed when the fill is complete.

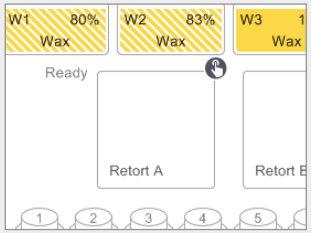
Tap **OK**.

Clean the retort if the residue is incompatible with the next run.

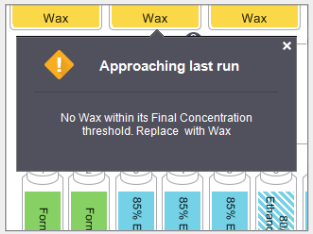
Leica BIOSYSTEMS

PELORIS 3 – Wax Replacement

1. When to Replace

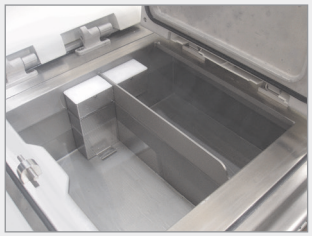


Replace wax when chambers appear hatched on the **Status** screen.



OR When warned at the start of the protocol.

2. Preparation

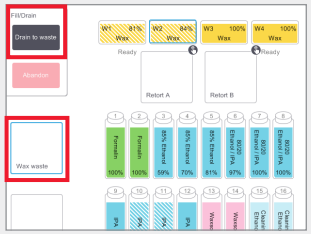


Ensure wax is molten then close the lid.

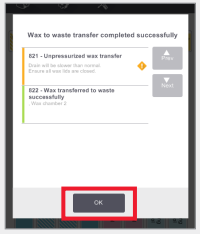
Connect wax waste line.

Insert hose into a stable container with sufficient capacity to avoid overflow.

3. Drain

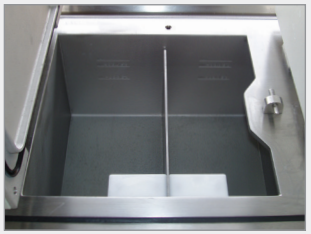


Go to Reagents > Remote Fill/Drain. Tap **Wax waste** and the wax chambers to drain, then tap **Drain To Waste**.

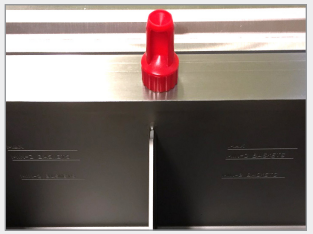


An action queue item is displayed when the drain to waste is complete. Tap **OK**.

4. Add New Wax*



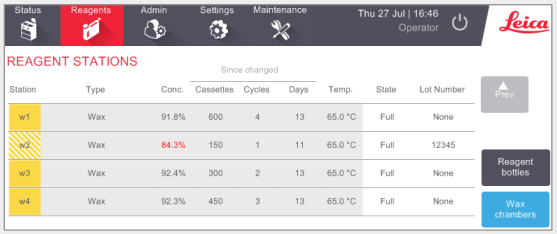
Clean the wax bath using a lint-free cloth.



Either Use Paraplast (molten or pellets). Use the LLS tool wax plug to ensure wax does not go down the wax vent.

OR Add wax directly to the bath. Use Parablocks for easy handling and rapid melt.

5. Update Station State



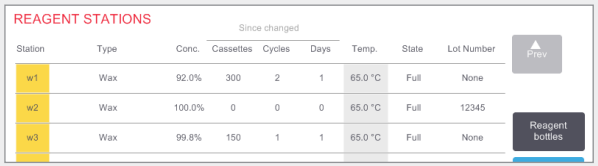
Go to Reagents > Stations > Wax Chambers.

Tap the wax chamber state.

Set the chamber state to **Full** (molten wax) or **Not molten** (Parablocks or pellets).

Optional: enter lot number.

Tap **OK**. Enter your user ID when prompted.



Wax concentration and cycle, cassette and day counts are automatically updated. The lot number is displayed here if entered.

***Warning:** The use of products containing DMSO may compromise processing quality on PELORIS 3.

PELORIS 3 Maintenance Tracking

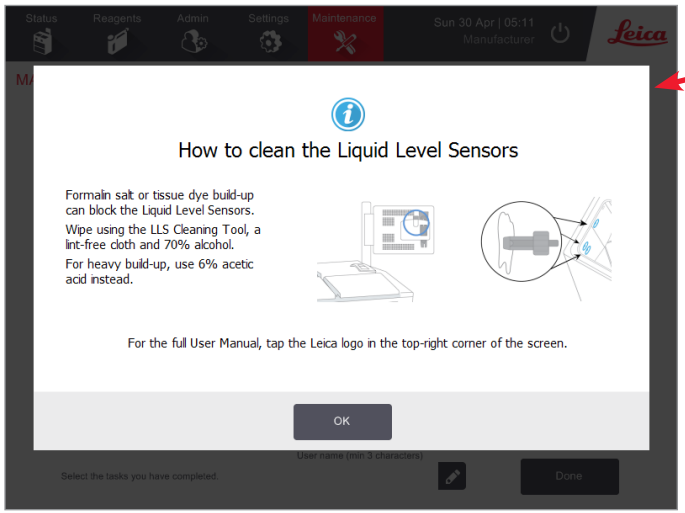
The **Maintenance** screen provides a way to record the activity and timing of routine maintenance functions.

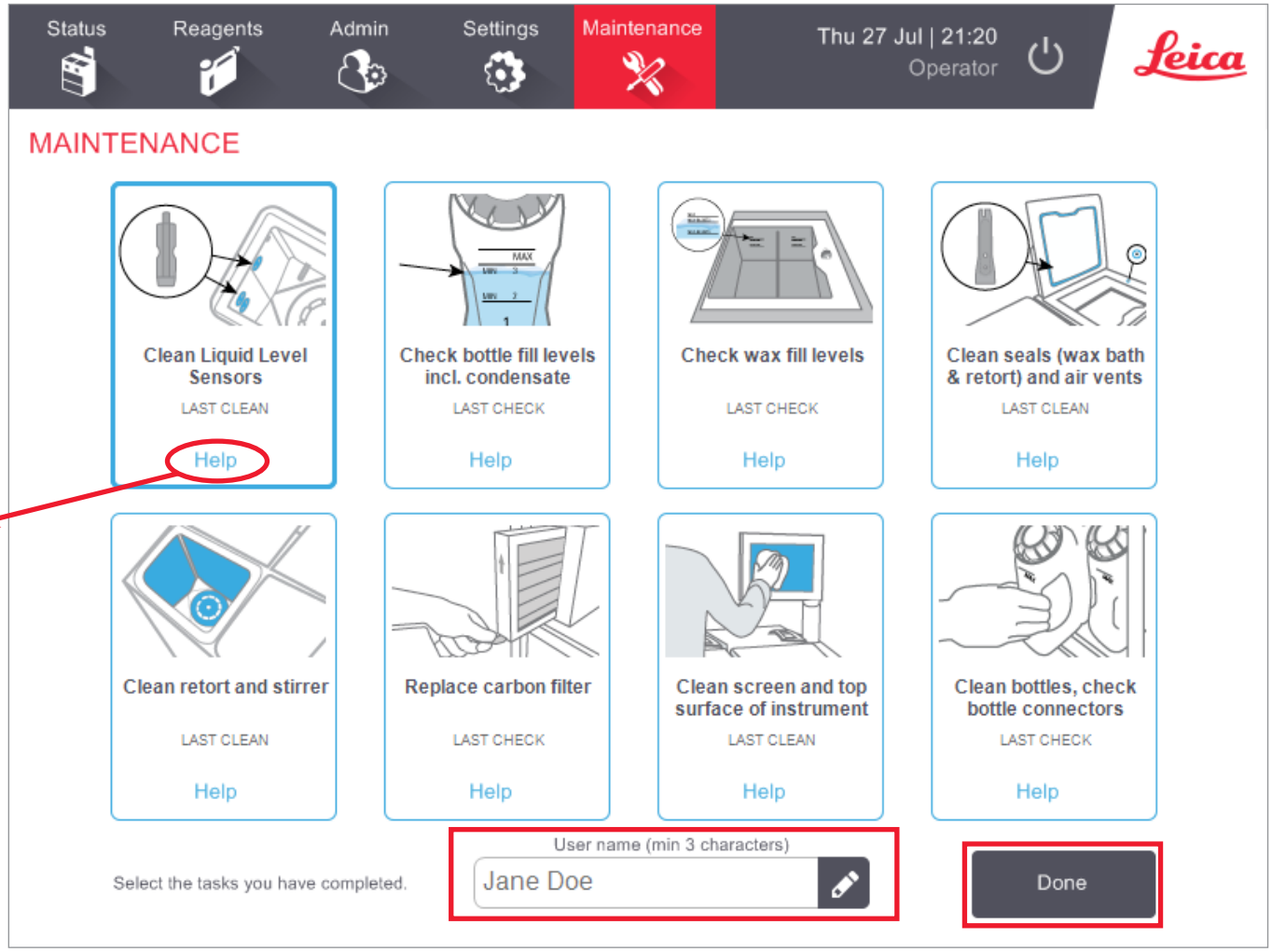
Routine maintenance tasks are displayed in the Maintenance screen.

The Help link provides instruction on the task (LLS example below).

Tap to select the task(s) you have completed, enter or scan your User ID and tap **Done**.

This will save the date and User ID against the task(s).





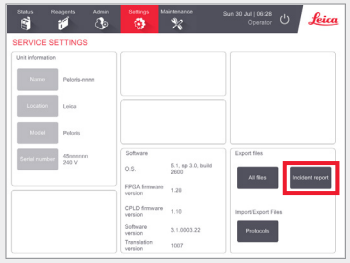
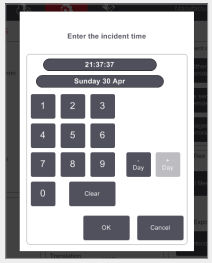
Refer to the User Manual for lists of recommended daily, weekly and monthly tasks.

Leica BIOSYSTEMS

PELORIS 3 Transferring Incident Reports or Log Files

1. Select Incident Reports or Log Files

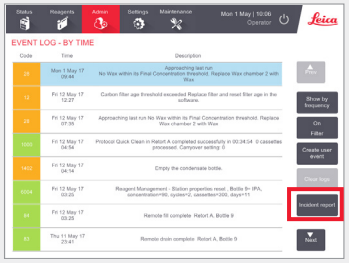
Choose the file type required:

Incident Reports: Go to Settings > Service > Export Files pane.

Tap **Incident Report**.

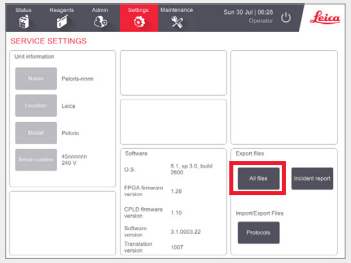
When prompted, enter the time and date of the incident. Tap **OK**.



OR Go to Admin > Event Log.

Tap a specific incident to select it.

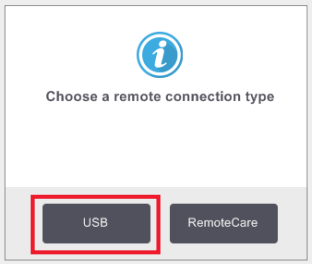
Tap **Incident Report**.



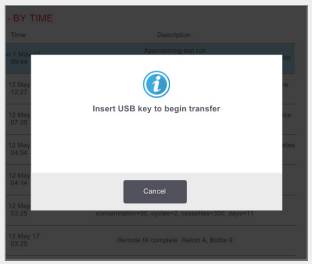
Full Logs: Go to Settings > Service > Export Files pane.

Tap **All Files**.

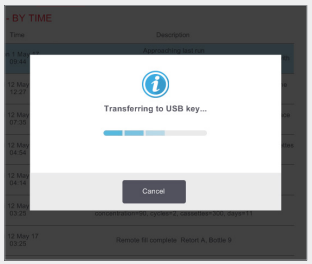
2. Transfer Files and Email to Leica Biosystems



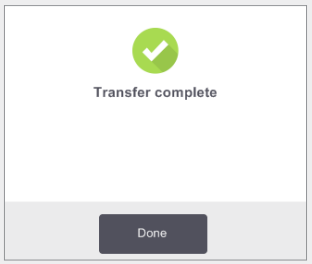
Choose a remote connection type, for example USB.



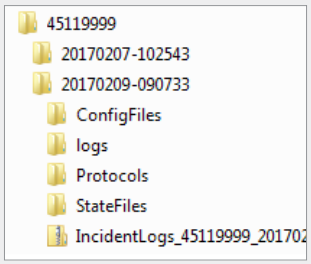
When prompted, insert your USB drive into the front port.

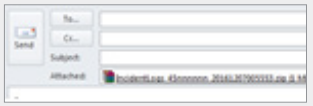


A dialog box is displayed showing the progress of the transfer.



When the transfer is complete, remove the USB drive.





Insert the USB drive into your computer.

Locate the file at X:\{transfer date and time}
(X is the location of the USB drive).

Email the incident report zip file to your local support center.

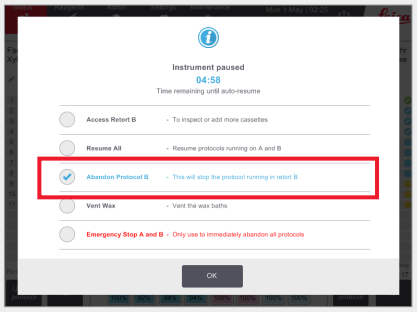
When to transfer log files:

Only transfer log files if requested by a Leica Biosystems representative. Use the method advised.

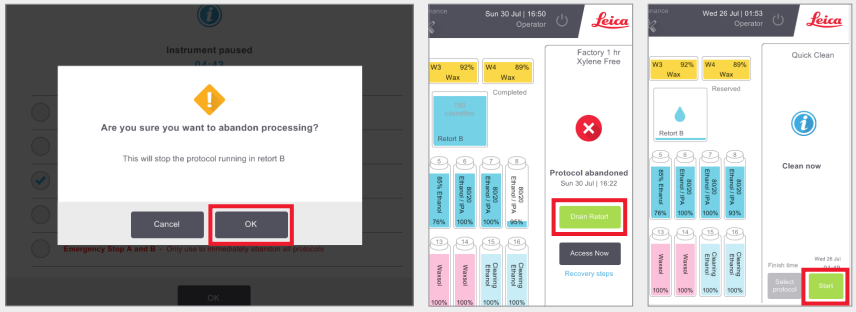
PELORIS 3 Abandoning Protocols

Abandoning a Single Protocol

On the **Status** screen, tap **Pause** on the protocol you wish to abandon.



On the **Instrument paused** dialog box, tap the **Abandon Protocol** option. This now has a tick and is highlighted in blue. Tap **OK**.



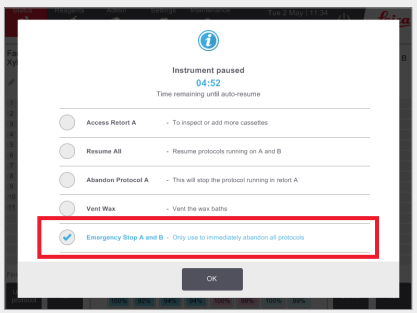
To confirm, tap **OK**.

Follow the prompts to drain the retort and remove the cassettes.

When completed, close the retort and start the quick clean.

Abandoning Both Protocols using Emergency Stop from the Instrument Paused Dialog

On the **Status** screen, tap **Pause** on the protocol you wish to abandon.



On the **Instrument paused** dialog box, tap the **Emergency Stop** option. This now has a tick and is highlighted in blue. Tap **OK**.

Follow the prompts to drain the retorts and remove the cassettes.

When completed, close the retorts and start the quick clean.

Leica BIOSYSTEMS

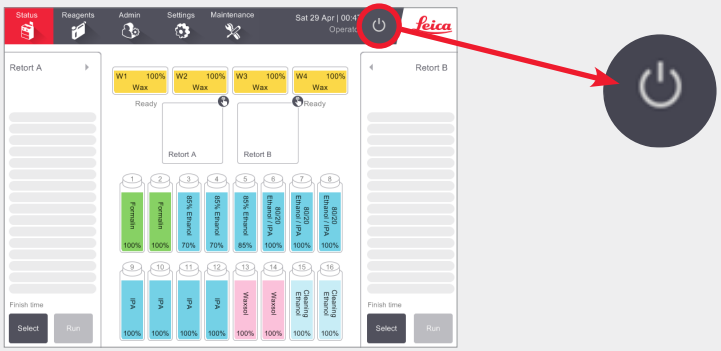
PELORIS 3 Shutdown

Normal Shutdown

When to shut down:

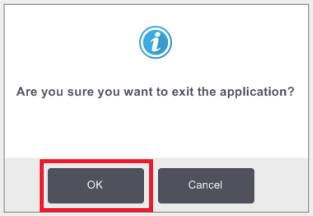
- Instrument is being moved or shipped.
- Before servicing.
- To avoid a potentially hazardous incident.

At all other times keep the instrument on, even if idle for extended periods.



Ensure the instrument is idle, with no protocols or other operations in progress.

Tap the **shutdown button** on the function bar as shown above.



Tap **OK** to confirm.

The software will now safely shut down.

Wait for the screen to go blank, then tap the **power button** at the front of the instrument.

Emergency Shutdown

In an emergency, tap the power button at the front of the instrument.

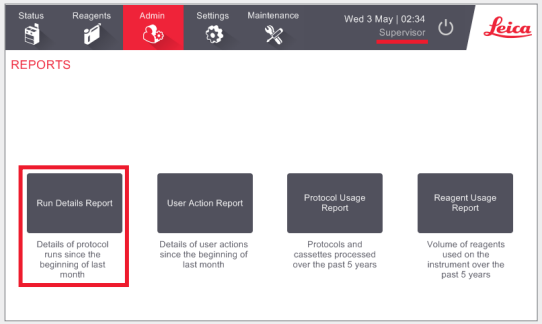
If conditions permit, also switch the power off at the mains socket and pull out the power cord.

Only use the emergency stop procedure when there is an immediate danger or risk to safety.

This procedure can damage the instrument and tissue being processed.

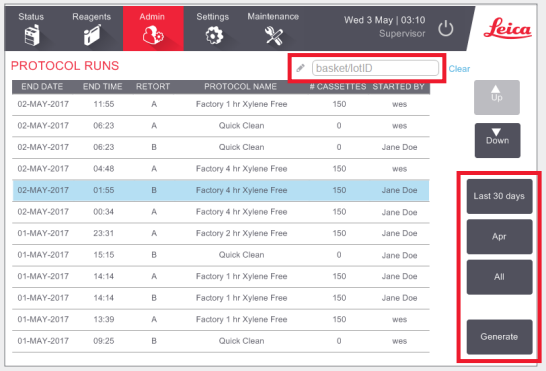
PELORIS 3 Reports

Run Details Report

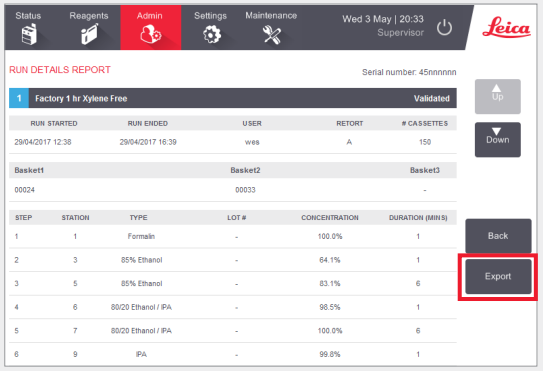


Navigate to Admin > Reports and tap **Run Details Report**.

User IDs are visible in Supervisor mode.



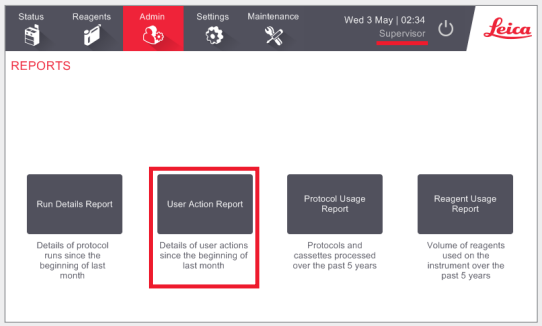
All protocols run since the beginning of the last month are available to view. You can filter runs by basket ID and reagent/ wax lot number. You can also choose to display All protocols run or those run in the last month or the last 30 days. Highlight the protocol reports you wish to view and tap **Generate**.



The **Run Details Report** contains all the information pertinent to that protocol run. Any events that occurred during the run are detailed at the bottom of the report under Run Events.

To export the report, insert a USB drive and tap **Export**. Exported files can be saved to your computer and viewed.

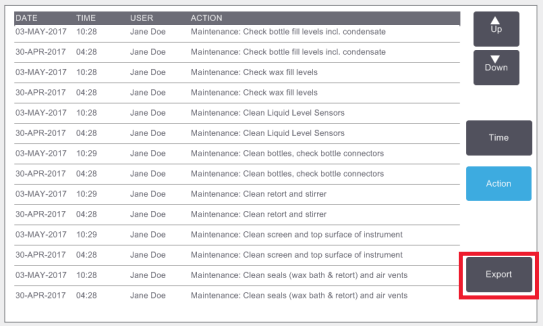
User Actions Report



Navigate to Admin > Reports and tap **User Actions Report**.

User IDs are visible in Supervisor mode.

The **User Actions Report** lists all actions performed requiring the operator's User ID since the beginning of the last month. The time, date and type of action are displayed.



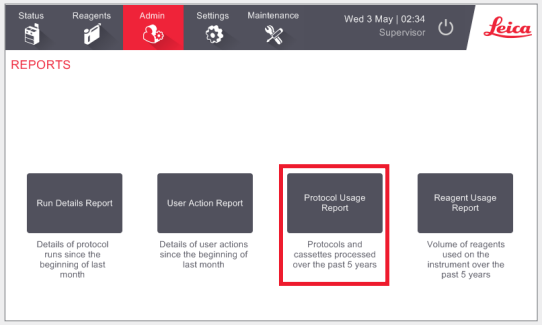
Actions can be filtered by time or the action.

To export the report, insert a USB drive and tap **Export**. Exported files can be saved to your computer and viewed.

Leica BIOSYSTEMS

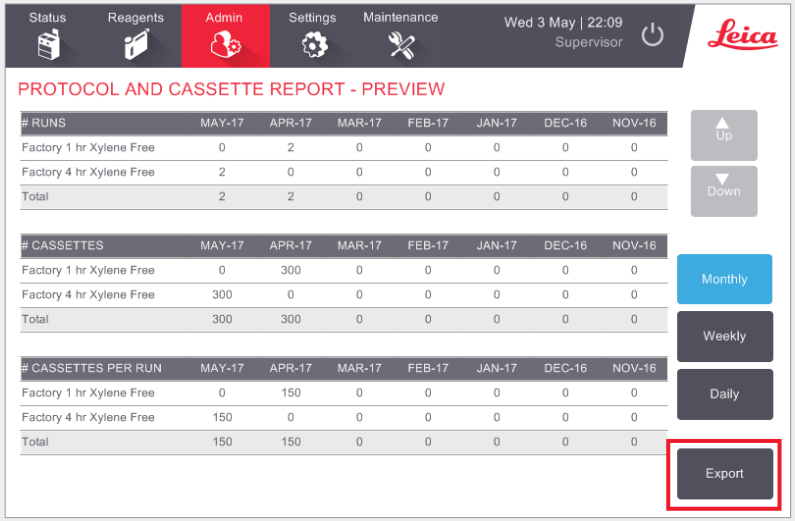
PELORIS 3 Reports

Protocol Usage Report



Navigate to Admin > Reports and tap **Protocol Usage Report**.

The Protocol and Cassette Report shows the number of protocol runs and cassettes used over the past 5 years.

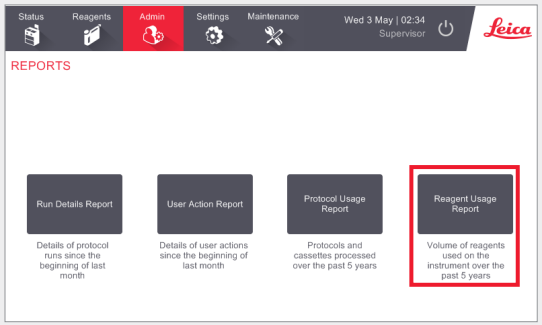


The **Protocol and Cassette Report** provides metrics on the protocol types run as well as the cassettes run per protocol.

The report can be filtered by day, week or month.

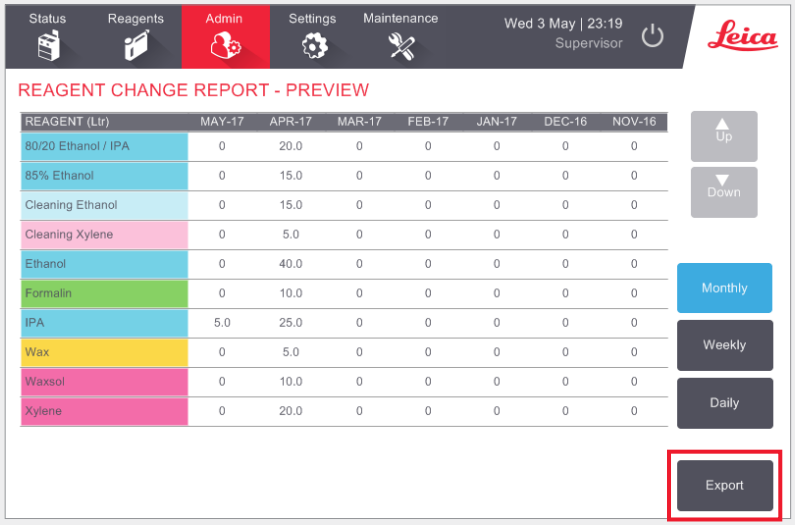
To export the report, insert a USB drive and tap **Export**. Exported files can be saved to your computer and viewed.

Reagent Usage Report



Navigate to Admin > Report and tap **Reagent Usage Report**.

The **Reagent Usage Report** shows the volume of reagents used on the instrument over the past 5 years.



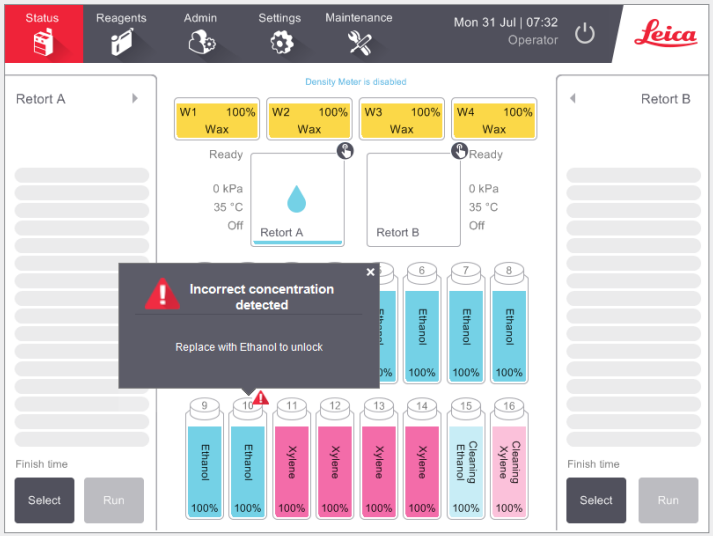
The **Reagent Usage Report** provides metrics on reagent usage.

The report can be filtered by day, week or month.

To export the report, insert a USB drive and tap **Export**. Exported files can be saved to your computer and viewed.

PELORIS 3 Troubleshooting

The Density Meter has Rejected a Reagent Bottle



The PELORIS 3 has two density meters, one for each retort. Only ethanol (including reagent-grade ethanol and IPA–ethanol mixtures), IPA and xylene reagents will be checked by the density meters. Fixatives, cleaning reagents and reagent substitutes (such as Histolene) are not checked. Checked Reagents are detailed in the HistoCore PELORIS 3 User Manual (which is located under the Leica symbol on the function bar).

The reagent concentration is checked by the density meter when it is first used in a protocol under either of the following conditions:

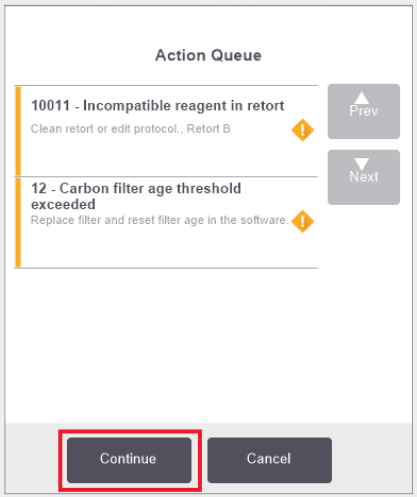
» The reagent has been replaced.

OR

» A supervisor has changed the concentration recorded for that reagent.

If the concentration measured by the density meter does not match the concentration value recorded for that bottle on the **Status** screen, the bottle is locked and the warning symbol/message is displayed for that bottle as shown. A locked bottle is skipped in any subsequent run (assuming the run can continue without the locked bottle).

The Action Queue Window



The **Action Queue** window warns you of any actions that are required or recommended before the protocol can be run. Ensure you take note of the message as it also includes steps to take for each code number.

Some of the messages are for information only. They do not prohibit the protocol from starting but should be noted or actioned when possible, for example the "12-Carbon filter age threshold exceeded" message informs the operator that the filter needs replacing. However, you can tap **Continue** and start the protocol.

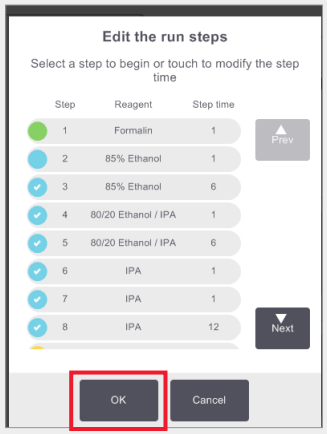
Some action queue messages require immediate operator intervention, as the software will not allow the protocol to be run. In the example shown, the "10011 – Incompatible reagent in retort" message informs the operator to either run a **Quick Clean** or edit the protocol (depending on the reagent in the retort).

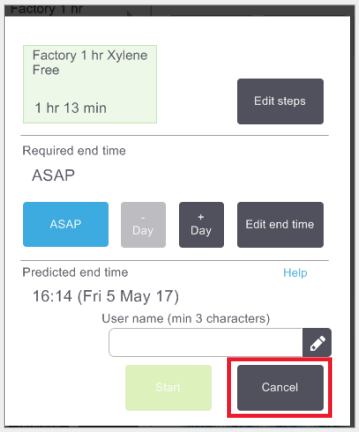
If immediate action must be taken and no operator intervention occurs, if you tap **Continue** the protocol will not start and the Action Queue will continue to be displayed.

Action Queue history is located in Admin > Event Logs.

PELORIS 3 Troubleshooting

What to do if you edit single protocol run steps in error



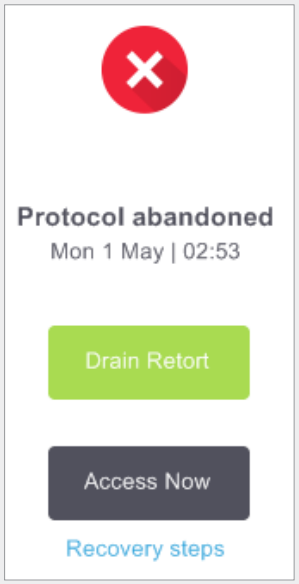


When you edit steps for a single protocol, the steps are removed from the protocol after you tap **OK**.

If you realize you have made an error, at this stage you can tap **Cancel**. The edited protocol is displayed on the **Status** screen. From here tap **Unload protocol** to remove and re-load the protocol.

If you have started the protocol and then realized you have made an error, you can abandon the protocol (please see the **Abandoning a Single Protocol** section in this document for steps) and start again.

What to do when a protocol is abandoned



Gather information

- Examine the Run Details Report (Admin > Reports > Run Details Report).
- Examine the event logs (Admin > Event Logs).

Use the information in the report and the logs to determine if the tissue should continue to be processed on the instrument.

- If the instrument is working correctly but a reagent bottle is missing or its level is low, fix the issue and then refer to the run Run Details Report to decide from which step to continue.
- If the instrument has failed, use the Run Details Report to decide on the next step. You may need to remove the tissue and continue on another instrument. Call service for assistance.

Warnings

Important Information for All Users

Persons operating the PELORIS 3 tissue processor MUST

- Follow the instructions for use exactly as described in the user manual. Any deviation from the instructions may result in sub-optimal tissue processing, potential loss of the patient sample and the consequent inability to make a diagnosis.
- Receive sufficient training to ensure that the instrument is used in accordance with the user manual.
- Be aware of any potential hazards or hazardous procedures before operating the instrument as described in the user manual.

General Warnings and Cautions

Persons operating the PELORIS 3 must be fully aware of the following warnings, in order to mitigate possible tissue damage or loss.

Reagent Configuration

WARNING

Always ensure that the reagents configured in the software are the actual reagents loaded on the instrument. A station containing different reagent could damage tissue samples.

Replacing Reagents

WARNING

Always change reagents when prompted.

Always update station details correctly – never update the details without replacing the reagent.

Failure to follow these directives can lead to tissue damage or loss.

WARNING

Do not alter the concentration of a used reagent unless you are able to verify the actual concentration. If the concentration is incorrect, a reduction in tissue processing quality or damage to the tissue sample may result.

Leica BIOSYSTEMS

Protocol Validation

WARNING

Do not set new protocols as validated until they have passed the validation procedures for your laboratory. Only then should you edit the protocol to set it as valid, making it available to operators for clinical use (see 4.1.4 Protocol Validation). Use of non-validated protocols may result in tissue damage or loss.

Basket and Cassette Loading

WARNING

Always ensure the cassettes are correctly inserted into the baskets and that the baskets are correctly placed in the retorts. Incorrectly placed cassettes or baskets may lead to samples being damaged, as some tissue may not be fully covered by reagent during processing (see 2.2.4 Cassette Baskets).

WARNING

Never place three baskets into a retort when the instrument is configured with a two-basket fill level. If this occurs, reagent will not cover the top basket and tissue samples will be damaged.

Cleaning Protocol

WARNING

Do not load unprocessed tissue samples into a retort prior to running a cleaning protocol. Formalin in the residue purged to the wax bath at the start of the cleaning run may damage tissue on subsequent runs.

If you inadvertently load unprocessed samples into a retort prior to running a cleaning protocol, remove the samples and attempt to load a processing protocol before loading the cleaning protocol. The purge before the cleaning run will be skipped.

WARNING

Remove all tissue from the retort before running a cleaning protocol, as the dry step will damage the tissue.

WARNING

Do not use cleaning protocols for reprocessing, as the dry step will damage the tissue.

Security and Malware

Access Level and Supervisor Password Rules

Use the **Access Level** screen (**Admin** > **Access Level**) to set a user's access level.

» To change the access level, tap the appropriate button: **Operator** or **Supervisor**. You have to provide a password if changing to supervisor level.

» To change the supervisor password, tap the **Change password** button beside the **Supervisor** button, enter the current password and then the new password. The new password must meet the following criteria:

- Must be at least 10 characters long.
- Must contain at least one character from at least three of the following groups:
  - Upper case letters of European languages
  - Lower case letters of European languages
  - Unicode characters (for languages that do not have upper/lower case characters)
  - Numeric values (0 – 9)
  - Non-alphanumeric characters (for example !, @, #, $, %, ^ or &)

» If the entered password does not meet the criteria above, the following message will be displayed:

Password entered does not meet complexity criteria – refer to User Manual.

» If the Supervisor password is forgotten or lost:

- You will have to provide a code which must be obtained from your technical support representative.
- Tap the **Reset Password** button.

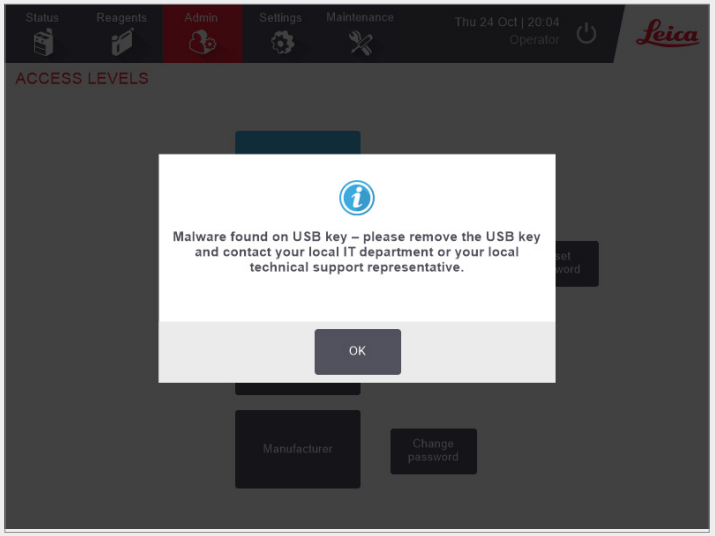
  Contact local technical support representative for a password reset code.

  Enter the code provided:
- Once the supplied code has been entered, you will be prompted to enter a new password twice. If the new passwords entered do not match, the following message is displayed:

  Passwords entered do not match – please retry.

Security and Malware

Malware Detection



The instrument is equipped with an anti-malware scanner which will scan any inserted USB key. The system will not complete the export or import operation until the anti-malware scan is completed. While the anti-malware scanner is scanning the inserted USB key, the following message will be displayed:

> Scanning of USB key in progress (scan time will depend on the contents of the USB key) …

If no malware is detected, the import/export operation will proceed as normal.

If the anti-malware scanner detects malware on the inserted USB key, the following message will be displayed, and the import or export operation will fail. Please remove the USB key and do not use it.

> Malware found on USB key – please remove the USB key and contact your local IT department or your local technical support representative.

Recommendations:

- Use a dedicated USB key for transfers.
- Manage the contents by deleting unnecessary files on the dedicated USB key to minimise scan times.
- If the scan takes longer than expected, remove the USB key (which aborts the scan and transfer) and remove unnecessary files and retry the operation.