Advancing Cancer Diagnostics
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Leica BIOSYSTEMS

ThermoBrite® Elite

User Manual

Model Number S600

For *in-vitro* diagnostic use

Revision Record

Revision	Issued	Sections Affected	Detail
A01	May 2020	-	First release
B01	June 2020	Using the ThermoBrite Software	Updated screen images to support FFPE.

1. Table of Contents

2. Introduction

2.1 Intended Use

For in-vitro diagnostic use only.

The ThermoBrite Elite System provides total automation for the pre and post hybridization steps in FISH testing, while providing accurate temperature control of on-board denaturation and hybridization.

2.2 Trademarks

Leica and the Leica logo are registered trademarks of Leica Microsystems IR GmbH and used under license. ThermoBrite is a trademark of Leica Biosystems. Other trademarks are the property of their owners.

2.3 Copyright

Doc. 3855-7500-501 Rev. B01

2.4 How to use the User Manual

This document is the User Manual for the ThermoBrite Elite System. Read this manual carefully before operating the instrument, since the manual contains instructions for safe installation, operation, maintenance, and troubleshooting. A thorough knowledge of the system is recommended before any installation or use of the system.

System operations are explained in detail, and as such, the manual may be used for user training. The system operations detailed in the manual include Theory of Operation, System Component review, sample and reagent preparation, and protocol development using the ThermoBrite Elite System.

Please retain this manual for future use.

2.5 Notes, Precautions, and Warnings

The User Manual includes information and warnings that must be observed by the user in order to ensure safe operation of the system. Important messages are highlighted with borders and special icons identifying the type of message enclosed.

There are four types of messages: Notes, Cautions, Warnings, and Biological Warnings. These are explained below:

2.5.1 Notes

Highlights important facts, gives helpful information and tips, and clarifies procedures.

2.5.2 Cautions

Electrical hazard! Unplug before handling.

Important information on the proper operation of the ThermoBrite Elite System. This information is crucial for preventing instrument damage and maintaining the system.

2.5.3 Warnings

Identifies potentially hazardous situations that could result in serious injury to laboratory personnel.

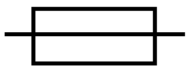
2.5.4 Biological Warnings

Use care when handling specimens. Always use personal protective equipment to prevent exposure to pathogens; i.e., bloody specimens. Incorrect or imprecise procedures may result in exposure to pathogens. This unit must be used only by users trained in proper procedures for clinical testing and handling of biohazardous waste.

2.6 Symbols

The following is a list of symbols used on the product labeling consumables, the instrument, and their meaning.

Symbol	Meaning
	Leica Biosystems product/catalog number
	Statement of caution: Read carefully
	Indicates potential electrical hazard
	Potentially flammable liquids
	Potentially harmful substances
	Identifies potentially hazardous situations that could result in serious injury to laboratory personnel
	Potentially hot surface
	Potentially toxic substances
	Potential biohazard
	Important information

Symbol	Meaning
	Use only as in-vitro diagnostic device
	Serial number (Unique Pack Identifier)
	Consult Instructions for Use
	Compliance to IVD Directive European Community
	Listed device with Intertek testing agency
	Rating: (located on serial number label, replace with same value and type)
	Single Phase Alternating Current
	Waste Electrical and Electronic Equipment Directive (WEEE)

2.7 Warnings, Precautions, Limitations

- Do not place the ThermoBrite Elite System in water.
- Do not drop or throw the instrument.
- Operate the instrument on a dry, level surface.

- Do not move the instrument while a run is in process.
- Plug the instrument into a grounded power source.
- Avoid sources of bright light/heat.

2.8 Instructions for In Vitro Diagnostic Equipment for Professional Use

This IVD equipment complies with the emission and immunity requirements of IEC 61326 part 2-6.

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.

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.

Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2.9 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.

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

2.10 Classification of Equipment Under CISPR 11 (EN 55011)

This equipment is classified as Group 1 Class A under CISPR 11 (EN 55011). The explanation for group and class is described below.

Group 1 - This is applicable for all equipment which is not classified as group 2 equipment.

Group 2 - This is applicable for all ISM (Industrial, Scientific and Medical) RF (Radio frequency) equipment in which radio - frequency energy in the frequency range 9 kHz to 400 GHz is intentionally generated and used or only used, in the form electromagnetic radiation, inductive and/ or capacitive coupling, for the treatment of material or inspection/ analysis purposes.

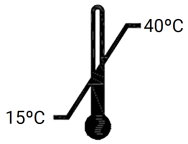
Class A - This is applicable for all equipment suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Class B - This is applicable for all equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

2.11 Precautions and Safety

Please pay close attention to the instructions that accompany the notes and symbols as well as the standard laboratory practices outlined by your facility and local regulatory agencies.

The ThermoBrite Elite unit weighs approximately 27 kgs (60 lbs), not including the Fluid Management System and accessories. Choose a place to set up the unit before completing its assembly.



Select a room to set up the unit where the temperature can be controlled between 15°C (59°F) and 40°C (104°F), and relative humidity non-condensing in a range of 80% maximum for a temperature <31°C (88°F) and 50% maximum for a temperature range of 31 °C -40°C (88°F - 104°F).

The equipment inside fixed covered areas of the instrument is not user serviceable and may present electrical shock hazards.

Always keep a distance of at least 5cm (2 inches) between the rear of the unit and the wall to allow for proper cooling.

Do NOT use power frequencies or voltage other than those specified in this document. Connection to an inappropriate power source may cause injury to a user or fire.

Make certain that the power supply for the ThermoBrite Elite is from a dedicated line that provides power to no other instruments or appliances. If power is not clean and steady, a UPS and/or power conditioner is recommended.

Do NOT disassemble or modify the unit. Doing so may cause injury to a user and/or instrument malfunction and void the warranty.

Place the unit on a stable and level surface free of vibration. Failure to do so may cause injury to a user or malfunction of the unit.

Do NOT place the unit where it may be affected by chemicals, corrosive gases or electronic noise. Doing so may cause injury or malfunction of the unit.

Do NOT place the unit where it may be affected by water, direct sunlight or draft. This may cause damage to the unit. Select a room to set up the unit where the temperature can be controlled between 15°C (59°F) and 40°C (104°F), and relative humidity non-condensing in a range of 80% maximum for a temperature <31°C (88°F) and 50% maximum for a temperature range of 31 °C -40°C (88°F - 104°F).

Do NOT install the system during lightning activity. For protection during lightning storms and power surges, contact your facility's electrical department.

For added protection of the unit during lightning and power surges, always unplug the power cable. If the instrument is not used for a long period of time, unplug the power cable.

To reduce the risk of electric shock, do not remove any panel unless under the direction of qualified personnel.

To reduce the risk of electric shock, do not use an extension cable, receptacle or other outlet unless the blades can be inserted completely with three-wire grounding type to prevent blade exposure.

Do NOT block any ventilation openings. Inadequate ventilation can result in overheating of the instrument or improper temperature control.

Do NOT use expired reagents. These consumables should be used within their expiry date.

Fan blades do NOT stop immediately when the lid is open during operation. DO NOT touch the fan blades when the fan is running.

For continued protection against risk of fire and hazard, replace only with the same type and rating fuse.

Equipment requires connection to protective earth ground for safety reasons.

The instrument's main power switch is used as the main disconnect device.

Observe Universal Precautions. Discard contaminated materials according to applicable regulations.

Dispose of waste product, unused product and contaminated packaging in compliance with applicable legal regulations. If unsure of the applicable legal requirements, contact the local authorities for information.

The Thermal Chambers may contain HOT liquid/reagent, handle with caution and DO NOT make direct contact to HOT liquid/reagent. Wear Heat Resistant and Chemical Resistant Gloves are recommended for hot reagents.

2.12 Leica Biosystems Contact Information

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

2.12.1 Authorized European Representative

CEpartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands

2.12.2 Manufacturer

Leica Biosystems Melbourne Pty Ltd.
495 Blackburn Road
Mt Waverley, Victoria, 3149
Australia

2.12.3 Important Information for All Users

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

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.

Persons operating the ThermoBrite Elite System must be adequately trained and warned of any potential hazards or hazardous procedures before operating the instrument. Only trained staff are to remove any covers or parts from the processing module, and only if instructed within this manual.

Repairs must only be carried out by qualified service personnel authorized by Leica Biosystems.

2.13 Warranty

2.13.1 Leica Biosystems Warranty

Leica Biosystems warrants that this device shall be free from defects in material and/or workmanship, under normal use and service, for the period expiring twelve (12) months from the date of installation, or thirteen (13) months from date of shipment, whichever is shorter. Accessories shall be free from defects in material and/or workmanship, under normal use and service, for the period outlined above. Leica Biosystems will, at its discretion, repair or replace any unit or part covered under this warranty returned to Leica Biosystems with shipping costs prepaid. Repaired or replaced instruments supplied under this warranty carry only the remaining portion of the original warranty and repairs shall not interrupt or prolong this warranty. For warranty terms and conditions outside the United States, contact your Authorized Leica Biosystems Distributor.

No warranty extended by Leica Biosystems shall apply to any instrument that has been damaged due to misuse, negligence, accident, or damage resulting from unauthorized repairs, alterations, or improper installation.

Leica Biosystems makes no warranty other than the one set forth herein. This warranty is given expressly in lieu of all other warranties, expressed or implied. The purchaser agrees that there is no warranty of merchantability or of fitness for any intended purpose and that there are no other remedies or warranties, expressed or implied, which extend beyond the description on the face of the agreement. No agent or employee of Leica Biosystems is authorized to extend any other warranty or assume for Leica Biosystems any liability except as set forth above. This warranty is only applicable to the original purchaser.

2.13.2 Limitation of Liability

Leica Biosystems shall not be liable for any loss of use, revenue or anticipated profits, or for any consequential or incidental damages resulting from the sale or use of the products. The purchaser shall be deemed liable for any and all claims, losses, or damages incurred by the use or misuse of the Leica Biosystems instrument by the purchaser, its employees or others, following receipt of the instrument or other items.

2.13.3 Use of Third Party Computer Products

Leica Biosystems does not recommend that the computers provided as a functional part of ThermoBrite Elite System be employed for performing any software or hardware-based applications other than those specifically furnished to operate and support the Leica Biosystems instrument system, or those recommended and offered by Leica Biosystems specifically as accessories or enhancements for the Leica Biosystems instrument system. No other third-party application software should be installed in these computers beyond those provided or recommended by Leica Biosystems, without the expressed approval of Leica Biosystems Technical Support, in order to avoid potential performance and reliability problems which can result from incompatibility factors, errors in use of such software, or software-based “viruses.”

Installation of such third-party software, or non-approved electronic cards or other devices, without advance Leica Biosystems approval may affect the terms of or void any Leica Biosystems warranty otherwise in effect, covering Leica Biosystems supplied software and hardware on the computers and the overall performance and reliability of the entire Leica Biosystems instrument system.

2.13.4 Use of External USB device to Netbook

It is advised that all the external USB devices are to be scanned with an up-to-date antivirus software program prior to connecting with the TBE Netbook.

3. Installation

3.1 Unpacking

Unpack the ThermoBrite Elite boxes and check the packaged items. If any of the items are damaged or missing, immediately notify Leica Biosystems or your distributor. If the ThermoBrite Elite unit, the Netbook, or the system accessories have been damaged during transport or are missing, notify your carrier immediately and contact customer service.

The ThermoBrite Elite unit weighs approximately 27 kgs (60 lbs), not including the Fluid Management System and accessories. Use safe lifting techniques and proper equipment when handling heavy objects. If necessary, obtain assistance to safely lift the instrument.

1. Position the shipping container upright and open the top flaps.

If using a utility knife, extend the blade to an appropriate length to avoid cutting any internal components.

2. Remove each box and set aside.
3. Remove the instrument by slowly lifting it vertically out of the shipping container by the foam end caps. Place the instrument on a stable surface.
4. Remove the foam end caps and place them in the shipping container for storage.
5. Check the contents of the box with the contents list.

Do NOT attempt to lift the instrument by the lid or by any component on the side panels as this could result in personal injury and/or damage to the unit.

3.2 Contents

3.2.1 ThermoBrite Elite System

Item# 3800-007000-001

Contents List	Quantity
ThermoBrite Elite Instrument	1
Netbook Kit: (1) Netbook with Pre-Installed Software (1) Power Cable (1) Power Supply (1) Mouse (1) USB Cable	1
ThermoBrite Elite Power Cable	1
Fluid Management System: (1) Bottle Rack (9) 1L Bottle Assembly (1) 2L Bottle Assembly (1) TBE Wash Bottle (1) Reagent Tube Kit	1
Peristaltic Pump Tubing Kit	4
0.5L Bottle Assembly	3
Module Filter Kit	1
Waste Bottle Kit	3
Waste Tubing Kit	1
Emergency Drain Tubing	1
Slide Carrier Kit	1
0.5L/1L Spare Bottle Cap	12
2L Spare Bottle Cap	2

3.2.2 Preventative Maintenance Kits

Item Description	Quantity	Item Number
Netbook	1	3800-007779-001
Peristaltic Pump Kit	2	3800-007742-001
Peristaltic Pump Tubes	2	3800-010022-001
Peristaltic Pump Tubes	12	3801-010021-001
0.5L Bottle Assembly	1	3800-007745-001
1L Bottle Assembly	1	3800-007749-001
2L Bottle Assembly	1	3800-007750-001
TBE Wash Bottle Assembly	1	3800-007865-001
Slide Carrier Kit	6	3800-007744-001
Module Filter Kit	6	3800-007743-001
Fluid Management System	1	3800-007687-001
Fuse Kit	5	3801-007769-001
Waste Bottle Kit	1	3800-007684-001
Waste Tubing Kit	3	3800-007746-001

3.3 Requirements

The space and facility requirements should be considered when choosing a location for the ThermoBrite Elite System. Improper layout and/or conditions can cause damage to the instrument, making it unsafe to operate.

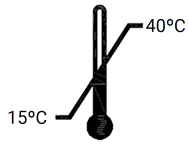
3.3.1 Electrical Requirements

The system requires alternating current at 100-240 VAC, 50-60 Hz, 10.0 A. Input voltage and frequency selection does not require customer intervention. Use properly grounded power outlets supplying 100-240 VAC @ 50-60 Hz for both the ThermoBrite Elite Unit and the Netbook.

An Uninterruptible Power Supply (UPS) is recommended for the ThermoBrite Elite System to maintain system operation during short power outages and brownouts. This allows for an orderly shutdown of the instrument and the Netbook without loss of data.

The equipment requires connection to protective earth for safety reasons.

3.3.2 Temperature Requirements



Select a room to set up the instrument where the:

- temperature is controlled between 15°C (59°F) and 40°C (104°F)
- relative humidity non-condensing is in a range of:
  - 80% maximum for a temperature <31°C (88°F)
  - 50% maximum for a temperature range of 31-40°C (88°F - 104°F).

3.3.3 Space Requirements

Dimensions for the ThermoBrite Elite System are listed in the Product Specification Table (see 9 - Specifications).

The bench for the instrument should be leveled, stable, and suitable for operation of laboratory equipment.

Allow enough space to place the Netbook.

Allow for enough space on either side of the ThermoBrite Elite Unit to place the Fluid Management System to the left and Waste Bottles to the right (if not placed underneath the instrument).

Avoid locating the instrument under overhead cabinets that might interfere with access to the unit.

3.3.4 Environmental Requirements

The system should be out of direct sunlight and away from sources of intense heat or cold, open flames, or sparks.

Some protocols may require the use of toxic, flammable, or dangerous reagents. Make sure appropriate safety precautions are taken, and reagents are disposed of, according to federal, state, and local regulations.

The ThermoBrite Elite does not ventilate or filter harmful substances from the air. If harmful vapors are expected or are a concern, the ThermoBrite Elite should be installed and operated under an appropriate approved ventilation hood.

Do NOT place the system on top of other equipment and do not place other objects or equipment on top of the system.

3.4 Installation

Make sure that all the Electrical, Space, and Environmental requirements have been met before installing the system. See 3.3 - Requirements.

Use a power cable with a grounded male connector suitable for the power outlet being used, which is rated at 10 Amps or more and has an IEC320/CEE22 female connector to attach to the ThermoBrite Elite instrument.

1. Connect the electrical cable to the power port located on the back of the ThermoBrite Elite and to an electrical grounded outlet.

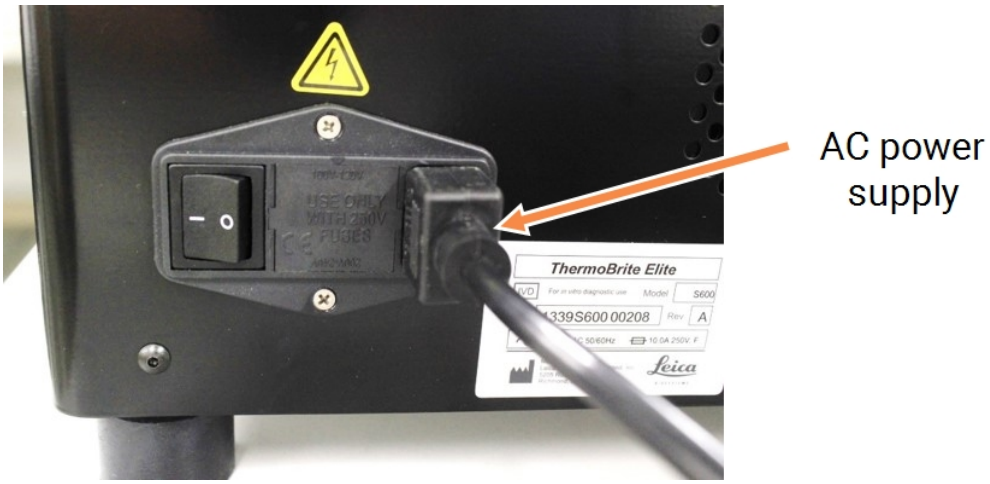


Figure 3-1: Power port located on the back of the instrument

2. Connect the Netbook to the power supply and plug the power supply to a grounded electrical outlet (see Figure 3-2 - Power supply cable). Connect the mouse USB cable to a USB port on the Netbook (see Figure 3-3 - Mouse USB cable).

Figure 3-2: Power supply cable

Figure 3-3: Mouse USB cable

3. Connect the USB communication cable provided to a USB port on the Netbook and to the communication port located in the center of the back panel.

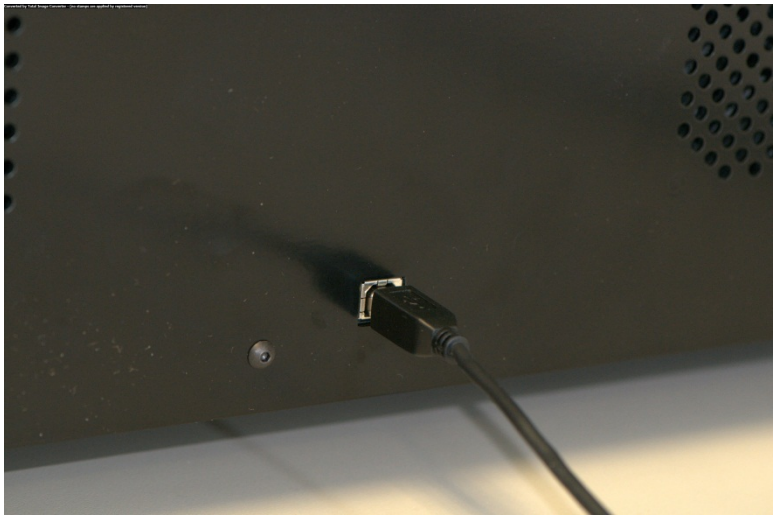


Figure 3-4: Communication port located in the center of the back panel

4. Press the ThermoBrite Elite power switch, located on the rear panel, next to the power cable, to the **On (I)** position.

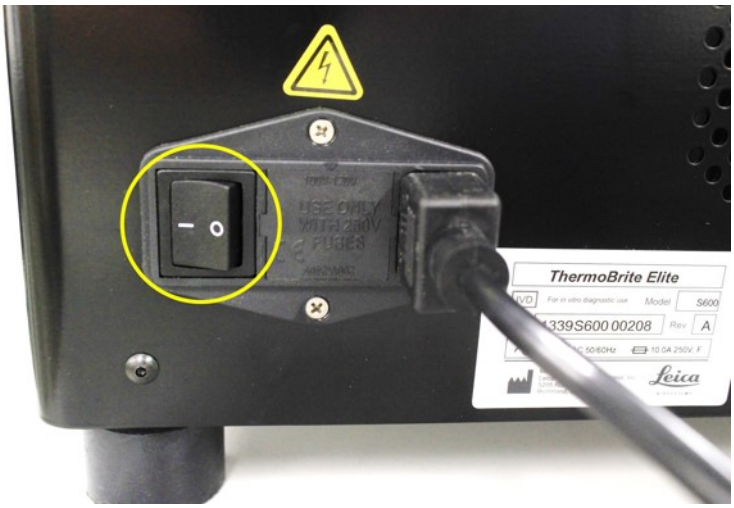


Figure 3-5: Main power switch

5. When the instrument successfully powers up, a two-beep ready signal sounds, and the **green** LED on the right side of the front panel illuminates.

6. If the two-beep ready signal does not sound, or the LED activity is not a continuous green light, see the Troubleshooting section.

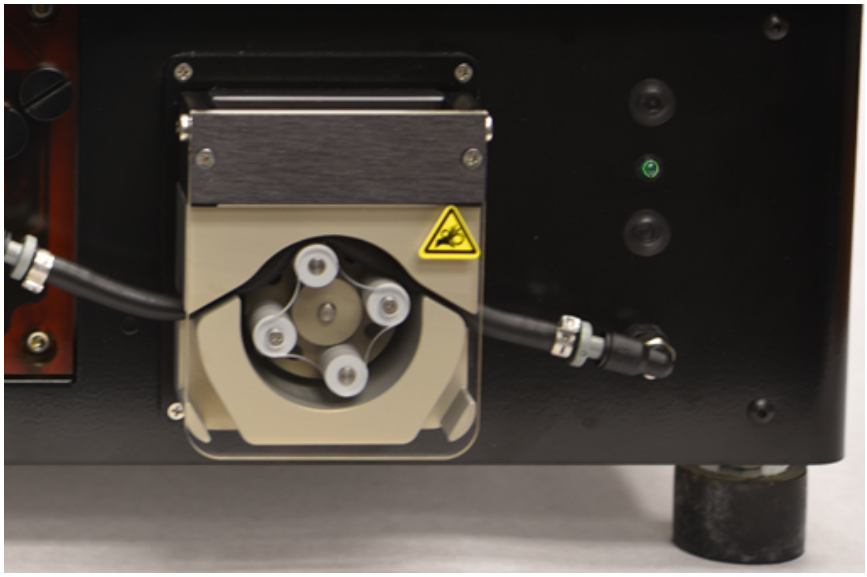


Figure 3-6: Green LED on the right side of the front panel

7. Press the power switch on the Netbook, see image below.

Figure 3-7: Netbook Power switch

8. Enter Windows Password: Thermobrite.

The ThermoBrite Elite System is shipped with a default password for ease of installation. Change this password in accordance with your organization's password policy as part of the installation. To change the default password, press Ctrl + Alt + Del, select **Change a password** and follow the prompts.

Make sure you record the password in a safe location for reference by a Service Engineer when on site.

9. On the desktop, double-click the ThermoBrite Elite software icon.
10. Read and Accept the 3.5 - End User License Agreement .

3.4.1 Fluid Management System

1. Position the Fluid Management System immediately to the left and with the base at the same level as the ThermoBrite Elite.

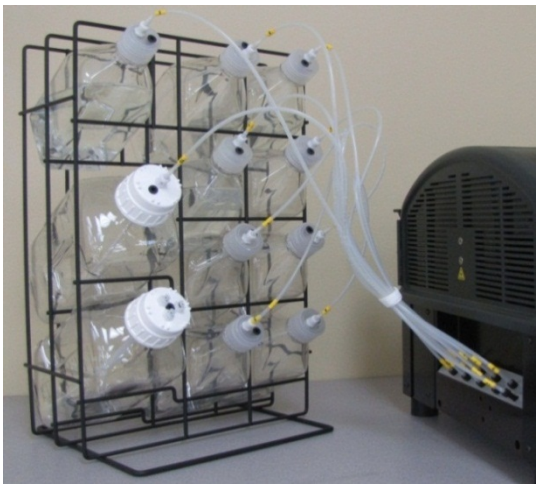


Figure 3-8: Fluid management system

Do NOT position the Fluid Management System above or below the level of the instrument as this could affect proper fluid flow.

2. Orient bottles such that the wire mesh filter is closest to the bottom-most edge for each respective bottle.

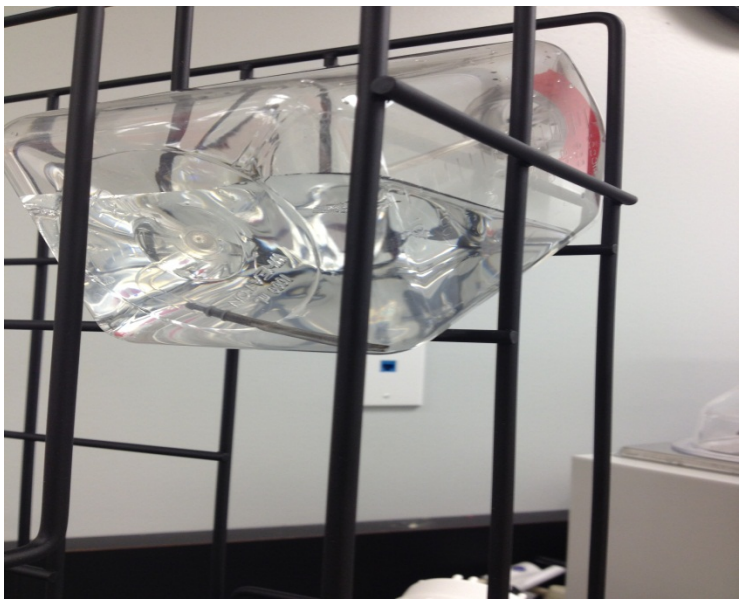


Figure 3-9: Bottle positioning

If the filter is not placed in the bottom-most edge of the bottle, flow errors might occur.

3. Carefully thread the black port connector into the appropriate port in the Reagent Manifold by turning clockwise until finger tight. Each tube is labeled with a number to match the port.

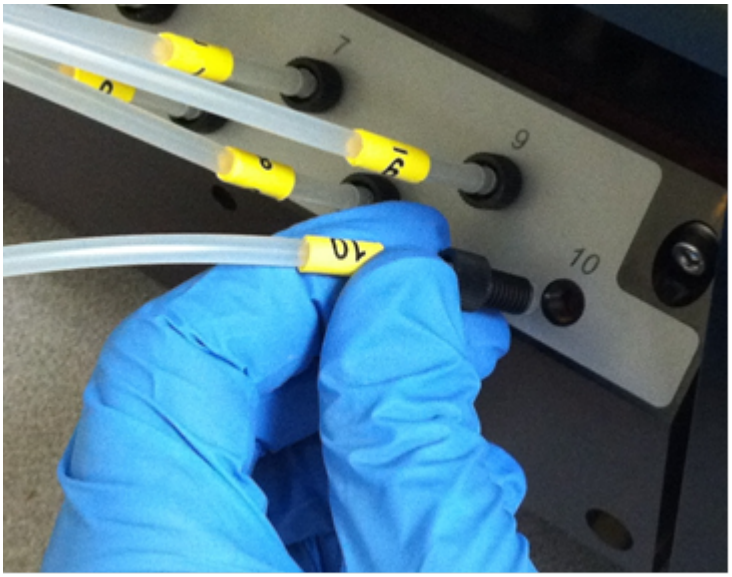


Figure 3-10: Reagent Manifold assembly

The connector must be fully engaged into the Reagent Manifold or leakage may occur.

If the connector does not screw in easily, then unscrew and re-align it. Do NOT force a misaligned connector as this may damage the thread and lead to leakage.

4. Insert the fitting on the cap of each Reagent Bottle and then twist to lock.

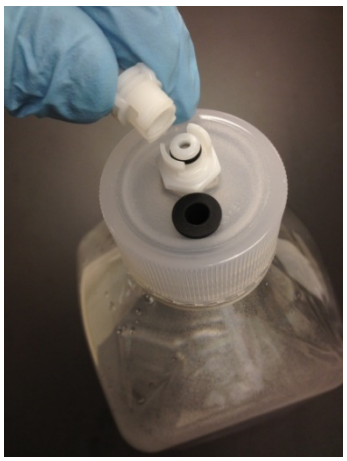


Figure 3-11: Reagent Bottle Cap Fitting

5. Screw the Waste Caps onto the Waste Bottles. Label each waste bottle A, B, or C to match the tubing port on the instrument.

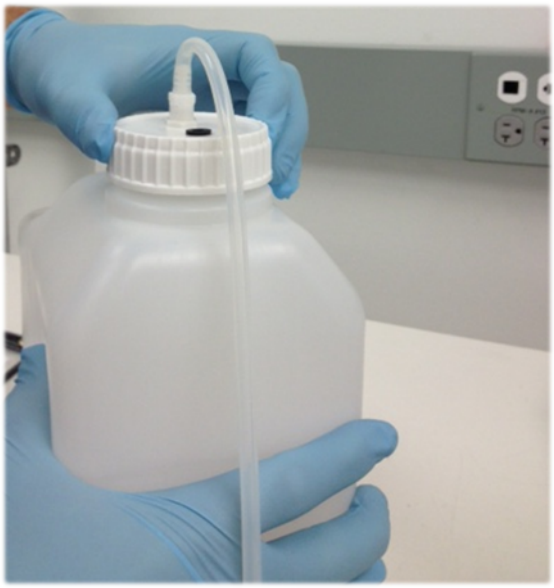


Figure 3-12: Screw Waste Caps onto Waste Bottles

6. Connect the end of the Waste Tube to the appropriate Waste Port.

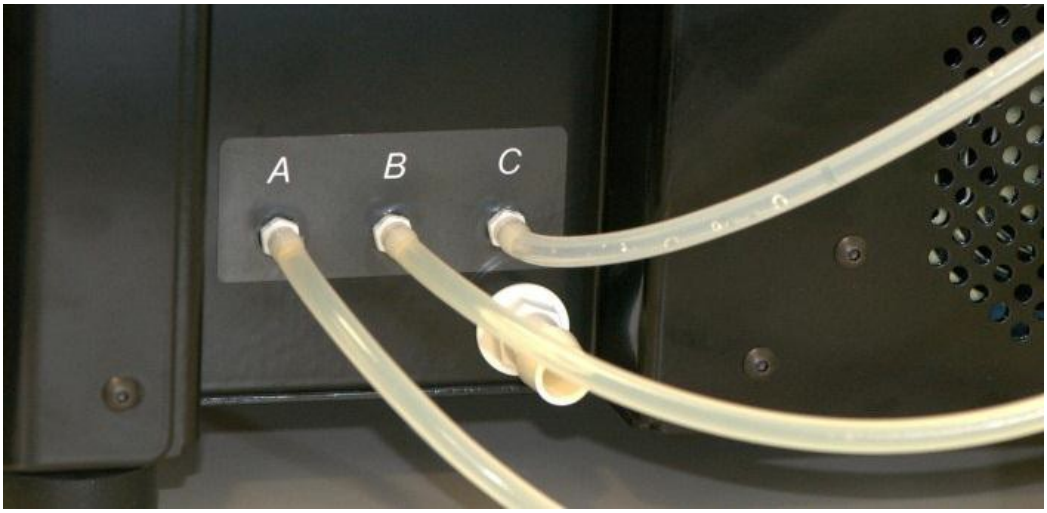


Figure 3-13: Connect Waste Tube to Waste Port

Waste Tubes are supplied in a 1.5m length. Tubing may be cut to desired length.

7. Position the Waste Bottles to the right of the instrument, leaving at least 5cm of space between the bottles and the instrument. The Waste Bottles can be placed at the same surface level as the unit, or below the benchtop.

Figure 3-14: Waste Bottle Positioning—Surface Level

Figure 3-15: Waste Bottle Positioning—Ground Level

8. Label each Waste Bottle with a description of its intended content that is compliant and necessary for proper disposal; consult Material Safety Data Sheets for labeling requirements.

Label the Waste Bottle that will receive the most toxic waste "C". Label the Waste Bottle that will receive the least toxic waste "A".

9. Connect the Emergency Waste Tube to the Emergency Waste Port.

Figure 3-16: Connect the Emergency Waste Tube to the Emergency Waste Port

10. Installation is complete.

3.5 End User License Agreement

When you start the Netbook for the first time, the End User License Agreement is displayed. Read this agreement, and then click **Accept**. The ThermoBrite Elite Software will be loaded automatically.

Read the entire End User License Agreement.

This End User License Agreement ("agreement") governs the use of certain computer programs contained in this Leica Biosystems ("Leica Biosystems") product, ThermoBrite Elite ("Leica Biosystems product"). Acceptance of this EULA for the Leica Biosystems product constitutes assent and acceptance of this agreement by you and the business entity on whose behalf the Leica Biosystems product is purchased (collectively "you" or "your") and signifies your agreement to be bound by the terms and conditions of this agreement. Leica Biosystems's permission for your use of this Leica Biosystems product is conditional upon your assent to the terms of this agreement to the exclusion of all other terms. If you do not agree with all of the terms and conditions of this agreement, you may not use the Leica Biosystems product, or the computer programs contained in the Leica Biosystems product.

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4. System Description

4.1 Theory of Operation

The ThermoBrite Elite System is a bench-top system for automating a variety of laboratory protocols, including FISH (Fluorescence In Situ Hybridization) for FFPE samples prepared on glass slides.

Reagent and Waste Bottles are connected to the system according to the user selected protocol.

Slides are loaded into a Slide Carrier prior to placement in the ThermoBrite Elite. Loading/unloading slides and application/removal of probe and cover slipping are the only manual steps.

According to the user selected protocol:

- Reagents are pumped into a sample chamber for deparaffinization, pretreatment, denaturation, hybridization, and post wash.
- Waste fluids are discarded into a Waste Bottle.

The ThermoBrite Elite can process up to 12 slides per run. The user can denature and hybridize samples on-board.

4.2 Components

The main components of the system include:

- ThermoBrite Elite Instrument
- Netbook with preinstalled software
- Fluid Management System and Waste Bottles

4.2.1 Front

Figure 4-1: ThermoBrite Elite Front View

4.2.2 Back

Figure 4-2: ThermoBrite Elite Back View

4.2.3 Fluidic System

4.2.3.1 Reagent Manifold

Ten (10) Reagent Ports, located on the left side of the system, allow input of specific reagents depending on the selected protocol.

Figure 4-3: Reagent Ports

4.2.3.2 Waste Manifold

Three user selectable Waste Ports, located on the right side of the system, are available for discarding waste fluids into separate Waste Bottles. The fourth port is the Emergency Waste Port. This serves as an overflow for any reagents that might accumulate in the base of the instrument.

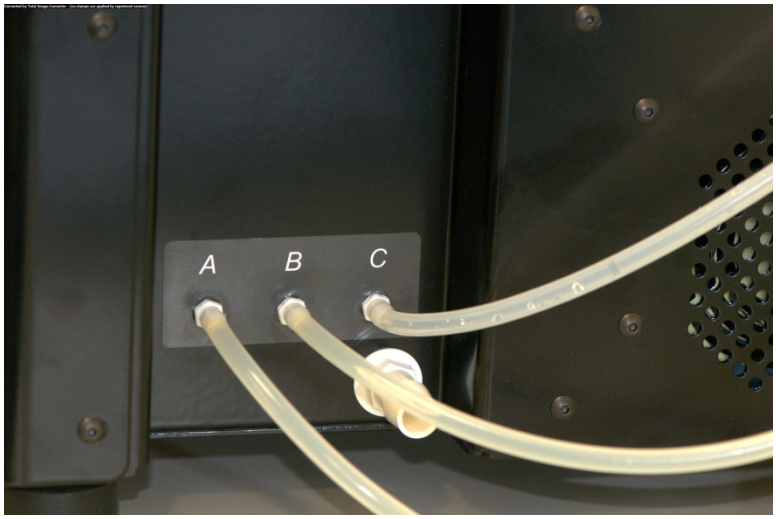

Figure 4-4: Waste ports located on the right side of the instrument

4.2.3.3 Pumps

Two peristaltic pumps are located on the front of the system, and are activated according to the selected protocol:

- **Reagent Pump**—The left peristaltic pump delivers reagents to the Sample Chamber(s) via the Module Manifold.
- **Waste Pump**—The right peristaltic pump discards waste fluids from the Sample Chamber(s) to the Waste Bottles (s) via the Module Manifold.

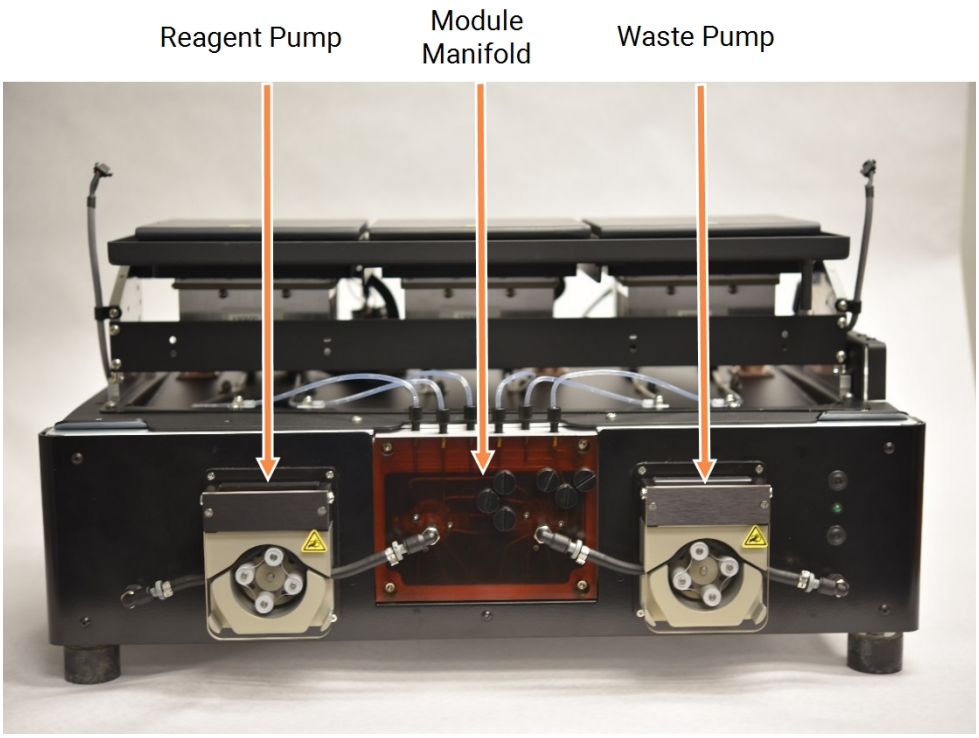

Figure 4-5: Peristaltic pumps located in front of the instrument

Module Manifold

The Module Manifold is located between the peristaltic pumps. Six tubes located on the top of the Module Manifold, are individually connected to each

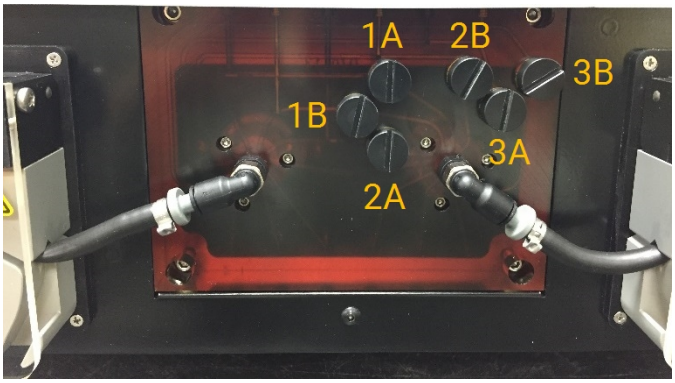

Figure 4-6: Module Manifold

4.2.4 Slide Carriers

Six Slide Carriers are provided with the ThermoBrite Elite System. Each Slide Carrier can hold up to two slides, allowing users to run up to 12 slides at one time. The Slide Carrier has a pivot that fits into grooves in the side of each Sample Chamber. The Slide Carriers allow convenient loading/unloading of slides into/from the instrument.

Figure 4-7: Sample Chambers

Sample chambers are surrounded by the Upper Drip Plate.

Figure 4-8: Upper Drip Plate

4.2.4.1 Sample Chambers

Three Thermal Modules are accessed by removing the instrument cover and opening the module lids. Each of the three Thermal Modules has two Sample Chambers, and has a temperature range from 25-95°C.

Figure 4-9: Sample Chambers

4.2.5 Electrical and Communication Connections

4.2.5.1 Power Port and Power Switch

Located on the back left-hand side of the system.

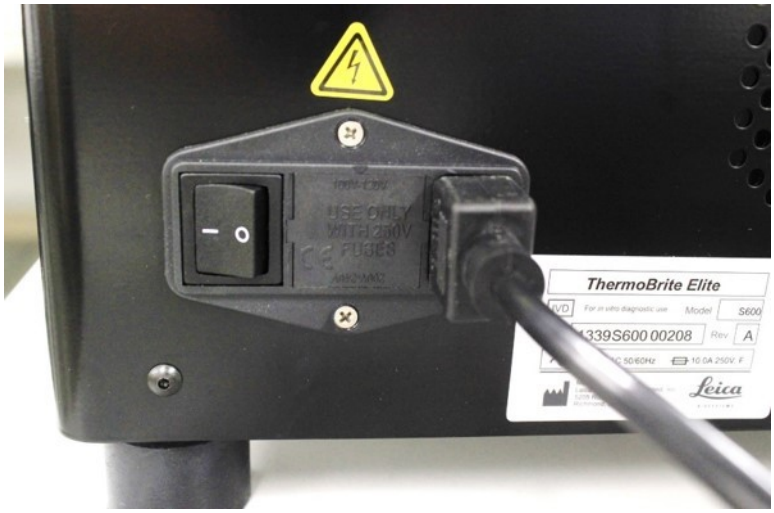

Figure 4-10: Power Switch - It includes the Fuse Box

The instrument's main power switch is used as the main disconnect device.

4.2.5.2 Netbook Communication Port

Located in the middle on the back of the system.

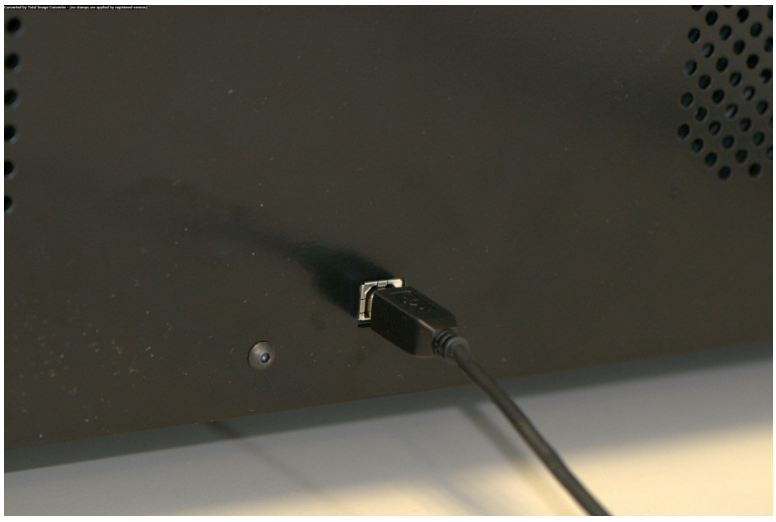

Figure 4-11: Netbook Communication Port

4.2.6 Software

User control of the system is achieved via the Leica Biosystems custom software running on a Netbook supplied with the instrument.

The intuitive easy-to-use software allows you to run standard protocols or configure and save custom protocols.

See 6 - Using the ThermoBrite Elite Software.

5. Preparing the System for Run

5.1 Reagents

5.1.1 Compatible Reagents

The following reagents may be used in the ThermoBrite Elite:

- Saline Sodium Citrate (SSC)
- Phosphate Buffered Saline (PBS)
- 2-(N-morpholino) Ethanesulfonic Acid (MES)
- Tris-HCL
- Citrate Based Buffers
- Proteases
- Sodium Thiocyanate
- 0.2N Hydrochloric Acid (and further dilutions)
- Ethanol
- Isopropanol
- Methanol
- 4% Formaldehyde
- 10% Neutral Buffered Formalin
- Hydrogen Peroxide
- Deionized/Distilled Water
- d-Limonene/Clearene

This list may not be all-inclusive.

Contact Technical Support before using reagents not included above.

Reagents other than those listed may damage some components of the instrument. Do NOT use xylene in the instrument.

A **Flush** step of ethanol/reagent grade alcohol/industrial methylated spirits is required after each fill of xylene substitute (d-Limonene).

A **Flush** step of distilled/deionized water is required after each fill of any low pH reagents.

5.1.2 Reagent Preparation and Connection

Before running a protocol on the instrument, perform the following steps:

1. Select the protocol to be run. The Protocol Run Dashboard displays:
    - The required reagent, including the volume
    - The input port for the reagent,
    - The output port for the waste fluids, including the volume.

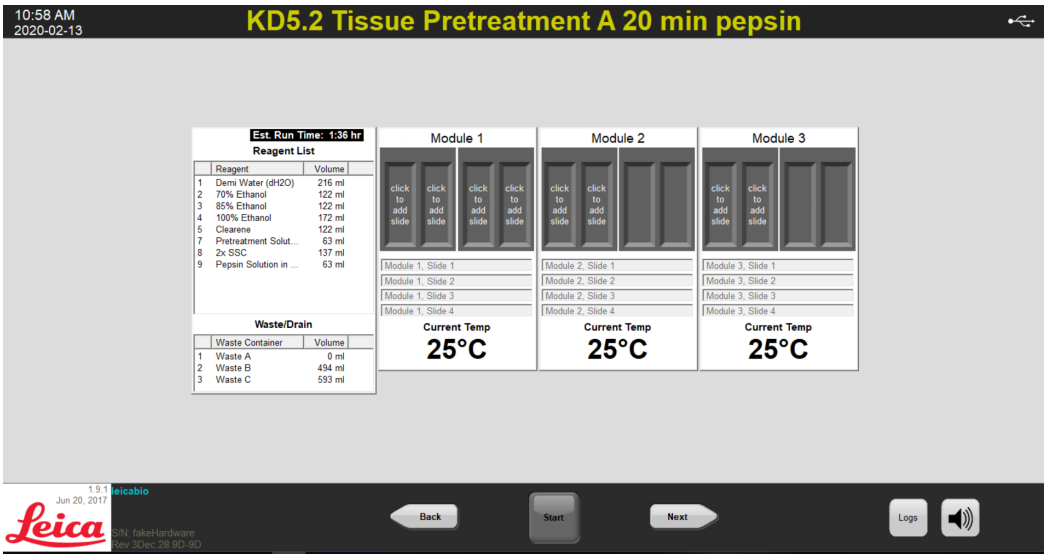

Figure 5-1: Dashboard—Select Protocol

2. Prepare the required reagents based on the Reagent List displayed on the screen. Reagent preparation instructions are provided in the ThermoBrite Elite Ancillaries document. Reagent Bottles should also be labeled with their contents.
3. Disconnect tubing from the appropriate Reagent Bottle caps by removing the tube fitting on the cap.

4. Carefully remove the reagent bottle cap with filter at an angle to avoid damaging the bottle filter.

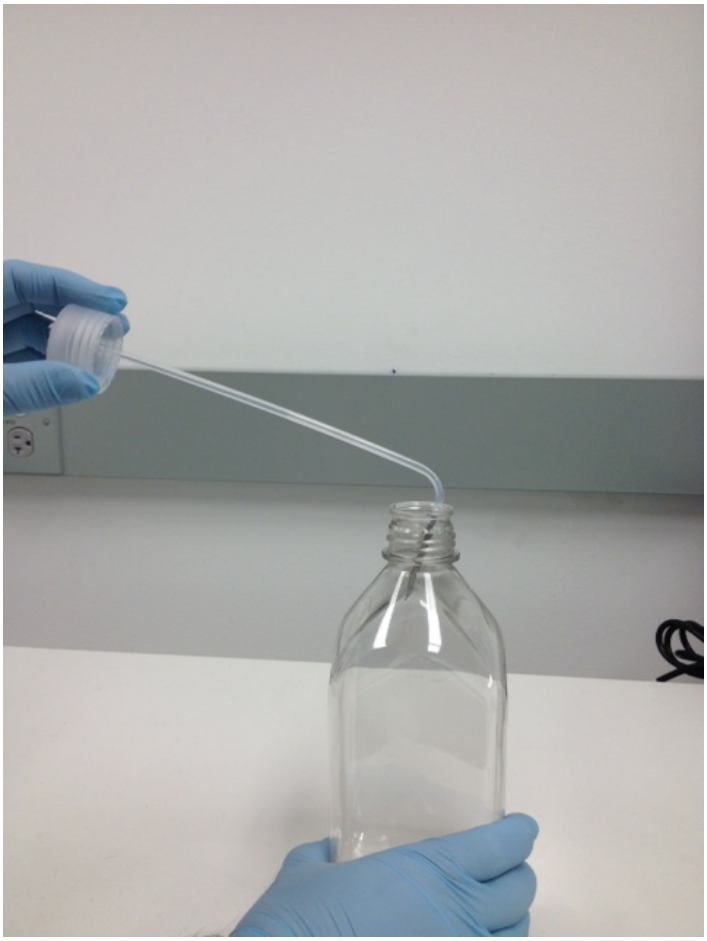

Figure 5-2: Removing Reagent Bottle Caps and Filters

5. Add reagents to Reagent Bottles in accordance with Reagent List displayed on the software screen.
6. Recap Reagent Bottles carefully; avoid damaging the bottle filter.
7. Insert then twist to lock the numbered Reagent Tube fitting to the cap of the appropriate Reagent Bottle.

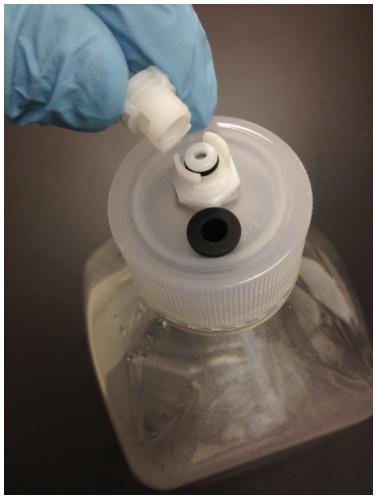

Figure 5-3: Lock Reagent Tube Fitting

8. Insert Reagent Bottles into the Fluid Management System Rack. Orient bottles such that the bottle filter is closest to the bottom-most edge for each respective bottle.

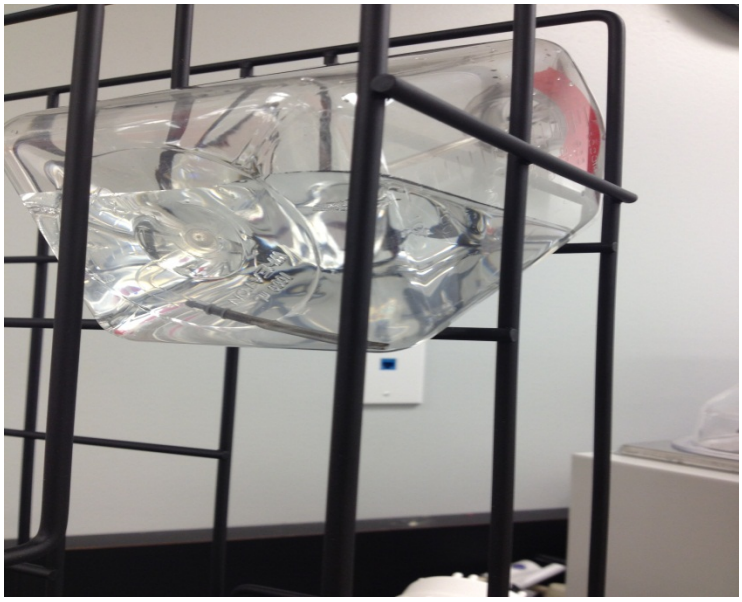

Figure 5-4: Reagent Bottle Positioning

If the bottle filter is not placed in the bottom-most edge of each reagent bottle, flow errors might occur.

If harmful vapors are expected or are a concern, it may be appropriate to operate the ThermoBrite Elite under an appropriate ventilation hood.

Waste Fluids

Some protocols may require the use of toxic, flammable, or dangerous reagents. The user is responsible for making sure that appropriate safety precautions are taken, and that reagents are disposed of, according to federal, state, and local regulations.

5.2 Slide Preparation

1. Transfer the specimen onto the slides according to the appropriate protocol to be run.
2. Place the prepared slides carefully into the Slide Carrier. Slides should be positioned specimen side face down during pretreatment and post wash. During denaturation and hybridization, slides should be inserted specimen side face up with a coverslip glued in place using Fixogum rubber cement (LK-071A or KCN-071A). The slide is maintained in position by spring loaded clips.
3. Hold the Slide Carrier by the pivot and insert it into an empty spot inside a Sample Chamber.

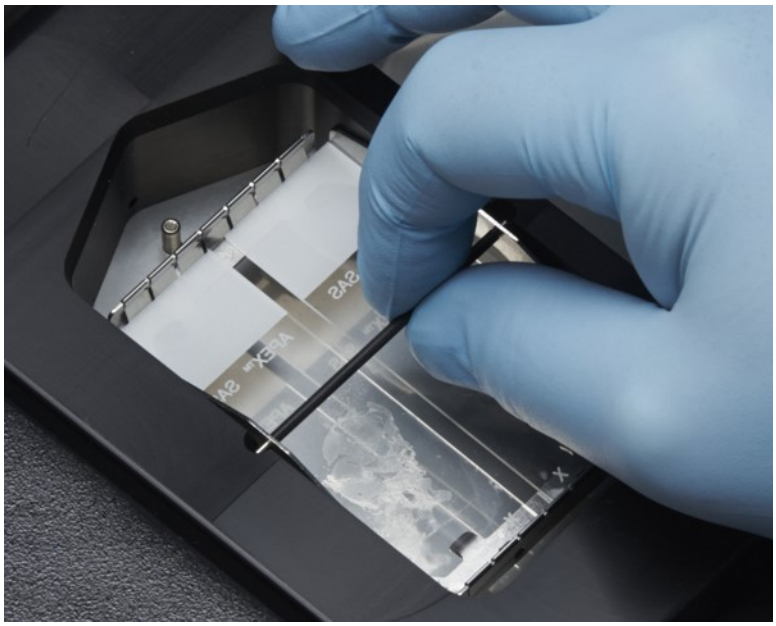

Figure 5-5: Insert Slide Carrier into Sample Chamber

5.3 System Ready

1. Make sure that the Netbook is connected to the ThermoBrite Elite instrument with a USB cable.
2. Make sure that the ThermoBrite Elite is powered up, and that the green LED is illuminated.
3. Make sure that the Netbook is powered up, and that the ThermoBrite Elite application is running.
4. Run the selected protocol. See 6 - Using the ThermoBrite Elite Software.

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6. Using the ThermoBrite Elite Software

6.1 Before operating the instrument

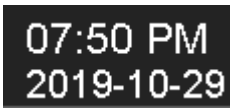
Before using the instrument to run a protocol, prepare the specimen slide and control slide(s) according to Good Laboratory Practices. See 5 - Preparing the System for Run.

6.2 The ThermoBrite Interface

All ThermoBrite Elite functions are performed on a series of screens, which are part of the software program installed on the provided Netbook. When you start ThermoBrite Elite, the Start screen is displayed.

Figure 6-1: Start screen

At the top of the screen the following information is displayed (from left to right):



Current date and time

System status or selected protocol

Connectivity status between the instrument and the Netbook

The Start screen has six functional buttons:

Run	Click to run a protected protocol.
Run/Create/Edit	Click to run, create, or edit a protocol before protecting it.
Line Wash	Click to begin a Line Wash.
Help	Click to access help or the User Manual.
Logs	Click to access logs for a particular day or run.
Mute icon	Click to silence the alarm.

6.3 Running a Protocol

6.3.1 Before running a protocol

Before running a protocol, check the following:

- Reagent bottle levels—ensure each bottle contains enough reagent for the protocol. You can see the required reagent volume on the Protocol Dashboard. If you need to refill a Reagent Bottle, see 3.4.1 - Fluid Management System and the ThermoBrite® Elite ancillaries document.
- **Reagent bottle filter position**—Make sure the bottle filter is closest to the bottom-most edge for each respective bottle.
- **Waste bottle volume**—ensure waste bottles have enough space to hold the waste from the protocol run. You can see the waste volume that will be created by the run on the Confirm Reagent and Waste Setup. If any of them are full, empty the Waste Bottles. See 7.2.1 - Discarding Liquid Waste.
- **Peristaltic pump condition**—check that the tubes are not crimped. If they are, first try massaging the tubes to get them back into shape. If that does not work, replace the tubes. See 7.6.2 - Replace the Peristaltic Pump Tubes.

Do NOT move the instrument while a run is in progress.

6.3.2 Select a Protocol to Run

1. On the Start screen click either:
   - **Run**– to select a protected protocol. You cannot modify a protected protocol.
   - **Run/Create/Edit**–to select a protected or unprotected protocol. Using this option, you can edit unprotected protocols before running them. You can also use this option to create a new protocol. For more information, see 6.4 - Creating a New Protocol.

Figure 6-2: Start screen

The system displays the protocols available for selection. If you selected **Run**, only protected protocols are displayed. If you selected **Run/Create Edit**, both protected and unprotected protocols are displayed. The protected protocols are bold and can be copied but not edited.

2. In the **Available Protocols** field, select a protocol name.

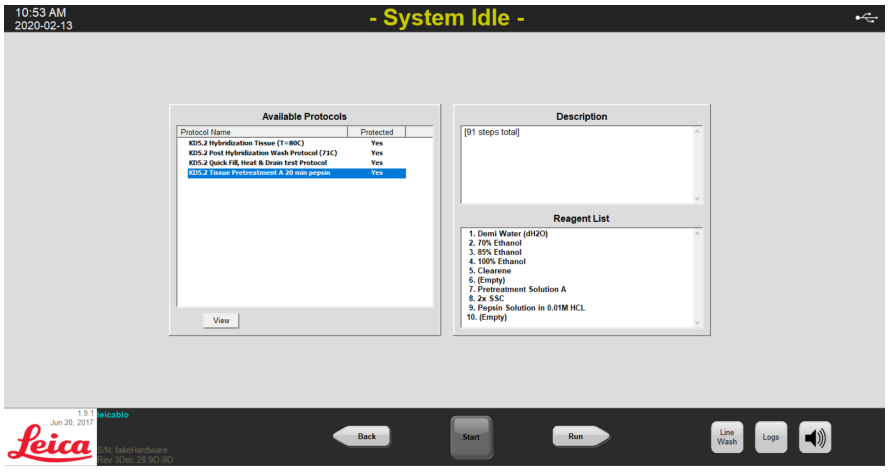


Figure 6-3: Select Protocol

The system displays the protocol's description and the list of reagents necessary to run the protocol.

3. Click **Run**. The Protocol Dashboard is displayed.

6.3.3 Add Slides to Module

The Protocol Dashboard is used to assign specimen slides to a Sample Chamber in one of three Thermal Modules.

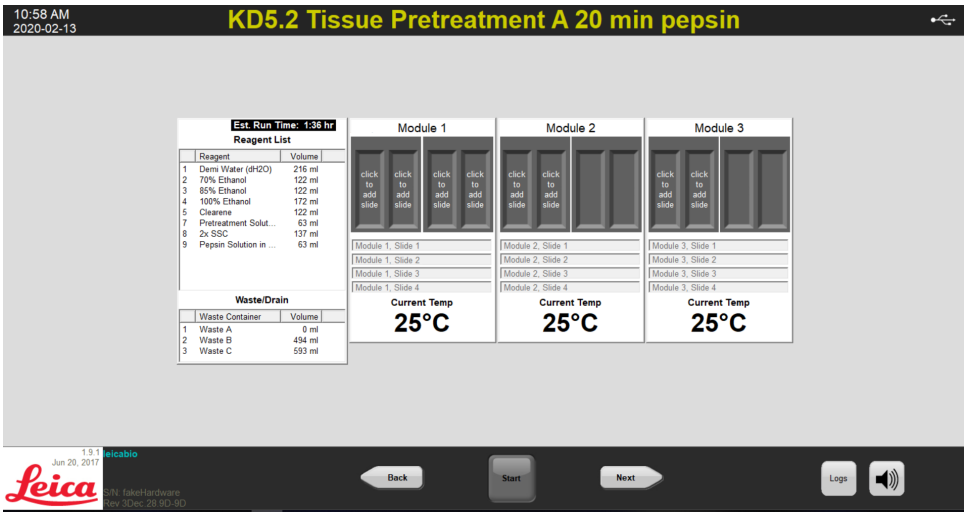


Figure 6-4: Protocol Dashboard—Empty Sample Chamber

There are three Thermal Modules; each contains two Sample Chambers, A & B. Each chamber can hold two slides.

A slide must be assigned to at least one of the Thermal Modules by clicking inside the first slide position. The left chamber of each module must be selected first.

1. On the Protocol Dashboard, click inside the Module slide position corresponding to the location of your slides. The gray area changes to look like a slide.

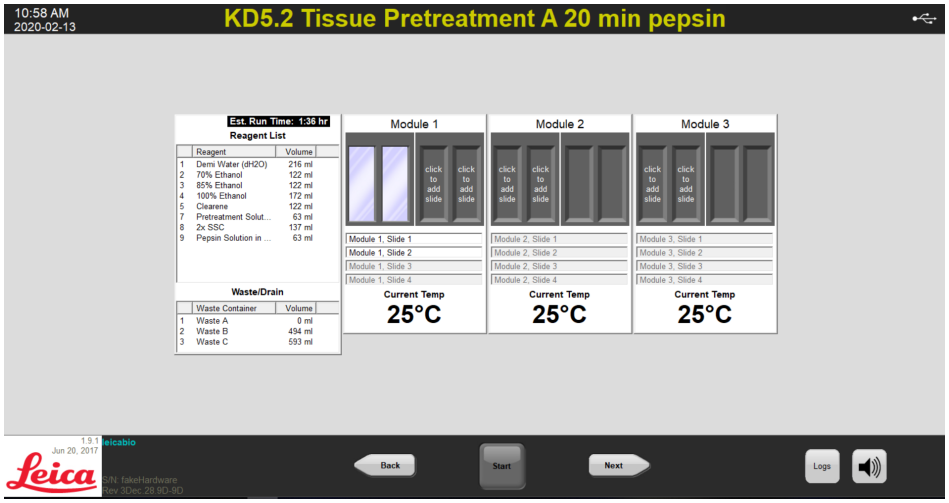


Figure 6-5: Protocol Dashboard—Slide in Sample Chamber

The area located below the slide diagram provides information about the slides that have been selected.

2. Select a slide, and then enter any data concerning the patient: i.e. Name, ID number. You can also overwrite the Module and slide number or add specific data next to the Module/slide numbers (see image below).

   Your data can include letters, numbers, or symbols up to 80 characters. However, only the first portion will be displayed in the field.

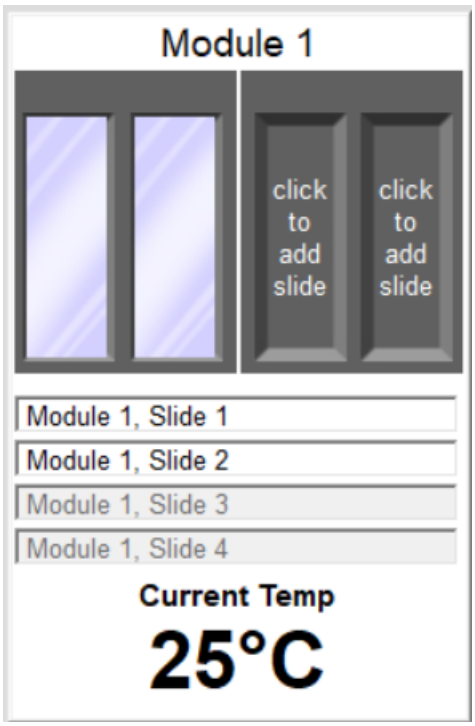


Figure 6-6: Protocol Dashboard—Selected Slide

3. When all slides you want have been added, click **Next** to display and verify the setup of the Reagent and Waste Bottles.
4. Check that all Reagent and Waste Bottles are in the position specified on the screen. If they are not, physically move the bottles as you cannot change the bottle position in the protocol.
5. Click the check box "I have confirmed that the reagent and waste setup matches the configuration above".

You cannot click the Next button until this check box is selected.

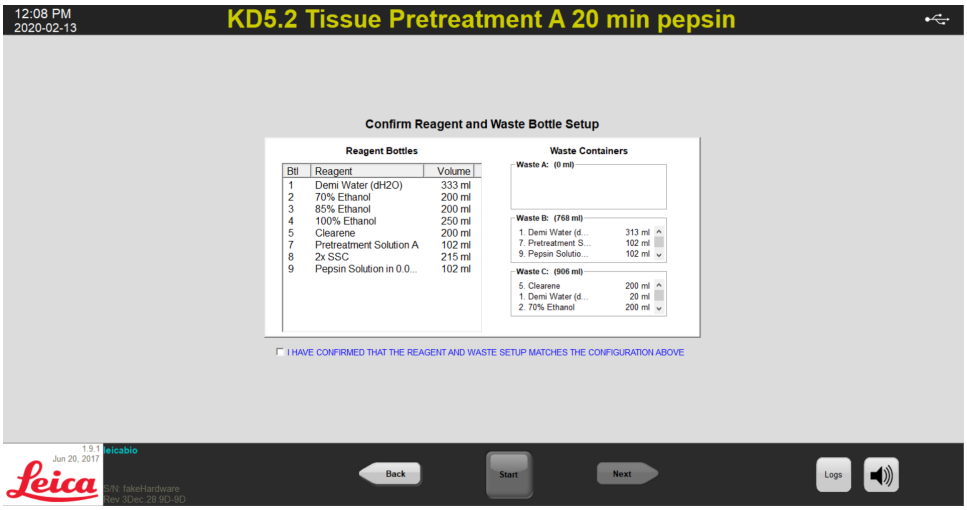


Figure 6-7: Confirm Reagent and Waste Setup

6. Click **Next**. The Protocol Dashboard is displayed.

6.3.4 Start the Protocol

1. If you have not already done so, load the slides in the corresponding Module slide position(s).

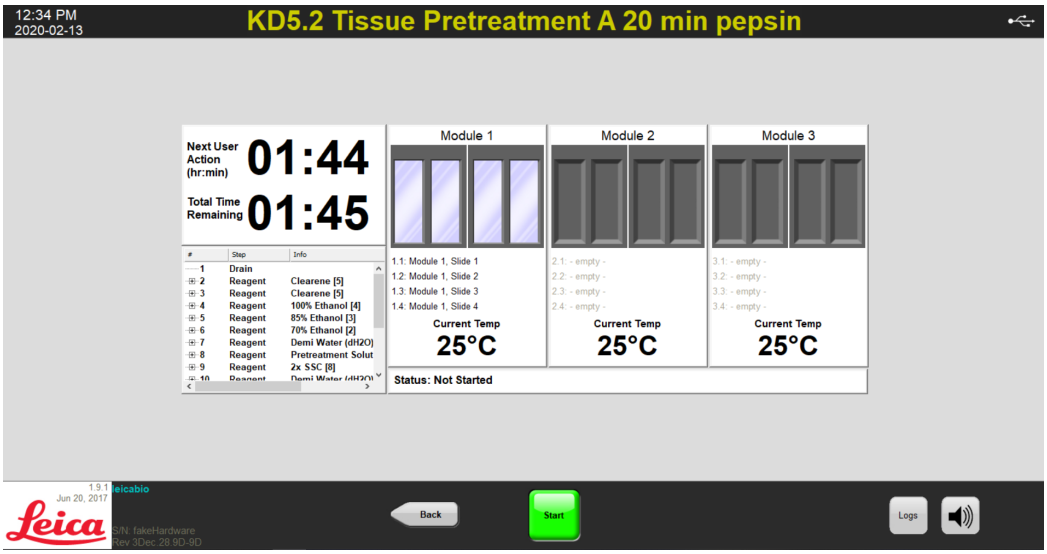


Figure 6-8: Protocol Dashboard –Start

2. On the Protocol Dashboard, click **Start**.
3. Type your initials and if required, any notes.
4. Click **Start Protocol** to begin running the protocol.

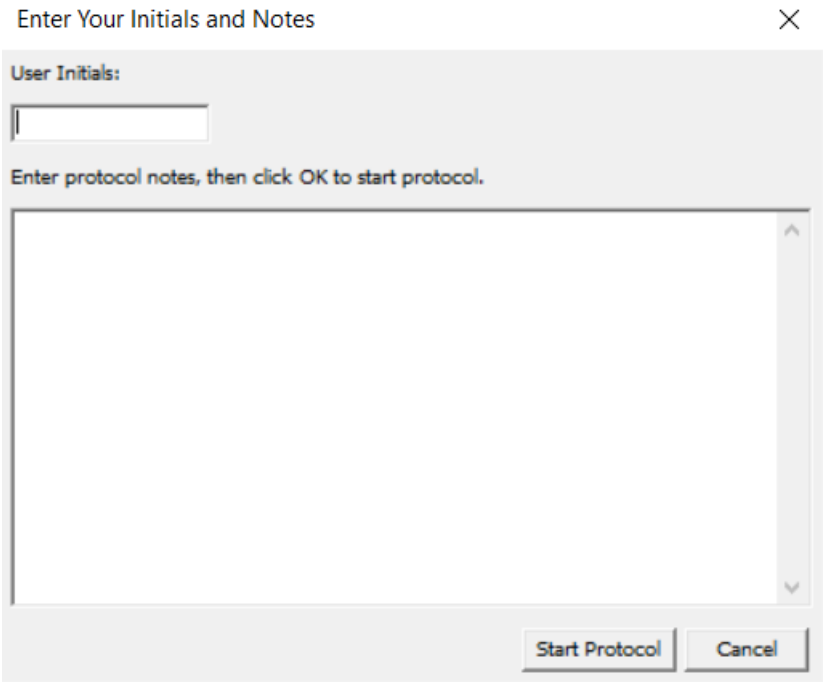


Figure 6-9: Protocol Dashboard–User Initials and Notes

The Protocol Dashboard is redisplayed showing the status of the protocol run.

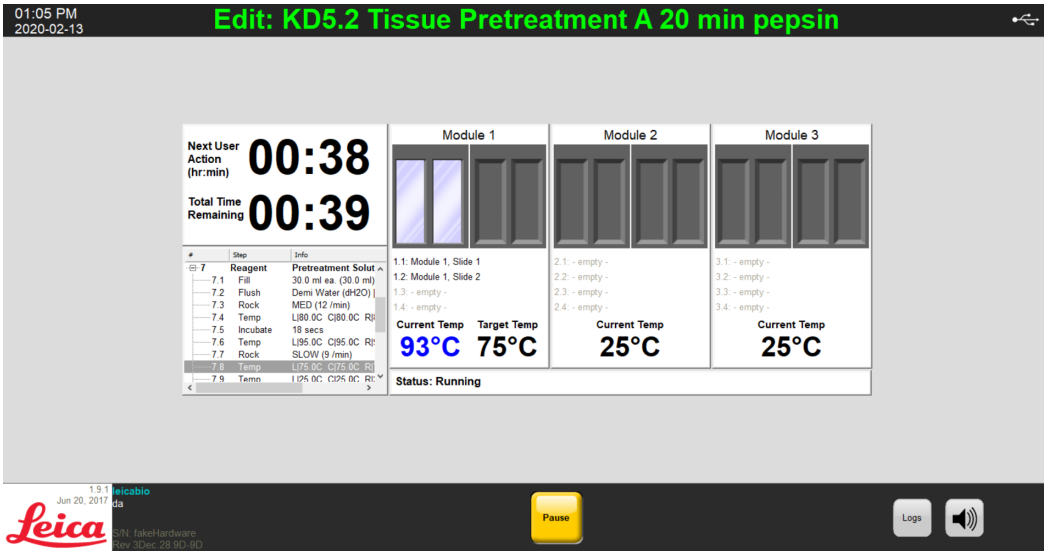


Figure 6-10: Protocol Dashboard—Protocol Run

5. If a protocol contains a **Pause** step, click **Resume** to continue.

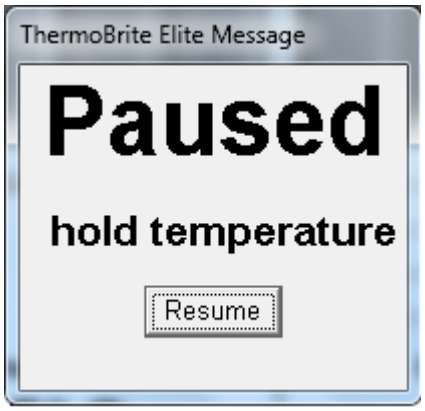


Figure 6-11: Pause Protocol Message

6.3.5 Monitor the Protocol Run Status

6.3.5.1 Slide Position

When you run a protocol, the status of the run, fill, and waste activity in each Module is displayed in the footer section of the screen, below the temperature indicators.

For example, the image below shows: Module 1 is **Running**, and Module 2 is **Draining** to Waste Bottle (C).

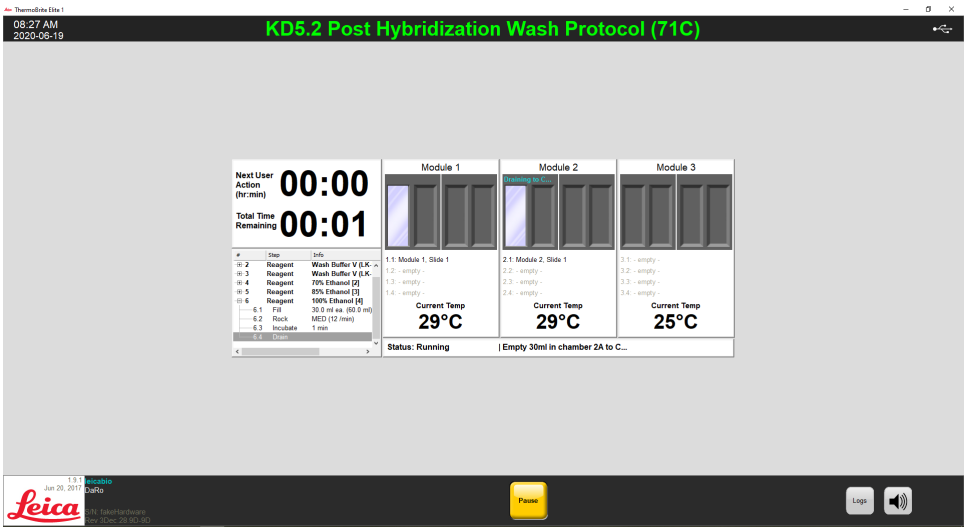


Figure 6-12: Protocol Dashboard –Run Protocol Status

6.3.5.2 Current Module Temperature

Current temperatures displayed in **red** indicate that the Module is heating.

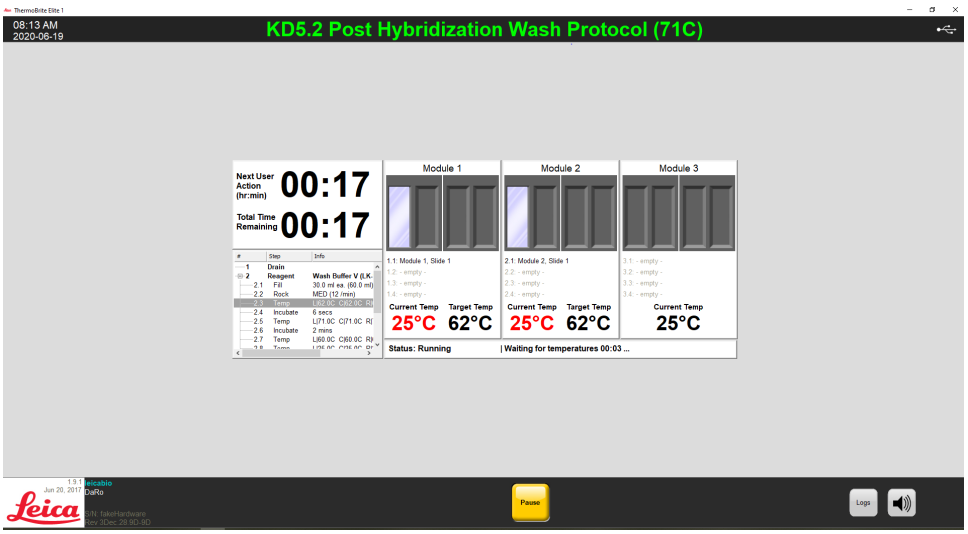


Figure 6-13: Protocol Dashboard—Temperature Status (Heating)

Current temperatures displayed in green indicate that the Module has reached its target temperature.

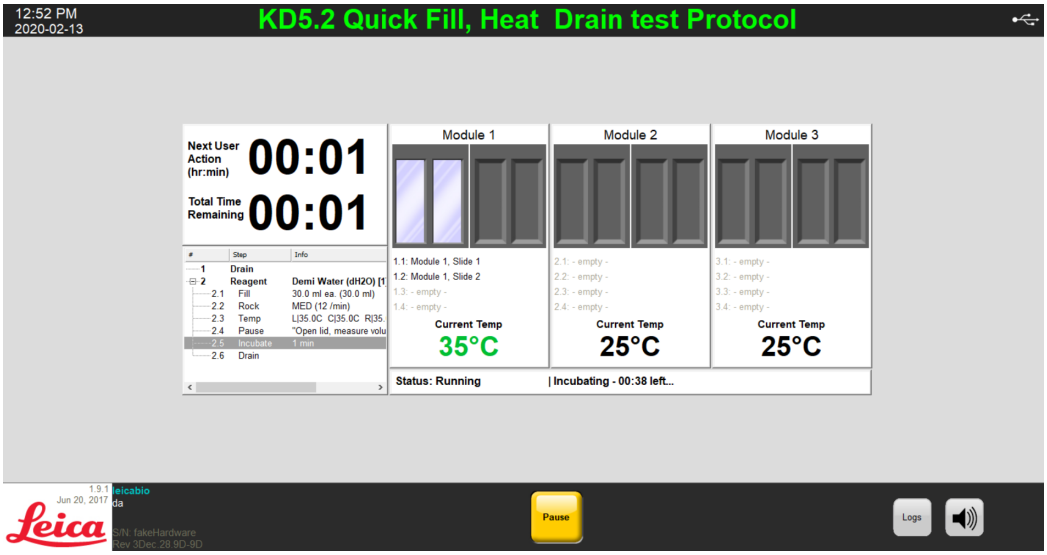


Figure 6-14: Protocol Dashboard—Temperature Status (Target Temperature)

Current temperatures displayed in blue indicate that the Module is cooling.

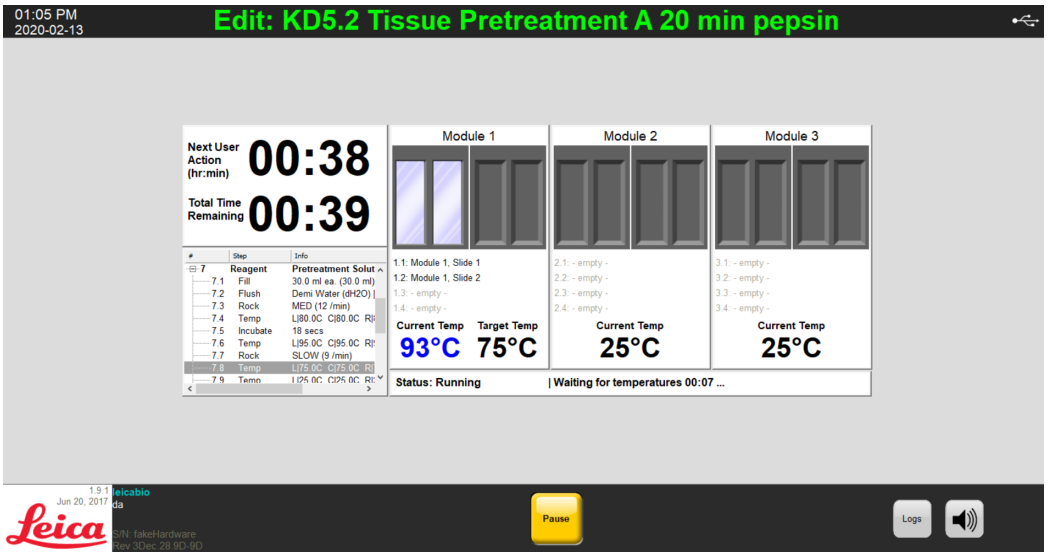


Figure 6-15: Protocol Dashboard—Temperature Status (Cooling)

6.3.6 Review the Protocol Completion Summary

When a protocol run is completed, the **Protocol Completion Summary** screen is displayed. If required, you can add comments about the Run to the Notes field.

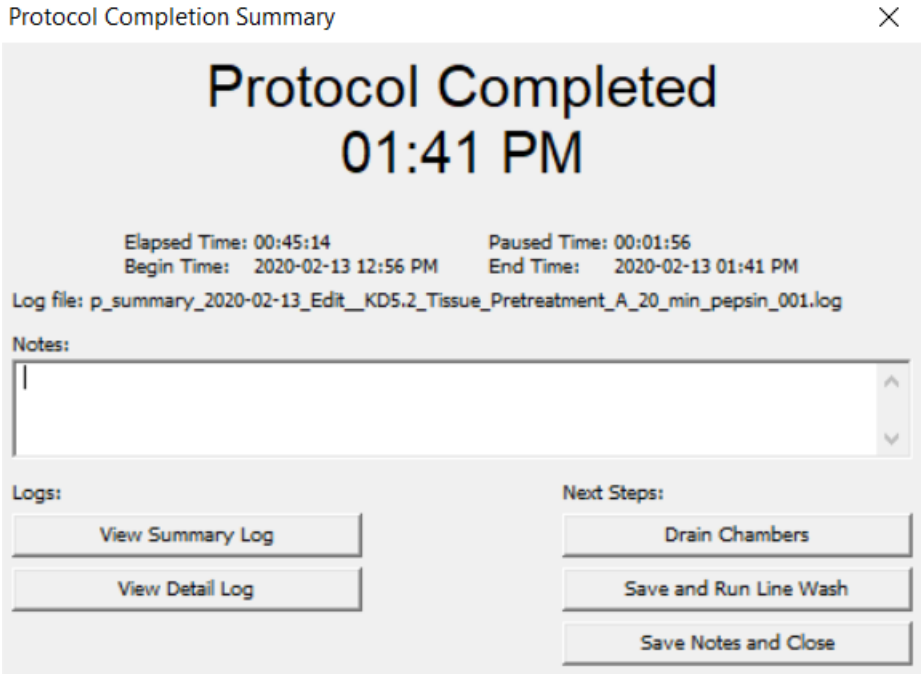


Figure 6-16: Protocol Completion Summary

This summary includes five (5) options:

- **View Summary Log** – See 6.3.6.1 - View Summary Log
- **View Detail Log** – See 6.3.6.2 - View Detail Log
- **Drain Chambers** – See 6.3.6.3 - Drain Chambers
- **Save and Run Line Wash** – See 6.3.6.4 - Save and Run Line Wash
- **Save Notes and Close** – See 6.3.6.5 - Save Notes and Close

6.3.6.1 View Summary Log

Click **View Summary Log** and select a specific summary log from the list. The log file is opened in Notepad. A summary option is also available from the **Protocol Completed** screen when a protocol finishes running.

Logs are named with the following format: log type, date, protocol name, protocol number of the day.

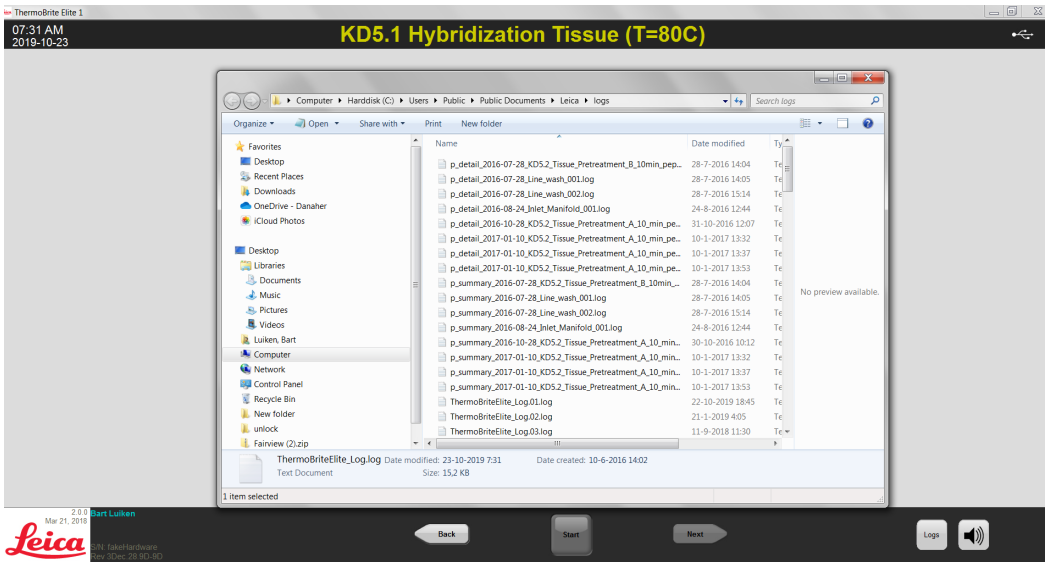


Figure 6-17: Log files

6.3.6.2 View Detail Log

Click **View Detail Log** and select a specific detail log from the list. The log file is opened in Notepad. A detail option is also available from the **Protocol Completed** screen when a protocol finishes running.

Logs are named with the following format: log type, date, protocol name, protocol number of the day.

6.3.6.3 Drain Chambers

This option is used to drain any remaining liquid from the Module's Sample Chambers. If a protocol is aborted, the Sample Chambers must be drained.

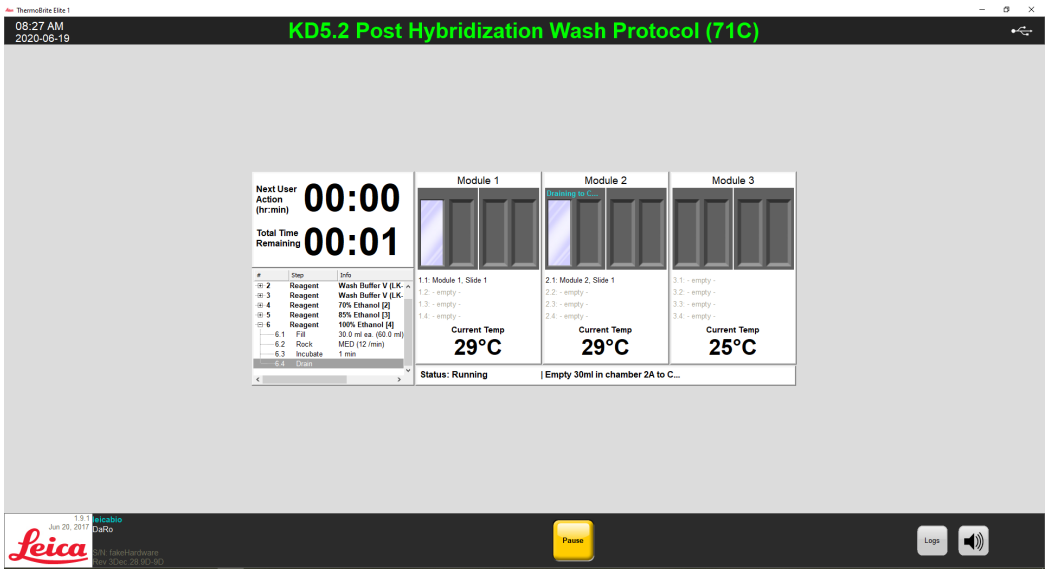


Figure 6-18: Protocol Dashboard—Drain Chambers

6.3.6.4 Save and Run Line Wash

This option is used to wash the Reagent Lines. See 7 - Maintenance.

6.3.6.5 Save Notes and Close

Closes with an option of selecting Logs from the Start screen to review the summary or details of this run at a later time. See 6.3.6.1 - View Summary Log or 6.3.6.2 - View Detail Log.

6.3.7 After running a protocol

After you have run a protocol, perform the following cleanup tasks:

- Clean and dry the chambers—see 7.4.1.1 - Clean Sample Chambers
- Clean Upper Drip plate—see 7.4.1.2 - Clean the Upper Drip Plate
- Clean the pepsin bottle—see 7.4.1.3 - Clean the Pepsin Bottle
- Clean the pepsin line—see 7.4.1.4 - Clean the Pepsin Line
- Raise the Peristaltic Pump Cover to release the pressure on the Peristaltic Pump Tubing.

If you do not leave the Peristaltic Pump Cover open while the instrument is not in use, the tubing could become damaged, which will affect reagent flow on future runs.

6.4 Creating a New Protocol

Creating a new protocol requires several steps:

- Add a name and description
- Add the protocol steps
- Assign the Reagent and Waste Bottles.

This is an example of setting up a reagent and is not a recommended setup for Clearene.

1. On the **Start** screen, click **Run/Create/Edit**.

Figure 6-19: Run/Create/Edit

2. Under the **Available Protocols** field, click **New**.

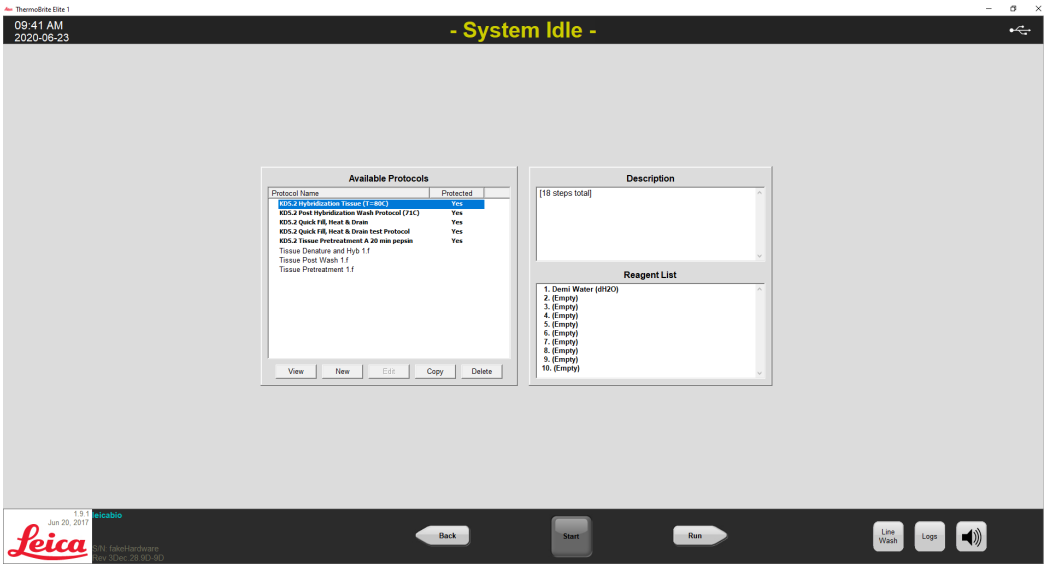


Figure 6-20: Add New Protocol

3. In the **Protocol Name** field, enter a meaningful name for the new protocol (up to 80 characters). The name must be unique. If it is not, an error message is displayed when you try to save the protocol (see 6.4.3.2 - Warning Invalid Protocol Name).

Move the cursor to the next field to continue. The Enter and Tab keys are not functional for this screen.

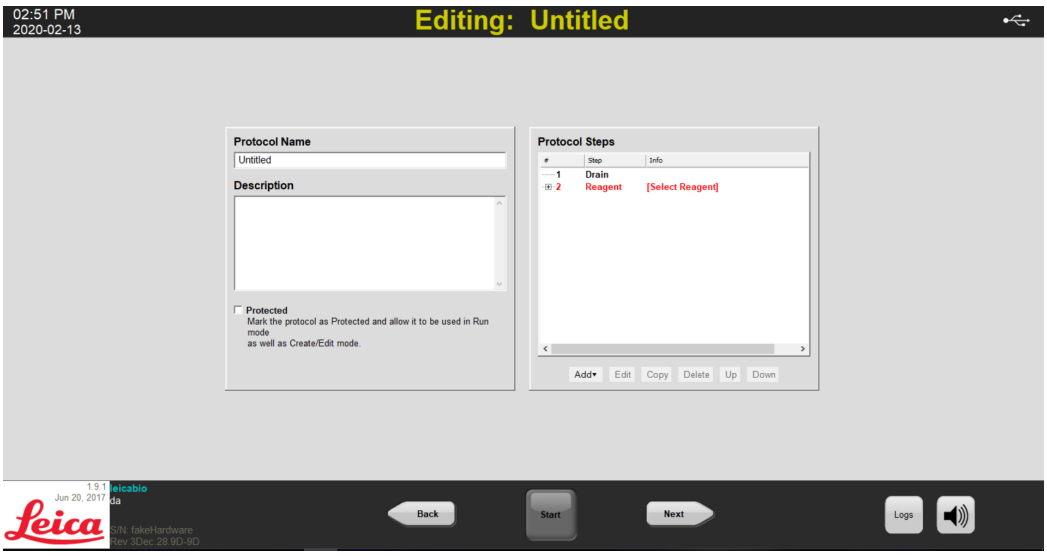


Figure 6-21: Edit New Protocol

4. Enter a description for the new protocol.

5. If you do not want the protocol to be editable in the future, click the **Protected** check box to protect the protocol.

If you select the **Protected** check box, the protocol cannot be edited after you click **Next**.

6.4.1 Add Protocol Steps

When you create a new protocol, a Drain and an empty Reagent step are automatically included. You can, however, add any number of the following steps:

- Reagent
- Prime
- Pause
- Drain

6.4.1.1 Reagent Step

1. Keep the first step as **Drain** to ensure that no reagent is present inside the chambers before starting a protocol.

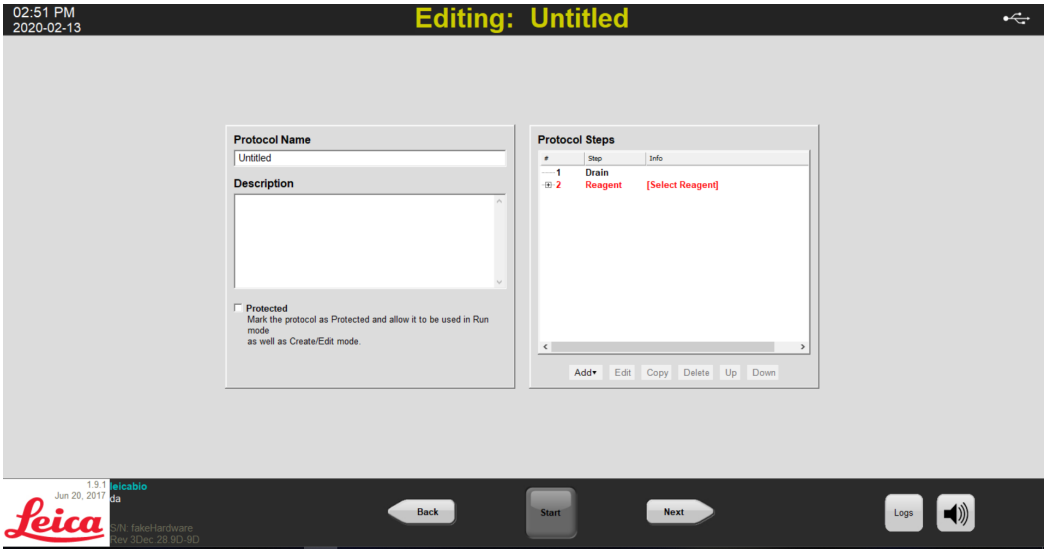


Figure 6-22: Figure 54: Add Protocol Steps

2. In the **Protocol Steps** field, double-click on **Reagent**.

New steps are added immediately after the currently highlighted step.

If you are adding a second or subsequent reagent, click **Add** below the **Protocol Steps** field and then select **Reagent.**

The Protocol Reagent Step window is displayed. By default, the Reagent steps are pre-populated with the following options:

- Fill (Required step)
- Rock
- Temp
- Incubate
- Drain

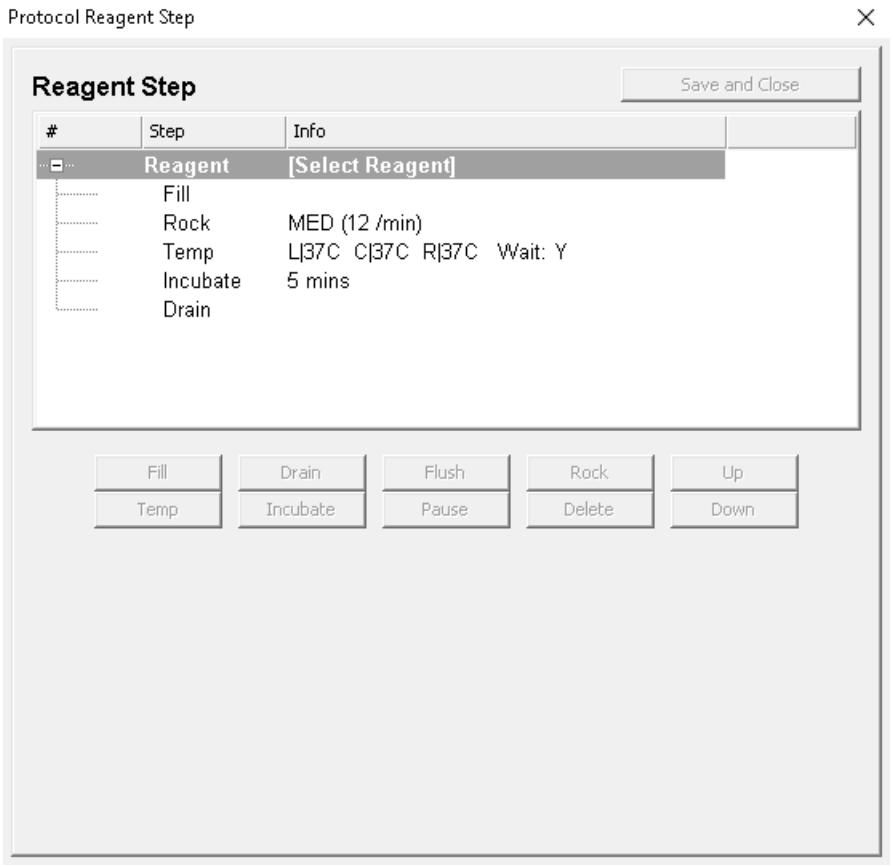


Figure 6-23: Protocol Reagent Step screen

3. Double-click on **Reagent** to select a specific Reagent and assign a Bottle number from the respective dropdown lists. If the reagent is not in the list, manually enter the name of the reagent.

Make sure the assigned bottle number matches the current bottle setup.

Selecting the option "Auto" automatically assigns the next available bottle number, which might not correspond with the appropriate reagent.

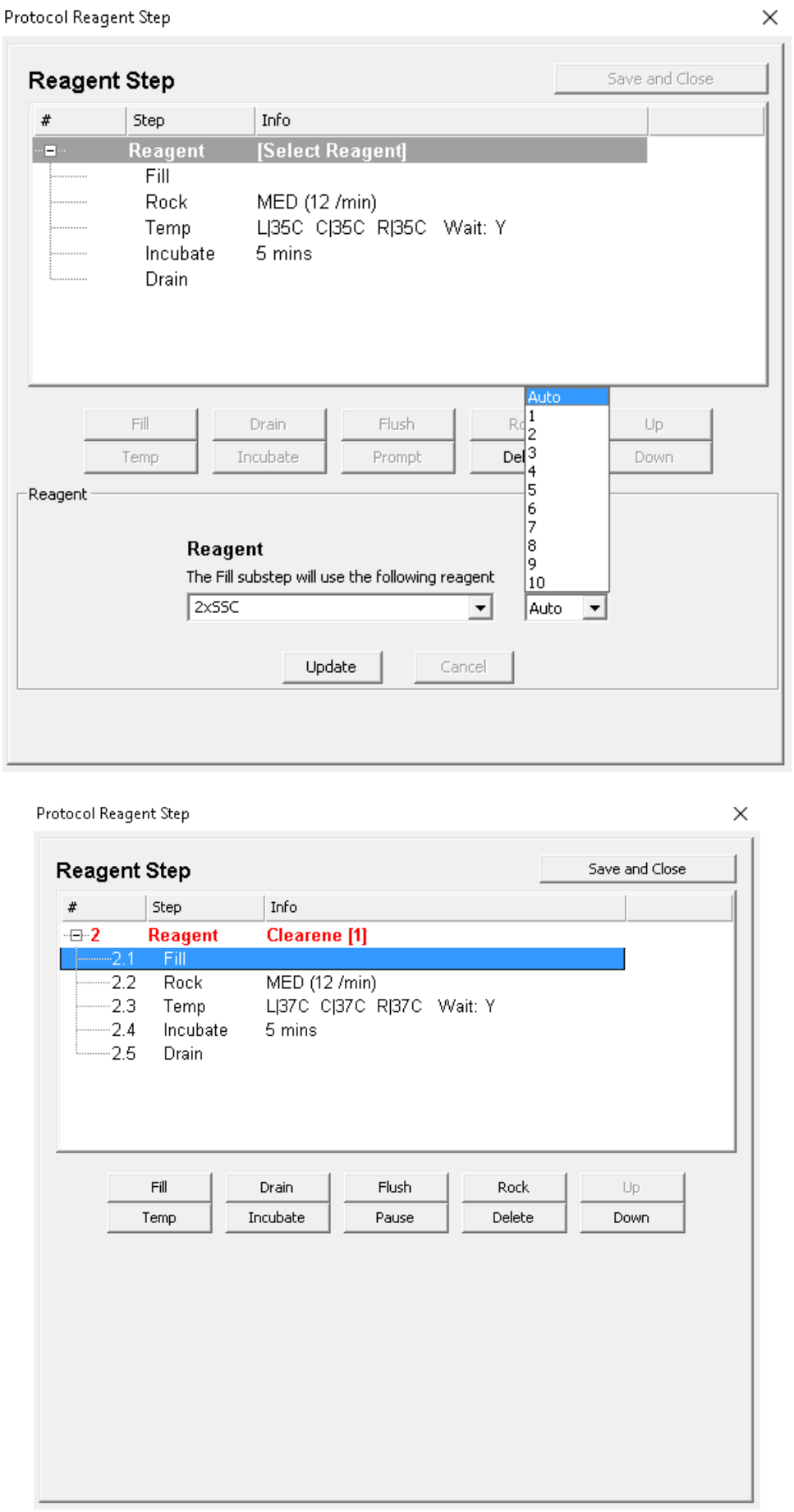


Figure 6-24: Protocol Reagent Step—Assign Bottle

4. Click **Update** to add the selected reagent and bottle. The Reagent Step screen is displayed with the bottle number displayed in brackets next to the reagent's name. For example, **Clearene [1]**.

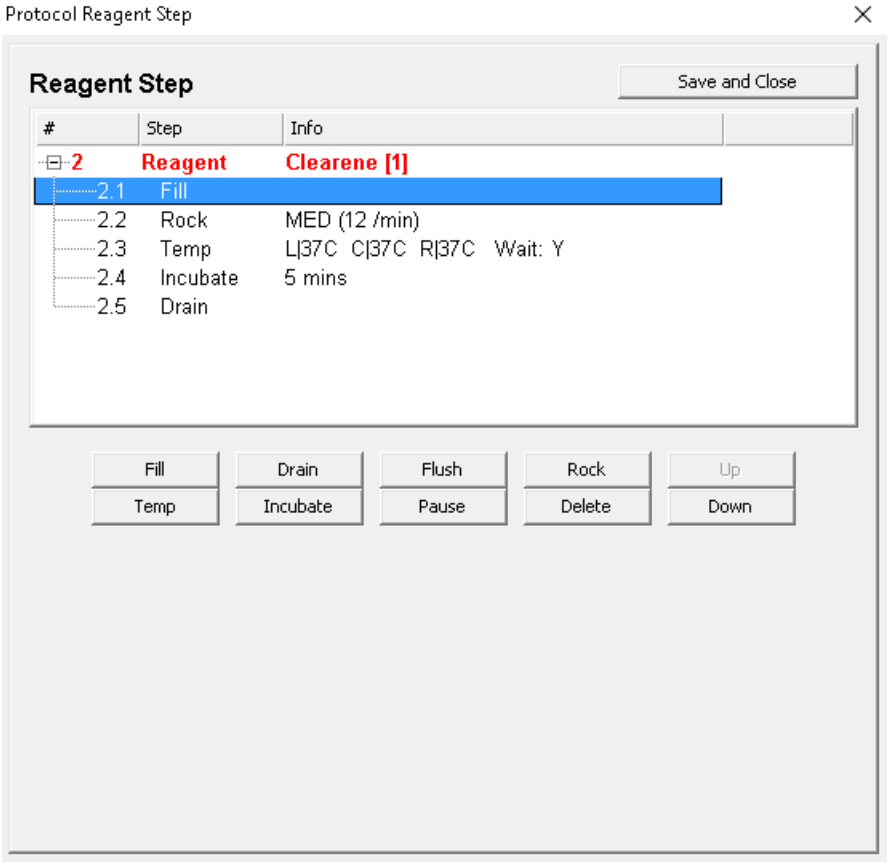


Figure 6-25: Protocol Reagent Step—Update

Reagent Fill

This option is used to define the reagent volume distributed inside the module chamber. The default is 100%, which corresponds to 30mL.

The **Fill** step is required.

1. Double-click **Fill.** If necessary, adjust the **Dispense** volume to a percentage between 25 and 200. In general, 100% fill volume is recommended during pretreatment and post wash and a 50% fill volume is recommended during denaturation and hybridization.

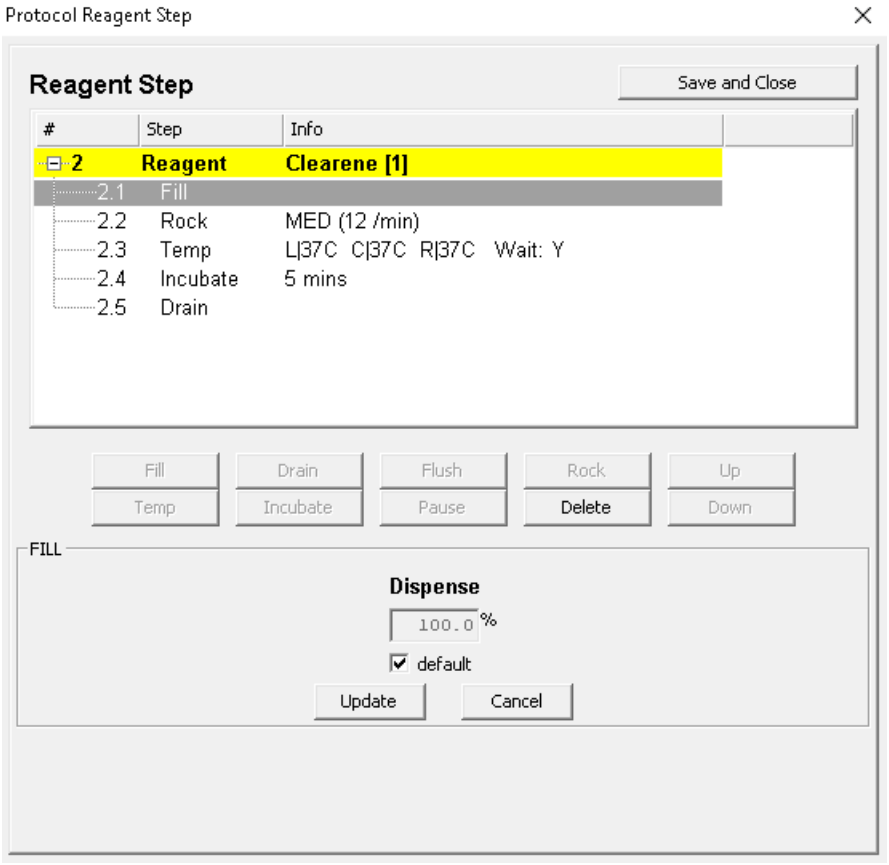


Figure 6-26: Protocol Reagent Step—Update

2. Click **Update** to validate the entry. The Reagent Step screen is displayed.

Reagent Rock

This option is used to define the cycle rate at which the ThermoBrite Elite will rock back and forth. The default is Medium speed – 12 cycles/minute.

We recommend not using Fast as it might damage the sample.

1. Double-click **Rock**.

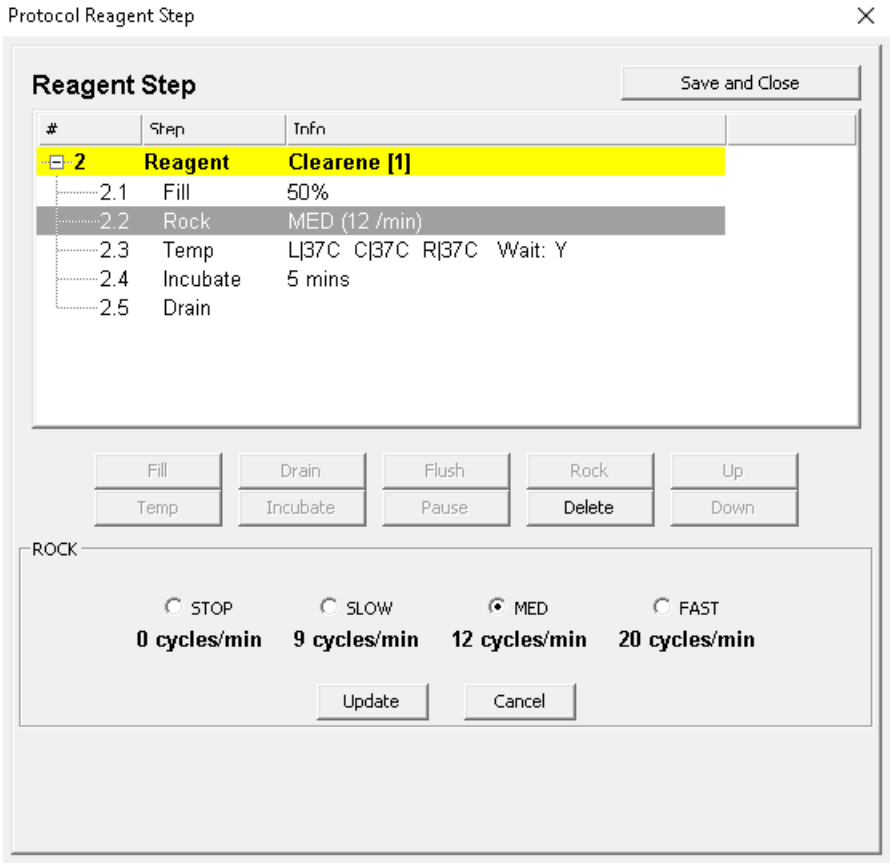


Figure 6-27: Protocol Reagent Step—Rock

2. Select the appropriate option:
   - **Stop -** the instrument will not rock
   - **Slow -** 9 cycles/minute
   - **Medium -** 12 cycles/minute
   - **Fast -** 20 cycles/minute

Selecting **Stop** will result in poor temperature control. Reagent steps that involve thermal control should not be set to **Stop**.

3. Click **Update** to validate the entry. The Reagent Step screen is displayed.

Reagent Temp

Use this option to define the temperature at which each chamber must be for the reagent step. The default is 37°C.

1. Double-click **Temp**. Enter a temperature between 25°C and 95°C.
2. Do not uncheck **On**. This will disable heating and cooling for the module.

> Selecting the **On** check box only enables heating/cooling for the module. Only modules that are loaded with slides at the time of operation will actually heat or cool.

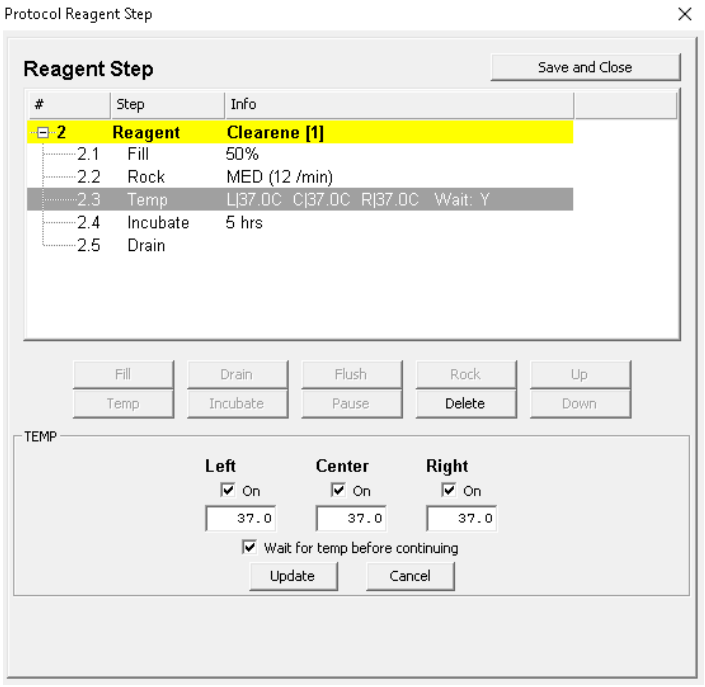
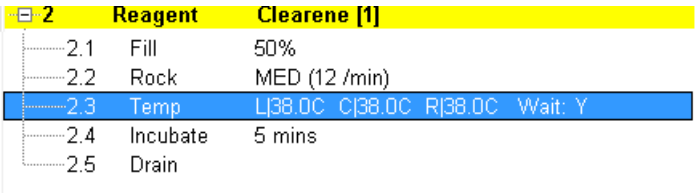


Figure 6-28: Protocol Reagent Step—Temperature

3. Select when you want the instrument to start heating/cooling:
   - Select the Wait for temp before continuing check box to prevent the next step from starting until the temperature has achieved the selected temperature.
   - Clear the Wait for temp before continuing check box to start the incubation time while the instrument begins to heat/cool toward the target temperature. At the end of the incubation time, it will then proceed to the next step. In general, when cooling, clear the check box.
4. Click **Update** to validate the entry. The Reagent Step screen is displayed. After updating, a **Wait: Y** or **Wait: N** will appear on the Reagent Step screen to the right of the temperature, indicating whether the "**Wait for temp before continuing**" check box was checked.



Reagent Incubate

This option is used to define the incubation time for the reagent step. The default is 5 minutes.

This step is relevant only if the Wait for temp before continuing check box was selected in the Temp step.

1. Double-click **Incubate**. Enter a time greater than 0.1 minutes for the specimen to remain at the temperature previously selected in the **Temp** option.

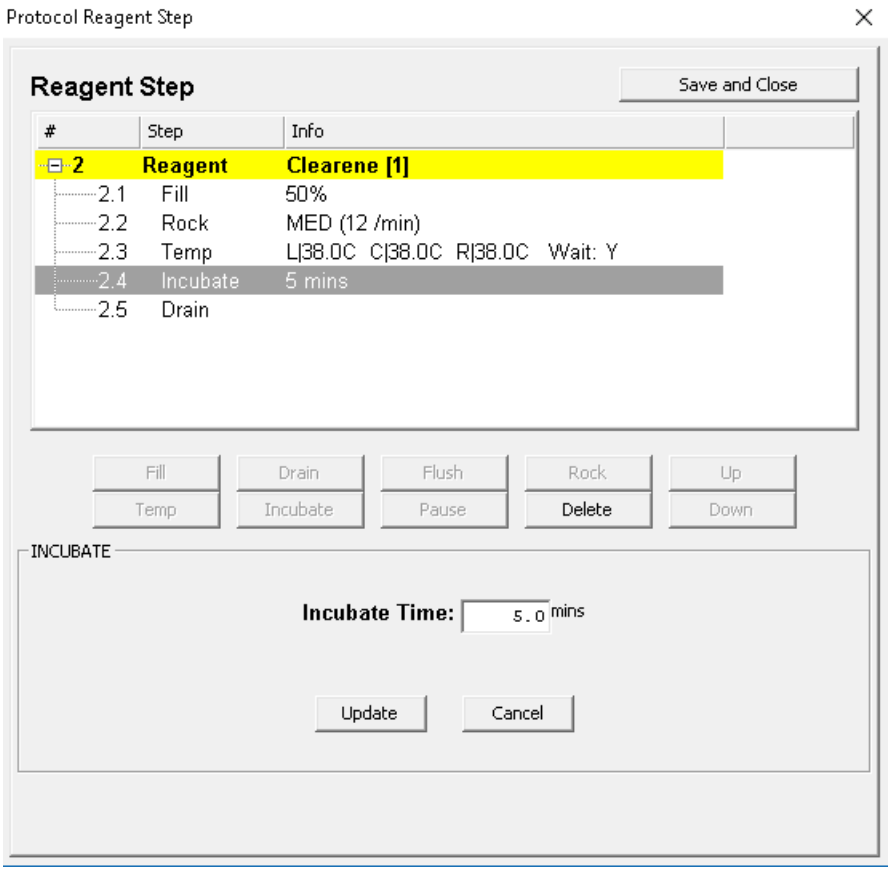


Figure 6-29: Protocol Reagent Step—Incubation

2. Click **Update** to validate the entry. The Reagent Step screen is displayed.

Reagent Drain

This option does not need input.

Reagent Step Options

The following steps can be added:

- Flush
- Pause

Flush

Use this option to add a **Flush** step. Use a Flush step to ensure previous reagents have been flushed out of the fluidic lines. This is particularly important when using reagents of high or low pH or solvents. Including a Flush step can increase the life of the peristaltic tubing.

When needed, the **Flush** step should be added after a **Fill** step has been selected. The default flush volume is 35.0mL.

A **Flush** step of ethanol/reagent grade alcohol/industrial methylated spirits must be programmed immediately after each fill of xylene substitute (d-Limonene).

A **Flush** step of distilled/deionized water must be programmed immediately after each fill of any low pH reagents.

1. Select the **Fill** step to precede the Flush step, and then click the **Flush** button.

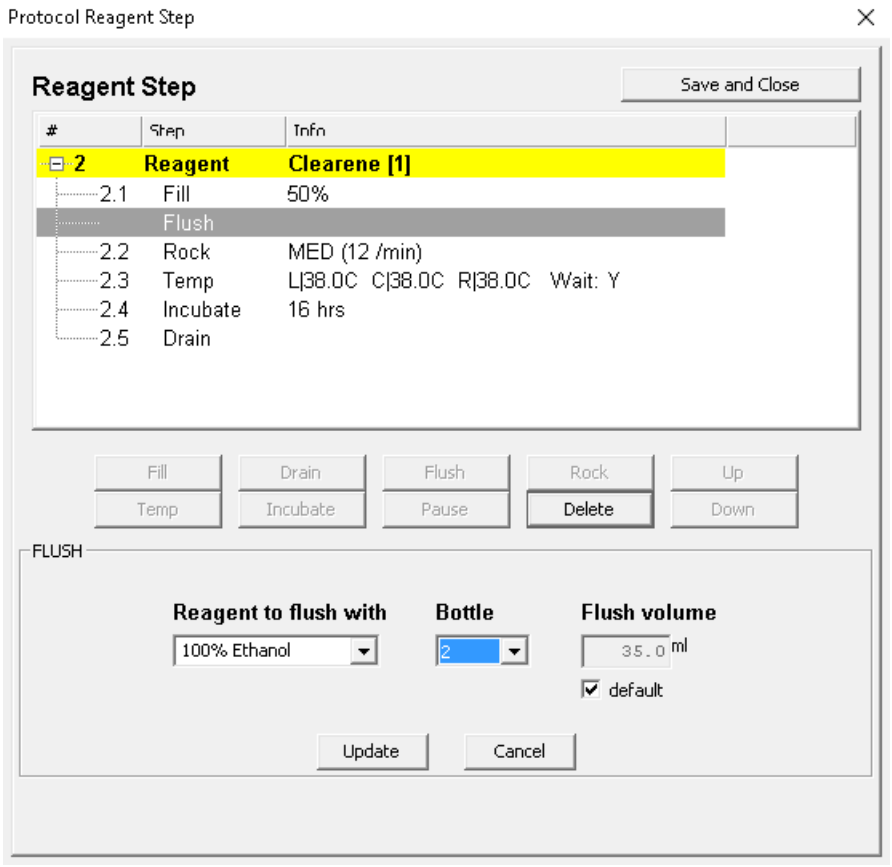


Figure 6-30: Protocol Reagent Step—Flush

2. Select a Reagent and a Bottle Number from their respective dropdown lists.
3. Accept the default or clear the default check box and adjust the **Flush volume** to a value greater than 35mL.
4. Click **Update** to validate the entry. The Reagent Step screen is displayed.

New steps are added immediately after the currently highlighted step.

Pause

Use this option to add a specific instruction and to pause the protocol run for a manual user action.

1. Select the step to precede the **Pause** step, and then click the **Pause** button.

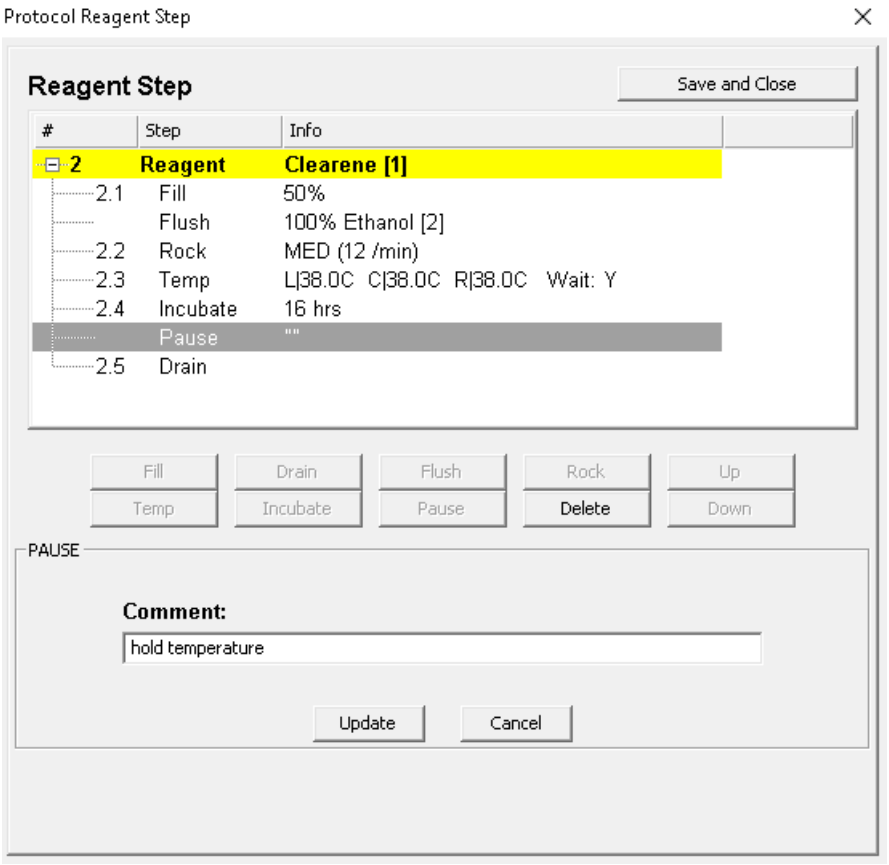


Figure 6-31: Protocol Reagent Step—Prompt

2. Enter a comment. During Pause, the Thermal Modules will hold temperature until the user clicks **Resume**. A Pause step may be useful post hybridization incubation to allow the user to return for post wash when ready.
3. Click **Update** to validate the entry. The Reagent Step screen is displayed.

Save and Close

Use the following options to edit, or save the protocol steps:

Save and Close	Save the reagent steps and display them in the **Protocol Steps** field
Delete	Delete the selection
Up	Move the selection one step up
Down	Move the selection one step down

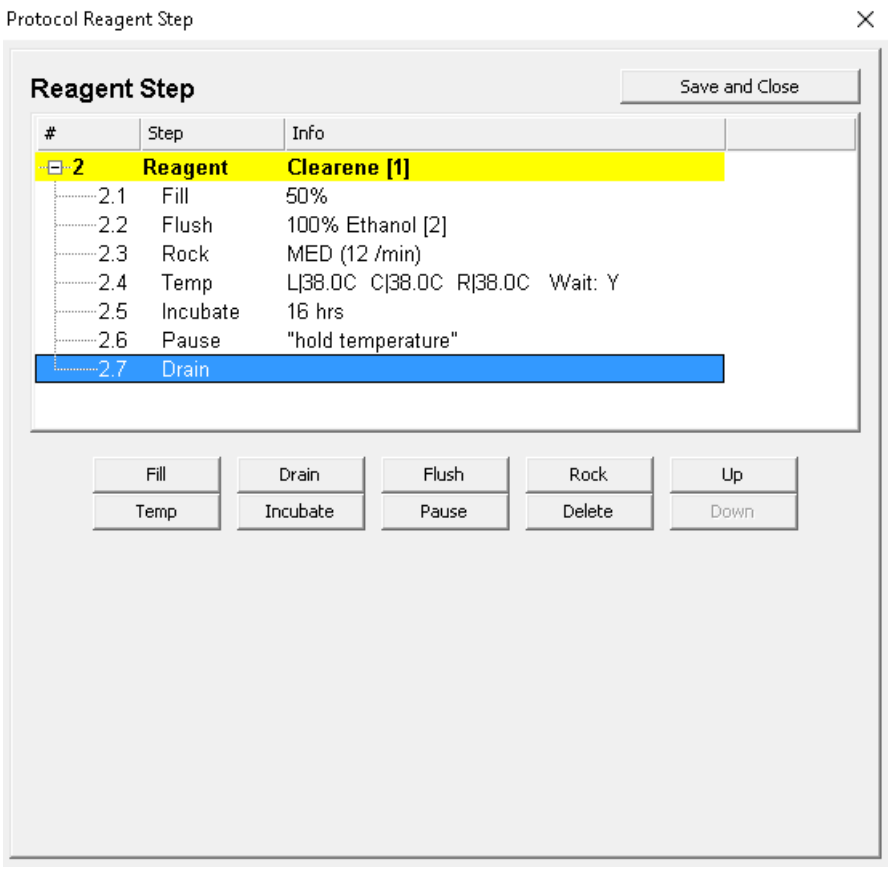


Figure 6-32: Protocol Reagent Step—Save

Before saving any protocol step, make sure the sub-steps are kept in proper sequence. If an option is out of sequence, use the Up or Down buttons.

There is no Undo option.

If you select **Back** after updating, the system displays "Any changes you have made will not be saved. Do you wish to discard changes and go back?". If you click **Yes**, none of the changes are saved. If you click **No**, the dialog box will close and you can continue adding steps.

6.4.1.2 Prime Step

The Prime step:

- removes fluid from a previous protocol using another reagent, and
- fills the lines to avoid flow errors.

You do not need to add a Prime step. The instrument automatically primes as it reaches each new step. Adding a Prime step will result in higher volume of reagent use.

1. In the **Protocol Steps** field, click **Add**.

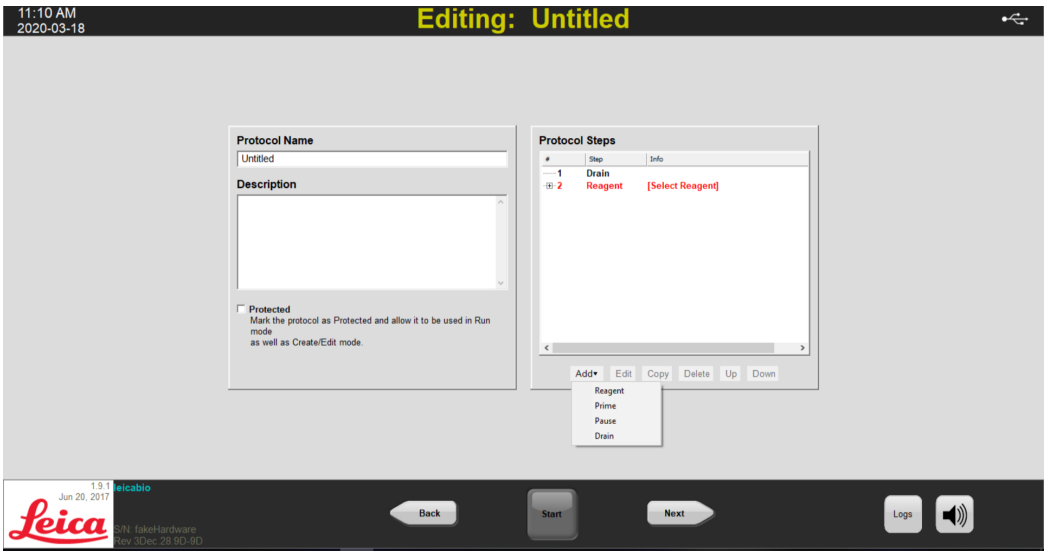


Figure 6-33: Add Prime Step

2. Click on **Prime**.

No options are available for the Prime step. The Protocol screen is displayed.

6.4.1.3 Pause Step

Use this option to add a specific instruction and to pause the protocol run. This option is the same as the **Pause** sub-step. See Reagent Step Pause.

1. In the **Protocol Steps** field, click **Drain**.

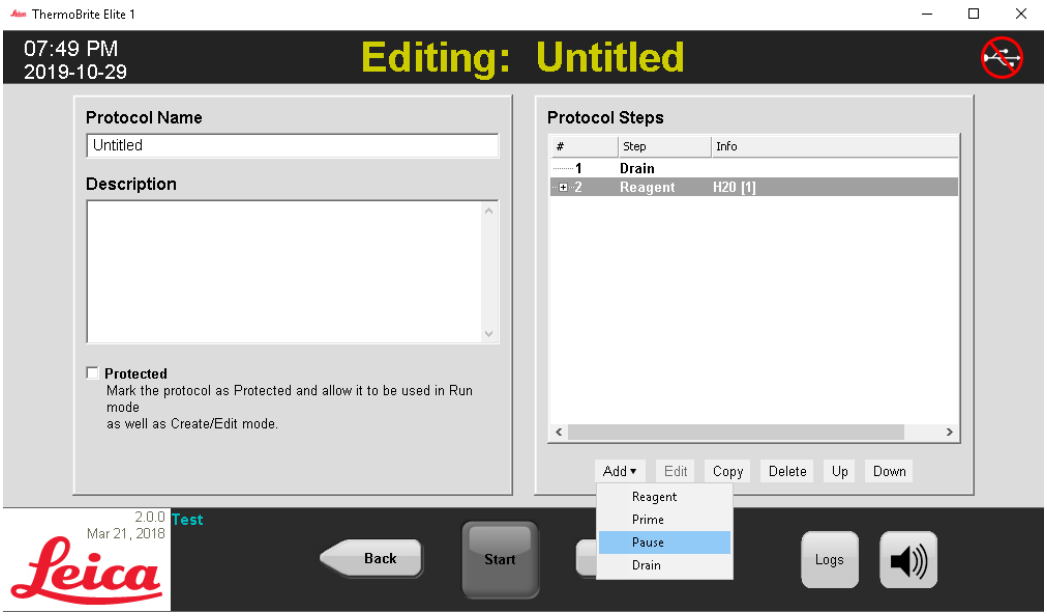


Figure 6-34: Add Pause Step

The Protocol Pause Step window is displayed.

2. In the **Comments** field, enter an instruction for the pause step.

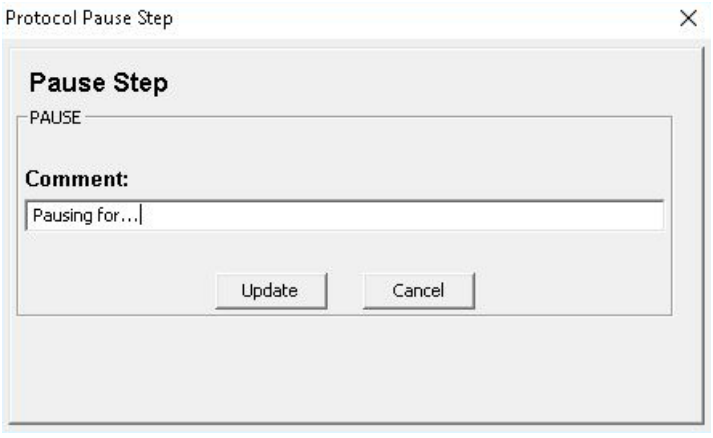


Figure 6-35: Protocol Pause Step

3. Click **Update**.

6.4.1.4 Drain Step

This option will drain the contents of the chamber modules into the Waste Bottles.

1. In the **Protocol Steps** field, click **Drain**.

   No options are available for the **Drain** step.

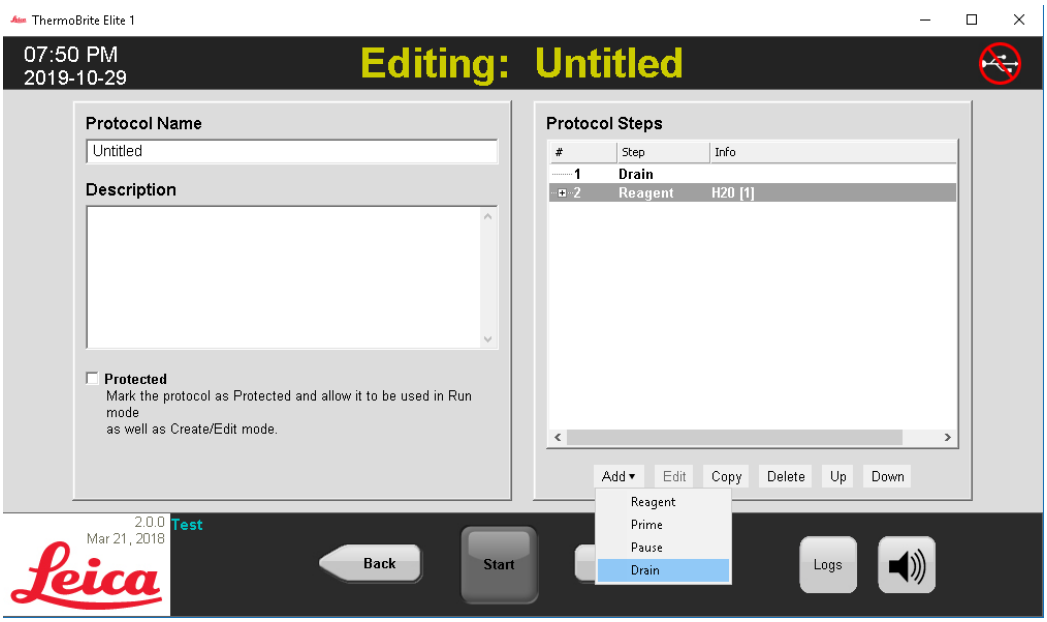


Figure 6-36: Drain Step

6.4.2 Assign Waste Bottles

After you have added all reagent steps, you need to assign containers to receive the waste product from the various steps in a run.

1. On the Main Protocol screen, click **Next.** The Assign Waste Location screen is displayed.

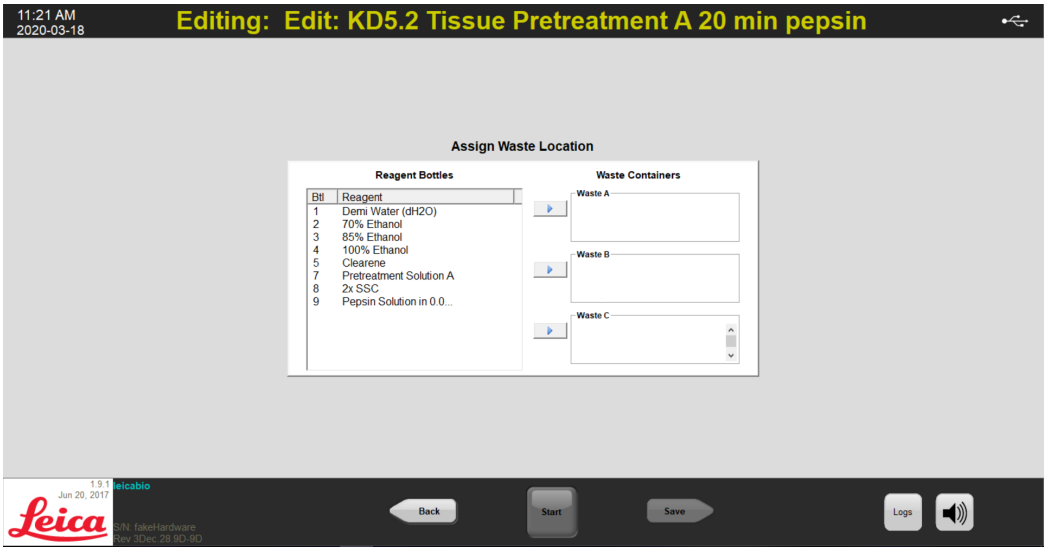


Figure 6-37: Protocol Dashboard—Confirm Reagent and Waste Setup

Waste "C" is the default because it is assumed to receive the most toxic waste. Use Waste "C" for ethanol and Xylene substitutes (such as Clearene or Sub-X). Use Waste "A" for the least toxic waste such as water. Use Waste "B" for all other waste such as Pepsin.

Do NOT assign Sodium Thiocyanate (NaSCN) and Hydrogen Chloride (HCL) to the same waste bottle. Assign the NaSCN and H_2O (used to flush the NaSCN line) to Waste container "A". Assign the HCL and Pepsin (in HCL) to Waste Container "B".

2. Select a reagent and click the appropriate forward arrow **>** to select the Waste Bottle. To change the reagent location, click on the reagent in the Waste Bottle field, and then click on the arrow to return the reagent to the Reagent Bottles field. See Figure 6-38 - Assign Waste Location below.

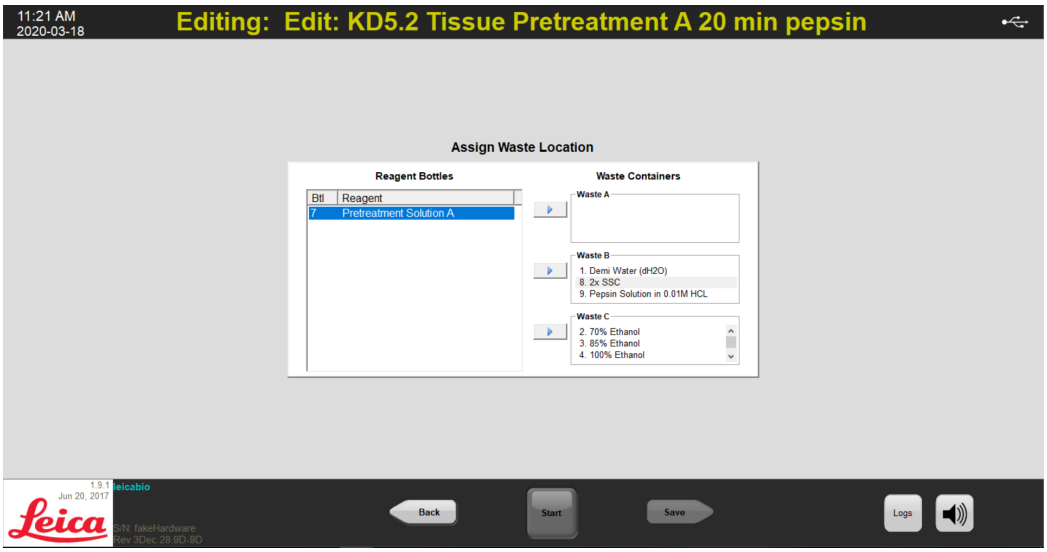


Figure 6-38: Assign Waste Location

Certain reagents may not be compatible and should not be assigned to the same Waste Bottle, such as sodium thiocyanate and acids. It is the user's responsibility to ensure reagent compatibility when assigning waste to a specific Waste Bottle.

Dispose of waste product in compliance with applicable legal regulations. If unsure of the applicable legal requirements, contact the local authorities for information.

3. Continue until all reagents in the **Reagent** field are assigned to the appropriate Waste Bottles.
4. Click **Save** to save and return to the Main Protocol screen.

6.4.3 Check Alerts

6.4.3.1 Warning Protocol Issues

This warning is displayed if there is a potential issue with one or more steps. It does not mean that the run will abort.

Figure 6-39: Warning—Protocol Issue

1. Click **Yes** to save and exit; or click **No** to make corrections.

6.4.3.2 Warning Invalid Protocol Name

This dialog is displayed when there is an existing protocol with the same name.

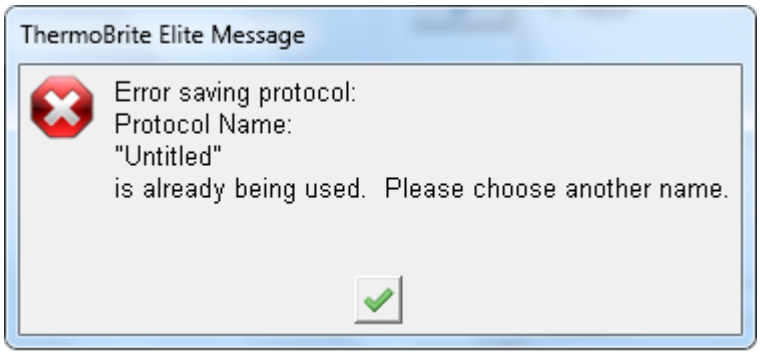


Figure 6-40: Warning—Invalid Protocol Name

1. Click the tick button and then rename the protocol.

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7. Maintenance

Do NOT expose the ThermoBrite Elite Unit or its Netbook to strong or concentrated acids, bases or oxidizing agents, aromatic or halogenated hydrocarbons, esters, or ketones.

Wear appropriate personal protective equipment to prevent exposure to pathogens. Discard contaminated materials according to applicable regulations.

Leica Biosystems recommends that instrument users perform periodic inspections and preventive maintenance on all instruments. Contact Customer Service or your distributor for optional services offered for this instrument.

Service

Contact Leica Biosystems Customer Service or your distributor for service of the instrument.

7.1 Cleaning and maintenance checklist

Use the schedule below to clean and maintain your ThermoBrite Elite.

Task	Section
Daily—Before each run	
Check reagent level volume	3.4.1 - Fluid Management System
Check reagent bottle filter position	3.4.1 - Fluid Management System
Check waste bottle volume	7.2.1 - Discarding Liquid Waste
Check the peristaltic tubing	7.6.2 - Replace the Peristaltic Pump Tubes
Daily—After each run	
Clean/dry sample chambers	7.4.1.1 - Clean Sample Chambers
Clean upper drip plate	7.4.1.2 - Clean the Upper Drip Plate
Open Peristaltic Pump Cover	
Clean pepsin bottle	7.4.1.3 - Clean the Pepsin Bottle
Clean pepsin line	7.4.1.4 - Clean the Pepsin Line
Weekly	
Line wash	7.3 - Line Wash
Line wash for Clearene lines	7.3 - Line Wash
Empty waste bottles	7.2.1 - Discarding Liquid Waste
Monthly	
Clean reagent bottles	7.4.2.3 - Clean Reagent Bottles and Filters
Clean waste bottles	7.4.2.4 - Clean Waste Bottles
Clean outside of ThermoBrite Elite	7.4.2.1 - Clean Instrument Surfaces
Clean slide carriers	7.4.2.2 - Clean Slide Carriers
Back up log files on laptop	7.5.2 - Back up Protocol Files on Laptop
Back up protocol files on laptop	7.5.1 - Back up Log Files on Laptop
As needed	
Replace the Module Manifest Filter	7.6.1 - Replace the Module Manifold Filters
Replace the Peristaltic Pump Tubing	7.6.2 - Replace the Peristaltic Pump Tubes
Replace the fuses	7.6.3 - Replace the Fuses

7.2 Disposition

7.2.1 Discarding Liquid Waste

Empty your Waste Bottles as part of your weekly maintenance or more frequently if needed.

Dispose of waste product in compliance with applicable legal regulations. If unsure of the applicable legal requirements, contact the local authorities for information.

7.2.2 Discarding Instrument Parts

1. Disconnect power from the instrument.
2. Drain all liquid out of the instrument.
3. Clean and decontaminate the instrument by performing a line wash with minimum of 70% Ethanol (see 7.3.1 - Run a line wash).

Dispose of the instrument or parts of the instrument in accordance with all procedures and local/government regulations that apply at the laboratory facility.

7.3 Line Wash

The Line Wash is a maintenance procedure that must be performed in order to sustain the optimal condition of the fluidics portion of the instrument.

Run the Line Wash:

- as part of a routine weekly maintenance,
- when recommended as a component of troubleshooting,
- just prior to not using the ThermoBrite Elite for a week.

This procedure consists of two steps:

1. An ethanol flush:
    - All reagents except Clearene—70% ethanol
    - Clearene or other Xylene substitutes—100% ethanol
2. An air flush.

7.3.1 Run a line wash

Items required: 70% ethanol (or reagent grade alcohol or deionized water), paper towel, and appropriate personal protective equipment.

For Clearene and line washes, use 100% ethanol.

1. Insert then twist to lock up to 3 Reagent Line fittings onto the cap of the ThermoBrite Elite Wash Bottle (filled with deionized water, 70% ethanol, or 100% ethanol for Clearene lines).

Figure 7-1: Insert Reagent Line Fittings onto Wash Bottle

2. From the Main screen, click the **Line Wash** button.

Figure 7-2: Select Line Wash

3. Check the line check box that corresponds to the lines to be washed, up to three at a time.

Figure 7-3: Line Wash

4. Select the desired Waste Bottle.

Dispose of waste product in compliance with applicable legal regulations. If unsure of the applicable legal requirements, contact the local authorities for information.

5. Click **Start**.

6. Add the appropriate amount of 70% ethanol (or equivalent) to the ThermoBrite Elite Wash Bottle, based on messaging that appears on screen.

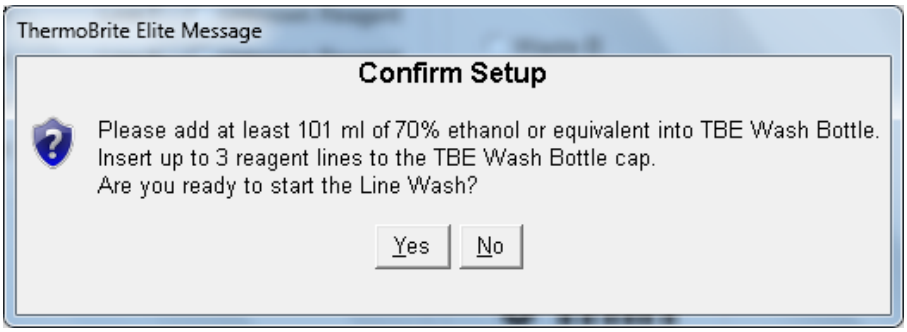


Figure 7-4: Confirm Setup

7. Click **Yes** to confirm.

8. When the flush has finished, follow the instructions on the screen and remove the fittings from the ThermoBrite Elite Wash Bottle cap to allow for an air flush.

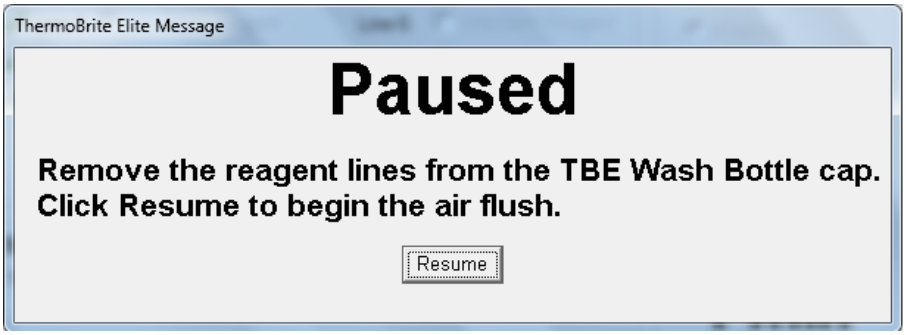


Figure 7-5: Pause message—Remove Reagent Lines

9. Click **Resume**.
10. Click **Save Notes and Close**.

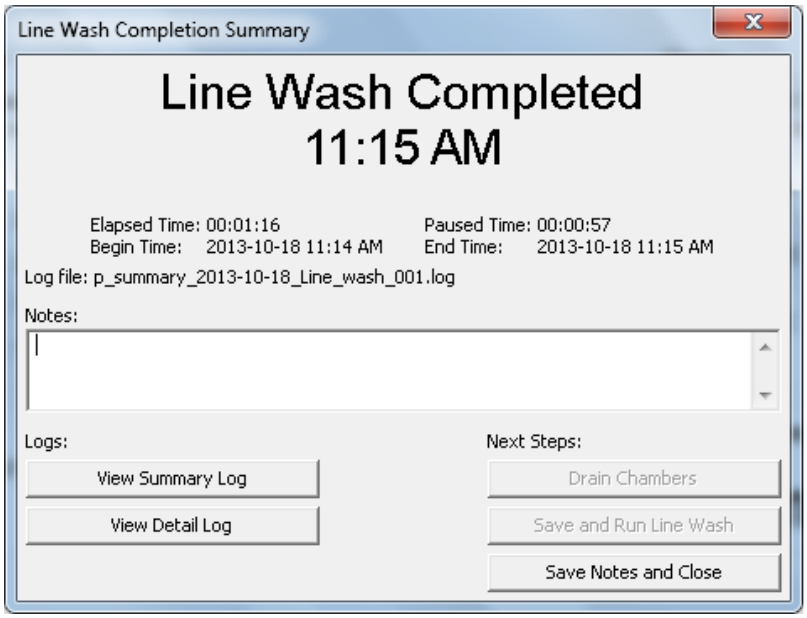


Figure 7-6: Pause message—Line Wash Completed

11. Repeat steps 1-10 for remaining lines to be washed.

7.4 Cleaning

Periodic cleaning is recommended for all laboratory instruments and frequency depends on the working environment. Recommended procedures are given below.

Unplug the ThermoBrite Elite Unit from the wall outlet and disconnect it from the Netbook before cleaning.

Before using any cleaning or decontamination methods other than those recommended, check with Technical Support that the proposed method will not damage the equipment.

7.4.1 After each run

Perform the following cleaning procedures after each run.

7.4.1.1 Clean Sample Chambers

Items required: Acceptable disinfectants are 70% or higher concentration alcohol, lint-free tissue, distilled water, and appropriate personal protective equipment.

1. Remove any Slide Carrier inside the instrument.
2. Moisten a lint-free tissue with 70% or higher concentration alcohol and clean the inner surfaces of the Modules.
3. Wipe using distilled water.
4. Wipe dry with a lint free tissue.
5. Leave chamber lids open to allow the chambers to completely dry.

7.4.1.2 Clean the Upper Drip Plate

Items required: Acceptable disinfectants are 70% or higher concentration alcohol, lint-free tissue, distilled water, and appropriate personal protective equipment.

1. Moisten a lint-free tissue with 70% or higher concentration alcohol and clean the surfaces of the Upper Drip Plate.
2. Wipe using distilled water.
3. Wipe dry with a lint free tissue.

7.4.1.3 Clean the Pepsin Bottle

Items required: Acceptable disinfectants are 70% or higher concentration alcohol, deionized water, lint-free tissue, and appropriate personal protective equipment.

1. Ensure the instrument is not in operation.
2. Remove the cap and empty the Pepsin Bottle. Dispose of the reagent in accordance with approved procedures at your facility.
3. Wash the bottles with 70% alcohol.
4. Rinse thoroughly with deionized water.
5. Allow the containers to dry before refilling with fresh reagent and returning to the instrument.

7.4.1.4 Clean the Pepsin Line

After each run, perform a line wash using 70% or higher alcohol on the Pepsin line. See 7.3.1 - Run a line wash

7.4.2 Monthly

Perform the following cleaning procedures monthly.

7.4.2.1 Clean Instrument Surfaces

Items required: Mild detergent, lint-free tissue, distilled water, and appropriate personal protective equipment.

1. Clean the outside surfaces of the ThermoBrite Elite Unit with a water-dampened lint-free tissue and mild detergent to remove any deposits.
2. Wipe again using distilled water.
3. Wipe dry.

7.4.2.2 Clean Slide Carriers

Items required: Acceptable disinfectants are 70% or higher concentration alcohol, lint-free tissue, distilled water, and appropriate personal protective equipment.

1. Remove any Slide Carriers from inside the instrument.
2. Soak the Slide Carrier in 70% or higher concentration alcohol for at least 5 mins. Do a visual check to ensure it is clean.
3. Rinse thoroughly using distilled water.
4. Wipe dry with a lint-free tissue.

7.4.2.3 Clean Reagent Bottles and Filters

Items required: Acceptable disinfectants are 70% or higher concentration alcohol, deionized water, lint-free tissue, and appropriate personal protective equipment.

1. Ensure the instrument is not in operation.
2. Remove the cap and empty the Reagent Bottles. Dispose of the reagent in accordance with approved procedures at your facility.
3. Wash bottles and filters with ethanol. For
    - Xylene substitutes (such as Clearene)—use 100% alcohol
    - All other reagents (including Pepsin and H_2O)—use 70% alcohol
4. Rinse thoroughly using deionized water.
5. Allow the bottles and filters to dry before refilling with fresh reagent and returning to the instrument.

7.4.2.4 Clean Waste Bottles

Items required: 0.5% bleach solution (w/v) or industrial strength detergent, deionized water, and appropriate personal protective equipment.

1. Ensure the instrument is not in operation.
2. Remove the cap and empty all waste from containers. Dispose of the waste in accordance with approved procedures at your facility.
3. Clean waste containers using a 0.5% bleach solution (w/v) or industrial strength detergent.
4. Rinse thoroughly with deionized water.
5. Return waste containers to the instrument.

7.4.2.5 Clean the Netbook

Follow the manufacturer's recommendations for cleaning the Netbook.

7.5 Back up Data

7.5.1 Back up Log Files on Laptop

Copy all files in the following folder to a USB:

```
C:\Users\Public\Public Documents\Leica\logs
```

Log files are stored in a text files.

7.5.2 Back up Protocol Files on Laptop

Copy all files in the following folder to a USB:

```
C:\Users\Public\Public Documents\Leica\protocols
```

Each protocol is stored in a comma-separated values (.csv) file.

7.6 As Needed Maintenance

7.6.1 Replace the Module Manifold Filters

The Module Manifold is located on the front of the instrument between the peristaltic pumps. If the instrument has not been maintained adequately, you might need to replace the Module Manifold Filters in between services. When running protocols, if you see multiple messages relating to either slow fill or critical fill errors for a chamber, you might need to replace the Module Manifold Filters.

A single error relating to problems with the fill does not necessarily indicate that the Module Manifold Filters need to be replaced. Wait until there are multiple errors for the same chamber.

Items required: Manifold Filter Kit, Item# 3800-007743-001, paper towel, and appropriate personal protective equipment.

1. Turn the main power switch located in the back panel to the Off (O)position Make sure the power cable to the ThermoBrite Elite Unit is unplugged.
2. Place paper towel underneath the Module Manifold to catch any possible fluid leak (see image below).

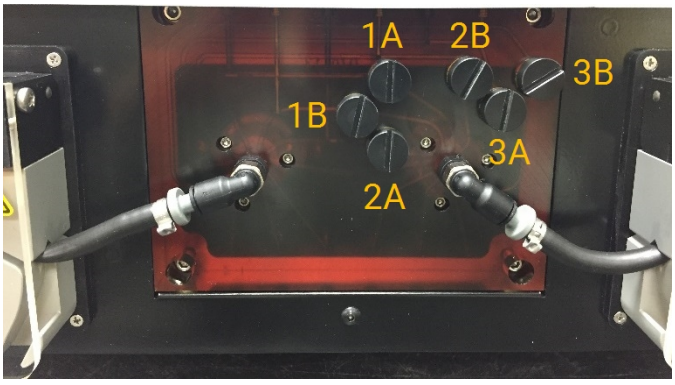


Figure 7-7: Module Manifold

3. Using a flat screwdriver and turning counterclockwise, remove each Manifold Filter.
4. Discard the old Manifold Filters according to applicable regulations.

Dispose of contaminated material in compliance with applicable legal regulations. If unsure of the applicable legal requirements, contact the local authorities for information.

5. Each Manifold Filter has a black O-ring. Make sure it is properly seated before installing the filter, see image on the right.

Figure 7-8: Manifold Filter

6. Using a flat screwdriver and turning clockwise, install a new filter into each of the six ports. Take care to align the threads. Do not force if the threads are not aligned.
7. Turn the main power switch located in the back panel to the **On (I)** position.
8. Run a short protocol or a **Line Wash** to make sure the filters are installed correctly and not leaking. See 7.3 - Line Wash .

7.6.2 Replace the Peristaltic Pump Tubes

With normal daily usage, the Peristaltic Pump Tubes will need to be replaced approximately every 3 months, however, this is dependent on the number of runs you perform, and the reagents used. You will be able to tell if they need replacing when:

- You see critical drain and fill errors while running protocols
- On visual inspection, the tubes look like they are crimped.

If you experience these problems after running an overnight hybridization run, first try massaging the tubes to get them back into shape. If that does not work, replace the tubes.

To maximize the life of the tubes, make sure you leave the Peristaltic Pump Cover open when the instrument is not in use. Occasionally you might see these problems after running an overnight hybridization run.

The Peristaltic Pumps have moving rollers that can pinch or trap fingers. Always power off the instrument before opening the Peristaltic Pump Cover. Never attempt to adjust or access the tube while the instrument is powered on.

Dispose of contaminated material in compliance with applicable legal regulations. If unsure of the applicable legal requirements, contact the local authorities for information.

Items required: Peristaltic Pump Tube Kit, Item# 3800-007742-001, paper towel, and appropriate personal protective equipment.

1. Turn the main power switch located in the back panel to the Off (0) position. Make sure the power cable to the ThermoBrite Elite Unit is unplugged.
2. Place some paper towels underneath the peristaltic pump to catch any possible fluid leak, see image below.

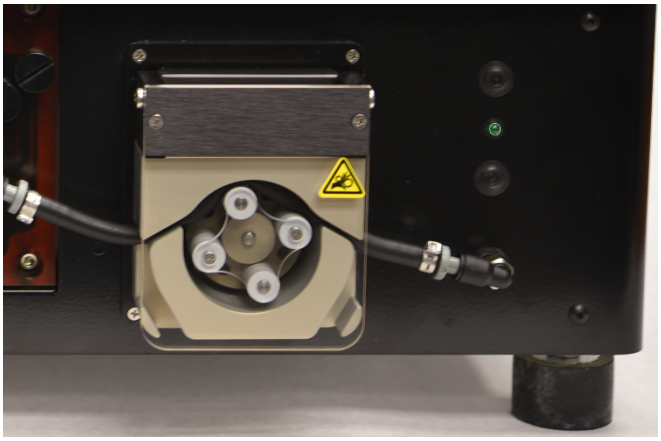


Figure 7-9: Peristaltic Pump

3. Lift the Peristaltic Pump Cover to access the pump. This raises the top part of the pump, giving full access to the tube, see Figure 7-10 - Remove Plug from Exit Port .
4. Remove the gray plug from the exit port by pulling upward on the plug and the tube, see image below.

Figure 7-10: Remove Plug from Exit Port

5. Repeat step 4 for the inlet port until the tube and the gray connectors are free.

6. Insert a new pump tube into the inlet and exit plugs. Push the tube all the way to avoid any possible leak.

Figure 7-11: Insert Plug into Exit and Inlet Port

7. Guide the tubing into the peristaltic pump, above the rollers. Make sure the tube rests in the V notch on both sides of the pump. See image below.

Figure 7-12: Tubing Position

8. Lower the Peristaltic Pump Cover to close the pump. This lowers the top part of the pump, securing the tube above the rollers.
9. Discard the old tube according to applicable regulations.
10. Repeat the procedure for the second peristaltic pump.

7.6.3 Replace the Fuses

Turn the main power switch located in the back panel to the **Off (0)** position. Unplug the ThermoBrite Elite Unit from the wall outlet and disconnect it from the Netbook before replacing the fuses.

For continued protection against risk of fire and hazard, replace only with the same type and rating fuses.

1. The instrument fuses are located on the rear panel, between the power cable receptacle and the power switch.

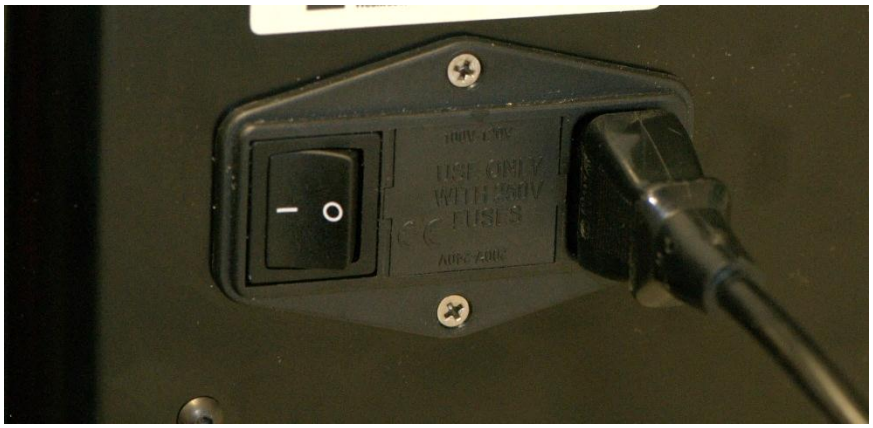


Figure 7-13: Power Switch—Fuse Box

2. Remove the power cable to access the fuse holder.
3. Using a small flat screwdriver on one side tab, pry the fuse holder out.

Figure 7-14: Power Switch—Access Fuse Holder

4. Remove the fuse holder. Two fuses are inserted inside the fuse holder.

Figure 7-15: Power Switch—Replace Fuse

5. Replace with fuses of the same type and rating: 10.0A 250V F 5 x 20 mm.
6. Reinstall the fuse holder in its compartment until it clicks into place.
7. Reconnect the Netbook to the unit.
8. Reconnect the power cable, and then press the power switch to the On (I) position.

8. Troubleshooting

A self-test is automatically performed when the ThermoBrite Elite Unit is powered on.

When the instrument successfully powers up, a two-beep ready signal sounds, and the **green** LED on the right side of the front panel illuminates.

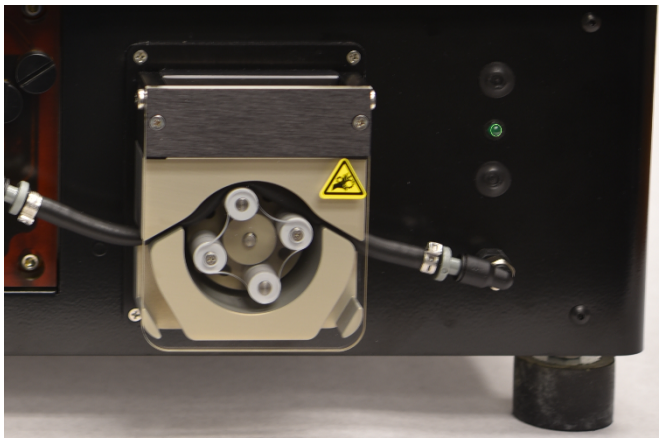
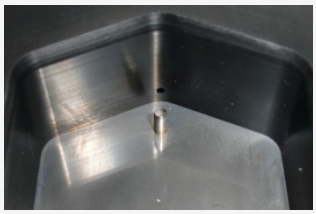
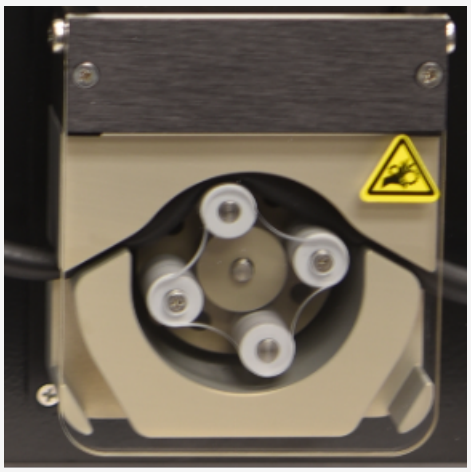
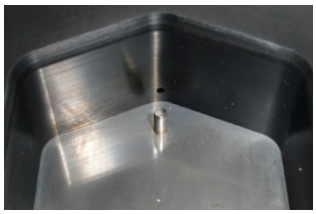


Figure 8-1: Peristaltic Pump

8.1 Troubleshooting by Symptoms

Symptom	Possible Cause	Remedies
The green LED light is not on and the instrument will not operate.	Loose power cable connection.	Make sure that the power cable on the back of the instrument is properly inserted into the power outlet.
	Unit not plugged in or power source faulty.	Make sure the instrument is properly connected to an electrical outlet. If the problem persists, call Technical Services or your distributor.
	Fuse blown or not installed.	See 7.6.3 - Replace the Fuses .
	Faulty internal power supply.	Call Technical Support or your distributor.
USB Communication Error 	Bad connections.	Check the connections on the back of the ThermoBrite Elite and on the USB port of the Netbook.
	Faulty cable	Replace the USB cable.

Symptom	Possible Cause	Remedies
Sample Chambers are not filling	Reagent Tube not properly connected. Reagent Tube kinked.	Check the tube connections on the Reagent Manifold and Reagent Bottle cap.
	Bottle filter obstructed.	Clean the bottle filter with 70% ethanol. Replace Filter Assembly.
	Tube not properly connected on the Module Manifold.	Check the tube connections on the Reagent Manifold. See Module Manifold .
	The inlet/outlet opening in the Sample Chamber may be obstructed. See image below. 	Clean the system; see 7.3 - Line Wash . If the problem persists, call Technical Support or your distributor.
	Reagent Bottle is empty.	Refill the Reagent Bottle with the appropriate reagent.
	The Reagent Pump is not pumping reagent, see image below. 	Check if the rollers are turning on the left pump located on the front of the instrument. If not, call Technical Support or your distributor.

Symptom	Possible Cause	Remedies
Sample Chambers are not emptying	Tube not properly connected on the Module Manifold.	Check the tube connections on the Reagent Manifold. See Module Manifold .
	The Waste Pump is not pumping waste liquid, see image below. 	Check if the rollers are turning on the right pump located on the front of the instrument. If not, call Technical Support or your distributor.
	The inlet/outlet opening in the Sample Chamber may be obstructed. See image below. 	Clean the system; see 7.3 - Line Wash . If the problem persists, call Technical Support or your distributor.
	Clogged Manifold Filters	Replace the Manifold Filters; see 7.6.1 - Replace the Module Manifold Filters .

8.2 Error Messages

8.2.1 Cannot load protocol

Causes	Remedies
The software cannot load the selected protocol.	Restart the Netbook. If the problem persists, contact Technical Support or your distributor.

8.2.2 Could not switch the # to

Causes	Remedies
An internal valve is not responding correctly.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.3 Drain Side Low Flow

Causes	Remedies
The waste flow is slow.	1. Check for Sample Chamber blockage 2. Replace Manifold Filters; see 7.6.1 - Replace the Module Manifold Filters . 3. Replace Waste Peristaltic Tubing; see 7.6.2 - Replace the Peristaltic Pump Tubes. If the problem persists, contact Technical Support or your distributor.

8.2.4 Error loading Protocol

Causes	Remedies
The software cannot load the selected protocol.	Restart the Netbook. If the problem persists, contact Technical Support or your distributor.

8.2.5 Exit valve failed to switch to bypass position

Causes	Remedies
The exit valve is not responding correctly.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.6 Inlet valve failed to switch to bypass position

Causes	Remedies
The inlet valve is not responding correctly.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.7 Inlet valve failed to switch to chamber

Causes	Remedies
The inlet valve is not responding correctly.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.8 Instrument failed self-test

Causes	Remedies
One or more of the instrument self-test did not pass.	Ensure cover is on. Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.9 Instrument thread is either terminated or unresponsive within 20sec. Software will terminate

Causes	Remedies
The instrument is not responding to a software command.	Restart the Netbook. If the problem persists, contact Technical Support or your distributor.

8.2.10 Modules did not reach target temperature(s) within 1 hour

Causes	Remedies
Firmware or Thermal Module issue.	Restart the Netbook and ThermoBrite Elite. If the problem persists, contact Technical Support or your distributor.

8.2.11 Internal software error

Causes	Remedies
The software stopped working.	Restart the Netbook. If the problem persists, contact Technical Support or your distributor.

8.2.12 Internal instrument error

Causes	Remedies
An internal component is not responding to a command.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.13 Internal operation error

Causes	Remedies
An internal component is not responding to a command.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.14 Internal runner module error

Causes	Remedies
An internal component is not responding to a command.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.15 No ThermoBrite Elite found

Causes	Remedies
The Netbook cannot connect to the ThermoBrite Elite.	Check the USB connections between the instrument and the Netbook. Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.16 Reagent valve failed to switch to reagent line

Causes	Remedies
The reagent valve is not responding correctly.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.17 Self-test failed to communicate with Instrument

Causes	Remedies
The Netbook cannot connect to the ThermoBrite Elite.	Unplug the USB from the Netbook and then plug it back in. Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.18 Sensors indicate a critical flow error

Causes	Remedies
Sensors indicate a critical flow problem while filling. Causes: • empty reagent bottle • disconnected reagent tube • blocked reagent bottle filter • worn Peristaltic Tube Sensors indicate a critical flow problem while draining. Causes: • obstructed Chamber Port • blocked Manifold Filter • worn Peristaltic Tube • full Waste Bottles	Restart the Netbook and instrument. • Perform a Line Wash, see 7.3.1 - Run a line wash • Refill any empty Reagent Bottle • Check the Reagent Tubes connections to the Reagent Bottles and the Reagent Manifold. • Replace the Peristaltic Tubes; see 7.6.2 - Replace the Peristaltic Pump Tubes. If the problem persists, contact Technical Support or your distributor.

8.2.19 Sensors indicate reduced flow rate warning(s)

Causes	Remedies
Sensors indicate a reduced flow problem while filling. Causes: • empty reagent bottle • disconnected reagent tube • blocked reagent bottle filter • worn Peristaltic Tube Sensors indicate a reduced flow problem while draining. Causes: • obstructed Chamber Port • blocked Manifold Filter • worn Peristaltic Tube • full Waste Bottles	Restart the Netbook and instrument. • Perform a Line Wash, see 7.3 - Line Wash . • Refill any empty Reagent Bottle. • Check the Reagent Tubes connections to the Reagent Bottles and the Reagent Manifold. • Replace the Peristaltic Tubes; see 7.6.2 - Replace the Peristaltic Pump Tubes. If the problem persists, contact Technical Support or your distributor.

8.2.20 The protocol has failed

Causes	Remedies
A problem caused the protocol to fail.	Restart the Netbook and instrument. Restart the protocol. If the problem persists, contact Technical Support or your distributor.

8.2.21 This protocol contains errors and it cannot be run

Causes	Remedies
The selected protocol contains errors in the configuration.	Verify the configuration steps and sub-steps. Restart the Netbook. If the problem persists, contact Technical Support or your distributor.

8.2.22 Unhandled exception

Causes	Remedies
An internal component is not responding to a command.	Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.2.23 USB Communication interruption

Causes	Remedies
The Netbook lost connection with the ThermoBrite Elite.	Unplug the USB from the Netbook and then plug it in again. Restart the Netbook and instrument. If the problem persists, contact Technical Support or your distributor.

8.3 Checking USB Connections

Connect the provided USB communication cable to a USB port on the Netbook and to the communication port located in the center of the back panel.

Figure 8-2: USB Connection between Netbook and Instrument

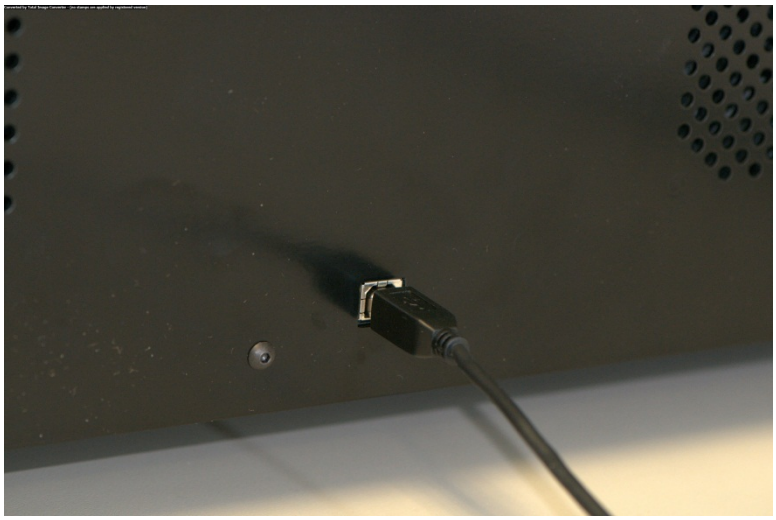
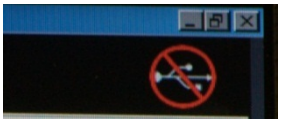


Figure 8-3: Netbook Communication Port

When the connection is established, the Main screen displays the USB connection icon.

Connected  Not Connected 

9. Specifications

Product Name	ThermoBrite Elite
Product Number	3800-007000-001
Model Number	S600
Computer	Netbook with ThermoBrite Elite software preloaded
Interface	USB port
Capacity	(12) 2.54cm X 7.62cm (1" X 3") slides
Electrical Power Requirement	100 – 240 VAC, 50-60Hz, 10.0 A
Dimensions	Height: 38.1cm (15.0") Width: 62.2cm (24.5") Depth: 39.4cm (15.5")
Weight	~27kgs (60lbs)
Environmental	For indoor use only
Fluid Waste	Waste is pumped from the instrument to a Waste Bottle. Drain must be below or at same height as the bench and should be less than 3m from the back of the instrument. If bottles at same height as bench, bottles must be a minimum of 5cm from the side of the unit.
Operational Temperature	15°C to 40°C (59°F to 104°F)
Relative Humidity	Maximum 80% for <31°C (<89°F) Maximum 50% for 31 to 40°C (89 to 104°F)
Storage/Transit Temperature	-10°C to +50°C (14°F to 122°F)

Specifications are subject to change.

9.1 References

1. CLSI. “Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition.” CLSI document M29-A3 [ISBN 1-56238-567-4]. CLSI, 940 West Valley Rd, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.
2. CDC. Recommendations for Prevention of HIV Transmission in Health Care Settings. MMWR (Suppl. No. 2S):2S-18S, 1987.
3. CDC. Updated: US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post Exposure Prophylaxis. Appendix A and B. MMWR 50 (RR-11): 1-42, June 29, 2001.

Index

Manufacturer
Leica Biosystems Melbourne Pty Ltd.
495 Blackburn Road
Mt Waverley, Victoria, 3149
AUSTRALIA

IVD

CE

EC REP

CEpartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands