BOND-PRIME

FULLY AUTOMATED IHC AND ISH STAINING SYSTEM

USER MANUAL

(NOT for use in China)



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Legal notices

Trademarks

BOND, BOND-III, BOND-MAX, BOND-PRIME, BOND-ADVANCE, Covertile, Bond Polymer Refine Detection, Bond Polymer Refine Red Detection, Parallel Automation, Compact Polymer, and Oracle are trademarks of Leica Biosystems Melbourne Pty Ltd ACN 008 582 401.

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Product identification

Doc. 91.7500.501 A10

Manufacturer



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

Important information for all users

This manual contains important information on how to use BOND. For the latest information on Leica Biosystems products and services, visit www.leicabiosystems.com.

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

Terminology

The following terms are used in this document:

- Leica Biosystems—refers to Leica Biosystems Melbourne Pty Ltd.
- BOND the Leica Biosystems platform that includes the BOND-III, BOND-MAX, and BOND-PRIME
- BOND-PRIME a type of automated IHC and ISH staining instrument
- BOND software the software application through which users can configure and operate the BOND-III, BOND-MAX, or BOND-PRIME system

Intended users

The intended users of BOND-PRIME are adequately trained laboratory personnel.

Persons operating a BOND-PRIME Processing Module must have received sufficient training to ensure that it is used in accordance with this document and be fully aware of any potential hazards or hazardous procedures, before operating the processing module. Only trained staff are to remove any covers or parts from the processing module, and only if instructed within this manual.

Installation and repairs

Installation and repairs must only be carried out by qualified service personnel authorized by Leica Biosystems.

Warranty claims can be made only if the product 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.

Serious incident reporting

The occurrence of any serious incident(s) that either has led to, or may lead to, death of a patient or user, or the temporary or permanent deterioration in the state of health of a patient or user must be reported to a local Leica Biosystems representative and the relevant local Regulatory Authority.

Statement for User Data Security and Privacy

Leica Biosystems respects, and is committed to protecting, personal data security and privacy. The Leica Biosystems Privacy Notice below describes the personal data that we may collect, use and retain.

Privacy Notice

The licensee shall comply with all applicable data protection and privacy laws in processing personal data using the BOND-PRIME, without limitation, by making all required notifications to, and obtaining all required consents from, patients and other data subjects prior to processing their personal data.

The following types of Personal Data exist on the BOND-PRIME Processing Module:

- Patient Name is held temporarily on the BOND-PRIME for tracking the run details of the slide whilst the slide is processed.
- **Doctor Name** is held temporarily on the BOND-PRIME for tracking the run details of the slide whilst the slide is processed.
- Slide ID is held temporarily on the BOND-PRIME for tracking the run details of the slide whilst the slide is processed.
- User account details User account details are encrypted in the data files and retained in the BOND Controller until deleted by a Supervisor. No user data is stored on the BOND-PRIME Processing Module.
- Slide Images Images of processed slides are collected for tracking the run details of the slide. Slide images are encrypted in the data files and retained on the BOND Controller indefinitely. The images are automatically removed from the BOND-PRIME Processing Module after one day.

Contacting Leica Biosystems

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

Revision record

Rev	Issued	Sections affected	Detail
A10	July 2024	General cautions 4.6 Use the BOND-PRIME Cleaning Kit	Added Proposition 65 caution. Corrected Maintenance screen image.
A09	December 2023	Regulatory notices Glossary of symbols 1.1 About BOND-PRIME 4.1 Maintenance schedules 4.14 Use the BOND-PRIME ARC Refresh Kit	Minor corrections.
A08	May 2023	Legal notices 4.14 Use the BOND-PRIME ARC Refresh Kit	Minor corrections.
A07	January 2023	All 4.14 Use the BOND-PRIME ARC Refresh Kit 6 Specifications 5 Troubleshooting Legal notices	Changed layout of the manual. Added slide count equivalency table. Enhanced slide specifications image. Added Service life and cybersecurity certificate life. Added Troubleshooting chapter. Added Statement of Intended Use of Personal Data.
A06	July 2022	2.10.4 Examples of Reagent Container icons 4.14 Use the BOND-PRIME ARC Refresh Kit 4.1 Maintenance schedules	Removed obsolete reagent container icons. ARC Refresh kit maintenance period changed to 4 months.
A05	April 2022	1.8 Reservoir Cabinet 1.9 AC power switch 1.4 Preload and Unload Drawers 2.5 Preload slides 2.6 Preload Screen 2.7 Unload slides 2.8 Unload Screen 3.4 Preload, process, and unload the slides 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter 4.14 Use the BOND-PRIME ARC Refresh Kit 4.16 Clean the Locked Bulk Reagent Containers 1.11.4 Wash Robots 5.3.3 Manually retrieve slides from ARC Modules 1 BOND-PRIME hardware 4.21 Replace power supply fuses 1.2 The BOND-PRIME Processing Module	Updated images of Reservoir Cabinet. Updated images of Preload and Unload Drawers. Updated image to remove and install Covertile. Added information about refilling the containers. Added notes about being able to manually move Wash Robots. Removed part numbers.

Rev	Issued	Sections affected	Detail
A04	January 2022	5.3 Manually retrieve slides from the processing module Glossary of symbols All	Added instructions for removing slides from the processing module. Updated Glossary of Symbols. Updated Intended Use statement. Various corrections and updates to reflect the latest touchscreen interface and to improve the usability of the manual. Removed Clean the Slide Preparation section.
A03	June 2021	Front cover General cautions 1.1 About BOND-PRIME 1.2 The BOND-PRIME Processing Module 1.7 Bulk Containers 1.11 The Work Surface (under the Hood) 1.11.6 Wash/Prime Stations 1.11.8 Slide Preparation Station 2.3 Status Screen 2.3.1.1 Slides not accepted 2.3.5 Unexpected events during processing 2.4 Action Queue and Alert Banner 2.5 Preload slides 3 Quick start 3.2 Start the processing module 4.1 Maintenance schedules 4.2 Refill the DI Water Container 4.4 Refill the Lot Tracked Bulk Containers 4.5 Empty the Waste Containers 4.6 Use the BOND-PRIME Cleaning Kit 4.8 Wipe internal surface of ARC Modules 4.14 Use the BOND-PRIME ARC Refresh Kit 4.11 Replace the Suction Cup 4.13 Clean the Wash/Prime Stations 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter 4.15 Clean the Bulk DI Water Container 4.16 Clean the Locked Bulk Reagent Containers 4.17 Clean the Waste Containers 4.18 Clean the Sump Tray 6 Specifications	Rebranding. Various corrections, updates and additions etc. in all listed sections affected.
A02	April 2021	All	First release.
A01	-	-	Not released.

Regulatory notices

Intended purpose



The BOND system automates clinical protocols for immunostaining of pathology specimens mounted on microscope slides. Microscope slides subsequently undergo interpretation by a qualified healthcare professional to aid diagnosis.

FCC compliance

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

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



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

CE marking



The CE Mark signifies compliance with the applicable EU Directives as listed on the manufacturer declaration of conformity.

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 and IEC 60601 part 1-2.

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) and/or magnetic fields, as these can interfere with the proper operation.



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

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



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

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 RF 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.

Definitions

ISM: Industrial, Scientific and Medical

RF: Radio Frequency

Glossary of symbols

This section describes the regulatory and safety symbols used in the product labeling.

Regulatory symbols

Explanation of the regulatory symbols used for BOND.



This glossary provides images of the symbols as presented in the relevant standards, however, some of the symbols may vary in color.

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

ISO 15223-1

Medical devices – symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Standard/ Regulation	Reference	Description
	ISO 15223-1	5.1.1	Manufacturer Indicates the medical device manufacturer.
EC REP	ISO 15223-1	5.1.2	Authorized representative in the European community Indicates the Authorized representative in the European Community.
M	ISO 15223-1	5.1.3	Date of manufacture Indicates the date when the medical device was manufactured.
	ISO 15223-1	5.1.4	Use by (expiration date) Indicates the date after which the medical device is not to be used.
LOT	ISO 15223-1	5.1.5	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	ISO 15223-1	5.1.6	Catalog number / Reference number Indicates the manufacturer's catalog number so that the medical device can be identified.
SN	ISO 15223-1	5.1.7	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol	Standard/ Regulation	Reference	Description
	ISO 15223-1	5.1.8	Importer Indicates the entity importing the medical device into the European Union.
	ISO 15223-1	5.1.9	Distributor Indicates the entity distributing the medical device into the locale.
I	ISO 15223-1	5.3.1	Fragile: handle with care Indicates a medical device that can be broken or damaged if not handled carefully.
7	ISO 15223-1	5.3.4	Keep away from rain Indicates that the transport package shall be kept away from rain and in dry conditions.
	ISO 15223-1	5.3.7	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1	5.4.2	Do not re-use Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
[]i	ISO 15223-1	5.4.3	Consult instructions for use Indicates the need for the user to consult the instructions for use.
Ţ	ISO 15223-1	5.4.4	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
IVD	ISO 15223-1	5.5.1	In Vitro Diagnostic medical device Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.

ISO 7000

Graphical symbols for use on equipment — Registered symbols.

Symbol	Standard/ Regulation	Reference	Description
	ISO 7000	1135	Recycle Indicates that the marked item or its material is part of a recovery or recycling process.

Symbol	Standard/ Regulation	Reference	Description
P	ISO 7000	1640	Technical manual: manual for service Identifies the location where the handbook is stored or to identify information that relates to the servicing instructions for the equipment. To indicate that the service manual or handbook should be considered when servicing the device close to where the symbol is placed.
\approx	ISO 7000	2594	Ventilation open Identifies the control that allows outside air into interior environment.
•	ISO 7000	3650	USB Identifies a port or plug as meeting the generic requirements of the Universal Serial Bus (USB). To indicate that the device is plugged into a USB port or is compatible with a USB port.

IEC 60417

Graphical symbols for use on equipment.

Symbol	Standard/ Regulation	Reference	Description
	IEC 60417	5007	On Indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved
	IEC 60417	5008	Off Indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved
	IEC 60417	5009	Stand-by Identifies the switch or switch position by means of which part of the equipment is switched on in order to bring it into the standby condition
	IEC 60417	5016	Fuse Identifies fuse boxes or their location.
	IEC 60417	5019	Protective earth: protective ground A terminal that is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
\sim	IEC 60417	5032	Single phase alternating current Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.

Symbol	Standard/ Regulation	Reference	Description
몽	IEC 60417	5988	Computer network Identifies the computer network itself or to indicate the connecting terminals of the computer network.
\bigcirc_{\circ}	IEC 60417	6057	Caution: moving parts An instructional safeguard to keep away from moving parts.
i	IEC 60417	6222	Information: general Identifies the control to examine the status of the equipment, e.g. multifunctional copying machines

Other symbols and markings

Symbol	Standard/ Regulation	Description
R_{Only}	21 CFR 801.15(c)(1) (i)F	Prescription only Recognized by the US FDA as an alternate to "Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner."
CE	The instrument Declaration of Conformity lists the Directives with which the system complies	European Conformity The instrument Declaration of Conformity lists the Directives with which the system complies.
	Directive 2012/19/EC EU: waste electrical and electronic equipment (WEEE)	Waste Electrical and Electronic Equipment (WEEE) Directive The electronic product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
		The presence of this label indicates that:
		 The device was put on the European Market after August 13, 2005.
		 The device is not to be disposed of via the municipal waste collection system of any member state of the European Union.
		Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment.
	AS/NZS 4417.1	Regulatory Compliance Mark (RCM) Indicates compliance with the Australian Communications Media Authority (ACMA) requirements (safety and EMC) for Australia and New Zealand.

Symbol	Standard/ Regulation	Description
10	People's Republic of China Electronic Industry Standard SJ/T11364	Restriction of Hazardous Substances (RoHS 2) Indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture.
	People's Republic of China Electronic Industry Standard SJ/T11364	Restriction of Hazardous Substances (RoHS 2) Indicates that this electronic information product does not contain any hazardous substances, or they do not exceed the concentration limits specified in GB/T 26572. It is a green environmentally friendly product that can be recycled.
F©	Title 47 United States Code of Federal Regulations Part 15	Federal Communications Commission (FCC) This product has been tested and found to comply with the limits pursuant to part 15 of the FCC Rules.
C UL US	N/A	Underwriters Laboratory (UL) certification mark Underwriter Laboratories have certified that the listed products comply with both US and Canadian safety requirements.
c B os	CSA International	Listed device with CSA Group testing agency CSA Group have certified that the listed products comply with both US and Canadian safety requirements.
c (NTED US	N/A	Listed device with Intertek testing agency Intertek Testing Agency have certified that the listed products comply with both US and Canadian safety requirements.
CH REP	Ordinance on In Vitro Diagnostic Medical Devices (IvDO) of 4 May 2022.	Swiss Authorised Representative Indicates the Swiss Authorised representative.
RH 10% - 95%	N/A	Relative humidity range Indicate the acceptable upper and lower limits of relative humidity for transport and storage. This symbol is accompanied by the applicable relative humidity limits.
A	N/A	Unconnected port This product has an unconnected port on the syringe pump.

Safety symbols

Explanation of the safety symbols used for BOND.

ISO 7010

Graphical symbols — Safety colors and safety signs — Registered safety signs.

Symbol	Standard/ Regulation	Reference	Description
<u>^</u>	ISO 7010	W001	General warning Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
*	ISO 7010	W004	Warning: laser beam Laser hazard. Potential for severe eye damage. Avoid direct eye contact with laser beams.
<u>**</u>	ISO 7010	W007	Warning: floor-level obstacle Floor-level obstacle hazard. Take care when in the vicinity of a floor-level obstacle.
	ISO 7010	W009	Warning: biological hazard Biological hazard. Potential exposure to a biological hazard. Follow directions in the accompanying documentation to avoid exposure.
4	ISO 7010	W012	Caution: risk of electric shock Electrical hazard. Potential risk of electric shock. Follow directions in the accompanying documentation to avoid damage to persons or equipment.
	ISO 7010	W016	Warning: toxic material Toxic hazard. Potential danger of severe health impacts if proper chemical handling procedures are not followed. Use gloves and protective eye wear when handling reagents.
	ISO 7010	W017	Warning: hot surface Heat hazard. Hot surfaces will cause burns if touched. Avoid touching parts identified with this symbol.
	ISO 7010	W020	Warning: Overhead obstacle Overhead obstacle. Take care to avoid being struck by or walking into an overhead obstacle.
	ISO 7010	W021	Warning: flammable material Flammable hazard. Flammable materials may ignite if proper precautions are not followed.

Symbol	Standard/ Regulation	Reference	Description
MINE	ISO 7010	W022	Warning: Sharp element Sharp element. Take care to avoid injury from sharp elements (e.g. needles, blades).
	ISO 7010	W023	Warning: corrosive substance Chemical hazard from a corrosive substance. There is a danger of severe health impacts if proper precautions are not followed. Always wear protective clothing and gloves. Immediately clean up spills using standard laboratory practice.
	ISO 7010	W024	Warning: crushing of hands Crush hazard. Hands or body parts can be crushed by a closing motion of mechanical parts of equipment.
	ISO 7010	W072	Warning: Environmental hazard Environmental hazard. Substance or mixture that can cause an environmental hazard.

General warnings

Warnings are notifications of hazards that could lead to personal injury, or where there is the possibility of losing, damaging, or misidentifying patient samples. Follow all safety precautions to avoid personal injury, damage, loss or misidentification of patient samples, and damage to equipment.

Warnings use symbols with a black border and yellow background.

General BOND-PRIME warnings appear below. Other warnings appear in the relevant sections in the manual.

Processing module operation



To make sure that the BOND-PRIME Processing Module operates correctly, always obey the approved instructions from Leica Biosystems Melbourne Pty Ltd. If you do not obey instructions correctly, this can cause unsatisfactory performance.



BOND-PRIME does not require network access to function and perform its intended use. To prevent malicious or unauthorized access, install BOND-PRIME without any connection to your network / infrastructure.

If you would like network connection, the preferred method is to connect BOND-PRIME to a fire walled Virtual Local Area Network (VLAN). Alternatively, you can implement and validate your own network security mechanisms in accordance with your standard operating procedures.

For more information, refer to the BOND 7+ Information Systems Guide (49.6539.811).



A malware infection on a BOND controller could lead to unexpected behaviors in operation, including disabling processing modules. Take care to ensure your USB storage devices are virus free before connecting them to the BOND controller. Further, Leica Biosystems Melbourne Pty Ltd does not pre-install an anti-virus solution; we recommend that you install your own enterprise anti-virus product. Contact your local Leica Biosystems Melbourne Pty Ltd representative for further information.

Electrical hazards



Only remove the processing module covers or try to access internal components if this document tells you to do so. There are dangerous voltages inside the processing module. Only qualified service technicians approved by Leica Biosystems Melbourne Pty Ltd must do electrical work.



Do not change the processing module's operating voltage. If you connect the processing module to an incorrect power-supply voltage, this can cause damage to the processing module.

Notify customer support if it is necessary to change the setting.



You must connect the processing module to an earthed power-outlet socket, which must be easily accessible.



Do not bypass or short-circuit fuses.

Before you replace a fuse, set the AC power switch on the processing module to OFF and disconnect the power-supply cable from the rear cover of the processing module. Use only approved replacement fuses. If it is necessary to regularly replace fuses, notify customer support.

Chemical hazards



Make sure that you correctly install the caps on removable bulk containers and reservoirs.

Do not let a flame or other source of ignition near the processing module. Some of the reagents in the bulk containers and reservoirs are flammable.



To prevent a fire, do not put flammable material on or near hot surfaces on the processing module.

Mechanical hazards



Use both hands when you lift the DI Water and Bulk/Hazardous Waste Containers for cleaning and maintenance tasks.



Before you try to operate the processing module, close the Hood. The processing module has interlocks that prevent operation when the Hood is open. Do not try to bypass the interlocks.



If the High-Speed Robot gets stuck in a position above the Work Surface, do not attempt to manually move it. Contact customer support about the problem.



When you close the Hood, make sure that your hands are away from the opening. The Hood is heavy and can cause injury.

While the processing module operates, the Hood is locked in the closed position. Do not try to open the Hood.



The High-Speed Robot and Wash Robots must not continue to operate when the Hood is open. If they do continue to operate, immediately notify customer support about the problem.



While the processing module operates, do not put your hands inside the Reagent Platform opening. The High-Speed Robot can move quickly and suddenly during operation.



If you need to move a processing module a long distance to a new location, notify customer support. The processing module is very heavy. Only approved personnel must move the processing module.

Processing module operation



To prevent contamination of reagents and slides, only operate the processing module in a clean environment as free as possible from dust and particulate matter.



To prevent contamination and unsatisfactory performance, make sure that you correctly install the Bulk Containers. The Bulk Container stations have color-coded name labels.

Refer to 1.7 Bulk Containers.

General cautions

Cautions are notifications of hazards that could lead to damage to the BOND equipment or other adverse consequences that do not endanger people.

Cautions use symbols with a black border and white background

General BOND-PRIME cautions appear below. Other cautions appear in relevant sections in the manual.

Personal Protective Equipment (PPE)

You must wear the minimum required PPE before you use reagents, operate, maintain or clean the processing module:

- Laboratory gloves
- Safety glasses
- Suitable protective clothing, for example a lab coat

Installation hazards



Do not seal the ventilation openings on the rear cover of the processing module.

Operational hazards



Position all parts of the slide label within all slide edges. An exposed sticky surface can cause the slide label (and slide) to stick to the Covertile or other equipment and damage the slide.



Do not leave any moisture or sticky residue on the slide label area as it can cause damage.



You must clean removable parts by hand only. To prevent damage, do not clean parts in an automatic dishwasher. Do not use solvents or harsh or abrasive materials to clean parts.



Do not use force when you install bulk containers. This can cause damage to the container.



Do not use damaged slides.



This product can expose you to chemicals including lead, which are known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information, go to https://www.P65Warnings.ca.gov.

Reagent hazards



Bulk reagents that are not compatible can cause unsatisfactory performance and damage to the processing module.

Refer to Leica Biosystems Melbourne Pty Ltd for information about compatible bulk reagents.



Do not use xylene, chloroform, acetone, strong acids (for example 20% HCl), strong alkalis (for example 20% NaOH) on BOND-PRIME Processing Modules.

If there is a spill of these chemicals on or near a processing module, clean the area immediately with 70% ethanol to prevent damage to the processing module covers.



Use only BOND-PRIME Dewax Solution, BOND-PRIME ER1, BOND-PRIME ER2 Solutions and BOND-PRIME Wash Solution Concentrate on BOND-PRIME Processing Modules.

Do not use xylene, xylene substitutes and other reagents that can degrade parts of the BOND-PRIME Processing Module and cause fluid leaks.

BOND-PRIME hardware

In this section:

1.1 About BOND-PRIME	25
1.2 The BOND-PRIME Processing Module	28
1.3 The Hood	30
1.4 Preload and Unload Drawers	31
1.5 Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter	32
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1.13 Disconnect the processing module	51
1.14 Move a processing module to a new location	53
1.15 Decommission and dispose of a processing module	55

1.1 About BOND-PRIME

The intended users of BOND-PRIME are adequately trained laboratory personnel.

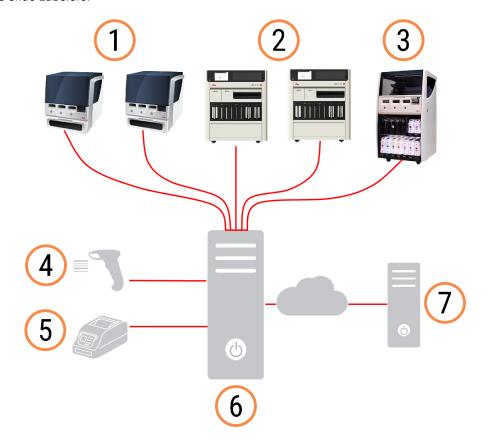
The BOND-PRIME has these primary components:

- One or more processing modules
- A BOND Controller or a BOND-ADVANCE Controller.



A BOND-ADVANCE System also has Terminals, and can include a secondary (backup) Controller.

- One or more hand-held Barcode Scanners
- One or more Slide Labelers.



- 1 BOND-MAX Processing Module
- 2 BOND-PRIME Processing Module
- 3 BOND-III Processing Module
- 4 Handheld Barcode scanner

- 5 Slide Label Printer
- 6 BOND Controller
- 7 LIS connection

Each new BOND-PRIME Processing Module has:

- Removable Preload Slide Drawer Insert
- Removable Unload Slide Drawer Insert
- Single Reagent Trays
- · Ethernet cable.

Other necessary items are:

- BOND-PRIME Detection Systems
- BOND-PRIME Ready-To-Use (RTU) reagents or concentrates
- BOND-PRIME Open Containers.

Refer to www.leicabiosystems.com for a full and up-to-date list of consumable items and spare parts.

1.1.1 BOND-PRIME ancillary materials and consumable items

Leica Biosystems Melbourne Pty Ltd supplies the following ancillary materials for use with the BOND-PRIME Processing Module.

To get best-quality stained slides and to prevent damage, do not use alternative ancillary materials.

Ancillary reagents

- BOND-PRIME Dewax Solution
- BOND-PRIME Wash Solution Concentrate
- BOND-PRIME Epitope Retrieval Solution 1
- BOND-PRIME Epitope Retrieval Solution 2
- BOND-PRIME Hematoxylin
- BOND-PRIME Cleaning Kit

Consumable items

- BOND Plus Slides or acceptable glass slides (refer to 6.6 Microscope slide specifications)
- BOND Open Containers (7 mL), 10 pack
- BOND Open Containers (30 mL), 10 pack
- BOND Titration Kit, 10 containers, 50 inserts
- BOND Slide Label and Print Ribbon Kit
- BOND-PRIME ARC Refresh Kit:
 - 24 ARC Covertiles
 - 1 Mixing Well Plate

Spares

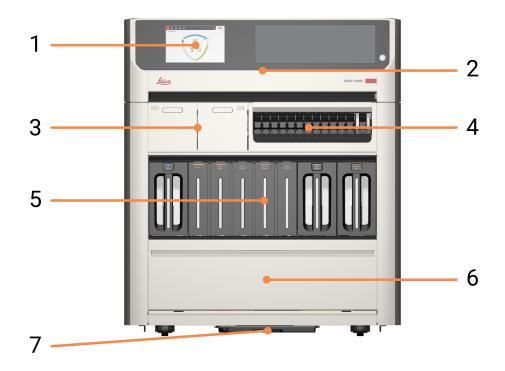
• BOND-PRIME Suction Cups

Required Reagents (not supplied by Leica Biosystems Melbourne Pty Ltd)

- Reagent-grade alcohol
- DI water

1.2 The BOND-PRIME Processing Module

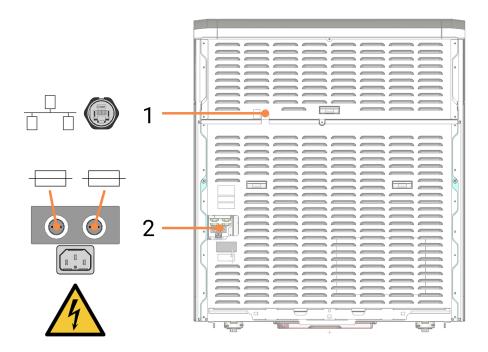
1.2.1 Front view



- 1 2 Touchscreen
- 2 1.3 The Hood
- 3 1.4 Preload and Unload Drawers
- 4 1.6 Reagent Platform

- 5 1.7 Bulk Containers
- 6 1.8 Reservoir Cabinet
- 7 Sump Tray

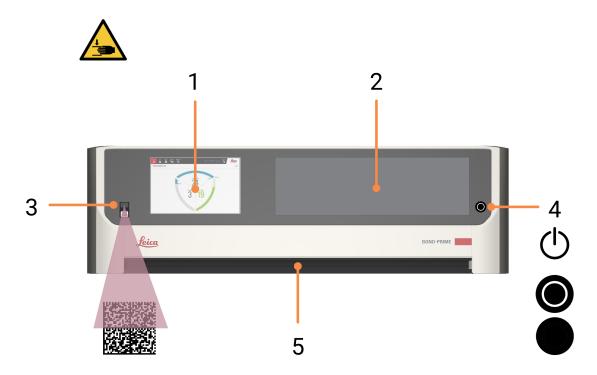
1.2.2 Rear view



- 1 Ethernet connection
- 2 Fuses and power-supply connection

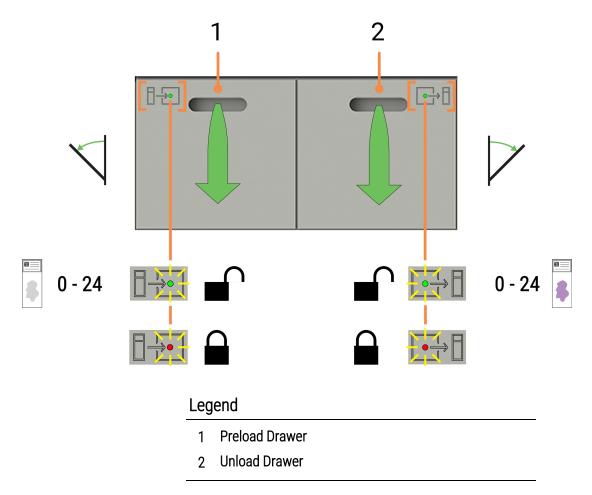


1.3 The Hood



- 1 2 Touchscreen
- 2 Viewing window
 Allows you to see the Work Surface while the processing module is in operation.
- 3 Barcode Scanner Used to scan bulk reagent supply bottles and the ARC Refresh Kit.
- 4 Standby power button with white LED Indicates when the processing module is on (white) or off (unlit).
- 5 Handle
 Used to open and close the Hood.

1.4 Preload and Unload Drawers



See also:

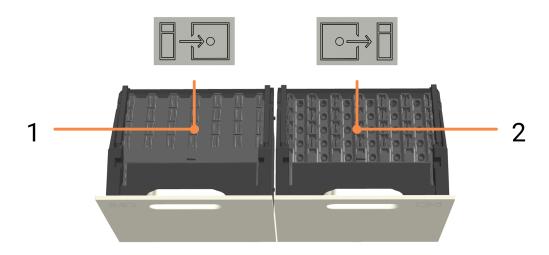
- 2.5 Preload slides
- 2.7 Unload slides
- 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter

1.5 Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter

1.5.1 Slide Drawer Inserts







Legend

- 1 Preload Slide Drawer Insert
- 2 Unload Slide Drawer Insert

See also:

- 2.5 Preload slides
- 2.7 Unload slides
- 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter

1.5.2 Waste Drains







Legend

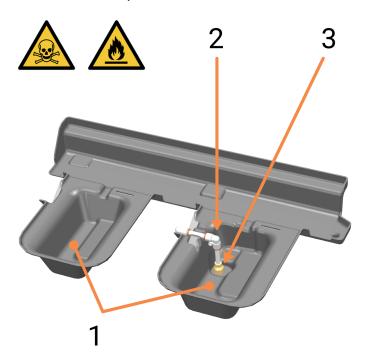
- 1 Preload Waste Drain
- 2 Unload Waste Drain

The Waste Drains are accessible after removal of the Slide Drawer Inserts from the opened drawers.

See also:

• 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter

1.5.3 Sumps and Pickup Tube with Filter



Legend

- 1 Sumps
- 2 Unload Drawer Pickup Tube
- 3 Pickup Filter

The Sumps are located under and behind the Preload and Unload Drawers. They are accessible via the Work Surface after fully opening the drawers.

In the Sump under the Unload Drawer, the Pickup Tube and Filter are used to extract the waste water that collects when the Unload Drawer is opened and closed.

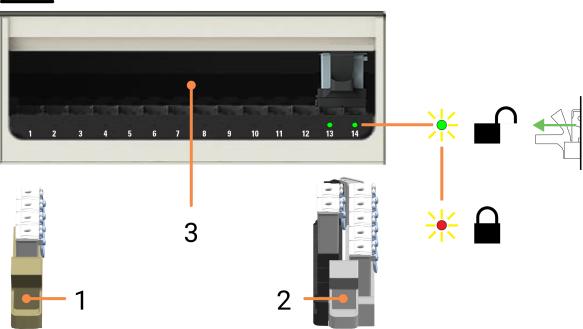
If there is liquid build up in a Sump, it might be because the Pickup Filter is blocked. Refer to 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter.

See also:

• 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter

1.6 Reagent Platform





Legend

- 1 Single Reagent Tray
- 2 Dual Reagent Tray

3 Reagent Platform with 14 lanes (total capacity of 70 reagent containers, in any combination of single and dual trays)

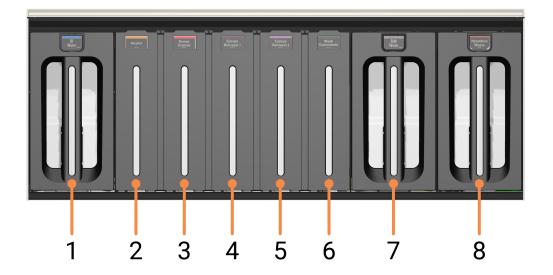
See also:

- 1.10 Reagent Trays
- 2.10.1 Prepare Reagent Container and Reagent Trays
- 2.10.2 Load Reagent Trays
- 2.10.6 Unload Reagent Trays
- 4.9 Wipe down Reagent Platform and ARC Bank Surfaces

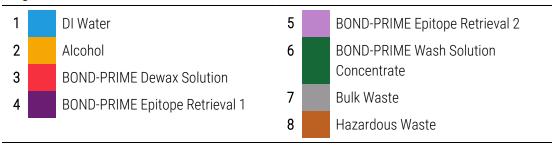
1.7 Bulk Containers







Legend





WARNING: Use both hands when you lift the DI Water and Bulk/Hazardous Waste containers for cleaning and maintenance tasks.

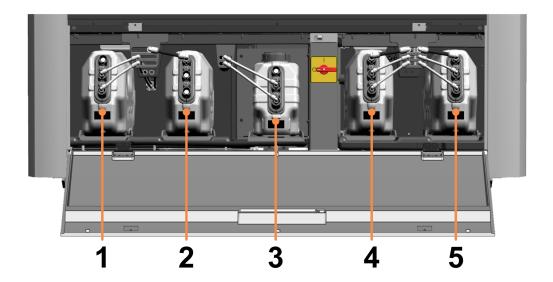
See also:

- 4.2 Refill the DI Water Container
- 4.15 Clean the Bulk DI Water Container
- 4.3 Refill the Alcohol Container
- 4.16 Clean the Locked Bulk Reagent Containers
- 4.4 Refill the Lot Tracked Bulk Containers
- 4.17 Clean the Waste Containers
- 4.5 Empty the Waste Containers

1.8 Reservoir Cabinet







Legend

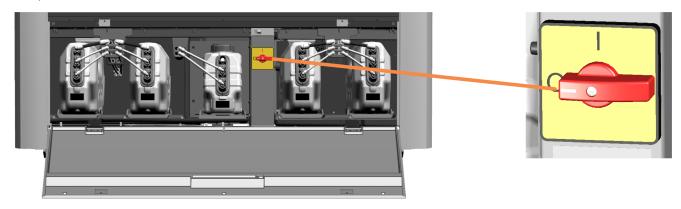
1	DI Water Reservoir	5L
2	Vacuum Reservoir	
3	BOND-PRIME Wash Working Solution Reservoir	1L
4	Bulk Waste Reservoir	5L
5	Hazardous Waste Reservoir	5L



WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.

1.9 AC power switch

The AC power switch is located in the Reservoir Cabinet.



Switch positions:

I ON

O OFF

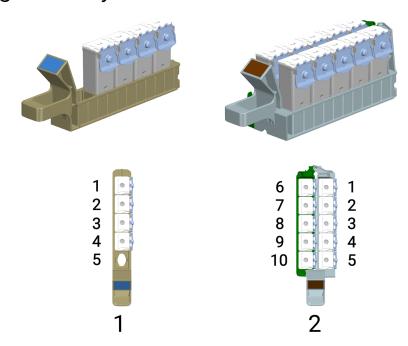


WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.

See also:

- 1.12 Connect the processing module and switch on
- 1.13 Disconnect the processing module

1.10 Reagent Trays



Legend

- Single Reagent Tray
 Can hold up to 5 reagent containers.
- 2 Dual Reagent Tray
 Can hold up to 10 reagent containers, although some reagent systems have only
 6 containers. You can insert additional reagent containers, for example the
 ancillary BOND-PRIME Hematoxylin (AR0096), into empty locations.

All BOND reagent containers and BOND-PRIME reagent systems must be registered on the BOND Controller before use.

See also:

- 1.6 Reagent Platform
- 2.10.1 Prepare Reagent Container and Reagent Trays
- 2.10.2 Load Reagent Trays
- 2.10.6 Unload Reagent Trays



Refer to the BOND 7 User Manual.

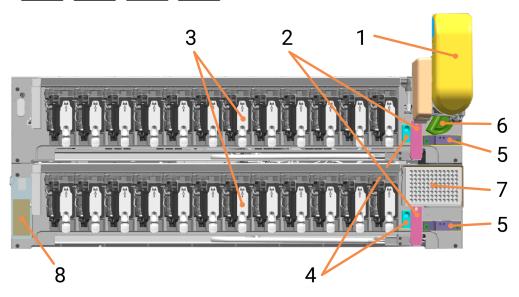
1.11 The Work Surface (under the Hood)











Legend

- 1 1.11.2 High-Speed Robot
- 2 1.11.4 Wash Robots (2)
- 3 1.11.5 ARC (Active Reagent Control) Modules
 - Bank A (rear) numbered 1-12 from left to right
 - Bank B (front) numbered 1-12 from left to right
- 4 1.11.6 Wash/Prime Stations

Wash Stations (for Wash Robots)

5 1.11.6 Wash/Prime Stations

For the ARC Probe on the High-Speed Robot:

- Standard Wash Station (rear)
- Hazardous Wash Station (front)
- 6 1.11.6 Wash/Prime Stations

Prime Station (for Bulk Reagent Probes)

- 7 1.11.7 Mixing Well Plate
- 8 1.11.8 Slide Preparation Station

See also:

- 4.14 Use the BOND-PRIME ARC Refresh Kit
- 4.7 Start Maintenance
- 5.3.3 Manually retrieve slides from ARC Modules
- 4.8 Wipe internal surface of ARC Modules
- 4.9 Wipe down Reagent Platform and ARC Bank Surfaces
- 4.13 Clean the Wash/Prime Stations

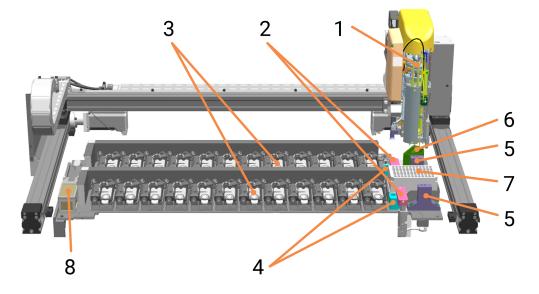
1.11.1 Work Surface (front view)









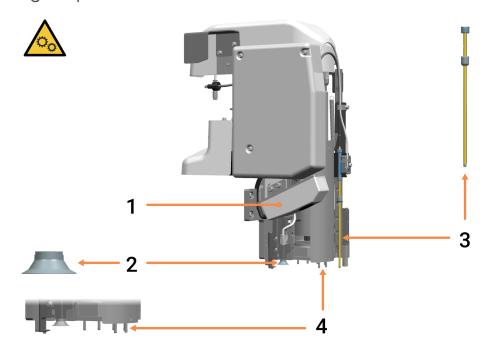


Legend

- 1 1.11.2 High-Speed Robot
- **2** 1.11.4 Wash Robots (2)
- 3 1.11.5 ARC (Active Reagent Control) Modules
 Bank A (rear) numbered 1-12 from left to right.
 Bank B (front) numbered 13-24 from left to right
- 4 1.11.6 Wash/Prime StationsWash Stations (for Wash Robots)

- 5 1.11.6 Wash/Prime Stations
 - For ARC Probe on High-Speed Robot: Standard Wash Station (rear) and Hazardous Wash Station (front)
- 6 1.11.6 Wash/Prime StationsPrime Station (for Bulk Reagent Probes)
- 7 1.11.7 Mixing Well Plate
- 8 1.11.8 Slide Preparation Station

1.11.2 High-Speed Robot



Legend

- 1 ID Imager
- 2 Suction Cup

For moving slides from Preload Drawer to ARC Modules to Unload Drawer.

Refer to 1.4 Preload and Unload Drawers and 1.11.5 ARC (Active Reagent Control) Modules.

3 ARC Probe

Dispenses reagents obtained from reagent to ARC Modules from:

- containers loaded on Reagent Platform.
 Refer to 1.6 Reagent Platform.
- mixed reagents obtained from Mixing Well Plate. Refer to 1.11.7 Mixing Well Plate.
- 4 Bulk Reagent Probes (also see next page)
 Dispense bulk reagents from bulk reagent containers to ARC Modules. Refer to 1.7 Bulk Containers.

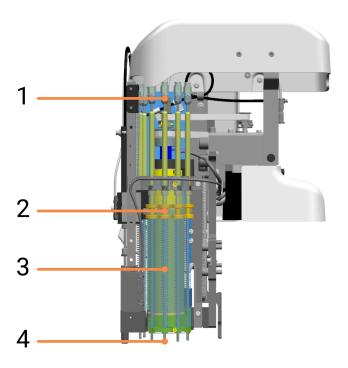


WARNING: If the High-Speed Robot gets stuck in a position above the Work Surface, do not attempt to manually move it. Contact customer support about the problem.

See also:

- 4.10 Clean the Suction Cup
- 4.11 Replace the Suction Cup

1.11.3 Probe Selector



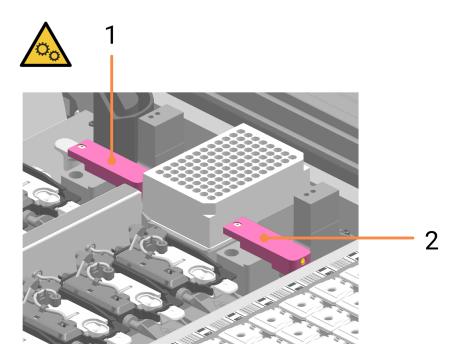
Legend

- 1 Tubing connectors
- 2 Bulk Reagent Probe Ferrules

- 3 Compression Springs
- 4 Bulk Reagent Probes

The Bulk Reagent Probes are attached to the Probe Selector on the Robot Head. The Probe Selector carousel rotates to position the required probe above an ARC Module.

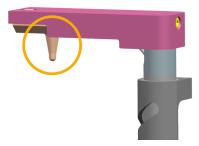
1.11.4 Wash Robots



Legend

- 1 Wash Robot (for ARC Modules Bank A)
- 2 Wash Robot (for ARC Modules Bank B)

Wash Robot Probe





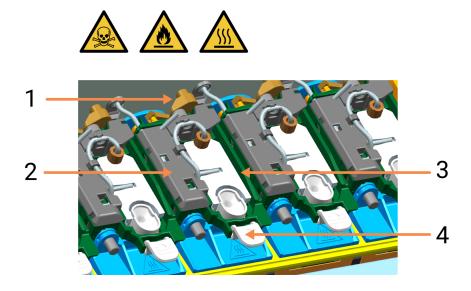
During maintenance, you can manually move the Wash Robots to gain better access to the ARC Modules.

If a Wash Robot gets stuck in a position above the Work Surface, do not attempt to manually move it anymore. Contact customer support about the problem

1.11.5 ARC (Active Reagent Control) Modules

Twenty-four ARC Modules mounted on two ARC Banks hold slides during staining. Collectively, they are known as the ARC Array. Reagents are dispensed by the Bulk Reagent Probes and the ARC Probe on the Robot Head. ARC Modules are cleaned using DI Water and BOND-PRIME Wash Working Solution dispensed by the Wash Robots.

Waste from the ARC Modules is directed to the Hazardous Waste Reservoir.



Legend

- ARC Module Latch
- 2 ARC Module Cover

- 3 ARC Module Lid Assembly
- 4 ARC Covertile:



If the Action Queue (see Action Queue and Alert Banner (on page 68)) indicates that an ARC Module is faulty, check that it has a Covertile.

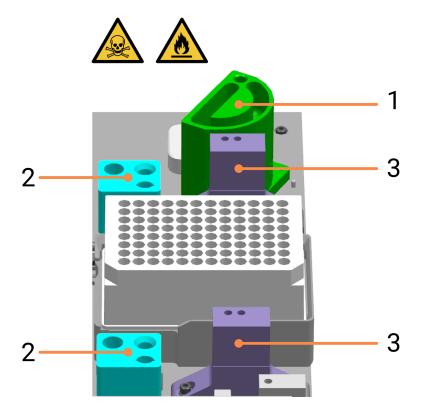
If an ARC Module is leaking, check the:

- condition of the Covertile and Covertile seal, and if necessary, replace the Covertile.
- ARC Module for debris, and if necessary, clean (Wipe internal surface of ARC Modules (on page 126)).

See also:

- 4.8 Wipe internal surface of ARC Modules
- 4.14 Use the BOND-PRIME ARC Refresh Kit
- 5.3.3 Manually retrieve slides from ARC Modules

1.11.6 Wash/Prime Stations



Legend

- 1 Bulk Probe Prime Station
- Wash Robot Wash Stations The right-hand port is used for washing.
- 3 ARC Probe Wash Stations
 The right-hand port is used for washing.

Waste liquid from:

- the ARC Probe Wash Station on Bank A (rear) is directed to the Bulk Waste Reservoir
- the ARC Probe Wash Station on Bank B (front) is directed to the Hazardous Waste Reservoir
- both Wash Robot Wash Stations is directed to the Hazardous Waste Reservoir.

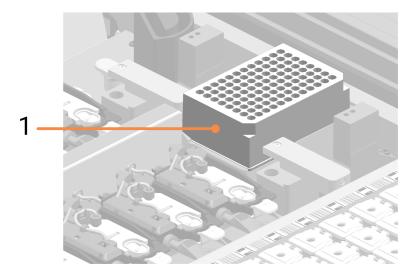
See also:

• 4.13 Clean the Wash/Prime Stations

1.11.7 Mixing Well Plate







Legend

1 Mixing Well Plate

This is where chromogen reagents are mixed before being dispensed onto slides in the ARC Modules by the ARC Probe. Refer to 1.11.5 ARC (Active Reagent Control) Modules and 1.11.2 High-Speed Robot.

The orientation of the Mixing Well Plate on the Mixing Block is not important, however it must be seated correctly within the holder.



The processing module will not complete initialization if there is no Mixing Well Plate installed.

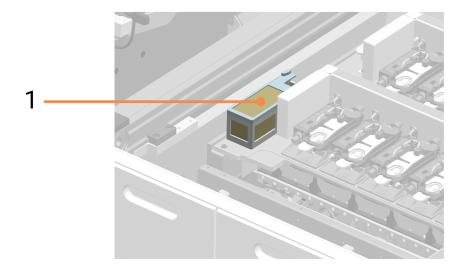
See also:

• 4.14 Use the BOND-PRIME ARC Refresh Kit

1.11.8 Slide Preparation Station







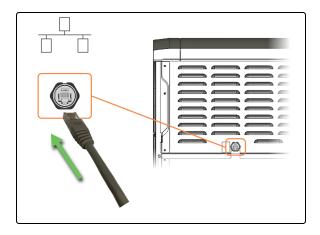
Legend

1 Slide Preparation Station



Before each slide is transferred to an ARC Module for processing, it is cleaned using compressed air jets in the Slide Preparation Station. This is designed to remove unwanted particles, particularly glass particles, from the slide surfaces so that the staining process is not compromised.

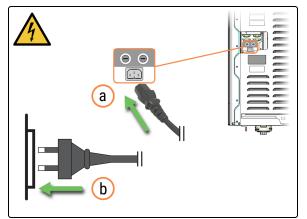
1.12 Connect the processing module and switch on



1. Plug in the Ethernet cable to the laboratory network port.



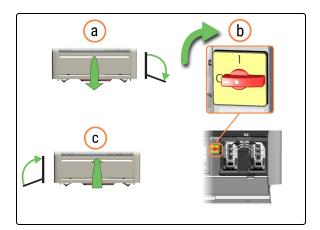
You may need to move the processing module for better access to the rear-panel connectors.



- 2. Plug in the mains power cable.
 - **a.** Plug the mains power cable into the rear of the processing module.
 - b. Plug the mains power cable into the wall socket.



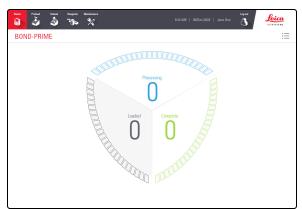
You may need to move the processing module for better access to the rear-panel connectors.



- 3. Power on the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch clockwise.
 - c. Close the Reservoir Cabinet door.



4. When the processing module is turned on, it initializes before displaying the Log In Screen. This process takes from 8 to 15 minutes. If the processing module fails to initialize, refer to 5.1 Failure to initialize.



The Status screen is displayed.

1.13 Disconnect the processing module

You must shut down and disconnect the processing module:

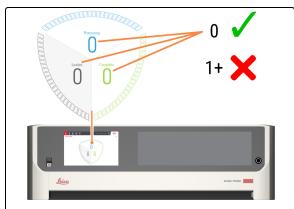
- · before moving the processing module to a new location
- · before decommissioning the processing module



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

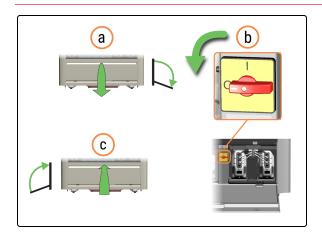


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

Refer to 2.3 Status Screen.



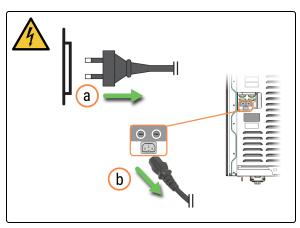
- 3. Power down the processing module.
 - a. Press the standby power button.A pop up window indicates that it is safe to shut down the processing module.
 - b. Tap Close.



- 4. Power off the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch counterclockwise.
 - c. Close the Reservoir Cabinet door.



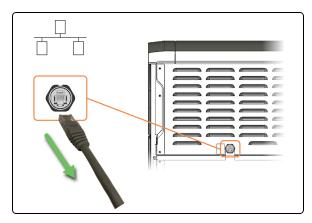
WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.



- 5. Unplug the mains power cable.
 - a. Unplug the mains power cable from the wall socket.
 - b. Unplug the mains power cable from the rear of the processing module.



You may need to move the processing module for better access to the rear-panel connectors.



6. Disconnect Ethernet cable from rear of of the processing module.

1.14 Move a processing module to a new location



WARNING: If you need to move a processing module a long distance to a new location, notify customer support. The processing module is very heavy. Only approved personnel should move the processing module.



CAUTION: Do not seal the ventilation openings on the rear cover of the processing module. Make sure there is sufficient airflow at the new location.



CAUTION: Do not use a forklift to lift a BOND-PRIME Processing Module.

If it is necessary to move a processing module only a short distance to a new location:

- Disconnect the processing module. Refer to 1.13 Disconnect the processing module.
- Empty the waste containers. Refer to 4.5 Empty the Waste Containers.
- Remove and clean the Sump Tray. Refer to 4.18 Clean the Sump Tray.
- Before you attempt to move a BOND-PRIME Processing Module, use a spanner to rotate the orange gears on the four wheel assemblies. Raise the central feet to allow the processing module to move freely on its wheels.



• Push **only** on the allowable push zones, shown highlighted in orange.







- At the new location, which should have a level surface, rotate the orange gears to lower the central feet until the processing module cannot move freely on its wheels.
- Adjust the height of the feet in the wheel assemblies to make sure that the processing module is level in all directions. Use a spirit level on top of the hood as a guide.
- Make sure that the floor has sufficient strength. Obey all local and relevant procedures. To find the dimensions and weight of the processing module, refer to 6 Specifications.
- Use only the approved power supply cable. Make sure that you can get access to the wall socket.
- Evaluate the electromagnetic environment prior to operation of the processing module for interference.



CAUTION: Do not operate a BOND-PRIME Processing Module near sources of strong electromagnetic radiation. For example unshielded intentional RF sources, which may interfere with proper operation.

1.15 Decommission and dispose of a processing module

The processing module, including parts and associated accessories used, must be disposed of according to applicable local procedures and regulations. Dispose of any reagents used with the processing module in accordance with the recommendations of the reagent manufacturer.

Clean and decontaminate in accordance with local procedures and regulations before returning or disposing of the processing module or parts and accessories.

In the EU, all electronic waste must be disposed of in accordance with Waste Electrical and Electronic Equipment (2012/19/EU). In regions outside of the EU, follow local procedures and regulations for the disposal of electronic waste.

If you need assistance, contact your local Leica Biosystems representative.

2

Touchscreen



In this section:

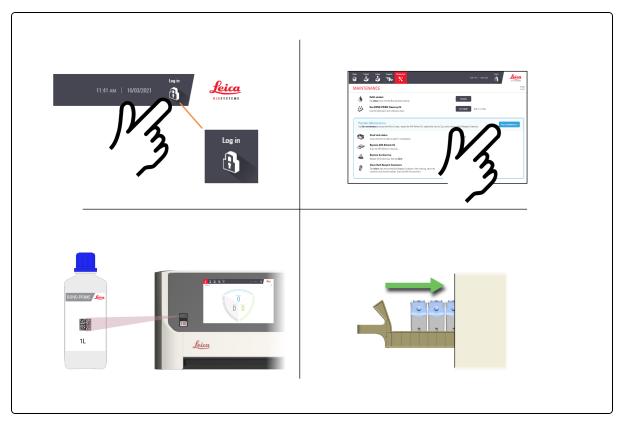
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2.8 Unload Screen	80
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2.10 Reagents Screen	88
2 11 Maintenance Screen	95

2.1 Log in and log out

2.1.1 Log in

If nobody is logged in, various actions will cause the **Log in** dialog to appear, for example:

- tapping the Log in button
- tapping the **Start maintenance** button on the **Maintenance** screen
- scanning the barcode on a bulk reagent supply bottle
- loading a Reagent Tray onto the Reagent Platform





- 1. Log in to the touchscreen.
 - a. On the Log in Screen, tap your user name.
 - b. Enter your PIN.

When you have logged in successfully, your name is displayed next to the date.



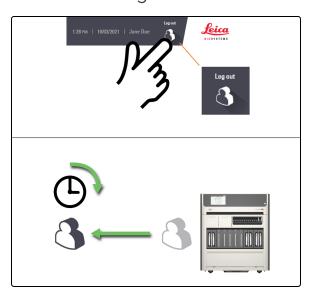


Refer to the BOND 7 User Manual for information about setting or changing your PIN.



Patient Health Information is visible on the GUI when logged in, and hidden when logged out.

2.1.2 Log out



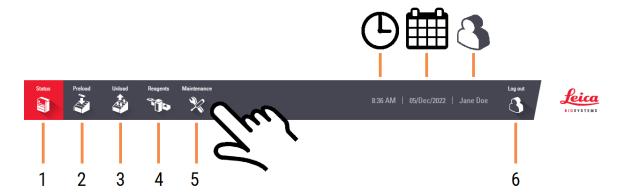
1. Tap the **Log out** button.

Or, if you do not interact with the processing module for a pre-determined time period, you will be logged out automatically.



You can change this time period in the Administration Client on the BOND Controller. Refer to the BOND 7 User Manual.

2.2 Navigation Bar

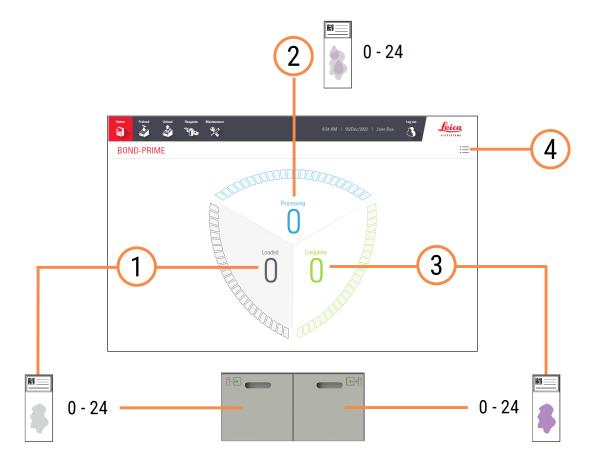


Legend

- 1 2.3 Status Screen
- 2 2.6 Preload Screen
- 3 2.8 Unload Screen

- 4 2.10 Reagents Screen
- 5 2.11 Maintenance Screen
- 6 Log in / Log out refer to 2.1 Log in and log out

2.3 Status Screen



Legend

- 1 2.3.1 Slides Loaded Segment
- 2 2.3.2 Slides Processing Segment
- **3** 2.3.3 Slides Processing Complete Segment
- 4 Action Queue button.
 Refer to 2.4 Action Queue and Alert Banner

2.3.1 Slides Loaded Segment

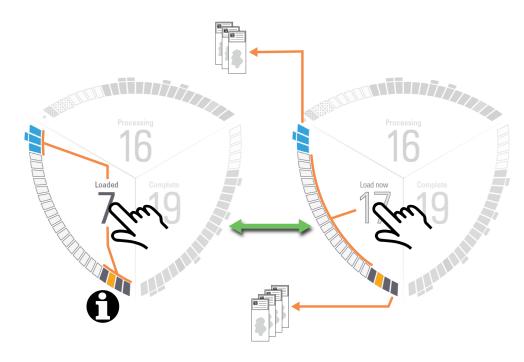
To alternately show the **Loaded** and **Load now** slide count, tap the displayed value.

After new slides are loaded into the Preload Drawer, they initially appear at the bottom of the segment and are grey. When slides are accepted, they move to the top of the segment and change to blue, earliest first. Slides that are not accepted remain at the bottom of the segment.



There is no relationship between slide positions in the Slides Loaded Segment and in the Preload Drawer.

Also refer to 2.3.4 View more slide information



Icon	Description
	Slide position available.
	Slide identified.
1	Last slide (of the loaded slides) in a case. When the last slide is accepted, this icon changes to blue.
	Slide accepted. Slides not accepted remain at the bottom of the segment. Also refer to 2.3.1.1 Slides not accepted.
	Rejected time-critical slide, or a slide with status "Warning".
	Rejected slide, or a slide with status "Caution".

2.3.1.1 Slides not accepted

On rare occasions, the processing module may fail to evaluate and accept a loaded slide.



When this happens, the slide remains at the bottom of the segment for an extended period.

To rectify this situation, you should:

- 1 Remove the slide from the Preload Drawer, then close the drawer.
- 2 Wait for the processing module to scan the drawer and update the Status screen.
- 3 Reload the slide into the Preload Drawer. The processing module should now be able to identify the slide and accept it for processing.

2.3.2 Slides Processing Segment

To alternately show the **Processing** and **Start now** slide count, tap the displayed value.

When slides are transferred to the ARC Modules for processing, they appear at the right of the segment, earliest first.

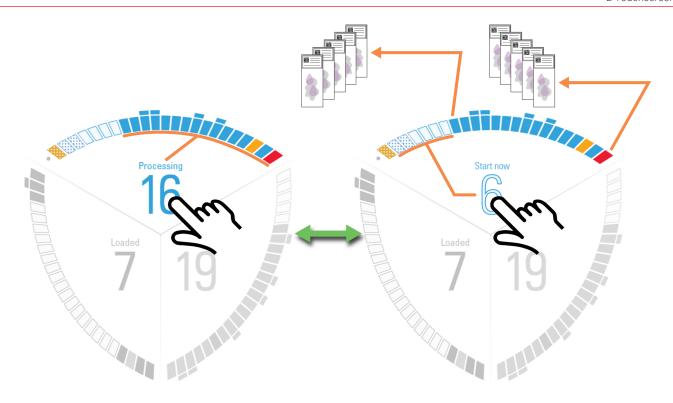
There is no relationship between slide positions in the Slides Processing Segment and in the ARC Modules.

Also refer to 2.3.4 View more slide information.

Status Screen updates

The processing module may not always prioritize loading slides. This is because the processing module automatically performs a basic clean of each ARC Module in between processing slides.

The basic cleaning process helps to ensure that the staining quality is maintained at a high level for every slide processed.



Icon	Description
	Slide position available
	A slide with status "Caution". Refer to 2.3.5 Unexpected events during processing.
	Last slide in a case
	Slide processing in progress
	Slide completed
	Faulty or disabled ARC Module. Refer to 1.11.5 ARC (Active Reagent Control) Modules
	The BOND-PRIME Cleaning kit is currently being applied, or a basic clean is being run between slides.
	ARC Module usage count has been reached. The ARC Module is disabled until the BOND-PRIME Cleaning kit is applied.
	Abandoned or canceled slide, or a slide with status "Warning".
	Abandoned slides remain in the ARC Module and need to be manually retrieved. Refer to 5.3.3 Manually retrieve slides from ARC Modules. Canceled slides are transferred to the Unload Drawer.

2.3.3 Slides Processing Complete Segment

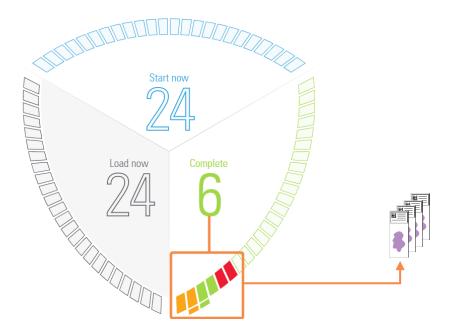
When completed slides are transferred from the ARC Modules to the Unload Drawer, they appear at the bottom of the segment, earliest first.

If the Unload Drawer is full, "slide completed" icons appear in the Slides Processing Segment until they can be transferred to the Slides Processing Complete Segment.



There is no relationship between slide positions in the Slides Processing Complete Segment and in the Unload Drawer.

Also refer to 2.3.4 View more slide information.



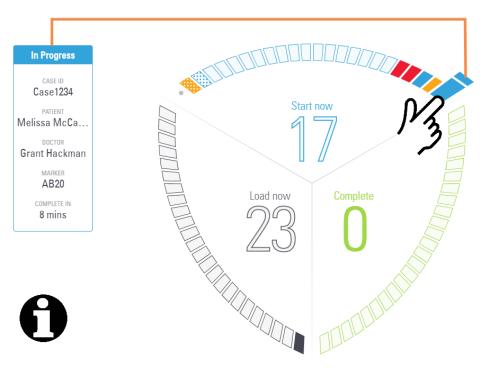
lcon	Description
	Slide position available
	Slide completed
	Last completed slide in a case
	Canceled slide or a slide with status "Warning"
	A slide with status "Caution"
	Also refer to 2.3.5 Unexpected events during processing

2.3.4 View more slide information

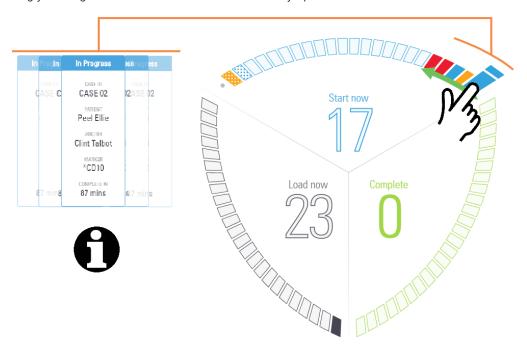
You must be logged in to view "protected" case and slide information.

Refer to 2.1 Log in and log out

Tap on a slide in the segment to view related slide information. Tap on the presented slide image to open the case window and view related case information.



Drag your finger from slide-to-slide to continuously update the information shown.



Also refer to 2.9 Detailed case and slide information for additional information concerning slide properties, start/finish times and case properties.

2.3.5 Unexpected events during processing

If you see an Action Queue Item (AQI) regarding an unexpected event that occurred during processing, you must take extra steps to confirm that the flagged slide is suitable for diagnostic use.

This notification does not necessarily indicate that staining was in any way unsatisfactory, however the system operator or laboratory supervisor must:

- 1 Examine the **Slide history** screen on the BOND Controller (refer to the *BOND 7 User Manual*).
- 2 Look for a slide with the status **Done (events noted)** that has the same **Slide ID** as the flagged slide removed from the BOND-PRIME Processing Module.
- 3 Select this slide then click the **Run events** button to generate the Run Events Report.
 - Any events that caused a notification are displayed in **Bold** text. The system operator or laboratory supervisor should carefully consider the notification events listed, as these provide important details about the nature of the slide notification events.
- 4 Carefully inspect any control slides.
- 5 Carefully inspect the stained tissue.

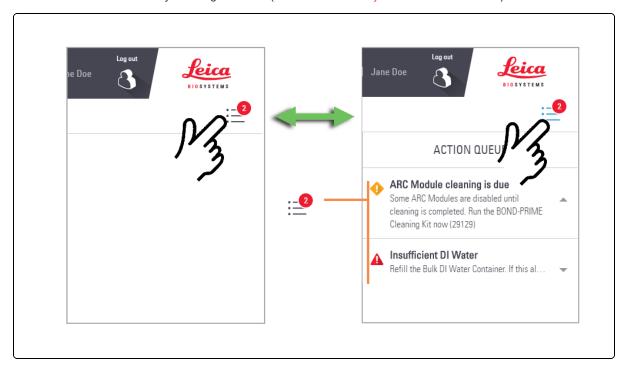
If the laboratory is unable to confirm the staining quality, then either the pathologist should be informed of the notification or the test should be rerun. Multiple notifications may be present within a single Run Events Report. If the slide completes with status **Done (events noted)**, ensure that the entire report is inspected. If the status is **Done (OK)**, there is no need to inspect the report.

2.4 Action Queue and Alert Banner

2.4.1 Show and hide the Action Queue

The Action Queue is a list of important messages concerning the status of the processing module, reagents, and/or slides. These messages can provide information about the processing module or an instruction to perform a maintenance task.

When there is a new Action Queue Item (AQI), an Alert Banner is displayed across the bottom of the Touchscreen. You can hide the Alert Banner by clicking on the X (see 2.4.3 Manually hide the Alert Banner).



- 1 To show or hide the Action Queue, tap the Action Queue button.
- 2 To show more or less information about each item in the Action Queue, tap the arrow to the right of the item.

The level of importance of each Action Queue item is indicated by an icon:



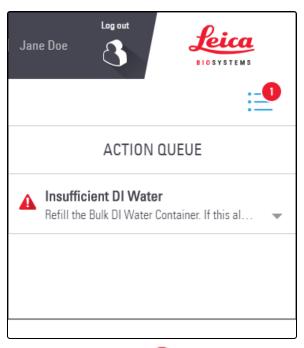
The number on the Action Queue button reflects the number of Warnings and Cautions only.

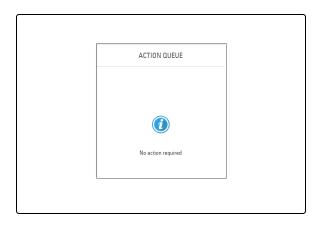
2.4.2 Complete a task suggested in an Action Queue Item

When you complete a task stated in an Action Queue Item, the item is automatically removed from the Action Queue and the Alert Banner is closed.

Action Queue Items providing information about a slide will remain in the Action Queue until that slide has finished the run and is removed from the processing module.

For maintenance related tasks, refer to 4 Cleaning and maintenance.

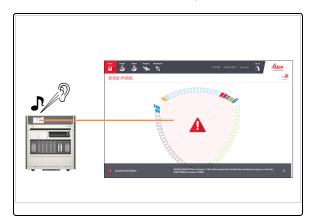




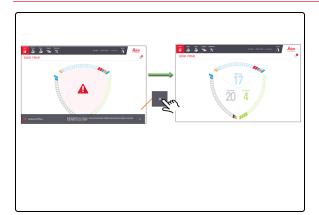




2.4.3 Manually hide the Alert Banner



When the Alert Banner is displayed, an audible alarm sounds when immediate action is required.



1. Tap the **X** in the banner at the bottom of the screen.



Although the BOND-PRIME software allows you to manually hide the Alert Banner, Leica Biosystems Melbourne Pty Ltd recommends that you should, if possible, complete the suggested task.

Refer to 2.4.2 Complete a task suggested in an Action Queue Item.

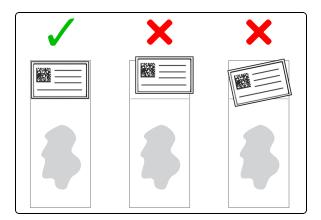
2.5 Preload slides



WARNING: You must wear the minimum required Personal Protective Equipment (PPE) before you use reagents or operate the processing module. Refer to **General cautions**.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.

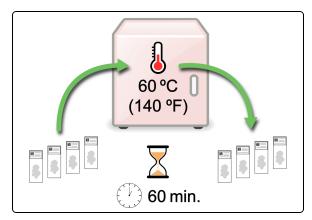


Make sure the slide labels are correctly affixed and positioned wholly on the slide.

Do not stack more than two labels on a slide.

Slides must be free of:

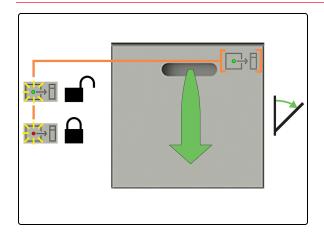
- excess moisture and debris, for example dust, wax and glass chips.
- sticky residue from removed/re-affixed labels.



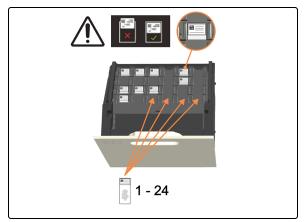
1. Bake slides at 60 °C (140 °F) for 60 minutes to improve tissue adhesion.



The Preload Drawer is the left-hand drawer.



2. Check that the Preload Drawer status LED is green, and then pull the handle to open the drawer.



3. Preload 1 - 24 slides label-side-up into any empty positions. Make sure no labels overhang.

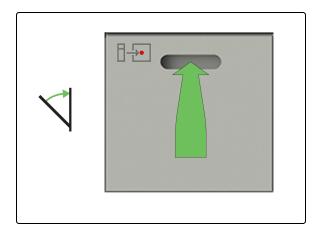
If there are any priority slides, preload these first and then close the Preload Drawer.



You can preload up to six dewaxed slides. Dewaxed slides must start processing within the "acceptable starting period", otherwise an alert appears on the touchscreen.



Slides that are scanned together are scheduled together.



4. Check that all slides are correctly located in the Slide Drawer Insert, and then close the Preload Drawer.

2.6 Preload Screen

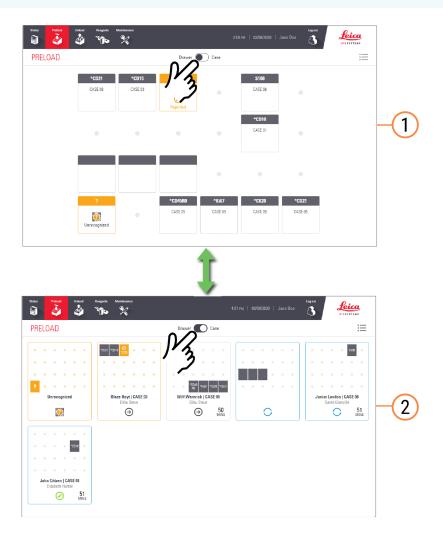
The Preload Screen has the following views:

- Preload Drawer view—displays a physical representation of the location of slides in the Preload Drawer
- **Preload Case view**—displays a physical representation of the location of each slide in each case in the Preload Drawer.

A toggle at the top of the screen allows you to switch views.



Loading slides together means they are scanned and then prioritized together. This enables the processing module to complete the last slide as efficiently as possible.



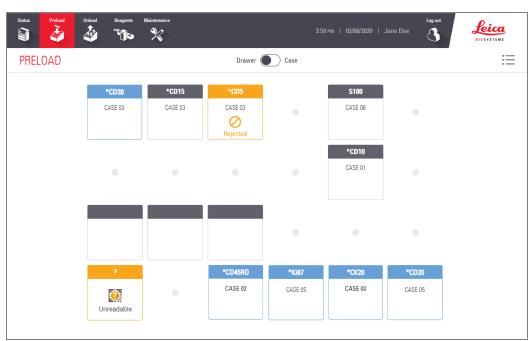
Legend

- 1 2.6.1 Preload Drawer view
- 2 2.6.2 Preload Case view

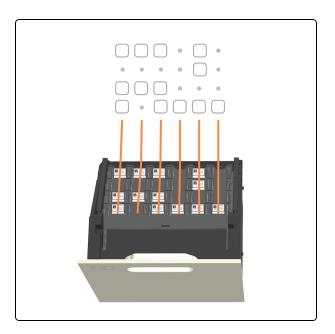
2.6.1 Preload Drawer view

The Preload Drawer view shows the relationship between the slide positions shown on-screen and their actual positions in the Preload Drawer. Slides that are currently being evaluated show no details until the evaluation process is complete.

Slide positions on the Preload Drawer view



Slide positions in the Preload Drawer

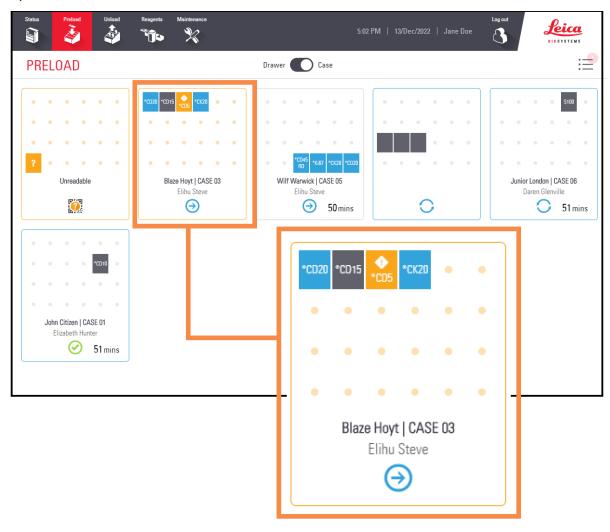


See also:

- 2.5 Preload slides
- 2.9 Detailed case and slide information

2.6.2 Preload Case view

Slide positions on the Preload Case view



lcon	Description
	Detected slide
?	Unreadable slide
CD5	Identified slide
CD20	Accepted slide

lcon	Description
CD8	Slide with status "Caution"
O CD5	Rejected slide
O CD5	Time-critical slide that is rejected
②	One or more slides in this case are either completed, abandoned, or canceled
▲ CK20	Slide with status "Warning"
Θ	Slides in this case are either accepted or evaluating
0	Slides in this case are in progress

See also:

- 2.5 Preload slides
- 2.9 Detailed case and slide information

2.7 Unload slides



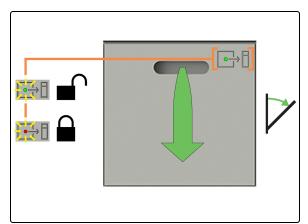
WARNING: You must wear the minimum required Personal Protective Equipment (PPE) before you use reagents or operate the processing module. Refer to General cautions.



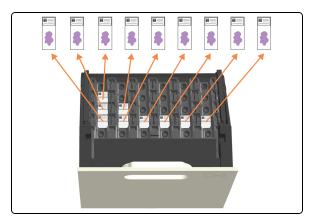
Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



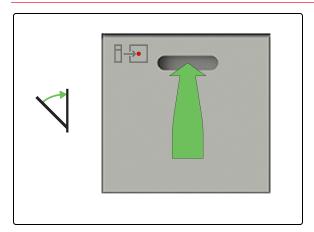
1. The Unload Drawer is the right-hand drawer.



2. Check that the Unload Drawer status LED is green, and then pull the handle to open the drawer.



- 3. Unload **all** of the slides before closing the drawer, otherwise you will see an "Unexpected slide" warning.
 - If you do not unload all the slides, they will no longer be hydrated and staining quality could be compromised.



4. Close the Unload Drawer.

2.8 Unload Screen

The Unload Screen has the following views:

- Unload Drawer view—displays a physical representation of the location of slides in the Unload Drawer
- **Unload case view**—displays a physical representation of the location of each slide in each case in the Unload Drawer.

A toggle at the top of the screen allows you to switch views.



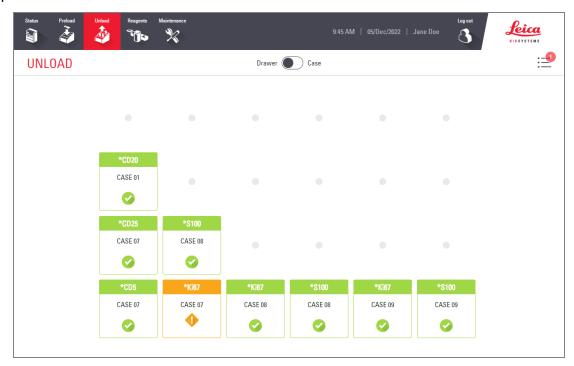
Legend

- 1 2.8.1 Unload Drawer view
- 2 2.8.2 Unload case view

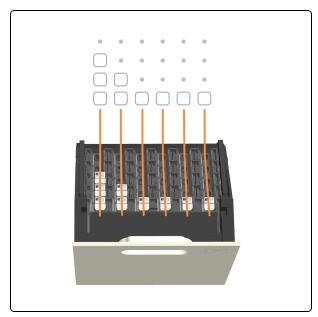
2.8.1 Unload Drawer view

The Unload Drawer view shows the relationship between the slide positions shown on-screen and their actual positions in the Unload Drawer.

Slide positions on the Unload Drawer view



Slide positions in the Unload Drawer

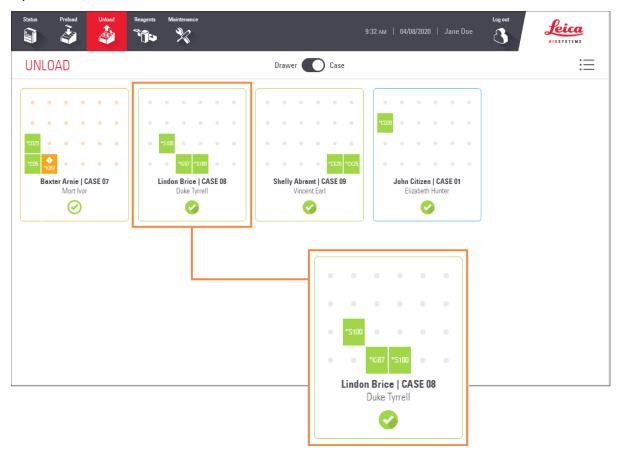


See also:

- 2.7 Unload slides
- 2.9 Detailed case and slide information
- 2.3.5 Unexpected events during processing (slides with status "Caution")

2.8.2 Unload case view

Slide positions on the Unload Case view



lcon	Description
CD15	Completed slide
CD8	Slide with status "Caution"
▲ CK20	Canceled, or slide with status "Warning"

Icon	Description
€	Slides in this case will be processed
0	Slides in this case are in progress
②	Some slides in this case have successfully completed processing
	All slides in this case have successfully completed processing
	Unexpected slide - refer to 2.7 Unload slides

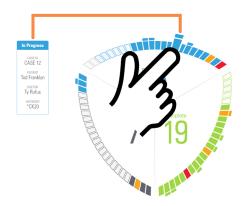
See also:

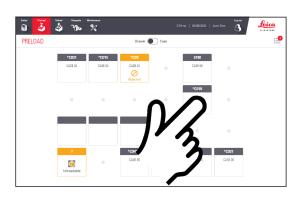
- 2.7 Unload slides
- 2.9 Detailed case and slide information
- 2.3.5 Unexpected events during processing (slides with status "Caution")

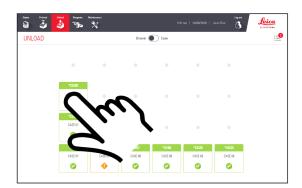
2.9 Detailed case and slide information

To view more detailed case and slide properties, you can tap on:

- the basic slide information on the Status screen
- a slide icon on the Preload or Unload screen (drawer or case view) the selected slide is highlighted in the information window that appears
- a case tile on the Preload or Unload screen (case view) the first slide in the case is highlighted in the information window that appears

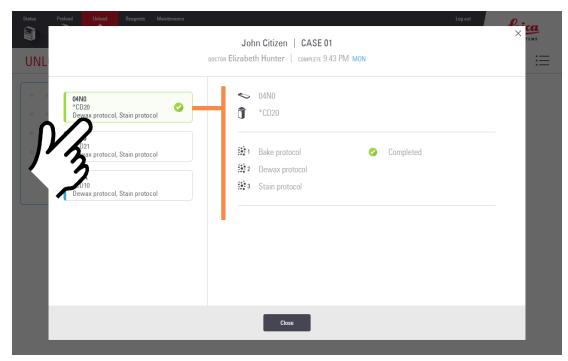








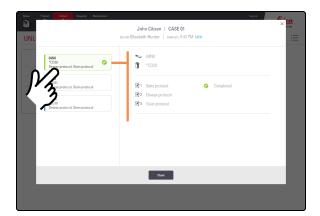
1 Tap a slide in the information window to view its details.



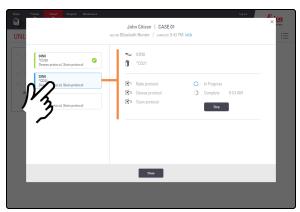
See also:

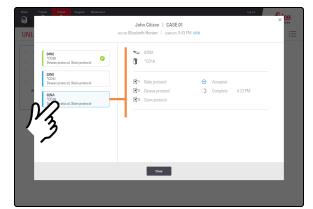
- 2.9.1 View each slide in a case
- 2.9.2 Stop a slide in progress

2.9.1 View each slide in a case

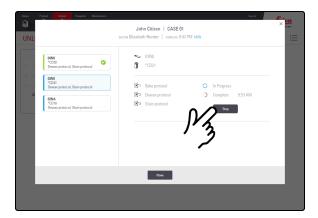


1. Tap a slide to display the details of that slide.

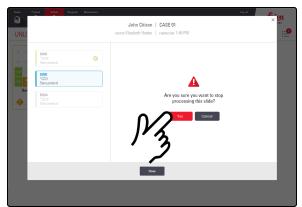




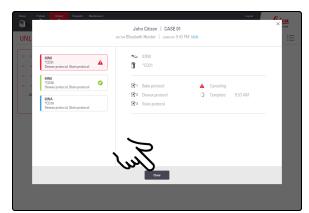
2.9.2 Stop a slide in progress



1. On the Case Details screen, select the slide, and then tap **Stop**.



2. Tap Yes.



3. Tap Close.

A canceled slide will be transferred to the Unload Drawer and will be shown in red.

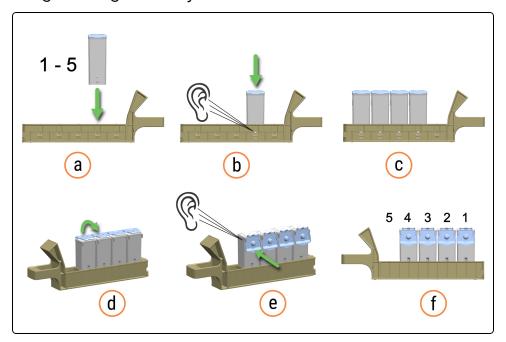
2.10 Reagents Screen

2.10.1 Prepare Reagent Container and Reagent Trays



WARNING: You must wear the minimum required Personal Protective Equipment (PPE) before you use reagents or operate the processing module. Refer to **General cautions**.

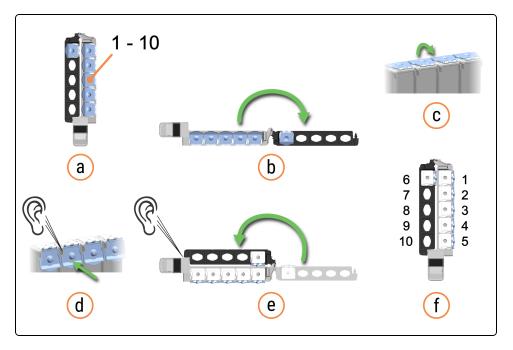
Single Reagent Tray



Dual Reagent Tray



WARNING: Pinch hazard when closing a Dual Reagent Tray.



You will hear a click when you fully insert a Reagent Container into a Reagent Tray. Make sure that the Reagent Container lids click fully into the tabs at the backs of the containers. If you do not, the lids may interfere with the alignment of the reagent containers in adjacent Reagent Lanes.

There is also a click when you fully close a Dual Reagent Tray.

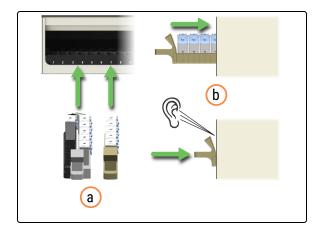
Make sure the top barcode labels are fully adhered to the containers – press down any labels that are lifting.

Wipe any moisture/condensation from the top barcode label.

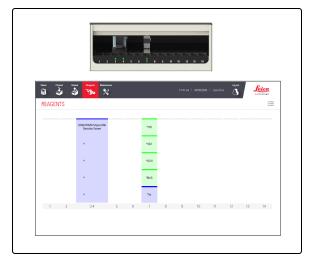
2.10.2 Load Reagent Trays



WARNING: You must wear the minimum required Personal Protective Equipment (PPE) before you use reagents or operate the processing module. Refer to **General cautions**.



- 1. Load both Reagent Trays onto the processing module.
 - a. Place the Reagent Tray in the Reagent Platform.
 - b. Push the Reagent Tray until you hear a click.



The Reagents screen displays the loaded reagents and detection system.

When loading a Reagent Tray, follow a smooth motion to avoid potential reagent spillage and contamination. You will hear a click when you fully insert a Reagent Tray into the Reagent Platform.

The background color of the on-screen icon is related to the contents of the loaded reagent system or container. Also, the background color changes if the reagent system or container is allocated to one or more slides. If a Reagent Tray or Reagent Container is unallocated, the icon's background color is light-gray.

The darker horizontal bar across the top of the icon represents the remaining reagent volume. A shorter bar indicates less remaining volume.

The time (in hours and minutes) that the Reagent Tray will be in use and locked is displayed underneath the Reagent Lanes. There is also red LED for that lane on the Reagent Platform.

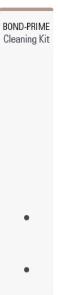
If a reagent is not registering after a few minutes, remove the Reagent Tray and re-insert it into a different Reagent Lane, to re-trigger the reagent scans.

2.10.3 Examples of reagent system icons

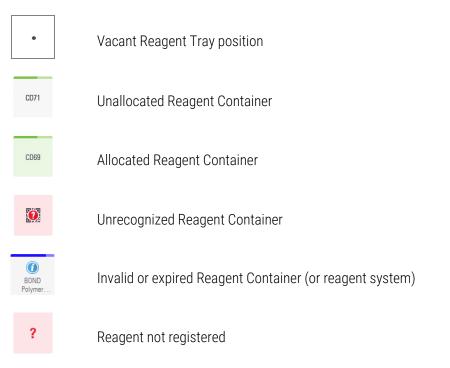
Allocated BOND-PRIME Polymer DAB Detection System (Dual Reagent Tray)

Unallocated BOND-PRIME Cleaning Kit (Single Reagent Tray)

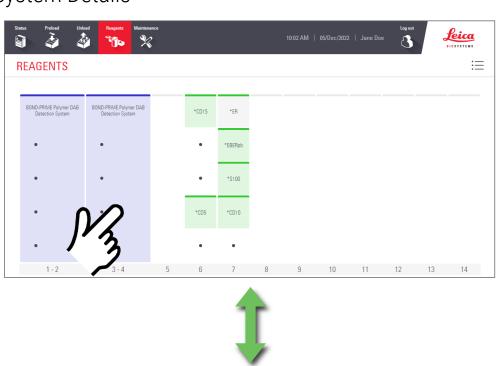


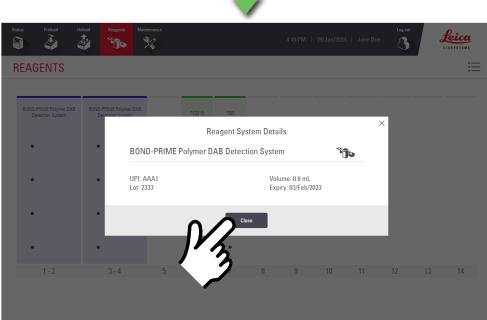


2.10.4 Examples of Reagent Container icons

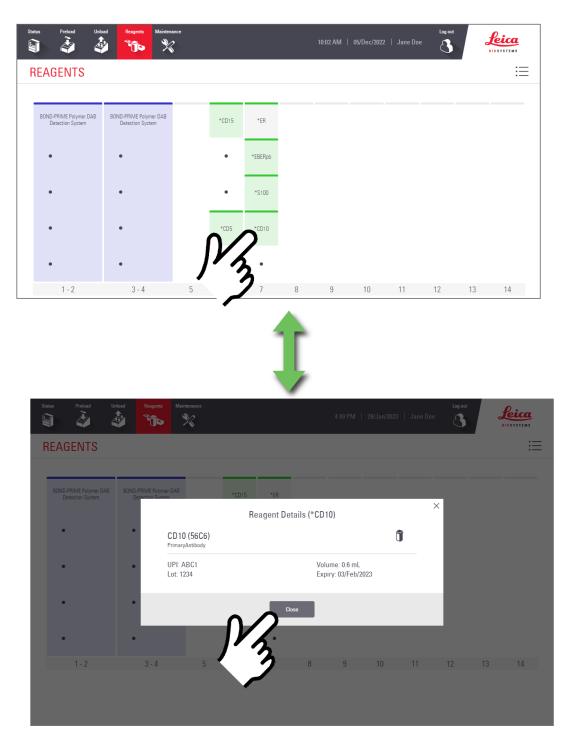


2.10.5 View reagent system and Reagent Container details Reagent System Details





Reagent Details

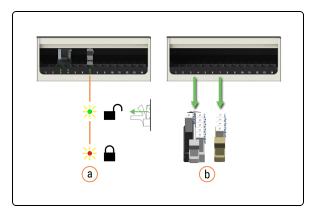


2.10.6 Unload Reagent Trays

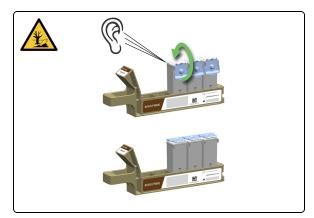


WARNING: You must wear the minimum required Personal Protective Equipment (PPE) before you use reagents or operate the processing module. Refer to **General cautions**.

The time a Reagent Tray is expected to be in use is displayed on the Reagents Screen. When it is no longer in use, you can remove the tray.



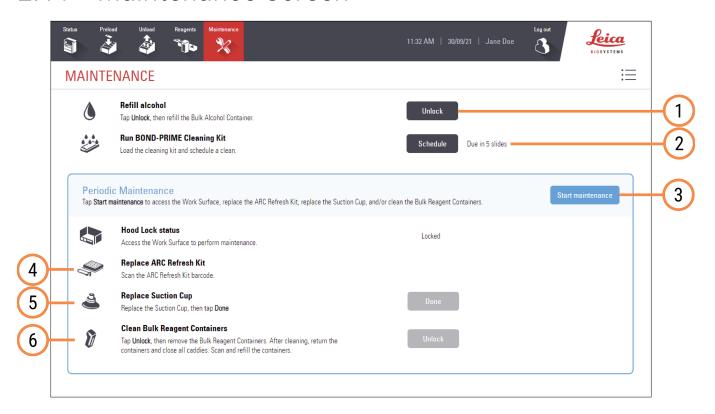
- 1. Remove the Reagent Trays from the processing module.
 - a. Wait until the Reagent Lane LED is green.
 - b. Remove the Reagent Trays from the Reagent Platform.



Close the Reagent Container lids firmly to prevent reagent evaporation. You will hear a click when you fully close the lid.

Immediately store the reagents as recommended on the label or reagent data sheet.

2.11 Maintenance Screen



Legend

- 1 Unlock4.3 Refill the Alcohol Container
- 2 Schedule4.6 Use the BOND-PRIME Cleaning Kit
- 3 Start maintenance 4.7 Start Maintenance

- 4 Replace ARC Refresh Kit 4.14 Use the BOND-PRIME ARC Refresh Kit
- 5 Replace Suction Cup4.11 Replace the Suction Cup
- 6 Clean Bulk Reagent Containers4.16 Clean the Locked Bulk Reagent Containers

Quick start



WARNING: You must wear the minimum required Personal Protective Equipment (PPE) before you use reagents or operate the processing module. Refer to **General cautions**.

In this section:

3.1 Introduction	97
3.2 Start the processing module	98
3.3 Load the Reagent Tray and DS9824 Detection System	100
3.4 Preload, process, and unload the slides	102

3.1 Introduction

This chapter shows you how to do an example run on the BOND-PRIME Processing Module.

You will create a sample case and configure and process four slides.

The process uses four BOND ready-to-use primary antibodies:

- *CD5
- *CD3
- *CD10
- *Bcl-6

The process uses the default protocol and detection system for these antibodies:

- *IHC Protocol F
- BOND-PRIME Polymer DAB Detection System (DS9824)

The process uses the ancillary BOND-PRIME Hematoxylin (AR0096).

The procedure is also applicable for ISH probes and protocols.

You can interchange the antibody for a probe and replace IHC protocols with ISH protocols.

For details of the following preliminary tasks, refer to the Quick Start chapter in the BOND 7 User Manual:

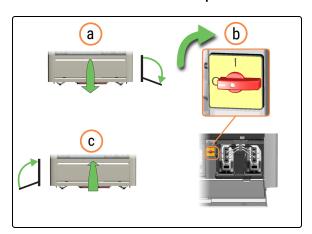
- Preliminary Checks and Startup*
- · Protocol and Reagent Checks
- Setting Up Slides (up to and including labeling slides)



To improve tissue adhesion, try baking for longer before loading slides.

^{*} related only to the Slide Labeler and BOND Controller (and Terminal, for BOND-ADVANCE)

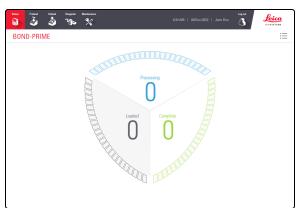
3.2 Start the processing module



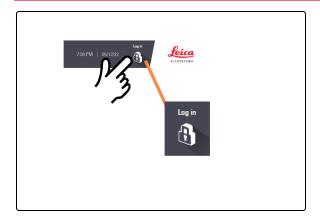
- 1. Power on the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch clockwise.
 - c. Close the Reservoir Cabinet door.



 When the processing module is turned on, it initializes before displaying the Log In Screen. This process takes from 8 to 15 minutes. If the processing module fails to initialize, refer to 5.1 Failure to initialize.



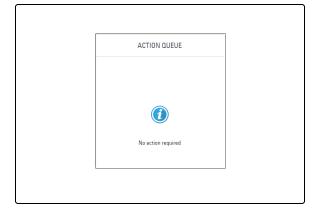
The Status screen is displayed.



3. When the processing module has initialized, tap **Log in**.



- 4. Log in to the touchscreen.
 - a. In the **Log in** Screen, tap your user name.
 - b. Enter your PIN.



5. Complete any Action Queue tasks that show action is required.

If the action specified in the Action Queue is maintenancerelated, refer to 4 Cleaning and maintenance

Action Queue Item status icon:



Warning: Take immediate action.



Caution: Take action at your next opportunity.



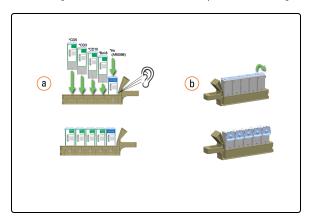
Information: For your awareness.



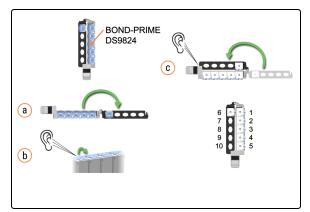
If the processing module does not initialize, refer to 5.1 Failure to initialize.

3.3 Load the Reagent Tray and DS9824 Detection System

Load reagents at the start of a run (before loading slides) to allow time for volume checks.



- 1. Load the Reagent Tray.
 - a. Insert the Reagent Containers into the Reagent Tray. Listen for a clicking sound to confirm the container is fully inserted.
 - b. Open all container lids.

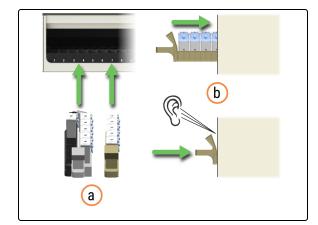


- 2. Load the BOND-PRIME Polymer DAB Detection System (DS9824).
 - a. Open the Detection System.
 - b. Open all container lids.
 - c. Close the Detection System.

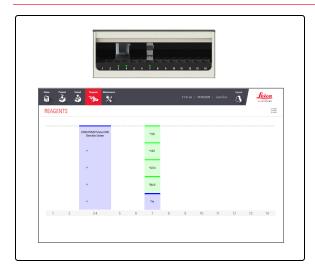


DS9824 has only 6 containers:

- Peroxide Block
- Post Primary
- Polymer
- DAB Part 1
- DAB Part B x 2

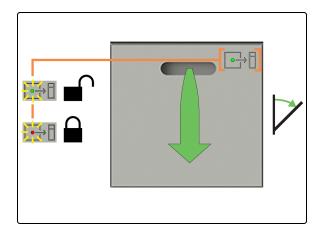


- Load both Reagent Trays onto the processing module.
 - a. Place the Reagent Tray in the Reagent Platform.
 - b. Push the Reagent Tray until you hear a click.

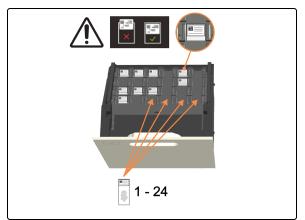


The Reagents screen displays the loaded reagents and detection system.

3.4 Preload, process, and unload the slides



1. Check that the Preload Drawer status LED is green, and then pull the handle to open the drawer.



2. Preload 1 - 24 slides label-side-up into any empty positions. Make sure no labels overhang.

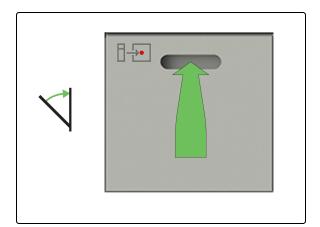
If there are any priority slides, preload these first and then close the Preload Drawer.



You can preload up to six dewaxed slides. Dewaxed slides must start processing within the "acceptable starting period", otherwise an alert appears on the touchscreen.



Slides that are scanned together are scheduled together.



3. Check that all slides are correctly located in the Slide Drawer Insert, and then close the Preload Drawer.

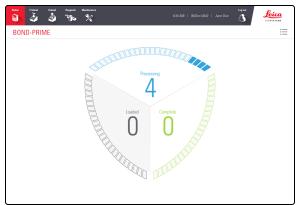




The Preload screen is automatically displayed when the Preload Drawer is opened.



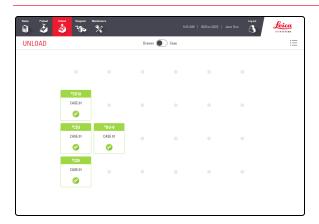
4. Tap **Status** to view the slide processing status. When slides are in the Preload Drawer, they are displayed in the Loaded area of the screen.



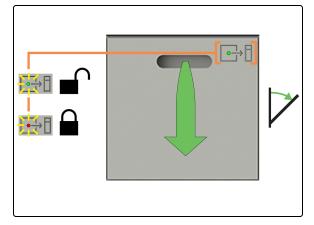
When slides are being processed on the Work Surface, they are displayed in the Processing area of the screen.



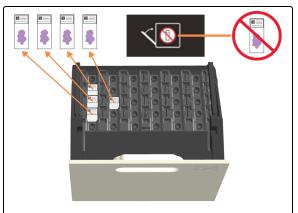
When slides are in the Unload Drawer, they are displayed in the Complete area of the screen.



5. Tap **Unload** to view the position of each slide in the Unload Drawer.

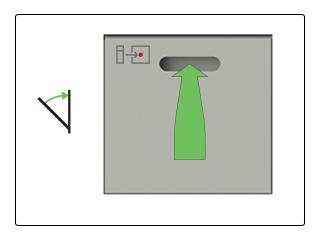


6. Check that the Unload Drawer status LED is green, and then pull the handle to open the drawer.



7. Remove all slides from the Unload Drawer.

Unload **all** completed slides frequently. If the Unload Drawer reaches capacity, it can hinder processing, extending the Estimated Time of Completion. When you close the Unload Drawer, it **must not** contain any slides.



8. Close the Unload Drawer.



When you have finished unloading the slides, check the Reagents screen to determine if there are any reagents that are no longer required for use. If there are, unload the reagents and then close Reagent Container lids firmly to prevent reagent evaporation. Immediately store the reagents as recommended on the label or reagent data sheet.

4

Cleaning and maintenance



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.

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4.1 Maintenance schedules

4.1.1 Preventative service reminder

When you use the BOND-PRIME Processing Module, look for leaks and worn or damaged parts. This user manual contains instructions that tell you how to clean or replace some parts. Notify customer support if it is necessary to repair or replace other parts.

A Leica Biosystems Melbourne Pty Ltd service engineer must regularly do preventative maintenance on the BOND-PRIME Processing Module.

Perform preventative maintenance annually or at 20,000 slides (whichever occurs first).

4.1.2 Cleaning and maintenance schedule

Use this schedule if you stain approximately 300 slides a week on each processing module. If you stain more slides than this, notify customer support. They can supply a customized schedule. Also refer to 4 Cleaning and maintenance.



If you stain more than 300 slides per week, do the tasks below that are marked with an asterisk more frequently.

Daily

Examine the Action Queue and Alert Banner on the Status Screen and do the applicable Cleaning and
maintenance as required. You should also do this whenever you return to the processing module during the
workday.

As required (ensure the processing module is connected to the BOND Controller)

- · Refill Bulk DI Water Container
- Refill Bulk Alcohol Container
- Refill Bulk Reagent Containers
- Empty Waste Containers

Weekly

- · Wipe internal surface of ARC Modules
- Wipe down Reagent Platform and ARC Bank Surfaces
- Clean Suction Cup

2-monthly

- Replace Suction Cup (3400 slides)
- Clean Slide Drawer Inserts, Waste Drain and Sumps, and Unload Drawer Pickup Filter*
- Clean Wash/Prime Stations*
- Clean Sump Tray*
- Clean external surfaces with a duster or cloth
- Clean Barcode Scanner (on Hood) using a lint-free cloth moistened with DI water

6-monthly (or if the processing module is idle for more than 14 days)

- Clean all bulk containers, including waste containers
- Clean hand-held barcode scanner (connected to BOND Controller) using a lint-free cloth moistened with DI water

8-monthly/7500 slides

• Use the BOND-PRIME ARC Refresh Kit (replace Mixing Well Plate and ARC Covertiles)

When you see a notification in the Action Queue

· Use the BOND-PRIME Cleaning Kit



ARC Modules must be cleaned when the usage count is between 17 and 23.

For a complete list of cleaning and maintenance tasks, refer to 4 Cleaning and maintenance.



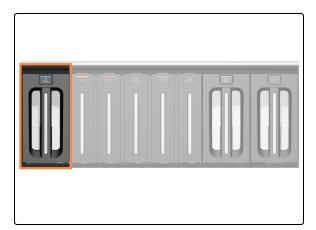
You can print the next page and use it as a checklist. You can also record the lot numbers of BOND-PRIME Wash Solution Concentrate, ER1, ER2 and Dewax Solutions.

4.1.3 Cleaning and maintenance checklist

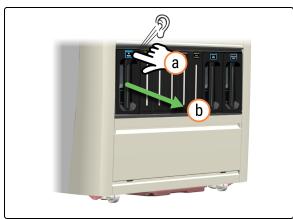
DAILY/AS REQUIRED	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Examine Action Queue and Alert Banner							
Refill/empty bulk containers as required							
BOND-PRIME Wash Solution Concentrate lot number							
ER1 lot number							
ER2 lot number							
Dewax Solution lot number							
NEEKLY							
Wipe internal surface of ARC Modules							
Wipe down Reagent Platform and ARC Bank Surfaces							
Clean Suction Cup							
2-MONTHLY							
Replace Suction Cup (3400 slides)							
Clean Slide Drawer Inserts, Waste Drain and Sumps, and Unload Drawer Pickup Filter*							
Clean Wash/Prime Stations*							
Clean Sump Tray*							
Clean external surfaces							
Clean Barcode Scanner (on Hood)							
5-MONTHLY							
Clean all bulk and waste containers							
Clean hand-held barcode scanner (on BOND Controller)							
3-MONTHLY/7500 slides							
Use the BOND-PRIME ARC Refresh Kit							
NOTIFICATION							
Jse the BOND-PRIME Cleaning Kit			* If it is necessary, do these tasks more frequently.				

For week starting _____to _____ For month of _____

4.2 Refill the DI Water Container



The DI Water Container is located at the left of the Bulk Containers Cabinet.



- 1. Remove the DI Water Container.
 - a. Press the DI Water button.
 - b. Pull the container out of the processing module.



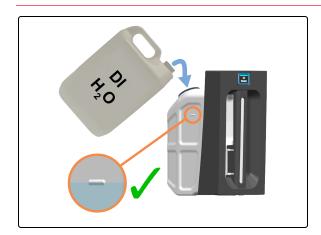
WARNING: Use both hands when you lift the DI Water Container.



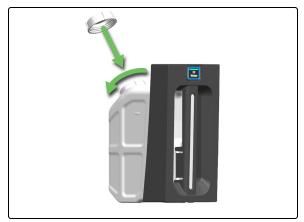
Return the container quickly to ensure there is DI Water available.



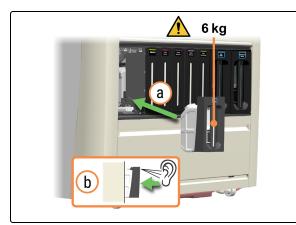
2. Remove the DI Water Container cap.



3. Pour DI Water into the container until it reaches the fill line.



4. Put the DI Water Container cap back on.



- 5. Reinsert the full DI Water Container.
 - **a.** Using two hands, reinsert the DI Water Container into the processing module.
 - b. Listen for a click sound to confirm the container is locked in place.

Make sure the container is fully inserted. Failure to do so can cause slides to be rejected in the Preload Drawer.

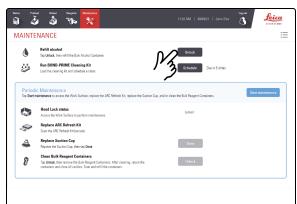
4.3 Refill the Alcohol Container



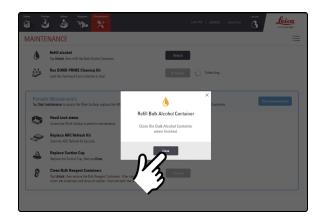
Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



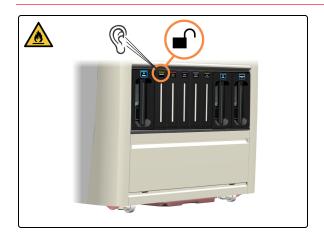
1. Tap Maintenance.



2. Tap Unlock next to Refill alcohol.



A popup window is displayed prompting you to refill the Bulk Alcohol Container.



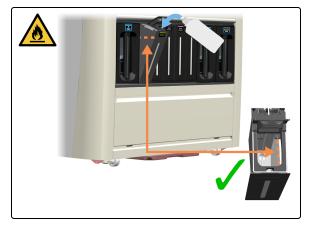
You will hear a click when the container unlocks. It will remain unlocked for only 30 seconds.



3. Pull the top of the container towards you.



4. Open the container lid.



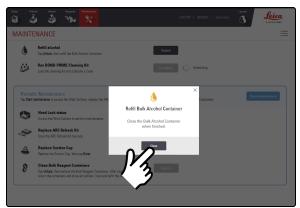
5. Pour the alcohol into the bulk container up to the maximum fill line.



6. Close the container lid.



7. Push the container into the processing module.

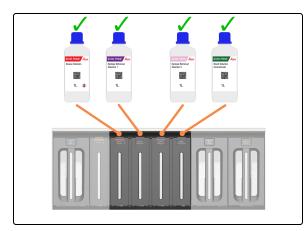


8. Tap Close.

4.4 Refill the Lot Tracked Bulk Containers

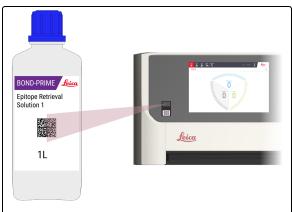


Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



BOND-PRIME has the following Lot Tracked Bulk Containers:

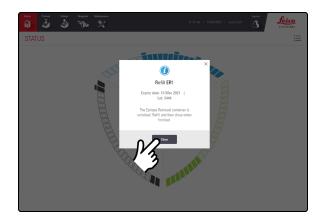
- Dewax Solution
- ER1
- ER2
- Wash Concentrate



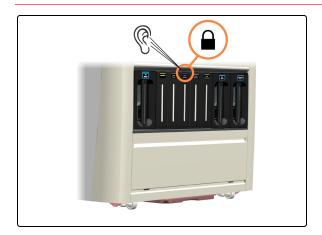
1. Scan the barcode on the supply bottle to ensure lot number tracking occurs.



To activate the laser, wave your hand in front of the scanner. You can also use the reflection of the bottle (on the Hood) to position the laser over the 2D barcode on the bottle.



2. Tap Close.



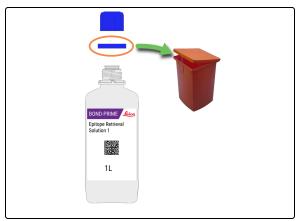
You will hear a click when the container unlocks. It will remain unlocked for only 30 seconds.



3. Pull the top of the container towards you.



4. Open the container lid.



5. Open the bottle and dispose of the tamper-proof seal ring according to laboratory procedures.



6. Pour the solution into the bulk containers up to the maximum fill line.



DO NOT dilute any reagents with water.



WARNING: To avoid spillage, **DO NOT** refill Bulk Reagent Containers while they are away from the processing module.



7. Close the container lid.

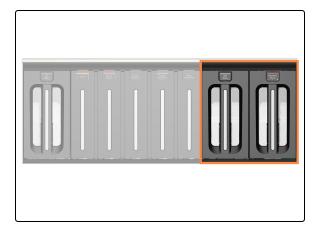


8. Push the caddy back into the processing module.

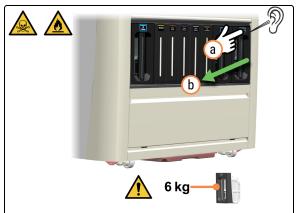
4.5 Empty the Waste Containers



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



The Waste Containers are located at the right of the Bulk Container Cabinet.



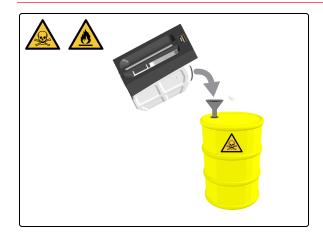
- 1. Remove the waste container.
 - a. Press the Waste button.
 - b. Pull the container out of the processing module.



WARNING: Use both hands when you lift the Waste containers.



2. Remove the Waste Container cap.



3. Empty the contents according to your laboratory procedures. Quickly return the container to the processing module to ensure there is waste capacity.



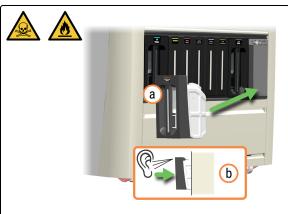
Hazardous waste example is shown.



WARNING: Dispose of waste in accordance with all procedures and government regulations that apply at the laboratory site.



4. Put the Waste Container cap back on.



- 5. Reinsert the Waste Container.
 - **a.** Reinsert the Waste Container into the processing module.
 - b. Listen for a click sound to confirm the container is locked in place.

Make sure the container is fully inserted. Failure to do so can cause slides to be rejected in the Preload Drawer.

4.6 Use the BOND-PRIME Cleaning Kit

If required:

- 4.2 Refill the DI Water Container
- 4.3 Refill the Alcohol Container
- 4.4 Refill the Lot Tracked Bulk Containers
- 4.5 Empty the Waste Containers



The BOND-PRIME Cleaning Kit cannot be preemptively scheduled.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



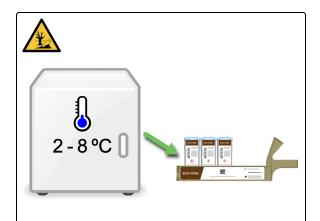
A message is displayed in the Action Queue when it is time to run the BOND-PRIME Cleaning Kit. ARC Modules must be cleaned when the usage count is between 17 and 23.

You must register the BOND-PRIME Cleaning Kit on the BOND Controller (refer to the BOND 7 User Manual).

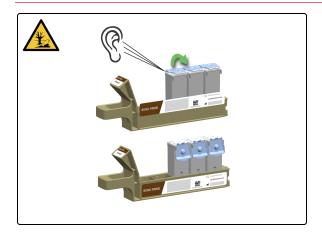
Some ARC Modules are disabled until cleaning is completed.



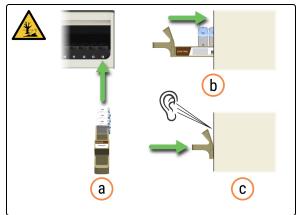
Ensure there are no slides in the Preload Drawer and Unload Drawer when starting a clean.



 Retrieve the Reagent Tray containing the BOND-PRIME Cleaning Kit.



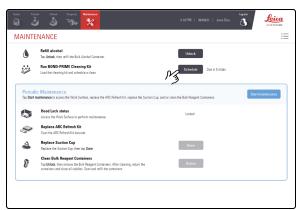
2. Open the Reagent Container Lid. You will hear a click as the lid is opened.



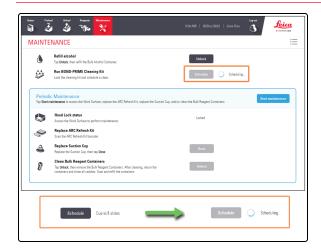
- 3. Insert the Reagent Tray into the processing module.
 - a. Take the Reagent Tray to the processing module.
 - b. Push the Reagent Tray into the Reagent Platform.
 - c. Listen for a click to confirm the tray is correctly inserted.



The BOND-PRIME Cleaning Kit is displayed on the Reagent screen.



4. Tap Schedule next to Run BOND-PRIME Cleaning Kit.



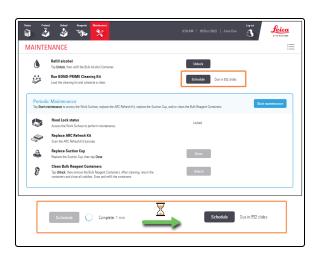
The **Schedule** button is disabled and a status icon next to the button indicates that scheduling is in progress.

You can load new slides into the Preload Drawer after the **Schedule** button becomes inactive and the spinning wheel is visible.



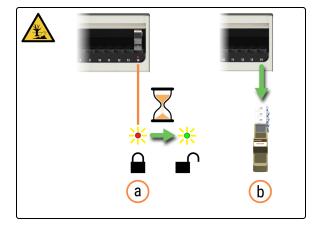
The time in minutes for the cleaning process to finish is displayed.



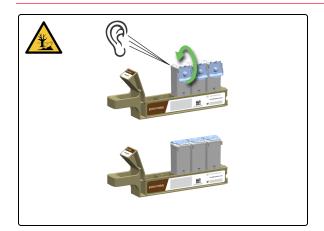


When the BOND-PRIME Cleaning Kit is completed, the **Schedule** button is enabled and the number of slides that can be processed before the kit is needed again is displayed.

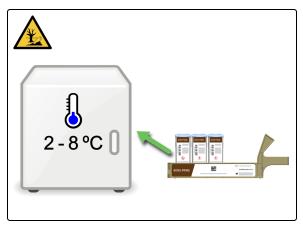




- 5. Remove the Reagent Tray.
 - **a.** Check that the Reagent Lane LED is red indicating that it is no longer in use.
 - b. Remove the Reagent Tray from the Reagent Platform.



6. Close the Reagent Container Lid. You will hear a click when the lid is secured.



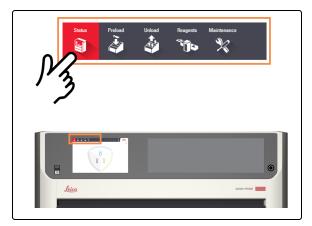
7. Store Reagent Containers between 2°C - 8°C.

4.7 Start Maintenance

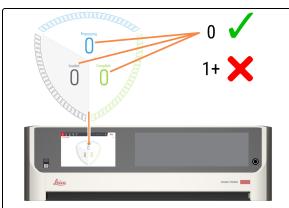
Use the **Start maintenance** procedure to access the Work Surface, clean the Bulk Reagent Containers, replace the Suction Cup, or use the BOND-PRIME ARC Refresh Kit.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

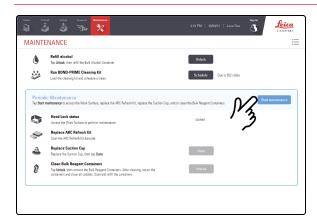


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

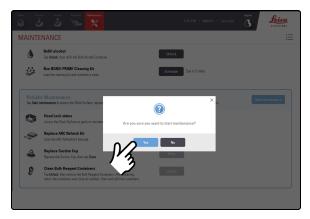
Refer to 2.3 Status Screen.



3. Tap Maintenance.



4. Tap Start Maintenance.

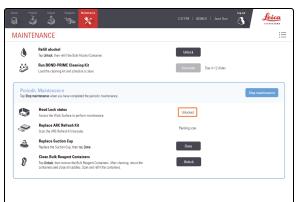


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

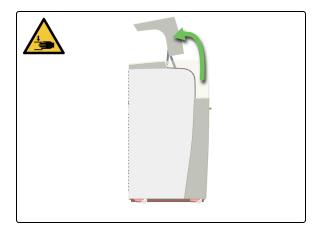


When maintenance is started, the processing module automatically opens all ARC Modules.





When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



6. Open the Hood.

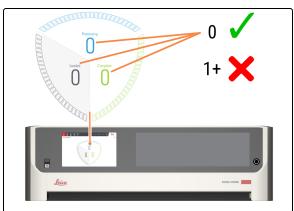
4.8 Wipe internal surface of ARC Modules



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.

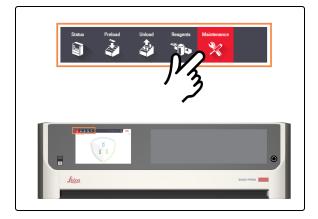


1. Tap Status.

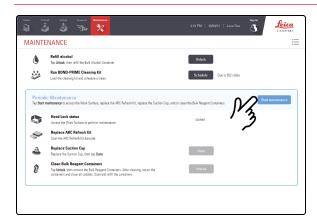


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

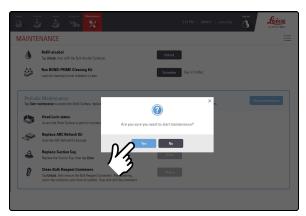
Refer to 2.3 Status Screen.



3. Tap Maintenance.



4. Tap Start Maintenance.

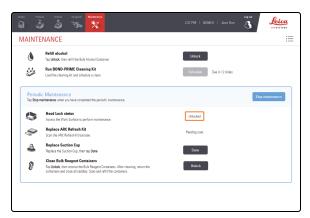


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

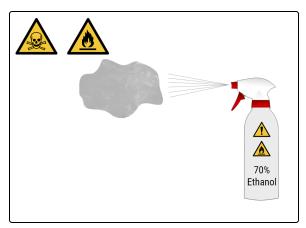


When maintenance is started, the processing module automatically opens all ARC Modules.

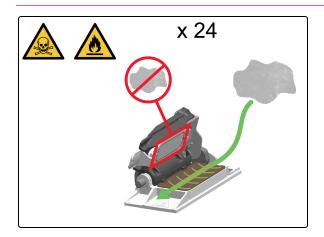




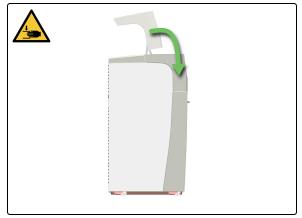
When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



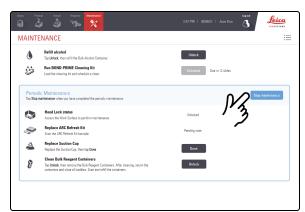
6. Moisten a clean lint-free cloth with 70% ethanol solution.



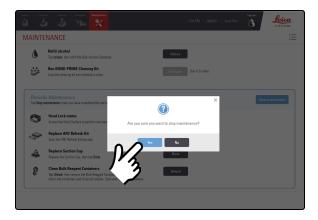
Wipe the ARC Module from the rear to the front to remove any particles or residue. Do not wipe the Covertile, as this may damage the Covertile Seal.



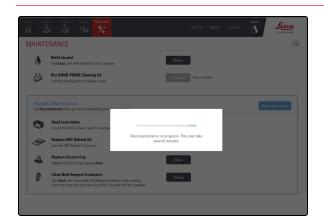
7. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



8. Tap Stop maintenance.



9. Tap Yes.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

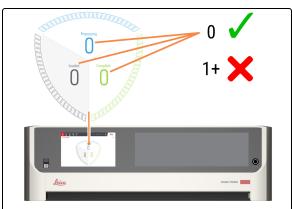
4.9 Wipe down Reagent Platform and ARC Bank Surfaces



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



1. Tap Status.

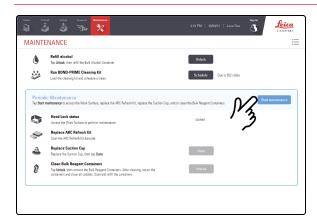


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

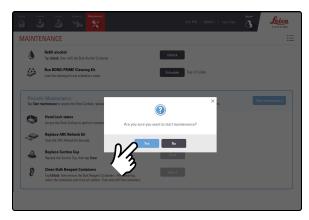
Refer to 2.3 Status Screen.



3. Tap Maintenance.



4. Tap Start Maintenance.

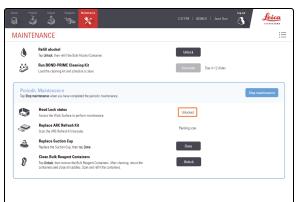


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

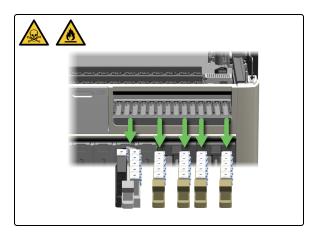


When maintenance is started, the processing module automatically opens all ARC Modules.

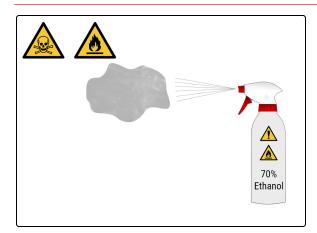




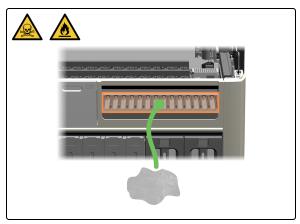
When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



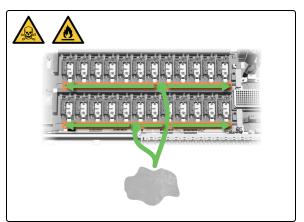
6. Remove all reagent trays from the Reagent Platform.



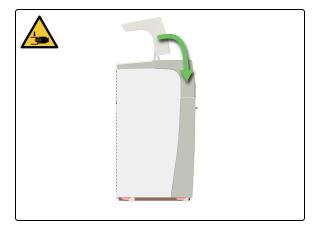
7. Moisten a clean lint-free cloth with 70% ethanol solution.



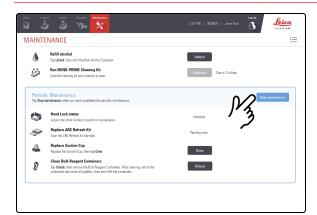
8. Wipe the surface of each lane on the Reagent Platform with the lint-free cloth.



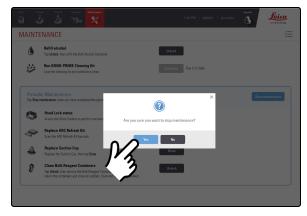
9. Wipe both Wash Robot rails.



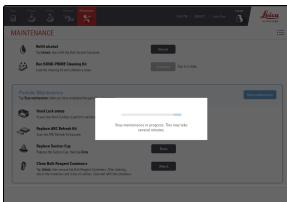
10. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



11. Tap Stop maintenance.



12. Tap Yes.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

4.10 Clean the Suction Cup



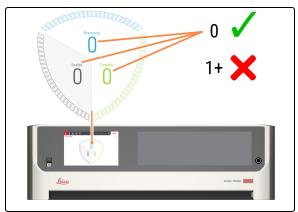
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

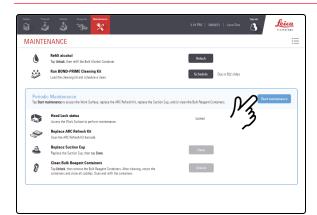


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

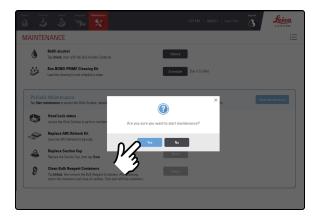
Refer to 2.3 Status Screen.



Tap Maintenance.



4. Tap Start Maintenance.

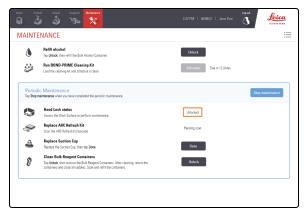


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

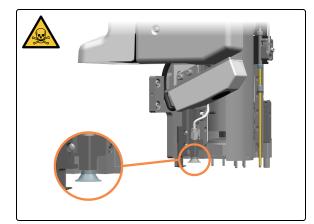


When maintenance is started, the processing module automatically opens all ARC Modules.





When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



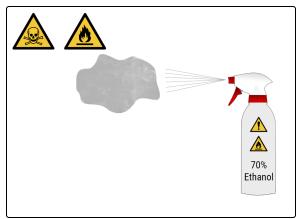
6. Locate the Suction Cup on the Robot Head.



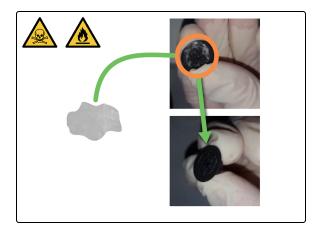
CAUTION: To help prevent dropping the Suction Cup into the processing module, carefully move the High-Speed Robot over the Reagent Platform.



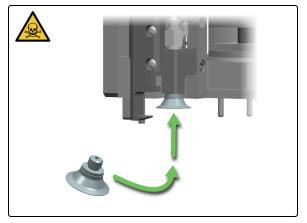
7. Remove the Suction Cup from the Robot Head.



8. Moisten a clean lint-free cloth with 70% ethanol solution.



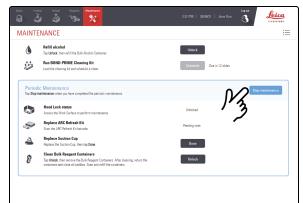
9. Flex the Suction Cup to remove residual wax, then clean with the lint-free cloth until no wax residue remains. Ensure the small hole is clear of any blockages.



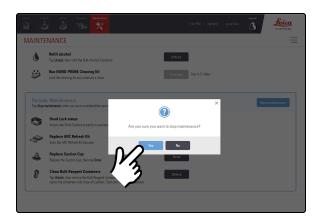
10. Refit the Suction Cup onto the Robot Head.



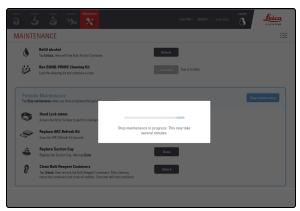
11. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



12. Tap Stop maintenance.



13. Tap Yes.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

4.11 Replace the Suction Cup

Replace the Suction Cup every 3400 slides or 2 months, whichever comes first.

To help prevent dropping the Suction Cup into the processing module, carefully move the High-Speed Robot over the Reagent Platform.



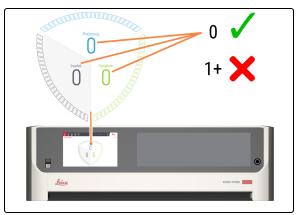
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

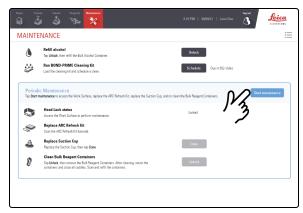


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

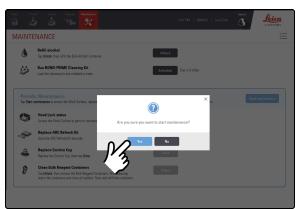
Refer to 2.3 Status Screen.



3. Tap Maintenance.



Tap Start Maintenance.

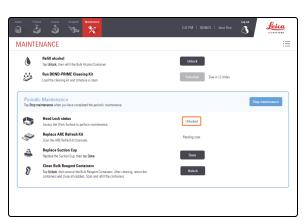


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.



When maintenance is started, the processing module automatically opens all ARC Modules.

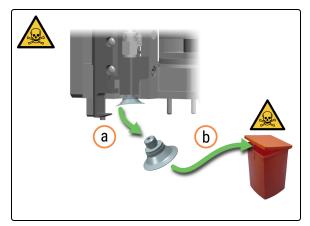




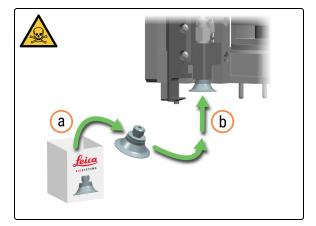
When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



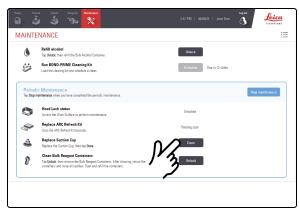
6. Locate the Suction Cup.



- 7. Remove the Suction Cup.
 - a. Detach the Suction Cup from the Robot Head.
 - **b.** Dispose of the Suction Cup according to laboratory procedures.



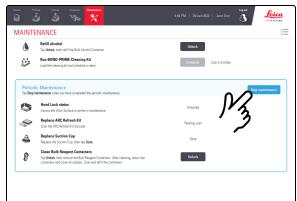
- 8. Install a new Suction Cup.
 - a. Remove the Suction Cup from its packaging.
 - b. Attach the Suction Cup to the Robot Head.



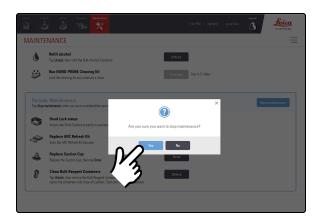
9. Tap **Done** next to **Replace Suction Cup**.



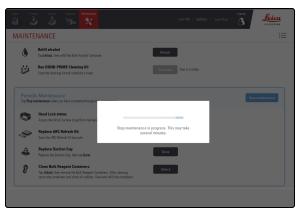
10. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



11. Tap Stop maintenance.



12. Tap Yes.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.

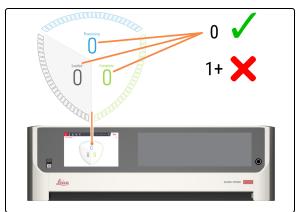


Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.

Clean the Slide Drawer Inserts



1. Tap Status.

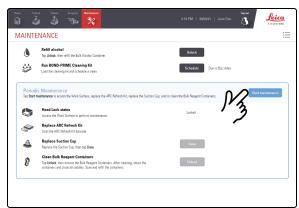


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

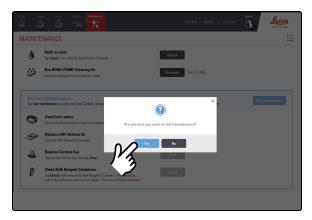
Refer to 2.3 Status Screen.



3. Tap Maintenance.



Tap Start Maintenance.

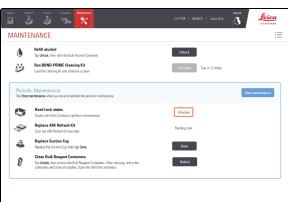


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

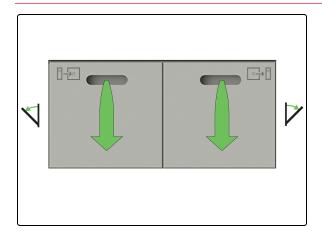


When maintenance is started, the processing module automatically opens all ARC Modules.

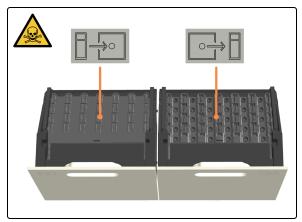




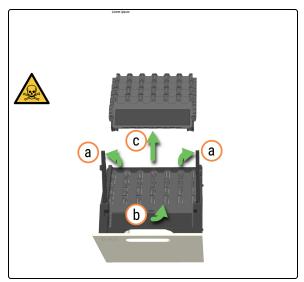
When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



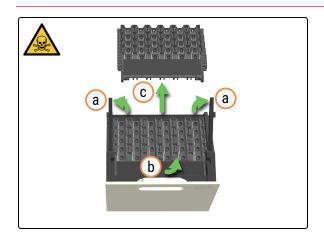
6. Open the Preload and Unload Drawers.



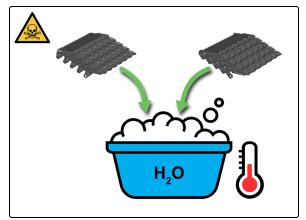
The Slide Drawer Inserts are accessible.



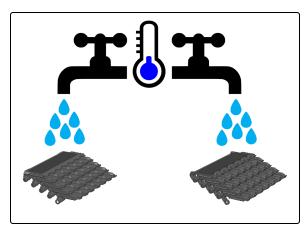
- 7. Remove the Slide Drawer Inserts from the Preload Drawer.
 - a. Pull the locking arms up.
 - b. Use the finger tab on the front fascia to assist in lifting the insert out of the drawer.
 - c. Remove the Slide Drawer Insert from the Preload Drawer.



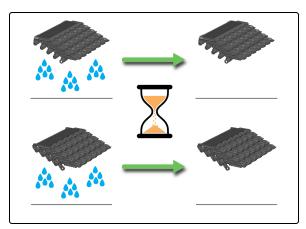
- 8. Remove the Slide Drawer Insert from the Unload Drawer.
 - a. Pull the locking arms up.
 - **b.** Use the finger tab available on the front fascia to assist in lifting the insert out of the drawer.
 - c. Remove the Slide Drawer Insert from the Unload Drawer.



9. Wash inserts with warm soapy water.

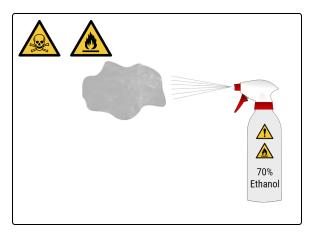


10. Rinse well with running water.

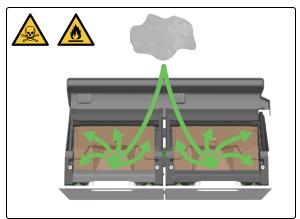


11. Allow to dry completely before re-installation in the same processing module.

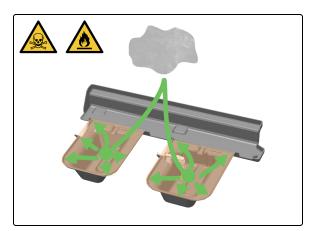
Clean the Waste Drains and Sump



12. Moisten a clean lint-free cloth with 70% ethanol solution.

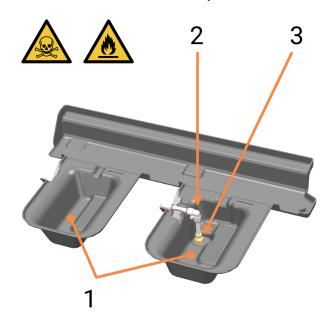


13. Wipe the Waste Drains with the lint-free cloth. The Waste Drains are accessible when the Slide Drawer Inserts have been removed from the opened drawers.



14. Wipe the Sumps with the lint-free cloth. The Sumps are located under and behind the Preload and Unload Drawers. They are accessible via the Work Surface after fully opening the drawers.

Clean the Pickup Tube and Filter



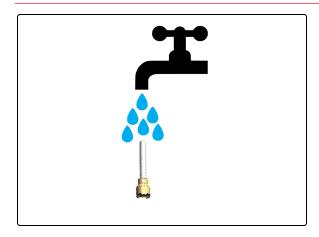
- 1 Sumps
- 2 Unload Drawer Pickup Tube
- 3 Pickup Filter



15. Rotate the Pickup Tube with Filter at elbow.



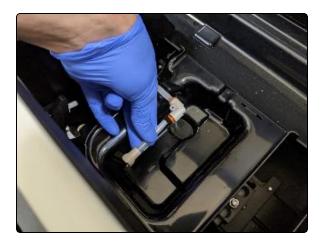
16. Press the orange sleeve to remove the Pickup Tube and Filter.



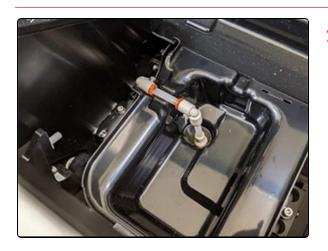
17. Flush Pickup Tube and Filter using clean water if required.



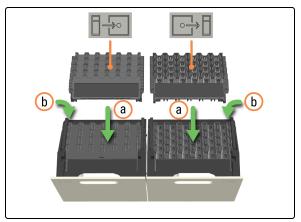
18. Confirm the Filter is free of debris.



19. Refit the Pickup Tube with Filter into the orange sleeve, making sure you push it in all the way.



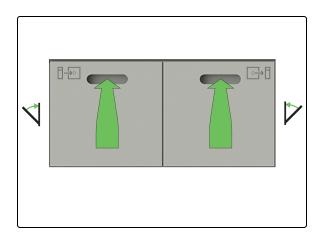
20. Rotate the Pickup Tube with Filter to the original position.
Ensure the Pickup Tube is fitted correctly to ensure it does not interfere with the alignment of the Slide Drawer Insert for the Unload Drawer.



- 21. Refit the Slide Drawer Inserts.
 - **a.** Install each Slide Drawer Insert, making sure they are fully inserted into the recess without jamming.
 - b. Close the locking arm after installing the inserts to autoalign the inserts and ensure good fitment.



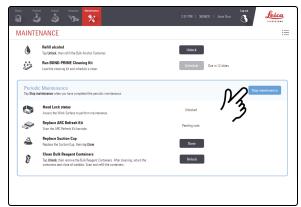
CAUTION: If you are cleaning multiple inserts, ensure that the correct insert is replaced in the correct drawer and correct processing module. You cannot swap inserts between processing modules.



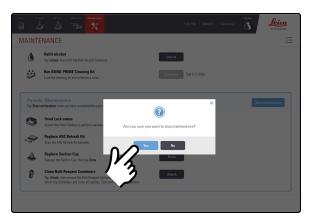
22. Close the Slide Preload and Unload Drawers.



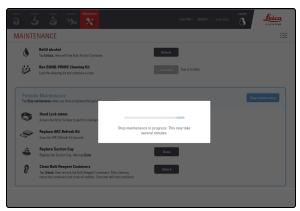
23. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



24. Tap Stop maintenance.



25. Tap Yes.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

4.13 Clean the Wash/Prime Stations



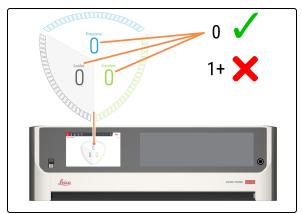
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

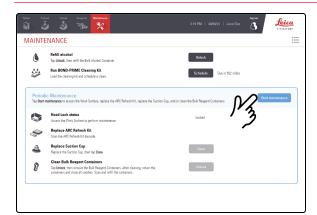


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

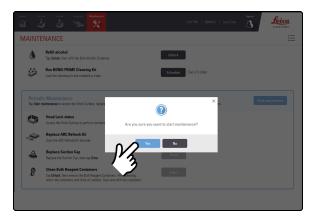
Refer to 2.3 Status Screen.



Tap Maintenance.



4. Tap Start Maintenance.

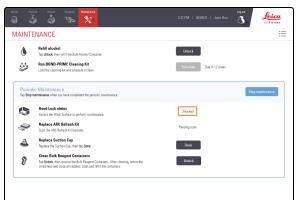


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

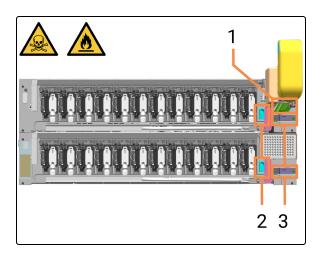


When maintenance is started, the processing module automatically opens all ARC Modules.





When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.

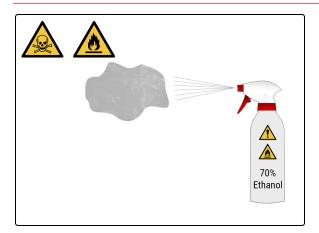


6. Locate the Wash/Prime Station locations (1, 2 & 3) on the Work Surface.

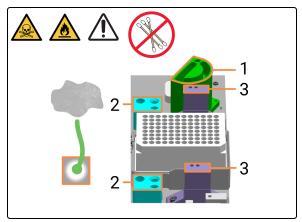


If the High-Speed Robot or Wash Robots are in the way, you can gently move them for better access to the Wash/Prime Stations.

- Bulk Probe Prime Station
- 2 Wash Robot Wash Stations
- 3 ARC Probe Wash Stations



7. Moisten a clean lint-free cloth with 70% ethanol solution.

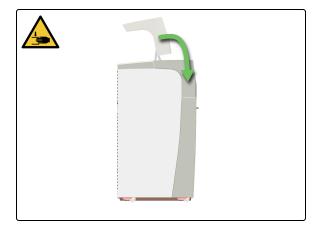


8. Clean **only** the top surfaces of Wash/Prime Stations with lint-free cloth.

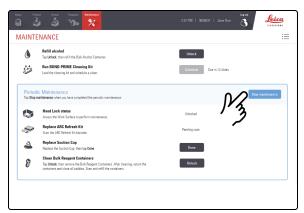


CAUTION: Do not use cotton buds.

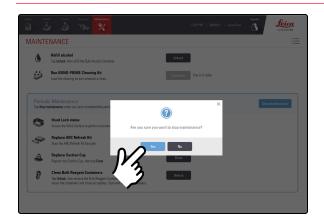
- 1 Bulk Probe Prime Station
- 2 Wash Robot Wash Stations
- 3 ARC Probe Wash Stations



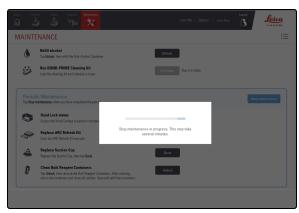
9. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



10. Tap Stop maintenance.



11. Tap **Yes**.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

4.14 Use the BOND-PRIME ARC Refresh Kit

The BOND-PRIME ARC Refresh Kit contains replacement:

- Covertiles
- Mixing Well Plate.

Use the ARC Refresh Kit every 7500 slides or 8 months, whichever comes first. Each IHC single stain counts as one usage for Covertile life purposes. Each ISH hybridization counts as two usages. The maximum usage per slide is capped at two. The table below indicates the equivalent slide count per slide type.

Slide type	Equivalent slide count
IHC slide	1
ISH slide	2
Multiplex 2 to 6	2



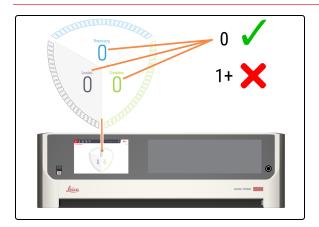
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

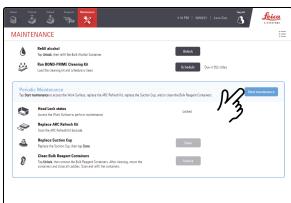


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

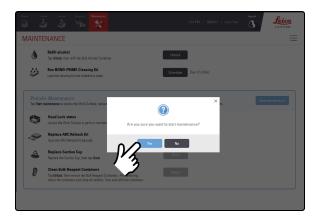
Refer to 2.3 Status Screen.



3. Tap Maintenance.



4. Tap Start Maintenance.

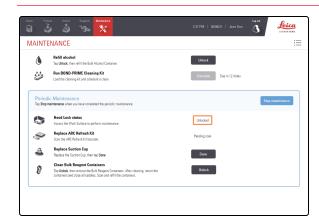


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

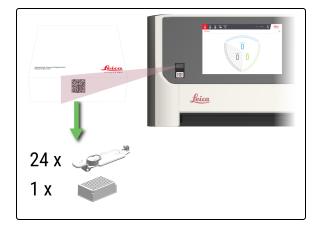


When maintenance is started, the processing module automatically opens all ARC Modules.





When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



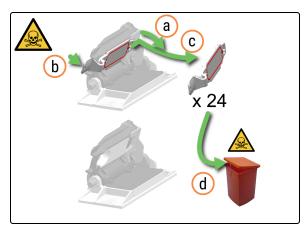
6. Scan the ARC Refresh Kit barcode.



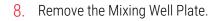
The scan is only accepted while in Maintenance Mode.



Scanning of the ARC Refresh Kit ensures that the Covertiles are cleaned with DI Water and BOND-PRIME Wash Working Solution before staining begins.



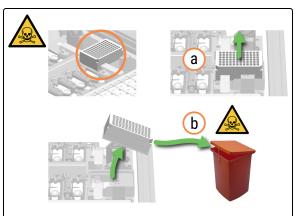
- 7. Remove the Covertiles.
 - **a.** Push the ARC Module Latch down to make the Covertile more accessible.
 - b. Gently pull the Covertile Thumbhold slightly forward and towards the right of the ARC Module lid.
 - **c.** Unhook the Covertile and remove it from the ARC Module.
 - d. Dispose of the Covertile according to laboratory procedures.

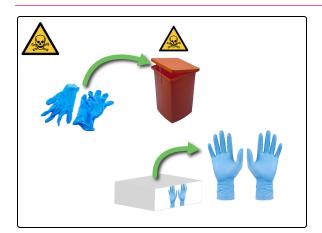


- a. Lift up the Mixing Well Plate.
- b. Dispose of the Mixing Well Plate according to laboratory procedures.

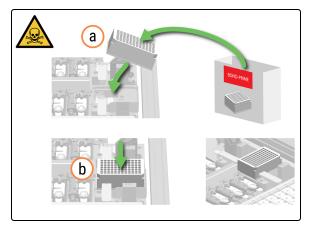


WARNING: Take care to prevent liquid spillage when removing and disposing of the Mixing Well Plate.



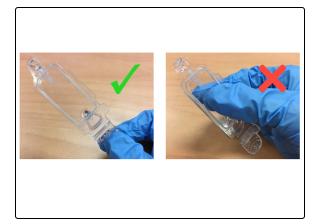


9. Remove your gloves and dispose of them according to laboratory procedures. Put on a new pair of gloves.

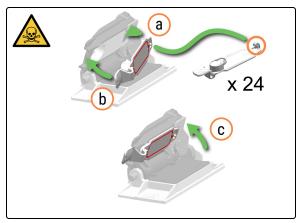


- 10. Install the new Mixing Well Plate.
 - a. Remove the Mixing Well Plate from its packaging.
 - b. Place the Mixing Well Plate on the Mixing Block.

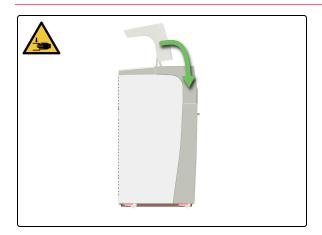
The orientation of the Mixing Well Plate in the Mixing Block is not important as long as it is sitting evenly within the holder.



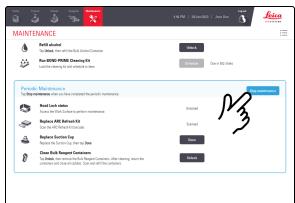
When holding the Covertile, use the thumb-hold. DO NOT put your fingers on the top plate.



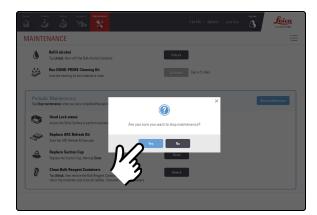
- 11. Insert the new Covertiles.
 - a. Attach the Covertile Hook to the rear of the ARC Module.
 - b. Gently push the Covertile Thumbnail until the Covertile is in place in the ARC Module.
 - c. Push the ARC Module Latch up.



12. Close the Hood.



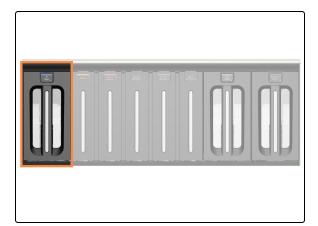
13. Tap Stop maintenance.



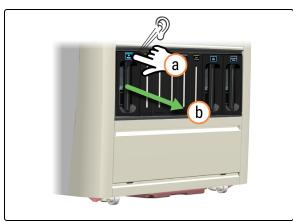
14. Tap Yes.

The processing module automatically closes the ARC Modules when you stop maintenance.

4.15 Clean the Bulk DI Water Container



The DI Water Container is located at the left of the Bulk Containers Cabinet.



- 1. Remove the DI Water Container.
 - a. Press the DI Water button.
 - b. Pull the container out of the processing module.



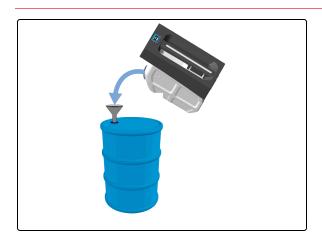
WARNING: Use both hands when you lift the DI Water Container.



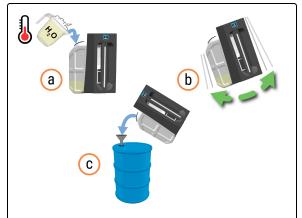
Return the container quickly to ensure there is DI Water available.



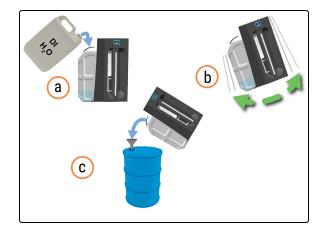
2. Remove the DI Water Container cap.



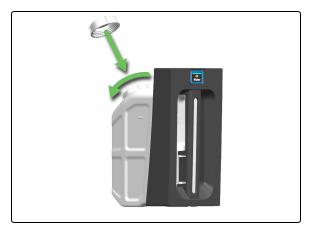
3. Dispose of the contents according to all procedures and government regulations that apply at the laboratory site.



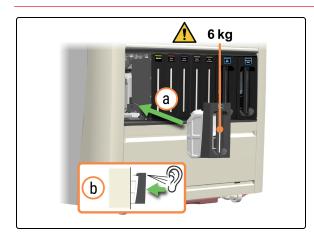
- 4. Clean the DI Water Container.
 - a. Quarter fill the DI Water Container with warm soapy water.
 - b. Put the lid back on the container and briskly shake the container.
 - **c.** Empty the contents according to your laboratory procedure.



- 5. Rinse the DI Water Container to remove any detergent.
 - a. Quarter fill the DI Water Container with DI water.
 - b. Put the lid back on the container and briskly shake the container.
 - **c.** Empty the contents according to your laboratory procedure.



6. Refill the DI Water Container and then put the DI Water Container cap back on.



- 7. Reinsert the full DI Water Container.
 - **a.** Using two hands, reinsert the DI Water Container into the processing module.
 - **b.** Listen for a click sound to confirm the container is locked in place.

Make sure the container is fully inserted. Failure to do so can cause slides to be rejected in the Preload Drawer.

4.16 Clean the Locked Bulk Reagent Containers



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



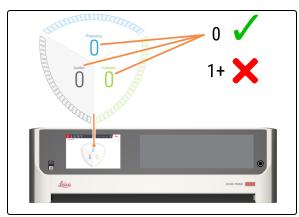
WARNING: Take care not to collide with the Bulk Container Drawers while they are open.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

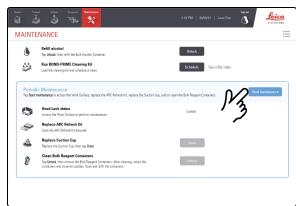


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

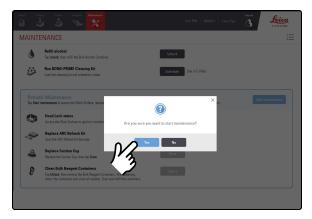
Refer to 2.3 Status Screen.



3. Tap Maintenance.



Tap Start Maintenance.

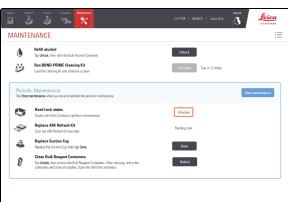


5. Tap Yes.

There is a wait time after tapping **Yes** while the processing module is preparing the Work Surface for maintenance and unlocking the Hood.

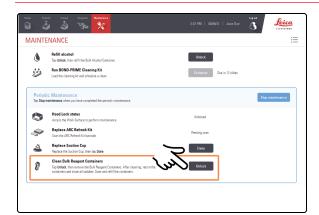


When maintenance is started, the processing module automatically opens all ARC Modules.





When the Hood is unlocked, the **Hood Lock Status** on the Maintenance screen changes to **Unlocked**.



6. Tap Unlock next to Clean Bulk Reagent Containers.



The Reagent Container Caddies remain unlocked for 30 seconds, to allow time for you to open **all** drawers to the maintenance position.

If you do not have time to open them all within 30 seconds, you can tap the **Unlock** button again.



7. Pull the Locked Reagent Container Caddies forward to open them.

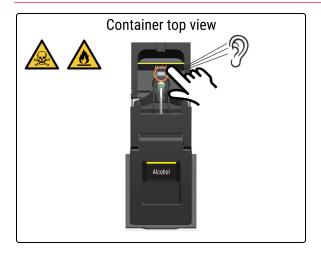
For the Alcohol and Dewax Solution Containers



The two locked containers on the left are the Alcohol and Dewax Solution Containers.



Clean and then reinstall one container at a time, as the containers cannot stand upright on a flat surface.



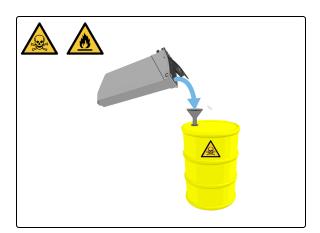
8. Press the caddy release lever at the rear of the tube connector. Listen for a click.



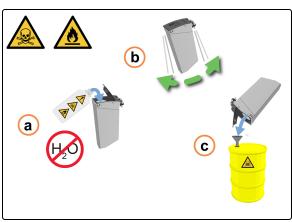
9. Slide the container up and out of the caddy.



WARNING: To avoid spillage, **DO NOT** refill Bulk Reagent Containers while they are away from the processing module.



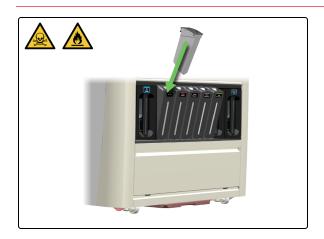
10. Empty the container into a hazardous waste drum.



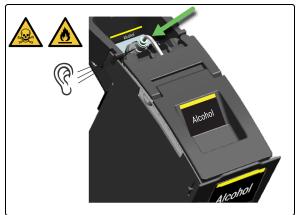


CAUTION: DO NOT use water or detergent to clean the Alcohol or Dewax Containers.

- 11. Decontaminate the container:
 - **a.** Rinse the container with a small amount of fresh Alcohol to remove any contaminants.
 - b. Gently shake the container.
 - c. Empty the container when completed.



12. Close the lid and return the container to its caddy.



13. Push the container down until you hear a click.



14. Close the caddy.



15. Repeat step 8 to step 14 for the Dewax Solution Container.

If you do not need to clean any other Reagent Containers, Stop maintenance.

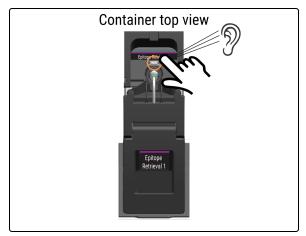
For the ER1, ER2 and BOND-PRIME Wash Solution Concentrate Containers



The 3 containers on the right are the ER1, ER2, and BOND-PRIME Wash Solution Concentrate Containers.



Clean and then reinstall one container at a time, as the containers cannot stand upright on a flat surface.



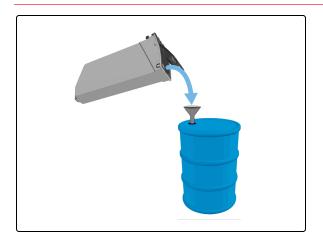
16. Press the caddy release lever at the rear of the tube connector. Listen for a click.



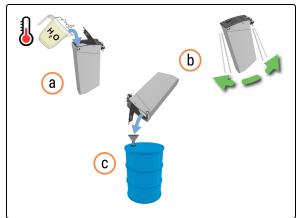
17. Slide the container up and out of the caddy.



WARNING: To avoid spillage, DO NOT refill Bulk Reagent Containers while they are away from the processing module.

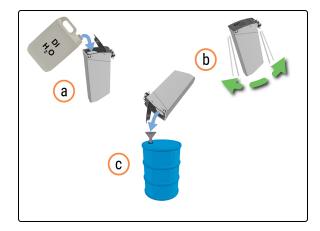


18. Empty the container according to laboratory procedures.



19. Clean the container:

- a. Quarter fill the container with an industrial strength detergent solution in warm tap water.
- b. Gently shake the container.
- c. Empty the container according to laboratory procedures



20. Rinse the container:

- a. Thoroughly rinse the container with DI Water.
- b. Gently shake the container.
- c. Empty the container according to laboratory procedures



21. Decontaminate the container:

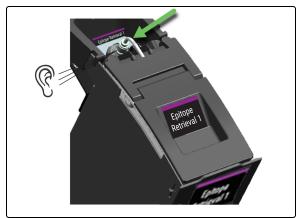
- **a.** Rinse the container with a small amount of fresh ER1 to remove any contaminants.
- b. Gently shake the container.
- c. Empty the container according to laboratory procedures.



22. Close the lid and return the container to its caddy.



Do not refill the container yet.



23. Push the container down until you hear a click.

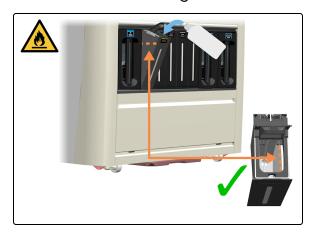


24. Close the caddy.



25. Repeat step 16 to step 24 for the remaining Locked Reagent Containers.

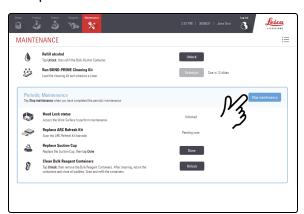
Refill the Bulk Reagent Containers



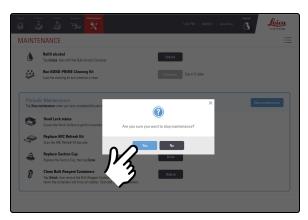
26. Refill the containers:

- 4.3 Refill the Alcohol Container
- 4.4 Refill the Lot Tracked Bulk Containers

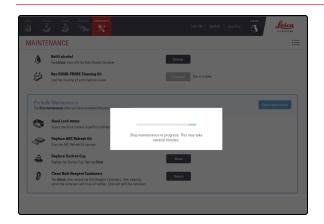
Stop maintenance



27. Tap Stop maintenance.



28. Tap Yes.



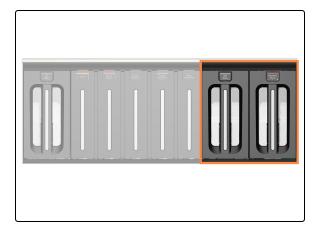
There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

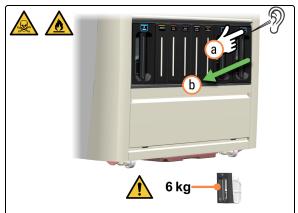
4.17 Clean the Waste Containers



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



The Waste Containers are located at the right of the Bulk Container Cabinet.



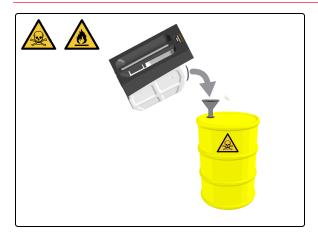
- 1. Remove the waste container.
 - a. Press the Waste button.
 - b. Pull the container out of the processing module.



WARNING: Use both hands when you lift the Bulk/Hazardous Waste containers.



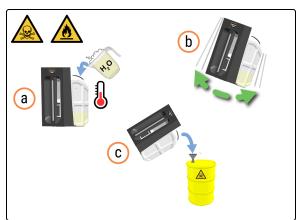
2. Remove the Waste Container cap.



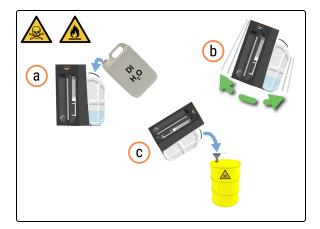
3. Dispose of the contents according to all procedures and government regulations that apply at the laboratory site.



Hazardous waste example is shown.



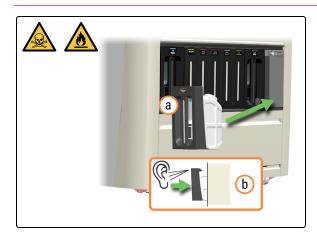
- 4. Clean the Waste Container.
 - **a.** Quarter fill the Waste Container with an industrial strength detergent solution in warm water.
 - b. Put the lid back on the container and briskly shake the container.
 - **c.** Empty the contents according to your laboratory procedure.



- 5. Rinse the Waste Container.
 - a. Quarter fill the Waste Container with DI water.
 - b. Put the lid back on the container and briskly shake the container.
 - **c.** Empty the contents according to your laboratory procedure.



6. Put the Waste Container cap back on.



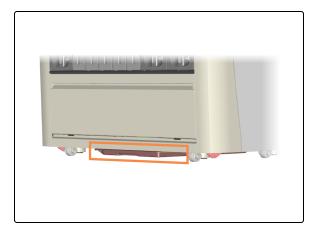
- 7. Reinsert the Waste Container.
 - **a.** Reinsert the Waste Container into the processing module.
 - **b.** Listen for a click sound to confirm the container is locked in place.

Make sure the container is fully inserted. Failure to do so can cause slides to be rejected in the Preload Drawer.

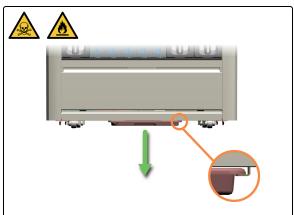
4.18 Clean the Sump Tray



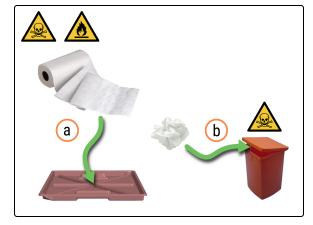
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



1. Locate the Sump Tray.



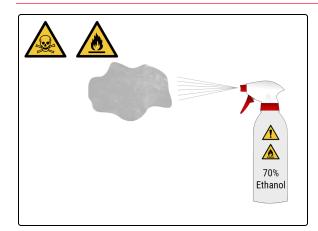
2. Stand to the side of the Sump Tray and remove it using two hands to avoid spillage. If required, follow the spill management procedures that apply at the laboratory site.



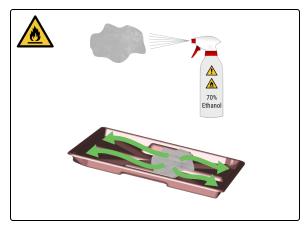
- 3. Soak up the excess waste reagent.
 - a. Absorb the bulk of the waste reagent using paper towels.
 - b. Dispose of the paper towels in accordance with laboratory procedures. Always treat the waste from the Sump Tray as hazardous.



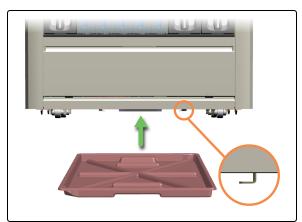
If there is an excessive amount of waste in the Sump Tray, contact Leica Biosystems Support.



4. Moisten a clean lint-free cloth with 70% ethanol solution.



5. Wipe the Sump Tray with the lint-free cloth.



6. Refit the Sump Tray in the processing module.

4.19 Stop maintenance

Before you stop maintenance, make sure:

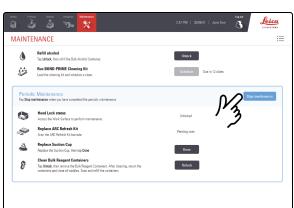
- · Covertiles are present
- the Mixing Well Plate is present (see 4.14 Use the BOND-PRIME ARC Refresh Kit)
- Bulk Reagent Containers have sufficient volume (see 4.4 Refill the Lot Tracked Bulk Containers and 4.3 Refill the Alcohol Container)
- no ARC Modules contain a slide (see 5.3.3 Manually retrieve slides from ARC Modules)
- the Hood is down



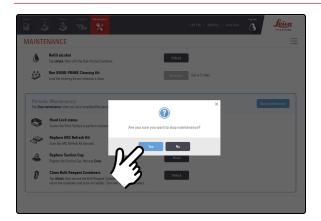
Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



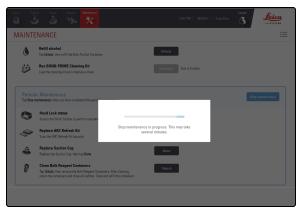
1. Tap Maintenance.



2. Tap Stop maintenance.



3. Tap Yes.



There is a wait time while the processing module is preparing to return to clinical operation.

The processing module automatically closes the ARC Modules and locks the Hood when you stop maintenance.

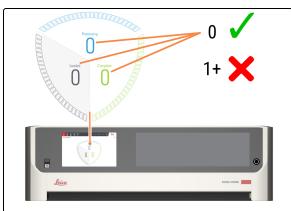
4.20 Shutdown the processing module



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



1. Tap Status.

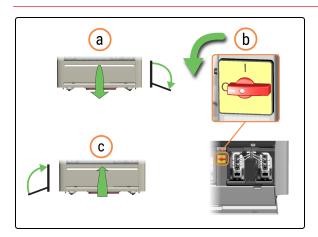


- 2. Check the Status screen to ensure there are:
 - no slides currently being processed (Processing)
 - no slides in the Preload Drawer (Loaded) and Unload Drawer (Complete).

Refer to 2.3 Status Screen.



- 3. Power down the processing module.
 - a. Press the standby power button.A pop up window indicates that it is safe to shut down the processing module.
 - b. Tap Close.

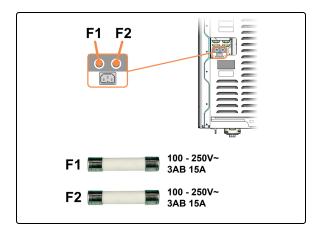


- 4. Power off the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch counterclockwise.
 - c. Close the Reservoir Cabinet door.



WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.

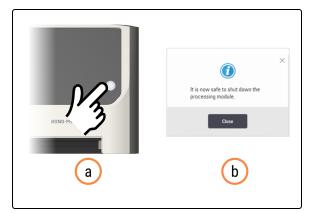
4.21 Replace power supply fuses



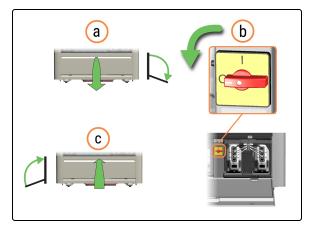
Ensure you have the correct fuses (F1, F2).
 The fuses are located at the rear of the processing module.



You may need to move the processing module for better access to the fuses and mains-power connector on the rear-panel.



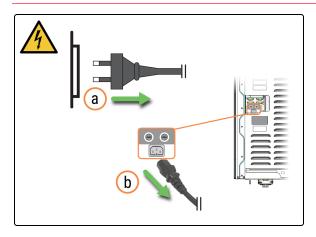
- 2. Power down the processing module.
 - a. Press the standby power button.A pop up window indicates that it is safe to shut down the processing module.
 - b. Tap Close.



- 3. Power off the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch counterclockwise.
 - c. Close the Reservoir Cabinet door.



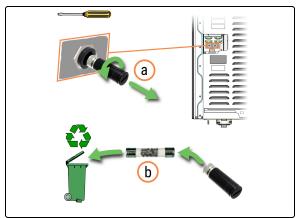
WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.



- 4. Unplug the mains power cable.
 - a. Unplug the mains power cable from the wall socket.
 - b. Unplug the mains power cable from the rear of the processing module.

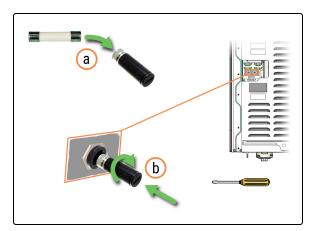


You may need to move the processing module for better access to the rear-panel connectors.

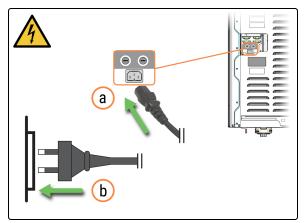


- 5. Dispose of the fuse.
 - a. Using a flat-bladed screwdriver, turn the fuse holder counter-clockwise and remove it from the processing module.
 - b. Dispose of the fuse in the recycling bin.

Do not dispose of old fuses in the general trash. Recycle if possible.



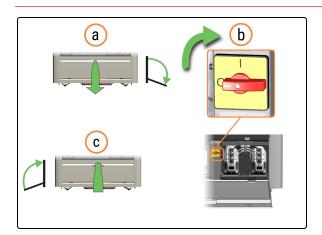
- 6. Install the new fuse.
 - a. Remove the new fuse from its packaging.
 - b. Insert the fuse holder into the processing module then use a flat-bladed screwdriver to turn the fuse holder clockwise until tight.



- 7. Plug in the mains power cable.
 - **a.** Plug the mains power cable into the rear of the processing module.
 - b. Plug the mains power cable into the wall socket.



You may need to move the processing module for better access to the rear-panel connectors.



- 8. Power on the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch clockwise.
 - c. Close the Reservoir Cabinet door.



9. When the processing module is turned on, it initializes before displaying the Log In Screen. This process takes from 8 to 15 minutes. If the processing module fails to initialize, refer to 5.1 Failure to initialize.



The Status screen is displayed.

5

Troubleshooting

In this section:

5.1 Failure to initialize	186
5.2 Network connectivity error	186
5.3 Manually retrieve slides from the processing module	186
5.4 Remove a slide fragment from an ARC Module	195

5.1 Failure to initialize

There are a number of reasons why the processing module may fail to initialize. These include:

- A Covertile has not been installed correctly in an ARC Module—refer to 4.14 Use the BOND-PRIME ARC Refresh
 Kit
- Robots are obstructed or prevented from moving freely—refer to 4.20 Shutdown the processing module
- There are slides left behind on the Work Surface—refer to 5.3.2 Manually retrieve slides from the Work Surface
- Mixing Well Plate is not present—refer to 4.14 Use the BOND-PRIME ARC Refresh Kit
- One or more Bulk Reagent Containers is empty or not inserted properly back into the processing module—refer to 4.4 Refill the Lot Tracked Bulk Containers
- Network connectivity issues—refer to 5.2 Network connectivity error.

If the problem persists, contact customer support.

5.2 Network connectivity error

1 Check that the processing module is connected to the BOND Controller and all network cables are plugged in.



The BOND Controller must be up and running before connecting the processing modules.

2 Restart the processing module.

5.3 Manually retrieve slides from the processing module

The processing module might occasionally indicate that slide processing cannot continue and you need to manually retrieve slides. You can retrieve slides from the following locations:

- Preload Drawer—refer to 5.3.1 Manually retrieve slides from Preload and Unload Drawers
- Unload Drawer—refer to 5.3.1 Manually retrieve slides from Preload and Unload Drawers
- Work Surface—refer to 5.3.2 Manually retrieve slides from the Work Surface
- ARC Modules—refer to 5.3.3 Manually retrieve slides from ARC Modules

There are a number of reasons why slides might be dropped. These include:

- the Suction Cup on the High-Speed Robot needs cleaning or replacement. Refer to 4.10 Clean the Suction Cup or 4.11 Replace the Suction Cup
- the label has been incorrectly placed on the slide, or there are more than two labels on the slide. Refer to Slide label specifications

- there is tissue, residue, or liquid on the slide label area.
- there is an issue with the Vacuum System
- the Preload Drawer or Unload Drawer has been replaced and is out of alignment.

The Action Queue will display a message indicating the cause of the issue and the action required to rectify it.

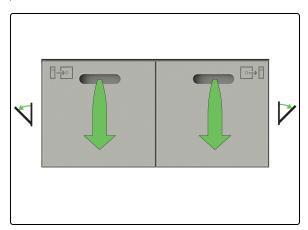
If slide transfer continuously fails, contact customer support.

5.3.1 Manually retrieve slides from Preload and Unload Drawers



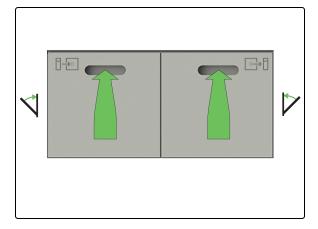
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.

If prompted by a message in the Action Queue to remove slides from the Preload or Unload Drawer, follow this procedure.



1. Open the Preload and Unload Drawers and remove the slides.

Check the drawers for debris. If there is debris, clean the drawers. Refer to 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter.



2. Close the Slide Preload and Unload Drawers.

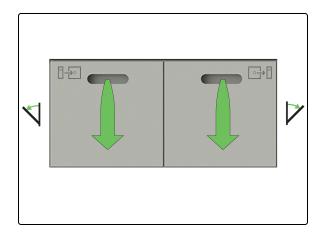
5.3.2 Manually retrieve slides from the Work Surface



WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.

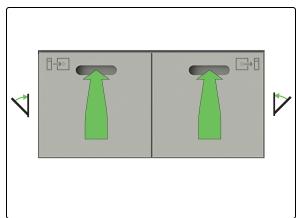


Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.

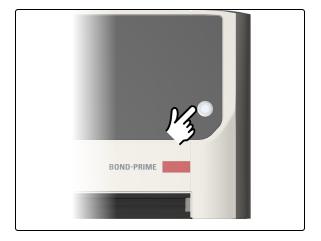


1. Open the Preload and Unload Drawers and retrieve the slides.

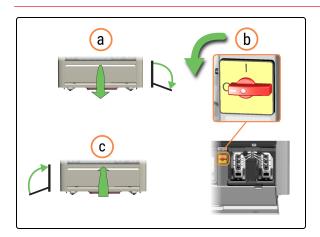
Check the drawers for debris. If there is debris, clean the drawers. Refer to 4.12 Clean the Slide Drawer Inserts, Waste Drains and Sumps, and Pickup Filter.



2. Close the Slide Preload and Unload Drawers.



3. Press the standby power button.



- 4. Power off the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch counterclockwise.
 - c. Close the Reservoir Cabinet door.

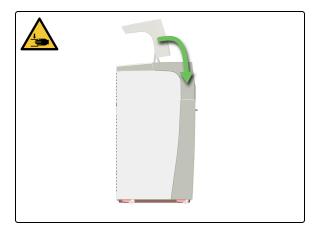


WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.



5. Open the Hood and retrieve the slides.

Check the Work Surface for debris. If there is debris, clean the Work Surface. Refer to 4.9 Wipe down Reagent Platform and ARC Bank Surfaces.



6. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



7. Restart the processing module. Refer to 3.2 Start the processing module.

5.3.3 Manually retrieve slides from ARC Modules



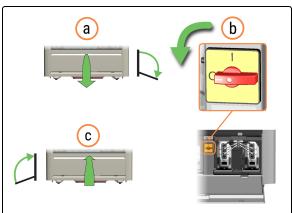
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



Before you start this procedure, ensure you are logged in to the processing module. Refer to 2.1 Log in and log out.



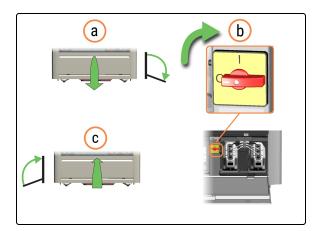
1. Press the standby power button.



- 2. Power off the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch counterclockwise.



WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.

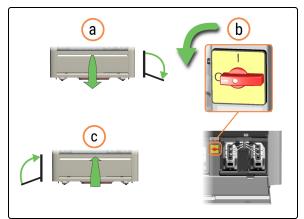


- 3. Power on the processing module.
 - a. Turn the AC power switch clockwise.

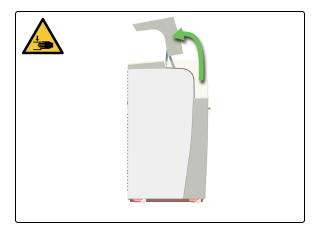




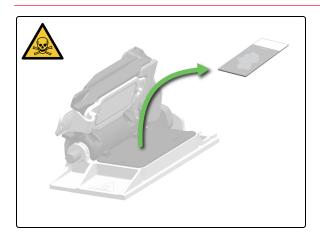
Initialization will fail, but the ARC Modules with slides detected are automatically opened.



- 4. Power off the processing module again.
 - a. Turn the AC power switch counterclockwise.
 - b. Close the Reservoir Cabinet door.



5. Open the Hood.



6. Remove the slide from the ARC Module and leave it fully opened. The ARC Modules are automatically closed when you restart the processing module.



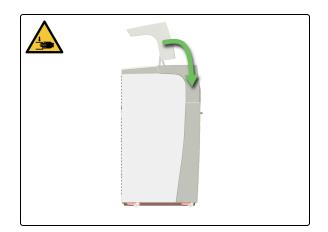
You can manually move the Wash Robots to gain better access to the ARC Modules.



CAUTION: Be careful not to drop slides when manually handling them over the Work Surface.



CAUTION: Do not close the ARC Modules manually. This is done automatically when you start the processing module.



7. If you no longer require access to the Work Surface, close the Hood and then continue with this procedure.



8. Restart the processing module. Refer to 3.2 Start the processing module.



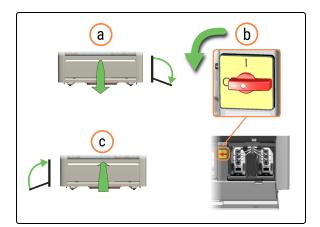
In the event of a power failure, refer to 5.3.4 Manually retrieve slides from ARC Modules during a power failure.

5.3.4 Manually retrieve slides from ARC Modules during a power failure

In the event of a power failure, you can follow these steps to manually remove slides.



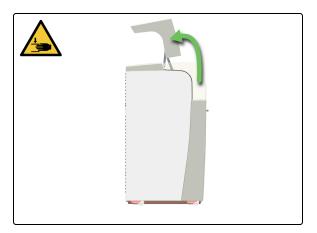
WARNING: You must wear the minimum required PPE before you maintain the processing module. Refer to General cautions.



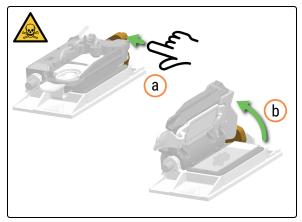
- 1. Power off the processing module.
 - a. Open the Reservoir Cabinet door.
 - b. Turn the AC power switch counterclockwise.
 - c. Close the Reservoir Cabinet door.



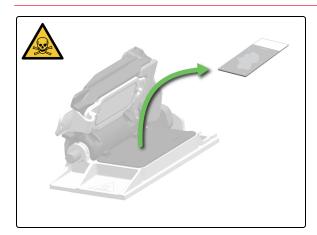
WARNING: Take care not to trip over the Reservoir Cabinet door when it is in the open position.



2. Open the Hood.



- 3. Manually open the ARC Module.
 - a. Press the ARC Module Latch.
 - b. Lift the ARC Module Lid.



4. Remove the slide from the ARC Module and leave it fully opened. The ARC Modules are automatically closed when you restart the processing module.



You can manually move the Wash Robots to gain better access to the ARC Modules.



CAUTION: Be careful not to drop slides when manually handling them over the Work Surface.



CAUTION: Do not close the ARC Modules manually. This is done automatically when you start the processing module.



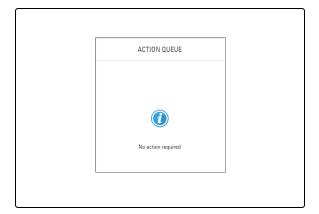
5. Close the Hood.

5.4 Remove a slide fragment from an ARC Module

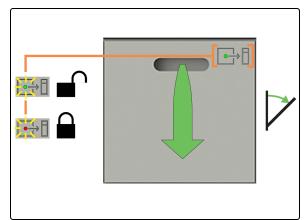
If you notice a slide with a portion missing in the Unload Drawer, you need to find and remove the slide fragment from the ARC Module.



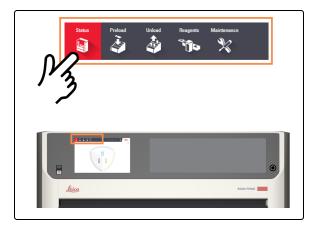
Do not load any new slides.



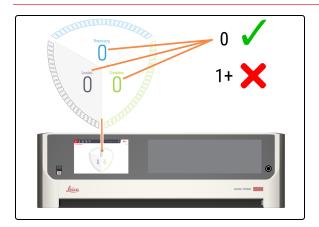
 Check the Action Queue to see if the error has been flagged by the processing module. If not, then the slide breakage has not been detected.



2. Open the Preload Drawer and remove the slides, then wait until all slides have finished processing.

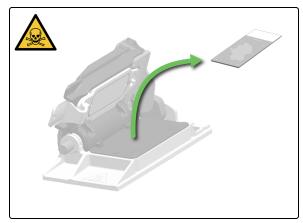


3. Tap Status.



4. Check the Status screen to ensure there are no slides currently being processed (Processing).

Refer to 2.3 Status Screen.



5. Check each ARC Module for glass fragments and manually remove the fragments according to 5.3.3 Manually retrieve slides from ARC Modules.

6

Specifications

In this section:

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6.3 Electrical power and UPS requirements	198
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6.1 System specifications

BOND Application 7 Clinical or later

BOND Controller Windows 10 IoT, Dell XE2, Dell XE3 or Dell XE4

BOND-ADVANCE Terminal Windows 10 IoT, Dell XE2 or Dell XE3

BOND-ADVANCE Controller Windows Server 2016, Dell T640, Dell T630 Network connection Ethernet IEEE802.3, 10/100/1000BASE-T

Network cables CAT5e or CAT6 shielded cables, with RJ-45 connectors

Ethernet switch requirements: Ethernet IEEE802.3, 10/100/1000BASE-T

Single-seat 8-port Ethernet switch (for a maximum of 5 processing

modules) *

BOND-ADVANCE

8- or 16-port Ethernet switches (for a maximum of 30

processing modules, when switches are connected together) * * any combination of processing modules: BOND-PRIME, BOND-

III. BOND-MAX

Leica Biosystems Melbourne Pty Ltd must supply the BOND Device specifications

Controller, BOND-ADVANCE Controllers, and BOND-ADVANCE

Terminals.

6.2 Physical specifications

Dimensions W – 1217 mm (47.9 in)

> H (hood closed) – 1400 mm (55.1 in) H (hood open) – 1820 mm (71.7 in)

D (Reservoir Cabinet Door closed) – 831 mm (32.7 in) D (Reservoir Cabinet Door open) – 1096 mm (43.1 in)

Weight (dry) 384 kg (847 lbs) Weight (loaded with reagent) 425 kg (937 lbs)

Necessary clearances Front – 800 mm (31.5 in) to access reagent containers

Rear - 50 mm (2 in) air gap

6.3 Electrical power and UPS requirements

90 V AC to 264 V AC (for nominal voltage 100 V AC to 240 V AC) Operating voltage

50/60 Hz Mains frequency 1260 VA Maximum power consumption

6.4 Environmental specifications

The information below is applicable only to installed processing modules.

 $\begin{array}{lll} \mbox{Maximum peak performance temperature} & 26 \ ^{\circ}\mbox{C} \ (79 \ ^{\circ}\mbox{F}) \\ \mbox{Minimum peak performance temperature} & 18 \ ^{\circ}\mbox{C} \ (64 \ ^{\circ}\mbox{F}) \\ \mbox{Maximum operating temperature} & 34 \ ^{\circ}\mbox{C} \ (93 \ ^{\circ}\mbox{F}) \\ \mbox{Minimum operating temperature} & 5 \ ^{\circ}\mbox{C} \ (41 \ ^{\circ}\mbox{F}) \\ \mbox{Maximum operating humidity (non-condensing)} & 80 \ ^{\circ}\mbox{RH} \\ \mbox{Minimum operating humidity (non-condensing)} & 30 \ ^{\circ}\mbox{RH} \\ \end{array}$

Maximum operating altitude 2700 m (8858 ft) above sea level

Minimum operating altitude 0 m (0 ft) above sea level

Level 0 to 1.5° gradient in any direction

Sound pressure level output (at 1 m) < 65 dBA normal operation

< 85 dBA maximum

Maximum heating energy output 1260 VA at power socket (~1100 W after power supply losses)

6.5 Operating specifications

Slides loaded capacity

Maximum 72 slides

Slide concurrent staining capacity

Maximum 24 slides

Reagent container capacity

7 mL and 30 mL

Reagent container dead volume $260~\mu\text{L}~(7~\text{mL})~\text{and}~932~\mu\text{L}~(30~\text{mL})$ Reagent container reserve volume $280~\mu\text{L}~(7~\text{mL})~\text{and}~280~\mu\text{L}~(30~\text{mL})$ Titration container capacity 6~mL~(maximum fill volume of~5.7~mL)

Titration container dead volume 220 µL

Titration container reserve volume 280 µL

Maximum number of reagent containers 70 (5 Reagent Containers x 14 Reagent Trays)

Ancillary reagents capacity:

Alcohol 1.25 L
BOND-PRIME Dewax Solution 1.25 L
BOND-PRIME Epitope Retrieval Solution 1 1.25 L
BOND-PRIME Epitope Retrieval Solution 2 1.25 L
BOND-PRIME Wash Solution Concentrate 1.25 L

BOND-PRIME Wash Working Solution Reservoir 1 L

Bulk DI Water capacity Container 4.5 L

Reservoir 5 L

Bulk waste capacity Container 4.5 L

Reservoir 5 L

Hazardous waste capacity Container 4.5 L

Reservoir 5 L

Chemical compatibility DI water grade only

All BOND-PRIME reagents

100% ethanol, or reagent grade alcohol. Reagent grade alcohol

comprises: Ethanol, greater than or equal to 90% (w/w); Isopropanol, no more than 5% (w/w); Methanol, no more than

5% (w/w).

70% ethanol solution is used to clean some parts.

Service life 7 years.
BOND-PRIME Cybersecurity certificate expiry 10 years

6.6 Microscope slide specifications

Slide specifications

Label area

Dimensions Width: 24.64–26.0 mm (0.97–1.02 in)

Length: 74.9-76.0 mm (2.95-2.99 in) Thickness: 0.9-1.2 mm (0.03-0.05 in)

Width: 24.64-26.0 mm (0.97-1.02 in)

Length: 16.9-21.0 mm (0.67-0.83 in)

Material Glass, ISO 8037/1

Usable slide area Refer to the diagram below.

Slide label specifications

Dimensions Width: 22–24 mm (0.87–0.94 in)

Length: 15–20 mm (0.59–0.79 in)

Maximum 2 stacked labels

Skew angle User to place the label on straight.

Usable slide label area (within top frosted surface)

and permitted slide label placement

No label overhang permitted.

21 mm (0.83 in) 20 mm (0.79 in) 24 mm (0.94 in) 26 mm (1.02 in)

Figure 6-1: Maximum dimensions

6.7 Transport and storage specifications

Crated dimensions	W - 1828 mm (72.0 in)
	H - 1590 mm (62.6 in)
	5 4464 (4444)

D - 1134 mm (44.6 in)

Crated weight 553 kg (1219 lbs)

Storage temperature -20 to +50 °C (-4 to +122 °F)

Storage humidity (non-condensing) < 80% RH

Uncrating requirements Allow a flat space of approximately 6000 mm x 4000 mm

(236.2 in x 157.4 in) to uncrate

Movement on casters Minimum door width of 850 mm (33.5 in)

Traverse a maximum ramp angle of 7 degrees

= 1.2 mm (0.05 in)

Shipping methods Road, air and sea freight compatible

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