Faxitron® Pro

Specimen Radiography System

User Guide

MAN-10284 Revision 001

HOLOGIC®

Faxitron® Pro

Specimen Radiography System

User Guide

For Software Version 3.1

Part Number MAN-10284
Revision 001
July 2023

Faxitron® Pro was previously known as UltraFocus and UltraFocus100.

HOLOGIC®

Technical Support

USA: +1.877.371.4372

Europe: +32 2 711 4690

Asia: +852 37487700

Australia: +1 800 264 073

All Other: +1 781 999 7750

Email: BreastHealth.Support@hologic.com

Table of Contents

List of Figures

List of Tables

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.

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

Faxitron® Pro is a fully shielded x-ray cabinet offering a large field of view and high-resolution for imaging a broad range of biological and light NDT samples.

1.2 System Capabilities

Faxitron Pro is a fully shielded x-ray cabinet offering a large field of view and high-resolution with 10x15cm or 23x29cm detectors for imaging a broad range of biological and light NDT samples.

The Faxitron Pro system provides geometric magnification of up to 10X.

The Faxitron Pro system is fully shielded and meets FDA radiation safety standards. It is self-contained with no additional x-ray shielding required.

A laser centering guide and viewing window ensure simple and proper sample positioning.

The Faxitron Pro is easy to use. No additional training or specialized x-ray requirements are needed to operate the system.

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

1.3 User Profiles

- The Faxitron Pro system does not utilize multiple User Profiles.
- System access is managed through the use of a physical key which serves as an ON/OFF switch.
- Service personnel have password protected 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
	Caution – Potentially infectious materials
	Warning Electricity
	Caution
	Follow instructions for use
REF	Catalog number
SN	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 Pro 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.

Caution:
Cautions the reader to use care in lifting heavy equipment to avoid personal injury and/or damage to the equipment

Note
Notes show additional information.

Chapter 2 General Information

2.1 System Overview

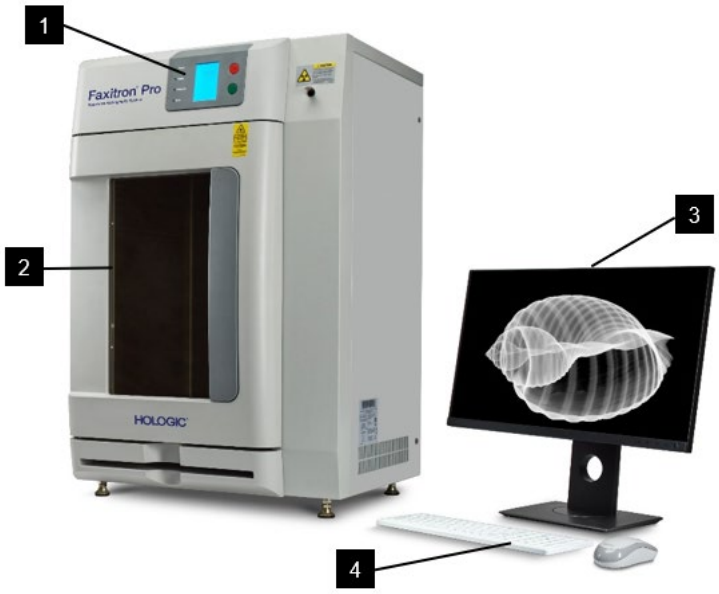


Figure 1: Faxitron Pro System

Figure Legend

1. Control Panel
2. X-Ray Imaging Chamber
3. Image Display Monitor
4. Keyboard & Mouse

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 5 cm (2 in.) from exterior surface at maximum kV.
- Certified to comply with standards set forth 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 Laboratory the US and Canada.

2.2.2 Interlocks

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

X-ray generation stops automatically when there is an interruption of an x-ray exposure. An x-ray exposure interruption may be caused by opening the cabinet door, pressing the stop button (either physical or software), or loss of communication between x-ray subsystem and the computer. The interruption may, or may not, generate an error message. *See figure below.*

Figure 2: Generator Timing Mismatch Error Message

1. Click **OK.**
2. Close and/or verify cabinet door is fully closed.
3. Repeat acquisition.

Note
Contact Hologic if the error message is persistent.

2.2.3 Laser Locator

The Faxitron Pro utilizes a pair of Laser generated lines to aid in positioning samples in the middle of the imaging field.

Compliance

The lasers comply with:

- IEC 60825-1:2007
- 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

The lasers require no assembly.

Note
There is no authorized operator maintenance on the lasers. The lasers are to be serviced only by a Hologic Authorized Representative.

Caution:
CLASS 2 LASER RADIATION WHEN THE CHAMBER DOOR IS OPEN. DO NOT STARE INTO THE BEAM.

Caution:
A laser beam can be damaging to the eyes. DO NOT look into the laser aperture when the laser is in operation.

Caution:
The laser apertures are located in the ceiling of the X-Ray chamber.

Caution:
Be aware that laser light can also be dangerous when reflected off a mirror-like surface.

Note
For further safety information regarding lasers, refer to ANSI-Z136.1 STANDARD FOR THE SAFE USE OF LASERS, available from the Laser Institute of America, phone 1-800-345-2737.

Laser CAUTION Label

Located on the upper right corner of the door. *Refer to Figure 4: Label Locations.*

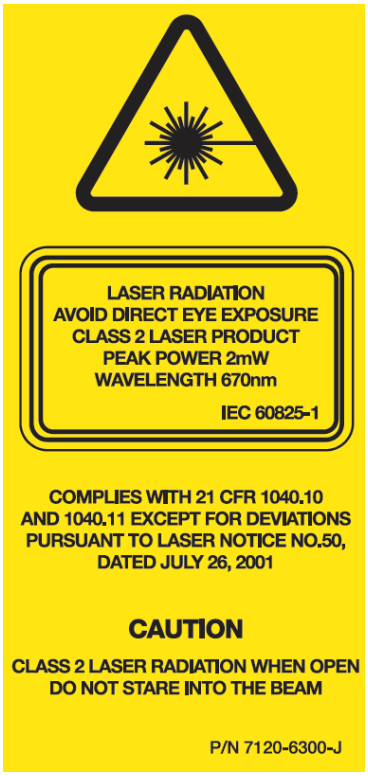


Figure 3: Laser Caution Label

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!
No modification of this equipment is allowed.

WARNING!
Do not attempt to use any x-ray cabinet 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 all power cords for the system are in good condition. A damaged power cord can be an electrical shock hazard. When disconnecting the cabinet, or computer components, 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 system, make sure that the power cords and any cables are unplugged and secured.

WARNING!
Before adjusting the position of the system, make sure the power cords 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.

Warning:
Do not move the cabinet with excessive force or speed. Do not make quick stops.

Warning:
When moving the cabinet, be aware of bumps, ramps, inclines, or declines. Use extra caution when moving the cabinet 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 cabinet and its components, use only the recommended cleaning methods.

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 sample 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.

2.4 Compliance

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

2.4.1 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 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.

2.4.2 Compliance Statements

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

UL, IEC, EN:

- IEC 61010-1: 2012 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
- IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for IVD medical equipment
- IEC 61326-1: 2013 Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements – Part 1: General Requirements
- IEC 61326-2-6 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
- IEC 60825-1:2007 – Safety of Laser Products; Part 1: Equipment classification and requirements
- 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.
- 21 CFR 1040.10 – Laser Products.
- 21 CFR 1040.11 – Specific Purpose Laser Products.
- 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

2.5 DICOM Standard

The Faxitron Pro system 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 DICOM Conformance Statement for more information.

2.6 Interoperable Connections

The Faxitron Pro 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 5.9 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 Path 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.
USB port at 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 at the front	To service and maintain the system files may need to be copied to and from the computer. For example, software updates or log files.	USB storage device (Flash Drive)	Hologic or facility IT personnel.
USB port at the rear	To allow connection of a printer. Vision software allows for connection of a DICOM printer or a standard windows compatible printer.	DICOM or windows printer	Clinicians or facility IT personnel.

2.7 Network / User Settings

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

2.8 Label Locations

All labels, except the Nameplate Label, are from P/N 7120-6300, Label Set, PathVision.

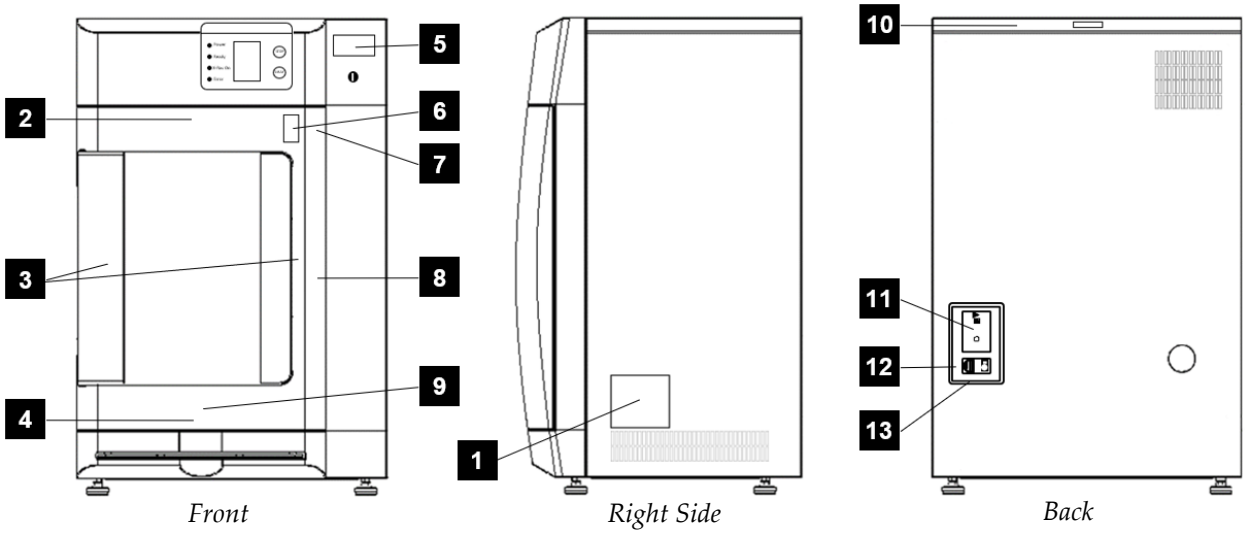


Figure 4: Label Locations

Figure Legend

1. I.D./Nameplate Label, LBL-09961

Items 2 through 13 are from P/N 7120-6300, PathVision Label Set

2. CAUTION – This device produces X-rays when energized – Keep door closed, Label D1 (Inside door)
3. Mag Shelf Labels, Label M (Inside chamber)
4. CAUTION – Lead Glass Warning, Label F (Inside door)
5. CAUTION – X-Rays Produced When Energized, Label A1
6. Laser CAUTION, Label J
7. Laser CAUTION, Label I (Inside door)
8. WARNING, SAFETY INTERLOCK – Do Not Tamper with Interlock, Label E (Inside door)
9. CAUTION, Specimens are potentially infections, Label C (Front of chamber floor)
10. CAUTION, No operator serviceable parts inside, Label O
11. Camera Outlet Panel, Label B1 (for Faxitron Detector) or B3 (for DALSA Detector)
12. WARNING, Possible Shock Hazard and Input Power Ratings, Label L
13. WARNING, Fuse Replacement – Type and Rating, Label K

Chapter 3 Components, Controls, and Indicators

3.1 System Components

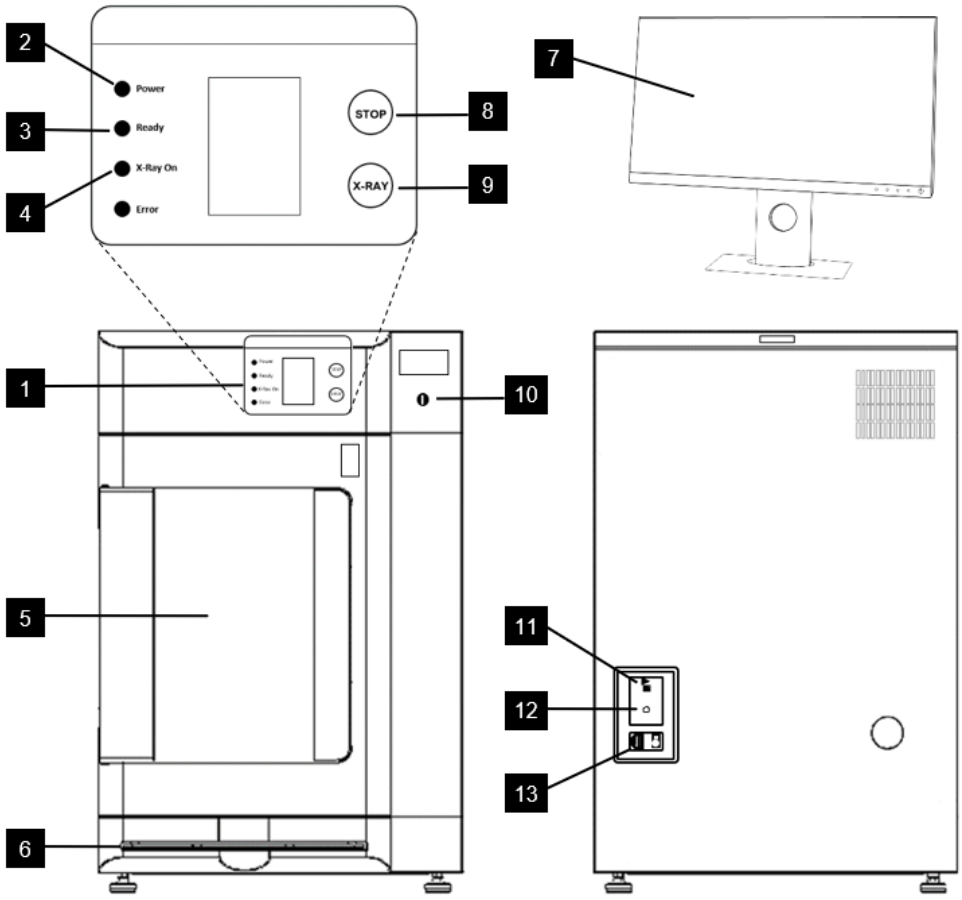


Figure 5: System Components

Figure Legend

1. Control Panel
2. Ready Light (Green)
3. Ready Light (Yellow)
4. X-Ray On Light (Red)
5. Imaging/X-Ray Chamber
6. Magnification Tray Storage Slot
7. System Imaging Monitor
8. Stop X-Ray Button
9. X-RAY On Button
10. Key Switch
11. USB Port - X-Ray Sub-system Communication
12. Camera/Detector Communication Port (Ethernet or Mini Coax)
13. System Power Switch and Power Cord Connection
14. Computer (Not Shown)
15. Keyboard & Mouse (Not Shown)

3.1.1 Imaging Cabinet Components

The cabinet houses a shielded imaging/X-ray chamber. The placement of the specimen tray determines the magnification level of the image.

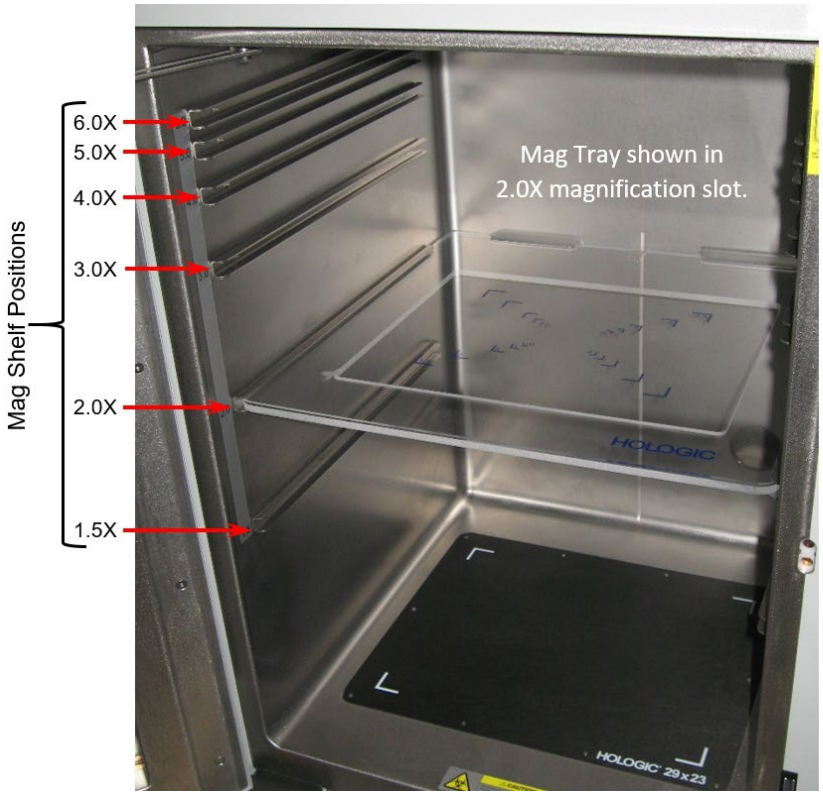


Figure 6: X-Ray Chamber with Magnification Levels

Magnification Tray

The Faxitron Pro system is supplied with a magnification tray (mag tray) which will have different markings depending on whether the system has a 23x29cm or 10x15cm detector installed. The markings define the active image area margins for each magnification level. Note that the 10x15cm mag tray only marks the 1.5x, 3.0x, and 6.0x mag margins due to space limitations.

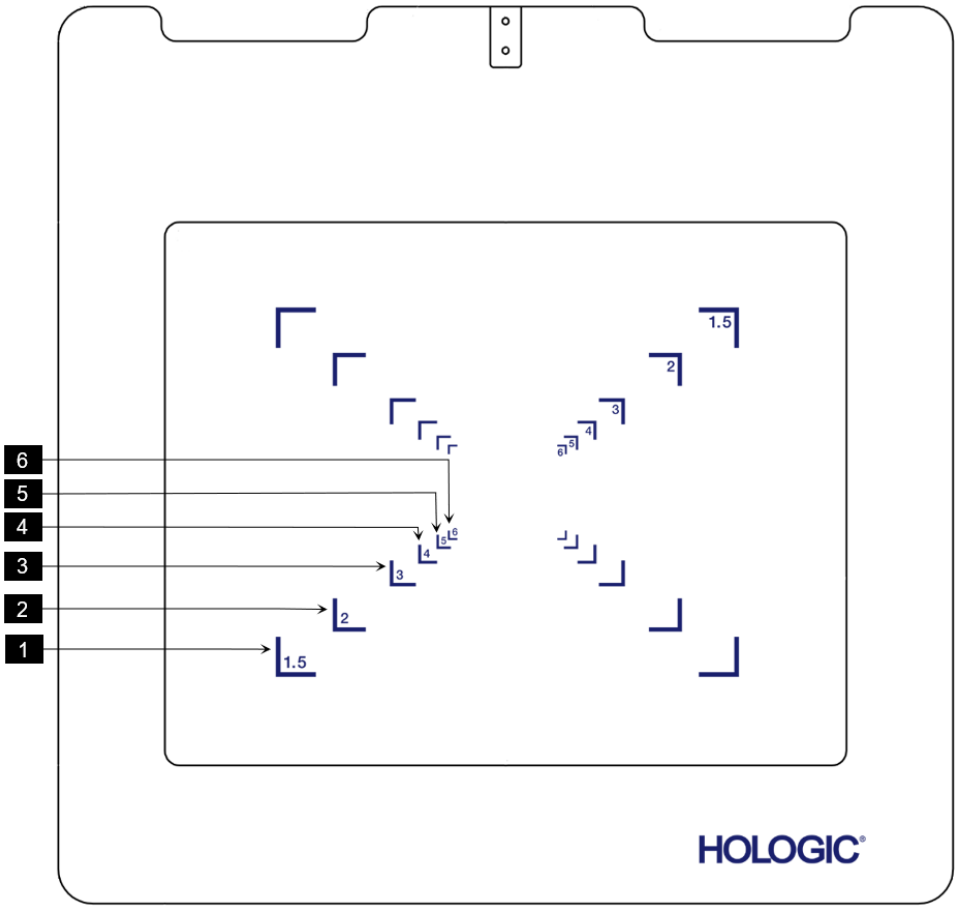


Figure 7: Mag Tray Markings – 23x29 Detector

Figure Legend

1. 1.5x Magnification Margins
2. 2.0x Magnification Margins
3. 3.0x Magnification Margins
4. 4.0x Magnification Margins
5. 5.0x Magnification Margins
6. 6.0x Magnification Margins

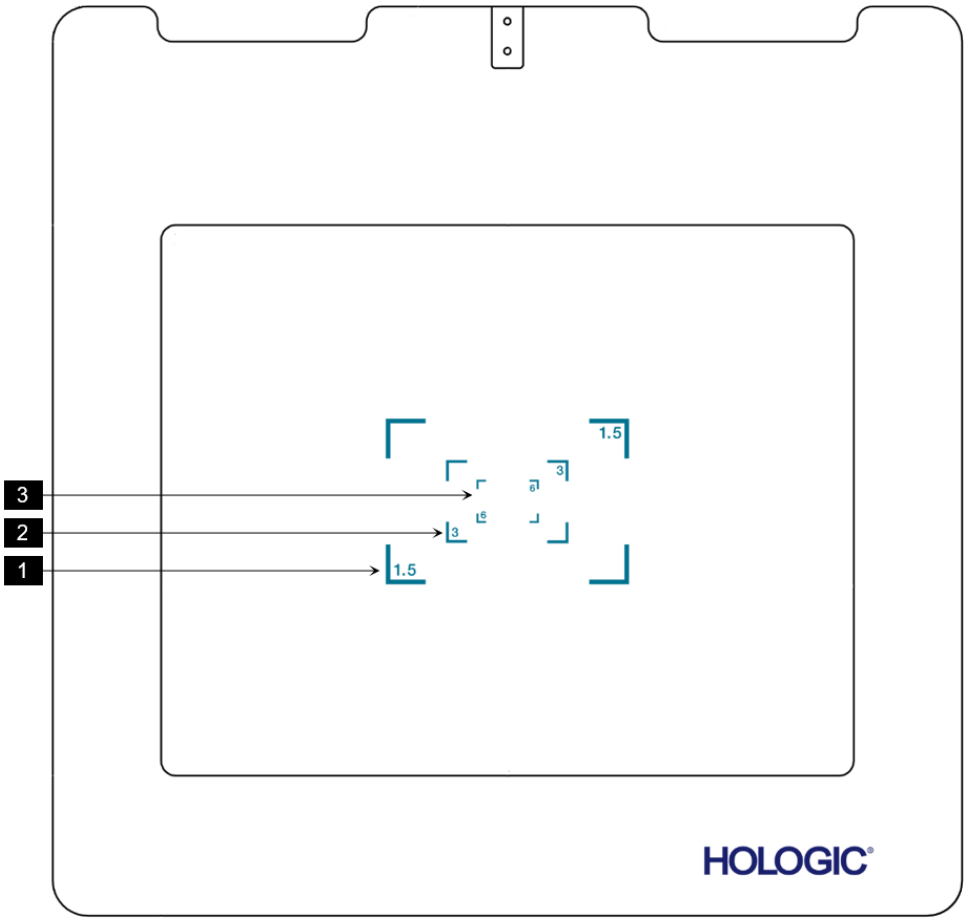


Figure 8: Mag Tray Markings – 10x15 Detector

Figure Legend

1. 1.5x Magnification Margins
2. 3.0x Magnification Margins
3. 6.0x Magnification Margins

The system is also provided with a "Mega Mag" tray which can be inserted into a set of rails at the top of the chamber to provide 10x magnification. Due to the high magnification level the sample size is limited to approximately 3.8cm x 1.7cm (1.5in. x 0.669 in.).

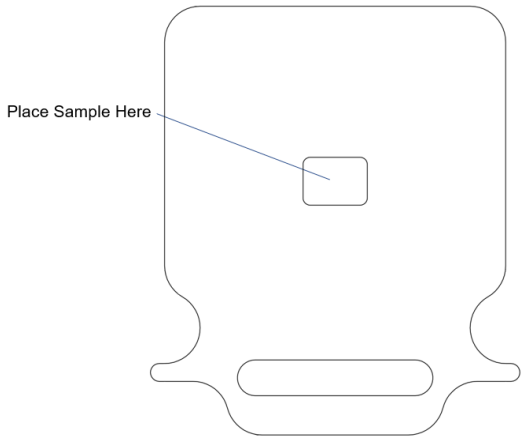


Figure 9: Mega Mag Tray

Caution
To prevent damage, use care when handling and cleaning the magnification trays.

Note
Store the standard magnification tray in the slot provided under chamber door.

3.2 System Connections

Also refer to the Quick Set-Up Guide, P/N 5081-4004.

1. Put the system where you can easily access power and network connections.
2. Connect the Monitor Cable and one of the Power Cords to the monitor. Image shown is an approximation and may vary slightly.

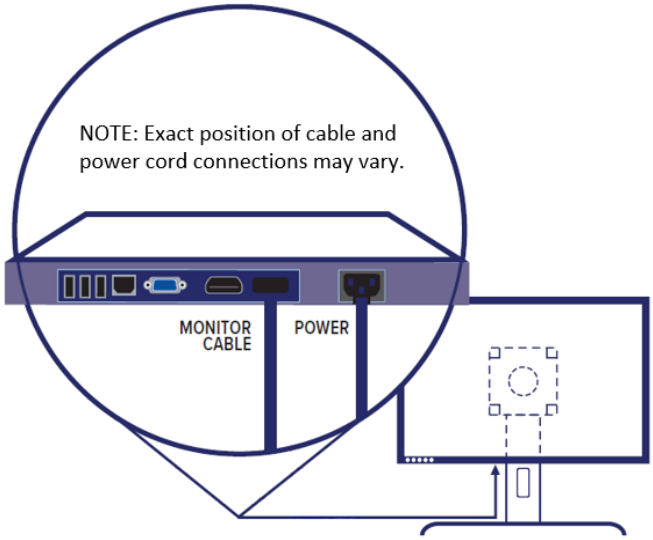


Figure 10: System Imaging Monitor

3. Connect the USB Cable and one of the Power Cords to the back of the Faxitron Pro cabinet.
4. Connect the camera/detector cable(s) to the back of the Faxitron Pro cabinet:
   a. Camera Link (ethernet) cable if your system has a DALSA 23x29cm detector installed.
   b. 2x coax cables if your system has a Faxitron 10x15cm detector installed. Make sure you match the color bands on the cable ends to the colored stripes on the cabinet outlet panel label.

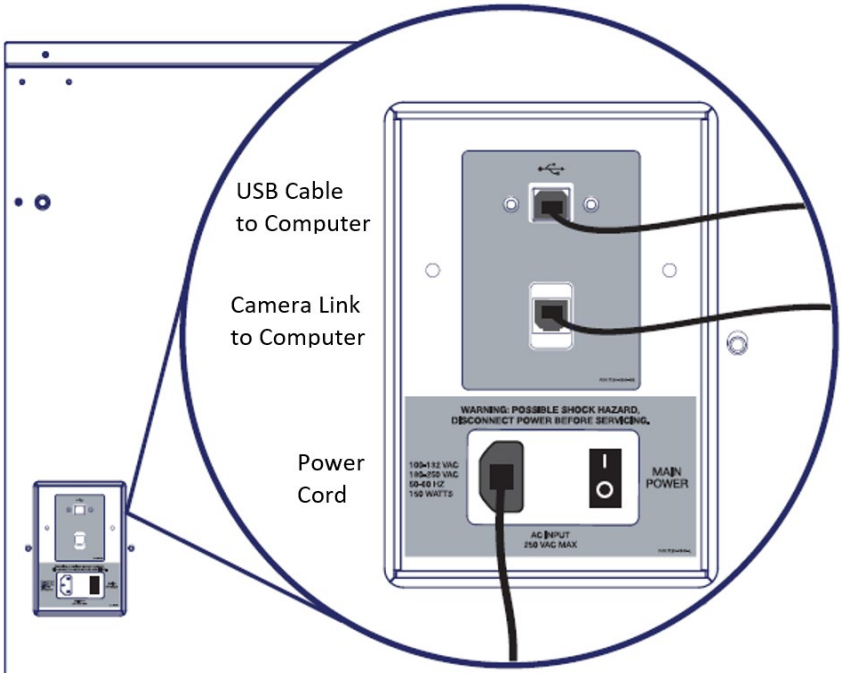


Figure 11: Back Panel Connections – DALSA 23x29cm Detector

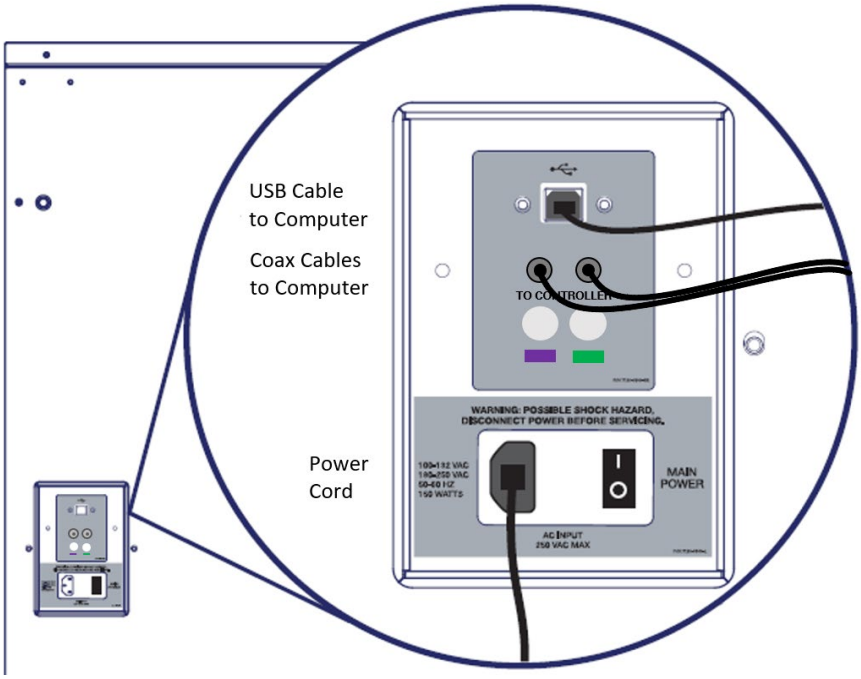


Figure 12: Back Panel Connections – Faxitron 10x15cm Detector

5. Connect the USB cable from the back of the cabinet to the Vision USB port on the back of the computer.
6. Connect the camera/detector cable(s) to the back of the computer:
   a. DALSA Detector: Connect the Camera Link (ethernet) cable to the integrated ethernet connector. Do not connect the Camera Link cable to the expansion card ethernet port.
   b. Faxitron Detector: Connect the coax cables to the coax connectors on the expansion card. Make sure you match the color bands on the cable ends to the colored stripes on the expansion card bracket.

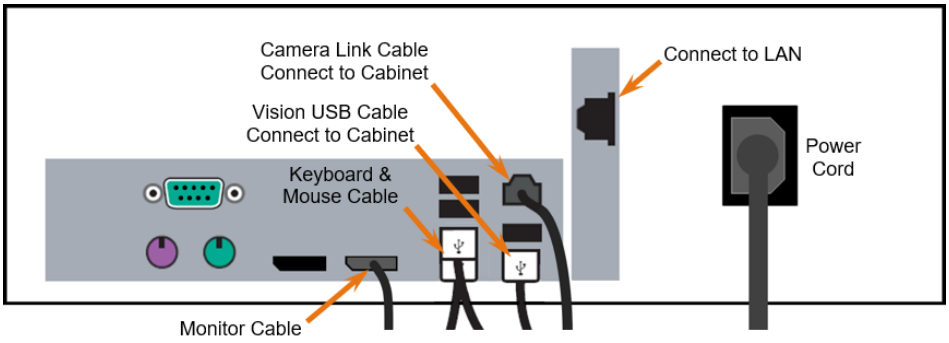


Figure 13: Computer Connections – DALSA Detector

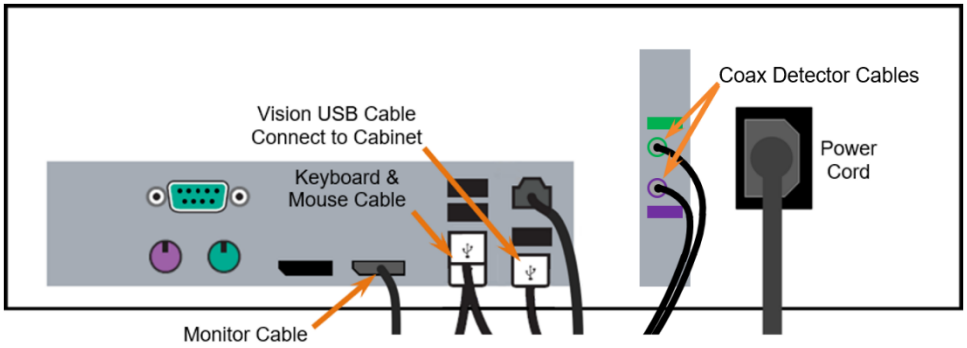


Figure 14: Computer Connections Faxitron 10x15cm Detector

7. Connect the monitor cable to one of the Display Port connections on the back of the computer.
8. Connect the keyboard and mouse cables to the back of the computer.
9. Connect one of the Power Cords to the computer.
10. Connect an ethernet cable to the computer and facility's network, if desired.
11. Connect the monitor, computer, and Faxitron Pro cabinet power cords into the facility's mains power receptable.

3.3 How to Move the Faxitron Pro System

Caution:
The Faxitron Pro cabinet weighs 188kg (415lbs). If the system must be moved use caution to avoid injury to personnel or damage to the equipment.

Note
The Faxitron Pro system was designed as a stationary system and normally should not be moved once installed.

Note
Hologic P/N 2050-0104, Faxitron Path Table with Monitor Arm, is a heavy-duty table designed specifically to support the Faxitron Pro cabinet, computer, keyboard, mouse, and monitor. This table can be purchased separately or ordered as a system add-on.

The Faxitron Path Table has casters which are intended to facilitate moving the system if it has to be relocated. This is not intended to convert the Faxitron Pro system into a mobile system.

Note
Contact Hologic for guidance if you need to move a Faxitron Pro system that is not installed on the Faxitron Path Table.

Note
Refer to MAN-07611, Faxitron Path Table User Guide, Section 3.2.2, Relocation, for instructions and information on moving a Faxitron Pro system installed on the Faxitron Path Table.

Chapter 4 Quick Start – Basic Operation of the Faxitron Pro System

4.1 System Start Up

The start-up sequence must be followed to ensure proper system functionality and image quality.

Note
Allow the system to perform a complete calibration daily prior to system use. The system is configured to perform this calibration if a calibration has not been performed in the previous 12 hours.

4.1.1 Power Up the System

1. Connect the system to power. If desired, connect the system to the network.
2. Set the power switch on the back of the Faxitron Pro cabinet to the "ON" (|) position.
3. Verify there is nothing in the Faxitron Pro chamber.
4. Insert the key into the key lock switch on the front of the cabinet and turn it to "ON" (clockwise to the 3 o'clock position). Note that the key cannot be removed in this position.

Figure 15: Key Switch

5. Turn on the computer and monitor.
6. Verify the GigE Vision Device (Camera) icon in the right side of the computer taskbar does not have a red slash through it.

Figure 16: Dalsa GigE Vision Device (Camera) Icon

4.1.2 Start the Software

The VisionLS software should automatically start when the Windows operating system has completed booting. If the software doesn't automatically start "Double Click" the VisionLS icon on the Windows desktop.

Figure 17: VisionLS Software Icon

Note
Allow the system to perform a complete calibration daily prior to system use.

4.1.3 Calibrate the System

Note
Calibration, including the x-ray tube warmup, take approximately 10 minutes.

1. Upon initial start-up of the day the software should open to the Calibration page.

Figure 18: Calibration Page

2. Click on the **Start Calibration** button and allow the system to complete the calibration. A dialog box will open showing calibration progress.

Figure 19: Calibration Dialog Box

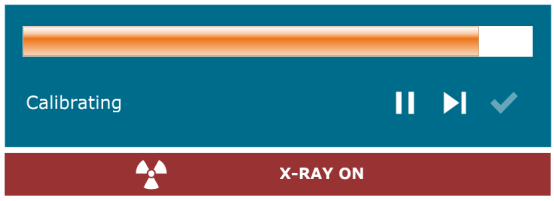


Figure 20: Calibration Dialog Box

3. Upon completion the "Calibration" screen will close, and the "Home Menu" screen will open.

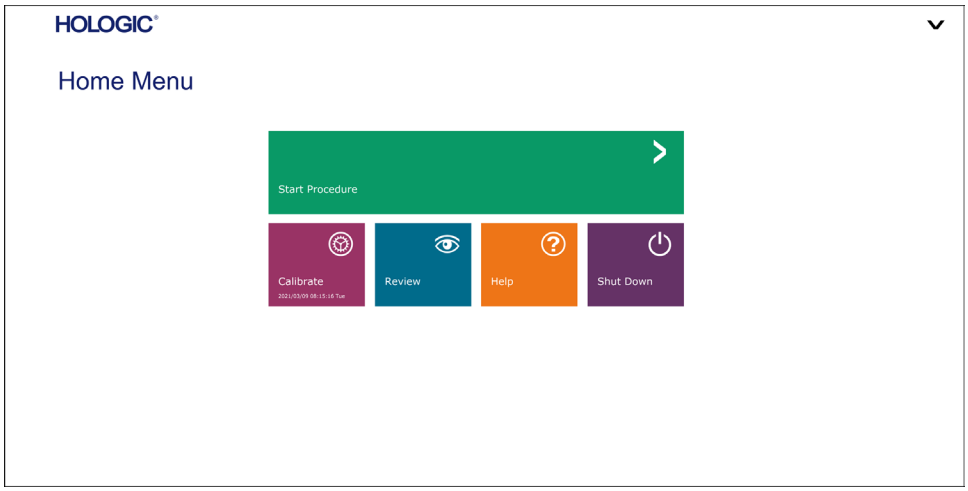


Figure 21: Home Menu Screen

Note
If a calibration has been completed within 12 hours VisionLS software will open directly to the "Home Menu" screen.

Note
The user may calibrate the system at any time by clicking on the **Calibrate** button in the Home Menu.

Note
See Section 5.2, Calibration, for additional calibration information.

4.1.4 Sample Data

1. The **Start Procedure** button on the "Home Menu" page opens a menu which allows the user to select the method for entering *Sample Data.*

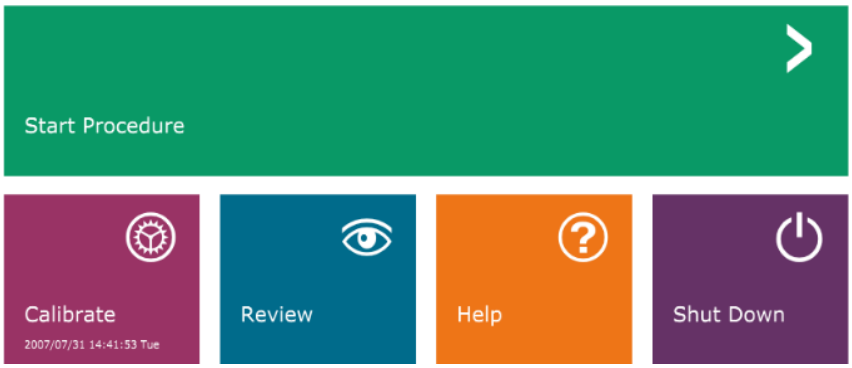


Figure 22: Home Menu

2. Click on the **Manual Entry** button which will open the "Sample Information" editor dialog box.

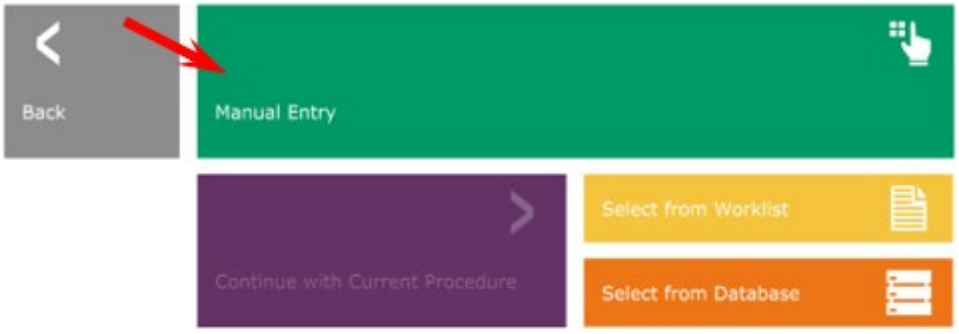


Figure 23: Sample Data Entry Menu

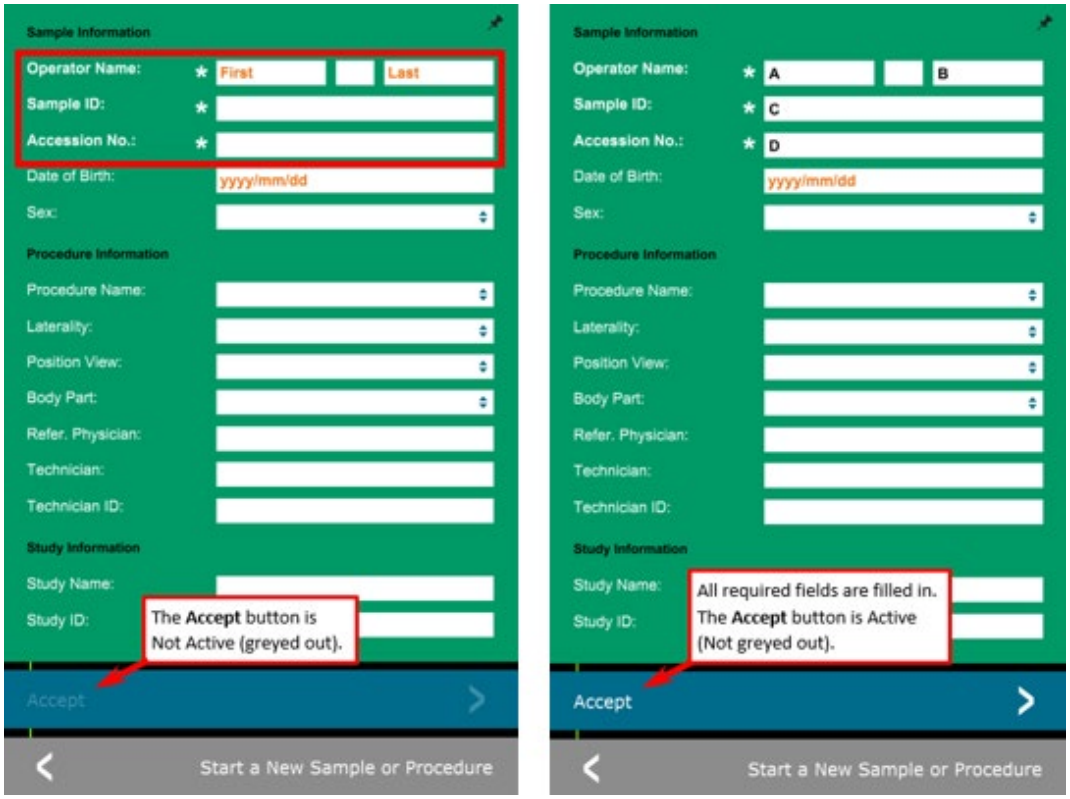


Figure 24: Sample Information Editor Dialog Box – Required Fields Empty and Filled In

3. Complete all required fields, which are indicated by an asterisk. Additional fields may be completed at the users' discretion. The **Accept** button will not be active (greyed out) until the required fields are completed. *See figure above.*

Note
If the date is entered it must be entered as yyyy/mm/dd (e.g., 1962/08/13).

Note
The "required fields" may be altered or deleted depending on the application. Contact Hologic support for further information.

4. Click on the **Accept** button. The software will open the Image Acquisition Screen. *See figure on next page.*

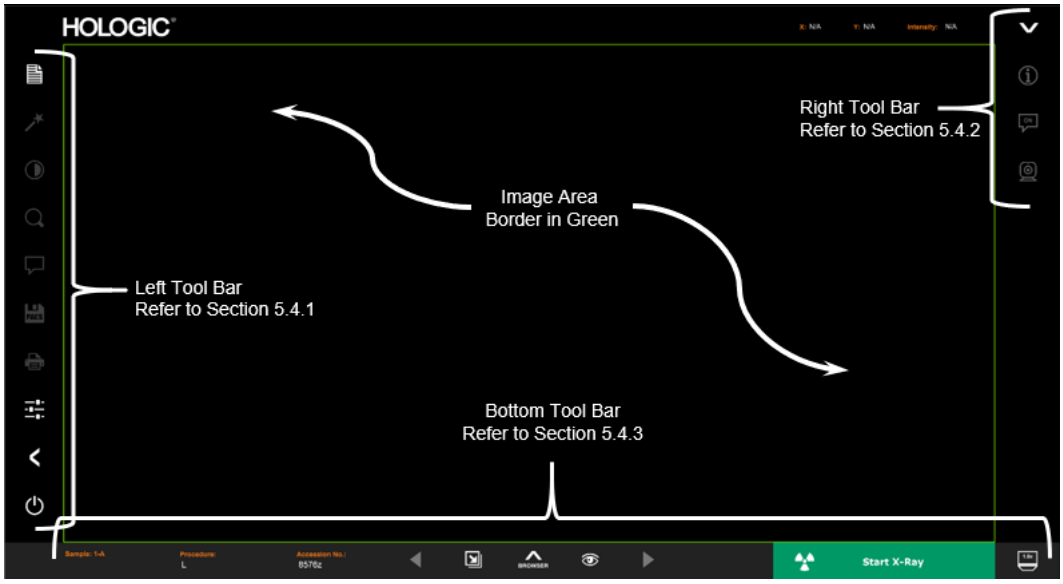


Figure 25: Image Acquisition Screen

4.1.5 Acquiring Images

This section provides a brief description of how to acquire images. Image acquisition is covered in greater detail in Section 5.4, Image Acquisition.

1. Place the sample in the active image area, or on the mag tray and insert the mag tray into the desired magnification level slot.

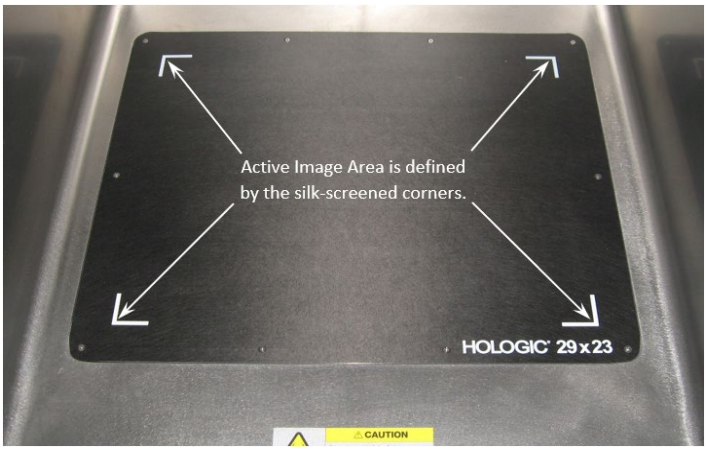


Figure 26: Chamber Floor – Active Image Area

Figure 27: X-Ray Chamber with Mag Tray Installed

2. Close the chamber door.
3. Press the **Start X-Ray** button in the software, or the **X-RAY** button on the control panel.

Figure 28: Start Buttons – Software and Cabinet Control Panel

4. The system will initiate the exposure and process the data. When complete the image will appear on the screen.

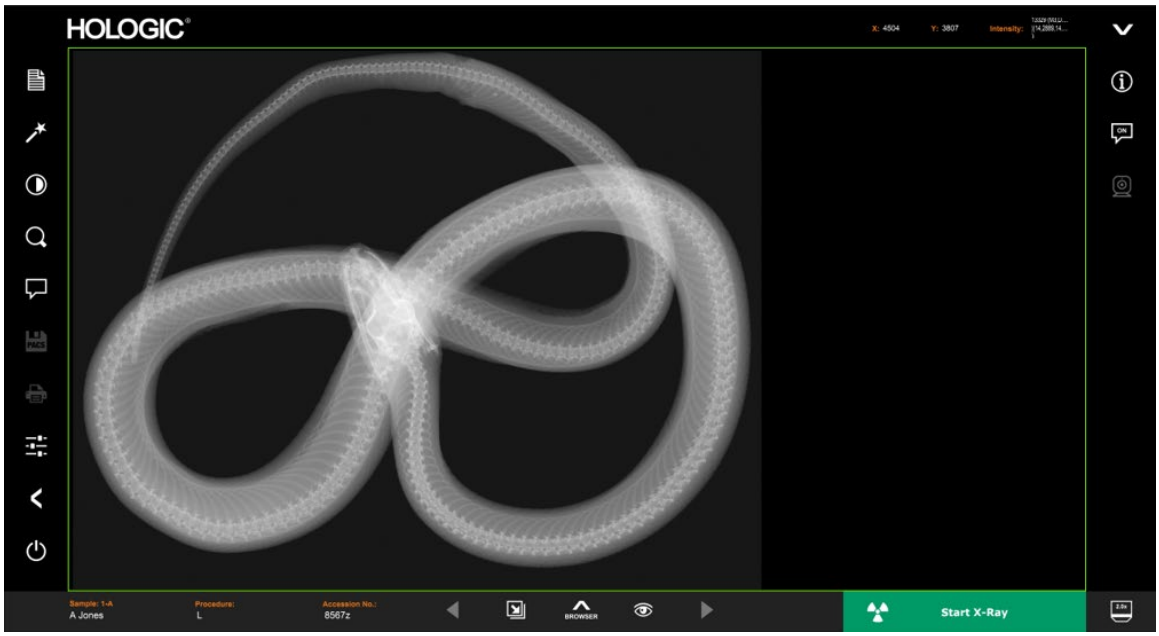


Figure 29: Image Acquisition Screen

Note
Image analysis, manipulation, saving, and retrieval are covered in Sections:

- 5.6 - Tool Bars and Menus
- 5.7 - Current Sample Images Browser
- 5.8 - Database / Review Mode
- 5.9 - DICOM Functionality and
- 5.10 - User Annotations

4.2 How to Shut Down the System

If more than one procedure is scheduled for the day, it is advisable to leave the system on. If the system is no longer needed for the day, begin the shutdown procedure.

1. System Shutdown can be initiated from either the Home Menu (Main Screen) or within the Image Acquisition Page. *See figures below.*

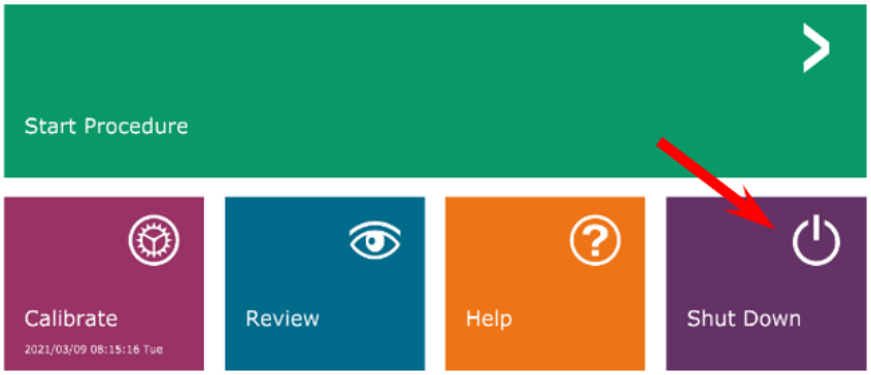


Figure 30: Shut Down Button in the Home Menu

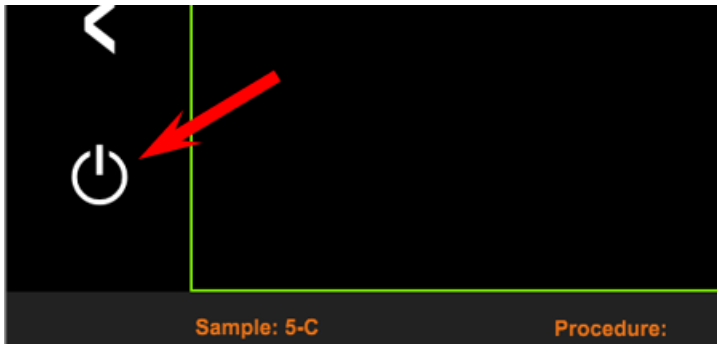


Figure 31: Shut Down Button on the Image Acquisition Screen

2. Clicking either **Shut Down** button will bring up the "Shutdown System" Confirmation Dialog box.

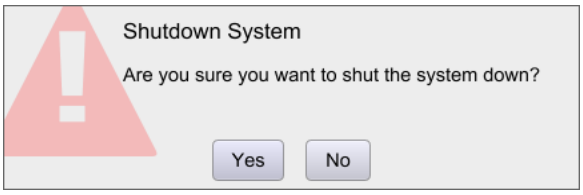


Figure 32: Shut Down Confirmation Dialog Box

3. Click **Yes** to continue the shutdown procedure. The VisionLS software will close, and the computer will shut off.
4. Turn the key on the front of the cabinet to the OFF position, counterclockwise 90°, then remove the key to prevent unauthorized use of the system.

4.2.1 How to Remove All Power from the System

1. Make sure that the computer system and cabinet are completely turned OFF.
2. Disconnect the X-Ray cabinet, computer, and monitor power cords from the electrical outlet.

Chapter 5 VisionLS Software Operation and User Interface

5.1 Overview of VisionLS Software

Hologic's VisionLS Software is a complete image acquisition and processing package, designed exclusively to work with Hologic's Faxitron line of Life Science X-Ray Generators (such as Faxitron Pro and MultiFocus systems). 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 Digital Imaging and Communications in Medicine (DICOM) compliant, allowing saving and printing of sample images in DICOM format 3.0.

Note
Refer to Section 4.1, System Start Up, for system and software startup.

5.2 Calibration

5.2.1 Calibration Introduction

To optimize image quality the Faxitron Pro system requires periodic calibration, which requires the acquisition of reference images. These reference calibration images are used to calibrate a "raw" X-Ray image on a pixel-by-pixel basis to generate a "corrected" image for display. Image corrections performed include gain, offset, and linearity.

An x-ray tube warm-up sequence, which helps prolong the life of the tube, is incorporated into the system calibration. The warm-up sequence exercises the x-ray tube through the system's full energy range.

Calibration is a critical component of the system operation. Upon initial start-up of the system, or at any time desired by the user, a system calibration may be requested and performed. Additionally, the software will prompt for a calibration whenever the VisionLS software is started, and a calibration has not been performed with 12 hours.

Note
Perform a system calibration whenever the Faxitron Pro X-Ray System is started after prolonged periods of inactivity.

Note
Perform a system calibration if the Faxitron Pro X-Ray System is moved to another room with potentially different ambient temperature/humidity settings.

5.2.2 Calibration Sequence

For convenience, VisionLS software combines the numerous steps of calibration into a single unified step.

To calibrate the system at any time, click the **Calibrate** button on the Home Menu (Start-up Screen), and then press **Start Calibration.** *See figures below.* The Dialog will display a status message during calibration. *See figures 36 & 37.*

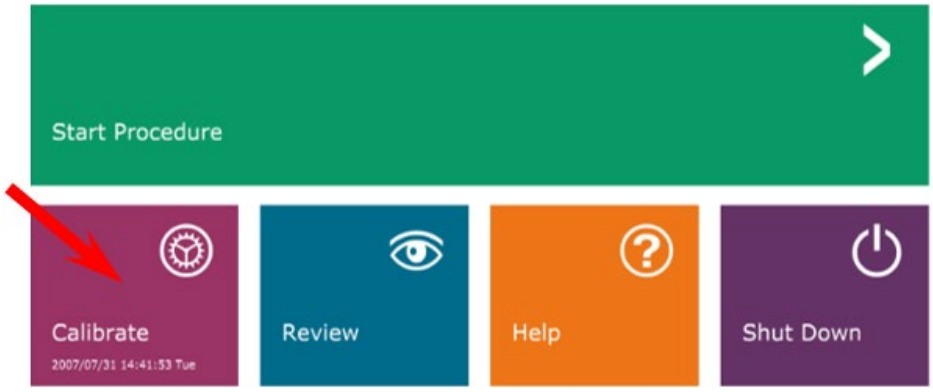


Figure 33: Calibrate Button

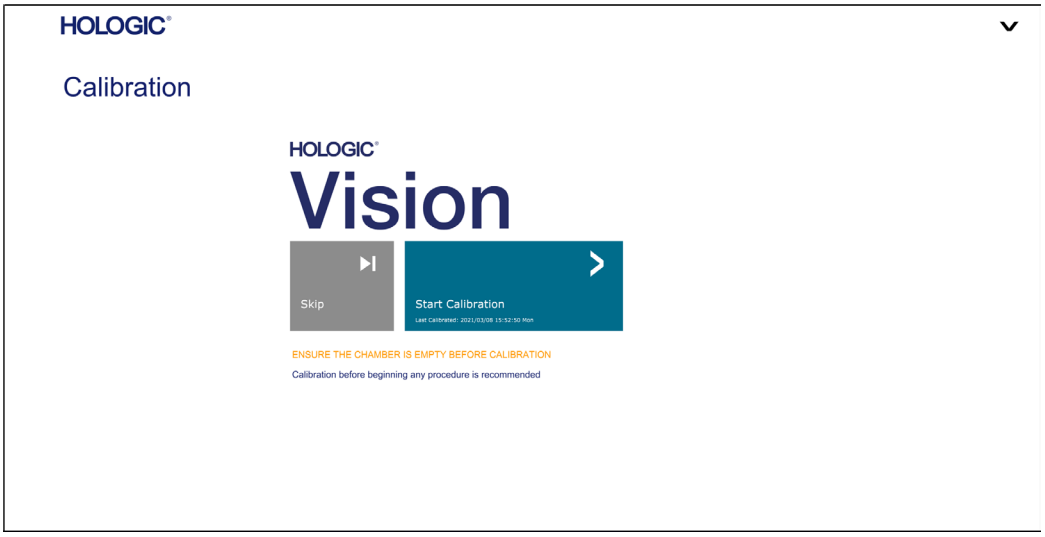


Figure 34: Calibration Screen

Figure 35: Calibration Progress

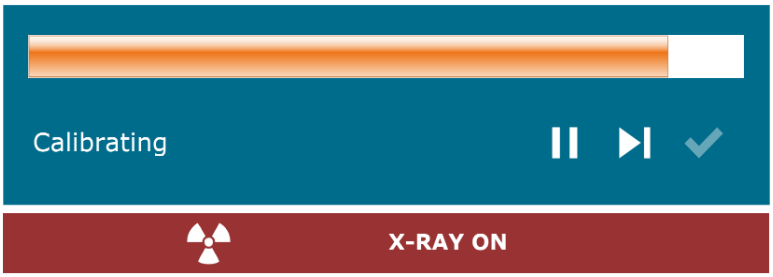


Figure 36: Calibration Progress

5.2.3 Advanced Calibration

At times it may be beneficial to incorporate the X-Ray attenuation characteristics of a uniform attenuator in the flat-field reference calibration images. For example, if all samples are imaged on a thin plastic plate, the X-Ray attenuation characteristics of the plate will be observed in every image acquired. However, placing the plate in the X-Ray beam during calibration could improve image quality, since the characteristics of the plate are captured in the reference images.

A summary of the advanced calibration protocol for "Both" (Flat Field and Image) follows:

1. Place the uniform attenuator on the detector. The entire detector surface should be covered by the attenuator. For best results, the attenuator should be larger than the detector's imaging area.
2. From the Home Menu screen press the **Reveal/Hide Top Menu** button ^ in the Right Tool Bar (the top-right corner of the screen).
3. Select *"Tools"*, *"Advance Tools"*, then *"X-Ray Calibration/Exposure Setup"*. The "X-ray Generator and Exposure Settings" Dialog opens. *See figure below*.

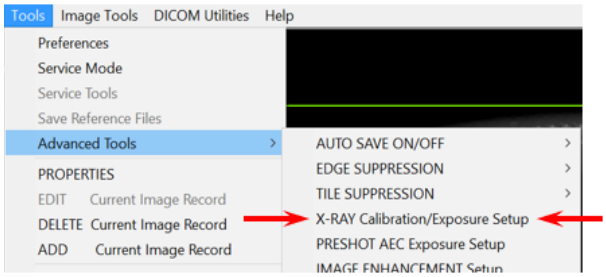


Figure 37: Tools Menu – Advanced Tools – X-Ray Calibration/Exposure Setup

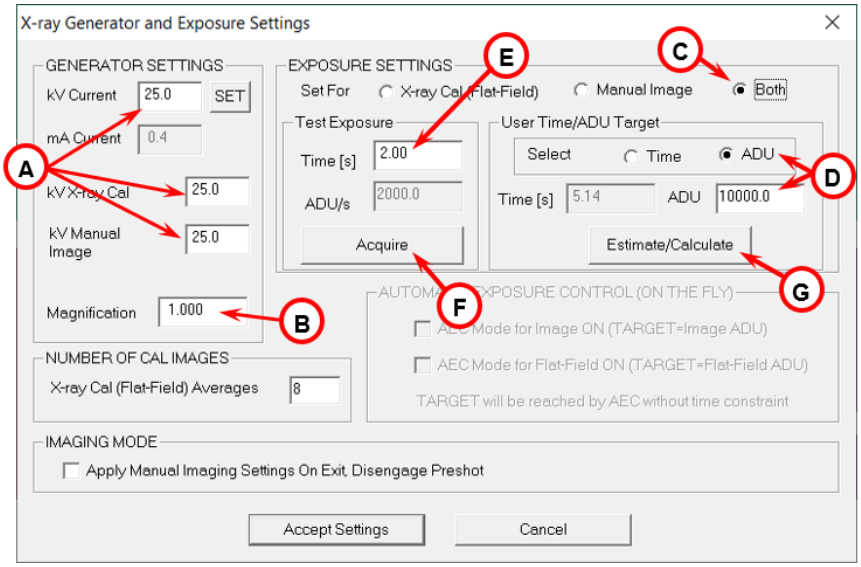


Figure 38: X-Ray Generator and Exposure Settings Dialog Box

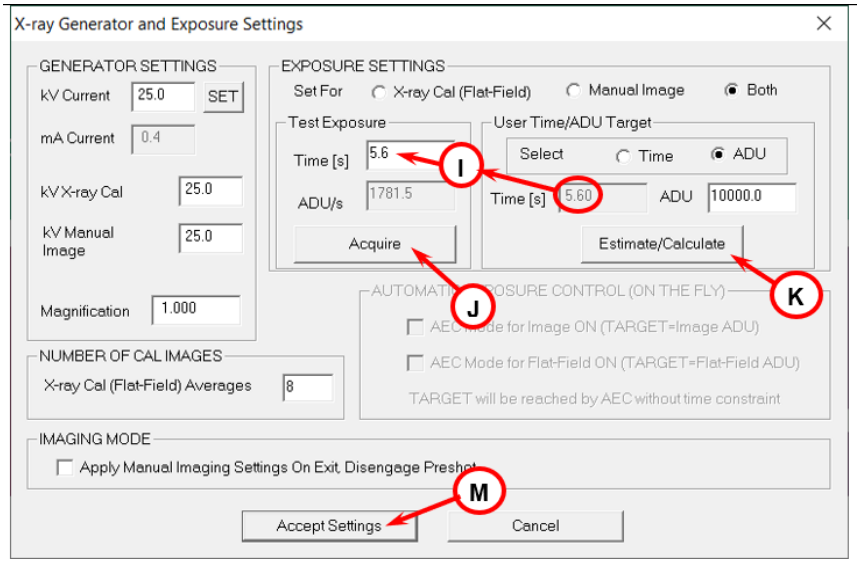


Figure 39: X-Ray Generator and Exposure Settings Dialog Box

Note
The values displayed in the example screens above are not necessarily correct for your system. kV and Exposure Time settings may vary from system to system. These settings may also change as the x-ray tube ages.

Note
The alphabetical references in the figures above correspond to the steps in the following procedure.

Refer to the above figures when performing the following procedure.

a. Under "X-Ray Generator and Exposure Settings", enter the generator kV setting in the appropriate field. This will normally be the Calibration kV value. (25.0 in the example shown.)

b. Enter the "Magnification" level or leave the default setting of 1.000.

c. Under "EXPOSURE SETTINGS" > "Set For", click *"Both".*

d. Under "User Time/ADU Target" verify that "ADU" is selected. Leave the default "user ADU target" setting. Typically, 10,000 for the 23x29 detector.

e. Leave the default "Test Exposure" time. 2.00 is typical.

f. Click the **Acquire** button. The system will automatically begin an x-ray exposure and obtain an image. Note that this image is not displayed on the screen.

g. When the exposure is complete, click on the **Estimate/Calculate** button.

h. Record the calculated exposure time "Time [s]" value under "User Time/ADU Target". This time is calculated by the software and the number is greyed out.

i. Enter the calculated exposure time reading "Time [s]" in the "Test Exposure" time box.

j. Press the **Acquire** button to begin another x-ray exposure and obtain an image.

k. When the exposure is complete, click on the **Estimate/Calculate** button.

l. Enter the calculated exposure time reading in the "Test Exposure" time box once again.

m. Click on the **Accept Settings** button.

n. Perform a standard calibration procedure, as described in Section 5.2.2, "Calibration Sequence". *However, make sure you leave the attenuator plate in the chamber.*

Additional Notes on Advanced Calibration

Experienced users may wish to determine optimum "EXPOSURE SETTINGS" for "X-Ray Cal (Flat-Field)" and "Manual Image" independently, or "Both" (simultaneously), as previously described. By selecting the "Flat Field" radio button, the system will determine the optimum exposure time for acquiring Flat Field (calibration) images at the desired ADU level. selecting "Manual Image" will determine the optimum exposure time

for the system with an object which will attenuate the X-Ray signal in the chamber. For best results, the entire imaging area of the detector must be covered by the object.

After the selection of either "X-Ray Cal (Flat-Field)" and "Manual Image" and the ADU level has been set, select the **Acquire** button. For the "Manual Image" selection, ensure the object or X-Ray attenuator is in the X-Ray beam. Press the **Acquire** button to generate X-Rays and obtain an image. When the X-Ray exposure is complete, click on the **Estimate/Calculate** button. The system calculates optimum exposure time, and the number is greyed out. Click the **Accept Setting** button to save the "Exposure Settings" to the system's configuration file. **Note: Only the settings for the selected radio button are saved.** Next perform a standard calibration procedure, as described in Section 5.2.2, "Calibration Sequence".

5.3 Automatic Exposure Control (AEC)

The Faxitron Pro utilizes Automatic Exposure Control (AEC) to provide the best possible image quality with a single press of the **Start X-Ray** button. The software analyses a *Preshot* x-ray exposure, typically 2-3 seconds, to calculate the optimal exposure kV and time settings needed to produce the best image quality. The Preshot AEC Exposure is configured at the factory and is turned on by default.

5.3.1 Preshot AEC Setup

"Preshot AEC Exposure Setup" allows the user to adjust the system for particular imaging requirements, or to compensate for system aging.

To access the "Preshot AEC settings" dialog go to the Top Menu Bar, select *"Tools"*, *"Advanced Tools"*, then *"PRESHOT AEC Exposure Setup"*.

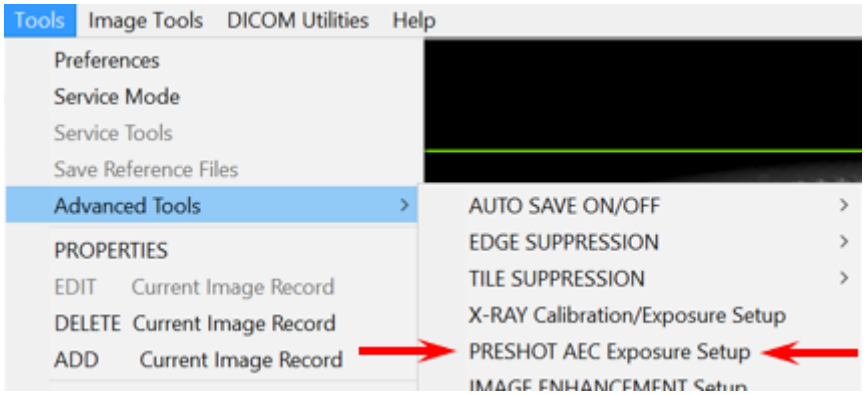


Figure 40: Tools Menu – Advanced Tools – PRESHOT AEC Setup

The "Preshot AEC Settings" dialog will open.

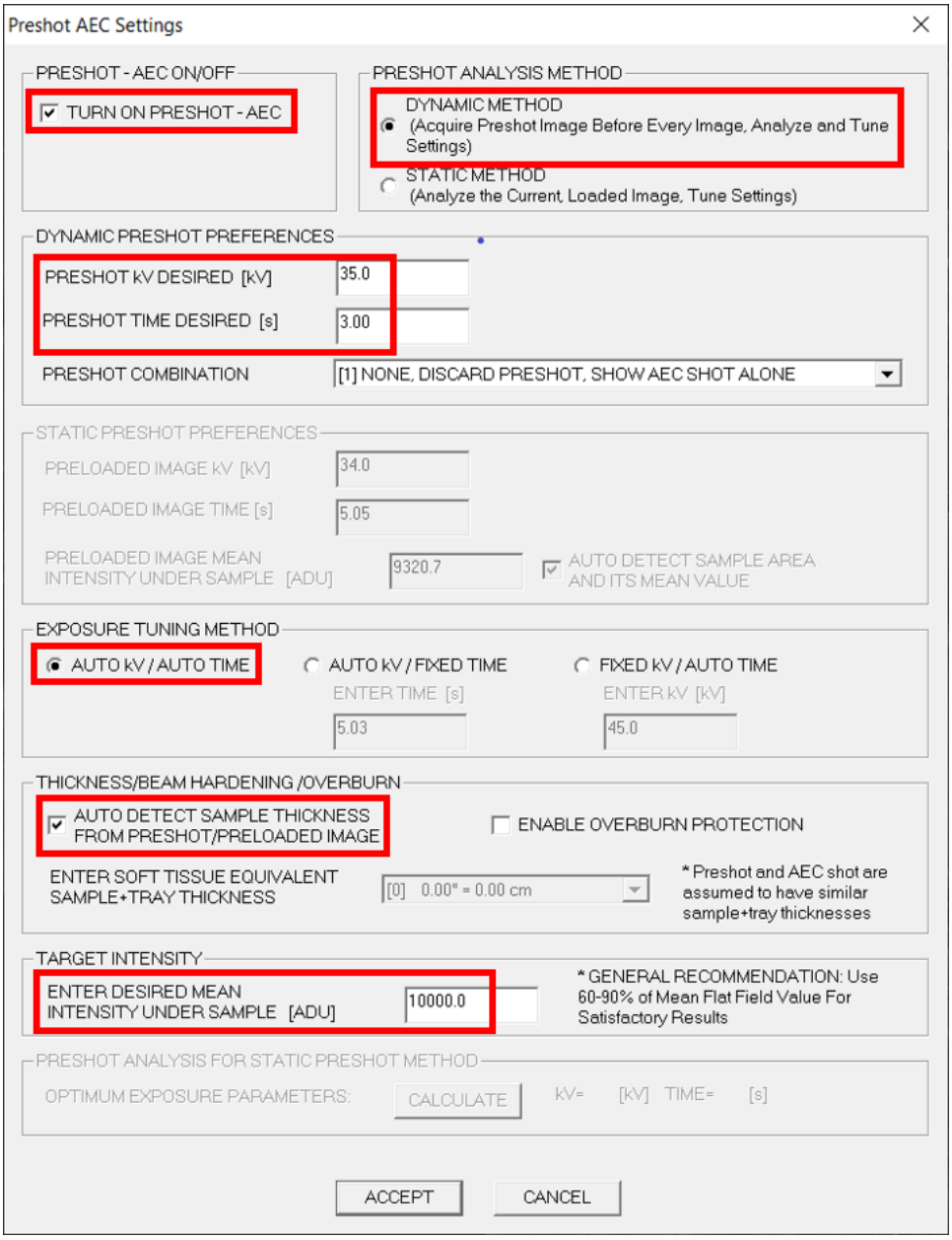


Figure 41: Preshot AEC Settings Dialog

- Verify that "TURN ON PRESHOT – AEC" is selected. It should be on by default.
- Verify that "DYNAMIC METHOD" is selected.
- Enter "PRESHOT kV DESIRED [kV]" and "PRESHOT TIME DESIRED [s]". Exposure time and kV shown will vary depending on the particular system. These values may also need to be adjusted as the system ages.
- Verify "AUTO kV / AUTO TIME" is selected. The software will calculate the best exposure kV and Time to provide optimum image quality based on the "Preshot"

exposure. Alternately you may choose to select and enter a "FIXED" exposure time or kV. The software will then calculate the best exposure kV or time.

- Verify that "AUTO DETECT SAMPLE THICKNESS FROM PRESHOT/PRELOADED IMAGE" is selected.
- And finally, "ENTER DESIRED MEAN INTENSITY UNDER SAMPLE (ADU)". This is typically 10000 for a Faxitron Pro with a DALSA detector installed. However, this value may vary depending on the type of sample being imaged.
- Click on the **ACCEPT** button.

Note
If the "STATIC METHOD" is used instead of the "DYNAMIC METHOD" the software will use Hologic predefined parameters.

Note
The user may also deselect "AUTO DETECT SAMPLE THICKNESS FROM PRESHOT/PRELOADED IMAGE" and enter the sample thickness. This may result in more accurate images.

Place the sample in the chamber and press the **Start** button in the VisionLS software (or on the Control Panel). The VisionLS software will perform a pre-shot exposure, create a Region of Interest (ROI) for obtaining the exposure parameters, then take the image exposure.

5.4 Sample Data

Sample data must be entered into the Sample Information Editor to initiate a procedure.

Clicking the **Start Procedure** button, *see figure below,* opens the Sample Data Entry page which provides methods to enter sample data. *See figure 44.* If a Work List has not been configured, the option will be greyed out and only the **Manual Entry** and **Select from Database** options will be accessible. The options are explained in the next sections.

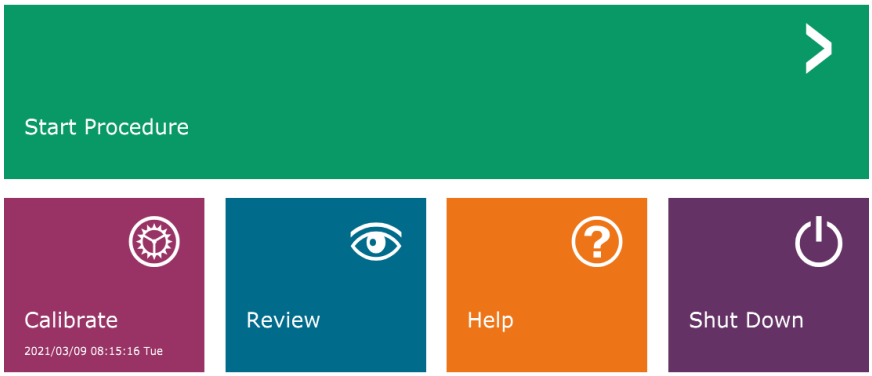


Figure 42: Home Menu

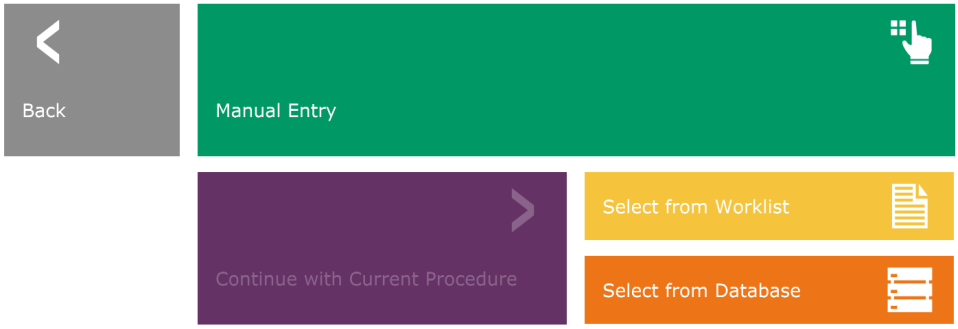


Figure 43: Sample Data Entry Options

5.4.1 Manual Entry

Also refer to Section 4.1.4.

1. Click on the **Manual Entry** button to manually enter a new Procedure. The "Sample Information Editor" will open.

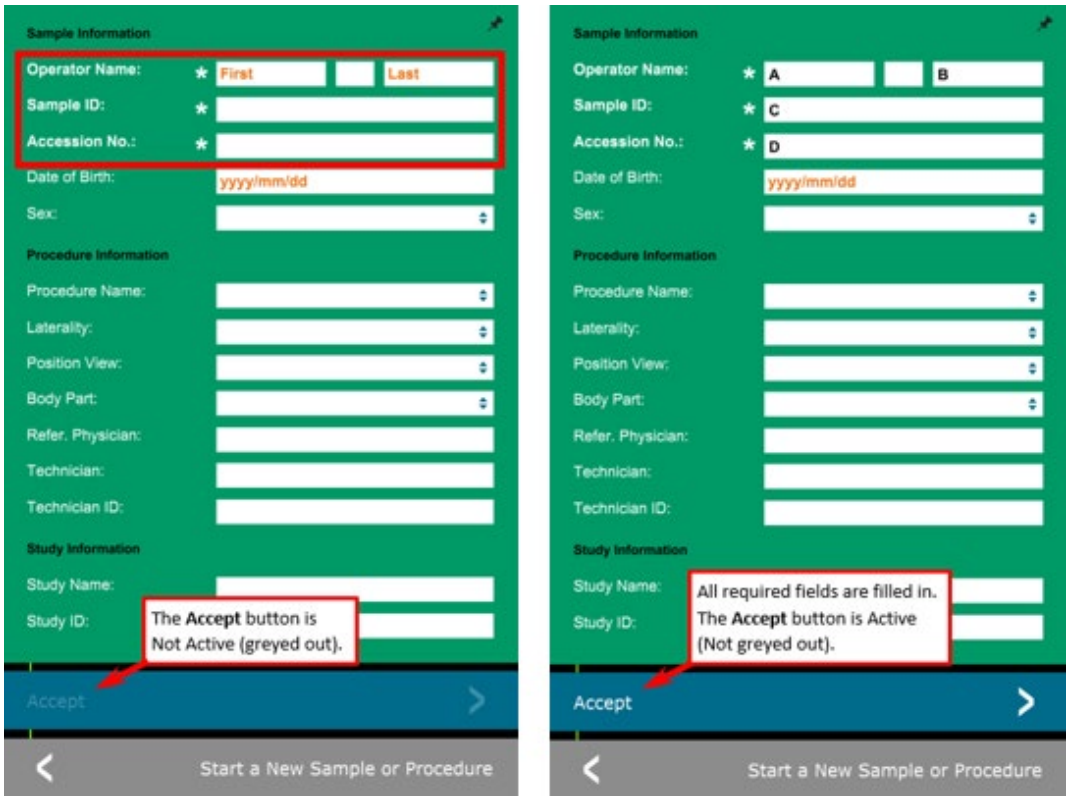


Figure 44: Sample Information Editor Dialog Box – Blank on Left, Complete on Right

2. Complete all required fields, which are indicated by an asterisk. Additional fields may be completed at the users' discretion. The **Accept** button will be greyed out (inactive) until the required entries are completed.

Note
If the date is entered it must be entered as yyyy/mm/dd (e.g., 1962/08/13).

Note
The "required fields" may be altered or deleted depending on the application. Contact Hologic support for further information.

3. Click the **Accept** button. The Image Acquisition screen will open.

5.4.2 Continue with Current Procedure

The **Continue with Current Procedure** button is not active in the VisionLS software at this time.

5.4.3 Select from Work List (Remote Modality Work List)

Work Lists are normally only utilized in clinical applications. However, if a Work List has been configured the user can click the **Select from Work List** button which will display a page similar to the Select from Database page. *See figure 46.*

The user can scroll through the list to find the desired procedure, or can use the *Search Parameters* window, on the left side of the page, to narrow down the list.

Click on the desired procedure then click on the **Submit** button, or simply double click on the procedure. This will open the Sample Information Editor Dialog Box shown in *figure 45.*

The Operator Name and Sample ID fields will be populated. Enter the Accession No. The **Accept** button will now be active.

Click the **Accept** button to open the Image Acquisition screen.

Note
The user may enter additional sample information as desired.

5.4.4 Select from Database

Clicking the **Select from Database** button will display the following page. *See figure below.*

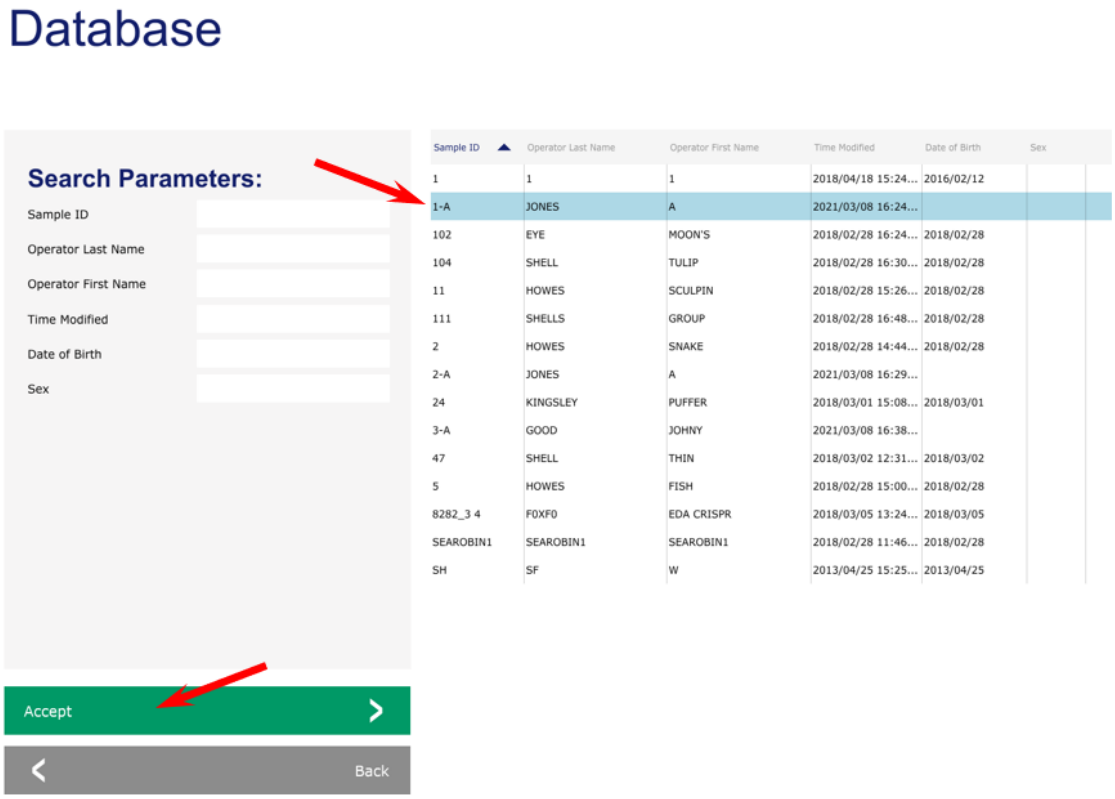


Figure 45: Select from Database Page

1. Select the sample from the table on the right side of the page.
2. Click on the **Accept** button (or double-click the sample entry in the table). The Sample Information Editor will open. *See figure 45.*
3. Complete the required fields, then click the **Accept** button. *Refer to Section 5.4.1, Manual Entry.*

The *"Search Parameters" window* allows the user to narrow the sample list by entering specific information in one or more fields. Only those samples matching all search parameters will be displayed. *See figure below.*

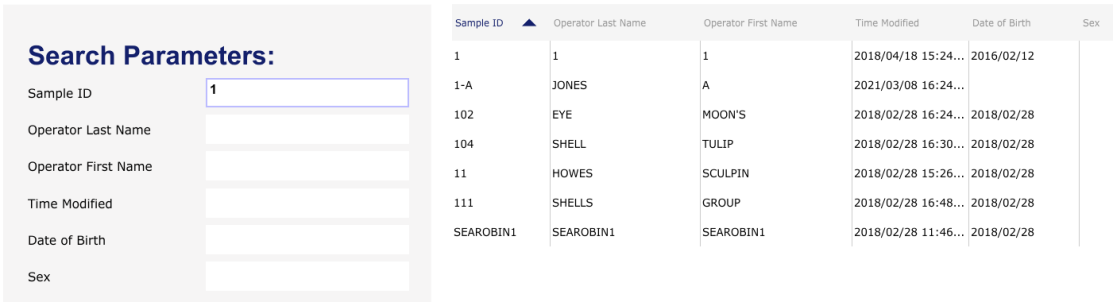


Figure 46: Select from Database – Using Search Parameters

5.5 Image Acquisition

X-rays are started by pressing the green **Start** button on the front of the Faxitron Pro cabinet or clicking the **Start X-Ray** button in the lower right corner of the screen. *See Section 4.1.5, **Acquiring Images**.* The system will take a short *"sample"* x-ray, or pre-shot (which is explained in Section 5.3) followed by a longer exposure to acquire the image. The software will process the image before it is displayed on the monitor screen. Once the image is displayed, buttons on the left and right side of the screen, *covered in Section 5.6, Tool Bars and Menus,* will be enabled.

5.6 Tool Bars and Menus

VisionLS software provides various tools and menus to control various image attributes or parameters, x-ray acquisition, image views, image tools, and DICOM settings/access. The tools most frequently used are in Tool Bars at the sides and bottom of the screen. The Tool Bars and Menus are described in more detail in the following pages.

5.6.1 Left Tool Bar

VisionLS software provides single click access to 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. *See figure below.*

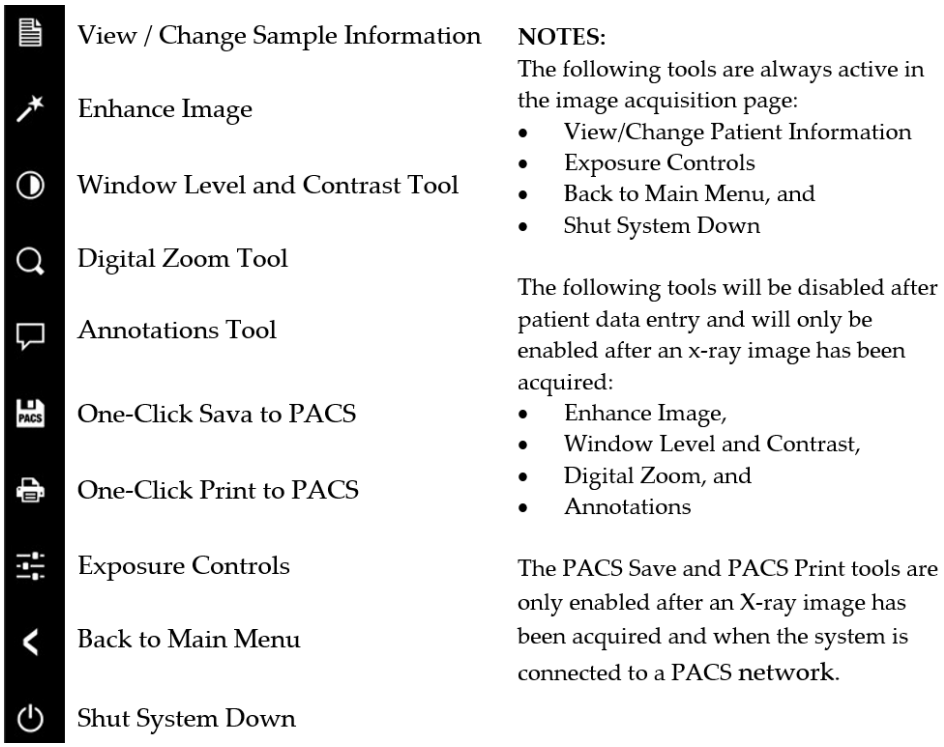


Figure 47: Left Tool Bar

View/Change Sample Information

Click the **View/Change Sample Information** button to view or change the sample information after it has been input. *See figure below.* Note that sample information can only be changed before an image has been taken. The button will turn green when the mouse is hovered over it and while the Sample Information Editor is open.

Figure 48: View/Change Sample Information Button

The Sample Information Editing Dialog box will open. This editing window will be populated with all the information that was previously entered/selected. Note that the dialog box will now include a **Cancel** button. *See figure on left below.*

After acquiring an image, the user may view, but not edit, the sample information. The Sample Information Dialog will now only have options to **Close** Dialog or **Start a New Sample or Procedure.** *See figure on right below.*

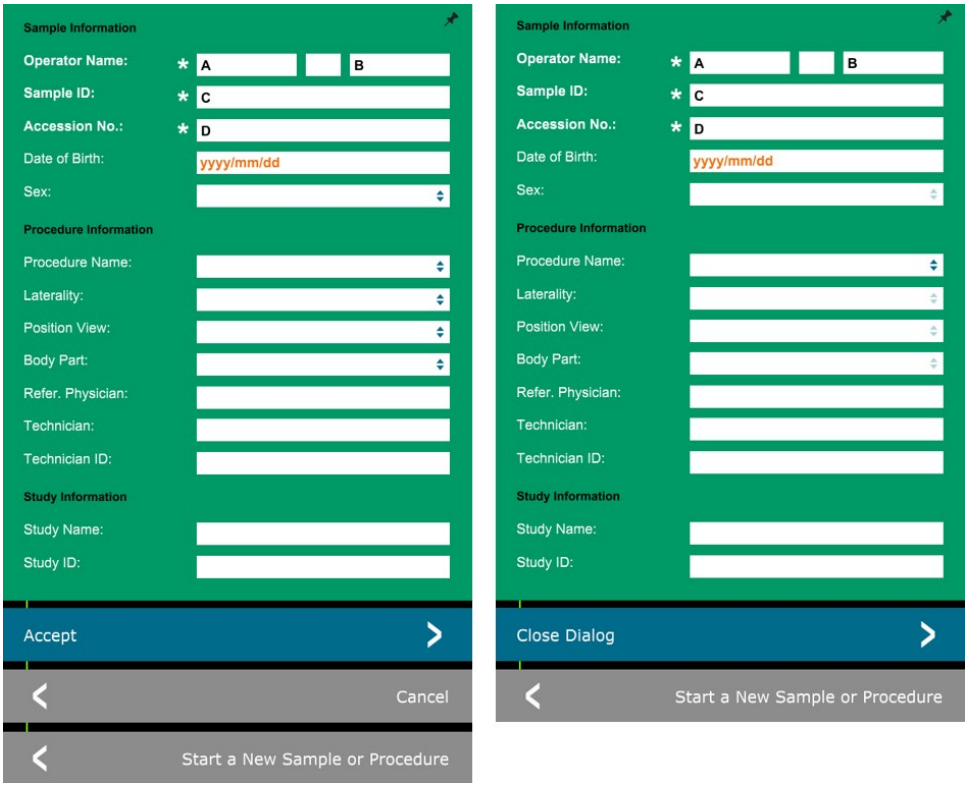


Figure 49: Sample Information Dialog Box - Imaging Mode: Before Image (Left), After Image (Right)

Clicking the **View/Change Sample Information** button while in Review Mode allows the user to view the sample information. The Sample Information Dialog will now only have the **Close Dialog** button.

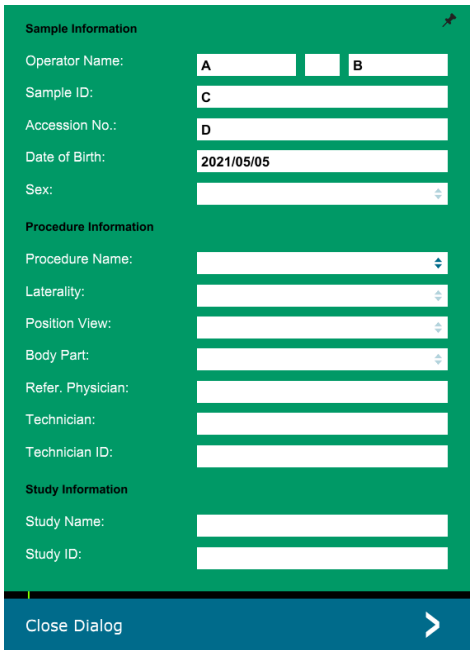


Figure 50: Sample Information Editing Dialog – Review Mode

Enhance Image

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

Figure 51: Enhance Image Button

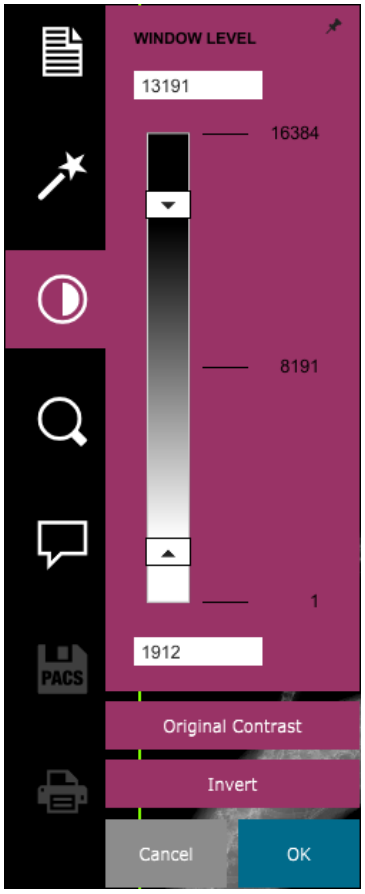
The algorithm, commonly known as "Peripheral Equalization" or "Thickness Equalization" in advanced imaging, is applied to the whole image. In addition to this algorithm, Hologic employs a second, internally developed algorithm called the "Calcification Emphasis" algorithm. This secondary algorithm was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

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

Note
The system may have shipped to automatically process "Image Enhancement" after every image. In that case pressing the button will load the "Un-Enhanced" image.

Window Level and Contrast Adjustment and Inverting the Image

The Window Level and Contrast Adjustment tool allows the user to adjust the image's window level and contrast, restore the images original contrast, or invert the image. Each is described below:



Use a pair of sliders (arrows) to adjust the window level and contrast. Clicking between the sliders and moving up or down will maintain the window width (range) while moving the center of the window up or down. Moving the sliders individually will adjust just the upper or lower window levels individually.

You may also type upper and lower window levels into the white text fields.

The **Original Contrast** button restores the images original contrast.

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

Figure 52: Window Level and Contrast Adjustment Tool

Click the **OK** button to accept the changes. The **Cancel** button restores the previous settings.

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, and left and right adjusts contrast. Release the mouse button when satisfied with the results.

The figures below show the same image with different window levels. Note the position of the sliders and the corresponding upper and lower limits displayed in the text fields above and below the sliders. Upper/lower limits of 13191/1912 versus 10649/5223.

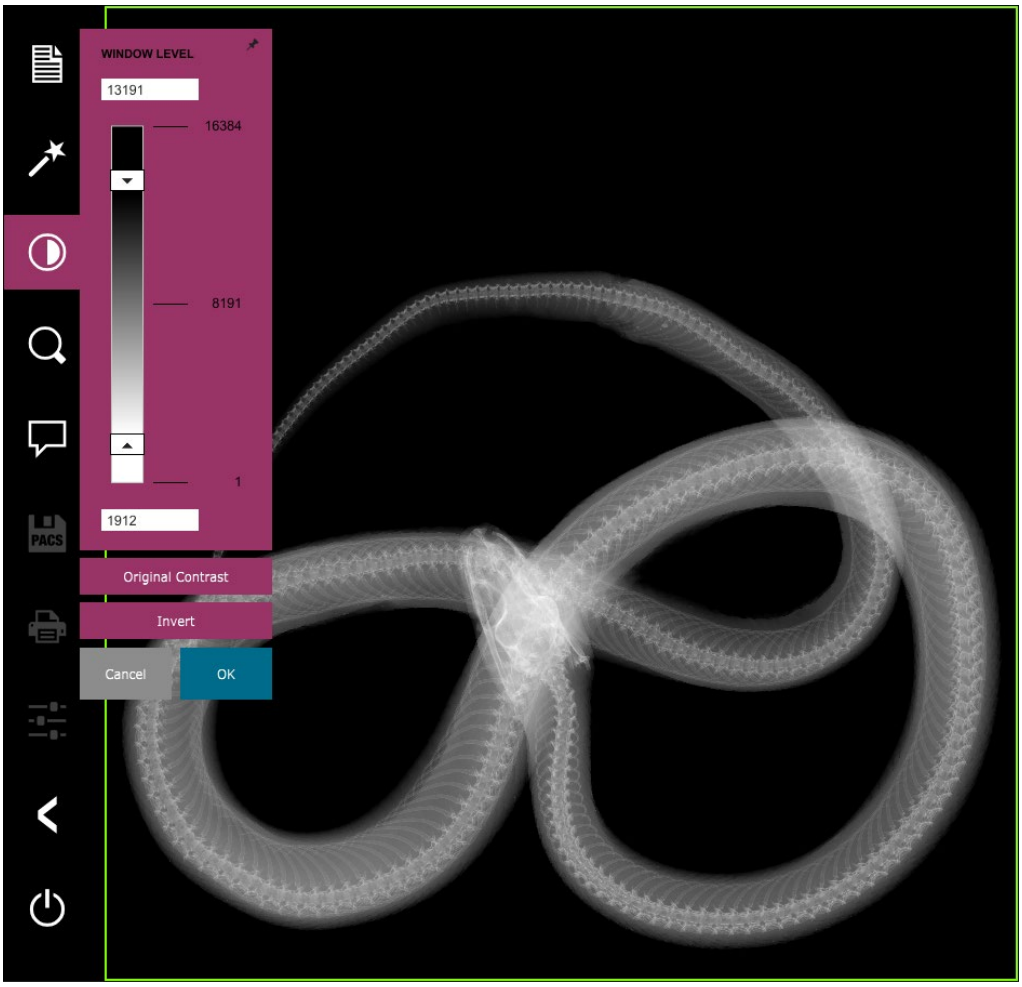


Figure 53: Window Level and Contrast Adjustment Tool

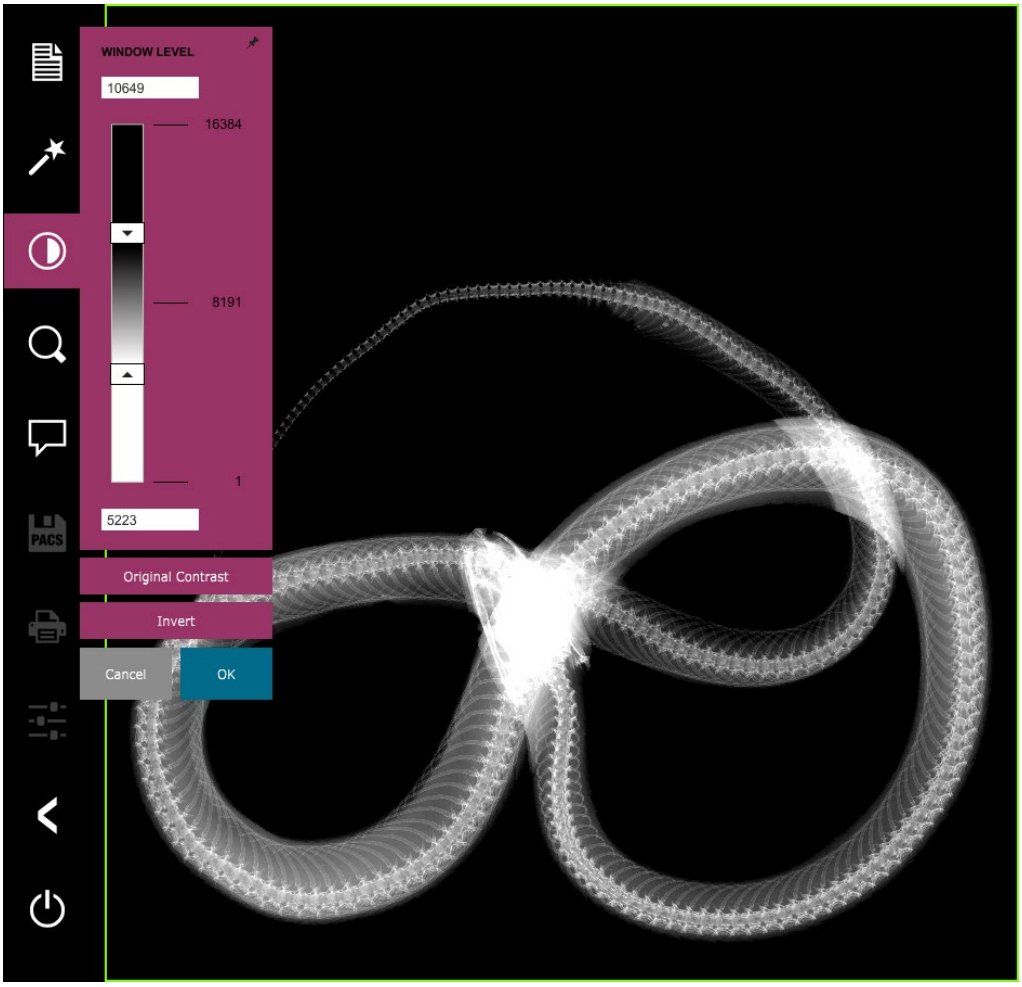


Figure 54: Window Level and Contrast Adjustment Tool

An example of inverting is shown below.

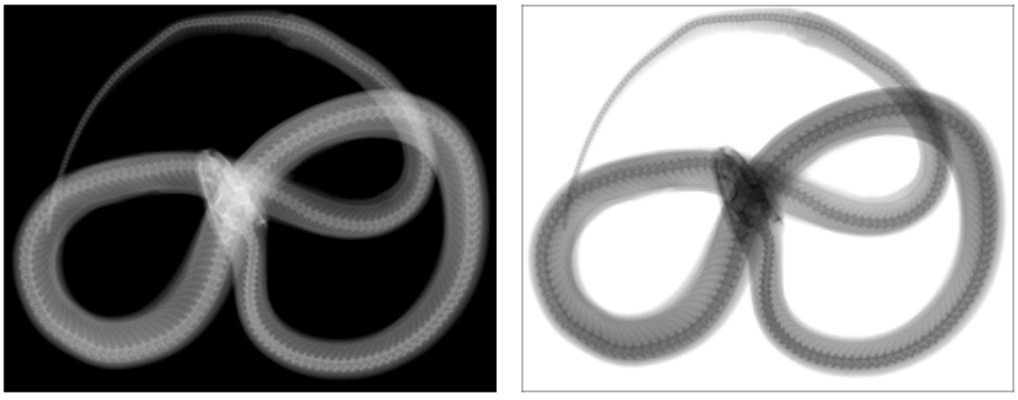
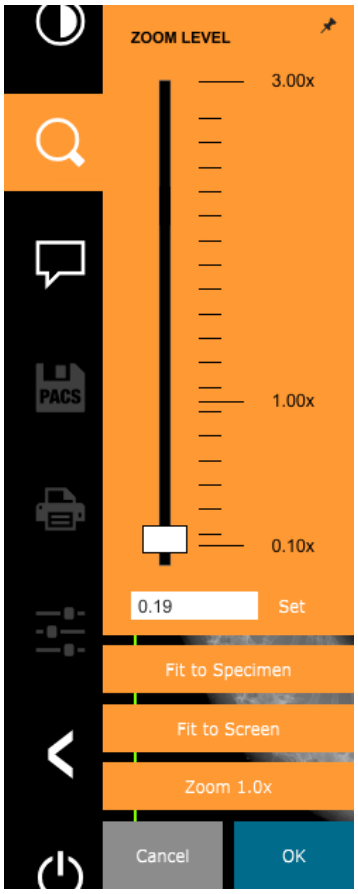


Figure 55: Example of Inverting: Inverted on the Left

Digital Zoom Tool Button

The **Digital Zoom Tool** button opens the Zoom Adjustment tool, which provides options for adjusting an image's zoom level.



Use the slider to manually adjust the zoom level from 0.10x to 3.00x

The **Fit to Specimen** button will attempt to detect and zoom in onto the specimen to ensure the sample is in full view. If a specimen is not detected, it will default to the previous mode (either "Fit to Screen" or "Zoom 1.0x")

Fit to Screen fits the image to the screen.

Zoom 1.0x or "Full Resolution". The image is adjusted for a 1:1 ratio with the monitor resolution.

Figure 56: Digital Zoom Tool Button and Dialog Box

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

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

The default mode is "Fit to Screen". The actual zoom level will vary depending on the size of the sample.

Note
Depending on the size of the specimen there may be minimal difference observed between **Fit to Specimen** and **Fit to Screen.**

The following images show the same sample at different zoom levels. The top figure is at the default zoom level. The bottom level is zoomed in to 1.00x.

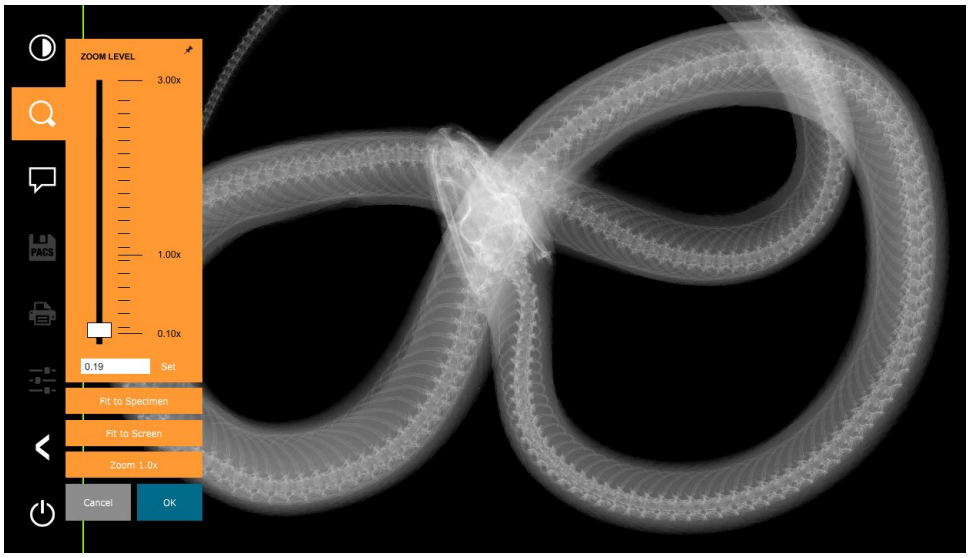


Figure 57: Image in Default Zoom Level

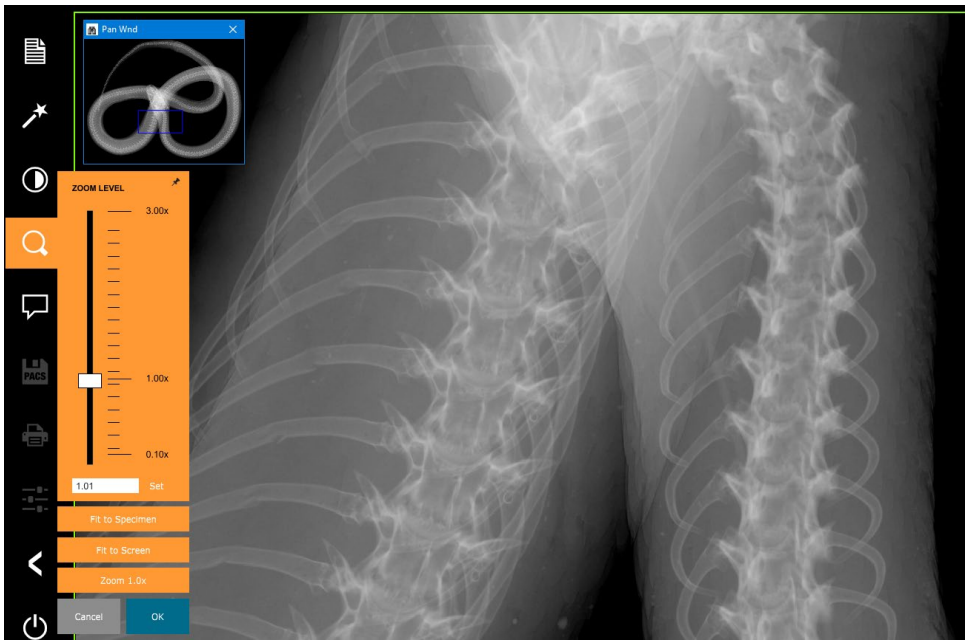


Figure 58: Same Image of Snake at 1.00x Zoom

Note that when the image no longer fits on the screen the "Pan Window" opens which allows the user to move the sample around the screen.

Annotation Tools Button

The **Annotation** Tools button opens the annotation tools Dialog. These tools and their functions are discussed in detail in Section 5.10, User Annotations.

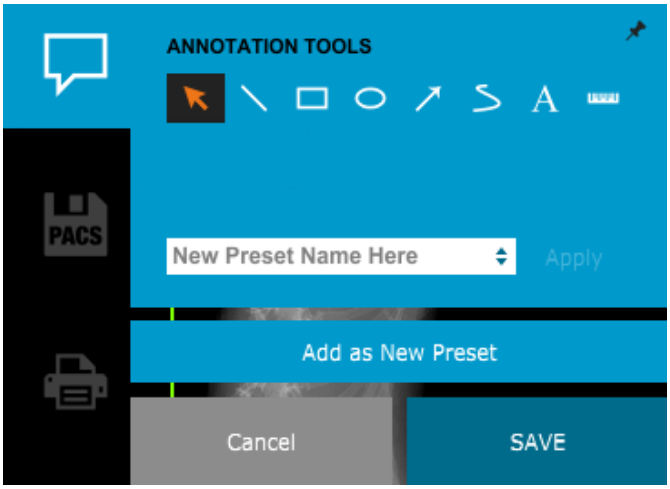


Figure 59: Annotation Tools Button and Dialog Box

PACS Store

The **PACS Store** button provides the ability for single click PACS storage. PACS Store only functions when the system is installed in a medical facility with a PACS network. To save files locally, please refer to Section 5.9, DICOM Functionality.

Figure 60: PACS Store Button

your

PACS Print

The **PACS Print** button provides the ability for single click print to a preconfigured PACS printer. PACS print will only function when the system is installed in a medical facility with a PACS network. Refer to Section 5.9, DICOM Functionality. For local printing please refer to Section 5.6.4, Top Menu Bar > Tools Menu > Print Current Image, and Section 5.8.2, Database Top Menu Bar > Additional Options > Print.

Figure 61: PACS Print Button

Exposure Control

The **Exposure Control** button opens the Exposure Mode Dialog box, which allows the user the convenience of controlling the X-Ray system through the software. The user can select the Exposure Mode, adjust X-Ray Tube kV and Exposure Time, adjust the number of images to acquire for Image Averaging (from 1 to 8), and initiate the X-Ray exposure.

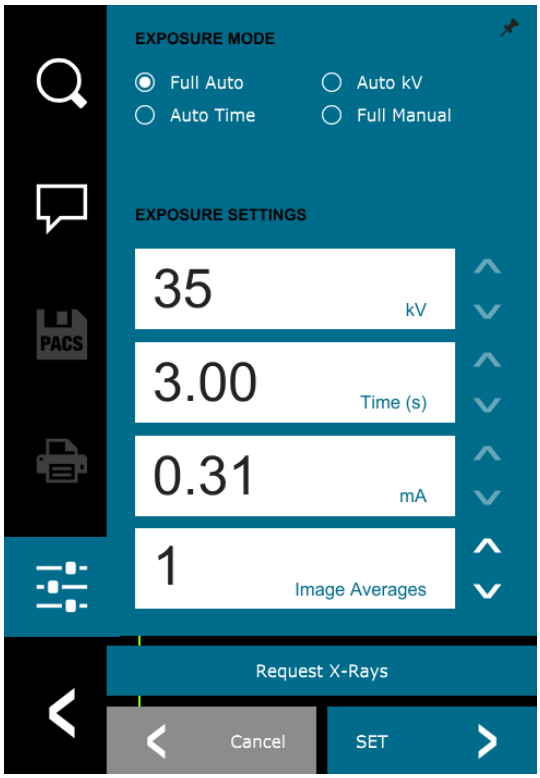


Figure 62: Exposure Control Button and Dialog Box

The status, or availability, of the Exposure Settings is indicated by the up/down arrows adjacent to the setting. The arrows will be white when the setting is active and light blue when inactive. The Exposure Settings that are active is dependent on which Exposure Mode is selected.

- X-Ray tube current (mA) is not adjustable via software in the Faxitron Pro system and will always be inactive (light blue).
- X-Ray tube kV and Exposure Time settings are active/in-active dependent on which Exposure Mode is selected. KV will only be active in “Auto Time” and “Full Manual” modes. The Exposure Time will only be active in “Auto kV” and “Full Manual” modes.
- Image Averages is always active.

The figure above shows that “Full Auto” mode has been selected and that kV and Time are inactive. Only Image Averages is active in Full Auto Mode.

When finished click on the **Request X-Rays** button to acquire an image, or the **Set** button to save the settings and close the Exposure Control Dialog. All x-ray exposures initiated with the **Start X-Ray** button (either the physical or software button) will be taken with the saved settings.

Clicking the **Cancel** button will close the Exposure Control Dialog and discard any changes.

Back to Main Menu

The button to the right exits the image acquisition mode and returns to the Home Menu screen

Figure 63: Back to Main Menu Button

Shut System Down

The button to the right will exit the software and shut down the computer.

Figure 64: Shut System Down Button

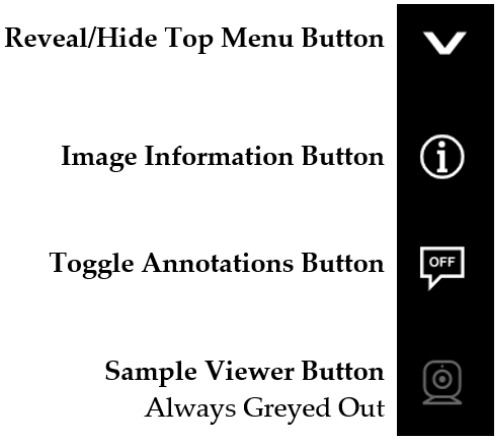
Undocking a Dialog

When a dialog is opened, it is “docked” to the left side of the screen. A user may un-dock the dialog box by clicking on the “Pin” icon in the upper-right corner of the box. They can now drag the dialog box anywhere on the screen. When the dialog box in un-docked the “pin” then turns into an “X” icon allowing for quick closing of the dialog.

Figure 65: Pin (Un-Docking) Icon

5.6.2 Right Tool Bar

The Right Tool Bar provides the user with one click ability to reveal or hide the Top Menu, reveal or hide current image information, and to toggle annotations on or off. Each button is described below.



NOTE: *The sample View is Not Available on the Faxitron Pro System.*

Figure 66: Right Side Menu Bar

Reveal/Hide Top Menu Button

The top menu is hidden by default when the VisionLS software is open. Clicking on the **Reveal/Hide** button brings the top menu into view. The top menu is hidden when the button is pointing down and revealed when the button is pointing up. This button is available in all screens and will be white or black, depending on the background.

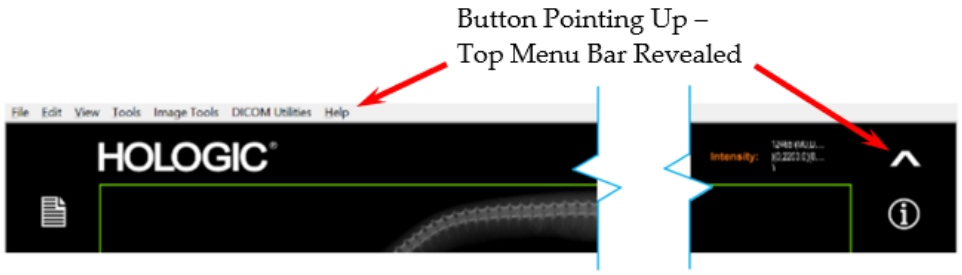


Figure 67: Reveal/Hide Top Menu Button

The Top Menu is discussed in detail in Section 5.6.4.

Image Information Button

Clicking on the **Image Information** button will either display or hide the current sample image information, depending on the current state. When the button is orange, *as shown below*, the image information box is revealed. The box is hidden when the button is white.

The Image Information box contains information such as the magnification level the image was taken at, date, time, and day the image was taken, dosage information, file

name of the image and the location of the image. It will also contain the name of the institution if it was entered.

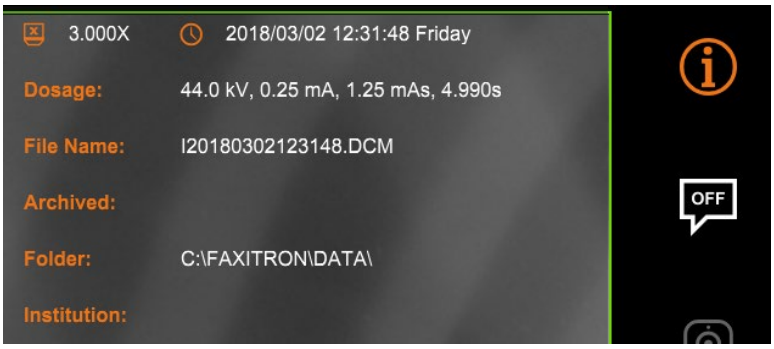


Figure 68: Image Information Button and Box

Toggle Annotations Button

The **Toggle Annotations** button will turn any annotations that have been made on an image On or Off. Turning the annotations Off temporarily hides them, it does not delete them from the image. The **Toggle Annotations** button will display "ON" or "OFF" as appropriate.

Figure 69: Toggle Annotations Button

Sample Viewer

The Sample View is currently not available on Faxitron Pro systems and will always be greyed out.

5.6.3 Bottom Tool Bar

The Bottom Tool Bar will vary depending on whether the system is in Imaging or Review Mode.

The left third of the Bottom Tool Bar *(see A in figure below)* will always show current sample information.

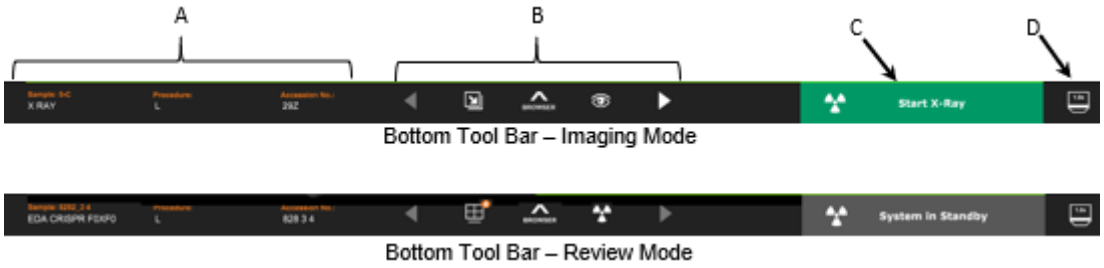


Figure 70: Bottom Tool Bar – Imaging & Review Modes

The middle third of the Bottom Tool Bar *(see B in figure above)* will vary between Imaging and Review modes.

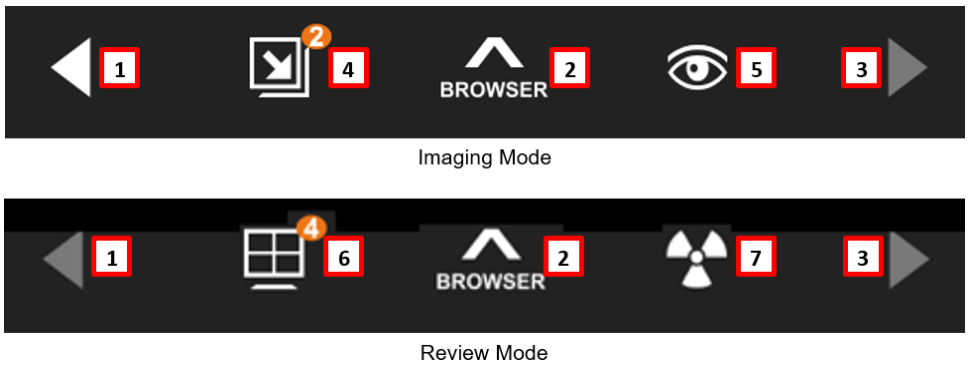


Figure 71: Bottom Tool Bar – Middle Section (B)

Refer to the above figure for the following descriptions:

- **1 & 3 - Left** and **Right Arrow** buttons (1 & 3 above): Open either the "Previous" or "Next" image in a procedure that has multiple images.
- **2 - Browser** button: Opens the "Current Sample Images" view, which is a thumbnail strip showing all the images in the current sample.
- **4 - Add Images to Review** button flags images in the thumbnail strip for review. The number in the orange circle indicates how many images have been flagged. Only available in "Image Mode.
- **5 - Eye** button: Will be displayed while in the "Image Acquisition Mode". Click this button to enter "Review Mode".

- **6 – Change Review Layout** button: Pulls up a menu to select the review pane configuration. Only available in "Review Mode".
- **7 - Radiation Symbol** button: Will be displayed while in "Review Mode". Click this button to return the system to the "Image Acquisition Mode".

The right third of the Bottom Tool Bar contains the system status bar and magnification info.

Figure 72: Bottom Tool Bar – Review Mode, Right Third

- The "Magnification" icon displays the mag tray position while in "Image Acquisition" mode. *See figure above.*
- System status will always display "System in Standby" while in the "Review" mode. *See figure above.*
- The system status bar turns into the **Start X-Ray** button when the system in is "Image Acquisition" mode. When an x-ray is initiated, the button will turn into a **Stop X-Ray** button. When the exposure is complete the button turns into a **Processing** status bar. Once the image is processed and displayed the button/status bar will return to the **Start X-Ray** button. *See figure below.*

Figure 73: Bottom Tool Bar – Buttons/Status Bar – Imaging Mode

5.6.4 Top Menu Bar

The software provides access to *"View", "Tools", "Image Tools", "DICOM Utilities" and "Help"* menus through the Top Menu Bar. *See figure below.* The Top Menu Bar is hidden by default and is displayed by clicking the **Reveal/Hide Top Menu** button in the Right Menu Bar. *See figures 67 & 68.* Each menu item is covered in detail in the following pages.

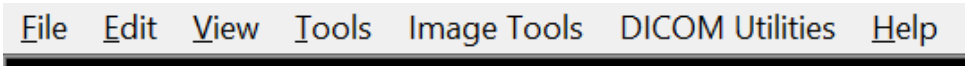


Figure 74: Top Menu

FILE MENU

This menu contains options commonly found in a Windows File Menu.

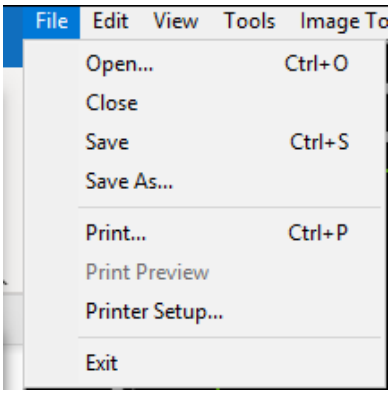


Figure 75: File Menu

EDIT MENU

This menu contains options commonly found in a Windows Edit Menu. However, all of the options are greyed out and unavailable to the user.

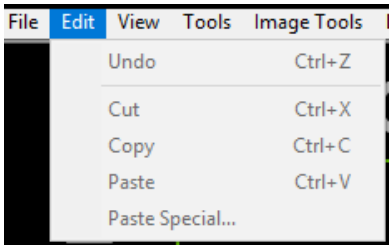


Figure 76: Edit Menu

VIEW MENU

The "View" menu provides the user the ability to modify the acquired images' display format or characteristics. Each of the "View" menu items has sub-menus. Each menu item is described below.

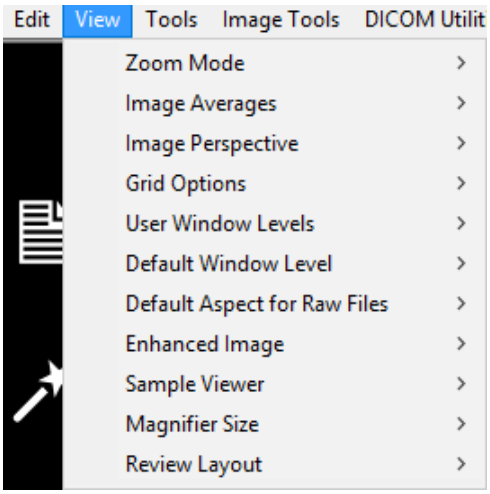


Figure 77: View Menu

Zoom Mode

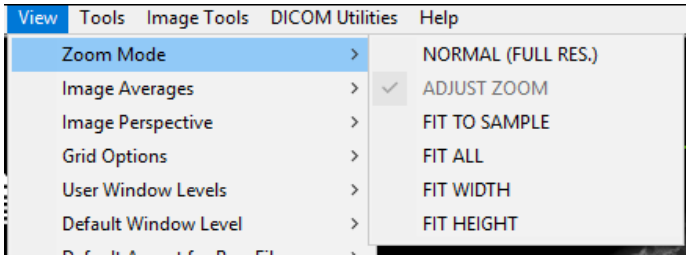


Figure 78: View Menu - Zoom Mode Options

- **NORMAL (FULL RES.)**

  Displays the acquired image in its native format. In full resolution the image in the Faxitron Pro system exceeds the monitors display area. A thumbnail window will be displayed in the top left corner of the image which allows the user to "pan" the image. Refer to Digital Zoom Tool in Section 5.6.1. The same function is provided by the **Zoom 1.0x** button in the Digital Zoom Tool.

- **ADJUST ZOOM**

  This option is greyed out and not available at this time.

- **FIT TO SAMPLE**

  This option adjusts the acquired image to best fit the specimen sample within the monitors display area. This option provides the same function as the Digital Zoom **Fit to Specimen** button.

- **FIT ALL**

  This option displays the entire acquired image, regardless of its native format. The Full Resolution options does not work in this view mode. Provides the same function as the Digital Zoom **Fit to Screen** button.
- **FIT WIDTH**

  This option displays the acquired image across the available width of the entire display area.
- **FIT HIEGHT**

  This option displays the acquired image across the available height of the entire display area.

Image Averages

This option allows the user to adjust the number of image averages to be taken per an exposure. The available options are 1x, 2x, 4x, or 8x shots. Default setting is 1x SHOT. If the user selects 2, 4, or 8 shots the software will acquire the number of images selected, one after the other, with a single push of the **Start** button, then average those images into a single image.

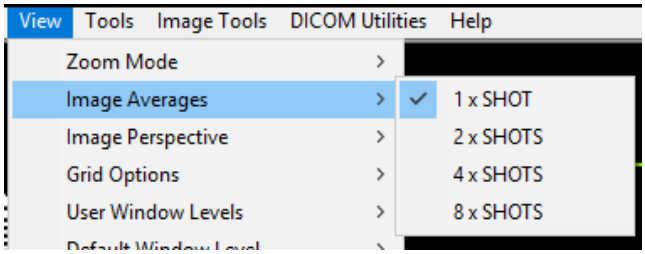


Figure 79: View Menu - Image Averages Options

Note
Images Averages may also be set in the Exposure Control Dialog Box accessed through the Side Tool Bar.

Image Perspective

This option allows the user to rotate the displayed image to 0, 90, 180, and 270 degrees.

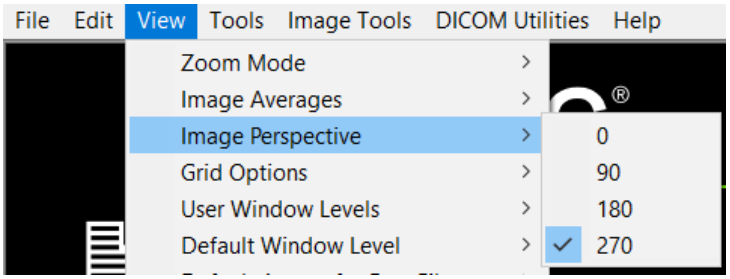


Figure 80: View Menu – Image Perspective

Note
The default Image Perspective for the Faxitron Pro with the 23x29cm detector is 270 degrees and 0 degrees with the 10x15cm detector.

Grid Options

Grid Options allows the user to superimpose a "Grid" over an image and select the size of that grid. Available grid sizes are 64, 128, and 256 pixels.

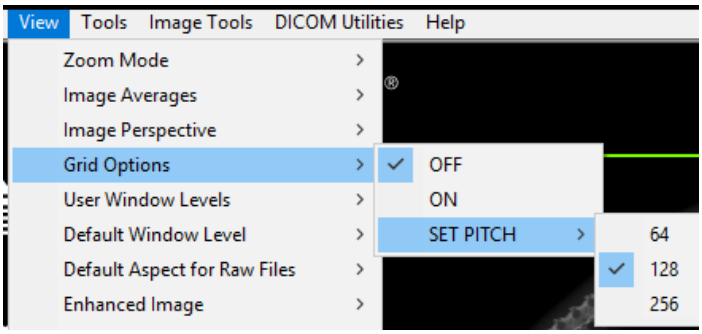


Figure 81: View Menu - Grid Options

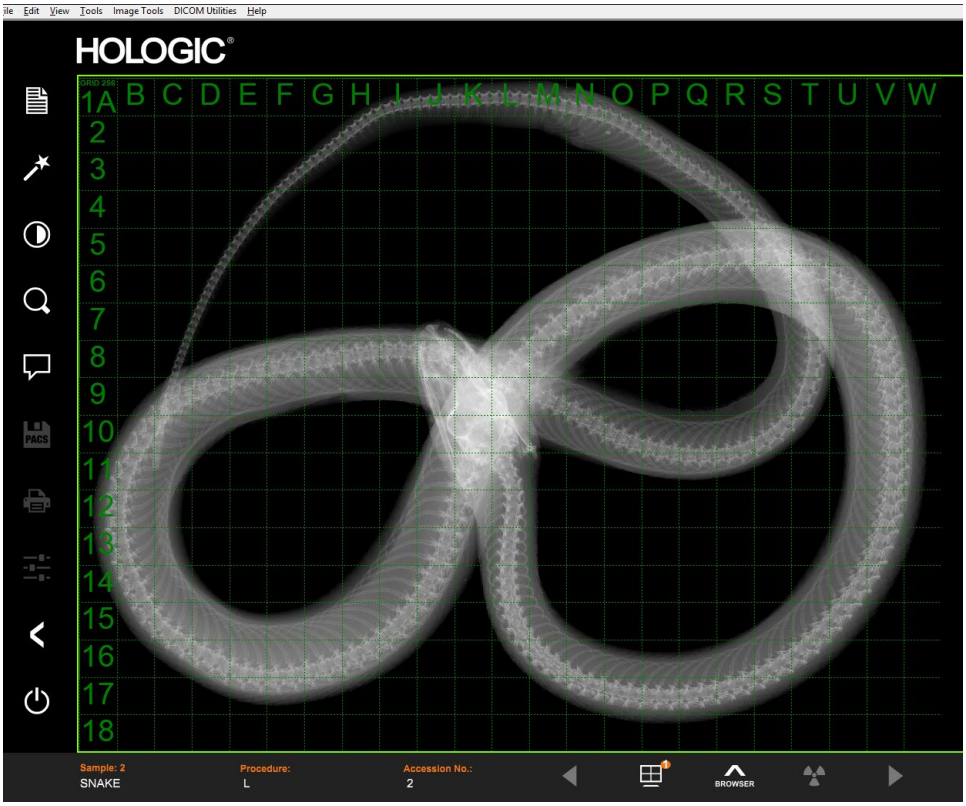


Figure 82: Grid Sample, Pitch Set to 256

User Window Levels

This allows the user to define up to three (3) pre-defined, user set Window Levels (WL).

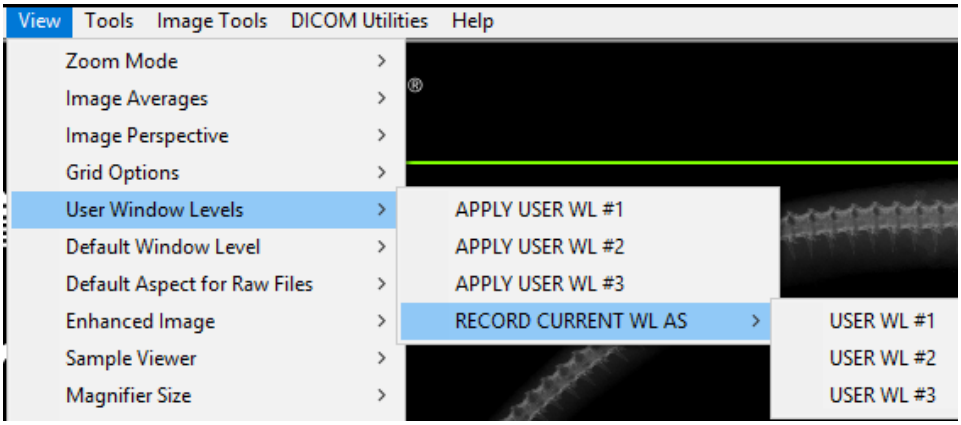


Figure 83: View Menu – User Window Levels

- Take an image, or open an image from the database,
- First select the **Window Level and Contrast Tool** button in the Side Menu Bar.
- Adjust the image to the desired level window level.
- Select "User Window Levels" from the "View" menu, then select "RECORD CURRENT WL AS", then select User WL #1, #2, or #3".
- The adjusted WL will be saved under the choice selected.

The user can now apply that saved window level to any other image by click on the "View" menu, then "User Window Levels", then "APPLY USER WL #X".

Default Window Level

There are 3 menu options under Default Window Level:

- "OPTIMIZE FOR WHOLE AREA" adjusts the window level for subsequent images for the entire image array.
- "OPTIMIZE FOR SAMPLE AREA" adjusts the window level for subsequent images to be optimized for the sample only. It ignores the image area outside of the sample. "Optimize for Sample Area" is the default setting.
- "Set Default Window Level to Current" applies the window level for the current image to all subsequent images. Adjust the window level for the enhanced image then select "Set Default Window Level to Current". Repeat for the un-enhanced image. All subsequent images will now have those approximate window levels applied.

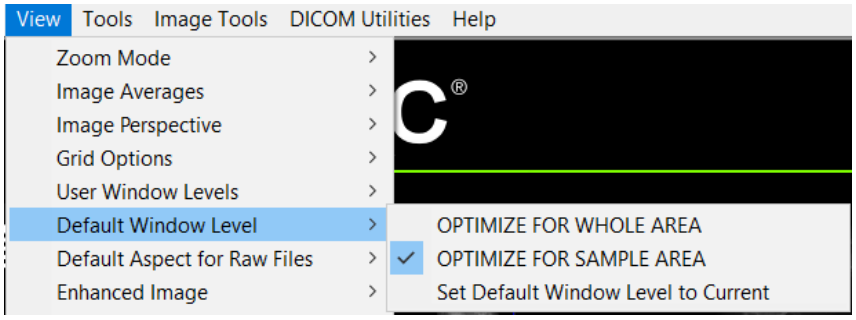


Figure 84: View Menu – Default Window Level

Default Aspect of Raw Files

"Default Aspect for Raw Files" helps when importing/opening previously saved image files with unknown file attributes, or binary image data without any header information. Since the exact imager array size is not available the software will import/open the image with *"best fit"* imager dimensions based on width being larger or smaller than height (default aspect information).

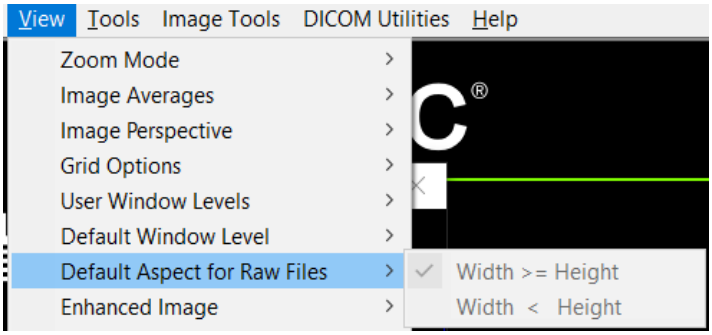


Figure 85: View Menu – Default Aspect for Raw Files

Note
These menu options are greyed out. Default setting is "Width > = Height and can't be changed by the user.

Enhance Image (same as the Enhance Image Button)

Processes current Sample image and enhances visualization of tissue located near the periphery of the sample.

This menu option acts the same as the **Enhance Image** button in the Left Side Tool Bar.

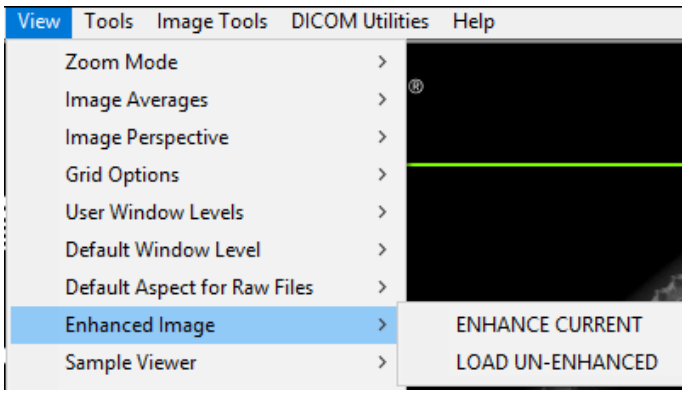


Figure 86: View Menu – Enhance Image

Sample Viewer

Not available in the Faxitron Pro system at this time.

Magnifier Size

"Magnifier Size" is used to adjust the size of the *Magnifier* under the "Image Tools" menu. There are 3 available settings: Small, Medium, and Large.

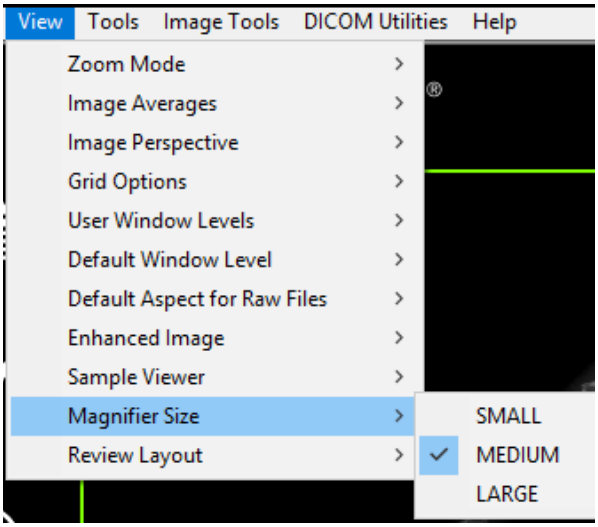


Figure 87: View Menu – Magnifier Size

Review Layout

"Review Layout" is used to select the configuration of the image panes in Review (Database) Mode. See figure below for available options.

This same function is available using the **Change Review Layout** button in the Bottom Tool Bar.

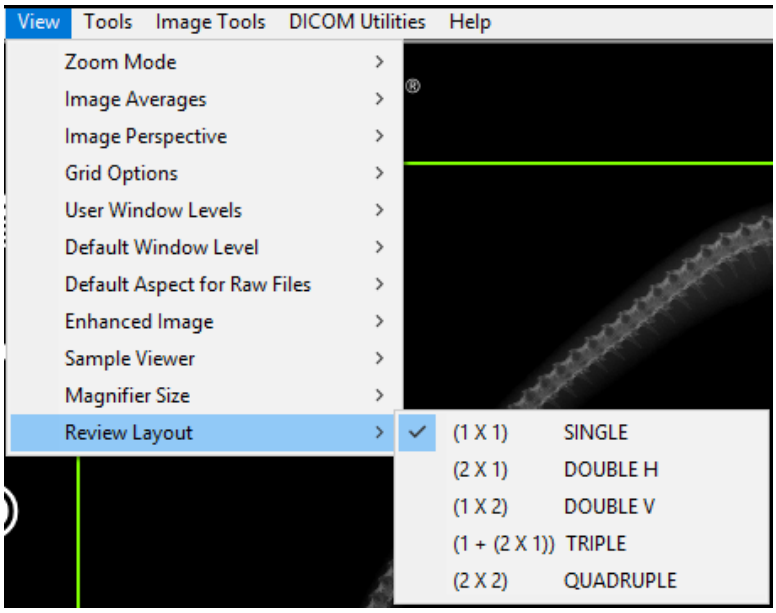


Figure 88: View Menu – Review Layout

An example of the (1 + (2 X 1)) Triple layout is shown below.

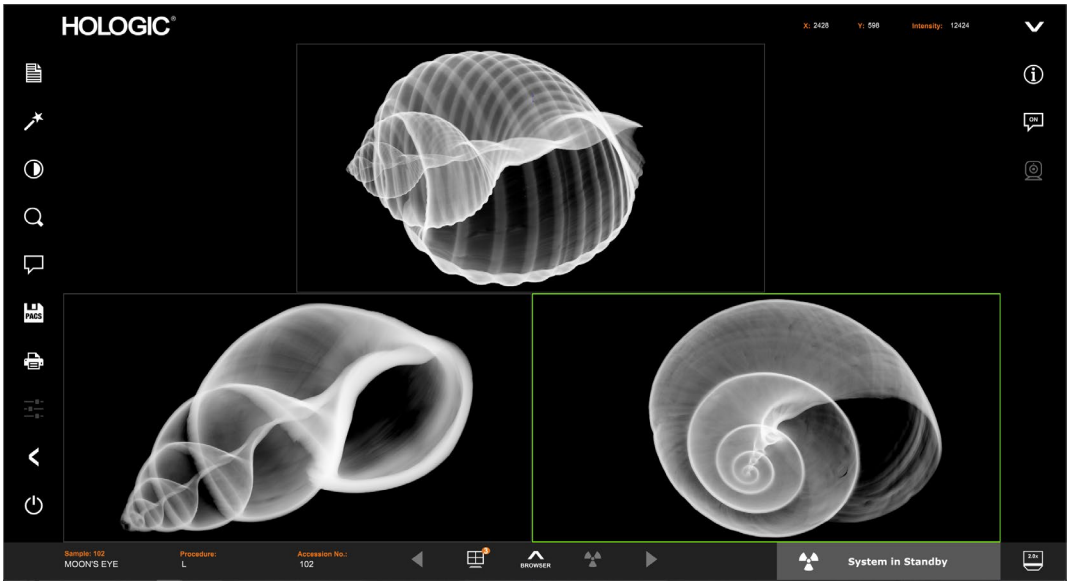


Figure 89: View Menu – Review Layout (1 + (2 X 1)) Triple

Note
See Section 5.8, Database/Review Mode for additional information on using multiple review panes.

TOOLS MENU

The *"Tools"* menu provides the user with a number of tools is located in the Top Menu Bar, found in the upper left-hand corner of the screen. These tools apply to the image currently displayed.

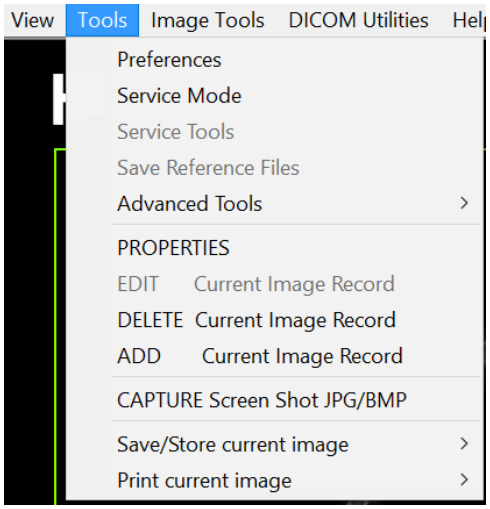


Figure 90: Tools Menu

Preferences

The *"Preferences"* menu opens a configuration management utility which can be used to change various options or parameters.

Note
The *"Preference"* tool option is password protected and should only be accessed by an authorized Hologic service representative.

Caution:
Changing configuration parameters without proper knowledge or authorization can cause loss of image quality, system damage, and system malfunctions.

Service Mode

"Service Mode" is password protected and turned on by Hologic authorized technicians for troubleshooting purposes.

Service Tools

"Service Tools" is normally greyed out. It is only turned on when the system is in *"Service Mode"*.

Save Reference Files

"Save Reference Files" is normally greyed out. It is turned on when the system is in *"Service Mode"*.

Advanced Tools Options

The Advanced Tools menu offers various options to configure aspects of the software such as post-processing and configuration options.

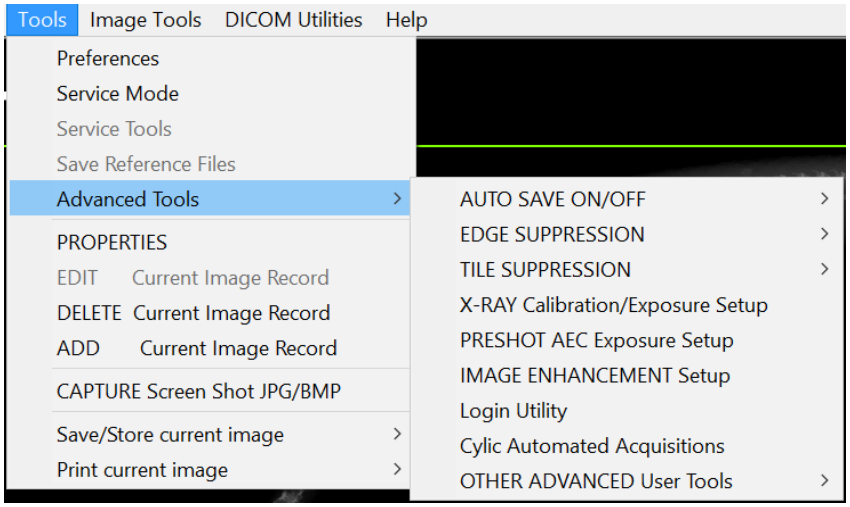


Figure 91: Advanced Tools Menu

- **Auto Save On/Off**

  "AUTO SAVE ON/OFF allows the user to turn the auto save feature on or off, as desired. Menu options are "On" or "Off".

  When *"Auto Save"* is "On", all subsequently acquired images are saved to the database. The files are written to a Database Directory defined in the configuration file.

  "Auto Save" is set to "On" by default.

- **Edge Suppression**

  Edge suppression is used to minimize the visual effects of the edges of CMOS sensors in the image. Menu options are "On" or "Off".

  Edge suppression is not used on the DALSA 23x29cm detector.

  Edge suppression is turned on at the factory for Faxitron Pro systems with the Faxitron 10x15cm detector installed.

- **Tile Suppression**

  Tile suppression is used to minimize the visual effect of the individual CMOS sensors in the image. Menu options are "On" or "Off".

  Tile suppression is not used on the DALSA 23x29cm detector.

  Edge suppression is turned on at the factory for Faxitron Pro systems with the Faxitron 10x15cm detector installed.

- **X-Ray Calibration/Exposure Setup**

  "X-Ray Calibration/Exposure Setup" aids the user in determining the calibration settings, proper exposure time for a selected kV setting for best image quality, or proper kV setting for a selected exposure time for best image quality. Please refer to Section 5.2.3, Advanced Calibration, for a more detailed description.

- **PRESHOT AEC Exposure Setup**

  "Preshot AEC Exposure Setup" allows the user to adjust the system for particular imaging requirements or to compensate for system aging. Please refer to Section 5.3.1, Preshot AEC Setup, for a more detailed description.

- **IMAGE ENHANCEMENT Setup**

  "Image Enhancement Setup" allows the user to adjust various parameters of the image enhancement algorithm.

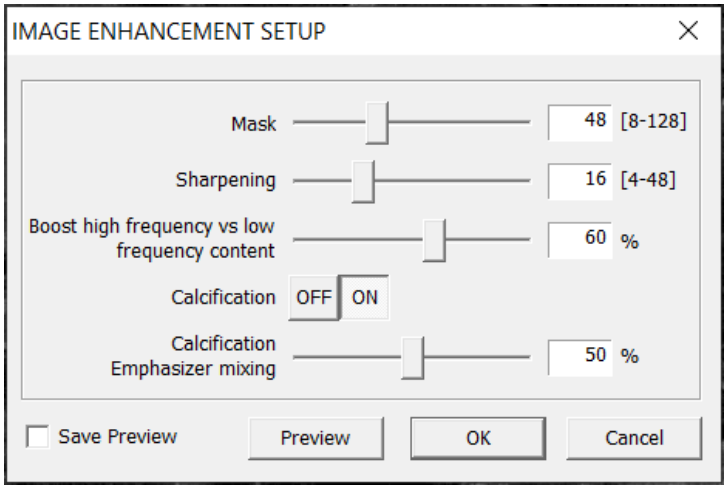


Figure 92: Advanced Tools – Image Enhancement Setup

Record the settings before making any adjustments so you can return the system to the default settings if needed.

- **Login Utility**

  The Login Utility allows the user to configure and activate *start-up password authentication* for VisionLS software. Activation of this feature is optional on the Faxitron Pro system. If the user activates the *password authentication,* they will be prompted for the password each time the program is opened. The program will close if the correct password is not entered.

  To activate *password authentication:*

  - Click on "Login Utility" under "Tools" > " Advanced Tools". The Login Utility Dialog will open.

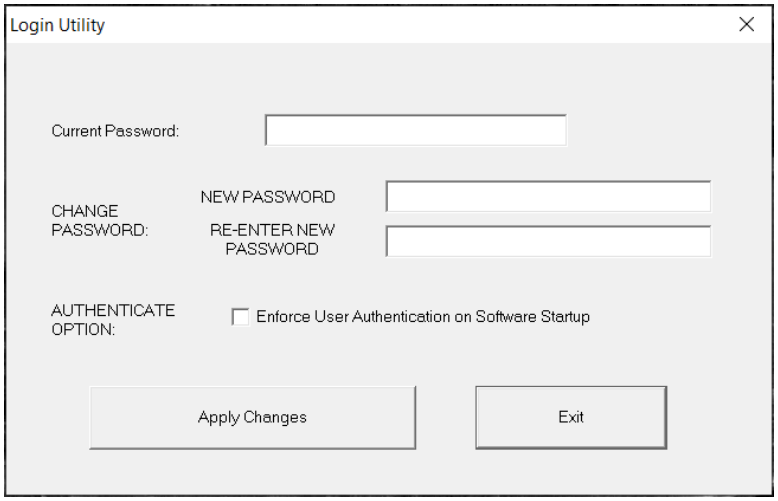


Figure 93: Login Utility Dialog Box

- Enter the Current Password. *Your authorized Hologic representative can provide you with your systems password.*
- Create a new password and enter it in the "NEW PASSWORD" and "RE-ENTER NEW PASSWORD" spaces.
- Click the checkbox for "Enforce User Authentication on Software Startup".
- Click the **Apply Changes** button, then click the **Exit** button.

The system will now require the password each time VisionLS software is started.

Caution:
You can activate *password authentication* using your systems default password. However, Hologic highly recommends creating a new password for enhanced system security.

- **Cyclic Automated Acquisitions**

  Cyclic Automated Acquisitions allows the user to automatically acquire sequential images with a user defined delay time between each image.

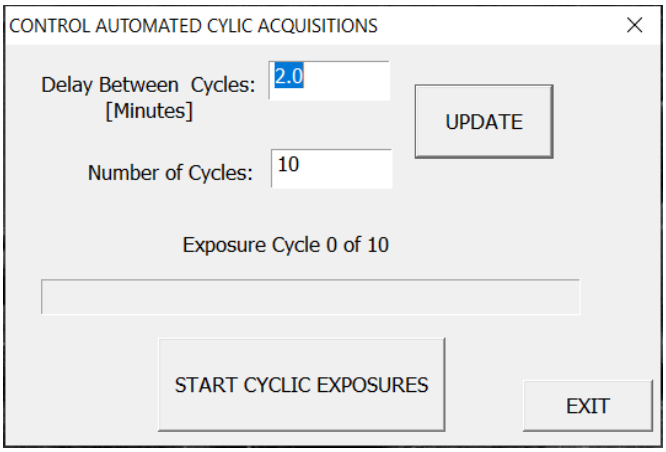


Figure 94: Advanced Tools – Cyclic Automated Acquisitions

  - Default settings are 10 cycles with a 2.0-minute delay between cycles.
  - Maximum delay between cycles is 1440 minutes.
  - Maximum number of cycles is 1000.

Enter the desired delay time and the number of cycles. Click the **UPDATE** button, then click the **START CYCLIC EXPOSURE** button. The system will begin the exposures. Each exposure will include all processing as if taking a single exposure. The sequence is as follows:

1. System will take a *"preshot"* exposure,
2. System will take the *"image"* exposure,
3. Unenhanced image will be displayed,
4. Software will process then display the enhanced image,
5. Software will start timing the *"delay between cycles"*,
6. When the defined delay time has elapsed, the system will start another *"cycle"* at step one.
7. The process will be repeated until the defined number of cycles has been completed.

All the images taken are saved and available for review from the Current Image Browser or the Database.

- **OTHER ADVANCED User Tools**

  All menu items except *"Multi Scale Enhancement"* are greyed out and not available to the user.

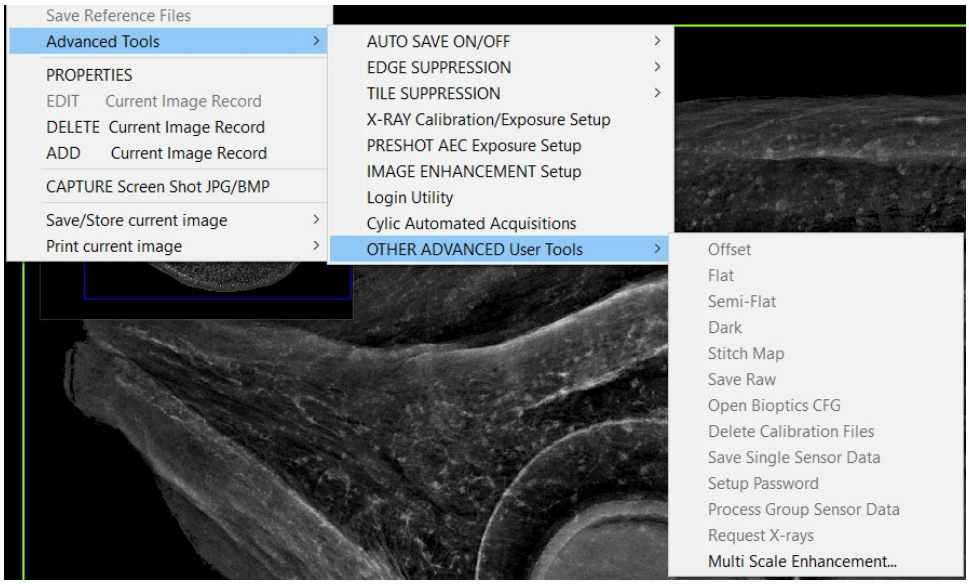


Figure 95: Advanced Tools – Other Advanced User Tools – Multi Scale Enhancement

  - **Multi Scale Enhancement** equalizes image details at multiple scales in the image, resulting in effective dynamic range compression and sharpening of faint image details.

PROPERTIES

"Properties" hides or shows the Image Properties Box.

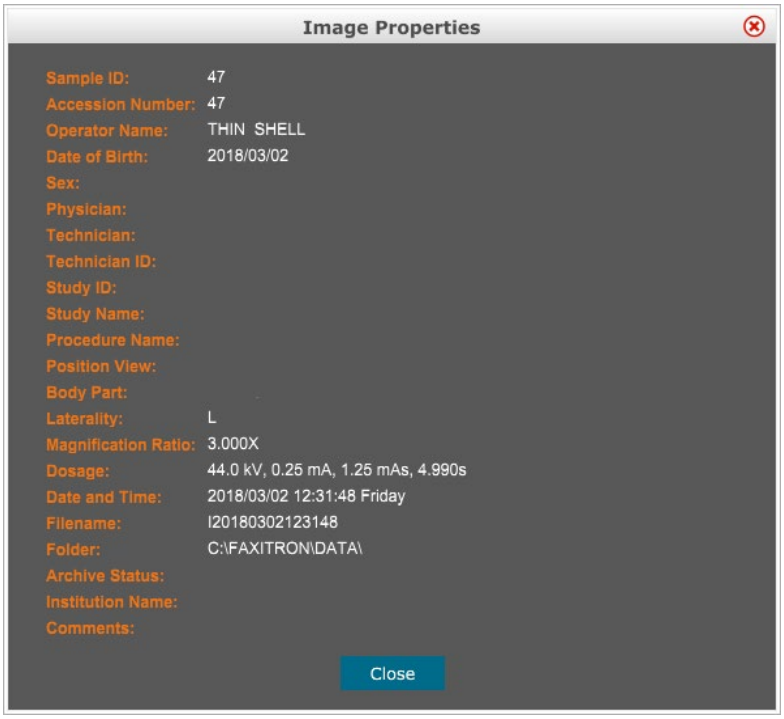


Figure 96: Advanced Tools - Properties

EDIT Current Image Record

Currently not used.

DELETE Current Image Record

Deletes the current image from the file directory as specified in the configuration file.

ADD Current Image Record

Adds the current image to the file directory as specified in the configuration file.

CAPTURE Screen Shot JPG/BMP

"CAPTURE Screen Shot JPG/BMP allows the user to capture and save a screen shot of the entire display. Clicking this menu option will open a "Save As" dialog. The dialog is populated with default/automated entries. The user can specify a different "Save in" directory, can create their own "File Name", choose between JPEG and BMP file types, and select the "Sub Type". *See figure below.*

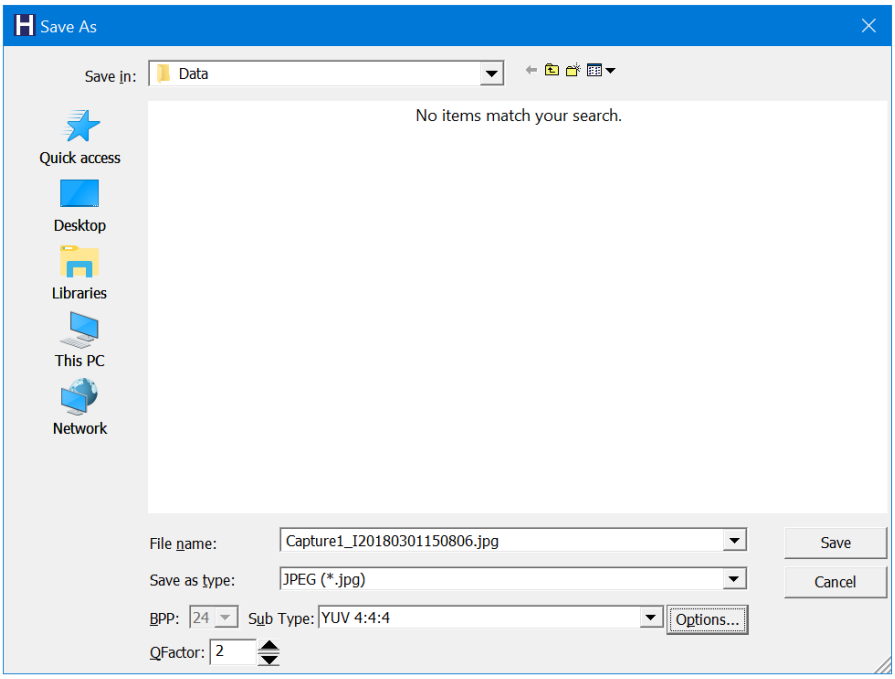


Figure 97: Tools Menu

Save/Store current image

"*Save/Store current* image provides the user options for saving the current image:

- LIS Archive Image,
- As local DICOM image,
- As local image, and
- More options.

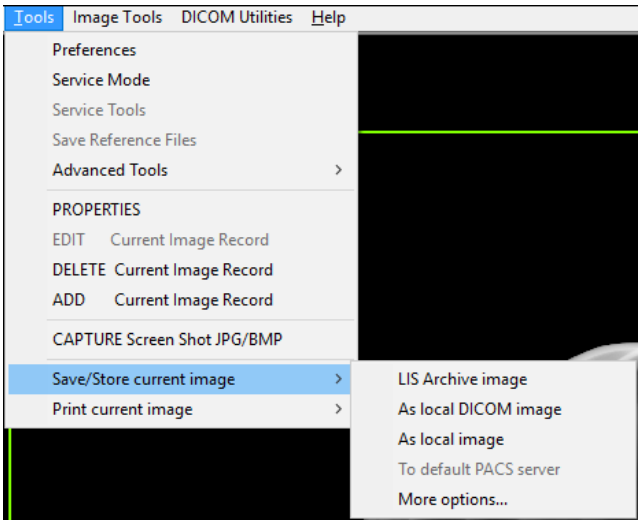


Figure 98: Tools – Save/Store Current Image

1. Selecting "LIS Archive Image" opens the dialog shown below.

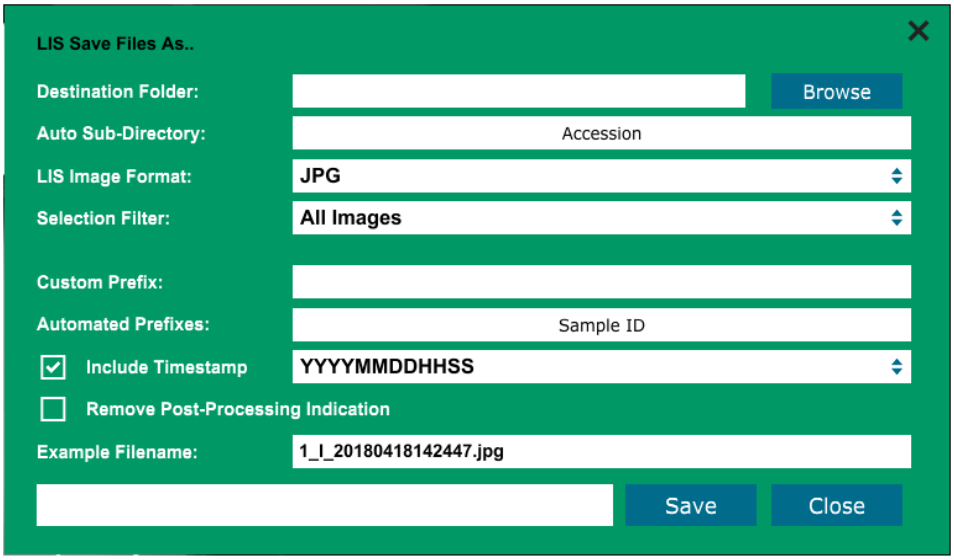


Figure 99: LIS Save File As Dialog

a. Click the **Browse** button to navigate to the directory you want the image saved in.

b. Select the image format from the drop-down menu. Choices are: JPG, PNG, and TIF-8. JPG is selected by default.

c. Leave the "Selection Filter" at "All Images" or choose "Enhanced Images Only", or "Un-Enhanced Images Only" from the drop-down menu.

d. Enter a "Custom Prefix" if desired.

e. Click the **Save** button. The displayed image will be saved to the specified directory.

2. Selecting "As Local DICOM Image" opens a "Save as DICOM File" dialog as shown below.

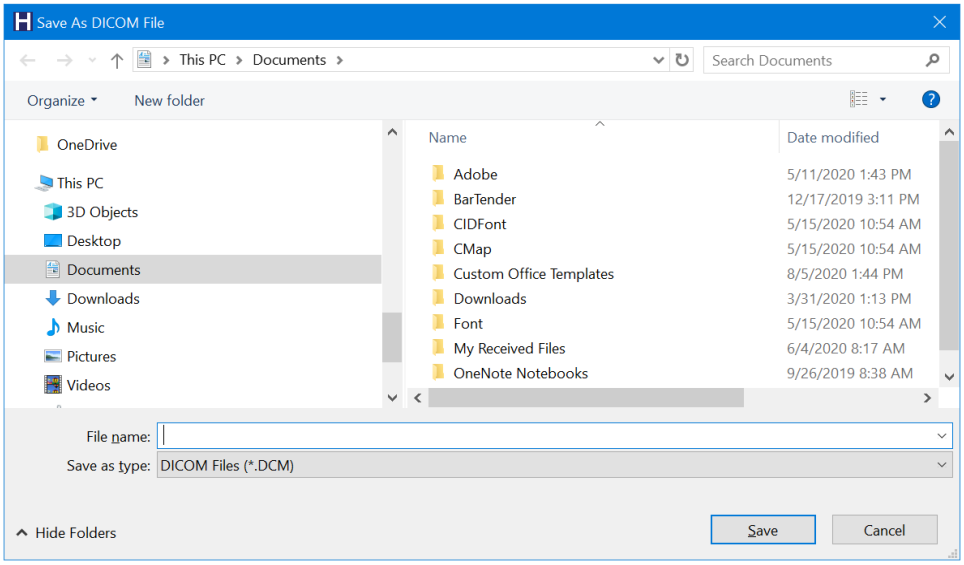


Figure 100: Save as DICOM File Dialog

a. Navigate to the desired directory,

b. Enter a "File Name",

c. Click the **Save** button. The image will be saved as a DCM file in the selected directory.

3. Selecting "As Local Image" opens the "Save As" dialog shown below.

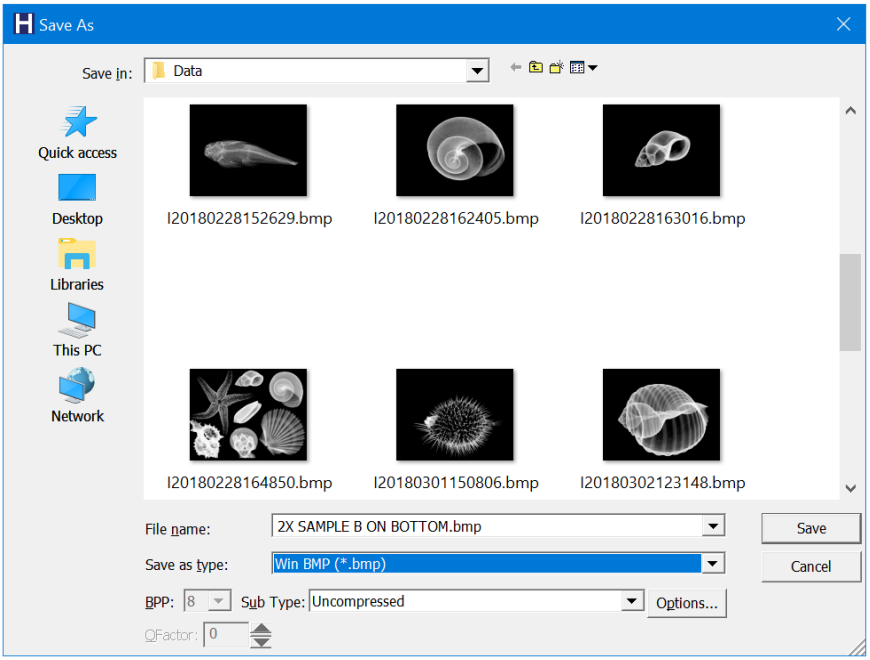


Figure 101: Save As Dialog

   a. Navigate to the directory you want the image saved in,

   b. Leave the system generated "File Name" or enter a "File Name" or your choice.

   c. Select the "Save as type" from the drop-down menu. Options are: Win BMP (*.bmp), JPEG (*.jpg), TIF (*.tif), or RAW (*.raw). Default file type is BMP.

   d. Leave "Sub Type" as "Uncompressed" or choose "RLE Compressed" from the drop-down menu.

   e. Click the **Save** button.

4. Selecting "More Options" opens a "DICOM Networking Dialog". *See Section 5.9, DICOM Functionality, for more information.*

Print current image

Prints current image to the WINDOWS printer.

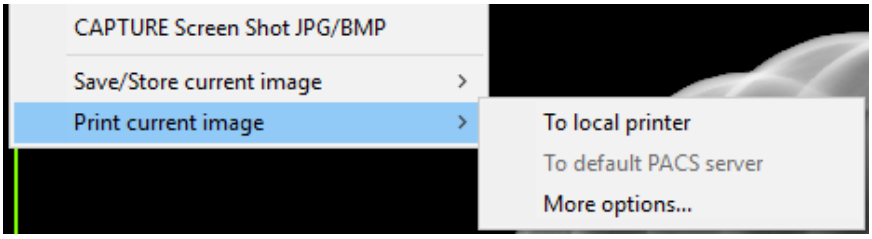


Figure 102: Print Current Image

Selecting *"To local printer"* opens the Windows Print Dialog.

Selecting *"More options…"* opens a DICOM Networking Dialog box. *See Section 5.9, DICOM Functionality, for more information.*

IMAGE TOOLS MENU

The "Image Tools" menu provides the user tools to aid the analysis of the image. Click on any menu item to activate the tool. Click again to turn the tool off.

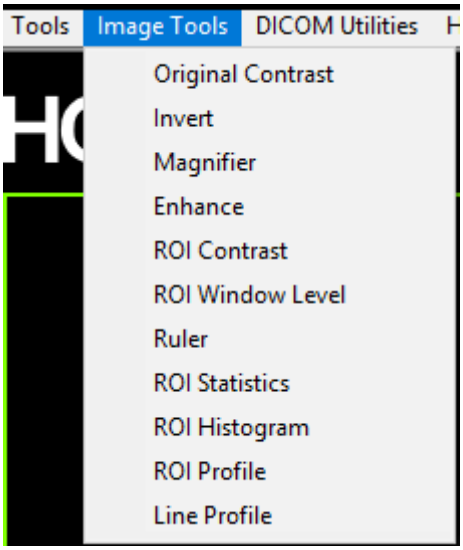


Figure 103: Image Tools Menu

Original Contrast

"Original Contrast" restores the images contrast levels. Behaves the same as the **Original Contrast** button in the Window Level and Contrast tool. *See Section 5.6.1, Left Tool Bar – Window Level and Contrast Adjustment and Inverting the Image, and figure 53.*

Invert

Clicking on *"Invert"* flips the grayscale values of the image, i.e., converts the image from a positive to a negative image, or vice versa. Click *"Invert"* to restore the image to its original state. Behaves the same as the **Invert** button in the Window Level and Contrast tool. *See 5.6.1, Left Tool Bar – Window Level and Contrast Adjustment and Inverting the Image, and figures 53 & 56.*

Magnifier

The *"Magnifier"* allows the user to magnify an area of interest, acting like a *Magnifying Glass.* Click on *"Magnifier"* to turn the feature on. Position the mouse cursor over the desired area to be magnified and click the left mouse button. The area of interest will be magnified. Click *"Magnify"* again to turn off the feature. *See figure below.* The size of the magnified area of interest can be adjusted by the user. *Refer to the "Magnifier Size" sub-menu in Section 5.6.4. Top Menu Bar - View Menu and figure 88.*

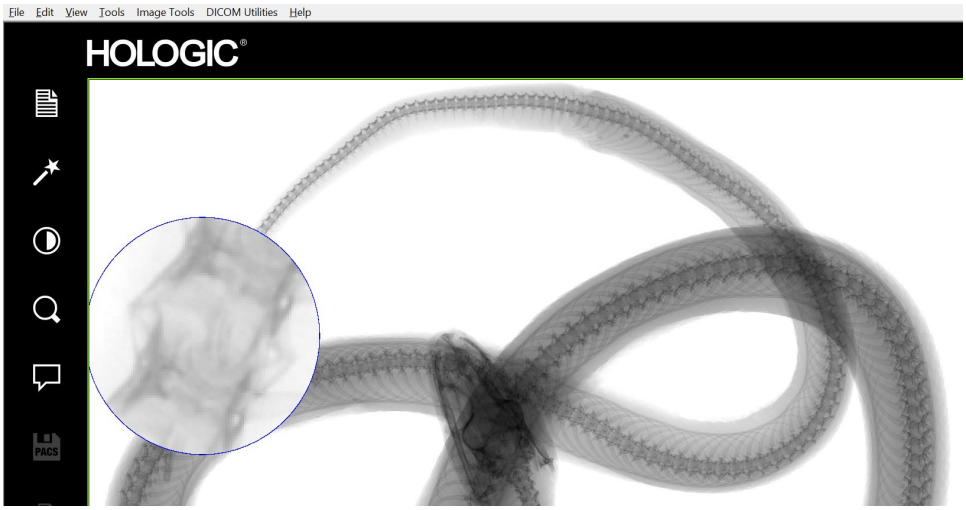


Figure 104: Image Tools Menu - Magnifier

Enhance

Clicking *"Enhance"* will create a sharper definition around the edges of regions with a contrast difference. This "Edge Enhancement" may amplify the noise in the image. Selecting the menu item again will turn off Edge Enhancement. Clicking on *"Original Contrast"* will also restore the image back to its original state. Note this is a different feature than the Enhance Image feature in Section 5.6.1, Left Tool Bar – Enhance Image and 5.6.4, Top Menu Bar – View Menu – Enhanced Image.

ROI Contrast

"ROI Contrast" will optimize the contrast levels within a user-defined region of interest (ROI). After selecting *"ROI Contrast"* click and hold the left mouse button at the starting point of the desired ROI, drag and release the mouse button at the desired ending point

of the ROI. The contrast will automatically adjust to the best levels for that ROI. *See figures below.*

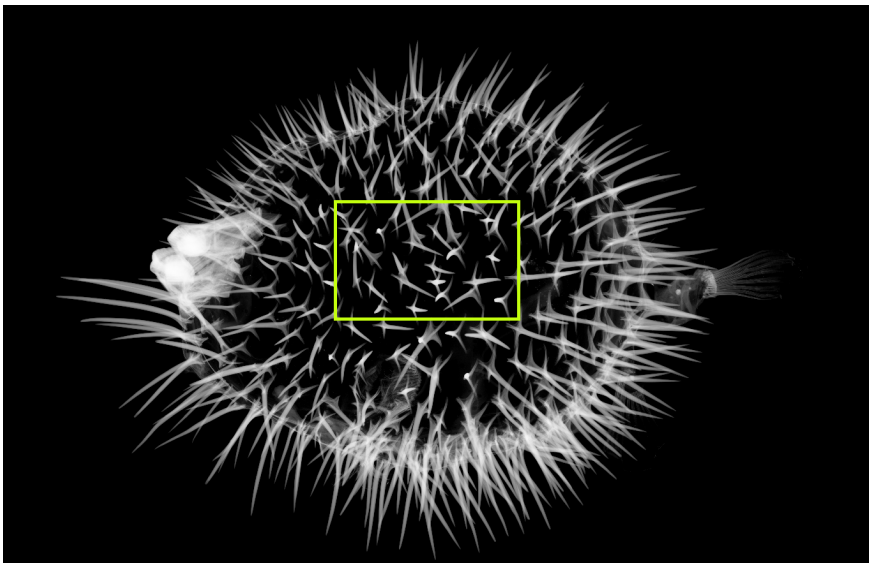


Figure 105: Image Tools Menu – ROI Contrast

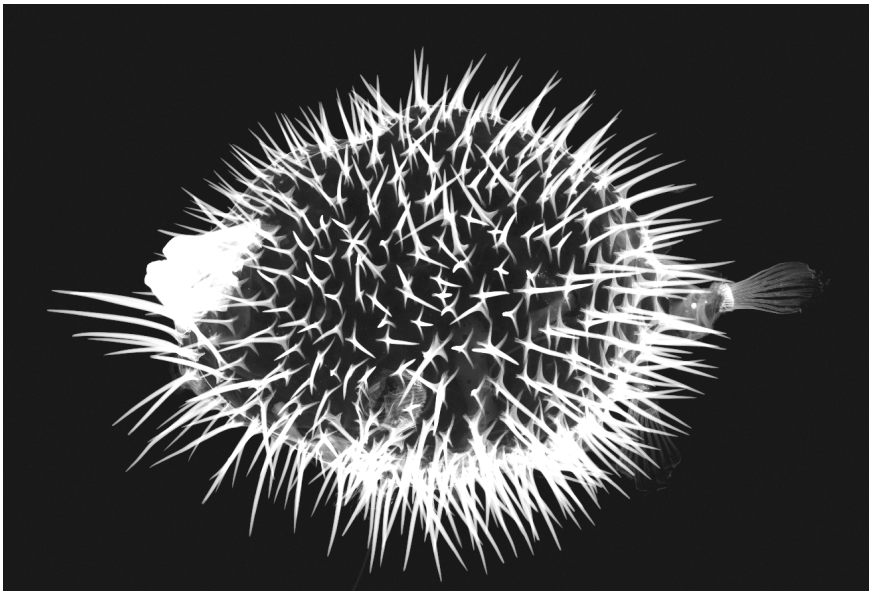


Figure 106: Image Tools Menu – ROI Contrast

ROI Window Level

The *"ROI Window Level"* function is not available in the current version of VisionLS software.

Ruler

"Ruler" allows the user to measure the distance between two points in the displayed image. Length measurements are in millimeters (mm). After selecting *"Ruler"* click and hold the left mouse button at the beginning of the point of measurement. Drag and release the mouse button at the end point of the measurement. The Ruler is displayed as a red line on the image with the measurement displayed at the end of the ruler.

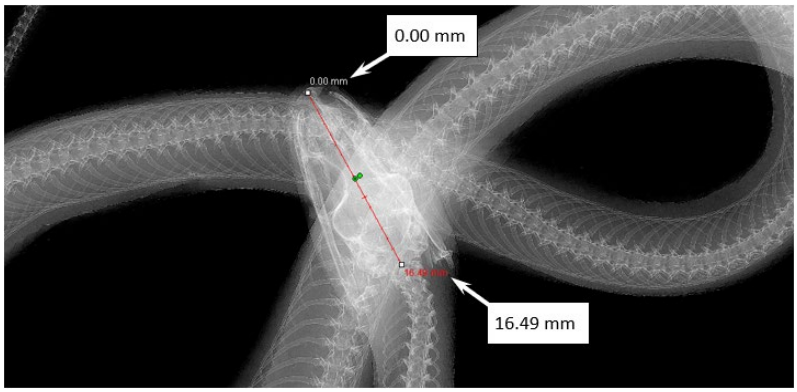


Figure 107: Image Tools Menu - Ruler

The Ruler remains active until the user selects another image tool or until another action is performed. Click *"Ruler"* again to turn off the feature.

Note
Hold the keyboard SHIFT key while drawing the ruler to get a perfectly horizontal, vertical, or 45-degree ruler.

ROI Statistics

Selecting *"ROI Statistics"* will enable the user to obtain the image statistics within a user defined ROI. Click and hold the left mouse button at the starting point of the desired ROI, drag and release the mouse button at the desired ending point of the ROI. A box will open displaying the images Statistical information. Statistics for the selected ROI is displayed on the left, and on the right for the whole image. The stats displayed are: beginning and end points of the ROI, Minimum, Maximum and Mean intensity values, and Standard Deviation (STD). To close the Statistics information box, simply click on the **Close** button. *See figure below.* Click *"ROI Statistics"* again to turn off the feature.

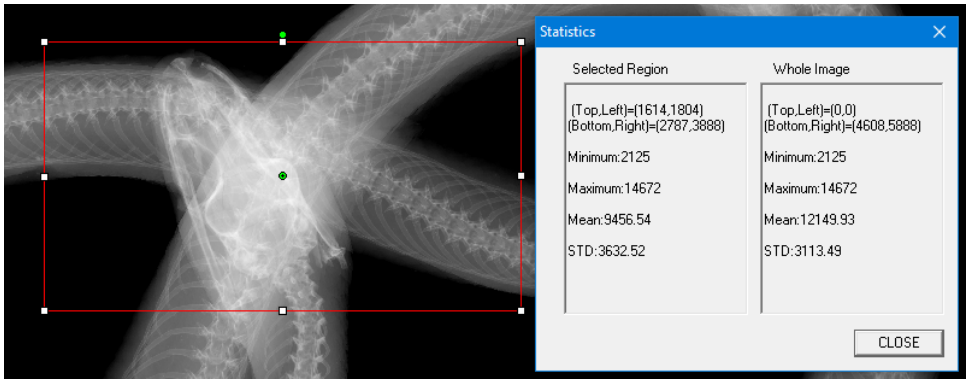


Figure 108: Image Tools Menu - ROI Statistics

ROI Histogram

Selecting *"ROI Histogram"* allows the user to create a histogram for a user defined ROI. Click and hold the left mouse button at the starting point of the desired ROI, drag and release the mouse button at the desired ending point. A "Graph Dialog" will open displaying Histograms for the selected ROI.

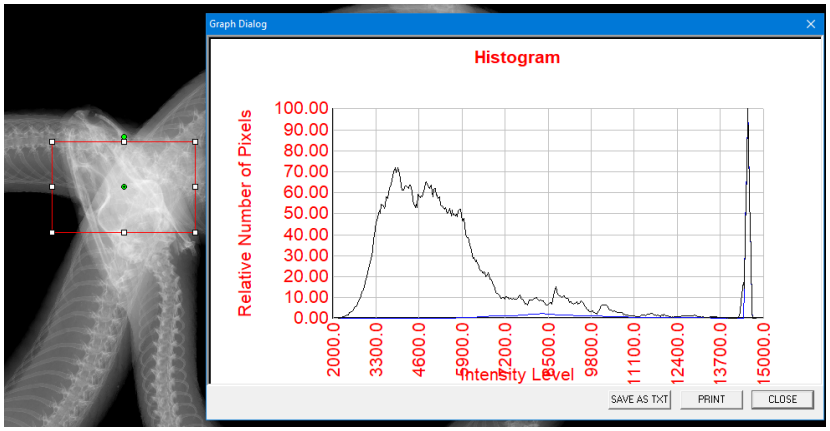


Figure 109: Image Tools Menu - ROI Histogram

The Black curve is the Histogram of the selected region. The Blue curve is the Histogram of the whole image. Both curves are normalized against the peak pixel value of the selected region of interest. Click *"ROI Histogram"* again to turn off the feature.

ROI Profile

Clicking *"ROI Profile"* allows the user to create a profile for a user defined ROI. Click and hold the left mouse button at the starting point of the desired ROI, drag and release the mouse button at the desired ending point of the ROI. A "Graph Dialog" will open displaying the profile of the selected ROI. By default, the averaging direction of the selected ROI is the short axis. Click the **SWITCH, HOR<->VERT** button to toggle the axis back and forth. Click *"ROI Profile"* again to turn the feature off.

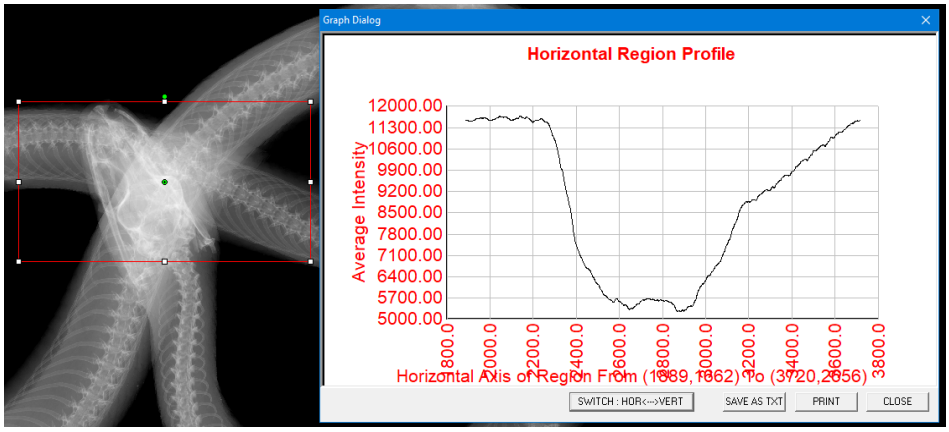


Figure 110: Image Tools Menu - ROI Profile

Line Profile

Clicking *"Line Profile"* allows the user to create a profile for a user defined line. Click and hold the left mouse button at the starting point of the line, drag and release the mouse button at the desired end point. A "Graph Dialog" will open displaying a profile of the drawn line.

The start and end point of the drawn line are displayed below the graph.

The starting point of the line will always be displayed on the left side of the graph.

Click *"Line Profile"* again to turn off the feature.

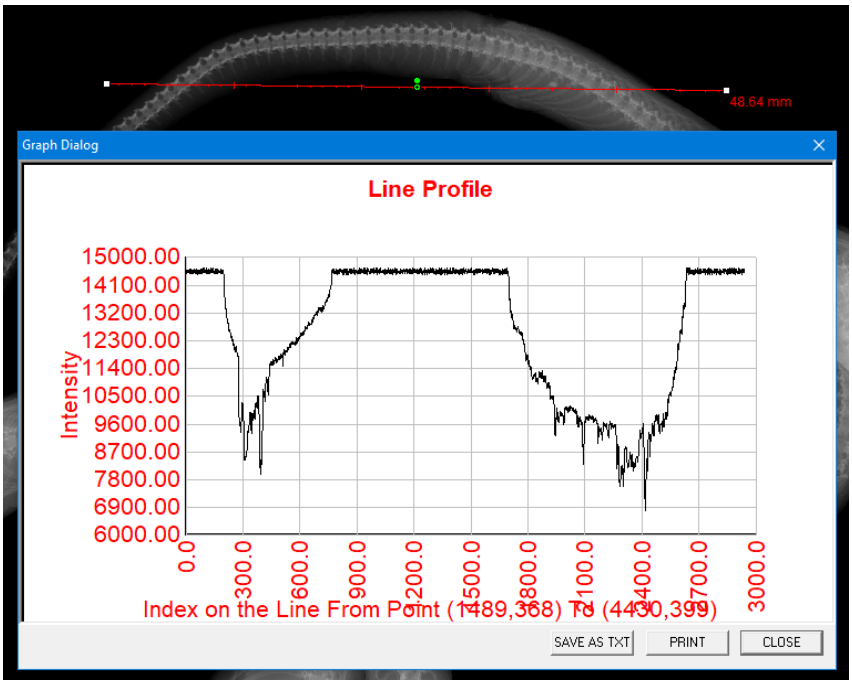


Figure 111: Image Tools Menu – Line Profile

DICOM Utilities Menu

There are two (2) drop down options in this menu:

- DICOM MODALITY Setup, and
- DUMP DICOM Header

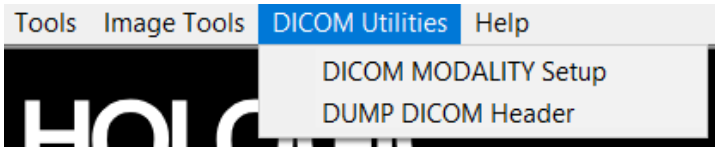


Figure 112: DICOM Utilities Menu

DICOM Modality Setup is discussed in Section 5.9, DICOM Functionality.

Selecting "DUMP DICOM Header" creates a text file of the images DICOM header.

Help Menu

The Help Menu provides options to *open the Faxitron Pro User's Manual* and to view information about the VisionLS software and related components.

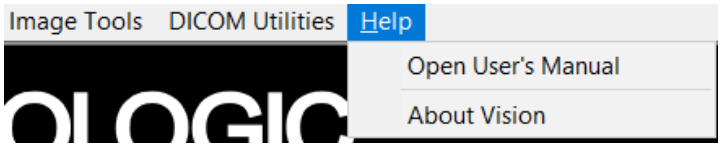


Figure 113: Help Menu

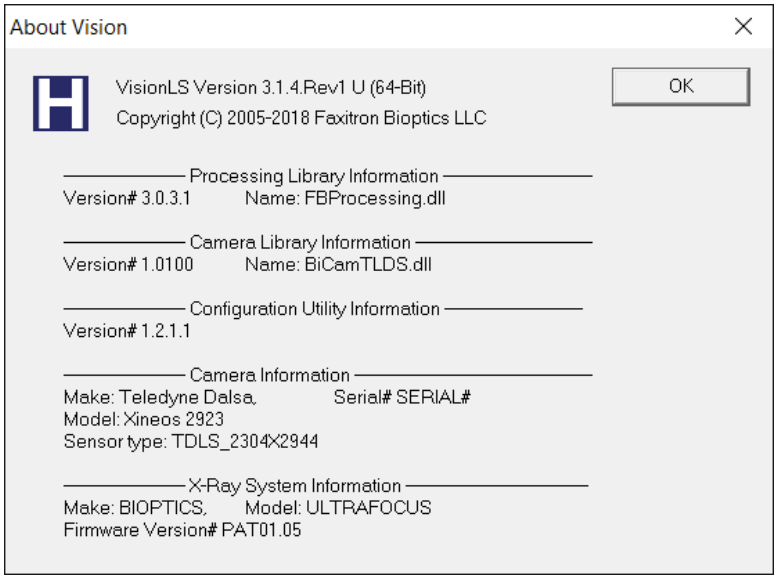


Figure 114: About Vision

5.7 Current Sample Images Browser

The **Current Sample Images Browser** button is located in the middle of the bottom tool bar. Clicking the **BROWSER** button opens a thumbnail strip of current sample images.

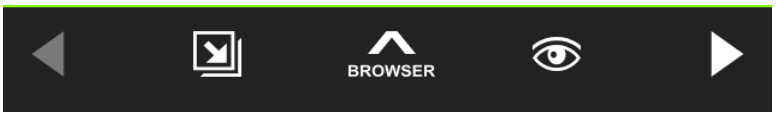


Figure 115: Current Sample Images Browser Button

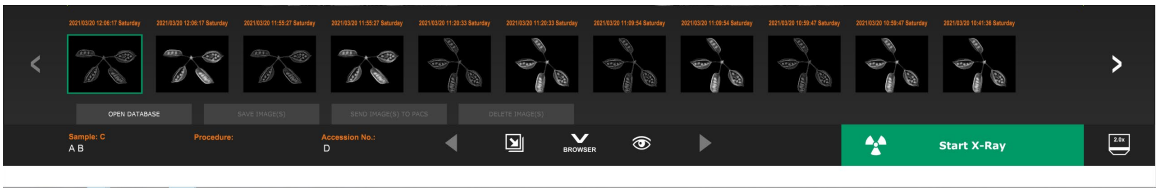


Figure 116: Current Sample Images Thumbnail Strip

The thumbnail strip displays the Procedure date, time, and day for each individual image in orange text along the top.

Figure 117: Current Sample Images Thumbnail Strip

The current image displayed in the image acquisition window will be highlighted in green. *See above figure.*

Images in the thumbnail strip can be *"dragged and dropped"* into the image display or review panes, as necessary.

The user can select (click on) multiple images and then Save the Images to a USB drive (or other location), send the images to PACS, or delete the images. The selected images are highlighted in orange.

There are arrows located to the left and right of the thumbnail strip which allows the user to scroll through images when they when they exceed the space provided in the thumbnail strip.

There is an **Open Database** button, which is used to enter the Review mode. The **Open Database** button is the equivalent of the **Review Mode** button in the Home Menu. *See figure 120.*

Figure 118: Open Database Button

5.8 Database/Review Mode

Review Mode allows the user to open images from the database. To enter Review Mode, click on the **Review** button in the Home Menu, or the **Open Database** button in the Current Image Browser. *See figures above and below.* Either button will open the Database. *See figure 121.* The system will be in Standby while in review mode.

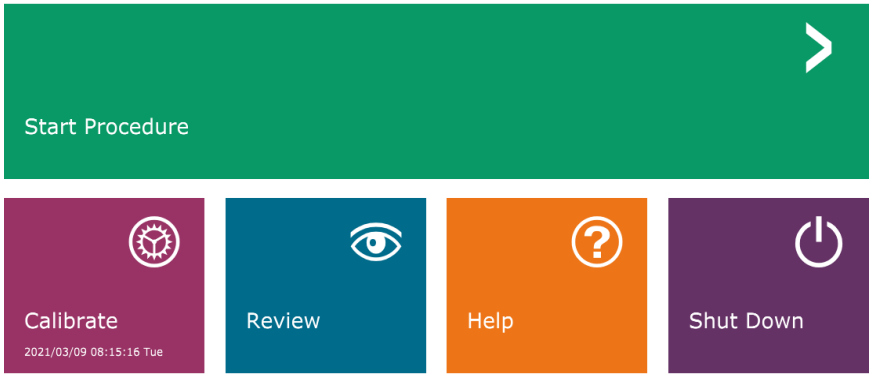


Figure 119: Review Mode Button in the Home Menu

The Database is comprised a Top Menu Bar and three main sections or sub-windows:

- The Sample List/Table, on the left,
- The Procedure List/Table, on the top right, and
- The Image Thumbnail List/Viewer located on the bottom right.

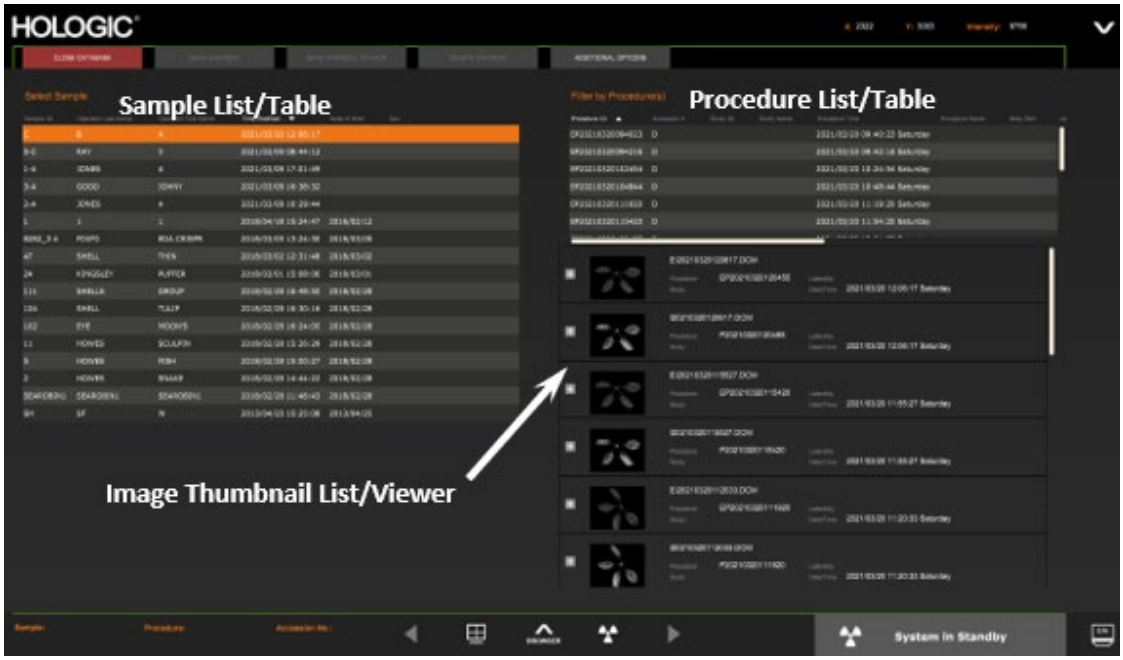


Figure 120: Image Database – Main Sections

The sections, or lists/tables, function in a top-down hierarchy:

Sample List→Procedure List→Image Thumbnail List/Viewer

Note
The Procedure List and Thumbnail List/Viewer will be empty until a sample is selected from the Sample List.

When a sample is selected, the Procedure window becomes active and displays a listing of all the procedures performed under the selected Sample. Additionally, all images for the selected Sample will be displayed in the Thumbnail List/Viewer. Selecting a procedure filters the images to only those taken under that procedure.

- Multiple procedure can be selected using the keyboard CTRL or SHIFT keys with the left mouse button. SHIFT + Click is used to select a group of adjacent procedures. CTRL + Click is used to select non-adjacent procedures. All the images belonging to all the selected procedures will be displayed.
- Multiple images can be selected by simply clicking on the specific images. The CRTL or SHIFT keys have no affect when selecting images.

The database may be sorted by clicking on the top fields of the Sample List/Table or Procedure List/Table. Clicking on a field such as Patient ID, Last Name, or Accession Number will sort the List/Table in ascending or descending order. The Field title used to sort the List/Table will contain an arrow to indicate whether the sorting is ascending or descending. The arrow will point up for ascending order and down for descending.

Scroll bars are located in the database to allow for ease of navigation when the List/Table content exceeds to available space.

Note
"Thumbnail" images are separate files from the actual image data (DCM, DAT, DMM, and RAW) files. They have the same file name as the image file but have a PNG or BMP file extension. If the image does not have a thumbnail VisionLS will attempt to create a thumbnail to be loaded into the database. If the software fails to create the thumbnail the image will not be displayed in the Thumbnail List/Viewer.

5.8.1 THE REVIEW PANE

The VisionLS allows up to 4 review panes to be opened in the review screen. These panes are only open in Review Mode.

Configuring the Review Panes

The review panes can be configured using the **Change Review Layout** button in the middle section of the VisionLS Bottom Tool Bar. The review layout can be configured with up to 4 panes. This button is only available during Review Mode.

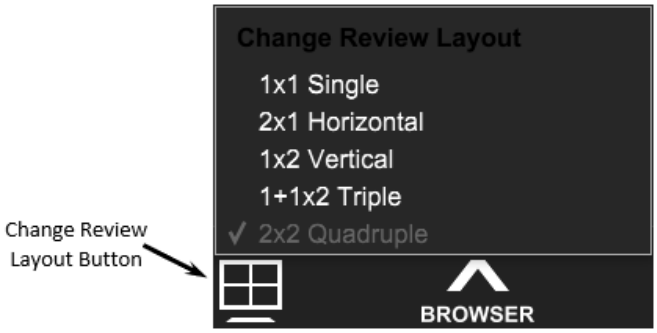


Figure 121: Change Review Layout Button and Menu

Note
The Review Pane Layout can also be configured using the *"Review Layout"* menu in the *"Top Menu Bar – View Menu"*. See Section 5.4.4.

Opening Images into Review Panes

- Open the Image Review screen.
- Click on the desired pane. The boarder of that pane will turn green indicating it is active.

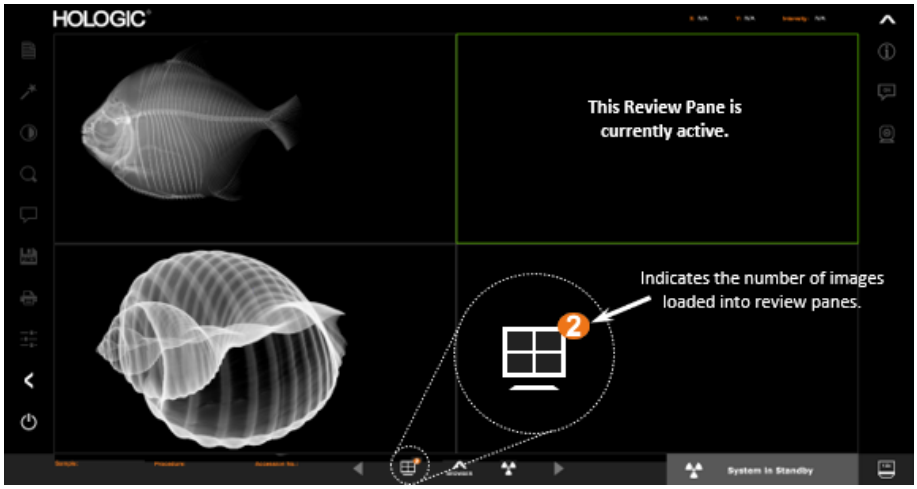


Figure 122: Review Panes

- Click on the **View Current Sample Images** (Browser) button in the middle of the Bottom Tool Bar.
- Select an image from the Thumbnail Strip, or click on the **Open Database** button, select a sample, select a procedure, then double click on an image. That image will be loaded into the active review pane and you will be returned to the Image Review screen.
- Repeat the above process for each Review Pane and image to be loaded.
- The **Change Review Layout** button indicates how many images have been loaded.

5.8.2 Database Top Menu Bar

The Top Menu bar consists of 4 buttons and a TAB along the top of the database screen.

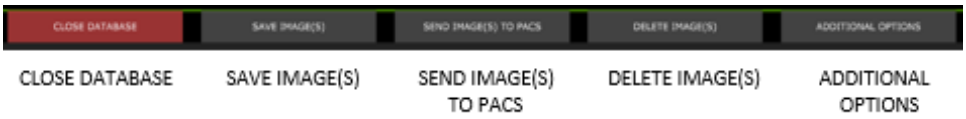


Figure 123: Database Top Menu Bar

Note
The left button will adjust from **CLOSE DATABASE** to **BACK TO MAIN MENU** depending on the workflow used to open the database. If the database was opened from the Acquisition Mode, the button will be **CLOSE DATABASE.** If the database was opened using the **Review** button in the Home Menu, the button will be **RETURN TO MAIN MENU.**

From left to right they are:

- **BACK TO MAIN MENU** or **CLOSE DATABASE**, depending on how Review Mode was opened.
- **SAVE IMAGE(S)**

- **SEND IMAGE(S) TO PACS**
- **DELETE IMAGE(S)**, and
- **ADDITIONAL OPTIONS** *(Opens a drop-down menu.)*

Prior to selecting an image, only the **BACK TO MAIN MENU/CLOSE DATABASE** button, and the ADDITIONAL OPTIONS tab will be active. The **SAVE IMAGE(S)**, **SEND IMAGE(S) TO PACS**, and **DELETE IMAGE(S)** buttons will only be active after an image is selected from the *Image Thumbnail List/Viewer.*

SAVE IMAGE(S)

The **SAVE IMAGE(S)** button is available when one or more entries from the Image List/Table or Thumbnail List is selected, otherwise it is disabled.

Click on the image(s) you want to save, then click the **SAVE IMAGE(S)** button. The "Save File As" dialog will open.

- Click the **Browse** button to navigate to the folder you want to save the images to.
- Enter a "Custom Prefix" if desired, or
- Select an "Automated Prefix" from a drop-down list. The options are: "Sample ID", "Operator Last Name", "Operator First Name", or "Accession Number".
- An example of the file name will be displayed towards the bottom of the dialog.
- Click the **Save** button to save the image(s). Note that the process may take a minute or more.
- The image is saved as a DCM file. A PNG thumbnail will also be created.

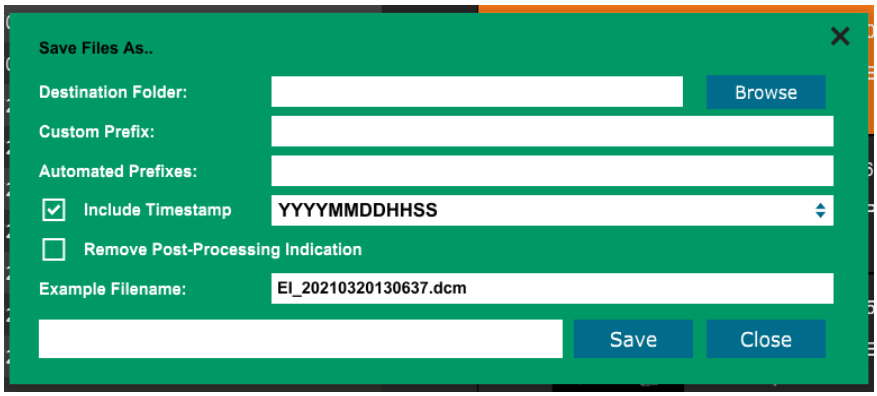


Figure 124: Save Images Dialog

Note
Entering or selecting a prefix is optional. Both Custom Prefix and Automated Prefixes entries can be left blank.

Note
The window level of the saved image is the default window level.

SEND IMAGE(S) TO PACS:

The **SEND IMAGE(S) TO** PACS button is used to send images to a pre-configured DICOM Server and will open a DICOM Networking Dialog Box. *Refer to Section 5.9, DICOM Functionality for additional information.*

DELETE IMAGE(S)

Allows the user to delete one or more images from a procedure. Select the image(s) to be deleted in the Image List/Viewer then click the **DELETE IMAGE(S)** button. The software will request confirmation that you want to delete the image(s). Click the **OK** button to continue deleting the image(s) from the database.

Figure 125: Delete Image(s) Confirmation

ADDITIONAL OPTIONS

The **ADDITIONAL OPTIONS** tab opens a menu of additional database options or functions. These options are described in the following pages.

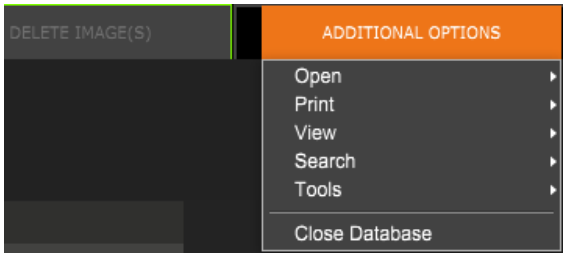


Figure 126: Additional Options Menu

Open Menu

The *"Open"* Menu has only one option *"Open Image from File"* which opens a standard Windows dialog box that allows the user to navigate to and open image files located on local or network drives.

Figure 127: Additional Options Menu - Open

Print Menu

The *Print"* menu provides options to print an image to a local printer, or to a DICOM printer (if one has been configured). Neither print option is enabled until an image is selected from the Image List/Table or Thumbnail List.

Figure 128: Additional Options Menu - Print

- *"Print Image to Local Printer"* sends the selected image to the local default Windows printer.

  The image will be printed with the default window level which may not provide an ideal printed image. If you require the window level to be adjust for the printed image, open the image in Review Mode, adjust the window level, then print using the *"Print Current Image"* in the *Top Menu, Tools Menu.*
- Print Image(s) to DCM Printer

  This function sends the image(s) to a pre-configured DICOM printer.

View Menu

The *"View"* Menu provides the user options affecting the Database view.

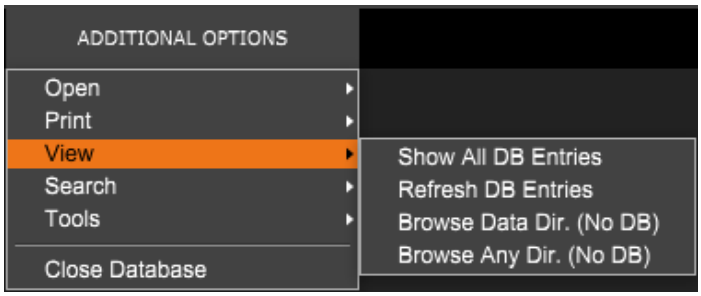


Figure 129: Database View Menu

- Show All DB Entries

  Reloads the Sample List/Table from the Database file. Any new changes or additions to the Database will be added to all the lists/tables. Any active Search Filter which may have been applied to the tables will be cleared.

  Search Filter is described under the Search menu item below.
- Refresh DB Entries

  Refreshes the Sample List/Table but maintains any existing Search Filter that has been applied.
- Browse Data Directory (No DB)

  Displays all thumbnail images (.png files) in the Data directory established by the configuration file. Default directory is C://Faxitron/Data. The files are

displayed in the Thumbnail List/Viewer. They are not associated with the Database, or table lists. This tool is helpful to review un-recorded images, or to debug database problems with images in the current data directory.

- Browse Any Directory (No DB)

  Opens a typical Windows *"Browse for Folder"* dialog, which allows the user to browse to any file directory. The files are displayed in the Thumbnail List/Viewer. They are not associated with the Database, or table lists. This tool is helpful to review an image directory which was never recorded in the database, or when database records are corrupted.

Search Menu

The database *"Search"* tool allows the user to perform a detailed and specific database search, or filtering.

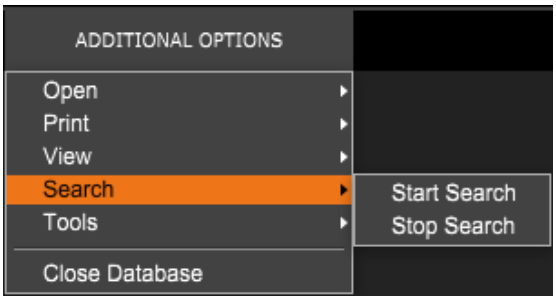


Figure 130: Database Search Menu

- Start Search

  "Start Search" opens the DB Search Dialog which allows the user to filter the database by the selected criteria. A Drop-down menu provides a list of *search categories*, such as Accession Number, First Name, Last Name, or Procedure Name. The user types in the search parameter for that search category, then clicks the **OK** button to start the search. The Sample List/Table will be filtered to display only those samples matching the search parameter. Subsequent searches can be conducted to further narrow down the samples, procedures, or images.

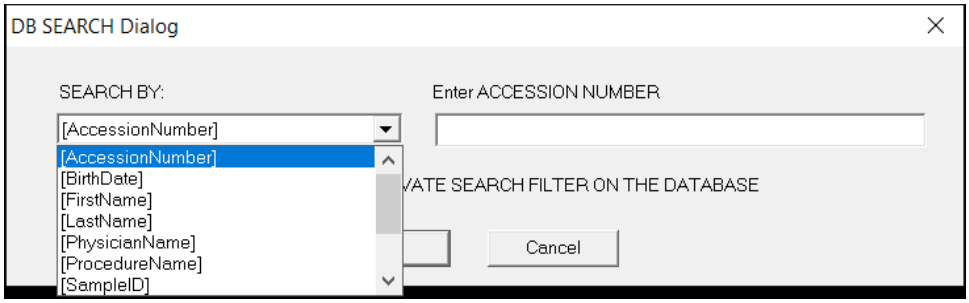


Figure 131: Database Start Search Dialog Box

Note
When the DB Search Dialog is opened, the Database page is temporarily closed, and the software opens the Image Review page. The Database page will re-open when the DB Search Dialog is closed.

- Stop Search

  "Stop Search" clears all active Search Filter and re-loads the list of all Samples to Sample List Table.

Tools Menu

The *"DB-Tools"* menu provides per Image/Procedure/Sample functions as well as some useful functions to repair or reformat the database.

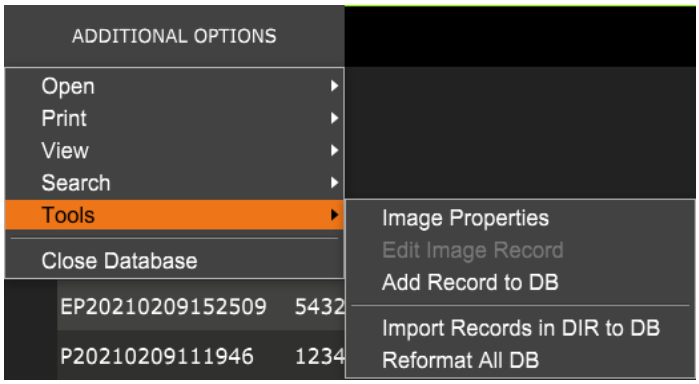


Figure 132: Database Tools Menu

- Image Properties

  This sub-menu is only active if an image has been selected from the Image List. Clicking on Image Properties will open the "Image Properties" window, which is the same "Image Properties" window that is opened from the Top Menu Bar – Tools – Properties. *See Section 5.6.4 and Figure 97.*

- Edit Image Record

  "Edit Image Record" is currently not available in VisionLS software.

- Add Record to DB

  "Add Record to DB" is only active when an entry from the Image List/Table or Thumbnail List is selected. This tool is useful for adding individual records/images to the database and can be used in conjunction with the "Browse Any Directory" function from the View Menu.

  Click on an image in the Image List/Viewer, then click on *"Add Record to DB"*. That image will now be added to the database.

Note
"Add Record to DB" only allows you to add 1 image/record at a time.

- Import Records in DIR to DB

"Import Records in DIR to DB" allows the user to import all the image files in a directory (including sub-directories) to the database. The image formats can be DCM, DAT, DMM and RAW. The software will create thumbnails (BMP files) if they are missing from any of the images.

Selecting *"Import Records in DIR to DB"* will open a "Browse for folder" which allows the user to click through (navigate) to the desired folder/directory. When the directory has been selected click the **OK** button. The software will prompt for confirmation before importing the images. *See figure below.*

Figure 133: Import Records Confirmation Dialog

- Reformat all DB

  "Reformat All DB" tool helps to reformat Date [YYYY/MM/DD], Date/Time [YYYYY/MM/DD HH:MM:SS] fields of tables and will also capitalizes letters of entries for some other fields. It is a useful tool when an older database file is imported and opened for the first time, or when the user alters database entries manually using MS Access.

- Close Database

  Closes the database and opens the Image Review Screen. The image area will be empty if an image had not been selected before closing the database.

5.8.3 Edit or Delete Sample or Procedure Information from the Database

The user may edit or delete SAMPLE or PROCEDURE information from within the database. Right click on the SAMPLE or PROCEDURE entry to open an on-screen menu.

Note
If the system has an "Authentication Password" activated (see Section 5.6.4, Top Menu Bar > Tools > Advanced Tools > Login Utility, and Figure 94), you will be prompted for the same password before sample or procedure records can be edited or deleted.

Edit Sample Information

1. Right Click on the sample in the Sample List to open the on-screen menu shown below.

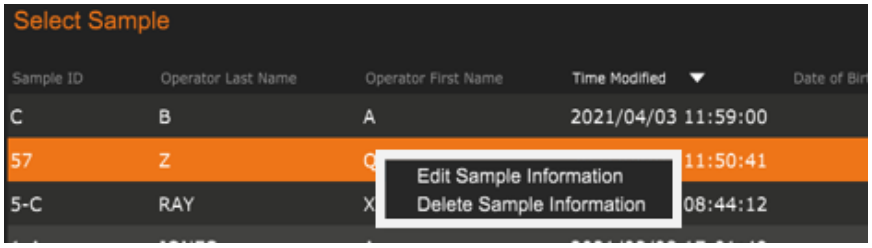


Figure 134: Edit or Delete Sample Information Menu

2. Select *"Edit Sample Information"* which will open a *"Sample Information Editor"* dialog box.

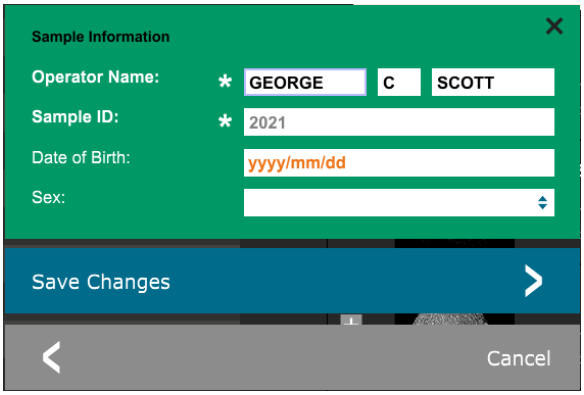


Figure 135: Sample Information Editor Dialog Box

3. Make the desired changes. You may edit the Operator Name, Date of Birth, and Sex. The Sample ID cannot be edited.
4. Click **Cancel** to close the dialog without making any changes.
5. Clicking the **Save Changes** button will open a *"Confirmation"* dialog box.

Figure 136: Edit Sample Information Confirmation Dialog Box

6. Click **Yes** to save the changes. Click **No** or **Cancel** to discard the changes.

Delete Sample Information

1. Right click on the sample in the Sample List to open the on-screen menu shown in figure 135.
2. Select *"Delete Sample Information"*, which will open a *"Confirmation"* dialog box.

Figure 137: Delete Sample Information Dialog Box

3. Click **Yes** to delete the records. Click **No** or **Cancel** to retain the records and close the dialog.

Edit Procedure Information

1. Right click on the procedure in the Procedure List to open the on-screen menu shown below.

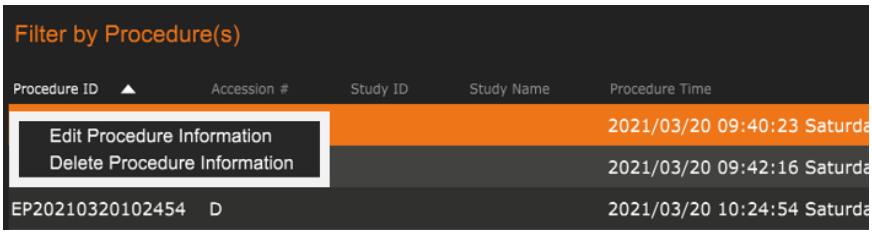


Figure 138: Edit or Delete Procedure Information Menu

2. Select *"Edit Procedure Information"* which will open a *"Sample/Procedure Information Editor"* dialog box.
3. Make the desired changes.

Note
None of the Sample Information fields can be edited.

Note
All Procedure and Study Information, including Accession No., can be edited.

4. Click **Cancel** to close the dialog without making any changes.
5. Clicking the **Save Changes** button will open a *"Confirmation"* dialog box. *See figure below.*

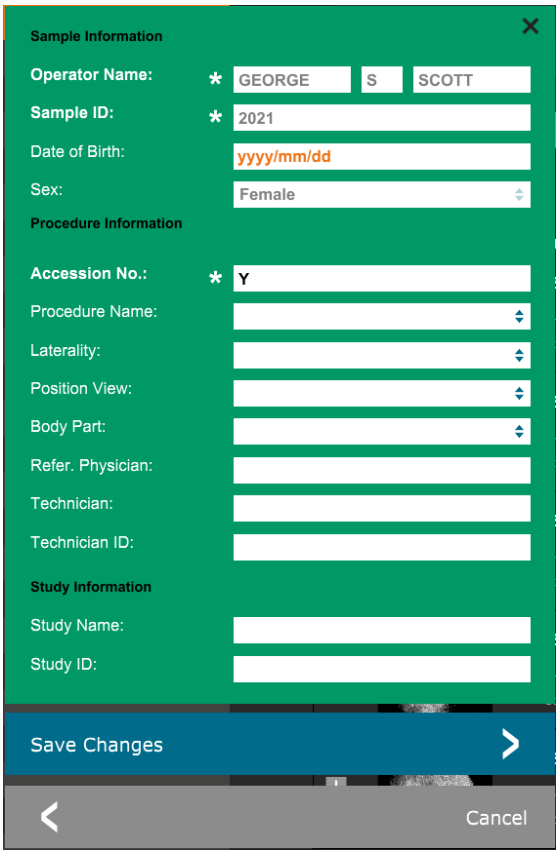


Figure 139: Sample/Procedure Information Editor

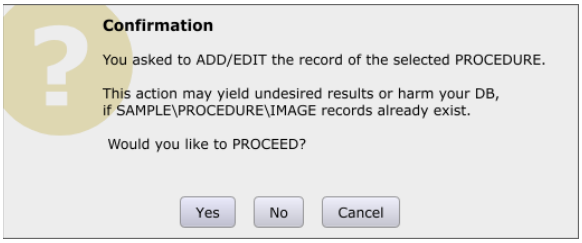


Figure 140: Edit Procedure Information Confirmation Dialog Box

6. Click **Yes** to save the changes. Click **No** or **Cancel** to discard the changes.

Delete Procedure Information

1. Right click on the Procedures List to open the on-screen menu shown in figure 139.
2. Select *"Delete Procedure Information"*, which will open a *"Confirmation"* dialog box.

Figure 141: Sample Information Editor Dialog box

3. Click **Yes** to delete the records. Click **No** or **Cancel** to retain the records and close the dialog.

5.9 DICOM Functionality

5.9.1 Modality

The DICOM file settings for Modality are accessed from the Top Menu Bar by selecting *"DICOM Utilities"* then *"DICOM Modality Setup"*.

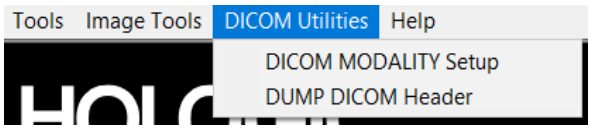


Figure 142: Top Menu – DICOM Utilities

Selecting *"DICOM MODALITY Setup"* opens the DICOM File/Transfer Settings dialog. Here the user can select the DICOM Storage Type (Presentation or Processing), DICOM Image Modality (Digital X-ray (General) or Digital X-ray Mammography Image) and may select Default DICOM Servers. The Value Representation and Transfer Syntax are not user definable. They are always assigned to be VR_IMPLICIT and META HEADER PRESENT, LITTLE_ENDIAN.

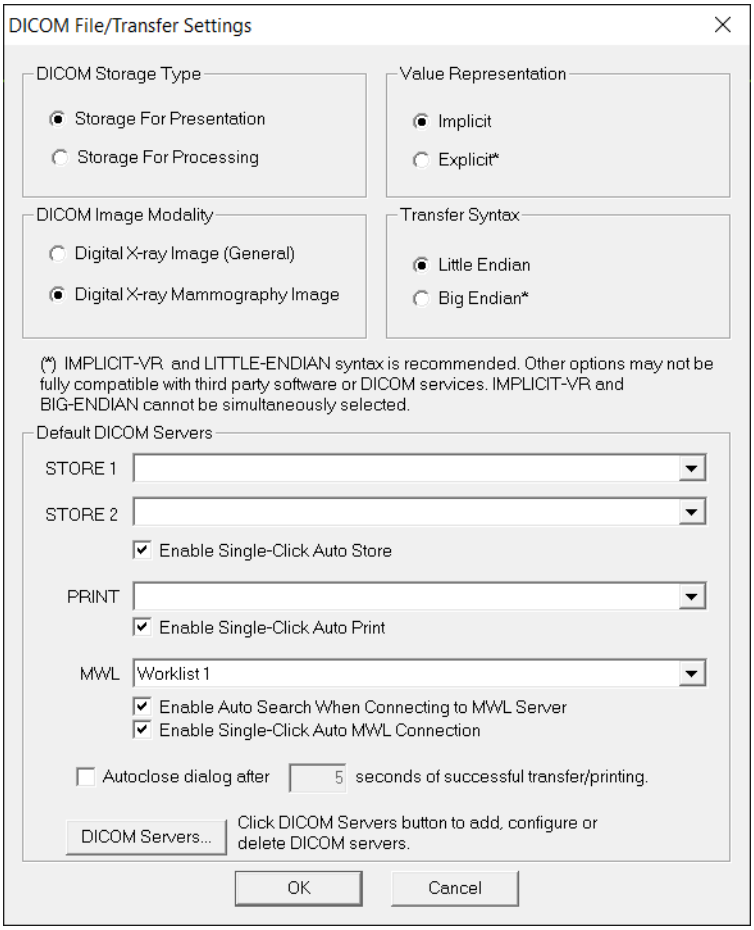


Figure 143: DICOM Modality Settings Dialog Box – Default Settings Shown

Note
Once the DICOM Modalities have been selected, they remain in effect even after the VisionLS software has been closed. The Modality settings are stored and will remain in the configured manner until they are change again using the DICOM File Settings. These settings (Storage Type & Modality, Transfer Syntax, and Value Representation) will be effective for all DICOM Local Save or Print functionalities.

5.9.2 Default DICOM Servers

Refer to Figure 144.

This section contains settings for default DICOM servers and to automate some of the processes when storing, printing, or searching PACS and MWL servers.

“Enable Single-Click Auto Store”, “Print” or “MWL Connection” checkboxes allow the user to store or print images or automatically connect to the MWL server. If you use a single PACS server for those actions or majority of your work involves a single PACS server, check a desired box to automate those actions.

"Enable Auto Search When Connecting to MWL Server" will tell the application to automatically perform a search with default search settings when looking up sample's data.

"Auto close dialog after N seconds of successful transfer/printing" will automatically close the DICOM Networking dialog after the specified number of seconds passed. The dialog will not close automatically if there was an error with transfer or printing.

Clicking the **DICOM Servers** button will open DICOM Networking dialog, where a user can add, modify, or delete DICOM servers.

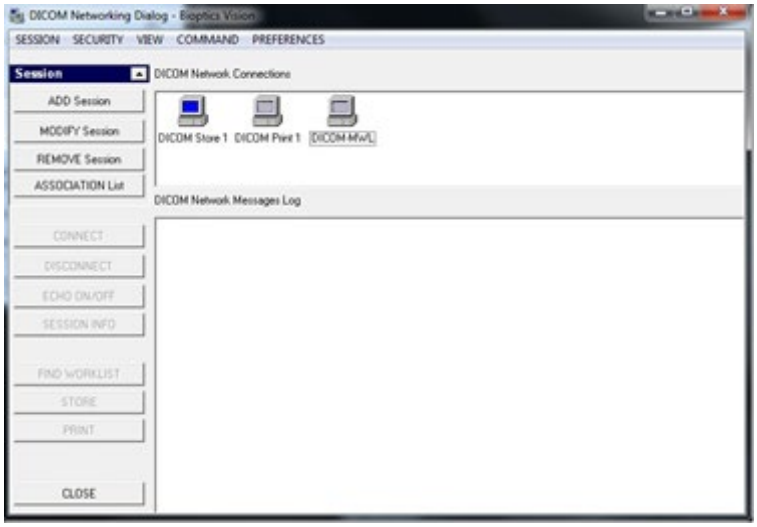


Figure 144: DICOM Networking Dialog Box

5.9.3 DICOM Save Local

To save the current image to a local drive/directory, right click anywhere in the image. This will open the menu shown below. Click *"Save/Store Current Image"* then *"As Local DICOM Image"*. This will bring up the standard Windows File Save Dialog. Browse or click through to the desired directory/folder, enter the file name and click **Save.**

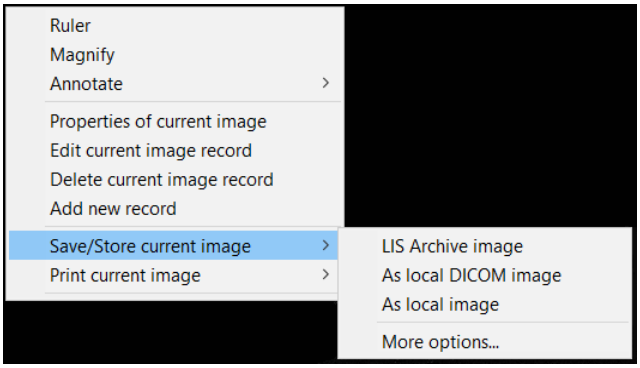


Figure 145: Image Right Click Menu – Save/Store Current Image

Each *"Save/Store Current Image"* sub-menu item is discussed in detail in Section 5.6.4, Top Menu Bar, under Tools Menu > Save/Store Current Image.

5.10 User Annotations

5.10.1 Overview

User Annotations in the Faxitron VisionLS 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, ellipses, and boxes. This allows additional information and "markers" to be added to the image if desired. Once applied to an image the annotations can be easily turned on or off, i.e., revealed or hidden, at will.

5.10.2 Operations

To begin annotating, select the **Annotations Tool** button from the left tool bar. *See figure 48 and figure below.* This opens the Annotations Dialog box and puts the software into annotations design mode.

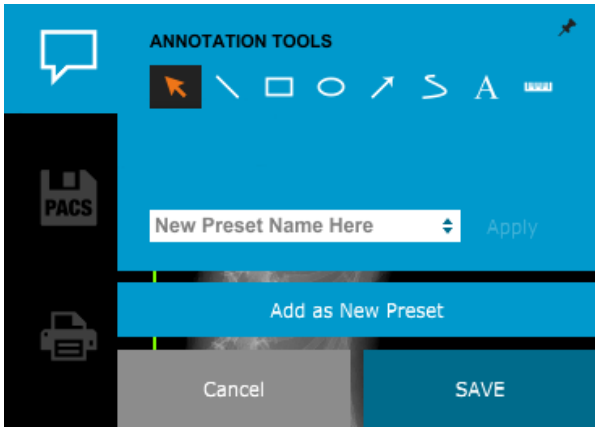


Figure 146: Annotation Tool Button and Dialog Box

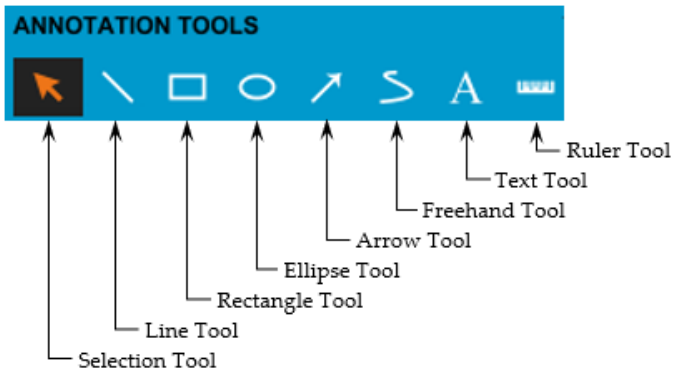


Figure 147: Annotation Tool Pallet

The tool pallet, along the top of the dialog box, consist of 8 annotation tools, described below.

Note
The method for drawing each of the annotation objects is basically the same: Position cursor at starting point, left click, drag, and release at the end point. All of the annotation objects, except the Freehand Tool, follow a linear path, starting point to end point. The Freehand Tool follows irregular movements of the mouser/cursor and allows the user to trace, or encompass, irregular features of the sample.

Selection Tool	The Selection Tool is used to select (highlight) one or more current annotation objects. • To select a single annotation object, click on the tool, move the cursor over the annotation object and click. The annotation object will be highlighted. • To select multiple objects, click on the selection tool, click and hold the left mouse button down near one of the objects, then drag the mouse to encompass the annotation objects you want to select. Release the mouse button. Any annotation object within the rectangle will be highlighted.
Line Tool	The Line Tool is used to draw a straight line on the image.
Rectangle Tool	The Rectangle Tool is used to draw a rectangle or square on the image.
Ellipse Tool	The Ellipse Tool is used to draw an ellipse or circle on the image.
Arrow Tool	The Arrow Tool is used to draw a straight line with arrowhead at one end.
Freehand Tool	The Freehand Tool is used to draw irregular shapes. The tool will follow the mouse movements.
Text Tool	The Text Tool is used to draw a text box in the image window, which allows the user to type text-based data, make notes on the image.
Ruler Tool	Creates a ruled line segment. This is similar to the Image Tools Ruler.

When all the desired annotations have been made click the **Save** button to *save* the annotations to the image. An additional image file with the extension ".ANN" will be created. The software will exit annotations mode and return to image acquisition mode.

Click the **Cancel** button to exit annotation mode without saving any annotations.

5.10.3 Design Mode and Mouse Right-Click Menu

Annotation Tool Properties

The user can modify the properties of each annotation tool, except for the Selection Tool.

- Select the desired annotation tool and draw the object on the image.
- Right click on the annotation object. A menu will open.

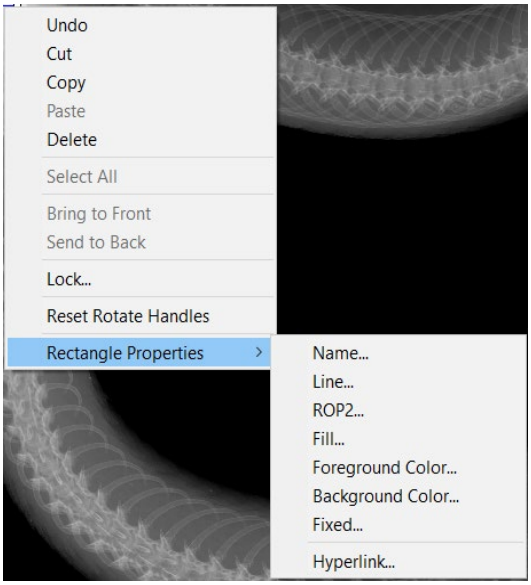


Figure 148: Annotation Tool Right Click Menu and Properties Menu

- Select Properties (i.e., "Rectangle Properties", "Line Properties", etc.). This will always be the bottom menu item.
- The properties menu will vary slightly depending on the annotation tool. But generally, the user will be able to change the line thickness, line type, fill color and pattern (if applicable), foreground and background colors, along with a few additional options. See figure above.
- The *"Fixed"* menu item allows the user to adjust the behavior of annotations when an image is zoomed or scrolled. Annotations that are not fixed move with the image. i.e., if the zoom level is changed, the annotations will be adjusted accordingly. When annotations are fixed, they are tied to the window. i.e., if the zoom level is changed, or the image is panned, the annotation does not adjust accordingly. It's size and position are locked to the monitor screen. *See figure below.*

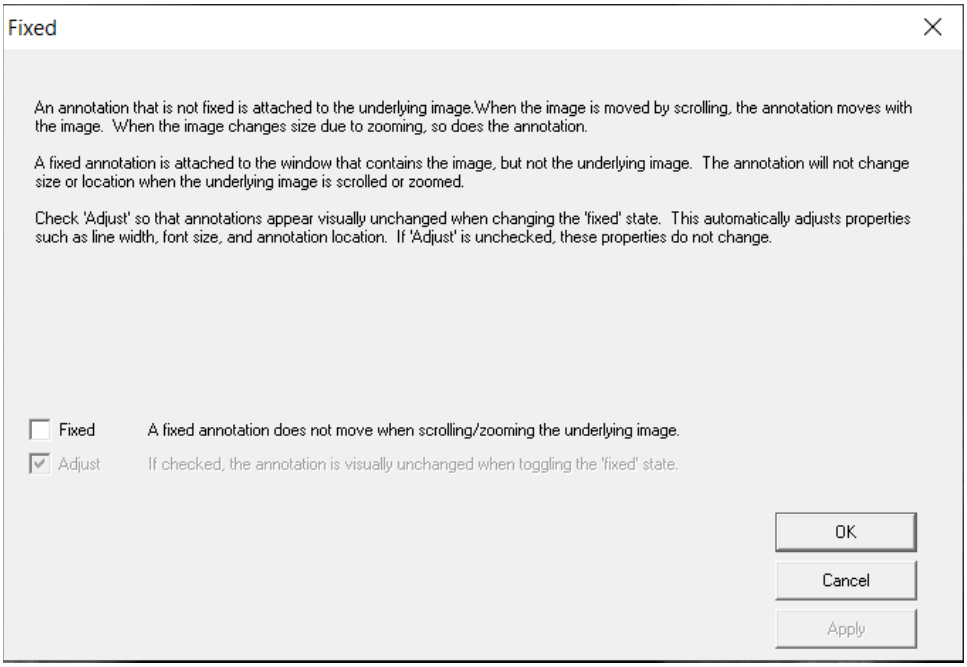


Figure 149: Annotation Tool Properties – Fixed Dialog Box

Preset Annotation Tools

The user may modify an annotation tools' properties and save those changes as a new preset. The new preset will retain all the tool properties applied at the time it was created. Additionally, the new preset will retain the exact size and location existing when it was created. The new preset may be applied to any image in the future.

- Select and draw the desired annotation tool.
- Modify the properties as described above.
- Assign a name to the modified annotation tool (i.e., *"Red Rule", "Wide Line"*) and enter that name in the "New Preset Name Here" space provided in the Annotations Tools Dialog box.

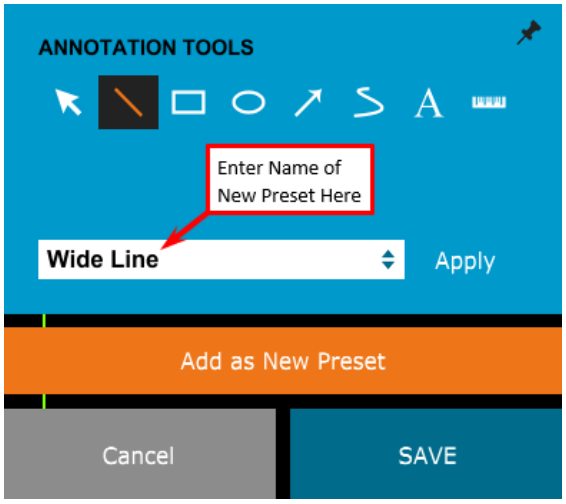


Figure 150: Adding Preset Annotation Tools

- Click on the **Add as New Preset** button.
- The new "line" will be added to the Preset Dropdown Menu.

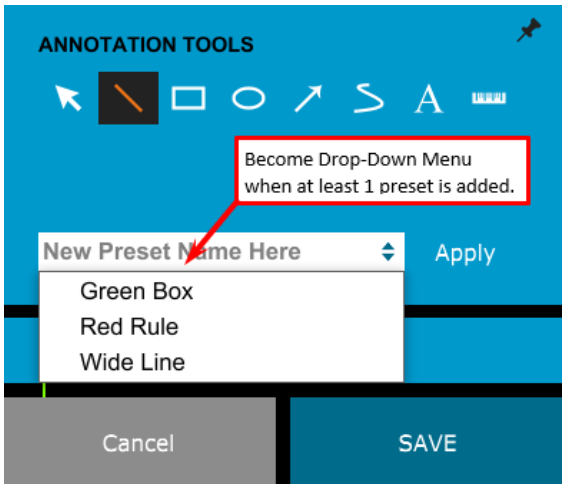


Figure 151: Preset Annotation Tools Drop-Down Menu

Note
Creating a New Preset temporarily applies the new presets' properties to all the annotation tools in the pallet. After creating a new preset, close the Annotation Tools Dialog box. Re-enter Annotation Mode by clicking the **Annotation Tools** button in the side tool bar. All Annotation Tool Pallet items will behave with the default properties.

Using Preset Annotation Tools

- To utilize preset annotation tools, click the down arrow in the *"New Preset Name Here"* box to display a list of the available presets.
- Select the desired preset, then click on **Apply.**
- The tool will be applied to the image. Note that the tool will be located in the exact position and orientation as when it was created.
- To move or re-orientate the tool click on the **Selection Tool** button, then click on the tool/object. Grab the tool/object handles and adjust as desired.
- Click the **Save** button to save the new annotation(s) to the image and return to the image acquisition mode.
- Click the **Cancel** button to delete any new image annotations and return to the image acquisition mode.

Universal Annotations Right-Click Menu

Right Clicking anywhere in the image screen will pull up a *"Universal"* Annotations menu.

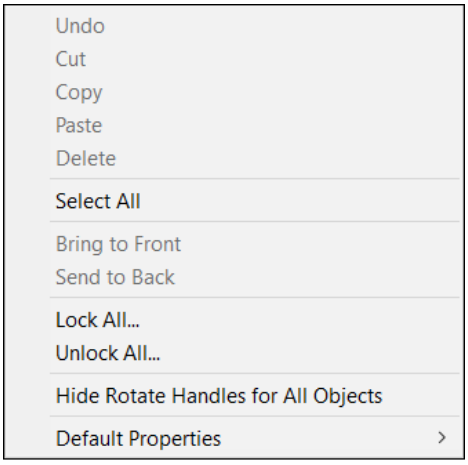


Figure 152: Annotation Tool Right Click Menu

Most of the menu items are inactive (greyed out) and not available for use.

A description of the active menu items follows:

- **Select All:** Clicking on Select All will draw a box around all annotation tools on the image. The user can delete all the selected tools using the keyboard "Delete" key. The user may also grab one of the selection box handles and resize all the selected tools.
- **Lock All…**: Lock All is used to prevent any active annotation tools from being deleted or altered. Clicking on Lock All brings up a password prompt. Your Hologic representative will provide you with the password.
- **Unlock All…:** Unlock All is used to reverse the Lock All action. As with Lock All, Unlock All will bring up a password prompt.

- **Hide Rotate Handles for All Objects.** Hides the Rotate Handles on all objects/tools. If an object is selected the Rotate Handles will not be shown. When active this menu item changes to **Show Rotate Handles for All Objects.**
- **Default Properties:** This menu item allows the user to set the *"Default Properties"* for all Annotation Tool Pallet items.

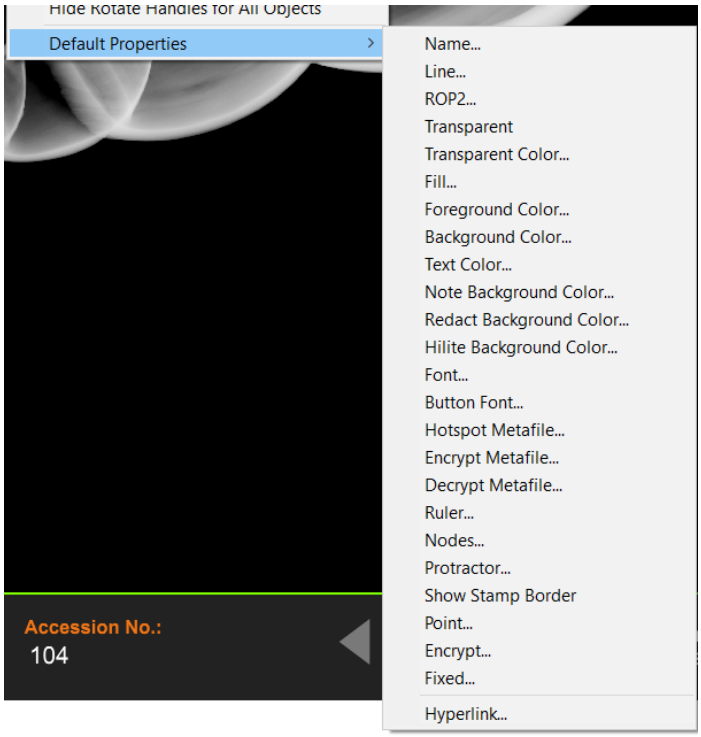


Figure 153: Annotation Tools - Right Click Menu – Default Properties Menu

5.10.4 Show – Hide Annotations

The **Toggle Annotations** button is located in the Right Tool Bar *(See Section 5.6.2 and Figure 67)* and allows users to quickly toggle annotations on and off. By default, the annotations will be toggled on.

Figure 154: Toggle Annotations Button

5.11 Help Button

The **Help** button is located in the Home Menu and is used to open the Help Menu.

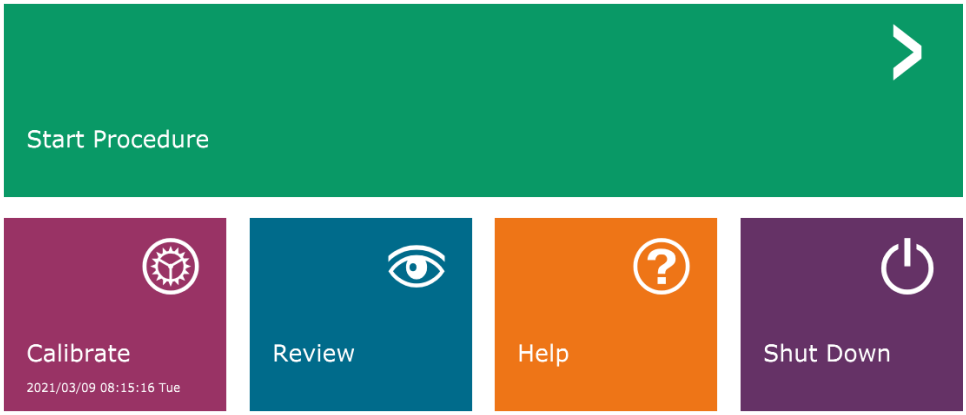


Figure 155: Help Button – Home Menu

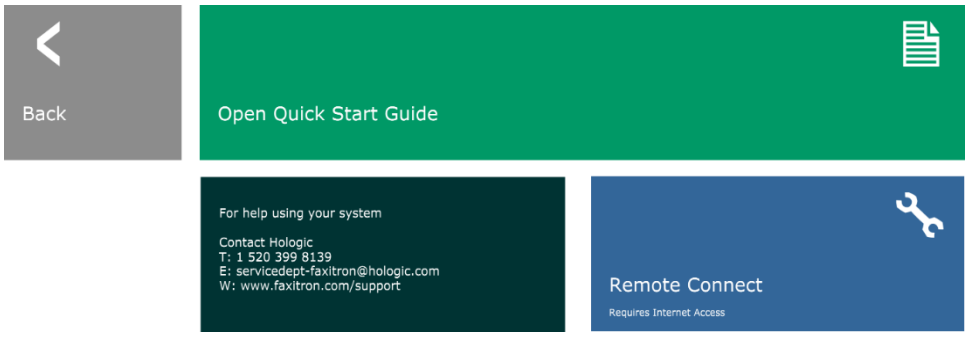


Figure 156: Help Menu/Page

From the Help Menu you can:

- Click the **Back** button to return to the Home Menu,
- **Open** the **Quick Start Guide**,
- Get the contact information for help in using your system, and
- Get information on contacting Hologic's technical support team through the **Remote Connect** button.

Chapter 6 Quality Control

6.1 Required Quality Control Procedures

The following procedures are necessary for correct system operation.

Table 1: Required Procedures

Test	Frequency
Calibration	Daily

6.2 Service and Troubleshooting

6.2.1 Service

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

6.2.2 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 cabinet.
- Verify power cords are plugged in and power to the system in ON.

Image looks like there is another object in the x-ray.

- Verify there are no other objects in the chamber during calibration.
- Remove objects and repeat calibration.

Poor image quality.

- Verify that the image intensity values (I (x,y)) found in the upper right-hand corner of the display screen are near 10,000 ADUs when preshot AEC target is also set to 10,000 ADUs, and exposure mode is set to Auto kV/Auto Time.
- Repeat the imaging procedure if needed.

6.3 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 even 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 7 Maintenance, Cleaning, and Disinfecting

7.1 General Information

7.1.1 For General Cleaning

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

User 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.

7.1.2 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.

7.1.3 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.

7.2 Component Specific Care

7.2.1 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 abrasive described above and used according to the directions of the manufacturer can be safety used.

7.2.2 Power Cord

How to Inspect the Power Cords

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

7.3 Maintenance

7.3.1 Preventive Maintenance Schedule

Table 2: User Preventive Maintenance

Action	Each Use	Daily	As Required
Clean and disinfect the specimen tray	✓		
Clean and disinfect the contact surface	✓		
Perform System Calibration		✓	
Clean and disinfect the Imaging Cabinet chamber			✓
Clean and disinfect the cabinet door handle			✓
Clean and disinfect the control display surface			✓

Table 3: Service Preventive Maintenance

Action	Done Annually
X-Ray Tube Conditioning Note 1	✓
Operational/Safety Checks	✓
Image Quality Check	✓
Radiographic Survey (X-Ray Leakage Test) Note 2	✓

Note 1: Performed annually, or if system has been unused for 2 months or more.

Note 2: Performed annually or as required by local regulatory agencies.

Appendix A System Specifications

A.1 Product Measurements

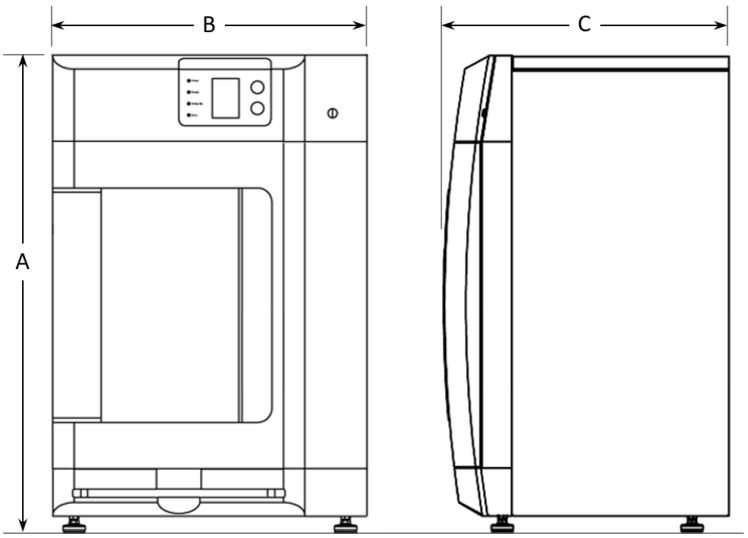


Figure 157: X-Ray Cabinet Measurements

A.	*Height*	*91.4 cm (36 inches)*
B.	*Width*	*58.4 cm (23 inches)*
C.	*Depth*	*53.3 cm (21 inches)*
	Weight	*188 kg (415 pounds)*

A.2 Operation and Storage Environment

A.2.1 General Conditions for Operation

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

Altitude	*To 2,000 m (6,562 feet)*
Degree of Pollution	Pollution Degree 2
Temperature Range	15.5 °C (60 °F) to 30 °C (86 °F)
Relative Humidity Range	*<75%*
Over-voltage Category	*II*

A.2.2 General Conditions for Transport and Storage

Temperature Range	*–20 °C (-4 °F) to 50 °C (122 °F)*
Relative Humidity Range	*<75%*

A.3 Technical Specifications

A.3.1 System Specs

Imaging Area	*23cm x 29cm (9″ x 11.5″), or* *10cm x 15cm (4″ x 6″)*
Pixel Pitch	*49.5µm (23cm x 29cm detector)* *48µm (10cm x 15cm detector)*
Resolution	*<10µm resolution at (50+lp/mm)*
Source to Imager Distance (SID)	*60.9cm (24.0″)*
Exposure Control	*Fully Automatic, Manual Time-Auto kV, Auto Time-Manual kV, or Fully Manual*
Geometric Magnification	*1.5:1, 2:1, 3:1, 4:1, 5:1, and 6:1 with standard magnification tray.*
	10:1 with mega mag tray
Energy Range	*20kV to 100kV, Configurable*
Typical Image Acquisition Time	*10 sec*
Target Material	*Tungsten (W)*
Beryllium Window Thickness	*0.25mm (0.010″)*
Tube Current	*0.3mA (Isowatt limited to 12W from 41-100kV)*
Focal Spot Size	*<15 microns*
Input Power	*100-240VAC ±10%, 50/60Hz, 200VA*
Heat Output	*500 BTU/hr MAX.*
Transient Overvoltages	*To the levels of Overvoltage Category II*
Peak line Current	*<5 Amps*
Line Connection	*Standard line cord and plug – medical grade*

A.3.2 Laser Information

Class	*II*
Peak Power	*2 mW*
Wavelength	*670 nm*
Line Width	*1mm Typical*
Beam Divergence	*85° Typical*
Operating Voltage	*3-6VDC*
Operating Current	*50mA Typical*
	80mA MAX

A.3.3 X-Ray Tube

	TRUFOCUS	**MXR**
Hologic P/N:	130-552023	130-55027
Manufacturer P/N:	TFX-8100 SW	18032
Max Anode Voltage	*100 kV*	*100 kV*
*Max Anode Current**	*0.3 mA*	*0.3 mA*
Maximum Power	*12 W*	*12W*
Duty Cycle	*50%*	*50%*
Focal Spot Size	*<15 microns*	*<15 um*
Anode Material / (Target)	*Tungsten (W)*	*Tungsten (W)*
Cooling	*Forced Air 100 cfm*	*Air cooled, 100 CFM fan recommended*
Beryllium Window Thickness	*0.25mm (0.010")*	*0.25mm (0.010")*
Window Material	*Beryllium IF-1®*	*Be 98.5%*
Cone Angle	*44 Degrees min*	*45 Degrees*
Operating/Storage Temp Range	*+10 °C to +55 °C / 0 °C to +60 °C*	*10° C-30° C*
Operating/Storage Humidity Range	*85% RH*	*10%-70% non-condensing*
Weight	*2 lbs*	*3 lbs*

***Note**
Max Anode current is limited by the UltraFocus® controller. Tube can operate at 0.5mA.

A.3.4 Computer Specifications

This table provide minimum recommended specifications at time of publication.

Hologic P/N: 2009-0029

Processor	*Intel® Core™ i5-8500 (6 Cores)*
Operating System	*Windows 10 (64 bit)*
System RAM	*8 GB (2s4GB) 2666MHz DDR4*
Hard Drive	*M.2 512GB NVMe Class 35 Solid State Drive*
Optical Drive	*N/A*
Network Connectivity	*Integrated Intel I219-LM Ethernet LAN 10/100/1000*
USB Ports	*FRONT Panel* *USB 2.0 – 2X* *USB 3.1 Gen 1 – 1X* *USB 3.1 Gen 1 Type-C – 1X* *REAR Panel* *USB 2.0 – 2X* *USB 3.1 Gen 1 – 4X*
Graphics	*Integrated Intel® HD Graphics 630*
Case/Chassis	*Small Form Factor (SFF)*
Dimensions (H x W x D)	*11.42″ x 3.7″ x 11.50″ (29.0cm x 9.26cm x 29.2cm)*
Min. Weight	*11.57 lbs (5.26 kg)*
Monitor *Hologic P/N: CMP-01803*	*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.

DICOM

Digital Imaging and Communications in Medicine

PACS

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

ROI

Region of Interest

SID

Source to Image Distance

HOLOGIC®

Hologic Inc.
600 Technology Drive
Newark, DE 19702 USA
1.800.447.1856
www.hologic.com

CE

Refer to the corporate website for more facilities worldwide.
www.hologic.com