A D V A N C E D  S T A I N I N G  I N S T R U M E N T S

# HISTOCORE PELORIS 3

## PREMIUM TISSUE PROCESSING SYSTEM

## QUICK TIPS

CE

Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

# Table of Contents


**Setup and Protocols**

**Xylene Mode**

» Recommended Setup
» Recommended Xylene Protocols

**Xylene-Free Mode**

» Recommended Setup
» Recommended Xylene-Free Protocols

**Tissue Size Recommendations – Xylene and Xylene-Free**

**Running Protocols**

» Scanning Baskets
» Running a Protocol
» Adding Baskets and Cassettes to a Running Protocol

**Managing Reagents**

» Reagent Top off/Top up
» Reagent Replacement – Manual
» Reagent Replacement – Remote Fill and Drain
» Wax Replacement

**Maintenance**

» Maintenance Tracking
» Transferring Incident Reports or Log Files

**Shut Down Procedures**

» Abandoning Protocols
» Shutdown

**Reports**

» Run Details Report
» User Actions Report
» Protocol Usage Report
» Reagent Usage Report

**Troubleshooting**

**Warnings**

**Security and Malware**

» Access Level and Supervisor Password Rules
» User Management
» Malware Detection


# 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 Biosystems symbol on the function bar.**

**Intended use**

The HistoCore PELORIS 3 dual retort rapid tissue processor automates preparation of tissue samples for sectioning. This is achieved by transforming fixed specimens into wax infiltrated specimens by exposing them to a sequence of reagents in the tissue processor. Tissue samples subsequently undergo interpretation by a qualified healthcare professional to aid diagnosis.

IVD

CE


Leica Biosystems Melbourne Pty Ltd
495 Blackburn Road
Mount Waverley VIC 3149
Australia


| Revision record | | | |
|---|---|---|---|
| **Rev.** | **Issued** | **Sections affected** | **Detail** |
| A05 | October 2021 | Table of Contents/Regulatory page | Updated to support IVDR |
| A06 | December 2021 | Front Cover<br>Running Protocols, Shut Down Procedures, Reports, Security and Malware | Rebranding<br>Updated for version 3.3 |


Copyright © 2021 Leica Biosystems Richmond Inc. All rights reserved. LEICA and the Leica Logo are registered trademarks of Leica Microsystems IR GmbH. HistoCore PELORIS 3 is a trademark of Leica Biosystems and its affiliates. Other logos, product and/or company names might be trademarks of their respective owners.

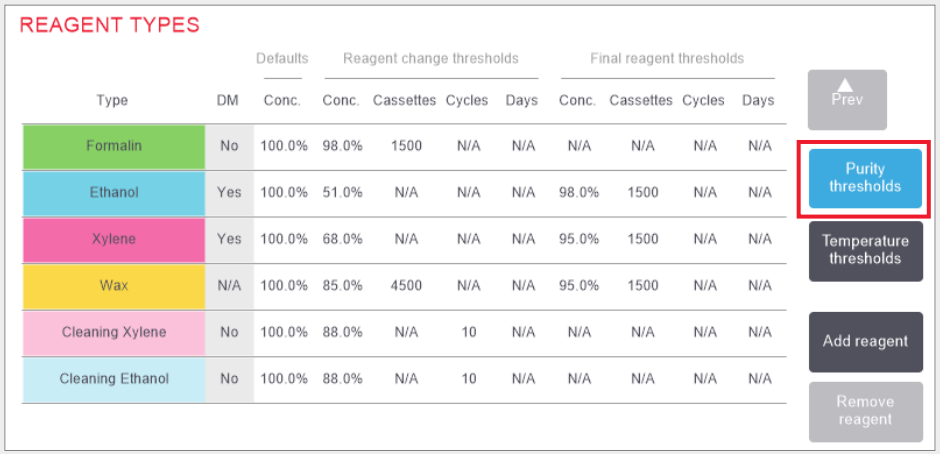


45.7538.500 Rev A06 12/2021

# 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

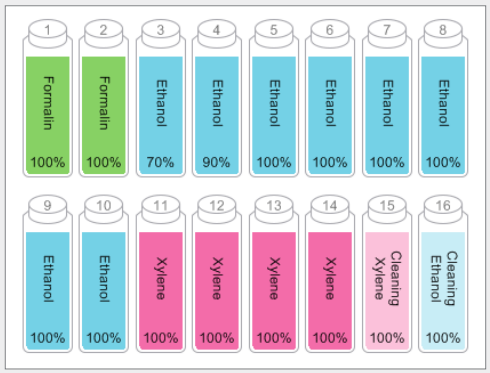



Admin > Reagent Types > Purity Thresholds

## Temperature Thresholds

Admin > Reagent Types > Temperature Thresholds

## Recommended Bottle Setup

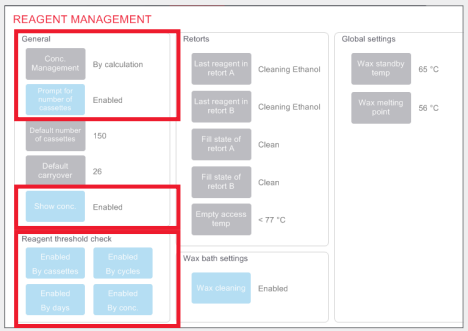



Configure the bottles as shown.

**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.

Leica BIOSYSTEMS

# 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 |

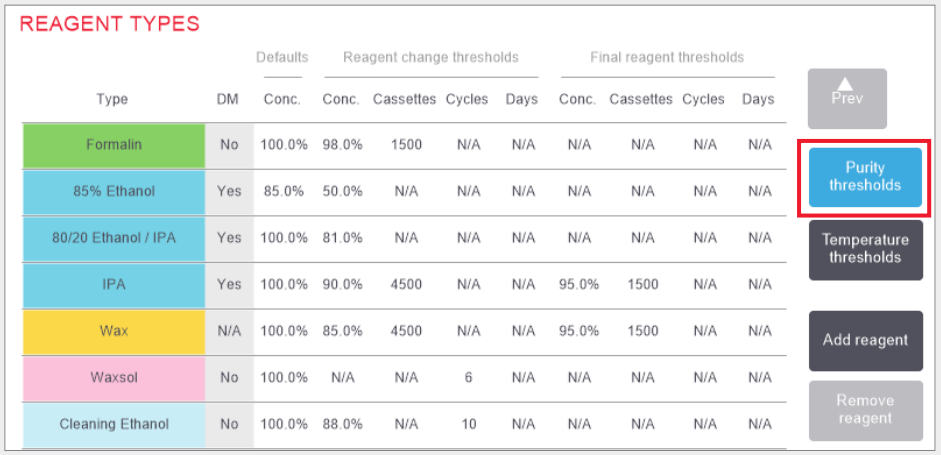
## 12 hour

| 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

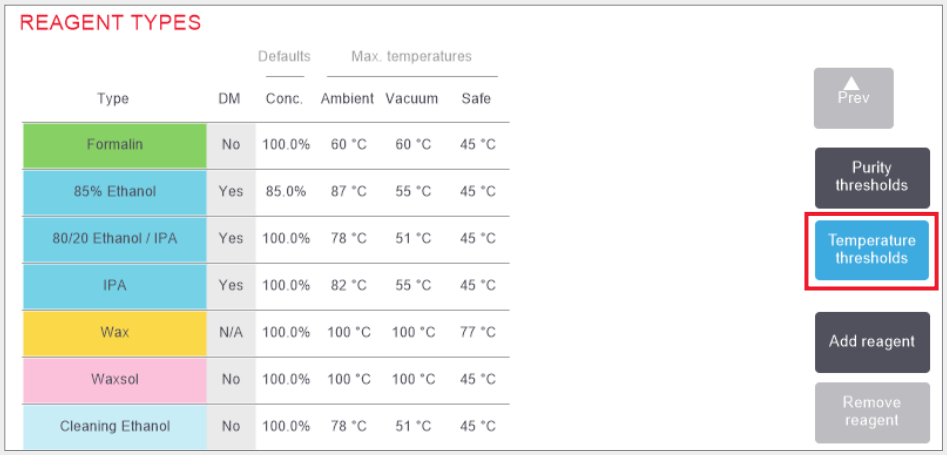
We recommend the setup shown in the images below. Setup must be validated by the laboratory prior to use, according to local or regional accreditation requirements.

## Concentration Defaults and Change Thresholds



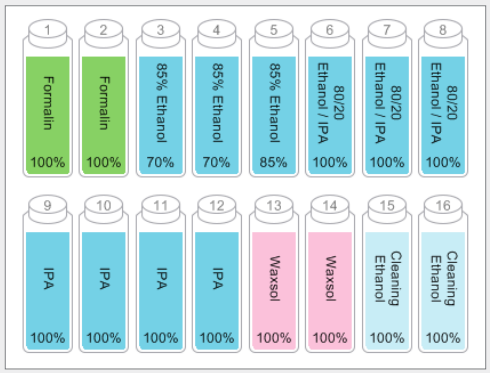

Admin > Reagent Types > Purity Thresholds

## Temperature Thresholds




Admin > Reagent Types > Temperature Thresholds

## Recommended Bottle Setup

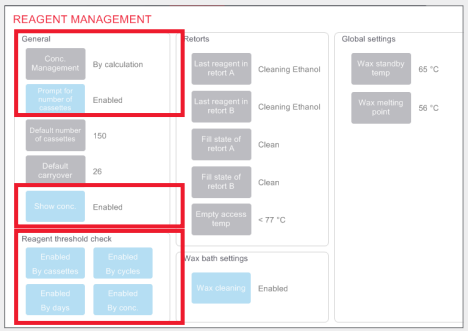



Configure the bottles as shown.

**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.

Leica BIOSYSTEMS

# 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 |

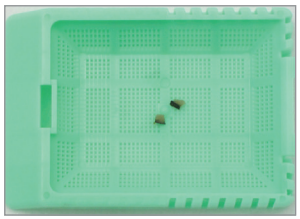
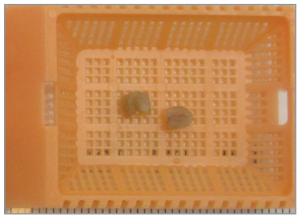
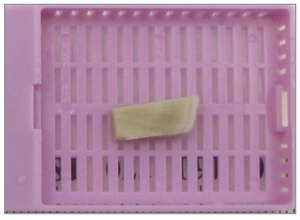
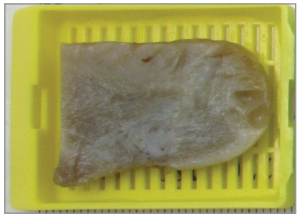
## 8 hour

| 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. |

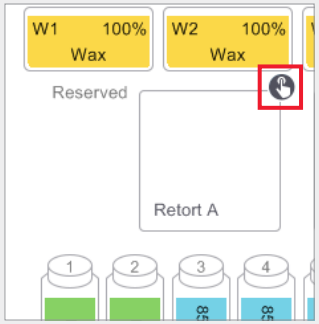
*Images not to scale.

Leica BIOSYSTEMS

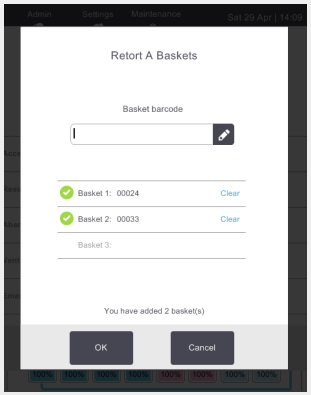
# Scanning Baskets

Each basket has a 2-D barcode on one of its anti-reflection tags. Scanning the barcode (or entering it by hand), and capturing the basket image (available with the HistoCore I-Scan only) is an optional step that can be completed at any time before starting a protocol run but doing so will help you track tissue specimens as they progress through the laboratory.

## Using the Barcode Scanner




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.



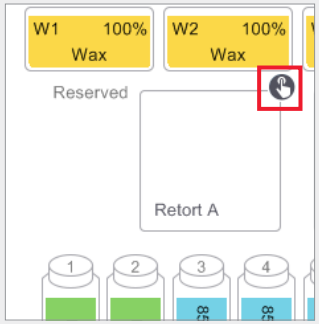

Using the attached hand-held scanner, scan the barcode located on the basket tab.

Alternatively, the barcode can be manually entered by tapping on the pen icon.

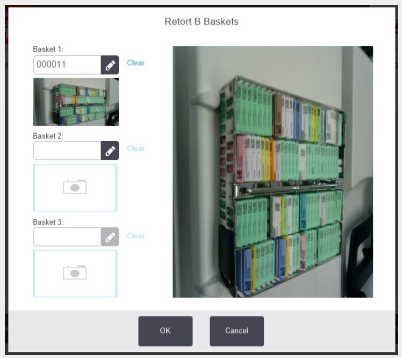
When entered, the barcode is displayed with a green tick and the cursor is ready for the next barcode in the text box.

When all baskets are scanned, tap **OK**.

## Using the HistoCore I-Scan




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 HistoCore I-Scan, scan the barcode located on the basket tab.

The scanner then swiches to camera mode. Capture an image of the basket.

When captured, the barcode and the image are displayed and the Histo-Core I-Scan is ready to scan the next basket barcode.

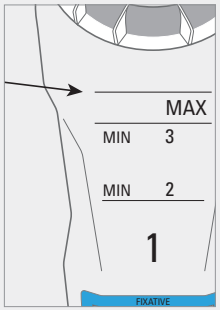
When all basket barcodes and images are captured, tap **OK**.

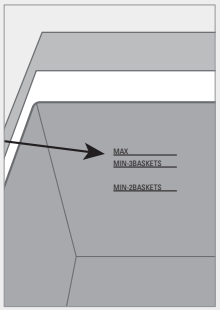
**Note:** Once a run is complete, basket images are available on the Run Details report.

Leica BIOSYSTEMS

# Running a Protocol

## 1. Conduct Pre-Run Checks

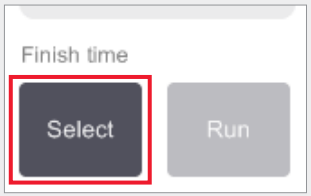



Check system status:

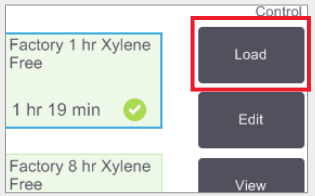
- Ensure retort is clean.
- Ensure no expired reagents.
- Check reagent and wax levels are between “MAX” and “MIN 3” (3 baskets) or “MIN 2” (2 baskets).

## 2. Load the Protocol



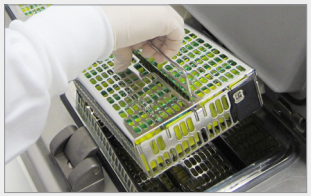

Tap **Select** on the Status screen.

Tap the required validated protocol.

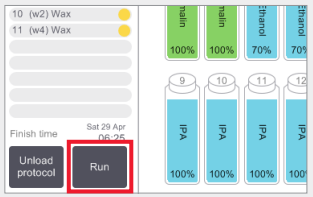



Tap **Load**.

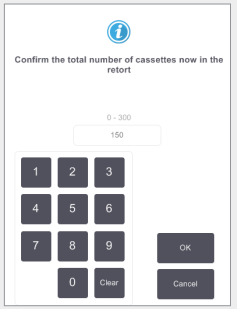
## 3. Start the Run



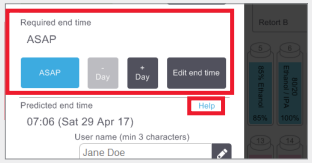
Place the baskets (1, 2 or 3) into the retort.




Tap **Run**.



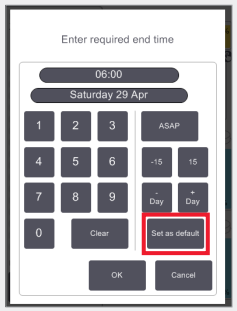

Enter the number of cassettes.




Set the end time:

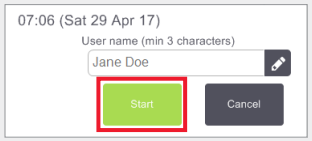
**ASAP** – for immediate start.

**Set end time** – for delayed start.




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

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



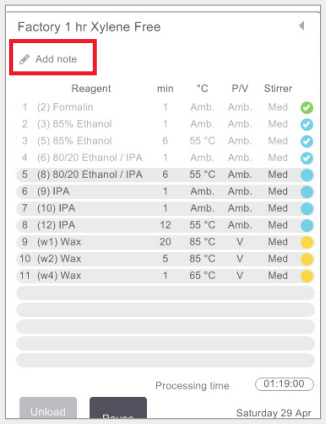

Scan or enter user name to enable Start button.

Tap **Start**.

Leica BIOSYSTEMS

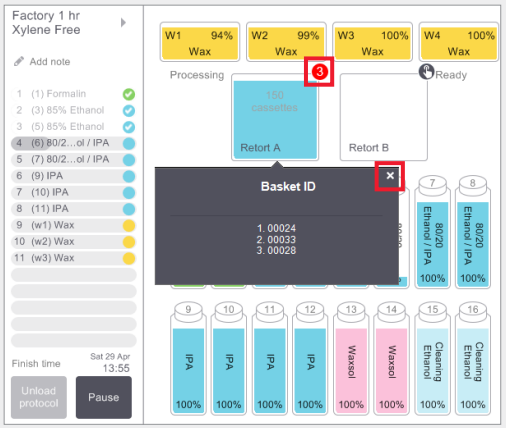
# Running a Protocol

## 4. Monitor the Progress




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

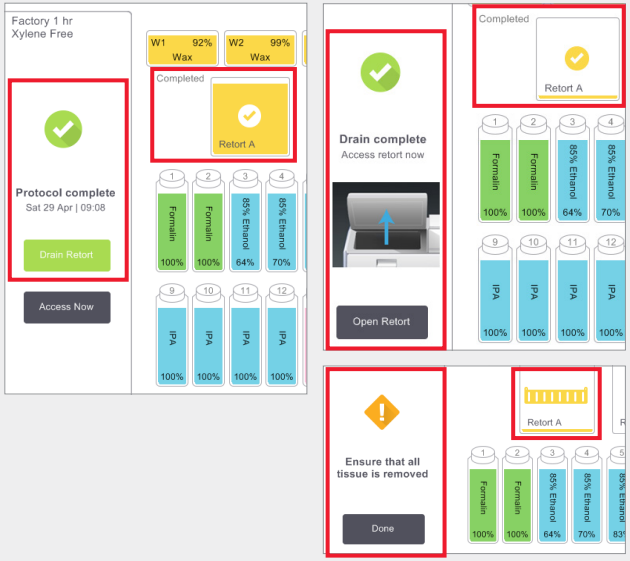
Protocol notes for a single run can be added prior to starting, or at any time during the protocol, by tapping **Add note**. This will display a keyboard.




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.

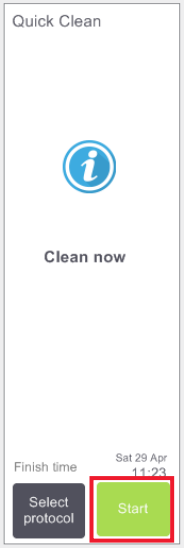
## 5. Complete the Run




Protocol complete.

Drain the retort.

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

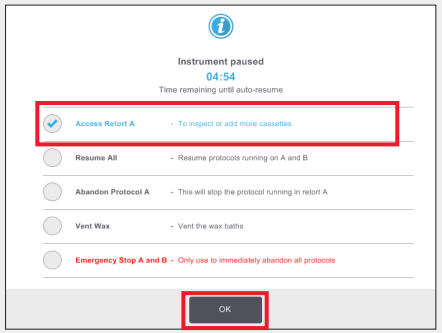



Tap **Start** to begin cleaning protocol.

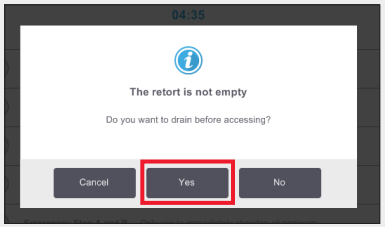
# Adding Baskets and Cassettes to a Running Protocol

## 1. Pause the Protocol

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

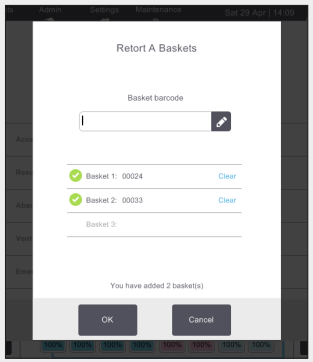



On the **Instrument paused** dialog box, tap **Access Retort**. A blue tick is displayed next to the tapped option. Tap **OK**.



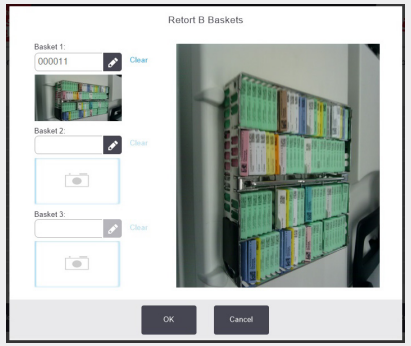

Wait for the above dialog box to appear. If you would like to drain the retort before accessing, tap **Yes**.

## 2. Add New Baskets/Cassettes and Restart the Protocol




If using a barcode scanner, scan the basket to be added and tap **OK**.

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



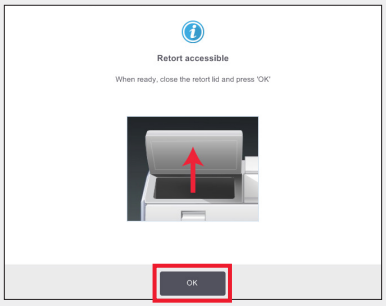

If using the HistoCore I-Scan, scan and capture an image of the basket to be added and tap **OK**.

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

Add the scanned basket

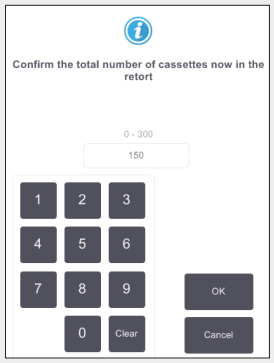
**OR** Remove the cassette basket from the retort and add the new cassettes.

## 3. Restart the Protocol



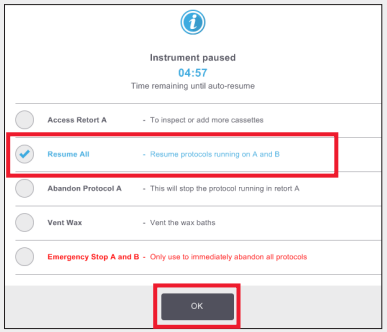

Place the basket into the retort.

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 name when prompted.



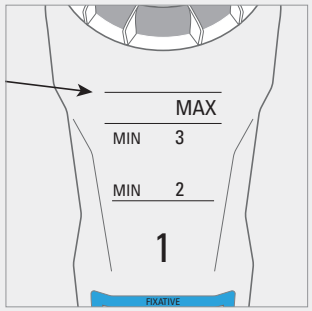

Wait for the **Instrument Paused** dialog to appear and tap **Resume All**.

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

Leica BIOSYSTEMS

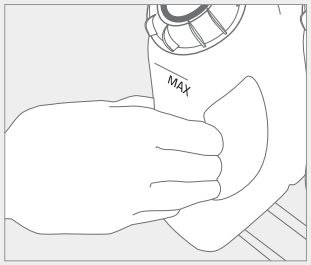
# PELORIS 3 Reagent Top off/Top up

## 1. Check the Bottle Contents and Remove if Necessary

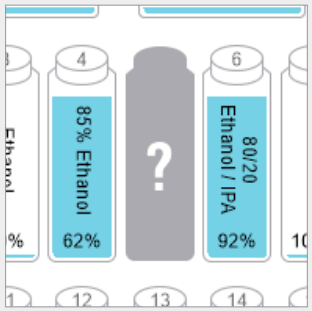



Top off/up the bottle when the reagent is below the minimum level.

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

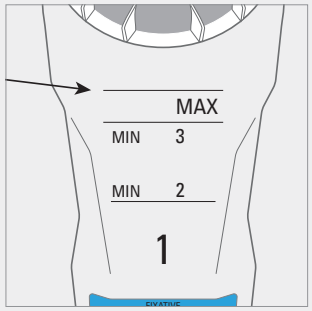



**Important!** Ensure no protocol is running then remove the bottle from the instrument.

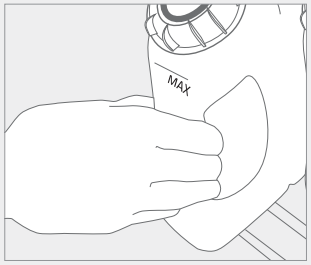



The software will indicate that the bottle is missing.

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

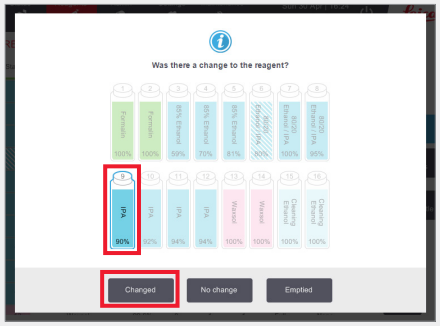



Fill the bottle to the maximum level and tighten the cap by hand.




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

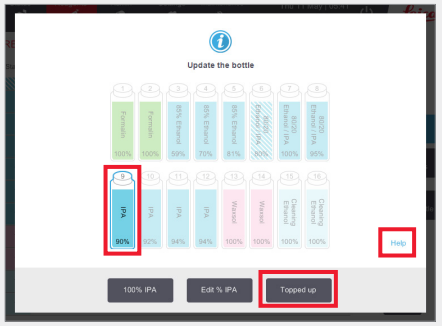
## 3. Update the Bottle Details




Select the bottle to update.

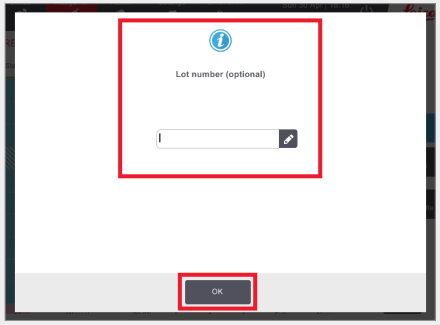
This enables the action options.

Tap **Changed**.



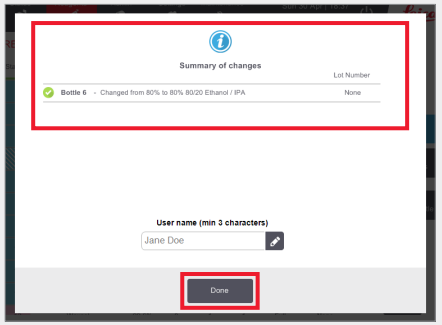

Tap **Topped Up**.

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




Lot number entry is optional.

Tap **OK** to continue.

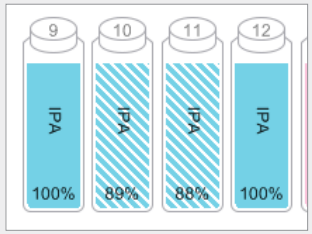



The summary of changes dialog is displayed. Enter your user name and tap **Done** to complete.

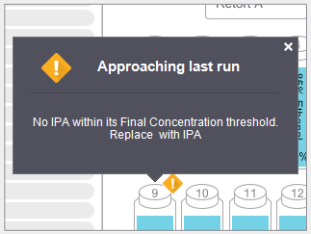
Leica BIOSYSTEMS

# PELORIS 3 Reagent Replacement – Manual

## 1. When to Replace Reagent



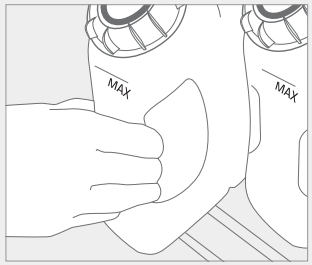

Replace reagent when bottles appear hatched on the **Status** screen.



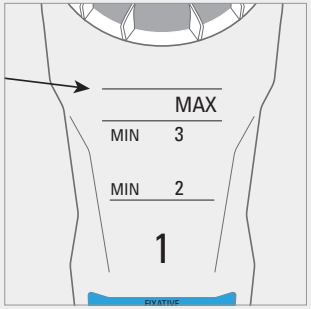

**OR** When warned at protocol start (final threshold exceeded).

Ensure no protocols are loaded or running.

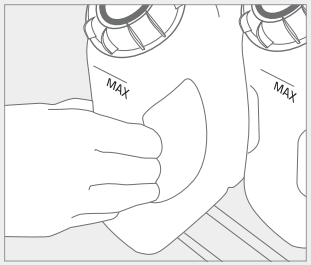
## 2. Empty and Replace the Reagent




Remove the bottle and safely dispose of the used reagent.

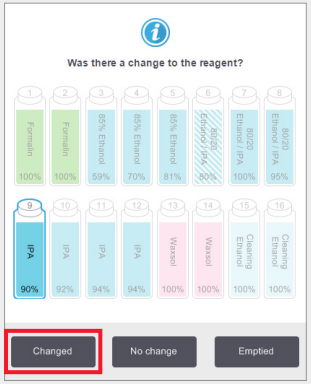



Fill the bottle to the maximum level and tighten the cap by hand.

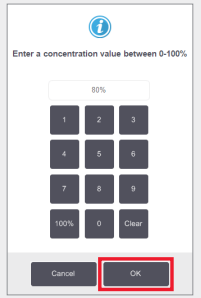



Return the bottle to the cabinet – push firmly into the rear connectors.

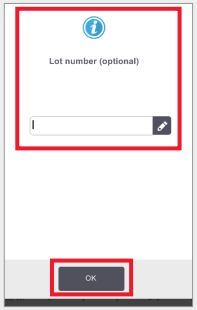
## 3. Update the Bottle Details




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

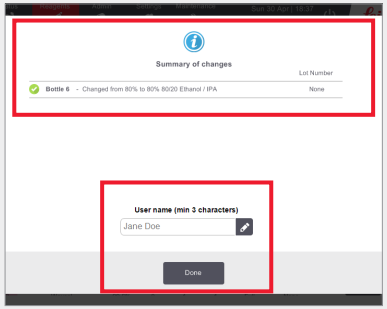



For the example shown, use the **100% IPA** option unless you need to change the concentration, in which case use **Edit % IPA** using the keypad. Tap **OK** when you are done.




Lot number entry is optional.

Tap **OK** to continue.



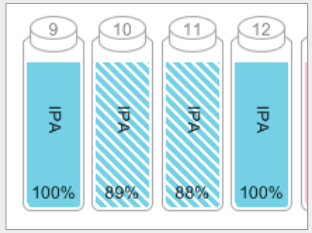

The summary of changes dialog is displayed. Enter your user name and tap **Done** to complete.

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

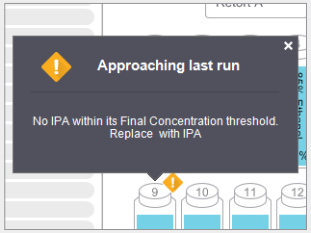
If you receive warnings that an out-of-threshold reagent has been selected for a protocol, do not proceed with the protocol run. Out-of-threshold reagents will result in poor-quality processing.

# PELORIS 3 Reagent Replacement – Remote Fill and Drain

## 1. When to Replace

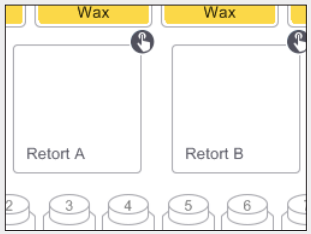



Replace reagent when bottles appear hatched on the **Status** screen.




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

## 2. Drain Preparation

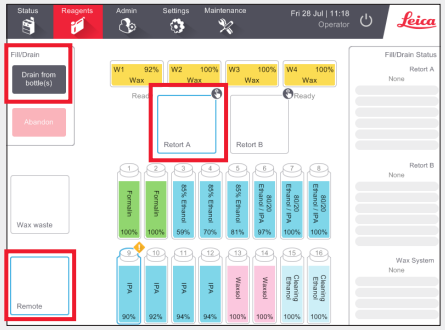



Ensure a clean retort is available.

Connect the remote fill/drain hose.

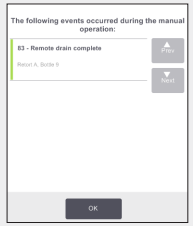
Insert the hose into a stable container with sufficient capacity to avoid overflow.

## 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 name to continue.




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

Tap **OK**.

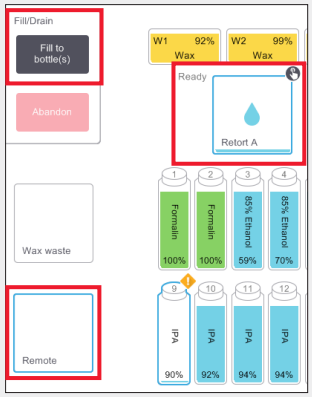
## 4. Fill Preparation

Connect the remote fill/drain hose.

Insert into reagent container.

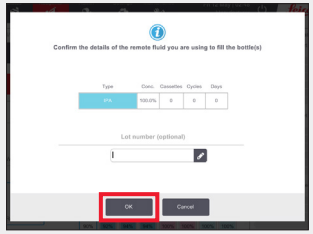
Ensure empty bottles are securely in position and the caps are not loose.

## 5. Fill




Go to Reagents> Remote Fill/Drain.

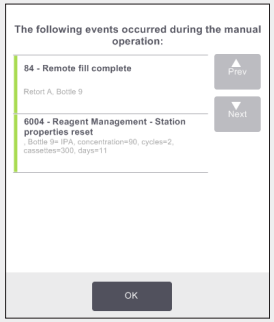
Tap **Remote**, a retort and the bottles to fill, and then tap **Fill to bottle(s)** and follow the instructions.




Confirm or change new reagent details when prompted.

Optional: Enter lot number when prompted.

Enter your user name when prompted.




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

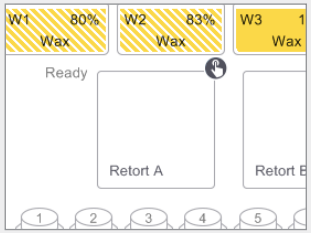
Tap **OK**.

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

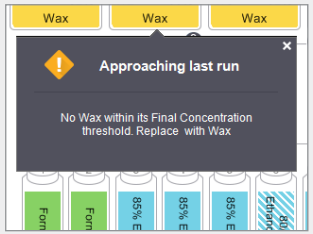
Leica BIOSYSTEMS

# PELORIS 3 – Wax Replacement

## 1. When to Replace

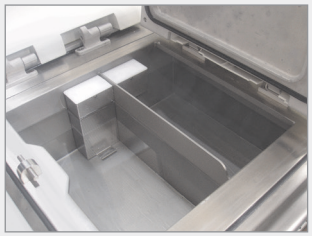



Replace wax when chambers appear hatched on the **Status** screen.




**OR** When warned at the start of the protocol.

## 2. Preparation

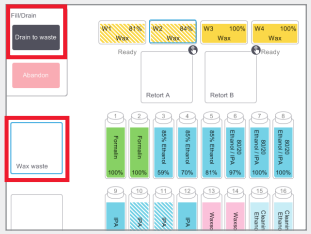


Ensure wax is molten then close the lid.

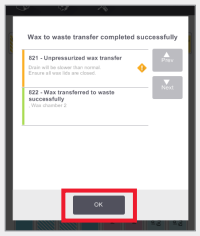
Connect wax waste line.

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

## 3. Drain

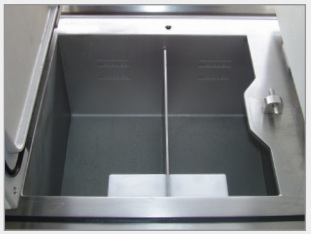



Go to Reagents > Remote Fill/Drain. Tap **Wax waste** and the wax chambers to drain, then tap **Drain To Waste**.

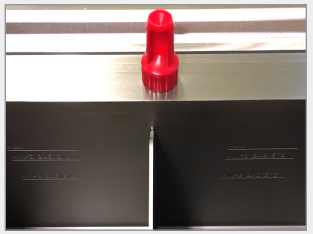



An action queue item is displayed when the drain to waste is complete. Tap **OK**.

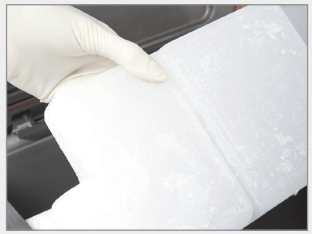
## 4. Add New Wax*



Clean the wax bath using a lint-free cloth.

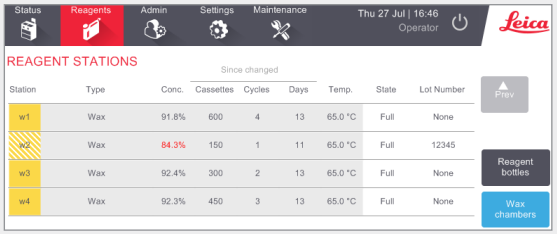


**Either** Use Paraplast (molten or pellets). Use the LLS tool wax plug to ensure wax does not go down the wax vent.



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

## 5. Update Station State



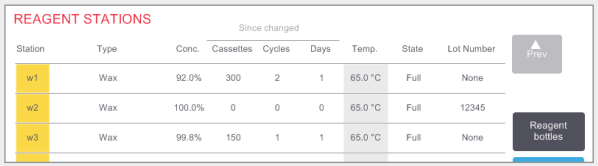

Go to Reagents > Stations > Wax Chambers.

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 name 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

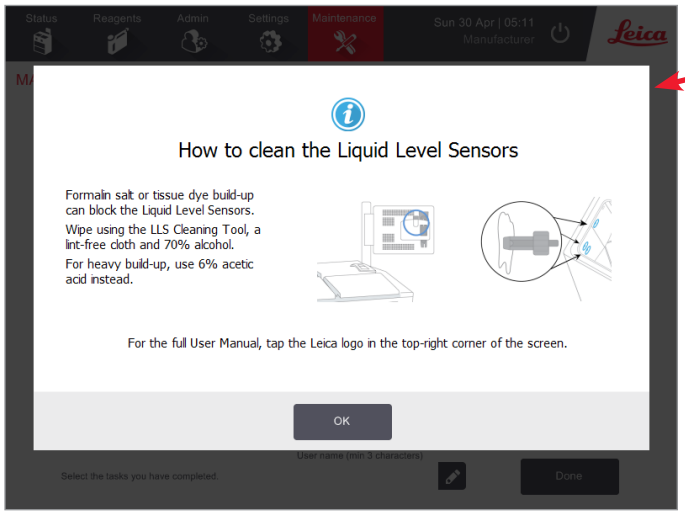
The **Maintenance** screen provides a way to record the activity and timing of routine maintenance functions.

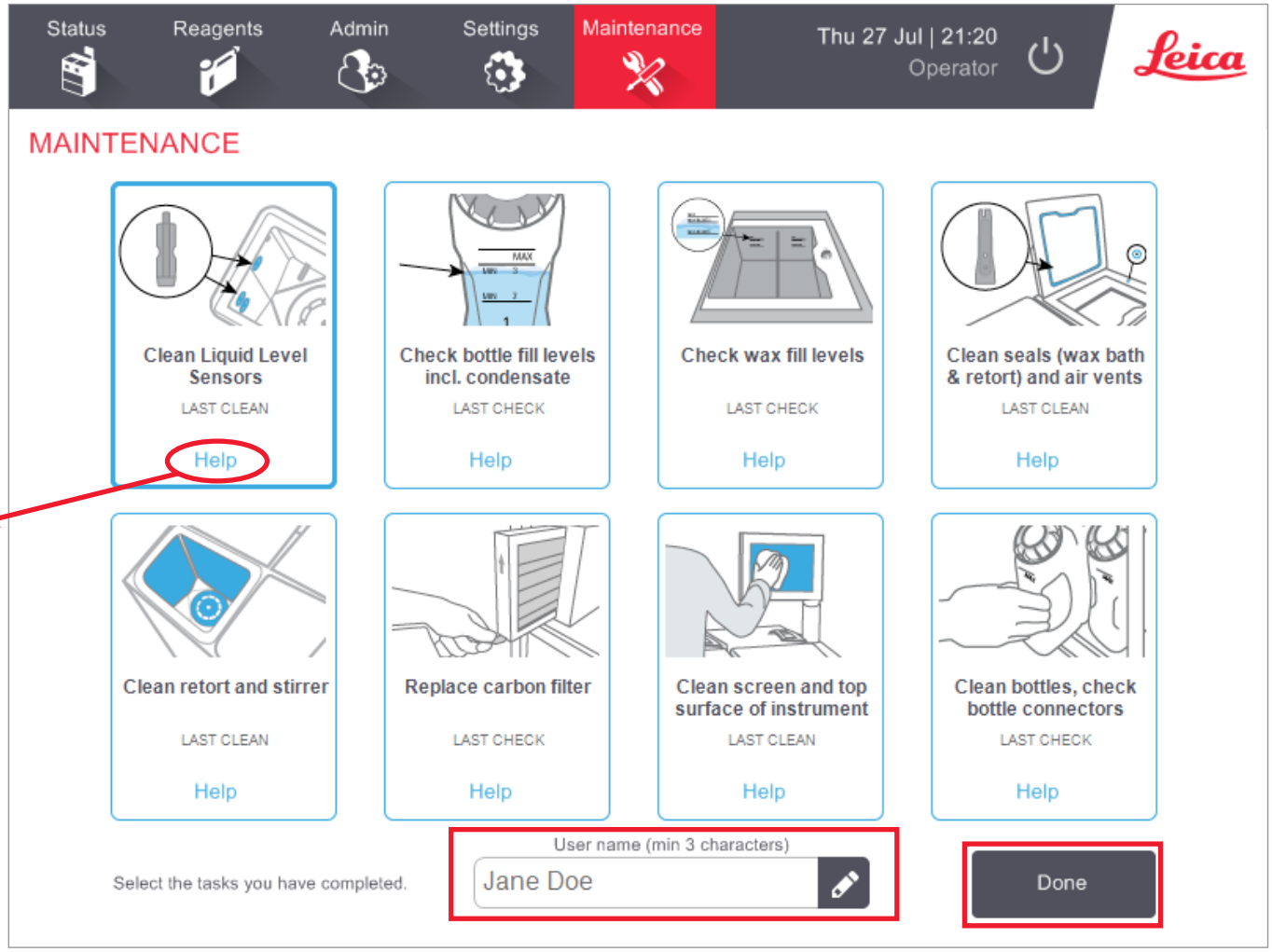
Routine maintenance tasks are displayed in the Maintenance screen.

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 name and tap **Done**.

This will save the date and user name against the task(s).



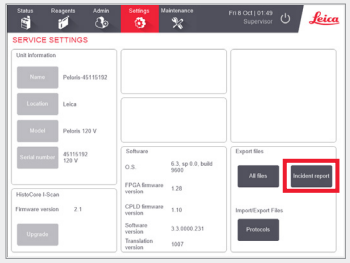

Refer to the User Manual for lists of recommended daily, weekly and monthly tasks.

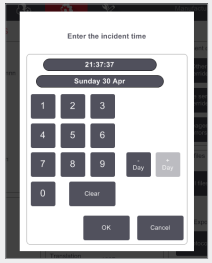
Leica BIOSYSTEMS

# PELORIS 3 Transferring Incident Reports or Log Files

## 1. Select Incident Reports or Log Files

Choose the file type required:

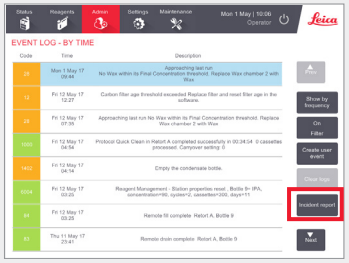





**Incident Reports**: Go to Settings > Service > Export Files pane.

Tap **Incident Report**.

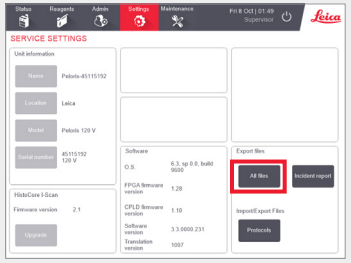
When prompted, enter the time and date of the incident. Tap **OK**.



**OR** Go to Admin > Event Log.

Tap a specific incident to select it.

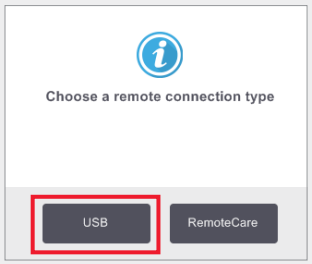
Tap **Incident Report**.



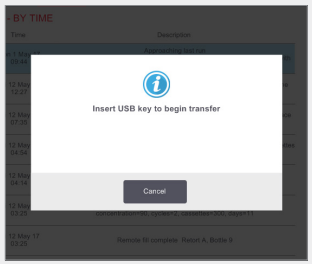
**Full Logs**: Go to Settings > Service > Export Files pane.

Tap **All Files**.

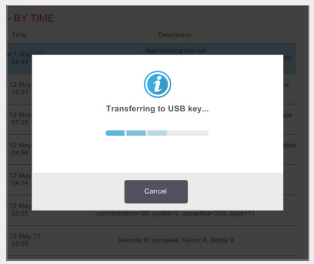
## 2. Transfer Files and Email to Leica Biosystems



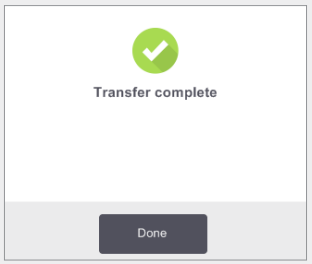

Choose a remote connection type, for example USB.



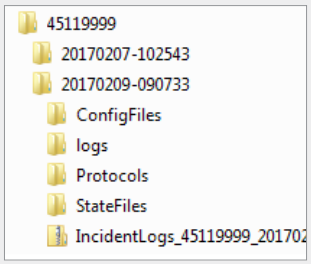

When prompted, insert your USB drive into the front port.

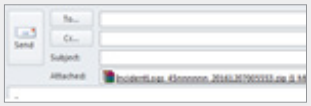



A dialog box is displayed showing the progress of the transfer.




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.

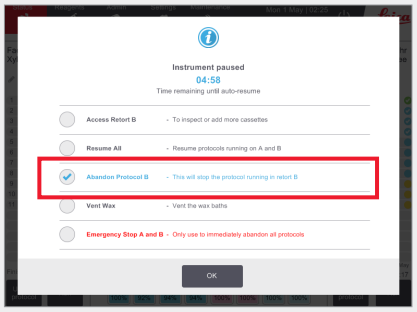
**When to transfer log files:**

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

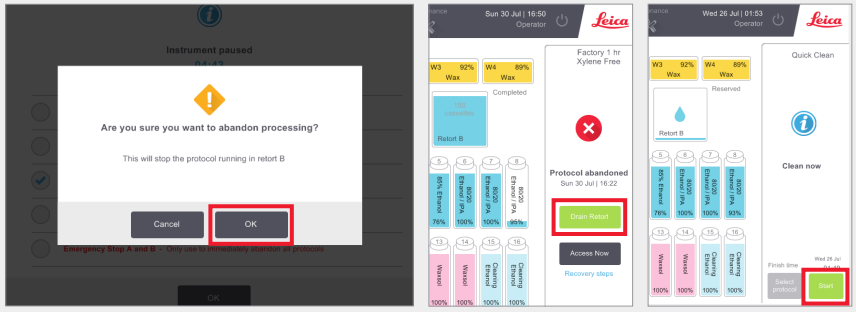
# PELORIS 3 Abandoning Protocols

## 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**.



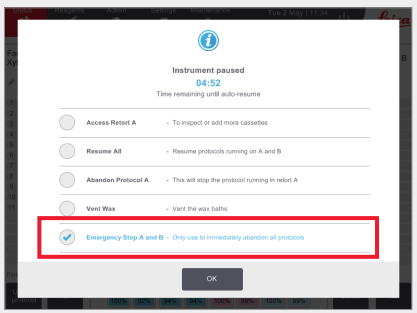
To confirm, tap **OK**.

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

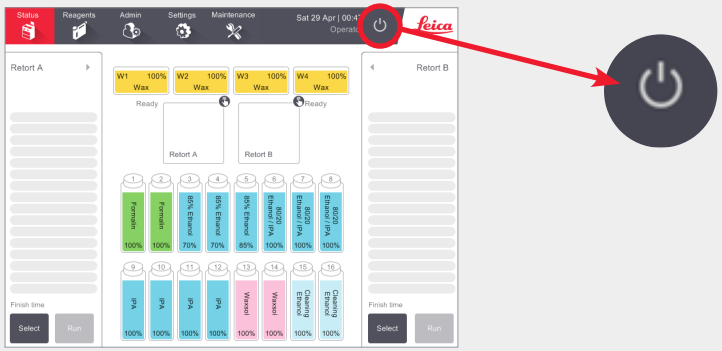
# PELORIS 3 Shutdown

## Normal Shutdown

**When to shut down:**

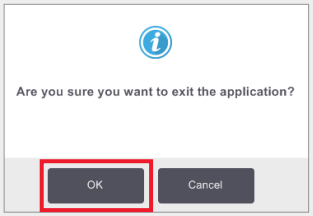
- Instrument is being moved or shipped.
- Before servicing.
- To avoid a potentially hazardous incident.

**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.**

## Extended Shutdown Period

**If the instrument is left unpowered for more than three days**, the steps below must be followed to ensure the instrument continues to meet the product standards.

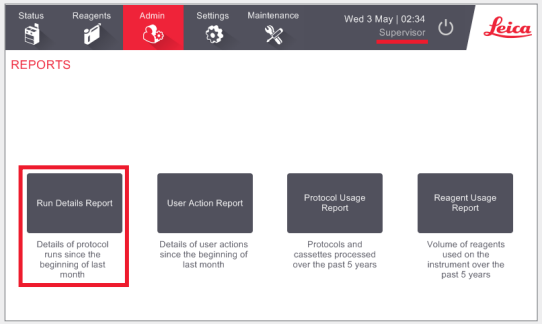
***Dry Out Procedure***

1. Ensure the mains power outlet socket is earthed.
2. Plug the power cable into the socket and switch on the power.
3. Move the circuit-breaker switch to the right to turn it on.
4. Press the power button on the front of the instrument.
5. Wait for 1 hour before any further interaction with the instrument.

The instrument is now ready for use.

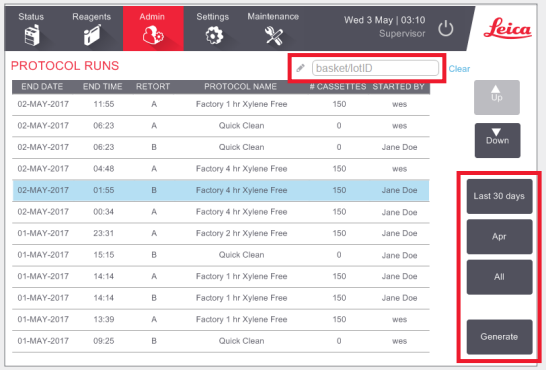
# PELORIS 3 Reports

## Run Details Report

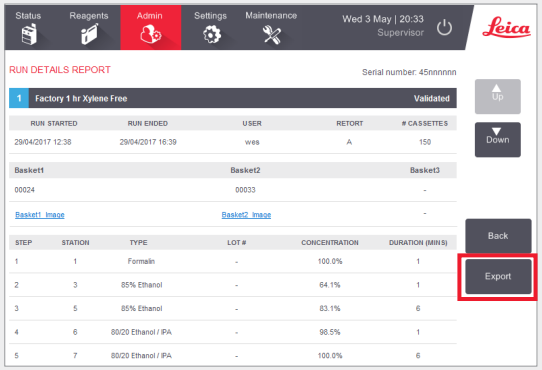



Navigate to Admin > Reports and tap **Run Details Report**.

User names are visible in Supervisor mode.



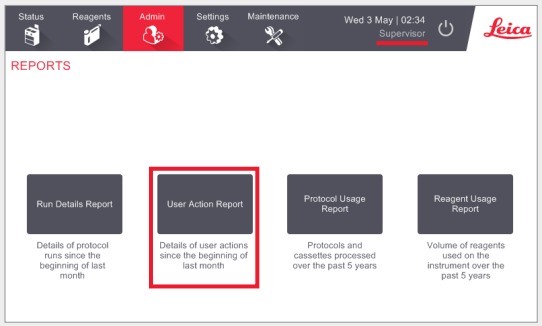

All protocols run since the beginning of the last month are available to view. You can filter runs by basket ID and reagent/ wax lot number. You can also choose to display All protocols run or those run in the last month or the last 30 days. Highlight the protocol reports you wish to view and tap **Generate**.




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.

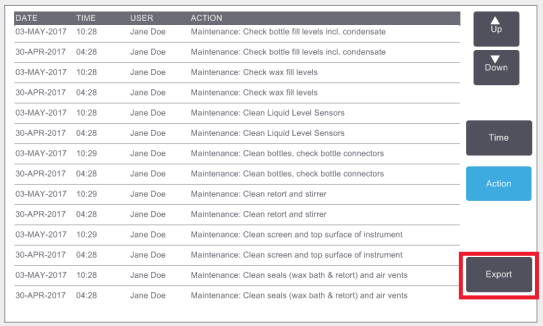
## User Actions Report




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

User names are visible in Supervisor mode.

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



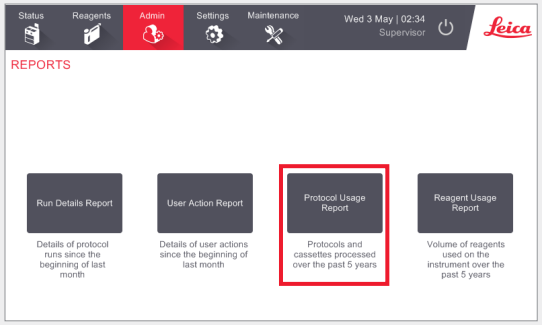

Actions can be filtered by time or the action.

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

Leica BIOSYSTEMS

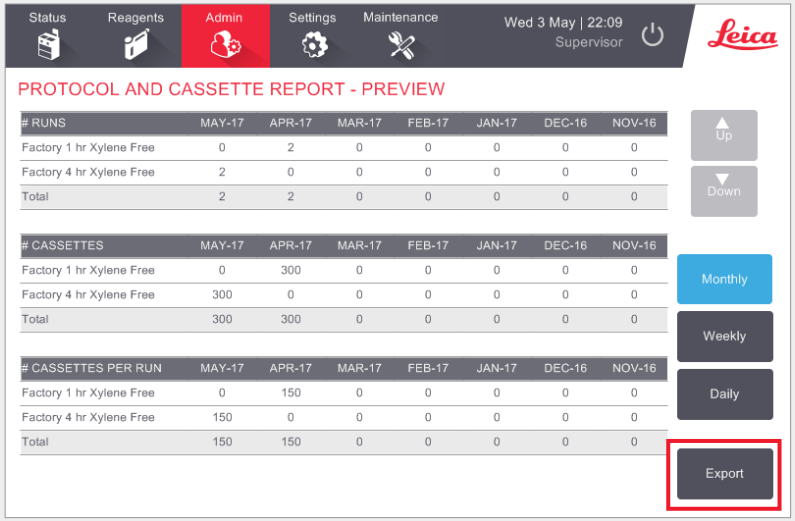
# PELORIS 3 Reports

## 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.

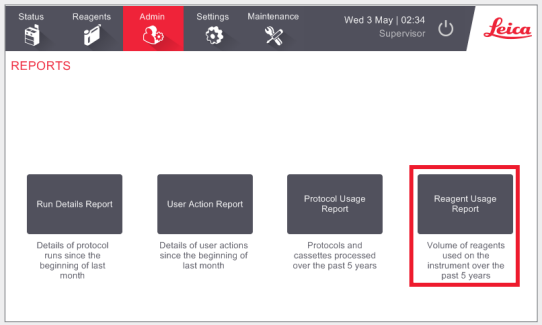



The **Protocol and Cassette Report** provides metrics on the protocol types run as well as the cassettes run per protocol.

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

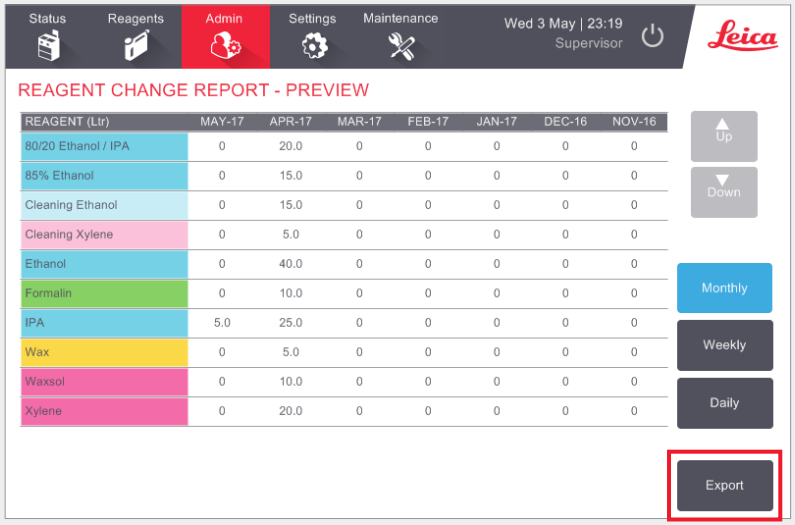
To export the report, insert a USB drive and tap **Export**. Exported files can be saved to your computer and viewed.

## 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.



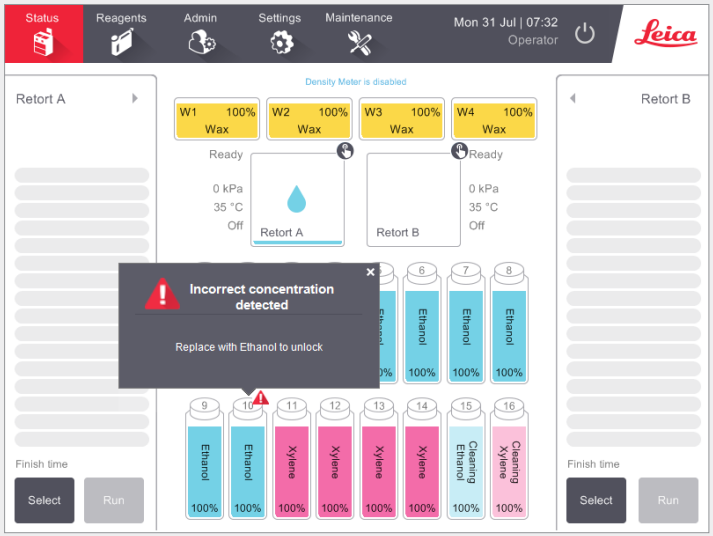

The **Reagent Usage Report** provides metrics on reagent usage.

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:

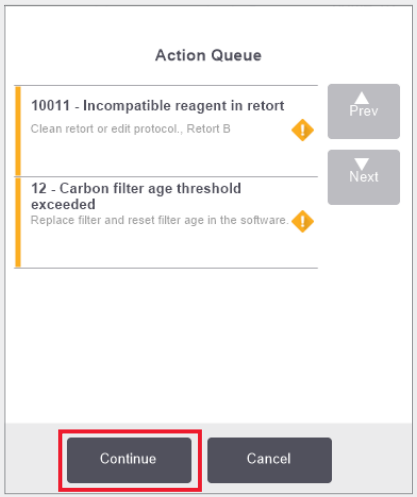
» The reagent has been replaced.

**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.

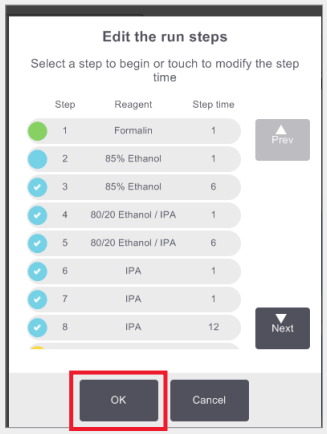
Some action queue messages require immediate operator intervention, as the software will not allow the protocol to be run. In the example shown, the "10011 – Incompatible reagent in retort" message informs the operator to either run a **Quick Clean** or edit the protocol (depending on the reagent in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

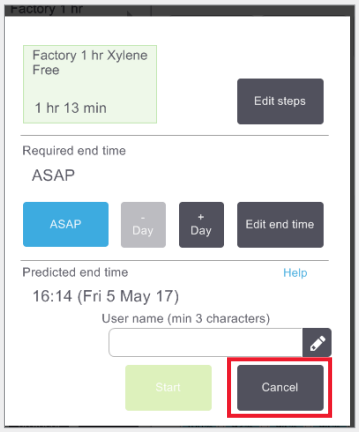
If immediate action must be taken and no operator intervention occurs, if you tap **Continue** the protocol will not start and the Action Queue will continue to be displayed.

Action Queue history is located in Admin > Event Logs.

# PELORIS 3 Troubleshooting

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



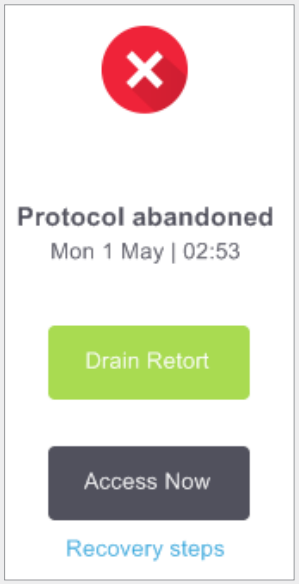




When you edit steps for a single protocol, the steps are removed from the protocol after you tap **OK**.

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.

## User Management

Each user must have a unique user name. They are required to enter their user name when prompted.

With Access Level set to **Supervisor**, use the **User Management** screen (**Admin > User Management**) to create new users and manage user details.

» To create a new user:

- Tap the **New** button.
- Enter the details for the new user. Note that each person's user name must be unique.
- Tap **Save**.

» To edit user details:

- Tap on the user to be edited to highlight it.
- Tap the **Edit** button.
- Edit the details as required.
- Tap **Save**.

» To delete a user:

- Tap on the user to be deleted to highlight it.
- The **Are you sure you want to delete...** message is displayed.
- Tap **OK** to confirm.

Use the **Import/Export** feature to copy the list of users from one PELORIS 3 instrument to other PELORIS 3 instruments of the same or above software version.

» Insert a USB key into a USB port on the PELORIS 3 instrument that has the list of users on it.

» Tap the **Export** button. The **Transfer Complete** message is displayed.

» Tap the **Done** button.

» Remove the USB key from the instrument.

» Insert the same USB key into another PELORIS 3 instrument of the same or above software version.

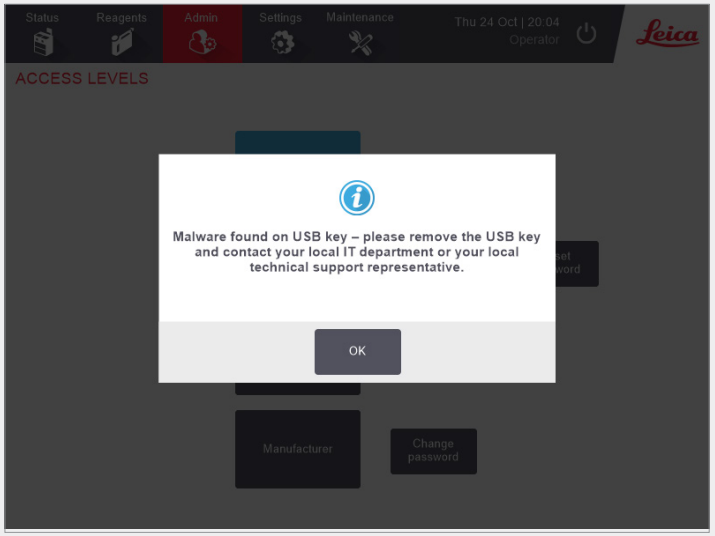
» Go to **Admin > User Management** and tap the **Import** button.

The list of users from the initial instrument is now available on the second instrument.

Leica BIOSYSTEMS

# 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), remove unnecessary files, and retry the operation.