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Trident™ Specimen Radiography System

User Guide

MAN-02098 Revision 008

Trident™
Specimen Radiography System

HOLOGIC®



Specimen Radiography System

User Guide

For Software Version 1.1

Part Number MAN-02098

Revision 008

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Chapter 1: Introduction

1.1 Intended Use

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

The Trident™ specimen radiography system is a cabinet x-ray system used to provide digital x-ray images of surgical and core biopsy specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the biopsy procedure.

Doing the verification in the same room as the procedure or nearby improves workflow, thus reducing the time the patient needs to be under examination.

1.2 Intended Use for the User Guide

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

1.3 System Capabilities

The Hologic® Trident system acquires and displays the radiographic images of surgical and core specimens taken from various anatomical regions. The system has the capability to transfer the images to external devices. The images acquired with this system are intended to confirm removal of a suspected lesion or pathology; the system is not intended for diagnostic purposes.

Specimen radiography systems are used in diagnostic imaging departments, pathology departments, or in surgical suites. Radiologic Technologists, surgical personnel, surgeons, radiologists and pathologists can use specimen radiography equipment.

Hologic recommends that users receive training in basic ionizing radiation safety before using the system.

1.4 Product Complaints

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

1.5 Technical Support

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

1.6 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.

1.7 Installation Instructions

Installation instructions are available in the Service Manual.

1.8 Users









- Primary System User (for example, operating room nurse) to perform basic system functions, except ones that require Manager privileges. The Primary System User is referred to in this document as the User.
- System Managers can perform all system functions, add and delete user accounts, and delete patients. The System Manager is referred to in this document as the Manager.
- Service personnel have full access to all system functions.

1.9 Terms and Definitions

AEC	Automatic Exposure Control
Annotations	Graphic or text marks on an image to indicate an area of interest.
DICOM	Digital Imaging and Communications in Medicine
Image Receptor	Captures and digitizes the x-ray images.
PACS	Picture Archiving and Communications System. A computer and network system that transmits and archives digital medical images.
ROI	Region of Interest
SID	Source to Image Distance
UPS	Uninterruptible Power Supply

1.10 International Symbols

This section describes the International Symbols on this system.

	"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.
	Manufacturer
	Date of Manufacture
	Caution—Radiation

1.11 Warnings, Cautions, and Notes

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



WARNING!

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



Warning:

The procedures that you must follow accurately to prevent injury.



Caution:

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



Note

Notes show additional information.

Chapter 2: General Information

2.1 System Description

The system components for x-ray generation are contained in the Shielded Cabinet. The user interface for data entry, patient selection, and image acquisition and review is mounted next to the Cabinet.

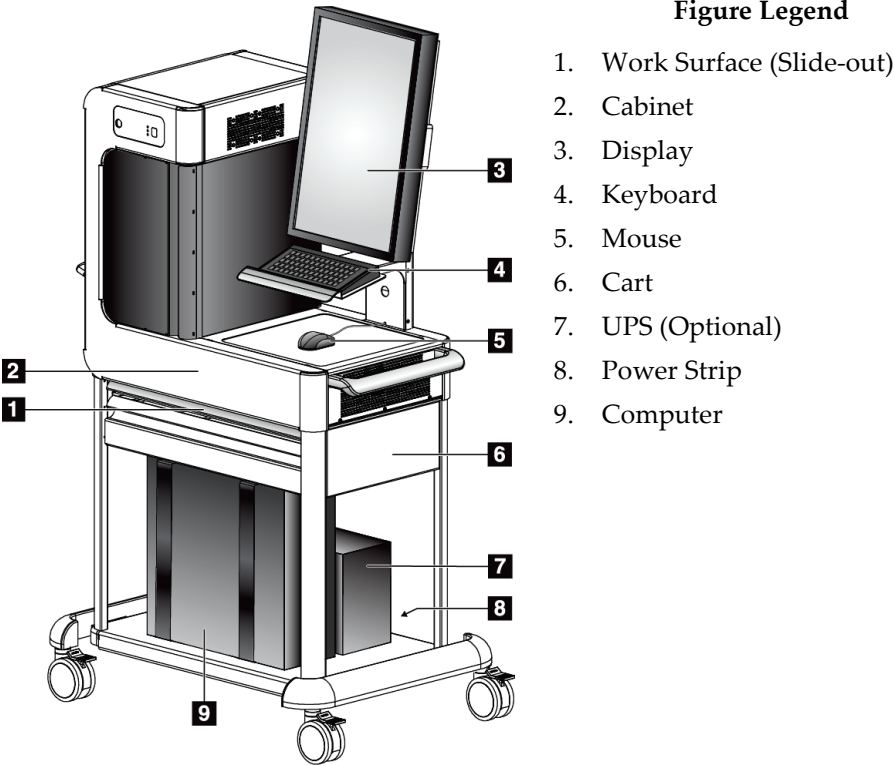


Figure 1: Trident System Components

2.2 Safety Information

Read and understand this manual before you use the system. Keep the manual available during the operation of the unit.

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

The system has safety interlocks, but the user must understand how to safely operate the system and be aware of the health hazards of x-ray radiation.

2.3 Warnings and Cautions



WARNING!

The users must understand that the system is not connected to earth ground if the UPS (optional) is disconnected from the power source.



WARNING!

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



WARNING!

Electrical equipment used near flammable anesthetics can cause an explosion.



WARNING!

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



WARNING!

The protection provided by the equipment is reduced if the equipment is used in a method not specified by Hologic



WARNING!

Always place the Trident a minimum of 1.5 meters (5 feet) from the patient.



Warning:

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



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:

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



Caution:

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



Caution:

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



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.



Caution:

The weight and mobility of this system require the following precautions:

- Be careful when you move the system on uneven or sloped surfaces.
- Make sure the wheels are locked when the system is stationary.
- Before you move the cart, make sure the cables are stored in a safe position on the cart.



Caution:

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

2.4 Interlocks

The x-ray generation stops automatically and an error message appears when there is an interruption of an x-ray exposure such as when the mAs timer or maximum exposure timer times out, the cabinet door is opened, or the key switch is turned to the locked position. To make another exposure:

1. Select the **OK** button in the error message dialog box.
2. Select the status icon (shaped like the Trident unit) in the taskbar at the bottom of the screen.
3. Complete any action (such as "Close the door") that shows in the system message area of the screen.
4. Select the **Clear All Faults** option.
5. When **READY** shows in the system message area, press the **X-RAY** button when you are ready to take another exposure.

2.5 Compliance

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

2.5.1 Compliance Requirements

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

- 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 must be installed to meet IEC Standards.



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.

2.5.2 Compliance Statements

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

- UL 61010-1, 2nd Edition, 2005-07-22 (Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements)
- CAN/CSA-C22.2 No. 61010-1, 2nd Edition, 2004-07, (Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements)
- IEC 61010-1:2001, 2nd Edition, and IEC 61010-1:2010, 3rd Edition.

2.6 Label Locations

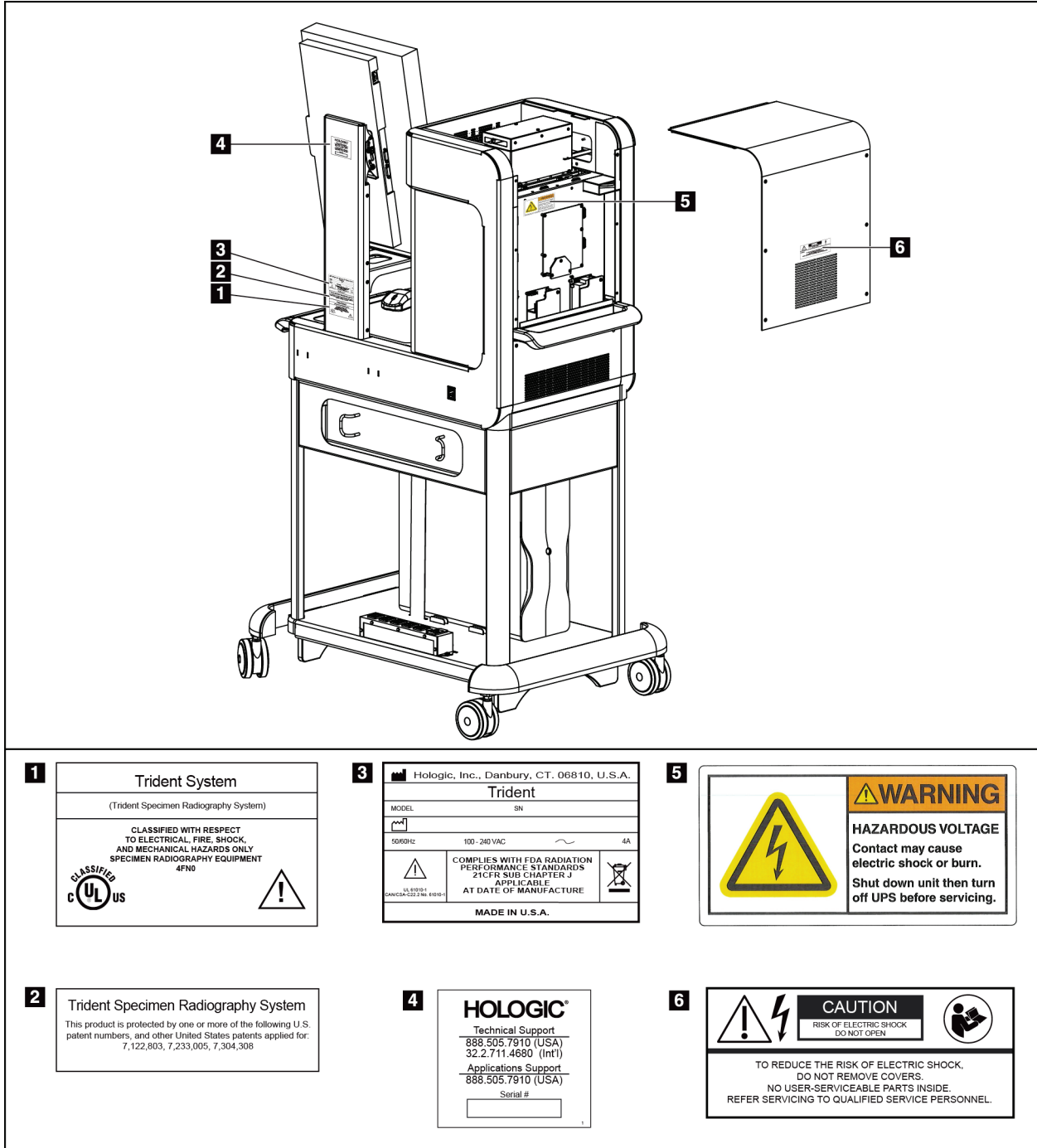


Figure 2: Label Locations

Chapter 3: Components, Controls, and Indicators

3.1 Shielded Cabinet Components

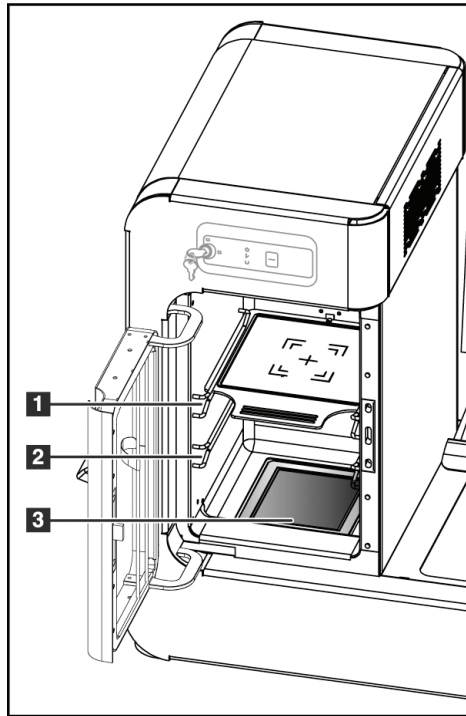


Figure Legend

1. Specimen location for 2.0x magnification image
2. Specimen location for 1.5x magnification image
3. Specimen location for contact image

Figure 3: Cabinet Components

3.2 Workstation Components

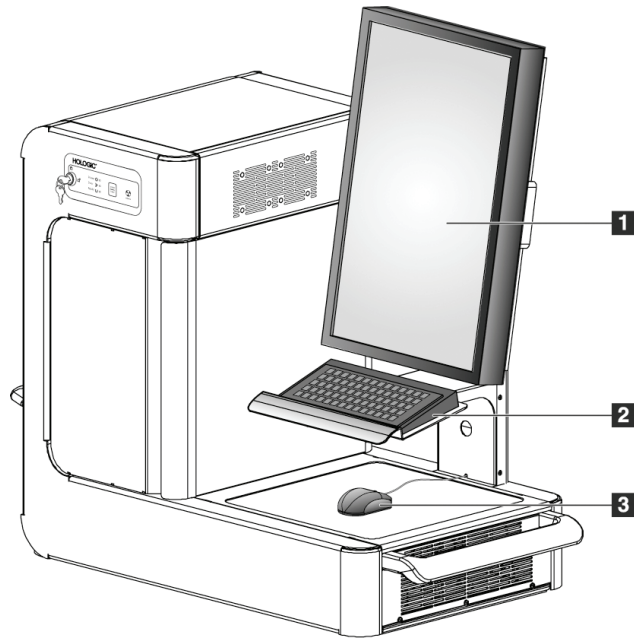


Figure Legend

- 1. Display
- 2. Keyboard
- 3. Mouse

Figure 4: Workstation Components

3.3 Cart Components

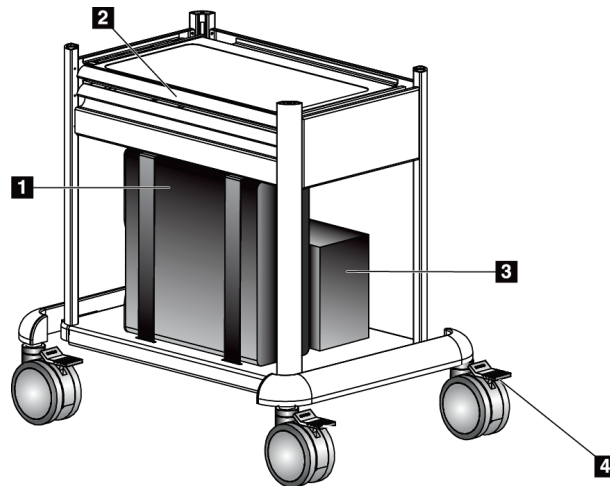


Figure Legend

- 1. Computer
- 2. Work Surface (Slide-out)
- 3. UPS (optional)
- 4. Locking Casters (4)

Figure 5: Cart Components



Note

The hooks (not shown) on the back of the Cart provide safe storage of the power cord during cart movement.

3.3.1 How to Lock a Caster

1. To lock a caster, step on the locking lever on the wheel until the lever locks.
2. To unlock a caster, lift the locking lever to the up position.

3.3.2 How to Move the Cart

1. Make sure all components and cables are in a safe position on the cart.
2. Unlock the caster locks.
3. Push the cart with one of the side handles.
4. Make sure to lock the casters when the cart is at the correct location.

3.4 Controls and Indicators

3.4.1 Cabinet Controls and Indicators

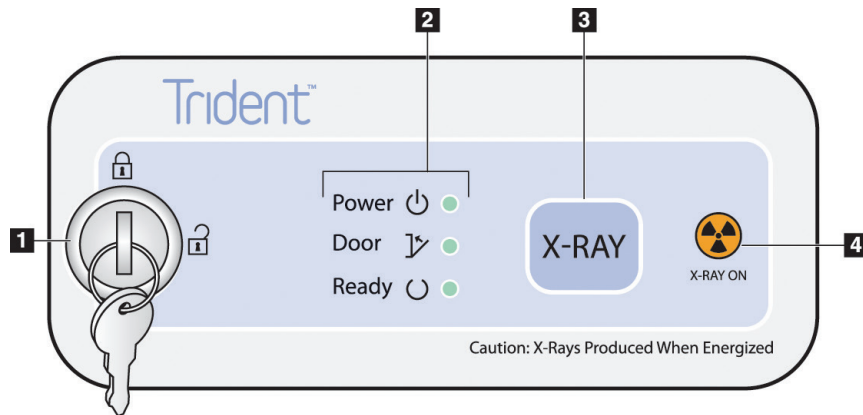


Figure 6: Cabinet Controls and Indicators

Figure Legend

1.	Key Switch	<ul style="list-style-type: none"> • Locked: X ray is disabled. • Unlocked: X ray is enabled.
2.	System Status Indicators	<ul style="list-style-type: none"> • Power: ON = LED is green. • Door: Closed = LED is green. Open = LED is Off. • Ready: X ray is ready = LED is green.
3.	Exposure Control	X-RAY: Press to begin an exposure. Press to end an exposure before automatic termination.
4.	X-ray On Indicator	X-RAY ON = LED is amber.

3.4.2 Display Controls and Indicators

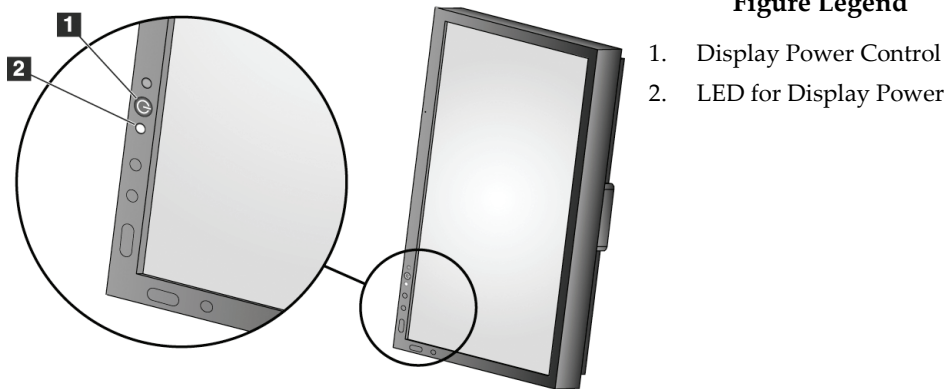


Figure 7: Display Control and Indicator

3.5 Cable Connections

Put the Trident in a location where you can easily access connections for power and network connections.

1. Connect the network cable to the network outlet in the wall.
2. Connect to AC power:
 - For systems without the UPS, connect the system power cord to the wall outlet.
 - For systems with the UPS, connect the UPS power cord to the wall outlet.

3.6 How to Start the System

1. If the UPS is stopped, press the UPS On button. (The UPS is an optional component.)
2. Press the power button on the Computer.
3. When the Startup Screen displays, select the **Log In** button.

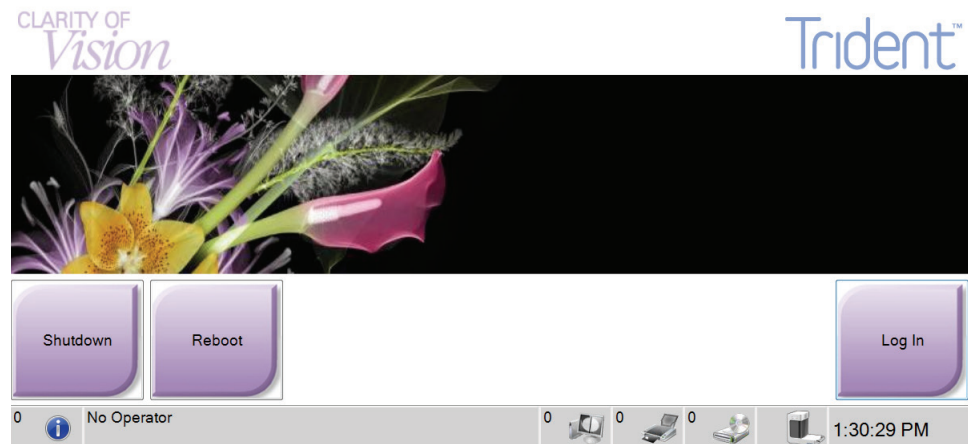


Figure 8: Startup Screen



Note

The control panel LEDs can blink when the system starts. The image can be shown sideways during the bootup procedure.



Note

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

3.6.1 Log In

The screen displays user names or user group (such as the Service group.) If your user name or group is not shown, click the **Show All** button.

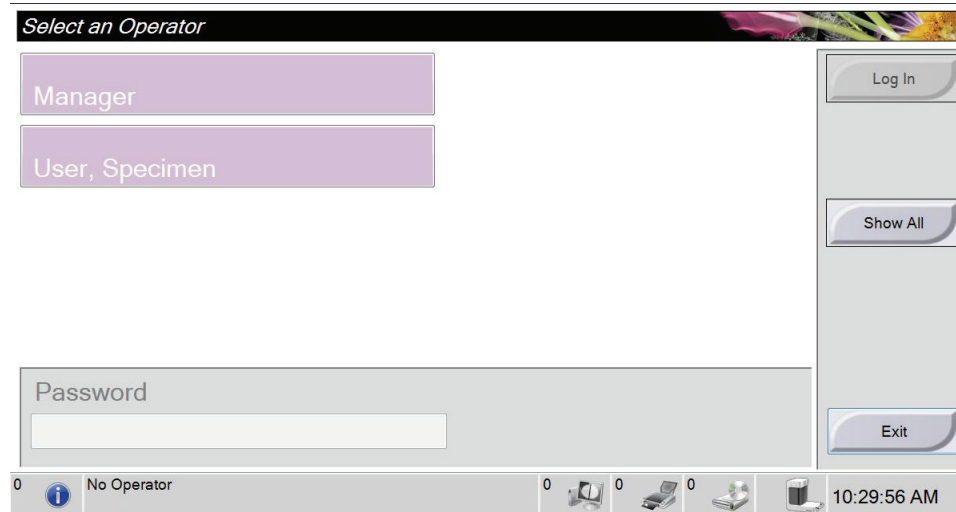


Figure 9: Select an Operator

1. Select your user name.
2. Enter your password.
3. Select the **Log In** button.



Note

To change the system language or other preferences, access the Admin screen (refer to the next section).

3.6.1.1 How to Access the Admin Screen

1. Right-click on the User Name area of the taskbar at the bottom of the screen.
2. Select the **Admin** option from the menu.

3.6.1.2 How to Change the Language


1. Right-click on the User Name area in the taskbar at the bottom of the screen.
2. Select the **Admin** option to display the Admin screen. For complete information about the functions on the Admin screen, refer to [How to Use the Admin Screen](#) on page 43.
3. Select the **My Settings** option.
4. From the **Locale** field, select a language from the drop-down menu.
5. Select the **Save** button, then select the **OK** button to the Update Successful message. The selected language displays.

3.7 How to Shutdown the System

1. Select the **Close Patient** button in the Procedure screen.
2. From the Select Patient screen, select the **Log Out** button.
3. From the Startup screen, select the **Shutdown** button. A prompt displays the option to continue with the system shutdown.
4. Select the **Yes** button to shutdown the system .

3.7.1 How to Remove All Power from the System

Table 1: Removal of All Power from the System

System without the optional UPS	System with the optional UPS
<ol style="list-style-type: none"> 1. Make sure the system is completely turned off. 2. Disconnect the power strip from the wall. 	<ol style="list-style-type: none"> 1. Make sure the system is completely turned off. 2. Press and hold the UPS power button  for five seconds. 3. Press the down arrow button to change the on screen selection to "Yes". 4. Press the enter button (left arrow). 5. Press the down arrow button to change on screen selection to "Off – No Delay". 6. Press the enter button (left arrow). 7. Disconnect the UPS from the wall.

3.8 Battery Power Operation

Systems that have a backup battery (the UPS) continue to operate when AC power is removed during system operation. The UPS automatically engages and the system gives audible and visual alerts about the battery status.

When the battery reaches the critical low limit, the Trident shuts down then the UPS shuts down. If AC power is restored while the battery is on, the UPS returns silently to normal operation.

3.8.1 Battery Alerts

When the system starts on battery power:

- A black battery icon appears in the status area of the taskbar at the bottom of the screen.
- The UPS beeps approximately four times every 30 seconds.

When the battery is near depletion:

- The battery icon in the taskbar at the bottom of the screen changes from black to red.
- The UPS continues to beep.

3.8.2 How to Stop the Beep from the UPS

Press the down arrow button on the front of the UPS.

Chapter 4: The User Interface

4.1 The Select Patient Screen

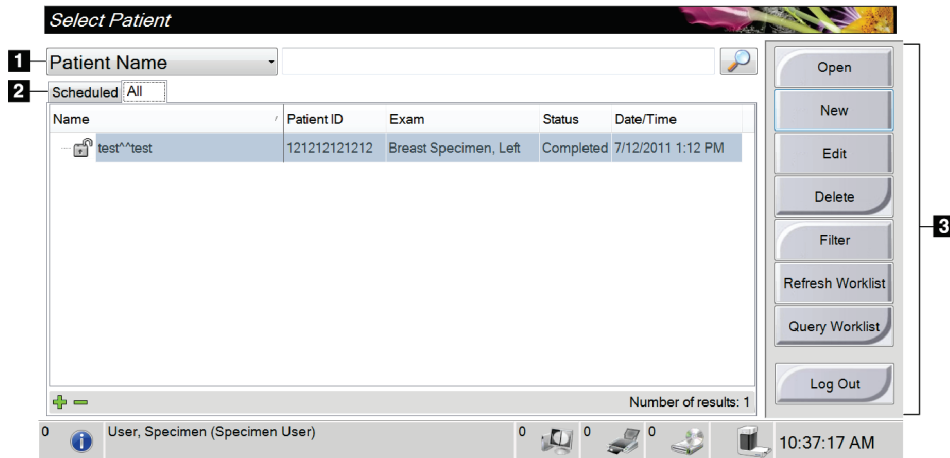


Figure 10: The Select Patient Screen

Figure Legend

1. Quick Search Search the local database for the Patient Name, Patient ID, or Accession Number.
2. Tabs Two tabs display at the top of the screen. These tabs are configurable. A Manager can delete tabs and create new tabs (refer to [The Filter and Column Tabs in the Patient Filter Screen](#) on page 22).
 - The Scheduled tab displays the scheduled procedures.
 - The All tab displays all procedures.
3. Other Functions You can perform many functions from this screen:
 - Open the procedure for the selected patient—refer to [How to Open a Procedure](#) on page 20.
 - Add a new Patient (New)—refer to [How to Add a New Patient](#) on page 20.
 - Edit the patient information (Edit)—refer to [How to Edit the Patient Information](#) on page 21.
 - Delete a patient from the worklist (Delete)—refer to [How to Delete a Patient](#) on page 21.
 - Use a Patient Filter (Filter)—refer to [The Patient Filter Screen](#) on page 22.
 - Search for a patient in the Modality Worklist (Query)—refer to [How to Query the Worklist](#) on page 23.
 - Exit (Log Out) and return to the Startup screen.
 - Find your patients in the database (tabs at the top of screen).

4.1.1 How to Open a Procedure

You can open a procedure in one of two ways:

- Double-click the patient entry in the displayed list on the Select Patient Screen.
- OR
- Select a patient from the displayed list, then select the **Open** button.

4.1.2 How to Add a New Patient

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

The screenshot shows a software window titled "Add Patient". The window contains a form with the following fields and values:

- Last: [Empty text box]
- First: [Empty text box]
- Middle: [Empty text box]
- Patient ID*: [Empty text box]
- Date of Birth*: [Three empty date input boxes]
- Gender*: Female (dropdown menu)
- Accession Number: [Empty text box]
- Procedure*: Breast Specimen, Left (dropdown menu)

On the right side of the form, there are two buttons: "Open" at the top and "Back" at the bottom. The bottom status bar of the application shows "0 Manager (Manager)", several icons, and the time "3:00:05 PM".

Figure 11: Add a New Patient

4.1.3 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.

The screenshot shows the 'Edit Patient' interface. The title bar indicates the patient name is 'test, test'. The form fields are as follows:

Field	Value
Last	test
First	
Middle	test
Patient ID*	121212121212
Date of Birth*	12/19/1972, 38
Gender*	Female
Accession Number	12312312312

Buttons: Save, Back

Status Bar: User, Specimen (Specimen User), 3:15:40 PM

Figure 12: The Edit Patient Information Screen

3. When the Update Successful screen displays, select the **OK** button.

4.1.4 How to Delete a Patient

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



Note

A Primary System User can not delete patients, but a Manager can.



Note

Reclamation normally removes the requirement to delete patients.

4.1.5 The Patient Filter Screen

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

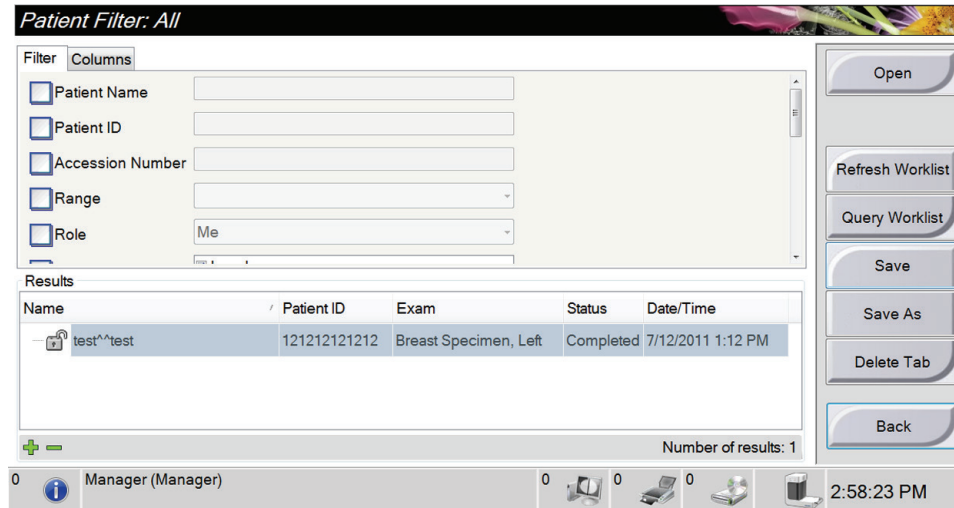


Figure 13: The Filter Tab in the Patient Filter Screen

4.1.5.1 The Filter and Column Tabs in the Patient Filter Screen

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



Note

A Manager can save these new filters to the selected tab in the Select Patient screen (refer to [Other Functions of the Filter Tab](#) on page 23).

The Column tab allows you to add more search options (for example, Age, Gender, Date of Birth) to the filtered list. The options display 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 double-click an entry in the results list (or select the **Open** button), the Procedure screen for the selected patient appears.

4.1.5.2 Other Functions of the Filter Tab

The Save, Save As, and Delete Tab buttons on the Filter tab allow Managers to add, change, or delete tabs in the Select Patient screen.

Table 2: The Filter Tab Options

Option	Step
Change the current patient filter parameters.	<ol style="list-style-type: none"> 1. Select a tab on the Select Patient 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 Select Patient screen.	<ol style="list-style-type: none"> 1. Select a tab on the Select Patient 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 Select Patient screen.	<ol style="list-style-type: none"> 1. Select a tab on the Select Patient screen. 2. Select the Filter button. 3. Select the Delete button 4. Select Yes to the confirmation prompt.

4.1.6 How to Refresh the Worklist

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

4.1.7 How to Query the Worklist

Use the Query Worklist feature to search for a patient or a list of patients. Use one or more fields to query the Modality Worklist Provider. All fields to query are configurable. The default fields are as follows: Patient name, Patient ID, Accession Number, Requested Procedure ID, Scheduled Procedure Date. The scheduled procedure displays and the patient is added to the local database.

4.2 The Procedure Screen

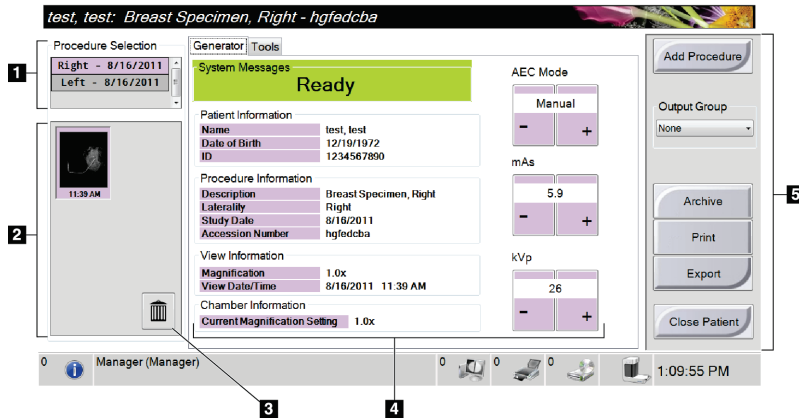


Figure 14: An Example Procedure Screen

Figure Legend

1. Procedure Selection Shows the accession number assigned to a procedure.
2. Image Thumbnails Shows small icons of images related to the selected accession number. A thumbnail image with a camera icon is a snapshot image that differs in size and resolution from the original image.
3. Trash Icon Deletes a selected thumbnail image. You cannot recover deleted images.
4. Generator Tab Contents of the Generator Tab.
5. Other Functions Add another procedure, select the location of acquired images, or close the procedure.

4.2.1 How to Select a Procedure

Select an entry from the list in the Procedure Selection area of the screen.

4.2.2 How to Set the Exposure Techniques

- Manual: The user selects the kV and mAs.
- AEC: Auto-kV: The system selects the kV and mAs.

To increase or decrease an Exposure Technique in one step increments, click then release the + or - button.

To move quickly through the values for an Exposure Technique, click and hold the + or - button.

4.2.3 How to Acquire an Image

1. Put the specimen in the center of the Stage (or Contact surface) in the Cabinet. Refer to [How to Set Up the Specimen Cabinet](#) on page 30.
2. Close the Cabinet door.
3. Make sure the procedure is Open (Active).
4. Make sure the Key Switch is in the unlocked position.
5. Make sure the system is in READY state.
6. Press the **X-RAY** button on the Cabinet control panel.
 - During the exposure, a message appears, a tone sounds, and the x-ray indicator on the control panel lights to indicate x-ray emission.
 - After the exposure ends, an image appears on the display and a thumbnail view appears on the left of the Procedure screen. The image is automatically accepted.
 - To acquire another image, wait for READY to show in the system message area, then press the **X-RAY** button.
 - To delete an image, select the thumbnail view then select the trash can icon.



Note You cannot restore a deleted image.

- To stop an exposure before automatic termination, press the **X-RAY** button. An error message appears.
- To start another exposure after you stopped one before automatic termination, select the **OK** button. Select the status icon in the taskbar at the bottom of the screen. Select the Clear All Faults option. When READY shows in the system message area, press the **X-RAY** button.

Refer to the [Clinical Procedures](#) on page 41 for additional information.

4.2.4 How to Add a Procedure

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

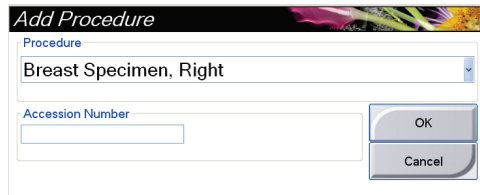


Figure 15: The Add Procedure Dialog Box

2. Use the drop-down menu to select the type of procedure to add.
3. Enter an Accession Number (optional).
4. Select the **OK** button. A new number displays in the Procedure Selection area of the Procedure screen.

4.2.5 How to Close a Procedure

Select the **Close Patient** button. The system returns to the Select Patient screen and automatically saves to the configured output devices any images that were not sent previously.

4.3 How to Access Image Review Features

Select the Tools tab on the Procedure screen to access the image review features. Refer to [The Tools Tab](#) on page 36 for information.

4.4 How to Use the Output Groups

The images are sent automatically to the output devices in the selected Output Group when a patient is closed.

4.4.1 How to Select an Output Group

Select an output device set like PACS, 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.

4.4.2 How to Add or Edit an Output Group



Note

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

To add a new Output Group:

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

To edit an Output Group:

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

4.5 How to Use the On-Demand Outputs

The On-Demand Outputs are: Archive, Print, or Export. You can manually Archive, Print, or Export an image until the procedure is closed.

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

4.5.1 How to Archive

1. Select the **Archive** button.
2. Select a storage device:
 - Select the **List Store Device** button and make your selection from the options that display.
 - OR, select the **List Output Group** button and make your selection from the options that display.
3. Select the **Send** button to copy all selected images from the opened case study to the selected device.



Note

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

4.5.2 How to Print

1. From the Procedure screen, select the **Print** button. The Print Screen displays. Refer to the [figure The Print Screen](#) on page 28 to prepare your print information.
2. Select the film format from the Options area of the page.
3. Select a thumbnail image.
4. Select the image display box on the right side of the screen to put the selected thumbnail image on the film.
5. To put other thumbnail images on the film, repeat steps 2 to 4.
6. To print a different film format of the same images, select the **New Film** button and repeat steps 1 to 4.
7. Select the **Print** button to print your films.

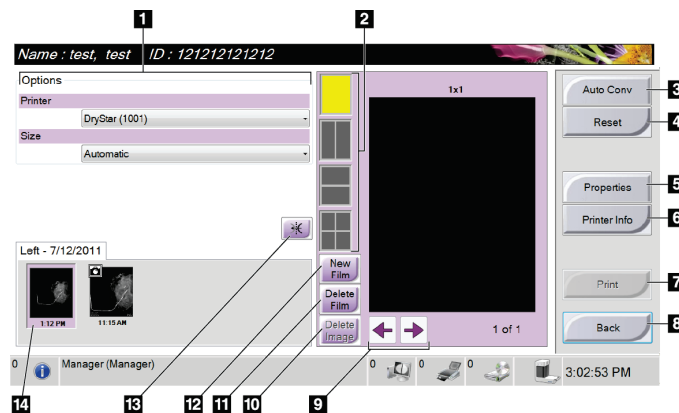


Figure 16: The Print Screen

Figure Legend

1. Select the printer options.
2. Select the film format (number of tiles).
3. Create (automatically) one film for each thumbnail image.
4. Return the screen to previous settings.
5. Open the Properties screen for selection of printer defaults.
6. Show the printer IP address, AE Title, Port and capability for True Size print.
7. Start the print process.
8. Return the screen to previous settings.
9. Step through the film pages.
10. Delete an image from the current film.
11. Delete the current film selection.
12. Create a new film.
13. Mirror the image.
14. Thumbnail image view

4.5.3 How to Export

1. Select the **Export** button.
2. Select a device (target) from a drop-down menu.
3. Select the **START** button to copy all images from the open procedure to the selected device.



Note

To make the patient-related information not known in the output image, select the Anonymized checkbox.

4.6 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 17: The Taskbar

Table 3: The Taskbar Menus

	Description	Menu
1	<p>Information Icon</p> <p>Select the Information icon to display a menu. This section of the taskbar flashes a yellow color if an alarm exists. Select Acknowledge All to remove the flashing indication. Select the Manage Alarms option to display and close any open alarms.</p>	<p>No Alarms</p> <p>Acknowledge All</p> <p>Manage Alarms ...</p>
2	<p>Current User Name</p> <p>Select the user name to display a menu. Admin displays the Admin screen. Log Out returns you to the Sign-in screen. My Settings displays the Edit Operator screen to review or edit Operator information, or change your password. Print prints the displayed patient list to a connected printer. Note that this popup menu is inactive in the Procedure screen.</p>	<p>Users Menu</p> <p>Admin ...</p> <p>Log Out ...</p> <p>My Settings ...</p> <p>Print ...</p>
3	<p>Output Device Icons</p> <p>Select an output icon (workstation/archive, printer, or CD-ROM) to display a menu. Each menu selection takes you to the screen for that selection. Manage Queues displays the status of jobs in the queue and job information for the selected output, and allows you to filter the queue display.</p>	<p>Queues Menu</p> <p>Manage Queues ...</p> <p><i>Output Group:None</i></p>
4	<p>System Status Icons</p> <p>Clear All Faults deletes all error messages. System Diagnostics accesses Subsystem settings. System Defaults opens the Defaults screen to set the default values. About displays information about the Workstation.</p>	<p>No Alarms</p> <p>Clear All Faults</p> <p>System Diagnostics ...</p> <p>System Defaults ...</p> <p>About ...</p>

4.7 How to Set Up the Specimen Cabinet

1. Open the Cabinet door.
2. Place the specimen.
 - For a contact image, put the specimen on the contact surface of the Cabinet.
 - For a magnification image, put the specimen on the 1.5X Stage or the 2.0X Stage in the Cabinet. See the [figure Cabinet Components](#) on page 11.
3. Close the Cabinet door.



Note

X-ray is enabled when the door is closed. If the door is opened during an exposure, the exposure ends automatically.

4. Turn the Key Switch from the locked position to the unlocked position.
5. Refer to [How to Acquire an Image](#) on page 25 for steps about image acquisition.



Note

If you press the X-RAY button to end an exposure, an error message appears. To start another exposure, select the OK button then select the status icon in the taskbar at the bottom of the screen. Select the Clear All Faults option. When READY shows in the system message area, press the X-RAY button.

4.8 How to Do the Gain Calibration

Do the Gain Calibration monthly and when artifacts are seen.



Note

When the system shows the Gain Calibration message, do the procedure before you shut down the system. If you do the Gain Calibration at a different time, access the procedure through the Admin screen. (From the User Name menu in the Taskbar, select Admin, then select the Gain Calibration button.)

1. Select **Yes** to do the calibration now. If you select **No**, the system shows the Startup screen.
2. If you select to do the calibration now, you are prompted to select the Gain Calibration mode (*Automatic, Automatic with Shutdown, or Manual*).
3. Select the Gain Calibration mode.
4. When the message to insert the Specimen Stage appears, slide a Specimen Stage into one of the Magnification slots (see [Shielded Cabinet Components](#) on page 11).
5. Make sure that there are no other items in the Cabinet, then close the Cabinet door.
6. Images are taken in the following manner:
 - *Automatic Gain Calibration:* The system takes six images and does the Gain Calibration automatically, then logs out the user.
 - *Automatic with Shutdown Gain Calibration:* The system takes six images and does the Gain Calibration automatically, then shuts down the system.
 - *Manual Gain Calibration:*
 - a. Press the **X-RAY** button.
 - b. Wait for the system to return to the Ready state, then press the **X-RAY** button.
 - c. Repeat step 2 until you acquire six images.
7. When the Gain Calibration is finished, a message about successful completion appears.

Chapter 5: The Images

5.1 Introduction

After you make an exposure, the acquired image displays and is accepted automatically. A thumbnail image appears in the left panel of the screen. Use the Image Tools (refer to [The Tools Tab](#) on page 36) to help with the review of the image and to add a comment.

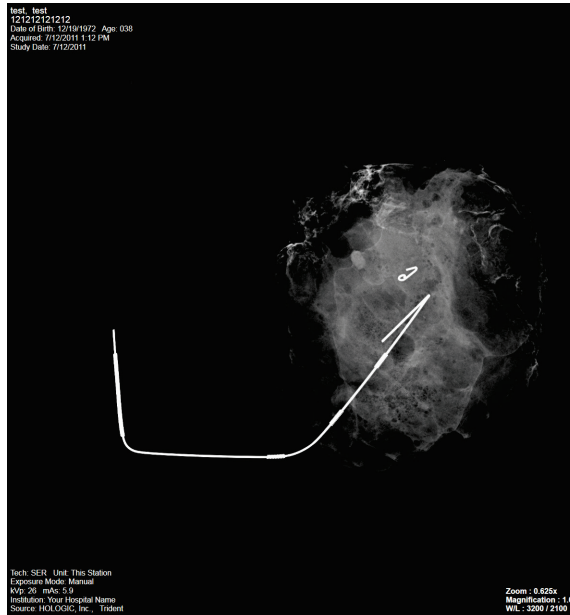


Figure 18: An Acquired Image

5.1.1 Information on the Left Side of the Image

Information about the patient and the exam displays to the left of the image. This information displays when the Patient Information tool is selected. Refer to [The Tools Tab](#) on page 36.

5.1.2 Information on the Right Side of the Image

- The Enhancement Level displays on the right side of the screen after the Enhanced Visualization tool is selected. The value changes with movement of the slider that appears on the Tools tab after the Enhanced Visualization tool is selected.
- The Zoom value changes when the Zoom tool is selected and the cursor is moved within the displayed image.
- The Magnification line indicates the magnification factor for the exposure.
- The W/L value changes when the Window/Level Fine Adjustment tool is selected and the cursor is moved within the displayed image.

This information displays when the Patient Information tool is selected. Refer to [The Tools Tab](#) on page 36.

5.2 How to Review the Images

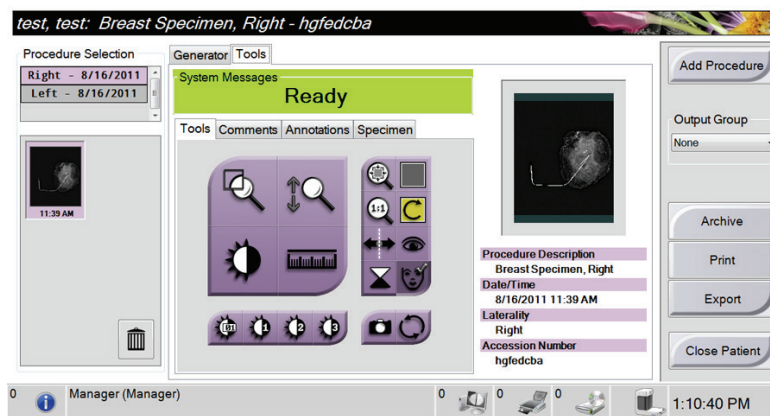


Figure 19: The Tools Tab in the Procedure Screen

1. Select a thumbnail image.
 - A preview image shows on the right side of the screen. When the review tools are used, this image shows the relationship between the area that is selected with the tool, and the whole image.
 - A larger image shows above the Procedure screen.
2. Use the image tools (refer to [The Tools Tab](#) on page 36) to enhance the whole image or areas of interest in the image.

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5.2.1 Image Review Tools

5.2.1.1 The Tools Tab

The Tools tab displays after an image is acquired. When you select the Tools tab, you have access to the image review tools. A checkmark appears on an active tool.

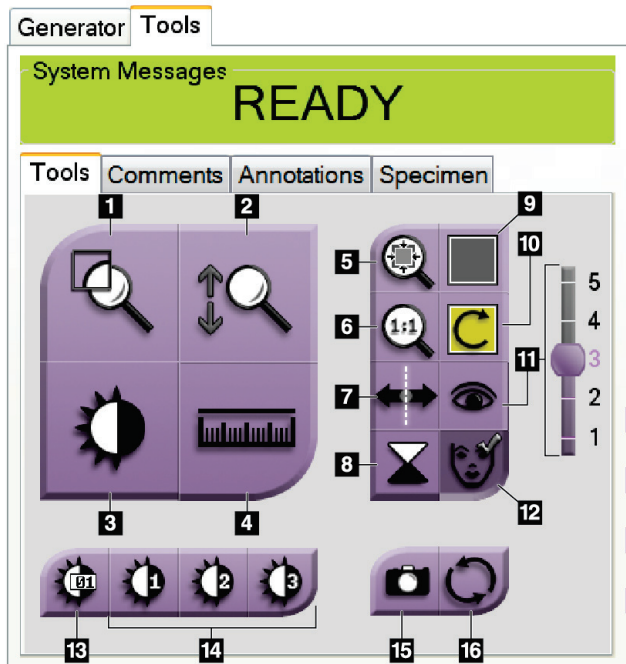


Figure 20: Image Review Tools

Figure Legend

1. The **Mag** tool magnifies a section of the image.
2. The **Zoom** tool magnifies the whole image.
3. The **Window/Level** tool is used with the mouse to change the brightness and contrast. To reset the Window/Level to the original values, double-click the image.
4. The **Ruler** tool displays a measurement of the distance between two points. To move the measurement line, click and drag the line to the new location.
5. The **Fit-to-Viewport** tool fits the image within the image tile.
6. The **View Actual Pixels** tool displays the image in full resolution.
7. The **Mirror** tool reverses (mirrors) the image.
8. The **Invert** tool changes blacks to white and whites to black.
9. The **Multi-Up Display** tool selects the number of tiles to display.
10. The **Image Tile Advance** tool sets the active Multi-Up tile.
11. The **Enhanced Visualization** tool adjusts the image sharpness with a slider.
12. The **Patient Information** tool activates the patient information display.
13. The **Window/Level Fine Adjustment** tool allows the entry of specified values for contrast and brightness, also allows a reset to the original default Window/Level values.
14. The **Pre-defined Window/Level** tools set the values most used.
15. The **Camera** button captures a snapshot of the image display area and adds the snapshot to the current procedure.
16. The **Reset** tool returns an enhanced image to the original state and keeps on-screen drawings and annotations. Your Service Engineer can set this tool to return to the original state without drawings or annotations.



Note

The Ruler, W/L Presets, and Enhanced Visualization tool are inactive for snapshot images.

5.2.1.2 The Comments Tab

This feature allows you to make notes or comments about image content.

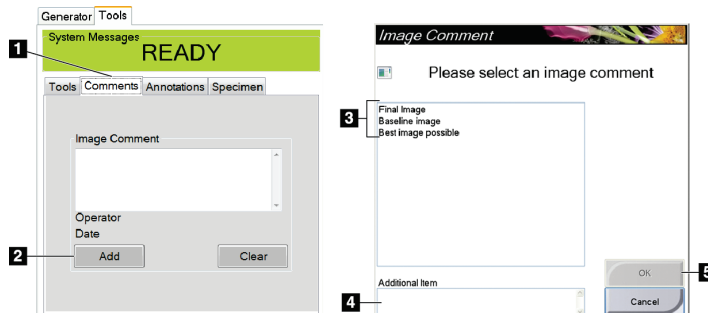


Figure 21: The Comments Tab

Figure Legend

1. Select the **Comments** tab.
2. Select the **Add** button.
3. In the Image Comments dialog box, select an option from the image list.
4. Use the keyboard to add comments in the Additional Item area of the screen.
5. Select the **OK** button.

To remove a comment, select the **Clear** button.

5.2.1.3 The Annotations Tab

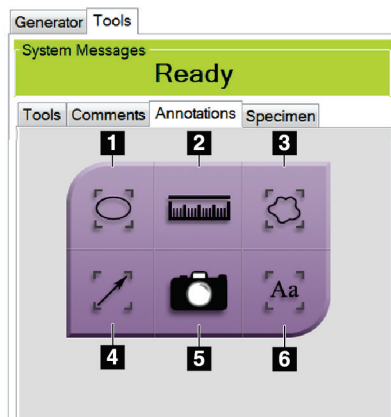


Figure 22: Annotations Tab

Figure Legend

1. Draws an elliptical pattern in the image. You can change the size and move this pattern within the display area, and you can add the text to this pattern.
 2. The **Ruler** tool displays a measurement of the distance between two points. To move the measurement line, click and drag the line to the new location.
 3. Draws a free-form in the image. You can move this pattern within the display area, and you can add the text to this pattern.
 4. Creates an arrow to point to an area of interest. You can change the size, move the arrow within the display area, and add the text to this pattern.
 5. The **Camera** button captures a snapshot of the image display area and adds the snapshot to the current procedure.
 6. Creates a text box. Click in the box, then use the keyboard to add the text. You can move this text within the display area.
- To move a pattern that you created in the display, click and hold the line of the pattern then move to the new location.
 - To change the size a pattern that you created in the display, click and hold an end dot of the pattern then drag.
 - To add text to the text box of a pattern, click in the box then use the keyboard to add text. Wherever you can move this box within the display area, the text stays connected to that pattern.

5.2.1.4 The Specimen Tab

The Specimen Tab shows if the Service Engineer changes the tab default value from Off to On. This tab allows you to enter information about the specimen.

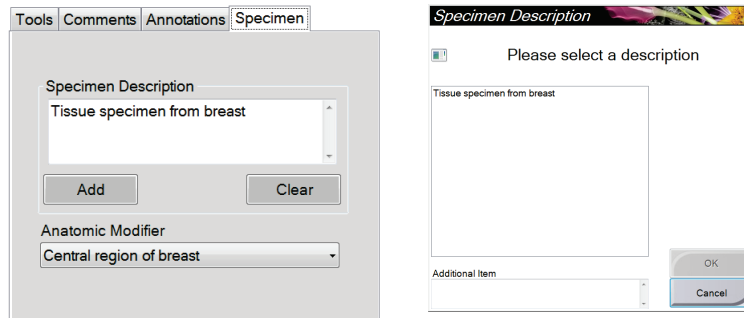


Figure 23: The Specimen Tab

1. Select the **Add** button on the Specimen tab.
2. When the Specimen Description screen displays, select a description from the list or type in a description in the Additional Item area.
3. Select the **OK** button.
4. To add an Anatomic Modifier, select from the drop-down list.
5. To remove a description from the Specimen tab, select the **Clear** button.

5.3 Send the Images to the Output Devices

You can send the images to output devices or use the Export function to copy images to a temporary storage device. Refer to [How to Use the Output Groups](#) on page 26 for instructions.

Chapter 6: Clinical Procedures

6.1 System Startup

Refer to [How to Start the System](#) on page 15 for complete information on the following steps.

1. Lock the cart casters and then connect the system to power and the network.
2. Press the computer power button.
3. Select the **Log In** button in the Startup screen.
4. Select your user name, enter your password, then select the **Log in** button

6.2 Image Acquisition

Refer to [The Select Patient Screen](#) on page 19 for information on the screen components.

1. Select a patient from the worklist in the Select Patient screen, or manually add a new patient (refer to [How to Add a New Patient](#) on page 20).
2. In the Procedure screen, set the exposure techniques and select the output devices.

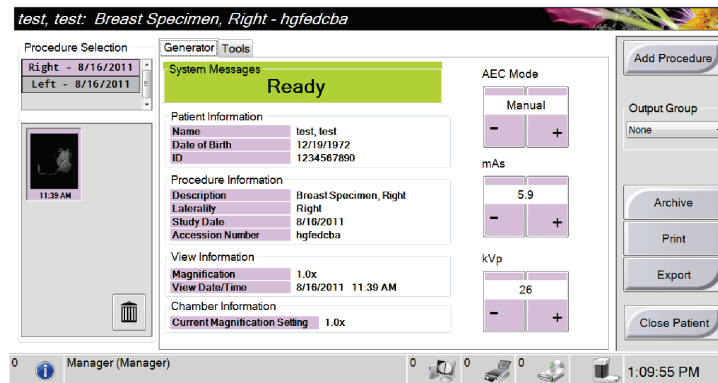


Figure 24: Procedure Example

3. Position the specimen in the Cabinet for contact or magnification imaging.
4. Close the Cabinet door and turn the Key Switch to the unlocked position.
5. Confirm that all exposure factors are set correctly.
6. Press the **X-RAY** button. The acquired image displays then saves automatically.
7. To delete an image, select the thumbnail then select the trash can icon.
8. Review the image and make necessary enhancements. Refer to [How to Review the Images](#) on page 34.
9. To acquire additional images of the same specimen, press the **X-RAY** button for each new image.

6.3 System Shutdown

1. When you finish the image acquisition process, remove the specimen then select the **Close Patient** button.
2. Select the **Log Out** button, then select the **Shutdown** button. A prompt displays the option to continue with the system shutdown.
3. Select the **Yes** button to shutdown the system.
4. Perform the recommended cleaning procedures. Refer to [Maintenance, Cleaning, and Disinfecting](#) on page 47.

Chapter 7: System Administration Interface

7.1 How to Use the Admin Screen

This section tells about the functions available in the Admin screen. To access this screen:

1. Log in to the system.
2. Select the User Name area of the taskbar at the bottom of the screen.
3. Select Admin from the pop-up menu to show the Admin screen. See the following figure.



Note

A Manager and a Hologic Service User have access to all functions on the Admin screen. A Primary Specimen User has access to some functions.

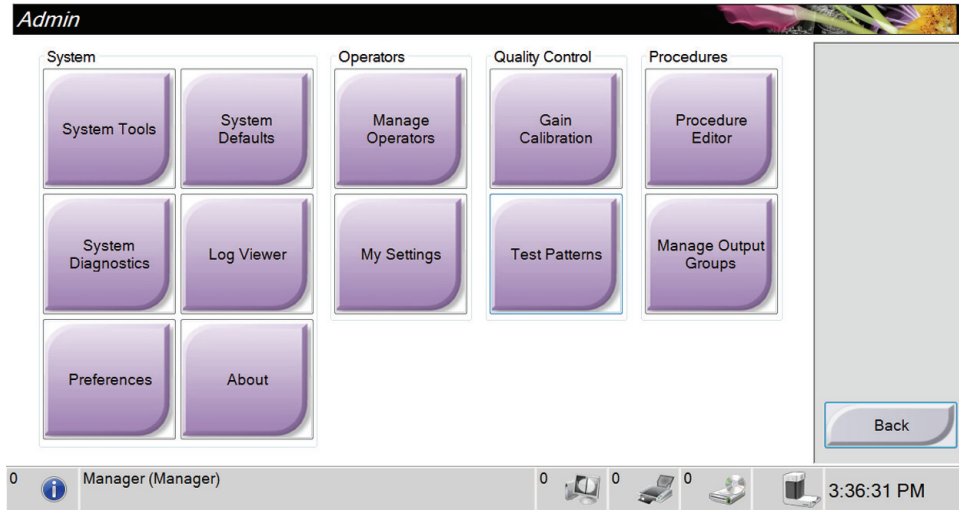


Figure 25: The Admin Screen

Table 4: Admin Screen Functions

Section	Screen Function	
System	System Tools	The Interface for Service for the configuration of and identification of problems.
	System Defaults:	Set the default values.
	System Diagnostics:	Shows the status of all subsystems.
	Log Viewer:	Review the system log files.
	Preferences:	Set the system preferences.
	About:	Tells about the system.
Operators	Manage Operators:	Add, delete or change Operator information.
	My Settings:	Change the information for the current Operator.
Quality Control	Gain Calibration:	Select the Gain Calibration procedure.
	Test Patterns:	Select and send the test patterns to output devices.
Procedures	Procedure Editor:	Add, edit, or delete the procedures.
	Manage Output Groups:	Add, delete, or edit output groups.
You must have permissions to access all features. The permission level controls the functions you can change.		

7.2 How to Use the System Tools

The Managers (and Hologic Service) can access the System Tools function. This function contains the configuration information about the system.

To access the System Tools function:

1. Log on as the Manager or Hologic Service.
2. Select the User Name area of the taskbar at the bottom of the screen.
3. Select the Admin option.
4. From the System area of the Admin screen, select the System Tools button.

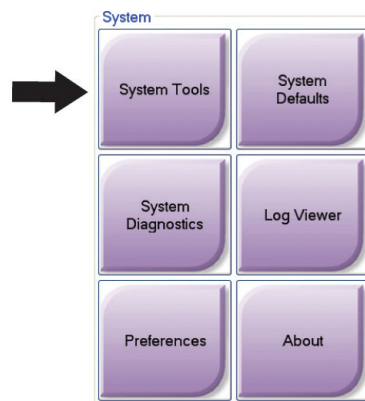


Figure 26: The System Tools Button

7.2.1 The System Tools Screen

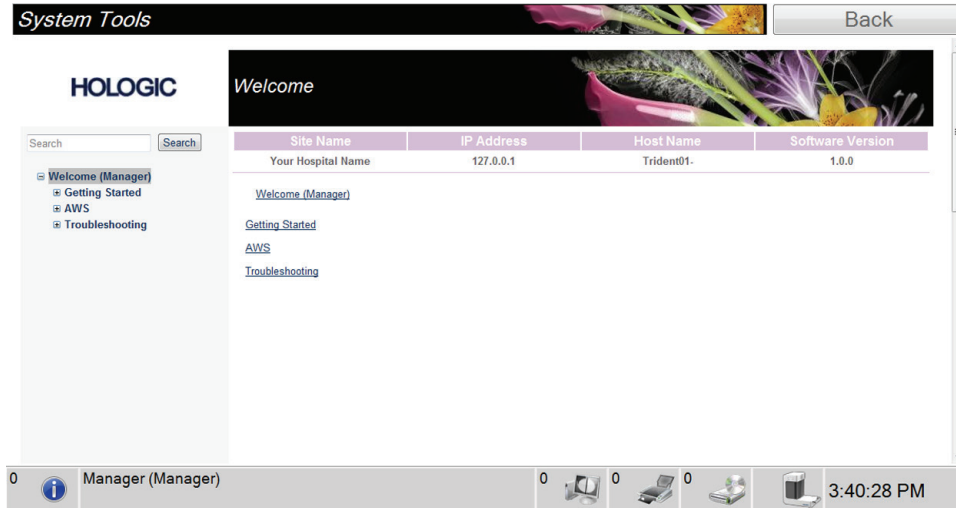


Figure 27: The System Tools Screen

Table 5: The System Tools

Section	Description	
Getting Started	About:	The introduction to the service tool.
	FAQ:	List of common questions.
	Glossary:	List of terms and descriptions.
	Platform:	List of directories, software version numbers, and system software statistics.
	Shortcuts:	List of Windows® shortcuts.
AWS	Connectivity:	List of Installed Devices.
	User Interface:	Change the options in the Software application.
	Internationalization:	Select the local language and culture.
Troubleshooting	AWS:	Allows for download of images.
	Computer:	Reboot or Shutdown; Current IP address; Change Host name.
	Log:	Change the event record options.
	Backups:	Control the backups for the system.

Chapter 8: Maintenance, Cleaning, and Disinfecting

8.1 General Information

8.1.1 For General Cleaning

This procedure includes cleaning the unit and the surfaces that the specimens do not contact.

Use a lint-free cloth and apply a diluted dishwashing liquid to clean components and surfaces.



Caution:

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

8.1.2 For Disinfecting

To disinfect the system's components and surfaces, Hologic recommends the following disinfecting solutions:

- 10% chlorine bleach and water with one part commercially available chlorine bleach (normally 5.25% chlorine and 94.75% water) and nine parts water. Mix this solution daily for best results.
- 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 clean cloth to clean the system, observing appropriate contact (wet) times.



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.

8.2 Workstation

8.2.1 How to Clean the Display

- Do not touch the display when working with specimens.
- Use care when you clean the outer surface of the display area.
- Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths, available at most stores, are recommended.
- Strong chemicals and abrasives can damage the display and should never be used.
- Never use a spray or flow a liquid onto the display.
- Never apply pressure to the display area.
- Never use a detergent with fluorides, ammonia, alcohol, or abrasives.
- Never use bleach.
- Never use steel wool.
- Never use a sponge with abrasives.

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

8.2.2 How to Remove the Keyboard Cover (if Equipped)

**Note**

Remove the keyboard cover from the keyboard before cleaning the cover.

1. Grasp the outer frame of the cover by one corner and lift the frame and cover sheath off in *one* piece (see the following figure). Do not remove the silicone sheath from its frame unless you are replacing the sheath itself.
2. When replacing the cover, locate and align the notch on the upper right corner of the cover frame to the upper right corner of the keyboard where the keyboard cable is attached (see the following figure). Press cover firmly back onto keyboard.



Figure 28: Removing/Replacing Keyboard Cover

8.2.3 How to Clean Keyboard Cover (if Equipped)



Note

Remove the keyboard cover from the keyboard before cleaning the cover.

1. Remove the cover from the keyboard (see [How to Remove the Keyboard Cover \(if Equipped\)](#) on page 48).
2. Clean the silicone cover using these cleaning/disinfectant materials:
 - Alcohol-based cleaning products
 - Chlorine bleach disinfectant wipes products
 - 10% bleach solution
 - 10% hydrogen peroxide
 - Disinfectant wipes
 - Soap and water



Note

Do NOT use the following fluids or actions to clean the cover:

- petroleum-based cleaning fluids such as gasoline (petrol), turpentine, or oil
- acetone
- cleaning fluid with over 10% bleach
- temperature sterilization
- abrasive scrubbing pads

8.2.4 How to Clean the Keyboard

Clean the key surfaces with a clean cloth. If material falls between the keys, clean the keyboard with a vacuum. If liquids enter the keyboard, or fluids are spilled onto the keyboard, call the Hologic Technical Support for guidance or replacement.

If the keyboard comes in contact with body fluids, the keyboard will require disinfecting. Use a commercially available product or alcohol for this purpose. Do not use bleach or hydrogen peroxide on the keyboard itself.

8.3 Preventive Maintenance Schedule



Note

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

Table 6: User Preventive Maintenance

Action	Recommended Frequency			
	Each Use	Each Week	Each Month	As Required
Clean and disinfect specimen tray	x			
Clean and disinfect contact surface	x			
Perform Gain Calibration			x	
Clean and disinfect chamber				x
Clean and disinfect x-ray control panel				x
Clean and disinfect chamber door handle				x

Appendix A: System Specifications

A.1 Shielded Cabinet, Workstation, and Cart

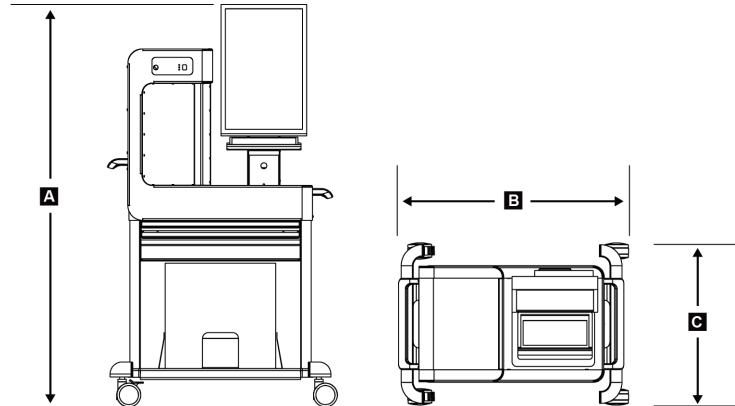


Figure 29: System Dimensions

A.	Height	170.2 cm (67.0 inches nominal)
B.	Width	95.3 cm (37.5 inches)
C.	Depth	67.3 cm (26.5 inches)
	Weight	124.9 kg (275 pounds without the UPS)

A.2 Operation and Storage Environment

A.2.1 General Conditions for Operation

This equipment is designed for safe and effective operation under the following conditions for Indoor Use:

Altitude	To 2,000 m
Degree of Pollution	Pollution Degree 2
Temperature Range	10 °C to 30 °C
Relative Humidity Range	20% to 80% Without condensing moisture

A.2.2 Storage Environment

Temperature Range	10 °C to 30 °C indefinitely 10 °C to 35°C for a maximum of 12 hours
Maximum rate of temperature change	Less than 10 °C per hour
Relative Humidity Range	20% to 80% Without condensing moisture
a-Se X-Ray Detector	Put in a package for storage in a building

A.3 Workstation Technical Information

A.3.1 General Information

<i>Operating System</i>	<i>Windows 7</i>
<i>Hard Disk Drive Capacity</i>	<i>500 GB minimum</i>
<i>Storage Device Disks</i>	<i>DVD+/-RW</i>
<i>Display</i>	<i>1920 x 1200 pixel resolution</i>

A.3.2 Network Environment

<i>Network Interface</i>	<i>Integrated Gigabit Ethernet controller</i>
<i>Cable Connection</i>	<i>RJ45</i>
<i>Cable Category</i>	<i>5e (minimum)</i>
<i>Cable Length</i>	<i>3 meters (maximum)</i>

A.4 Electrical Input

The system is designed for temporary overvoltages on the Mains supply.

<i>Line Voltage Range</i>	<i>100-240 VAC ±10%</i>
<i>Mains supply voltage fluctuations</i>	<i>To 10% of the nominal voltage</i>
<i>Transient overvoltages</i>	<i>To the levels of Overvoltage Category II</i>
<i>Operating Frequency</i>	<i>50/60 Hz ±2%</i>
<i>Peak Line Current</i>	<i>4 amps</i>
<i>Power Consumption</i>	<i>450 watts maximum</i>
<i>Line Connection</i>	<i>Standard line cord and plug - medical grade</i>
<i>UPS Operation</i>	<i>The (optional) UPS provides full power to the system for 30 minutes from a full charge (limited to four exposures within the 30 minutes)</i>
<i>Duty Cycle</i>	<i>10 seconds on, 20 seconds off</i>

A.5 X-ray Tube Technical Information

<i>Source-to-Image Distance (SID)</i>	<i>49 cm nominal</i>
<i>Focal Spot</i>	<i>50 micron nominal</i>
<i>Tube Voltage</i>	<i>20 kV to 35 kV</i>
<i>Anode Material</i>	<i>Tungsten</i>
<i>X-Ray Window</i>	<i>Beryllium 125 µm</i>

A.5.1 X-Ray Generator

<i>kV Range</i>	<i>20 kV to 35 kV</i>
<i>mA</i>	<i>1 mA</i>
<i>mAs</i>	<i>10 mAs maximum</i>

A.6 Imaging System Technical Information

A.6.1 Image Receptor

<i>Fluid Ingress</i>	<i>The Image Receptor is protected from accidental spillage on the Cabinet floor.</i>
<i>Active Imaging Area</i>	<i>12 cm by 14 cm nominal</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>Image Pixel Size</i>	<i>70 μm</i>
<i>Digital Image Receptor MTF</i>	<i>> 40% at Nyquist frequency</i>

Appendix B: System Messages and Alerts

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 correct the condition, then clear the status from the Taskbar. Some conditions require a system restart or indicate that more action is necessary (for example to call Hologic Technical Support.) This chapter describes the message categories and your actions to return the system to normal operation. If errors repeat, contact Hologic Technical Support.

B.2 Types of Messages and Alert Messages

B.2.1 Fault Levels

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

B.2.1.1 Warning Faults

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

Warning fault designs:

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

B.2.1.2 Minor Faults

Minor fault designs:

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

B.2.1.3 Major Faults

Major fault designs:

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

B.2.1.4 Critical Faults

Critical fault designs:

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

B.2.1.5 Alert Messages

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

B.2.2 System Messages

Select the system status icon on the Taskbar to get information about the cause and correction of a system problem. When you correct the problem, the System Message area displays a Ready status.

B.3 Troubleshooting

- To restart the System after a critical fault, select the **Start** button that displays on the desktop.
- If you select the Exit button, a message advises you that this option shuts down the computer.

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