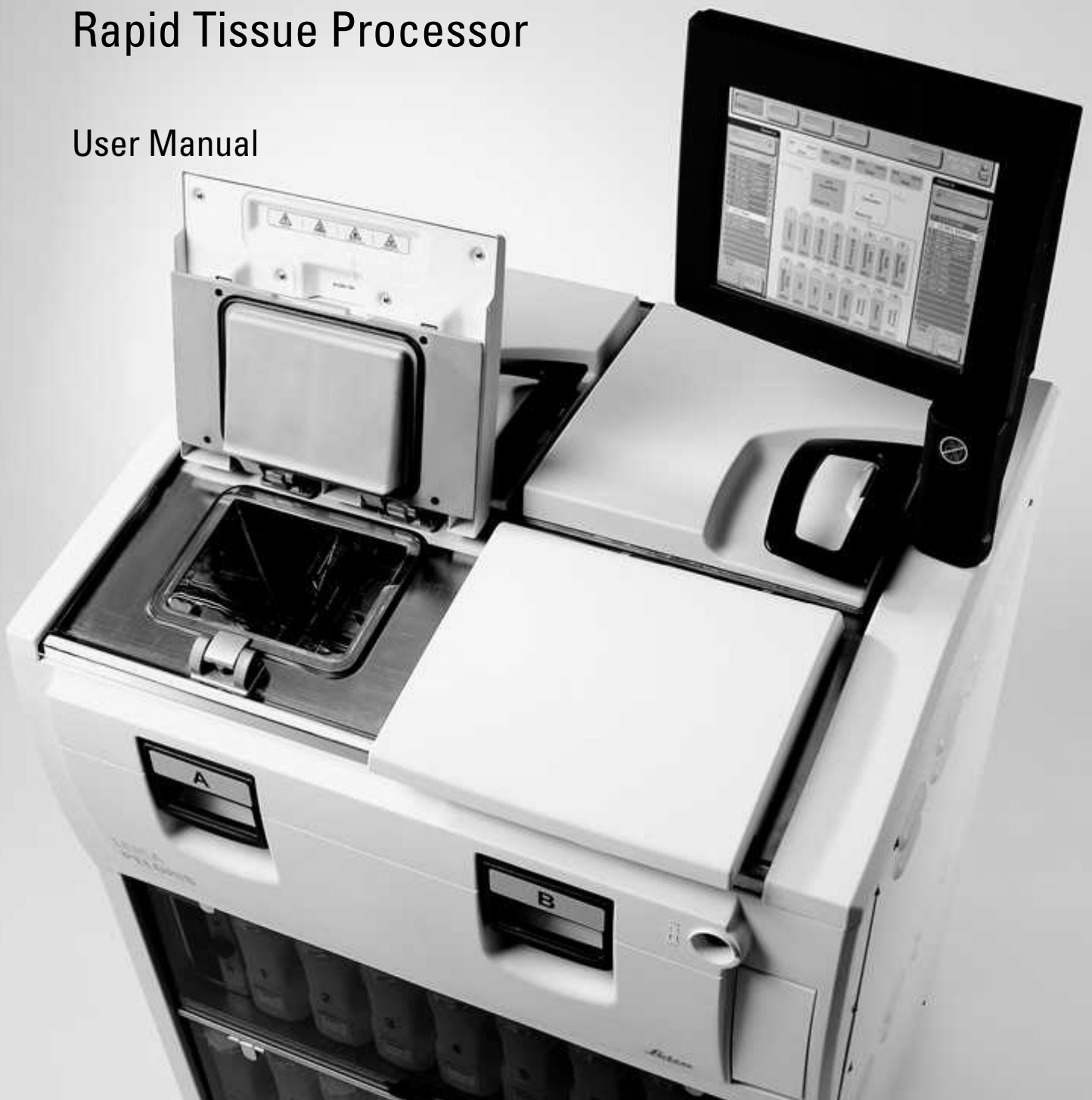Advancing Cancer Diagnostics
Improving Lives

PELORIS
PELORIS II

Rapid Tissue Processor

User Manual

Legal Notices

Intended Use Statement

The PELORIS dual retort rapid tissue processor prepares tissue samples for sectioning by transforming fixed samples into wax embedded samples. This is achieved by exposing the tissue samples to a sequence of reagents in the processing retorts.

Trademarks

Leica and the Leica logo are registered trademarks of Leica Microsystems IR GmbH and used under license.

PELORIS, PELORIS II, Waxsol, Parablocks, ActivFlo and RemoteCare are trademarks of Leica Biosystems Melbourne Pty Ltd ACN 008 582 401. Other trademarks are the property of their owners.

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Manufacturer

Leica Biosystems Melbourne Pty Ltd
495 Blackburn Rd
Mt. Waverley VIC 3149
Australia

Important Information for All Users

<table>
<tr><td rowspan="4">⚠️</td><td>Persons operating the PELORIS tissue processor MUST:</td></tr>
<tr><td>● Follow the instructions for use exactly as described in this 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.</td></tr>
<tr><td>● Receive sufficient training to ensure that the instrument is used in accordance with this user manual.</td></tr>
<tr><td>● Be aware of any potential hazards or hazardous procedures before operating the instrument as described in this user manual.</td></tr>
</table>

The term "Leica Biosystems" when used in text in this document refers to Leica Biosystems Melbourne Pty Ltd.

The term "PELORIS" when used in text in this document refers to PELORIS and PELORIS II.

Due to a policy of continuous improvement, Leica Biosystems reserves the right to change specifications without notice.

Warranty claims can be made only if the system has been used for the specified application and operated according to the instructions in this document. Damage resulting from inappropriate handling and/or misuse of the product will invalidate the warranty. Leica Biosystems cannot assume liability for any such damage.

Only trained staff are to remove any covers or parts from the processor, and only if instructed within this manual. Repairs must only be carried out by qualified service personnel authorized by Leica Biosystems.

Revision Record

Rev.	Issued	Detail
M01	September 2012	Rebranding
M02	February 2016	Rebranding Added Russian Federation contact details Added note regarding decommissioning and disposal
M03	June 2016	Regulatory Notices (updated)

Contacting Leica Biosystems

For service or support contact your local representative or see www.LeicaBiosystems.com

Russian Federation:

"BioLine LLC" (Pinsky lane 3 letter A, 197101, Saint Petersburg, the Russian Federation).

e-mail: main@bioline.ru

Tel: (812) 320-49-49

Fax: (812) 320-49-40

Service Hotline: 8-800-555-49-40

Software License Terms

1   Defined terms & interpretation

1.1   Defined terms

In this agreement:

"Leica Biosystems" includes Vision BioSystems Pty Ltd ACN 008 582 401, prior to changing its company name, and Leica Biosystems Melbourne Pty Ltd ACN 008 582 401 after changing its name.

"Confidential Information" means all information:

(a)   treated by Leica Biosystems as confidential or of its nature confidential; and

(b)   disclosed by Leica Biosystems to the Licensee or of which the other party becomes aware,

except information:

(c)   the other party creates independently of Leica Biosystems; or

(d)   that is public knowledge (otherwise than as a result of a breach of confidentiality by the Licensee or any of its permitted disclosees).

"Designated Computer" means the computer or microprocessor controlled unit supplied by Leica Biosystems to the Licensee under the Supply Agreement or otherwise recommended for use by Leica Biosystems.

"Documentation" means the manuals, user documentation, proprietary notices, product catalog, website notices and bulletins generally supplied by Leica Biosystems with or relating to the Software.

"Effective Date" means the date the Goods, as defined in the Supply Agreement, are delivered by Leica Biosystems.

"Intellectual Property" means all existing and future intellectual property rights including:

(e)   patents, copyright (including all copyright and software), software and associated documentation including the specific design and structure of individual programs, registered designs, trade marks, proprietary documentation and notices, and any right to have information or know-how kept confidential; and

(f)   any application or right to apply for registration of any of the rights referred to in **paragraph (e)** above.

"Licensee" means the Purchaser or lessee of the Goods containing the Software, or, where the Licensee is a distributor of the Goods containing the Software, the end user of the Goods containing the Software.

"Licensor IP" means all Intellectual Property relating to:

(a)   the Software and Documentation;

(b)   any modifications, upgrades, new versions or new releases of the materials referred to in **paragraph (a)** above; and

(c)   other works created by Leica Biosystems in the course of, or as a result of, performing this Agreement.

"Release" means each release of a new Version of the Software."

"Software" means any program, firmware or electronic files that provides instructions or data to a computer or microprocessor and, shall for the purposes of this agreement, include original versions, modified versions, upgrades, updates, bug fixes, and backup copies.

"Supply Agreement" means the agreement between the Licensee and Leica Biosystems, or where the Licensee is not a direct customer of Leica Biosystems, between Leica Biosystems' distributor and Leica Biosystems, for the sale, lease or use of the Goods.

"Third Party Material" means any Material owned by a third party that is not a Related Body Corporate (as that term is defined in the Corporations Act 2001 (Cth)) of Leica Biosystems.

1.2   Other definitions

In this agreement, "Goods", "Purchaser", and "Leica Biosystems" have the same meaning as in the Supply Agreement.

2   Grant of licence

2.1   Licensee gives consent

The Licensee agrees to be bound by all the terms of this License by downloading or installing the Software, or by agreeing to purchase, lease or otherwise use the Software or the Goods containing the Software.

2.2   Leica Biosystems grants license

Subject to this agreement, Leica Biosystems grants the Licensee a non-transferable, non-exclusive license to use the Software and Documentation for its internal business purposes in accordance with the terms of this agreement.

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The Licensee must:

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   (i)   laboratory practices that are consistent with industry practice;

   (ii)   all applicable laws, regulations, guidelines and decisions of judicial or regulatory bodies;

   (iii)   any patent or other proprietary rights of third parties; and

   (iv)   as envisaged by the Documentation, and this agreement;

(b)   not install, or procure the installation of, any software on the Designated Computer without Leica Biosystems' prior written consent;

(c)   not copy all or part of the Software or Documentation, or allow all or part of the Software or Documentation to be copied (other than one copy of the Software for backup purposes), without obtaining Leica Biosystems' prior written permission;

(d)   not publish, distribute or commercialise all or part of the Software or Documentation, or any adaptation, modification or derivative of the Software or Documentation;

(e)   not sell, rent, lease, sub-license, assign or transfer all or part of the Software or Documentation or any of its rights under this agreement;

(f)   not use the Software or the Documentation for the benefit of any third party, or disclose the Software or the Documentation to any third party, except with Leica Biosystems' prior written consent;

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(h)   not decompile, decrypt, reverse engineer, disassemble or otherwise reduce the Software to human readable form to gain access to trade secrets or confidential information in the Software or permit third parties to do the same; and

(i)   comply with any reasonable directions of Leica Biosystems from time to time in relation to the installation or use of the Software and the Documentation.

4   Intellectual property

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The Licensee must not alter or remove any notices of proprietary rights, any rights management information or any serial numbers appearing on, attached to or incorporated in Licensor IP or any copies thereof, and must not use or attempt to register any trademark, trade name, business name or company name which is confusingly similar to any trademark or trade name of Leica Biosystems.

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The Licensee must:

(a) notify Leica Biosystems immediately if it knows of or suspects any unauthorised use, or violation, of any Licensor IP; and

(b) provide promptly, at its cost, all assistance reasonably requested by Leica Biosystems to protect the relevant rights in Licensor IP and prosecute any claims arising from such uses or violations.

4.4 Compliance

The Licensee must comply, at all times, with any terms and conditions relating to the Third Party Material notified to the Licensee by Leica Biosystems and/or the third party supplier of that Third Party Material.

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5.1 New releases and new versions

Leica Biosystems may, at its sole discretion, provide the Licensee with new Releases or new Versions of the Software.

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If requested by the Licensee to do so, Leica Biosystems, its designated distributor or agent may, at its sole discretion, install a new Release or new Version of the Software on the Designated Computer.

5.3 Downloading of data

Leica Biosystems, or its designated agent may, at its sole discretion, download data that has been generated by the use of the Software by the Licensee as a means of debugging Software faults and otherwise analyzing the performance of the Software or Goods containing the Software supplied by Leica Biosystems under the Supply Agreement.

6 Back up and security of data

It is the Licensee's responsibility to:

(a) perform regular backups of data and to store these; and

(b) provide contingency plans for the event of a failure of any sort (eg: fire, flood, and theft);

and Leica Biosystems has no liability (including for negligence) for any loss whether direct or indirect, that could have been prevented by the Licensee performing the above responsibilities, or which occurs as a consequence of inadequate back up, computer viruses or the ongoing functions of computer hardware (including backup hardware), whether supplied by Leica Biosystems or any other supplier.

7 Confidentiality and privacy

7.1 Use and disclosure

The Licensee must, in relation to the Confidential Information:

(a) keep it confidential;

(b) use it only as permitted under this agreement and only disclose it:

  (i) to employees, contractors and agents that have a need to know and who have undertaken to comply with this clause 7; or

  (ii) to the extent (if any) the Licensee is required by law to do so; and

(c) promptly comply with any request by Leica Biosystems to return or destroy the Confidential Information unless required by law to be retained.

7.2 Recipient's obligations

The Licensee must:

(a) safeguard the Confidential Information from unauthorised access or use; and

(b) notify Leica Biosystems of, and take all steps to prevent or stop, unauthorised copying, use or disclosure.

7.3 Privacy

In performing its obligations under this agreement, the Licensee must comply, and use all reasonable efforts to ensure that its contractors comply, with all applicable legislation relating to privacy of personal information.

8 Exclusions and limitations

8.1 Acknowledgments

The Licensee acknowledges that:

(a)   it has selected the Goods from a range of products and has satisfied itself that the Goods meet the Licensee's requirements;

(b)   no oral or written information, representation or advice given by or on behalf of Leica Biosystems, other than as contained in this agreement, creates a warranty or in any way increases the scope of this agreement; and

(c)   unless expressly agreed otherwise in writing, the Licensee has not relied on any information, representation or advice given by or on behalf of Leica Biosystems in selecting the Goods; and

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8.2 Exclusion of implied terms

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8.3 Non-excludable conditions

To the extent permitted by law, Leica Biosystems' liability for any breach of any Non-Excludable Condition is limited to:

(a)   in the case of services, the resupply of the services or the cost of having the services supplied again (at Leica Biosystems' option); and

(b)   in the case of goods, the lowest of the cost of replacing the goods, acquiring equivalent goods or having the goods repaired.

8.4 Exclusion of liability

To the extent permitted by law, Leica Biosystems excludes all liability (including liability for negligence) for:

(a)   any indirect or consequential expenses, losses, damages or costs (including, without limitation, loss of profits, loss of revenue, loss of or damage to data, failure to achieve anticipated savings or benefits, and any third party claims) incurred by or awarded against the Licensee under or in any way connected with this agreement or the use of the Software or Documentation;

(b)   without limiting the foregoing, any expenses, losses, damages or costs incurred by or awarded against the Licensee arising directly or indirectly in respect of clinical (including without limitation diagnostic, prescription and other treatment) errors made while using, or otherwise associated with the use of, the Software or Documentation; and

(c)   the operation or performance of, and any expenses, losses, damages or costs suffered or incurred by the Licensee as a result of its use of, any Third Party Material.

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To the extent permitted by law, Leica Biosystems limits its total aggregate liability (including liability for negligence) for any damage arising under or in any way connected with this agreement or the use of the Software to the price paid by the Licensee for the Software or the Goods containing the Software under the Supply Agreement.

9   Indemnity

The Licensee indemnifies Leica Biosystems against all expenses, losses, damages and costs (on a solicitor and own client basis) incurred by or awarded against Leica Biosystems arising directly or indirectly from or in relation to:

(a)   any use of the Software not in compliance with this agreement;

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(c)   the Licensee's infringement of Leica Biosystems' Intellectual Property rights;

(d)   clinical (including without limitation diagnostic, prescription and other treatment) errors made while using, or otherwise associated with the use, of the Software or Documentation;

(e)   any failure by the Licensee to comply with laboratory practices that are consistent with industry practice, laws, guidelines or decisions in the handling or use of the Software;

(f)   the Licensee's negligent acts or omissions; and/ortany other use or misuse of the Software by the Licensee.

10   Term and termination

10.1   Term

This agreement commences on the Effective Date and continues until terminated in accordance with this agreement.

10.2   Termination

(a)   The Licensee may terminate this agreement at any time by destroying all copies of the Software and Documentation.

(b)   The Licensee's rights under this agreement will terminate immediately without notice from Leica Biosystems if the Licensee fails to comply with any provision of this agreement or if the Licensee does not strictly observe the terms of payment under the Supply Agreement, and on termination, the Licensee must destroy all copies of Software and Documentation in its possession or control.

10.3   Accrued rights and remedies

Termination of this agreement under this **clause 10** does not affect any accrued rights or remedies of either party.

10.4   Survival

Clauses 4 (Intellectual property), **7** (Confidentiality and privacy), **8** (Exclusions and limitations), **9** (Indemnity), **10.3** (Accrued rights and remedies), **10.4** (Survival), **11** (Force majeure) and **12** (General) continue after termination of this agreement.

11   Force majeure

Neither party will be liable for any delay or failure to perform its obligations pursuant to this agreement (other than on obligation to pay money) if that delay is due to Force Majeure. If a delay or failure of a party to perform its obligations is caused by or anticipated due to Force Majeure, the performance of that party's obligations will be suspended. Either party may terminate this agreement if a Force Majeure persists for a continuous period of 90 days.

12   General

12.1   Severance

Part or all of any provision of this agreement that is illegal or unenforceable may be severed from this agreement and the remaining provisions will continue in force.

12.2   Entire agreement

This agreement (including any additional terms notified to the Licensee by Leica Biosystems) constitutes the entire agreement between the parties and supersedes any prior representations, warranties, understandings or agreements that relate to the same subject matter.

12.3   Variation

This agreement may only be amended by agreement in writing between the parties.

12.4   Governing law

This agreement is governed by the laws of the State of Victoria, Australia, and the parties submit to the non-exclusive jurisdiction of the courts in that State.

Safety Notices

The PELORIS tissue processor is designed to provide safe, trouble-free operation when used in accordance with this document. Follow all safety precautions to avoid personal injury, damage to patient samples, and damage to the instrument. Clean and maintain the instrument as described in Chapter 7, Cleaning and Maintenance.

The Safety Notice Types section below describes the types of safety notices in the manual.

The General Warnings and Cautions section has general warnings for the PELORIS instrument – other notices appear in relevant sections in the manual.

Safety Notice Types

Safety notices in this manual are either warnings or cautions.

Warnings

Warnings are notifications of hazards that could lead to personal injury to PELORIS users or people in the vicinity of the instrument.

Warnings are also used when there is the possibility of damaging patient tissue samples.

Warnings in this manual use symbols with a red border, as illustrated below:

TOXIC HAZARD
There is danger of ingestion, inhalation or skin contact with toxic material.

HEAT HAZARD
There is danger of burns.

CHEMICAL HAZARD
There is a danger of exposure to corrosive chemicals.

ELECTRICAL HAZARD
There is danger of electric shock.

GENERAL HAZARD
There is danger of personal injury or damage to patient tissue samples.

Cautions

Cautions are notifications of hazards that could lead to damage to the PELORIS instrument or other equipment.

Cautions in this manual use symbols with a yellow border, as illustrated below:

CAUTION
There is danger of damage to the PELORIS instrument or other equipment.

General Warnings and Cautions

Persons operating the PELORIS 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

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.

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.

Instrument Setup

WARNING

Do not use the instrument without installing the drip tray.

WARNING

The instrument must be installed and configured by an approved service representative.

WARNING

Always use suitably rated lifting equipment (such as a trolley or forklift) when moving a PELORIS tissue processor more than a few meters.

Only use the instrument's castors to reposition an instrument for service access.

Electrical Hazards

WARNING

The PELORIS tissue processor must be connected to an earthed mains power outlet socket.

WARNING

Dangerous voltages are present inside the PELORIS tissue processor. Only service technicians approved by Leica Biosystems should remove any of the instrument's covers or access the internal components.

WARNING

The instrument's operating voltage is factory set and it must not be changed.

Severe damage will occur if an instrument is connected to an incorrect power supply voltage.

WARNING

Do not pull out the mains cable whilst the instrument is operating unless there is an emergency situation and both the front panel power button and the mains wall switch are inaccessible.

WARNING

Locate the instrument so that either the mains wall outlet or the instrument's appliance inlet socket is accessible. You must be able to disconnect the mains power cable without moving the instrument.

WARNING

Do not move the instrument unless the power cable is disconnected.

Reagents

WARNING

Chloroform vapors may cause severe injury, incapacitation, or death.

When using chloroform with the PELORIS tissue processor, Leica Biosystems recommends that an external fume extraction system be installed. Chloroform vapors may accumulate during normal operation or in the unlikely event of a spill. The extraction system must keep these vapors below dangerous levels.

Never open a retort that contains chloroform or chloroform residue.

WARNING

Do not heat reagents above their boiling points. Boiling reagents will release large quantities of fumes that may overload the internal carbon filter or (if fitted) the external filtering system. Boiling reagents are also likely to lead to excessive pressures within the instrument, increased reagent contamination and reagent spills.

Reagent boiling points are lower when in a retort operating with a vacuum or with pressure/vacuum cycling.

WARNING

Handle and dispose of reagents and condensate in accordance with all relevant procedures and government regulations that apply at the laboratory site.

WARNING

Do not use fixatives containing picric acid as picric acid is explosive when dry.

WARNING

Molten wax is hot and may cause burns. Use caution when handling wax and removing baskets.

CAUTION

Do not use acetone or other ketones. These damage the instrument's valves.

CAUTION

Do not use reagents containing corrosive chemicals such as mercuric salts, picric acid, nitric acid and hydrochloric acid.

Regulatory Notices

In Vitro Diagnostics Symbol

IVD

EU Representative

EC | REP
Leica Biosystems Newcastle Ltd, Balliol Business Park, West Benton Lane, Newcastle upon Tyne, NE12 8EW, United Kingdom

FCC Compliance

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 subpart B of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

To maintain compliance use only the cables supplied with the instrument.

Warning: Any changes or modifications not expressly approved by Leica Biosystems could void the user's authority to operate this equipment.

CE Marking and European Union Notice

CE
The CE mark on the equipment indicates compliance with the EEC Directives for Electromagnetic Compatibility (2014/30/EU), Waste Electrical and Electronic Equipment (2012/19/EU), Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (2011/65/EU), and In Vitro Diagnostic Medical Devices (98/79/EC).

Declaration of Conformity

A "Declaration of Conformity" in accordance with the preceding directives and standards has been made and is on file at Leica Biosystems Melbourne Pty Ltd, 495 Blackburn Road, Mount Waverley, Victoria 3149, Australia, and Leica Biosystems Newcastle Ltd, Balliol Business Park, West Benton Lane, Newcastle upon Tyne, NE12 8EW, United Kingdom.

Instructions for in vitro diagnostic equipment for professional use

The IVD equipment complies with the emission and immunity requirements described in this part of the IEC 61326-2-6.

Warning: This equipment was designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may need to take measures to mitigate the interference.

The electromagnetic environment should be evaluated prior to operation of the device.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

Standards

IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1 General requirements
UL 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1 General requirements
CAN/CSA C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1 General requirements
IEC 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2 Particular requirements for the heating of materials
IEC 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2 Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1 General requirements
IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use – EMC requirements. Part 2-6 In Vitro diagnostic (IVD) medical equipment
FCC Part 15 Subpart B	Class A Unintentional Radiators
ISO 13485	Medical Devices - Quality management systems - Requirements for regulatory compliance

Computer regulatory requirements: UL Listed (UL 60950), IEC 60950 certified.

Contents

1

Introduction

The PELORIS rapid tissue processor is a dual retort tissue processor that offers fast, high quality tissue processing for histology laboratories. With reagent capacity sufficient to run the two retorts independently, it allows a high degree of scheduling flexibility. Intelligent software lets you configure the instrument to suit your laboratory's workflows while providing checks and restrictions that help you avoid mistakes that could damage tissue. The reagent management system closely tracks reagent condition. Depending on your setup, it uses this information to select the optimal reagent for each protocol step. It alerts you when to replace reagent so that quality is never compromised, at the same time ensuring you get full use of all reagents. The clear, intuitive, touch-screen interface makes loading and monitoring runs easy, and protocol configuration, reagent setup and other system settings are equally straightforward. And behind all this you have the support of Leica Biosystems, with years of experience developing top quality, industry-leading histology equipment.

Congratulations on your purchase of the PELORIS rapid tissue processor. We trust it will provide you with years of fast, efficient, high quality tissue processing.

This chapter has the following sections:

- 1.1 Summary of Chapters

- 1.2 Using the Software

- 1.3 Help

1.1 Summary of Chapters

- **Chapter 1, Introduction**: general introduction, chapter summary, general instructions for using the software, and help resources.

- **Chapter 2, Hardware**: descriptions of the main components of the PELORIS instrument.

- **Chapter 3, Running Protocols**: main steps for running protocols, further configuration options and scheduling, monitoring processing on the **Status** screen.

- **Chapter 4, Protocol Setup**: descriptions of protocol types and the reagent selection methods used; protocol validation and the carryover setting. Creating and editing protocols.

- **Chapter 5, Reagent Setup**: reagent groups, types and stations, and reagent management on the PELORIS. Setting up reagent types and stations in the software. Replacing reagents.

- **Chapter 6, Settings & Ancillary Operations**: basic instrument settings, independent operation of instrument components, event monitoring, alarms, and transfer of system files.

- **Chapter 7, Cleaning and Maintenance**: daily and as-required maintenance, accessories available from Leica Biosystems.

- **Chapter 8, Reference**: descriptions of the pre-defined protocols and recommended bottle configurations. Recommended reagent thresholds and reagent compatibility tables.

- **Chapter 10, Consumables and Accessories**: a list of PELORIS consumables and accessories with part numbers for easy ordering.

- **Chapter 11, Specifications**: system specifications.

1.2 Using the Software

Control all instrument functions from the touch-screen. This section describes basic touch-screen operation and how to navigate the software, with a summary of all the software screens. It also describes user access levels.

See sections:
- 1.2.1 Basic Operation
- 1.2.2 Navigation
- 1.2.3 Access Levels

1.2.1 Basic Operation

Buttons

Tap buttons to open menus, screens and dialogs, and to start and stop actions in the instrument. Enabled buttons are blue and appear raised. Selected buttons are orange and appear sunken. Disabled buttons are dimmed.
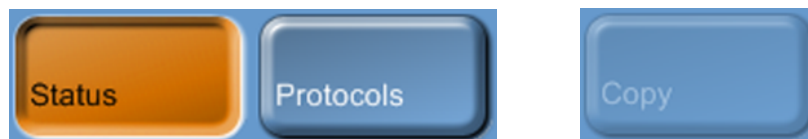
Figure 1. Button states—selected, available and unavailable

Icons

Icons are used to represent various PELORIS tissue processor elements including reagent stations and retorts. Selectable icons appear raised. A selected icon appears raised with a red outline. Nonselectable elements appear flat and are used for indication only. Select an icon by tapping it, as you would a button.
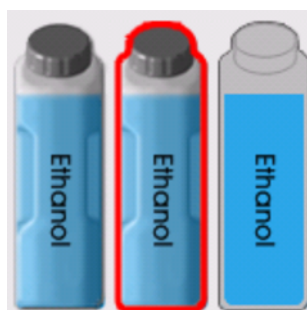
Figure 2. Reagent station—selectable, selected, not selectable

Tables

Tables display configuration information such as reagent station and protocol setup. You can edit some table cells but others are locked. The background color of locked cells is dimmed. Select editable table cells by tapping within the cell boundaries.
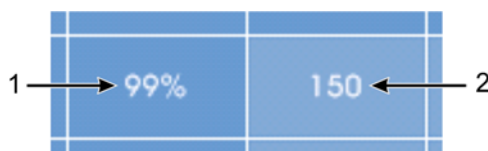
Figure 3. Table cells—editable (1) and locked (2)

Keypads

Keypads appear as needed to allow you to enter text and numbers. There are two types of keypad: alphanumeric (text and numbers) and numeric (numbers only). The keypads are analogous to a computer keyboard with on-screen buttons acting as keys (1). Enter text and numbers by tapping the appropriate buttons in order and use the **Caps Lock** button (4) or **Shift** button (5) to select upper or lower case characters. As you type, the characters you select are displayed in the text window (6). The alphanumeric keypad has a **Back Space** button (7) to delete the last character while all keypads include a **Clear** button (3) to remove all characters. When you have finished, tap the **Esc** button (2) to exit without saving or the **Enter** button (8) to confirm your entry.
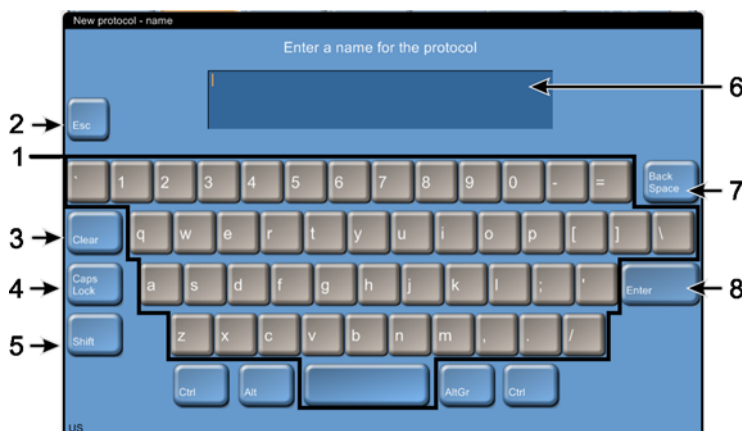
Figure 4. Alphanumeric keypad

1.2.2 Navigation

Navigate the software from the Function bar at the top of the screen.
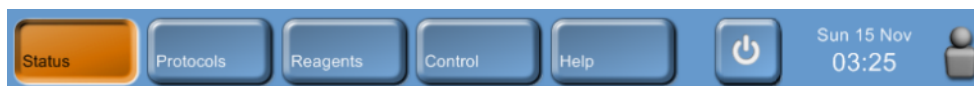
Figure 5. The Function bar

The Function bar is always visible, so you can always find the screen you want. Tap a button in the bar to change screens immediately or open a menu with buttons for a number of related screens.

Some screens have alternative "views" to divide the information presented. For example, the **Reagent stations** screen has two views, one each for bottle and wax chamber information. Use buttons on the screens themselves to move between the alternative views.

The table below lists all the screens in the PELORIS software with brief descriptions of the screen functions, and links to relevant sections of the manual.

Function bar button	Menu button	Screen purpose	Refer to:
Status	—	Load and run protocols, and view system status.	3.3 Status Screen
Protocols	—	Select, create, edit and manage protocols.	4.2 Creating, Editing and Viewing Protocols
Reagents	**Stations**	Set up reagent stations. You can also view the current reagent concentrations and wax bath temperatures.	5.3 Managing Reagent Stations
	Types	Manage your list of active reagent types.	5.2 Managing Reagent Types
	Remote fill/drain	Fill or drain reagent bottles and drain wax stations.	5.4 Replacing Reagents
	Manual operations	Manually control individual instrument components.	6.1.1 Manual Operations
	Management	Set basic reagent management options.	6.1.2 Reagent Management
Control	**Instrument settings**	Set options for time display, the carbon filter, fill levels and manual operation drip time.	6.2.1 Instrument Settings
	Device settings	Change sound, touch-screen and alarm settings.	6.2.2 Device Settings
	Service settings	View the instrument serial number and software versions.	6.2.3 Service Settings
	Event log	View all system events.	6.2.4 Event Log
	Alarms	Clear or silence active alarms.	6.2.5 Alarms
	Access level	Set the access level.	6.2.6 Access Level
	File transfer	Transfer files to and from the instrument.	6.2.7 File Transfer
Help	—	Open an HTML version of the user manual in the PELORIS software.	1.3 Help

1.2.3 Access Levels

PELORIS has two user access levels available to laboratory staff: operator and supervisor. Operators can carry out all routine tasks such as running protocols and replacing reagents. But operators cannot edit protocols or set bottle configurations – you must have supervisor rights for these actions. Supervisors also have greater rights to configure the system.

Some configuration settings displayed in the software require service level access to change. These are provided so you can view the settings, but you must contact your customer support representative if you want to change them.

You automatically begin at operator level when you start the software. Supervisors need a password to change to their access level on the access level screen (**Control** menu, **Access level**). If a supervisor does not interact with the software for more than 10 minutes the access level automatically reverts to operator.

An icon on the Function bar indicates your current access level.

Figure 6. Access level icons with operator (1) and supervisor (2)

1.3 Help

This user manual is provided in PDF format on a CD. It is also included (in HTML format) in the PELORIS software. Tap the **Help** button in the Function bar to open. Use buttons on the **Help** screen and links in the text to navigate the online Help.

2

Hardware

The PELORIS tissue processor is a free-standing processor with two retorts, sixteen reagent bottles and four wax chambers. A touch-screen mounted on the top of the instrument connects to an on-board computer for control of all instrument operations.

Touch-screen

Wax bath:
with four wax chambers

Two retorts

Power button

Reagent cabinet

Figure 1. PELORIS tissue processor – main features

This chapter describes the main features of PELORIS instrument.

See sections:

- 2.1 Switching On and Shutting Down
- 2.2 Retorts
- 2.3 Wax Bath
- 2.4 Reagent Cabinet
- 2.5 Touch-screen
- 2.6 External Vapor Removal Systems
- 2.7 Alarm Connections

2.1 Switching On and Shutting Down

Under normal conditions keep the PELORIS on at all times, even when idle for extended periods. Shut down for servicing or if moving the instrument.

Start

1. Plug the power cable into the mains socket and switch on the power.

2. Press the power button to start the instrument.

Normal Shutdown

For a normal shutdown the instrument must be idle with no protocols or other operations in progress:

1. Tap the shutdown button on the Function bar to shut down the software in an orderly manner.

2. Wait for the touch-screen to go blank then press the power button to remove all power from the instrument.

3. Switch the power off at the mains socket and pull out the power cable.

Emergency Shutdown

For emergency shutdown, press the power button immediately.

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

2.2 Retorts

The PELORIS tissue processor has two independent processing retorts with each retort holding up to 300 tissue samples in three PELORIS cassette baskets. Each retort operates independently with separate temperature, pressure/vacuum and stirrer speed control. The PELORIS tissue processor schedules resources to ensure both retorts operate efficiently with one set of reagents.

- 2.2.1 Opening and Closing Retort Lids
- 2.2.2 Fill Levels
- 2.2.3 Magnetic Stirrer
- 2.2.4 Cassette Baskets

2.2.1 Opening and Closing Retort Lids

Use the handles on the front of the instrument to latch and unlatch the retort lids.

Figure 2. Opening a retort lid

Always be aware of the contents, temperature and pressure of a retort before opening it. In some cases you may need to set the retort pressure and temperature manually before you can safely open it (see Venting a Retort below).

You may see a warning if the retort temperature is greater than either the retort empty access temperature (view on the **Reagent management** screen) or the safe access temperature associated with the reagent in the retort (set on the **Reagent types** screen).

The retort lids can be removed for cleaning (see Clean Lids and Seals in 7.2 Daily Tasks).

Some instruments have retort latch locks to disallow opening retorts when a protocol is running or the retort temperature is high. See your service representative if you have latch locks on your instrument.

WARNING

Retorts may contain very hot fluid that could cause severe burns. Wear suitable protective clothing and eyewear when opening a retort.

WARNING

Retorts may contain hazardous reagents and vapors. Wear suitable protective clothing and eyewear and ensure adequate ventilation when opening a retort.

WARNING

Take care not to knock retort lids when they are open. They could crush fingers or hands.

Venting a Retort

You must ensure there is no pressure or vacuum inside a retort before you open the lid. The retorts automatically vent at the start and end of a protocol, and also during a pause in a protocol. However, you may need to manually vent a retort if an automatic vent fails or if you wish to access a pressurized or evacuated retort at other times.

Use the **Manual operations** screen to manually vent the retorts. Set the **Pressure** button to **Ambient** for the retort that you want to open. You may need to wait up to one and a half minutes for the pressure to equalize. If your instrument has retort latch locks, use the **Lock/Unlock retort** button; it may take several cycles to successfully vent a retort.

If you leave a hot retort closed for an extended time, the air in the retort will cool and create a vacuum. You must then vent the retort before attempting to open the lid.

2.2.2 Fill Levels

Retorts can be filled with enough reagent for two or three cassette baskets. Supervisors set the required fill level on the **Instrument settings** screen (see Reagent Fill Levels in 6.2.1 Instrument Settings).

The two basket fill volume is 3.8 liters (1 gallon US) and the three basket fill volume is 5 liters (1.32 gallon US).

Use markings on the reagent bottles (Figure 3) and wax chambers (Figure 4) to ensure you have enough reagent to fill the retorts to the required level. Always keep the reagent or wax volumes well above the markings, but below the maximum (MAX) level. Reagent levels below the minimum will cause protocols to either fail or use a sub-optimal reagent sequence.
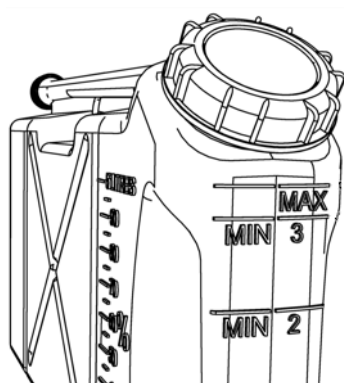
Figure 3. Bottle fill levels
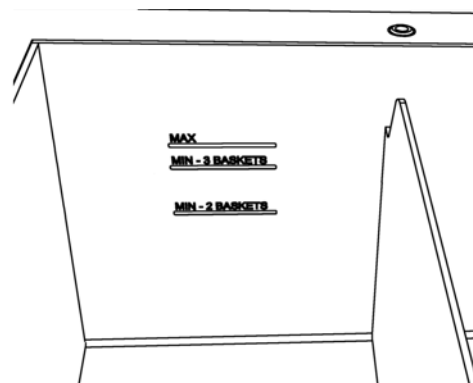
Figure 4. Wax chamber fill levels

Liquid Level Sensors
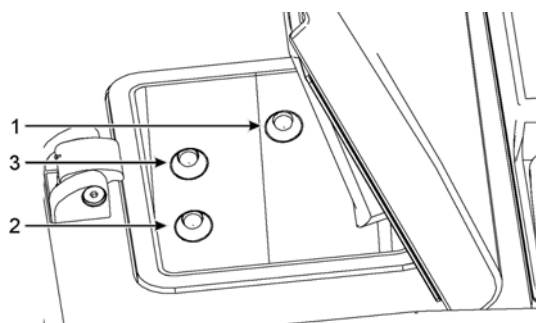
Figure 5. Liquid level sensors for—
maximum (1), three-basket (3) and two-basket (2) retort fill levels

Each retort has three liquid level sensors to monitor fluid levels. The two lower sensors monitor the two and three basket levels. The top, maximum, sensor responds to a fluid level of 5.3 liters. It serves a safety function ensuring no more reagent is pumped into the retort if triggered.

The sensors may occasionally be affected by a buildup of condensation or deposited material. If this occurs the software will direct you to wipe the appropriate sensor. Always ensure the sensors are kept clean as part of regular retort cleaning (see Clean Retorts in 7.2 Daily Tasks).

2.2.3   Magnetic Stirrer

Each retort has as magnetic stirrer that stirs the reagent or wax to ensure temperature consistency and good tissue penetration. The stirrer is driven by a magnetically-coupled external motor. The stirrer speed can be controlled for each protocol step and is easily removed for cleaning (see Clean Retorts in 7.2 Daily Tasks).
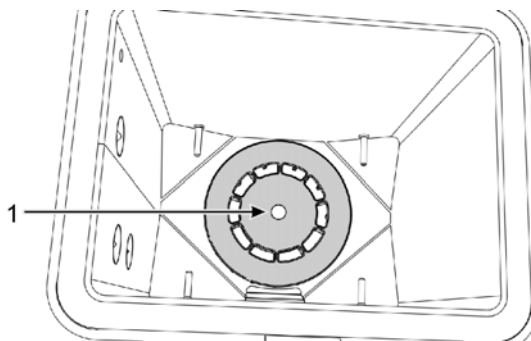
Figure 6. Magnetic stirrer (1)

2.2.4   Cassette Baskets

There are two PELORIS basket types: the configurable high-capacity basket that accommodates the maximum number and type of cassettes; and the spaced basket that ensures optimal reagent flow.

The high-capacity cassette baskets accept most common cassette types and include configurable dividers that allow for different cassette sizes and packing densities.

The spaced baskets include dividers that ensure optimum reagent flow with minimal carryover. This basket type accepts 72 standard cassettes. Spaced baskets must be used for all xylene-free protocols.

Cassette baskets stack into the retorts with the lids upwards and handles dropped flat. Make sure the first basket sits flat on the rack on the pins at the bottom of the retort (Figure 8). Stack additional baskets so they sit flat on the lower ones – crooked baskets can leave cassettes exposed, damaging the tissue in them.

Figure 7. Placing a basket into a retort
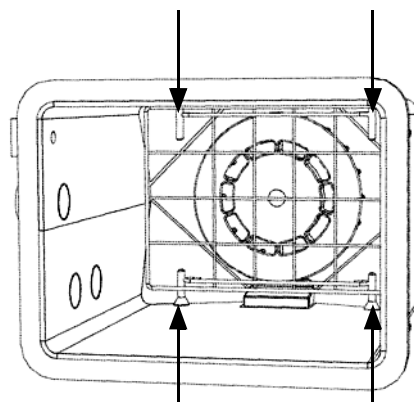
Figure 8. Retort pins

> ⚠️ **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.

> ⚠️ **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.

Opening and Closing Cassette Baskets

The lid is held by two catches and is completely removable to aid cassette access.
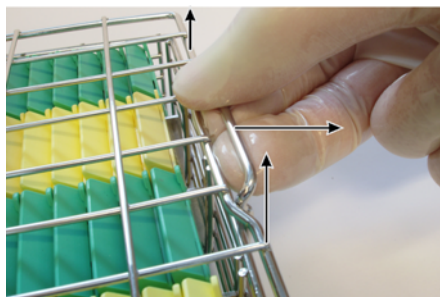
Figure 9. Releasing the lid

Figure 10. Replacing the lid

- To remove the lid, release one catch then swing the lid up and off the basket (see Figure 9).

- To replace the lid, insert one end into a catch then swing the other end down so it firmly engages the second catch (see Figure 10).

- Make sure the lid is firmly held by both catches or the body and cassettes may fall when the basket is lifted.

High-capacity Baskets

High-capacity baskets include dividers to configure the baskets to hold different numbers of cassettes. Use all the dividers to configure the baskets for orderly packing (up to 88 cassettes) or the long dividers only for tight packing (up to 100 cassettes).

For orderly packing, insert both the long and short dividers into the basket. This arrangement makes it easier to insert and remove the cassettes (see Figure 11 and Figure 12). Six standard cassettes can be placed in the end sections of each row and five in the middle sections, giving 88 cassettes per basket.

Figure 11. Basket arranged for orderly packing

Figure 12. Basket packed with 88 cassettes

For tight packing, insert only the long dividers. This allows you to pack the maximum number of cassettes — 25 per row (see Figure 13 and Figure 14).

Figure 13. Basket arranged for tight packing

Figure 14. Basket packed with 100 cassettes

For large or unusually shaped cassettes use the baskets with all dividers removed.

> **CAUTION**
> Do not use high-capacity baskets for xylene-free protocols as this may lead to wax build up that will eventually require service intervention.

Spaced Baskets

The spaced baskets include a fixed divider that ensures that the cassettes are correctly spaced for optimal processing. Each spaced basket can fit up to 72 standard cassettes inserted into the spacing springs as shown in Figure 15.
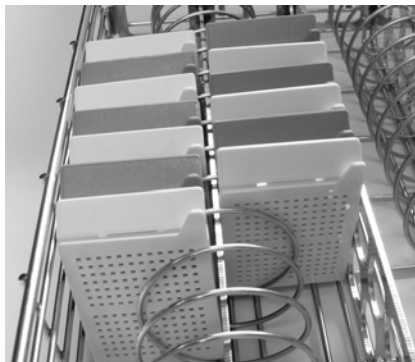
Figure 15. Detail of cassettes packed into a spaced basket

You must use spaced baskets when running xylene-free protocols.

2.3   Wax Bath

The wax bath at the top rear of the instrument has four wax chambers accessed by two lids. Each chamber acts independently, holding enough wax to fill a retort. Although wax does not move between the chambers, they are connected for air flow and so always have the same pressure.

Use the lid handles to open the lids. Always use the handles to close the lids, ensuring the lids are properly latched. Be sure not to knock the lids when they are open as they may slam shut.

Figure 16. Opening a wax bath lid

Always ensure the wax bath pressure is at ambient pressure before opening the lids. If the pressure is not ambient, vent the bath first. You can do this when you pause a running protocol or from the **Manual operations** screen.

View the current temperature of each wax station in the wax chambers view of the **Reagent stations** screen.

Depending on the reagents you use you can set the instrument to clean the wax in the bath (see Wax Bath Settings in 6.1.2 Reagent Management).

Drain used wax with commands on the **Remote fill/drain** screen. Directly fill with molten or solid wax (see 5.4.5 Replacing Wax).

	WARNING
⚠	Take care when opening the wax bath after a xylene-free protocol as the protocol will leave very hot wax in the bath.

	WARNING
⚠	Never open a wax bath lid when there is wax in a retort or wax is being transferred; hot wax may splash out of the bath.

	WARNING
⚠	Take care not to knock wax bath lids when they are open. They could crush fingers or hands.

2.4   Reagent Cabinet

Figure 17. Reagent cabinet

The reagent cabinet houses the reagent bottles, carbon filter, and condensate bottle.

- 2.4.1 Reagent Bottles
- 2.4.2 Condensate Bottle
- 2.4.3 Carbon Filter

2.4.1   Reagent Bottles

The reagent cabinet holds sixteen reagent bottles. This is three more than standard tissue processors and it ensures there are sufficient reagents to simultaneously schedule protocols in both retorts while also having ample cleaning reagents on board and ready to use. The bottle at each station holds sufficient reagent to fill a single retort.

To remove a bottle, pull the bottle out. Push back in position to return – you will feel the bottle pushing into its connection point on the back of the cabinet. Replace reagent in the bottles either manually, with the bottles removed from the instrument, or in position on the instrument using the **Remote fill/drain** screen (see 5.4.1 Remote Fill/Drain Screen).

ⓘ Some chemicals may cause the bottles to expand over time; this is normal and does not impact the performance of the instrument.

WARNING
Never run the instrument with missing bottles or with loose or missing bottle lids as fluid spills and vapor leaks will occur.

2.4.2   Condensate Bottle

A separate bottle collects condensate fluid. It sits beside the reagent bottles in the lower section of reagent cabinet. Empty weekly. Do not allow the bottle to overflow as condensate fluid will spill from the instrument or contaminate other reagents.

WARNING
Never run the instrument with the condensate bottle missing or its lid either loose or missing as fluid spills and vapor leaks will occur.

2.4.3   Carbon Filter

The carbon filter absorbs reagent fumes to prevent them from entering the laboratory atmosphere. To ensure the filter is operating effectively, it must be replaced periodically. Use the **Carbon filter threshold** button to set the replacement interval (see 6.2.1 Instrument Settings).

ⓘ The carbon filter can be bypassed and the instrument connected to an external vapor removal system (see 2.6 External Vapor Removal Systems).

WARNING
Never run the instrument without the carbon filter or an external filter system; this will release potentially dangerous fumes into the laboratory.

The filter must be installed with the direction arrow on the front pointing up and the locking mechanism closed (see Change Carbon Filter in 7.4 60–90 Days).

2.5   Touch-screen

A touch-screen mounted on the right of the PELORIS connects to a computer in the instrument that controls all instrument operations.

Use the PELORIS software on the touch-screen to configure the instrument, run protocols, and perform ancillary operations such as replacing reagents. Tap buttons and icons with your finger or a blunt object – do not use sharp objects. Ensure no strong solvents come into contact with the touch-screen.

Optional stick-on/ peel-off touch-screen protectors, provided by Leica Biosystems, can be used to protect to the touch-screen.

In its normal operating position the touch-screen sits over the wax bath lid, but can be rotated to give clearance to open the lid. The screen can be remounted so its normal position is to the right of the mounting stem rather than over the instrument. See your service representative if you want to change the touch-screen position.

> ⚠️ **CAUTION**
> If the touch-screen goes blank or is unreadable, turn off the instrument immediately.

2.6   External Vapor Removal Systems
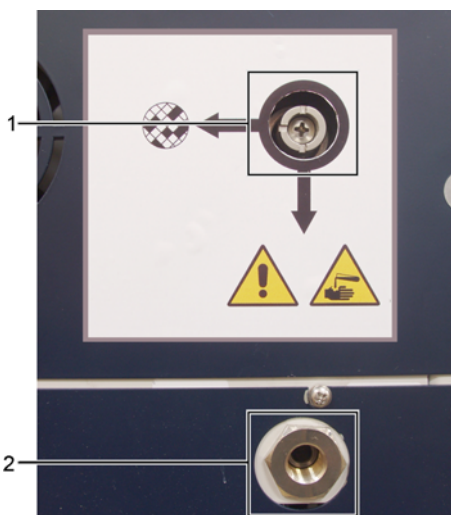
Figure 18. Vapor select valve (1) and vapor outlet (2)

The outlet for instrument vapors can be switched between the internal carbon filter and an external vapor extraction system. At the rear of each instrument there is a valve that directs vapors to either the carbon filter or to an outlet that can be connected into the external system.

- For instructions on changing to an external vapor system, see Connecting to an External System below.

- For instructions on returning to the internal carbon filter system, see Returning to the Internal Filter System.

🛈 Some instruments do not have the vapor select valve fitted. However your service representative can easily connect these instruments to an external vapor system.

Connecting to an External System

> **WARNING**
> When the vapor select valve is in the external position, you must ensure an external vapor system is correctly installed or potentially dangerous fumes will be released into the laboratory environment.

Use the following procedure to connect the instrument to an external vapor system.

1. Connect the instrument's vapor outlet into the external system (see item 2 in Figure 18).

2. Turn the vapor select valve a quarter turn anticlockwise to direct vapors to the vapor outlet (see Figure 19).

    Note: to access the valve you may need to remove a blanking plug.

Figure 19. Vapor select valve in the external system position

3. Set the carbon filter threshold to one of the following options.

    (i)   The inspection interval for the external system (see 6.2.1 Instrument Settings).

    (ii) The maximum value (1000) to limit the number of unwanted warnings (see 6.2.1 Instrument Settings).

    (iii) Overridden (contact your service representative to arrange this setting).

Returning to the Internal Filter System

> ⚠️ **WARNING**
> When the vapor select valve is in the internal position, you must ensure the carbon filter is correctly installed or potentially dangerous fumes will be released into the laboratory environment.

Use the following procedure to reconfigure an externally connected instrument to internal carbon filter use.

1. Ensure a new carbon filter is correctly installed (see 2.4.3 Carbon Filter).

2. Turn the vapor select valve a quarter turn clockwise to direct the vapors to the internal carbon filter (see Figure 20).

    Note: to access the valve you may need to remove a blanking plug.

Figure 20. Vapor select valve in the internal filter position

3. If required, disconnect the external system from the vapor outlet (see item 2 in Figure 18). You may leave the external system connected as the vapor valve effectively isolates this outlet.

4. Set the carbon filter threshold to a value appropriate for your instrument's work load.

    We recommend an initial threshold of 60 days with adjustments only if you are sure the carbon filter is becoming saturated earlier or is still in good condition after this time (see 6.2.1 Instrument Settings).

ℹ️ If the carbon filter threshold has been overridden the carbon filter buttons will not be available. Arrange for your service representative to cancel the override.

2.7 Alarm Connections
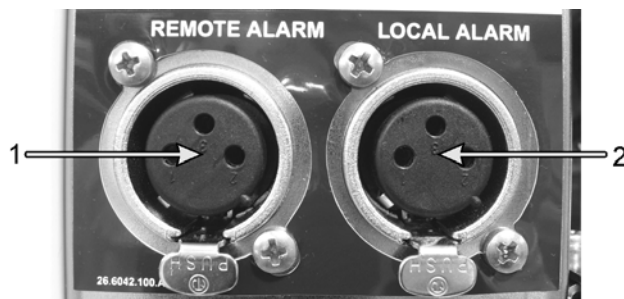
Figure 21. Remote alarm (1) and local alarm (2) connectors

Each PELORIS tissue processor has two external alarm connections — a local alarm connection and a remote alarm connection (see Figure 21). These connections may be used to control a range of alarm indication devices including audible alarms, visual alarms or automatic phone dialers.

Speak to your service representative to configure the events that will trigger each of the external alarms, and to set whether the alarms are a single signal or continuous.

Alarm Connector Specifications

The load connected to either alarm connector must not exceed the following specifications.

- Maximum voltage: 30 VDC
- Maximum current: 1A (resistive load)
- Maximum current: 0.5A (inductive load)

Alarm Connector Pins

Each alarm connector has three pins as follows (see Figure 22):

- Pin 1 — Normally open (item 1)
- Pin 2 — Normally closed (item 2)
- Pin 3 — Common (item 3)
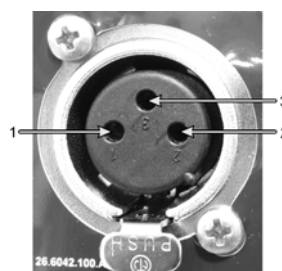
Figure 22. Alarm connector pins

Pin Schematic During Normal Operation

When the instrument is operating normally (no alarm) the alarm pins connect as shown in Figure 23.

- Pin 1 (normally open) is open.

- Pin 2 (normally closed) is connected to Pin 3 (common).
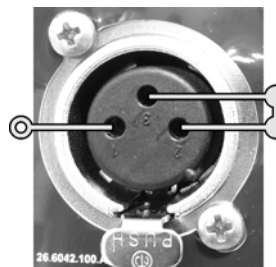
Figure 23. Alarm pins in normal state

Pin Schematic During Alarm Conditions

When the instrument has an active alarm, the alarm pins connect as shown in Figure 24 below.

- Pin 1 (normally open) is connected to Pin 3 (common).

- Pin 2 (normally closed) is open.
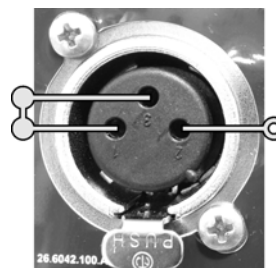
Figure 24. Alarm pins in alarm state

<u>Note</u>

Decommissioning and disposal

The instrument or parts of the instrument must be disposed of according to existing applicable, local regulations.

3

Running Protocols

This chapter describes how to run protocols on the PELORIS system. The first section gives all the steps to run a protocol once reagents and protocols have been configured. The second describes cleaning protocols, and the third describes the **Status** screen, where you control and monitor processing. The fourth and fifth sections give details about modifying or pausing protocol runs. The sixth section discusses general issues about scheduling protocols.

- 3.1 Quick Start – Running a Protocol
- 3.2 Cleaning Protocols
- 3.3 Status Screen
- 3.4 Protocol Run Options
- 3.5 Pausing and Abandoning Protocols
- 3.6 Retort Scheduling

3.1   Quick Start – Running a Protocol

Follow the instructions below to run a protocol.

Before you begin all the reagents you need must be configured and there must be a validated protocol ready to load. See 5.3 Managing Reagent Stations and 4.2 Creating, Editing and Viewing Protocols for direction on these topics.

Instrument Checks and Setup

1.   On the screen, tap the **Status** button to view the **Status** screen:
     (i)   Check that the retort icon shows the retort is clean or has residue of a reagent compatible with the first reagent of the protocol.
     (ii) Check for hatched bottle or wax chamber icons.
           Replace the reagent in hatched stations (see 5.4 Replacing Reagents).

2. Check that the instrument is ready:

   (i) All 16 bottles are properly installed on the instrument.

   (ii) There is enough reagent in the bottles and wax chambers.

   Fill to at least the MIN 2 level if you fill retorts to the two-basket level, or at least the MIN 3 level for the three-basket level (view the instrument fill level in the **Reagent fill levels** section on the **Instrument settings** screen).

   (iii) Open the retort to use. Check that it is clean, or that any residue is a reagent compatible with the first reagent in the protocol.

3. Prepare your cassettes and load them into baskets (see 2.2.4 Cassette Baskets).

Load Protocol

4. Tap the **Select** button at the bottom left or right corner of the **Status** screen, depending on the retort you want to use.

   The **Protocol selection** screen opens.

5. Select a protocol and tap **Load**.

   Only validated protocols can be selected by operator-level users (see 4.1.4 Protocol Validation).

   The **Status** screen reopens with the protocol loaded.

Run Protocol

6. Tap the **Run** button.

   Review any warnings and rectify as required. If necessary, cancel the warnings dialog box while you rectify conditions.

   If the first step of the protocol uses a reagent that is incompatible with retort residue you may need to abandon the protocol to run a cleaning protocol. Alternatively, you may be able to skip the first steps of the protocol (see 3.4.2 Editing the Protocol for a Single Run). If so, tap **Continue** in the warnings dialog box.

7. If prompted, enter the number of cassettes in the run in the **Number of cassettes** dialog box.

   It is important to enter the correct number of cassettes – this is used by the reagent management system to calculate reagent concentrations.

8. Open the retort lid and insert the cassettes when directed in the **Insert cassettes** dialog box.

   Tap **Done** in the dialog box when you have inserted the cassettes and closed the retort.

9. View the protocol end-time in the **Scheduling** dialog box.

   If acceptable, tap **Start**, or set a different end time (see 3.4.1 Scheduling Protocols).

   Tap **Edit steps** in the **Scheduling** dialog box to skip initial protocol steps or change step durations (see 3.4.2 Editing the Protocol for a Single Run).

10. When you tap **Start** the system schedules the protocol.

    • If the system is unable to schedule the protocol, you will see a list of errors. Tap **OK** and correct all errors before attempting to run the protocol again (see 3.6.2 Unavoidable Reagent Clashes for a description of possible scheduling difficulties).

    • If the system was able to schedule the run, the protocol will begin.

    • If you have set a delayed end time, an initial fill condition will occur (see 3.6.1 Delayed End Times and Initial Fills).

11. View the progress of the protocol in the **Status** screen.

    You can pause processing to add additional cassettes, or abandon protocols completely (see 3.5 Pausing and Abandoning Protocols).

Finish Protocol Run

12. When the protocol is finished the **Protocol complete** dialog box opens and the alarm sounds; tap **OK** to continue.

13. Tap **Drain retort before accessing** from the **Drain/Access retort** dialog box.

    You can remove the baskets before draining the retort (tap **Access retort now**) – this option is not recommended.

14. Wait for the **Retort accessible** dialog box to appear then open the retort and remove the cassettes.

    Tap **OK** to close the dialog box.

Run Cleaning Protocol

15. The **Run cleaning protocol** dialog box appears.

    (i) Recommended: tap **Clean now** to load a cleaning protocol.

    If you have more than one cleaning protocol use the **Prev** and **Next** buttons to select the protocol you want to use.

    (ii) Not recommended: tap **Clean later** to end the procedure and leave the retort full or with residue in it.

    If you select this option heating continues to keep the wax in the retort and valves molten.

    See 3.2 Cleaning Protocols below for information about cleaning protocols.

16. Place the used cassette baskets into the retort when prompted with the **Insert baskets** dialog box.

    Remove all tissue as the cleaning protocol will damage any tissue left in the retort.

    Tap **Done** in the dialog box when you have inserted the baskets and closed the retort.

17. Tap **Start** in the **Scheduling** dialog box to begin the run.

    If required change the protocol's end time before starting.

18. View the progress of the protocol in the **Status** screen.

19. When the protocol is finished the **Protocol complete** dialog box opens and the alarm sounds; tap **OK** to continue.

20. When the **Remove baskets** dialog box appears, open the retort lid and remove the baskets.

    Tap **OK** to continue.

21. Tap **Unload protocol** in the **Status** screen so the retort is available for the next protocol.

WARNING

Do not open a retort while a protocol is running as the retort could be pressurized and may contain hot reagent and fumes. Always follow the retort access instructions detailed in 3.5 Pausing and Abandoning Protocols if you need to access a retort during processing.

3.2 Cleaning Protocols

Cleaning protocols clean the retorts and reagent lines. Always run a cleaning protocol as soon as possible after processing runs; unless there are specific reasons not to, always select the **Clean now** option when prompted at the end of a run. Also clean retorts after replacing reagent by remote fill and drain, or if you filled the retorts using manual operations.

For most laboratories the pre-defined "Quick Clean" protocol should be the only cleaning protocol required. Under normal conditions the protocol purges residue in the retort to the wax bath before the first step (see Pre-cleaning Purges below). Then there are two reagent steps – cleaning solvent (e.g. Xylene) and cleaning alcohol. These are followed by a "dry step" that applies high temperature, vacuum and air flow to evaporate all reagent residue. At the end of the dry step the heaters turn off but air flow continues to cool the retorts before the next protocol.

Load and run cleaning protocols like other protocols, but never put tissue in the retort – the dry step will damage it. This means cleaning protocols should never be used for reprocessing runs – use a reprocessing protocol instead.

If required, copy the Quick Clean protocol and edit to create your own cleaning protocols. You can add, delete and edit all the reagent steps as for other protocols, but the dry step cannot be deleted or edited. Cleaning protocols do not require a water step and work well with conventional cleaning reagents.

To completely remove xylene from your instrument, Leica Biosystems can supply Waxsol™, a xylene-free cleaning solution (see 5.1.4 Recommended Reagents).

⚠	**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.

⚠	**CAUTION** Always run a cleaning protocol after wax has been in the retort.

⚠	**CAUTION** Do not reuse contaminated dehydrants as cleaning alcohol. The contaminated dehydrants will contain formalin (or other fixatives) and the "dry step" will cause salts to crystallize on the retort's internal surfaces.

Cleaning Laboratory Implements

You can clean metal laboratory implements such as cassette lids and metal molds during cleaning runs, but it is important to set reagent purity thresholds that take this into account.

All the pre-defined cleaning reagents have "cycle" purity thresholds. Under these the reagents must be replaced after ten or six cleaning runs (if they do not exceed a concentration threshold first). But the thresholds are designed for cleaning runs with only cassette baskets in the retorts – any additional material increases the rate that the cleaning reagents degenerate, requiring lower cycle thresholds. If you clean implements other than baskets lower the cycle thresholds for the reagents used, so the reagents are replaced more frequently (see 5.2.2 Editing Active Reagent Types). Depending on the number of implements you typically place in the retorts you may need to reduce the thresholds by half or more. Contact your technical support representative for advice if required.

> ⚠️ **CAUTION**
>
> If you clean laboratory utensils, metal cassette lids, metal molds etc. in cleaning runs lower the cycle purity thresholds for the cleaning reagents used. Failure to do so can lead to overly contaminated cleaning reagents and lower quality cleaning.

Modifying Cleaning Protocols for Different Retort Residues

Always run a complete cleaning protocol as soon as possible if wax or clearing reagent are left in the retorts.

For alcohol residue skip the first step of the protocol to start at the alcohol step (see 3.4.2 Editing the Protocol for a Single Run).

A residue of clean formalin can be allowed to stay in a retort if the next processing protocol begins with a formalin step. If you are left with formalin in a retort at the end of a protocol tap **Clean later** when prompted, to continue without cleaning. If you need to clean a retort with formalin residue in it, start the cleaning protocol with the alcohol step, as for alcohol residue.

Pre-cleaning Purges

Cleaning protocols are generally run to clean wax residue from the retorts, as wax is the final step of processing protocols. To help maximize the useful life of the cleaning solvent, the instrument usually purges any wax residue from the retort to the wax chamber it came from before the cleaning protocol begins.

If you attempt to load a processing protocol to a retort with incompatible residue you are warned with event 10011, "Incompatible reagent in retort. Clean retort or edit protocol." A cleaning protocol run after this warning will not have the normal purge to the wax chamber. This is in case fresh cassettes were placed in the retort, contaminating the wax residue with formalin. A purge under these conditions would contaminate the wax chamber with formalin.

If you ever place fresh cassettes into a dirty retort in preparation for processing, remove the cassettes and then attempt to load a processing protocol before loading the cleaning protocol. The 10011 warning raised when you attempt to load the processing protocol causes the cleaning protocol to skip the wax bath purge. The retort residue, now with formalin in it, will not go into the wax bath but into the cleaning solvent.

After the cleaning protocol finishes replace the cleaning solvent, which will now be contaminated with formalin.

In general, avoid this situation by always cleaning the retort immediately after a processing run, when prompted. Do not put fresh cassettes into a retort that is showing residue in it, as indicated by the icon at right (formalin residue may be acceptable).

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.

3.3 Status Screen

Use the **Status** screen to run protocols and monitor protocol progress. The main features of the screen are shown in Figure 25.
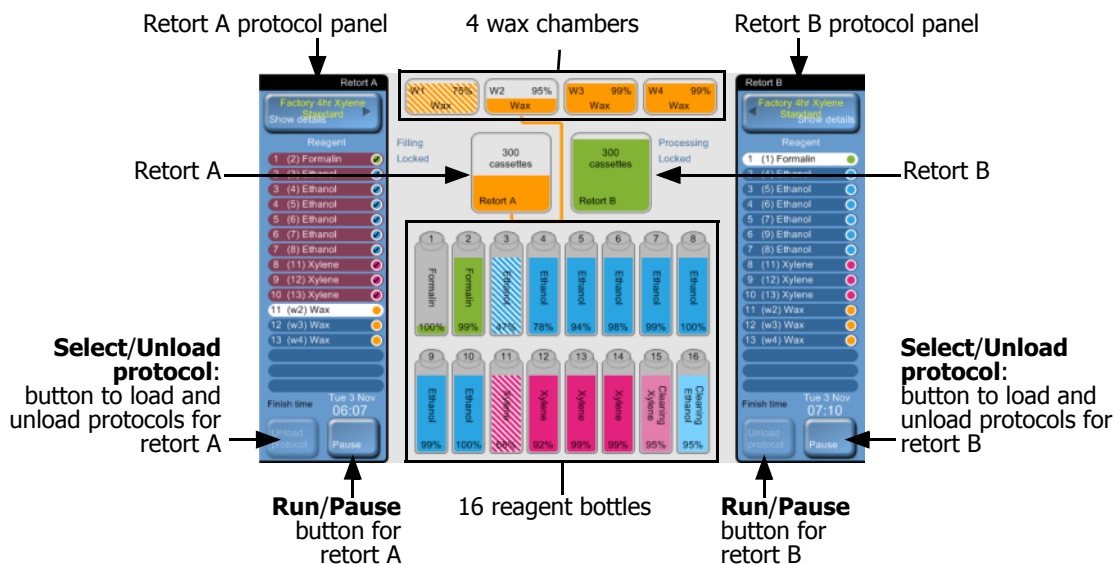
Figure 25. **Status** screen

The central area of the screen shows the status of the stations and retorts. Panels at either side of the screen show protocols loaded for the retorts.

- 3.3.1 Status Area
- 3.3.2 Protocol Panels

3.3.1 Status Area

The status area provides a visual guide to the status of the bottles, wax chambers and retorts, as shown below.

Bottle Icons
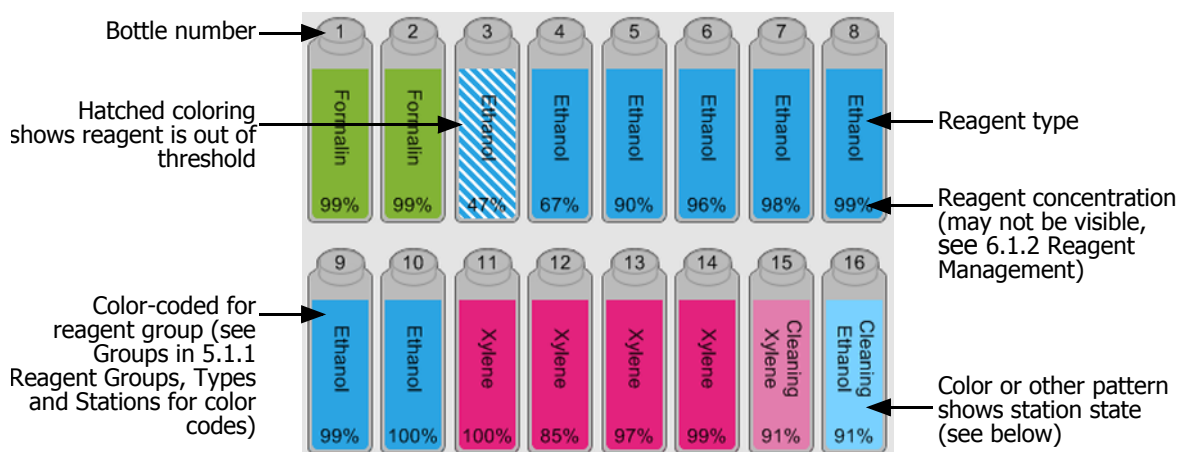
Figure 26. Bottle icons on the **Status** screen

Bottles have six possible station states:

	Full	**In use**	**Empty**	**Dry**	**No bottle**	**Unknown**
Means	The bottle holds sufficient reagent to fill a retort at the specified basket level.	A reagent transfer is in progress or was abandoned. The reagent level is between full and empty.	The bottle has been used to fill a retort. There is still reagent in the bottle.	The bottle has been completely drained leaving only a small amount of residue.	The bottle has been removed.	A previously missing bottle has been replaced. Enter reagent and state details before using this station.
Icon						

Wax Chamber Icons

Padlock symbol shows
there is a vacuum in
the chamber

Wax concentration
(may not be visible, see 6.1.2
Reagent Management)

Wax chamber number →

W1 🔒 100%
Wax

W2 🔒 99%
Wax

W3 97%
Wax

W4 84%
Wax

Hatched coloring
shows wax is out of
threshold

Reagent type
(i.e. type of wax)

Color-code orange for
reagent group "Wax"

Color or other pattern
shows station state
(see below)
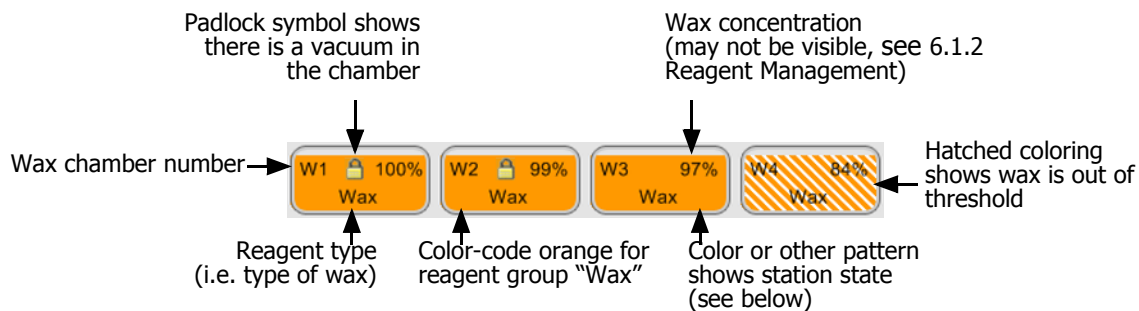
Figure 27. Wax chamber icons on the **Status** screen

Wax chambers have four possible station states:

	Means	**Icon**
Full	The chamber has enough wax to fill a retort to the specified basket level.	Wax
Part full	A wax transfer is in progress or has been abandoned. The wax level is between full and empty.	Wax
Empty	The chamber has been drained to fill a retort. There is still wax in the chamber.	Wax
Not molten	The wax in the chamber has not melted and is unavailable.	

Retort Icons

Color-coded for reagent group
currently in the retort

Color or other pattern shows
retort state (see below)

The number of cassettes in
the retort →

300
cassettes

Draining

Current retort operation (see
below)

0 kPa
35 °C
Medium

Retort pressure, temperature,
and stirrer speed (supervisors
only)

Retort name →
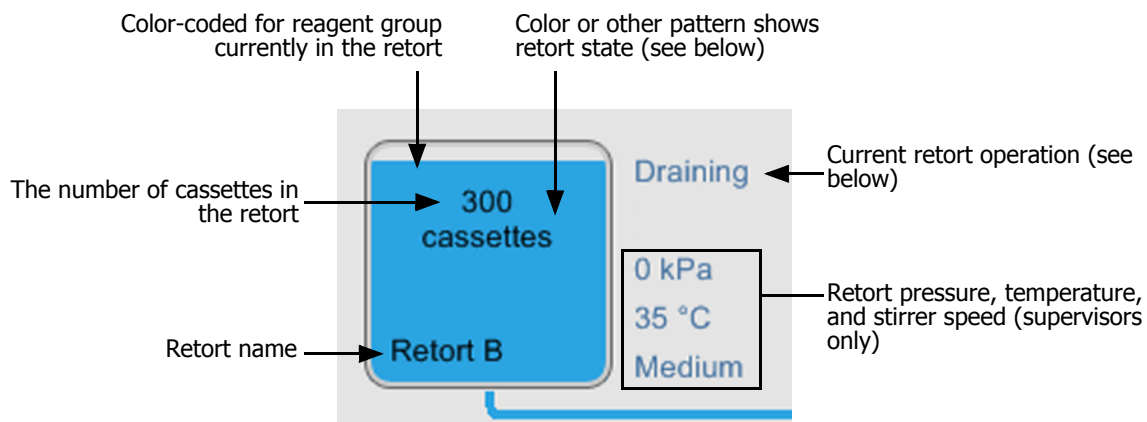
Retort B

Figure 28. Retort icon on the **Status** screen

There are ten operations reported for the retorts:

- **Ready** — the retort is available for any new action
- **Reserved** — a protocol is loaded but has not yet started
- **Processing** — the retort is currently running a protocol
- **Completed** — the retort has completed the loaded protocol
- **Drying** — the retort is being dried as the final step of a cleaning protocol
- **Filling** — the retort is currently filling
- **Draining** — the retort is currently draining
- **Pending (drain or fill)** — the retort is waiting for resources to perform a fill or drain
- **Abandoning** — the retort is abandoning the current action
- **Unavailable** — the retort cannot be used, contact your service representative.

Retorts have five possible states:

	Means	**Icon**
Full	The retort contains the correct amount of wax or reagent for the specified basket level.	
Part full	The reagent or wax level is between full and empty, this usually occurs during a fill or drain operation.	
Empty	The retort is drained but contains residue.	
Clean	There is no residue in the retort. This only occurs after a cleaning protocol.	
Retort inoperative	A red cross over a retort indicates that a hardware failure has occurred and the retort is unavailable. Contact your service representative.	

3.3.2 Protocol Panels

Panels on each side of the **Status** screen show the steps of the protocols loaded for each retort. Use the panels to load and unload protocols, initiate processing runs, and monitor protocol runs.

You can view the panels in two modes: standard and expanded (see images below).
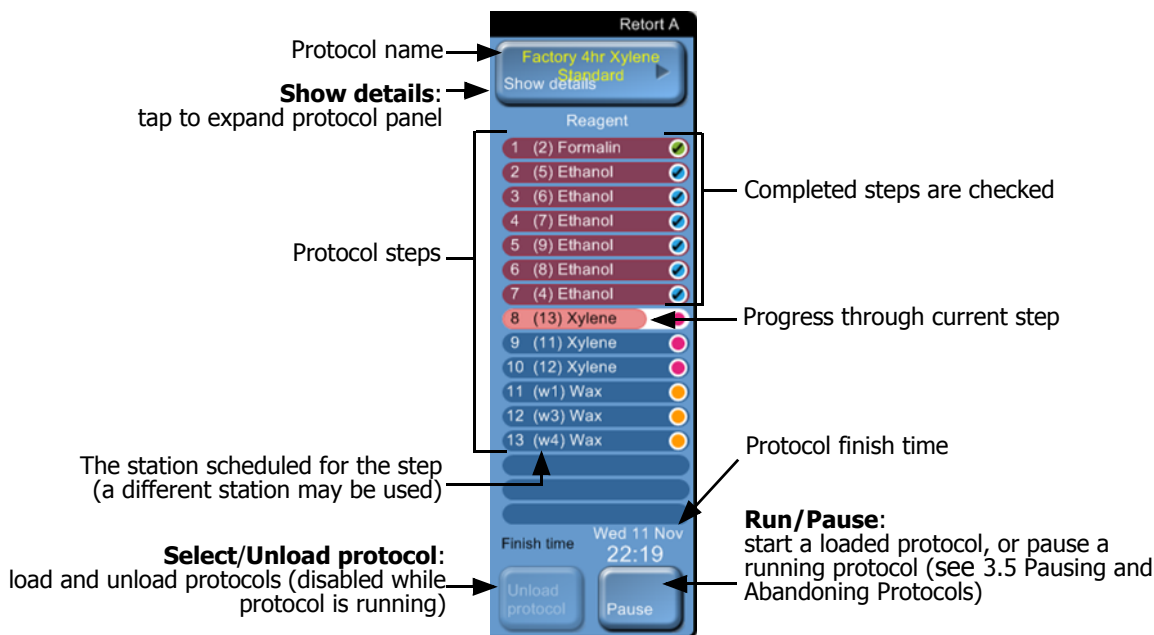
Figure 29. Protocol panel: standard mode

In expanded mode the protocol notes, processing time, and step details are also shown.

Figure 30. Protocol panel: extended mode

3.4   Protocol Run Options

You can schedule each protocol run so it finishes at a convenient time. You can also modify the protocol for a run, to start at the second or later steps, and to change step durations.

- 3.4.1 Scheduling Protocols
- 3.4.2 Editing the Protocol for a Single Run

3.4.1   Scheduling Protocols

Schedule protocol runs in the **Scheduling** dialog box. The dialog box opens automatically for every protocol run after you have loaded the protocol, tapped **Run**, cleared any warning messages, and placed cassettes in the retort. When you tap **Start** in the **Scheduling** dialog box there are no further configuration options or warnings and the protocol run starts.

The **Scheduling** dialog box also gives access to the **Edit protocol instance** dialog box where you can edit some protocol features for the run (see 3.4.2 Editing the Protocol for a Single Run).
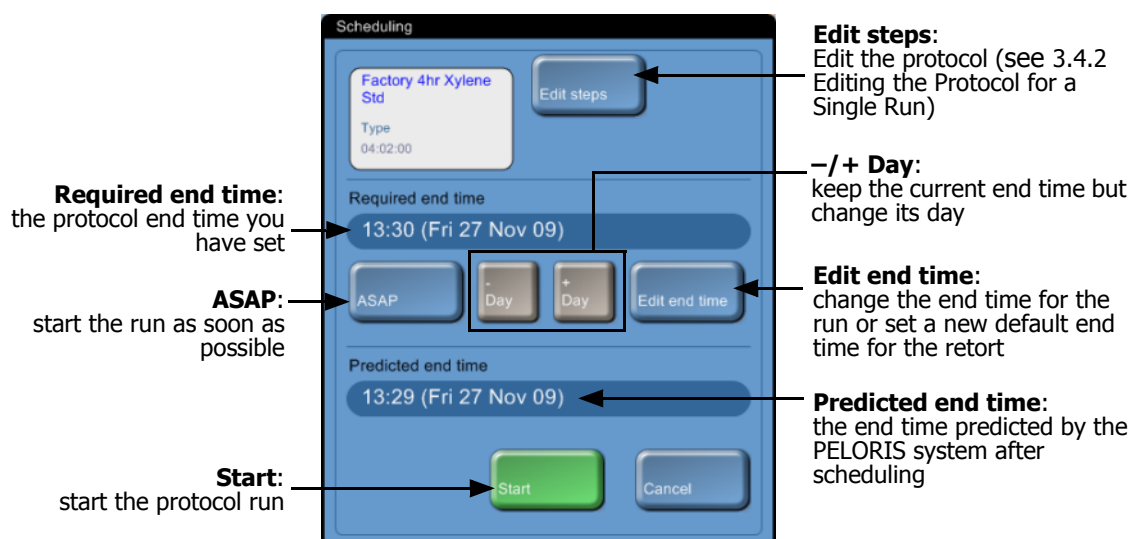
Figure 31. The **Scheduling** dialog box

Each retort (note, not each protocol) has a default scheduling setting. The **Scheduling** dialog box always opens showing the retort's default setting. You can accept the default or change the setting for the run with options to set a different end time or run the protocol as soon as possible (the **ASAP** option). Also change the retort defaults from the **Scheduling** dialog box.

The system considers the required end time as the latest acceptable protocol completion time. To avoid resource clashes, protocols may be scheduled to finish earlier than the required end time. A red highlight indicates that the required end time is not possible and a later end time has been set.

The required end time for cleaning protocols is always set to **ASAP**.

Always check the predicted end time to ensure it is suitable before starting a protocol.

How To Schedule a Protocol Run

When the **Scheduling** dialog box opens the retort's default end time is shown.

- If the default end time is set to **ASAP** the protocol is scheduled to end at the earliest possible time.

- If the default setting is a specific time of day, the dialog box defaults to that time on the following day.

You have four options:

1. Accept the default values as they are.

   Edit the protocol for the run if required (see 3.4.2 Editing the Protocol for a Single Run) then tap **Start** to begin the run.

2. Keep the default time but change the day the protocol will run.

   Tap the **+ day** or **– day** button to keep the default end time but change the day.

   If the default setting is a specific time of day the dialog box opens with the run set to the following day. To run the protocol on the current day tap the **– day** button once. Depending on the time you do this the new end time may not be possible. If so, the **Predicted end time** is highlighted red.

3. Start the run as soon as possible.

   Tap the **ASAP** button.

   The protocol will normally start immediately. However, if there is a reagent clash caused by a protocol running in the other retort the actual start of the protocol may be delayed (see 3.6.1 Delayed End Times and Initial Fills).

4. Set a new end time.

   Tap the **Edit end time** button to open the **Run protocol – edit end time** dialog box (see the next section for instructions).

Entering a New End Time or Default Scheduling Setting

Change the end time for a specific run in the **Run protocol – edit end time** dialog box, opened from the **Scheduling** dialog box with the **Edit end time** button.

Also set the default scheduling setting for the current retort in the **Run protocol – edit end time** dialog box.
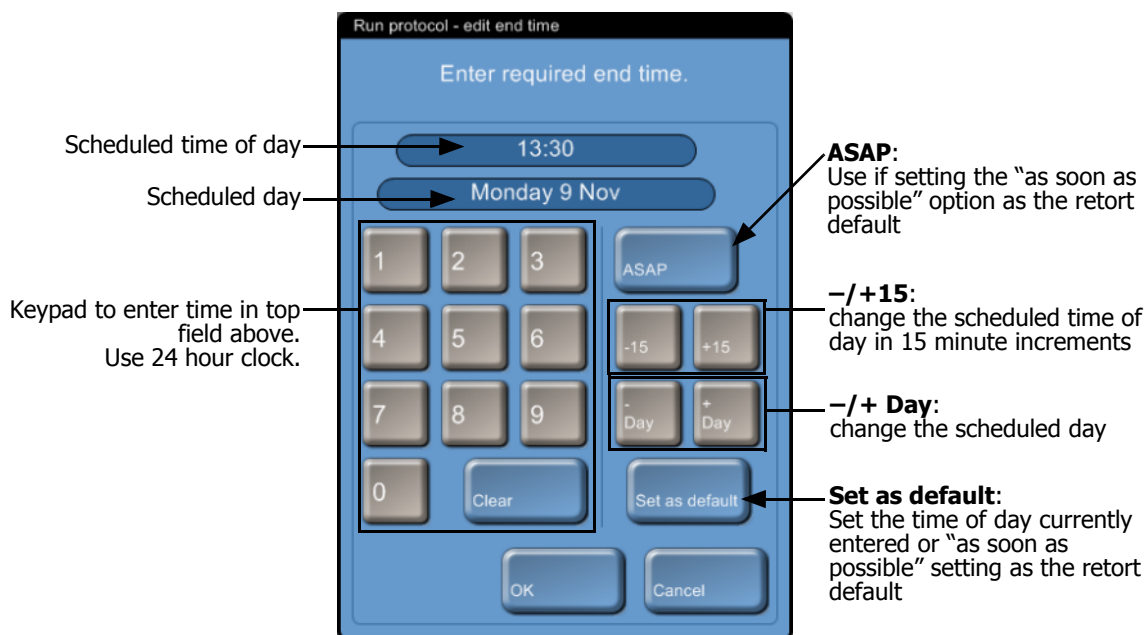
Figure 32. The **Run protocol – edit end time** dialog box

- ● To set a new end time for a protocol run use the keypad to enter the required end time of day (24-hour format) or use the **−15** or **+15** buttons to increment the time in 15 minute steps. Use the **+ Day** and **− Day** buttons to change the day. Tap **OK** when finished.

- ● To set a new retort scheduling default enter a time of day (as you would to change the end time for an individual run) or tap **ASAP**. The day is not relevant to the default setting. Tap **Set as default** then **OK**.

3.4.2   Editing the Protocol for a Single Run

You can edit the protocol for an individual run just before the run is started. You can make two types of change:

1.   Skip the first steps of the protocol

2.   Change step durations

Make both types of change in the **Edit protocol instance** dialog box opened from the **Scheduling** dialog box. Start a protocol run as normal from the **Status** screen and continue until the **Scheduling** dialog box opens. Tap the **Edit steps** button to open the **Edit protocol instance** dialog box.

No check in the circle shows this step will be skipped

Tap the step that will be the first to run in the protocol

Tap on a step time to open the **Duration** dialog box to set a new step duration
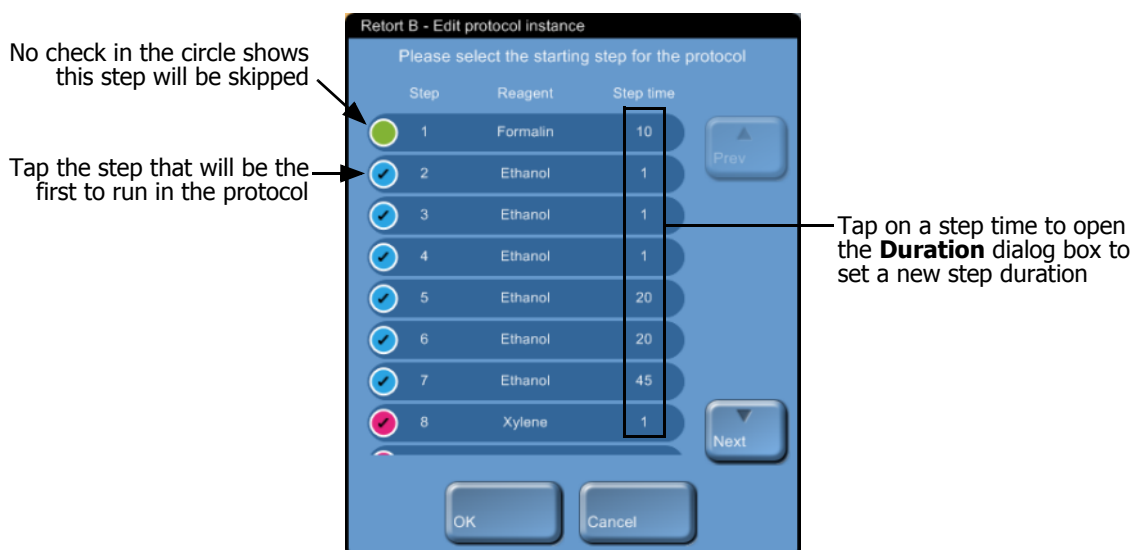
Figure 33.   **Edit protocol instance** dialog box

- To skip protocol steps tap the step that you want to start the run with. Steps prior to this are unchecked to show they will not run.

   The reagent selected as the new first step will be used for an initial fill if required (see 3.6.1 Delayed End Times and Initial Fills).

- To change a step time tap the current step time. Set a new time in the **Duration** dialog box.

Skipping steps and changing step durations will affect protocol scheduling – confirm that the new **Predicted end time** shown in the **Scheduling** dialog box is acceptable before you start the run.

3.5 Pausing and Abandoning Protocols

To stop a protocol that has started use one of the **Pause** buttons on the **Status** screen protocol panels. When you tap either **Pause** button protocols in both retorts stop running, and the **Paused** dialog box opens with a number of options:

- Abandon all processing or just the protocol in one retort.

- Access a retort, for example to add more cassettes, and then resume the protocol running in it.

- Vent the wax baths so you can open them.

After you pause the instrument you have five minutes to select an option, after which processing automatically resumes.
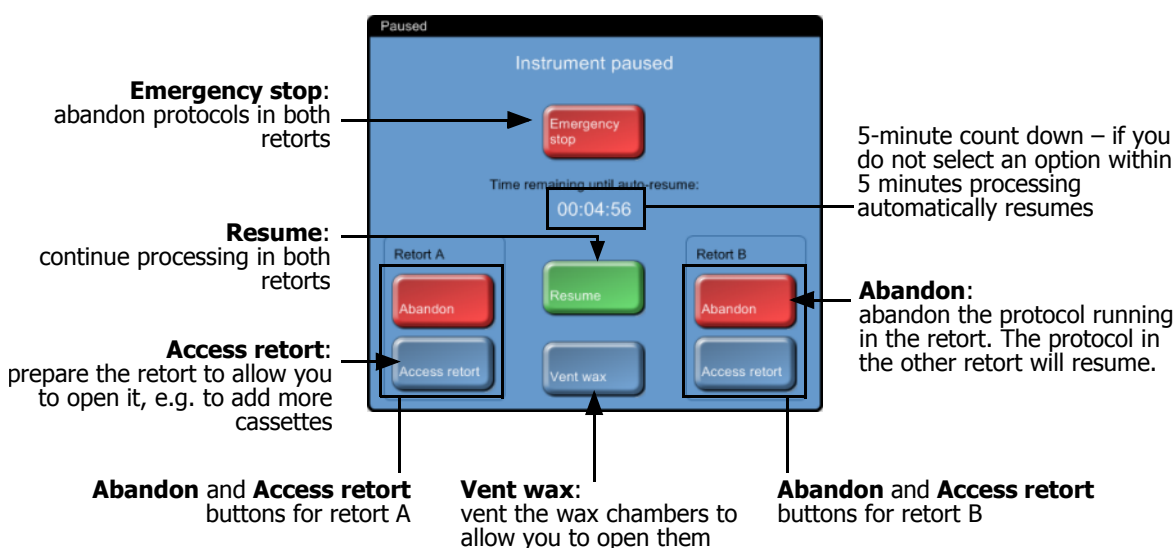
Figure 34. **Paused** dialog box

⚠	**WARNING**
	Take care if opening a retort or wax chamber after pausing the instrument. Retorts may contain very hot fluid that could cause severe burns, and hazardous reagents and vapors. Read any warning messages, e.g. if the retort is above safe access temperature, and take appropriate precautions before continuing.

Emergency Stop and Abandon

After you have paused the instrument you can abandon all protocols with the **Emergency stop** button. Note that this does not shut down or remove power from the instrument (see 2.1 Switching On and Shutting Down).

Alternatively, abandon the protocol run in one retort only with the appropriate **Abandon** button. Any protocol running in the other retort will resume.

When processing stops the PELORIS goes through the same routines carried out at the end of a normal protocol run. It prompts you to drain the retort (if full), remove cassettes, and run a cleaning protocol.

After abandoning a protocol you may wish to run a reprocessing protocol to recover your cassettes. In this case do not remove your cassettes or run a cleaning protocol when prompted to do so.

If the last reagent was a fixative you may skip the cleaning protocol as the residue will not prevent you running a typical processing protocol. If you decide to run a cleaning protocol, set the first step to a cleaning alcohol. Cleaning solvents are incompatible with fixatives.

Access Retort

You can access retorts in a paused instrument in order to add or retrieve samples.

> **CAUTION**
> Take care when adding fixed samples to a running protocol. The additional fixative will contaminate the reagent used in the current step and this contamination will not be tracked by the reagent management system.

> **CAUTION**
> The further a protocol has progressed before you add more samples the more compromised the processing quality for those samples. We therefore recommend that you only add samples during fixative steps or during the first dehydrant step.

To access a retort while the instrument is processing:

1. Pause the instrument with one of the **Pause** buttons on the **Status** screen.
2. Tap the appropriate **Access retort** button in the **Paused** dialog box.
3. Select to drain the retort or not in the **Temporary access drain** dialog box.
   Follow the prompt to wait if draining.
4. When the **Retrieve samples** dialog box opens remove the baskets from the retort and add or retrieve cassettes, as required.
5. Return the baskets to the retort and tap **OK** in the **Retrieve samples** dialog box.
6. If prompted, enter the new number of cassettes in the **Number of cassettes** dialog box.
   Follow the prompt to wait if refilling the retort.
7. Tap **Resume** in the **Paused** dialog to resume the protocol.

3.6 Retort Scheduling

The PELORIS tissue processor allows you to simultaneously run protocols in both retorts. The automatic scheduling function attempts to assign reagent stations and start times so that there are no clashes and it may alter your requested end time by starting the protocol early or by inserting a delay time (see 3.6.1 Delayed End Times and Initial Fills).

Also, when starting a second protocol you may notice that the reagent stations assigned when a protocol was loaded change as it begins to run. This occurs when the instrument must alter the assignment to allow for the first protocol's current reagent requirements.

It is sometimes not possible to schedule a second protocol. This situation and possible remedies are discussed in 3.6.2 Unavoidable Reagent Clashes. Also, protocols will sometimes fail if a reagent station unexpectedly becomes unavailable. 3.6.3 Unavailable Reagents describes the best ways to avoid this situation.

- 3.6.1 Delayed End Times and Initial Fills
- 3.6.2 Unavoidable Reagent Clashes
- 3.6.3 Unavailable Reagents

3.6.1 Delayed End Times and Initial Fills

Protocols do not need to start immediately and it is possible to set a required end time that necessitates a delay before the actual protocol begins. This delay period can extend to many days. Also, when selecting the ASAP (As Soon As Possible) scheduling option, or if you have requested an end time that is not achievable, the PELORIS tissue processor may be forced to delay the start of the protocol. During the protocol delay period the PELORIS tissue processor will protect your cassettes by covering them with reagent; this process is called an initial fill.

During the initial fill, the retort is filled with the first scheduled reagent (usually a fixative) to protect the samples. Unless the reagent is wax no heating or agitation occurs. If the initial step is wax (for reprocessing or wax only protocols), the retort temperature will be set to wax standby, and the stirrer will be set to the first step's speed. Once the initial fill period is over the protocol will run normally and will finish at the predicted end time.

We recommend that all protocols start with a fixative step (even if only very short) so that a fixative is used for any initial fill. If there is no fixative step, an initial fill may leave your tissue covered with dehydrant for a long period and this can cause the tissue to become hard and brittle.

3.6.2 Unavoidable Reagent Clashes

Unavoidable clashes often occur when there are insufficient reagent stations available for both protocols to satisfy the reagent selection rules (see 4.1.2 Reagent Selection Method). This occurs more frequently when using "by type" and "by station" protocols as they have limited station assignment flexibility.

Always ensure sufficient stations of the first reagent group or type so a station is available for an initial fill.

3.6.3   Unavailable Reagents

Once a protocol starts, group and type select protocols may reassign stations to recover from errors caused by unavailable reagents (for example when a bottle is removed or if a station contains insufficient reagent). This reassignment may use reagents assigned to the other protocol.

Station-selection protocols will fail if an assigned reagent becomes unavailable. Type-selection protocols will fail if there is only one station with an assigned type and it becomes unavailable.

Some common causes of station unavailability, and ways to avoid them, are described below.

- The station contains insufficient reagent.

  Prior to each run, check the reagent level in each station is sufficient for the current fill level (see **Instrument settings** screen for the reagent fill level).

- A bottle scheduled for use is removed from the reagent cabinet.

  For safety reasons you should not remove any bottle whilst a protocol is running. However if you choose to do so, you must make sure the bottle you intend to remove is not scheduled for use in either retort.

- A wax station is not molten at the time it is required.

  Make sure there is adequate time for the wax to melt and that the correct wax station state is set (see 5.3.2 Setting Reagent Station Properties).

4

Protocol Setup

Protocols control all aspects of the tissue processing runs carried out on the PELORIS. This chapter gives an overview of PELORIS protocols and how to create, edit and view protocols with the software interface.

- 4.1 Protocol Overview

- 4.2 Creating, Editing and Viewing Protocols

4.1   Protocol Overview

Protocols consist of sequences of steps applied to tissue in a retort. In each step (with one exception) the retort is filled with reagent and held for a time under conditions controlled by the protocol. Protocol steps have the following properties:

- the reagent used

- the time the reagent is in the retort

- the temperature of the reagent

- the retort pressure: ambient, pressurized or vacuum, or cycling between pressurized and vacuum

- the retort stirrer speed

- the drip time: the time allowed for reagent to drip from the cassettes and retort walls before ending a drain. Longer drip times reduce carryover.

The one step type that is an exception is the final "dry" step of a cleaning protocol, where no reagent is used.

There are five protocol types. A protocol's type sets limits on which reagents can be used and the order of their use.

Other protocol properties are the reagent selection method and a carryover value that must be set for each protocol. These, and protocol validation, pre-defined protocols and file saving are described in the sections below.

- 4.1.1 Protocol Types
- 4.1.2 Reagent Selection Method
- 4.1.3 Pre-defined Protocols
- 4.1.4 Protocol Validation
- 4.1.5 Carryover Setting
- 4.1.6 Saving Protocol Files

4.1.1   Protocol Types

The PELORIS tissue processor uses five protocol types for different processing functions. The protocol types allow different reagent sequences and temperature ranges (see 8.5 Reagent Compatibility Tables and 8.4 Protocol Step Temperatures). Once a protocol is created you cannot change its type.

The protocol types are:

- **Standard** — conventional tissue processing sequences using a clearer such as xylene. Suitable for normal processing requirements. These protocols can be constructed with or without defatting steps.
- **Standard reprocessing** — to recover under-processed tissue on an instrument configured for standard processing. These protocols start with cleaning reagents before moving to a standard tissue processing sequence.
- **Xylene-free** — protocols with high temperature wax steps and advanced processing techniques to process tissue without conventional clearing steps. Suitable for normal processing requirements.
- **Xylene-free reprocessing** — to recover under-processed tissue on an instrument configured for xylene-free processing. These protocols start with cleaning reagents before moving to a xylene-free tissue processing sequence.
- **Cleaning** — protocols to clean the retorts and reagent lines. Always run a cleaning protocol as soon as possible after wax has been in the retort. See 3.2 Cleaning Protocols for further information.

See Protocol Icons in 4.2.1 The Protocol Selection Screen for the icons used for each protocol type.

Note the following points:

- **Xylene-free reagent selection** — xylene-free protocols use two sets of dehydrants rather than dehydrant followed by clearer, as used in standard protocols. This means xylene-free protocols cannot use group reagent selection (see 4.1.2 Reagent Selection Method).
- **Xylene-free baskets** — always use spaced cassette baskets for xylene-free protocols.
- **Reprocessing carryover** — during reprocessing protocols there is significant reagent carry-over following the cleaning stages. After running a reprocessing protocol you should replace the first three processing reagents that are used after the last cleaning reagent.

4.1.2 Reagent Selection Method

All protocols use one of three reagent selection methods: group, type or station (see 5.1.1 Reagent Groups, Types and Stations for definitions of these terms). Once a protocol is created you cannot change its reagent selection method.

A protocol's reagent selection method determines the way the system selects reagent stations when the protocol is run. With the station selection method you define exactly the station to use for each step, so the system makes no "choices". For group and type selection the system selects a station from a number that are available to it, to get the best concentration for the protocol step (see Station Selection Rules below). In summary:

- **Group selection** — the system selects from all stations with reagent of the group defined for the protocol step. A station's reagent name (its type) is not used for selection, only the reagent group and concentration.

  For example, if you have bottles with reagent types "Ethanol 70%" and "Ethanol 90%" on the instrument, the system will pick an "Ethanol 90%" bottle for the first dehydrant step if that bottle has the lowest (in-threshold) concentration. Both reagent types are dehydrants, so are equal candidates for dehydrant steps.

- **Type selection** — the system selects from all stations with reagent of the type defined for the protocol step. Station reagent names (i.e. types) and concentration are used for selection.

  Using the example above, with "Ethanol 70%" and "Ethanol 90%" bottles on the instrument, if the first dehydrant step in the protocol specifies "Ethanol 70%" then the Ethanol 70% bottle with the lowest (in-threshold) concentration will be used, even if there is an Ethanol 90% bottle with lower concentration. Because Ethanol 70% and Ethanol 90% are different reagent types the system does not consider them both.

- **Station selection** — the system uses the stations defined in the protocol (typically, users define the bottles in order: bottle 1 first, then bottle 2, 3, etc.). Stations are defined by number, so the name of the reagent in a station (its type), nor the reagent group are used for selection.

  Again using the example above, if there are two Ethanol 70% bottles on the instrument and the first dehydrant step of the protocol is configured to the first of these bottles, that bottle will be used regardless of the concentration of reagent in the other bottle.

Station Selection Rules

The system uses the following rules to select stations for protocols with group and type reagent selection. "Sequence", as used below, means a series of protocol steps using the same reagent group or reagent type.

- The first step of a sequence uses the lowest concentration station available.

- The last step of a sequence uses the highest concentration station available.

- Intermediate steps in a sequence use the lowest concentration station that has not already been used.

- Where there is a single step for a particular reagent group or type the highest concentration station is used.

- Stations that have exceeded any of their use thresholds (and are not locked out) are not selected unless there is no other station available.

Reagent Selection Methods Compared

When creating protocols decide which method best suits your processing needs and reagent management strategy. Note, however, that xylene-free protocols cannot use group selection. Xylene-free protocols use dehydrants for two different functions and group selection cannot differentiate these.

Group selection ensures optimal reagent selection with minimal management. You get maximal use from reagents and with the widest range of stations to select from scheduling conflicts are minimized. You must however take some care when using group selection as the PELORIS tissue processor may use a reagent type you wished to reserve for a particular purpose. In these cases use the type or station selection method or, for one-off instances, temporarily block a station by setting its state to "In use" (see Setting Station States in 5.3.2 Setting Reagent Station Properties).

Type selection offers the same sorts of benefits as group selection – optimal selection of reagents according to concentration, minimal reagent management, efficient reagent use, and minimal scheduling conflicts. However, (provided there is more than one reagent type per group) the system selects from a smaller range of stations, so the benefits are lessened. On the other hand you have greater control over reagent selection.

Station selection gives you total control over reagent selection. However, as reagents degrade, you need to rearrange bottles between protocols if you want to ensure the most suitable reagents are used. This is a significant management burden that opens the possibility for errors. Also, the station select method does not allow the instrument any flexibility when scheduling protocols and it will not be able to recover from a processing error caused by unexpected reagent unavailability.

ℹ️ Station selection protocols are not recommended for overnight processing. If a reagent becomes unavailable for any reason then the protocol cannot be completed.

ℹ️ When running station selection protocols always check the concentration of the assigned stations before starting a run as the concentrations may not be correctly ordered if other protocols have run.

Your decision about the reagent selection method must be made in combination with decisions about how many, and which, reagent types you use, and the concentration thresholds to set for these. Note that all the pre-defined protocols in the PELORIS system use type selection but with recommended bottle configurations that have the minimal number of reagent types (see 8.2.2 List of Pre-defined Protocols and 8.3 Station Configurations). This combination provides a system that is similar to group selection, with all the consequent benefits.

4.1.3   Pre-defined Protocols

Each PELORIS system includes 11 pre-defined protocols – 1, 2, 4, 8 and 12 hour protocols for standard and xylene-free processing, and a cleaning protocol (see 8.2.2 List of Pre-defined Protocols). Access the pre-defined protocols from the **Protocol selection** screen by selecting **New** and then selecting the **Pre-defined** icon.

The pre-defined protocols are designed for use with the bottle configurations described in 8.3 Station Configurations. Leica Biosystems has extensively tested the protocols and found they give excellent results (in combination with proper reagent management and instrument maintenance). However, users should validate all protocols, including the pre-defined protocols, for use in their laboratories, where different conditions could give different outcomes.

Pre-defined protocols can be copied to appear in the **Protocol selection** screen where they become available for use. They can be copied as they are, even keeping the name unchanged, or once copied you can modify them to suit your purposes. The original versions cannot be changed. See Copying Protocols in 4.2.3 Creating New Protocols for directions to copy a pre-defined protocol.

In new PELORIS systems the pre-defined protocols are all provided, ready for use, in the **Protocol selection** screen. In case these versions are edited or deleted, however, the original versions remain available under the **Pre-defined** icon accessed with the **New** button.

4.1.4   Protocol Validation

Supervisors creating or editing protocols (or copying pre-defined protocols) have the option to "validate" them in the PELORIS software. This serves as a sign that the protocols have passed the laboratory's validation tests and can be used for regular clinical processing. Supervisors can also make valid protocols invalid.

Protocols that have been marked as valid can be run by operator-level users, while invalid protocols cannot. Invalid protocols can be run by supervisors.

Icons for validated protocols have a green check, while the icons for invalid protocols have a red cross:

Figure 35. Icon for a valid protocol	Figure 36. Icon for an invalid protocol
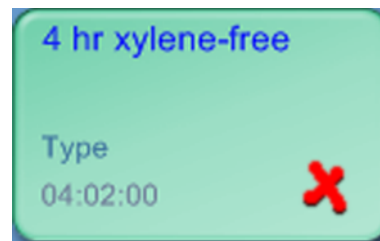
Set protocol validity status on the **Edit protocol** screen, with the **Validate protocol** / **Invalidate protocol** button.

4.1.5   Carryover Setting

The **Carryover** setting is a protocol setting for the additional carryover due to biopsy pads and other small-tissue carriers.

This section has, first, a general overview of carryover in the PELORIS system, then describes how to use the **Carryover** setting in particular.

Carryover – Overview

When reagent drains out of a retort and is replaced with reagent from another station a certain amount of the first reagent remains in the retort and mixes with the new reagent. The PELORIS reagent management system calculates the amount of this "carryover" and uses it to determine reagent concentrations.

Carryover has three main components:

- Reagent on retort walls and baskets
- Reagent on cassettes, and on and infiltrated into tissue
- Reagent on and infiltrated into small-tissue carriers (e.g. biopsy pads, biopsy cassettes, wraps etc.).

The reagent management system automatically calculates the carryover on retort walls and baskets, taking into account the retort fill level and drip time.

The carryover due to cassettes and tissue is calculated using the number of cassettes entered by users at the start of each run (in some cases an average number of cassettes may be used, see 6.1.2 Reagent Management). The amount of carryover on a standard cassette is used in the calculation. Drip time is also included.

The reagent management system calculates carryover from small-tissue carriers using the protocol **Carryover** value you set.

Carryover values are on a scale from 0 to 100:

- A setting of 0 indicates that there is no carryover due to small-tissue carriers like biopsy pads, i.e. the run has only standard cassettes with no small-tissue carriers.
- A setting of 100 indicates there is carryover equivalent to having all the tissues in a run using biopsy pads (biopsy pads have the maximum carryover of all small-tissue carriers).

Because biopsy pads can have up to 10 times the carryover of standard cassettes it is important to set a truly representative **Carryover** value in your protocols (as it is to accurately enter the number of cassettes in each run). If you set too high a **Carryover** value the system calculates too rapid degradation of reagents and requires you to replace them sooner than necessary. With too low a setting the system calculates that reagents are more pure than they are. You will use reagents beyond their optimal effectiveness resulting in poor processing quality.

Protocol carryover values are set by supervisors on the **Edit protocol** screen (the default value is set on the **Reagent management** screen). Tap the **Carryover** button and enter a number between 0 (no carryover from small-tissue carriers) and 100 (maximum carryover from small-tissue carriers).

How to Calculate Carryover Values

Carryover is dependent on the types of cassettes and other small-tissue carriers used: e.g. biopsy pads, paper or tissue inserts, mini cassettes, biopsy cassettes etc. It also depends on the proportion of these in each run.

The carryover setting is a protocol property, so it must be set to the average carryover value for runs that use the protocol.

The following table shows the carryover values that should be used for a range of cassettes and pads etc. provided by Leica Biosystems. The values in the table apply when all the tissue in the run uses the respective cassette or pad type.

Leica Biosystems products	Generic description of tissue carrier	Carryover value if 100% of tissue uses carrier
Surgipath® ActivFlo™ Routine I	Standard cassette	0
Surgipath Biopsy Pads in Surgipath ActivFlo Routine I	Biopsy pad in standard cassette	100
ActivFlo Mini Cassette in Surgipath ActivFlo Routine I	Mini cassette in standard cassette	50
Surgipath Biopsy Wraps in Surgipath ActivFlo Routine I	Biopsy wrap in standard cassette	20
Surgipath IP ActivFlo Biopsy I McCormick™ MC-605	Biopsy cassettes with >1 mm pore size	0

Sample Calculation

The average run of a protocol uses the following proportions of tissue carriers:

- Surgipath ActivFlo Routine I: 40%

- Surgipath Biopsy Wraps in Surgipath ActivFlo Routine I: 60%

Multiply the proportion of each carrier with its value from the table above to calculate the additional carryover value for that carrier:

- Surgipath ActivFlo Routine I: 40% × 0 = 0

- Surgipath Biopsy Wraps in Surgipath ActivFlo Routine I: 60% × 20 = 12

Add the resulting values:

- 0 + 12 = 12

Enter a carryover value of 12 for the protocol.

PELORIS software versions before version 1.40 had a "Biopsy pad" setting for small-tissue carrier carryover. Users with satisfactory "Biopsy pad" settings in those versions should use the same numeric value for the **Carryover** setting.

Other Products

For small-tissue carriers other than those in the table above we recommend you start with a carryover setting of 50. Use your own observations of tissue and reagent quality to refine this value. Tissue shrinkage in the block and excess solvent in the wax bath might both be indications that you have too low a carryover setting.

🛈 It is users' responsibility to validate the carryover settings in their protocols.

🛈 Contact your technical support representative if you require assistance setting suitable carryover settings.

4.1.6   Saving Protocol Files

Protocols are saved in "cfg" extension files that you can back up or to send to your service representative for troubleshooting. See Transferring Protocols in 6.2.7 File Transfer for instructions to copy protocol files on and off the instrument.

4.2   Creating, Editing and Viewing Protocols

Supervisors can create and edit protocols from the **Protocol selection** screen. Operators cannot create or edit protocols, but can view protocol details from the **Protocol selection** screen.

- 4.2.1 The Protocol Selection Screen

- 4.2.2 Editing Protocols

- 4.2.3 Creating New Protocols

- 4.2.4 Viewing Protocols

4.2.1   The Protocol Selection Screen

Tap the **Protocols** button in the Function bar to open the **Protocol selection** screen where you access all protocol configuration options.
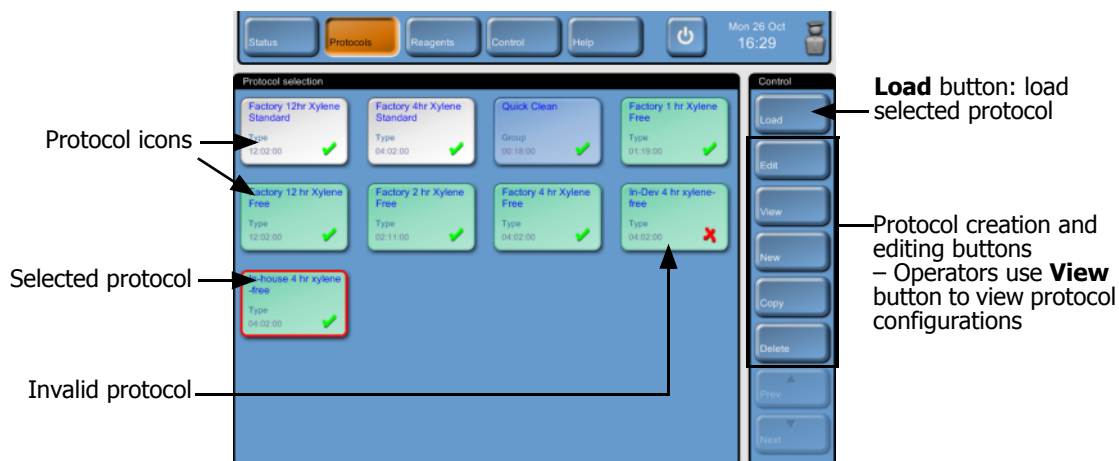
Figure 37.   The **Protocol selection** screen

Protocol Icons

On the **Protocol selection** screen each protocol is represented by a selectable icon. Each icon contains the following protocol details:

Figure 38. Protocol icon

Icons for the five protocol types (see 4.1.1 Protocol Types) have different background patterns and colors as shown below:
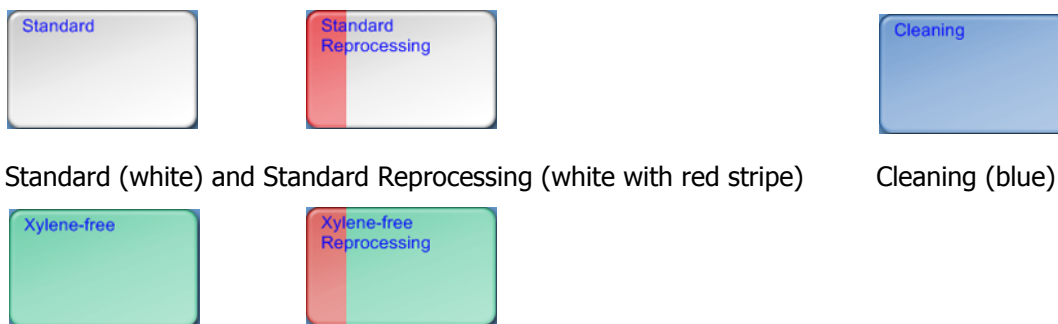
Standard (white) and Standard Reprocessing (white with red stripe)   Cleaning (blue)

Xylene-free (green) and Xylene-free Reprocessing (green with red stripe)

4.2.2   Editing Protocols

To edit an existing protocol open the **Protocol selection** screen, select the protocol, then tap **Edit** to open the **Edit protocol** screen.

Steps can be added and removed and step details – time, temperature etc. – changed. The protocol's name, notes, carryover setting and validation status can all be changed. You cannot change the protocol type or reagent selection method. You cannot remove the dry step from a cleaning protocol.

Only supervisors can edit protocols.

Figure 39 and Figure 40 show the **Edit protocol** screen and describe its use.
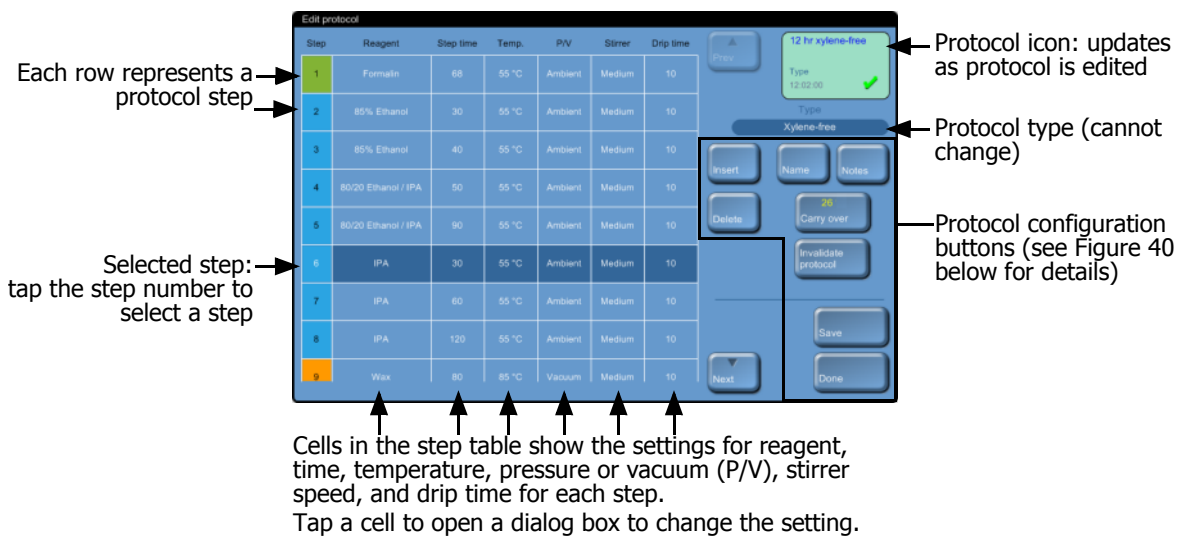
Figure 39. **Edit protocol** screen
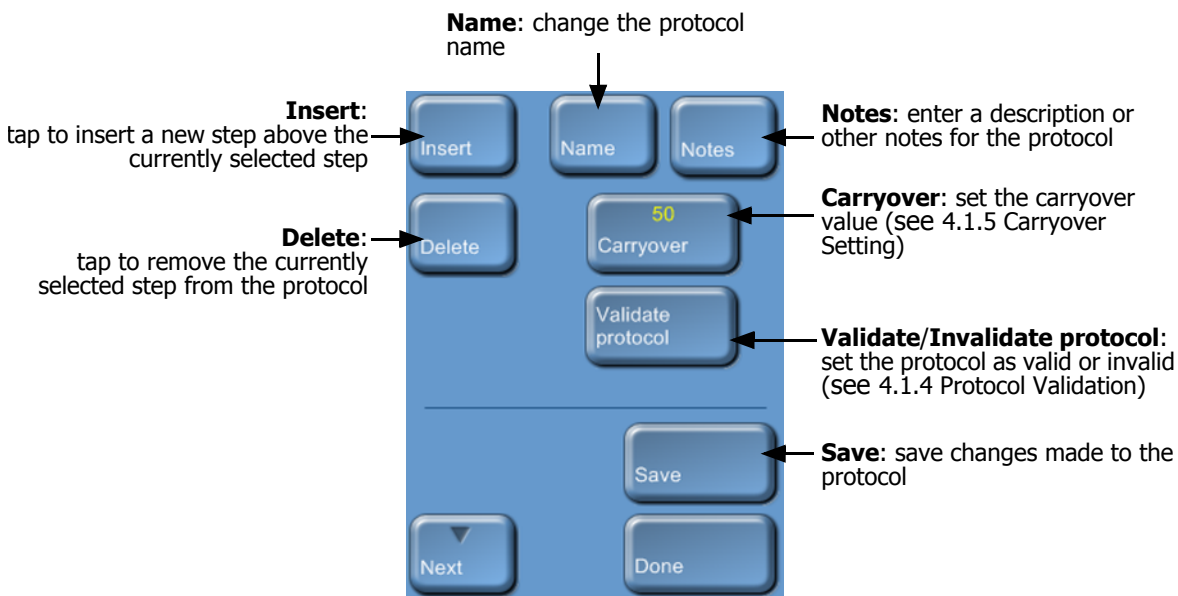
Figure 40. Configuration buttons on the **Edit protocol** screen

Selecting Reagents

When you select the Reagent cell in the protocol step table to add or change a reagent the dialog box you see depends on the reagent selection method.

For all the methods you can show only reagents that are compatible with the preceding protocol step (for the protocol's type), or all reagents. For station selection you can hide stations that have already been selected. If you choose an incompatible or hidden reagent it is added to the protocol table with an asterisk to indicate that it is disallowed. You cannot load the protocol or run the protocol.

Group Reagent Selection

If the protocol uses group reagent selection you can see the protocol types configured for the instrument, but can only select by group.

Tap anywhere on the group button to select the reagent group

Show compatible: show only compatible reagent groups

Show all: show all reagent groups
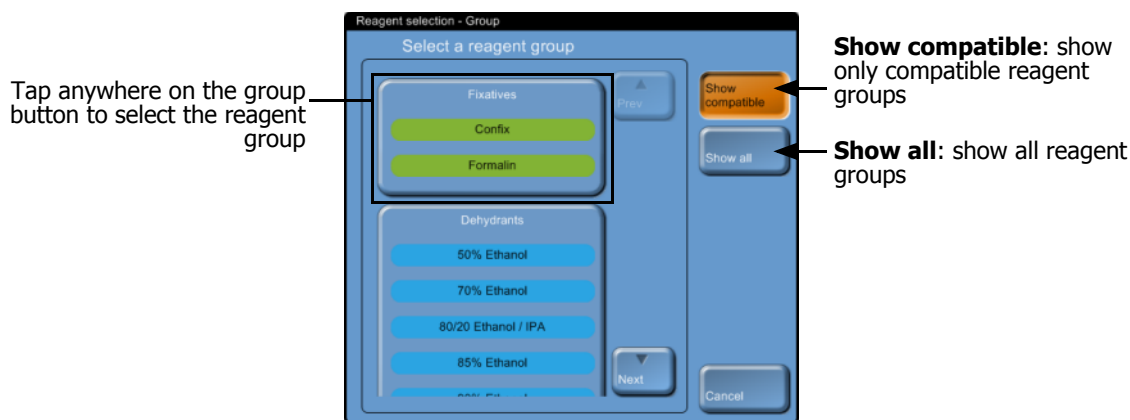
Figure 41. **Reagent selection – Group** dialog box

Type Reagent Selection

If the protocol uses type reagent selection you can see the protocol types configured for the instrument, ordered by group. Select specific types.

Tap on a type button to select the reagent type

Show compatible: show only compatible reagent groups

Show all: show all reagent groups
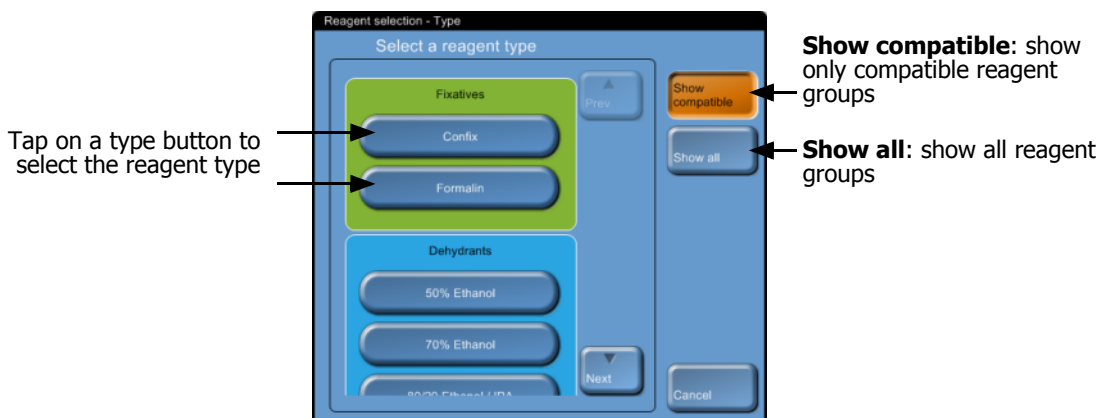
Figure 42. **Reagent selection – Type** dialog box

Station Reagent Selection

If the protocol uses station reagent selection you can see the stations configured for the instrument. Bottles that are available for selection are drawn in 3D with lids and handles. Bottles that are not available, because they have already been used or are incompatible, are drawn in 2D without lids or handles. Wax stations are similarly drawn as 3D buttons (available) or 2D icons (unavailable). Select specific stations for your protocol.

The wax chambers are all unavailable because they are not compatible with the preceding protocol step

Show compatible: show only compatible stations as available

This station is "hidden" because it has already been used for a previous step

Show all: show incompatible stations as available

Hide used: show stations that have already been selected as unavailable

These stations are available for selection

These stations are unavailable because they are not compatible with the preceding protocol step

Figure 43. **Reagent selection – Station** dialog box

Deleting a Protocol

To delete a protocol select the protocol icon on the **Protocol selection** screen and tap **Delete**.

Pre-defined protocols can be restored if required, with the normal protocol creation procedure. Other protocols cannot be retrieved unless you have copied them to an external device using the file transfer functions (see 6.2.7 File Transfer).

4.2.3 Creating New Protocols

Create new protocols from scratch or copy an existing or pre-defined protocol to modify. Make sure you select the right protocol type and reagent selection method when you start (or copy a protocol of the right type and reagent selection method) because these settings cannot be changed after you have started protocol configuration.

> **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.

Instructions below describe how to create new protocols from scratch. See Copying Protocols below for instructions to create a new protocol by copying another one.

Creating New Protocols From Scratch

1. Open the **Protocol selection** screen (**Protocols** in the Function bar) and tap **New**.

2. Select the protocol type (see 4.1.1 Protocol Types).

3. Select a reagent selection method (see 4.1.2 Reagent Selection Method).

   Automatic dialog boxes will now guide you through the creation of the first step.

4. Tap the next row in the protocol table to add the second step.

   You are prompted to supply the reagent and step duration – other step properties (pressure, stirrer etc.) are inherited from the previous step. Tap the appropriate cell to change any of these values.

   Cleaning protocols automatically have a final dry step. You cannot edit this step.

5. Add further steps as required.

6. Tap the **Name** button to name your protocol.

7. Optionally tap the **Notes** button to add any information you want to keep with the protocol.

8. Set a carryover value with the **Carryover** button (see 4.1.5 Carryover Setting).

9. Tap the **Save** button to save the protocol.

10. Tap the **Done** button to finish.

Your new protocol will now be available in the protocol selection list.

Copying Protocols

You can copy any protocol displayed on the **Protocol selection** screen in order to create a new one based on it. Alternatively copy a pre-defined protocol.

1. Open the **Protocol selection** screen (**Protocols** in the Function bar) and:

    (i) select a protocol to copy on the **Protocol selection** screen

    OR

    (ii) tap the **New** button and then the yellow **Pre-defined** icon. Then select the pre-defined protocol to copy.

2. Tap the **Copy** button from the control panel.

3. Use the keypad to enter a new name for your protocol.

    The **Edit protocol** screen opens with the copied protocol.

4. Modify the protocol as described in 4.2.2 Editing Protocols.

    You cannot edit the final dry step in cleaning protocols.

5. Tap the **Save** button to save the protocol.

6. Tap the **Done** button to finish.

Your new protocol will now be available in the protocol selection list.

4.2.4   Viewing Protocols

Operator-level users cannot create or edit protocols. However they can view all protocol details including step details, notes, and the date and time the protocol was last modified.

To view a protocol's details select the protocol icon on the **Protocol selection** screen (**Protocols** on the Function bar) and tap the **View** button.

5

Reagent Setup

This chapter gives an overview of PELORIS reagent management as well as providing instructions to replace reagents and configure them in the software.

- 5.1 Reagents Overview
- 5.2 Managing Reagent Types
- 5.3 Managing Reagent Stations
- 5.4 Replacing Reagents

5.1   Reagents Overview

Using the right reagent at the right time, at the right concentration, is of utmost importance for high quality tissue processing. The PELORIS system has an advanced reagent management system that helps ensure consistently high quality processing while allowing you flexibility to fit into your laboratory's workflows.

The Reagents Overview section describes the main features of reagent management in the PELORIS system:

- 5.1.1 Reagent Groups, Types and Stations
- 5.1.2 Concentration Management
- 5.1.3 Thresholds
- 5.1.4 Recommended Reagents
- 5.1.5 Tissue Marking
- 5.1.6 Reagent Compatibility

5.1.1   Reagent Groups, Types and Stations

The PELORIS tissue processor manages reagents by groups, types and stations.

Groups

Groups specify reagent function. For example, the fixatives reagent group includes all reagents that can be used as a fixative.

There are nine factory-defined groups. Each group has a color-code used in the PELORIS software and on bottle labels. Refer to the following table for a list of the groups and their colors and functions.

Group	Function	Color
Fixatives	Tissue preservative.	Green
Dehydrants	Removes fixative reagents from tissue.	Blue
Defat	Removes fat deposits from tissue.	Yellow
Post defat	The dehydrant used after a defatting step.	Purple
Clearers	Clears the dehydrants from the tissue.	Pink
Wax	The embedding medium.	Orange
Cleaning solvents	First cleaning reagent.	Light pink
Cleaning alcohols	Second cleaning reagent.	Light blue
Cleaning water	Third retort cleaning reagent.	Grey

The reagent group determines reagent compatibility (see 5.1.6 Reagent Compatibility).

Types

Reagent types are the specific reagents within each group, e.g. formalin, xylene, Waxsol. As well as the chemical constituent, reagent type definitions can include concentrations. For example "70% Ethanol" and "80% Ethanol" are reagent types defined in PELORIS.

Reagent types have the following properties:

- A unique name

- Default concentration: the concentration of the reagent when fresh.

- Purity thresholds: to ensure you replace degraded reagent (see 5.1.3 Thresholds).

- Temperature thresholds: used to ensure processing quality and safe usage of the reagent (see 5.1.3 Thresholds).

The PELORIS software includes a number of pre-defined reagent types. These are adequate for most laboratories, however you can create your own reagent types if needed.

Use the **Reagent types** screen to define and edit reagent types (see 5.2 Managing Reagent Types).

Reagent type names do not affect reagent concentration. For example, when assigning a reagent type called "Ethanol 70%" to a station, the initial concentration value would be the type's default value (probably 70%) but you could set the initial concentration to anything between 0 and 100%.

Stations

The PELORIS tissue processor has 20 reagent stations: the 16 reagent bottles and the 4 wax chambers.

Each station has the following properties:

- The reagent type that the station contains

- The concentration of the reagent in the station, as calculated by the PELORIS system

- The station's use history:
  - The number of cassettes processed with the reagent in the station
  - The number of runs (cycles) processed with the reagent in the station
  - The number of days the reagent has been in the station

- The station's state:
  - **Dry**: the station has been completely drained leaving only a small amount of residue. It can be filled with any reagent.
  - **Empty**: reagent has been removed from the station to fill a retort. Reagent in excess of the amount needed to fill the retort remains in the station.
  - **In use**: a reagent transfer is in progress or has been abandoned.
  - **Full**: the station holds enough reagent to fill a retort.
  - **Not molten**: for wax chambers only, the state to set when adding solid wax (see 5.4.5 Replacing Wax).

- For wax chambers only, the chamber's current temperature.

Use the **Reagent stations management** screen to define reagent stations and to monitor their use history and concentration (see 5.3 Managing Reagent Stations).

5.1.2 Concentration Management

The high quality tissue processing delivered by the PELORIS system is largely due to its accurate monitoring of the concentration of the reagents in each station. This section describes the main features of concentration management in the system.

Concentration in the PELORIS System

Concentration is the proportion of a reagent that is of the group to which the reagent is assigned. The following examples illustrate how the concentration is determined.

- A dehydrant that is 80% ethanol (a dehydrant) and 20% water (not a dehydrant) has a concentration of 80%.

- A dehydrant that is 80% ethanol (a dehydrant) and 20% IPA (also a dehydrant) has a concentration of 100%.

- Absolute ethanol (100% dehydrant) contaminated by carryover from absolute IMS (100% dehydrant) has a concentration of 100%, as both the original reagent and the contaminant are dehydrants.

- A new xylene (100% clearer) contaminated by carryover from absolute ethanol (100% dehydrant) has a reduced concentration — typically around 94% after one cycle — as it will consist of 94% xylene (clearer) and 6% ethanol (not a clearer).

A reagent that is used early in a sequence of the same group will have a rapid concentration decline as most of the contamination it receives will be from the previous group. A reagent that is used late in a sequence will have a slow concentration decline as most of the contamination it receives will be from the same group.

Managing Concentrations

The PELORIS software uses reagent concentrations to select stations when protocols are run (unless the protocol uses station reagent selection). It selects the station with the lowest (in-threshold) concentration of a reagent group or type for the first step using that group or type, then stations of increasing concentration for following steps. It always uses the highest concentration reagent for the last step before changing to another reagent group or type. The software also uses concentration information (amongst other factors) to prompt you to change reagents that have exceeded purity thresholds.

It is very important, then, for high quality processing and efficient reagent use, that the concentration information the software uses is accurate. The software automatically tracks the concentration of the reagent in each station, updating values after each run. For it to do this effectively you must enter accurate information for it to work with, e.g. set realistic protocol carryover values and enter the correct number of cassettes in each run. It also means you should update the software properly whenever you change reagents.

Under default settings the software assigns concentrations "by calculation". This uses information such as the retort fill level, the number of cassettes processed, the carryover setting and the reagent groups involved to calculate concentration in each station.

Concentrations can also be assigned "by cycles" or "by position" (i.e. by station). These methods rank station concentration by the number of processing runs each station has been used for or the physical order of the stations, respectively.

Leica Biosystems does not recommend the "by cycles" or "by position" options, which must be set by a technical support representative.

For consistently high quality processing always replace reagents as soon as you are prompted, with fresh reagent at the default concentration. If you remove a bottle from the instrument, always check that you enter the correct reagent information for the bottle when you return it. Supervisors can manually change station concentration values in the **Reagent stations** screen if they believe the value there is incorrect. Be sure that you independently verify the concentration if making such a change.

5.1.3   Thresholds

Each reagent type has a range of thresholds that supervisors can configure on the **Reagent types** screen. The thresholds for the pre-defined reagent types should be adequate for most laboratories, but alternative settings may suit some laboratories better – contact customer support for advice before changing threshold settings. Validate any threshold changes using the procedures that apply to your laboratory.

The thresholds fall into two categories:

- Purity thresholds set usage limits for reagents according to their purity.
- Temperature thresholds set limits on the retort temperatures for reagents to help ensure high processing quality and safety.

Purity Thresholds

PELORIS uses purity thresholds to limit the use of reagent as it becomes increasingly contaminated with reagent carried over from other groups.

When a threshold is exceeded the software warns you that you need to replace reagent. Under default settings you are able to use a station with out-of-threshold reagent for one more run after such a warning. Following this the station is locked (meaning it cannot be used at all), and/or you cannot run further protocols until fresh reagent is loaded. Your customer support representative can change the number of runs allowed after reagent replacement warnings.

Reagent purity is assessed using one or more of four different "reagent threshold check" methods:

- Concentration of the reagent
- Number of cassettes processed with the reagent
- Number of processing runs (cycles) the reagent has been used for
- Number of days the reagent has been loaded on the instrument

By default, all of these methods are available for you to configure for individual reagent types. The Reagent threshold check section of the **Reagent management** screen shows the methods enabled for your system (these settings can only be changed by customer support representatives).

The checking methods are configured to monitor two types of purity threshold:

- reagent change thresholds, and
- final reagent thresholds, explained below.

Reagent Change Thresholds

Reagent change thresholds set the limits for any use of reagent on the PELORIS system. Reagent that has exceeded its change threshold should be replaced with fresh reagent immediately.

Stations with reagent that has exceeded its change threshold are shown with a hatched icon on the **Status** screen (bottle icon shown at right). In addition, the system displays a warning message.

The PELORIS system does not use out-of-change-threshold stations unless no other stations are available. If no other stations are available out-of-threshold stations will be used for one run (default setting) before being locked. Locked stations cannot be used at all until the reagent is replaced. The system will not allow you to load protocols that require a locked station.

Final Reagent Thresholds

Final reagent thresholds set limits on reagent purity for use in protocol steps that precede a change to another reagent group (or type, for protocols configured by type), in the next step.

Final reagent thresholds are set higher than change thresholds. This ensures minimum contamination from the preceding reagent group to the subsequent reagent group.

Reagents that have exceeded their final threshold are displayed as usual on the **Status** screen, however PELORIS displays a warning message. Following the warning you are able to process one run (default setting) that uses reagent that is out of threshold for the final step. After this, you will not be able to load protocols that require the reagent group affected.

When you are warned that reagent has exceeded the final threshold replace the least pure bottle of the reagent type concerned. The bottle that exceeded the final reagent threshold, triggering the warning, will still have reagent with a relatively high concentration. It will still be acceptable for steps in the protocol sequence before the final step, so it is inefficient to replace it.

Temperature Thresholds

There are three temperature thresholds for each reagent type:

- **Ambient** — the highest allowable temperature for the reagent in the retort at ambient (and high) pressure.

- **Vacuum** — the highest allowable temperature for the reagent in the retort when the retort is evacuated.

- **Safe** — the highest temperature at which it is safe to open a retort containing the reagent.

The PELORIS software will not allow you to create protocols that put reagents in conditions that exceed their ambient or vacuum temperature thresholds. The software warns you if you perform an action that requires you to open a retort if the retort contains reagent above its safe temperature threshold.

WARNING

Take extreme care if changing reagent temperature thresholds. Raised thresholds can lead to reagents boiling and/or the release of large quantities of fumes that can overload the filtering system. Boiling reagents can produce excessive pressures within the instrument increasing the chance of reagent contamination and spills.

5.1.4   Recommended Reagents

While each laboratory is responsible for its choice of reagents and wax, using reagents other than those recommended for PELORIS can result in poor processing or compromise instrument reliability. Compliance with the following guidelines will ensure superior tissue processing.

The use of alternative reagents must be validated by the end user according to their local or regional accreditation requirements.

Adequate fixation of tissue samples is required for optimum results and should be achieved prior to placement on PELORIS or incorporated into the fixative step of the protocol. The following reagents have been validated for use on PELORIS.

Fixatives

- 10% Neutral Buffered Formalin (NBF)

Alcohols

- Histological grade ethanol
- Reagent (grade) ethanol
- Absolute ethanol
- Isopropyl alcohol (dehydrant)

Denatured ethanol is acceptable if:

- It is at least 99% ethanol, and
- It is denatured with methanol and/or isopropyl alcohol (IPA)
- Ethanol containing acetone must not be used.

Clearing Agents

- Xylene is the recommended clearing agent.
- Xylene-free processing requires the use of isopropyl alcohol as the clearing agent. It has been fully tested and validated.

Paraffin

- Use histological wax for histology

- Parablocks™

- Paraplast®

Cleaning Agents

- Use ethanol for the cleaning alcohol solution.

- In xylene processing mode, we recommend xylene as the cleaning solvent.

- For true xylene-free processing, we recommend Waxsol™ as the cleaning solvent.

5.1.5 Tissue Marking

Some laboratories have traditionally added eosin (or other dyes) to formalin or alcohol during tissue processing, to aid in the visualization of tissue during embedding. This practice is NOT recommended for the PELORIS tissue processor. The dyes can build up on the liquid level sensors and compromise performance. If you need to mark tissue for embedding, Leica Biosystems recommends you add the dye at the grossing stage.

In spite of this recommendation, eosin can be used on the PELORIS if the customer feels there are strong reasons for doing so, and due care is taken. If using eosin on the PELORIS add the dye to the fixative in preference to the alcohol. However, rapid turnaround times can mean that tissue is at the grossing stage for only a short time, and fixation steps on the PELORIS can also be short. So some customers prefer to add eosin at the alcohol stage. This is also acceptable if due care is taken.

Recommended eosin concentrations for the different stages are given below. Testing was conducted using Surgipath Alcoholic Eosin (1%) – catalog no. 3801600.

> **CAUTION**
> If adding eosin to reagents on the PELORIS be sure to clean the retorts daily to avoid buildup of dye on the liquid level sensors, which can compromise performance. See Clean Retorts in 7.2 Daily Tasks.

Preference 1 – At Grossing

Use 10mL of 1% liquid eosin per liter of formalin.

You can vary the concentration to correspond with the length of the processing protocol, where some dye will be lost. A disadvantage of staining at grossing is that specimens are not immersed in dyed formalin for the same amount of time.

Preference 2 – In Fixative on PELORIS

Use 50 mL of 1% liquid eosin per 5 L PELORIS reagent bottle of formalin.

Preference 3 – In Alcohol on PELORIS (Xylene)

Use 10mL to 25mL of 1% liquid eosin per 5L PELORIS reagent bottle of ethanol (there are eight ethanol bottles in the recommended bottle configuration for xylene processing).

Specimens are immersed in the marking reagent for the same amount of time, giving consistent staining. Protocols longer than two hours may cause overstaining – reduce the eosin concentration as required.

Preference 3 – In Alcohol on PELORIS (Xylene-free)

Use 250mL of 1% liquid eosin per 5L PELORIS reagent bottle of 85% ethanol (there are three bottles of 85% ethanol in the recommended bottle configuration for xylene-free processing).

Specimens are immersed in the marking reagent for the same amount of time, giving consistent staining. Protocols longer than two hours may cause overstaining – reduce the eosin concentration as required.

5.1.6   Reagent Compatibility

As tissue processing requires the use of incompatible reagents, the PELORIS tissue processor software uses a set of rules to ensure that only compatible reagents are allowed to mix. Reagent mixing usually occurs when a reagent enters a retort of state **Empty**, containing residual amounts of the previous reagent. This may happen as part of a protocol, during manual operations or during remote and fill/drain procedures.

The software will not allow you to create a protocol that has an incompatible reagent sequence and you are also prevented from mixing incompatible reagents during remote fill/drain procedures. You cannot run a protocol where the first reagent is incompatible with the retort residue. You can however load a protocol with an incompatible first step but the reagent sequence must be edited during scheduling to select a new first step that is compatible with the retort residue (see 3.4.2 Editing the Protocol for a Single Run).

Reagent compatibility varies depending on the action or protocol being undertaken. Use the reagent tables in 8.5 Reagent Compatibility Tables to check reagent compatibility before creating protocols, conducting manual operations or initiating remote fill/drain procedures.

5.2   Managing Reagent Types

The PELORIS software uses two lists of reagent types – an "active" list for reagents you use and a "dormant" list with all reagent types configured in the system. Supervisors can edit the default concentrations and purity and temperature thresholds (see 5.1.3 Thresholds) for active reagents. They can easily move reagents on and off the active list, and create new reagent types. Operators can only view the active list.

See sections below for editing and managing reagent types:

- 5.2.1 Pre-defined Reagents
- 5.2.2 Editing Active Reagent Types
- 5.2.3 Managing the Reagent Types Lists

5.2.1 Pre-defined Reagents

A number of reagent types are pre-defined in the PELORIS system. You can edit the properties of these reagent types but they can cannot be deleted. There is no requirement to use the pre-defined types however – you can leave them on the dormant list.

If you change the properties of pre-defined reagent types you cannot use the software to automatically return them to their original values. However the default values for many of the pre-defined reagents are shown in 8.1 Reagent Threshold Guidelines.

5.2.2 Editing Active Reagent Types

Use the **Reagent types** screen (**Reagents** menu, **Types**) to view and edit the active reagent types list. You also access other reagent type management options from this screen.

When you open the screen you see the list of active reagent types. These reagent types are available to set for reagent stations. There are two views of the active list – one each for purity and temperature thresholds (both views show default concentrations). Change views with the **Purity thresholds** and **Temperature thresholds** buttons. Figure 44 and Figure 45 show the two views.
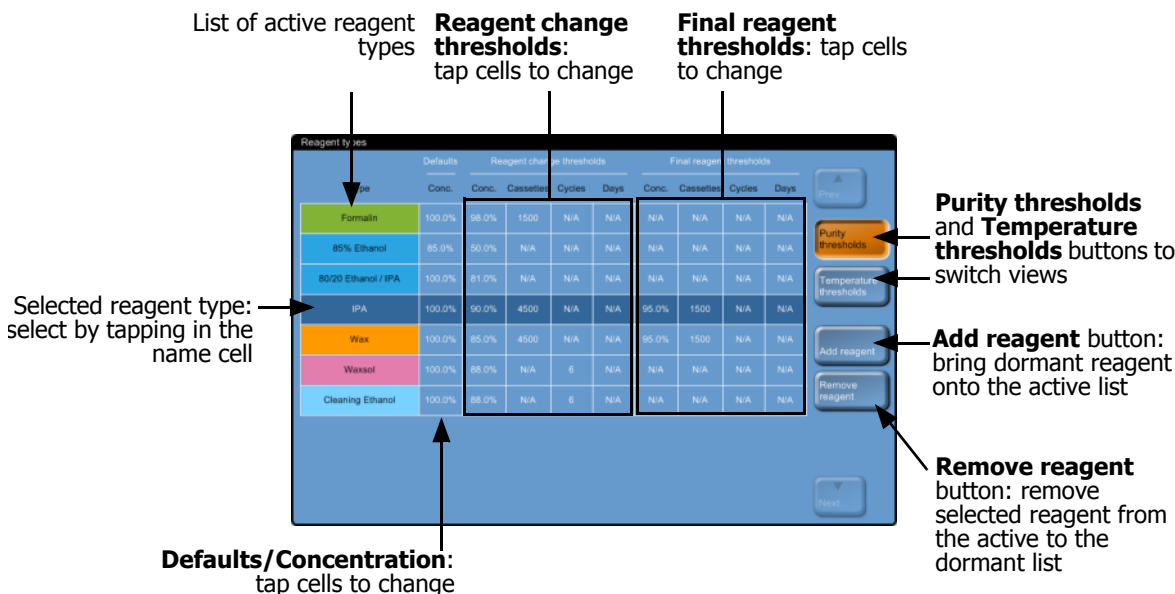
Figure 44. **Reagent types** screen, purity thresholds view, using recommended reagent types for xylene-free processing
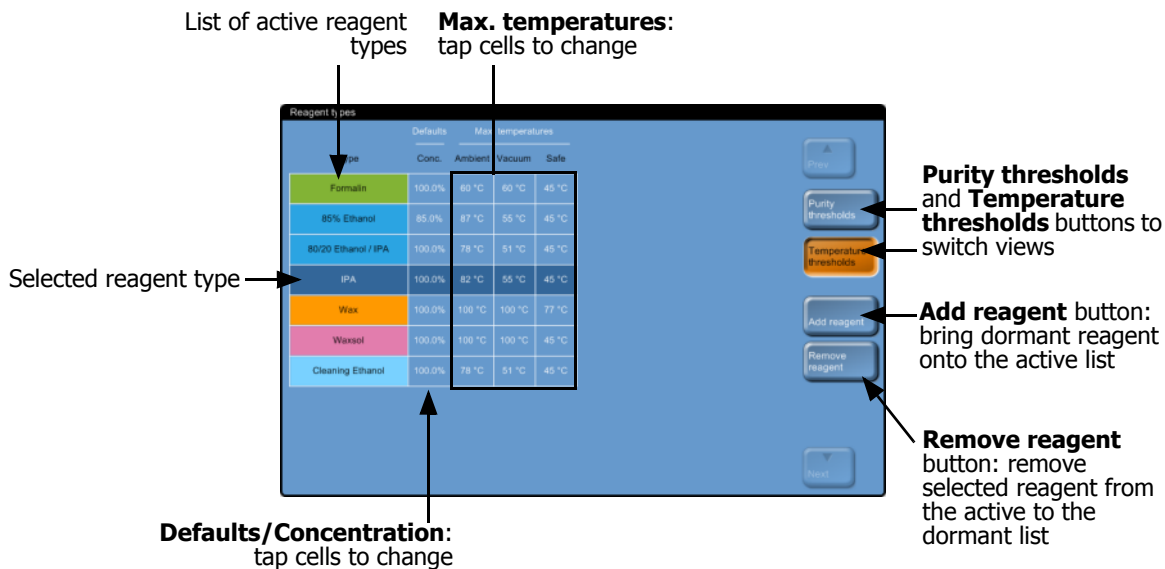
Figure 45. **Reagent types** screen, temperature thresholds view, using recommended reagent types for xylene-free processing

Supervisors can edit the default concentration, purity thresholds, and temperature thresholds for all active reagent types.

You edit a type's attributes by tapping the appropriate table cell then entering the required value using the resultant keypad. The attributes update immediately and are applied to all reagent stations and protocols that use the reagent type. The changes will not affect running protocols.

Lowering temperature thresholds may make protocol steps invalid. You must lower the step temperature to comply with the new reagent threshold before you can load or run the protocol.

Leica Biosystems does not recommend you lower reagent concentration thresholds. Raising thresholds can help to correct poor quality processing due to impure reagents.

If you no longer use a reagent in the active list you can remove it to the dormant list, to keep the active list as small and easy to manage as possible. Select the reagent type by tapping in its name cell, then tap **Remove reagent**.

5.2.3 Managing the Reagent Types Lists

Apart from editing the properties of active reagents and moving them to the dormant list, all management of the reagent types lists uses the **Add reagents** dialog box (Figure 46) opened from the **Reagent types** screen. The dialog box lists all reagent types, ordered by reagent group, on the left. Filter the list by reagent group with buttons on the right.
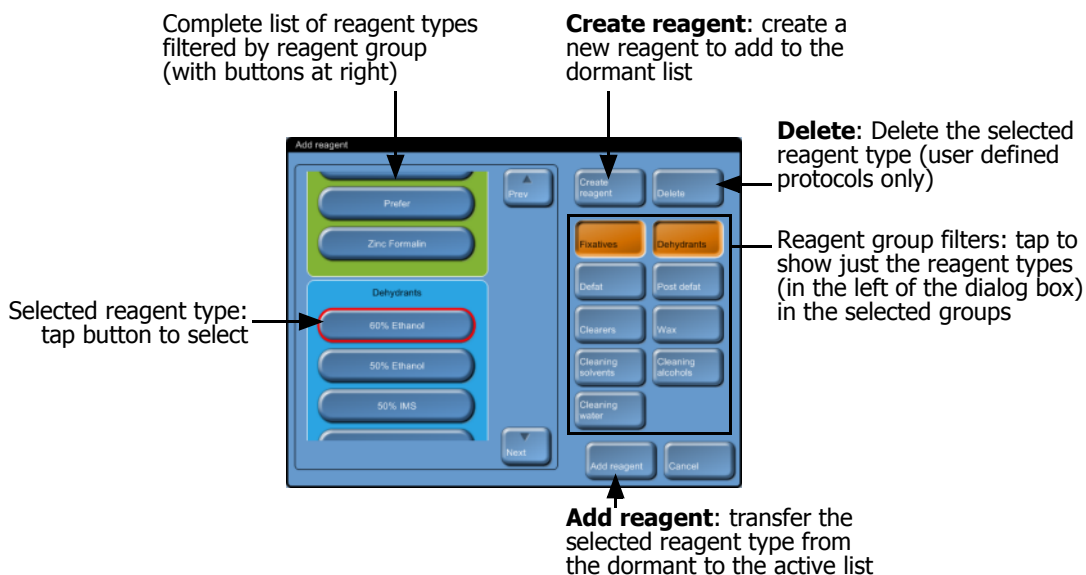
Figure 46. **Add reagent** dialog box

To add reagent types to the active list select a reagent type from the list and tap the **Add reagent** button.

To add a new reagent type to the dormant list tap the **Create reagent** button. Choose a reagent group for the new reagent type and then set a unique name for it.

Use the **Delete** button to remove user defined reagent types from the dormant list. This deletes them from the software completely. You cannot delete pre-defined reagent types.

5.3 Managing Reagent Stations

The PELORIS processor has 20 stations – 16 reagent bottles and four wax chambers.

You must set the stations in the software to the reagent types loaded on the instrument. Once this is done the system tracks each station's use history (the numbers of runs and cassettes processed and number of days loaded on the instrument), current concentration, and, for wax chambers, the current temperature. See Stations in 5.1.1 Reagent Groups, Types and Stations for further details.

Supervisors can set the reagent type for each station and change concentration values if they know that actual concentrations are different from those in the system. Both supervisors and operators can change station states if required. The use history details can only be viewed.

It is essential for safe operation of the PELORIS that there are bottles loaded into all bays in the reagent cabinet. If you do not wish to use a particular station, set its state to **Dry** and (for non wax stations) insert an empty bottle into the station's reagent cabinet location.

The choice of which reagent types to load on the instrument, and how many bottles of each, is an important question that you must decide along with consideration of the protocols you run. See 8.3 Station Configurations for configurations suitable for the default protocols.

- 5.3.1 Reagent Stations Screen
- 5.3.2 Setting Reagent Station Properties

5.3.1 Reagent Stations Screen

Use the **Reagent stations** screen (**Reagents** menu, **Stations**) to set up and manage reagent stations. There are two views of the screen – one for the 16 reagent bottles and the other for the four wax chambers. Change views with the **Reagent bottles** and **Wax chambers** buttons.

See Figure 47 and Figure 48 for descriptions of the information and options on the **Reagent stations** screen.
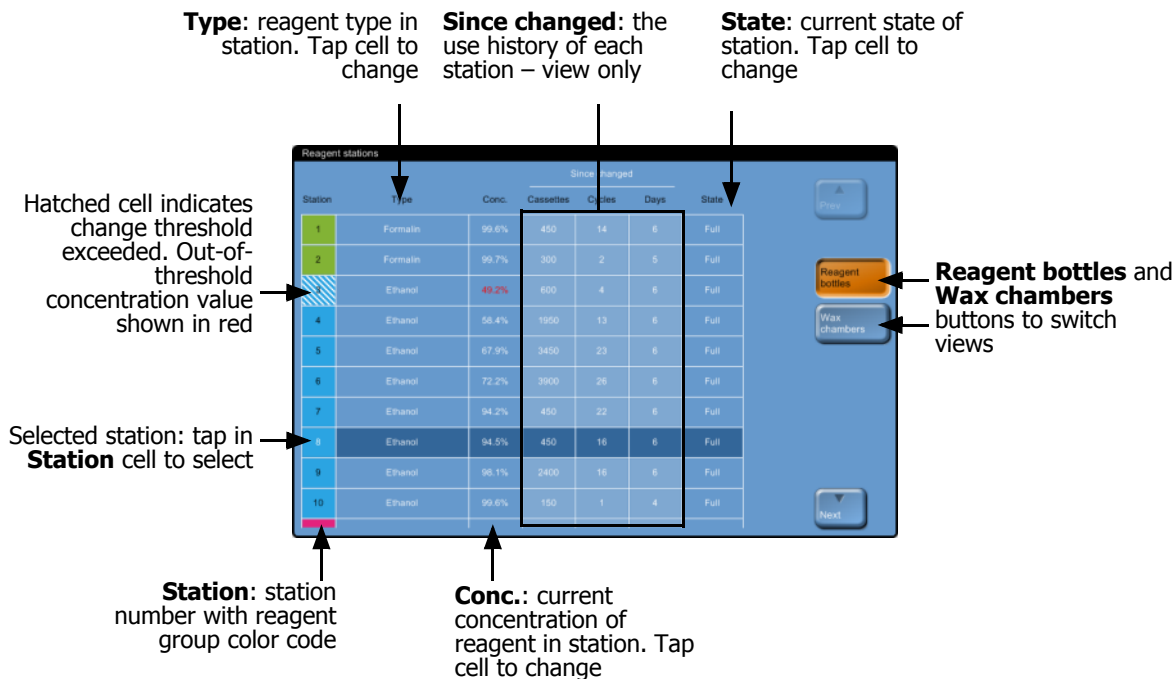
Figure 47. **Reagent stations** screen, reagent bottles view
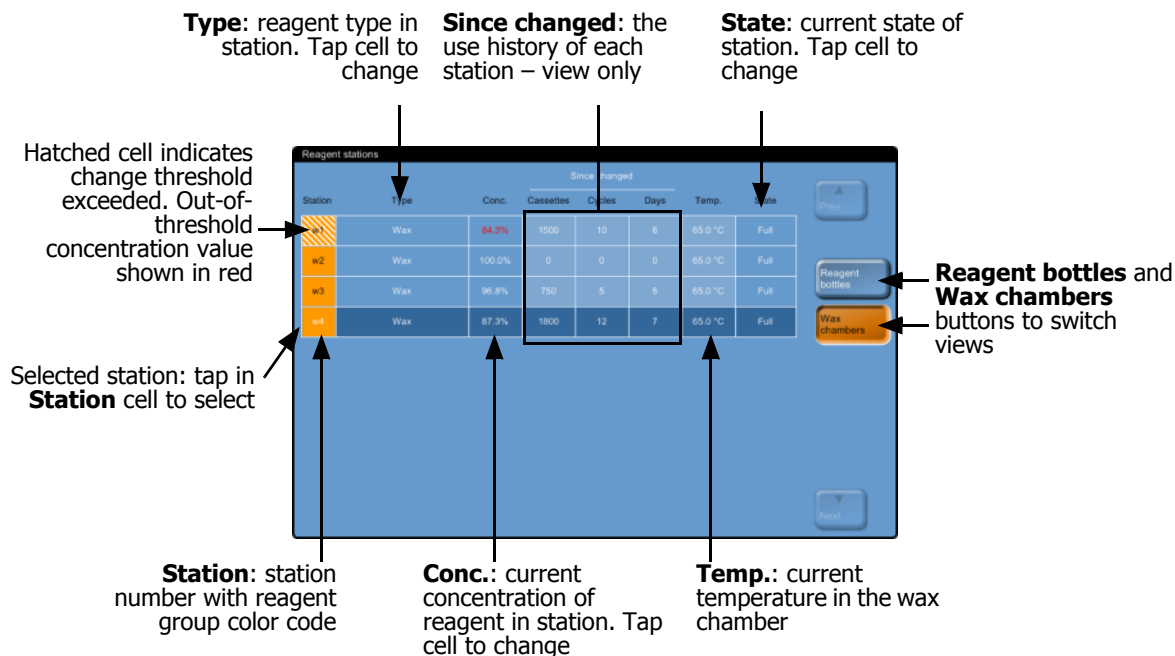
Figure 48. **Reagent stations** screen, wax chambers view

5.3.2 Setting Reagent Station Properties

See sections:

- Assigning New Reagents to Stations
- Changing Reagent Concentration
- Setting Station States

⚠️ **CAUTION**
Altering reagent station configurations while protocols are running may cause abandoned protocols.

Assigning New Reagents to Stations

If you change the type of reagent loaded in a station you must change the reagent type assigned to the station in the software.

Follow the steps below to change the reagent type for a station:

1. Remove the bottle (or drain the wax chamber) with the reagent type you are replacing.

2. In the **Reagent stations** screen tap in the station's **Type** cell to open the **Reagent selection** dialog box.

3. Select the new reagent type from the list.

   The dialog box shows all the current active reagent types (see 5.2.3 Managing the Reagent Types Lists).

4. When prompted, tap **Yes** to reset the station properties. This sets the use history counts to zero and the station concentration to the default for the new reagent type.

5. Clean the bottle if necessary and fill with fresh reagent of the new type. Load the bottle back onto the instrument (or fill the wax chamber).

6. For a bottle, in the **Inserted bottle configuration** dialog box, select the bottle in the table and then tap the **Emptied and refilled** button.

   For a wax chamber, set the station state to **Full** on the **Reagent stations** screen.

When you change the reagent type for a station on the **Reagent stations** screen you are always prompted to reset the station's concentration and use history. If you select **No** you will retain the previous reagent's concentration and use history. Use this option only if you are correcting a previous error in the identification of the reagent in the station, and you are not actually changing the station's contents.

⚠️ **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.

Changing Reagent Concentration

You can set a station's "calculated" concentration value. Tap the station's **Conc.** cell. Enter the new concentration in the keypad.

⚠️ **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.

Setting Station States

All users can change station states (**Full**, **Empty**, **In use**, **Dry**, and **Not molten**) in the **Reagent stations** screen.

For reagent bottles you should not normally need to do this – you update the bottle states when you remove and replace bottles and then the software tracks the state automatically. Change bottle station states only if the wrong state is displayed or you want to make a full bottle unavailable for use (by setting it to **In use**).

For wax chambers you must change the station state in the **Reagent stations** screen as a normal part of wax replacement.

To change a station state tap the station's **State** cell and select the appropriate icon in the dialog box.
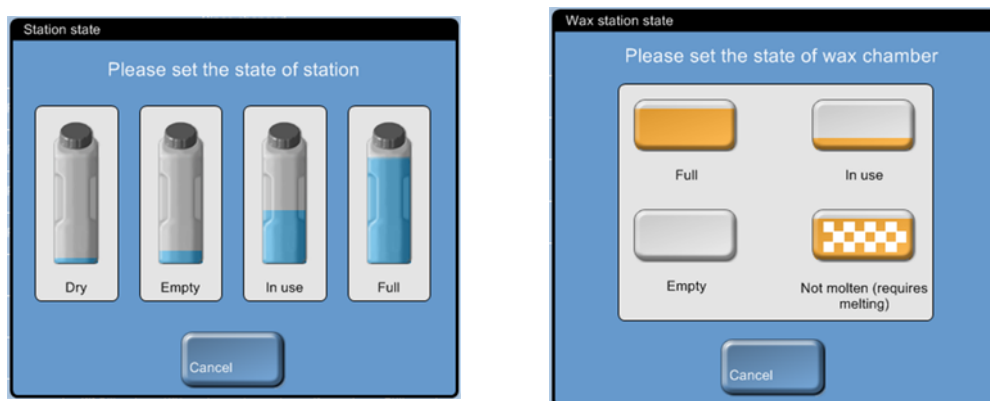
Figure 49. Station state dialog box for reagent stations (L) and wax stations (R)

See 3.3.1 Status Area for detailed information on reagent station states.

⚠️ **WARNING**

Ensure you set the station state to the actual condition of the station. An incorrect reagent station state may cause fluid leaks or abandoned processing runs.

5.4   Replacing Reagents

Always replace reagents as soon as possible after the system alerts you.

There are two methods to replace reagent in bottles:

- **Remote fill/drain** — pump the old reagent out and new reagent back in without removing the bottle, using commands on the **Remote fill/drain** screen.
- **Manually** — remove the bottle, drain and refill, then replace on the instrument.

For wax you must drain the chamber using the **Remote fill/drain** screen, fill the chamber manually, and then update the software.

See sections below:

- 5.4.1 Remote Fill/Drain Screen
- 5.4.2 Remote Fill/Drain Connections
- 5.4.3 Replacing Reagent – Remote Fill and Drain
- 5.4.4 Replacing Reagent – Manual
- 5.4.5 Replacing Wax
- 5.4.6 Filling and Draining Retorts

5.4.1   Remote Fill/Drain Screen

Use the **Remote fill/drain** screen (**Reagents** menu, **Remote fill/drain**) to drain the wax baths and to fill and drain reagent bottles without removing them from the instrument. You are able to fill/drain stations individually or as a group of compatible stations in a single operation. You can also fill and drain retorts from this screen to enable recovery from partially completed fill/drain operations.

All users can perform the functions on the **Remote fill/drain** screen.

Figure 50 shows the **Remote fill/drain** screen with the main features described:

Fill to/Drain from bottles, **Drain to waste,** or
Fill/Drain retort:
start fill or drain when appropriate station, remote
source and retort are selected

Abandon:
stop the drain or fill

Wax waste:
select with a wax
chamber to drain the
chamber

Remote:
select with a retort and
bottle to fill or drain
the bottle

Retort A:
scheduled fill/drain
operations for retort A

Retort B:
scheduled fill/drain
operations for retort A

Wax System:
scheduled fill/drain
operations for the wax
chambers
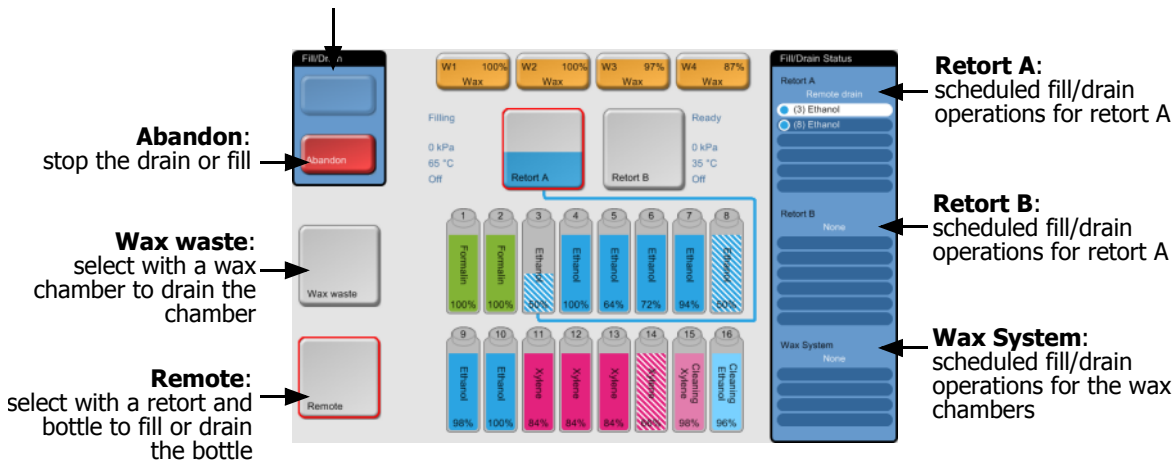
Figure 50.   **Remote fill/drain** screen

5.4.2   Remote Fill/Drain Connections

The remote fill/drain line and the wax drain outlet sit above the carbon filter in the reagent cabinet (see Figure 52). A protective flap covers the outlets. The wax waste line is heated to ensure that the wax does not solidify during the drain.
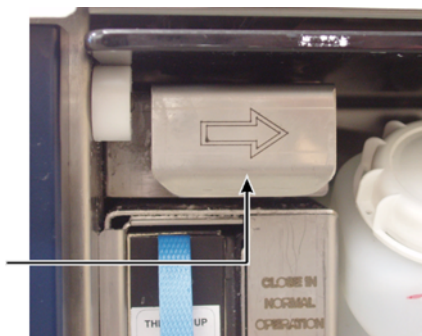
Figure 51. Remote fill/drain flap closed

Figure 52. Remote fill/drain flap open with reagent line (left) and wax waste line (right)

- Before draining a wax station, slide back the fill/drain flap then fit the wax waste hose to the wax waste line (right connection in Figure 52).
  Ensure the wax waste hose drains into a suitable container.

  Ensure the hose remains out of the drained wax so that wax can't solidify on the end of hose.

- Before filling or draining reagent bottles, connect the remote fill/drain hose (see Figure 53) to the remote fill/drain line (left connection in Figure 53). The hose has a push-fit coupling that ensures a secure connection to the line.

To fit the hose, slide back the fill/drain flap, and push the coupling onto the end of the line. To remove the hose, slide back the locking ring (item 1 in Figure 53) and pull the hose off the remote fill/drain line.
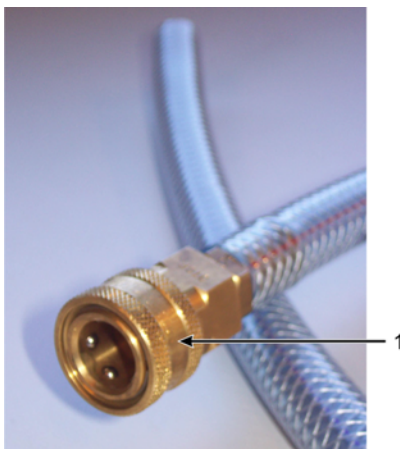
Figure 53. Remote fill/drain hose with locking ring (1)

WARNING

Always ensure that you fill from or drain to a large stable container. The fill/drain functions include a strong purge which may cause an unstable container to tip over and spill. The container must also be of sufficient volume to easily accommodate all of the drained fluid.

If you need to use a small container you must support the container and hose during the fill or drain.

WARNING

Always use the hose supplied with the PELORIS system for reagent bottle operations.

WARNING

Ensure you use the correct size wax drain hose to avoid wax leakage. Old and new instruments have different sized wax waste line connectors.

WARNING

Always wear suitable eye protection and other protective clothing when handling reagents to protect yourself from splashed reagent.

5.4.3   Replacing Reagent – Remote Fill and Drain

You can drain and then refill reagent bottles without removing the bottles from the instrument. The process drains each bottle to a retort then drains the retort to the remote fill/drain line. The reverse procedure is used for the fill.

If you routinely use remote drain and fill do not forget to check if bottles need cleaning, once a week.

Before you begin a remote fill or drain ensure there is a retort available:

- the retort must not have a protocol loaded or running;
- The retort must be clean or empty;
- The retort residue (if any) must be compatible with the reagent in the bottle(s).

Follow the instructions below to replace reagent in a bottle.

Drain

1. Connect the remote fill/drain hose and place the end in a suitable container (see 5.4.2 Remote Fill/Drain Connections).

2. From the **Remote fill/drain** screen (**Reagents** menu, **Remote fill/drain**), select:
   - The retort to use
   - The **Remote** icon
   - The bottle(s) to drain (multiple bottles must all have reagent in the same group).
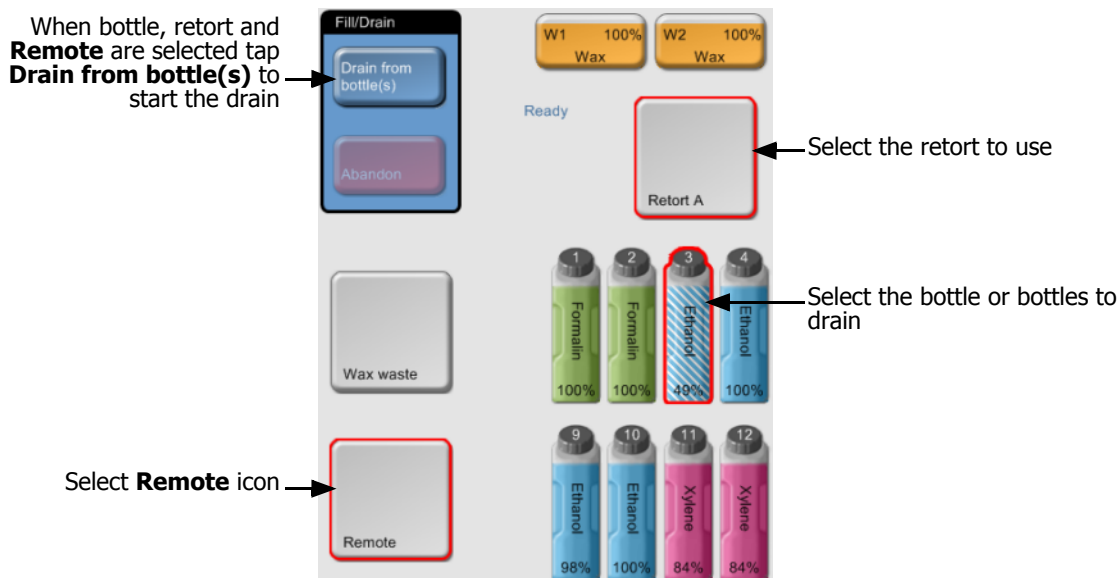
Figure 54. Remote fill/drain setup for draining bottles

3. Tap **Drain from bottle(s)** to begin the drain.

4. When prompted, check that the retort lid is closed and the remote fill/drain hose is properly connected.

   Tap **OK** to begin the drain.

5. The instrument will now drain the bottle(s) via the selected retort.

   Monitor the drain progress in the status panel.

   When the drain completes, the retort state will be **Empty** and the bottle state **Dry**.

> ⚠️ **WARNING**
> Do not remove the remote fill/drain hose until the software indicates the process is complete and pressurized air has cleared the hose. A cessation of reagent flow is not an indication that the procedure is complete.

Fill

6. Place the hose into the container of fresh reagent.

   The reagent source must be above 5°C to ensure that all reagent sensors operate correctly.

7. From the **Remote fill/drain** screen, select:

   - The retort to use
   - The **Remote** icon
   - The bottle(s) to fill (multiple bottles must all be **Dry** and set to the same reagent type)

   Any bottle residue must be compatible with the new reagent.

8. Tap **Fill to bottle(s)** to begin filling.

9. When prompted, check that the retort lid is closed and the remote fill/drain hose is properly connected.

   Tap **OK** to begin the fill.

10. The **Remote fill/drain - Reagent details** dialog box will now appear.
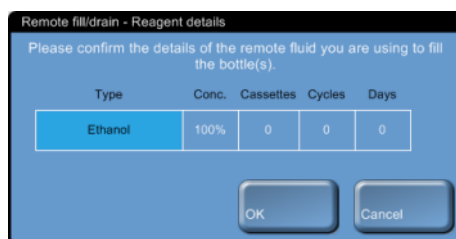
Figure 55. **Reagent details** dialog box with reagent type, concentration and use history for the new reagent

11. Confirm that the reagent type, concentration and use history details are correct, or tap in the table cells for any of these values to change the settings.

    If you set a new reagent type the station must have already been set to that type (see Assigning New Reagents to Stations in 5.3 Managing Reagent Stations). The reagent must be compatible with the retort and bottle residue.

    Tap **OK** to start the fill.

12. The instrument will now fill the bottle(s) via the selected retort.

    The fill volume is determined by the reagent fill level set in the **Instrument settings** screen (see 6.2.1 Instrument Settings).

    Monitor the fill progress in the status panel.

    When finished the retort will have an **Empty** state and the bottle will have a **Full** state.

ℹ At any time during the drain or fill you can tap the **Abandon** button to terminate all current and pending fill/drain operations.

ℹ If you abandon a drain such that both the retort and bottle are left partially full, you must drain the retort back to the original bottle to continue. To drain the retort, deselect the **Remote** icon then tap the **Drain retort** button.

⚠ **WARNING**
Do not open a retort while it is being used for a remote fill or drain operation as the retort could be pressurized and may contain hot reagent and fumes. Allow the fill or drain to complete or abandon the process before opening the retort.

Remote Fill and Drain Sequences

The following reagent sequences are recommended when filling and draining multiple bottles:

Order	Drain sequence	Fill sequence
1	Fixatives	Cleaning solvents
2	Cleaning alcohols	Clearers
3	Dehydrants	Defatting solvents
4	Defatting alcohols	Defatting alcohols
5	Defatting solvents	Cleaning alcohols
6	Cleaning solvents	Dehydrants
7	Clearers	Fixatives

5.4.4   Replacing Reagent – Manual

To replace bottles manually remove the bottles and dispose of the old reagent following your laboratory's standard procedures. Clean the bottle if necessary, and then fill with fresh reagent. Load back on to the instrument.

When the bottle is reinserted the **Inserted bottle configuration** dialog box opens, showing the reagent type, concentration and use history for either:

- the bottle when it was removed, or
- the bottle as configured in the **Reagent stations** screen, if you assigned a new reagent type to the station after the bottle was removed (see Assigning New Reagents to Stations).
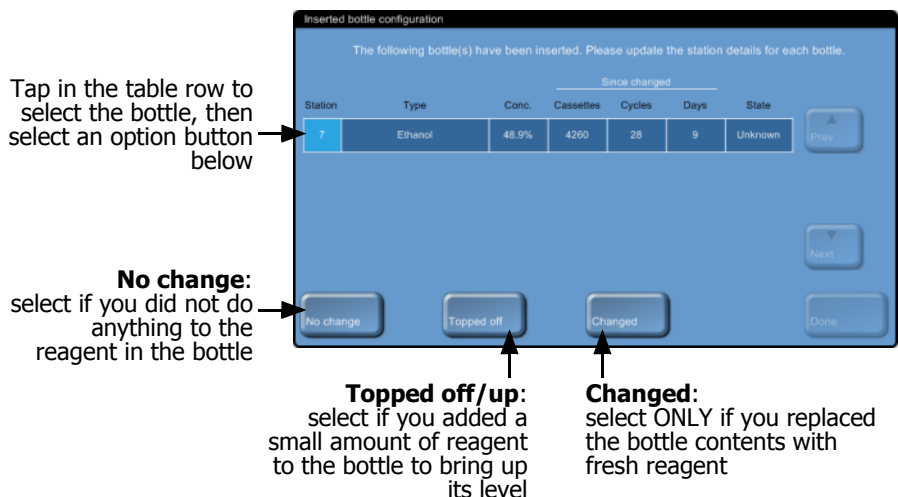
Figure 56. **Inserted bottle configuration** dialog box

The bottle state is set to **Unknown** in the dialog box.

Tap the table row and select one of the options at the bottom of the dialog box:

- **Changed** — select if you replaced the old reagent with fresh reagent.

  With this option the software prompts you to accept the default concentration for the reagent in the station. If you know the concentration to be other than the default you can enter a different concentration.

  The use history values are all set to zero.

  If you changed the reagent type in the bottle you cannot update it in the software from this dialog box. Tap **No change** and then remove the bottle again. Change the reagent assigned to the bottle in the **Reagent stations** screen (see Assigning New Reagents to Stations), then reinsert the bottle.

- **Topped off/up** — select if you did not change all the reagent but added a small amount of fresh reagent of the same type to bring up its level in the bottle.

  With this option the bottle state changes to **Full**. The concentration and use history details do not change.

- **No change** — select if you made no changes to the reagent in the bottle at all.

With this option you must select the bottle state. The concentration and use history details do not change.

> ⚠️ **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**
> Ensure lids are tight and the bottles are correctly plugged into the manifold after replacing reagent to avoid reagent spills.

5.4.5 Replacing Wax

To replace wax:

1. Drain the wax chamber using the **Remote fill/drain** screen commands.
2. Refill the wax chamber manually with molten or solid wax, and then
3. Reset the state of the wax chamber.

Before you begin ensure there is a retort available. Draining wax does not fill a retort, but it does use retort scheduling resources, so at least one retort must be available. The retort does not need to be clean.

The wax to be drained must be molten.

Follow the instructions below to replace wax in a chamber.

Drain

1. Connect the wax waste hose and place the end in a suitable container (see 5.4.2 Remote Fill/Drain Connections).

2. From the **Remote fill/drain** screen (**Reagents** menu, **Remote fill/drain**), select:

   • The wax stations to drain

   • The **Wax waste** icon

When wax chamber and **Wax waste** icon are selected tap **Drain to waste** to start the drain

Select the wax chamber or chambers to drain

Select **Wax waste** icon
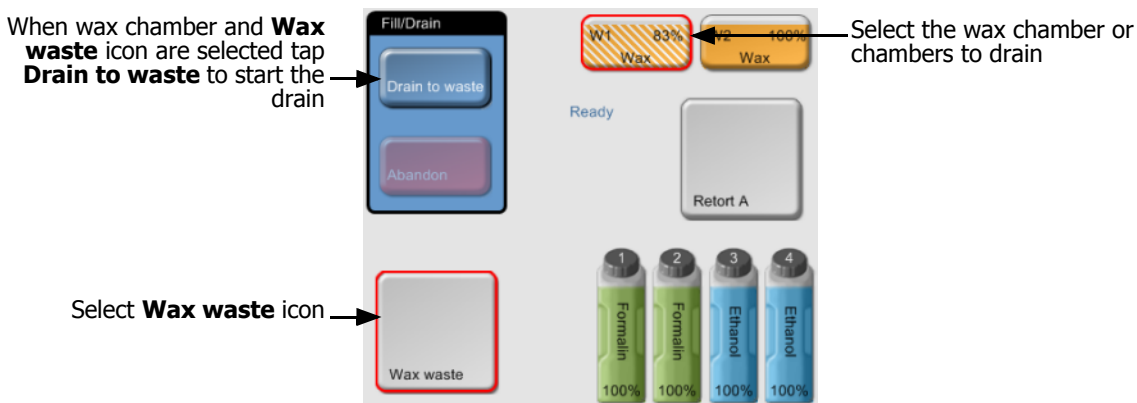
Figure 57. Remote fill/drain setup for draining wax chambers

3. Tap **Drain to waste** to begin the drain.

4. When prompted, check that the wax waste hose is properly connected and feeding into a suitable container.

   Tap **OK** to begin the drain.

5. The instrument will now drain the chamber(s).

   Monitor the drain progress in the status panel. Wax drains may take up to three minutes.

   When the drain completes, the chamber state will be **Empty**.

⚠️ **WARNING**

The wax leaving the waste wax line will be hot and may cause burns. Make sure the wax drains to a suitable container and stand clear while it drains.

⚠️ **WARNING**

Do not remove the wax drain container or hose until the software indicates that the drain has completed. A cessation of wax flow is not an indication that the drain procedure is complete.

If no wax drains it is likely that the wax hose is blocked. If you remove a blocked hose before the drain is abandoned hot wax will spurt from the front of the instrument. Abandon the drain before removing the hose and melting the wax with hot water.

---

6. To stop wax solidifying in the drain hose, promptly remove the hose from the drained wax.

At any time during the drain you can tap the **Abandon** button to terminate all current and pending fill/drain operations.

Fill

7. Fill the wax chamber with molten or solid wax.

8. Open the **Reagent stations** screen, wax chambers view (**Reagents** menu, **Stations**, then tap the **Wax chambers** button).

   The row for the drained wax chamber shows the default concentration and all use history values set to zero. The station state is **Dry**.

   The reagent type is unchanged from the wax that you drained unless you changed the type assigned to the station after the drain (see Assigning New Reagents to Stations).

9. Tap the **State** cell for the chamber:

   - If using molten wax, set the state to **Full**.

   - If using solid wax, set the state to **Not molten** to begin the rapid wax heating process. While in the **Not molten** state the wax bath chamber temperature is higher than normal to ensure the wax melts quickly.

     You may need to add extra wax as it melts.

     The station's state automatically changes to **Full** when the wax is ready to use.

5.4.6 Filling and Draining Retorts

The **Remote fill/drain** screen allows you to fill and drain the retorts to assist recovery from incomplete remote fill/drain operations. The retort fill and drain functions operate with a series of rules designed to avoid reagent contamination, reagent overflow spills and reagent overheating. You can override some rules but this will often result in reduced reagent concentration.

You can also fill and drain retorts using the **Manual operations** screen (see 6.1.1 Manual Operations).

The rules for manually filling and draining retorts are as follows.

- The retort must be clean or empty before you commence a retort fill operation.

- If the retort is empty the selected station must have compatible reagent (see 8.5 Reagent Compatibility Tables).

- You cannot fill a retort with a reagent that has a temperature threshold below the set retort temperature.

- When draining a retort, the reagent must return to its original station.

- When draining a retort, the station must have sufficient capacity for the retort contents.

To avoid fluid spills, ensure adequate station capacity before overriding insufficient capacity errors.

To fill or drain a retort select the retort and the reagent station to fill from or drain to, on the **Remote fill/drain** screen. Tap the **Fill retort** or **Drain retort** button. To stop the fill at any stage, tap the **Abandon** button.

WARNING
Never fill a reagent station when its contents are in a retort. This may cause fluid spills.

6

Settings & Ancillary Operations

This chapter describes basic system configuration options and ancillary operations such as manually pressurizing a retort or heating a wax line, viewing the event log, handling alarms, changing user access level, and transferring system files onto external media.

Access reagent-related ancillary options from the **Reagents** menu (6.1 Reagents Menu):

- 6.1.1 Manual Operations
- 6.1.2 Reagent Management

All other ancillary functions are in the **Control** menu (6.2 Control Menu):

- 6.2.1 Instrument Settings
- 6.2.2 Device Settings
- 6.2.3 Service Settings
- 6.2.4 Event Log
- 6.2.5 Alarms
- 6.2.6 Access Level
- 6.2.7 File Transfer

6.1 Reagents Menu

Manually control reagent handling components of the instrument or configure or view basic reagents settings in two screens opened from the **Reagents** menu:

- 6.1.1 Manual Operations
- 6.1.2 Reagent Management

6.1.1 Manual Operations

The **Manual operations** screen (**Reagents** menu, **Manual operations**) allows you to manually control the instrument. The screen displays the current instrument status including station states, the retort states and the retort condition. You control the instrument by selecting instrument elements from the status area and control functions from the panels on either side.

All users can perform manual operations functions.

You can fill a retort from any station and then set conditions in the retort: temperature, pressure and stirrer. If intending to move wax into a retort preheat the wax path by turning on the wax heater. Use the wax vent function to neutralize the pressure in the wax bath so the wax bath lids can be opened easily and safely.

You cannot override a running protocol from the **Manual operations** screen and you cannot fill or drain a retort that has a loaded protocol.

Figure 58 shows the **Manual operations** screen with function buttons explained:
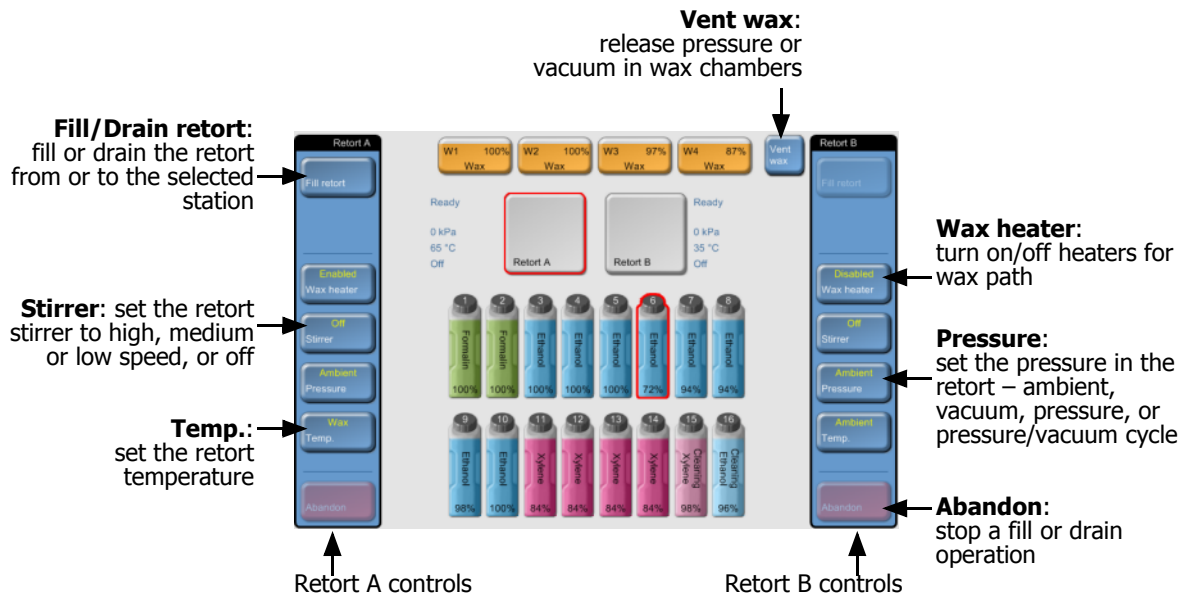
Figure 58. **Manual operations** screen

Retort Temperature Range

The retort temperature range is limited to the following values.

- **Reagent** — 35ºC minimum to 85ºC maximum (restricted to 65ºC maximum when running tissue processing protocols).

- **Wax** — (Wax melting point + 2ºC) minimum to 85ºC maximum (restricted to 77ºC when running standard protocols).

    View the current wax melting point temperature on the **Reagent management** screen.

Additional limitations may apply depending on the retort state and the reagent in the retort. You cannot raise the retort temperature above the safe temperature threshold of the reagent.

Wax Transfers

The wax path (comprising the wax valves and the transfer pipes) and the retort must be at the wax standby temperature before you attempt to fill a retort with wax. Use the **Wax heater** buttons for at least five minutes to enable wax path heating. Use the **Temp.** button to set the retort to the wax standby temperature and wait until the retort reaches the temperature before filling.

Filling and Draining Retorts

Fill or drain the retorts from any reagent station using commands on the **Manual operations** screen. The fill and drain functions operate with a series of rules designed to avoid reagent contamination, reagent overflow spills and reagent overheating. You can override some rules but this will often result in reduced reagent concentration.

The rules for manually filling and draining retorts are as follows.

- The retort must be clean or empty before you commence a retort fill operation.

- When filling a retort, the selected reagent station must be compatible with the retort residue. See 8.5 Reagent Compatibility Tables.

- You cannot fill a retort with a reagent that has a temperature threshold below the set retort temperature.

- When draining a retort, the reagent should return to its original station.

- You cannot drain wax to a reagent bottle or non-wax reagents to a wax station.

- When draining a retort, the station must have sufficient capacity for the retort contents.

Always ensure the retort is in a suitable state before filling. To fill, select the retort and reagent station then tap **Fill retort**.

To drain a retort select the retort and the station the retort contents came from. Tap the **Drain retort** button. The system will not allow you to drain a retort to a station other than the one the reagent came from.

You can stop a fill or drain at any time with the **Abandon** button. Recover from an abandoned fill or drain by restarting the operation, or return the reagent to the station or retort it came from with the opposite operation.

> **WARNING**
>
> Do not open a retort if it has been filled with hot reagent and pressurized using the manual operations functions. Always use the manual operations functions to de-pressurize a retort before opening and wear suitable protective clothing (including eye protection) if the retort contains hot reagent.

6.1.2   Reagent Management

Use the **Reagent management** screen (**Reagents** menu, **Management**) to set the default number of cassettes per run and default carryover setting per run, to turn wax cleaning on and off, and to set wax standby and melting temperatures. Supervisor access is required.

A range of other configuration settings can be viewed but not changed – contact customer support to change any of these. The screen also displays the state of each retort and the last reagent in each retort.

Controls on the **Reagent management** screen are described below, grouped by section.

General

- **Conc. Management** — (view only) the method the system uses to assign concentration values to reagent bottles (see 5.1.2 Concentration Management).

- **Prompt for number of cassettes** — (view only) under the default "enabled" setting PELORIS prompts you to enter the number of cassettes before each run. When the function is disabled, the system assumes that each run processes the default number of cassettes (see below).

- **Default number of cassettes** — set the default number of cassettes for each processing run. If **Prompt for number of cassettes** is enabled the prompt dialog box opens before each run showing this number of cassettes to accept or change. If **Prompt for number of cassettes** is disabled then the system uses the number of cassettes entered here for all processing runs. In this case be sure to enter an accurate average value – the number is used by the reagent management system to calculate reagent concentrations.

- **Default carryover** — the default carryover setting used for new protocols until a new value is set (see 4.1.5 Carryover Setting).

- **Show conc.** — (view only) hides or shows the current wax and bottle concentrations on the **Status** screen.

Reagent Threshold Check

The four buttons in the **Reagent threshold check** section of the **Reagent management** screen show which types of reagent thresholds the system is using (see 5.1.3 Thresholds). By default all four threshold types are enabled. Contact your customer support representative to change any of these settings.

- **By cassettes** — the system tracks the number of cassettes processed by the reagent in each station. If the reagent type has a cassette threshold set you are alerted when the station goes beyond that threshold.

- **By cycles** — the system tracks the number of processing runs performed by the reagent in each station. If the reagent type has a cycle threshold set you are alerted when the station goes beyond that threshold.

- **By days** — the system tracks the number of days the reagent in each station has been loaded. If the reagent type has a days threshold set you are alerted when the station goes beyond that threshold.

- **By conc.** — the system tracks the concentration of reagent in each station. If the reagent type has a concentration threshold set you are alerted when the station goes beyond that threshold.

Retorts

The **Retorts** section of the **Reagent management** screen shows the state of and last reagent used for each retort. It also shows the empty access temperature – the temperature up to which it is safe to open empty retorts. The system warns you if you perform any action that requires you to open an empty or clean retort with a temperature exceeding this value.

The settings in this section can only be changed by your service representative.

Wax Bath Settings

Turn wax cleaning on and off with the **Wax clean** button on the **Reagent management** screen. The wax clean function improves the quality of the wax by periodically evacuating the wax bath (for approximately 30 seconds) to draw off any contaminants. You may need to periodically add small amounts of wax to replace solvents that have been removed.

- Enable wax cleaning for protocols that use xylene and/or IPA.

- Disable wax cleaning for protocols that use xylene or IPA substitutes – these clearers are not efficiently removed by the evacuation process.

By removing contaminants wax cleaning increases wax concentrations. The system automatically updates the concentration of each wax station after each wax clean cycle.

Wax cleaning occasionally delays the start of a protocol or other action for up to 30 seconds.

Global Wax Settings

Set the wax melting and wax standby temperatures in the **Global settings** section of the **Reagent management** screen.

- The wax standby temperature is the temperature the instrument heats the wax to in the wax stations. The default temperature is 65ºC.

- The wax melting point is the temperature at which the instrument considers the wax molten. The default temperature is 56ºC.

6.2 Control Menu

The control screens allow you to alter hardware settings, view event logs and system information, manage alarms and set the access level. The **File transfer** screen allows you to back up and retrieve log, protocol and other system files.

There are seven screens in the Control menu:

- 6.2.1 Instrument Settings
- 6.2.2 Device Settings
- 6.2.3 Service Settings
- 6.2.4 Event Log
- 6.2.5 Alarms
- 6.2.6 Access Level
- 6.2.7 File Transfer

6.2.1 Instrument Settings

Use the **Instrument settings** screen (**Control** menu, **Instrument settings**) to configure time display, the carbon filter age and threshold, reagent fill levels and manual operation drip time. Supervisor access is required for all operations except time format configuration.

You can also close down the instrument from this screen. Other settings on the **Instrument settings** screen can be viewed but can only be changed by a service representative.

- Carbon Filter Settings
- Time and Date
- Instrument Shutdown
- Reagent Fill Levels
- Manual Drain Drip Time
- Language and Unit Settings

Carbon Filter Settings

Tap the **Carbon filter age** button to reset the age of the carbon filter to zero days. You should do this when replacing the carbon filter so the PELORIS tissue processor can track its age and provide proper warnings when it exceeds its age threshold.

Tap the **Carbon filter threshold** button to set the number of days a filter can be used before it should be replaced. The correct threshold value depends on the average number of protocols you run each day and the type of reagents used. We recommend an initial threshold of 60 days with adjustments only if you are sure the carbon filter is becoming saturated earlier or is still in good condition after this time.

If you are using an external vapor removal system, set the carbon filter threshold to either:

- The inspection interval for the external system

- The maximum value (1000) to limit the number of unwanted warnings

- Overridden (contact your service representative to arrange this setting)

See 2.6 External Vapor Removal Systems for more information.

Time and Date

Supervisor-level users can change the time on the instrument on the **Instrument settings** screen. Any user can configure the three date and time formats (shortened, normal and extended) used in the system.

- To change the system time tap the **Set time** button then use the **Up** and **Down** buttons as required to set the correct time.

- To change time formats tap the **Set date/time format** button and then the **Modify** button for the format you want to change. Select the required format from the list in the **Select time format** or **Select date format** dialog box.

Instrument Shutdown

Tap the **Shutdown instrument** button on the **Instrument settings** screen to turn off the instrument in an orderly manner. This uses the same shutdown routine as the shutdown button on the Function bar. When the touch-screen goes blank, turn off the red power button.

See 2.1 Switching On and Shutting Down.

Reagent Fill Levels

The reagent fill levels determine the volume used to fill a retort and the reagent volume needed for a station to have a full state. You configure the instrument to fill the retorts with sufficient reagent to process either two or three cassette baskets. If the retorts are set for three baskets the bottle fill level must also be three baskets, to ensure sufficient reagent to fill the retorts.

You must be a supervisor to change fill levels (on the **Instrument settings** screen).

- To set the retort fill level, tap the **Retort fill level** button and select two or three baskets.

- To set the reagent station fill level, tap the **Bottle fill level** button and select two or three baskets.

If you increase the fill volume you must visually check each reagent station to ensure it holds sufficient reagent. A protocol may be abandoned if a station does not hold sufficient reagent.

Manual Drain Drip Time

Supervisors can change the drip time for manual drain operations on the **Instrument settings** screen. The drip time is the length of time the system waits for reagents to drip from cassettes and retort walls before completing the drain operation.

- Tap the **Manual drain drip time** button then enter the required number of seconds.

Language and Unit Settings

You can view the instrument's language and temperature and pressure unit settings in the **Instrument settings** screen. Contact your service representative to change either setting.

6.2.2 Device Settings

The **Device settings** screen (**Control** menu, **Device settings**) allows users to control display settings and lock the screen for cleaning. Supervisors can configure instrument sounds and enable and disable "power off" alarms for the external alarm connectors.

- Sound Settings
- Touch-screen Settings
- Alarm Power Off Settings
- Color Schemes
- Screen Lock

Sound Settings

Supervisors can select from a range of sounds to be heard for particular types of event, or have no sound for these events. For example a sound can be set for key touches on the touch-screen, or to accompany a prompt dialog box or warning. There is also volume control for all instrument sounds.

- To change the sound associated with an event type, tap the cell beside the event type in the **Sound settings** table. Select a sound file in the **Select sound file** dialog box then tap **OK**. Select **<no sound>** to have no sound for the event type.

  To hear a sound in the **Select sound file** select it then tap **Play**.

- To change sound volume tap the cell beside **Master volume** in the **Sound settings** table. Set a value between 100 (loudest) and 0 (silent).

Touch-screen Settings

All users can change the brightness of the touch-screen on the **Device settings** screen. Tap the the cell beside **Brightness** in the **Touch screen settings** table then enter the required value from 0 (dimmest) to 100 (brightest). The default value is 70%.

Alarm Power Off Settings

Use the alarm power off settings on the **Device settings** screen to control the behavior of the external LOCAL ALARM and REMOTE ALARM (see 2.7 Alarm Connections) in the event of a power failure. If the "power off" state is set to **Enabled** the alarm will activate (sound) if there is a power failure.

- To change the setting tap the cell beside **Local alarm** or **Remote alarm** in the **Alarm power off settings** table then **OK** in the dialog box.

You require supervisor level access to alter these settings.

Color Schemes

There are two software color schemes – one lighter and one darker. Select the better color scheme for the lighting conditions in your laboratory.

- To change the color scheme tap the cell beside **Color scheme** in the **Color schemes** table on the **Device settings** screen. Select **Original blue** or **Dark blue**.

Screen Lock

Use the screen lock function on the device settings screen to lock the touch-screen for cleaning.

- To lock the screen, tap the **Lock for cleaning** button. The **Clean screen** dialog box opens – you can safely clean the screen without accidentally selecting any controls while this is open.

  When finished cleaning tap the **Clean screen** buttons in the correct order to unlock the screen and return to normal operation.

6.2.3 Service Settings

Use the **Service settings** screen (**Control** menu, **Service settings**) to view instrument and software information.

The unit information area shows the instrument name, location, model and serial number. Supervisors can change the instrument name; other values are read-only.

The software area displays the current software, firmware and translation version numbers. The software version may be needed when reporting a fault.

6.2.4 Event Log

The event log (**Control** menu, **Event log**) displays a history of system events. You can sort the events by time or by frequency and you can also filter events so you can decide which types of event to view. You can add a message and save it as a "user event", or retrieve information relevant to a particular event to send to your service representative.

In the "by time" view each event instance is listed, ordered with the most recent events at the top of the screen. Each event has the event type number, the event severity color code (see Event severity below), the time the event occurred, and the event description.

In the "by frequency" view there is one row for each event type number, e.g. all the 1000 events – "protocol completed successfully" – are represented in one row. As well as the event number, severity color code and description, the number of instances of the event and the dates and times of the first and last instances of the event are shown.

The event log can only be cleared by service personnel.

- Toggle the **Show by time/Show by frequency** button to switch between the two views.

- Tap the **Filter** button to open the **Events log filter** dialog box where you set filters to select the types of events to view.

  Select buttons in the **Retorts filters**, **Severity filters** and **Alarm filters** sections to see the associated types of events. You must select at least one button in each section to see any events. E.g. if you select **Retort A** in **Retorts filters**, **Information** in **Severity filters** and **Non-alarmed events** in **Alarm filters** you will see all information events for retort A that do not raise an alarm.

  The **Run log entry** button in the filter dialog box is only enabled for service personnel.

- To create a user event select **Create user event** to open the on-screen keyboard. Type in the information you want to record and tap **Enter** to add the message as an event. The event severity will be "Information".

- To create an incident report file for a specific event (to send to your service representative) select the event row in the table and tap **Incident report** (see Transferring Incident Report Files in 6.2.7 File Transfer).

Event severity

There are four event severity levels and each level has a color code as shown in the following table.

Severity level	Description	Color code
Information	A normal event that requires a response (e.g. a protocol successfully completed) or an unusual event that has no detrimental effect (e.g. a user abandoned protocol).	Dark green
Warning	An error or potential error that does not stop processing, or a request for user action. For example, an out-of-threshold reagent used in a protocol.	Orange
Error	An error that causes an operation to abandon (e.g. a protocol abandons because there is no station available).	Red
Critical error	An error that makes part of the instrument (e.g. one retort) or the entire instrument unusable.	Blue

6.2.5   Alarms

PELORIS uses alarms to alert users when events of certain types occur. These events are mostly for error conditions that require quick intervention, but alarms also activate for some normal conditions that it is useful to be informed about, such as when a protocol has finished.

When an alarm activates the associated event is displayed on the **Alarms** screen (**Control** menu, **Alarms**) and one or more of the following occurs, depending on how the alarm is configured (contact your service representative to reconfigure alarm outputs):

- the instrument's internal alarm sounds;
- the LOCAL ALARM connection turns on, triggering any connected alarm (see 2.7 Alarm Connections);
- the REMOTE ALARM connection turns on, triggering any connected alarm (see 2.7 Alarm Connections);
- a dialog box (popup) opens in the software displaying the alarm message.

Active alarms can be cleared (i.e. turned off) on the **Alarms** screen. If an alarm has triggered a popup it can also be cleared from the popup.

Alarms can also be "silenced" from the **Alarms** screen and alarm popups. This turns off the instrument internal alarm and closes the popup, but the local and remote alarms remain on until the alarm is cleared. This allows an operator at the instrument to continue to use the software, without the alarm sounding, while the external alarms continue in order to bring assistance.

The internal, local, and remote alarms have one of two "on" states: **Momentary** triggers the alarm once only, while **Repetitive** continues the alarm until it is cleared or, for the internal alarm only, silenced.

- To clear or silence an active alarm in the **Alarms** screen tap the **Activated** cell for the alarm event and tap **Off** or **Silenced**.

  Off stops all alarm outputs and removes the event from the **Alarms** screen.

  Silenced silences the internal alarm, but the alarm is still active on the **Alarms** screen.

- To clear or silence an alarm in an alarm popup select the event in the table of alarm events (there may be more than one alarm active at once) and tap **Clear** or **Silence**.

  Clear stops all alarm outputs and removes the event from the popup (and **Alarms** screen). The popup closes if there is only one alarm event.

  Silence silences the internal alarm, but the alarm is still active on the **Alarms** screen. The popup closes if there is only one alarm event.

  If there is more than one alarm event in a popup you can use **Clear all** or **Silence all** to clear or silence all the alarms at once.

6.2.6   Access Level

Use the **Access level** screen (**Control** menu, **Access level**) to set the user access level in the PELORIS system (see 1.2.3 Access Levels).

● To change access level select 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.

6.2.7   File Transfer

The file transfer functions (**Control** menu, **File transfer**) allow you to copy protocol, configuration, current state, log and event summary files to and from 3.5" floppy disks or USB memory devices. You can then use these files as a backup (especially useful for protocols) or to send to Leica Biosystems or your service representative to aid system health diagnosis.

All user levels can transfer files.

Basic configuration for file transfer consists of three steps:

1.   Set PELORIS to use a USB key (or floppy disk) and attach the device to the instrument.

2.   Configure which files to transfer.

3.   Tap **Transfer files** to copy the files onto the remote device.

The **File transfer** screen is shown in Figure 59 with the areas used for the three steps shown.
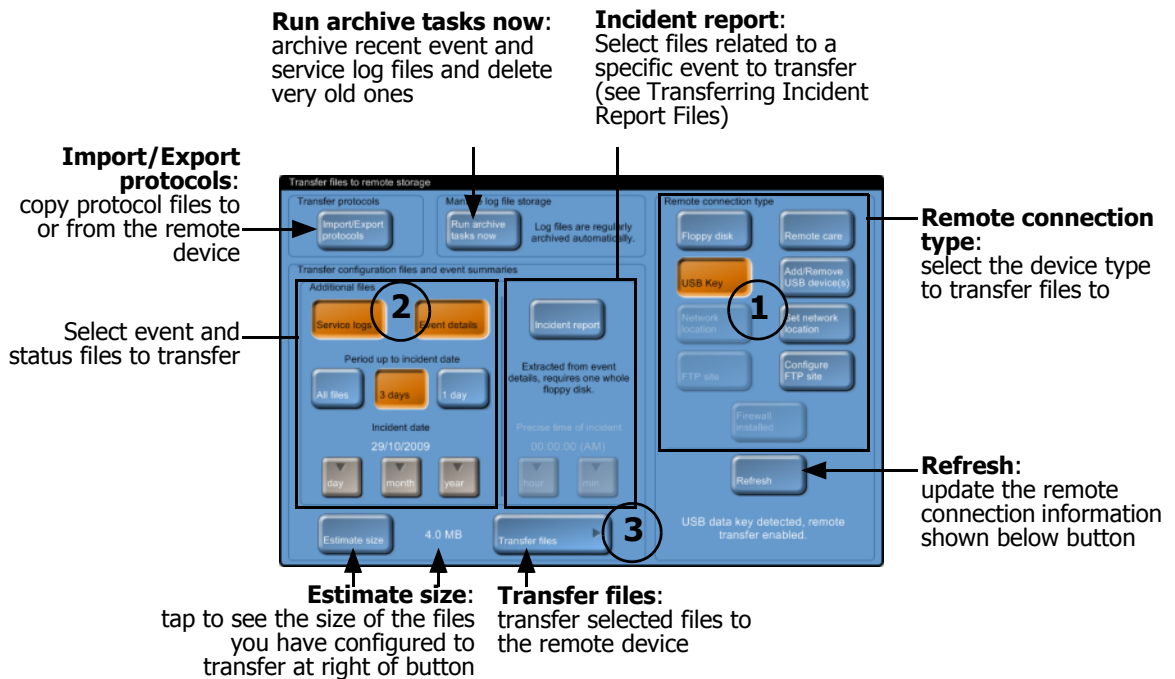
Figure 59. **File transfer** screen

Refer to the following sections for detailed file transfer instructions:

- Attach or Remove a USB Key
- Transferring Protocols
- Transferring Instrument Condition Files, Service Logs, and Event Details
- Transferring Incident Report Files
- Remote Device File Structure
- Archiving Log Files

Attach or Remove a USB Key

Use a USB key to copy files to. Only use the network, FTP or RemoteCare™ options if instructed by a service representative. You can use a floppy disk, but this may not hold all the files to transfer.

Prepare the instrument on the **File transfer** screen before connecting or disconnecting the USB key.

Any running protocols will pause while the instrument is attempting to connect to the USB key.

Follow the instructions below to either connect or disconnect a USB key.

1. Open the **File transfer** screen (**Control** menu, **File transfer**).
2. Tap the **Add/Remove USB device(s)** button in the **Remote connection type** section.
3. Wait as prompted in the **Add/Remove devices** dialog box.
4. When the instrument is ready the message changes.

   You have 30 seconds to add or remove the key before the function automatically times out – plug or unplug your USB key into/from the USB port at the front of the instrument.
5. To continue either:
   - Tap the **OK** button from the **Add/Remove devices** dialog box, or
   - Wait for the auto-continue function to activate after 30 seconds.
6. The **Updating devices** dialog box now appears.

   You may also see some additional dialog boxes as the instrument reconfigures. Ignore these dialog boxes as they will cease to appear after approximately 10 seconds.
7. When all dialog boxes have closed:
   - **Attach key**: tap the **USB Key** button in the **Remote connection type** section.
   - **Remove key**: continue with normal operation. You have now completed these instructions.
8. If you attached a USB key check the connection status at the bottom of the **Remote connection type** section.

   If the key is detected proceed to file transfer configuration.

   If the key is not detected tap the **Refresh** button. If this does not work, remove the device following these instructions, check that it is switched on (if required) then repeat these installation instructions.

Transferring Protocols

The protocol transfer functions provide an easy way to backup your protocols so they may be restored if lost. The functions also allow you to share protocols across instruments.

1. Attach a USB device to the instrument (see Attach or Remove a USB Key above).

2. Tap the **Import/Export protocols** button on the **File transfer** screen.

    The **Transfer protocol files** screen opens.

    Protocols on the instrument are in the left column, **Local protocols**, and protocols on the USB key in the right column, **Remote protocols**.

3. Select individual protocols in either column to import or export, or use the **Ex port all** or **Import all** buttons to copy all of the protocols on the instrument to the USB key, or from the USB key to the instrument.

    If, when exporting protocols onto the USB key, there is a protocol of the same name already on the key, you are prompted with the option to overwrite the existing copy, or skip the transfer.

    In contrast, you cannot overwrite a protocol that is already on the instrument with a protocol of the same name on the USB key.

4. Tap **Done** when finished.

    Protocols transferred to the instrument will now be available in the **Protocol selection** screen.

    Protocols transferred to the remote device will be stored in the "protocols" folder on the device.

Transferring Incident Report Files

Use this procedure to transfer a group of files providing information relating to a specific incident. These files can be used by Leica Biosystems or your service representative to aid system health diagnosis. The information is compressed into a single file small enough to be emailed.

1. Attach a USB device to the instrument (see Attach or Remove a USB Key above).

2. Open the **Event log** screen (**Control** menu, **Event log**) and select the event that you want to report. Events must be shown by time.

3. Tap the **Incident report** button.

    You are returned to the **File transfer** screen. The **Incident report** button on that screen is selected, and the date and time of the event you selected are entered.

    In an alternative workflow you can manually enter the date and time of the incident with the **Incident date** and **Precise time of incident** buttons.

4. Tap **Transfer files** to begin the file transfer.

5. Tap **OK** in the confirmation dialog box to continue with the transfer.

    Tap **Cancel** to terminate the procedure if there is not room for the files on your USB key.

Transferring Instrument Condition Files, Service Logs, and Event Details

There is a range of other file types you can transfer to your service representative for troubleshooting. Transfer the following file types if your service representative asks for them.

- **Instrument condition files** — basic system configuration files

- **Service logs** — instrument information up to a specified date and time

- **Event details** — more detailed information around a specified date and time

- **Incident report** — detailed information at the time of a specific event. See Transferring Incident Report Files below for instructions for this procedure.

Use the following procedure to transfer instrument condition files, service log files, and/or event detail files. Instrument condition files are automatically transferred with service logs and event details.

1. Attach a USB device to the instrument (see Attach or Remove a USB Key above).

2. Configure the **Transfer configuration files and event summaries** section of the **File transfer** screen as described below, depending on the types of files you want to transfer:
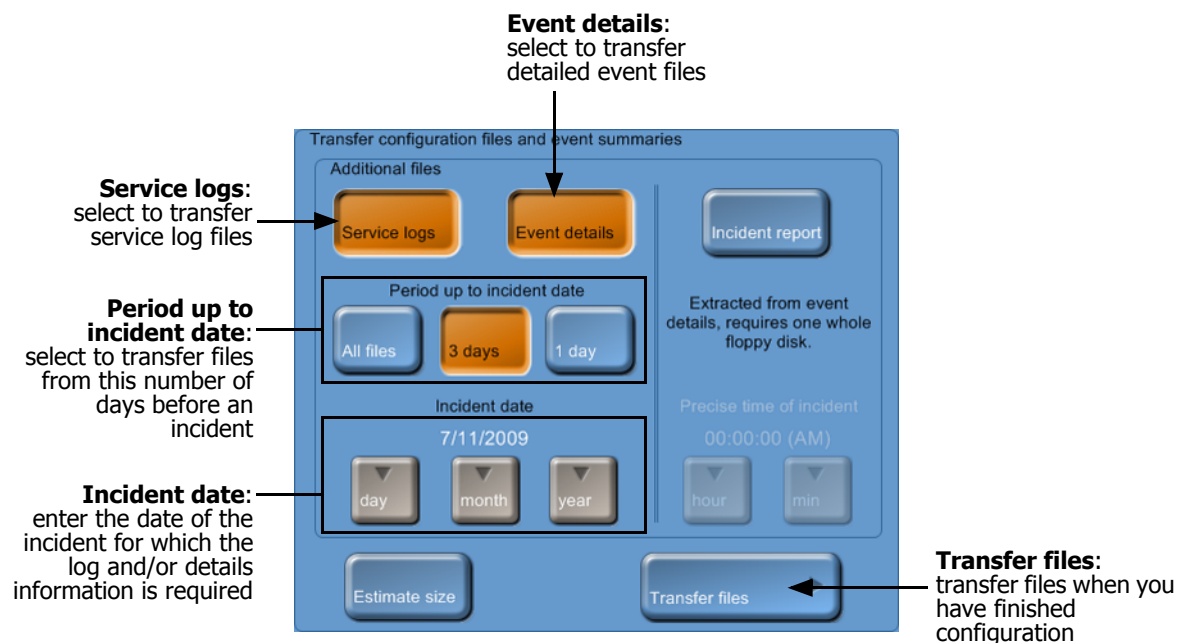
Figure 60. **Transfer configuration files and event summaries** section of **Transfer files** screen

- To transfer instrument condition files, do not tap any of the additional file type buttons (**Service logs**, **Event details**, or **Incident report**). Go straight to the **Transfer files** button (next step).

- To transfer service logs tap **Service logs** and set an incident date. Check the **Event log** screen to identify when the event you are interested in occurred. Select whether to transfer all service logs up to that date, or logs for three or one days preceding the date.

- To transfer event details tap **Event details** and set an incident date. Check the **Event log** screen to identify when the event you are interested in occurred. Select whether to transfer all event details up to that date, or event details for three or one days preceding the date.

3. Tap **Transfer files** to begin the file transfer.

4. Tap **OK** in the confirmation dialog box to continue with the transfer.

   Tap **Cancel** to terminate the procedure if there is not room for the files on your USB key.

Remote Device File Structure

The file structure on the remote device is as follows.

1. All files for a particular instrument are stored in a folder with the instrument's name (see item 1 in Figure 61).

2. Each file transfer operation creates a sub-directory with a name corresponding to the time and date the transfer commenced (see item 2 in Figure 61).
   Incident report places a compressed file in this sub-directory.

3. Each file type (except Incident report) has a sub-directory that contains the transferred files (see item 3 in Figure 61).
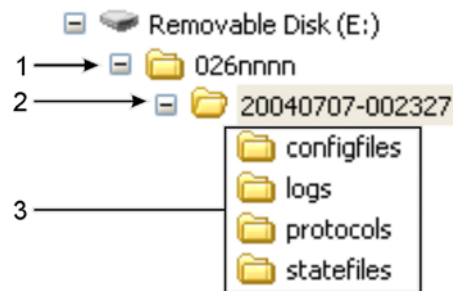
Figure 61. Remote device folder structure

The configuration files are placed in the "configfiles" folder; the protocol files are placed in the "protocols" folder; the state files are placed in the "statefiles" folder. The "logs" folder contains the additional log files, if selected.

The compressed incident report file produces the same sub-directory structure when uncompressed.

Archiving Log Files

Archiving log files has two purposes. It compacts the files so they take up less space on your instrument. It discards any files older than three months. Archiving normally happens automatically, but you may be required to manually archive the log files if requested by your service representative. Archived files can be copied to a remote device and sent to Leica Biosystems or your service representative.

Tap the **Run archive tasks now** button on the **File transfer** screen to archive files.

7

Cleaning and Maintenance

Follow the maintenance and cleaning instructions in this chapter to keep your PELORIS processor in top condition. This will help ensure quality processing at all times, and avoid unnecessary service calls.

Besides the tasks listed below, ensure that the PELORIS is left on at all times, even when idle. This keeps wax molten and allows preventative maintenance routines controlled by the software to be carried out.

Ensure that the instrument has a preventative maintenance service call once a year – contact your service representative to organize this.

> **WARNING**
> Always wear gloves and other suitable protective clothing when cleaning the instrument.

> **CAUTION**
> Do not use any cleaning methods other than the ones described below. Use of other methods may damage the instrument.

- 7.1 Cleaning and Maintenance Schedule
- 7.2 Daily Tasks
- 7.3 Weekly Tasks
- 7.4 60–90 Days
- 7.5 Retort Acid Clean

7.1 Cleaning and Maintenance Schedule

See the list below for regular cleaning and maintenance tasks and how often they should be carried out.

The table on the next page is a weekly maintenance and cleaning checklist that you can print to use as a record of maintenance tasks. Initial the relevant cells in the table as tasks are carried out.

Daily

- Clean Lids and Seals
- Clean Retorts
- Check Reagent Levels
- Clean Top Surface
- Clean Touch-screen

Weekly

- Empty Condensate Bottle
- Check Reagent Bottles
- Clean Wax Bath
- Check Bottle Connectors
- Clean Exterior Surfaces

60–90 Days

- Change Carbon Filter
- Check Lid Seals

As Required

- Retort Acid Clean

PELORIS User Maintenance Chart

Week:													Serial No:	
	Mon		**Tues**		**Wed**		**Thurs**		**Fri**		**Sat**		**Sun**	
Date:														
Daily Tasks														
Clean lids and seals														
Clean retorts														
Check reagent levels Checked = OK Topped off/up = T Changed = C	Initial	OK/T/C	Initial	OK/T/C	Initial	OK/T/C	Initial	OK/T/C	Initial	OK/T/C	Initial	OK/T/C	Initial	OK/T/C
Bottle 1														
Bottle 2														
Bottle 3														
Bottle 4														
Bottle 5														
Bottle 6														
Bottle 7														
Bottle 8														
Bottle 9														
Bottle 10														
Bottle 11														
Bottle 12														
Bottle 13														
Bottle 14														
Bottle 15														
Bottle 16														
Wax 1														
Wax 2														
Wax 3														
Wax 4														
Clean top surface														
Clean touch-screen														
Weekly Tasks														
Empty condensate bottle														
Check reagent bottles														
Clean wax bath														
Check bottle connectors														
Clean exterior surfaces														
Every 60–90 Days														
Change carbon filter														
Check lid seals														

7.2   Daily Tasks

Clean Lids and Seals

Use the plastic scraper provided to scrape wax off the inside surfaces of the retort and wax bath lids. Carefully remove wax from around the lid seals. Replace any seals that are damaged (see Check Lid Seals).

Remove the retort lids to clean. To remove, open the lids fully then slide to the left.
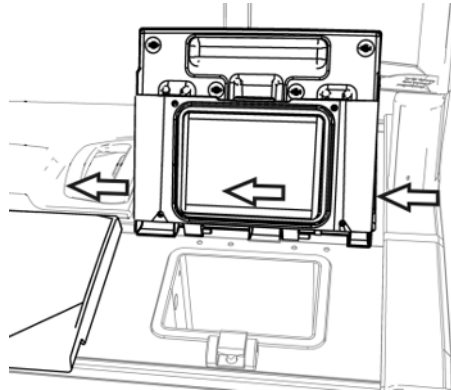
Figure 62. Removing a retort lid

Scrape around the rims of the retorts and wax bath on the top of the instrument, where the lids sit. Ensure that the lids seal fully when closed.

In the wax bath, make sure that the air vent on the back rim under the left lid is clear of wax. Do not allow wax to fall into the vent.
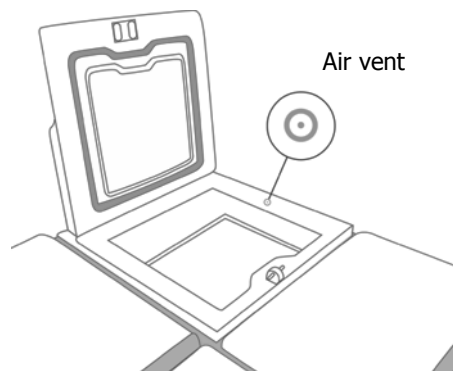
Air vent

Figure 63. Wax bath air vent

> ⚠️ **CAUTION**
> Only use the plastic scraper provided to clean the lids to avoid damage to the retort lid seals and to the polished surfaces.

Clean Retorts

Clean the retort walls daily with a lint-free cloth moistened with 70% alcohol.
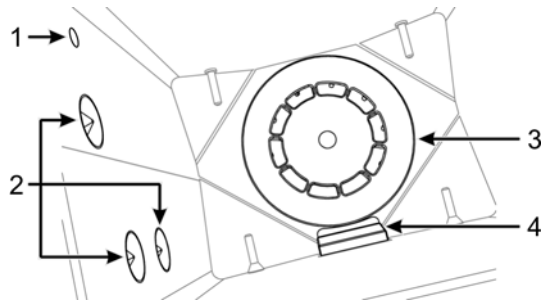
Figure 64. Retort interior with: air hole (1), level sensors (2), stirrer (3), and filter (4)

- Ensure the air hole is unobstructed.

- Carefully wipe the liquid level sensors. If you cannot remove stains with the alcohol solution, use a lint-free cloth moistened with 6% acetic acid or CLR®, then wipe again with ethanol. If still not clean, do a retort acid clean (see 7.5 Retort Acid Clean).

- Inspect the filter. If soiled, lift it out and clean with 70% alcohol.

> ⚠ **CAUTION**
> Take care not to drop anything into the opening when the filter is removed. Foreign material in the line could stop valves operating properly.

- Inspect the stirrer. If dirty, lift it out and clean with 70% alcohol. If damaged or showing signs of rust, contact your service representative for replacement.

  To replace the stirrer, hold it as indicated in Figure 65 and carefully allow it to slide onto the spindle in the bottom of the retort.
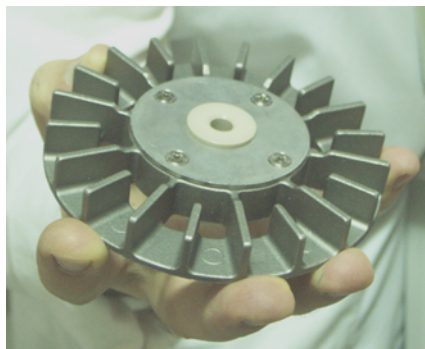
Figure 65. Stirrer handling—correct (left) and incorrect (right)

> ⚠ **WARNING**
> The magnetic coupling will pull the stirrer towards the bottom of the retort. To avoid pinching your fingers, do not allow them to be trapped between the stirrer and the bottom of the retort.

If the retort has a build up of salt precipitate from formalin or other fixatives that you cannot remove by wiping, run a retort acid clean (7.5 Retort Acid Clean).

Check Reagent Levels

Ensure that all reagent bottles and wax chambers are filled to the two- or three-basket level (depending on the reagent fill level setting for your instrument, on the **Instrument settings** screen). Add more reagent or wax if required (see 5.4 Replacing Reagents).

Clean Top Surface

Use a lint-free cloth with 70% alcohol and, if necessary, the plastic scraper to clean the lids and other surfaces on the top of the instrument. Ensure all wax is removed. Take special care that wax does not go down the wax bath vent (see Figure 63).

Clean Touch-screen

Wipe the touch-screen (or touch-screen protector) with a lint-free cloth moistened with 70% alcohol. Replace the touch-screen protector (if using) if necessary.

Lock the touch-screen before cleaning (see 6.2.2 Device Settings).

Never use abrasive cleaners or strong solvents on the touch-screen.

7.3 Weekly Tasks

Empty Condensate Bottle

Empty the condensate bottle weekly. This is especially important if running xylene-free protocols, which have more condensate.

Check Reagent Bottles

Check all bottles weekly. Note bottles that are becoming dirty. Clean the bottles when next replacing reagent.

While bottles are removed wipe the interior of the reagent cabinet with 70% alcohol.

To clean bottles pour in a small amount of fresh reagent (i.e. the reagent the bottle is used for), cap the openings, and shake. Use sealing caps from Leica Biosystems to seal the bottle. Empty the bottle and check it is clean. If so refill and replace in the instrument (see 5.4 Replacing Reagents for instructions to reset the station properties).

If the bottle is still stained use a bottle brush and laboratory detergent to clean. Rinse thoroughly with water. Then prepare the bottle to refill with reagent:

- For formalin and alcohol bottles (where the reagent is miscible with water) rinse with a small amount of the bottle's reagent to clear the water, then refill.

- For clearer and cleaning solvent bottles (e.g. xylene, where the reagent is not miscible with water), dry thoroughly before adding fresh reagent, or rinse with a small amount of alcohol then a small amount of the bottle's reagent before refilling.

WARNING
Wear suitable protective clothing and eyewear to avoid splashes when cleaning bottles.

WARNING
Ensure lids are tight and the bottles are correctly plugged into the manifold after replacing reagent to avoid reagent spills.

CAUTION
Do not clean reagent bottles in an automatic dishwasher as they may be damaged.

Clean Wax Bath

Check the wax chambers weekly and note if they are becoming dirty. Clean the chambers when next replacing the wax.

Clean the wax chambers while they are warm after draining spent wax out of the instrument. Never attempt to clean a chamber while the wax from the chamber is in the retort.

Wipe the bottom and sides of the chamber with a lint-free cloth to remove any debris or sludge. Do not remove the chimney filters. Be careful not to dislodge the filters. Take care no material goes into the air hole on the wax bath rim.

WARNING

Never open a wax bath lid when there is wax in a retort or wax is being transferred; hot wax may splash out of the bath.

WARNING

Take care when cleaning the wax bath walls. The walls could be hot and may cause burns.

Check Bottle Connectors

The bottle connectors that plug into the instrument can become loose. Check the connector whenever you pull out a bottle. Tighten firmly if necessary.

Clean Exterior Surfaces

Wipe down the exterior surfaces of the PELORIS weekly with a damp cloth (water or 70% alcohol). Do not use strong solvents. Dry with a lint-free cloth.

7.4 60–90 Days

Change Carbon Filter

Change the carbon filter every 60 to 90 days.

> **WARNING**
>
> Always replace the carbon filter when the software indicates that it has expired. Running the instrument with an out-of-date carbon filter may release potentially dangerous fumes into the laboratory.

Ensure you have the carbon filter threshold set to a suitable number of days to alert you when filter changes are due. See Carbon Filter Settings in 6.2.1 Instrument Settings.

Use the following procedure to replace a used filter.

1. Unlock the filter by turning the latch 1/4 turn clockwise and slide the old filter out.

Figure 66.   Unlocking the filter

Figure 67.   Removing the filter

2. Remove the plastic wrap from the new filter.

3. Slide the new filter into the housing with the direction arrow pointing up (see Figure 68).
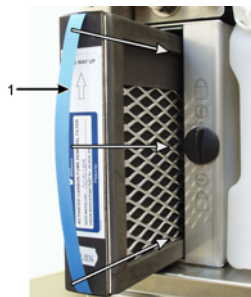
Figure 68.   Replacing the carbon filter with direction arrow (1) pointing up

Figure 69.   Locking the filter

4. Turn the latch 1/4 turn anti-clockwise to lock the filter in place (see Figure 69).

5. Make sure the filter is unwrapped, fully inserted, and that it is locked into the housing.

6. Reset the carbon filter age from the **Instrument settings** screen (see 6.2.1 Instrument Settings).

Check Lid Seals

Inspect the retort and wax bath lid seals every 60–90 days. Replace if worn or damaged.

1. Pull the old seals out of the grooves.

2. Clean the grooves if necessary with the wax scraper and 70% alcohol.

3. Push the new seals into the grooves. Ensure they are fully seated.
    Figure 70 and Figure 71 show how seals fit into the grooves.
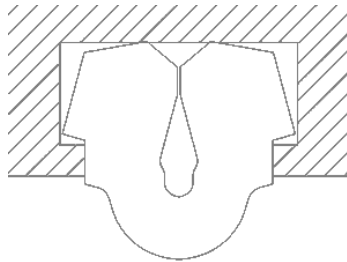
Figure 70. Cross section of retort seal in lid   Figure 71. Cross section of wax bath seal in lid
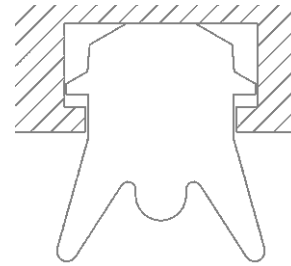
4. Equalize the tension in each seal by running your finger around the seal to remove any tight or loose sections.

7.5   Retort Acid Clean

Common fixative reagents (for example formalin) may cause a build-up of precipitate (salt crystals) on the retort walls. If these cannot be removed by wiping with 70% alcohol follow the procedure below.

1. If the salt build-up is light, wipe the retort walls with a lint-free cloth dampened with 6% acetic acid.

2. If the build-up is heavy or is not easily removed, fill a reagent bottle with 6% acetic acid solution then fill the retort with the solution using the instrument's remote fill and drain functions.

3. Leave the acetic acid solution in the retort for one hour at ambient temperature then drain the acid back to the bottle.

4. Remove the acetic acid solution from the instrument and clean the bottle thoroughly before using it for any other reagent.

5. Use a clean wax scraper or a lint-free cloth dampened with the acetic acid solution to remove any remaining salt build-up.

6. Run a cleaning protocol in the retort and select a cleaning alcohol as the initial step.

WARNING
Wear suitable protective clothing when handling the acetic acid solution.

8

Reference

This chapter has useful reference information to help you set up and operate the instrument.

- 8.1 Reagent Threshold Guidelines
- 8.2 Protocols
- 8.3 Station Configurations
- 8.4 Protocol Step Temperatures
- 8.5 Reagent Compatibility Tables

8.1   Reagent Threshold Guidelines

The tables in this section list the recommended thresholds for commonly used reagents. There are separate tables for xylene and xylene-free processing:

Xylene Processing

For the best results, xylene-processing reagent changes should be based on concentration thresholds, while cleaning reagent thresholds should be based on cycles.

Thresholds for xylene-processing reagents, including cleaning reagents, using non-graded alcohol are:

Type	Reagent change thresholds		Final reagent thresholds		Max. temperatures °C		
	Conc. (%)	Cassettes or cycles	Conc. (%)	Cassettes or cycles	Ambient	Vacuum	Safe
Formalin	98.0	1500 cass.	N/A	N/A	60	60	45
Ethanol	51.0	N/A	98.0	1500 cass.	78	51	45
Xylene	68.0	N/A	95.0	1500 cass.	138	99	45
Wax	80.0	4500 cass.	95.0	1500 cass.	100	100	77
Cleaning xylene	88.0	10 cycles	N/A	N/A	138	99	45
Cleaning ethanol	88.0	10 cycles	N/A	N/A	78	51	45

Xylene-free Processing

In general, xylene-free processing reagent changes should be based on concentration thresholds, and cleaning reagent changes based on cycles.

Type	Reagent change thresholds		Final reagent thresholds		Max. temperatures °C		
	Conc. (%)	Cassettes or cycles	Conc. (%)	Cassettes or cycles	Ambient	Vacuum	Safe
Formalin	98.0	1500 cass.	N/A	N/A	60	60	45
85% ethanol	50.0	N/A	N/A	N/A	87	55	45
80/20 ethanol/IPA	81.0	N/A	N/A	N/A	78	51	45
IPA	90.0	4500 cass.	95.0	1500 cass.	82	55	45
Wax	85.0	4500 cass.	95.0	1500 cass.	100	100	77
Cleaning Waxsol	88.0	6 cycles*	N/A	N/A	100	100	45
Cleaning ethanol	88.0	6 cycles*	N/A	N/A	78	51	45

* This differs from the recommendation for cleaning ethanol in xylene processing because the cleaning solvent in xylene-free protocols is less efficient than the cleaning solvent in xylene protocols.

8.2 Protocols

The protocols in this section have been developed and extensively tested by Leica Biosystems for use on the PELORIS tissue processor. Some are included as pre-defined protocols with all PELORIS systems.

When used for the recommended tissue types the protocols all produce optimum processing quality with consistent, high-quality results. Use these protocols and the suggested station configurations (see 8.3 Station Configurations) as a reference point when developing protocols that suit your specific requirements and practices.

This section has the following subsections:

- 8.2.1 Specimen Type and Protocol Duration
- 8.2.2 List of Pre-defined Protocols
- 8.2.3 Xylene Protocols
- 8.2.4 Xylene-free Protocols
- 8.2.5 Cleaning Protocol

8.2.1 Specimen Type and Protocol Duration

The following table lists recommended protocol durations for different specimen types.

Duration (hours)	Maximum tissue dimensions (mm)	Specimen type
1	1.5	Endoscopies and needle biopsies
2	<3	All biopsies up to 3 mm diameter: gastrointestinal biopsies, renal, prostatic, hepatic and breast cores; punch biopsies of skin, small colonic polyps
4	3	Small specimens of non-dense tissues (e.g. kidney, liver, bowel), excisional and incisional skin biopsies; skin ellipses
6	15 x 10 x 3	All routine tissues up to maximum dimensions (excluding fatty or brain specimens)
8	15 x 10 x 4	All routine tissues up to maximum dimensions (excluding fatty or brain specimens)
12	20 x 10 x 5	All routine tissues up to maximum dimensions. Very thick fatty specimens may require a longer protocol.

8.2.2 List of Pre-defined Protocols

Leica Biosystems provides 11 pre-defined protocols with each PELORIS system. You can use these as they are, or base new protocols on them (see Copying Protocols in 4.2.3 Creating New Protocols for instructions to copy pre-defined protocols).

Descriptions of the pre-defined protocols are included in the following sections.

The pre-defined protocols are:

- Factory 1hr Xylene Standard (see Xylene 1 Hour)
- Factory 2hr Xylene Standard (see Xylene 2 Hour)
- Factory 4hr Xylene Standard (see Xylene 4 Hour)
- Factory 8hr Xylene Standard (see Xylene 8 Hour)
- Factory 12hr Xylene Standard (see Xylene 12 Hour)
- Factory 1 hr Xylene Free (see Xylene-free 1 Hour)
- Factory 2 hr Xylene Free (see Xylene-free 2 Hour)
- Factory 4 hr Xylene Free (see Xylene-free 4 Hour)
- Factory 8 hr Xylene Free (see Xylene-free 8 Hour)
- Factory 12 hr Xylene Free (see Xylene-free 12 Hour)
- Quick Clean (see Quick Clean)

8.2.3 Xylene Protocols

All the xylene protocols below are designed for use with the xylene bottle configuration in 8.3 Station Configurations.

Xylene 1 Hour

- Pre-defined protocol "Factory 1hr Xylene Standard"
- Carryover setting in pre-defined protocol: 100

Step	Reagent type	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	Fixatives	1	Ambient	Ambient	Medium	10
2	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
3	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
4	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
5	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
6	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
7	Ethanol	Dehydrants	18	45	Ambient	Medium	10
8	Xylene	Clearers	1	Ambient	Ambient	Medium	10
9	Xylene	Clearers	1	Ambient	Ambient	Medium	10
10	Xylene	Clearers	14	45	Ambient	Medium	10
11	Paraffin wax	Wax	2	65	Vacuum	Medium	10
12	Paraffin wax	Wax	1	65	Vacuum	Medium	10
13	Paraffin wax	Wax	14	65	Vacuum	Medium	10
Processing time			1:25:00				

Xylene 2 Hour

- Pre-defined protocol "Factory 2hr Xylene Standard"
- Carryover setting in pre-defined protocol: 75

Step	Reagent type	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	Fixatives	1	Ambient	Ambient	Medium	10
2	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
3	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
4	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
5	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
6	Ethanol	Dehydrants	11	45	Ambient	Medium	10
7	Ethanol	Dehydrants	30	45	Ambient	Medium	10
8	Xylene	Clearers	1	Ambient	Ambient	Medium	10
9	Xylene	Clearers	1	Ambient	Ambient	Medium	10
10	Xylene	Clearers	28	45	Ambient	Medium	10
11	Paraffin wax	Wax	5	65	Vacuum	Medium	10
12	Paraffin wax	Wax	5	65	Vacuum	Medium	10
13	Paraffin wax	Wax	20	65	Vacuum	Medium	10
Processing time			2:14:00				

Xylene 4 Hour

- Pre-defined protocol "Factory 4hr Xylene Standard"
- Carryover setting in pre-defined protocol: 50

Step	Reagent type	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	Fixatives	10	45	Ambient	Medium	10
2	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
3	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
4	Ethanol	Dehydrants	1	Ambient	Ambient	Medium	10
5	Ethanol	Dehydrants	20	45	Ambient	Medium	10
6	Ethanol	Dehydrants	20	45	Ambient	Medium	10
7	Ethanol	Dehydrants	45	45	Ambient	Medium	10
8	Xylene	Clearers	1	Ambient	Ambient	Medium	10
9	Xylene	Clearers	10	45	Ambient	Medium	10
10	Xylene	Clearers	45	45	Ambient	Medium	10
11	Paraffin wax	Wax	10	65	Vacuum	Medium	10
12	Paraffin wax	Wax	10	65	Vacuum	Medium	10
13	Paraffin wax	Wax	40	65	Vacuum	Medium	10
Processing time			4:02:00				

Xylene 6 Hour

- Not a pre-defined protocol

Step	Reagent type	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	Fixatives	15	45	Ambient	Medium	10
2	Ethanol	Dehydrants	15	45	Ambient	Medium	10
3	Ethanol	Dehydrants	15	45	Ambient	Medium	10
4	Ethanol	Dehydrants	15	45	Ambient	Medium	10
5	Ethanol	Dehydrants	15	45	Ambient	Medium	10
6	Ethanol	Dehydrants	30	45	Ambient	Medium	10
7	Ethanol	Dehydrants	45	45	Ambient	Medium	10
8	Xylene	Clearers	20	45	Ambient	Medium	10
9	Xylene	Clearers	20	45	Ambient	Medium	10
10	Xylene	Clearers	45	45	Ambient	Medium	10
11	Paraffin wax	Wax	30	65	Vacuum	Medium	10
12	Paraffin wax	Wax	30	65	Vacuum	Medium	10
13	Paraffin wax	Wax	45	65	Vacuum	Medium	10
Processing time			6:08:00				

Xylene 8 Hour

- Pre-defined protocol "Factory 8hr Xylene Standard"
- Carryover setting in pre-defined protocol: 25

Step	Reagent type	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	Fixatives	20	45	Ambient	Medium	10
2	Ethanol	Dehydrants	20	45	Ambient	Medium	10
3	Ethanol	Dehydrants	20	45	Ambient	Medium	10
4	Ethanol	Dehydrants	20	45	Ambient	Medium	10
5	Ethanol	Dehydrants	20	45	Ambient	Medium	10
6	Ethanol	Dehydrants	40	45	Ambient	Medium	10
7	Ethanol	Dehydrants	60	45	Ambient	Medium	10
8	Xylene	Clearers	30	45	Ambient	Medium	10
9	Xylene	Clearers	30	45	Ambient	Medium	10
10	Xylene	Clearers	60	45	Ambient	Medium	10
11	Paraffin wax	Wax	40	65	Vacuum	Medium	10
12	Paraffin wax	Wax	40	65	Vacuum	Medium	10
13	Paraffin wax	Wax	60	65	Vacuum	Medium	10
Processing time			8:08:00				

Xylene 12 Hour

- Pre-defined protocol "Factory 12hr Xylene Standard"
- Carryover setting in pre-defined protocol: 25

Step	Reagent type	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	Fixatives	44	45	Ambient	Medium	10
2	Ethanol	Dehydrants	30	45	Ambient	Medium	10
3	Ethanol	Dehydrants	30	45	Ambient	Medium	10
4	Ethanol	Dehydrants	30	45	Ambient	Medium	10
5	Ethanol	Dehydrants	30	45	Ambient	Medium	10
6	Ethanol	Dehydrants	60	45	Ambient	Medium	10
7	Ethanol	Dehydrants	90	45	Ambient	Medium	10
8	Xylene	Clearers	45	45	Ambient	Medium	10
9	Xylene	Clearers	45	45	Ambient	Medium	10
10	Xylene	Clearers	90	45	Ambient	Medium	10
11	Paraffin wax	Wax	60	65	Vacuum	Medium	10
12	Paraffin wax	Wax	60	65	Vacuum	Medium	10
13	Paraffin wax	Wax	80	65	Vacuum	Medium	10
Processing time			12:02:00				

8.2.4 Xylene-free Protocols

All the xylene-free protocols below are designed for use with the xylene-free bottle configuration in 8.3 Station Configurations.

Xylene-free 1 Hour

- Pre-defined protocol "Factory 1 hr Xylene Free"

- Carryover setting in pre-defined protocol: 100

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	1	Ambient	Ambient	Medium	10
2	85% Ethanol	1	Ambient	Ambient	Medium	10
3	85% Ethanol	6	55	Ambient	Medium	10
4	80/20 Ethanol/IPA	1	Ambient	Ambient	Medium	10
5	80/20 Ethanol/IPA	6	55	Ambient	Medium	10
6	IPA	1	Ambient	Ambient	Medium	10
7	IPA	1	Ambient	Ambient	Medium	10
8	IPA	12	55	Ambient	Medium	10
9	Wax	20	85	Vacuum	Medium	10
10	Wax	5	85	Vacuum	Medium	10
11	Wax	1	65	Vacuum	Medium	10
Processing time		1:19:00				

Xylene-free 2 Hour

- Pre-defined protocol "Factory 2 hr Xylene Free"

- Carryover setting in pre-defined protocol: 75

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	1	Ambient	Ambient	Medium	10
2	85% Ethanol	1	Ambient	Ambient	Medium	10
3	85% Ethanol	12	55	Ambient	Medium	10
4	80/20 Ethanol/IPA	1	Ambient	Ambient	Medium	10
5	80/20 Ethanol/IPA	25	55	Ambient	Medium	10
6	IPA	1	Ambient	Ambient	Medium	10
7	IPA	1	Ambient	Ambient	Medium	10
8	IPA	25	55	Ambient	Medium	10
9	Wax	25	85	Vacuum	Medium	10
10	Wax	10	85	Vacuum	Medium	10
11	Wax	5	65	Vacuum	Medium	10
Processing time		2:11:00				

Xylene-free 4 Hour

- Pre-defined protocol "Factory 4 hr Xylene Free"
- Carryover setting in pre-defined protocol: 50

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	10	55	Ambient	Medium	10
2	85% Ethanol	3	Ambient	Ambient	Medium	10
3	85% Ethanol	22	55	Ambient	Medium	10
4	80/20 Ethanol/IPA	10	Ambient	Ambient	Medium	10
5	80/20 Ethanol/IPA	40	55	Ambient	Medium	10
6	IPA	3	Ambient	Ambient	Medium	10
7	IPA	10	55	Ambient	Medium	10
8	IPA	45	55	Ambient	Medium	10
9	Wax	45	85	Vacuum	Medium	10
10	Wax	20	85	Vacuum	Medium	10
11	Wax	10	65	Vacuum	Medium	10
Processing time		4:02:00				

Xylene-free 6 Hour

- Not a pre-defined protocol

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	20	55	Ambient	Medium	10
2	85% Ethanol	15	55	Ambient	Medium	10
3	85% Ethanol	20	55	Ambient	Medium	10
4	80/20 Ethanol/IPA	20	55	Ambient	Medium	10
5	80/20 Ethanol/IPA	45	55	Ambient	Medium	10
6	IPA	15	55	Ambient	Medium	10
7	IPA	30	55	Ambient	Medium	10
8	IPA	60	55	Ambient	Medium	10
9	Wax	45	85	Vacuum	Medium	10
10	Wax	40	85	Vacuum	Medium	10
11	Wax	30	65	Vacuum	Medium	10
Processing time		6:04:00				

Xylene-free 8 Hour

- Pre-defined protocol "Factory 8 hr Xylene Free"
- Carryover setting in pre-defined protocol: 26

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	30	55	Ambient	Medium	10
2	85% Ethanol	20	55	Ambient	Medium	10
3	85% Ethanol	30	55	Ambient	Medium	10
4	80/20 Ethanol/IPA	30	55	Ambient	Medium	10
5	80/20 Ethanol/IPA	60	55	Ambient	Medium	10
6	IPA	20	55	Ambient	Medium	10
7	IPA	40	55	Ambient	Medium	10
8	IPA	80	55	Ambient	Medium	10
9	Wax	60	85	Vacuum	Medium	10
10	Wax	50	85	Vacuum	Medium	10
11	Wax	40	65	Vacuum	Medium	10
Processing time		8:04:00				

Xylene-free 12 Hour

- Pre-defined protocol "Factory 12 hr Xylene Free"
- Carryover setting in pre-defined protocol: 26

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Formalin	68	55	Ambient	Medium	10
2	85% Ethanol	30	55	Ambient	Medium	10
3	85% Ethanol	40	55	Ambient	Medium	10
4	80/20 Ethanol/IPA	50	55	Ambient	Medium	10
5	80/20 Ethanol/IPA	90	55	Ambient	Medium	10
6	IPA	30	55	Ambient	Medium	10
7	IPA	60	55	Ambient	Medium	10
8	IPA	120	55	Ambient	Medium	10
9	Wax	80	85	Vacuum	Medium	10
10	Wax	70	85	Vacuum	Medium	10
11	Wax	60	65	Vacuum	Medium	10
Processing time		12:02:00				

8.2.5 Cleaning Protocol

Quick Clean

- Pre-defined protocol "Quick Clean".

- Bottle configuration: one bottle each of cleaning solvent and cleaning alcohol.

- Never run a cleaning protocol while tissue is in the retort as the dry step will damage the tissue.

Step	Reagent group	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Cleaning solvents	12	75	Ambient	High	10
2	Cleaning alcohols	6	55	Ambient	High	10
3	Dry step	12	80	N/A	Off	N/A
Processing time		0:34:00				

8.3   Station Configurations

Use the station configurations in this section for the protocols described in 8.2 Protocols.

If considering alternative station configurations remember to take into account how you will configure your protocols, including the reagent selection method (see 4.1.2 Reagent Selection Method). For example, some laboratories use explicitly graded alcohols with reagent types identified as "Ethanol 70%", "Ethanol 90%" etc. This sort of station configuration requires that protocols use type (or station) selection, and of course the protocols must be configured to use the alcohol grades in the correct order.

Xylene Configuration

This is the suggested station configuration when running xylene protocols (see 8.2.3 Xylene Protocols). See note below for special conditions for initial bottle setup.

Station	Reagent type	Reagent group
Bottle 1	Formalin	Fixative
Bottle 2	Formalin	Fixative
Bottle 3	Ethanol*	Dehydrant
Bottle 4	Ethanol*	Dehydrant
Bottle 5	Ethanol	Dehydrant
Bottle 6	Ethanol	Dehydrant
Bottle 7	Ethanol	Dehydrant
Bottle 8	Ethanol	Dehydrant
Bottle 9	Ethanol	Dehydrant
Bottle 10	Ethanol	Dehydrant
Bottle 11	Xylene	Clearer
Bottle 12	Xylene	Clearer
Bottle 13	Xylene	Clearer
Bottle 14	Xylene	Clearer
Bottle 15	Cleaning Xylene	Cleaning solvent
Bottle 16	Cleaning ethanol	Cleaning alcohol
Wax 1	Wax	Wax
Wax 2	Wax	Wax
Wax 3	Wax	Wax
Wax 4	Wax	Wax

*All alcohol dehydrants after fixative should be labeled and named in the software "Ethanol". However, if setting up bottles on a new instrument or replacing all the ethanol bottles at once, the first and second bottles should be filled with 70% and 90% ethanol respectively. As operation continues and you are prompted to replace degraded bottles, replace with 100% ethanol. Other, initially higher-concentration bottles will have degraded, so there will always be at least one bottle at a low concentration.

Xylene-free Configuration

This is the suggested station configuration when running xylene-free protocols (see 8.2.4 Xylene-free Protocols). See note below for special conditions for initial bottle setup.

Station	Reagent type
Bottle 1	Formalin
Bottle 2	Formalin
Bottle 3	85% Ethanol*
Bottle 4	85% Ethanol*
Bottle 5	85% Ethanol
Bottle 6	80/20 Ethanol/IPA
Bottle 7	80/20 Ethanol/IPA
Bottle 8	80/20 Ethanol/IPA
Bottle 9	IPA
Bottle 10	IPA
Bottle 11	IPA
Bottle 12	IPA
Bottle 13	Waxsol™
Bottle 14	Waxsol™
Bottle 15	Cleaning ethanol
Bottle 16	Cleaning ethanol
Wax 1	Wax
Wax 2	Wax
Wax 3	Wax
Wax 4	Wax

*All alcohol dehydrants after fixative should be labeled and named in the software "85% Ethanol". However, if setting up bottles on a new instrument or replacing all the ethanol bottles at once, the first two bottles should be filled with 70% ethanol (but still be named "85% Ethanol"). As operation continues and you are prompted to replace degraded bottles, replace with 85% ethanol. Other, initially higher-concentration bottles will have degraded, so there will always be at least one bottle at a low concentration.

8.4 Protocol Step Temperatures

The PELORIS tissue processor uses five protocol types to accommodate different processing functions. Each protocol type has a set of reagent compatibility sequences that comply with the intended use (see 8.5 Reagent Compatibility Tables for more information). The allowable temperature range for each step is also dependent on the protocol type. The following sections list the protocol temperature ranges and typical protocol sequences.

Protocol type	Retort temp. range for reagent	Retort temp. range for wax	Wax bath temp. range
Standard	35ºC to 65ºC	2ºC above wax melt temp. to 77ºC	55ºC to 85ºC
Xylene-free	35ºC to 65ºC	2ºC above wax melt temp. to 85ºC	55ºC to 85ºC
Cleaning	35ºC to 85ºC	N/A	55ºC to 85ºC

The current wax melting temperature is shown on the **Reagent management** screen.

8.5 Reagent Compatibility Tables

The reagent compatibility tables determine the allowable reagent sequences. The sequences vary depending on the operation or protocol type.

Manual Operations

Current step ☑ = compatible	Previous step						
	None	Fixatives	Dehydrants	Clearers	Wax	Cleaning solvents	Cleaning alcohols
Fixatives	☑	☑	☑				☑
Dehydrants	☑	☑	☑	☑		☑	☑
Clearers	☑		☑	☑		☑	☑
Wax	☑			☑	☑	☑	
Cleaning solvents	☑		☑	☑	☑	☑	☑
Cleaning alcohols	☑	☑	☑	☑		☑	☑

Standard Protocols

Current step ☑ = compatible	Previous step						
	None	Fixatives	Dehydrants	Clearers	Wax	Cleaning solvents	Cleaning alcohols
Fixatives	☑	☑					☑
Dehydrants	☑	☑	☑				☑
Clearers	☑		☑	☑			
Wax	☑			☑	☑		

Xylene-free Protocols

Current step ☑ = compatible	Previous step						
	None	Fixatives	Dehydrants	Clearers	Wax	Cleaning solvents	Cleaning alcohols
Fixatives	☑	☑					☑
Dehydrants	☑	☑	☑				☑
Clearers							
Wax	☑		☑		☑		

Cleaning Protocols

Current step ☑ = compatible	Previous step						
	None	Fixatives	Dehydrants	Clearers	Wax	Cleaning solvents	Cleaning alcohols
Cleaning solvents	☑		☑	☑	☑	☑	☑
Cleaning alcohols	☑	☑	☑	☑		☑	☑

9

Troubleshooting

If you have processing problems, review this chapter to try to identify the cause.

- 9.1 Preliminary Questions
- 9.2 Flowcharts
- 9.3 Reprocessing Recommendations

9.1 Preliminary Questions

When faced with blocks that are difficult to section first collect as much information as possible to assist in analyzing the problem. Some questions to ask are:

1. Did the instrument software indicate an error in the run? Instrument warnings and alarms will be displayed on screen and in the event log.

2. Was there anything different about the run that produced the problem specimens compared to previous successful runs, e.g. a recently changed reagent bottle?

3. Is there a possibility that an error was made when replacing reagents on the processor? Do a visual check of reagent bottles – is the correct reagent in each bottle?

4. The **Reagent stations** screen records reagent concentrations and how many cassettes and cycles have been put through a reagent. Check to see if these are correct.

5. Are any reagents over their recommended purity thresholds?

6. Was the intended processing protocol actually used? For example, is it possible that specimens intended for a longer processing protocol were placed on a shorter processing protocol?

7. Were the specimens processed using the usual protocol for specimens of this size and type, and that generally produces good results? If so, the problem is probably not in the protocol parameters.

8. Were the specimens at the very top of the retort? Is the instrument set up for a two-basket level when three baskets were processed? Were the baskets placed in the retort correctly?

9. Were all the specimens in the batch affected, or just some of them? Were all the specimens of a similar type? Were they all from the same source? Answers to these questions may indicate a problem prior to tissue processing.

10. Was normal fixation applied to the problem specimens?

These questions should help you determine what has gone wrong. If you remain uncertain as to the cause of the problem you must gather as much information as possible by carefully examining the specimens. Close examination of the blocks can confirm what you suspect may have happened. Microscopic examination will also provide valuable information to indicate what may have gone wrong.

9.2 Flowcharts

This section has eight flowcharts for different processing problems.

- 9.2.1 Under-processed Tissue – Instrument Setup

- 9.2.2 Over-processed Tissue – Instrument Setup

- 9.2.3 Under- or Over-processed Tissue – Reagents

- 9.2.4 Poor Processing – Incorrect Protocol

- 9.2.5 Poor Processing – Correct Protocol

- 9.2.6 Cutting Artifact

- 9.2.7 Staining Artifact

- 9.2.8 Block Artifact

9.2.1 Under-processed Tissue – Instrument Setup

Under-processed tissue (soft/mushy/wet)

Are any error codes present?
— Yes → If a user warning, fix the issue. If a service warning, contact service → **Retest. Is the tissue processed correctly?** — Yes ►
— No ↓ / No ←

Was the correct protocol used?
— No → Check:
- tissue size
- step times
- pressure and vacuum
- temperatures
- drip times

Are the settings appropriate?
Optimize the reagent using the predefined protocols as a guideline
→ **Retest. Is the tissue processed correctly?** — Yes ► / No ↓
— Yes ↓

Was the correct carryover value, number of cassettes, entered?
— No → Enter correct values for carryover and cassettes for the reagent management system to work correctly. → **Retest. Is the tissue processed correctly?** — Yes ► / No ↓
— Yes ↓

Is the lab workflow appropriate?
— No → Check:
- Transfer fluid (formal saline?)
- Fixation time
- Water introduced after processing?
- Quality of embedding wax

Are these all correct?
→ **Retest. Is the tissue processed correctly?** — Yes ► / No ↓
— Yes ↓

Go to 9.2.3 Under- or Over-processed Tissue – Reagents

Stop: well processed tissue

9.2.2 Over-processed Tissue – Instrument Setup

Over-processed tissue (cooked/ crispy/ burnt)

Are any error codes present?
- Yes → If a user warning, fix the issue. If a service warning, contact service → Retest. Is the tissue processed correctly?
  - Yes →
  - No →
- No ↓

Was tissue allowed to dry out?
- Yes → Check:
  - How was the tissue submitted to the lab- in formalin?
  - Was tissue in solution between grossing and processing?
  - Was the protocol in dehydrant for too long?
  - Was the protocol in solvent for too long?
  - Was tissue left in the retort in wax for too long?
  - Was the tissue left in the embedding instrument too long?
  → Retest. Is the tissue processed correctly?
    - Yes →
    - No →
- No ↓

Was the correct protocol used?
- No → Check:
  - tissue size
  - step times
  - pressure and vacuum
  - temperatures
  - drip times

  Are the settings appropriate?
  Optimise the reagent using the pre-defined protocols as a guideline.
  → Retest. Is the tissue processed correctly?
    - Yes →
    - No →
- Yes ↓

Was the correct carryover value, number of cassettes, entered?
- No → Enter correct values for Carryover and cassettes for the reagent management system to work correctly. → Retest. Is the tissue processed correctly?
  - Yes →
  - No →
- Yes ↓

Is the lab workflow appropriate?
- No → Check:
  - Transfer fluid (formal saline?)
  - Fixation time
  - Water introduced after processing?
  - Quality of embedding wax
  Are these all correct?
  → Retest. Is the tissue processed correctly?
    - Yes →
    - No →
- Yes →

Go to 9.2.3 Under- or Over-processed Tissue – Reagents

Stop
Well Processed Tissue

9.2.3 Under- or Over-processed Tissue – Reagents

Under/over-processed tissue -reagents

Are the reagents physically correct? — No →

Check:
- reagent concentrations with a hydrometer
- the reagent change and final reagent thresholds
- bottles are in their correct stations
- the reagents in the bottles are correct
- reagent storage conditions
- reagent threshold check method

Are they all correct? — No →

Yes ↓

Are the reagents clean? — No →

Check:
- reagents are clean

Factors that could affect reagent purity are:
- recycled reagents
- running reprocessing protocols
- failing to clean the retorts before or after remote drain or fill operations

— No →

Discard incorrect or dirty reagents. Rinse reagent bottles and fill and drain retort with fresh reagent to clean reagent lines.

Yes ↓

Is the wax contaminated or does it smell like formalin? — Yes →

Open a service call to have Leica Microsystems test the instrument and repair if required.

Is the instrument functioning correctly? — Yes →

No ↓

Retest. Is the tissue processed correctly?

Yes ↓

Stop
Well processed tissue

9.2.4 Poor Processing – Incorrect Protocol

Poor processing – incorrect protocol

- **Was the original protocol too long?**
  - Yes → Tissue is over-processed. Reprocessing will not help. → Try:
    - soaking the block in a softening agent, such as fabric softener, before cutting.
    - Cutting thinner sections.
    - Warming the block slightly before sectioning
  - No ↓

- **Was the original protocol too short?**
  - Yes → Tissue is under processed. Reprocess. NB: Do not use the Peloris clean cycle to reprocess the tissue as the drying step will cause the tissue to dry out.
    - **Is it large delicate tissue?**
      - Yes → Try a longer protocol with less heat and agitation.
      - No ↓
    - **Is it large robust tissue?**
      - Yes → Try a longer, protocol with more heat and efficient agitation.
      - No ↓
    - **Is it xylene processing?**
      - No →
      - Yes ↓
    - **Is it fatty tissue?**
      - Yes → Try a defatting step of 50/50 xylene and ethanol. Put step between ethanols and xylene, ensuring that there is a 100% ethanol step after defat, before xylene.
      - No
  - No ↓

- **Was wax infiltration incomplete?**
  - Yes → If tissue is dehydrated and cleared there is no need for reprocessing. Re-infiltrate tissue with wax only.
  - No →

- **Is tissue processed adequately?**
  - No → Contact customer support
  - Yes → Adequately processed tissue

9.2.5 Poor Processing – Correct Protocol

9.2.6 Cutting Artifact

	Cause		Suggestion for fix	

Is the tissue hard, brittle or has chatter?

Cause	Suggestion for fix
Over-dehydration	Decrease time in dehydrant
Over-clearing	Decrease time in xylene
Cold plate too cold	Warm cold plate slightly or wet face of block just prior to cutting
Poor microtomy	Check knife tilt and ensure proper cutting techniques

Are there breaks in the ribbon or compression?

Cause	Suggestion for fix
Inadequate processing	Check protocol and adjust times as needed
Incorrect size mould	Re-embed tissue in bigger mould
Poor microtomy	Check knife tilt and ensure proper cutting techniques, replace blade
Block not cold enough	Allow block to cool longer on cold plate

Does the sections have disruption, holes, and tears?

Cause	Suggestion for fix
Insufficient dehydration	Increase step time in dehydration
	Change or replace solutions in reagent bottles
Aggressive trimming or facing of block	Trim blocks at a smoother pace and fine trim prior to cutting
Poor microtomy	Check knife tilt and ensure proper cutting techniques
Poor wax infiltration	Increase step time in wax

Is it hard to get the tissue to flatten?

Cause	Suggestion for fix
Tissue related	Nature of tissue - typically seen in brain and bowel
Is the water bath at correct temperature?	
Inadequate wax infiltration	Increase step time in wax

Are there cracks In the tissue sections?

Cause	Suggestion for fix
Tissue over-processed	Decrease time in dehydrants/ xylenes also check the step temperatures are appropriate
Rough trimming	Trim blocks at a smoother pace and fine trim prior to cutting

9.2.7 Staining Artifact

Does the tissue have blue hue or smudge?
— Yes → **Water present in tissue** → **Increase step time in dehydration** → **Change or replace solutions in reagent bottles**

Is there zonal fixation?
— Yes → **Under fixed** → **Make sure tissue is placed in an adequate amount of formalin for an adequate amount of time. As soon as possible after removal from patient** → **Ensure tissue is not too big for cassette**

Is there coarse or fine cracking?
→ **Inadequate fixation**
→ **Over processed** → **Change or replace solutions in reagent bottles** → **Ensure protocol step times are adequate** → **See sections 9.2.1, 9.2.2, 9.2.3**

Is there formalin pigment?
— Yes → **pH of formalin is too high** → **Fix tissue in neutral buffered formalin, and change regularly**

Is there cellular detail?
— No → **Under/Over processed** → **Ensure protocol step times are adequate** → **See sections 9.2.1, 9.2.2, 9.2.3**
→ **Change or replace solutions in reagent bottles**

9.2.8 Block Artifact

Always try to ensure that protocol length is correct for the size of the tissue

Opaque block
- Insufficient processing → Ensure reagents are clean and at correct purity → Increase processing
- Insufficient dehydration → Increase dehydration steps

Sweating tissue
- Insufficient dehydration → Increase dehydration steps
- Insufficient tissue clearing → Increase clearing

Tissue shrinkage
- Insufficient processing time → Increase processing time
- Incorrect reagent thresholds → Ensure reagents are clean and at correct purity → Adjust thresholds → Decrease tissue size when processing

Soft tissue
- Insufficient clearing, dehydration and/ or infiltration → Increase protocol step times
- Inappropriate fixation → Increase fixation

9.3   Reprocessing Recommendations

Not all problem tissue requires reprocessing. Some common problems and possible solutions are listed below:

1. Tough, Brittle, Over-Processed Tissue

2. Gritty Tissue due to Calcium Deposits

3. Hard Shriveled Tissue – Dried Out Before Wax Infiltration

4. Hard Shriveled Tissue – Dried Out but Processed Through to Wax

5. Tissue Insufficiently Infiltrated with Wax

6. Adequately Fixed Under-processed Tissue

7. Tissue Affected by Formalin During Clearing or Wax Infiltration

8. Inadequately Fixed, Under-Processed Tissue

1. Tough, Brittle, Over-Processed Tissue

Treat the surface of the exposed tissue in the block with a rehydrating or softening agent, e.g:

- Melting ice
- 0.2% aqueous Teepol™ or other wetting agent
- Fabric softener at 5% (e.g. Downy™)
- Mollifex™
- 9% glycerol in 60% ethanol

Treat for a few minutes, rinse, rechill and recut.

Reprocessing is inappropriate because it will cause further over-processing.

2. Gritty Tissue due to Calcium Deposits

Treat the surface of the exposed tissue in the block with decalcifying agent for 15–30 min (the time depends on the decalcifier used). Rinse to remove acid, rechill and recut.

Reprocessing tissue that contains calcium or other mineral deposits does not improve its cutting qualities. The calcium must be removed.

3. Hard Shriveled Tissue – Dried Out Before Wax Infiltration

Soak in a large volume of reconstitution solution. Time (2–24 hr) depends on the size and nature of the tissue and the severity of drying. Reconstitution solutions include:

- Neutral buffered formalin
- Isotonic saline

- Sandison's solution
    - 50 mL 1% aqueous formalin
    - 30 mL 96% ethanol
    - 20 mL 5% sodium carbonate
- Ethanol-glycerol
    - 90 mL 60% ethanol
    - 10 mL glycerol

Then process tissue normally.

4. Hard Shriveled Tissue – Dried Out but Processed Through to Wax

Remove wax and rehydrate as detailed in problem 6, below. Apply a reconstitution solution as described in problem 3.

5. Tissue Insufficiently Infiltrated with Wax

Place the cassettes back into the wax bath with vacuum and stirrer on and temperature at 65°C. This may be necessary when tissue has been prematurely removed from the wax.

6. Adequately Fixed Under-processed Tissue

This problem can be due to too short a protocol, too large a specimen, or processor failure. Four methods are recommended, but first identify the problem and rectify it. Test your fix by running control tissue through the processor before reprocessing the patient tissue (or use another processor).

For all the following solutions first melt down the blocks, blot off excess wax, and then place the specimens in new cassettes. This minimizes wax contamination of the processing reagents.

A. Taggart's Method

Place the cassettes into a beaker of isotonic saline (aqueous solution of 0.9% sodium chloride) in an incubator at 65°C for 1 hr. The wax rises to the surface. Remove the tissue and reprocess from formalin using a protocol suitable for its size and nature (see 8.2.1 Specimen Type and Protocol Duration).

The saline gently rehydrates the tissue, which can then be processed normally. Saline is a non-toxic reagent that can be safely used in an open laboratory.

B. Rapid Reverse Process

Process using a fast modified cleaning protocol (see Rapid Reverse Cleaning Protocol below). Do not use the default Quick Clean protocol or protocols derived from this, because they finish with a drying step that will damage the tissue. After the cleaning protocol reprocess from formalin using a schedule suitable for the size and nature of the specimen (see 8.2.1 Specimen Type and Protocol Duration).

Processor cleaning reagents provide a convenient automated method to remove wax and take the tissue back to alcohol. It is however, a potentially harsher method than methods A or C.

C. Slow Reverse Process

Process using a modified cleaning protocol for a period equal to the time required to forward process the tissue (see Slow Reverse Cleaning Protocol below). Then reprocess from formalin using a schedule suitable for the size and nature of the specimen (see 8.2.1 Specimen Type and Protocol Duration).

A long reverse process is very gentle on the tissue. If time permits this is the favored option.

D. Direct Reprocessing

In this method wax is not removed before reprocessing. Place cassettes directly back into formalin and then, with no other pretreatment, reprocess using a schedule suitable for the size and nature of the specimen (see 8.2.1 Specimen Type and Protocol Duration).

This method is the quickest, however it causes wax contamination of the reagents on the processor. Change all reagents (except wax) after direct reprocessing.

7. Tissue Affected by Formalin During Clearing or Wax Infiltration

This problem can occur if a leaking valve allows back-flow of formalin into the wax bath. Contact customer support to test your instrument if you see this problem.

Formalin contamination is characterized by "blue hue" in the nuclei, loss of chromatin detail, nuclear shrinkage, variable eosinophilia and cytoplasmic swelling and/or shrinkage.

First melt down the blocks, blot off excess wax, and then place the specimens in new cassettes. This minimizes wax contamination of the processing reagents. Then reverse-process the blocks by any of the methods listed for problem 6. After this, soak in a high pH Tris-HCl retrieval solution (e.g. BOND Epitope Retrieval Solution 2) for 2–12 hrs at room temperature.

This treatment improves the staining qualities of the H&E, the cutting qualities of the tissue and the cohesiveness of the section. Nuclear detail, cytoplasmic swelling and definition are unlikely to improve.

8. Inadequately Fixed, Under-Processed Tissue

A possible remedy is to slowly reverse-process the tissue (see 6C), apply additional formalin fixation, then reprocess using a schedule suitable for the size and nature of the specimen (see 8.2.1 Specimen Type and Protocol Duration).

Unfixed or poorly-fixed tissue is damaged by processing – the alcohol and high temperatures exert a fixative effect different to that of formaldehyde. As a result blocks become more susceptible to hardening and shrinkage. When combined with under-processing, blocks may be unusable.

Rapid Reverse Cleaning Protocol

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Cleaning solvent	12	65	Ambient	High	10
2	Cleaning ethanol	6	55	Ambient	High	10
Processing time		18				

Slow Reverse Cleaning Protocol

Step	Reagent type	Time (min)	Temp (°C)	P/V	Stirrer	Drip time (s)
1	Cleaning solvent	60	65	Ambient	High	10
2	Cleaning solvent	60	65	Ambient	High	10
3	Cleaning ethanol	60	45	Ambient	High	10
4	Cleaning ethanol	60	45	Ambient	High	10
Processing time		240				

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Consumables and Accessories

The following consumable items and accessories are available from Leica Biosystems.

Name	Part No.
Waxsol™ Cleaning Solution (20 liters)	S26.0390
Reagent bottle labels	S26.6001
Carbon filter	S26.0434
Touch-screen protectors (10)	S26.0389
Reagent bottle	S26.0802
Condensate bottle	S26.0812
Bottle caps	S26.0301
Bottle connector sealing caps	S26.0822
Bottle connector retaining caps	S26.0819
High capacity cassette basket (no dividers)	S26.0512
High capacity basket (with dividers)	S26.4506
Spaced basket	S26.4505
High capacity cassette basket dividers	S26.0516
Wax scraper	S26.0027
Reagent fill and drain hose	S26.0432
Wax drain hose	S26.1400
Drip tray	S26.0020
Bottle cap wrench	S26.1910
Remote alarm connector	S26.4098

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Specifications

Operating

Dimensions (H x W x D): ....1500 × 857 × 721 mm
(59 × 33.7 × 28.4 inches)

Weight (dry): .... 331 kg (730 lb)

Weight (including reagents): ....430 kg (950 lb)

Work surface height (from floor): ....Front − 1070 mm (42.1 inches)
Rear − 1110 mm (43.7 inches)

Cassette capacity (standard protocols): .... 600 (maximum)
528 (spaced)

Cassette capacity (xylene-free protocols): 432

Retort vacuum (max): .... − 70 kPa (g)

Retort pressure (max): .... + 45 kPa (g)

Retort agitation: ....Magnetically coupled stirrer
(user-selectable operation)

Reagent bottles: 16

Reagent volume: .... 3.8 L (1 US gal) min
5 L (1.32 US gal) max

Paraffin wax stations: .... 4 (each station is capable of filling one retort)

Environmental

Maximum ambient temperature: .... 35°C

Minimum ambient temperature: .... 5°C

Humidity (noncondensing): .... 10 to 80% RH

Altitude: .... 0 to 2000 m above sea level

Sound pressure level output (at 1 m): .... < 65 dB

Maximum heating energy output: .... 1450 W (100 to 120 V~)
2150 W (220 to 240V~)

Electrical

Operating voltage: .... 100 to 120 V~
220 to 240V~

Operating current (maximum): .... 15A (100 to 120V~)
10A (220 to 240V~)

Mains frequency: .... 50–60 Hz (100 to 120 V~)
50 Hz (220 to 240V~)

Power consumption: .... 1450 W (100 to 120 V~)
2150 W (220 to 240V~)

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