



User's Manual

BioVision

Document #: 05-5280-04

Version: 3.0

12 June 2012

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Printed: May 2012

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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 BioVision hardware and the Vision Software System, both developed by Faxitron Bioptics LLC.

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



1

SECTION 1
User's Manual
BioVision

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

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

Thank you from all of us at Faxitron Bioptics LLC.

Additional Information

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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 Bioptics 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.



1.0.0 Introduction

1.1.0 Warning and Caution Symbols in this Manual



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 posses a great deal of energy.

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

Sources of X-Ray radiation in medical facilities include:

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

Cabinet X-ray machines. Cabinet x-ray machines are enclosed, 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.

2.0.0 Introduction

2.1.0 X-rays

2.2.0 Sources of Radiation

2.2.0 Cont.

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.

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

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

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

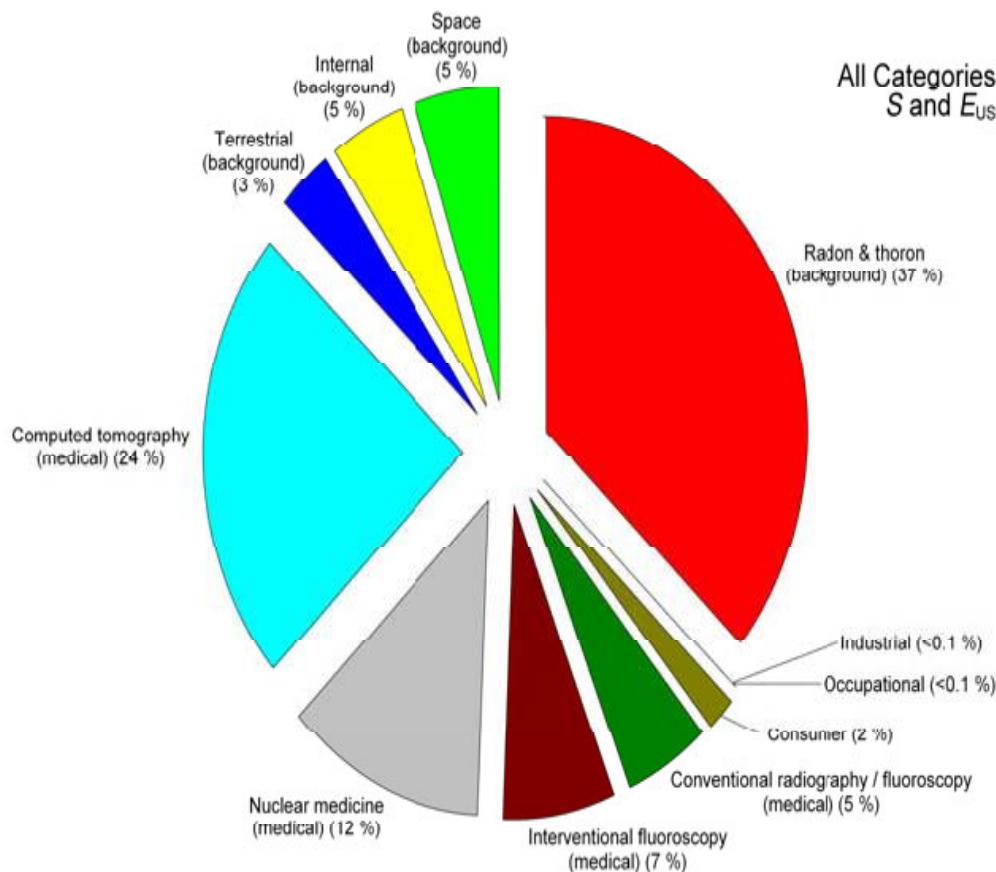


Figure 2.2.1
Sources of Radiation Dose in the United States.

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

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

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

2.3.0
**Biological Effects
of Radiation**

2.3.1
**Deterministic and
Stochastic Effects**

2.3.1 Cont.

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.

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 relative low radiosensitivity. Also, radiosensitivity is greatest during the fetal stage and becomes progressively smaller through adolescence and adulthood.

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

2.3.2 Radiosensitivity

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).

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.

2.3.3 Risks from Radiation Exposure

2.3.4 Conclusions on Health Risks

2.4.0 ICRP Dose Limits

ICRP Recommended annual dose limits for individual organs or tissues

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

1 The limitation on effective dose provides sufficient protection for the skin against stochastic effects. An additional limit is needed for localised exposures in order to prevent tissue reactions.

2 Averaged over 1 cm² area of skin regardless of the area exposed.

2.4.0 Cont.

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

2.5.0

Risk Management

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.

REFERENCE SOURCES

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3

SECTION 3 About Your BioVision System

The **BioVision Digital Specimen Radiography (DSR) System** is a stand-alone cabinet digital X-ray imaging system intended to provide rapid verification that the correct tissue has been excised during percutaneous biopsy.

Performing the verification directly in the same biopsy procedure room enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls. This device is intended to be operated wherever the medical professionals deem appropriate, including a surgical suite or a room adjacent to a surgical suite.

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

Service

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

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Troubleshooting

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

SCHEDULE OF MAINTENANCE

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

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.

3.0.0 Overview

3.0.1 Service and Troubleshooting

3.0.2 Schedule of Maintenance

3.0.3 Regulatory Requirements

3.0.4 Physical Attributes

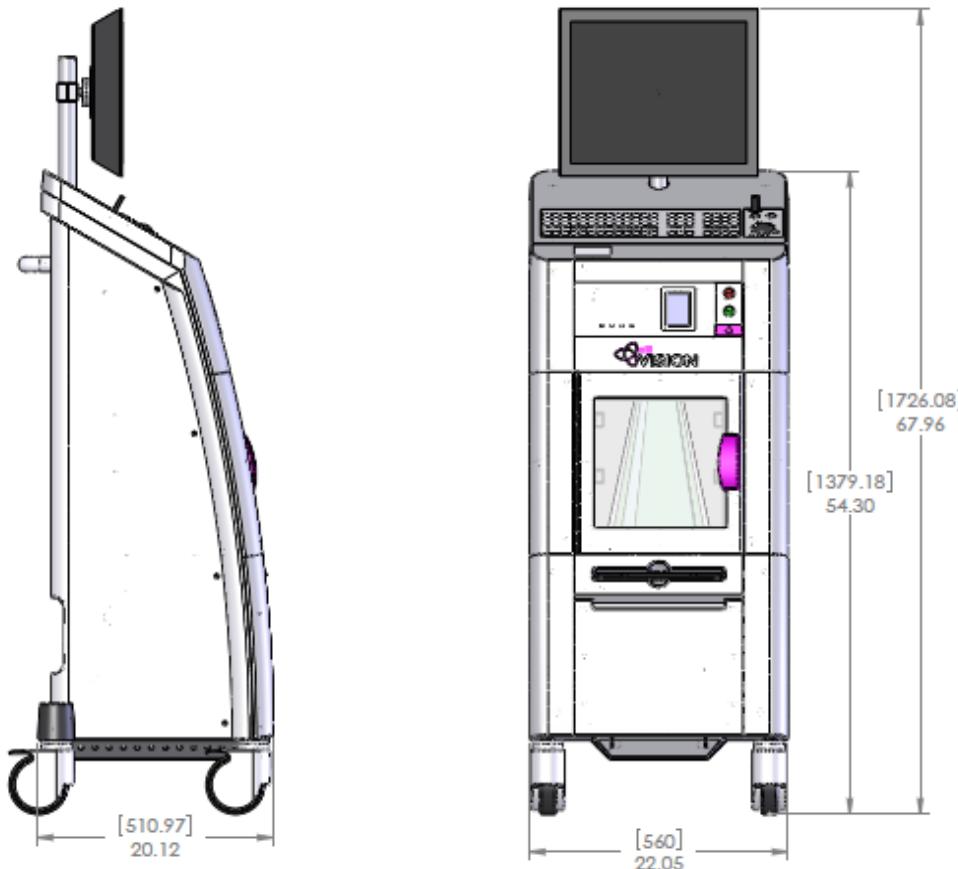


Figure 3.0.1
Dimensions & Weight

Weight: 200 lbs (90 kg)

INPUT POWER

120VAC 60Hz 600W Max
Or
230VAC 50Hz 720W Max

3.0.5 Input Power

Cabinet X-Ray Design Safety

3.1.0 Safety

The primary hazard of cabinet x-ray equipment is the ionizing radiation produced by this type of equipment and the potential for biological damage as a result of exposure to x-rays. The BioVision DSR has been designed to minimize this risk.

The X-ray chamber is self shielding. The sides, back and top are 2mm (0.079in) type 304 Stainless Steel. The chamber floor is 3.6mm (0.14in) type 304 Stainless Steel.

The X-ray chamber access door is constructed of a 22mm thick leaded acrylic (lead equivalency of 1mm), a 2mm (0.079in) thick stainless steel back, and plastic frame.

There are 2 interlock switches on the front door to prevent the generation of X-rays unless the door is closed. Systems for Canada have an additional set of interlock switches for the systems back cover.

The following controls and indicators are located on the systems control panel:

- System Power Button
- X-Ray On Button
- Red Emergency Stop
- Power On Indicator (LED)
- System Ready indicator (LED)
- X-Ray On Indicator (LED)
- Error Indicator (LED)
- LCD panel

There is an audible alarm to indicate X-rays are being generated.

The system imaging software displays system status at the bottom of the screen. Also, messages will be displayed in the image window when; the system is calibrating, X-rays are being generated, or if there are system errors.

An X-Ray warning label is installed on the front of the system.

A software key (password) is required to open VISION (the imaging software). X-Rays cannot be generated independent of the software. If the software is closed, the password must be re-entered.

Emission Limits

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

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.

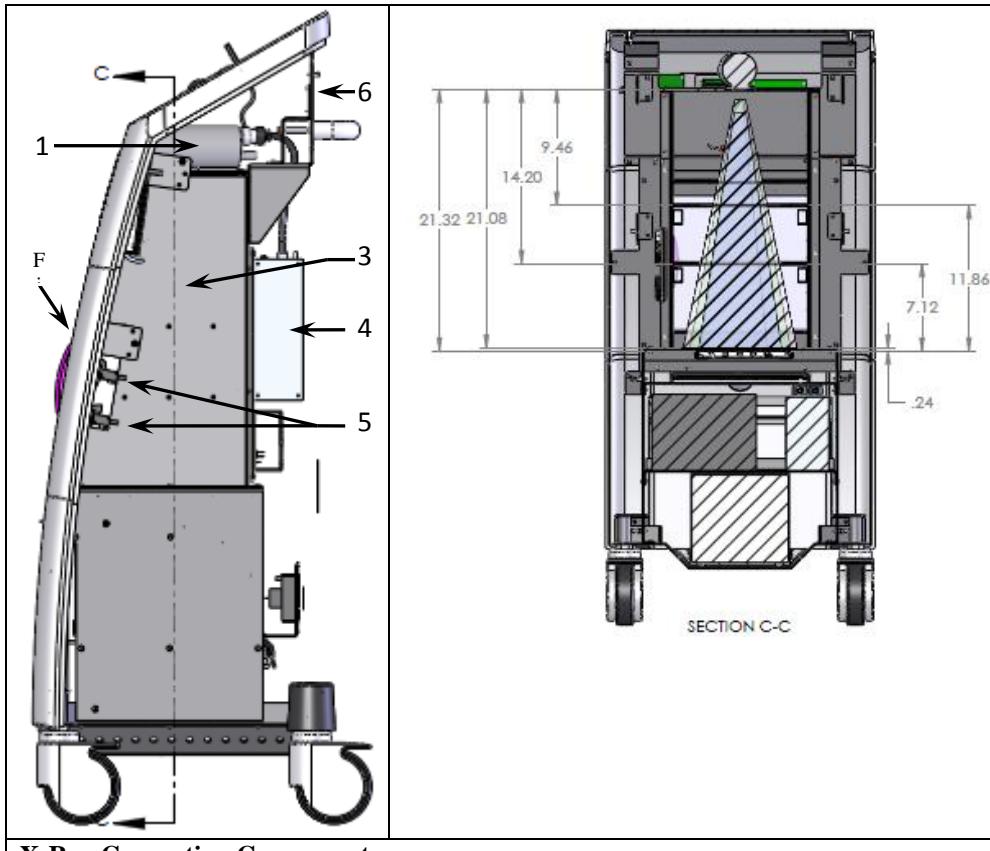
Typical background radiation measurements at the Faxitron Bioptrics manufacturing facility are 0.1 $\mu\text{Sv}/\text{hr}$.

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 $\mu\text{Sv}/\text{hour}$.

3.2.0
**Shielding and
Attenuation**

Faxitron Bioptrics 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
ALARA

X-Ray Sub-System Images

X-Ray Generating Components

- 1 – X-Ray Tube: Oxford Instruments, Series 5000
- 2 – X-Ray Chamber Door, Faxitron Bioptics, 304 Stainless Steel and Leaded Acrylic
- 3 – X-Ray Chamber: Faxitron Bioptics, Type 304 Stainless Steel
- 4 – HVPS, High Voltage Power Supply: Spellman, MNX 50P75
- 5 – Interlock Switches, Chamber Door: Cherry
- 6 – Interlock Switches, Back Cover: Cherry (NOTE: At this time only installed on Systems for Canada)

DISTANCE FROM TOP OF THE CAMERA TO THE IMAGER (NOT SHOWN) IS .230"

DISTANCES:

- TUBE TARGET TO IMAGER: 23.20" [589.28]
- TUBE TARGET TO SAMPLE POSITION (NO MAG): 22.73 [577.34]
- TUBE TARGET TO LOWER MAG TRAY: 15.85" [402.59]
- TUBE TARGET TO UPPER MAG TRAY: 11.11" [282.19]
- IMAGER TO SAMPLE POSITION (NO MAG): 0.47" [11.94]
- IMAGER TO LOWER MAG TRAY: 7.35" [186.69]
- EFFECTIVE MAGNIFICATION AT LOWER TRAY: 1.46:1
- IMAGER TO UPPER MAG TRAY: 12.09" [307.09]
- EFFECTIVE MAGNIFICATION AT UPPER TRAY: 2.09:1

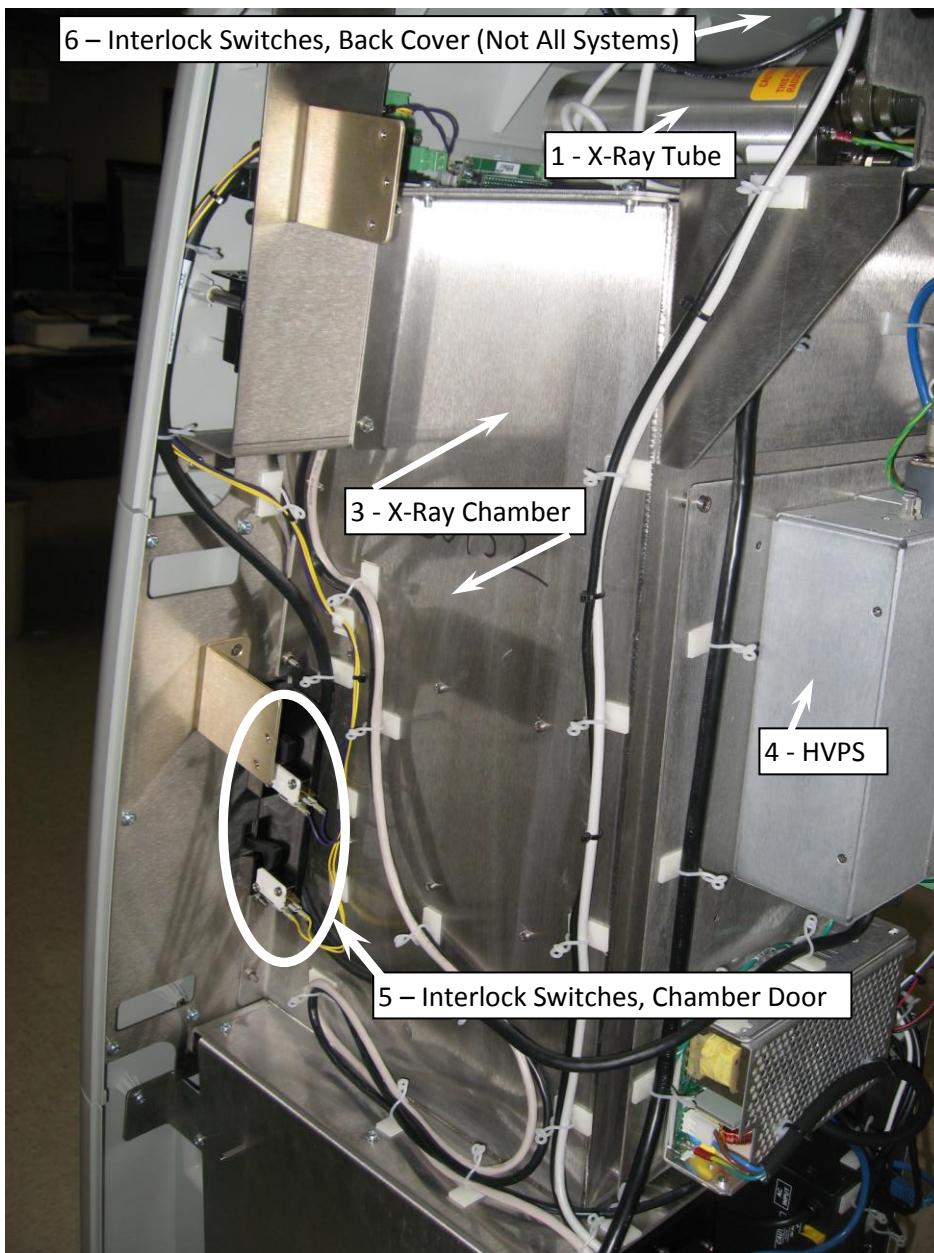
Source-to-Imager (SID) and Source-to-Object (SOD) Distances of BioVision

3.4.0
X-Ray Sub-System
3.4.1
X-Ray Generating and Safety Components

Figure 3.4.1
Location and Identification of X-Ray Generating Components

3.4.1 Cont.

Figure 3.4.2
Component Location – Right Side View



3.4.1 Cont.

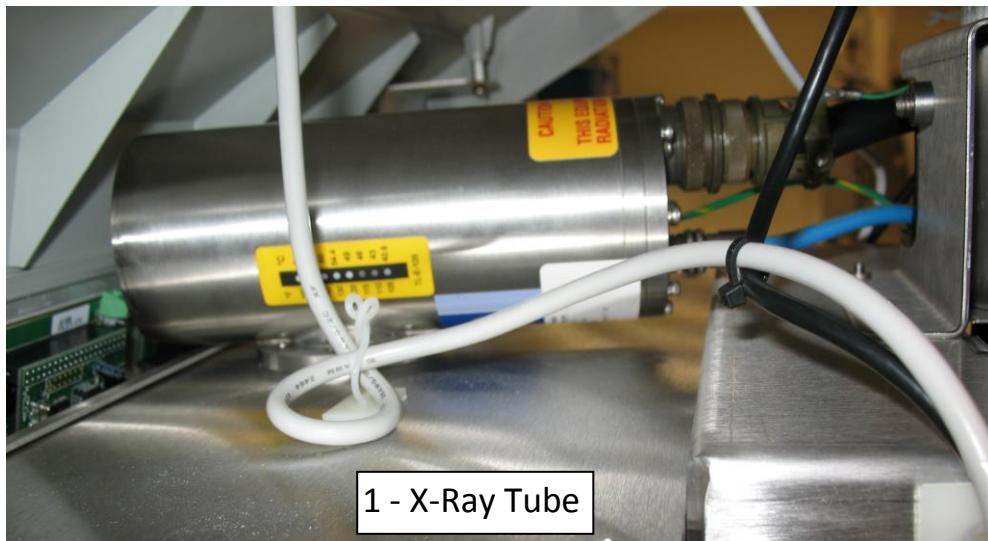


Figure 3.4.3
X-Ray Tube

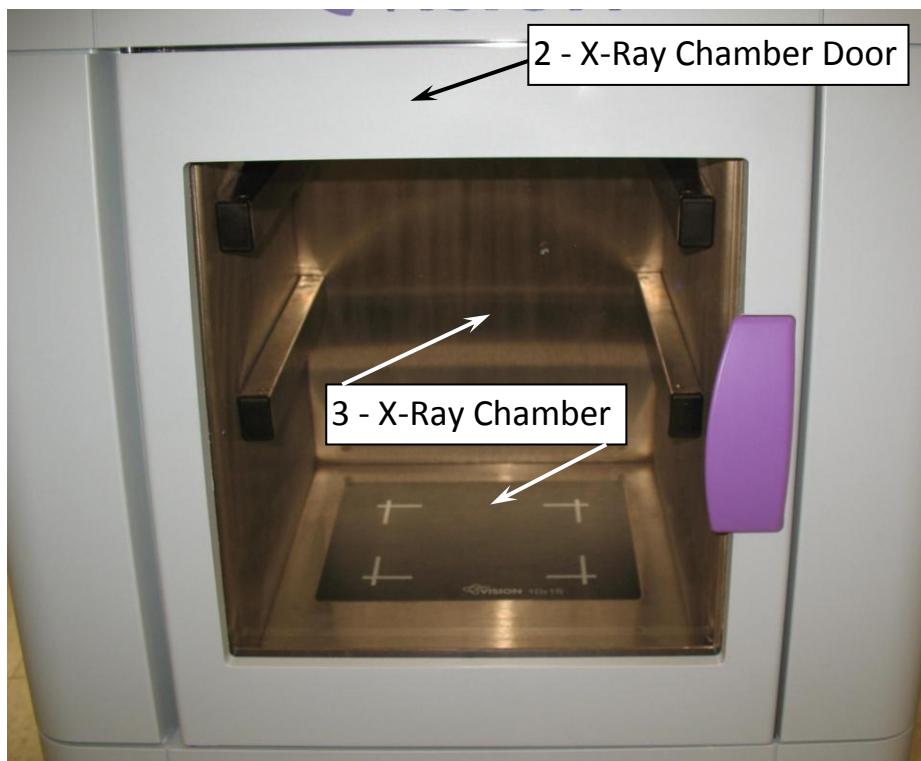


Figure 3.4.4
X-Ray Chamber and Door

3.4.1 Cont.



Figure 3.4.5
X-Ray Chamber

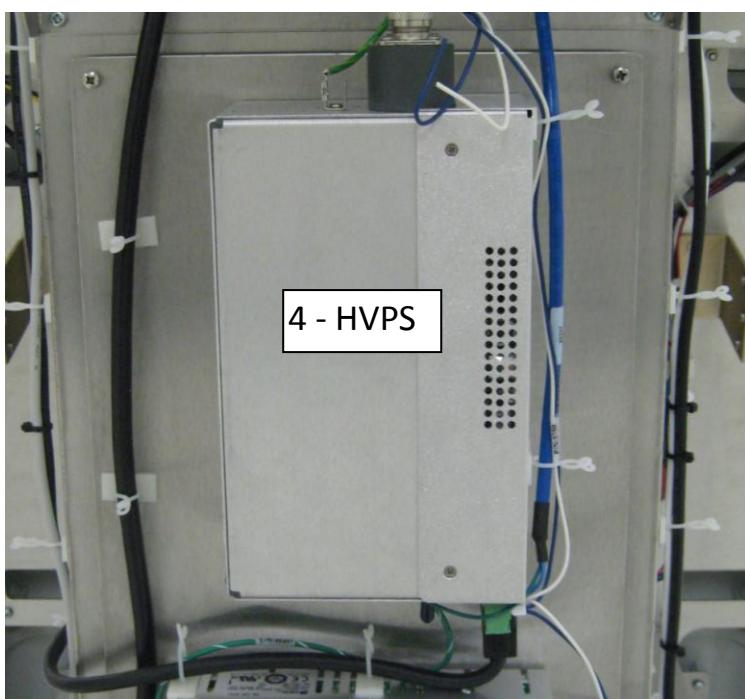


Figure 3.4.6
High Voltage Power Supply

3.4.1 Cont.

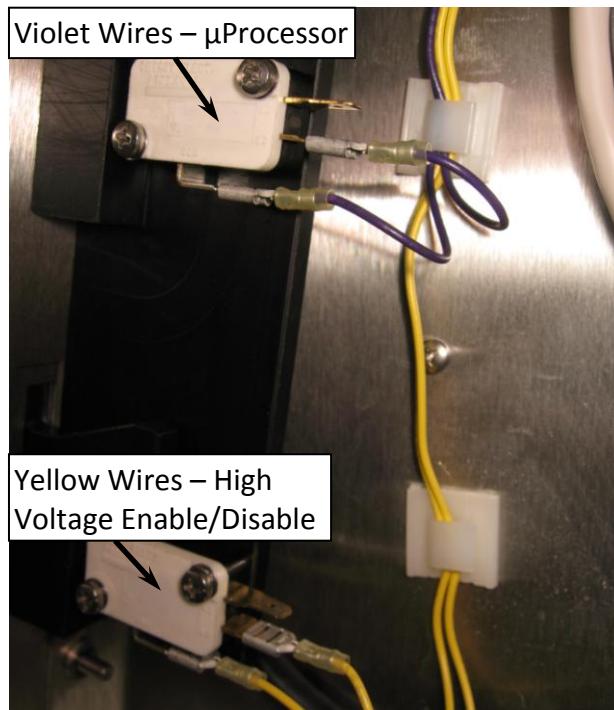


Figure 3.4.7
Interlock Switches, Chamber Door



Figure 3.4.8
Interlock Switch, Back Cover - μ Processor



Figure 3.4.9
Interlock Switch, Back Cover – High Voltage

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.

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

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

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

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

3.4.2 X-Ray Control System

Controls and Indications

3.4.2 Cont.



Figure 3.4.10
Labels and Containment

3.4.2 Cont.



*Figure 3.4.11
X-Radiation Labels for Canada*

3.4.2 Cont.

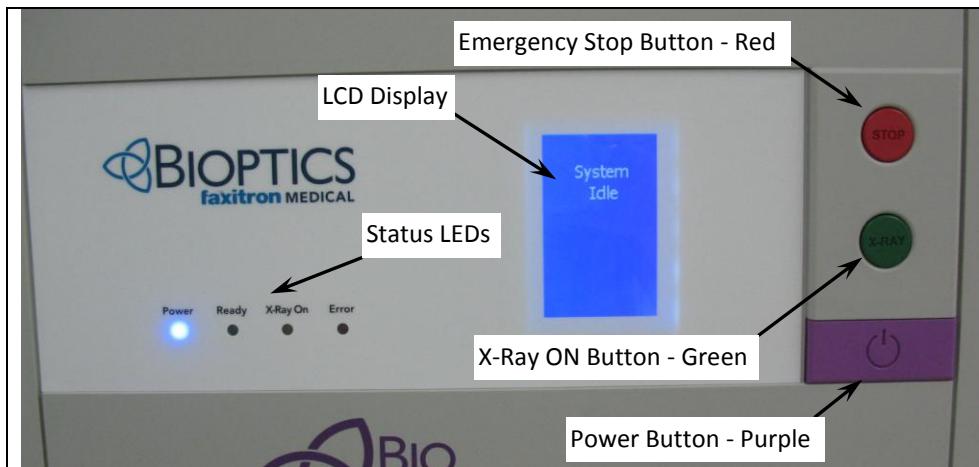


Figure 3.4.12
Controls and Indicators

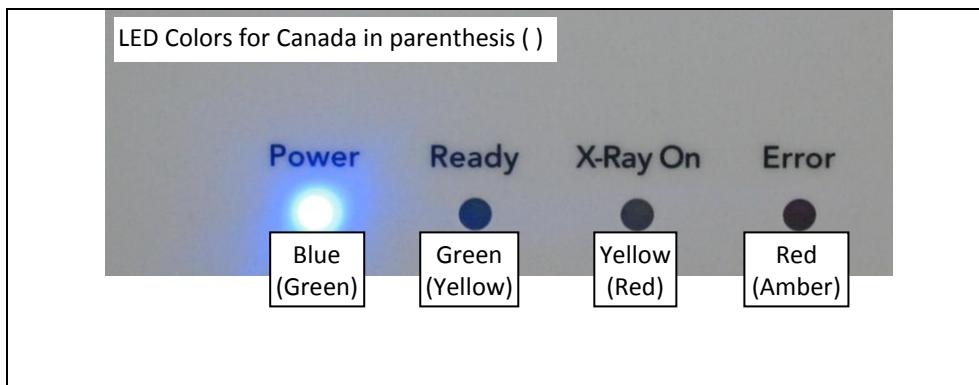


Figure 3.4.13
Status LEDs

3.4.2 Cont.

Opening Vision Imaging Software

VISION, Bioptics Imaging software, must be open to acquire images/X-ray exposures. The X-ray components are not “Armed” until VISION is open and Patient Data is entered. See Section 5 of this manual for Basic operating instruction.

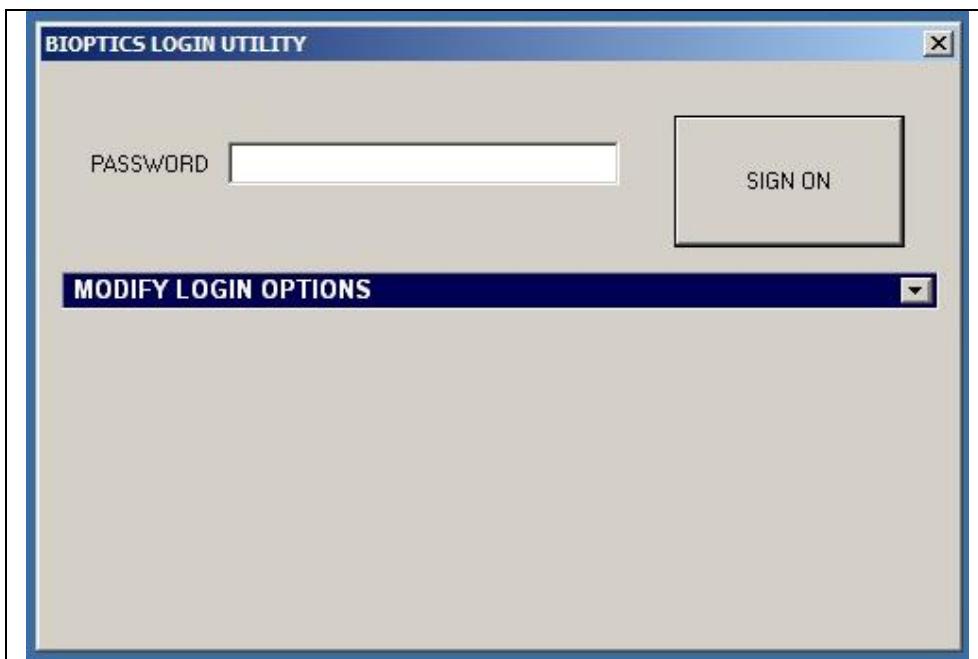
Click on the VISION Icon



Figure 3.4.14
Bioptics Vision Software Icon

The Password Entry (Software Key) Dialog Box will open.
Enter password and click “Sign On”.

Figure 3.4.15
VISION Password Dialog Box



The VISION Intro screen opens. At this time the System is Idle and not ready to Acquire Images. System indications and notices will be as shown in **Figures 3.4.16, 3.4.17, & 3.4.18.**

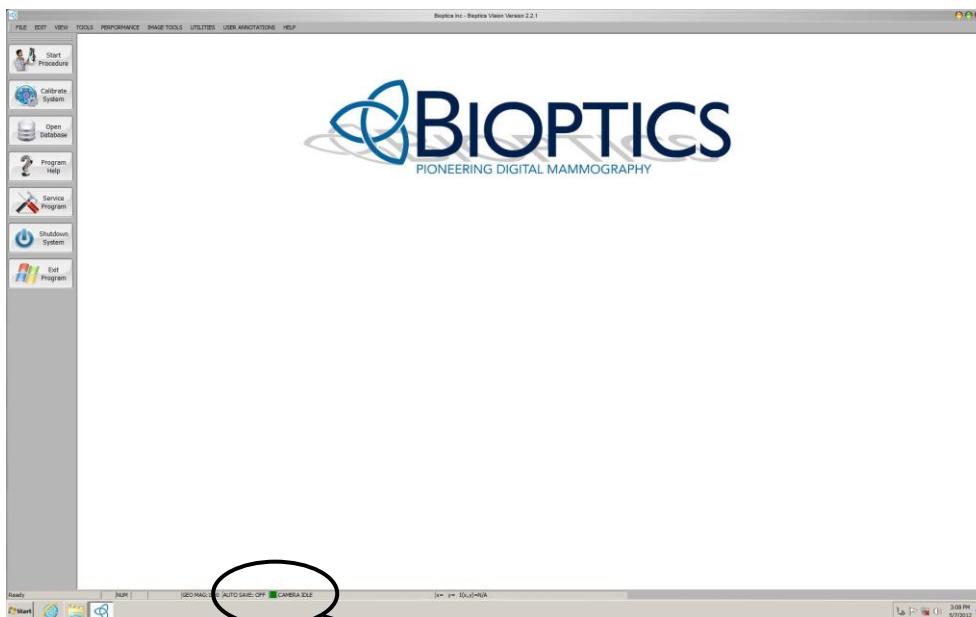


Figure 3.4.16
Vision Intro Screen

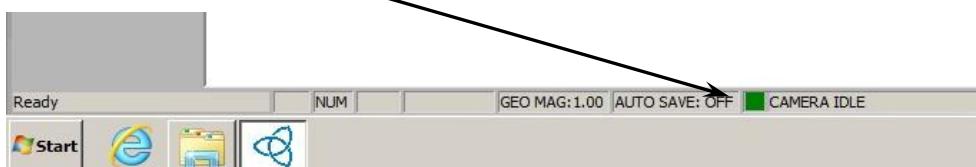


Figure 3.4.17
Vision Status Notification

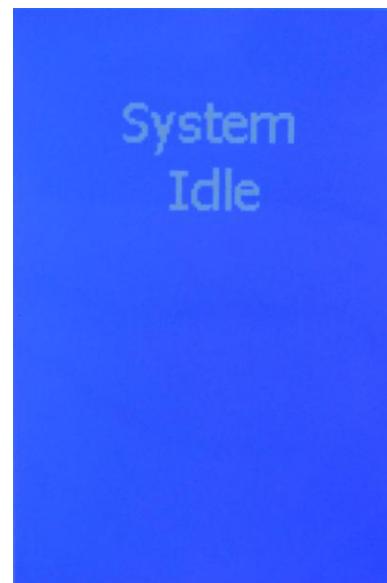


Figure 3.4.18
LCD Display System Status
Notification

3.4.2 Cont.

To start a new imaging procedure, patient data must be entered in the Imaging Information Editor window that appears upon entering a new imaging routine. The acquired or retrieved image will be displayed in the display area. **SEE SECTION 5 - Basic System Operation.**

Once patient data has been entered correctly the system is “Ready for Exposure and Collection”. System indications and notifications will be as shown in **Figures 3.4.19, 3.4.20, & 3.4.21**.

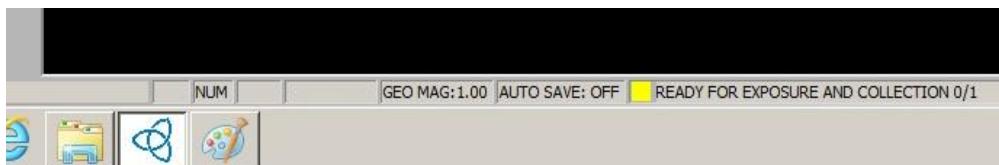


Figure 3.4.19
VISION Status Notification



Figure 3.4.20
Control Panel Status Indicators

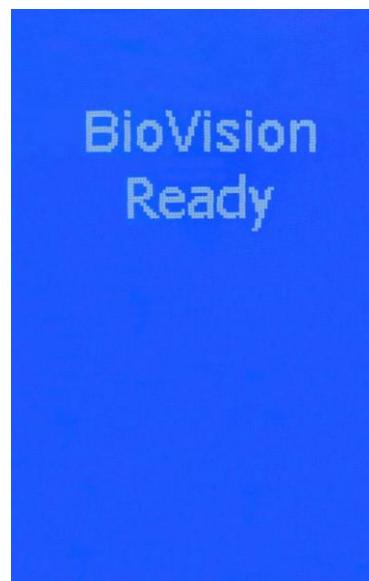


Figure 3.4.21
*LCD Display System Status
Notification*

3.4.2 Cont.

System is now ready to Acquire Images. See Section __ - Basic System Operation.

Place specimen in X-Ray Chamber – Image area indicated on chamber floor.

Press the Green X-Ray ON Button. Exposure Begins. Audible Alarm sounds for duration of X-Rays. Indication and Notifications will be as shown in **Figures 3.4.22, 3.4.23, 3.4.24, & 3.4.25**.



Figure 3.4.22
Vision Status Notification



Figure 3.4.23
Control Panel Status Indicators



Figure 3.4.24
LCD Display Status Notification

NOTE: kV and Time will vary as required by object being imaged.

3.4.2 Cont.



Figure 3.4.25
Software Notification

NOTE: Notification will be displayed in image window.

After the X-Ray Exposure the system will process the image/data. While processing the software will display the notifications shown in **Figures 3.4.26 & 3.4.27**.



Figure 3.4.26
VISION Status Notification



Figure 3.4.27
VISION Status Notification

After processing the image will be displayed.

Emergency Stop

If the Emergency Stop button is pressing during Image Acquisition/ X-Ray Exposures: X-Rays Generation will immediately stop, The audible alarm will go off, The X-Ray ON LED will go out, and a “BIOPTICS X-RAY HANDSHAKE ERROR” message will be displayed in the software image window. **Refer to Figure 3.4.28**



Figure 3.4.28
Handshake Error Message

Pressing the “Enter” key on the keyboard will clear the message and the system will once again be ready for Image Acquisition.

Interlocks

If the interlocks are open during X-Ray Exposure (chamber door is opened): X-Ray ExposuresX-Rays Generation will immediately stop, The audible alarm will go off, The X-Ray ON LED will go out, the Error LED will come on and a “BIOPTICS X-RAY HANDSHAKE ERROR” message will be displayed in the software image window. **Refer to Figure 3.4.28 & 3.4.29.**



Figure 3.4.29
Control Panel Status Indicator

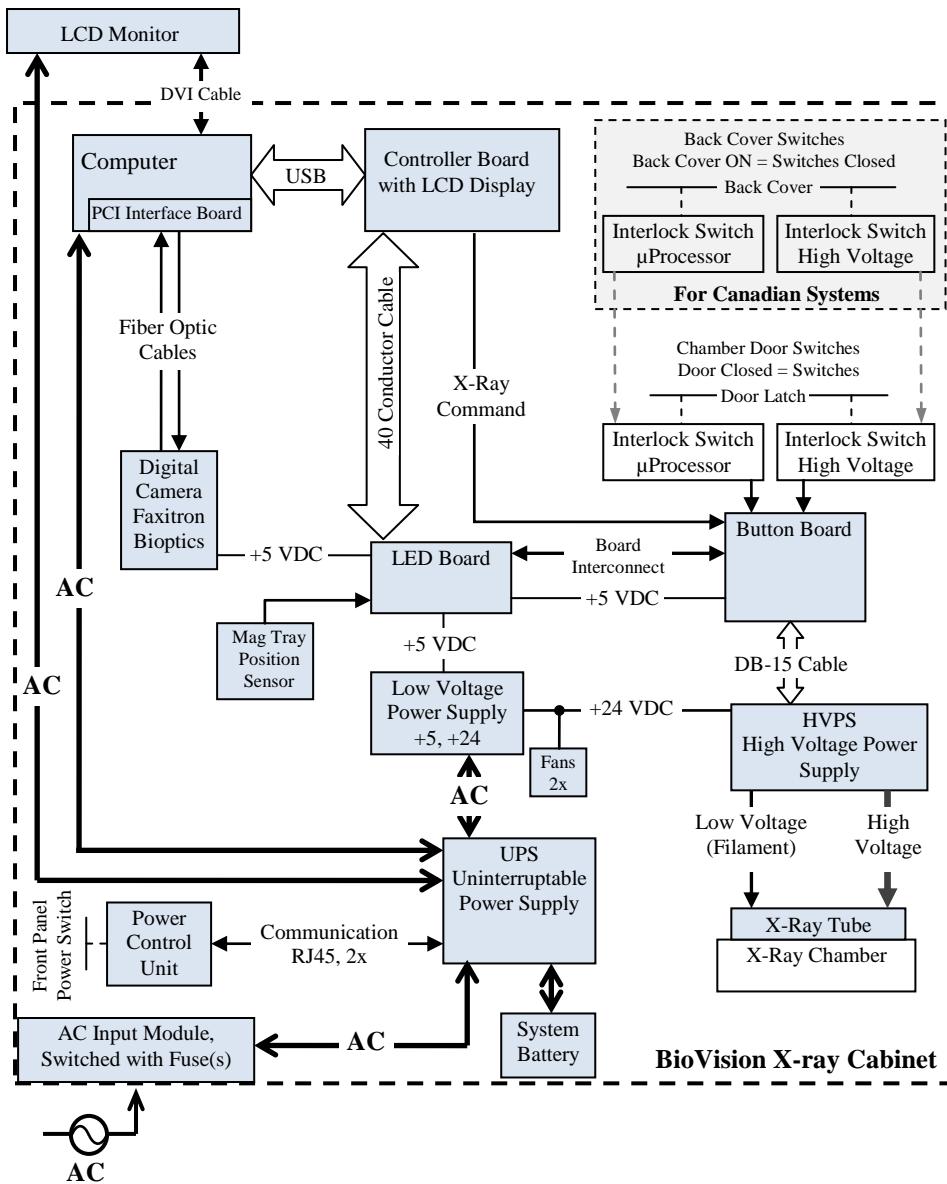
3.4.3 Cont.

When the interlock switches are opened the µProcessor interrupts (or prevents) the X-Ray command signal from being generated AND the High Voltage circuit in the HVPS is disabled.

To re-enable the system: Close the chamber door (close the interlock switches) and press the "Enter" key on the keyboard. System is once again ready for Image Acquisition.

3.4.4 System and Interlock Diagrams

Figure 3.4.30
BioVision System Block Diagram



INTERLOCK SWITCH – High Voltage: Enables/Disables High Voltage in the HVPS.

INTERLOCK SWITCH - µProcessor: Allows or Interrupts X-Ray Command signal in the Controller Board. Also, when Open, generates a "Door Open" message for LCD display Panel.

3.4.4 Cont.

The Controller Board provides the X-ray Command Signal to the High Voltage Power Supply. Interlock 2 must be closed.

If Interlock 2 is Open, the controller board microprocessor will terminate the X-ray Command Signal, AND it will generate a signal to display the "Door Open" message on the LCD Panel.

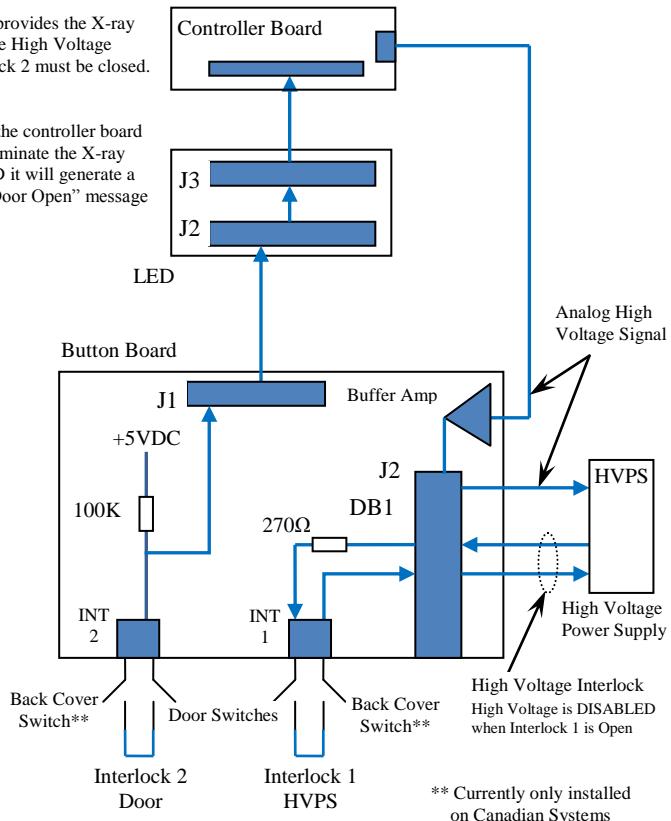


Figure 3.4.31
BioVision Interlock Block Diagram

BioVision Interlock Diagram



4

SECTION 4

BioVision Installation and Set-up

General Precautions**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.

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 camera system has a fiberoptic faceplate and care should be taken in order to prevent camera damage. The camera system must never be mishandled, hit, knocked or dropped.

**4.0.0
BioVision
Specimen DR
System
Precautions****System Start-up Sequence Protocol**

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

- Turn the power on to the BioVision System by switching the power button on (the power button is located on the back of the system above the power cord outlet). Switch to "1" for "Power ON" and "0" for "Power OFF".
- Turn the BioVision System "ON" by pressing and releasing its power button (rectangular purple button).
- Computer should turn on and boot itself up. Ensure monitor power is on if it appears blank.
- Allow the system to warm up for a minimum of one half hour before calibration and image acquisition.
- From the WINDOWS desktop, double click on the Vision Software icon.
- Refer to the "Camera Calibration Overview" section for calibration protocols.

Additional Recommendations for Consistent Image Quality

Allow the system to perform a complete calibration daily prior to initial system use. The system is configured to perform this calibration when you start the Vision software.

Perform a complete system calibration after moving the system to another room to avoid potential imaging difficulties associated with room-to-room ambient temperature and humidity differences.

The BioVision should be set up by a Faxitron Bioptics LLC authorized representative. Contact Faxitron Bioptics 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 crates 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 Bioptics at 520-399-8180.

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

Lifting and Transporting the Crates

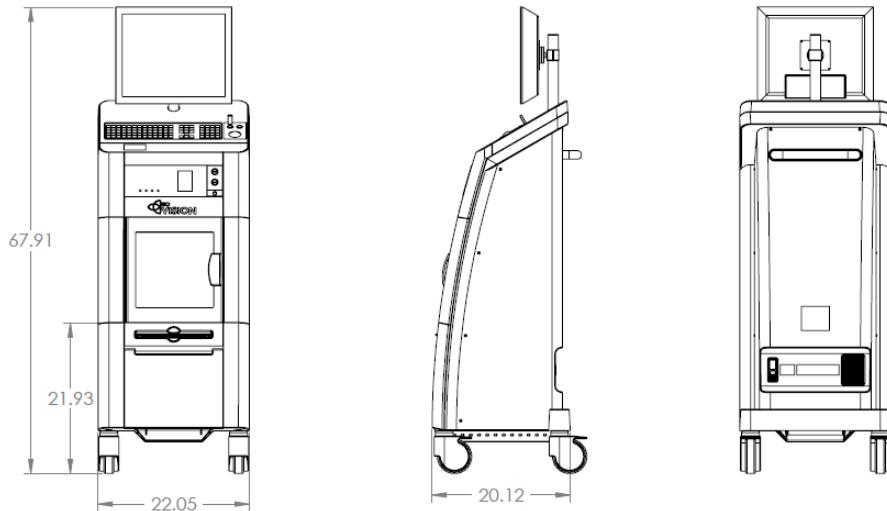
Caution: The crate weighs approximately 475 pounds (215 kg). The packaged system should be kept upright as indicated on the shipping crate. To prevent damage to the crate and system, Faxitron Bioptics recommends using a pallet jack, not a forklift, to move the crate. Move the crate only if necessary.

4.1.0 BioVision Specimen DR System Setup



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.



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 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.

Shutdown Procedure

Shutdown procedures for BioVision systems may differ depending on if system is equipped or not equipped with PC-UPS Synchronization Module, so appropriate shutdown sequence needs to be followed.

Follow these steps to shutdown BioVision systems:

(a) For BioVision Systems Not Equipped With PC-UPS Synchronization Module

1. Go to the "Start-up Screen" also known as the "Main Screen" (See *Figure 4.3.1*).
2. Click on the "Shutdown System" button, and then choose "OK." This will turn off the computer (See *Figure 4.3.2*).
3. Once the computer is off, press and hold the power (purple) button on the Bioptics BioVision System until a beep is heard to turn the power off (See *Figure 4.3.3*).

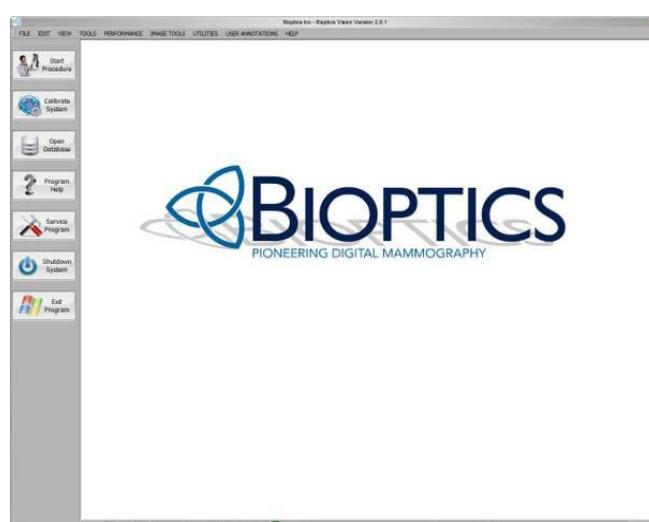


Figure 4.3.1
Vision Program Start-up (Main) Screen



Figure 4.3.2
Shutdown System Button

(b) For BioVision Systems Equipped With PC-UPS Synchronization Module

4.2.0 Cont.

• Method 1:

Activate system shutdown from either Windows Start menu or from Vision program's start-up screen "Shutdown System" button. The computer system will gracefully shutdown itself first, then UPS system will follow. You will hear a beep when UPS system turns its power off.

• Method 2:

Press the power (purple) button on the BioVision System shortly and release immediately (*). The computer system will gracefully shutdown itself first, then UPS system will follow. You will hear a beep when UPS system turns its power off.

(*) Avoid extended press on power button over 5 seconds. Extended press over 5 seconds will cause forced shutdown as oppose to graceful shutdown of computer. This kind of forced shutdown can be used only when computer seems locked up or not responding.

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.

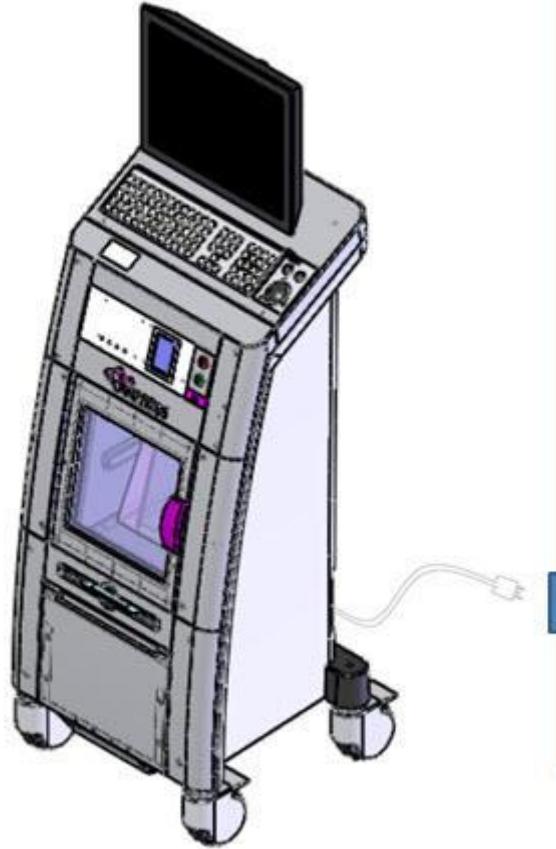
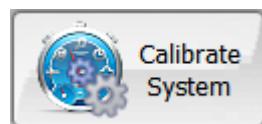
4.2.0 Cont.

Figure 4.3.3
BioVision System Connecting to Electrical Outlet

Power on the system in its new location and start the Vision software:

- Turn the BioVision System "ON" by pressing and releasing its power button (rectangular purple button).
- Computer should turn on and boot itself up. Ensure monitor power is on if appears blank.
- Allow the system to warm up for a minimum of one half hour before calibration and image acquisition.
- From the WINDOWS desktop, double click on the Vision Software icon.

Click the button on the Vision software Main menu. You should calibrate the system in order to avoid potential imaging difficulties associated with room-to-room ambient temperature and humidity differences.



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.





5

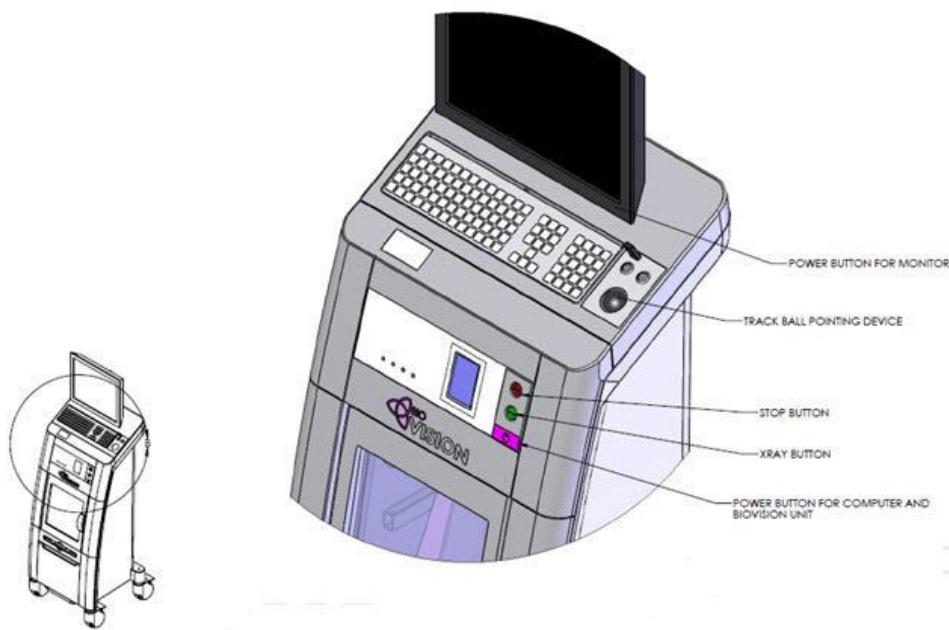
SECTION 5

Quick Start and Basic Operation of the BioVision DR System

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 impaired operation of the equipment or personal injury.



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



Imaging Sequence Summary

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

- Place the specimen(s) in a specimen container provided by Faxitron Bioptron 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.
- 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. 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, through 5.6.0 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.

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

NOTES ON SYSTEM WARM UP:

It is recommended that for optimum image quality that, the system be allowed to warm up before it is calibrated and used. If the system is needed for immediate use, it can be calibrated and used immediately with no restrictions. Although satisfactory image quality is immediately obtainable without warm up time, optimum image quality will be obtained if the system can be warmed up at least 15 minutes (preferably 30 minutes) before calibration and use. Ideally the system would be turned on and left to warm up until a procedure is started before it is calibrated. The closer the calibration time to the time of actual use, the better the image quality will be.

Ensure main power switch on back of cabinet is turned on:

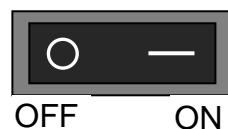
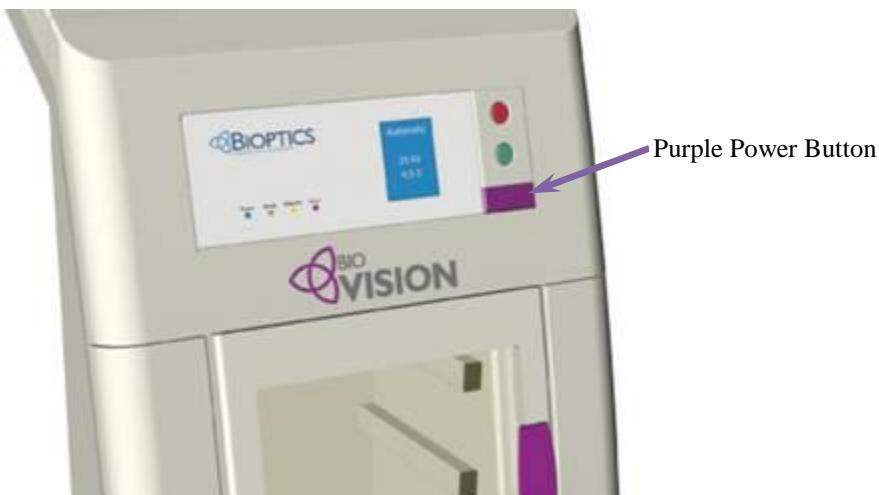


Figure 5.1.1
Main Power Switch

System Start-Up

On BioVision system, press the **power button** (rectangular purple button) until a beep is heard to power “**ON**” the system.



5.1.1
System Start Up

Figure 5.1.2
System Power Button

Computer should turn on and boot up by itself. If display appears blank, ensure the **monitor** is turned on.

If warm up time is being allowed (highly recommended), leave the system booted up, but do not start the software at this time. Once the system is warmed up, proceed to paragraph 5.1.2.

If system is to be immediately used, warm-up bypassed, proceed to paragraph 5.2.0.

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

5.1.2 Calibration

Starting VISION Software

Start the VISION imaging software by clicking on the desktop Icon.



Figure 5.1.3
Bioptics VISION Desktop Icon

The Password (Software Key) Dialog box will open.



Figure 5.1.4
Password Dialog Box

Enter the password and Click the "SIGN ON" button. Software will proceed to open.

While the Vision software is loading, three Dialog boxes will appear during software initialization:

- The first will read: "Starting Bioptics Vision System, Please Wait..."
- Second: "Camera Test in Progress, Please Wait..."
- Third: "Bioptics Vision System Initializing, Please Wait..."

When the software has completed loading the VISION Start-up Screen will be displayed.



Figure 5.1.5
VISION Start-Up Screen

Calibration

5.1.2 Cont.

NOTE: The system will automatically proceed into Calibration if the system has not been calibrated within 12 hours.

To manually start Calibration click on the “Calibrate System” button on the left side of the screen.

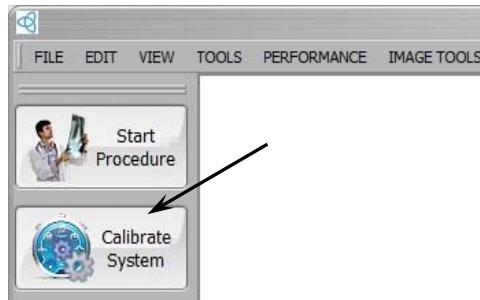


Figure 5.1.6
Calibrate System Button

System will start to Calibrate. The calibration is performed in 2 steps: Dark Field Calibration and X-Ray Calibration. During each step a dialog box is displayed.



Figure 5.1.7
Dark Calibration Dialog Box

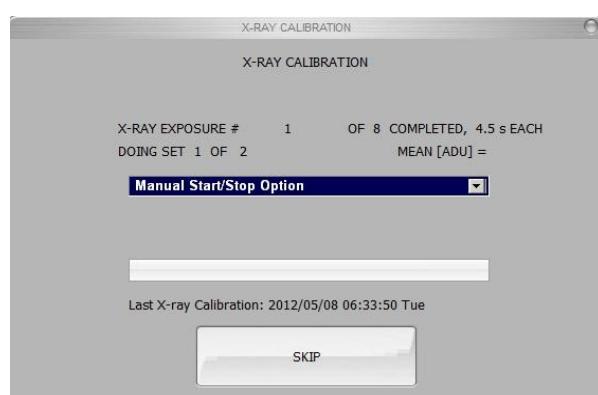


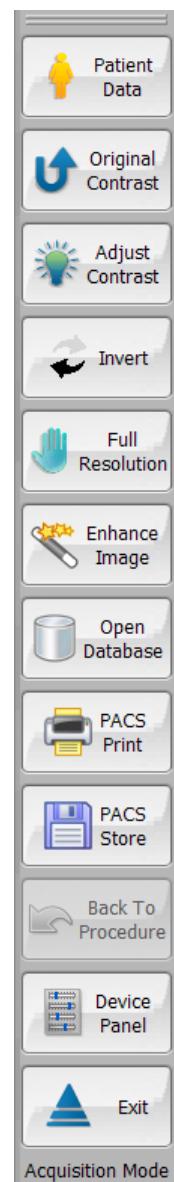
Figure 5.1.8
X-Ray Calibration Dialog Box

During the X-Ray Calibration an “Exposure Status” dialog box, with the message: “X-RAY IS ON, WAIT FOR COMPLETION” will be displayed. As each X-Ray exposure is completed and processed, the blue status bar will increment until completion.

The Dialog box will close when Calibration is complete.

Starting an Imaging Procedure

The *Start* button initiates a new imaging procedure. In this session, images can be taken and manipulated. After activating the *Start* button on the start-up screen (**Refer to Figure 5.1.5**), a new window will open displaying a new set of buttons on the left side of the screen. **Refer to Figure 5.2.1.** Descriptions and definitions for these buttons follow.



5.2.0 Image Acquisition

Figure 5.2.1
Imaging Buttons

5.2.0 Cont.

To start a new imaging procedure, patient data must be entered in the Imaging Information Editor window that appears upon entering a new imaging routine. The acquired or retrieved image will be displayed in the display area.

Entering Patient Data

Patient data must be entered into the Imaging Information Editor in order to initiate a procedure. Upon selection of the "Patient Data" button, the "Select a New Entry or Continue Current Entry" Dialog box is displayed. Refer to Figure 5.2.2.

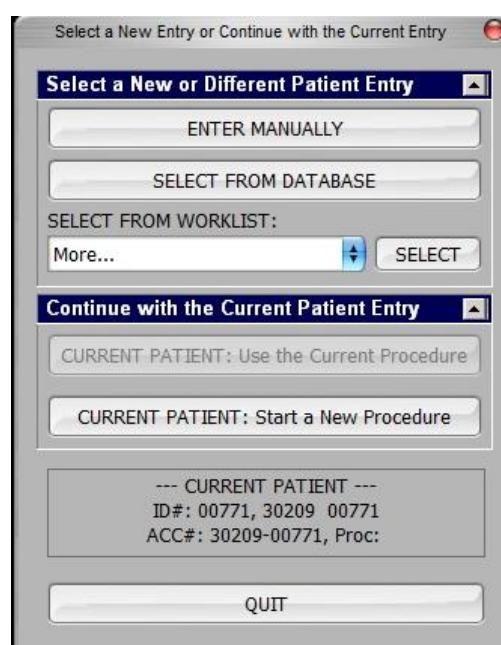


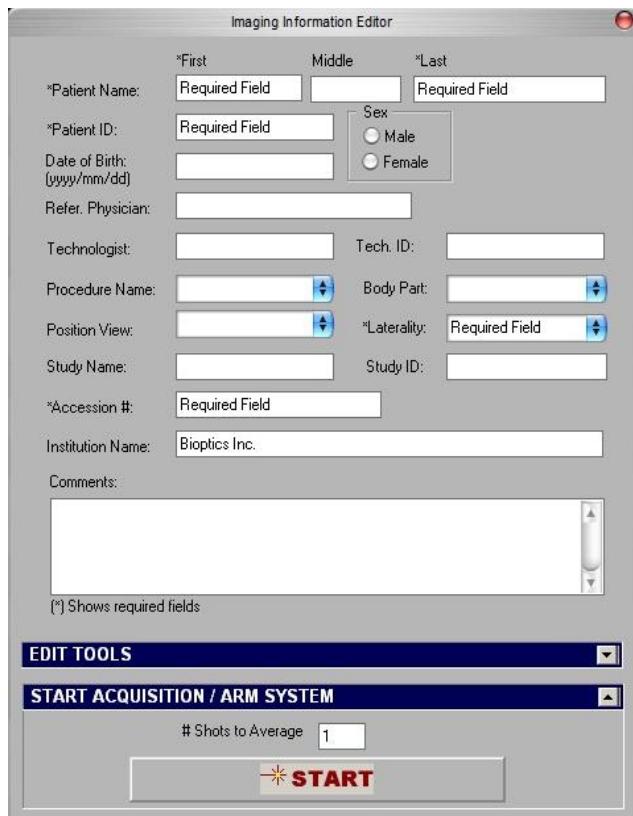
Figure 5.2.2
Select a New Entry or Continue with the Current Entry Dialog Box

There are 3 methods of entering New Patient Data: Manually, Selecting from Database, or Selecting from a Worklist.

Also, if you are Continuing with the Current Patient, you can "Use the Current Procedure" or "Start a New Procedure"

Enter Manually

To manually enter a new Procedure, select the "ENTER MANUALLY" button. The "Imaging Information Editor" window is displayed. Refer to Figure 5.2.3.



5.2.1 Enter Manually

Figure 5.2.3
Imaging Information Editor

The START button will be inactive (grayed out) when the Imaging Information Editor window first opens. The START button will become active when all the required fields have been filled.

The user must enter the Patient Name (First and Last), Patient ID, Laterality, and Accession Number. The user may enter Birth Date, Sex, Referring Physician, Procedure Name, Technologist, Position View, Study ID, Institution Name and optional Comments if so desired. The Procedure Name and Position View are chosen by a drop down menu.

Note: The patient's Birth Date must be entered as year, month, day (e.g. 1962/08/13). If entered incorrectly, an error message will appear.

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

Edit Tools options are provided to edit the 'Imaging Information Editor'. Select Accept/Exit to accept or Cancel/Exit to return to the main menu.

Click on the START button to start the imaging procedure.

Once the Imaging Procedure has been started (by clicking on the START button in the Imaging Information Editor box) the current image information (image properties) will be displayed in the upper right corner of the graphics window. At this time there will be no entries. Refer to Figure 5.2.4. (The entries will be populated once an image is acquired or loaded) The box is semi-transparent; this allows one to see what's underneath the box.

5.2.1 Cont.

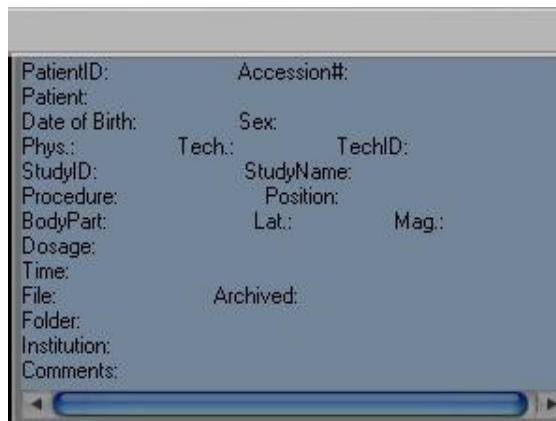


Figure 5.2.4
Image Properties Box

You can select to show or hide the image properties information box using the View drop down menu in the horizontal menu bar. Refer to Figure 5.2.5.

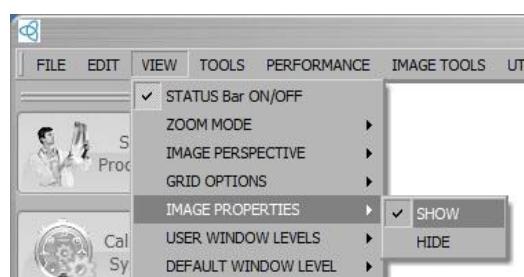


Figure 5.2.5
*View Image Properties –
Show/Hide*

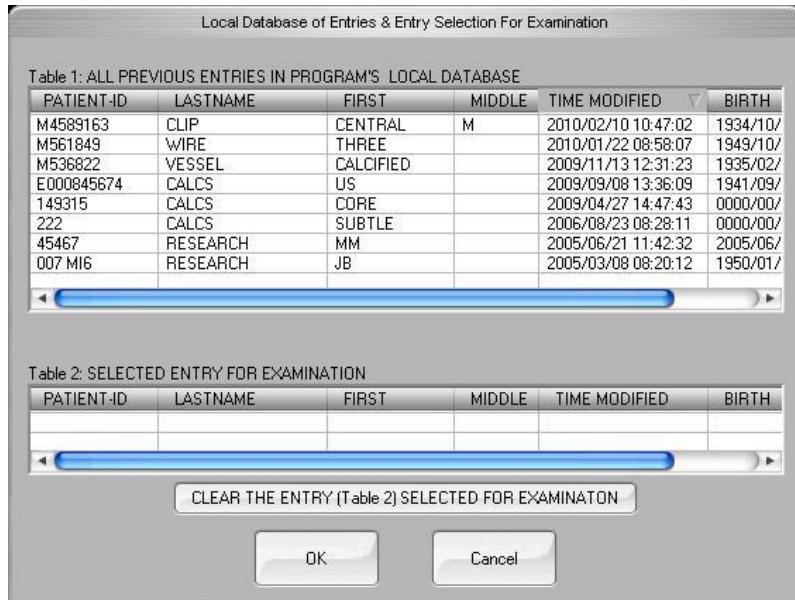
By pressing the Patient Data button, the "New Entry or Continue Current Entry" Dialog box is displayed again. Options for the Current patient's procedure are provided; "Use the Current Procedure" or "Start a New Procedure" may be selected. The Imaging Information Editor will be displayed with the information fields completed. Once again, the Edit Tools may be used to edit the Procedure. At this time changes can be made to the patient's record and saved by clicking the Accept/Exit button. The changes will be updated in the Patient Information Box shown in the upper left hand corner of the graphics window. The system is now ready to acquire an image. The patient information box is a semi-transparent yellow box when system is properly armed and displays the summary information of patient under the current acquisition procedure.

The Cancel/Exit button will return the user to the Imaging Procedure session without making any changes to the patient's record.

NOTICE: Patient information must be entered before acquiring any images.

Select from Database

To enter Patient Data from the Database, click the SELECT FROM DATABASE button in the "Select a New Entry or Continue Current Entry" Dialog box. Refer to Figure 5.2.2. The "Local Database of Entries..." Dialog box will open. Refer to Figure 5.2.6.



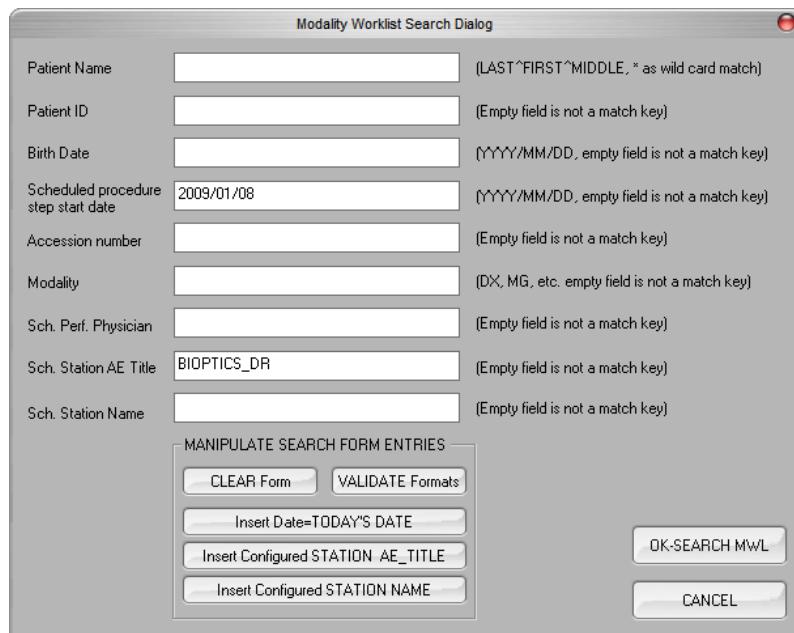
By double clicking an entry within Table 1 of the Local Database of Entries, the selection will be displayed in Table 2. Selecting "OK" completes the information in the Imaging Information Editor.

5.2.2 Select from Database

Figure 5.2.6
Selecting Patient From Local
Database Entries

Select From WWorklist (Remote Modality Work list)

Scheduled procedures can be searched for Station Application Entity (AE) by clicking "SELECT" button under the "Select From Worklist:" heading (refer to *Figure 5.2.2*). To specify search criteria the Modality Worklist Search Dialog is used as shown on *Figure 5.2.7*. Any single field or any combination of fields maybe used as a filter to perform search for the AE shown in "Sch. Station AE Title" field. NOTE: The dialog will be omitted and default search will be performed if "Enable Auto Search When Connecting to MWL Server" option is turned on in Dicom Modality Setup dialog (refer to section 6.7.0 DICOM Functionality in chapter 6 of this manual on how to enable and disable automatic worklist search). The criteria can be revised after the search to narrow down or widen the number of results.



5.2.3
**Select from
Worklist**

Figure 5.2.7
Modality Worklist Search Dialog

By selecting "OK-SEARCH WML" the following Dialog box will be displayed. See figure 5.2.8 below.

5.2.3 Cont.

Modality Worklist Report & Entry Selection

Table 1: LIST OF RECEIVED ENTRIES (17 TOTAL)

PatientID	Accession#	Patient Name(L^F^M)	BirthDate	Sex	Modality
pidP645	00000187	One^Secondary Capture I...	1980/07/16	M	MA
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I2		Two^Secondary Capture I...		O	CT
SC-I2		Two^Secondary Capture I...		O	CT
SC-I2		Twin^Secondary Capture I...		O	CT

Table 2: SELECTED ENTRY FOR EXAMINATION

PatientID	Accession#	Patient Name(L^F^M)	BirthDate	Sex	Modality

CLEAR THE ENTRY (Table 2) SELECTED FOR EXAMINATION

Table 3: REPORT OF THE HIGHLIGHTED ENTRY ON "Table 1"

Tags	Value
Patient Name	One^Secondary Capture Image
Patient ID	pidP645
Patient Birth Date	1980/07/16
Patient Sex	M
Patient Weight	80.000000
Patient Confidentiality	
Patient State	
Pregnancy Status	unknown
Medical Alerts	MT
Contrast Allergies	
Special Needs	
Accession Number	00000187
Modality	MA
Study Description	
Series Description	
Scheduled Station AE Title	BIOPTICS_DR
Scheduled Procedure Step Start Date	2012/05/09
Scheduled Procedure Step Start Time	16:51:04
Scheduled Procedure Step End Date	
Scheduled Procedure Step End Time	
Scheduled Performing Physician	
Scheduled Procedure Step Description	CSPINE
Scheduled Procedure Step ID	000001020C

PRINT Report on Table 3 Revise Search Criteria... OK Cancel

Figure 5.2.8
Modality Work list Report
& Entry Selection

To narrow down or widen the search results click "Revise Search Criteria..." button to return to Modality Worklist Search Dialog where you can modify the search criteria and perform the new search. By using the mouse to double click on an entry listed in Table 1 of the Modality Work list Report & Entry Selection and selecting "OK" at the bottom of the dialog box, the Imaging Information Editor will automatically be completed. Upon returning to the Imaging Information Editor, select "START" to continue.

When the procedure has been started (by completing prior step) the system is “Armed” or ready to acquire images/X-Ray exposures.

5.2.4 Acquiring Images

System Status Indications and Notifications

The following indications and Notifications will show that the system is ready for Image Acquisition:

The software will display “Ready for Exposure and Collection”. Refer to Figure 5.2.9.

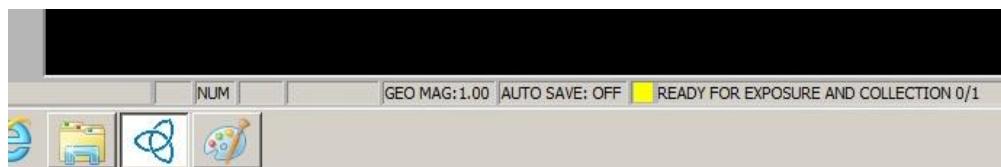


Figure 5.2.9
Software Status Notification

The “Ready” light on the Control Panel will be illuminated. Refer to Figure 5.2.10



Figure 5.2.10
Control Panel Ready Light

The LCD panel will display “BioVision Ready”. Refer to Figure 5.2.11



Figure 5.2.11
LCD Display Ready Notification

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.
- Press the Green Start Button on the control panel.

Image Acquisition/X-Ray Exposure will begin. Indications/Notifications will be as follows:

- Audible Alarm will sound (beep) for the duration of the Exposure.
- The Software Status will display:

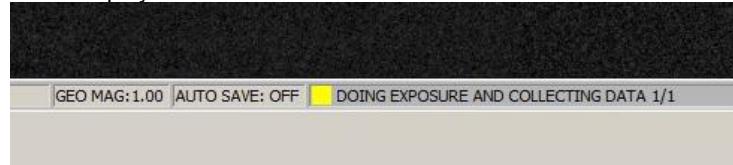


Figure 5.2.12
Software Status Message

- A Dialog Box will be displayed in the Software Image window:

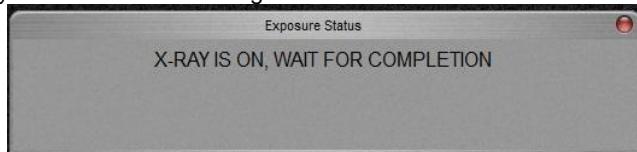


Figure 5.2.13
Exposure Status Message

- The control panel Ready LED will go out and the X-Ray On LED will illuminate

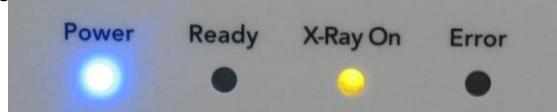


Figure 5.2.14
Display Panel LEDs

- The LCD panel will display "Acquiring Image"



Figure 5.2.15
LCD Display

NOTE: kV and Time will vary as required by specimen being imaged.

5.2.5 Cont.

After the exposure is complete the system will collect a “Dark Reference” and Process the image. The image will be displayed in the software’s Image window.

The fields in the Image Properties Box will be populated and the Current Patient box will be displayed in the upper left corner of the image. Refer to Figures 5.2.16 & 5.2.17.

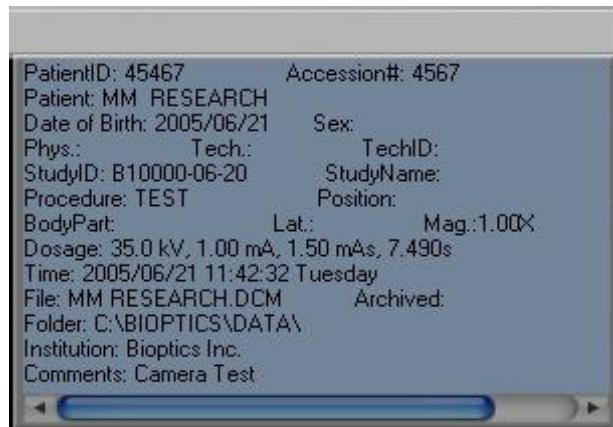


Figure 5.2.16
Image Properties Box – Fields
Populated

ID#: 12345, Firstname Lastname
ACC#: 12345, Proc: Specimen Img

Figure 5.2.17
Current Patient Box

Adjusting Image Brightness and Contrast

To adjust image brightness and contrast; position the cursor over the image, press and hold the left trackball button and move the cursor up and down for brightness, left and right for contrast. Release button when satisfied with adjustments.

You may also adjust the image contrast by clicking on the Adjust Contrast button and moving the sliders. Click OK when satisfied with image.



Figure 5.2.18
Current Patient Box

Returning Image to Original Contrast

To return the image to its original contrast click on the Original Contrast button.



Figure 5.2.19
Original Contrast Button

Saving Images

Images are automatically saved to the BioVisions local hard drive.

See User's Manual Section 6 for PACS Storage.

5.2.6 Image Storage

ADVANCED SOFTWARE FEATURES

Bioptics VISION imaging software includes many advanced features.

SEE USER'S MANUAL SECTION 6 FOR ADVANCED SOFTWARE FEATURES AND OPERATION.

5.2.7 Advanced Software Operation

Shutdown procedures for BioVision systems may differ depending on if system is equipped with PC-UPS Synchronization Module. Follow appropriate shutdown sequence.

(A) For BioVision Systems Not Equipped With PC-UPS Synchronization Module

Exit VISION Software

Click on the EXIT button. This returns you to the Start-up Screen (or Main Screen)



5.3.0 Shutting Down the System

Figure 5.3.1
Image Area Exit Button

Click on the "Shutdown System" button, and then choose "OK." This will turn off the computer



Figure 5.3.2
Shutdown System and Exit
Program buttons

Turn Off System

Once the computer is off, press and hold the power (purple) button on the Bioptics BioVision DSR System until a beep is heard to turn the power off. The Power LED and the LCD Display will go out.

5.3.0 Cont.

(B) For BioVision Systems Equipped With PC-UPS Synchronization Module

Method 1:

Activate system shutdown from either Windows Start menu or from Bioptics VISION program's Start-up screen "Shutdown System" button. REFER TO FIGURE 5.3.2.

The computer system will gracefully shutdown first, then UPS system will follow. You will hear a beep when UPS system turns off power off. Power LED and LCD Display will go out when UPS system is off.

Method 2:

Press and release (*) the power button (purple) on the Bioptics BioVision system.

The computer system will gracefully shutdown first, then UPS system will follow. You will hear a beep when UPS system turns off power off. Power LED and LCD Display will go out when UPS system is off.

(*) Avoid holding the power button in for more than 5 seconds. Holding the power button in for over 5 seconds will cause a forced shutdown of the computer, as opposed to a graceful shutdown. Only use a forced shutdown if computer is locked up or not responding.



6

SECTION 6

Vision Software Operation

Faxitron Bioptics Vision Software is a complete image acquisition and processing package, designed exclusively to work with Faxitron Bioptics X-Ray Generators (such as CoreVision and BioVision Systems.) In addition to the acquisition and processing functions, the software offers an extensive database module that allows user control and maintenance of image archiving, storage, filing and retrieval. The software is also Digital Imaging and Communications in Medicine (DICOM) compliant, allowing saving and printing of specimen images in DICOM format 3.0.

When the software program is activated, system calibration Dialog boxes will be displayed prior to the Main Start-Up Menu. System calibration is required at the beginning of every new day of system use.

Calibration may also be performed at any time by the user. After system calibration, the Main Start-Up Menu will be displayed. It is from this screen that navigation to all other areas of the software is carried out. For ease of use, application buttons are provided, see *Figure 6.0.1*. These buttons are located on the left side of the screen. Button descriptions and definitions are outlined in the following sections of this manual.

Upon start-up, the right side of the screen (graphics window) will display the Bioptics logo. This area will also be used as the display area for acquired images.

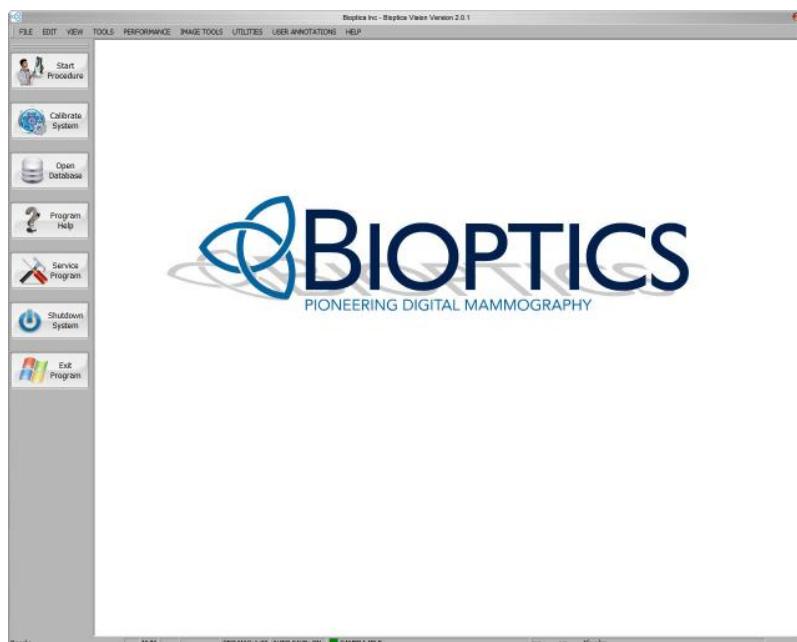


Figure 6.0.1
Vision Software
Start-up Screen

Sequence Protocol

The following is a brief description of the BioVision start-up sequence. For detailed instructions refer for Section 5, Quick Start and Basic Operation, of this manual.

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

- Turn the BioVision System "ON" by pressing and releasing its power button (rectangular purple button).
- Computer should turn on and boot itself up. Ensure monitor power is on if appears blank.
- Allow the system to warm up for a minimum of one half hour before calibration and image acquisition.
- From the WINDOWS desktop, double click on the Vision Software icon.
- Refer to the "Camera Calibration Overview" section for calibration protocols.

Vision Software has been pre-installed on the computer packaged with your particular x-ray system. To activate the Vision Software, simply "double click" the left mouse button on the Vision Software icon located on the WINDOWS desktop. See *Figure 6.1.1*.

6.1.0 Software Start-up



Figure 6.1.1
Vision Software Desktop Icon

While the Vision software is loading, three Dialog boxes will appear during software initialization:

- The first will read: "Starting Bioptics Vision System, Please Wait..."
- Second: "Camera Test in Progress, Please Wait..."
- Third: "Bioptics Vision System Initializing, Please Wait..."

Faxitron Bi optics recommends at least daily system calibration to ensure optimum image quality.

Calibration may be performed upon initial start up of the system, or any time the user chooses.

To optimize image quality, Vision Software and the hardware require periodic calibration. This calibration requires the acquisition of reference images. These images can be grouped into three (3) categories: Offset images, Dark images, and Flat-field images.

These reference calibration images are used to calibrate a "raw" X-ray image on a pixel-by-pixel basis to generate a "corrected" image for display. Image corrections performed include gain, offset and linearity corrections.

Calibration

NOTE: The system will automatically proceed into Calibration if the system has not been calibrated within 12 hours.

To manually start Calibration click on the "Calibrate System" button on the left side of the screen.

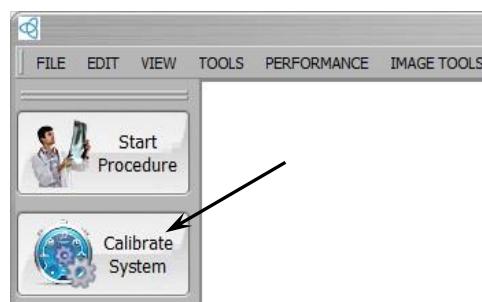


Figure 6.2.1
Calibration Button

CALIBRATION DIALOG BOXES

Detector Offset Calibration

An offset image is a zero (0) second exposure image. This is simply an image of what the detector "sees" in an instantaneous (zero (0) second) exposure without an X-ray signal.

System will start to Calibrate. The calibration is performed in 2 steps: Dark Field Calibration and X-Ray Calibration. During each step a dialog box is displayed.

6.2.0 Cont.

Detector Dark Field Calibration

A dark image is a timed exposure without an X-ray signal. Dark images may have exposure times ranging from zero (0) to approximately thirty (30) seconds. For convenience, Vision software combines Offset and Dark Calibration in one unified step.

When a Faxitron Bioptics X-Ray System has been turned off for longer than twelve (12) hours, the system will automatically 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 System button on the Vision Start up Screen (main screen). The "SKIP" feature may be used to skip the calibrations if desired. This could result in sub-standard image quality. Refer to Figure 6.2.2. The Dialog will display a status message during calibration.

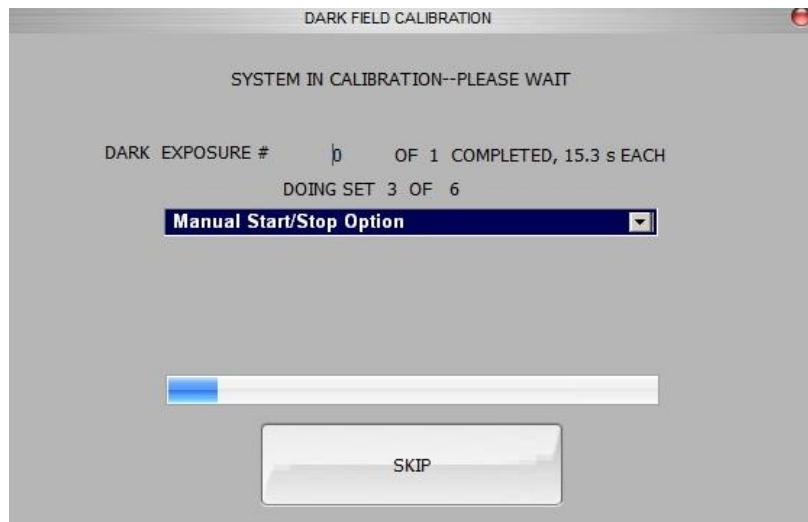


Figure 6.2.2
Dark Field Calibration Dialog Box

6.2.0 Cont.

Detector X-ray (Flat Field) Calibration

A flat-field image is a timed X-ray exposure with either no X-ray attenuation or an object placed in the X-ray beam with uniform attenuation. Under normal operating conditions, there should be no objects in the X-ray beam during calibration.

During the X-Ray Calibration an “Exposure Status” dialog box, with the message: “X-RAY IS ON, WAIT FOR COMPLETION” will be displayed. As each X-Ray exposure is completed and processed, the blue status bar will increment until completion.

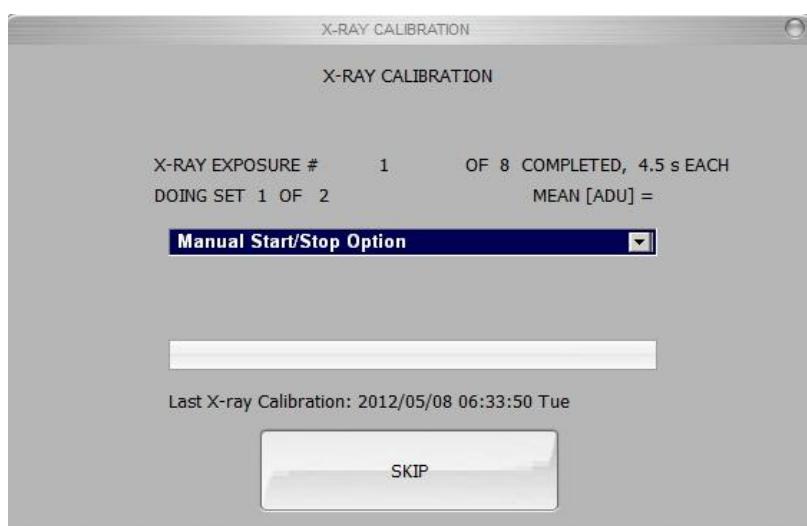


Figure 6.2.3
X-Ray Calibration Dialog Box

The Dialog box will close when Calibration is complete.

You may occasionally need to adjust the Calibration parameters.

The X-Ray Calibration Intensity Levels (MEAN (ADU)) are typically set for approximately 7500. If that value has drifted you can increase either the X-ray energy level (kV setting) or X-ray exposure time in the “X-ray Generator and Exposure Settings” Dialog Box.

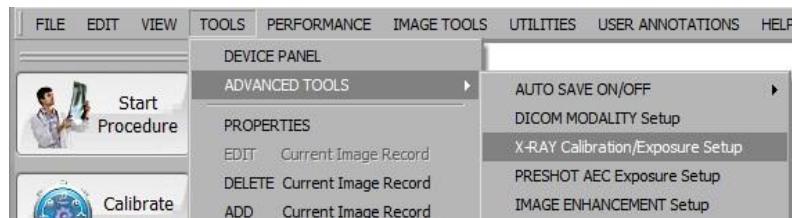
Occasionally it may be desirable to incorporate the X-ray attenuation characteristics of a uniform attenuator in the flat-field reference calibration images. For example, if all objects to be imaged are placed on a thin plastic plate, X-ray attenuation characteristics of the plate will be observed in 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.

Note: different Faxitron Bioptics X-Ray generators have slightly different settings.

6.2.0 Cont.

X-ray (Flat Field) Calibration Set-Up

To adjust the X-Ray Calibration parameters open the X-Ray Generator and Exposure Setting dialog box. On the top menu bar click on TOOLS > ADVANCED TOOLS > X-RAY GENERATOR AND EXPOSURE SETUP.



The X-Ray Calibration and Exposure Setup Dialog box opens.

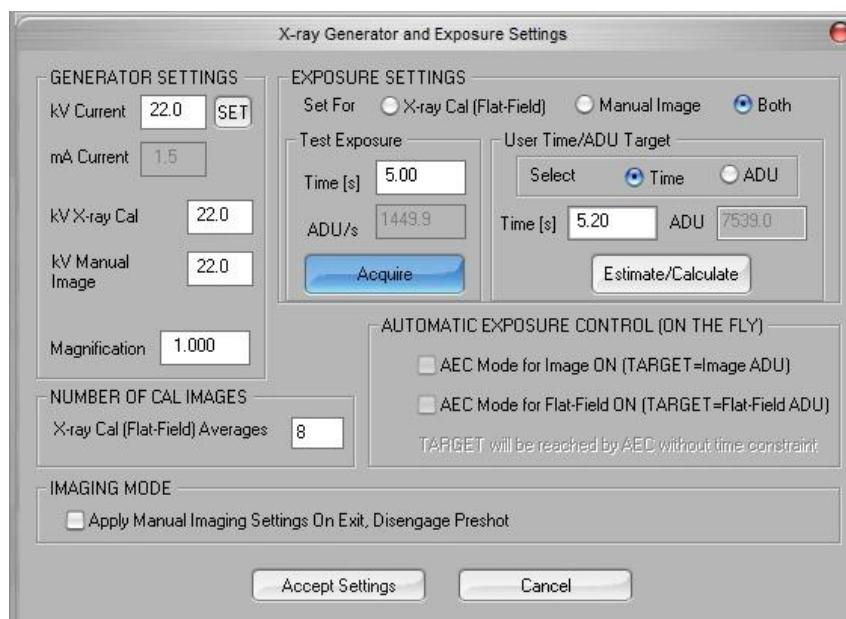


Figure 6.2.4
Advanced Tools Menu

Figure 6.2.5
X-Ray Generator and Exposure Settings Dialog Box

Select "Both" in EXPOSURE SETTINGS and "Time" in User Time/ADU Target.

"kV X-ray Cal and kV Current under GENERATOR SETTINGS should both be the X-ray calibration setting. Adjust if needed and click on "SET".

Set "Time [s]" under Test Exposure to 5.00 and click on "Acquire". System will take a 5 second exposure. Watch for the "ADU/s" under Test Exposure to change.

Click on "Estimate/Calculate" under User Time/ADU Target and check "ADU".

If ADU level is close to desired X-Ray Calibration level click "Accept Settings" at bottom of dialog box. If not, adjust "Time [s]" under User Time/ADU Target, and click on "Estimate/Calculate". Repeat until desire ADU value is attained, then click "Accept Settings"

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

6.2.0 Cont.

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 start-up screen of the imaging software, select the drop down menu item "Tools" in the horizontal menu located at the top of the screen.

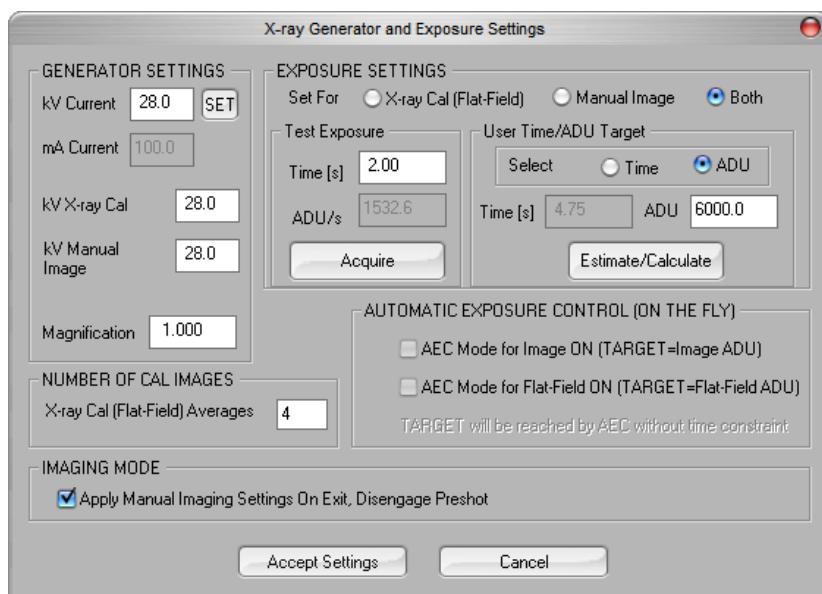


Figure 6.2.6
X-ray Generator and Exposure Dialog Box

NOTICE: The values displayed in the example screen above are NOT necessarily correct for your type of X-Ray generator.

- 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" "Flat-field" 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 "Press exposure button on the generator" Dialog box will be displayed on the screen. Click the "Start" button on the Bioptics X-ray generator panel to activate X-rays.
- When the X-ray exposure is complete, click on the "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. The "Press exposure button on the generator" Dialog box should be displayed on the screen. Click the "Start" button on the Bioptics panel to activate X-rays.
- When X-ray exposure is complete, click on the "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.

6.2.0 Cont.

Experienced users may wish to set the "Flat Field" and "Image" "Exposure Settings" independently or "Both" (Flat Field and Image) dependently 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 "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 "Flat Field" and "Image" and the ADU level has been set, select the "Acquire" button. For the "Image" selection, it is desired to have the object or X-ray attenuator in the X-ray beam. The "Press exposure button on the generator" Dialog box will be displayed on the screen. Click the "Start" button on the Bioptics X-ray generator panel to activate X-rays. When X-ray exposure is complete, click on the "Calculate" button. The system calculates optimum time, and the number is greyed out. When the "Accept Setting" is selected, the "Exposure Settings" are saved 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.

The BioVision system leaves the Faxitron Bioptrics manufacturing facility with the AEC (Automatic Exposure Control) setup to automatically detect specimen thickness. It may be necessary to adjust the AEC settings for optimized results.

6.3.0 AEC Set-up

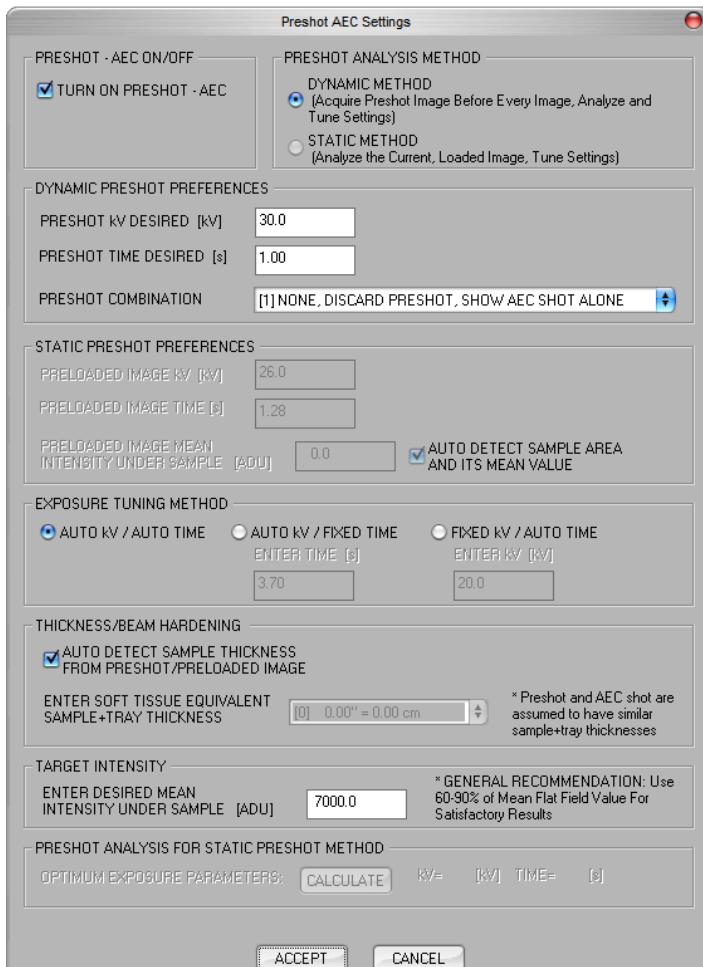


Figure 6.3.1
PreshotAECSettings Dialog Box

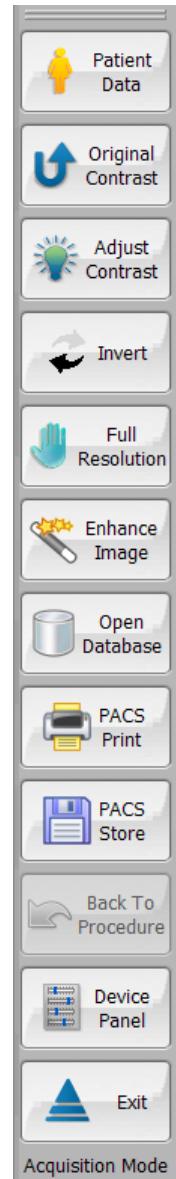
Enter the PRESHOT AEC values in the following window. NOTE the values in the image below are examples only. The correct values will need to be input for your particular system.

The above settings reflect a 30 kV and 1 second exposure time 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 Bioptrics 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 thickness and the TARGET INTENSITY in ADUs. NOTE the values in the above image are an example only. The correct value needs to be determined.

For the AUTOMATIC EXPOSURE CONTROL mode, push the START button within the Vision software. The Vision software will perform a pre-shot (a short, low dose, pre-exposure) of the sample specimen to create a Region of Interest (ROI) for obtaining the exposure parameters for the optimum image exposure.

The *Start* button initiates a new imaging procedure. In this session, images can be taken and manipulated. After activating the *Start* button on the start-up screen, a new window will open displaying a new set of buttons on the left side of the screen. Please refer to *Figure 6.4.1*. Descriptions and definitions for these buttons follow.



6.4.0 Advanced Imaging

Figure 6.4.1
Imaging Buttons

To start a new imaging procedure, patient data must be entered in the Imaging Information Editor window that appears upon entering a new imaging routine. The acquired or retrieved image will be displayed in the display area.

Patient data must be entered into the Imaging Information Editor in order to initiate a procedure. Upon selection of the "Patient Data" button, the "New Entry or Continue Current Entry" Dialog box is displayed. See *Figure 6.4.2* below.

6.4.1 Patient Data Entry

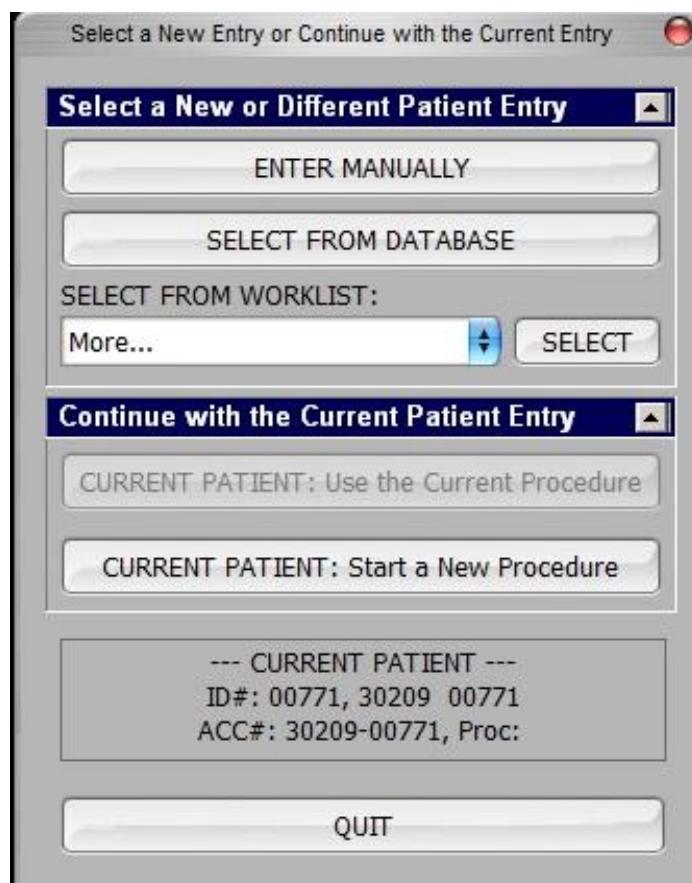


Figure 6.4.2
New Entry or Continue Current
Entry Dialog Box

ENTER MANUALLY
6.4.1 Cont.

To manually enter a new Procedure, select the "ENTER MANUALLY" button. The "Imaging Information Editor" window is displayed. See *Figure 6.4.3*.

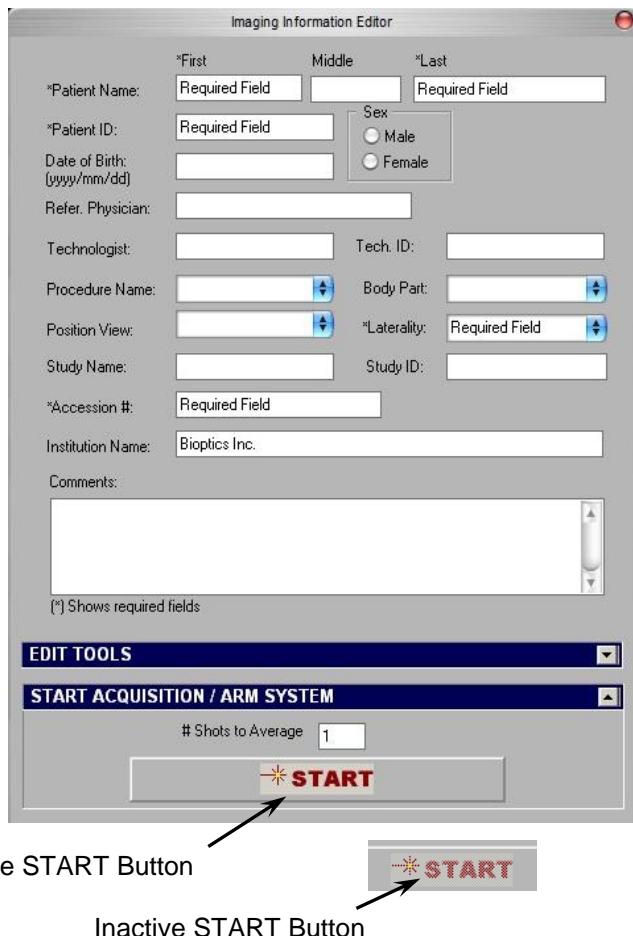


Figure 6.4.3
Imaging Information Editor

The START button will be inactive (grayed out) when the Imaging Information Editor window first opens. The START button will become active when all the required fields have been filled.

The user must enter the Patient Name (First and Last), Patient ID, Laterality, and Accession Number. The user may enter Birth Date, Sex, Referring Physician, Procedure Name, Technologist, Position View, Study ID, Institution Name and optional Comments if so desired. The Procedure Name and Position View are chosen by a drop down menu.

Note: The patient's Birth Date must be entered as year, month, day (e.g. 1962/08/13). If entered incorrectly, an error message will appear.

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

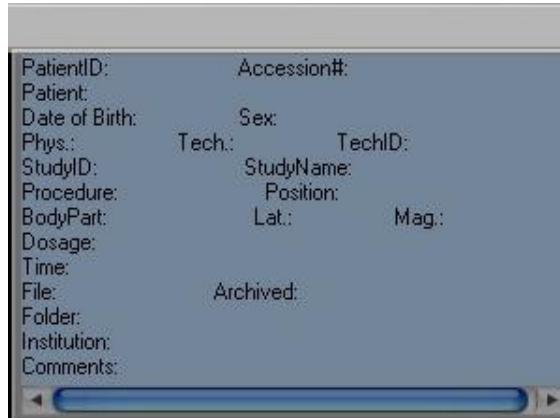
Edit Tools options are provided to edit the 'Imaging Information Editor'. Select Accept/Exit to accept or Cancel/Exit to return to the main menu.

Click on the START button to start the imaging procedure.

The current image information (image properties) is shown in the upper right corner of the graphics window (when image is acquired/loaded), as in Figure 6.4.4. Under the View drop down menu in the horizontal menu bar, the Image Properties hides or shows the Image Properties Box. The box is semi-transparent; this allows one to see what's underneath the box.

6.4.1 Cont.

Figure 6.4.4
Image Properties Box



By pressing the Patient Data button, the "New Entry or Continue Current Entry" Dialog box is displayed again. Options for the Current patient's procedure are provided; "Use the Current Procedure" or "Start a New Procedure" may be selected. The Imaging Information Editor will be displayed with the information fields completed. Once again, the Edit Tools may be used to edit the Procedure. At this time changes can be made to the patient's record and saved by clicking the Accept/Exit button. The changes will be updated in the Patient Information Box shown in the upper left hand corner of the graphics window. The system is now ready to acquire an image. The patient information box is a semi-transparent yellow box when system is properly armed and displays the summary information of patient under the current acquisition procedure.

The Cancel/Exit button will return the user to the Imaging Procedure session without making any changes to the patient's record.

NOTICE: Patient information must be entered before acquiring any images.

SELECT FROM DATABASE

6.4.1 Cont.

Choosing the SELECT FROM DATABASE button will display the following Dialog box. See *Figure 6.4.5 below*.

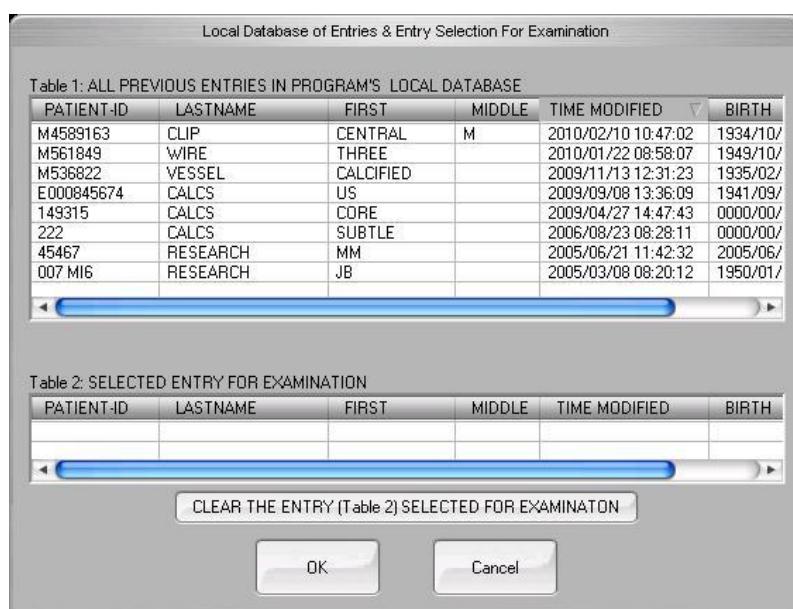


Figure 6.4.5
Selecting Patient From Local Database Entries

By double clicking an entry within Table 1 of the Local Database of Entries, the selection will be displayed in Table 2. Selecting "OK" completes the information in the Imaging Information Editor.

SELECT FROM WORKLIST (Remote Modality Work list)

Choosing the "SELECT FROM WORKLIST" button will display the following Dialog box. See *Figure 6.4.6 below*.

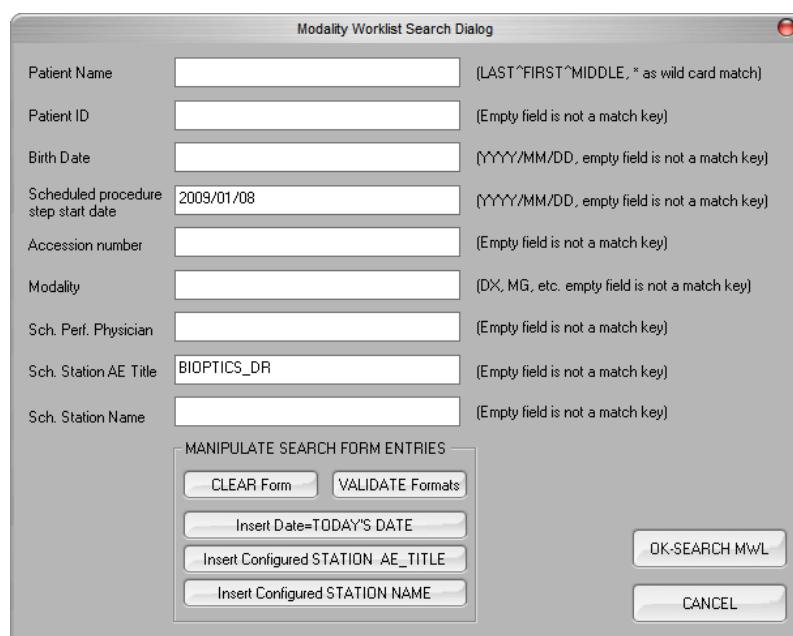


Figure 6.4.6
Modality Worklist Search Dialog box

The Modality Worklist Search Dialog box 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 "OK-SEARCH WML" the following Dialog box will be displayed. See figure 6.4.7 below.

6.4.1 Cont.

Modality Worklist Report & Entry Selection

Table 1: LIST OF RECEIVED ENTRIES (17 TOTAL)

PatientID	Accession#	Patient Name(L^F^M)	BirthDate	Sex	Modality
pidP645	00000187	One^Secondary Capture I...	1980/07/16	M	MA
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I1		One^Secondary Capture I...		O	OT
SC-I2		Two^Secondary Capture I...		O	CT
SC-I2		Two^Secondary Capture I...		O	CT
SC-I2		Two^Secondary Capture I...		O	CT

Table 2: SELECTED ENTRY FOR EXAMINATION

PatientID	Accession#	Patient Name(L^F^M)	BirthDate	Sex	Modality

CLEAR THE ENTRY (Table 2) SELECTED FOR EXAMINATION

Table 3: REPORT OF THE HIGHLIGHTED ENTRY ON "Table 1"

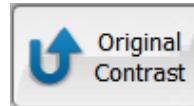
Tags	Value
Patient Name	One^Secondary Capture Image
Patient ID	pidP645
Patient Birth Date	1980/07/16
Patient Sex	M
Patient Weight	80.000000
Patient Confidentiality	
Patient State	
Pregnancy Status	unknown
Medical Alerts	MT
Contrast Allergies	
Special Needs	
Accession Number	00000187
Modality	MA
Study Description	
Series Description	
Scheduled Station AE Title	BIOPTICS_DR
Scheduled Procedure Step Start Date	2009/01/08
Scheduled Procedure Step Start Time	2009/01/08
Scheduled Procedure Step End Date	
Scheduled Procedure Step End Time	
Scheduled Performing Physician	
Scheduled Procedure Step Description	CSPINE
Scheduled Procedure Step ID	000001070C

PRINT Report on Table 3 OK Cancel

Figure 6.4.7
Modality Worklist Report & Entry Selection

By using the mouse to double click on an entry listed in Table 1 of the Modality Worklist Report & Entry Selection and selecting "OK" at the bottom of the Dialog box, the Imaging Information Editor will automatically be completed. Upon returning to the Imaging Information Editor, select "START" to continue.

This button will restore the original contrast levels of the image.



6.4.2 Original Contrast

This button will adjust the image contrast and brightness levels. To change the Image levels, select the *Adjust Contrast* button and a Dialog box will appear. Adjust the slider bar for desired image contrast. See *figure 6.3.9*. (Informally this is also known as "Window Leveling".)



6.4.3 Adjust Contrast

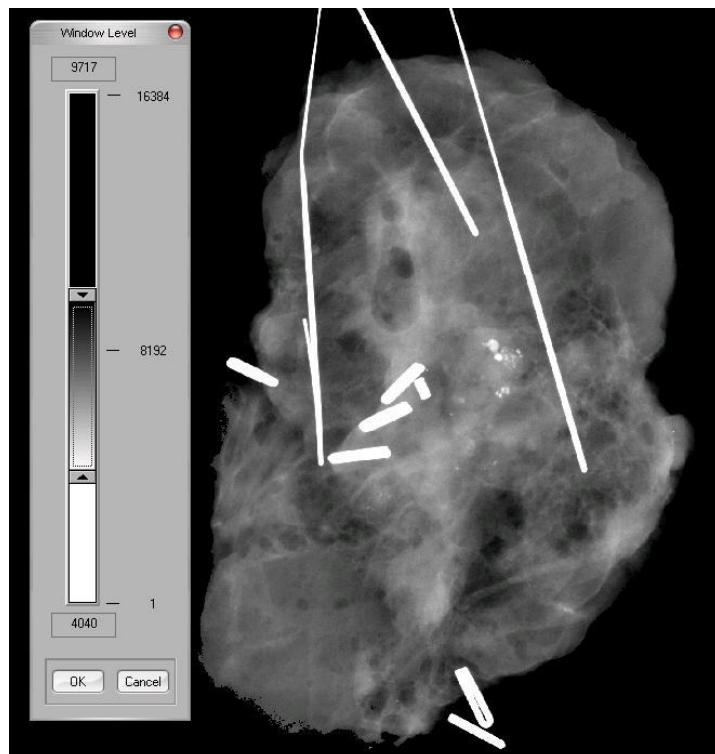


Figure 6.4.8
Adjust Contrast / Window Level

This button will invert the current image. This means what was once white will now be black and vice-versa.



6.4.4 Invert

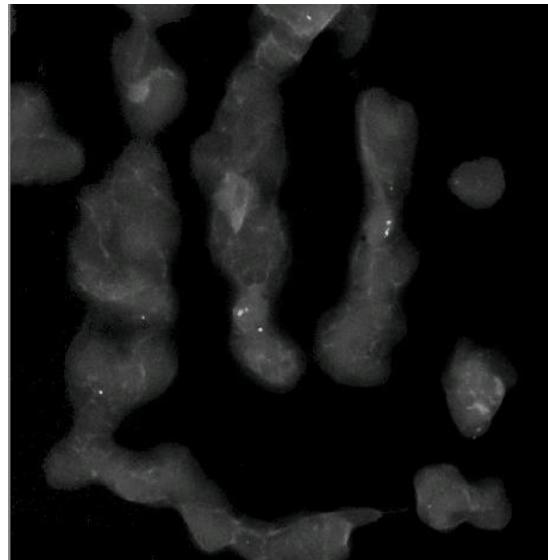


Figure 6.4.9
A "normal" image before invert

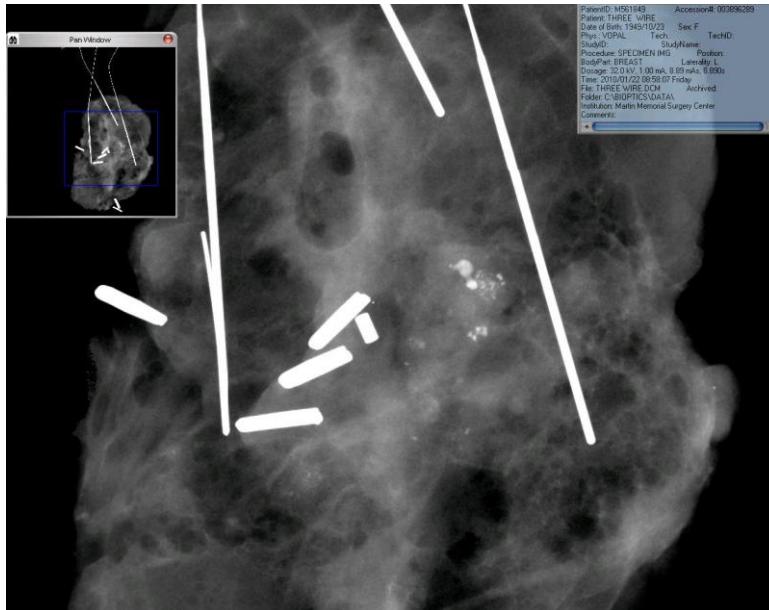


Figure 6.4.10
The same image after the invert operation

This button will move the image around the main screen. After selecting the Full Resolution button, click and hold the left button over the image and move the mouse to move the image around in the main screen. This feature is disabled when the zoom mode is set to *Fit All*.



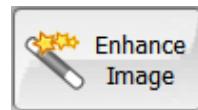
Note that traditionally, this feature is also called "Pan View" and/or "Pan and Scan."



6.4.5 Full Resolution

Figure 6.4.11
Full Resolution (Pan View)

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

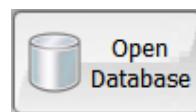


The algorithm commonly known as "Peripheral Equalization" or "Thickness Equalization" in mammographic imaging is applied to the whole image. In addition, Faxitron Bioptrix employs a second custom, internally developed, algorithm we call the "Calcification Emphasis" algorithm. Its purpose is to bring out possible calcifications in the image and make them much easier to see and diagnose.

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

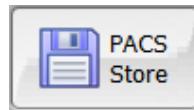
The system will be idle during the processing and once completed the button will stay depressed/active. The user can undo the process by pressing the button again.

This button will initiate and display the Image Database where images can be retrieved and displayed. Once an image has been opened from the database, a new button will be available: *Back to Procedure*. Please see *Database* for more detailed information.



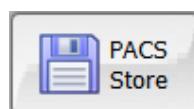
6.4.7 Open Database

This button will automatically connect to your PACS network and print to the default PACS printer.



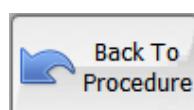
6.4.8 PACS Print

This button will automatically save the current image in DICOM 3.0 format to your default PACS network storage area.



6.4.9 PACS Store

This button will automatically save the current image in DICOM 3.0 format to your default PACS network storage area.



6.4.10 Back to Procedure

This button will help controlling the panel settings on the x-ray system through the software for convenience. The mode of exposure, tube kV, and exposure time can be selected easily from the dialog shown below.



6.4.11 Device Control Panel

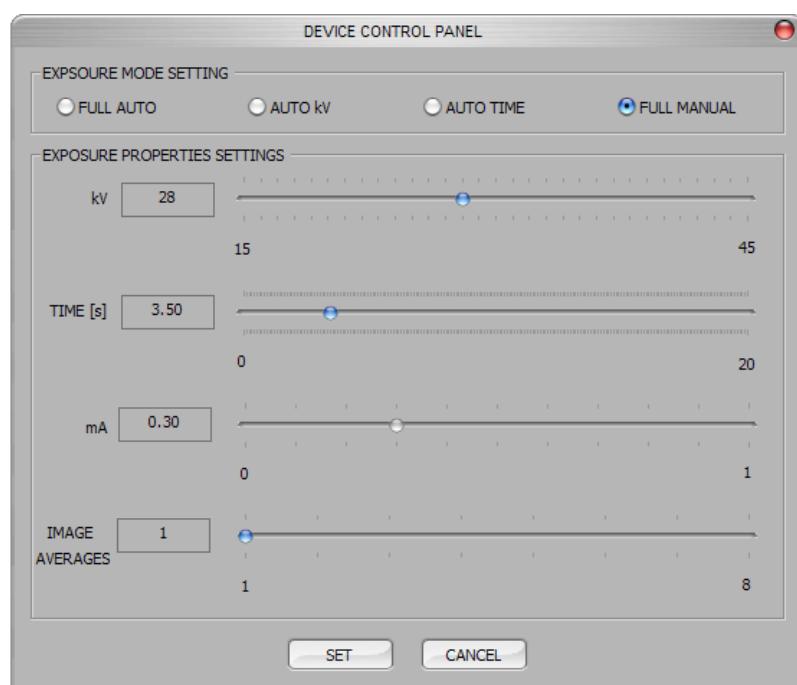


Figure 6.4.12
Device Control Panel Dialog box

This button will exit the imaging area and returns to the Startup screen, (also known as the Main Screen).

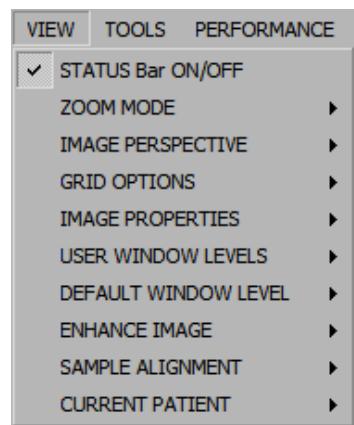
This button will exit the imaging area and returns to the Startup screen, (also known as the Main Screen).



6.4.12 Exit

Display of Acquired Image

The format in which the acquired image is displayed is determined from a main-menu choice View, located in the top of the screen. The user may display the acquired image in the following formats:



6.4.13 View Display

Figure 6.4.13
View Menu

Status Bar

Toggles the status bar, located along the bottom of the Vision software, on or off. The status bar displays system and image level information (i.e. camera status, pixel location and intensity).

Normal

Displays the acquired image in it's native format and for large area images (100 X 100 mm), scroll bars are provided to view the image, as the image exceeds the available graphics area. The middle scroll button on the mouse may be used to scroll up and down the display area. Additionally, the Full Resolution button can be used to view the entire image.

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 Perspective

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

Grid Options

6.4.13 Cont.

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.

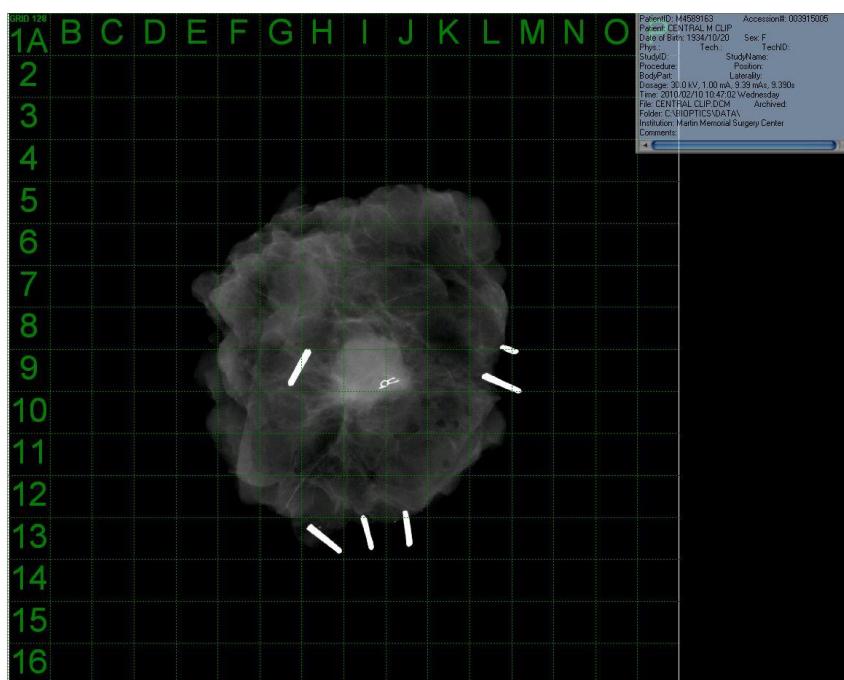


Figure 6.4.14
Sample grid display

Image Properties

Shows or hides the Patient Information Box.

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. 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. This adjusts the WL for the entire image. The Optimize for sample, adjusts the WL for under the sample area only.

Enhance Image (same as the Enhance Image button)

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

Sample Alignment

Currently not used.

6.4.13 Cont.

Current Patient

Shows or hides the Patient Information Box

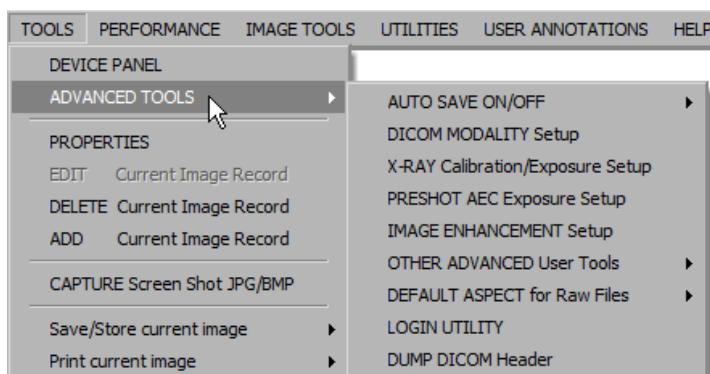
Review Layout

Helps user configure multiple image panes in the Review (Database) Mode of program. Available options are dual horizontal, dual vertical, triple and 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 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 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).

The *Tools* menu is located in the horizontal menu found in the upper left hand corner of the main screen. *These tools apply to the image currently displayed.*

6.4.14 Tools

Figure 6.4.15
Tools menu



Device Panel

Same functionally as explained previously under "Device Control Panel". The menu option activates the device panel to control x-ray system.

ADVANCED TOOLS Options

Many configuration options for advanced users can be modified through available submenu items of Advanced Options.

Auto Save On/Off

This is placed under ADVANCED TOOLS. When Auto save is "on", all acquired images are saved to the database written to a Data Directory define in the configuration file.

DICOM Modality Setup

6.4.14 Cont.

This is placed under ADVANCED TOOLS. DICOM and Database features and functionality will be described in greater detail in another section of the Advanced User Manual. See Open Database and DICOM Functionality.

X-ray Calibration/Exposure Set-up

This is placed under ADVANCED TOOLS. The X-ray generator/exposure setup aids the user in determining the proper exposure time for a selected kV setting for best image quality.

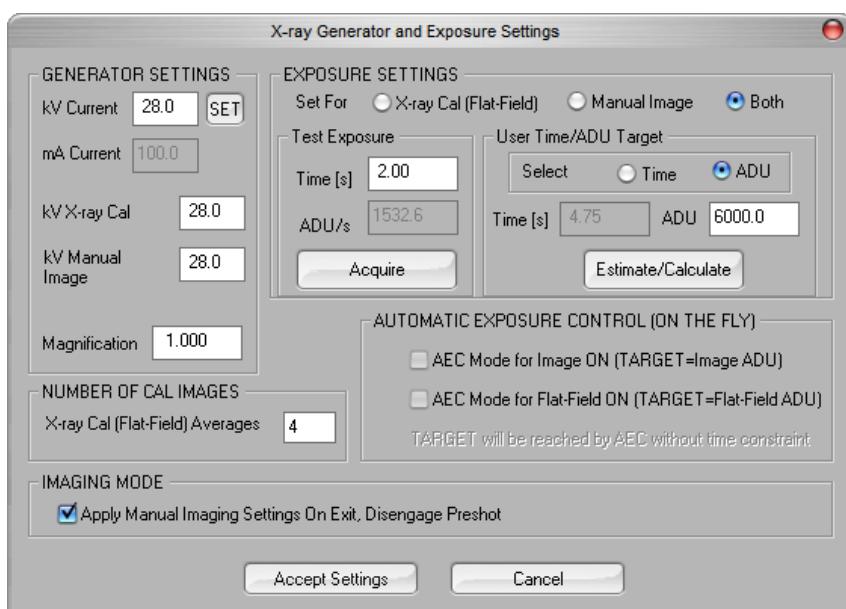


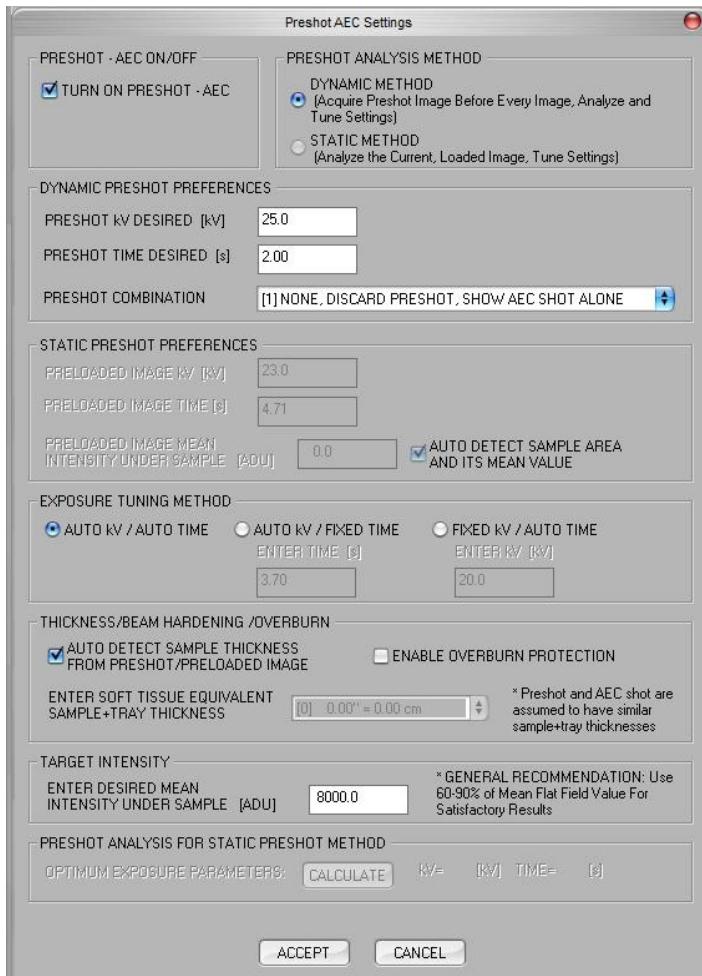
Figure 6.4.16
X-Ray Generator and Exposure Settings Dialog Box

Preshot AEC Exposure Setup

This is placed under ADVANCED TOOLS. It was explained in Quick Start Section under "AEC Automatic Basic Operation"

6.4.14 Cont.

Figure 6.4.17
Preshot AEC Settings Dialog Box



Enter the PRESHOT AEC values in the following window. NOTE the values in the image below are examples only. The correct values will need to be input for your particular system.

The above settings reflect a 30 kV and 1 second exposure time 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 Bioptics 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 thickness and the TARGET INTENSITY in ADUs. NOTE the values in the above image are an example only. The correct value needs to be determined.

For the AUTOMATIC EXPOSURE CONTROL mode, push the START button within the Vision software. The Vision software will perform a pre-shot (a short, low dose, pre-exposure) of the sample specimen to create a Region of Interest (ROI) for obtaining the exposure parameters for the optimum image exposure.

6.4.14 Cont.

Image Enhancement Setup

This is placed under ADVANCED TOOLS. The dialog allows a user to configure and tune image enhancement algorithm (see section 6.5.4. Enhance Image for more).

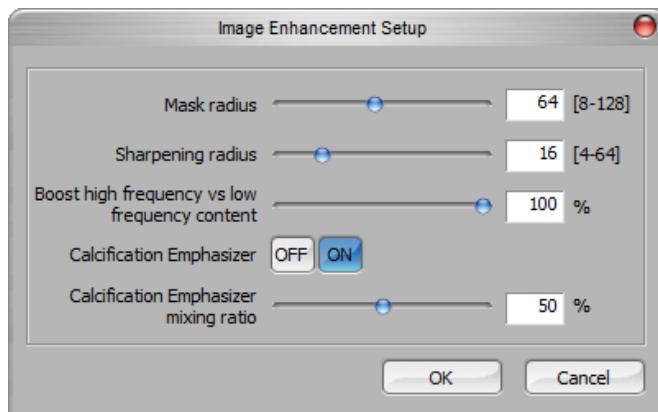


Figure 6.4.18
Image Enhancement Setup Dialog Box

Login Utility

This is placed under ADVANCED TOOLS. It helps configure and activate/deactivate the start-up password authentication for the program. The desired changes will only apply if user password is entered correctly. If password authentication is activated the program will ask and verify the password at the startup of the program and will exit the program if correct password is not given.

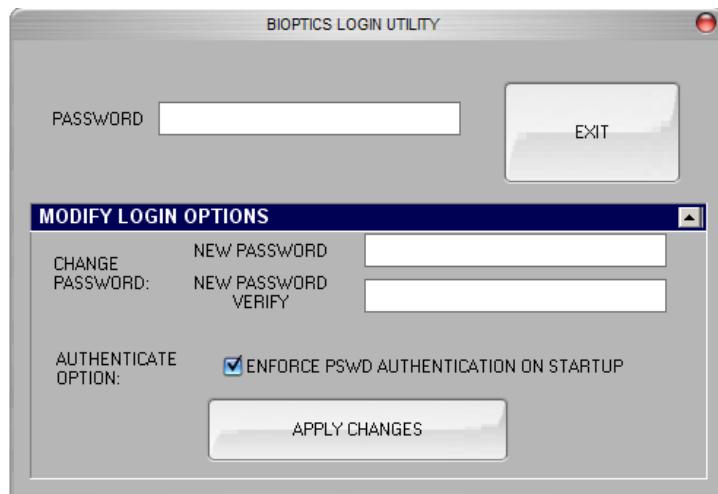


Figure 6.4.19
Login Utility Dialog Box

Default Aspect of Raw Files

This tool is placed under ADVANCED TOOLS. 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).

6.4.14 Cont.

Digital Imaging and Communications in Medicine (DICOM)

Properties

The Properties hides or shows the Patient Information Box.

Edit

Currently not used.

Delete

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

Add

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

Save/Store current image

This sub-menu contains commands for saving current image to local disk or storing to PACS server. For details see Save/Store image in 5.5. DB-TOOLS Menu section.

Print current image

This sub-menu contains commands for printing current image on a local printer or a PACS printer. For details see Print image in 5.5. DB-TOOLS Menu section.

Save Local

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.

DICOM Local
6.4.14 Cont.
Save, Store and Print (PACS Store, PACS Print)

This functionality is applied to the image which is currently in session. Please refer to the "DICOM Functionality" section for a detailed review of these features.

Capture Screen 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 or BMP as the saved file format.

The following features are available to edit the acquired or retrieved image by clicking on the Image Tools menu on the main-menu. See *Figure 6.9*.

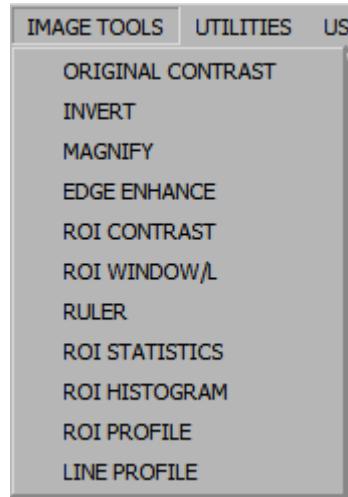
6.5.0
Image Tools


Figure 6.5.1
Image Tools Menu

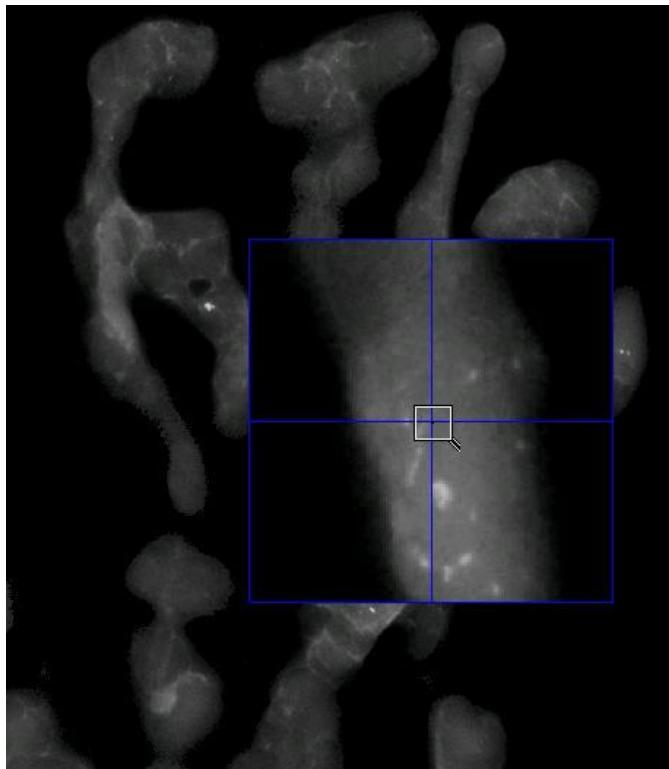
By selecting the *Original Contrast* from the Image Tools menu, the image contrast levels will be restored. Same behavior as the Original Contrast button.

6.5.1
Original Contrast

By selecting Invert from the Image Tools menu, the displayed image will 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.

6.5.2
Invert

By selecting Magnify from the Image Tools menu, it 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.



6.5.3 Magnify

Figure 6.5.2
Magnify

Selecting *Edge Enhance* from the Image Tools menu 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. Selecting the *Original Contrast* button will also restore the image back to its original state. Note this is a **different** feature than the Enhance Image feature.

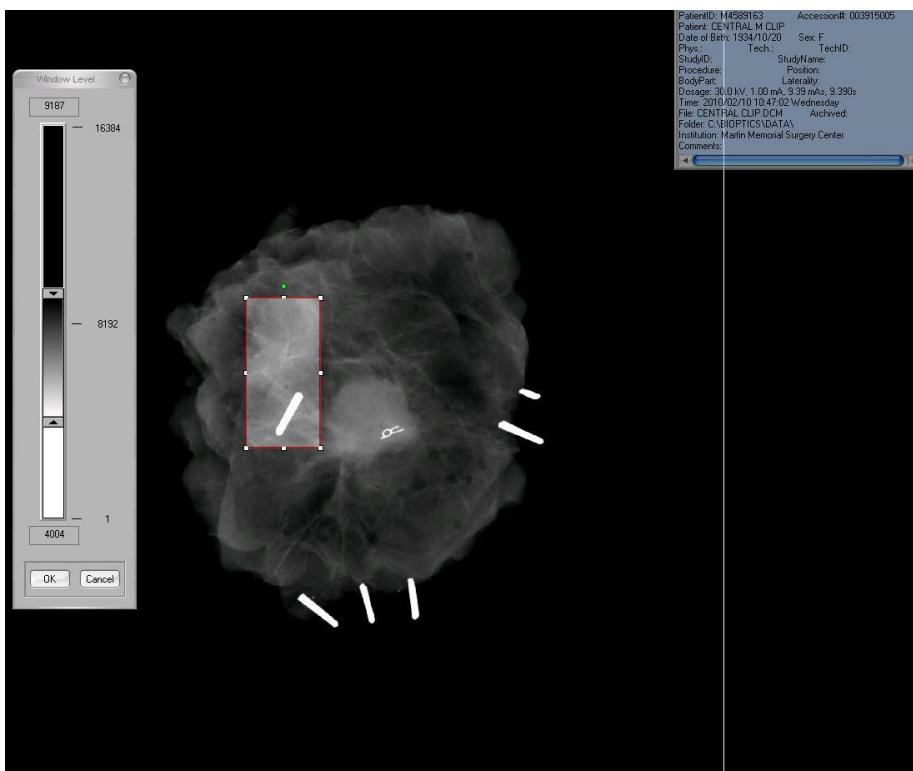
6.5.4 Edge Enhance

Selecting ROI Contrast from the Image Tools menu will optimize the contrast levels within a user-defined region of interest (ROI). After selecting the ROI Contrast menu button, 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. (See the Definitions section for ROI)

6.5.5 ROI Contrast

Selecting the *ROI Window/L* (window Level) function from the Image Tools menu can be used to adjust the image contrast and brightness levels in a user-defined ROI. After selecting the *ROI Window/L*, click and hold the left mouse button at the desired starting point of the desired ROI, drag the mouse and release the mouse button at the desired ending point of the ROI. See figure 6.5.3 below. To modify the contrast and brightness levels, move the bar up or down. Click *ROI Window/L* again to turn off this feature. (See the Definitions sections for ROI)

6.5.6 ROI Window/L



**Figure 6.5.3
ROI W/L**

By selecting Ruler from the Image Tools menu, this will allow the user to measure the distance between two points in the displayed image. Length measurements are in millimeters (mm). After selecting the Ruler from the Image Tools menu, click and hold the left mouse button starting at the point of measurement, drag the mouse and release the mouse button at the ending point of measurement.

6.5.7 Ruler

Measurements (in mm) are displayed on the bottom right side of the graphics window. The Ruler remains active until the user selects another image tool and a line is displayed in red until another action is performed. See *Figure 6.5.4 below*. 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.

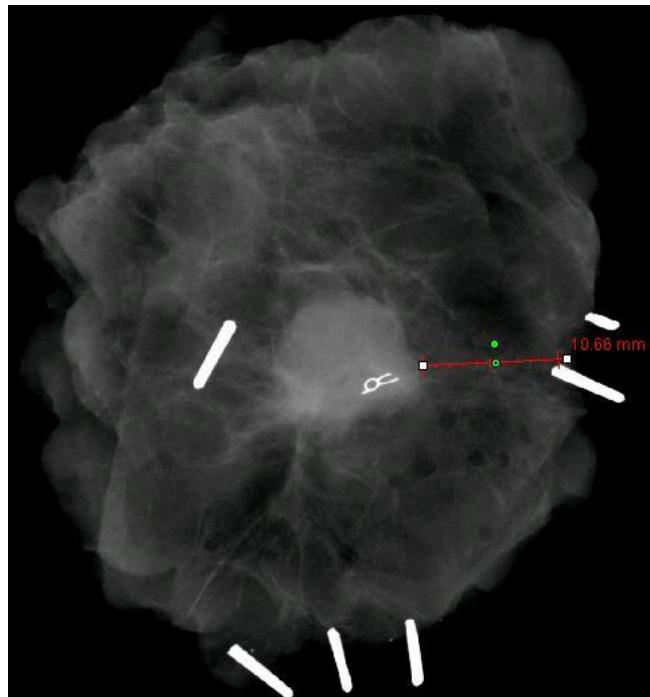
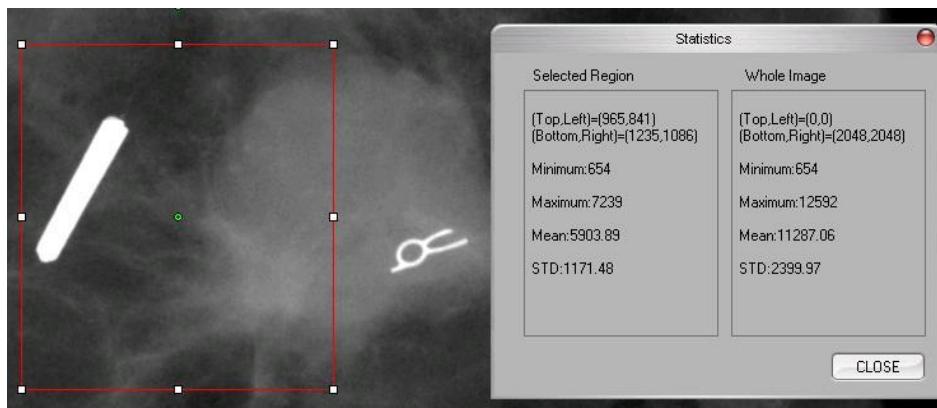


Figure 6.5.4
Ruler

After selecting the ROI Statistics from the Image Tools menu, click and hold the left mouse button over main image's region-of-interest (ROI), drag cursor to make selection around area, then release the mouse button. Statistical information will be displayed for that particular ROI, including Mean, Standard Deviation, Max/Min intensity values and total Pixels. To close the Statistics information box, simply click on the Close button. See *figure 6.5.5*. Click ROI Statistics again to turn off the feature.



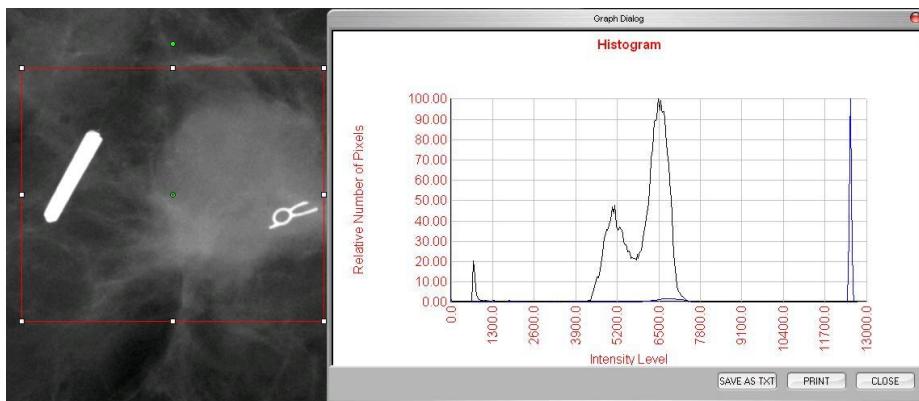
6.5.8
ROI Statistics

Figure 6.5.5
ROI Statistics

The *ROI Histogram* from the Image Tools menu will create a histogram for the ROI the user defines.

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 6.5.6

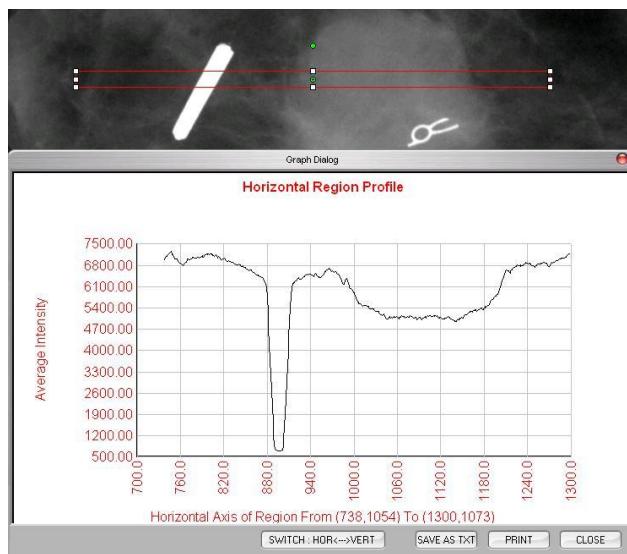
The Black curve is the Histogram of the selected region. The Blue curve is the Histogram of the whole image. Both curves are normalized against the peak maximum pixel value of the selected region of interest. Click *ROI Histogram* again to turn off the feature.



6.5.9
ROI Histogram

After selecting the ROI Profile from the Image Tools menu, place the cursor in the displayed image.

While holding down the left mouse button, move 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 value of the defined ROI, please refer to figure 6.5.7. 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.

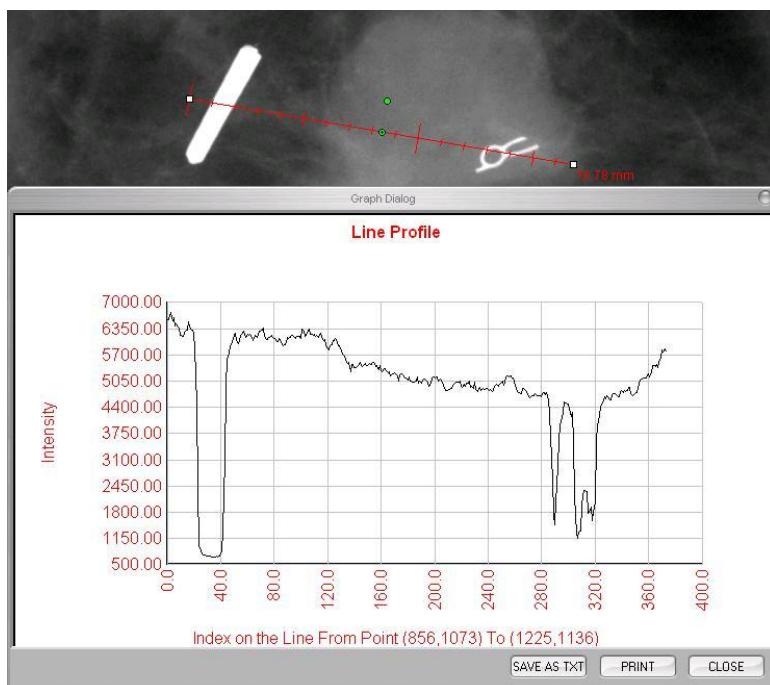


6.5.10
ROI Profile

After selecting the *Line Profile* from the Image Tools menu, place the cursor in the displayed image.

While holding down the left mouse button, 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 value of the defined line, please see *figure 6.5.8*. 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.



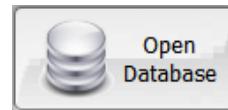
6.5.11 Line Profile

This feature is an "automatic" feature. This is no button or menu item to select it. Once an image has been acquired or retrieved from the database and is displayed on the screen, a built-in Windows Level is available automatically giving the user the ability to adjust the image contrast and brightness levels.

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

6.5.12 Built-In Window Level

By pressing this button, the Image Database dialog window is displayed.



6.6.0 Database

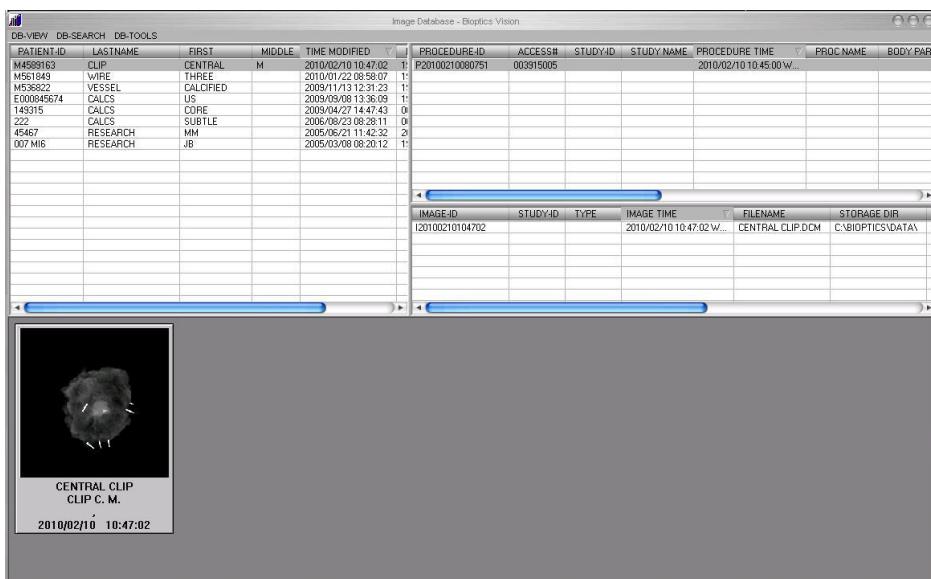


Figure 6.6.1
Image Database

The Database is basically comprised of four sections or sub-windows. The Patient List Table section, the Procedure List Table section, the Image List Table section and the Image Thumbnail List/Viewer section.

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

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

- The Patient selection window is the upper left most window. The Procedure window is the upper right most window.
- 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.
- When a Procedure is selected, a listing of all of the images is displayed in the Image section, which is located in the lower Right-hand window. Additionally, "thumbnails" (if one exists) for the image, will be displayed in the Thumbnail List/Viewer at the bottom of the Vision desktop.

Important Note: The "thumbnail" images (.bmp) 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 (.bmp) file extension. It is possible to have an image file and no "thumbnail".

To create a "thumbnail" image of an existing image file, simply select the image file from the Image section of the database, click the right mouse button, and select 'Add Record'. This will automatically create the "thumbnail" image and display it in the Thumbnail Viewer, if the "thumbnail" is missing.

If the Image section of the Database is selected, the selected image is highlighted in the Thumbnail Viewer. Conversely, if a thumbnail image is selected, its associated image file is highlighted.

6.6.0 Cont.

The computer's keyboard may also be used to navigate through the Dialog boxes. The "Tab" key selects the window of interest and the arrow keys move the fields.

The user may select any field (PATIENT-ID, LASTNAME, FIRST, MIDDLE, PROCEDURE-ID, IMAGE-ID are examples) in the database. When the mouse cursor is clicked on 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.

When you click any row in the database, the associated data files are also highlighted. Clicking within the displayed image thumbnail will also highlight its associated file. Simply double-click the image thumbnail of interest and the image is displayed in the main viewing window. When the image is displayed, the Image Database window automatically minimizes for future ease of use.

Image Database Menu Functions and Tools

There are functions to navigate, search in the database, or to edit, delete, add records into the database. Those functions are explained through database menu items.

DB-VIEW Menu

The DB-View Dialog box is shown below.

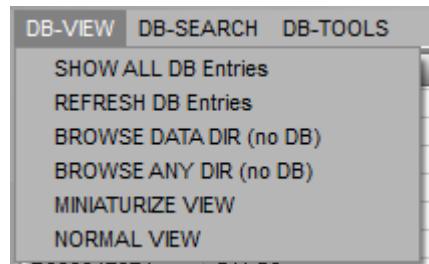


Figure 6.6.2
DB-VIEW Dialog box

Show All DB Entries

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

Refresh DB Entries

Refreshes the Patient table, but maintains any existing "SEARCH FILTER" that has been applied.

Browse Data Directory (No DB)

6.6.0 Cont.

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

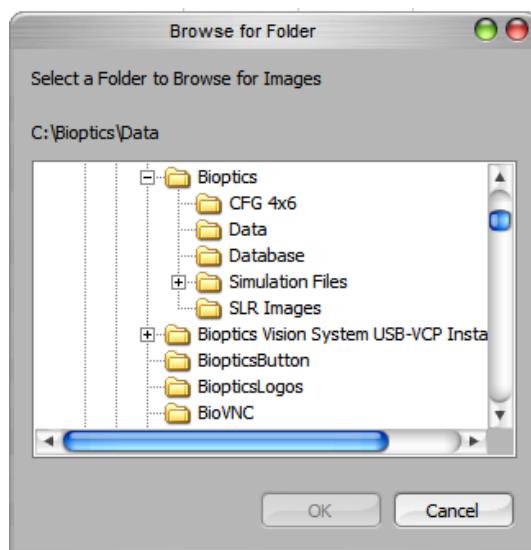


Figure 6.6.3
Window for Browse Any Directory

DB-SEARCH Menu

The database search tools provide detailed searches or database filtering. By selecting the DB-SEARCH menu, a detailed and specific search may be performed. When search criteria is entered and activated in the DB Search Dialog (explained below), 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 DB-SEARCH menu or "SHOW All DB Entries" from DB-VIEW menu. The active "SEARCH FILTER" is always shown in the caption of Image Database dialog.

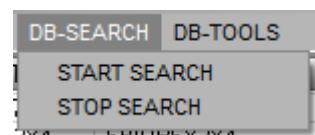


Figure 6.6.4
Starting a DB-SEARCH

START SEARCH:
6.6.0 Cont.

"STOP SEARCH" disables any active "SEARCH FILTER" and clears all list tables and reloads the list of all patients to Patient List Table.



Figure 6.6.5
DB SEARCH Dialog box

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 the Start button to initiate the search. If the category can have more than one discrete entry, all entries for that category will be displayed.

STOP SEARCH:

"STOP SEARCH" disables any active "SEARCH FILTER" and clears all list tables and reloads the list of all patients to Patient List Table.

DB-TOOLS Menu

"DB-TOOLS" menu provides per Image/Procedure/Patient functions as well as some useful functions to repair or reformat the database.



Figure 6.6.6
DB-TOOLS Menu

PROPERTIES**6.6.0 Cont.**

"PROPERTIES" item is available when entry from Image Table or Thumbnail List is selected, otherwise disabled. It generates Image Properties pop up dialog box, which gives the summary of image properties as shown below.

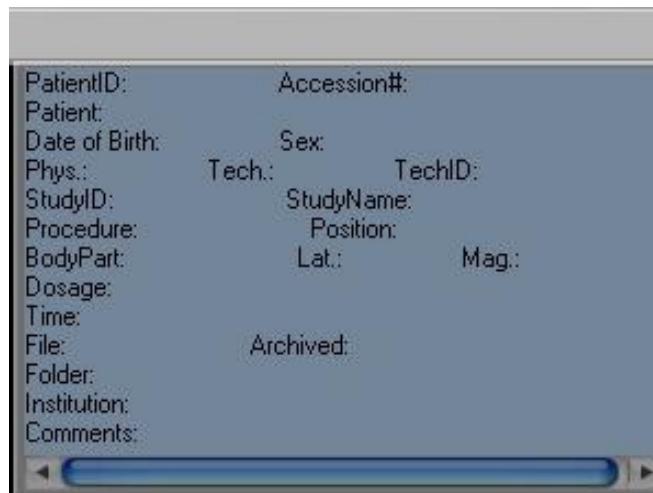
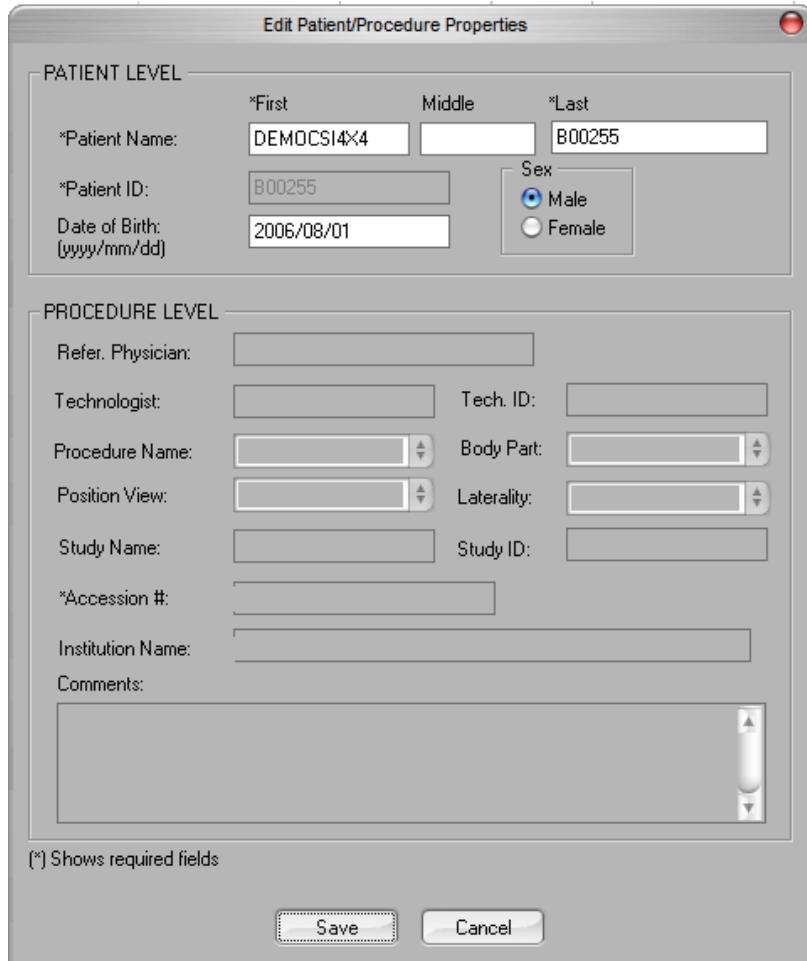


Figure 6.6.7
Properties Dialog box

EDIT Record:
6.6.0 Cont.

"EDIT Record" item is available when entry from Patient or Procedure Table is selected; this option is disabled when Image entry is selected. When "EDIT Record" is selected, the Edit Patient/Procedure Properties dialog box will pop up. The user needs to fill in the area according to the selection level which is either Procedure Entry or Patient Entry. The entries on the other level will be disabled. As seen below, when the user selects a procedure entry from Procedure Table to edit, the procedure parameters will be enabled to edit and others disabled (Patient parameters). PatientID is never allowed to be changed.



The dialog box is titled "Edit Patient/Procedure Properties". It has two main sections: "PATIENT LEVEL" and "PROCEDURE LEVEL".

PATIENT LEVEL:

- *Patient Name: DEMOCSI4X4
- Middle: (disabled)
- *Last: B00255
- *Patient ID: B00255
- Date of Birth: (yyyy/mm/dd): 2006/08/01
- Sex: Male Female

PROCEDURE LEVEL:

- Refer. Physician: (disabled)
- Technologist: (disabled)
- Tech. ID: (disabled)
- Procedure Name: (disabled)
- Body Part: (disabled)
- Position View: (disabled)
- Laterality: (disabled)
- Study Name: (disabled)
- Study ID: (disabled)
- *Accession #: (disabled)
- Institution Name: (disabled)
- Comments: (disabled)

(*) Shows required fields

Buttons at the bottom: Save, Cancel

Figure 6 .6.8
Edit Patient/Procedure
Properties Dialog

DELETE Record:

Depending on the final selection level i.e. whether the last click of the user is on Patient Table/Procedure Table/Image Table, the user can delete all database entries associated with the selection. The image file(s), the thumbnail(s) associated with the selection will be erased from the disk. When all images under a Procedure are deleted, the program will delete the procedure entry from DB automatically.

However, a patient entry will never be deleted even it has no procedures under that patient entry. To delete a patient entry from DB, the user should always request this action. For all delete requests, a message box will pop up with a warning and confirmation of request before an actual deletion occurs.

ADD Record:
6.6.0 Cont.

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 database about 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 create full database entries for all the image files under the selected directory (including subdirectories). The formats for images can be DCM, DAT, DMM, or 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.

Save/Store image Sub-menu:

This menu contains commands for saving an image or a group of images to a local disk or storing it to a PACS server. The menu contains, among a set of fixed commands described below, a list of PACS servers defined in the application capable of storing images (for information on defining PACS servers see paragraph PACS STORE in section 6.7.0 DICOM Functionality). Activating one of those commands will bring up the DICOM Networking dialog and automatically store image(s) to the selected server.

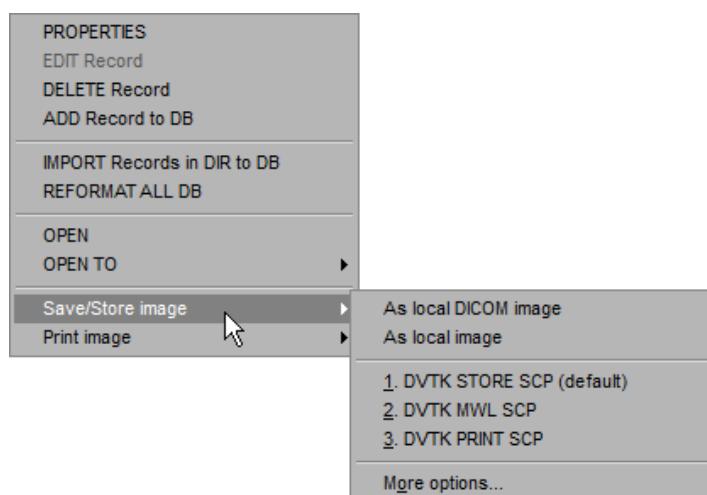


Figure 6.6.9
Save/Store Image Menu

As local DICOM image:

6.6.0 Cont.

This item is available when entry from the Image Table or Thumbnail List is selected, otherwise it is disabled. The selected image will be saved as a DICOM file, an additional dialog box will pop up and the user will select the path and pathname for the file from a dialog box.

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

As local image

This item is available when an entry from the Image Table or Thumbnail List is selected, otherwise it is disabled. The selected image can be saved in the following popular 8-bit image formats: JPEG, BMP, TIFF, or RAW. It can also save in 16-bit TIFF format.

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

More options...:

This item is available when entry from the Procedure List, or Image Table or Thumbnail List is selected, otherwise it is disabled. The selected image(s) will be marked for DICOM storage and DICOM Networking dialog will be started to do the actual network transaction with DICOM Storage Server (DICOM Storage SCP). The window level of the DICOM stored image is the default window level. When selected entry is from the Procedure list, all the images under the selected procedure will be marked for DICOM store.
(this command has been previously known as PACS STORE)

Print image Sub-menu:

This menu contains commands for printing an image or a group of images to a local printer or to a PACS server. The menu contains, among a set of fixed commands described below, a list of PACS servers defined in the application capable of printing images (for information on defining PACS servers see paragraph PACS PRINT in section 6.7.0 DICOM Functionality). Activating one of those commands will bring up the DICOM Networking dialog and automatically print image(s) to the selected server.

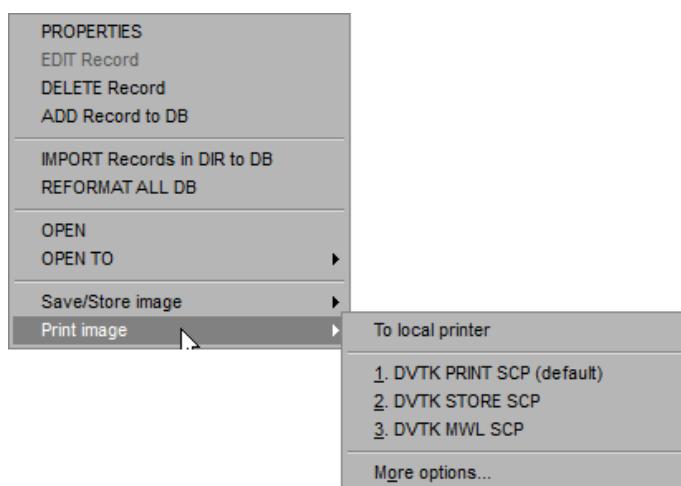


Figure 6. 6.10
Print Image Sub-Menu

To local printer:
6.6.0 Cont.

This item is available when entry from the Image Table or Thumbnail List is selected, otherwise it is disabled. The selected image will be printed using local default printer of Windows system.

The window level of the printed image is the default window level. It is not recommend 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

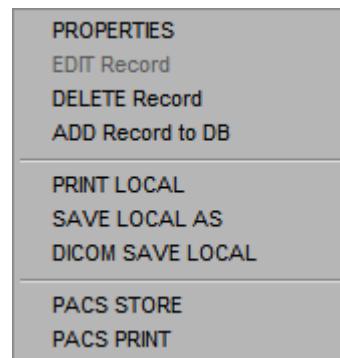


Figure 6. 6.11
Right Mouse button is selected over thumbnail image

More options...:

This item is available when entry from the Image Table or Thumbnail List is selected, otherwise it is disabled. The selected image will be marked for DICOM printing and DICOM Networking dialog will be started to do the actual network transaction with DICOM Print Server (DICOM Print SCP).

(this command has been previously known as PACS PRINT)

The window level of the DICOM printed image is the default window level. It is not recommend to use DICOM Print from this menu, unless the user is satisfied with the print outs, set to the default window levels calculated by the program. The user can load the image first into 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 DICOM Print from the menu of Image View window.

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.

RIGHT CLICK Mouse Menu

Depressing the Right click mouse button on a table list or thumbnail list entry (on Image Database dialog) will pop up a menu shown below. All the menu items are included in DB-TOOLS menu and explained previously, their functionalities are identical.

6.6.0 Cont.

EXIT, MINIMIZE, and SIZE Image Database Dialog

Image Database dialog provides standard exit, minimize, maximize window tools on the right corner of the caption. Just click on [x], [-], or [+] to exit, minimize or maximize the database view dialog window.

The Dialog is also resizable; the thumbnails will arrange themselves according to the total Dialog space.

Difference between PRINT and PRINT LOCAL or SAVE and SAVE LOCAL:

As well as "PRINT LOCAL..", "SAVE LOCAL.." and "DICOM SAVE LOCAL..", there will be so called "unspecified" PRINT and SAVE drop down menu options or buttons. These menu and button tools will prompt the user to select whether to PRINT on the LOCAL system (provided by Windows System infrastructure) or DICOM Networking environment (provided by this program's DICOM Networking infrastructure) and whether to SAVE the image in an 8-bit JPEG, BMP, TIFF, RAW format or in a 16-bit DICOM or 16-bit TIFF format.

The DICOM Standard

What is the DICOM Standard?

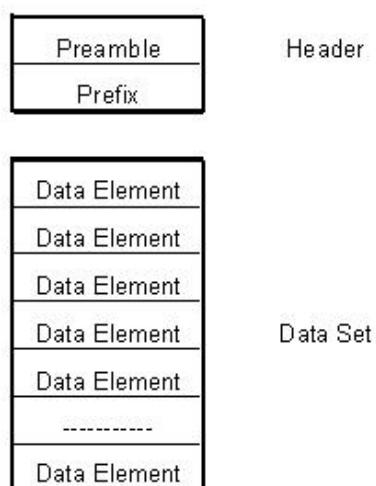
The Digital Imaging and Communications in Medicine (DICOM) Standard is a series of protocols used by medical equipment and software to allow data to be compatible and interchangeable with other medical equipment or software.

When a file is saved in a DICOM format, a file is created that includes relevant patient data, imaging equipment and 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:

6.7.0

DICOM Functionality

Figure 6.7.1
DICOM Protocol Structure



Where the Preamble consists of 128 bytes, all typically set to 00H unless it is not used 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 Cont.

Modality

The DICOM file settings for Modality are accessed from the main-menu Tools menu. From the Tools menu, the "DICOM Modality Setup" can be selected.

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.

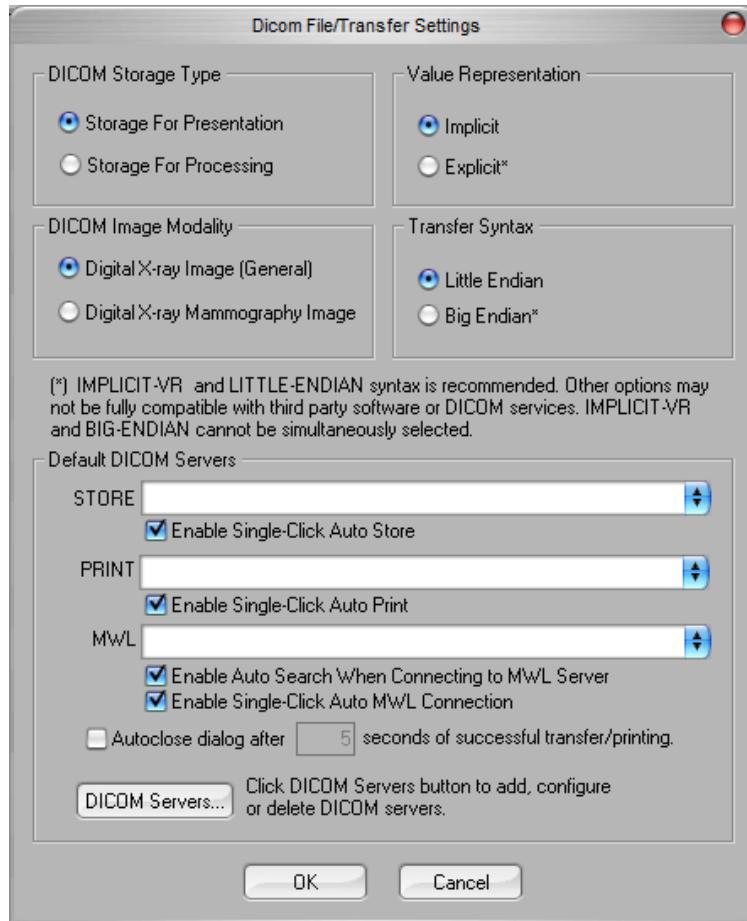


Figure 6.7.2
DICOM Modality Settings
Default settings shown

NOTE: Once the DICOM Modalities have been selected, they remain in effect, even after the Vision software has been closed. The Modality settings are stored and will remain in the configured manner until they are changed again, using the DICOM File Settings. These settings (Storage Type & Modality, Transfer Syntax, and Value Representation) will be effective for all DICOM LOCAL SAVE, PACS STORE or PACS 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 use PACS 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.

"Autoclose 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 DICOM Servers... button will open DICOM Networking dialog, where a user can add, modify or delete DICOM servers.

Saving a DICOM File

This command option appears in several places within the Vision software; review "DICOM SAVE LOCAL".

DICOM SAVE LOCAL

The DICOM Save option (which is provided at various locations throughout the Vision software) displays the following window. The user may enter the File name under which the procedure information is to be stored. Additionally the user may select the folder in which to save the file.

PACS STORE and PACS PRINT

The Vision software allows for PACS (DICOM) Store and PACS (DICOM) Printing. These options are provided for throughout the Vision software. For example, if the PACS Store button is selected, the following DICOM Networking Dialog window is displayed.

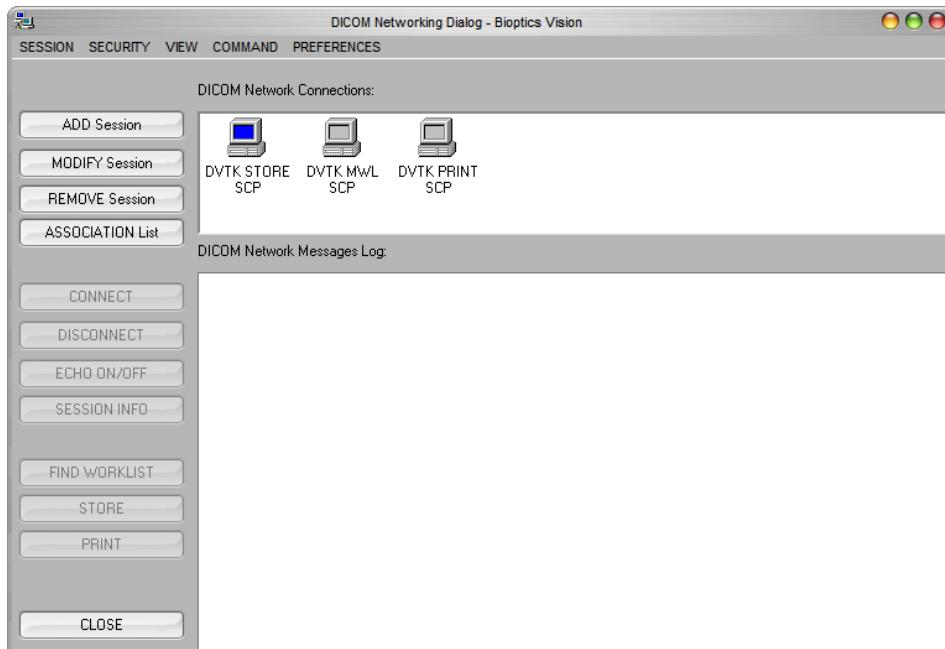


Figure 6.7.3
DICOM Networking Dialog box

From this displayed Dialog box, the user may choose to do a DICOM Store or DICOM Print. This Dialog box enables the user to Add, Modify or Remove DICOM Network connections or Peripherals.

6.7.0 Cont.

PACS DICOM STORE

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

6.7.0 Cont.

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 the figures below. A list also follows:

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

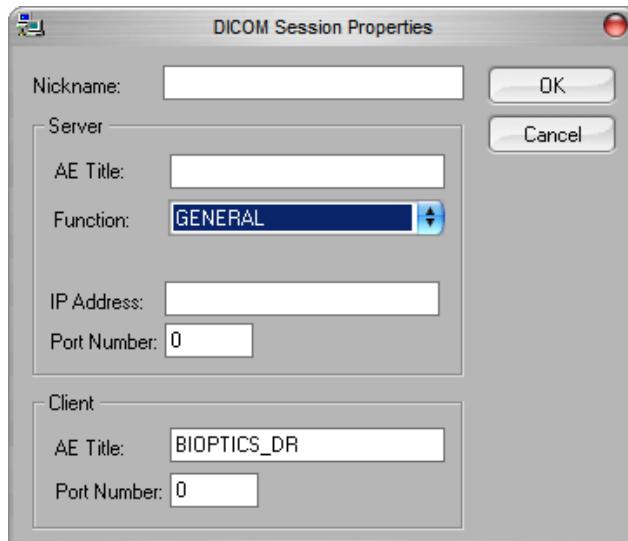


Figure 6.7.4
Session Properties Dialog box

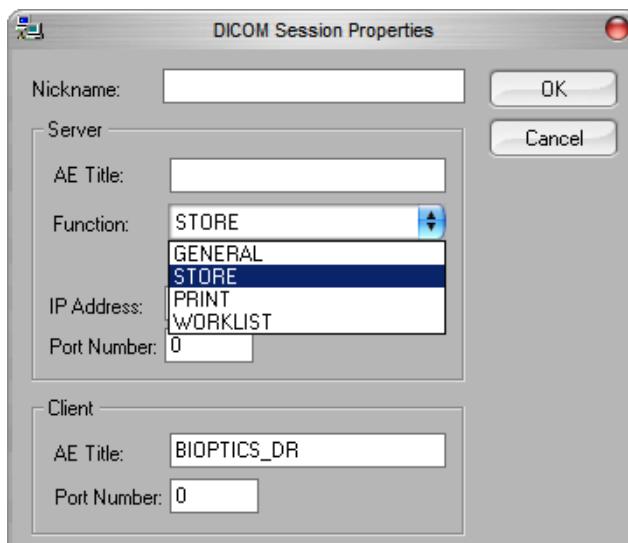


Figure 6.7.5
Functions Shown

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 5.41 above*) 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 5.41 above, we have three (3) icons representing, in order, a PACS Store, a Modality Worklist and a DICOM printer. Because the PACS Store button (see Figure 5.42) was chosen previously, only the PACS Store icon (DVTK STORE SCP) is active. It works the same for the other modes as well.

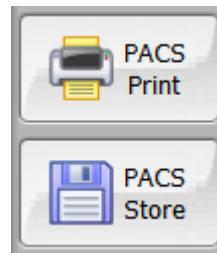


Figure 6.7.6
PACS Print and PACS Store Buttons

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 Advanced User Manually re-enters the requisite data through the Add Session button. A confirmation of action will be requested, see below.

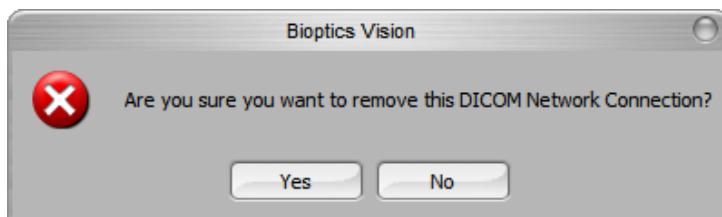


Figure 6.7.7
Verifying Removal of an Existing DICOM Network Connection

Association

6.7.0 Cont.

The Association List button open the Association Dialog box as 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.

Film Attributes

Selecting the Set Film Attributes button displays the Film Session Dialog box. 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.

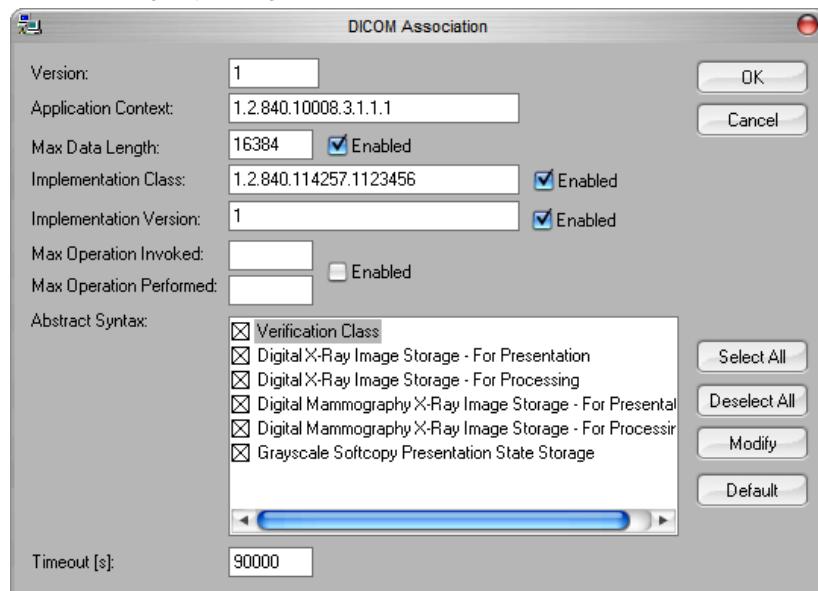


Figure 6.7.8
DICOM Association Window

6.7.0 Cont.

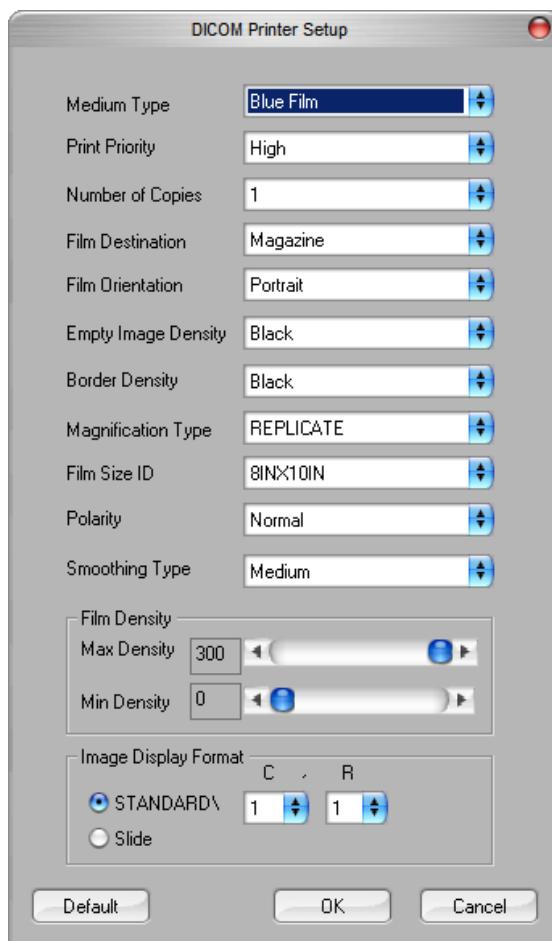


Figure 6.7.8
DICOM PrinterSetup Dialog Box

PACS PRINT

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

Close

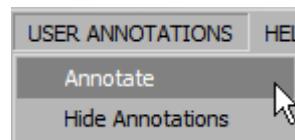
The Close button closes the DICOM Networking dialog box and returns the user to the area from which the DICOM command was executed. This command also closes the connection or association between the Vision software and the remote DICOM device if a connection was established.

Overview

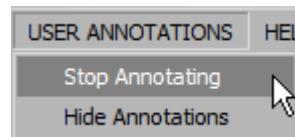
User Annotations in the Bioptics Vision Software allows one to apply a transparent graphic "overlay" commonly called "annotations" to an image. These annotations take the form of text, lines, "free form" lines (Bezier curves), arrows, ellipse and boxes. This allows additional information and "markers"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

Operation

To begin select "USER ANNOTATIONS" from the Startup Screen Menu (main menu) and click Annotate.



This command will immediately put the user into design mode. It will also display a "Tool Pallet." See below. Selecting "Stop annotating" from "USER ANNOTATIONS" menu or clicking "Stop Annotating" button in the User Annotation Tool Pallet will leave any annotations on screen, but will return you to normal imaging mode.



The tool pallet consists of fifteen (15) tool options that follow. Note the behavior of most of these tool options involve using the mouse to guide the on screen dynamic position and shape. Mouse "clicks" are used to set the final position and shape. The term "swipe" infers holding down the left-mouse button and moving the object around the screen. Letting go of the left mouse, or clicking the right mouse button will "set" the annotation into a "permanent" or final position.



Figure 6.8.1
Start Designing User Annotations

Figure 6.8.2
Stop Designing User Annotations.

Figure 6.8.3
User Annotation Design
Tool Pallet

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

- 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.

Note "holding the left mouse down," moving the mouse around to perform the operation and then releasing the left mouse button to complete it, is a very common procedure.

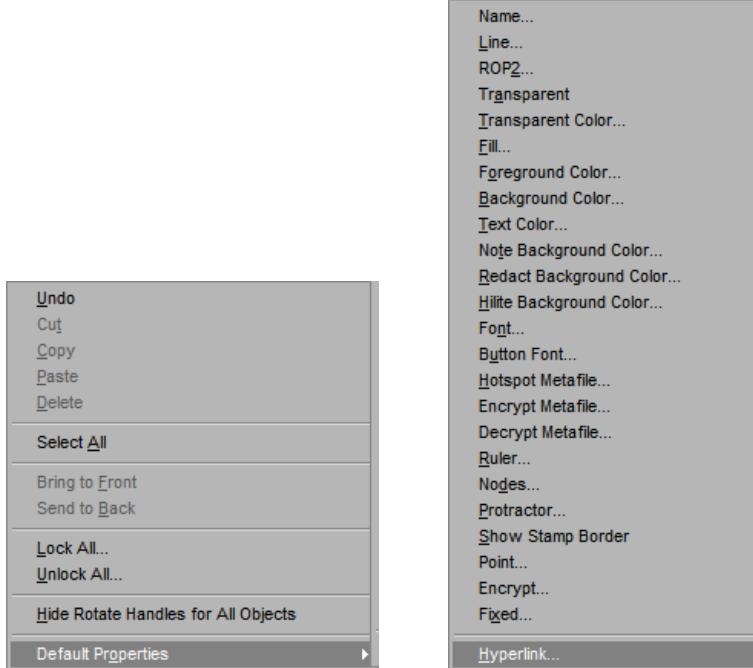
6.8.0 Cont.

- **Line Tool:** Draw a straight line with this option. Mouse behavior same as above.
- **Box Tool:** Draws a box. Mouse behavior same as above.
- **Ellipse (and Circle) Tool:** Draws an Ellipse or circle. Mouse behavior same as above.
- **Polygon Open Line Tool:** Draws non-straight "open segmented" lines. Left-click mouse, hold button, and draw. Release left button, this sets a line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
- **Polygon Closed Line Tool:** Draws non-straight "closed segmented" lines. Left-click mouse, hold button, and draw. Release left button, this sets a line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
- **Curved Open Line Tool:** Draws curved "open segmented" lines. (Bezier curves.) Left-click mouse, hold button, and draw. Release left button, this sets a curved-line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
- **Curved Closed Line Tool:** Draws curved "closed segmented" lines. (Bezier curves.) Left-click mouse, hold button, and draw. Release left button, this sets a curved-line segment. Repeat as desired. Right-click mouse button and tool operation is complete.
- **Arrow Tool:** Draws a line with an arrow at the end. Mouse behavior same as Line Tool.
- **Text Tool:** Creates a "textbox" where you can type text-based data.
- **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.
- **Ruler Tool:** Creates a ruled line segment. Very much like the Image Tools Ruler feature.
- **Segmented Ruler:** Draws non-straight "open segmented" ruled lines. Left-click mouse, hold button, and 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 specimen.
- **Protractor Tool:** Draws an angle on screen and provides the degree of the angle. Just like a protractor.
- **Orthogonal Ruler Tool:** Provides two (2) ruled lines that are orthogonal to each other.

Design Mode and Mouse Right-Click Menu

6.8.0 Cont.

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



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 click this button. This enlarges the image and you should be able to clearly see any annotation.



Figure 6.8.5
Full Resolution Button

Show - Hide Annotations Menu

Choosing SHOW will display all annotations "attached" to the current image on screen. Choosing HIDE will not display any annotations on screen.

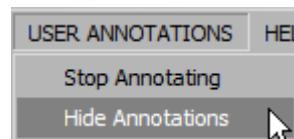


Figure 6.8.6
Show/Hide Option For User Annotations

Vision software help documentation is available in PDF format and Windows Compiled HTML Help File format. The user has to install Windows Internet Explorer 4 or above in order to run Vision software online help. Select "HELP Topics" under the Help menu for online Help.

6.9.0 About Help

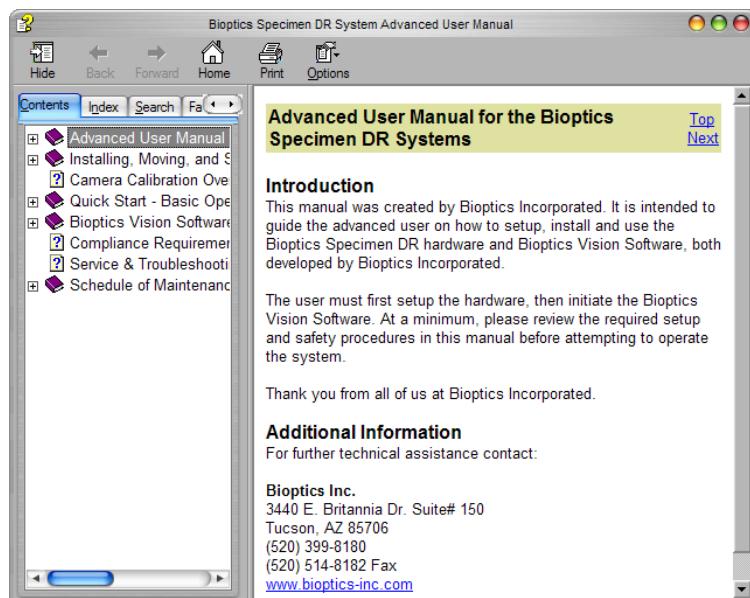
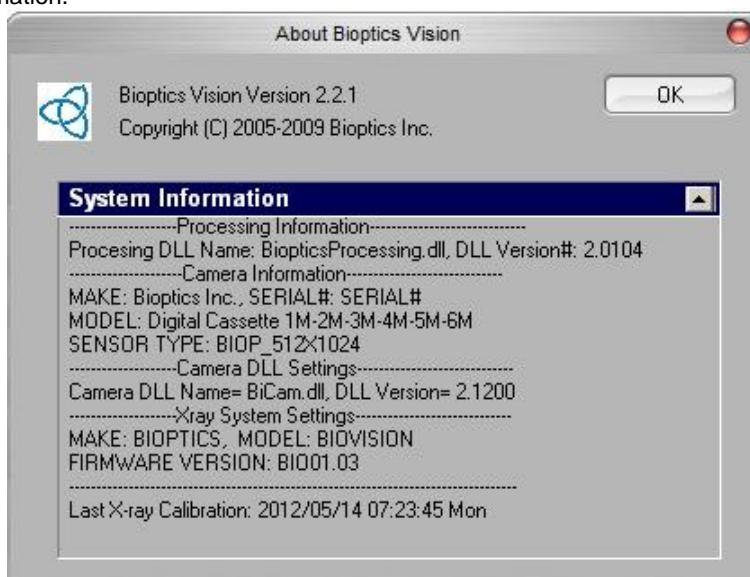


Figure 6.9.1
Online Help Dialog Box

The About button opens a Dialog box that shows the Vision software version and copyright date and system information.



6.10.0 About Bioptrics Vision Software

Figure 6.10.1
About Bioptrics Vision Information Dialog Box

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