



Instructions for Use

SELENIA®
Dimensions®



Instructions for Use

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Preface

Rx Only United States federal law restricts this device to use by, or on the order of, a physician.

1.0 Intended Use

The Hologic® Selenia® Dimensions® System generates digital mammography images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions (2D or 3D) system is intended for use in the same clinical applications as 2D mammography systems for screening mammograms. Specifically, the Selenia Dimensions system can be used to acquire 2D digital mammograms and 3D mammograms. The screening examination will consist of a 2D image set or a 2D and 3D image set. The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.



Note

In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with conventional mammography (2D image set).

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 Product Complaints

Report any complaints or problem in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic. (See the title page for contact information.)

4.0 Installation Instructions

Installation instructions are available in the *Selenia Dimensions Service Manual*.

5.0 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.

6.0 User Profiles

6.1 Mammography Technologist

- Meets all requirements that apply to the location in which the Mammography Technologist operates.
- Completed training on the mammography system.
- Has training in mammography positions.
- Knows how to operate a computer and its peripherals.

6.2 Radiologist

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

6.3 Medical Physicist

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

7.0 Training Requirements

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

The user has options available for training, which include but are not limited to onsite applications, training by a Hologic Clinical Services Specialist, and facility on the job training also known as peer training. Additionally, the user's instruction manual is a reference for directions on how to use the system.

Your Hologic representative can arrange for training by a clinical services specialist.

All users must ensure that they receive training on proper use of the system prior to use on patients.

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

8.0 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.

9.0 Technical Support

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

10.0 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
EMC	Electromagnetic Compatibility
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).
Reclamation	The automatic removal of patient images and related information to allow new patient image acquisitions.
RF	Radio Frequency
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 focal planes (slices) within the object (Tomosynthesis option).
UPS	Uninterruptible Power Supply

11.0 Warnings, Cautions, and Notes

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



WARNING!

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



Warning:

The procedures that you must follow accurately to prevent injury.



Caution:

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



















Note

Notes indicate additional information.

12.0 International Symbols

This section describes the International Symbols on this system.

	Type B Applied Part
	Potential Equalization terminal
	Protective Earth terminal
	"OFF" (power)
	"ON" (power)
	"OFF" for part of the equipment
	"ON" for part of the equipment
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Dangerous Voltage
	Manufacturer
	Date of Manufacture
	This system transmits non-ionizing radiation
	Caution—Radiation
	Follow operating instructions
	Follow instructions for use
	Caution

13.0 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

1.1 Tubestand

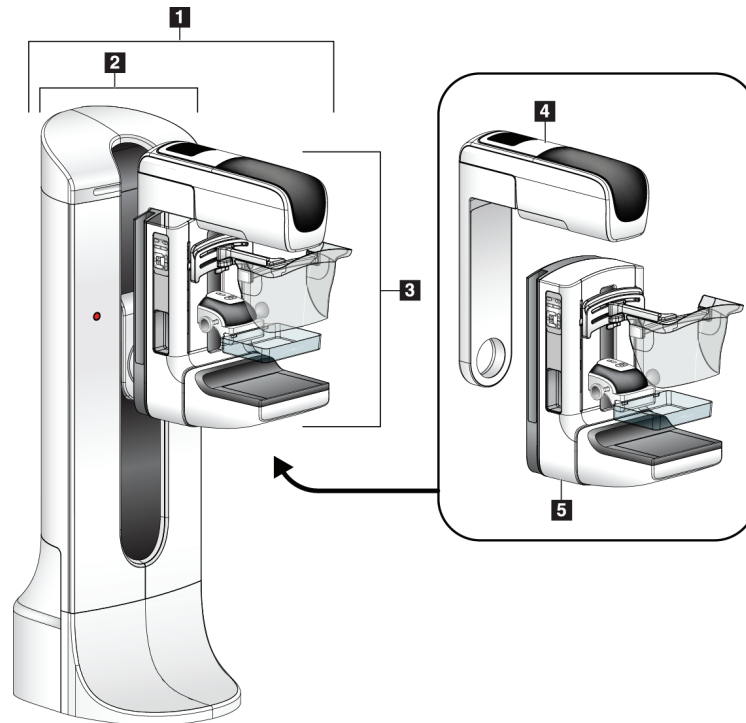


Figure 1: Selenia Dimensions

Figure Legend

1. Tubestand (Gantry and C-Arm)
2. Gantry
3. C-Arm (Tube Arm and Compression Arm)
4. Tube Arm
5. Compression Arm

1.2 Acquisition Workstation

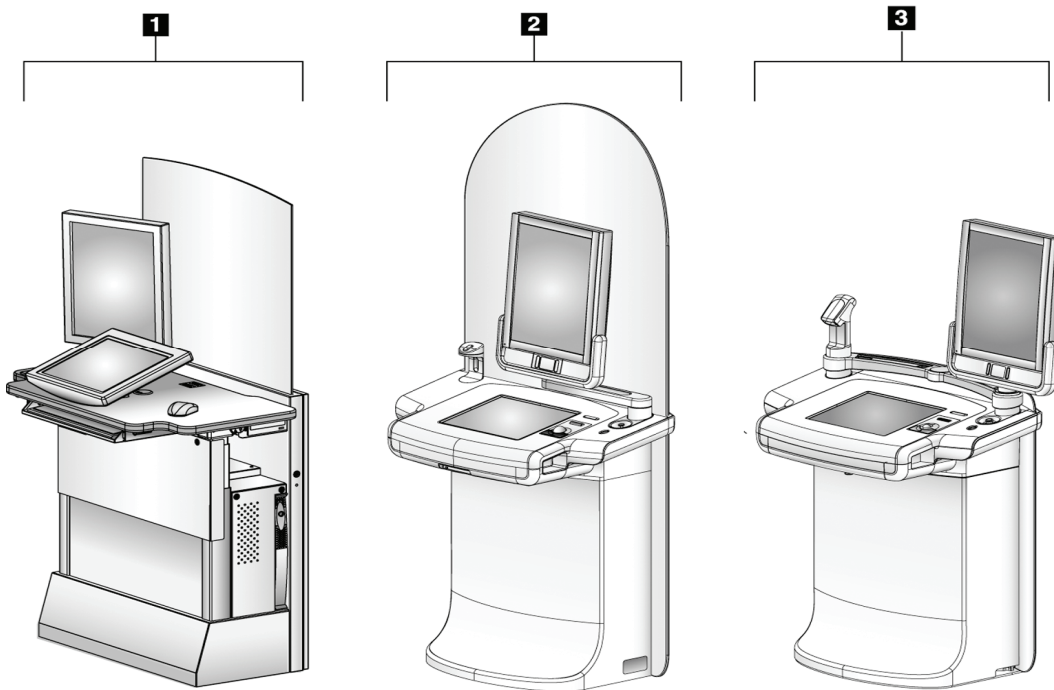


Figure 2: Acquisition Workstations

Figure Legend

1. Standard Acquisition Workstation
2. Premium Acquisition Workstation
3. Mobile Acquisition Workstation

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



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



WARNING!

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



WARNING!

Only trained service engineers authorized by Hologic can open any of the panels. This system contains lethal voltages.



WARNING!

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



WARNING!

Electrical equipment used near flammable anesthetics can cause an explosion.



WARNING!

The user must correct problems before the system is used. The user must arrange for preventive maintenance by an authorized Service Engineer.

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Chapter 1—General Information
Safety Information



Warning:

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



Warning:

If a paddle touches possible infectious materials, contact 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.



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 system.



Warning:

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



Warning:

The C-Arm movement is motorized.



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.



Warning:

To prevent a higher radiation dose to the patient, do not put unauthorized materials in the x-ray beam path.

2.3 Radiation Safety



Warning:

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



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:

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



Warning:

The Face Shield does not protect from radiation.



Warning:

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



Warning:

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

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 use any heat source (like a heating pad) 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:

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



Caution:

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



Caution:

To prevent damage to the electronic components, do not spray disinfectant on the system.

2.6 Emergency Off Switches

The Emergency Off switches remove the power from the Gantry and the Standard Acquisition Workstation Lift Mechanism. Do not normally use the Emergency Off switches to turn off the system. See *Emergency Off Switches Functionality* on page 27 for complete information on the Emergency Off switches.

2.7 Interlocks

The Selenia Dimensions has safety interlocks:

- C-arm vertical movement and rotation are disabled when compression force is applied. A servicing engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).
- If the x-ray button is released before the end of the exposure, the exposure stops and an alarm message shows.
- When in Tomo mode, the system does not let the Grid in the x-ray field (Tomosynthesis option).
- Mirror and Filter interlocks prevent x rays 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.



Caution:

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



Caution:

Portable and mobile RF communications can affect medical electrical equipment.



Caution:

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



Caution:

 The Medical Electrical (ME) Equipment or ME System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ME Equipment or ME System should be observed to verify normal operation in the configuration in which it is used.



Caution:

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



Caution:

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



Caution:

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

3.2 Compliance Statements

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

- CAN/CSA - ISO 13485-03 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes (Adopted ISO 13485:2003 second edition, 2003-07-15)
- CAN/CSA C22.2 NO. 60601-1-08 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12), includes Corrigendum 1:2011; also CAN/CSA C22.2 NO. 601.1-M90 (R2005) Medical Electrical Equipment Part 1: General Requirements for Safety
- EN 60601-1:2006 Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance; also EN 60601-1:1990 +A1+A11+A12+A2+A13 Medical Electrical Equipment—General Requirements for Safety
- ETSI EN 300 330-1: V1.3.1, and ETSI EN 300 330-2: V1.5.1: 2006—Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
- ETSI EN 301 489-1: V1.6.1, and ETSI EN 301 489-3: V1.8.1: 2008—Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services
- FCC, 47 CFR Part 15, Subpart C, Section 15.225: 2009
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1 Ed. 3.0:2005 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; also IEC 60601-1 Ed. 2.0:1988 +A1+A2:1995 Medical Electrical Equipment—General Requirements for Safety
- IEC 60601-1-1Ed. 2.0:2000 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2 Ed. 3.0:2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-3 Ed. 2.0:2008 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment; also IEC 60601-1-3 Ed. 1.0:1994 Medical Electrical Equipment – Part 1: General Requirement for Safety -3. Collateral Standard: Requirements for Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-4 Ed. 1.1:2000 Medical Electrical Equipment – Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems

- IEC 60601-2-28 Ed. 2.0:2010 Medical Electrical Equipment - Part 2-28: Particular Requirements for the Basic Safety and Essential Performance of X-ray Tube Assemblies for Medical Devices; also IEC 60601-2-28 Ed. 1.0:1993 Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis
- IEC 60601-2-32 Ed. 1.0:1994 Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment
- IEC 60601-2-45 Ed. 3.0:2011 Medical Electrical Equipment – Part 2-45: Particular Requirements for Basic Safety and Essential Performance of Mammographic X-Ray Equipment and Mammographic Stereotactic Devices; also IEC 60601-2-45 Ed. 2.0:2001 Medical Electrical Equipment Part 2-45: Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices
- RSS-210: Issue 7, 2007 Radio Standards Specification Low-power License-exempt Radiocommunication Devices: Category I Equipment
- ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, includes amendment (2010); also UL 60601-1 1st Edition: Medical Electrical Equipment, Part 1—General Requirements for Safety

Selenia Dimensions Instructions for Use

Chapter 1—General Information Label Locations



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

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

13 Hologic, Inc., Danbury, CT, 06810, U.S.A.
Selenia Dimensions AWS
MODEL: SN
MADE IN U.S.A.
50-60Hz 100V/120V/200V/208V/220V/230V/240V 8A
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 System
MODEL: SN
GANTRY PART NUMBER
50-60Hz 200V/208V/220V/230V/240V 4A (60A max. for ≤ 5 sec.)
COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE.
FCC ID: YUJ-PCB00116 / IC: 9218A-PCB00116
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

14 **Selenia Dimensions System**
(Selenia Dimensions Gantry)
(Selenia Dimensions Acquisition Workstation)
Medical - Applied Electromagnetic Radiation Equipment
6D32
CLASSIFIED C UL US

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:
5,666,589 5,627,869 5,706,327 5,729,585 5,814,235 5,930,327 6,075,840, 7,152,853 7,152,854 7,233,005 7,354,368 7,319,135 7,438,272 7,616,862, 7,702,142 7,760,853 7,752,245 7,831,296 7,869,563 7,881,428

7 **8** **9**

10 X-RAY TUBE
INSERT SER: _____ USA: _____
INSERT SER: _____ HSG: _____
MINIMUM INHERENT FILTRATION: _____ COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE

4 **HOLOGIC** Model: _____
CLARITY Of Vision P/N: _____
Direct Radiography Corp. REV: _____
Newark, DE 19702 USA S/N: _____
MFG: _____
SFWD SHIPPED Made in U.S.A.

11 **HOLOGIC** Technical Support
877-371-4372 (USA)
32-2-711-4060 (intl)
Applications Support
888-679-0689 (USA)
Serial # _____

12 **CE**
0044

15 **LIFT MECHANISM IS NOT RATED FOR CONTINUOUS OPERATION**

Figure 3: Label Locations

Chapter 2 System Controls and Indicators

1.0 System Power Controls

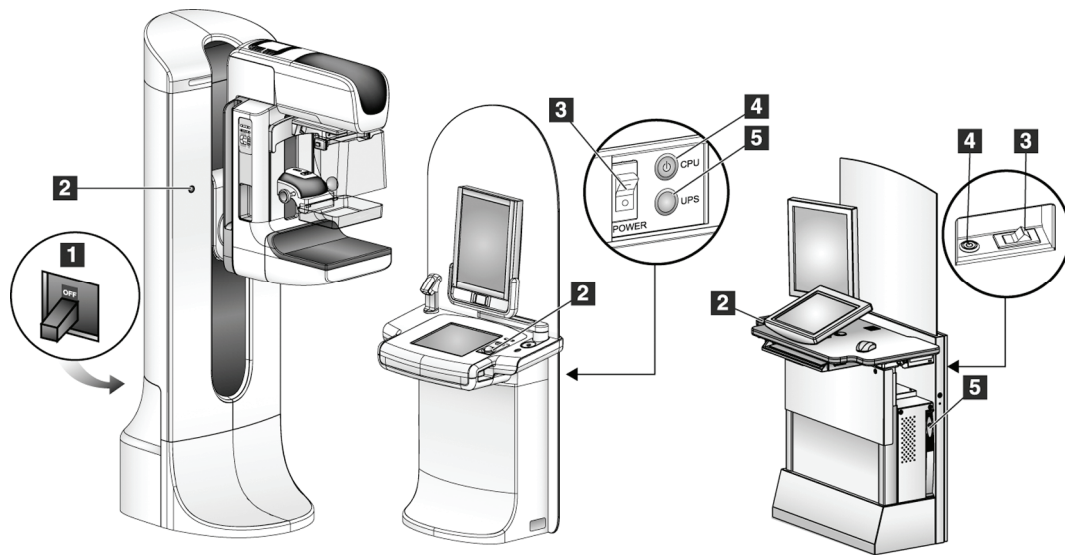


Figure 4: System Power Controls

Figure Legend

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

2.0 Acquisition Workstation Controls and Indicators

2.1 Premium Acquisition Workstation Controls and Displays

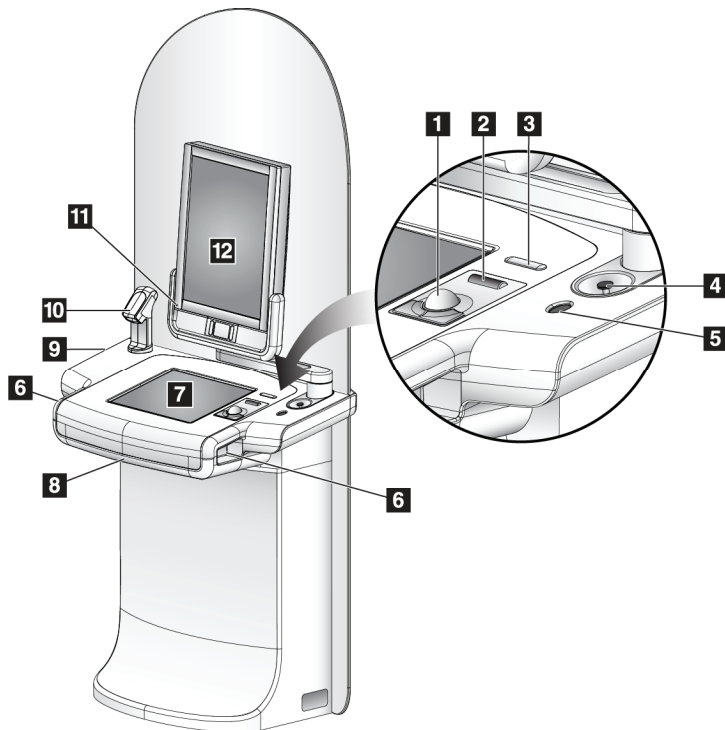


Figure Legend

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

Figure 5: Premium Acquisition Workstation Controls and Displays



Note

The controls for the AWS installed in a mobile environment are the same as the controls for the Premium AWS.

2.2 Standard Acquisition Workstation Controls and Displays

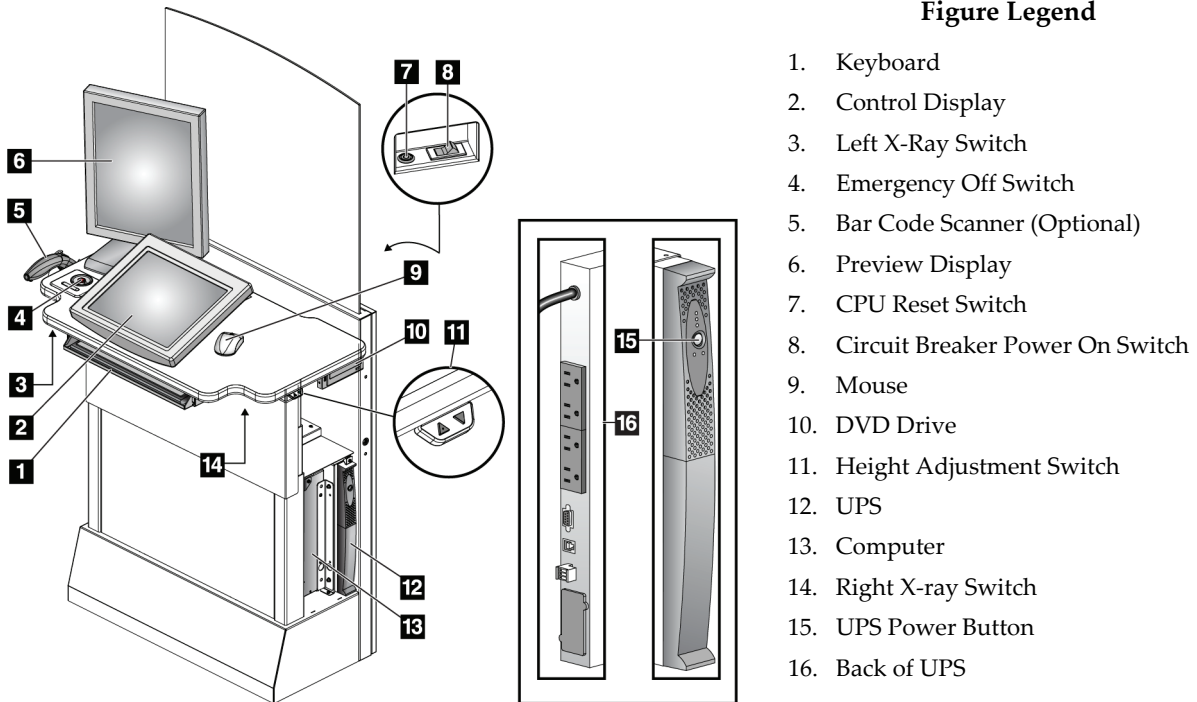


Figure 6: Standard Acquisition Workstation Controls and Displays

2.3 Keyboard

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

2.4 Bar Code Scanner

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

2.5 Premium Acquisition Workstation Touchscreen Display

Use the Touchscreen or trackball to select items.

2.6 Standard Acquisition Workstation Control Display

Use the Mouse to select items.

2.7 Preview Display

See the images on the Preview Display.



Note

Your Preview Display may appear different from the Preview Displays shown in this manual, but the function is identical

3.0 Tubestand Controls and Indicators

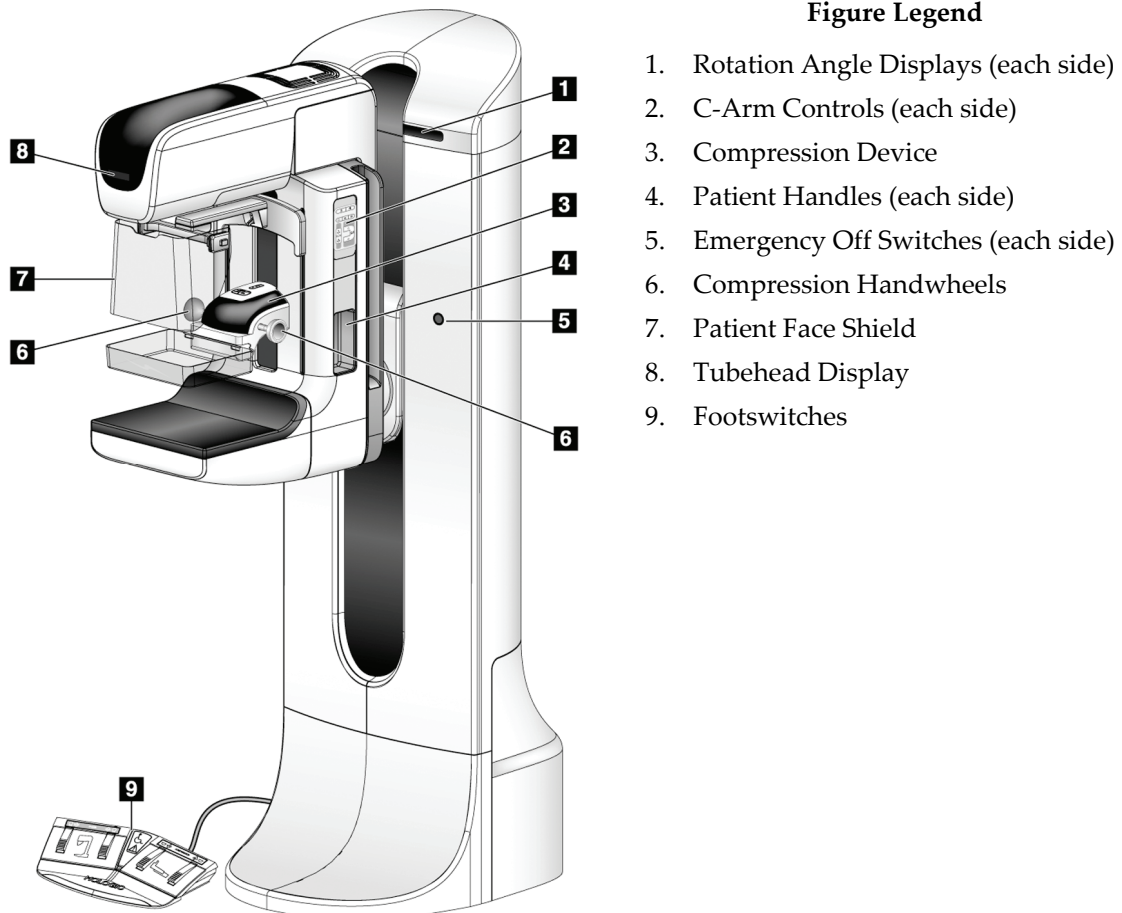


Figure 7: Tubestand Controls and Indicators

3.1 C-Arm Controls

The C-Arm Controls provide the Collimator and C-Arm functions. See *Perform the Functional Tests* on page 22.

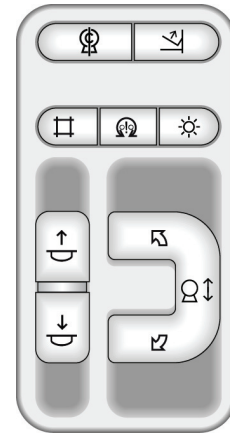


Figure 8: C-Arm Controls

3.2 Compression Device Controls and Displays

Figure Legend

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

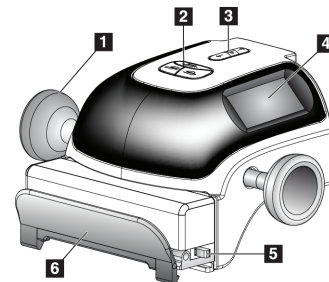


Figure 9: Compression Device

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 5 seconds)

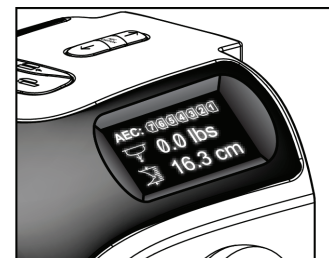


Figure 10: Compression Display

3.3 Tubehead Display

The Tubehead Display shows:

- SID
- Filter Type
- Collimator Setting
- Paddle Position

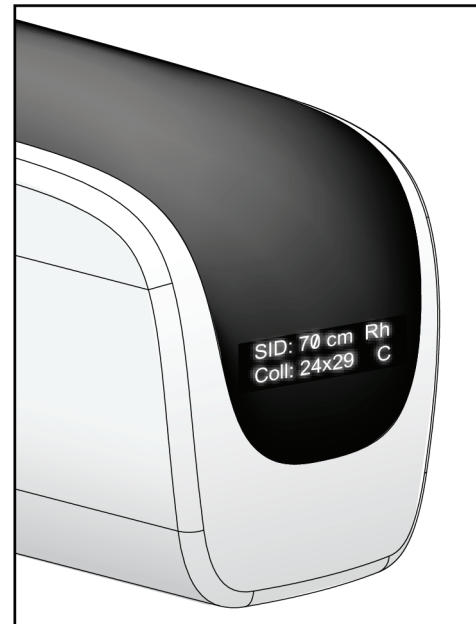


Figure 11: Tubehead Display

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.

Figure Legend

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

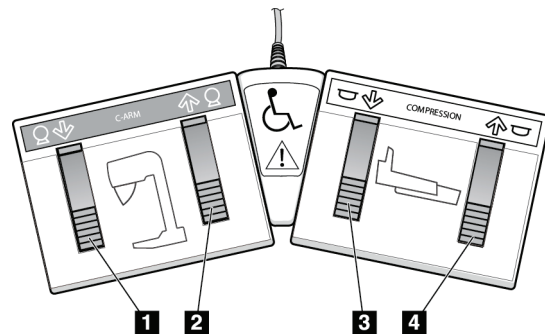


Figure 12: Dual Function Footswitches

4.0 How to Turn On the Selenia Dimensions

4.1 Preparation

1. Reset all three Emergency Off switches by turning each Emergency Off switch by one-quarter turn.

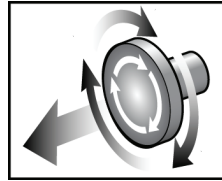


Figure 13: Reset the Emergency Off Switches

2. Make sure that both system circuit breakers are in the On position.
3. Remove blockages to the C-Arm movement and to the view of the Operator.

4.2 Startup

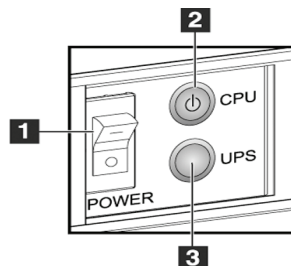


Figure 14: Premium Acquisition Workstation Power Buttons

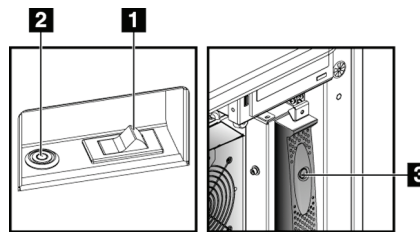


Figure 15: Standard Acquisition Workstation Power Buttons

Figure Legend

1. Acquisition Workstation Circuit Breaker
2. Computer Power Button
3. UPS Power Button

1. If the UPS was shut down, press the UPS power button (at the rear of the Premium Acquisition Workstation or on the side of the Standard Acquisition Workstation).
2. Press the computer power button at the rear of the Acquisition Workstation.

Selenia Dimensions Instructions for Use

Chapter 2—System Controls and Indicators
How to Turn On the Selenia Dimensions

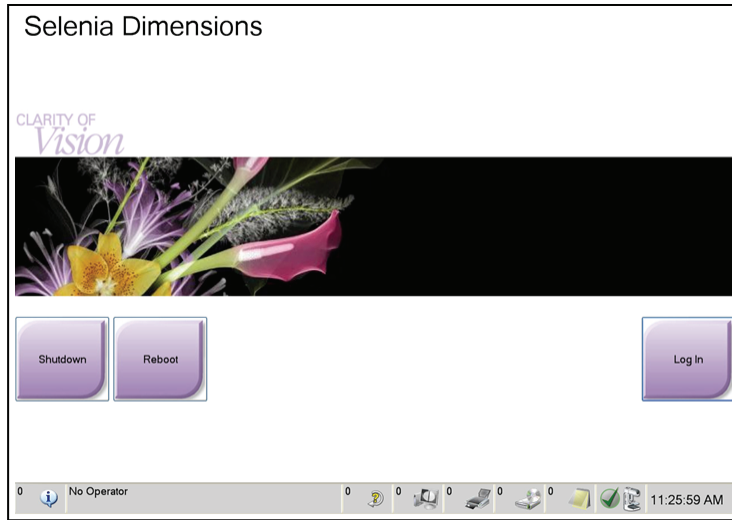


Figure 16: The Startup Screen

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



Note

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



Note

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

4.3 Log In

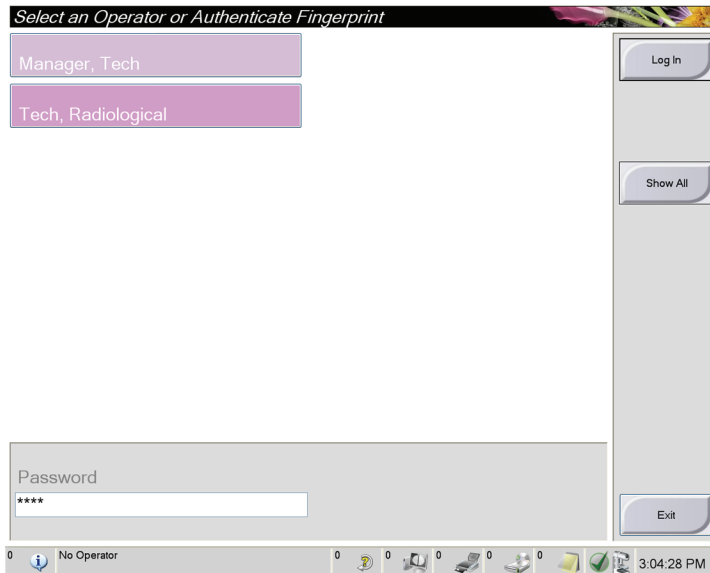


Figure 17: How to Log In

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.



Note

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

5.0 How to Change the Language

1. Select the **Admin** button.
2. Select the **My Settings** option.
3. From the **Locale** field, select a language from the drop-down menu.
4. Select the Save button, then select the OK button to the Update Successful message. The selected language displays.

6.0 Perform the Functional Tests

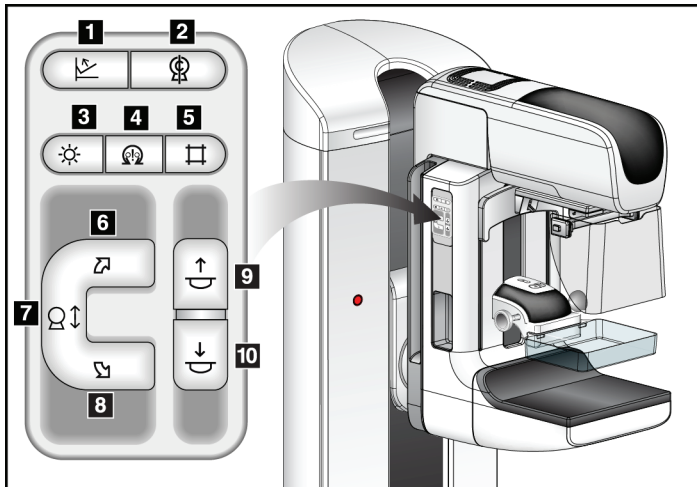


Figure Legend

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

Figure 18: C-Arm Controls (left side shown)

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

Perform the Functional Tests as part of your monthly visual checklists to make sure that the control operates correctly.

Table 1: C-Arm Functional Tests

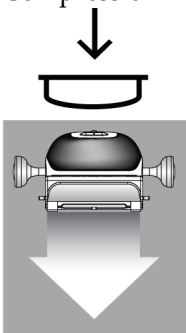
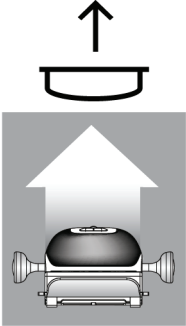

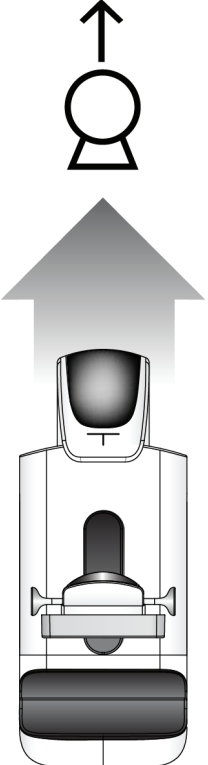
Function	Functional Test
Compression Down 	Press a Compression Down button: <ul style="list-style-type: none"> • The compression brake engages. • The light field lamp illuminates. • The compression device lowers. <p><i>Note... When you press the Compression Down button, the compression brake remains engaged until the Compression Release button is pressed.</i></p> Compression down movement stops: <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 1: C-Arm Functional Tests

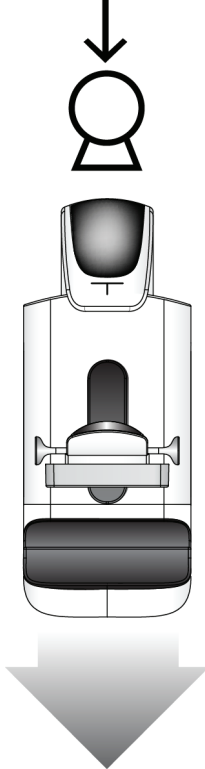
Function	Functional Test
<p>Compression Up</p> 	<p>Press a Compression Up button:</p> <ul style="list-style-type: none"> The Compression Device moves toward the top. The Compression Up button <i>does not</i> release the Compression Brake. <p>Compression Up movement automatically stops:</p> <ul style="list-style-type: 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 Newtons (10 pounds) or greater is applied, or when 22 Newtons (5 pounds) or greater is applied with the Affirm attached.

Selenia Dimensions Instructions for Use

Chapter 2—System Controls and Indicators
Perform the Functional Tests



Table 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 Newtons (10 pounds) or greater is applied, or when 22 Newtons (5 pounds) or greater is applied with the Affirm attached.
<p>Counterclockwise C-Arm Rotation</p>	<p>Press the Counterclockwise C-Arm Rotation button to start counterclockwise C-arm rotation.</p>
<p>Left Panel</p>	<p>Right Panel</p>

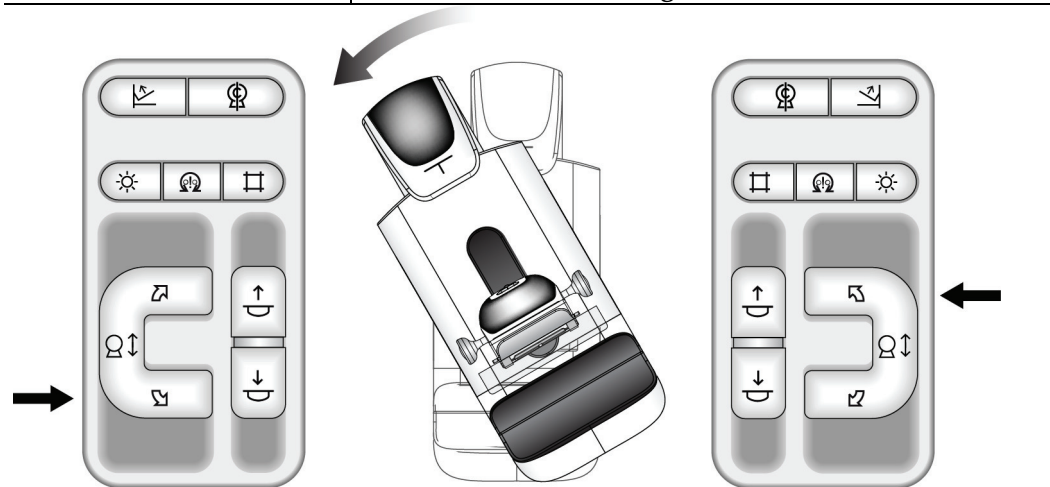
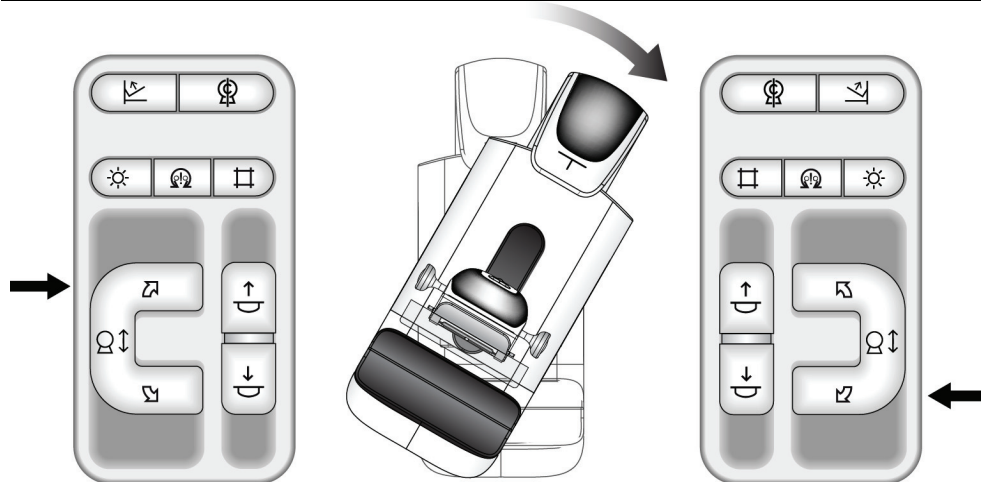


Table 1: C-Arm Functional Tests

Function	Functional Test
Clockwise C-Arm Rotation	Press the Clockwise C-Arm Rotation button to start clockwise C-Arm rotation.
Left Panel	Right Panel



NOTE: C-Arm movement is disabled when a compression force of 45 Newtons (10 pounds) or greater is applied, or when 22 Newtons (5 pounds) or greater is applied with the Affirm attached.

C-Arm Rotation Switch	Push the C-Arm Rotation switch away from you to move the C-Arm toward you. Pull the C-Arm Rotation switch toward you to move the C-Arm away. The C-Arm movement stops when the switch is released.
-----------------------	--

Selenia Dimensions Instructions for Use

Chapter 2—System Controls and Indicators
Perform the Functional Tests



Table 1: C-Arm Functional Tests

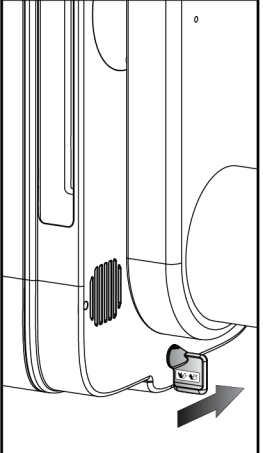
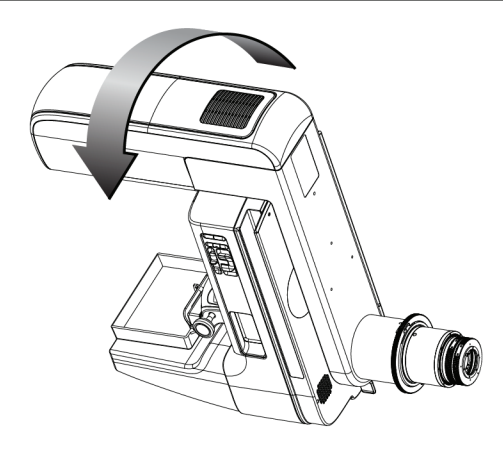
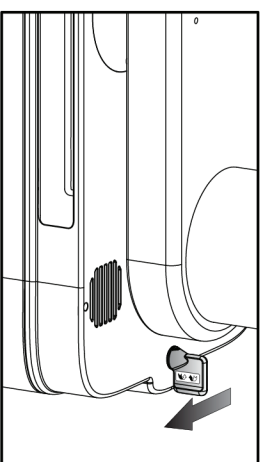
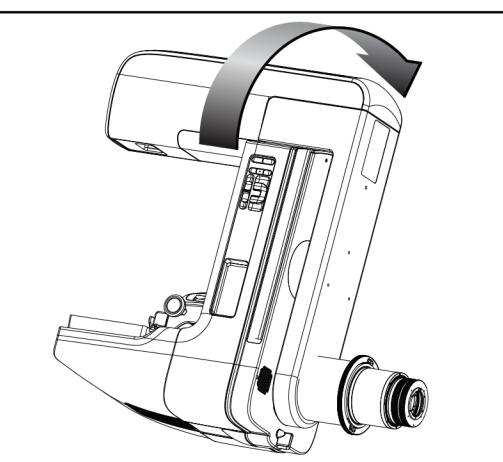




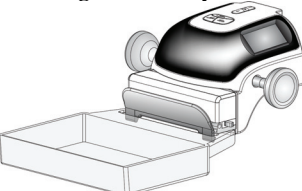
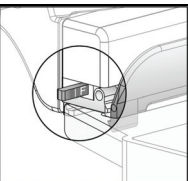
Function	Functional Test
	
	
<p>Collimator Override</p> 	<p>The Collimator Override button changes the collimation through the different x-ray fields. Press the light field lamp button to show the x-ray field, then press the Collimator Override button to select an x-ray field.</p>
<p>Light Field Lamp</p> 	<p>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.</p>
<p>Motor Enable</p> 	<p>Reserved for provisional use.</p>

Table 1: C-Arm Functional Tests

Function	Functional Test
C-Arm Zero 	Reserved for provisional use.
Shifting Paddle System 	<p>The 18 x 24 cm Screening Paddle moves approximately 2.5 cm into the left, center, or right position. While compression is applied, you cannot move the paddle. The collimator is programmed to follow the position of the paddle.</p> <p>To test this function:</p> <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.
	<p>A FAST Compression Mode Slide on the Compression Device lets you set the system for FAST Compression Mode or for Normal Compression Mode.</p> <p>To select the mode, move the Slide to the "F" position from either side of the Compression Device.</p>

7.0 Emergency Off Switches Functionality

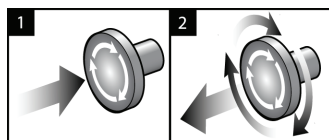


Figure 19: Emergency Off Switch Functionality

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

1. Press any of the Emergency Off switches to turn Off the Gantry and disable the Standard Acquisition Workstation Lift Mechanism.
2. Turn the Emergency Off switch by one-quarter turn to reset the switch.

8.0 How to Turn Off the System

1. Close any open patient procedures. See *How to Close a Procedure* on page 42.
2. From the Select Patient screen, select the **Log Out** button.
3. From the Startup screen, select the **Shutdown** button.
4. Select the **Yes** button in the confirmation screen.

9.0 How to Remove All Power from the Acquisition Workstation

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

1. After the system completes the shutdown, press the UPS button (see item 3 in the *figure Premium Acquisition Workstation Power Buttons* on page 19 and the *figure Standard Acquisition Workstation Power Buttons* on page 19).
2. Turn off the Acquisition Workstation circuit breaker (see item 1 in the *figure Premium Acquisition Workstation Power Buttons* on page 19 and the *figure Standard Acquisition Workstation Power Buttons* on page 19).
3. Disconnect the Acquisition Workstation power cable.

To restart the system:

1. Connect the Acquisition Workstation power cable.
2. Turn On the Acquisition Workstation circuit breaker (see item 1 in the *figure Premium Acquisition Workstation Power Buttons* on page 19 and the *figure Standard Acquisition Workstation Power Buttons* on page 19)
3. Press the UPS button (see item 3 in the *figure Premium Acquisition Workstation Power Buttons* on page 19 and the *figure Standard Acquisition Workstation Power Buttons* on page 19).
4. Wait for the console fans to turn on.
5. Press the Computer Power button.

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.

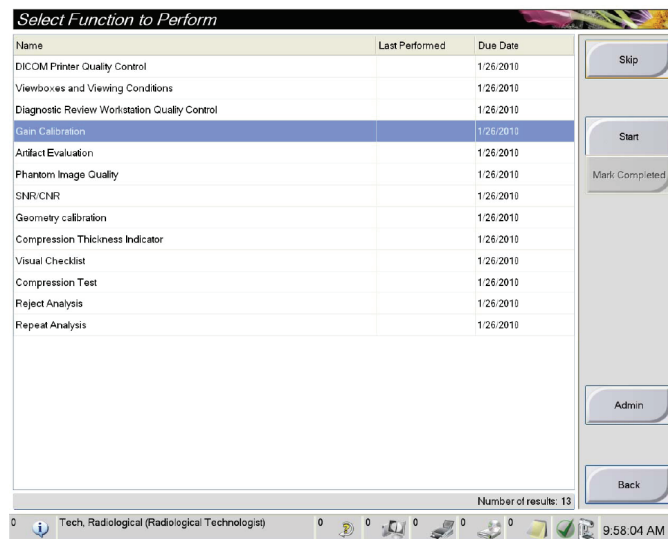


Figure 20: An Example Select Function to Perform Screen

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.

If you select the Admin button, the Admin screen appears. See *How to Use the Admin Screen* on page 81 for information about this screen.

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.

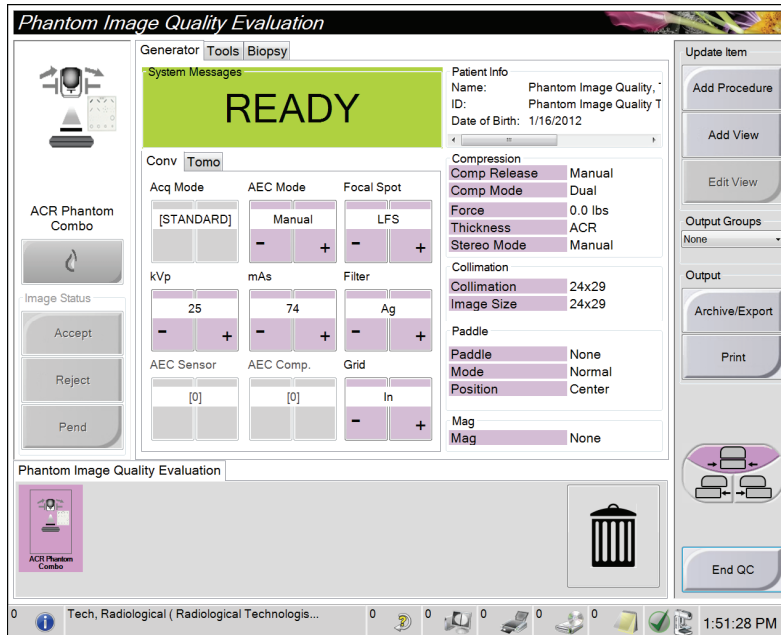


Figure 21: An Example Quality Control Screen



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 any time. Select the Admin button (on The Select Patient Screen). Select the Quality Control button on the Admin screen to display the list.

3.0 The Select Patient Screen

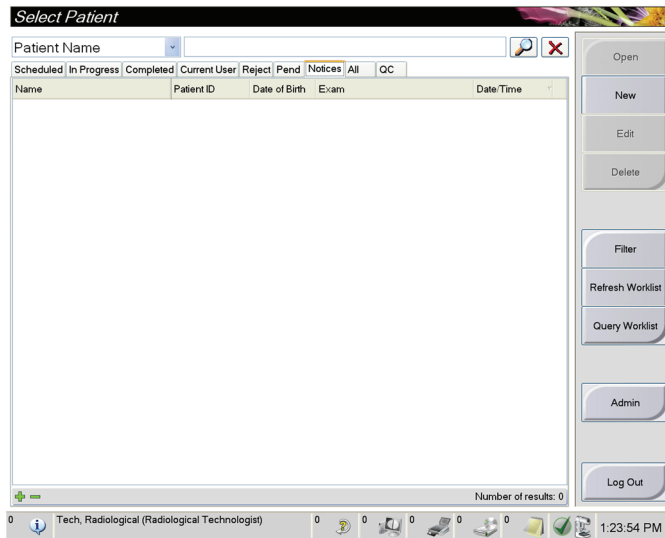


Figure 22: The Select Patient Screen

Table 2: The Select Patient Screen

Item	Description
1. Quick Search	Search the local database for the Patient Name, Patient ID, or Accession #.
2. Tab	<p>The tabs at the top of the screen are configurable. A user with the right permissions can delete tabs and create new tabs.</p> <ul style="list-style-type: none"> • The Scheduled tab displays the scheduled procedures. • The In Progress tab displays the procedures not complete. • The Completed tab displays the completed procedures. • The Current User tab displays the procedures for the current Operator. • The Reject tab displays the procedures with rejected views. • The Pend tab displays the procedures with pending views. • The All tab displays all procedures for all users. • The Notices tab displays the Patients with unviewed notices by default. See <i>About the Notices Tab</i> on page 32 for complete information. • The QC tab displays the Quality Control procedures. • The Enterprise tab shows if you have the <i>Advanced Workflow Manager</i> on page 36. This tab displays the procedures acquired on all networked Selenia Dimensions.

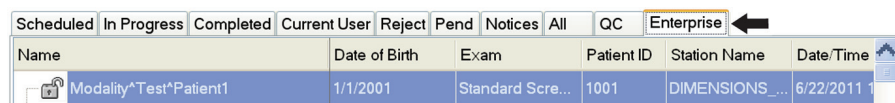


Figure 23: The Enterprise Tab

Table 2: The Select Patient Screen

Item	Description
<p>3. Other Functions</p>	<p>You can perform many functions from this screen:</p> <ul style="list-style-type: none"> • Add a new Patient (New)—see <i>How to Add a New Patient</i> on page 33. • Edit the patient information (Edit)—see <i>How to Edit the Patient Information</i> on page 33. • Delete a patient from the worklist (Delete)—see <i>How to Delete a Patient Manually</i> on page 33. • Use a Patient Filter (Filter)—See <i>The Patient Filter Screen</i> on page 34. • Search for a patient in the Modality Worklist (Query)—see <i>How to Query the Worklist</i> on page 36. • Use the Admin Screen (Admin)—see <i>How to Use the Admin Screen</i> on page 81. • Exit (Log Out)—see <i>How to Log Out</i> on page 36. • Find your patients in the database (tabs at the top of screen).

3.1 About the Notices Tab

- When you select the Notices tab from the Select Patient screen, a list of the Patients with Notices displays.
- The default value for the displayed list is patients with Unviewed Notices.
- The value can be changed to show patients with Viewed Notices or patients with Unviewed and Viewed Notices.
- When you select the **Open** button, the procedure screen for the selected patient opens.

3.2 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.

3.3 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 appears.

Figure 24: How to Add a New Patient

3.4 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.

3.5 How to Delete a Patient Manually



Note

Reclamation normally removes the requirement to delete patients manually. See *About Reclamation* on page 80.

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



Note

The Technologists do not have permissions to delete patients.

3.6 The Patient Filter Screen

When you select the **Filter** button in the Select Patient screen, the Patient Filter screen for the selected tab appears.

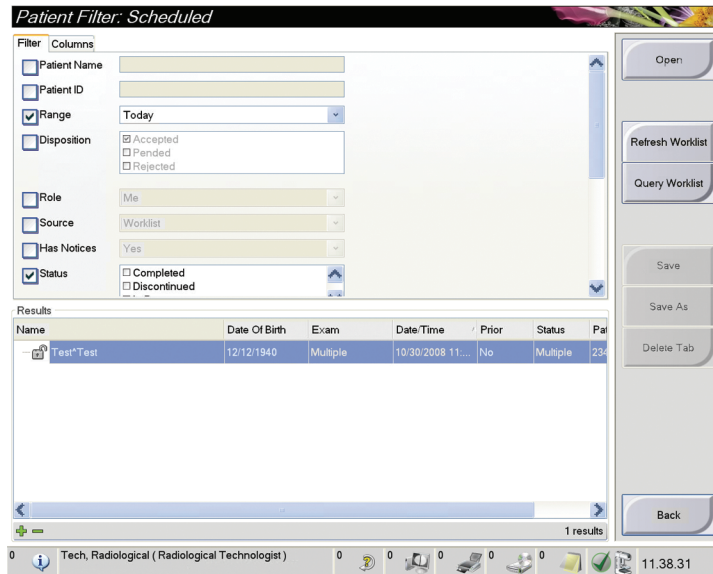


Figure 25: The Filter Tab in the Patient Filter Screen

3.6.1 The Filter and Column Tabs in the Patient Filter Screen

The Filter tab allows you to change the filter options for the patient list that displays. When you select or deselect an option, the change shows in the Results area of the screen.



Note

The Manager level of system access is required to save these new filters to the selected tab in the Select Patient screen (see *Other Functions of the Filter Tab* on page 35).

The Column tab allows you to add more search options (for example, Age, Gender, Notices) to the filtered list. The options display as columns in the results area. To add more columns to a filtered list, select the Column tab, then select the options.



Note

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

3.6.2 Other Functions of the Filter Tab

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

Table 3: The Filter Tab Options (Require Access Privileges)

<ul style="list-style-type: none"> Change the current patient filter parameters. 	<ol style="list-style-type: none"> Select a tab on the Select Patient screen. Select the Filter button. Select the filter options. Select the Save button Make sure the name of the tab you selected is in the name box. Select OK.
<ul style="list-style-type: none"> Create a new tab for the Select Patient screen 	<ol style="list-style-type: none"> Select a tab on the Select Patient screen. Select the Filter button. Select the filter options for the tab. Select the Save As button. Enter a new name for the tab. Select OK.
<ul style="list-style-type: none"> Delete a tab from the Select Patient screen. 	<ol style="list-style-type: none"> Select a tab on the Select Patient screen. Select the Filter button. Select the Delete button Select Yes to the confirmation prompt.

3.7 How to Refresh the Worklist

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

3.8 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 Scanner**—The field in which the bar code scanner 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: Patient name, Patient ID, Accession Number, Requested Procedure ID, Scheduled Procedure Date. The scheduled procedure displays and the patient is added to the local database.

3.9 About the Admin Button

See *System Administration Interface* on page 81.

3.10 How to Log Out

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

4.0 Advanced Workflow Manager

The Advanced Workflow Manager is a workflow engine that allows many Selenia Dimensions systems to communicate and exchange images with each other. This system keeps track of all patients, procedures, and images acquired on all Selenia Dimensions systems that are linked to it. In addition, the Advanced Workflow Manager synchronizes notices and provides prior images to all Selenia Dimensions systems that are linked to it.

Selenia Dimensions linked to the Advanced Workflow Manager display the Enterprise tab on The Select Patient Screen. This tab displays the procedures acquired on all linked Selenia Dimensions systems.

5.0 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 *The Image Review Tools Tab* on page 55).



Note

The Biopsy tab is always available when the system is licensed for biopsy. For non-biopsy procedures, all biopsy-related controls are disabled on the Biopsy tab. Refer to the *Affirm User Manual* for information about the Biopsy tab.

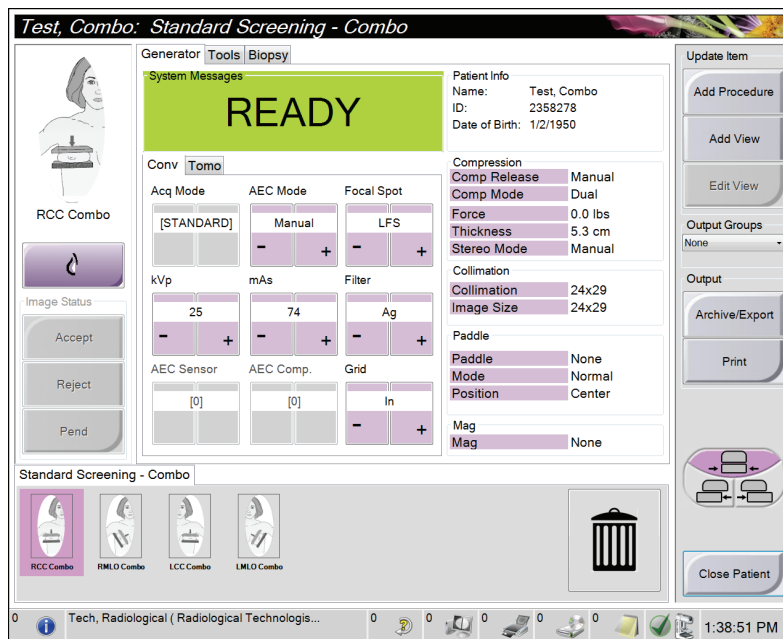


Figure 26: The Generator Tab in an Example Procedure Screen

5.1 How to Set the Exposure Parameters

5.1.1 Select the Image Acquisition Mode (Tomosynthesis option)

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

5.1.2 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.

5.1.3 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 toward the nipple edge (position 7). The automatic position selects two regions within an area that extends from the chest wall to the nipple.

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

5.2 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 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 any procedure tabs contain an ID view.

5.3 How to Acquire an Image

See *Clinical Procedures* on page 73, 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 full exposure. During the exposure, a System Message shows, 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 image transmits to output devices with all attributes and marks.
 - You can **Reject** the image. When the dialog box appears, select the reason for the reject. 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.

**Note**

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

5.4 How to Add or Remove a View

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

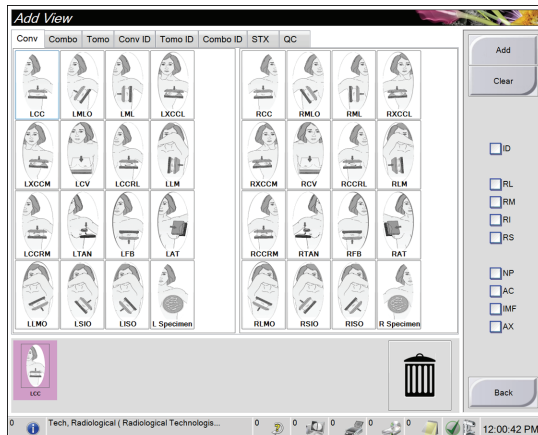


Figure 27: The Add View Screen

View Modifiers

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



Note

When you select the STX tab, Stereo View Modifiers appear.

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

5.5 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.

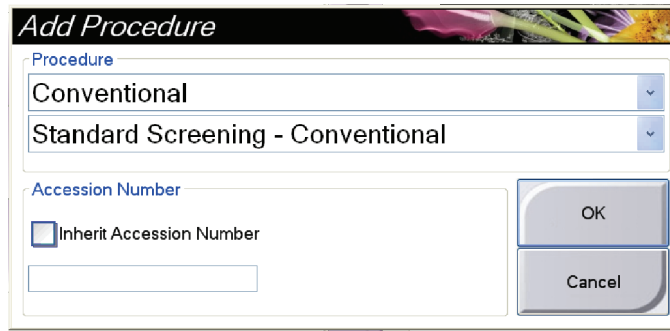


Figure 28: The Add Procedure Dialog Box

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.

5.6 How to Edit a View

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

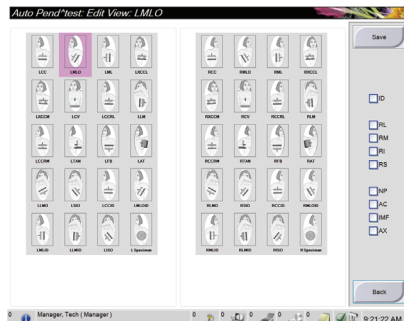


Figure 29: The Edit View Screen

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 the figure *The Add View Screen* on page 40 for a description of the View Modifiers.
4. Select the **Save** button.
5. When the Update Successful screen displays, select the **OK** button.

5.7 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:

<ul style="list-style-type: none"> • Close Procedure Complete 	Closes the procedure and puts the procedure in the Complete tab.
<ul style="list-style-type: none"> • Close Procedure In Progress 	Closes the procedure and puts the procedure in the In Progress tab.
<ul style="list-style-type: none"> • Close Procedure Discontinue 	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.
<ul style="list-style-type: none"> • Return To Procedure 	Returns to procedure.

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

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

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.

6.0 How to Access Image Review Features

Select the Tools tab on the Procedure screen to access the image review features. See *The Image Review Tools Tab* on page 55 for information.

7.0 How to Use the Output Groups

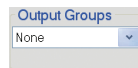
The Accepted images are sent automatically to the output devices in the selected Output Group. The system configuration controls if the images are sent after a patient is closed or after the image is Accepted.



Note

Tomosynthesis images are not sent to a print device in the selected Output Group. You can print tomosynthesis images with the Print utility.

7.1 How to Select an Output Group



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



Note

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

7.2 How to Add or Edit an Output Group



Note

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

To add a new Output Group:

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

To edit an Output Group:

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

7.3 How to Use the Custom Output

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

To make a custom group from the Procedure screen:

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

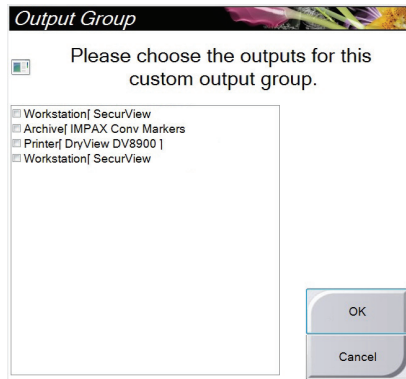


Figure 30: An Example Custom Output Group

8.0 How to Use the On-Demand Outputs

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

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

8.1 How to Archive

1. Select the **Archive/Export** button.
2. Select the procedure or views in the On Demand Archive screen:
 - **Select All** button selects all items that show in this screen.
 - **Clear** button deselects items that are selected in this screen.
 - **Priors** button shows previous procedures and views for this patient.
 - **Reject** button shows rejected views for this patient.
3. Select a storage device:
 - Select the **List Store Device** button and make your selection from the options in the Storage Device drop-down menu.OR
 - Select an output group from the **Output Group** drop-down menu.
4. Select the **Archive** button to copy the selected images to the selected archive.



Note

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

8.2 How to Export

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

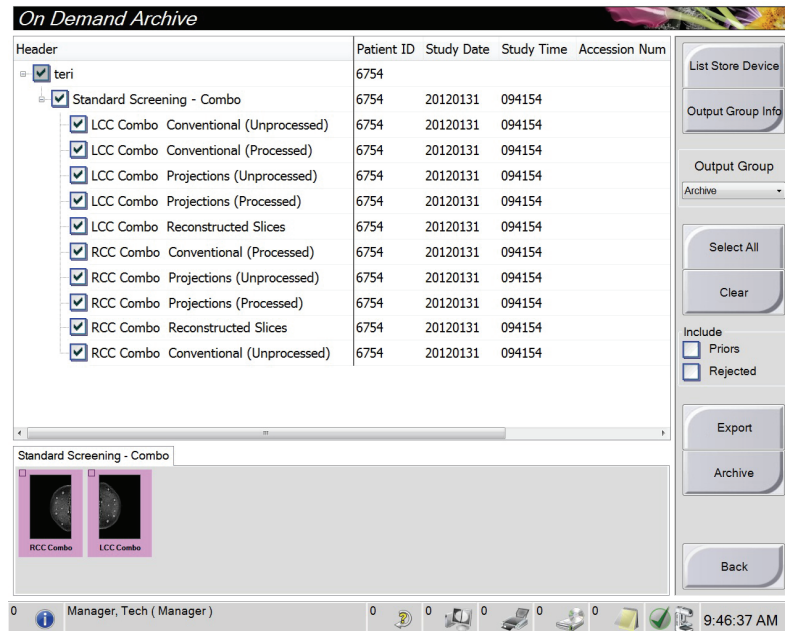
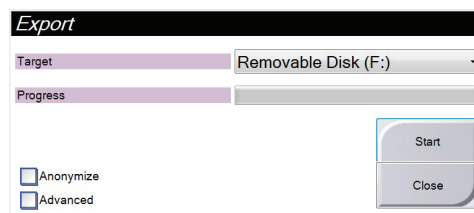


Figure 31: Select the Images for Export

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



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

8.3 How to Print

1. From the Procedure screen, select the **Print** button to show the Print screen. See the figure *The Print screen* on page 46 to prepare your print data.
2. Select the film format from the film format area of the screen.
3. Select a thumbnail image.
4. Select the image mode (Conventional, Projection, Reconstruction, or Tomo).
5. Select the image display area (item 16) in the Print screen. The image that shows in this area is the image that prints on the film.
6. To put other images on the same multiformat film, repeat steps 3 through 5.
7. To print a different film format of the same images, select the **New Film** button (item 12), then complete steps 2 through 6.
8. Use the buttons in the top left area of the Print screen (item 1 through item 6) to hide or show patient data, markings and annotations, and to change the orientation of the image.
9. Select the **Print** button to print your films.

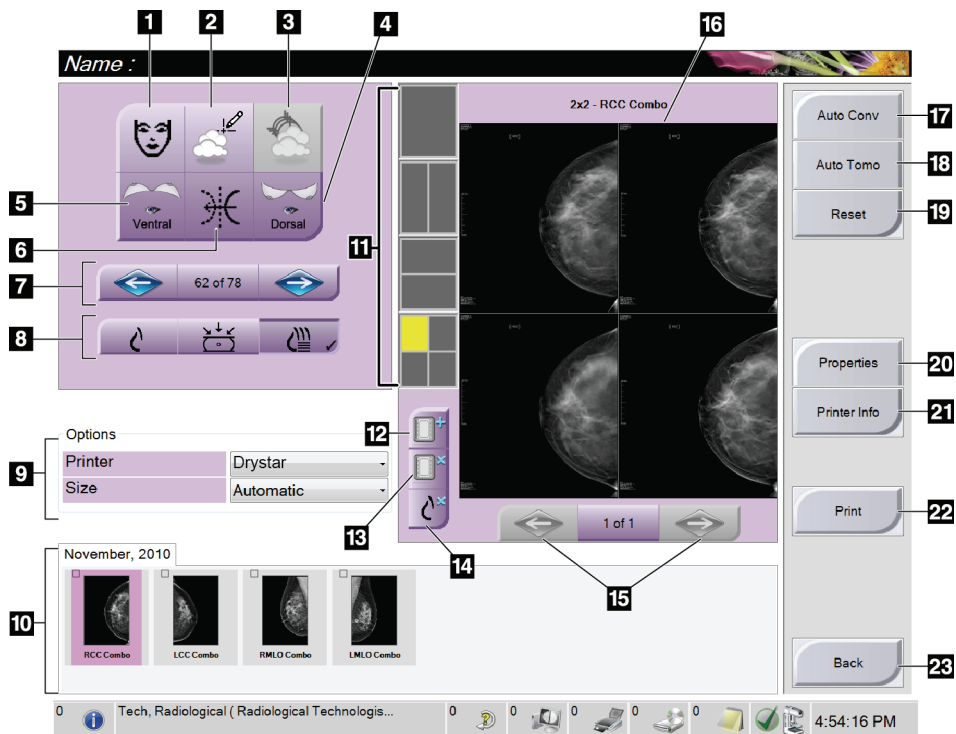


Figure 32: The Print screen

Figure Legend

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

9.0 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 for that view.
2. From the paddle shift section of the screen, you can bypass the default paddle position for the selected view. The paddle moves to the new position.

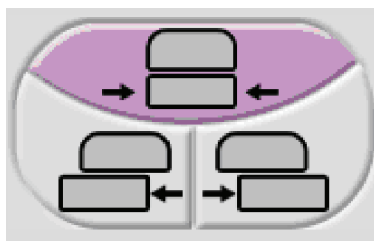








Figure 33: Paddle Shift Buttons


10.0 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 4: 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.</p> <p>Select Acknowledge All to remove the flashing indication.</p> <p>Select the Manage Alarms option to display and close any open alarms.</p>	<ul style="list-style-type: none"> No Alarms Acknowledge All Manage Alarms ...
2	<p>Current User Name</p> <p>Select the user name to display a menu.</p> <p>Log Out returns you to the Sign-in screen.</p> <p>My Settings lets you select user settings and workflow preferences.</p> <p>Print prints the displayed patient list to a connected printer.</p>	<ul style="list-style-type: none"> Users Menu Log Out My Settings ... Print ...
3    	<p>Output Device Icons</p> <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 information for the selected output, and allows you to filter the queue display.</p>	<ul style="list-style-type: none"> Queues Menu Manage Queues ... <i>Output Group:None</i>
4 	<p>Notices Icon</p> <p>Select the Notice icon to display the Patients with Unviewed Notices screen. The number on the icon shows the number of patients with Unviewed Notices.</p>	

<p>5</p> 	<p style="text-align: center;">System Status Icons</p> <p>Select the Tubehead icon to display a menu. When the detector and generator are ready for use, a green checkmark appears next to the tubehead icon.</p> <p>Clear All Faults deletes all fault messages.</p> <p>X-ray Tube, 0 Degrees puts the tubehead at zero degrees of rotation for the next exposure.</p> <p>X-ray Tube, -15 Degrees puts the tubehead at -15 degrees of rotation for a stereo exposure.</p> <p>X-ray Tube, +15 Degrees puts the tubehead at +15 degrees of rotation for a stereo 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>	<table border="1"> <tr> <td>No Alarms</td> </tr> <tr> <td>Clear All Faults</td> </tr> <tr> <td>X-Ray Tube, 0 Degrees</td> </tr> <tr> <td>X-Ray Tube, -15 Degrees</td> </tr> <tr> <td>X-Ray Tube, +15 Degrees</td> </tr> <tr> <td>System Diagnostics ...</td> </tr> <tr> <td>System Defaults ...</td> </tr> <tr> <td>About ...</td> </tr> </table>	No Alarms	Clear All Faults	X-Ray Tube, 0 Degrees	X-Ray Tube, -15 Degrees	X-Ray Tube, +15 Degrees	System Diagnostics ...	System Defaults ...	About ...
No Alarms										
Clear All Faults										
X-Ray Tube, 0 Degrees										
X-Ray Tube, -15 Degrees										
X-Ray Tube, +15 Degrees										
System Diagnostics ...										
System Defaults ...										
About ...										

Chapter 4 The Images

1.0 Introduction

After you make an exposure, the acquired image displays on the Preview screen.



Figure 34: The Preview Screen

Figure Legend

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

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



Note

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

- 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.

1.1 Conventional Imaging Sequence of Events

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



Note

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

1.2 Tomosynthesis Imaging Sequence of Events (Tomosynthesis option)

- Wait for the image reconstruction to complete.
- Review projection images for motion.
- Accept, Reject, or Pend the images.



Note

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

1.3 About Auto-Hanging and Auto-Pairing

To set the system for Auto-Hanging and Auto-Pairing:

1. Select the current user name area of the taskbar at the bottom of the screen.
2. Select the My Settings option to display the Edit Operator screen.
3. Select the Workflow tab.
 - Select the Auto-Hanging checkbox to show a prior study in 4-up mode automatically.
 - Select the Auto-Pairing checkbox to show a prior view in multi-up mode next to a newly captured image.
4. Select **Save**.

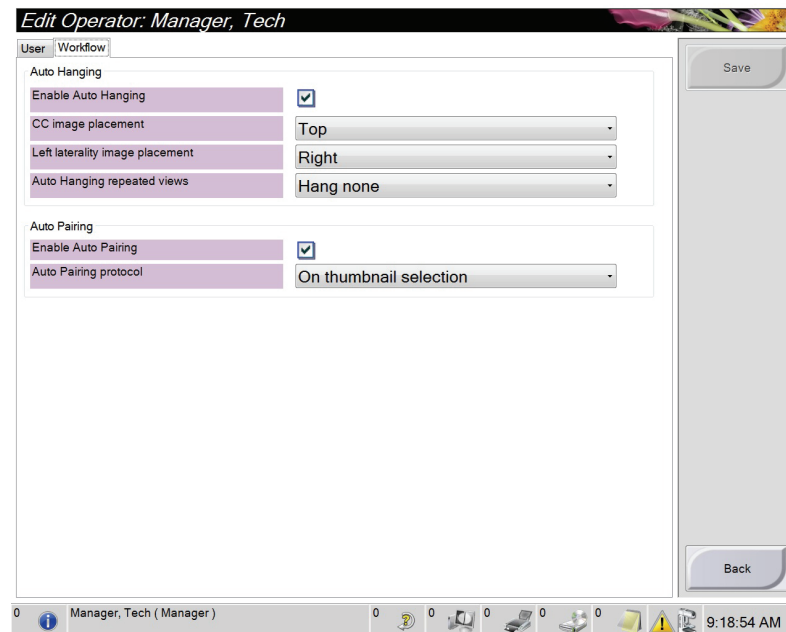


Figure 35: Enable Auto-Hanging and Auto-Pairing

2.0 How to Review the Images

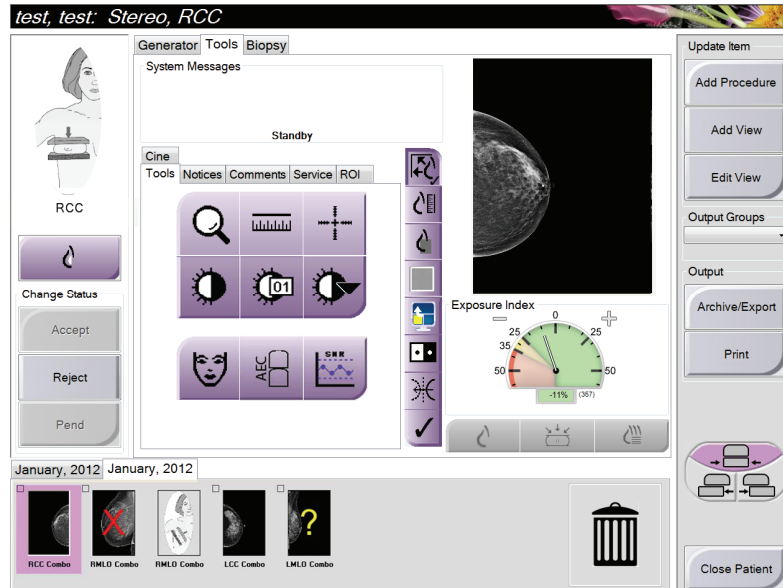


Figure 36: The Tools Tab (Tomosynthesis option shown)

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

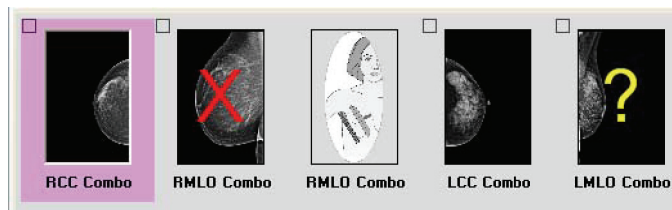


Figure 37: Marked Images in a Procedure (Tomosynthesis option shown)

2.1 The Image Review Tools Tab

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

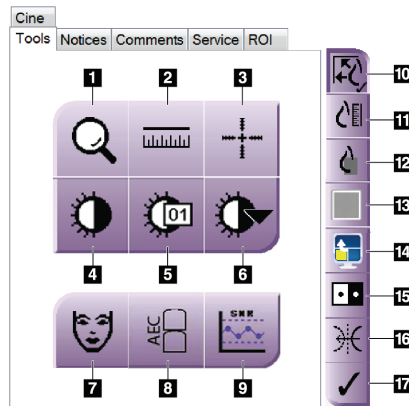


Figure 38: Image Review Tools

Figure Legend

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

2.2 The Notices Tab

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

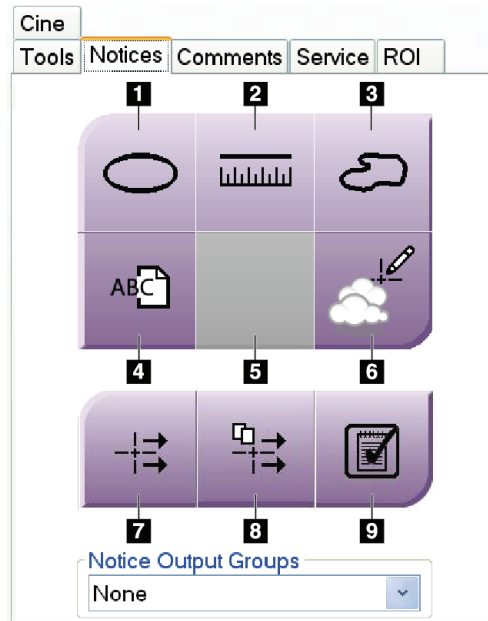


Figure 39: The Notices Tools Tab

Figure Legend

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

2.2.1 How to View the Notices

1. Select the patient in the Unviewed Notices list.
2. Open the patient.

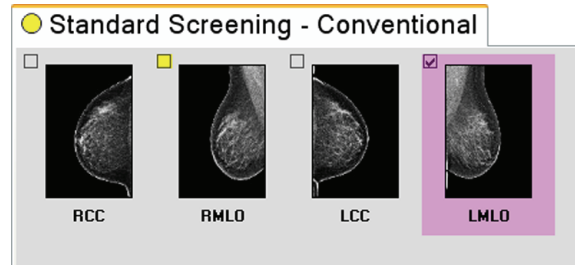


Figure 40: Yellow and Clear Checkboxes

- A yellow box on a thumbnail image indicates that image has unviewed notices.
- A clear box with a checkmark on a thumbnail image indicates the notices for that image were viewed.



Note

When your system is connected to an Advanced Workflow Manager and the selected patient images are in the cluster but not in the local database, the following sequence occurs:

- Blank icons appear in the thumbnail image area and a small asterisk appears on the thumbnail image tab.
- As the images are received, the thumbnail images replace the blank icons.
- When all images for that procedure are received, the asterisk disappears.

2.2.2 Image Markings

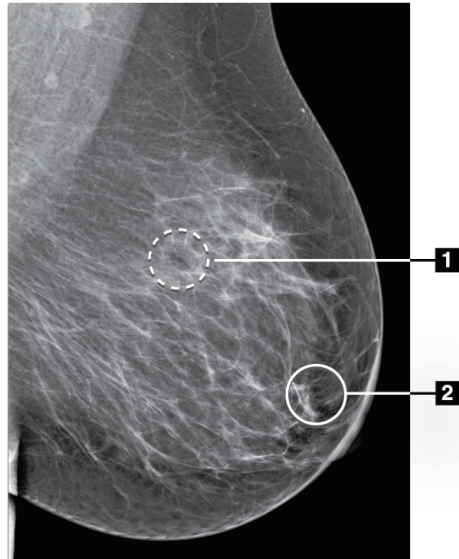


Figure Legend

1. Dashed lines indicate the marking was received in a notice.
2. A solid line indicates a marking created by a user.

Figure 41: Image Markings

- When you mark an image, an annotation box appears next to your marking. You can enter comments in this box. If you move the box, the comment you entered moves with the box. The date/time and user initials always display.



Note

The Date/Time field denotes when the notice was sent to a SecurView or sent from a SecurView.

- A received Notice includes the marking, annotation, the user initials, and the date and the time the Notice was received. You cannot move a marking or annotation that was received in a Notice.
- Markings and annotations created by the user that are not sent remain on the image until the patient is deleted.
- After you send a marked or annotated image, you cannot move that marking or annotation.

2.2.3 Delete a Marking

You can delete a Marking and the related Annotation or a Text Annotation.


1. Select either the Marking or the related Annotation.
2. Click the "X" that appears to delete the Marking, the related Annotation, and the label.



Note

After you send the Markings and Annotations (Notice), you cannot delete these Markings and Annotations.

2.2.4 Change Unviewed Notices to Viewed

1. After you finish with the image that contained a Notice, select the Tools tab in the Procedure screen.
2. Select the Notices tab.
3. Select the Viewed button  to mark the Notice as viewed.

2.3 Other Image Review Tools

2.3.1 The Other Tabs

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

2.3.2 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.



Figure 42: Exposure Index

2.3.3 Display Modes (Tomosynthesis option)

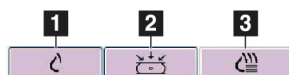


Figure Legend

1. Conventional button
2. Projections button
3. Reconstruction button

Figure 43: Display Modes

Use the Conventional, Projections, and Reconstruction buttons to select the type of view to display in the Preview Screen. You can change between conventional, projections, and reconstruction to display the combination images.

- Use Conventional to display conventional images.
- Use Projections to display the 15 projections.
- Use the Reconstruction to display the reconstructed slices.

2.4 How to Correct and Reprocess Implant Images

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

2.4.1 If the Image Is Not Accepted

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



2.4.2 If the Image Is Accepted

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 the **Accept** button to accept the changes.



Note

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

3.0 Send the Images to the Output Devices

You can send the images to output devices or use the Archive/Export function to copy images to temporary storage media. See *How to Use the Output Groups* on page 43 and *How to Use the On-Demand Outputs* on page 44 for instructions.

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.

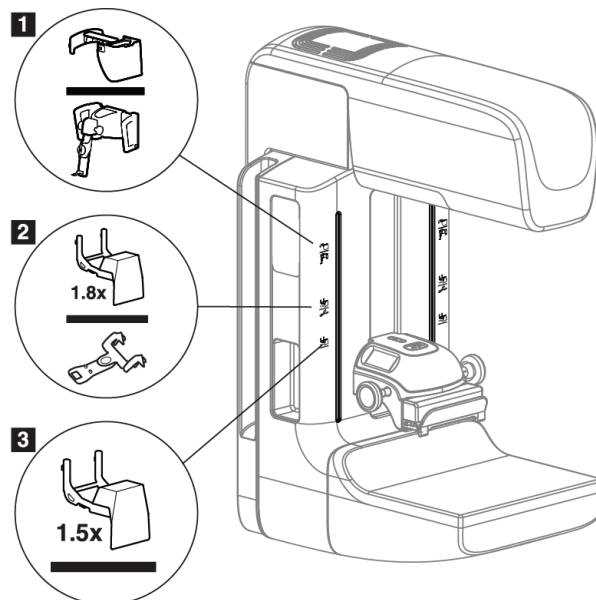


Figure 44: C-Arm Accessories

Figure Legend

1. Slot for Retractable Face Shield (Tomosynthesis option)
2. Slot for 1.8x Mag Stand and Localization Crosshairs
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 Retractable Face Shield

To install the Retractable Face Shield:

1. Completely extend the Face Shield to the outer position.
2. Align the hooks of the Face Shield with the mounting slots on the C-Arm, indicated by a face shield icon.
3. Put the hooks on both sides of the Face Shield into the mounting slots on the C-Arm. The Unlock Lever (see item 1 in the following figure), 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.

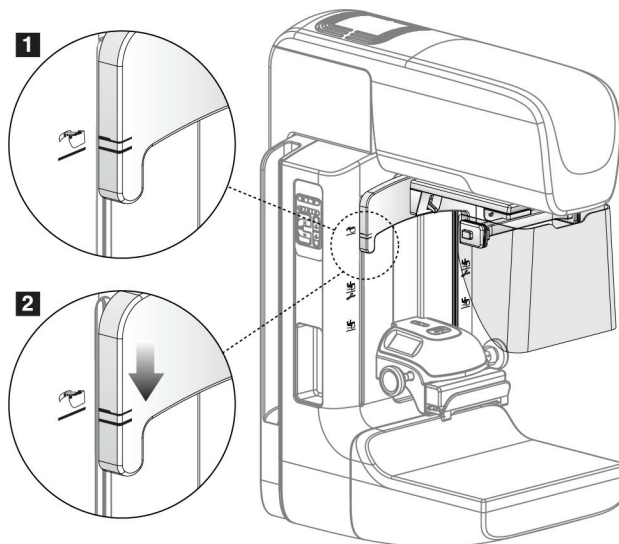


Figure 45: How to Align the Retractable Face Shield on the C-Arm

To remove the Retractable Face Shield:

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

3.2 How to Use the Retractable Face Shield



Note

Before you make an exposure, make sure the Face Shield is completely extended or completely retracted.

To extend the Face Shield, pull the Face Shield away from the C-Arm until the device latches in the outer position.

To retract the Face Shield:

1. Press a Latch Release (see item 2 in the *figure Face Shield Operation* on page 63)—one on each side).
2. Push the Face Shield toward the C-Arm until the device stops.

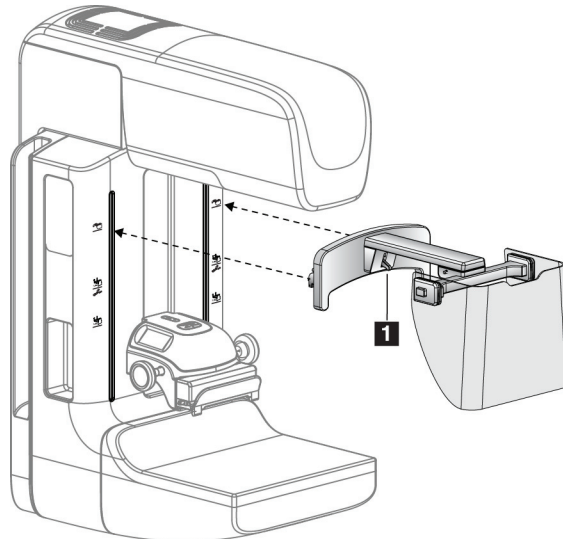


Figure 46: Face Shield Installation

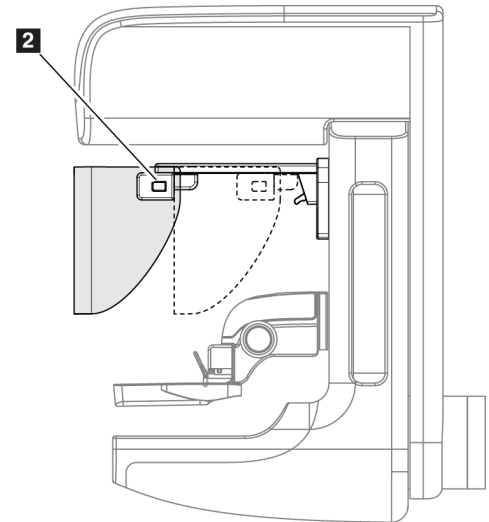


Figure 47: Face Shield Operation



Note

You cannot make an exposure unless the Face Shield is completely extended.

3.3 How to Install or Remove the Conventional Face Shield

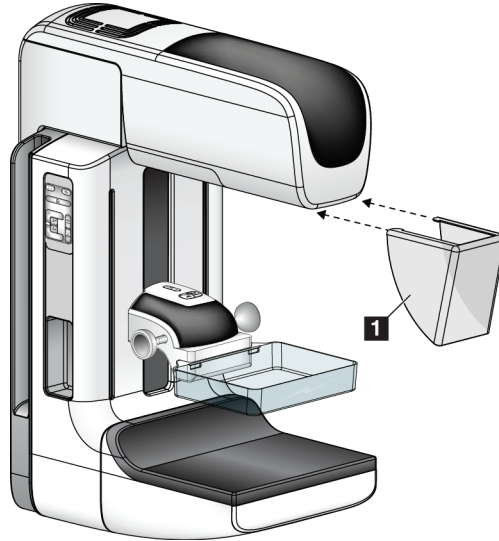


Figure 48: How to Install the Conventional Face Shield

To install the Conventional Face Shield:

1. Carefully put the tab ends of the Face Shield (item 1 in the previous 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.

4.0 Compression Paddles

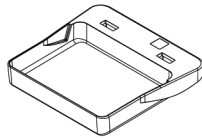


Note

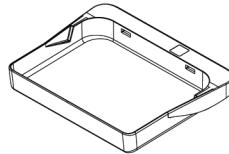
Some paddles are optional and may not be included with your system.

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

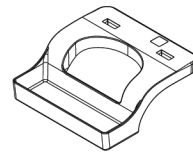
4.1 Routine Screening Paddles



**18 x 24 cm Frameless
Screening Paddle**

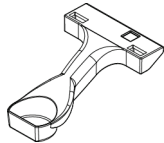


**24 x 29 cm Frameless
Screening Paddle**

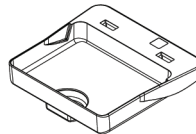


**Small Breast
Frameless Paddle**

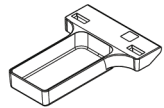
4.2 Contact and Spot Compression Paddles



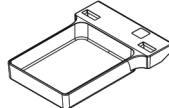
**7.5 cm Spot Contact
Frameless Paddle**



**Spot Contact
Frameless Paddle**



**10 cm Contact
Frameless Paddle**



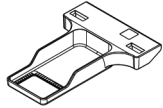
**15 cm Contact
Frameless Paddle**

Selenia Dimensions Instructions for Use

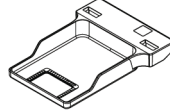
Chapter 5—How to Use the Accessories
Compression Paddles



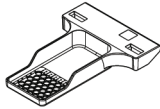
4.3 Localization Paddles



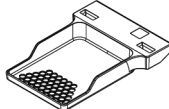
10 cm Rectangular Opening
Localization Paddle



15 cm Rectangular Opening
Localization Paddle



10 cm Perforated
Localization Paddle

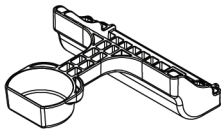


15 cm Perforated
Localization Paddle

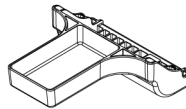


10 cm Magnification
Localization Perforated
Paddle

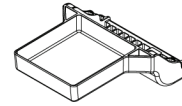
4.4 Magnification Paddles



7.5 cm Spot Magnification
Paddle

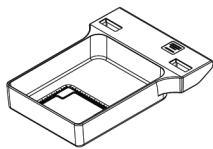


10 cm Magnification
Paddle



15 cm Magnification
Paddle

4.5 Large Ultrasound Paddle



15 cm Large Ultrasound
Paddle

4.6 How to Install or Remove a Compression Paddle

See the *figure How to Install a Compression Paddle* on page 67 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 (item 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 (item 2).
4. Compress the Paddle Clamp (item 3) with your free hand.
5. Rotate the paddle up (item 4), then release the Paddle Clamp to lock the paddle.

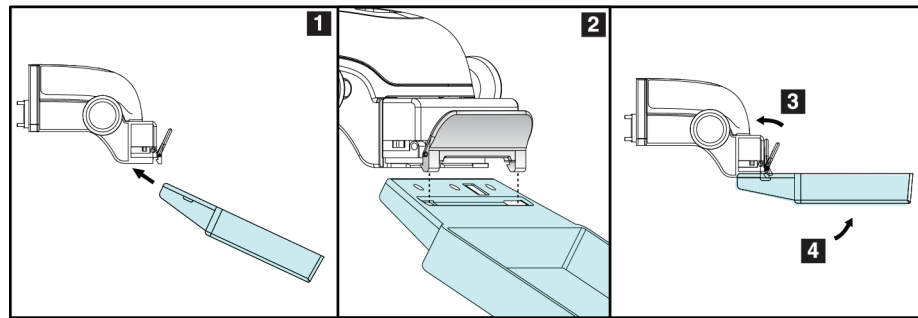


Figure 49: How to Install a Compression Paddle

See the *figure How to Remove the Compression Paddle* on page 67 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 (item 1).
2. Lower the paddle (item 2) and remove the paddle from the Compression Device (item 3), then release the Paddle Clamp.

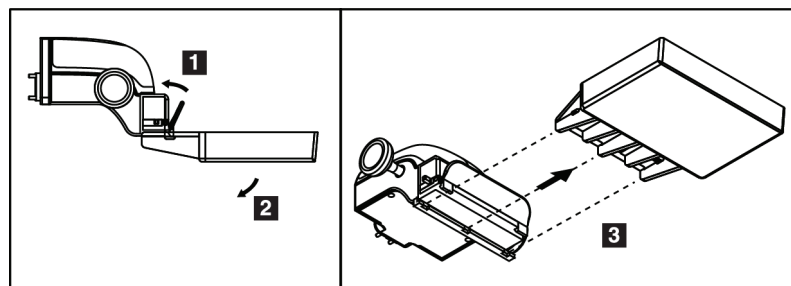


Figure 50: How to Remove the Compression Paddle

4.7 Maintenance and Cleaning

Clean the paddles after each use. See *Maintenance and Cleaning* on page 77 for cleaning instructions.

4.8 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.

4.9 FAST Compression Mode

4.9.1 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.

4.9.2 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.

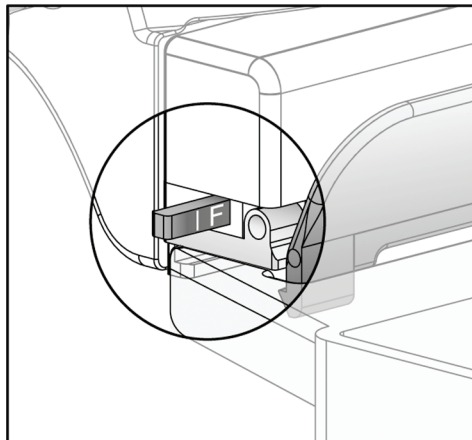


Figure 51: The FAST Compression Mode Slide

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 *Magnification Paddles* on page 66).

5.1 How to Install and Remove the Magnification Stand

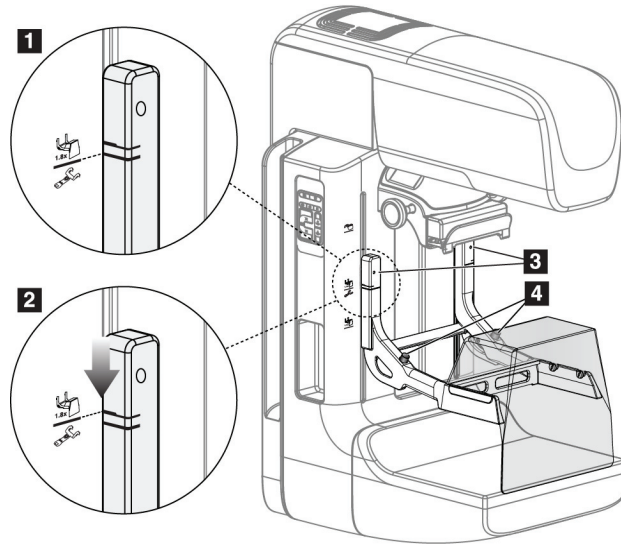


Figure 52: Installation of the Magnification Stand

To install the Magnification Stand:

1. Remove the Face Shield (see *The Patient Face Shields* on page 62) and the compression paddle.
2. Move the Compression Device completely to the top.
3. Hold the stand on each side just below the black buttons, item 4. Do not press the black buttons.



Note

The black buttons are used only when removing the Magnification Stand.



Note

There are two sets of hook locations for the Magnification Stand—One set is for 1.8x, and the other set is for 1.5x. See numbers 2 and 3 in the *figure C-Arm Accessories* on page 61.

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 item 1 in the previous figure.
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 item 2 in the previous figure.

Selenia Dimensions Instructions for Use

Chapter 5—How to Use the Accessories Magnification Stand



6. The locking pins slide into holes and lock the device. You hear an audible click.



Note

If the Magnification Stand is not installed correctly, there is an indicator with a red shaft which protrudes. See item 3 in the previous figure. When the stand is installed correctly, the indicator is retracted.

To remove the Magnification Stand:

1. Remove the Magnification paddle.
2. Hold the handles of the Magnification Stand and press the black buttons.
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

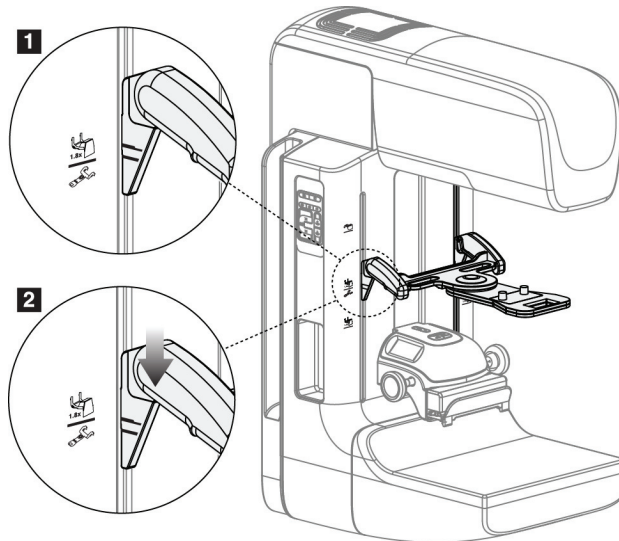


Figure 53: How to Attach the Localization Crosshair Device

6.1.1 To install the Localization Crosshair Device

1. Remove the face shield (see *The Patient Face Shields* on page 62).
2. Move the Compression Device below the mounting slots, indicated by a crosshair icon. See item 2 in the *figure C-Arm Accessories* on page 61.
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

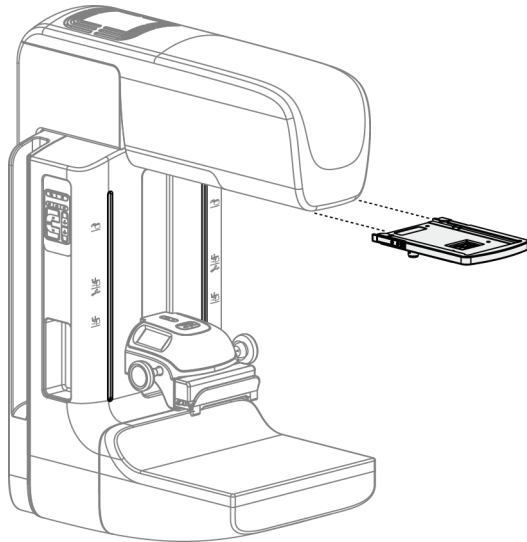


Figure 54: How to Install and Remove the Magnification Crosshair Device

6.3.1 To install the Magnification Crosshair Device

1. Remove the face shield (see *How to Install or Remove the Conventional Face Shield* on page 64).
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.

Chapter 6 Clinical Procedures



Warning:

The C-Arm movement is motorized.



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

1.1 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.

1.2 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.

1.3 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 Screening Procedure Example

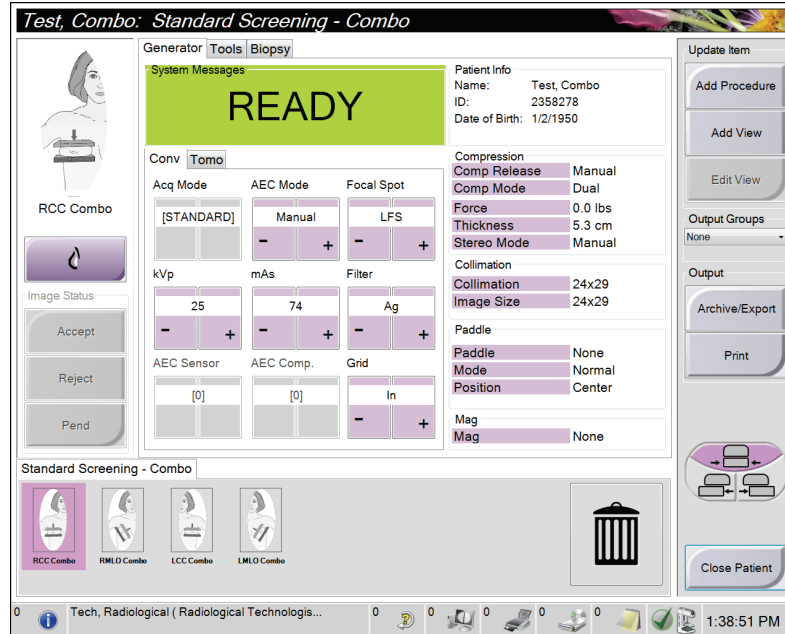


Figure 55: Screening Example

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 *How to Set the Exposure Parameters* on page 38 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 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



Note

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

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 show 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.



Note

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

Chapter 7 Maintenance and Cleaning

1.0 Cleaning

1.1 General Information About Cleaning

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



Caution:

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

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

1.2 For General Cleaning

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



Caution:

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

If 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.



Warning:

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



Caution:

To prevent damage to the electronic components, do not spray disinfectant on the system.

1.3 To Prevent Possible Injury or Equipment Damage

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

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

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

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



Caution:

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

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

1.4 Acquisition Workstation

1.4.1 How to Clean the Preview Display

Avoid touching the display screen.

Use care when cleaning the outer surface of the LCD screen. Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths are recommended.

- 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.

1.4.2 How to Clean the Touchscreen Display

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

1.4.3 How to Clean the Keyboard

Wipe the surfaces with a CRT wipe. If necessary, clean the keyboard with a vacuum. If liquids enter the keyboard, contact Technical Support for a replacement.

1.4.4 How to Clean the Fingerprint Scanner



Caution:

To protect the Fingerprint Scanner:

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

To clean the Fingerprint Scanner 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 Scanner window.

2.0 Maintenance

2.1 Preventive Maintenance Schedule



Note

The Preventive Maintenance Schedule for the Service Engineer is in the Service Manual.

Table 5: User Preventive Maintenance

Maintenance Task Description	Recommended Frequency					
	Each Use	Weekly	Biweekly	Monthly	Bimonthly	Semiannually
Clean & disinfect paddle	x					
Clean & disinfect breast platform	x					
Visually inspect all paddles for damage	x					
Detector Flat Field Calibration *		x				
Artifact Evaluation *		x				
Phantom Image *		x				
Signal to Noise / Contrast to Noise Measurements *		x				
Geometry Calibration (Tomosynthesis Option) *						x
Compression Thickness Indicator *			x			
Visual Checklist *				x		
Compression *						x

* Refer to Quality Control Manual

2.2 About Reclamation

Reclamation is an automatic function that makes disk storage space available for new procedures. Configurable parameters let a given number of images collect before space reclamation starts.

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.)

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Chapter 8—System Administration Interface
How to Use the Admin Screen



Refer to the *table Admin Screen Functions* on page 83 for descriptions of the Admin screen functions.



Figure 56: The Admin Screen

Table 6: Admin Screen Functions

Section	Button Name	Function
Operators	Manage Operators	Add, delete or change Operator information.
	My Settings	Change the information for the current Operator.
Procedures	Procedure Editor	Add or Edit the procedures, or change the view order for each user.
	Procedure Order	Change the procedure list order.
	QAS	Access the QAS Needle Test screen.
Quality Control	Quality Control	Select a Quality Control task to perform or mark completed.
	QC Report	Create a QC Report.
	Test Patterns	Select and send the test patterns to output devices.
	Reject and Repeat Report	Create a Reject and Repeat Report.
System	System Tools	The Interface for Service for the configuration of and identification of problems in the Acquisition Workstation.
	System Defaults	Set the Gantry default values.
	System Diagnostics	Displays the status of all subsystems.
	Log Viewer	Review the system log files.
	Preferences	Set the system preferences.
	About	Describes the system.
	Biopsy Devices	Lists available biopsy devices.
Connectivity	Query Retrieve	Query the configured devices.
	Import	Import the data from a DICOM source.
	Manage Output Groups	Add, delete, or edit output groups.
	Incoming Log	Shows log entries for images that do not import during manual import or DICOM store.
	Archive	Send local studies to networked storage or export to removable media devices.
Connectivity	Query Retrieve	Query the configured devices.
	Import	Import the data from a DICOM source.
	Manage Output Groups	Add, delete, or edit output groups.
	Incoming Log	Shows log entries for images that do not import during manual import or DICOM store.
	Archive	Send local studies to networked storage or export to removable media devices.

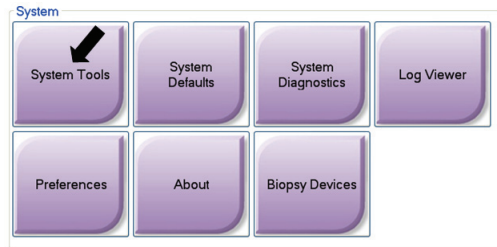
You must have permissions to access all features. The permission level controls the functions you can change.

2.0 How to Use the System Tools

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

To access the System 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

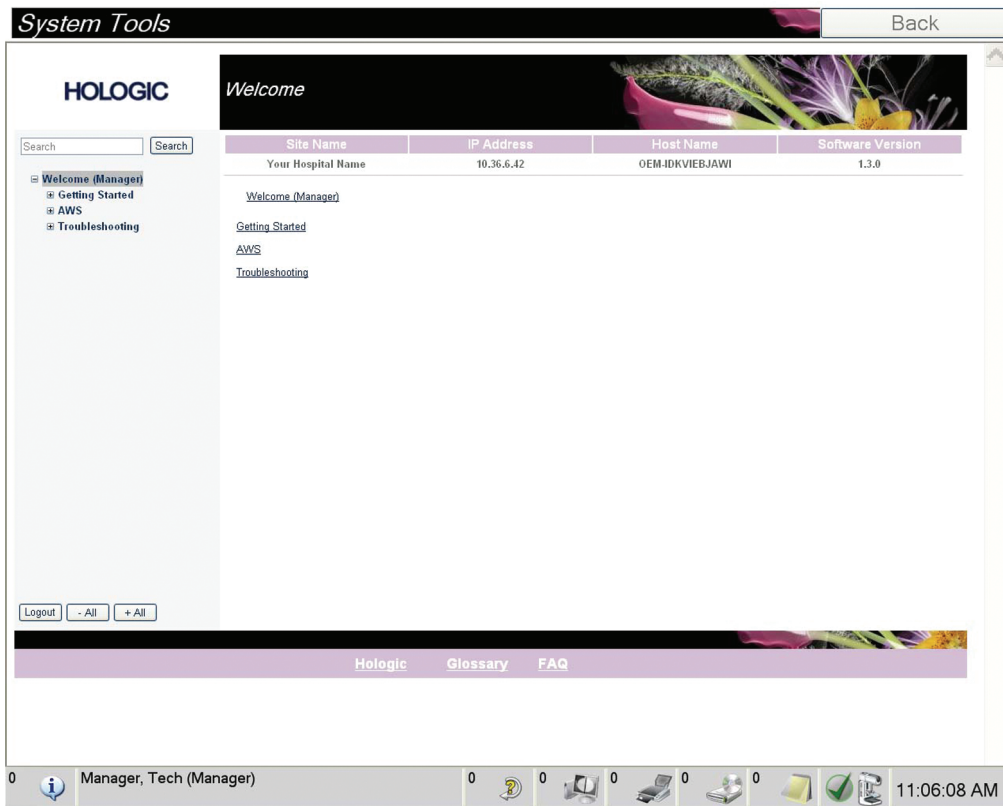


Table 7: Radiologic Technologist Manager—Service Tools Functions

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

3.0 How to Use the Archive Tool

The archive feature in the Admin screen lets you:

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

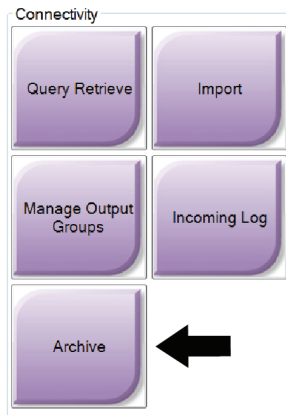


Figure 57: Archive Tool Button



Note

Radiologic technologists do not have access to the Archive tool.

To archive:

1. Select the **Archive/Export** button in the Admin screen to show the On Demand Archive screen.
2. To search for a patient, enter at least two characters in the Search parameters area and click the magnifying glass.

A list of patients that match the search criteria displays.

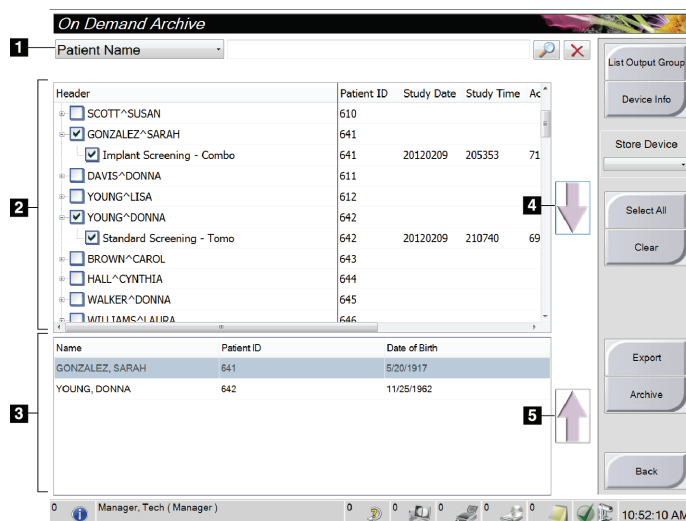


Figure 58: The On Demand Archive Screen

Figure Legend

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

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



Note

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

- Select the procedures for each patient.
 - Select the Down Arrow (item 4) on the screen to move the selected patients to the Patients To Be Archived area (item 3).
 - Select the Up Arrow (item 5) on the screen to remove the selected patients from the To Be Archived area (3).
4. Select a storage device.
 - Select an option from the Store Device drop-down menu.
 Or
 - Select the **List Output Group** button, then select an option.
 5. Select the **Archive** button. The list in the To Be Archived area copies to the selected archive devices



Note

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

To Export:

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



Note

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

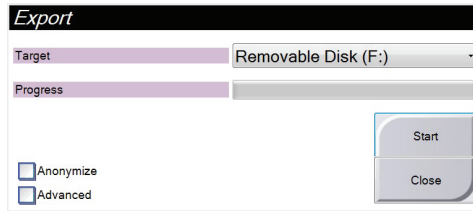
- Select the procedures for each patient.
 - Select the Down Arrow (item 4) on the screen to move the selected patients to the Patients To Be Archived area (item 3).
 - Press the Up Arrow (item 5) on the screen to remove the selected patients from the To Be Archived area (3).
2. Select the **Export** button.

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How to Use the Archive Tool



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



4. Select other options, if necessary:
 - **Anonymize:** to anonymize patient data.
 - **Advanced:** to select a folder on your local system to keep the selections, and also to select the Export types.
5. Select the **Start** button to copy the selected images to the selected device.

Appendix A Specifications

1.0 Product Measurements

1.1 Tubestand (Gantry with C-Arm)

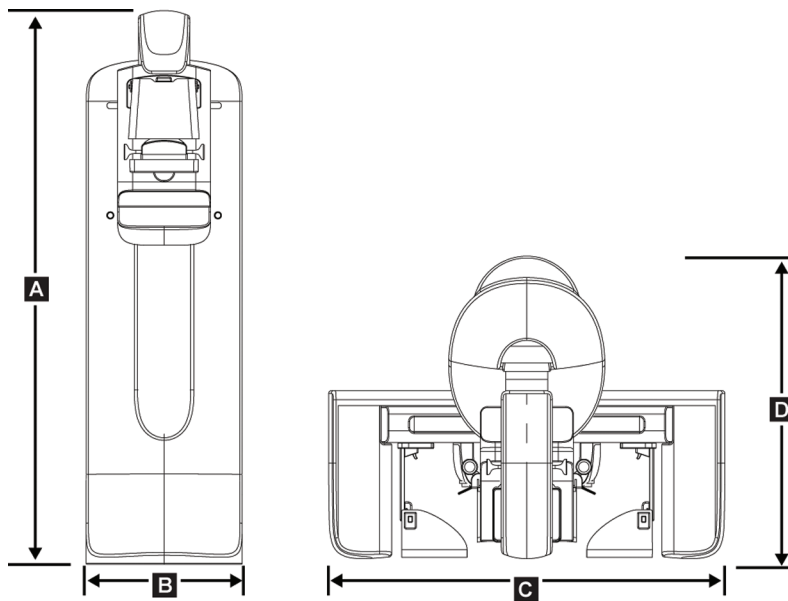


Figure 59: Tubestand Dimensions

A.	Height	223 cm (87.8 inches)
B.	Width	66 cm (26 inches)
C.	Width	173 cm (68 inches)
D.	Depth	138 cm (54.25 inches)
	Weight	Maximum of 400 kg (882 pounds)

1.2 Premium Acquisition Workstation

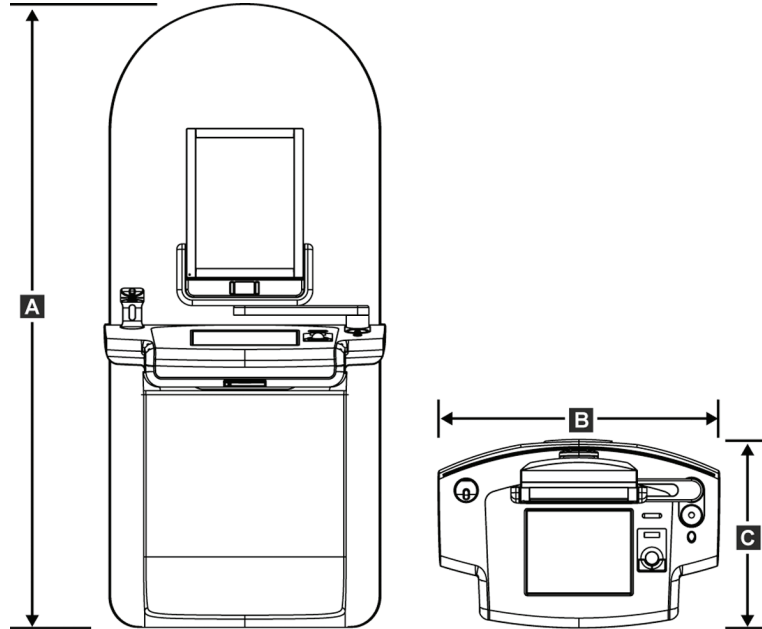


Figure 60: Premium Acquisition Workstation Dimensions

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

1.3 Standard Acquisition Workstation

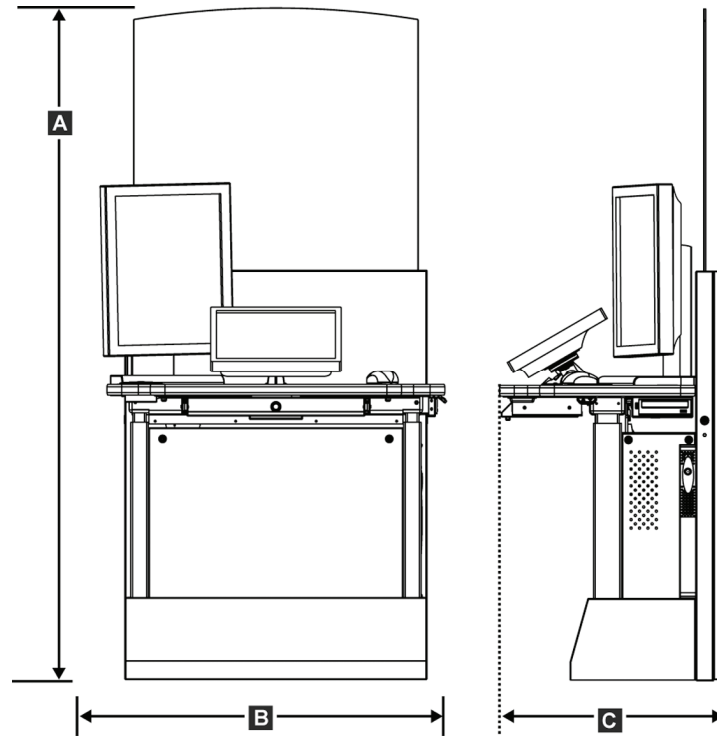


Figure 61: Standard Acquisition Workstation Dimensions

A.	Height	203 cm (80 inches)
B.	Width	107 cm (42 inches)
C.	Depth	76 cm (30 inches)
	Weight	219 kg (462 pounds)

2.0 Operation and Storage Environment

2.1 General Conditions for Operation

<i>Temperature Range</i>	20 °C (68 °F) to 30 °C (86 °F)
<i>Relative Humidity Range</i>	20% to 80% without condensing moisture

2.2 Storage Environment

2.2.1 Gantry

<i>Temperature Range</i>	-10 °C (14 °F) to 40 °C (104 °F)
<i>Relative Humidity Range</i>	0% to 95% without condensing moisture

(Put in a package for storage in a building.)

2.2.2 X-ray Detector

<i>Temperature Range</i>	10 °C (50 °F) to 30 °C (86 °F) indefinitely 10 °C (50 °F) to 35 °C (95 °F) for a maximum of 12 hours
<i>Maximum rate of temperature change</i>	Less than 10 °C (50 °F) per hour
<i>Relative Humidity Range</i>	10% to 80% without condensing moisture

(Put in a package for storage in a building.)

2.2.3 Acquisition Workstation

<i>Temperature Range</i>	-10 °C (14 °F) to 40 °C (104 °F)
<i>Relative Humidity Range</i>	0% to 95% without condensing moisture

(Put in a package for storage in a building.)

3.0 Acquisition Workstation Technical Information

<i>Operating System</i>	Windows XPE/Windows 7
<i>Computer Memory</i>	4 GB RAM minimum
<i>Hard Disk Drive Capacity</i>	750 GB minimum
<i>Storage Device Disks</i>	DVD+/-RW
<i>Display</i>	2 or 3 Megapixels as required
<i>Touchscreen Display</i>	17-inch diagonal, minimum
(Touch screen not required for Standard Acquisition Workstation)	
<i>Network Interface</i>	100/1000Base-T Ethernet
<i>Remote Diagnostics</i>	Internet
<i>Graphic User Interface</i>	Application specific
<i>Radiation Shield Lead (Pb) equivalent</i>	0.5 mm lead for x ray energy to 35 kV

4.0 Electrical Input

4.1 Tubestand

<i>Mains Voltage</i>	200/208/220/230/ 240 VAC ±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 ±5%
<i>Average Current over 24 Hours</i>	< 5 A
<i>Peak Line Current</i>	4 A (65 A maximum for ≤ 5 seconds)

4.2 Acquisition Workstation

<i>Mains Voltage</i>	100/120/200/208/220/230/240 VAC ±10%
<i>Mains Frequency</i>	50/60 Hz ±5%
<i>Power Consumption</i>	< 1000 watts
<i>Duty Cycle (Standard AWS)</i>	10% ~ 6 minutes per hour or 2 minutes on, 18 minutes off

5.0 Tubestand Technical Information

5.1 C-Arm

<i>Rotation Range</i>	Conventional Mammography: +195° +3°/-0.5° to 0° ±0.5° to -155° +0.5°/-3° Tomosynthesis option: +180° ±0.5° to 0° ±0.5° to -140° ±0.5°
<i>Absolute Angular Position</i>	accurate to ±0.5°
<i>Rotation Acceleration</i>	18°/s ² +18/-9%
<i>Rotation Deceleration</i>	18°/s ² +18/-9%
<i>Rotational Positioning Angular Velocity</i>	18°/s ±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 ±15% (1.66 inches/s ±15%)</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>±20 N (±4.5 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>±0.5 cm (±0.2 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</i>
	<i>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 (nominal) (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 8: Maximum mA Setting as a Function of kV

kV	LFS mA	SFS 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

<i>Type</i>	Constant Potential High Frequency Inverter
<i>Rating</i>	7.0 kW, maximum (isowatt), 200 mA at 35 kV
<i>Electrical Power Capacity</i>	9.0 kW maximum
<i>kV Range</i>	20 kV to 49 kV in 1 kV increments
<i>kV accuracy</i>	±2%, over range 20-49 kVp
<i>mAs Range</i>	3.0 mAs to 500 mAs in Manual Mode mAs (8 mAs minimum in AEC Mode)
<i>mAs Accuracy</i>	±(10% + 0.2 mAs)
<i>mA Range</i>	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.

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.

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Appendix B—The System Messages and Alert Messages
Types of Messages and Alert messages



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.

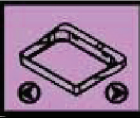









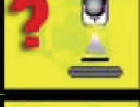

2.1.5 Alert Messages

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

Table 9: System Messages

Icon	Message	User Action
	Paddle is moving	There is no action required.
	Sending notice	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	Fully extend or fully retract the Face Shield. (Tomosynthesis option)
	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.
	Compression is less than 4.5 cm during calibration	Move the compression paddle higher than 4.5 cm to complete the calibration procedure.
	FAST compression is engaged	Disengage FAST compression and install a paddle indicated for this mode.
	License is missing	One of your features does not have a license.
	License has expired	One of your features does not have a valid license and is disabled.
	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)

Selenia Dimensions Instructions for Use

Appendix B—The System Messages and Alert Messages
Types of Messages and Alert messages



Table 9: System Messages

Icon	Message	User Action
	Configuration file is missing	Applies to Service Personnel.
	Waiting for Detector	There is no action required.
	System in Test Mode	Applies to Service Personnel.
	Affirm cable is not connected	Connect the Affirm cable to the side of the gantry.
	Affirm is not locked	Lock both sides of the Affirm.
	BCM cable is not connected	Connect the Biopsy Control Module cable to the side of the Affirm.
	View requires Affirm to be installed OR View cannot be completed with Affirm installed	Install the Affirm to acquire this view. OR Remove the Affirm to acquire this view.
	Tube needs to be manually positioned (move to 0 degrees)	Rotate the C-arm to 0 degrees to complete the next view.
	Tube needs to be manually positioned (move to -15 degrees)	Rotate the C-arm to -15 degrees to complete the next view.
	Tube needs to be manually positioned (move to 15 degrees)	Rotate the C-arm to +15 degrees to complete the next view.
	The Emergency Stop switch has been deactivated.	Turn the Emergency Off switch one-quarter turn to reset the switch.

Appendix C

Dimensions Mobile

1.0 General Information

This appendix describes the Selenia Dimensions system installed in a mobile environment.

2.0 Conditions for Safety and Other Precautions

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



Warning:

The Dimensions radiation shield is not approved for mobile use and is not provided. The coach manufacturer must provide adequate shielding.



Caution:

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



Caution:

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



Caution:

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

3.0 Mobile Specifications

3.1 Shock and Vibration Limits

Vibration Limit

Maximum of 0.30 G (2 Hz to 200 Hz), measured at the point where the system mounts to the coach.

Shock Limit

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

3.2 Coach Environment

3.2.1 Operation Environment

Temperature Range

20 °C (68 °F) to 30 °C (86 °F)

Relative Humidity Range

20% to 80% without condensing moisture

3.2.2 Non-operating/Transit Environment

Temperature Range

10 °C (50 °F) to 35 °C (95 °F) for a maximum of 12 hours

10 °C (50 °F) to 30 °C (86 °F) indefinitely

Maximum Rate of Temperature Change

<10 °C/hr.

Relative Humidity Range

10% to 80% without condensing moisture

4.0 Electrical Input

4.1 Gantry

<i>Mains Voltage</i>	200/209/220/230/ 240 VAC ±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 ±5%
<i>Average Current over 24 Hours</i>	< 5 A
<i>Peak Line Current</i>	4 A (65 A maximum for 3 seconds)

4.2 Acquisition Workstation

<i>Mains Voltage</i>	100/120/200/ 208/220/230/ 240 VAC ±10%
<i>Mains Frequency</i>	50/60 Hz ±5%
<i>Power Consumption</i>	< 1000 watts

5.0 Prepare the System for Travel

Before travel, perform these steps:

1. Rotate the C-Arm to 0 degrees (CC position).
2. Lower the C-Arm to its lowest position.
3. Turn off the system through the user interface.
4. Lock the keyboard tray:
 - a. Close the tray.
 - b. Find the knob under the tray.
 - c. Turn the knob 90° until the knob fits into the lock. Position A (below) is the locked position.
5. Remove all system accessories.
6. Put all accessories in a safe storage area.

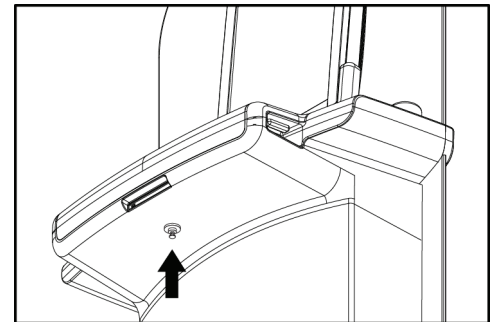
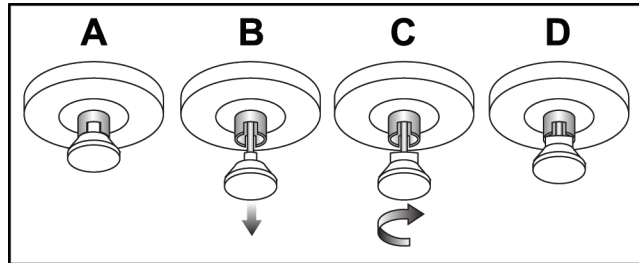


Figure 62: Keyboard Tray Lock Knob

6.0 Prepare the System for Use



1. Unlock the keyboard tray:
 - a. Find the knob under the tray.
 - b. Pull the knob down.
 - c. Turn the knob 90°. This position keeps the latch open. Position D (in the previous figure) is the unlocked position.
2. Pull the tray out, if needed.

7.0 Test the System after Travel

7.1 Selenia Dimensions Controls and Functional Tests

Perform the Controls and Functional Tests. Refer to *Perform the Functional Tests* on page 22.

- Compression Up/Down
- Compression Release
- C-Arm Rotation
- C-Arm Up/down
- Collimator Override
- Light Field Lamp
- Shifting Paddle System
- Emergency Off Switches

8.0 Quality Control Tests

Refer to your quality control manual for quality system checks.

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