



User Guide

MAN-10622 Revision 001

HOLOGIC®

Selenia[®] Dimensions[®]

Digital Mammography System

Digital Tomosynthesis System

User Guide

For Software Version 1.8 with C-View

Part Number MAN-10622

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HOLOGIC[®]

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Table of Contents

List of Figures _____ xi

List of Tables _____ xv

1: Introduction _____ 1

1.1 Intended Use..... 1
1.2 Potential Adverse Effects of Mammography Systems on Health 1
1.3 Contraindications..... 2
1.4 Intended Use for the User Guide..... 2
1.5 System Capabilities..... 2
1.6 More Information About Tomosynthesis 2
1.7 About C-View 4
 1.7.1 C-View Software 4
 1.7.2 Warnings 4
 1.7.3 C-View Theory of Operation..... 4
1.8 Product Complaints..... 5
1.9 Technical Support 5
1.10 Warranty Statement..... 5
1.11 Hologic Cybersecurity Statement 6
1.12 Quality Control Requirements 6
1.13 Where to Find the Installation Instructions..... 6
1.14 User Profiles..... 6
 1.14.1 Mammography Technologist 6
 1.14.2 Radiologist 6
 1.14.3 Medical Physicist 6
1.15 Training Requirements..... 7
1.16 Terms and Definitions..... 7
1.17 Symbols 8
1.18 Descriptions of Warnings, Cautions, and Notes 10
1.19 Document Conventions 10

2: General Information _____ 11

2.1 System Description..... 11
 2.1.1 Tubestand 11
 2.1.2 Acquisition Workstation 12
2.2 Safety Information 13
2.3 Warnings and Precautions..... 13
2.4 Emergency Off Switches 17
2.5 Interlocks..... 17
2.6 Compliance 18
 2.6.1 Compliance Requirements 18
 2.6.2 Compliance Statements..... 19
2.7 Label Locations 21

Selenia Dimensions System User Guide

Table of Contents

3: System Controls and Indicators	25
3.1 System Power Controls	25
3.2 Acquisition Workstation Controls and Indicators.....	26
3.2.1 Universal Acquisition Workstation Controls and Displays.....	26
3.2.2 Premium Acquisition Workstation Controls and Displays	27
3.2.3 Standard Acquisition Workstation Controls and Displays.....	28
3.2.4 Keyboard.....	29
3.2.5 Bar Code Scanner	29
3.2.6 Universal Acquisition Workstation Display	29
3.2.7 Premium Acquisition Workstation Touchscreen Display	29
3.2.8 Standard Acquisition Workstation Display	29
3.2.9 Preview Display	29
3.3 Tubestand Controls and Indicators	30
3.3.1 C-Arm Controls.....	31
3.3.2 Compression Device Controls and Displays.....	31
3.3.3 Tubehead Display	32
3.3.4 Dual Function Footswitches	32
3.4 How to Turn On the Selenia Dimensions System	33
3.4.1 Preparation.....	33
3.4.2 Startup	33
3.4.3 Log In.....	35
3.5 How to Change the Language.....	36
3.6 Perform the Functional Tests.....	36
3.6.1 Compression Functional Tests	37
3.6.2 C-Arm Movement Functional Tests	38
3.7 Emergency Off Switches Functionality	44
3.8 How to Turn Off the System	45
3.9 How to Remove All Power from the Acquisition Workstation.....	45
4: The User Interface	47
4.1 Select the Function to Perform	47
4.2 About the Taskbar.....	48
4.3 How to Perform the Quality Control Tasks	51
4.4 The Select Patient Screen.....	52
4.4.1 About the Notices Tab.....	53
4.4.2 How to Open a Patient.....	53
4.4.2.1 How to Add a New Patient	54
4.4.3 How to Edit the Patient Information.....	54
4.4.4 How to Delete a Patient Manually.....	54
4.4.5 The Patient Filter Screen	55
4.4.6 How to Refresh the Worklist	56
4.4.7 How to Query the Worklist	56
4.4.8 About the Admin Button	57
4.4.9 How to Log Out	57
4.4.10 Advanced Workflow Manager.....	57

4.5	The Procedure Screen.....	57
4.5.1	How to Set the Exposure Parameters.....	58
4.5.2	How to Use the Implant Present Button.....	59
4.5.3	How to Use the Paddle Shift Feature.....	59
4.5.4	How to Acquire an Image.....	60
4.5.5	How to Add or Remove a View.....	62
4.5.6	Procedure Information Dialog Box.....	63
4.5.7	How to Add a Procedure.....	64
4.5.8	How to Edit a View.....	65
4.5.9	How to Close a Procedure.....	66
4.6	How to Access Image Review Features.....	66
4.7	How to Use I-View 2D Contrast.....	67
4.7.1	How to Define Contrast Settings.....	70
4.8	How to Use the Output Groups.....	72
4.8.1	How to Select an Output Group.....	72
4.8.2	How to Add or Edit an Output Group.....	72
4.8.3	How to Use the Custom Output.....	73
4.9	How to Use the On-Demand Outputs.....	73
4.9.1	How to Archive.....	73
4.9.2	How to Export.....	74
4.9.3	How to Print.....	75
5:	The Images	77
5.1	Introduction.....	77
5.1.1	Conventional Imaging Sequence of Events.....	78
5.1.2	Tomosynthesis Imaging Sequence of Events (Tomosynthesis Option).....	78
5.1.3	About Auto-Hanging and Auto-Pairing.....	79
5.2	How to Review the Images.....	80
5.2.1	The Image Review Tools Tab.....	81
5.2.2	The Notices Tab.....	82
5.2.3	Other Image Review Tools.....	83
5.2.4	Slice Indicator.....	84
5.2.5	How to Correct and Reprocess Implant Images.....	84
5.3	Send the Images to the Output Devices.....	85
6:	How to Use the Accessories	87
6.1	Introduction.....	87
6.2	How to Install Accessories on the C-Arm.....	87
6.3	The Patient Face Shields.....	88
6.3.1	How to Install or Remove the Retractable Face Shield.....	88
6.3.2	How to Use the Retractable Face Shield.....	89
6.3.3	How to Install or Remove the Conventional Face Shield.....	90
6.4	Compression Paddles.....	91
6.4.1	Routine Screening Paddles.....	92
6.4.2	Contact and Spot Compression Paddles.....	92

Selenia Dimensions System User Guide

Table of Contents

6.4.3	Magnification Paddles.....	92
6.4.4	Localization Paddles.....	93
6.4.5	Large Ultrasound Paddle.....	93
6.4.6	How to Install or Remove a Compression Paddle	94
6.4.7	Maintenance and Cleaning.....	94
6.4.8	Paddle Shift.....	95
6.4.9	FAST Compression Mode.....	95
6.5	Magnification Stand.....	96
6.5.1	How to Install and Remove the Magnification Stand.....	96
6.6	Crosshair Devices.....	97
6.6.1	How to Install and Remove the Localization Crosshair Device	97
6.6.2	How to Use the Localization Crosshair Device	98
6.6.3	How to Install and Remove the Magnification Crosshair Device	99
6.6.4	How to Align the Crosshair Device.....	100
7: Clinical Procedures		101
7.1	Standard Workflow	101
7.1.1	Preparation.....	101
7.1.2	At the Gantry	101
7.1.3	At the Acquisition Workstation	102
7.2	Screening Procedure Example.....	102
7.2.1	How to Position the Patient.....	103
7.2.2	Set the Exposure Techniques.....	103
7.2.3	How to Acquire the Exposure.....	103
7.2.4	How to Automatically Store the Image	105
7.2.5	How to Accept a Rejected Image	105
7.2.6	How to Accept or Reject a Pended Image	105
7.3	Procedure for Needle Localization with Tomosynthesis	106
8: Maintenance and Cleaning		109
8.1	Cleaning	109
8.1.1	General Information About Cleaning	109
8.1.2	For General Cleaning.....	109
8.1.3	To Prevent Possible Injury or Equipment Damage	110
8.1.4	Acquisition Workstation	111
8.2	Maintenance.....	112
8.2.1	Preventive Maintenance Schedule.....	112
8.2.2	About Reclamation	112
9: System Administration Interface		113
9.1	How to Use the Admin Screen.....	113
9.2	The About Screen.....	115
9.3	How to Use the System Tools.....	116
9.3.1	The System Tools for the Radiologic Technologist Manager.....	117
9.3.2	Remote Access to Image Reports.....	118

9.4	How to Use the Archive Tool.....	120
Appendix A Specifications		123
A.1	Product Measurements	123
A.1.1	Tubestand (Gantry with C-Arm).....	123
A.1.2	Acquisition Workstations	124
A.2	Operation and Storage Environment	128
A.2.1	General Conditions for Operation.....	128
A.2.2	Storage Environment.....	128
A.3	Radiation Shield	129
A.4	Electrical Input	129
A.4.1	Tubestand	129
A.4.2	Acquisition Workstation.....	129
A.5	Tubestand Technical Information.....	129
A.5.1	C-Arm.....	129
A.5.2	Compression.....	130
A.5.3	X-ray Tube	131
A.5.4	X-ray Beam Filtration and Output.....	131
A.5.5	X-ray Collimation.....	132
A.5.6	Light Field Indication	132
A.5.7	X-ray Generator.....	132
A.6	Imaging System Technical Information.....	133
A.6.1	Image Receptor.....	133
Appendix B The System Messages and Alert Messages		135
B.1	Error Recovery and Troubleshooting.....	135
B.2	Types of Messages	135
B.2.1	Fault Levels.....	135
B.2.2	System Messages.....	135
B.3	UPS Operation.....	138
Appendix C Dimensions Mobile		139
C.1	General Information	139
C.2	Conditions for Safety and Other Precautions	139
C.3	Mobile Specifications.....	140
C.3.1	Shock and Vibration Limits.....	140
C.3.2	Coach Environment.....	140
C.4	Electrical Input	140
C.4.1	Gantry.....	140
C.4.2	Acquisition Workstation.....	141
C.5	Prepare the System for Travel.....	141
C.6	Prepare the System for Use.....	143
C.7	Test the System after Travel	144
C.7.1	Selenia Dimensions Controls and Functional Tests	144
C.8	Quality Control Tests	144

Selenia Dimensions System User Guide

Table of Contents

Appendix D Dose Information	145
D.1 EUREF Dose Tables	145
Index	147

List of Figures

Figure 1: Selenia® Dimensions® System Tubestand	11
Figure 2: Acquisition Workstation	12
Figure 3: Label Locations	21
Figure 4: System Power Controls	25
Figure 5: Universal Acquisition Workstation Controls and Displays	26
Figure 6: Premium Acquisition Workstation Controls and Displays	27
Figure 7: Standard Acquisition Workstation Controls and Displays	28
Figure 8: Tubestand Controls and Indicators	30
Figure 9: C-arm Controls	31
Figure 10: Compression Device	31
Figure 11: Compression Display	31
Figure 12: Tubehead Display	32
Figure 13: Dual Function Footswitches	32
Figure 14: Reset the Emergency Off Switches	33
Figure 15: Universal Acquisition Workstation Power Buttons	33
Figure 16: Premium Acquisition Workstation Power Buttons	33
Figure 17: Standard Acquisition Workstation Power Buttons	33
Figure 18: Startup Screen	34
Figure 19: Log In Screen	35
Figure 20: C-arm Controls (left side shown)	36
Figure 21: Emergency Off Switch Functionality	44
Figure 22: Universal Acquisition Workstation Power Buttons	45
Figure 23: Premium Acquisition Workstation Power Buttons	45
Figure 24: Standard Acquisition Workstation Power Buttons	45
Figure 25: An Example Select Function to Perform Screen	47
Figure 26: The Taskbar	48
Figure 27: An Example Quality Control Screen	51
Figure 28: The Select Patient Screen	52
Figure 29: The Enterprise Tab	52
Figure 30: How to Add a New Patient	54
Figure 31: The Filter Tab in the Patient Filter Screen	55
Figure 32: The Generator Tab in an Example Procedure Screen	57
Figure 33: Paddle Shift Buttons	59
Figure 34: Exposure In Progress	60
Figure 35: Exposure Complete	61
Figure 36: The Add View Screen	62
Figure 37: The Procedure Info Window	63
Figure 38: Add Procedure Dialog Box	64
Figure 39: The Edit View Screen	65
Figure 40: I-View 2D Contrast Screen	67
Figure 41: I-View 2D Contrast Screen, Waiting Period	68
Figure 42: I-View 2D Contrast Screen, Optimal Imaging Period	69

Selenia Dimensions System User Guide

Table of Contents

Figure 43: I-View 2D Contrast Settings.....	70
Figure 44: I-View 2D Contrast Settings, Admin screen.....	71
Figure 45: Output Groups Field.....	72
Figure 46: An Example Custom Output Group.....	73
Figure 47: Select the Images for Export.....	74
Figure 48: Export Screen.....	74
Figure 49: The Print Screen.....	76
Figure 50: The Preview Screen.....	77
Figure 51: Enable Auto-Hanging and Auto-Pairing.....	79
Figure 52: The Tools Tab (Tomosynthesis option shown).....	80
Figure 53: Marked Images in a Procedure (Tomosynthesis option shown).....	80
Figure 54: Image Review Tools.....	81
Figure 55: The Notices Tools Tab.....	82
Figure 56: Exposure Index.....	83
Figure 57: Display Modes.....	83
Figure 58: Slice Indicator.....	84
Figure 59: C-arm Accessories.....	87
Figure 60: How to Align the Retractable Face Shield on the C-arm.....	88
Figure 61: Face Shield Installation.....	89
Figure 62: Face Shield Operation.....	89
Figure 63: How to Install the Conventional Face Shield.....	90
Figure 64: How to Install a Compression Paddle.....	94
Figure 65: How to Remove the Compression Paddle.....	94
Figure 66: The FAST Compression Mode Slide.....	95
Figure 67: Installation of the Magnification Stand.....	96
Figure 68: How to Attach the Localization Crosshair Device.....	97
Figure 69: How to Install and Remove the Magnification Crosshair Device.....	99
Figure 70: Screening Example.....	102
Figure 71: Exposure In Progress.....	104
Figure 72: Exposure Complete.....	104
Figure 73: Calculating needle depth.....	107
Figure 74: The Admin Screen.....	113
Figure 75: About (the Acquisition Workstation) Screen with the System Tab Showing.....	115
Figure 76: The System Tools Screen.....	117
Figure 77: Remote Logon Screen for Service Tools.....	118
Figure 78: Service Tools Welcome Screen.....	119
Figure 79: Create Image Report Parameters.....	119
Figure 80: Create Image Report.....	120
Figure 81: Archive Button.....	120
Figure 82: Multi Patient On Demand Archive Screen.....	121
Figure 83: Export Screen.....	122
Figure 84: Tubestand (Gantry with C-arm) Dimensions.....	123
Figure 85: Universal Acquisition Workstation Dimensions system.....	124
Figure 86: Premium Acquisition Workstation Dimensions system.....	125
Figure 87: Standard Acquisition Workstation Dimensions system.....	126

Figure 88: Mobile Universal Acquisition Workstation Dimensions system.....	127
Figure 89: Mobile (non-Universal) Acquisition Workstation Dimensions system	128
Figure 90: UPS LCD Display	138
Figure 91: Keyboard Tray Lock Knob	141
Figure 92: Keyboard Tray Lock Knob	141
Figure 93: Tray Lock Release from Locked (A) to Unlocked (D)	141
Figure 94: Swivel Lock Knobs for Preview Display on Mobile Universal Acquisition Workstation.....	142
Figure 95: Tray Lock Release from Locked (A) to Unlocked (D)	143
Figure 96: Swivel Lock Knobs for Preview Display on Mobile Universal Acquisition Workstation.....	143

List of Tables

Table 1: List of Labels.....	22
Table 2: Compression Tests.....	37
Table 3: C-arm Up and Down Movement.....	38
Table 4: C-arm Counterclockwise Rotation.....	40
Table 5: C-arm Clockwise Rotation.....	40
Table 6: C-arm Rotation Switch.....	41
Table 7: Automatic C-arm Counterclockwise Rotation.....	42
Table 8: Automatic C-arm Clockwise Rotation.....	43
Table 9: Automatic C-arm Movement to Zero Position.....	43
Table 10: C-arm Collimation.....	43
Table 11: Shifting Paddle.....	44
Table 12: Taskbar Menus.....	48
Table 13: The Select Patient Screen.....	52
Table 14: The Filter Tab Options (Require Access Privileges).....	56
Table 15: Procedure Groups.....	64
Table 16: Available Accessories.....	91
Table 17: User Preventive Maintenance.....	112
Table 18: Admin Screen Functions.....	114
Table 19: Radiologic Technologist Manager—System Tools Functions.....	117
Table 20: Maximum mA Setting as a Function of kV.....	131
Table 21: System Messages.....	136
Table 22: 2D Dose (EUREF).....	145
Table 23: BT Dose (EUREF).....	145
Table 24: CEDM Dose (EUREF).....	145

Chapter 1 Introduction

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

1.1 Intended Use

The Hologic® Selenia® Dimensions® system generates digital mammographic 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 a 2D mammography system for screening mammograms. Specifically, the Selenia Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

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

The 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 a 2D image (either a FFDM image or 2D image generated from the 3D image set).

Contrast Enhanced Digital Mammography

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

1.2 Potential Adverse Effects of Mammography Systems on Health

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

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

1.3 Contraindications

There are no known contraindications.

1.4 Intended Use for the User Guide

Always refer to the User Guide for instructions on using the system.

1.5 System Capabilities

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

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

1.6 More Information About Tomosynthesis

The Hologic Selenia Dimensions system received FDA approval for the Hologic Tomosynthesis option on 11 Feb 2011 (refer to PMA number P080003). This FDA approval applies to screening and diagnostic imaging. More information is available from the FDA website at

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm246400.htm>.

The Generated 2D option (C-View™) in conjunction with Tomosynthesis received FDA approval on 16 May 2013 (refer to PMA number P080003 S001). More information is available from the FDA website at

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/recently-approveddevices/ucm353734.htm>.

A list of scientific publications about Breast Tomosynthesis is available from the Hologic website. The majority of the studies were done with the commercially released Hologic Selenia Dimensions Tomosynthesis system. See the publication at

<http://www.hologic.com/sites/default/files/Tomo-Bibliography-Rev-13.pdf>.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Breast Cancer Screening Using Tomosynthesis in Combination With Digital Mammography

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

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

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

**IMPORTANT:**

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

1.7 About C-View

1.7.1 C-View Software

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

1.7.2 Warnings



Warning:

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

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

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



Warning:

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

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

1.7.3 C-View Theory of Operation

Overview

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

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

Configuration

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

Workflow

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

1.8 Product Complaints

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

1.9 Technical Support

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

1.10 Warranty Statement

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

1.11 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.

1.12 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.

1.13 Where to Find the Installation Instructions

Installation instructions are available in the Service Manual.

1.14 User Profiles

1.14.1 Mammography Technologist

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

1.14.2 Radiologist

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

1.14.3 Medical Physicist

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

1.15 Training Requirements

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

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

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

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

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

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

1.16 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
BT	(Breast Tomosynthesis) An imaging procedure that provides information about the breast in three dimensions
C-View™	A licensed Hologic feature where a digital mammogram (DM) image is generated from data acquired during a breast tomosynthesis scan
CEDM	Contrast Enhanced Digital Mammography
CE2D	Hologic term for CEDM
Collimator	Device at the x-ray tube to control the area of the receptor that is exposed
Combo Mode	Hologic acquisition mode consisting of a traditional digital mammogram (DM) with a breast tomosynthesis (BT) scan under the same compression
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
DM	Digital Mammography (2D)
EMC	Electromagnetic Compatibility
FAST Paddle™	(Fully Automatic Self-Adjusting Tilt) Paddle
Gantry	A part of the Selenia Dimensions system that has the Detector, Generator and X-ray Source, Positioning/Compression, Power Distribution, and Accessories Subsystems



Selenia Dimensions System User Guide















Chapter 1: Introduction

Grid	Element within the Digital Image Receptor that reduces scatter radiation during the exposure
HIS	Hospital Information System
I-View™	A licensed feature for 2D Contrast Enhanced Digital Mammography
Image Receptor	Assembly of x-ray detector, x-ray scatter reduction grid, and carbon fiber cover
MPPS	Modality Performed Procedure Step
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 (pending 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 technique that recombines a number of breast images taken at different angles through the breast to achieve various effects (tomosynthesis images can be reconstructed to show planes or slices within the breast)
UDI	Unique Device Identifier
UPS	Uninterruptible Power Supply

1.17 Symbols

This section describes the Symbols on this system.

Symbol	Description
	Type B Applied Part
	Potential Equalization terminal

Symbol	Description
	Protective Earth terminal
	"OFF" (power)
	"ON" (power)
	"OFF" for part of the equipment
	"ON" for part of the equipment
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Dangerous Voltage
	Manufacturer
	Date of Manufacture
	This system transmits radio frequency (RF) energy (non-ionizing radiation)
	Caution – Radiation
	Follow operating instructions
	Follow the <i>User Guide</i>
	Caution

1.18 Descriptions of Warnings, Cautions, and Notes

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



WARNING!

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



Warning:

The procedures that you must follow accurately to prevent injury.



Caution:

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



Note

Notes show additional information.

1.19 Document Conventions

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

Chapter 2 General Information

2.1 System Description

2.1.1 Tubestand

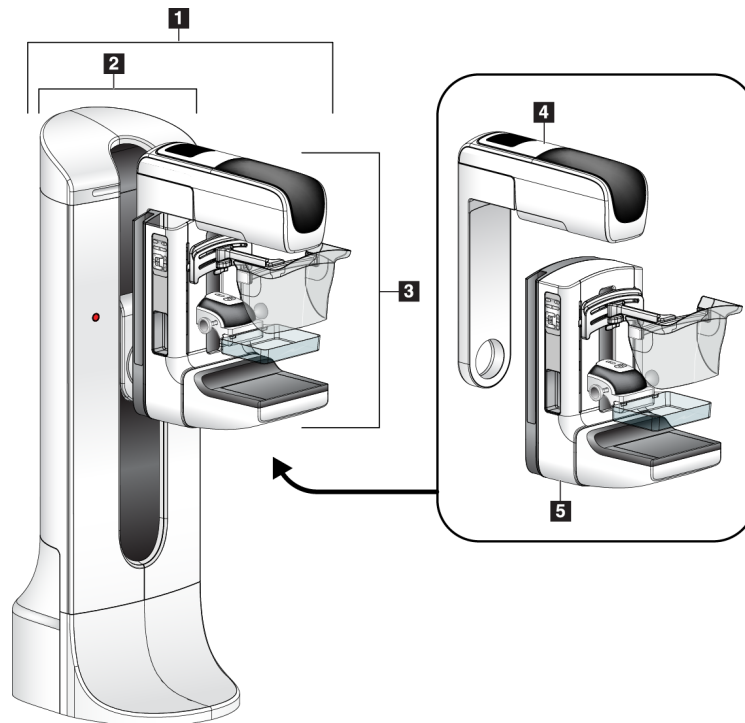


Figure 1: Selenia® Dimensions® System Tubestand

Figure Legend

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

2.1.2 Acquisition Workstation

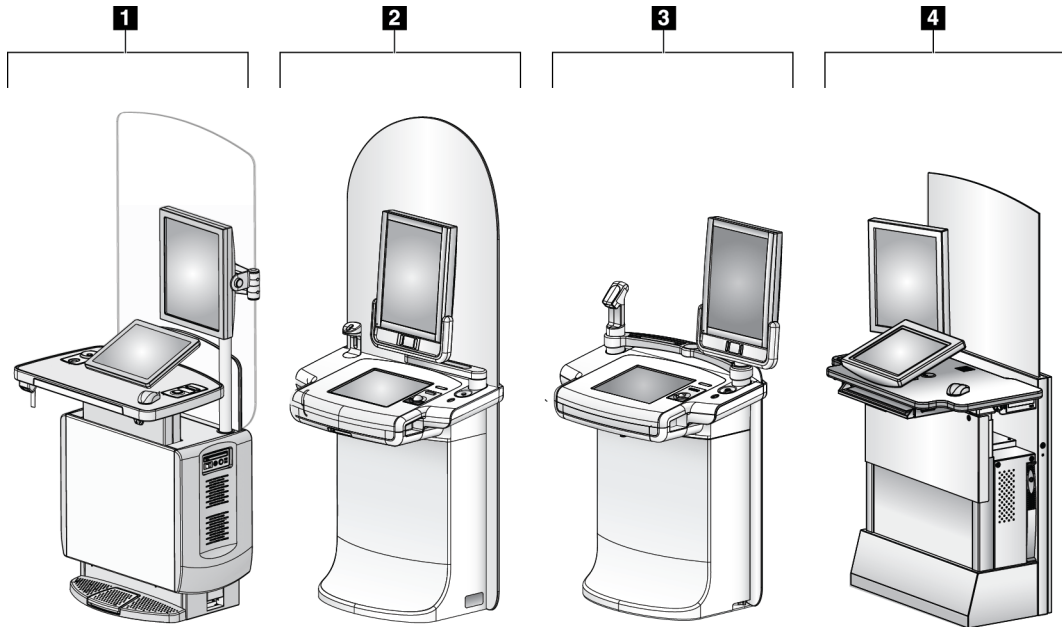


Figure 2: Acquisition Workstation

Figure Legend

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

2.2 Safety Information

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

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

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

2.3 Warnings and Precautions



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



WARNING!

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



WARNING!

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



WARNING!

Electrical equipment used near flammable anesthetics can cause an explosion.



WARNING!

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



WARNING!

Keep a 1.5 meter safe distance between the patient and any non-patient devices.

Do not install non-patient system components (like the Workflow Manager, a diagnostic review workstation, or a hard copy printer) in the Patient Area.



WARNING!

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



WARNING!

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



WARNING!

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



Warning:

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



Warning:

C-arm movement is motorized.



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

Do not leave the patient unattended during the procedure.



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

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



Warning:

The Face Shield does not protect the patient from radiation.



Warning:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



Note:

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

2.4 Emergency Off Switches

The Emergency Off switches remove the power from the Gantry and the 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 44 for complete information on the Emergency Off switches.

2.5 Interlocks

The Selenia Dimensions system has safety interlocks:

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

2.6 Compliance

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

2.6.1 Compliance Requirements

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

- The electrical installation of the room meets all requirements.
- The equipment is used according to the *User Guide*.
- The assembly operations, extensions, adjustments, changes, or repairs are performed only by authorized persons.
- The network and communication equipment is installed to meet IEC Standards. The complete system (network and communications equipment and 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, make sure that the ME Equipment or ME System operates correctly in this configuration.



Caution:

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



Caution:

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



Caution:

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

2.6.2 Compliance Statements

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

- 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

Selenia Dimensions System User Guide

Chapter 2: General Information

- IEC 60601-1-1 Ed. 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

2.7 Label Locations

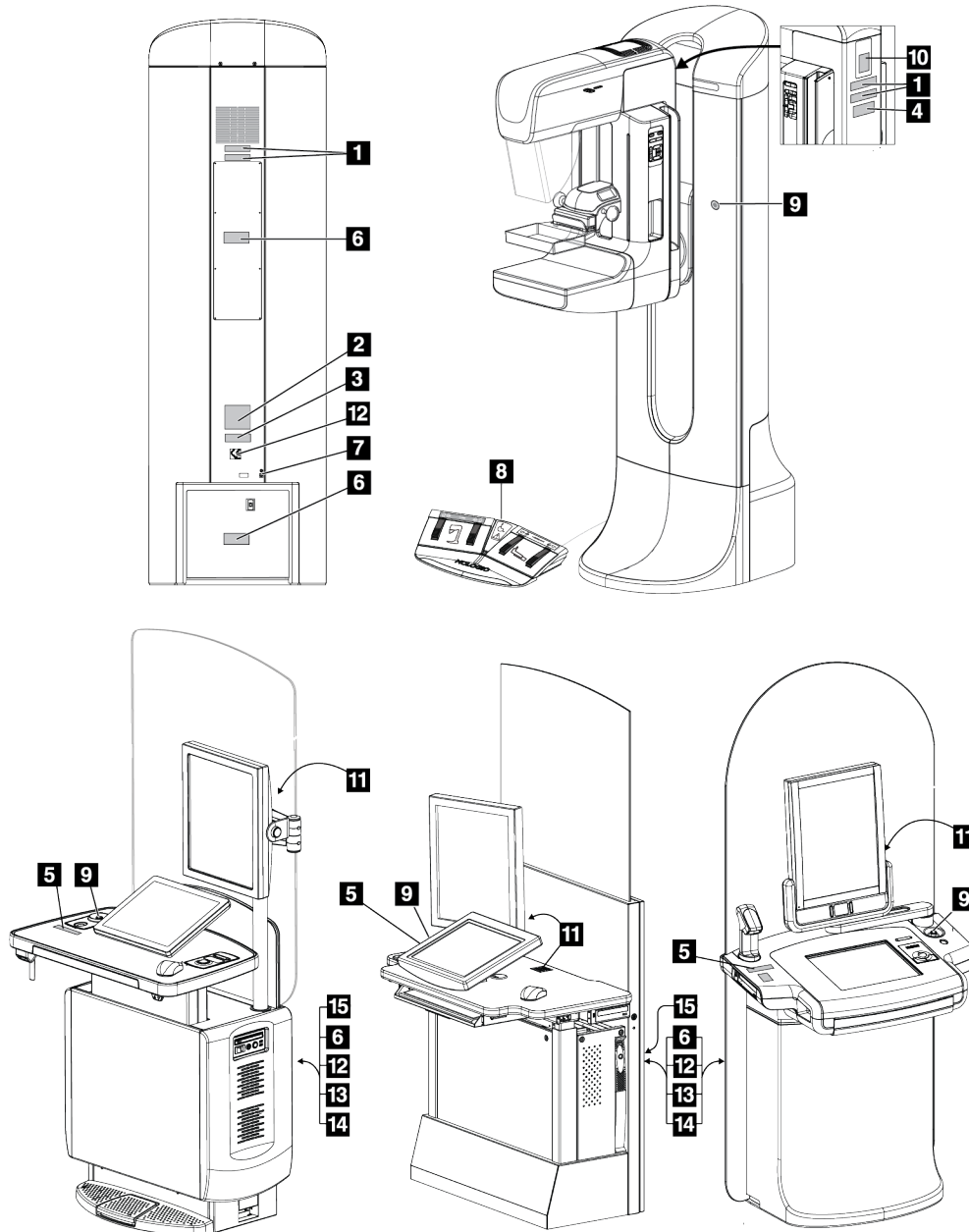


Figure 3: Label Locations

Selenia Dimensions System User Guide

Chapter 2: General Information

Table 1: List of Labels

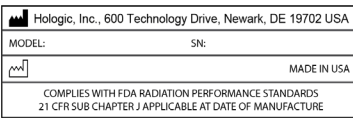
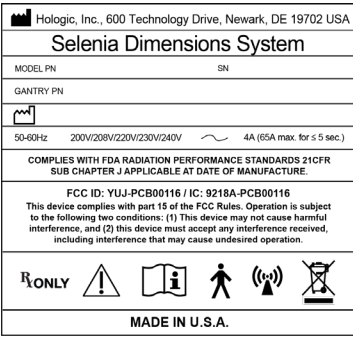

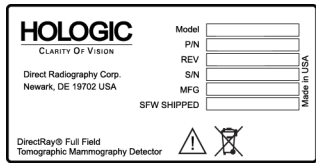





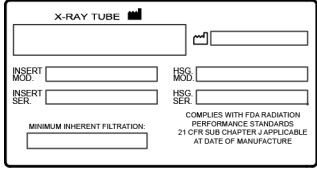


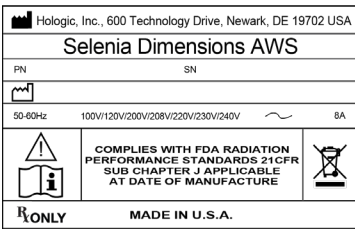
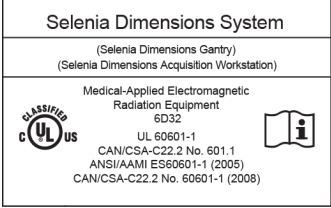

	Label Identification	Description
1	 <p>Hologic, Inc., 600 Technology Drive, Newark, DE 19702 USA MODEL: SN: MADE IN USA COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21 CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE</p>	Serialized Device Label
2	 <p>Hologic, Inc., 600 Technology Drive, Newark, DE 19702 USA Selenia Dimensions System MODEL PN SN GANTRY PN 50-60Hz 200V/208V/220V/230V/240V 4A (R5A max. for ≤ 5 sec.) COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21CFR 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. R ONLY ⚠️ ⓘ ⚠️ ⚠️ ⚠️ MADE IN U.S.A.</p>	System Nameplate Label
3	 <p>This product may be covered by one or more U.S. or foreign patents as identified at: www.hologic.com/patents</p>	Patent Label
4	 <p>HOLOGIC Model _____ CLARITY OF VISION PIN _____ Direct Radiography Corp. REV _____ Newark, DE 19702 USA SIN _____ MFG _____ SFW SHIPPED _____ Made in USA DirectRay® Full Field Tomographic Mammography Detector ⚠️ ⚠️</p>	Tomographic Mammography Detector Label
5	 <p>WARNING This X-Ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.</p>	X-ray Device Warning
6	 <p>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.</p>	Electrical Shock Warning
7		Potential Equalization Terminal
8		Wheelchair Warning for Footswitch
9		Emergency Stop Switch

Table 1: List of Labels

	Label Identification	Description
10		X-ray Tube Serial Number
11		Technical Support Contact Label
12		CE Marking
13		Acquisition Workstation Nameplate Label
14		Gantry and Acquisition Workstation Certification
15		Acquisition Workstation Lift Limit Label* *This label and the associated lift mechanism are not available on some Acquisition Workstation models.

Chapter 3 System Controls and Indicators

3.1 System Power Controls

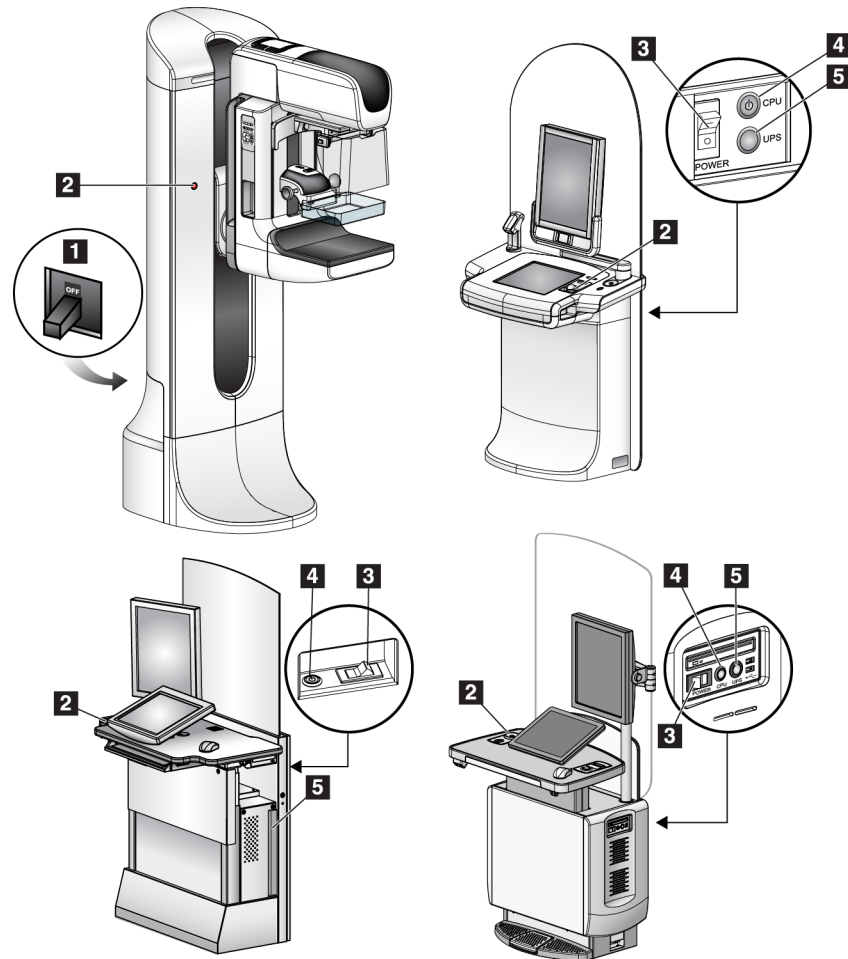


Figure 4: System Power Controls

Figure Legend

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

3.2 Acquisition Workstation Controls and Indicators

3.2.1 Universal Acquisition Workstation Controls and Displays

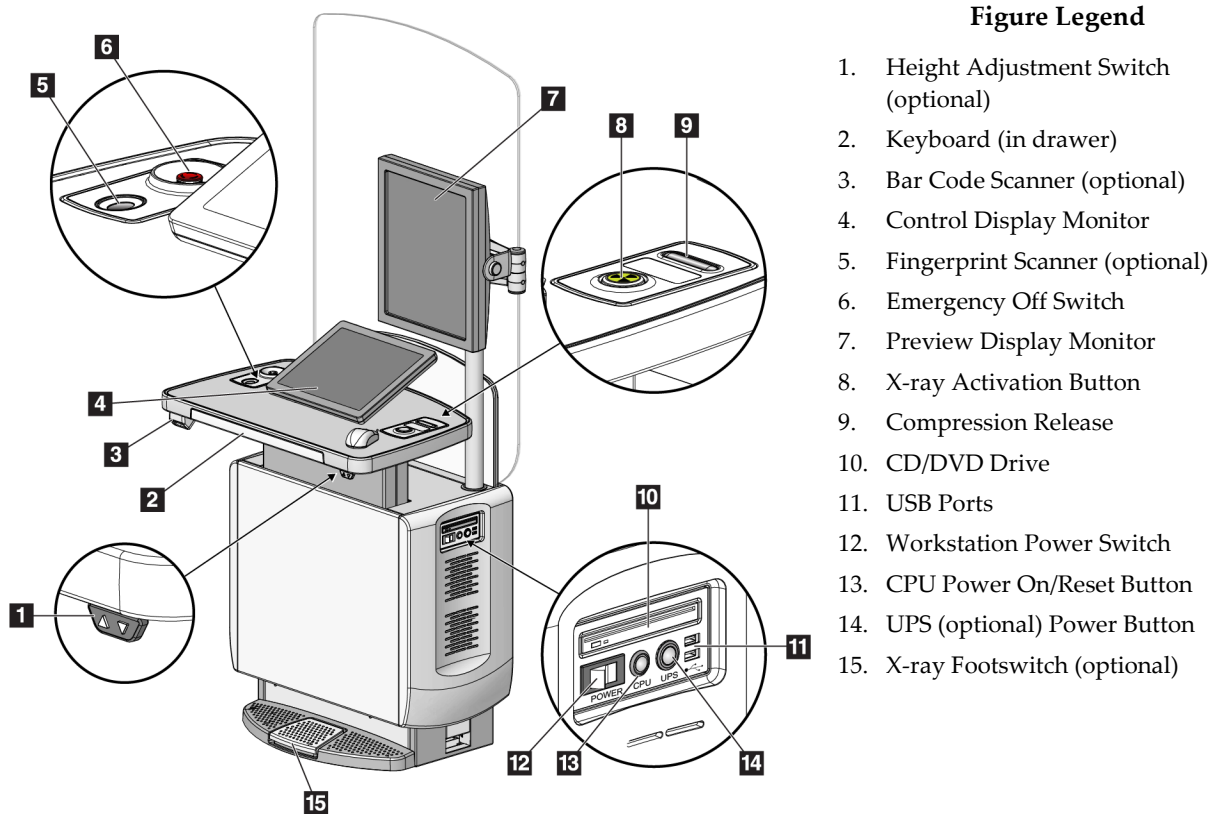


Figure 5: Universal Acquisition Workstation Controls and Displays



Note

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

3.2.2 Premium Acquisition Workstation Controls and Displays

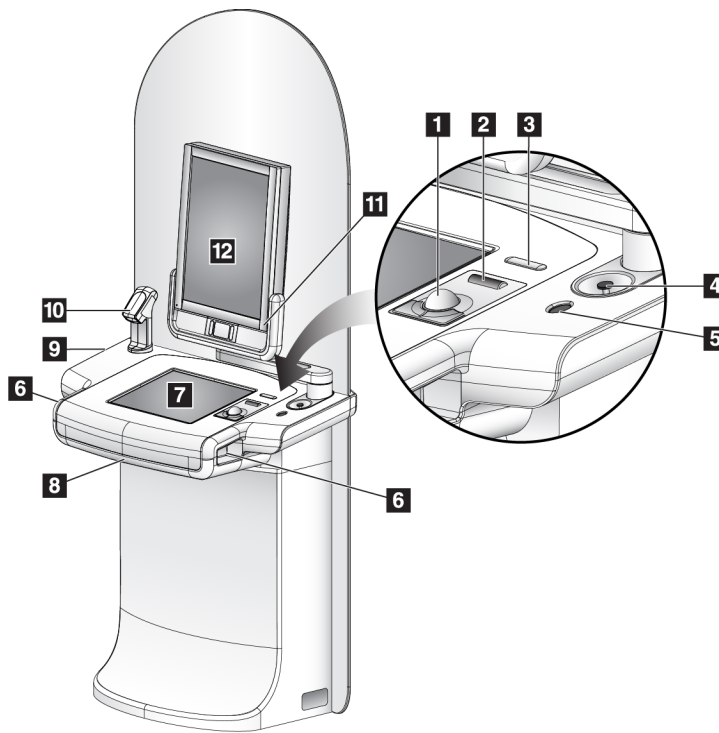


Figure Legend

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 (Light Turns Off After Initial Start)
12. Preview Display

Figure 6: Premium Acquisition Workstation Controls and Displays



Note

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

3.2.3 Standard Acquisition Workstation Controls and Displays

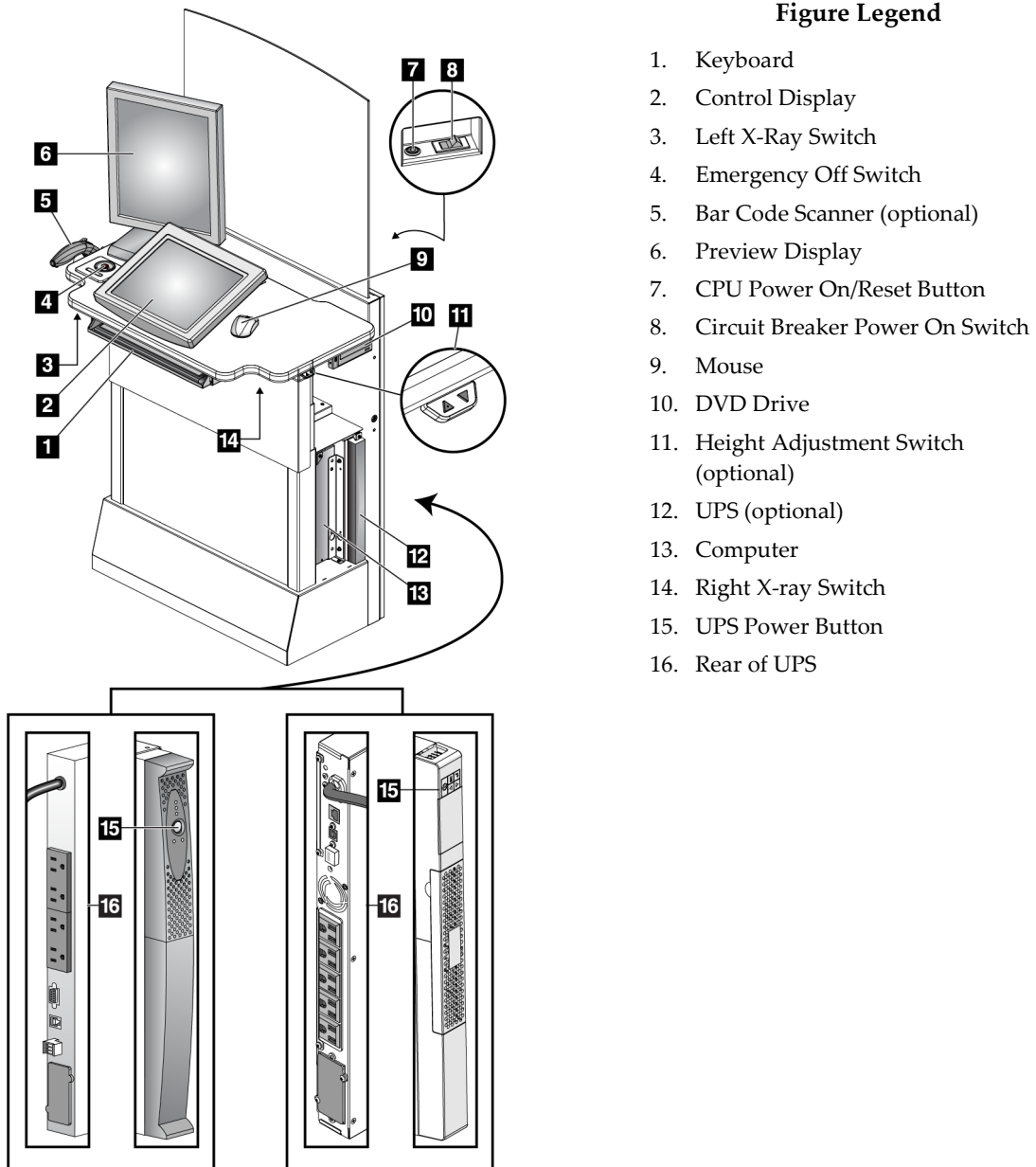


Figure 7: Standard Acquisition Workstation Controls and Displays

3.2.4 Keyboard

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

3.2.5 Bar Code Scanner

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

3.2.6 Universal Acquisition Workstation Display

Use the mouse or the optional Touchscreen to select items.

3.2.7 Premium Acquisition Workstation Touchscreen Display

Use the Touchscreen or trackball to select items.

3.2.8 Standard Acquisition Workstation Display

Use the mouse to select items.

3.2.9 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.

3.3 Tubestand Controls and Indicators

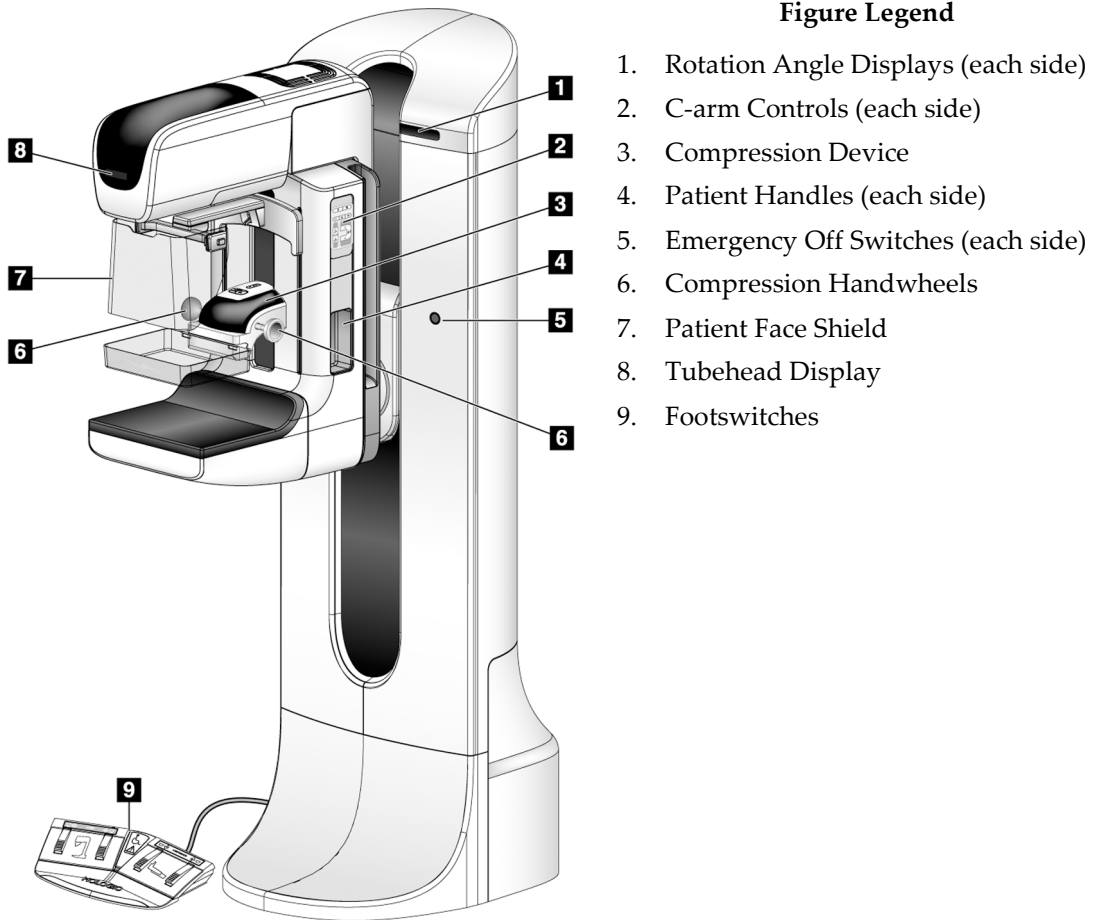


Figure 8: Tubestand Controls and Indicators

3.3.1 C-Arm Controls

The C-arm Controls provide the Collimator and C-arm functions. See [Perform the Functional Tests](#) on page 36.

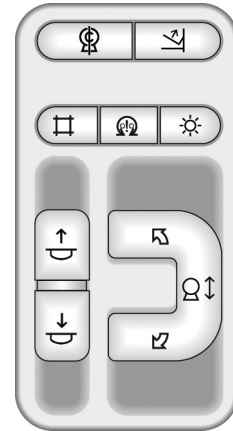


Figure 9: C-arm Controls

3.3.2 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

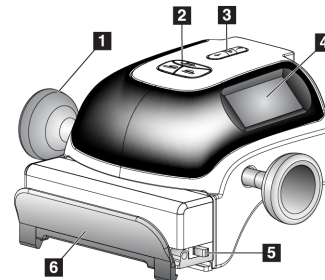


Figure 10: Compression Device

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)

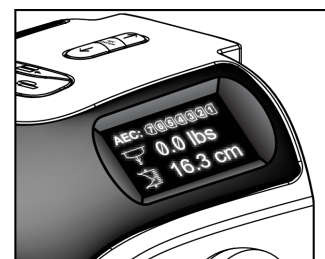


Figure 11: Compression Display

3.3.3 Tubehead Display

The Tubehead Display shows:

- SID
- Filter Type
- Collimator Setting
- Paddle Position



Figure 12: Tubehead Display

3.3.4 Dual Function Footswitches



Warning:

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



Warning:

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

To use the 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

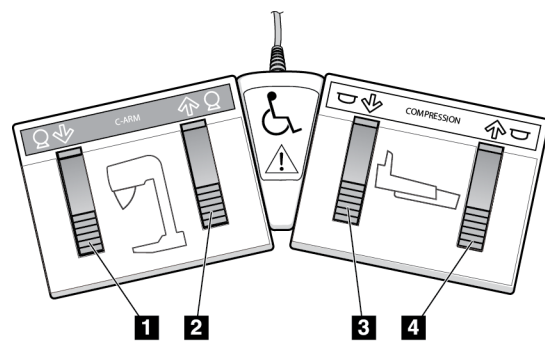


Figure 13: Dual Function Footswitches

3.4 How to Turn On the Selenia Dimensions System



Note

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

3.4.1 Preparation

1. Reset all three Emergency Off switches by turning each switch about one-quarter turn clockwise until it springs back up.

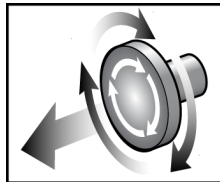


Figure 14: Reset the Emergency Off Switches

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.

3.4.2 Startup

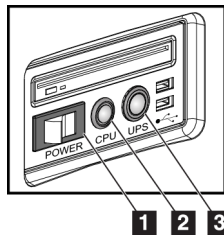


Figure 15: Universal Acquisition Workstation Power Buttons

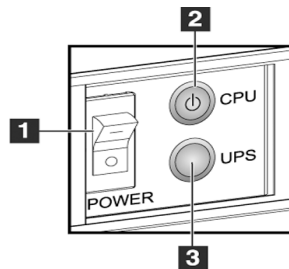


Figure 16: Premium Acquisition Workstation Power Buttons

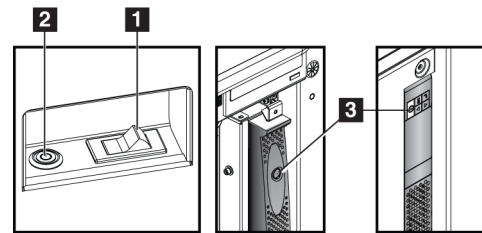


Figure 17: Standard Acquisition Workstation Power Buttons

Figure Legend

1. Acquisition Workstation Power Switch
2. CPU Power On/Reset Button
3. UPS (optional) Power Button

To start up the Acquisition Workstation (Standard, Premium, or Universal):

1. Make sure the workstation power switch is set to ON.
2. If the UPS was shut down, press the UPS power button (see the previous figure).
3. Wait for the green light of the CPU power on/reset button to turn on, then press the CPU power button (see the previous figure).

Selenia Dimensions System User Guide

Chapter 3: System Controls and Indicators

4. Select the **Log In** button on the control display user interface (see the following figure).

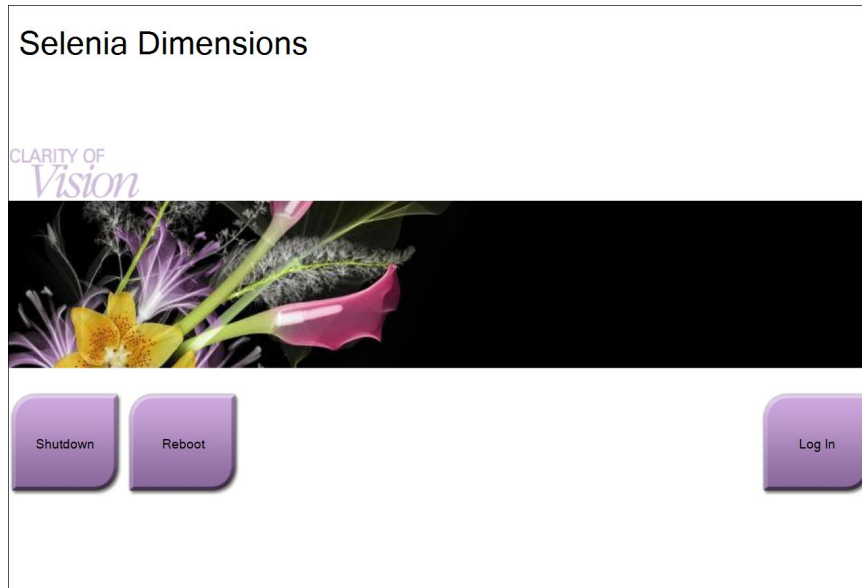


Figure 18: Startup Screen



Note

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



Note

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

3.4.3 Log In

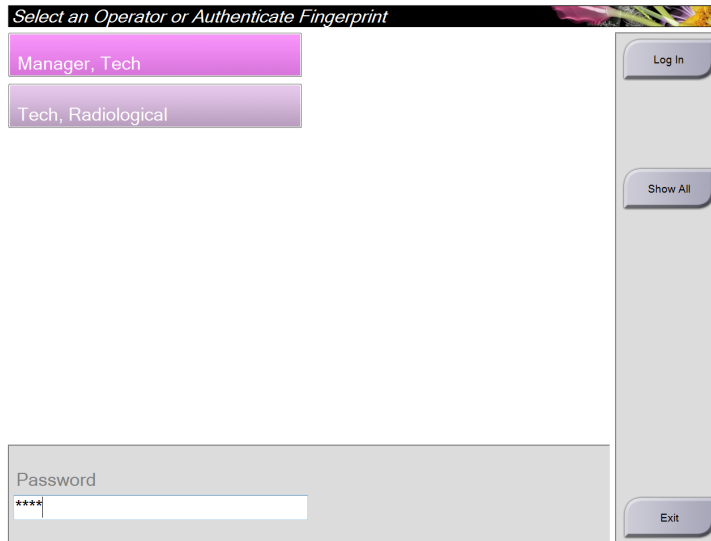


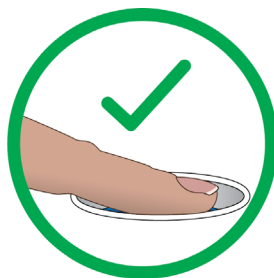
Figure 19: Log In Screen

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, type your password, and select the **Log In** button.

Or

Validate your fingerprint by pressing your finger in the fingerprint reader. Most of the unique, repeatable fingerprint information is from the pad of the finger, not the fingertip. Flat finger placement as shown on the left image results in fast and accurate fingerprint identification.



Correct operation



Incorrect operation



Note

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

3.5 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.

3.6 Perform the Functional Tests

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

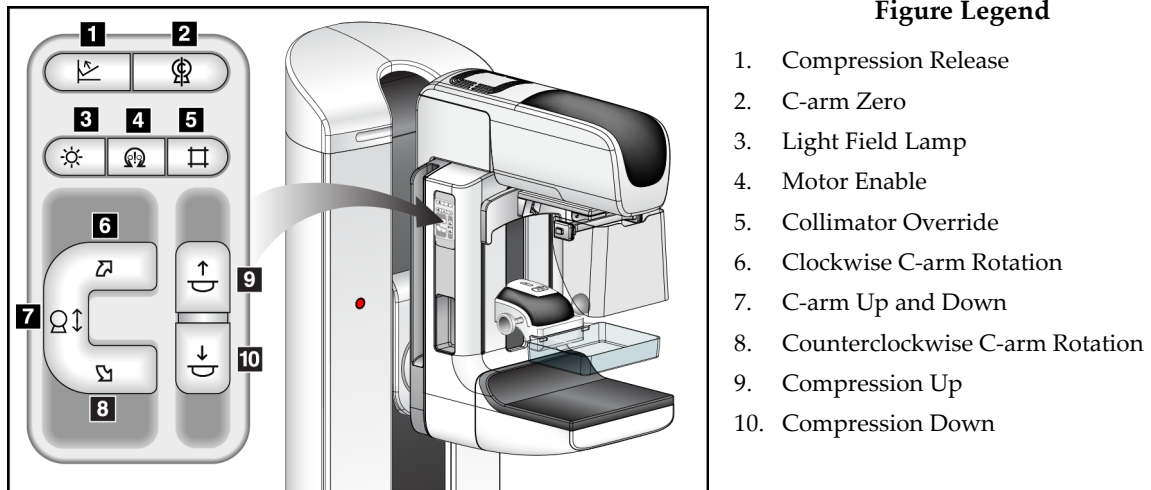


Figure 20: C-arm Controls (left side shown)

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

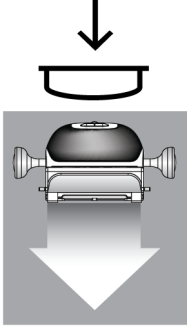
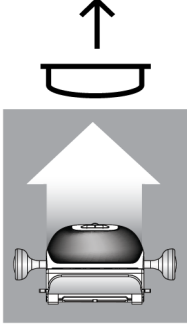



Note

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

3.6.1 Compression Functional Tests

Table 2: Compression Tests

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

3.6.2 C-Arm Movement Functional Tests

C-Arm Up and Down Movement

Table 3: C-arm Up and Down Movement

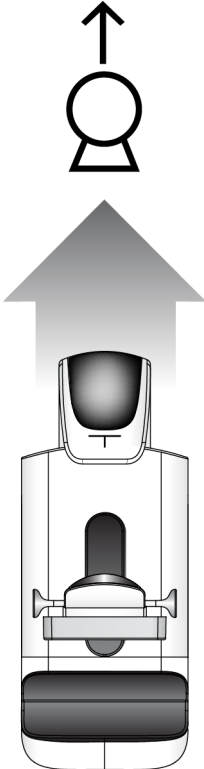
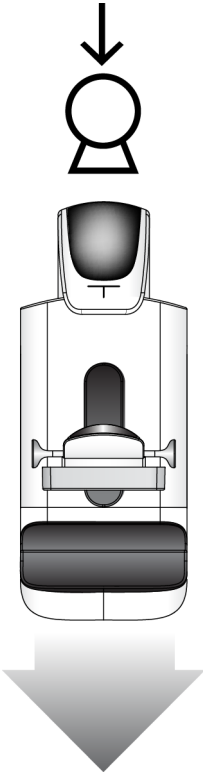
Function	Functional Test
<p>C-arm Up</p> 	<p>Press the C-arm Up button:</p> <ul style="list-style-type: none"> • The C-arm movement automatically stops when the button is released. • The C-arm movement automatically stops when the C-arm reaches the upper travel limit. • C-arm vertical movement and rotation are disabled when compression force is applied. A Service Engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).

Table 3: C-arm Up and Down Movement

Function	Functional Test
<p data-bbox="315 348 480 380">C-arm Down</p>  <p>The diagram illustrates the C-arm down movement. At the top, a small downward-pointing arrow is positioned above a circle, which is above a triangle. Below this is a detailed line drawing of the C-arm assembly, showing the upper housing, the central column, and the lower housing. A large, shaded downward-pointing arrow is positioned below the entire assembly, indicating the direction of movement.</p>	<p data-bbox="659 348 1024 380">Press the C-arm Down button:</p> <ul data-bbox="659 394 1328 695" style="list-style-type: none"><li data-bbox="659 394 1328 464">• The C-arm movement automatically stops when the button is released.<li data-bbox="659 474 1328 543">• The C-arm movement automatically stops when the C-arm reaches the lower travel limit.<li data-bbox="659 554 1328 695">• C-arm vertical movement and rotation are disabled when compression force is applied. A Service Engineer can configure the lockout force from 22 Newtons (5 pounds) to 45 Newtons (10 pounds).

C-Arm Rotation

Table 4: C-arm Counterclockwise Rotation

Function	Functional Test
Counterclockwise C-arm Rotation	Press the Counterclockwise C-arm Rotation button (1) to start counterclockwise C-arm rotation. To fine-tune the C-arm rotation in one degree segments, hold the button down for a second, then let go quickly. Repeat as necessary.
Left Panel	Right Panel

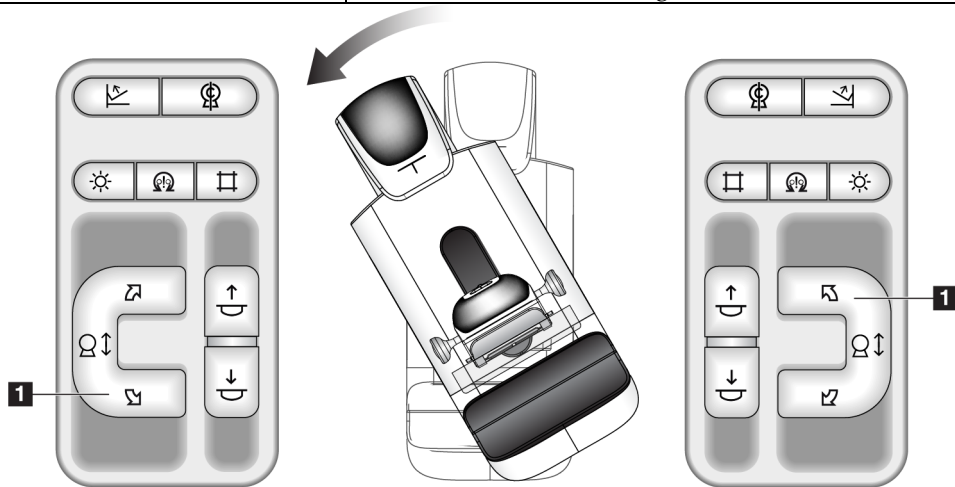


Table 5: C-arm Clockwise Rotation

Function	Functional Test
Clockwise C-arm Rotation	Press the Clockwise C-arm Rotation button (1) to start clockwise C-arm rotation. To fine-tune the C-arm rotation in one degree segments, hold the button down for a second, then let go quickly. Repeat as necessary.
Left Panel	Right Panel

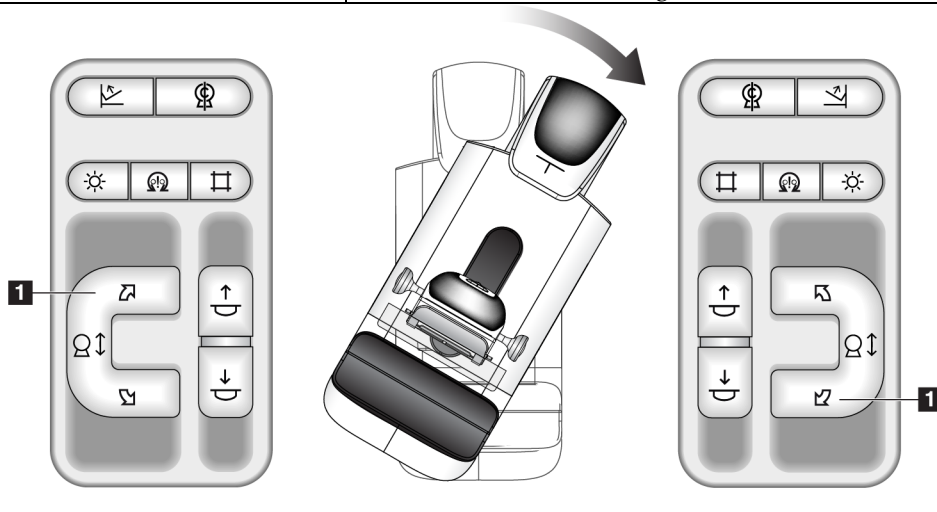
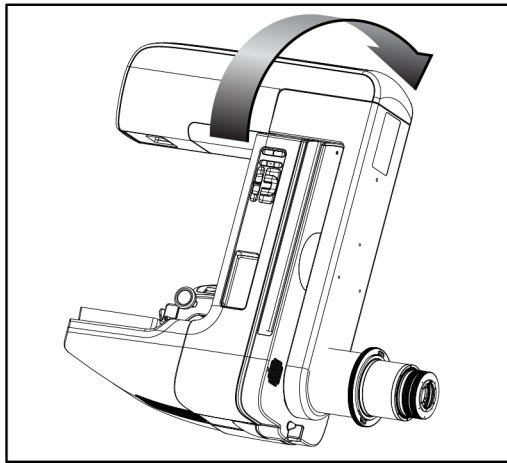
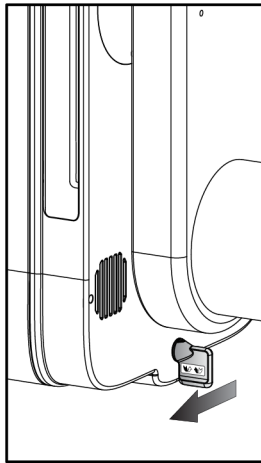
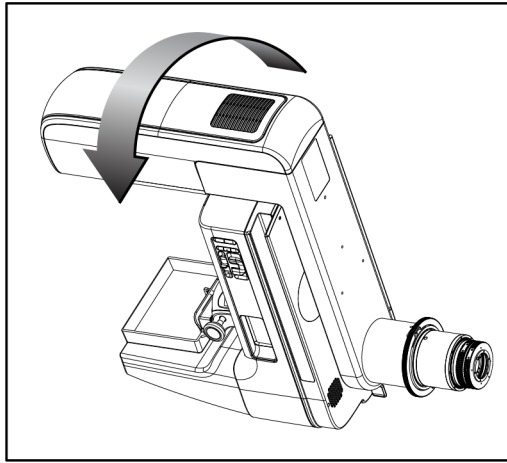
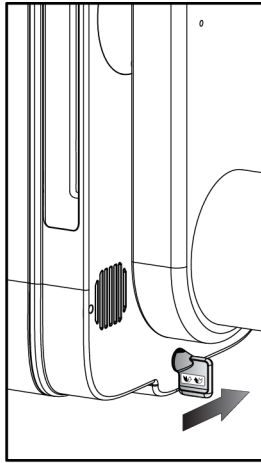


Table 6: C-arm Rotation Switch

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



C-Arm Automatic Rotation (Auto-Rotate)



Warning:

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



Note

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



<p>Motor Enable</p> 	<p>Press and hold the Motor Enable button and the Rotation button to enable auto-rotation movement clockwise or counterclockwise.</p>
<p>C-arm Zero</p> 	<p>Press and hold the C-arm Zero button and the Motor Enable button to return the C-arm to the zero position automatically.</p>

Table 7: Automatic C-arm Counterclockwise Rotation

Function	Functional Test
<p>Automatic Counterclockwise C-arm Rotation</p>	<p>Press and hold the Motor Enable button (2) and the Counterclockwise C-arm Rotation button (3 or 4, based on Panel). The machine beeps and then the C-arm moves automatically counterclockwise.</p>
<p>Left Panel</p>	<p>Right Panel</p>

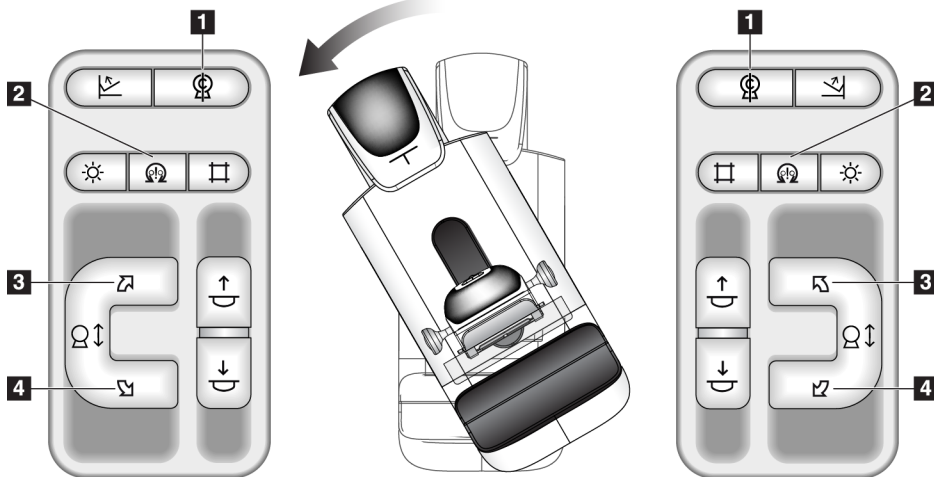


Table 8: Automatic C-arm Clockwise Rotation

Function	Functional Test
Automatic Clockwise C-arm Rotation	Press and hold the Motor Enable button (2) and the Clockwise C-arm Rotation button (3 or 4, based on Panel). The machine beeps and then the C-arm moves automatically clockwise.
Left Panel	Right Panel

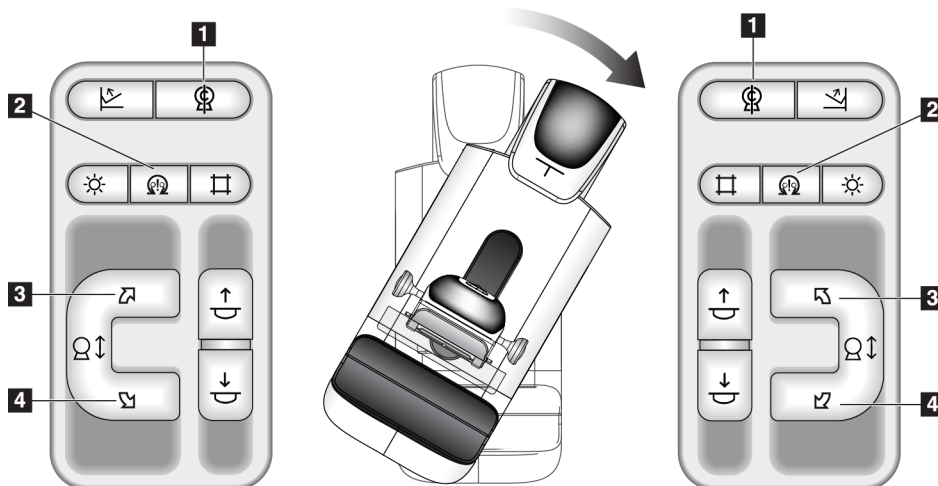
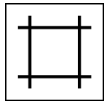



Table 9: Automatic C-arm Movement to Zero Position

Function	Functional Test
Automatic C-arm Movement to Zero Position	Press and hold the Motor Enable button (2) and the C-arm Zero button (1). The machine beeps and then the C-arm automatically returns to the zero position.

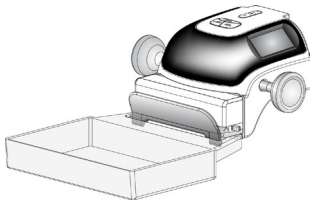
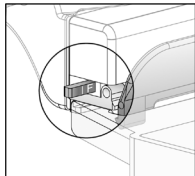
Collimation

Table 10: C-arm Collimation

Function	Functional Test
Collimator Override 	The Collimator Override button changes the collimation through the different x-ray fields. Press the Light Field Lamp button to show the x-ray field, then press the Collimator Override button to select an x-ray field.
Light Field Lamp 	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.

Shifting Paddle

Table 11: Shifting Paddle

Function	Functional Test
<p>Shifting Paddle System</p> 	<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>

3.7 Emergency Off Switches Functionality

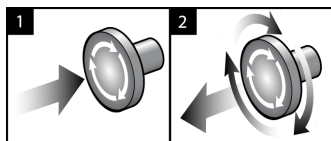


Figure 21: Emergency Off Switch Functionality

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.

3.8 How to Turn Off the System

1. Close any open patient procedures. See [How to Close a Procedure](#) on page 66.
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.

3.9 How to Remove All Power from the Acquisition Workstation

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

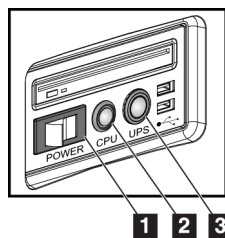


Figure 22: Universal Acquisition Workstation Power Buttons

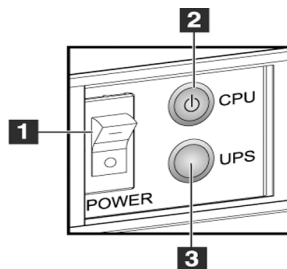


Figure 23: Premium Acquisition Workstation Power Buttons

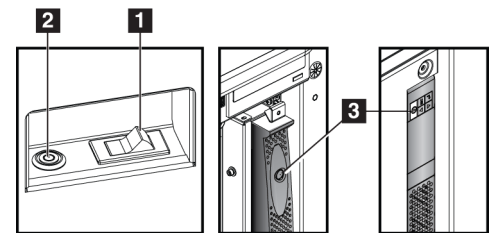


Figure 24: Standard Acquisition Workstation Power Buttons

Figure Legend

1. Acquisition Workstation Power Switch
2. CPU Power On/Reset Button
3. UPS (optional) Power Button

To remove all power from the workstation (Universal, Premium, and Standard):

1. Shut down the computer including all software applications.
2. If your system includes the optional UPS, press the UPS button (item 3).
3. Power OFF the workstation power switch (item 1).
4. Unplug the workstation power cable from the AC outlet.

To restart the system:

1. Plug in the workstation power cable to the AC outlet.
2. Power ON the workstation power switch.
3. If your system includes the optional UPS, press the UPS button.
4. Wait for the green light of the CPU power on/reset button to turn on, then press the CPU power button.

Chapter 4 The User Interface

4.1 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.

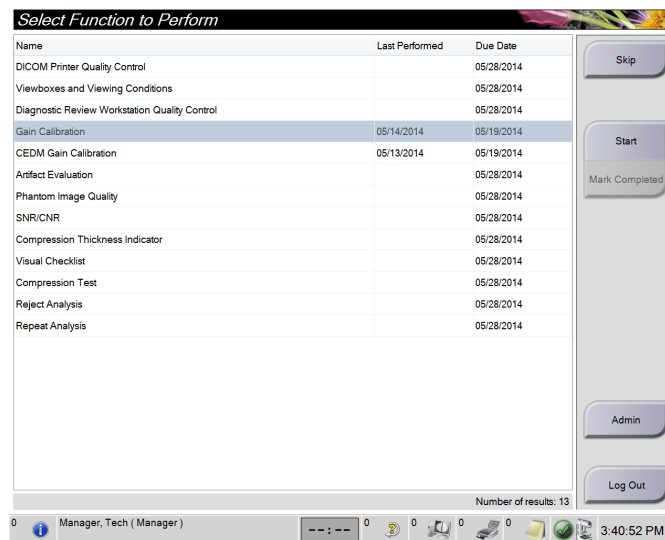


Figure 25: An Example Select Function to Perform Screen

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 113 for information about this screen.

4.2 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.

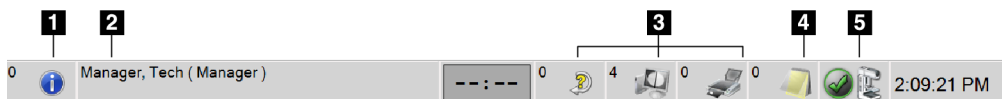


Figure 26: The Taskbar

Table 12: Taskbar Menus





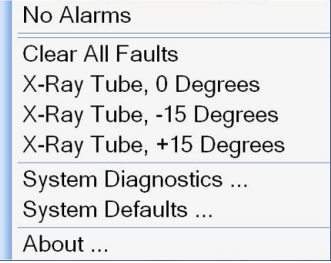
	Description	Menu
1 	<p>Select the Information icon to display a menu.</p> <p>This section of the taskbar flashes a yellow color when an alarm exists.</p> <p>Select Acknowledge All to stop the flashing indication.</p> <p>Select the Manage Alarms option to display and close any open alarms.</p>	<ul style="list-style-type: 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 any output device icon to display the Manage Queues screen. This screen displays the status of jobs in the queue, job information for the selected output, and allows you to filter the queue display.</p>	
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>	

Table 12: Taskbar Menus

	Description	Menu
<p>5</p> 	<p>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. If the tubehead icon is red with a number next to it, the system needs to wait the listed number of minutes shown before the next set of images can safely be taken.</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 biopsy exposure.</p> <p>X-ray Tube, +15 Degrees puts the tubehead at +15 degrees of rotation for a biopsy 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 (see The About Screen on page 115).</p>	

4.3 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.

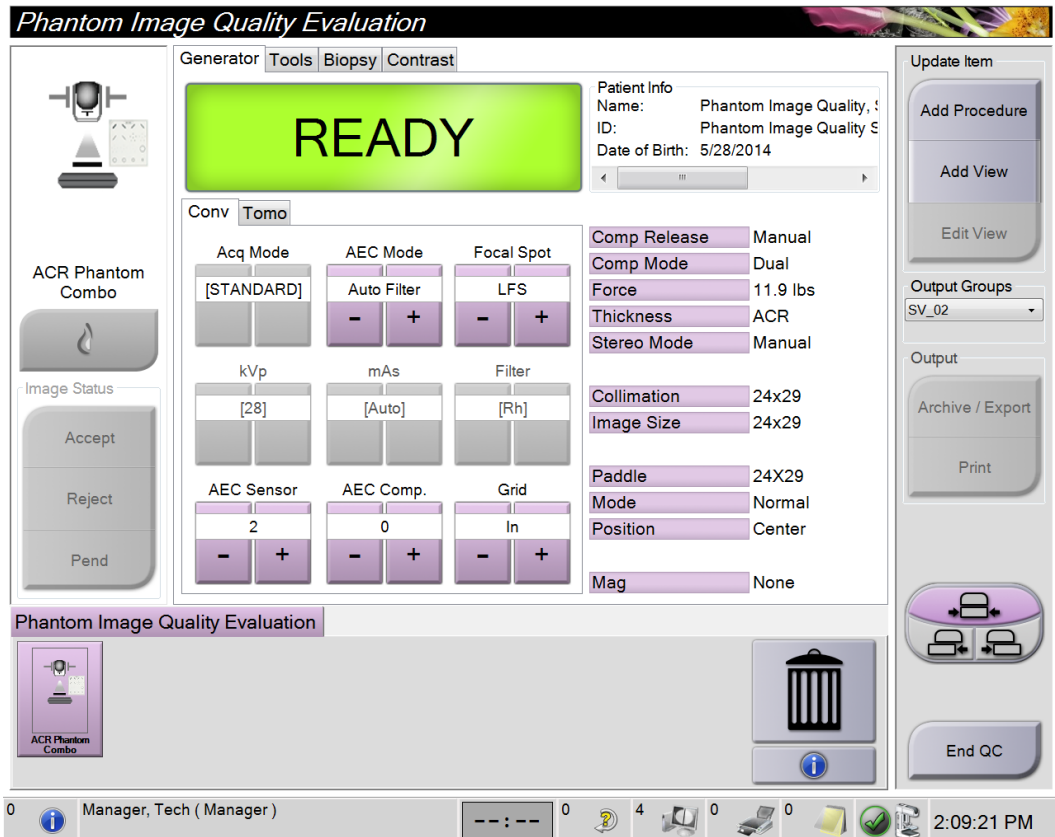


Figure 27: An Example Quality Control Screen



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](#) on page 52). Select the **Quality Control** button on the Admin screen to display the list.

4.4 The Select Patient Screen

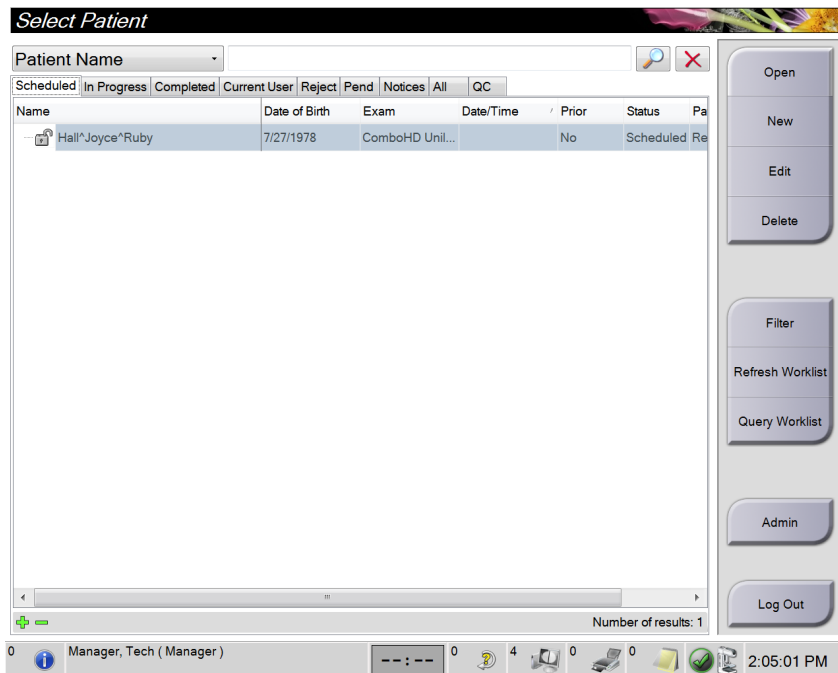


Figure 28: The Select Patient Screen

Table 13: 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 About the Notices Tab on page 53 for complete information. The QC tab displays the Quality Control procedures. The Enterprise tab shows if you have the Advanced Workflow Manager on page 57. This tab displays the procedures acquired on all networked Selenia Dimensions systems.

The screenshot shows the 'Enterprise' tab selected in the 'Select Patient' window. The table displays one patient record: 'Modality*Test*Patient1' with a date of birth of 1/1/2001 and exam type 'Standard Scre...'. The 'Enterprise' tab is highlighted with a black arrow.

Figure 29: The Enterprise Tab

Table 13: The Select Patient Screen

Item	Description
3. Other Functions	<p>Many functions are accessed from this screen by selecting a particular button:</p> <ul style="list-style-type: none"> • Add a new Patient (New)—see How to Add a New Patient on page 54. • Edit the patient information (Edit)—see How to Edit the Patient Information on page 54. • Delete a patient from the worklist (Delete)—see How to Delete a Patient Manually on page 54. • Use a Patient Filter (Filter)—See The Patient Filter Screen on page 55. • Search for a patient in the Modality Worklist (Query)—see How to Query the Worklist on page 56. • Use the Admin Screen (Admin)—see How to Use the Admin Screen on page 113. • Exit (Log Out)—see How to Log Out on page 57. • Find your patients in the database (tabs at the top of screen).

4.4.1 About the Notices Tab

- After selecting 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.
- Select the **Open** button to display the procedure screen for the selected patient.

4.4.2 How to Open a Patient

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

4.4.2.1 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.

The screenshot shows a web-based form titled "Add Patient". The form has several input fields: "Last", "First", "Middle", "Patient ID*", "Date of Birth*", "Gender*" (a dropdown menu currently showing "Female"), "Accession Number", and "Procedure*" (a dropdown menu currently showing "Conventional"). To the right of the form are two buttons: "Open" at the top and "Back" at the bottom. The form is displayed within a browser window, and the Windows taskbar is visible at the bottom, showing the user name "Manager, Tech (Manager)" and the time "2:05:47 PM".

Figure 30: How to Add a New Patient

4.4.3 How to Edit the Patient Information

1. In the *Select Patient* screen, select the patient name then select the **Edit** button.
2. In the *Edit Patient* screen, make changes then select the **Save** button.
3. When the *Update Successful* dialog box appears, select the **OK** button.

4.4.4 How to Delete a Patient Manually



Note

Reclamation normally removes the requirement to delete patients manually. See [About Reclamation](#) on page 112.

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.

4.4.5 The Patient Filter Screen

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

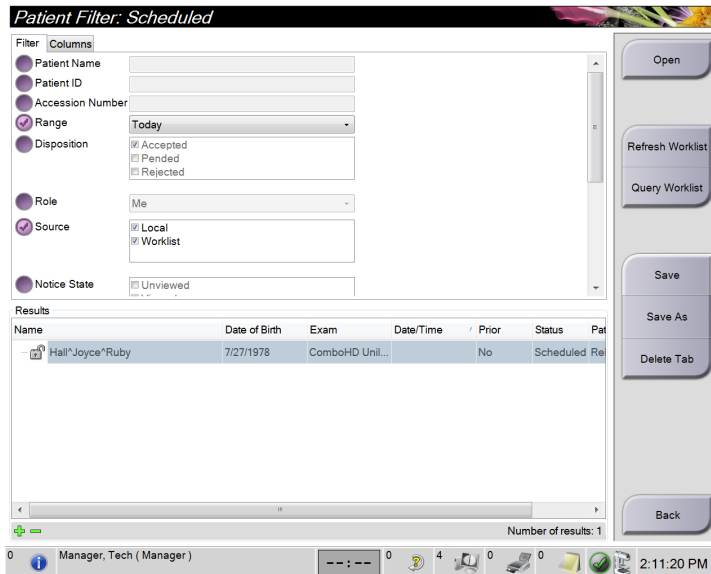


Figure 31: The Filter Tab in the Patient Filter Screen

The Filter and Column Tabs in the Patient Filter Screen

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



Note

You must have Manager level access to save these new filters to the selected tab in the *Select Patient* screen. (See [Other Functions of the Filter Tab](#) on page 56.)

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



Note

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

Other Functions of the Filter Tab

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

Table 14: The Filter Tab Options (Require Access Privileges)

Change the current patient filter parameters.	<ol style="list-style-type: none"> 1. Select a tab on the <i>Select Patient</i> screen. 2. Select the Filter button. 3. Select the filter options. 4. Select the Save button. 5. Make sure the name of the tab you selected is in the name box. 6. Select OK.
Create a new tab for the <i>Select Patient</i> screen.	<ol style="list-style-type: none"> 1. Select a tab on the <i>Select Patient</i> screen. 2. Select the Filter button. 3. Select the filter options for the tab. 4. Select the Save As button. 5. Enter a new name for the tab. 6. Select OK.
Delete a tab from the <i>Select Patient</i> screen.	<ol style="list-style-type: none"> 1. Select a tab on the <i>Select Patient</i> screen. 2. Select the Filter button. 3. Select the Delete button. 4. Select Yes in the confirmation dialog box.

4.4.6 How to Refresh the Worklist

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

4.4.7 How to Query the Worklist

Select the **Query Worklist** button 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 shows, and the patient is added to the local database. By default, the user can scan 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 shows, and the patient is added to the local database.

4.4.8 About the Admin Button

See [System Administration Interface](#) on page 113.

4.4.9 How to Log Out

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

4.4.10 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 systems linked to the Advanced Workflow Manager show the Enterprise tab on [The Select Patient Screen](#) on page 52. This tab lists the procedures acquired on all linked Selenia Dimensions systems.

4.5 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 81).



Note

Depending on the license settings for your system, you may see different tabs. For information specifically about the Biopsy tab, refer to the Affirm system *User Guide*.



Figure 32: The Generator Tab in an Example Procedure Screen

4.5.1 How to Set the Exposure Parameters

Select the Image Acquisition Mode (Tomosynthesis Option)

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



Warning:

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

Select the Exposure Mode

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

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

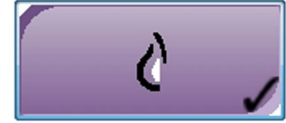
How to Use the AEC Sensor

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.

4.5.2 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 check mark appears on the button.



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



Note

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

4.5.3 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.

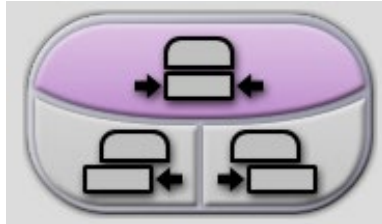


Figure 33: Paddle Shift Buttons

4.5.4 How to Acquire an Image

See [Clinical Procedures](#) on page 101, 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 and/or **footswitch** for the full exposure.

During the exposure:

- A System Message with a yellow background displays (see the following figure)
- An audible tone continues to sound during the exposure

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

- The x-ray indicator on the control panel lights to show x ray emission

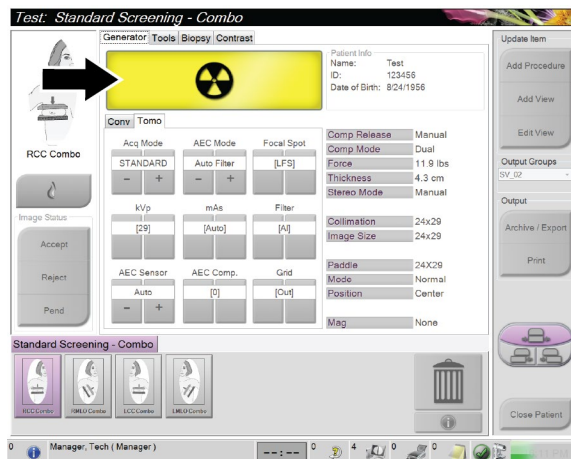


Figure 34: Exposure In Progress

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

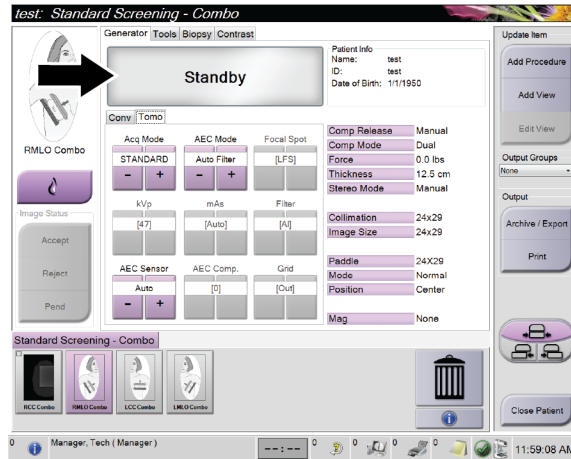


Figure 35: Exposure Complete

- The image appears when the x-ray is finished.
Select one of the following options to complete the acquisition:
 - Accept** the image. The image transmits to output devices with all attributes and marks.
 - Reject** the image. When the dialog box appears, select the cause for the reject. The Preview closes. You can repeat the rejected view, or select another view.
 - Pend** the image. The image saves for future review.
- Repeat steps 1 to 3 for each view.



Note

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

4.5.5 How to Add or Remove a View

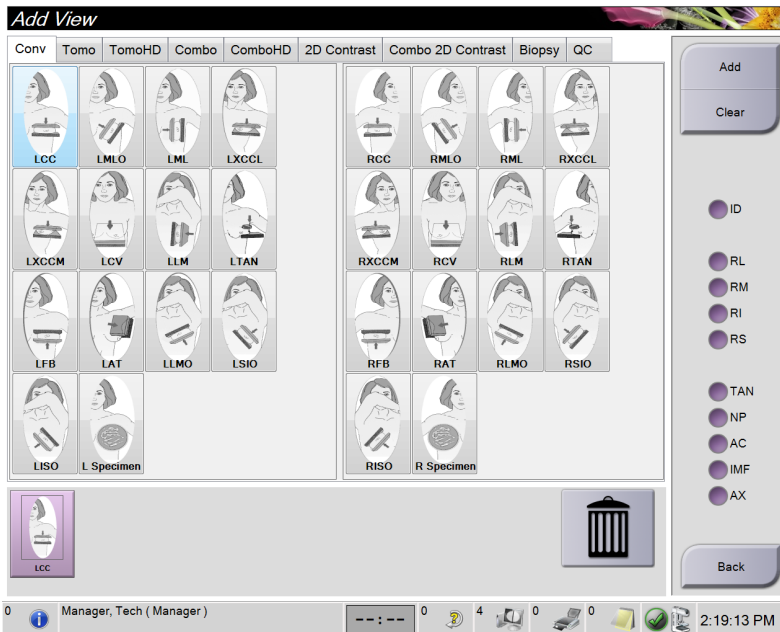
To Add a View

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



Note

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



View Modifiers

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

Figure 36: The Add View Screen

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

To Remove a View

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

4.5.6 Procedure Information Dialog Box

To show procedure information, select the **Procedure Information** button located beneath the **Delete View** (trash can) button. The Procedure Info window displays with the following information:

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

For Procedures that contain no exposed views, select the **Delete Procedure** button in the Procedure Information window to remove the selected procedure from the patient.

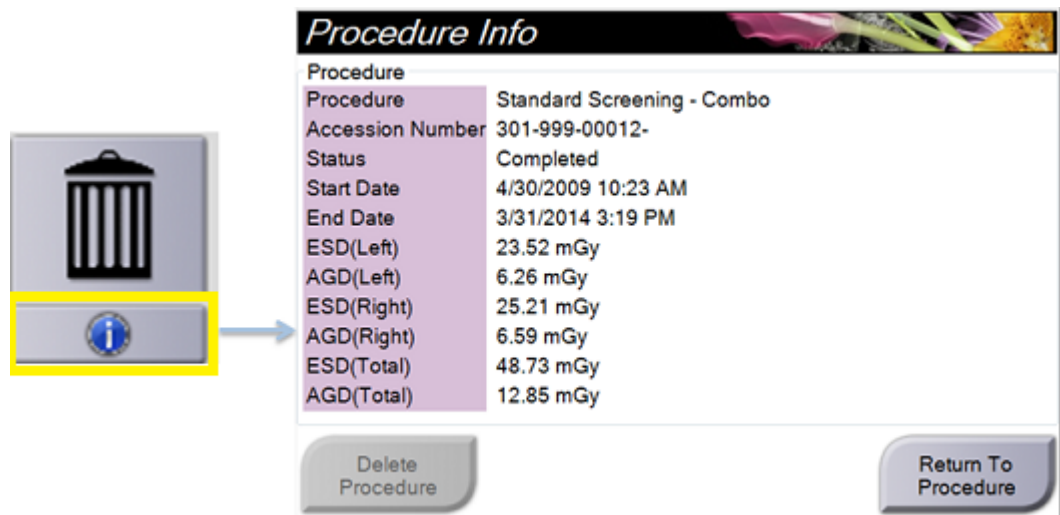


Figure 37: The Procedure Info Window

4.5.7 How to Add a Procedure

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

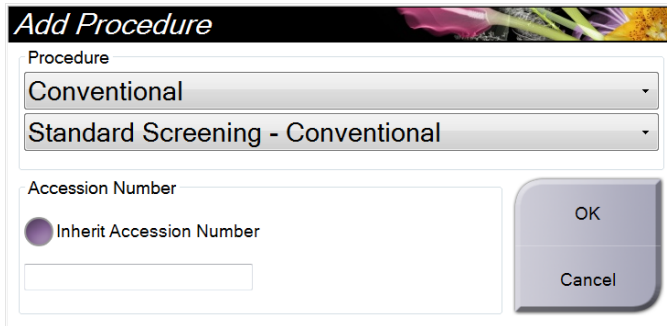


Figure 38: Add Procedure Dialog Box

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

Available Procedures

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



Note

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

Table 15: Procedure Groups

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

4.5.8 How to Edit a View

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

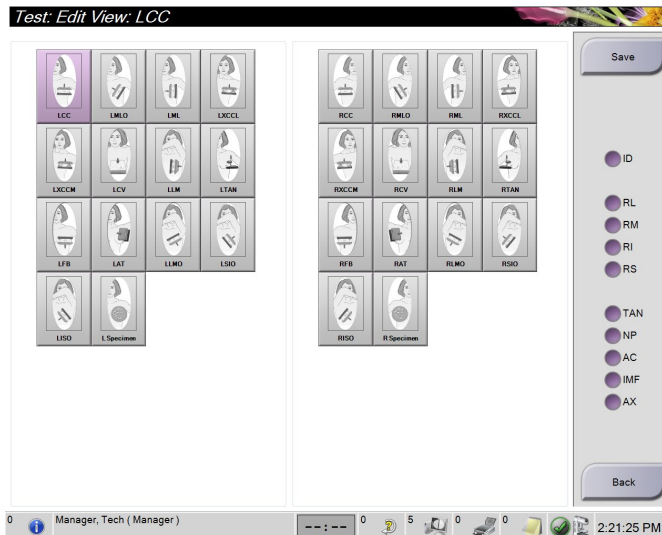


Figure 39: The Edit View Screen

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 three View Modifiers. See the figure [The Add View Screen](#) on page 62 for a description of the View Modifiers.
4. Select the **Save** button.
5. When the Update Successful screen displays, select the **OK** button.



Note

The Edit View Screen for biopsy procedures shows different View Modifiers. Refer to the Affirm system *User Guide*.

4.5.9 How to Close a Procedure

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

Close Procedure Complete	Closes the procedure and puts the procedure in the Complete tab.
Close Procedure In Progress	Closes the procedure and puts the procedure in the In Progress tab.
Close Procedure 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.
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.

4.6 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 81 for information.

4.7 How to Use I-View 2D Contrast

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

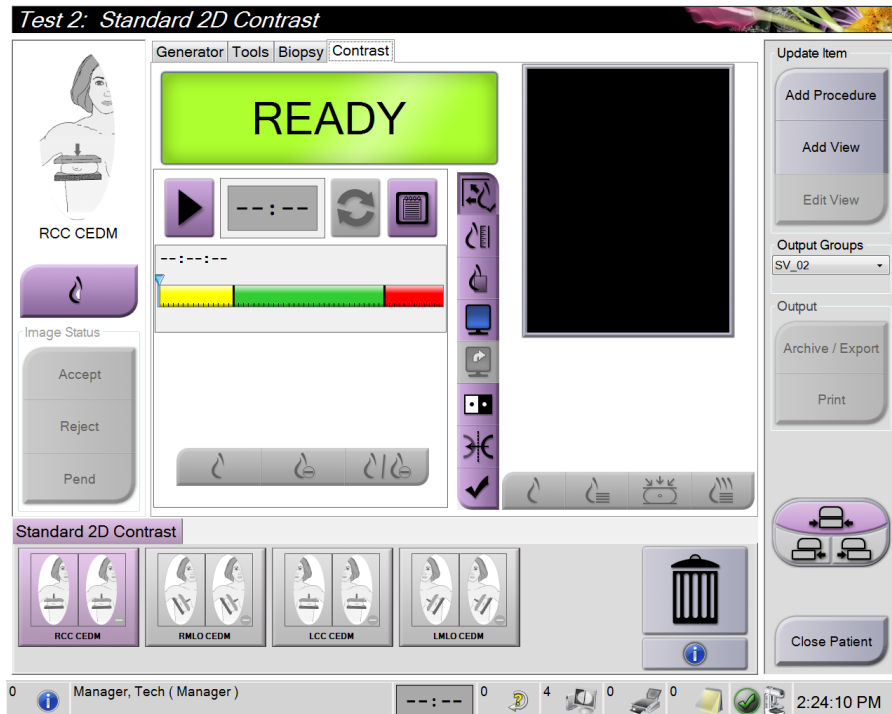


Figure 40: I-View 2D Contrast Screen

2. Set contrast settings. For more information, refer to [How to Define Contrast Settings](#) on page 70.



Note

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

3. To begin the contrast dose and start the timer, click **Start**.

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



Note

You can adjust the default length of time for the **Waiting Period** and **Optimal Imaging Period** phases of the timer. Refer to [How to Define Contrast Settings](#) on page 70.

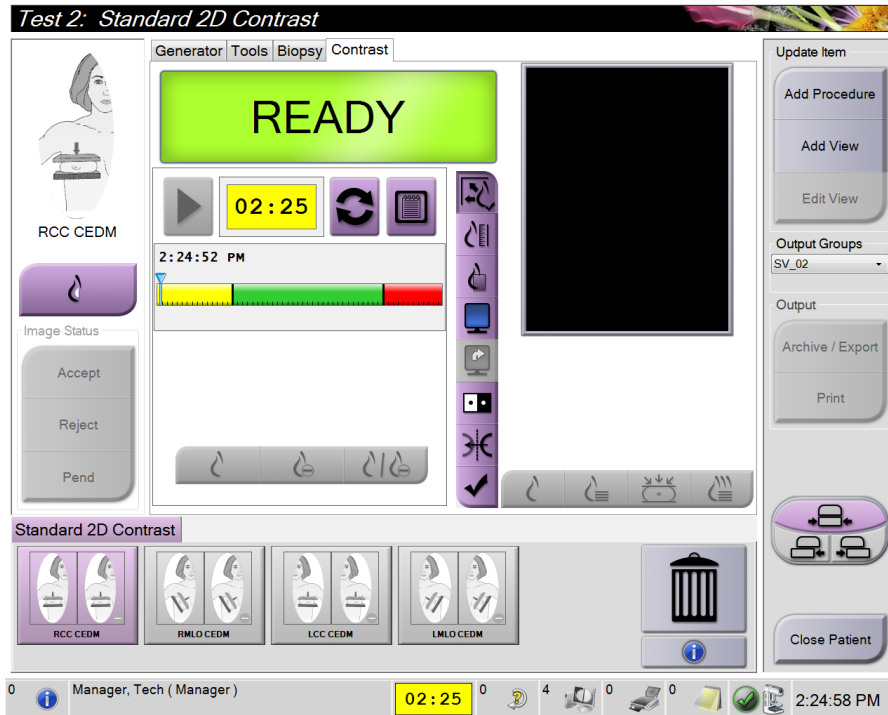


Figure 41: I-View 2D Contrast Screen, Waiting Period



Note

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

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

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

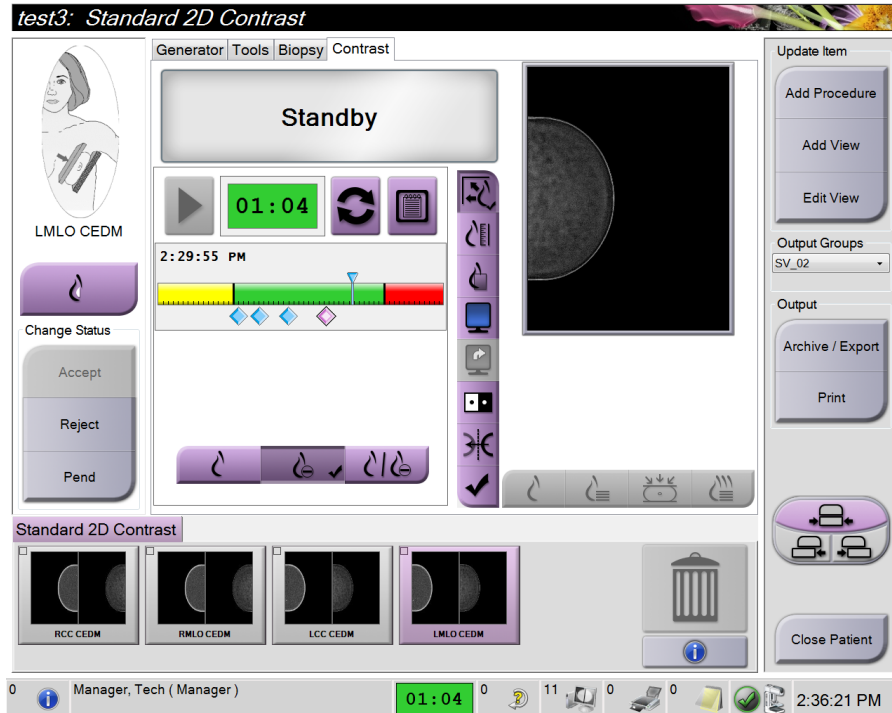


Figure 42: I-View 2D Contrast Screen, Optimal Imaging Period

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



Caution:

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



red, a recommended wait time is shown. This wait time lets the x-ray tube temperature decrease to avoid damage that can void the x-ray tube warranty. Always make sure that the x-ray tube status icon is green



before starting an I-View 2D Contrast procedure. If the x-ray tube status icon turns red during a procedure, complete the procedure quickly using the minimum number of exposures.

4.7.1 How to Define Contrast Settings

1. Select the **Conf** button to edit contrast settings. The Contrast Information dialog box appears.

Field	Value	Unit
Contrast Entry Route	Intra-arterial route	
Contrast Agent	Diatrizoate	
Contrast Agent Concentration	240	mg/ml
Total Bolus Volume	0.0	ml
Patient Weight	0.0	lb
Patient Weight	0.0	kg
Contrast Concentration Per Body Weight	0.0	ml/kg
Amount of Contrast Agent	0.0	ml

Figure 43: I-View 2D Contrast Settings

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

Set the Default Timer Period

1. From the Admin screen, select the **Contrast** button.

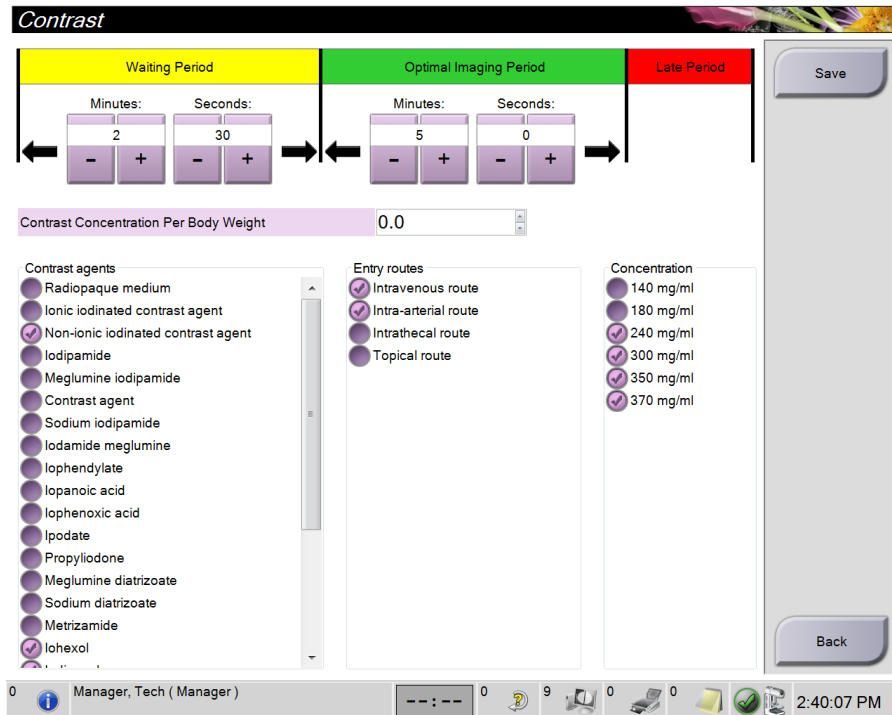


Figure 44: I-View 2D Contrast Settings, Admin screen

2. Choose the plus (+) or minus (-) buttons to change the Minutes and Seconds for **Waiting Period** and **Optimal Imaging Period**.
3. Click **Save**.

Your changes appear as the default timer settings on the 2D Contrast screen.

Set the Default Contrast Information

1. From the Admin screen, select the **Contrast** button. Refer to the previous image.
2. Select one or more **Contrast agents**, **Entry routes**, and **Concentration**.
3. Click **Save**.

The selections you made automatically appear as default options on the Contrast Information dialog box.

4.8 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 from the *Print* screen.

4.8.1 How to Select an Output Group

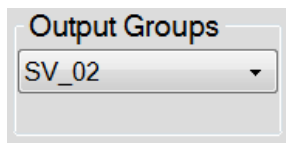


Figure 45: Output Groups Field

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.

4.8.2 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 appears, 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 appears, select **OK**.

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

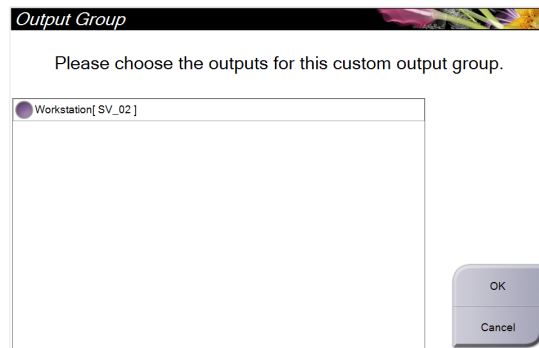


Figure 46: An Example Custom Output Group

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

4.9.1 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.
 - **Rejected** button shows rejected views for this patient.
3. Select a storage device:
 - Select the **Device List** button and make your selection from the options in the *Storage Device* drop-down menu.

OR

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



Note

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

4.9.2 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.

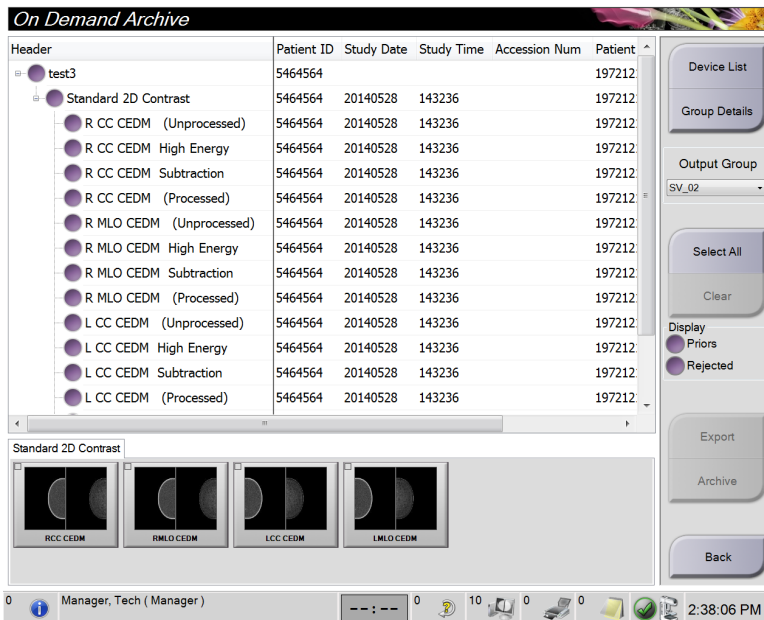


Figure 47: Select the Images for Export

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

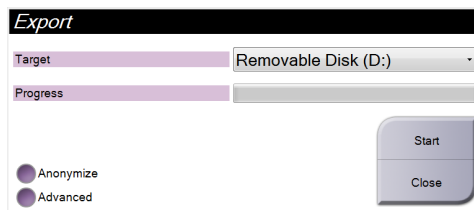


Figure 48: Export Screen

- 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.

4.9.3 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 76 to prepare your print data.
2. Select the film format from the film format area of the screen.
3. Select a thumbnail image.
4. Select the image mode (Conventional, Projection, or Reconstruction). The C-View button shows if the system is licensed for C-View imaging.
5. Select the 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.

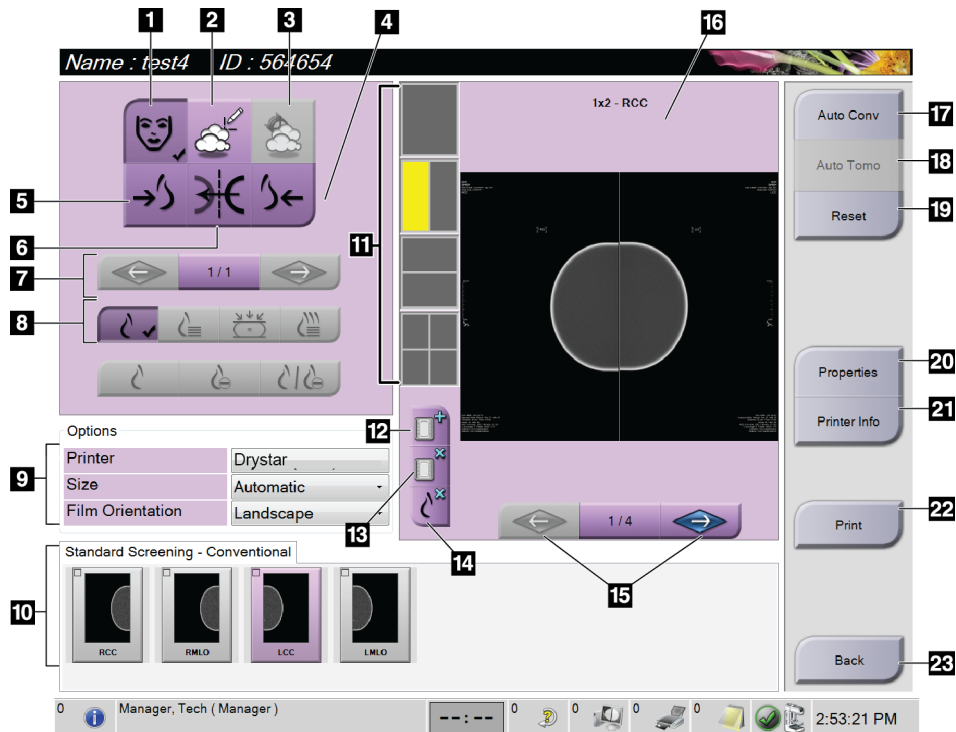


Figure 49: The Print Screen

Figure Legend

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

Chapter 5 The Images

5.1 Introduction

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



Figure 50: 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 technologist information

5.1.1 Conventional Imaging Sequence of Events

- Review the image after the exposure and add a comment, if necessary.
- 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.

5.1.2 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.

5.1.3 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**.

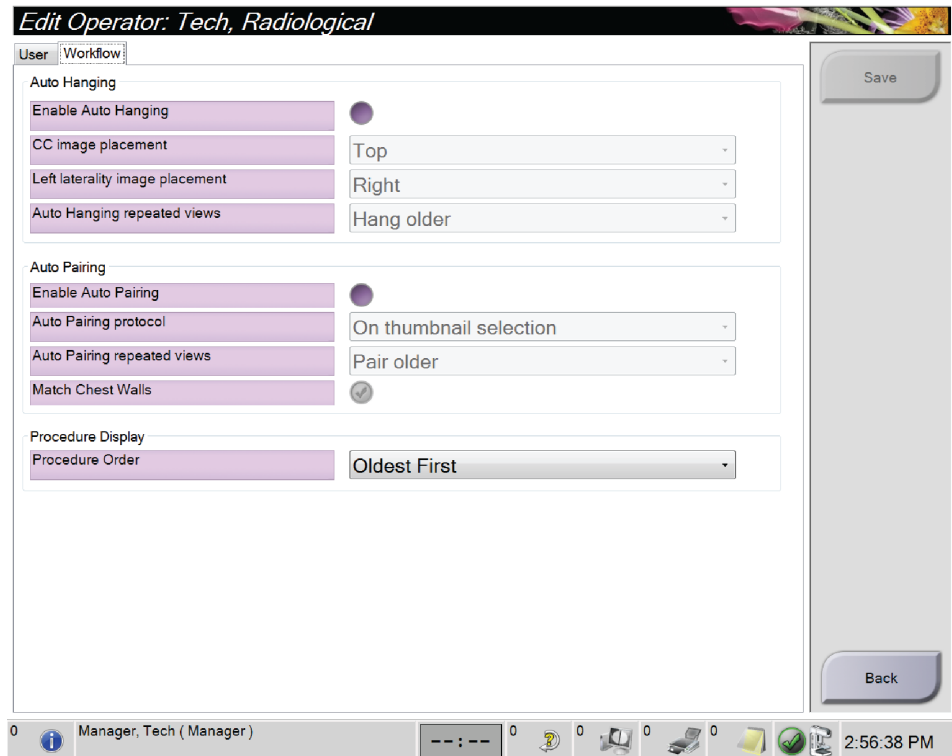


Figure 51: Enable Auto-Hanging and Auto-Pairing

5.2 How to Review the Images

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

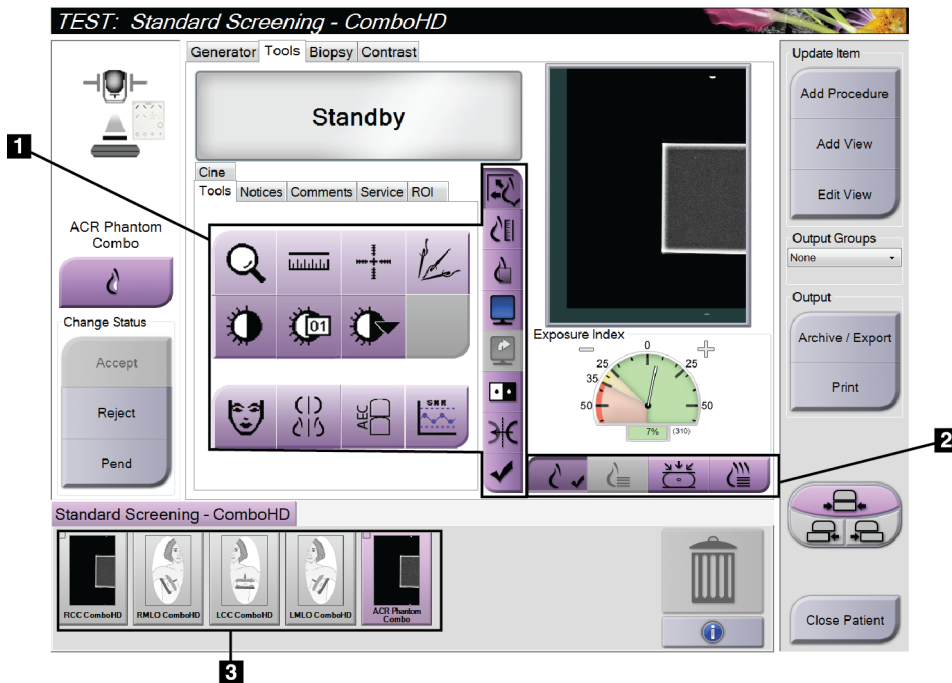


Figure 52: The Tools Tab (Tomosynthesis option shown)

Figure Legend

1. Image Review Tools - refer to [The Image Review Tools Tab](#) on page 81.
2. Image Display Modes - refer to [Display Modes \(Tomosynthesis Option\)](#) on page 83.
3. Thumbnail Images

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

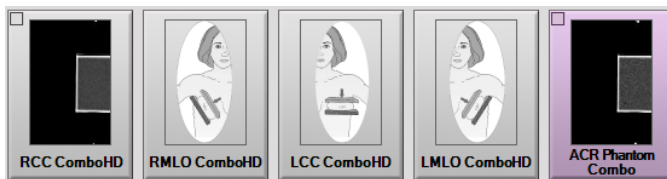


Figure 53: Marked Images in a Procedure (Tomosynthesis option shown)

5.2.1 The Image Review Tools Tab

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

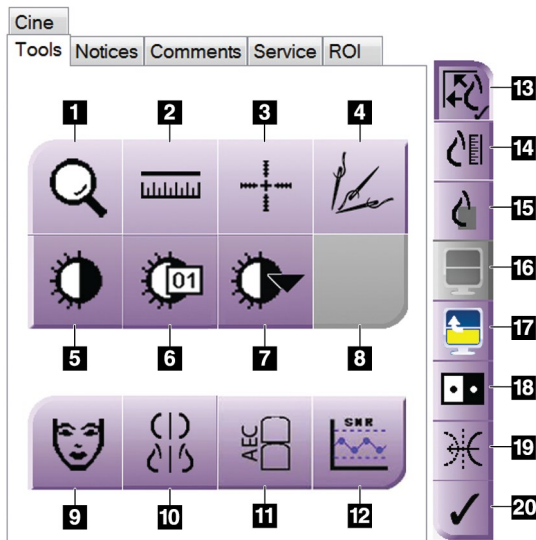


Figure 54: Image Review Tools

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

5.2.2 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.

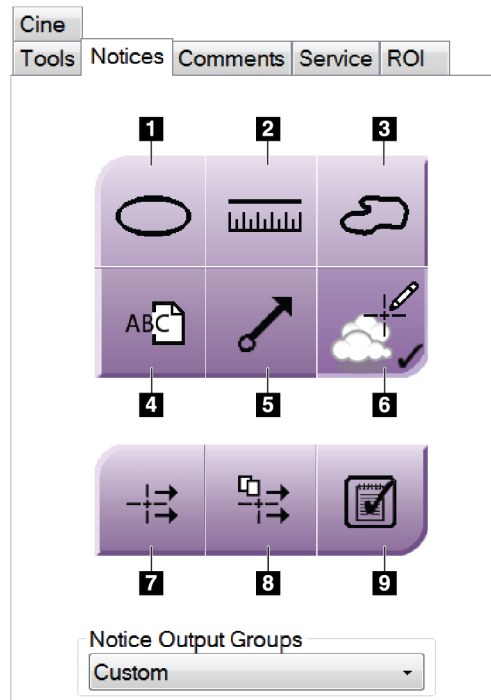


Figure 55: The Notices Tools Tab

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. The Arrow tool draws an arrow marking on the image.
6. The Markings tool shows or hides markings and annotations on an image.
7. The Send Notice tool sends a notice for the current image to the selected destination.
8. The Send All Notices tool sends all notices for all images in the opened procedure to the selected destination.
9. The Viewed tool changes the Patient's Notices status to viewed.

5.2.3 Other Image Review Tools

The Other Tabs

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

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.

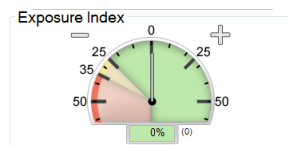


Figure 56: Exposure Index

Display Modes (Tomosynthesis Option)

Use the buttons in the Display Modes area of the screen to select the type of view to show in the Preview Screen. You can change between conventional, C-View, projections, and reconstruction to show the combination images.

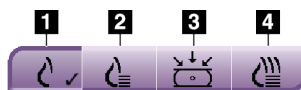


Figure 57: Display Modes

Figure Legend

1. Conventional button shows conventional images
2. C-View button shows a conventional 2D image generated from the acquired tomographic image.
3. Projections button shows the 15° images.
4. Reconstruction button shows reconstructed slices

5.2.4 Slice Indicator

The Slice Indicator shows only on tomographic reconstructions.

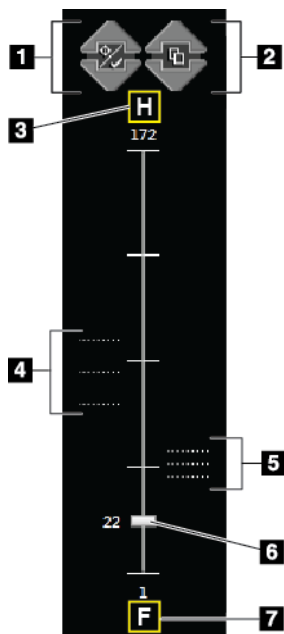


Figure 58: Slice Indicator

Figure Legend

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

5.2.5 How to Correct and Reprocess Implant Images

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

If the Image Is Not Accepted

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



If the Image Is Accepted

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



Note

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

5.3 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 72 and [How to Use the On-Demand Outputs](#) on page 73 for instructions.

Chapter 6 How to Use the Accessories

6.1 Introduction

The Selenia Dimensions system 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.

6.2 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.

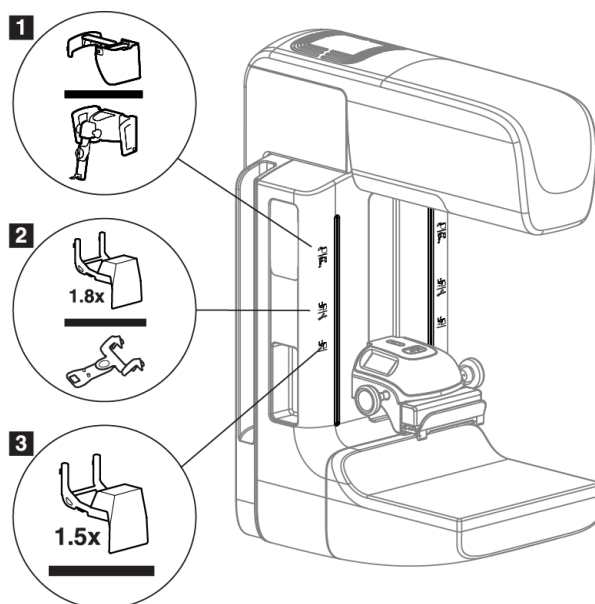


Figure 59: C-arm Accessories

Figure Legend

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

6.3 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 the patient from radiation.

6.3.1 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) is in the Up position.
4. Push the Face Shield to the down and locked position. The Unlock Lever is in the Down position when the Face Shield locks.

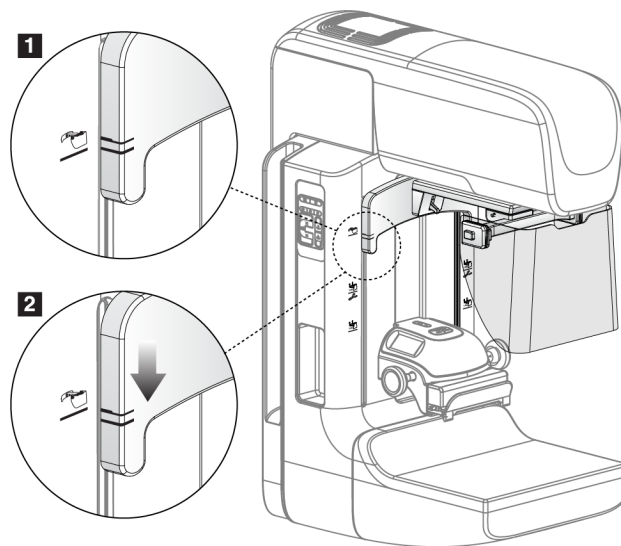


Figure 60: How to Align the Retractable Face Shield on the C-arm

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.

6.3.2 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 89—one on each side).
2. Push the Face Shield toward the C-arm until the device stops.

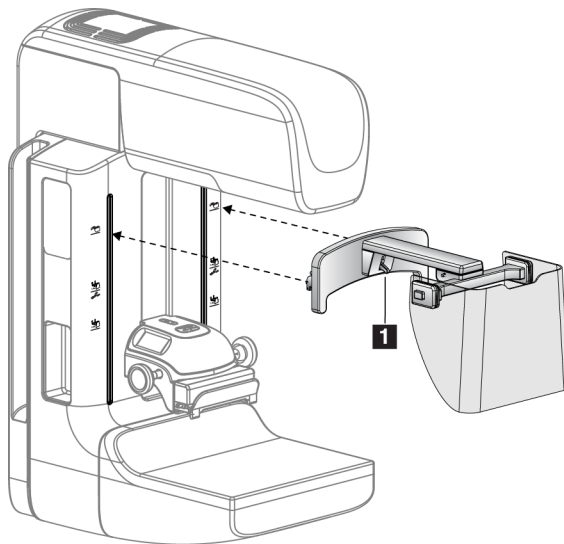


Figure 61: Face Shield Installation

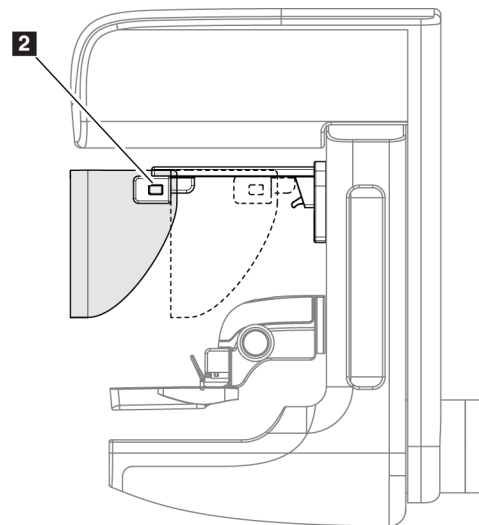


Figure 62: Face Shield Operation

6.3.3 How to Install or Remove the Conventional Face Shield

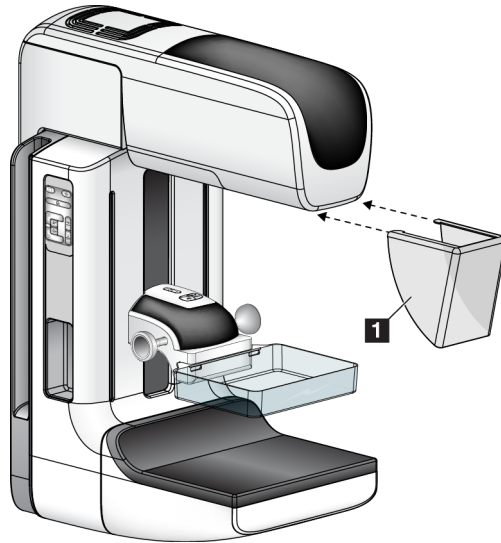


Figure 63: How to Install the Conventional Face Shield

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.

6.4 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.

Available accessories depend on your system configuration. The Selenia Dimensions system performs screening and diagnostic applications. The Selenia Dimensions 2D screening system performs only screening applications.

Table 16: Available Accessories

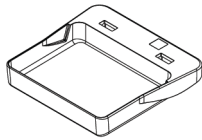
Accessory		2D/BT	2D Screening
Routine Screening Paddles	18 x 24 cm	*	*
	24 x 29 cm	*	*
	Small Breast	*	*
Contact and Spot Compression Paddles	10 cm Contact	*	
	15 cm Contact	*	
	7.5 cm Spot Contact	*	See Note
	Frameless Spot Contact	*	
Magnification Paddles	7.5 cm Spot Mag	*	
	10 cm Mag	*	
	15 cm Mag	*	
Localization Paddles	10 cm Rectangular Open	*	
	15 cm Rectangular Open	*	
	10 cm Perforated	*	
	15 cm Perforated	*	
	10 cm Mag Perforated Loc	*	
	10 cm Mag Localization	*	
Ultrasound Paddle	15 cm Large Ultrasound	*	
Patient Face Shield		*	*
Magnification Stand		*	
Localization Crosshair Device		*	
Magnification Crosshair Device		*	



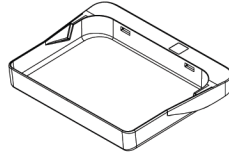
Note

On the Selenia Dimensions 2D Screening system, only use the 7.5 cm Spot Contact Paddle for compression thickness calibration.

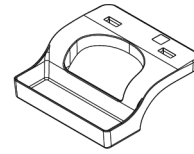
6.4.1 Routine Screening Paddles



**18 x 24 cm Frameless
Screening Paddle**

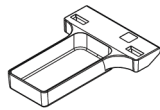


**24 x 29 cm Frameless
Screening Paddle**

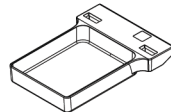


**Small Breast
Frameless Paddle**

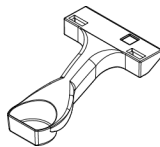
6.4.2 Contact and Spot Compression Paddles



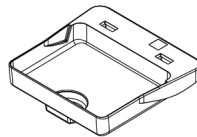
**10 cm Contact
Frameless Paddle**



**15 cm Contact
Frameless Paddle**

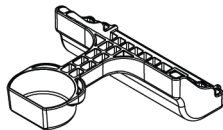


**7.5 cm Spot Contact
Frameless Paddle**

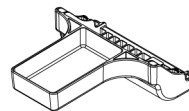


**Spot Contact
Frameless Paddle**

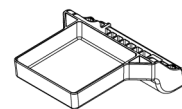
6.4.3 Magnification Paddles



**7.5 cm Spot Magnification
Paddle**

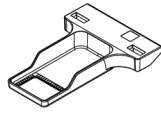


**10 cm Magnification
Paddle**

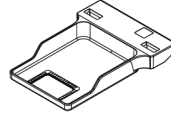


**15 cm Magnification
Paddle**

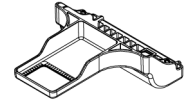
6.4.4 Localization Paddles



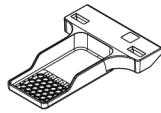
**10 cm Rectangular Opening
Localization Paddle**



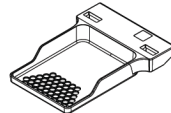
**15 cm Rectangular Opening
Localization Paddle**



**10 cm Magnification
Localization Paddle**



**10 cm Perforated
Localization Paddle**

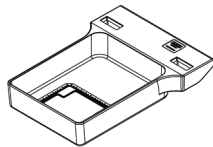


**15 cm Perforated
Localization Paddle**



**10 cm Magnification
Localization Perforated
Paddle**

6.4.5 Large Ultrasound Paddle



**15 cm Large Ultrasound
Paddle**

6.4.6 How to Install or Remove a Compression Paddle

See the figure [How to Install a Compression Paddle](#) on page 94 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.

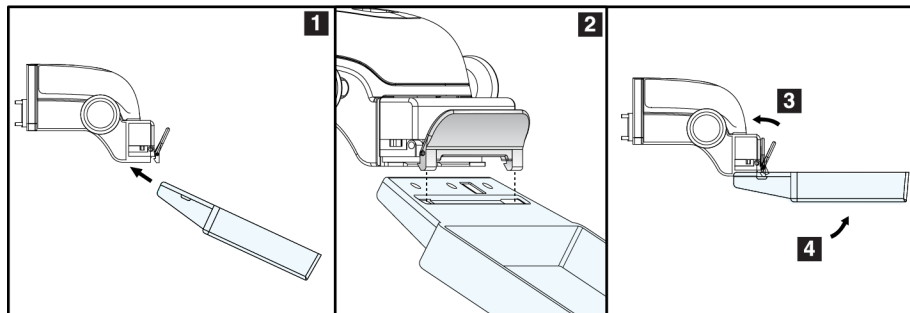


Figure 64: How to Install a Compression Paddle

See the figure [How to Remove the Compression Paddle](#) on page 94 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.

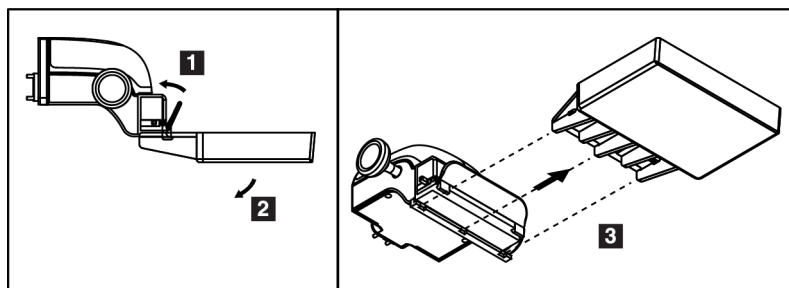


Figure 65: How to Remove the Compression Paddle

6.4.7 Maintenance and Cleaning

Clean the paddles after each use. See [Maintenance and Cleaning](#) on page 109 for cleaning instructions.

6.4.8 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.

6.4.9 FAST Compression Mode

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.

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.

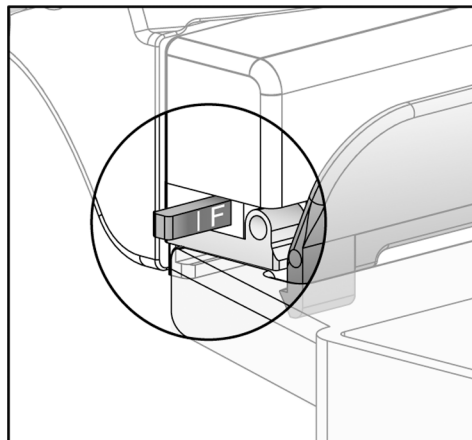


Figure 66: The FAST Compression Mode Slide

6.5 Magnification Stand

The Selenia Dimensions Magnification Stand has a breast platform and an abdominal shield. When the Magnification Stand is installed, the 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 92).

6.5.1 How to Install and Remove the Magnification Stand

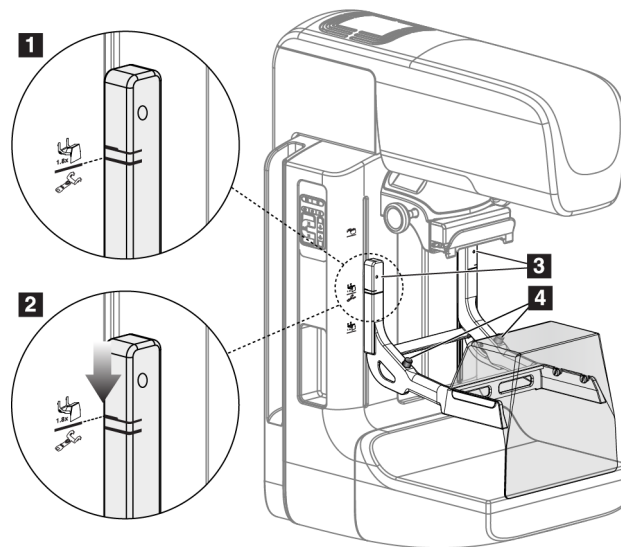


Figure 67: Installation of the Magnification Stand

To Install the Magnification Stand

1. Remove the Face Shield (see [The Patient Face Shields](#) on page 88) 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 87.

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.
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.

6.6 Crosshair Devices

6.6.1 How to Install and Remove the Localization Crosshair Device

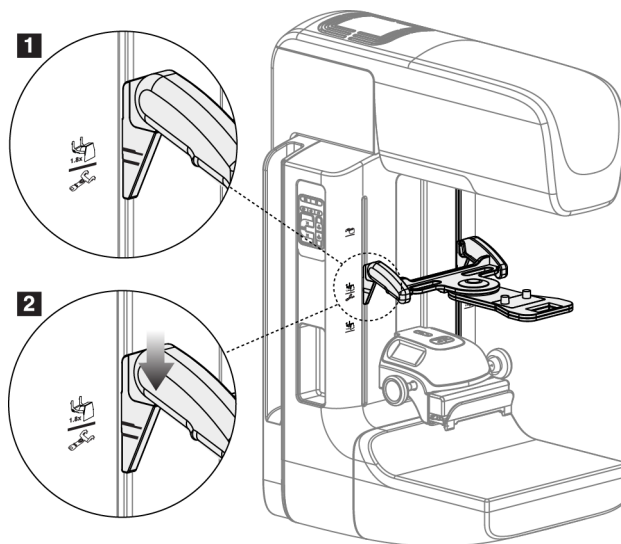


Figure 68: How to Attach the Localization Crosshair Device

To Install the Localization Crosshair Device

1. Remove the face shield (see [The Patient Face Shields](#) on page 88).
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 87.
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.

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.

6.6.2 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.

6.6.3 How to Install and Remove the Magnification Crosshair Device

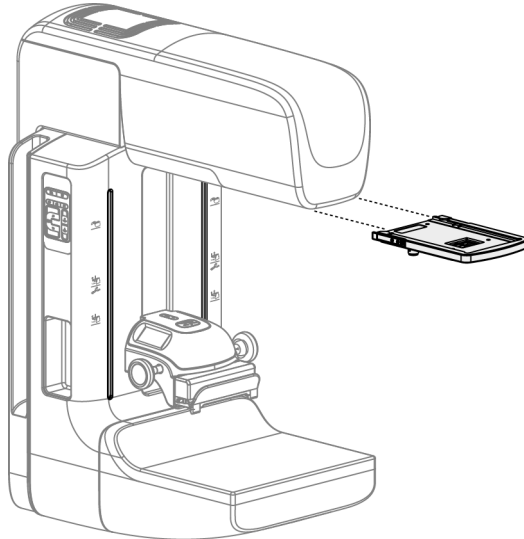


Figure 69: How to Install and Remove the Magnification Crosshair Device

To Install the Magnification Crosshair Device

1. Remove the face shield (see [How to Install or Remove the Conventional Face Shield](#) on page 90).
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.

To Remove the Magnification Crosshair Device

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

6.6.4 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 7 Clinical Procedures



Warning:
C-arm movement is motorized.



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



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



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

7.1 Standard Workflow

7.1.1 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.

7.1.2 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.

7.1.3 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.

7.2 Screening Procedure Example

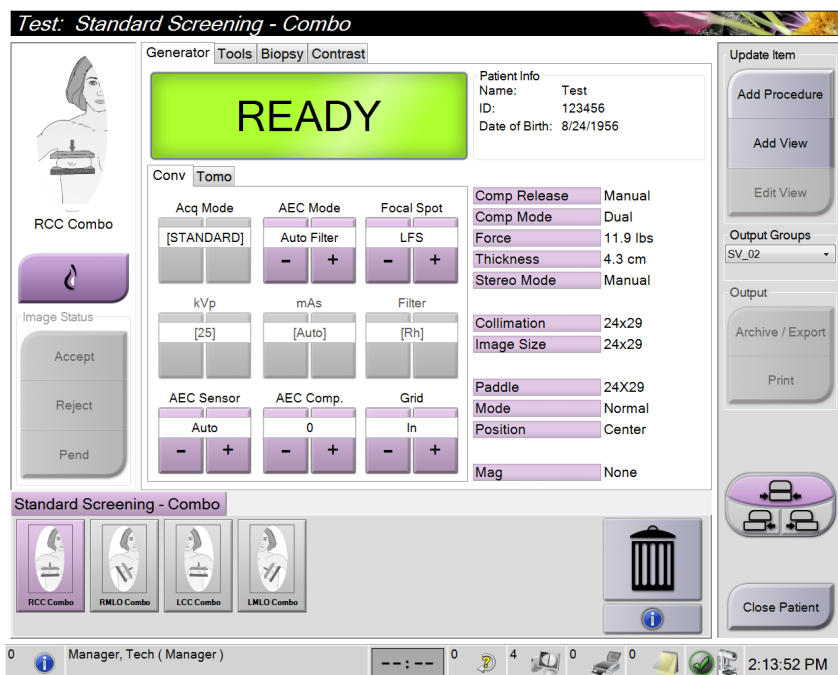


Figure 70: Screening Example

7.2.1 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.

7.2.2 Set the Exposure Techniques

Select the exposure techniques for the procedure. See [How to Set the Exposure Parameters](#) on page 58 for information.

7.2.3 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** button and/or **footswitch** for the full exposure.

During the exposure:

- A System Message with a yellow background is displayed (see the following figure)
- An audible tone continues to sound during the exposure

The behavior of the audible tone during a combo exposure has changed to avoid early releases of the x-ray button and/or footswitch by users. The audible tone is now a continuous sequence of tones. The tone sounds during the entire combo acquisition from the initiation of the exposure to the end of the conventional view. There is no interruption of the audible tone between breast tomosynthesis and conventional digital mammography exposures. Do not release the exposure switch during the audible tone.

- The x-ray indicator on the control panel lights to show x ray emission.

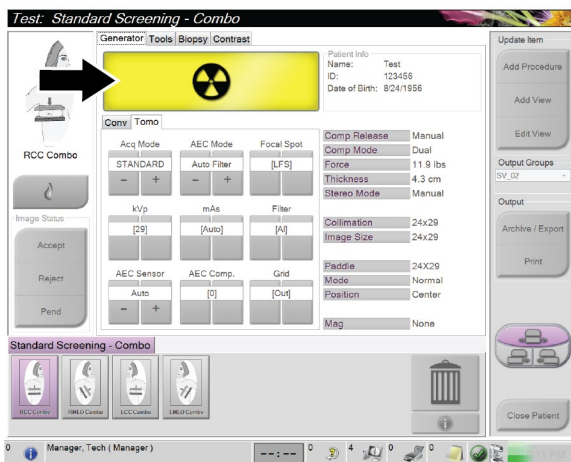


Figure 71: Exposure In Progress

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

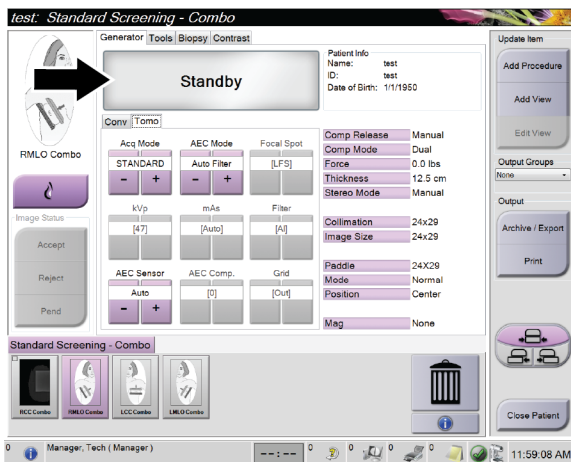


Figure 72: Exposure Complete

- Release the compression device. If the automatic release feature is set, the compression device automatically lifts after the exposure.

7.2.4 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.

7.2.5 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.

7.2.6 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.

7.3 Procedure for Needle Localization with Tomosynthesis

1. Install a Localization Paddle, and install the Crosshair Device at the Tubehead. Be sure that the crosshair guides are out of the x-ray field.
2. Open a new procedure with a Tomo or TomoHD view for your approach.
3. Position the patient and apply compression.
4. Acquire a Tomo Scout. Make sure that the ROI is visible inside the Localization Paddle opening. If not, reposition the patient and repeat.
5. Note the Compression Thickness, and note the thickness of the excess tissue through the opening of the Localization Paddle.
6. Scroll through the reconstruction slices to identify where the lesion is best seen. Note the slice number (each slice is 1 mm in thickness).
7. Place the Acquisition Workstation crosshair on the lesion.
8. To find the coordinates for the Gantry Crosshair Device, scroll through the reconstructions until you can identify the alpha numeric coordinates.
9. Calculate the needle depth:

Value	Example
Breast Compression Thickness	50 mm
(+) Thickness of the tissue through the opening of the paddle	+ 7 mm
(-) Slice number where the lesion is found	- 30 mm
(+) Optional distance past the ROI for the wire	+ 5-15 mm
(=) Needle depth of the localization wire	32- 42 mm

10. Turn on the collimator light and align the Crosshair Device at the Tubehead to match the Acquisition Workstation crosshair.
11. Position and insert the needle.
12. Move the Crosshair Device guides out of the x-ray field.
13. Acquire another Tomo image to be sure that the needle is in the correct location. To calculate if a correction is necessary, compare the slice number of the point of the needle and the slice number of the lesion.
14. Insert the guide wire through the needle, and then remove the needle, if desired, leaving the wire in position.
15. If desired, complete the following steps:
 - a. Acquire a Conventional or Tomo view to be sure of correct wire placement.
 - b. Take the orthogonal view to document wire or needle placement (either in Tomo or conventional).
16. Only add one view icon at a time for orthogonal views to remove the possibility of paddle shift due to possible minimal compression.

Example: Calculating Needle Depth with Tomosynthesis

In this example, use the values from the table on the previous page and refer to the following figure.

Calculate the needle depth from the tissue skin line (item 1) rather than from the localization paddle (item 9). Insert the needle a minimum of 27 mm (breast compression + bulging tissue).

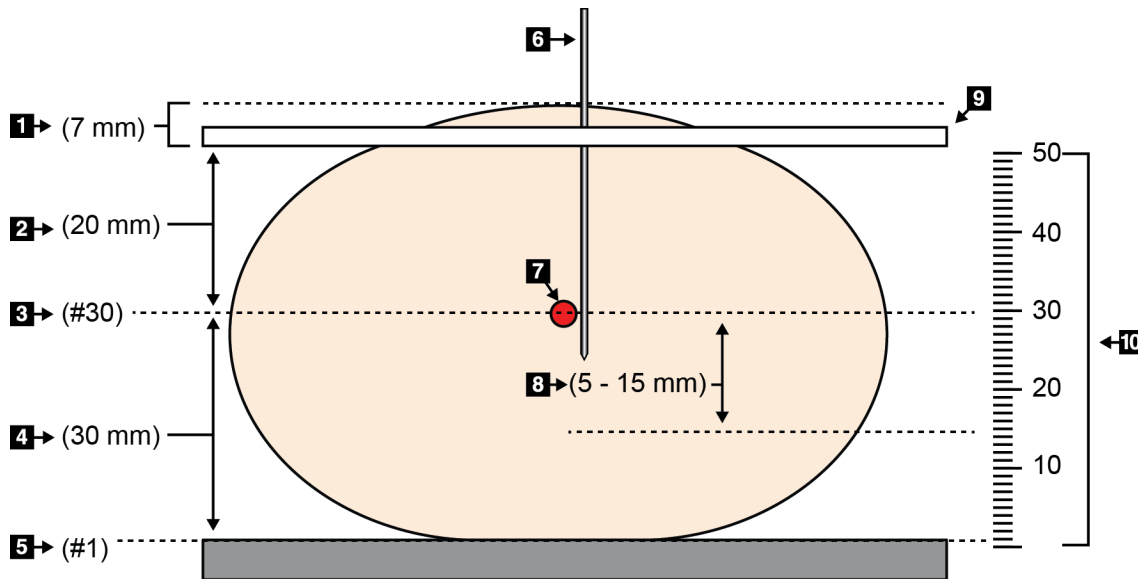


Figure 73: Calculating needle depth

Item	Description	Example
1	Thickness of the tissue through the opening of the localization paddle	7 mm
2	Thickness measured from the localization paddle to the lesion	
3	Lesion slice number (the slice number where lesion is best seen (clearest))	30 mm
4	Thickness measured from the detector to the lesion	
5	Slice number 1	
6	Needle	
7	Lesion	
8	Advancing the needle 5 - 15 mm more than the lesion (optional)	5 - 15 mm
9	Localization paddle	
10	Thickness of the breast compression from the detector (0 mm) to the localization paddle (50 mm in this example)	50 mm

Chapter 8 Maintenance and Cleaning

8.1 Cleaning

8.1.1 General Information About Cleaning

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



Caution:

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

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

8.1.2 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 to remove contamination from the paddle.



Caution:

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

8.1.3 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.

8.1.4 Acquisition Workstation

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.

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.

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.

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.

8.2 Maintenance

8.2.1 Preventive Maintenance Schedule



Note

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

Table 17: 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

8.2.2 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 9 System Administration Interface

9.1 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.

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



Note

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

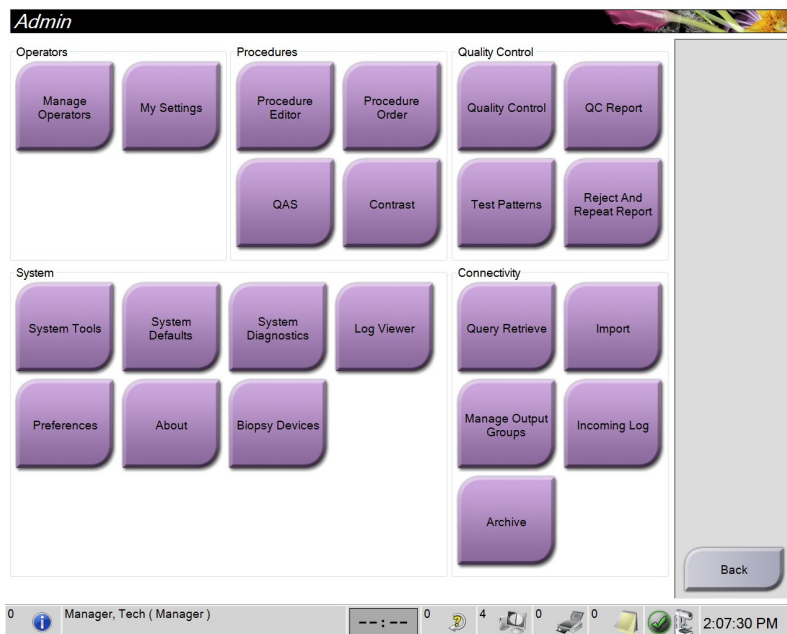


Figure 74: The Admin Screen

Selenia Dimensions System User Guide

Chapter 9: System Administration Interface

Table 18: 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.
	Contrast	Access the contrast enhanced digital mammography functionality.
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. See The About Screen on page 115.
	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.
You must have permission to access all features. The permission level controls the functions you can change.		

9.2 The About Screen

The About screen provides information about the machine, such as system level, IP address, and Gantry serial number. This type of data can be useful when you are working with Hologic to resolve a system issue or configure the system.

The screen is accessed in two ways:

- *User Login* - Select Patient Screen > “Tube Icon” on Taskbar > About...
- *Admin/Manager/Service Login* - Admin > About (in System Grouping)

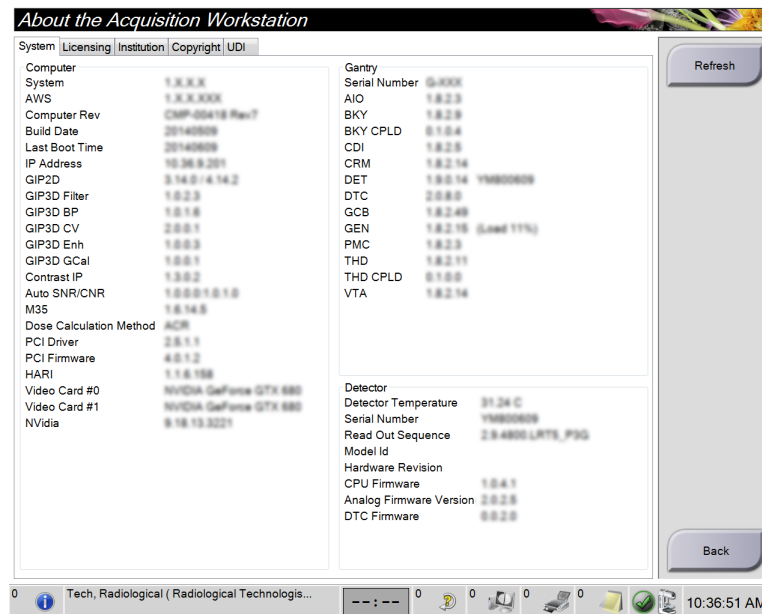


Figure 75: About (the Acquisition Workstation) Screen with the System Tab Showing

There are five tabs on the About screen:

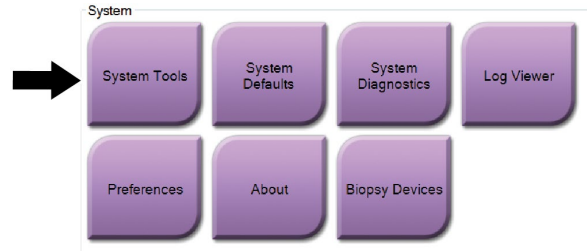
- *System Tab* (default) - lists system configuration information
- *Licensing Tab* - lists the Hologic-licensed options installed on this machine
- *Institution Tab* - lists the name and address of the organization assigned to this machine
- *Copyright Tab* - lists the copyrights of Hologic and third-party software installed on this machine
- *UDI Tab* - lists the unique device identifier(s) of this machine

9.3 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 system.

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**.



9.3.1 The System Tools for the Radiologic Technologist Manager

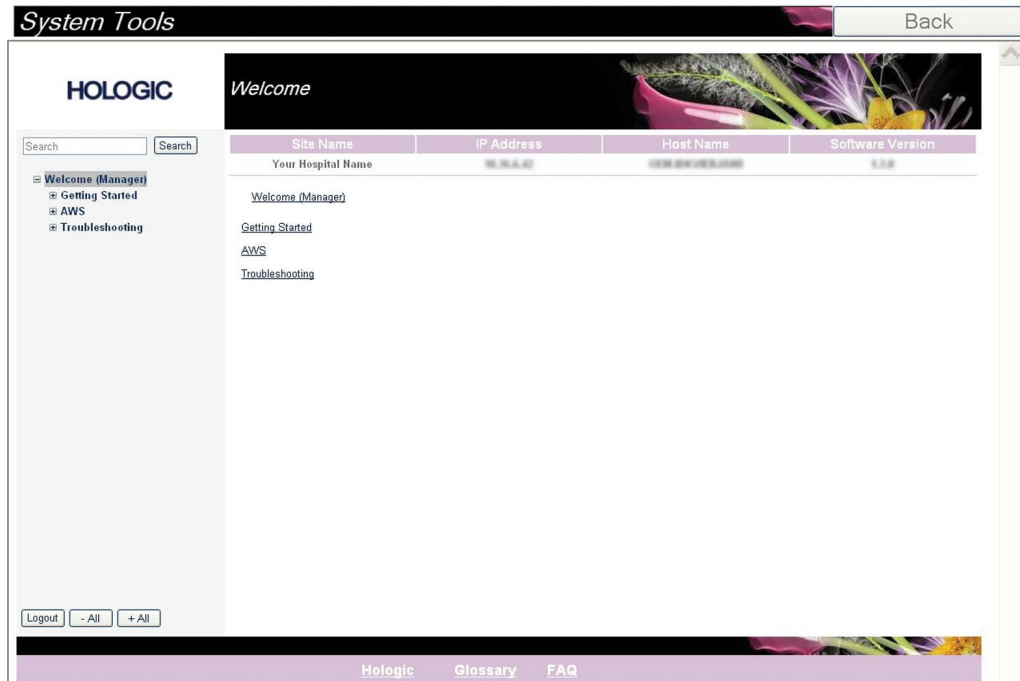


Figure 76: The System Tools Screen

Table 19: Radiologic Technologist Manager – System 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. (*You can also access this report from a remote computer. Refer to Remote Access to Image Reports on page 118.)</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>

9.3.2 Remote Access to Image Reports

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

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

1. Get the IP Address for the system you want to access. You can get the IP Address from your IT administrator or from the system. From the system, go to **Select Patient Screen > "Tube Icon" on Taskbar > About... > System Tab > IP Address**. Write down the IP Address.
2. Using an internet browser on your remote computer, navigate to `http:// [IP address]/Hologic.web/MainPage.aspx`. Use the IP Address from step 1.
3. The *Service Tools Logon* screen displays. Type a Manager-level user name and password, and then click **Submit**.



Figure 77: Remote Logon Screen for Service Tools

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

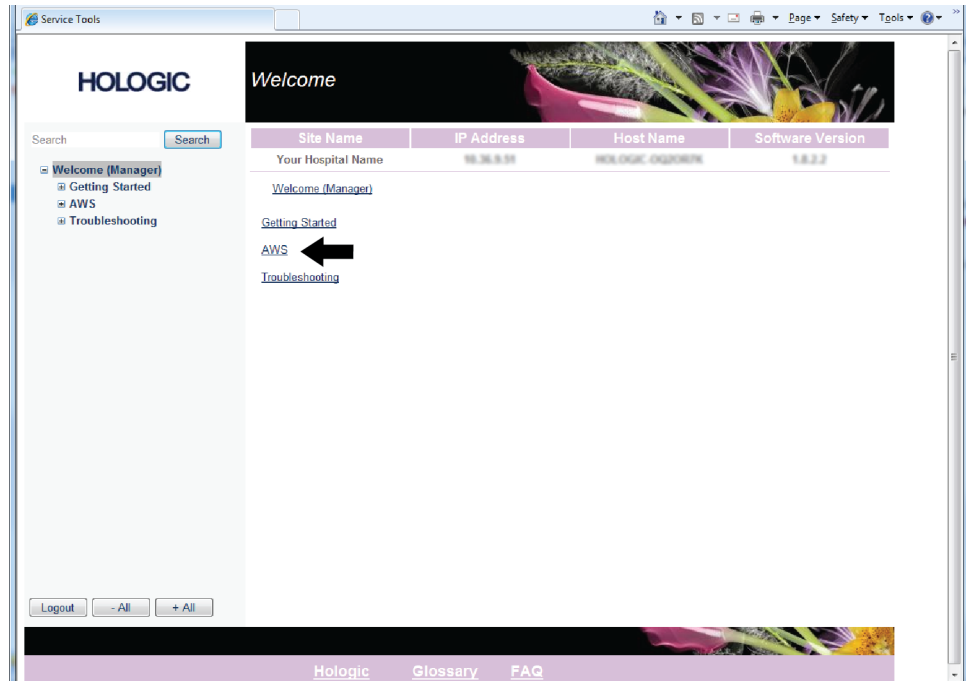


Figure 78: Service Tools Welcome Screen

- Select the parameters for the report and click **Generate**.

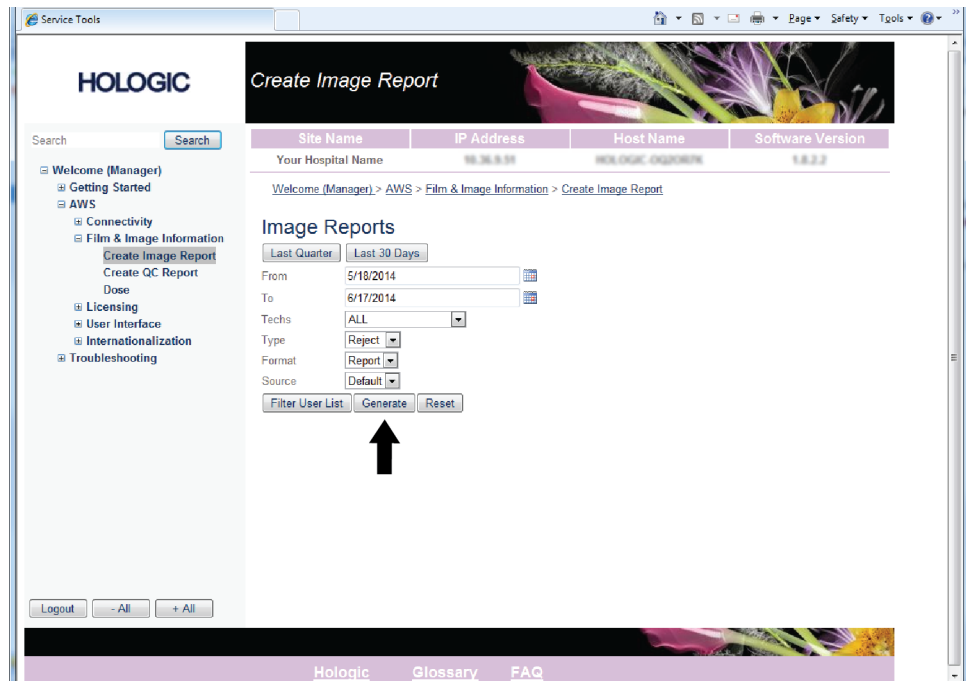


Figure 79: Create Image Report Parameters

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

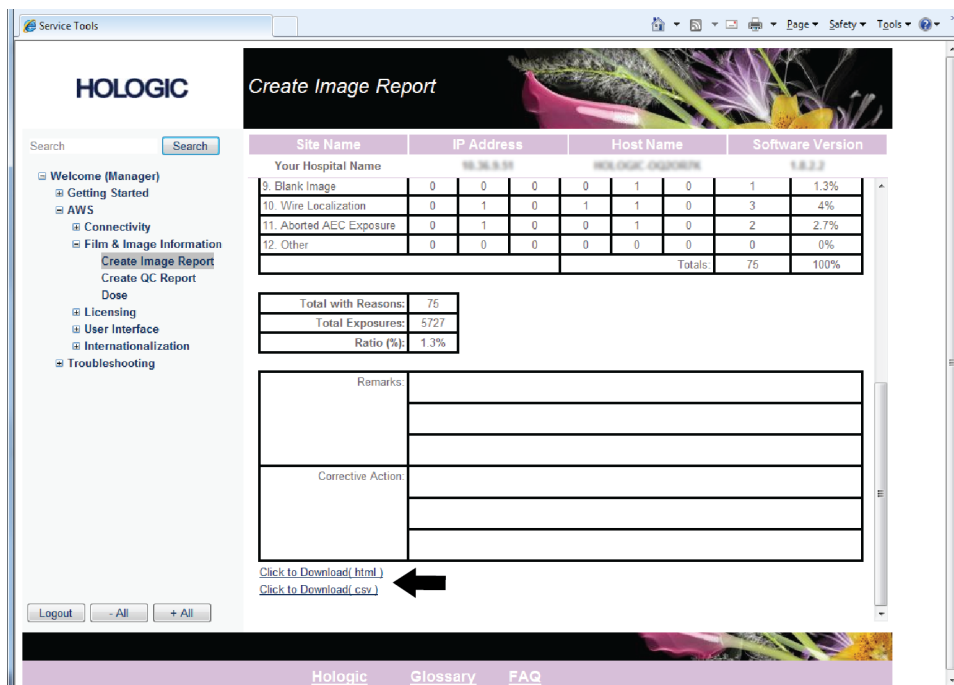


Figure 80: Create Image Report

- Select a folder on the computer, and then click **Save**.
- Log out** from Service Tools when finished.

9.4 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.

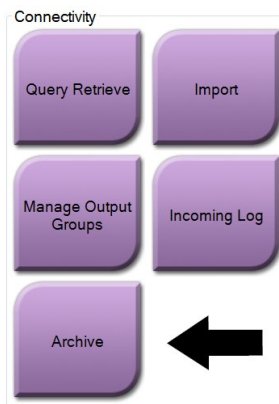


Figure 81: Archive Button

1. Select the **Archive** button in the *Admin* screen to show the *Multi Patient 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.

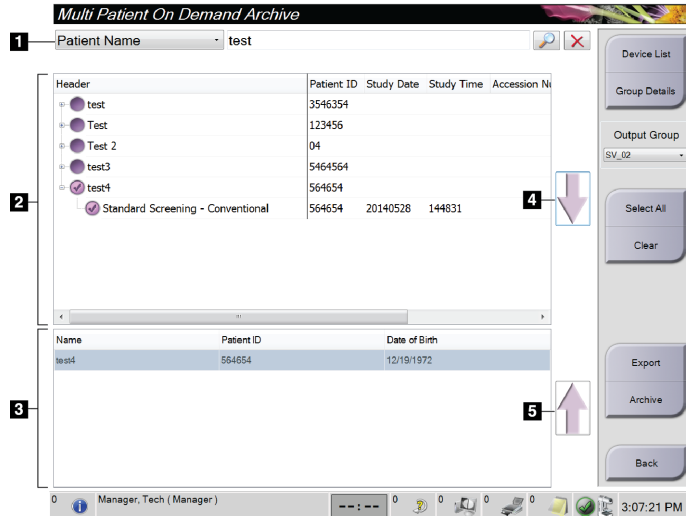


Figure Legend

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.

Figure 82: Multi Patient On Demand Archive Screen

To Archive:

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



Note

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

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

OR

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



Note

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

To Export:

1. Select 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).
 - Select the **Up Arrow** (item 5) on the screen to remove the selected patients from the Patients To Be Archived area (item 3).
2. Select the **Export** button.
 3. In the *Export* dialog box, select the Target from the drop-down menu of media devices.

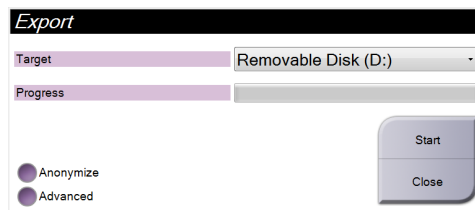


Figure 83: Export Screen

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

A.1 Product Measurements

A.1.1 Tubestand (Gantry with C-Arm)

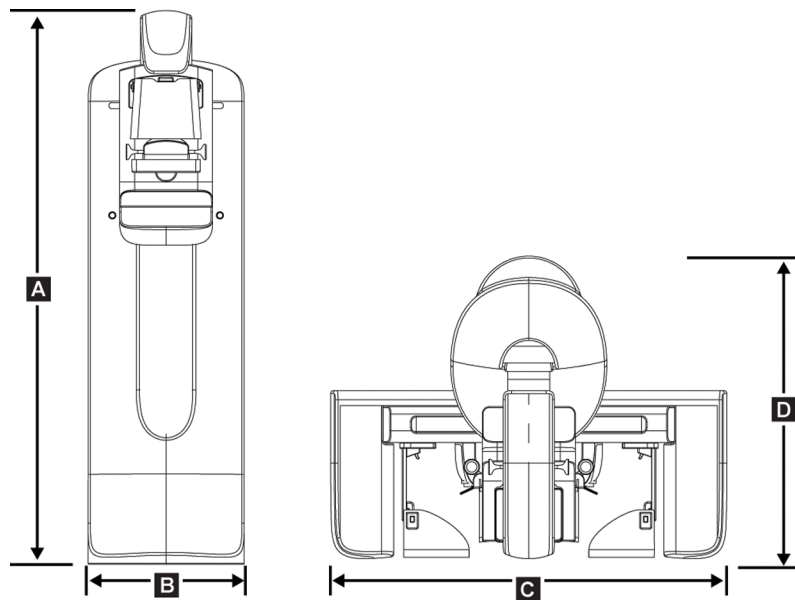


Figure 84: Tubestand (Gantry with C-arm) Dimensions

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)

A.1.2 Acquisition Workstations

Universal Acquisition Workstation

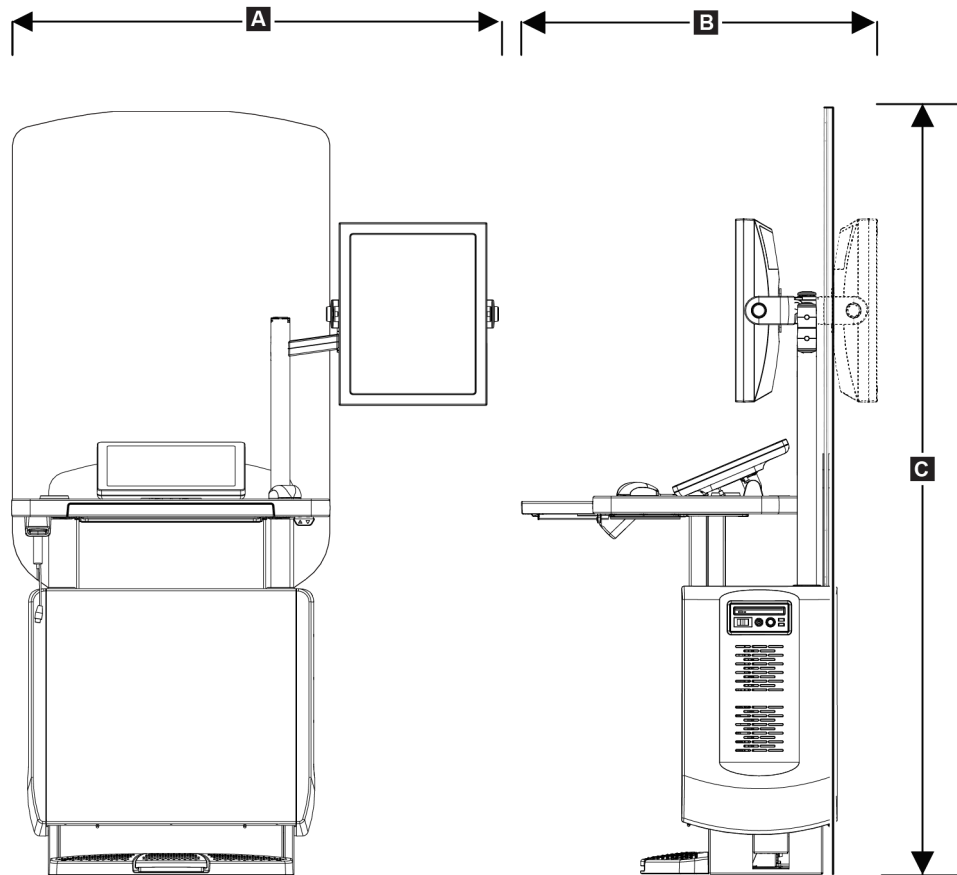


Figure 85: Universal Acquisition Workstation Dimensions system

A.	Width (max.) with optional display arm extended	135.6 cm (53.4 inches)
	Width (max.) with standard display arm	93.8 cm (36.9 inches)
B.	Depth (max) with keyboard tray extended and optional display monitor arm rotated to rear	122.0 cm (48.4 inches)
C.	Height (max)	204 cm (80.3 inches)
	Weight (max)	209 kg (460 pounds)

Premium Acquisition Workstation

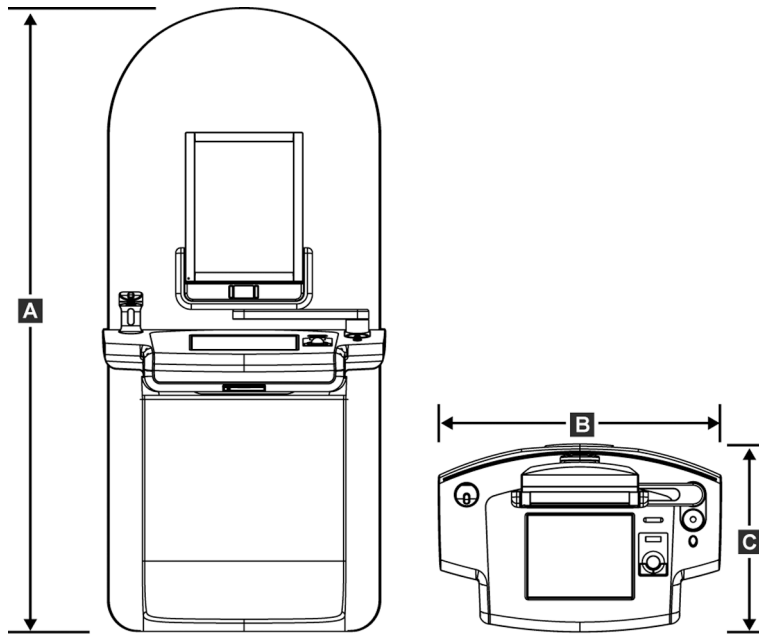


Figure 86: Premium Acquisition Workstation Dimensions system

A.	Height	202.1 cm (79.75 inches)
B.	Width	92.7 cm (36.5 inches)
C.	Depth	58.5 cm (23 inches)
	Weight	154 kg (340 pounds)

Standard Acquisition Workstation

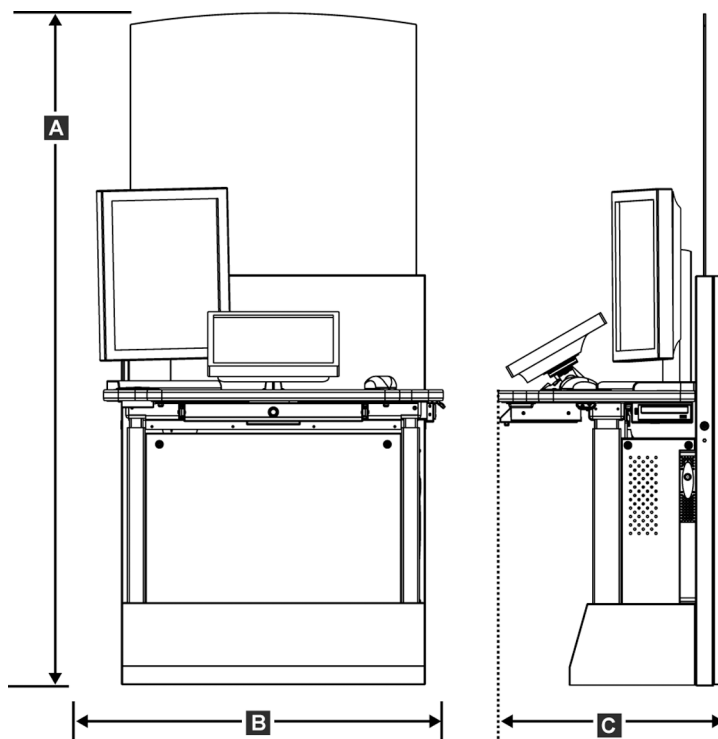


Figure 87: Standard Acquisition Workstation Dimensions system

A.	Height	191.3 cm (75.32 inches)
B.	Width	107 cm (42 inches)
C.	Depth	76 cm (30 inches)
	Weight	219 kg (462 pounds)

Acquisition Workstations for Mobile Use

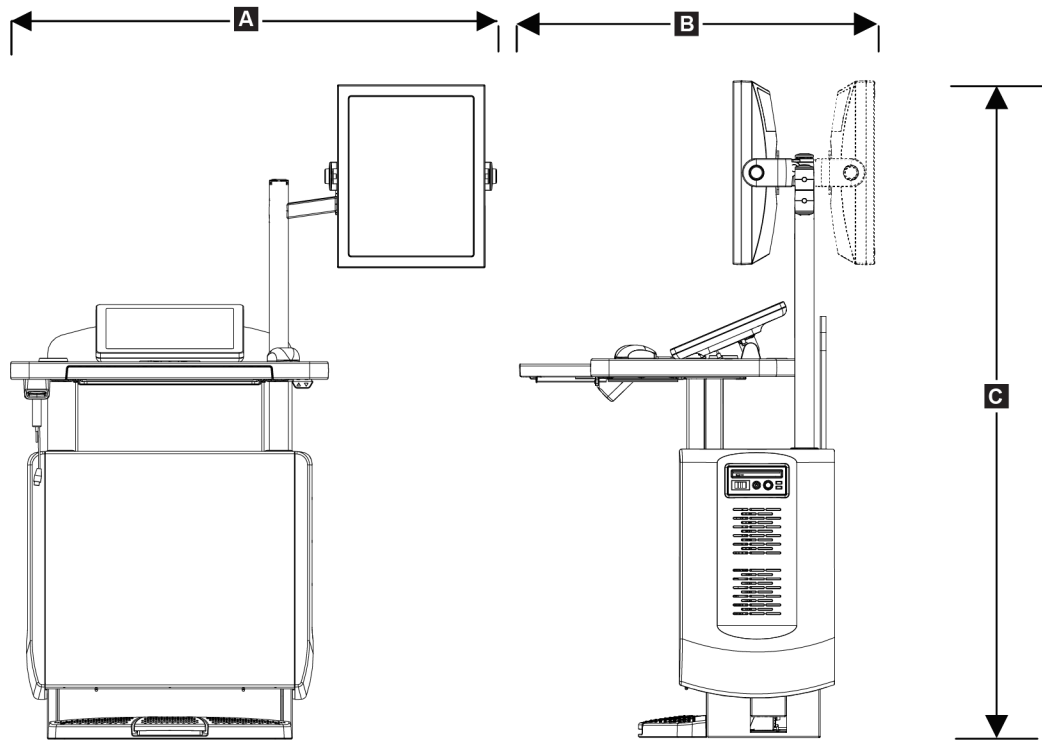


Figure 88: Mobile Universal Acquisition Workstation Dimensions system

A.	Width (max.) with optional display arm extended	128 cm (50.5 inches)
	Width (max.) with standard display arm	100 cm (39.5 inches)
B.	Depth (max)	85 cm (33.5 inches)
C.	Height (max)	180 cm (71 inches)
	Weight (max)	179 kg (395 pounds)

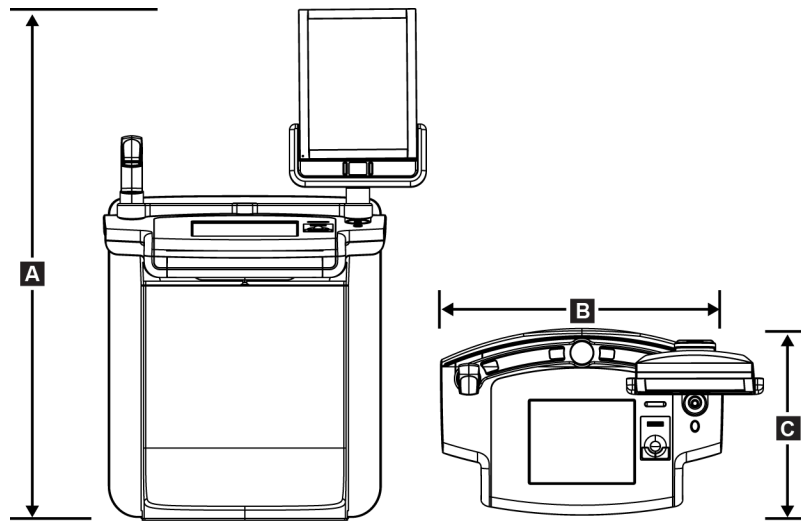


Figure 89: Mobile (non-Universal) Acquisition Workstation Dimensions system

A.	Height	167.6 cm (66.0 inches)
B.	Width	105.5 cm (41.5 inches)
C.	Depth	58.5 cm (23 inches)
	Weight	154 kg (340 pounds)

A.2 Operation and Storage Environment

A.2.1 General Conditions for Operation

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

A.2.2 Storage Environment

Gantry

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

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

X-ray Detector

Temperature Range	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
Maximum rate of temperature change	Less than 10 °C (50 °F) per hour
Relative Humidity Range	10% to 80% without condensing moisture

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

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.)

A.3 Radiation Shield

<i>Radiation Shield Lead (Pb) equivalent</i>	0.5 mm lead for x ray energy to 35 kV
--	---------------------------------------

A.4 Electrical Input

A.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)

A.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 Acquisition Workstation)</i>	10% ~ 6 minutes per hour or 2 minutes on, 18 minutes off
<i>Overcurrent Protection</i>	8A

A.5 Tubestand Technical Information

A.5.1 C-Arm

<i>Rotation Range</i>	<p><i>Conventional Mammography:</i> +195° +3°/-0.5° to 0° ±0.5° to -155° +0.5°/-3°</p> <p><i>Tomosynthesis option:</i> +180° ±0.5° to 0° ±0.5° to -140° ±0.5°</p>
<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>	<i>70.0 cm ±1.0 cm (27.6 inches ±0.4 inches) (Focus position deviation is ±5 mm)</i>
<i>Patient Support (non-magnification)</i>	
<i>Vertical Position Lower Limit</i>	<i>70.5 cm +5.1/-0 cm (27.75 inches +2.0/-0 inches)</i>
<i>Vertical Position Upper Limit</i>	<i>141 cm +0/-17.8 cm (55.5 inches +0/-7.0 inches)</i>

A.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 LCDs on the Compression Device show the compression force through the range of 18 N to 300 N in 1 N increments (4 pounds to 67 pounds in 1 pound 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>

A.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>
<i>Tube leakage test conditions</i>	<i>49 kVp, 2.0 mA</i>

A.5.4 X-ray Beam Filtration and Output

<i>Filtration</i>	<i>Five-position filter wheel:</i> <i>Position 1: Rhodium, 0.050 mm ±10%</i> <i>Position 2: Aluminum, 0.70 mm (nominal) (Tomosynthesis option)</i> <i>Position 3: Silver, 0.050 mm ±10%</i> <i>Position 4: Copper, 0.3mm</i> <i>Position 5: Lead (provided for servicing)</i>
-------------------	--

kV/mA Range

Table 20: 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	

Table 20: Maximum mA Setting as a Function of kV

kV	LFS mA	SFS mA
43	160	
44	150	
45	150	
46	150	
47	140	
48	140	
49	140	

mAs Steps (Table 1, default)

4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 22, 25, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5, 65, 67.5, 70, 75, 80, 85, 90, 95, 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500

Attenuation of Carbon Fiber

Image Receptor

< 0.3 mm Al

Magnification Platform

< 0.3 mm Al

A.5.5 X-ray Collimation

Collimation Fields

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

A.5.6 Light Field Indication

Light Field to X Ray Congruency

Within 2% of SID

A.5.7 X-ray Generator

Type

Constant Potential High Frequency Inverter

Rating

7.0 kW, maximum (isowatt), 200 mA at 35 kV

Electrical Power Capacity

9.0 kW maximum

kV Range

20 kV to 49 kV in 1 kV increments

kV accuracy

±2%, over range 20-49 kVp

mAs Range

3.0 mAs to 500 mAs in Manual Mode mAs (8 mAs minimum in AEC Mode)

mAs Accuracy

±(10% + 0.2 mAs)

mA Range

10 mA to 200 mA, Large Focal Spot

10 mA to 50 mA, Small Focal Spot

A.6 Imaging System Technical Information

A.6.1 Image Receptor

<i>Fluid Ingress</i>	<i>No fluid from accidental spillage on the Image Receptor may seep inside.</i>
<i>Deflection</i>	<i>Does not exceed 1.0 mm at maximum compression.</i>
<i>Active Imaging Area</i>	<i>Not less than 23.3 cm by 28.5 cm (9.2 inches x 11.2 inches)</i>
<i>DQE Conventional Mammography</i>	<i>Not less than 50% at 0.2 lp/mm</i>
	<i>Not less than 15% at the Nyquist limit</i>
<i>DQE (Tomosynthesis option)</i>	<i>Not less than 30% at 0.2 lp/mm</i>
	<i>Not less than 15% at the Nyquist limit</i>
<i>Dynamic Range and Linearity</i>	<i>Detector Subsystem response is linear with linearity of 0.999 over a dynamic range of 400:1 in x-ray exposure.</i>
<i>Uniformity</i>	<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.</i>

Appendix B The System Messages and Alert Messages

B.1 Error Recovery and Troubleshooting

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

B.2 Types of Messages

B.2.1 Fault Levels

Each Message has a particular set of the following characteristics:

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

Displayed Messages

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

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

Additional Message Information

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

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

B.2.2 System Messages

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

Selenia Dimensions System User Guide

Appendix B: The System Messages and Alert Messages

Table 21: System Messages

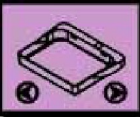






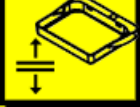














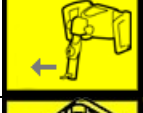

Icon	Message	User Action
	Paddle is moving	No action needed.
	Sending notice	No action needed.
	Invalid use of Magnification Stand	You selected a tomographic view with the Magnification Stand installed. Select a non-tomographic view. (Tomosynthesis option)
	Face shield is not secured	Fully extend or fully retract the Face Shield. (Tomosynthesis option)
	Invalid use of compression paddle	Remove the Magnification Stand or install the Magnification Paddle.
	Paddle position does not match selected view	Shift the Paddle to the correct location 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 designated for this mode.
	License is missing	A license is necessary to use this feature or function. (This message is for your information only. There are no user actions.)
	Invalid detector calibration	Install the Magnification Stand for Small Focal Spot calibration. Remove the Magnification Stand to do Large Focal Spot calibration.
	Invalid geometry calibration	Repeat the geometry calibration before you try to take an exposure. (Tomosynthesis option)
	Configuration file is missing	Applies to Service Personnel.
	Waiting for Detector	No action needed.

Table 21: System Messages

Icon	Message	User Action
	System in Test Mode	Applies to Service Personnel.
	Affirm cable is not connected	Connect the Affirm system cable to the side of the Gantry.
	Affirm is not locked	Lock each side of the Affirm system.
	BCM cable is not connected	Connect the Biopsy Control Module cable to the side of the Affirm system.
	View requires Affirm to be installed OR View cannot be completed with Affirm installed	Install the Affirm system to acquire this view. OR Remove the Affirm system to acquire this view.
	Tube needs to be manually positioned (move to 0 degrees)	Rotate the C-arm to 0 degrees.
	Tube needs to be manually positioned (move to -15 degrees)	Rotate the C-arm to -15 degrees.
	Tube needs to be manually positioned (move to 15 degrees)	Rotate the C-arm to +15 degrees.
	The Emergency Stop switch has been deactivated.	Turn the Emergency Off switch one-quarter turn to reset the switch.
	The needle needs to be moved to the correct location.	Move the needle to the correct location for Biopsy QAS.
	Compression too low for tomo reconstructions.	Move the Compression Paddle higher than 0.5 cm to take tomography exposures.

B.3 UPS Operation



Note

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

The LCD in the UPS shows the power status.

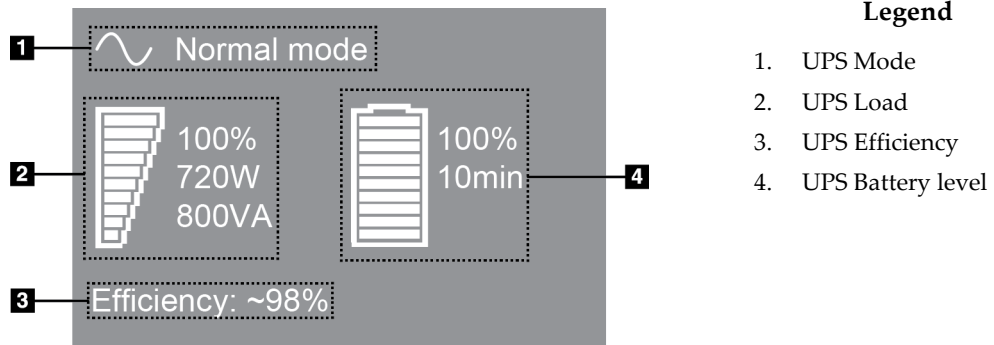


Figure 90: UPS LCD Display

If the UPS battery expires, the Mode icon changes as shown. Contact your service representative to replace the battery.



Appendix C Dimensions Mobile

C.1 General Information

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

C.2 Conditions for Safety and Other Precautions

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



Warning:

The 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](#) on page 140.) Proper system function and performance can only be ensured if continuous true sinusoidal VAC power is supplied per the system power input specifications and loading characteristics. Intermittently, the power source must provide 65 Amps at 208 VAC for 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.



Note

If a mobile power generator is used, make sure that it is at least 3 meters (10 feet) from the system. If this distance requirement cannot be met, additional EMI or RF shielding can be required.

C.3 Mobile Specifications

C.3.1 Shock and Vibration Limits

Vibration Limit

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

Shock Limit

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

C.3.2 Coach Environment

Operation Environment

Temperature Range

20 °C (68 °F) to 30 °C (86 °F)

Relative Humidity Range

20% to 80% without condensing moisture

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

C.4 Electrical Input

C.4.1 Gantry

Mains Voltage

200/209/220/230/ 240 VAC $\pm 10\%$

Mains Impedance

Maximum line impedance not to exceed

0.20 ohms for 208/220/230/240 VAC,

0.16 ohms for 200 VAC

Mains Frequency

50/60 Hz $\pm 5\%$

Average Current over 24 Hours

< 5 A

Peak Line Current

4 A (65 A maximum for 3 seconds)

C.4.2 Acquisition Workstation

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

C.5 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. Place the mouse in the keyboard tray.
5. Lock the keyboard tray (see the following figures):
 - 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 in the following figure shows the locked position.

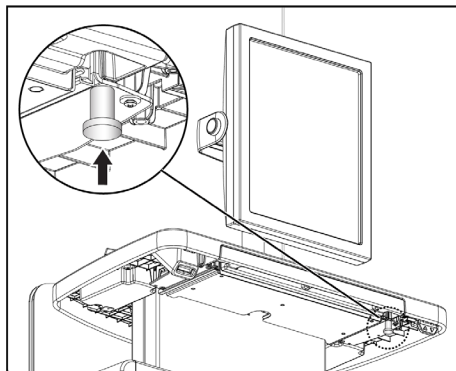


Figure 91: Keyboard Tray Lock Knob

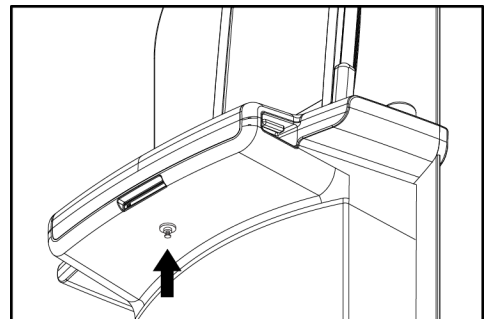


Figure 92: Keyboard Tray Lock Knob

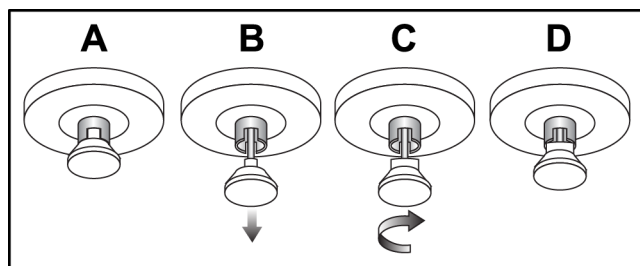


Figure 93: Tray Lock Release from Locked (A) to Unlocked (D)

Selenia Dimensions System User Guide

Appendix C: Dimensions Mobile

6. If using the mobile Universal Acquisition Workstation, lock the swivel display using the knobs provided (see the following figure).

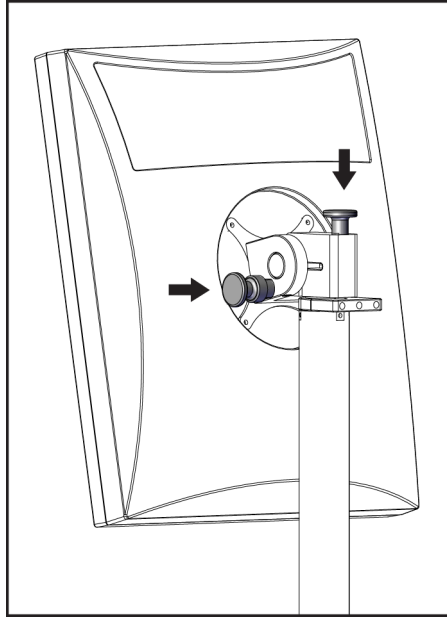


Figure 94: Swivel Lock Knobs for Preview Display on Mobile Universal Acquisition Workstation

7. Lower the work surface to the minimum height.
8. Remove all system accessories.
9. Put all accessories in a safe storage area.

C.6 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 following figure) shows the unlocked position.

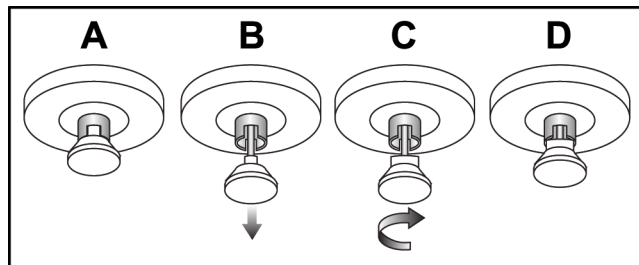


Figure 95: Tray Lock Release from Locked (A) to Unlocked (D)

2. Pull the tray out, if needed.
3. If using the mobile Universal Acquisition Workstation, unlock the swivel display (see the following figure).

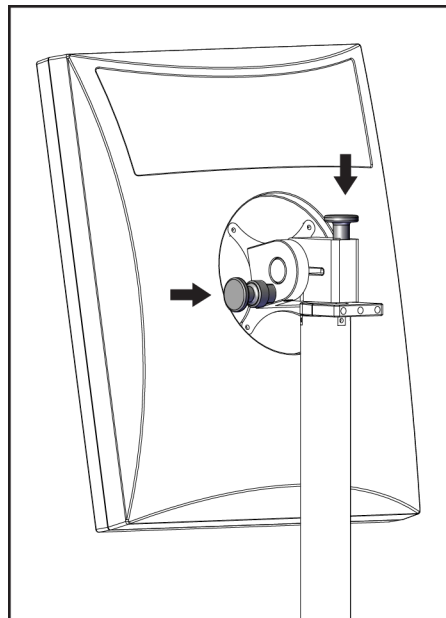


Figure 96: Swivel Lock Knobs for Preview Display on Mobile Universal Acquisition Workstation

C.7 Test the System after Travel

C.7.1 Selenia Dimensions Controls and Functional Tests

Perform the Controls and Functional Tests. Refer to [Perform the Functional Tests](#) on page 36.

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

C.8 Quality Control Tests

Refer to your quality control manual for quality system checks.

Appendix D Dose Information

D.1 EUREF Dose Tables



Notes

This information is only applicable for the European Union.
The following values are for the default dose tables.

The following tables show typical dose values when operating the system in 2D and in BT imaging modes. The tables follow the procedures given in the *European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth edition*: section **2a.2.5.1 Dosimetry**, and **Appendix 5: Procedure for determination of average glandular dose**.

Table 22: 2D Dose (EUREF)

Phantom	cm	kV	Anode	Filter	EUREF dose (mGy)
2.0 cm PMMA	2.1	25	W	0.05 mm Rh	0.55
3.0 cm PMMA	3.2	26	W	0.05 mm Rh	0.75
4.0 cm PMMA	4.5	28	W	0.05 mm Rh	1.05
4.5 cm PMMA	5.3	29	W	0.05 mm Rh	1.42
5.0 cm PMMA	6	31	W	0.05 mm Rh	2
6.0 cm PMMA	7.5	31	W	0.05 mm Ag	2.7
7.0 cm PMMA	9	34	W	0.05 mm Ag	3.1

Table 23: BT Dose (EUREF)

Phantom	cm	kV	Anode	Filter	EUREF dose (mGy)
2.0 cm PMMA	2.1	26	W	0.7 mm Al	1
3.0 cm PMMA	3.2	28	W	0.7 mm Al	1.15
4.0 cm PMMA	4.5	30	W	0.7 mm Al	1.5
4.5 cm PMMA	5.3	31	W	0.7 mm Al	2.00
5.0 cm PMMA	6	33	W	0.7 mm Al	2.5
6.0 cm PMMA	7.5	36	W	0.7 mm Al	3.9
7.0 cm PMMA	9	42	W	0.7 mm Al	5.15

Table 24: CEDM Dose (EUREF)

Phantom	cm	kV	Anode	Filter	EUREF dose (mGy)
2.0 cm PMMA	2.1	26/45	W	0.05/0.3 mm Rh/Cu	0.83
3.0 cm PMMA	3.2	26/45	W	0.05/0.3 mm Rh/Cu	1.1
4.0 cm PMMA	4.5	28/45	W	0.05/0.3 mm Rh/Cu	1.6
4.5 cm PMMA	5.3	29/49	W	0.05/0.3 mm Rh/Cu	2.1
5.0 cm PMMA	6	31/49	W	0.05/0.3 mm Rh/Cu	3.0
6.0 cm PMMA	7.5	32/49	W	0.05/0.3 mm Ag/Cu	4.1
7.0 cm PMMA	9	33/49	W	0.05/0.3 mm Ag/Cu	4.7

Index

2

- 2D contrast - 67
- 2D contrast settings - 70

A

- About (Acquisition Workstation) Screen - 115
- accept images - 105
- accept rejected images - 105
- accessories
 - crosshair devices - 97
 - face shield - 88
 - install on C-arm - 87
 - Magnification Stand - 96
- acquire images - 60, 103
- acquisition modes - 58
- Acquisition Workstation
 - About (Acquisition Workstation) Screen - 115
 - controls - 27
 - controls and displays - 27
 - maintenance - 111
 - Touchscreen - 27, 29
- Acquisition Workstation, Standard
 - controls and display - 28
- add
 - procedure - 64
 - view - 62
- admin screen - 113
 - About (Acquisition Workstation) Screen - 115
 - Admin button - 57
 - functions - 113
 - Remote Access to Image Reports - 118
- AEC
 - buttons - 31
 - Sensor position - 31
- alerts - 135
- archive - 73
- auto-hanging, auto-pairing - 79
- auto-rotation - 42

B

- bar code scanner - 27, 29

C

- calibrations, perform - 51
- C-arm
 - auto-rotation - 42
 - controls and indicators - 31
 - displays - 31
 - rotation - 36, 42
 - slots for accessories - 87
- cine tab - 83
- clinical procedures - 101
- close
 - patient - 66
 - procedure - 66
- collimator
 - override - 36
 - programmed to paddle position - 36
- column tab - 55
- comments tab - 83
- compression
 - controls and displays - 27
 - release - 103
- compression force, range - 31
- contact paddles - 92
- controls
 - Acquisition Workstation - 27
 - C-arm - 32
 - collimator override - 36, 43
 - compression - 32, 36, 37
 - compression brake - 36, 37
 - handwheels - 31
 - indicators - 25
 - light field lamp - 36, 43
 - manual compression release - 36, 37
 - system - 25
- conventional face shield, install - 90
- custom output - 73
- cybersecurity statement - 6

D

- data loss - 13
- definitions - 7
- delete patient - 54
- display
 - Acquisition Workstation - 27

- clean - 111
- compression force - 31
- preview image - 29
- thickness - 31
- types of images selection - 83
- window level - 81

dose information - 145

- EUREF dose tables - 145

E

edit

- patient information - 54
- user information - 48
- view - 65

Emergency Off Switch - 27

- functional test - 36

export - 74

exposure

- parameters - 58
- sequence - 103
- techniques, set - 58

F

face shield - 88

faults - 135

filter tab - 55, 56

- other functions - 56

fingerprint scanner - AWS - 27

footswitches, AWS - 32

function, select to perform - 51

functional tests

- Emergency Off Switch - 36, 44

G

generator tab, set techniques - 58

glossary - 7

H

Hologic technical support - 109

I

images

- accept - 105
- acquisition mode - 58

- output options - 85
- preview - 77, 105
- reject - 105
- Remote Access to Image Reports - 118
- review - 80
- review tools - 66
- review tools tab - 81
- store - 105
- unacceptable - 105

Implant Displaced views - 62

Implant Present button - 59

indicators - 25

install

- compression paddles - 94
- conventional face shield - 90
- retractable face shield - 88

international symbols - 8

K

keyboard - 27, 29

L

laser film printer, isolation requirements - 13

light field lamp - 36, 43

- use - 103

localization crosshair device

- align - 100

- install and remove - 97

- use - 98

localization paddles - 93

Log In - 35

- Fingerprint reader - 35

Log Out - 57

M

magnification crosshair device, install and remove

- 99

magnification paddles - 92

Magnification Stand - 96

- install and remove - 96

maintenance

- general - 109

manage

- alarms - 48

- notices - 48

- output groups - 72
- messages and alerts - 135
- mobile system
 - QC tests - 144
 - safety - 139
 - specifications - 140
 - test after travel - 144
- My Settings icon - 48

N

- needle localization - 106
- Notices tab - 83

O

- on-demand outputs - 73
- open patient procedure - 53
- output devices
 - custom output - 73
 - manage output groups - 48
 - output groups - 85
 - taskbar icons - 48
- output groups, manage - 85
- output groups, select - 72
- outputs, on-demand - 73

P

- Paddle Shift buttons - 31
- paddles
 - compression - 92
 - install - 94
 - remove - 94
 - shift - 95
 - shift to new position - 59
- patient
 - delete - 54
 - edit information - 54
 - face shield - 88
 - open - 53
 - position - 103
- pending image, accept or reject - 105
- permissions, by user group - 116
- power button - 27
- Premium Acquisition Workstation - 27
- prerequisites for system use - 6
- preview image screen - 29, 77, 105

- procedure screen - 57
- procedures
 - add - 54
 - close - 66

Q

- QC tasks, perform - 51
- quality control requirements - 6
- query worklist - 56

R

- radiation safety - 13
- reject images - 105
 - print - 75
- Remote Access to Image Reports - 118
- remove
 - compression paddles - 94
 - conventional face shield - 90
 - localization crosshair device - 97
 - magnification crosshair device - 99
 - Magnification Stand - 96
 - retractable face shield - 88
 - view - 62
- requirements
 - quality control - 6
 - skills needed - 6
 - training - 7
- retractable face shield
 - install - 88
 - use - 89
- review
 - images - 80
 - rejected image - 105
- ROI tab - 83

S

- safety
 - data loss - 13
 - equipment damage - 13
 - general information - 13
 - radiation - 13
- screening
 - acquire the image - 103
- screens
 - add view - 62

- admin - 113
- preview image - 77
- query - 56
- scroll wheel - 27
- select
 - exposure parameters - 58
 - output groups - 72
- send images to outputs - 85
- shift paddle - 59, 95
- Shifting Paddle system - 36, 44
- specifications - 123
 - electrical - 129
- spot compression paddles - 92
- statement, cybersecurity - 6
- system
 - administration - 113
 - capabilities - 2
 - description - 11
 - ready - 103
 - status icons - 48

T

- tabs
 - filter, column - 55, 56
- taskbar - 48
- technical support - 5
- terms and definitions - 7
- tools, image review - 81
- Touchscreen - 29
- training requirements - 7
- tubehead, display - 32
- turn on system - 33
 - Log In - 35
 - preparation - 33

U

- user interface - 47
- user profiles - 6
- users menu - 48

V

- view
 - add - 62
 - edit - 65

W

- window level - 81
- workflow, standard - 101
- worklist, query - 56

X

- x-ray
 - acquire image - 60, 103
 - collimated fields - 36, 43
 - indicators - 60, 103
 - switch (button) - 27

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