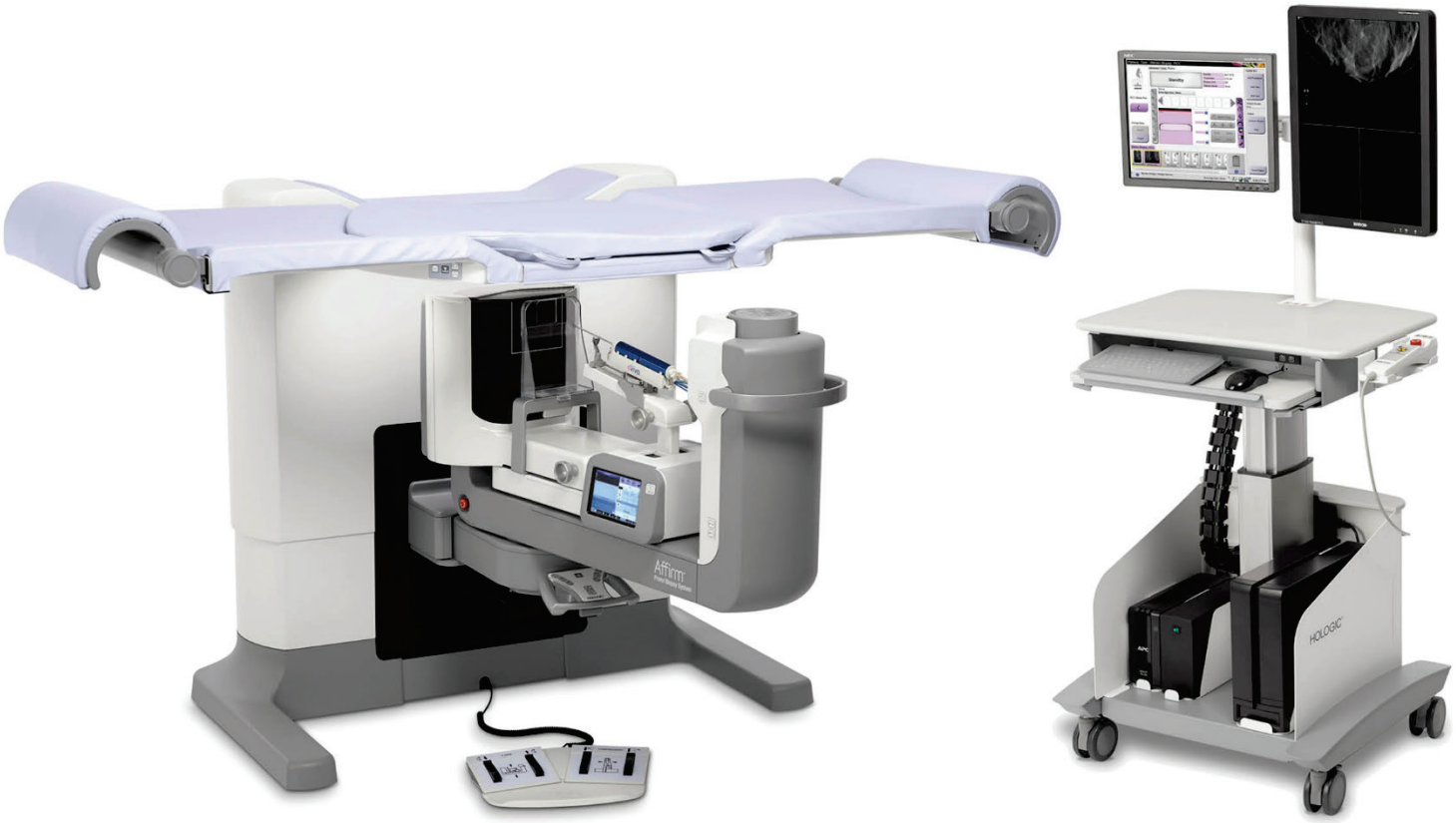
Affirm®
Prone Biopsy System



User Guide

MAN-10153-002 Revision 003

HOLOGIC®

Affirm®

Prone Biopsy System

User Guide

For Software Version 1.1

Part Number MAN-10153-002
Revision 003
August 2024

HOLOGIC®

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Chapter 1: Introduction

Read all this information carefully before operating the system. 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.

Note
Hologic configures some systems to meet specific requirements. Your system configuration may not have all the options and accessories included in this manual.

1.1 Intended Use

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

The Affirm® prone biopsy system is intended for lesion location for biopsy while the patient is in the prone position to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

1.1.1 Indications for Use

The Affirm prone biopsy system combines the function of a standard x-ray mammography unit with that of a lesion localization system to produce a device that has specific application in first accurately localizing lesions in the breast in two and/or three dimensions, and then providing guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices) for lesions determined to be suspicious through prior mammographic examination.

1.1.2 Contraindications

- Patient weighs more than 181 kg (400 pounds).
- Inability to visualize the lesion under mammographic imaging.
- Patient cannot remain in a prone position during the entire procedure.

1.2 Essential Performance

The essential performance requirements of the Affirm prone biopsy system is as defined in IEC-60601-2-45: 2005. These include: accuracy of loading factors, automatic control system, imaging performance, missed tissue at chest wall side, breast compression device, linearity of air kerma over limited intervals of loading factors, and reproducibility of the X-radiation output.

1.3 System Capabilities

The Affirm prone biopsy system is a tomosynthesis-capable mammography system for performing breast biopsies on patients lying in the prone position. The system localizes suspicious lesions, as determined through prior mammographic examinations, using either stereotactic or tomosynthesis techniques. The system then affords a physician the capacity of performing vacuum-assisted needle core biopsy or needle (wire) localization of the lesion.

Localization can be accomplished either via conventional stereotactic imaging, or by examination of a tomosynthesis data set. With tomosynthesis, the image plane or "slice" most fully containing the suspected lesion is chosen by the physician from the data set to identify the lesion depth within the breast.

1.4 User Profiles

1.4.1 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.
- Understands sterile procedures.

1.4.2 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.
- Understands sterile procedures.
- Gives local anesthesia.
- Understands basic surgical procedures for core biopsy.

1.4.3 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.

1.5 Training Requirements

In the United States, users must be Registered Radiologic Technologists meeting criteria to perform mammography. The mammography users must meet all applicable MQSA personnel requirements under FDA guidelines for conventional and digital mammography.

The user has options available for training, which include but are not limited to:

- Onsite applications training by a Hologic Clinical Services Specialist
- Onsite on the job training also known as peer training

Additionally, the user manual is a guide for directions on how to use the system.

All users must make sure that they receive training on correct operation of the system before using on patients.

Hologic does not accept the responsibility for injury or damage from incorrect system operation.

1.6 Quality Control Requirements

Perform all Quality Control tests within the correct time frame.

1.7 Where to Find the Installation Instructions

Installation instructions are available in the *Service Manual*.

1.8 Where to Find Technical Description Information

Technical description information is available in the *Service Manual*.

1.9 Warranty Statement

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

1.10 Technical Support

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

1.11 Product Complaints

Report any complaints or problems in 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 Hologic.

1.12 Hologic Cybersecurity Statement

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

To maintain computer and network security, all cybersecurity updates provided by Hologic should be installed.

Unapproved software should not be installed on the system.

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

1.13 Symbols

This section describes the Symbols on this system.

Symbol	Description
	Type B Applied Part
	Potential Equalization terminal
	Protective Earth terminal
	"OFF" (power)
	"ON" (power)
	"OFF" for part of the equipment
	"ON" for part of the equipment
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Dangerous Voltage
	Manufacturer
	Date of Manufacture
	This system transmits radio frequency (RF) energy (non-ionizing radiation)
	Wi-Fi connection
	Caution—Radiation
	Alternating current

Symbol	Description
	Follow operating instructions
	Follow the *User Guide*
	Caution
	Warning electricity
	Fragile, handle with care
	Temperature limit
	Humidity limitation
	Do not immerse in any liquid
	No pushing
	No stepping on surface
	No sitting
	Combined weight of the equipment and its safe working load
EC REP	Authorized representative in the European community
REF	Catalog number
SN	Serial Number

1.14 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.

Chapter 2: General Information

2.1 System Overview

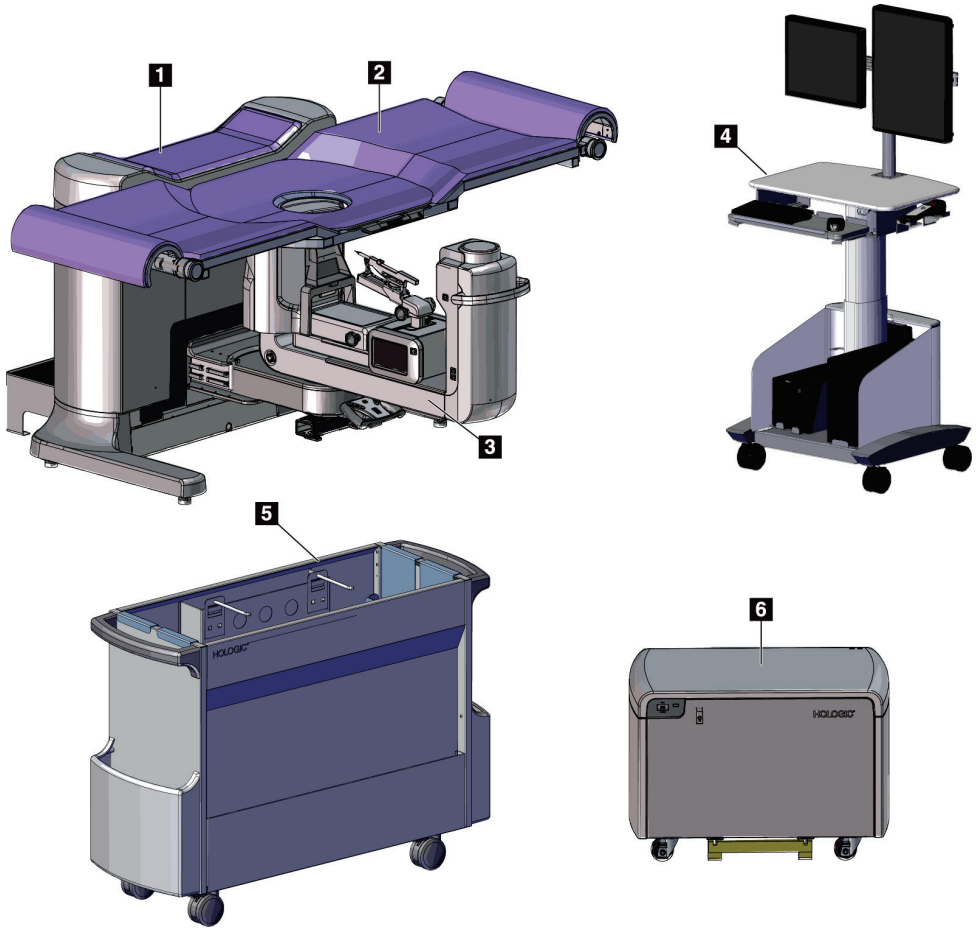


Figure 1: Affirm Prone Biopsy System

Figure Legend

1. Gantry
2. Patient Support Platform
3. C-Arm
4. Acquisition Workstation
5. Accessory Cart
6. High Voltage Generator

Warning:
This system produces ionizing radiation which may be dangerous to patients and operators unless the safety and operating instructions in this manual are followed.

Warning:
Electrical circuits inside the system may generate electromagnetic radiation that can interfere with other equipment or implanted devices.

Warning:
Pushing on the Acquisition Workstation with the wheels locked can result in an overbalance situation resulting in injury.

Pushing on the Table can result in an overbalance situation resulting in injury or death.

Note
The Acquisition Workstation has wheels for ease of positioning only. The system is NOT a mobile unit.

Note
A radiation shield is not provided with the Affirm prone biopsy system.

2.1.1 C-Arm Overview

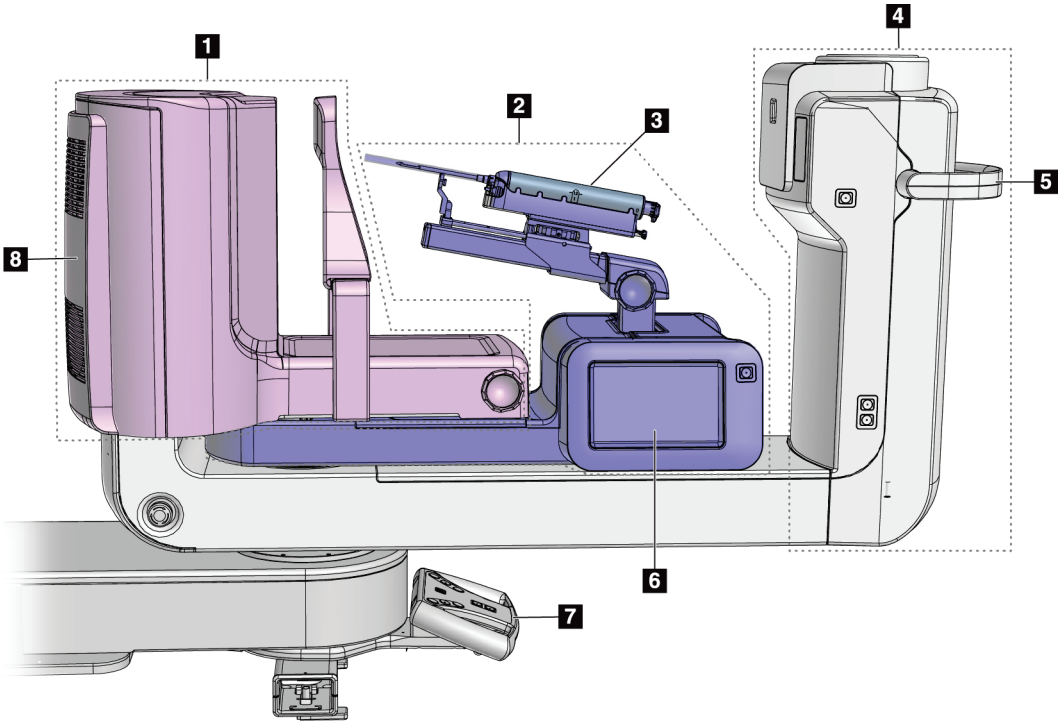


Figure 2: C-arm Overview

Figure Legend

1. Compression Arm
2. Biopsy Arm
3. Biopsy Device
4. Tubehead
5. C-arm Rotation Handle
6. Biopsy Control Module Display
7. Control Handle
8. Image Receptor

2.2 Safety Information

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

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 Account Executive.

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

2.3 Warnings and Precautions

This system is classified as CLASS I, TYPE B APPLIED PART, IPX0, permanently connected equipment, continuous operation with short term loading per IEC 60601-1. There are no special provisions to protect the system from flammable anesthetics or ingress of liquids.

APPLIED PARTS include Compression Paddles, Breast Platform, and Patient Platform.

WARNING!
Risk of electric shock. Only connect this equipment to supply mains with Protective Earth.

WARNING!
For North American electrical safety requirements, use a Hospital Grade receptacle to supply a correct Ground.

WARNING!
The system is not designed for use in explosive atmosphere (for example, in the presence of a flammable anesthetics mixture with air or oxygen or nitrous oxide).

WARNING!
Do not touch a system that is on fire. Leave the area. Only use fire extinguishers approved for electrical fires.

WARNING!
To correctly isolate the system, attach only approved accessories or options to the system. Only approved personnel can change the connections.

WARNING!
Keep a 1.5 meter safe distance between the patient and any non-patient devices.
Do not install non-patient system components (like the Workflow Manager, a diagnostic review workstation, or a hard copy printer) in the Patient Area.

WARNING!
Keep a 1.5 meter safe distance between the patient platform and the acquisition workstation.

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

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

WARNING!
After power failure, remove the patient from the system before you apply power.

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

Warning:
C-arm movement is motorized.

Warning:
You increase the patient dose to high levels when you increase the AEC exposure adjustment. You increase the image noise or decrease image quality when you decrease the AEC exposure adjustment.

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

Warning:
The disk drives installed in this system are a Class I Laser Product. Prevent direct exposure to the beam. Hidden laser radiation exists if the case to a disk drive is open.

Warning:
Keep your full body behind the radiation shield during the exposure.

Warning:
Do not move the C-arm while the system retrieves the image.

Warning:
If a paddle touches possible infectious materials, contact your Infection Control Representative to remove contamination from the paddle.

Warning:
Make sure nothing is placed between the patient's breast and the breast platform during the biopsy procedure.

Warning:
Do not leave the patient unattended during the procedure.

Warning:
Keep the hands of the patient away from all buttons and switches at all times.

Warning:
Place each footswitch in a position where, when used, they remain in reach of the Emergency Off Switches.

Warning:
Position the footswitches to prevent accidental operation by a patient or wheelchair. To avoid tripping or accidental activation, patients and operators of the system should be aware of the location of the footswitches and associated cabling.

Warning:
To prevent a higher radiation dose to the patient, only put approved materials in the x-ray beam path.

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

Warning:
Use protective radiation shielding with a lead equivalent of more than .08 mm.

Warning:
Do not sit on or step on the generator.

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

Caution:
Do not turn off the Acquisition Workstation circuit breaker except in emergency. The circuit breaker can turn off the Uninterruptible Power Supply (UPS) and risk data loss.

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

Caution:
Do not use any heat source (like a heating pad) on the image receptor.

Caution:
Do not block or cover the fan ports located on the rear cover of the Digital Image Receptor.

Caution:
To prevent possible damage from thermal shock to the Digital Image Receptor, follow the recommended procedure to turn off the equipment.

Caution:
The display is calibrated for compliance to DICOM standards. Do not make any brightness or contrast adjustments to the display.

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.

2.4 Emergency Off Switches

A red Emergency Off (E-Stop) switch is located on each side of the tube arm and on the x-ray remote control. The Emergency Off switch disables C-arm and Patient Platform movement and removes power from the Gantry.

Do NOT use the E-Stop switches for routine system shutdown.

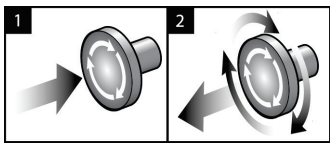


Figure 3: Emergency Off Switch Functionality

1. Press any of the Emergency Off switches to power OFF the Gantry.
2. To reset the Emergency Off switch, turn clockwise approximately one-quarter turn until the switch pops back out.

2.5 Interlocks

- The electronic System Lock only allows C-arm movement when the **System Lock** button on the Control Handle is in unlocked mode.
- The system does not allow x-ray exposure unless in a Ready state and the **System Lock** button on the Control Handle is in locked mode.
- If the x-ray button is released before the end of the exposure, the exposure stops and an alarm message shows.

- The system does not enter a Ready state following an exposure until the x-ray button is released.

2.6 Compliance

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

2.6.1 Compliance Requirements

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

- The electrical installation of the room meets all requirements.
- The equipment is used according to the *User Guide*.
- The assembly operations, extensions, adjustments, changes, or repairs are performed only by authorized persons.
- The network and communication equipment is installed to meet IEC Standards. The complete system (network and communications equipment and the Affirm Prone Biopsy System) must be in compliance with IEC 60601-1.

Caution:
Medical Electrical Equipment needs special precautions about EMC and must be installed, put into service and used according to the EMC information provided.

Caution:
Portable and mobile RF communications can affect medical electrical equipment.

Caution:
The use of unauthorized accessories and cables can result in increased emissions or decreased immunity. To keep the isolation quality for the system, attach only approved Hologic accessories or options to the system.

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

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

2.6.2 Compliance Statements

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

IEC:

- IEC 60601-1: 2005 - Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3: 2008 - General requirements for radiation protection in diagnostic x-ray equipment
- IEC 60601-1-6: 2010 - Collateral Standard: Usability
- IEC 60601-2-28: 2017 - Particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
- IEC 60601-2-45: 2011 - Particular requirements for the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices

FDA:

- 21 CFR §900 – Mammography Quality Standards Act (MQSA)
- 21 CFR §1020.30 – Diagnostic x-ray systems and their major components
- 21 CFR §1020.31 – Radiographic equipment

CE:

- 93/42/EEC – CE marking according to MDD
- 2006/42/EC – Machinery Directive of 17 May 2006
- 2002/95/EC – Restriction of Hazardous Substances Directive of 27 January 2003
- 2002/96/EC – Waste Electrical and Electronic Equipment Directive of 27 January 2003

CAN/CSA:

- CAN/CSA-C22.2 No. 60601-1 (2008): Medical electrical equipment - Part 1: General requirements for safety

ANSI/AAMI:

- ANSI/AAMI ES60601-1 (2005) - Medical electrical equipment— Part 1: General requirements for basic safety and essential performance

2.7 Label Locations

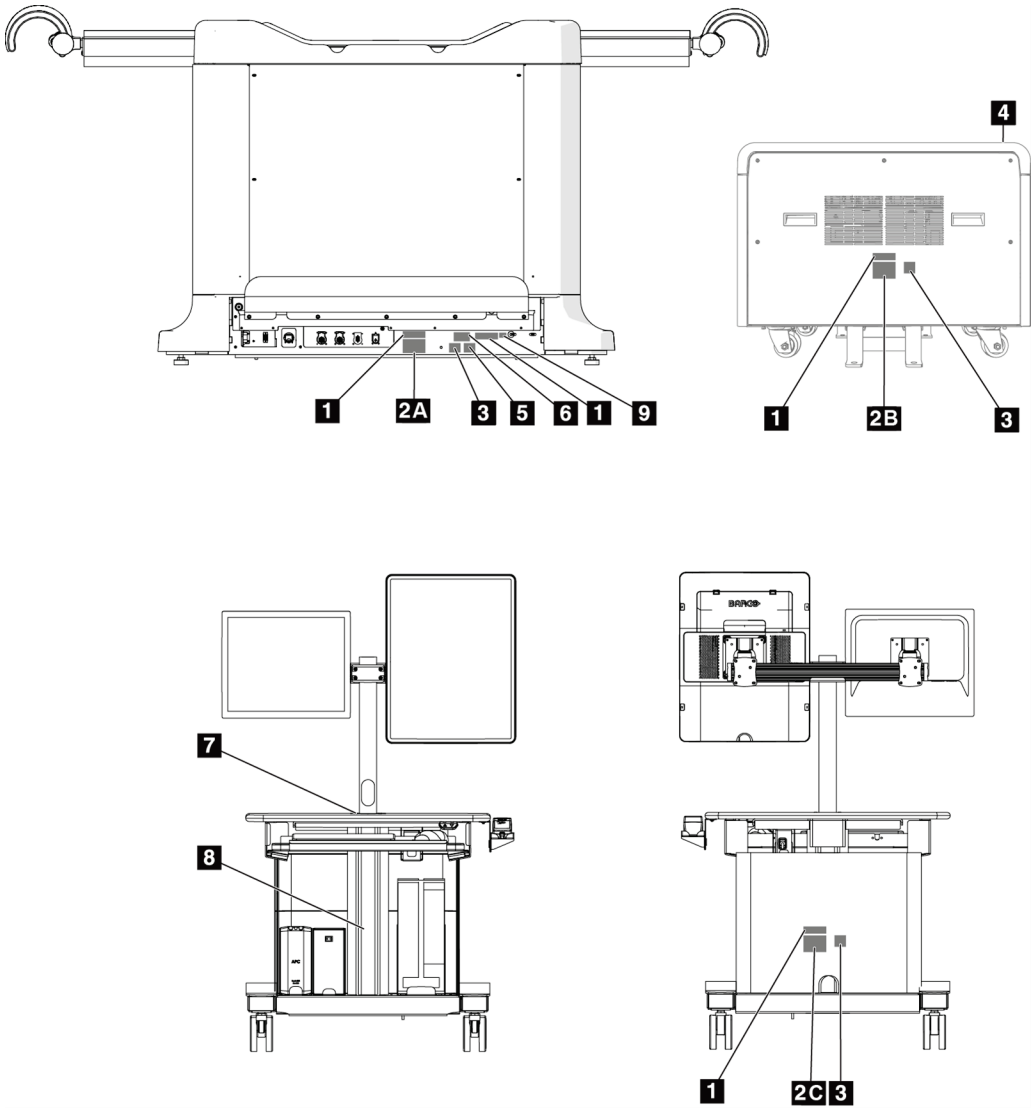


Figure 4: Label Locations

Table 1: System Labels

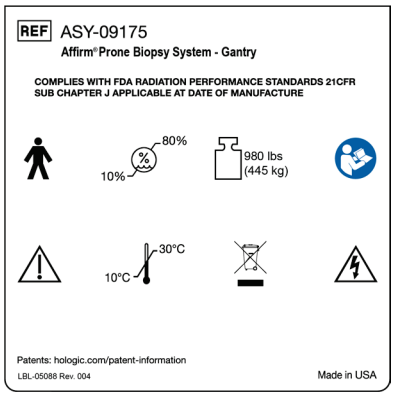
1

Serialized Device

9

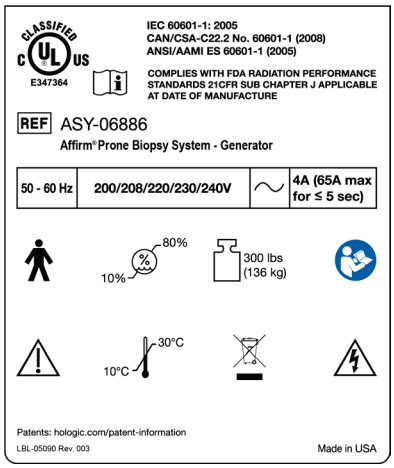
Brazilian Compliance

2A



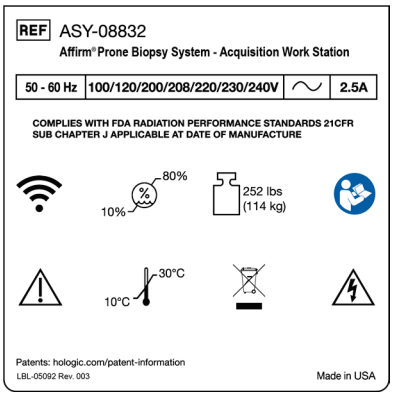
Gantry Nameplate

2B



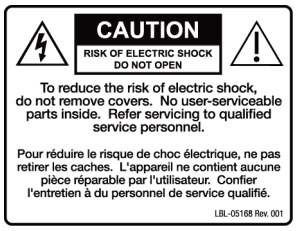
Generator Nameplate

2C



Acquisition Workstation Nameplate

3

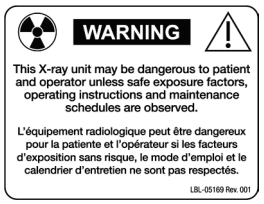


Electrical Shock Warning

4

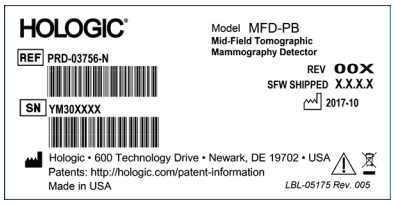
Do Not Sit or Stand on Device

5



X-ray Device Warning

6



Detector

7

Do Not Sit, Stand, or Push on Device

8

Product Support

Chapter 3: System Controls and Indicators

3.1 System Power Controls

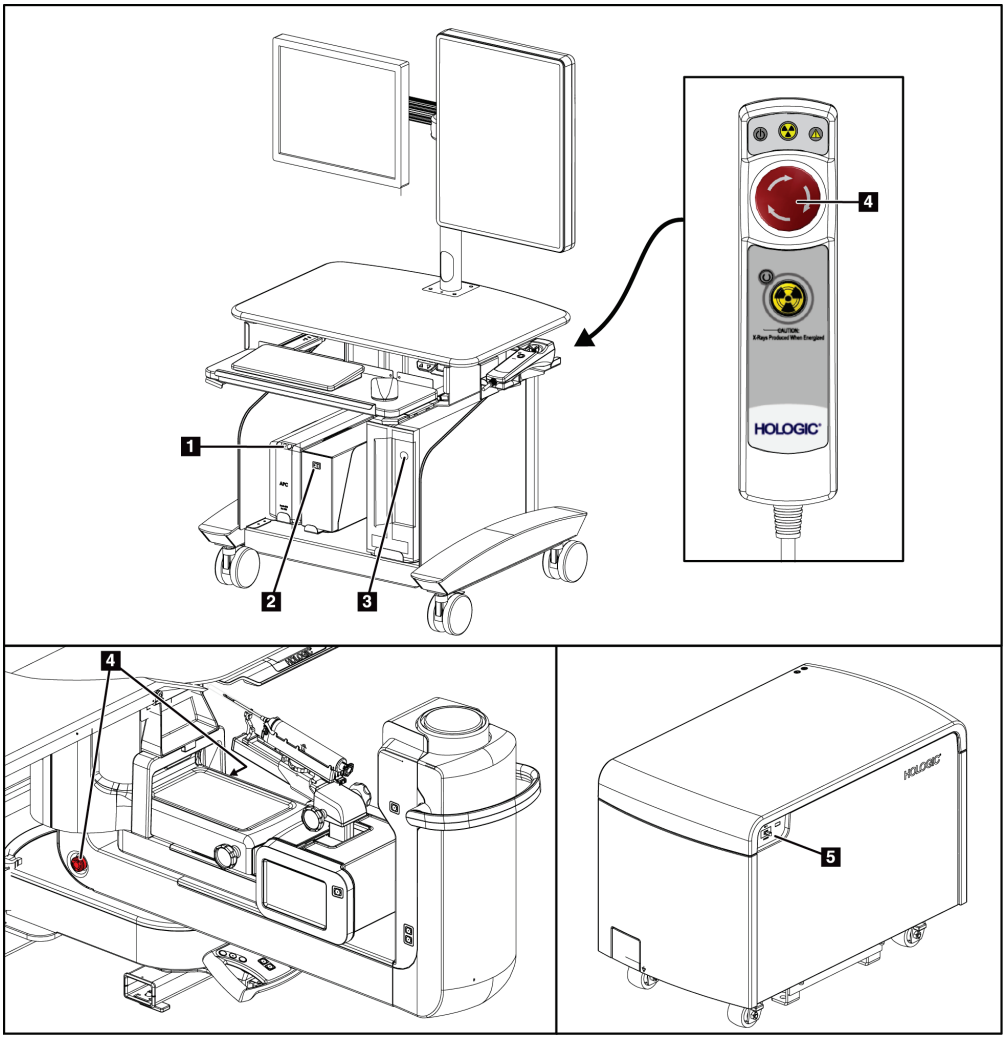


Figure 5: System Power Controls

Figure Legend

1. Uninterruptible Power Supply (UPS) Power/Reset Button
2. Isolation Transformer Power Switch
3. Computer Power On/Reset Button
4. Emergency Off (E-Stop) Switches
5. Generator Circuit Breaker

3.2 C-Arm Controls

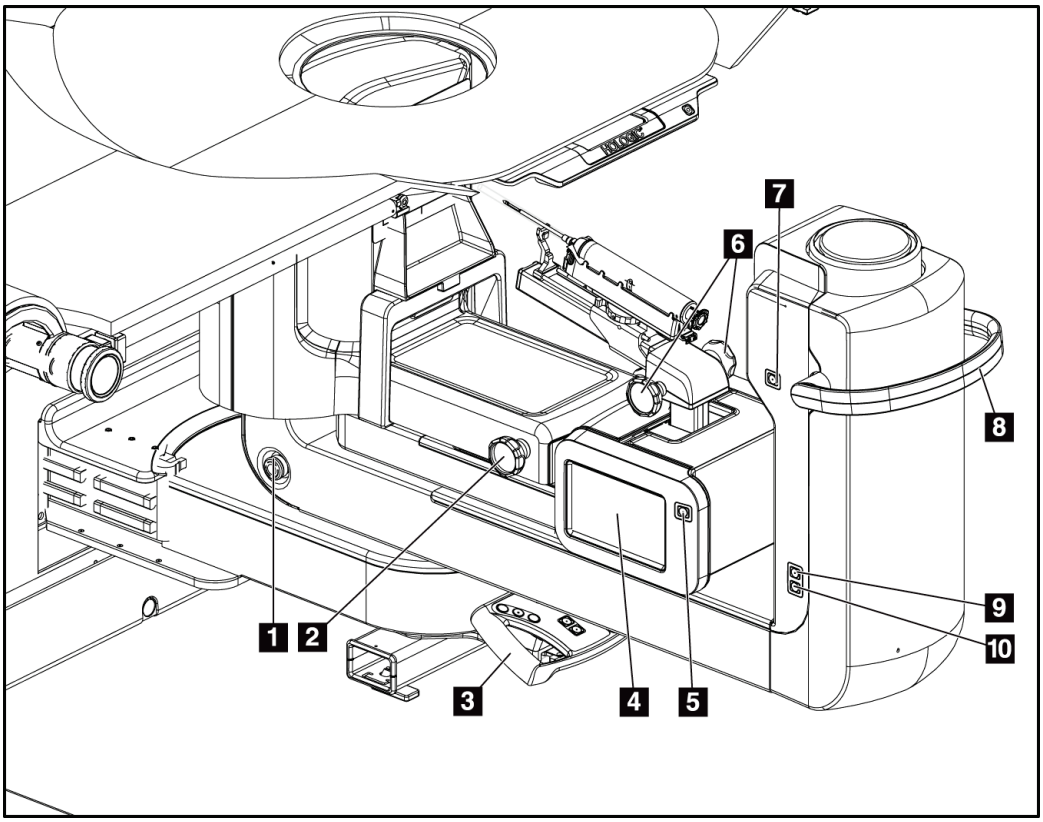


Figure 6: C-arm Controls and Displays

Figure Legend

1. Emergency Off (E-Stop) Switch
2. Manual Compression Adjust Knob
3. Control Handle
4. Biopsy Control Module Touch Screen Display
5. Biopsy Arm Motor Enable Button
6. Manual Biopsy Device Advance/Retract Knob
7. Task Lighting On/Off
8. C-arm Rotation Handle
9. C-arm Sweep – Away from User
10. C-arm Sweep – Toward User

3.2.1 Biopsy Arm Controls

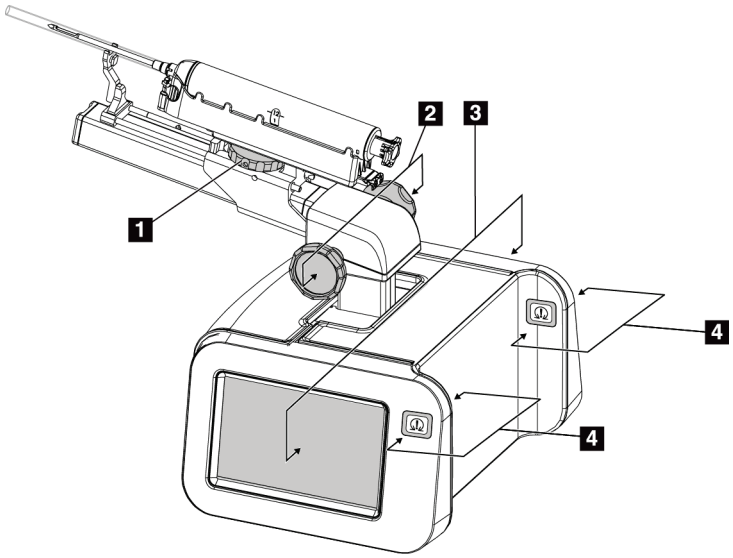


Figure 7: Biopsy Arm – Detailed View

Figure Legend

1. Biopsy Device Mount Knob
2. Manual Needle Advance/Retract Knobs
3. Biopsy Control Module Touch Screen Displays
4. Biopsy Control Module Motor Enable Buttons

Note
Refer to User Interface - Biopsy Control Module for information on using the Biopsy Control Module touch screen display.

Note
The Biopsy Control Module motor enable buttons consist of two pairs of buttons located on either side of the Biopsy Control Module. Each pair is located back to back on one of the module cover extensions and is meant to be pinched with one hand. To enable the Biopsy Control Module motor, press and hold one of the Motor Enable button pairs.

3.2.2 Control Handle Controls

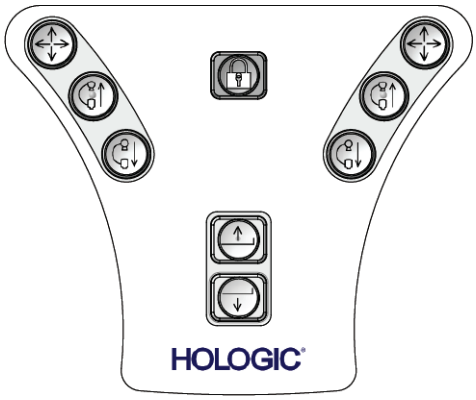


Figure 8: Control Handle -- Detailed View

Button	Function
	C-arm Translate (horizontal plane)
	C-arm Up
	C-arm Down
	System Lock
	Patient Platform Up
	Patient Platform Down

3.2.3 Footswitch Controls

Warning:
Place each footswitch in a position where, when used, they remain in reach of the Emergency Off Switches.

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

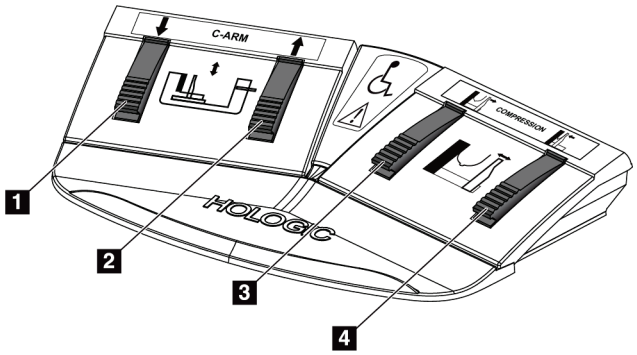


Figure 9: Footswitch – Detailed View

Figure Legend

1. C-arm Down
2. C-arm Up
3. Compression Release
4. Compression Apply

3.3 Patient Platform Controls

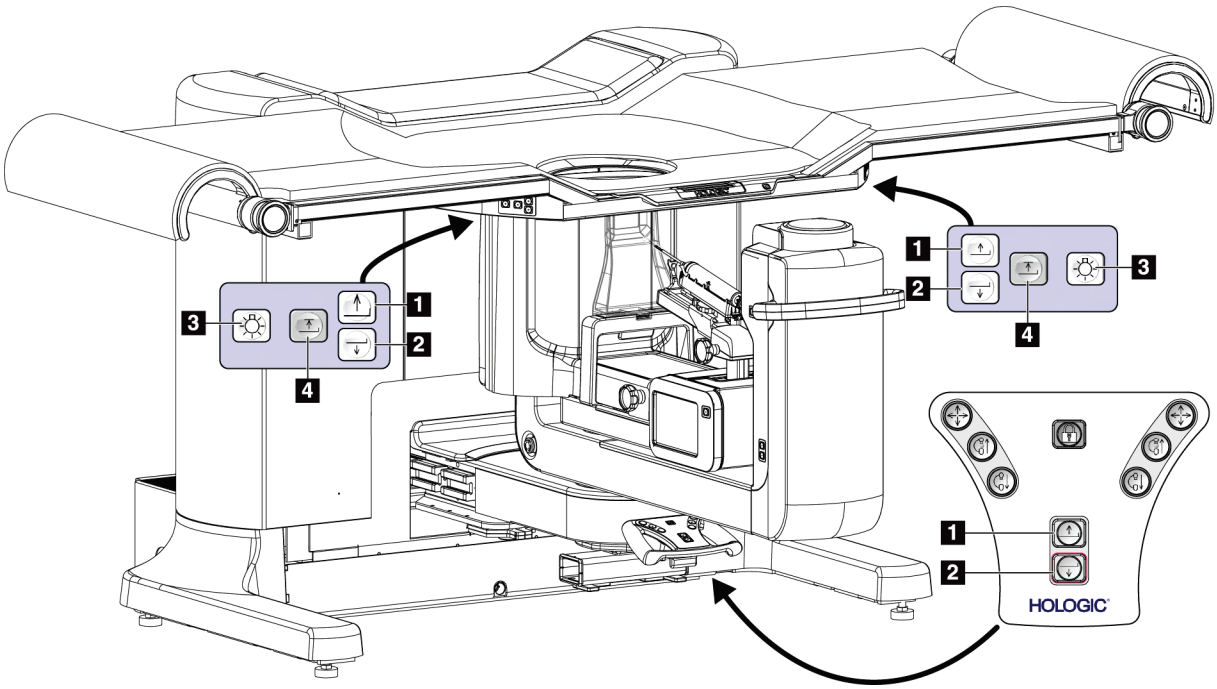


Figure 10: Patient Platform Controls

Figure Legend

1. Patient Platform Up
2. Patient Platform Down
3. Task Light On/Medium/Low/Off
4. Patient Platform Up Limit (Full Height)

3.4 Acquisition Workstation Controls

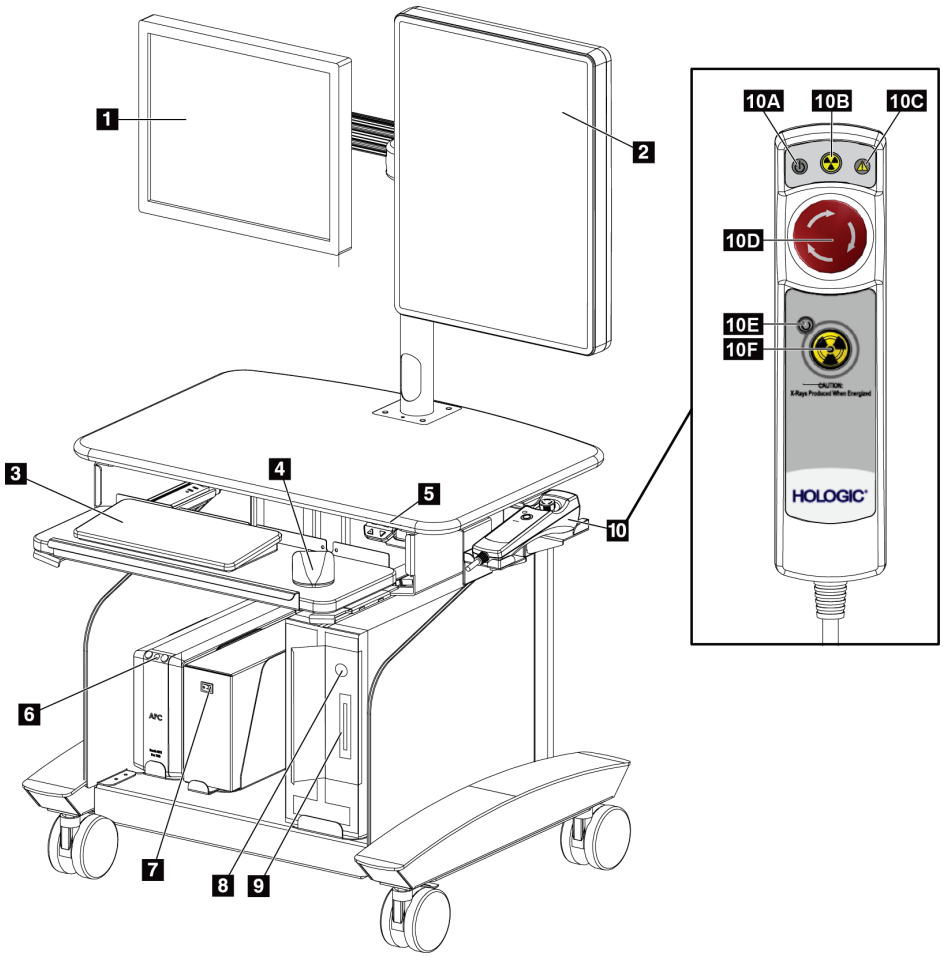


Figure 11: Acquisition Workstation Controls

Figure Legend

1. Control Monitor
2. Image Display Monitor
3. Keyboard
4. Mouse
5. Workstation Work Surface Up and Down Controls
6. Uninterruptible Power Supply (UPS) Power Button
7. Isolation Transformer Power Switch
8. Computer Power On/Reset Button
9. CD/DVD Drive
10. Emergency Off/X-ray Activation Remote
    - A. Power On Light
    - B. X-ray Active Light
    - C. System Alert Light
    - D. Emergency Off Switch
    - E. Ready for X-ray Light
    - F. X-ray Activation Button

Chapter 4: Startup, Functional Tests, and Shutdown

4.1 How to Start the System

Note
See the figure *System Power Controls* on page 23 for the locations of power buttons.

1. Make sure that there are no obstructions to C-arm or Patient Platform movement.
2. Make sure that all three Emergency Off switches are in the reset position (unpushed).
3. Make sure that the Generator circuit breaker is in the ON position.
4. Make sure that the Isolation Transformer power switch is in the ON position.
5. Make sure that the UPS is powered ON.
6. Press the **Power/Reset** button on the computer. The computer powers on and the *Windows 10 Login* screen opens on the Acquisition Workstation Control monitor.

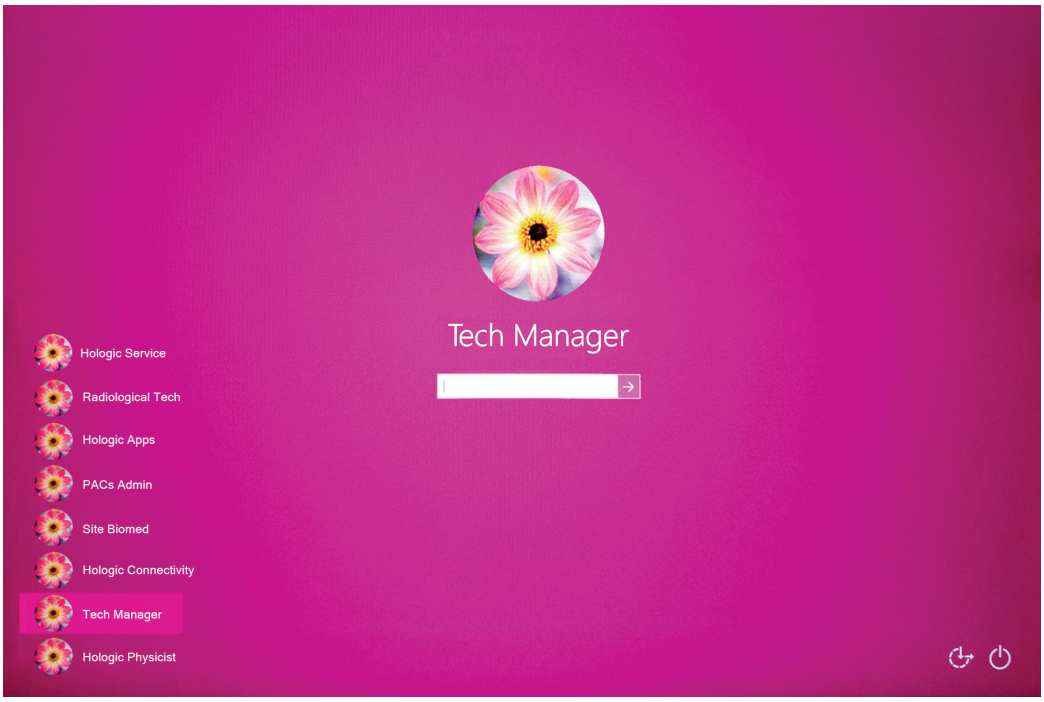


Figure 12: Windows 10 Login Screen

7. Select your user name from the user list.
8. Enter your password then select the **arrow** icon.

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

9. After a moment, the *Startup* screen for the Affirm prone biopsy system opens on the Acquisition Workstation control monitor. The Gantry then automatically powers on. At the *Startup* screen, select the **Patient List** button.

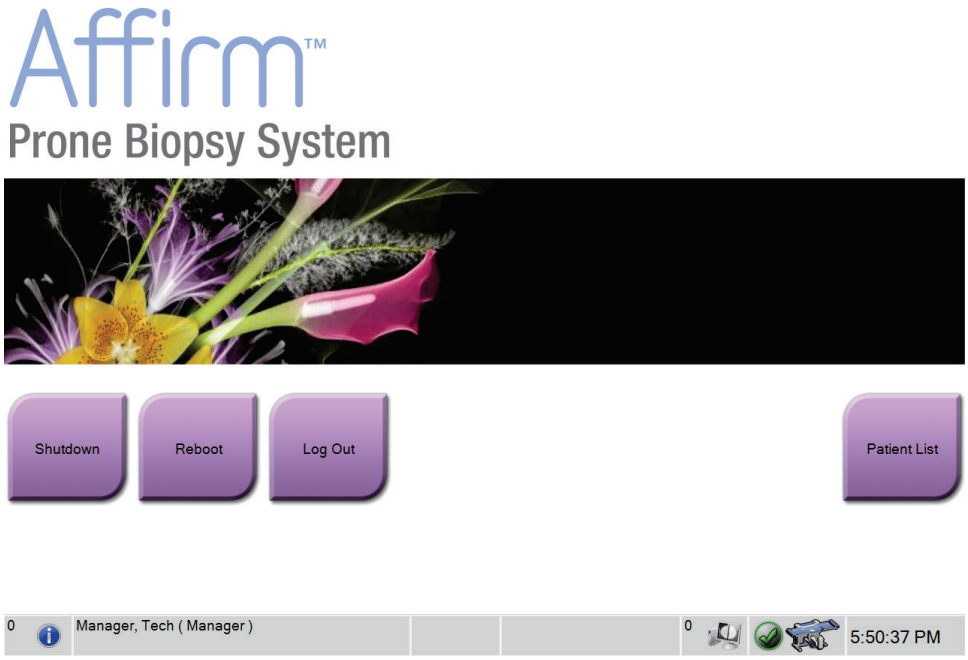


Figure 13: Startup Screen

Note
If Quality Control tasks are due, the *Select Function to Perform* screen opens. Perform the quality control tasks or select **Skip**.

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

Note
The *Startup* screen includes a **Shutdown** button that turns off the system, and a **Reboot** button that restarts the system.

Note
The system can require between five minutes and fifteen minutes to prepare for image acquisition. The wait time depends on the detector power configuration. A timer in the Taskbar displays the wait time before the system is ready. Do not acquire clinical or QC images unless the System Status Icon indicates that the system is Ready.

Note
To change the system language or other preferences, refer to *Change the User Language Preference* on page 132.

4.2 Functional Tests

4.2.1 Compression Functional Tests

Table 2: Compression Tests

Function	Functional Test
Compression Apply	Press a Compression Apply button: • The Compression Paddle moves toward the image receptor. Compression Apply movement stops: • When the button is released. • When the inner travel limit is reached.
Compression Release	Press a Compression Release button: • The Compression Paddle moves away from the image receptor. Compression Release movement automatically stops: • When the button is released. • When the outer travel limit is reached.

Warning:
Before initiating any motion of the compression-arm or tube-arm, make sure the motion path is clear of all persons and obstructions.

Note
The compression paddle and the biopsy device mount move separately.

Note
The system is designed to prevent collisions between the paddle and the selected biopsy device. To make sure that the compression paddle travels to its maximum limit, move the biopsy device mount as far away from the breast platform as possible.

4.2.2 C-arm Movement Functional Tests

Table 3: C-arm Tests

Function	Functional Test
C-arm Up	Press a C-arm Up button: • The C-arm moves up. C-arm up movement stops: • When the button is released. • When the upper travel limit is reached.
C-arm Down	Press a C-arm Down button: • The C-arm moves down. C-arm down movement stops: • When the button is released. • When the lower travel limit is reached.

4.2.3 Patient Platform Functional Tests

Table 4: Patient Platform Tests

Function	Functional Test
Patient Platform Up	Press a Patient Platform Up button: • The Patient Platform moves up. Patient Platform up movement stops: • When the button is released. • When the upper travel limit is reached.
Patient Platform Down	Press a Patient Platform Down button: • The Patient Platform moves down. Patient Platform down movement stops: • When the button is released. • When the lower travel limit is reached.
Patient Platform Up Limit	Press the Patient Platform Up Limit button: • The Patient Platform moves up automatically to its upper travel limit. Patient Platform movement stops: • When the upper travel limit is reached. • When the Up Limit button is pressed again. • When any Patient Platform up/down button is pressed.

4.3 Emergency Off Switches Functionality

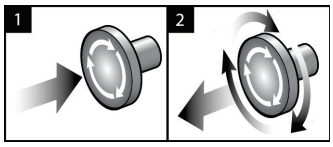


Figure 14: Emergency Off Switch Functionality

There are three Emergency Off switches, one on each side of the Gantry and one on the Acquisition Workstation.

1. To turn Off the Gantry and disable the Acquisition Workstation Lift Mechanism, press any of the Emergency Off switches.
2. To reset the Emergency Off switch, turn clockwise approximately one-quarter turn until the switch pops back out.

4.4 How to Turn Off the System

1. Close any open patient procedures.
2. From the *Select Patient* screen, select the **Back** button.
3. From the *Startup* screen, select the **Shutdown** button.
4. Select **Yes** in the confirmation dialog box. The user is logged out and the system turns off.

Note
To log out, at the *Startup* screen, select the **Shutdown** button then select **Yes** in the confirmation dialog box.

4.4.1 How to Remove All Power from the System

1. Turn off the system.
2. Press the UPS power/reset button to power off the UPS.
3. Turn OFF the Isolation Transformer power switch.
4. Turn OFF the Generator circuit breaker.
5. Turn OFF the Facility Mains circuit breaker.

Chapter 5: User Interface - Control Monitor

5.1 Select Function to Perform Screen

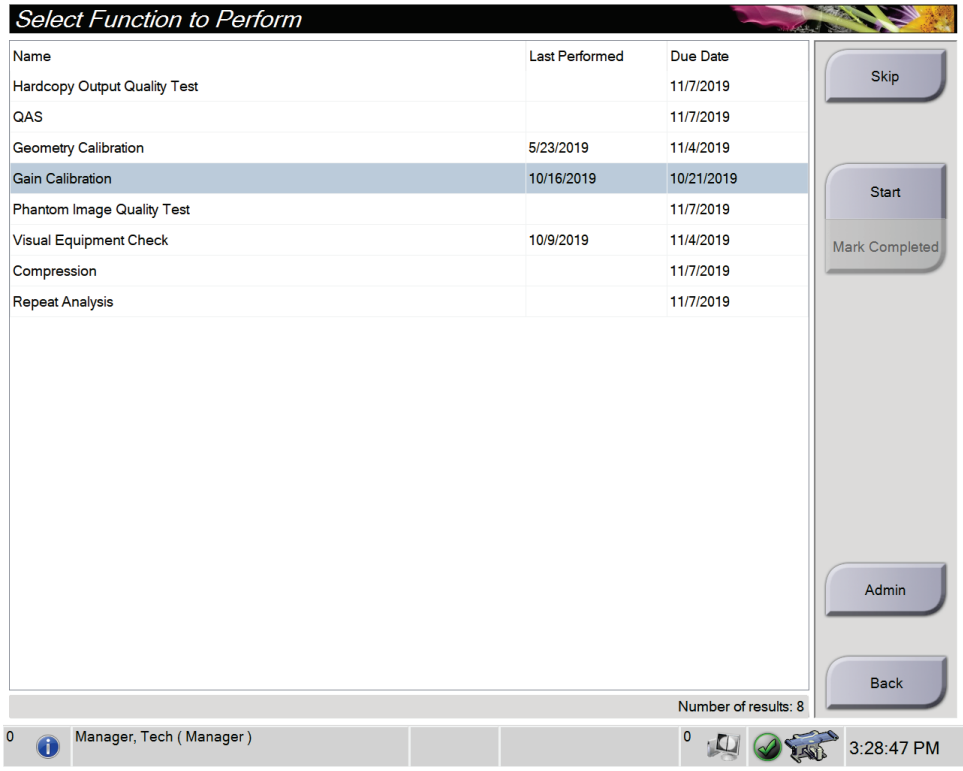


Figure 15: Select Function to Perform Screen

After login, the *Select Function to Perform* screen opens. This screen shows the Quality Control tasks that are due.

Note
The *Select Patient* screen opens when no Quality Control tasks are scheduled to be done.

To complete a scheduled Quality Control task:

1. Select a Quality Control task from the list.
2. Select the **Start** button. Follow the messages to complete the procedure. (The **Start** button is not available for all types of tests.) Then select **End QC**.

   - OR -

   Select the **Mark Completed** button to mark the status of this procedure as finished. Select **Yes** to confirm the selected procedure is completed.

To proceed without completing all scheduled Quality Control tasks:

If none of the Quality Control tasks from the displayed list are being completed at this time, select the **Skip** button.

Note
If you select the **Skip** button, the *Select Patient* screen opens. Refer to *Select Patient Screen* on page 38 for information about this screen.

If you select the **Admin** button, the *Admin* screen opens. Refer to *The Admin Screen* on page 129 for information about this screen.

Note
Quality Control tasks are available to complete at any time. Select the **Admin** button then the **Quality Control** button to access the list of Quality Control tasks.

5.2 About the Taskbar

The taskbar at the bottom of the screen shows additional icons, which can be selected to access information or perform system tasks.

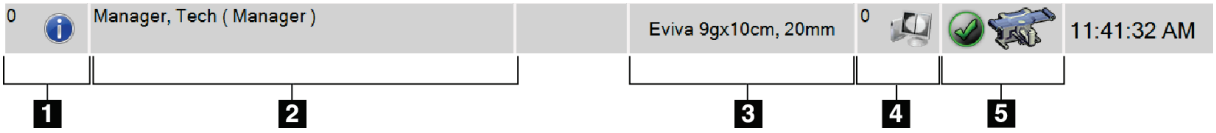
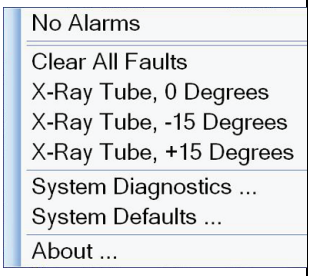


Table 5: Taskbar Menus

	Description	Menu
1 	**Information Icon** Select the **Information** icon to display the Alarm menu. This section of the taskbar flashes a yellow color when an alarm exists. Select **Acknowledge All** to stop the flashing indication. Select the **Manage Alarms** option to display and close any open alarms.	
2	**Current User Name** Select the user name to display the Users menu. **Log Out** returns you to the *Startup* screen. **My Settings** opens the *Edit Operator* screen to customize user settings and workflow preferences. **Print** sends the displayed patient list to a connected printer.	
3	**Selected Biopsy Device**	

Table 5: Taskbar Menus

	Description	Menu
4 	**Output Device Icons** Select any output device icon to access the *Manage Queues* screen. This screen shows the status of jobs in the queue, job information for the selected output, and allows you to filter the queue display.	
5 	**System Status Icons** Select the **System Status (Table)** icon to display a menu. When the detector and generator are ready for use, a green check mark shows next to the System Status icon. If the System Status icon is red with a number next to it, the system needs to wait the number of minutes shown before the next set of images can safely be taken. **Clear All Faults** deletes all fault messages. **X-ray Tube, 0 Degrees** puts the tubehead at zero degrees of rotation for the next exposure. **X-ray Tube, -15 Degrees** puts the tubehead at -15 degrees of rotation for a biopsy exposure. **X-ray Tube, +15 Degrees** puts the tubehead at +15 degrees of rotation for a biopsy exposure. **System Diagnostics** accesses Subsystem settings. **System Defaults** opens the *System Defaults* screen to set the Compression and Generator default values. **About** displays information about the Acquisition Workstation (refer to *The About Screen* on page 131).	

5.3 Select Patient Screen

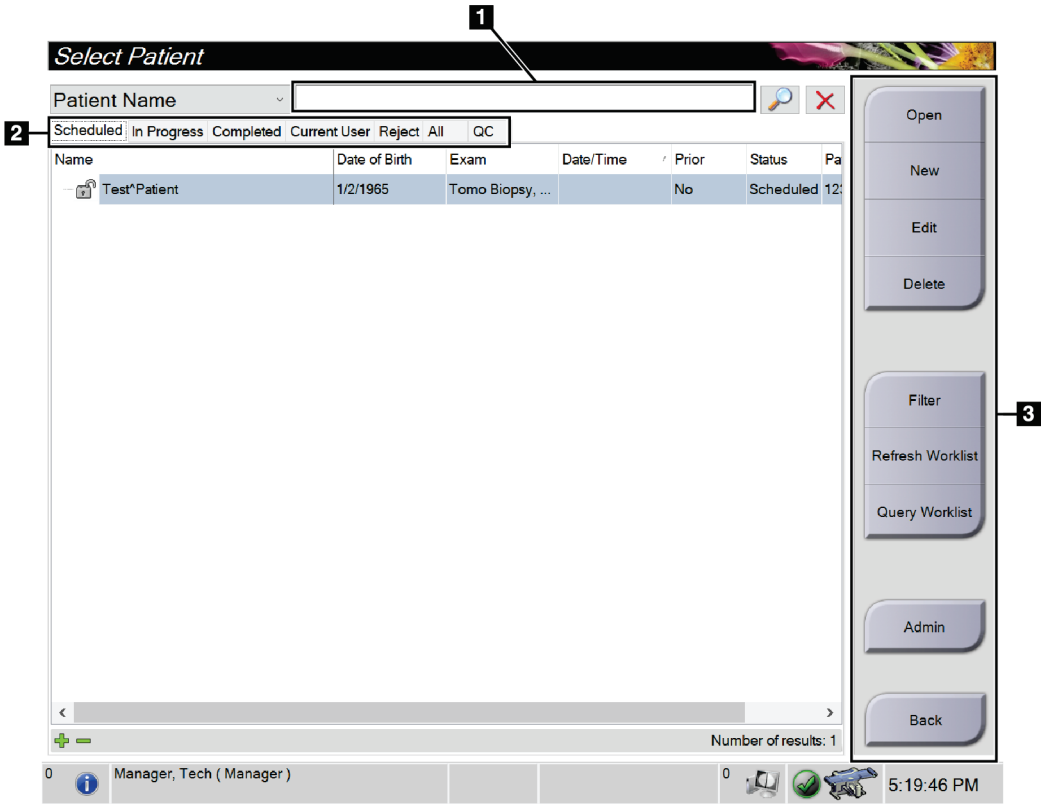


Figure 16: Select Patient Screen

Table 6: The Select Patient Screen

Item	Description
1. Quick Search	Search the local database for the Patient Name, Patient ID, or Accession number.
2. Tabs	The filter tabs at the top of the screen are configurable. A user with the correct permissions can delete tabs and create new tabs. • The **Scheduled** tab shows the scheduled patient procedures. • The **In Progress** tab shows the patient procedures not complete. • The **Completed** tab shows the completed patient procedures. • The **Current User** tab shows the patient procedures for the current Operator. • The **Reject** tab shows the patient procedures with rejected views. • The **All** tab shows all patient procedures for all users. • The **QC** tab shows the Quality Control procedures.

Table 6: The Select Patient Screen

Item	Description
3. Buttons	Many functions are accessed from this screen by selecting a particular button: • **Open:** Open the selected patient. • **New:** Add a new patient—refer to *Add a New Patient* on page 40. • **Edit:** Edit the patient information—refer to *Edit the Patient Information* on page 40. • **Delete:** Delete the selected patient from the worklist—refer to *Delete a Patient* on page 40. • **Filter:** Configure the Patient Filters—refer to *Filters for Patients* on page 41. • **Refresh Worklist:** Update the Scheduled Patient worklist information—refer to *Refresh the Worklist* on page 43. • **Query Worklist:** Search for a patient in the Modality Worklist—refer to *Query the Worklist* on page 43. • **Admin:** Access the *Admin* screen—refer to *The Admin Screen* on page 129. • **Back:** Return to the *Startup* screen.

5.3.1 Open a Patient

1. Select a tab to show the desired list of patients.
2. Select a patient from the list. The **Open** button becomes active.
3. Select **Open** to access the *Procedure* screen for that patient.

5.3.2 Add a New Patient

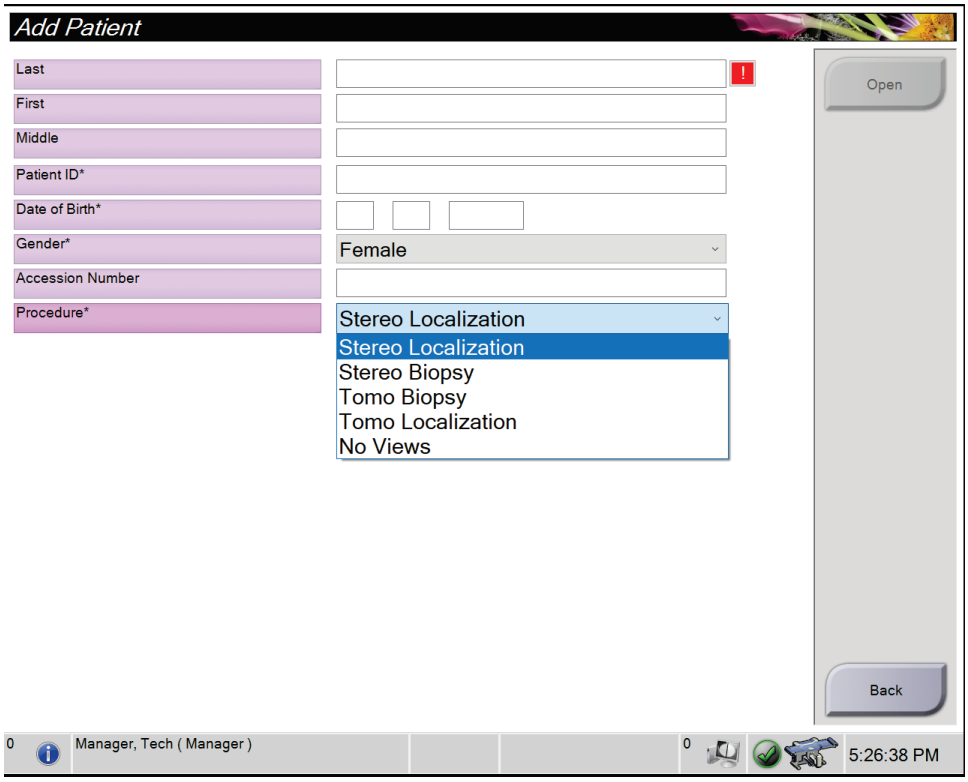


Figure 17: Add Patient Screen

1. In the *Select Patient* screen, select the **New** button. The *Add Patient* screen opens.
2. Enter the new patient information and select a procedure.
3. Select the **Open** button. The *Procedure* screen for the new patient opens.

5.3.3 Edit the Patient Information

1. In the *Select Patient* screen, select the patient name then select the **Edit** button.
2. In the *Edit Patient* screen, make changes then select the **Save** button.
3. Select **OK** to the *Update Successful* message.

5.3.4 Delete a Patient

1. In the *Select Patient* screen, select one or more patients.
2. Select the **Delete** button.
3. When the confirmation dialog box opens, select **Yes**.

Note
The Technologists do not have permissions to delete patients.

5.3.5 Filters for Patients

After selecting the **Filter** button in the *Select Patient* screen, the *Patient Filter* screen for the selected tab opens.

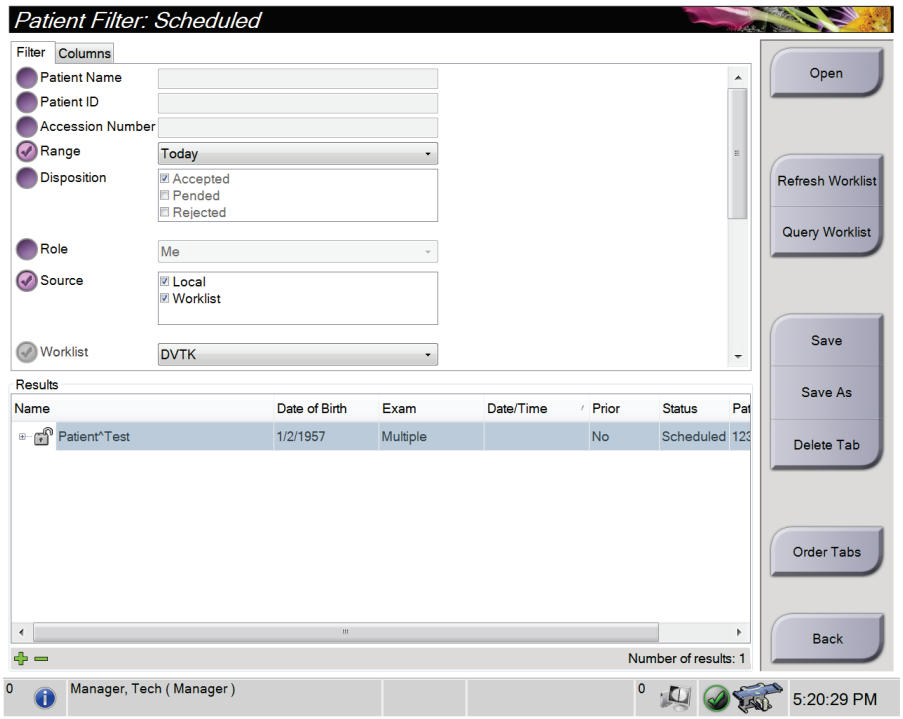


Figure 18: Filter Tab in the Patient Filter Screen

Filter Tab

Use the **Filter** tab to change the filter options for the patient list. When you select or cancel an option, the change shows in the Results area of the screen.

Note
You must have Manager level access to save these new filters to the selected tab in the *Select Patient* screen. (Refer to *Other Functions of the Filter Tab* on page 42.)

Note
When you select a line in the results list then select the **Open** button, the *Procedure* screen for the selected patient opens.

Other Functions of the Filter Tab

The **Filter** tab allows users with access privileges to add, change, or delete tabs in the *Select Patient* screen. Refer to the following table.

Table 7: Filter Tab Options (Require Access Privileges)

Change the current patient filter parameters.	1. Select a tab on the *Select Patient* screen. 2. Select the **Filter** 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 box. 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** 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** button. 3. Select the **Delete** button. 4. Select **Yes** in the confirmation dialog box.

Columns Tab

Use the **Columns** tab to add more search options (for example, Age, Gender, Notices) to the filtered list. The options show as columns in the results area. To add more columns to a filtered list, select the **Columns** tab then select the options.

Note
You must have Manager level access to save these new columns to the patient filter.

Note
When you select a line in the results list then select the **Open** button, the *Procedure* screen for the selected patient opens.

Order Tabs Button

Select the **Order Tabs** button to change the order of the patient list tabs.

5.3.6 Refresh the Worklist

Select the **Refresh Worklist** button to update the Scheduled patient list from the Modality Worklist Provider.

5.3.7 Query the Worklist

Select the **Query Worklist** button to search the Modality Worklist Provider for a patient or a list of patients.

Type the query information into one or more fields. The scheduled procedure is displayed, and the patient is added to the local database. All fields to query are configurable. The default fields are Patient name, Patient ID, Accession Number, Requested Procedure ID, and Scheduled Procedure Date.

5.3.8 Admin

Select the **Admin** button to access the *Admin* screen and the system administration functions. Refer to *System Administration Interface* on page 129 for more information.

5.3.9 Log Out

Select the **Log Out** button to exit the system and return to the *Startup* screen.

5.4 Procedure Screen

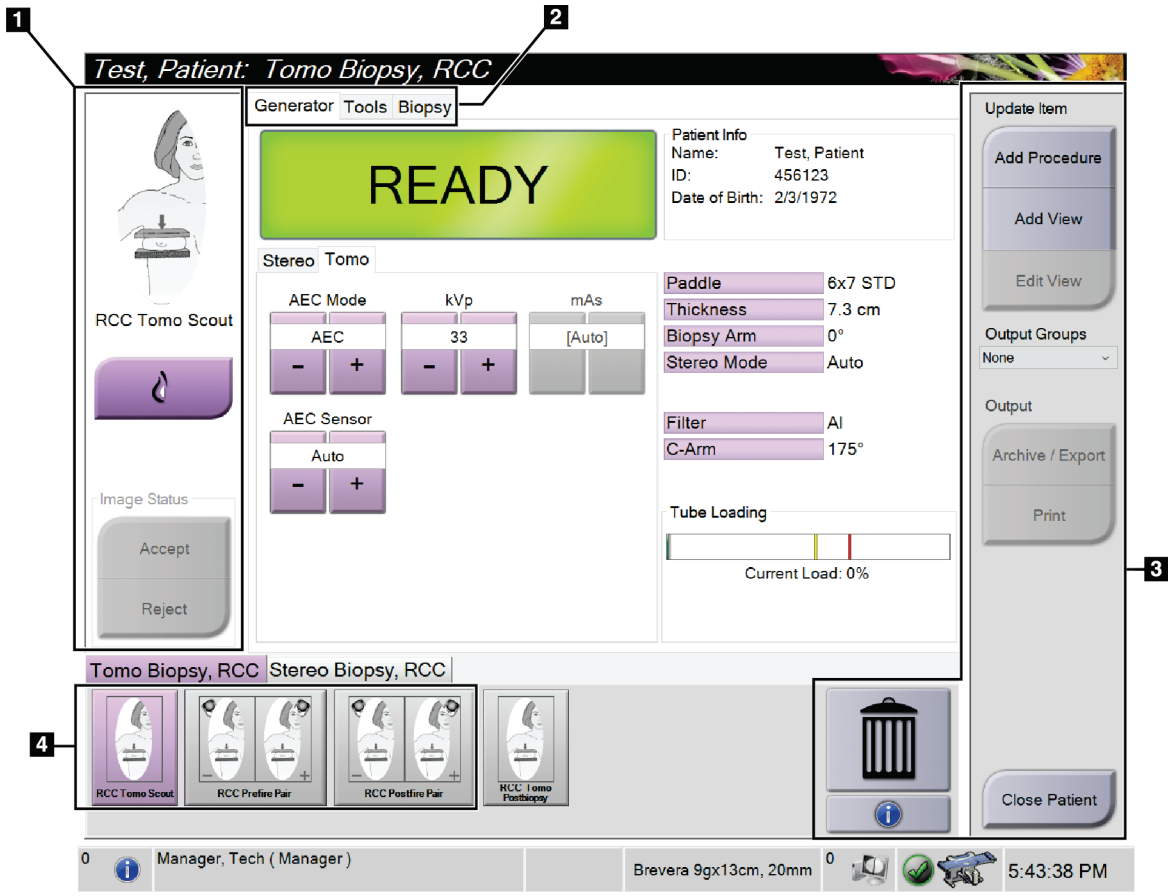


Figure 19: Procedure Screen

Table 8: The Procedure Screen

Item	Description
1. Image Status	The view icon shows the current selected view. **Implant Present** button—select when the patient has an implant. **Accept** button—select to accept the image. **Reject** button—select to reject the image.
2. Tabs	Select the **Generator** tab to adjust the exposure techniques for the procedure. Select the **Tools** tab to review the images—refer to *The Image Review Tools Tab* on page 74. Select the **Biopsy** tab to create targets—refer to *Biopsy Tab* on page 79.
3. Buttons	Many functions are accessed from this screen by selecting a particular button: **Add Procedure:** Add a new procedure—refer to *Add a Procedure* on page 46. **Add View:** Add a new view—refer to *Add a View* on page 47. **Edit View:** Assign a different view to an image—refer to *Edit a View* on page 48. **Archive/Export:** Send images to an output—refer to *On-Demand Outputs* on page 53. **Print:** Print—refer to *Print* on page 55. **Close Patient:** Exit the patient and procedure—refer to *Close a Patient* on page 50. **Trash Can:** Delete a view. **Procedure Information:** Open the *Procedure Info* dialog box—refer to *Procedure Info* on page 49.
4. Thumbnails	Select a procedure tab to show the thumbnail views or thumbnail images for that procedure.

5.4.1 How to Use the Implant Present Button

The **Implant Present** button is above the **Accept** button on the *Procedure* screen. This button applies special implant processing to the implant and implant displaced views, and changes the "Implant Present" DICOM tag in the image header. When this button is selected, a check mark appears on the button.

Select the **Implant Present** button for both implant and implant displaced views before you acquire the image.

Note
The **Implant Present** button is automatically selected if any procedure tabs contain an ID view.

5.4.2 Add a Procedure

1. To add another procedure, select the **Add Procedure** button on the *Procedure* screen to access the *Add Procedure* dialog box.

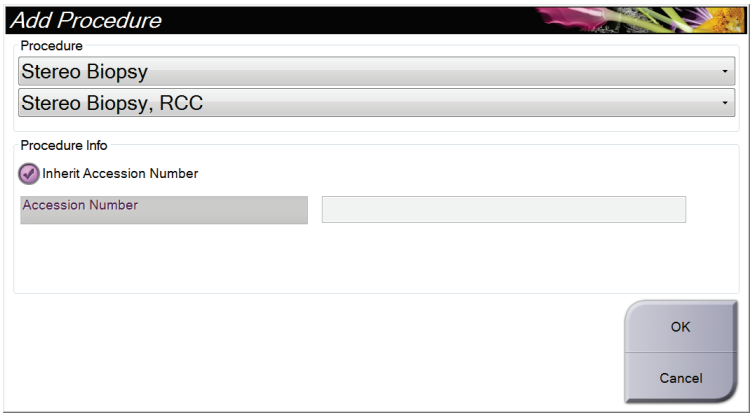


Figure 20: Add Procedure Dialog Box

2. Use the drop-down lists to select the type of procedure to add.
3. Type an Accession Number or select the Inherit Accession Number check box to use the current number.
4. Select the **OK** button. A new tab is added with the thumbnail views for the procedure that was selected.

5.4.3 Add a View

To add a view:

1. Select the **Add View** button to access the *Add View* screen.

Note
Depending on the license settings for your system, you may see different tabs.

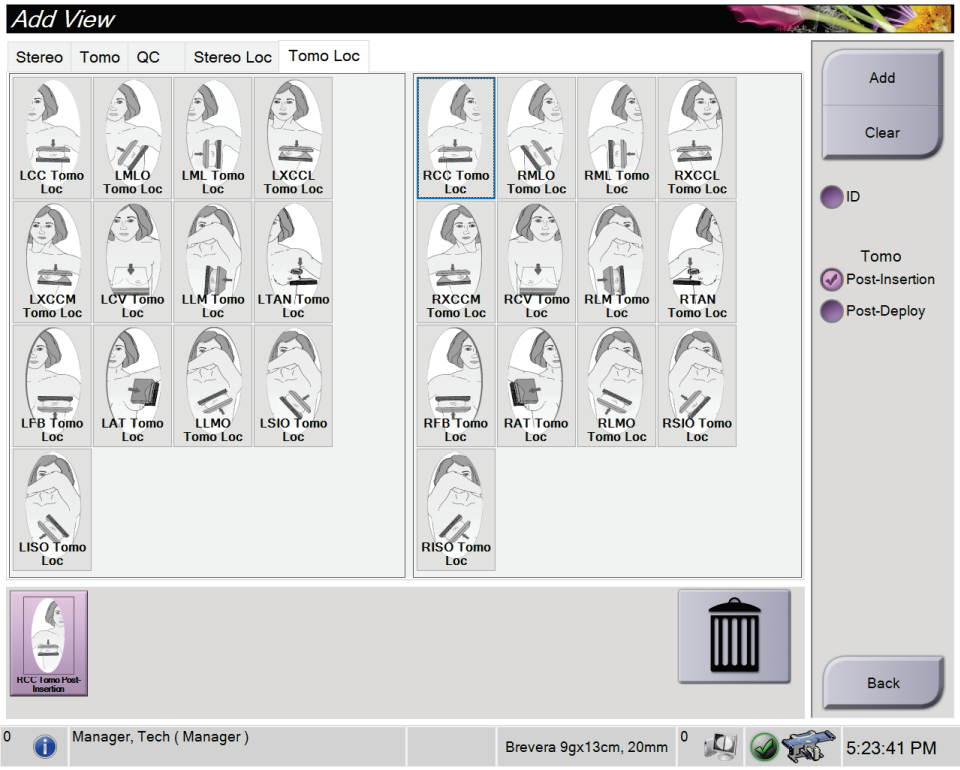


Figure 21: Add View Screen

2. Select the tab, select the view, and select a View Modifier from the right panel of the screen.
3. Select the **Add** button. A thumbnail of each selected view appears in the Image Thumbnails panel.

To remove a view from the Add View list:

- To remove a single view from the added list: in the Image Thumbnails panel, select the thumbnail view then select the **Trash Can** icon.
- To remove all views from the added list: select the **Clear** button.

5.4.4 Edit a View

Use the *Edit View* screen to assign a different view to an image.

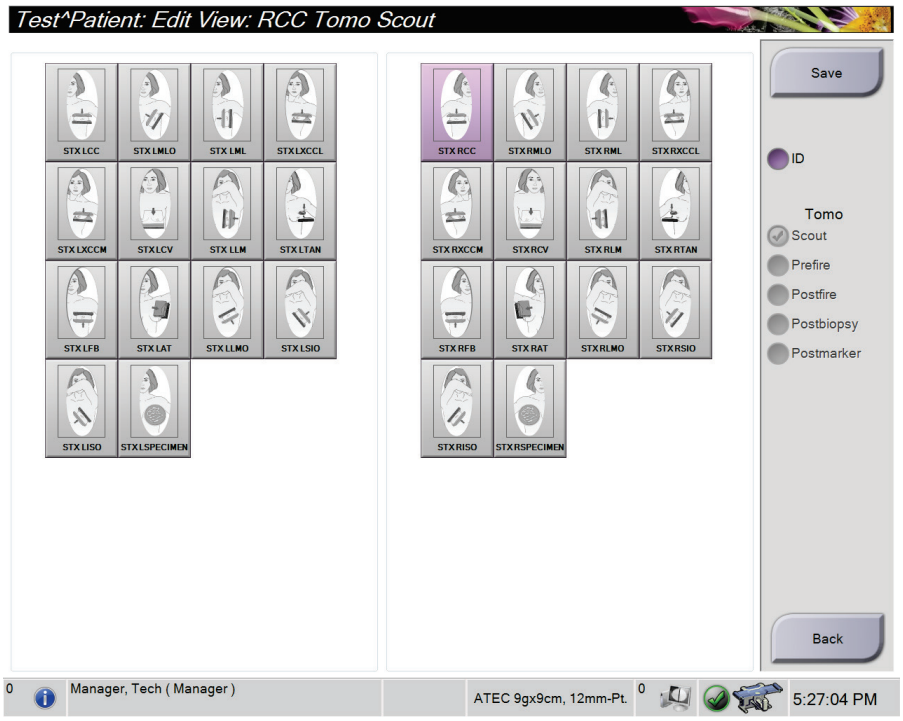


Figure 22: Edit View Screen

To edit a view:

1. In the *Procedure* screen, select an exposed thumbnail image.
2. Select the **Edit View** button to open the *Edit View* screen.
3. Select the view, then select the View Modifier from the right side of the screen.
4. Select **Save**.
5. When the *Update Successful* dialog box opens, select **OK**.

5.4.5 How to Remove a View

To remove a view from the procedure:

In the *Procedure* screen, in the image thumbnails panel, select the thumbnail view to delete. Then select the **Trash Can** icon.

Note
You can only remove views that have not been exposed.

5.4.6 Procedure Info

To show procedure information, select the **Procedure Information** button located below the **Delete View** (trash can) button. The *Procedure Info* dialog box opens with the following information:

- Procedure Name
- Accession Number
- Procedure Status
- Procedure Start and End Date and Time
- Dose Information (per Breast and Cumulative)

For procedures that contain no exposed views, select the **Delete Procedure** button to remove the selected procedure from the patient. Select **Return to Procedure** to exit the dialog box.

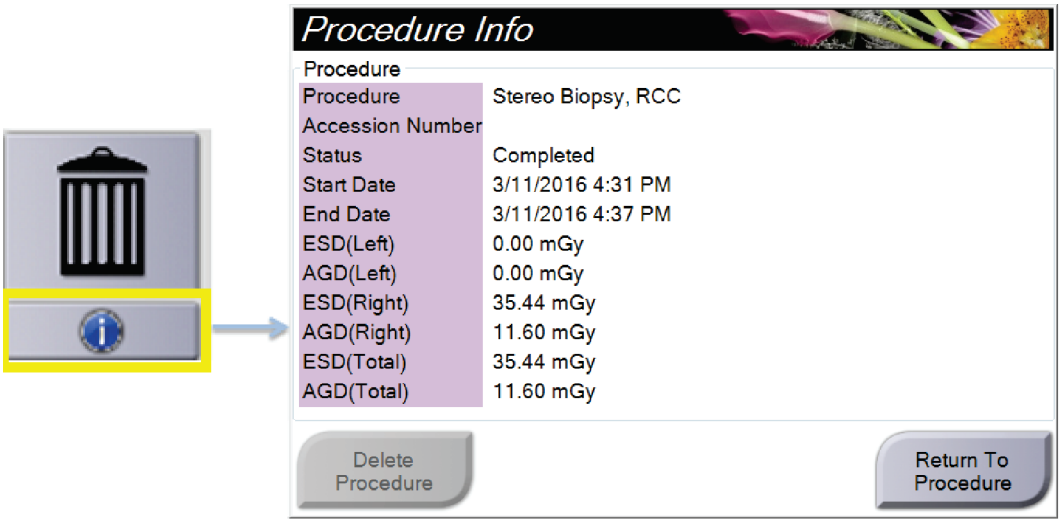
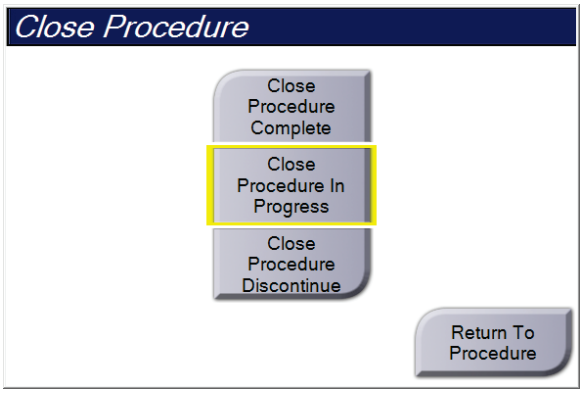


Figure 23: The Procedure Info Window

5.4.7 Close a Patient

Select the **Close Patient** button. If images were acquired, a *Close Procedure* dialog box opens. Select one of the following options:



Close Procedure Complete: Closes the procedure and puts the procedure in the **Completed** tab.
Close Procedure In Progress: Closes the procedure and puts the procedure in the **In Progress** tab.
Close Procedure Discontinue: Closes the procedure and puts the procedure in the **All** tab. A dialog box opens and you must select the reason the procedure was discontinued from a list or add a new reason.
Return To Procedure: Returns to the procedure.

5.5 How to Access the Image Review Features

Select the **Tools** tab on the *Procedure* screen to access the image review features. Refer to *The Image Review Tools Tab* on page 74 for information.

5.6 How to Access the Biopsy Options

Select the **Biopsy** tab on the *Procedure* screen to access target information and biopsy options. Refer to *Biopsy Tab* on page 79 for information.

5.7 Output Groups

The accepted images are sent automatically to the output devices in the selected Output Group. The system configuration controls if the images are sent after a patient is closed or after the image is accepted.

Note
Tomosynthesis images are not sent to a print device in the selected Output Group. You can print selected tomosynthesis images from the *Print* screen.

5.7.1 Select an Output Group

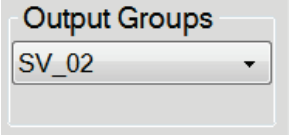


Figure 24: Output Groups Field

Select an output device group like PACS, Diagnostic Workstations, CAD devices and printers from the Output Groups drop-down list in the *Procedure* screen.

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

5.7.2 Add or Edit an Output Group

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

To add a new Output Group:

1. Access the *Admin* screen.
2. Select the **Manage Output Groups** button.
3. Select the **New** button, enter the information, then select the output device(s).
4. Select **Add,** then select **OK** in the *Update Successful* message.
5. You can select any group to set as the default.

To edit an Output Group:

1. Access the *Admin* screen.
2. Select the **Manage Output Groups** button.
3. Select the **Edit** button, then make the changes.
4. Select **Save**, then select **OK** in the *Update Successful* message.

5.7.3 Custom Output

The Custom Output Group option lets you make an output group from the *Procedure* screen. The custom output group that you make stays as the Custom option until another custom output group is made.

To make a Custom Output Group from the *Procedure* screen:

1. In the *Procedure* screen, select **Custom** from the Output Groups drop-down list.
2. In the *Output Group* dialog box, select from the list of available devices, then select **OK**.

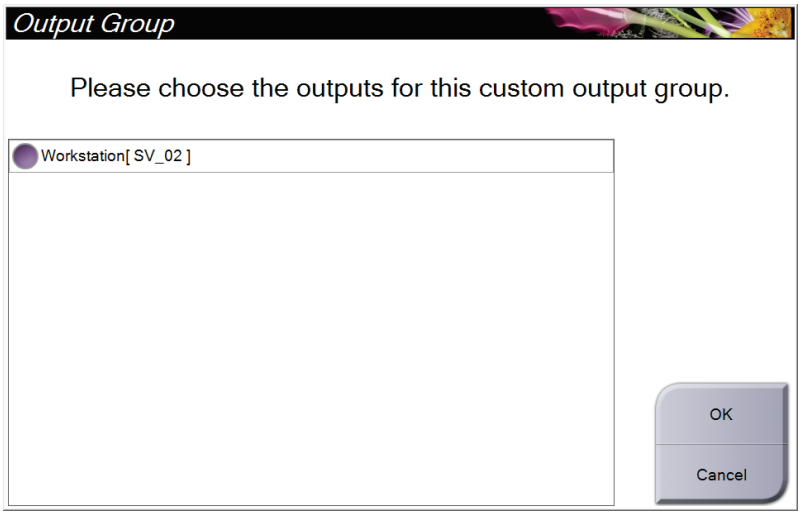


Figure 25: An Example Custom Output Group

5.8 On-Demand Outputs

The On-Demand Outputs are **Archive/Export** or **Print**. You can manually Archive, Export, or Print the currently opened patient until the procedure is closed.

When you select an **On-Demand Output** button, you have the option to send images from the patient that is open to any of the configured output devices.

5.8.1 Archive

1. Select the **Archive/Export** button.
2. Select the procedure or views in the *On Demand Archive* screen:
   - **Select All** button selects all items that show in this screen.
   - **Clear** button deselects items that are selected in this screen.
   - **Priors** button shows previous procedures and views for this patient.
   - **Rejected** button shows rejected views for this patient.
3. Select a storage device:
   - Select the **Device List** button and make your selection from the options in the *Storage Device* drop-down menu.

   -OR-

   - Select an output group from the *Output Group* drop-down list.
4. Select the **Archive** button to send the selected images to the selected archive.

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

5.8.2 Export

1. In the *Procedure* screen, select the **Archive/Export** button. The *On Demand Archive* screen opens.
2. Select the images to export, then select the **Export** button.

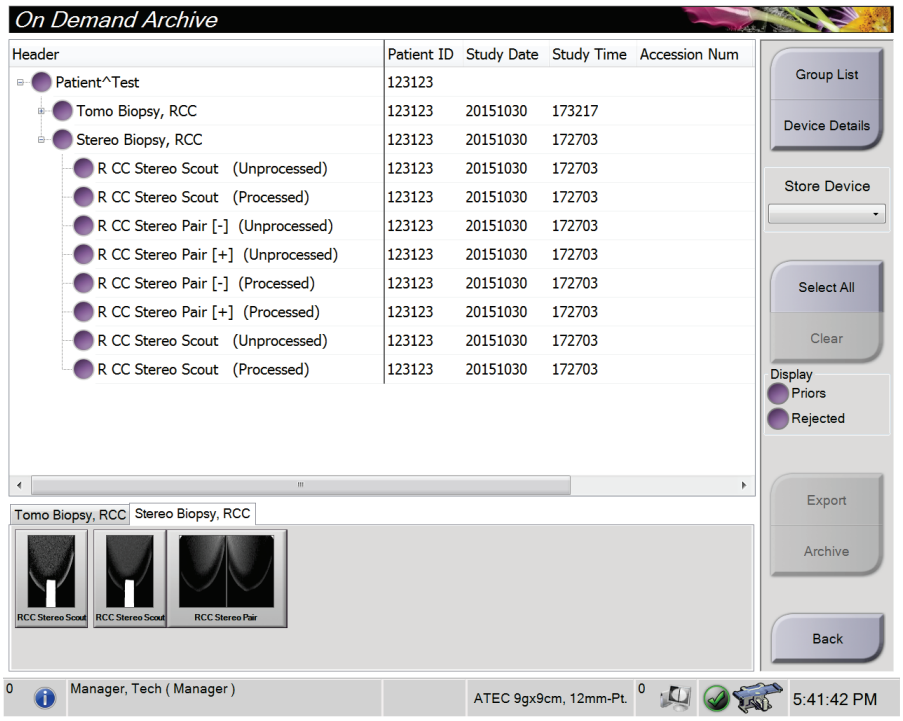


Figure 26: On Demand Archive Screen

3. In the *Export* dialog box, select the target from the drop-down list of media devices.

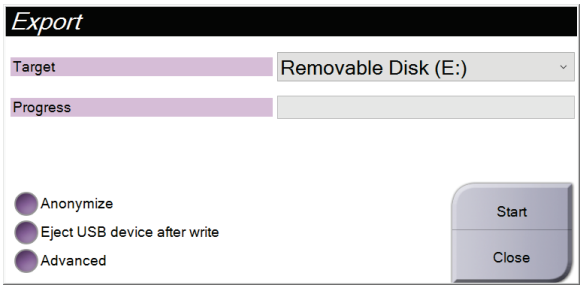


Figure 27: Export Dialog Box

- To anonymize patient data, select **Anonymize.**
- 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**.

4. Select the **Start** button to send the selected images to the selected device.

5.8.3 Print

1. From the *Procedure* screen, select the **Print** button to open the *Print* screen. See the figure *The Print Screen* on page 56 to prepare your print data.
2. Select the film format from the film format area of the screen (item 11).
3. Select a thumbnail image.
4. Select the image mode: Conventional, Projection, or Reconstruction (item 8).
5. Select the Print Preview area (item 16) in the *Print* screen. The image that shows in this area is the image that prints on the film.
6. To put other images on the same multi-format film, repeat steps 3 through 5.
7. To print a different film format of the same images, select the **New Film** button (item 12), then complete steps 2 through 6.
8. Use the buttons in the top left area of the *Print* screen (items 1-6) to hide or show patient data, markings and annotations, and to change the orientation of the image.
9. Select the **Print** button to print your films.

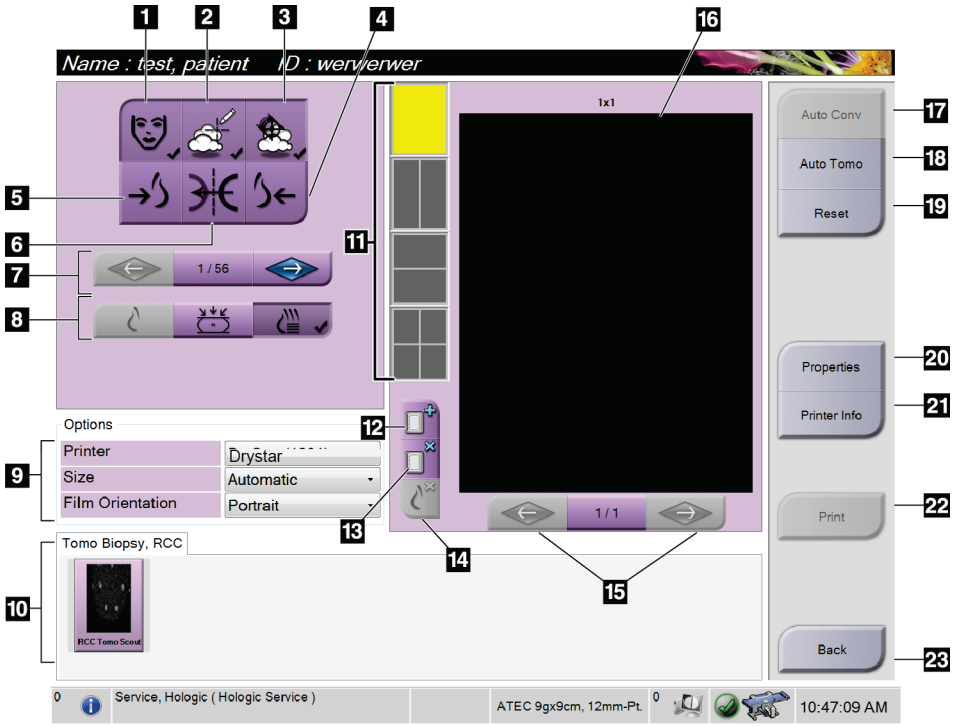


Figure 28: Print Screen

Figure Legend

1. Show or hide patient data.
2. Show or hide markings and annotations.
3. Show or hide targets in images from a biopsy.
4. Print the image from a dorsal perspective.
5. Print the image from a ventral perspective.
6. Reverse (mirror) the image.
7. Go to the previous or next tomosynthesis slice or projection (Tomosynthesis option).
8. Select Conventional, Projection, or Reconstruction views (Tomosynthesis option).
9. Select the printer options.
10. View thumbnail images.
11. Select the film format (number of tiles).
12. Create a new film.
13. Delete a film.
14. Delete an image from a film.
15. Step through the film pages.
16. Print preview area.
17. Print Conventional with the default setup.
18. Print tomosynthesis images (slices or projections) Tagged for Print (Tomosynthesis option).
19. Return the *Print* screen to default settings.
20. Open the *Properties* screen.
21. Show the printer IP address, AE Title, Port, and capability for True Size print.
22. Start the print process.
23. Return to the *Procedure* screen.

Printing Stereo Pair Images

When you select a stereo pair from the thumbnail images in the *Print* screen, the image mode buttons change.

- Select the -15 button to show that stereo image in the display area.
- Select the +15 button to show that stereo image in the display area.
- Select the middle button to make a 2-up horizontal film with the +15 degree image on top and the -15 degree image on the bottom.

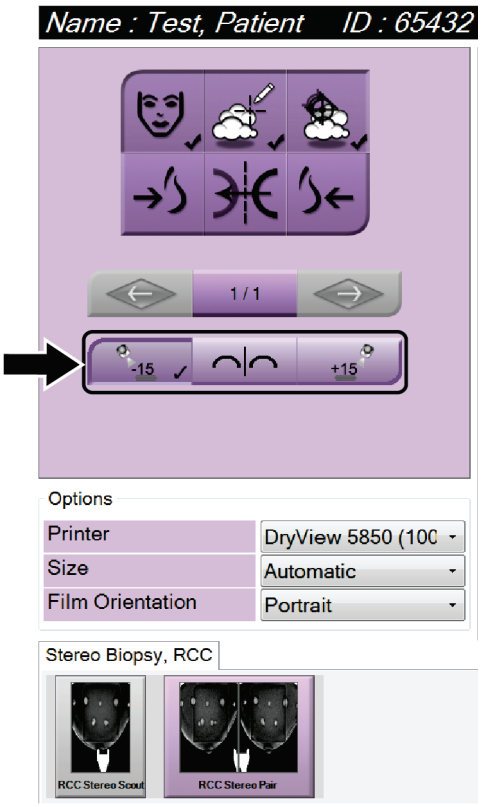


Figure 29: Stereo Pair Print Screen

Chapter 6: User Interface - Biopsy Control Module

6.1 Biopsy Control Module Screens

6.1.1 Home Screen

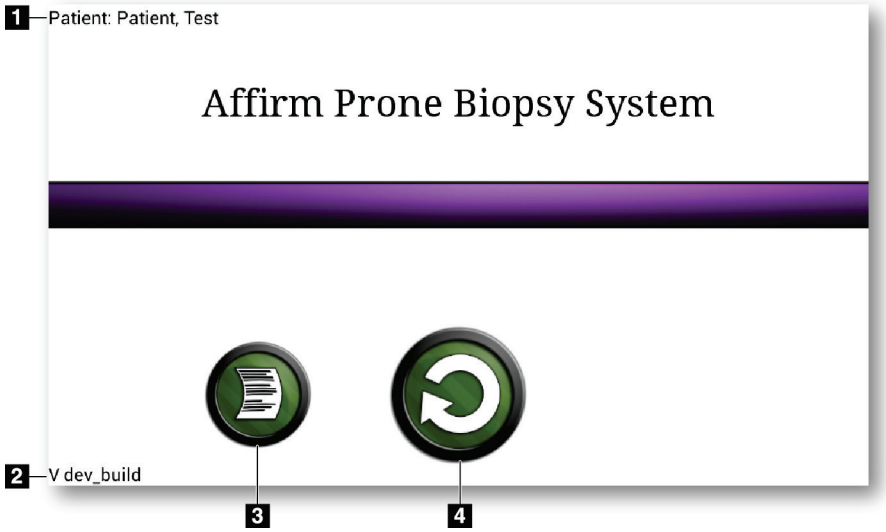


Figure 30: Home Screen

Figure Legend

1. Patient Name
2. Biopsy Control Module Version Number
3. Go to the *Log Viewer* screen
4. Go to the *Target Guidance* screen

6.1.2 About the Taskbar for the Biopsy Control Module

The taskbar at the bottom of the screen shows additional information about the C-arm and the system.

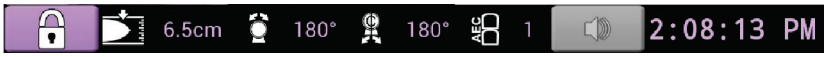


Figure 31: Taskbar for the Biopsy Control Module

Biopsy arm lock status

Compression thickness

Tubehead position

C-arm position

AEC Sensor position

Sound

6.1.3 Target Guidance Screen

The *Target Guidance* screen is the main screen for the biopsy control module. This screen shows the current position of the biopsy device, the selected target coordinates, and the Cartesian difference between the two positions. The screen also shows the safety margins, the system status, and the biopsy device installed on the system. The left side of the display has a 3-D depiction of the current system state.

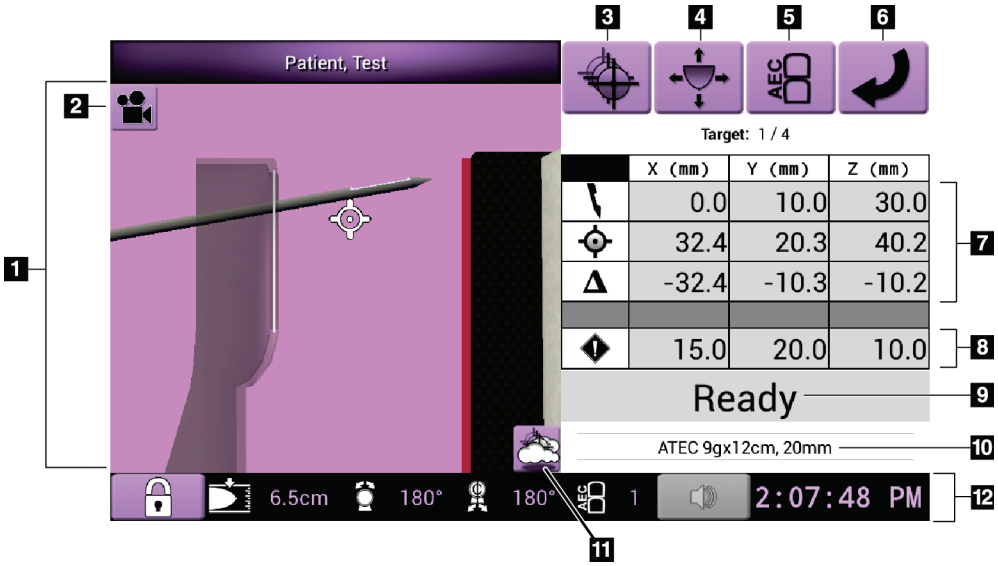


Figure 32: Target Guidance Screen

Figure Legend

1. 3-D Navigation Viewer
2. Change View button
3. Go to the *Select Target* screen
4. Go to the *Jog Mode* screen
5. Go to the *AEC Adjust* screen
6. Go to the previous screen
7. Target information
8. Safety margins
9. System status
10. Selected biopsy device
11. Show or hide target points
12. Taskbar

Colored Cells in the Screens

Green Cells

When all Differential cells are **Green**, the biopsy device is in the correct position for the selected target. When the biopsy device is fired, the target is at the center of the aperture of the device.

Yellow Cells

Yellow indicates that the biopsy device is in the correct position for that axis, but you must move the device to the final Z-position. When the biopsy device is in the final Z-position, the yellow cell changes to green.

Red Cells

Red indicates an infringement of a safety margin. The **Sound** button turns red and the system makes repeated beeps. Make adjustments in the axis indicated by red. When the cell is not red, the device is within the safety limits.

The Sound Button

- When a safety margin is exceeded, the icon on the **Sound** button changes to red and the system repeats a beep sound.
- To stop the sound, press the **Sound** button. All system beep sounds are muted, and the icon on the button changes to include the no symbol.
- When you correct the safety margin infringement, the button changes back to normal.
- If you press the button and do not correct the system fault within two minutes, the system beep sounds are enabled automatically.

Select Target Screen

The *Select Target* screen allows the user to select a different target for biopsy guidance or to move to one of the home positions.

To move the biopsy device to one of the targets shown in this screen:

1. Select one of the **Target Coordinates** buttons. The biopsy guidance module returns to the *Target Guidance* screen.
2. Press and hold a **Motor Enable** button pair on one of the Biopsy Control Module cover extensions.

Note
You must simultaneously press both buttons of a **Motor Enable** button pair to start the motor movement.

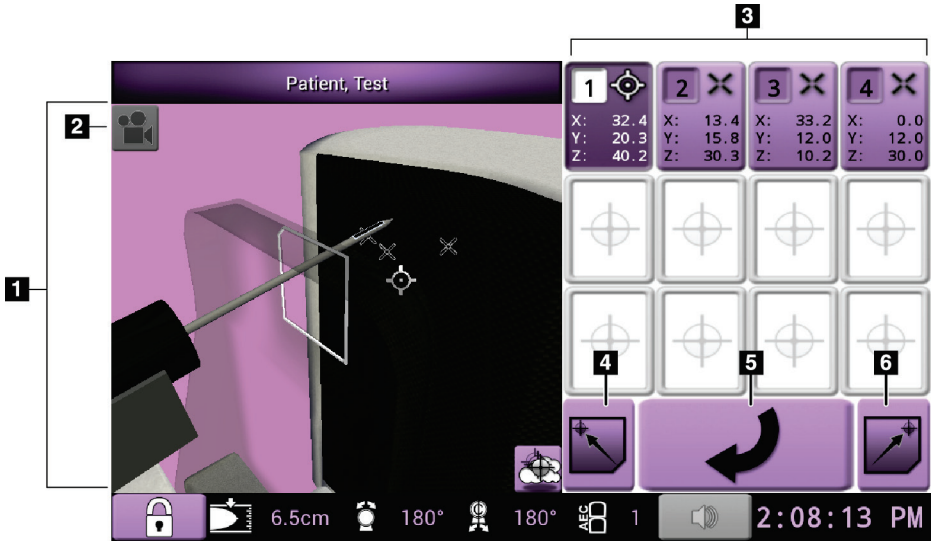


Figure 33: Select Target Screen

Figure Legend

1. 3-D Navigation Viewer
2. Change View button
3. Target coordinates buttons
4. Go to the Home Left position
5. Go to the previous screen
6. Go to the Home Right position

Jog Mode Screen

The *Jog Mode* screen allows the user to manually overwrite the targeting coordinates of the Biopsy Control Module. The arrow buttons in the *Jog Mode* screen change the Jog value of each of the coordinates.

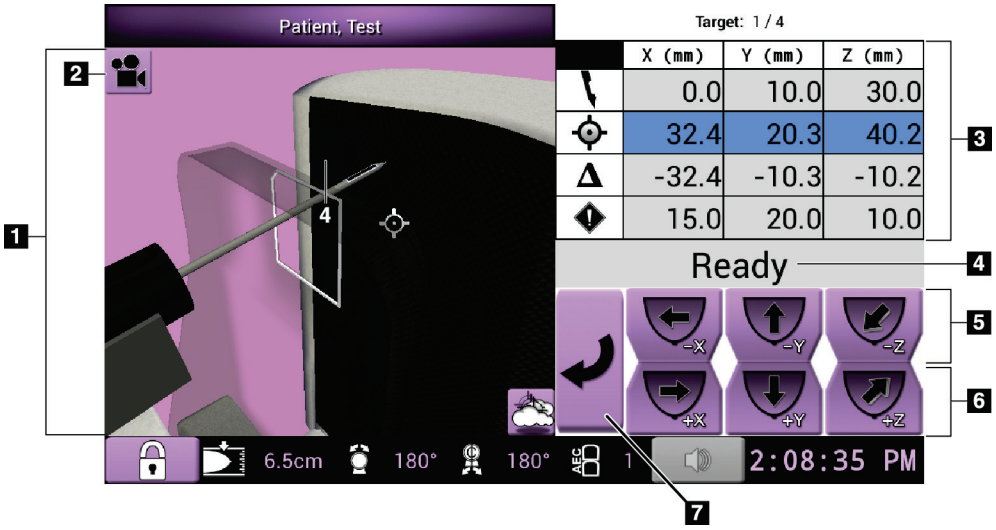


Figure 34: Jog Mode Screen

Figure Legend

1. 3-D Navigation Viewer
2. Change View button
3. Target information
4. System status
5. Change X, Y, and Z-axis Jog values in negative direction
6. Change X, Y, and Z-axis Jog values in positive direction
7. Go to the previous screen

AEC Adjust Screen

The *AEC Adjust* screen allows the user to select the AEC Sensor positions. The AEC Sensor has five manual positions and an automatic position.

Use the plus (+) and minus (-) buttons on the screen to change the sensor position. Auto AEC allows the system to calculate the best exposure for the breast.

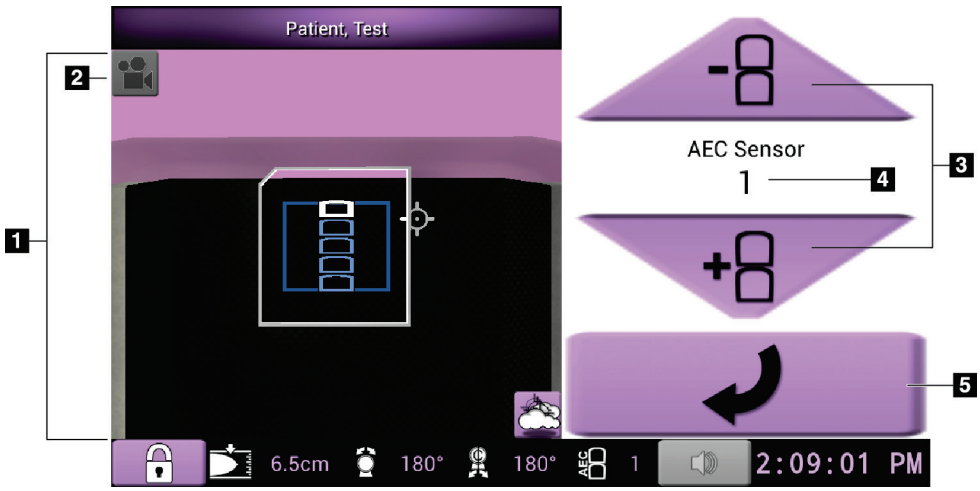


Figure 35: AEC Adjust Screen

Figure Legend

1. 3-D Navigation Viewer
2. Change View button
3. AEC position adjust buttons
4. AEC Sensor position
5. Go to the previous screen

Chapter 7: Images

7.1 Image Display Screen

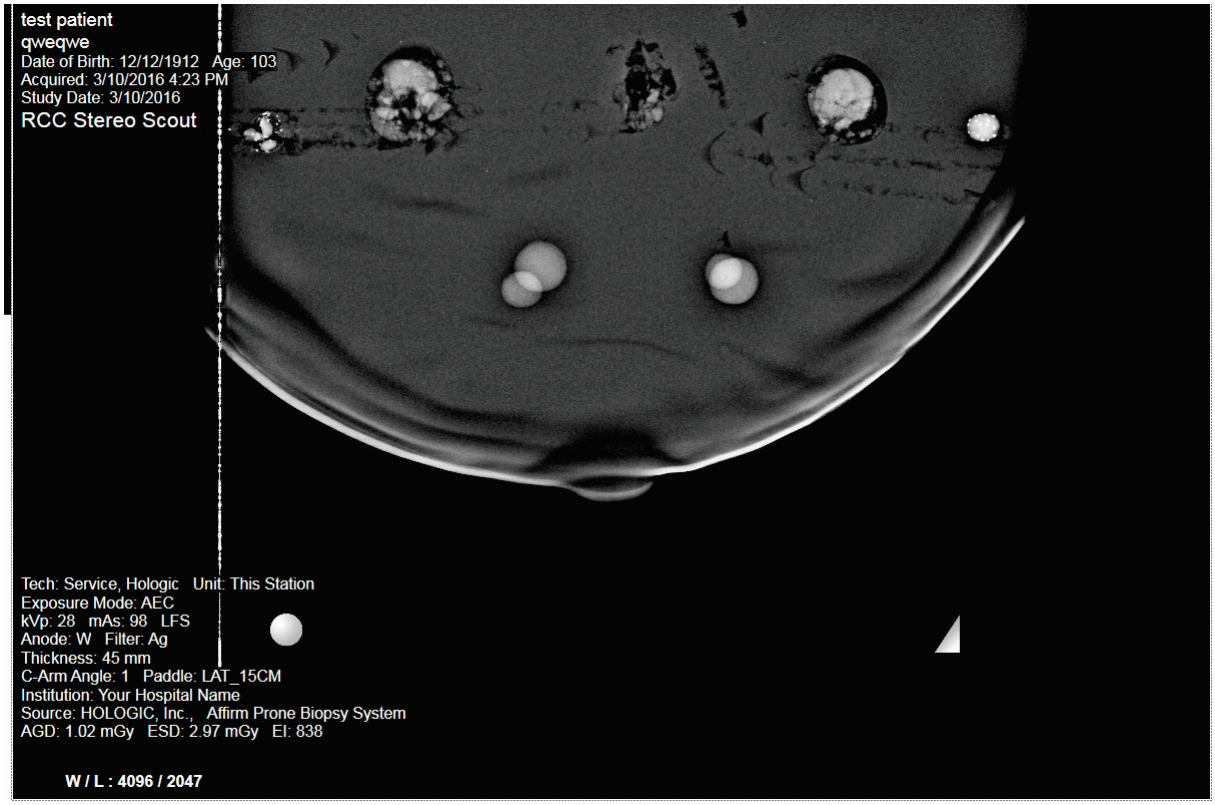


Figure 36: Image Display Screen

After you make an exposure, the acquired image opens on the Image Display monitor. The image is always oriented with the chest wall at the top of the screen and the nipple pointing down.

Patient and procedure information can be displayed on the *Image Display* screen. The top corner of the image shows patient information and the exam date. The bottom corner of the image shows procedure information including: exposure mode, patient dose, compression thickness, C-arm angle, and facility and technologist information. To turn the information on or off, go to the **Tools** tab and select the **Patient Information** button.

7.1.1 Conventional Imaging Sequence of Events

- Review the image after the exposure and add a comment, if necessary.
- Accept or Reject the image. A thumbnail image appears in the Case Study area of the screen.

Note
A manager user can configure the system to Auto-Accept new images.

- If you select the **Reject** button, an "X" appears on the thumbnail image.

7.1.2 Tomosynthesis Imaging Sequence of Events

- Wait for the image reconstruction to complete.
- Accept or Reject the images.

Note
A manager user can configure the system to Auto-Accept new images.

7.2 How to Set the Exposure Parameters

7.2.1 Select the Exposure Mode

Use the Automatic Exposure Control mode (AEC) to let the system control the exposure techniques. AEC modes are available from 20-49 kV.

- Manual — The user selects the kV, mAs, and Filter.
- AEC — The system selects the kV, mAs, and Filter.

7.2.2 How to Use the AEC Sensor

The AEC Sensor has five manual positions and an automatic position. The manual positions start at the chest wall edge (position 1) and reach toward the nipple edge (position 5). The automatic position selects two regions within an area that extends from the chest wall to the nipple.

Use the plus (+) and minus (-) keys on the Biopsy Control Module or in the AEC Sensor area of the screen to change the sensor position. You can select Auto AEC to allow the system to calculate the best exposure for the breast.

7.3 How to Acquire an Image

Refer to *Sample Clinical Sequences* on page 109 for information about clinical procedures.

1. On the Control Handle, press the **System Lock** button to lock the C-arm. (The system does not allow x-rays unless the **System Lock** button is on.)
2. At the Acquisition Workstation, select a view from the thumbnail views at the bottom of the screen.
3. Press and hold the **X-ray** button for the full exposure.

   During the exposure:

   - The System Status bar shows the radiation symbol and a yellow background (see the following figure).

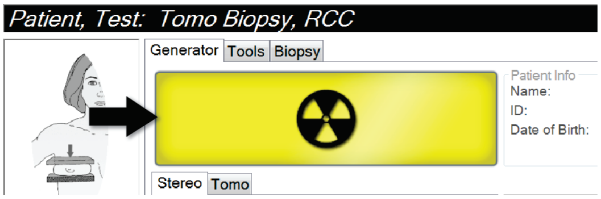


Figure 37: Exposure in Progress

   - An audible tone sounds:

     Scout – X-Ray tone is on continuously during the exposure.

     Biopsy – X-Ray tone is on only during the exposure at -15 and then again at +15 degrees. The X-Ray tone is not on while the Tube Arm is moving from the -15 to +15 degree positions.

     Tomo – X-Ray tone is pulsed along with the exposures – 30 individual X-Ray beeps are heard during the Tomo exposure sequence.

4. When the tone stops and the System Status bar shows **Standby** (see the following figure), release the **X-ray** button.

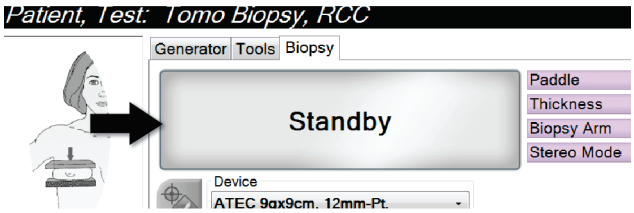


Figure 38: Exposure Complete

5. When the x-ray is finished, the image opens on the Image Display monitor. The *Procedure* screen automatically changes to the **Tools** tab.

   Select one of the following options to complete the acquisition:

   - **Accept** the image. The image transmits to output devices with all attributes and marks. (If Auto-Accept is selected, the **Accept** button is disabled.)
   - **Reject** the image. When the dialog box opens, select the cause for the reject. The *Image Display* screen closes. You can repeat the rejected view or select another view.

6. Repeat steps 2 through 5 for each view.

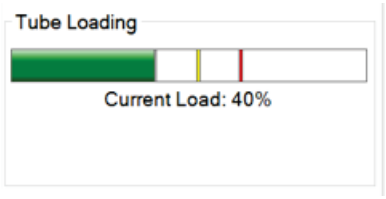
Note
A manager user can configure the system to Auto-Accept new images. Auto-Accept disables the **Accept** button.

7.3.1 Tube Loading Indicator

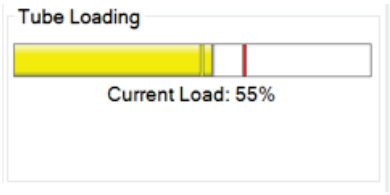
The **Generator** tab of the *Procedure* screen includes a Tube Loading indicator. This indicator shows the current heat load of the X-ray tube.

The Tube Loading indicator displays one of the following three statuses:

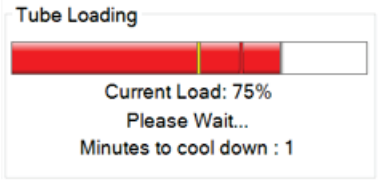
- The X-ray tube heat load is at an acceptable level. The system status icon in the taskbar is green. Continue to acquire images and finish the procedure.



- The X-ray tube heat load is above the warning limit (default = 53%) but below the maximum limit (default = 65%). Finish acquiring the current image, then allow the X-ray tube to cool before finishing the procedure.



- The X-ray tube heat load is above the maximum limit (default = 65%). The system status icon in the taskbar is red and shows the number of minutes required for the X-ray tube to cool. Do not acquire any images. Delay the procedure until the X-ray tube cools.



Caution:
Excessive heat buildup can damage the X-ray tube.

7.3.2 How to Accept a Rejected Image

If a rejected image is better than the new image, you can retrieve and use the old image. Select the thumbnail image on the *Procedure* screen to review the image, then **Accept** the image.

7.3.3 How to Correct and Reprocess Implant Images

You must correct the image if you acquire an implant or an implant displaced view without the **Implant Present** button activated.

If the Image Is Not Accepted

Select the **Implant Present** button on the *Procedure* screen to indicate an implant exists. A check mark appears on the button and the image reprocesses.

If the Image Is Accepted

1. Select the image.
2. Select the **Implant Present** button on the *Procedure* screen to correct the image. A check mark appears on the button and the image reprocesses.
3. Select the **Accept** button to accept the changes.

Note
The corrected image is sent automatically to the selected output devices if the system is set to send images when the **Accept** button is selected.

7.4 How to Review the Images

Review of images involves use of the thumbnails, image review tools, and display modes.

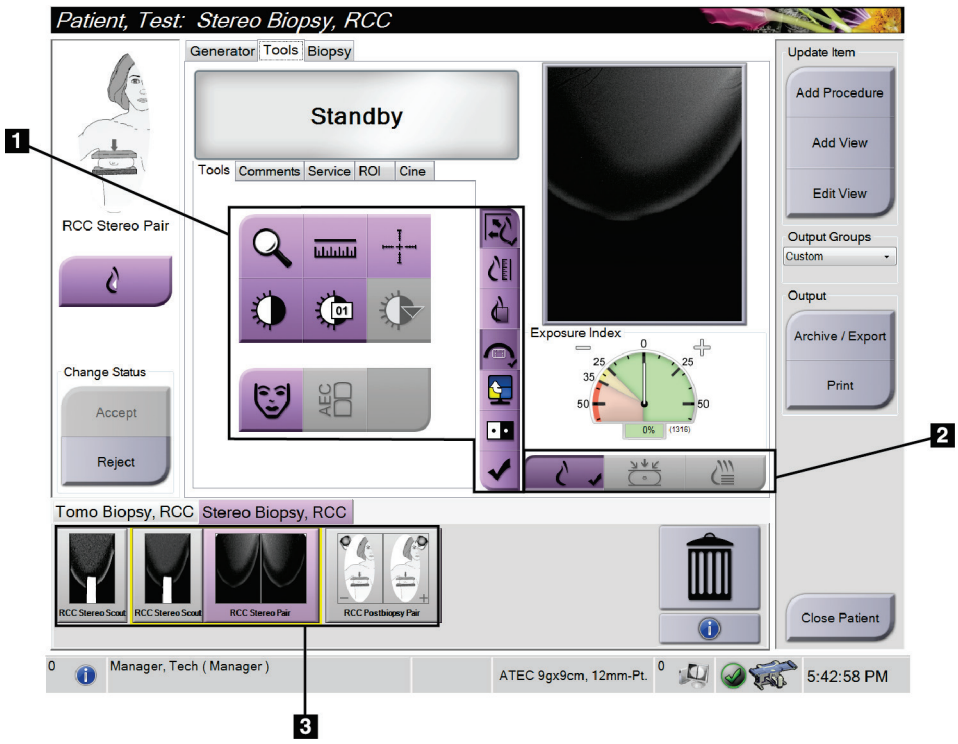


Figure 39: Tools Tab

Figure Legend

1. Image Review Tools - refer to *The Image Review Tools Tab* on page 74.
2. Image Display Modes - refer to *Display Modes (Tomosynthesis option)* on page 75.
3. Thumbnail Views and Thumbnail Images - Select any thumbnail image to display that image on the Image Display monitor.

7.4.1 The Image Review Tools Tab

The **Tools** tab in the *Procedure* screen provides the image review tools. A check mark appears on an active tool.

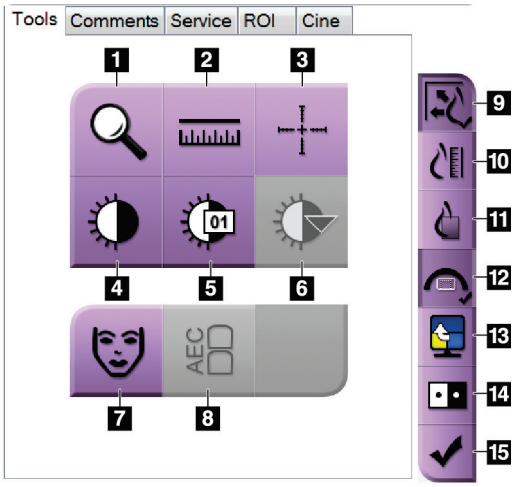


Figure 40: Image Review Tools

Figure Legend

1. The **Zoom** tool magnifies a section of the image.
2. The **Ruler** tool measures the distance between two points.
3. The **Crosshair** tool displays a crosshair on the Image Display monitor.
4. The **Window/Level** tool changes the brightness and contrast.
5. The **Window/Level Fine Adjustment** tool allows the entry of specific window and level values.
6. The **LUT Selection** tool scrolls through available Window/Level settings for a displayed image with LUTs attached.
7. The **Patient Information** button activates the patient information display.
8. The **AEC** button displays the AEC Sensor areas used for the exposure calculation. The sensor areas display on the Image Display monitor.
9. The **Fit-to-Viewport** button fits the image within the image tile.
10. The **True Size** button displays the image in the actual size of the breast.
11. The **View Actual Pixels** button displays the image in full resolution.
12. The **Biopsy View Overlay** button displays the allowable target area.
13. The **Image Tile Advance** button sets the active tile.
14. The **Invert Image** tool changes blacks to whites and whites to black.
15. The **Tag for Print** button tags the projection or reconstruction images of a tomosynthesis image to print later (Tomosynthesis option).

7.4.2 Other Image Review Tools

Other Tabs

- **Comments**: Add comments to an image.
- **Service**: Mark an image for service use.
- **ROI**: Draw a Region of Interest on the Image Display monitor.
- **Cine**: Show a series of images as a movie (Tomosynthesis option).

Exposure Index

The Exposure Index is an image quality guide. When the Exposure Index indicates the red or yellow area, review the selected image for noise and decide whether to reacquire the image.

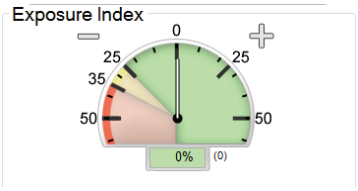


Figure 41: Exposure Index

Display Modes (Tomosynthesis option)

Use the Conventional, Projections, and Reconstruction buttons to select the type of view to display on the Image Display monitor. You can change between conventional, projections, and reconstruction to display the combination images.

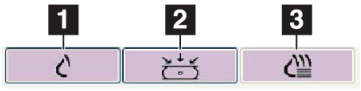


Figure 42: Display Modes

Figure Legend

1. **Conventional** button shows conventional images.
2. **Projections** button shows the 15° images.
3. **Reconstruction** button shows reconstructed slices.

7.4.3 Slice Indicator

The Slice Indicator shows only on tomographic reconstructions.

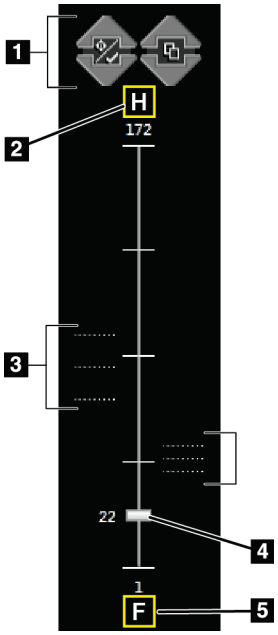


Figure 43: Slice Indicator

Figure Legend

1. Up and Down arrows let you change between slices that contain a lesion target and slices that are tagged for printing.
2. "H" (anatomical reference to head direction)
3. Slices that contain targets or are tagged for printing.
4. Scroll bar moves through the slices of the reconstruction.
5. "F" (anatomical reference to foot direction)

Chapter 8: Biopsy

8.1 Biopsy Approach

The system has the capability to do biopsies from a standard needle approach or a lateral needle approach. When a standard needle approach is not optimal, the lateral needle approach allows the needle to enter the breast parallel to the breast platform and perpendicular to the Compression arm. Lateral needle approach is useful when the thickness of the breast or the location of the lesion makes the standard needle approach impractical.

To make both approaches possible, the C-arm and Biopsy Arm are each capable of a wide angle of movement. The C-arm has a full 180° range of motion and can be positioned at any angle throughout the range of motion. The Biopsy Arm also moves 180° with three detent positions relative to the C-arm. The detent positions are 0°, +90°, and -90° with counterclockwise (from the prone patient point of view) being the positive direction.

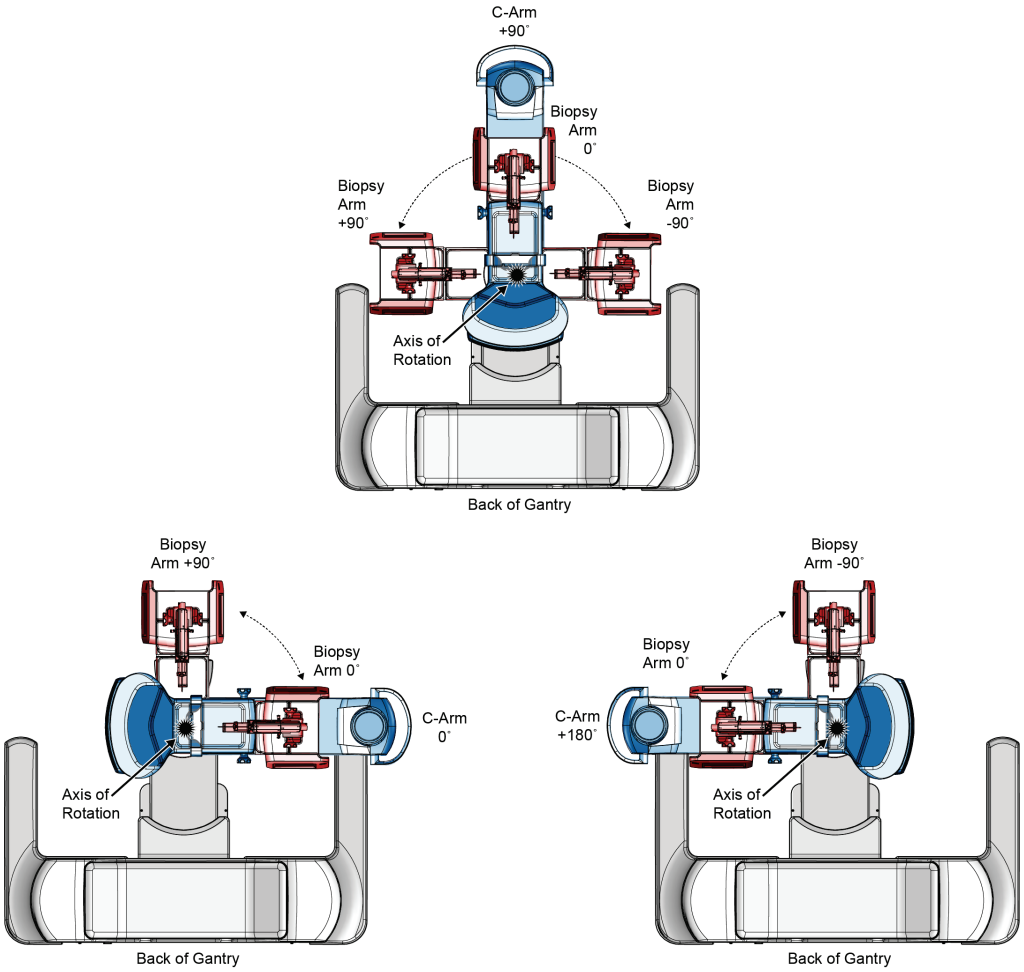


Figure 44: Biopsy Arm Angles of Rotation

8.2 Biopsy Coordinate System

Positive and negative directional movements are in relation to the breast platform. The X direction is the medial-lateral axis (chest wall) with the positive direction to the right of the breast platform. The Y direction is the chest wall to the nipple axis with the positive direction pointed down. The Z direction is the breast platform to the breast paddle axis with the positive direction pointed away from the breast platform.

The 0, 0, 0 coordinate is located at the center top edge of the breast platform.

- X = 0 at horizontal center of the breast platform
- Y = 0 at the top edge of the breast platform
- Z = 0 at the surface of the breast platform

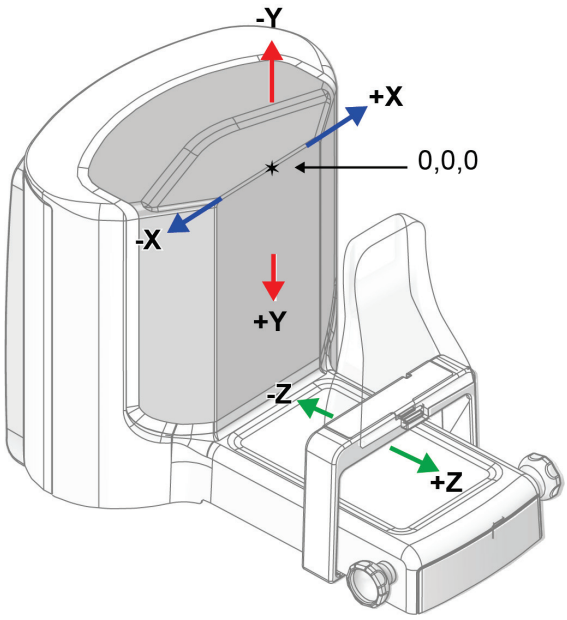


Figure 45: Directional Movement for the X, Y, Z Axes

With a standard needle approach, the biopsy device moves along the Z axis.

With a lateral needle approach, the biopsy device moves along the X axis.

8.3 Biopsy Views

When performing a 2D biopsy procedure, the biopsy guidance system requires stereo views. Stereo views are images taken at +15° and -15° angles. Collectively, these two images are called a stereo pair. The word "stereo" in the biopsy procedures refers to the +15° and -15° projections. The stereo pair images are used to determine the three-dimensional (X-Y-Z) Cartesian coordinates of the region of interest.

When performing a 3D™ biopsy procedure, the biopsy guidance system requires a tomosynthesis image set. The tomosynthesis slice is used to determine the three-dimensional (X-Y-Z) Cartesian coordinates of the region of interest.

8.4 Biopsy Tab

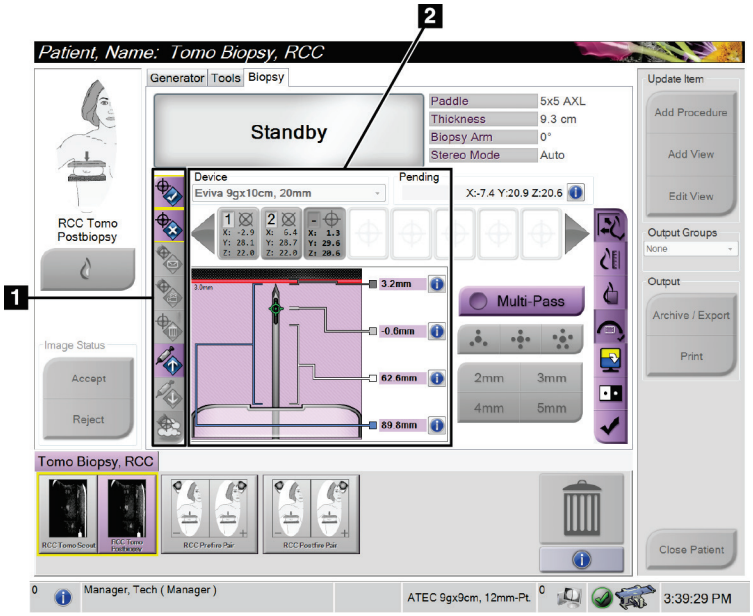


Figure Legend

1. Target Function Buttons
2. Biopsy Options Area

Figure 46: Biopsy Tab

When you select the **Biopsy** tab, the Biopsy Options are displayed. The Biopsy Options area of the screen shows information about the targets and the biopsy device installed on the system. The buttons on the left side of this area let you send selected targets to the Biopsy Control Module. Refer to *Biopsy Options* on page 80 for information about the button functions and data fields on the **Biopsy** tab.

8.4.1 Biopsy Options

The buttons in the Biopsy Options area communicate target information to the Biopsy Control Module. The area on the right side of the buttons shows the selected biopsy device (item 9), the targets (item 10), and the needle position (item 11). Select a target on the Image Display monitor to create a target icon with the target coordinates.

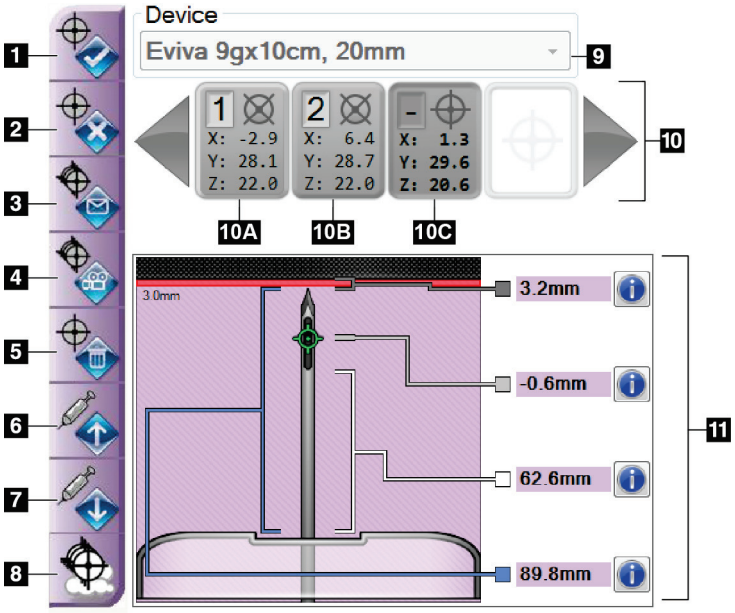


Figure Legend

1. Create Target Button
2. Reject Target Button
3. Resend Target Button
4. Project Target Button
5. Delete Target Button
6. Move Z-Target Positive Button
7. Move Z-Target Negative Button
8. Show/Hide Targets Button
9. Selected Biopsy Device
10. Target Set
11. Status Indicators

Figure 47: Function Buttons and Data on the Biopsy Tab

No.	Description
1.	**Accept Target** accepts the selected target and transfers the target coordinates to the Biopsy Control Module.
2.	**Reject Target** removes the selected target from the target set if that target has not been accepted.
3.	**Resend Target** resends the selected target to the Biopsy Control Module.
4.	**Project Target** shows the selected target on an additional stereo pair on the Image Display monitor.
5.	**Delete Target** deletes the selected target from the target set if that target was accepted.

6.	 **Move Z-Target Positive** moves the final position of the needle toward the Breast Platform and the graphic of the lesion upward. The values for the safety margins change accordingly.
7.	 **Move Z-Target Negative** moves the final position of the needle away from the Breast Platform and the graphic of the lesion downward. The values for the safety margins change accordingly.
8.	 **Show/Hide Targets** shows/hides all targets in the list of targets on the Image Display monitor.
9.	**Device** shows the name of the selected biopsy device that was chosen from the drop-down list.

Warning:
Patient injury can occur if the device you select in the Biopsy tab is not the device that is installed on the system.

10.	**Target Set** displays all the biopsy targets that have been generated and/or accepted in this session. You can generate multiple targets up to a maximum of twelve target points. Use the left and right arrow keys to scroll through the target set if necessary. a. Target #1 - The "1" indicates the target number that has been assigned and is accepted (based on the creation order). A yellow border around the target indicates that it is the active target at the Biopsy Control Module. A single point in the crosshairs indicates that it is a single point target. An asterisk (*) indicates that the target coordinates were later changed at the Biopsy Control Module. b. Target #2 - The "2" indicates the target number that has been assigned and is accepted (based on the creation order). Multiple points in the crosshairs indicate that it is a multiple point target generated by the Multi-Pass feature (refer to *Lesion Targeting Using Multi-Pass* on page 87). c. Target blank - No number indicates that the target coordinates were generated but not accepted (a user has not selected the **Accept Target** button). A single point in the crosshairs indicates that it is a single point target. A depressed target icon indicates that it is the active target *on the user interface*.

Note
The target coordinates displayed on a Multi-Pass target icon represent the center point. Right-click and hold on the target icon to view the coordinates of all of the points.

11.	**Status Indicators** show the distance information: • The distance from the needle tip (post fire) to the breast platform. • The distance of the target from the center of the aperture. • The distance between the Biopsy Paddle and the top of the aperture. • The distance from the Biopsy Paddle to the needle tip. The distance indicator fields change colors with movement of the needle. • Purple indicates that it is safe to proceed. • Red indicates that the current coordinates exceed the safety margin. • Yellow warns of being near the safety limit.

Note
To make a target active, select a target icon from the target set and select the **Resend** button.

8.5 Lesion Targeting in a 2D Biopsy Procedure

Note
You can use the Zoom tool (in the **Tools** tab or **View Actual Pixels** button) to magnify the area of interest in an image.

Note
It is important to confirm that the needle data is entered in the system. To check, go to the *Biopsy Devices* screen and confirm that the needle is listed. If the needle needs to be added, the Needle Validation process must be completed before performing the procedure. Please contact Product Support for the Needle Validation process.

Note
Make sure that the biopsy device is out of the imaging area.

1. Acquire a stereo pair of images.
2. Select the **Accept** button to save the stereo images.

Note
Your Service representative can configure the system to Auto-Accept new images.

3. Click in the area of interest of the lesion in one of the stereo images.
4. Select the other stereo image, then click in the area of interest of the lesion.
5. Select the **Create Target** button to save the target. The active target set automatically transmits to the Biopsy Control Module with the creation of each new target.
6. Repeat this procedure to create multiple targets (a maximum of twelve).

Note
The target that shows on the *Target Guidance* screen of the Biopsy Control Module is the last target created. The target or target set that shows on the *Select Target* screen is the last target or target set sent to the Biopsy Control Module.

Note
To target a lesion, you can also use the Scout and one of the stereo images.

8.5.1 Lateral Needle Approach

Use a lateral needle approach when it is apparent that the lesion is not reachable with a standard needle approach or is close to the breast platform.

1. Position the biopsy device fully back on the Biopsy Arm away from the paddle.
2. Press and hold the **Lock** icon on the Biopsy Control Module taskbar to unlock the Biopsy Arm. After the **Lock** icon changes to unlocked, you can move the Biopsy Arm.

Note
If it is not safe to move into a lateral needle approach, an alarm message shows on the Biopsy Control Module taskbar. Move the biopsy device as needed.

3. Move the Biopsy Arm to the desired side of approach. As the Biopsy Arm moves, watch the Biopsy Control Module taskbar. When the light on the taskbar changes to a green dot, stop moving the Biopsy Arm and hold it in place. The Biopsy Arm detents and locks, and the Biopsy Control Module **Lock** icon automatically changes to locked status.

Note
Depending on the C-arm position, Biopsy Arm movement can be limited.

4. Any active targets are deleted. Follow the steps for lesion targeting to create the new lateral targets.

8.5.2 Verify the Position of the Biopsy Device

If desired, use the following steps to verify the position of the biopsy device.

1. Acquire the pre-fire images as necessary to identify the correct needle position.
   - Verify the needle position.
   - Make adjustments as necessary.
2. If applicable, fire the biopsy device.
3. If desired, acquire the post-fire images.
   - Verify the needle position.
   - If necessary, make adjustments.
4. If desired, acquire specimens with the attached biopsy device.
5. If desired, acquire post procedure images.

8.6 Lesion Targeting in a 3D Biopsy Procedure

Lesion targeting in a 3D™ biopsy procedure requires system licenses for tomosynthesis biopsy.

Note
It is important to confirm that the needle data is entered in the system. To check, go to the *Biopsy Devices* screen and confirm that the needle is listed. If the needle needs to be added, the Needle Validation process must be completed before performing the procedure. Please contact Product Support for the Needle Validation process.

Note
Make sure that the biopsy device is out of the imaging area.

1. Acquire the Tomographic target (scout) image.
   - If your system is set to Auto Accept, the Tomographic target (scout) cine runs briefly and then the system automatically accepts the image.
   - If Auto Accept is not set, the cine stops after two passes through the slice deck (or if the **Accept** button is pressed before the second cine run finishes).
2. Use the scroll wheel to scroll through the slices of the Tomographic target (scout) to find the best view of the lesion.
3. Click on the lesion.
   - A line appears in the Slice Indicator beside the selected slice.
   - The X, Y, and Z values for the target are established automatically at the area of the click.
4. Select the **Create Target** button to save the target. The active target set automatically transmits to the Biopsy Control Module.
5. Repeat steps 2 through 4 to create multiple targets (a maximum of twelve).

Note
The target that shows on the *Target Guidance* screen of the Biopsy Control Module is the last target created. The target or target set that shows on the *Select Target* screen is the last target or target set sent to the Biopsy Control Module.

8.6.1 Lateral Needle Approach

Use a lateral needle approach when it is apparent that the lesion is not reachable with a standard needle approach or is close to the breast platform.

1. Position the biopsy device fully back on the Biopsy Arm away from the paddle.
2. Press and hold the **Lock** icon on the Biopsy Control Module taskbar to unlock the Biopsy Arm. After the **Lock** icon changes to unlocked, you can move the Biopsy Arm.

Note
If it is not safe to move into a lateral needle approach, an alarm message shows on the Biopsy Control Module taskbar. Move the biopsy device as needed.

3. Move the Biopsy Arm to the desired side of approach. As the Biopsy Arm moves, watch the Biopsy Control Module taskbar. When the light on the taskbar changes to a green dot, stop moving the Biopsy Arm and hold it in place. The Biopsy Arm detents and locks, and the Biopsy Control Module **Lock** icon automatically changes to locked status.

Note
Depending on the C-arm position, Biopsy Arm movement can be limited.

4. Any active targets are deleted. Follow the steps for lesion targeting to create the new lateral targets.

8.6.2 Verify the Position of the Biopsy Device

If desired, use the following steps to verify the position of the biopsy device.

1. Acquire the pre-fire images as necessary to identify the correct needle position.
   - Verify the needle position.
   - Make adjustments as necessary.
2. If applicable, fire the biopsy device.
3. If desired, acquire the post-fire images.
   - Verify the needle position.
   - If necessary, make adjustments.
4. If desired, acquire specimens with the attached biopsy device.
5. If desired, acquire post procedure images.

8.6.3 Project Targets on Post-Fire Scout Image

To project targets from the pre-fire tomosynthesis target (scout) onto the post-fire tomosynthesis target (scout), follow these steps:

1. Select the pre-fire tomosynthesis target (scout) thumbnail. The image shows in the bottom half of a 2-Up screen on the Image Display monitor.
2. Select the post-fire tomosynthesis target (scout) thumbnail. The image shows in the bottom half of the 2-Up screen.
3. Select the **Project Target** button in the Biopsy Options area to show the pre-fire targets on the post-fire tomosynthesis target (scout).

8.7 Lesion Targeting Using Multi-Pass

The Multi-Pass feature allows you to automatically generate up to five offset target points all equidistant (up to 5 mm away) from the original target.

Multi-Pass can work with either stereo or tomographic biopsy images.

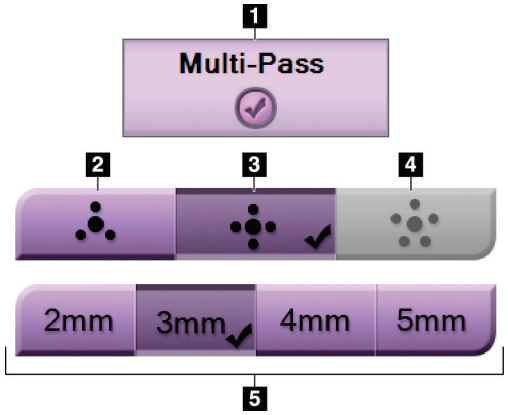


Figure 48: Multi-Pass Options

Figure Legend

1. Multi-Pass Selection
2. Three Offset Points
3. Four Offset Points (default)
4. Five Offset Points
5. Offset Point Distances (3 mm is default)

Note
It is important to confirm that the needle data is entered in the system. To check, go to the *Biopsy Devices* screen and confirm that the needle is listed. If the needle needs to be added, the Needle Validation process must be completed before performing the procedure. Please contact Product Support for the Needle Validation process.

Note
Make sure that the biopsy device is out of the imaging area.

1. Acquire a stereo pair or tomographic image.
2. Locate the region of interest for the lesion. Click on the lesion, either on both stereo images or on the best tomographic slice.
   - A circle with crosshairs displays around the target point.
   - The X, Y, and Z values for the target are established at the lesion.
   - [Tomographic images] A line appears in the Slice Indicator beside the selected slice.
3. Select the **Create Target** button. A target coordinates icon displays on the list of targets.
4. Select the **Multi-Pass** button.
5. Select the number of offset target points (three, four, or five) you require around the center target point.

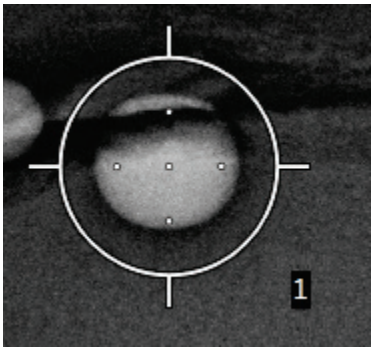


Figure 49: Four Offset Target Points Established Around Center Target Point

Note
Keep in mind that the center target point is included in the total target points. Choosing a "four" offset, for example, generates a total of five target points.

6. Select how far the offset target points are automatically generated from the center target point - 2 mm, 3 mm (the default), 4 mm, or 5 mm.

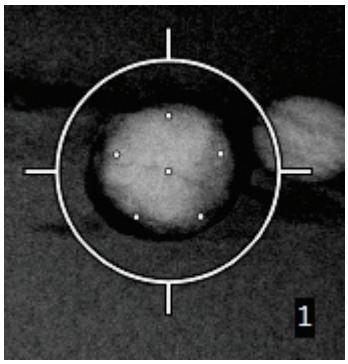


Figure 50: 3 mm Spacing of Offset Points

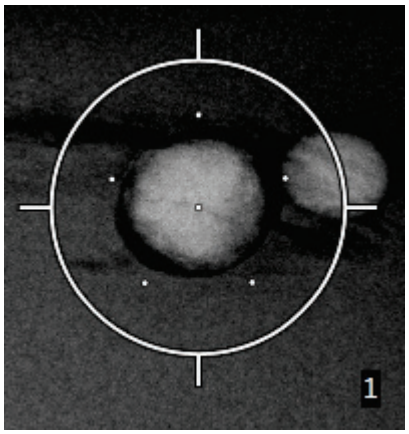


Figure 51: 5 mm Spacing of Offset Points

The crosshairs pattern for the target changes when the target is selected or deselected. See the following figures.

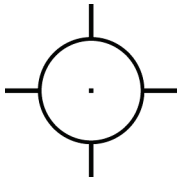


Figure 52: Single Point Target Selected

Figure 53: Single Point Target Deselected

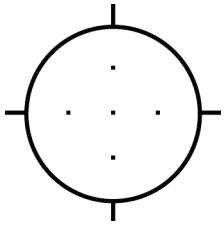


Figure 54: Multi-Pass Target Selected

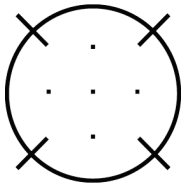


Figure 55: Multi-Pass Target Deselected

7. Select the **Create Target** button to accept the Multi-Pass target. The target becomes the active target coordinates icon on the target set and the coordinates are sent to the Biopsy Control Module.

Note
The coordinates displaying on a Multi-Pass target icon represent the center point. Left-click and hold on the target icon to view the coordinates of all of the points.

Note
A maximum of twelve target points can be generated at any one time. As the number of target points increase in the target set being created, the available Multi-Pass options change to reflect the balance of target points that are available for assignment. For example, in a scenario where seven target points have already been created, then only the "three" and "four" offset target options in Multi-Pass become available. This is because the "three" and "four" offset options are the only ones capable of generating twelve or less target points when totaled with the other seven target points.

8. The biopsy order of the target points is as follows:
   - The number displayed at the bottom right of the crosshairs circle indicates the order between target sets. The first target is labeled "1", the second is "2", and so on. See the following figure.

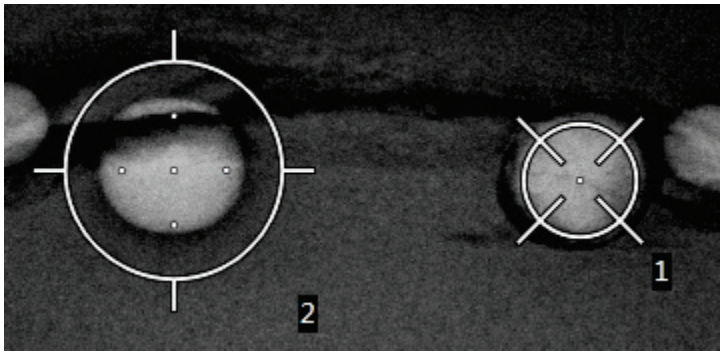


Figure 56: Example of Biopsy Order of Target Sets

   - The order within a Multi-Pass target starts at the center target point. After the center target point, the order moves to the 12 o'clock position and continues clockwise through the offset points. See the following figures.

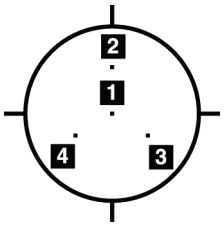


Figure 57: Biopsy Order of a Three Offset Target

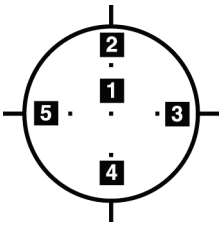


Figure 58: Biopsy Order of a Four Offset Target

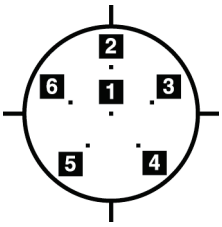


Figure 59: Biopsy Order of a Five Offset Target

9. Verify the position of the Biopsy Device (refer to *Verify the Position of the Biopsy Device* on page 84). If necessary, observe the targets on post-Tomosynthesis scout images (refer to *Project Targets on Post-Fire Scout Image* on page 87).

8.8 Post Biopsy

1. Put in a biopsy site marker, if desired.
2. Move the biopsy device away from the breast.
3. Acquire images as necessary.
4. Release compression.

8.9 2D Wire Localization Procedure

Note
It is important to confirm that the needle data is entered in the system. To check, go to the *Biopsy Devices* screen and confirm that the needle is listed. If the needle needs to be added, the Needle Validation process must be completed before performing the procedure. Please contact Product Support for the Needle Validation process.

Note
Make sure that the biopsy device is out of the imaging area.

Prepare the system and the patient:

1. Open the patient procedure on the Acquisition Workstation.
2. Position and prepare the patient.
3. Acquire a scout image using Auto AEC Mode.
4. Acquire a stereo pair of images.
5. Select the biopsy device (needle) from the drop-down list.
6. Target the lesion or clip.
7. View the biopsy stage pictogram to confirm the ability to place the needle.
8. Create the target and confirm the transmission to the biopsy control module.
9. Place the appropriate needle guides onto the needle guide holders.

Perform the wire localization procedure:

1. Press the **Motor Enable** button to position the stage at the X and Y coordinates.
2. Insert the needle into the needle guides.
3. Move the needle near the patient's skin. If necessary, inject anesthesia.
4. Remove the needle and return it to the sterile tray.
5. Using the Manual Biopsy Device Advance knob, dial and advance the needle guides toward the breast until the differentials for X, Y, and Z are green. Then advance the Z-axis to a -5 mm to -15 mm differential.
6. Reinsert the needle into the needle guides.
7. Advance the needle into the breast until the hub of the needle is resting against the stationary needle guide.
8. If desired, acquire pre-fire images as necessary to identify the correct needle position.
9. Engage the wire. If desired, remove the needle.
10. If desired, acquire post-fire images.
11. Slowly release compression.
12. If required, prepare the patient for the orthogonal views to document placement of the wire or needle.

8.10 3D Wire Localization Procedure

Note
It is important to confirm that the needle data is entered in the system. To check, go to the *Biopsy Devices* screen and confirm that the needle is listed. If the needle needs to be added, the Needle Validation process must be completed before performing the procedure. Please contact Product Support for the Needle Validation process.

Note
Make sure that the biopsy device is out of the imaging area.

Prepare the system and the patient:

1. Open the patient procedure on the Acquisition Workstation.
2. Position and prepare the patient.
3. Acquire a tomosynthesis scout image using Auto AEC Mode.
4. Select the biopsy device (needle) from the drop-down list.
5. Target the lesion or clip on the correct slice.
6. View the biopsy stage pictogram to confirm the ability to place the needle.
7. Create the target and confirm the transmission to the biopsy control module.
8. Place the appropriate needle guides onto the needle guide holders.

Perform the wire localization procedure:

1. Press the **Motor Enable** button to position the stage at the X and Y coordinates.
2. Insert the needle into the needle guides.
3. Move the needle near the patient's skin. If necessary, inject anesthesia.
4. Remove the needle and return it to the sterile tray.
5. Using the Manual Biopsy Device Advance knob, dial and advance the needle guides toward the breast until the differentials for X, Y, and Z are green. Then advance the Z-axis to a -5 mm to -15 mm differential.
6. Reinsert the needle into the needle guides.
7. Advance the needle into the breast until the hub of the needle is resting against the stationary needle guide.
8. If desired, acquire pre-fire images as necessary to identify the correct needle position.
9. Engage the wire. If desired, remove the needle.
10. If desired, acquire post-fire images.
11. Slowly release compression.
12. If required, prepare the patient for the orthogonal views to document placement of the wire or needle.

Chapter 9: Accessories

9.1 Maximum Comfort Package

General instructions for installation and use are given in the table below. For specific instructions for using the Arm Through accessories, see the table *Installation of the Arm Through Max Comfort Package* on page 97.

Table 9: Installation and Use of the Maximum Comfort Package

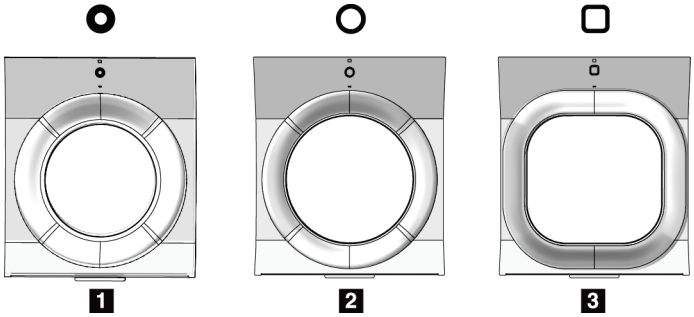
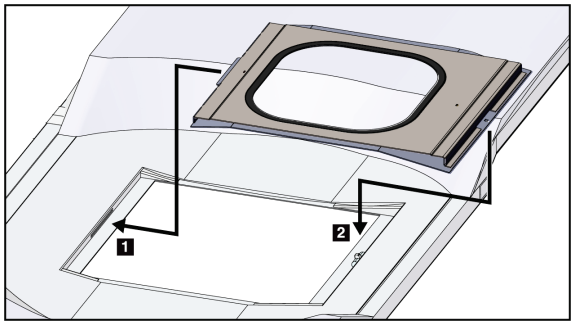
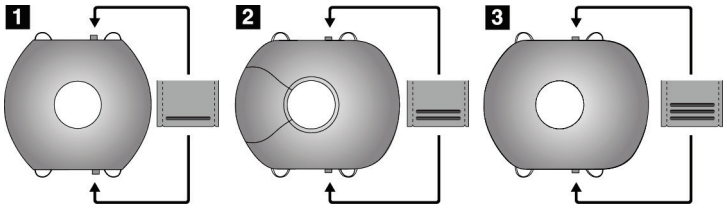
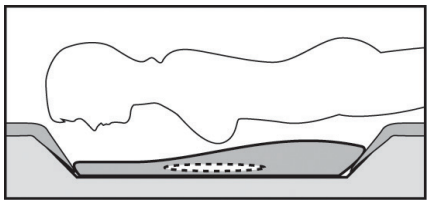
Step	What the step looks like
1. Select the aperture. • item 1 Standard • item 2 Large • item 3 Arm through (see the table *Installation of the Arm Through Max Comfort Package* on page 97).	
2. Install the aperture into the slot in the patient platform (item 1) then lower the aperture into position until the latch fastens (item 2).	
3. Select the aperture cushion. • item 1 Maximum Access • item 2 Standard • item 3 Maximum Comfort 4. Put the tabs by the hip of the patient.	
5. Put the cushion on the patient platform in the correct direction. Position the patient on the patient platform.	

Table 9: Installation and Use of the Maximum Comfort Package

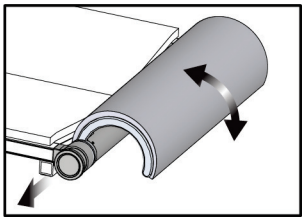
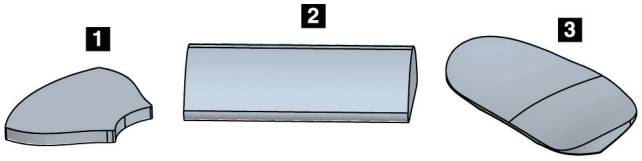
Step	What the step looks like
6. Adjust the footrest. a. Pull and hold the knob on the footrest. b. Adjust the footrest: Rotate the footrest and pull out or push in to the desired position. c. Release the knob to lock the footrest. 7. Repeat for the headrest as needed.	
8. Use additional cushions for support as needed. • item 1 Head cushion • item 2 Wedge cushion • item 3 Hip cushion	

Table 10: Installation of the Arm Through Maximum Comfort Package

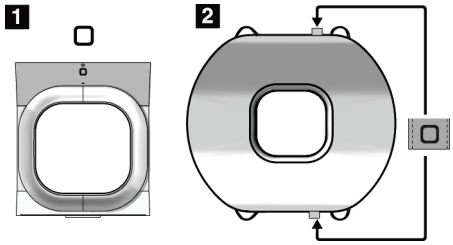
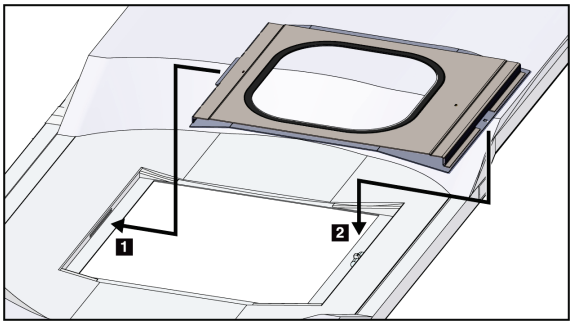
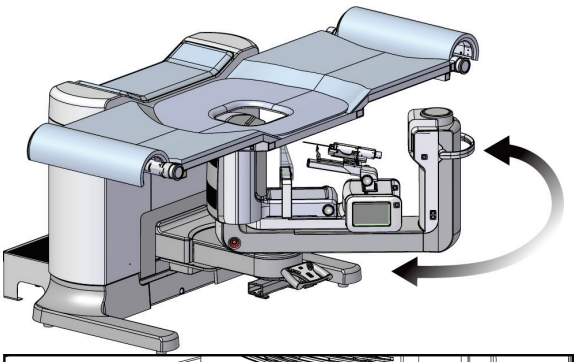
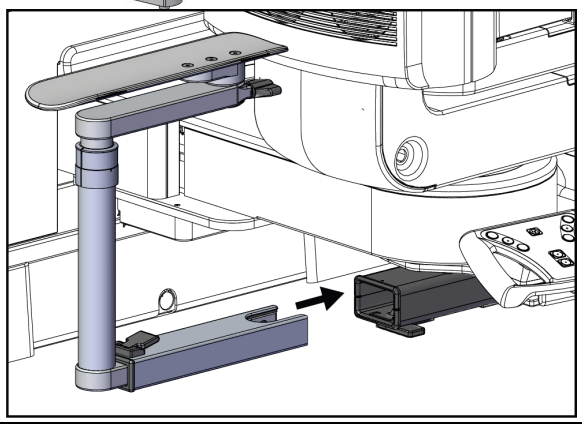
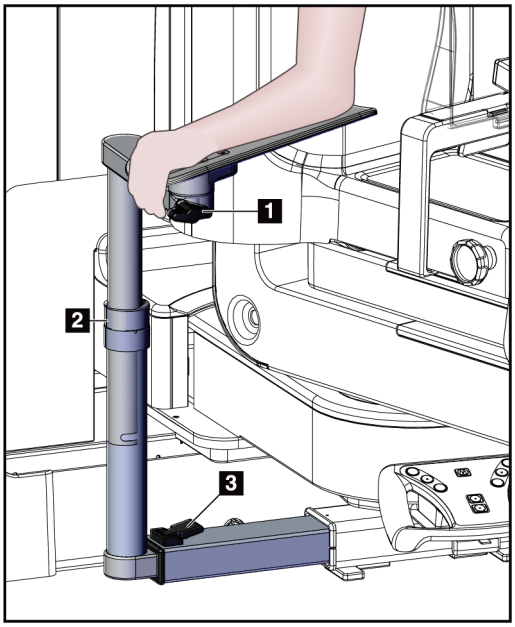
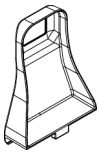
Step	What the step looks like
1. Select the Arm Through accessories. • item 1 Aperture • item 2 Aperture cushion	
2. Install the aperture into the slot in the patient platform (item 1) then lower the aperture into position until the latch fastens (item 2). 3. Install the aperture cushion.	
4. Rotate the C-arm to the approach angle. Install the armrest on the bottom of the C-arm.	 

Table 11: Use of the Arm Through Maximum Comfort Package

Step	What the step looks like
1. Position the patient on the patient platform. 2. Position the arm of the patient on the arm support and lock the support into position. There are three locks: • item 1 Position lock • item 2 Height lock • item 3 Bottom attachment lock	

9.2 Biopsy Paddles



5 x 5 cm Axilla Paddle

5 x 5 cm Biopsy Paddle

6 x 7 cm Biopsy Paddle

15 cm Lateral Paddle

9.2.1 How to Install or Remove a Paddle

How to install a paddle:

1. Move the compression mechanism away from the breast platform.
2. Hold the paddle in one hand with the flat compression side facing the image receptor.
3. Tilt the paddle (between 30 and 45 degrees) toward the image receptor, then put the tabs of the paddle into the slots in the rear of the Compression Device.
4. Compress the Paddle Clamp with your free hand.
5. Rotate the paddle into a vertical position and release the Paddle Clamp to lock the paddle.

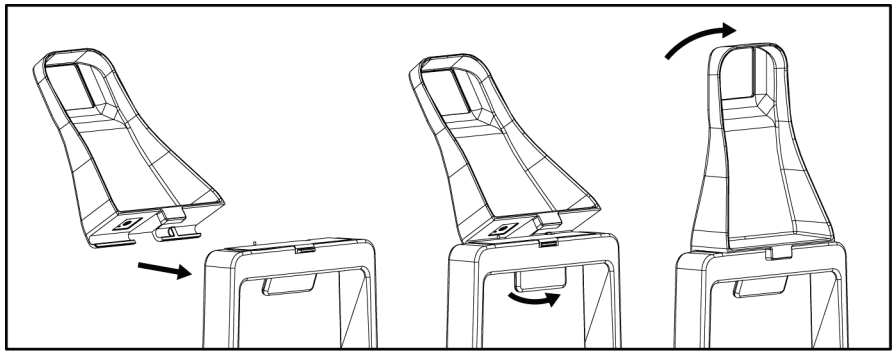


Figure 60: How to Install a Compression Paddle

How to remove a paddle:

1. Move the compression mechanism away from the breast platform.
2. Hold the paddle with one hand. Use the free hand to compress the Paddle Clamp to release the locked paddle.
3. Tilt the paddle toward the image receptor, and pull the paddle away from the Compression Device.
4. Release the Paddle Clamp.

9.3 Biopsy Devices and Components

9.3.1 Needle Guides

Warning:
Always use sterile techniques when you use Needle Guides during the patient procedures.

Warning:
It is important to install the device correctly. Be sure to insert the needle through the Needle Guides.

To install a disposable needle guide:

1. Align the Needle Guide so that the raised-square side of the Needle Guide fits between the two lobes of the Needle Guide Mount.
2. Slide the open area of the U-shape in the Needle Guide around the pin in the Needle Guide Mount.
3. Push the Needle Guide in until it locks into position.

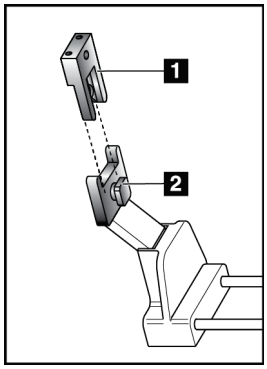


Figure Legend

1. Needle Guide
2. Needle Guide Mount

Figure 61: How to Install the Needle Guides

Note
The Needle Guides can look different from the Needle Guide shown.

To remove a disposable needle guide:

1. Remove the biopsy device.
2. Pull the Needle Guide away from the pin and remove from the Needle Guide Mount.
3. Discard the Needle Guide in accordance with local regulations.

9.3.2 Biopsy Device Adapter

To install a biopsy device adapter:

1. Align the outer holes in the biopsy device adapter (item 1) with the guide pins on the device mount.
2. Align the middle hole in the biopsy device adapter with the mount screw (item 2).
3. Turn the mount knob (item 3) to secure the biopsy device adapter.

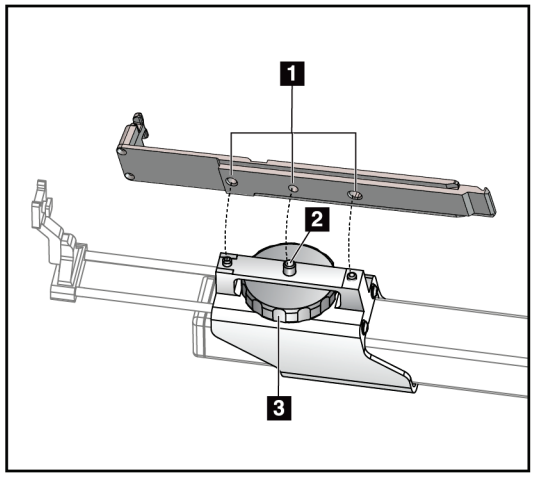


Figure 62: Attach the Biopsy Device Adapter

Figure Legend

1. Biopsy Device Adapter Holes
2. Mount Screw
3. Mount Knob

To remove a biopsy device adapter:

1. Turn the mount knob to release the biopsy device adapter.
2. Pull the biopsy device adapter away from the mount.

9.3.3 Biopsy Device

Warning:
Always apply the device safety and cock the biopsy device before you install the device on the biopsy device mount.

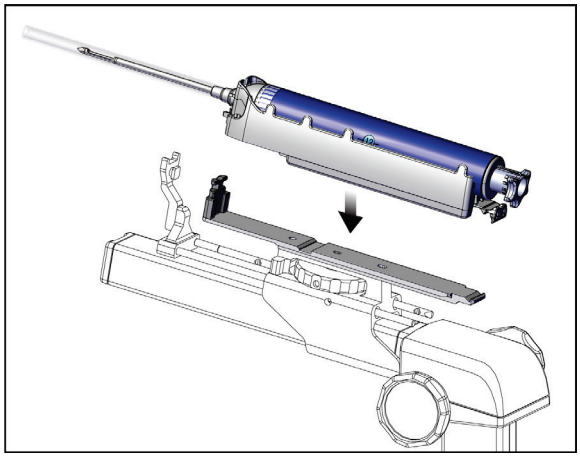


Figure 63: Attach the Biopsy Device

1. Turn the biopsy device knob to move the biopsy device mount fully back.
2. Move the needle guide fully forward.
3. Slide the biopsy device fully into the biopsy device adapter from the rear (open end).
4. Make sure that the needle goes through the hole in the sterile needle guide.

Note
Refer to the biopsy device product information for specific installation instructions.

9.4 Equipment Drape Set

The Drape Set is used to prevent fluids from contaminating portions of the C-arm.

The Drape Set consists of three sections:

- drape for the breast platform (with a clear plastic pocket to cover the paddle mount)
- drape for the biopsy device mount (with a flap section for inside the paddle)
- clear cover for the control panel

Warning:
Change the drapes and the control panel cover after each patient.

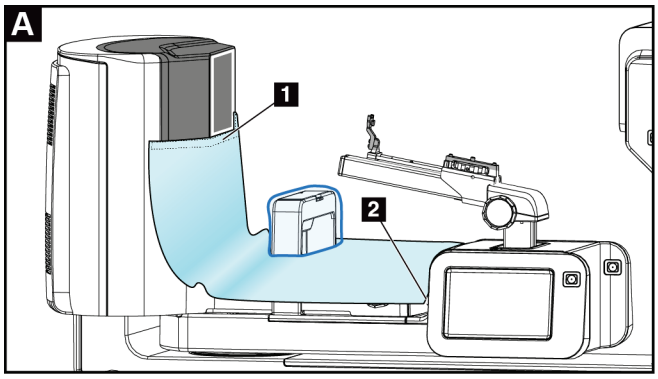
Warning:
Discard the materials as you would any other contaminated material.

Note

Keep in mind the following when installing the drapes:

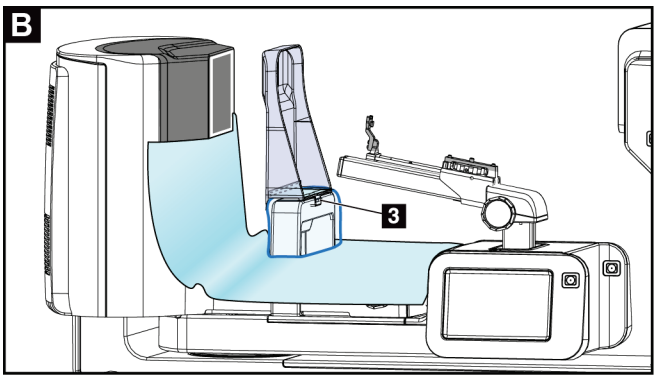
- Install the needle guide holder on the biopsy device mount *before* installing the drapes.
- Install the paddle and biopsy device in the order shown in these illustrations.
- Place the blue (absorbent) side of the drape facing up.

1. Place the drape section for the breast platform on the breast platform and over the paddle mount.
2. Remove the adhesive liner under the drape. Attach the adhesive strip to the image receptor directly below the white square (item 1). Do not cover the white square area.

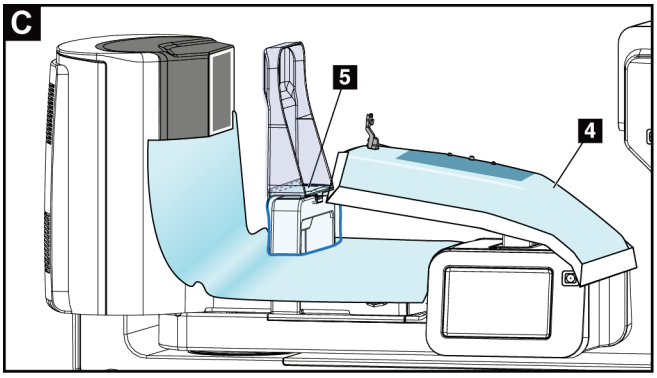


3. Tear off the excess drape at the perforation (item 2) and save for later.

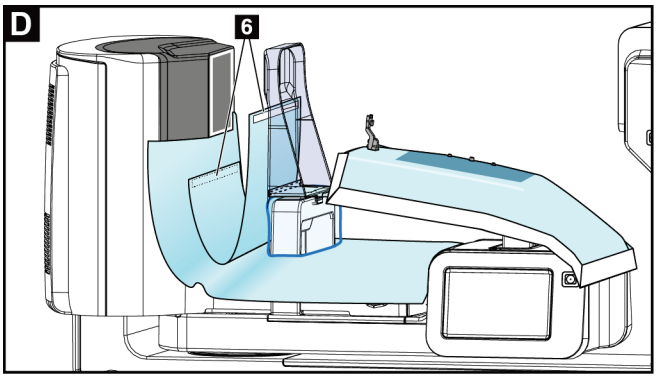
4. Attach the paddle on the paddle mount over the clear plastic pouch section of the drape (item 3).



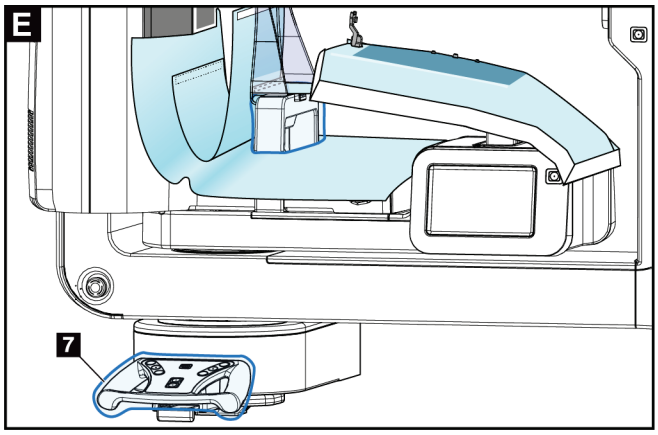
5. Place the drape section for the biopsy device mount over the biopsy device mount (item 4). Make sure that the needle guide holder and the three protrusions on the biopsy device mount line up with the respective openings in the drape.



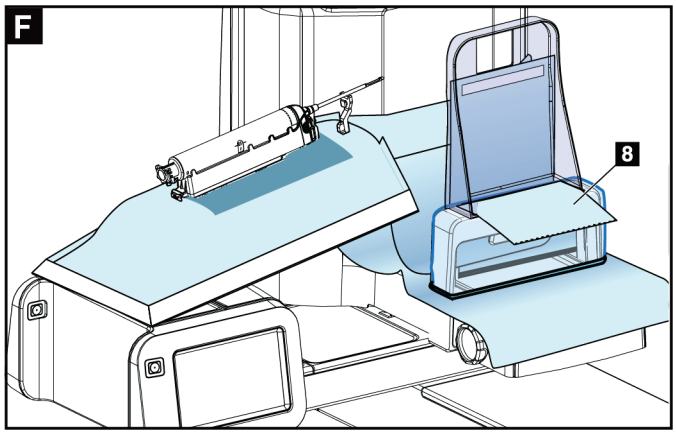
6. Remove the adhesive liner under the paddle side of the drape. Attach the drape edge to the inside edge of the paddle along the paddle mount side (item 5).
7. Locate the torn off piece of the breast platform drape section, and place it between the paddle and the breast platform.
8. Remove the adhesive liner on the paddle side of the drape piece. Attach the edge of the drape piece to the paddle below the paddle opening (item 6).



9. Remove the adhesive liner on the breast platform side of the drape piece. Attach the edge of the drape piece to the drape on the breast platform (item 6).
10. Install the clear cover (item 7) over the control panel.



11. To use a lateral needle approach, the biopsy device mount drape can be divided into two sections. Separate the drape at the perforation between the biopsy device and the paddle (item 8).



9.4.1 Symbols

This section describes the Symbols on the Drape Set.

Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer	QTY	Quantity		Follow operating instructions
	Date of Manufacture	LOT	Batch code		Do not re-use
REF	Catalog number	EC REP	Authorized representative in the European community	NON STERILE	Non-sterile

9.5 Accessory Cart

9.5.1 Pad Hangers

The system is equipped with four aperture pads. The accessory cart includes two hooks (pad hangers) to hang the pads.

To install the pad hangers:

A mounting bracket is affixed to the inside of the accessory cart. The pad hangers are installed in the two outer mounting holes on the mounting bracket (see the following figure).

Firmly push each pad hanger (item 1) over the top edge of the mounting bracket. Continue pushing each pad hanger down until the two hanger tabs engage fully (item 2) inside the circular mounting hole.

Note
Some force is required to push the pad hangers into their locking position. Contact the facilities department of your organization if you need assistance.

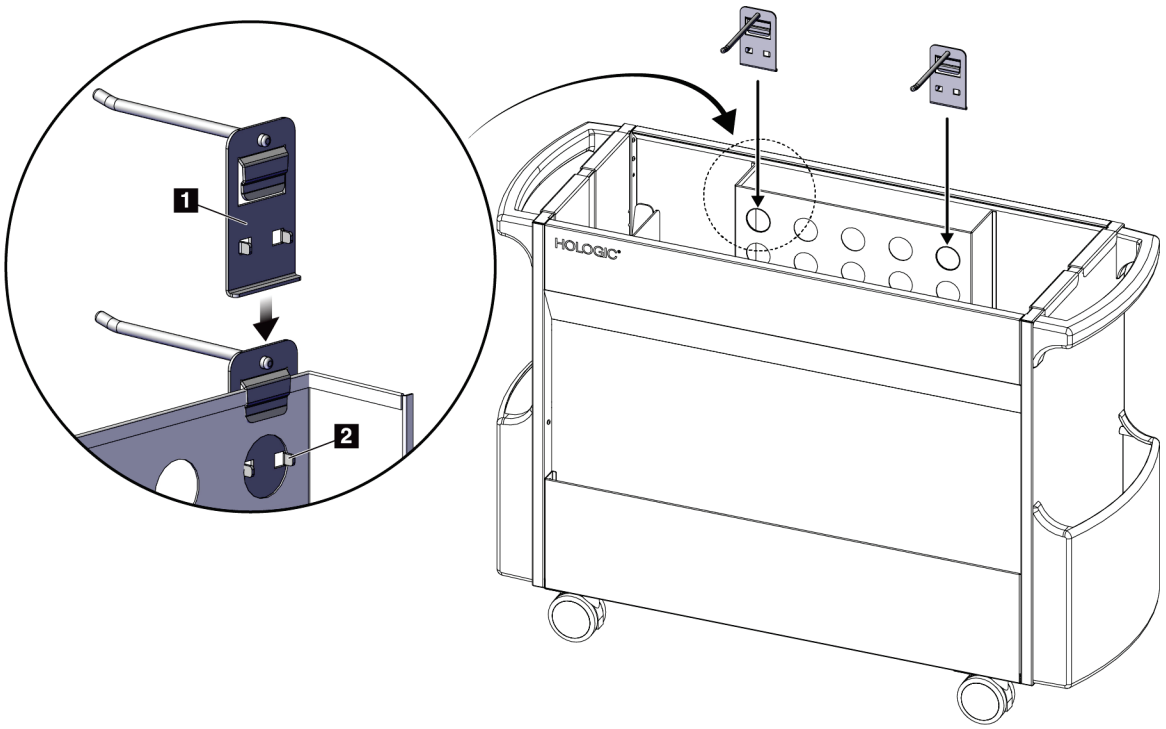


Figure 64: Pad Hanger Installation

9.5.2 Paddle Holders

The system is equipped with four paddles. The accessory cart includes a paddle holder for each of the paddles.

To install the paddle holders:

Slide the paddle holders over the narrow sides of the cart. The pockets of the paddle holders go inside the cart (see the following figure). Item 1A shows the paddle holders moving into position; item 1B shows the paddle holders in place.

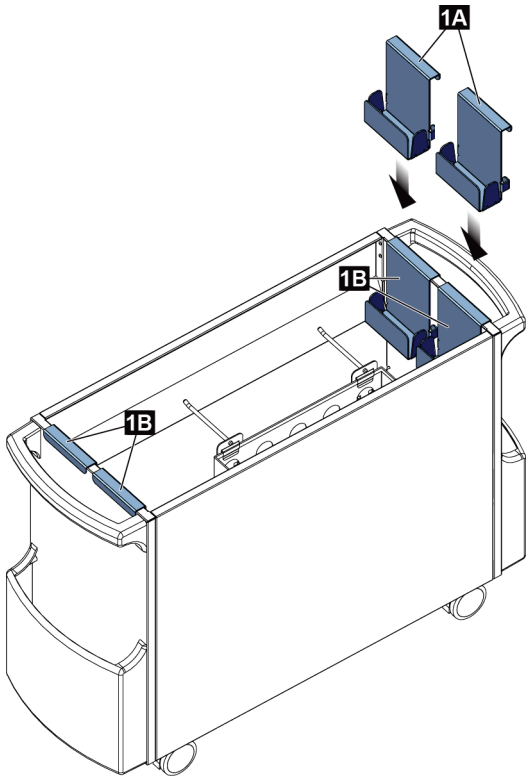
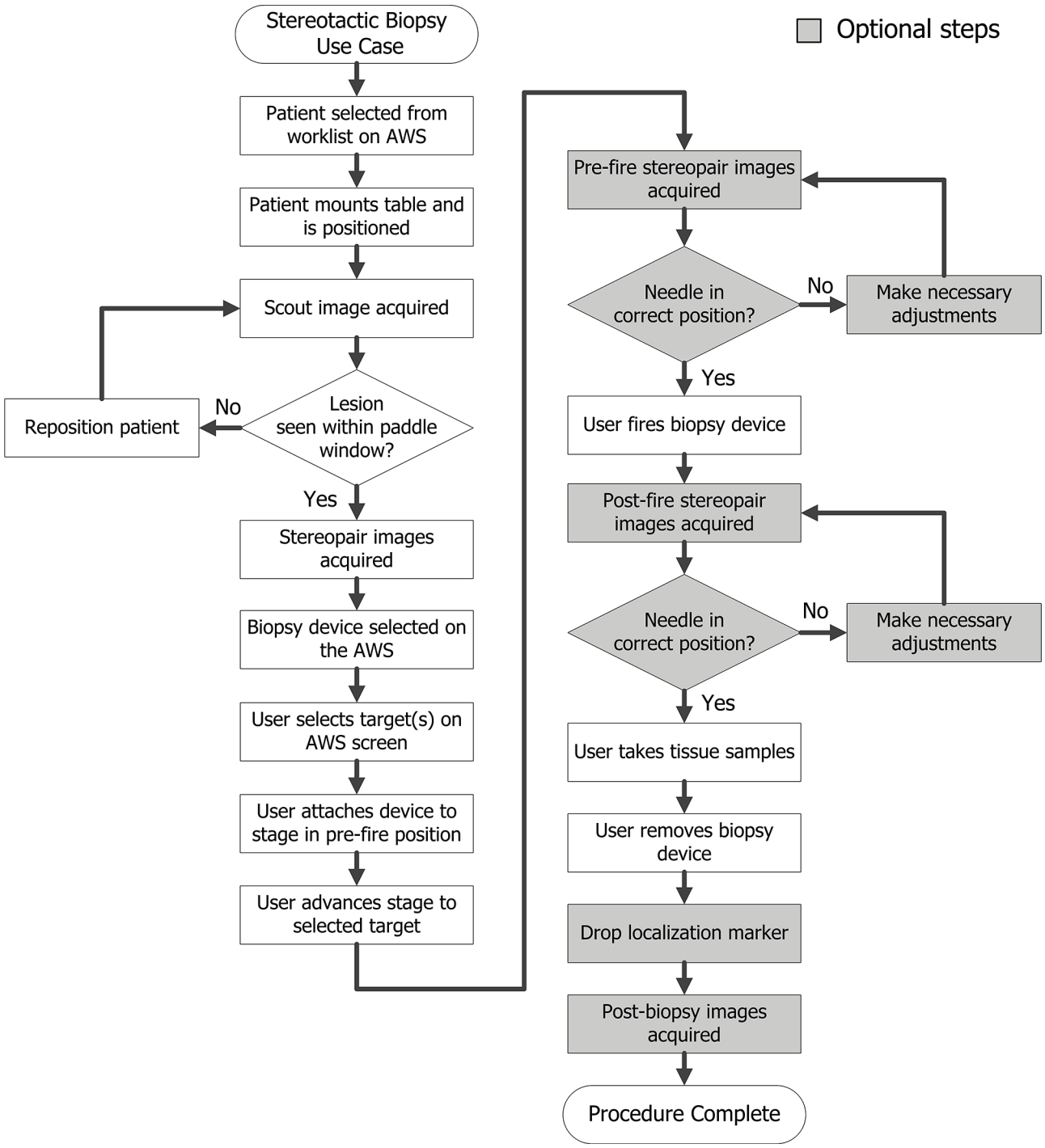


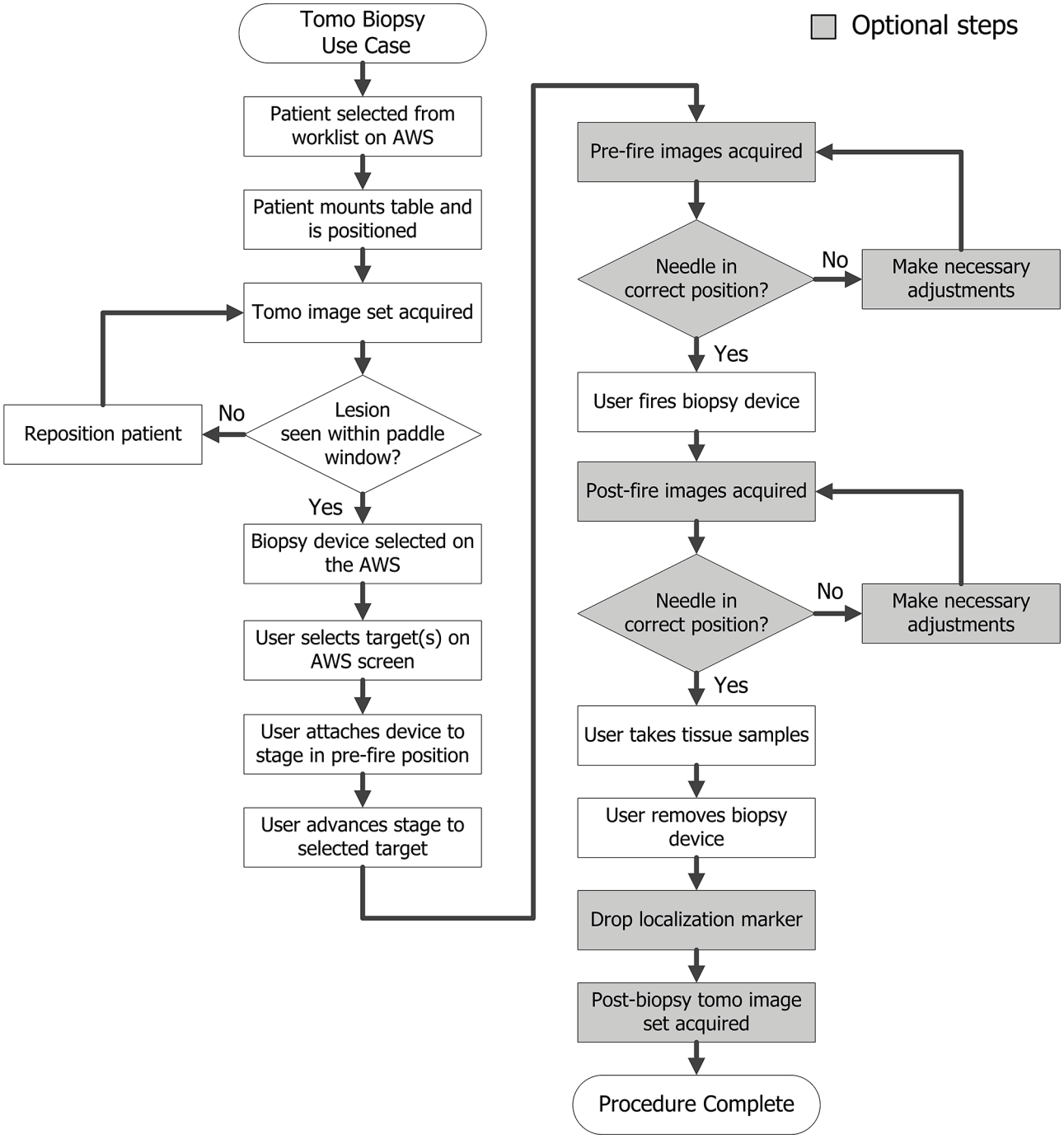
Figure 65: Paddle Holder Installation

Chapter 10: Sample Clinical Sequences

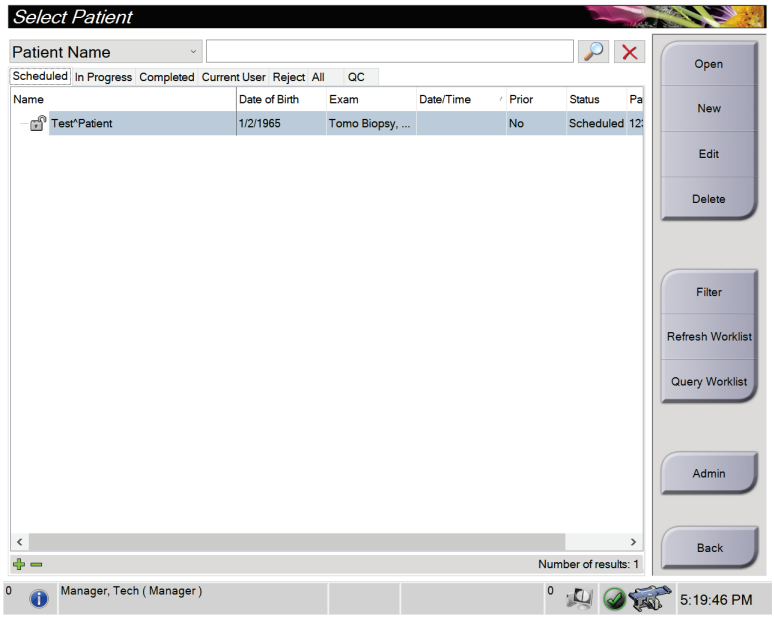
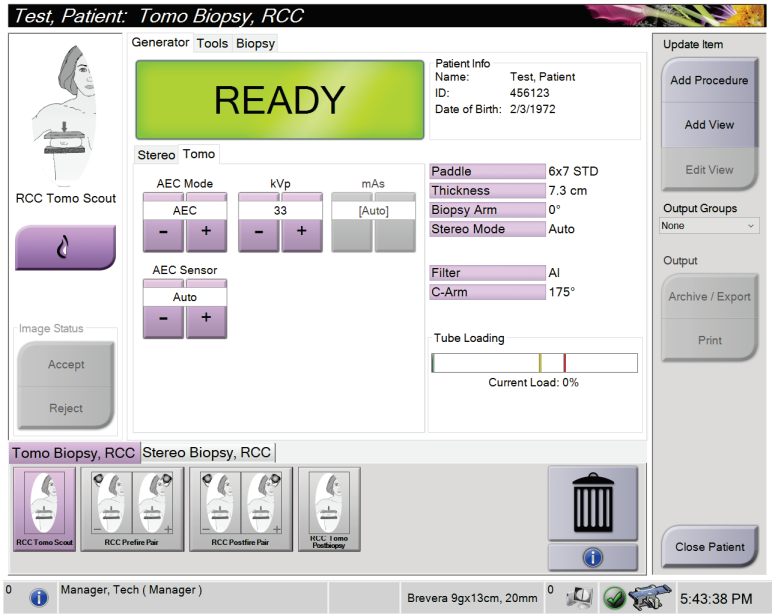
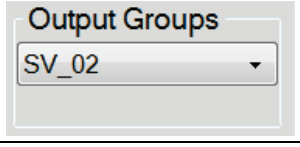
10.1 Example Stereotactic Biopsy Procedure

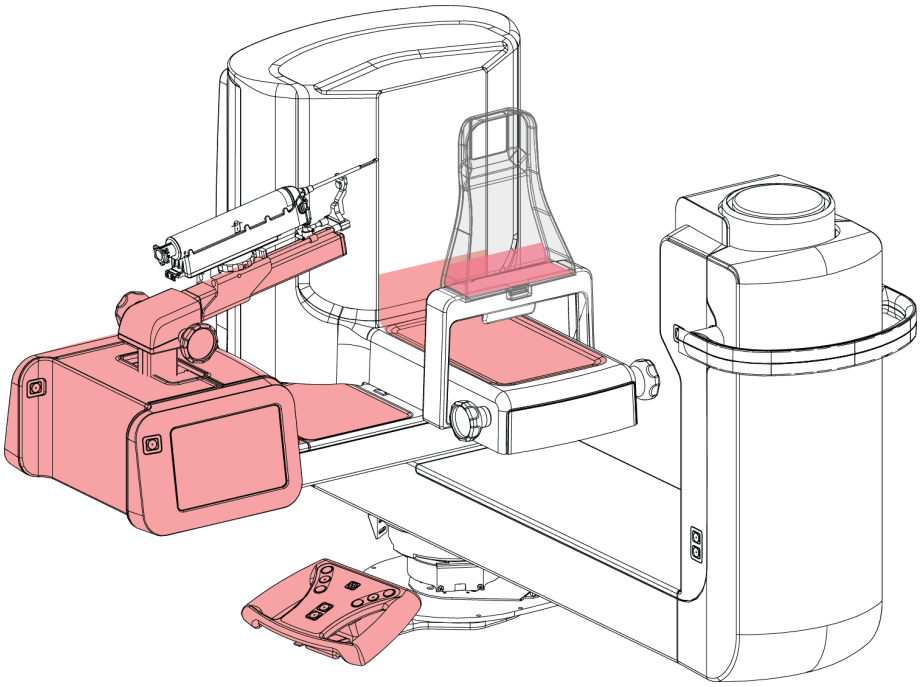
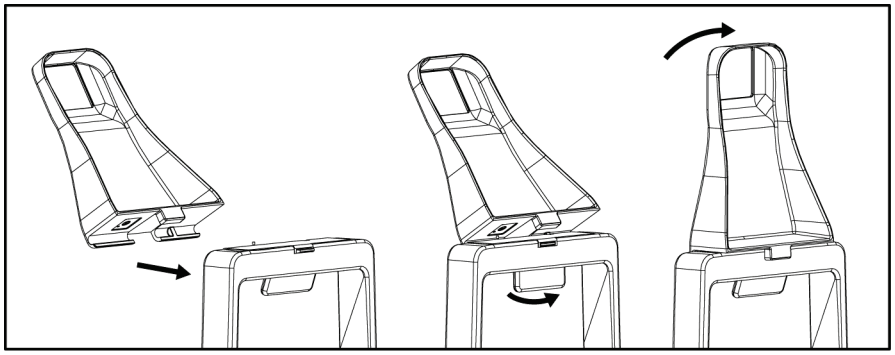


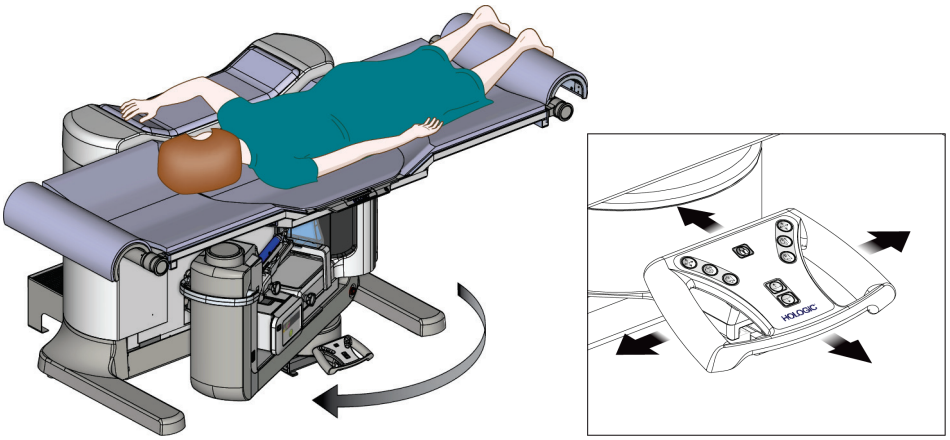
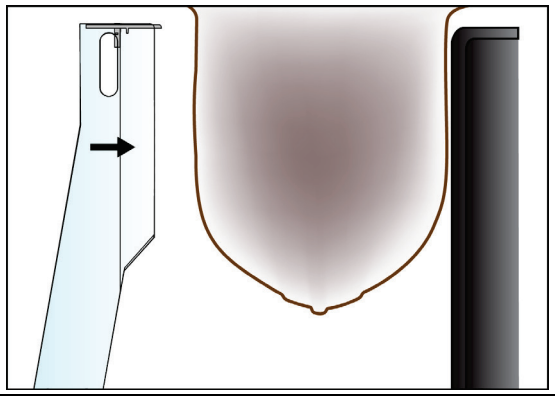
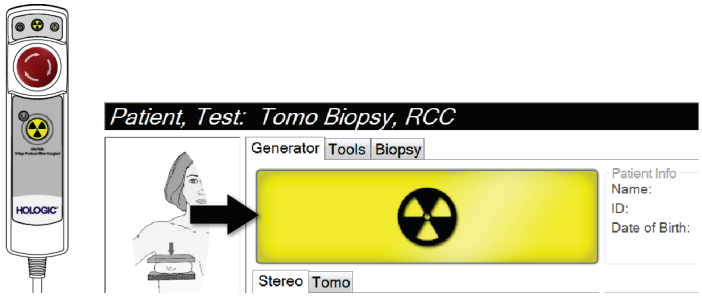
10.2 Example Tomography Biopsy Procedure

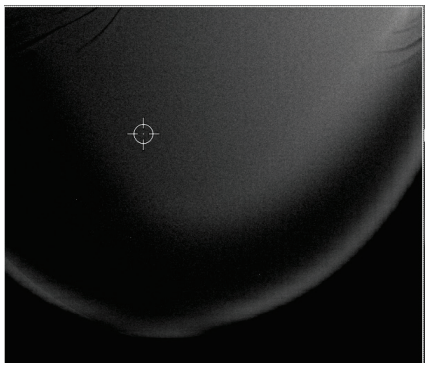
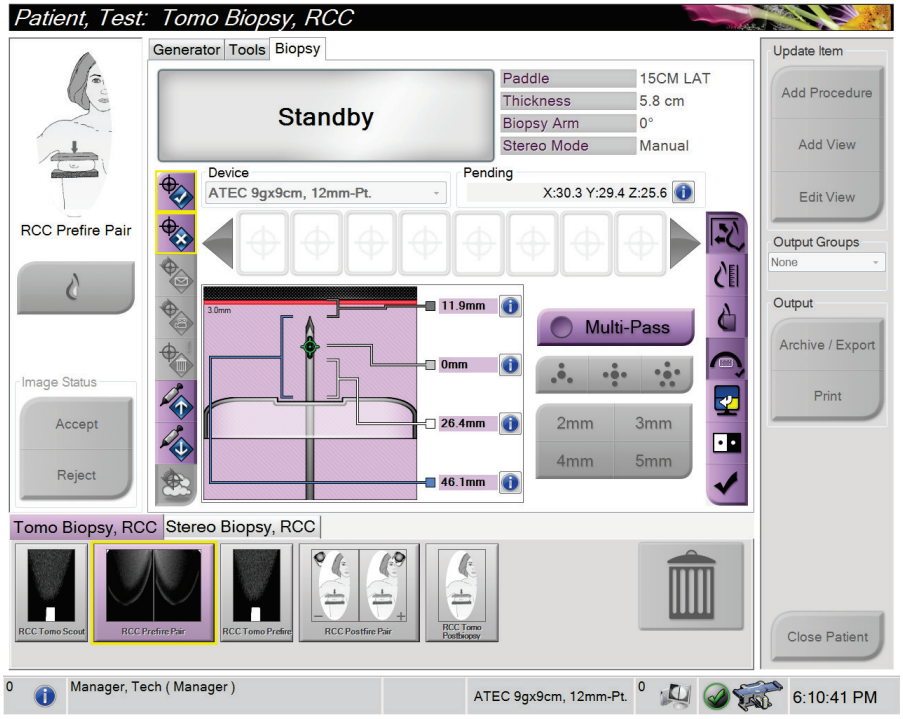
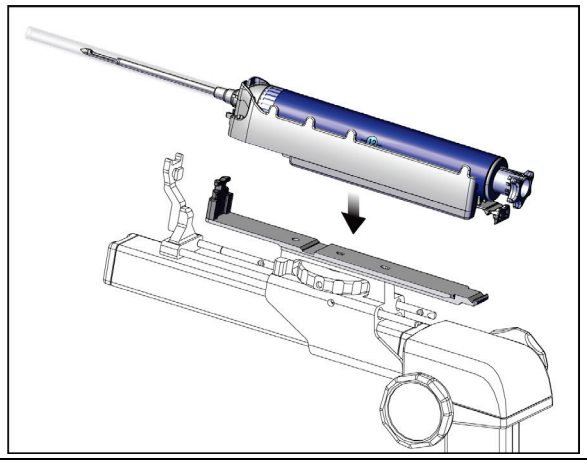


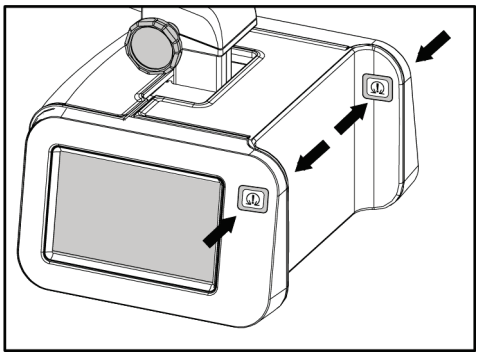
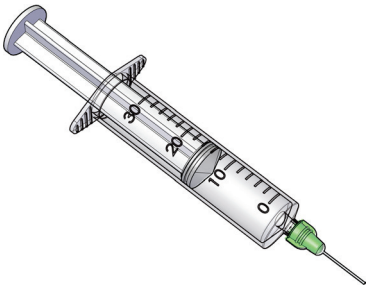
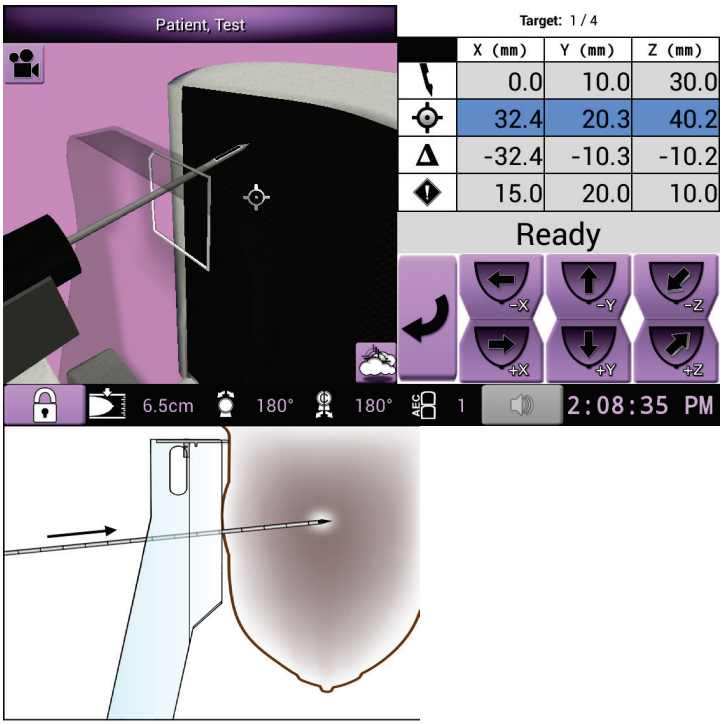
10.3 Example Sequence of Operation

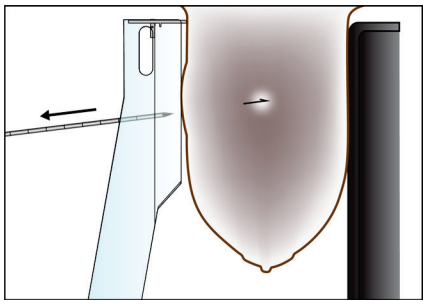
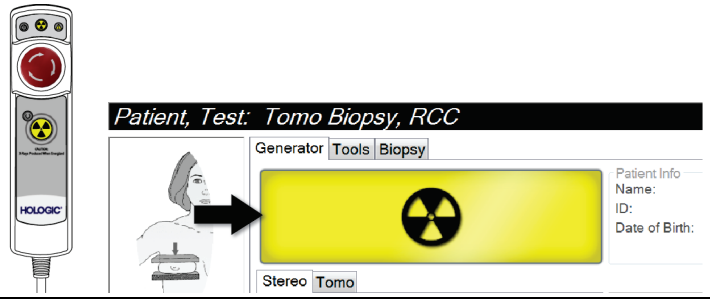
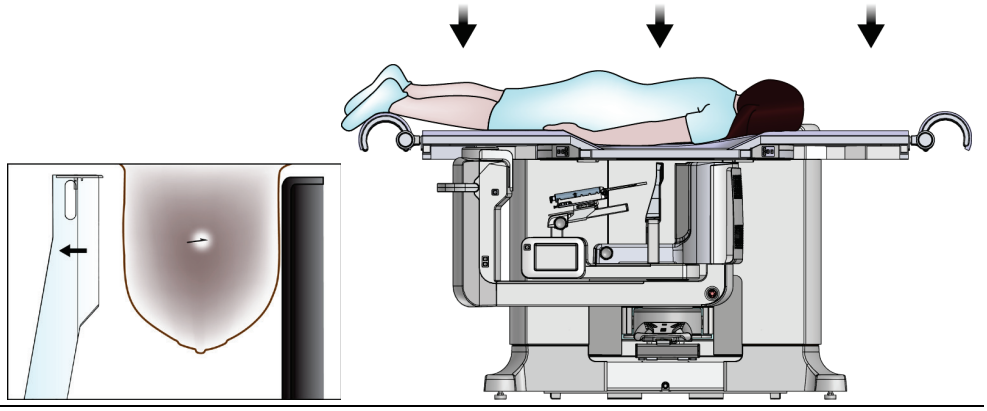
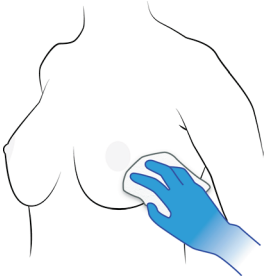
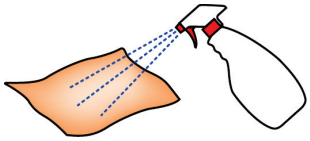
Step	Where this action is done
At the Acquisition Workstation, select the patient name, procedure, and output (if desired).	  

Step	Where this action is done
Protect the system with equipment drapes.	
Install the biopsy paddle.	

Step	Where this action is done
Position the patient, the patient platform, and the C-arm.	
Compress the breast.	
Acquire the image.	

Step	Where this action is done
On the Acquisition Workstation, target the lesion then accept the target to transmit it to the Biopsy Control Module.	 
Make sure that the device mount is moved fully back. Attach the biopsy device.	

Step	Where this action is done
Enable the Biopsy Control Module motor to move the biopsy device to the X and Y positions. Use the knobs to manually move the biopsy device close to the breast.	
Administer the anesthetic.	
Perform the biopsy.	

Step	Where this action is done
Insert a biopsy marker (if desired).	
Acquire post-biopsy images (if desired).	
Release compression. Lower the patient platform.	
Apply pressure to the biopsy site as needed.	
Remove the drapes and clean the system per cleaning instructions	

Chapter 11: Quality Control

MQSA has no requirements for interventional procedures (such as breast biopsy). If your facility is ACR accredited for breast biopsy, refer to the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual on how to do quality control. If your facility is seeking ACR accreditation, refer to the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual to start a quality control program.

Outside of the United States, follow local requirements (such as EUREF guidelines) to create a quality control program for breast biopsy systems).

Note
Refer to *CNR Correction for Biopsy* on page 163 for CNR correction factors.

11.1 Required Quality Control Procedures

The following procedures are necessary for correct system operation.

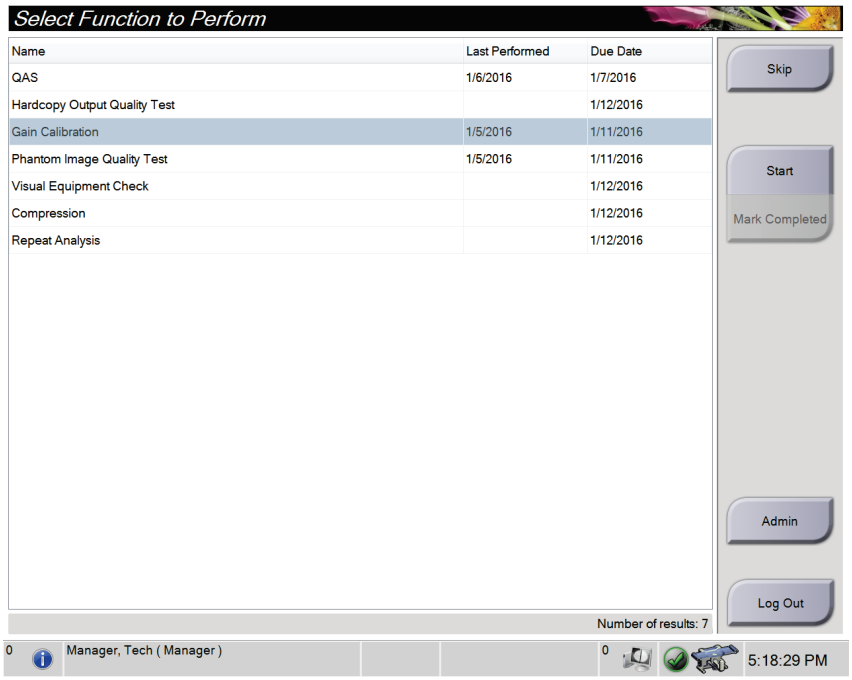
Table 12: Required Procedures

Test	Frequency
QAS Test	Daily - before clinical use
Gain Calibration	Weekly
Geometry Calibration	Semi-annually

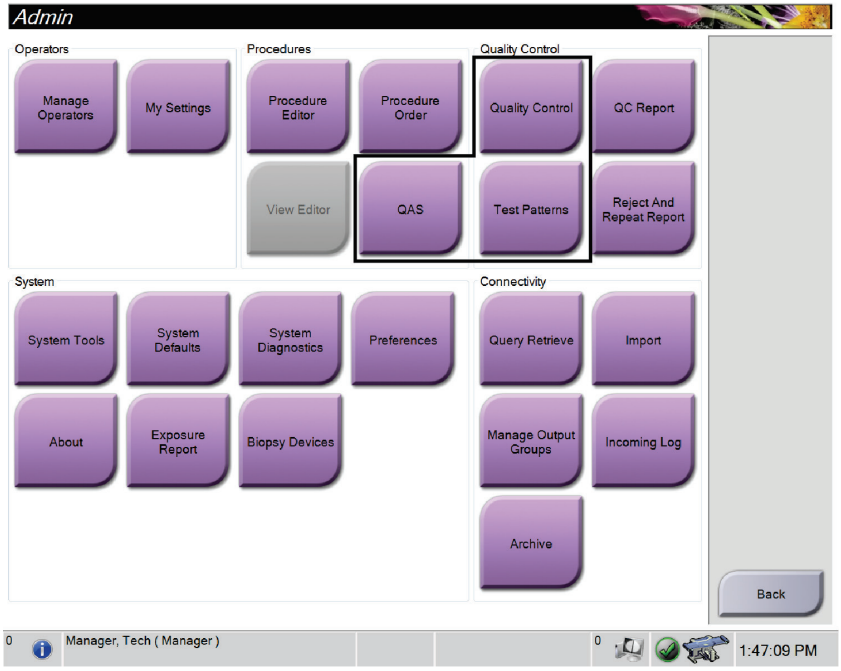
11.2 How to Access Quality Control Tasks

There are two ways to access the Quality Control Tasks.

- After logging in, the *Select Function to Perform* screen opens. This screen lists the quality tasks that are due.



- From the *Admin* screen, select one of the following buttons: **QAS**, **Quality Control**, or **Test Patterns**. All Quality Control Tasks can be accessed this way at any time.



11.3 QAS Test

Each day that the system is used, do this test one time to confirm the system accuracy. Record the results in the *QAS Test Checklist* on page 171.

1. Make sure that all paddles are removed.
2. On the Acquisition Workstation, from the *Select Patient* screen, select the **Admin** button.
3. On the *Admin* screen, select the **QAS** button.

Figure 66: QAS Button on the Admin Screen

The *QAS* screen opens. A dialog box prompts you to install the QAS phantom and shows the position of the coordinates for the test.

Note
The dialog box says to install the QAS "needle" but is referring to the QAS phantom.

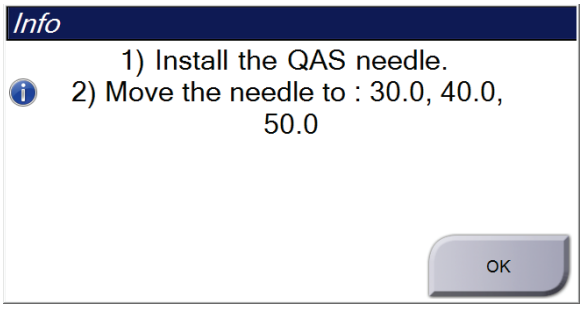


Figure 67: QAS Test Info Dialog Box

4. Install the QAS phantom.
5. In the *Info* dialog box, select **OK**.
6. On the *QAS* screen, select the **Biopsy** tab. Make sure that Affirm QAS shows in the Device field.

Figure 68: Device Field in the Biopsy Tab

7. Press and hold a **Motor Enable** button pair on the Biopsy Control Module. The QAS Phantom moves automatically to pre-programmed X and Y positions.
8. Turn the Biopsy Device Knob to show 0.0 on the Differential line in all three columns of the Biopsy Control Module.
9. Select Manual exposure mode, 25 kV, 30 mAs, silver filter in the *QAS* screen. (If the QAS Phantom uses a needle, select the Manual exposure mode, 25 kV, 10 mAs, silver filter in the *QAS* screen.)
10. Acquire and accept an image for the first view in the procedure. Note that the Auto-Accept feature is not enabled during the QAS procedure, and that targeting on the QAS Phantom occurs automatically.
11. Select the **Create Target** button to send the target to the Biopsy Control Module. Verify that the target coordinates are within ± 1 mm of X, Y, and Z numbers on the current line of the Biopsy Control Module.

Warning:
If the targeting coordinates are not within ± 1 mm, contact Technical Support. Do not try to adjust the system. Do not perform any biopsy procedure with the Affirm system until Technical Support indicates the system is ready for use.

Warning:
The user or a Service Engineer must correct problems before the system is used.

12. Repeat steps 10 and 11 for all unexposed views.
13. At the Acquisition Workstation, select the **End QC** button.
14. At the Biopsy Control Module, press a **Home Position** button (Left or Right) to move the QAS Phantom to the side.
15. Remove the QAS Phantom.

11.4 Gain Calibration

Note
Allow the system to warm up for at least 30 minutes before doing the Gain Calibration.

1. Select the **Admin** button on the Acquisition Workstation Control monitor, then select the **Quality Control** button from the *Admin* screen.

Figure 69: Admin Screen

2. Position the Gain Calibration Device.
3. Select the **Start** button.
4. Follow the instructions in the *Info* dialog box, then select **OK**.
5. When the System Message shows "Ready", press and hold the **X-ray** button to take an exposure. Release the button when the tone stops and the System Message shows "Standby".
6. Select **Accept**.
7. Repeat steps 5 and 6 for all unexposed views.
8. When the *Successfully Completed* dialog box opens, select **OK**.
9. Select **End Calibration**.

11.5 Geometry Calibration

Note
It is important to clean the Geometry Calibration paddle and the surface of the digital image receptor before starting the calibration procedure.

1. Select the **Admin** button on the Acquisition Workstation Control monitor, then select the **Quality Control** button from the *Admin* screen.

Figure 70: Quality Control Button on the Admin Screen

2. Position the Geometry Calibration Paddle.
3. Select the **Start** button.
4. Follow the instructions in the *Info* dialog box, then select **OK**.
5. When the System Message shows "Ready", press and hold the **X-ray** button to take an exposure. Release the button when the tone stops and the System Message shows "Standby".
6. Select **Accept**.
7. Repeat steps 5 and 6 for all unexposed views.
8. When the *Successfully Completed* dialog box opens, select **OK**.
9. Select **End Calibration**.
10. Perform the QAS test.

Chapter 12: Care and Cleaning

12.1 Cleaning

12.1.1 General Information About Cleaning

Before each examination, clean and use a disinfectant on any part of the system which touches a patient. Give the attention to the paddles and the image receptor.

Caution:
Do not use any hot source (like a heating pad) on the image receptor.

Be careful with the compression paddles. Inspect the paddles. Replace the paddle when you see damage.

12.1.2 For General Cleaning

Use a lint-free cloth or pad and apply a diluted dishwashing liquid.

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

If liquid is spilled on the system, turn the system off immediately. Do not turn the system on until the liquid has dried completely. Do not splash or spray cleaning solution on the system.

If more than soap and water is required, Hologic recommends any one of the following:

- 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)
- 3% maximum concentration of hydrogen peroxide solution

After you apply any of the above solutions, use a pad and apply a diluted dishwashing liquid to clean any parts that touch the patient.

Warning:
If a paddle touches possible infectious materials, contact your Infection Control Representative to remove contamination from the paddle.

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

12.1.3 How to Clean the Biopsy Control Module Screen

There are many commercially available products to clean LCD screens. Make sure the product that you select is free of strong chemicals, abrasives, bleach, and detergents that contain fluorides, ammonia, and alcohol. Follow the directions of the manufacturer of the product.

12.1.4 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 apply cleaning sprays or liquids to the equipment. Always use a clean 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 electric shock.

Always follow instructions from the manufacturer of the product you use for cleaning. 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.

12.2 General Information about Equipment Drapes

To reduce potential for contamination and equipment damage, protect the equipment with drapes during biopsy procedures. See the following figure for the areas on the Affirm prone biopsy system that require protection.

Warning:
Protect the equipment to guard against fluids entering the system.

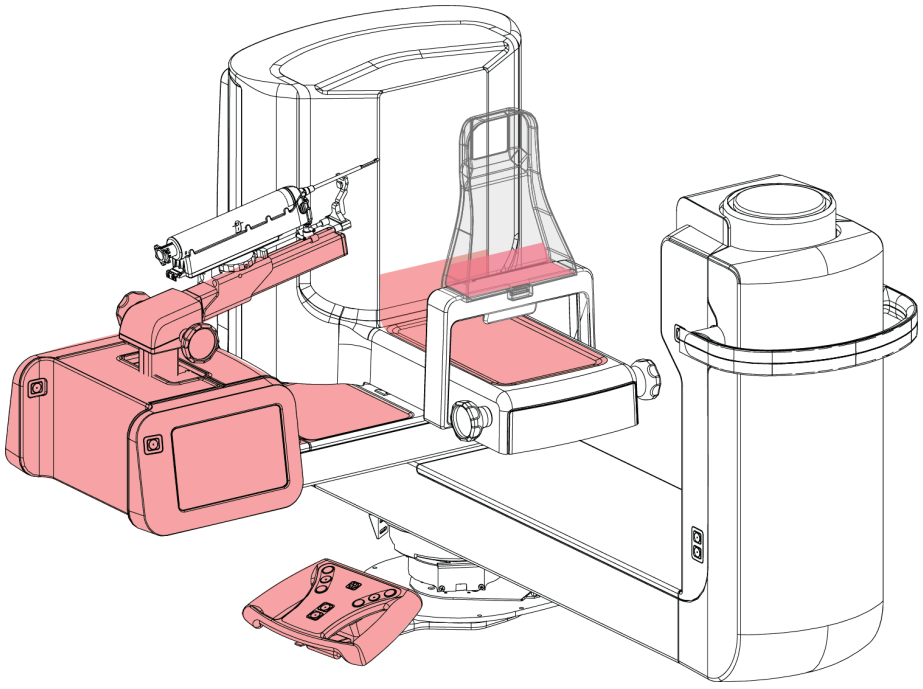


Figure 71: Areas to Protect with Drapes

12.3 Preventive Maintenance Schedule for the User

Table 13: Operator Preventive Maintenance Schedule

Maintenance Task Description	Each use	Daily	Weekly	Semiannually
Clean the Biopsy Paddle with a disinfectant after use.*	x			
Clean the Breast Platform with a disinfectant after use.*	x			
Inspect the Biopsy Paddle for damage before use.	x			
Inspect the calibration Phantom for damage.	x			
Inspect all cables for wear and damage before use.	x			
Make sure that the Needle Guides are installed correctly before use.	x			
Make sure that all displays are illuminated.	x			
Make sure that all locks and controls function and move smoothly.		x		
Make sure that all lights and their switches function.		x		
Perform QAS Procedures before use of the system.		x		
Perform Gain Calibration procedures.			x	
Inspect the overall integrity of the system for loose or missing hardware or components and signs of damage.			x	
Geometry Calibration (refer to Geometry Calibration)				x
Make sure that all labels are readable and properly affixed.				x

*Refer to *For General Cleaning* on page 123 for acceptable cleaning solutions. Contact Technical Support before using alternate cleaning solutions.

12.4 Preventive Maintenance Schedule for Service

Table 14: Service Engineer Preventive Maintenance

Maintenance Task Description	Recommended Frequency	
	Semiannually	**Annually**
Clean and inspect the Gantry, Detector, and Acquisition Workstation	x	
Check all primary power connections	x	
Check interlocks, safety, and limit switches	x	
Inspect C-arm and lubricate drive lead screw	x	
C-arm / Verify all C-arm buttons	x	
Verify Compression Force Calibration	x	
Verify Detent Angle Calibration	x	
Verify C-arm Angle Calibration	x	
Perform C-arm Brake verification	x	
Verify Tomo Arm Positioning	x	
Verify kV Calibration and Tube Current Calibration	x	
Check HVL Evaluation	x	
Verify AEC Performance/Scaling	x	
Verify X-ray Tube Alignment	x	
Inspect/Lubricate Patient Platform Up/Down Drive Screws	x	
Perform System Resolution Test	x	
Perform Phantom Image Quality Evaluation	x	
Perform Image Artifact Evaluation	x	
Perform System Backup including Node Calibrations	x	
Empty Reject Bin	x	
Check UPS performance status	x	
Voltage Verification (via CalTool)	x	
Replace Detector Fan Filters	x	
Service Filter Wheel	x	
Service X-ray Tube	x	

Chapter 13: System Administration Interface

13.1 Admin Screen

To access all functions in this screen, log in to the system as a user with administrator, manager, or service permissions.

Refer to the following table for descriptions of the *Admin* screen functions.

Figure 72: Admin Screen

Table 15: Admin Screen Functions

Section	Button Name	Function
Operators	**Manage Operators**	Add, delete, or change Operator information.
	My Settings	Change the information for the current Operator.
Procedures	**Procedure Editor**	Add or edit the procedures, or change the view order for each user.
	Procedure Order	Change the procedure list order.
	QAS	Access the *QAS Test* screen.

Table 15: Admin Screen Functions

Section	Button Name	Function
Quality Control	**Quality Control**	Select a Quality Control task to perform or mark completed.
	QC Report	Create a QC Report.
	Test Patterns	Select and send the test patterns to output devices.
	Reject and Repeat Report	Create a Reject and Repeat Report.
System	**System Tools**	The Interface for Service for the configuration of and identification of problems in the Acquisition Workstation.
	System Defaults	Set the Gantry default values.
	System Diagnostics	Displays the status of all subsystems.
	Preferences	Set the system preferences.
	About	Describes the system. Refer to *The About Screen* on page 131.
	Exposure Report	Create a report of the number of exposures by modality.
	Biopsy Devices	Set and manage the biopsy devices.
	Windows OS Tools	Access Computer Management, Local Security Policy, Local Users and Groups, and Local Group Policy in the Windows OS.
	Eject USB	Eject a media storage device connected to the USB port.
Connectivity	**Query Retrieve**	Query the configured devices.
	Import	Import the data from a DICOM source.
	Manage Output Groups	Add, delete, or edit output groups.
	Incoming Log	Shows log entries for images that do not import during manual import or DICOM store.
	Archive	Send local studies to networked storage or export to removable media devices.
You must have permission to access all features. The permission level controls the functions you can change.		

13.2 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 System Grouping)

Figure 73: System Tab of the About Screen

There are four tabs on the *About* screen:

- **System Tab** (default) - lists system configuration information
- **Licensing Tab** - lists the Hologic-licensed options installed on this machine
- **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

13.3 Change the User Language Preference

Users can set the language on the user interface to automatically change to their individual preference when logging in.

1. In the Operators group of the *Admin* screen, select **My Settings**.

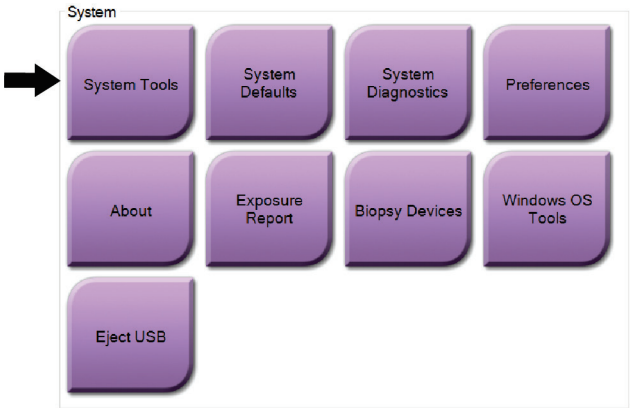
Note
You can also access **My Settings** through the taskbar. Select the User Name area then select **My Settings** in the pop-up menu.

2. The **Users** tab of the *Edit Operator* screen opens. From the Locale field, select a language from the drop-down list.
3. Select **Save**, then select **OK** to the *Update Successful* message. The user interface changes to the selected language.

13.4 How to Access the System Tools

The Radiologic Technologist Managers and users with Service permissions can access the System Tools function. The System Tools function contains the configuration information about the system.

1. Log in as Tech Manager or Service.
2. From the *Select Function to Perform* screen or the *Select Patient* screen, select the **Admin** button.
3. From the System area of the *Admin* screen, select **System Tools**.



13.4.1 System Tools for the Radiologic Technologist Manager

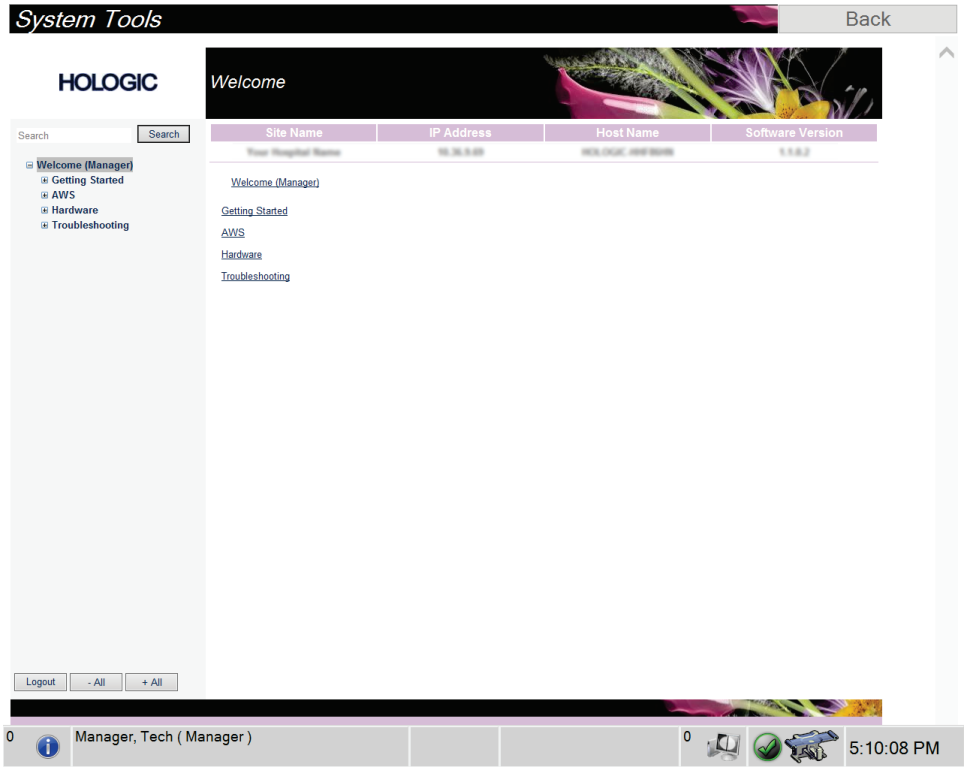


Figure 74: System Tools Screen

Table 16: Radiologic Technologist Manager—System Tools Functions

Section	Screen Functions
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	**Connectivity:** List of Installed Devices. **Film & Image Information:** Create an Image Report*. Create a QC Report. (*You can also access this report from a remote computer. Refer to Remote Access to Image Reports.) **Licensing:** List of Installed Licenses. **User Interface:** Change the options in the Software application. **Internationalization:** Select the local language and culture.
Hardware	**Tube Loading:** Configure the tube load parameters. (Only availabe for users with Service permissions.)
Troubleshooting	**AWS:** Allows for download of images. **Computer:** System Management and Network Information. **Log:** Change the event record options. **Backups:** Control the backups for the system.

13.4.2 Remote Access to Image Reports

Access image reports via a remote computer networked to the system. This function can be useful for sites that do not permit USB downloads of reports directly from the system.

Follow these steps to access image reports from a remote computer. You must log in to the System Tools as a Manager-level user for this procedure.

1. Get the IP Address for the system you want to access. You can get the IP Address from your IT administrator or from the system. Write down the IP Address.

   From the system:

   a. Go to the *About* screen.

   b. Select the **System** tab. The IP Address is listed in the Computer section.

2. Using an internet browser on your remote computer, go to `http:// [IP address]/Hologic.web/MainPage.aspx`. Use the IP Address from step 1. The *Service Tools Logon* screen opens.
3. Type a Manager-level user name and password then select **Submit**.

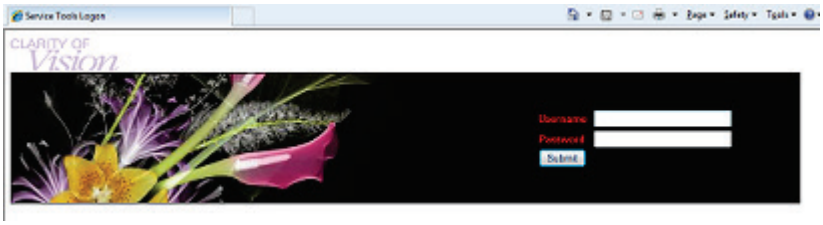


Figure 75: Remote Logon Screen for Service Tools

4. The *Service Tools Welcome* screen opens. Go to **AWS > Film & Image Information > Create Image Report.**

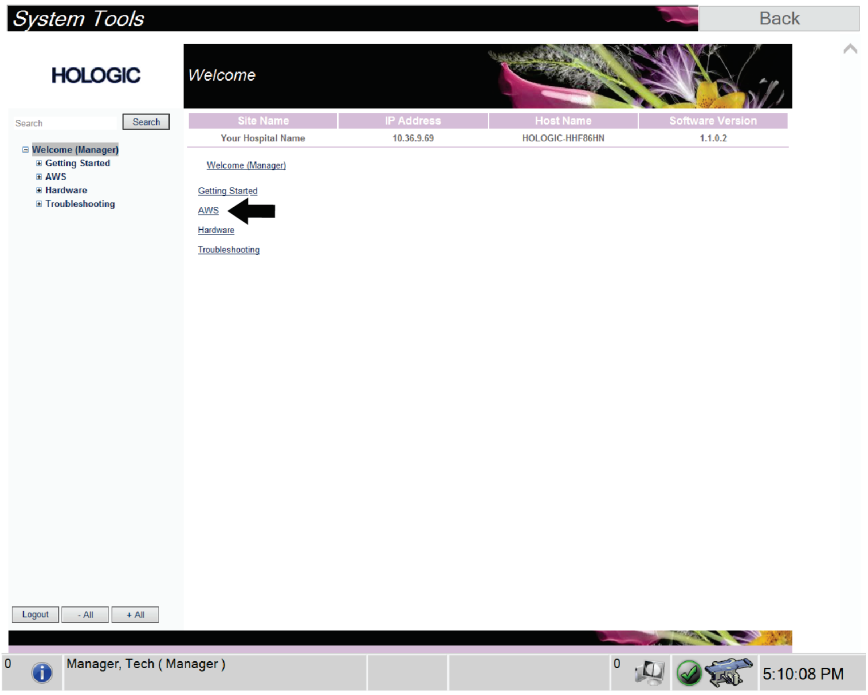


Figure 76: System Tools Welcome Screen

5. Select the parameters for the report and select **Generate**.

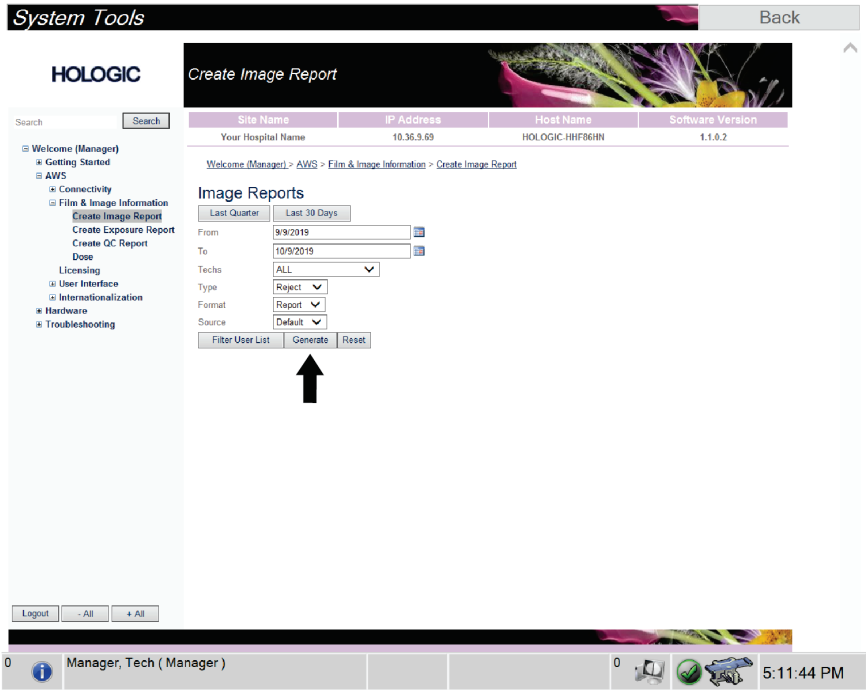


Figure 77: Create Image Report Parameters

6. The report shows on the screen. Scroll to the bottom of the report and select either the **Click to Download (html)** option or the **Click to Download (csv)** option for your file download type. Select **Save** when prompted.

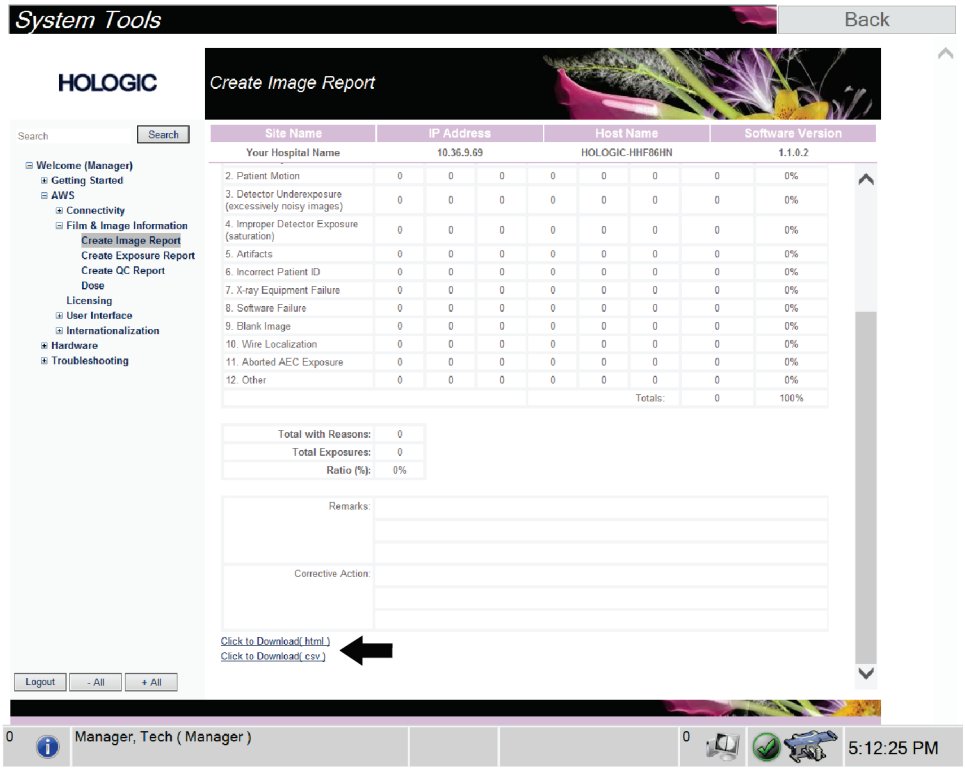


Figure 78: Download Image Report

7. Select a folder on the computer then select **Save**.
8. When finished, select the **Log out** button.

13.5 Archive Tool

The archive feature in the *Admin* screen lets you:

- Send local studies to an archive.
- Export studies to removable media.

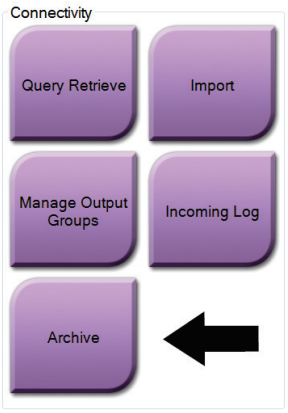


Figure 79: Archive Button

1. From the Connectivity group in the *Admin* screen, select the **Archive** button. The *Multi Patient On Demand Archive* screen opens.
2. To search for a patient, enter at least two characters in the Search parameters area and select the magnifying glass.

   A list of patients that match the search criteria is displayed.

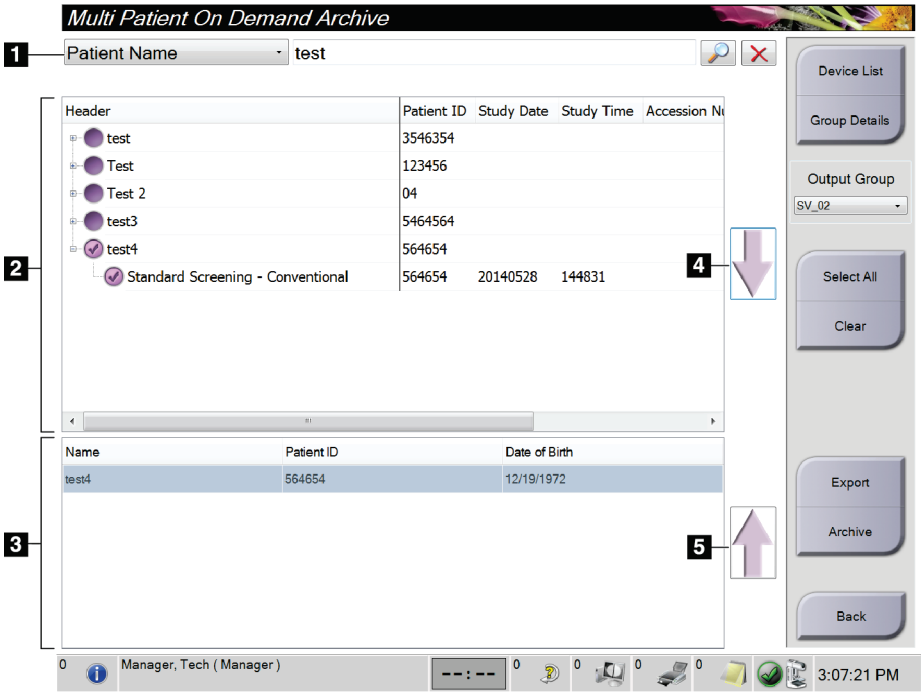


Figure 80: Multi Patient On Demand Archive Screen

Figure Legend

1. Search parameters
2. Patient List area
3. Patients to Be Archived or Exported area
4. Add selection in the Patient List area to the Patients to Be Archived or Exported area
5. Remove the selection from the Patients to Be Archived or Exported area

To Archive:

1. Select the patients and the procedures to archive.
   - Select patients from the patient list, or do a search with the search parameters (item 1) and select patients from the search results.

Note
The **Select All** button (on the right side of the screen) selects all the patients in the Patient List area. The **Clear** button (on the right side of the screen) clears selections.

   - Select the procedures for each patient.
   - Select the **Down Arrow** (item 4) on the screen to move the selected patients to the Patients To Be Archived area (item 3).
   - Select the **Up Arrow** (item 5) on the screen to remove the selected patients from the Patients To Be Archived area (item 3).
2. Select a storage device.
   - Select an option from the Store Device drop-down menu.

   -OR-

   - Select the **Group List** button, then select an option.
3. Select the **Archive** button. The list in the Patients To Be Archived area copies to the selected archive devices.

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

To Export:

1. Select the patients and the procedures to export.
   - Select patients from the patient list, or do a search with one of the search parameters (item 1) and select patients from the search results.

Note
The **Select All** button (on the right side of the screen) selects all the patients in the Patient List area. The **Clear** button (on the right side of the screen) clears selections.

   - Select the procedures for each patient.
   - Select the **Down Arrow** (item 4) on the screen to move the selected patients to the Patients To Be Archived area (item 3).
   - Select the **Up Arrow** (item 5) on the screen to remove the selected patients from the Patients To Be Archived area (item 3).
2. Select the **Export** button.
3. In the *Export* dialog box, select the Target from the drop-down list of media devices.

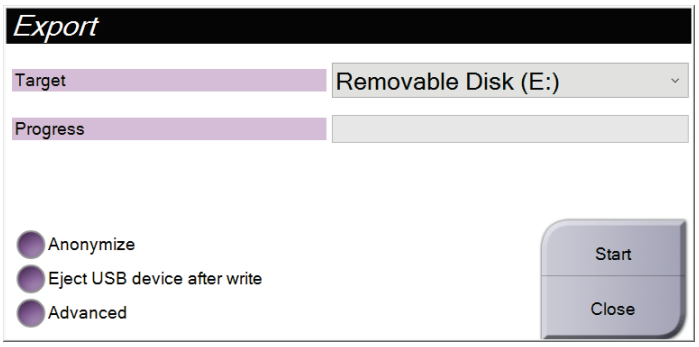


Figure 81: Export Dialog Box

4. Select other options, if necessary:
   - **Anonymize**: to anonymize patient data.
   - **Eject USB device after write**: to automatically eject the removable media storage device when the export is complete.
   - **Advanced**: to select a folder on your local system for storage of your selections, and also to select the Export Types of the images.
5. Select the **Start** button to send the selected images to the selected device.

Appendix A: Specifications

A.1 Product Measurements

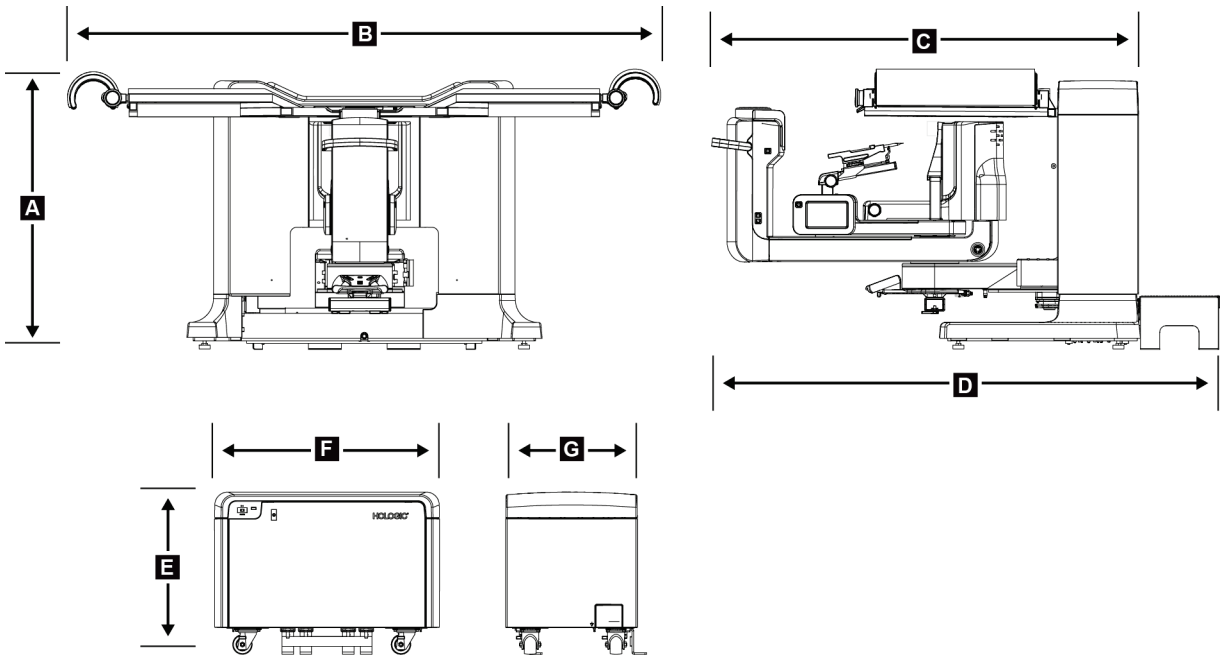


Figure 82: Gantry and Generator Measurements

Gantry/Patient Platform Measurements

A.	*Height*	*107 cm (42 inches)*
B.	*Width*	*229 cm (90 inches)*
C.	*Depth with C-arm*	*178 cm (70 inches)*
D.	*Overall Depth*	*198 cm (78 inches)*
	Total Weight	*445 kg (980 pounds)*

Generator Measurements

E.	*Height*	*63 cm (25 inches)*
F.	*Width*	*87 cm (34 inches)*
G.	*Depth*	*55 cm (22 inches)*
	Weight	*136 kg (300 pounds)*

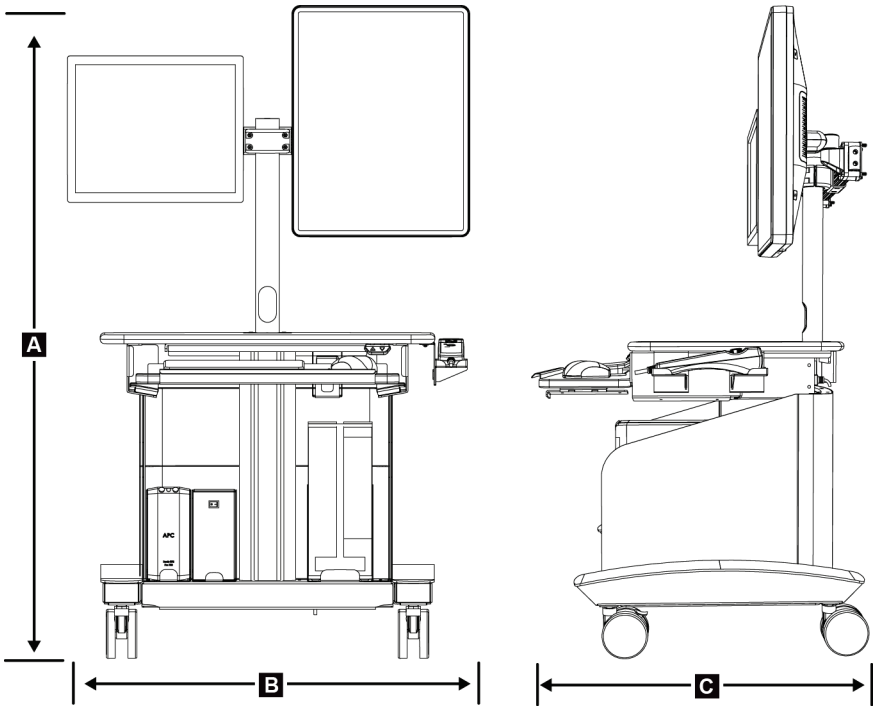


Figure 83: Acquisition Workstation Measurements

Acquisition Workstation Measurements

A.	*Height*	*138.4 cm (54.5 inches)*
	Overall Height Range	*138.4 cm (54.5 inches) to 179.1 cm (70.5 inches)*
	Height Range (floor to work surface)	*71.1 cm (28 inches) to 111.8 cm (44 inches)*
B.	*Width*	*85.4 cm (34 inches)*
C.	*Depth*	*75.1 cm (30 inches)*
	Total Weight	*114 kg (252 pounds)*

A.2 Operation and Storage Environment

A.2.1 General Conditions for Operation

Temperature Range	*10 °C (50 °F) to 30 °C (86 °F)*
Relative Humidity Range	*10% to 80% without condensing moisture*
BTU Output	*less than 5700 BTU per hour*

A.2.2 General Conditions for Transport and Storage

Temperature Range	*10 °C (50 °F) to 35 °C (95 °F)*
Relative Humidity Range	*10 to 80%, not packaged for outdoor storage*

A.3 Electrical Input

A.3.1 Generator/Gantry

Mains Voltage	*200/208/220/230/ 240 VAC ±10%*
Mains Impedance	*Maximum line impedance not to exceed 0.20 ohms for 208/220/230/240 VAC, 0.16 ohms for 200 VAC*
Mains Frequency	*50/60 Hz ±5%*
Average Current over 24 Hours	*< 5 A*
Line Current	*4 A (65 A maximum for < 5 seconds)*

A.3.2 Acquisition Workstation

Mains Voltage	*100/120/200/208/220/230/240 VAC ±10%*
Mains Frequency	*50/60 Hz ±5%*
Power Consumption	*< 1000 watts*
Duty Cycle	*13.3% ~ 8 minutes per hour or 2 minutes on, 13 minutes off*
Line Current	*2.5 A*

A.4 Gantry Technical Information

A.4.1 C-arm

Rotation Range	*180°*
Source-to-Image Distance (SID)	*80 cm*
Stereo Range	*±15°*
Tomosynthesis Range	*±7.5°*

A.4.2 Compression System

Manual Compression Force	*300 N (67.4 lb) maximum*
Motorized Compression Force	*62.3 N (14.0 lb) minimum*
	200 N (45.0 lb) maximum

A.4.3 Biopsy Guidance Module

Accuracy of Biopsy Arm Controller	*Maximum deviation: 1 mm in either direction of target coordinate*

A.4.4 X-ray Tube

Focal Spot	*Large (0.3 mm) Nominal*
Tube Voltage	*20-49 kVp in 1 kVp increments*
Anode Material	*Tungsten*
X-ray Window	*0.63 mm Beryllium*
Reference Angle (angle of the reference axis to the plane of the image reception area)	*90°*

A.4.5 X-ray Beam Filtration and Output

Filtration	*Aluminum, 0.70 mm (nominal)*
	Silver, 0.050 mm ±10%

A.4.5.1 kV/mA Range

Table 17: Maximum mA as a Function of kV

kV	LFS mA		kV	LFS mA		kV	LFS mA
20	100		30	170		40	170
21	110		31	180		41	170
22	110		32	190		42	160
23	120		33	200		43	160
24	130		34	200		44	150
25	130		35	200		45	150
26	140		36	190		46	150
27	150		37	180		47	140
28	160		38	180		48	140
29	160		39	180		49	140

A.4.6 X-ray Generator

Type	*Constant potential, three-phase, high frequency inverter*
Rating	*7.0 kW maximum (200 mA at 35 kVp)*
Electrical Power Capacity	*9.0 kW maximum*
kV Range	*20-49 kVp in 1 kVp increments*
kV Accuracy	*±5%*
mA Range	*10-200 mA*
mAs Accuracy	*±(10% + 0.2 mAs)*
mAs Range	*(2D) 4.0 – 500 mAs*
	(3D) 6.0 – 300 mAs

A.4.7 Image Receptor Technical Information

Dimensions	
Height	*33 cm (13 inches)*
Width	*21.5 cm (8.46 inches)*
Depth	*10 cm (3.94 inches)*
Weight	*7.3 kg (16 pounds)*
Imaging Area	*14 cm x 12 cm*
Effective Field of View	*12.4 cm x 10.2 cm at the Breast Platform*
Image Device	*Direct conversion amorphous Selenium coated TFT array*
Pixel Count	*2048 (H) x 1792 (V)*
Pixel Size	*70 µm (H) x 70 µm (V)*
Digitizing Resolution	*14 bit data*
Detective Quantum Efficiency (DQE)	*Not less than 50% at 0.2 lp/mm (stereotactic mode)* *Not less than 30% at 0.2 lp/mm (tomosynthesis mode)* *Not less than 15% at 7.1 lp/mm (stereotactic and tomosynthesis modes)*
Modulation Transfer Function (MTF)	*Not less than 40% at 7.1 lp/mm*
Synchronization	*Interlocked with x-ray control signal*

A.4.8 Shielding

Operator	*Radiation shield (customer supplied) between patient platform and handheld remote for x-ray activation*
Patient	*The patient platform provides the necessary radiation protection.*

A.5 Acquisition Workstation Technical Information

A.5.1 Network Environment

Network Interface	*100/1000 BASE-T Ethernet*

A.5.2 Acquisition Workstation Cart

Monitor Arm Weight Rating	*11.3 kg (25 pounds)*

Appendix B: System Messages and Alerts

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

B.2.1 Fault Levels

Each Message has a particular set of the following characteristics:

- Aborts an exposure in progress (yes/no)
- Prevents an exposure from starting (yes/no)
- Displays a message to the user on the Acquisition Workstation (yes/no)
- May be reset by the user (yes/no)
- May be reset automatically by the system (yes/no)

B.2.1.1 Displayed Messages

All displayed messages will be shown in the user's selected language.

Any message which aborts an exposure or prevents an exposure from starting will always display a message directing the user's actions required to proceed.

B.2.1.2 Additional Message Information

Technical information about the message is available in the log file.

Some messages always show as a critical fault (a system restart is necessary). These messages result from a condition which prevents an exposure, and which cannot be reset by the user or the system.

B.2.2 System Messages

When the following system messages show, do the step shown in the User Action column to clear the message and allow the next exposure.

Table 18: System Messages

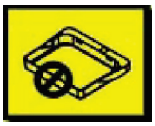
Icon	Message	User Action
	Waiting for Detector	No action needed.
	C-Arm is unlocked	Press the System Lock button on the control handle to lock the system.
	C--Arm brake is disabled	Press the System Lock button on the control handle to lock the C-arm. If necessary, unlock and relock.
	Biopsy STX cal required	Install the gain paddle and perform Gain Calibration.
	Biopsy geometry calibration required	Install the geometry paddle and perform Geometry Calibration.
	Invalid detector calibration: Repeat flat field calibration	Repeat Gain Calibration.
	Invalid geometry calibration: Repeat geometry calibration	Repeat Geometry Calibration.
	Invalid use of compression paddle	Install the correct paddle.
	Configuration file is missing	Call Service.

Table 18: System Messages

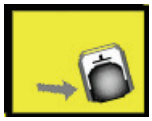
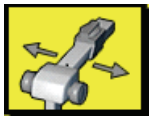
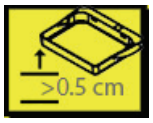
Icon	Message	User Action
	An E-Stop has been pressed	When safe, turn the Emergency Off switch one-quarter turn to reset the switch.
	Tube needs to be manually positioned (move to 0 degrees)	Manually rotate the C-arm to 0 degrees.
	Tube needs to be manually positioned (moved to +15 degrees)	Manually rotate the C-arm to the right.
	Tube needs to be manually positioned (moved to -15 degrees)	Manually rotate the C-arm to the left.
	The needle needs to be moved to the correct location	Move the needle to the correct location.
	The stage arm needs to be moved to either the lateral left or right position	Move the biopsy arm to either lateral left or right.
	The stage arm needs to be moved to the -90 position	Move the biopsy arm to -90 degrees approach.
	The stage arm needs to be moved to the +90 position	Move the biopsy arm to +90 degrees approach.
	The stage arm needs to be moved to the standard approach	Move the biopsy arm to 0 degree approach.
	The stage arm control is not locked	Lock the biopsy arm.

Table 18: System Messages

Icon	Message	User Action
	Compression too low for tomo reconstructions	Move the Compression Paddle to greater than 0.5 cm.
	Compression is less than 4.5 cm during calibration	Move the Compression Paddle to greater than 4.5 cm.
	*not licensed	A license is necessary to use this feature or function. (Call Service to install the license.)

B.3 UPS Messages

Note
The User Guide for the UPS is supplied with the system. Refer to the UPS *User's Guide* for complete instructions.

The LCD Display Interface in the Uninterruptible Power Supply (UPS) shows the status of various utility and battery backup conditions.

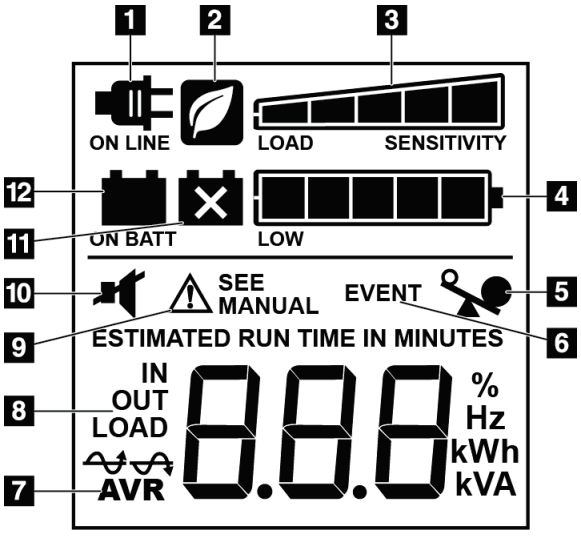


Figure 84: UPS LCD Display

Figure Legend

1. On Line Power
2. Power-Saving Mode On
3. Load Capacity
4. Battery Charge Level
5. UPS Overload
6. Event
7. Automatic Voltage Regulation
8. Input/Output Voltage
9. System Fault
10. Mute
11. Replace Battery
12. On Battery Power

If the UPS battery expires, the Replace Battery icon shows. Contact your service representative to replace the battery.

Appendix C: Use in a Mobile Environment

C.1 General Information

This appendix describes the Affirm prone biopsy system installed in a mobile environment.

C.2 Conditions for Safety and Other Precautions

An acceptable, stable, clean VAC power source is required to make sure that the system meets all its performance specifications. Where available, shore power correctly supplied to the system provides the best performance. If a mobile power generator is used, you must keep the specifications for input power during all load conditions.

Warning:
Electrical circuits inside the system can cause serious injury or death. The covers should not be removed or modified except by authorized service personnel. If the power cable to the gantry or AWS is damaged, the system should be powered off and repaired before use.

Caution:
When shore power is unavailable, mobile power sources that provide equivalent performance may be employed. (Refer to *Specifications for Mobile Use* on page 152.) Proper system function and performance can only be ensured if continuous true sinusoidal VAC power is supplied per the system power input specifications and loading characteristics. Intermittently, the power source must provide 65 Amps at 208 VAC for a minimum of 5 seconds, and 4 Amps maximum continuous otherwise. This load must be supported once every 30 seconds. In the event of shore or mobile power service interruption, the UPS must be capable of providing the operational power described above for a minimum of 4 minutes. Acquisition Workstation and Gantry power must be fed on separate dedicated circuits. The use of an uninterruptible power supply with active line conditioner is recommended on each power circuit. Accordingly, all ancillary mobile coach power should be distributed by other circuits. The electrical installation must be verified to meet system power input specifications and IEC 60601-1 safety requirements after initial installation and upon each relocation of the mobile coach.

Caution:
The temperature and humidity inside the vehicle must be maintained at all times. Do not allow environmental conditions to exceed stated specifications when the unit is not in use.

Caution:
Voltages cannot change by more than ±10% when the x-ray unit or other equipment (for example, heating or air conditioning) is operated.

Caution

To avoid image artifacts from occurring:

- **Do not locate or park the mobile coach near sources of high power (such as power transmission lines and outdoor transformers).**
- **Make sure that any mobile power generator, uninterruptible power supply (UPS), or voltage stabilizer is at least 3 meters (10 feet) from the closest point of the image detector travel.**

Damage to the breast platform or paddles may cause artifacts within the image.

C.3 Specifications for Mobile Use

The following system specifications are for mobile use only. For all other specifications, refer to the section Specifications.

C.3.1 Shock and Vibration Limits

Vibration Limit	*Maximum of 0.30 G (2 Hz to 200 Hz), measured at the point where the system mounts to the coach.*
Shock Limit	*Maximum of 1.0 G (1/2 sine pulse), measured at the point where the system mounts to the coach. An "air ride" coach suspension is recommended.*

C.4 Prepare the System for Travel

Note
Start preparing the system for travel with the system power on. (Do not power off the system until the C-arm is correctly positioned and supported.)

1. Push the footrests fully in.
2. Raise the patient platform to its full height.
3. Rotate the biopsy arm to 0 degrees.
4. From the acquisition workstation, select the table icon in task bar and rotate the tube arm to 0 degrees.
5. Rotate the C-arm to +180 degrees. Raise the C-arm above the height needed to place the C-arm cradle in position.

6. Put the C-arm cradle into position under the C-arm. Confirm that the cradle is correctly seated on the circular mounting block.

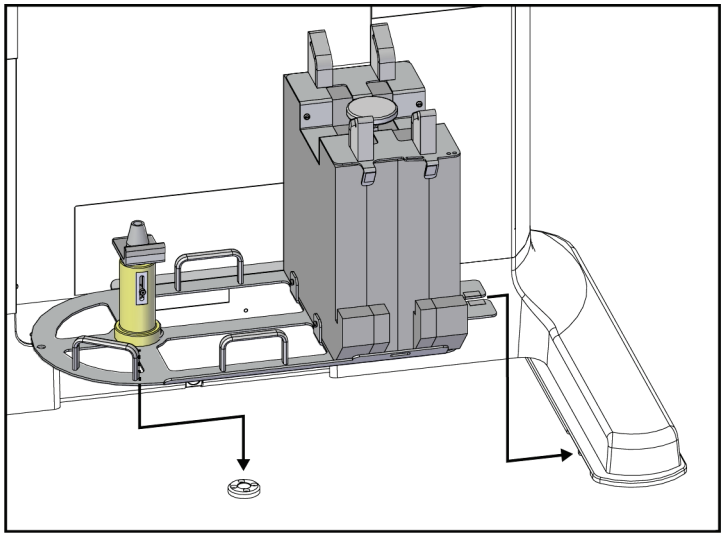


Figure 85: Set the C-arm Cradle

7. A height tool is tethered to the C-arm cradle. Use the height tool to set the C-arm height in relation to the patient platform. Put the height tool flat on the tubehead. Raise the C-arm until there is no space between the tool and the bottom of the platform. Remove the height tool.

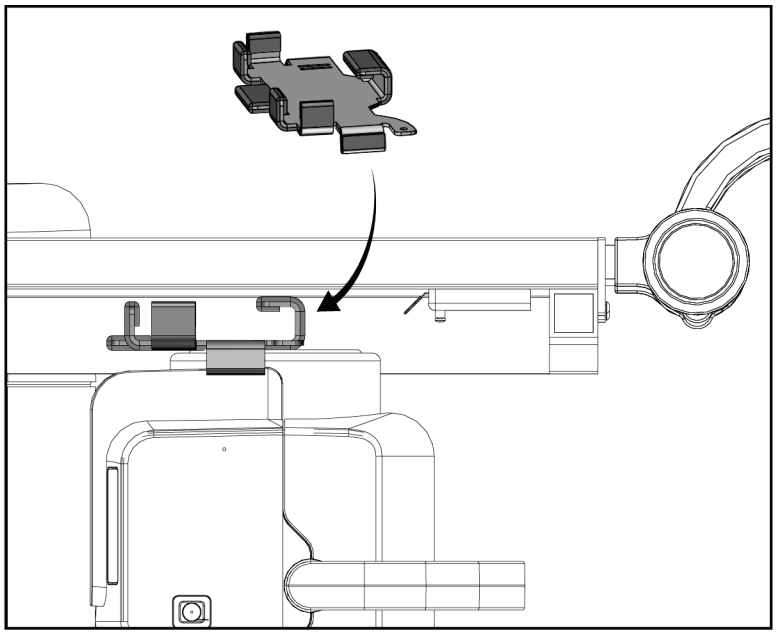


Figure 86: Set the C-arm Height with the Height Tool

8. Use the height tool to lock the biopsy arm in position. Place the tool on the tube arm between the biopsy arm and the tubehead. Make sure to use the hook and loop strap for extra support.

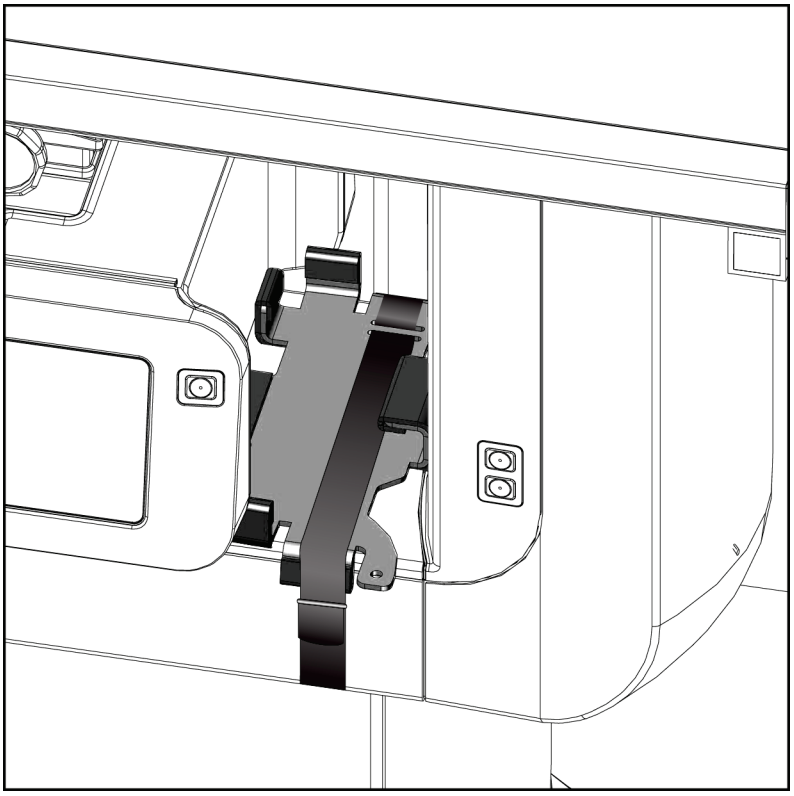


Figure 87: Lock the Biopsy Arm with the Height Tool

9. Put the footswitch into the footswitch channels in the C-arm cradle and secure with the hook and loop strap.

Caution:
Make sure that the footswitch cord is positioned safely to prevent damage from being compressed between the C-arm and the C-arm cradle.

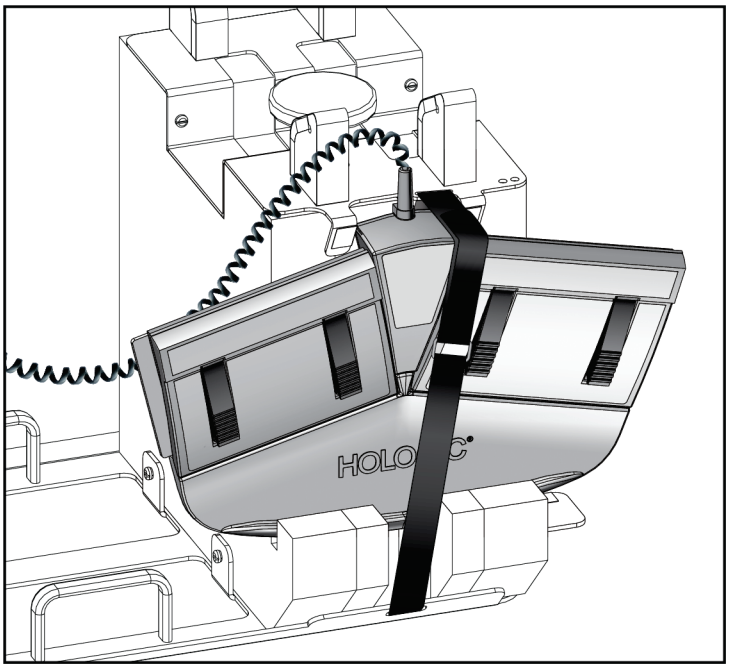


Figure 88: Correct Footswitch Storage

10. While pressing the **C-arm Translate** button, push the C-arm in completely toward the Gantry.

11. Continue pressing the **C-arm Translate** button and adjust the C-arm as needed while lowering the patient platform into the C-arm cradle. The marking on the C-arm aligns with the support bracket on the C-arm cradle.

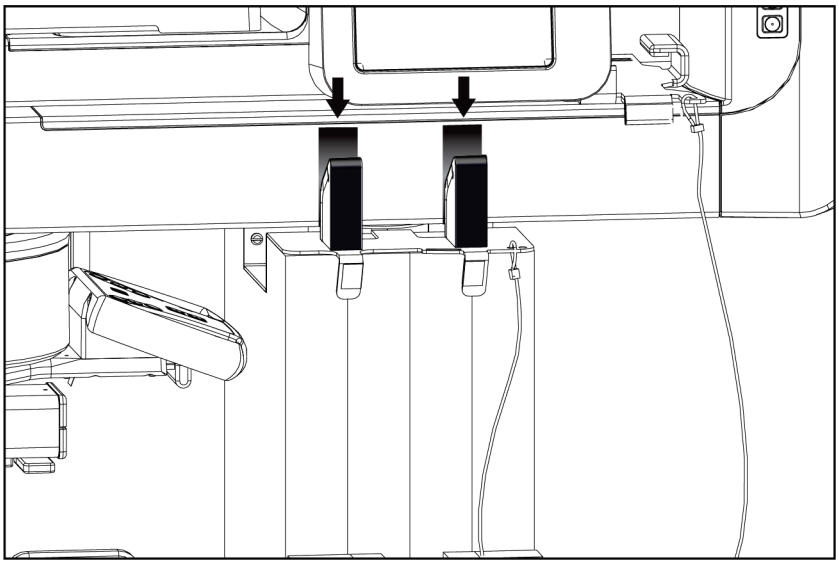


Figure 89: Alignment of Markings on the C-arm with the C-arm Cradle

12. Lower the work surface on the acquisition workstation to the minimum height.
13. Shut down the system.
14. Make sure the x-ray switch is secure in its holder.
15. Put the mouse in the mouse holder on the right of the keyboard tray (see item 2 in the following figure).
16. Close and lock the keyboard tray.

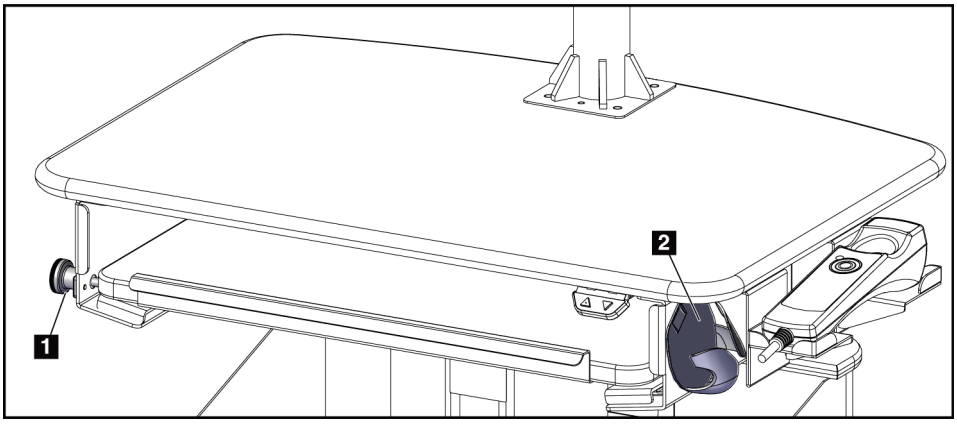


Figure 90: Mouse Holder (2) and Keyboard Tray Lock Knob (1)

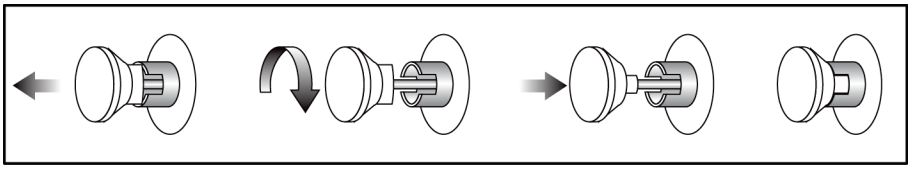


Figure 91: Set the Lock Knob to Locked Position

17. Release the monitor lock knobs to adjust the monitors for transport. Swivel the monitors to center position until the lock knobs lock. Tilt the monitors fully forward until the lock knobs lock.

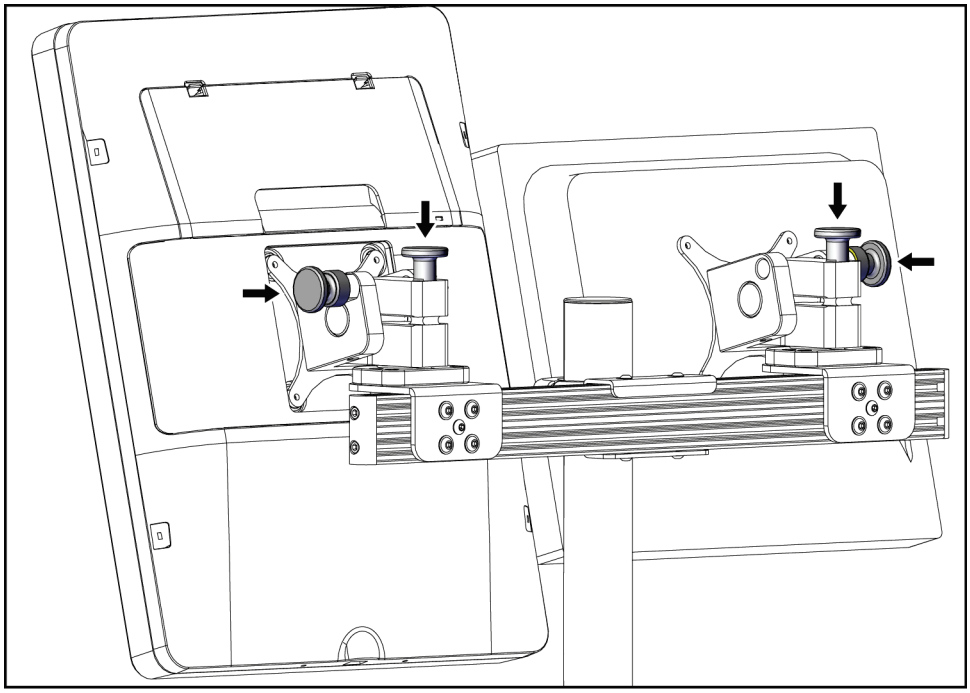


Figure 92: Release the Lock Knobs on the Monitors

C.5 Prepare the System for Use

1. Unlock and adjust the monitors.
2. Adjust the work surface height of the acquisition workstation.
3. Unlock and open the keyboard tray.
4. Remove the mouse from the mouse holder.
5. Power on the system.
6. Raise the patient platform to its full height.
7. Remove the footswitch from the C-arm cradle. Follow all safety requirements when positioning the footswitch.
8. Remove the height tool from the C-arm. Store the height tool in the C-arm cradle.
9. Remove the C-arm cradle and put in a safe storage area.

C.6 Test the System after Travel

C.6.1 Functional Tests After Travel

Perform the Functional Tests. Refer to the section *Functional Tests* on page 32.

- Compression Apply and Release
- C-arm Up and Down
- Patient Platform Up and Down
- Patient Platform Up Limit

C.6.2 Quality Control Tests After Travel

Perform the Quality Control tests as recommended for the non-mobile Affirm prone biopsy system.

Appendix D: Dose Conversion Tables for the Medical Physicist

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
W/Ag Target-Filter Combination with 4.2-cm 50/50 Breast

	X-ray Tube Voltage (kVp)												
HVL	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**
0.400	222	226	229	231	234	236	239	241	244	246	248	250	252
0.425	233	236	239	242	244	246	248	251	253	256	258	260	262
0.450	244	247	249	252	254	256	258	260	263	265	267	269	271
0.475	254	257	260	262	264	266	268	270	273	275	277	279	281
0.500	265	267	270	272	274	276	278	280	282	284	286	288	290
0.525	275	278	280	282	284	286	288	290	292	294	296	298	300
0.550	286	288	290	292	294	296	298	299	301	303	305	307	309
0.575	296	298	300	302	304	305	307	309	311	313	315	317	318
0.600	306	308	310	312	313	315	317	319	320	322	324	326	328
0.625	316	318	320	322	323	325	326	328	330	332	333	335	337
0.650	326	328	330	331	333	334	336	338	339	341	343	344	346
0.675	336	338	339	341	342	344	345	347	349	350	352	354	355
0.700	346	348	349	350	352	353	355	356	358	359	361	363	364
0.725	356	357	358	360	361	362	364	365	367	368	370	372	373
0.750	365	367	368	369	370	372	373	375	376	378	379	381	382
0.775	374	376	377	378	379	381	382	383	385	386	388	390	391
0.800	384	385	386	387	388	390	391	392	394	395	397	398	400
0.825	393	394	395	396	397	399	400	401	403	404	406	407	408
0.850	402	403	404	405	406	407	409	410	411	413	414	416	417
0.875	410	411	412	413	415	416	417	418	420	421	423	424	425
0.900	419	420	421	422	423	424	425	427	428	429	431	432	434

(Tomosynthesis Option)

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
W/Al Target-Filter Combination with 4.2-cm 50/50 Breast

	X-ray Tube Voltage (kVp)												
HVL	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**
0.20	120	125	133	138	143	148	156	160	165	169	177	181	185
0.25	143	148	155	160	165	169	176	181	185	189	196	200	204
0.30	166	171	177	182	187	191	197	202	206	210	216	220	223
0.35	189	195	200	204	209	213	218	222	226	230	236	239	243
0.40	212	217	222	226	231	235	239	243	247	251	255	258	262
0.45	234	239	244	248	252	256	260	264	268	271	275	278	281
0.50	256	261	265	269	273	277	280	284	288	291	294	297	300
0.55	278	282	286	290	293	297	300	304	307	310	313	316	319
0.60	300	303	307	310	313	317	320	323	326	329	332	335	337
0.65	321	324	327	330	333	336	339	342	345	347	350	353	355
0.70	341	344	347	350	352	355	358	361	363	366	368	370	373
0.75	360	363	366	369	371	374	376	379	381	383	386	388	390
0.80	379	382	385	387	389	392	394	396	398	401	403	405	407
0.85	398	400	403	405	407	409	411	413	415	417	419	421	423
0.90	415	418	420	422	424	426	428	430	432	434	435	437	439
0.95	432	435	437	438	440	442	444	446	448	449	451	453	454
1.00	448	451	453	454	456	458	460	461	463	465	466	467	469

(Tomosynthesis Option)

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
W/Al Target-Filter Combination with 4.2-cm 50/50 Breast

	X-ray Tube Voltage (kVp)												
HVL	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**
0.20	188	195	198	200	203	208	216	219	222	225	231	234
0.25	207	213	216	219	221	226	233	236	239	241	247	250
0.30	226	232	235	237	239	244	250	253	256	258	264	266
0.35	246	250	253	255	257	262	267	270	273	275	280	282
0.40	265	269	271	273	275	280	285	287	290	292	296	298
0.45	284	287	290	292	294	298	302	304	307	309	313	315
0.50	303	306	308	310	312	316	319	321	324	326	329	331
0.55	322	324	326	328	330	334	336	339	341	343	345	347
0.60	340	342	344	346	348	351	354	356	358	360	362	363
0.65	358	360	362	363	365	368	370	372	374	376	378	380
0.70	375	377	379	380	382	385	387	389	390	392	394	395
0.75	392	394	395	397	398	401	403	404	406	408	409	411
0.80	408	410	412	413	414	417	418	420	421	423	424	426
0.85	425	426	427	429	430	432	434	435	436	438	439	440
0.90	440	442	443	444	445	447	449	450	451	452	454	455
0.95	455	457	458	459	460	462	463	464	465	467	468	469
1.00	470	471	472	474	475	476	477	478	479	480	481	482

Appendix E: CNR Correction for Biopsy

E.1 CNR Correction for Stereotactic Biopsy

E.1.1 AEC Table 0 (Standard Stereotactic Biopsy Dose)

Compression Thickness	CNR Correction Factor
2.0 cm	0.71
4.0 cm	0.94
6.0 cm	1.30
8.0 cm	1.71

E.1.2 AEC Table 1 (EUREF Stereotactic Biopsy Dose)

Compression Thickness	CNR Correction Factor
2.0 cm	0.69
4.0 cm	0.98
6.0 cm	1.09
8.0 cm	1.53

E.2 CNR Correction for Biopsy under Tomosynthesis Option

E.2.1 AEC Table 0 (Tomosynthesis Option: Standard Tomo Dose)

Compression Thickness	CNR Correction Factor
2.0 cm	0.88
4.0 cm	0.94
6.0 cm	1.53
8.0 cm	2.32

E.2.2 AEC Table 1 (EUREF Tomosynthesis Biopsy Dose)

Compression Thickness	CNR Correction Factor
2.0 cm	0.65
4.0 cm	0.96
6.0 cm	1.61
8.0 cm	2.91

Appendix F: Multipliers for Wire Localization

Multipliers for the StereoLoc and TomoLoc views have been developed to adjust the mAs calculated from the biopsy scout views that are acquired using AEC. These multipliers are applied only to the AEC-Locked TomoLoc and StereoLoc views in order to reduce the heat load on the x-ray tube for wire localization procedures that involve the placement of multiple wires.

Note
The resulting mAs on the TomoLoc and StereoLoc views will always be less than or equal to the mAs of the preceding biopsy scout view.

F.1 Multipliers for Wire Localization with StereoLoc Views

Compression Thickness	Multiplier
2.0 cm	0.75
4.0 cm	0.70
6.0 cm	0.40
8.0 cm	0.35

F.2 Multipliers for Wire Localization with TomoLoc Views

Compression Thickness	Multiplier
2.0 cm	1.00
4.0 cm	0.90
6.0 cm	0.90
8.0 cm	0.85

Appendix G: Technique Tables

G.1 Recommended Technique Table for Stereotactic Procedures

Compressed Breast Thickness (mm)	Fatty Breast		Normal Breast		Dense Breast	
	kVp	mAs	kVp	mAs	kVp	mAs
10	25	50	25	50	25	56
20	25	56	25	56	25	63
30	26	80	26	90	26	100
40	28	90	28	125	28	140
50	28	140	28	180	28	220
60	30	180	30	250	30	280
70	32	250	32	320	32	360
80	34	250	34	320	34	400
90	36	360	36	450	36	500
100	38	320	38	360	38	450
110	39	280	39	360	39	450
120	39	320	39	400	39	500

G.2 Recommended Technique Table for Tomosynthesis Procedures

Compressed Breast Thickness (mm)	Fatty Breast		Normal Breast		Dense Breast	
	kVp	mAs	kVp	mAs	kVp	mAs
10	26	28	26	28	26	32
20	26	32	26	32	26	36
30	26	50	26	56	26	63
40	27	71	27	80	27	100
50	29	80	29	90	29	110
60	31	90	31	100	31	140
70	33	125	33	140	33	160
80	35	140	35	160	35	200
90	38	160	38	180	39	200
100	39	140	39	160	41	180
110	41	140	41	160	43	160
120	43	126	43	140	45	160

Appendix H: Ancillary Parts for Biopsy

H.1 Hologic Factory-Verified Biopsy Devices

Table 19: Hologic Factory-Verified Biopsy Devices

Manufacturer	Description	Model
Hologic	Affirm QAS Needle	ASY-03949
Hologic	ATEC® 9 g x 12 cm, 12 mm (Petite)	ATEC 0912-12
Hologic	ATEC 9 g x 12 cm, 20 mm	ATEC 0912-20
Hologic	ATEC 12 g x 12 cm, 20 mm	ATEC 1212-20
Hologic	ATEC 9 g x 9 cm, 12 mm (Petite)	ATEC 0909-12
Hologic	ATEC 9 g x 9 cm, 20 mm	ATEC 0909-20
Hologic	ATEC 12 g x 9 cm, 20 mm	ATEC 1209-20
Hologic	ATEC 9 g x 14 cm, 20 mm	ATEC 0914-20
Hologic	Brevera® 9 g x 13 cm, 20 mm (Standard) or 12 mm (Petite)	BREV09
Hologic	Eviva® 9 g x 13 cm, 12 mm (Blunt Petite)	Eviva 0913-12
Hologic	Eviva 9 g x 13 cm, 12 mm (Trocar Petite)	Eviva 0913-12T
Hologic	Eviva 9 g x 13 cm, 20 mm	Eviva 0913-20
Hologic	Eviva 12 g x 13 cm, 20 mm	Eviva 1213-20
Hologic	Eviva 9 g x 10 cm, 12 mm (Blunt Petite)	Eviva 0910-12
Hologic	Eviva 9 g x 10 cm, 12 mm (Trocar Petite)	Eviva 0910-12T
Hologic	Eviva 9 g x 10 cm, 20 mm	Eviva 0910-20
Hologic	Eviva 12 g x 10 cm, 20 mm	Eviva 1210-20

Appendix I: Forms

I.1 QAS Test Checklist

Date	Tech	X Diff	Y Diff	Z Diff	Pass/Fail

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I.2 Geometry Calibration

Serial Number: _____

Year:					
Date:					
Initials:					
Completed:					

Year:					
Date:					
Initials:					
Completed:					

Year:					
Date:					
Initials:					
Completed:					

Year:					
Date:					
Initials:					
Completed:					

Remarks

Date	Action

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I.3 Gain Calibration

Serial Number: _____

Year:					
Date:					
Initials:					
Completed:					

Year:					
Date:					
Initials:					
Completed:					

Year:					
Date:					
Initials:					
Completed:					

Year:					
Date:					
Initials:					
Completed:					

Remarks

Date	Action

Glossary of Terms

ACR
American College of Radiology

AEC
Automatic Exposure Control

Annotations
Markings on an image to indicate an area of interest.

BCM
Biopsy Control Module

Collimator
A device at the x-ray tube to control the x-ray beam exposure area.

DICOM
Digital Imaging and Communications in Medicine

EMC
Electromagnetic Compatibility

Image Receptor
Assembly of the x-ray detector and carbon fiber cover.

Lateral Needle Approach
Biopsy device approach that is parallel to the imaging plane and perpendicular to the plane of compression.

LUT
Look Up Table. A list of settings to apply to other vendor images for optimal viewing.

MQSA
Mammography Quality Standards Act

RF
Radio Frequency

ROI
Region of Interest

SID
Source to Image Distance

Standard Needle Approach
Biopsy device approach that is parallel to the plane of compression and perpendicular to the imaging plane.

Stereo Pair
The stereotactic image pair acquired from the ±15° projections.

Stroke
Excursion of needle when the biopsy instrument is fired. The Stroke is entered into the system and depends on the instrument used. Each instrument has a specified stroke.

Stroke Margin
The safety margin (in mm) which remains between the fired needle position and the breast platform. This margin is calculated by the system according to the "Z" coordinate, the Stroke, and the compression amount.

Tomosynthesis
An imaging procedure that combines a number of breast images taken at different angles. The tomosynthesis images can be reconstructed to show focal planes (slices) within the breast.

UDI
A United States Food and Drug Administration program for Unique Device Identification (UDI). For more information about UDI, go to *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm*.

UPS
Uninterruptible Power Supply

X-axis

Refers to the horizontal plane across the biopsy window. When the Needle Guidance Stage moves left of the reference point, the movement in the X direction is negative. When the stage moves right of the reference point (from the point of view of the patient), the movement is positive.

Y-axis

Refers to the vertical plane directly above the biopsy window. When the Needle Guidance Stage moves away from the reference hole (from the point of view of the chest wall edge of the biopsy paddle), the Y direction movement increases in value. When the Stage moves toward the reference hole, Y decreases in value.

Z-axis

Refers to the depth through the biopsy window. The value of Z increases as the Stage moves toward the breast platform, and decreases as the stage moves away from the platform.

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