

## 7.2.2 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 85—one on each side).
2. Push the Face Shield toward the C-arm until the device stops.

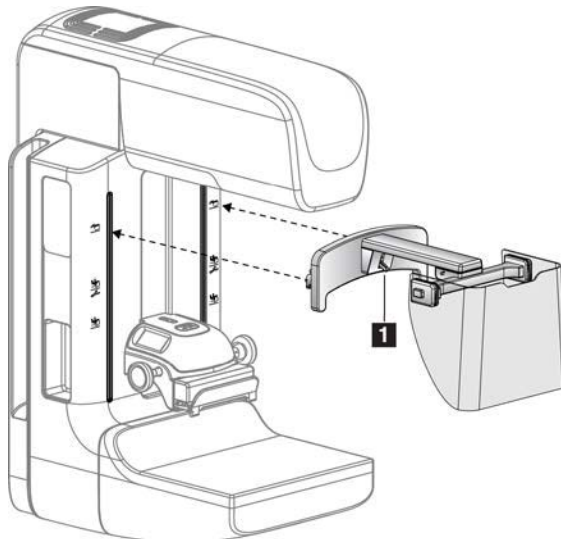


Figure 56: Face Shield Installation

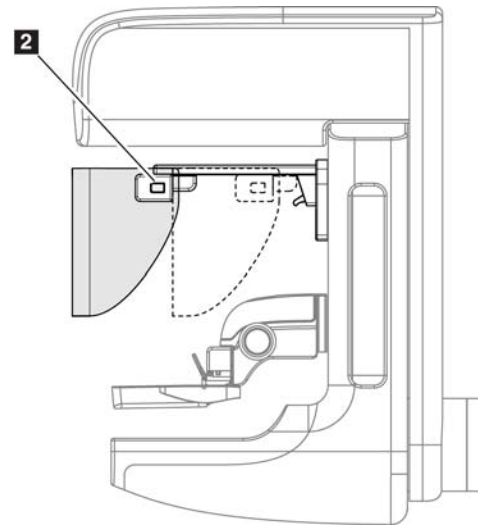
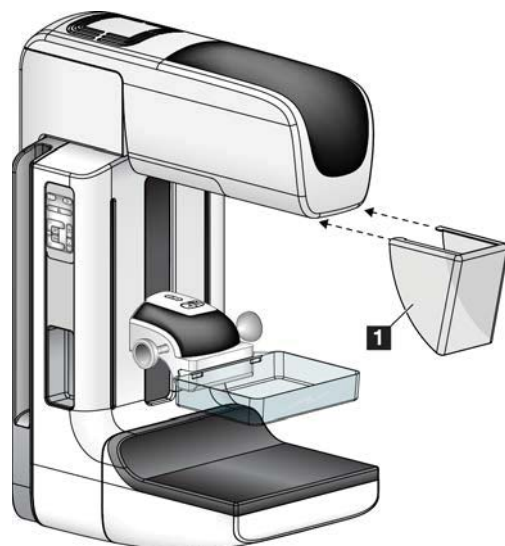


Figure 57: Face Shield Operation

#### 7.2.3 How to Install and Remove the Conventional Face Shield



*Figure 58: 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.

## 7.3 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.

Table 17: Available Accessories

Accessory		2D/BT	2D Screening
Routine Screening Paddles	18 x 24 cm	*	*
	24 x 29 cm	*	*
	Small Breast	*	*
	18 x 24 cm SmartCurve™	*	*
	24 x 29 cm SmartCurve	*	*
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 2D screening system, only use the 7.5 cm Spot Contact Paddle for compression thickness calibration.

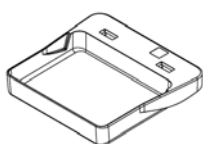
---

**Note**

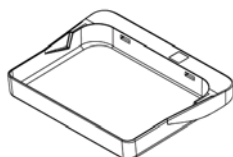
The 24 x 29 cm frameless screening paddle, the 24 x 29 cm SmartCurve system paddle, the magnification paddles, and the localization paddles are NOT compatible with the paddle shift function.

---

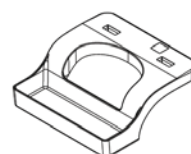
### 7.3.1 Routine Screening Paddles



**18 x 24 cm Frameless  
Screening Paddle**



**24 x 29 cm Frameless  
Screening Paddle**



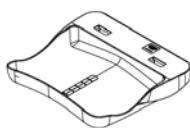
**Small Breast  
Frameless Paddle**

### SmartCurve System Paddles

**Warning:**

The SmartCurve™ system paddles do not meet the IEC 60601-2-45 standards for minimum range of movement that require the paddle to compress to 10 mm. To ensure adequate compression of very small or very thin breasts, use the standard flat screening paddle.

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**18 x 24 cm SmartCurve System  
Frameless Screening Paddle**



**24 x 29 cm SmartCurve System  
Frameless Screening Paddle**

**Note**

The SmartCurve system paddles may not be suitable for patients with very small breasts. If the breast cannot be properly immobilized or compressed due to the curvature of the paddles, use the standard flat screening paddles.

---


**Note**

The SmartCurve system paddles are not recommended for cleavage views, rolled views, or mosaic views of very large breasts. Use the standard flat screening paddles for these views.

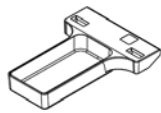

**Note**

The SmartCurve system paddles accommodate most breast sizes. Due to the curvature of the paddles, some patients who would use the smaller standard flat paddle may be more easily positioned using the larger SmartCurve paddle.

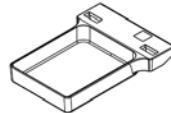

**Note**

SmartCurve system paddles are not compatible with FAST Compression mode.

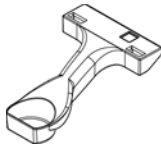
### 7.3.2 Contact and Spot Compression Paddles



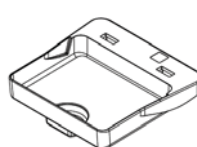
**10 cm Contact  
Frameless Paddle**



**15 cm Contact  
Frameless Paddle**

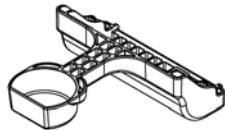


**7.5 cm Spot Contact  
Frameless Paddle**

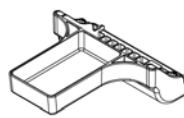


**Spot Contact  
Frameless Paddle**

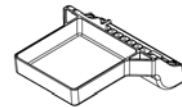
### 7.3.3 Magnification Paddles



**7.5 cm Spot Magnification  
Paddle**



**10 cm Magnification  
Paddle**

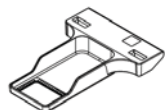


**15 cm Magnification  
Paddle**

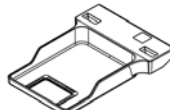

**Note**

You cannot acquire Tomosynthesis images with the Magnification paddles.

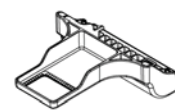
#### 7.3.4 Localization Paddles



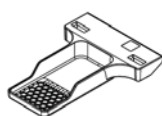
**10 cm Rectangular Opening  
Localization Paddle**



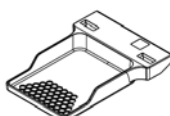
**15 cm Rectangular Opening  
Localization Paddle**



**10 cm Magnification  
Localization Paddle**



**10 cm Perforated  
Localization Paddle**

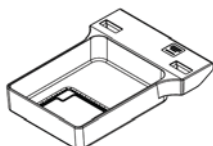


**15 cm Perforated  
Localization Paddle**



**10 cm Magnification  
Localization Perforated  
Paddle**

#### 7.3.5 Large Ultrasound Paddle



**15 cm Large Ultrasound  
Paddle**

### 7.3.6 How to Install and Remove a Compression Paddle

See the figure [How to Install a Compression Paddle](#) on page 91 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.

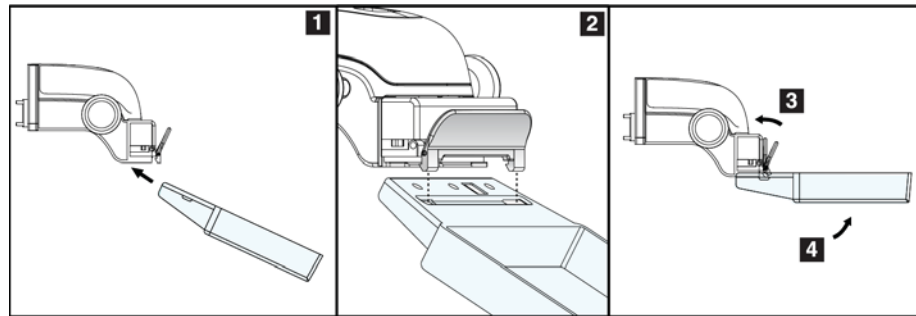


Figure 59: How to Install a Compression Paddle

See the figure [How to Remove the Compression Paddle](#) on page 91 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.

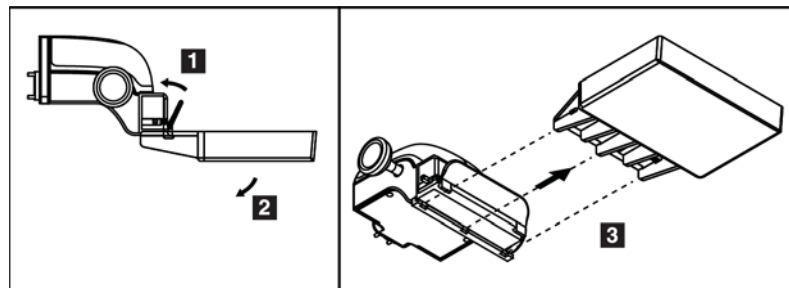


Figure 60: How to Remove a Compression Paddle

### 7.3.7 Paddle Maintenance and Cleaning

Clean the paddles after each use. Refer to [Maintenance and Cleaning](#) on page 105 for cleaning instructions.

#### 7.3.8 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.



---

**Note**

The 24 x 29 cm frameless screening paddle, the 24 x 29 cm SmartCurve system paddle, and the magnification paddles are NOT compatible with the paddle shift function.

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#### 7.3.9 FAST Compression Mode

##### About FAST Compression Mode

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
- More uniform compression, 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 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.



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**Note**

Only the 18 x 24 cm Frameless Screening Paddle and the 24 x 29 cm Frameless Screening Paddle are compatible with FAST Compression Mode.

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**Note**

The system beeps when FAST Compression Mode is engaged but is not compatible with the current paddle.

---



### How to Use the FAST Compression Mode Slide

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

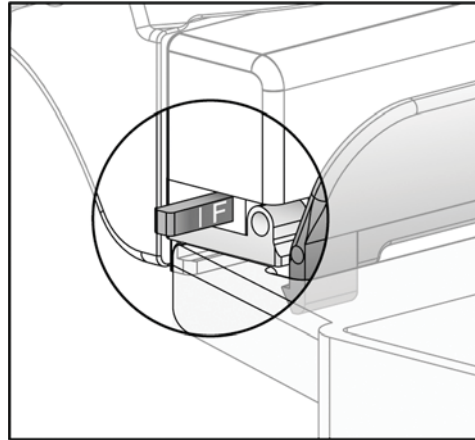


Figure 61: The FAST Compression Mode Slide

## 7.4 Magnification Stand

The 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. Only use the Magnification paddles when the Magnification Stand is installed (refer to [Magnification Paddles](#) on page 89).

### 7.4.1 How to Install and Remove the Magnification Stand

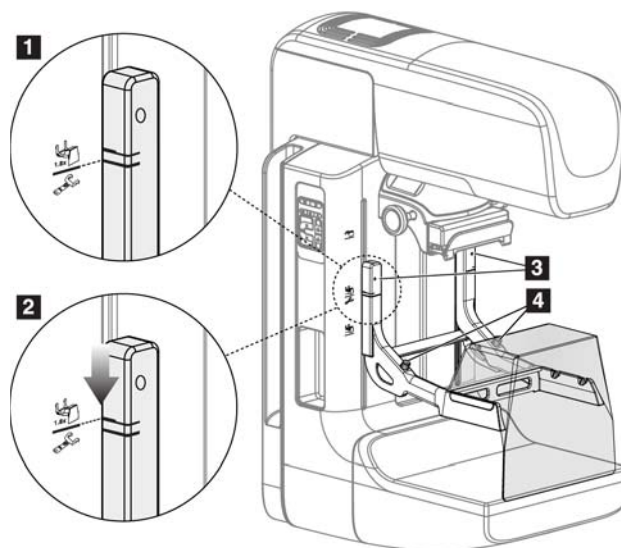


Figure 62: Installation of the Magnification Stand

#### To Install the Magnification Stand

1. Remove the Face Shield (refer to [Patient Face Shields](#) on page 84).
2. Remove the compression paddle (refer to [How to Remove the Compression Paddle](#) on page 91).
3. Move the Compression Device completely to the top.
4. 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.

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**Note**

There are two sets of mounting slots 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 83.

---

5. 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.
6. 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.
7. 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.

## 7.5 Crosshair Devices

### 7.5.1 How to Install and Remove the Localization Crosshair Device

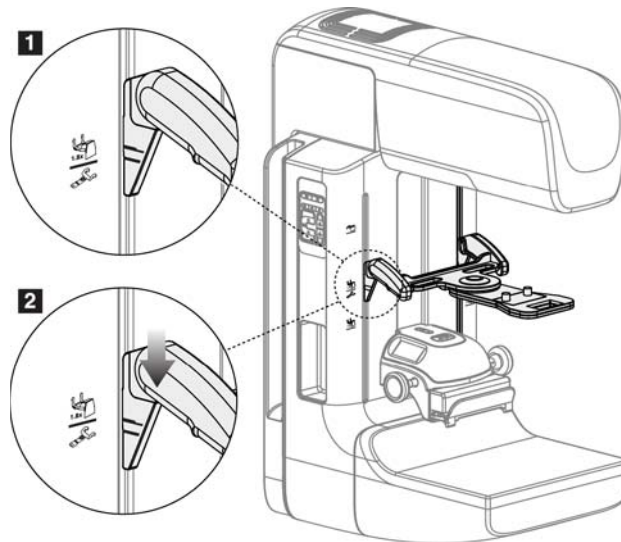


Figure 63: Installation of the Localization Crosshair Device

#### To Install the Localization Crosshair Device

1. Remove the face shield (refer to [Patient Face Shields](#) on page 84).
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 83.
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.

#### 7.5.2 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.

#### 7.5.3 How to Install and Remove the Magnification Crosshair Device

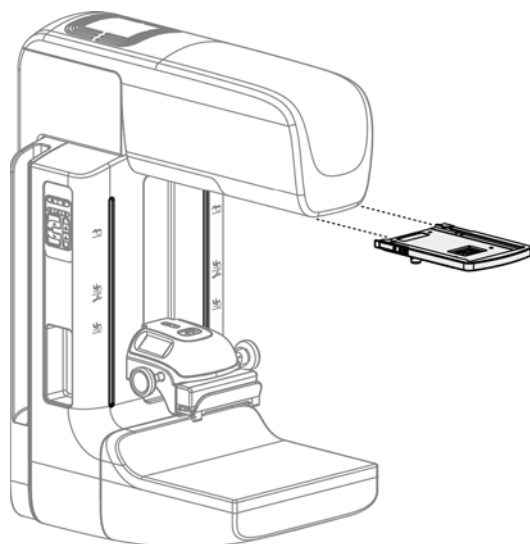


Figure 64: How to Install and Remove the Magnification Crosshair Device

##### To Install the Magnification Crosshair Device

1. Remove the face shield (refer to [How to Install and Remove the Conventional Face Shield](#) on page 86).
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.

### 7.5.4 How to Align the Crosshair Device



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**Note**

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

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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 8 Clinical Procedures



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**Warning:**  
**C-arm movement is motorized.**

---



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

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**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.**

---

### 8.1 Standard Workflow

#### 8.1.1 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.

#### 8.1.2 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.

#### 8.1.3 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 image review 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.

#### 8.2 Screening Procedure Example

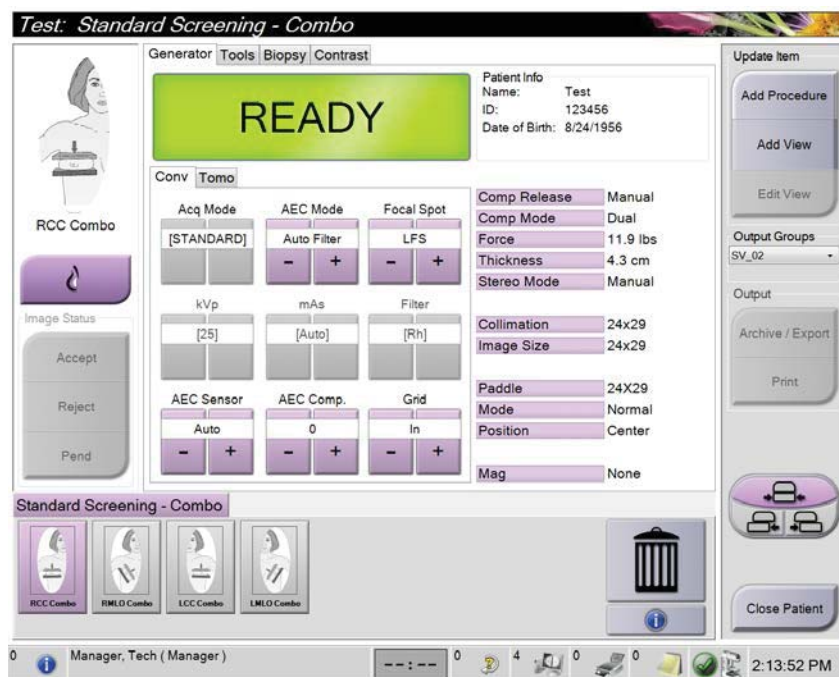


Figure 65: Example of a Screening Procedure Screen



### 8.2.1 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 compression slowly. As necessary, stop and make the adjustments to patient position.
  - Use the handwheels for final compression.

### 8.2.2 Set the Exposure Techniques

Select the exposure techniques for the procedure. Refer to [How to Set the Exposure Parameters](#) on page 70 for information.

### 8.2.3 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 the **x-ray footswitch** for the full exposure.

During the exposure:

- A System Message with the radiation symbol and 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 the x-ray 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.

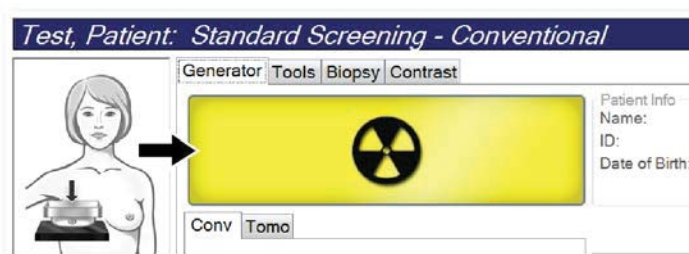


Figure 66: Exposure In Progress

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

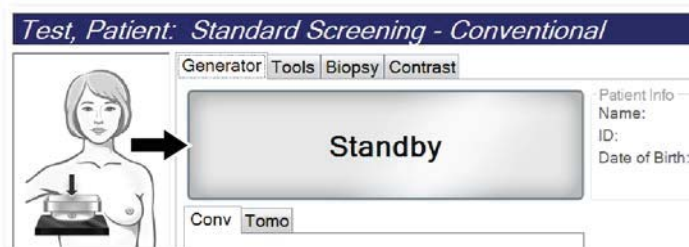


Figure 67: Exposure Complete

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

### 8.3 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).

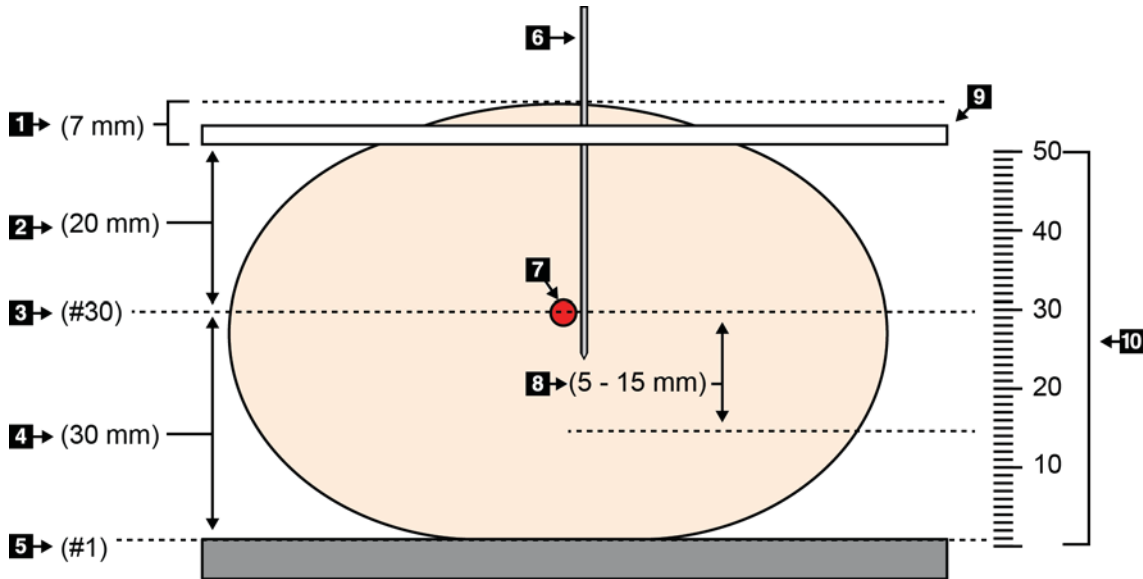


Figure 68: Calculating needle depth

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 9 Maintenance and Cleaning

### 9.1 Cleaning

#### 9.1.1 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.

#### 9.1.2 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.**

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**Caution:**

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

---

#### 9.1.3 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.

### **9.1.4 Acquisition Workstation**

#### **How to Clean the Image Display Screen**

Avoid touching the display screen of the Image Display monitor.

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.

## 9.2 Maintenance

### 9.2.1 Preventive Maintenance Schedules

*Table 18: 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						



Table 19: Service Engineer Preventive Maintenance

Maintenance Task Description	Recommended Frequency	
	Semiannually	Annually
Clean and Inspect the Gantry and Acquisition Workstation	x	
Inspect the radiation shield for chips, cracks, breaks, and for tight attachments.	x	
Check all primary power connections	x	
Check interlocks, safety and limit switches	x	
Inspect/Lubricate C-arm	x	
C-arm / Verify all C-arm buttons	x	
Verify C-arm and Rotational Calibration	x	
Replace Breast Platform Filter	x	
Verify Compression Force Calibration	x	
Verify Compression Thickness Calibration	x	
Inspect LED Collimator Lamp for dust and dirt	x	
Clean & lubricate collimator, and worm screws	x	
Perform Rotational Brake verification	x	
Verify X-ray Field / Light Field Calibration	x	
Verify kV Calibration and Tube Current Calibration	x	
Check HVL Evaluation	x	
Verify Target Dose Verification	x	
Verify AEC Exposure Compensation 2D	x	
Perform System Resolution Test *	x	
Perform Phantom Image Quality Evaluation *	x	
Perform Image Artifact Evaluation *	x	
Backup Acquisition Workstation files	x	
Evaluate UPS Performance Status/ Batteries Status	x	
Backup all Calibration Data	x	
* Refer to Quality Control Manual		

#### 9.2.2 About Reclamation

Reclamation is an automatic function that makes disk space available for storing newly acquired images. Configurable parameters let a given number of images collect before reclamation starts and older images are removed from the system.

## Chapter 10 System Administration Interface

### 10.1 Admin Screen

This section describes the functions available in the *Admin* screen. To access all the functions in this screen, log in to the system as a user with 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 69: Admin Screen

Table 20: Admin Screen Functions

Group	Button	Function
Operators	<b>Manage Operators</b>	Add, delete or change Operator information.
	<b>My Settings</b>	Change the information for the current Operator.
Procedures	<b>Procedure Editor</b>	Add or Edit the procedures, or change the view order for each user.
	<b>Procedure Order</b>	Change the procedure list order.
	<b>View Editor</b>	Set the default view order for a procedure and edit individual views.
	<b>Contrast</b>	Access the contrast enhanced digital mammography functionality.

Table 20: Admin Screen Functions

Group	Button	Function
Quality Control	<b>Quality Control</b>	Select a Quality Control task to perform or mark completed.
	<b>QC Report</b>	Create a QC Report.
	<b>Test Patterns</b>	Select and send the test patterns to output devices.
	<b>Reject and Repeat Report</b>	Create a Reject and Repeat Report.
System	<b>System Tools</b>	The Interface for Service for the configuration of and identification of problems in the Acquisition Workstation.
	<b>System Defaults</b>	Set the Gantry default values.
	<b>System Diagnostics</b>	Shows the status of all subsystems.
	<b>Preferences</b>	Set the system preferences.
	<b>About</b>	Describes the system. Refer to <a href="#">About Screen</a> on page 113.
	<b>Exposure Report</b>	Create a radiation Exposure Report.
	<b>Biopsy Devices</b>	Lists available biopsy devices.
	<b>QAS</b>	Access the <i>QAS Needle Test</i> screen.
	<b>Lateral QAS</b>	Access the <i>Lateral QAS Needle Test</i> screen.
Connectivity	<b>Query Retrieve</b>	Query the configured devices.
	<b>Import</b>	Import the data from a DICOM source.
	<b>Manage Output Groups</b>	Add, delete, or edit output groups.
	<b>Incoming Log</b>	Shows log entries for images that do not import during manual import or DICOM store.
	<b>Archive</b>	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.		

## 10.2 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. To access the About screen, select **About** from the System group in the *Admin* screen.



### Note

You can also access the *About* screen through the Taskbar. Select the **Tube Icon** then select **About....**

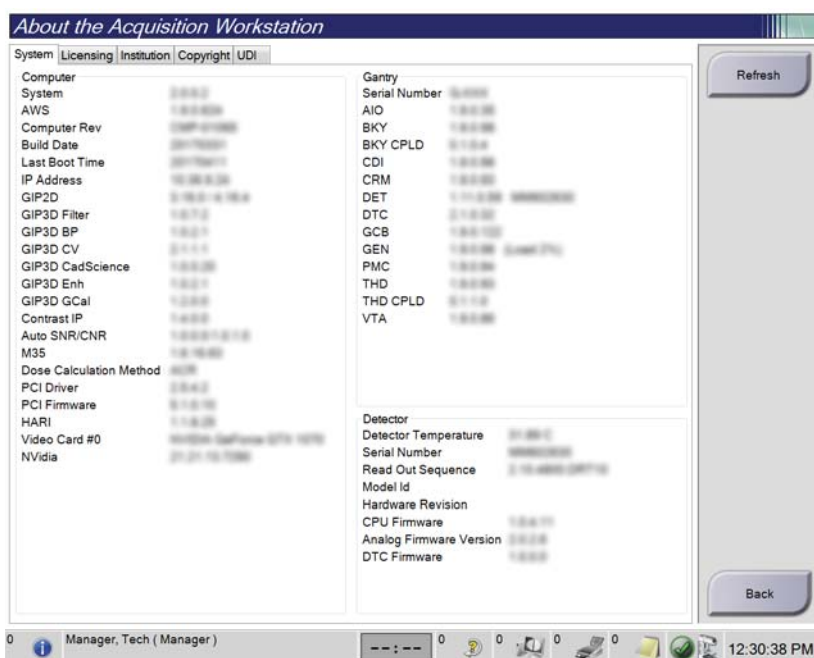


Figure 70: System Tab of the About (the Acquisition Workstation) Screen

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

### 10.2.1 Licensing Tab

The **Licensing** tab of the *About* screen shows all the licenses installed on your system.



#### Note

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

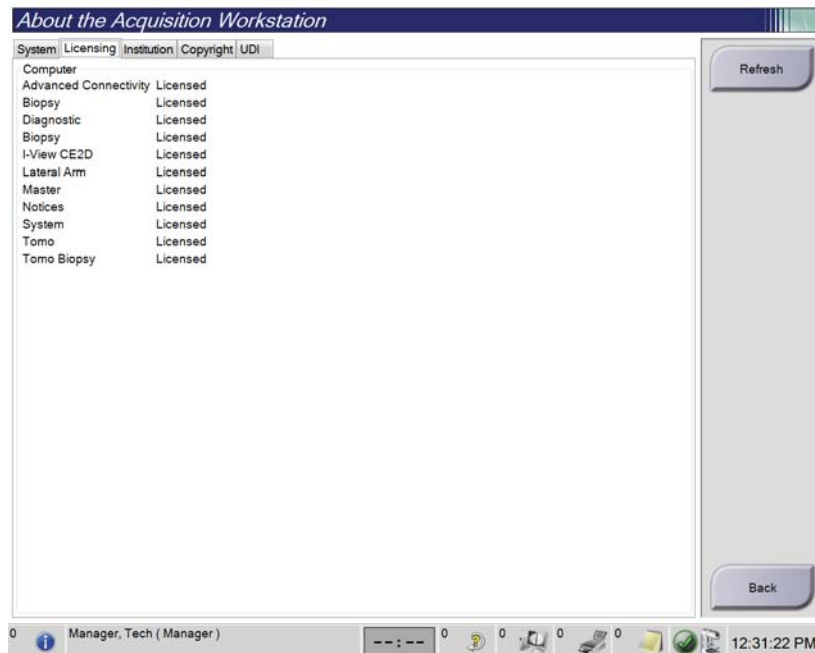


Figure 71: Licensing Tab of the About Screen

### 10.3 Change the User Language Preference

Users can set the language on the user interface to automatically change to their individual preference when logging in.

1. In the Operators group of the *Admin* screen, select **My Settings**.



#### Note

You can also access **My Settings** through the taskbar. Select the User Name area then select **My Settings** in the pop-up menu.

2. The **Users** tab of the *Edit Operator* screen opens. From the Locale field, select a language from the drop-down list.
3. Select **Save**, then select **OK** to the *Update Successful* message. The user interface changes to the selected language.

## 10.4 Set Auto-Hanging and Auto-Pairing

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

1. In the Operators group of the *Admin* screen, select **My Settings**.



### Note

You can also access **My Settings** through the Taskbar. Select the User Name area then select **My Settings** in the pop-up menu.

2. The *Edit Operator* screen opens. Select the **Workflow** tab.
  - Select the Auto-Hanging check box to show a prior study in 4-up mode automatically.
  - Select the Auto-Pairing check box to show a prior view in multi-up mode next to a newly captured image.

*Edit Operator: Manager, Tech*

User Workflow

Auto Hanging

Enable Auto Hanging ☒

CC image placement Top

Left laterality image placement Right

Auto Hanging repeated views Hang older

Auto Pairing

Enable Auto Pairing ☒

Auto Pairing protocol On thumbnail selection

Auto Pairing repeated views Pair older

Match Chest Walls ☒

Figure 72: Enable Auto-Hanging and Auto-Pairing

3. Select **Save**, then select **OK** to the *Update Successful* message.

## 10.5 Set Multi Line Procedure Tabs

You can set the operator preferences to display more of the procedure name in the top of the procedure tabs. To change the procedure tabs from a single line of text to multiple lines of text:

1. In the Operators group of the *Admin* screen, select **My Settings**.



### Note

You can also access **My Settings** through the Taskbar. Select the User Name area then select **My Settings** in the pop-up menu.

2. The *Edit Operator* screen opens. Select the **Workflow** tab.

3. Select the **Use Multi Line Procedure Tabs** check box.

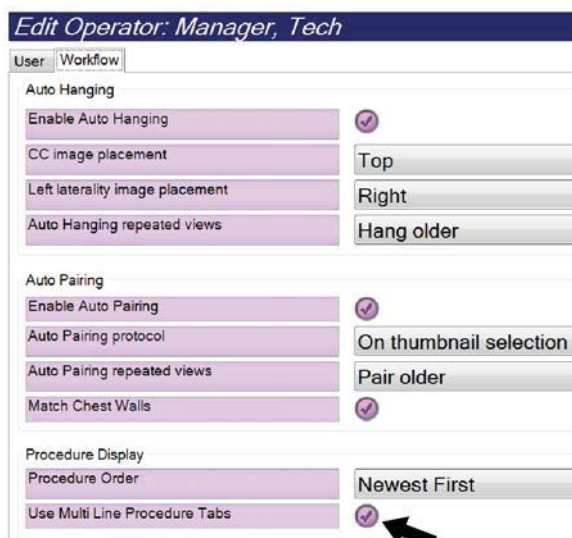


Figure 73: Enable Multi Line Procedure Tabs

4. Select **Save**, then select **OK** in the *Update Successful* message.

## 10.6 Enable and Set the Height Memory

Users can enable and set the acquisition workstation height to automatically change to their individual preference when logging in. To enable and set the height adjust memory:

1. In the Operators group of the *Admin* screen, select **My Settings**.



Figure 74: My Settings Button in the Admin Screen



### Note

You can also access **My Settings** through the Taskbar. Select the User Name area then select **My Settings** in the pop-up menu.

2. In the *Edit Operator* screen, select the **Console** tab.



3. To enable the height adjust memory, select the radio button to the right of the "Auto-Height adjustment on login" field. A check mark appears. (To disable the height adjust memory, clear the radio button.)

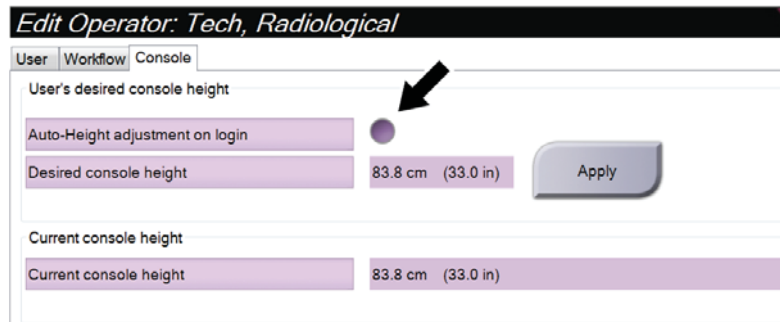


Figure 75: Console Tab of the Edit Operator Screen

4. Use the ▲ UP and ▼ DOWN buttons on the height adjust control panel to set the desired height (see the following figure).

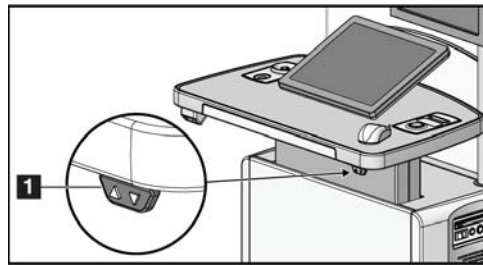


Figure 76: Height Adjust Control Panel

5. The Desired console height field displays the height as it is now positioned. The Current console height field displays the most recently saved height. (See the following figure.) To save your desired height setting, select **Apply**.

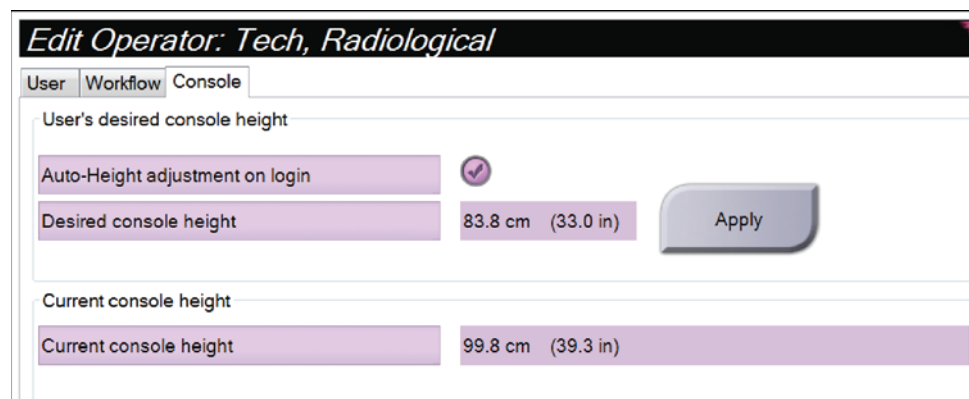


Figure 77: Desired Console Height and Current Console Height Fields

6. Select **Save**, then select **OK** to the *Update Successful* message.

## 10.7 Set Auto-Accept and Auto-Pend Images

A manager user can configure the system to automatically accept or automatically pend new images.

1. In the System group of the *Admin* screen, select **Preferences**. The *System Preferences* screen opens.
2. Select the **Image Auto Disposition** tab.
3. Use the drop-down menus to select the auto disposition for each type of image.
  - Select **Manual** to manually accept, reject, or pend each newly acquired image.
  - Select **Accept** to automatically accept newly acquired images.
  - Select **Pend** to automatically pend newly acquired images.

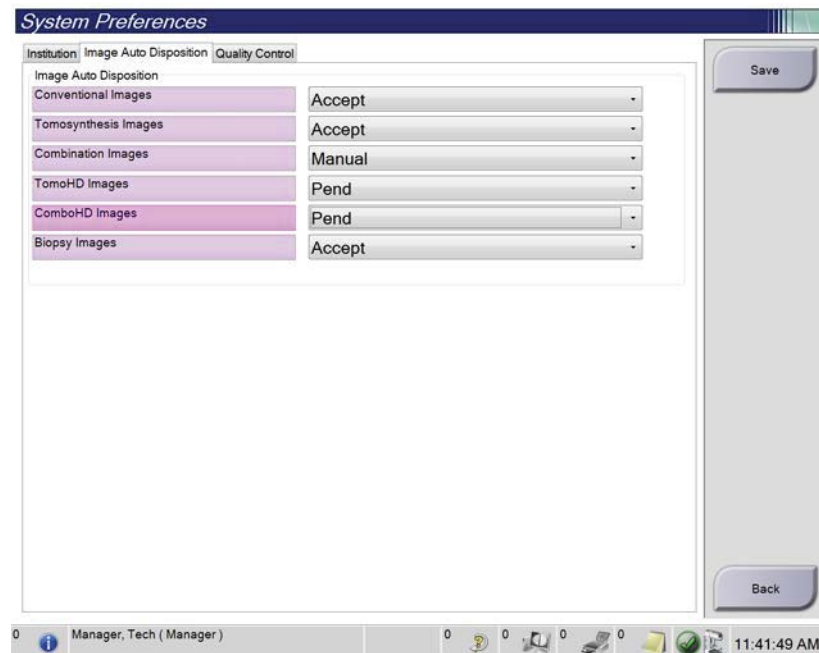


Figure 78: Set Image Auto Disposition

4. Select **Save**, then select **OK** to the *Update Successful* message.

## 10.8 How to Set the Contrast Defaults

A manager user can configure the default timer periods and the default contrast information.

### Set the Default Timer Periods

1. From the Procedures group in the *Admin* screen, select the **Contrast** button.

Figure 79: I-View 2D Contrast Default Settings

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

Your selections appear as the default timer settings on the **Contrast** tab.

### Set the Default Contrast Information

1. From the Procedures group in the *Admin* screen, select the **Contrast** button.
2. Select one or more **Contrast agents**, **Entry routes**, and **Concentration**. See the previous figure.
3. Select **Save**.

Your selections appear as the default options in the Contrast Information dialog box.

## 10.9 Enable and Set the Default Height

A manager can set the acquisition workstation to automatically return to a default height when a user logs out. To enable and set the default height:

1. In the system group of the *Admin* screen, select **Preferences**.

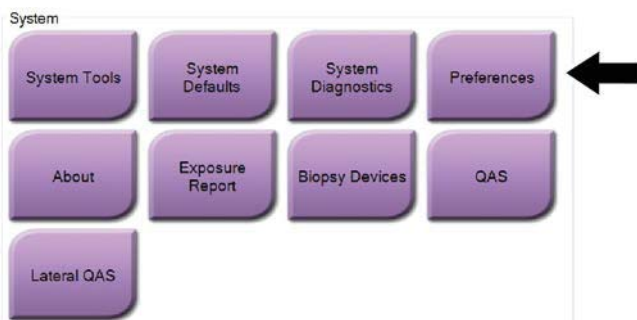


Figure 80: Preferences Button in the Admin Screen

2. In the *System Preferences* screen, select the **Console** tab.
3. To enable the default height, select the radio button to the right of the "Auto-Height adjustment on logout" field. A check mark appears. (To disable the default height option, clear the radio button.)

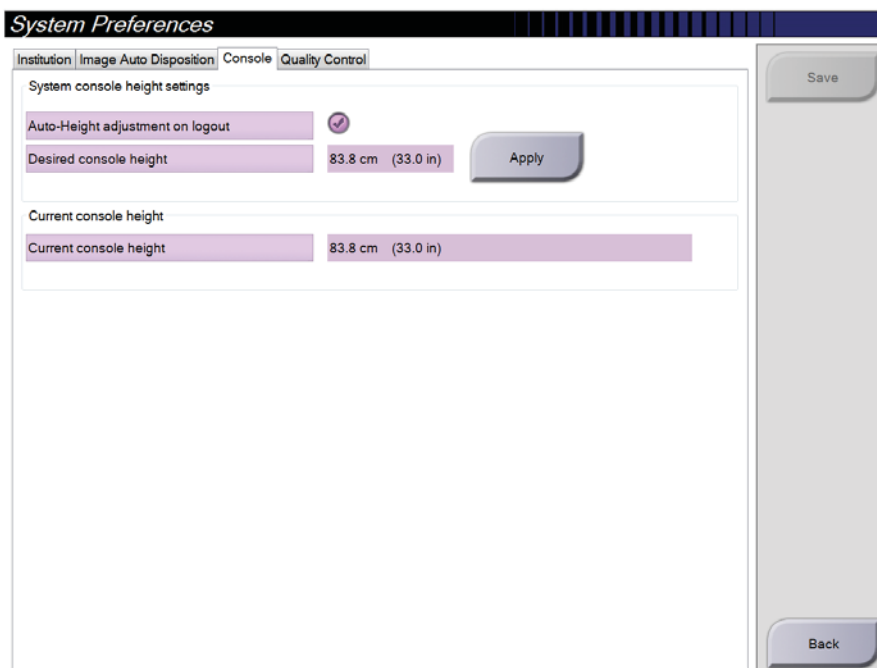


Figure 81: Console Tab of the System Preferences Screen

4. Use the ▲ UP and ▼ DOWN buttons on the height adjust control panel to set the desired height (see the following figure).

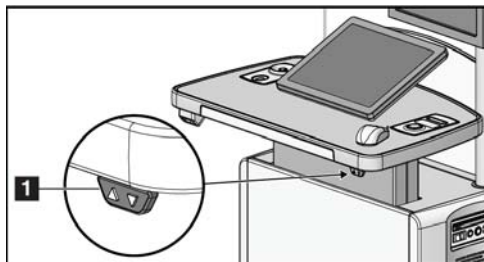


Figure 82: Height Adjust Control Panel

5. The Desired console height field displays the height as it is now positioned. The Current console height field displays the most recently saved height. (See the following figure.) To save your desired height setting, select **Apply**.

System Preferences			
Institution	Image Auto Disposition	Console	Quality Control
System console height settings			
Auto-Height adjustment on logout		<input checked="" type="checkbox"/>	
Desired console height	83.8 cm (33.0 in)	Apply	
Current console height			
Current console height	121.2 cm (47.7 in)		

Figure 83: Desired Console Height and Current Console Height Fields

6. Select **Save**, then select **OK** to the *Update Successful* message.

## 10.10 System Tools

The Radiologic Technologist Managers and users with Service permissions can access the System Tools utility. The System Tools utility contains the configuration information about the system. To access the utility, select **System Tools** from the System group in the *Admin* screen.

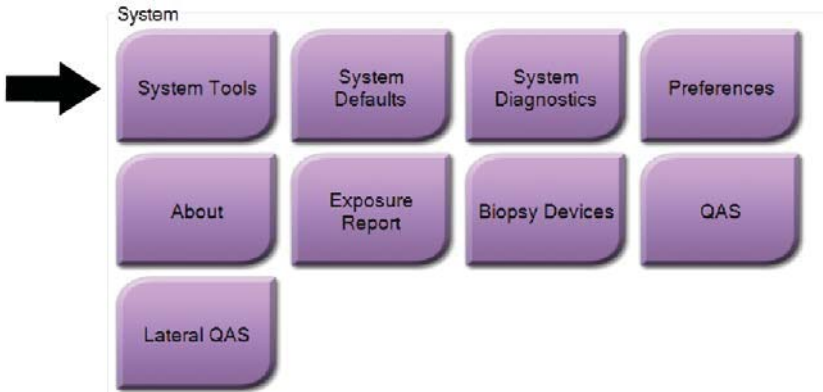


Figure 84: System Tools Button

### 10.10.1 System Tools for the Radiologic Technologist Manager

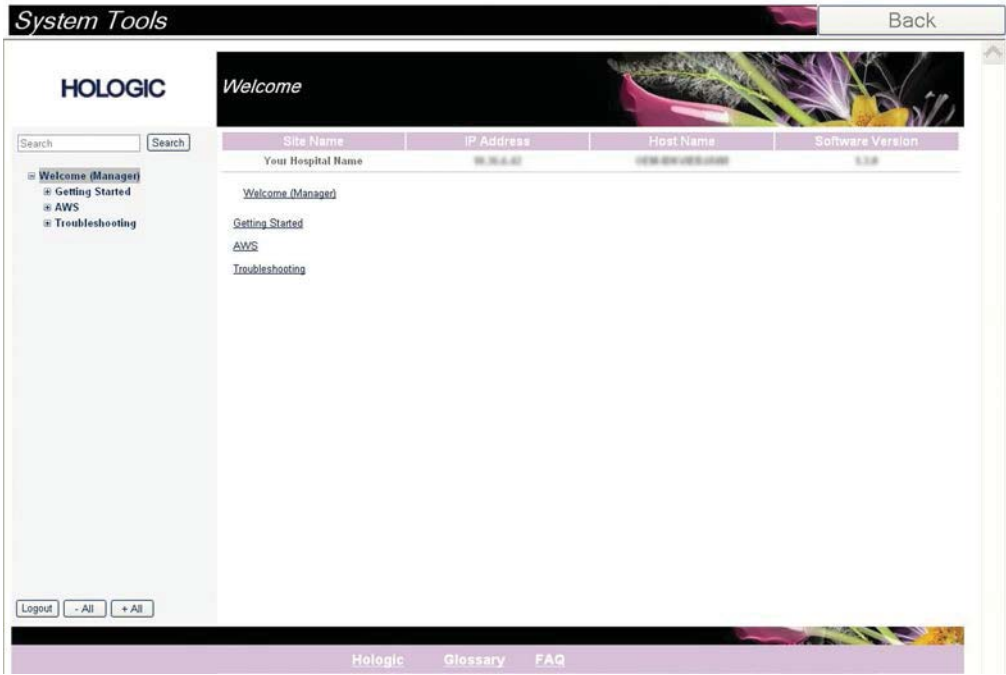


Figure 85: System Tools Screen

*Table 21: Radiologic Technologist Manager—System Tools Functions*

Section	Screen Functions
Getting Started	<p><b>About:</b> The introduction to the service tool.</p> <p><b>FAQ:</b> List of common questions.</p> <p><b>Glossary:</b> List of terms and descriptions.</p> <p><b>Platform:</b> List of directories, software version numbers, and system software statistics.</p> <p><b>Shortcuts:</b> List of Windows shortcuts.</p>
AWS	<p><b>Connectivity:</b> List of Installed Devices.</p> <p><b>Film &amp; Image Information:</b> Create an Image Report*. Create a QC Report. (*You can also access this report from a remote computer. Refer to <a href="#">Remote Access to Image Reports</a> on page 124.)</p> <p><b>Licensing:</b> List of Installed Licenses.</p> <p><b>User Interface:</b> Change the options in the Software application.</p> <p><b>Internationalization:</b> Select the local language and culture.</p>
Troubleshooting	<p><b>AWS:</b> Allows for download of images.</p> <p><b>Computer:</b> System Management and Network Information.</p> <p><b>Log:</b> Change the event record options.</p> <p><b>Backups:</b> Control the backups for the system.</p>

### 10.10.2 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 opens. Type a Manager-level user name and password, and then click **Submit**.

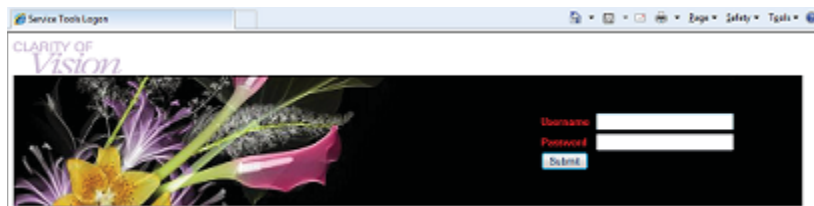


Figure 86: Remote Logon Screen for Service Tools



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

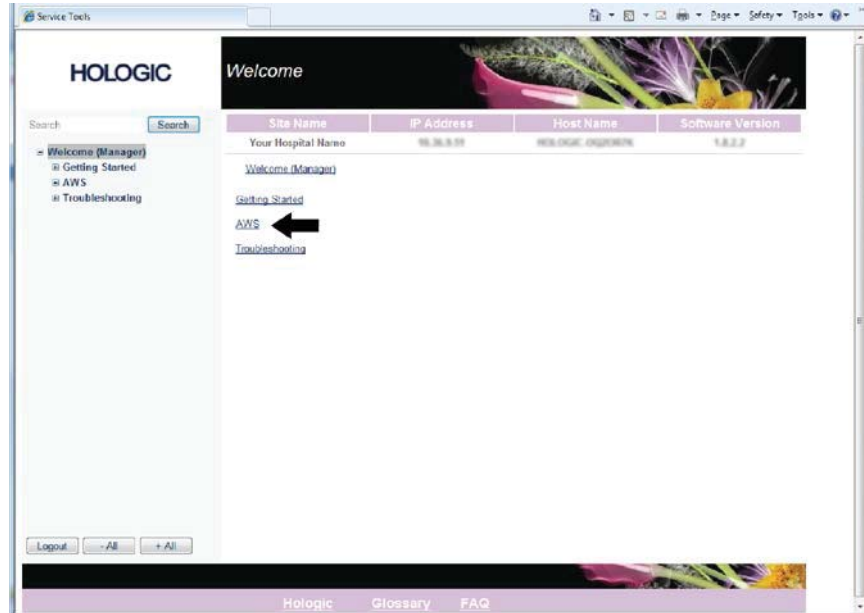


Figure 87: Service Tools Welcome Screen

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

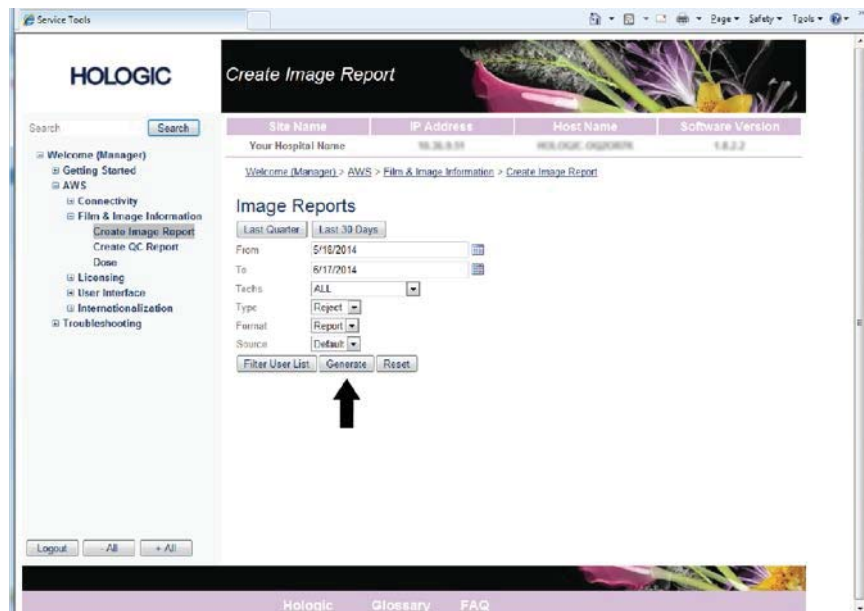


Figure 88: Create Image Report Parameters

6. 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.

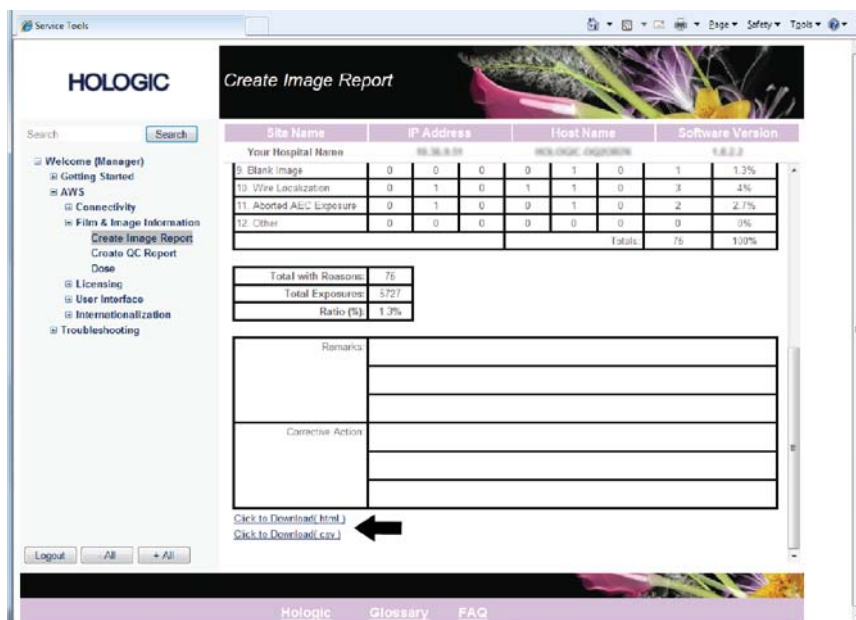


Figure 89: Create Image Report

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

## 10.11 Archive Tool

The archive feature in the *Admin* screen lets you:

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

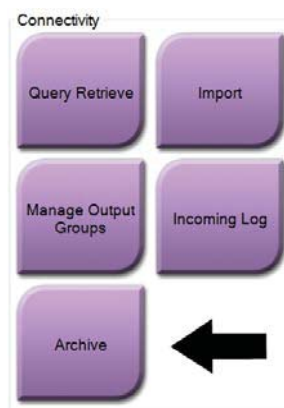


Figure 90: Archive Button

1. From the Connectivity group in the *Admin* screen, select the **Archive** button. The *Multi Patient On Demand Archive* screen opens.
  2. To search for a patient, enter at least two characters in the Search parameters area and select the magnifying glass.
- A list of patients that match the search criteria is displayed.

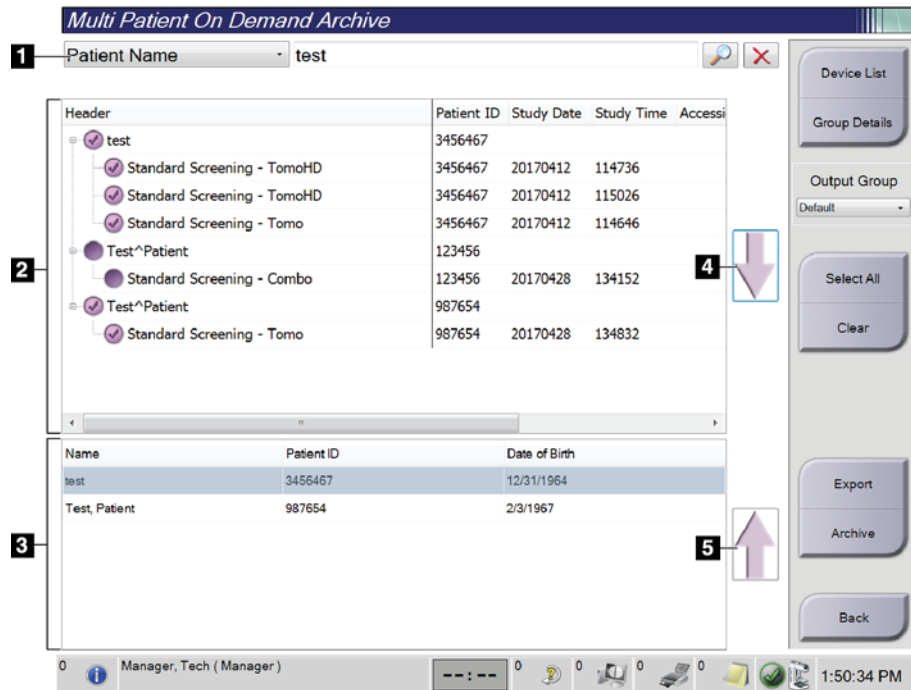


Figure Legend

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 91: Multi Patient On Demand Archive Screen

#### To Archive:

1. Select the patients and the procedures to archive.
  - 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 Store 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 the patients and the procedures to export.
  - 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.

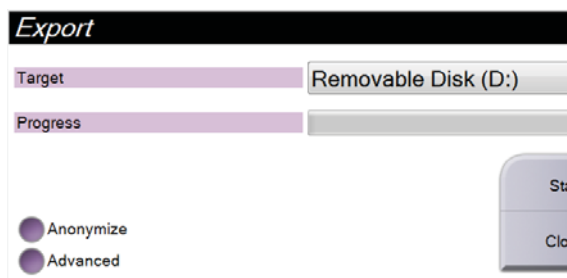


**Note**

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 92: 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)

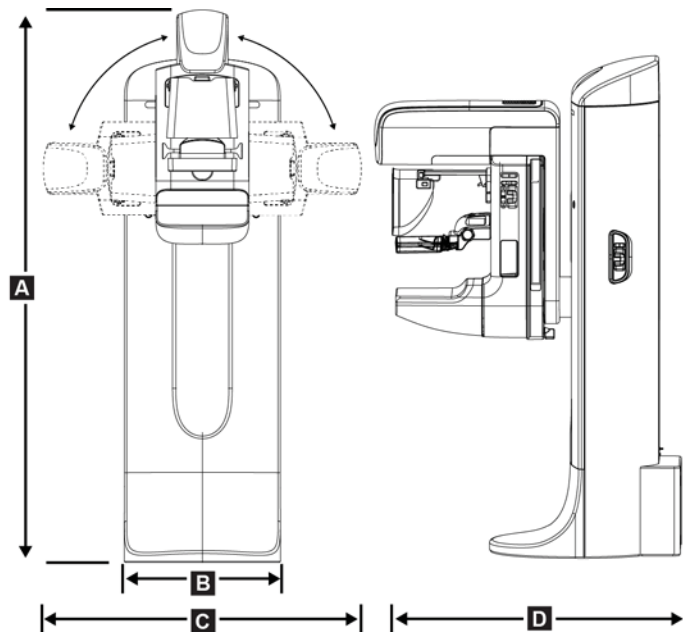


Figure 93: Tubestand (Gantry with C-arm) Measurements

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

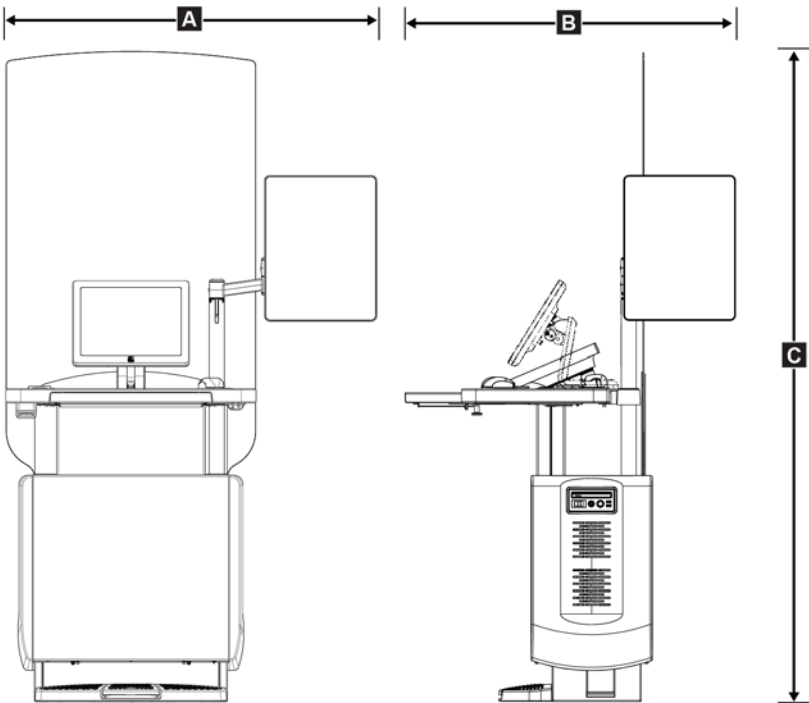


Figure 94: Universal Acquisition Workstation Measurements

A.	Width (maximum) with optional articulated display arm extended	136 cm (53.4 inches) - series I UAWS
		128 cm (50.3 inches) - series II UAWS
	Width (maximum) with standard display arm	94.0 cm (36.9 inches) - series I UAWS
		107 cm (42.0 inches) - series II UAWS
B.	Depth (maximum) with keyboard tray extended and optional articulated display monitor arm	122 cm (48.4 inches) - series I UAWS, rotated to the side
		115 cm (45.1 inches) - series II UAWS, rotated to the side
	Depth (maximum) with keyboard tray extended and standard display arm	83.6 cm (32.9 inches) - series I and II UAWS
C.	Height (nominal)	219 cm (86.1 inches) after August 2017
		204 cm (80.3 inches) before September 2017
	Weight (maximum)	209 kg (460 pounds)

### Acquisition Workstation for Mobile Use

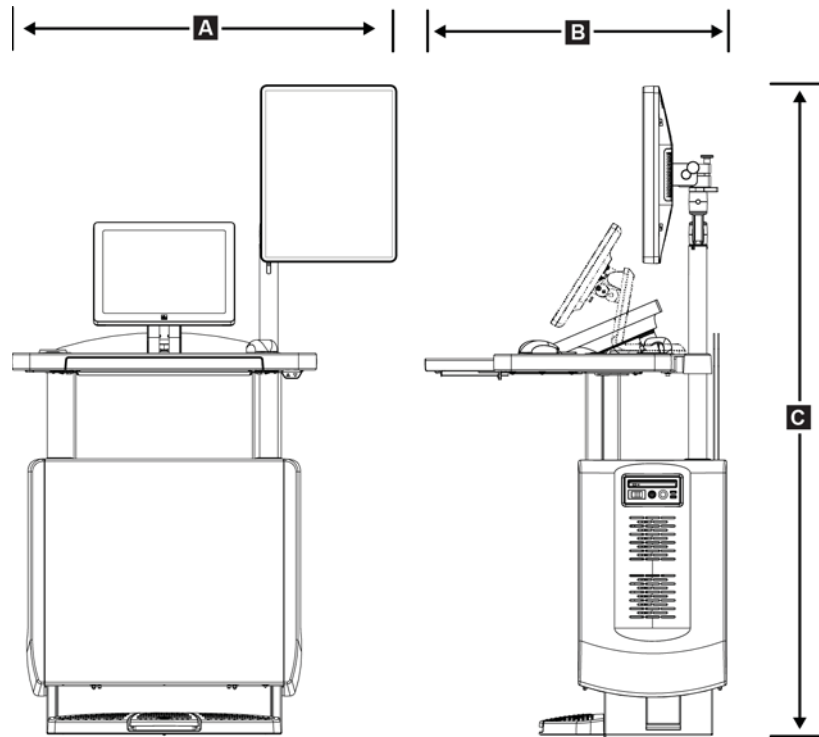


Figure 95: Mobile Universal Acquisition Workstation Measurements

A.	Width (maximum) with mobile display arm	100 cm (39.5 inches) - series I UAWS
		107 cm (42.0 inches) - series II UAWS
B.	Depth (maximum) with keyboard tray extended	85 cm (33.5 inches)
C.	Height (maximum)	180 cm (71 inches)
	Weight (maximum)	179 kg (395 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

<i>Temperature Range</i>	<i>–10 °C (14 °F) to 40 °C (104 °F)</i>
<i>Relative Humidity Range</i>	<i>10% to 90% without condensing moisture</i>

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

##### X-ray Detector

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

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

##### Acquisition Workstation

<i>Temperature Range</i>	<i>–10 °C (14 °F) to 40 °C (104 °F)</i>
<i>Relative Humidity Range</i>	<i>10% to 90% without condensing moisture</i>

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

#### A.3 Radiation Shield

<i>Radiation Shield Lead (Pb) equivalent</i>	<i>0.5 mm lead for x ray energy to 35 kV</i>
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#### A.4 Electrical Input

##### A.4.1 Tubestand

<i>Mains Voltage</i>	<i>200/208/220/230/ 240 VAC ±10%</i>
<i>Mains Impedance</i>	<i>Maximum line impedance not to exceed 0.20 ohms for 208/220/230/240 VAC, 0.16 ohms for 200 VAC</i>
<i>Mains Frequency</i>	<i>50/60 Hz ±5%</i>
<i>Average Current over 24 Hours</i>	<i>&lt; 5 A</i>
<i>Peak Line Current</i>	<i>4 A (65 A maximum for ≤ 5 seconds)</i>



## A.4.2 Acquisition Workstation

<i>Mains Voltage</i>	100/120/200/208/220/230/240 VAC $\pm 10\%$
<i>Mains Frequency</i>	50/60 Hz $\pm 5\%$
<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>	<i>Conventional Mammography:</i> $+195^{\circ} +3^{\circ}/-0.5^{\circ}$ to $0^{\circ} \pm 0.5^{\circ}$ to $-155^{\circ} +0.5^{\circ}/-3^{\circ}$  <i>Tomosynthesis option:</i> $+180^{\circ} \pm 0.5^{\circ}$ to $0^{\circ} \pm 0.5^{\circ}$ to $-140^{\circ} \pm 0.5^{\circ}$
<i>Absolute Angular Position</i>	accurate to $\pm 0.5^{\circ}$
<i>Rotation Acceleration</i>	$18^{\circ}/s^2$ $\pm 18\%$
<i>Rotation Deceleration</i>	$18^{\circ}/s^2$ $\pm 18\%$
<i>Rotational Positioning Angular Velocity</i>	$18^{\circ}/s$ $\pm 25\%$



#### Note

The angular velocity is the average of the velocity of the tube arm rotating clockwise between  $0^{\circ}$  and  $90^{\circ}$  or rotating counterclockwise between  $90^{\circ}$  and  $0^{\circ}$ . The angular velocity does not include the time to accelerate from zero velocity and decelerate to zero velocity.

<i>Source-to-Image Distance (SID)</i>	$70.0\text{ cm} \pm 1.0\text{ cm}$ (27.6 inches $\pm 0.4$ inches) (Focus position deviation is $\pm 5\text{ mm}$ )
<i>Patient Support (non-magnification)</i>	
<i>Vertical Position Lower Limit</i>	$70.5\text{ cm} +5.1/-0\text{ cm}$ (27.75 inches $+2.0/-0$ inches)
<i>Vertical Position Upper Limit</i>	$141\text{ cm} +0/-17.8\text{ cm}$ (55.5 inches $+0/-7.0$ inches)

#### 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 Motorized Release 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 <math>\pm</math>15% (1.66 inches/s <math>\pm</math>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><math>\pm</math>20 N (<math>\pm</math>4.5 pounds)</i>
<i>Compression Thickness Display</i>	<i>Two LCDs on the Compression Device measure compression thickness in 0.1 cm increments. The display is visible from both sides of the patient.</i>
<i>Compression Thickness Accuracy</i>	<i><math>\pm</math>0.5 cm (<math>\pm</math>0.2 inches) for thicknesses between 0.5 cm and 15 cm (5.9 inches)</i>
<i>Breast Tomosynthesis Compression Thickness</i>	<i>Standard resolution tomosynthesis Maximum: 24 cm (restricted by compression device geometry)  High resolution tomosynthesis Maximum: 15 cm (restricted by DICOM limitations)</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>
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**kV/mA Range***Table 22: Maximum mA Setting as a Function of kV*

<b>kV</b>	<b>LFS mA</b>	<b>SFS mA</b>
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

Table 22: Maximum mA Setting as a Function of kV

kV	LFS mA	SFS mA
32	190	50
33	200	50
34	200	50
35	200	50
36	190	50
37	180	50
38	180	50
39	180	50
40	170	
41	170	
42	160	
43	160	
44	150	
45	150	
46	150	
47	140	
48	140	
49	140	

*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

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

### A.5.6 Light Field Indication

<i>Light Field to X Ray Congruency</i>	<i>Within 2% of SID</i>
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### A.5.7 X-ray Generator

<i>Type</i>	<i>Constant Potential High Frequency Inverter</i>
<i>Rating</i>	<i>7.0 kW, maximum (isowatt), 200 mA at 35 kV</i>
<i>Electrical Power Capacity</i>	<i>9.0 kW maximum</i>
<i>kV Range</i>	<i>20 kV to 49 kV in 1 kV increments</i>
<i>kV accuracy</i>	<i>±2%, over range 20-49 kVp</i>
<i>mAs Range</i>	<i>3.0 mAs to 500 mAs in Manual Mode mAs (8 mAs minimum in AEC Mode)</i>
<i>mAs Accuracy</i>	<i>±(10% + 0.2 mAs)</i>
<i>mA Range</i>	<i>10 mA to 200 mA, Large Focal Spot</i>
	<i>10 mA to 50 mA, Small Focal Spot</i>

## 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.</i> <i>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 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

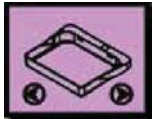
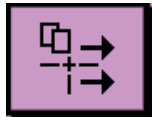





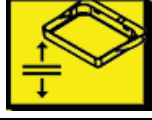


Technical information about the message is available in the log file.

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.

Table 23: 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.



*Table 23: System Messages*

Icon	Message	User Action
	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.
	System in Test Mode	Applies to Service Personnel.
	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 engaged.	Turn the Emergency Off switch one-quarter turn to reset the switch.
	Compression too low for tomo reconstructions.	Move the Compression Paddle higher than 0.5 cm to take tomography exposures.

## B.3 UPS Messages



### Note

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

The LCD in the UPS shows the power status.

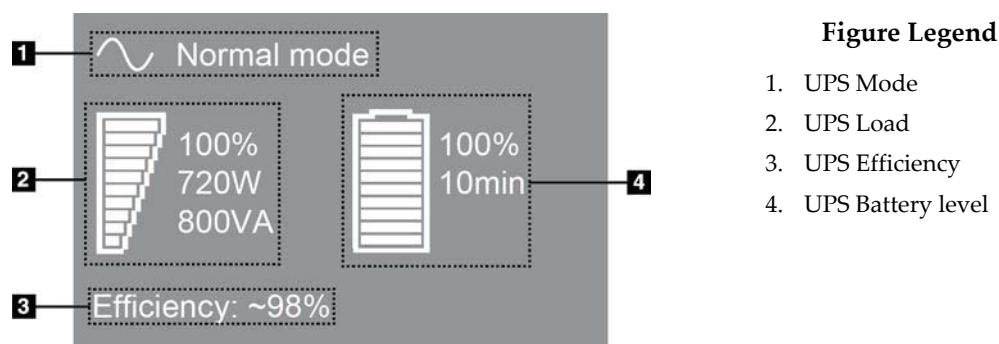


Figure 96: UPS LCD Display

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



## Appendix C Use of Mobile System

This appendix describes the system installed in a mobile environment.

### C.1 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 system provides the best performance. If a mobile power generator is used, you must keep the specifications for input power during all load conditions.



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**Warning:**

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

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**Caution:**

When shore power is unavailable, mobile power sources that provide equivalent performance may be employed. (Refer to [Specifications for Mobile Use](#) on page 144.) 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 a 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.

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**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.**

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**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.**

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**Caution**

To avoid image artifacts from occurring:

- Care should be exercised not to locate or park the mobile coach near sources of high power (such as power transmission lines and outdoor transformers).
  - Make sure that any mobile power generator, uninterruptible power system (UPS), or voltage stabilizer is at least 3 meters (10 feet) from the closest point of the image detector travel.
- 

## C.2 Specifications for Mobile Use

The following system specifications are for mobile use only. For all other specifications, refer to the section [Specifications](#) on page 129.

### C.2.1 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.2.2 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.3 Electrical Input**

### **C.3.1 Gantry**

<i>Mains Voltage</i>	<i>200/209/220/230/ 240 VAC ±10%</i>
<i>Mains Impedance</i>	<i>Maximum line impedance not to exceed</i> <i>0.20 ohms for 208/220/230/240 VAC,</i> <i>0.16 ohms for 200 VAC</i>
<i>Mains Frequency</i>	<i>50/60 Hz ±5%</i>
<i>Average Current over 24 Hours</i>	<i>&lt; 5 A</i>
<i>Peak Line Current</i>	<i>4 A (65 A maximum for 3 seconds)</i>

### **C.3.2 Acquisition Workstation**

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

## C.4 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.

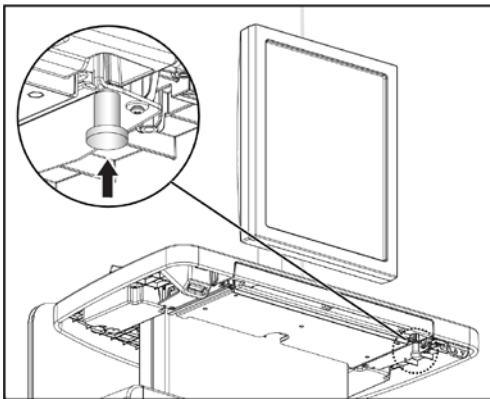


Figure 97: Keyboard Tray Lock Knob

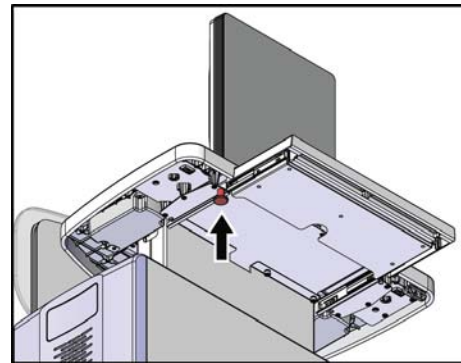


Figure 98: Keyboard Tray Lock Knob

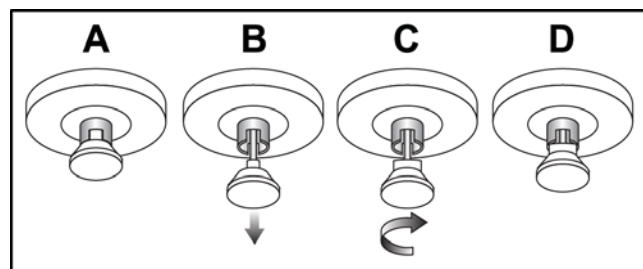
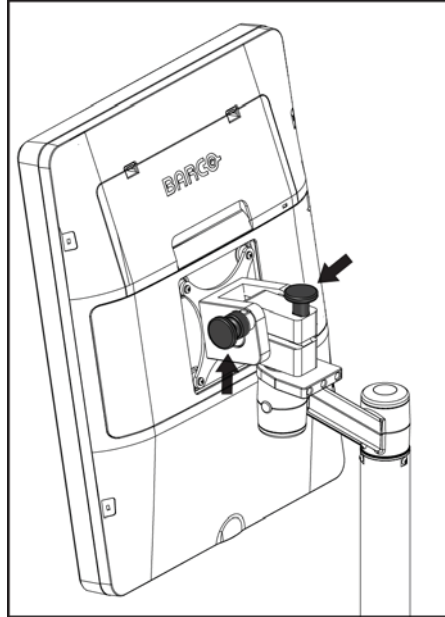


Figure 99: Tray Lock Release from Locked (A) to Unlocked (D)

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

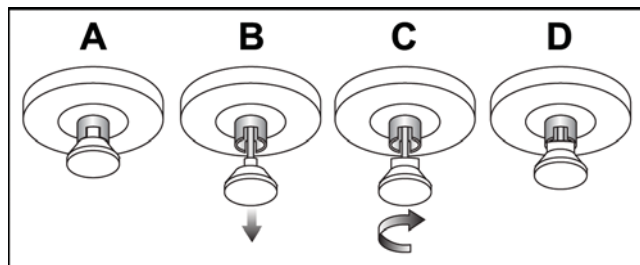


*Figure 100: Swivel Lock Knobs for Image Display Monitor on Mobile Universal Acquisition Workstation*

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

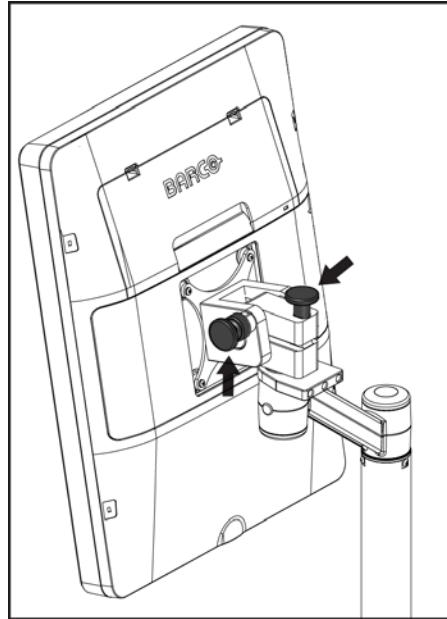
## C.5 Prepare the System for Use

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 101: 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 102: Swivel Lock Knobs for Image Display Monitor on Mobile Universal Acquisition Workstation*

## C.6 Test the System after Travel

### C.6.1 Mobile System Controls and Functional Tests

Perform the Controls and Functional Tests. Refer to [Perform the Functional Tests](#) on page 32.

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

## C.7 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 24: 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 25: 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 26: 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

## Glossary of Terms

**ACR**

American College of Radiology

**AEC**

Automatic Exposure Control

**Annotations**

Markings on an image to indicate an area of interest.

**BT**

Breast Tomosynthesis. An imaging procedure that provides information about the breast in three dimensions

**CEDM**

Contrast Enhanced Digital Mammography

**Collimator**

A device at the x-ray tube to control the x-ray beam exposure area.

**Conventional Mammography**

Single projection x-ray images of views for screening and diagnostic purposes

**C-View**

A licensed Hologic feature where a digital mammography (DM) image is generated from data acquired during a breast tomosynthesis (BT) scan

**DICOM**

Digital Imaging and Communications in Medicine

**DM**

Digital Mammography (2D)

**EMC**

Electromagnetic Compatibility

**FAST Paddle**

Fully Automatic Self-adjusting Tilt Paddle

**FDA**

Food and Drug Administration (in the United States)

**Grid**

An element within the Digital Image Receptor that reduces scatter radiation during the exposure

**Image Receptor**

Assembly of the x-ray detector, x-ray scatter reduction grid, and carbon fiber cover

**Intelligent 2D**

A licensed Hologic feature where a high-resolution digital mammography (DM) image is generated from data acquired during a high resolution breast tomosynthesis (BT) scan

**I-View**

A licensed feature for 2D Contrast Enhanced Digital Mammography

**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 that transmits and archives digital medical images.

**Pend**

The action taken on an image to mark the image if the Technologist is not positive about the image quality (pending images must be Accepted or Rejected before the procedure is closed)

**Projection Image**

One of a group of breast tomosynthesis images taken at different projection angles and used to produce the final reconstructed image

**Reclamation**

Automatic removal of patient images and related information to allow storage of new patient image acquisitions

**RF**

Radio Frequency

**ROI**

Region of Interest

**SID**

Source to Image Distance

**Tomosynthesis**

An imaging procedure that combines a number of breast images taken at different angles. The tomosynthesis images can be reconstructed to show focal planes (slices) within the breast.

**UDI**

A United States Food and Drug Administration program for Unique Device Identification (UDI). For more information about UDI, go to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm>.

**UPS**

Uninterruptible Power Supply

**USB**

Universal Serial Bus

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