Brevera®

Breast Biopsy System



Brevera® Breast Biopsy System
User Guide

MAN-07980-002 Revision 002

Brevera®

Breast Biopsy System

User Guide

Models BREV100, BREV200
Part Number MAN-07980-002
Revision 002
September 2026

HOLOGIC®

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Chapter 1 Introduction

1.1 Preface

Read all this information carefully before installation and operation. Follow all warnings and precautions as stated in this manual. Keep this manual available during procedures. Physicians should tell patients about all potential risks and adverse events described in this manual with respect to the operation of the system.

1.2 Indications for Use

℞ONLY Caution: United States federal law restricts this device to sale by or on the order of a physician.

The Hologic® Brevera® breast biopsy system with CorLumina® imaging technology is intended to provide breast tissue samples for diagnostic sampling of breast abnormalities. The Brevera breast biopsy system excises targeted tissue and optionally delivers in-line radiographic images of the excised tissue. The Brevera breast biopsy system is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (for example, fibroadenoma, fibrocystic lesion), the Brevera breast biopsy system may also be used to partially remove such palpable lesions. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histological abnormality, for example, malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.

1.3 Contraindications

- The Brevera breast biopsy system with CorLumina imaging technology is not intended for therapeutic applications.
- The Brevera breast biopsy system with CorLumina imaging technology is contraindicated for those patients who, based on the physician's judgment, may be at increased risk or develop complications associated with core removal or biopsy. Patients receiving anticoagulant therapy or who may have bleeding disorders may be considered at increased risk of procedural complications.

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1.4 Patient Target Group

The Brevera breast biopsy system is intended to be used on patients with suspicious breast tissue abnormalities that need to be histologically sampled via biopsy for the primary diagnosis of said abnormality.

1.5 Clinical Benefits

The Brevera breast biopsy system performs biopsies in a time efficient manner by combining vacuum-assisted tissue acquisition, real-time imaging verification, and advanced post-biopsy handling in one integrated system. Real time imaging enables visual confirmation of tissue acquisition steps, allowing physicians to make informed clinical decisions with confidence thereby avoiding repeated biopsy.

1.6 Potential Adverse Effects

The following potential adverse effects can occur or have been reported in association with the use of the Brevera breast biopsy system:

- Hematoma
- Perforation
- Blunt Trauma
- Infection
- Tissue Damage
- Pain
- Bleeding
- Inflammation
- Electric Shock
- Annoyance/Distractions
- Foreign Body Reaction
- Misdiagnosis
- Embolism
- Migration of Marker from Intended Location
- Additional Intervention

1.7 Essential Performance

The essential performance of the Brevera breast biopsy system is to maintain compliance with the applicable requirements of IEC 61010-2-91:2019 to prevent exposure of the patient, operator, or other individuals to unacceptable levels of X-ray radiation.

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1.8 System Capabilities

The Hologic Brevera breast biopsy system with CorLumina imaging technology is a vacuum-assisted biopsy device which is used to remove breast tissue in a minimally invasive manner using stereotactic or tomosynthesis imaging. The system is designed for biopsy and for specimen radiographic image acquisition and display only. The system is NOT intended to be used outside the standards, specifications, and limitations outlined in these instructions for use.

The Brevera biopsy needle is single-use and is disposable. The user connects the biopsy needle to a reusable device driver and connects the biopsy device components to the console. The biopsy needle primarily consists of a hollow needle with a side aperture and a sharpened inner cannula that, when connected to the Brevera breast biopsy system, rotates and extends across the aperture to acquire targeted tissue. The Brevera device driver contains mechanical and electrical components that drive needle rotation and advancement. During the biopsy process, vacuum created inside the biopsy device pulls tissue into the aperture. The cannula translates and rotates to cut the tissue. The tissue sample is then aspirated through a tubing line to a tissue filter. Saline is supplied through the biopsy device to lavage the cavity and deliver tissue to the tissue filter.

When the Brevera biopsy needle is connected to the Brevera device driver, the combination is referred to as the Brevera breast biopsy device.

An introducer, specifically designed for use with the Brevera breast biopsy system, is packaged with the biopsy needle. This introducer maintains access to the targeted area of interest and allows for deployment of a biopsy site marker. The introducer is used to control the variable aperture function of the device. The introducer also prohibits the user from administering medication through the Y-site in the tubing while the device is in the armed (pre-fire) position.

The Brevera breast biopsy system with CorLumina imaging technology acquires and displays the radiographic images of core specimens contained in the tissue filter. A tissue filter, specifically designed for use with the Brevera breast biopsy system, is provided with the biopsy needle. The Brevera breast biopsy system with CorLumina imaging technology also has the capability to display images as well as to transfer these images to external devices. The images acquired with this system are intended to confirm removal of tissue from a suspected lesion or pathology. The system is not intended for diagnostic purposes.

Radiology technologists, surgical personnel, surgeons, radiologists, and pathologists can use the specimen radiography equipment in the Brevera breast biopsy system with CorLumina imaging technology.

Hologic recommends that users receive training in basic ionizing radiation safety before using the system.

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1.9 User Profiles

1.9.1 Mammography Technologist

- Meets all requirements that apply to the location in which the Mammography Technologist operates.
- Completed training on the mammography system.
- Has training in mammography positions.
- Understands stereotactic breast biopsy procedures.
- Understands how to operate a computer and its peripherals.
- Understand sterile procedures.

1.9.2 Radiologists, Surgeons

- Meets all requirements that apply to the location in which the Physician operates.
- Understands stereotactic breast biopsy procedures.
- Understands how to operate a computer and its peripherals.
- Understand sterile procedures.
- Gives local anesthesia.
- Understands basic surgical procedures for core biopsy.

1.9.3 Medical Physicist

- Meets all requirements that apply to the location in which the Medical Physicist operates.
- Understands mammography.
- Has experience with digital imaging.
- Understands how to operate a computer and its peripherals.

1.10 Where to Find the Installation Instructions

Contact Hologic Technical Support for installation instructions.

1.11 Where to Find Technical Description Information

Contact Hologic Technical Support for technical description information.

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1.12 Warranty Statement

Hologic's sales terms and conditions for US customers can be found at the following URL: *https://www.hologic.com/hologic-sales-terms-conditions*.

For all other customers, please contact your local sales representative for any applicable warranty information.

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1.13 Technical Support.

Refer to the title page of this manual for contact information for product support.

1.14 Product Complaints

Report any complaints or problems regarding the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to the Hologic Authorized Representative and Competent Authority of the respective member state or country.

The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

1.15 Hologic Cybersecurity Statement

Hologic continuously tests the current state of computer and network security to examine possible security problems. When necessary, Hologic provides updates to the product.

For Cybersecurity Best Practices documents for Hologic products, refer to the Hologic Internet site at *www.Hologic.com*.

This information is also available in the Product Security Manual. Contact your service representative for more information.

1.16 Antivirus Information

Contact your service representative for antivirus installation.

1.17 Where to Obtain Copies of the Manuals

To obtain a PDF file of the User Guide, go to the support pages at *www.Hologic.com*. (Adobe Acrobat Reader version 5.0 or higher is required to view the PDF file.)

To order printed manuals, contact the Hologic Parts Support Group.

E-mail: *parts@hologic.com*

Tel: 781-761-7003

Fax: 877-574-3244

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1.18 Symbols

This section describes the symbols on this device. To obtain additional information regarding symbols and standards, refer to the Breast and Skeletal Health Products and Labels Glossary of Symbols at the following URL: *https://www.hologic.com/package-inserts/symbol-legend-and-glossary*.

Symbol	Description	Standard
	"ON" and "OFF" (power) [variation from standard of "Stand-by"]	IEC 60417, Reference 5009
	Alternating current (AC)	IEC 60417, Reference 5032
	Atmospheric pressure limitation	ISO 15223-1, Reference 5.3.9
	Authorized Representative in the European Community	ISO 15223-1/ Amd 1, Reference 5.1.2
	Batch code	ISO 15223-1, Reference 5.1.5
	Catalog number	ISO 15223-1, Reference 5.1.6
	Note	Hologic
	Caution	ISO 15223-1, Reference 5.4.4
	Warning	ISO 7010, Reference W001
	Prescription use only	FDA 21 CFR 801.109
	Caution—Radiation	Hologic
	Mass; weight	ISO 60417, Reference 1321A

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Symbol	Description	Standard
	Consult Instructions for Use	ISO 15223-1, Reference 5.4.3
	Contents	N/A
	Date of Manufacture	ISO 15223-1, Reference 5.1.3
	Device driver and remote control connection	Hologic
	Device driver cord management plate	Hologic
	Do not re sterilize	ISO 15223-1, Reference 5.2.6
	Do not re-use	ISO 15223-1, Reference 5.4.2
	Stacking limit by number	ISO 7000, Reference 2403
	Do not use if package is damaged	ISO 15223-1, Reference 5.2.8
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.	WEEE Directive 2012/19/EU
	Refer to instruction manual or booklet	ISO 7010, Reference M002
	Footswitch connection	Hologic

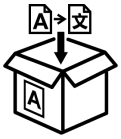
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Symbol	Description	Standard
	Footswitch cord management plate	Hologic
	Humidity limitation	ISO 15223-1, Reference 5.3.8
	Keep dry	ISO 15223-1, Reference 5.3.4
	Manufacturer	ISO 15223-1, Reference 5.1.1
	Medical -General medical Equipment as to equipment as to electrical shock, fire, and mechanical hazards only in accordance with ANSI/AAMI ES 60601-1:2005+A1:2012+A2:2021 CAN/CSA-C22.2 No. 60601-1:14+A2:22	ETL Classification
	Conditional use for magnetic resonance imaging	ASTM F2503 Reference no. Table 2; 7.4.6.1; Fig. 6,7
	Not safe for magnetic resonance imaging	ASTM F2503 Reference no. Table 2, Symbol 7.3.3; 7.4.9.1; Fig. 9
	Quantity	Hologic
	Saline tubing management plate	Hologic
	Serial Number	ISO 15223-1, Reference 5.1.7
	Sterilized using irradiation	ISO 15223-1, Reference 5.2.4

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Symbol	Description	Standard
	Single sterile barrier system with protective packaging inside	ISO 7000, Reference 3708
	Single sterile barrier system	ISO 7000, Reference 3707
	Temperature limit	ISO 15223-1, Reference 5.3.7
IPX8	The equipment or accessory is suitable for continuous immersion in water (up to 1 m of submersion for 1 hour).	IEC 60529
	This way up	ISO 7000, Reference 0623
	Type BF applied part	IEC 60417, Reference 5333
	No Push Do not Push the equipment. Pushing may cause instability, tip-over, or damage the system.	ISO 7010, Symbol P017
	Use-by Date	ISO 15223-1, Reference 5.1.4
	Warning electricity	ISO 7010, Reference W012
	Wi-Fi	Hologic
	Equipotentiality	IEC 60417, Reference 5021
	Computer network	IEC 60417, Reference 5988
	Pinch point	ISO 7010

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Symbol	Description	Standard
	Locking, general	IEC 60417, Reference 5569
	Unlocking	IEC 60417, Reference 5570
	USB	IEC 60417-1
	Made in United States of America	Hologic
	Medical Device	ISO 15223-1, Reference 5.7.7
	Made in Costa Rica	Hologic
	CE Mark with Notified Body reference number	MDR regulation (EU) /745
	Translations in box	Hologic per ISO 7000, Reference 3728
	Patents	Hologic
	Country code for translation	ISO 3166

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1.19 Descriptions of Warnings, Cautions, and Notes

Descriptions of Warnings, Cautions, and Notes used in this manual:



WARNING!
The procedures that you must follow accurately to prevent possible dangerous or fatal injury.



Warning:
The procedures that you must follow accurately to prevent injury.



Caution:
The procedures that you must follow accurately to prevent damage to equipment, loss of data, or damage to files in software applications.



Note
Notes show additional information.

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Chapter 2 General Information

2.1 System Overview

The Brevera breast biopsy system with CorLumina imaging technology has system components for vacuum-assisted breast tissue biopsy and system components for x-ray generation and image acquisition. The user interface for data entry, patient selection, and image acquisition and review is on the Imaging display. The user interfaces for controlling the modes of the biopsy device are buttons on the Technologist display and also on the remote control. The user interface for arming and firing the biopsy device is on the remote control. The user adjusts the rotation of the aperture on the biopsy device with the aperture knob on the disposable biopsy needle. The user adjusts the dimension of the aperture on the biopsy device using the introducer.

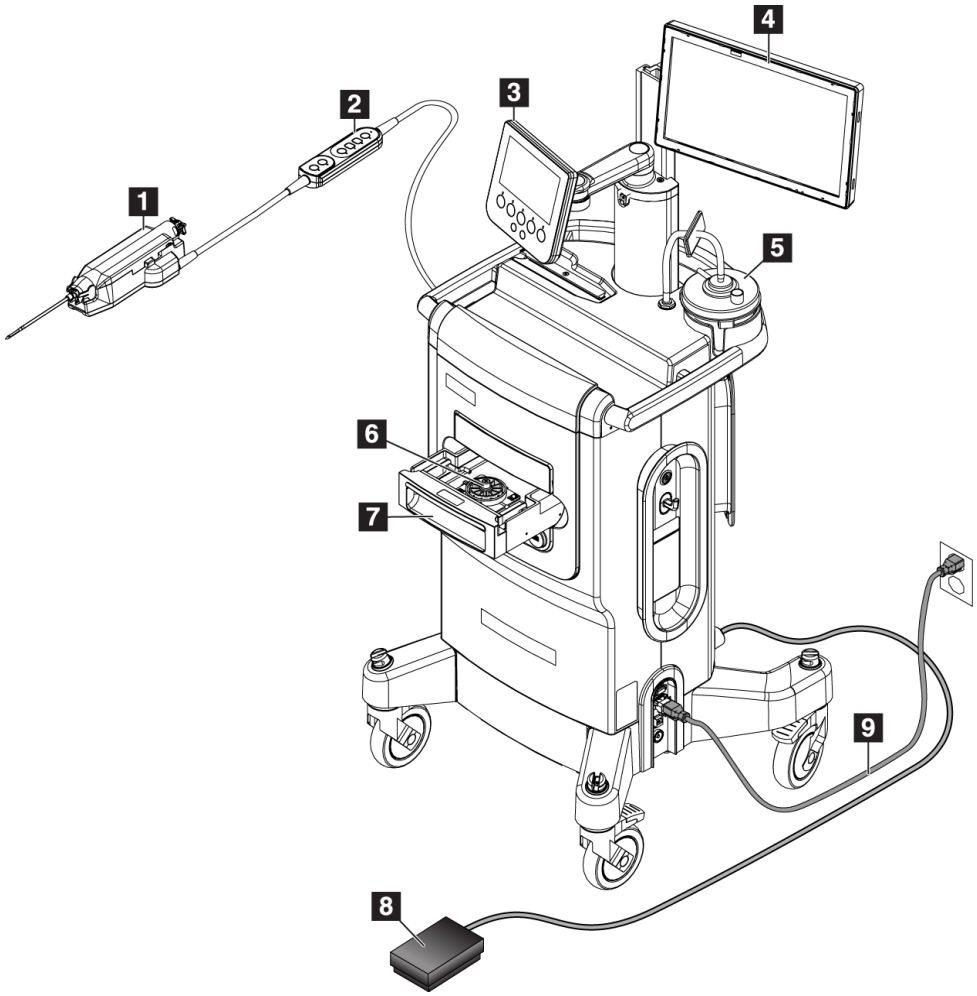


Figure Legend

1. Biopsy device
2. Remote control for mode control and arming or firing the biopsy device
3. Technologist display
4. Imaging display
5. Vacuum line assembly and suction canister
6. Tissue filter assembly
7. Tissue filter drawer
8. Footswitch
9. Power cord

Figure 1: Brevera Breast Biopsy System Overview

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2.2 Safety Information

Read and understand this manual before you use the system. Keep the manual available during the operation of the unit.

Always follow all the instructions in this manual. Hologic does not accept responsibility for injury or damage from incorrect system operation. For training options, contact your Hologic representative.

The system has safety interlocks, but the user must understand how to safely operate the system and be aware of the health hazards of x-ray radiation.

2.3 Warnings and Precautions

WARNING!
The Brevera breast biopsy system must be installed and put into service according to the guidance provided in these instructions to ensure its electromagnetic compatibility. Refer to the electromagnetic emissions and immunity tables.

WARNING!
Portable and mobile RF communications equipment can affect the Brevera breast biopsy system. Do not use portable RF communications equipment any closer than 30 cm (12 inches) to any part of the Brevera system, including cables.

WARNING!
The Brevera breast biopsy system console is designed to use the power cord provided. Do not use a different power cord. Using a different power cord can create an electrical and fire hazard. DO NOT remove the ground wire or ground prong from any power plug. DO NOT use an extension cord with this equipment. An adapter may be necessary depending on the outlet used.

WARNING!
Make sure that the power cord for the Brevera breast biopsy system console is in good condition. A damaged power cord can be an electrical shock hazard. When disconnecting the console from power, always grasp the plug at the insertion point and pull lightly. NEVER pull on the cord to unplug the unit.

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WARNING!
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Check grounding continuity regularly.

WARNING!
To prevent shock hazard, do not use the polarized plug for the console with a receptacle unless the blades can be fully inserted.

WARNING!
To prevent fire or shock hazard, do not expose the console to rain or moisture.

WARNING!
Only trained Service Engineers authorized through Hologic can open any of the panels. This system contains lethal voltages.

WARNING!
Electrical equipment used near flammable anesthetics can cause an explosion.

WARNING!
Do not use the system in an oxygen-rich environment.

WARNING!
The user must correct problems before the system is used. Contact an approved service representative for preventive maintenance.

WARNING!
Do not attempt to use any console that could present a shock hazard. Immediately contact Hologic or your distributor.

WARNING!
Do not touch the metal parts of the device driver and the patient at the same time.

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WARNING!
Grounding reliability can only be achieved when this equipment is connected to a receptacle marked "hospital grade". Check grounding continuity regularly.

WARNING!
The console should not touch other electrical equipment during use.

WARNING!
Use caution when attaching sharp devices to the adapter.

WARNING!
Avoid operator or instrument contact with the sheathed needle part of the Brevera biopsy needle.

WARNING!
Dispose of all opened disposable instruments whether used or not.

WARNING!
Do not resterilize or reuse the Brevera biopsy needle or the introducer. Resterilization or reuse can compromise the integrity of the instrument. This can lead to potential risks of failure of the biopsy needle to perform as intended or to cross-contamination associated with using inadequately cleaned and sterilized devices.

WARNING!
No modification of this equipment is allowed.

WARNING!
The protection provided by the equipment is reduced if the equipment is used in a method not specified by Hologic.

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WARNING!
This device contains magnets. Magnets may interfere with the function of implanted medical devices such as pacemakers and implantable cardioverter defibrillators (ICDs). Keep the device at least 15 cm (6 inches) away from implanted medical devices. Consult your physician before use if you have an implanted medical device.

WARNING!
Use care when advancing, manipulating, or withdrawing the needle. Excessive force, unintended bending, or use under conditions not described in this Instructions for Use may increase the risk of needle damage. If needle fracture, breakage, or dislodgement is suspected, discontinue use and assess the patient using appropriate clinical judgement.

WARNING!
The Brevera System is intended to collect up to 24 consecutive tissue cores during a biopsy procedure. If 24 consecutive cores are acquired, place the system in Standby mode for a minimum of 20 minutes before collecting additional tissue samples.

Warning:
This device contains dangerous material. Send decommissioned material to Hologic or contact your service representative.

Warning:
This system is intended for use by healthcare professionals only and should be operated in a professional healthcare facility.

Warning:
Control the access to the equipment according to local regulations for radiation protection.

Warning:
This system can be dangerous to the patient and the user. Always follow the safety precautions for x-ray exposures.

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Warning:
As with any medical procedure, make sure that users wear appropriate personal protective equipment to guard against potential contact with bodily fluids.

Warning:
The Brevera breast biopsy system with CorLumina imaging technology is not for use with MRI or Ultrasound.

Warning:
The Brevera system breast biopsy procedure should be performed only by persons with sufficient training and familiarity with this procedure. Consult medical literature relative to techniques, complications, and hazards before performing any minimally invasive procedure.

Warning:
The Brevera biopsy device should only be used by physicians trained in percutaneous biopsy procedures.

Warning:
Use sound professional judgment when using the Brevera breast biopsy device on patients with breast implants.

Warning:
Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic may not be compatible with the Brevera breast biopsy system. Use of such products can lead to unanticipated results and possible injury to the user or patient.

Warning:
Instruments or devices that come into contact with bodily fluids can require special disposal handling to prevent biological contamination.

Warning:
Cables and cords can pose a tripping hazard. Position cords safely out of the way. When not in use, wind cords securely around the cord management plates.

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Warning:
Do not use the needle if it appears bent or damaged, as device performance may be compromised.

Caution:
If the console will not be used for several days or an extended period of time, disconnect the console from the electrical outlet. Place the console in a location where it will not be damaged.

Caution:
The console can radiate radio frequency energy and, if not installed and used in accordance with the instructions, can cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If the console does cause harmful interference to other devices, which can be determined by turning the console off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving device; increase the separation between the equipment; connect the console to an outlet on a circuit different from that to which the other device is connected; or consult Technical Support.

Caution:
To prevent internal heat buildup, allow sufficient air circulation around the console. Do not place the console within .3 meters (1 foot) of any obstructive surface.

Caution:
Use and store the console in a location away from heat sources such as radiators or air ducts, direct sunlight, excessive dust, mechanical vibration, or shock.

Caution:
Do not operate the equipment at altitudes higher than 3,000 meters (9,842 feet). Do not store or operate the equipment in conditions outside of the stated equipment storage, transport, and operating environmental conditions.

Caution:
Allow the console to acclimate for 24 hours before use after removal from storage.

Caution:
Risk of data loss. Do not put any magnetic media near or on devices that create any magnetic fields.

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Caution:
To prevent possible damage to the system, follow the recommended procedure to turn off the equipment.

Caution:
Never use strong solvents or abrasive cleansers to clean the console since these will damage the console casing. Clean the console after the power cord is disconnected from the power outlet.

Caution:
Use the least possible amount of cleaning fluids. The fluids must not flow or run.

Caution:
To prevent damage to the electronic components, do not use disinfectant sprays on the system.

Caution:
The weight and mobility of this system require the following precautions:

- **Be careful when you move the system on uneven or sloped surfaces.**
- **Make sure that the wheels are locked when the system is stationary.**
- **Before you move the system, make sure that the cables are stored in a safe position and that the display screens are pushed down to their lowest heights. Make sure that all four casters are unlocked.**
- **Do not make quick stops. Do not move with excessive force.**

Caution:
The system is a laboratory device and not a normal computer. Do not make changes to the hardware or software that are not authorized. Install this device behind a firewall for network security. The computer virus protection or network security for this laboratory device is not provided (for example, a computer firewall). The network security and anti-virus provisions are the responsibility of the user.

Caution:
If you are a Hologic customer in the United States, contact Hologic if you cannot correct a problem using these instructions for use. Outside of the United States, contact your distributor or local Hologic representative with questions, comments, or technical service issues.

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2.4 Interlocks

The x-ray generation stops automatically and a system message or alert appears when there is an interruption of an x-ray exposure. (Examples of x-ray interruptions include: the mAs timer or maximum exposure timer times out, the tissue filter drawer is opened, or the key switch is turned to the locked position.) To make another exposure:

1. Select the **OK** button in the system message dialog box.
2. Select the status icon (shaped like the Brevera breast biopsy console) in the taskbar at the bottom of the Imaging display screen.
3. Complete any action (such as "close the drawer") that shows in the system message area of the Imaging display screen.
4. Select the **Clear All Faults** option.

2.5 Compliance

This section describes the system compliance requirements and the responsibilities of the manufacturer.

2.5.1 Compliance Requirements

The manufacturer has the responsibility for the safety, reliability, and performance of this equipment with the following provisions:

- The equipment is used according to the instructions for use.
- The assembly operations, extensions, adjustments, changes, or repairs are performed only by authorized persons.
- The network and communication equipment must be installed to meet IEC Standards.



Caution:
This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.



Caution:
The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer sufficient protection to radio-frequency communication services. The user may need to take mitigation measures, such as relocating or re-orienting the equipment.

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Caution:
The Medical Electrical (ME) Equipment or ME System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, make sure that the ME Equipment or ME System operates correctly in this configuration.

Caution:
Changes or modifications not expressly approved by Hologic could void your authority to operate the equipment.

2.5.2 Compliance Statements

The manufacturer states this device is made to meet the following requirements:

- IEC 60601-1:2005+A1:2012+A2:2020 (Ed.3.2) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- ANSI/AAMI ES 60601-1: 2005 A1: 2012, C1: 2009/(R)2012 and A2: 2010/(R)2012 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance
- CAN/CSA-C22.2 No. 60601-1 (2014) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- EN 60601-1: 2006 / A1: 2013 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014+ A1:2020 (Ed4.1) Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-6: 2010/AMD1: 2013 and IEC 62366: 2007/AMD1: 2014 Application of Usability Engineering to Medical Devices

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2.6 System Label Location

For the location of the system label and serial number, refer to the figure that follows.

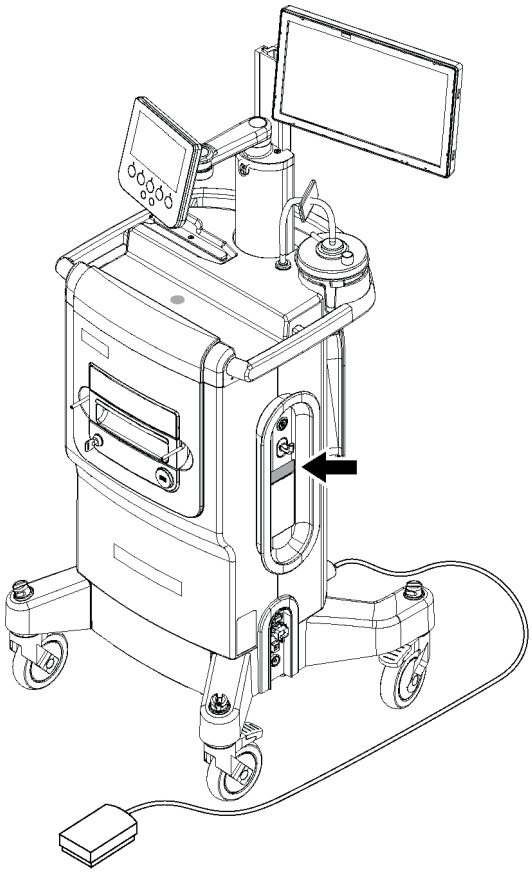


Figure 2: Location of the System Label

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Chapter 3 Components, Controls, and Indicators

3.1 System Components

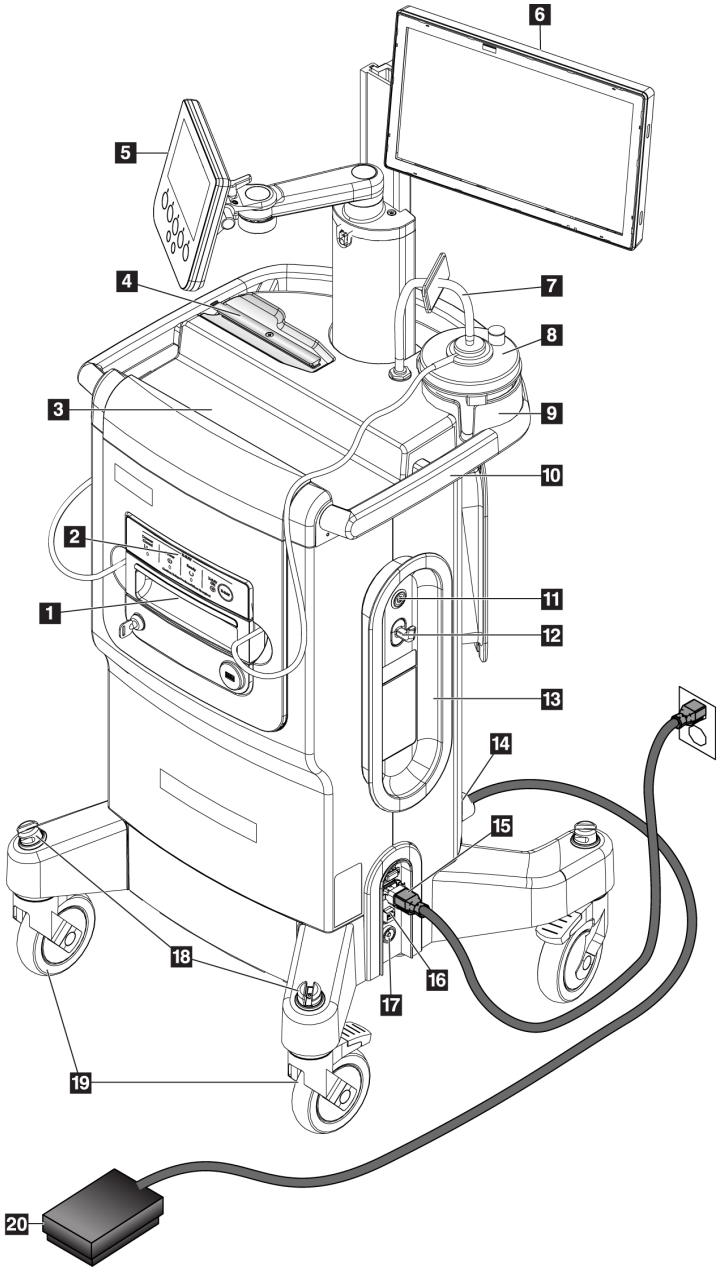


Figure 3: System Components (Front, Right)

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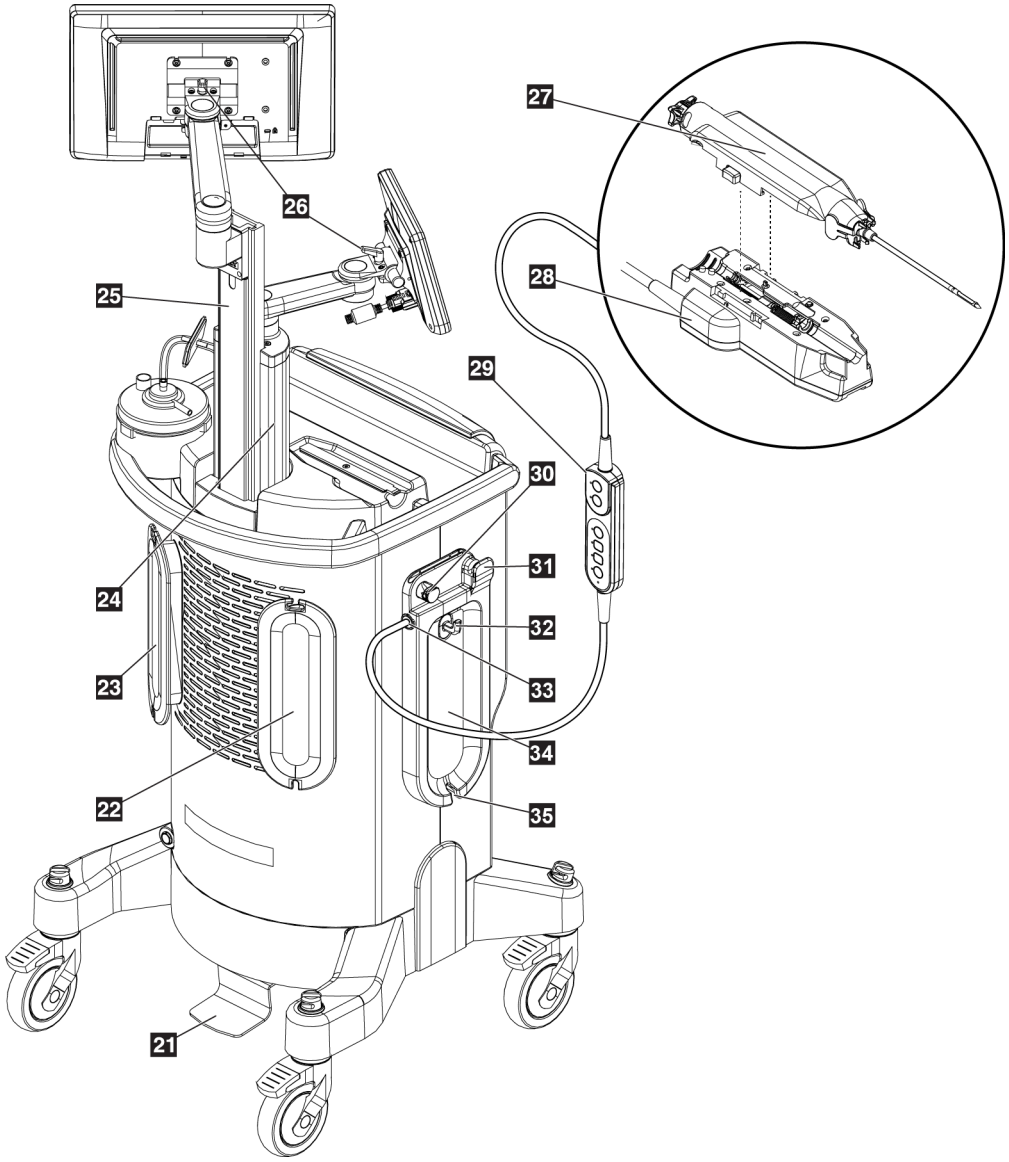


Figure 4: System Components (Back, Left)

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Figure Legend

1	Tissue filter drawer	The compartment where biopsy cores are collected and imaged.
2	Imaging panel	Includes status indicators and lockout key for the x-ray system.
3	Console tray	Storage and staging area for the biopsy needle packaging.
4	Device driver holder	Storage and setup area for the device driver.
5	Technologist display	The display screen shows the current status of the system, and the buttons provide one of the two methods for selecting the system mode. The display has an articulating arm and is attached to the display mounting post.
6	Imaging display	User interface touch screen display for viewing, annotating, saving, and exporting radiographic images. The display is secured to an adjustable slide in the display mounting post.
7	Vacuum line assembly	Clear tubing attached to the console at one end. The other end has a blue connection that attaches to the suction canister lid at the port labeled "VACUUM". The vacuum line assembly includes a hydrophobic filter to prevent fluid backflow.
8	Suction canister	Disposable canister used for the collection, retention, and disposal of liquid medical waste.
9	Suction canister holder	Recessed area of the console tray that holds the suction canister.
10	Console handle	Move the console by pushing this handle.
11	Power button	Push-button switch that powers ON the system. The power button illuminates green when the console is powered on.
12	Utility hook	Hook for hanging reference cards or patient charts.
13	Power cord management plate	Provides safe storage for the power cord when moving or storing the console. Wind the power cord clockwise around the power cord management plate.
14	Footswitch connection	Receptacle for the footswitch cord. The red dots align at the top when attached correctly.
15	Power connection	AC inlet. Receptacle for the hospital grade power cord (provided).
16	Ethernet connection	Port for Ethernet (network) cable. (Optional Wi-Fi available.)
17	Potential equalization connection	Receptacle for equipotential ground.
18	Cord management slots	Slots for cord management.
19	Casters	All four casters allow for 360-degree swivel and have locking brakes to hold the unit in place.
20	Footswitch	Depressing the footswitch activates the biopsy device.

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Figure Legend

21	Imaging display height-adjust pedal	Depressing the pedal releases the Imaging display mounting slide to allow for height adjustment. Release the pedal to lock the slide.
22	Device driver cord management plate	Provides safe storage for the device driver cord when moving or storing the console. Wind the device driver cord clockwise around the device driver cord management plate.
23	Footswitch cord management plate	Provides safe storage for the footswitch and the footswitch cord when moving or storing the console. Wind the footswitch cord counter-clockwise around the footswitch management plate.
24	Display mounting post	Stationary post that the Technologist display is mounted on. The mounting post also houses and guides the Imaging display mounting slide.
25	Imaging display mounting slide	Height-adjustable slide that the Imaging display is mounted on. The slide is released and locked with the Imaging display height-adjust pedal.
26	Display tilt-adjust levers	Release the lever to adjust the tilt of the display. Engage the lever to lock the display into the desired tilt position.
27	Biopsy needle	Single-use, disposable biopsy needle for acquiring biopsy specimens. Refer to *Biopsy Needle Components* on page 31.
28	Device driver	This electromechanical component is powered by the console. When the device driver is connected to the biopsy needle, the device driver propels the rotation and the advancement of the cutting cannula in the biopsy needle. The device driver also arms and fires the biopsy needle.
29	Remote control	This in-line, hand-held component allows the physician to arm and fire the biopsy device. The remote control also provides one of the two methods for selecting the system mode.
30	Saline pinch valve	Area to insert the saline tubing to control the flow of saline.
31	Saline tubing conduit	Slot used to guide the saline tubing toward the saline pinch valve.
32	Saline bag hook	Hook for hanging the saline bag (250 cc recommended).
33	Device driver and remote control connection	Receptacle for the cord for the device driver and remote control. The red dots align at the top when attached correctly.
34	Saline tubing management plate	Wind the saline tubing counterclockwise around the saline tubing management plate.
35	Saline tubing notch	Recess in the saline tubing management plate used to guide the saline tubing from the saline bag and around the saline tubing management plate.

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3.1.1 Imaging Cabinet Components

The Brevera console houses a cabinet where the biopsy cores are collected and imaged. The cores are collected in a disposable tissue filter that is placed in the drawer of the imaging cabinet. The imaging cabinet includes a panel that gives status information about the x-ray system.

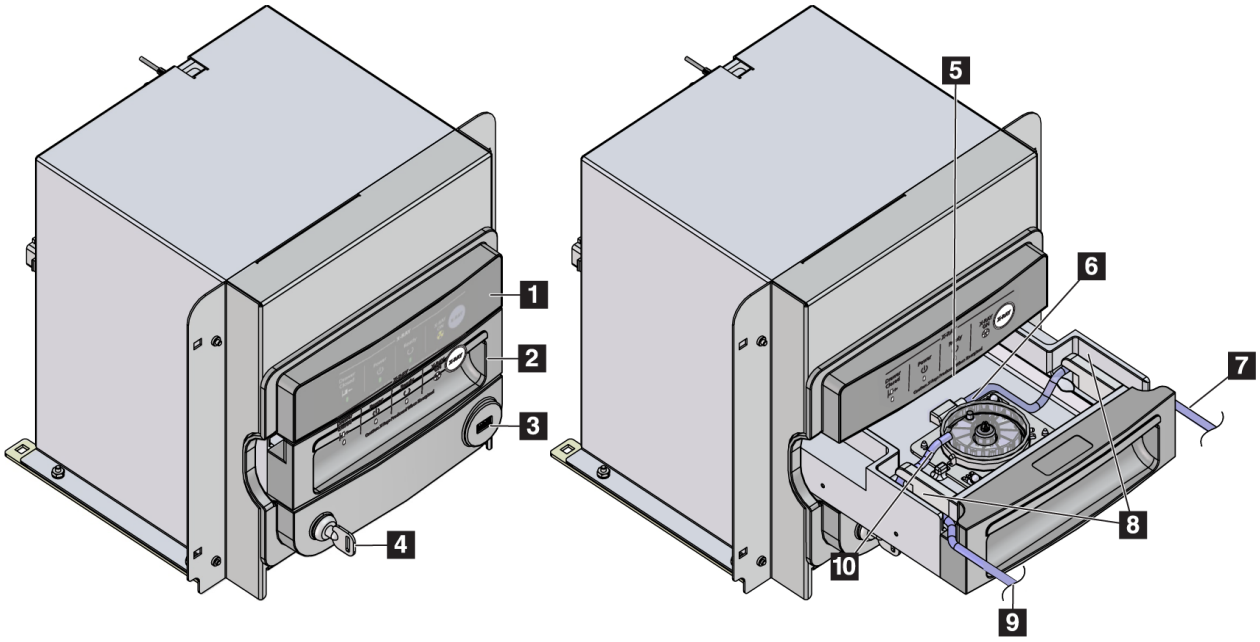


Figure 5: Imaging Cabinet Components

Figure Legend

1. Imaging panel
2. Tissue filter drawer
3. USB port (for non-powered USB flash drive only)
4. Key switch
5. Detector plate
6. Tissue filter assembly
7. Tubing outlet to the suction canister
8. Tubing channels
9. Suction tubing inlet from the biopsy needle
10. Locator pin (each corner)

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3.1.2 Suction Canister Components

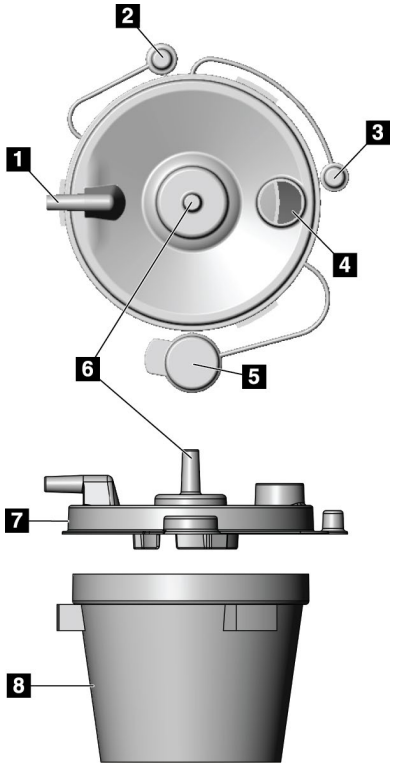


Figure 6: Suction Canister Components

Figure Legend

1. "Patient" port – receives the suction tubing (clear with a blue connector end) from the tissue filter
2. Cap for patient port
3. Cap for vacuum port
4. Large opening
5. Cap for large opening
6. "Vacuum" port – receives the vacuum line assembly connection from the console
7. Suction canister lid
8. Suction canister base

Note
The suction canister is a single-use product with a recommended maximum volume of 400 cc.

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3.1.3 Biopsy Device Components

The Brevera breast biopsy device consists of a sterile, disposable biopsy needle that locks into the non-sterile, Brevera reusable device driver. The biopsy needle includes a tissue filter assembly to collect the biopsy cores for imaging.

Device Driver Components

The device driver is the electromechanical component of the biopsy device. When connected to the biopsy needle, the device driver rotates and advances the cutting cannula. The device driver also arms and fires the biopsy needle.

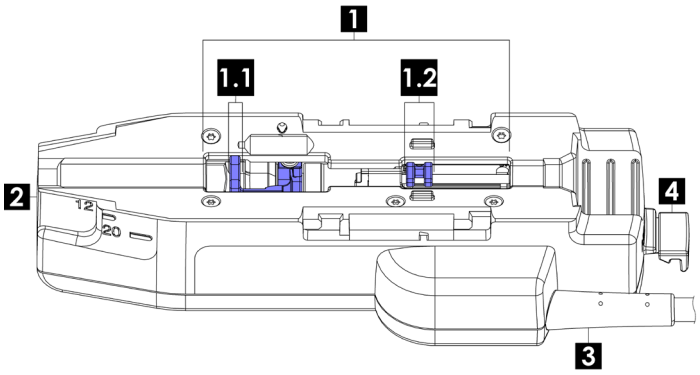
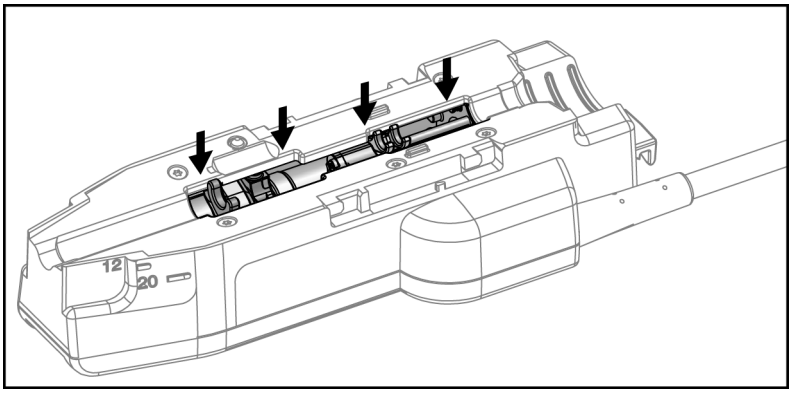


Figure 7: Device Driver Components

Figure Legend

1. Connection to the biopsy needle
   1.1 Outer Cannula Fork
   1.2 Inner Cannula Fork
2. Connection point to the biopsy device adapter (groove on bottom)
3. Device driver cord
4. Release latch for the biopsy device adapter

Warning:
Do not touch the metal parts of the device driver and the patient simultaneously.



Metal Parts of the Device Driver

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Note
Store the device driver on the top of the console in the device driver holder. Wrap the device driver cord (with the remote control) clockwise around the corresponding cord management plate on the back of the console.

Biopsy Needle Components

The biopsy needle includes the disposable needle itself and the tubing for the vacuum and saline lines. The biopsy needle also includes a tissue filter assembly to collect the biopsy cores for imaging. The biopsy needle is packaged with the tissue filter assembly and the introducer.

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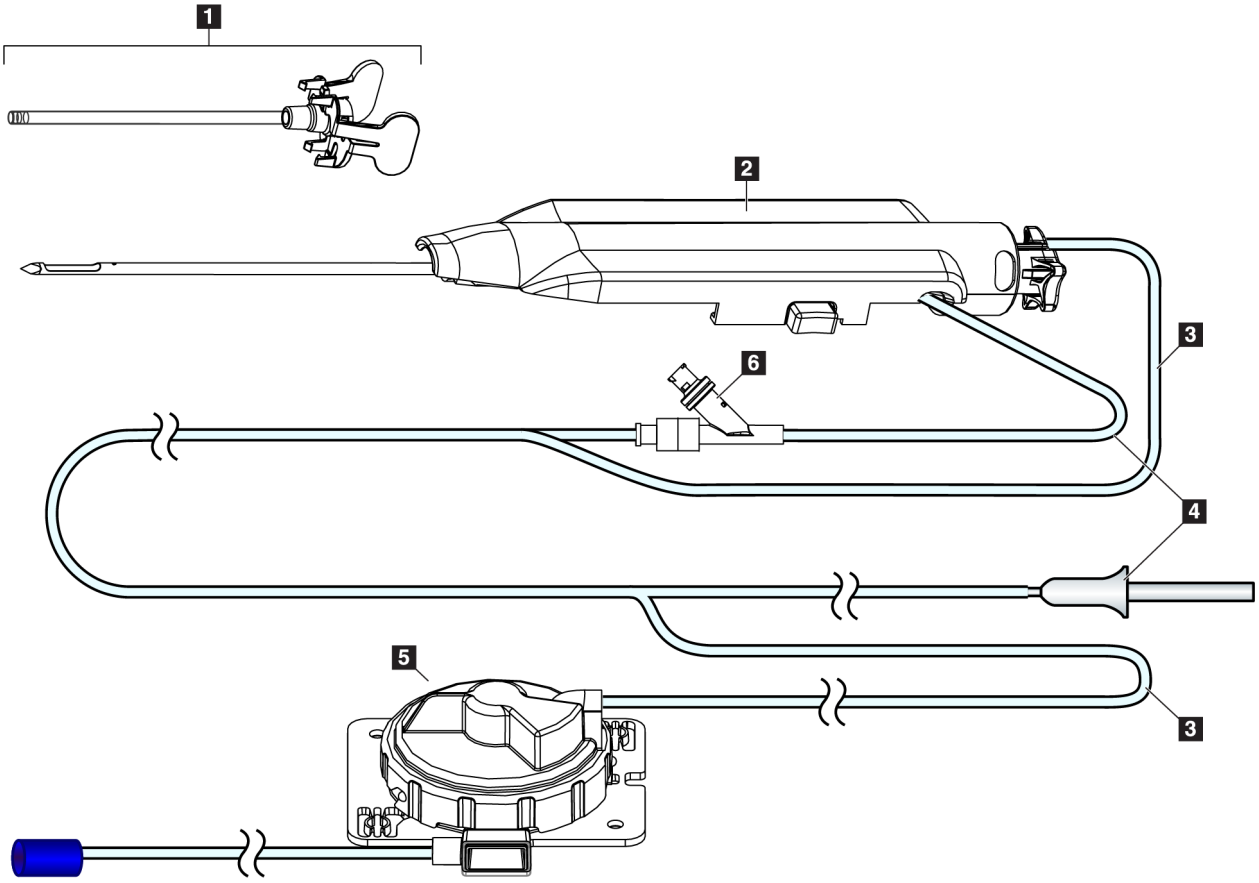


Figure 8: Biopsy Needle Components

Figure Legend

1. Introducer
2. Biopsy needle (attaches to the device driver)
3. Suction line
4. Saline line
5. Tissue filter assembly (Component may appear different in markets where product is not yet available.)
6. Y-valve

Note
The biopsy needle comes packaged with a tissue filter. Refer to *Tissue Filter Components* on page 34 for details on the tissue filter.

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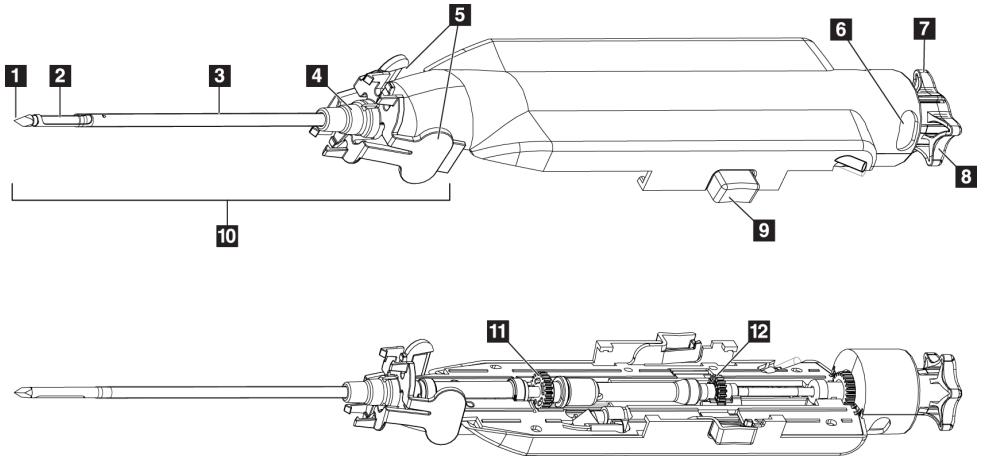


Figure 9: Biopsy Needle Components - Detailed

Figure Legend

1. Trocar tip
2. Outer cannula aperture
3. Outer cannula/introducer
4. Introducer hub
5. "Wing" tabs on introducer hub
6. "Clock" position indicators for outer cannula aperture orientation
7. Tactile flat area on the thumbwheel that indicates the outer cannula aperture orientation (flat at 12 o'clock position)
8. Thumbwheel
9. Button for engaging and disengaging the biopsy needle and device driver (both sides)
10. Introducer, with lilac-colored hub (shown with protective sheath removed)
11. Outer cannula gears
12. Inner cannula gears

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Tissue Filter Components

The tissue filter is a twelve-chambered container where the biopsy cores are collected for imaging. During the biopsy process, the tissue samples are aspirated through the biopsy needle tubing to the in-line tissue filter. A tissue filter cap is provided to cover and seal the tissue filter for storage in formalin.

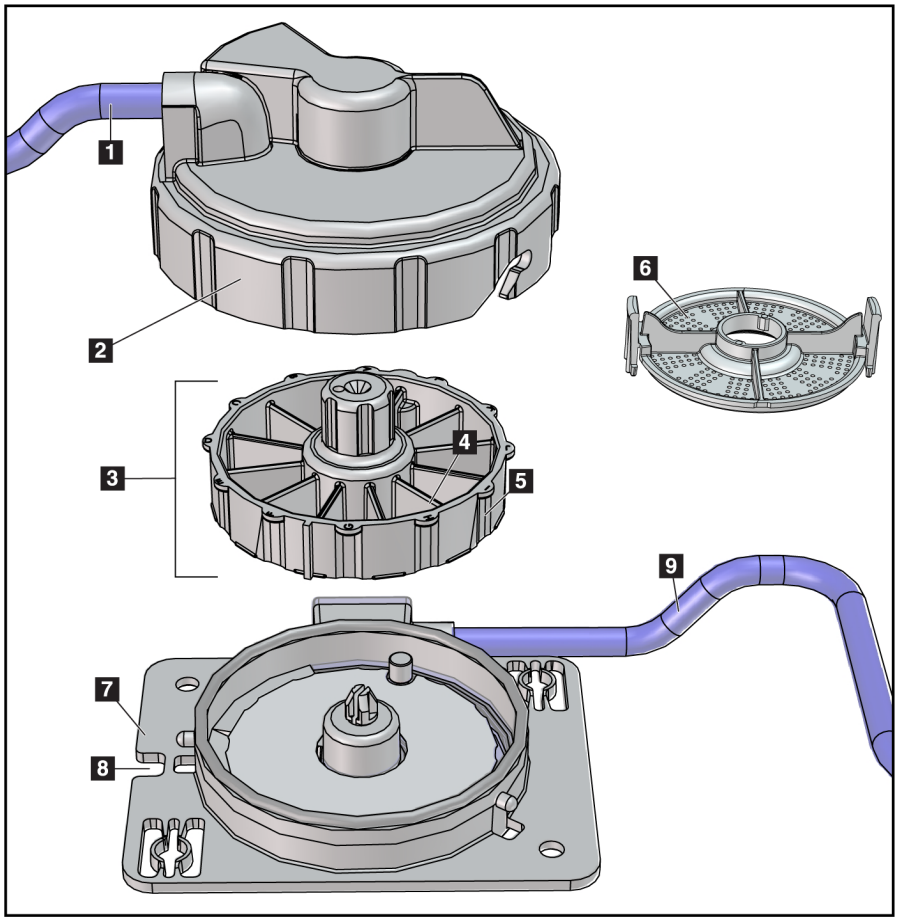


Figure 10: Tissue Filter Components

Figure Legend

1. Tubing inlet from the biopsy needle
2. Tissue filter housing cover
3. Tissue filter
4. Tissue filter chamber (12 chambers)
5. Tissue filter chamber indicator (12 letter designations)
6. Tissue filter cap
7. Tissue filter base
8. Notch
9. Tubing outlet to the suction canister (waste)

Components may appear different in markets where products are not yet available.

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3.2 System Connections

This section provides information on how to make all of the necessary connections to set up the Brevera breast biopsy system for use. The following connections will be explained:

1. Power and network connections
2. Footswitch connection
3. Device driver and remote control connection
4. Suction canister connections
5. Biopsy needle (needle, tubing, and tissue filter) connections

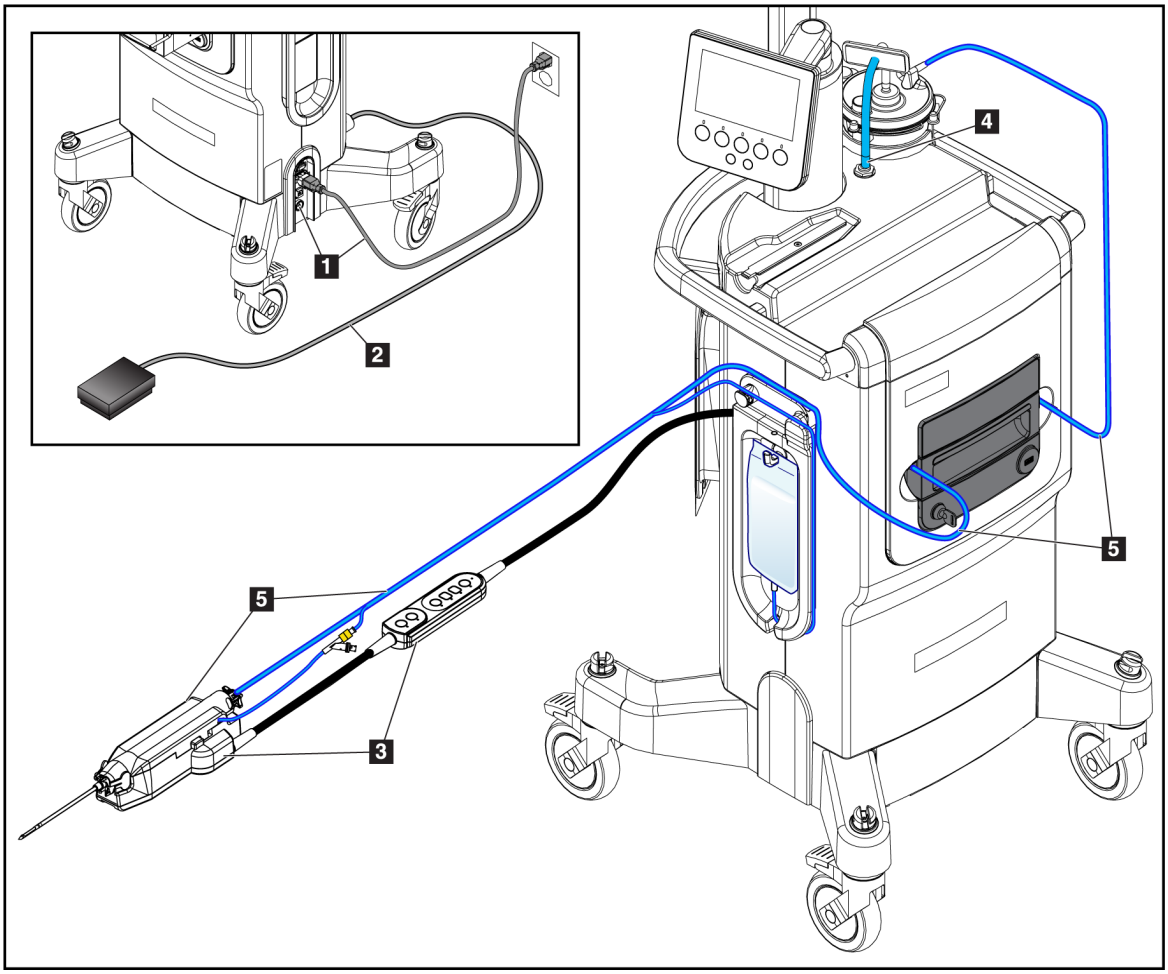


Figure 11: System Connections

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WARNING!
The Brevera breast biopsy system console is designed to use the power cord provided. Do not use a different power cord. Using a different power cord can create an electrical and fire hazard. DO NOT remove the ground wire or ground prong from any power plug. DO NOT use an extension cord with this equipment. An adapter may be necessary depending on the outlet used.

WARNING!
Make sure that the power cord for the Brevera breast biopsy system console is in good condition. A damaged power cord can be an electrical shock hazard. When disconnecting the console from power, always grasp the plug at the insertion point and pull lightly. NEVER pull on the cord to unplug the unit.

Warning:
The use of any cables or accessories other than those specified in these instructions can result in increased emissions or decreased immunity of the Brevera breast biopsy system.

Caution:
Grounding reliability can only be achieved when this equipment is connected to a receptacle marked "hospital grade". Check grounding continuity regularly.

3.2.1 Power and Network Connections

1. Put the Brevera breast biopsy system in a location where you can easily access power connections and network connections.
2. Connect the system AC power cord to the electrical outlet.

Note
Position the console so that you can easily access the AC power cord connection to the electrical outlet.

3. (Optional) Connect the network cable to the Ethernet connector.

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3.2.2 Footswitch Connection

Warning:
Position the footswitch and power cords to prevent accidental tripping.

Warning:
Position the footswitch to prevent accidental operation by a patient or wheelchair.

The footswitch is initially installed by a Service Engineer. If the footswitch is disconnected from the console, insert the footswitch cord into the footswitch receptacle (on the back of the console). The red dots align at the top when attached correctly.

3.2.3 Device Driver and Remote Control Connections

The device driver cord has an in-line remote control. The device driver cord attaches to the device driver receptacle on the left side of the saline tubing management plate, near the saline pinch valve. The red dots will align at the top when attached correctly.

Warning:
Do not place fingers on the metal parts of the device driver. These parts can move during system use.

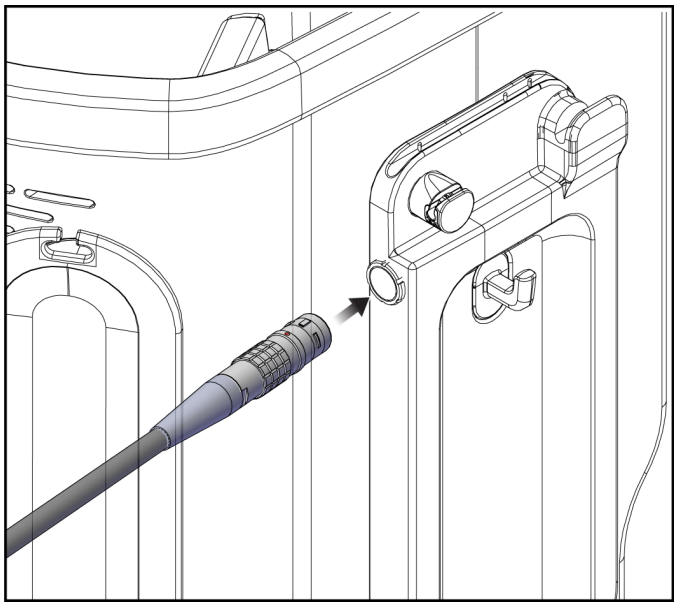


Figure 12: Device Driver Connection

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3.2.4 Suction Canister Connections

The system will generate vacuum when the proper modes are selected. The vacuum connections require a suction canister. The suction canister connects to the suction tubing from the tissue filter and to the tubing of the vacuum line assembly. The vacuum line assembly includes a hydrophobic filter and is required to prevent backflow into the console.

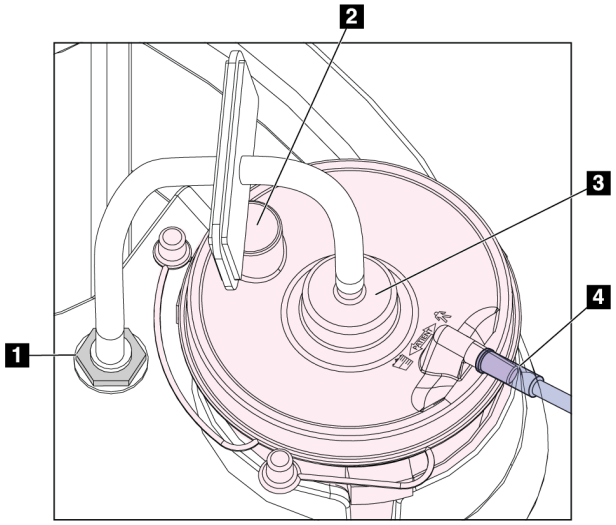


Figure 13: Suction Canister Connections

Figure Legend

1. Connection where the vacuum line assembly attaches to the console
2. Large opening sealed with the large opening cap
3. Connection where the vacuum line assembly attaches to the top port on the suction canister lid labeled "VACUUM"
4. Connection where the clear suction tubing from the tissue filter attaches to the horizontal side port on the suction canister lid labeled "PATIENT"

3.2.5 Biopsy Needle Connections

WARNING!
Improper alignment between the biopsy needle gears and the device driver forks may result in device malfunction, unusual noise, or procedure interruption that may require additional intervention.

Action:
If improper alignment or unusual noise is observed, stop use immediately and discard the needle. Disconnect and reconnect the driver to ensure it is in the install position (homed) and place a new needle on the driver.

Warning:
Before use, inspect the protective packaging and the needle to confirm that neither has been damaged during shipment. If the packaging or the needle appear to be compromised, do not use the needle.

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Warning:
Do not connect the biopsy needle until the system is powered on and the device driver is homed and ready. Device driver forks and biopsy needle gears must be properly aligned before installation.

Warning:
To maintain sterility, leave the protective sheath on the tip of the biopsy needle.

The biopsy needle is packaged with the suction and saline tubing, the tissue filter, and the introducer. The biopsy needle is already connected to the suction and saline lines. The suction tubing includes an in-line tissue filter assembly. The tissue filter comes preassembled and is placed in the tissue filter drawer. Refer to *Tissue Filter Connections* on page 40 for more information on connecting the tissue filter.

The biopsy needle is powered by the device driver. The biopsy needle is connected to the device driver by aligning the needle gears with the device driver forks and then carefully lining up and moving the needle down over the driver until it engages. The needle is then slid forward until it locks into position. The connected combination of the biopsy needle and the device driver is referred to as the biopsy device. For complete instructions on connecting the biopsy needle to the device driver, refer to *Connect the Device Driver and the Biopsy Supplies* on page 72.

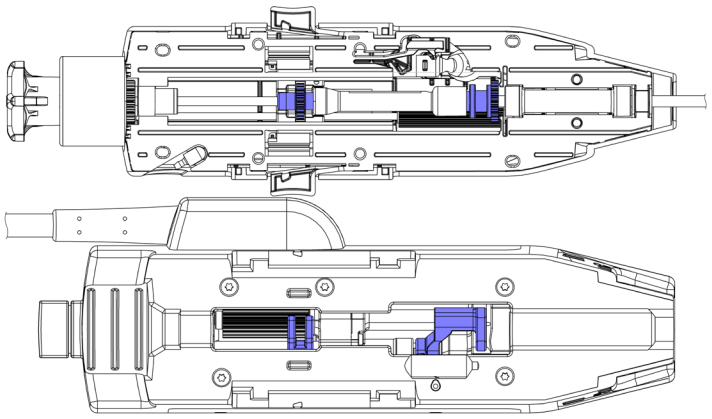


Figure 14: Biopsy Needle and Device Driver Connection

Warning:
Make sure that the biopsy needle is fully latched onto the device driver.

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Tissue Filter Connections

The biopsy core travels through the suction tubing to the tissue filter in the tissue filter drawer when the proper modes are selected.

Note
Each Brevera disposable biopsy needle package includes a tissue filter cap. Save the tissue filter cap until the biopsy acquisition is complete. The tissue filter cap covers the tissue filter when the biopsy cores are placed in formalin.

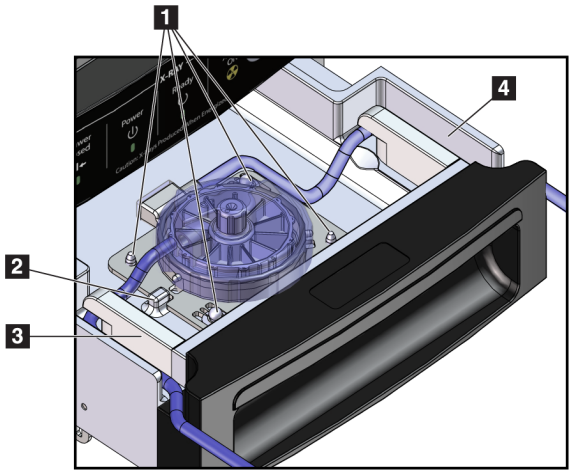


Figure 15: Tissue Filter Connections in the Tissue Filter Drawer

Figure Legend

1. Locator pin holes align with locator pins
2. Tissue filter base notch aligns with the alignment tab
3. Guide for the gray tubing from the biopsy needle
4. Guide for the suction tubing (clear tubing with a blue connector end) to the suction canister

*Component may appear different in markets where product is not yet available.

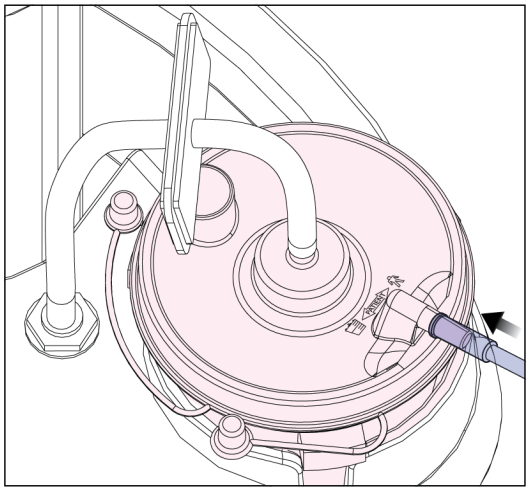


Figure 16: Tissue Filter Tubing Connection to the Suction Canister

*Component may appear different in markets where product is not yet available.

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3.2.6 Combination Device Information

Brevera breast biopsy system is compatible with Hologic's Affirm® prone biopsy system and Affirm® breast biopsy guidance system, MammoTest, and GE Senographe® Stereotaxy guidance systems.

Refer to the following setup guides for Adapter setup information:

- Brevera System Setup Guide for Hologic Affirm and MultiCare® Platinum Products
- Brevera System Setup Guide for MammoTest
- Brevera System Setup Guide for GE Senographe DS Stereotaxy and GE Senographe Essential Stereotaxy

3.3 Controls and Indicators

3.3.1 Imaging Panel Controls and Indicators

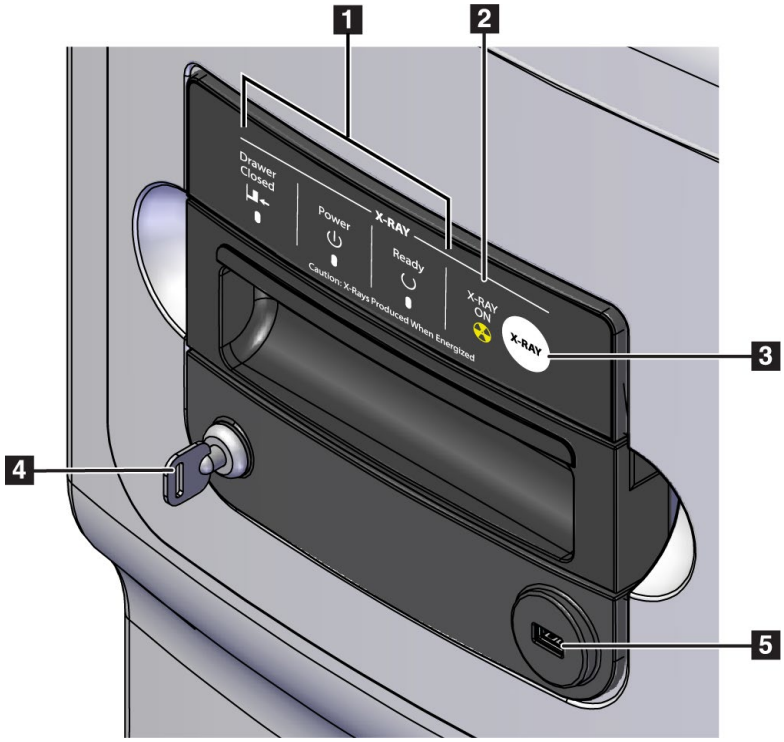


Figure 17: Imaging Panel Controls and Indicators

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Figure Legend

1.	Status indicators	**Drawer Closed** = LED is green when the tissue filter drawer is fully closed. **Power** = LED is green when the power is on. **Ready** = LED is green when the drawer is ready to receive cores.
2.	X-ray On indicator	**X-RAY ON** = LED is amber when an x-ray is in progress.
3.	X-ray button	Button used for Manual Gain Calibration and to abort current x-ray exposure
4.	Key switch	Locked: X ray is disabled (orientation as shown). Unlocked: X ray is enabled.
5.	USB port	Connection for non-powered USB device (optional)

3.3.2 Mode Controls and Biopsy Device Arm and Fire Controls

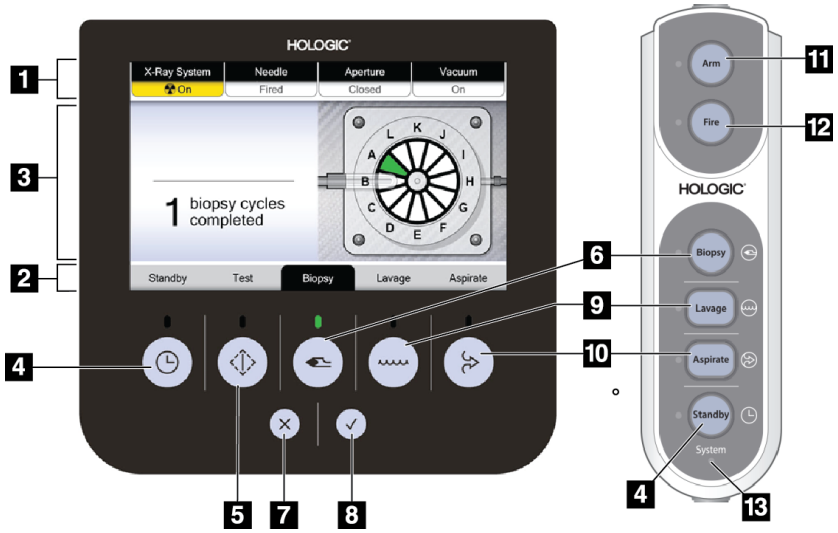


Figure 18: Mode, Arm and Fire Buttons

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Figure Legend

1.	System status	At the top of the Technologist display screen, four tabs indicate the x-ray status, the needle position, the aperture size, and the vacuum status.
2.	Mode indicator	At the bottom of the Technologist display screen, the black highlight and green light indicate the current mode.
3.	Message area	At the center of the Technologist display screen, the system provides instructions and other notifications.
4.	**Standby** button	This push-button control turns the vacuum off and closes the aperture on the needle.
5.	**Test** button	This push-button control allows for the self-priming of the system with saline. When placed in Test mode, the saline pinch valve is opened and the vacuum is turned on. When placed in Test mode, the user is guided through a series of tests to confirm the flow of saline and the completion of a cutting cycle.
6.	**Biopsy** button	When placed in Biopsy mode, the biopsy device is ready for tissue acquisition. Footswitch input will initiate a biopsy cycle.
7.	**X** button	Reject the message on the Technologist display.
8.	✔ button	Accept the message on the Technologist display.
9.	**Lavage** button	When placed in Lavage mode, the saline pinch valve is opened and the inner cutting cannula is retracted. In Lavage mode, the vacuum is turned on.
10.	**Aspirate** button	When placed in Aspirate mode, the saline pinch valve is closed and the inner cutting cannula is retracted. In Aspirate mode, the vacuum is turned on.
11.	**Arm** button	This push-button control retracts the outer cannula on the biopsy needle. The user must press and hold the **Arm** button to arm the needle.
12.	**Fire** button	This push-button control advances the inner and outer cannulas by the stroke noted on the product label. The position and orientation of the introducer determine whether the needle is in its petite or standard orientation. The user must press and hold the **Fire** button to fire the needle.
13.	System power indicator	Green light illuminates when the console is powered on. Red light illuminates when there is a device driver or biopsy needle issue.

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3.4 Lock and Unlock a Caster

- To lock a caster, step on the locking lever on the wheel until the lever locks.
- To unlock a caster, lift the locking lever on the wheel to the UP position.

3.5 Move the Console

Note
The power cord and footswitch cord wrap on the right side of the console to provide safe storage of the cords during console movement.

Note
The device driver cord wraps on the left side of the console to provide safe storage of the cord during console movement.

1. Wrap all cords on the corresponding cord management plates.
2. Make sure all components and cables are in a safe position on the console.
3. Depress the Imaging display height adjust release pedal and push the Imaging display to slide down to the lowest height. Release the pedal to lock the height.
4. Rotate both the Imaging display and the Technologist display so that they are as compact as possible.
5. Unlock all the caster locks.
6. Move the console by pushing the console handle.
7. Make sure to lock the casters when the console is at the correct location.

3.6 How to Start the System

Warning:
Do not place fingers on the metal parts of the device driver. These parts can move when the system powers on.

Note
The console beeps three times before resetting the position of the metal parts of the device driver.

1. Lock the console casters.
2. Connect the system to power and the network.
3. Press the **Power** button on the side of the console.

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4. The system powers on and the Windows 10 *Login* screen opens on the Imaging display.

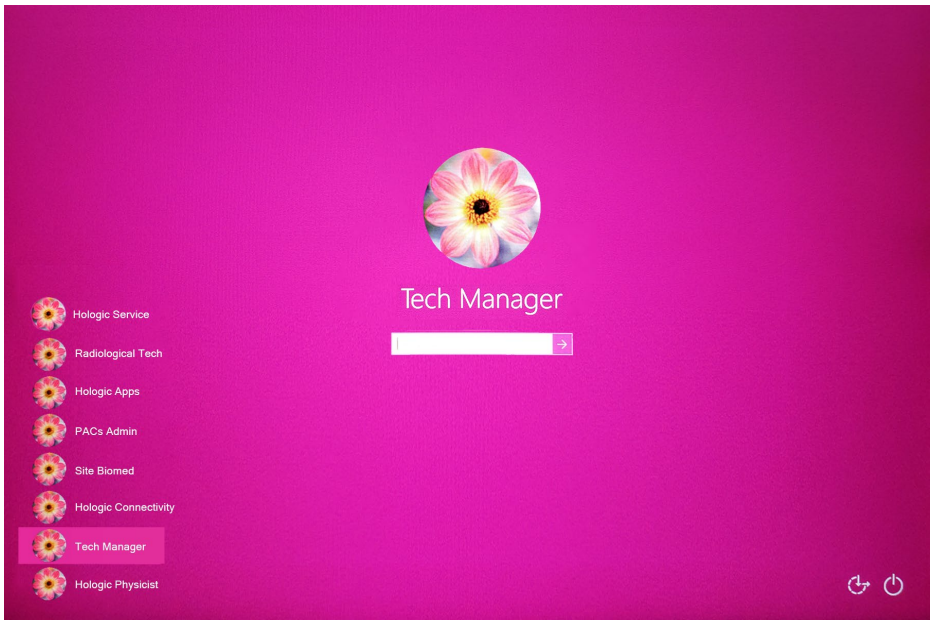


Figure 19: Windows 10 Login Screen

5. Select your user name from the user list.
6. Enter your password then select the **arrow** icon.

Note
To show or hide the virtual keyboard, tap the background.

7. The *Startup* screen for the Brevera breast biopsy system opens on the Imaging display. On the *Startup* screen, select the **Patient List** button to go to the *Select Patient* screen.

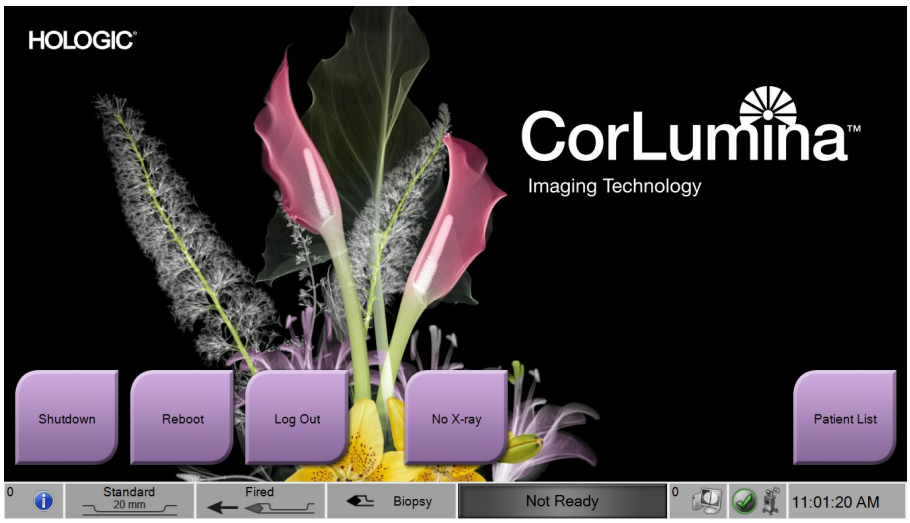


Figure 20: Startup Screen

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Note
To log out of the Windows 10 operating system, select the **Log Out** button.

Note
The control panel LEDs can blink when the system starts.

Note
The *Startup* screen includes a **Reboot** button that restarts only the computer.

Note
To change the system language or other preferences, go to the *Admin* screen.

3.7 How to Shut Down the System

1. From the *Procedure* screen, select the **Close Patient** button.
2. From the *Select Patient* screen, select the **Close** button.
3. Select the **Shutdown** button on the Imaging display or press the console Power button.
   - If the system is not ready for shutdown, a prompt displays the option to continue or cancel the system shutdown. Select the **Check** button on the Technologist display to stop all pending jobs and continue shutdown. Select the **X** button on the Technologist display to keep the system running and finish pending jobs.

3.7.1 How to Remove All Power from the System

1. Make sure that the computer system and console are completely turned OFF.
2. Disconnect the power cord from the electrical outlet.

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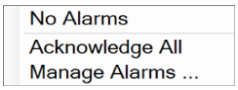
Chapter 4 User Interface Imaging Display

4.1 About the Taskbar

The taskbar at the bottom of the screen displays additional icons. For some of the icons, you can select the icon to access information or perform system tasks.

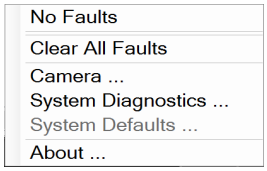
Figure 21: The Taskbar

Figure Legend

	Description	Menu
1. 	**Information Icon** Select the **Information** icon to display the Alarms menu. This section of the taskbar flashes a yellow color if an alarm exists. Select **Acknowledge All** to remove the flashing indication. Select the **Manage Alarms** option to display and close any open alarms.	
2.	**Aperture Status Indicator** When a biopsy device is connected to the system, this section indicates if the aperture on the biopsy needle is standard or petite.	
3.	**Needle Status Indicator** When a biopsy device is connected to the system, this section indicates if the biopsy needle is armed or fired. Note: Arming and firing of the biopsy device is controlled with the remote control.	
4.	**Mode Indicator** This section indicates the current mode for the biopsy system. Note: The mode is changed with the buttons on the remote control or the buttons on the Technologist display.	

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Figure Legend

5. 	**X-ray Status Indicator** Ready, Not Ready, or X-ray in progress.	
6. 	**Output Device Icons** Select this icon to display a menu. **Manage Queues** displays the status of jobs in the queue and job information for the selected output, and allows you to filter the queue display.	
7.	**System Status Icons** If the yellow exclamation mark icon is displayed and this taskbar section flashes yellow, select the icon for more information about the error. If the green check mark icon is displayed, select the icon to display the Faults menu. **Clear All Faults** deletes all error messages that can be cleared by the user. **Camera** opens the camera screen to view inside the closed tissue filter drawer. **System Diagnostics** accesses subsystem settings. **About** displays information about the workstation.	

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4.2 Select Patient Screen

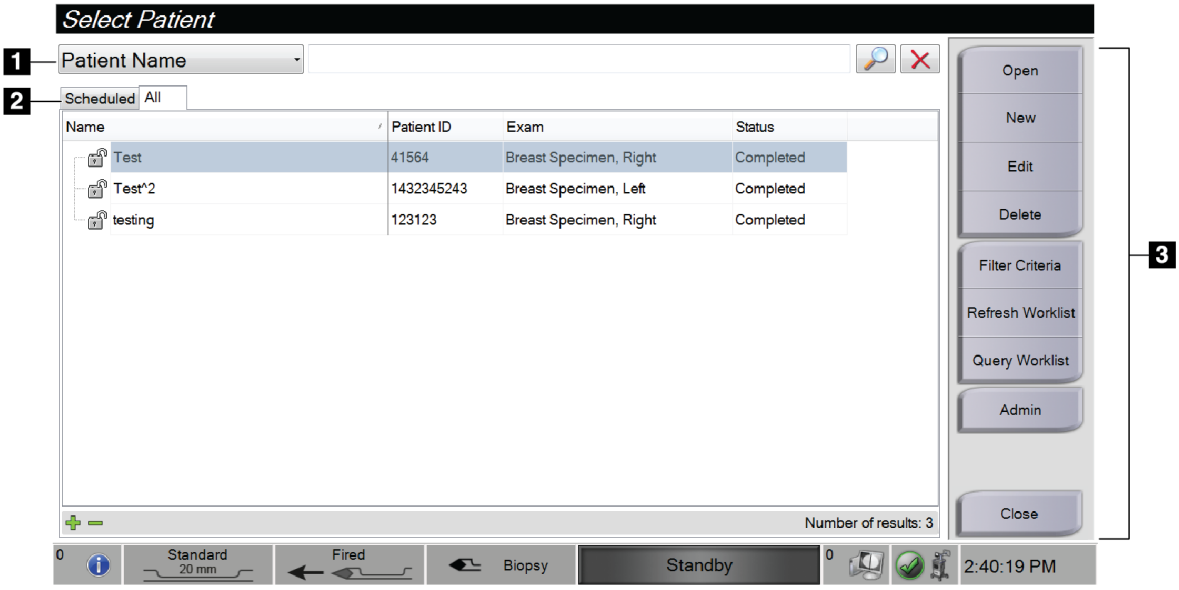


Figure 22: Select Patient Screen

Figure Legend

1. Quick Search	Search the local database for the Patient Name, Patient ID, or Accession Number.
2. Tabs	Two tabs display at the top of the screen. These tabs are configurable. A Manager can delete tabs and create new tabs (see *The Filter Criteria and Columns Tabs in the Patient Filter Screen* on page 53). • The **Scheduled** tab displays the scheduled procedures. • The **All** tab displays all procedures on this CorLumina system.
3. Button Functions	You can perform many functions from this screen using the buttons in this area. • **Open**: Open the procedure for the selected patient. Refer to *Open a Patient* on page 103. • **New**: Add a new Patient. Refer to *Add a Patient* on page 50. • **Edit**: Edit the patient information. Refer to *Edit the Patient Information* on page 51. • **Delete**: Delete a patient from the worklist. Refer to *Delete a Patient* on page 52. • **Filter Criteria:** Use a Patient Filter. Refer to *Filters for Patients* on page 52. • **Refresh Worklist**: Update the patient list. • **Query Worklist**: Search for a patient in the Modality Worklist. Refer to *Query the Worklist* on page 54. • **Admin**: Access the administration functions. Refer to *System Administration Interface* on page 100. • **Close**: Exit and return to the *Startup* screen.

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4.2.1 Open a Patient

To open a patient and start a procedure, select a patient from the list, then select the **Open** button.

4.2.2 Add a Patient

1. On the *Select Patient* screen, select the **New** button.
2. Type in new patient information (fields with an asterisk are required). Use the arrows to access the next or previous screen. Select a procedure.

Figure 23: Add Patient Screens

3. Select the **Open** button. A *Procedure* screen for the new patient opens.

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4.2.3 Edit the Patient Information

1. On the *Select Patient* screen, select the patient name, then select the **Edit** button.
2. On the *Edit Patient* screens, make the changes. Use the arrows to access the next or previous screen.

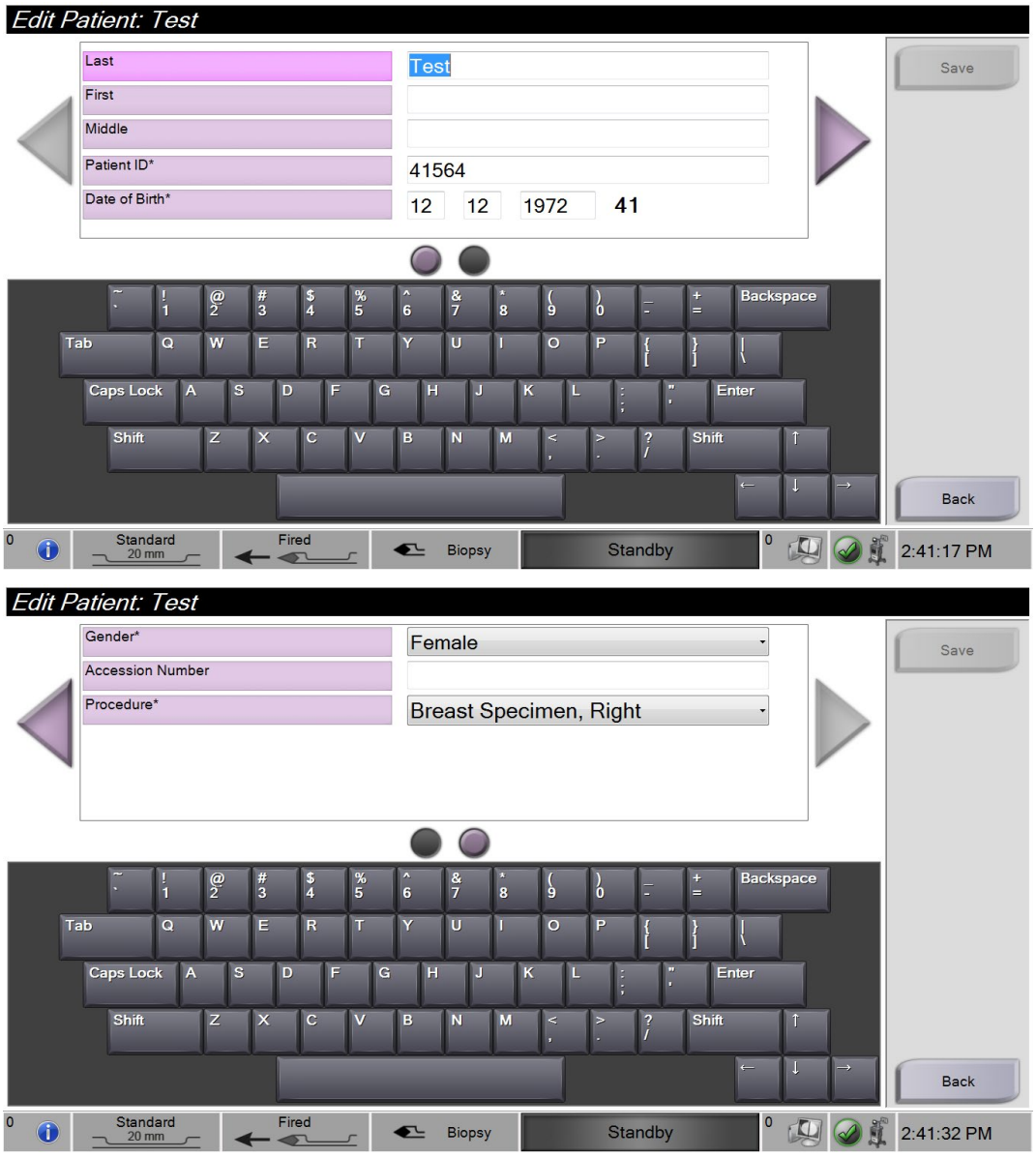


Figure 24: Edit Patient Screens

3. Select **Save**.
4. When the Update Successful message is displayed, select **OK**.

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4.2.4 Delete a Patient

1. On the *Select Patient* screen, select one or more patients.
2. Select the **Delete** button.
3. To the Confirmation Required prompt, select **Yes**.

Note
Only a Manager can delete patients.

Note
Reclamation normally removes the requirement to delete patients.

4.2.5 Filters for Patients

When you select the **Filter Criteria** button on the *Select Patient* screen**,** the *Patient Filter* screen opens.

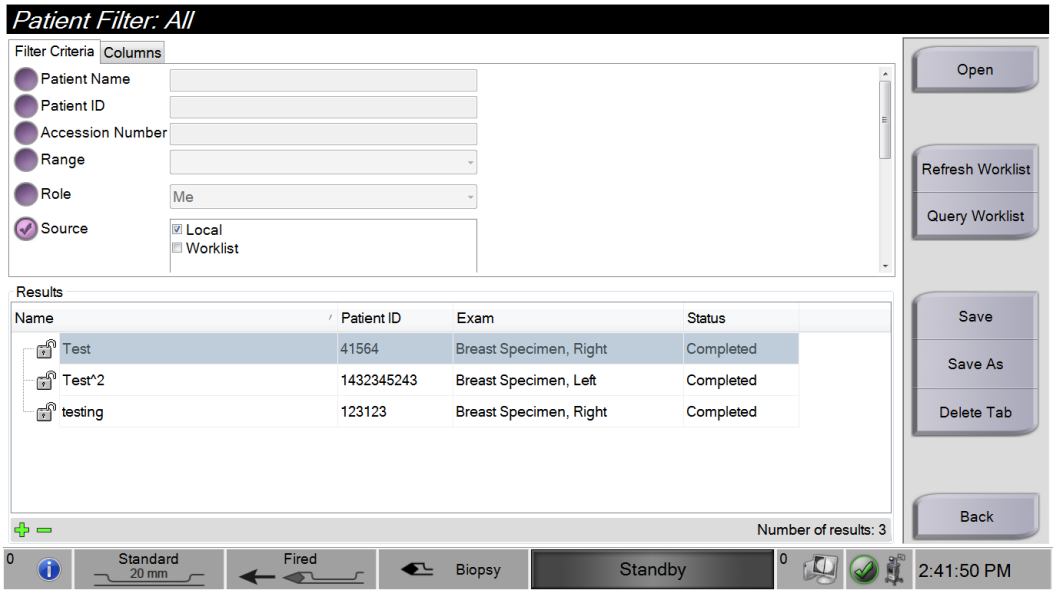


Figure 25: Filter Criteria in the Patient Filter Screen

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Filter Criteria and Columns Tabs in the Patient Filter Screen

The **Filter Criteria** tab allows you to change the filtering options for the patient list. When you select or deselect an option, the change shows in the results area of the screen.

Note
A Manager can save these new filters to the selected tab on the *Select Patient* screen (refer to *Other Functions of the Filter Criteria* on page 53).

The **Columns** tab allows you to add more search options (for example, Age, Gender, Date of Birth) to the filtered list. The options display as columns in the results area. To add more columns to a filtered list, select the **Columns** tab, and then select the options.

Note
When you select the **Open** button, the *Procedure* screen for the selected patient opens.

Other Functions of the Filter Criteria

The **Save**, **Save As**, and **Delete Tab** buttons on the *Patient Filter* screen allow Managers to add, change, or delete tabs on the *Select Patient* screen.

Table 1: Filter Criteria Options

Option	Step
Change the current patient filter parameters.	1. Select a tab on the *Select Patient* screen. 2. Select the **Filter Criteria** button. 3. Select the filter options. 4. Select the **Save** button. 5. Make sure the name of the tab you selected is in the name field. 6. Select **OK**.
Create a new tab for the *Select Patient* screen.	1. Select a tab on the *Select Patient* screen. 2. Select the **Filter Criteria** button. 3. Select the filter options for the tab. 4. Select the **Save As** button. 5. Enter a new name for the tab. 6. Select **OK**.
Delete a tab from the *Select Patient* screen.	1. Select a tab on the *Select Patient* screen. 2. Select the **Filter Criteria** button. 3. Select the **Delete** button. 4. Select **Yes** to the confirmation prompt.

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4.2.6 Refresh the Worklist

Select the **Refresh Worklist** button to update the patient lists.

4.2.7 Query the Worklist

Use the Query Worklist feature to search for a patient or a list of patients. Use one or more fields to query the Modality Worklist Provider. All fields to query are configurable. The default fields are as follows: Patient Name, Patient ID, Accession Number, Requested Procedure ID, Scheduled Procedure Date. The scheduled procedure is displayed and the patient is added to the local database.

4.3 Procedure Screen

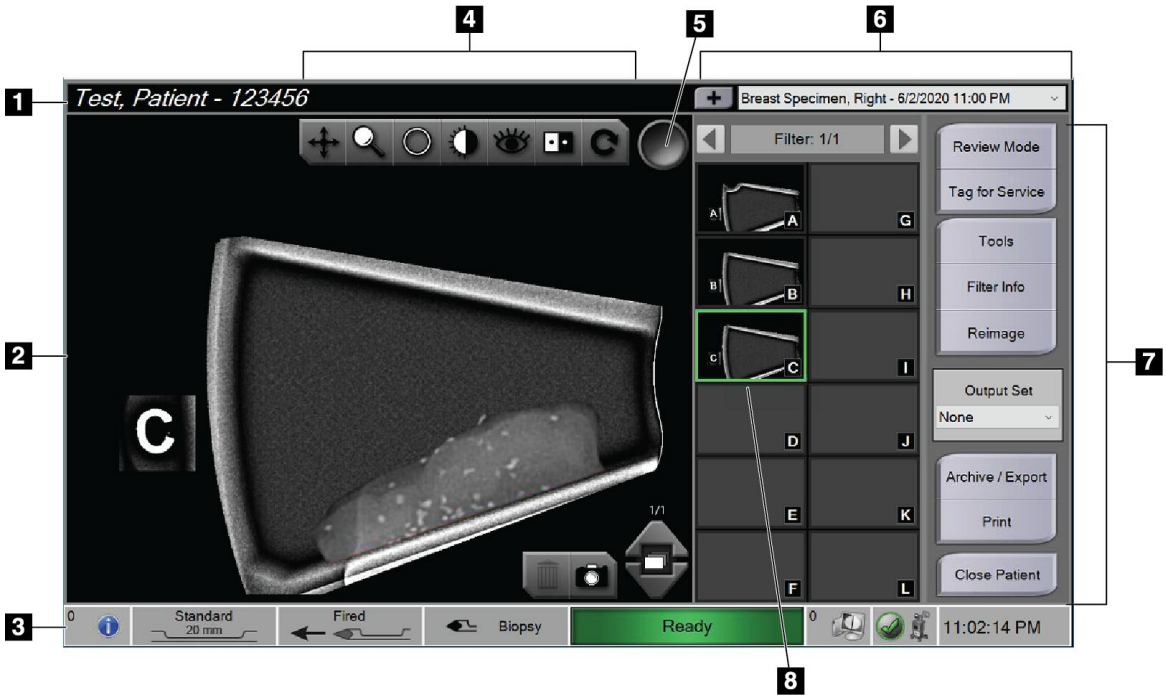


Figure 26: An Example Procedure Screen

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Figure Legend

1.	Patient information	Shows the patient name and ID.
2.	Image	Real-time image of the specimen in the tissue filter. The letter-designation on the tissue filter chamber is visible in the image.
3.	Taskbar	Shows the status of the console, needle, and imaging functions. A green name in the imaging status area of the taskbar indicates that function is in a ready status. A gray name in the imaging status area indicates that function is not ready. A yellow/orange  in the imaging status indicates that an x-ray is being taken. Refer to *About the Taskbar* on page 47 for more information on the taskbar.
4.	Image enhancement tools	Use the image enhancement tools (refer to *Image Enhancement Tools* on page 97) to enhance the whole image or areas of interest in the image.
5.	Tag tool	Selects a particular image or images. Tagged images show a green check mark in a circle in the upper right corner of the image as well as the image thumbnail.
6.	Procedure information	View the list of procedures for the current patient. Use the + button to add a procedure for the current patient.
7.	Other functions	Review and annotate images, reimage specimens already in the tissue filter chambers, select the output destination for acquired images, or close the patient.
8.	Image thumbnails	Shows small icons of images related to the selected tissue filter. A thumbnail image with a camera icon is a snapshot image. Use the Filter bar at the top of the image thumbnails ("Filter: 1/1" shown) to navigate through multiple tissue filters.

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4.3.1 Select a Procedure

Select an entry from the list in the Procedure information area of the screen.

4.3.2 Add a Procedure

1. To add another procedure for the active patient, select the **+** button on the upper right of the *Procedure* screen to display the Add Procedure dialog box.

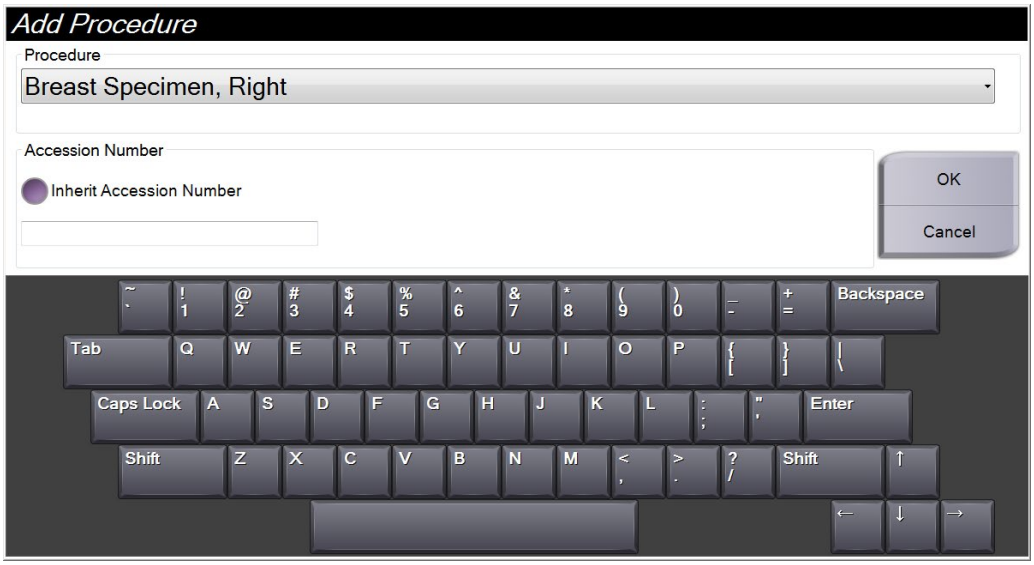


Figure 27: Add Procedure Dialog Box

2. Use the drop-down list to select the type of procedure to add.
3. Enter an Accession Number (optional).
4. Select the **OK** button. A new number displays in the Procedure Information area of the *Procedure* screen.

4.3.3 Access the Review Mode Screen

Select the **Review Mode** button on the *Procedure* screen to access the *Review Mode* screen and the image review features. Refer to *Review Mode Screen* on page 95 for more information.

4.3.4 Access the Image Enhancement Tools

Select the **Tools** button on the *Procedure* screen to access the tools bar and image enhancement features. Refer to *Image Enhancement Tools* on page 97 for more information.

4.3.5 Access the Filter Info

Select the **Filter Info** button to access filter information such as laterality, accession number, procedure information, and filter comments. Refer to *Filter Info and Comments Screen* on page 97 for more information.

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4.3.6 Access the Reimage Feature

Select the **Reimage** button to acquire a new image of a specimen already in the tissue filter chambers. Refer to *Reimage* on page 99 for more information.

4.3.7 Close a Patient

Select the **Close Patient** button. Select **Yes** to the confirmation prompt. The system returns to the *Select Patient* screen and automatically saves to the configured output devices any images that were not sent previously.

4.4 Output Sets

The images are sent automatically to the output devices in the selected Output Set when a patient is closed.

4.4.1 Select an Output Set

Select an output device set like PACS, CAD devices, and printers from the Output Set drop-down list in the *Procedure* screen.



Note
Images are not sent if an Output Set is not selected.

4.4.2 Add or Edit an Output Set



Note
The configuration of Output Sets occurs during installation, but you can edit existing groups or add new groups.

To add a new Output Set:

1. Go to the *Admin* screen.
2. Select the **Manage Output Groups** button.
3. Select the **New** button, type the information, then select the output device(s).
4. Select the **Add** button. When the Update Successful message is displayed, select **OK**.
5. You can select any group to set as the default by selecting the **Set As Default** button.

To edit an Output Set:

1. Go to the *Admin* screen.
2. Select the **Manage Output Groups** button.
3. Select the group to be edited.
4. Select the **Edit** button, then make the changes.
5. Select the **Save** button. When the Update Successful message is displayed, select **OK**.

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4.5 On-Demand Outputs

The On-Demand Outputs are: Archive, Export, or Print. You can manually Archive, Export, or Print an image until the patient is closed. When you select an On-Demand Output button, you have the option to send the image to any of the configured Outputs.

4.5.1 Export

The export function sends data to a mapped drive such as a local hard drive, a USB device connected to the console, or a network drive.

1. Select the **Archive/Export** button. The images from the current procedure appear in the main window.
   - The archive function sends data to a PACS device.
2. Touch one or more images to select the images to archive or export. Touch again to deselect an image. Use the **Select All** button to select all of the images for the current procedure. Use the **Select Tagged** button to select only the images marked with a green check mark.

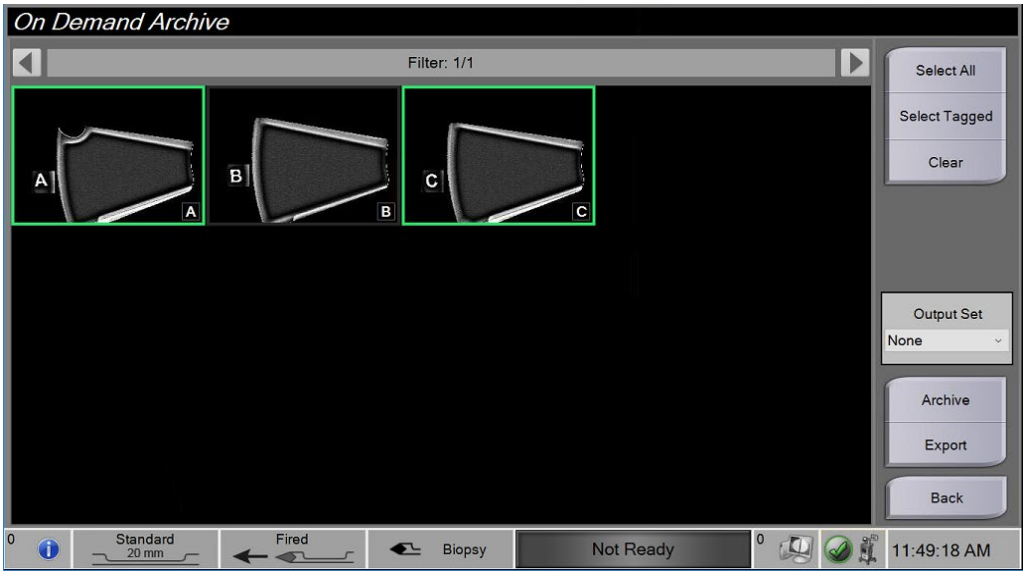


Figure 28: Two Images Selected for Archive or Export

3. Select the **Export** button. The Export dialog box opens.
4. In the Export dialog box, select the destination from the options in the drop-down list.
   - To make the patient-related information not known during the export, select the Anonymized check box.
   - To automatically eject the removable media storage device when the export is complete, select **Eject USB device after write.**
   - To select a folder on your local systems for storage of your selections and to select the Export Type for the image, select **Advanced**.

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5. Select the **Start** button to export the images, or select the **Cancel** button to cancel the export.

4.5.2 Archive

The archive function sends data to a PACS device.

1. Select the **Archive/Export** button. The images from the current procedure appear in the main window.
2. Touch one or more images to select the images to archive or export. Touch again to deselect an image. Use the **Select All** button to select all of the images for the current procedure. Use the **Select Tagged** button to select only the images marked with a green check mark.

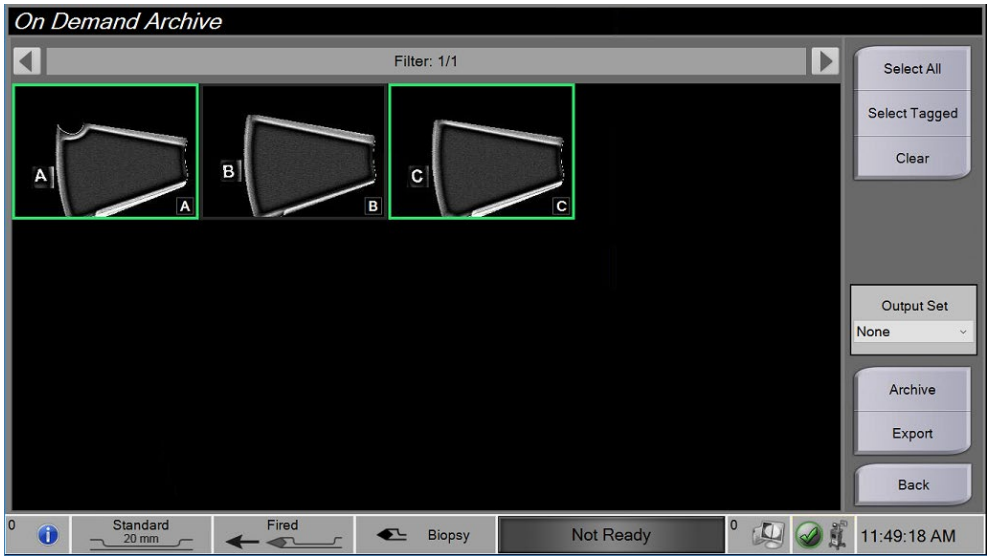


Figure 29: Two Images Selected for Archive or Export

3. Select the **Archive** button.
4. Select a storage device from an existing Output Group, or create an Output Group. (See *Output Sets* on page 57 for more information.)
5. Select the **Send** button to copy all selected images from the open case study to the selected device.

Note
Use the Manage Queue utility in the taskbar to review the archive status.

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4.5.3 Print

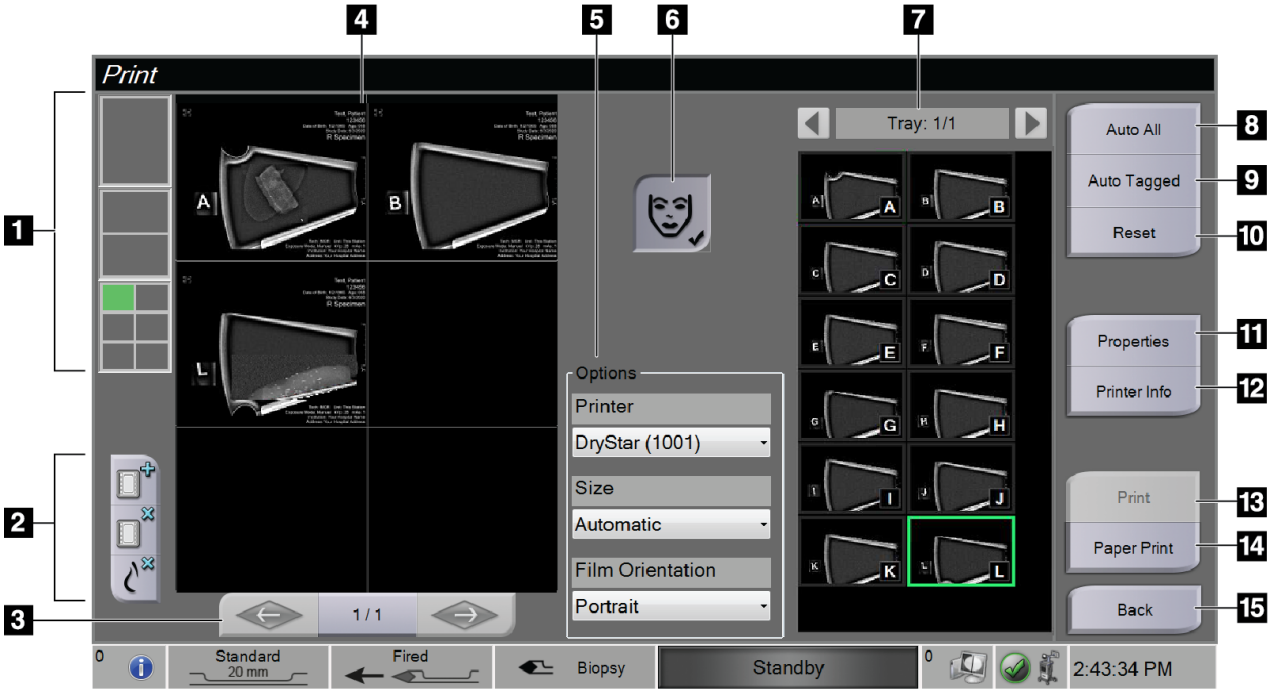


Figure 30: Example of the Print Screen

Figure Legend

1.	Film format	Select one, two, or six images per film (number of tiles per film). A green rectangle indicates the position that the active image will have on the film.
2.	New film, Delete film, and Delete image from film	Select the "**+**" button to create a new film. Select the "**x**" button to delete the current film selection. Select the **Delete image from film** button to delete only the active image from the film.
3.	Step	When more than one film is being printed, use these arrows to step through the print preview of the film output.
4.	Print preview area	Shows a preview of the final film.
5.	Printer Options	Select the printer options. The Automatic setting will automatically determine a suitable size for the printed images.
6.	Patient information	Activate or deactivate the patient information display. The check mark indicates that the patient information display is active and patient information will appear on a film. Touching the **Patient Information** button will deactivate the patient information only on the current film for the same patient.

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7.	Image thumbnails	Choose the images to output by touching the image thumbnail. The selected image thumbnail is surrounded by a green box in the thumbnail area and the position of that image appears as a green box in the film format area.
8.	Auto All	Automatically select all of the images for that procedure to be printed.
9.	Auto Tagged	Automatically select the images that are tagged on the *Procedure* screen for that procedure to be printed, and automatically create a film or films for them.
10.	Reset	Return the *Print* screen to its previous settings and remove any images from a film or films.
11.	Properties	Open the *Properties* screen for selection of the printer defaults.
12.	Printer Info	Show the printer IP address, AE Title, Port and capability for True Size print.
13.	Print	Output the current films to the print preview area and start the printing process. To allow for subsequent printing and printing to another device, the images remain in the print preview until the user removes them.
14.	Paper Print	Output the current films to the print preview area and start the process for printing to paper. To allow for subsequent printing and printing to another device, the images remain in the print preview until the user removes them.
15.	Back	Cancel the print job and return to the *Procedure* screen. If print jobs have been created but not yet printed, the system will ask the user to confirm the cancelation.

1. On the *Procedure* screen, select the **Print** button. The *Print* screen opens.
2. Select the film format from the Options area of the screen.
3. Select an image thumbnail from the right side of the screen.
4. Select the Print preview on the left side of the screen to put the selected image on the film.
5. To put other images on the film, repeat steps 3 and 4.
6. To print a different film format of the same images, select the **New Film** button and repeat steps 2 to 4.
7. Select the **Print** button or the **Paper Print** button to print your films.



Note
When you choose Paper Print, the Windows Print dialog box opens. Select your desired print and printer options.

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4.6 Gain Calibration

Do the Gain Calibration monthly and when artifacts are seen.

Note
When the system shows the Gain Calibration message, do the calibration before you proceed with using the system. If you do the Gain Calibration at a different time, access the procedure through the *Admin* screen.

1. Select **Yes** to do the calibration now. If you select **No**, the system shows the *Select Patient* screen.
2. If you select to do the calibration now, you are prompted to select an Automatic Gain Calibration mode. Select **Yes** for Automatic Gain Calibration or **No** for Manual Gain Calibration.
3. Make sure that there are no items in the tissue filter drawer and that the surface of the x-ray imaging area is clean. Close the tissue filter drawer. Select **OK** to begin.
4. For Automatic Gain Calibration, the system takes four images.

Note
In the event that the system is unable to complete an Automatic Gain Calibration, the user can continue with Manual Gain Calibration. To continue calibration, use the manual x-ray function until four images are acquired. The system can complete Gain Calibration using the combination of automatically acquired and manually acquired images.

5. After four images have been acquired, select the **Complete Calibration** button to start the calibration. When the Gain Calibration is finished, a message about successful completion is displayed. Select **OK** to return to the previous screen.

For Manual Gain Calibration:

1. Make sure that there are no items in the tissue filter drawer and that the surface of the x-ray imaging area is clean. Close the tissue filter drawer. Press **OK** to begin.
2. Press the **X-ray** button.
3. Wait for the system to return to the Ready state.
4. Repeat steps 2 and 3 until you acquire four images.
5. After four images have been acquired, select the **Complete Calibration** button to start the calibration. When the Gain Calibration is finished, a message about successful completion is displayed. Select **OK** to return to the previous screen.

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Chapter 5 User Interface Technologist Display

The system has five biopsy system modes controlled by the Technologist display: Standby, Test, Biopsy, Lavage, and Aspirate.

5.1 Technologist Display Screens and Modes

When the Brevera breast biopsy system powers on, it requires setup and a test cycle. Setup and testing are completed by following the prompts on the Technologist display.

5.1.1 Setup

After powering on the system, the *Setup* screen opens on the Technologist display. The system will automatically detect and confirm the connections for the device driver, biopsy needle, tissue filter assembly, and x-ray system. Follow the prompts to manually finish setup. The X-ray system will not show a Ready status until patient information is entered on the Imaging display.

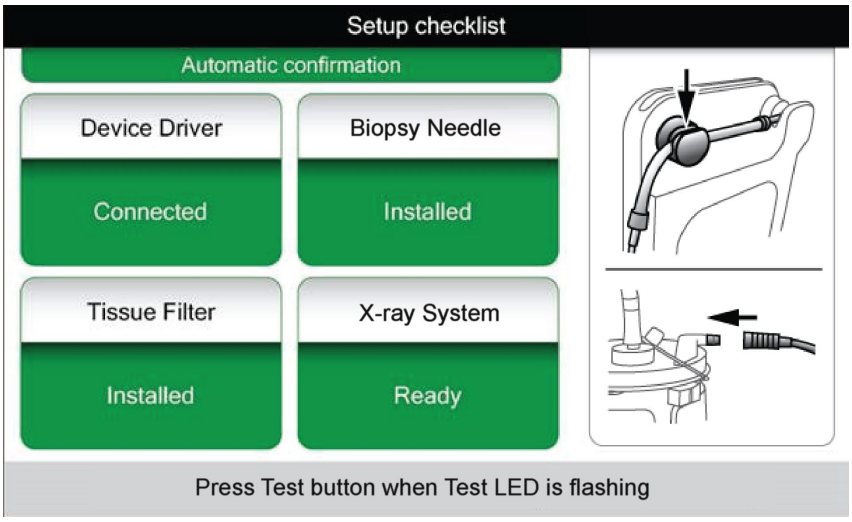


Figure 31: Setup Screen

5.1.2 Test

After setup is successful, the system requires testing. The device driver, biopsy needle, and tissue filter must be connected and installed to run Test mode. It is not necessary for the X-ray system to be ready to run Test mode. When the system is in Test mode, it tests the vacuum, prompts the user to confirm saline flow at the tip of the needle, then tests the cutting cycle. The system cannot use the x-ray function in Test mode.

When the system is ready for testing, the green light above the **Test** button flashes. Press the **Test** button to begin the testing procedure. Follow the prompts to complete testing. The Arm and Fire functions can also be tested. After testing is complete, the system can be put into Standby mode.

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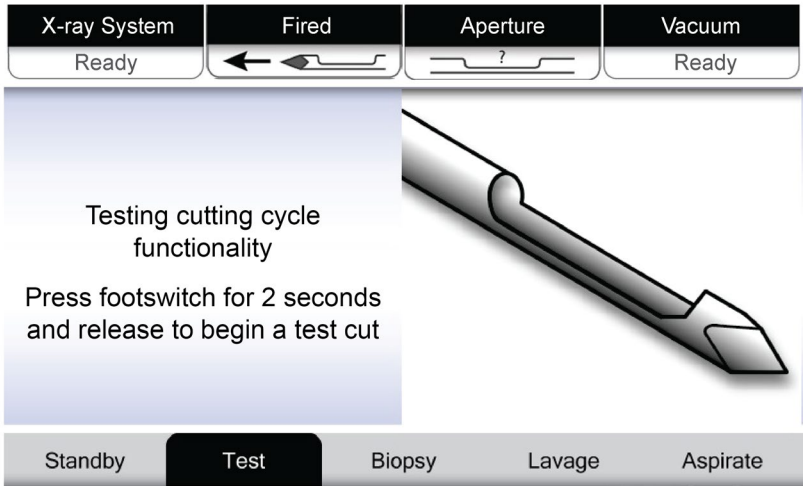


Figure 32: Test Screen

Warning:
Keep fingers and hands away from the biopsy device during Arm and Fire testing.

Warning:
Leave the protective sheath on the biopsy device tip during Arm and Fire testing.

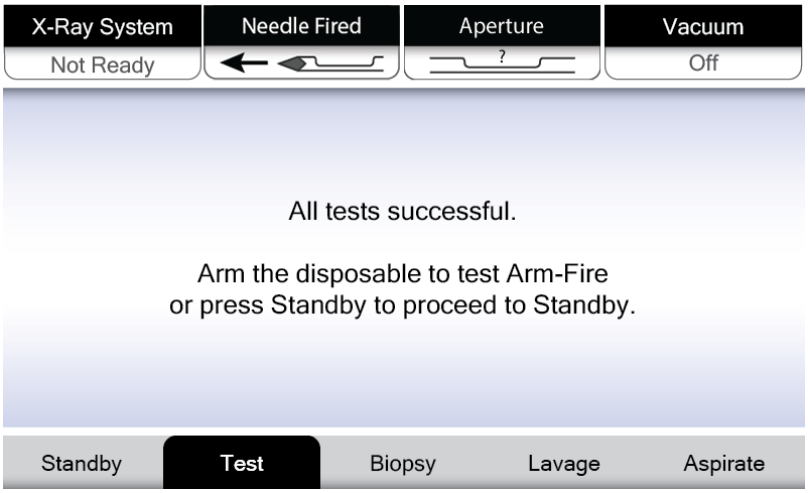


Figure 33: Test Screen - Arm and Fire

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5.1.3 Standby

When the system is in Standby mode, the vacuum is off and, if a biopsy device is connected, the aperture on the needle is closed. The system cannot arm or fire the biopsy needle when it is in Standby mode. The user must change the console from Standby mode to Biopsy mode to use the biopsy device and x-ray function.

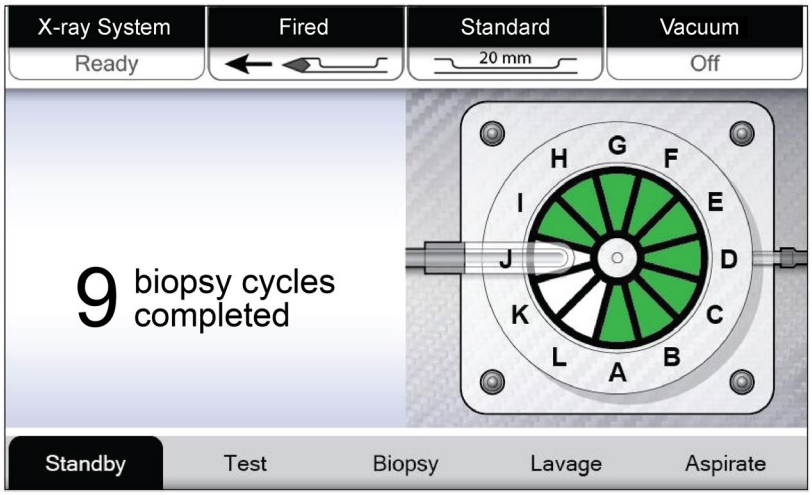


Figure 34: Standby Screen

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5.1.4 Biopsy

When the system is in Biopsy mode, depressing the footswitch activates the vacuum and operation of the biopsy device. In Biopsy mode, the biopsy device can be armed and fired with the remote control. As part of the normal cutting cycle, the system performs a brief aspiration with each core acquisition. Removing pressure from the footswitch inactivates or stops the device *after* completion of the current cycle.

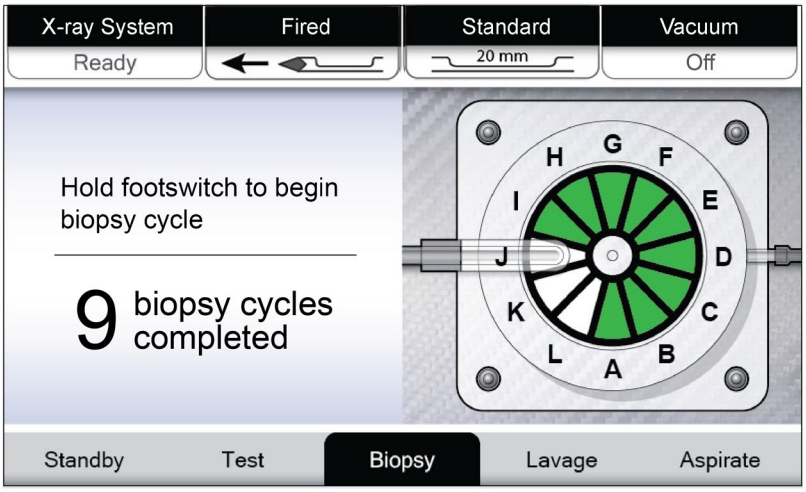


Figure 35: Biopsy Screen

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5.1.5 Lavage

When the system is in Lavage mode, the vacuum system is activated and will pull saline through the system. The aperture on the needle is open during Lavage mode. Depressing the footswitch does not control the flow of saline in Lavage mode.

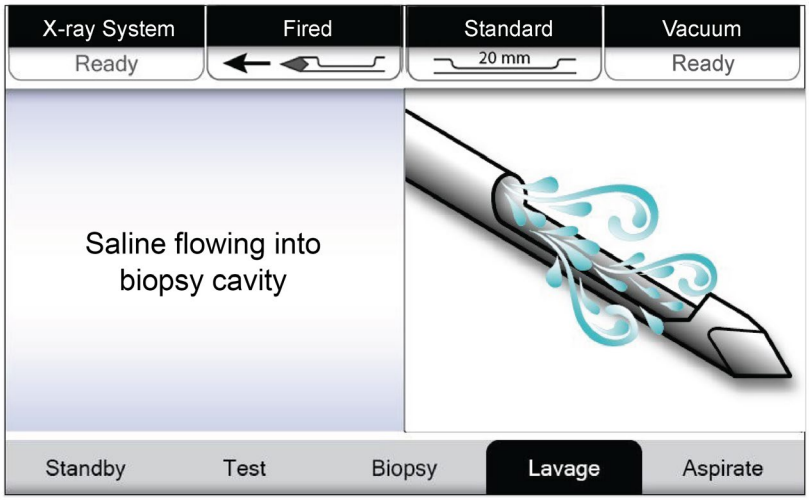


Figure 36: Lavage Screen

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5.1.6 Aspirate

When the system is in Aspirate mode, the vacuum system is continuously on and the aperture on the needle is open. Aspirate mode allows for continuous vacuum to aspirate the biopsy cavity. Saline does not flow in Aspirate mode. Depressing the footswitch does not control the flow of air or the vacuum in Aspirate mode.

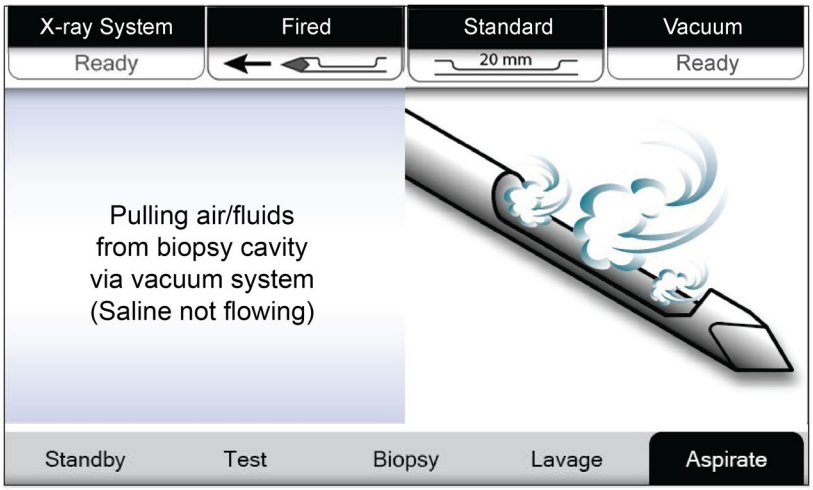


Figure 37: Aspirate Screen

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Chapter 6 Imaging System Modes

6.1 X-ray Mode

X-ray mode is the default mode of the Imaging system. To use the X-ray mode, start up the system and log in. Make sure the key switch on the imaging panel is in the unlocked position.

6.2 No X-ray Mode

The system also has a No X-ray mode that allows the user to perform a biopsy without taking any images. To enter No X-ray mode, select the **No X-ray** button on the *Startup* screen on the Imaging display.

When the system is in No X-ray mode, the tissue filter moves one position after each biopsy cycle and the number of biopsy cycles completed is shown on the Technologist display (same as in X-ray mode). Standby, Test, Biopsy, Lavage, and Aspirate modes operate in normal fashion. The user interface screens on the Imaging display are absent. In place of the X-ray image, a real-time video of the tissue filter is displayed.

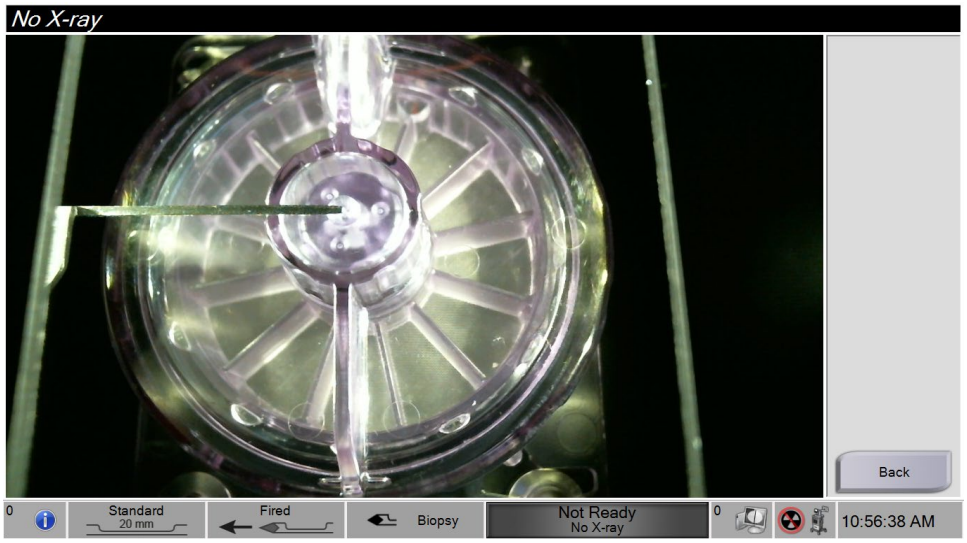


Figure 38: No X-ray Screen

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6.3 Single Chamber Mode

The system has a specialized mode that enables the user to perform a biopsy without taking any images when the Imaging system cannot detect or index the tissue filter. The Single Chamber tissue filter does not move or change position during the biopsy acquisition cycle. The number of biopsy cycles/acquisitions completed is displayed on the Technologist display (same as the other system modes). Standby, Test, Biopsy, Lavage, and Aspirate modes operate in normal fashion.

To enter Single Chamber mode, select the System Status icon on the taskbar, then select **Single Chamber** from the menu.

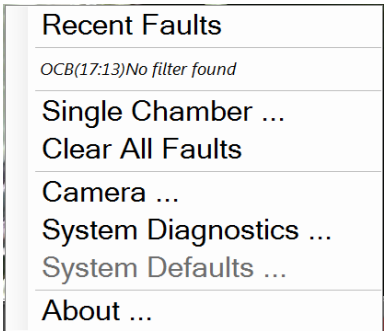


Figure 39: Menu Option for Single Chamber Mode

In Single Chamber mode, only a Single Chamber tissue filter can be used. The system prompts the user to install the Single Chamber tissue filter.

WARNING!
Do not proceed with the biopsy until the single chamber tissue filter is installed. Failure to install the single chamber tissue filter can result in lost cores.

Warning:
Using a twelve chamber tissue filter during single chamber mode causes all cores to collect in one chamber and can cause system damage.

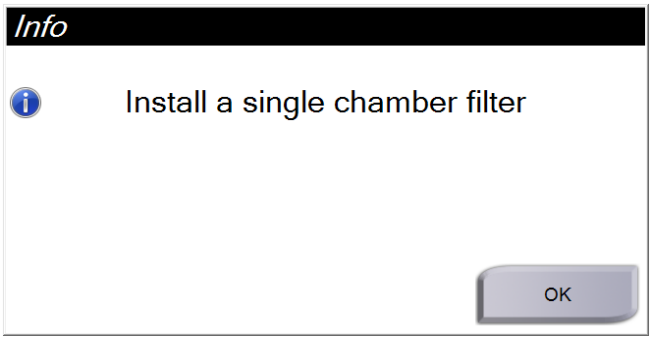


Figure 40: Prompt for the Single Chamber Tissue Filter

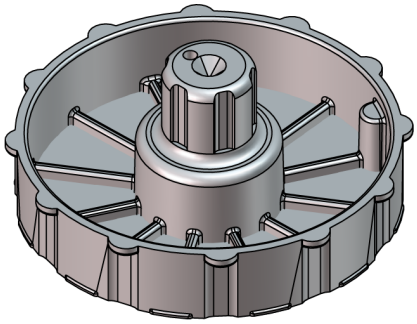


Figure 41: Single Chamber Tissue Filter

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The Imaging display does not show the usual user interface screens. In place of the x-ray image, the Imaging display shows a real-time video of the tissue filter.

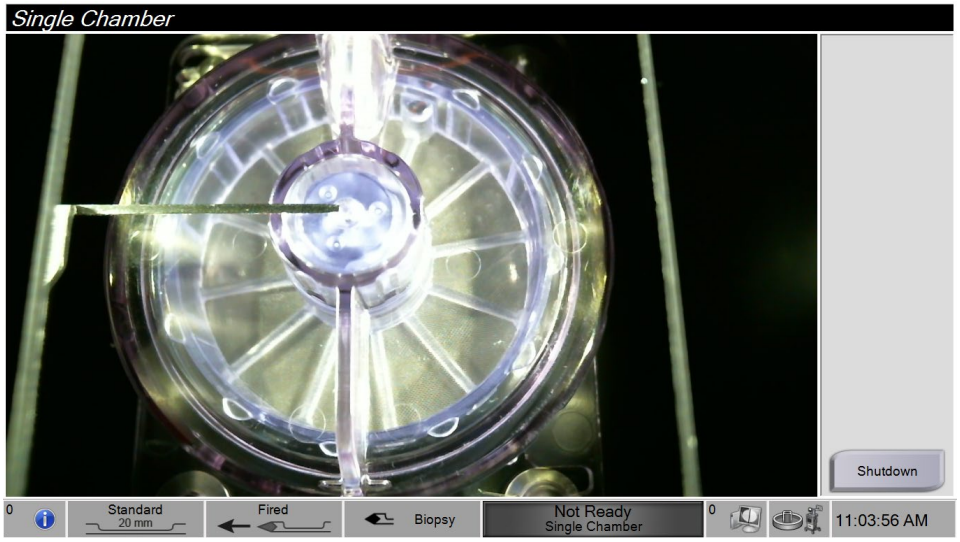


Figure 42: Single Chamber Video

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Chapter 7 Biopsy

7.1 Set Up the Console

1. Move the console into position and lock the casters.
2. Make sure the footswitch is connected.
3. Connect the console to power.
4. Connect the network cable to the Ethernet port (optional).
5. Unwind the footswitch and place it on the floor in front of the console.



Warning:
Position the footswitch and power cords to prevent accidental tripping.

6. Power on the console.



Warning:
Do not place fingers on the metal parts of the device driver. These parts can move when the system powers on.

7.2 Prepare for Image Acquisition

Refer to *Select Patient Screen* on page 49 for detailed information on the screen components.

1. On the Windows 10 *Login* screen, log in with your user name and password.
2. On the *Startup* screen, select the **Patient List** button to go to the *Select Patient* screen.
3. Select a patient from the worklist on the *Select Patient* screen, or manually add a new patient (refer to *Add a Patient* on page 50).

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4. On the *Procedure* screen, select the output devices.

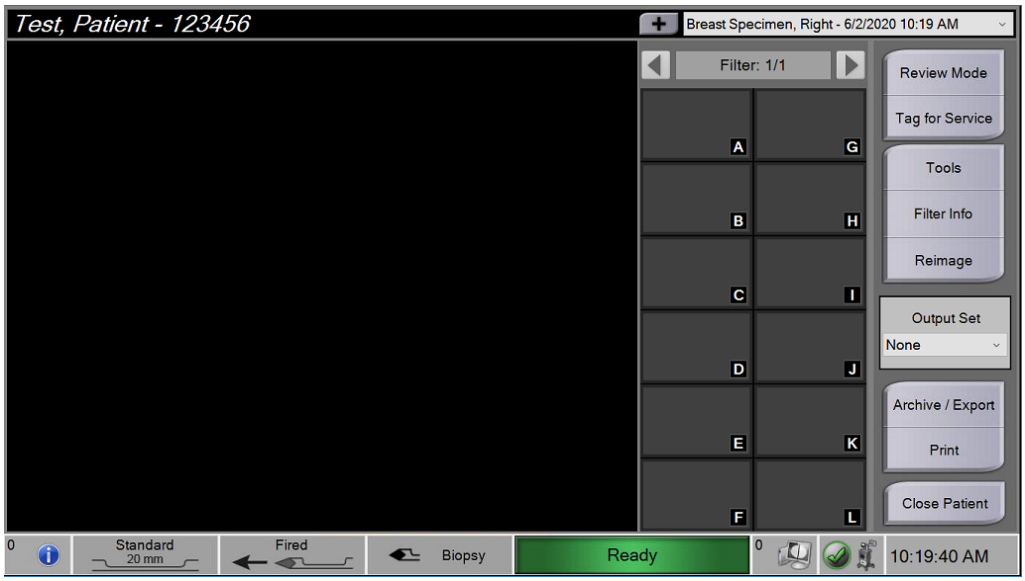


Figure 43: Procedure Example

5. Confirm that the tissue filter drawer is closed and that the system is free of any error messages.
6. Turn the Key switch to the unlocked position.

7.3 Connect the Device Driver and the Biopsy Supplies

Suction Canister

1. Attach the canister lid to the canister base.
2. Secure the large opening cap onto the large opening.
3. Place the suction canister in the canister holder on the console with the patient port pointing to the right.
4. Plug the vacuum line assembly into the top port labeled "VACUUM" on the suction canister lid.
5. Make sure that all connections are secure and sealed to avoid vacuum leaks.

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Device Driver



Warning:
Do not place fingers on the metal parts of the device driver. These parts can move before a biopsy needle is installed.

1. Slide the device driver onto the device driver holder on the console until it clicks.
2. Confirm that the device driver cord is connected to the receptacle. The receptacle is on the left side of the console, near the saline pinch valve.



Note
The console beeps three times before resetting the position of the metal parts of the device driver.

3. Wait for the device driver to home before attaching the biopsy needle.
4. Press the **Check** button on the Technologist display if the device driver needs to be rehomed. If the check button does not appear, disconnect and reconnect the cord of the device driver into the receptacle on the console to home the device driver.



Note
The device driver forks must be rehomed before installing a new biopsy needle.

Biopsy Needle and Tubing



Warning:
Before use, inspect the protective packaging and needle to verify that neither has been damaged during shipment. If it appears that the packaging or needle has been compromised, do not use the needle.



WARNING!
Do not connect the biopsy needle until the system is powered on and the device driver is homed and ready. Device driver forks and biopsy needle gears must be properly aligned before installation.



WARNING!:
Misalignment between biopsy needle gears and device driver forks can cause device malfunction, unusual noise, or interruption of the procedure requiring additional intervention.

Action:
If improper alignment or unusual noise is observed, stop use immediately and discard the needle. Disconnect and reconnect the driver to ensure it is in the install position (homed) and place a new needle on the driver.

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1. Place the sealed packaging for the biopsy needle on the console tray.
2. Peel open the sterile packaging of the biopsy needle. If the needle starts to lift out of the tray, place your hand above the needle and hold the needle in place until the top of the packaging is removed.
3. Remove the biopsy needle from the tray, leaving the tubing and the tissue filter in the tray. Make sure the biopsy needle gears are fully forward, toward the needle tip and both needle and driver are in the homed position. If the driver is not in the homed position, disconnect and reconnect the cord on the device driver into the receptacle on the console to home the device driver.

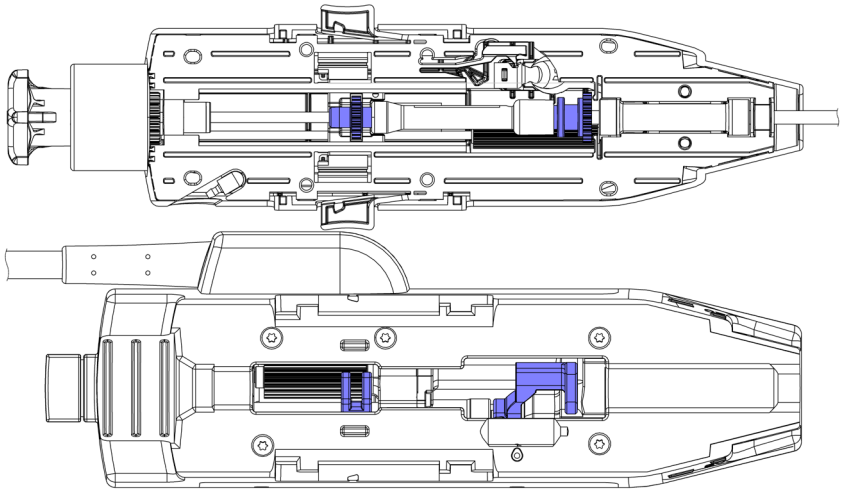


Figure 44: Biopsy Needle and Device Driver Fully forward in the homed position

Warning:
To maintain sterility, leave the protective sheath on the tip of the biopsy needle.

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4. Hold the biopsy needle in one hand, with the gears facing down and the sheathed needle tip facing to the right. Line up the tab on the biopsy needle with the notch in the device driver.

Warning:
Do not place fingers on the metal parts of the device driver. These parts can move before a biopsy needle is installed.

5. Carefully move the biopsy needle straight down, aligning the back of the tab with the back of the notch, until the needle engages with the driver. Do not drag the biopsy needle across the device driver.

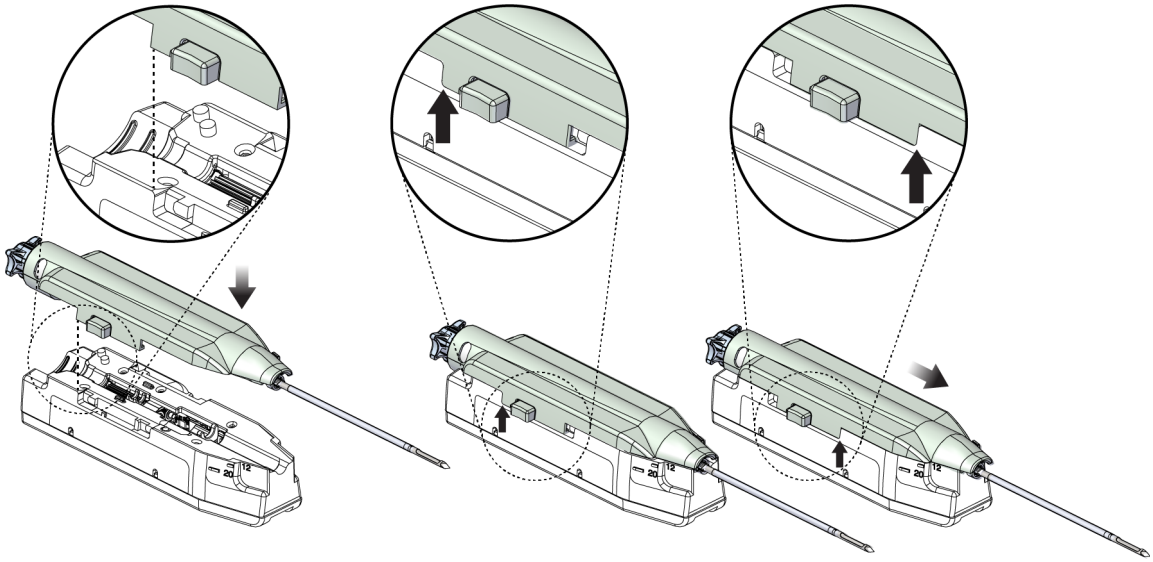


Figure 45: Connect the Biopsy Needle to the Device Driver

Warning:
Do not place fingers on the device driver when system power is on. Parts can move unexpectedly.

6. Slide the biopsy needle forward (to the right) until it locks into position with a click.

Warning:
Make sure that the biopsy needle is fully latched onto the device driver.

7. Remove the clear vacuum tubing from the biopsy needle packaging.

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8. Push the blue connector on the end of the vacuum tubing onto the horizontal side port marked "PATIENT" on the suction canister lid.

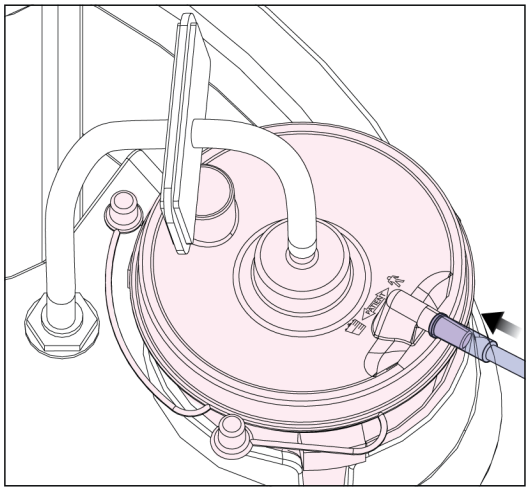


Figure 46: Connect the Tissue Filter Tubing to the Suction Canister

9. Get a saline bag and remove the protective cap. (A 250 cc saline bag is recommended.)
10. Remove the saline tubing from the biopsy needle packaging.
11. Insert the spike into the saline bag.

WARNING!
Make sure you use an aseptic technique when spiking the saline bag to prevent contamination.

12. Place the saline bag on the saline bag hook on the left side of the console.
13. Insert the larger diameter section of the saline tubing into the saline pinch valve. Make sure the saline tubing is fully seated.

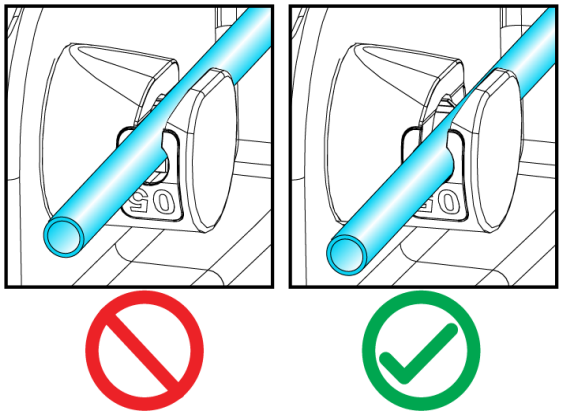


Figure 47: Placement of the Saline Tubing in the Saline Pinch Valve

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Tissue Filter

1. Pull open the tissue filter drawer.
2. Remove the tissue filter assembly from the biopsy needle packaging.
3. Confirm that the tissue filter housing is securely in place. (If needed, refer to *Tissue Filter Components* on page 34 for component assembly instructions.)
4. Put the tissue filter assembly in the center of the tissue filter drawer. Align the notch on the left-hand side of the tissue filter with the tab in the drawer. Seat the tissue filter on the four locator pins. Keep the tissue filter housing cover on the tissue filter as shown in the following figure. (*Component may appear different in markets where product is not yet available.)

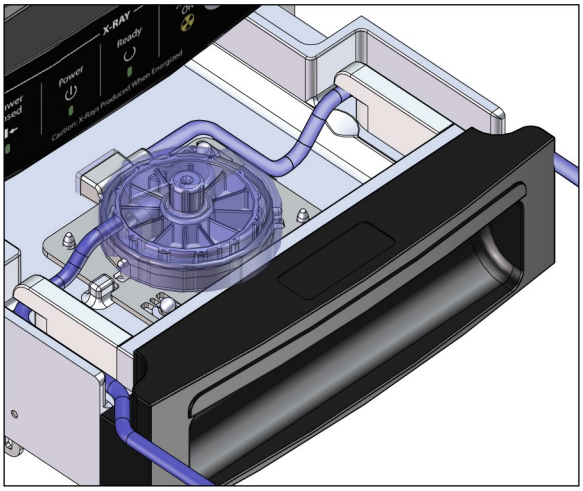


Figure 48: Seat the Tissue Filter in the Tissue Filter Drawer

Note
Each Brevera disposable biopsy needle includes a tissue filter cap. Save the tissue filter cap until the biopsy acquisition is complete. The tissue filter cap covers the tissue filter when the biopsy cores are placed in formalin.

5. Feed the gray tubing through the guide on the left side and feed the clear tubing through the guide on the right side of the drawer so that the drawer is able to close.
6. Close the tissue filter drawer.

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7.4 Pre-Procedure System Check

1. With the console in the desired location and powered on, the default mode is Standby. In Standby mode, the green LED indicator flashes above the **Test** button.
2. Assemble the Brevera breast biopsy device. Refer to *Connect the Device Driver and the Biopsy Supplies* on page 72 for information on assembling the biopsy device.

Warning:
Leave the protective sheath on the biopsy device tip to maintain sterility.

3. Confirm that the suction canister and tissue filter are assembled and placed in the console. Confirm that the vacuum line assembly and tubing are correctly connected. See *Components, Controls, and Indicators* on page 24 for more information on individual component assembly and connections.
4. Confirm that the silicone section of the saline tubing line is properly positioned in the saline pinch valve.
5. Confirm that the saline spike is correctly positioned in the saline bag and that the saline bag is hanging from the saline hook. Confirm that the saline flows freely from the bag.
6. Press the **Test** button on the Technologist display to switch the mode to Test mode. Follow the prompts on the Technologist display. Test mode will prime the system and generate vacuum.
7. Visually verify the flow of saline into the aperture of the biopsy device. Press the **Check** button on the Technologist display to confirm the saline flow.

WARNING!
Make sure the saline flows into the biopsy device to prevent lost cores and patient injury.

Warning:
Moving parts.

8. Step on the footswitch for two seconds and release the footswitch to initiate a test cutting cycle. Verify that the aperture opens and closes smoothly during the cutting test.

Warning:
If the aperture does not open and close smoothly, remove the biopsy needle and install a new one. Confirm driver is rehomed prior to installation of new needle.

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WARNING!
Improper alignment between the biopsy needle gears and the device driver forks may result in device malfunction, unusual noise, or procedure interruption that may require additional intervention.

Action:
If improper alignment or unusual noise is observed, stop use immediately and discard the needle. Disconnect and reconnect the driver to ensure it is in the install position (homed) and place a new needle on the driver.

9. After the test, the system gives two options: Go to Standby mode or test the Arm and Fire functions of the biopsy needle. (The console returns to Standby mode after the Arm and Fire test is completed.)
10. After completion of a successful test cycle, the system is ready for tissue acquisition.

7.5 Attach the Introducer to the Biopsy Device

1. With the system in Standby mode, remove the protective sheath from the biopsy needle.
2. Carefully slide the introducer over the needle of the biopsy device. Advance the hub of the introducer up to the device driver.

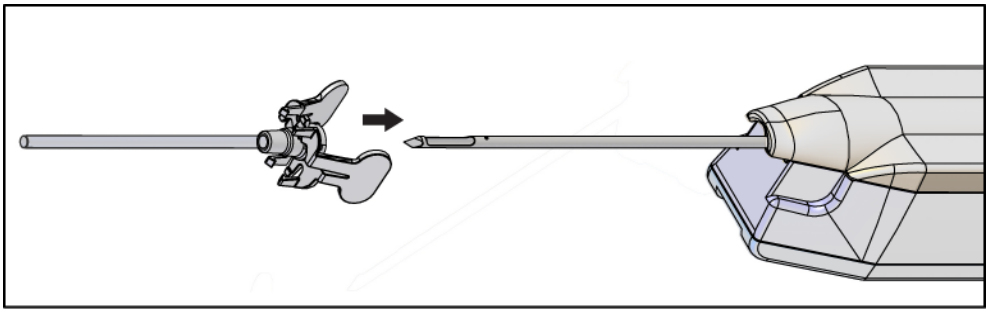


Figure 49: Slide the Introducer onto the Biopsy Device

WARNING!
Make sure to use an aseptic technique when attaching the introducer to prevent contamination.

3. Orient the introducer to select a petite or standard aperture. For an aperture of 20 mm, the 20 mm mark on the introducer lines up with the long mark on the device driver. Rotate the introducer 180° for an aperture of 12 mm, where the 12 mm mark on the introducer lines up with the short mark on the device driver.

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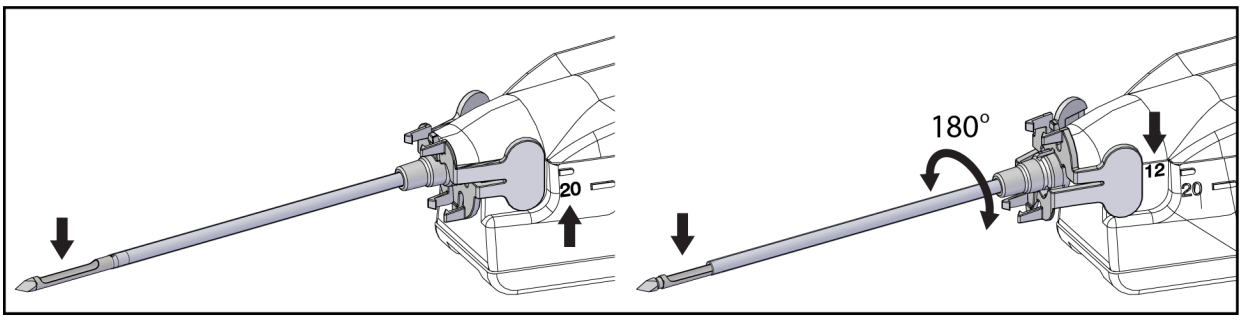


Figure 50: Use Standard or Petite Aperture

7.6 Attach a Biopsy Device Adapter to the Biopsy Guidance System

A biopsy device adapter is required to hold the biopsy device in place on a compatible biopsy guidance system. Attach the correct adapter to the biopsy guidance system.

Hologic offers biopsy device adapters for the Brevera breast biopsy system. Refer to the instructions for use provided with the Brevera biopsy needle and with the biopsy device adapter for additional information.

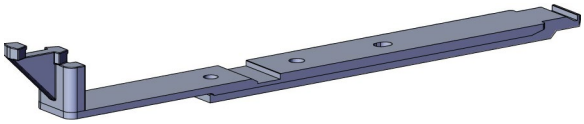


Figure 51: Biopsy Device Adapter

Warning:
Make sure the needle guide is installed correctly before use.

Note
Use only biopsy device adapters approved by Hologic.

7.6.1 Using the System with Stereotactic (STX) Guidance

Note
Complete training and understanding of your stereotactic guidance system should be provided by the vendor of your stereotactic system.

For additional training or questions on specific stereotactic applications, contact Product Support at 877-371-4372 or your local Hologic representative.

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7.7 Attach the Biopsy Device to the Biopsy Device Adapter

1. Place the system in Biopsy mode.
2. Press the **Arm** button on the remote control for at least two seconds to arm the biopsy device.
3. Align the biopsy device with the biopsy device adapter.
4. Slide the biopsy device forward until the introducer on the distal end of the Brevera breast biopsy device engages with the biopsy device adapter and the release latch of the driver engages with the proximal end of the biopsy device adapter. There is an audible click when the pieces are properly engaged, and the biopsy device will no longer slide on the adapter.

7.8 Performing a Biopsy and Acquiring Real-time Images

Perform all steps per standard interventional technique.

1. Identify the targeted area and prepare the site as required.
2. Assemble the biopsy device and advance it to the desired coordinates provided by the imaging system.

Warning:
If there is a problem advancing the needle into the breast, check the sharpness of the trocar needle tip. Replace the needle if necessary. Confirm driver is rehomed prior to installation of new needle.

WARNING!
Improper alignment between the biopsy needle gears and the device driver forks may result in device malfunction, unusual noise, or procedure interruption that may require additional intervention.

Action:
If improper alignment or unusual noise is observed, stop use immediately and discard the needle. Disconnect and reconnect the driver to ensure it is in the install position (homed) and place a new needle on the driver.

Note
X-ray is enabled when the drawer is closed. If the drawer is opened during an exposure, the exposure ends automatically.

3. Confirm that the system is ready to perform a biopsy procedure.
   - Confirm that the system is free of any error messages.

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- Confirm that all patient entry steps are complete and that the *Procedure* screen is displayed on the Imaging display.
- Confirm the aperture size and that the biopsy device is armed.
- Confirm that the Key switch is in the unlocked position.
- Confirm that the system is in Biopsy mode.

4. Fire the biopsy device by pressing and holding the **Fire** button on the remote control for at least 2 seconds.
5. Administer anesthetic (optional).
   - To initiate automatic delivery of anesthetic: Attach a 10 cc needleless syringe of anesthetic to the Y-valve. Inject 1–2 cc of anesthetic via the needleless syringe.
   - To manually administer anesthetic to the area of interest before tissue acquisition: (the biopsy device has been fired, the footswitch has not been depressed) Manually inject anesthetic via syringe and rotate the thumbwheel to allow 360 degrees of access.
   - To manually administer anesthetic to the area of interest during tissue acquisition: (the biopsy device has been fired, the footswitch has been depressed) place the system in Standby mode to close the aperture. Manually inject anesthetic via syringe and rotate the thumbwheel to allow 360 degrees of access. Once complete, return the system to Biopsy mode to continue tissue acquisition.



Note
The device does not allow the Y-valve injection when the device is in the armed (pre-fire) position.

6. Begin tissue acquisition. Press down on the footswitch and hold it in the depressed position throughout the biopsy procedure.
   - Removing your foot from the footswitch will inactivate or stop the device **after** completing the current cycle and the x-ray for the core in that cutting cycle.
   - The system beeps to indicate that it has completed a cutting cycle. A tissue filter icon appears in the thumbnail area to confirm that the cutting cycle is complete and ready for x-ray.
7. Acquire a real-time image.
   - The core handling system beeps to indicate that it is taking an x-ray. This beep is significantly softer in volume and tone than the beep that signals the end of the cutting cycle.
   - The Imaging display updates as each x-ray is available. A letter appears to indicate which core sample the image is associated with. The letters A–L in each image indicate the tissue filter chamber.
   - Touch the thumbnail image on the Imaging display to review the image at full size on the Imaging display.
8. Rotate the aperture on the outer cannula of the biopsy device by turning the thumbwheel to the next desired position immediately after the system beeps to

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indicate that it has completed a cutting cycle. The numbers in the window on the biopsy device and the line on the thumbwheel clock dial indicate the position of the aperture.

9. Continue tissue and image acquisition until the desired target area has been sampled and imaged. The system beeps two times after twelve cores are taken.
10. Review the images and make necessary enhancements. Refer to *Review the Images* on page 93.

7.8.1 When the Twelve Chambers of the Tissue Filter Contain Cores

The Brevera breast biopsy system with CorLumina imaging technology can acquire more than twelve biopsy cores per tissue filter. For these cases, when each of the twelve chambers in the tissue filter contains a biopsy core, the Brevera breast biopsy system presents two options: to continue using the existing filter or to continue with a new filter.



WARNING!
The Brevera System is intended to collect up to 24 consecutive tissue cores during a biopsy procedure. If 24 consecutive cores are acquired, place the system in Standby mode for a minimum of 20 minutes before collecting additional tissue samples.

Continue with the Existing Tissue Filter

1. Release the footswitch.
2. Press down on the footswitch and hold it in the depressed position throughout the biopsy procedure.
3. Continue to acquire biopsy specimens and to view their x-rays on the Imaging display.
4. At the end of the tissue acquisition or after the twenty-fourth core specimen, whichever comes first, continue with the instructions for *Lavage and Aspirate* on page 85.

Continue with a New Tissue Filter

1. Release the footswitch.
2. Open the tissue filter drawer.
3. Remove the tissue filter cover from the tissue filter assembly.
4. Place a dry tissue filter cap on the tissue filter. (The tissue filter cap is provided with the biopsy needle.)
5. Remove the used filter from the tissue filter assembly and the tissue filter drawer.
6. Place the used tissue filter in a specimen jar on the surface of the formalin.

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Note
The specimen jar should have a minimum inner diameter of 6.1 cm (2.4 inches) and a minimum height of 5.7 cm (2.25 inches) in order to fit a Brevera tissue filter.

7. Slowly submerge the tissue filter to allow the formalin to enter the chambers and air to escape. (Do not allow the tissue filter to float on top of the formalin.) Prepare the specimens for pathology per facility policy.
8. Install a new tissue filter.
9. Replace the cover on the tissue filter assembly, and close the tissue filter drawer. The system is ready when the indicators on the Imaging display return to green.
10. Select **Yes** on the Imaging display when asked if a new filter was inserted into the drawer.
11. Depress the footswitch.
12. Continue to acquire biopsy specimens and to view their x-rays on the Imaging display.
13. At the end of tissue acquisition or after the twenty-fourth core specimen, whichever comes first, continue with the instructions for *Lavage and Aspirate* on page 85.

7.8.2 Lavage and Aspirate

Lavage

Select Lavage mode to irrigate the cavity and to clear the biopsy device of tissue. The system will turn the vacuum on, open the aperture, open the saline pinch valve, and close the aspiration valve in order to push saline through the aperture. It is not necessary to depress the footswitch.

Aspirate

Select Aspirate mode to vacuum the cavity. The system will turn the vacuum on, open the aperture, close the saline pinch valve, and open the aspiration valve in order to push air through the aperture. It is not necessary to depress the footswitch.

7.8.3 Conclude Tissue Acquisition

1. Release the footswitch. Select Standby mode to close the aperture prior to removal of the biopsy device from the biopsy cavity.
2. Remove the biopsy needle and device driver as a unit from the biopsy device adapter while leaving the introducer in place for marker deployment. (Use the release latch on the back of the device driver to detach the biopsy device from the adapter.)
3. After removing needle from the breast, use the aspirate mode to clear the needle aperture.
4. Press the buttons on the sides of the biopsy needle to disengage it from the device driver. Detach the biopsy needle from the device driver and discard in a sharps container. (The tubing and tissue filter are removed from the console later.)

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Warning:
Do not place fingers on the metal parts of the device driver. These parts can move during system use.



Note
The console beeps three times before resetting the position of the metal parts of the device driver.

5. Slide the device driver onto the device driver holder on the console until it clicks.

7.8.4 Deploy a Biopsy Site Marker

To deploy a biopsy site marker, refer to the biopsy site marker instructions for use.



Note
Make sure that the correct biopsy marker is selected for the needle length used.

After deploying an optional biopsy site marker, retract the introducer and stereotactic adapter from the patient (refer to *Remove the Biopsy Device Adapter* on page 86).

7.8.5 Remove the Biopsy Device Adapter

1. After deploying an optional biopsy site marker, pull back the introducer and the biopsy site marker deployment device from the breast as one unit by moving the biopsy device adapter away from the patient.
2. After everything is retracted from the patient, remove the introducer and biopsy site marker deployment device as a unit from the biopsy device adapter by pinching the wing tabs on the introducer. Slide the introducer back from the adapter. Dispose of the introducer and marker deployment device per facility policy.
3. Refer to the instructions for use provided with the biopsy device adapter for additional information regarding removal of the adapter from the biopsy guidance system.
4. Immediately following the procedure, properly clean and disinfect the biopsy device adapter as recommended in the section *Maintenance, Cleaning, and Disinfecting* on page 108.



Note
Complete training and understanding of your biopsy guidance system should be provided by your biopsy guidance system vendor.

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7.9 Conclude the Procedure

1. Confirm that the console is in Standby mode.
2. Open the tissue filter drawer.
3. Remove the tissue filter cover from the tissue filter assembly.
4. Place a dry tissue filter cap on the tissue filter. (The tissue filter cap is provided with the biopsy needle.) To install, gently lower the tissue filter cap onto the tissue filter until the two tabs snap into place.

Warning:
Make sure that the protrusions in the center of the tissue filter cap align with the grooves on the tissue filter spindle. Make sure both tabs are fully latched.

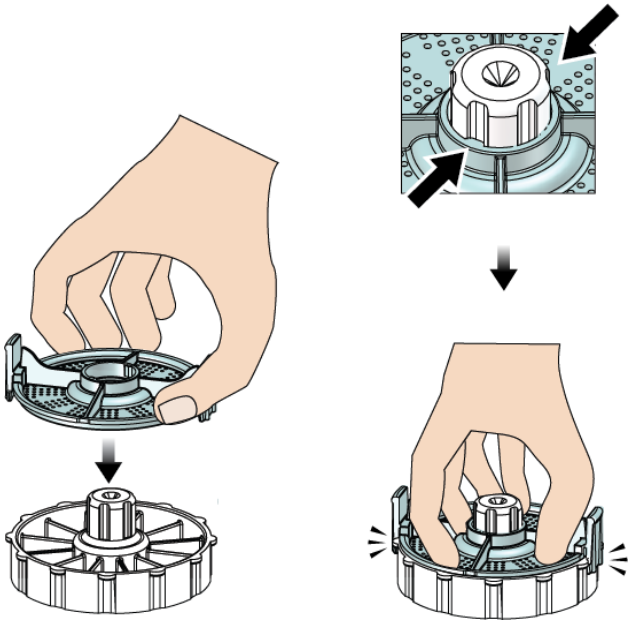


Figure 52: Install the Tissue Filter Cap

5. Remove the used filter from the tissue filter assembly and the tissue filter drawer.
6. Place the used tissue filter in a specimen jar on the surface of the formalin.

Note
The specimen jar should have a minimum inner diameter of 6.1 cm (2.4 inches) and a minimum height of 5.7 cm (2.25 inches) in order to fit a Brevera tissue filter.

7. Slowly submerge the tissue filter to allow the formalin to enter the chambers and air to escape. (Do not allow the tissue filter to float on top of the formalin.) Prepare the specimens for pathology per facility policy.

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8. Replace the cover on the tissue filter assembly.
9. Release the tissue filter assembly from the locator pins and temporarily leave in the drawer.
10. Remove the suction tubing from the tubing guides on the two sides of the drawer.
11. Remove the suction tubing from the suction canister.
12. Remove the saline tubing from the saline pinch valve. Remove the spike from the saline bag.
13. Gather all the tubing and the tissue filter assembly and discard in the sharps container with the previously discarded biopsy needle.
14. Dispose of the saline bag per facility policy.
15. Dispose the needle guide per facility policy.
16. Close the tissue filter drawer.
17. Disconnect the vacuum line assembly from the suction canister, and close the suction canister ports. Dispose of the suction canister per facility policy for biohazardous waste.
18. After logout and shutdown, perform the recommended cleaning and disinfection procedures. Refer to *Maintenance, Cleaning, and Disinfecting* on page 108 for more information.

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7.10 How to Change the Biopsy Needle Between Procedures

Follow these instructions to change the biopsy needle for a new procedure.

1. Confirm that the console is in Standby mode.
2. Press the buttons on the sides of the biopsy needle to disengage it from the device driver. Detach the needle from the driver and place it in a sharps container.



Warning:
Do not place fingers on the metal parts of the device driver. These parts can move before a biopsy needle is installed.



Note
The console beeps three times before resetting the position of the metal parts of the device driver.

3. Slide the device driver onto the device driver holder on the console until it clicks.
4. Wait for the device driver to automatically home in preparation for a new biopsy needle.
5. Follow the instructions in *Conclude the Procedure* on page 87 to disconnect and remove the biopsy supplies.
6. Confirm device driver is in the homed position. Install the new biopsy supplies and the new biopsy needle. Refer to *Connect the Device Driver and the Biopsy Supplies* on page 72 for detailed instructions.



Warning:
Improper alignment between the biopsy needle gears and the device driver forks may result in device malfunction, unusual noise, or procedure interruption that may require additional intervention.

Action:
If improper alignment or unusual noise is observed, stop use immediately and discard the needle. Disconnect and reconnect the driver to ensure it is in the install position (homed) and place a new needle on the driver.

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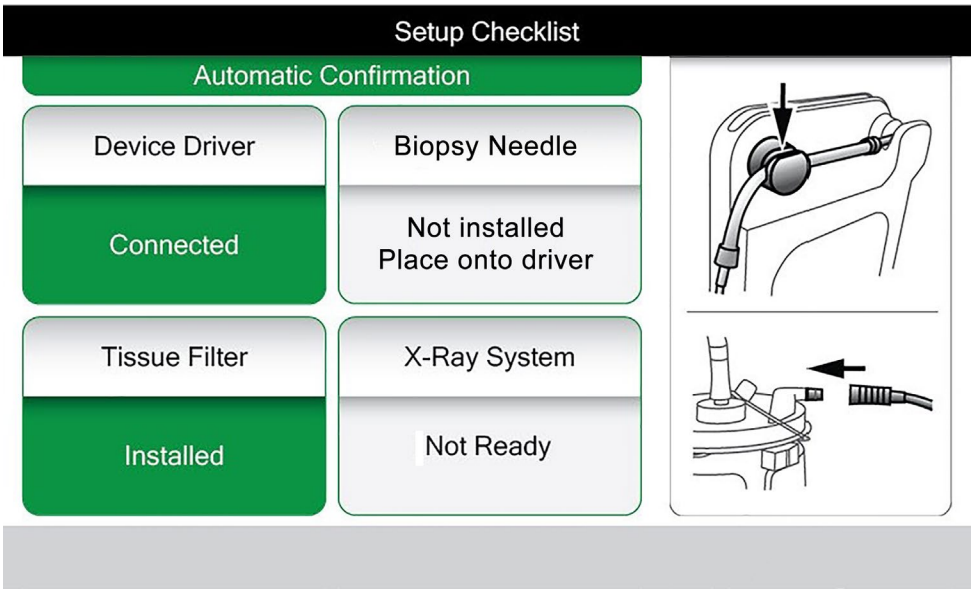


Figure 53: System Recognizes When the Device Driver Is Ready

7.11 How to Change the Biopsy Needle During Troubleshooting

Follow these instructions to change the biopsy needle to troubleshoot issues during setup and testing.

1. Slide the device driver onto the device driver holder on the console until it clicks.
2. Press the buttons on the sides of the biopsy needle to disengage it from the device driver. Detach the needle from the driver and place it in a sharps container.

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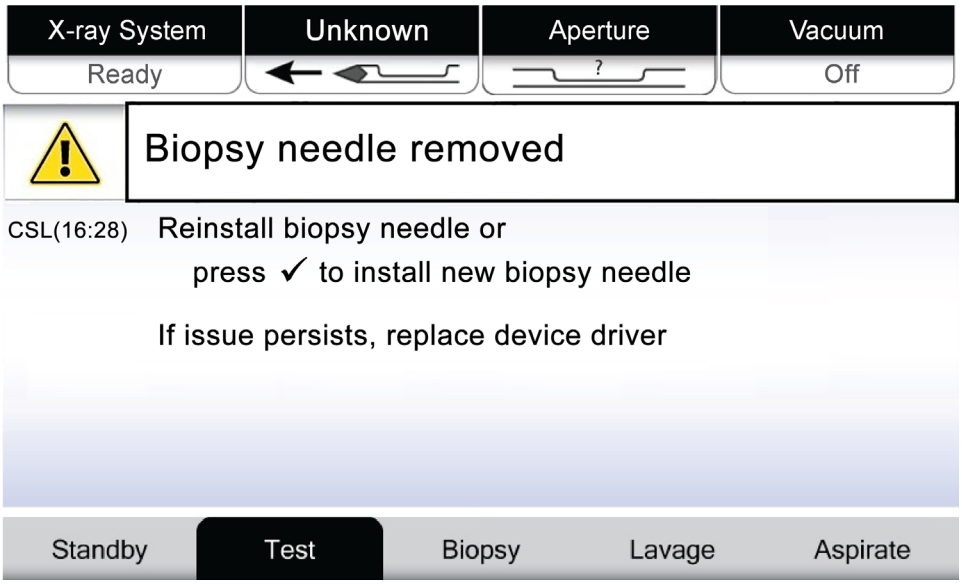


Figure 54: System Recognizes That the Biopsy Needle Is Removed

3. Refer to the instructions in *Conclude the Procedure* on page 87 to disconnect and remove the biopsy supplies.
4. Press the **Check** button on the Technologist display to home the device driver. If check button does not appear, disconnect and reconnect the cord on the device driver into the receptacle on the console to home the device driver.

Warning:
Do not place fingers on the metal parts of the device driver. These parts can move before a biopsy needle is installed.

Note
The console beeps three times before resetting the position of the metal parts of the device driver.

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5. Wait for the device driver to home.
6. Install the new biopsy supplies and the new biopsy needle. Refer to *Connect the Device Driver and the Biopsy Supplies* on page 72 for detailed instructions.

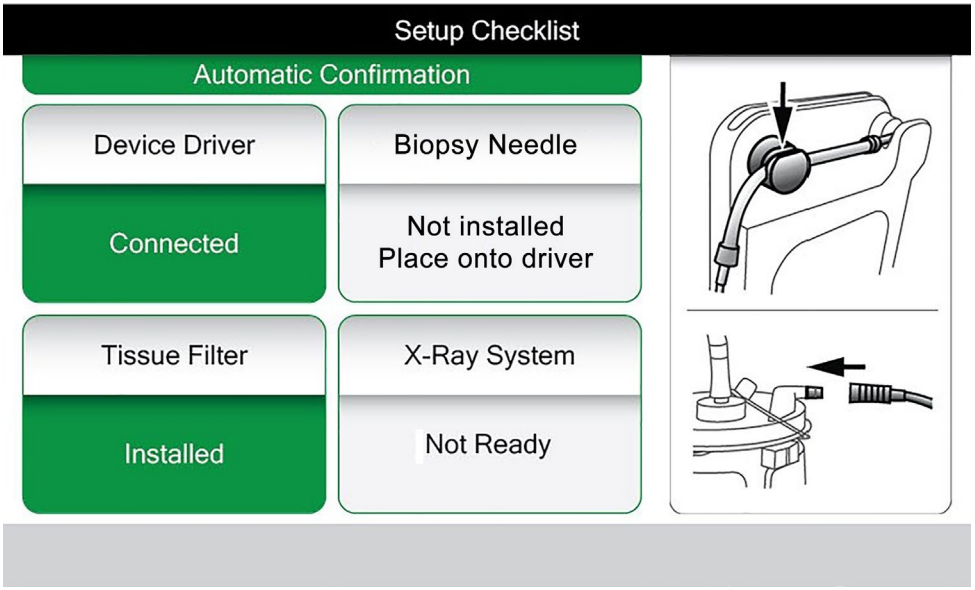


Figure 55: System Recognizes When the Device Driver Is Ready

Warning:
Improper alignment between the biopsy needle gears and the device driver forks may result in device malfunction, unusual noise, or procedure interruption that may require additional intervention.

Action:
If improper alignment or unusual noise is observed, stop use immediately and discard the needle. Disconnect and reconnect the driver to ensure it is in the install position (homed) and place a new needle on the driver.

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Chapter 8 Images

8.1 Introduction

After you make an exposure, the acquired image displays and is accepted automatically. A thumbnail image appears on the screen, with the corresponding letter designation for the tissue filter chamber. Use the image functions to tag, review, enhance, and annotate the images or reimage the cores.

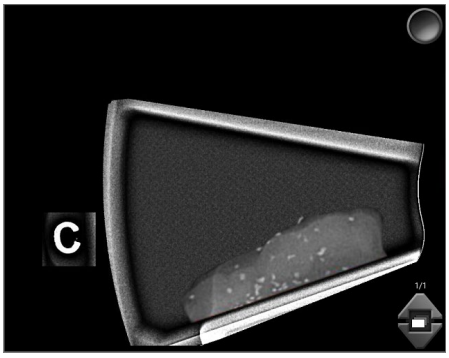


Figure 56: An Acquired Image

8.2 Review the Images

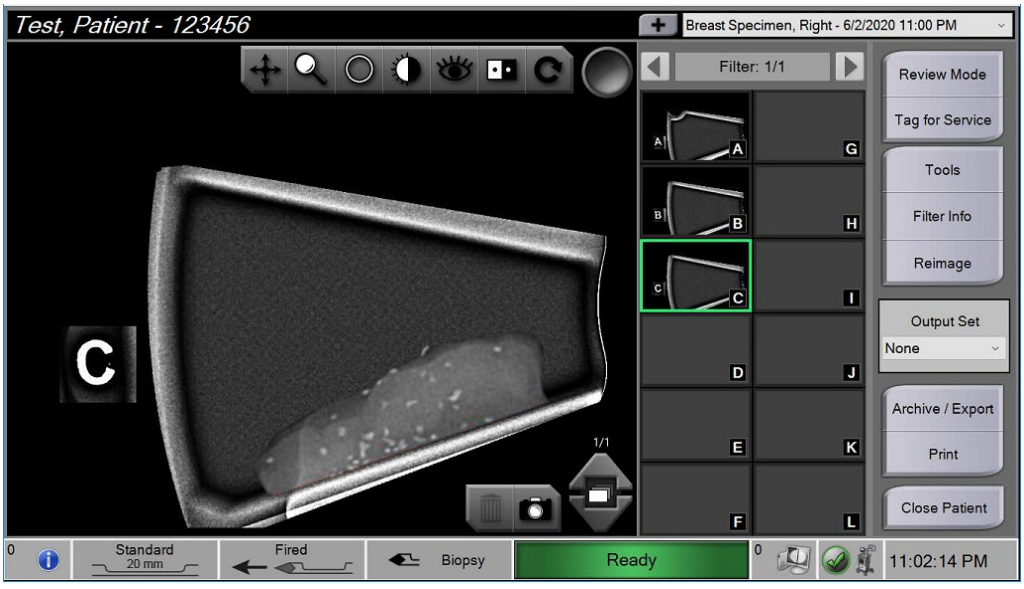


Figure 57: Image Tools in the Procedure Screen

Select a thumbnail image.

- A preview image shows in the large window on the screen.
- Use the image tools (refer to *Image Enhancement Tools* on page 97) to enhance the whole image or areas of interest in the image.

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8.2.1 Tag an Image

The Tag tool is the round button in the upper right corner of the image. Pressing this button selects or deselects the active image. Tagged images show a green check mark in the upper right of the image and the image thumbnail. The check mark is burned into the tagged images that are exported, archived, or printed.



Figure 58: An Example Tagged Image

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Tag an Image for Service

You can tag an image to allow Hologic service personnel to access it easily.

1. In the right panel of the *Procedure* screen, select the **Tag for Service** button.

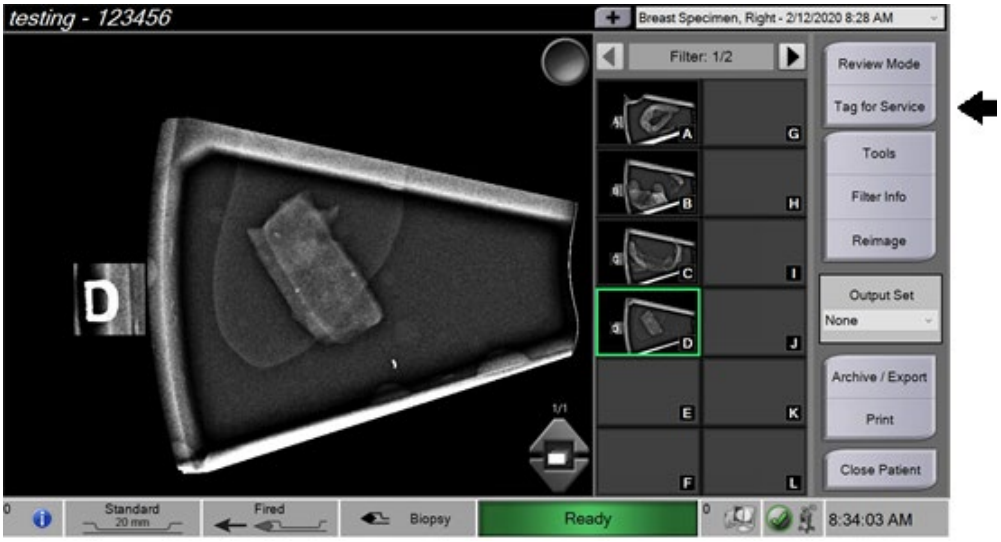


Figure 59: Tag for Service Button on the Procedure Screen

2. On the *Tag for Service* screen, select the image of concern.

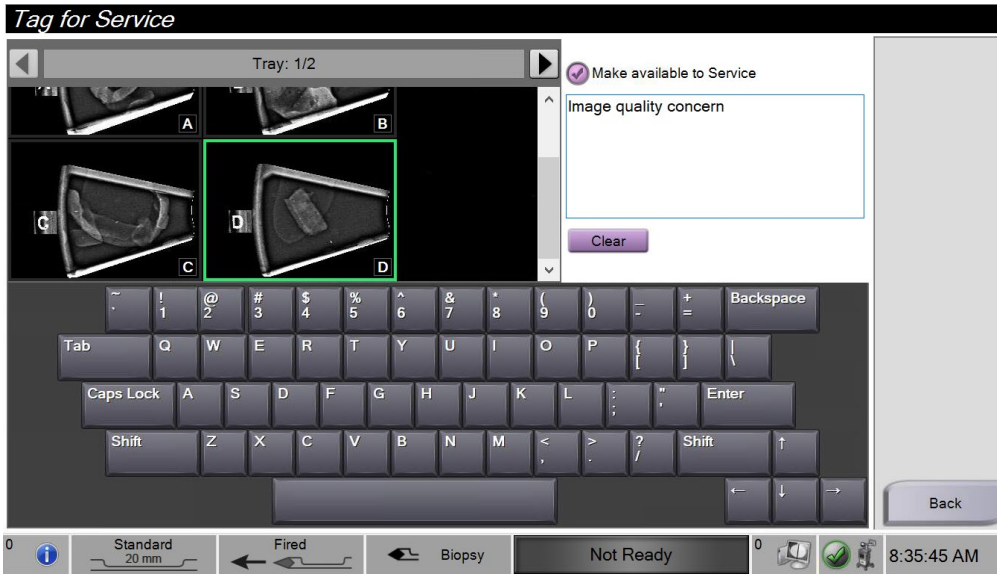


Figure 60: Tag for Service Screen

3. Enter a description of the concern.
4. Select the **Back** button when complete.

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8.2.2 Review Mode Screen

The *Review Mode* screen allows for a quick review of the images. The *Review Mode* screen no longer shows an active image and instead shows larger thumbnails of the images. The images can be quickly tagged by selecting them from the group of images instead of tagging them individually from the *Procedure* screen. The *Review Mode* screen includes a Tag All and a Clear All feature.

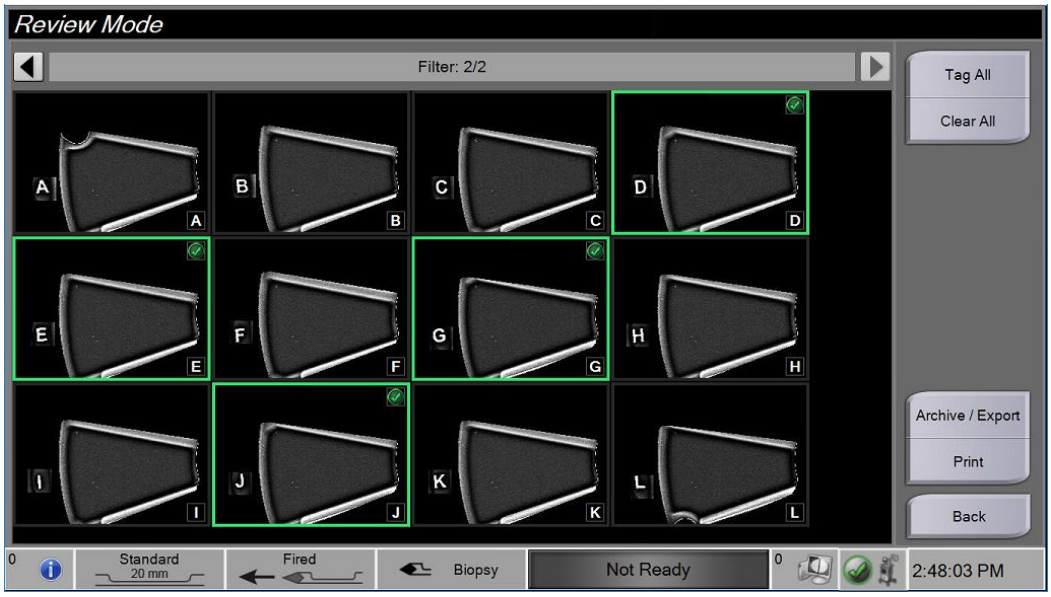


Figure 61: Review Mode Screen

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8.2.3 Image Enhancement Tools

When you select the **Tools** button, the Image Enhancement Tools bar displays on the active image. Select the tool icon to enable it. The active tool appears to be pressed into the tools bar.

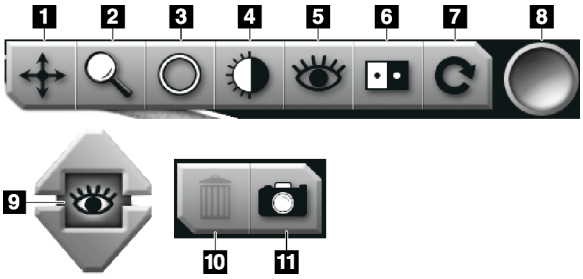


Figure 62: Image Enhancement Tools

Figure Legend

1. The Pan tool is used to move the view to a different portion of the image by dragging.
2. The Zoom tool magnifies the whole image. Drag up to zoom in and make the image larger. Drag down to zoom out and make the image look smaller.
3. The Circle tool is used to draw a circle on the image. Drag up or down to make the circle larger or smaller. Once the circle is placed its size cannot be changed, but it can be moved by dragging or deleted by double-tapping.
4. The Window/Level tool is used to change the brightness and contrast.
5. The Enhanced Visualization tool adjusts the image sharpness.
6. The Invert tool changes blacks to white and whites to black.
7. The Reset tool returns an image to the original state. Any annotations, panning, zooming, etc. are removed.
8. The Tag tool selects a particular image or images. Tagged images show a green check mark in the upper right of the thumbnail image. The check mark is burned into the tagged images that are exported, archived, or printed off the system.
9. The Enhancement Level is displayed when the Enhanced Visualization tool is active. The level of enhancement can be adjusted from greater (5) to lesser (1) in real time.
10. The **Delete** button deletes a snapshot.
11. The **Camera** button captures a snapshot of the image display area and adds the snapshot to the current procedure.

Note
The Enhanced Visualization tool is inactive for snapshot images.

8.2.4 Filter Info and Comments Screen

From the *Procedure* screen, click on the **Filter Info** button to make notes or comments about image content. One set of comments can be added per tissue filter. Comments are saved with the images from that tissue filter and are exported with the image or images.

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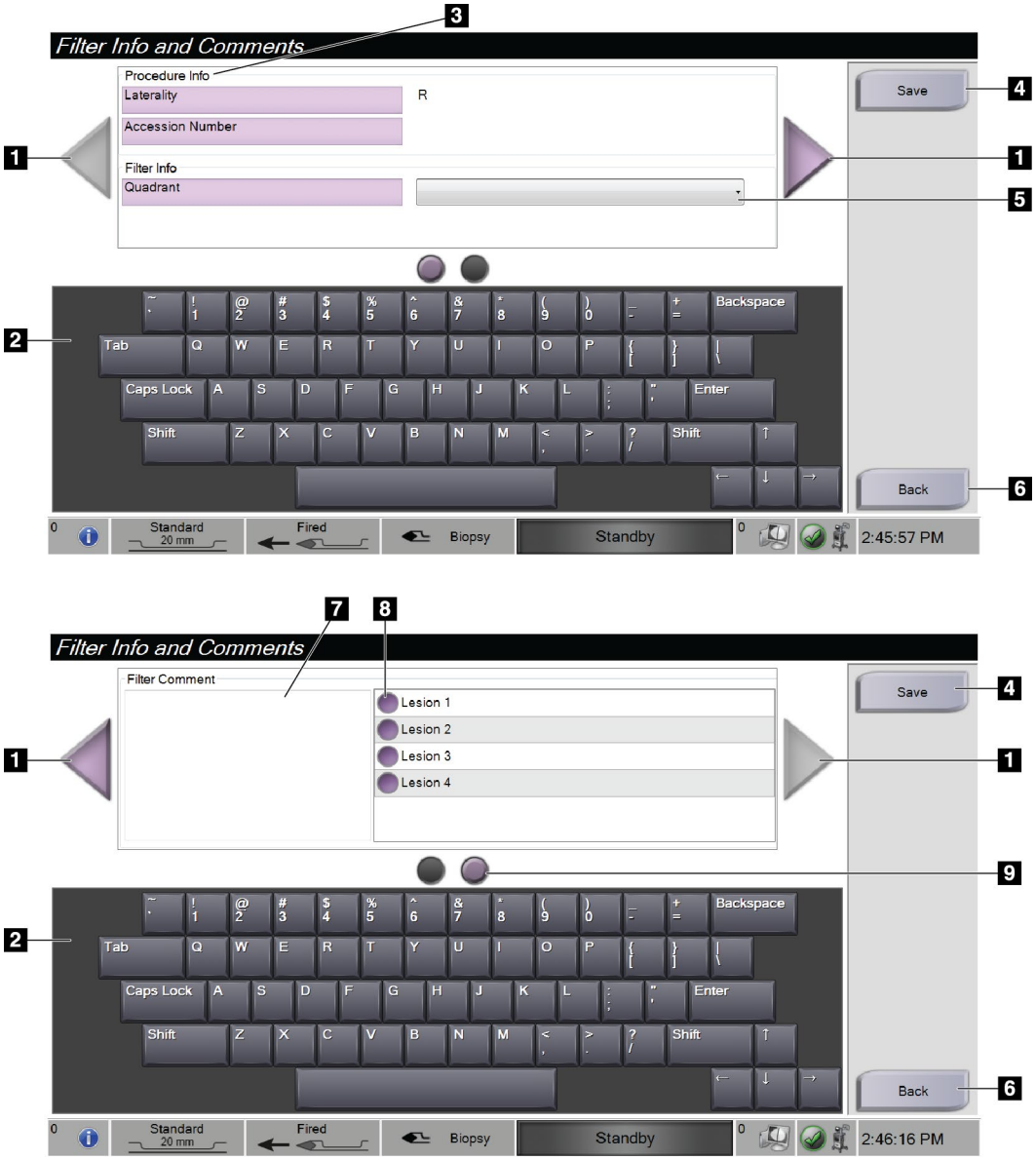


Figure 63: Filter Info and Comments Screens

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Figure Legend

1. Scroll between the two screens using the arrows.
2. Use the on-screen keyboard to type, edit, and remove Filter Comments.
3. The Procedure Info is the information already in the system for the procedure. It cannot be edited on the *Filter Info and Comments* screen.
4. Select the **Save** button to save the Filter Info and Comments.
5. Indicate the quadrant for the specimens in that particular tissue filter.
6. Select the **Back** button to exit the *Filter Info and Comments* screen without saving and return to the previous screen. If there are unsaved changes, a prompt displays the option to save or continue without saving the comments.
7. Enter, edit, and remove additional Filter Comments using the on-screen keyboard.
8. Select from a predefined list describing the specimens in that particular tissue filter.
9. Use these circles to scroll between the two screens. A red exclamation point in a circle indicates that there is an error that needs to be fixed on that screen.

8.2.5 Reimage

Select the **Reimage** button to acquire a new image of the core shown in the active image.

8.3 Send the Images to the Output Devices

You can send the images to output devices or use the Export function to copy images to a temporary storage device. Refer to *Output Sets* on page 57 for instructions.

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Chapter 9 System Administration Interface

9.1 Admin Screen

This section describes the functions available in the *Admin* screen. To access this screen:

1. Log in to the system.
2. In the *Startup* screen, select the **Patient List** button to go to the *Select Patient* screen.
3. In the right panel of the *Select Patient* screen, select the **Admin** button. The *Admin* screen opens.

Note
The figures in this User Guide show the *Admin* screen with Manager level access. A Radiological Tech (Primary User) has access to some functions on the *Admin* screen. A Manager system user has access to more functions on the *Admin* screen. A Hologic Service User has access to all functions on the *Admin* screen.

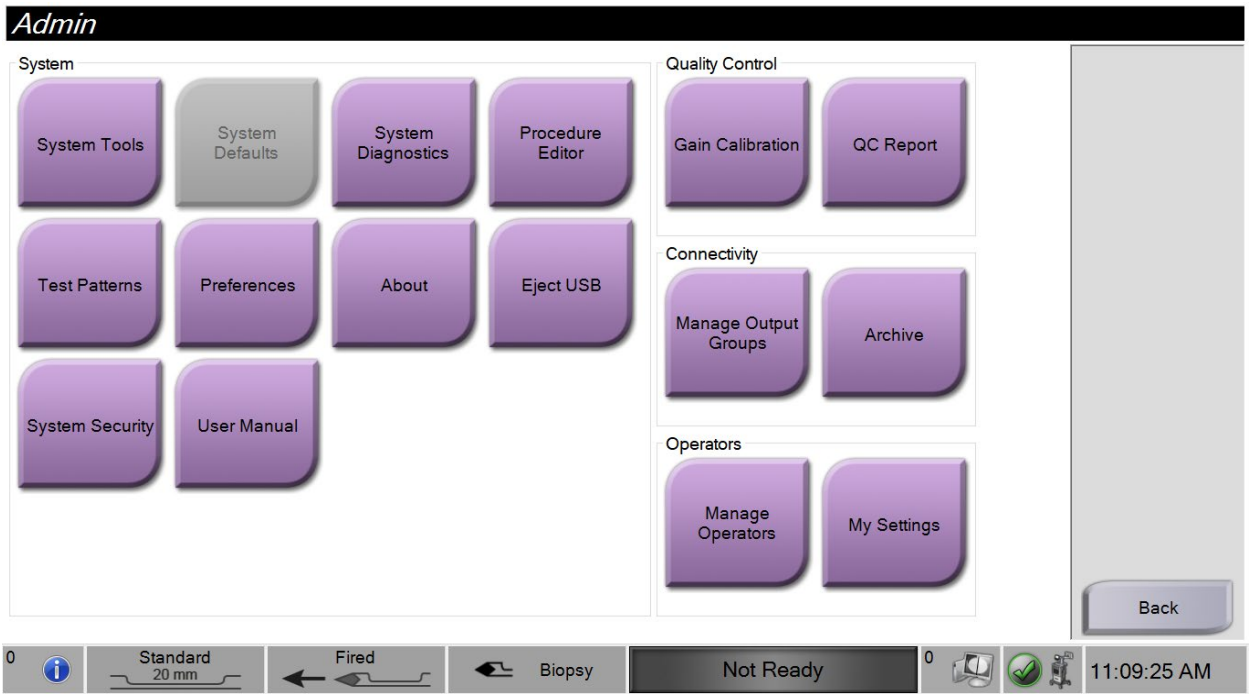


Figure 64: Admin Screen

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Table 2: Admin Screen Functions		
Section	**Screen Function**	
System	**System Tools**	The interface for service for the configuration of and identification of problems.
	System Diagnostics	Shows the status of all subsystems including the x-ray detector and the camera above the tissue filter drawer.
	Procedure Editor	Add, edit, or delete the procedures.
	Test Patterns	Select and send the test patterns to output devices.
	Preferences	Set the system preferences.
	About	Tells about the system.
	Eject USB	Eject a media storage device connected to the USB port.
	System Security	Access Account Security settings and the Windows OS Tools.
	User Manual	Access the User Guide and other user documents.
Quality Control	**Gain Calibration**	Select the Gain Calibration procedure.
	QC Report	View information on the most recent Gain Calibration.
Connectivity	**Manage Output Groups**	Add, delete, or edit output groups.
	Archive	Export or archive one or more procedures for one or more patients all at one time.
Operators	**Manage Operators**	Add, delete, or change Operator information.
	My Settings	Change the information for the current Operator. All user permission levels allow a user to edit fields in the My Settings screens.
You must have permissions to access all features. The permission level controls the functions you can change.		

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9.2 About Screen

The *About* screen provides information about the machine, such as system level, IP address, and serial number. This type of data can be useful when working with Hologic to configure the system or resolve a system issue.

The screen is accessed in two ways:

- From the *Select Patient* screen - select the **System Status** icon (on the taskbar) then select **About…**
- From the *Admin* screen - select **About** (in the System group)

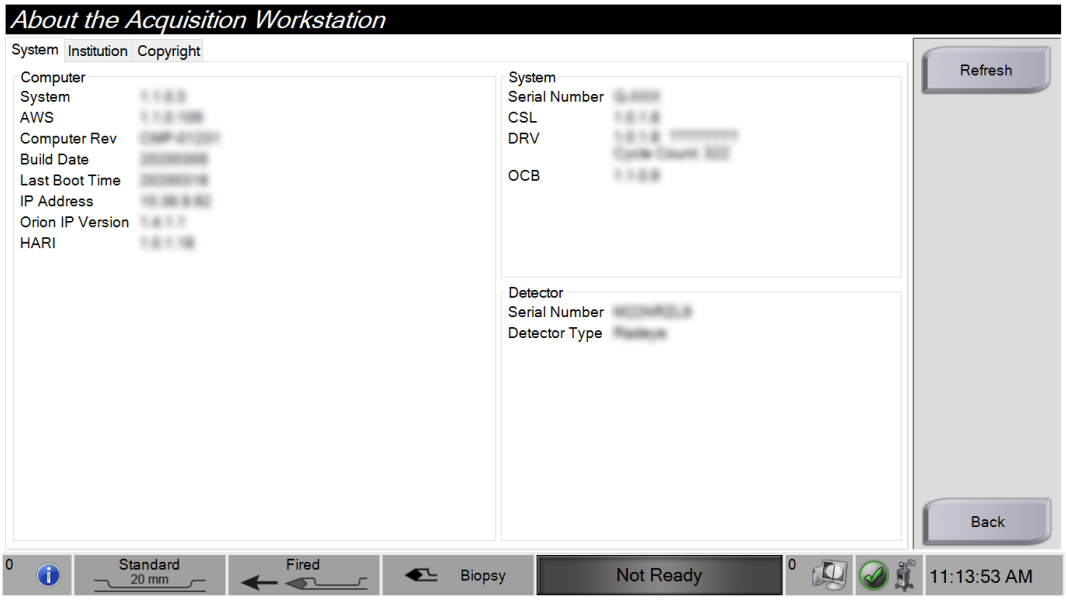


Figure 65: System Tab of the About Screen

There are three tabs on the *About* screen:

- **System Tab** (default) - lists system configuration information
- **Institution Tab** - lists the name and address of the organization assigned to this machine
- **Copyright Tab** - lists the copyrights of Hologic and third-party software installed on this machine

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9.3 Change the User Language Preference

1. In the Operators group of the *Admin* screen, select the **My Settings** button.
2. Go to the second page. In the **Locale** field, select a language from the drop-down list.
3. Select **Save**, then select **OK in** the *Update Successful* message. The user interface changes to the selected language.

9.4 Change the Keyboard Layout

The system supports both the QWERTY keyboard and the AZERTY keyboard.

1. In the Operators group of the *Admin* screen, select the **My Settings** button.
2. Go to the second page. In the **Keyboard** field, select a keyboard from the drop-down list.
3. Select **Save**, then select **OK in** the *Update Successful* message. The user interface changes to the selected keyboard.

Letters with Accents

Both keyboard layouts support accented letters. To display the accent options for a letter, press and hold (long press) the on-screen key.



Figure 66: Accented Letters on the On-screen Keyboard

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9.5 Account Security Settings

Users with Windows Administrator permissions can change some of the Windows 10 password and account policy settings. To update the settings:

1. Log in as a Manager.
2. Go to the *Admin* screen.
3. In the Operators group of the *Admin* screen, select the **System Security** button.
4. The *System Security* screen opens. Select the **Account Security** button.
5. Make the desired changes, then select **Save**.

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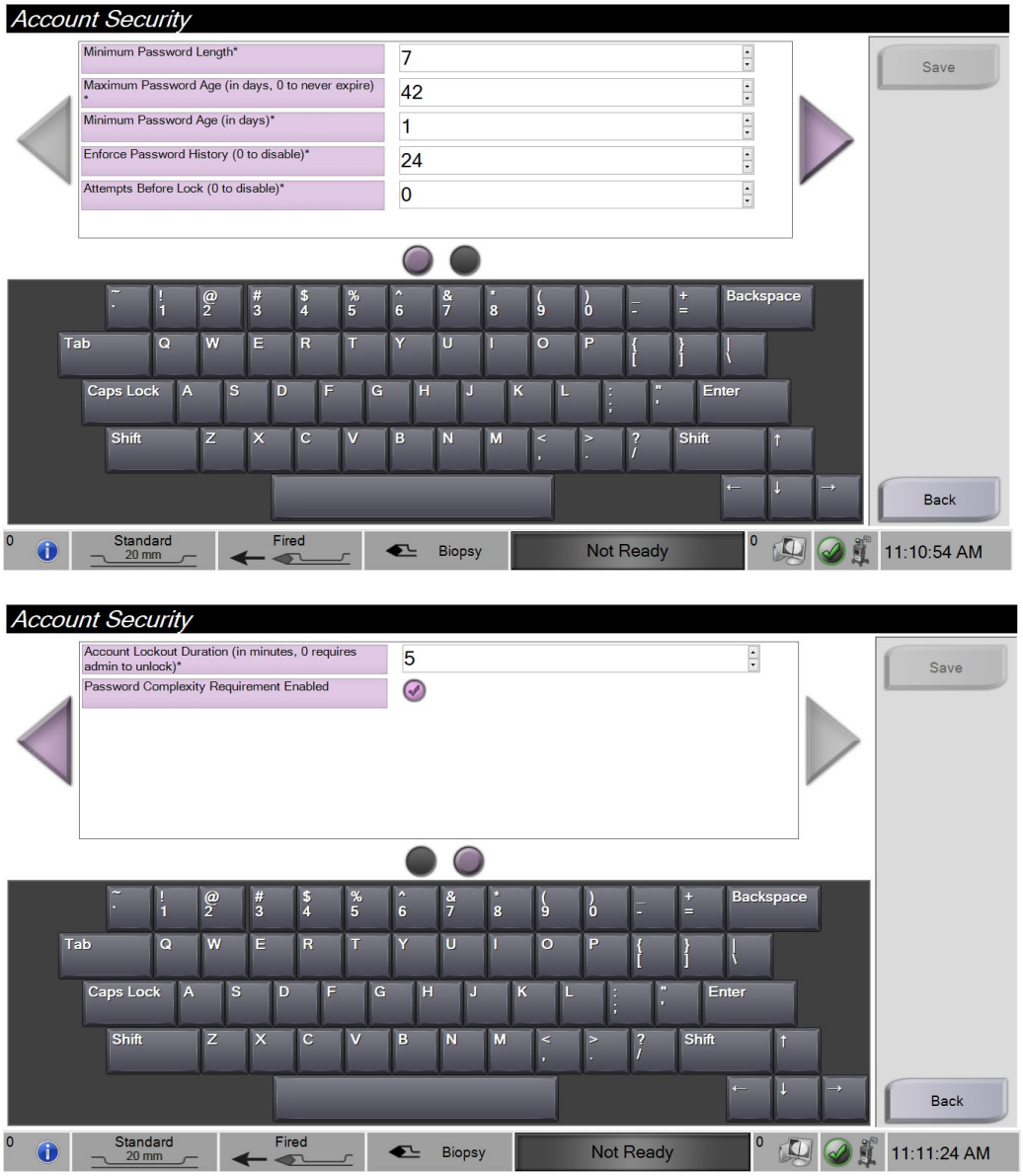


Figure 67: Account Security Screens

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9.6 System Tools

The Managers (and Hologic Service) can access the System Tools function. This function contains the configuration information about the system.

To access the System Tools function:

1. Log on as a Manager.
2. On the *Startup* screen, select the **Patient List** button to go to the *Select Patient* screen.
3. In the right panel of the *Select Patient* screen, select the **Admin** button.
4. From the System group of the *Admin* screen, select the **System Tools** button.

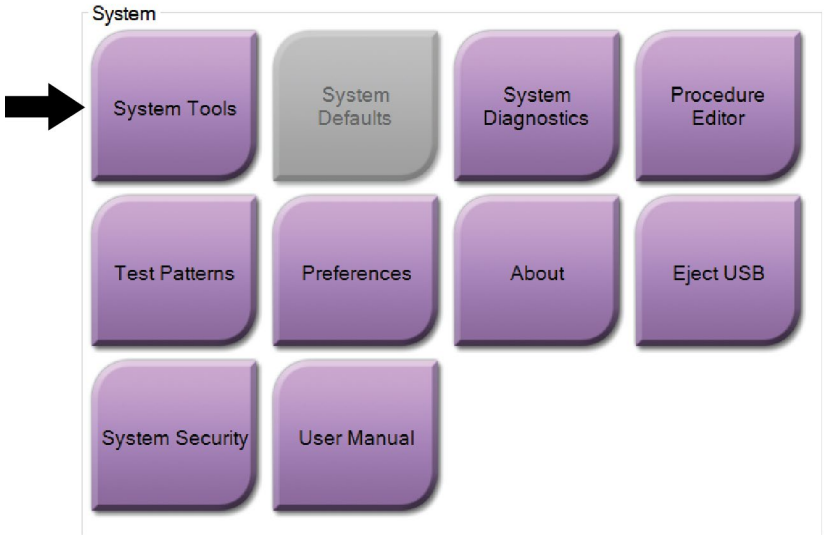


Figure 68: System Tools Button

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9.6.1 System Tools Screen

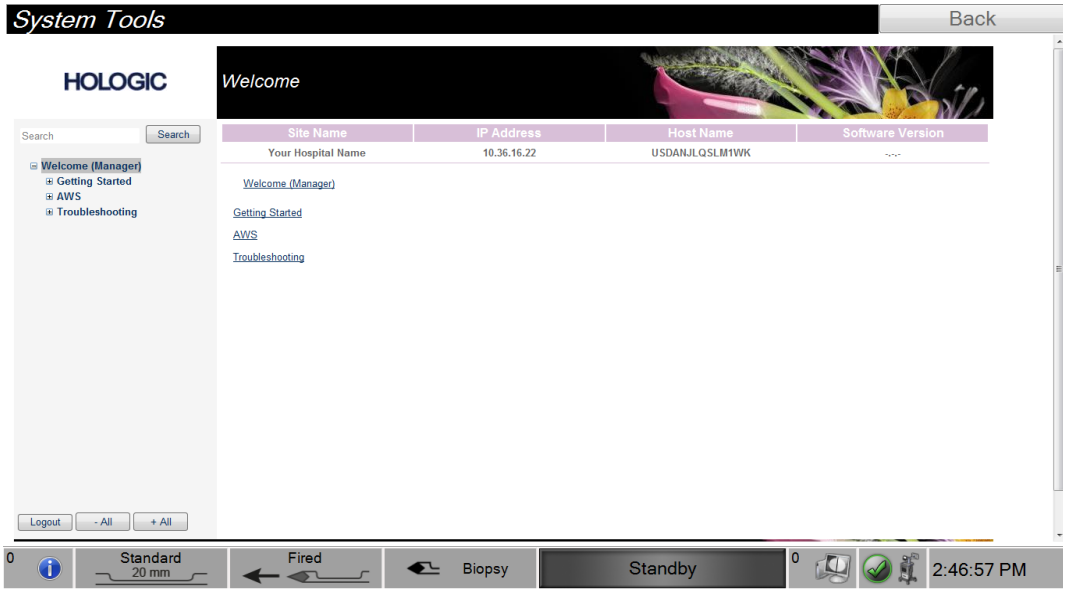


Figure 69: System Tools Screen

Table 3: The System Tools

Section	Description	
Getting Started	**About**	The introduction to the service tool.
	FAQ	List of common questions.
	Glossary	List of terms and descriptions.
	Platform	List of directories, software version numbers, and system software statistics.
	Shortcuts	List of Windows® shortcuts.
AWS (Acquisition Workstation)	**Connectivity**	List of Installed Devices.
	Film and Image Information	Set of tools and options related to film and images.
	Licensing	List of installed licenses.
	User Interface	Change the options in the Software application.
	Internationalization	Select the local language and culture.
Troubleshooting	**Acquisition Workstation**	Allows for download of images.
	Computer	Reboot or Shutdown; Current IP address; Change Host name.
	Log	Change the event record options.
	Backups	Control the backups for the system.

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Chapter 10 Maintenance, Cleaning, and Disinfecting

Warning:
Do not perform maintenance, cleaning procedures, or disinfection while the system is being used on a patient.

10.1 General Information

10.1.1 For General Cleaning

This procedure includes cleaning the unit and the surfaces that the specimens do not contact.

Use a lint-free cloth and apply a diluted, mild detergent to clean components and surfaces. To remove more difficult soils, use a soft bristle brush as needed.

Caution:
Use the least possible amount of cleaning fluids. The fluids must not flow or run.

10.1.2 For Disinfecting

To disinfect the system's components and surfaces, Hologic recommends the following disinfecting solutions:

- 10% chlorine bleach solution and water with one part commercially available chlorine bleach solution (normally 5.25% chlorine and 94.75% water) and nine parts water. Mix this solution daily for best results.
- Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
- Commercially available wipes containing less than or equal to 2% quaternary ammonium compounds by weight in water.

Apply disinfecting solutions to the system using a clean, lint-free cloth or wipe. Wipe the system with the wet cloth, observing appropriate contact (wet) times. Do not spray cleaning solutions directly on the console or other parts of the Brevera breast biopsy system.

Caution:
To prevent damage to the electronic components, do not use disinfectant sprays on the system.

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10.1.3 To Prevent Possible Injury or Equipment Damage

Do not use a corrosive solvent, abrasive detergent, or polish. Select a cleaning/disinfecting agent that does not damage the plastics, aluminum, or carbon fiber.

Do not use strong detergents, abrasive cleaners, high alcohol concentration, or methanol at any concentration.

Do not expose equipment parts to steam or high temperature sterilization.

Do not let liquids enter the internal parts of the equipment. Do not directly apply cleaning sprays or liquids to the equipment. Always use a clean, lint-free cloth and apply the spray or liquid to the cloth. If liquid enters the system, disconnect the electrical supply and examine the system before returning it to use.



Caution:
Wrong cleaning methods can damage the equipment, decrease imaging performance, or increase the risk of electrical shock.

Always follow instructions from the manufacturer of the product you use for cleaning and disinfection. The instructions include the directions and precautions for the application and contact time, storage, wash requirements, protective clothing, shelf life, and disposal. Follow the instructions and use the product in the most safe and effective method.

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10.2 Component Specific Cleaning and Disinfection

WARNING!
The console must be disconnected from electrical power source prior to cleaning. Failure to do so may cause electrical shock or death.

WARNING!
Do not immerse the console in water. Immersion in water will cause damage and may cause electrical shock or death.

10.2.1 Clean and Disinfect the Console Exterior Surfaces

- Disconnect the console from the electrical power source.
- After each use, clean the console using a soft, damp cloth and mild detergent. Wipe dry.
- After cleaning, use a pre-moistened disinfectant wipe or apply a disinfectant solution to a clean cloth. Wipe all surfaces with the wipe or wet cloth, observing appropriate contact (wet) times. Refer to *General Information* on page 108 for recommended disinfecting solutions.
- Do not spray cleaning or disinfectant solutions directly on the console or other parts of the Brevera breast biopsy system.

10.2.2 Clean and Disinfect the Device Driver and Remote Control

- Disconnect the console from the electrical power source.
- After each use, clean the reusable device driver using a soft, damp cloth and mild detergent. Wipe dry.
- After cleaning, use a pre-moistened disinfectant wipe or apply a disinfectant solution to a clean cloth. Wipe all surfaces with the wipe or wet cloth, observing appropriate contact (wet) times. Refer to *General Information* on page 108 for recommended disinfecting solutions.
- Do not spray cleaning or disinfectant solutions directly on the reusable device driver, the remote control, or other parts of the Brevera breast biopsy system.
- Do not immerse the reusable device driver in liquid.

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10.2.3 Clean and Disinfect the Tissue Filter Drawer

- Disconnect the console from the electrical power source.
- After each use, clean the tissue filter drawer using a soft, damp cloth and mild detergent. Wipe dry.
- After cleaning, use a pre-moistened disinfectant wipe or apply a disinfectant solution to a clean cloth. Wipe all surfaces with the wipe or wet cloth, observing appropriate contact (wet) times. Refer to *General Information* on page 108 for recommended disinfecting solutions.
- Do not spray cleaning or disinfectant solutions directly in the drawer or other parts of the Brevera breast biopsy system.

10.2.4 Clean the Imaging Display

- Disconnect the console from the electrical power source.
- Use care when you clean the outer surface of the display area.
- Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths, available at most stores, are recommended.
- Use a pre-moistened disinfectant wipe or apply disinfectant solution to a clean cloth. Wipe all surfaces with the pre-moistened wipe or wet cloth, observing appropriate contact (wet) times. Refer to *General Information* on page 108 for recommended disinfecting solutions.
- Strong chemicals and abrasives can damage the display window and should never be used.
- Never apply pressure to the display window.
- Never use a spray or flow a liquid onto the display.
- Never use steel wool.
- Never use a sponge with abrasives.

Note
There are many commercially available products to clean LCD displays. Any product that is free of the ingredients or abrasives described above and used according to the directions of the manufacturer can be safely used.

Note
There are commercially available disposable monitor drape products to drape LCD touch screen displays. Always follow instructions from the manufacturer of the product you use.

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10.2.5 Clean the Technologist Display

- Disconnect the console from the electrical power source.
- Do not touch the display when working with specimens.
- Use care when you clean the outer surface of the display area.
- Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths, available at most stores, are recommended.
- To clean the button area of the technologist display, use a pre-moistened disinfectant wipe or apply a disinfectant solution to a clean cloth. Wipe all surfaces with the pre-moistened wipe or wet cloth, observing appropriate contact (wet) times. Refer to *General Information* on page 108 for recommended disinfecting solutions.
- Strong chemicals and abrasives can damage the display window and should never be used.
- Never apply pressure to the display window.
- Never use a detergent with fluorides, ammonia, alcohol, bleach, or abrasives to clean the display window.
- Never use a spray or flow a liquid onto the display.
- Never use steel wool.
- Never use a sponge with abrasives.

Note
There are many commercially available products to clean LCD displays. Any product that is free of the ingredients or abrasives described above and used according to the directions of the manufacturer can be safely used.

10.2.6 Clean the Footswitch

WARNING!
Do not immerse the footswitch in water. Immersion in water will cause damage and may cause electrical shock or death.

1. Disconnect the footswitch from the console.
2. Periodically clean the footswitch using a soft, damp cloth and mild detergent.
3. Wipe the footswitch dry.

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10.2.7 Cleaning Schedule

Action	Recommended Frequency	
	Each Use	As Required
Clean and disinfect the console unit	✓	
Clean and disinfect the device driver	✓	
Clean and disinfect the tissue filter drawer interior	✓	
Clean and disinfect the tissue filter drawer handle and the Imaging panel	✓	
Clean and disinfect the Imaging display screen	✓	
Clean and disinfect the Technologist display screen	✓	
Clean the footswitch		✓

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10.3 Preventive Maintenance

Every twelve months, the preventive maintenance service is to be performed only by Hologic Technical Services or a Hologic-certified technician.

Contact Hologic Technical Support or your local Hologic representative for more information on preventive maintenance and biomedical training.

10.3.1 Vacuum Line Assembly

Inspect the Vacuum Line Assembly

1. Once a week, visually inspect the tubing for any fluid or moisture.
2. Visually inspect the white side of the in-line hydrophobic filter for any discoloration.
3. If the tubing is wet or the filter is discolored, replace the vacuum line assembly.

Replace the Vacuum Line Assembly

1. Power off the system.
2. Locate the white lock collar where the vacuum line assembly attaches to the console.
3. Lift up the vacuum line assembly approximately 3 mm (1/8 inch) to expose a gap between the white collar and the base of the black barb.
4. Hold down the white collar and pull the vacuum line assembly up and out of the connector. Discard as biohazardous waste.
5. Press a new vacuum line assembly into the vacuum line assembly connector.
6. Pull up to check that the new vacuum line assembly is locked into the connector. The vacuum line assembly will have a small amount of vertical movement but should not pull free of the connector.



Note
Do not twist the vacuum line assembly as you pull up.

7. Power on the system.
8. Plug the vacuum inlet line using your thumb or finger.
9. Press the **Test** button on the console.
10. Check that the system displays an indicator that the vacuum system is functioning correctly.
11. Power off the system if desired.

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10.3.2 Device Driver

Inspect the Device Driver

1. Once a week, visually inspect the cable and connectors. The cable should not be cracked or damaged.
2. Once a week, visually inspect the area where the biopsy needle connects with the device driver.
3. If the device driver or its cable appears worn or damaged, replace the device driver.

Replace the Device Driver

1. Power off the system.
2. Completely unwrap the device driver cord and remove it from the cord management plate.
3. Unplug the device driver from the console.
4. Using a new device driver, insert the cord into the receptacle. (The red dots align at the top when attached correctly.)
5. Wrap the cord around the cord management plate.
6. Power on the system. The console beeps, and the *Setup* screen opens on the Technologist display.
7. Install a suction canister, biopsy needle, saline, and tissue filter assembly as if performing a biopsy.
8. Check that the system displays an indicator that the device driver, biopsy needle, and tissue filter are connected and installed. Complete the Setup check list as prompted.
9. When the system is ready for Test mode, the green **Test** button will flash. Press the **Test** button to begin the testing procedure.
10. Follow the prompts on the Technologist display until testing is complete.
11. When testing is successful, the system goes into Standby mode.
12. Power off the system if desired.
13. To return the device driver, contact your local Hologic representative or refer to the "Important Replacement Information" and "Customer Instructions for Returning Brevera Biopsy Driver" instructions.

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10.3.3 Footswitch

Inspect the Footswitch Cord

1. Once a week, visually inspect the cord and connector. The cord should not be cracked or damaged.
2. Verify that the footswitch cord is wrapped counter-clockwise (CCW) direction around the cord management plate.
3. If the footswitch or its cord appears worn or damaged, replace the footswitch.

Replace the Footswitch

1. Power off the system.
2. Completely unwrap the footswitch cord and remove it from the cord management plate.
3. Unplug the footswitch cord from the console.
4. Using a new footswitch, plug the cord into the console.
5. Wrap the footswitch cord counter-clockwise around the cord management plate.
6. Power on the system. The console beeps, and the *Setup* screen opens on the Technologist display. Install a suction canister, biopsy needle, saline, and tissue filter assembly as if performing a biopsy.
7. Check that the system displays an indicator that the device driver, biopsy needle, and tissue filter are connected and installed. Complete the Setup check list as prompted.
8. When the system is ready for Test mode, the green **Test** button will flash. Press the **Test** button to begin the testing procedure.
9. Follow the prompts on the Technologist display until testing is complete.
10. When testing is successful, the system goes into Standby mode.
11. Power off the system if desired.
12. Contact your local Hologic representative for product return instructions.

10.3.4 Power Cord

Inspect the Power Cord

1. Once every quarter, visually inspect the power cord for cuts, damage to the cover, or strain relief.
2. If the power cord appears damaged, contact Hologic for replacement of the power cord.

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10.3.5 Preventive Maintenance Schedule for the User

Table 4: Recommended Maintenance Schedule for the User

Action	Recommended Frequency			
	Weekly	**Monthly**	**Quarterly**	**Annually**
Inspect cable for the device driver	✓			
Inspect the footswitch cord	✓			
Inspect the vacuum line assembly	✓			
Perform Gain Calibration		✓		
Inspect the power cord			✓	
Preventive maintenance by Hologic Technical Service				✓

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10.3.6 Preventive Maintenance Schedule for the Service Engineer

Table 5: Service Engineer Preventive Maintenance

Maintenance Task Description	Recommended Frequency	
	Semiannually	Annually
Obtain previous copy of PM		✓
Check with customer for any questions or concerns that they may have		✓
Check error logs		✓
Upgrade to current software / firmware configuration if under warranty / contract		✓
Check covers and drawers for mechanical integrity, missing hardware, clean vents		✓
Input wiring inspected for safety and integrity		✓
Inspect all ground wiring for integrity		✓
Inspect specimen drawer for integrity and sensing		✓
Verify operation of all interlocks and bypass functions		✓
Verify exposure parameters		✓
Check motor accuracy		✓
Evaluate image quality		✓
Verify completion of Gain Calibration		✓
Perform backup timer procedure		✓
Clear error log		✓
Perform monitor check		✓
Test the current leakage on the system		✓
Test the resistance on the power cord		✓

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Appendix A System Specifications

A.1 Product Measurements

A.1.1 Console

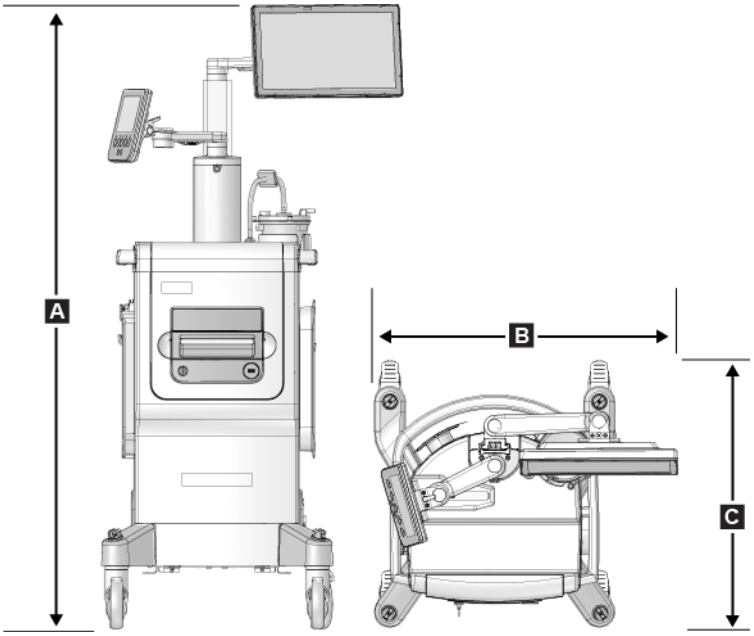


Figure 70: Brevera System Measurements

A.	*Height*	*1647 mm (64.8 in.) nominal*
B.	*Width*	*766 mm (30.2 in.) nominal*
C.	*Depth*	*630 mm (24.8 in.) nominal*
	Weight	*90.7 kg (200 lbs.) nominal*
	Vacuum Generated	*~66 cm Hg at sea level (~26 in. Hg)*

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A.1.2 Device Driver

Height	*4 cm (1.6 in.) nominal*
Width	*5.6 cm (2.2 in.) nominal*
Depth	*19.6 cm (7.7 in.) nominal*
Weight	*949.7 g (33.5 oz.) with remote nominal*

A.1.3 Biopsy Needle

Height	*3 cm (1.2 in.) nominal*
Width	*5.6 cm (2.2 in.) nominal*
Depth	*22.4 cm (8.8 in.) nominal*
Weight	*269.3 g (9.5 oz.) with tubing set nominal*

A.2 Operation and Storage Environment

A.2.1 General Conditions for Operation

This equipment is designed for safe and effective operation under the following conditions for Indoor Use:

Altitude	*3000 meters*
Degree of Pollution	*N/A*
Temperature Range	*10 °C (50 °F) to 40 °C (104 °F)*
Relative Humidity Range	*20% to 75% without condensing moisture*

A.2.2 Storage Environment

Temperature Range	*-10 °C (14 °F) to 60 °C (140 °F)*
Maximum rate of temperature change	*N/A*
Relative Humidity Range	*10% to 80% without condensing moisture*

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A.3 Electrical Input

The system is designed for temporary overvoltages on the Mains supply.

Brevera 100	
Line Voltage Range	*100 V-120 V*
Line Current	*10 Amps*
Operating Frequency	*50 Hz-60 Hz*
Brevera 200	
Line Voltage Range	*220 V-240 V*
Line Current	*5 Amps*
Operating Frequency	*50 Hz-60 Hz*
Line Connection	*Supplied Cord*
Duty Cycle	*24 consecutive cores with 20-minute standby*

A.4 Classification



Type of protection against electric shock: Class I

Degree of protection against electric shock: Type BF

Degree of protection against ingress of water:

System (unless specifically identified): Ordinary

Footswitch: IPX 8

Mode of operation: Continuous

APPLIED PARTS	*Disposable biopsy needle (when mounted on the reusable device driver)*

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A.5 Console Technical Information

A.5.1 General Information

Operating System	*Windows 10*
Hard Disk Drive Capacity	*500 GB*
Imaging Display	*38.1 cm (15 in.) 1366 x 768 wide screen, touch screen monitor*
Technologist Display	*18 cm (7 in.) 800 x 480 screen*

A.5.2 Network Environment

Network Interface	*Itox Realtek RTL8821AE Mini-PCIe Wi-FI card, 100/1000 BASE T Ethernet*

A.6 X-Ray Tube Technical Information

Source-to-Image Distance (SID)	*7.20" (18.3 cm)*
Focal Spot	*50 µm*
Tube Voltage	*20-35 kVp*
Tube Beam Angle	*25°/+0°, -2.5°*
Beam Output Angle	*15° ± 1°*
Anode Material	*Tungsten*
X-Ray Window	*Beryllium*
Physical Mass	*6.5 lbs (maximum)*
Duty Cycle	*1:4 (Continuous)*
Input Power	*+24 volts DC, ± 10%, 2.4 A (nominal)*
Reference Axis	*Integrated automatic tissue handling system with fixed imaging window and reference axis.*
Reference Axis Position Accuracy	*zero-angle reference ± 1.25 degrees*

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A.6.1 X-Ray Generator

kV Range	*20-35 kVp adjustable*
kV Accuracy	*± 1 %*
mA	*1 ma Fixed*
mA Accuracy	*± 2 %*

A.6.2 Disposal



Equipment to be disposed in compliance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).

A.7 Imaging System Technical Information

A.7.1 Image Receptor

Active Imaging Area	*33 x 24.9 mm Min.*
Pixel Pitch	*20 µm Max.*
Modulation Transfer Function	*>60% @ 2 lp/mm* *<20% @ 6 lp/mm*
Detector Dynamic Range	*2000:1*
Detector Digitization	*12 bits*

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Appendix B Troubleshooting

B.1 Error Recovery and Troubleshooting

Most faults and alert messages are cleared without result to your workflow. Follow the instructions on the screen or fix the condition then clear the status from the Taskbar. Some conditions require a system restart or indicate that more action is necessary (for example, to call Hologic Technical Support). This appendix describes the message categories and your actions to return the system to normal operation. If errors repeat, contact Hologic Technical Support.

B.2 Types of Messages and Alert Messages

B.2.1 Fault Levels

There are five fault levels: Warning, Minor, Major, Critical, and Alerts.

Warning Faults

The Warning faults are not displayed to the user. These faults are recorded in the log files.

Warning fault designs:

- Resolve through the software or communications commands.
- Do not cancel an exposure that is in progress.
- Do not prevent the start of a new exposure.

Minor Faults

Minor fault designs:

- Resolve through the software or communications commands.
- Do not cancel an exposure that is in progress.
- Require a response before a new exposure can start.

Major Faults

Major fault designs:

- Resolve through the software or communications commands.
- Cancel an exposure that is in progress.
- Prevent the start of a new exposure.

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Critical Faults

Critical fault designs:

- Not resolved through the software or communications commands.
- Cancel an exposure that is in progress.
- Prevent the start of a new exposure.

Alert Messages

The Alert Messages are routine messages that can prevent an exposure. An Alert message remains active until the required action is complete or the condition no longer exists.

B.2.2 System Messages

Select the system status icon on the Taskbar to get information about the cause and correction of a system problem. When you correct the problem, the System Message area displays a Ready status.

B.3 System Restart

- To restart the computer system after a critical fault, select the **Reboot** button.
- If you select the **Exit** button, a message advises that this option shuts down only the computer.

B.4 Troubleshooting During Setup

Table 6: Resolving Possible Issues During Setup

Problem	Possible Cause	Suggested Action
Console will not turn on.	Power cord is not plugged in at the console and/or at the power outlet.	Check power cord for proper engagement to console and power outlet.
"Vacuum system not at required pressure" message	Protective sheath is not fully on the tip of the biopsy needle cannula.	Reinstall the protective sheath.
	Suction canister lid is not sealed onto the canister.	Properly seal the lid of the suction canister.
	Suction canister is cracked.	Replace the suction canister with a new one.
	The large port on the suction canister lid is not capped with the large plug.	Cap the large port with the large plug.

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Table 6: Resolving Possible Issues During Setup

Problem	Possible Cause	Suggested Action
	The biopsy needle suction fitting is not connected to the suction canister lid.	Connect the suction fitting to the canister.
	The biopsy needle fitting is not connected to the correct port on the suction canister lid.	Connect the biopsy needle suction fitting to the horizontal port marked "PATIENT" on the suction canister lid.
	The console vacuum line is not connected to the suction canister.	Connect the console vacuum line to the port marked "VACUUM" on the suction canister lid.
	The spike on the biopsy needle tubing is not inserted into the saline bag.	Install the spike into the saline bag.
	Defective biopsy needle.	Retain the biopsy needle. Record the lot number and contact your local Hologic representative. Retry with a new biopsy needle.
Biopsy device connection error.	The biopsy needle is not properly connected or difficult to attach to the device driver.	Properly assemble the biopsy needle to the device driver. Make sure that the device driver is homed by pressing the ✔ button on the Technologist Display when prompted to do so. Make sure that the needle gears are pushed all the way forward before reinstalling the needle. If this does not work, try a new needle. If this does not work, try a new driver.
	The device driver is not properly connected to the console.	With the biopsy needle removed, disconnect and reconnect the cord on the device driver into the receptacle on the console.
	Defective biopsy needle.	Retain the biopsy needle. Record the lot number and contact your local Hologic representative. Retry with a new biopsy needle.
	Defective device driver.	Retain the device driver. Record the lot number and contact your local Hologic representative. Retry with a new reusable device driver.

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Table 6: Resolving Possible Issues During Setup

Problem	Possible Cause	Suggested Action
Biopsy device makes unusual noises during test mode.	The biopsy needle is not properly connected to the device driver.	Properly attach the biopsy needle to the device driver. Make sure that the device driver is homed by pressing the ✔ button on the Technologist Display when prompted to do so. Make sure that the needle gears are pushed all the way forward before reinstalling the needle. If this does not work, try a new needle. If this does not work, try a new driver.
"Device driver loss of communication" message "Device driver error" message	The biopsy needle is not properly connected to the device driver.	Properly attach the biopsy needle to the device driver. With the biopsy needle removed, disconnect and reconnect the cord on the device driver into the receptacle on the console. Repeat 2 or 3 times until the device driver is homed. Make sure that the needle gears are pushed all the way forward before reinstalling the needle. If this does not work, try a new driver.

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B.5 Troubleshooting During a Procedure

Table 7: Resolving Possible Issues During a Procedure

Problem	Possible Cause	Suggested Action
System does not respond to the Arm Button.	Incorrect mode selected.	Select Biopsy Mode.
	Remote malfunction.	Replace the device driver.
System does not respond to the footswitch.	Incorrect mode selected.	Select Biopsy Mode.
	Footswitch malfunction.	Replace the footswitch.
Biopsy device makes unusual noises during procedure.	The biopsy needle is not properly connected to the device driver.	Remove the biopsy device from the patient and disassemble it (refer to *Conclude Tissue Acquisition* on page 85). Place the device driver on the console. If cores are present, place the cap on the tissue filter, and place the tissue filter in formalin. Make sure that the device driver is homed by pressing the ✔ button on the Technologist Display when prompted to do so. Install a new needle. Make sure the needle is properly attached to the device driver. If this does not work, try a new driver.

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Table 7: Resolving Possible Issues During a Procedure

Problem	Possible Cause	Suggested Action
"Device driver loss of communication" message "Device driver error" message	The biopsy needle is not properly connected to the device driver.	**If the biopsy needle is clean:** Remove the biopsy needle. Disconnect and reconnect the cord on the device driver into the receptacle on the console. Make sure that the needle gears are pushed all the way forward before reinstalling the needle. If this does not work, try a new driver. **If the biopsy needle is not clean:** Remove the biopsy device from the patient and disassemble it (refer to *Conclude Tissue Acquisition* on page 85). Place the device driver on the console. If cores are present, place the cap on the tissue filter, and place the tissue filter in formalin. Make sure that the device driver is homed by pressing the ✔ button on the Technologist Display when prompted to do so. Install a new needle. Make sure the needle is properly attached to the device driver. If this does not work, try a new driver.

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Table 7: Resolving Possible Issues During a Procedure

Problem	Possible Cause	Suggested Action
Poor quality biopsy cores or no cores.	The biopsy needle fitting is not connected to the port on the suction canister lid. The biopsy needle fitting is not connected to the correct port on the suction canister lid.	Connect the biopsy needle suction fitting to the horizontal port marked "PATIENT" on the suction canister lid.
	Suction canister is cracked. Reduced or no vacuum at the tip of the biopsy needle cannula.	Replace the suction canister with a new one. Retain the biopsy needle. Record the lot number and contact your local Hologic representative.
	Biopsy needle occlusion.	Retain the biopsy needle. Record the lot number and contact your local Hologic representative. Retry with a new biopsy needle.
	The tissue filter is occluded by blood.	Replace with a new tissue filter or retry with a new biopsy needle.
	The biopsy needle tubing is twisted.	Reposition the biopsy needle tubing. Select Aspirate mode, Select Biopsy mode, and retry the biopsy.
No image is acquired for sample. Thumbnail marked with red chamber letter.	Detector readout failure.	After tissue acquisition is complete, select the chamber and reimage. If this does not work: Restart the detector. Select the **System Status** icon on the taskbar. Select System Diagnostics from the pop-up menu. Select the **Restart Detector** button. Select the **Back** button. Use the Reimage feature to capture an image for the chamber that previously failed.

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Table 7: Resolving Possible Issues During a Procedure

Problem	Possible Cause	Suggested Action
"Unable to position tissue filter" message "Indexing core handler fault" message	Broken belt or indexer motor fault. Unable to move the tissue filter for any reason.	Enter Single Chamber mode: Select the **System Status** icon on the taskbar. Select **Single Chamber** from the pop-up menu. Follow the prompts on the Technologist display.
"No filter found" message	Filter not in tissue filter drawer.	Insert the tissue filter into the tissue filter drawer.
"No filter found" message "Filter sensor fault" message	Broken belt. No magnet in filter assembly. Magnet sensor is broken.	Replace the tissue filter. If the error does not clear, enter Single Chamber mode: Select the **System Status** icon on the taskbar. Select **Single Chamber** from the pop-up menu. Follow the prompts on the Technologist display.

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Appendix C Brevera Compatible Components and Accessories

C.1 Hologic Factory-Verified Compatible Components and Accessories

The Brevera system is compatible with the following components and accessories:

Catalog Number	Description
BREV100	Brevera 100 System
BREV200	Brevera 200 System
BREVDRV	Driver
BREVDISP07*	Stereotactic Biopsy Needle, 7 Guage
BREVDISP09	Stereotactic Biopsy Needle, 9 Guage
BREV-NG07L	7ga Needle Guide for Hologic Systems
BREV-NG07R	7ga Needle Guide for Non-Hologic Systems
BREVADPTR	Adapter
BREVADPTRM	Adapter for MammoTest
BREVSTYLBRKT	Stylet Bracket
EVIVA CALIBRATE 13CM	Calibration Handpiece 13 cm
EVIVA NG HOLDER	Needle Guide Holder for MammoTest
BREVADPTRG	Adapter for GE Senographe® Stereotaxy
EVIVA BUSHING GE	Bushing for GE Senographe® Stereotaxy
BREVTF01	Single Chamber Tissue Filter
BREVTF12	12 Chamber Tissue Filter
EVIVA_NG09L	Needle Guide
EVIVA_NG09R	Needle Guide
ATEC CANISTER	Suction canister with lid
SMark-Eviva-13	Titanium Biopsy Site Marker
SMark-Eviva-2S-13	Titanium Biopsy Site Marker
SMark-E13-ss1	Stainless Steel Biopsy Site Marker
SMark-E13-ss2	Stainless Steel Biopsy Site Marker
SMark-E13-ss3	Stainless Steel Biopsy Site Marker

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TriMark-Eviva-13	Titanium Biopsy Site Marker
TriMark-Eviva-2S-13	Titanium Biopsy Site Marker

*Catalog number may not be available in all markets.

C.2 List of system cables and accessories

Cable/Connection	**Where Used**	**Typical Length**	**Supplied with system (Yes/No)**
Power Cord	Connects the Brevera console AC mains power supply	20 ft (6 m)	Yes
Ethernet Cable	Network connection for data transfer, software updates, and remote service access	Up to 100m (Cat5e/Cat6)	Optional
Footswitch Cable	Connects the footswitch to the console for Hands-free operation	20 ft (6 m)	Yes
Handpiece/Vaccum Tubing Set	Connects the Brevera handpiece to the console vacuum system	Supplied as part of the disposable biopsy set: length per manufacturer specification	Yes
Potential Equalization (Grounding)Cable	Used for equipotential bonding in medical installations	Installation dependent	Optional/External

C.3 Electromagnetic Capability

This section provides information about the electromagnetic compatibility of Brevera breast biopsy system with CorLumina imaging technology per IEC 60601-1-2.

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C.3.1 Electronic Emissions

Table 8: Electronic Emissions Brevera 100 (120V)

Electromagnetic Emissions		
The Brevera breast biopsy system is intended for use in the electromagnetic environment specified below. The customer or the user of the Brevera breast biopsy system should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Brevera breast biopsy system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Brevera breast biopsy system is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	
Note: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 classA). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment."		

Table 9: Electronic Emissions Brevera 200 (240V)

Electromagnetic Emissions		
The Brevera breast biopsy system is intended for use in the electromagnetic environment specified below. The customer or the user of the Brevera breast biopsy system should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Brevera breast biopsy system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Brevera breast biopsy system is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power
Harmonic emissions IEC 61000-3-2	Class A	

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Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	supply network that supplies buildings used for domestic purposes.
Note: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 classA). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment."		

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C.3.2 Electromagnetic Immunity

Table 10: Electromagnetic Immunity Part 1

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2	±8 kV Contact ±2kV, ±4kV, ±8kV and ±15kV Air	±8 kV Contact ±2kV, ±4kV, ±8kV and ±15kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst EN/IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout EN/IEC 61000-4-11	>95 % dip for 0.5 cycle 0°,45°,90°,135°,180°, 225°,270°,315° **>95% dip for 1 cycle at 0 degrees** 70% dip-25/30 cycles Single phase: at 0 degrees >95 % dip for 250/300 cycles	>95 % dip for 0.5 cycle 0°,45°,90°,135°,180°, 225°,270°,315° 70% dip-25/30 cycles Single phase: at 0 degrees >95 % dip for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Brevera breast biopsy system requires continued operation during power mains interruptions, it is recommended that the Brevera breast biopsy system be powered from an uninterruptible power supply or battery.
Power Frequency (50/60Hz) Magnetic Field EN/IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

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Table 11: Electromagnetic Immunity Part 2

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF **IEC 61000-4-6** ISM Frequency Bands **Amateur radio frequency bands** **Radiated RF** **IEC 61000-4-3**	3 Vrms 150 kHz to 80MHz 6 Vrms 6 Vrms 3 V/m 80 MHz to 2.7 GHz	3 Vrms 6 Vrms 6 Vrms Recommended separation distance: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 3 V/m 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Brevera breast biopsy system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			
* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Brevera breast biopsy system is used exceeds the applicable RF compliance level above, the Brevera breast biopsy system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Brevera breast biopsy system. ** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Table 12: Test Specification For Enclosure Port Immunity To rf Wireless Communications

Test Frequency	Band a) (MHz)	Service a)	Modulation	Immunity test level
385	380 to 390	TETRA 400	Pulse modulation b)18Hz	27
450	430 to 470	GMRS 460,FRS 460	FM c) +/- 5kHz deviation 1 kHz sine	28
710 745 780	704 to 787	LTE Band 13,17	Pulse modulation b)217 Hz	9
810 870 930	800 to 960	GSM800/900,TETRA 800,Isen 820,CDMA 850,LTE Band5	Pulse modulation b)18 Hz	28
1720 1845 1970	1700 to 1990	GSM1800;CDMA 1900;DECT;LTE Band 1,3,4,25;UMTS	Pulse modulation b)217 Hz	28
2450	2400 to 2570	Bluetooth,WLAN,802.11 b/g/n,RFID 2450,LTE Band 7	Pulse modulation b)217 Hz	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation b)217 Hz	9
If necessary to achieve the IMMUNITY TEST LEVEL,the distance between the transmitting antenna and the ME Equipment or ME system may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are induced. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using 50% duty cycle square wave signal at 18Hz. While it does not represent actual modulation, it would be worst case.				

Table 13: Test Specifications For Enclosure Port Immunity To Proximity Magnetic Fields

Test Frequency	Modulation	IMMUNITY TEST LEVEL;(A/m)
30 kHz a)	CW	8
134,2 kHz	Pulse modulation b) 2,1 kHz	65 c)
13,56 MHz	Pulse Modulation b) 50 kHz	7,5 c)
a. This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTH CARE ENVIRONMENT. b. The carrier shall be modulated using a 50% duty cycle square wave signal. c. r.m.s., before modulation is applied		

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C.3.3 Separation Distances For RF Equipment

Table 14: Separation Distances For RF Equipment

Recommended separation distances between portable and mobile RF communications equipment and the Brevera breast biopsy system			
The Brevera breast biopsy system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Brevera breast biopsy system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Brevera breast biopsy system as recommended in the following table, according to the maximum output power of the communications device.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.** **NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			

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Appendix D Owner's Record

D.1 Brevera Breast Biopsy System with CorLumina Imaging Technology

The serial number of the Brevera breast biopsy system console is located on the panel on the left side of the console. Record this number in the space provided below. Refer to this serial number whenever you contact your local Hologic representative regarding your Brevera system.

REF Model Number: BREV100 or BREV200

SN Serial Number: _____

Glossary of Terms

Annotations

Graphic or text marks on an image to show an area of interest

DICOM

Digital Imaging and Communications in Medicine

Image Receptor

Captures and digitizes the x-ray images

PACS

Picture Archiving and Communications System. A computer and network system that transmits and archives digital medical images.

ROI

Region of Interest

SID

Source to Image Distance

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