HISTOCORE PELORIS 3

PREMIUM TISSUE PROCESSING SYSTEM

QUICK TIPS



CE

Advancing Cancer Diagnostics Improving Lives



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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 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.





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Revisio	on record		
Rev.	Issued	Sections affected	Detail
A05	October 2021	Table of Contents/Regulatory page	Updated to support IVDR
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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

		Defaults	Rea	igent chang	e thresh	olds	Fi	nal reagent	threshold	ds	
Туре	DM	Conc.	Conc.	Cassettes	Cycles	Days	Conc.	Cassettes	Cycles	Days	Prev
Formalin	No	100.0%	98.0%	1500	N/A	N/A	N/A	N/A	N/A	N/A	Purity
Ethanol	Yes	100.0%	51.0%	N/A	N/A	N/A	98.0%	1500	N/A	N/A	threshold
Xylene	Yes	100.0%	68.0%	N/A	N/A	N/A	95.0%	1500	N/A	N/A	Temperatu
Wax	N/A	100.0%	85.0%	4500	N/A	N/A	95.0%	1500	N/A	N/A	
Cleaning Xylene	No	100.0%	88.0%	N/A	10	N/A	N/A	N/A	N/A	N/A	Add reage
Cleaning Ethanol	No	100.0%	88.0%	N/A	10	N/A	N/A	N/A	N/A	N/A	Remove

Admin > Reagent Types > Purity 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.

Temperature Thresholds



Admin > Reagent Types > Temperature Thresholds

Reagent Management Method

General		Retorts		Global settings	
Conc. Management	By calculation	Last reagent in retort A	Cleaning Ethanol	Wax standby temp	65 °
Prompt for number of cassettes	Enabled	Last reagent in retort B	Cleaning Ethanol	Wax melting point	56 °
Default number of cassettes	150	Fill state of retort A	Clean		
Default carryover	26	Fill state of refort B	Clean		
	Enabled	Empty access temp	< 77 °C		
Reagent threshold	check				
Enabled By cassettes	Enabled By cycles	Wax bath settings			
Enabled	Enabled	Wax cleaning	Enabled		

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.



Recommended Xylene Protocols

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

Reage	ent Step [*] (min)		P/V	Stirrer	Drip Time (s)
Forma	alin 10	45	Ambient	Med	10
Ethan	ol 1	Ambient	Ambient	Med	10
Ethan	ol 1	Ambient	Ambient	Med	10
Ethan	ol 1	Ambient	Ambient	Med	10
Ethan	ol 20	45	Ambient	Med	10
Ethan	ol 20	45	Ambient	Med	10
Ethan	ol 45	45	Ambient	Med	10
Xylene	e 1	Ambient	Ambient	Med	10
Xylene	e 10	45	Ambient	Med	10
Xylene	e 45	45	Ambient	Med	10
Wax	10	65	Vacuum	Med	10
Wax	10	65	Vacuum	Med	10
Wax	40	65	Vacuum	Med	10

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

Reage	ent Ste (mi	ep Time iin)	Temp (°C)	P/V	Stirrer	Drip Time (s)		Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)	Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Forma	alin 1		Ambient	Ambient	Med	10		Formalin	15	45	Ambient	Med	10	Formalin	44	45	Ambient	Med	10
Ethan	ol 1		Ambient	Ambient	Med	10	-	Ethanol	15	45	Ambient	Med	10	Ethanol	30	45	Ambient	Med	10
Ethan	ol 1		Ambient	Ambient	Med	10	-	Ethanol	15	45	Ambient	Med	10	Ethanol	30	45	Ambient	Med	10
Ethan	ol 1		Ambient	Ambient	Med	10	-	Ethanol	15	45	Ambient	Med	10	Ethanol	30	45	Ambient	Med	10
Ethan	ol 1		Ambient	Ambient	Med	10	-	Ethanol	15	45	Ambient	Med	10	Ethanol	30	45	Ambient	Med	10
Ethan	ol 11		45	Ambient	Med	10	-	Ethanol	30	45	Ambient	Med	10	Ethanol	60	45	Ambient	Med	10
Ethan	ol 30		45	Ambient	Med	10	-	Ethanol	45	45	Ambient	Med	10	Ethanol	90	45	Ambient	Med	10
Xylene	e 1		Ambient	Ambient	Med	10		Xylene	20	45	Ambient	Med	10	Xylene	45	45	Ambient	Med	10
Xylene	e 1		Ambient	Ambient	Med	10		Xylene	20	45	Ambient	Med	10	Xylene	45	45	Ambient	Med	10
Xylene	e 28		45	Ambient	Med	10	5	Xylene	45	45	Ambient	Med	10	Xylene	90	45	Ambient	Med	10
Wax	5		65	Vacuum	Med	10		Wax	30	65	Vacuum	Med	10	Wax	60	65	Vacuum	Med	10
Wax	5		65	Vacuum	Med	10		Wax	30	65	Vacuum	Med	10	Wax	60	65	Vacuum	Med	10
Wax	20		65	Vacuum	Med	10	0	Wax	45	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

REAGENT TYPES											
		Defaults	Rea	igent chang	e thresh	olds	Fi	nal reagent	threshold	ds	
Туре	DM	Conc.	Conc.	Cassettes	Cycles	Days	Conc.	Cassettes	Cycles	Days	Prev
Formalin	No	100.0%	98.0%	1500	N/A	N/A	N/A	N/A	N/A	N/A	Purity
85% Ethanol	Yes	85.0%	50.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	thresholds
80/20 Ethanol / IPA	Yes	100.0%	81.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Temperature thresholds
IPA	Yes	100.0%	90.0%	4500	N/A	N/A	95.0%	1500	N/A	N/A	
Wax	N/A	100.0%	85.0%	4500	N/A	N/A	95.0%	1500	N/A	N/A	Add reagent
Waxsol	No	100.0%	N/A	N/A	6	N/A	N/A	N/A	N/A	N/A	Demous
Cleaning Ethanol	No	100.0%	88.0%	N/A	10	N/A	N/A	N/A	N/A	N/A	Remove reagent

Admin > Reagent Types > Purity 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.

Temperature Thresholds



Admin > Reagent Types > Temperature Thresholds

Reagent Management Method

General		Retorts		Global settings	
Conc. Management	By calculation	Last reagent in retort A	Cleaning Ethanol	Wax standby temp	65 °C
Prompt for number of cassettes	Enabled	Last reagent in retort B	Cleaning Ethanol	Wax melting point	56 °C
Default number of cassettes	150	Fill state of retort A	Clean		
Default carryover	26	Fill state of retort B	Clean		
Show conc.	Enabled	Empty access temp	< 77 °C		
Reagent threshole	d check				
		Wax bath settings			
Enabled By days	Enabled By conc.	Wax cleaning	Enabled		

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.



Recommended Xylene-Free Protocols

	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
Z	IPA	12	55	Ambient	Med	10
	Wax	20	85	Vacuum	Med	10
	Wax	5	85	Vacuum	Med	10
	Wax	1	65	Vacuum	Med	10

	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
4	Wax	10	65	Vacuum	Med	10

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

Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)		Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)		Reagent	Step Time (min)	Temp (°C)	P/V	Stirrer	Drip Time (s)
Formalin	1	Ambient	Ambient	Med	10		Formalin	20	55	Ambient	Med	10		Formalin	68	55	Ambient	Med	10
85% Ethanol	1	Ambient	Ambient	Med	10		85% Ethanol	15	55	Ambient	Med	10		85% Ethanol	30	55	Ambient	Med	10
85% Ethanol	12	55	Ambient	Med	10		85% Ethanol	20	55	Ambient	Med	10		85% Ethanol	40	55	Ambient	Med	10
80/20	1	Ambient	Ambient	Med	10		80/20	20	55	Ambient	Med	10		80/20	50	55	Ambient	Med	10
80/20	25	55	Ambient	Med	10		80/20	45	55	Ambient	Med	10		80/20	90	55	Ambient	Med	10
IPA	1	Ambient	Ambient	Med	10		IPA	15	55	Ambient	Med	10		IPA	30	55	Ambient	Med	10
IPA	1	Ambient	Ambient	Med	10		IPA	30	55	Ambient	Med	10		IPA	60	55	Ambient	Med	10
IPA	25	55	Ambient	Med	10		IPA	60	55	Ambient	Med	10		IPA	120	55	Ambient	Med	10
Wax	25	85	Vacuum	Med	10		Wax	45	85	Vacuum	Med	10		Wax	80	85	Vacuum	Med	10
Wax	10	85	Vacuum	Med	10	_	Wax	40	85	Vacuum	Med	10	N	Wax	70	85	Vacuum	Med	10
Wax	5	65	Vacuum	Med	10	10	Wax	30	65	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.

Setup and Protocols

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 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.

Admin Setting	gs Maintenance	Sat 29 Apr 1	4:(
	Retort A Basket	5	
	Basket barcode	_	
		ď	
🥝 Basket	1: 00024	Clear	
Basket : Basket :	2: 00033	Clear	
,	You have added 2 baske	(8)	
ок	< c	ancel	
100%	100%	100% 100% 100%	ĺ

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 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 $\ensuremath{\textbf{OK}}$

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



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



3. Start the Run

into the retort.



Place the baskets (1, 2 or 3)





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.



07:06 (Sat 2	9 Apr 17)	
Use	r name (min 3 c	haracters)
Ja	ane Doe	ø
	Start	Cancel

Scan or enter user name to enable Start button.

Tap Start.



Running Protocols

Running a Protocol

4. Monitor the Progress

Ð	Add note					
	Reagent	min	°C	P/V	Stirrer	
1	(2) Formalin	1	Amb.	Amb.	Med	e
2	(3) 85% Ethanol	1	Amb.	Amb.	Med	C
3	(5) 85% Ethanol	6	55 °C	Amb.	Med	C
4	(6) 80/20 Ethanol / IPA	1	Amb.	Amb.	Med	C
5	(8) 80/20 Ethanol / IPA	6	55 °C	Amb.	Med	
6	(9) IPA	1	Amb.	Amb.	Med	•
7	(10) IPA	1	Amb.	Amb.	Med	
8	(12) IPA	12	55 °C	Amb.	Med	
9	(w1) Wax	20	85 °C	V	Med	
10	(w2) Wax	5	85 °C	V	Med	
11	(w4) Wax	1	65 °C	V	Med	
			essina tin		01:19:	00

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 \boldsymbol{X} to hide the basket ID box.

5. Complete the Run



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.

Instrument paused 04:54 Time remaining until auto-resume	_
Access Retort A - To inspect or add more cassettes	
Resume All - Resume protocols running on A and B	
Abandon Protocol A - This will stop the protocol running in retort A	
Vent Wax - Vent the wax baths	
Emergency Stop A and B - Only use to immediately abandon all protocols	

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**.

3. Restart the Protocol



Place the basket into the retort.

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



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.



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.



 \bigcirc

Running Protocols

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 twobasket 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.

3. Update the Bottle Details





Select the bottle to update.

This enables the action options.

Tap Changed.







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.



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.

Managing Reagents

PELORIS 3 Reagent Replacement – Manual



bottles appear hatched on the Status screen.

protocol start (final threshold exceeded). loaded or running.

2. Empty and Replace the Reagent





Remove the bottle and safely Fill the bottle to the dispose of the used reagent. 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





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.

(1)

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

Lot number entry is optional. Tap **OK** to continue.

	Summary of changes	Lot Number
🥝 Bottle 6 - Chan	ged from 80% to 80% 80/20 Ethanol / IPA	None
	User name (min 3 characters)	
	User name (min 3 characters) Jane Doe	

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

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

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.



hose.



Connect the remote fill/drain Insert the hose into a stable container with sufficient capacity to avoid overflow.

3. Drain



Go to Reagents > Remote Fill/Drain.



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

Тар **ОК**.

4. Fill Preparation



Connect the remote fill/drain Insert into reagent container.





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

5. Fill

hose.



The following events occurred during the manua operation

84 - Remote fill complete

6004 - Reagent Management - St

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.



displayed when the fill is

complete.

Тар **ОК**.

Confirm or change new reagent details when prompted.

Optional: Enter lot number when prompted.

Enter your user name when prompted.



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



Managing Reagents

PELORIS 3 – Wax Replacement

1. When to Replace



Wax roaching last run ithin its Final Concentration **OR** When warned at the start of the protocol.

2. Preparation



chambers appear hatched

on the Status screen.

Ensure wax is molten then close the lid.



Connect wax waste line.



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 Add wax directly to the or pellets). Use the LLS tool wax plug to ensure wax does handling and rapid melt. not go down the wax vent.

bath. Use Parablocks for easy

5. Update Station State

Status	Reagents	Admin	Settings		enance		hu 27 Jul O	16:46 perator ひ	Lei
REAGEN	T STATIONS	1	Sinc	e changed					
Station	Туре	Conc.	Cassettes	Cycles	Days	Temp.	State	Lot Number	Prev
w1	Wax	91.8%	600	4	13	65.0 °C	Full	None	
142	Wax	84.3%	150	1	11	65.0 °C	Full	12345	
w3	Wax	92.4%	300	2	13	65.0 °C	Full	None	Reager bottles
w4	Wax	92.3%	450	3	13	65.0 °C	Full	None	Wax chambe

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.

REAG	SENT STATIONS		Sinc	e changed					
Station	Туре	Conc.	Cassettes	Cycles	Days	Temp.	State	Lot Number	Prev
w1	Wax	92.0%	300	2	1	65.0 °C	Full	None	
w2	Wax	100.0%	0	0	0	65.0 °C	Full	12345	
w3	Wax	99.8%	150	1	1	65.0 °C	Full	None	Reagent bottles

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.

Maintenance

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.



acid instead

Maintenance

PELORIS 3 Transferring Incident Reports or Log Files

1. Select Incident Reports or Log Files

Choose the file type required:

Status	Resperts	Admin	Settings N	takriteriance %		t Leica	6			
ERVICE	SETTINGS							Enter the inci	dent time	
Unit Informa	5on							21:37:37	_	
Νατο	Pelaris-451	15192						Sunday 30 /		Ď
Location	Leica						1	2 3		
Model	Peloris 120	v					4	5 6		
Serial ram	45115192 120 V		Software 0.S.	6.3, sp 0.0, build 9500	Export files	Incident report	7	8 9	Day	• Di
HistoCore I-			FPGA femware version CPLD femware	1.28			0	Clear		
Dimware ve Upgrade			CPLD Innovane version Software version Translation	1.10 3.3.0000.231 1007	Import/Export File			ок		ance

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

Tap Incident Report.

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

	Reaperts	Admin 🚯	Settings	Maintenance %	Mon 1 May 10:06 Operator	Leice					
VENTI	LOG - BY TIN	1E				-					
Code	Time			Description							
	Man 1 May 17 09.44	No Wee	Approaching last run No Wax within its Final Concentration Breahold, Replace Wax chember 2 with Wax								
12	Fri 12 May 17 12:27	Carbor	Carbon filter age threshold exceeded Replace filter and reset litter age in the software.								
	Pri 12 May 17 07:35	Approac	Approaching last run No Wax within its Final Concentration threshold. Replace Wax chamber 2 with Wax								
	Fit 12 May 17 04:54	Protocol	Protocol Quick Clean in Relat A completed successfully in 00.34.54 0 cassettes processed. Campover setting: 0								
	Fri 12 May 17 04:14		Empty the condensate bottle.								
	Fri 12 May 17 03:25		Reagent Management - Station properties reset , Ballis D= IPA, concentration=R0, system=2, cassettes=200, days=11								
	Fri 12 May 17 03:25		Remote fill complete: Retort A. Bottle 9								
	Thu 11 May 17 23:41		Rem	ole drain complete Re	ort A, Bottle 9	Next					

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.

45119999 20170207-102543

20170209-090733

ConfigFiles
logs

Protocols

StateFiles

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.

IncidentLogs_45119999_201702

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.

¢x...

cidentings Generate 2040.07905033.cg 0.5



When to transfer log files:

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

PELORIS 3 Abandoning Protocols

Abandoning a Single Protocol



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

	Instrument paused	
	04:58	
	Time remaining until auto-resume	
	Access Retort B - To inspect or add more cassettes	
_	Resume All - Resume protocols running on A and B	.
	Abandon Protocol B - This will stop the protocol running in retort B	
	Vent Wax - Vent the wax baths	
	Emergency Stop A and B - Only use to immediately abandon all protocols	
	ок	

On the **Instrument paused** dialog box,

This now has a tick and is highlighted

(i)

tap the Abandon Protocol option.

 Instrument paused

 <t

To confirm, tap **OK**.

 \otimes

Follow the prompts to drain the retort and remove the cassettes. When completed, close the retort and start the quick clean.

Leica

Factory 1 hr Xylene Free

 \bigotimes

Abandoning Both Protocols using Emergency Stop from the Instrument Paused Dialog

in blue. Tap **OK**.



 Image: Strategy of the strate

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.



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

S) 🖡	🚯 🚯	Sur Sur	Porvisor U Leico
PORTS			
Run Details Report	User Action Report	Protocol Usage Report	Reagent Usage Report
		Report	Report
Details of protocol runs since the beginning of last month	Details of user actions since the beginning of last month	Protocols and cassettes processed over the past 5 years	Volume of reagents used on the instrument over the past 5 years

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

User names are visible in Supervisor mode.

Status	Reagents	Admin	Settings Maintenand	^{ce} Wed	3 May 03:10 Supervisor	Ċ	Le
ROTOC	OL RUNS			& basket/lot	D	Clear	
END DATE	END TIME	RETORT	PROTOCOL NAME	# CASSETTES	S STARTED BY	- I	
02-MAY-201	17 11:55	A	Factory 1 hr Xylene Free	150	wes		
02-MAY-201	06:23	A	Quick Clean	0	Wes		•
02-MAY-201	06:23	В	Quick Clean	0	Jane Doe		Down
02-MAY-201	04:48	A	Factory 4 hr Xylene Free	150	Wes	_	
02-MAY-201	17 01:55	В	Factory 4 hr Xylene Free	150	Jane Doe	La	ast 30 c
02-MAY-201	00:34	A	Factory 4 hr Xylene Free	150	Jane Doe		
01-MAY-201	7 23:31	A	Factory 2 hr Xylene Free	150	Jane Doe		
01-MAY-201	17 15:15	В	Quick Clean	0	Jane Doe		
01-MAY-201	17 14:14	A	Factory 1 hr Xylene Free	150	Jane Doe		
01-MAY-201	17 14:14	в	Factory 1 hr Xylene Free	150	Jane Doe		
01-MAY-201	17 13:39	A	Factory 1 hr Xylene Free	150	wes		
01-MAY-201	09:25	В	Quick Clean	0	wes		

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**.

(III)	ť	C a c a c a c a c a c a c a c a c a c a	<u> </u>		Supervisor	Leic
RUN DET	TAILS REPO	RT		Ser	al number: 45nnnnn	
1 Fac	tory 1 hr Xyle	ne Free			Validated	Up
RUN	STARTED	RUN ENDED	USER	RETORT	# CASSETTES	
29/04/201	29/04/2017 12:38 29/04		wes	A	150	Down
Basket1			Basket2		Basket3	
00024			00033		-	
Basket1	image		Basket2 Image			
STEP	STATION	TYPE	LOT#	CONCENTRATION	DURATION (MINS)	Back
1	1	Formalin	-	100.0%	1	
2	3	85% Ethanol	-	64.1%	1	Export
3	5	85% Ethanol	-	83.1%	6	
4	6	80/20 Ethanol / IPA		98.5%	1	
5		80/20 Ethanol / IPA		100.0%	6	

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.

Status	Reagents	Admin	Settings	Maintenance	Wed 3 May 04:50 Supervisor		Leica
USER AC	TIONS R	EPORT					
DATE	TIME	USER	ACTION				
02-MAY-2017	11:15	wes	Started run -	Factory 1 hr Xylene Free			Ūρ
02-MAY-2017	05:43	wes	Started run -	Quick Clean			
02-MAY-2017	05:42	wes	Started run -	Quick Clean			Down
02-MAY-2017	00:47	wes	Started run -	Factory 4 hr Xylene Free			
01-MAY-2017	23:46	Jane Doe	Started run -	Factory 4 hr Xylene Free		_	
01-MAY-2017	21:43	Jane Doe	Started run -	Factory 4 hr Xylene Free			Time
01-MAY-2017	21:36	Jane Doe	Started run -	Factory 2 hr Xylene Free		_ (
01-MAY-2017	14:39	Jane Doe	Started run -	Quick Clean			Action
01-MAY-2017	14:05	Jane Doe	Started run -	Factory 1 hr Xylene Free			
01-MAY-2017	14:02	Jane Doe	Started run -	Factory 1 hr Xylene Free			
01-MAY-2017	03:51	wes	Started run -	Quick Clean			

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.

03-MAY-2017	10:28	Jane Doe	Maintenance: Check bottle fill levels incl. condensate	- Op
30-APR-2017	04:28	Jane Doe	Maintenance: Check bottle fill levels incl. condensate	
03-MAY-2017	10:28	Jane Doe	Maintenance: Check wax fill levels	Down
30-APR-2017	04:28	Jane Doe	Maintenance: Check wax fill levels	_
03-MAY-2017	10:28	Jane Doe	Maintenance: Clean Liquid Level Sensors	
30-APR-2017	04:28	Jane Doe	Maintenance: Clean Liquid Level Sensors	Time
03-MAY-2017	10:29	Jane Doe	Maintenance: Clean bottles, check bottle connectors	
30-APR-2017	04:28	Jane Doe	Maintenance: Clean bottles, check bottle connectors	Action
03-MAY-2017	10:29	Jane Doe	Maintenance: Clean retort and stirrer	Action
30-APR-2017	04:28	Jane Doe	Maintenance: Clean retort and stirrer	
03-MAY-2017	10:29	Jane Doe	Maintenance: Clean screen and top surface of instrument	
30-APR-2017	04:28	Jane Doe	Maintenance: Clean screen and top surface of instrument	
03-MAY-2017	10:28	Jane Doe	Maintenance: Clean seals (wax bath & retort) and air vents	Expo
30-APR-2017	04.28	Jane Doe	Maintenance: Clean seals (wax bath & retort) and air vents	

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.



PELORIS 3 Reports

Protocol Usage Report

Status Rea	agents Admin	Settings M	aintenance	Wed 3 May 02 Superv		Leica
REPORTS						
Run Details	Report	User Action Report	Protoco	I Usage port	Reagent Us Report	age
Details of pro runs since beginning o month	the si	etails of user actions nee the beginning of last month	cassettes	ols and processed ast 5 years	Volume of rea used on t instrument ov past 5 yea	he er the

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.

Status Reagents	Admin	Setting:	s Main	tenance	Wed	I 3 May 2 2 Superv		Leic
PROTOCOL AND (CASSETTE	E REPOR	T - PRE	EVIEW				
# RUNS	MAY-17	APR-17	MAR-17	FEB-17	JAN-17	DEC-16	NOV-16	Up
Factory 1 hr Xylene Free	0	2	0	0	0	0	0	Op
Factory 4 hr Xylene Free	2	0	0	0	0	0	0	
Total	2	2	0	0	0	0	0	Down
# CASSETTES	MAY-17	APR-17	MAR-17	FEB-17	JAN-17	DEC-16	NOV-16	
Factory 1 hr Xylene Free	0	300	0	0	0	0	0	Monthly
Factory 4 hr Xylene Free	300	0	0	0	0	0	0	wonuny
Total	300	300	0	0	0	0	0	Weekly
# CASSETTES PER RUN	MAY-17	APR-17	MAR-17	FEB-17	JAN-17	DEC-16	NOV-16	
Factory 1 hr Xylene Free	0	150	0	0	0	0	0	Daily
Factory 4 hr Xylene Free	150	0	0	0	0	0	0	
Total	150	150	0	0	0	0	0	
								Export

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.

REAGENT CHANG	E REPOF	RT - PRE	VIEW					
REAGENT (Ltr)	MAY-17	APR-17	MAR-17	FEB-17	JAN-17	DEC-16	NOV-16	Up
80/20 Ethanol / IPA	0	20.0	0	0	0	0	0	Up
85% Ethanol	0	15.0	0	0	0	0	0	
Cleaning Ethanol	0	15.0	0	0	0	0	0	Down
Cleaning Xylene	0	5.0	0	0	0	0	0	
Ethanol	0	40.0	0	0	0	0	0	
Formalin	0	10.0	0	0	0	0	0	
IPA	5.0	25.0	0	0	0	0	0	
Wax	0	5.0	0	0	0	0	0	Weekly
Waxsol	0	10.0	0	0	0	0	0	
Xylene	0	20.0	0	0	0	0	0	Daily

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

Gather information

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



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.



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

What to do when a protocol is abandoned



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

» Examine the Run Details Report (Admin > Reports > Run Details Report).

» Examine the event logs (Admin > Event Logs).

- » 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.

\bigcirc

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.



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.



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.