

Faxitron[®] CT

Specimen Radiography System



User Guide

MAN-10405 Revision 001

HOLOGIC[®]

Faxitron[®] CT

Specimen Radiography System

User Guide

For Software Version 1.2.4

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www.hologic.com/package-inserts

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Chapter 1 Introduction

Read all this information carefully before operating the system. Follow all warnings and precautions as stated in this manual. Keep this manual available during procedures. Physicians should tell patients about all potential risks and adverse events described in this manual with respect to the operation of the 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.

1.1 Intended Use

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

The Faxitron® CT is a Cabinet x-ray system that is used to provide two and three-dimensional digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

Doing the verification directly in the same room or nearby enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

1.2 System Capabilities

The Faxitron CT system acquires and displays 2D and 3D radiographic images of surgical 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.

1.3 User Profiles

- The Faxitron CT system does not utilize multiple User Profiles. There is a single log-in to the system software.
- Service personnel have full access to all system functions.

1.4 Quality Control Requirements

Perform all Quality Control tests within the correct time frame.

1.5 Where to Find the Installation Instructions

Installation instructions are available in the *Service Manual*.

1.6 Where to Find Technical Description Information

Technical description information is available in the *Service Manual*.

1.7 Warranty Statement

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation (“Warranty Period”); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer’s warranties shall extend to Hologic’s customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer’s refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or “as-is” basis.

1.8 Technical Support

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

1.9 Product Complaints

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic.















1.10 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 at www.Hologic.com.

1.11 Symbols

This section describes the Symbols on this system.

Symbol	Description
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Manufacturer
	Date of Manufacture
 or 	Caution—Radiation (X-Rays Produced)
	Caution - Potentially infectious materials
	Warning Electricity
	Caution
 or 	Follow or consult instructions for use
	This system transmits radio frequency (RF) energy (non-ionizing radiation)
	Medical Device
	Catalog number
	Serial number

1.12 Descriptions of Warnings, Cautions, and Notes

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



WARNING!

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



Warning:

The procedures that you must follow accurately to prevent injury.



Warning:

Warns the reader that ionized radiation is emitted into the labeled area when the x-ray beam is energized. The Faxitron CT system has safety interlocks to prevent the labeled area from being accessed while the x-ray beam is energized.



Warning:

Warns the reader to use appropriate protection, such as gloves or an approved specimen container, to avoid exposure to potentially infectious materials such as patient tissue samples.



Caution:

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



Note

Notes show additional information.

Chapter 2 General Information

2.1 System Overview



Figure 1: Faxitron CT System

Figure Legend

1. Control Panel/Touchscreen
2. X-ray Imaging Chamber
3. Image Display Monitor
4. Keyboard & Trackball

The Faxitron CT system reconstructs excised specimens in real-time. CT is designed to help achieve better surgical outcomes and improve intraoperative specimen margin assessment by providing a full 3D reconstruction of the specimen with 0.1mm slices in the X, Y, and Z-Axes.

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 responsibility for injury or damage from incorrect system operation. Hologic can arrange 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.

2.2.1 Radiation Safety and Emissions Limits

- Radiation shielded cabinet.
- X-Ray chamber door equipped with dual safety interlocks. *See Sections 2.2.2 and 2.4 of this Manual.*
- Radiation: Less than 0.1 mR/hr at any point 5 cm (2 in.) from exterior surface at maximum kV. For countries requiring emission values measured at 10 cm from external surfaces, the radiation does not exceed 1.0 μ S/hr at 10 cm.
- Certified to comply with standards set by the US Food and Drug Administration, Center for Devices and Radiological Health, (21 CFR 1020.40).

2.2.2 Interlocks

The Faxitron CT system has two independent safety interlocks on the chamber door. Opening the door will immediately terminate x-ray generation.

2.3 Warnings and Precautions



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 Faxitron CT system a minimum of 1.5 meters (5 feet) from the patient.



WARNING!

No modification of this equipment is allowed.



WARNING!

Do not attempt to use any console that could present a shock hazard. Immediately contact Hologic or your distributor.



WARNING!

To prevent shock hazard, do not use the system unless the blades of the polarized plug can be fully inserted in the electrical outlet.



WARNING!

Before each use, check that the power cord is in good condition and is fully inserted in the electrical outlet.



WARNING!

Make sure that the power cord for the system console is in good condition. A damaged power cord can be an electrical shock hazard. When disconnecting the console from power, always grasp the plug at the insertion point and pull lightly. NEVER pull on the cord to unplug the unit.



WARNING!

Before moving the console, make sure that the power cord and any cables are unplugged and wrapped securely around the cord management plate.



WARNING!

Before adjusting the position of the console, make sure the power cord and any cables are safely positioned out of the way.



WARNING!

To prevent fire or shock hazard, do not expose the system to rain or moisture.



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:

Do not use the system if the glass is cracked or damaged.



Warning:

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



Warning:

Cables and cords can pose a tripping hazard. Position cords safely out of the way. When not in use, wind cords securely around the cord management plate.



Warning:

Before moving the console, make sure the caster locks are unlocked. Trying to move the system with the casters locked can cause the console to tip over.



Warning:

Before moving the system, rotate the Image Display monitor to a position that provides clear visibility while pushing the console.



Warning:

Do not move the console with excessive force or speed. Do not make quick stops.



Warning:

When moving the console, be aware of bumps, ramps, inclines, or declines. Use extra caution when moving the console on an uneven or sloped surface.



Warning:

Make sure there is adequate space to completely open the Imaging Cabinet door and to safely insert or remove the specimen tray.



Warning:

Keep the Imaging Cabinet door closed when not in use. Leaving the door open can pose a tripping hazard.



Warning:

Use the Imaging Cabinet door handle to open and close the door. Closing the Imaging Cabinet door incorrectly can cause a pinch hazard.



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

To prevent damage to the console and its components, use only the recommended cleaning methods.



Caution

Do not spill or put fluids or liquids on the touch screen or the touch pad. Fluids or liquids on the touch screen and the touch pad can cause a malfunction. Make sure that the touch screen and touch pad are clean and dry before using the system.



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.



Caution

To prevent possible damage to the system, follow the recommended procedure to turn off the equipment.



Caution

The system must be installed and put into service according to the guidance provided in these instructions to ensure its electromagnetic compatibility.



Caution

Portable and mobile RF communications can affect medical electrical equipment.



Caution

To prevent low image quality, perform system calibrations when prompted.



Caution

To prevent low image quality, make sure to remove all patient material from the Imaging Cabinet and specimen tray. Use the recommended cleaning methods to clean and disinfect the Imaging Cabinet and specimen tray.



Caution

To prevent damage, use care when handling and cleaning the specimen tray.



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 console, make sure the cables are stored in a safe position on the console.
 - Before you move the console, rotate the Image Display screen to allow for an unobstructed view.
 - Do not make quick stops. Do not move with excessive force or speed.
-

2.4 Interlock Operation

X-ray generation stops automatically whenever the Interlock system is interrupted. The Interlock system may be interrupted due to user action, i.e., opening the chamber door, or a fault in the system, such as a failed switch or a fault in the Interlock system wiring. An error message may be generated and displayed on the monitor, depending on the cause of the interruption.

System messages will be displayed when the chamber door is opened during an x-ray exposure. The messages will vary depending on whether the system is in 2D or 3D (CT) imaging mode.

- In 2D imaging mode “Motion Error” and “Radiography Scan Canceled” error messages will be displayed. The error messages will be superimposed one over the other. To clear the error messages, click the **Okay** button on the top message and then the remaining message. *See figures below.*
- In 3D imaging mode “Motion Error” and “CT Scan Canceled” error messages will be displayed. The error messages will be superimposed one over the other. To clear the error messages, click the **Okay** button on the top message and then the remaining message. When a CT scan is canceled for any reason, i.e., door is opened, **Stop** button is pressed, or loss of detector communication, the system will remain in STANDBY for about 1 minute before it is ready for another scan. *See figures below.*

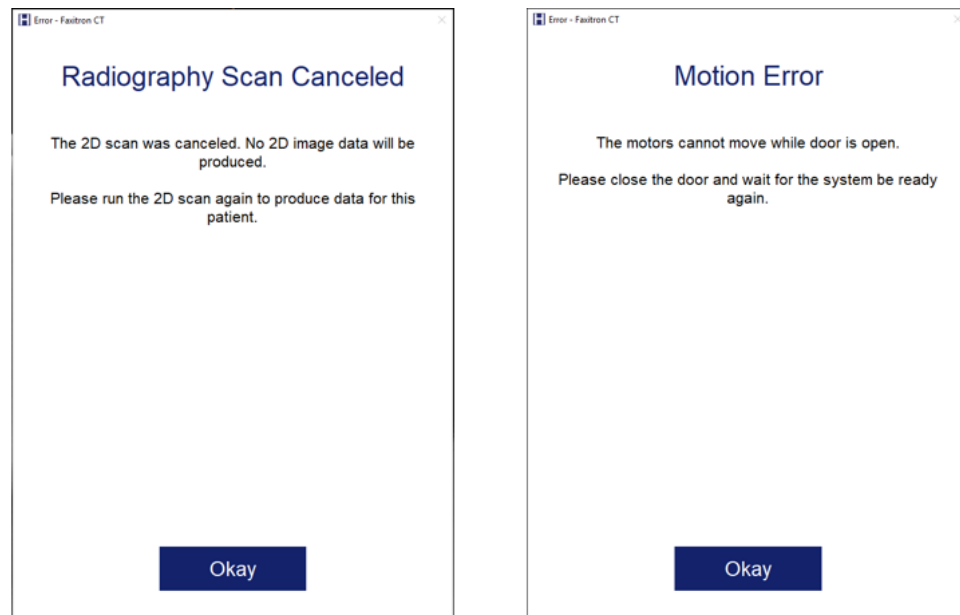


Figure 2: “Motion Error” and “Radiography Scan Cancelled” Error Messages

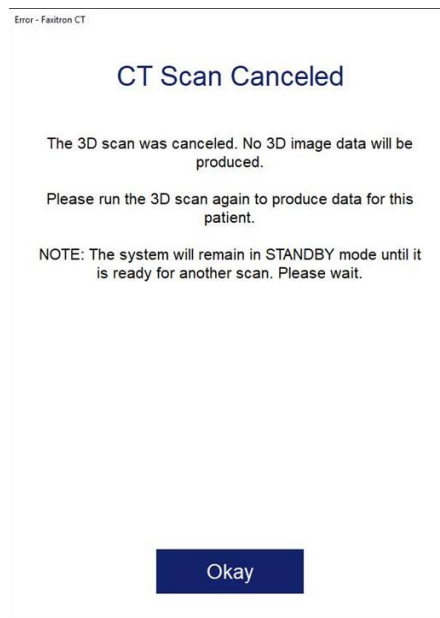


Figure 3: "CT Scan Cancelled" Error Message

The system will revert to "Standby" whenever the door is opened during x-ray generation.

1. Click the **Okay** button in each error message,
2. Close and/or verify the chamber door is fully closed,
3. The system should now be "Ready" for x-ray acquisition.
4. Repeat acquisition.



Note

Contact Hologic if error message is persistent.

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 instructions for use.
- The assembly operations, extensions, adjustments, changes, or repairs are performed only by authorized persons.
- The network and communication equipment must be installed to meet IEC Standards.



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:

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer sufficient protection to radio frequency communication services. The user may need to take mitigation measures, such as relocating or re-orienting the equipment.



Caution:

The Medical Electrical (ME) Equipment or ME System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, make sure that the ME Equipment or ME System operates correctly in this configuration.



Caution:

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:

IEC, EN:

- IEC 61010-1: 2010, 3rd Edition - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
- IEC 61010-2-091:2012, 1st Edition – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems
- IEC 61010-2-101:2015, 2nd Edition - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for IVD medical equipment
- EN 61326-1:2013 - Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements – Part 1: General Requirements
- EN 61326-2-6:2013 - Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 2-6: Particular requirements – IVD medical equipment

- EN 55011 and CISPR 11 (Class A) - Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement
- EN ISO 14971 – Medical Devices – Application of risk management to medical devices
- EN ISO 13485 Medical Devices – Quality management systems – requirements for regulatory purposes
- EN ISO 18113-1 In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) Part 1: Terms, definitions, and general requirements
- EN ISO 18113-3 In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) Part 3: In vitro instruments for professional use
- EN ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

CFR:

- 21 CFR § 1020.40 - Cabinet X-ray Systems
- 47 CFR Part 15.5 - General Conditions of Operation

CAN/CSA:

- CAN/CSA-C22.2 No. 61010-1, 3rd Edition - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements

2.6 DICOM Standard

Faxitron CT uses the latest DICOM Standard:

- NEMA PS3 / ISO 12052, Digital Imaging and Communications in Medicine (DICOM) Standard, National Electrical Manufacturers Association, Rosslyn, VA, USA (available free at <http://www.dicomstandard.org/>)
- See Faxitron CT DICOM Conformance Statement for more information.

2.7 Interoperable Connections

The Faxitron CT is capable of operating as a standalone device without any input or output to other devices. Images can be captured, stored, and reviewed directly on the system.

However, the system does come with several interfaces. The primary one is the network connection which allows the system to be connected to a Picture Archiving and Communications System (PACS). Images can then be transmitted from the device directly to the facilities network via our software in a DICOM format. See Section 6 for details on DICOM functionality.

**Caution:**

Only Hologic employees or trained IT personnel at the user facility should set up this communication.

The system's connections and their intended use are listed below. No other type of devices should be connected to the Faxitron CT without approval from Hologic.

Connection	Purpose	Device Type	Intended User
Ethernet port at rear	To store radiographic images to networked data storage.	PACS or Network Storage	Set up by Hologic or facility IT personnel. Used by clinicians.
Ethernet port at rear	To allow remote connection by the Hologic service team, so Hologic can diagnose and repair the system.	Network internet connection	Hologic or facility IT personnel at the direction of Hologic only.
USB port on the front	To transfer images from device. This should only be used if PACS or network is not available.	USB storage device (Flash Drive)	Clinicians or IT personnel with approved access to the system.
USB port on the front	To service and maintain the system. For example, files copied to and from the computer for software updates or to export log files.	USB storage device (Flash Drive)	Hologic or facility IT personnel.

2.8 Network / User Settings

The detector on the Faxitron CT uses an ethernet (network) connection to communicate. Adding users or setting additional network security can prevent the detector from communicating to the software.



Caution:

Set up additional users with local administration rights to ensure the software runs correctly. Work with the Hologic team during installation to make sure the system is configured properly.

2.9 Label Locations

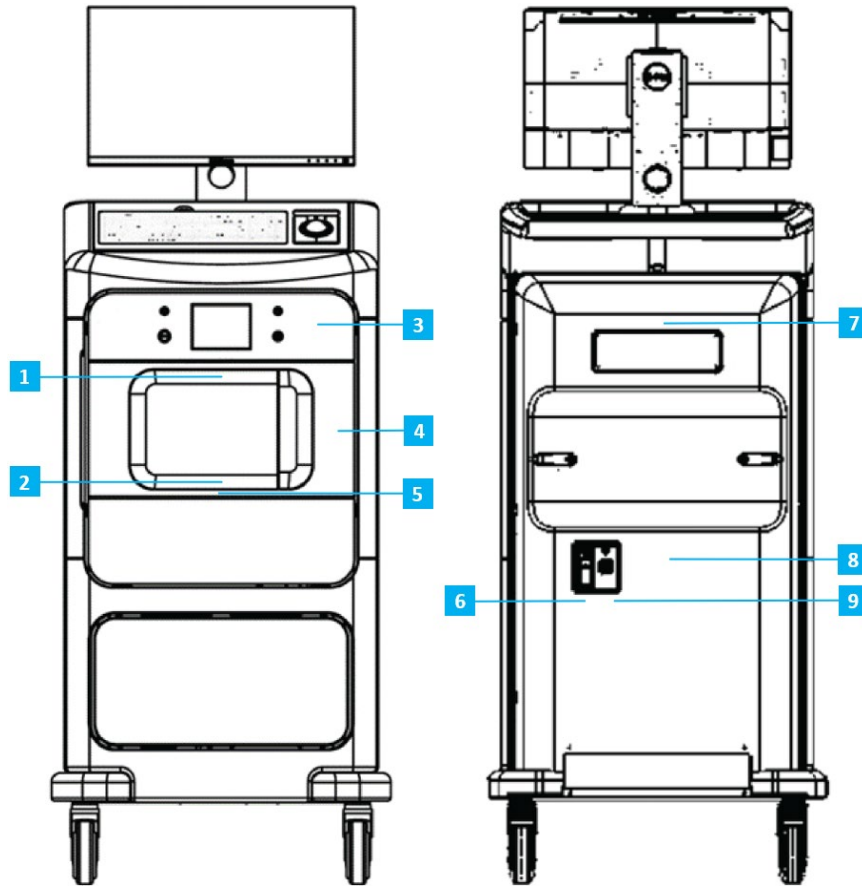


Figure 4: Label Locations

Figure Legend

NOTE 1: Unless specified all labels are from P/N 7120-6300, PathVision Label Set.

NOTE 2: Labels A2 and D2 installed on systems for Canada. Labels A1 and D1 for all others.

1. CAUTION – This device produces X-rays when energized – Keep door closed, Label D1 or D2 (Inside Door)
2. CAUTION – Lead Glass Warning, Label F (Inside Door)
3. CAUTION – X-Rays Produced When Energized, Label A1 or A2
4. WARNING, SAFETY INTERLOCK – Do Not Tamper with Interlock, Label F
5. CAUTION, Specimens are potentially infectious, Label C (Front of chamber floor)
6. INPUT VOLTAGE and FUSE Rating, P/N 05-0260-04 Label E
7. CAUTION – No operator serviceable parts inside, Label O
8. ID./Nameplate Label, P/N LBL-09946
9. CAUTION – Fuse Replacement and WARNING – Hazardous Voltage Inside, P/N 05-0260-04 Label C

Chapter 3 Components, Controls, and Indicators

3.1 System Components

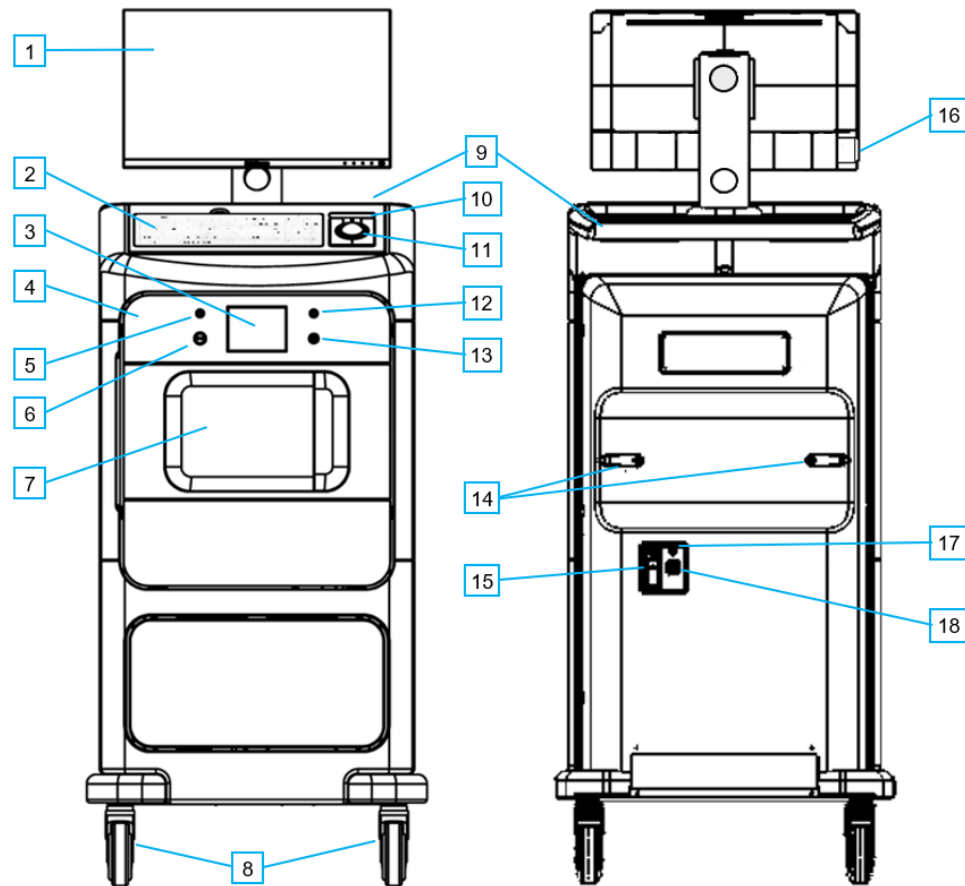


Figure 5: System Components

Figure Legend

- | | |
|--------------------------|---|
| 1. Image Display Monitor | 11. Trackball |
| 2. Keyboard | 12. Power ON Light |
| 3. Touch Screen | 13. Power On/Off Button |
| 4. Control Panel | 14. Cord Management Hooks |
| 5. X-Ray ON Light | 15. System Power Switch and Power Cord Connection |
| 6. Stop Button | 16. 2X USB Ports |
| 7. X-Ray/Imaging Chamber | 17. Computer Reset Button |
| 8. Caster | 18. Ethernet Port |
| 9. Console Handle | |
| 10. USB Port | |

3.1.1 X-Ray/Imaging Chamber Components

The console houses a shielded imaging cabinet. The placement of the specimen tray determines the magnification level of the image.

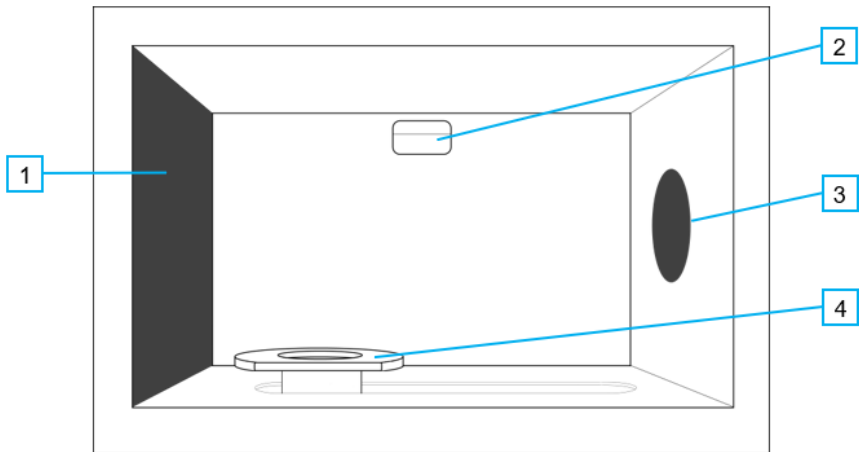


Figure 6: X-Ray/Imaging Chamber

Figure Legend

- 1. Carbon Fiber Detector Cover
- 2. Chamber Light
- 3. Carbon Fiber X-Ray Tube Cover
- 4. Specimen Pedestal

Compartment Interior Dimensions (Approximate)

	cm	Inches
Height	19	8
Width	30	12
Depth	19	8

3.2 System Connections

Power and Network Connections

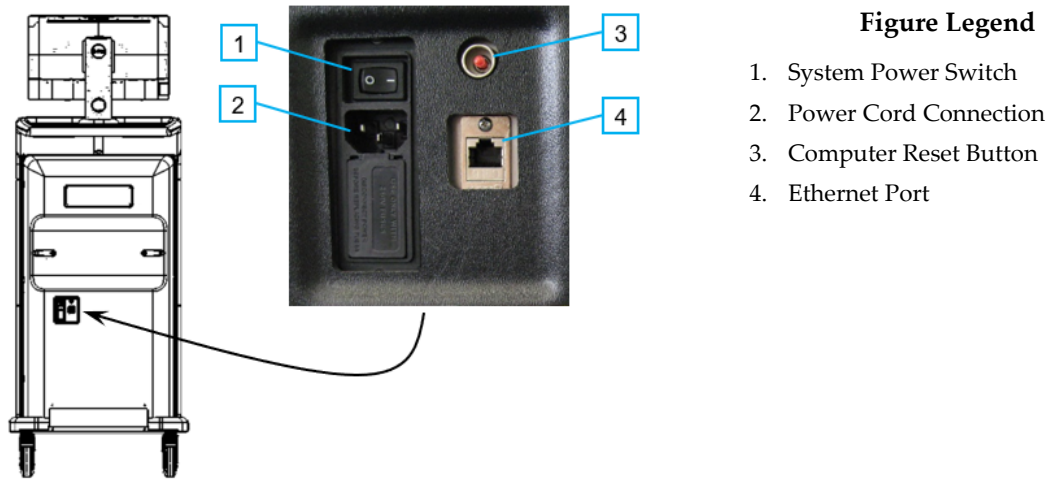


Figure 7: Power and Network Connections

1. Put the system in a location where you can easily access power connections and network connections.
2. Connect the system power cord to the electrical outlet.
3. If desired, connect the network cable to the ethernet port.

USB Connections

The console has two USB ports located at the back of the control display.

Additionally, there are 2 USB ports on the left side of the monitor.

3.3 How to Lock and Unlock a Caster

- To lock a caster, step on the locking lever on the wheel until the lever locks.
- To unlock a caster, press forward on the top of the locking lever until the lever snaps to the UP position.

3.4 How to Move the Console

1. Make sure that the computer system and console are completely turned OFF.
2. Make sure that the power cord is unplugged, and any network cables are disconnected.
3. Wrap the power cord on the cord hooks on the back of the cabinet.
4. Make sure all components and cables are in a safe position on the console.
5. Position the Image Display monitor so that you have an unobstructed view while pushing the console.
6. Unlock the caster locks.
7. Move the console by pushing the console handle.
8. Lock the casters when the console is in the correct location.

Chapter 4 Quick Start – Basic Operation of the Faxitron CT

4.1 System Start-Up



Caution:

The Faxitron CT has a battery back-up which allows the system to be moved without powering down. However, the system must be on mains power when capturing images, including during calibration.



Note

This start-up sequence must be followed to ensure proper system function and image quality.

- Turn the power on to the Faxitron CT System by switching the mains power switch located on the back of the system above the power cord outlet. Switch to “I” for “Power ON”.
- Turn the Faxitron CT System “ON” by pressing the ON/OFF button, located on the front panel.
- The computer and monitor, and the touch screen on the front of the system will all power up.
- Ideally, allow the system to warm up for 30 minutes before calibration and image acquisition.
- From the Windows desktop, double-click on the Software icon. A Password Authentication Screen will open.
- Enter the password provided, then click the **Submit** button to enter the software.



Figure 8: Faxitron CT

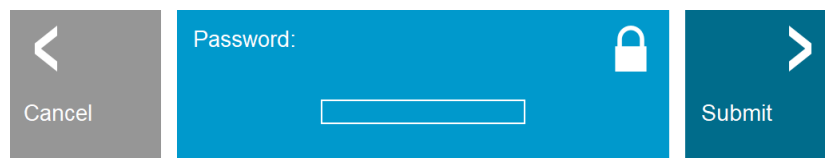


Figure 9: Password Authentication Dialog



Additional Recommendations for Consistent Image Quality:

- Allow the system to perform a complete calibration daily prior to initial system use. The system is configured to prompt for this calibration, if needed, when you start the software.
- Perform a calibration after moving the system to another room to avoid potential imaging difficulties associated with room-to-room ambient temperature and humidity differences.



Note

During operation the touch screen on the Faxitron CT control panel will show the status at the top of the screen. For example – Calibrating, Stand-by, and Ready.

4.2 Calibration



Note

This section provides a summary of Image Calibration only. Refer to Chapter 5, Calibration, for instructions on Geometric and Uniformity Calibration.

Ideally allow the system to warm up for 30 minutes before calibration. This will ensure that the internal detector electronics have stabilized, and the system will produce a higher quality image.

The software is configured to require Image Calibration at the start of each day, or if 12 hours have elapsed since the last calibration. Follow the prompts provided on the screen.

To calibrate the system at any time, click the **Calibrate** button in the Home Menu then click **Image Calibration**.



Figure 10: Calibrate Button

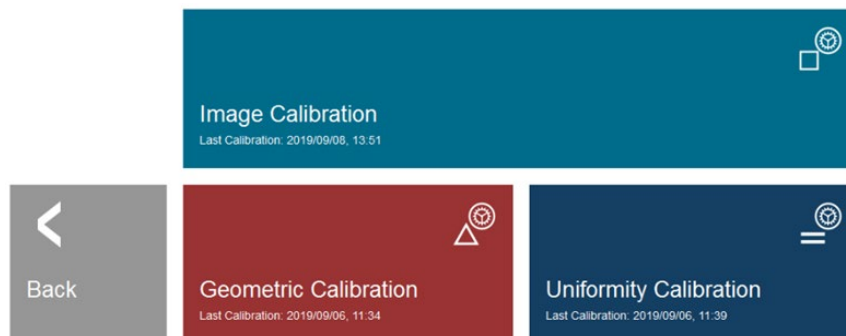
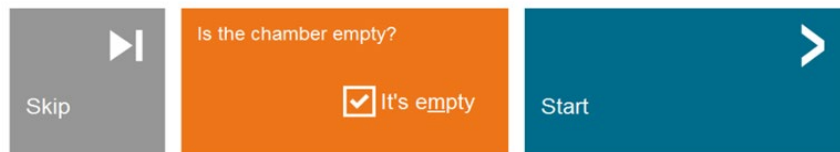


Figure 11: Calibration Menu

Ensure the chamber is empty, including the foam tray, check the box to confirm the chamber is empty, then click the **Start** button.



THE CHAMBER MUST BE EMPTY FOR WARMUP AND CALIBRATION

Figure 12: Start Image Calibration

A Calibration Progress window will open, and the system will begin Image Calibration.

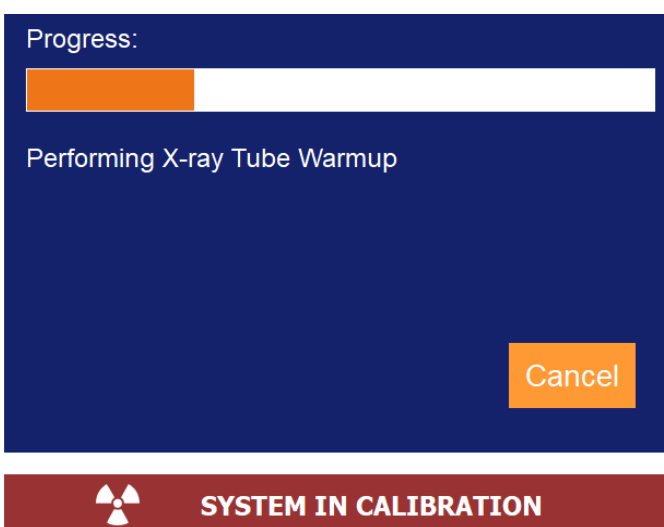


Figure 13: Calibration Progress Window

X-Rays are generated as part of the warmup and calibration procedures. If the user needs to stop the calibration, they may click the **Cancel** button in the Calibration Progress window, press the physical **Stop** button on the system control panel, or press the **Stop** button in the control panel touch screen.

4.3 Basic Imaging Procedure



Warning:

Use approved containers or gloves in order to avoid contact with any potentially hazardous samples.



Caution:

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Place the specimen in a Faxitron CT Specimen Tray. The specimen must fit completely within the inner ring shown below. (10 trays were provided with your system.)



Caution:

To Ensure the DICOM data is correct, place the Posterior face down on the foam with the Inferior (Caudal) side facing the marker shown below with the arrow.

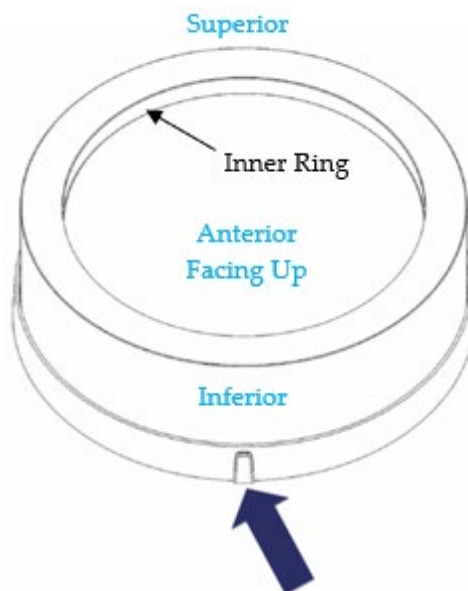


Figure 14: Faxitron CT Consumable Tray

Place the tray on the pedestal with the marker facing out, as shown below. You may need to rotate the tray side to side slightly to get it to sit down securely. Check that it is not free to rotate and is stable.



Figure 15: Specimen Orientation

Close the chamber door.

4.3.1 Enter Patient Data

Click the **Start Procedure** button in the Home Menu.

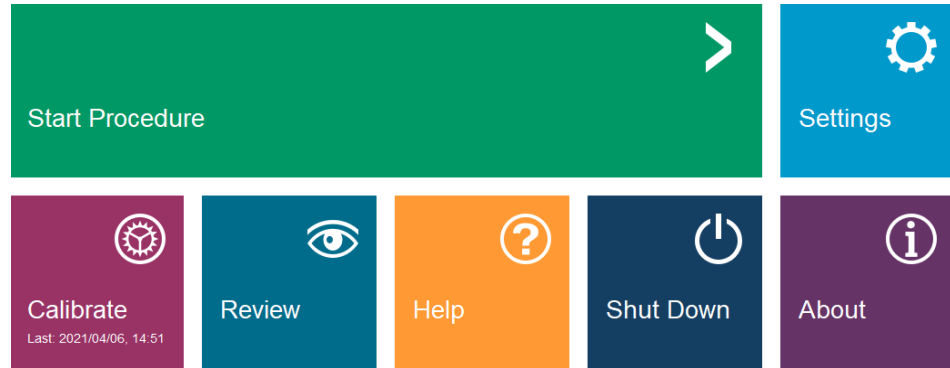


Figure 16: Home Menu

This will open the Start Procedure Menu, which provides options to **Select from Work List**, if configured, **Continue with Current Patient**, if there is a previous patient used, **Manual Entry**, or **Select from Database**. See Chapter 6 for more details.

Click the **Manual Entry** button.

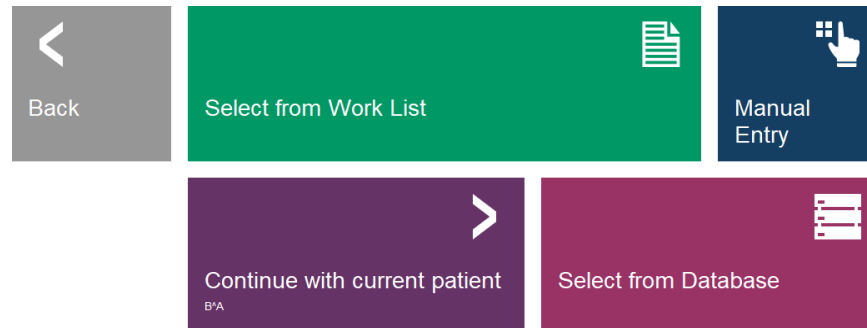


Figure 17: Start Procedure Menu

The Patient Information Editor Dialog will open.

- Enter the Patient Name and ID, Procedure Accession#, and Laterality.



Note

If the patient's middle initial is entered, then all occurrences of the patient name will display the middle initial.

- Tissue specimens can be transferred in Digital Mammography X-Ray Image Storage – For Presentation (MG), or Digital X-Ray Image Storage (DX) format, when Body Part is set to Breast (selected from drop-down menu). All tissue specimens of other anatomy, or when Body Part is left blank, are transferred in Digital X-Ray Image Storage – For Presentation (DX) format. *Refer to 6.11 DICOM/PACS Functionality.*
- Press the “Accept” button. Note that this does not take an X-Ray but activates the system, so it is ready to take an image.
Note: The **Accept** button will be greyed out until all required fields, indicated by an asterisk (*), are completed.

Figure 18: Patient Information Editor

4.3.2 Acquire Images



Caution:

To ensure optimum image quality do not touch the Faxitron CT system during either 2D or 3D image acquisition.

The CT system has 2 modes – 2D imaging and 3D imaging. The system defaults to 2D mode as shown below. You can switch 3D mode by clicking the 3D icon.

2D Imaging Mode



Figure 19: 2D Mode Selected

With a sample in the X-Ray chamber, click the green **X-Ray** button in the bottom right-hand corner of the software (shown above) or press the green X-Ray button on the touch panel to start the exposure.

When the exposure is complete the computer will process the data and after a few seconds display two orthogonal images.



Figure 20: 2D Image Screen

3D (CT) Imaging Mode

Select 3D mode by selecting the 3D icon then click the green **Start** button to begin the scan. The CT reconstruction takes approximately 4 minutes. If there is metal in the specimen, the software takes an additional 1 min to post process the image to remove any metal artifacts.



Figure 21: 3D Mode Selected



Note

Processing times are for guidance only and may change based on the size of the specimen and future system improvements.

When the exposure and processing are complete a four-pane view is displayed.

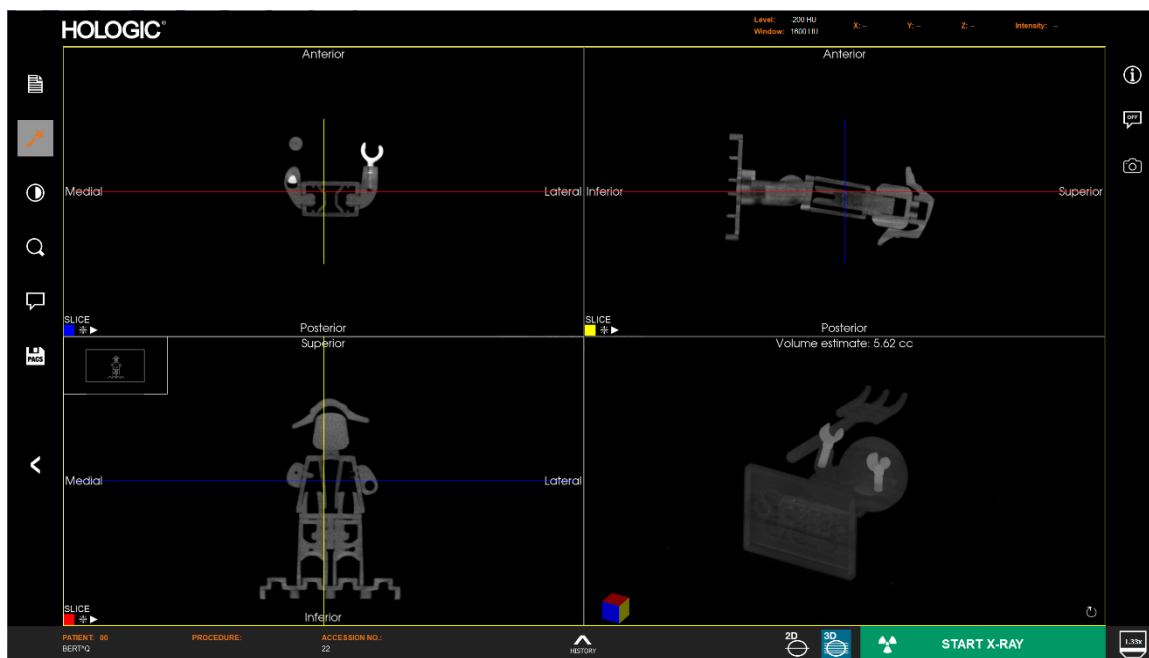


Figure 22: 3D Image Screen

When a CT scan is canceled for any reason, i.e., door is opened, the **Stop** button is pressed, or loss of detector communication, the system will generate a “CT Scan Canceled” error message. The system will remain in STANDBY for about 1 minute before it is ready for another scan. See figure to right.

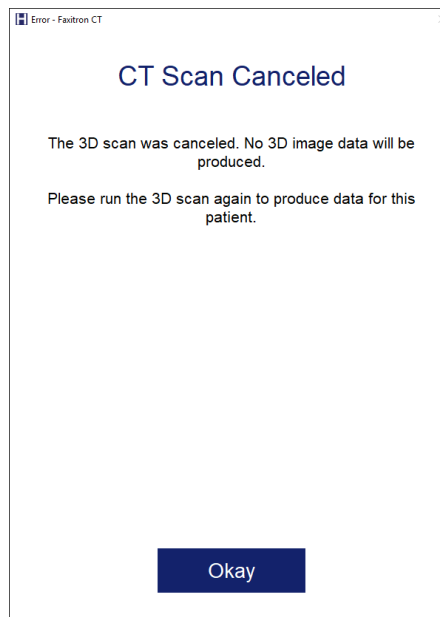


Figure 23: “CT Scan Cancelled” Error Message



Note

See Chapter 6 for information on adjusting images, reviewing, and save options.

4.4 Saving Images to PACS

The 2D and 3D (CT) image series can be sent to the PACS network for storage, assuming a PACS connection has been configured, by clicking the **PACS Store** button in the left tool bar.



Figure 24: PACS Store Button



Note

The system will send the images that are currently shown on the screen at the time the **PACS Store** Button is clicked.

The green **Start X-Ray** Button becomes a **SENDING TO PACS** status bar and will revert back to the **Start X-Ray** button when storage to PACS is complete.

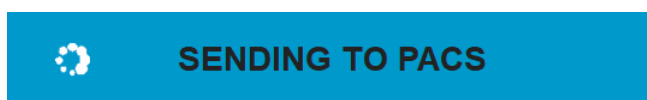


Figure 25: SENDING TO PACS Status Bar



Caution:

To avoid the risk of lost or corrupt files do not shut down the system while the images are still being sent.



Note

All images are automatically saved locally as a backup.

4.5 Shutdown Procedure

There are 2 options to shutdown Faxitron CT systems:

1. Press and hold the ON/OFF button on the front of the system until a “Beep” is heard. This will shut down the software, computer, and system.
2. Or, from the software click the **Shut Down** button from the Home Menu. A second screen will pop-up to confirm that the Shut Down. Click **Okay**.

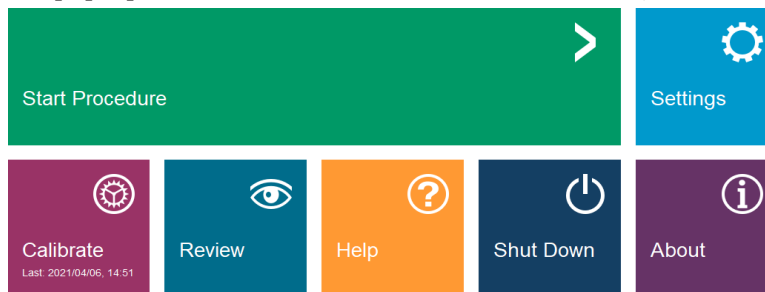


Figure 26: Shut Down Button – Home Menu

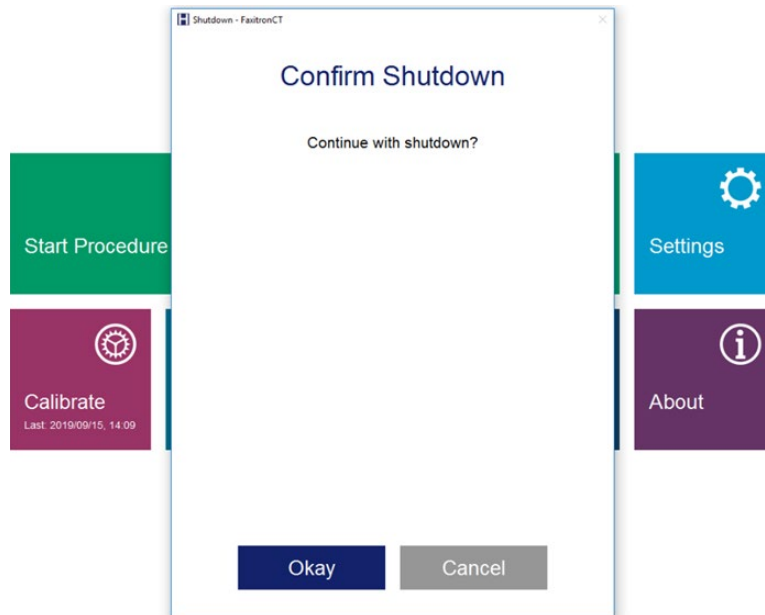


Figure 27: Confirm Shutdown Dialog

Chapter 5 Calibration

To optimize image quality, the Faxitron CT Software and hardware require periodic calibration. During calibration a number of reference images are acquired.

On first installation the system should be allowed to reach the ambient room temperature and a full calibration performed.

There are 3 calibrations for Faxitron CT which should be performed at the interval shown:

- | | |
|--------------------------|----------------|
| • Image Calibration | Daily |
| • Geometric Calibration | Every 3 months |
| • Uniformity Calibration | Every 3 months |

Each day when the system is started the user will be prompted to complete a warmup and image calibration. In addition, it is recommended that the system be re-calibrated after the system is moved from one room to another room with potentially different ambient temperature and humidity.



Note

If the system has been knocked or moved over an uneven floor, all 3 calibrations should be performed to maintain the image quality.



Caution:

The Faxitron CT has a battery back-up which allows the system to be moved without powering down. However, the system must be on mains power when capturing images, including during calibration.

5.1 Image Calibration

Ideally allow the system to warm up for 30 minutes before calibration. This will ensure that the internal detector electronics have stabilized, and the system will produce a higher quality image.

To calibrate the system at any time, click the **Calibrate** button in the Home Menu then click **Image Calibration**.

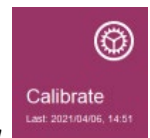


Figure 28: Calibrate Button



Figure 29: Calibration Menu

Ensure the chamber is empty, including the foam tray, check the box to confirm the chamber is empty, then click the **Start** button.



Figure 30: Start Image Calibration

A Calibration Progress Window will open, and the system will begin Image Calibration.

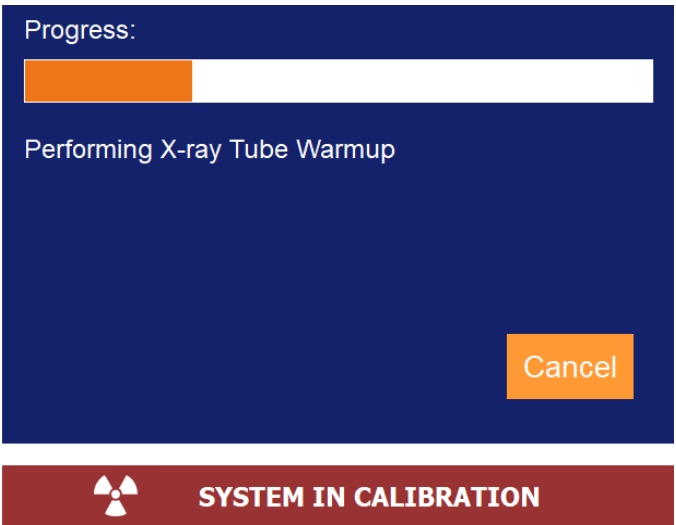


Figure 31: Calibration Progress Window

X-Rays are generated as part of the warmup and calibration procedures. If the user needs to stop the calibration, they may click the **Cancel** button in the Calibration Progress

window, press the physical **Stop** button on the system control panel, or press the **Stop** button in the control panel touch screen.

5.2 Geometric Calibration

Geometric Calibration ensures the system is set up correctly to perform the highly precise reconstruction of the CT images (3D). This can be performed at any time to ensure image quality but must be conducted at least every 3 months.

If the 3D image quality degrades at any time, i.e., rings visible in the image, conduct a geometric calibration.

Click on the **Calibrate** button in the Home Menu then select **Geometric Calibration** in the Calibration Menu. A Geometric Calibration Instruction Dialog will open.



Figure 32: Geometric Calibration Instruction Dialog

The Geometric Calibration utilizes a white Geometric Calibration Phantom. The bottom of the phantom has a flat cut into it which matches the recess in the CT pedestal. This recess ensures the phantom is properly positioned and prevents it from shifting during calibration.

Place the Geometric Calibration Phantom on the pedestal then click the **Okay** button in the dialog. The Start Geometric Calibration Dialog will open.

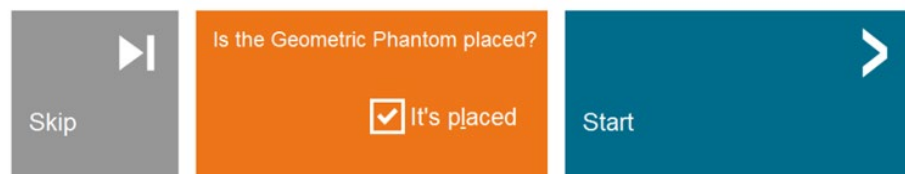


Figure 33: Start Geometric Calibration

Check the box to confirm the Phantom is placed then click the **Start** button.

The calibration will begin taking a full 360-degree image of the phantom which takes up to four minutes.

5.3 Uniformity Calibration

The uniformity calibration ensures that density measurement of the system (Hounsfield units) is calibrated correctly.

Click the Calibrate button in the Home Menu, then **Uniformity** Calibration in the Calibrate Menu. A Uniformity Calibration Instruction Dialog will open.



Figure 34: Uniformity Calibration Instruction Dialog

Uniformity Calibration utilizes a clear Uniformity Calibration Phantom. The bottom of the phantom has a flat cut into it which matches the recess in the CT pedestal. This recess ensures the phantom is properly positioned and prevents it from shifting during calibration.

Place the Uniformity Calibration Phantom on the pedestal then click the **Okay** button in the dialog. The Start Uniformity Calibration Dialog will open.

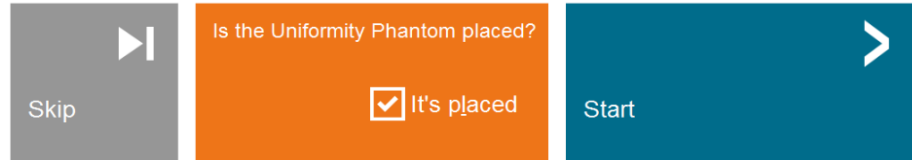


Figure 35: Image Display Screen

Check the box to confirm the Phantom is placed then click the **Start** button.

The calibration will begin taking a full 360-degree image of the phantom which takes up to 4 minutes.

Chapter 6 Faxitron CT Software Operation

6.1 Software Overview

Faxitron CT Software is a complete image acquisition and processing package, designed exclusively to work with the Faxitron CT system. In addition to the acquisition and processing functions, the software offers an extensive database module that allows user control and maintenance of image archiving, storage, filing and retrieval. The software is also Digital Imaging and Communications in Medicine (DICOM) conformant, allowing network transfer of patient images in DICOM format. The software has been pre-installed on the computer that was installed in your Faxitron CT system.

System calibration is required at the beginning of every new day of system use for best image quality. The system user may also perform calibration at any time to ensure optimum image quality.

After calibration, the Home Menu will be displayed, which allows navigation to all other areas of the software. For ease of use, application buttons are provided. *See figure below.* These buttons are in the center of the screen. Button descriptions and definitions are outlined in the following sections of this manual.

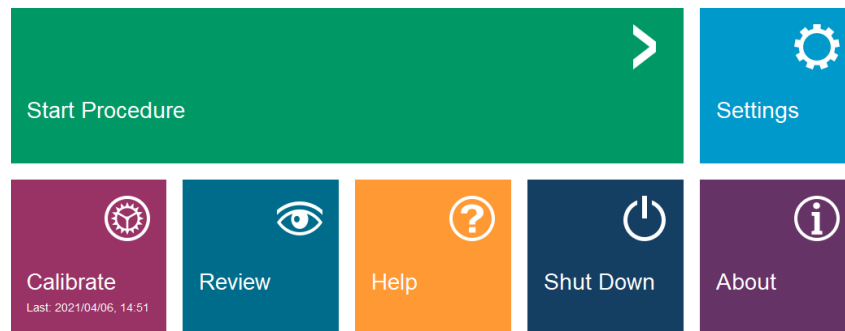


Figure 36: Faxitron Software, Home Menu

6.2 Software Start-Up

See Chapter 4, *Quick Start – Basic Operation of the Faxitron CT*, for software start-up procedure.



Note

A password is required to enter the software and initiate X-Rays.

6.3 Calibration

See Chapter 5, *Calibration*, for details on the calibration process.



Note

Perform an Image Calibration at the start of each day to ensure optimum image quality.

6.4 Patient Data

The **Start Procedure** button takes the user to the Patient Data Entry Menu which provides methods to enter patient data. If a Work List has been configured correctly, the button will be green. The options are explained in the following pages.

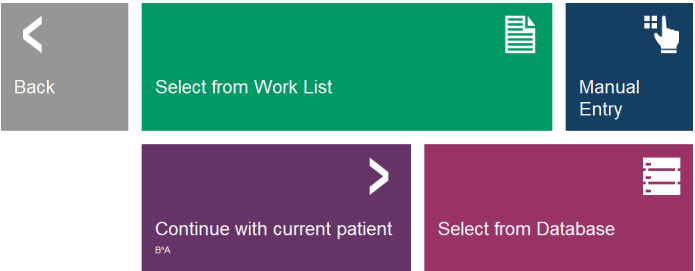


Figure 37: Start Procedure Menu



Notes

- If patient data is entered manually, and includes the patient's middle initial, then all occurrences of the patient name will display the middle initial.
- If patient data is selected from a Work List and a complete middle name was received it will be displayed as middle initial in the Patient Information Editor/Viewer. The full middle name will be stored in the Database, displayed in the Review Mode Patient List, the lower left corner of the image viewer screen, and included in the DICOM image headers.

6.4.1 Select from Work List (Modality Work List)

If a Work List has been configured the user can click the **Select from Work List** button which will display the following pages.

HOLOGIC®
Work List

Patient Name: DAVIS/BETTY
Patient ID: TST02
Date of Birth: 19720304
Procedure Date: 20210415
Accession Number: 00002
Modality: CT
Referring Physician: ROGERS
Physician Name: ROSS
Station/AE Title: FAXITRONCT
Station Name: STATOIFAXITRONCT

12 / 41 records shown
Clear Query Data
Save to Database
Query
Submit
Back

Patient ID	Accession #	Patient Name	Birth Date	Sex	Modality	Admission ID	Ref. Physician	Ref. Physician	Ref. Phys. ID	Ref. Phys. Priority	Contract Agent
TST02	0002	ABRAHAM BRUCE	1976080	M	CT	P0003	RAU	PETERS	RP0007	HIGH	
TST01	0001	ACTON BRUCE	1980084	M	CT	0001	ROGERS	THOMPSON	RP04024	LOW	BARBARALEST
TST02	0002	BENEFY-JACQUELINE	1970004	F	CT	0002	NEWMAN	ROGERS	RP00009	HIGH	
TST11	0001	BRADSHAW-CRIVILLE	1970026	M	CT	0001	ROSS	SMITH	RP00080	HIGH	THORUM
TST03	0003	BRAXTON-SEANOUR	1980707	M	CT	0003	RAU	ROGERS	RP00067	HIGH	
TST04	0004	BROOKS-ROSLYN	1952401	F	CT	0004	MULLER	KENDALL	RP04001	LOW	
TST05	0005	CHAMBERS-JEFF	1970004	F	CT	0005	NEWMAN	THOMPSON	RP00007	HIGH	
TST06	0006	COLE-CHARL	1970004	M	CT	P0003	RAU	PETERS	RP00067	HIGH	
TST11	0001	HARLOW-CHARLES	1970026	M	CT	0001	ROSS	SMITH	RP00080	HIGH	THORUM
TST01	0001	SMITH-JOE	1980004	M	CT	0001	ROGERS	THOMPSON	RP04024	LOW	BARBARALEST
TST03	0003	THOMPSON-WILLIAM	1980707	M	CT	0003	RAU	ROGERS	RP00067	HIGH	
TST04	0004	WILSON-MRANDA	1952401	F	CT	0004	MULLER	KENDALL	RP04001	LOW	

NOTE: All patient data is fictitious. Any resemblance to actual persons is strictly coincidence.

Figure 38: Modality Work List Dialog

On the left are various filters that may be used to search for scheduled procedures. Enter a search parameter into the field(s) and select the **Query** button located in the bottom left corner. The table is re-populated with the entries that match the queried information. Up to 1025 matching results are displayed in a scrollable list.



Note

If more than 1025 matching results are returned the excess results are ignored. This limit is not configurable.

A patient's information can be imported to the local Database from the Modality Work List by clicking the **Save to Database** button. A dialog will pop-up confirming that the information was added to the database. Click the **Okay** button.

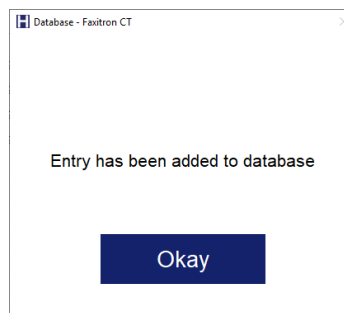


Figure 39: Admin Screen

The user can then select any entry then click the **Submit** button to automatically populate the Patient Information Editor with the patient information.

The Patient Information Editor (Set/Edit Patient Data Dialog) will open. Complete any remaining required fields and click the **Accept** button to proceed to image acquisition.

- Required Fields are indicated by a white asterisk (*). Default required fields are: Patient Name, Patient ID, Accession Number, and Laterality.
- The user must enter all required fields prior to being able to select the **Accept** button. The user may also enter any other field as desired.
- The Procedure Name, Position View and Body Part are chosen by a drop-down menu.
- Tissue specimens can be transferred in Digital Mammography X-Ray Image Storage – For Presentation (MG), or Digital X-Ray Image Storage (DX) format, when Body Part is set to Breast (selected from drop-down menu). All tissue specimens of other anatomy, or when Body Part is left blank, are transferred in Digital X-Ray Image Storage – For Presentation (DX) format. *Refer to 6.11 DICOM/PACS Functionality.*
- The Date must be entered as yyyy-mm-dd (e.g., 1962 08 13). Failure to enter a valid date may cause errors when attempting to retrieve images.
- The "required fields" may be altered or deleted depending on the application. Contact support for further information.
- Select **Accept** to continue or **Select a New Patient** to return to the Patient Data Entry page.

Figure 40: Patient Information Editor

6.4.2 Continue with Current Patient

If a Patient's data had been previously been loaded, you can click the **Continue with Current Patient** button. The Patient Information Editor will open. Complete any remaining required fields. *Refer to Section 6.4.1.*

6.4.3 Manual Entry

See Chapter 4, Quick Start – Basic Operation of the Faxitron CT System for details.

Click on the **Manual Entry** button to enter a Patient's details manually. The Patient Information Editor will open. Complete all required fields and click the **Accept** button. *Refer to Section 6.4.1.*

6.5.1 Image Screen - 2D Mode

After an image is acquired in 2D mode two orthogonal images will appear on the screen as shown below.

Orthogonal images are two images taken at right angle to each other. For example, if the sample is placed correctly the left image will be Latero-Medial (LM) for the left breast and Medio-Lateral (ML) for the right breast. The right image will be Caudal Cranial (CC).



Figure 43: 2D Image Screen

6.5.2 Image Screen – 3D Mode

After an image is acquired in 3D mode four images will appear on the screen as shown below. The bottom right image is a 3D rendering of the reconstruction volume. All other views are reconstructed slice views of the specimen.

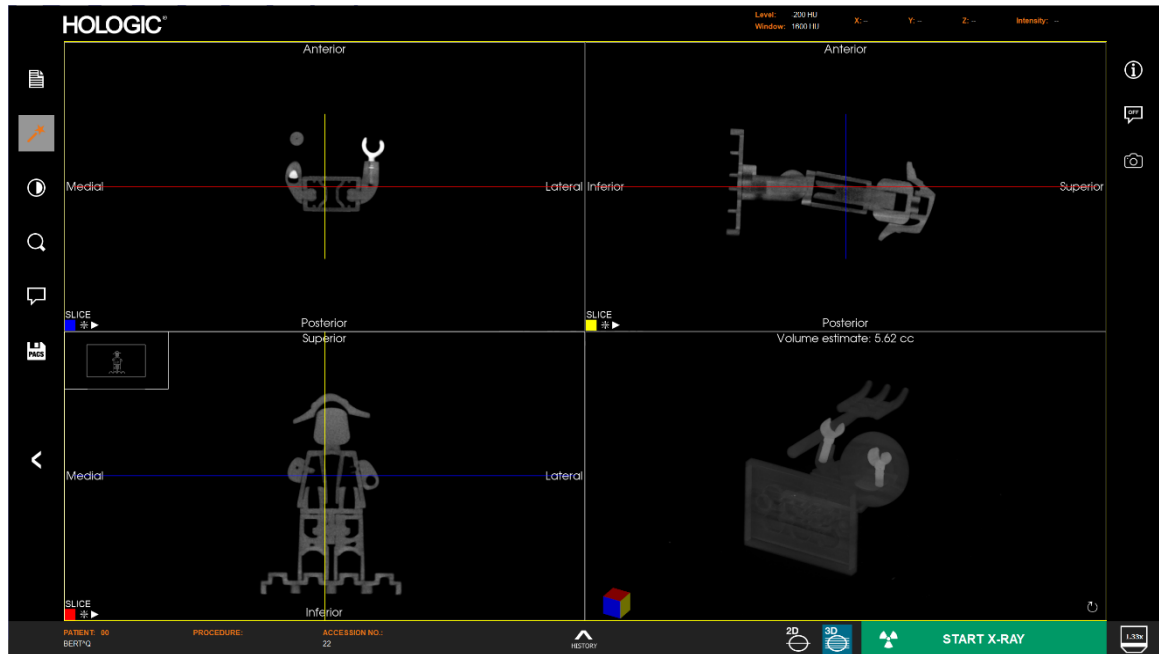


Figure 44: 3D Image Screen

When a CT scan is canceled for any reason, i.e., door is opened, the **Stop** button is pressed, or loss of detector communication, the system will generate a “CT Scan Canceled” error message. The system will remain in STANDBY for about 1 minute before it is ready for another scan. *See figure to right.*

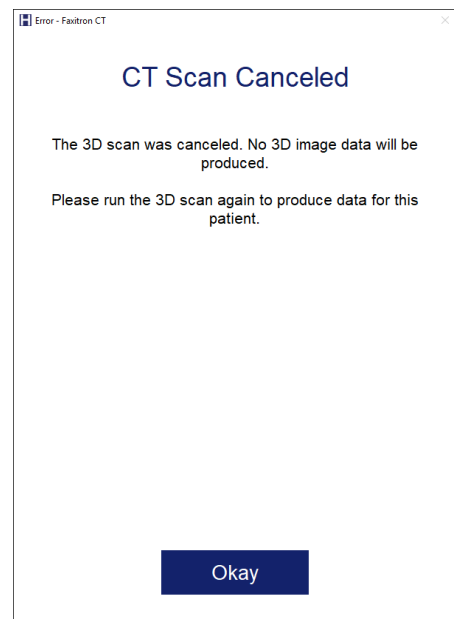



Figure 45: “CT Scan Cancelled” Error Message

The following sections outline the manipulation of the images.


6.6 Left Tool Bar/Image Tools

The software provides various tools to control various image attributes or parameters, x-ray acquisition, image views, image tools, and DICOM settings/access. The most commonly used tools are in a Tool Bar. The Tool Bar and Menus are described in more detail in the following pages.


The software provides single click access to a number of commonly used tools or functions with a vertical tool bar located on the left side of the screen. More detailed descriptions follow in the next pages.




Set/Edit Patient Data
(Patient Information Viewer)




Toggle Image Enhancement On/Off




Adjust Image Contrast
(Window Level Tool)




Adjust Image Zoom
(Zoom Level Tool)




Access Image Annotation Tools
(Annotation Tools)



Save Image Data to PACS



Back to Main Menu (Home Menu)



NOTES:

The following tools will only be enabled after an x-ray image has been acquired:

- Toggle Image Enhancement on/off
- Adjust Image Contrast
- Adjust Image Zoom
- Access Image Annotations Tools

These same tools will be disabled during subsequent image acquisitions.

The PACS Save tool is enabled when the system is connected to a PACS network.

Figure 46: Left Side Tool Bar

Undocking Tools and Dialogs

The Patient Information Editor (Dialog), Window Level Tool, Zoom Tool, and Annotation Tools are docked to the left side of the image window when they are opened. They can be undocked by clicking on the pin Icon in the upper right corner. Undocking

the tool allows it to be dragged anywhere in the image window. When undocked the pin Icon turns into an “X” which can be clicked to close the tool. Clicking the “X” also locks the tool into the location it was left in. Closing the tool using the **OK** button will leave the tool undocked, i.e., if the tool is opened again it can be freely moved.

6.6.1 Set/Edit Patient Data

The **Set/Edit Patient Data** button opens the Patient Information Viewer.



The Patient Information Viewer will open populated with all the information that was previously entered.

If the Patient Information Viewer is opened in the image Acquisition mode, the dialog will have **Close Dialog** and **Select New Patient** buttons. When opened Review mode the dialog will only have the **Close Dialog** button.

Image Acquisition Mode

Review Mode

Figure 47: Patient Information Viewer – Image Acquisition and Review Modes

6.6.2 Enhance Image

Toggle Image Enhancement on/off (2D Image Mode Only)

The button shown will process the image on the display to emphasize the smaller details, such as micro-calcifications, and small masses in the image.



Figure 48: Image Enhancement Button

The algorithm, commonly known as “Peripheral Equalization” or “Thickness “Equalization” in advanced imaging, is applied to the whole image. In addition to this algorithm, the CT software employs a second, internally developed algorithm called the “Calcification Emphasis” algorithm. This secondary algorithm is made to bring out small details in the image and make them much easier to see and analyze.

Since Patient images constitute a more general category, in terms of possible geometries and variety of thickness, there may be some challenging sample geometries, and the user should use this tool with care.

The system will be idle (in Standby) during the processing. Once completed the button will stay depressed/active. The user can undo the process by pressing the button again.

6.6.3 Window Level

The Faxitron CT Software provides 2 methods for adjusting the brightness and contrast of the image: The Window Level tool, accessed through the Left Side Tool Bar, and a “Built-in Windowing Tool” feature. Both are described below.

Window Level Tool

Clicking on the **Adjust Image Contrast** button in the Left Side Tool Bar opens the Window Level Tool. This tool allows the user to adjust the images window level and width, or brightness and contrast.



Figure 49: Adjust Image Contrast Button

Window Level (brightness) is adjusted by moving the center bar up to increase brightness or down to decrease brightness.

Window Width (contrast) is adjusted by dragging the end bars up or down. The end bars move together to either decrease or increase the Window Width. Decreasing the Window Width increases contrast while increasing the Window Width decreases contrast.

Click the **Invert** button to flip the grayscale values in the image, i.e., converts the image from a negative to a positive, or vice versa.

Clicking the **Link Contrast** button applies any adjustments to all the views for that image.

The user may also restore the Original Contrast by clicking the **Original Contrast** button.

Click **OK** or **Cancel** to exit.

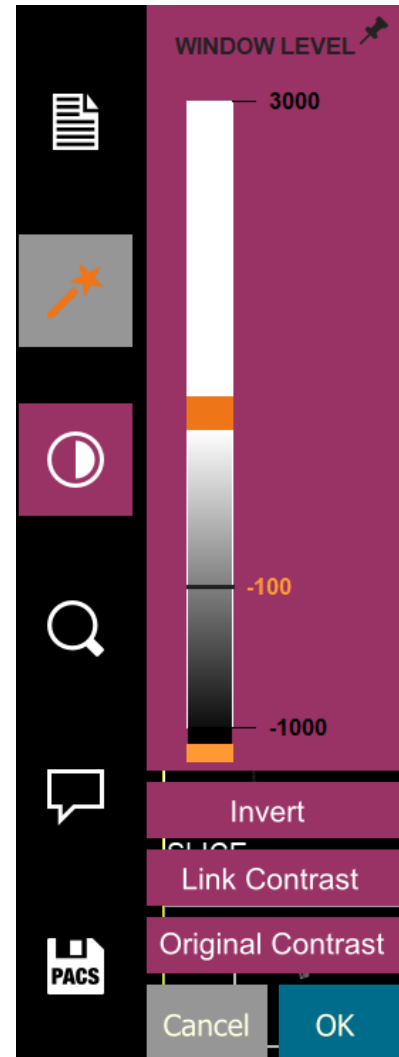


Figure 50: Adjust Image Contrast Tool

Built-in Windowing Tool

The user may also adjust the Window Level and Width using mouse movements. This “Built-in Windowing Tool” can be used on any image, whether just acquired or opened in review mode.

Position the mouse over the displayed image then click and drag to adjust the brightness and contrast. Moving the mouse up and down adjusts brightness, left and right adjusts contrast. Release the mouse button when satisfied with the results.

6.6.4 Image Zoom

Clicking on the **Adjust Image Zoom** button in the Left Side Tool Bar opens the Zoom Level Tool.

Figure 51: Adjust Image Zoom Button



The Zoom Level Tool provides the user with a number of options to adjust the image zoom:

The Slider Bar provides zoom adjustments from 0.1x to 3.00x.

The user may also type in a zoom value in the *text field* and click **Set**.

The **Fit All** button will attempt to detect and zoom in onto the specimen as to ensure that the specimen is in full view. If a specimen is not detected, it will default to the previous mode.

Zoom 1.0x, or “Full Resolution” adjust the image to a 1:1 ratio with the monitor resolution.

Click **OK** to accept the adjustments.

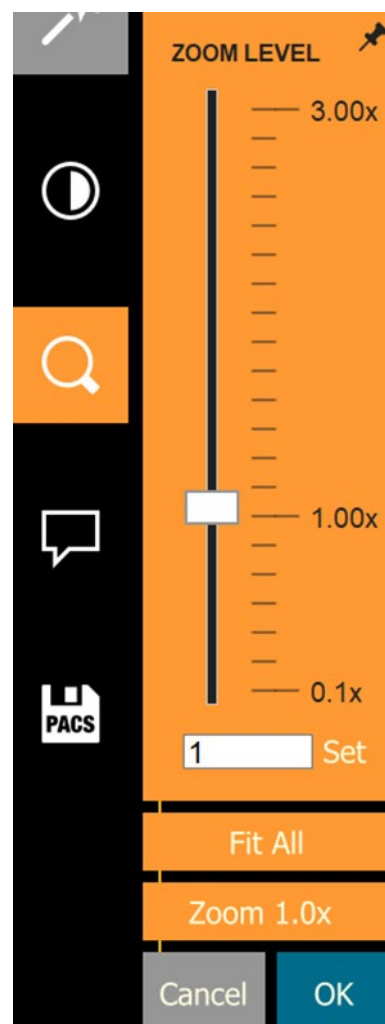


Figure 52: Zoom Level Tool

Pan Zoom Thumbnail

Zooming in on an image may require panning to navigate around the image. A thumbnail will appear in the top left corner of the screen. A smaller box inside the thumbnail indicates the portion of the image displayed on the screen. Click in the inner box and move it around the thumbnail to move the image in the pane.

Traditionally, this feature is also called “Pan View” and/or “Pan and Scan”.

6.6.5 Annotations

User Annotations in the Faxitron CT Software allows the user to apply a graphic “overlay” commonly called “annotations” to an image. These annotations take the form of text, lines, “free form” lines, arrows, ellipse, and boxes. This allows additional information and “markers” to be added to the image if desired. Once applied to the image annotations can be easily turned on and off, i.e., revealed or hidden at will.

Click the **Access image annotations tools** button to open the Annotation Tools.



Figure 53: Access Image Annotations Tools Button

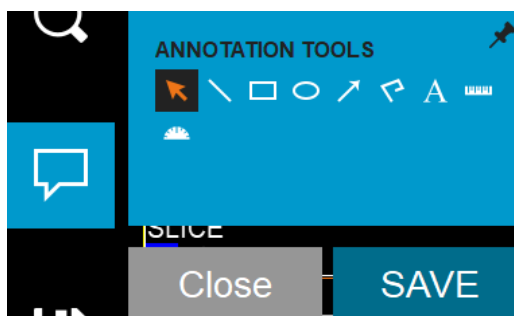











Figure 54: Annotations Tools

The tool pallet consists of nine (9) tool options.

	Selection Tool	Used to “Select” annotations currently displayed in an image. Once selected the annotation(s) can be modified or deleted.
	Line Tool	Draws a straight line.
	Box Tool	Draws a box.
	Circle Tool	Draws a circle.
	Arrow Tool	Draws a line with an arrow at the end.
	Polygon Open Line Tool	Draws freeform “open segmented” lines. The line will follow your mouse movements, no matter how complicated.
	Text Tool	Creates a “textbox” where you can type text-based data.
	Ruler Tool	Draws a ruled line segment and displays the length of the line in millimeters (mm).
	Protractor Tool	Draws an angle on screen and provides the degree of the angle. Just like a protractor.

All the Annotation Tools, except as noted, are drawn with “Click-Move-Click” mouse movements. i.e., Click at the starting point, move the mouse, click at the end point.

The Polygon Open Line Tool can be drawn with the “Click-Move-Click” mouse movements in which case the shape will follow the mouse movements exactly. You can also insert as many click points as desired, in which case the software will create Bezier curves calculated from the position of the nodes. Complete the Polygon Open Line shape by double-clicking, or right clicking the end point.

The Protractor Tool is drawn using “Click-Move-Click-Move-Click” mouse movements. Click at the start point, move the mouse to the vertex and click, then move the mouse to the end point and click again.

For the Rectangle and Circle Tools the initial click will be the center of the shape.

To resize any of the objects click on an end point, or handle, and drag.

To modify the Polygon Open Line, click on a node and drag.

To move a box or circle, click on the center point and drag.

When an image has saved annotations clicking on the Selection Tool “selects” all the objects. Click on an end point, or handle, of the object of interest. Modify the object by dragging the end, center point, or a node. Delete the object using the keyboards “Delete” key.



Note

Annotations are not available in the 3D Rendered View.

An example of each Annotation Tool is shown below.

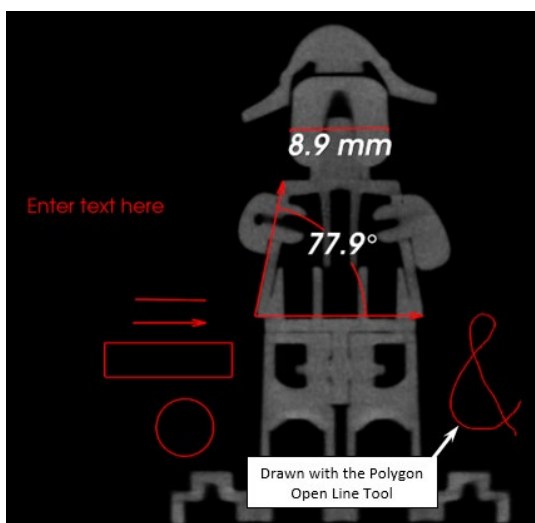


Figure 55: Annotation Examples



Note

In 2D Mode all annotations will be blue.

In 3D Mode All annotations will be the color of the square in the lower left corner of the image pane, i.e., red, blue, or yellow.

When you select the Text Tool and click in the image “Enter text here” along with a Text Editor dialog.



Figure 56: Text Tool with Text Editor Dialog

The Text Editor allows you to select between Arial, Courier, and Time New Roman fonts, specify the font size, apply Bold and Italics attributes to the text, and change the text color.

Click on the **normal** button to open a Color Palette which allows you to change the text color.

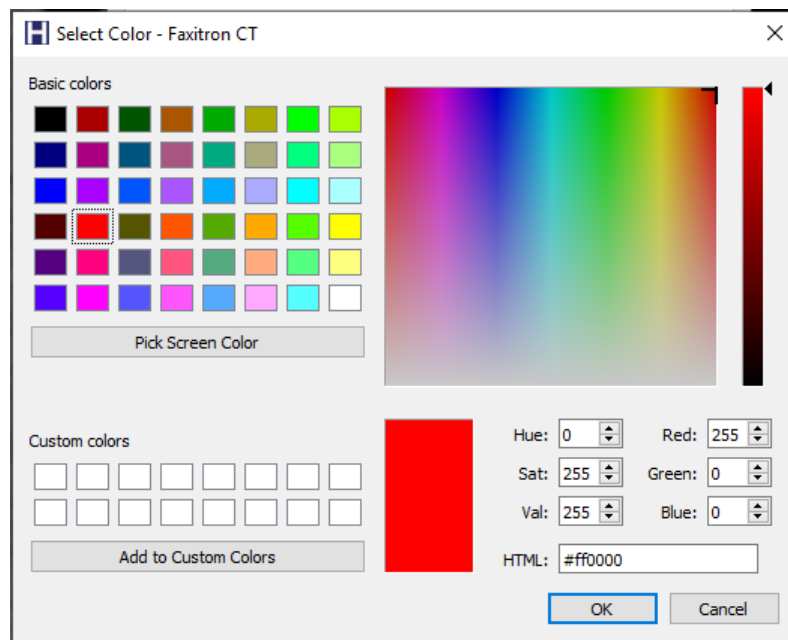


Figure 57: Text Tool Color Palette

The following figure shows all annotation tools selected. Note the end points (or handles), center points, and the nodes in the Polygon Open Line Tool (the Ampersand).

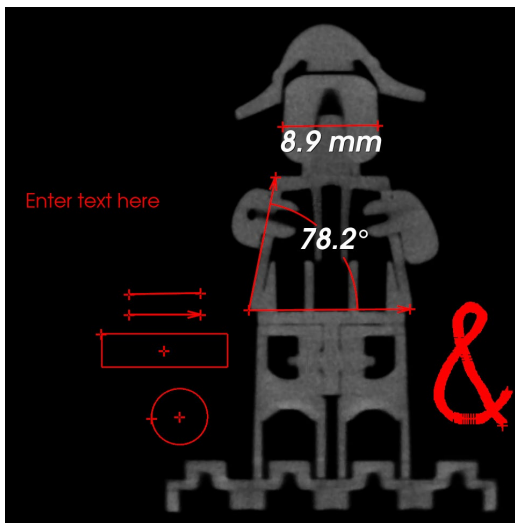


Figure 58: All Annotation Tools/Objects Selected

Selecting **Save** or **Close** from this dialog box will save the current annotations to the window or will close the annotation dialog. It will also return you to normal imaging mode.



Note

Annotations may be toggled on or off using the **Show/Hide Image Annotations** button in the right tool bar. See Section 6.7.2.

6.6.6 Save Image data to PACS (Save)

The button shown will only function when the system is connected to a medical facility's PACS network. Click the **PACS Store** button and the active images in the viewer will be sent to the PACS server.



Figure 59: PACS Store Button

The button in the bottom right corner will show the status.

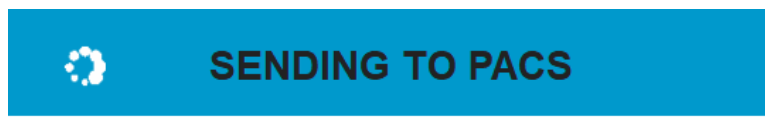


Figure 60: Sending to PACS Status Bar

A confirmation will appear once the transfer is complete.



Caution:

Do not shut down the system when images are being sent to PACS. 3D images are very large and may take several minutes to send to the server.

6.6.7 Back to Main Menu

The **Back** button exists the Image Acquisition or Review Mode and returns to the Home Menu.

Figure 61: Back to Main Menu Button



6.7 Right Tool Bar

The Right Tool Bar, located in the upper right corner of the image screen, provide quick access to a few useful functions. These tools are only active if an image is displayed.



Figure 62: Right Tool Bar

6.7.1 Show/Hide Image Info (Image Properties)

After an image is taken, the current image properties can be viewed by pressing the (i) button in the Right Tool Bar. The image Properties Dialog box will be displayed in the top right corner of the image.

Figure 63: Show/Hide Image Info Button



The exact content of the image properties dialog is dependent on whether it is opened in Imaging Mode or Review Mode. See figures below.

Series Instance UID:	1.2.840.114561.100100.20210408.120224.1.2
Directory:	D:\data\20210408.120224\CT-001\
Series Date:	April 08, 2021

Figure 64: Image Properties from Image Acquisition Screen

Series Instance UID:	1.2.840.114561.100100.20210408.120224.1.2
Directory:	D:/data/20210408.120224/CT-001
Series Date:	April 08, 2021
Series Time:	12:06:18

Figure 65: Image Properties from Review Screen

6.7.2 Show/Hide Image Annotations

The **Show/Hide Image Annotations** button allows the user to easily toggle annotations on or off. This button does not delete the annotations from the image.



Figure 66: Show/Hide Image Annotations Button

Annotations are “On” by default. When the annotations are hidden the button will read “Off”.

6.7.3 Save Snapshot

The **Save Snapshot** button allows the user to save a screen shot of the image currently displayed in the viewer.



Figure 67: Save Snapshot Button

Clicking on the **Save Snapshot** buttons opens a Snapshot Dialog.

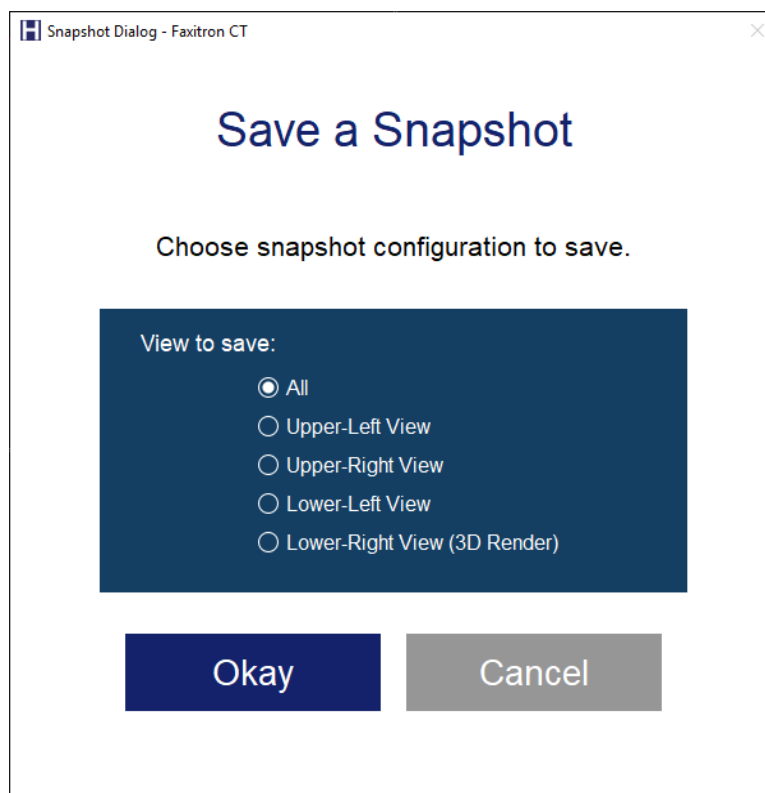


Figure 68: Save A Snapshot Dialog

Select the view you want to save. *See above figure.* Note that in 2D Mode you can select the *Left View*, *Right View*, or *All*. Then click **Okay**.

A typical Windows Save As dialog will open.

Type in a name for the screen shoot, choose the file type you want to save the screen shot in, then navigate to the location you want the file save in.

The screen shot can be saved in any of the file types shown below:

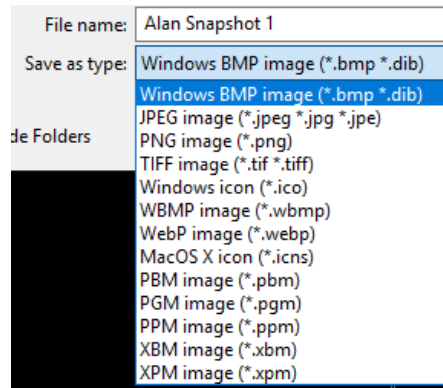


Figure 69: Save Snapshot File Types

6.8 3D Images

The 3D View is divided into 4 images, which are described later in this section.

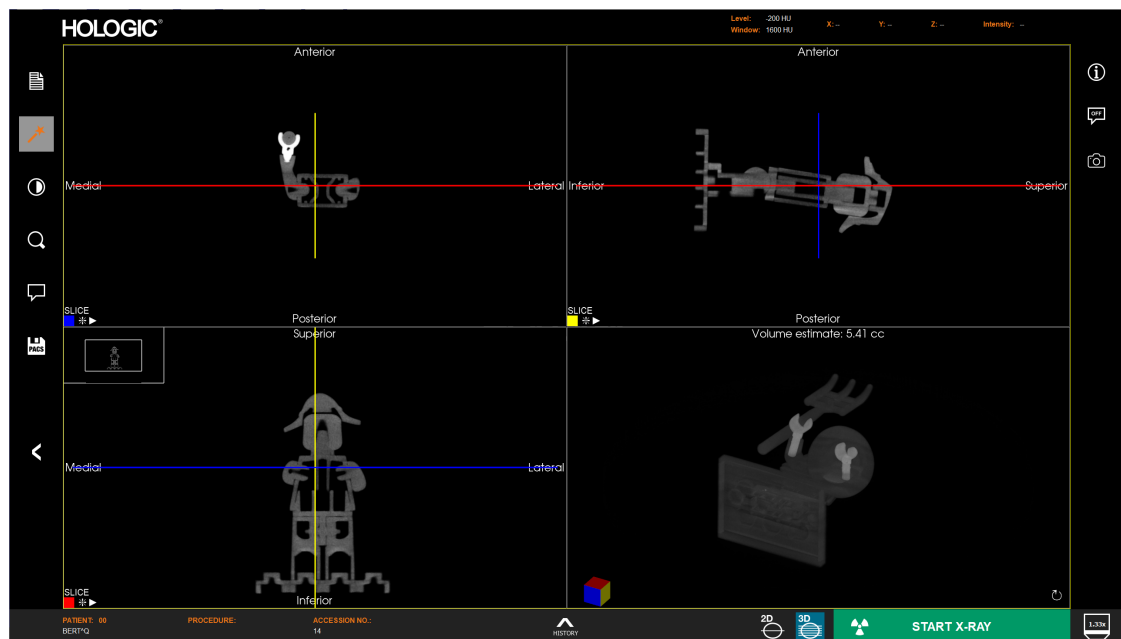


Figure 70: Faxitron CT (3D) Display

The bottom right image is the 3D rendered view of the specimen. Holding down the left mouse button allows the user to rotate the specimen in 3D. As the specimen is rotated the cube in the bottom left corner will rotate in the same way to help with orientation.

Use the right mouse button for zooming in and out.

The middle button for pan (move left, right, up, or down).

Each of the 4 views can be maximized to full screen by clicking the square button in the top right corner of the window.

The circular arrow button in the bottom right is the view reset button, which will reposition the specimen back to its original view.

There is a **PLAY** button displayed in each slice view. Pressing the **PLAY** button automatically moves the scroll bar through the slice. The scroll bar will always move to the right through the end of the view frame, then start at the far left and continue scrolling until the **PLAY** button is pressed again. The colored lines in the other 2 views will move in unison to display the corresponding slices in those views.



Figure 71: Play Button

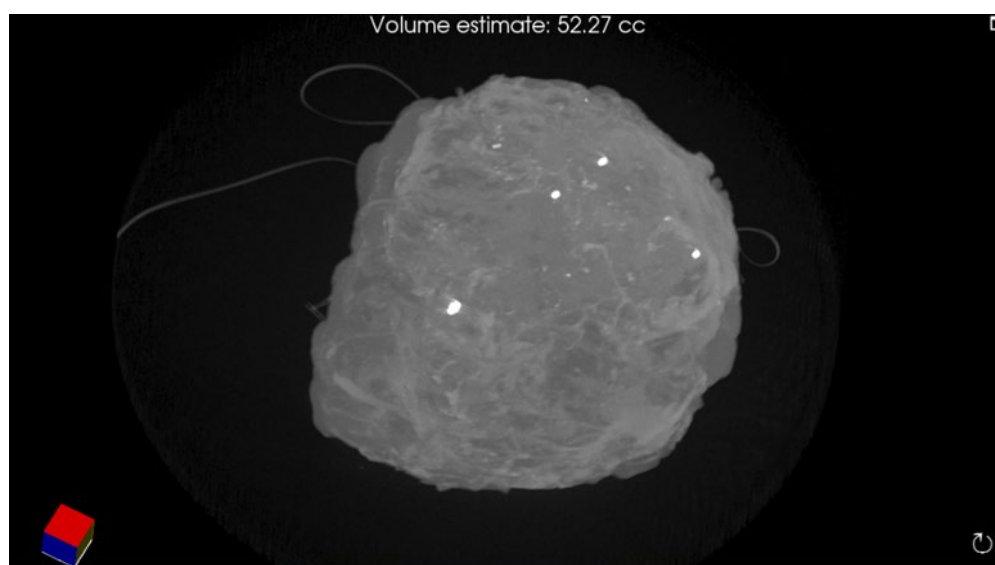


Figure 72: Faxitron CT 3D View

Estimated volume of the specimen is displayed at the top of this view in cubic centimeters (CC).

6.8.1 Specimen Orientation

When imaging, the specimen should be placed on the foam in the orientation shown below by the toy figure. When placed correctly the DICOM tags in the image header will match the orientation of the stored pixel data with respect to the patient.

The posterior should be on the foam with the caudal (inferior) pointing towards the front of the system and the marker on the foam tray as shown below.



Figure 73: Specimen Orientation

This will produce the image shown below.

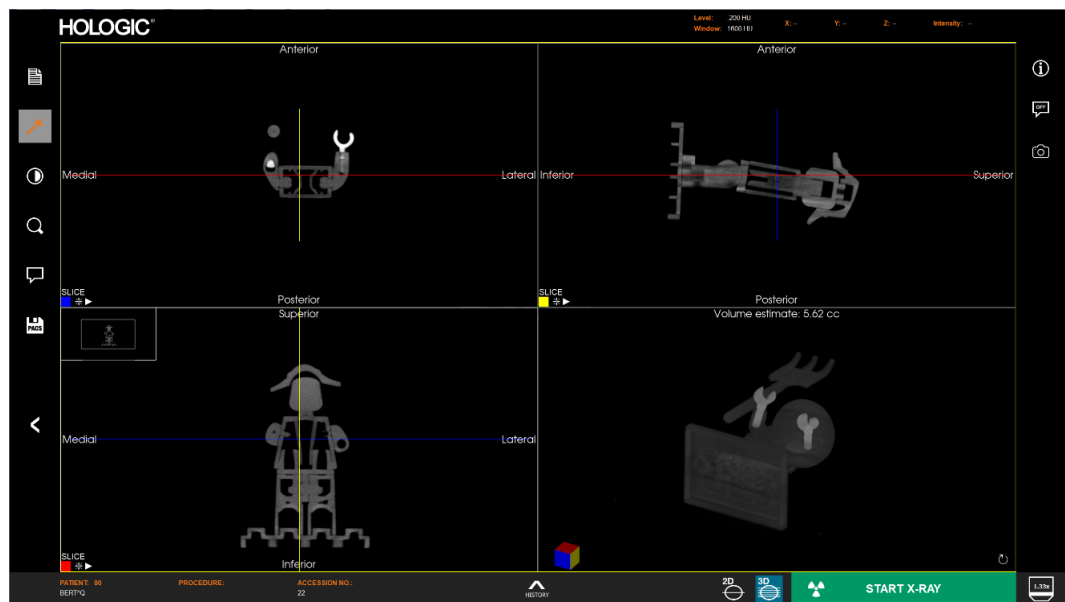


Figure 74: Faxitron CT 3D Display



Note

The orientation only applies to specimens that are placed on the foam correctly.



Note

The anatomical positions for the following views are referenced with the scroll bar in each view moving from left to right as when the **Play** button in that view has been pressed.

View 1, upper left quadrant, is Caudal Cranial (CC).

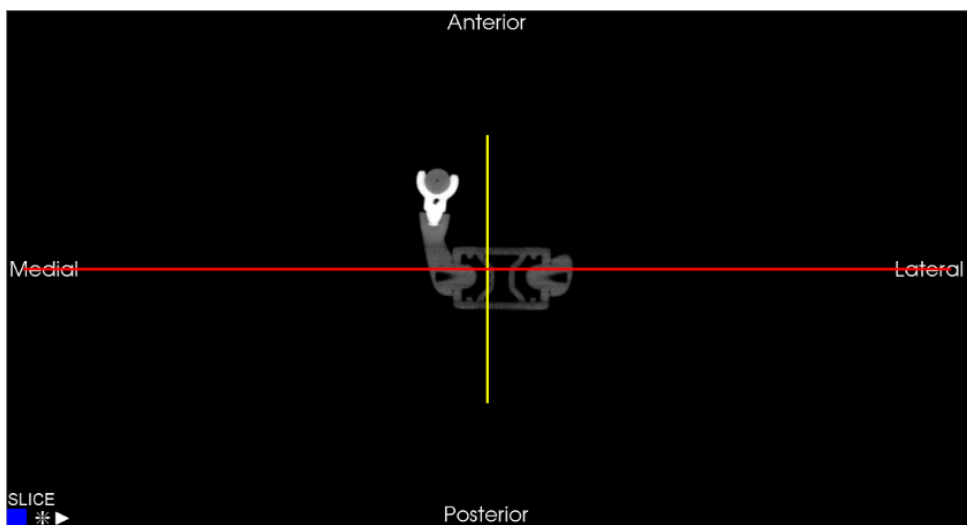


Figure 75: CC View

View 2, upper right quadrant, is Latero-Medial (LM) for a right specimen, and Medio-Lateral (ML) for a left specimen.

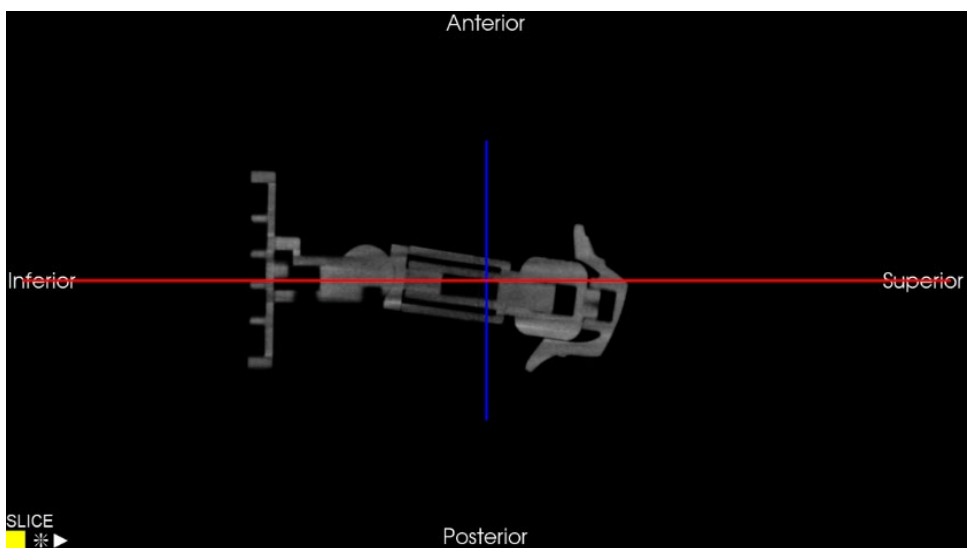


Figure 76: LM/ML View

View 3, lower left quadrant, is Posterior Anterior (PA).

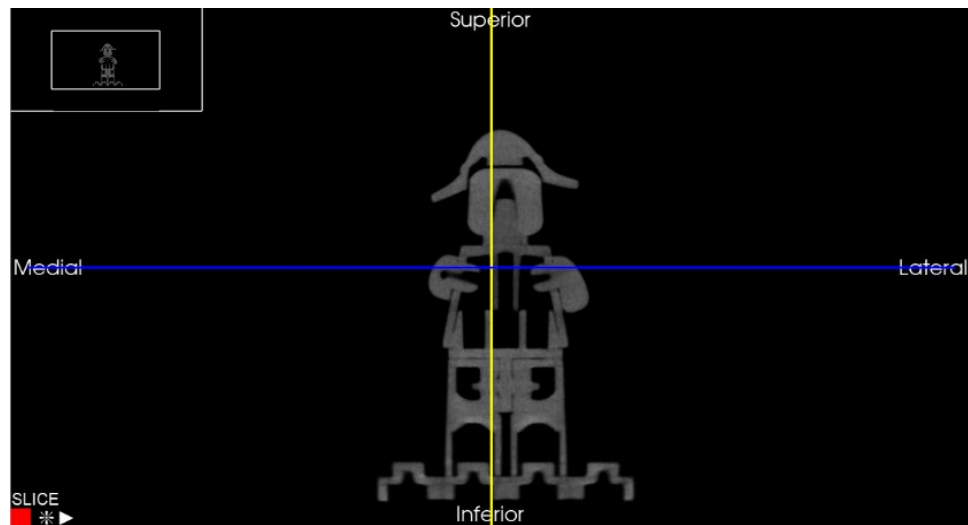


Figure 77: AP View

View 4, lower right, is the 3D Rendered View.



Figure 78: 3D Rendered View

The colored faces of the Cube in the 3D view correspond to the squares in the corner of the other 3 views. In this example the red face is the top of the cube (Anterior) and the Slice view with the red square in the corner, *see figure 73*, is the top-down view (Anterior Posterior).

This coloring of the Cube is similar to how specimens are linked to show their orientation.

Orientation Markers can be displayed in each view to aid the user in associating each slice view to the precise anatomical direction.



Figure 79: Orientation Marker Button

Click the **Orientation Marker** button to toggle the markers on or off. The button only toggles the markers for that particular view or pane.

Orientation Markers will be displayed as follows:

- Medial, Lateral, Anterior, and Posterior in the upper left view,
- Inferior, Superior, Anterior, and Posterior in the upper right view, and
- Medial, Lateral, Superior, and Inferior in the lower left view.

Upper and lower left views shown below.

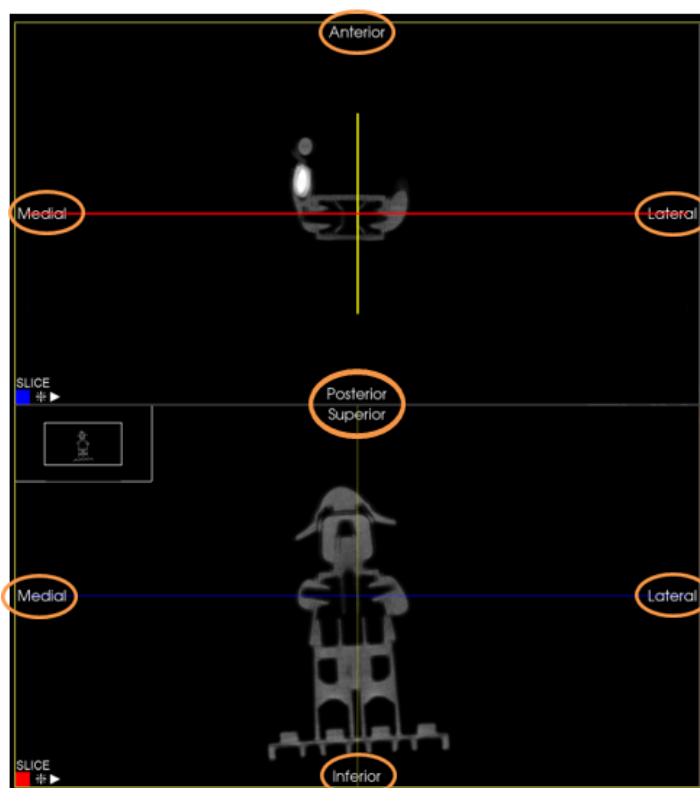


Figure 80: Faxitron CT Orientation Markers

6.8.2 Slice Views

The bottom right image is a reconstructed 3D view of the specimen. The other 3 views show the reconstructed specimen slices in each of the main axis.

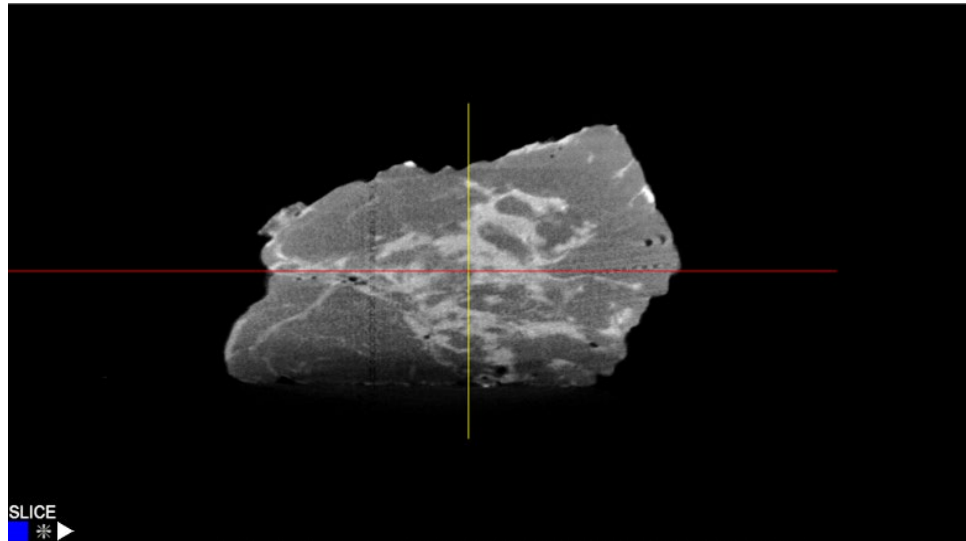


Figure 81: Faxitron CT Slice View

The blue colored square shows that the view above is the slice of the specimen through the blue line shown below.

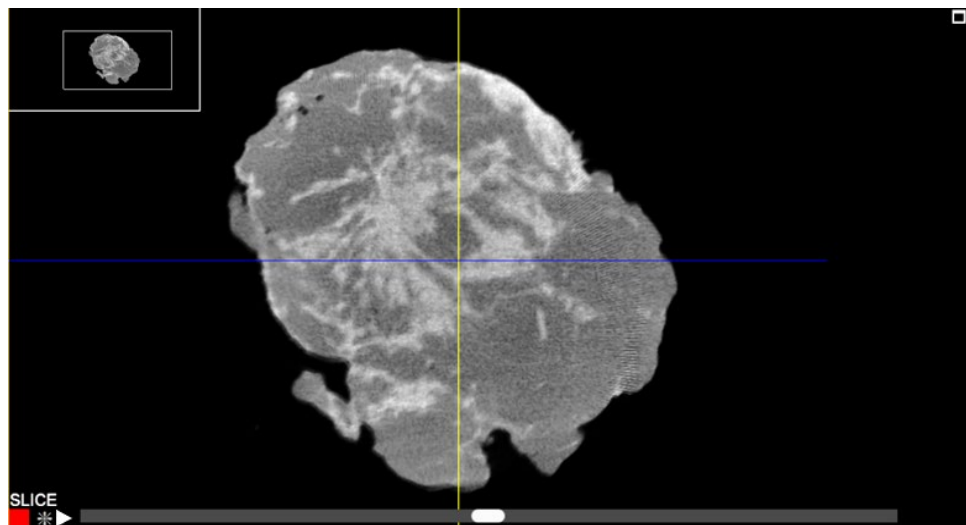


Figure 82: Faxitron CT Slice View

When a slice view is selected a scroll bar will appear under the image. Moving this scroll bar will adjust the position of the slice along an axis perpendicular to the screen. This is indicated by the corresponding line moving up and down in the other view.

In addition, by selecting the line in the other view it can be dragged up and down to move the slice position. This is the same for all 3 axes.

For example, as the scroll bar goes left the Red line on the other view moves down indicating the position of the slice.

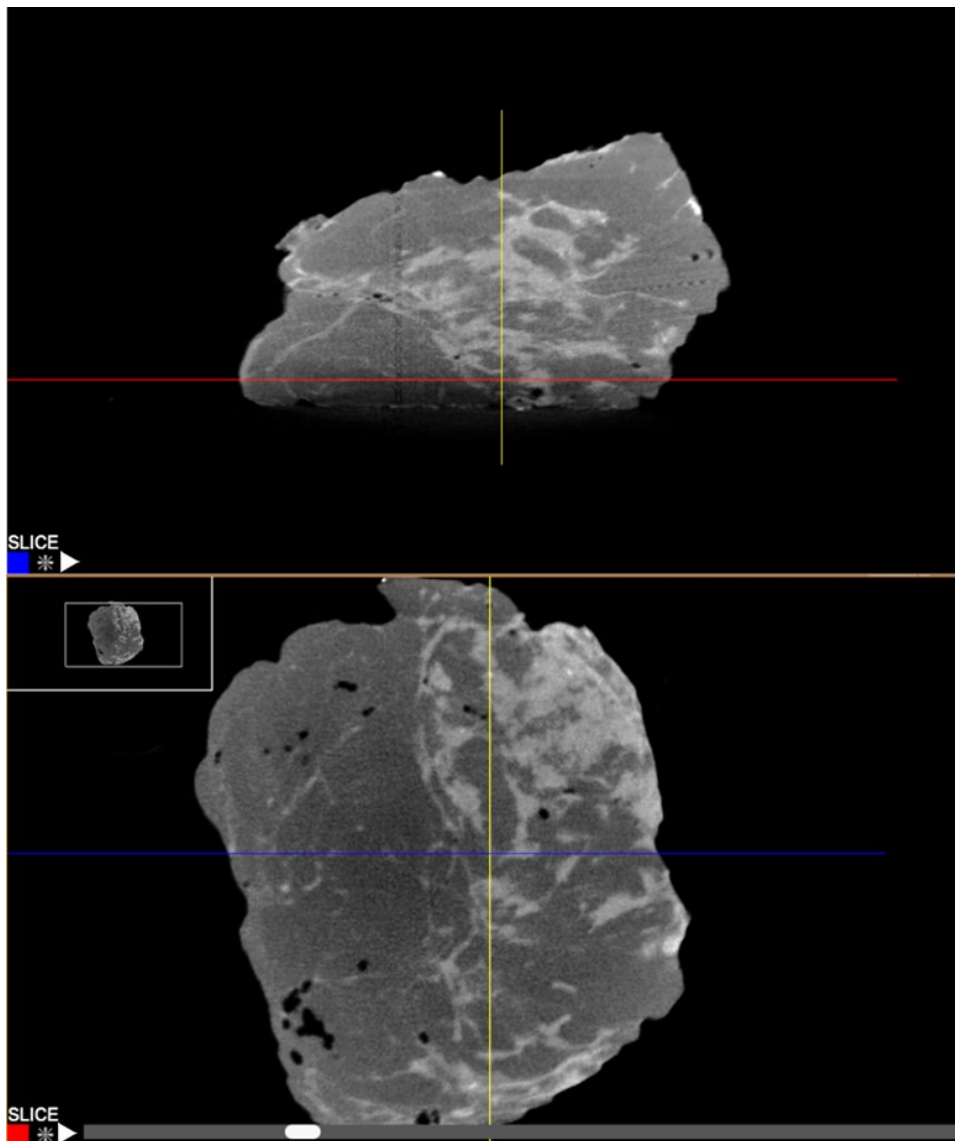


Figure 83: Faxitron CT Slice Views

6.8.3 MIP View

Each of the slices view can be changed to a MIP (Maximum Intensity Projection) view. This takes all the slices together and calculates the maximum brightness. This is very useful to find calcifications and markers within the tissue.

In this exchange the top image is the MIP view. By grabbing the line in the top view with a left click and hold, the user can move to a position that dissects an area of interest, like a calcification circled below. Then in the corresponding slice view the position of that

calcifications can be seen relative to the true edge of the specimen in the corresponding view below.

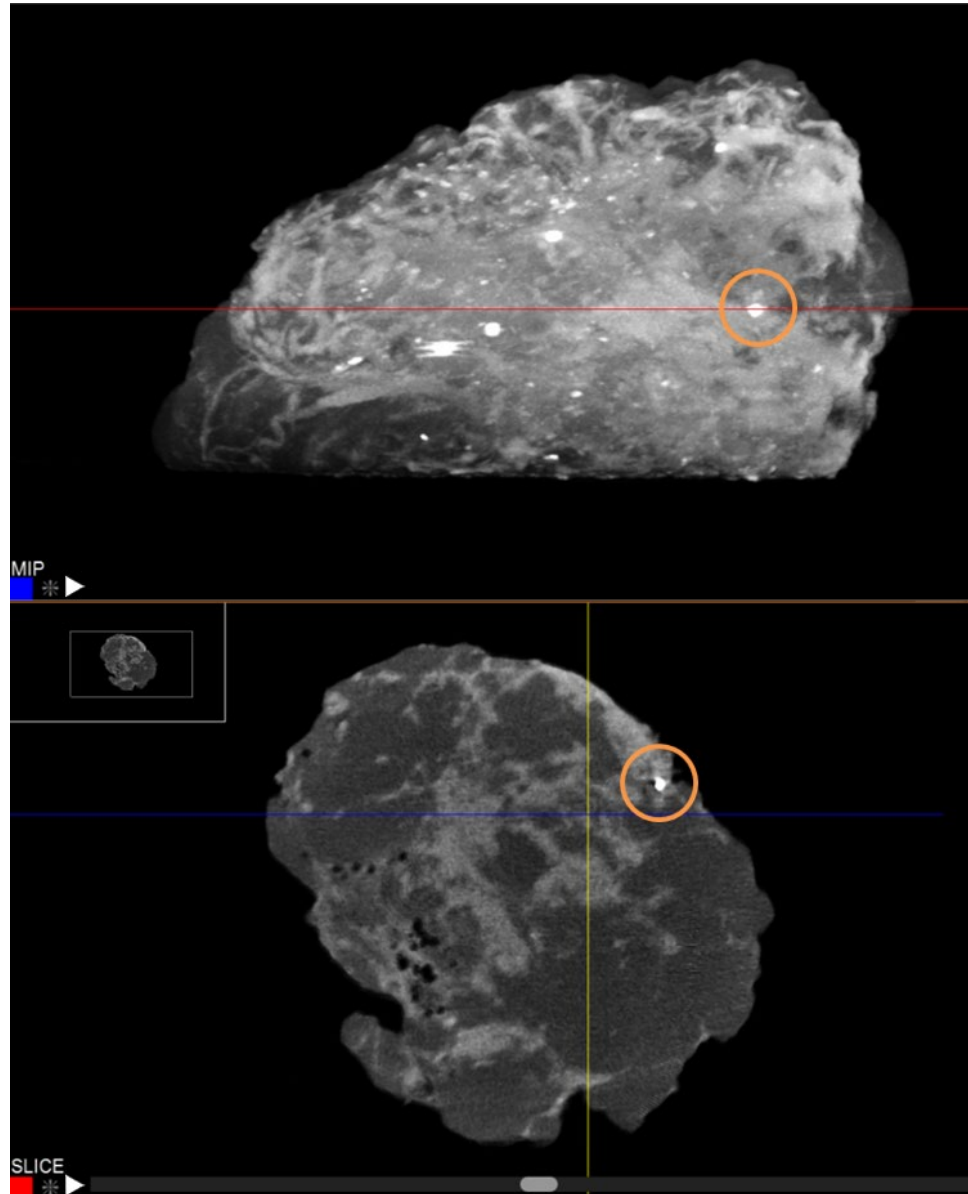


Figure 84: Faxitron CT MIP and Slice Views

To switch between MIP and SLICE view simply click on the word in the bottom left corner.

6.8.4 Hounsfield Units

The X, Y, and Z position of the cursor on the specimen, plus the Hounsfield unit, circled, are displayed in the top right of the view window.

The Hounsfield unit is a quantitative scale for describing radiosensitivity relative to water, defined as 0, and air, defined as -1000. It is frequently used in CT scans. Simply place the cursor over the area you want to measure. The following images show the Hounsfield Units for a fatty region, denser fibrous tissue, and a calcification, respectively.

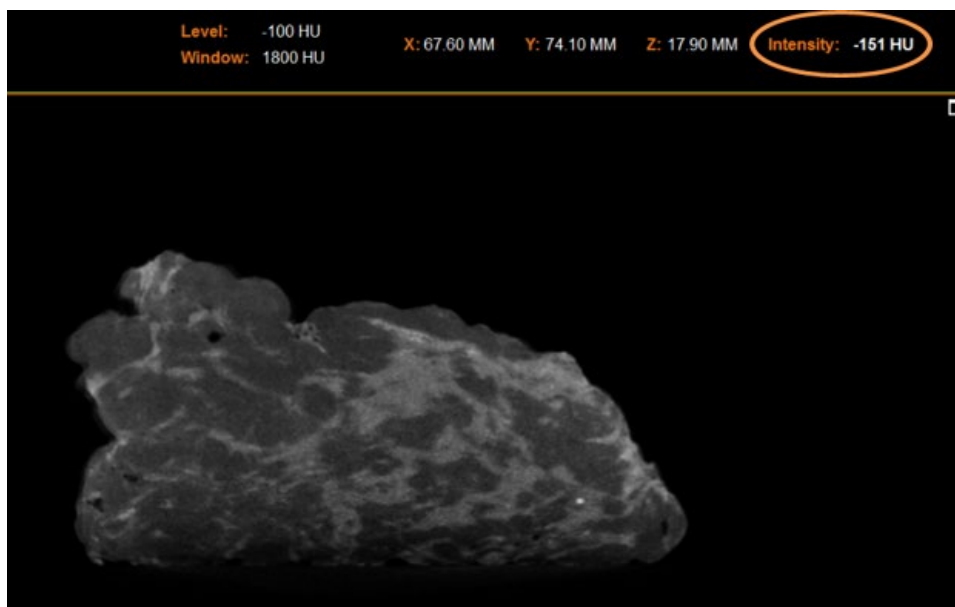


Figure 85: Hounsfield Units – Fatty Tissue



Figure 86: Hounsfield Units – Denser Fibrous Tissue



Figure 87: Hounsfield Units - Calcification

6.9 Current Patient Image History

Previous images captured during a procedure may be reviewed by clicking the **History** button at the bottom of the screen.

Figure 88: Image History Button



A “Thumbnail Strip” along the bottom will show thumbnails of the images captured during this procedure. Select the image you want to load onto the main view.

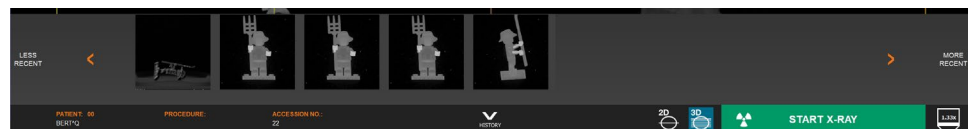


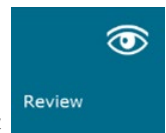
Figure 89: Image History Thumbnail Strip

The **History** button will point up when the Image History Thumbnail strip is hidden, and down when the strip is shown.

6.10 Review

Click the **Review** button in the Home Menu page to enter Review mode.

Figure 90: Review Mode Button in the Home Menu



The Review page is comprised of 4 sections. The Patient List at the top, the Procedure List on the lower left, the Image List on the lower right and the image preview in the middle.

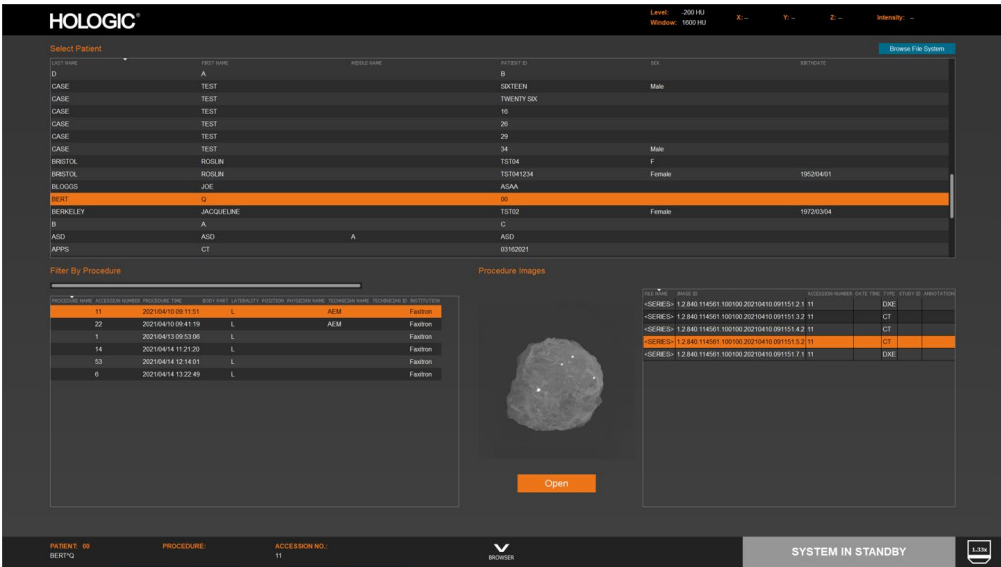


Figure 91: Review Page

Note that the system is in standby while in Review mode.

When the Review page is first opened only the Patient List will be populated. The lower part of the screen will be empty. Selecting a patient opens the Procedure List in the lower left part of the page. Selecting a procedure will then open the Image List in the lower right part of the page. Clicking on an image in the list will display an image preview in the lower middle section. Click the **Open** button to open the image in the viewer.

Once the image is opened it can be reviewed and manipulated in the same ways described before, including sending them to PACS.

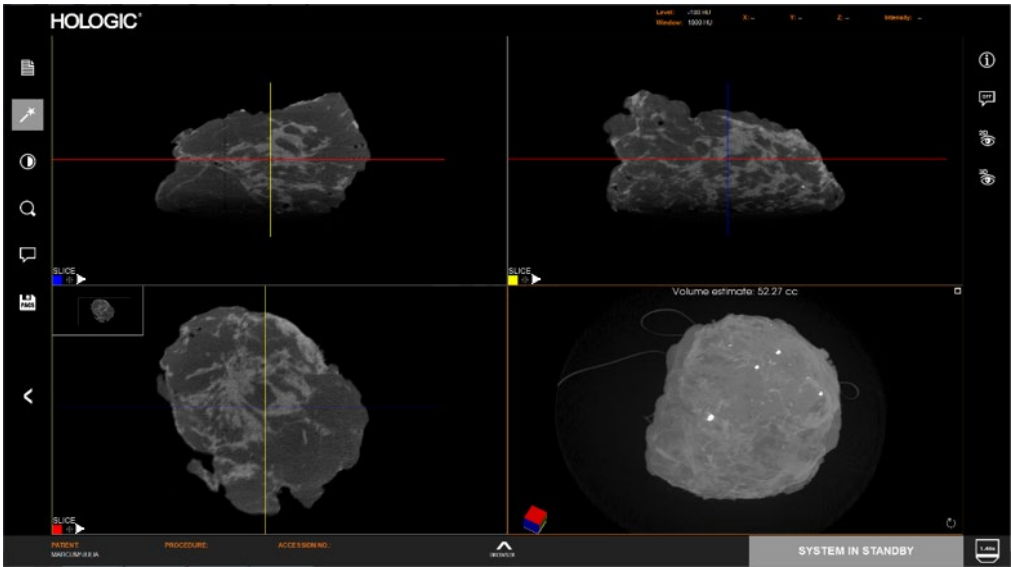


Figure 92: Viewer (Review Screen)

To go back to the REVIEW screen simply click the browser button at the bottom of the screen.

Figure 93: Browser Button



Images not in the Database can be opened by clicking the **Browse File System** button in the upper right corner of the Review Page. This will open a standard Windows browser where the user can locate images they want to review. If there are a series of images, simply pick one image in the series and the software will load them.

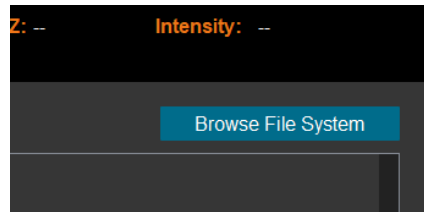


Figure 94: Browser File System Button

6.11 DICOM / PACS Functionality

DICOM Services Configuration

All images on the Faxitron CT are saved and transmitted to PACS in DICOM format.

To connect the system to a PACS server click on the settings page from the home screen.

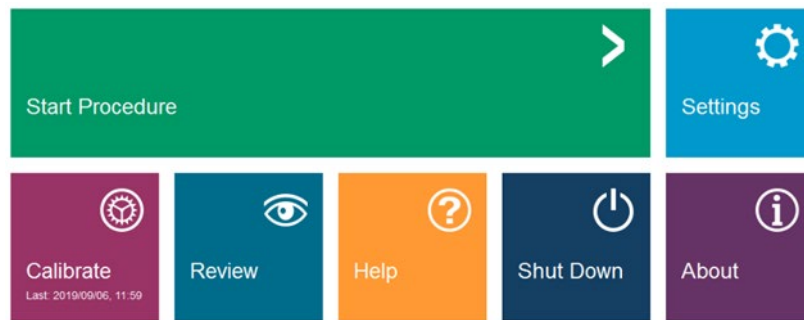


Figure 95: Home Menu

Then select the DICOM tab. Complete the fields in accordance with your system settings. You should work with the internal bio tech or IT department plus the Hologic representative to ensure that these setting are correct.

HOLOGIC®

Settings

Figure 96: DICOM Settings

Local Settings

- Institution Name, Institution Address, Station Name: Information included in DICOM images.
- Station AE Title: Identification of Faxitron CT in DICOM Store and DICOM Modality Worklist communications.

DICOM Store Settings

- Breast Specimen SOP Class, 2D: Images of breast tissue specimens can be transferred in Digital Mammography X-Ray Image Storage – For Presentation (MG), or Digital X-Ray Image Storage – For Presentation (DX) format, when Body Part is set to Breast in the Patient Information Editor dialog. All tissue specimens of other anatomy, or when Body Part is left blank, are transferred in Digital X-Ray Image Storage – For Presentation (DX) format.
- PACS Address, PACS AE Title, PACS Port: Identification of PACS that is to receive Faxitron CT images in DICOM format.

DICOM Modality Worklist Settings

- Work List Address, Work List AE Title, Work List Port: Identification of DICOM Modality Worklist provider that will respond to queries for scheduled specimen imaging procedures using **Select from Work List**.

6.12 Settings

DICOM settings are described in Section 6.11.

There are four (4) additional categories of settings access through the Home Menu **Settings** button:

**Note**

Access to most system settings is available only to authorized Hologic Service personnel.

Viewer Settings

These settings affect the image panes or views.

Figure 97: Viewer Settings

Directories

The settings to define the Default Directories are only available to authorized Hologic Service Personnel.

Imager Parameters

The 2 settings available to the user are the comm port settings for the x-ray subsystem and pedestal movement. These settings should only be changed as directed by Hologic personnel.

Figure 98: Imager Parameters

Image Enhancement

Image Enhancement settings are only available to authorized Hologic Service personnel.

6.13 About

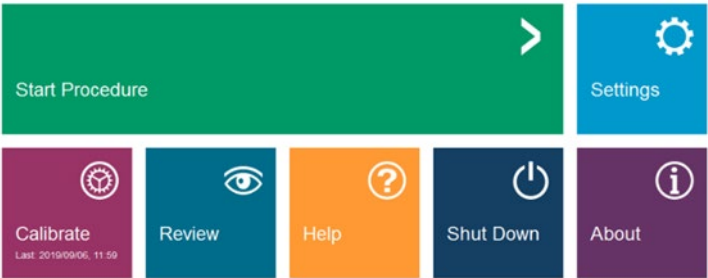


Figure 99: Home Menu

Clicking **About** from the Home Menu will open an information window shown below. The About window provides software version and imager information.

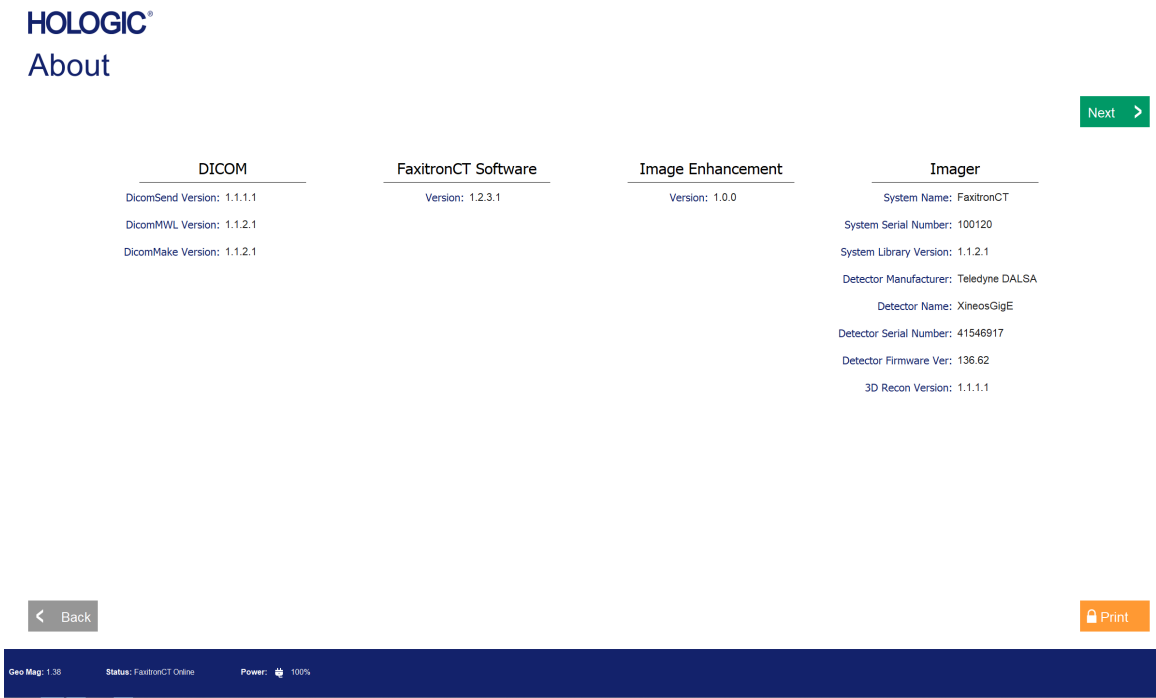


Figure 100: About Faxitron CT – System Information

6.14 Help

Clicking the **Help** button brings the user to the Help page.

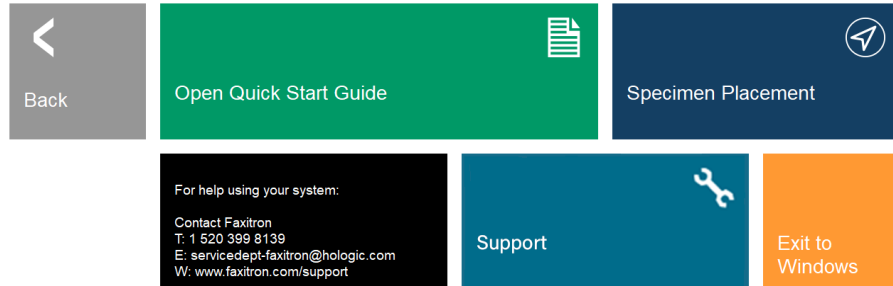


Figure 101: Help Menu

From the Help menu you can:

- **Open the Quick Start Guide,**
- View a short animation demonstrating the proper **Specimen Placement,**
- Get the contact information for help in using your system,
- The **Support** button provides information on contacting Hologic's technical support team and
- **Exit to Windows.**

Chapter 7 Quality Control

7.1 Required Quality Control Procedures

The following procedures are necessary for correct system operation.

Table 1: Required Procedures

Procedures	Frequency	Instructions
Image Calibration	Daily	Section 5.1
Geometric Calibration	Quarterly	Section 5.2
Uniformity Calibration	Quarterly	Section 5.3

7.2 Service and Troubleshooting

7.2.1 Service

There are no serviceable parts in the Faxitron CT. Refer to the copyright page at the front of this manual.

7.2.2 Troubleshooting

The following are a few issues that you may be able to solve with some basic troubleshooting steps.

Computer or System will not turn on.

- No power to the computer or X-Ray system.
- Verify power to system is ON and power cables are plugged in and the rear power switch is set to (I) ON.

System turned off when acquiring 3D image.

- The must be on mains power to acquire an image. If not, the power could overload the UPS and shut down.
- Check to make sure the system is connected to mains and the power inlet is switched on.

There appears to be another object in the image.

- Verify that during "Calibration" there were no objects in the X-ray chamber, including the disposable tray.
- Remove objects and repeat Calibration.

Poor image quality.

- If artifacts are seen in the image complete a full Calibration.

7.3 Cybersecurity

If a cybersecurity event occurs disconnect the system from the network and contact Hologic immediately. We will work with your IT department to resolve the issue.

A cybersecurity event can be detected in a number of ways:

- Slower than normal operation and/or network connection.
- Suspicious pop-ups or home page changed in internet browser.
- Password(s) no longer working.
- Unidentified programs in start menu or system tray.
- Missing, corrupt, or altered data.

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 solution and water with one part commercially available chlorine bleach solution (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 Component Specific Care

8.2.1 How to Clean the Image Display Monitor

- 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 Power Cord

How to Inspect the Power Cord

1. Once every quarter, visually inspect the power cord for cuts, damage to the cover, or strain relief.
2. If the power cord appears damaged, contact Hologic for replacement of the power cord.

8.3 Maintenance

8.3.1 Preventive Maintenance Schedules

<i>Table 2: User Preventive Maintenance</i>			
Action	Daily	Quarterly	As Required
Perform Image Calibration	✓		
Perform Geometric Calibration		✓	
Perform Uniformity Calibration		✓	
Clean and disinfect the Imaging Cabinet chamber			✓
Clean and disinfect the cabinet door handle			✓
Clean and disinfect the control display surface			✓

<i>Table 3: Service Preventive Maintenance</i>			
Action	Annually	Semi-Annually	As Needed
X-ray Tube Conditioning			<i>Note 1</i>
Operational/Safety Checks	✓		
Perform kV Verification	✓		
Image Quality Checks	✓		
Check and Adjust Low Voltage Power Supply	✓		
Perform Radiographic Survey		✓	

Appendix A System Specifications

A.1 Product Measurements

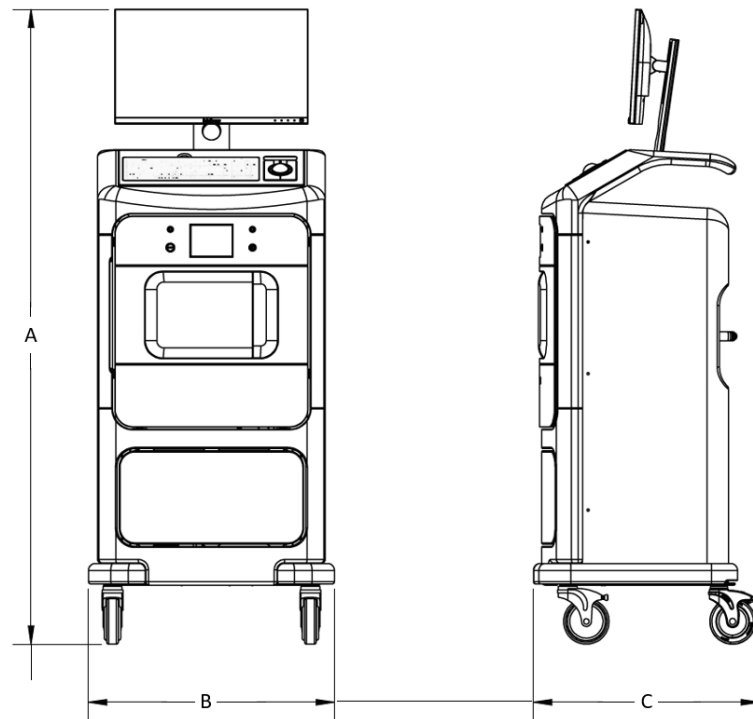


Figure 102: Cabinet Measurements

A.	Height	180 cm (70 inches)
B.	Width	70 cm (27 inches)
C.	Depth	65 cm (25 inches)
	Weight	140 kg (315 pounds)
		290 kg (640 pounds) – (Shipping)

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:

<i>Altitude</i>	<i>To 2,000 m (5,562 feet)</i>
<i>Degree of Pollution</i>	<i>Pollution Degree 2</i>
<i>Temperature Range</i>	<i>15.5 °C (60 °F) to 30 °C (86 °F)</i>
<i>Relative Humidity Range</i>	<i><75%</i>
<i>Over-voltage Category</i>	<i>II</i>

A.2.2 General Conditions for Transport and Storage

<i>Temperature Range</i>	<i>–20 °C (–4 °F) to 50 °C (122 °F)</i>
<i>Relative Humidity Range</i>	<i>20% to 90% without condensing moisture</i>

A.3 Technical Specification

A.3.1 System Specifications

<i>Spatial Resolution</i>	100 μ m or better
<i>Source to Imager Distance (SID)</i>	14.4" (36.6cm)
<i>Exposure Control</i>	Fully Automatic (or fixed)
<i>Geometric Magnification</i>	1.2X to 4.0X (Automatically optimized depending on specimen size)
<i>Imaging Area</i>	15cm x 15cm
<i>Energy Range</i>	15kV to 50kV
<i>Typical Image Acquisition time</i>	~25 seconds for 2D ~210 seconds for 3D without MAC (Metal Artifact Correction), and ~330 seconds for 3D with MAC
<i>Target Material</i>	Tungsten (W)
<i>Beryllium Window Thickness</i>	254 μ m (0.010")
<i>Tube Current</i>	1.0mA max (Isowatt Limited to 11.5W max)
<i>X-Ray Duty Cycle</i>	75%
<i>Focal Spot Size</i>	< 15 microns
<i>Input Power</i>	100-240VAC, 50/60Hz, 200VA Max
<i>DICOM Interface</i>	Store, Print, Annotate, Modality Worklist, and CT Image Modality capabilities

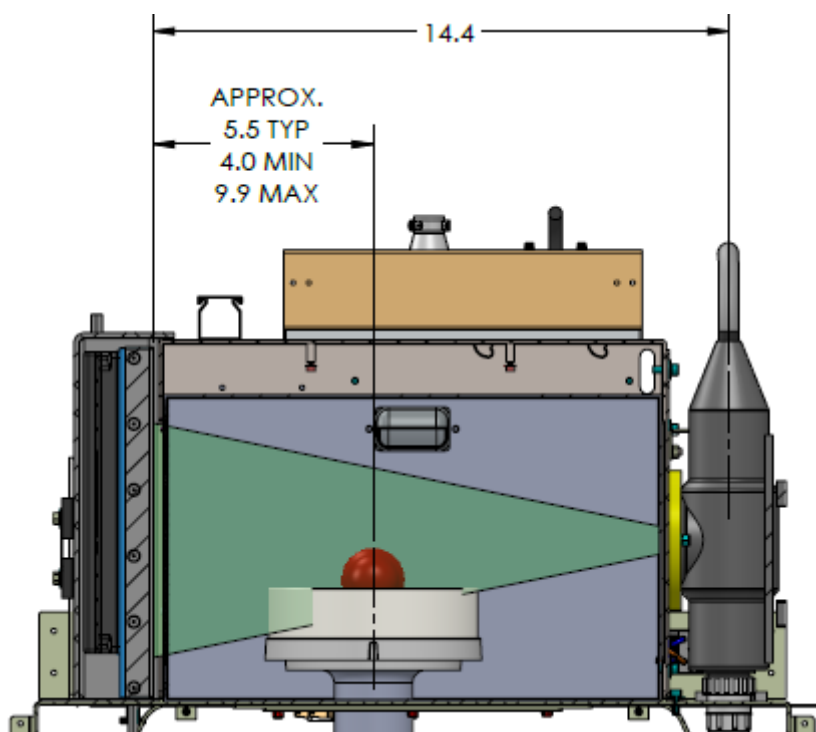
A.3.2 X-Ray CMOS Detector

<i>Detector Pixels:</i>	1548 x 1548 @ 99 μ m pitch
<i>Frame Rate:</i>	Typically, 2.5 fps for best image quality, (max 22 fps)
<i>Saturation Dose:</i>	14 μ Gy
<i>Dynamic Range:</i>	76dB
<i>DQE (@ 0 lp/mm, RQA5):</i>	70%
<i>Scintillator:</i>	Medical grade columnar cesium-iodide Dx1 (TI)

A.3.3 Object to Imager and Source to Object Distance Chart

<i>Mag Position. Factor</i>	<i>OID cm (inches)</i>	<i>SOD cm (inches)</i>
4	25.1 (9.9")	1.8 (4.5")
1.4	14.0 (5.5")	3.5 (8.9")
1.2	10.2 (4.0")	4.1 (10.4")

See Figure on next page.



Object to Imager dimensions shown at 1.2x magnification (minimum), 1.4x magnification (typical), and 1.4x magnification (maximum)

Figure 103: Source to Imager and Object to Imager Dimensions

A.3.4 X-ray Tube Technical Information

Hologic P/N:	130-552025
Manufacturer P/N:	MF90150 (Oxford Instruments)
<i>Max Anode Voltage</i>	50 kV
<i>Max Anode Current*</i>	1.0 mA
<i>Maximum Power</i>	12W continuous (Isowatt limited to 11.5W max)
<i>Focal Spot Size</i>	<15 μ m
<i>Anode Material / (Target)</i>	Tungsten (W)
<i>Cooling</i>	Air cooled, 150 CFM at 100mm (4.0") recommended
<i>Beryllium Window Thickness</i>	0.25mm (0.010")
<i>Window Material</i>	Be 98.5%
<i>Cone Angle</i>	40.5 Degrees \pm 0.5°
<i>Maximum Operating Temperature</i>	50°C (at potting surface)
<i>Ambient Operating Conditions</i>	0°C to 40°C; 0-95% RH up to 5,000ft
<i>Weight</i>	3 lbs
<i>Storage Temperature Range</i>	-10°C - 55°C
<i>Storage Humidity Range</i>	10-90% (no condensation)

A.3.5 Computer Specifications

This table provides minimum recommended specifications at time of publication.

Hologic P/N: 2001-0031

<i>Processor</i>	Intel® Core™ i7-7700 (4 Cores)	
<i>Operating System</i>	Windows 10 Enterprise LTSC (64 bit)	
<i>System RAM</i>	32 GB, DDR4, 2666MHz	
<i>Hard Drive</i>	3.5-inch 4TB 7200rpm SATA	
	2.5-inch 480GB SATA MLC/TC	
<i>Optical Drive</i>	DVD-RW SATA	
<i>Network Connectivity</i>	Integrated Intel® i219LM Ethernet + Intel® i21AT LAN 10/100/1000	
<i>USB Ports</i>	FRONT Panel USB 2.0 – 2X	REAR Panel USB 2.0 – 2X USB 3.0 – 4X
<i>Graphics Card</i>	GeForce® RTX 2080 Ti 11GB GDDR6 Memory Or NVIDIA Quadro RTX5000 16GB GDDR6 Memory	
<i>Case/Chassis</i>	4U Rack Mount	
<i>Dimensions (H x W x D)</i>	6.9" x 16.8" x 16.1" (17.5cm x 42.7cm x 40.9cm)	
<i>Min. Weight</i>	34.8 lbs (15.8 kg)	
<i>Monitor</i>	24" 2560 x 1440 (3.7MPX) Native Resolutions 1000:1 Contrast Ratio 300 cd/m ² Brightness Display Port Input	

Glossary of Terms

AEC

Automatic Exposure Control

Annotations

Markings on an image to indicate an area of interest.

Anterior

In front of, at or near the front of the body.

Caudal (Inferior)

Toward the back or tail

CT

Computed Tomography

DICOM

Digital Imaging and Communications in Medicine

Hounsfield Units

A quantitative scale for describing radiosensitivity relative to water, defined as 0, and air, defined as -1000.

Inferior (Caudal)

Below, under, away from the head/upper part of a structure.

Lateral (Latero)

Toward the side, away from the midline, farther from midline.

Medial (Medio)

Toward the midline, away from the side, nearer to midline.

PACS

Picture Archiving and Communications System. A computer and network system that transmits and archives digital medical images.

Posterior

After, behind, at or near the back of the body.

OID

Object to Imager Distance

ROI

Region of Interest

SID

Source to Image Distance

Superior

Above, over, toward the head/upper part of a structure.

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