3Dimensions™

User Guide

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HOLOGIC®

3Dimensions™

Digital Mammography System

Digital Tomosynthesis System

User Guide

For Software Version 2.0

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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

Caution: Federal law restricts this device to sale by or on the order of a physician.

The Hologic® 3Dimensions™ system is indicated to generate digital mammographic images that can be used for screening and diagnosis of breast cancer. The 3Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the 3Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set

  - OR -

- a 2D and 3D image set, where the 2D image can be either an FFDM or a 2D image generated from the 3D image set

The 3Dimensions system may also be used for additional diagnostic workup of the breast.

Note
In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either a FFDM image or 2D image generated from the 3D image set).

Contrast Enhanced Digital Mammography

Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the 3Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.

1.1.1 Contraindications

There are no known contraindications.

1.2 Potential Adverse Effects of Mammography Systems on Health

Below is a list of the potential adverse effects (such as complications) associated with the use of the device (these risks are the same as for other screen-film or digital mammography systems):

- Excessive breast compression
- Excessive x-ray exposure
- Electric shock
- Infection
- Skin irritation, abrasions, or puncture wounds

1.3 System Capabilities

The system provides the user interfaces for the performance of screening and diagnostic mammograms:

- Conventional mammography with a digital image receptor equivalent in size to large mammography film.
- Tomosynthesis scan with a digital image receptor equivalent in size to large mammography film (Tomosynthesis option).
- Conventional digital mammogram and tomosynthesis scan during one compression (Tomosynthesis option).

1.4 About the Genius 3D Mammography Exam

The Genius™ 3D Mammography™ exam (also known as Genius™ exam) is acquired on a Hologic® 3D Mammography™ system, and has a 2D and 3D™ image set. The 2D image can be either an acquired 2D image or a 2D image generated from the 3D™ image set. The Genius™ exam is only available on a Hologic® 3D Mammography™ system.

Genius™ 3D Mammography™ is the brand name of a Hologic 3D Mammography™ exam, and may not be available in all markets.

1.5 More Information About Tomosynthesis

The Hologic Selenia Dimensions system received FDA approval for the Hologic Tomosynthesis option on 11 Feb 2011 (refer to PMA number P080003). This FDA approval applies to screening and diagnostic imaging. More information is available from the FDA website at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003*.

The Generated 2D option (C-View) in conjunction with Tomosynthesis received FDA approval on 16 May 2013 (refer to PMA number P080003 S001). More information is available from the FDA website at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003S001*.

A list of scientific publications about Breast Tomosynthesis is available from the Hologic website. The majority of the studies were done with the commercially released Hologic Selenia Dimensions Tomosynthesis system. See the publication at *http://www.hologic.com/sites/default/files/Tomo-Bibliography-Rev-13.pdf*.

The Hologic website has several white papers and summary cards about breast imaging publications. See the documents at *http://www.hologic.com/en/learning-center/white-papers/breastimaging/*.

Independent publications have examined Hologic Selenia Dimensions Tomosynthesis systems in population-based screening sequences in Europe. Results consistently show a significant increase in invasive cancer detection rate at the same time as a reduction in false positives. The following publications are recommended.

Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study.

Ciatto S, Houssami N, Bernardi D, Caumo F, Pellegrini M, Brunelli S, Tuttobene P, Bricolo P, Fantò C, Valentini M, Montemezzi S, Macaskill P.

Lancet Oncol. 2013 Jun;14(7):583-9. doi: 10.1016/S1470-2045(13)70134-7. Epub 2013 Apr 25.

http://www.ncbi.nlm.nih.gov/pubmed/23623721

Prospective trial comparing full-field digital mammography (FFDM) versus combined FFDM and tomosynthesis in a population-based screening programme using independent double reading with arbitration.

Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, Izadi M, Jebsen IN, Jahr G, Krager M, Hofvind S.

Eur Radiol. 2013 Aug;23(8):2061-71. doi: 10.1007/s00330-013-2820-3. Epub 2013 Apr 4.

http://www.ncbi.nlm.nih.gov/pubmed/23553585

Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program.

Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, Izadi M, Jebsen IN, Jahr G, Krager M, Niklason LT, Hofvind S, Gur D.

Radiology. 2013 Apr;267(1):47-56. doi: 10.1148/radiol.12121373. Epub 2013 Jan 7.

http://www.ncbi.nlm.nih.gov/pubmed/23297332

Two-view digital breast tomosynthesis screening with synthetically reconstructed projection images: comparison with digital breast tomosynthesis with full-field digital mammographic images.

Skaane P, Bandos AI, Eben EB, Jebsen IN, Krager M, Haakenaasen U, Ekseth U, Izadi M, Hofvind S, Gullien R.

Radiology. 2014 Jun;271(3):655-63. doi: 10.1148/radiol.13131391. Epub 2014 Jan 24

http://www.ncbi.nlm.nih.gov/pubmed/24484063

Breast Cancer Screening Using Tomosynthesis in Combination With Digital Mammography

Sarah M. Friedewald, MD1; Elizabeth A. Rafferty, MD2; Stephen L. Rose, MD3,4; Melissa A. Durand, MD5; Donna M. Plecha, MD6; Julianne S. Greenberg, MD7; Mary K. Hayes, MD8; Debra S. Copit, MD9; Kara L. Carlson, MD10; Thomas M. Cink, MD11; Lora D. Barke, DO12; Linda N. Greer, MD13; Dave P. Miller, MS14; Emily F. Conant, MD15

JAMA. 2014;311(24):2499-2507. doi:10.1001/jama.2014.6095

http://jama.jamanetwork.com/article.aspx?articleid=1883018

IMPORTANT:
Hologic strongly recommends that users make themselves familiar with local or regional regulations. These regulations could impose restrictions on the different types of clinical use. Because the regulations could evolve and change over time, periodic review is recommended.

1.6 About C-View and Intelligent 2D

Note
Intelligent 2D™ may not be available in all regions. Contact your sales representative for information

1.6.1 C-View and Intelligent 2D Software

The C-View™ and Intelligent 2D™ software uses image data available from a breast tomosynthesis acquisition to generate one digital mammogram (2D) per breast tomosynthesis acquisition. The generated 2D image is created without the need for an additional digital mammography exposure. The generated 2D image is designed to appear similar to, and serve the same purpose as, a digital mammogram (2D) when used as part of a screening study employing tomosynthesis. The C-View or Intelligent 2D image is interpreted in combination with a breast tomosynthesis image set and is not intended to be used without the accompanying breast tomosynthesis images to make a clinical decision or diagnosis.

1.6.2 C-View and Intelligent 2D Warnings

Warning:
Do not make a clinical decision or diagnosis from the C-View or Intelligent 2D images without reviewing the accompanying tomosynthesis image set.

Use the C-View or Intelligent 2D generated 2D images in the same way you would use conventional digital mammography (2D) when performing a screening study employing tomosynthesis.

- While reviewing the C-View or Intelligent 2D images for items or areas of interest, compare to a prior digital mammogram (2D) if priors exist and then review the related tomosynthesis images carefully.
- Carefully examine the entire tomosynthesis image set before making a clinical decision.

Warning:
The appearance of a C-View or Intelligent 2D generated 2D image may differ from that of a conventional digital mammography (2D) image, just as 2D film and digital mammography (2D) images from different vendors may look different.

Users should ensure they are adequately trained and are familiar with the appearance of C-View and Intelligent 2D generated 2D images before using them in conjunction with tomosynthesis image sets.

1.6.3 C-View and Intelligent 2D Theory of Operation

Overview

The C-View and Intelligent 2D software is an image processing application for post-processing the pixel data from tomosynthesis data, captured on a Hologic tomosynthesis imaging system, into a digital mammography (2D) image. The C-View or Intelligent 2D generated 2D image can be used in place of a digital mammogram (2D) as part of a screening study employing tomosynthesis.

The C-View and Intelligent 2D software processes tomosynthesis data to generate 2D images which are designed to appear similar to and serve the same purpose as a digital mammogram (2D) when used as part of a screening study employing tomosynthesis.

Configuration

The C-View and Intelligent 2D software has no user-configurable settings that influence the appearance of the resulting generated 2D images. C-View and Intelligent 2D images are produced in either DICOM Breast Tomosynthesis Image object format, as a single thick slice, or DICOM Digital Mammography Image object format. The site PACS administrator, in consultation with Hologic connectivity engineers, can select the output format most appropriate for the site's IT infrastructure and workstations. Each C-View or Intelligent 2D image DICOM header contains the information needed to differentiate it from any accompanying conventional 2D image(s) or tomosynthesis image sets in the same view. An annotation ("C-View" or "Intelligent 2D") will also be burned to the generated 2D image pixel data.

Workflow

As with any imaging study, the technologist selects the patient and identifies the type of imaging procedure that will be done. For an exam with C-View or Intelligent 2D images, the process of imaging the subject and completing the study is all that is necessary. The C-View and Intelligent 2D software itself operates with no direct human intervention.

1.7 User Profiles

1.7.1 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.
- Knows how to operate a computer and its peripherals.

1.7.2 Radiologist

- Meets all requirements that apply to the location in which the Radiologist operates.
- Knows how to operate a computer and its peripherals.

1.7.3 Medical Physicist

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

1.8 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 use on patients.

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

1.9 Quality Control Requirements

Facilities in the United States must use the Quality Control Manual to create a Quality Assurance and Quality Control program. The facility must create the program to meet the requirements of the Mammography Quality Standards Act or to be accredited by ACR or another accreditation body.

Facilities outside the United States can use the Quality Control Manual as a guide to create a program to meet the local standards and regulations.

1.10 Where to Find the Installation Instructions

Installation instructions are available in the *Service Manual*.

1.11 Where to Find Technical Description Information

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

1.12 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.

1.13 Technical Support

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

1.14 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. (See the copyright page for contact information.)

1.15 Hologic Cybersecurity Statement

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

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

1.16 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)
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Warning Electricity
	Manufacturer
	Date of Manufacture
	This system transmits radio frequency (RF) energy (non-ionizing radiation)
	Caution—Radiation
	Follow instructions for use
	Caution
	Catalog number
	Serial number
	Part number

1.17 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.

1.18 Document Conventions

When prompted to add text, enter the text printed in `monospaced font` exactly as shown.

Chapter 2 General Information

2.1 System Overview

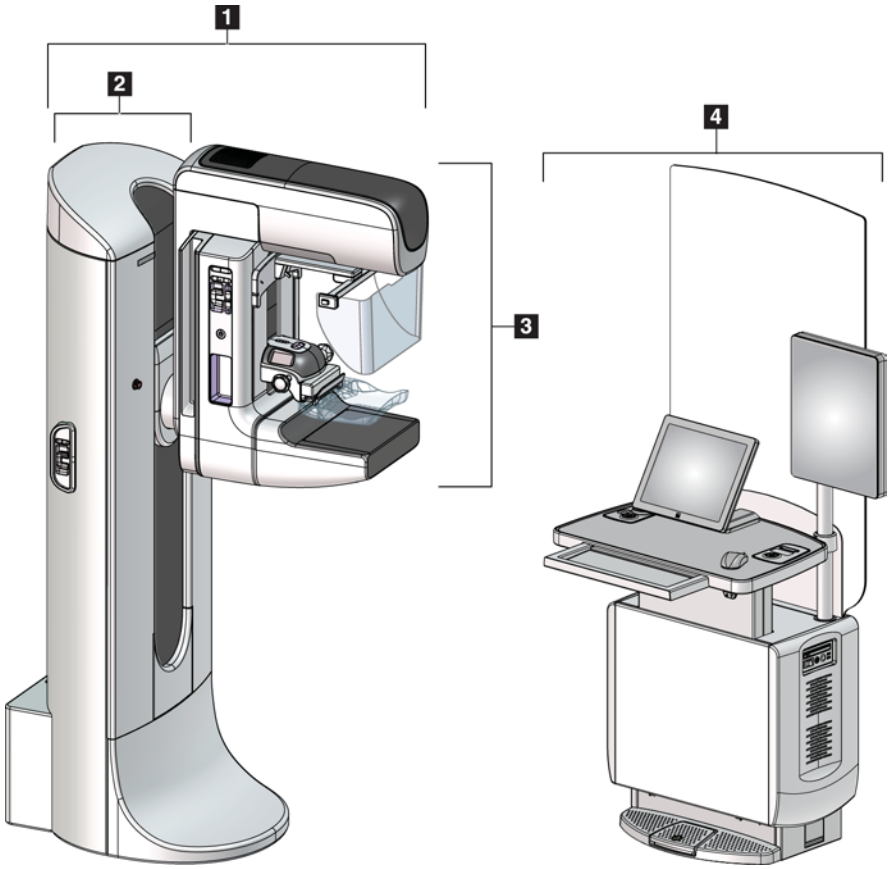


Figure 1: 3Dimensions™ System

Figure Legend

1. Tubestand (Gantry and C-arm)
2. Gantry
3. C-arm (Tube Arm and Compression Arm)
4. Universal Acquisition Workstation

2.1.1 C-Arm Overview

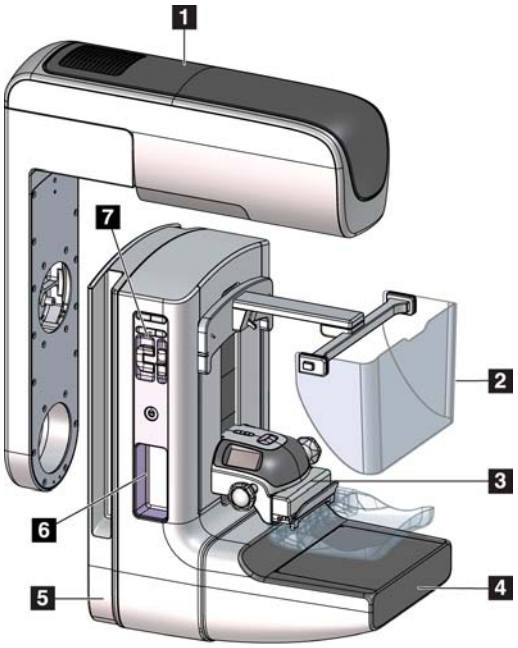


Figure 2: C-arm Overview

Figure Legend

1. Tube Arm
2. Patient Face Shield
3. Compression Device
4. Image Receptor
5. Compression Arm
6. Patient Handle
7. C-arm Control Panel

2.2 Safety Information

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

Always follow all the instructions in this manual. Hologic does not accept the responsibility for injury or damage from incorrect system operation. Hologic can schedule training at your facility.

The system has protective devices, but the Technologist must understand how to safely use the system. The Technologist must remember the health hazards of x rays.

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.

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

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!
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:
The bar code scanner installed in this system is a Class II Laser Product. Prevent direct exposure to the beam. Hidden laser radiation exists if the cover is opened.

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:
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.

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:
For exposures except magnification case studies, always use the Face Shield.

Warning:
The Face Shield does not protect the patient from radiation.

Warning:
Risk of entrapment. Make sure that the C-arm has 50 cm (20 inches) of clearance to any object during C-arm rotation. Do not use Auto Rotation when C-arm clearance is less than 50 cm (20 inches).

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:
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.

Note:
Hologic does not supply the Gantry power cable for some countries. If the power cable is not supplied, the installed cable must meet the following requirements and all local codes that apply: 3 conductor, 8 AWG (10 mm^2) copper not more than 25 feet (7.62 meters) in length.

2.4 Emergency Off Switches

The Emergency Off switches remove the power from the Gantry and the Acquisition Workstation Lift Mechanism (on the workstations that include that option). Do not routinely use the Emergency Off switches to turn off the system.

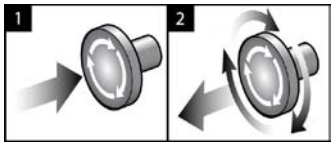


Figure 3: Emergency Off Switch Functionality

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.

2.5 Interlocks

The 3Dimensions system has safety interlocks:

- C-arm vertical movement and rotation are disabled when compression force is applied. A Service Engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).
- If the x-ray button or x-ray footswitch is released before the end of the exposure, the exposure stops and an alarm message is displayed.
- When in Tomo mode, the system does not allow an exposure if the Grid is in the x-ray field (Tomosynthesis option).
- Mirror and Filter position flags also prevent x rays when the Light Field Mirror or the Filter Assembly is not correctly positioned.

2.6 Compliance

This section describes the mammography 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 mammography 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.

Caution:
Based on ENCLOSURE PORT IMMUNITY to RF WIRELESS COMMUNICATIONS EQUIPMENT test level per IEC 60601-1-2 ed. 4, this device shows susceptibility to GMRS 460, FRS 460 transmission frequency. Provide a minimum separation of 30 cm between GMRS and FRS radios and the system.

Caution:
This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

2.6.2 Compliance Statements

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

Medical – Applied electromagnetic radiation equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1 (2005) and CAN/CSA-C22.2 No. 60601-1 (2008)

- CAN/CSA - ISO 13485-03 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes (Adopted ISO 13485:2003 second edition, 2003-07-15)
- CAN/CSA C22.2 NO. 60601-1-08 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12), includes Corrigendum 1:2011
- EN 60601-1:2006 Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance
- ETSI EN 300 330-1: V1.3.1, and ETSI EN 300 330-2: V1.5.1: 2006—Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
- ETSI EN 301 489-1: V1.6.1, and ETSI EN 301 489-3: V1.8.1: 2008—Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services
- FCC, 47 CFR Part 15, Subpart C, Section 15.225: 2009
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1 Ed. 3.0:2005 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Ed. 3.0:2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-3 Ed. 2.0:2008 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-28 Ed. 2.0:2010 Medical Electrical Equipment - Part 2-28: Particular Requirements for the Basic Safety and Essential Performance of X-ray Tube Assemblies for Medical Devices
- IEC 60601-2-45 Ed. 3.0:2011 Medical Electrical Equipment – Part 2-45: Particular Requirements for Basic Safety and Essential Performance of Mammographic X-Ray Equipment and Mammographic Stereotactic Devices
- RSS-210: Issue 7, 2007 Radio Standards Specification Low-power License-exempt Radiocommunication Devices: Category I Equipment
- ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, includes amendment (2010)

2.7 Label Locations

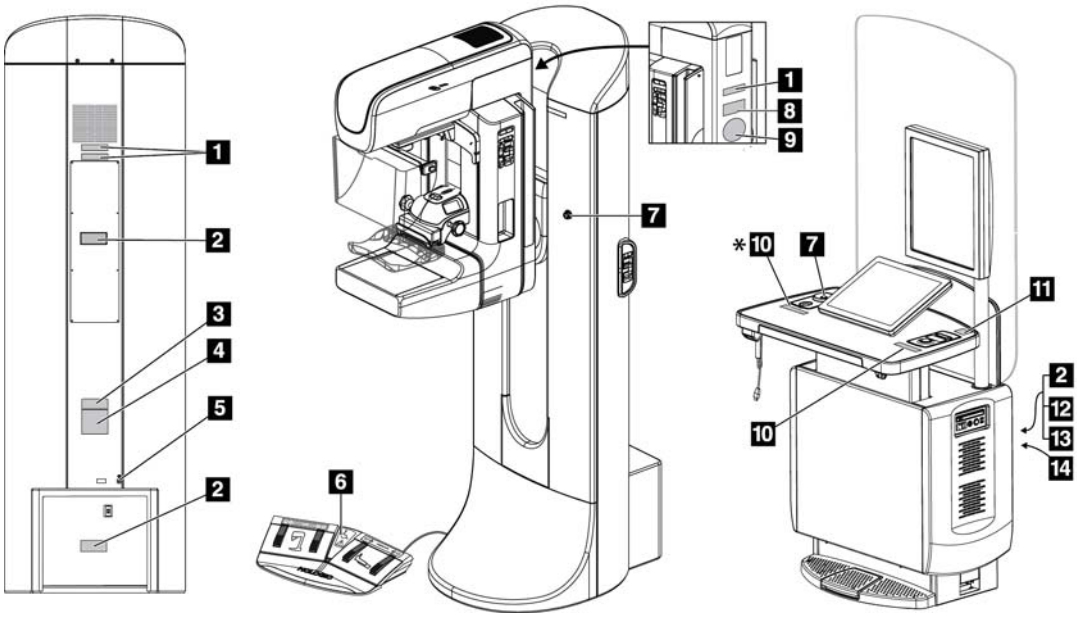
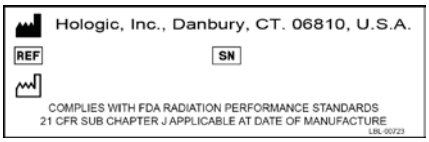


Figure 4: Label Locations

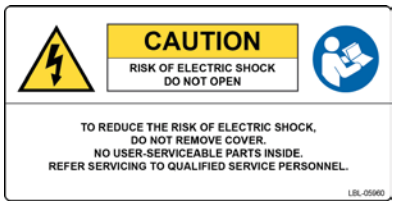
Table 1: System Labels

1



Serialized Device

2



Electrical Shock Warning

3

System Model

4

Gantry Nameplate

5

Potential Equalization Terminal

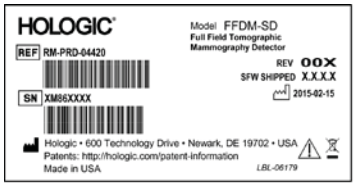
6

Wheelchair Warning for Footswitch

7

Emergency Stop Switch

8

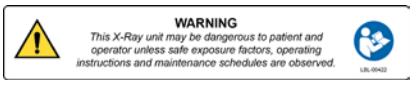


Tomographic Mammography Detector

9

Vendor-supplied X-ray Tube Serial Number

10

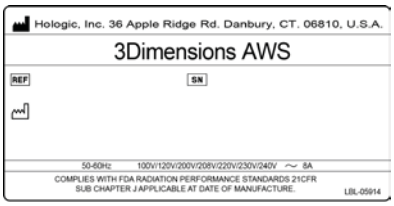


X-ray Device Warning

11

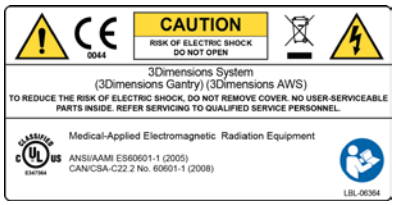
Technical Support Contact

12



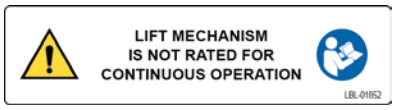
Acquisition Workstation Nameplate

13



Compliance

14



Acquisition Workstation Lift Limit

Chapter 3 System Controls and Indicators

3.1 System Power Controls

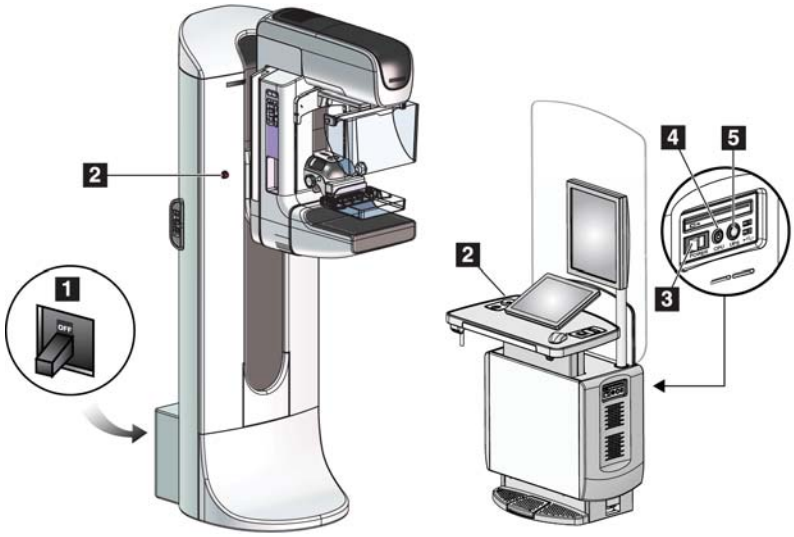


Figure 5: System Power Controls

Figure Legend

1. Gantry Power Circuit Breaker
2. Emergency Off Switch (two on the Gantry, one on the Acquisition Workstation)
3. Acquisition Workstation Power Switch
4. Computer Power On/Reset Button
5. Uninterruptible Power Supply (UPS) Power Button

3.2 Tubestand Controls and Indicators

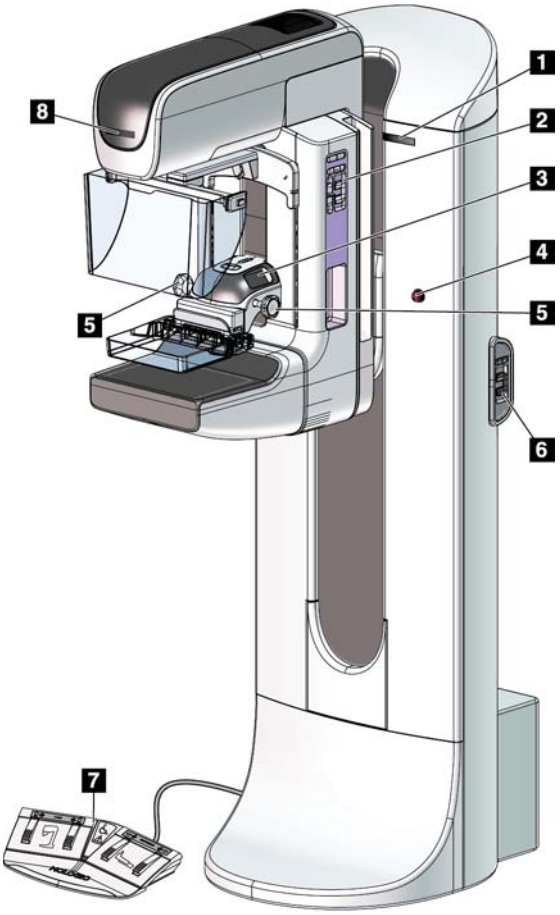


Figure Legend

1. Rotation Angle Displays (each side)
2. C-arm Control Panels (each side)
3. Compression Device
4. Emergency Off Switches (each side)
5. Compression Handwheels
6. Gantry Control Panels (each side)
7. Footswitch
8. Tubehead Display

Figure 6: Tubestand Controls and Indicators

3.2.1 Tubehead Display

The Tubehead Display shows:

- SID
- Filter Type
- Collimator Setting
- Paddle Position

Figure 7: Tubehead Display

3.2.2 Compression Device Controls and Display

Figure Legend

1. Manual Compression Handwheels
2. Paddle Shift Buttons
3. AEC Sensor Buttons
4. Compression Device Display
5. FAST Compression Mode Slide
6. Paddle Clamp

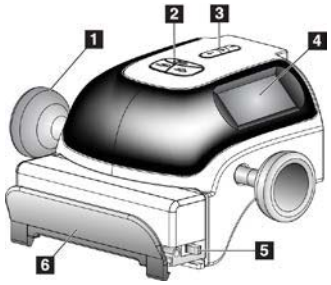


Figure 8: Compression Device

The Compression Device Display shows:

- AEC Sensor Position
- Compression Force (displays 0.0 when force is less than 4 pounds)
- Compression Thickness
- Angle of the C-arm after rotation (for 5 seconds)

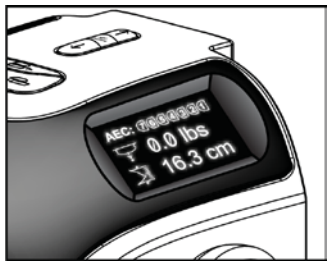


Figure 9: Compression Device Display

3.2.3 C-Arm Control Panels

There is a C-arm control panel on both the left side and right side of the C-arm. These buttons provide the Collimator and C-arm functions.

Figure 10: C-arm Control Panel

Figure Legend

1. MLO Rotation
2. C-arm Zero
3. Light Field Lamp
4. Motor Enable
5. Collimator Override
6. Clockwise C-arm Rotation
7. C-arm Up and Down
8. Counterclockwise C-arm Rotation
9. Compression Up
10. Compression Down

3.2.4 Gantry Control Panels

Control panels on the Gantry provide additional access to C-arm functions. There is a C-arm control panel on both the left side and right side of the Gantry.

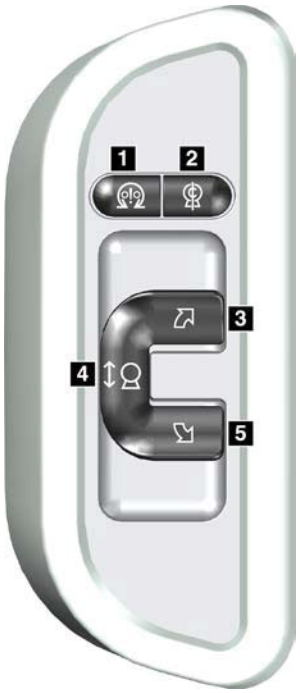


Figure 11: Gantry Control Panel

Figure Legend

1. Motor Enable
2. C-arm Zero
3. Clockwise C-arm Rotation
4. C-arm Up and Down
5. Counterclockwise C-arm Rotation

3.2.5 Dual Function Footswitch

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 use the footswitch:

1. Press the footswitch to actuate.
2. Release the switch to stop the movement.

Figure Legend

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

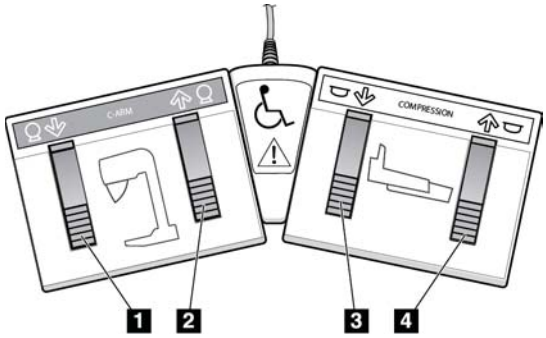


Figure 12: Dual Function Footswitch

3.3 Universal Acquisition Workstation Controls and Displays

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

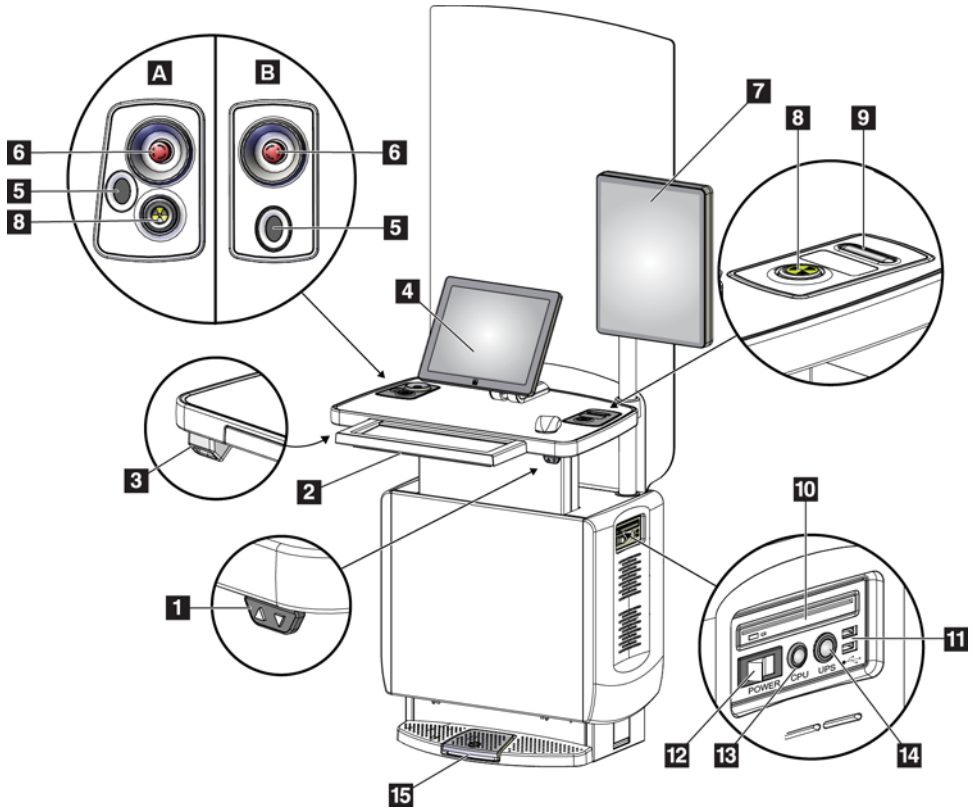


Figure 13: Universal Acquisition Workstation Controls and Displays

Figure Legend

1. Height Adjustment Switch
2. Keyboard (in drawer)
3. Bar Code Scanner
4. Control Monitor
5. Fingerprint Scanner*
6. Emergency Off Switch*
7. Image Display Monitor
8. X-ray Activation Button*
9. Compression Release Button
10. CD/DVD Drive
11. USB Ports
12. Acquisition Workstation Power Switch
13. Computer Power On/Reset Button
14. Uninterruptible Power Supply (UPS) Power Button
15. X-ray Footswitch

*A = series II UAWS layout; B = series I UAWS layout

Note
The controls for the Universal Acquisition Workstation installed in a mobile environment are the same as the controls for the Universal Acquisition Workstation.

Chapter 4 Startup, Functional Tests, and Shutdown

4.1 How to Start the System

Note
If the system remains on overnight, restart the system daily to guarantee best performance.

1. Make sure that there are no obstructions to C-arm movement or to the view of the Operator.
2. Make sure that all three Emergency Off switches are in the reset position (unpushed).

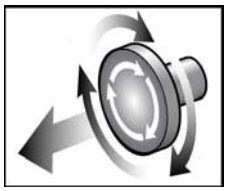


Figure 14: Turn to Reset the Emergency Off Switches

3. Make sure that the Gantry circuit breaker is in the ON position.
4. If the UPS was turned OFF, press the UPS power button to apply power to the UPS (see the following figure).

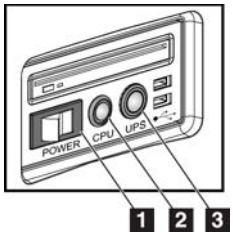


Figure 15: Universal Acquisition Workstation Power Buttons

Figure Legend

1. Acquisition Workstation Power Switch
2. Computer Power On/Reset Button
3. UPS Power Button

5. Turn ON the Acquisition Workstation power switch (see the previous figure).

6. Press the computer power button (see the previous figure). The computer powers on and the *Startup* screen opens on the Acquisition Workstation control monitor. The Gantry then automatically powers on.

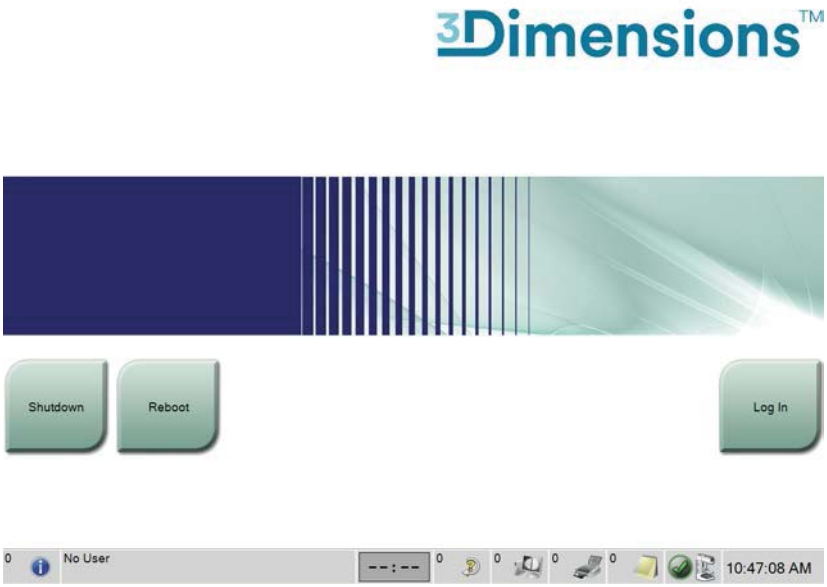


Figure 16: Startup Screen

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.

4.2 Log In

1. Select the **Log In** button on the *Startup* screen.
2. The *Select an Operator* (Log In) screen opens and shows a list of Manager and Technologist user names. If necessary, select the **Show All** button to list the Service, Applications, and Physicist user names.
3. Choose an operator by selecting the applicable user name.

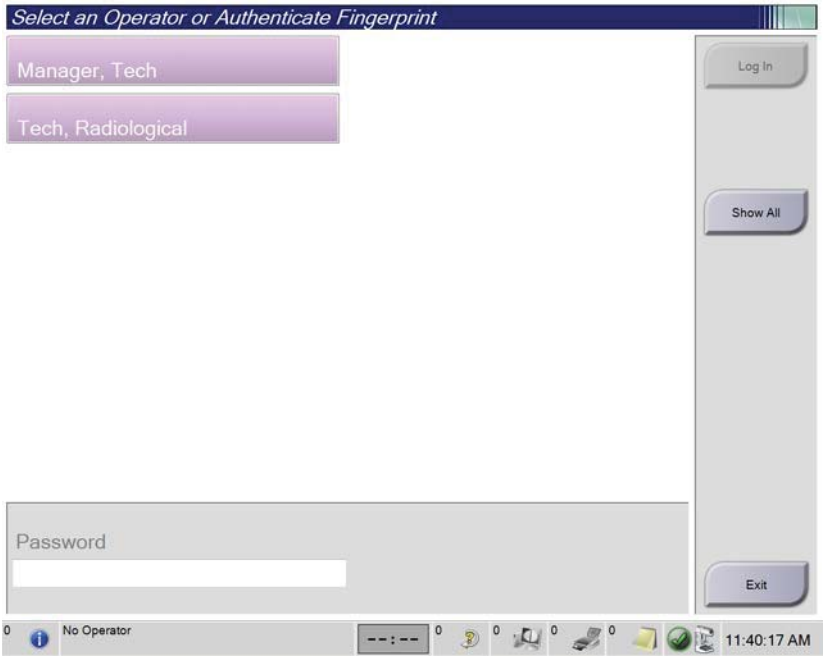


Figure 17: Select an Operator (Log In) Screen

4. Type in your password and select **Log In**.

   -OR-

   Validate your fingerprint by pressing your finger in the fingerprint scanner.

Note
Most of the unique, repeatable fingerprint information is from the pad of the finger, not the fingertip. Flat finger placement as shown in the left image results in fast and accurate fingerprint identification.

Correct operation Incorrect operation

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

4.3 Perform the Functional Tests

To make sure that the controls operate correctly, do the Functional Tests as part of your monthly visual checklist. Make sure that all buttons work correctly (Gantry and C-arm control panels, left and right sides).

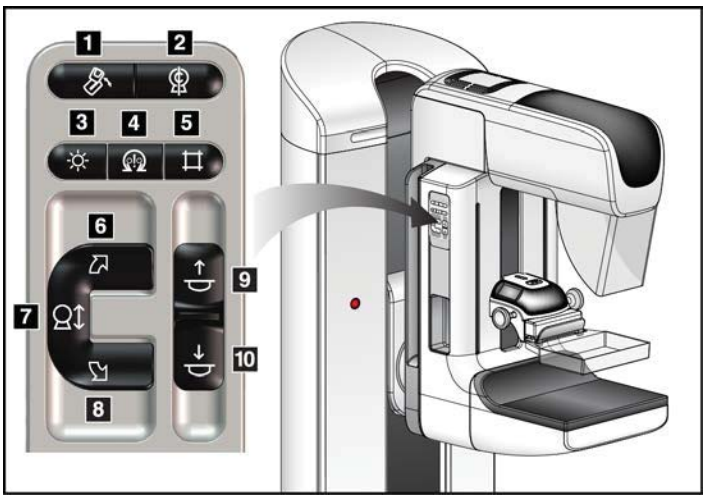


Figure 18: C-arm Control Panel (left side shown)

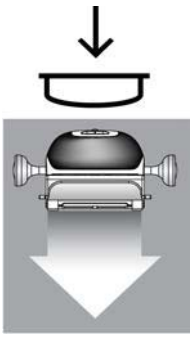
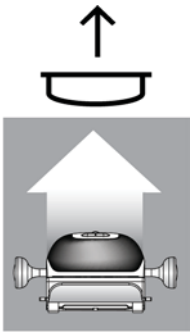
Figure Legend

1. MLO Rotation
2. C-arm Zero
3. Light Field Lamp
4. Motor Enable
5. Collimator Override
6. Clockwise C-arm Rotation
7. C-arm Up and Down
8. Counterclockwise C-arm Rotation
9. Compression Up
10. Compression Down

Note
C-arm vertical movement and rotation are disabled when compression force is applied. A Service Engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).

4.3.1 Compression Functional Tests

Table 2: Compression Tests

Function	Functional Test
Compression Down 	Press a **Compression Down** button: • The compression brake engages. • The light field lamp illuminates. • The compression device lowers. *Note… When you press the **Compression Down** button, the compression brake remains engaged until the **Compression Release** button is pressed.* Compression down movement stops: • When you release the button. • When you reach the Down Force limit. • When you reach the lower travel limit.
Compression Up 	Press a **Compression Up** button: • The Compression Device moves toward the top. *Note… The **Compression Up** button does NOT release the Compression Brake.* Compression up movement automatically stops: • When you release the button. • When you reach the upper travel limit.

4.3.2 C-Arm Movement Functional Tests

C-Arm Up and Down Movement

Table 3: C-arm Up and Down Movement

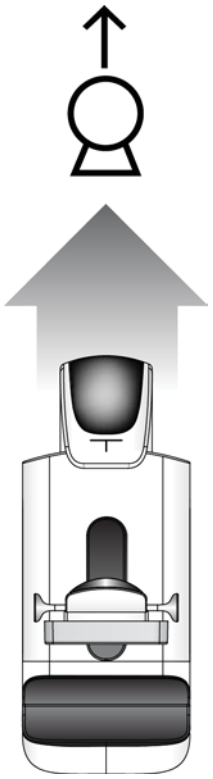
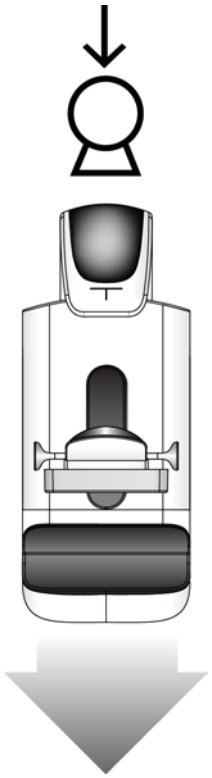
Function	Functional Test
C-arm Up 	Press the **C-arm Up** button. • C-arm movement stops when the button is released. • C-arm movement stops when the C-arm reaches the upper travel limit. • C-arm vertical movement and rotation are disabled when compression force is applied. A Service Engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).

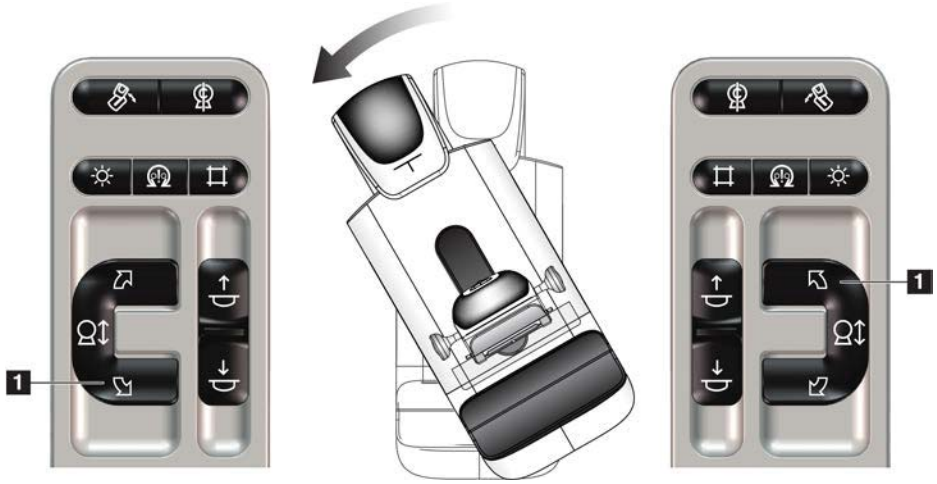
Table 3: C-arm Up and Down Movement

Function	Functional Test
C-arm Down 	Press the **C-arm Down** button. • C-arm movement stops when the button is released. • C-arm movement stops when the C-arm reaches the lower travel limit. • C-arm vertical movement and rotation are disabled when compression force is applied. A Service Engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).

C-Arm Rotation

Table 4: C-arm Counterclockwise Rotation

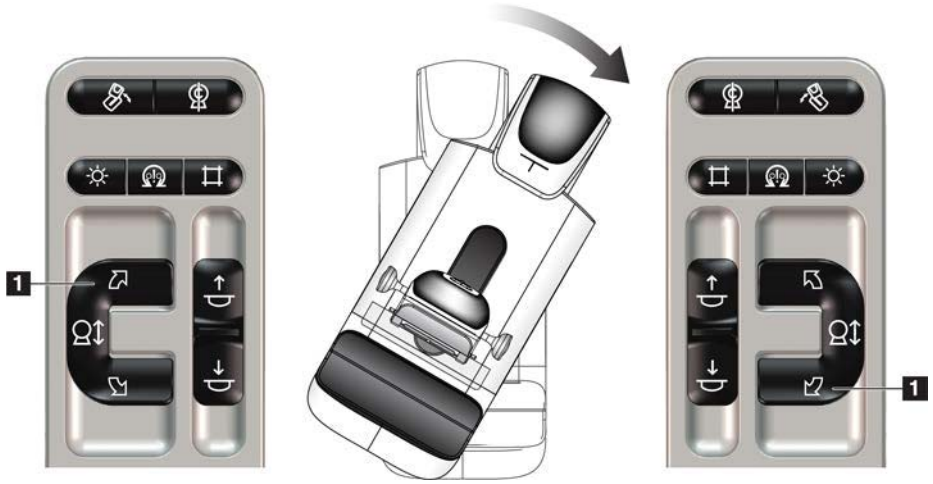
Function	Functional Test
Counterclockwise C-arm Rotation	Press the **Counterclockwise C-arm Rotation** button (item 1) to start counterclockwise C-arm rotation. C-arm movement stops when the switch is released. To fine-tune the C-arm rotation in one degree segments, hold the button down for a second, then let go quickly. Repeat as necessary.



Left Panel *Right Panel*

Table 5: C-arm Clockwise Rotation

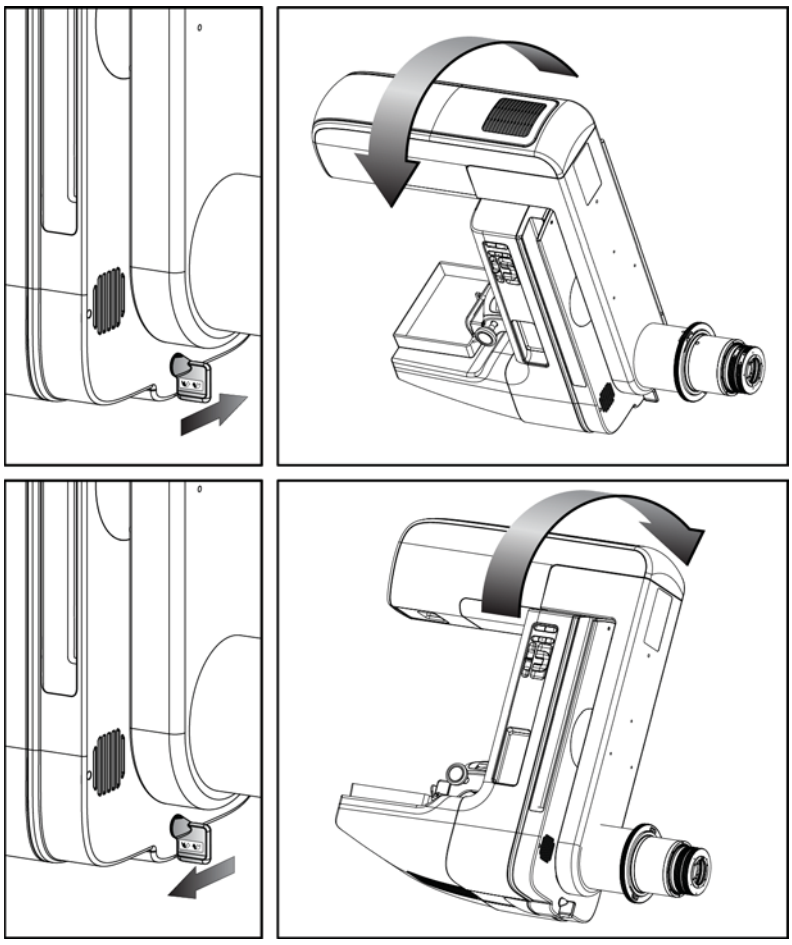
Function	Functional Test
Clockwise C-arm Rotation	Press the **Clockwise C-arm Rotation** button (item 1) to start clockwise C-arm rotation. C-arm movement stops when the switch is released. To fine-tune the C-arm rotation in one degree segments, hold the button down for a second, then let go quickly. Repeat as necessary.



Left Panel *Right Panel*

Table 6: C-arm Rotation Switch

Function	Functional Test
C-arm Rotation Switch	Push the C-arm Rotation switch away from you to move the C-arm toward you. Pull the C-arm Rotation switch toward you to move the C-arm away from you. C-arm movement stops when the switch is released.



C-Arm Automatic Rotation (Auto-Rotate)

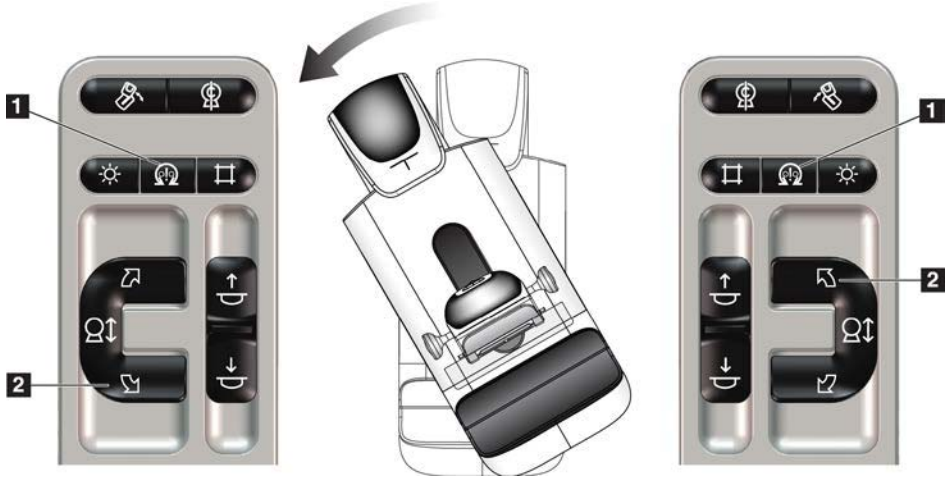
Warning:
Risk of entrapment. Make sure that the C-arm has 50 cm (20 inches) of clearance to any object during C-arm rotation. Do not use Auto Rotation when C-arm clearance is less than 50 cm (20 inches).

Note
To stop the C-arm automatic rotation movement, press any button or the Emergency Stop switch.

Motor Enable	Press the **Motor Enable** button and a **Rotation** button at the same time to enable auto-rotation movement clockwise or counterclockwise.
C-arm Zero	Press the **Motor Enable** button and the **C-arm Zero** button at the same time. Release the buttons. The machine beeps and the C-arm returns automatically to the zero position.

Table 7: Automatic C-arm Counterclockwise Rotation

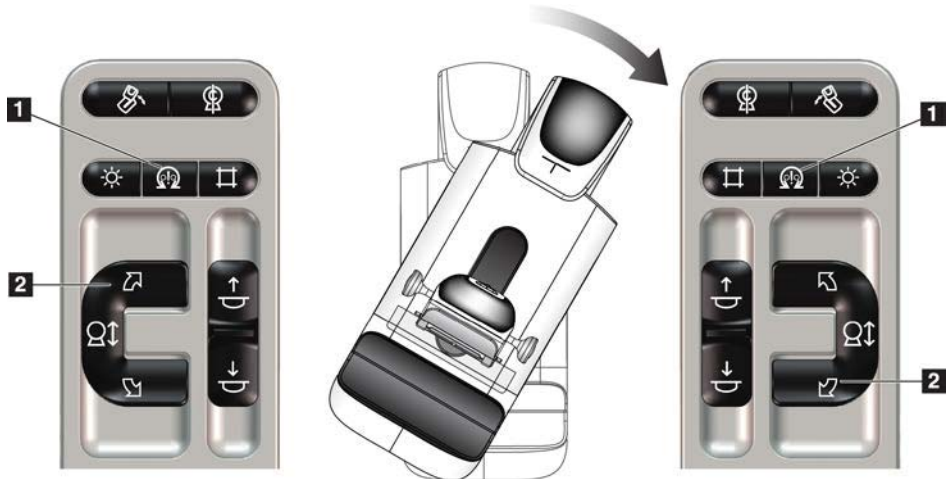
Function	Functional Test
Automatic Counterclockwise C-arm Rotation	Press the **Motor Enable** button (item 1) and the **Counterclockwise C-arm Rotation** button (item 2) at the same time. Release the buttons. The machine beeps and the C-arm moves automatically counterclockwise.



Left Panel *Right Panel*

Table 8: Automatic C-arm Clockwise Rotation

Function	Functional Test
Automatic Clockwise C-arm Rotation	Press the **Motor Enable** button (item 1) and the **Clockwise C-arm Rotation** button (item 2) at the same time. Release the buttons. The machine beeps and the C-arm moves automatically clockwise.

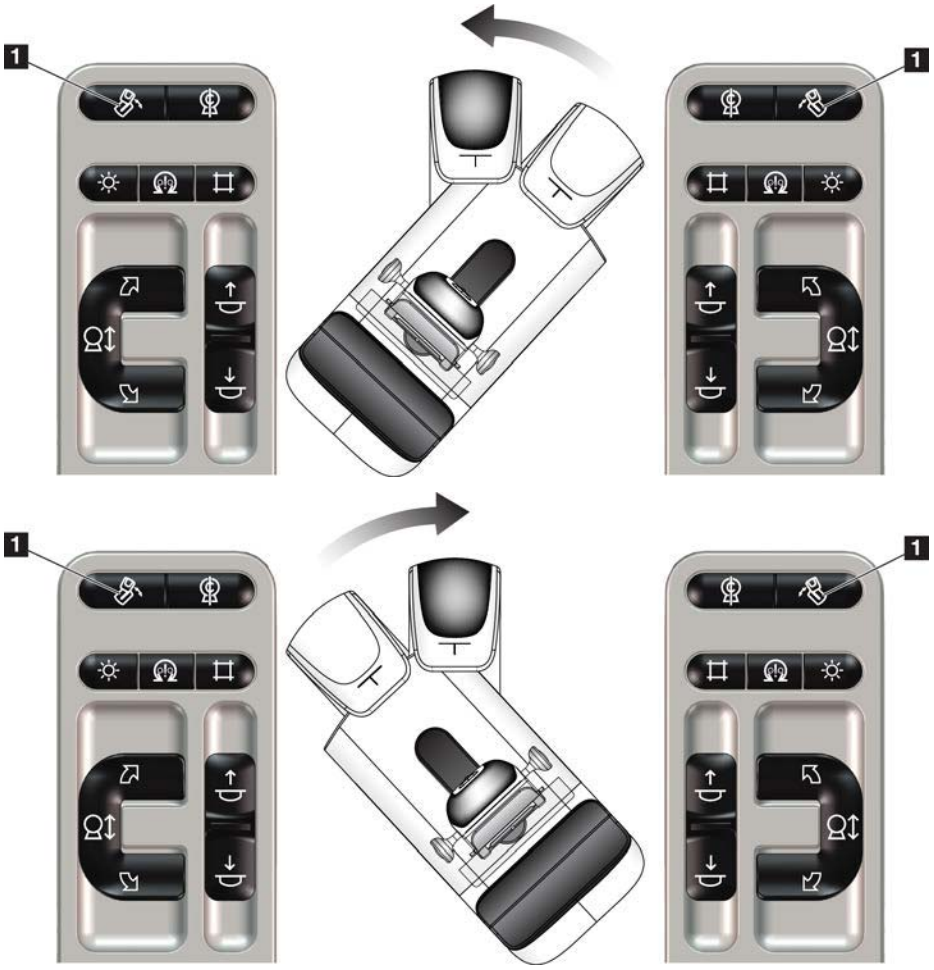


Left Panel *Right Panel*

MLO Automatic Rotation

Table 9: Automatic MLO Rotation

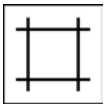
Function	Functional Test
Automatic Tubehead Rotation to Zero Position	Position the C-arm at an angle greater than 15 degrees. Press the **MLO Rotation** button (item 1). The Tubehead moves automatically to the zero position. The Compression Arm stays in its angled position. Press the MLO Rotation button again to return the Tubehead to its original position.



Left Panel *Right Panel*

4.3.3 Collimation

Table 10: C-arm Collimation

Function	Functional Test
Collimator Override 	The **Collimator Override** button changes the collimation through the different x-ray fields. Press the **Light Field Lamp** button to show the x-ray field, then press the **Collimator Override** button to select an x-ray field.
Light Field Lamp	For compression paddles: Press the **Light Field Lamp** button to see the x-ray field for two minutes. For localization paddles: Press the **Light Field Lamp** button to see the x-ray field for the configured amount of time. The default time for biopsy or needle localization paddles is ten minutes. Press the **Light Field Lamp** button again to turn off the light field lamp. The light field lamp automatically illuminates with the start of the Compression Down movement.

4.3.4 Shifting Paddles

Note
Most paddles can be used with the Shifting Paddle function. The large 24 x 29 cm Frameless Screening Paddle, the large 24 x 29 cm SmartCurve™ system paddle, and the Magnification paddles are not compatible with the Shifting Paddle function.

Use the 18 x 24 cm Frameless Screening Paddle to test the Shifting Paddle function.

Table 11: Shifting Paddle

Function	Functional Test
Paddle Shift	The 18 x 24 cm Screening Paddle moves approximately 2.5 cm into the left, center, or right position. While compression is applied, you cannot move the paddle. The collimator is programmed to follow the position of the paddle. To test this function: 1. Install the 18 x 24 cm paddle in the Compression Device. 2. Select a view. 3. Use the **Paddle Shift** buttons on the *Procedure* screen to override the position. 4. Verify that the paddle automatically moves to the new position. 5. Turn on the light field lamp. 6. Confirm that the collimator position matches the paddle position. 7. Repeat this procedure for the other paddle positions.

4.4 Emergency Off Switches Functionality

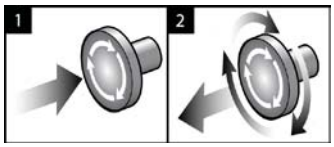


Figure 19: Emergency Off Switch Functionality

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.

4.5 How to Turn Off the System

1. Close any open patient procedures. Refer to *Close a Patient* on page 62.
2. From the *Select Patient* screen, select the **Log Out** button.
3. From the *Startup* screen, select the **Shutdown** button.
4. Select **Yes** in the confirmation dialog box.

4.6 How to Remove All Power from the System

See the following figure for illustrations of the buttons and switches referenced in the following procedures.

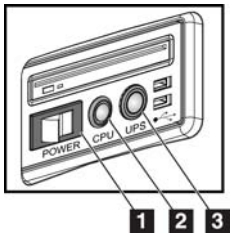


Figure 20: Universal Acquisition Workstation Power Buttons

Figure Legend

1. Acquisition Workstation Power Switch
2. Computer Power On/Reset Button
3. UPS Power Button

To remove all power from the system:

1. Turn off the system.
2. If your system includes the UPS, press the UPS button (item 3).
3. Turn OFF the acquisition workstation power switch (item 1).
4. Unplug the acquisition workstation power cable from the AC outlet.
5. Turn OFF the Gantry circuit breaker.
6. Turn OFF the Facility Mains circuit breaker.

Chapter 5 User Interface

5.1 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.

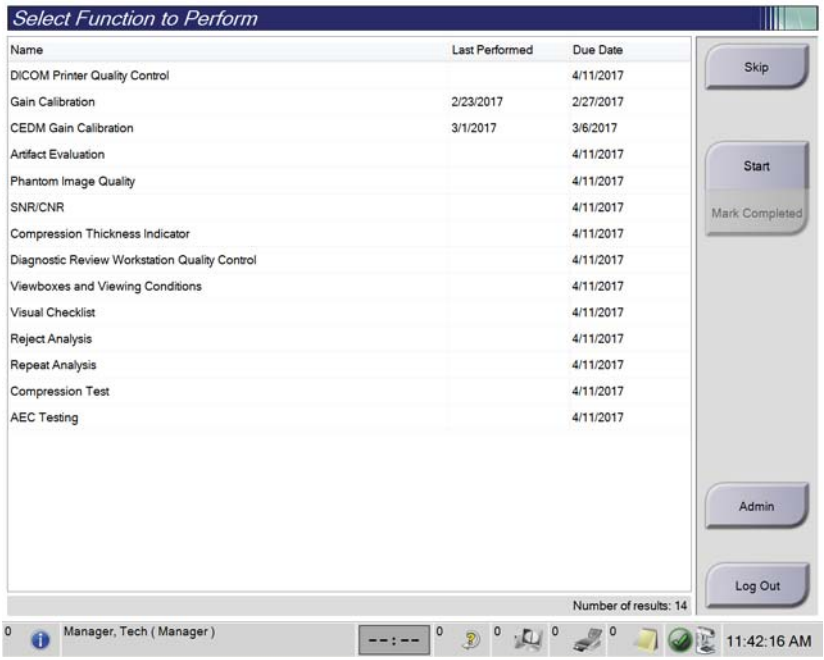


Figure 21: An Example Select Function to Perform Screen

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.)

   - OR -

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

To Proceed Without Completing All Scheduled Quality Control Tasks:

If all Quality Control tasks are not 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 48 for information about this screen.

If you select the **Admin** button, the *Admin* screen opens. Refer to *Admin Screen* on page 111 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

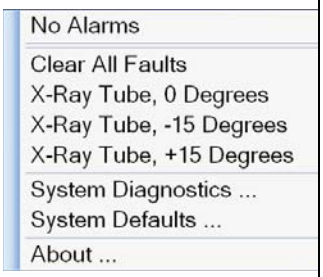
The taskbar at the bottom of the screen displays additional icons. Select the icon to access information or perform system tasks.

Figure 22: Taskbar

Table 12: Taskbar Menus

	Description	Menu
1	**Information Icon** Select the **Information** icon to display a menu. This section of the taskbar flashes a yellow color when an alarm exists. Select **Acknowledge All** to stop the flashing indication. Select **Manage Alarms** to display and close any open alarms.	
2	**Current User Name** Select the user name section of the taskbar to display the Users Menu. **Log Out** returns you to the *Startup* screen. **My Settings** lets you select user settings and workflow preferences. **Print** sends the displayed patient list to a connected printer.	
3	**Output Device Icons** Select any output device icon to display the *Manage Queues* screen. This screen displays the status of jobs in the queue, job information for the selected output, and allows you to filter the queue display. The number on the icon shows the number of jobs that remain in the queue.	

Table 12: Taskbar Menus

	Description	Menu
4	**Notices Icon** Select the **Notice** icon to display the *Patients with Unviewed Notices* screen. The number on the icon shows the number of patients with Unviewed Notices.	
5	**System Status Icons** Select the **Tubehead** icon to display a menu. When the detector and generator are ready for use, a green checkmark appears next to the tubehead icon. If the **Tubehead** icon is red with a number next to it, the system needs to wait the number of minutes shown before the next image 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 an exposure. **X-ray Tube, +15 Degrees** puts the tubehead at +15 degrees of rotation for an exposure. **System Diagnostics** accesses Subsystem settings. **System Defaults** opens the *Gantry Defaults* screen to set the Compression and Generator default values. **About** displays information about the Acquisition Workstation (refer to *About Screen* on page 113).	

5.3 Select Patient Screen

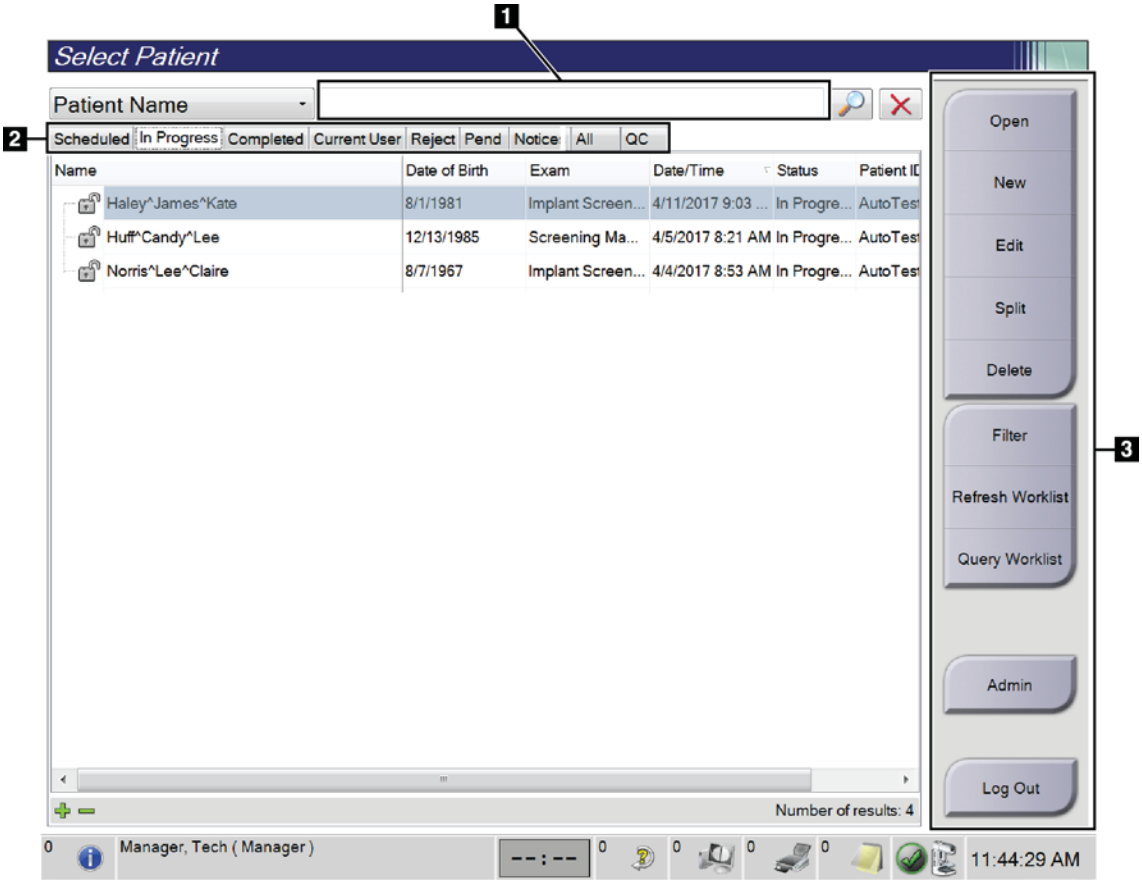
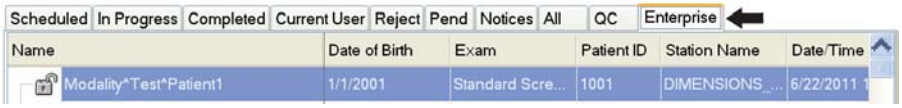


Figure 23: Select Patient Screen

Table 13: The Select Patient Screen

Item	Description
1. Quick Search	Search the selected tab for the Patient Name, Patient ID, or Accession #.

Table 13: The Select Patient Screen

Item	Description
2. Tabs	The tabs at the top of the screen are configurable. A user with the correct permissions can delete tabs and create new tabs. • **Scheduled** tab shows the scheduled procedures. • **In Progress** tab shows the procedures not complete. • **Completed** tab shows the completed procedures. • **Current User** tab shows the procedures for the current operator. • **Reject** tab shows the procedures with rejected views. • **Pend** tab shows the procedures with pending views. • **All** tab shows all procedures for all users. • **Notices** tab shows the patients with unviewed notices by default. Refer to *About the Notices Tab* on page 50 for complete information. • **QC** tab shows the Quality Control procedures. • **Enterprise** tab is displayed if you have the *Advanced Workflow Manager* on page 56. This tab shows the procedures acquired on all compatible networked systems.  *Figure 24: Enterprise Tab*
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 50. • **Edit**: Edit the patient information — refer to *Edit the Patient Information* on page 51. • **Split**: Remove the images from a procedure or a patient and move the images to a different procedure or patient — refer to *Split the Patient Records* on page 51. • **Delete**: Delete the selected patient — refer to *Delete a Patient* on page 53. • **Filter**: Use a Patient Filter — refer to *Filters for Patients* on page 53. • **Refresh Worklist**: Update the Scheduled Patient Worklist information — refer to *Refresh the Worklist* on page 55. • **Query Worklist**: Search for a patient in the Modality Worklist — refer to *Query the Worklist* on page 55. • **Admin**: Access the *Admin* Screen — refer to *Admin Screen* on page 111. • **Log Out**: Exit the system — refer to *Log Out* on page 55.

5.3.1 About the Notices Tab

- After selecting the **Notices** tab from the *Select Patient* screen, a list of the Patients with Notices is shown.
- The default value for the list is patients with Viewed and Unviewed Notices.
- You can change the value to show patients with Viewed Notices or patients with Unviewed Notices.
- Select **Open** to access the *Procedure* screen for the selected patient.

5.3.2 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.

5.3.3 Add a New Patient

1. In the *Select Patient* screen, select the **New** button. The *Add Patient* screen opens.

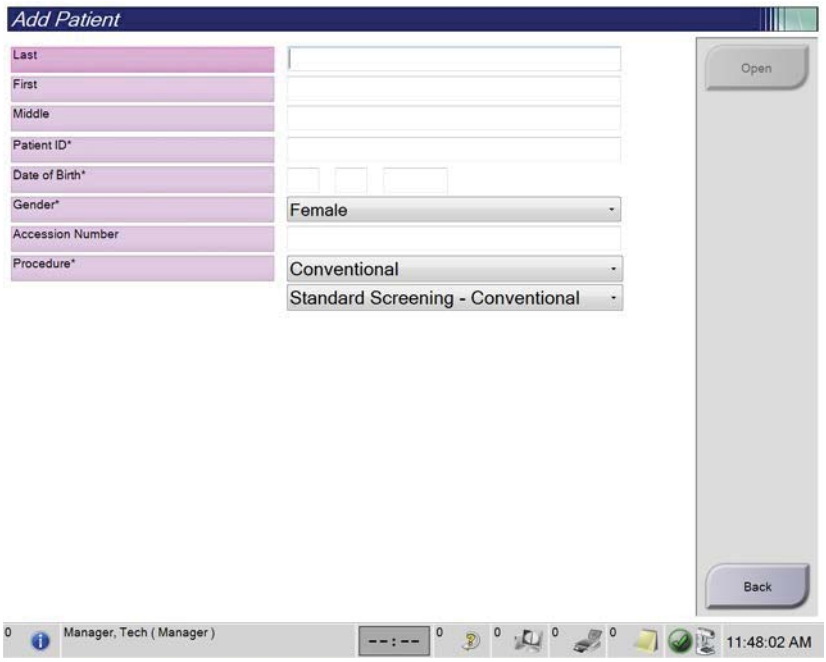


Figure 25: Add Patient Screen

2. Enter the new patient information and select a procedure.
3. Select the **Open** button. The *Procedure* screen for the new patient opens.

5.3.4 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.

5.3.5 Split the Patient Records

The Split function lets you move images when you acquired the images in the wrong procedure or the wrong patient.

Note
You cannot split images for protected patients.

Note
Archived patient records still need correction on PACS or other archive systems after using the Split function.

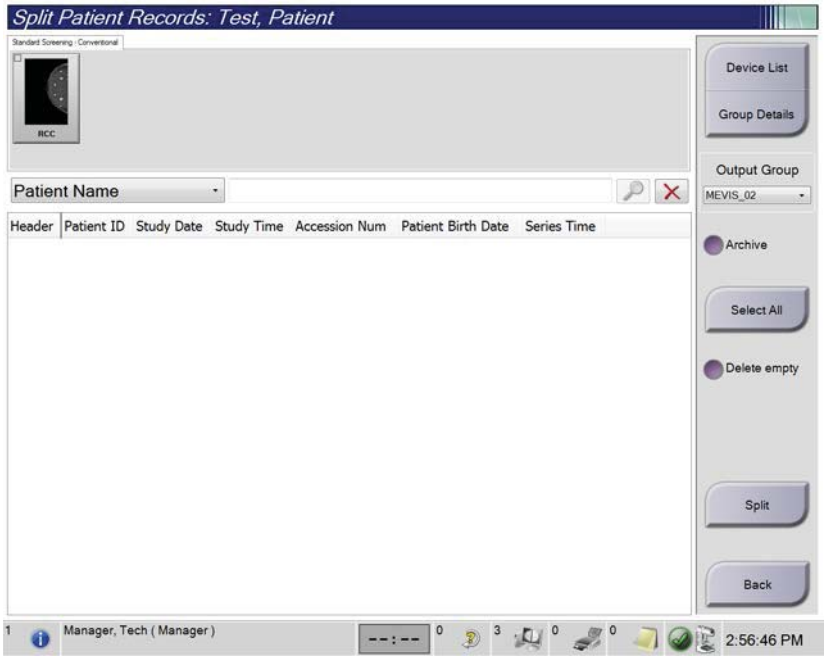


Figure 26: Split Patient Records Screen

Images Acquired in the Wrong Procedure

1. In the *Select Patient* screen, select the patient.
2. Select the **Split** button. The *Split Patient Records* screen opens.
3. Select the images to move. If all images are being moved, select **Select All**.

4. Select your search criteria (for example, Patient Name or Accession Number) using the drop-down menu below the images.
5. Enter the same patient information and select the **Search** button (the magnifying glass).
6. When the Patient name appears, select the correct procedure for the images.
7. If you want to archive the images, select **Archive**.
8. Select **Split**, then select **OK** to the *Split Successful* message.

Images Acquired in the Wrong Patient

1. In the *Select Patient* screen, select the patient that has the images that need to be moved.
2. Select the **Split** button. The *Split Patient Records* screen opens.
3. Select the images to move. If all images are being moved, select **Select All**.
4. Select your search criteria (for example, Patient Name or Accession Number) using the drop-down menu below the images.
5. Enter the search criteria and select the **Search** button (the magnifying glass).
6. When the Patient name appears, select the correct procedure.

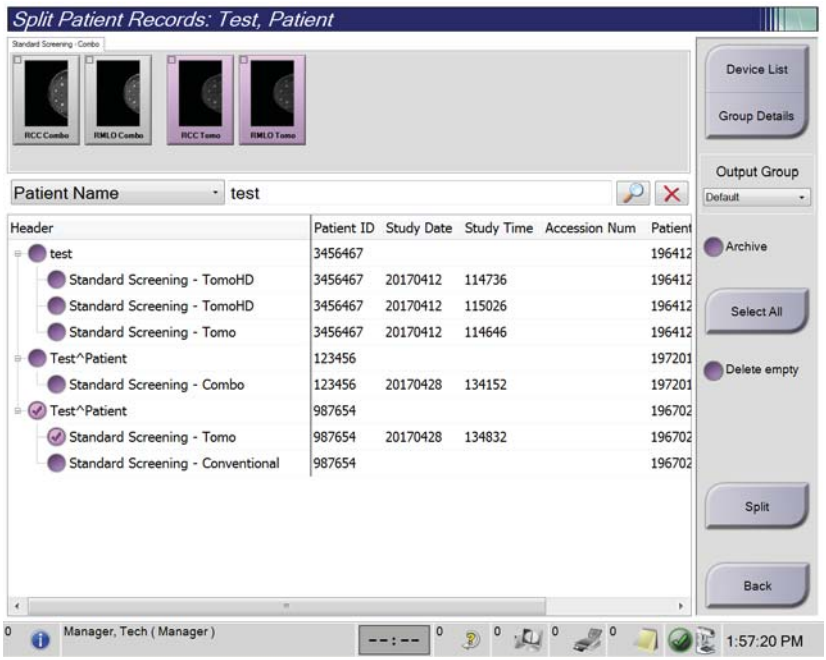


Figure 27: Select the Correct Procedure to Split Patient Records

7. If all images are being moved and you want to delete the incorrect patient from the Patient List, check **Delete Empty**.
8. If you want to archive the images, select **Archive**.
9. Select **Split**, then select **OK** to the *Split Successful* message.

5.3.6 Delete a Patient

Note
Reclamation normally removes the requirement to delete patients manually. Refer to *About Reclamation* on page 110.

1. In the *Select Patient* screen, select one or more patients.
2. Select the **Delete** button.
3. When the confirmation prompt is shown, select **Yes**.

Note
The Technologists do not have permissions to delete patients.

5.3.7 Filters for Patients

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

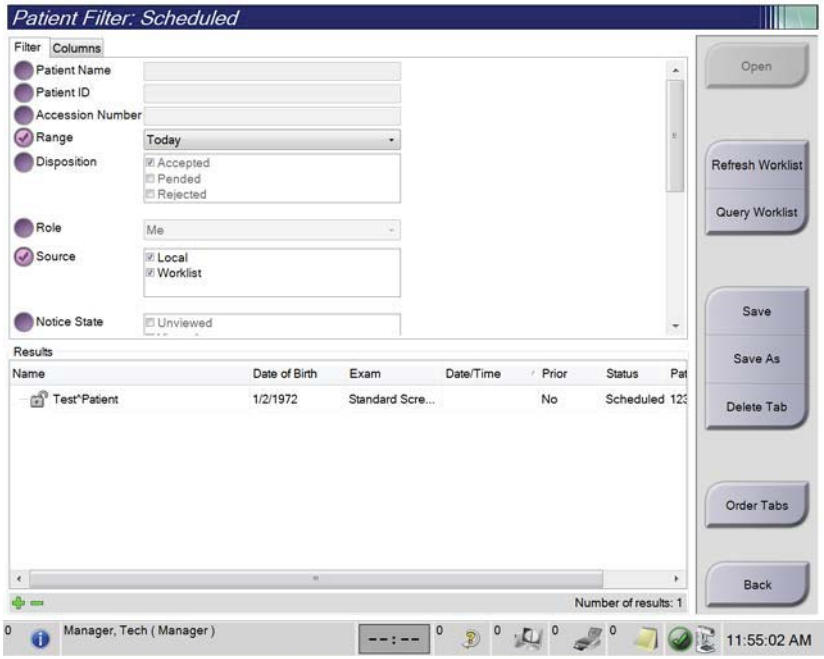


Figure 28: Filter Tab in the Patient Filter Screen

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 54.)

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 14: 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.

5.3.8 Refresh the Worklist

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

5.3.9 Query the Worklist

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

There are two methods to enter the query information:

- **Keyboard**—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.
- **Bar Code Scanner**—Scan the bar code for the configured query field. The scheduled procedure is displayed, and the patient is added to the local database. The field in which the bar code scanner scans is configurable. The default query field can be the Patient ID, Accession Number, or Requested Procedure ID.

5.3.10 Admin

Select the **Admin** button to access the *Admin* screen and the system administration functions. Refer to *System Administration Interface* on page 111 for more information.

5.3.11 Log Out

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

5.3.12 Advanced Workflow Manager

The Advanced Workflow Manager is a workflow engine that allows compatible Hologic systems to communicate and exchange images with each other. The Advanced Workflow Manager keeps track of all patients, procedures, and images acquired on all systems within an Advanced Workflow Manager cluster. In addition, the Advanced Workflow Manager synchronizes notices and provides images to all systems within the cluster.

Systems with Advanced Workflow Manager show the Enterprise tab on the *Select Patient Screen* on page 48. This tab lists the procedures acquired on all systems within an Advanced Workflow Manager cluster.

5.4 Procedure Screen

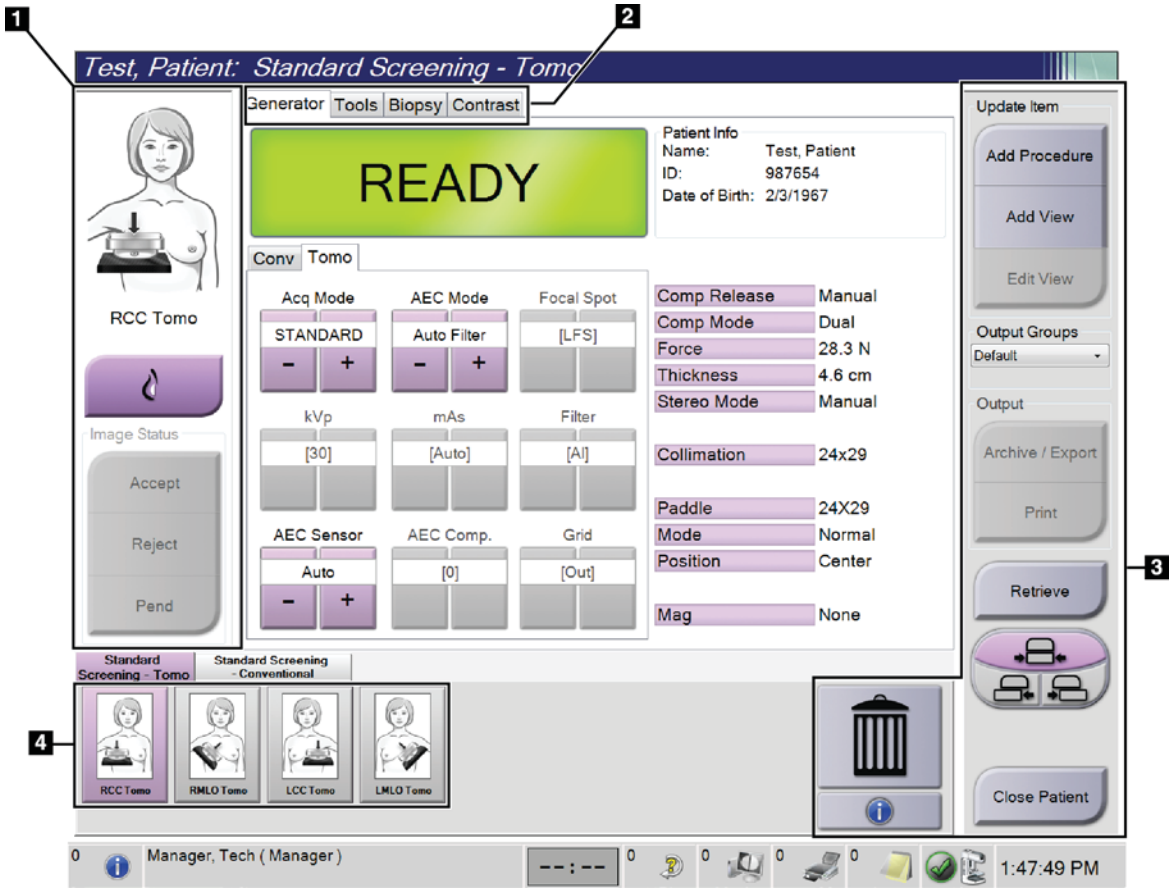


Figure 29: Procedure Screen

Table 15: 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. **Pend** button—select to save the image for future review.
2. Tabs	Select the **Generator** tab to adjust the exposure techniques for the procedure. Select the **Tools** tab to review the images. Select the **Biopsy** tab to create targets. Select the **Contrast** tab to perform I-View™ 2D Contrast procedures.
3. Buttons	Many functions are accessed from this screen by selecting a particular button: **Add Procedure:** Add a new patient. **Add View:** Add a new view. **Edit View:** Assign a different view to an image. **Archive/Export:** Send images to an output. **Print:** Print images. **Retrieve:** Query the configured devices with the current patient information. **Paddle Shift:** Bypass the default paddle position for the selected view. **Close Patient:** Exit the patient and procedure. **Trash Can:** Delete a view.
4. Thumbnails	Select a tab to show the thumbnail views or the 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 How to Use the Paddle Shift Feature

Refer to Paddle Shift for information about the Paddle Shift feature.

1. In the *Procedure* screen, select an unexposed thumbnail image view. The paddle moves to the default position for that view.
2. Select a paddle shift button to bypass the default paddle position for the selected view. The paddle moves to the new position.

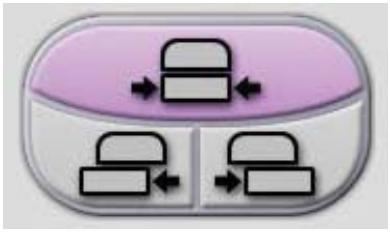


Figure 30: Paddle Shift Buttons

5.4.3 Procedure Information Dialog Box

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 (each 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.

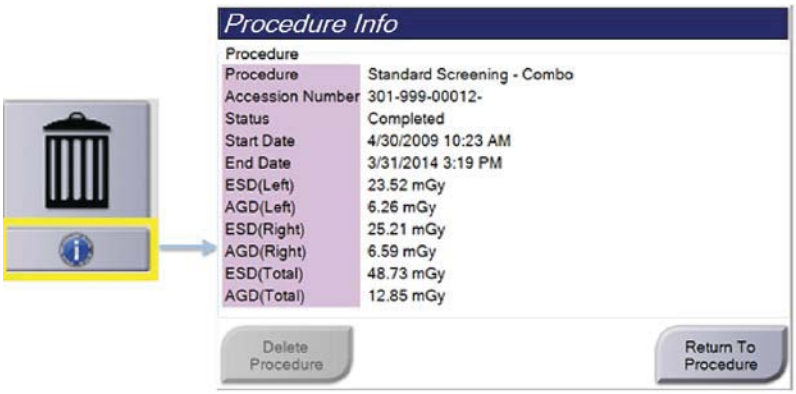


Figure 31: Procedure Info Dialog Box

5.4.4 Add a Procedure

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

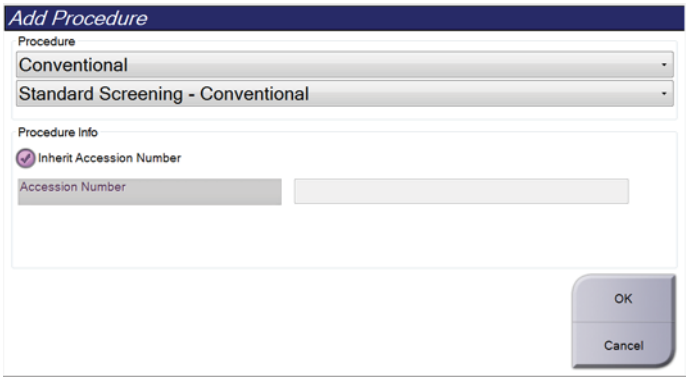


Figure 32: Add Procedure Dialog Box

2. Use the drop-down menus to select the type of procedure to add.
3. The current Accession Number is automatically used. To use a different Accession Number, deselect the "Inherit Accession Number" check box and enter the desired number.
4. Select the **OK** button. A new tab is added with the thumbnail views for the procedure that was selected.

Available Procedures

The table that follows shows the major groups of procedures that are available on the system.

Note
Some procedures in the list show only when the system is licensed for that procedure.

Table 16: Procedure Groups

Procedure	Description
Conventional	Digital mammography (2D) imaging only
Combo	Digital mammography (2D) and breast tomosynthesis imaging
Tomo	Breast tomosynthesis imaging only
TomoHD	Breast tomosynthesis imaging and a generated 2D image
ComboHD	Digital mammography (2D) and breast tomosynthesis imaging and a generated 2D image
Stereo Biopsy	Biopsy that uses stereotactic targeting
Tomo Guided Biopsy	Biopsy that uses tomosynthesis targeting
Specimen	Specialized specimen imaging
2D Contrast	Contrast enhanced digital imaging

5.4.5 Add (or Remove) 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.

View Modifiers

ID = Implant Displaced
RL = Rolled Lateral
RM = Rolled Medial
RI = Rolled Inferior
RS = Rolled Superior
NP = Nipple in Profile
AC = Anterior Compression
IMF = Infra-Mammary Fold
AX = Axillary Tissue

Figure 33: Add View Screen

2. Select the tab, then select the view. You can select a maximum of three View Modifiers from the right panel of the screen.
3. Select the **Add** button. A thumbnail image of each selected view is added in the bottom panel of the screen.

To Remove a View

- To remove a single view from the added list: select the view then select the trash can icon.
- To remove all views from the added list: select the **Clear** button.

5.4.6 Edit a View

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

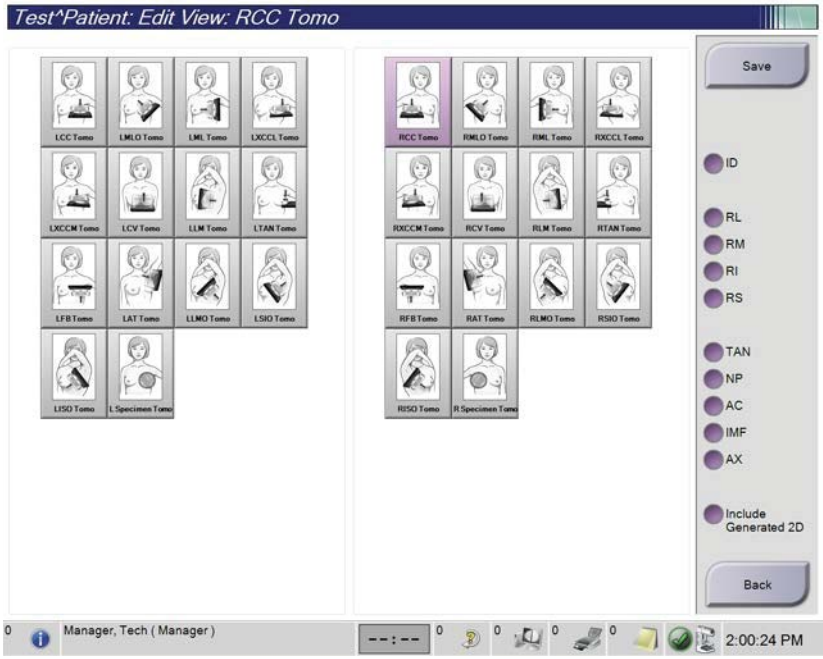


Figure 34: Edit View Screen

1. In the *Procedure* screen, select an exposed thumbnail image view.
2. Select the **Edit View** button.
3. Select the view from the screen. You can select a maximum of three View Modifiers. See the figure *The Add View Screen* on page 60 for a description of the View Modifiers.
4. Select **Save,** then select **OK** to the *Update Successful* message.

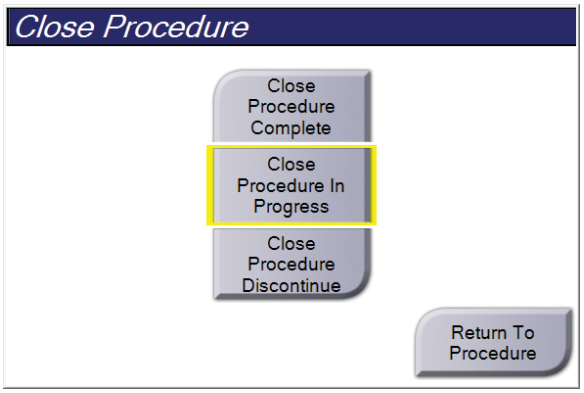
Note
The *Edit View* screen for biopsy procedures shows different View Modifiers. Refer to the Affirm System *User Guide*.

5.4.7 Retrieve

Select the **Retrieve** button to query the configured devices with the current patient information. The **Retrieve** button performs the same function as the **Query Retrieve** button in the *Admin* screen.

5.4.8 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.

If there are images marked as Pend, a dialog box opens with the following options:

- Accept All and Close Complete
- Close Procedure In Progress
- Return to Procedure

If MPPS is activated, procedure status information is sent to the output devices when you select **Complete** or **Discontinue**. You can also click and hold the tab above the thumbnail images to resend a message about the procedure status during the procedure. A Procedure Action dialog box opens with buttons to resend a status or to return 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 *Image Review Tools Tab* on page 75 for information.

5.6 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.

5.6.1 Select an Output Group

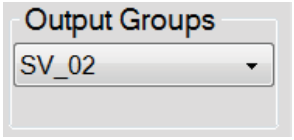


Figure 35: Output Groups Field

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.

5.6.2 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.

5.6.3 Custom Output

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

To Make a Custom Group from the *Procedure* screen:

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

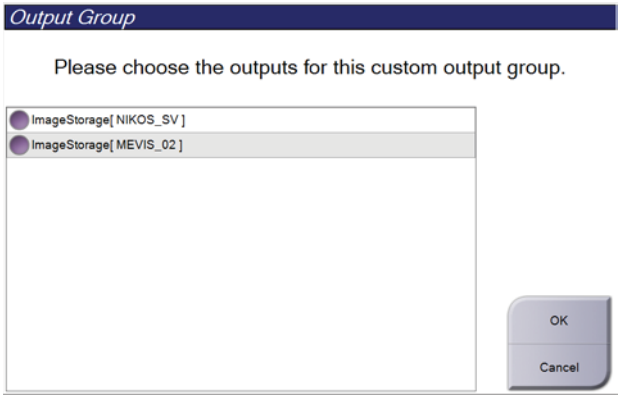


Figure 36: An Example Custom Output Group

5.7 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.

5.7.1 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.

5.7.2 Export

1. Select the **Archive/Export** button (on the right side of the *Procedure* screen).
2. Select the images to export, then select the **Export** button.

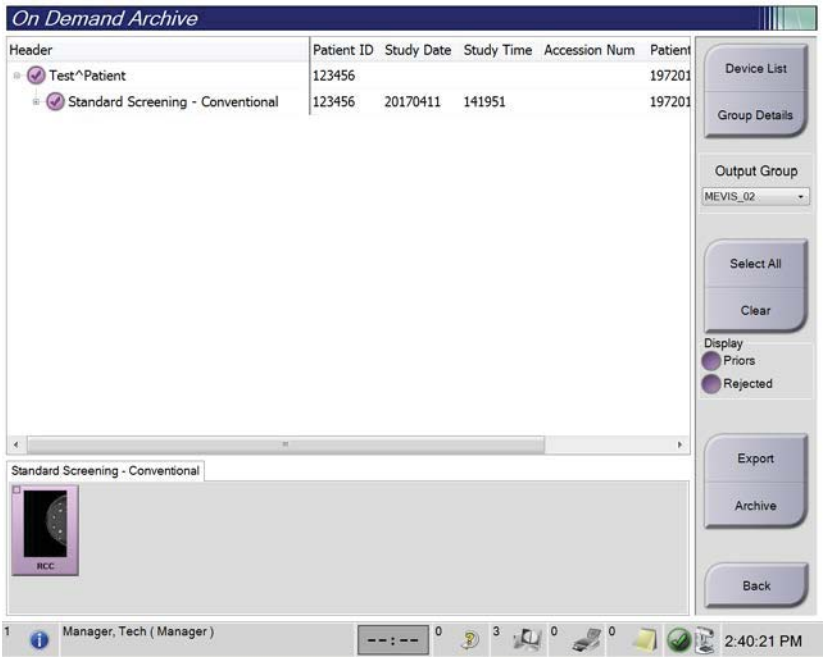


Figure 37: Select the Images for Export

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

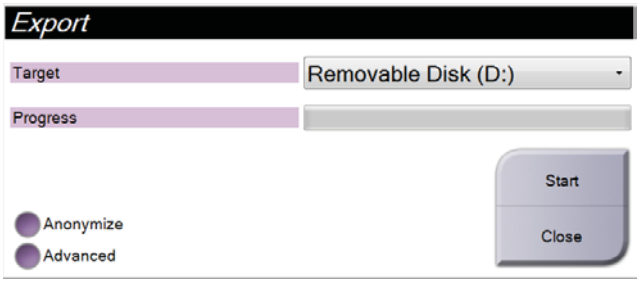


Figure 38: Export Dialog Box

   - To anonymize patient data, select **Anonymize**
   - To select a folder on your local systems for storage of your selections and to select the Export types, select **Advanced**.
4. Select the **Start** button to copy the selected images to the selected device.

5.7.3 Print

1. From the *Procedure* screen, select the **Print** button to show the *Print* screen. See the figure *The Print Screen* on page 67 to prepare your print data.
2. Select the film format from the film format area of the screen.
3. Select a thumbnail image.
4. Select the image mode (Conventional, Projection, or Reconstruction). The C-View button shows if the system is licensed for C-View imaging.
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 multiformat 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 (item 1 through item 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.

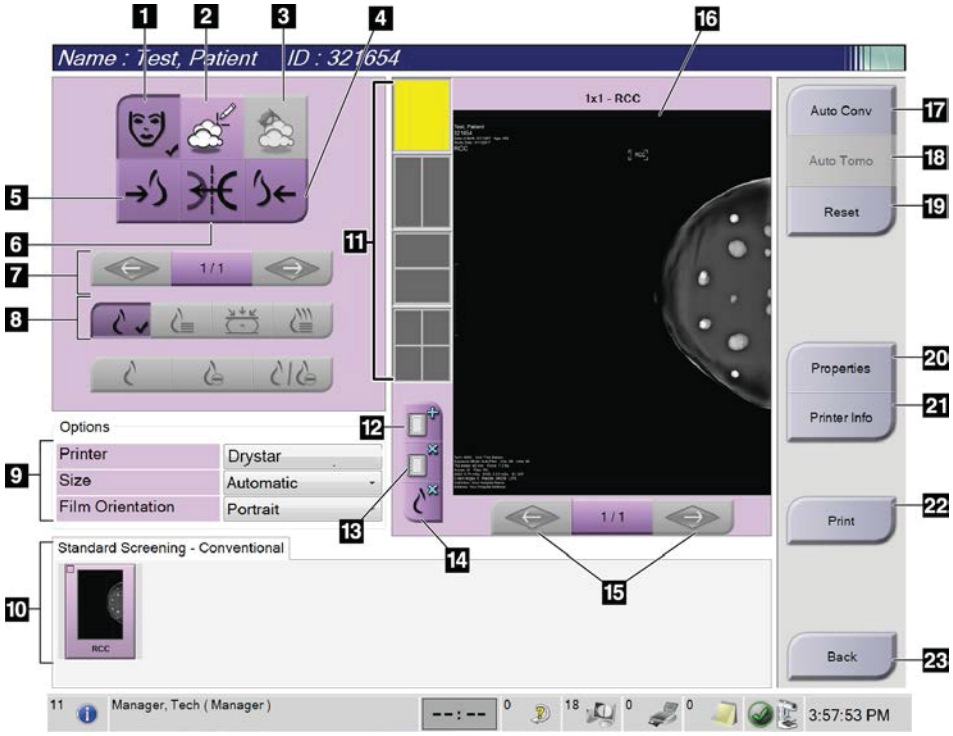


Figure 39: Print Screen

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 previous or next tomosynthesis slice or projection (Tomosynthesis option).
8. Select Conventional, Projection, or Reconstruction views (Tomosynthesis option). The C-View button shows if the system is licensed for C-View imaging.
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 (and C-View images, if system is licensed) 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.

Chapter 6 Images

6.1 Image Display Screen

After you make an exposure, the acquired image opens on the Image Display monitor. Patient and procedure information can be displayed on the screen. To turn the information on or off, go to the **Tools** tab in the *Procedure* screen and select the **Patient Information** button.

Figure 40: Image Display Screen

Figure Legend

1. Patient information and exam date
2. Exposure information, including:
   - Exposure techniques
   - Patient dose
   - C-arm angle
   - Compression thickness and force
   - Facility and technologist information

6.2 How to Set the Exposure Parameters

6.2.1 Select the Image Acquisition Mode (Tomosynthesis Option)

- Standard — For routine Tomosynthesis screening procedures
- Enhanced — For diagnostic Tomosynthesis views

Warning:
Enhanced acquisition mode with combo mode imaging (DM + BT) can produce radiation dose that is higher than the MQSA screening limit of 3.0 mGy and therefore should only be used in diagnostic evaluation.

6.2.2 Select the Exposure Mode

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

- Manual — The user selects the kV, mAs, Focal Spot, and Filter.
- AEC: Auto-Time — The user selects the kV, Focal Spot, and Filter. The system selects the mAs.
- AEC: Auto-kV — The user selects the Focal Spot. The system selects the kV, mAs, and Filter (Rhodium).
- AEC: Auto-Filter — The user selects the Focal Spot. The system selects the kV, mAs, and Filter.

6.2.3 How to Use the AEC Sensor

The AEC Sensor has seven manual positions and an automatic position. The manual positions start at the chest wall edge (position 1) and reach toward the nipple edge (position 7). 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 Compression Device 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.

6.3 How to Acquire an Image

Refer to *Clinical Procedures* on page 99 for information about clinical procedures.

1. Select a view from the thumbnail views at the bottom of the *Procedure* screen.
2. Press and hold the **x-ray** button and/or the **x-ray footswitch** for the full exposure.

   During the exposure:

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

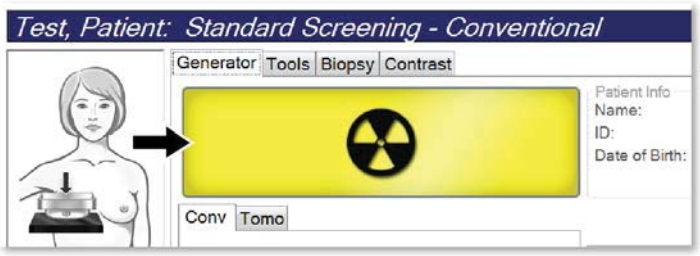


Figure 41: Exposure In Progress

   - An audible tone continues to sound during the exposure

     The audible tone is a continuous sequence of tones. The tone sounds during the entire combo acquisition from the initiation of the exposure to the end of the conventional view. There is no interruption of the audible tone between breast tomosynthesis and conventional digital mammography exposures. Do not release the exposure switch during the audible tone.

3. When the tone stops and the System Status bar shows **Standby** (see the following figure), release the **x-ray** button and/or the **x-ray footswitch**.

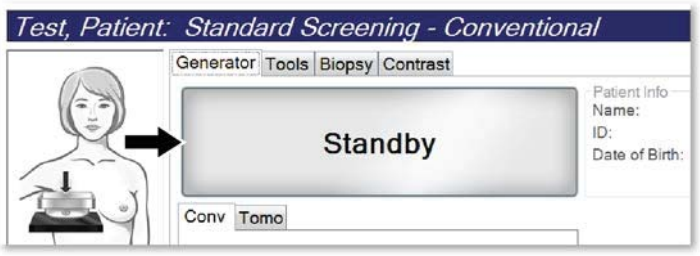


Figure 42: Exposure Complete

4. When the x-ray is finished, the image appears 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.
   - **Reject** the image. When the dialog box opens, select the reason for rejecting the image. The *Image Display* screen closes. You can repeat the rejected view, or select another view. If you select **Reject**, an "X" appears on the thumbnail image.
   - **Pend** the image. The image saves for future review. If you select **Pend**, a question mark "?" appears on the thumbnail image.

Figure 43: Marked Images in a Procedure

5. Repeat steps 1 through 4 for each view.

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

6.3.1 Conventional Imaging Sequence of Events

1. Review the image after the exposure and add a comment, if necessary.
2. **Accept**, **Reject**, or **Pend** the image. A thumbnail image replaces the thumbnail view in the Case Study area of the screen.

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

6.3.2 Tomosynthesis Imaging Sequence of Events

1. Wait for the image reconstruction to complete.
2. Review the projection images for motion.
3. **Accept**, **Reject**, or **Pend** the images. A thumbnail image replaces the thumbnail view in the Case Study area of the screen.

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

6.3.3 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.

6.3.4 How to Accept or Reject a Pended Image

To accept or reject a Pended image, select the Pended thumbnail image, then select the **Accept** button or the **Reject** button.

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

6.4 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.

6.4.1 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.

6.4.2 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.

6.5 How to Review the Images

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

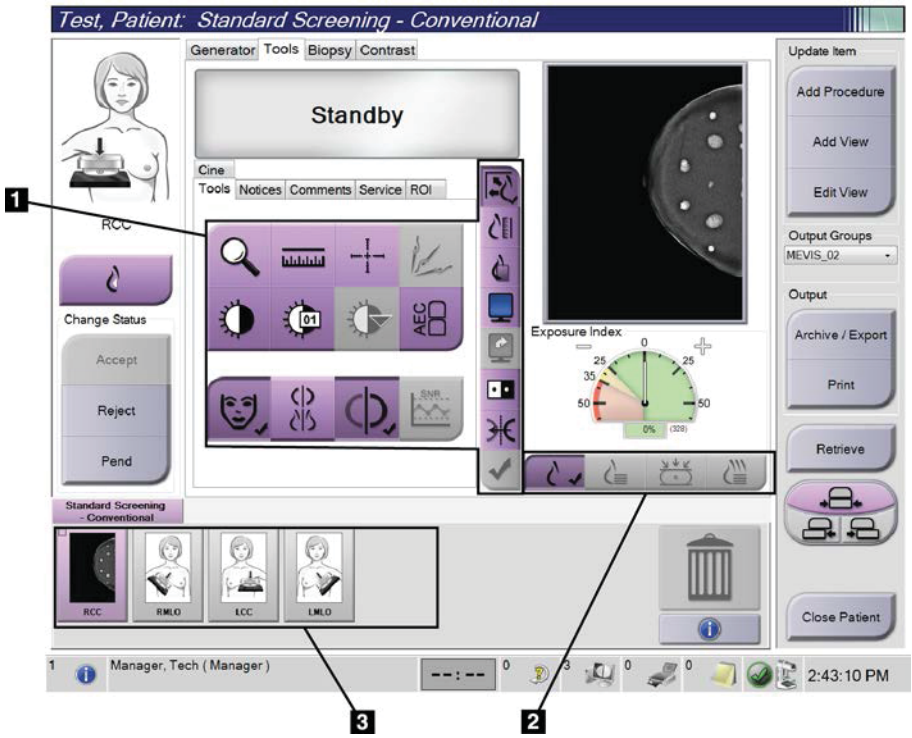


Figure 44: Tools Tab (Tomosynthesis option shown)

Figure Legend

1. Image Review Tools - refer to *Image Review Tools Tab* on page 75.
2. Image Display Modes - refer to *Display Modes* on page 77.
3. Thumbnail Views and Thumbnail Images. Select any thumbnail image to display that image on the Image Display monitor.

6.5.1 Image Review Tools Tab

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

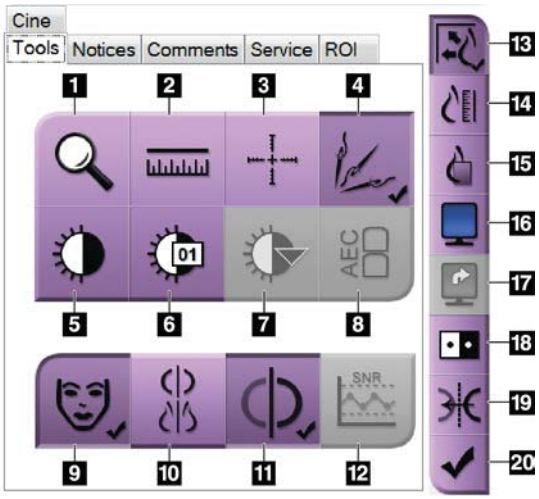


Figure 45: Image Review Tools

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* screen.
4. The **Demetalizer** tool for processing tomosynthesis images that contain metal objects.
5. The **Window/Level** tool changes the brightness and contrast.
6. The **Window/Level Fine Adjustment** tool allows the entry of specific window and level values.
7. The **LUT Selection** tool scrolls through available Window/Level settings for a displayed image with LUTs attached.
8. The **AEC** button displays the AEC Sensor areas used for the exposure calculation. The sensor areas display on the *Image Display* screen.
9. The **Patient Information** button activates the patient information display.
10. The **Auto-Hanging** button automatically hangs the currently selected study in a 4-up configuration.
11. The **Auto-Pairing** button turns off auto-pairing for the currently selected image in a multi-up configuration.
12. The **SNR/CNR** button calculates the signal-to-noise ratio and contrast-to-noise ratio on the ACR Phantom.
13. The **Fit-to-Viewport** button fits the image within the image tile.
14. The **True Size** button displays the image in the actual size of the breast.
15. The **View Actual Pixels** button displays the image in full resolution.
16. The **Multi-Up Display** button selects the number of tiles to display.
17. The **Image Tile Advance** button sets the active Multi-Up tile.
18. The **Invert Image** tool changes blacks to whites and whites to black.
19. The **Mirror** button reverses (mirrors) the image.
20. The **Tag for Print** button tags the projection or reconstruction images of a tomosynthesis image to print later.

6.5.2 Notices Tab

The tools on the **Notices** tab allow you to mark and annotate images and send notices about the displayed image or procedure. The Notice Output Groups drop-down menu at the bottom of the tab allows you to select the destination for the Notices.

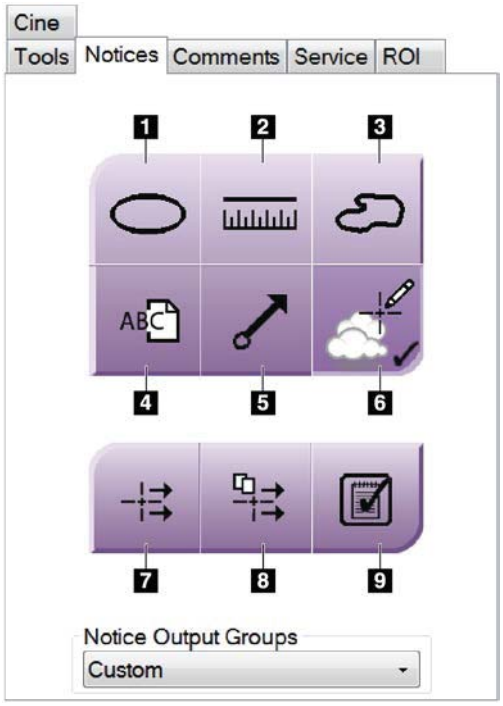


Figure 46: Tools on the Notices Tab

Figure Legend

1. The **Oval** tool draws an oval marking on the image.
2. The **Ruler** tool measures the distance between two points.
3. The **Freehand** tool draws a freehand marking on the image.
4. The **Text** tool adds a text note to the image without a marking.
5. The **Arrow** tool draws an arrow marking on the image.
6. The **Markings** tool shows or hides markings and annotations on an image.
7. The **Send Notice** tool sends a notice for the current image to the selected destination.
8. The **Send All Notices** tool sends all notices for all images in the opened procedure to the selected destination.
9. The **Viewed** tool changes the Patient Notices status to viewed.

6.5.3 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 47: Exposure Index

Display Modes

Use the buttons in the Display Modes area of the screen to select the type of view to show on the Image Display monitor. You can change between conventional, generated 2D, projections, and reconstructions to show the combination images.

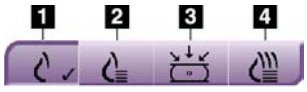


Figure 48: Display Modes

Figure Legend

1. **Conventional** button shows conventional images.
2. **Generated 2D** button shows a conventional 2D image generated from the acquired tomographic image.
3. **Projections** button shows the 15° projection images.
4. **Reconstructions** button shows reconstructed slices.

6.5.4 Slice Indicator

The Slice Indicator on the Image Display monitor shows only on tomographic reconstructions.

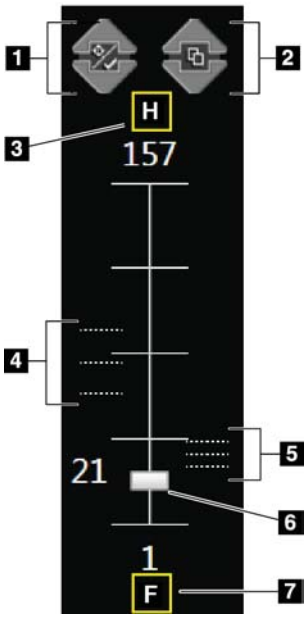


Figure 49: Slice Indicator

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

6.6 How to Send the Images to the Output Devices

You can send the images to output devices or use the Archive/Export function to copy images to temporary storage media. Refer to *Output Groups* on page 63 and *On-Demand Outputs* on page 64 for instructions.

6.7 How to Use I-View 2D Contrast

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. Select the **Contrast** tab to access the I-View™ 2D Contrast (CE2D) function.

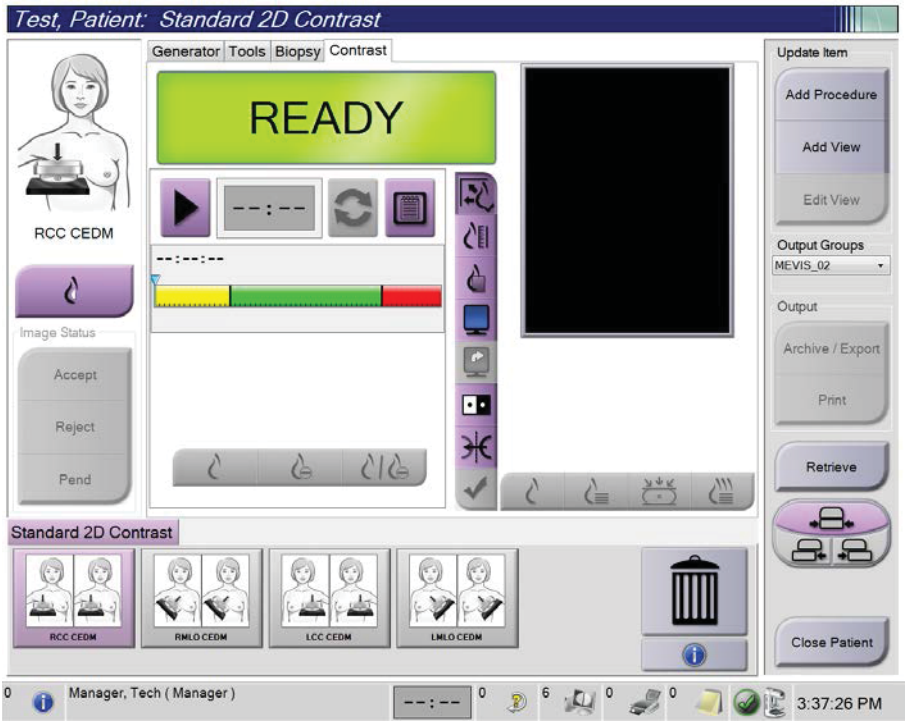


Figure 50: I-View 2D Contrast Screen

2. Set the contrast settings. For more information, refer to *How to Set the Contrast Defaults* on page 119.

Note
When you set contrast information, it appears in the DICOM header of the images.

3. To begin the contrast dose and start the timer, select the **Start** (arrow) button.

   The timer begins in the **Waiting Period**, which appears with a yellow background.

Note
You can adjust the default length of time for the **Waiting Period** and **Optimal Imaging Period** phases of the timer. Refer to *How to Set the Contrast Defaults* on page 119.

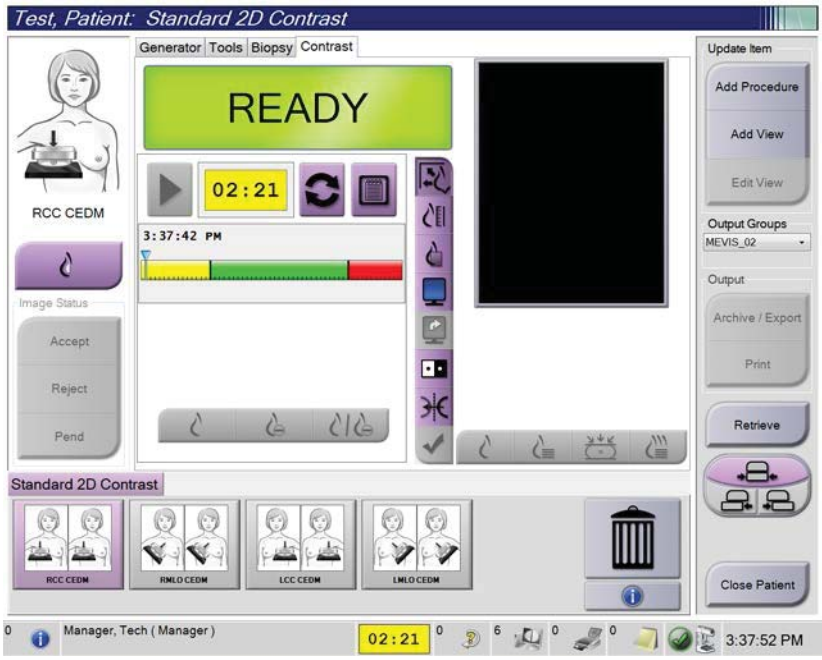


Figure 51: I-View 2D Contrast Screen, Waiting Period

Note
The timer function does not allow you to stop the timer, only to start and reset it. The timer stops only when you exit the patient procedures.

After the **Waiting Period**, the timer begins the **Optimal Imaging Period**, which appears with a green background.

4. Acquire the images during the **Optimal Imaging Period**.
   After you acquire an image, a marker will appear below the timer.

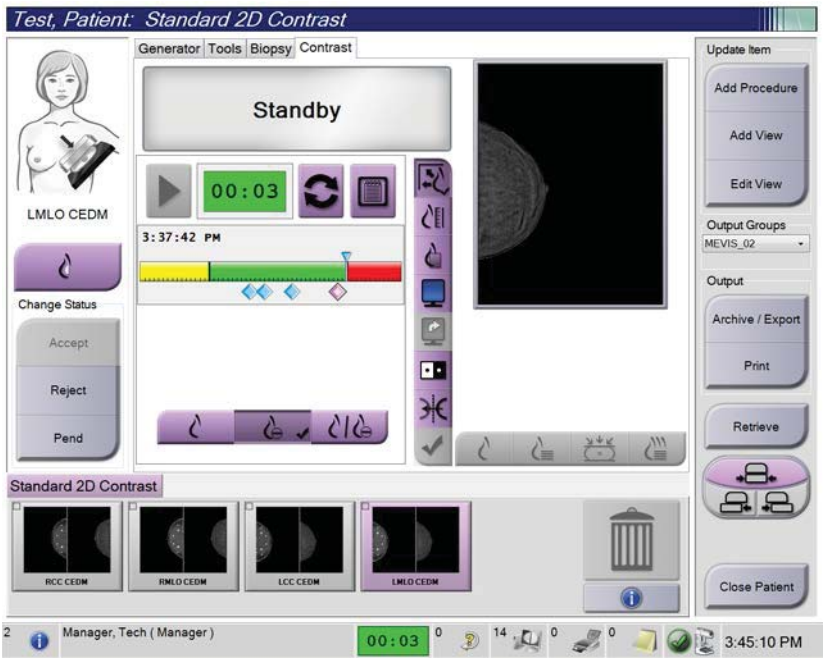


Figure 52: I-View 2D Contrast Screen, Optimal Imaging Period

5. Select the low and high exposure buttons to acquire both low and high energy images.
   - **Low**: Conventional low-energy image
   - **Sub**: Contrasted, subtracted image
   - **Low Sub**: Shows both the low and sub screen images side-by-side in a split screen.

Caution:
Using I-View 2D Contrast increases the recovery time the machine needs before more images are acquired. When the x-ray tube status icon appears red

, a recommended wait time is shown. This wait time lets the x-ray tube temperature decrease to avoid damage that can void the x-ray tube warranty. Always make sure that the x-ray tube status icon is green **before starting an I-View 2D Contrast procedure. If the x-ray tube status icon turns red during a procedure, complete the procedure quickly using the minimum number of exposures.**

6.7.1 How to Configure Contrast Settings

1. From the **Contrast** tab, select the **Configure Contrast** button to edit the contrast settings. The Contrast Information dialog box opens.

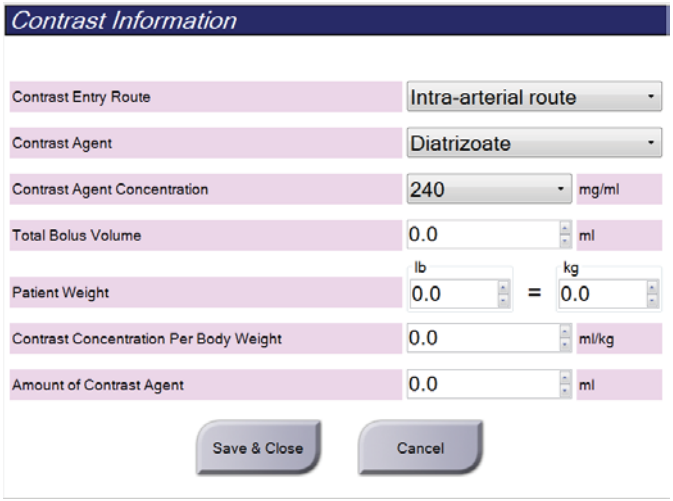


Figure 53: I-View 2D Contrast Information

2. Use the drop-down menus to select the appropriate settings.
3. Enter data for the **Contrast Concentration Per Body Weight** field or the **Amount of Contrast Agent** field. The other field automatically populates with the correct information.
4. Click **Save & Close**.

Chapter 7 Accessories

The system can perform screening or diagnostic applications with specified accessories. This chapter describes how to use all possible system accessories.

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

7.1 How to Install Accessories on the C-Arm

The Retractable Face Shield, Magnification Stand, and Localization Crosshairs are installed in slots on the C-arm. The slots have labels with icons to indicate the accessory that attaches in the slot. Each accessory has two lines. Align the accessory with the related line on the C-arm. When the hook on the accessory is at the correct depth, the second, thinner line aligns with the line on the C-arm. The next sections contain installation instructions for each accessory.

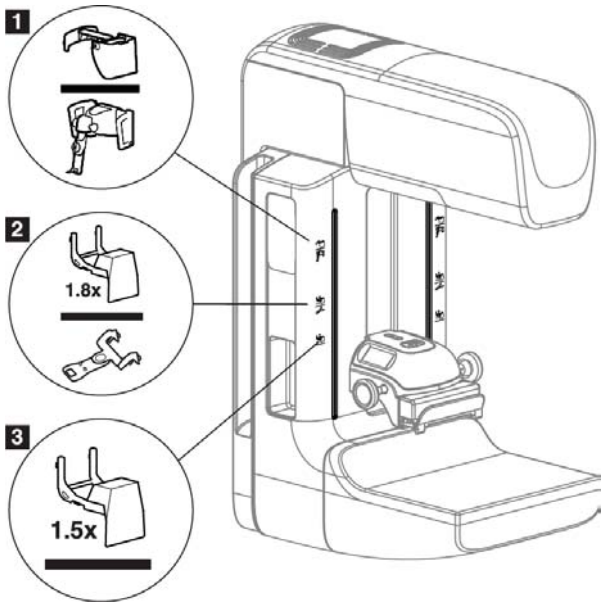


Figure 54: C-arm Accessories

Figure Legend

1. Slot for Retractable Face Shield (Tomosynthesis option) or the Affirm® breast biopsy guidance system (biopsy option)
2. Slot for 1.8x Mag Stand and Localization Crosshairs
3. Slot for 1.5x Mag Stand

7.2 Patient Face Shields

The Face Shield keeps the head and face of the patient away from the x-ray field during the examination. Inspect the shield each day before use.

Warning:
The Face Shield must be attached for all exposures except magnification case studies.

Warning:
The Face Shield does not protect the patient from radiation.

7.2.1 How to Install and Remove the Retractable Face Shield

To install the Retractable Face Shield:

1. Completely extend the Face Shield to the outer position.
2. Align the hooks of the Face Shield with the mounting slots on the C-arm, indicated by a face shield icon.
3. Put the hooks on both sides of the Face Shield into the mounting slots on the C-arm. The Unlock Lever (see item 1 in the following figure) is in the Up position.
4. Push the Face Shield to the down and locked position. The Unlock Lever is in the Down position when the Face Shield locks.

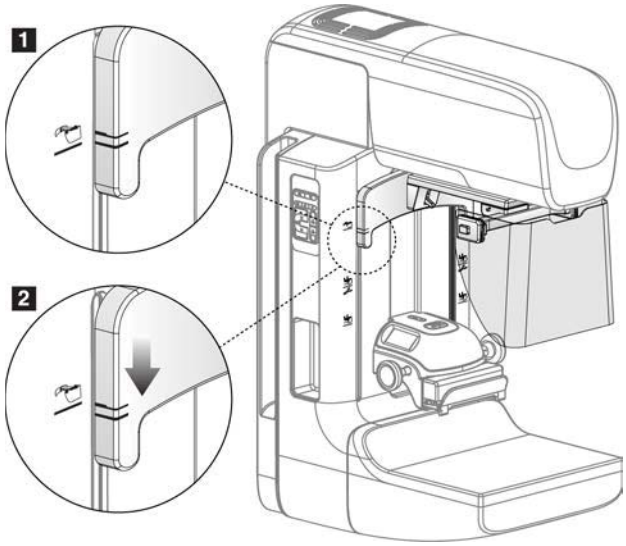


Figure 55: Align the Retractable Face Shield on the C-arm

To remove the Retractable Face Shield:

1. Press and hold the Unlock Lever (see item 1 in the previous figure) in the Up position.
2. Lift the Face Shield from the slots and remove from the C-arm.