

Faxitron[®] Core

Specimen Radiography System

User's Manual

from Hologic[®]

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August 2021

Faxitron Core was previously known as CoreVision

HOLOGIC[®]

Faxitron[®] Core

Specimen Radiography System

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Read all this information carefully before operating the system. Follow all warnings and precautions as stated in this manual. Keep this manual available during procedures. Always follow all the instructions in this manual. Hologic, Inc. does not accept responsibility for injury or damage from incorrect system operation. Hologic, Inc. can arrange training at your site.

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Faxitron® Core

Specimen Radiography System

Foreword

This manual was created by Hologic®, Inc. It is intended to guide the advanced user on how to setup, install and use the Faxitron Core hardware and the Vision Software System, both developed by Hologic, Inc.

The user must first setup the hardware, then initiate the Vision Software. Please review the required setup procedures in Section 4 of this manual before continuing.

Indications for Use

The **Faxitron Core Digital Specimen Radiography (DSR) System** is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of various anatomical regions, and to provide rapid verification that the correct tissue has been excised during percutaneous biopsy. Performing the verification directly in the same biopsy procedure room enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls. This device is intended to be operated wherever the medical professionals deem appropriate, including a surgical suite or a room adjacent to a surgical suite.



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Faxitron[®] Core

Specimen Radiography System

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SECTION 1
User's Manual
Faxitron[®] Core

This manual was created by Hologic, Inc. It is intended to guide the user on how to setup, install and use the Faxitron Core hardware and Vision Software, both developed by Hologic, Inc.

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

Thank you from all of us at Hologic, Inc.

1.0.0 Introduction

Manufacturer and Contact Information



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Danbury, CT 06810 USA
1.800.447.1856
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2 Lyon Park Road
Macquarie Park NSW 2113
Tel: 02 9888 8000



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



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

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



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



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



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




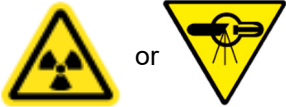



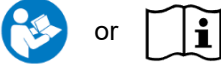







Warns the reader to use appropriate protection (such as surgical gloves or an approved specimen container) to avoid exposure to potentially infectious materials such as patient tissue samples.



1.1.0 Warning and Caution Symbols in this Manual

1.1.1 Warning and Caution Symbols on the Label

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
	Caution—Radiation (X-Rays Produced)
	Caution - Potentially infectious materials
	Warning Electricity
	Caution
	Follow or consult instructions for use
	This system transmits radio frequency (RF) energy (non-ionizing radiation)
	European Authorized Representative
	Medical Device
	Catalog number
	Serial number

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SECTION 2
**Radiation Safety
and X-Rays**

Radiation is energy in the form of waves or particles. High frequency, high energy radiation, which has sufficient energy to displace an electron from its orbit around a nucleus, is referred to as **ionizing radiation**. X-rays, gamma rays, beta particles, alpha particles, and neutrons are all forms of ionizing radiation and can be given off by radioactive material, stars, and high-voltage equipment.

We cannot see, feel, taste, smell, or hear ionizing radiation, so monitoring equipment is required for us to detect it.

X-Rays

X-rays are high frequency, high energy radiation having sufficient energy to displace an electron from its orbit around a nucleus and are called "ionizing" radiation. X-rays are capable of traveling long distances through air and most other materials. The amount of energy carried by radiation is directly proportional to the frequency, and inversely proportional to the wavelength. X-rays have a relatively short wavelength and high frequency, thus possess a great deal of energy.

X-rays can produce biological changes in tissue that can be beneficial when used in radiation therapy. However, x-rays can also be harmful to biological organisms because of their ability to damage chromosomes.

Sources of X-Ray radiation in medical facilities include:

X-ray Machines. X-Ray machines are used for treatment (radiation therapy) and diagnostic purposes. Diagnostic X-Ray machines are used to X-Ray various parts of the body, chest, leg, breasts, etc for diagnostic purposes. Today, in the US alone, diagnostic radiology accounts for two-thirds of our dose from man-made sources. X-Ray machines can produce high levels of ionizing radiation.

Cabinet X-ray machines. Cabinet x-ray machines are enclosed, shielded, and interlocked irradiation chambers. The machine can only operate when the chamber door is securely closed. The exposure rates at every location on the exterior meets the rate specified for uncontrolled areas.

Sources of Radiation

We are all exposed to radiation every day. According to the NCRP, National Council on Radiation Protection, the average background dose in the United States is 360 mrem/year (3.6 mSv/yr). These exposures are mostly from natural sources of radiation, such as radon, cosmic radiation, and natural deposits in the earth. Even our bodies contain natural radioactivity!

There are 2 sources of radiation: Natural and Man-Made.

Natural Sources of Radiation include Cosmic rays, Terrestrial gamma rays, Radionuclides in the body, and Radon and its decay products. The worldwide average annual effective dose from natural sources is estimated to be 2.4 mSv (240mrem). There are factors that affect the effective doses from these natural sources of radiation: The cosmic ray dose rate depends on height above sea level and latitude, the terrestrial gamma-ray dose rate depends on local geology, and the dose from radon decay products depends on local geology and housing construction and use. See Table 1 for annual effective doses from these natural sources.

Table 1

Annual effective dose to adults from natural sources

Source of exposure	Annual effective dose (mSv)	
	Typical	Elevated *
Cosmic Rays	0.39	2.0
Terrestrial gamma rays	0.46	4.3
Radionuclides in the body (except radon)	0.23	0.6
Radon and its decay products	1.3	10
TOTAL (rounded)	2.4	-

*The elevated values are representative of large regions. Even higher values occur locally.

2.0.0 Introduction

2.1.0 X-rays

2.2.0 Sources of Radiation

Medical X-Rays are a major source of man-made radiation. Medical X-rays utilize ionizing radiation for both the diagnosis and treatment of injuries and disease. UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) estimates that individual exposure to medical radiation ranges from 0.4 to 1 mSv annually. Exposure from medical radiation exceed those from all other man-made sources, but amount to less than half the exposure to natural background radiation.

The doses of ionizing radiation used in diagnostic X-rays are usually quite low, $\leq 50\text{KeV}$.

The chart below shows the contributions from various sources of radiation.

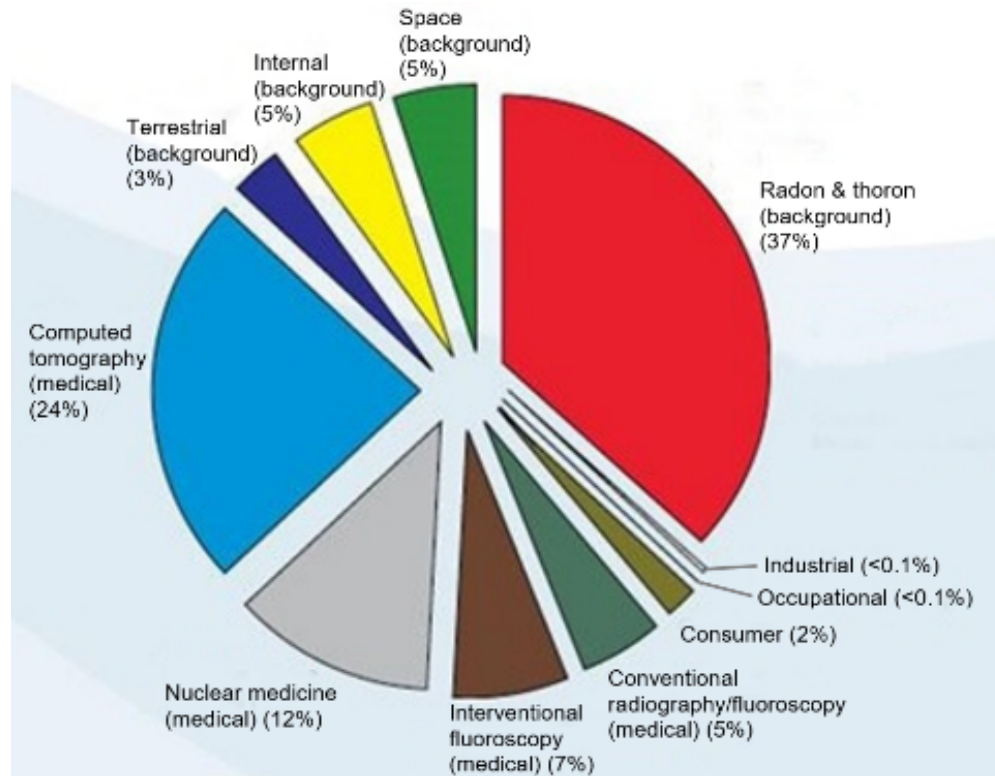


Figure 2.2.1
Sources of Radiation Dose in the United States.

From NCRP 160, Fig. 1.1.
Percent contribution of various sources of exposure to the total collective effective dose (1,870,000 person-Sv) and the total effective dose per individual in the U.S. population.

Exposure to ionizing radiation can have adverse health effects by causing atoms and molecules to change. When ionizing radiation passes through tissue, large amounts of energy are transferred to individual molecules. This energy transfer causes electrons to be dislodged from atoms, initiating a variety of chemical and physical effects. The most critical of these effects is damage to DNA molecules. The body has mechanisms in place that normally repair this damage, but extensive or certain types of damage may not be repaired. When the body is unable to repair the damage the cell may die or be mutated. Mutated cells have the potential to turn into cancers. The extent of damage is proportional to the energy imparted, or the dose of ionizing radiation received.

Health effects of exposure to x-ray radiation come in two general types, direct or indirect. X-rays are thought to create radicals in exposed cells of your body that may break or modify chemical bonds within critical biological molecules.

2.3.0 Biological Effects of Radiation

As a result

- (1) Cells may be injured or damaged, although many cells repair themselves, resulting in no residual damage,
- (2) Cells may die, which millions of body cells do every day, and are replaced in a normal biological process,
- (3) Cells may incorrectly repair themselves, resulting in a biophysical change. Finally, X rays may pass through the body with no interaction.

The damage to cells from ionizing radiation can result in:

- Production of free radicals
- Breakage of chemical bonds
- Production of new chemical bonds and cross-linkage between macromolecules
- Damage to molecules which regulate vital cell processes (e.g. DNA, RNA, proteins)

Dose Rate, Total Dose Received, Energy of the radiation, Area of the body exposed, the individual's sensitivity, and Cell sensitivity, are all factors that determine the biological effects of radiation exposure.

There are two types of effects from exposure to ionizing radiation: deterministic effects and stochastic effects.

DETERMINISTIC AND STOCHASTIC EFFECTS

Potential biological effects depend on how much and how fast a radiation dose is received. Radiation doses can be grouped into two categories, *acute* and *chronic* dose.

Acute Dose and Deterministic Effects

Acute radiation exposure is a high radiation dose occurring over a short period of time, normally seconds to days. The effects caused by acute radiation doses are called *deterministic*; the severity of the effect is determined by the amount of dose received. Deterministic effects usually have some threshold level - below which, the effect will probably not occur, but above which the effect is expected. Above the threshold, *the severity of the effect increases as the dose increases*.

For example, a whole body dose of about 300 rems (3 Sv), 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death without medical treatment. These effects would not occur if the dose 300 rems (3 Sv) were accumulated gradually over many years.

There is also a difference between whole body and partial body exposures. Where an acute dose of 600rem (6 Sv) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. However, an acute dose of that magnitude to the whole body could cause death within a short time without medical treatment.

The utilization of appropriate radiation protection mechanisms and occupational exposure dose limits reduce the likelihood of these effects occurring.

The occupational dose limits are far below the thresholds for deterministic effects.

2.3.0 Cont.

2.3.1 Deterministic and Stochastic Effects

2.3.1 Cont.

Chronic Dose and Stochastic Effects

A chronic dose is a relatively small amount of radiation received over a long period of time (e.g. years). The body is better equipped to tolerate a chronic dose than an acute dose, since the body has time to repair damage because a smaller percentage of the cells need repair at any given time. The body also has time to replace dead or non-functioning cells with new, healthy cells. However, this does not mean there is no risk related to chronic radiation exposure.

The term stochastic means “random”, with the implication that low levels of radiation exposure are not certain to produce an effect. These low levels, below the threshold for deterministic effects, may or may not result in detrimental effects to the body.

However keep in mind that:

- 1) There is no threshold level of radiation exposure below, which we can say with certainty that effects will not occur
- 2) Doubling the radiation dose, doubles the probability that effects will occur.

Chronic exposure may produce only effects that can be observed some time following initial exposure. These may include genetic effects and other effects such as cancer, precancerous lesions, benign tumors, cataracts, skin changes, and congenital defects. Generally, the greatest concern is the development of some form of cancer.

Immediate effects are not seen below doses of 25 rem (0.25 Sieverts). Latent effects may appear years after a dose is received. It has been found through studies of populations exposed to ionizing radiation (> 0.5 Sv) that the probability of a fatal cancer occurring from radiation exposure is approximately 5 percent per Sv.

RADIOSENSITIVITY

Radiosensitivity is the probability of a cell, tissue, or organ suffering an effect per unit dose of radiation. Radiosensitivity is highest in cells which divide rapidly (highly mitotic) or are relatively non-specialized (undifferentiated). For this reason the basal epidermis, bone marrow, thymus, gonads, and lens cells are highly radiosensitive. Muscle, bones, and nervous system tissues have a relative low radiosensitivity. Also, radiosensitivity is greatest during the fetal stage and becomes progressively smaller through adolescence and adulthood.

Basic Law of Radiobiology: Biological effects are directly proportional to the mitotic index and the mitotic future of the exposed cell, and inversely proportional to the degree of differentiation. Mitosis refers to the natural division of a cell nucleus during cell reproduction; differentiation refers to the cell's degree of specialization to perform a specific function in an organism.

RISKS FROM RADIATION EXPOSURE

It is estimated that approximately 20% (1 in 5) of all deaths in the United States are due to some type of cancer.

If every member of a population of 1 million were to receive 10 mrem (0.1 mSv) of radiation, it is possible that 5 additional deaths would be observed. Remember that out of this population of 1 million, about 200,000 will die of cancer, making these few additional deaths statistically impossible to detect.

Additionally, the risk of cancer death is 0.08% per rem (10 mSv) for doses received rapidly (acute) and might be 2 times (0.04%, or 4 in 10,000) less than that for doses received over a long period of time (chronic).

2.3.2 Radiosensitivity

2.3.3 Risks from Radiation Exposure

From currently available data, the NRC has adopted the risk value for an occupational dose of 1 rem (0.01 Sv) as representing a risk of 4 in 10,000 of developing a fatal cancer.

The International Commission on Radiological Protection (Publication 103, 2007) indicates a value of 5.5 % per sievert for cancer and 0.2 % per sievert for heritable effects after exposure to radiation at low dose rate

The risk associated with the diagnostic uses of ionizing radiation are normally limited to late stochastic effects, which are estimated to occur at a frequency of perhaps 0.01% for an average examination (deterministic skin damage may occur after fluoroscopy in extreme cases). At the individual level, these risks are almost always small compared to the benefit of diagnosis and treatment.

CONCLUSIONS ON HEALTH RISKS

We assume that any radiation exposure, no matter how small, carries with it some risk. However, we know that on average these risks are comparable to or smaller than risks we encounter in other activities or occupations that we consider safe. Since we have extensive control over how much radiation exposure we receive on the job, we control and minimize this risk. The best approach is to keep our dose As Low As Reasonably Achievable, or ALARA – a term we will discuss in detail later. **Minimizing the dose minimizes the risk.**

ICRP DOSE LIMITS

The international Commission on Radiological Protection (ICRP) has established radiation dose limits based on available data. These dose limits are maximum allowed values for whole body exposures. The dose unit of measure is called the Sievert (Sv) which accounts for various factors to determine a quantity called *effective dose*. The dose limits were last updated in 2007.

For members of the public the dose limit is 1mSv/yr (0.001 Sieverts per year)

For occupational workers (those who work in the nuclear industry the dose limit is 20 mSv/yr (0.02 Sieverts per year)

The dose limits exclude the effects of background radiation.

ICRP Recommended annual dose limits for individual organs or tissues

Radiation weighted dose in	Workers	Public
Lens of the eye	150 mSv	15 mSv
Skin ^{1,2}	500 mSv	50 mSv
Hands and feet	500 mSv	-

1. The limitation on effective dose provides sufficient protection for the skin against stochastic effects. An additional limit is needed for localised exposures in order to prevent tissue reactions.
2. Averaged over 1 cm² area of skin regardless of the area exposed.

2.3.3 Cont.

2.3.4
Conclusions on Health Risks

2.4.0
ICRP Dose Limits

Determining Factors

The effects of x-ray exposure depend upon the duration of exposure, how fast the dose is delivered, Energy – How much energy was in the x-ray, the total dose – the magnitude of the dose, and whether the exposure is whole body or localized. Low energy (<50KeV) X-rays can cause damage only to skin or outer part of body while high energy X-rays can penetrate the body to the internal organs. A large acute dose delivered at once would have a greater effect than the same dose administered over time as incremental fractions.

In medical environments risk of radiation exposure can be minimized by:

- Avoiding all unnecessary exposures to radiation
- Using Doses that are As Low As Reasonably Achievable (ALARA)
- Following equipment manufacturers operating instructions
- Following equipment manufacturers preventive maintenance instructions
- Utilizing appropriate shielding

ALARA

The ALARA concept is based on the assumption that any radiation dose, no matter how small, can have some adverse effect. Under ALARA, every reasonable means of lowering exposure is used.

There are three general rules to reduce a person's exposure to any type of ionizing radiation

1. Reduce the time you are exposed to the radiation source.
 - Reducing the exposure time reduces the radiation dose.
2. Increase the distance between yourself and the radiation source.
 - Increasing the distance from a source of radiation significantly reduces the radiation dose.
 - Doubling the distance from a radiation source means one-fourth the dose rate.
 - Tripling the distance gives one-ninth the rate.
3. Increase shielding between yourself and the radiation source.
 - The use of appropriate shielding greatly reduces dose.
 - The material used and thickness of the shield depends on the source of the radiation.
 - Lead is a common shielding material.

Consult your Radiation Safety Officer for the rules and guidelines of specific to your facility.

2.5.0 Risk Management

REFERENCE SOURCES

2.6.0 References

Radiation Safety Training and Reference Manual, California Institute of Technology, Training and Reference Manual, March 1995 (Revised June, 1996)

Radiation Safety Manual(Revised March 2010), Stanford University, Veterans Affairs Palo Alto, Health Care System, Environmental Health and Safety, Stanford University, Stanford California

Radiation and X-Ray Training - Environmental Health and Safety - University of North Carolina at Chapel Hill

USF (University of Southern Florida) Radiation Safety – Research X-Ray Safety Manual, Radiation Safety Office – 2003

University of Oklahoma Chemical Crystallography Lab, 11-APR-2011

European Nuclear Society – Glossary of Nuclear Terms
<http://www.euronuclear.org/info/encyclopedia.htm>

United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR 1993, Report to the General Assembly, With Scientific Annexes, UNITED NATIONS PUBLICATION, Sales No. E.94.IX.2, ISBN 92-1-142200-0

JEFFERSON LAB - Thomas Jefferson National Accelerator Facility (Jefferson Lab)

Ionizing Radiation Effects and Their Risk to Humans, **T.R. Goodman, MD** *Yale University School of Medicine, New Haven, CT*

IMAGE WISELY – Radiation Safety in Adult Medical Imaging
<http://www.imagewisely.org/Imaging-Professionals/Imaging-Physicians/Articles/Ionizing-Radiation-Effects-and-Their-Risk-to-Humans.aspx>

Seibert 2004: Seibert J A “X-ray imaging physics for nuclear medicine technologists.” Part1: Basic principles of x-ray production *J Nucl Med Technol*32 139-47

Shultis 2005: Shultis J K and Faw R E 2005 Radiation shielding technology *Health Phys* 88 297-322

Simpkin 1995: Simpkin D J 1995 Transmission Data for Shielding Diagnostic X-Ray Facilities *Health Phys* 68 704-709

3

SECTION 3
**About Your
Faxitron Core System**

The **Faxitron Core Digital Specimen Radiography (DSR) System** is a compact desktop cabinet digital X-ray imaging system intended to provide rapid verification of core biopsies.

Performing the verification directly in the same biopsy procedure room enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls. The Faxitron Core's small footprint allows it to be setup in surgical suites or offices with limited space.

The **Faxitron Core Digital Specimen Radiography System** employs the use of **Vision**, a full featured and powerful image acquisition and data manipulation software. Vision software handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal. **Vision** software is the central part of this system. **Vision** software is Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and comes with DICOM Print, Store and Modality Work List (MWL).

3.0.0 Overview

DICOM Version

Hologic uses the latest DICOM standard:

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

And complies with:

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

Storage Classes

Faxitron DR provides Standard Conformance to the following DICOM V3.0 SOP Class as a SCU.

SCU SOP Class

SOP Class	SOP Class UID
Computed Radiography Image Storage SOP	1.2.840.10008.5.1.4.1.1.1
Digital X-ray Image Storage Presentation	1.2.840.10008.5.1.4.1.1.1.1
Digital X-ray Image Storage Processing	1.2.840.10008.5.1.4.1.1.1.1.1
Digital X-ray Mammography Image Storage Presentation	1.2.840.10008.5.1.4.1.1.1.2
Digital X-ray Mammography Image Storage Processing	1.2.840.10008.5.1.4.1.1.1.2.1
Study Root Query/Retrieve Info. Model -FIND	1.2.840.10008.5.1.4.1.2.2.1
Patient Root Query/Retrieve Info. Model -FIND	1.2.840.10008.5.1.4.1.2.1.1
Modality Worklist information Model-FIND	1.2.840.10008.5.1.4.31
Greyscale Softcopy Presentation Storage	1.2.840.10008.5.1.4.1.1.11.1

For further details refer to the full DICOM Conformance Statement stored on the system. The file is in C:\Faxitron and a shortcut is provided on the desktop.

If required, a copy of the DICOM Conformance Statement is available from Hologic on request.

3.0.1 DICOM Version

Service

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

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

Troubleshooting

Refer to the Faxitron Core Service Manual, contact your Hologic representative, or contact Hologic Customer Service.

SCHEDULE OF MAINTENANCE

Refer to the Faxitron Core Service Manual, contact your Hologic representative, or contact Hologic Customer Service.

3.0.2 Service and Troubleshooting

3.0.3 Schedule of Maintenance

3.1.0 Specifications

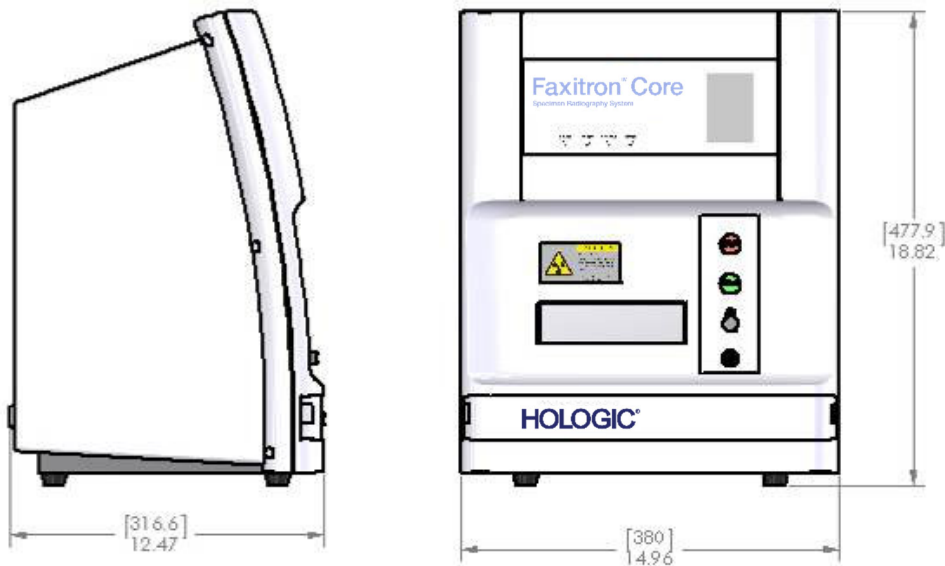


Figure 3.0.1
Dimensions & Weight

SOURCE-to-IMAGER (SID) and SOURCE-to-OBJECT (SOD) DISTANCES:

- Top of Camera to Imager: 0.230" (5.8mm)
- Tube Target to Imager: 12.90" (327.66mm)
- Tube Target to Sample Position: 8.94" (227.08mm)
- Imager to Sample Position: 3.96" (100.58mm)
- Effective Magnification: 1.44:1

WEIGHT: 40 lbs (18 kg)

POWER REQUIREMENTS: 120VAC 60Hz 150W Max or 230VAC 50Hz 150W Max

HEAT OUTPUT: 500 BTU/hr Max

X-RAY DUTY CYCLE: 50%

EXPOSURE CONTROL: Automatic or Manual

Requirements | Faxitron Core Compliance

It is the responsibility of the facility or institution operating this system to ensure that all local, regional, and federal regulations affecting the use of Ionizing Radiation Equipment are followed

Emission Limits

X-Ray Radiation emitted from the Faxitron Core unit does not exceed an exposure of 0.3 milli-Roentgens (mR) per hour at any point 5 centimeters (cm) outside the external surface. For countries requiring emission values measured at 10 cm from the external surfaces, the radiation does not exceed 0.1 mR per hour at 10 cm.

Safety Interlocks

The Faxitron Core Specimen DR system has two safety interlocks on the specimen drawer, the front access panel, and the back cover to prevent the generation of x-rays unless they are closed/installed.

Start Button

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

Key Actuated Control

Key Lock switch located on the front panel, which requires a key to be inserted and turned clockwise to the 3 o'clock position in order to provide power to the cabinet system. The key is captive in the "ON" position.

Emergency Stop Button

The Emergency Stop button on the Faxitron Core front panel is available to terminate the generation of X-rays. This is in addition to the safety interlocks on the system drawer.

X-ray Generation Indicators

The Faxitron Core has an X-ray On indicator light on the front panel and graphical user interface, and also produces an audible tone when generating x-rays.

Software Access – Optional Password

The user has the option to implement a "Password" requirement to open Vision software. When this option is on the correct "*user defined password*" must be entered to open Vision software. If the correct password is not entered the software closes.

X-Ray Control System

The X-Ray control system consists of the system electronics, Interlock Switches, X-ray On Button, Emergency Stop Button, and the system Imaging Software (Vision).

The Faxitron Core system is fully dependent on the software for image acquisition/X-ray generation.

3.2.0 Compliance Requirements and Safety Measures

3.3.0 X-Ray Control System

The software and controller board firmware monitor system conditions to determine:

- 1) If Image Acquisition is allowed
- 2) the acquisition parameters (energy level and duration)
- 3) If Image Acquisition should be aborted
- 4) what, if any messages are to be displayed
- 5) The appropriate indicators to activate.

The following condition must be present for Image Acquisition/X-ray generation to occur:

- 1) Vision software must be open
- 2) System must be armed – patient data entered
- 3) Interlock Switches must be closed
- 4) Controller board communicating with System Software (Vision)
- 5) Digital Imager communicating with System Software
- 6) X-ray On button pressed

If the above conditions are met: The software determines the image acquisition parameters, (energy level and duration), and the software sends these parameters to the controller board. The controller processes the signal and routes it to the HVPS (High Voltage Power Supply). If the High Voltage circuit is active, the HVPS generates High Voltage which is sent to the X-Ray Tube – X-rays are generated. Indicators and messages are activated to inform the user that Image Acquisition/X-ray generation is in progress.

If at any time during Image Acquisition an interlock is open the acquisition will be terminated and the appropriate indications and messages will be displayed.

Shielding

The Faxitron Core system is designed to generate ionizing radiation energies at or below 30keV.

The stainless steel used in the manufacturer of the Faxitron Core X-Ray chamber is a high-Z material that effectively absorbs almost 100% of the ionizing radiation at this energy level.

No additional shielding is required.

Attenuation

The primary beam from the Faxitron Core X-ray tube is directed towards the floor of the system. Any reflected or scattered beams will be absorbed by the X-ray chamber top, walls, and drawer front.

Typical background radiation measurements at the Hologic manufacturing facility are 0.1 μ Sv/hr (0.01mR/hr).

Dose measurements are taken at 30keV energy levels with a 6mm acrylic block in the primary beam path to represent maximum system energy levels and maximum beam scatter. Measurements at accessible surfaces are typically between 0.1 and 0.5 μ Sv/hour (0.01 and 0.05 mR/hr).

Hologic advocates following ALARA, As Low As Reasonably Achievable. Use energy levels no greater than necessary to perform the task. The use of AEC, Automatic Exposure Control, ensures that the lowest ionizing radiation energy levels possible will be generated to obtain optimum image quality. With AEC activated the system will take a short sample exposure at a predetermined energy level and duration. The software will evaluate the sample image and calculate best energy and time settings.

3.3.0 Cont.

3.4.0 Shielding and Attenuation

3.5.0 ALARA

4

SECTION 4
**Faxitron Core
Installation and Set-up**

REGULATORY REQUIREMENTS

It is the responsibility of the facility or institution operating this system to ensure that all local, regional, and federal regulations affecting the use of Ionizing Radiation Equipment are followed.

Warnings

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



General Precautions

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

- Never connect or disconnect communication and/or power cables, while the camera system power is on. Damage to the CMOS detector or the camera electronics may occur if the cables are connected/disconnected while the power is on.
- The camera system is fragile and care should be taken in order to prevent camera damage. The camera system must never be mishandled, hit, knocked or dropped.
- The Faxitron Core System has a calibration mode. Calibration must be completed daily to ensure proper system function. Refer to Sections 5 and 6 of this manual for the Calibration Procedure.
- Be sure the Specimen Drawer is fully closed before turning the unit off.
- Be sure the Specimen Drawer is clean and free of specimens and/or any residue before turning the unit off.



4.0.0 System Warnings & Precautions

Interoperable Connections

4.0.0 Cont.

The Faxitron Core system 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 interface is the network connection which allows the system to be connected to a Picture Archiving and Communication System (PACS). Images can then be transmitted from the device directly to the facilities network via our software in a DICOM format. See Section 6 for details on DICOM version. Only Hologic employees or trained IT personnel at the user facility should set up this communication.

The system's connections and their intended use are listed below. No other type of devices should be connected to the Faxitron Core system 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

Cybersecurity

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



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

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

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

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

The unit comes with a physical key that powers on the X-Ray system. This allows the system to be locked out so even if the software is accessed no x-rays can be initiated.

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

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

Additional security measures, including encryption, can be implemented and Hologic can work with the facilities IT department to reduce the risk to patients as a result of a cybersecurity breach.

Cybersecurity Events

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

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

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

Cleaning

Internal Chamber

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

The only part of the x-ray chamber accessible for cleaning is the sample drawer. You may gently wipe down the sample drawer with a soft lint free cloth moistened with 70-90% isopropyl alcohol or diluted sodium hypochlorite (5-25%-6.15% household bleach diluted 1:500 provides the proper concentration.)

- Do not use abrasives or harsh solvents.
- Do not scrub the recessed image area of the drawer as this may scratch the surface and create image artifacts.
- Test cleaning agents on small inconspicuous areas of the drawer to verify they will not damage the material

External

Periodically wipe down the exterior surfaces with isopropyl alcohol, sodium hypochlorite, or mild soap and water. (See above for appropriate concentrations.) Do not drench or flood surfaces and do not use abrasives which may scratch surfaces. Do not allow any moisture to contact any of the systems electrical components. Test cleaning agents on a small inconspicuous area of the covers to verify they will not damage the material.

4.0.0 Cont.



System Setup

The Faxitron Core should be set up by a Hologic Inc. authorized representative.

Inspecting the Boxes

The Faxitron Core System arrives in one (1) cardboard box. The box contains the Faxitron Core X-Ray Cabinet, the computer, the monitor, power cord, video cable, cables, cords, documentation, X-Ray Cabinet keys, and 25 sample trays.

Have the shipping agent transport the box to an area where they can be kept safe from theft, damage, or environmental extremes until the Hologic Inc. authorized representative can install the system.

Check the box for damage. If any damage is noted, contact Hologic at 1-800-447-1856.

Lifting and Transporting the Boxes

Caution: The box weighs approximately 80 pounds (36.3 kg). The box should be kept upright as indicated by the labels. Use caution when moving to prevent injury and damage to the system.



Unpacking and Setting up the System

The Faxitron Core system is to be unpacked and set up on site by a Hologic Inc. authorized representative.

Location

Leave at least 6" (15cm) of clear space behind the cabinet when installed to allow proper ventilation and access to the power cord and cables.

Environmental Conditions

Operational:

Temperature: 15.5 to 30 degrees C or 60 to 86 degrees F.

Relative humidity: < 75 percent.

Storage and transport:

Temperature: -20 to 50 degrees C or -4 to 122 degrees F.

Relative humidity: < 75 percent.

The equipment is designed for the following conditions:

- Indoor use,
- Altitude to 2000 meters (6562 feet),
- Pollution Degree 2,
- Over-voltage Category II

4.1.0

Faxitron Core Specimen System Setup

POWER REQUIREMENTS: 120 VAC 60 Hz 150W Max OR 240VAC 50 Hz 150W Max

HEAT OUTPUT: 500 BTU/hr Max

X-RAY DUTY CYCLE: 50%

RADIATION SAFETY: Refer to Section 2 of this manual.

4.1.0 Cont.

The Faxitron Core was designed as a stationary system to be set up on a desktop, countertop, or table.

Moving the Faxitron Core System - Not Recommended.

Once placed at its final location it is **recommended the Faxitron Core System not be moved.**

The Faxitron Core System is not designed to be a portable unit. Currently there is no cart provided, so the computer system will be placed on a non-portable surface as well.

Caution: The Faxitron Core X-Ray Cabinet weighs approximately 40 lbs (18 kg) and is not designed to be lifted and carried. It is a precision instrument that needs to be handled appropriately. Do not try to lift or carry the system.

Please do not block the area behind or immediately in front of the unit as this open space is needed for ventilation of the system and PC. There is adequate ventilation in the rear of the system as long as no objects are placed between the unit and the wall that contains the system's power receptacle.

Ensure that there is a flat, level surface free of hazards in front of the system to enable personnel to safely access the specimen door, computer keyboard, monitor, and system control panel.

Note: Allow enough space beside the system to easily access the system power cord.

Caution: If you must move the Faxitron Core System:

- Ensure all components are fully powered down
- Disconnect the power cords from the power receptacle
- Disconnect all interconnecting cords and cables (i.e. Fiber optic cable)
- Use care when moving the Faxitron Core X-Ray cabinet.

Warning: The Faxitron Core System power cord is supplied with a grounded plug. If a suitable receptacle matching the system power cord plug is not available, enlist the services of qualified personnel to provide a suitable electrical receptacle. Do not attempt to modify the plug or receptacle yourself.

Warning: To avoid damage to the unit and/or contact with infectious tissues, ensure that the Faxitron Core is thoroughly cleaned and properly packaged prior to removal from use for servicing, transportation, or disposal.

4.2.0 Moving the Faxitron Core Specimen System



5

SECTION 5

Quick Start and Basic Operation of the Faxitron Core System

Before powering up the system, please make sure that the power cords are securely plugged into the Faxitron Core cabinet, computer, and monitor before plugging the cords into the facilities mains power receptacles. Also, if needed plug a Cat5 or Cat6 network cable into the Faxitron Core computer and facilities network connection.

Refer to Section 4, Installation and Set-up, of this manual, and the Quick Set-up and Quick Start Guides provided with your Faxitron Core system.

5.0.0 Quick Start Overview

Figure 5.0.1
Faxitron Core Front Panel



Basic Imaging Procedures

Warning: Use of the Faxitron Core in a manner other than that described in this manual may result in impaired operation of the equipment or personal injury.

Warning: Use approved containers or gloves in order to avoid contact with potentially hazardous patient tissue samples.



Imaging Sequence Summary

Refer to the Faxitron Core Quick Start Guide for a summary of system operation.

- Open specimen drawer (press the **black** button).
- Place the specimen(s) in a specimen container provided by Hologic, Inc. or your institution and place it inside the Faxitron Core drawer.
- Close the specimen drawer (press the **black** button).
- Choose or enter a patient in the Vision software and start an image acquisition from the software.
- Press the **Start** (green) button on the Faxitron Core control panel or in the software. This will begin the X-ray exposure.
- Wait until image is displayed.
- Use the mouse to move the cursor over the displayed image and move cursor up and down for brightness/darkness levels or left and right for low/high contrast. Move cursor until image is at desired level.
- Repeat process for additional specimens.

See Section 5.2 for more detailed operating instructions.

See User's Manual Section 6 for Advance Software Operation.

General Start-up Information

Power-Up (starting the system) is completed one-time at the start of system usage. It is recommended that once the Power-Up sequence has been performed; leave the system ON the rest of the day if planning to use it again.

System Start-up Sequence Protocol

Power Up System

- Turn the computer and monitor “ON” and allow to fully boot into Windows.
- Set the power switch on the back of the Faxitron Core cabinet to the “ON” position. See Figure 5.1.1.
- Turn the key on the front of the Faxitron Core cabinet to “ON” (clockwise to the three o’clock position). See Figure 5.1.2.
- Verify there is nothing in the Faxitron Core sample drawer.

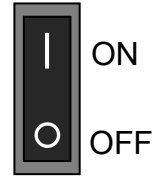


Figure 5.1.1
Main Power Switch



Figure 5.1.2
Key Switch

Start Software

- “Double Click” the **Vision** Icon on the Windows desktop.
- A Dialog box will appear briefly to indicate the software has initialized and is loading.
- The software will open to the “Home Menu” or “Calibration” screen, depending on elapsed time since completion of the last calibration.



Figure 5.1.3
VISION Desktop Icon

The software will open to the Home Menu if a calibration has been completed within the last 12 hours.

To ensure optimum image quality Hologic recommends calibrating the system upon initial start-up each day or if the system has been moved.

To manually start a calibration, click on the **Calibrate** button in the Home Menu, and then click on the **Start Calibration** button. The software will return to the Home Menu when calibration is complete. See Figures 5.1.4 and 5.1.5.

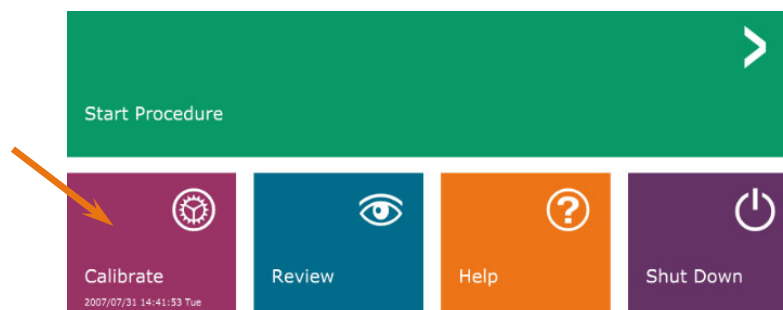


Figure 5.1.4
Start Calibration Button

Calibrate

NOTE: For optimum image quality it is recommended that the system be calibrated at least once a day, prior to first use.

- The software will open to the Calibration screen if it has been 12 hours since the last calibration.
- Press the **Start Calibration** button and allow the system to complete the calibration.

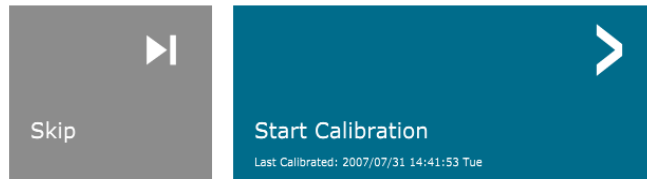


Figure 5.1.5
Start Calibration Button

ENSURE THE CHAMBER IS EMPTY BEFORE CALIBRATION

Calibration before beginning any procedure is recommended

- The Calibration Dialog box will open showing the calibration progress.



Figure 5.1.6
X-Ray Calibration Dialog Box

- The Dialog box will close when the calibration is complete. The software will go to the Home Menu page.

Starting an Imaging Procedure

- From the Home Menu page (See Figure 5.1.4) select the **Start Procedure** Button.
- The user will be given options to **Select from Worklist**, **Manual Entry**, **Select from Database** or **Continue with current patient**. See Figure 5.2.1.

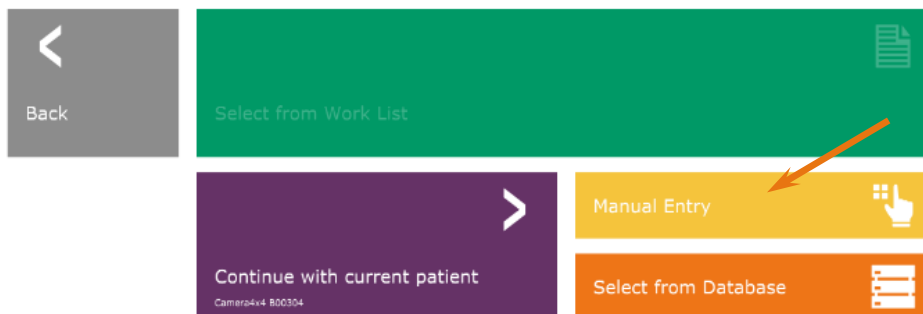


Figure 5.2.1
Patient Data Entry buttons

5.2.0 Image Acquisition

- To manually enter a new procedure, select the **Manual Entry** button.

NOTE: This section only covers “Manual Entry” of patient data, the remaining options are covered in Section 6 of this manual.

- The "Patient Information Editor" dialog box will open.

5.2.1 Entering Patient Data Manually

Figure 5.2.2
Imaging Information Editor

The screenshot shows a mobile application interface for entering patient data. The form is titled "Patient Information" and is organized into three main sections: "Patient Information", "Procedure Information", and "Study Information".

- Patient Information:** Includes fields for Patient Name (Jane Doe), Patient ID (JD12), Accession # (123456789), Date of Birth (1920/03/16), and Sex (dropdown menu). Asterisks (*) indicate required fields.
- Procedure Information:** Includes fields for Procedure Name (dropdown), Laterality (L), Position View (dropdown), Body Part (dropdown), Refer. Physician (text), Technician (text), and Technician ID (text). Asterisks (*) indicate required fields.
- Study Information:** Includes fields for Study Name (text) and Study ID (text).

At the bottom of the form, there is a blue "Accept" button with a right-pointing arrow. Below that is a grey button with a left-pointing arrow and the text "Start a New Patient or Procedure".

Note: Required Fields are indicated by a white asterisk (*). Default required fields are: Patient Name, Patient ID, Accession Number, and Laterality.

- Enter all required fields. The **Accept** button will not be active if any required field is missing. The user may complete other fields as desired.

Note: The Date must be entered as yyyy/mm/dd (e.g. 1962/08/13).

- Select **Accept** to enable image acquisition.
- The system is ready to acquire images.

Taking an Image/Starting X-Ray Exposure

To take an X-Ray image with the Faxitron Core system:

- Open the X-Ray Chamber drawer by pushing the **black** button and place the Faxitron Core tray with the specimens in the drawer. Close the drawer by pressing the **black** button again.
- Press the Green **Start X-Ray** button on the control panel or software.
- Wait for the image to be displayed.

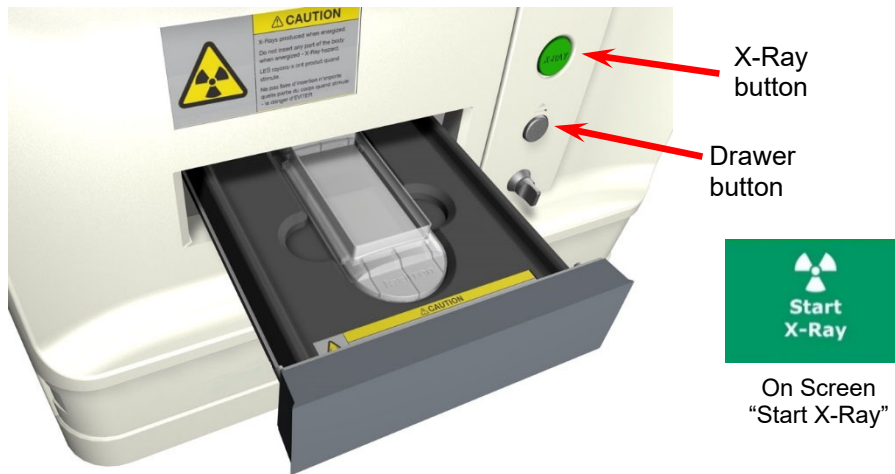


Figure 5.2.3
Faxitron Core Drawer

NOTE: Default X-ray mode for the Faxitron Core is Full Auto. The system will take two x-rays; the first to work out optimal settings and the second to take the image. The settings used during the exposures will be displayed on the cabinets LCD.

The Vision software is configured to automatically save the image to the Faxitron database on the system computer's local drive. The user can also save the image to the facilities server by clicking on the "PACS" icon. See Sections 6.4.1, 6.6.0 and 6.7.0 for more information on saving images.

For more information on adjusting the image settings, X-ray controls, and reviewing and saving options, see Section 6.

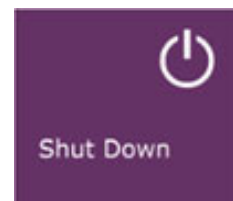
Exit VISION Software

Click on the **Shut Down** button, and then click **OK**" This will turn off the computer. Shut down can be selected on the home screen or image acquisition screen using the buttons shown below.

Shut Down button from Acquisition screen.



Shut Down button from the Home Menu.



5.2.3 Shutting Down the System

Figures 5.3.1 and 5.3.2
Shutdown System and Exit
Program buttons

Turn Off the Faxitron Core X-Ray Cabinet

Once the computer is off, turn the key switch Off (key to vertical position).

6

SECTION 6
**Vision Software
Operation**

Vision Software is a complete image acquisition and processing package, designed exclusively to work with Hologic X-Ray Generators (such as VersaVision, Faxitron Path, Faxitron Core and Faxitron OR Systems.) In addition to the acquisition and processing functions, the software offers an extensive database module, which allows user control, maintenance of image archiving, storage, filing and retrieval. The software is also Digital Imaging and Communications in Medicine (DICOM) compliant, allowing saving and printing of Patient images in DICOM format 3.0. The software has been pre-installed on the computer that was packaged with your x-ray system.

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

After calibration, the Home Menu will be displayed, which allows navigation to all other areas of the software. For ease of use, application buttons are provided. See Figure 6.0.1. These buttons are in the center of the screen. Button descriptions and definitions are outlined, in the following sections of this manual.

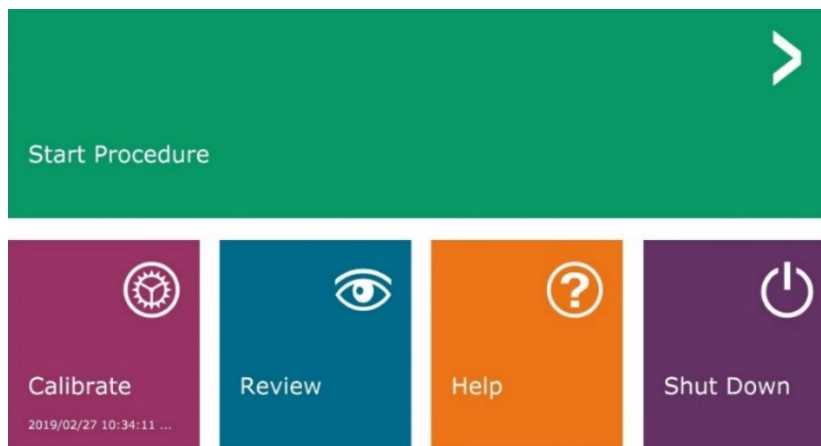


Figure 6.0.1
Vision Software
Home Menu (Start-up Screen)

Sequence Protocol

This start-up sequence must be followed to ensure proper system functionality and image quality:

- Turn the Faxitron Core Cabinet power on using the switch on the back of the cabinet. (The power switch is next to the power cord receptacle). Depress “1” for “Power ON” and “0” for “Power OFF”.
- Turn the Faxitron Core System “ON” by inserting the Faxitron Core key into the key lock switch, located on the front panel, and turning it clockwise to the 3 o’clock position. Note: the key cannot be removed in this position.
- Turn on the computer and monitor.
- Double click the left mouse button on the **Vision Software** icon (located on the Windows desktop) if Vision does not automatically start. See Figure 6.1.1. A dialog box will briefly appear to indicate the software has initialized and is loading.
- Vision software will open to the Home Menu (see Figure 6.0.1) or the Calibration page (see Figure 6.2.2) depending on elapsed time since the last system Calibration.
- Refer to Section 6.2.0 “Camera Calibration Overview” for calibration protocols.



6.1.0 Software Start-up



Figure 6.1.1
Vision Software Desktop Icon

Calibration Introduction

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

Upon initial start-up of the system, or at any time desired by the user, a system calibration may be requested and performed. It is recommended that after an elapsed time of twelve (12) hours, the following calibrations be performed.

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 corrections.

Calibration Sequence

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

When a Hologic X-Ray System has been turned off for longer than twelve (12) hours, the system will automatically request to re-calibrate. It is highly recommended that the system be re-calibrated, after extended periods of inactivity, or after the system is moved from one room to another room, with potentially different ambient temperature/humidity settings.

To calibrate the system at any time, click the **Calibrate** button on the Vision Home Menu (Start-up Screen) and then press **Start Calibration**. See Figures 6.2.1 & 6.2.2. The Dialog will display a status message during calibration. See Figure 6.2.3.

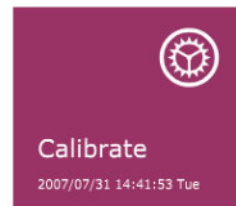


Figure 6.2.1
Home Menu calibrate button

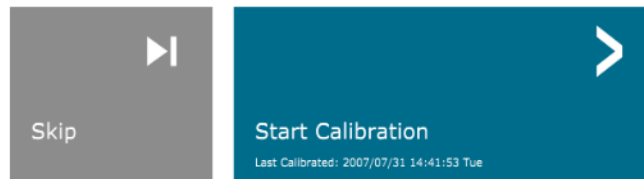


Figure 6.2.2
Start Calibration button

ENSURE THE CHAMBER IS EMPTY BEFORE CALIBRATION

Calibration before beginning any procedure is recommended




Figure 6.2.3
Calibration Status

During calibration, X-Rays may be generated. During X-Ray generation, a **Stop X-Ray** button will be made visible, to allow a user the option to stop X-Ray, through software.

The following is a summary of the advanced calibration protocol, for "Both" (Flat Field and Image):

Place the uniform attenuator on the detector. The entire detector surface should be covered by the attenuator. For ideal results, the attenuator should be larger than the detector's imaging area.

From the Home Menu of the imaging software, press the top-right  icon to bring the menu into focus. Select the drop-down menu item "Tools", in the horizontal menu, located at the top of the screen, and then proceed to "Advanced Tools", then to "X-Ray Calibration/Exposure Setup".

6.2.0 Cont.

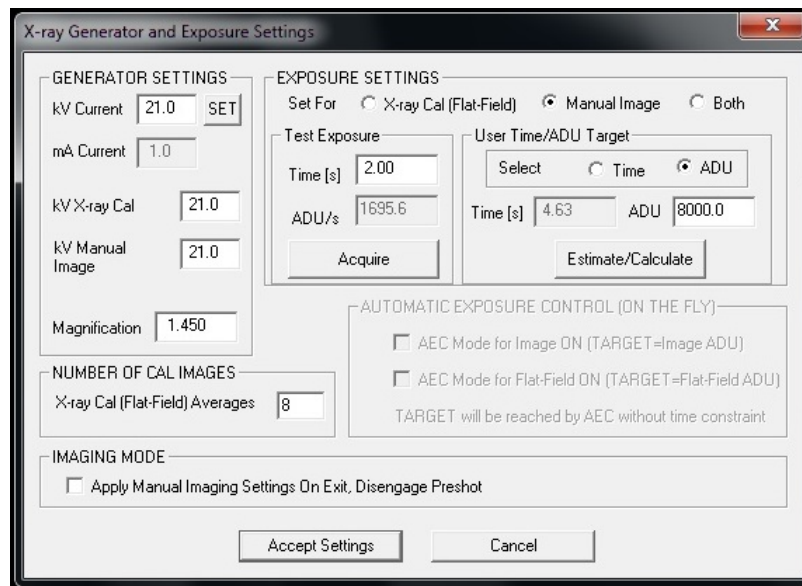


Figure 6.2.4
X-Ray Generator and Exposure
Dialog Box

NOTE: The kV, Exposure Time, and ADU/s values may vary from those shown.

- Under "X-Ray Generator and Exposure Settings", enter the generator kV setting, in the appropriate field.
- Leave "Magnification" at the default setting of 1.450. (The magnification is fixed in the Faxitron Core system)
- Select the "Set for" "Both" button in the dialog box.
- Leave the default "user ADU target" setting. X-Ray exposure will be terminated when the detector has accumulated a mean signal level of ADUs that are acceptable for the X-Ray generator you have.
- Leave the default test exposure time and click on the **Acquire** button. The system will automatically begin X-Rays and obtain an image.
- When the X-Ray exposure is complete, click on the **Estimate/Calculate** button.
- Record the calculated exposure time "Time [s]" reading. The system calculates this time, and the number is greyed out.
- Enter the calculated exposure time reading "Time [s]" in the "Test Exposure" time box. Press the **Acquire** button to automatically begin X-Rays and obtain an image.
- When the X-Ray exposure is complete, click on the **Estimate/Calculate** button.
- Record the calculated exposure time "Time [s]" reading.
- Enter the calculated exposure time reading in the "Test Exposure" time box once again.

- Click on the **Accept Settings** button.
- Perform a standard calibration procedure, as described in the "Camera Calibration Overview" section.

Experienced users may wish to set the "X-Ray Cal (Flat-Field)" and "Manual Image" "Exposure Settings" independently, or "Both" (Flat-Field and Manual Image), as previously described. By selecting the "Flat Field" radio button, the system will determine the optimum exposure time, for acquiring Flat Field images, at the desired ADU level. Accordingly, the selection of "Manual Image" will determine the optimum exposure time, for the system with an object, which will attenuate the X-Ray signal. For best results, the entire imaging area of the detector must be covered, by the object.

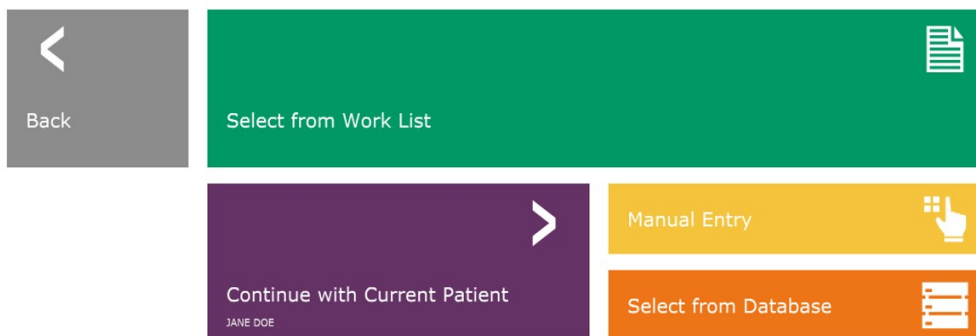
After the selection of either "X-Ray Cal (Flat-Field)" and "Manual Image", the ADU level has been set; select the **Acquire** button. For the "Manual Image" selection, it is desired to have the object or X-Ray attenuator, in the X-Ray beam. Press the **Acquire** button to generate X-Rays and obtain an image. When X-Ray exposure is complete, click on the **Estimate/Calculate** button. The system calculates optimum 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 the "Camera Calibration Overview" section.

Occasionally it may be desirable to incorporate the X-Ray attenuation characteristics, of a uniform attenuator in the flat-field reference calibration images. For example, if all objects to be imaged are placed on a thin plastic plate, X-Ray attenuation characteristics of the plate will be observed, in every image acquired. In this case, placing the plate in the X-Ray beam, during flat-field reference calibration image acquisition, could improve image quality.

The **Start Procedure** button (See Figure 6.0.1) takes the user to the Patient Data Entry page, which provides methods to enter patient data. If a Work List has not been configured, the option will be greyed out and only the **Continue with Current Patient, Manual Entry**, and **Select from Database** options will be accessible. The options are explained in the next sections.



6.2.0 Cont.

6.2.1 Advanced Calibration

6.3.0 Patient Data

Figure 6.3.1
Patient Data Entry screen

Select from Work List (Remote Modality Work List)

If a Work List has been configured the user can click on the **Select from Work List** button which will display the page shown in Figure 6.3.2.

6.3.1 Select from Work List

Figure 6.3.2
Modality Worklist Search Dialog

Worklist

Patient ID	Accession #	Patient Name	Birth Date	Sex	Modality	Re
AV35671	00001	KRISTY**KAITLYN	1678/03/04	F	MG	SP
AV35672	00002	GARCIA**MARIA	1678/03/04	F	MG	NE
AV35673	00003	SMITH**MARY	1678/03/04	F	MG	FA
AV35674	00004	HOUSTON**CARLA	1732/04/31	F	MG	MI
AV35675	00005	DOE**JANE	1678/03/04	M	MG	FA

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

On the left are various filters, which may be used to search for scheduled procedures for the Station Application Entity (AE). Verify that the station AE Title is defined, then any single field or any combination of fields may be used as a filter to search for scheduled procedures, for this AE. By selecting the **Query** button, located in the bottom left corner, the table is re-populated with the entries, that match the queried information.

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

NOTICE: The user may also double click any entry, within the table, to quickly go into the Imaging Information Editor without having to press **Submit**.

The Imaging Information Editor (Patient Information Dialog) will open. See Figure 6.3.3. Complete remaining required fields and click on **Accept** to proceed to image acquisition.

Note: Required Fields are indicated by a white asterisk (*). Default required fields are: Patient Name, Patient ID, Accession Number, and Laterality.

The user must enter all required fields, prior to being able to select the **Accept** button. The user may also enter a Date, Referring Physician, Procedure Name, Sex, Technician, Position View, Body Part, and Study ID, if so desired. The Procedure Name, Position View and Body Part are chosen by a drop-down menu.

Note: The Date must be entered in the format: yyyy/mm/dd (e.g. 1962/08/13). Failure to enter a valid date may cause errors when attempting to retrieve images.

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

Select **Accept** to continue or **Start a New Patient or Procedure**, to return to the Patient Data Entry page.

6.3.1 Cont.

Figure 6.3.3
Imaging Information Editor

Continue with Current Patient

Click on this button to **continue the current** patient procedure. The "Image Information Editor" will open. See Figure 6.3.3. Follow the above procedure and notes.

6.3.2 Continue with Current Patient

Manual Entry

Click on this button to **manually** enter a new Procedure. The "Imaging Information Editor" will open. See Figure 6.3.3. Follow the above procedure and notes.

6.3.3 Manual Entry

Select from Database

Choosing the **Select from Database** button will display the following page. See *Figure 6.3.4 below*.

Database

Patient ID	Last Name	First Name	Middle Name	Time Modified	Date of Birth
DJ9856	DOE	JENNIFER		2019/03/22 12:4...	1935/05/0
JD4587	DOE	JANE		2019/03/22 12:5...	1920/03/0
JD56	DOE	JAN		2019/03/22 12:4...	1932/02/1

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

6.3.4 Select from Database

Figure 6.3.4
Selecting Patient From Local Database Entries

The user selects a patient from the table on the right side of the page and then clicks on the **Accept** button which opens the Image Information Editor. (**Note:** The user may also double click the entry in the table to open the Image Information Editor.) Then follow the procedure and notes on page 6-7.

Note: Use the scroll bar at the bottom of the screen to view hidden patient information.

Vision allows the user to narrow the patient list by entering specific information in the “Search Parameters” window on the left side of the page. Only those patients matching all search parameters will be displayed.

If the user wishes to change or view the information after it has been input, but before an image has been taken, they may click on the **Patient Data** icon in the top left corner of the screen. See Figure 6.3.5.



6.3.5 Patient Data Icon

Figure 6.3.5
Patient Data Icon

The Patient/Imaging Information Editing window will open. This editing window will be populated with all the information that was previously entered/selected. See Figure 6.3.6. Note: The Editing window will now include a **Cancel** button.

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

- The **Accept** button to save the changes and continue to image acquisition,
- The **Cancel** button to cancel changes and continue to image acquisition. The software will revert to the original patient information entered, or
- The **Start a New Patient or Procedure** button which will return the user to the Patient Data Entry Screen. See Figure 6.3.1.

Figure 6.3.6
Imaging Information Editor

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

X-rays are started by pressing the green **Start** button on the front of the Faxitron Core cabinet or clicking on the **Start X-Ray** button in the lower right corner of the screen. See Section 5.2.2, *Starting Exposure*. The system will take a short “sample” x-ray, or pre-shot (which is explained in Section 6.4.4) 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 throughout this section*, will be enabled.

The user may view, but not edit, the patient information after acquiring an image by clicking on the Patient Data icon shown in Figure 6.3.5. This will display a modified Patient Information dialog box as shown in Figure 6.3.7. This box provides two buttons: Close Dialog or Start a New Patient or Procedure. The user may view, but not edit, the patient information after acquiring an image by clicking on the Patient Data icon shown in Figure 6.3.4. This will display a modified Patient Information dialog box as shown in Figure 6.3.7. This box provides two buttons: “Close Dialog” or “Start a New Patient or Procedure”.

Patient Information

Patient Name: * Jane Doe

Patient ID: * JD4587

Accession #: * 918273

Date of Birth: 1920/03/20

Sex: [Dropdown]

Procedure Information

Procedure Name: [Dropdown]

Laterality: * L [Dropdown]

Position View: [Dropdown]

Body Part: [Dropdown]

Refer. Physician: [Text]

Technician: [Text]

Technician ID: [Text]

Study Information

Study Name: [Text]

Study ID: [Text]

Close Dialog >

< Start a New Patient or Procedure

6.3.5 Cont.

Figure 6.3.7
Patient Information Dialog after Image Acquisition



Figure 6.3.8
Image Properties dialog

Once an image is taken, the current image properties can be viewed by pressing the (i) icon in the top-right corner. See Figure 6.3.8. The Image Properties Dialog box will be displayed in the top-right corner of the image. The box is semi-transparent to allow one to see what’s underneath the box. See Figure 6.3.9.

1.450X 2019/02/27 10:45:43 Wednesday

Dosage: 21.0 kV, 1.00 mA, 4.29 mAs, 4.29s, 0.33s, 0.00s

File Name: I20190227104543.dcm

Archived: [Status]

Folder: C:\Faxitron\Data\

Institution: Faxitron Bioptics, LLC

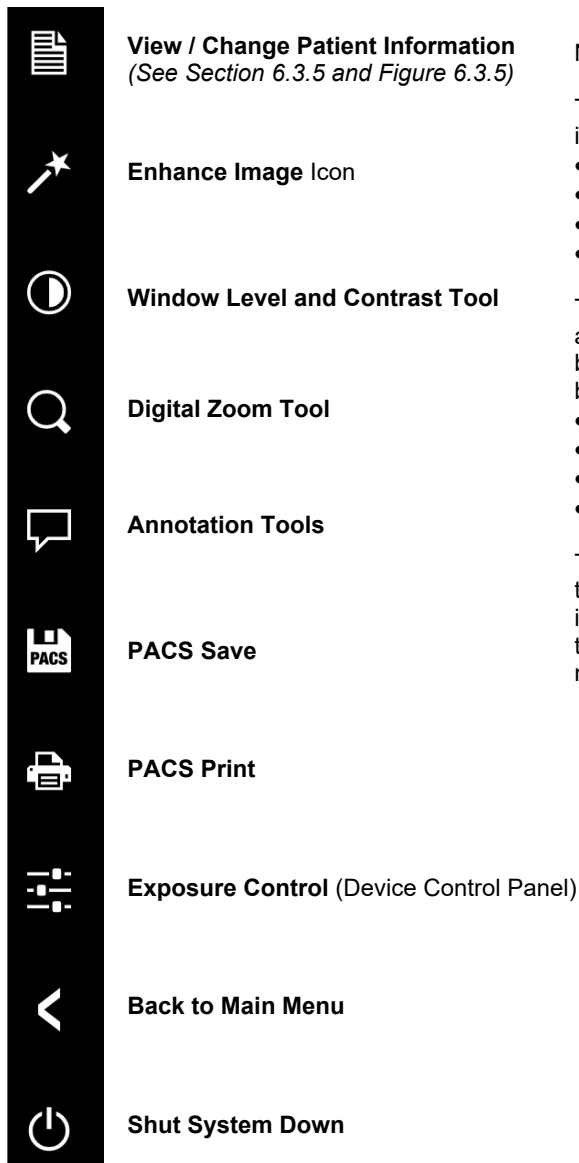
Figure 6.3.9
Image Properties (View Only)

Vision 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 most commonly used tools are in a Tool Bar. The Tool Bar and Menus are described in more detail in the following pages.

6.4.0 Tool Bar and Menus

Vision software provides single click access to a number a 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 6.4.1.

6.4.1 Side Tool Bar



NOTES:

The following tools are always active in the image acquisition page:

- View/Change Patient Information
- Exposure Control,
- Back to Main Menu, and
- Shut System Down

The following tools will be disabled after patient data entry and will only be enabled after an x-ray image has been acquired:

- Enhance Image,
- Window Level and Contrast,
- Digital Zoom, and
- Annotation

The PACS Save and PACS Print tools are only enabled after an x-ray image has been acquired and when the system is connected to a PACS network.

Figure 6.4.1
Side Tool Bar

Enhance Image

The button shown in Figure 6.4.2 will process the image on the display to emphasize the smaller details, such as micro-calcifications, and small masses in the image.



Figure 6.4.2
Image Enhancement icon

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 made, to bring out small details, in the image, and make them much easier to see, and analyze.

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

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

Inverting, Window Level and Contrast Adjustment

The button, shown in Figure 6.4.3, will open the Window Level and Contrast adjustment tool. This tool allows the user to adjust the image's window level and contrast. The user may also restore the Original Contrast by pressing the **Original Contrast** button, or invert the image, by pressing the **Invert** button. Inverting flips the color scheme, from being predominantly black, to being predominantly white, or vice versa. See Figure 6.4.4 below.

6.4.1 Cont.

The user may also adjust the slider bar for desired image contrast by clicking on the bar and moving it up and down, or by clicking on either of the indicator arrows on the bar, to move the lower or upper window level limits. See Figure 6.4.3 (Informally this is also known as "Window Leveling.").

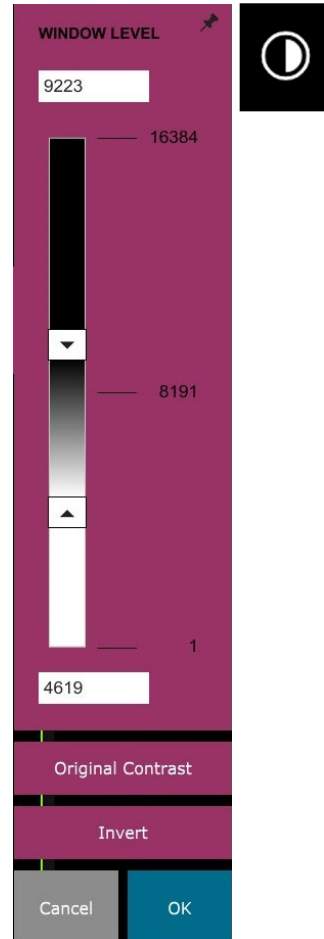
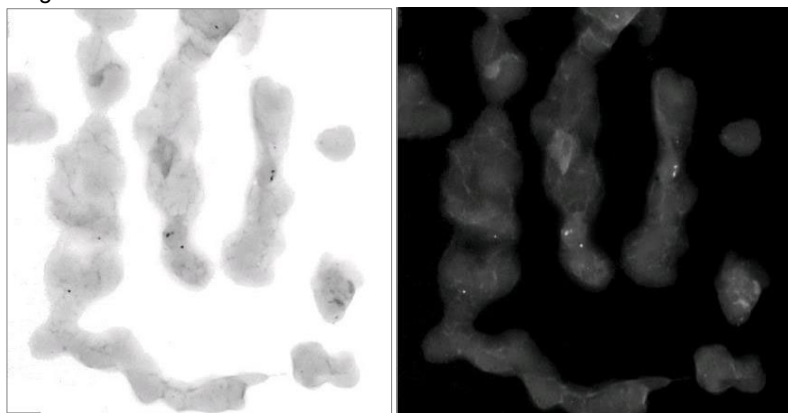


Figure 6.4.3
Window Level and Contrast Tool
Icon and Controls

An example of inverting is shown below:



Figures 6.4.4
Example of inverting with the
Window Level and Contrast tool

Dynamic Zoom Adjustment

6.4.1 Cont.

The **Zoom Tool** icon, *Figure 6.4.5*, will open the Zoom Adjustment tool. After opening this tool, the user may use the slider bar to adjust the zoom level or click the buttons to **Fit to Specimen**, **Fit to Screen**, or **Zoom 1.0x** (full resolution). See *Figure 6.4.6*. When the image has been zoomed in, panning is necessary to navigate around the image. A thumbnail dialog will appear in the top left corner of the screen. See *Figure 6.4.7* below. Click and hold the left button over the image and move the mouse to move the image around in the main screen.

Note that traditionally, this feature is also called "Pan View" and/or "Pan and Scan."



Figure 6.4.5
Zoom tool icon

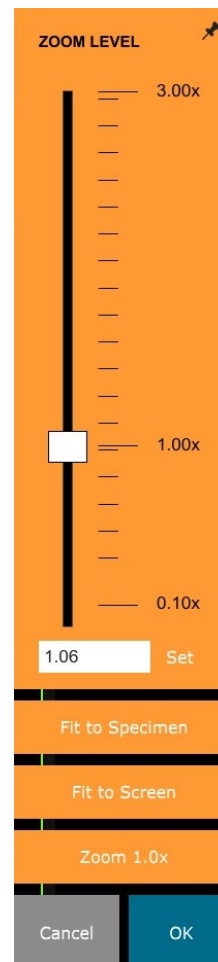
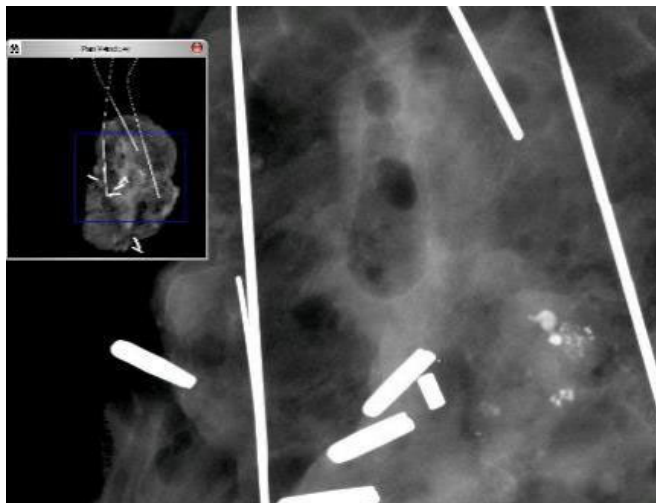


Figure 6.4.6
Zoom Level Adjustment tool

Figure 6.4.7
Pan View example (left)

The **Fit to Specimen** button will attempt to detect, and zoom in onto the specimen, to ensure that the specimen 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 is traditionally called "Full Resolution", as it brings the image to a 1-1 view, with the monitor resolution.

Annotations

The button shown in *Figure 6.4.8* will open the annotation tools. These tools and their many features are discussed in further detail in Section 6.8.0.



Figure 6.4.8
Annotations icon

PACS Store

The button shown in Figure 6.4.9 will only function when the system is installed in a medical facility with a PACS network. To save your files locally please refer to section 6.7.0.



6.4.1 Cont.

Figure 6.4.9
PACS Store icon

PACS Print

The button shown in Figure 6.4.10 will only function when the system is installed in a medical facility with a PACS network. For local printing please refer to section 6.7.0.



Figure 6.4.10
PACS Print icon

Device Control Panel

The button shown in Figure 6.4.11 will open the Device Control Panel, which allows the device user the convenience of controlling the X-Ray system through the software. The user can easily select the Exposure Mode, X-Ray Tube kV setting, Exposure Time, and the number of images to acquire for Image Averaging (if desired), and initiate the X-Ray exposure.



Figure 6.4.11
Device Control Panel Icon

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

Figure 6.4.12 to the right shows Full Manual mode has been selected and the kV, Time and Image Averages are all active. The user can adjust each of these settings.

Note that the mA setting in the Faxitron Core system is not adjustable via software and will always be inactive.

When finished click on the **Request X-Rays** button to acquire an image, or the **Set** button to save the settings and close the Device Control Panel.

If the **Cancel** button is clicked the Device Control Panel will close without saving any of the changes.

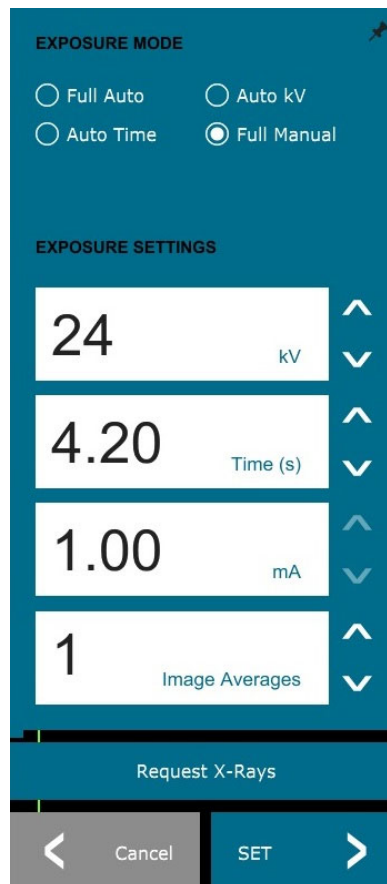


Figure 6.4.12
Device Control Panel

Back to Procedure

The button shown in Figure 6.4.13 exits the image acquisition mode and returns to the Home Menu screen.



6.4.1 Cont.

Figure 6.4.13
Back to Home Menu icon

Shutdown

The button, shown in Figure 6.4.14 will exit the software, and shut down the computer.



Figure 6.4.14
Shutdown System Icon

Additional dialog notes

When a dialog is opened, it is “docked” to the left side of the screen. If a user wishes to un-dock the dialog box, they may click the top-right “Pin” icon, to undock the dialog box, and be able to drag the box freely. The “pin” then turns into a “X” icon, allowing for quick closing.

Users can also quickly navigate between the various dialogs by clicking through the left menu. By doing so, the left menu will quickly close, and open the applicable dialogs, as appropriate.

Top Menu Bar

The software provides access to “View”, “Tools”, “Image Tools”, “DICOM Utilities” and “Help” menus through a Top Menu Bar. See Figure 6.4.15. The Top Menu Bar is hidden by default and is displayed by clicking on the **Arrow** button in the top right corner of the screen. See Figure 6.4.16. The **Arrow** button will be black or white depending on the software page/screen background. Each menu item is covered in detail in the following pages.



6.4.2 Top Menu Bar

Note: The arrow will point down when the Top Menu Bar is hidden and will point up when it is display.

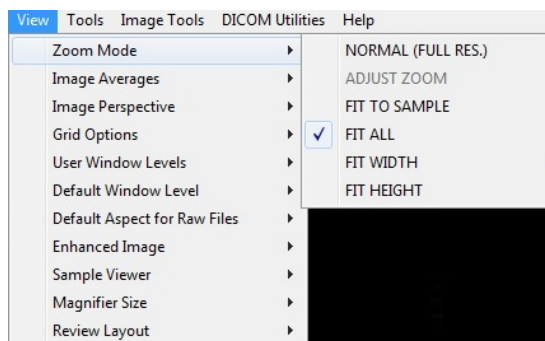


Figure 6.4.15
Top Menu Bar

Figure 6.4.16
Top Menu Bar buttons

View Menu

The “View” Menu is located in the top Main Menu and contains the sub-menu items shown in Figure 6.4.17 below. Each of these options will be described in more detail in the following pages.



6.4.3 View Menu

Figure 6.4.17
View Menu

Zoom Mode

6.4.3 Cont.

Normal

Displays the acquired image in its native format. The native format for the Faxitron Core image fits within the monitors display area. The user may zoom in on the image if desired. Refer to Dynamic Zoom Adjustment in Section 6.4.1.

Adjust Zoom

This option is greyed out and is 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.

Fit All

This option displays the entire acquired image, regardless of its native format. The Full Resolution option does not work in this view mode.

Fit Width

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

Fit Height

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 Shots. If the user selects 2, 4 or 8 shots the software will acquire the number of images selected back to back with a single push of the Start button and average those images into a single image.

Image Perspective

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

Grid Options

When an image is displayed, either as an acquired image or a retrieved image from the database, the user may activate a grid. Also allows the user to set grid spacing (pitch). See example below.

6.4.3 Cont.

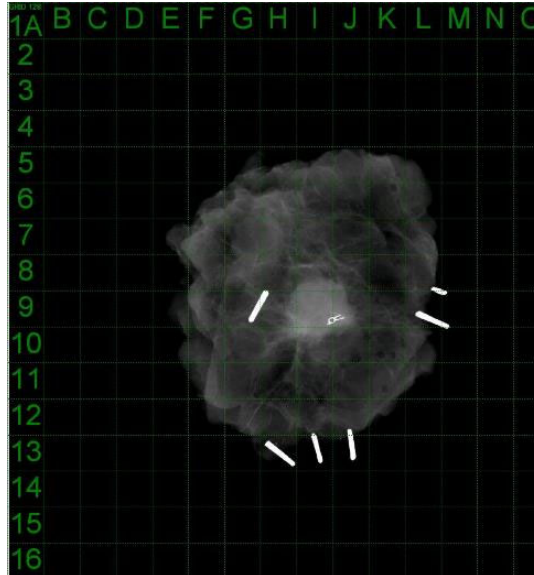


Figure 6.4.18
Sample grid display

User Window Levels

This allows the user to define up to three (3) pre-defined, user set Window Levels (WL). First select the **Window Level** button and adjust the WL to the desired level. From the “View” menu, select “User Window Levels”. Select “Record Current WL” as USER WL #1, #2 or #3. The adjusted WL will be saved under the choice previously selected.

Default Window Level

The user has two choices of “Default Window Levels” (WL). “Optimize for whole area”, which adjusts the WL for the entire image, or “Optimize for sample”, which adjusts the WL for under the sample area only. Additionally, there is an option to “Set Default Window Level”, which is used for all obtained images located here as well. This will set the default window level based off the image statistics and will need to be done for the un-enhanced and enhanced images separately.

Default Aspect of Raw Files

It helps importing/opening of previously saved image files with unknown file attributes or binary image data without any header information. Since exact imager array size is not available from header of image data file, a closest fitting imager dimensions will be used to import/open such images based on width being larger or smaller than height (default aspect information).

Enhance Image (same as the Enhance Image button)

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

Sample Viewer

Sample View toggles a webcam viewer to aid specimen alignment. A webcam cannot be added to the Faxitron Core system.

Magnifier Size

6.4.3 Cont.

Allows the user to select the size of the Magnifier tool (see the Image Tools menu). The options are “Small”, “Medium” and “Large”.

Review Layout

Helps user configure multiple image panes in the Review (Database) Mode of program. Available options are; “(1 X 1) Single”, “(2 X 1) Double H”, “(1 X 2) Double V”, “(1 + (2 X 1) Triple” and “(2 X 2) Quadruple” layout. During multiple pane operation, the user can click on desired pane/image once, to make it current selection, the current selected pane will get a green rectangular border around. The images in database list view, or database thumbnail view, will be opened into current selected pane, when double clicked on them. User can also open the images into desired panes directly from right click menu of the mentioned database views. After right click menu is activated the user can select from the panes listed under OPEN TO→ which will provide available panes, to open the image into (left, right, top, bottom etc).

Tools Menu

6.4.4 Tools Menu

The “Tools” menu is located in the Top Menu Bar, found in the upper left hand corner of the main screen.

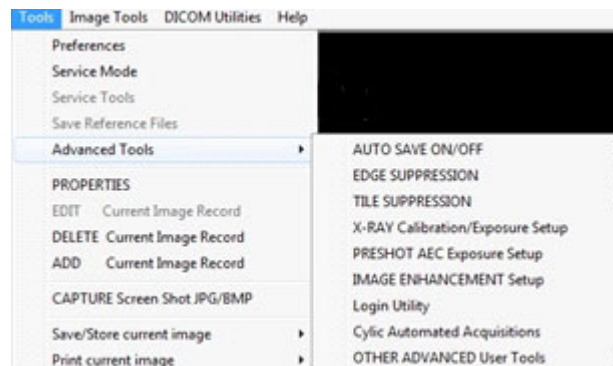


Figure 6.4.19
Tools menu

Preferences

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

NOTE: The “Preferences” tool option is password protected and should only be accessed by an authorized Hologic service representative.

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

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

6.4.4 Cont.

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

Advanced Tools Options

“*Advanced Tools*” offer various options to configure aspects of the software such as post-processing and configuration options.

Auto Save On/Off

When “*Auto save*” is “on” all subsequently acquired images are saved to the database. The files are written to a Data Directory defined in the configuration file.

X-Ray Calibration/Exposure Set-up

This is placed under *Advanced Tools*. The “*X-Ray Calibration/Exposure Setup*” aids the user in determining the proper exposure time for a selected kV setting for best image quality. Please refer to section 6.2.0 and Figure 6.2.4 for a more detailed description.

Preshot AEC Exposure Setup

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

“*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 Exposure Setup*” dialog go to the Top Menu Bar, select “*Tools*”, “*Advanced Tools*” then “*PRESHOT AEC Exposure Setup*”. See Figure 6.4.19. The Preshot AEC Settings dialog box shown in Figure 6.4.20 will open.

Enter the PRESHOT AEC values in the window shown at right.

The settings shown reflect a 23 kV and 2 second exposure time with a target intensity of 8000 ADUs for the pre-shot setting. Users can enter pre-shot parameters only when DYNAMIC METHOD (in the PRESHOT ANALYSIS METHOD section) is selected. The STATIC METHOD selection will use Hologic predefined parameters. In addition, the user has the option of selecting the kV, and exposure time settings, from the EXPOSURE TUNING METHOD section.

For more accurate images the user can enter the SOFT TISSUE (Sample) thickness and the TARGET INTENSITY in ADUs.

Note: The values shown are within the typical range for a Faxitron Core system but may vary.

For the AUTOMATIC EXPOSURE CONTROL mode, push the **Start** button, within the Vision software (or on the Control Panel). The Vision software will perform a

pre-shot (a short, low dose, pre-exposure) of the sample to create a Region of Interest (ROI) for obtaining the exposure parameters for the optimum image exposure.

6.4.4 Cont.

Figure 6.4.20
Preshot AEC Exposure Setup

Login Utility

The Login Utility is under the “Advanced Tools” menu and allows the user to configure and activate the start-up password authentication for Vision software. Activation of this feature is optional on the Faxitron Core system. If the user activates 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.

Figure 6.4.21
Login Utility

Properties

6.4.4 Cont.

"*Properties*" hides or shows the Image Information Box. See Figure 6.3.9.

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

By selecting this menu choice, the user can do a screen capture of the displayed active window. The user can specify a file name and choose between JPG and BMP as the saved file format.

Save / Store Current Image

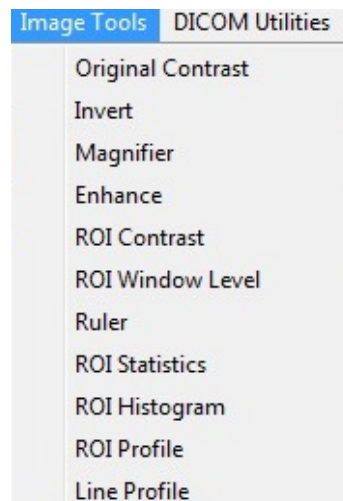
The user may "browse" to the directory or file folder to which the image is to be saved. A file name must be assigned in the field provided. The user may save the image as a BMP, JPEG, TIF, RAW Data, or DICOM file type. To save the file in a DICOM format, please refer to the "DICOM Functionality" section.

Print Current Image

Prints current image to Windows printer.

Image Tools

The following features are available to edit the acquired or retrieved image by clicking on the "*Image Tools*" menu. See Figure 6.4.22. The sub-menu options are activated or accessed with a single mouse click on the desired option.



6.4.5 Image Tools

Figure 6.4.22
Image Tools Menu

Original Contrast

6.4.5 Cont.

“*Original Contrast*” restores the image contrast levels. This serves the same purpose as the **Original Contrast** button in the Window Level and Contrast tool. See Section 6.4.1 and Figure 6.4.3.

Invert

“*Invert*” causes the displayed image to become inverted or reversed. Inverting an image reverses its transparency: what is black becomes white, and what is white becomes black. Greys are assigned their mirror transparency. Click “*Invert*” again to turn off the feature. Performs the same function as the **Invert** button. Refer to Section 6.4.1 and Figures 6.4.3 and 6.4.4.

Magnify

“*Magnify*” allows the user to magnify an area of interest. To use the Magnify feature place 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. Refer to Figure 6.4.23. The size of the magnified area of interest can be adjusted by the user. Refer to the “*Magnifier Size*” sub-menu in Section 6.4.3.

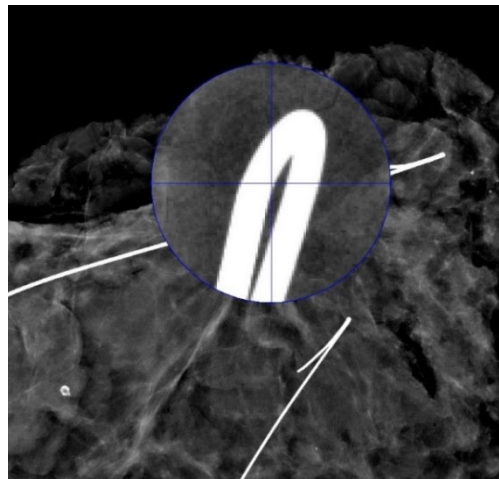


Figure 6.4.23
Magnify

Edge Enhance

“*Edge Enhance*” will create a sharper definition around edges of regions with a contrast difference. Edge Enhancement may amplify the noise in the images in general. Selecting the menu item again will turn off the 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 Sections 6.4.1 and 6.4.3.

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 the mouse, 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.

ROI Window Level

The “*ROI Window Level*” function is not available in the current version of Vision software.

Ruler

“Ruler” allows the user to measure the distance between two points in the displayed image. Length measurements are in millimetres (mm). After selecting “Ruler” click and hold the left mouse button, starting at the beginning point of measurement, drag the mouse and release the mouse button at the ending point of measurement. The Ruler is displayed as a red line on the image.

The measurement (in mm) is displayed at the end of the Ruler. The Ruler remains active until the user selects another image tool or until another action is performed. See Figure 6.4.24. Click “Ruler” again to turn off the feature.

Hint: To get a perfectly horizontal, vertical or 45-degree ruler, hold down the SHIFT key (on the keyboard), while holding down the left-mouse button, and drag.

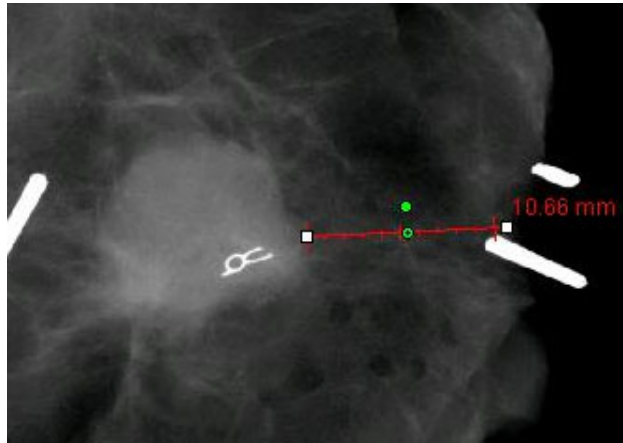


Figure 6.4.24
Ruler

ROI Statistics

“ROI Statistics” will display a dialog box containing image statistics. Click and hold the left mouse button over main image’s region-of-interest (ROI), drag the cursor to make selection around area, and then release the mouse button. Statistical information for the selected region will be displayed on the left side of the dialog box and for the whole image on the right side of the box. The stats displayed are; The 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 6.4.25. Click “ROI Statistics” again to turn off the feature.

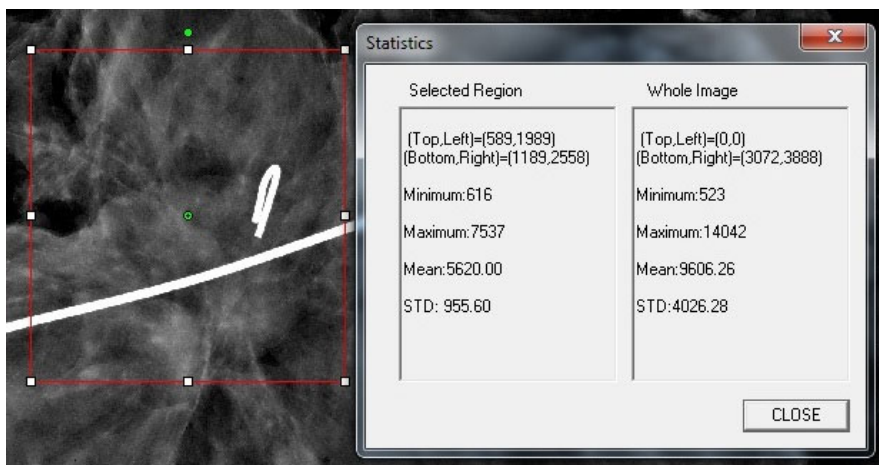


Figure 6.4.25
ROI Statistics

ROI Histogram

“ROI Histogram” will create a histogram for a user defined ROI. After selecting the menu item, place the mouse cursor in the displayed image, press and hold down the left mouse button, and drag the cursor to make the desired ROI selection. Release the mouse button. Histograms for the selected ROI will be displayed. See Figure 6.4.26.

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 maximum pixel value of the selected region of interest. Click “ROI Histogram” again to turn off the feature.

6.4.5 Cont.

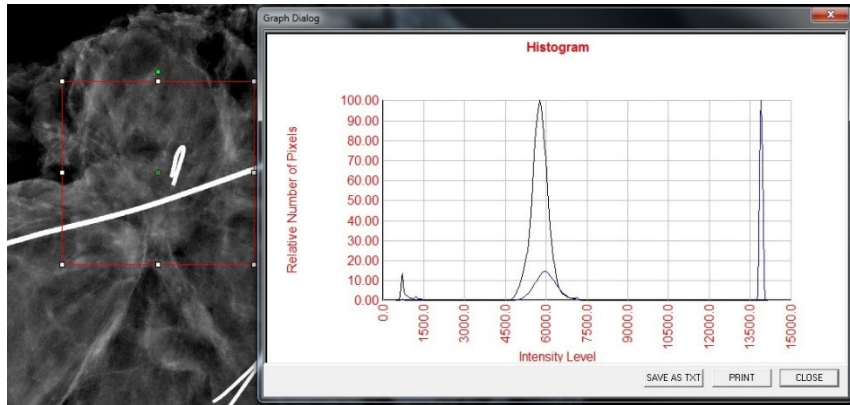


Figure 6.4.26
ROI Histogram

ROI Profile

“ROI Profile” will create a profile for a user defined ROI. After selecting the menu item place the cursor in the displayed image. Hold down the left mouse button and move the cursor across the image to draw a user-defined box around the desired ROI. Release the left mouse button and a profile will be displayed showing the individual pixel values of the defined ROI. See Figure 6.4.27. By default, the averaging direction of the selected ROI is the short axis. The axis may be toggled back and forth by selecting the **SWITCH, HOR<->VERT** button. Click “ROI Profile” again to turn off the feature.

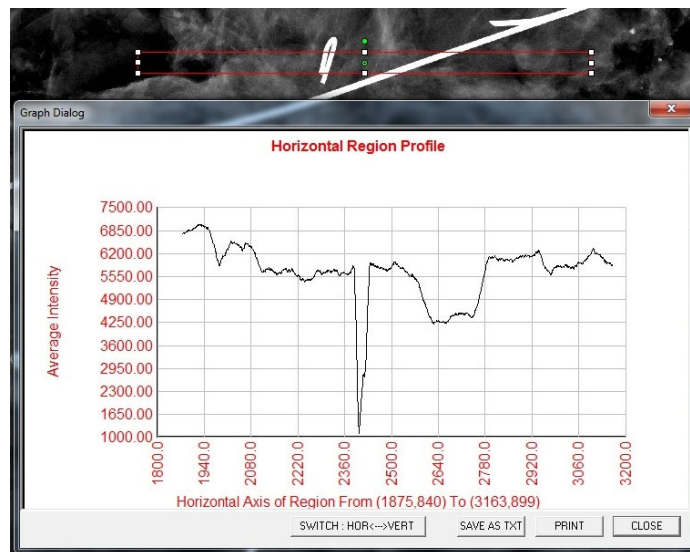


Figure 6.4.27
ROI Profile

Line Profile

6.4.5 Cont.

“Line Profile” will display a profile for a user defined line. After selecting “Line Profile” place the cursor in the displayed image. Hold down the left mouse button and move the cursor across the image to draw a user-defined line. Release the left mouse button and a profile will be given showing the individual pixel values of the defined line. See Figure 6.4.28. By default the first selected point is always the left most (near origin) portion of the plot (i.e. horizontal axis of the graph can have increasing or decreasing pixel (i,j) indexes, depending on the selected start/end points). Click “Line Profile” again to turn off the feature.

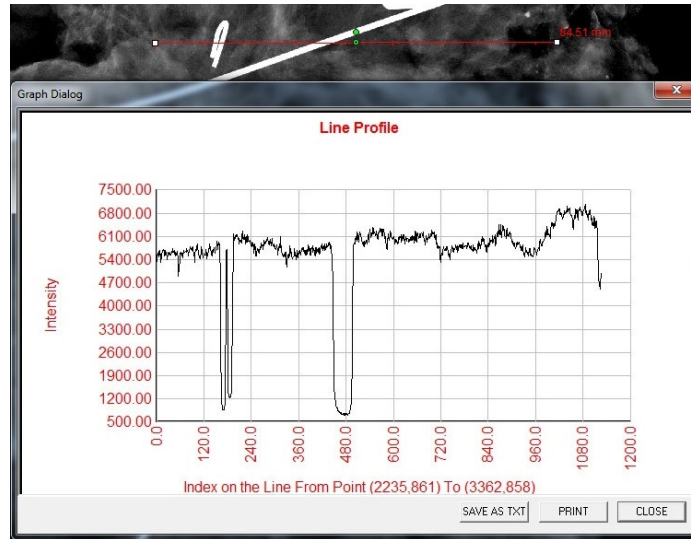


Figure 6.4.28
Line Profile

Built-In Window Level

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

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

By pressing the button shown in Figure 6.5.1, located along the bottom of the image acquisition window, the current patient images thumbnail strip appears. See Figure 6.5.2.



6.5.0 Current Patient Images Browser

Figure 6.5.1
Current Patient Images
Browser icon

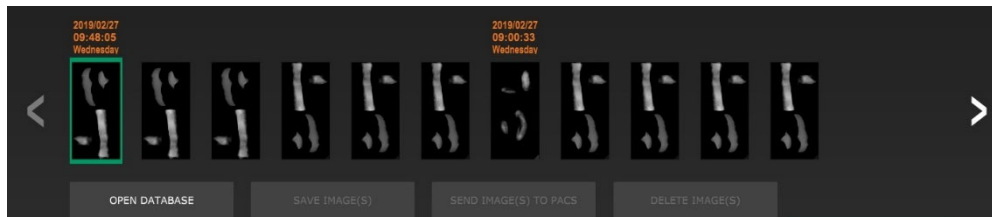


Figure 6.5.2
Current Patient Images
Browser



Figure 6.5.3
Image Database button

The thumbnail strip displays the Procedure date for each individual image series in orange text along the top.

The current image displayed in the image acquisition window will be highlighted in green.

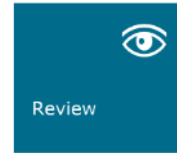
The thumbnail strip supports drag and drop operations to place images into the image display or review panes as necessary.

In addition, with a single click, the user can select multiple images and then select from the various options to Save the images to a USB drive, send the images to PACS, or delete the images. Selected images are highlighted in orange.

There are arrows located to the left and to the right. In the event of many images being taken, the user may traverse the images taken, date ascending, by pressing on the left/right arrows.

There is also an option available to **Open the Database** (see Figure 6.5.3), which enters Review mode. This same button is the equivalent of pressing **Review Mode**, from the Home Menu. See Figure 6.0.1 and 6.6.1.

Review mode can be entered by clicking the **Review** button in the Home Menu page, *Figures 6.6.1 and 6.0.1*, or the **Open Database** button in the Current Image Browser. See Figure 6.5.3 above. Clicking either of these buttons will open the Database as shown in Figure 6.6.2. The system will be in Standby while in review mode.



6.6.0 Database

Figure 6.6.1
The Review Mode icon displayed on the Home Menu

The Database is basically comprised of three sections, or sub-windows. The Patient List Table section, at the top, the Procedure List Table section, in the middle, and the Image Thumbnail List/Viewer section, located at the bottom.

The screenshot shows the 'Image Database' interface with a dark theme. At the top, there are navigation buttons: 'CLOSE DATABASE', 'SAVE IMAGE(S)', 'SEND IMAGE(S) TO PACS', 'DELETE IMAGE(S)', and 'ADDITIONAL OPTIONS'. Below these is a 'Select Patient' section with a table of patient records. The third row is highlighted in orange.

Patient ID	Last Name	First Name	Middle Name	Time Modified	Date of Birth	Sex
ID6749	DOE	JAN		2019/03/27 10:45:40		
ID987	DOE	JENN		2019/03/27 10:44:31	1930/03/03	
ID123	DOE	JANE		2019/03/27 10:43:06	1920/03/27	

Below the patient list is a 'Filter by Procedure(s)' section with a table of procedure records. The first row is visible.

Procedure ID	Accession #	Study ID	Study Name	Procedure Time	Procedure Name	Body Part	Laterality	Position	Physician	Technician II
P201903271...	946130			2019/03/27 10...			L			

At the bottom, there is an 'Image Thumbnail List/Viewer' section showing two image thumbnails with their respective metadata.

	I20190327104306.DCM	Procedure: P20190327104029	Laterality: L	Study: 2019/03/27 10:43:06 Wednesday
	I20190327104230.DCM	Procedure: P20190327104029	Laterality: L	

Figure 6.6.2
Image Database

The list tables work in top-to-down hierarchy as indicated by the arrow:

The Patient List--->Procedure List--->Image Thumbnail List/Viewer.

When a Patient field is selected, the Procedure window becomes active. The Procedure window displays a listing of all Procedures performed under the selected Patient. Additionally, all images corresponding to the patient are displayed in the bottom right.

When a Procedure is selected, the image thumbnail list/viewer is filtered to only show the images which correspond to the selected procedure. Multiple procedures can be selected by holding the Shift key and left-clicking each procedure. All the images for selected procedures will be displayed accordingly.

The database may have its sorting adjusted by clicking on the top fields such as Patient ID and Last Name to sort by either one. When the mouse cursor is clicked over one of the database fields, a small arrow indicator is displayed within the field. Using the Left Mouse button and selecting the field again changes the arrow from ascending to descending or vice versa. The field selected will be automatically sorted accordingly.

Scroll bars are located in the database to allow for ease of navigation.

The thumbnail list/viewer allows for a user to click on the "+" symbol to automatically add the image to a review pane. A user may add up to four images into the review panes. The review panes are automatically adjusted to encompass the four images.

All the options from the Current Patient Images Browser (see Figure 6.5.2) are also available at the top of the Database page. Also, additional options are described in section 6.6.1.

Important Note: The "thumbnail" images (.PNG) are separate files from the actual image data (DCM, DAT, DMM or RAW) files. They have the same file name as the image file, but they have a (.PNG) file extension. It is possible to have an image file and no "thumbnail". In that event, Vision will attempt to create a thumbnail automatically for the image to be loaded into the database. However, if this is unsuccessful, the image will not be displayed.

Save Image(s)

The **Save Image(s)** button is available when an entry from the Image Table or Thumbnail List is selected, or through the current patient images, otherwise it is disabled. The selected image can be saved in the following popular 8-bit image formats: JPEG, BMP, TIFF and RAW. It can also be saved in 16-bit TIFF format.

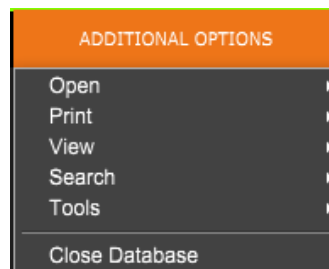
The window level of the saved image is the default window level. If the user requires that the window level be arranged, he/she should load the image to the Image View and print from there rather than printing from database dialog.

Send Image(s) to PACS:

This function sends the image(s) to a pre-configured DICOM PACS Server. Please refer to Section 6.7.0 for more information.

Image Database Menu Functions and Tools

There are functions to navigate, search in the database, and to edit, delete, and add records to the database. Those functions are explained through database menu items. They are accessed from the top-level button labelled **Additional Options** within the database.



6.6.1 Database Additional Options

Figure 6.6.3
Additional Options Menu

Open Menu

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

Print Menu

The “DB-Print” menu provides for Image/Procedure/Patient print functionality. See Figure 6.6.4.

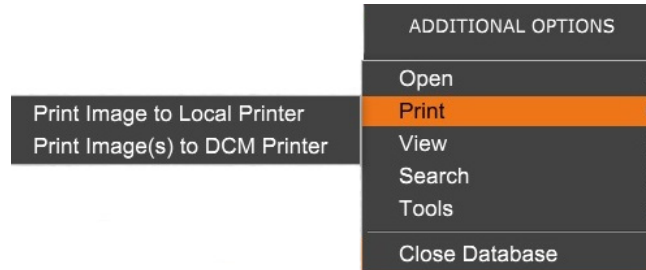


Figure 6.6.4
Database Print Menu

Print Image to Local Printer

“Print Image to Local Printer” is available when entry from the Image Table or Thumbnail List is selected, otherwise it is disabled. The selected image will be printed using the local default printer of Windows system.

The window level of the printed image is the default window level. It is not recommended that users Print from this menu, unless they are satisfied with the print outs set to the default window levels as calculated by the program. The user can load the image first into the Image View (Review) window, and then adjust the image to the desired window levels. When satisfied with the window level, the user can then initiate Print from the menu of Image View window. A Format Options dialog provides a choice between printing formats.

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 a number of options affecting the Database view. See Figure 6.6.5.

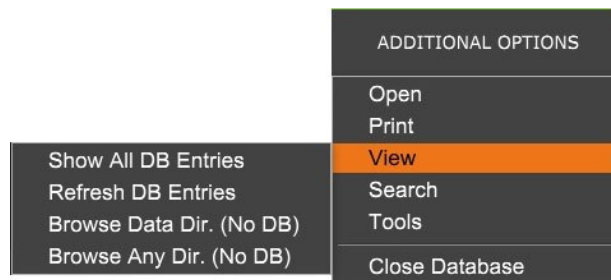


Figure 6.6.5
Database View Menu

Show All DB Entries

Reloads the Patient table from the Database file. Any new changes or additions to the Database will be applied to the table. This selection also clears any active Search Filter which may have been applied to the tables. Search Filter is explained in detail under the Database Search subject below.

Refresh DB Entries

Refreshes the Patient table, but maintains any existing Search Filter that has been applied.

Browse Data Directory (No DB)

6.6.1 Cont.

Displays all thumbnail images, in the Data directory established by the configuration file. These files are displayed in the Thumbnail Viewer. They are not associated with the Database or table lists. This tool is helpful to review un-recorded images, or debug database problems with images in the current data directory.

Browse Any Directory (No DB)

Allows user to browse to any file directory. These files are displayed in the Thumbnail 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” tools, see Figure 6.6.6, provide detailed searches, or database filtering. Selecting the “DB-Search” menu allows the user to perform a detailed and specific search. When search criteria is entered and activated in the DB Search Dialog, see Figure 6.6.7, the search filter is applied to all list tables in the Image Database dialog. The activated search criterion is called Search Filter and this filter remains effective until the user selects “Stop Search” from the “DB-Search” menu, or “Show all DB Entries” from the “DB-View” menu. The active Search Filter is always shown in the caption of Image Database dialog.

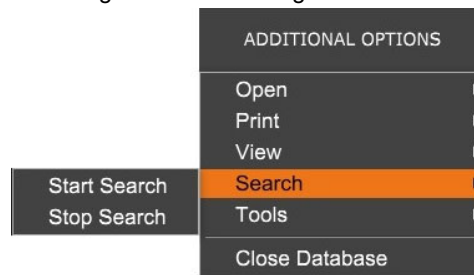


Figure 6.6.6
Database Search Menu

Start Search

“Start Search” opens the DB Search Dialog which allows the user to place an active SEARCH FILTER on the database. When the Search Dialog is opened, the Database page is closed and the software goes back to the Image Acquisition page. The Database page will reopen automatically after the Search Dialog is closed.

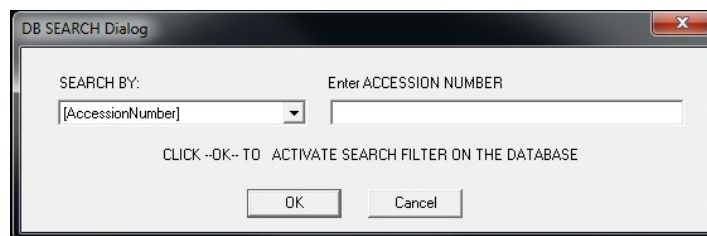


Figure 6.6.7
Starting a Database Search

Drop down menus provide a listing of the search categories. Select a search category and type in the desired search parameter to start the search. Select “Start” to initiate the search. If the category can have more than one discrete entry, all entries for that category will be displayed.

Stop Search

“Stop Search” disables any active Search Filter, clears all list tables, and re-loads the list of all Patients to Patient List Table

Tools Menu

The “DB-Tools” menu provides for Image/Procedure/Patient functions, as well as some useful functions to repair or reformat the database.

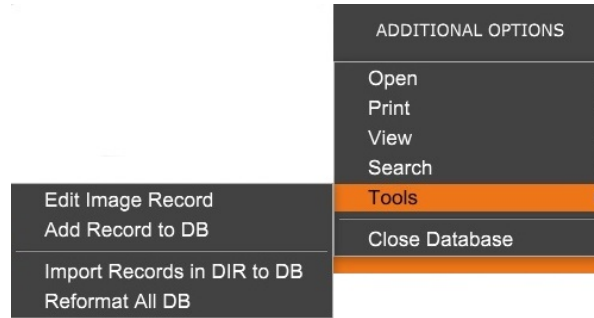


Figure 6.6.8
Database Tools Menu

6.6.1 Cont.

Edit Image Record

The “*Edit Image Record*” function is not currently available in Vision software.

Add Record to DB

Available when entry from Image Table or Thumbnail List is selected, otherwise disabled. This is especially useful when a directory is browsed, without database having entries available for images in that directory. The user can select a single image from the thumbnail list and add records of that image into the database. If the database entry already exists for the selected image, it will not do any harm, it may only update the database, in terms of where the image file is currently located, i.e. file/folder name.

Import Records in DIR to DB

This tool helps to browse and select a folder, and then populate the database with all the corresponding entries for all the image files under the selected directory (including subdirectories). The formats for images can be DCM, DAT, DMM and RAW. If thumbnails of images are missing, this tool will also generate BMP thumbnails, in the same directory.

Reformat All DB

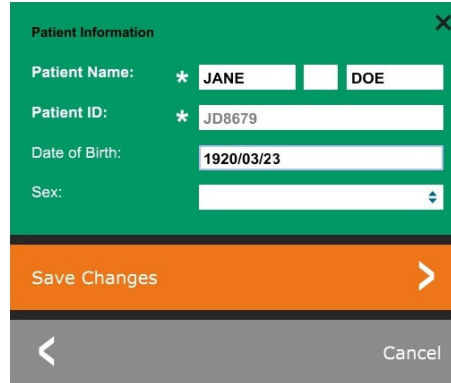
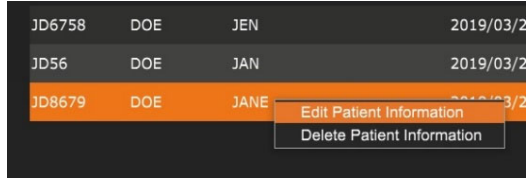
“*Reformat All DB*” tool helps to reformat Date [YYYY/MM/DD], Date/Time [YYYY/MM/DD HH:MM:SS] fields of tables, and also capitalizes letters of entries for some other fields. It is a useful tool when some older database file is imported, and opened for the first time, or when the user alters database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

Additional Notes on the Database

- The ability to Exit the database, staying within the Review mode, is located under **Additional Options**.
- The top-left button will adjust itself to take the user **Back to Acquisition**, **Back to the Main Menu**, or will become the **Close Database** button dependent on the workflow used to enter the Database screen, and what is most appropriate.

Edit or Delete Patient Information from the Database

The user may edit or delete patient information from within the database. Right click on the patient's entry in the top section of the database to open a Dialog box. See Figure 6.6.9.



6.6.1 Cont.

Figure 6.6.9
Edit/Delete Dialog Box (Left)

Figure 6.6.10
Patient Information (Right)

Clicking on “*Edit Patient Information*” will open a “Patient Information” dialog box. See Figure 6.6.10. Click **Cancel** to return to the database without making or saving changes. Clicking **Save Changes** will open a “Confirmation” Dialog box. Click **Yes** to confirm and proceed. Changes are now saved and the user will be returned to the database. **No** will void the changes and return to the database. **Cancel** will return the user to the “Patient Information” dialog.

Note: If the system has a start-up password activated (see the Login Utility topic in Section 6.4.4 and Figure 6.4.21), the same password will be requested when trying to “*Delete Patient Information*” from the database.

The DICOM Standard

What is the DICOM Standard?

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

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

A file created using the DICOM protocol has the following structure:

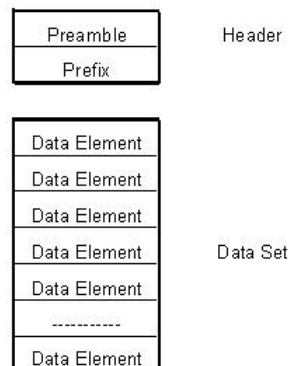


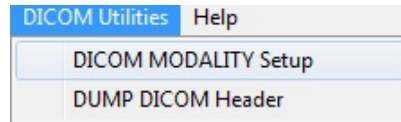
Figure 6.7.1
DICOM Protocol Structure

Where the Preamble consists of 128 bytes, all typically set to 00H unless it is not use by an Application Profile or a specific implementation; the Prefix consists of 4 bytes, making up the character string "DICM" encoded as uppercase characters of the ISO 8859 G0 Character Repertoire; and the Data Elements are arbitrarily large (or small) and contain the data.

6.7.0 DICOM Functionality

Modality

The DICOM file settings for Modality are accessed from the Top Menu Bar by selecting “DICOM Utilities”, then “DICOM Modality Setup”.



6.7.0 Cont.

Figure 6.7.2
DICOM Utilities menu

The DICOM storage type, either Presentation or Processing may be selected. The same Dialog box allows for selecting the DICOM Image Modality, either Digital X-Ray or Digital X-Ray Mammography. The Transfer Syntax and Value Representation are not user definable. They are always assigned to be META HEADER PRESENT, LITTLE_ENDIAN and VR_IMPLICIT.

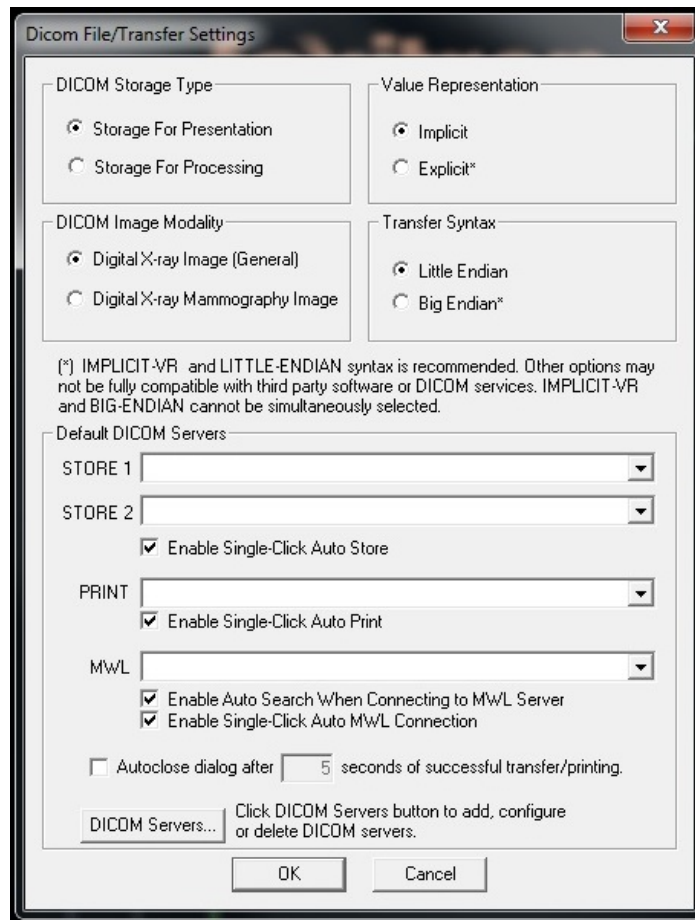


Figure 6.7.3
DICOM Modality Settings
Default settings shown

NOTE: Once the DICOM Modalities have been selected, they remain in effect even after the Vision software has been closed. The Modality settings are stored and will remain in the configured manner until they are changed 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.

Default DICOM Servers

6.7.0 Cont.

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 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 patient’s data.

“Auto close dialog after N seconds of successful transfer/printing” will automatically close the DICOM Networking dialog after 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. See Figure 6.7.5.

DICOM Save Local

To save the current image to a local drive/directory, right click anywhere in the image. This will display the dialog box shown in Figure 6.7.4 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**.

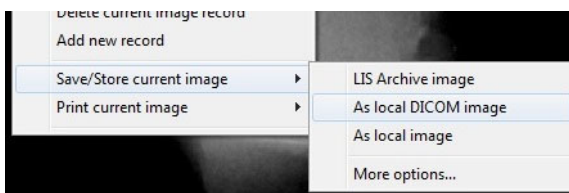


Figure 6.7.4
Save Current Image Dialog

PACS Store and PACS Print

The Vision software allows for PACS (DICOM) Store and PACS (DICOM) Printing. These options are available throughout the software. For example, if the **PACS Store** button is selected, the following DICOM Networking Dialog window can be displayed. This Dialog box allows the user to do a DICOM Store, DICOM Print, or to Add, Modify or Remove DICOM Network connections or Peripherals.

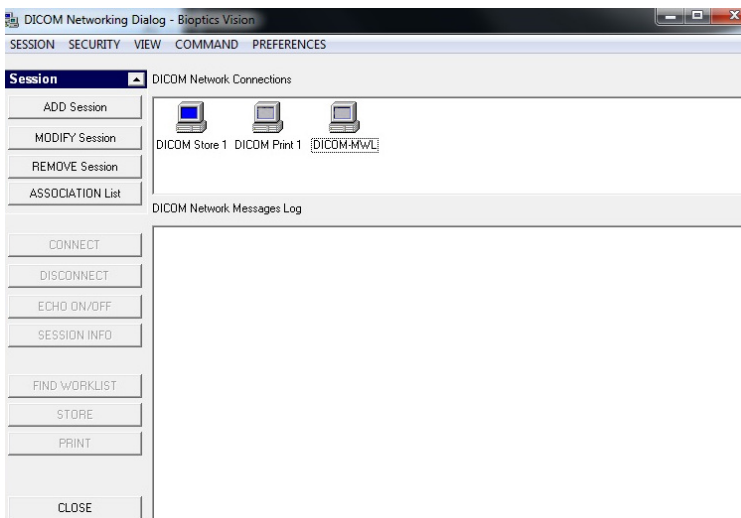


Figure 6.7.5
DICOM Networking Dialog box

PACS DICOM Store

6.7.0 Cont.

The Vision software supports DICOM 3.0 C-STORE Service. This allows for sending an image or a series of images (under a specified Procedure) to a remote DICOM Application Entity (AE) compliant storage system such as PACS. Again, the DICOM Store capability is provided for throughout the Vision software. Modifications to the Presentation and Processing may be made through the DICOM Modality Setup, under the Tools menu.

Note: For DICOM Store, the "SET FILM Attributes" will be grayed out.

The user can add a new configuration for a remote DICOM AE to which to send the image or select from an already configured one, shown under the DICOM Network connections, in the DICOM Networking Dialog. By double clicking (or single click, followed by pressing the **Connect** button) the icon for the remote DICOM AE, the Vision software will connect and establish a DICOM association with the selected remote AE. Once the association is successfully established, the image can be sent for storage by pressing the **Store** button. After the **Store** button is selected, the Vision software will send the selected image to the defined remote DICOM AE. If the Store operation is successful, the remote DICOM AE will send a confirmation of reception and storage of the image(s). If the operation fails, the remote DICOM AE will send an error code indicating the reason for failure.

A single image can also be sent for storage by clicking the Right Mouse button on the image "thumbnail" while in the Database Browser and following the same procedure described previously. It is possible to send a whole Series (Procedure) of images for storage. This is accomplished by clicking the Right Mouse button on the Series (Procedure) name, displayed in the Database Browser screen and again, following the same protocol described above.

Add Session

The **Add Session** button opens the Session Dialog box through which the user can configure a new connection to a remote DICOM Application Entity.

To create a new connection configuration to a remote DICOM AE, the user must have the following information available: the Application Entity Title (AE Title), the choice of DICOM / PACS "function to perform", the IP Address and the Port Number for the Sever (i.e. the DICOM printer or PACS system).

The AE Title and Port Number of the user's system (i.e. the client) are also required. Complete the appropriate data fields and select **OK** to create a new configuration.

Choosing DICOM / PACS Default Session Function Behavior

There are currently four (4) types of functions which a DICOM session can represent as a default. These are found in the Function drop-down list (combo box) seen in Figure 6.7.6 below. A list also follows:

1. A GENERAL DICOM / PACS Connection
2. A DICOM STORE Connection
3. A DICOM PRINTER Connection
4. A DICOM Modality WORKLIST Connection

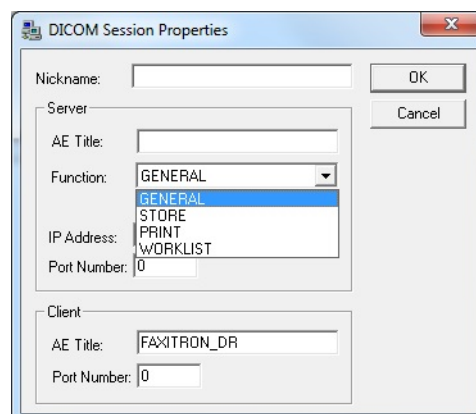


Figure 6.7.6
Session Properties Dialog box

The purpose of the DICOM "Function" is to allow a Session/Connection to be created (added) that allows a DICOM / PACS "device" to only be used, as the user has configured it, for a particular function category. Once configured, when you view or use the "DICOM Networking Dialog" (see figure 6.7.5), only the icon that matches the function chosen will be "active and lit up." That is, it will have a blue color as opposed to a "grayed out" color. For example, in figure 6.7.5 there are three (3) icons representing in order: a PACS Store (*DICOM Store 1*), a PACS Print (*DICOM Print 1*), and a Modality Worklist (*DICOM-MWL*). Because the **DICOM Store** icon was chosen previously it is the only one active (blue screen). It works the same for the other modes as well.

6.7.0 Cont.

Modify Session

The **Modify Session** button opens the Dialog box for the selected DICOM AE. In this window, the user may modify the Server and Client information described in the Add Session description.

Remove Session

The **Remove Session** button removes the selected DICOM AE configuration from the Vision software. Once removed, a DICOM AE configuration cannot be restored, unless the user manually re-enters the requisite data through the Add Session button. A confirmation of action will be requested, see below.

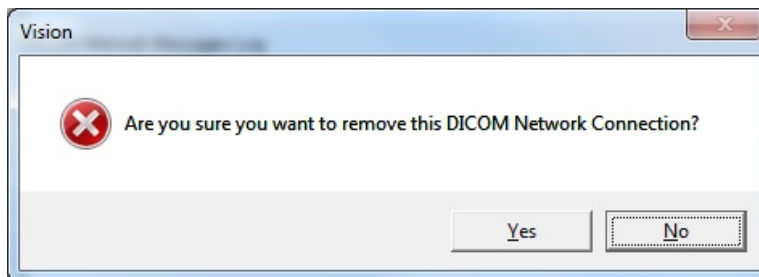


Figure 6.7.7
Verifying Removal of an Existing DICOM Network Connection

Association

6.7.0 Cont.

The **Association List** button opens the Association Dialog box, depicted below, through which the user can edit the parameters and protocols used by the Vision software when negotiating a connection with a remote DICOM AE. These options should only be modified by an advanced user familiar with DICOM association protocols.

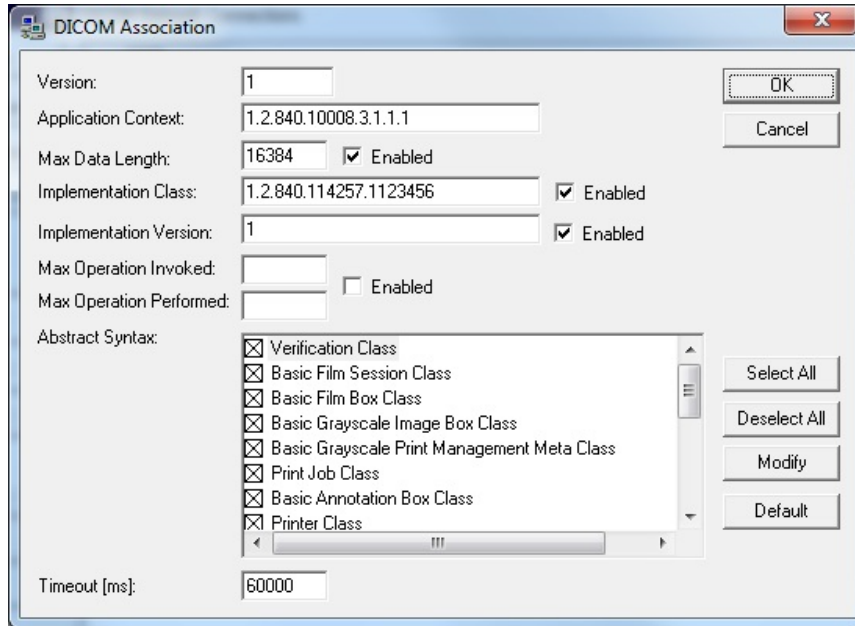


Figure 6.7.8
DICOM Association Window

Film Attributes

Selecting the “Set DICOM Print Film Attributes” under the “Command” menu (Figure 6.7.9), displays the DICOM Printer Setup Dialog box. See Figure 6.7.10. In this Dialog box, the user may select various options governing the film and print format. Selecting **Default** restores all of the default options. Configurations to the settings are provided through drop down menus. To accept the modified configuration, select **OK**. To reject the options and exit the window without making any changes, select **Cancel**.

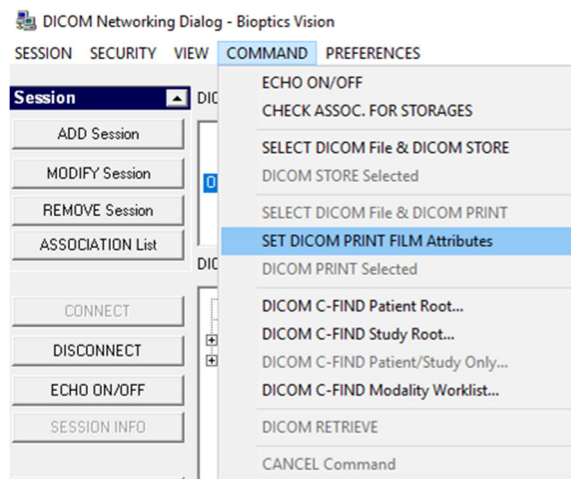
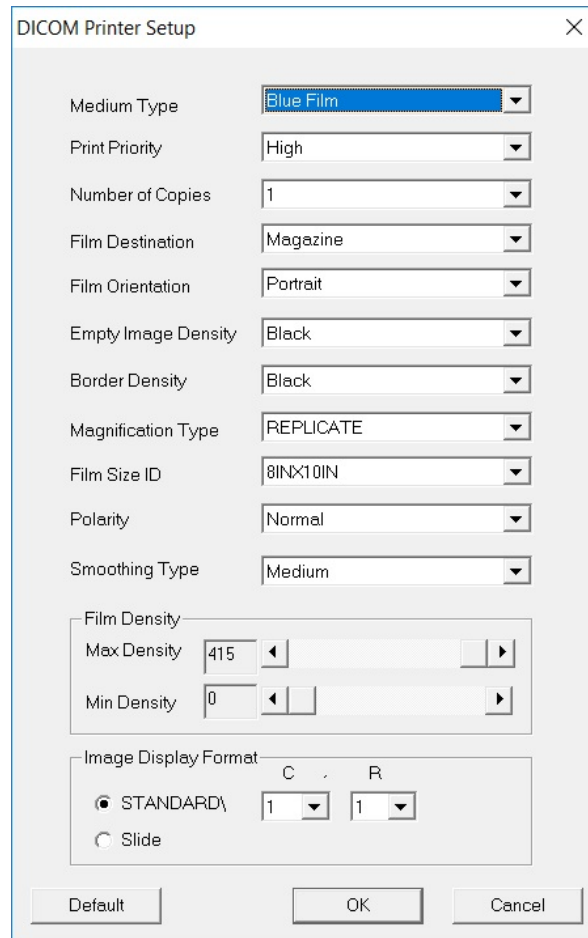


Figure 6.7.9
Set DICOM PRINT FILM
Attributes



6.7.0 Cont.

Figure 6.7.10
DICOM Printer Setup Dialog Box

PACS Print

The **PACS Print** option sends the selected image to the selected PACS DICOM printer. The image is printed according to the film, and print format options, found in the Set Film Attributes Dialog previously described. If the user initiates PACS Print from Image View, then the window level will be chosen, from the Image View. If PACS Print is initiated from the Database Dialog, then the Window Level will be the default window level, calculated by the Vision software.

Close

The **Close** button closes the DICOM Networking dialog box and returns the user to the area from which the DICOM command was executed. This command also closes the connection or association, between the Vision software and the remote DICOM device, if a connection was established.

Overview

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

Operation

To begin annotating, select the **Annotations** tool from the left menu. See Figures 6.4.1 and 6.8.1. By opening this dialog, the software will immediately put the user into design mode. It will also display a "Tool Pallet." See Figure 6.8.2 below.



6.8.0 User Annotations

Figure 6.8.1
User Annotation Design
Tool Pallet

Selecting **Save** or **Cancel** from this dialog will either cancel the previous annotations or Save the current annotations to the window. It will also return you to normal imaging mode.

The tool pallet consists of fifteen (15) tool options that follow. However, the tools may be truncated based on the needs of the user to the most common 8 tools, which are displayed in the top row of the dialog box.

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

The term "swipe" infers holding down the left-mouse button and moving the object around the screen. Letting go of the left mouse or clicking the right mouse button will "set" the annotation into a "permanent" or final position.

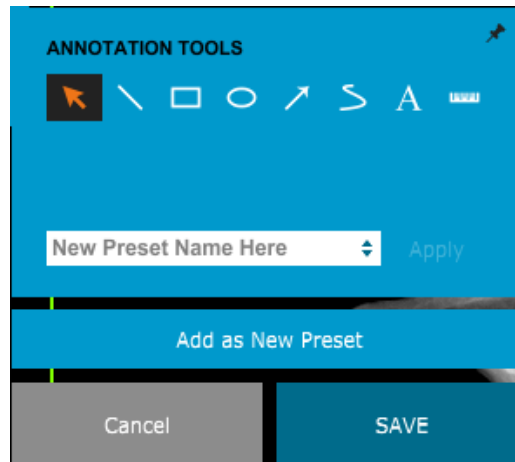


Figure 6.8.2
User Annotation Design
Tool Pallet

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

1. **Selection Tool:** Use this to select (highlight) a current annotation object. Click and hold the left mouse button down, which sets a starting position, then move the mouse around. Whatever annotations are inside the box being displayed will be selected, for further use. Release the left mouse button to finish the operation.
2. **Line Tool:** Draw a straight line with this option. Mouse behavior same as above.
3. **Box Tool:** Draws a box. Mouse behavior same as above.
4. **Ellipse (and Circle) Tool:** Draws an Ellipse or circle. Mouse behavior same as above.
5. **Arrow Tool:** Draws a line with an arrow at the end. Mouse behavior same as Line Tool.
6. **Polygon Open Line Tool:** Draws non-straight "open segmented" lines. Left-click mice, hold button, draw. Release left button, this sets a line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
7. **Text Tool:** Creates a "textbox" where you can type text-based data.
8. **Ruler Tool:** Creates a ruled line segment. Very much like the Image Tools Ruler feature.
9. **Polygon Closed Line Tool:** Draws non-straight "closed segmented" lines. Left-click mice, hold button, draw. Release left button, this sets a line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
10. **Curved Open Line Tool:** Draws curved "open segmented" lines. (Bezier curves.) Left-click mice, hold button, draw. Release left button, this sets a curved-line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
11. **Curved Closed Line Tool:** Draws curved "closed segmented" lines. (Bezier curves.) Left-click mice, hold button, draw. Release left button, this sets a curved-line segment. Repeat, as desired. Right-click mouse button and tool operation is complete.
12. **Text "Balloon" Tool:** Creates a textbox with a line segment protruding from a corner of the text box. This can be used to "link" text to something on your image.
13. **Segmented Ruler:** Draws non-straight "open segmented" ruled lines. Left-click mice, hold button, draw. Release left button, this sets a ruled line segment. Repeat as desired. Right-click mouse button and tool operation is complete. The length of all the ruled line segments is shown, at the end of the ruler. Useful for a rough estimate of the periphery of an object or Patient.
14. **Protractor Tool:** Draws an angle on screen and provides the degree of the angle. Just like a protractor.
15. **Orthogonal Ruler Tool:** Provides two (2) ruled lines that are at right angles to each other.

6.8.0 Cont.

Design Mode and Mouse Right-Click Menu

6.8.0 Cont.

While in User Annotation Design Mode, but not in a specific operation mode, one can right-click the mouse and get a context sensitive menu. See below.

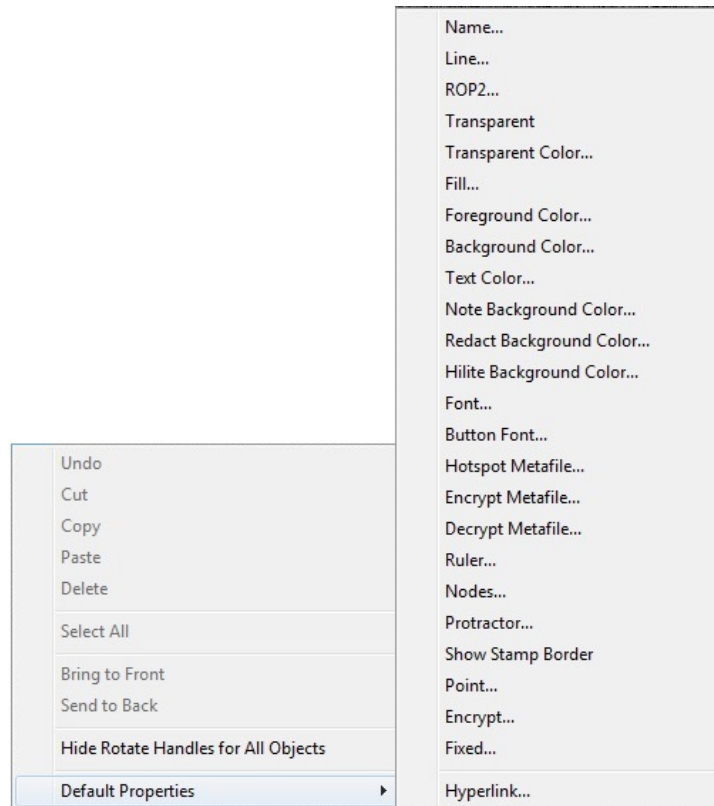


Figure 6.8.3
Right-click Mouse Context Sensitive Menu (Only During Design Mode of User Annotations)

Many specific settings can be made from these context sensitive menus.

Note: If an item seems too small to read or see correctly you can possibly change it from the Right click menus, shown above. Alternatively, you can choose to zoom into the image, using the Dynamic Zoom tool. This enlarges the image, and you should be able to clearly see any annotation.

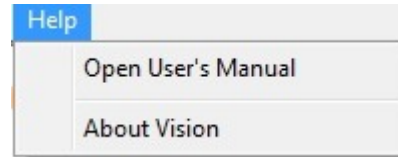
Show - Hide Annotations

The **Toggle Annotations** button, shown as Figure 6.8.4, allows users to quickly toggle annotations on and off. By default, the annotations will be toggled on. The button is located in the right-side menu, near the upper right corner.



Figure 6.8.4
Show/Hide Option For User Annotations

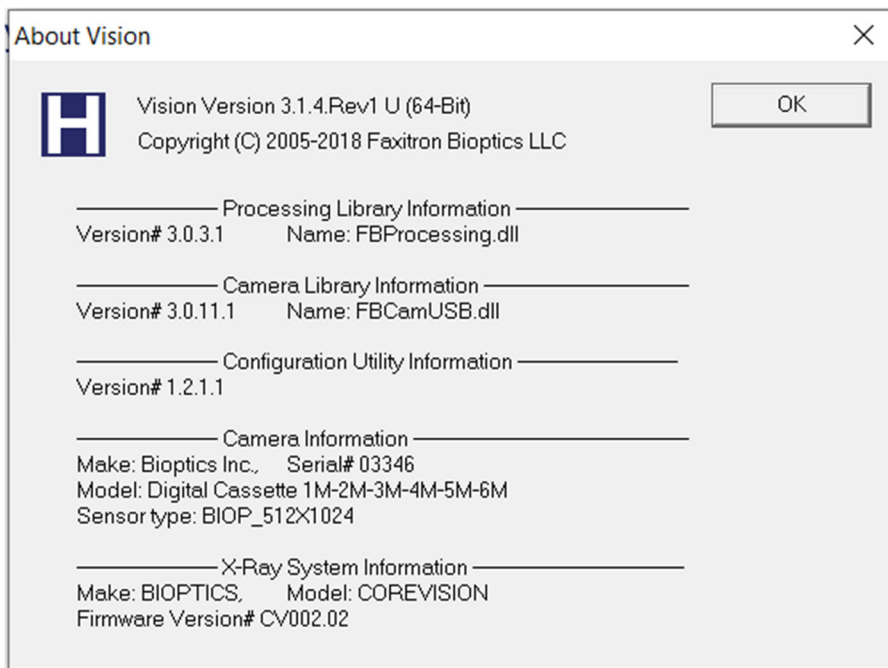
The “Help” menu, see Figure 6.9.1, is located on the top menu bar and provides quick access to the Faxitron Core “User’s Manual” and “About Vision”. Refer to Figure 6.10.1.



6.9.0 Help

Figure 6.9.1
Help Menu

The “About Vision” submenu opens a Dialog box, that shows the Vision software version, copyright, date and system information.



6.10.0 About Vision Software

Figure 6.10.1
About Vision Information Dialog
Box

Revision History

Revision	Date	Description of Change	Author/Originator	Approved by
2.0.2	April 2010	Initial Faxitron Core User's Manual	Unknown	Unknown
3.0	7-23-2012	<ul style="list-style-type: none"> • Changed Document # from 1043C to 05-5280-04 • Changed title from "Advanced User Manual for the Bioptics Faxitron Core" to "Faxitron Core User's Manual" • Changed name on title page to Faxitron. • Changed all company references from Bioptics to Faxitron Bioptics. • Deleted Sections 3 & 6. This material covered in other sections. • Deleted Sections 7 & 8. This material covered in BioVision Technical Manual. • Insert New Section 2: Radiation and X-Ray Radiation Safety • Insert New Section 3: About Your BioVision. • Substantial Revision made throughout remainder of document. 	Alan Mihalko	Akif Baysal
3.1	2-4-2015	<p>Updated images throughout manual to reflect current Faxitron Core color scheme and company logo.</p> <p>Added Revision History Table</p>	Paul Hess	Mikhail Viznyuk
3.2	07-28-2015	<p>Pg 78. Typo correction of figure.</p> <p>Pg 81/82 Deletion of repeat text.</p> <p>Pg 86. Correction of reference location</p> <p>Pg 88. Correction of figure reference.</p> <p>Pg 98. Deletion of repeat text.</p> <p>Pg 99. Correction of search description</p> <p>Pg 103. Deletion of repeat text.</p> <p>Pg. 109 Correction of references</p>	Paul Hess	Mikhail Viznyuk
3.3	07-07-2016	<p>Pg 61 Corrected label for Fig 5.2.18</p> <p>Pg 65 Corrected errors in Sequence Protocol</p> <p>Pg 90 Corrected Figure reference from 6.9 to 6.5.1 in Section 6.5.0</p> <p>Pg 98 Deleted extra 'period' from Figure 6.6.4</p> <p>Pg 101 Deleted extra 'period' from Figure 6.6.8</p>	Alan Mihalko	Mikhail Viznyuk
4.0	10-24-2018	<p>Major update to include new Vision software (metro). EU Rep added.</p> <p>Images updated as required. Section</p>	Cary McLaughlin	Ciaran Purdy

Revision	Date	Description of Change	Author/Originator	Approved by
		numbers added and Index removed.		
041	07-16-2019	<ul style="list-style-type: none"> • Section 0 updated to include Indications for Use • Authorized EU Rep updated in Section 1 • Updated Sources of Radiation Dose chart is Section 2 • Section 3 – added DICOM version info and Heat Output • Section 4 – added Interoperability and Cybersecurity info • Section 5 – Streamlined and re-organized section. <ul style="list-style-type: none"> ○ Deleted material that was not directly related to basic operation of the system. • Section 6 – Re-organized numerous sub-sections for more logical progression, <ul style="list-style-type: none"> ○ Revised Start-up sequence ○ Revised Camera Calibration section ○ Changed flow of Patient Data ○ Revised various sub-section for clarity • Updated screenshots throughout 	Alan Mihalko	S. Howerton J. Mudd D. Canny D. Saraiya R. Nash T. Longo M. Fremont
042	12-03-2019	Updated branding	Dhaval Saraiya	See CCB
043	12-10-2020	Updated branding	Steven Holmes	See CCB
044	August 2021	Added “Consult IFU” symbol and “package-inserts” web address/link Added AU Sponsor and Brazilian Contact Information Added Table for “Warning and Caution Symbols on the Label” Updated Service Contact Information	Alan Mihalko	See CCB
045	August 2021	Removed Brazilian Contact information	Alan Mihalko	See CCB