



User Manual

SELENIA®
Dimensions®



Selenia Dimensions User Manual

Part Number MAN-01964

Revision 001

July 2010

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Preface

1.0 Intended Use

The Hologic Selenia® Dimensions® Digital Breast Tomosynthesis System generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions system is intended for use in the same clinical applications as Full Field Digital Mammography systems for screening mammograms. Specifically, the Selenia Dimensions system can be used to acquire two-dimensional full field digital mammograms and three-dimensional tomosynthesis mammograms. The screening examination will consist of a two-dimensional image set or a two-dimensional and tomosynthesis image set. The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.

2.0 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).

3.0 Users

- A Technologist to acquire and review images
- A Technologist with the manager permissions to perform the Quality Assurance
- A system administrator to enable permissions
- A Medical Physicist to perform the Quality Control tests
- A Radiologist can use the system with a Technologist
- The service personnel to install the system, set the site system configurations and calibrations, and find faults

4.0 Skills Needed for System Use

You must know how to do the following:

- Perform the trackball operations, like click, drag, and/or select
- Perform the touchscreen operations
- Select from menus
- Type information in text fields
- Select the options in the screens
- Select the entries from drop-down lists
- Use scroll bars

5.0 Training Requirements

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

Make sure that you receive training on the Selenia Dimensions before use on patients. Hologic training programs address MQSA training regulations for any Technologist or Physician.

Refer to this manual for directions on how to use Selenia Dimensions.

6.0 Quality Control Requirements

The 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.

The 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.

7.0 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.

8.0 Warnings, Cautions, and Notes

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



WARNING!

Procedures that you must follow accurately to prevent possible serious injury or death.



Warning:

Procedures that you must follow accurately to prevent injury.



Caution:

Cautions point out procedures that you must follow accurately to prevent the damage to equipment, loss of data, or damage to files in software applications.



Note...

Notes indicate additional information.

9.0 Terms and Definitions

ACR	American College of Radiology
AEC	Automatic Exposure Control
Annotations	Graphic or text marks on an image to indicate an area of interest.
Collimator	Device at the x-ray tube to control the area of the receptor that is exposed.
Combo Procedure	An image acquisition procedure for which the system takes a conventional mammography image and a tomosynthesis scan during a single patient compression (Tomosynthesis option).
Conventional Mammography	Single projection x-ray images of views for screening and diagnostic purposes.
Diagnostic Workstation	Softcopy workstation for diagnoses from digital images.
DICOM	Digital Imaging and Communications in Medicine
Gantry	A part of the Selenia Dimensions that has the Detector, Generator and x-ray Source, Positioning/Compression, Power Distribution, and Accessories Subsystems.
Grid	Element within the Digital Image Receptor that reduces scatter radiation during the exposure.
HIS	Hospital Information System
HTC™	High Transmission Cellular Grid
Image Receptor	Assembly of x-ray detector, x-ray scatter reduction grid, and carbon fiber cover.
MQSA	Mammography Quality Standards Act
Notice	Annotations and comments per image communicated between Diagnostic Review Workstations, Technologist Workstations, and Acquisition Workstations.
PACS	Picture Archiving and Communications System. A computer and network system for the transfer and archive of digital medical images.
Pend	A mark on the image to indicate the Technologist is not positive about the image quality. Pended images must be Accepted or Rejected before the procedure is closed.
Projection Images	The group of x-ray images for tomosynthesis taken at different projection angles through the breast (Tomosynthesis option).
RIS	Radiology Information System
ROI	Region of Interest
SID	Source to Image Distance
Tomosynthesis	An imaging procedure which combines a number of projections taken at different angles. The tomosynthesis images can be reconstructed to show planes or slices within the object (Tomosynthesis option).
UPS	Uninterruptible Power Supply

10.0 International Symbols

This section describes the International Symbols on the Selenia Dimensions.

	Potential Equalization terminal	Connection for a conductor different from the Protective Earth for a direct connection between two or more pieces of electrical equipment.
	Protective Earth terminal	For the connection of the line cord ground or ground cable of the equipment and there is no other purpose.
	Off	Power disconnected from the main power source.
	On	Power connection to the main power source.
	Off	Only a part of the equipment is disconnected from the main power source.
	On	Only a part of the equipment is connected to the main power source.
	WEEE	Symbol that indicates separate removal for electrical and electronic equipment.
	Dangerous Voltage	Identifies an area of possible lethal voltage.
	Manufacturer	
	Date of Manufacture	

11.0 Document Standards

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

Chapter 1—General Information

1.0 System Description

Legend for Figure 1-1

1. Gantry
2. C-arm
3. Acquisition Workstation

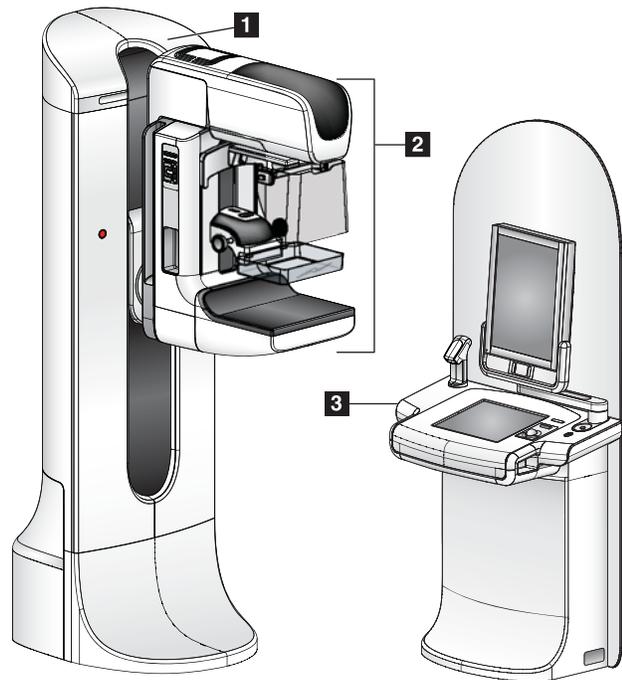


Figure 1-1: Selenia Dimensions

2.0 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 wrong system operation. Hologic can arrange for training at your facility.

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

2.1 General Safety



The Selenia Dimensions 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!

Lethal voltages exist inside of this system. Do not open any of the panels.



WARNING!

Per North American electrical safety requirements, you must use a Hospital Grade receptacle to provide a correct Ground.



WARNING!

Do not use the electrical equipment near flammable anesthetics.



Warning:

This device contains dangerous material. Return to Hologic all material removed from service.



Warning:

The user or the service personnel must correct problems before the system is used.



Warning:

The user must arrange for preventive maintenance by an authorized service representative.



Warning:

If a paddle touches possible infectious materials, call your Infection Control Representative for decontamination instructions.



Caution:

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



Caution:

Only use the approved accessories with this equipment. The failure to follow this caution can cause errors and possible data loss.



Note...

Hologic does not provide the Gantry power cable for some countries. If the power cable is not provided, the installed cable must meet the following requirements and all local codes that apply: 3 conductor, 8 AWG (10 mm²) copper not more than 25 feet (7.62 meters) in length.

2.2 Patient Safety



WARNING!

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



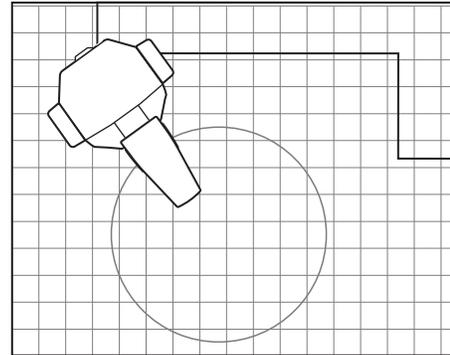
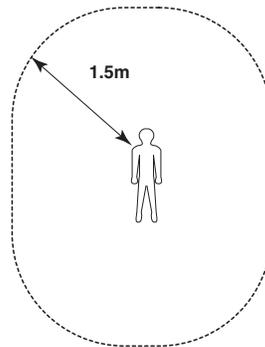
WARNING!

To keep the isolation quality for the system, attach only approved accessories or options to the system. Only the authorized personnel can make changes to the connections.



WARNING!

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



Warning:

Never leave the patient during the procedure if in contact with the mammography system.



Warning:

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



Warning:

The C-arm movement has drive motors.



Warning:

You increase the patient dose to high levels if you increase the AEC exposure adjustment setting. You increase the image noise or decrease image quality if you decrease the AEC exposure adjustment setting.



Warning:

Put both footswitches away from the patient and C-arm area to prevent any accidental footswitch use. When the patient has a wheelchair, put the footswitches away from the area.



Warning:

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

2.3 Radiation Safety



WARNING!

This x-ray 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 from radiation.



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 reader 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:

You must keep your complete body behind the radiation shield for the time of the exposure for maximum protection from x-ray exposure.

2.4 Data Loss



Warning:

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



Caution:

Never 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:

Do not put any magnetic media near or on devices that create any magnetic fields, because stored data can be lost.

2.5 Equipment Damage



Caution:

Do not put any heat source on the image receptor.



Caution:

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



Caution:

Do not make any brightness or contrast adjustments to the display unless the SMPTE test pattern is on the screen.



Caution:

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



Caution:

Do not spray disinfectant on the system, because the moisture can enter the system and damage the electronic components.

2.6 Emergency Off Switches

The Emergency Off switches remove the power from the Gantry. Do not normally use the Emergency Off switches to turn off the system. See Chapter 2, page 23 for complete information.

2.7 Interlocks

The Selenia Dimensions has safety interlocks:

- The C-arm vertical drive and rotation is disabled when 45 Newtons (10 pounds) or greater of compression force is displayed.
- If the x-ray button is released before the end of the exposure, the exposure stops and an alarm message appears.
- When in Tomo mode, the system does not allow the Grid in the x-ray field (Tomosynthesis option).
- Mirror and Filter interlocks prevent the x-ray exposure when the Light Field Mirror or the Filter is not aligned.

3.0 Compliance

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

3.1 Compliance Requirements

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

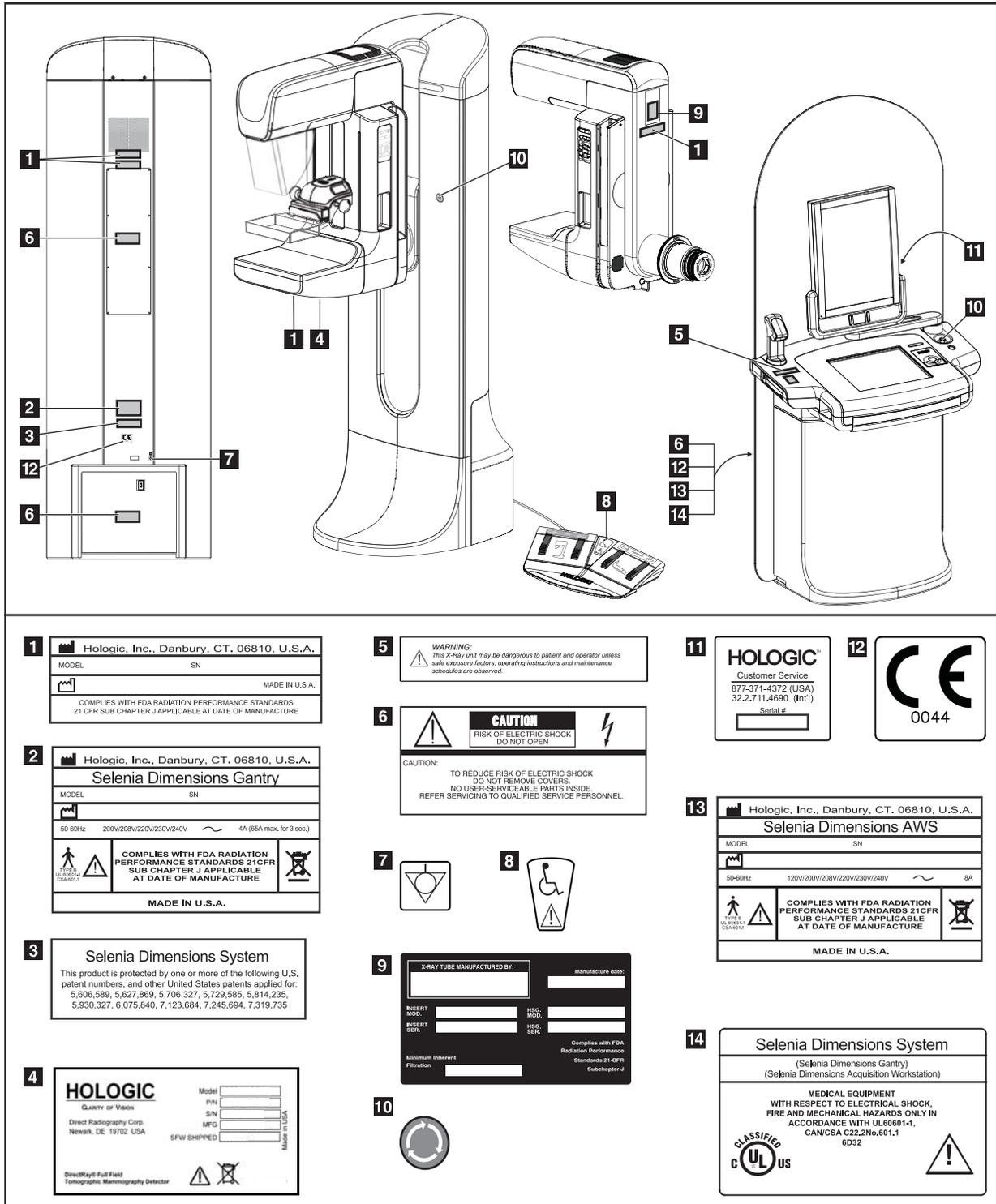
- The electrical installation of the room meets all requirements.
- The equipment is used according to Instructions for Use.
- The assembly operations, extensions, adjustments, changes, or repairs are performed only by authorized persons.
- The network and communication equipment must be installed to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

3.2 Compliance Statements

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

- CAN/CSA ISO 13485:2003
- EN 60601-1:1990 +A1+A11+A12+A2+A13 Medical Electrical Equipment—General Requirements for Basic Safety and Essential Performance
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1:1988 +A1+A2:1995 +A13:1996 Medical Electrical Equipment—General Requirements for Safety
- IEC 60601-1-1:2000-12 Medical Electrical Equipment—Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2001 Medical Electrical Equipment—Collateral Standard: Electromagnetic Compatibility for Medical Electric Systems
- IEC 60601-1-3:1994 Medical Electrical Equipment—Collateral Standard: Requirements for Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-4:1996 +A1:1999 Medical Electrical Equipment—Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-2-7:1998 Medical Electrical Equipment—Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-ray Equipment
- IEC 60601-2-28:1993-03 Medical Electrical Equipment—Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis
- IEC 60601-2-32:1994 Medical Electrical Equipment—Particular Requirements for the Safety of Associated Equipment of X-ray Equipment
- IEC 60601-2-45:2001 Medical Electrical Equipment—Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices
- UL 60601-1: Medical Electrical Equipment, Part 1—General Requirements for Safety
- CAN/CSA: Medical Electrical Equipment Part 1: C22.2 No. 601.1–M90—General Requirements for Safety

4.0 Label Locations



1 Hologic, Inc., Danbury, CT. 06810, U.S.A.
 MODEL SN
 MADE IN U.S.A.
 COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS
 21 CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE

2 Hologic, Inc., Danbury, CT. 06810, U.S.A.
Selenia Dimensions Gantry
 MODEL SN
 50-60Hz 200V/220V/230V/240V 4A (6SA max. for 3 sec.)
 COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE
 MADE IN U.S.A.

3 Selenia Dimensions System
 This product is protected by one or more of the following U.S. patent numbers, and other United States patents applied for:
 5,606,589, 5,627,869, 5,706,327, 5,729,585, 5,814,235, 5,930,327, 6,075,840, 7,123,684, 7,245,694, 7,319,735

4 **HOLOGIC**
 CLARITY OF VISION
 Direct Radiography Corp.
 Newark, DE 19702 USA
 Model PIN
 SN MFG
 SFW SHIPPED
 Made in USA
 DirectRay® Full Field Tomographic Mammography Detector

5 **WARNING:**
 This X-Ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

6 **CAUTION**
 RISK OF ELECTRIC SHOCK
 DO NOT OPEN
 CAUTION:
 TO REDUCE RISK OF ELECTRIC SHOCK
 DO NOT REMOVE COVERS
 NO USER-SERVICEABLE PARTS INSIDE
 REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.



9 X-RAY TUBE MANUFACTURED BY: Manufacture date:
 INSERT MOD. HSG. MOD.
 INSERT SER. HSG. SER.
 Minimum Inherent Filtration
 Complies with FDA Radiation Performance Standards 21-CFR Subchapter J



11 **HOLOGIC**
 Customer Service
 877-371-4372 (USA)
 32.2.711.4690 (Int'l)
 Serial #

12 **CE**
 0044

13 Hologic, Inc., Danbury, CT. 06810, U.S.A.
Selenia Dimensions AWS
 MODEL SN
 50-60Hz 120V/200V/220V/230V/240V 8A
 COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE
 MADE IN U.S.A.

14 Selenia Dimensions System
 (Selenia Dimensions Gantry)
 (Selenia Dimensions Acquisition Workstation)
 MEDICAL EQUIPMENT
 WITH RESPECT TO ELECTRICAL SHOCK,
 FIRE AND MECHANICAL HAZARDS ONLY IN
 ACCORDANCE WITH UL60601-1,
 CAN/CSA C22.2No.601.1
 6032
 CLASSIFIED C UL US

Figure 1-2: Label Locations

Chapter 2—System Controls and Indicators

1.0 System Power Controls

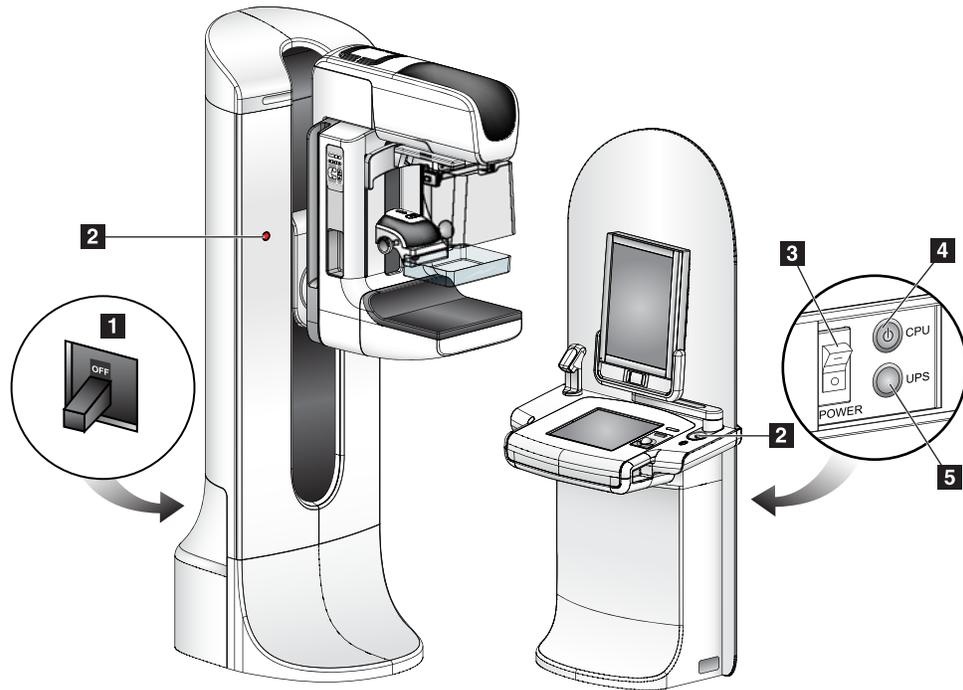


Figure 2-1: System Power Controls

Legend for Figure 2-1

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

2.0 Acquisition Workstation Controls and Display

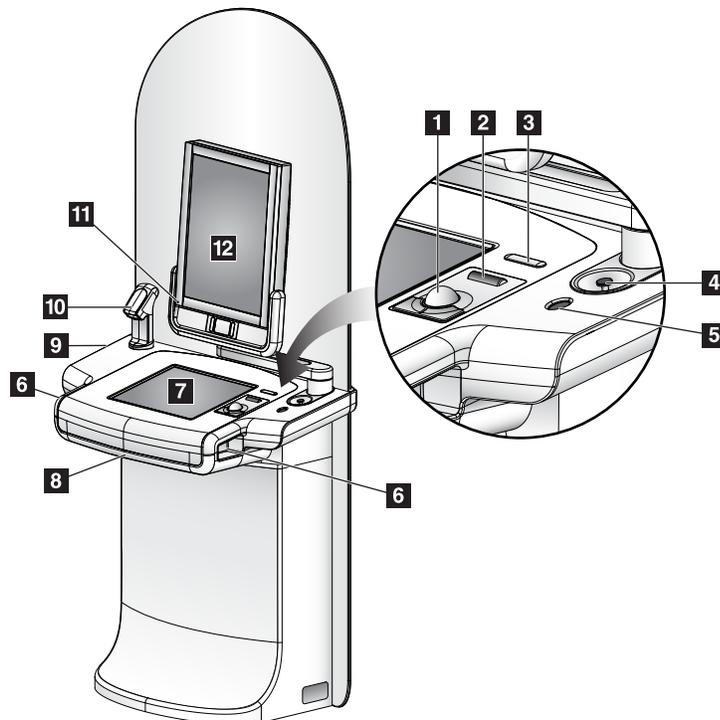


Figure 2-2: Acquisition Workstation Controls and Displays

Legend for Figure 2-2

1. Trackball
2. Scroll Wheel
3. Compression Release
4. Emergency Off Switch
5. Fingerprint Reader
6. X-ray Button (one on each side)
7. Touchscreen Display
8. Keyboard (in drawer)
9. CD/DVD Drive
10. Bar Code Reader
11. LED for Preview Display Power
12. Preview Display

2.1 Keyboard

Use the keyboard in the front drawer of the Acquisition Workstation for data entry.

2.2 Bar Code Reader

Use this device for data entry from bar codes for patient or procedure records.

2.3 Acquisition Workstation Touchscreen Display

Use the Touchscreen or trackball to select items.

2.4 Preview Display

See the images on the Preview Display.

3.0 Tubestand Controls and Indicators

Legend for Figure 2-3

- 1. The Rotation Angle Displays (each side)
- 2. The C-arm Controls (each side)
- 3. The Compression Device
- 4. The Patient Handles (each side)
- 5. The Emergency Off Switches (each side)
- 6. The Compression Handwheels
- 7. The Patient Face Shield
- 8. The Tubehead Display
- 9. The Footswitches

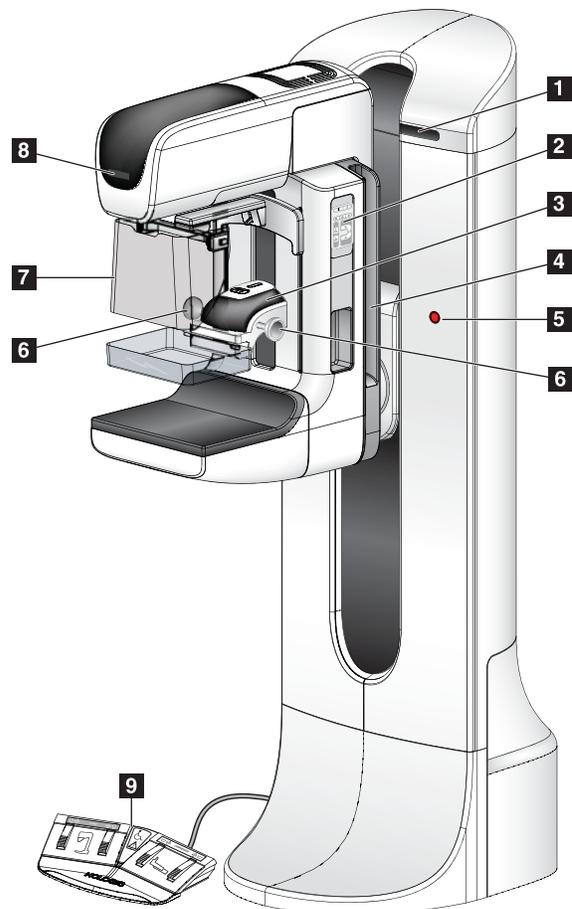


Figure 2-3: Tubestand Controls and Indicators

3.1 C-arm Controls

The C-arm Controls provide the Collimator and C-arm functions. See Section 5.0, page 17.

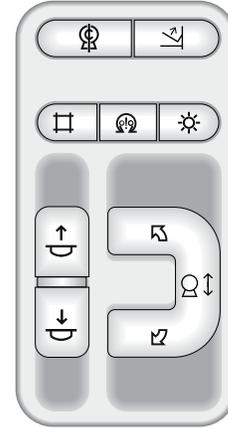


Figure 2-4: C-arm Controls

3.2 Compression Device Controls and Displays

Legend for Figure 2-5

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

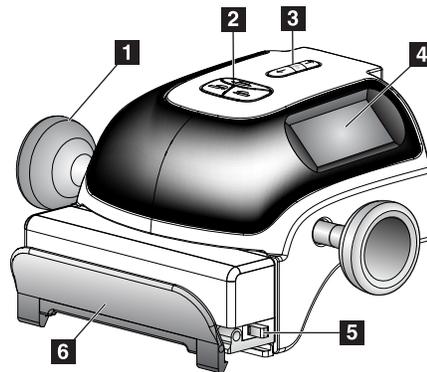


Figure 2-5: Compression Device

The Display on the compression device shows:

- AEC Sensor Position
- Compression Force (displays 0.0 when force is less than 4 pounds)
- Compression Thickness
- Angle of C-arm after rotation (for 10 seconds)



Figure 2-6: Compression Display

3.3 Tubehead Display

The Tubehead Display shows:

- SID
- Filter Type
- Collimator Setting
- Paddle Position



Figure 2-7: Tubehead Display

3.4 Dual Function Footswitches



Warning:

Put both footswitches away from the patient and C-arm area to prevent any accidental footswitch use. When the patient has a wheelchair, put the footswitches away from the area.

To use the footswitches:

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

Legend for Figure 2-8

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

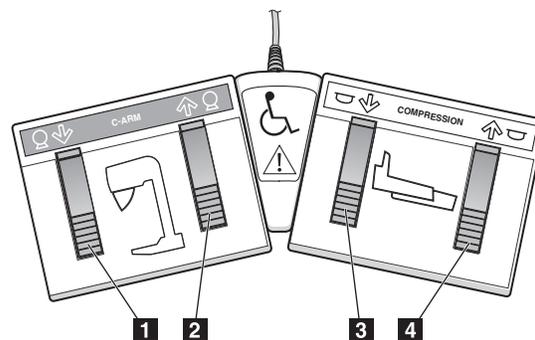


Figure 2-8: Dual Function Footswitches

4.0 How to Turn On the Selenia Dimensions

4.1 Preparation

1. Reset all three Emergency Off switches.
2. Make sure that both system circuit breakers are in the On position.
3. Remove any obstructions to the C-arm movement and to the view of the Operator.

4.2 Startup

1. Press the UPS button at the rear of the Acquisition Workstation if the UPS was shut down.
2. Press the computer power button at the rear of the Acquisition Workstation (see Figure 2-1, page 9, number 4).

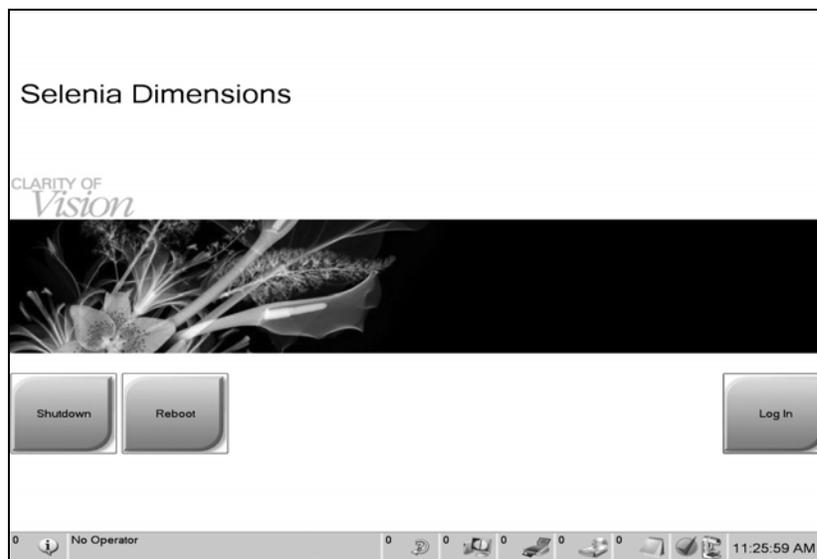


Figure 2-9: The Startup Screen

3. Select the **Log In** button.



Note...

The system requires between 5 minutes and 45 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 the system is Ready.



Note...

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

4.3 Log In

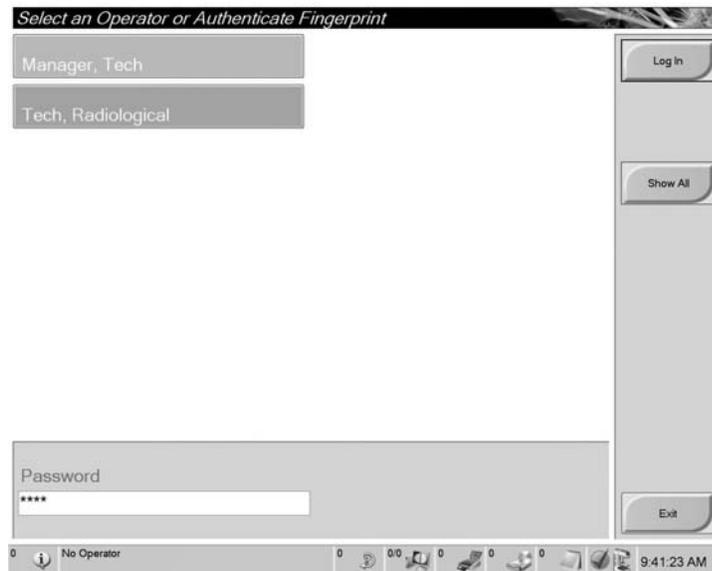


Figure 2-10: How to Log In

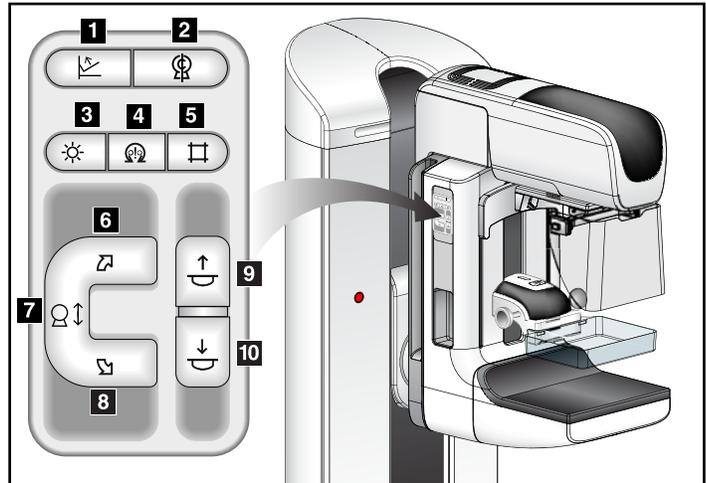
When the user Log In screen displays, all Managers and Technologists show in the list of Operators.

1. To display the Service, Applications, and Physicists user names, select the **Show All** button.
2. Select your user name, enter your password, and select the **Log In** button.
Or
Validate your fingerprint.

5.0 Perform the Functional Tests

Legend for Figure 2-11

1. Compression Release
2. (Future use)
3. Light Field Lamp
4. (Future use)
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



A C-arm control panel is on both the left and right sides of the Gantry.

Figure 2-11: C-arm Controls (left side shown)

The following Functional Tests make sure that the control operates correctly.

Table 2-1: C-arm Functional Tests

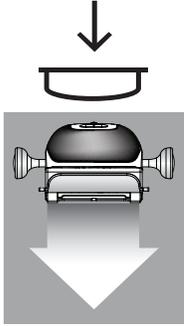
Function	Functional Test
<p>Compression Down</p> 	<p>Press a Compression Down button:</p> <ul style="list-style-type: none"> • The compression brake engages. • The light field lamp illuminates. • The compression device lowers. <p><i>Note...</i> When you press the Compression Down button, the compression brake remains engaged until the Compression Release button is pressed.</p> <p>Compression down movement stops:</p> <ul style="list-style-type: none"> • When you release the button. • When you reach the Down Force limit. • When you reach the Lower Travel limit.

Table 2-1: C-arm Functional Tests

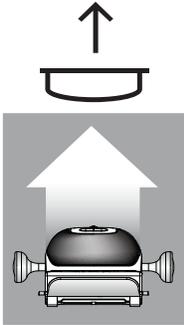
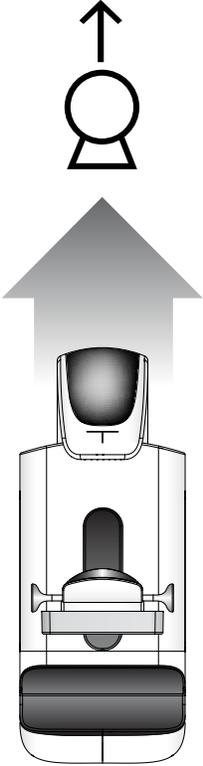
Function	Functional Test
<p>Compression Up</p> 	<p>Press a Compression Up button:</p> <ul style="list-style-type: none"> • The Compression Device moves toward the top. • The Compression Up button <i>does not</i> release the Compression Brake. <p>Compression Up movement automatically stops:</p> <ul style="list-style-type: none"> • When you release the button. • When you reach the upper travel limit.
<p>Compression Release</p> 	<p>Press the Compression Release button:</p> <ul style="list-style-type: none"> • The Compression Motor Brake releases. • The Compression Device lifts.
<p>C-arm Up</p> 	<p>Press the C-arm Up button:</p> <ul style="list-style-type: none"> • The C-arm movement automatically stops when the button is released. • The C-arm movement automatically stops when the C-arm reaches the upper travel limit. • The C-arm movement is disabled when a compression force of 45 N (10 pounds) or greater is applied.

Table 2-1: C-arm Functional Tests

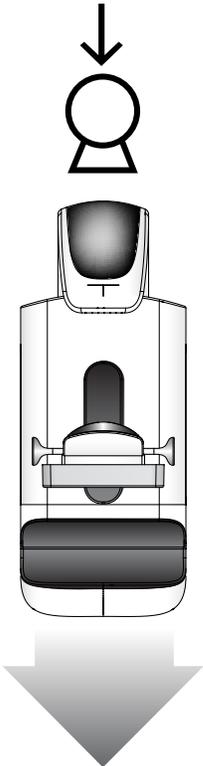
Function	Functional Test
<p>C-arm Down</p> 	<p>Press the C-arm Down button:</p> <ul style="list-style-type: none"> • The C-arm movement automatically stops when the button is released. • The C-arm movement automatically stops when the C-arm reaches the lower travel limit. • The C-arm movement is disabled when a compression force of 45 N (10 pounds) or greater is applied.

Table 2-1: C-arm Functional Tests

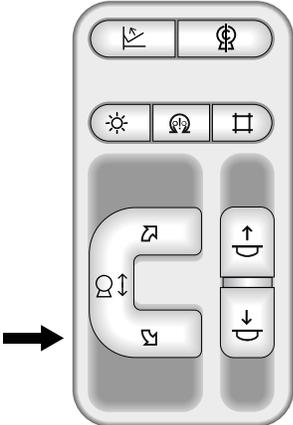
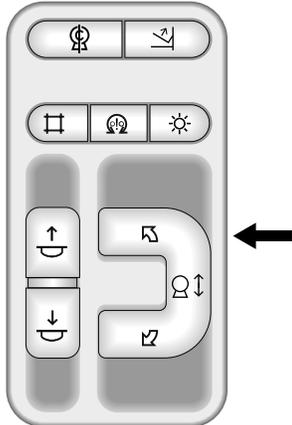
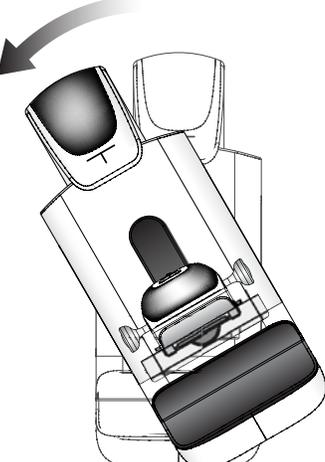
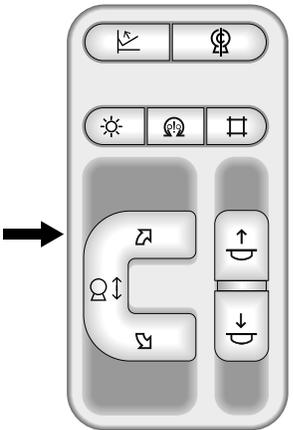
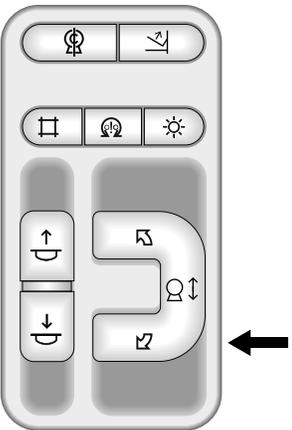
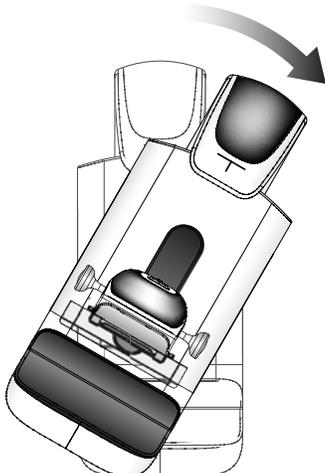
Function	Functional Test
<p>Counterclockwise C-arm Rotation</p> <p>Left Panel</p> 	<p>Press the Counterclockwise C-arm Rotation to start counterclockwise C-arm rotation.</p> <p>Right Panel</p>  
<p>Clockwise C-arm Rotation</p> <p>Left Panel</p> 	<p>Press the Clockwise C-arm Rotation button to start clockwise C-arm rotation.</p> <p>Right Panel</p>  

Table 2-1: C-arm Functional Tests

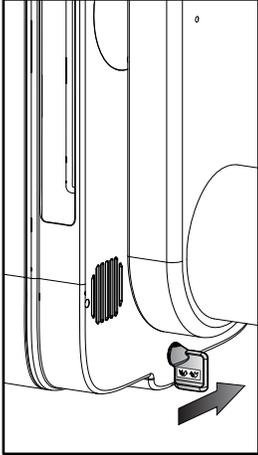
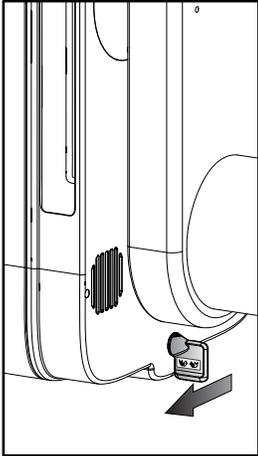
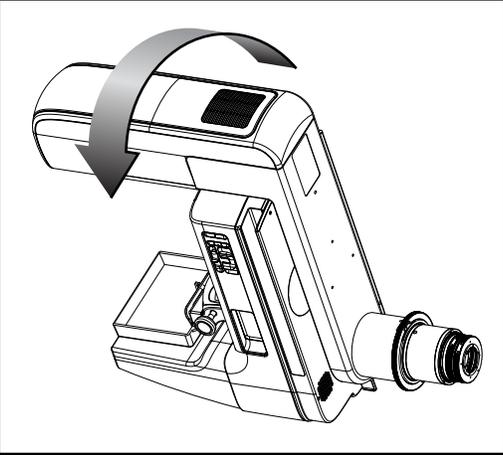
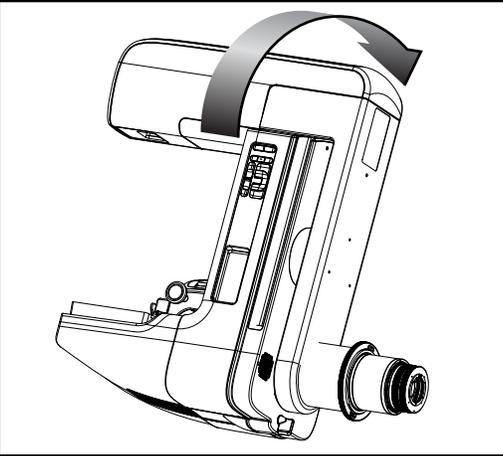
Function	Functional Test
<p data-bbox="444 386 704 415">C-arm Rotation Switch</p>  	<p data-bbox="782 386 1464 541">Push the C-arm Rotation switch away from you to move the C-arm toward you. Pull the C-arm Rotation switch toward you to move the C-arm away. The C-arm movement stops when the switch is released.</p>  

Table 2-1: C-arm Functional Tests

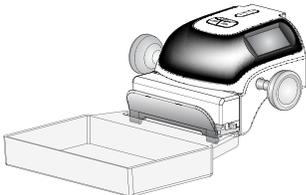
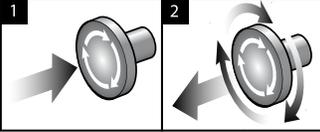
Function	Functional Test
Collimator Override 	The Collimator Override button changes the collimation through the different x-ray fields. Press the light field lamp button to show the x-ray field, then press the Collimator Override button to select an x-ray field.
Light Field Lamp 	Press the light field lamp button to see the x-ray field for approximately 30 seconds. The light field lamp automatically illuminates with the start of the Compression Down movement.
Motor Enable 	Reserved for future use.
C-arm Zero 	Reserved for future use.
Shifting Paddle System 	The 18 x 24-cm Screening Paddle moves approximately 2.5 cm into the left, center, or right position. While the compression is applied, you can not move the paddle. The collimator is programmed to follow the position of the paddle. To test this function: <ol style="list-style-type: none"> 1. Install the 18 x 24-cm paddle in the Compression Device. 2. Select a view. Use the Paddle Shift buttons on the procedure screen to override the position. Verify that the paddle automatically moves to the new position. 3. Turn on the light field lamp. Confirm that the collimator position matches the paddle position. 4. Repeat this procedure for the other paddle positions. A FAST Compression Mode Slide on the Compression Device lets you set the system for FAST Mode or for Normal Mode. To select the mode, move the Slide to the “F” position from either side of the Compression Device. The default shift positions are configurable through Service Tools.

Table 2-1: C-arm Functional Tests

Function	Functional Test
<p>Emergency Off Switches</p> 	<p>There are three Emergency Off switches, one on each side of the Gantry and one on the Acquisition Workstation. Press any of the Emergency Off switches to turn Off the Gantry. Turn the Emergency Off switch by one-quarter turn to reset the switch.</p>

6.0 How to Turn Off the System

1. Close any open patient procedures.
2. From the Select Patient screen, select the Log Out button.
3. From the Select an Operator screen, select the **Exit** button.
4. From the Startup screen, select the **Shutdown** button.
5. Select the **Yes** button in the confirmation screen.

7.0 How to Remove All Power from the Acquisition Workstation

Perform the procedures in this section after shutdown of the Acquisition Workstation.

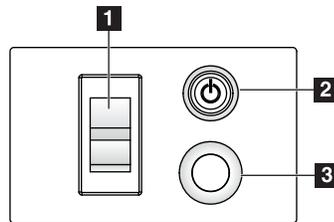


Figure 2-12: Power Buttons

1. After the system completes the shutdown, press the UPS button (Number 3) next to the Acquisition Workstation circuit breaker.
2. Turn off the Acquisition Workstation circuit breaker (Number 1).
3. Disconnect the Acquisition Workstation power cable.

User Manual

Chapter 2—System Controls and Indicators

How to Remove All Power from the Acquisition Workstation



Chapter 3—The User Interface

1.0 Select the Function to Perform

After you log in, the Select Function to Perform screen displays.



Note...

The Select Patient screen appears if you are not scheduled to perform any Quality Control tasks.

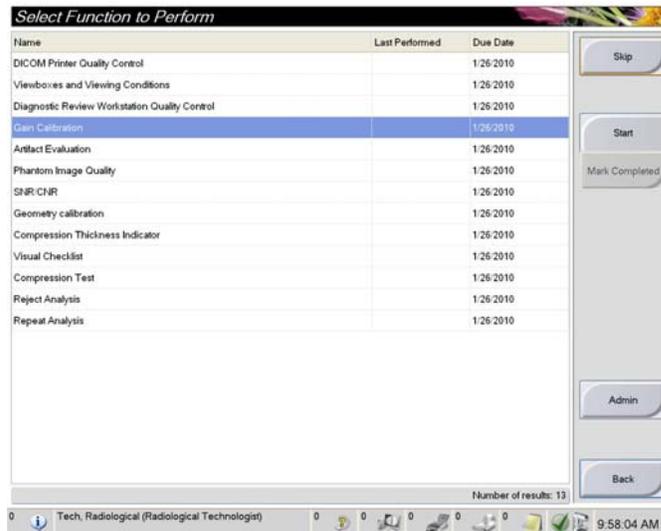


Figure 3-1: An Example Select Function to Perform Screen

1. Select an item in the list.
 2. Select the **Start** button or the **Mark Completed** button. The **Start** button is not available for all types of tests.
 3. Follow the messages to complete the procedure.
- If all Quality Control tasks will not be performed at this time, you can select the **Skip** button.



Note...

*If you select the **Skip** button, the Select Patient screen appears.*

2.0 How to Perform the Quality Control Tasks

1. Select a Quality Control task from the Select Function to Perform screen.
2. Select the **Start** button.
3. Follow the on-screen prompts to complete the procedure.

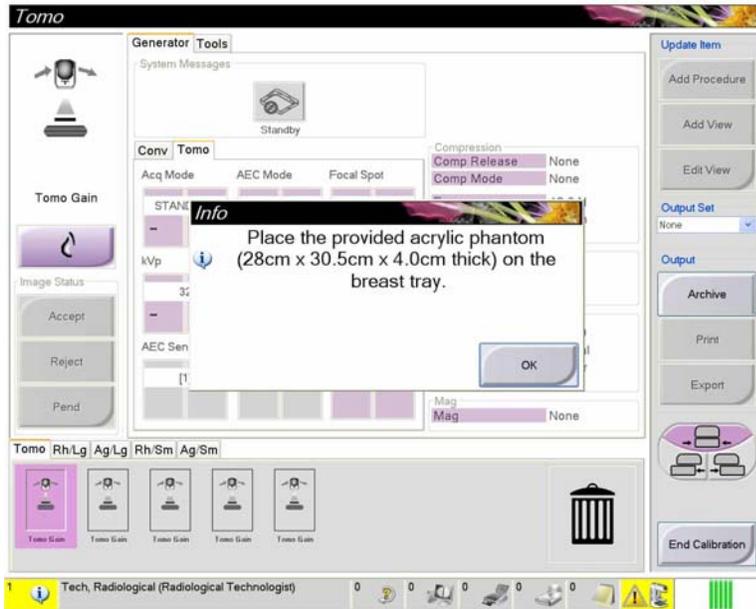


Figure 3-2: An Example Gain Calibration Screen



Note...

When the **Start** button is not enabled for a Quality Control task, select the **Mark Completed** button.



Note...

You can perform required Quality Control tasks at another time. Select the **Admin** button (on the Select Patient screen). Select the **Quality Control** button on the Admin screen to display the list.



Note...

If a calibration is scheduled on the current date, you can not perform a procedure until the calibration is completed.

3.0 How to Select a Patient

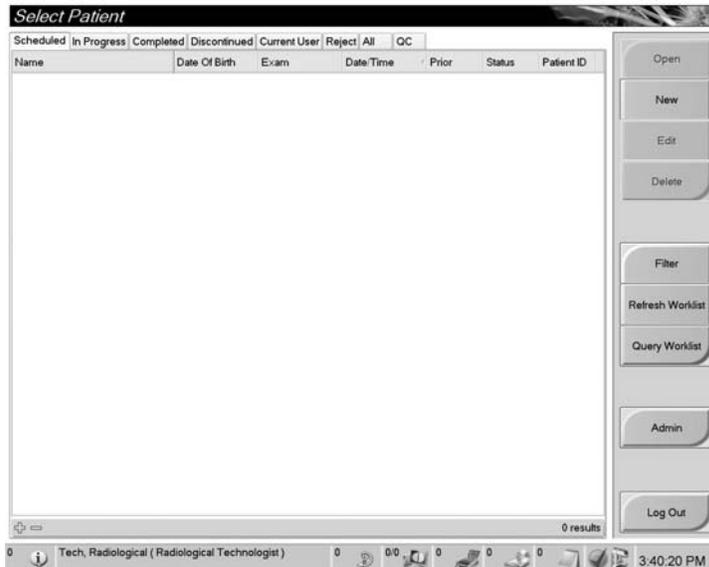


Figure 3-3: How to Select a Patient

Eight tabs display at the top of the screen. These tabs are configurable. A user with the right permissions can delete tabs and create new tabs.

- The **Scheduled** tab displays the scheduled procedures.
- The **In Progress** tab displays the procedures not complete.
- The **Completed** tab displays the completed procedures.
- The **Discontinued** tab displays the procedures started, but discontinued.
- The **Current User** tab displays the procedures for the current Operator.
- The **Reject** tab displays the procedures with rejected views.
- The **All** tab displays all procedures for all users.
- The **QC** tab displays the Quality Control procedures.

You can perform many functions from this screen:

- Add a new Patient (New)—see Section 3.2, page 28.
- Edit the patient information (Edit)—see Section 3.3, page 28.
- Delete a patient from the worklist (Delete)—see Section 3.4, page 28.
- Use a Patient Filter (Filter)—See Section 3.5, page 29.
- Search for a patient in the Modality Worklist (Query)—see Section 3.7, page 30.
- Use the Admin Screen (Admin)—see Chapter 8, page 67.
- Exit (Log Out)—see Section 3.9, page 30.
- Find your patients in the database (tabs at the top of screen).

3.1 How to Open a Procedure

1. When you select a patient from the list in any of the tabs, the **Open** button activates.
2. When you select the **Open** button, the Procedure screen for that patient appears.

3.2 How to Add a New Patient

1. In the Select Patient screen, select the **New** button.
2. Enter new patient information and select a procedure.
3. Select the **Open** button. A screen for the new patient information appears.

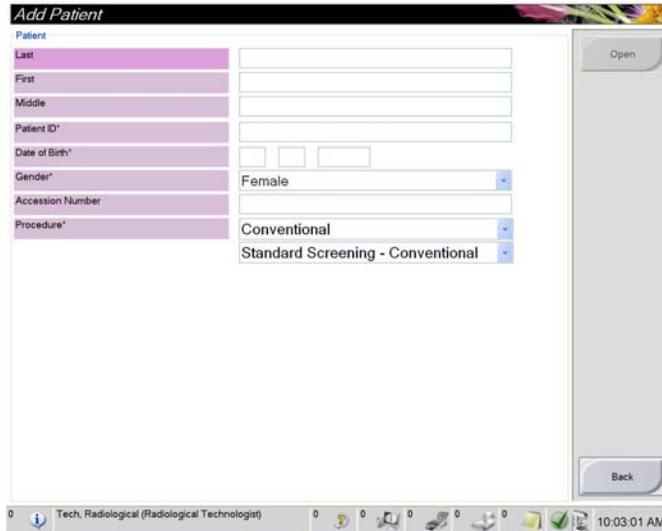


Figure 3-4: How to Add a New Patient

3.3 How to 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. When the Update Successful screen displays, select the **OK** button.

3.4 How to Delete a Patient

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



Note...

The Technologists do not have the user permission to delete patients.



Note...

Reclamation normally removes the requirement to delete patients.

3.5 How to Use a Patient Filter

When you select the **Filter** button in the Select Patient screen, the Patient Filter screen for the selected tab appears. See Figure 3-5.

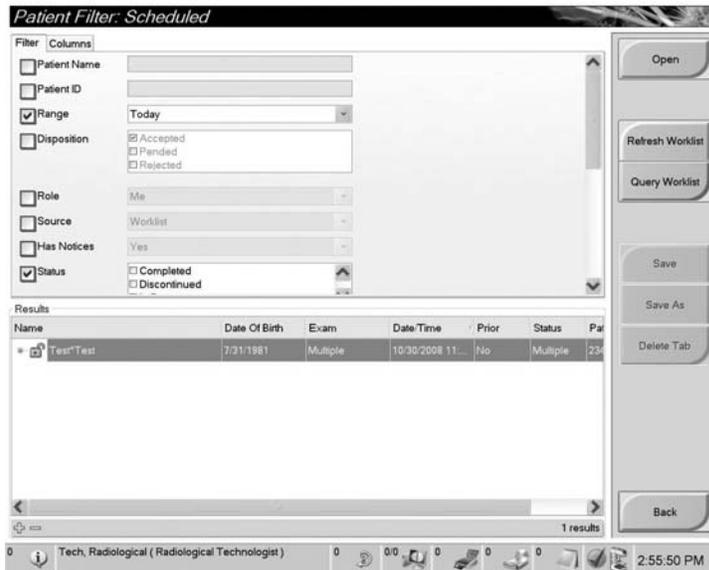


Figure 3-5: The Filter Tab in the Patient Filter Screen

From the Filter and Column tabs, select the information that appears on the selected tab page of the Select a Patient screen.

- The Filter tab accesses the parameters that select the patients who appear on the selected tab page.
- The Columns tab adds or removes columns on the selected tab page.
- Select a line in the Results list to activate the **Open** button. When you select the **Open** button, the Procedure screen for that patient appears.



Note...

*Your logon permissions can allow you to add, change or delete the tabs on the Select a Patient screen from the Patient Filter screen.
The **Save** button changes the name of the selected tab.
The **Save As** button creates a new tab.
The **Delete** button deletes the selected tab.*

3.6 How to Refresh the Worklist

Select the **Refresh Worklist** button to update the screen.

3.7 How to Query the Worklist

Use the Query Worklist feature to search for a patient or a list of patients.

There are two methods to enter the query information:

- **Bar Code Reader**—The field in which the bar code reader scans is configurable. Scan the configured field bar code. The scheduled procedure displays and the patient is added to the local database. By default, the user can scan on the Patient ID, Accession Number, or Requested Procedure ID.
- **Keyboard**—Use one or more fields to query the Modality Worklist Provider. All fields to query are configurable. The default fields are as follows: the Patient name, the Patient ID, Accession Number, Requested Procedure ID, Scheduled Procedure Date. The scheduled procedure displays and the patient is added to the local database.

3.8 About the Admin Button

See “Chapter 8—System Administration Interface,” page 67.

3.9 How to Log Out

Select the **Log Out** button to return to the Startup screen.

4.0 The Procedure Screen

Select the Generator tab (at the top of the screen on the left side) to adjust the exposure techniques for the procedure. Select the options in the Tools tab (at the top of the screen on the left side) for image review (see Chapter 4, Section 2.0, page 42).

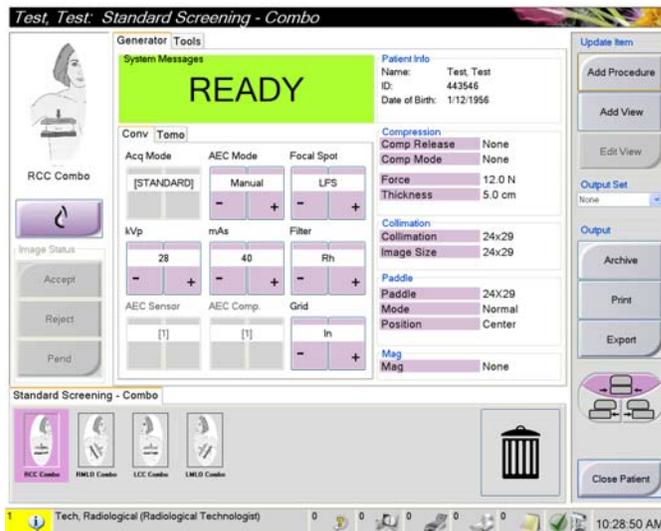


Figure 3-6: An Example Generator Tab in the Procedure Screen

4.1 How to Set the Exposure Parameters

4.1.1 Select the Image Acquisition Mode (Tomosynthesis option)

- Standard For routine Tomosynthesis screening procedures
- Enhanced For diagnostic views. This mode increases the patient dose.

4.1.2 Select the Exposure Mode

- 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.

Use the Automatic Exposure Control modes (AEC) to let the system control the exposure techniques.

4.1.3 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 to the nipple edge (position 7). The automatic position is Position 8.

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.

4.2 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 the implant displaced views, and changes the “Implant Present” DICOM tag in the image header. When this button is selected, a checkmark 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 there is an ID view in the open procedure.

4.3 How to Acquire an Image

See Chapter 6, page 59 for information about clinical procedures.

1. Select a view from the thumbnail images at the bottom of the screen.
2. Press and hold the x-ray button for the complete exposure. During the exposure, a System Message appears, a tone sounds, and the x-ray indicator on the control panel lights to indicate x-ray emission.
3. The image displays when the x-ray is complete. You must select how to complete the acquisition.
 - You can **Accept** the image. The locked image transmits to output devices with all attributes and marks.
 - You can **Reject** the image. The Preview closes. You can repeat the rejected view, or select another view.
 - You can **Pend** the image. The image saves for future review.
4. Repeat the steps 1 to 3 for each view.

4.4 How to Add or Remove a View

1. To add a view, select the **Add View** button to display the Add View screen.

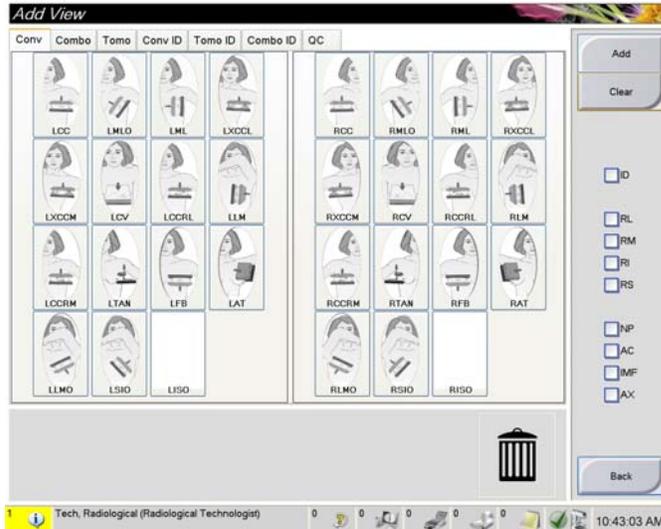


Figure 3-7: The Add View Screen

View Modifiers

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



Note... *ID indicates Implant Displaced.*

2. Select the tab, then select the view. You can select a maximum of 3 View Modifiers from the right panel of the screen.
3. Select the **Add** button. A thumbnail image for each view that you select appears in the bottom of the window.
4. To remove a selected view, select the view then select the **TRASH** icon.
5. To remove all selected views, select the **Clear** button.

4.5 How to Add a Procedure

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

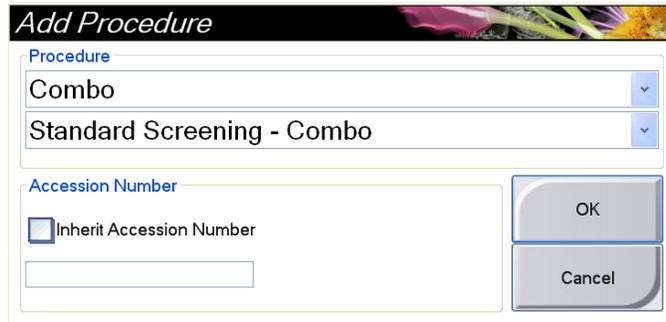


Figure 3-8: The Add Procedure Dialog Box

2. Use the drop-down menus to select the type of procedure to add.
3. Enter an Accession Number or select the “Inherit Accession Number” checkbox to use the current number.
4. Select the **OK** button. A new tab displays with the thumbnail images for the procedure which was added.

4.6 How to Edit a View

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

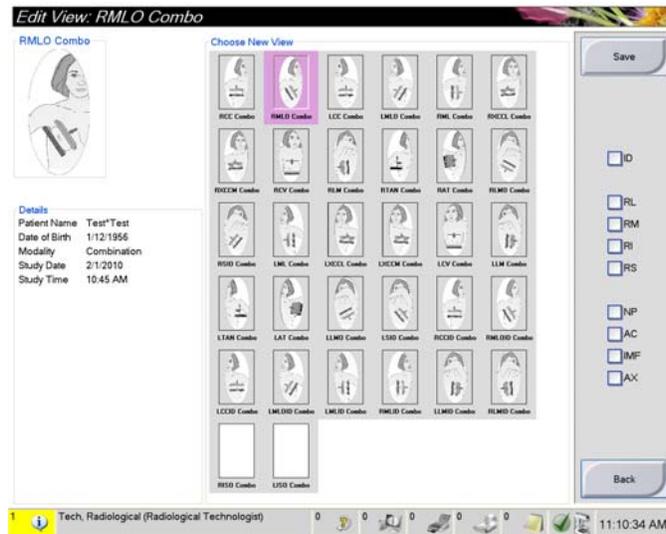


Figure 3-9: The Edit View Screen

To edit a view:

1. Select an exposed thumbnail image view in the Procedure screen.
2. Select the **Edit View** button.
3. Select the view from the screen. You can select a maximum of 3 View Modifiers. See Figure 3-7 for a description of the View Modifiers.
4. Select the **Save** button.
5. When the Update Successful screen displays, select the **OK** button.

4.7 How to Close a Procedure

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

• Close Procedure Complete	Closes the procedure and puts the procedure in the Complete tab.
• Close Procedure In Progress	Closes the procedure and puts the procedure in the In Progress tab.
• Close Procedure Discontinued	Closes the procedure and puts the procedure in the Discontinued tab. A dialog box appears and you must select the reason the procedure was discontinued from a list or add a new reason.
• Return To procedure	Returns to procedure.

If there are images marked as Pend, you must respond to the confirmation prompt to close the procedure In-Progress.

If MPPS is activated, messages are sent to the output devices when you select Complete and 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 appears with buttons to resend a status or to return to the procedure.

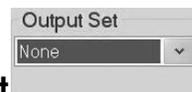
5.0 How to Access Image Review Features

Select the Tools tab on the Procedure screen to access the image review features. See Chapter 4, Section 2.1, page 43 for information.

6.0 How to Use the Output Sets

The Accepted images are sent automatically to the output devices in the selected Output Set. The default values for the site control if the images are sent after a patient is closed or after the image is Accepted.

6.1 How to Select an Output Set



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



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

6.2 How to Add or Edit an Output Set



Note... The configuration of Output Groups (Sets) is done during installation, but you can add other groups (Sets).

To add a new Output Set:

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.
4. Select the **Add** button. When the Update Successful message displays, select **OK**.

To edit an Output Set:

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

7.0 How to Use the On-Demand Outputs

You can manually Archive, Print, or Export an image until the procedure is closed.

When you press an On-Demand output button, you have the option to send the image to any of the configured Output Sets.

7.1 How to Archive

1. Select the **Archive** button.
2. Select a storage device from a drop-down menu.
3. Select the **Start** button to copy all selected images from the opened case study to the selected device.



Note...

Use the Manage Queue utility in the task bar to review the image status.

7.2 How to Print

7.2.1 The Print Screen

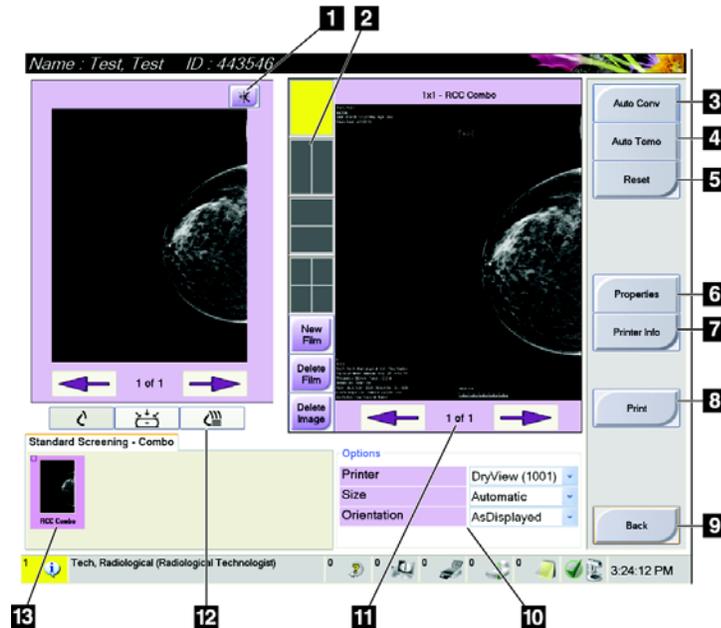


Figure 3-10: The Print Screen

Legend for Figure 3-10

1. Mirrors the image.
2. Selects the film format (number of tiles).
3. Prints Conventional images with the default setup.
4. Prints tomo images (slices or projections) that have been Tagged for Print (Tomosynthesis option).
5. Returns the screen to previous settings.
6. Opens the Properties screen.
7. Shows the printer IP address, AE Title, Port and capability for True Size print.
8. Starts the print process.
9. Returns you to the Procedure screen.
10. Selects the printer options.
11. Allows you to step through the film pages.
12. Selects Conventional, Projection, or Reconstruction views (Tomosynthesis option).
13. Shows the Thumbnail image view.

7.2.2 How to Use the Print Screen

1. From the Procedure screen, select the **Print** button. The Print Screen displays. Refer to Figure 3-10 to prepare your print information.
2. Select the film format from the Options area of the page.
3. Select a thumbnail image.
4. Select the image display box on the right side of the screen to put the selected thumbnail image on the film.
5. To put other thumbnail images on the film, repeat steps 2 and 3.
6. To print a different film format of the same images, select the **New Film** button and repeat steps 1 to 4.
7. Select the **Print** button to print your films.

7.3 How to Export

1. Select the **Export** button.
2. Select a device from a drop-down menu.
3. Select the **Start** button to copy all accepted images from the open procedure to the selected device.

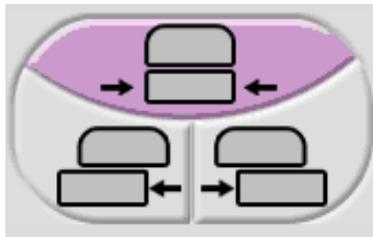
8.0 How to Use the Paddle Shift Feature

1. In the Procedure screen, select an unexposed thumbnail image view. The paddle moves to the default position.



Note... A default paddle position for each view is set in Service Tools.

2. From the paddle shift section of the screen, select the button for the new paddle position. The paddle moves to the new position.



9.0 About the Taskbar

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



Table 3-1: Taskbar Menus

	Description	Menu
1 	<p>Select the Information icon to display a menu.</p> <p>This section of the taskbar flashes a yellow color if an alarm exists. Select Acknowledge All to remove the flashing indication. Select the Manage Alarms option to display and close any open alarms.</p>	<div style="border: 1px solid gray; padding: 5px;"> <p>No Alarms</p> <hr/> <p>Acknowledge All</p> <p>Manage Alarms ...</p> </div>
2	<p>Select the user name to display a menu.</p> <p>Log Out returns you to the Sign-in screen.</p> <p>My Settings displays the Edit Operator screen to review or edit Operator information, change your password, or use the Fingerprint Capture feature.</p> <p>Print prints the displayed patient list to a connected printer.</p>	<div style="border: 1px solid gray; padding: 5px;"> <p>Users Menu</p> <hr/> <p>Log Out</p> <p>My Settings ...</p> <p>Print ...</p> </div>
3 	<p>Select an output icon (query retrieve, workstation/archive, printer, or CD-ROM) to display a menu. Each menu selection takes you to the screen for that selection.</p> <p>Manage Queues displays the status of jobs in the queue and job details for the selected output, and allows you to filter the queue display.</p>	<div style="border: 1px solid gray; padding: 5px;"> <p>Queues Menu</p> <hr/> <p>Manage Queues ...</p> <p><i>Output Group:None</i></p> </div>
4 	<p>Select the Notice icon to display a menu.</p> <p>Select Acknowledge All to remove the flashing indication.</p> <p>The Manage Notices icon allows you to select the display options for the message like date or title.</p>	<div style="border: 1px solid gray; padding: 5px;"> <p>No Notices</p> <hr/> <p>Acknowledge All</p> <p>Manage Notices ...</p> </div>
5 	<p>Select the Tubehead icon to display a menu. When a green checkmark appears next to the tubehead icon, the detector and generator are ready for use.</p> <p>Clear All Faults deletes all error messages.</p> <p>Zero Tubehead puts the tubehead at zero degrees of rotation for the next exposure.</p> <p>System Diagnostics accesses Subsystem settings.</p> <p>System Defaults opens the Gantry Defaults screen to set the Compression and Generator default values.</p> <p>About displays information about the Acquisition Workstation.</p>	<div style="border: 1px solid gray; padding: 5px;"> <p>No Alarms</p> <hr/> <p>Clear All Faults</p> <p>Zero Tubehead</p> <hr/> <p>System Diagnostics ...</p> <p>System Defaults ...</p> <hr/> <p>About ...</p> </div>

User Manual

Chapter 3—The User Interface
About the Taskbar



Chapter 4—The Images

1.0 Introduction

After you make an exposure, the acquired image displays on the Preview screen. Review the image and add the annotations, then Accept, Reject, or Pend the image. A thumbnail image appears in the Case Study area of the screen.

- If you select the **Reject** button, an “X” appears on the thumbnail image.
- If you select the **Pend** button, a question mark “?” appears on the thumbnail image.



Figure 4-1: The Preview Screen

1.1 Conventional Sequence of Events

- Review the image after the exposure.
- Accept, Reject, or Pend the image.

1.2 Tomosynthesis Sequence of Events (Tomosynthesis option)

- Wait for the image reconstruction to complete.
- Review a few slices from the reconstruction.
- Accept, Reject, or Pend the images.

2.0 How to Review the Images

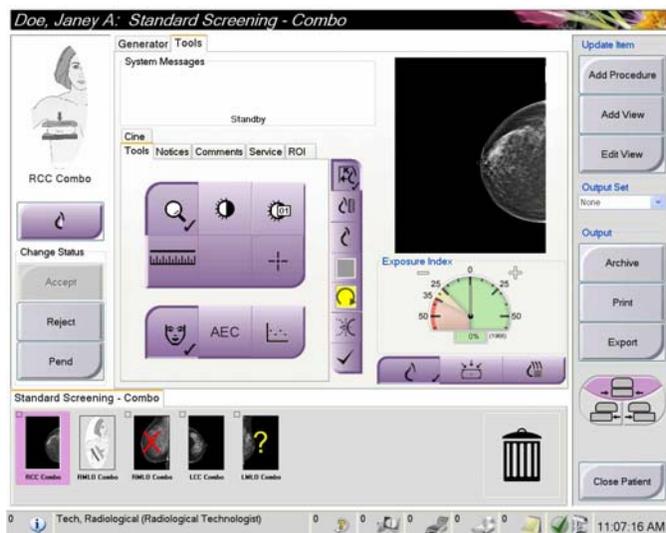


Figure 4-2: The Tools Tab in the Procedure Screen

Select any thumbnail image to display that image in the Preview screen. The thumbnail image is marked if the image is not accepted.

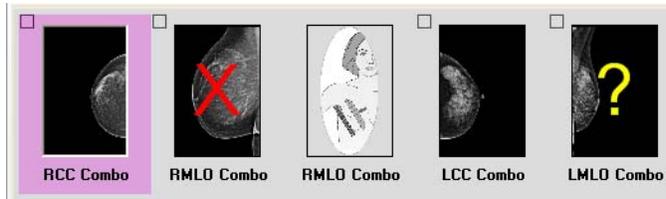


Figure 4-3: Marked Images in a Procedure

2.1 The Image Review Tools Tab

The Tools tab in the Procedure screen provides the image review tools. A checkmark appears on the button of an active tool.

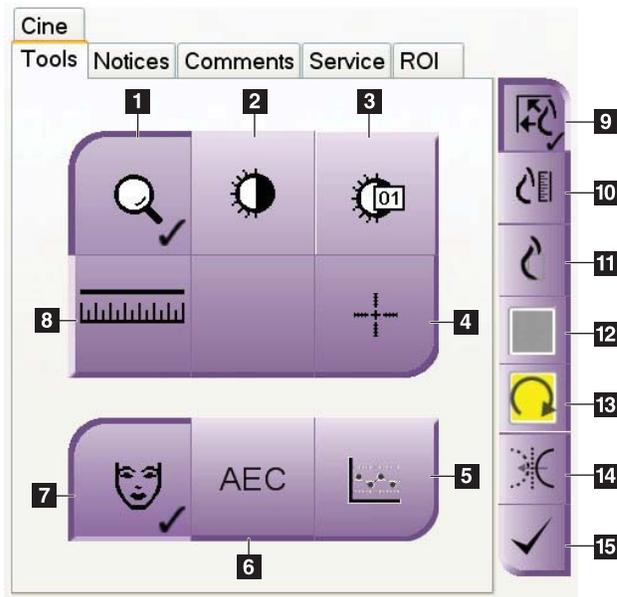


Figure 4-4: Image Review Tools

Legend for Figure 4-4

1. The **Zoom** tool magnifies a section of the image.
2. The **Window Level** tool with the Trackball changes the brightness and contrast.
3. The **Window Level Fine Adjustment tool** enters the specified contrast and brightness values.
4. The **Crosshair** tool displays a crosshair on the Preview Screen.
5. The **SNR/CNR** button calculates the signal-to-noise ratio and contrast-to-noise ratio in the ACR Phantom image.
6. The **AEC** button displays the AEC Sensor areas used for the exposure calculation. The sensor areas display on the Preview Screen.
7. The **Patient Information** button activates the patient information display.
8. The **Ruler** displays a measurement of the distance between two points.
9. The **Fit-to-Viewport** button fits the image within the image tile.
10. The **True Size** button displays the image in the actual size of the breast.
11. The **View actual pixels** button displays the image in full resolution.
12. The **Multi-Up Display** button selects the number of tiles to display.
13. The **Image Tile Advance** button sets the active Multi-Up tile.
14. The **Mirror** button reverses (mirrors) the image.
15. The **Tag for Print** button tags the projection or reconstruction images of a tomosynthesis image to print later (Tomosynthesis option).

2.2 Other Image Review Tools

2.2.1 The Image Review Tabs

Each tab provides additional image review functions.



Figure 4-5: Image Review Tabs

- **Cine:** Show a series of images as a movie (Tomosynthesis option).
- **Notices:** Make annotations about the image. Use the Draw or Elliptical button (Numbers 1 and 2) in Figure 4-6 to mark the area of interest. Use the Arrow button (Number 3) to send the annotation as a Notice.

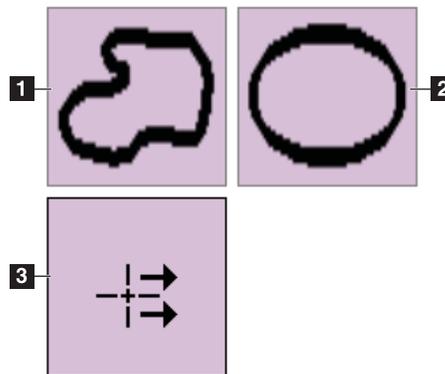


Figure 4-6: Icons Available on the Notices Tab

- **Comments:** Add comments.
- **Service:** Mark an image for service use.
- **ROI:** Draw a Region of Interest on the image display.

2.2.2 The Exposure Index



Figure 4-7: The 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 make a decision about a retake.

2.2.3 Display Modes (Tomosynthesis option)

Use the **CONV**, **PRJ**, and **REC** buttons to select the type of view to display in the Preview Screen. You can change between **CONV** (conventional), **PRJ** (projections), and **REC** (reconstruction) to display the combination images.

- Use **CONV** (conventional) to display conventional images.
- Use **PRJ** (projections) to display the 15 projections.
- Use the **REC** (reconstruction) to display the reconstructed slices.

2.3 How to Correct and Reprocess Implant Images

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

2.3.1 If You Did Not Accept the Image:

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



2.3.2 If You Accepted the Image:

1. Re-preview the image.
2. Select the **Implant Present** button on the Procedure screen to correct the image. A checkmark appears on the button and the image reprocesses.
3. Select **Accept** to accept the changes.



Note...

The corrected image is automatically sent to the selected output devices.

3.0 Send the Images to the Output Devices

You can send the images to output devices or use the Export function to copy images to a temporary storage device. See Chapter 3, Section 6.0, page 35 and Section 7.0, page 36 for instructions.

User Manual

Chapter 4—The Images

Send the Images to the Output Devices



Chapter 5—How to Use the Accessories

1.0 Introduction

The Selenia Dimensions can perform screening or diagnostic applications with specified accessories. This chapter describes how to use all possible system accessories. Your accessories depend on your system configuration.

2.0 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.

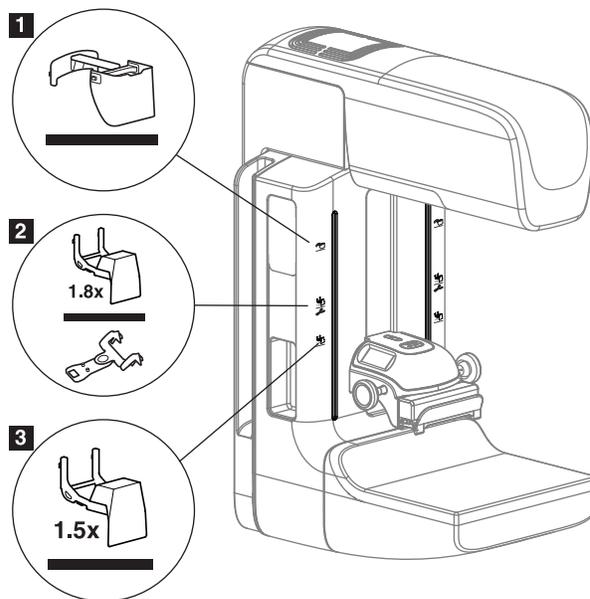


Figure 5-1: C-arm Accessories

Legend for Figure 5-1

1. Slot for Retractable Face Shield (Tomosynthesis option)
2. Slot for 1.8x Mag Stand
3. Slot for 1.5x Mag Stand

3.0 The 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 from radiation.

3.1 How to Install or Remove the Conventional Face Shield

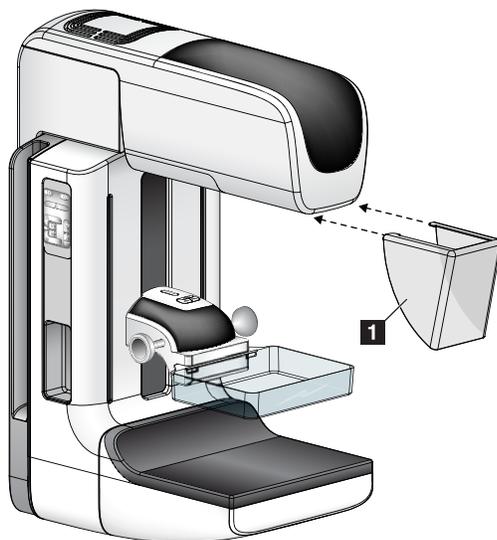


Figure 5-2: How to Install the Conventional Face Shield

See Figure 5-2 to install the Conventional Face Shield:

1. Carefully put the tab ends of the Face Shield (Number 1 in the Figure) into the slots at the front of the tubehead mount.
2. Slide the Face Shield on the tubehead mount until the Face Shield locks.

To remove the Conventional Face Shield:

1. Pull the sides of the Face Shield in a horizontal direction (away from the tubehead).
2. Remove the Face Shield.

3.2 How to Install or Remove the Retractable Face Shield

To install the Retractable Face Shield, see Figure 5-4, page 50:

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 (number 1, Figure 5-4) will be 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.

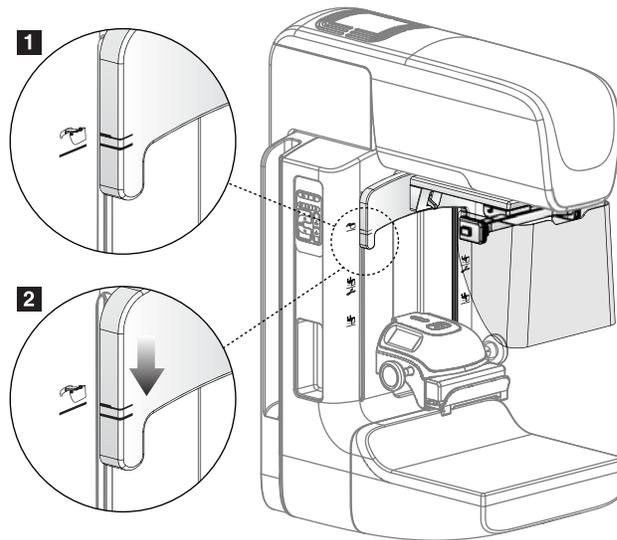


Figure 5-3: How to Align the Retractable Face Shield on the C-arm

To remove the Retractable Face Shield:

1. Press and hold the Unlock Lever (number 1, Figure 5-4) in the Up position.
2. Lift the Face Shield from the slots and remove from the C-arm.

3.3 How to Use the Retractable Face Shield

1. Always completely extend the Face Shield before an exposure.
2. To extend the Face Shield, pull the shield away from the C-arm until the device latches in the outer position.

To retract the Face Shield

1. Press one of the Latch Release buttons (number 2, Figure 5-5—one on each side).
2. Push the Face Shield toward the C-arm until the device stops.

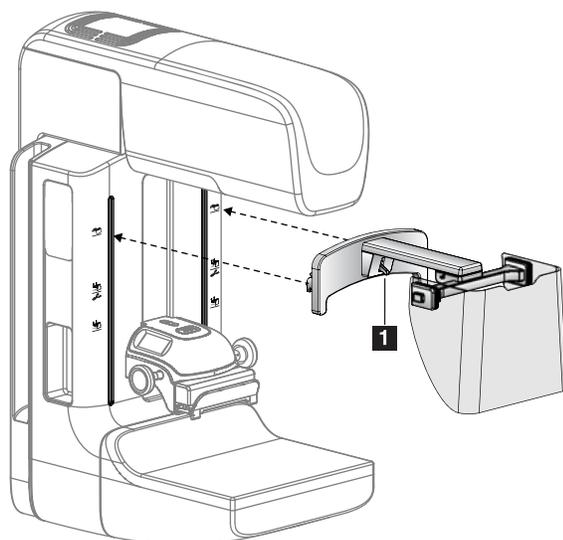


Figure 5-4: Installation

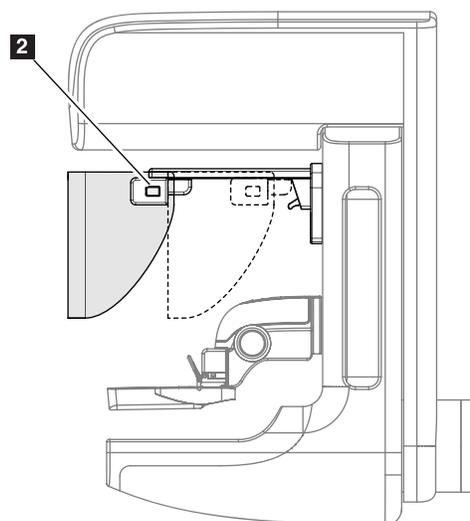
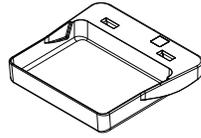


Figure 5-5: Operation

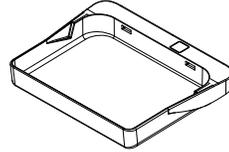
4.0 Compression Paddles

The system can identify each paddle and automatically adjust the collimator.

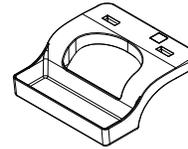
4.1 Routine Screening Paddles



**18 x 24 cm Frameless
Screening Paddle**

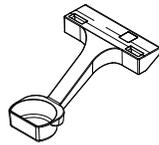


**24 x 29 cm Frameless
Screening Paddle**

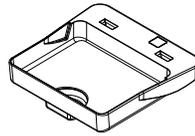


**Small Breast Frameless
Paddle**

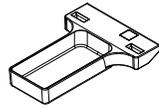
4.2 Contact and Spot Compression Paddles



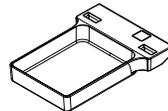
**7.5 cm Spot Contact
Frameless Paddle**



**Spot Contact
Frameless Paddle**

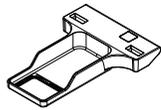


**10 cm Contact
Frameless Paddle**

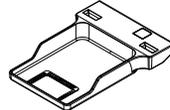


**15 cm Contact
Frameless Paddle**

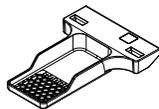
4.3 Localization Paddles



**10 cm Rectangular Opening
Localization Paddle**



**15 cm Rectangular Opening
Localization Paddle**

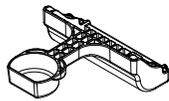


**10 cm Perforated
Localization Paddle**

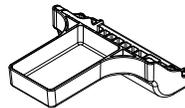


**15 cm Perforated
Localization Paddle**

4.4 Magnification Paddles



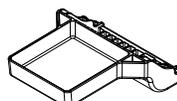
**7.5 cm Spot Magnification
Paddle**



**10 cm Magnification
Paddle**



**10 cm Magnification
Localization Perforated
Paddle**



**15 cm Magnification
Paddle**

4.5 How to Install or Remove a Compression Paddle

See Figure 5-6 to install a Compression Paddle:

1. Hold the front of the paddle with one hand in front of the Compression Device.
2. Tilt the paddle (between 30 and 45 degrees), then put the rear of the paddle on the groove in the rear of the Compression Device (Number 1).
3. Slide the paddle along the groove until the slots on the top of the paddle are under the locks on the Paddle Clamp (Number 2).
4. Compress the Paddle Clamp (Number 3) with your free hand.
5. Rotate the paddle up (Number 4), then release the Paddle Clamp to lock the paddle.

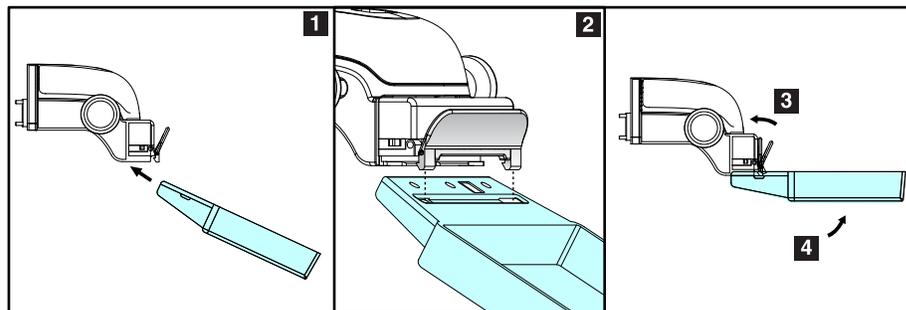


Figure 5-6: How to Install a Compression Paddle

See Figure 5-7 to remove the Compression Paddle:

1. Hold the paddle with one hand while you use the free hand to compress the Paddle Clamp to release the lock (Number 1).
2. Lower the paddle (Number 2) and remove the paddle from the Compression Device (Number 3), then release the Paddle Clamp.

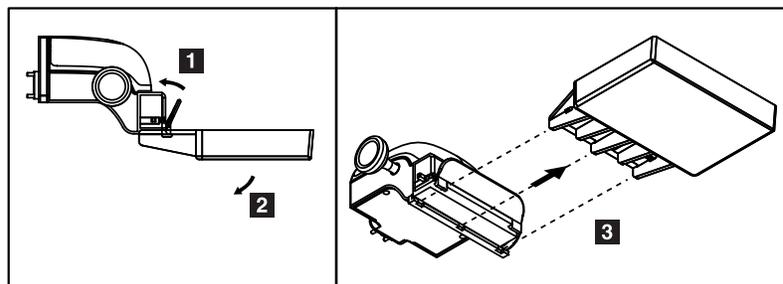


Figure 5-7: How to Remove the Compression Paddle

4.6 Maintenance and Cleaning

Clean the paddles after each use. See Chapter 7, page 63 for cleaning instructions.

4.7 Paddle Shift

The system allows most paddles to move to the left or right of the center position. The feature helps small-breast examinations with lateral views. When a lateral view is selected, the system automatically moves the collimator for the selected paddle position.

4.8 FAST Compression Mode

4.8.1 How the FAST Compression Mode Works

The Fully Automatic Self-adjusting Tilt (FAST) Compression Mode is for use when the composition of the breast tissue does not allow uniform compression across the complete breast with a flat compression paddle. For these patients, not enough compression can cause an image to appear to be out of focus at the anterior region from both involuntary motion and not enough compression.

The FAST Compression mode used with this type of breast provides these features:

- Reduced motion artifacts, because the compression is more effective.
- The compression is more uniform from the chest wall to the nipple.
- Maximum patient comfort, because over compression at the chest wall is prevented.

When the FAST Compression mode is selected, the paddle automatically tilts when the compression is applied. The paddle starts at the flat position until some compression force is applied. The paddle then tilts until its maximum angle is reached.

The FAST Compression mode does not require excessive compression, but you must use enough compression to prevent the movement of the breast. You should use a consistent amount of compression, especially for related left and right views.

The FAST Compression mode may not be best for breasts that are equal or symmetrical in thickness from the chest wall to the anterior area of the breast.

4.8.2 How to Use the FAST Compression Mode Slide

To engage the FAST Compression Mode, push the slide (from either side) until the “F” is visible and the slide clicks into position.

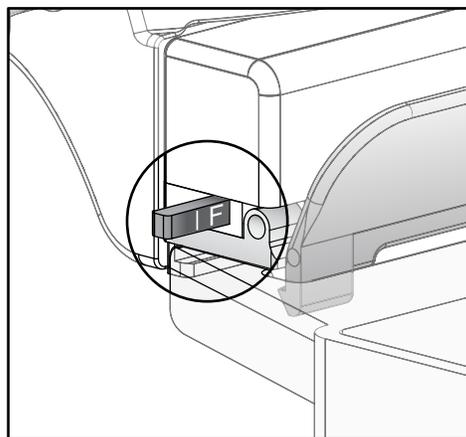


Figure 5-8: The FAST Compression Mode Slide

5.0 Magnification Stand

The Selenia Dimensions Magnification Stand has a breast platform and an abdominal shield. When the Magnification Stand is installed, the HTC grid automatically retracts and the x-ray exposure techniques are set to the Magnification default values. When the platform is installed, only use the Magnification paddles (see Section 4.4, page 52).

5.1 How to Install and Remove the Magnification Stand

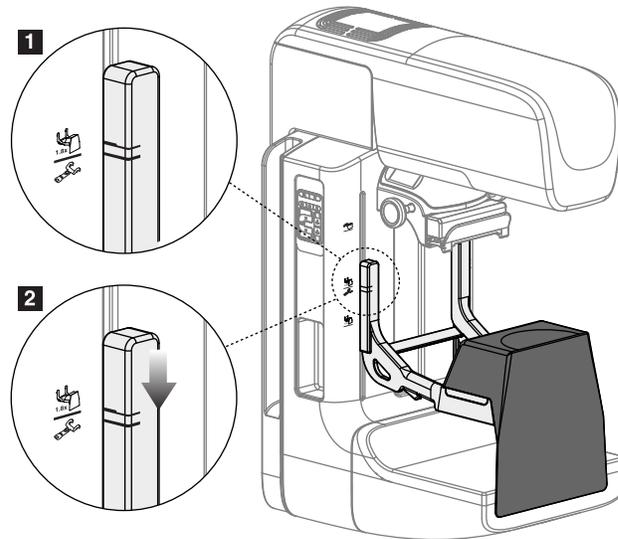


Figure 5-9: Installation of the Magnification Stand

To install the Magnification Stand:

1. Remove the Face Shield (see Section 3.0, page 48) and the compression paddle.
2. Move the Compression Device completely to the top.
3. Hold the Magnification Stand with the handles. Compress the release levers on the bottom of each handle, and hold the levers open.
4. Align the thick black lines on the Magnification Stand with the thick black lines on the C-arm. When these lines meet, the hooks of the Magnification Stand align to the mounting slots on the C-arm. See Figure 5-9, number 1.



Note...

There are two sets of hooks for the Magnification Stand—One set is for 1.8x, and the other set is for 1.5x. See Figure 5-1, page 47, numbers 2 and 3.

5. Put the hooks of the Magnification Stand into the C-arm slots. Slide the Magnification Stand down, until the thin black lines on the Magnification Stand and the black line of the C-arm meet. See Figure 5-9, number 2.
6. Release the levers. The locking pins slide into holes and lock the device.

To remove the Magnification Stand:

1. Remove the Magnification paddle.
2. Hold the handles of the Magnification Stand and compress the release levers.
3. Lift and remove the device from the C-arm.

6.0 Crosshair Devices

6.1 How to Install and Remove the Localization Crosshair Device

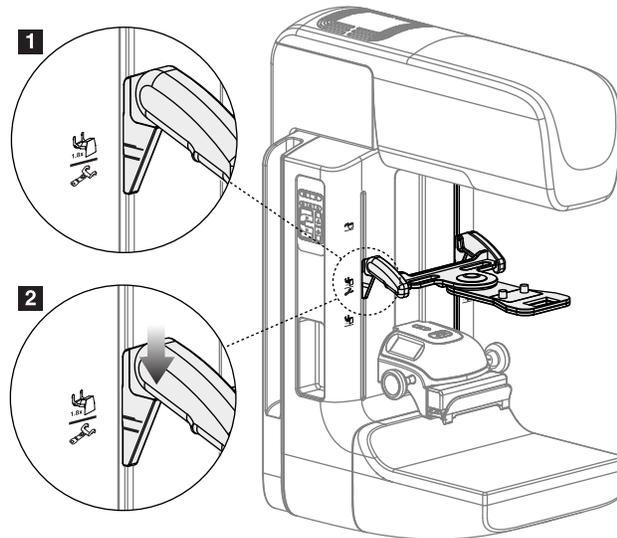


Figure 5-10: How to Attach the Localization Crosshair Device

6.1.1 To install the Localization Crosshair Device

1. Remove the face shield (see Section 3.0, page 48).
2. Move the Compression Device below the mounting slots, indicated by a crosshair icon. See Figure 5-1, page 47, number 2.
3. Hold the crosshair device by the handles and align the thick lines on the device with the line on the C-arm. Compress the release levers.
4. Put the hooks into the C-arm slots.
5. Slide the hooks toward the bottom until the thin black lines on the crosshair meet the black line on the C-arm.
6. Release the levers. The locking pins slide into holes and lock the device in position.

6.1.2 To remove the Localization Crosshair Device

1. Compress the release levers.
2. Lift the frame toward the top and remove the hooks from the C-arm slots.

6.2 How to Use the Localization Crosshair Device

1. The crosshair device rotates to the left or right of the tubehead. Rotate the device away from the x-ray beam during the exposure acquired with the localization paddle.
2. When you rotate the device back to the front for use, make sure the rotation continues until the device clicks into position.
3. Turn on the light field lamp.
4. Rotate the two crosshair knobs until the shadow on the breast matches the crosshairs on the image that identifies the suspect lesion.

6.3 How to Install and Remove the Magnification Crosshair Device

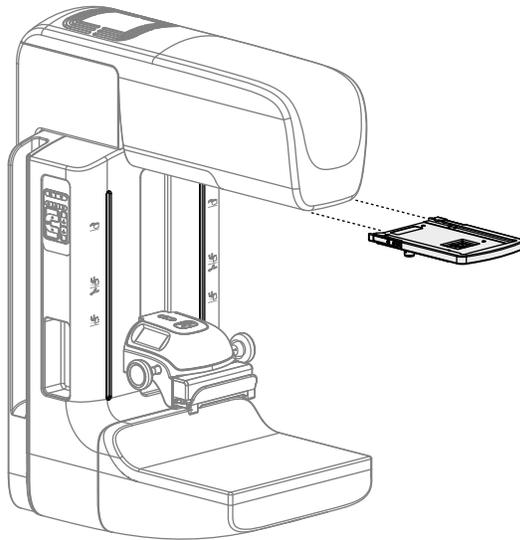


Figure 5-11: How to Install and Remove the Magnification Crosshair Device

6.3.1 To install the Magnification Crosshair Device

1. Remove the face shield (see Section 3.1, page 48).
2. Align the Magnification Crosshair Device with the tubehead.
3. Slide the crosshair device on the rails on each side of the tubehead that are used by the Conventional Face Shield. Make sure the device locks into position.
4. Install the remaining magnification devices.

6.3.2 To remove the Magnification Crosshair Device

1. Hold the sides of the device.
2. Pull the device toward you and remove from the tubehead.

6.4 How to Align the Crosshair Device



Note...

If the crosshair light rectangle appears skewed to the opening in the paddle, perform this alignment procedure.

1. Install the rectangular localization paddle.
2. Loosen the adjustment lock screw on the bottom of the Crosshair Device.
3. Put a piece of white paper on the image receptor to make the shadows of the crosshairs easier to see.
4. Move the localization paddle approximately 6 cm above the image receptor.
5. Turn on the light field.
6. Rotate the Crosshair Device until the rectangle of light aligns with the opening in the localization paddle.
7. Tighten the adjustment screw.

User Manual

Chapter 5—How to Use the Accessories
Crosshair Devices



Chapter 6—Clinical Procedures



Warning:

The C-arm movement has drive motors.



Warning:

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



Warning:

Put both footswitches away from the patient and C-arm area to prevent any accidental footswitch use. When the patient has a wheelchair, put the footswitches away from the area.

1.0 Standard Workflow

Preparation:

1. Select a patient from the worklist, or manually add a new patient.
2. Identify the required procedures.
3. Select the output device set if a different or additional device is needed.
4. Install the paddle.
5. Select the first view.

At the Gantry:

1. Set C-arm height and rotation angle.
2. Make sure the light field illuminates the correct area.
3. Position the patient and compress the breast.

At the Acquisition Workstation:

1. Set the exposure technique.
2. Acquire the image.
3. Release the patient.
4. Preview the image. Look at the Exposure Index to make sure that the exposure is within acceptable range.
5. You can use the Window/Level tool or other Preview options during image preview.
6. Accept, Reject, or Pend the image.
7. Perform the Acquisition cycle as required for the requested procedures.
8. If necessary, add an additional view or procedure.
9. Make sure that the patient is safely away from the system after you complete the examination.
10. Close the procedure.

2.0 Example Screening Procedure

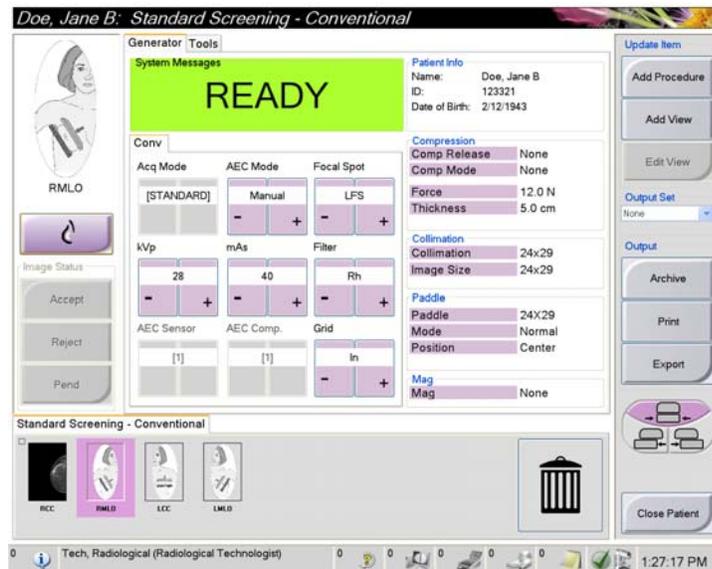


Figure 6-1: Screening Example, Conventional Procedure

2.1 How to Position the Patient

1. Lift or lower the breast platform for the patient.
2. Move the tubehead to the projection angle.
3. Move the patient to the C-arm.
4. Position the patient as required.
5. Put the arm or hand of the patient on the Patient Handle or against the side of the body.
6. Tell the patient to keep away from system controls.
7. Compress the breast.
 - When possible, use the footswitch controls to provide hands-free compression control and C-arm height adjustment.
 - Use the light field lamp as necessary to see the x-ray field.
 - Apply the compression slowly. As necessary, stop and make the adjustments to patient position.
 - Use the handwheels for final compression.

2.2 Set the Exposure Techniques

Select the exposure techniques for the procedure. See Chapter 3, Section 4.1, page 31 for information.

2.3 How to Acquire the Exposure

1. Confirm that all exposure factors are set correctly.
2. If the system does not display Ready in 30 seconds, verify that the accessories are correctly installed and the paddle is locked into position. When the generator status displays **Ready**, the system is ready for exposure.



WARNING!

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

3. Press and hold the x-ray buttons for the complete exposure. During the exposure, a System Message, a tone, and the x-ray indicator on the control panel indicate an exposure is in progress.
4. Release the compression device. If the automatic release feature is set, the compression device automatically lifts after the exposure.

2.4 How to Automatically Store the Image

1. Confirm the patient position and the exposure level.
2. **Accept, Reject, or Pend** the image.
 - You can **Accept** the image. Wait for the image to appear as a thumbnail image on the Procedure screen. The image transmits to the output device.
 - If there are image problems, you can **Reject** the image and you must enter the reason. The system automatically adds another icon for the same view. Repeat the exposure.
 - You can **Pend** the image. The image saves for future review.

The selection to send the image to the Output Devices at the close of the patient or when accepted is service-configurable.

2.5 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 repreview the image, then **Accept** the image.

2.6 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.

User Manual

Chapter 6—Clinical Procedures
Example Screening Procedure



Chapter 7—Maintenance and Cleaning

1.0 General Information

Call the Hologic Technical Support telephone number for the current list of recommended cleaning solutions.

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



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

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

1.1 For General Cleaning

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



Caution: *The fluid must not flow or run.*

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

- 10% chlorine bleach and water with one part commercially available chlorine bleach (normally 5.25% chlorine and 94.75% water) and nine parts water
- Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
- 3% maximum concentration of hydrogen peroxide solution

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



Caution: *Do not spray disinfectant on the system, because the moisture can enter into the system and damage the electronic components.*



Warning: *If a paddle touches any possible infectious materials, call your Infection Control Representative for decontamination instructions.*

1.2 To prevent Possible Injury or Equipment Damage

Never use a corrosive solvent or abrasive detergents or polishes. Select a cleaning agent which will not damage plastics, aluminum, or carbon fiber.

- Do not use a strong detergent, abrasive cleaner, high alcohol concentration, or methanol at any concentration. If skin preparation contains a high alcohol concentration, allow time to dry before compression.
- Do not expose equipment parts to any steam or temperature sterilization.
- Never allow any liquids to enter the internal parts of the equipment. Do not apply cleaning sprays or liquids to the equipment. Always use a clean cloth and apply the spray or liquid. If liquid enters the system, disconnect the electrical supply and schedule inspection by service personnel before the system is returned to use.



Caution:

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

- Always follow the instructions from the germicide manufacturer. The instructions include the methods of concentration, storage, application, contact time, wash requirements, protective clothing, shelf life, and for removal. The instructions make sure best and safe product use.

2.0 Acquisition Workstation

2.1 How to Clean the Preview Display

- If you touch the display area, you will leave prints.
- Be careful when you clean the outer surface of the screen.
- Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths, available at most camera stores, are recommended.
- Strong chemicals and abrasives can damage the display.
- Never use a spray or flow a liquid on the display.
- Never apply any pressure to the display area.
- Never use a detergent with fluorides, ammonia, alcohol, or abrasives.
- Never use any bleach.
- Never use any steel wool.
- Never use a sponge with abrasives.

There are many commercially available products to clean LCD displays. Any of the products free of the ingredients described above and used according to the directions of the manufacturer can be used.

2.2 How to Clean the Touchscreen Display

Use a window or glass cleaning product to clean the Touchscreen display. Apply the product to a cloth, then clean the Touchscreen display. Do not apply the product to the display without the cloth.

2.3 How to Clean the Keyboard

Clean the key surfaces with a CRT wipe. If necessary, clean the keyboard with a vacuum. If liquids enter the keyboard, call the Hologic Technical Support for a replacement.

2.4 How to Clean the Fingerprint Reader



Caution:

To protect the Fingerprint Reader:

- **Do not apply any liquid product directly on the Fingerprint Reader window.**
 - **Do not use products that contain alcohol.**
 - **Never put the Fingerprint Reader under liquid.**
 - **Never apply any pressure to the Fingerprint Reader window with abrasive material.**
 - **Do not push the Fingerprint Reader window.**
-

To clean the Fingerprint Reader window, do one of the following:

- Apply the adhesive side of cellophane tape, then remove the tape.
- Apply a product with ammonia base to a cloth, and clean the Fingerprint Reader window.

User Manual

Chapter 7—Maintenance and Cleaning
Acquisition Workstation



Chapter 8—System Administration Interface

1.0 How to Use the Admin Screen

This section describes the functions available in the Admin screen. To access all functions in this screen, log In to the system as a user with the administrator, manager, or service permissions.

(Continued on next page.)

Refer to Table 8-1, page 69 for descriptions of the Admin screen functions.

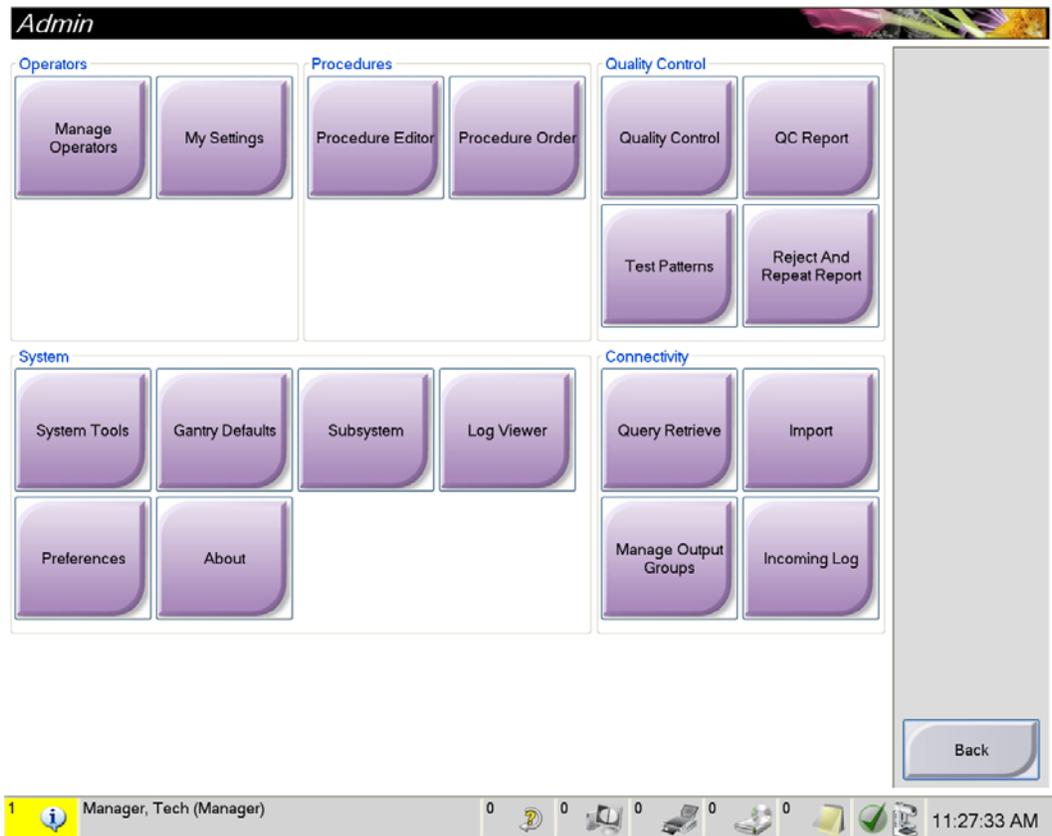


Figure 8-1: The Admin Screen

Table 8-1: Admin Screen Functions

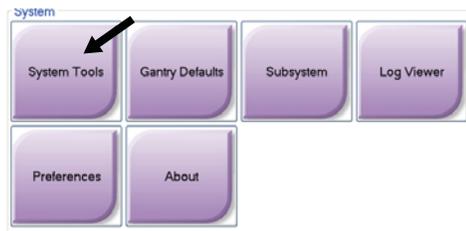
Section	Screen Function	Description
Operators	Manage Operators	Add, delete or change Operator information.
	My Settings	Change the information for the current Operator.
Procedures	Procedure Editor	Add or Edit the procedures, or change the view order for each user.
	Procedure Order	Change the procedure list order.
Quality Control	Quality Control	Select a Quality Control task to perform or mark completed.
	QC Report	Create a QC Report.
	Test Patterns	Select and send the test patterns to output devices.
	Reject and Repeat Report	Create a Reject and Repeat Report.
System	System Tools	The Interface for Service for the configuration of and identification of problems in the Acquisition Workstation.
	Gantry Defaults	Set the Gantry default values.
	Subsystem	Displays the status of all subsystems.
	Log Viewer	Review the system log files.
	Preferences	Set the system preferences.
	About	Describes the system.
Connectivity	Query Retrieve	Query the configured devices.
	Import	Import the data from a DICOM source.
	Manage Output Groups	Add, delete, or edit output groups.
	Incoming Log	Shows log entries for images that do not import during manual import or DICOM store.
You must have permissions to access all features. The permission level controls the functions you can change.		

2.0 How to Use the System Tools

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

To access the Service Tools function:

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



2.1 The Radiologic Technologist Manager

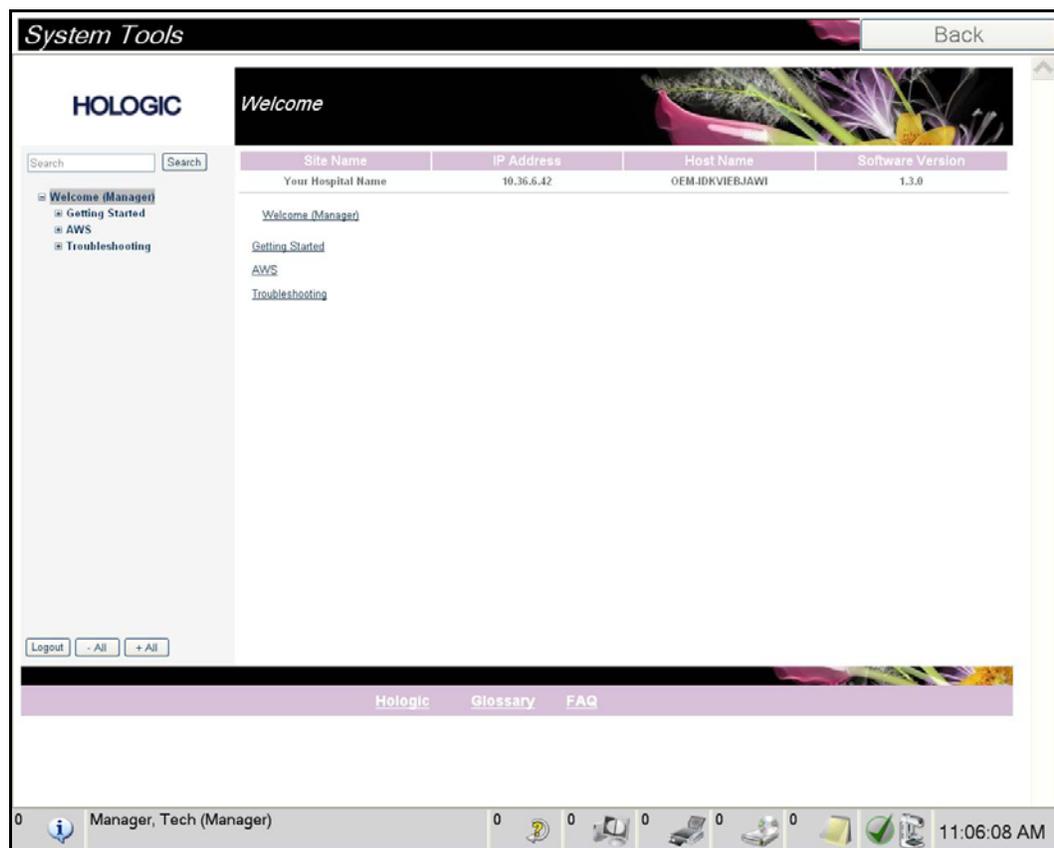


Table 8-2: Radiologic Technologist Manager—Service Tools Functions

Section	Screen Functions	Description
Getting Started	About	The introduction to the service tool.
	FAQ	List of common questions.
	Glossary	List of terms and descriptions.
	Platform	List of directories, software version numbers, and system software statistics.
	Shortcuts	List of Windows shortcuts.
AWS	Connectivity	List of Installed Devices.
	Film & Image Information	Create an Image Report. Create a QC Report.
	Licensing	List of Installed Licenses.
	User Interface	Change the options in the Software application.
	Internationalization	Select the local language and culture.
	QC	Set Quality Control Settings.
Troubleshooting	AWS	Allows for download of images.
	Computer	System Management and Network Information.
	Log	Change the event record options.
	Backups	Control the backups for the system.

User Manual

Chapter 8—System Administration Interface
How to Use the System Tools



Appendix A—Specifications

1.0 Product Measurements

1.1 Tubestand (Gantry with C-arm)

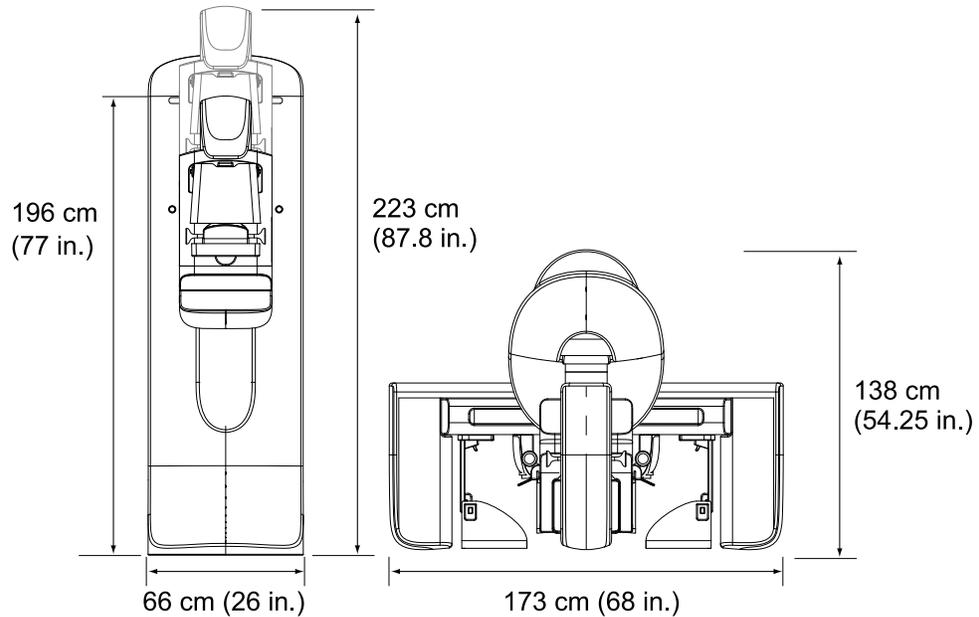


Figure A-1: Tubestand Dimensions

Height	223 cm (87.8 inches)
Width	66 cm (26 inches)
Depth	138 cm (54.25 inches)
Weight	Maximum of 400 kg (882 pounds)

1.2 Acquisition Workstation

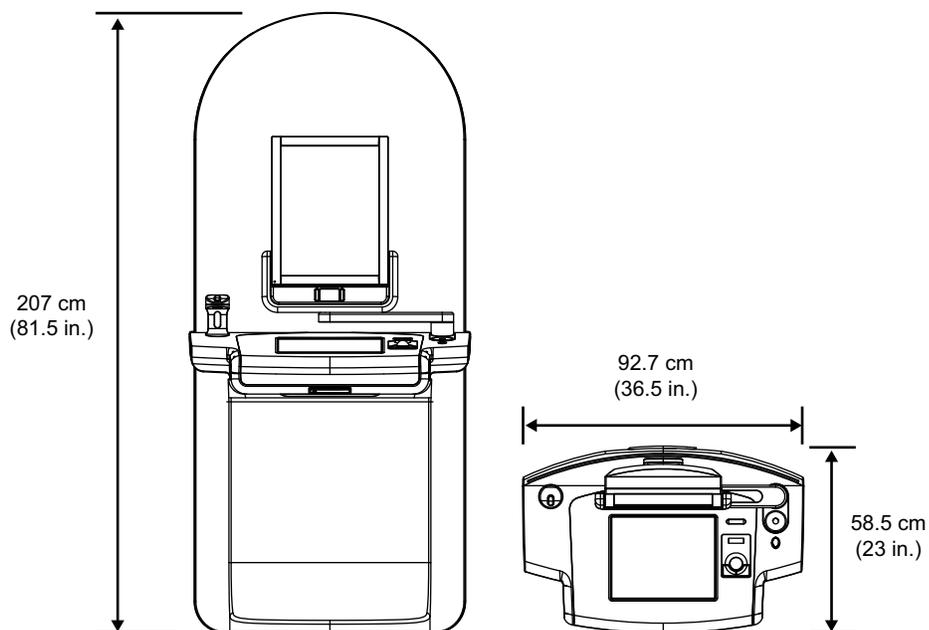


Figure A-2: Acquisition Workstation Dimensions

Height	207 cm (81.5 inches)
Width	92.7 cm (36.5 inches)
Depth	58.5 cm (23 inches)
Weight	154 kg (340 pounds)

2.0 Operation and Storage Environment

2.1 General Conditions for Operation

<i>Temperature Range</i>	<i>20 °C to 30 °C</i>
<i>Relative Humidity Range</i>	<i>20% to 80% Without condensing moisture</i>

2.2 Storage Environment

2.2.1 Gantry

<i>Temperature Range</i>	<i>-10 °C to 40 °C</i>
<i>Relative Humidity Range</i> <i>(Put in a package for storage in a building)</i>	<i>0% to 95% Without condensing moisture</i>

2.2.2 X-ray Detector

<i>Temperature Range</i>	<i>10 °C to 30 °C indefinitely</i> <i>10 °C to 35°C for a maximum of 12 hours</i>
<i>Maximum rate of temperature change</i>	<i>Less than 10 °C per hour</i>
<i>Relative Humidity Range</i> <i>(Put in a package for storage in a building)</i>	<i>10% to 80% Without condensing moisture</i>

2.2.3 Acquisition Workstation

<i>Temperature Range</i>	<i>-10 °C to 40 °C</i>
<i>Relative Humidity Range</i> <i>(Put in a package for storage in a building)</i>	<i>0% to 95% Without condensing moisture</i>

3.0 Acquisition Workstation Technical Information

<i>Operating System</i>	<i>Windows XPE</i>
<i>Computer Memory</i>	<i>4 GB RAM minimum</i>
<i>Hard Disk Drive Capacity</i>	<i>700 GB minimum</i>
<i>Storage Device Disks</i>	<i>CDRW/CDR/DVD+/-RW/DAT</i>
<i>Display</i>	<i>2 or 3 Megapixels as required</i>
<i>Touchscreen Display</i>	<i>17-inch diagonal, minimum</i>
<i>Network Interface</i>	<i>100/1000Base-T Ethernet</i>
<i>Remote Diagnostics</i>	<i>Internet</i>
<i>Graphic User Interface</i>	<i>Application specific</i>
<i>Radiation Shield Lead (Pb) equivalent</i>	<i>0.5 mm lead for x-ray energy to 35 kV</i>

4.0 Electrical Input

4.1 Tubestand

<i>Mains Voltage</i>	200 to 240 VAC $\pm 10\%$
<i>Mains Impedance</i>	Maximum line impedance not to exceed 0.20 ohms for 208/220/230/240 VAC, 0.16 ohms for 200 VAC
<i>Mains Frequency</i>	50/60 Hz $\pm 5\%$
<i>Average Current over 24 Hours</i>	< 5 A
<i>Peak Line Current</i>	65 A for 3 seconds

4.2 Acquisition Workstation

<i>Mains Voltage</i>	100 to 240 VAC $\pm 10\%$
<i>Mains Frequency</i>	50/60 Hz $\pm 5\%$
<i>Power Consumption</i>	< 1000 watts

5.0 Tubestand Technical Information

5.1 C-arm

<i>Rotation Range</i>	Conventional Mammography: $+195^\circ +3^\circ/-0.5^\circ$ to $0^\circ \pm 0.5^\circ$ to $-155^\circ +0.5^\circ/-3^\circ$ Tomosynthesis option: $+180^\circ \pm 0.5^\circ$ to $0^\circ \pm 0.5^\circ$ to $-140^\circ \pm 0.5^\circ$
<i>Absolute Angular Position</i>	accurate to $\pm 0.5^\circ$
<i>Rotation Acceleration</i>	$18^\circ/s^2 +18/-9\%$
<i>Rotation Deceleration</i>	$18^\circ/s^2 +18/-9\%$
<i>Rotational Positioning Angular Velocity</i>	$18^\circ/s \pm 25\%$



Note...

The angular velocity is the average of the velocity of the tube arm rotating clockwise between 0° and 90° or rotating counterclockwise between 90° and 0° . The angular velocity does not include the time to accelerate from zero velocity and decelerate to zero velocity.

<i>Source-to-Image Distance (SID)</i>	70.0 cm ± 1.0 cm (27.6 inches ± 0.4 inches)
<i>Patient Support (non-magnification)</i>	
<i>Vertical Position Lower Limit</i>	70.5 cm $+5.1/-0$ cm (27.75 inches $+2.0/-0$ inches)
<i>Vertical Position Upper Limit</i>	141 cm $+0/-17.8$ cm (55.5 inches $+0/-7.0$ inches)

5.2 Compression

<i>Manual Compression Force</i>	<i>Maximum of 300 N (67.4 pounds)</i>
<i>Motorized Compression</i>	<i>Functions in three operating modes, Pre-compression, Full-Range, Dual Compression, user selectable through software</i>
<i>Pre-Compression Force</i>	<i>15 pounds to 30 pounds (67 to 134 N), motorized</i>
<i>Full Range Compression Force</i>	<i>20 pounds to 40 pounds (89 to 178 N), motorized</i>
<i>Dual Mode Compression</i>	<i>Provides Pre-Compression force upon first activation of compression switch; then, if switch is activated within 2 seconds, the force is increased incrementally for each additional switch activation, up to the user selected full compression force.</i>
<i>Compression Controls</i>	<i>Up/Down controls on both sides of C-arm and on 2-position footswitch (Motorized). Handwheel on both sides of Compression Device (Manual).</i>
<i>Compression Release</i>	<i>Manual or Automatic. Motorized Release mode controlled by push-buttons on both sides of the C-arm.</i>
<i>Automatic Compression Release</i>	<i>User selectable automatic release mode raises Compression Device upon exposure termination.</i>
<i>Down Motion Variable Speed</i>	<i>4.2 cm/s \pm15% (1.66 inches/s \pm15%)</i>
<i>Compression Force Display</i>	<i>Two LEDs on the Compression Device show the compression force through the range of 44.5 N to 300 N (10 pounds to 67.4 pounds) in 4.4 N (1 pounds) increments.</i>
<i>Compression Force Display Accuracy</i>	<i>\pm20 N (\pm4.5 pounds)</i>
<i>Compression Thickness Display</i>	<i>Two LCDs on the Compression Device measure between 0 and 15 cm above image receptor in 0.1 cm increments. The display is visible from both sides of the patient.</i>
<i>Compression Thickness Accuracy</i>	<i>\pm0.5 cm (\pm0.2 inches) for thicknesses between 0.5 cm and 15 cm (5.9 inches)</i>
<i>Compression Paddles</i>	<i>Compression Paddles are transparent. The paddles are composed of polycarbonate resin or the equivalent. With compression applied, paddle deflection from a plane parallel to the patient support surface shall be less than or equal to 1.0 cm.</i>

5.3 X-ray Tube

<i>Focal Spot</i>	<i>Large (0.3 mm) Nominal Small (0.1 mm) Nominal</i>
<i>Tube Voltage</i>	<i>20 kV to 49 kV</i>
<i>Anode Material</i>	<i>Tungsten</i>
<i>X-ray Window</i>	<i>Beryllium 0.63 mm</i>

5.4 X-ray Beam Filtration and Output

Filtration

Five-position filter wheel:

Position 1: Rhodium, 0.050 mm ±10%

Position 2: Aluminum, 0.70 mm ±10% (Tomosynthesis option)

Position 3: Silver, 0.050 mm ±10%

Position 4: Lead (provided for servicing)

Position 5: Lead (provided for servicing)

5.4.1 kV/mA Range

Table A-1: mA Setting as a Function of kV

kV	LG FS mA	SM FS mA
20	100	30
21	110	30
22	110	30
23	120	30
24	130	30
25	130	40
26	140	40
27	150	40
28	160	40
29	160	40
30	170	50
31	180	50
32	190	50
33	200	50
34	200	50
35	200	50
36	190	50
37	180	50
38	180	50
39	180	50
40	170	
41	170	
42	160	
43	160	
44	150	
45	150	
46	150	
47	140	
48	140	
49	140	

5.5 X-ray Collimation

<i>Collimation Fields</i>	7.0 cm x 8.5 cm 10 cm x 10 cm 15 cm x 15 cm 18 cm x 24 cm 18 cm x 29 cm (Tomosynthesis option) 24 cm x 29 cm
---------------------------	---

5.6 Light Field Indication

<i>Light Field to X-Ray Congruency</i>	Within 2% of SID
--	------------------

5.7 X-ray Generator

Type	Constant Potential High Frequency Inverter
Rating	7.0 kW, maximum (isowatt), 200 mA at 35 kV
Electrical Power Capacity	9.0 kW maximum
kV Range	20 kV to 49 kV in 1 kV increments
kV accuracy	±2%, over range 20-49 kVp
mAs Range	3.0 mAs to 500 mAs
mAs Accuracy	±(10% + 0.2 mAs)
mA Range	10 mA to 200 mA, Large Focal Spot 10 mA to 50 mA, Small Focal Spot

6.0 Imaging System Technical Information

6.1 Image Receptor

<i>Fluid Ingress</i>	No fluid from accidental spillage on the Image Receptor may seep inside.
<i>Deflection</i>	Does not exceed 1.0 mm at maximum compression.
<i>Active Imaging Area</i>	Not less than 23.3 cm by 28.5 cm (9.2 inches x 11.2 inches)
<i>DQE (Conventional Mammography)</i>	Not less than 50% at 0.2 lp/mm Not less than 15% at the Nyquist limit
<i>DQE (Tomosynthesis option)</i>	Not less than 30% at 0.2 lp/mm Not less than 15% at the Nyquist limit
<i>Dynamic Range and Linearity</i>	Detector Subsystem response is linear with linearity of 0.999 over a dynamic range of 400:1 in x-ray exposure.
<i>Uniformity</i>	Detector Subsystem can correct pixel-to-pixel gain variations. For conventional mammography procedures, the uniformity of flat field image response of the detector shall be no greater than 2% after gain calibration is applied over an exposure range of 0.5 mR to 200 mR.

User Manual

Appendix A—Specifications
Imaging System Technical Information



Appendix B—The System Messages and Alert Messages

1.0 Error Recovery and Troubleshooting

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

2.0 Types of Messages and Alert messages

2.1 Fault Levels

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

2.1.1 Warning Faults

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

Warning fault designs:

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

2.1.2 Minor Faults

Minor fault designs:

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

2.1.3 Major Faults

Major fault designs:

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

2.1.4 Critical Faults

Critical fault designs:

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

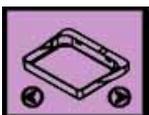
2.1.5 Alert Messages

The alert messages are routine messages that can prevent an exposure. An Alert message remains active until the required action is complete or the condition does not exist.

2.2 System Messages

When the following system messages appear, perform the action indicated to clear the message and allow the next exposure.

Table B-1: System Messages

Icon	Message	User Action
	Invalid use of compression paddle.	Remove the Mag Stand or install the Mag Paddle.
	Paddle position does not match selected view	Shift the Paddle to the correct position for the selected view.
	Paddle is moving	There is no action required.
	Invalid use of magnification platform	You selected a Tomo view with the Mag Stand installed. Select a non-Tomo view. (Tomosynthesis option)
	Face shield is not secured	Completely extend or completely retract the Face Shield (Tomosynthesis option).
	Invalid detector calibration	Install the Mag Stand for Small Focal Spot calibration. Remove the Mag Stand to do Large Focal Spot calibration.
	Invalid geometry calibration	Repeat the geometry calibration before you try to take the next exposure (Tomosynthesis option).
	Configuration file is missing	Applies to Service Personnel.
	Waiting for Detector	There is no action required.
	System in Test Mode	Applies to Service Personnel.

List of Addenda

Write the title of all Addenda which are supplied for this manual, with their part number and revision.

Add all the Addenda to the manual after this record page.

Title	Part Number	Revision

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