

# Faxitron™ OR and BioVision+

Specimen Radiography System

# User's Manual

# Faxitron™ OR & BioVision+

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December 2019

Faxitron OR was previously known as BioVision

**HOLOGIC®**

# Faxitron™ OR and BioVision+

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. Faxitron Bioptics, LLC does not accept responsibility for injury or damage from incorrect system operation. Faxitron Bioptics, LLC can arrange training at your site.

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Specimen Radiography System

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# Faxitron™ OR and BioVision+

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## *Foreword*

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

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

## *Indications for Use*

The Faxitron OR **(and BioVision+)** **Digital Specimen Radiography (DSR) System** is a cabinet digital x-ray imaging system intended to generate and control X-rays for examination of harvested specimens from various anatomical regions, and to provide rapid verification that the correct tissue has been excised. 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.

# Faxitron™ OR and BioVision+

Specimen Radiography System

# 1

## SECTION 1 User's Manual

# Faxitron™ OR & BioVision+

**HOLOGIC®**

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

The Faxitron OR and BioVision+ operate in virtually identical ways so throughout this manual the system will be referred to as BioVision unless specific features are unique to one system or the other.

The user must first setup the hardware, then initiate the Faxitron 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 Faxitron Bioptics, LLC.

## Additional Information

For further technical assistance contact:

### Faxitron Bioptics, LLC (a Hologic company)

3440 E. Britannia Dr. Suite# 150

Tucson, AZ 85706, USA

Tel: +1 (877) 910-0030

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### Authorized European Representative

(for regulatory information)

Hologic BVBA

Da Vincilaan 5

1930 Zaventem

Belgium

Tel: +32 2 711 46 80

Fax +32 2 725 20 87



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

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

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



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



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



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






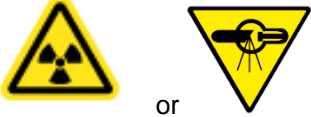









Warns the reader to use appropriate protection (such as surgical gloves or an approved specimen container) to avoid exposure to potentially infectious materials such as patient tissue samples.



## 1.1.0 Warning and Caution Symbols in this Manual

## 1.1.1 Warning and Caution Symbols On Labels

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



# Faxitron™ OR and BioVision+

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# 2

## 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 machines.** Cabinet X-ray machines are enclosed, self-shielded, 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 (except radon), 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

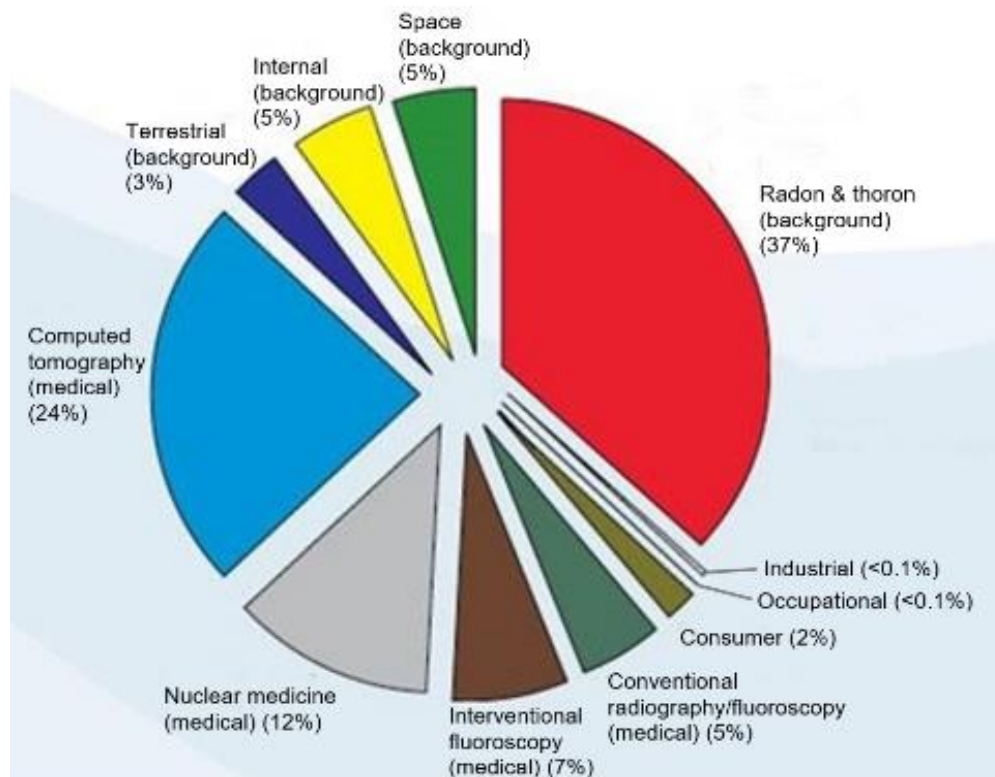
## 2.1.0 X-rays

## 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,

## 2.2.0 Cont.

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.

## 2.3.0 Biological Effects of Radiation

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.

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) or 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

## 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, and
- 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 relatively 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).

## 2.3.1 Cont.

## 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 <sup>1,2</sup>	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 cm<sup>2</sup> 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

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

## 2.6.0 References



# Faxitron™ OR and BioVision+

Specimen Radiography System

# 3

## SECTION 3 About Your Faxitron OR / BioVision+ System

The **Faxitron OR (and BioVision+) Digital Specimen Radiography (DSR) System** is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of harvested specimens from various anatomical regions, and to provide rapid verification that the correct tissue has been excised.

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.

Both the **Faxitron OR and BioVision+** employ the use of **Vision**, a full featured and powerful image acquisition and data manipulation software, developed by Faxitron Bioptics. 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 the ability to do DICOM Print and Store functions and follows the Modality Work List (MWL) protocol for image transfer.

## DICOM Version

Faxitron 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 Faxitron on request

## 3.0.0 Overview

### 3.0.1 DICOM Version

## Service

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

Faxitron Bioptics, LLC  
3440 E. Britannia Drive, Suite 150  
Tucson, AZ 85706  
USA  
T (520) 399-8139  
F (520) 399-8182  
E-mail: [support@faxitron.com](mailto:support@faxitron.com)  
Website: [www.hologic.com](http://www.hologic.com)

## Troubleshooting

Refer to the Faxitron OR or BioVision+ Technical Manual, contact your Faxitron representative, or contact Faxitron Customer Service.

## SCHEDULE OF MAINTENANCE

Refer to the Faxitron OR or BioVision+ Technical Manual, contact your Faxitron representative, or contact Faxitron Customer Service.

## 3.0.2 Service and Troubleshooting

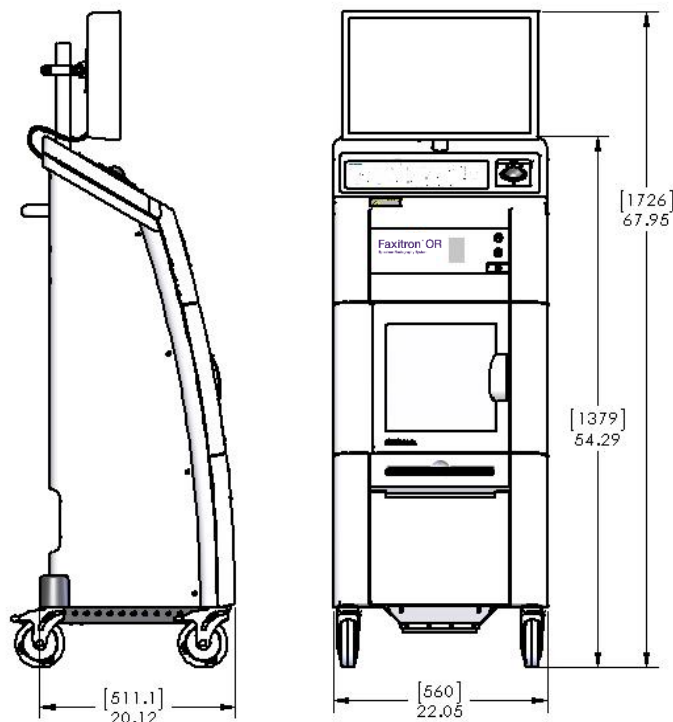
## 3.0.3 Schedule of Maintenance

# Faxitron™ OR and BioVision+

Specimen Radiography System

## 3.1.0 Specifications

**Figure 3.0.1**  
Dimensions & Weight



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

Distances	Faxitron OR	BioVision+
Top of Camera to Imager	0.23" [5.8mm]	0.26" [6.6mm]
Tube Target to Imager	23.2" [589mm]	15.9" [405mm]
Tube Target to Sample Position (No Mag)	22.7" [577mm]	15.6" [396mm]
Tube Target to Lower Position (1.5 Mag)	15.8" [403mm]	10.7" [270mm]
Tube Target to Middle Position (2.0 Mag)	11.1" [282mm]	8.0" [203mm]
Tube Target to Top Position (3.0 Mag)	N/A	5.3" [135mm]
Imager to Sample Position	0.5" [12mm]	0.35" [9mm]
Imager to Lower Tray Position	7.4" [187mm]	5.3" [134mm]
Imager to Middle Position	12.1" [307mm]	8.0" [202mm]
Imager to Top Position	N/A	10.6" [270mm]

**WEIGHT:** 200 lbs (90 kg)

**INPUT POWER:** 120VAC 60Hz 600W Max      230VAC 50Hz 600W Max  
100VAC 50/60Hz 600W Max      230VAC 60Hz 600W Max

**HEAT OUTPUT:** 2000 BTU/hr Max

**X-RAY DUTY CYCLE:** 50%

**EXPOSURE CONTROL:** Automatic or Manual

### Requirements | BioVision 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 BioVision unit does not exceed an exposure of 0.1 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.

#### Start Button

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

#### Safety Interlocks

The BioVision Specimen DR system has two safety interlocks on the specimen door to prevent the generation of X-rays unless the door is closed/installed.

#### Software Key (Password) Actuated Control

The BioVision utilizes a software key in-lieu-of a physical Key Lock switch. The password (software key) must be correctly entered each time the Vision imaging software is opened. X-rays cannot be generated in the BioVision system independent of the software.

#### Emergency Stop Button

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

#### X-ray Generation Indicators

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

### 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 BioVision system is fully dependent on the software for image acquisition/X-ray generation. A software key (password) is required to open the Vision software. If the software is closed, the key is required to re-open.

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.

### 3.2.0

## Compliance Requirements and Safety Measures

### 3.3.0

## X-ray Control System

The following conditions 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 must be communicating with System Software (Vision)
- 5) Digital Imager must be communicating with System Software
- 6) X-ray On button pressed either in the software or on the unit

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 BioVision system is designed to generate ionizing radiation energies at or below 40keV.

The stainless steel used in the manufacturer of the BioVision X-ray chamber is a high-Z material that effectively absorbs approximately 99% of the ionizing radiation at this energy level.

No additional shielding is required.

## Attenuation

The primary beam from the BioVision 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 door.

Typical background radiation measurements at the Faxitron manufacturing facility are 0.1  $\mu\text{Sv/hr}$ .

Dose measurements are taken at 40keV energy levels with a 25mm 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  $\mu\text{Sv/hour}$ .

Faxitron 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 OR & BioVision+**  
**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 Faxitron 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.
- The 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 BioVision 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 Faxitron OR and BioVision+ camera system has a USB cable and care should be taken in order to prevent camera damage. The camera system must never be mishandled, hit, knocked or dropped.
- The BioVision 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.

## 4.0.0

### BioVision Precautions





## Interoperable Connections

### 4.0.0 Cont.

The BioVision 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 Faxitron 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 BioVision without approval from Faxitron.

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 Faxitron or facility IT personnel. Used by clinicians.
Ethernet port at rear	To allow remote connection by the Faxitron service team, so Faxitron can diagnose and repair the system.	Network internet connection	Faxitron 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)	Faxitron 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 Faxitron and the health care facilities. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. Faxitron maintains a set of cybersecurity controls to assure the cybersecurity of its units and to maintain their functionality and safety.



All our units use standard Windows operating 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) is password protected so certain users can get on to the operating system without being able to open the Vision software.

### 4.0.0 Cont.

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 Faxitron, or (b) the Facility takes adequate precautions to ensure the cybersecurity of the unit from threats related to its internet connection.

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

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

### Cybersecurity Events

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

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

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

### CLEANING

#### Internal Chamber

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

Periodically wipe the interior of the cabinet with 70-90% isopropyl alcohol or diluted sodium hypochlorite (5-25%-6.15% household bleach diluted 1:500 provides the proper concentration.) Ensure the specimen area, marked on the chamber floor, is thoroughly cleaned.



#### External

Periodically wipe down the 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.

## System Setup

The BioVision should be set up by a Faxitron Bioptics, LLC authorized representative. Contact Faxitron at telephone number 520-399-8180 to confirm that the system has arrived and to arrange a time for system installation and setup.

## Inspecting the Crate

The BioVision System arrives in one large wood crate. Have the shipping agent transport the crate to an area where it can be kept safe from theft, damage, or environmental extremes until the Faxitron Bioptics, LLC authorized representative can install the system.

Check the crate for any damage. If the crate appears to be damaged, contact Faxitron at 520-399-8180.

The crate is about six feet tall. This crate contains the BioVision, the display monitor, and system manuals.

## Lifting and Transporting the Crates

Caution: The crate weighs approximately 475 pounds (215 kg). The packaged system should be kept upright as indicated on the shipping crate. To prevent damage to the crate and system, Faxitron recommends using a pallet jack, not a forklift, to move the crate. Move the crate only if necessary.



## Unpacking and Setting up the System

The BioVision system is to be unpacked and set up on site by a Faxitron Bioptics, LLC authorized representative. Please contact Faxitron Bioptics, LLC at 520-399-8180 when your system arrives to arrange for system setup.

## Location

Leave at least 6" (15cm) of clear space behind the BioVision system to allow proper ventilation and access to the power cord and network cable (if applicable).

## Environmental Conditions

### Operational:

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

Relative Humidity: < 75 percent.

### Storage and transport:

Temperature: 0 to 45 degrees C or 32 to 113 degrees F.

Relative humidity: < 75 percent.

### 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 BioVision Setup

**POWER REQUIREMENTS:** 120VAC 60Hz 600W Max      230VAC 50Hz 600W Max  
100VAC 50/60Hz 600W Max      230VAC 60Hz 600W Max

**HEAT OUTPUT:** 2000 BTU/hr Max

**X-RAY DUTY CYCLE:** 50%

**RADIATION SAFETY:** Refer to Section 2 of this manual.

## 4.1.0 Cont.

The BioVision can be easily moved from one room to another. Follow these procedures to move the system to another location, such as a different operating room.

### Relocation Procedure

Grasping the plug and not the cord, unplug the system from the wall receptacle and wrap the cord around the cart handle to prevent someone from tripping over it.

**Caution: The BioVision unit is heavy and is not designed to be lifted. Do not try to lift or carry the system.**

Use the handle on the back of the system, to carefully roll the system to the desired location. The system can be moved by one person. Be sure that the system will allow easy access to the wall outlet after the system power cable is connected.

The system requires an area approximately 60 cm wide by 62 cm deep by 166 cm tall. The system is designed to be placed on a standard floor in a medical facility such as an operating room. Do not block the area behind or immediately in front of the cart as this open space is needed for ventilation of the PC in the cart. There is adequate ventilation to the rear of the system as long as no objects are placed between the cart 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 cart to enable personnel to safely access the specimen door, computer keyboard and monitor, and system control panel.

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

**Warning:** The BioVision 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.

Unwrap the power cord from the cart handle and plug it into the wall receptacle.

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

## 4.2.0 Moving the Biovision



# Faxitron™ OR and BioVision+

Specimen Radiography System

# 5

## SECTION 5

# Quick Start and Basic Operation of the Faxitron OR & BioVision+ Systems

# Faxitron™ OR and BioVision+

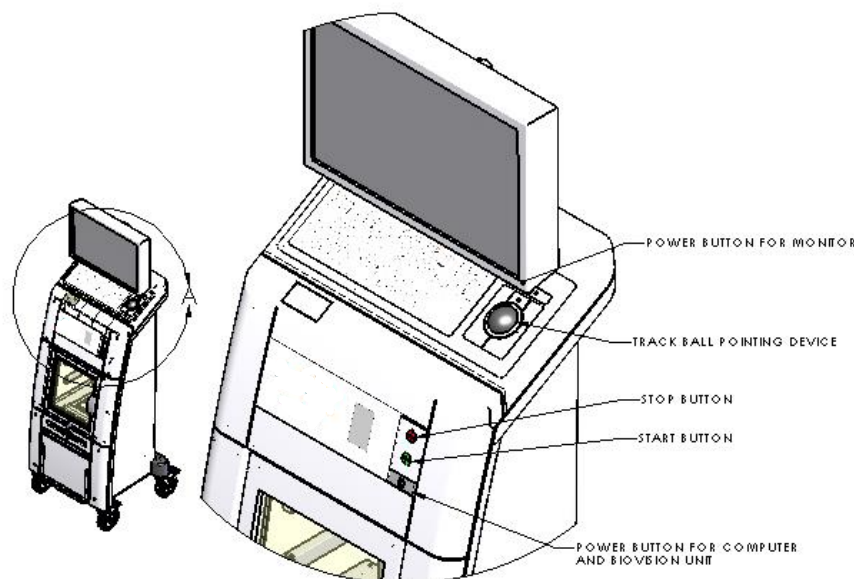
Specimen Radiography System

The Faxitron OR and BioVision+ operate in virtually identical ways so throughout this manual the system will be referred to as BioVision unless specific features are unique to one system or the other.

Before powering up the system, please make sure that the power cord is securely plugged into the power entry receptacle on the BioVision cabinet and the mains power receptacle. Also, if needed, plug a Cat5 or Cat6 network cable into the BioVision and facilities network connection.

## 5.0.0 Quick Start Overview

**Figure 5.0.1**  
BioVision Front Panel



### Basic Imaging Procedures

**Warning:** Use of the BioVision in a manner other than that described in this manual may result in degraded 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 BioVision Quick Start Guide for a summary of system operation.

- Place the specimen(s) in a specimen container provided by Faxitron Bioptics, LLC or your institution and lay it inside the BioVision unit for imaging. The imaging area is designated by an outline on the chamber floor.
- Close the x-ray chamber door.
- Choose or enter a patient in the Vision software and start an image acquisition from the software.
- Press the **Start** (green) button on the BioVision control panel or in the software. This will begin the X-ray exposure.
- Wait until image is displayed.
- Use the track ball pointing device 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 Sections 5.2.0 for more detailed operating instructions.

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

## General Start-up Information

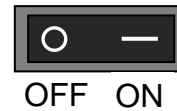
Power-Up (starting the system) is completed one-time at the start of system usage. It is recommended that once the Power-Up sequence has been performed; leave the system ON the rest of the day if planning to use it again.

**Caution:** To prevent draining the battery, plug the BioVision system power cord into an appropriate mains power source.

## System Start-Up Sequence Protocol

### Power Up System

- Ensure main power switch on back of cabinet is turned on. See Figure 5.1.1.
- Press the **Power** button (rectangular grey button on the control panel) until a beep is heard to power “**ON**” the system. See Figure 5.1.2.
- The computer should turn on and boot up by itself. If display appears blank, ensure the monitor is turned on.



## 5.1.0 Power Up Sequence



## 5.1.1 System Start Up

**Figure 5.1.1**  
Main Power Switch



**Figure 5.1.2**  
System Power Button

## Start Vision Software

- “Double Click” the **Vision** icon on the Windows desktop. See Figure 5.1.3.
- An initialization splash dialog box will appear briefly to indicate the software has initialized and is loading.
- The user will be prompted to enter the password. Enter the password and click the **Log In** button. See Figure 5.1.4.



**Figure 5.1.3**  
VISION Desktop Icon

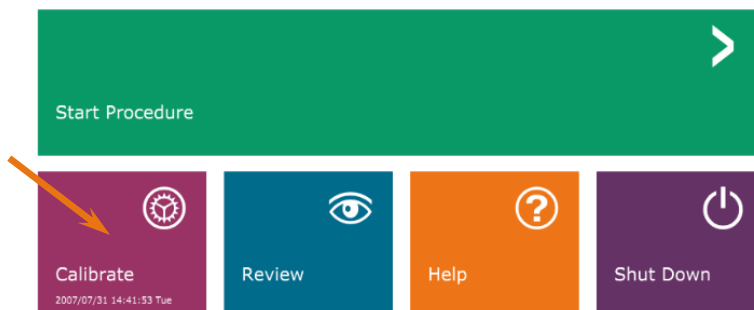
HOLOGIC®  
**Vision**

Password  Type Password Here



**Figure 5.1.4**  
Password Dialog Box

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



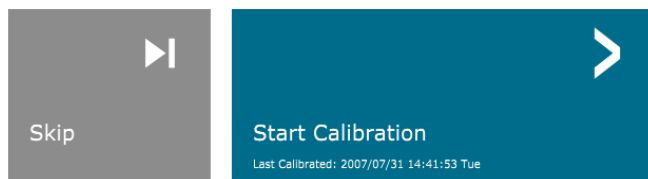
**Figure 5.1.5**  
VISION Home Menu

### Calibration

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

**Caution:** Verify the chamber is empty prior to starting calibration.

- To manually start Calibration, click on the **Calibrate** button in the Main Menu, then click on the **Start Calibration** button. See Figures 5.1.5 and 5.1.6.



### 5.1.2 Calibration



**Figure 5.1.6**  
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. See Figure 5.1.7.



**Figure 5.1.7**  
X-Ray Calibration Dialog box

- The software will automatically go to the Main Menu on completion of the calibration.



## Starting an Imaging Procedure

- From the Home Menu page select the **Start Procedure** button. See Figure 5.1.5.
- The user will be given option to **Select from Worklist**, **Manual Entry**, **Select from Database** or **Continue with current patient**. See Figure 5.2.1.

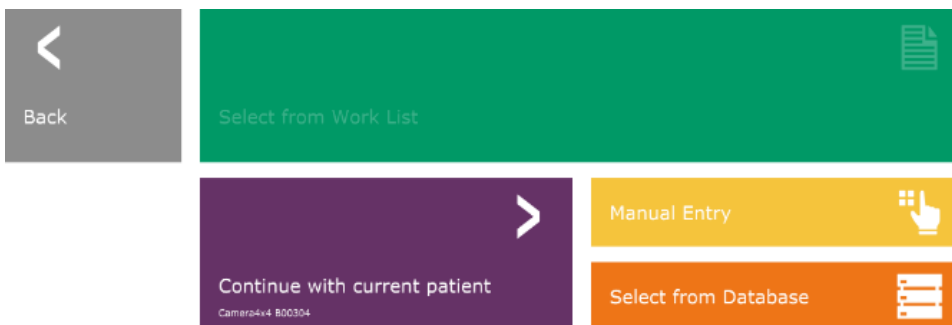


Figure 5.2.1  
Patient Data Entry buttons

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

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

- The “Patient Information Editor” dialog box will open.

**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).

## 5.2.1 Enter Patient Data Manually

Figure 5.2.2  
Imaging Information Editor

- 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 BioVision system:

- Open the X-Ray Chamber door and place the specimen in the image area marked on the floor of the chamber or on the magnification tray, if magnification is desired.
- Press the Green **Start** Button on the system control panel or press the **Start X-Ray** button in software.



- Wait for the image to be displayed.

**NOTE:** The default X-ray mode for the BioVision 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 exposure will be displayed on the BioVision 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 6.3.11, 6.5.0 and 6.6.0 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.**

## Shutdown Procedure

The user may turn off the system using the grey **power** button on the system control panel or through the software.

### Power Button

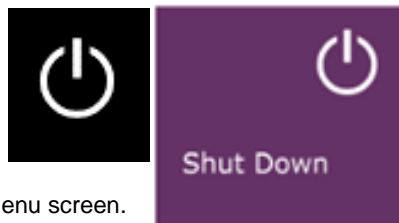
- Press and hold the **power** button until you hear a beep (typically less than 1 second).
- Let go of the **power** button and the system will proceed through a coordinated shut down.
- **NOTE:** Do not hold the **power** button after the beep. This will force a hard computer shut down which could potentially corrupt data.

### Software

The user may turn off the system from within the Vision software.

- Click on the **Shut Down** button, and then click **OK**. This will turn off the computer and system.
- The shut-down can also be selected on the home menu screen or image acquisition screen using the button shown below.

**Shut Down** button from Acquisition screen.



**Shut Down** button from the Home Menu screen.

- Windows shut down will be indicated on monitor screen.
- Monitor will go dark.
- Control Panel LEDs and LCD will go out.

## 5.2.2

### Starting Exposure

**Figure 5.2.3**

Start X-Ray button (Software)

## 5.3.0

### Shutting Down the System



**Figure 5.3.1**

System Shut Down buttons

# Faxitron™ OR and BioVision+

Specimen Radiography System

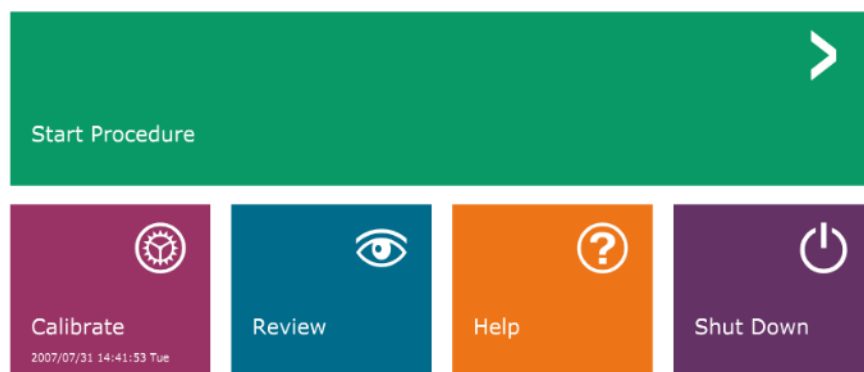
# 6

## SECTION 6 VISION Software Operation

Vision Software is a complete image acquisition and processing package, designed exclusively to work with Faxitron Bioptics X-Ray Generators (such as VersaVision, Faxitron Path, Faxitron Core and BioVision 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 BioVision's computer.

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**  
Faxitron 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 BioVision System power on using the switch on the back of the system. (The power switch is above the power cord receptacle). Depress “1” for “Power ON” and “0” for “Power OFF”.
- Press the **power** button (rectangular grey button) on the control panel until a beep is heard. Let go of the button. The Power LED and the LCD on the control panel should illuminate.
- The system computer should turn on and boot up by itself. If the system monitor appears blank, ensure the monitor is turned on.
- Double click the **Vision Software** icon on the Windows desktop. Refer to 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.



**Figure 6.1.1**  
Vision Software Desktop Icon

## 6.1.0 Software Start-up

## 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 Faxitron 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 and 6.2.2. The Dialog will display a status message during calibration. See Figure 6.2.3.

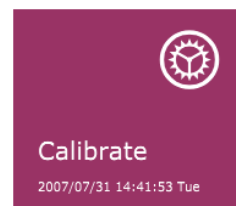


Figure 6.2.1  
Home Menu Calibrate button

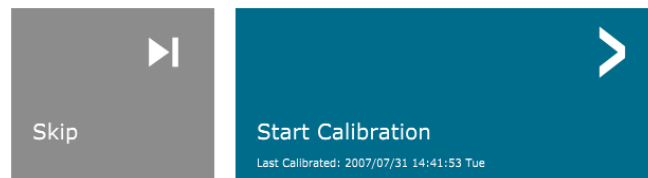


Figure 6.2.2  
Start Calibration button

ENSURE THE CHAMBER IS EMPTY BEFORE CALIBRATION

Calibration before beginning any procedure is recommended



Figure 6.2.3  
Calibration Status

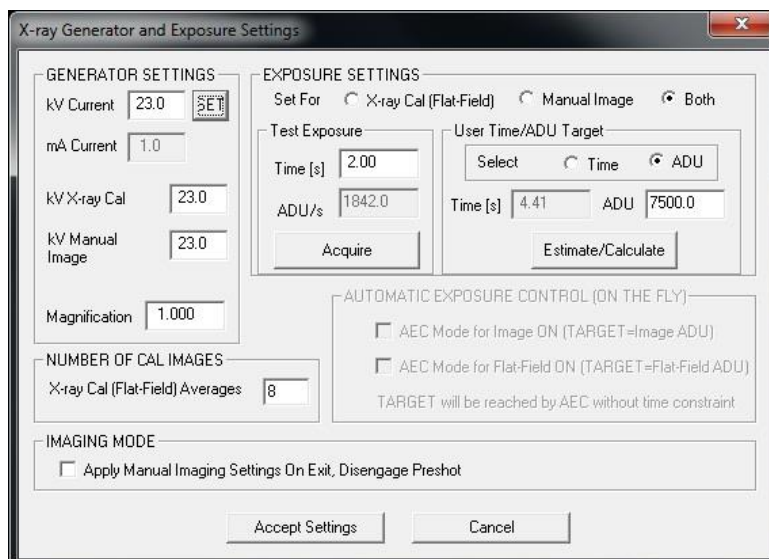
During calibration, X-Rays may be generated. During X-Ray generation, a **Stop X-Ray** button will be made visible to allow a user the option to stop X-Ray through software.

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.
- Set a "Magnification" or leave as the default setting of one (1.0).
- 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 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.

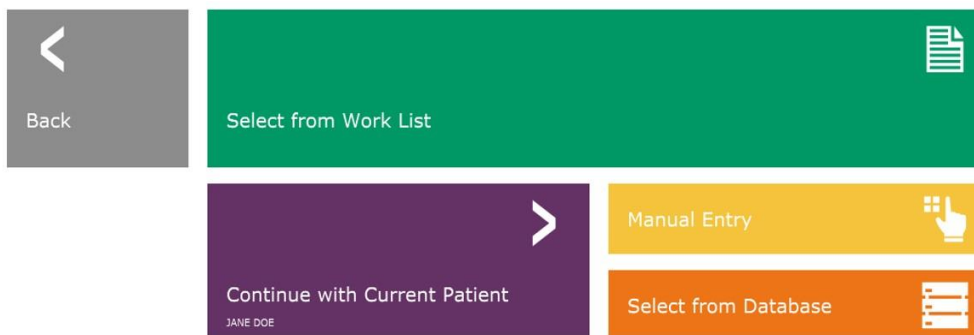
After the selection of either "X-Ray Cal (Flat-Field)" and "Manual Image" and the ADU level has been set, select the **Acquire** button. For the "Manual Image" selection, it is desired to have the object or X-Ray attenuator in the X-Ray beam. Press the **Acquire** button to generate X-Rays and obtain 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.



**Figure 6.3.1**  
Patient Data Entry screen

## 6.2.0 Cont.

## 6.2.1 Advanced Calibration

## 6.3.0 Patient Data

## 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

Patient ID	Accession #	Patient Name	Birth Date	Sex	Modality	Perf. Physician	Ref. Phys. ID	Ref. Phys. Priority	Stn. Station AE Title	Stn. Proc. Start Date/Time	Perf. Phys.
AV25671	00001	KRISTY*KAATLYN	1676/03/04	F	MG	SMITH	RP4542234	LOW	FAXITRON_OR	2019/03/28 08:58:07	JOHNSON
AV25672	00002	GARCIA*MAKIA	1676/03/04	F	MG	NEWMAN	RP48899429	HIGH	FAXITRON_OR	2019/03/28 16:07:00	ROSS
AV25673	00003	SMITH*HARRY	1676/03/04	F	MG	FALK	RP56567	HIGH	FAXITRON_OR	2019/03/28 13:55:58	CONARD
AV25674	00004	HOUSTON*CARLA	1732/04/31	F	MG	MILLER	RP54265	LOW	FAXITRON_OR	2019/03/28 16:57:09	METER

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

**Figure 6.3.2**  
Modality Worklist Search Dialog

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 Faxitron 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

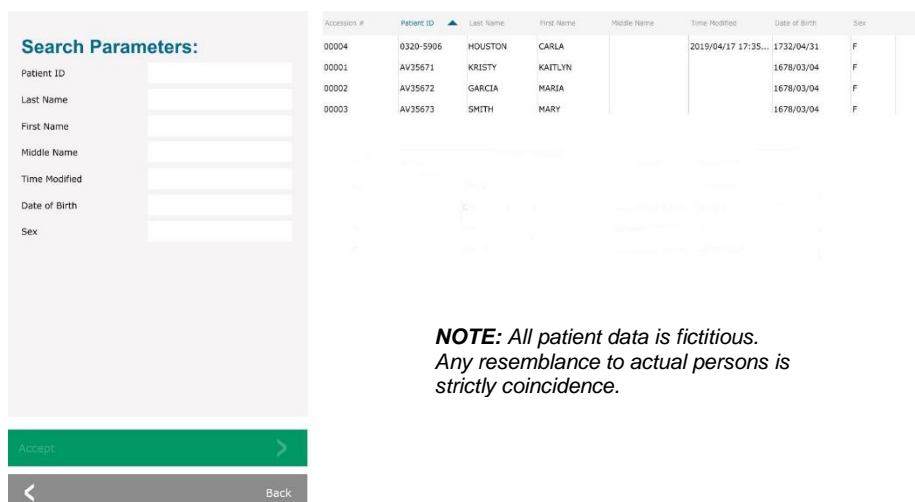
Click on this button to **manually** enter a new Procedure. The "Imaging Information Editor" will open. See Figure 6.3.3. Follow the above procedure and notes

## 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.

### 6.3.4 Select from Database



**Figure 6.3.4**  
*Selecting Patient From Local Database Entries*

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

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 BioVision 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 dialog box is titled "Patient Information" and is divided into three sections: Patient Information, Procedure Information, and Study Information. At the bottom, there are two buttons: "Close Dialog" and "Start a New Patient or Procedure".

Patient Information	
Patient Name:	* Jane Doe
Patient ID:	* JD4587
Accession #:	* 918273
Date of Birth:	1920/03/20
Sex:	
Procedure Information	
Procedure Name:	
Laterality:	* L
Position View:	
Body Part:	
Refer. Physician:	
Technician:	
Technician ID:	
Study Information	
Study Name:	
Study ID:	

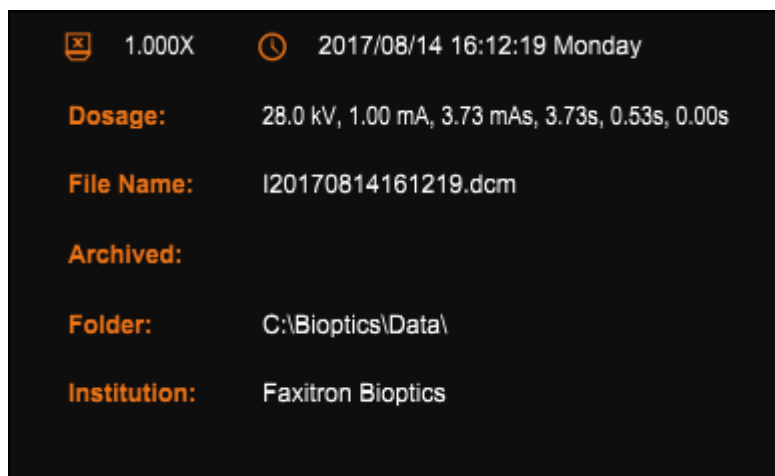
## 6.3.5 Cont.

**Figure 6.3.7**  
Patient Information Dialog after Image Acquisition

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..



**Figure 6.3.8**  
Image Properties dialog



The dialog box displays the following information:

1.000X	2017/08/14 16:12:19 Monday
<b>Dosage:</b>	28.0 kV, 1.00 mA, 3.73 mAs, 3.73s, 0.53s, 0.00s
<b>File Name:</b>	I20170814161219.dcm
<b>Archived:</b>	
<b>Folder:</b>	C:\Bioptics\Data\
<b>Institution:</b>	Faxitron Bioptics

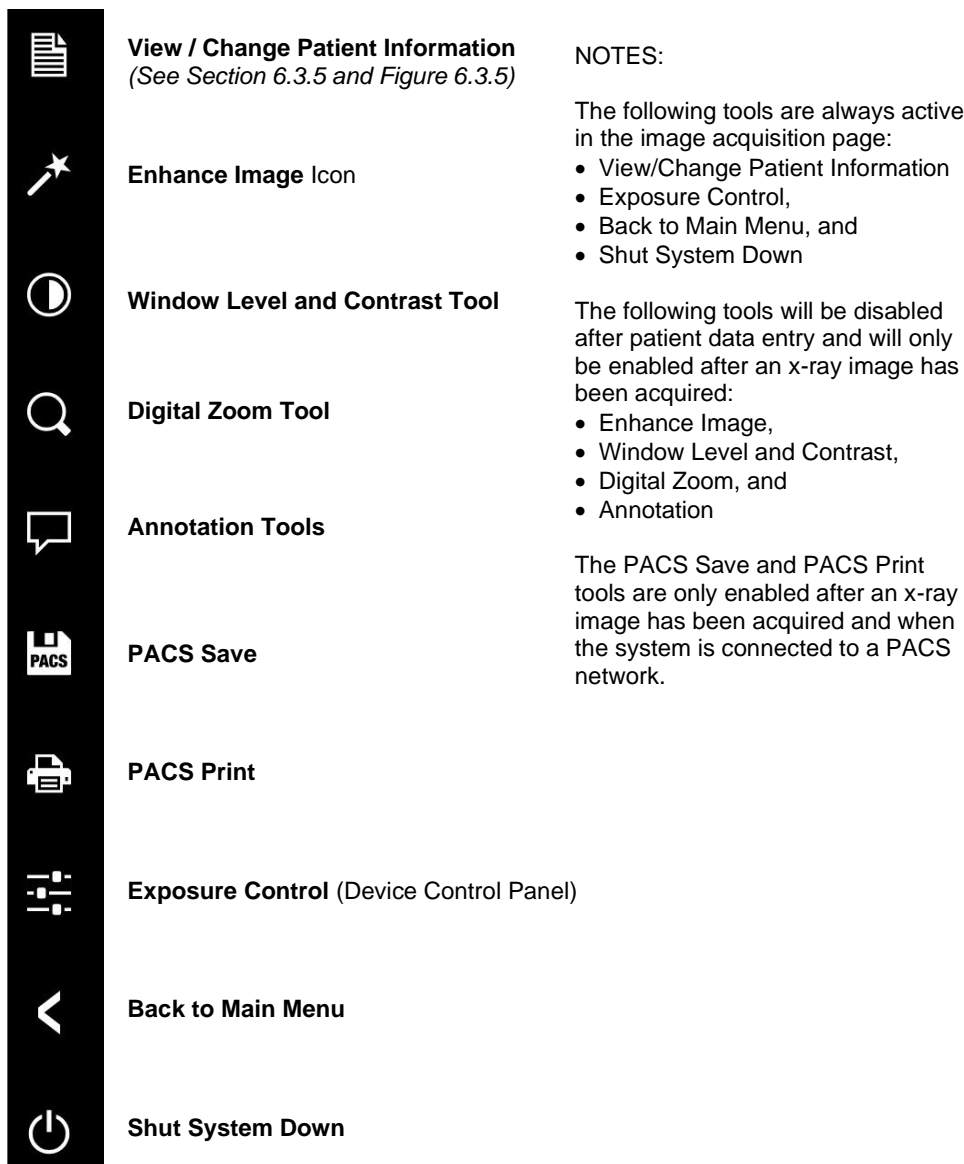
**Figure 6.3.9**  
Image Properties (View Only)

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.

Vision software provides single click access to a number of commonly used tools or functions with a vertical tool bar located on the left side of the screen. More detailed descriptions follow in the next pages. See Figure 6.4.1.

## 6.4.0 Tool Bar and Menus

### 6.4.1 Side Tool Bar



**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, Faxitron 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.

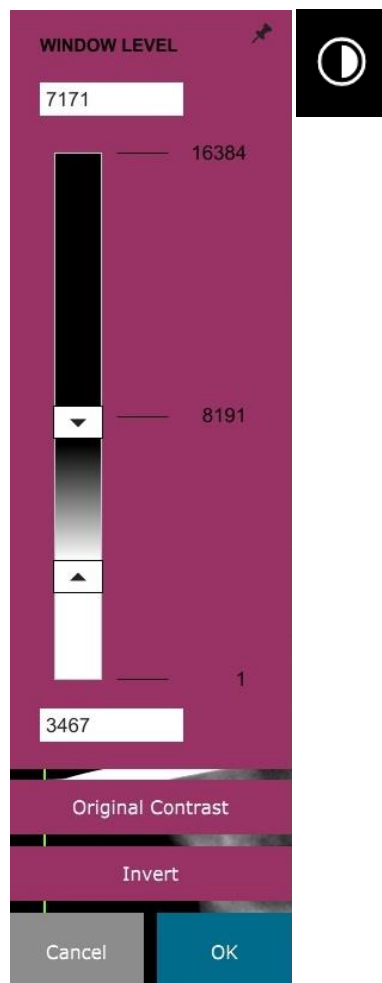
The system will be idle (in Standby) during the processing, once completed the button will stay depressed/active. The user can undo the process, by pressing the button again.

## 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 and vice versa. See Figure 6.4.4 below.

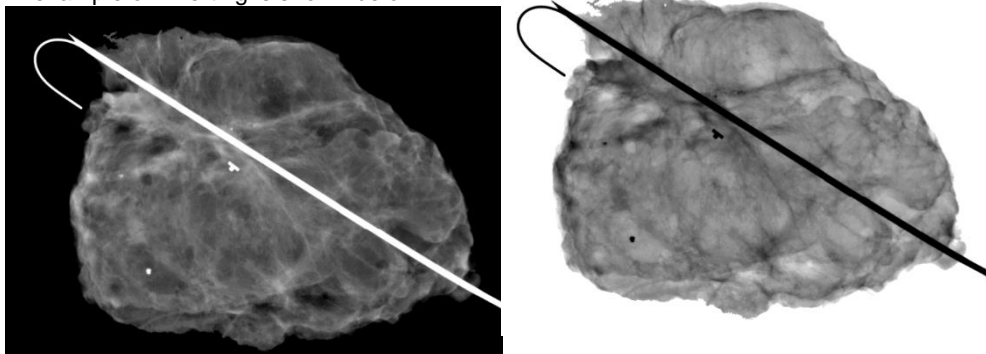
### 6.4.1 Cont.

**Figure 6.4.3**  
Window Level and Contrast Tool icon and controls



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 any of the indicated 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.").

An example of inverting is shown below:



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

## Dynamic Zoom Adjustment

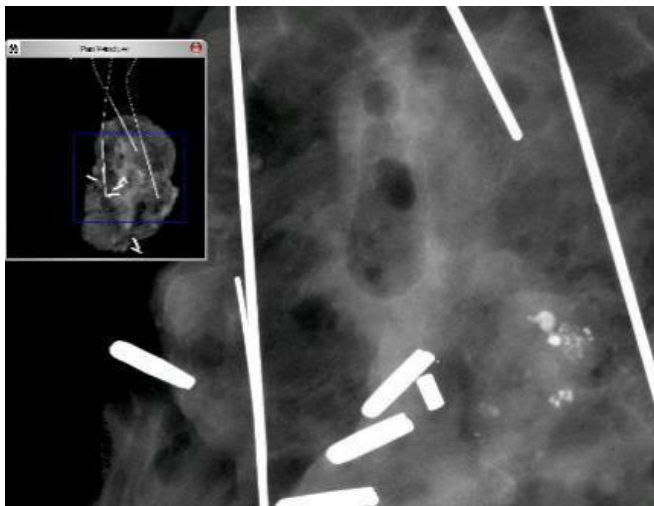
### 6.4.1 Cont.

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.

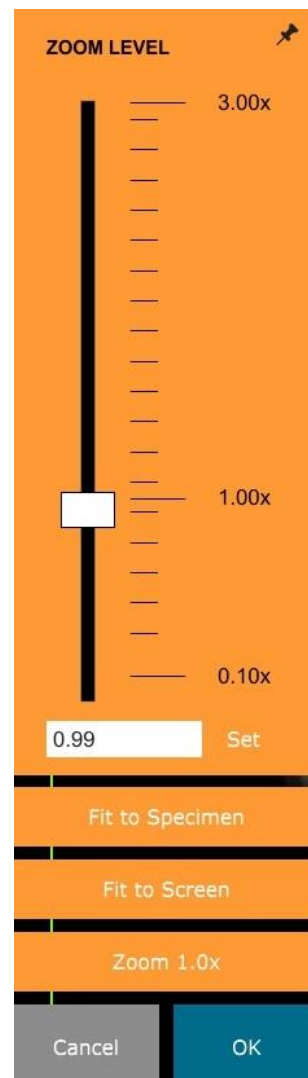
Note that traditionally, this feature is also called "Pan View" and/or "Pan and Scan."



**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 as 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.



### 6.4.1 Cont.

**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.



**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

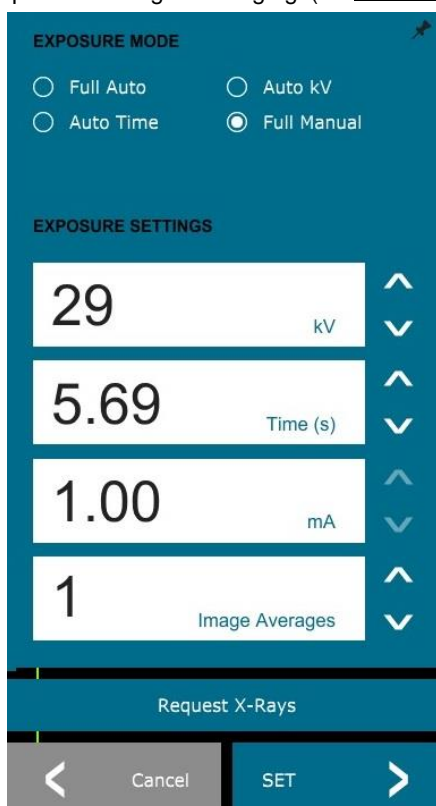
The button shown in Figure 6.4.11 will open the Device Control Panel, which allows the device user the convenience of controlling the X-Ray system through the software. The user can easily select the Exposure Mode, X-Ray Tube kV setting, Exposure Time and the number of images to acquire for Image Averaging (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 that kV, Time, and Image Averages are all active. The user can adjust each of these settings.



**Figure 6.4.12**  
Device Control Panel

Note that the mA setting in the BioVision system is not adjustable via the software. The mA settings will always show as 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.

## 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 system.



**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.



**Figure 6.4.15**  
Top Menu Bar

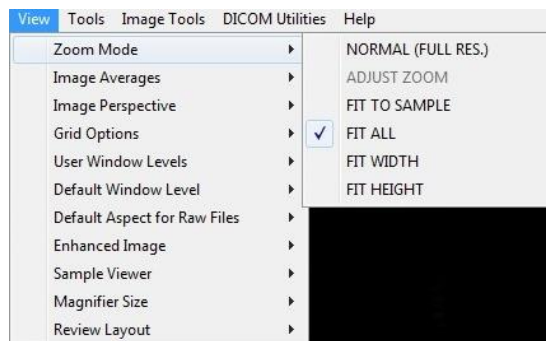
**Note:** The **arrow** will point down when the Top Menu Bar is hidden and will point up when it is displayed.



**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 sub-menu item will be described in more detail in the following pages.



**Figure 6.4.17**  
View Menu

### 6.4.2 Top Menu Bar

### 6.4.3 View Menu

## Zoom Mode

6.4.3 Cont.

### Normal

Displays the acquired image in its native format. The image in BioVision systems exceeds the monitors display area. A thumbnail dialog box will be displayed in the top left corner of the image which allows the user to “pan” the image. 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.

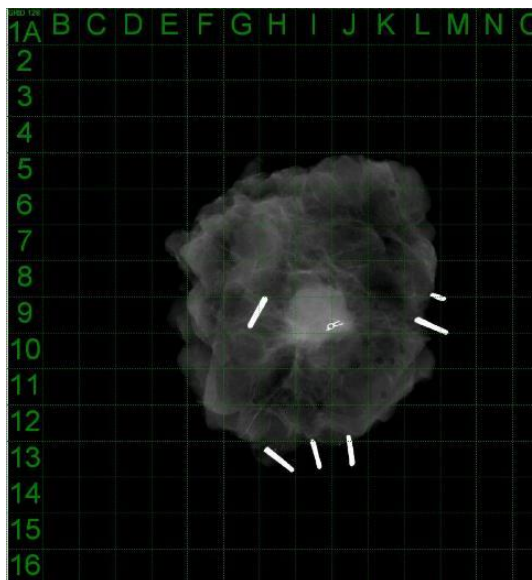


Figure 6.4.18  
Sample grid display

### 6.4.3 Cont.

### 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" tools, select the "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 of 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 tissue located near the periphery of the sample.

### Sample Viewer

In the event that the system has a web camera, this toggles the systems' web camera viewer to allow for specimen orientation and alignment.

## 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.

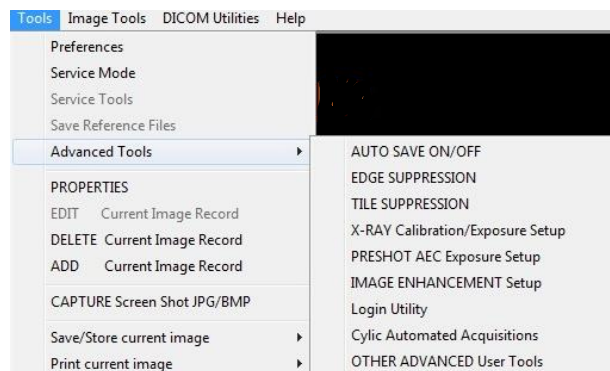


Figure 6.4.19  
Tools menu

## Preferences

The “Preference” 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 Faxitron 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 Faxitron 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” offers 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 BioVision 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, shown on the next page, will open.

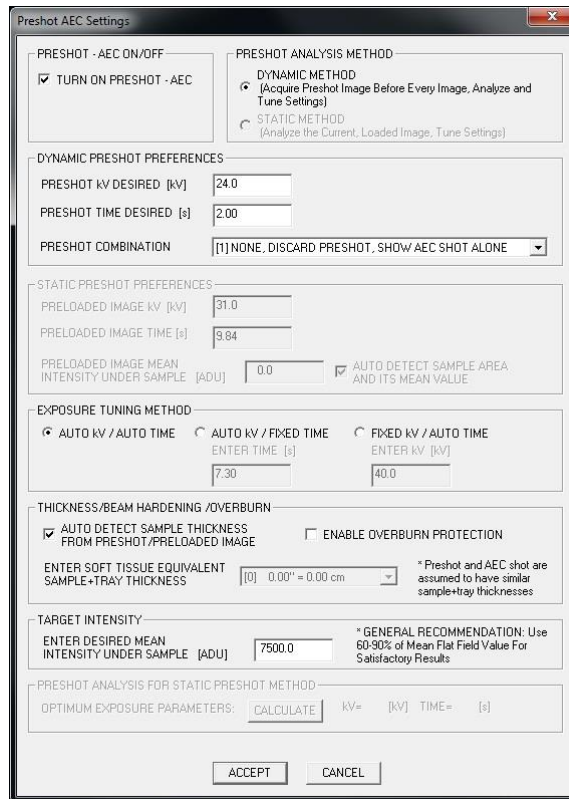
Enter the PRESHOT AEC values in the window shown at right.

The settings shown reflect a 24 kV and 2 second exposure time with a target intensity of 7500 ADUs for the pre-shot setting. Users can enter the selection of pre-shot parameters only with the selection of DYNAMIC METHOD in the ANALYSIS METHOD section. The STATIC METHOD selection will use Faxitron 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 BioVision 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 Vision Login Utility is located under the “Advanced Tools” menu and allows the user to change the Vision software start-up password. When the software is opened the user will be prompted to enter a password. The program will close if the correct password is not entered.

**NOTE:** The Vision password authentication is used in-lieu-of a physical key on the BioVision system. It is set to on at the factory and cannot be turned off by the user.



**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

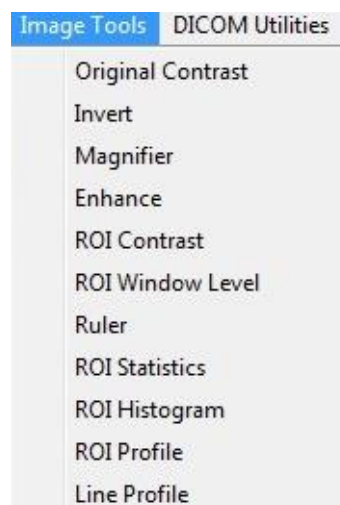
The user may "browse" to the directory or file folder, to which the image is to be saved. A file name must be assigned in the field provided. Select a file type to save the image as. There are many file types provided. To save the file in a DICOM format, please refer to the "DICOM Functionality" section.

### 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.

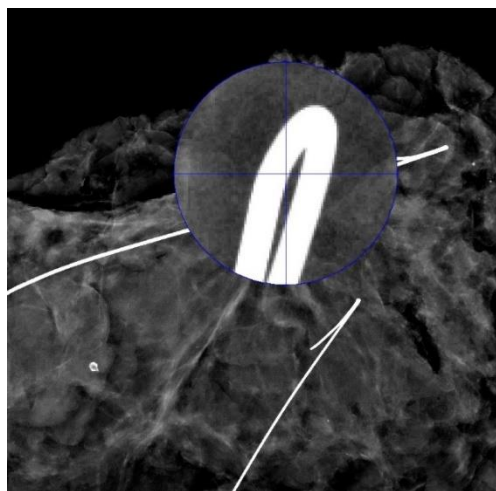
“*Original Contrast*” restores the image contrast levels. This serves the same purpose as the **Original Contrast** button in the Window Level and Contrast tool. See Section 6.4.1 and Figure 6.4.3.

### 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. Grays 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 Section 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 to the right. Click “Ruler” again to turn off the feature.

**Hint:** To get a perfectly straight line or a line at a perfect 45 degree angle, hold down the SHIFT key (on the keyboard) while holding down the left-mouse button and drag.

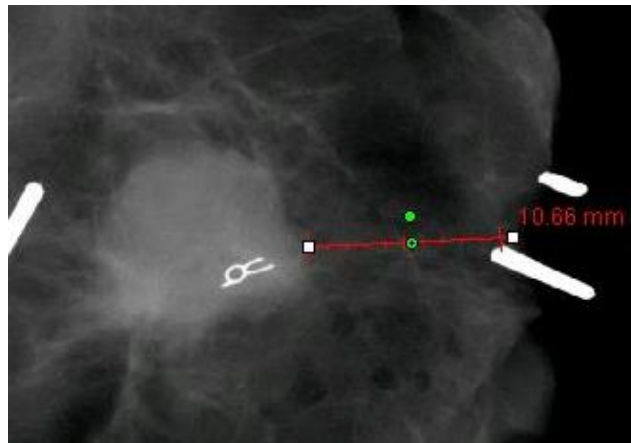


Figure 6.4.24  
Ruler

## 6.4.5 Cont.

## 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, 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.

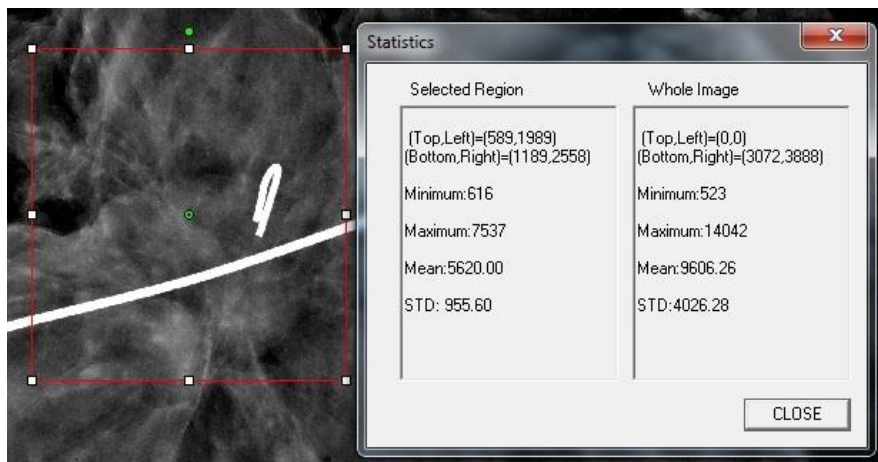


Figure 6.4.25  
ROI Statistics

## ROI Histogram

### 6.4.5 Cont.

“*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. A histogram 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.

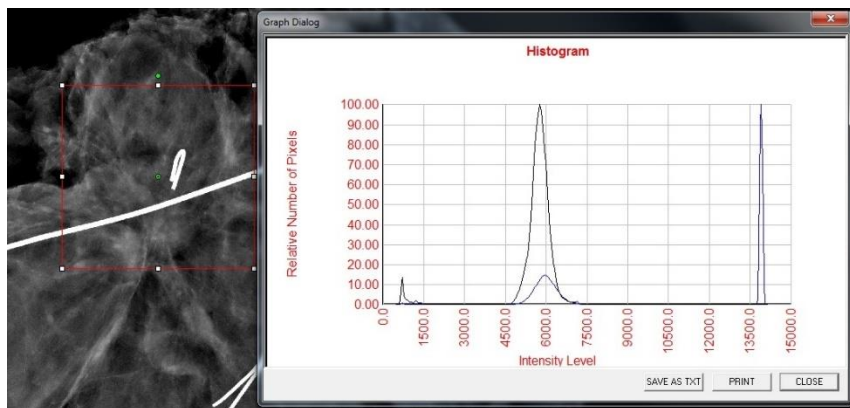


Figure 6.4.26  
ROI Histogram

## 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.

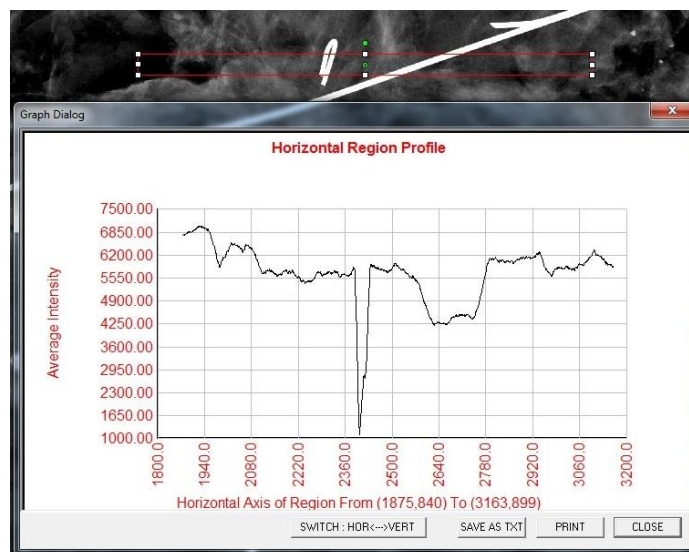


Figure 6.4.27  
ROI Profile

## 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 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.

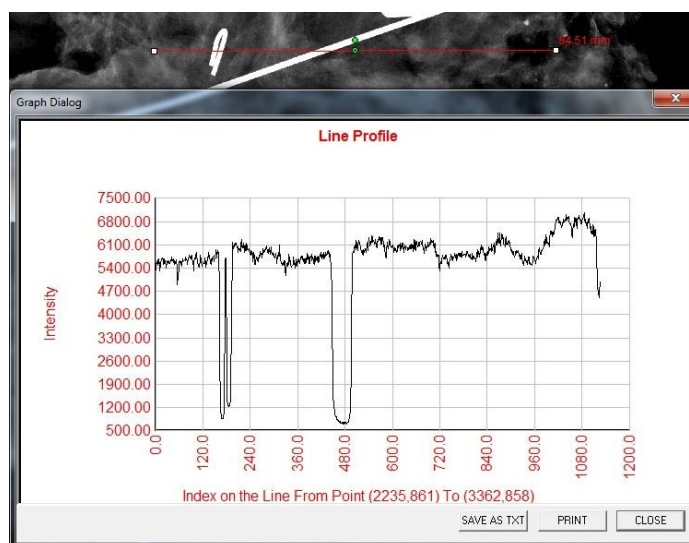


Figure 6.4.28  
Line Profile

## 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.

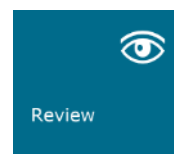
The thumbnail strip supports drag and drop operations to place images into the image display or review panes as necessary.

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 Figures 6.0.1 and 6.6.1.

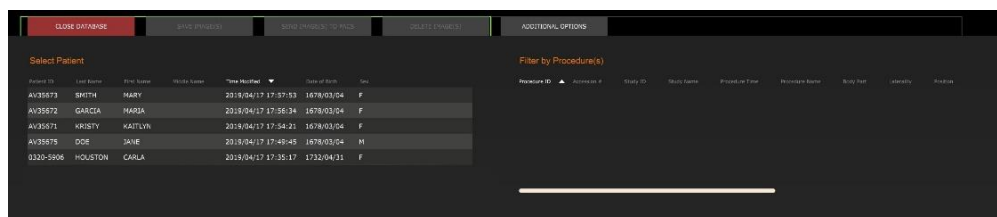
Review mode can be entered by clicking the **Review** button in the Home Menu page, Figures 6.6.1 and 6.0.1, or the **Open Database** button in the Current Image Browser. See Figure 6.5.3 above. Clicking either of these buttons will open the Database as shown in Figure 6.6.2. The system will be in Standby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



## 6.6.0 Database

**Figure 6.6.1**  
Review Mode icon displayed on  
the Home Menu

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



**Figure 6.6.2**  
Image Database

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

## 6.6.0 Cont.

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. It is not possible to select multiple patients.

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

The same options as available in the Current Patient Images Browser (see Figure 6.5.2) are also located at the top of the Database. However, additional options are also made available, 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.

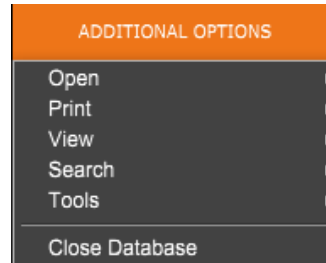
The window level of the saved image is the default window level. If the user requires that the window level be arranged, he/she should load the image to the Image View and print from there rather than printing from database dialog.

### Send Image(s) to PACS

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

### 6.6.1 Cont.

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)

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. By 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 on 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 DB-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.



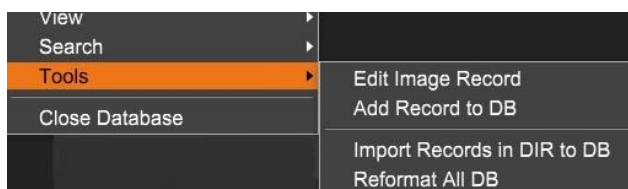
## Stop Search

### 6.6.1 Cont.

"*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*

## 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 to 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

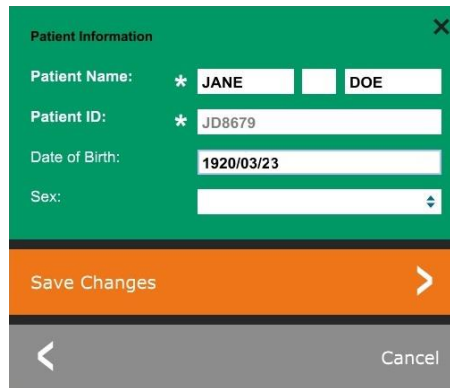
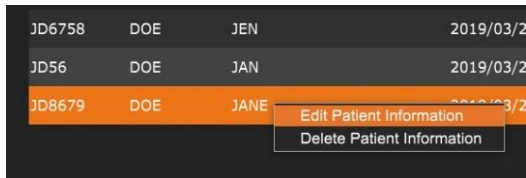
"*Reformat All DB*" tool helps to reformat Date [YYYY/MM/DD], Date/Time [YYYY/MM/DD HH:MM:SS] fields of tables, and also capitalizes letters of entries for some other fields. It is a useful tool when some older database file is imported and opened for the first time, or when the user alters database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

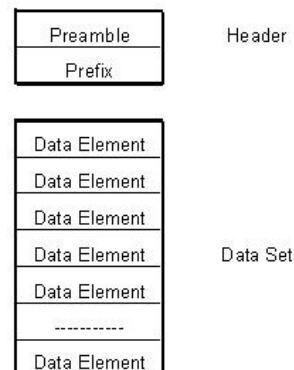
## The DICOM Standard

### 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:



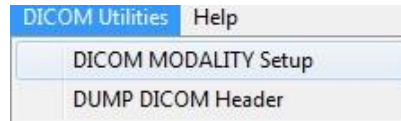
**Figure 6.7.1**  
DICOM Protocol Structure

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.

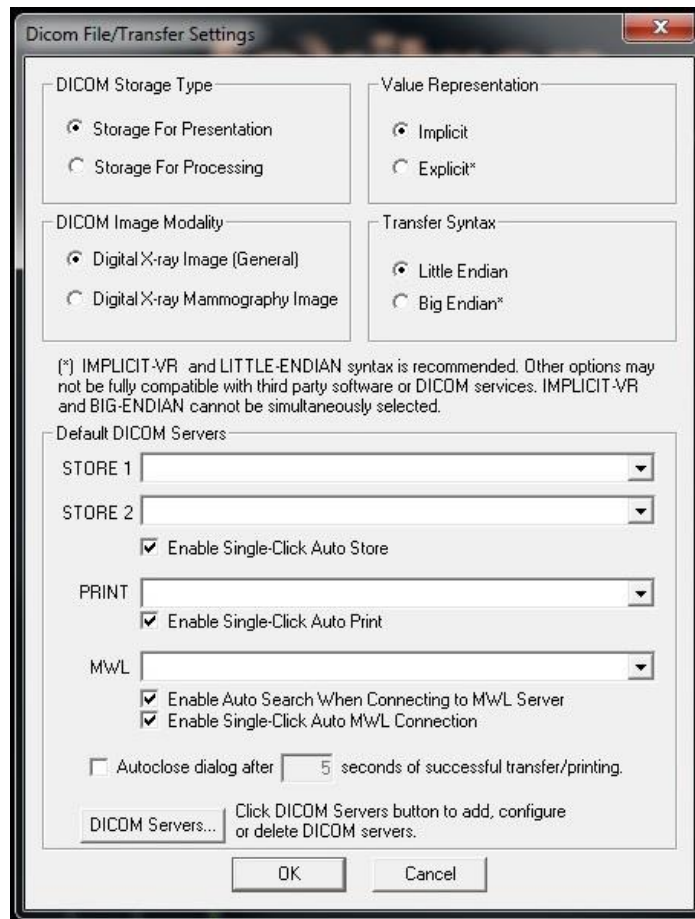


Figure 6.7.3  
DICOM Modality Settings  
Default settings shown

**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, 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/directly, right click anywhere in the image. This will display the dialog box show 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 directly/folder, enter the file name and click **Save**.

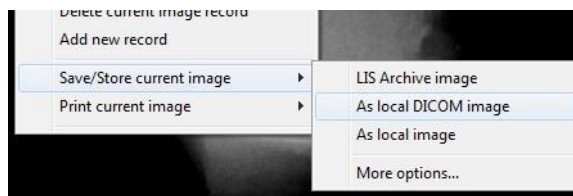


Figure 6.7.4  
Save Current Image Dialog

## 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.

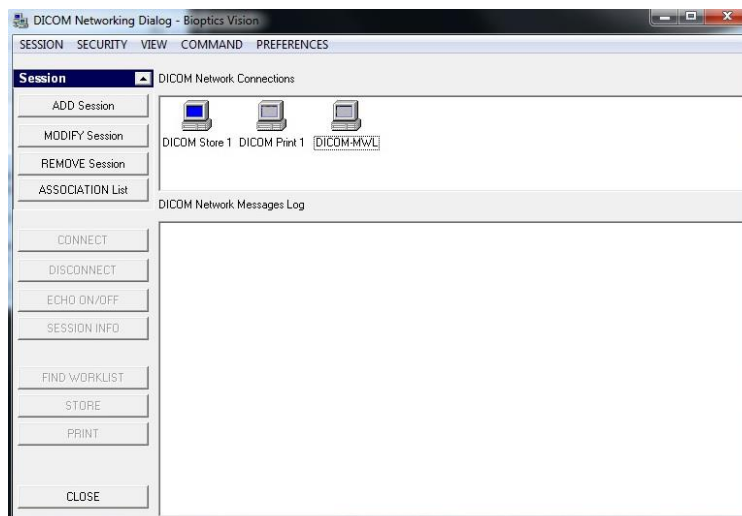


Figure 6.7.5  
DICOM Networking Dialog box

## 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.

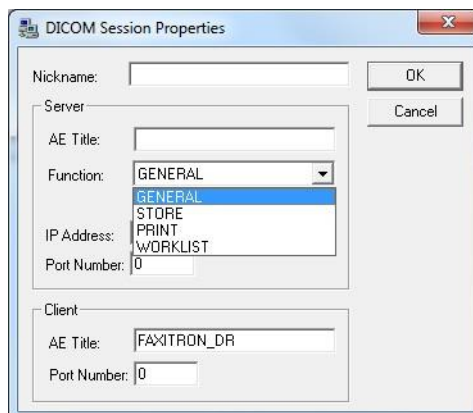
To create a new connection configuration to a remote DICOM AE, the user must have the following information available: the Application Entity Title (AE Title), the choice of DICOM / PACS "function to perform", the IP Address and the Port Number for the Sever (i.e. the DICOM printer or PACS system).

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 that 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 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.

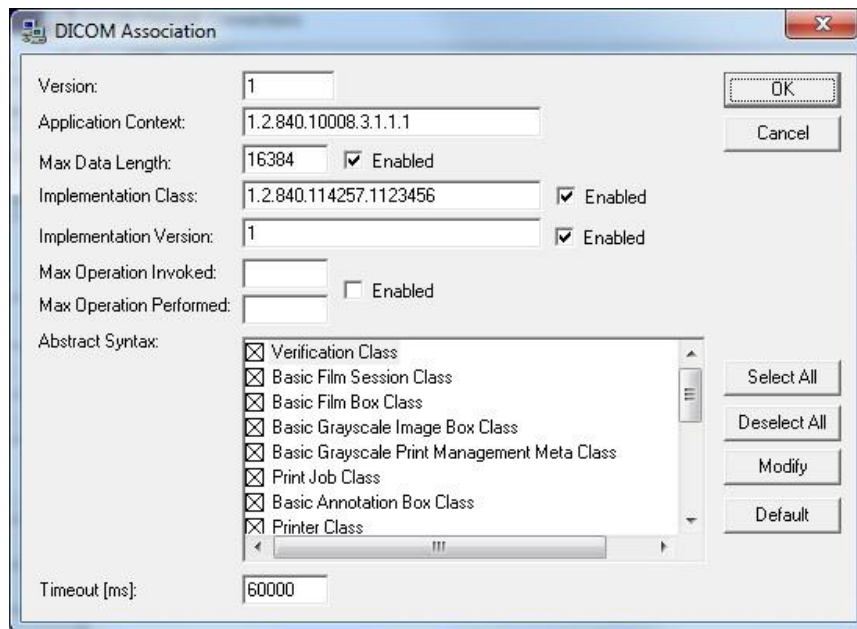


**Figure 6.7.7**  
*Verifying Removal of an Existing  
DICOM Network Connection*

## Association

## 6.7.0 Cont.

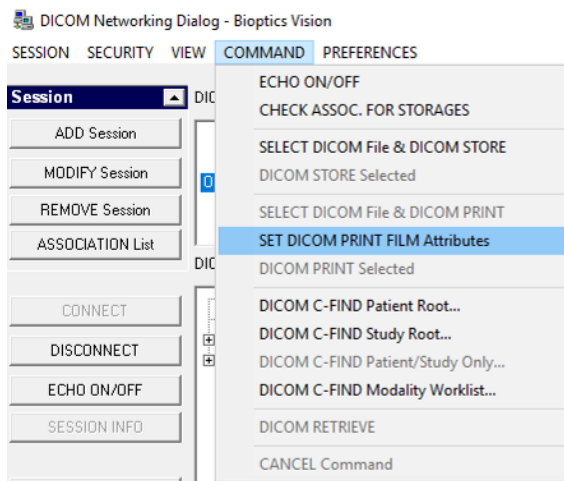
The **Association List** button opens the Association Dialog box, depicted below, through which the user can edit the parameters and protocols used by the Vision software when negotiating a connection with a remote DICOM AE. These options should only be modified by an advanced user familiar with DICOM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

DICOM Printer Setup

Medium Type: Blue Film

Print Priority: High

Number of Copies: 1

Film Destination: Magazine

Film Orientation: Portrait

Empty Image Density: Black

Border Density: Black

Magnification Type: REPLICATE

Film Size ID: 8INX10IN

Polarity: Normal

Smoothing Type: Medium

Film Density

Max Density: 415

Min Density: 0

Image Display Format

STANDARD  Slide

C: 1 R: 1

Default OK Cancel

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

## Operation

To begin annotating, select the **Annotations** tool icon 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

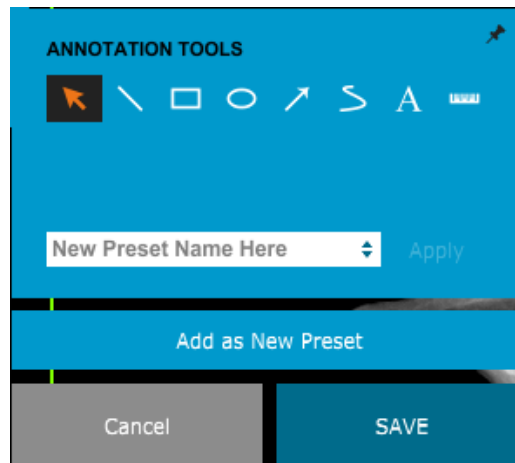
**Figure 6.8.1**  
Annotation Icon

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.

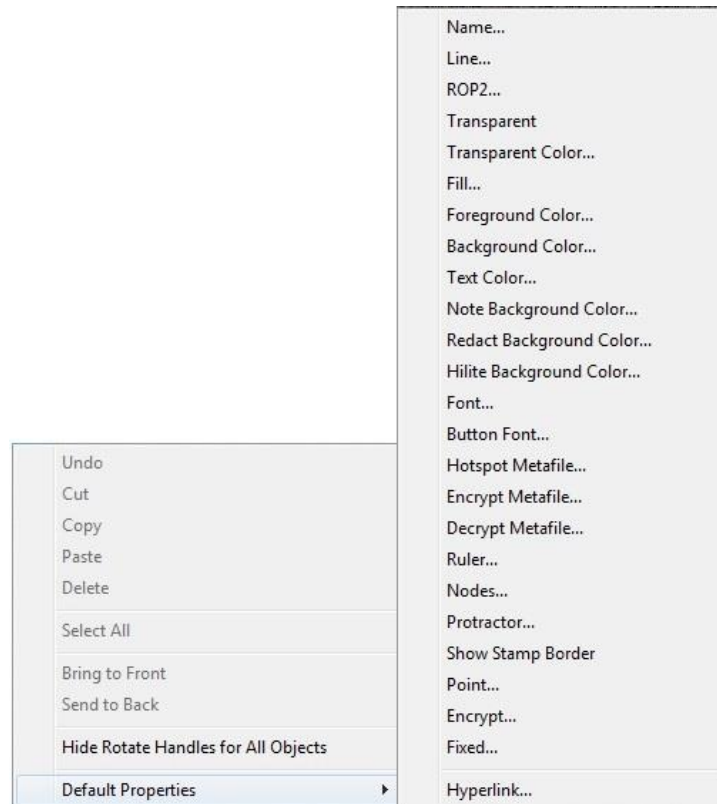
## 6.8.0 Cont.

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 mouse, 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 mouse, 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 mouse, 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 mouse, 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 mouse, 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 orthogonal to each other.

## Design Mode and Mouse Right-Click Menu

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.

### 6.8.0 Cont.



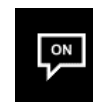
**Figure 6.8.3**  
Right-click Mouse Context Sensitive Menu (Only During Design Mode of User Annotations)

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.

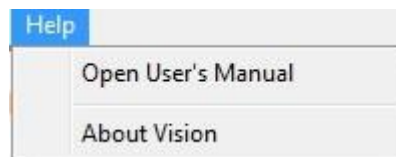
## Show - Hide Annotations

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

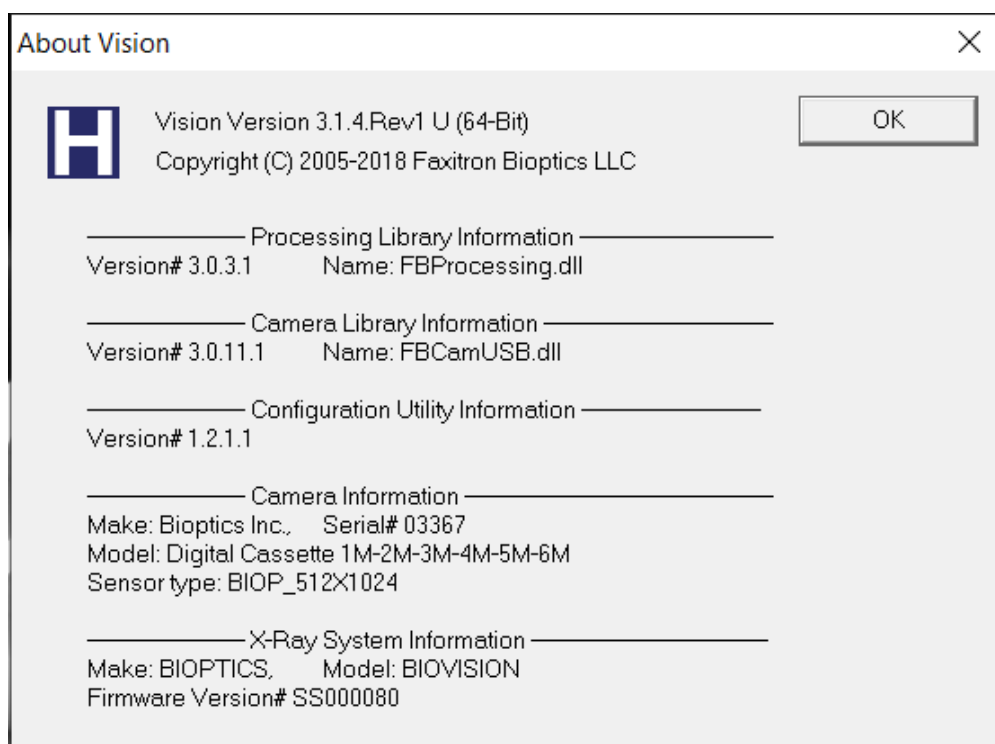
The “*Help*” sub-menu, see Figure 6.9.1, is located on the top menu bar and provides quick access to the BioVision “*User’s Manual*” and “*About Vision*”. Refer to Figure 6.10.1.



## 6.9.0 About Help

**Figure 6.9.1**  
*Online Help Dialog Box*

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



## 6.10.0 About Faxitron Vision Software

**Figure 6.10.1**  
*About Faxitron Vision Information  
Dialog Box*

## Revision History

Revision	Date	Description of Change	Author/Originator	Approved by
2.0.2	April 2010	Initial BioVision Users Manual	Unknown	Unknown
3.0	7-23-2012	<ul style="list-style-type: none"> <li>• Changed Document # from 1043C to 05-5280-04</li> <li>• Changed title from “Advanced User Manual for the Bioptics BioVISION” to “BioVision Users Manual”</li> <li>• Changed name on title page to Faxitron.</li> <li>• Changed all company references from Bioptics to Faxitron Bioptics.</li> <li>• Deleted Sections 3 &amp; 6. This material covered in other sections.</li> <li>• Deleted Sections 7 &amp; 8. This material covered in BioVision Technical Manual.</li> <li>• Insert New Section 2: Radiation and X-Ray Radiation Safety</li> <li>• Insert New Section 3: About Your BioVision.</li> <li>• Substantial Revision made throughout remainder of document.</li> </ul>	Alan Mihalko	Akif Baysal
3.1	11-12-2013	Changed 1 <sup>st</sup> paragraph of Section 3.0.0 on page 17 to match 510(k) Indications for use.	Alan Mihalko	Akif Baysal
3.2	2-4-2015	Updated images throughout manual to reflect current BioVision color scheme and company logo. Added Revision History Table	Paul Hess	Mikhail Viznyuk
3.3	07-23-2015	<p>Pg 21. Correction of notation of components</p> <p>Pg 78. Typo correction of figure.</p> <p>Pg 81 Replaced PACS print image</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 103. Deletion of repeat text.</p> <p>Pg. 109 Correction of references</p>	Paul Hess	Mikhail Viznyuk

# Faxitron™ OR and BioVision+

Specimen Radiography System

3.4	07-06-2016	<p>Pg 59 Corrected label for Figure 5.2.18</p> <p>Pg 64 Minor corrections to 'sequence protocol'</p> <p>Pg 64 Corrected Figure Reference in section 6.5.0</p> <p>Pg 97 Deleted extra 'period' from Figure 6.6.4</p> <p>Pf 98 Deleted extra 'period' from Figure 6.6.5</p> <p>Pg 100 Deleted extra 'period from Figure 6.6.8</p>	Alan Mihalko	Mikhail Viznyuk
4.0	21-Jan-16	<p>Updated to include BioVision Plus – all sections.</p> <p>P7 Indications of Use added</p> <p>P7 Authorized EU REP added and CE mark</p> <p>P18 Location information added to allow for ventilation and access to power cord</p> <p>P19 System warnings, precautions and cleaning instructions added</p> <p>P22 BioVision+ pictures and SIDs added</p> <p>P24 BioVision+ tube picture included</p> <p>P25 BioVision+ HVPS picture added</p> <p>P40 Additional notes added to regulatory requirements.</p>	Paul Hess	Ciaran Purdy
5.0	19-Mar-18	<p>Major Revision for release of updated software. Sections 5 and 6 affected the most. Other sections updated as needed and to reflect new branding.</p> <p>Updated the manuals pagination.</p> <p>Deleted Index from manual.</p>	Mikhail Viznyuk	Ciaran Purdy
051	07-16-2019	<ul style="list-style-type: none"> <li>• Section 0 updated to include Indications for Use</li> <li>• Authorized EU Rep updated in Section 1</li> <li>• Updated Sources of Radiation Dose chart in Section 2</li> <li>• Section 3 – added DICOM version info and Heat Output</li> <li>• Section 4 – added Interoperability and Cybersecurity info</li> <li>• Section 5 – Streamlined and re-organized section.</li> </ul>	Alan Mihalko	<p>S. Howerton</p> <p>J. Mudd</p> <p>D. Canny</p> <p>D. Saraiya</p> <p>R. Nash</p> <p>T. Longo</p> <p>M. Fremont</p>

# Faxitron™ OR and BioVision+

Specimen Radiography System

		<ul style="list-style-type: none"> <li>▪ Deleted material that was not directly related to basic operation of the system.</li> <li>• Section 6 – Re-organized numerous sub-sections for more logical progression,</li> <li>▪ Revised Start-up sequence</li> <li>▪ Revised Camera Calibration section</li> <li>▪ Changed flow of Patient Data</li> <li>▪ Revised various sub-sections for clarity.</li> <li>• Updated screenshots</li> </ul>		
052	12/03/2019	Updated branding	Dhaval Saraiya	C. Purdy D. Saraiya R. Nash M. Fremont D. Canny S. Howerton T. Longo