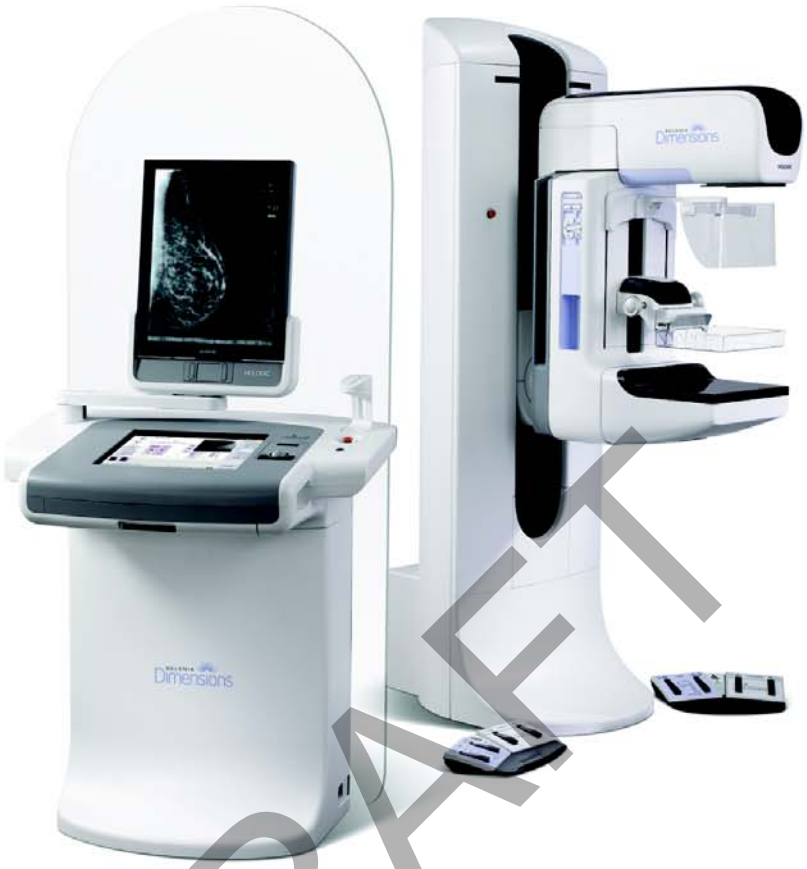
BREAST IMAGING SOLUTIONS



User Manual

SELENIA® Dimensions®

HOLOGIC®

MAN-01964

SELENIA® Dimensions®

Selenia Dimensions User Manual

Part Number MAN-01964

Revision 001

November 2010

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CE 0044

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Preface

1.0 Intended Use Statements

℞ Only United States Federal Law restricts this device to use by, or on the order of, a physician.

1.1 Intended Use

The Selenia® Dimensions® Full Field Digital Mammography system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions Full Field Digital Mammography system is intended for use in the same clinical applications as traditional screen-film mammographic systems. Mammographic images can be interpreted on either hard copy film or soft copy review workstations.

1.2 Intended Use (Tomosynthesis Option)

The Selenia® Dimensions® Full Field Digital Mammography system acquires the digital mammography images which can be used for screening and diagnosis of breast cancer. The Selenia Dimensions system is intended for the clinical methods used with conventional Full Field Digital Mammography systems. The Selenia Dimensions system can acquire conventional full field digital mammograms in two dimensions and tomosynthesis mammograms in three dimensions. The screening examination has a conventional image set, or a conventional image set and a tomosynthesis image set.

Note… *In Canada, 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 Users

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

4.0 Skills Needed for System Use

You must know how to do the following:

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

5.0 Training Requirements

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

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

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

6.0 Quality Control Requirements

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

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

7.0 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.)

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 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.*

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).
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 planes or slices within the object (Tomosynthesis option).
UPS	Uninterruptible Power Supply

11.0 International Symbols

This section describes the International Symbols on the Selenia Dimensions.

	Potential Equalization terminal	Connection for a conductor, except the Protective Earth terminal, for a direct connection between two or more pieces of electrical equipment.
	Protective Earth terminal	Connector used for connection to ground of the line cord or ground cable of the equipment and no other purpose.
	Off	Power disconnected from the main power source.
	On	Power connection to the main power source.
	Off	Only a part of the equipment is disconnected from the main power source.
	On	Only a part of the equipment is connected to the main power source.
	WEEE	Shows the compliance to the EC Directive on Waste Electrical and Electronic Equipment (WEEE).
	Dangerous Voltage	Identifies an area of possible lethal voltage.
	Manufacturer	
	Date of Manufacture	
	Radio Icon	This system transmits non-ionizing radiation
	X-ray Radiation	Caution—Radiation

12.0 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

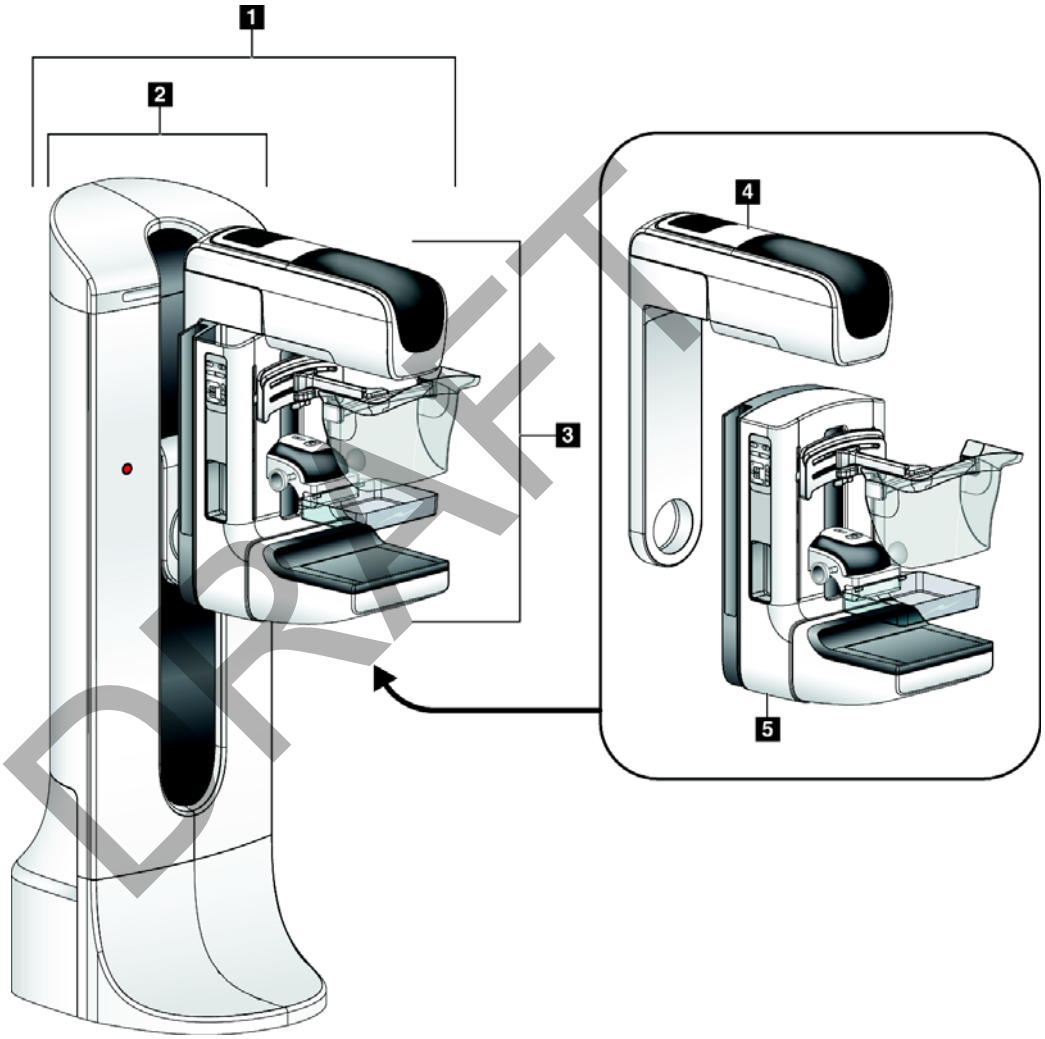


Figure 1-1: Selenia Dimensions

Legend for Figure 1-1

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

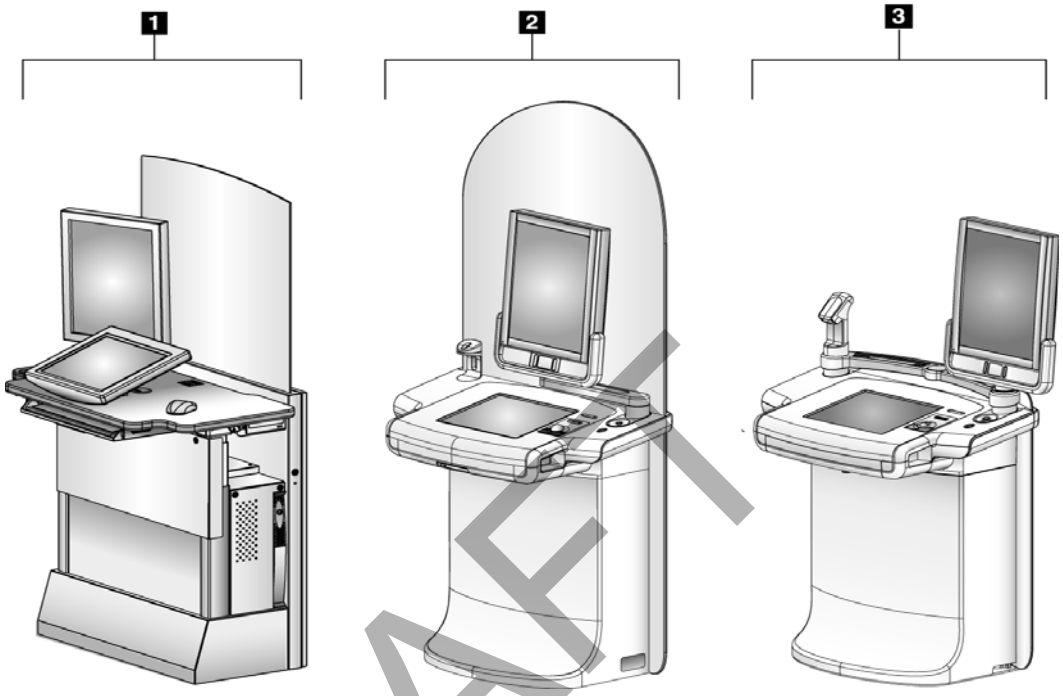


Figure 1-2: Acquisition Workstations

Legend for Figure 1-2

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

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

WARNING! ***Do not 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.***

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

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

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

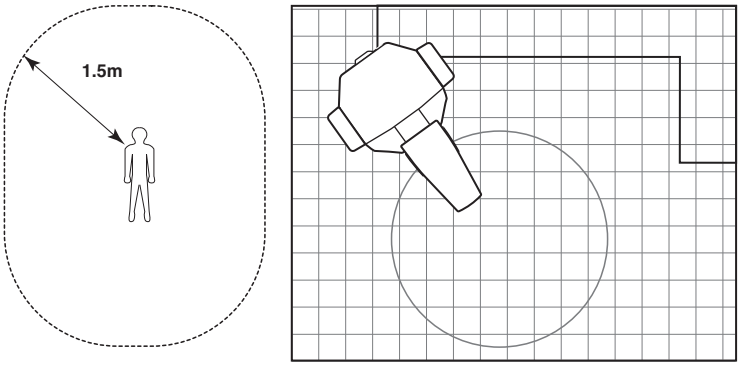
Note… *Hologic does not provide the Gantry power cable for some countries. If the power cable is not provided, the installed cable must meet the following requirements and all local codes that apply: 3 conductor, 8 AWG (10 mm^2) copper not more than 25 feet (7.62 meters) in length.*

2.2 Patient Safety

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

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

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



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

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

Warning: ***The C-Arm movement 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.***

2.3 Radiation Safety

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

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

2.4 Data Loss

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

Caution: ***Never turn off the Acquisition Workstation Circuit Breaker except in emergency. The circuit breaker can turn off the Uninterruptible Power Supply (UPS) and risk data loss.***

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

2.5 Equipment Damage

Caution: ***Do not put any heat source on the image receptor.***

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

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

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

Caution: ***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 Chapter 2, page 25, for complete information.

2.7 Interlocks

The Selenia Dimensions has safety interlocks:

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

3.0 Compliance

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

3.1 Compliance Requirements

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

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

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 13485:2003
- CAN/CSA: Medical Electrical Equipment Part 1: C22.2 No. 601.1–M90 (R2005)—General Requirements for Safety
- EN 60601-1:1990 +A1+A11+A12+A2+A13 Medical Electrical Equipment—General Requirements for Basic Safety and Essential Performance
- ETSI EN 300 330-1 V1.7.1(2010-02)—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: V1.8.1 (2008-04)—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]
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1:1988 +A1+A2:1995Medical Electrical Equipment—General Requirements for Safety
- IEC 60601-1-1:2000 Medical Electrical Equipment—Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2007 Medical Electrical Equipment—Collateral Standard: Electromagnetic Compatibility for Medical Electric Systems
- IEC 60601-1-3:1994 Medical Electrical Equipment—Collateral Standard: Requirements for Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-4:1996 +A1:1999 Medical Electrical Equipment—Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-2-28:1993 Medical Electrical Equipment—Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis
- IEC 60601-2-32:1994 Medical Electrical Equipment—Particular Requirements for the Safety of Associated Equipment of X-ray Equipment
- IEC 60601-2-45:2001 Medical Electrical Equipment—Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices
- RSS-210: Issue 7, 2007
- UL 60601-1 1st Edition: Medical Electrical Equipment, Part 1—General Requirements for Safety

4.0 Label Locations

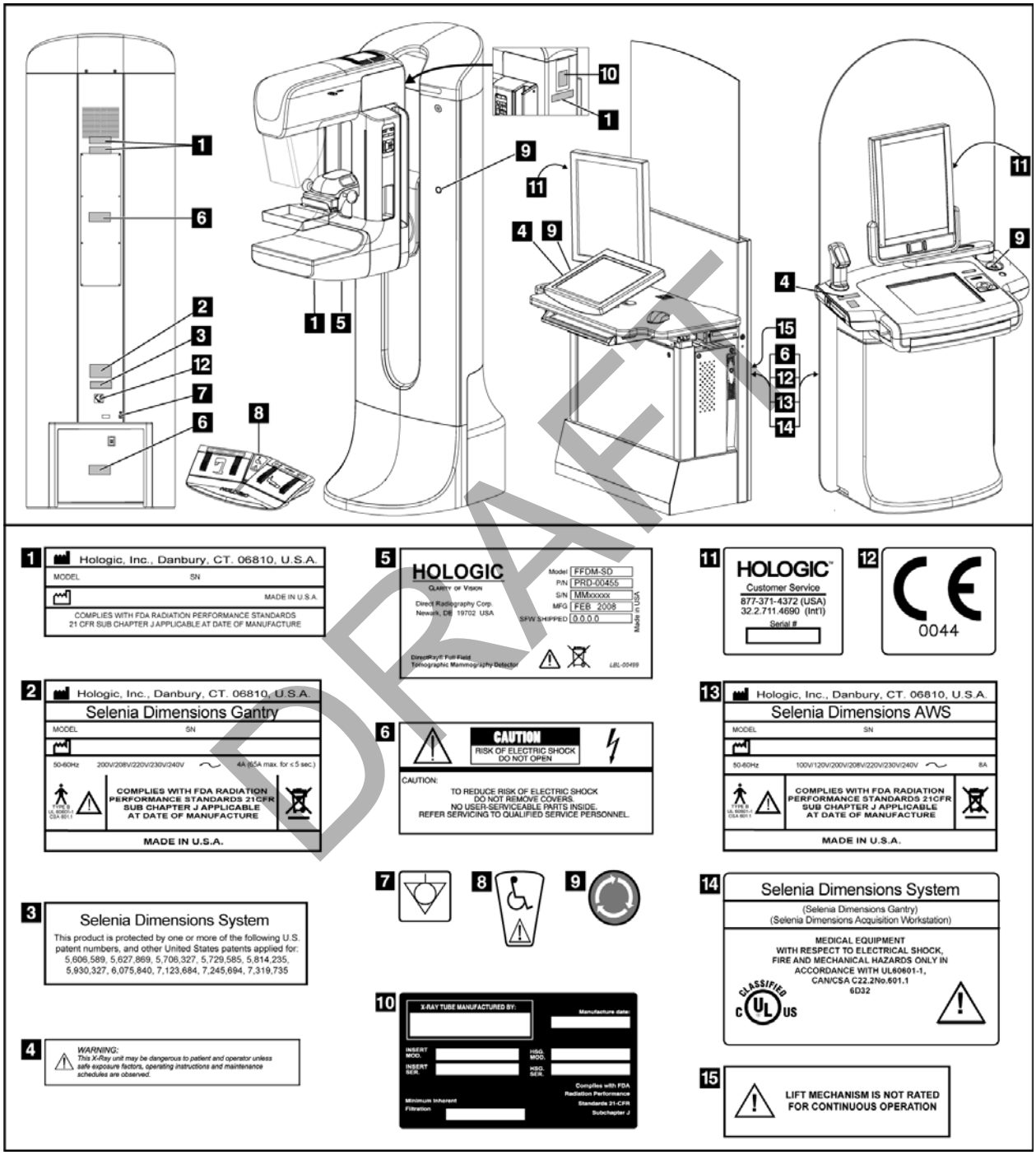


Figure 1-3: Label Locations

Chapter 2—System Controls and Indicators

1.0 System Power Controls

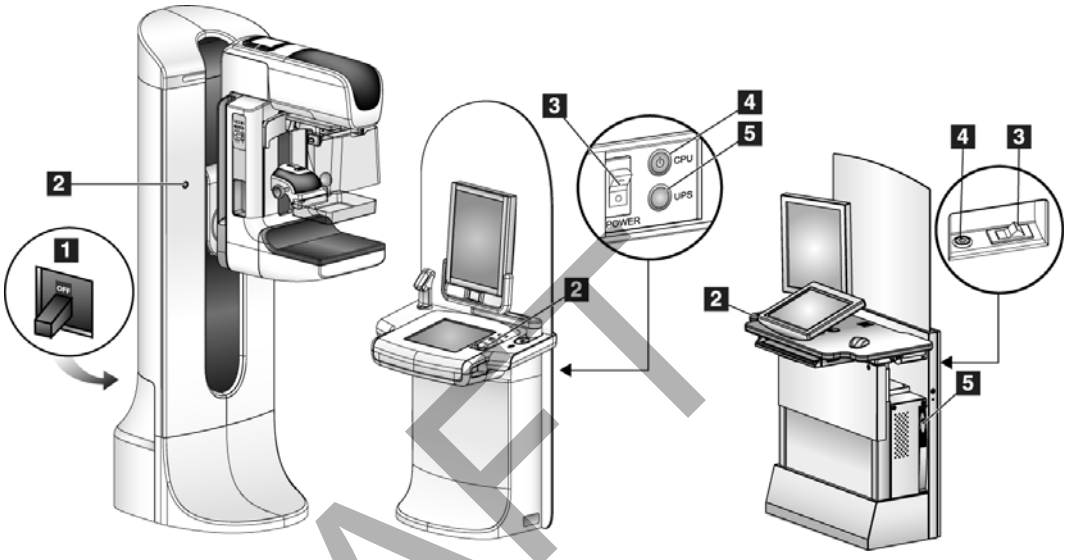


Figure 2-1: System Power Controls

Legend for Figure 2-1

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

2.0 Acquisition Workstation Controls and Indicators

2.1 Premium Acquisition Workstation Controls and Displays

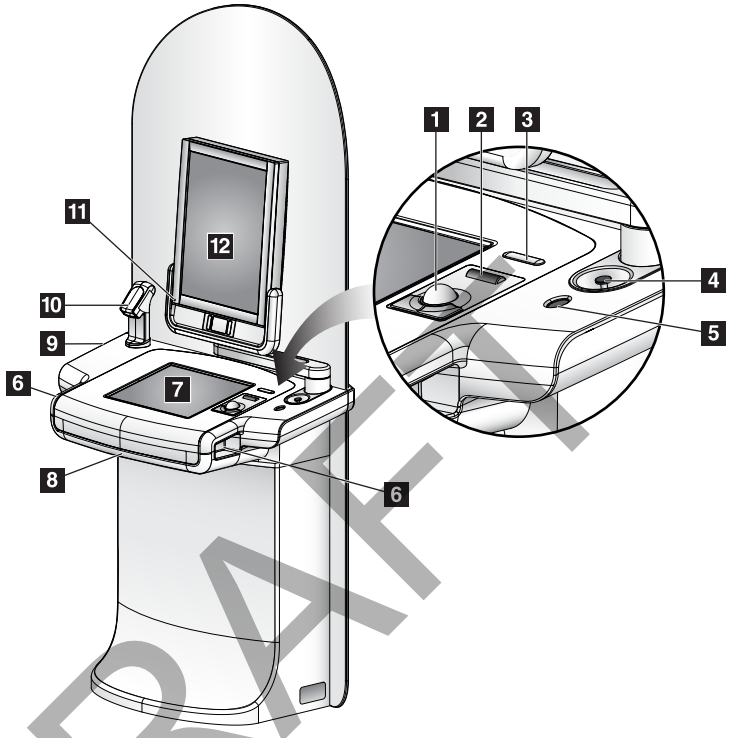


Figure 2-2: Premium Acquisition Workstation Controls and Displays

Legend for Figure 2-2

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

2.2 Standard Acquisition Workstation Controls and Displays

Legend for Figure 2-3

1. Keyboard
2. Control Display
3. Left X-Ray Switch
4. Emergency Off Switch
5. Bar Code Scanner (Optional)
6. Preview Display
7. CPU Reset Switch
8. Circuit Breaker Power On Switch
9. Mouse
10. DVD Drive
11. Height Adjustment Switch
12. UPS
13. Computer
14. Right X-Ray Switch
15. UPS Power Button

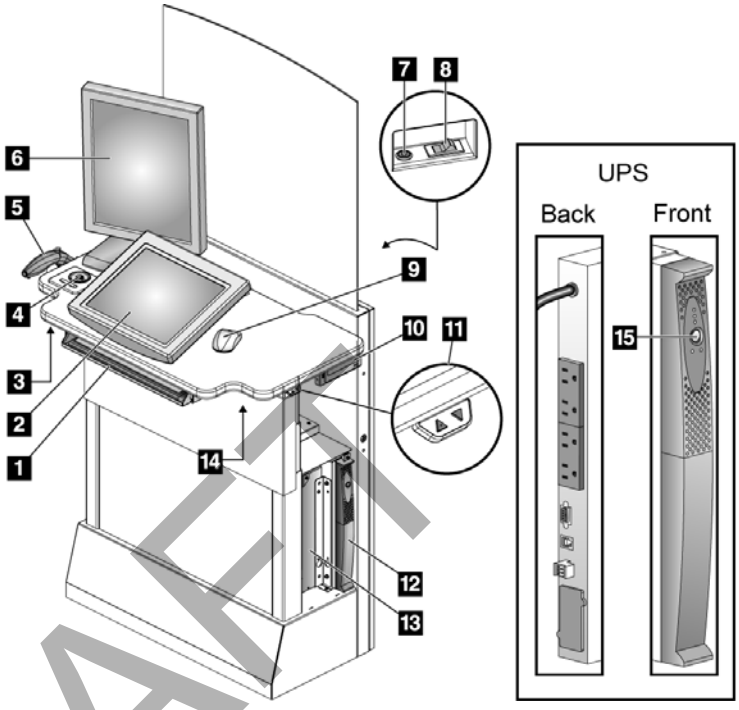


Figure 2-3: Standard Acquisition Workstation Controls and Displays

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.

3.0 Tubestand Controls and Indicators

Legend for Figure 2-4

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

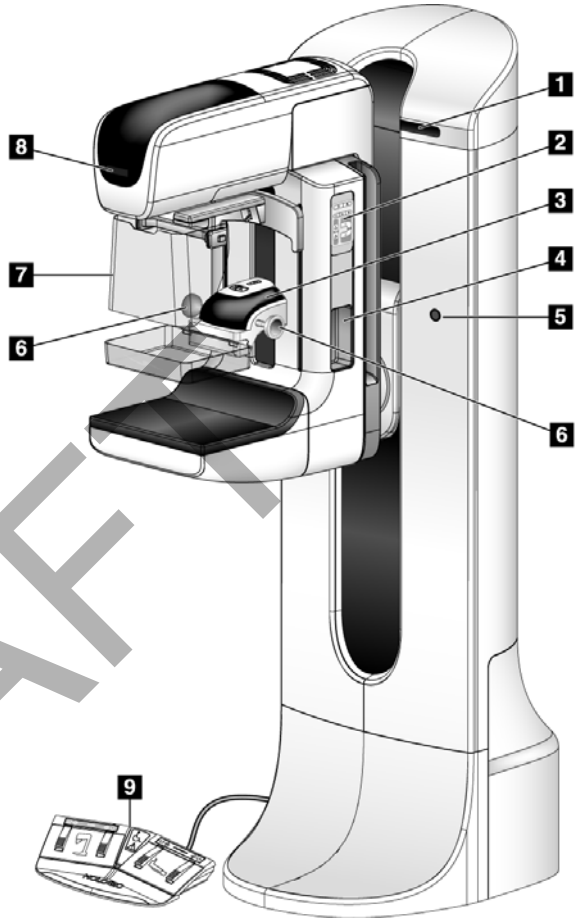


Figure 2-4: Tubestand Controls and Indicators

3.1 C-Arm Controls

The C-Arm Controls provide the Collimator and C-Arm functions. See Section 6.0, page 19.

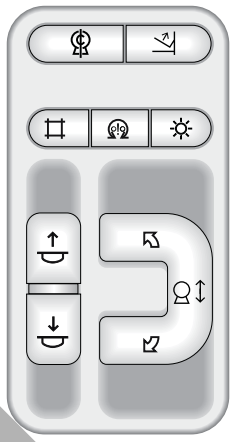


Figure 2-5: C-Arm Controls

3.2 Compression Device Controls and Displays

Legend for Figure 2-6

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

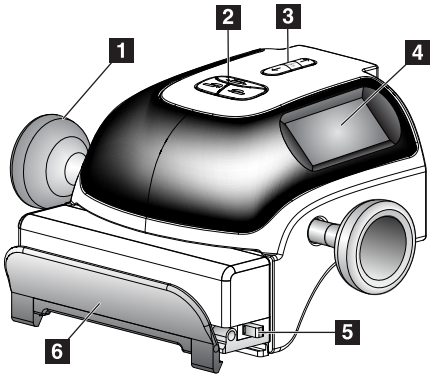


Figure 2-6: Compression Device

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)

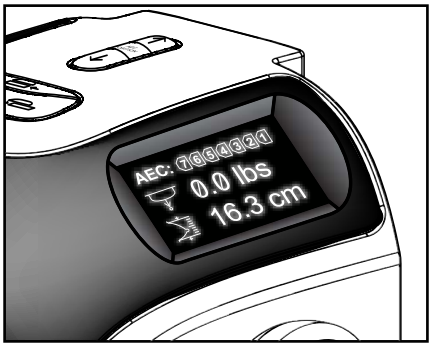


Figure 2-7: Compression Display

3.3 Tubehead Display

The Tubehead Display shows:

- SID
- Filter Type
- Collimator Setting
- Paddle Position

Figure 2-8: Tubehead Display

3.4 Dual Function Footswitches

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

To use the footswitches:

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

Legend for Figure 2-9

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

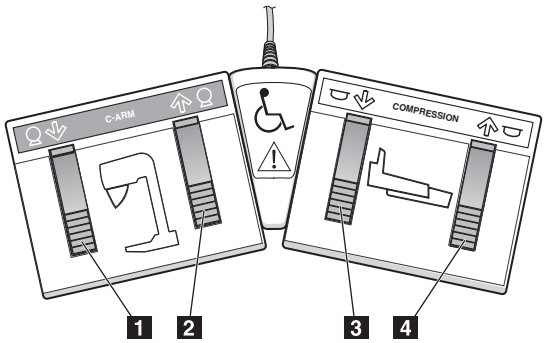


Figure 2-9: Dual Function Footswitches

4.0 How to Turn On the Selenia Dimensions

4.1 Preparation

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

4.2 Startup

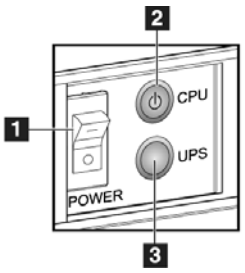


Figure 2-10: Premium Acquisition Workstation Power Buttons

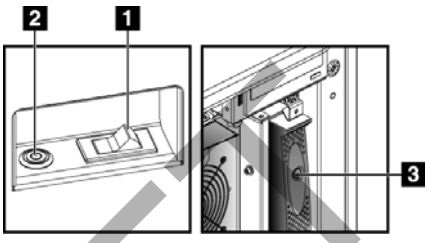


Figure 2-11: Standard Acquisition Workstation Power Buttons

Legend for Figure 2-10 and Figure 2-11

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.

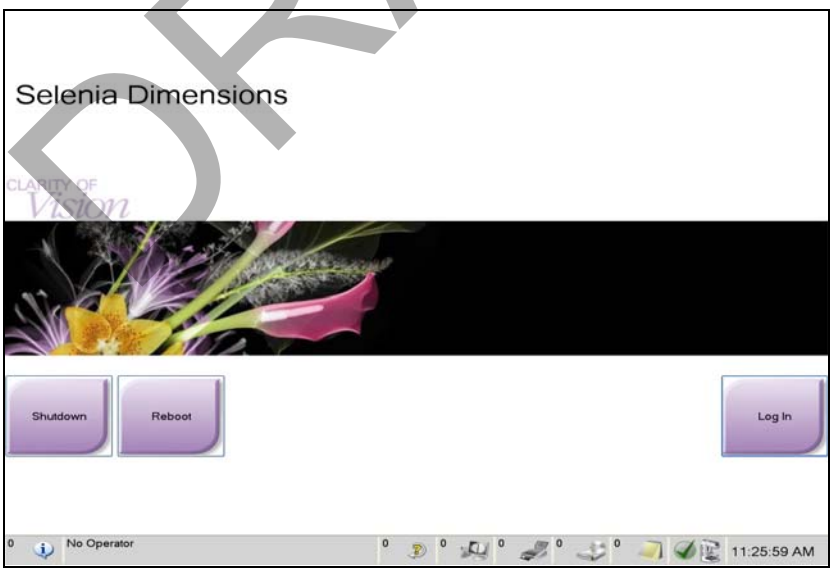


Figure 2-12: The Startup Screen

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 forty-five 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

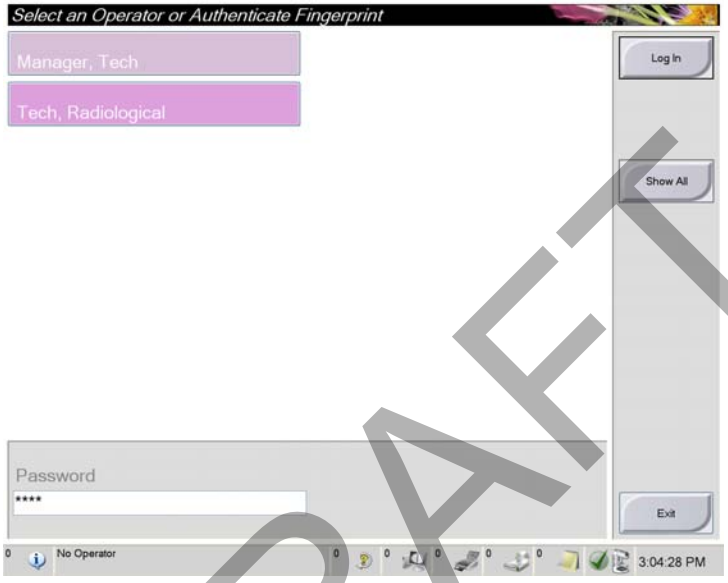


Figure 2-13: How to Log In

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

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

   Or

   Validate your fingerprint.

5.0 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

Legend for Figure 2-14

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

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

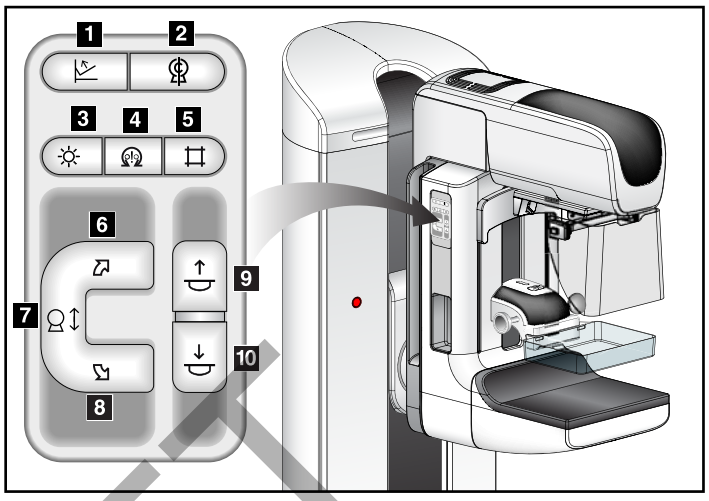


Figure 2-14: C-Arm Controls (left side shown)

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

Table 2-1: C-Arm Functional Tests

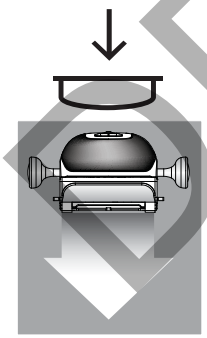
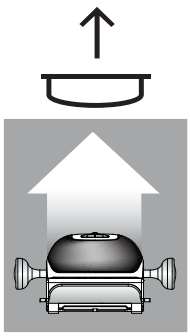
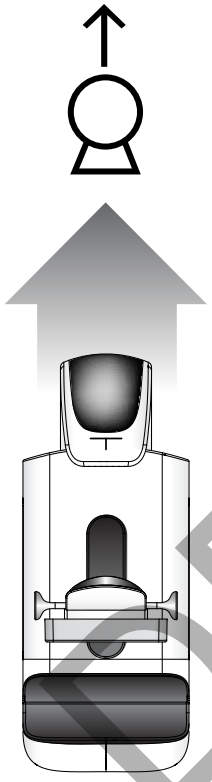
Function	Functional Test
Compression Down 	Press a Compression Down button: • The compression brake engages. • The light field lamp illuminates. • The compression device lowers. *Note… When you press the Compression Down button, the compression brake remains engaged until the Compression Release button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

Table 2-1: C-Arm Functional Tests

Function	Functional Test
Compression Release 	Press the Compression Release button: • The Compression Motor Brake releases. • The Compression Device lifts.
C-Arm Up 	Press the C-Arm Up button: • The C-Arm movement automatically stops when the button is released. • The C-Arm movement automatically stops when the C-arm reaches the upper travel limit. • The C-Arm movement is disabled when a compression force of 45 N (10 pounds) or greater is applied.