

Faxitron[®] CT

Specimen Radiography System



User's Manual

from Hologic[®]

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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. Always follow all the instructions in this manual. Faxitron Bioptics, LLC does not accept responsibility for injury or damage from incorrect system operation. Faxitron Bioptics, LLC can arrange for training at your site.

Revision Record

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Foreword

This manual was created by Faxitron Bioptics LLC. It is intended to guide the user on how to setup, install and use the Faxitron CT hardware and the Software System, both developed by Faxitron Bioptics LLC.

Faxitron CT was previously known as VisionCT, and associated software was referenced as Vision software. The software is now referred to as the Faxitron CT software.

The user must first setup the hardware, then initiate the Faxitron CT Software. Please review the required setup procedures in Part 2 of this manual before continuing.

Intended Use

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.

✓Prescription use (Part 21 CFR 801 Subpart D)

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

The system can operate as a stand alone device. If connected to a network it is critical that measures are implemented to reduce the risk to patients by decreasing the likelihood that device functionality is intentionally or unintentionally compromised by inadequate cybersecurity.

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SECTION 1
Introduction

This manual was created by Faxitron Bioptics LLC. It is intended to guide the user on how to setup, install and use the Faxitron CT hardware and the Software, both developed by Faxitron Bioptics LLC.

The user must first setup the hardware, then initiate the Faxitron CT Software. At a minimum, please review the required setup and safety procedures in this manual before attempting to operate the system.

The Faxitron CT comes as a mobile device and has an internal uninterruptable power supply (UPS) to allow it to be moved without powering down the system.

Thank you from all of us at Faxitron Bioptics LLC.

Additional Information

For further technical assistance, contact:



Faxitron Bioptics LLC (a Hologic company)

3440 E. Britannia Dr. Suite# 150
Tucson, AZ 85706
+1 (520) 399-8139
+1 (520) 514-8182 Fax
www.hologic.com



Authorized European Representative

Hologic BVBA
Da Vincilaan 5
1930 Zaventem
Belgium
Tel: +32 2 711 46 80
Fax: +32 2 725 20 87

The following symbols are used in this manual and online help system:

Warns the reader of potential electrocution should the reader ignore the warning and deliberately use specialized tools to open a sealed electrical cabinet and handle its contents. Note: No tools are provided by Faxitron Bioptics LLC.



Warns the reader of a hazardous condition. This symbol is generally accompanied by a more specific symbol and appropriate instructions as to the nature of the hazard, the expected outcome of the hazard, and information on avoiding the hazard.



Cautions the reader to use care in lifting heavy equipment in order to avoid personal injury and damage to the equipment.



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
















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



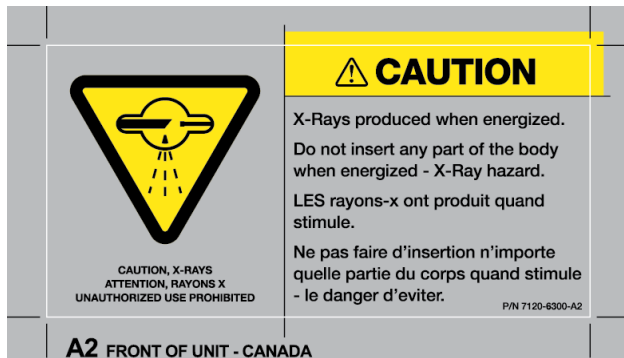
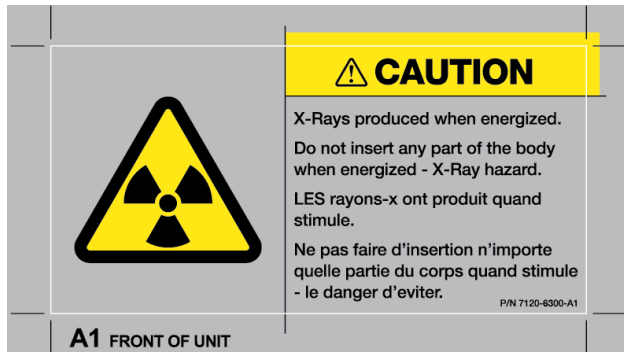
1.0.0 Introduction

1.1.0 Warning and Caution Symbols in this Manual

1.1.1 Warning and Caution Symbols On Labels

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

Label A – Standard and Canadian Versions

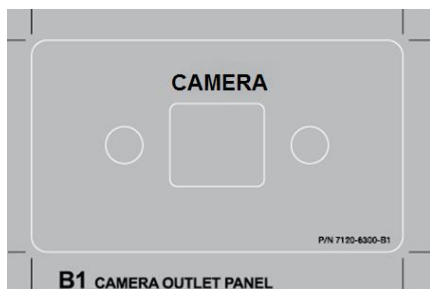


1.2.0

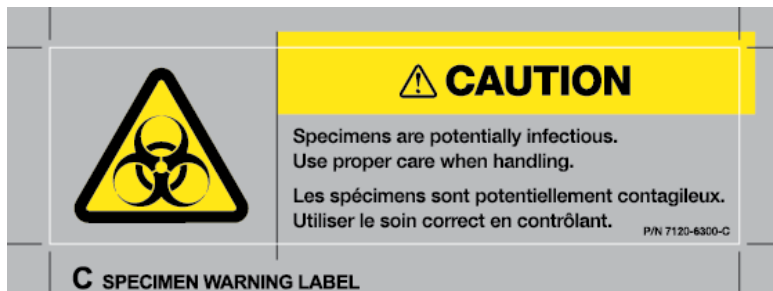
Product Labels

*Figure 1.3.1
Warning and Safety Labels*

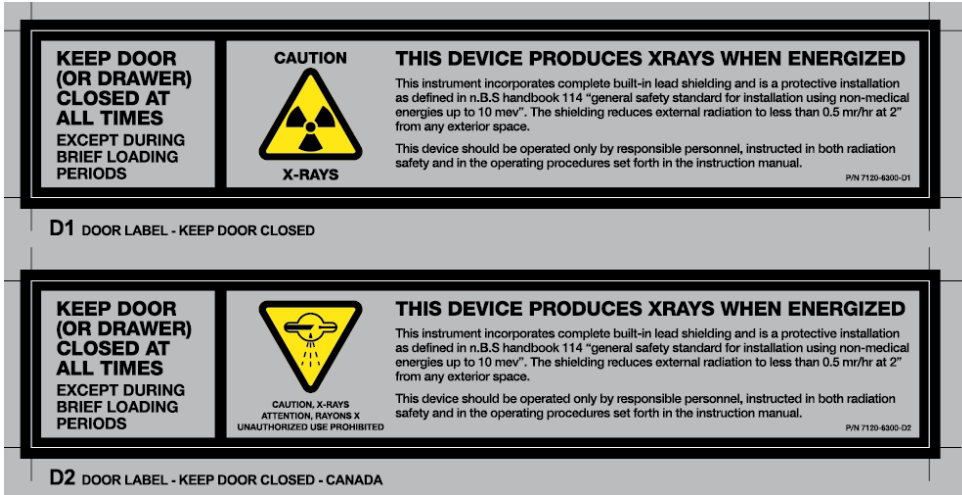
Label B



Label C



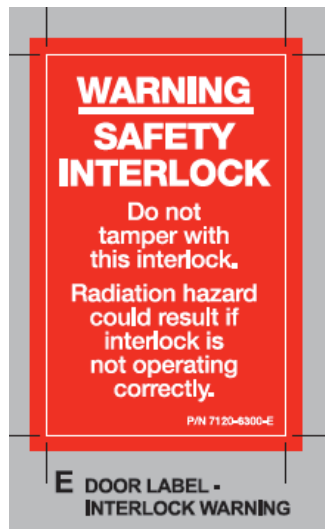
Label D – Standard and Canadian Version



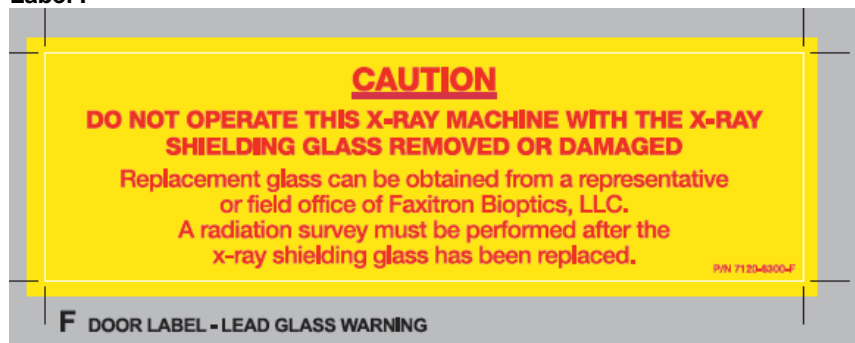
1.2.0 Product Labels

Figure 1.3.1 (Continued)
Warning and Safety Labels

Label E



Label F



Label G

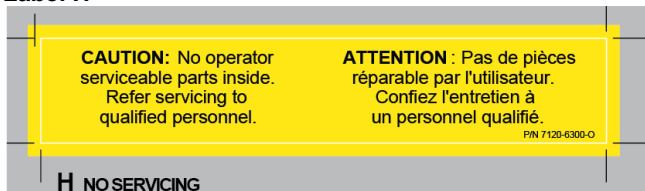


1.2.0

Product Labels

*Figure 1.3.1 (Continued)
Warning and Safety Labels*

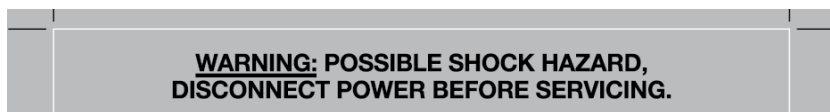
Label H









Label K



Label L









Barcode, Identification and Compliance Label - Mobile System 120VAC

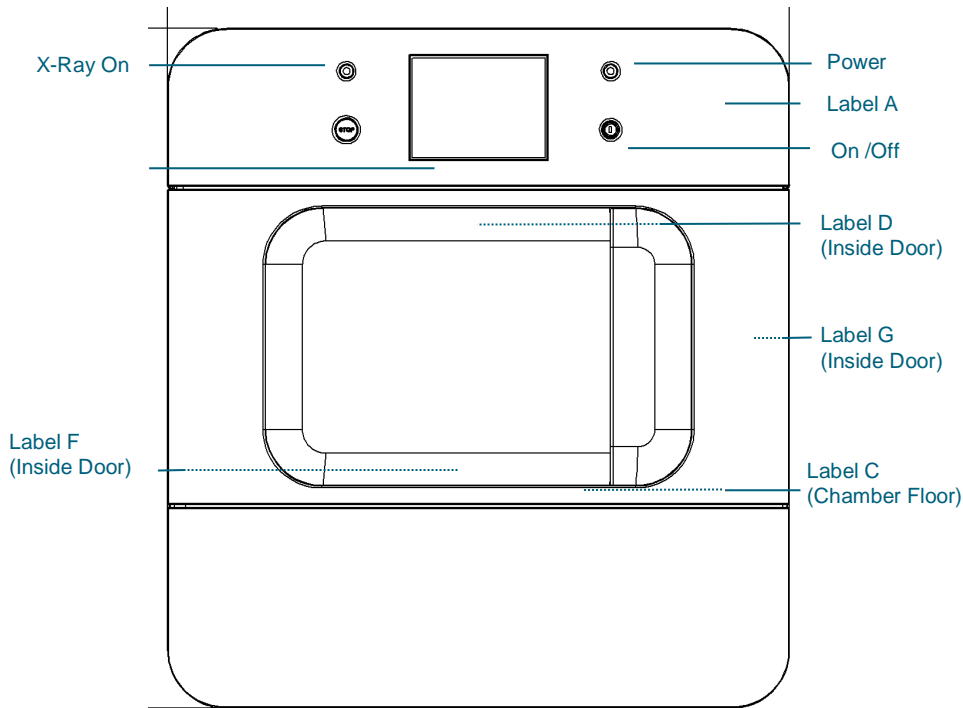
 (01) 00857069006302 (11) 190916 (21) 2333A100103 Model: FAX-019 Mfg Date: September 2019 Serial No: 2333A100103 Faxitron CT Digital Specimen Radiography System	
<p>Faxitron Bioptics, LLC. 3440 E. Britannia Dr., Suite 150, Tucson, Arizona 85706, U.S.A.</p> <p>(520) 399-8180 www.faxitron.com service@faxitron.com</p>	<p>Complies with DHHS Radiation Performance Standards, 21 CFR, Subchapter J</p> <p>Conforms to: IEC 61010-1:2010 Ed.3</p> <p>FCC 47CFR 15B cIA</p> <p>EU Directives: IVDD 98/79/EEC EMC 2004/108/EC</p> <p>Certified to CSA STD: C22.2 NO 61010-1 C22.2 NO 61010-2-101</p>
<p>Input Voltage</p> <p>120 VAC</p> <p>60 Hz</p> <p>700W MAX</p>	 Intertek 3113109    
<p>AW-20228 Rev.001</p>	

**1.2.0
Product Labels**

*Figure 1.3.1 (Continued)
Warning and Safety Labels*

Barcode, Identification and Compliance Label - Mobile System 230VAC

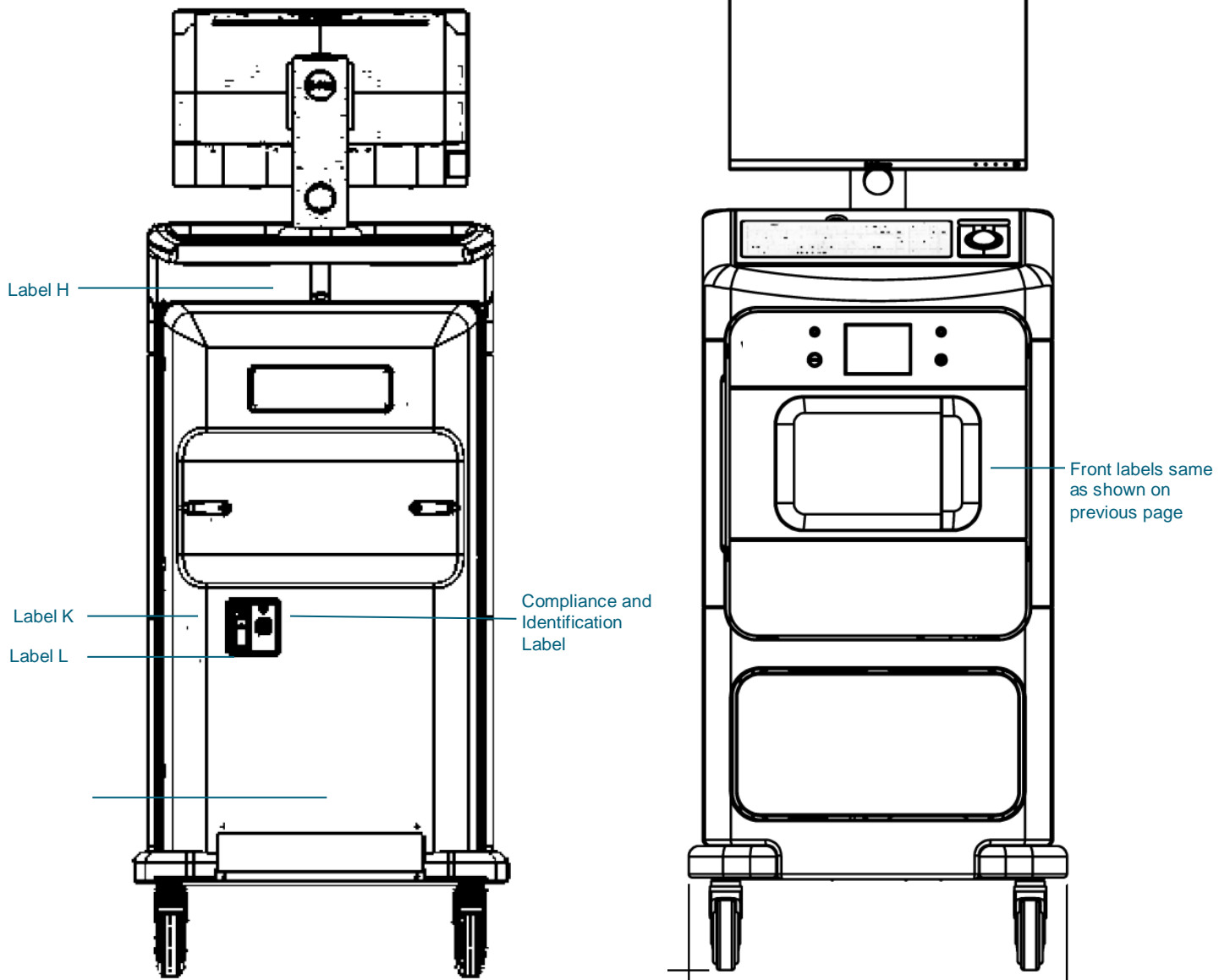
 (01) 00857069006319 (11) 190916 (21) 2333A100102 Model: FAX-020-INT Mfg Date: September 2019 Serial No: 2333A100102 Faxitron CT Digital Specimen Radiography System	
<p>Faxitron Bioptics, LLC. 3440 E. Britannia Dr., Suite 150, Tucson, Arizona 85706, U.S.A.</p> <p>(520) 399-8180 www.faxitron.com service@faxitron.com</p>	<p>Complies with DHHS Radiation Performance Standards, 21 CFR, Subchapter J</p> <p>Conforms to: IEC 61010-1:2010 Ed.3</p> <p>FCC 47CFR 15B cIA</p> <p>EU Directives: IVDD 98/79/EEC EMC 2004/108/EC</p> <p>Certified to CSA STD: C22.2 NO 61010-1 C22.2 NO 61010-2-101</p>
<p>Input Voltage</p> <p>230 VAC</p> <p>50 Hz</p> <p>700W MAX</p>	 Intertek 3113109    
<p>AW-20229 Rev.001</p>	



1.2.0 Cont. Product Labels

Figure 1.3.2
Label Locations
Continued on next page

Label G used on the inside for the Tube, Camera and Lower Rear Cover Interlock.



2

SECTION 2
Installation and Set-up

Warnings

- Please read the instructions carefully before using the system.
- Do not use the system in any other way than its intended use as described in this manual. If in doubt contact Hologic or your authorized distributor.
- Not all power cords have the same rating. Do not use any other power cord with this system other than the one provided. Do not use the power cord from this system on any other equipment.
- This system is tested to the highest international standards, however it is recommended that you contact your national authorities recording any local operational requirements.
- This system is not intended for public use. It must be located in an area where the general public cannot access the system without an operator being present.

2.1.0 System Warnings & Precautions



General Precautions

The following precautions must be taken to prevent damage to your Faxitron CT System:

- Never connect or disconnect communication and/or power cables, while the camera system power is on. Damage to the CMOS detector or the camera electronics may occur if the cables are connected / disconnected while the power is on.
- The camera system is fragile and care should be taken in order to prevent camera damage. The camera system must never be mishandled, hit, knocked or dropped.
- The Faxitron CT System has a calibration mode. Calibration must be completed daily to ensure proper system function. Please refer to the Calibration Procedure.
- Caution – Use of controls, or adjustments to performance of procedures, other than those specified herein may result in hazardous radiation exposure



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 Communication 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 version. 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

Cybersecurity

Device security is a shared responsibility between Faxitron and the health care facilities. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. Faxitron maintains a set of cybersecurity controls to assure the cybersecurity of its units and to maintain their functionality and safety.

All our units use standard Windows operating system. At installation, we recommend the facility install all the necessary security measures as defined by their own internal requirements, as they would with any other PC connected to the network.

The facility can set up the Windows operating system with all the network protocols and permissions necessary. For example, they can add

- User ID and passwords,
- Layered authorization with appropriate authentication,
- Restrictions on software installations,
- Trusted content requirements, including code signature verification,
- Set up windows updates including security releases.

In addition, our imaging software is password protected so certain users can get on to the operating system without being able to open the software.

This unit is designed to be used either as a standalone unit or connected to the Facility's internal PACS or another closed-loop network. It is not intended to be connected to the Internet, unless (a) the Facility is specifically instructed to do so by Faxitron, or (b) the Facility takes adequate precautions to ensure the cybersecurity of the unit from threats related to its Internet connection.

Faxitron will develop updates or patches for the Faxitron software to continue to assure the product's safety, as needed throughout the lifecycle of the unit.

Additional security measures, including encryption, can be implemented and Faxitron can work with the facilities IT department to reduce the risk to patients as a result of cybersecurity breach. The Faxitron CT should be set up by an authorized representative. Contact your local representative to confirm that the system has arrived and to arrange a time for system installation and setup.

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

Cleaning

Internal Chamber

Samples containing biological specimens can harbor infectious agents that are hazardous to your health. Follow appropriate biosafety procedures; wear gloves when handling tissue specimens or any materials which they come in contact with.

Periodically wipe down the interior of the cabinet with 70-90% isopropyl alcohol or diluted sodium hypochlorite (5.25%-6.15% household bleach diluted 1:500 provides the proper concentration). Ensure the specimen area, marked on the chamber floor, is thoroughly cleaned

External

Periodically wipe down the system with mild soap and water using a moistened cloth. No harsh abrasives, chemicals or cleaners should be used on the system. Do not allow any moisture whatsoever to come in contact with the electrical components of the unit.

2.1.0 Cont. System Warnings & Precautions



The Faxitron CT should be set up by a Hologic authorized representative. Contact your local representative to confirm that the system has arrived and to arrange a time for system installation and setup.

2.2.0 Faxitron CT System Setup

Inspecting the Crates

The Faxitron CT System arrives in one large wooden crate. Have the shipping agent transport the crates to an area where they can be kept safe from theft, damage, and environmental extremes until an authorized representative can install the system.

Check crate for any damage. If it appears to be damaged, contact Hologic at +1 520-399-8139.

The crate is about 5 feet tall. It contains the specimen unit, the display monitor, the computer, and the system manuals.

Lifting and Transporting the Crates

Caution: The crate weighs approximately 315 pounds (140 kg). The packaged system should be kept upright as indicated on the shipping crates.



Unpacking and Installing the System

The Faxitron CT system will be unpacked and assembled on site by a Hologic authorized representative. Please contact your local representative when your system arrives to arrange for system setup.

During Installation, the representative will conduct a radiation scan, safety and operational test – see Section 8 for details.

Location & Building Requirements

The Faxitron CT system has ventilation and the power entry connector is at the rear of the cabinet. Leave at least 6" (15cm) of clear space behind the unit when installed to allow the air to flow and give the user access to disconnect the power cord.

The system is mobile and can be transported across a smooth floor. Avoid going over any uneven floors as the internal imaging system is sensitive to shocks.



Environmental Conditions

Operational:

Temperature: 15.5 to 30 degrees C or 60 to 86 degrees F.
Relative humidity: < 75 percent.

Storage and transport:

Temperature: 0 to 45 degrees C or 32 to 113 degrees F.
Relative humidity: < 75 percent.

This equipment is designed for the following conditions:

- Indoor use
- Altitude up to 2000 meters
- Pollution Degree 2
- Over-voltage Category II

RADIATION SAFETY

- Radiation shielded cabinet.
- Compartment door equipped with dual safety interlocks.
- Radiation: Less than 0.1 mR/hr at 5 cm (2 in.) from exterior surface at maximum kV.
- Certified to comply with standards set by the US Food and Drug Administration, Center for Devices and Radiological Health, (21 CFR-1020.40).
- Designed to comply with standards set forth by Underwriters Laboratories in the US and Canada.

X-RAY TUBE

Focal spot size	< 15 um
kV	15-50kV
mA	1.0mA max
Power	Isowatt limited to 11.5W max
Beryllium window thickness	0.010"(254um)
X-ray beam divergence	40 deg. min.
Target Material	Tungsten (W)

RADIOGRAPHIC MAGNIFICATION: Variable

EXPOSURE CONTROL: Automatic or Manual.

X-RAY DUTY CYCLE: 75%

POWER REQUIREMENTS: 100 - 240 VAC, 50/60 Hz, 200VA Max
Note: The system requires a dedicated 10A outlet.

MINIMUM PC SPECIFICATIONS

- Full height PC with at least 2 PCIe card slots
- 3.0GHz or higher
- At least 8GB of RAM computer memory
- 500Gb Hard Drive
- Nvidia Graphics card with at least 2GB video memory
- 24 inch or better monitor with at min 1280x1024 resolution
- 6x USB Slots including 2x USB 3.0
- 2x Ethernet ports including one with 9000 bytes jumbo packet
- Windows 10 OS based PC
- Internet Browser

2.3.0

Faxitron CT Specifications

X-RAY CMOS DETECTOR

Detector Size: 15cm x 15cm

Detector Pixels: 1548 x 1548 @ 99um pitch

Spatial Resolution: 100um or better

Frame Rate: Typically, 2.5 fps for best image quality, (max 22 fps)

Saturation Dose: 14uGy

Dynamic Range: 76dB

DQE (@0 lp/mm, RQA5): 70%

Scintillator: Medical grade columnar cesium-iodide CsI (TI)

2.3.0 Cont. Faxitron CT Specifications

EXTERIOR DIMENSIONS (Approximate)

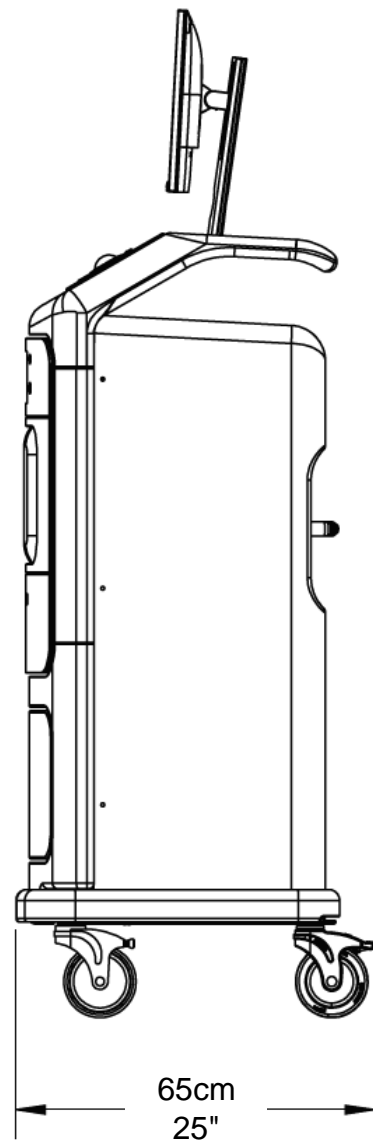
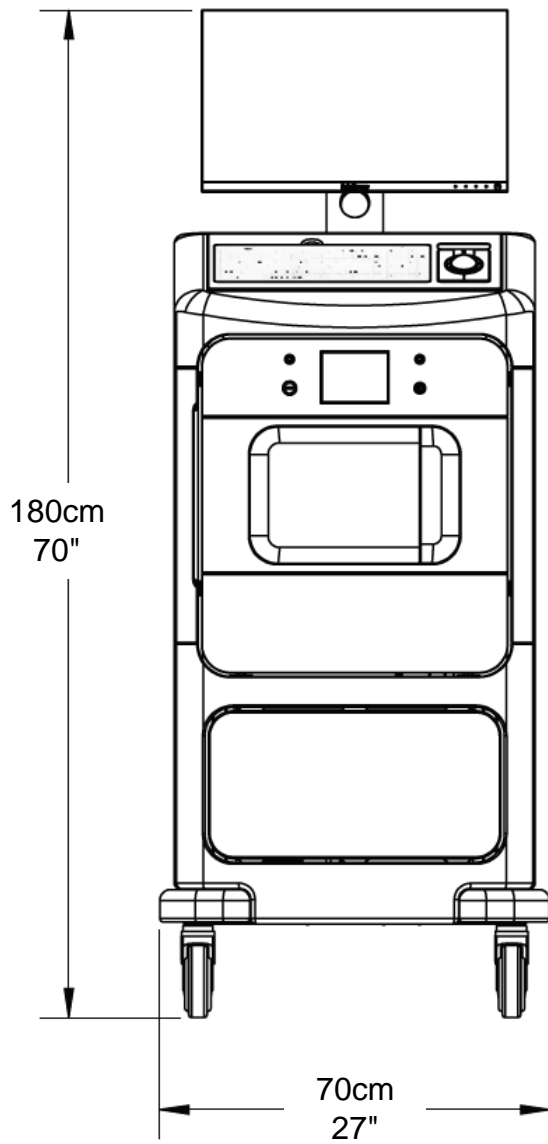
	cm	inches
Height	180	70
Width	70	27
Depth	65	25

COMPARTMENT INTERIOR DIMENSIONS (Approximate)

	cm	inches
Height	19	8
Width	30	12
Depth	19	8

WEIGHT (Approximate)

	kg	lbs
Net	140	315
Shipping	290	640



3

SECTION 3
Calibration

Calibration

To optimize image quality, the Faxitron CT Software and the hardware requires periodic calibration. This calibration requires the acquisition of reference images.

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 each interval shown

Image Calibration	Daily
Geometric Calibration	Every 3 months
Uniformity Calibration	Every 3 months

Each day when the system is started up 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/humidity settings.

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

WARNING

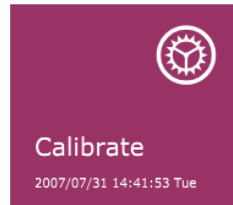
The CT has a battery back up to move the unit without powering down, but the system **must** be on mains power when capturing images, including calibration.



Daily System Warmup and Image Calibration Sequence

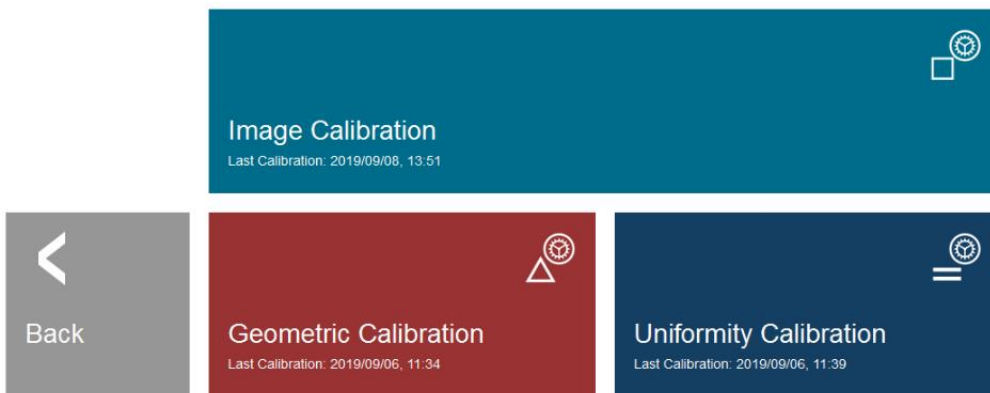
Ideally, allow the system to warm up for 30 minutes before calibration. This will ensure that the internal detector electronics have stabilised, and the system will produce a higher quality image.

To calibrate the system at any time, click the Calibrate button on the Startup Screen (main screen).



3.1.1 Image Calibration

Then click Image Calibration.



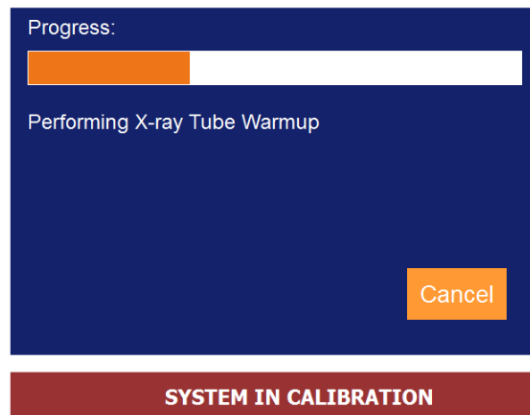
For the daily image calibration ensure the chamber is completely empty, including the foam tray. Check the box to confirm the chamber is empty and proceed by clicking Start.

3.1.1 Image Calibration Cont.



THE CHAMBER MUST BE EMPTY FOR WARMUP AND CALIBRATION

During warmup and calibration, X-Rays may be generated. During X-Ray generation, a “Cancel” button will be made visible to allow a user the option to stop X-Rays through software or touch control panel.



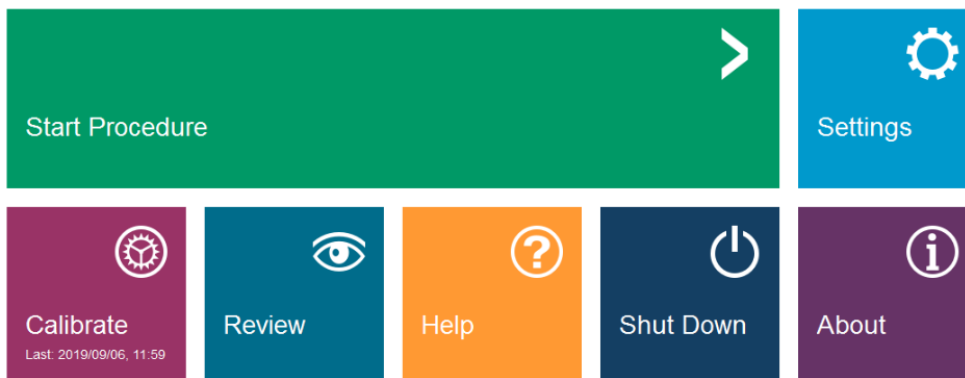
Geometric Calibration Sequence

3.1.2 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, visible rings in the image for example, conduct a geometric calibration.

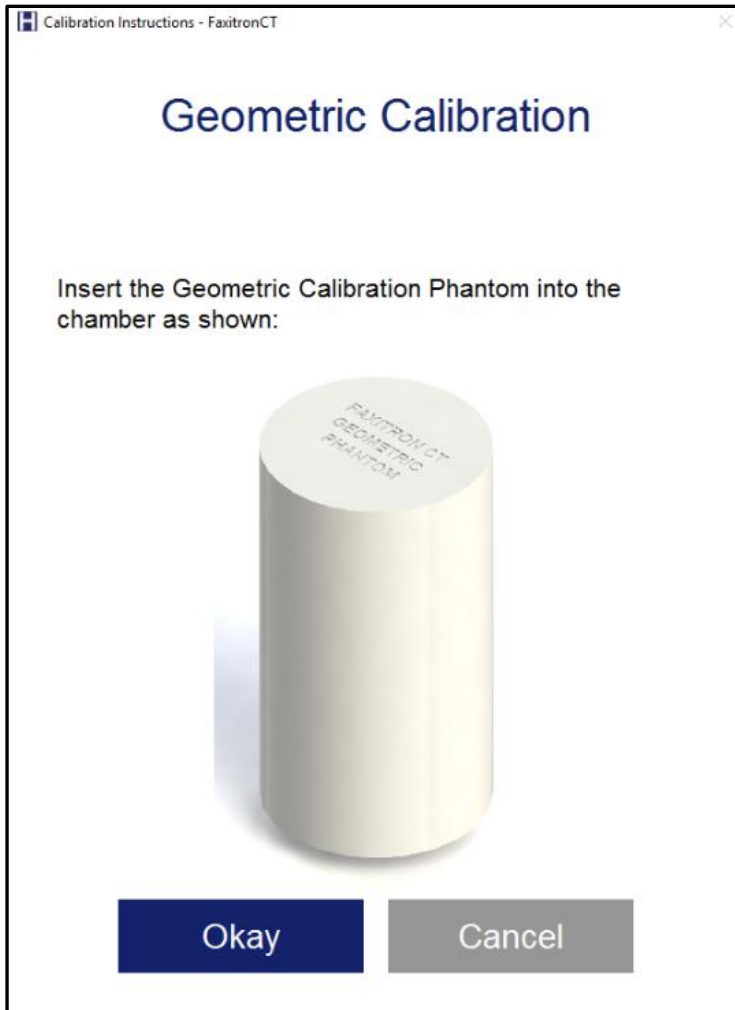
Go to the main screen and click on the Calibrate button, as before, and then select Geometric Calibration.



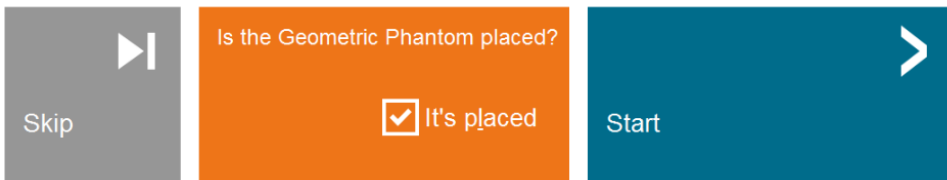
This time insert the white Geometric calibration phantom by placing it on the CT pedestal.

The phantom has a location stud that will center the phantom on the pedestal. Once positioned click Okay.

3.1.2 Geometric Calibration Cont.



Check the box to confirm the Phantom is placed and proceed by clicking Start.



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

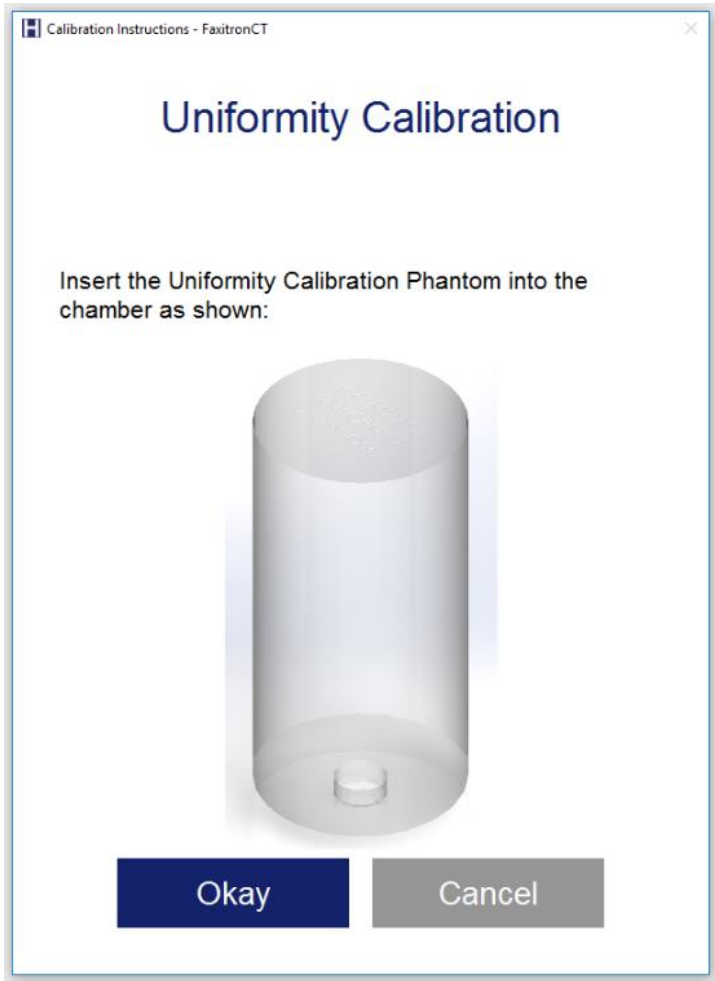
Uniformity Calibration Sequence

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

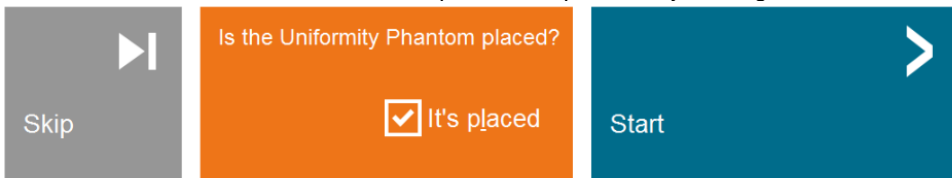
As per the previous calibration, go to the calibration page and click on Uniformity Calibration. This time insert the clear Uniformity Calibration phantom by placing it on the CT pedestal.

The phantom has a location stud that will center the phantom on the pedestal. Once positioned click Okay.

3.1.3 Uniformity Calibration



Check the box to confirm the Phantom is placed and proceed by clicking Start.



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

4

SECTION 4
Quick Start
Basic Operation of the
Faxitron CT

Before powering up the system, please make sure that all cabling connections are secured.

WARNING

The CT has a battery back up to move the unit without powering down, but the system **must** be on mains power when capturing images.

System Start-up Sequence Protocol

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 "1" for "Power ON"
- Turn the Faxitron CT System "ON" by pressing on/off button, located on the front panel.
- The computer and monitor and touch panel 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, then enter the password provided to enter the software.



4.1.0 Quick Start



*Figure 4.1.1
Faxitron CT*

On / Off
Button

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 perform this calibration 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.

Refer to the previous section on Calibration for more details.

Note: During the set-up of the detector and software the touch panel on the X-Ray cabinet will show the status at the top of the screen. For example – Calibrating, Stand-by and Ready.



Basic Imaging Procedures

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 sample in a sample container provided. The specimen must fit completely within the inner ring shown below.

- **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.**



- 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.

- Close the chamber door.

- Select the “Start Procedure” from the main screen

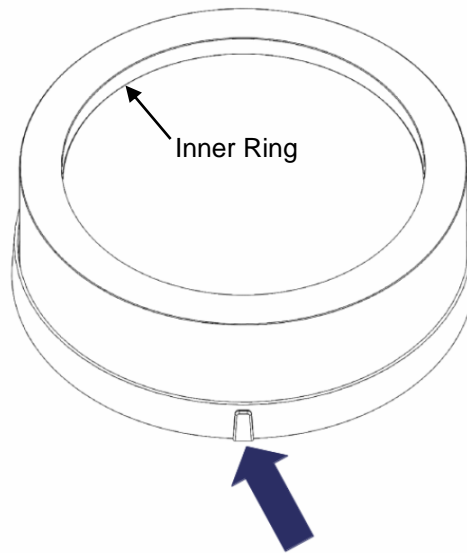


Figure 4.1.2
Faxitron CT Consumable Tray

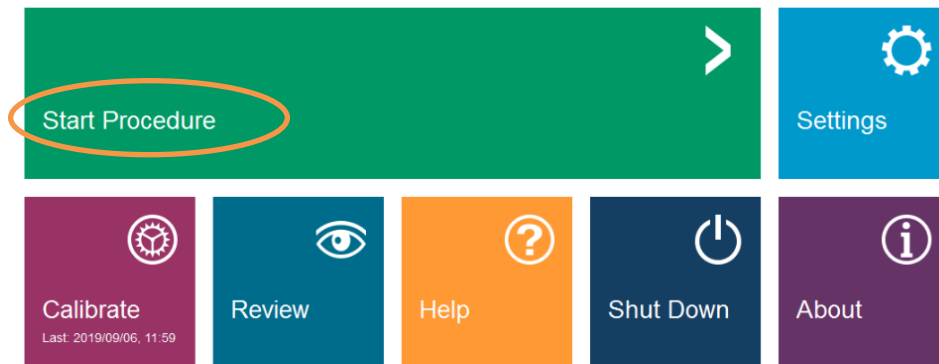


Figure 4.1.3
Select Procedure Screen

On the next screen, you have the option to either Select from Work List, if configured, Continue with Current Patient if there is a previous patient used, Manual Entry, or Select from Database. For this example, we will use manual entry. In the other options the Patient information will be imported. See next section for more details.

- Select "Manual Entry"

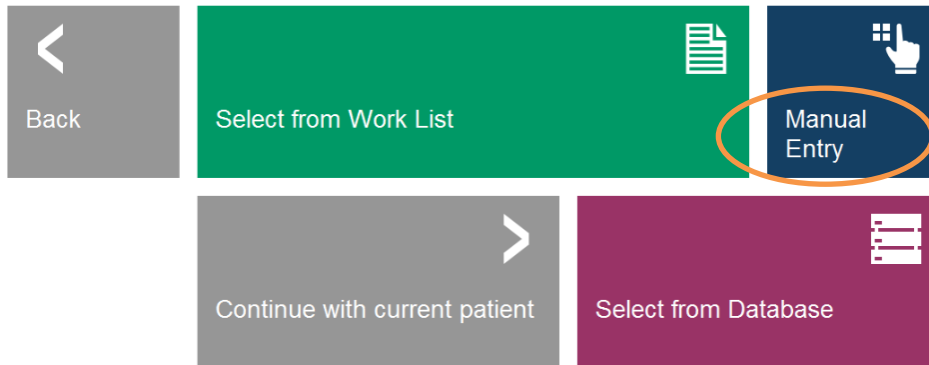


Figure 4.1.4
Enter Manual Data

- Type in the name and ID for the Patient. The starred (asterisk) boxes must have a value in them. For a Patient you will also need an accession number and laterality.

The screenshot shows the 'Set/Edit Patient Data Screen' with the following fields:

- PATIENT INFORMATION:**
 - Patient Name: * JANE [] DOE []
 - Patient ID: * 1 []
 - Accession #: * 1 []
 - Date of Birth: 1968 [] 11 [] 1 []
 - Gender: Female []
- PROCEDURE DETAILS:**
 - Procedure Name: []
 - Laterality: * []
 - Position View: []
 - Body Part: []
 - Refer. Physician: []
 - Technician: []
 - Technician ID: []
- STUDY INFORMATION:**
 - Study Name: []
 - Study ID: []

At the bottom, there are two buttons: 'ACCEPT >' (blue) and '< SELECT NEW PATIENT' (grey).

Figure 4.1.5
Set/Edit Patient Data Screen

- 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.
- The CT systems has 2 modes - 2D imaging and 3D Imaging. The system defaults to 2D mode initially and this is shown by the icon below. You can switch and go to 3D mode by clicking the 3D icon.

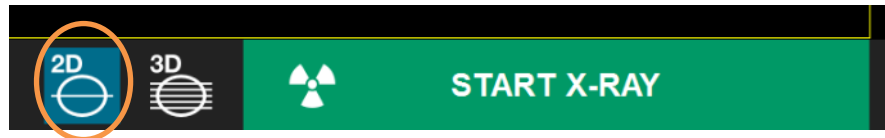


Figure 4.1.7
2D Mode

- 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.
- In 2D mode, when the exposure is complete the computer will process the data and after a few seconds display two orthogonal images.



Figure 4.1.8
Image Screen

- The 2D image series can then be sent to the PACS network by clicking the PACS Store icon, assuming a PACS connection has been configured on the system. All images are automatically “save local”.



Figure 4.1.9
Save to PACS

- The button in the bottom left will show the send status. Do not shut down the system while the images are still sending.

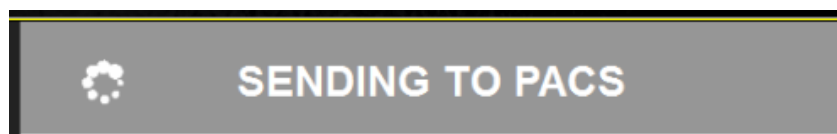
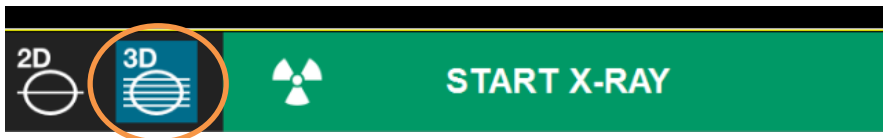


Figure 4.1.10
Sending to PACS

- Select 3D mode by selecting the icon and press Start to begin the scan. The CT reconstruction takes up to 3.5 mins plus, if there is metal in the specimen, an additional 1min to post process the image to remove any metal artifacts.

Note: Times are for guidance only and may change based on size of specimen and future system improvements.



Note: The 2D images can still be reviewed while the 3D scan is happening in the background.

- When the exposure is complete a four pane view is shown.



Figure 4.1.11
Image Screen

- To send the CT image series to the PACS network click on the PACS Store icon, assuming a PACS connection has been configured on the system. All images are saved locally as a backup.

Note: The system will send the images that are currently shown on the screen at the time PACS save is clicked.



Figure 4.1.12
Save to PACS

- As before do not shut down the system while the images are still sending.
(Note: A backup of all images are stored on the local drive)

For more information on adjusting the image, reviewing and save options, see Section 5.

Shutdown Procedure

4.2.0

Shutdown

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.



Figure 4.2.1
System Shutdown

2. Or, from the software click the Shut Down button from the main screen. A second screen will pop-up to confirm that the Shut Down. Click Okay.

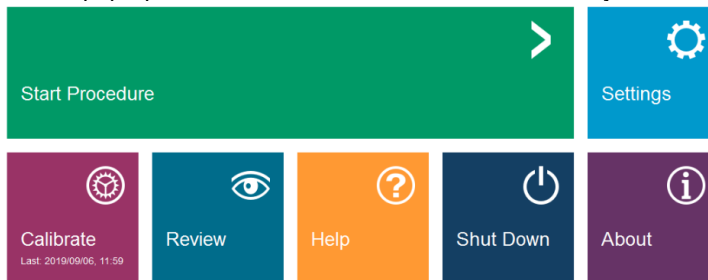


Figure 4.2.2
Software System Shutdown

5

SECTION 5
Faxitron CT
Software Operation

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) compliant, allowing saving of Patient images in DICOM format 3.0. The software has been pre-installed on the computer that was packaged with your x-ray 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 5.0.1*. These buttons are in the center of the screen. Button descriptions and definitions are outlined in the following sections of this manual.

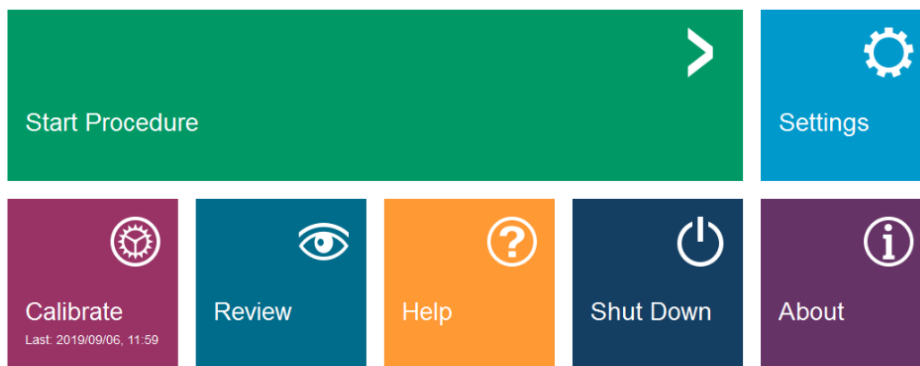


Figure 5.0.1
Faxitron Software
Home Menu (Start-up Screen)

See Section 4, Quick Start, for software start-up procedure.

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

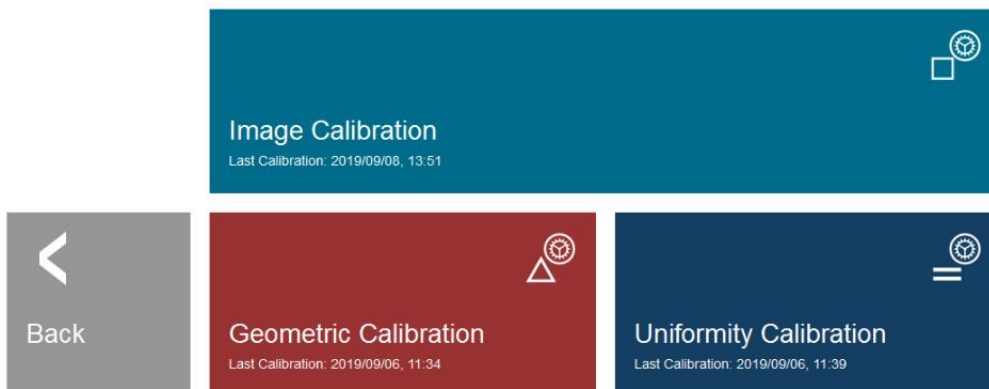


5.1.0 Software Start-up



Figure 5.1.1
Password Entry

See Section 3, Calibration, for details on the calibration procedures.



5.2.0 Calibration

Figure 5.2.1
Calibration Screen

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

5.3.0 Patient Data

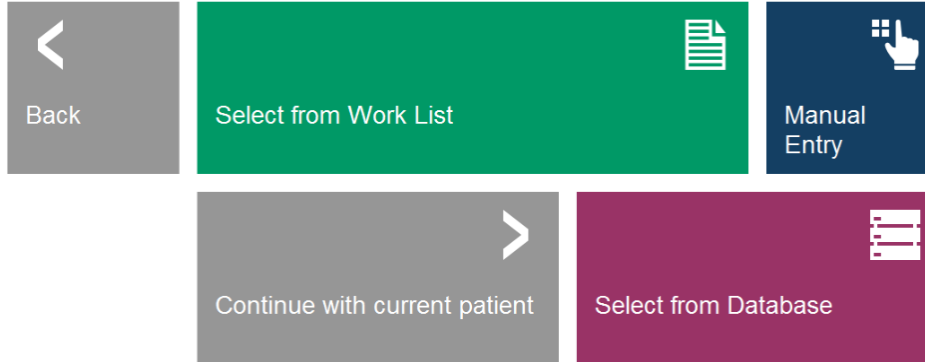


Figure 5.3.1
Patient Data Entry screen

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 page.

5.3.1 Select from Work List

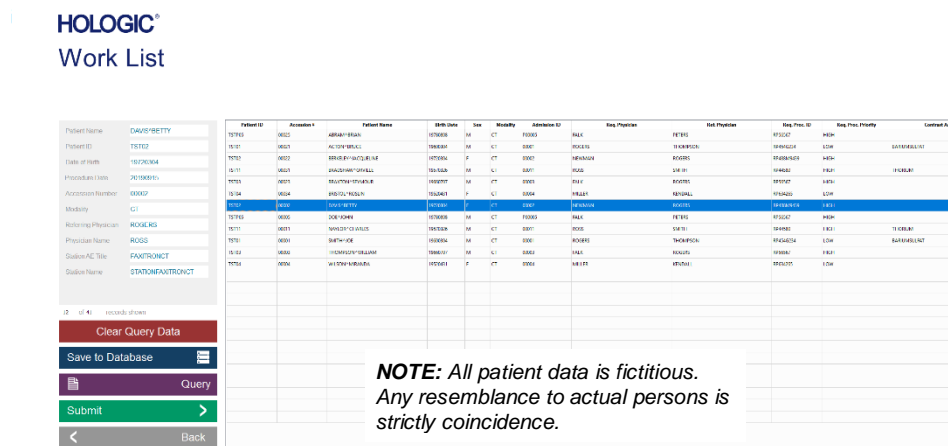


Figure 5.3.2
Modality Worklist Dialog



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.

The user can then single-click any entry and hit **Submit** to automatically populate the Imaging Information Editor with the patient information.

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

A patient's information can be imported to the local Database from the Modality Work List by selecting Save to Database.

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 a Date, Referring Physician, Procedure Name, Sex, Technician, Position View, Body Part, and Study Name and ID if so desired.

The Procedure Name, Position View and Body Part are chosen by a drop-down menu.

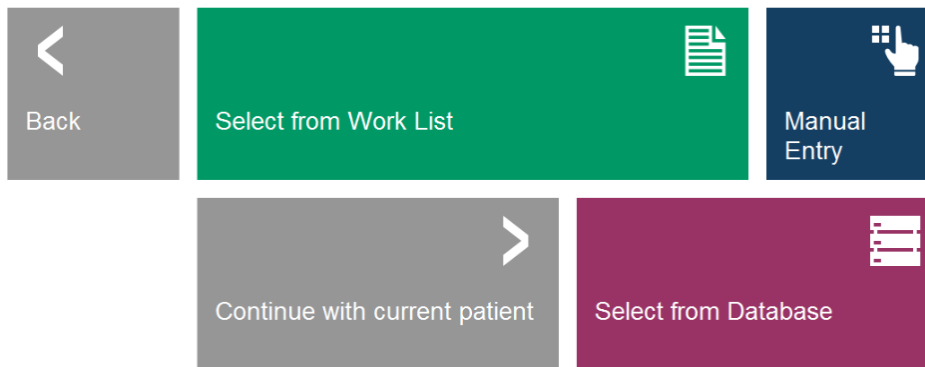
The Date must be entered as yyyy-mm-dd (e.g. 1962 08 13). Failure to enter a valid date may cause errors when attempting to retrieve images.

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.

5.3.1 Cont.

Figure 5.3.3
Imaging Information Editor



5.3.2 Continue with Current Patient

Figure 5.3.4
Patient Data Entry screen

Continue with Current Patient

If a Patient has previously been loaded, you can click on this button to **Continue with Current Patient** procedure. The Patient Information editor will open, as shown above, and you can continue as before.

Manual Entry

Click on the Manual Entry button to enter a Patient's details manually using the Patient Information editor. See Quick Start Section for details.

5.3.3 Manual Entry

If the user wishes to change or view the information after it has been input, but before an image has been taken, they may press the **Set/Edit Patient Data** icon in the top left corner.



5.4.0 Patient Information

Figure 5.3.5
Set/Edit Patient Data Icon

The Patient Information editing window will open. This editing window will be populated with all the information that was previously entered/selected as shown below.

The user can change or add information as desired then click on:

- The **Accept** button to save the changes and continue to image acquisition.
- The **Select New Patient** button which will return the user to the Patient Data Entry Screen.

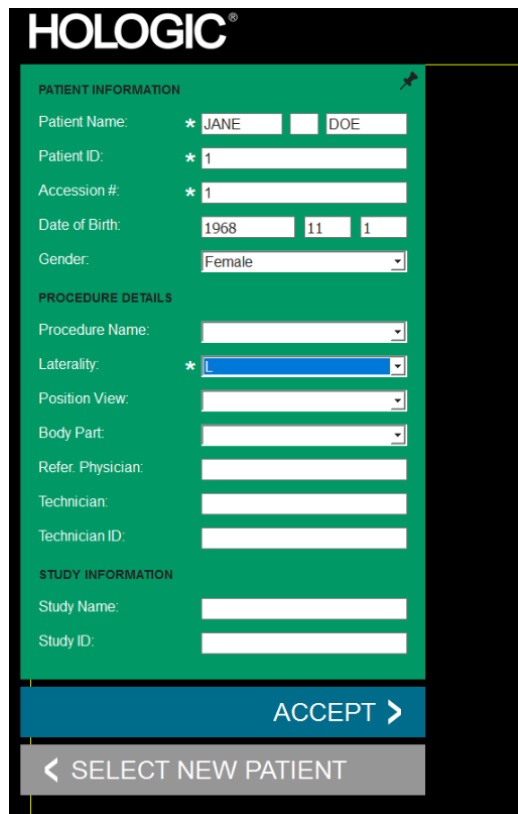


Figure 5.4.1
Set/Edit Patient Data dialog

Once the user clicks the **Accept** button the system is ready for image acquisition/x-rays.

The user may view, but not edit, the patient information after acquiring an image by clicking on the **Set/Edit Patient Data** icon again.

See Section 4 Quick Start for information on how to place the specimen into the system and acquire an Image.



5.5.0 Image Acquisition

Figure 5.51
Start X-Ray Button

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 would be in the Medial Lateral (ML) and the right image the Cranial Caudal (CC) view.



Figure 5.6.1
2D Image Screen

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.

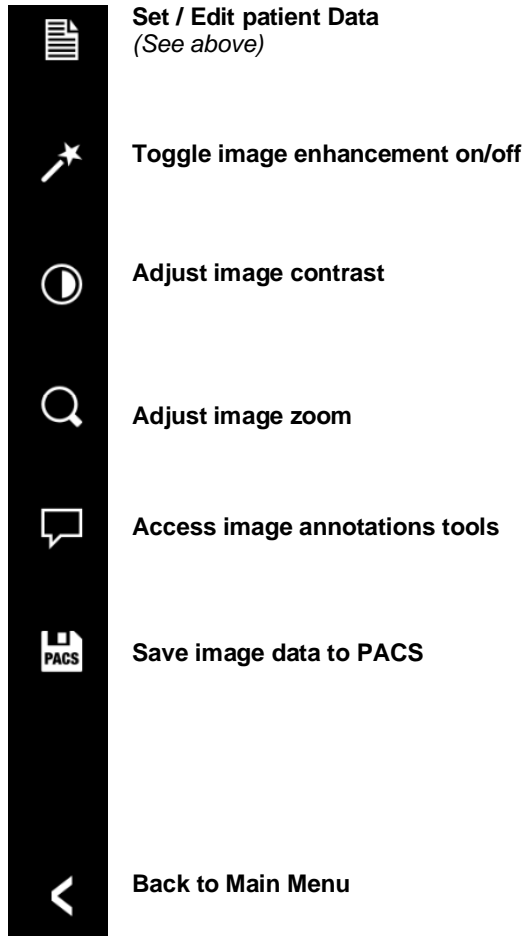


Figure 5.6.2
3D Image Screen

The following sections outline the manipulation of the images.

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.



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, and
- Access image annotations tools

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

Figure 5.7.1
Side Tool Bar

5.7.0 Image Tools

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.



The algorithm, commonly known as “Peripheral Equalization” or “Thickness Equalization” in advanced imaging, is applied to the whole image. In addition to this algorithm, Faxitron 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.

5.7.1 Enhance Image

Figure 5.7.2
Image Enhancement icon

Built-In Window Level

The Software comes with a “built-in” Window Level feature. There is no button or menu item to select it. The Window Level feature is automatically activated whenever an image is acquired or retrieved from the database for review. This feature gives the user the ability to adjust the image contrast and brightness levels using the mouse/cursor.

Click and hold the left mouse button over the displayed image and move the cursor up and down for brightness/darkness levels or move the cursor left and right for low/high contrast. Move the cursor until image is at desired levels.

Adjust Image Contrast

The button shown, will open the Window Level and Contrast adjustment tool. This tool allows the user to adjust the image’s window level and contrast.



This tool location can be undocked by selecting the pin icon in the top right corner.

The user can adjust the slider bar for desired image contrast by clicking on the center bar and moving it up and down or by widening the range by clicking and dragging the ends.

By clicking **Link Contrast** all the views will match the selected settings.

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

Click OK or Cancel to exit.

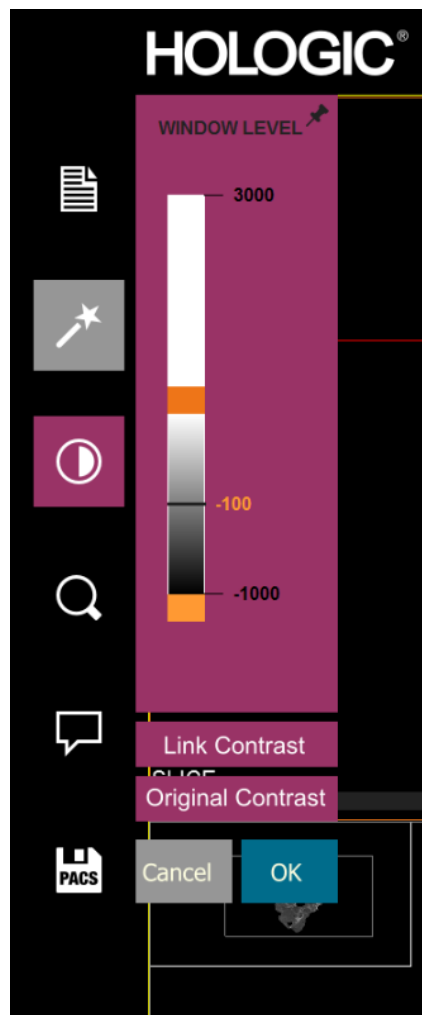


Figure 5.7.3
Window Level and Contrast Tool
Icon and Controls

Adjust Image Zoom

The Zoom Tool icon, *Figure 5.7.4*, will open the Zoom Adjustment tool. After opening this tool, the user may use the slider bar to adjust the zoom level, click the button to **Fit All** or **Zoom 1.0x** for full resolution. See Below.



5.7.3 Dynamic Zoom

Figure 5.7.4
Zoom tool icon

When the image has been zoomed in, it may be necessary to pan the image. Use the middle mouse button to pan.

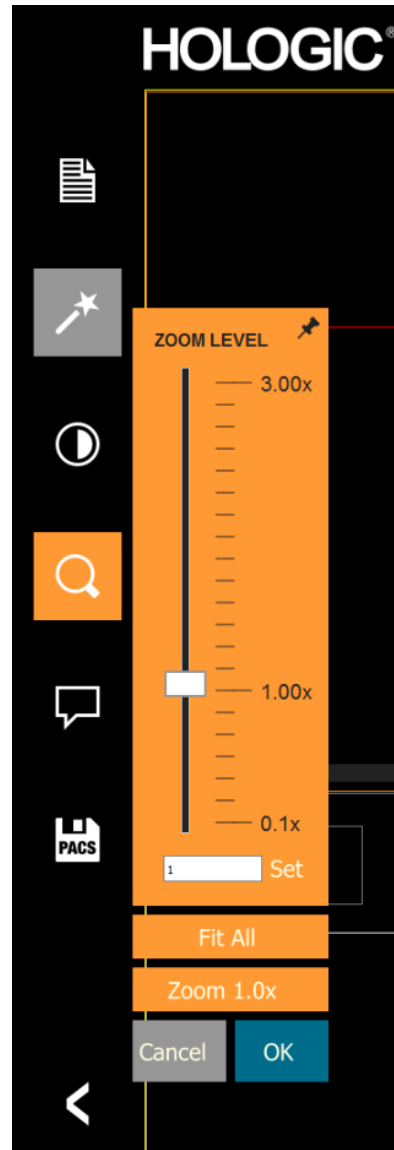


Figure 5.7.5
Zoom Level Adjustment tool

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 is traditionally called “Full Resolution” as it brings the image to a 1-1 view with the monitor resolution.

The user can also type in a zoom value and click **Set**

Click OK or Cancel to exit.

Access image annotation tools

The button shown will open the annotation tools.

User Annotations in the Faxitron CT Software allows one to apply a transparent graphic “overlay” commonly call “annotations” to an image. These annotations take the form of text, lines, “free form” lines (Bezier curves), arrows, ellipse and boxes. This allows additional information and “markers” to be added to the image if desired. Note that all annotations can be easily turned on or off, in other words they can be shown or hidden at will.



5.7.4 Annotations

*Figure 5.7.6
Annotations icon*

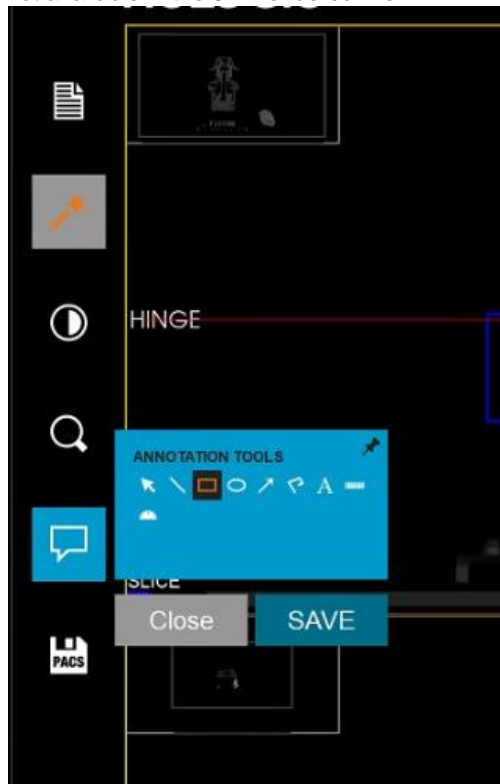
Selecting **Save** or **Close** from this dialog box will save the current annotations to the window or will close the annotation dialog. It will also return you to normal imaging mode.

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

Note the behavior of most of these tool options involve using the mouse to guide the on-screen dynamic position and shape. Mouse “clicks” are used to set the final position and shape.

The term “swipe” infers holding down the left-mouse button and moving the object around the screen. Or clicking the left mouse button will “set” the annotations into a “permanent” or final position.

Note: Annotations are not available in the 3D Rendered View.



*Figure 5.7.7
Annotations Tool*

Starting from the upper-left of the above figure a description follows of each tool options.

- Selection Tool: Use this to select (highlight) a current annotation object. Click and hold the left mouse button down, which sets a starting position, then move the mouse around. Whatever annotations are inside the box being displayed will be selected for further use. Release the left mouse button to finish the operation.
- Line Tool: Draw a straight line with this option. Mouse behavior same as above.
- Box Tool: Draws a box. Mouse behavior same as above.
- Ellipse (and Circle) Tool: Draws an Ellipse or circle. Mouse behavior same as above.
- Arrow Tool: Draws a line with an arrow at the end. Mouse behavior same as Line Tool.
- Polygon Open Line Tool: Draws non-straight “open segmented” lines. Left-click mouse, hold button, draw. Release left button; this sets a line segment. Repeat as desired. Right-click mouse button and the tool operation are complete.
- Text Tool: Creates a “textbox” where you can type text-based data.
- Ruler Tool: Creates a ruled line segment. Very much like the Image Tools Ruler feature.
- Protractor Tool: Draws an angle on screen and provides the degree of the angle. Just like a protractor.

The example below shows the ruler and text tool.

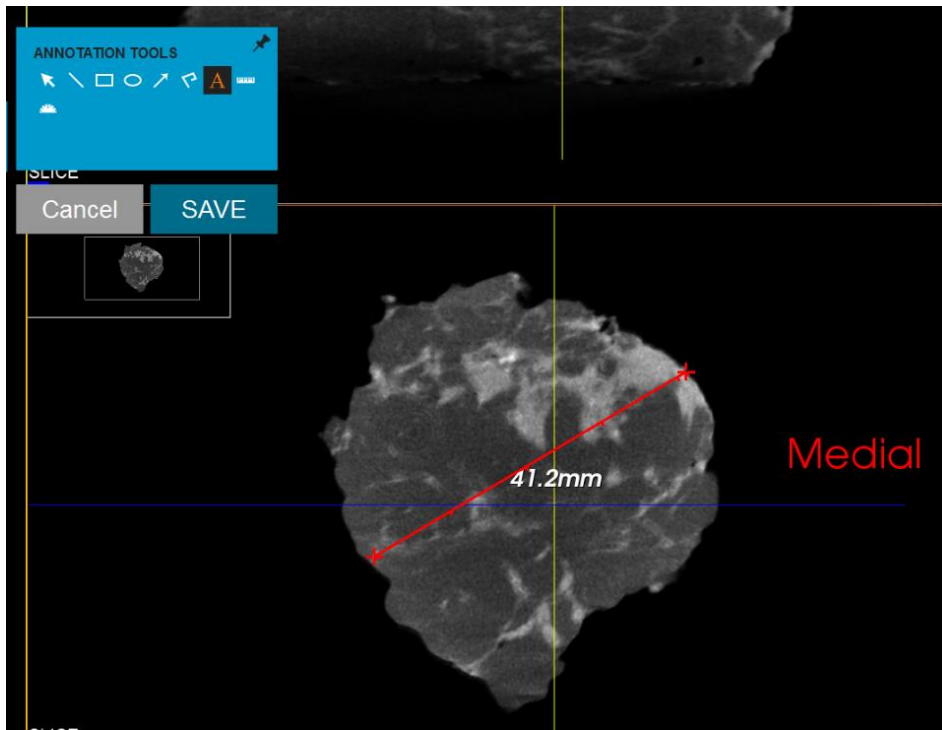


Figure 5.7.8
Annotation Examples

Show/Hide image annotations

The **Show/Hide image annotations** button, shown in Figure 5.7.9, allows users to quickly toggle annotations on and off. By default, the annotations will be toggled on.

The button is located in the right-side menu near the upper right corner.

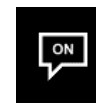


Figure 5.7.9
Show/Hide image annotations

Save image data to PACS

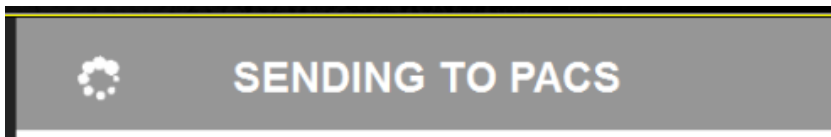
The button shown will only function when the system is installed in a medical facility with a PACS network. Click PACS Store button and the active images in the viewer will be sent to the PACS server.



5.7.5 Save image data to PACS (Save)

*Figure 5.7.9
PACS Store icon*

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



*Figure 5.7.10
Sending to PACS*

IMPORTANT

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

A confirmation will appear once it is complete.

After an image is taken, the current image properties can be viewed by pressing the **(i)** icon in the top-right corner. The Image Properties Dialog box will be displayed in the top right corner of the image. The box is semi-transparent to allow one to see what's underneath the box.



*Figure 5.7.11
Show/Hide image info icon*

Image properties from image acquisition screen:



Image properties from Review screen:



Back

The button shown in Figure 5.4.13 exits the image acquisition mode and returns to the Main Menu screen.



*Figure 5.7.12
Back to Home Menu icon*

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

5.8.0 3D Images



Figure 5.8.1
Faxitron CT 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 icon 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.

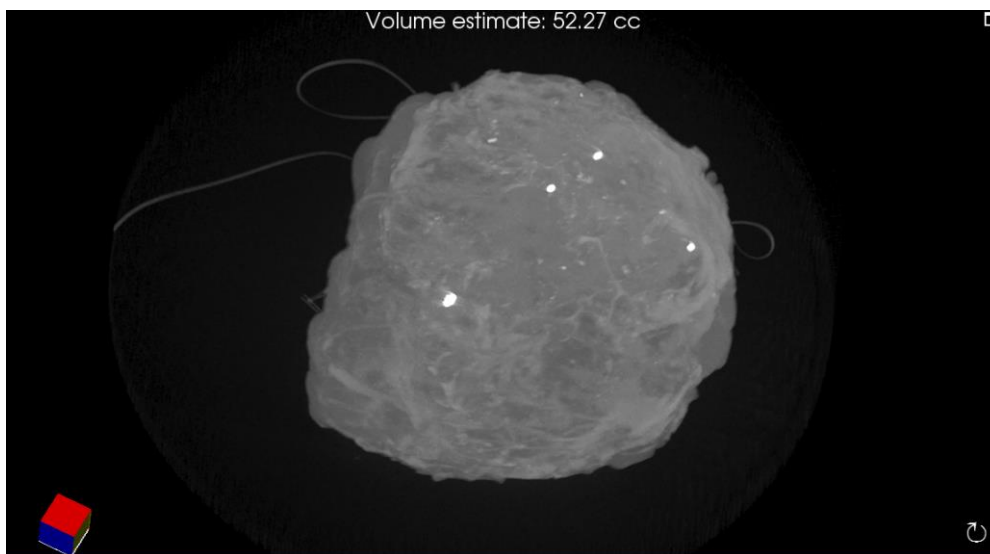


Figure 5.8.2
Faxitron CT 3D view

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

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 will match the orientation of the patient.

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

5.8.1 Specimen Orientation

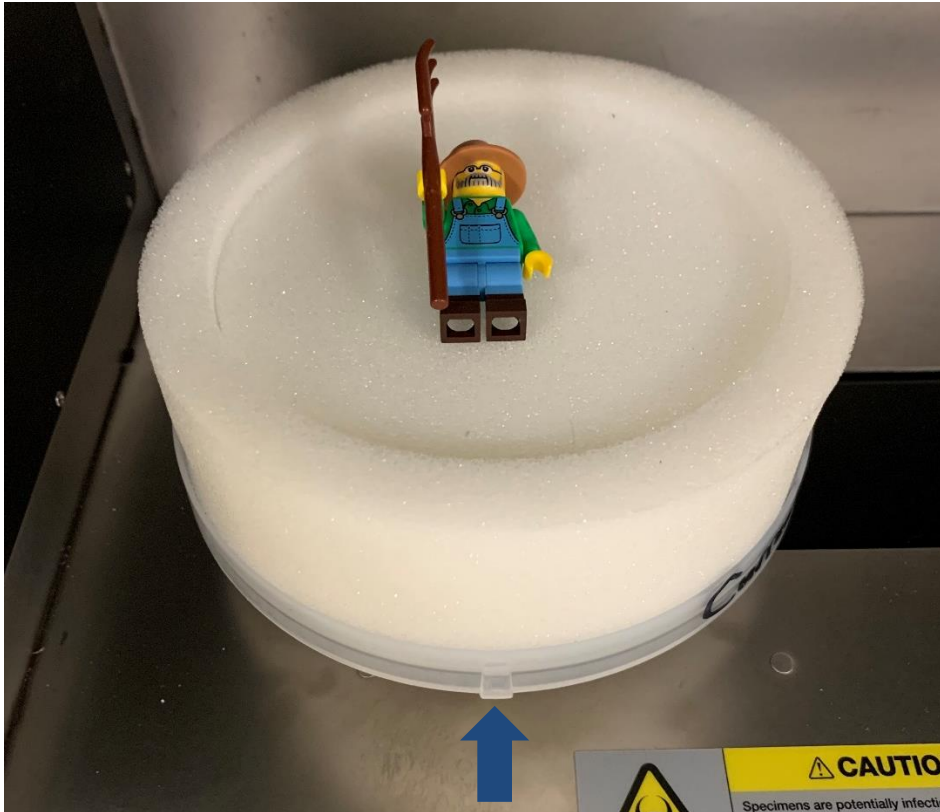


Figure 5.8.3
Specimen Orientation

This will produce the image shown below,

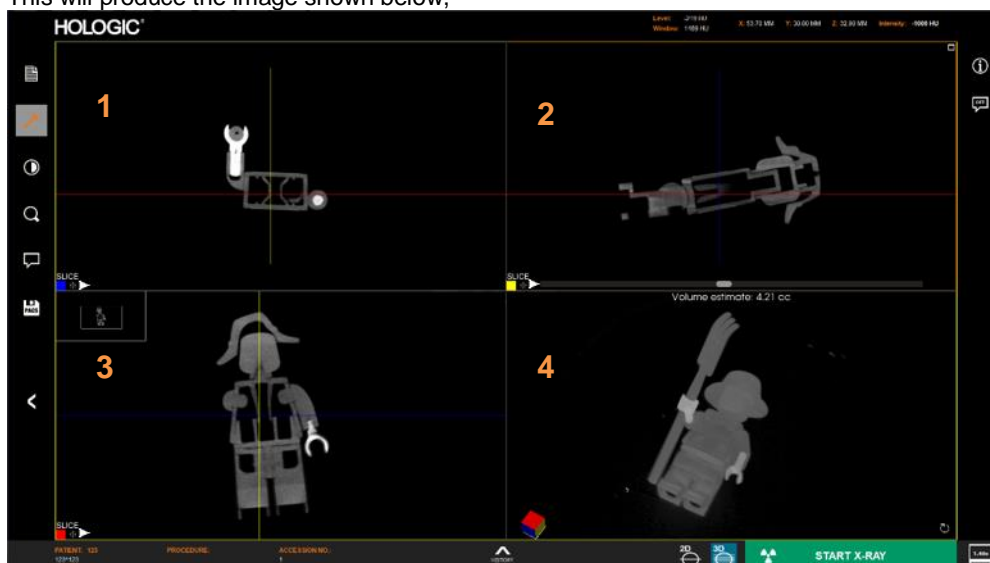
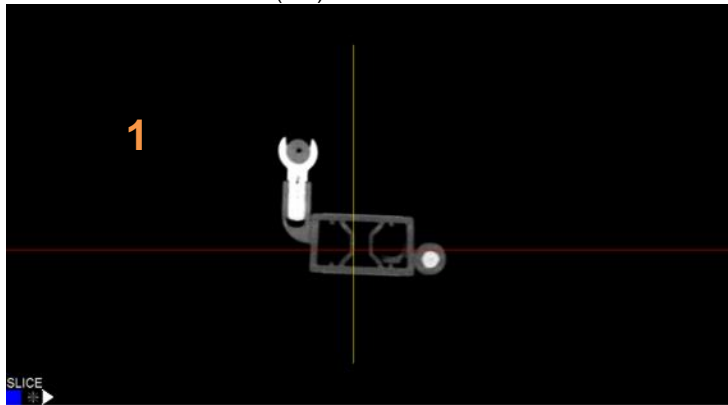


Figure 5.8.4
Faxitron CT Display

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

View 1 is Cranial Caudal (CC)



5.8.1 Cont. Specimen Orientation

Figure 5.8.5
CC View

View 2 in Medial Lateral (ML)

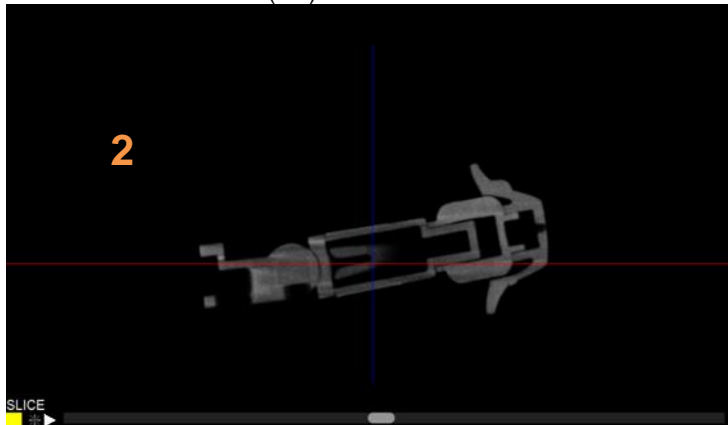


Figure 5.8.6
ML View

View 3 is Anterior Posterior (AP)

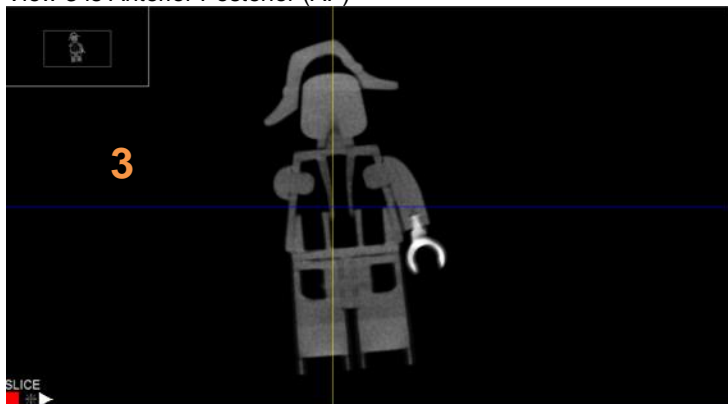


Figure 5.8.7
AP View

View 4 is the 3D View



5.8.1 Cont Specimen Orientation

Figure 5.8.8
Faxitron CT 3D 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 shown below is the top down view (Anterior Posterior).

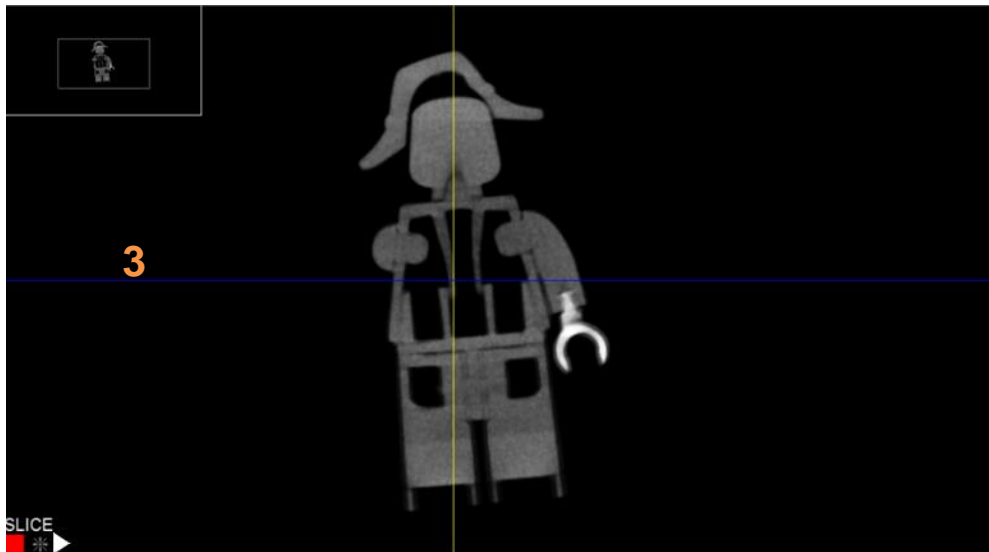


Figure 5.8.9
Faxitron CT Slice View

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

Orientation Markers Can be displayed in each view to aid



This will display position of the sample relative to the system.

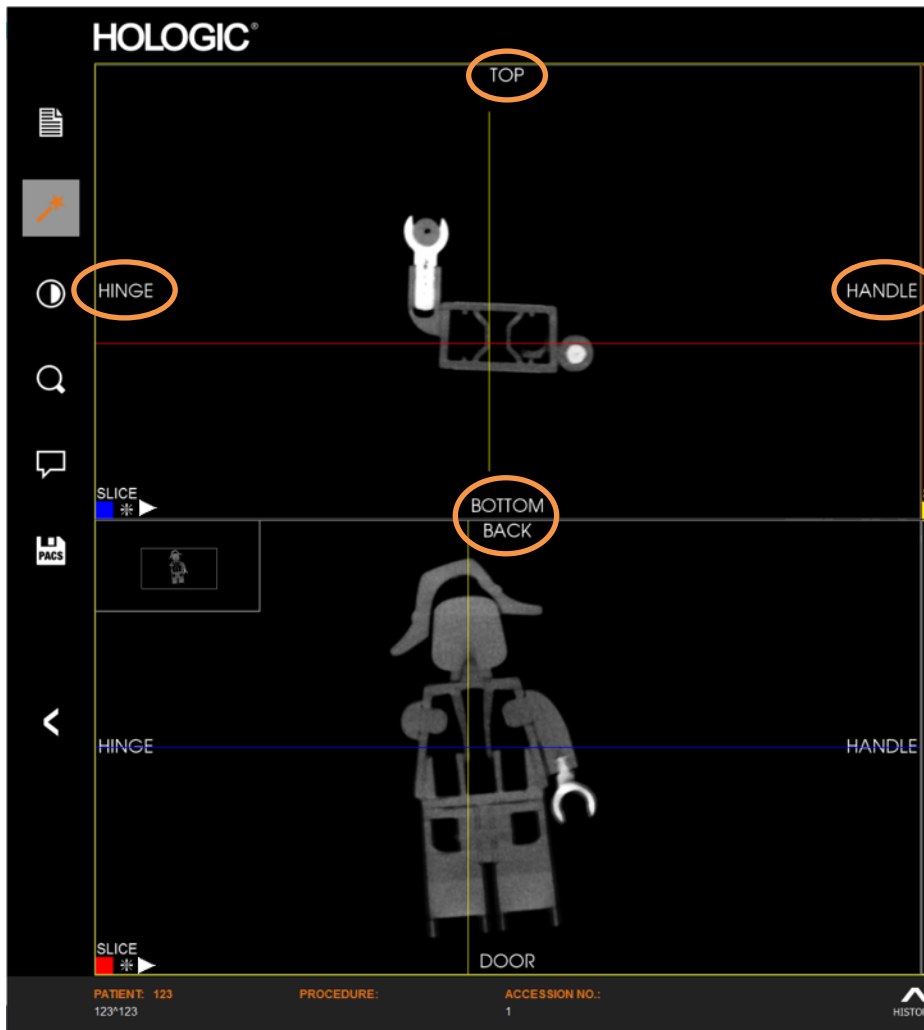
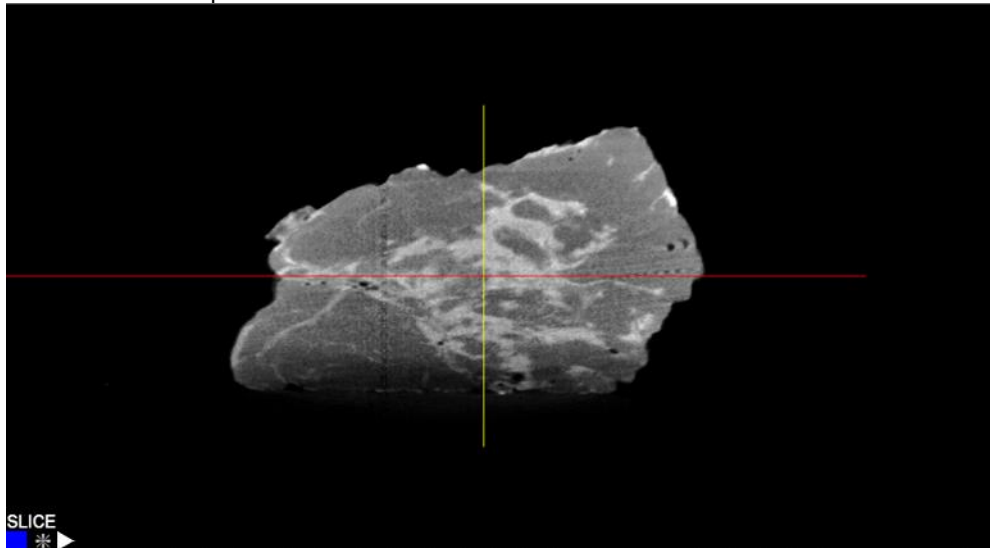
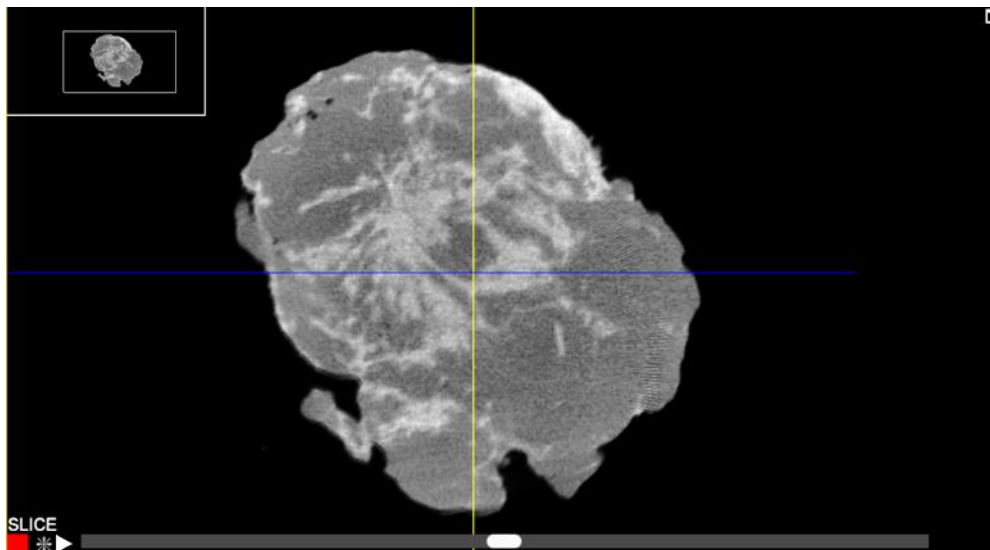


Figure 5.8.10
Faxitron CT Orientation Markers

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.



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



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 or down to move the slice position. This is the same for all 3 axis.

5.8.2 Slice Views

Figure 5.8.11
Faxitron CT Slice Views

Figure 5.8.12
Faxitron CT Slice Views

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

5.8.2 Cont. Slice Views

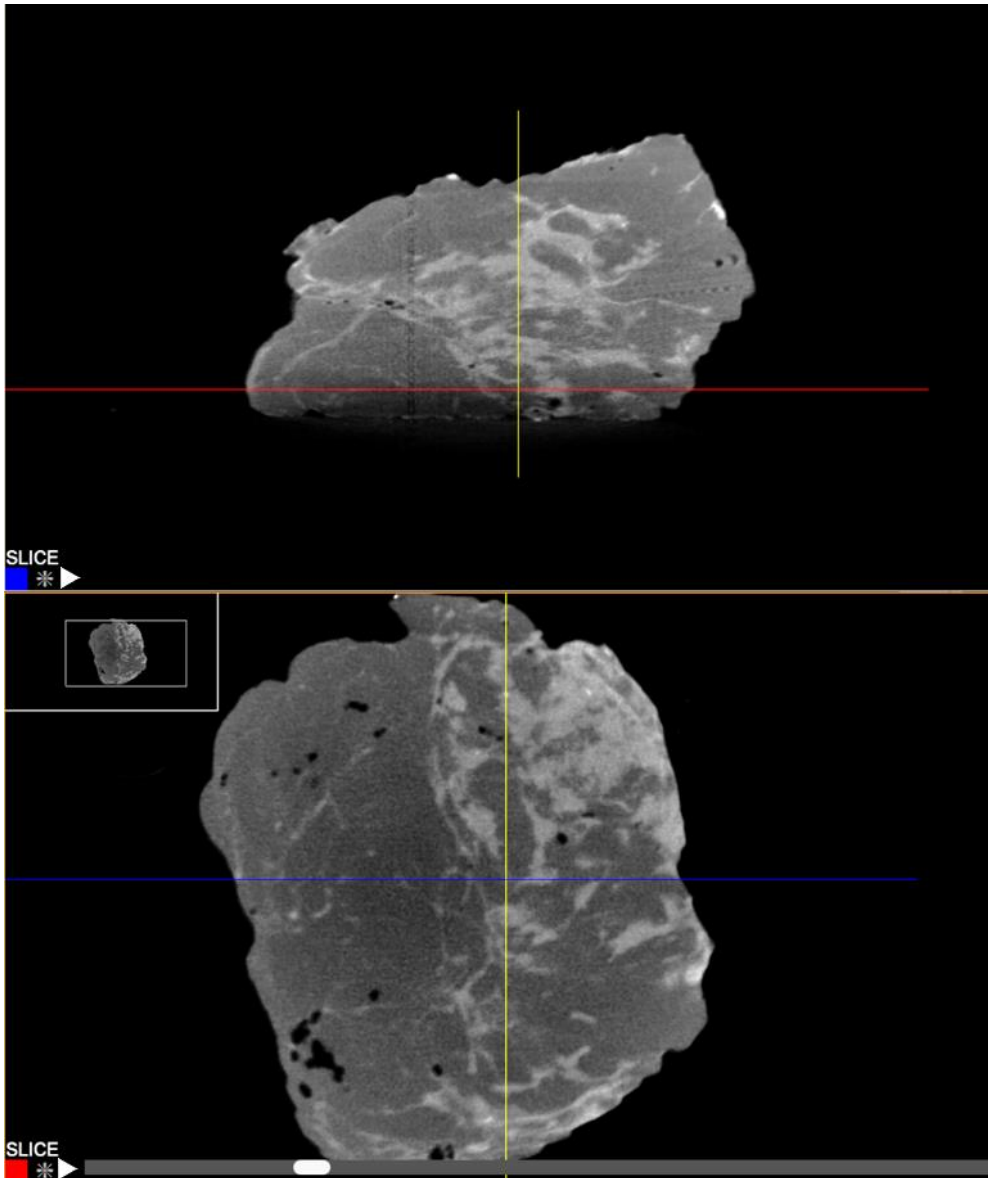


Figure 5.8.13
Faxitron CT Slice Views



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.

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.

5.8.3
MIP View

In this example 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.

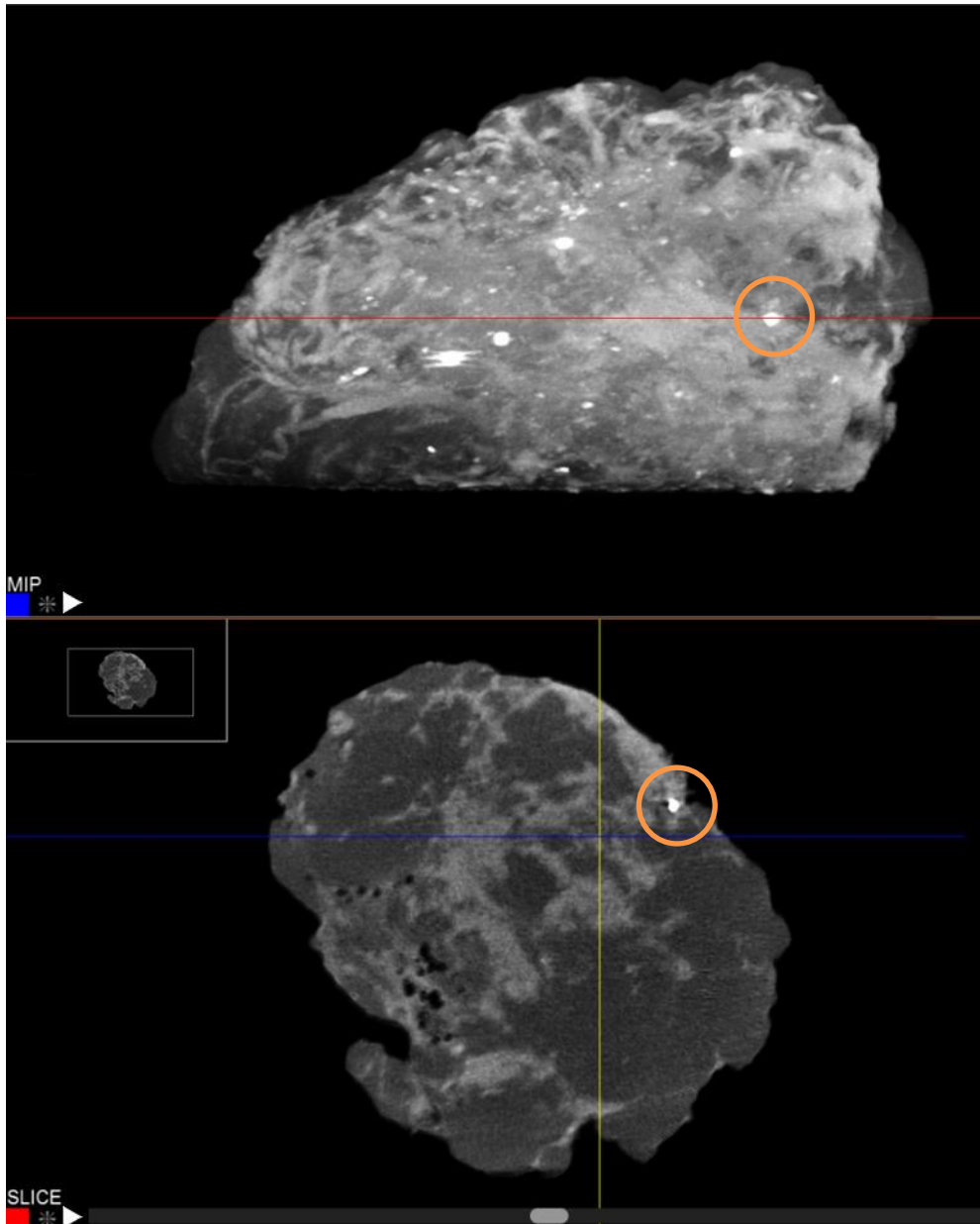


Figure 5.8.14
Faxitron CT MIP View

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

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.

Hounsfield unit is a quantitative scale for describing radiodensity relative to water defined as 0 and air defined as -1000. It is frequently used in CT scans. Simply place the mouse cursor over the area you want to measure. For example, below is a fatty region.

5.8.4 Hounsfield Units

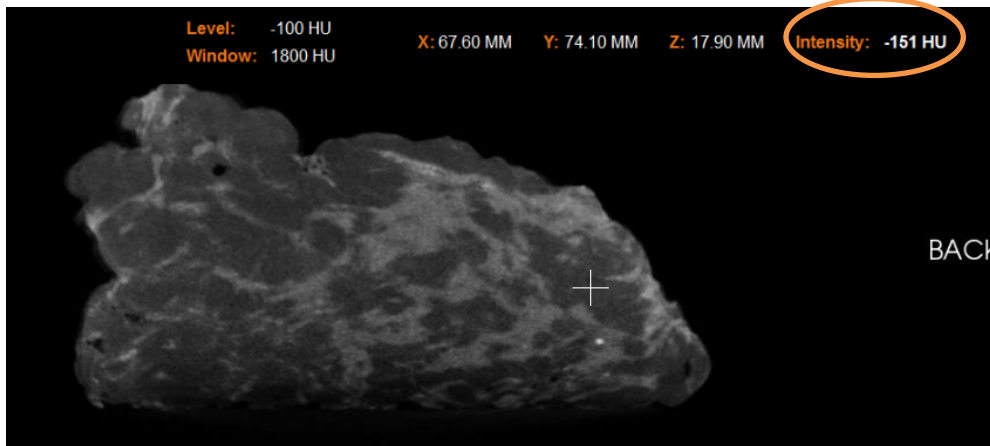


Figure 5.8.15
Fatty Tissue

Denser fibrous tissue

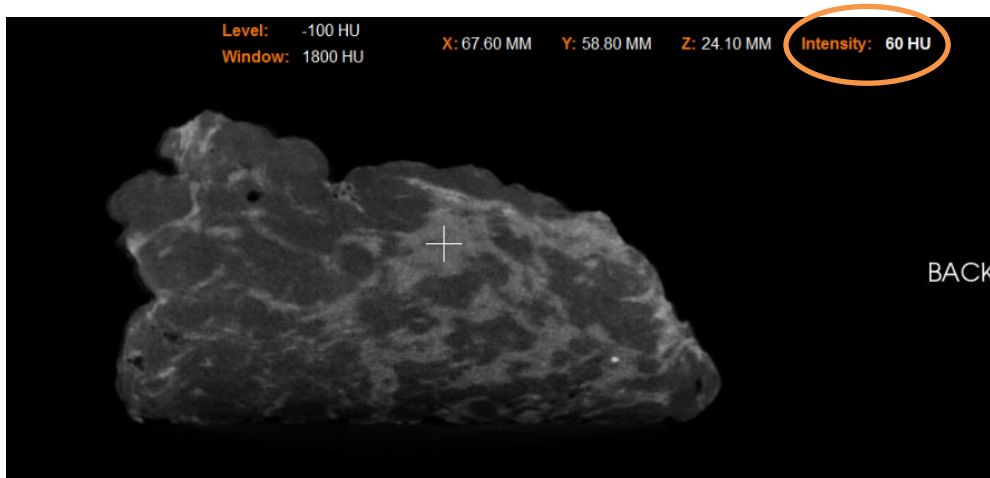


Figure 5.8.16
Denser Tissue

A calcification

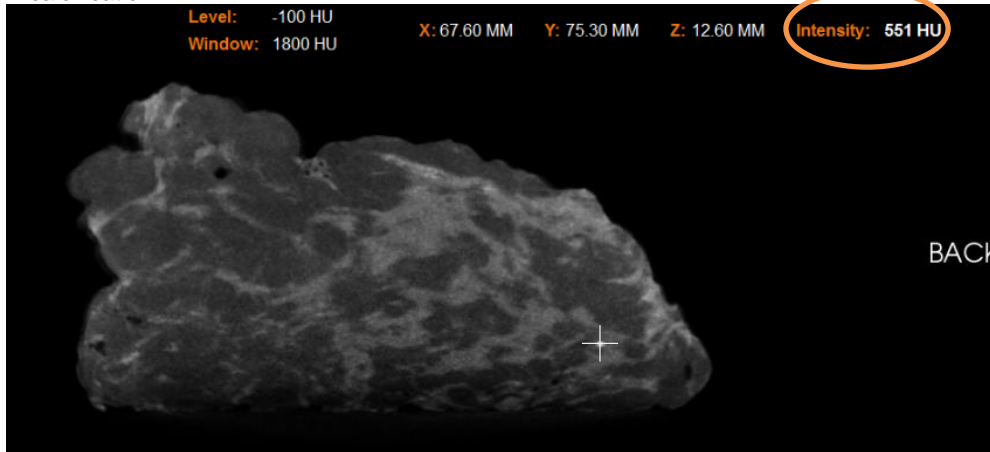


Figure 5.8.17
Calcification

During a procedure the previous images captured can be reviewed by clicking the history button at the bottom of the screen.



5.8.5 Current Patient Image History

Figure 5.8.18
Image History

A "film 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.

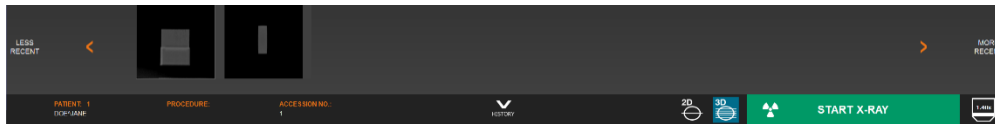
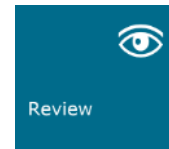


Figure 5.8.19
Image History Strip

Review mode can be entered by clicking the Review button in the Home Menu page.



5.9.0 Review

Figure 5.9.1
Review Mode icon displayed on
the Home Menu.

The Review page is basically 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.

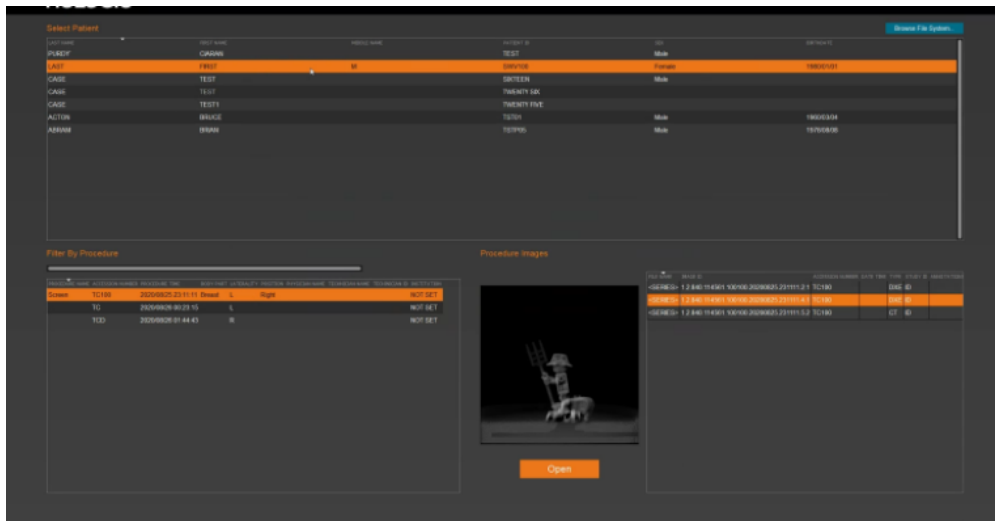


Figure 5.9.2
Review Page

To Open an image, select the patient, procedure, the image and then click Open.

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

5.9.0 Cont. Review

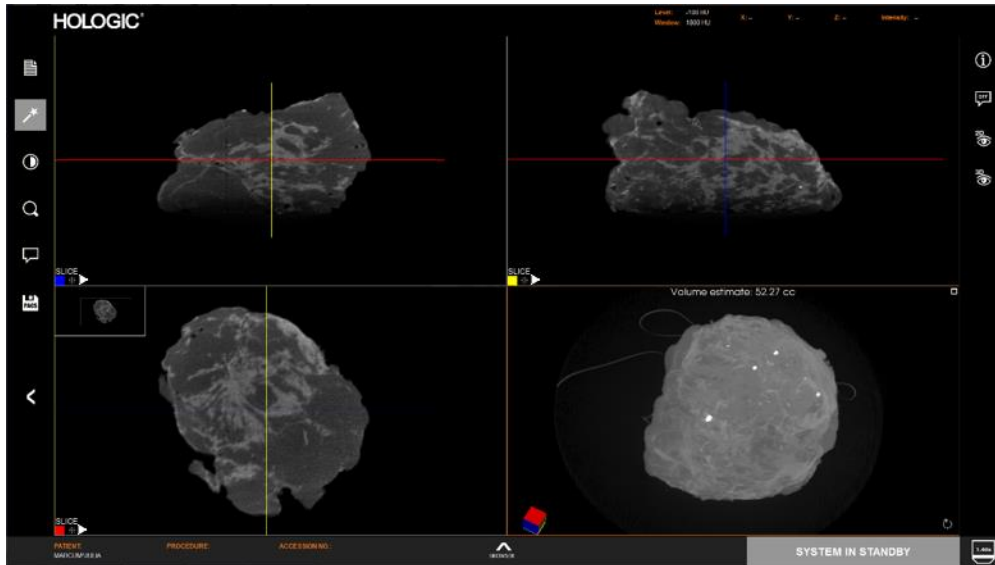


Figure 5.9.3
Review Screen

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

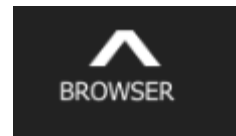


Figure 5.9.4
Browser Button

Images not in the Database can be Opened. Go to the Database Window and in the Top Right corner select the Browse File System. 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.

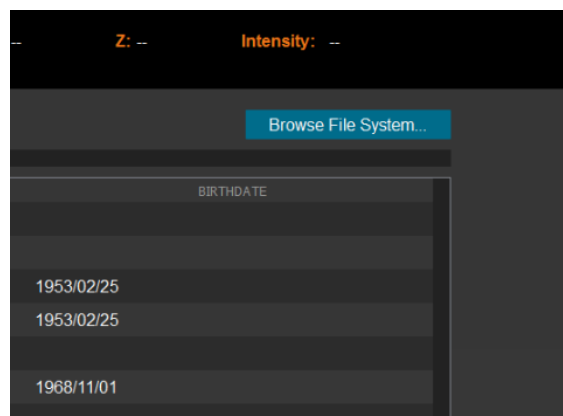


Figure 5.9.5
Browser File System

The DICOM Standard

The Digital Imaging and Communications in Medicine (DICOM) Standard is a series of protocols used by medical equipment and software to allow data to be compatible and interchangeable with other medical equipment or software.

When a file is saved in a DICOM format, a file is created that includes relevant Patient data, imaging equipment, hardware data, and image data, all in a single file. Additionally, the saved file contains specific characteristics that identify it to computer and software as a DICOM Standard file. Once a software application recognizes the file as a DICOM Standard file it can initiate a DICOM reader and extract the data properly, regardless of the file's origin.

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

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

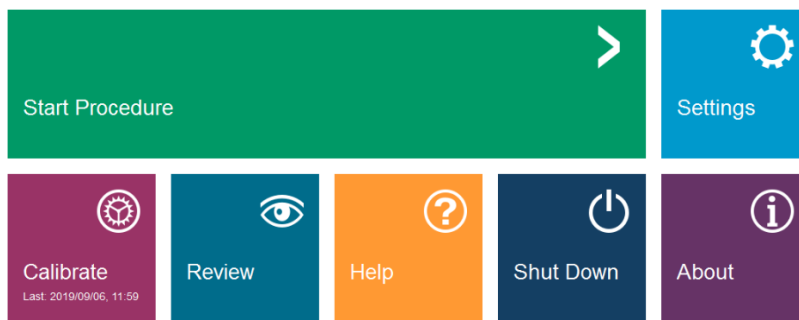


Figure 5.10.1
Home Screen

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 settings are correct.

HOLOGIC® Settings

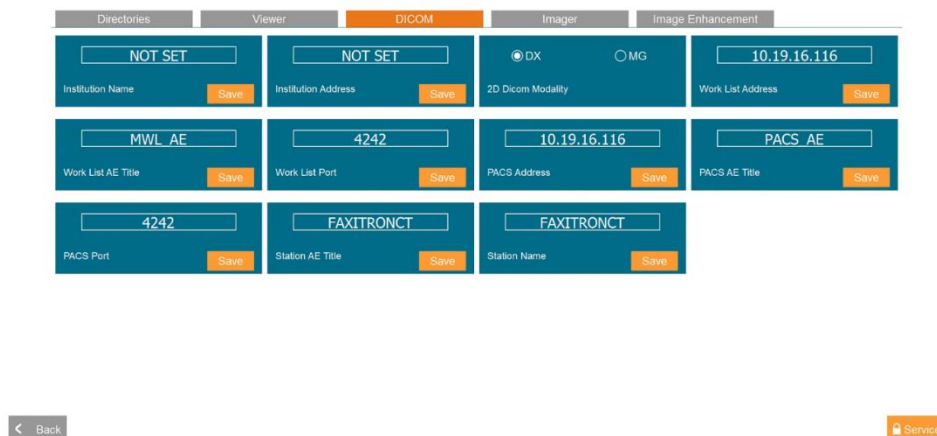


Figure 5.10.2
DICOM Settings

Most of the other settings are not accessible to the user unless directed by a service engineer.

These include the following:

Default directories



Figure 5.11.1
Default Directories

Viewer settings



Figure 5.11.2
Viewer Settings

Imager parameters

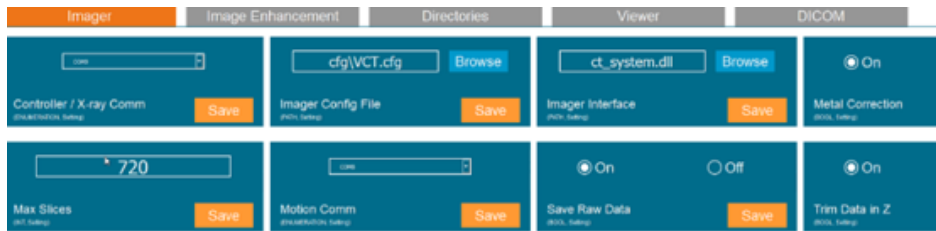
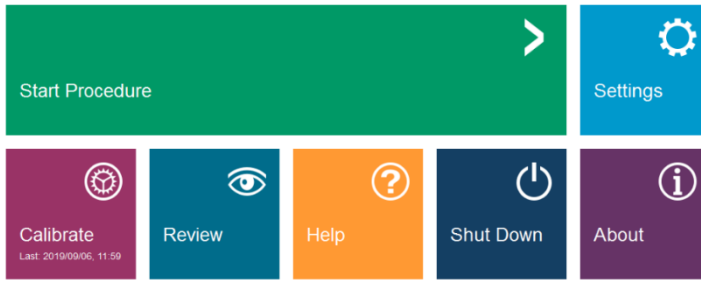


Figure 5.11.3
Imager Settings

And Image Enhancement settings



Figure 5.11.4
Image Enhancement



5.12.0 About

Figure 5.12.1
Home or Main Screen

Clicking **About** from the main screen will open an information window shown below. This may be required to help understand the version of your system.



Figure 5.12.2
About Faxitron CT Information
Dialog Box

Clicking **Help** brings the user to the Help page. There they can:

- Open the Quick Start Guide
- Review a simple animation showing how the specimen should be placed
- Get the contact information for support
- Support connect the system to the Hologic team
- Exit to Windows

5.13.0 Help

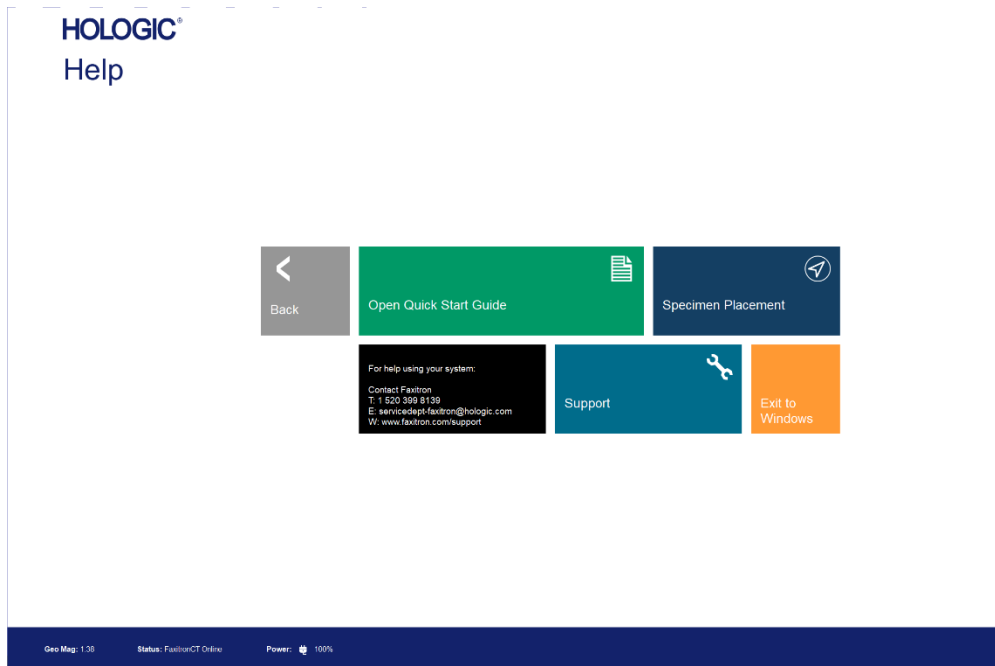
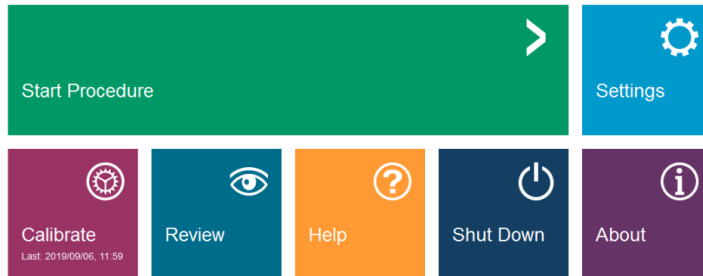


Figure 5.13.1
Help Dialog Box

Shutdown



5.14.0 Shutdown

Figure 5.14.1
Main or Home Screen

To shut down from the software, simply click **Shut Down** and the entire system will shut down.

A message will appear to confirm the system will be shut down. Click **Okay** to continue and let the system fully power down.

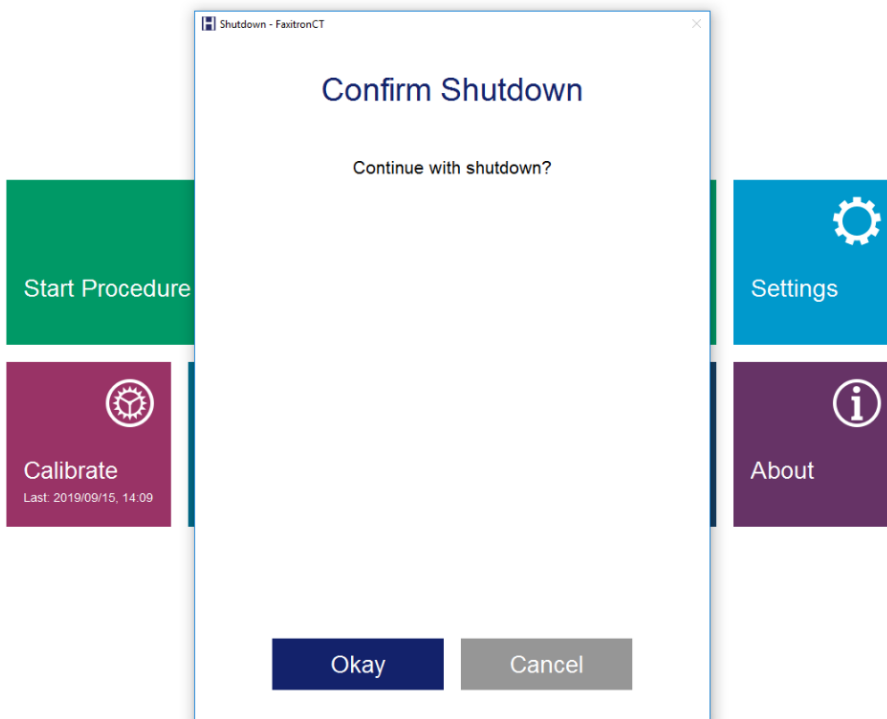


Figure 5.14.2
Shutdown Dialog

6

SECTION 6
**Compliance Requirements
and Safety Measure**

Requirements | Faxitron CT Compliance

Emission Limits

Radiation emitted from the Faxitron CT unit does not exceed an exposure of 0.1 milli-Roentgen (mR) per hour at any point 5 centimetres (cm) outside the external surface. For countries requiring emission values measured at 10 cm from the external surfaces, the radiation does not exceed 1.0 μ S/hr per hour at 10 cm.

Safety Interlocks

Faxitron CT system has two independent safety interlocks on the specimen door.

Start Button

Following interruption of X-Ray generation by the safety interlocks, the Start button on the front panel will resume X-Ray generation when ready.

Password Control

The control system is protected with a Password that must be entered to generate X-Rays.

Stop Button

Along with the software and touch panel Stop button there is a physical Stop button on the Faxitron CT front panel to terminate the generation of X-Rays. This is in addition to the safety interlocks on the system doors.

X-Ray Generation Indicators

The Faxitron CT has an X-Ray On indicator light on the front panel, on the touch panel and graphical user interface, plus it produces an audible tone when generating X-Rays.

Power Ratings

120VAC 60Hz or 230VAC 50Hz 700W Max.

Tested Standards

Testing carried out by Intertek, a US Nationally Recognized Testing Laboratory and European Notified Body

UL 61010-1

3rd Edition, 2012-05

Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use.

IEC 61326-1: 2012

Electrical equipment for measurement, control and laboratory use - EMC requirements.

IEC 61326-2-6: 2013

Electrical equipment for measurement, control and laboratory use - EMC requirements. Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Complies with DHHS radiation performance standards, 21 CFR, Subchapter J

DICOM Version

Faxitron CT uses the latest DICOM standard:

ACR-NEMA Digital Imaging and Communications in Medicine (DICOM) v3.0, Final Draft, Aug. 1993.

And complies with:

NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine Set

See DICOM Conformance Statement for more Information

6.1.0

Compliance Requirements and Safety Measure

6.2.0

DICOM Standard

7

SECTION 7
**Service and
Troubleshooting**

Service

There are no serviceable parts in Faxitron equipment. Please contact your authorized Faxitron representative for servicing.

Faxitron Bioptics LLC (a Hologic company)
3440 E. Britannia Drive, Suite 150
Tucson, AZ 85706, USA

Tel: +1 520 399-8139
Fax: +1 520 399-8182
E-mail: servicedept-faxitron@hologic.com
Website: www.hologic.com

Troubleshooting

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 a 3D image.

The system 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 cabinet. Remove objects and repeat **Calibration**.

Poor image quality

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

Cybersecurity

If a cybersecurity event occurs disconnect the system from the network and contact Faxitron 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

7.1.0

Service and Troubleshooting

8

SECTION 8
**Schedule of
Maintenance**

This document provides a schedule of testing and maintenance for the Faxitron CT. It is strongly recommended that the maintenance and tests described in this section be performed at the intervals of time indicated to ensure that your Faxitron X-Ray generator continues to operate at optimal performance.

8.0.0 Maintenance

Warning: Samples containing tissue can harbor infectious agents that are hazardous to your health. Follow appropriate biosafety procedures; wear gloves when handling tissue specimens or any materials with which they come in contact.

8.1.0 Internal Cleaning

Wipe down the interior of the cabinet with 70-90% isopropyl alcohol or diluted sodium hypochlorite (5.25%-6.15% household bleach diluted 1:500 provides the proper concentration). Ensure the specimen area, marked on the chamber floor, is thoroughly cleaned.



Do NOT use the following on the specimen door's window:

- Isopropyl Alcohol
- Acetone

Periodically wipe down the system with a cloth moistened with mild soap and water. No harsh abrasives or cleaners should be used on the system to prevent scratching. Do not allow any moisture whatsoever to come in contact with the electrical components of the unit.

8.2.0 External Cleaning

Detector
1070-7002 DALSA 15X15 XINEOS DETECTOR

8.3.0 Replaceable Parts

Computer System
2001-0031 COMPUTER, CORVALENT RACK, CT
2009-0025 MONITOR, DELL 24 QHD P2418D
2013-0027 KEYBOARD, USA, KSI-U10020-US-HOL-2 (for other languages contact Hologic)

Controller
2001-0034 TOUCHSCREEN, 7 INCH, LCD
43805-65335 PCB ASSY, CONTROLLER BOARD

X-Ray Tube and HV Power Supply
130-552025 TUBE, MICROFOCUS 50KV TUNGSTEN
131-10256 POWER SUPPLY, 50KV 1.0MA

Low Voltage Power Supply
131-20010 SWITCHING POWER SUPPLY ASTEC LPQ252-C

Door Interlock
3101-1989 PLUNGER ASSY, INTERLOCK SWITCH
3101-1990 SWITCH BODY ASSY, INTERLOCK

For other replaceable parts contact Hologic. See below for phantoms and single use trays.

ACR Phantom (Nuclear Associates P/N 18-250) (P/N 5020-0002)
Ion chamber Survey Meter, Inovision Model 451B-DE-SI-RYR or similar
Uniformity Phantom, (P/N 5020-0028)
Geometric Phantom, (P/N 2020-0029)
Resolution Phantom, (P/N 5020-0030).
CT Single Use Trays, (P/N 120-807650)

8.4.0 Equipment Needed

The following definitions apply for the terms listed below when referenced in this Schedule of Maintenance.

ACR Phantom- American College of Radiology Accreditation Phantom.

Contrast: Percent of difference between object intensity and background intensity.

8.5.0 Definitions

The system must be maintained twice per annum. More regular intervals for radiation surveys and image tests can be conducted by the user in accordance with the instructions in this manual. Refer to local government regulations and facility procedures for further guidance and compliance.

A radiation survey must be conducted every time the system is relocated or damaged.

Cybersecurity

Any software or firmware updates that have been released since the last maintenance that resolve a safety or security issue can be provided, as necessary.

The firmware is hard coded into the control board so if a firmware update is required, replace the control panel PCB.

8.6.0 Periodic Maintenance

Interlocks, lights, Error Messages – To be performed annually.

Record results under “Safety Interlocks and Indicators” on the Periodic Maintenance Record, located at the end of the Section, or on an approved form.

1. System must be powered on.
2. Make sure the green “Power” led comes on, and no other LED comes on at this time.
3. Make sure the LCD screen illuminates and displays “Standby” and there are no other messages, such as “Door Open” at this time.
4. Open the specimen door. The LCD screen will display “Door Open” icon. When the door is closed, this message should disappear.
5. Double-click the Faxitron CT icon to start the imaging software. If this initiates a calibration, allow the calibration to fully complete.
6. Next, Click the **Start Procedure** button and choose the **Enter Manually** button to access the patient entry screen. Fill all fields marked with an asterisk (*), and click the **Start** button. This will allow for an exposure to be taken.
7. Verify that the green **Start X-Ray** software button is on.
8. In 2D mode press the green **X-ray** button on the touchscreen on the front of the Faxitron CT. The system should begin taking an x-ray exposure. Verify that:
 - The Touchscreen LCD displays X-Ray On and displays kV and time.
 - Software displays X-Ray On (bottom right corner)
 - Audible noise heard during entire exposure
 - Red “X-Ray On” LED comes on.Let the exposure finish and make sure the 2 images show up on the computer screen
9. Press the green button again to start another exposure. While the exposure is taking place, press the red **Stop** button on the front of the system and the exposure should stop within 2 seconds of pressing the button. Most notably the buzzer will stop sounding to indicate the exposure has stopped. The software will display interruption errors, which is expected. The errors can be cleared which will enable x-rays to be taken.
10. Repeat 2 more times using the software **Stop** button and the **Stop** button on the touch LCD.
11. Press the green button again and let the exposure start. This time open the specimen door, which should disengage the safety switches and force the exposure to stop. The software may display errors, clear them.

**8.7.0
Safety Interlocks
and Indicators**

ACR Phantom (Wax Insert Only)

Note: Other test phantoms can be used. Contact Faxitron / Hologic for guidance.

Record results under “ACR Phantom Test” on the Periodic Maintenance Record, located at the end of the Section, or on an approved form.

The user should be familiar with using the Faxitron CT and should know the procedures of taking X-Rays. Go through the setup procedures and make sure that the system is fully calibrated - Image, Geometric and Uniformity.

Wax insert needs to be taken out of its acrylic holder. Using tape or a small slit in the single use foam tray place the ACR phantom standing on its side facing the X-Ray source. Take a 2D image of the wax insert portion of mini ACR Phantom shown in Figure 8.8.1.

The Mini ACR Phantom contains 12 objects: 4 masses, 4 fibers, and 4 groups of calcifications (specks). Each calcification group contains 6 individual calcifications or specks.

At minimum the brightest 3 out for 4 masses, fibres, and calcifications must be visible in 2D mode.

8.8.0 ACR Phantom Test

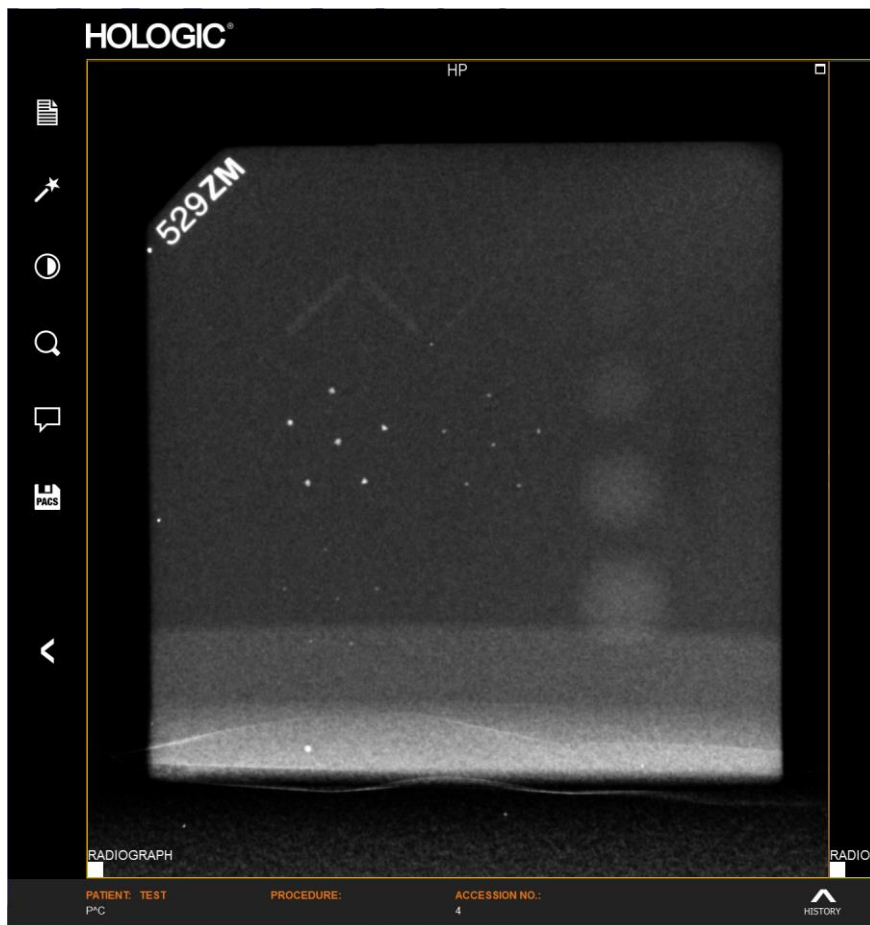


Figure 8.8.1
Typical X-ray image of mini
ACR Phantom (wax insert
only)

Repeat the test in 3D mode, with the wax phantom insert lying flat on the foam. This time all 4 masses, fibres and groups of calcs must be clearly visible in the slice view (MIP) and 3D rendered view, as shown below.

8.8.0 Cont.

Figure 8.8.2
Typical X-ray image of mini ACR Phantom (wax insert only) in 3D mode

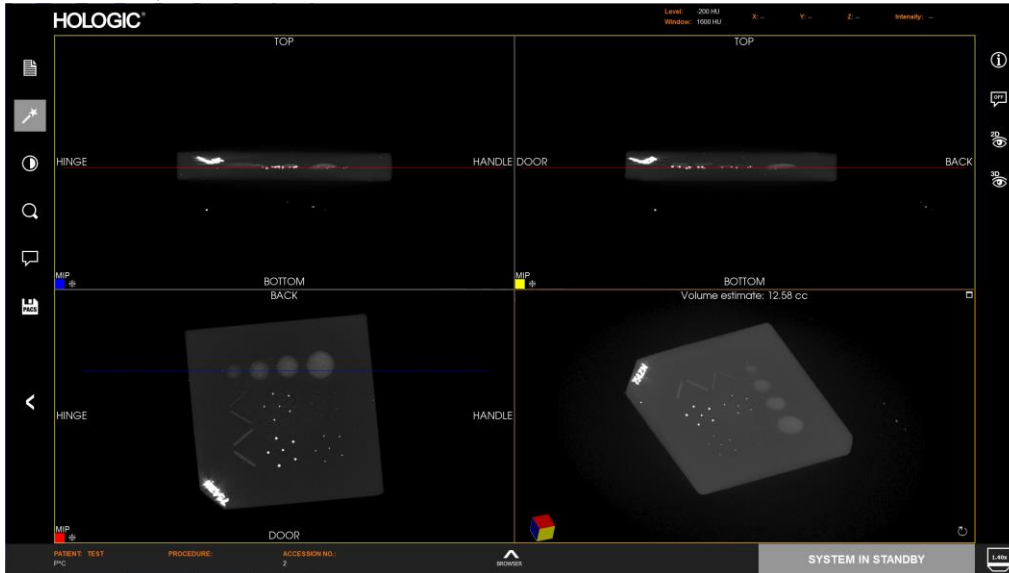
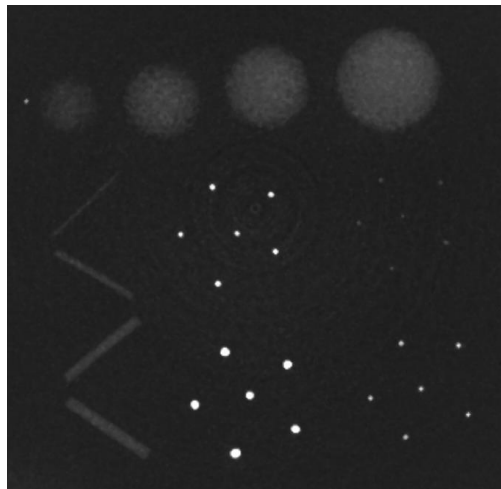


Figure 8.8.3
Close up view of wax insert shows all groups visible.



ACCEPTANCE REQUIREMENTS

1. Configure the system to take an image of the wax insert of the Mini ACR Phantom in 2D mode.
2. Make sure that the Phantom is clean and free of debris.
3. Stand the wax insert on its side facing the center of the X-Ray beam without using any attenuator blocks.
4. Still in 2D mode start X-Rays and wait for all processing to be completed and the image to be displayed.
5. Adjust contrast and brightness levels as needed for the best image.
6. Once the image is corrected, the brightest 3 objects of each type must be visible.
7. Lay the wax phantom flat on the foam and repeat image acquisition using 3D mode.
8. In 3D mode all groups of objects must be clearly visible. Switch the slice view to MIP to make it easier to see all the objects on one plane.
9. Record results on the Periodic Maintenance Record.

The manufacturer recommends that a radiographic survey be performed at least once every six months to ensure that there is no significant excess radiation emission. If the machine is damaged in any way after installation, the radiographic survey should be conducted prior to putting the machine back into use at the facility.

Record results under “Radiographic Survey” on the Periodic Maintenance Record, located at the end of the Section, or on an approved form.

Required Tools

- Ionization chamber type Radiation Survey Meter with adequate accuracy at maximum kVp and beam quality of the x-ray unit surveyed.
- Uniformity phantom

Verify Survey Meter Operation

1. Calibration date: Make certain that the survey meter calibration is current.
2. Battery Check: Check for proper battery condition. Replace batteries before survey if required.
3. Check Operation: (If check source is available).

Note: The following steps apply to the Inovision 451B or similar Ion Chamber Survey Meters. Follow manufacturers' instructions for other meters.

- Open the sliding Beta Shield on the bottom of the Survey Meter.
- Set the meter down on the Check Source and monitor for 30 seconds.
- Survey Meter should read within tolerance listed on Calibration label.
- Enter the reading on the Periodic Maintenance Record.
- Close the meter's Beta Shield.

Important Notes

1. All radiation measurements are taken with the radiation Survey Meter no more than 2 inches (5cm) from the surface of the Faxitron CT unit.
2. When recording the radiation measurements, they may need to be multiplied by 0.1 to convert the reading from uSv/hr to mR/hr. For example, 12 uSv/hr is equal to 1.2 mR/hr.

8.9.0 Radiation Survey

Radiation Survey Procedure

8.9.0 Cont.

1. Take a background radiation reading (point meter toward the center of the room) and record the value (Note the units used on the Record / Form).
2. Complete an image calibration including a full system warm-up.
4. Open the chamber door and place the uniformity phantom on the CT pedestal.
5. In 3D mode press the “START” button and survey radiation emissions at the top, front, back, and both sides of the cabinet. Slowly scan the entire surface with the meter. A 3D scan takes several minutes but it can be repeated to give time to complete the survey.
6. Record the readings for each test location, except left side (the side with the detector).
7. If any readings are higher than the Faxitron radiation emission limit of 0.1 milli-Roentgen (mR) per hour (1.0 μ Sv/h) at any point 5 centimeters (cm) outside the external surface (*), contact a Faxitron or Hologic representative to discuss repair options.

(*) 0.5 mR/h at 5 cm from external surfaces is the upper limit by US FDA CDRH for cabinet x-ray systems. If used in another country, please check with the hosting country's official limits for cabinet based in-vitro diagnostic radiography equipment.

For some countries, the test points should be at 10 cm from external surfaces and in this case Faxitron radiation emission should read less than 0.1 mR/h at 10 cm from external surfaces.

8. Remove the uniformity phantom from the x-ray chamber.
9. Repeat the survey for the left side of the system without the uniformity phantom. Verify there is nothing in the x-ray chamber, start a 3D x-ray and scan the side of the system closest to the detector.
10. Record which ever reading (with or without phantom) was higher for the left side.

3D Uniformity Test

The user should be familiar with using the Faxitron CT and be familiar with performing a 3D scan. In this procedure, the Uniformity Phantom will be scanned in 3D mode, reconstructed, and measurements performed on the reconstructed data.

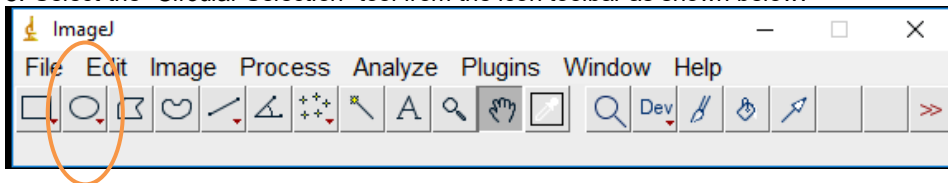
As per standard procedure, the 3D volume data of the reconstruction will be stored in New Volume (D:) > data directory. The file name is by timestamp and – unless more data was taken after scanning the uniformity phantom – will be the most recent file in the directory. The volume data will be opened using ImageJ. To be accepted, the volume data of the Uniformity Phantom must meet specified criteria for mean and standard deviation values.

Required Materials

- The Uniformity Phantom is required for this test which is provided with the system.

ACCEPTANCE REQUIREMENTS

1. Place the Uniformity Phantom in the center on the CT pedestal taking care to make sure the phantom is clean and free from debris.
2. Perform a 3D scan procedure on the Phantom and allow the reconstruction to finish.
3. Locate the reconstructed volume data in New Volume (D:) > data directory. It is named by timestamp and will be the most recent file in the directory. The filename format is `yyyymmdd.#####`. (i.e. `20191220.101916`).
4. Open ImageJ from the Windows Start menu or navigate to Local Disk (C:) > Faxitron > support > ImageJ and double click the ImageJ Application (should be at the bottom of the folder). Open one of the central slices of the reconstructed volume.
5. Select the “Circular Selection” tool from the icon toolbar as shown below.



6. In ImageJ, make sure that the Standard Deviation Measurement is set by going to the menu Analyze>Set Measurements... and then making sure the check box next to Standard Deviation is selected.
7. Use the Circular Selection tool to select the full area of the reconstruction slice inside the Phantom. There are nodes on the circle to allow it to be adjusted to cover as much of the phantom cross section as possible without going outside it. NOTE: Ensure the entire circle is inside the phantom boundaries.
8. Once selected, go to Analyze>Measure (or use keyboard shortcut Ctrl+M). A window will pop up showing the resulting measurements from the selected area.
9. From the window, record the value under the columns for “Mean” and “StdDev”.
10. The values should meet the following criteria for acceptance:
 - a. The **mean** should lie in the range: **-50 to +50**
 - b. The **standard deviation** should be **less than or equal to: 100**NOTE: If the 3D Uniformity Test fails repeat the Uniformity Calibration.

8.10.0

3D Uniformity Test

3D Resolution

The user should be familiar with using the Faxitron CT and be familiar with performing a 3D scan. In this procedure, the 3D Resolution Phantom will be scanned in 3D mode, reconstructed, and measurements performed on the reconstructed data.

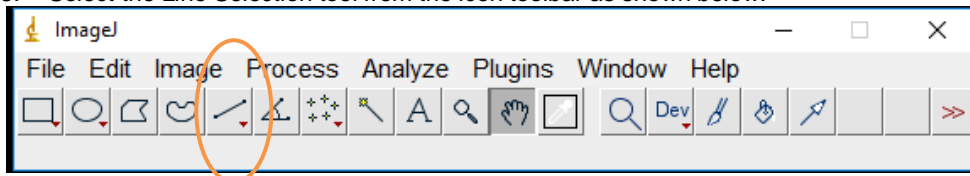
As per standard procedure, the 3D volume data of the reconstruction will be stored in New Volume (D:) > data directory. The file name is by timestamp and – unless more data was taken after scanning the resolution phantom – will be the most recent file in the directory. The volume data will be opened using ImageJ. To be accepted, the volume data of the 3D Resolution Phantom must meet certain criteria for 3D resolution by measuring a line profile through the wire in the middle of the reconstructed 3D Resolution Phantom.

Required Materials

- The 3D Resolution Phantom is required for this test which is provided with the system.

ACCEPTANCE CRITERIA

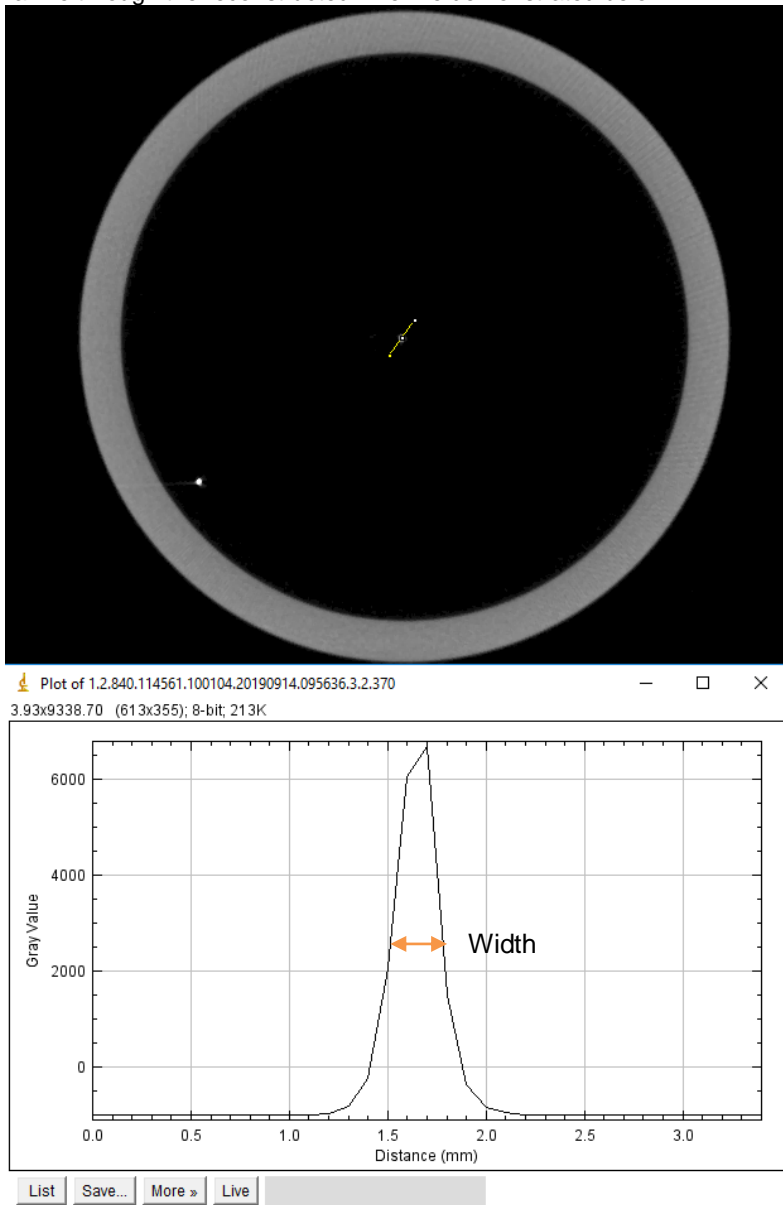
1. Place the Resolution Phantom in the center on the CT pedestal, taking care to make sure the phantom is clean and free from debris.
2. Perform a 3D scan procedure on the 3D Resolution Phantom and allow the reconstruction to finish.
3. Locate the reconstructed volume data in the “Data” folder of the software installation directory. It is named by timestamp and will be the most recent file in the directory.
4. Open the reconstructed volume in the ImageJ software.
5. Select the Line Selection tool from the icon toolbar as shown below.



8.11.0 3D Resolution Test

6. Draw a line through the reconstructed wire like demonstrated below.

8.11.0 Cont.



7. Once the line is drawn through the wire, from the menu select Analyze>Plot Profile (or equivalently use keyboard shortcut Ctrl+K). A window will pop up showing an intensity profile plot along the line drawn.
8. Select the window with the plotted line profile through the wire. It will look similar to the example above.
9. On the line provided below, record the width of the profile at half the height of its peak. Use the cursor to measure the X position on the left side of the width and on the right side and calculate the difference.
10. This value should be less than 0.4 mm for acceptance.

NOTE: If the 3D Resolution Test fails repeat the Geometric Calibration.

Periodic Maintenance Record - Faxitron CT

System S/N: _____ Detector S/N: _____

Safety Interlocks and Indicators – per Section 8.7.0 Refer Section 8.7.0 Failure Criteria on page 8-13. Pass: _____ Fail: _____ Initials: _____ Date: _____	
ACR Phantom Test – per Section 8.8.0 This test fails if 3 Masses, 3 Fibers and 3 Calcification Groups are not visible in the 2D image or 4 Masses, 4 Fibers and all 6 Calcifications, in all 4 Groups are not visible in the 3D image. Number of objects observed in 2D: Masses: _____ Fibers: _____ Calcification Groups: _____ Number of objects observed in 3D: Masses: _____ Fibers: _____ Calcification Groups: _____ Pass: _____ Fail: _____ Initials: _____ Date: _____	
Radiographic Survey – per Section 8.9.0 This test fails if any reading is > 0.1 mR/hr (1.0 μSv/hr) Radiation Readings in: <input type="checkbox"/> mR/hr <input type="checkbox"/> μSv/hr Check Source: _____ Background: _____ Front: _____ Right Side: _____ Top: _____ Back: _____ Left Side: _____ Bottom: _____ Pass: _____ Fail: _____ Initials: _____ Date: _____	
3D Uniformity Test – per Section 8.10.0 This test fails if Mean Value is <-50 or > +50, or Standard Deviation is >100 Mean Value: _____ Standard Deviation: _____ Pass: _____ Fail: _____ Initials: _____ Date: _____	
3D Resolution Test – per Section 8.11.0 Width Measurement: _____ This test fails if the Width Measurement is > 0.4mm Pass: _____ Fail: _____ Initials: _____ Date: _____	
If any failed, state the reason and the actions taken to correct the failure. _____ _____ Initials: _____ Date: _____	

The periodic maintenance identified above was completed by: _____

Date Completed: _____ Signature: _____

Section 8.7.0 Failure Criteria:

The Safety Interlocks and Indicators test fails if any of the following conditions are observed:

- Green Power LED does not illuminate when system is powered on,
- Red X-Ray On LED does not illuminate during X-ray exposures,
- Audible Intermittent Beep does not sound during X-ray exposures,
- Touch Screen Display does not show yellow and black “X-Ray On” message. Note: Top left corner of the screen will also display “X-Ray On” in blue text,
- X-ray exposure does not stop within 2 seconds after “Stop X-ray” button on the display monitor, the “Stop” button on the Touch Screen, or the physical “Stop” button on the control panel is pressed,
- X-ray exposure does not stop immediately when the door is open, or
- The Touch Screen does not display “Door Open” any time the chamber door is open.

9

SECTION 9
Revision History

Version	Date	Description of Change	Author/Originator	Approved by
Draft 1.0	14-Jun-2017	Engineering Initial Draft	Ciaran Purdy	Eng. Draft
Draft 1.1	06-Jul-2017	Updated with new product name	Ciaran Purdy	Eng. Draft
Draft 1.2	07-Jul-2017	Added 3D Uniformity/Resolution tests	Jared Moore	Eng. Draft
Draft 1.3	8-Oct-2017	PC Requirements added and software sections update with 3D image functionality.	Ciaran Purdy	Mikhail Viznyuk
Draft 2.0	30-Jan-2019	Updated for Faxitron CT - Mobile Version	Ciaran Purdy	Ciaran Purdy
Revision 001	18-Sep-2019	Initial Production Release Software sections updated based on final release.	Ciaran Purdy	See CCB
Revision 002	See ECO in Agile	Updated images in Sections 4 & 5 Updated Section 8 for added clarity	Alan Mihalko	See CCB
Revision 003	See ECO in Agile	Updated images in Sections 4 & 5 Updated tool names in section 5	Ciaran Purdy	See CCB