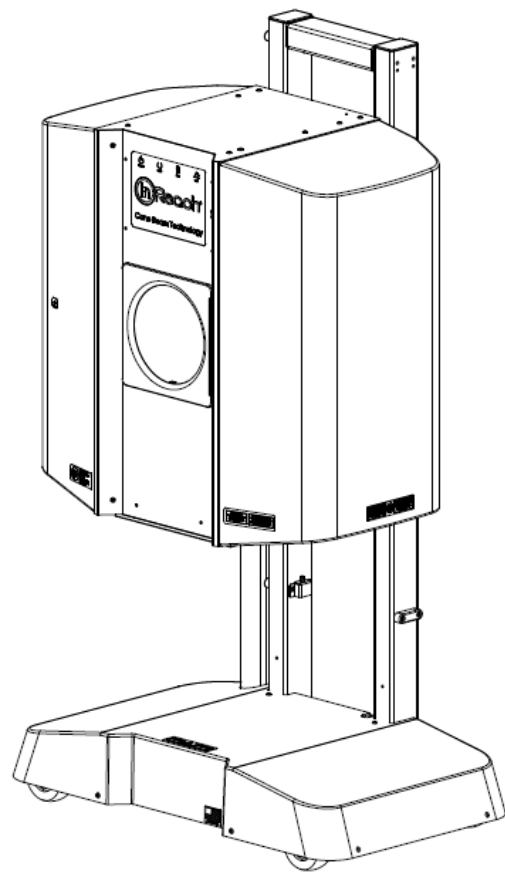# Computed Tomography
Imaging X-Ray System

CurveBeam

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90020 Rev 09.01.17

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InReach Manual

CHAPTER 1: Introduction

In order to maintain the safety of patient's and operators of this device, it is important to operate and maintain the system correctly, following all instructions, warnings, cautions in this manual and labeling on the system itself. Installation Instructions are detailed in Appendix I.

The InReach has been evaluated against European MDD requirements and carries the CE_{0473} mark.

For technical support or questions contact CurveBeam at 267-483-8081

Warnings, Cautions, Advice, and Notes:
Before attempting to operate the equipment, it is recommended that you read this manual thoroughly including all cautions and warnings. This guide uses the following conventions to describe situations that are potential hazards to the Patient or Operator, potential loss of data, or potential damage to the equipment.

⚠️**WARNING**
Warnings are intended to alert the user that failure to follow the procedure could cause fatal or serious injury to the user, Patient, or any other person, or result in a misdiagnosis.

❗**CAUTION**
Cautions are intended to alert the user that failure to follow the procedure could cause damage to the equipment or cause loss of data.

✓**NOTE**
Notes are used to highlight important or unusual points to be brought to the attention of the operator.

Advice
Refer to user manual.

Safety Precautions:

⚠️**WARNING** The patient must wear a protective full wrap X-ray shielding apron (lead apron) during a scan.

⚠️**WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure.

⚠️**WARNING** Do not remove covers or cables on system. High voltage is present in the system. To avoid personal injury from electrical shock, do not operate the system with any covers open or cables removed.

⚠️**WARNING** This device may cause detrimental interaction with active implantable medical devices and body worn active medical devices. Consult the manufacturer of such devices for more information.

⚠️**WARNING** No modification of this equipment is allowed.

⚠️**WARNING** Service and maintenance can only be performed by CurveBeam authorized service personnel. ONLY Curvebeam authorized replacement parts can be used in the equipment. These requirements must be followed in order to avoid a hazard to the equipment, operator and/or patient.

🛈**CAUTION** When initiating an exposure, the external Warning Light is activated a few seconds before the X-ray ON alarm (buzzer) and X-ray ON lights are activated**.**

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

🛈**CAUTION:** No auxiliary software should be installed on the system server and thin client terminals.

Electrical Hazards:

Installation and system wiring must meet all requirements of local governing authorities. Please check your local authorities and local codes to determine best practices for a safe installation. Do not place any liquid or food on any part of the consoles or other modules of the system. Observe all fire regulations. Fire extinguishers should be provided for both electrical and non-electrical fires. All operators should be fully trained in the use of fire extinguishers and other fire-fighting equipment and in local fire procedures.

⚠ **WARNING** In the event of an electrical fire, only use extinguishers that are labelled for that purpose. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.

⚠ **WARNING** In the event of an electrical fire, to reduce the risk of electrical shock, try to isolate the equipment from the electric source before attempting to extinguish the fire.

⚠ **WARNING** To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Explosion Hazards:

Do not use the System in the presence of explosive gases or vapors, including anaesthetic gases. Use of this system in an environment for which it is not designed can lead to fire or explosion.

⚠ **WARNING** This unit is not suitable for use in a flammable air mixture environment. If hazardous substances are detected while the system is turned on, do not attempt to turn off the system. Evacuate the area and then remove the hazards before turning off the system.

Mechanical Hazards:

⚠ **WARNING** Do not operate the system with any covers open or removed. Operating the system with open or removed covers could expose mechanical operating systems that could cause serious or fatal personal injury to you or the Patient. Only qualified and authorized service personnel should remove covers from the system.

Radiation Safety:

X-rays are dangerous to both operator and others in the vicinity unless established safe exposure procedures are strictly observed. Use the following safety measures to ensure safety to the Patient and Operator. The useful and scattered beams can produce serious or fatal bodily injuries to Patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid or reduce exposure to the useful beam or

to scattered radiation. Operators are strongly urged to comply with the current recommendations of the International Commission on Radiological Protection and, in the United States, the US National Council for Radiological Protection.

Use the following measures to protect yourself and the patient from unintended exposure to radiation. Anyone who is near the patient during test procedures must observe the following precautions:

- Maintain distance from exposed radiation source in accordance with the facility survey or site plan and shielding designs, provided by a medical physicist. The plan/survey will be created based off of Scatter Measurements provided in this manual. Refer to "typical InReach Layout" towards the end of Chapter 5 of this manual for additional details.
- Keep exposure times to a minimum.
- Ensure that flexable shields, provided with the machine, are both attached, in place and used during the duration of the scan.
- Wear a PEN dosimeter and/or film badge.
- If you are required in the exam room during a procedure, stay as far from the scanner as possible or behind a mobile protective wall.
- The physician is responsible for protecting the patient from unnecessary radiation.

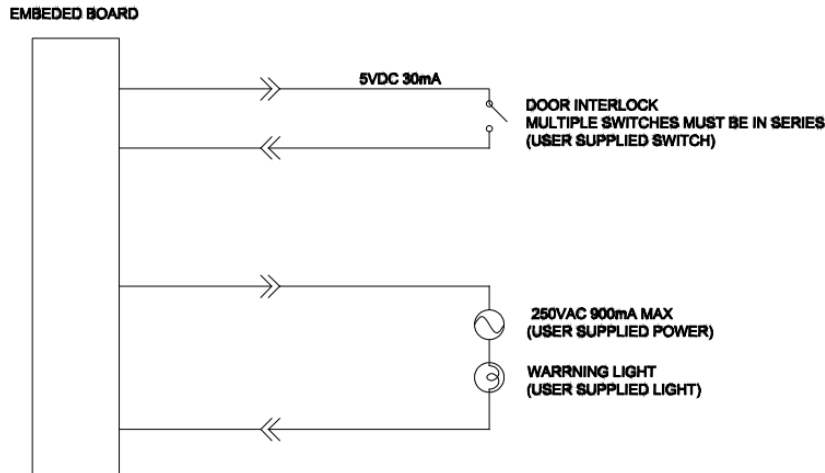**System Safety Devices:**

Emergency Stop: In the event of an emergency (any moving component collides with any parts of the equipment or items in the environment, or that could cause physical injury to the Patient), the Operator or Patient should utilize one of the 2 designated Emergency Stop buttons to turn off the power to the X-ray and all moving parts in order for the Patient to be safely removed from the machine. There is an Operator E-stop button on the Operator Control Box and there is a Patient E-Stop button. The Emergency Stop(s) when activated will remove ALL power from the machine.

Warning System: The System is equipped with provisions for warning lights and/or audible alarms when X-ray power is energized. An externally powered Warning System can be connected to the cable provided which is capable of 250 volts, 50/60 hertz, and 1 amp. When X-ray power is energized the warning system is also energized.

Interlock System: This System is equipped with provisions for an Interlock Circuit which, when opened, will turn off X-ray power. This is a low voltage circuit, 5 volts DC. To use the Interlock Circuit disconnect the factory installed Shorting Plug. Connect the supplied Interlock Cable to the scanner. Connect door switches (NO/COM terminals) and/or emergency stop switches (NC/COM terminals) in series between the other end of the Interlock Cable wires. Multiple door switches and/or emergency stop switches can be connected as long as the devices are connected in series. The entire circuit must be a closed loop when all of the doors are closed and/or emergency stop switches are in their normally closed state.

Whenever the door switch or switches are opened or emergency stop button(s) pressed the X-ray power will be turned off. X-ray power cannot be turned on when the interlock circuit is open.

Interlock and Warning System Schematic:

Patient Preparation Recommendations:

We recommend that the bore (cylinder where patient places anatomy to scan) is lined with Medical Barrier Film with sanitation and convenience in mind. The Medical Barrier Film should be transparent when placing on top of the hand or elbow platform to allow for positioning markers to show through.

Also recommended that the patient wear gloves when scanning their elbow since their hand will then come out the back of the scanner.

After each patient scan, clean and disinfect all items which come in contact with the patient.

Cabling Requirements:

System cabling connections must be installed away from walkways and doorways. It is recommended to run cabling along wall perimeters. If there is a chance of mechanical damage due to the cable location, then the use of conduit or other means of protection should be considered.

Emergency Removal of a Patient:

The system has undergone extensive testing of the mechanical, electrical and software performance, but if an unexpected occurrence is observed and/or the software locks up during a

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scan or an emergency arises where it becomes necessary to interrupt a scan and/or remove a patient from the system before a scan is completed, please follow these steps:
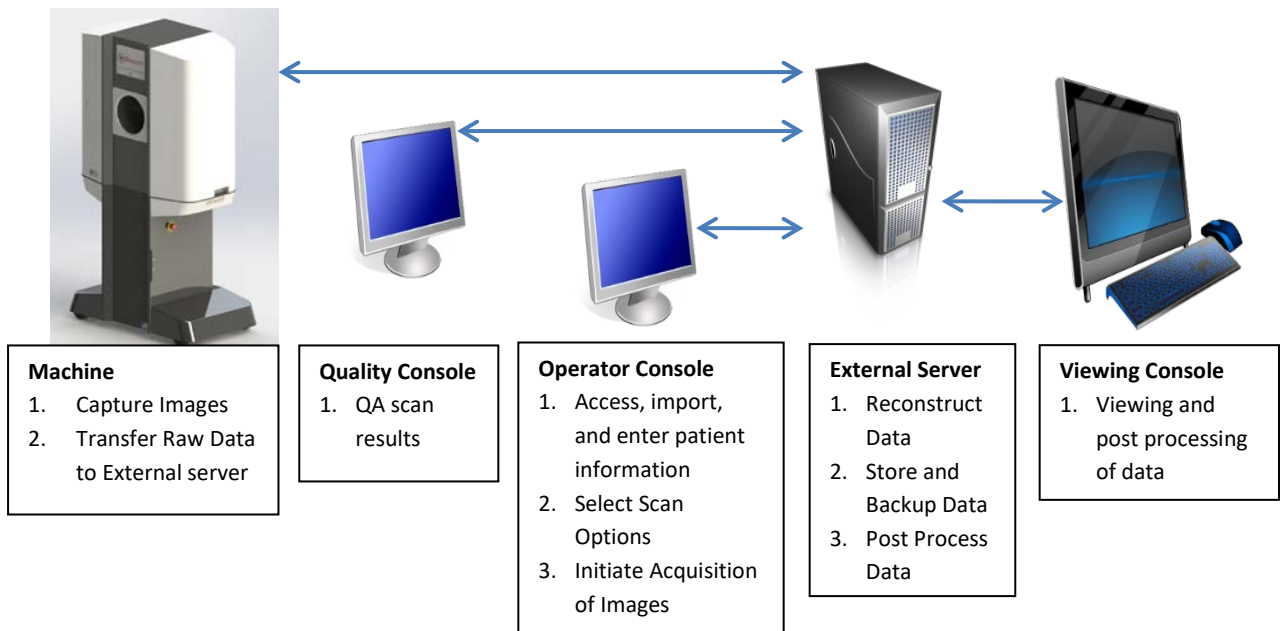
1. Press the EMERGENCY STOP button. This will halt the X-ray as well as the motors to the machine functions and all power to the machine. The message below will display on screen and will terminate the "CB Scanning Device" Acquisition software:

2. Carefully assist the patient to remove hand/arm or foot/leg out of the scan area.

3. Reset the machine: Close the InReach Acquisition, "CB Scanning Device" software (if not already). Release the E-stop by turning the knob to the right until it pops up. Then turn the machine power back ON at the Main Circuit Breaker. Re-launch the InReach Acquisition "CB Scanning Device" software. Now the system can be operated again as expected.

System Description

The InReach is a Computed Tomography X-ray system or Cone Beam Volumetric Tomography x-ray system for 3D reconstruction Imaging device for the hand, wrist, elbow, foot, ankle, and knee. The system is designed for an in-office setting with components consisting of the Scanner, Operating Computer (External Server), Operator's Console and Viewing Console.

Machine	Quality Console	Operator Console	External Server	Viewing Console
1. Capture Images 2. Transfer Raw Data to External server	1. QA scan results	1. Access, import, and enter patient information 2. Select Scan Options 3. Initiate Acquisition of Images	1. Reconstruct Data 2. Store and Backup Data 3. Post Process Data	1. Viewing and post processing of data

The External Server consists of 4 Virtual Machines:

ACQ VM: accessed via the Main Desktop icon on the ACQ thin client terminal

Viewing Station/MD VM: accessed via the Main Desktop icon on the QCW thin client terminal or the QA Station thin client terminal.

RECON VM: accessed via the Remote Desktop Connection icon on the ACQ thin client terminal.

Database VM: accessed via the Remote Desktop Connection icon on the ACQ thin client terminal.

Major Device Components:
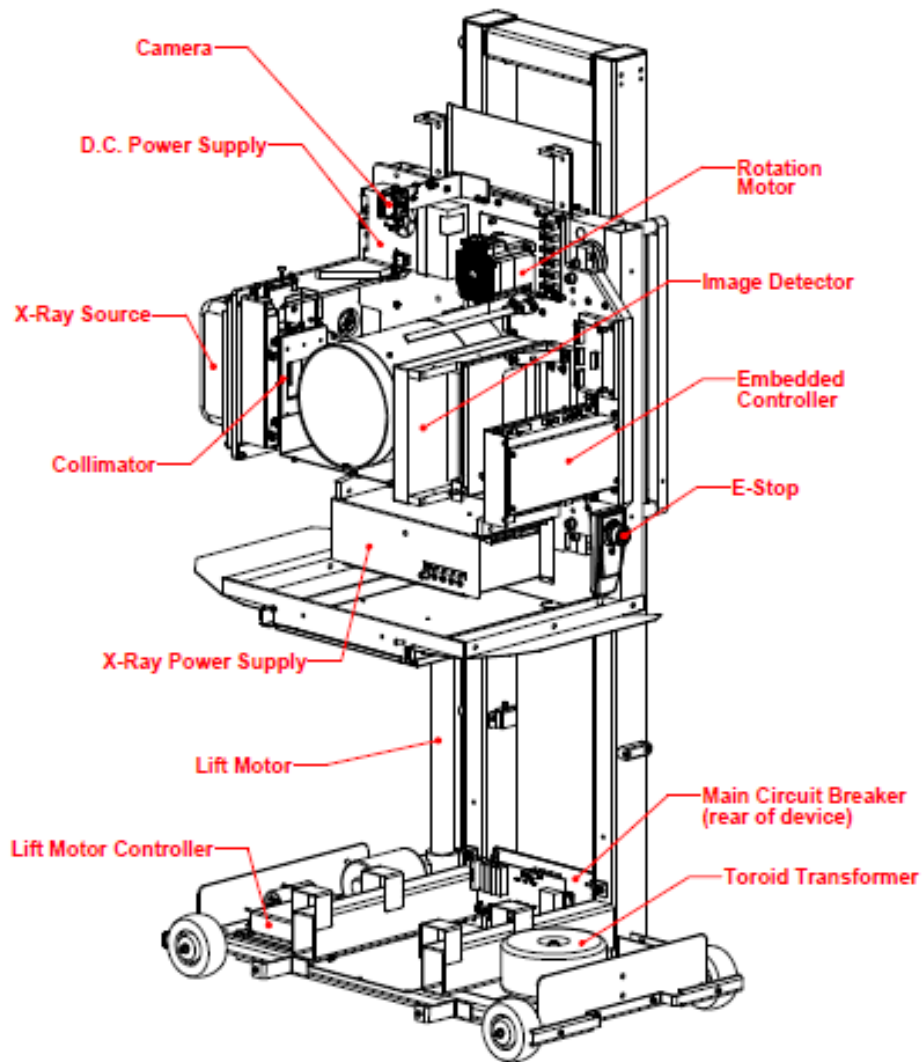
Intended Use of the Device:

The InReach is intended to be used for 3-D imaging of the hand, wrist, elbow, knee, foot, and ankle regions, to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures. This modality is anticipated to be applicable to pediatric* cases as well as adults*, when appropriate diagnosis of a given hand, wrist, elbow, knee, foot or ankle condition is considered necessary.

* Patient parameters: 50lbs to 400lbs

Major System Items:

- Scanner
- Dell server with hard drives, network cards, DVD drive, etc and Uninterrupted Power Supply (UPS)
- External Cable Kit
  - Door Interlock, 50' (
  - 15.24 m)
  - Warning System, 50' (15.24 m)
  - Door interlock, shorting plug
  - InReach E-Stop Hand Switch
  - Operator Control Box Assembly, 50' (15.24 m)
- Ethernet Cable, CAT6, gray, 50' (15.24 m) (QTY 2)
- Ethernet cable, CAT 6, green, 50' (15.24 m)
- Ethernet cable, CAT6, red, 50' (15.24 m)
- Ethernet cable, CAT6, yellow, 50' (15.24 m)
- Power cord, 10' (3.05 m)
  - Note: For non-US distribution, distributer is responsible for ensuring a properly certified power cord to meet the following minimum specifications.
    - 14AWG wires
    - Cable type: SJT
    - Jacketing: PVC
    - Voltage rating equal or greater to the mains line voltage of installation site
    - Max temperature rating: Min 60ºC
- Varian Panel, 2520DX
- X-Ray tube assembly and power supply

About the Operators' Manual:

This documentation describes the safe and effective operation of the system. The information is intended to provide trained Technologists and Physicians the necessary guidance to operate the system in a safe and effective manner.

CurveBeam assumes no liability for the use of this document if any unauthorized changes to the content or format have been made.

Conventions Used in the User Manual:

Main Menu items and Tabs are in quotes (" "). Software Programs are in quotes (" ")

Interface buttons are capitalized" (BUTTON).

Standard Limited Warranty

CurveBeam, LLC warrants the original purchaser that this hardware system will be free from defects for a period of one (1) year from the date of delivery. During the warranty period, CurveBeam, LLC will correct any defects in material or workmanship, at no charge for material, labor or travel. Any replacement parts shall be new or serviceable used parts and are warranted for the remainder of the original warranty or thirty (30) days, whichever is longer. This original warranty includes software maintenance upgrades*, but excludes new optional application modules or major new features. Also included in the warranty is free telephone consultation which will be furnished without charge by CurveBeam LLC. Data back-up is not covered and is the customer's responsibility.

* CurveBeam, LLC reserves the right to determine which software upgrades are included in the warranty.

The warranty period is not extended as a result of purchasing any additional parts from CurveBeam, LLC. The original purchaser must promptly notify CurveBeam, LLC in writing if there is a defect in material or workmanship. Written notice in all events must be received by CurveBeam, LLC before expiration of the warranty period. This warranty is not transferable. This One-Year Limited Warranty covers normal use.

CurveBeam, LLC **does not warrant or cover the following:**

- Damage caused by impact with other objects, dropping, falls, spilled liquids or immersion in liquids
- Damage caused by a disaster such as fire, flood, wind, earthquake, or lightning
- Damage caused by unauthorized attachments, alterations, modifications or foreign objects
- Damage caused by failure to provide a suitable operating environment
- Damage caused by the use of the hardware system for purposes other than those for which it was designed
- Damage from improper maintenance performed by other than OEM trained personnel
- Damage from improper electrical connection or supply
- Damage caused by any other abuse, misuse, mishandling, or misapplication
- Damage to internal or external computer, software, or operating system caused by:
    o Unauthorized additions or changes, Viruses, spyware or gaming software
    o Applications other than its intended use
    o Damage caused by third party software or damage caused by unauthorized changes to the system software
    o Damage caused by unauthorized upgrades, additions, deletions or unnecessary internet use, or any other unauthorized application.
- Under no circumstances shall CurveBeam, LLC be liable for any special, incidental, or consequential damages based upon breach of warranty, breach of contract, negligence, strict liability or any other legal theory. Such damages include, but are not limited to, loss of data, loss of profits, loss of revenue, loss of use of hardware system or any associated equipment, cost of capital, cost of substitute or replacement equipment, facilities or services, down time, purchaser's time, the claims of third party, including customers, and injury to property.

Disclaimer of Warranties The warranty stated above is the only warranty applicable to this product, all other warranties, expressed or implied including all implied warranties of merchantability or fitness for a particular purpose, are hereby dis-claimed. No oral or written information or advice given by CurveBeam, LLC, its agents or employees shall create a warranty or in any way increase the scope of this warranty.

CHAPTER 2: Product Information

Technical Specifications:

Description	Specification
Tube voltage	100 kVp, 120 kVp, (+/-10%)
Tube current	5 mA, (+/-10%)
CBCT Scan time*	24 sec
CBCT Procedure time**	26 sec
Max exposure time (based on typical pulse width)	5.9 sec
Image detector	Amorphous Silicon flat panel
Gray scale	16 bit
CBCT Imaging Volume	17 cm (6.7") high x 16 cm (6.3") diameter
Typical slice thickness	0.5mm (+/-0.5mm); Slice Spacing 0.2
Typical voxel size	0.2 mm voxel
Measurement accuracy	± 2 voxel
Body part scanned	Hand, Wrist, Elbow, Foot, Ankle, Knee
Size of system: h x d x w	60.63" x 22.84" x 35.88" (154 cm x 58 cm x 91 cm)
Weight	300 lbs (136 kg)
Power Requirements	1150VA

*Scan time is defined as the duration in which the exposure alarm (buzzer) is ON and X-ray ON light is illuminated.

**Procedure time is from time the exposure button is pressed to when the patient is able to safely remove their body part, after the scan.

X-ray Source:

Tube Voltage:	100 kVp(eff), 120 kVp(eff), +/- 10%
Tube Current:	5 mA, +/- 10%
Voltage Wave Shape:	Constant Potential
Focal Spot:	0.0197 inches (0.5 mm)
Duty Cycle:	3%

Source to Sensor distance: 17.332" (44.023 cm)

Source to Rotation Center distance: 12.647" (32.124 cm)

Minimum Filtration (at 90 kVp(eff)) (mm of aluminum equivalent): 10 mm or greater

Maximum Rated Continuous Tube Operation: 130 kVp @ 0.5 mA

Maximum Rated Pulsed Tube Operation: 130 kVp @ 5mA

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⊘ NOTE: Leakage technique factors are measured at the maximum specified energy.

Timer: ± 0.1 seconds or 5%, whichever is greater

X-ray Beam Size: 7.874" (20 cm) wide x 9.8425" (25 cm) high

Image Detector: Amorphous Silicon Flat Panel (readable area): 9.6" (24.38 cm) height x 7.68" (19.50 cm) width.

Sensor Front Panel Attenuation Value: Less than 1mm of aluminum equivalent (information for reference only)

Gray Scale: 16 bit

Voxel Size: 0.2 voxel

CBCT Image Acquisition: 1 orbit, 360 degree rotation (maximum)

CBCT Field of View: 16 cm (6.3") diameter x 17 cm (6.7") height (1 orbit)

CBCT Procedure Times: 50 sec

Patient Protocol options available for scanning:

Patient Parameters	Exposure Factors	Type
Small Size: Weight: 50 to 100 lbs (23-45kg)	100 kVp, 5mA	Hand, Wrist, Elbow, Knee, Ankle, Foot
Weight: 101 to 400 lbs (46-181 kg)	100 kVp, 5mA or 120 kVp, 5mA	Hand, Wrist, Elbow, Knee, Ankle, Foot

CBCT Primary Reconstruction: Maximum 5 minutes

CBCT Secondary Reconstruction: Real Time

Essential Performance
- X-Ray Specifications – Technique Factors (kV, mA, Time)
- Supply Regulation
- Digital Receptor Image Quality
- Accuracy of Imaging Software Measurements
- X-Ray Filtration / Half Value Layer
- Lift Motion Control

Power Requirements:

The Scanner requires a Dedicated Line and/or Filtered Line. A Surge Protector is recommended. The Scanner is suitable for continuous connection to a power supply in stand-by mode.

Line Voltage: 100VAC, 115VAC, 200VAC all ± 10% (Factory Set)

210 to 240VAC (which covers 220, 230 and 240 VAC power supplies) (Factory Set)

Line Current: 10 Amps (100V), 10 Amps (115V), 5 Amps (200V) or 5 Amps (230V)

Line Frequency: 50 Hz / 60 Hz

Phase: Single

Main Circuit Breaker: 10 Amps (100V), 10 Amps (115V), 5 Amps (200V), or 5 Amps (230V)

Nominal Electrical Input Power to Supply: Volume Scan = 300W (120kV, 5mA); Scan Time has no effect on electrical power output.

Apparent Resistance of Supply Mains:

For the purpose of obtaining the apparent resistance of supply mains, resistance is determined according to the following formula:

$$R = \frac{U_O - U_1}{I_1}$$

Where:
U0 is the no-load Mains Voltage
U1 is the Mains Voltage under load.
I1 is the Mains Current under load.

Circuit Breaker Assembly	UO	UI	I1	Apparent Resistance
100VAC	100VAC	98.8VAC	2.5A	0.48ohms
115VAC	115.4VAC	114.2VAC	2.1A	0.57ohms
200VAC	200.4VAC	198.1VAC	1.3A	1.77ohms
230VAC	230.8VAC	228.0VAC	1.2A	2.33ohms

Environmental Specifications:

Operating:

- The operational temperature range shall be 59°F to 86°F (+15°C to +30°C).
- The operational humidity range shall be 25 to 60% relative humidity, non-condensing.
- The minimum time period that the room environmental operating conditions must be maintained prior to powering the system is 1 hour.
- The minimum time period that the system must be on before operating is 5 minutes.
- The operational atmospheric pressure range shall be 94 kPa to 102 kPa.

Transportation and Storage:

- The storage and transport temperature range shall be -4°F to 122°F (-20°C to +50°C).
- The storage & transport humidity range shall be 10% to 95% relative humidity, non-condensing.

Scanner and Acquisition Computer (server):

- Requires a Dedicated Line and a Surge Protector is recommended.

Disposal:

Follow local regulations on disposal of waste parts. The *X-ray source assembly, image sensor* and *all electronic circuits* should be regarded as non-environmentally friendly waste product. The system does not generate, or require the use of, any materials that require special disposal instructions as part of regular operation.

Extension Cords:

Do not use any extension cords which are not provided with the system. Be aware that multiple portable socket outlets or extension cords are not to be connected to the system.

External Items:

Do not connect any items or equipment to this system which are not part of the system.

Instruction for maintaining BASIC Safety and Essential performance for the expected Service life

> **NOTE:** Do not change the once installed final application due to EMC, view Immunity test levels (IEC 60601-1-2:2014)

Electromagnetic or other Interference (Emissions and Immunity):

The system was tested and it was determined to meet the class A (non-residential) limits. The system pass testing with the criteria contained in IEC 60601-1-2 Edition 4 Issued 2014, with EMC deviations per IEC 60601-2-44: 2009, A1:2012.

Test Name	Test Level/ Equipment Class	Results/Notes	Immunity Performance Criteria Met
Emissions Testing			
Radiated Emissions	Class A: Group 1	Compliant	-
Conducted Voltage Emissions	Class A: Group 1	Compliant	-
IEC61000-3-2 Harmonic Current Emissions	Class A	Compliant	-
IEC61000-3-3 Voltage Changes, Voltage Fluctuations and Flicker	Dmax 4%	Compliant	-
Immunity Testing			
61000-4-2 Electrostatic Discharge	±8kV Contact, ±15kV Air	Compliant	A
61000-4-3 Radiated Immunity	3V/m 1kHz 80% AM 80-2700MHz	Compliant	A
61000-4-4 Electrical Fast Transients	±2kV (100kHz Rep Rate)	Compliant	A
61000-4-5 Surge Immunity	±1 kV Line to Line, ±2 kV Line to Earth	Compliant	A
61000-4-6 Conducted Immunity	3Vrms 150kHz-80MHz 6Vrms in ISM Bands	Compliant	A
61000-4-8 Power Frequency Magnetic Field	30A/m at 50/60Hz	Compliant	A
61000-4-11 Voltage Dips and Short Interruptions	Per Table 5	Compliant	A
61000-4-3 Clause 8.10	Table 9	Compliant	A

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⚠️**WARNING** This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. Follow the following recommendations below.

Recommended separation distances between portable and mobile RF communications equipment and the InReach
The InReach is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InReach can help prevent electromagnetic interference by maintaining a minimum distance of 10 feet (3 m) between portable and mobile RF communications equipment (transmitters) and the InReach. Refer to the portable and mobile RF communications equipment user's manual for recommended clearance distances to other equipment based on the maximum output power of the communications equipment. Maintain a minimum distance of 10 feet (3m) between the InReach and portable and mobile RF communication equipment, otherwise, degradation of the performance of this equipment could result. Other cables and accessories may affect EMI performance. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals(CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Equipment Standards:

The InReach has been designed and evaluated to meet the requirements of the following standards. The device has passed all applicable sections of these standards.

IEC 60601-1, third edition, 12/2005	IEC 60601-1, second edition, 12/1995
IEC 60601-1-2, third edition, 03/2007	
IEC 60601-1-3, second edition, 01/2008	IEC 60601-1-3, first edition, 01/1994
IEC 60601-1-6, third edition, 01/2010	IEC 60601-1-6, first edition, 01/2006
IEC 60601-1-8, second edition, 10/2006	IEC 60601-1-8, first edition, 1/2003
IEC 60601-2-7, second edition, 02/1998	
IEC 60601-2-44, third edition, 02/2009	IEC 60601-2-44, second edition, 01/2002
IEC 62304, first edition, 05/2006	
ISO 15223-1:2012	
ANSI/AAMI ES60601-1, third edition, 01/2005	
CSA C22.2 NO. 60601-1:08-CAN/CSA, third edition, 07/2008	
BS EN ISO 14971:2009	
EN ISO 15223-1:2012	
BS EN 1041:2008	

The InReach conforms to the provisions of MDD 93/42/EEC (as transposed into national law in the United Kingdom through Statutory instrument SI 618 2002 Medical Device Regulations 2002 and as amended by SI 2008 No. 2936).and Australian Medical Device Directives, TGA , v1.1, May, 2011

Equipment Class:

- Protection against electric shock: Class I
- Applied part has degree of protection against electric shock: Class B
- Class of equipment against ingress of liquids: Ordinary Equipment: IPX0
- Radiated emissions: Class B

Regulatory Class:

Governing Body	Classification
FDA	2
Health Canada	3
Medical Device Directive(93/42/EEC)	IIb

Cleaning:

⚠️**WARNING** Prior to performing any cleaning, ensure the machine is not in use, and patient is not in the scanner.

Routinely and after each patient scan, clean and disinfect all items which come in contact with the patient.

Cleaning the equipment frequently, especially if corroding chemicals are present is a function of the Operator. Unless otherwise instructed, use a cloth **moistened** with warm water and mild soap. Do not use strong cleaners and solvents as these may damage the finish. <u>Be careful when cleaning to avoid liquid leaking outside of the bore and into the Gantry</u>. DO NOT ALLOW WATER TO COME INTO CONTACT WITH THE IMAGE RECEPTOR.

For disinfecting, use Biocide ® from Biotrol International or equivalent cleaner and disinfectant. Biocide® is an Iodophor formulation that kills HIV, Tuberculosis and Polio in 10 minutes. Moisten a cloth with the disinfectant and then wipe down the area. Do not spray disinfectant directly onto the equipment.

Preventive Maintenance Schedule - for Owner / User:

⚠️ **WARNING** Prior to performing any preventative maintenance, ensure the machine is not in use, and patient is not in the scanner.

- *Daily:*

  Routine Dusting - all surfaces.

  Clean and Disinfect all items which come in contact with the patient after each patient scan.

- *Monthly*:

  Clean/Disinfect all surfaces, check for failed/faulty indicator lights.

- *Quarterly:*

  Perform Panel Calibration (Gain, Air)

- *Yearly:*

  Check for satisfactory image quality.

> IT IS THE RESPONSIBILITY OF THE USER TO INSURE THAT THE EQUIPMENT IS MAINTAINED IN COMPLIANCE WITH THE MANUFACTURER'S RECOMMENDED MAINTENANCE SCHEDULE. THE MANUFACTURER AND THE ASSEMBLER / INSTALLER ARE RELIEVED FROM RESPONSIBILITY IN THOSE CASES WHERE NON-COMPLIANCE WITH THE STANDARD RESULTS FROM THE USER'S FAILURE TO HAVE THE MANUFACTURER'S RECOMMENDED MAINTENANCE PERFORMED.
>
> The actual maintenance inspection and consequent service must be accomplished either by an authorized factory trained technician or by a competent serviceman of the user's choice who has adequate training in those aspects of the Performance Standards of the Radiation Control for Health and Safety Act of 1968 that are applicable to this equipment. Neither the inspection nor service is part of the equipment warranty. (To be arranged for by the Owner or User with the Dealer's Service Department).

Planned Maintenance – Monthly Schedule:

The system requires monthly maintenance check for failed or faulty indicators/lights and machine stability.

1. Procedure for checking for failed or faulty indicators/lights. If any of the below do not behave as expected, then please contact CurveBeam Technical Support at the number on the front cover of this manual.
   CB-ToolShed Program:
   - From the ACQ Desktop area, click on the CB-ToolShed icon. This icon will open the interface required for the checks.
   - WARNING LIGHT: In this interface, first click on WARNING LIGHT TEST tab. If your system has a warning light installed, then the WARNING LIGHT should turn ON. Warning lights on the Operator Control Box should also illuminate. If the warning light does not function check the electrical connections, power and indicator lights/audible alarms for proper operation. If the warning system components are found non-functional then contact CurveBeam Technical Support.
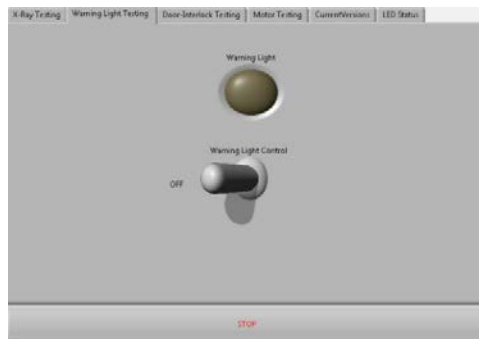
   - DOOR INTERLOCK: Next, if you have a Door Interlock, first close the X-ray Room Door.   Click on the DOOR-INTERLOCK TESTING tab. If functioning properly, then a message will appear indicating so. Then Open the X-Ray Room Door and click on the DOOR INTERLOCK TEST button again. The message should indicate that the Door is opened and no x-ray can be taken at this time.

   - EXPOSURE: This will check the Exposure Switch, audible exposure sound and both visual X-Ray ON indicator lights. Click on the X-RAY

TESTING tab. Select either MultiShot or Continuous, then FIRE.

> ⚠️**WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

Observe for the audible sound and that the X-ray ON lights on the machine and the Operator's Control Box are illuminated in Amber color during this exposure. Select the second option of either MultiShot or Continuous and repeat.

- LED: In this interface, click on the LED STATUS tab. Click on the toggle button to the left of each status light. The light should illuminate on both the front of the machine and on the Operator Control Box. If the LED lights do not function check the electrical connections, power and indicator lights/audible alarms for proper operation. If any of the LED status lights are found non-functional then contact CurveBeam Technical Support.

- EMERGENCY STOP: Exit the CB-Tools program by clicking on the X in the upper right corner. With the machine Main Circuit Breaker in the ON position, Power Light ON, press the EMERGENCY STOP button. The Main Circuit Breaker should trip. Release the EMERGENCY STOP by turning the knob to the right until it pops up. Turn the Main Circuit Breaker to the ON position and re-launch the InReach ACQ Software. Repeat for the patients emergency stop button.

2. Ensure that the machine is not able to roll, wheel locks are still in place. And that the wall strap is still in place and connected both to the wall and the back of the scanner.

Planned Maintenance – Quarterly Schedule:

The system requires quarterly maintenance check for Panel Calibration. This can be performed by the end user with CurveBeam Technical Support if necessary.

1. The procedure for the panel calibration is in the section under **Calibrations: Panel for Gain & Air Calibration**.

   Advice: Please refer to that section for instructions on performing this procedure. (Chapter 4: Calibration & QA Procedures).

   If panel calibrations are not routinely performed, there may be suboptimal image quality. The scan results may have symptoms of artifacts commonly referred to as "circle or ring artifacts". Below are samples of circle artifacts in scan results. If these are observed than a panel calibration should be performed.

   Advice: Please refer to Chapter 4 and also contact CurveBeam Technical Support.
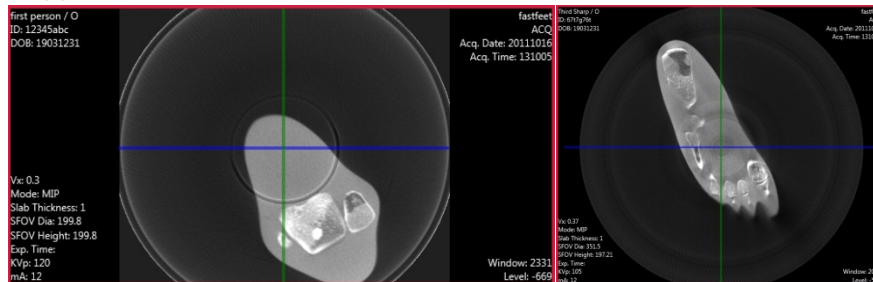
UPS (Uninteruptible Power Supply) **Maintenance:**

Please refer to the Dell Line-Interactive Rack UPS (1000W, 1920/1500W and 2700/2300W) User's Guide for UPS maintenance recommendations.

Planned Maintenance - Annual Schedule:

The system requires normal periodic inspection and maintenance. Scheduled periodic inspections are necessary to detect problems which can result from excessive wear, loose items, chafing wires, and mis-adjusted parts from continual system use. A visual inspection of the system, including the drive belt, will be included. In addition to mechanical inspection and calibration, a series of image performance tests are to be conducted. Planned maintenance is to be performed annually by a factory trained Service Technician. If there are any questions regarding the annual maintenance, please contact CurveBeam Technical Support.

Cyber Security Recommendations:

CurveBeam uses commercially available software in the device that may be susceptible to unintended installation of malware or other malicious software that could compromise the full functionality of the device. Therefore, it is highly recommended that steps be taken to protect against possible vectors of infection. An industry standard, commercially available, active monitoring program such as anti-malware and antivirus program should be installed to protect the device against such attacks. Other protections such as strong security policies, access control policies, and strong network protection including the use of hardware and software firewalls are recommended in addition to active monitoring, in order to avoid infection or otherwise unintended consequences related to infection. It is important to protect the equipment from unauthorized access, unauthorized software, and insecure network access. Failure to sufficiently protect the equipment from possible attacks may result in unintended consequences including failure of the device.

Replacement Parts:

Part Description	Part Number
Gantry Belt	200145
Rotation Motor	100109
Breaker Switch Assembly 100 VAC	4012-100-0
Breaker Switch Assembly 115VAC	4012-115-0
Breaker Switch Assembly 200VAC	4012-200-0
Breaker Switch Assembly 230VAC	4012-230-0
X-Ray Power Supply Assembly	4016-0
Embedded Board Assembly	4014-0
120VAC Breakout Assembly	4017-0
X-Ray Tube Head	2007-0
Image Receptor (Panel)	100090
Ethernet Cable CAT 6 GREEN, 50'	100105
Ethernet Cable CAT 6 RED, 50'	100106
Operator's Control Box Assembly	5130-0
Geometric Phantom	2809
Line Pair and Water Phantom	2807
Hand Platform Assy	2058-1-0
Elbow Platform Assy	2058-2-0
Flex Shield, Top	2058-10-1
Flex Shield, Bottom	2058-10-2
E-Stop Hand Switch	5110-0
Camera	100183
Wall Strap Kit	2906-0

Accessories:

The system has no accessories.

System Dimensions:

61.83"
[157cm]

12.00"
[30cm]
MIN.

BACK

22.84"
[58cm]

FRONT

TOP VIEW

35.88"
[91cm]

TOP

60.63"
[154cm]

Ø7.75"
[20cm]

MAX: 49" [124.4cm]
MIN: 25.5" [64.7cm]

BOTTOM

FRONT VIEW
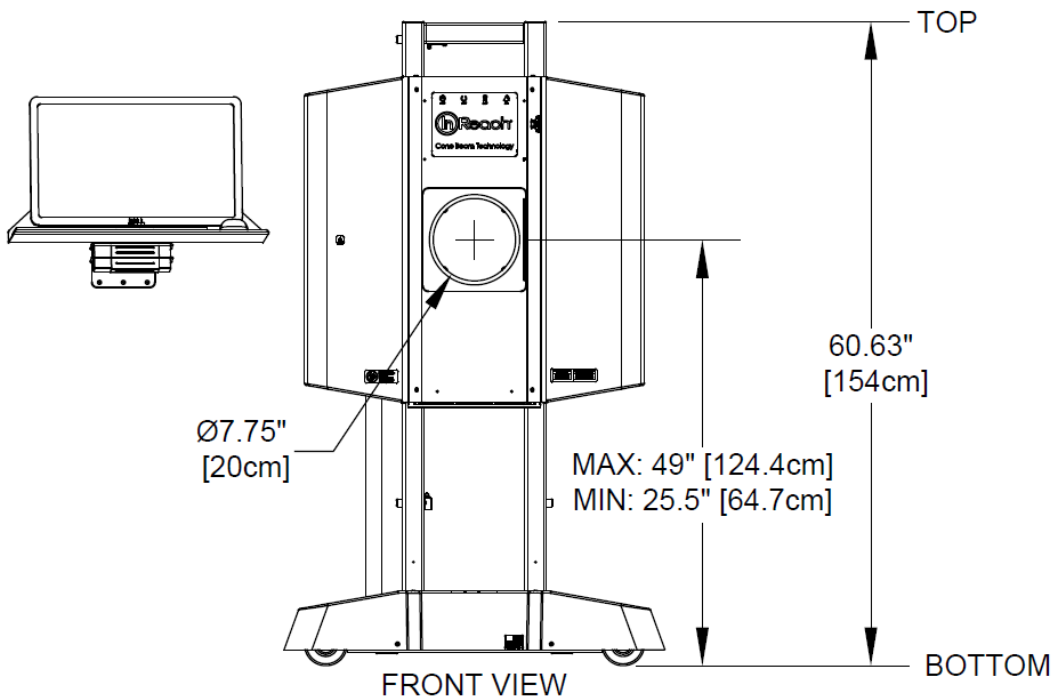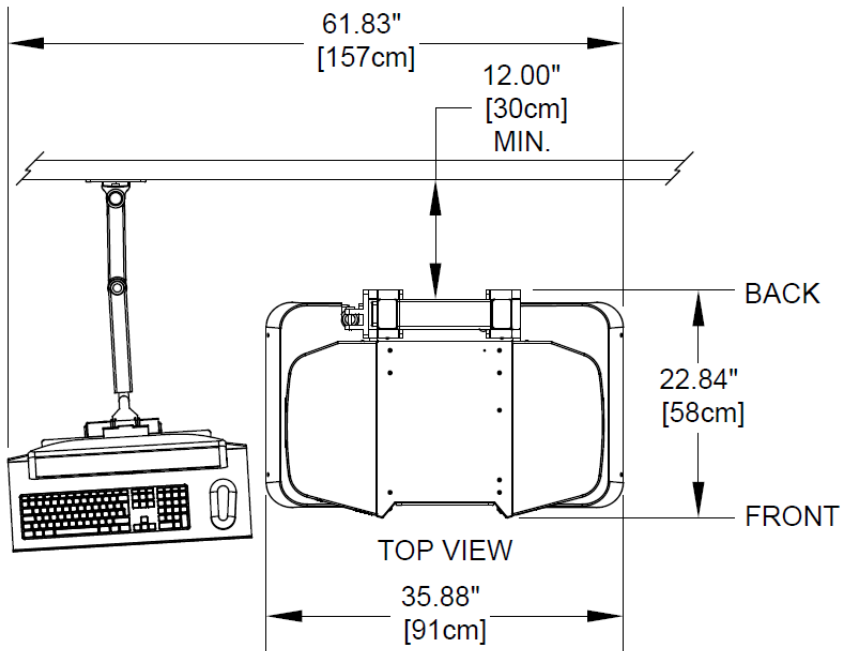
CHAPTER 3: Safety Items

In order to maintain the safety of patients and operators of this device, it is important to operate and maintain the system correctly, following all instructions, warnings, cautions in this manual and labeling on the system itself.

System Safety Devices:

Emergency Stop: In the event of an emergency (any moving component collides with any parts of the equipment or items in the environment, or that could cause physical injury to the Patient), the Operator or Patient should utilize one of the 2 designated Emergency Stop buttons to turn off the power to the X-ray and all moving parts in order for the Patient to be safely removed from the machine. There is an Operator E-stop button on the Operator Control Box and there is a Patient E-Stop button on the machine. The Emergency Stop (s) when activated will remove ALL power from the machine.

Warning System: The System is equipped with provisions for warning lights and/or audible alarms when X-ray power is energized. An externally powered Warning System can be connected to the cable provided which is capable of 250 volts, 50/60 hertz, and 1 amp. When X-ray power is energized the warning system is also energized.

Wheel Locks and Wall Strap: The System is equipped with locks on each wheel to prevent the machine from moving once it is in the appropriate position in the room, this is done at set up of the machine. Additionally a Wall Strap is attached from the wall to the scanner to prevent the machine from being pulled or pushed over.

Interlock System: This System is equipped with provisions for an Interlock Circuit which, when opened, will turn off X-ray power. This is a low voltage circuit, 5 volts DC. To use the Interlock Circuit disconnect the factory installed Shorting Plug. Connect the supplied Interlock Cable to the scanner. Connect door switches (NO/COM terminals) and/or emergency stop switches (NC/COM terminals) in series between the other end of the Interlock Cable wires. Multiple door switches and/or emergency stop switches can be connected as long as the devices are connected in series. The entire circuit must be a closed loop when all of the doors are closed and/or emergency stop switches are in their normally closed state.

Whenever the door switch or switches are opened or emergency stop button(s) pressed the X-ray power will be turned off. X-ray power cannot be turned on when the interlock circuit is open.

Interlock and Warning System Schematic:

Cabling Requirements:

System cabling connections must be installed away from walkways and doorways. It is recommended to run cabling along wall perimeters. If there is a chance of mechanical damage due to the cable location, then the use of conduit or other means of protection should be considered.

Emergency Removal of a Patient:

The system has undergone extensive testing of the mechanically, electrically and software performance, but if an unexpected occurrence is observed and/or the software locks up during a scan or an emergency arises where it becomes necessary to interrupt a scan and/or remove a patient from the system before a scan is completed, please follow these steps:

1. Press the EMERGENCY STOP button. This will halt the X-ray as well as the motors to the machine functions and all power to the machine. The message below will display on screen and will terminate the "CB Scanning Device" Acquisition software:

2. Carefully assist the patient to remove hand/arm or foot/leg out of the scan area.

3. Reset the machine: Close the InReach Acquisition, "CB Scanning Device" software (if not already). Release the E-stop by turning the knob to the right until it pops up. Then turn the machine power back ON at the Main Circuit Breaker. Re-launch the InReach Acquisition "CB Scanning Device" software. Now the system can be operated again as expected.

System Labels:

Operator Control Box: E-Stop, Power ON light, X-ray Ready light, X-ray ON light, Fault light, Scan/Exposure Button.
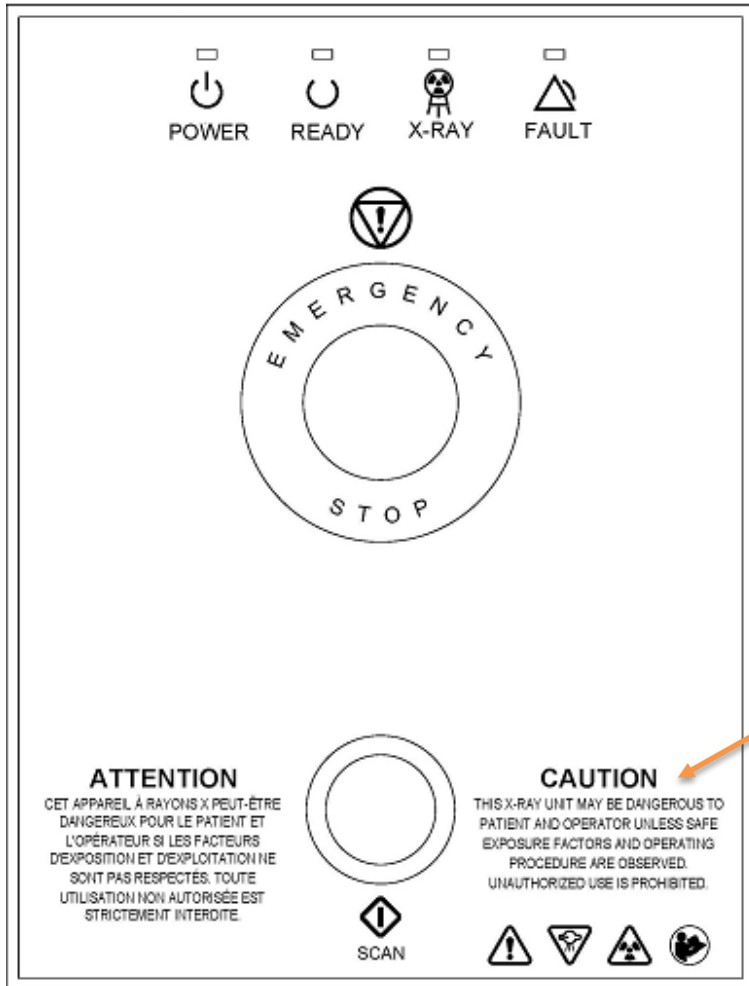
Zoomed in on the Verbiage:
CAUTION
THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING PROCEDURE ARE OBSERVED. UNAUTHORIZED USE IS PROHIBITED.

Operator Exposure\Scan Switch (Pushbutton):

Rear Connector Panel:

System Label location
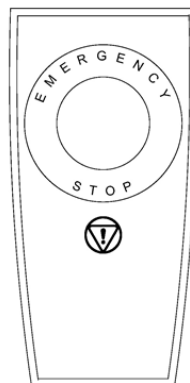
Input Power Label location
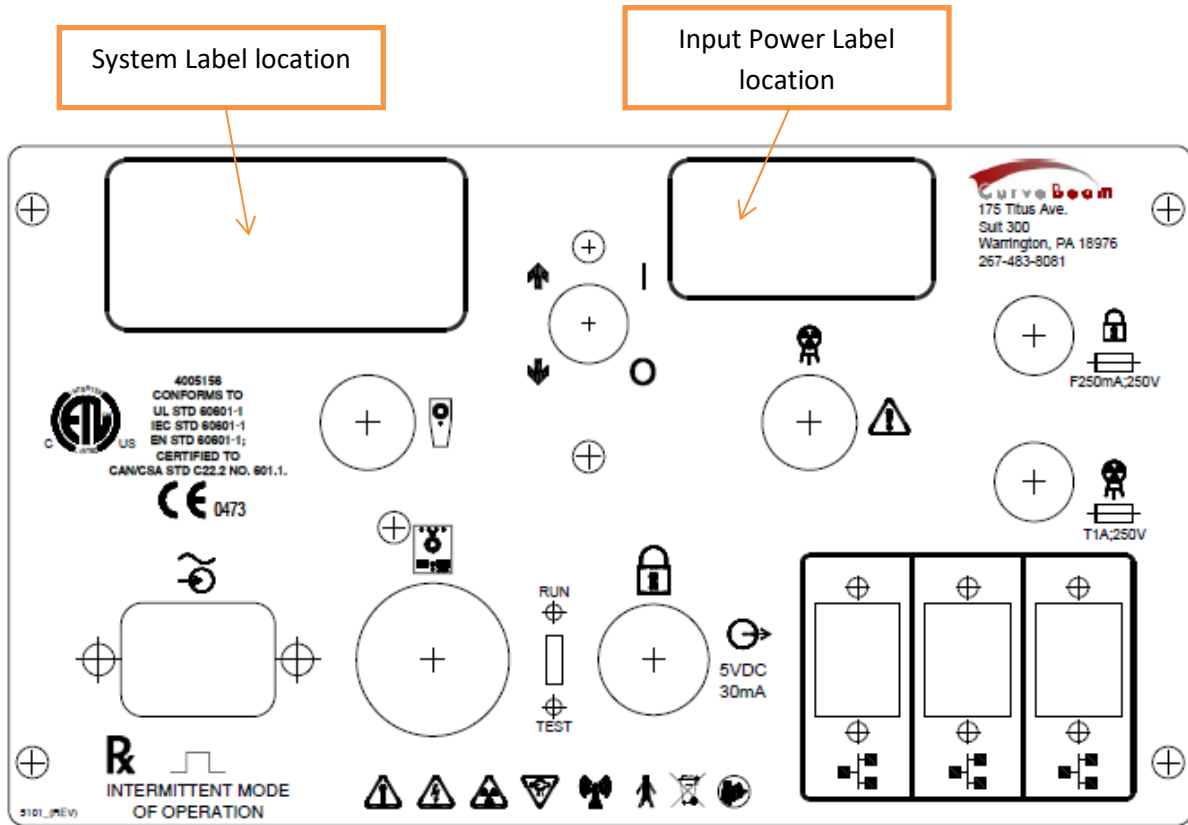
Indicator Panel (front of machine):

0473

Non-Portable Device label:

Focal Spot label:

X-Ray Warning label:
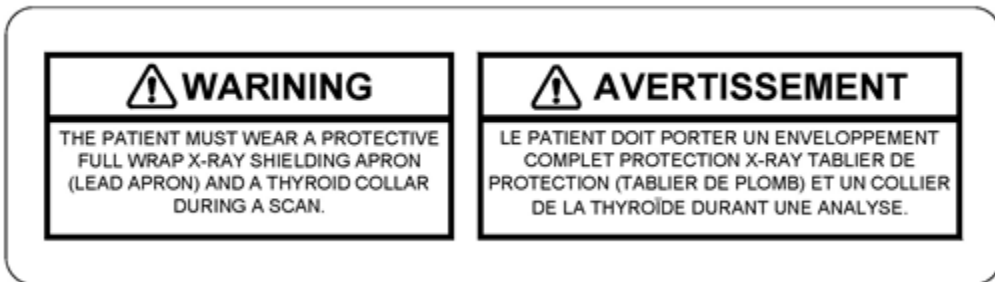
Foot Pinch Point Label:

Chair Capacity label:

Lift Switch Label:

Cleaning Instructions Label:

REFER TO OPERATORS
MANUAL FOR CLEANING
INSTRUCTIONS

CONSULTER LE MANUEL
POUR LES INSTRUCTIONS
DE NETTOYAGE

5016_(REV)

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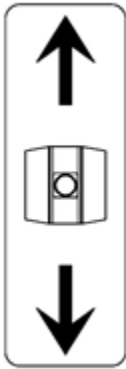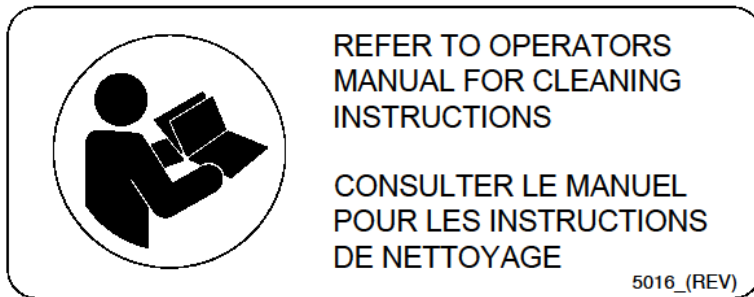
Input Power Label:
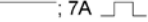

```
CB250VAC 10A

115V ~ 50/60Hz 1150VA
1.5A ⎓ ; 10A ⊓
```

```
QF250V ~ 5A
210-240V ~ 50/60Hz
1150VA @ 230V ~
1,5A ⎓ ; 5A ⊓
```

```
QF250V ~ 5A
200V ~ 50/60Hz 1000VA
1,5A ⎓ ; 7A ⊓
```

```
QF250V ~ 10A
100V ~ 50/60Hz 1000VA
1,5A ⎓ ; 15A ⊓
```

System Label:

Depending on description, the
following may be in this field:
InReach
X-Ray Power Supply
Beam Limiter
Control Box

CurveBeam LLC.
This product complies with DHHS standards under the Radiation Control Act of 1968
applicable at date of manufacture. This product complies with 21 CFR 1020.30 – 1020.31

(see description on left)

(Manufactured Date as YYYY-MM)
REF (Model No/Rev)
SN (Serial No)

Manufactured by CurveBeam LLC.
175 Titus Ave. Warrington, PA 18976 USA   5008_(REV)

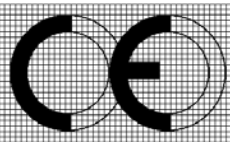Tube Head Label:

CurveBeam LLC.
This product complies with DHHS standards under the Radiation Control Act of 1968
applicable at date of manufacture. This product complies with 21 CFR 1020.30 – 1020.31

Tube Head Assembly   X-Ray Tube
(Manufactured)   Superior x-Ray
REF 2007-0   REF SXR-130-20-0.5
SN (Serial No)   SN (Serial No)

120kVp, 5mA   10.5mm Al, fs 0.5mm
Manufactured by CurveBeam LLC.
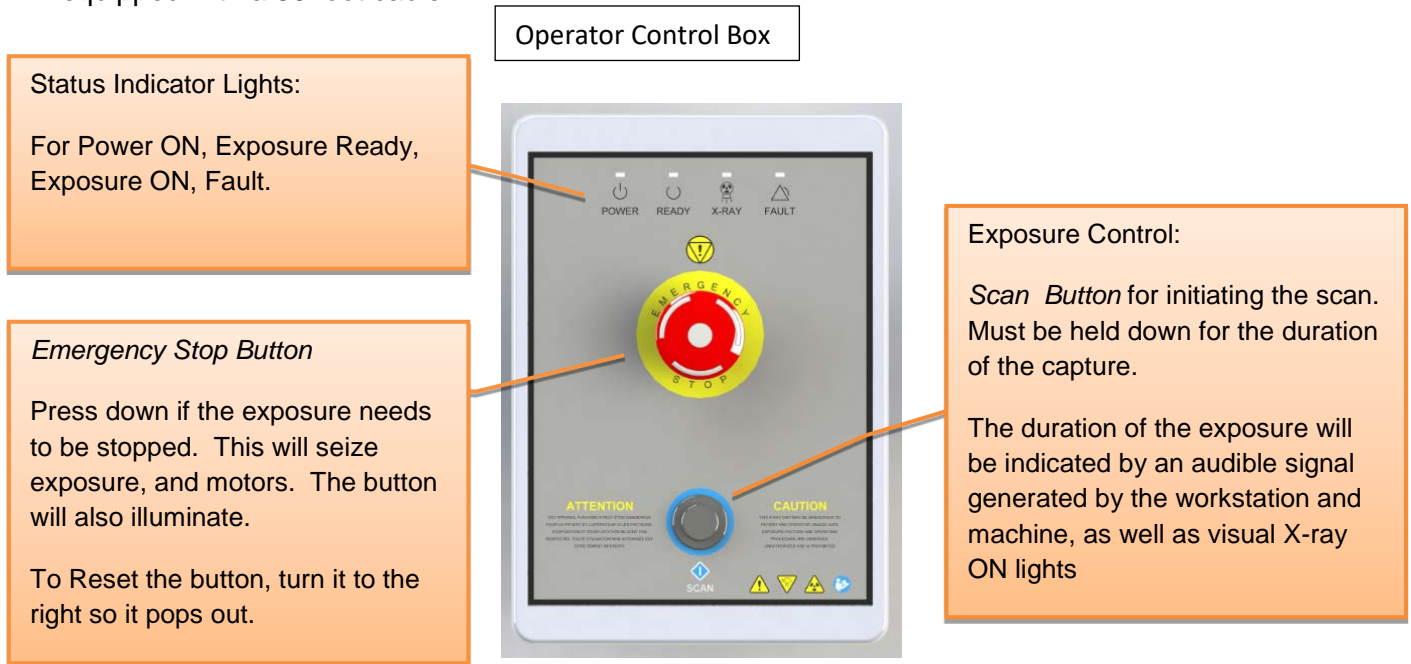175 Titus Ave. Warrington, PA 18976 USA   5008_(REV)

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SYMBOLS:

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
⚠	General Warning	☢	Ionizing Radiation	⚡	Electrical Hazard	∿→	AC In
🛑	Emergency Stop		X-Ray Radiation	((•))	Non-Ionizing Radiation		Network Cable
⏻	Power		Follow Operating Instructions for use	🧍	Type B (body) applied part complies with IEC 60601-1		Control Box
⏾	Ready	◇	Scan		Recycle		Pinch Point
	X-Ray On	🔒	Interlock	⊖→ 5VDC 30mA	Output for Interlock		Maximum weight capacity for sitting.
△	Fault				Patient E-Stop		

Symbol	Meaning	Symbol	Meaning	CE Mark	
⎓	Fuse T1A250V, T=time delay, 1amp, 250volt fuse F250mA250V, F=fast acting, 250mA, 250volt fuse	I 0	Power/Circuit ON Power/Circuit OFF	**CE Mark** CE class IIb	This product carries the CE Mark. The CE Declaration (CE Conformity) becomes invalid if the product is changed without explicit consent of the manufacturer! This applies to all parts, not only to safety elements.

European Authorized Representative:	CurveBeam Europe Limited Devonshire House 1 Devonshire Street London W1W 5DR

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System Controls and Indicators:

Operator Control Box:

The Operator Control Box contains the status indicator lights as well as the Emergency Stop button and the Exposure Control Switch. This can sit on a table or be mounted on a wall. It is equipped with a 50 foot cable.

Operator Control Box

Status Indicator Lights:

For Power ON, Exposure Ready, Exposure ON, Fault.

Emergency Stop Button

Press down if the exposure needs to be stopped. This will seize exposure, and motors. The button will also illuminate.

To Reset the button, turn it to the right so it pops out.

Exposure Control:

Scan Button for initiating the scan. Must be held down for the duration of the capture.

The duration of the exposure will be indicated by an audible signal generated by the workstation and machine, as well as visual X-ray ON lights

Patient Emergency Stop Button:

This Emergency Stop button on the side of the machine is intended for the patient to stop exposure during a scan. This will seize exposure and all motors. The button will also illuminate. To Reset the button, turn it to the right so it pops out.

Patient Alignment:

A camera is provided to assist with the patient alignment. The camera image is provided prior to and during the scan. Place the patients hand, wrist, elbow, foot, knee, or ankle inside the device. Use the camera to assist in positioning. If needed, the chair may be used to assist in patient positioning and stability. The maxium weight capacity on the chair is 400 pounds, do not exceed this limit. Once patient is positioned, instruct them to remain still for the duration of the scan.

System Status Indicators

There are 4 indicator lights. These indicator lights are on the Operator's control box and on the machine itself on the upper center cover. There are also similar indicators within the Acquisition software program.

The lights are as follows:

- **POWER:** This is solid **Green** when the machine is ON.

- **READY:** This is the Exposure Ready light and is **Green** when the machine is in Ready state for exposing. This would indicate that it is time to press the exposure button.

- **X-RAY:** This is an **Amber** color when the system is exposing, emitting X-ray.

- **FAULT:** This would be **Red** in color if there was a failure in the system.

Status Indicator panel on Operator Control Box: *above Emergency Stop button.*

Status Indicator panel on machine: *front center cover*

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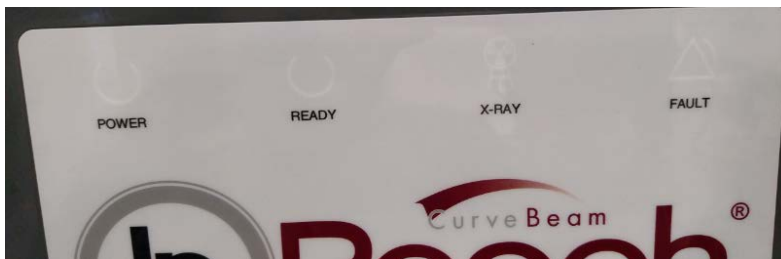
CHAPTER 4: Calibration and Quality Assurance (QA) Procedures

Calibration Procedures:

Calibrations are necessary for proper performance of the InReach. When calibration is required, a pop up message will appear during the start up screen for the Acquisition software and the service light will be illuminated. When this occurs, there will only be a limited number of days in which the machine will be operational without a current calibration.

Additionally, there are some calibration procedures that should only be run by a factory trained technician. These can be found in Appendix IV of this document. If the factory trained technician needs to perform the Advanced Calibrations, those should be done first, then the calibrations in this section should be run.

The instructions here will guide the user through the following calibrations:
- Panel Gain Calibration (Gain)
- Normalization File Creation for Reconstruction engine (Norm)
- Image Quality Analysis (QA)

Prior to starting the calibrations, ensure nothing is in the bore, this includes patient platforms.

⚠️**WARNING** Prior to performing any calibrations, ensure the machine is not in use, and patient is not in the scanner.

Once the pop up message in Acquisition alerts the user that a Calibration is needed, the user can exit the Acquisition software and start up the CB-ToolShed software, located on the desktop of the Acquisition terminal. Double click on the CB-ToolShed icon to start the calibration software.

When the CB-ToolShed software is started, a startup screen similar to Acquistion will be displayed.
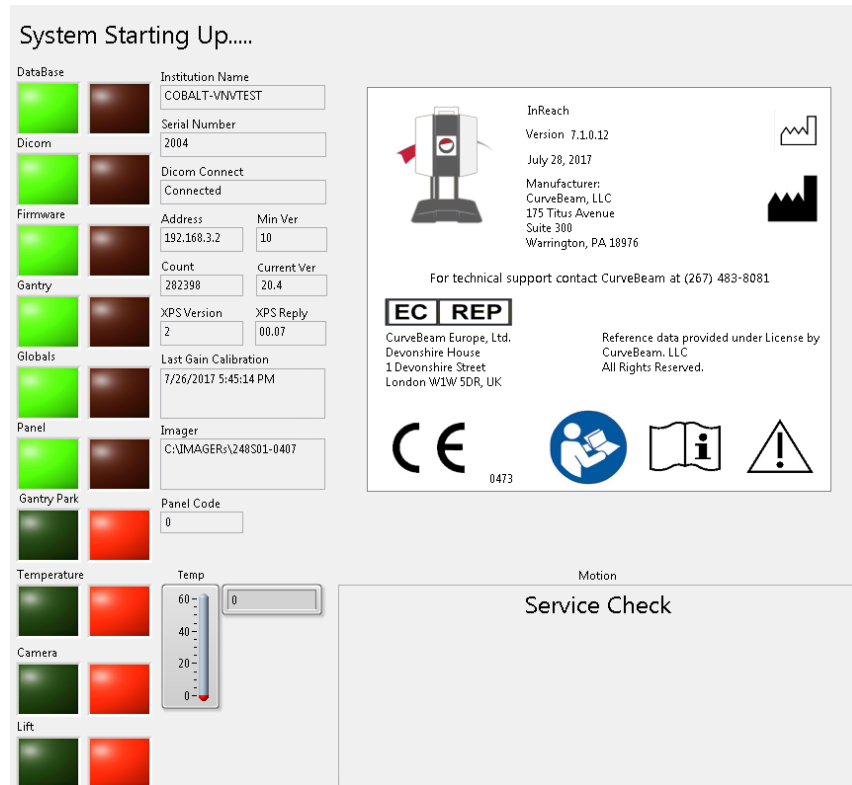

As CB-ToolShed starts up and checks all of the parts of the system, lights should change from red to green to indicate that the scanner is able to be used for calibrations.

It is possible that a warning message might also appear, as shown below, just click "Continue" as the calibrations about to be performed will fix the issue that created the warning message. Warning message such as this may appear:
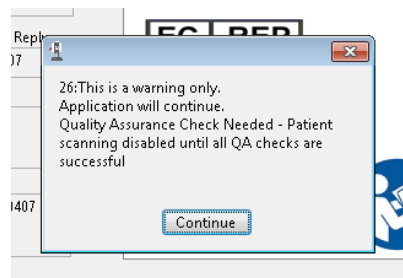
Followed then by this warning message on the initial screen that says Quality Assurance Check Needed:
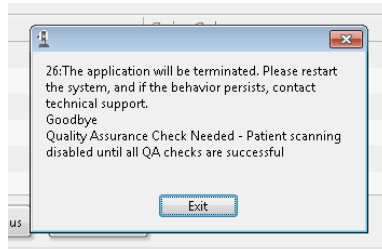

Click on the "Exit" in the pop up window and CB-ToolShed will then be usable for calibrations. The screen will look as shown:

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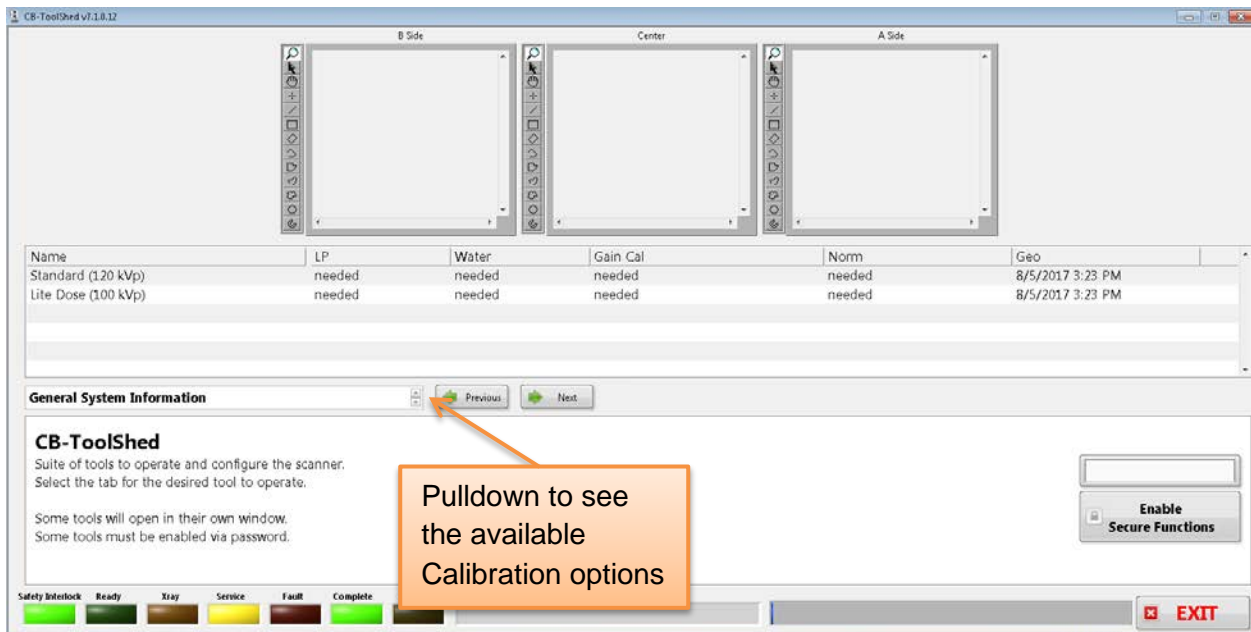
The first calibration that needs to be performed is the Panel Gain Calibration. Click on the pulldown next to General System Information to display the list of calibrations possible. The available options will appear as follows:
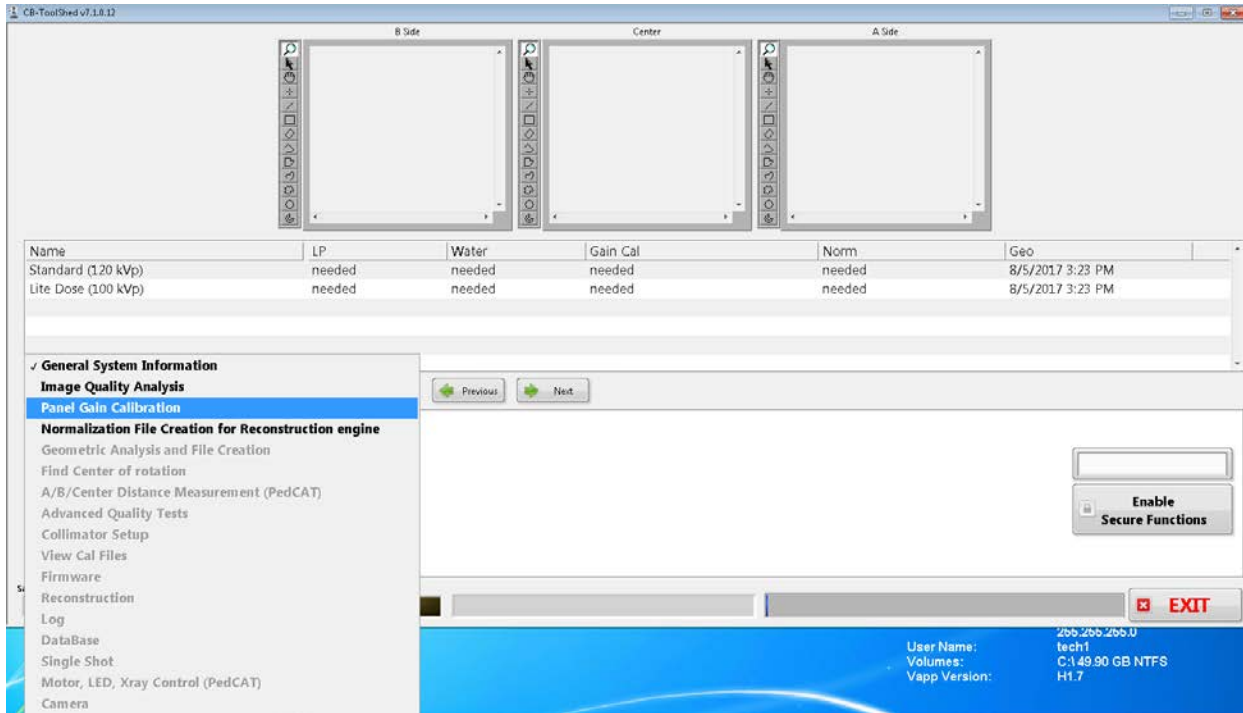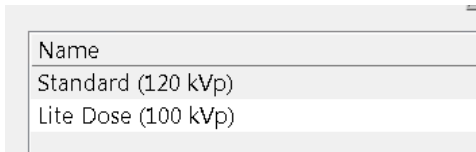

From the pulldown list, select the "Panel Gain Calibration" and the following will appear:
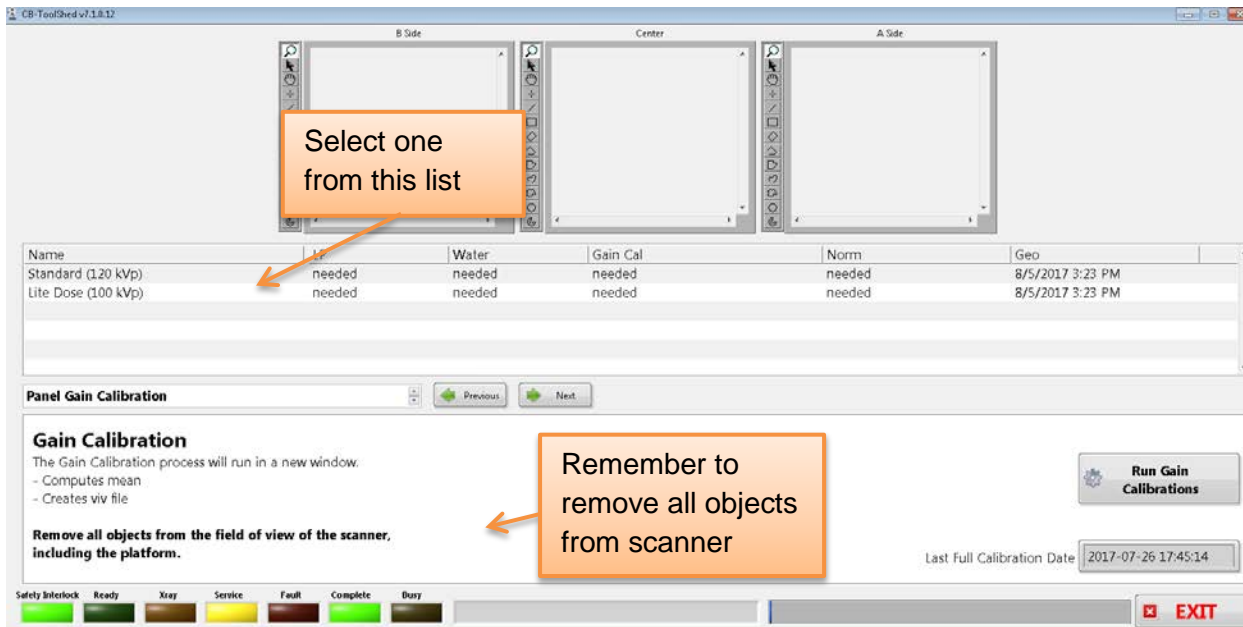
Before starting the Panel Gain Calibration, it is important to remove all objects from the scanner, including any patient platforms.

Then, to start the Panel Gain Calibration, select one of the entries listed under "Name", as shown below:


Then click on the "Run Gain Calibrations" button: to start the calibration and the following screen will open on top of the current window:
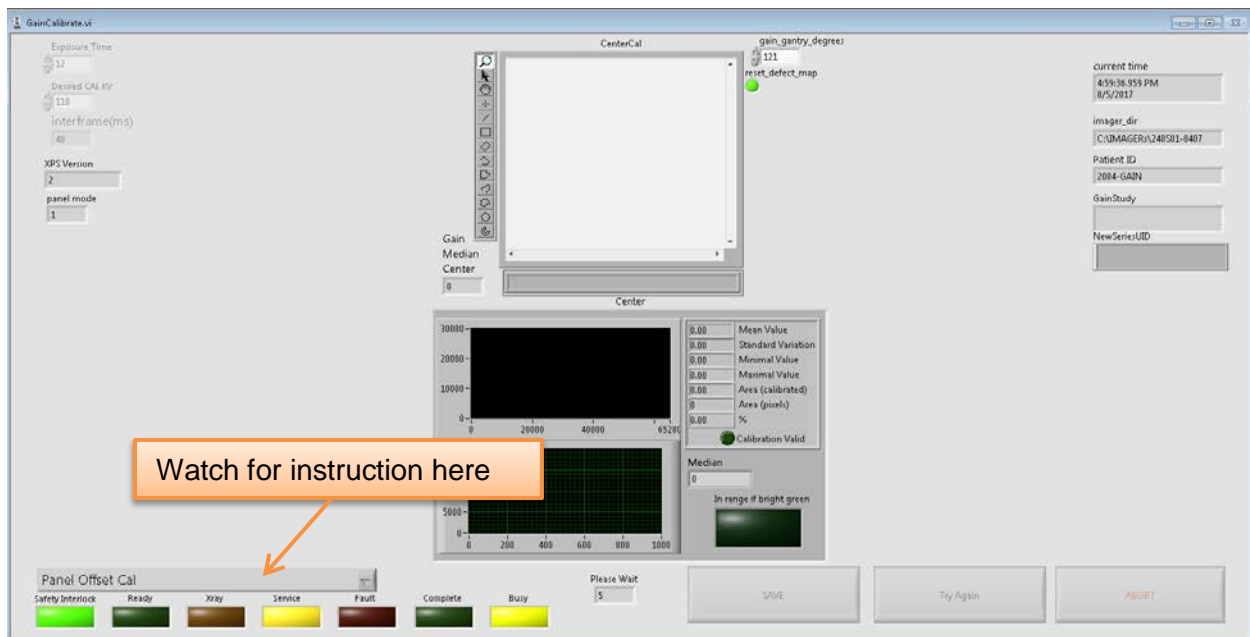
The user will receive message and updates on what is happening as well as instructions on what to do (when to fire x-ray) in the window on the lower left corner. There will be a message to fire x-ray to perform the gain calibration. When prompted, Press and Hold the Scan button to fire the x-ray.

⚠️**WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

After the x-ray has completed, release the scan button. The image on the screen will look similar to the below image where the Center Cal window will now show an image of the empty panel as part of the calibration:
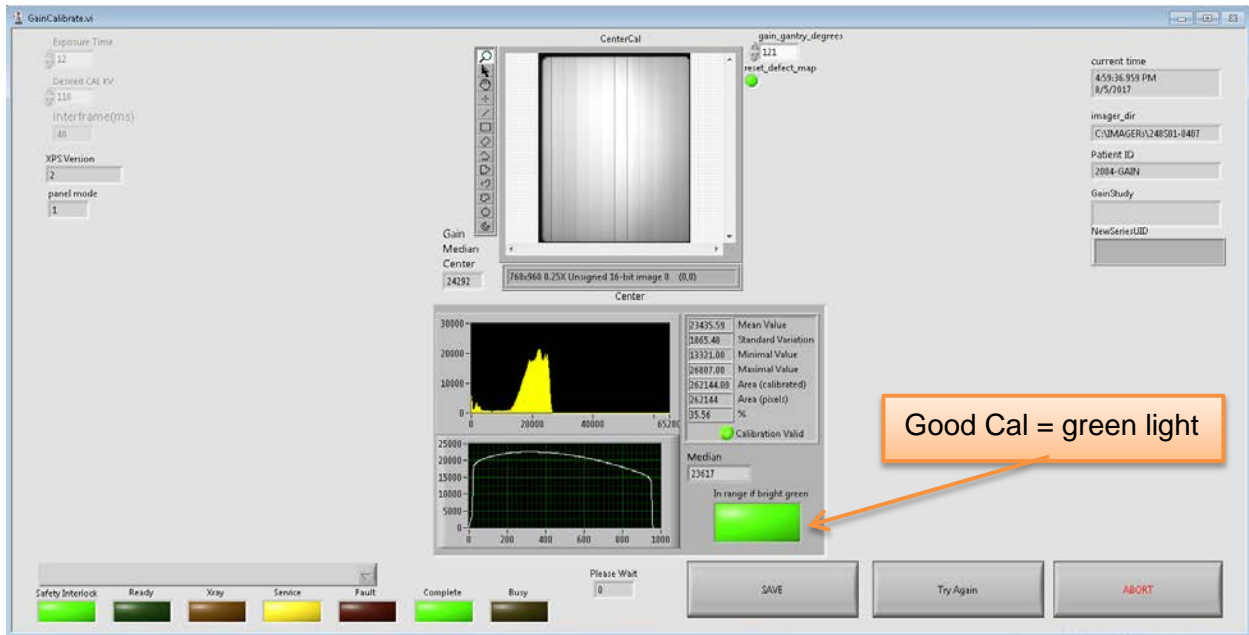

Once the calibration scan has been taken, the three buttons at the bottom of the screen, "SAVE", "Try Again", and "ABORT" will all become active and selectable. If the calibration was successful, there will be a bright green light illuminated under the text "In range if bright green" as shown in the above picture. If the section was not successful, the light will remain unilluminated. *If the calibration was successful, click on the "SAVE" button at the bottom.* If the button is not illuminated bright green then select "Try Again" and run through the calibration another time. This can be done repeatedly. This can be done if the user realizes something was left in the FOV and therefore will cause a failed calibration. If after two attempts, the calibration still is not successful, select ABORT. This will revert back to the last good values before this calibration was run. These values will be able to be used for 21 days before a message appears on the Acquistion start up that will tell the user to run the calibrations again. If you see this message, please contact CurveBeam Technical Support for assistance.

After "SAVE" is selected, a series of pop up messages will appear, as shown below. They are just there to show that there are more required calibrations to do and that the Quality Assurance check is also needed, eventually, before scanning patients. Just click the "Continue" or "Exit" buttons to dismiss them.
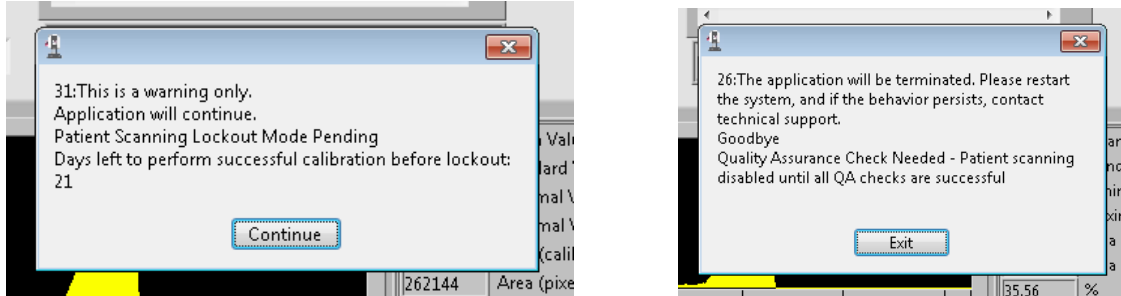

And finally back on the main CB-ToolShed Gain Calibration screen, another pop up message will appear:
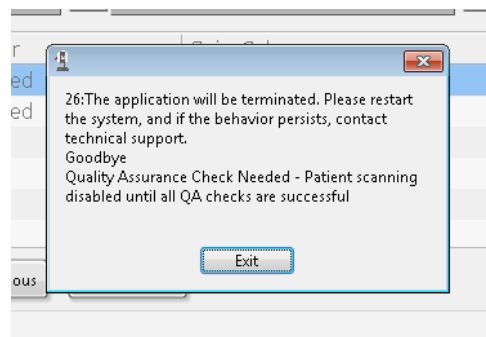

This message indicates also that Quality Assurance checks are still needed as a result of having changed the Panel Gain Calibration. Click "Exit". Once all of the pop up windows have been dismissed, the Gain Calibration is complete.

From the pulldown next to "Panel Gain Calibration," select the "Normalization File Creation for Reconstruction engine" entry as shown below:
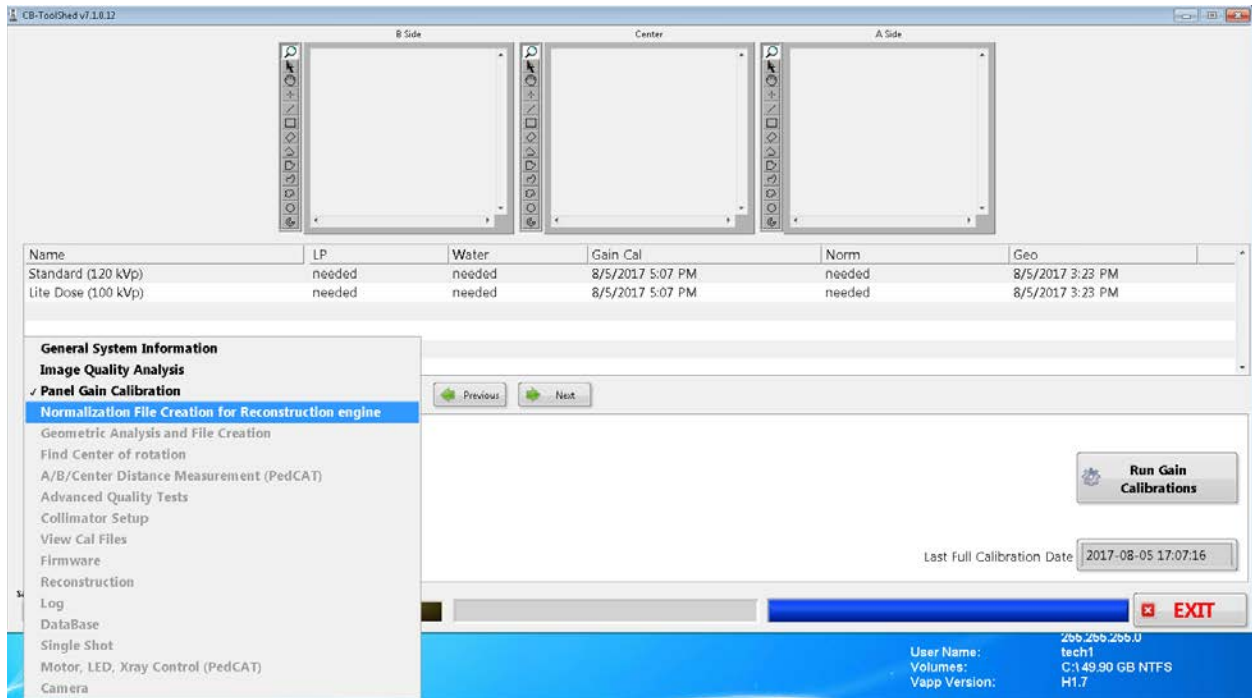

After the "Normalization File Creation for Reconstruction engine" is selected, the screen for this calibration will display as follows:
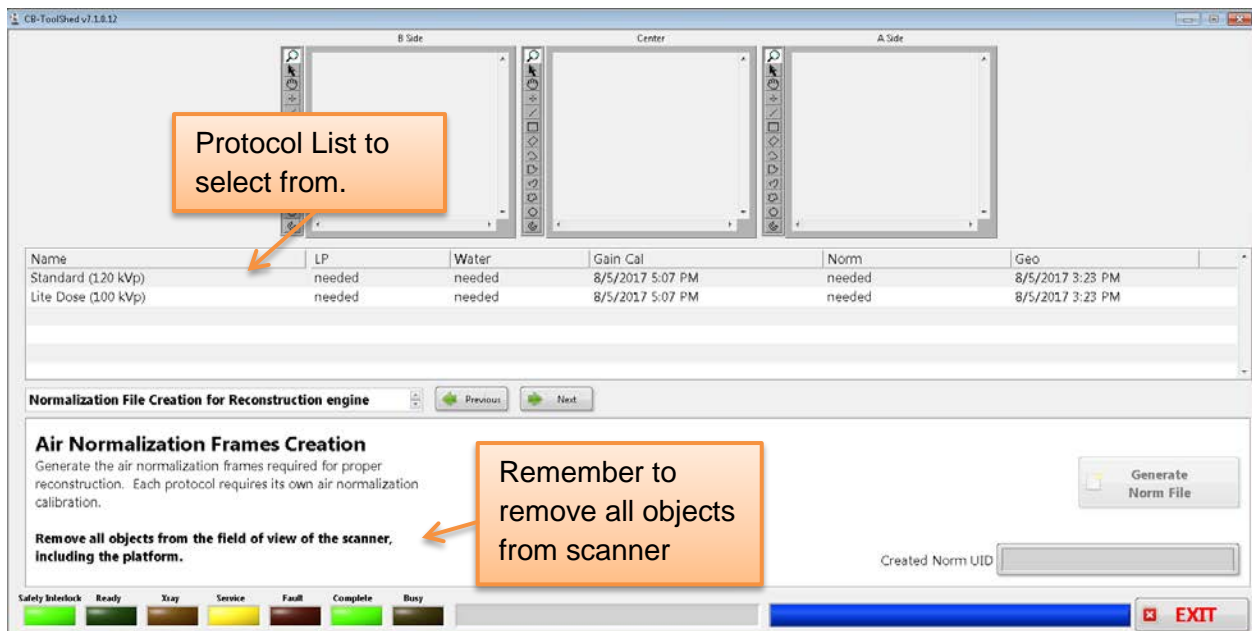
Before starting the Air Normalization Frames Creation, it is important to remove all objects from the scanner, including any patient positioning platforms.

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This calibration will create a norm file for each of the protocols listed. In order to do this, a scan must be taken using each protocol. Ensure that there is nothing in the FOV, including the patient platform. To start, click on the first protocol in the "Name" list, which will appear as follows:
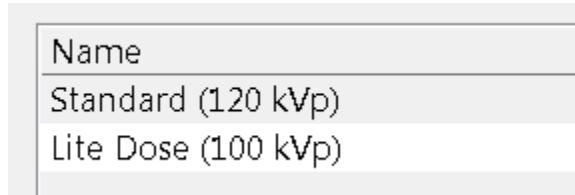
Once the first entry in the Protocol Name list is highlighted, the "Generate Norm File" button will be active and able to be selected. Click on the "Generate Norm File" button:

 to start the norm file generation. During this process, it is normal for the screen to appear all washed out and be a light gray as shown below:
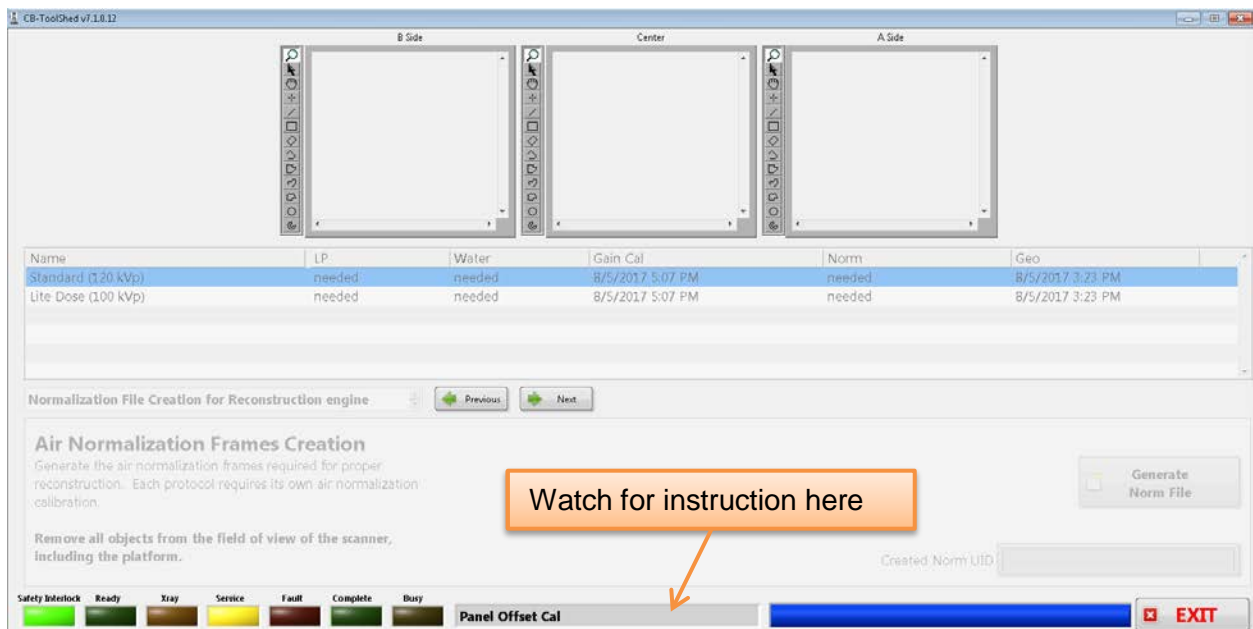
The screen will look mostly grayed out for a bit. Instructions will then indicate when to fire the x-ray for the protocol selected. When prompted, Press and Hold the Scan button to fire the x-ray.

> ⚠️**WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

Once the x-ray has completed, release the scan button.

Then an image will appear in the Center box at the top of the screen and a warning pop up message will appear as follows:
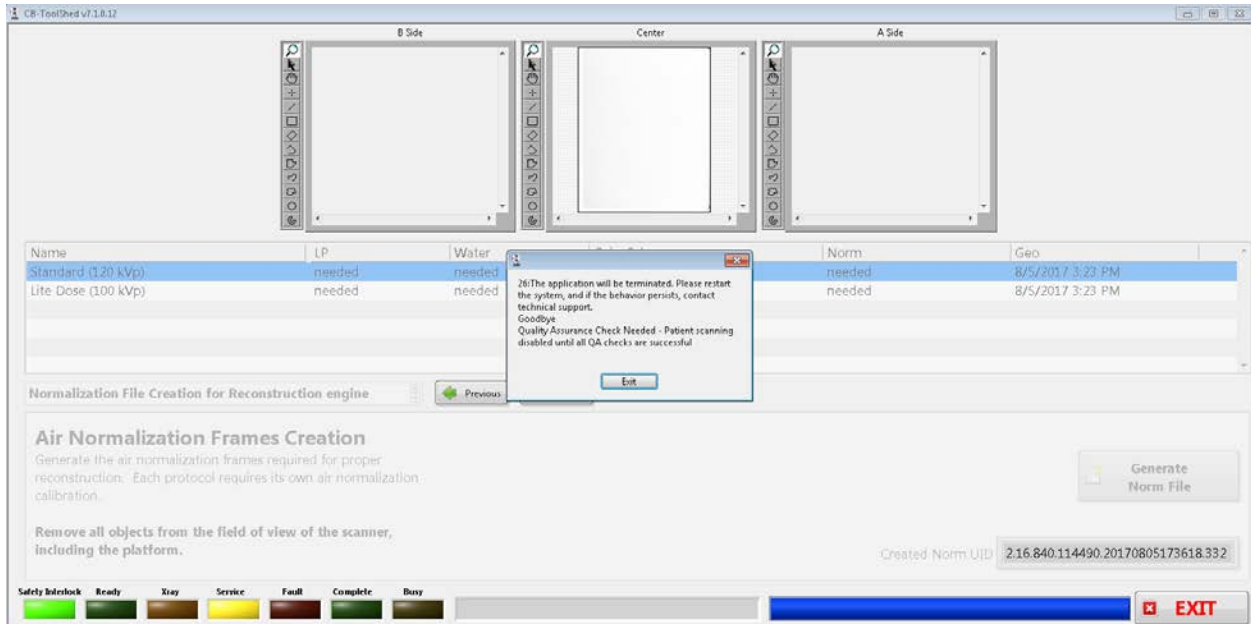
Click "Exit" to dismiss the pop up message that Quality Assurance checks are still needed.

Once the Norm file is created for the current Protocol (Name), the date of the Norm file will be updated with the current date and time. To view this, to see how many calibrations have already been completed, use the slider under the Protocol Names to find the "Norm" column as show below:
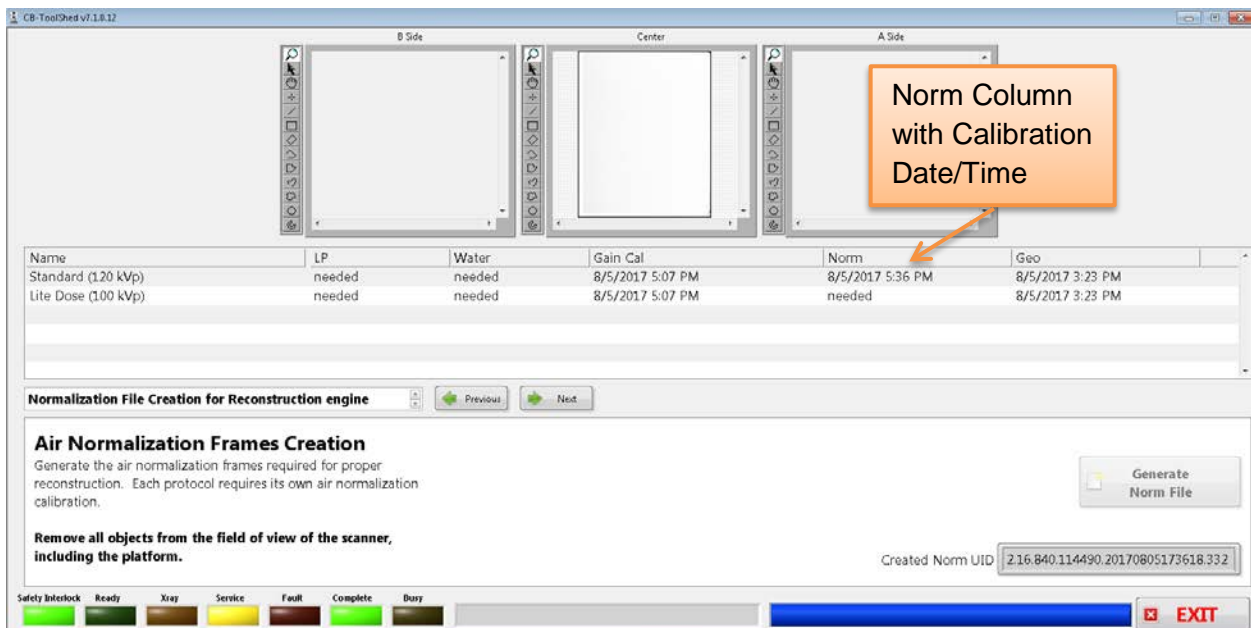
Continue with all of the protocols until each has an updated Norm date and time listed.

From the pulldown next to "Normalization File Creation for Reconstruction engine," select the "Image Quality Analysis" entry as shown below:
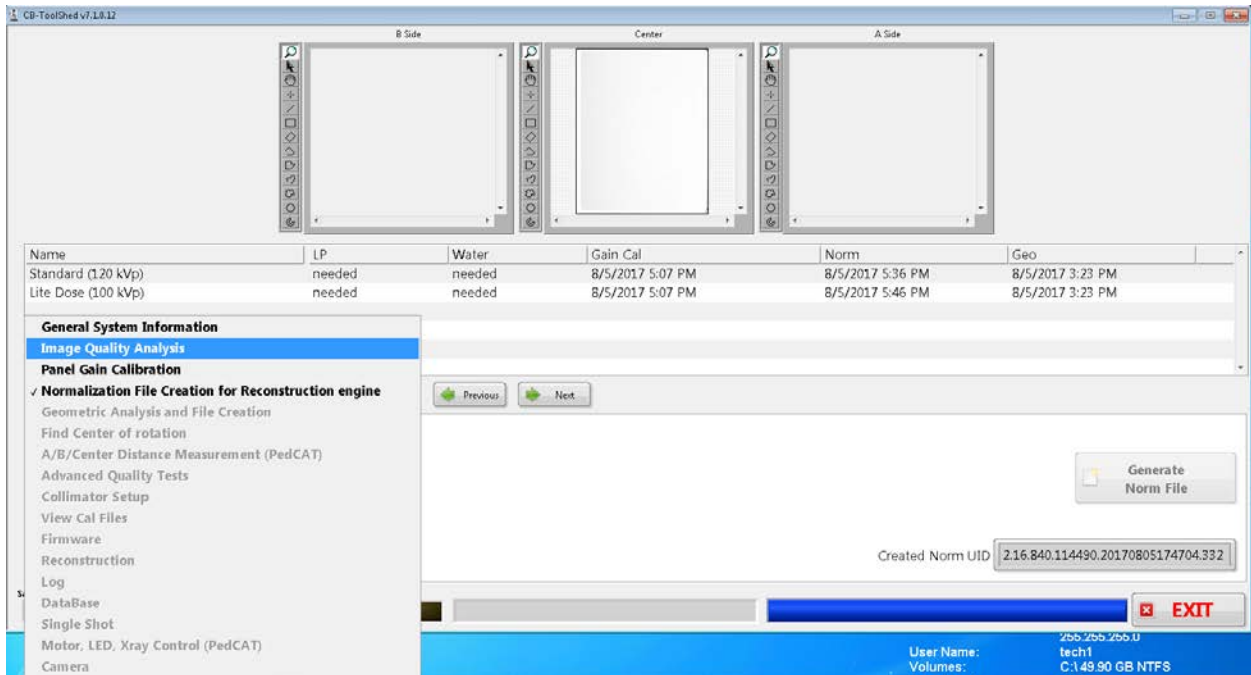
After the "Image Quality Analysis" is selected, the screen for the Image Quality Analysis will display as follows:

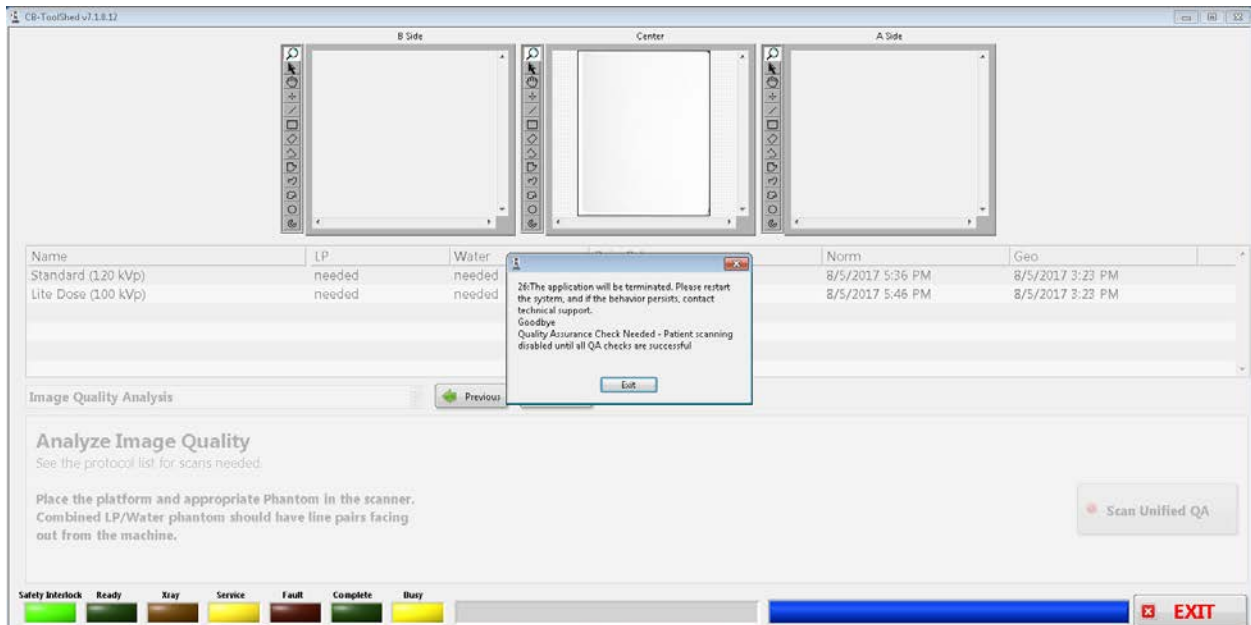Click on the "Exit" button on the pop up message in the center of the screen. It is just a warning that this final calibration is needed. Then the screen will appear as follows:
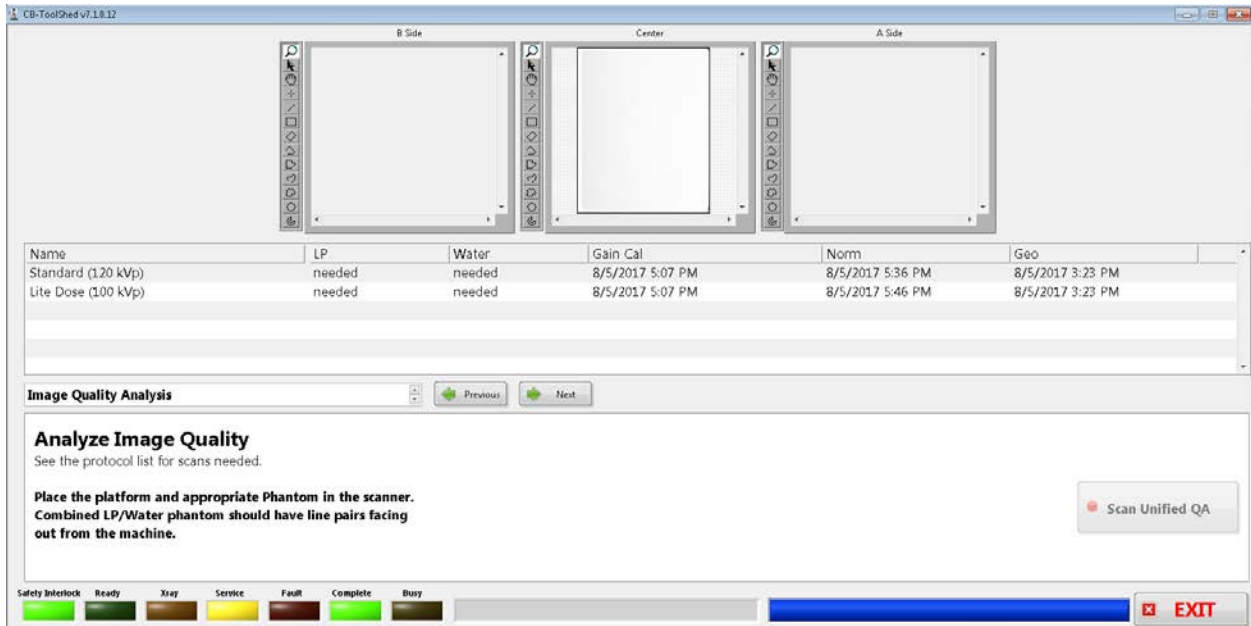
Before starting, the Platform and the QA Phantom must be placed in the scanner. Using the QA Platform, place the QA Phantom as shown below:

Ensure that the platform is placed so that the metal piece fits in the hole in the front of the bore. Make sure that the Line pairs are visible from the front of the scanner and that they are horizontal.

This calibration will assess the image quality for each of the protocols listed. In order to do this, a scan must be taken of the phantom, using each of the protocols. To start, click on the first protocol in the "Name" list, which will appear as follows:
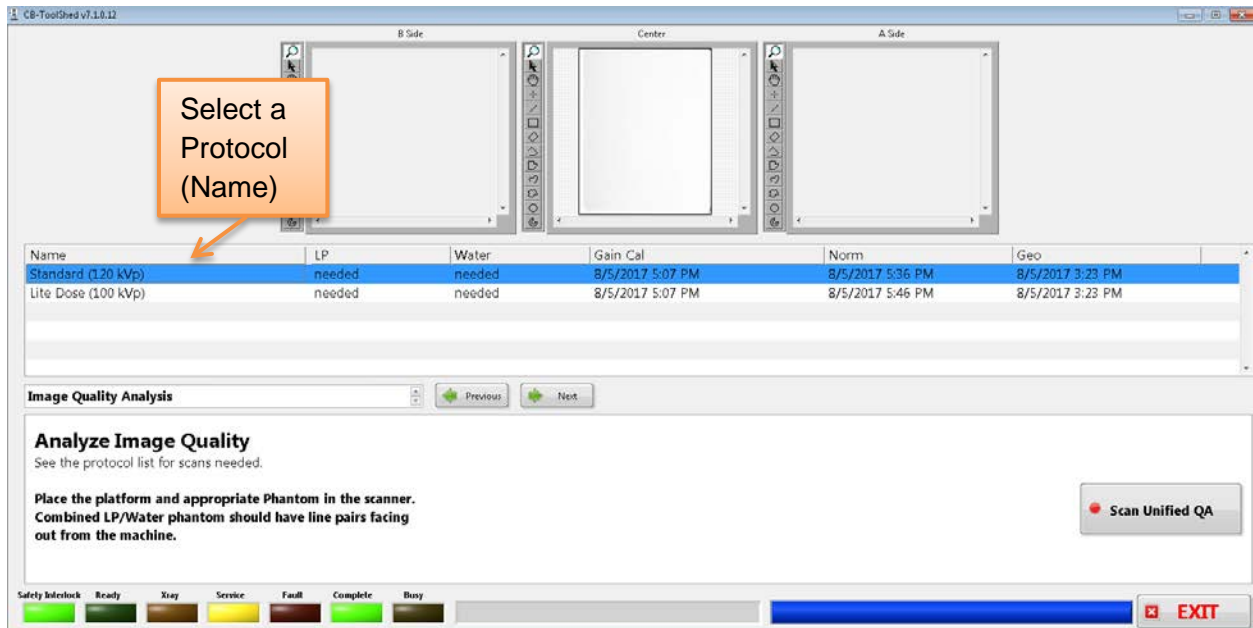
Once the first entry in the Protocol Name list is highlighted, the "Scan Unified QA" button will be active and able to be selected. Click on the "Scan Unified QA" button: [Scan Unified QA] to start the Image Quality Analysis. During this process, it is normal for the screen to appear all washed out and be a light gray as shown below:
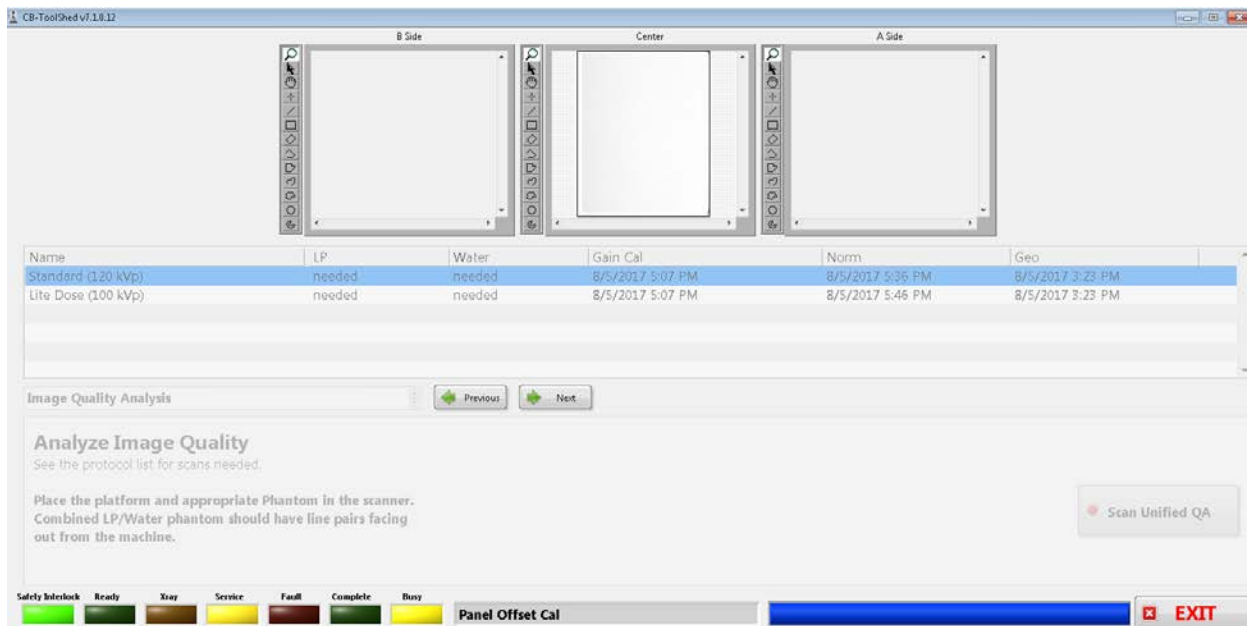
The screen will look mostly grayed out for a bit.

Instructions will indicate when to fire the x-ray for the protocol selected. When prompted, Press and Hold the Scan button to fire the x-ray.

> ⚠️**WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

Once the x-ray has completed, release the scan button.

This calibration will take a few minutes to complete. Once it has, another window will appear on top, with the results of the scan, as shown below:
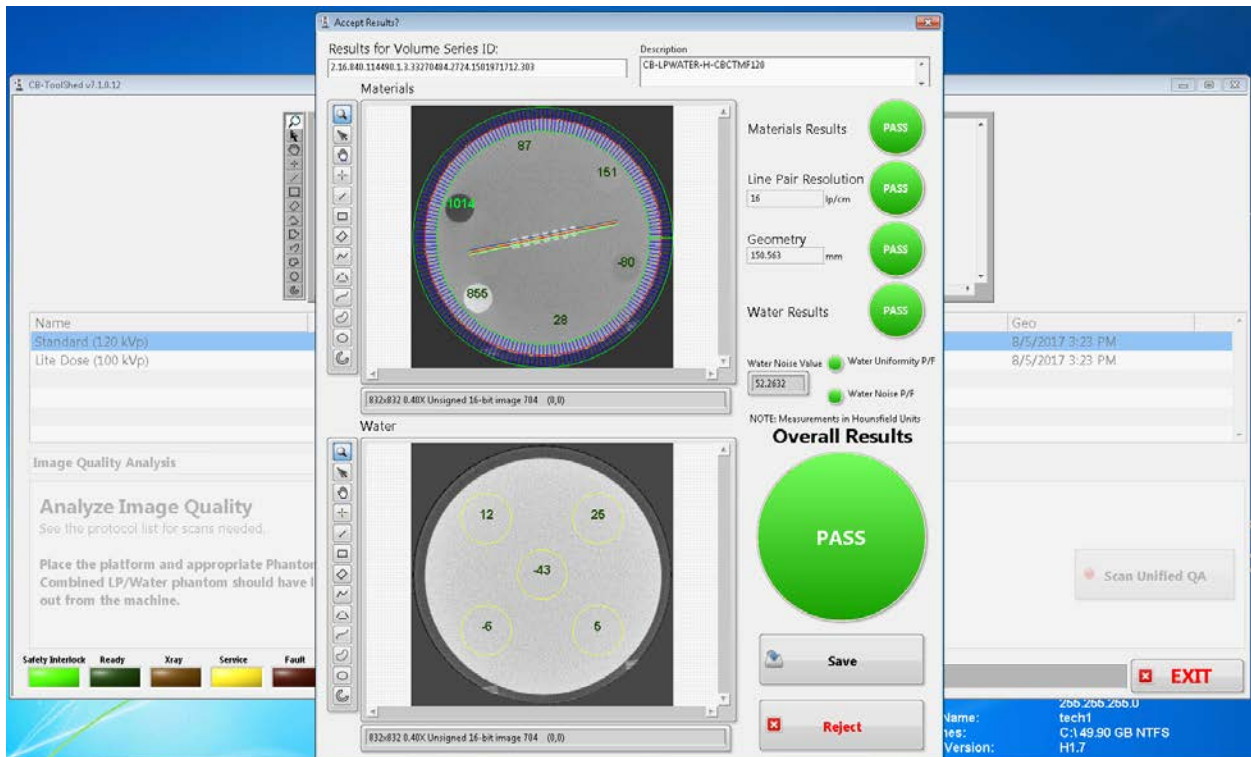
If all lights are illuminated green with "PASS" written in them, the values are good and the user should click the "Save" button. If the colors are red, the values are bad and the user should reject the scan. The user can then try the scan again, if the scan is continually rejected, then please contact CurveBeam Technical Support.

If the calibration was successful, and once "Save" is selected, the following screen will appear:
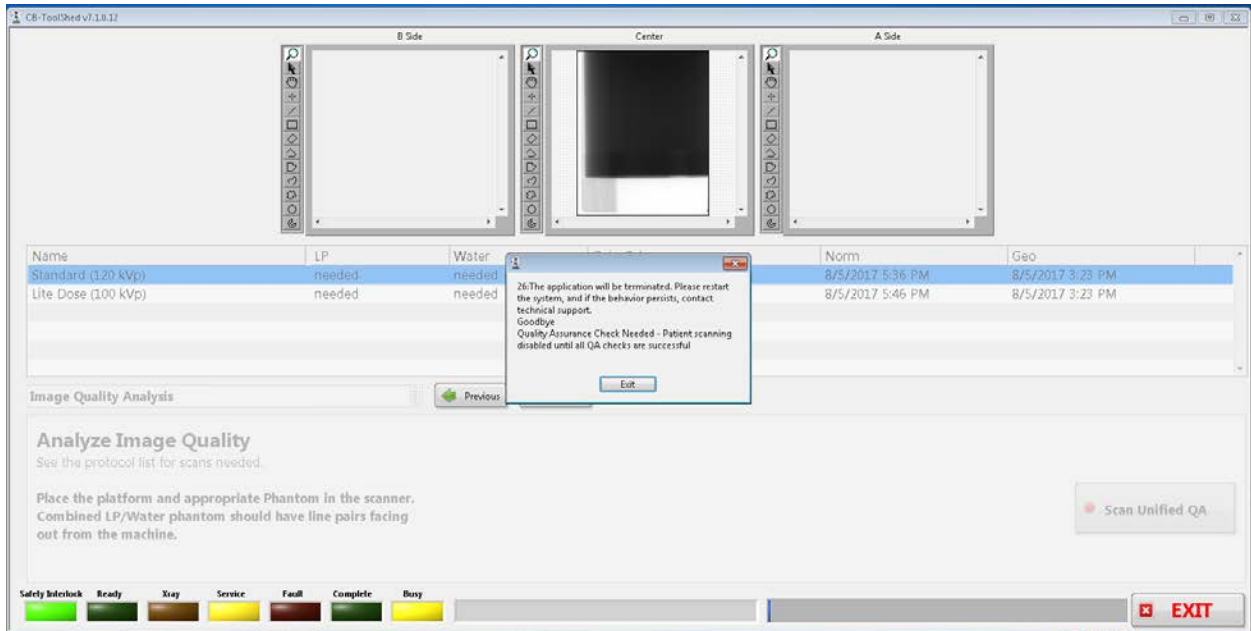
Click the "Exit" on the pop up window, as an additional scan is required still. After the pop up window closes, if the calibration passed, the date and time will be filled in for the LP (Line Pair) and Water columns.
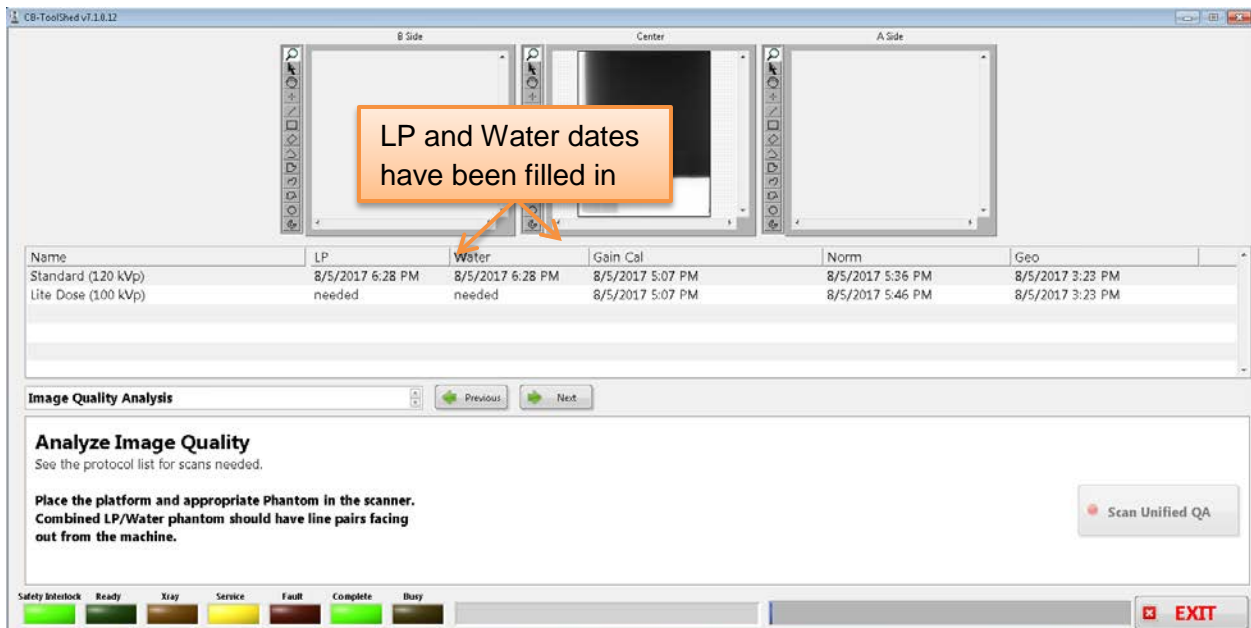
Select the second protocol in the list. Perform the remainder of the Line Pair scans. If the protocol has "needed" listed under the LP or Water column, then that protocol still needs a scan.

Once all of the entries in the LP and Water columns are filled in with date and times and no longer say "needed", remove the Quality Assurance Phantom and Platform from the scanner.

The User Calibrations are completed. For additional calibrations, performed by CurveBeam technicians, refer to Appendix IV.

Quality Assurance Procedures

The QA test procedures are designed to check for Image Quality, Accuracy of Distance Measurements, and Consistency. These tests can be performed by a InReach owner/operator, or any service technician or radiation physicists. It is recommended that this QA test procedure be performed quarterly or if there are any indications of image quality or accuracy issues.

⚠️**WARNING** Prior to performing any quality assurance procedures, ensure the machine is not in use, and patient is not in the scanner.

The QA tests will be performed by scanning the QA phantom provided by CurveBeam. This phantom includes a QA Line Pair/Chamber and Water Phantom. Image Data will be captured and assessed for acceptable values. The QA is done as a final step of the calibrations that the user can complete. This ensures an accurate assessment of the QA Phantom. Please refer to the beginning of this chapter for instructions on performing system calibrations, which include the QA Assessment as the final calibration.

The items assessed for Image Quality will be:

- High Contrast Spatial Resolution measured via line pairs.
- Hounsfield Units (HU) accuracy of 5 Density chambers (Air, Acrylic, LDPE, Teflon, and Nylon)

Density Material	Expected HU value Ranges
AIR (black chamber):	-1100 to -900
ACRYLIC (light gray chamber):	-50 to 200
LDPE (dark gray chamber):	-250 to -50
TEFLON (white chamber):	700 to 1200
NYLON (light gray chamber):	0 to 200

Radiation Output Test:

⚠️**WARNING** Prior to performing any radiation output testing, ensure the machine is not in use, and patient is not in the scanner.

It is recommended that a check of the kVp(eff) and Radiation Output of the X-ray source be performed annually by a qualified Physicist. The incident Absorbed Dose at the detector may be measured using a dosimeter. Tests are performed to assess output value and to check for tube output consistency and timer accuracy.

1. Attach a dosimeter to the detector such that the sensor is positioned where the vertical and lower horizontal laser lights intersect.
2. Perform a Standard scan, either for Hand or Foot, and record the time and dose from the meter.

> ☢️**WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

CHAPTER 5: Radiation Environment Survey

The following protocol were tested for scatter radiation, as well as a number of image quality tests:

kVp	mA	Pulse Duration (seconds)	Number of Pulses per Scan	mAS	Slice Thickness (mm)	Number of Slices	Scan Diameter (cm)
100	5	0.012	481	28.86	0.2	872	11.77
120	5	0.012	481	28.86	0.2	872	11.77

Scatter Measurements

Methodology

Below is a diagram of where scatter measurements were taken, at distances of 1 m and 2 m from the isocenter of the scanner. Measurements were also taken 1 m above and 1 m below isocenter, as well as diagonally above and below. An anthropomorphic elbow phantom was positioned in the center of the scanner. A Fluke 451p Ionization Chamber (SN# 2859 Calibrated 9/22/16) was used to measure the scattered radiation.

Patient

CE 0473
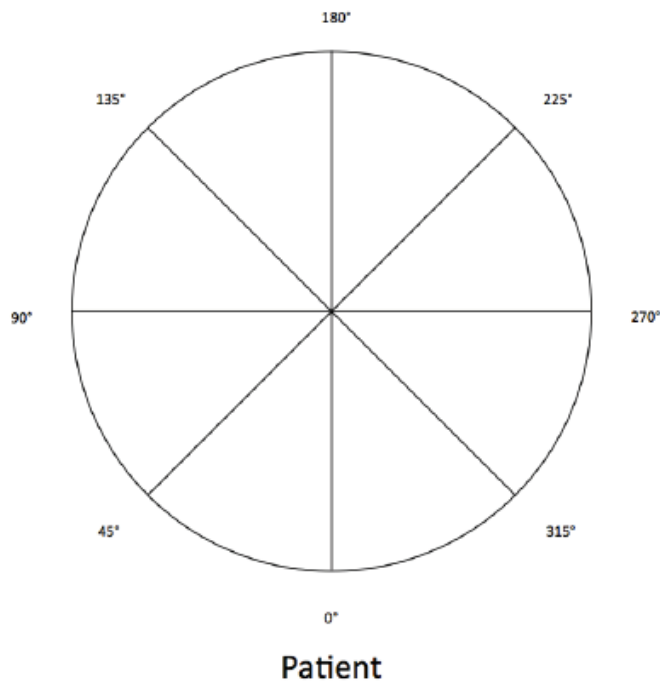
100 kVp:

Location (Degrees)	Distance (m)	Exposure (mR)	Exposure (µR)	Exposure (µR/mAs)	10 scans/week mR/week	25 scans/week mR/week	50 scans/week mR/week
0	1	0.240	240	8.32	2.40	6.00	12.00
	2	0.055	55	1.92	0.55	1.38	2.77
45	1	0.149	149	5.17	1.49	3.73	7.47
	2	0.040	40	1.40	0.40	1.01	2.02
90	1	0.065	65	2.25	0.65	1.63	3.25
	2	0.017	17	0.59	0.17	0.43	0.85
135	1	0.033	33	1.13	0.33	0.82	1.63
	2	0.012	12	0.42	0.12	0.30	0.60
180	1	0.223	223	7.74	2.23	5.58	11.17
	2	0.050	50	1.73	0.50	1.25	2.50
225	1	0.038	38	1.31	0.38	0.94	1.88
	2	0.013	13	0.46	0.13	0.33	0.67
270	1	0.074	74	2.56	0.74	1.85	3.70
	2	0.018	18	0.62	0.18	0.45	0.90
315	1	0.203	203	7.05	2.03	5.08	10.17
	2	0.052	52	1.81	0.52	1.31	2.62
0 (w/ shielding)	1	0.079	79	2.74	0.79	1.98	3.95
	2	0.023	23	0.80	0.23	0.58	1.15
45 (w/ shielding)	1	0.062	62	2.14	0.62	1.54	3.08
	2	0.017	17	0.59	0.17	0.43	0.85
315 (w/ shielding)	1	0.079	79	2.75	0.79	1.98	3.97
	2	0.018	18	0.61	0.18	0.44	0.88

Location Distance (m)		Exposure (mR)	Exposure (µR)	Exposure (µR/mAs)	10 scans/week (mR/week)	25 scans/week (mR/week)	50 scans/week (mR/week)
1 m above	--	0.053	53	1.82	0.53	1.32	2.63
	1 m in front (no shielding)	0.088	88	3.05	0.88	2.20	4.40
	1 m in front (with shielding)	0.035	35	1.22	0.35	0.88	1.77
	1 m in back	0.023	23	0.79	0.23	0.57	1.13
1 m below	--	0.082	82	2.83	0.82	2.04	4.08
	1 m in front (no shielding)	0.085	85	2.95	0.85	2.13	4.25
	1 m in front (with shielding)	0.024	24	0.83	0.24	0.60	1.20
	1 m in back	0.030	30	1.04	0.30	0.75	1.50

120 kVp:

| Location (Degrees)	Distance (m)	Exposure (mR)	Exposure (μR)	Exposure (μR/mAs)	10 scans/week mR/week	25 scans/week mR/week	50 scans/week mR/week
0	1	0.480	480	16.63	4.80	12.00	24.00
	2	0.108	108	3.73	1.08	2.69	5.38
45	1	0.307	307	10.63	3.07	7.67	15.33
	2	0.082	82	2.83	0.82	2.04	4.08
90	1	0.141	141	4.89	1.41	3.53	7.05
	2	0.041	41	1.41	0.41	1.02	2.03
135	1	0.067	67	2.31	0.67	1.67	3.33
	2	0.027	27	0.95	0.27	0.68	1.37
180	1	0.428	428	14.81	4.28	10.69	21.38
	2	0.088	88	3.04	0.88	2.19	4.39
225	1	0.085	85	2.95	0.85	2.13	4.25
	2	0.026	26	0.90	0.26	0.65	1.30
270	1	0.158	158	5.49	1.58	3.96	7.92
	2	0.046	46	1.59	0.46	1.15	2.30
315	1	0.380	380	13.17	3.80	9.50	19.00
	2	0.100	100	3.45	1.00	2.49	4.98
0 (w/ shielding)	1	0.107	107	3.71	1.07	2.68	5.35
	2	0.050	50	1.74	0.50	1.26	2.52
45 (w/ shielding)	1	0.134	134	4.64	1.34	3.35	6.70
	2	0.042	42	1.46	0.42	1.05	2.10
315 (w/ shielding)	1	0.167	167	5.79	1.67	4.18	8.35
	2	0.040	40	1.39	0.40	1.00	2.00

Location Distance (m)		Exposure (mR)	Exposure (μR)	Exposure (μR/mAs)	10 scans/week (mR/week)	25 scans/week (mR/week)	50 scans/week (mR/week)
1 m above	--	0.112	112	3.88	1.12	2.80	5.60
	1 m in front (no shielding)	0.175	175	6.08	1.75	4.38	8.77
	1 m in front (with shielding)	0.070	70	2.44	0.70	1.76	3.52
	1 m in back	0.049	49	1.70	0.49	1.23	2.45
1 m below	--	0.171	171	5.94	1.71	4.28	8.57
	1 m in front (no shielding)	0.171	171	5.93	1.71	4.28	8.55
	1 m in front (with shielding)	0.060	60	2.08	0.60	1.50	3.00
	1 m in back	0.059	59	2.04	0.59	1.48	2.95

Dose Profile

Methodology

The dose profile was measured by exposing strips of GAF chromic film, which was aligned at the isocenter of the scanner. The film was then digitized and the profile was measured. A nominal beam width of 17.793 cm was used for all exposures. The full width at half maximum was determined.
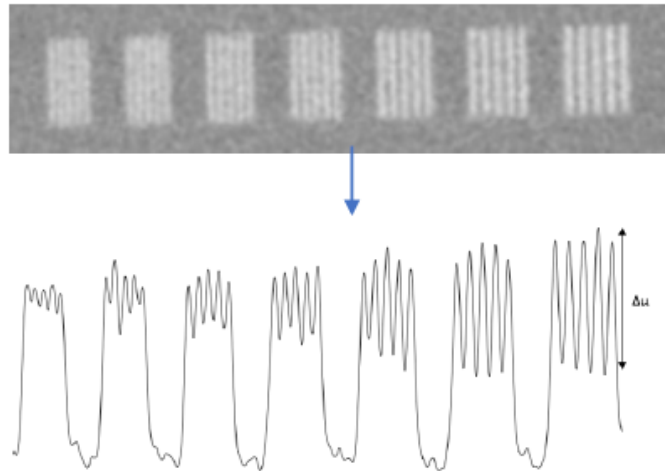
Results
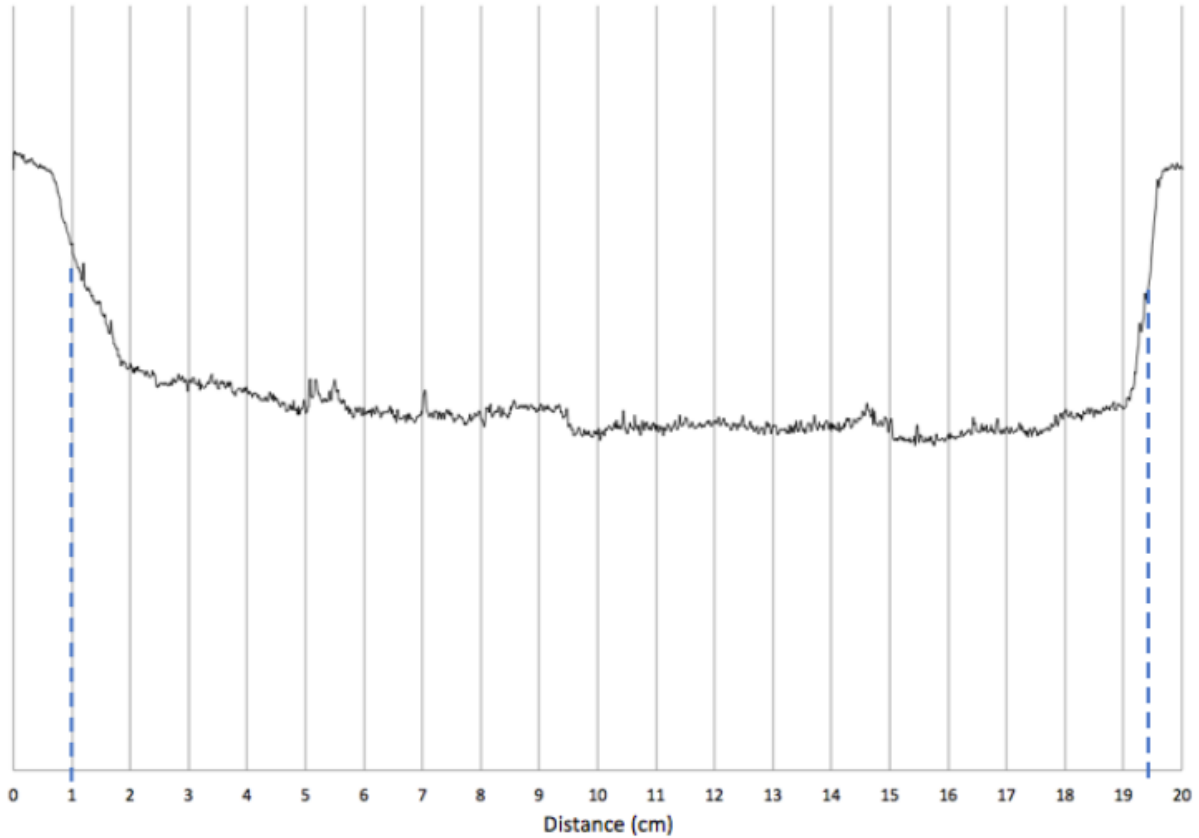
Dose Profile (FWHM) (cm)	18.2

CE 0473

Modulation Transfer Function (MTF)

Methodology

Using the manufacturer's Quality Control Phantom, a series of high contrast line pairs were scanned. The profile of each line pair group was plotted, the average peak pixel value and the average low pixel value were compared to the pixel value of the bar material and the background. As the spatial frequency increases the amplitude of the signal (peak to trough pixel values) drops, relative to the bar material and background, yielding the MTF. The MTFs for each scan type are plotted and shown with the 0.10 MTF being reported in the table in Mm. This approach is in alignment with the approach proposed in GJB 5312-2004.

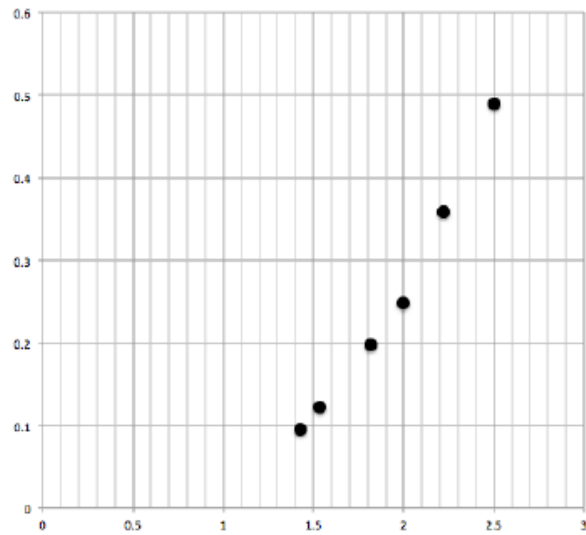$$pMTF \; line \; pair \; (i) = \frac{\Delta\mu(i)}{\Delta\mu}$$

Results

100 kVp:
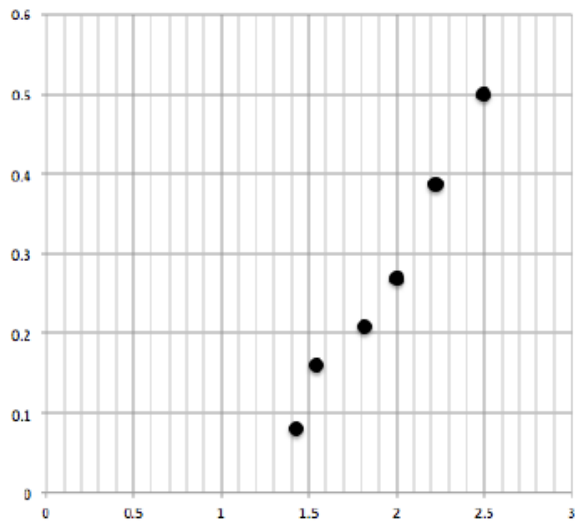
Limiting Resolution (MTF < 0.1)	
Line Pair per mm (lp/mm)	13
mm	1.45

120 kVp:

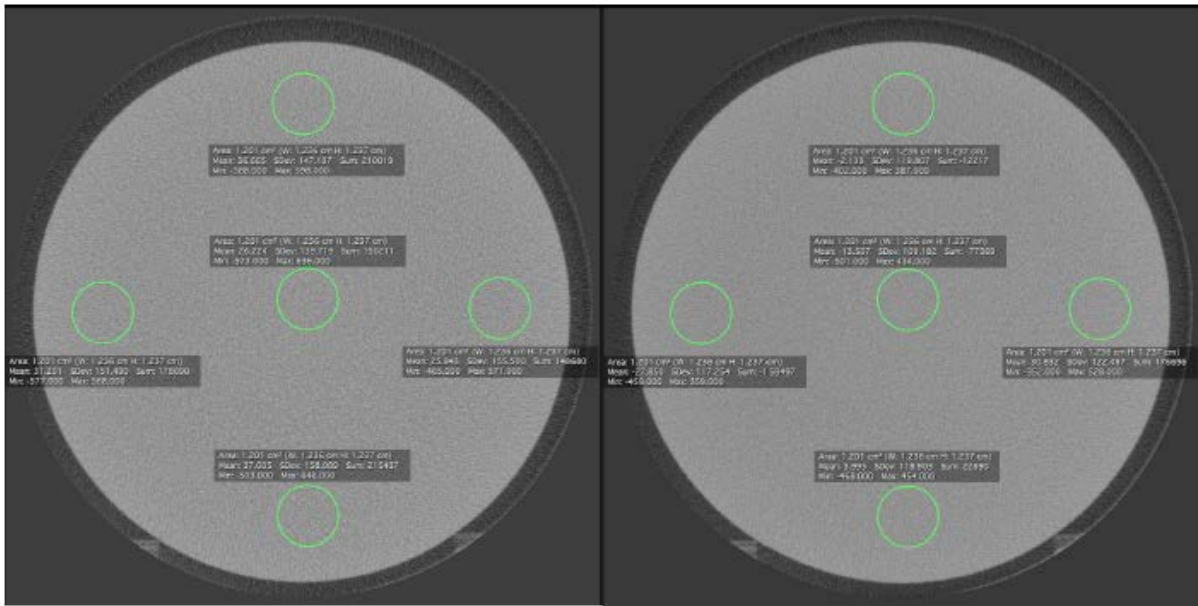| Limiting Resolution (MTF < 0.1)	
Line Pair per mm (lp/mm)	13
mm	1.45

Uniformity

Methodology

Uniformity was determined in the water-equivalent phantom. One center region of interest (ROI) is compared to 4 peripheral ROIs. Limits are determined by the manufacturer.
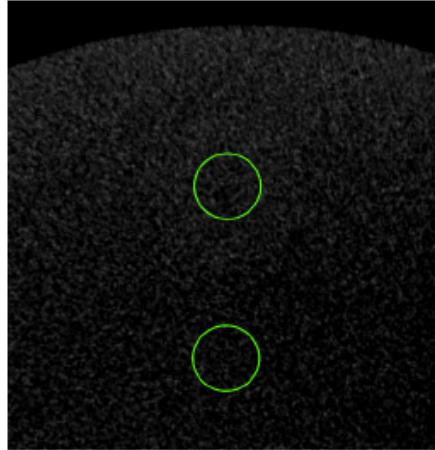
Results

Protocol	Maximum Center-Peripheral Deviation	Limit (set by manufacturer)
100 kVp	11.381	<100
120 kVp	44.339	<100

Noise and Low Contrast Resolution

Methodology

Low contrast resolution is defined for this unit based on the detection of an 18.26 mm nylon disk embedded in the background clear urethane. An ROI with an area of 77.76 mm^2 is used to take measurements in both the nylon and the urethane. The contrast to noise ratio (CNR) is defined by taking the difference of the CT number of the background material from the CT number of the nylon disk, then dividing that number by the standard deviation of the ROI of background material.

Results

Protocol	Standard Deviation	Limit (set by manufacturer)	CNR
100 kVp	135.139	TBD	0.52
120 kVp	105.674	TBD	0.71

CT Number Accuracy

Methodology

CT number accuracy was tested for this unit using the manufacturer's quality control phantom, which includes cylinders of 4 different materials – Teflon, acrylic, air, and low density polyethylene. LDPE. ROIs of 77.76 mm^2 were used to measure the CT numbers of these materials. These values were then compared to the expected values.

Results

Protocol	Material	Measured CT Number	Expected Value
100 kVp	Teflon	853.911	850 ±250
	Acrylic	147.624	75 ±125
	Water	26.224	0 ±150
	LDPE	-79.003	-150 ±100
	Air	-964.601	-100 ±200
120 kVp	Teflon	846.746	850 ±250
	Acrylic	95.671	75 ±125
	Water	-13.571	0 ±150
	LDPE	-124.957	-150 ±100
	Air	-1007.948	-100 ±200

CTDI Measurements

Methodology

A 16 cm acrylic CTDI phantom was placed in the center of the scanner. A 100 mm pencil ion chamber was used to measure exposure in the phantom. The edge measurement (1 cm from edge of phantom) with the highest exposure was used.

Results

100 kVp

CTDI Head Phantom (16-cm diameter PMMA phantom)	Measured	Calculated
kVp	100	
mA	5	
Exposure time per rotation (s)	16	
Source-to-Detector Distance (mm)	440.23	
Object-to-Detector Distance (mm)	118.99	
Beam Width at Isocenter (mm)	177.93	
Active Chamber length (mm)	100	
Chamber correction factor	1	
Center		
Average of above 6 measurements (mR)		369.3
CTDI at isocenter in phantom (mGy)		3.213
9 o'clock position (Highest extremity measurement)		
Average of above 6 measurements (mR)		405.00
CTDI at12 o'clock position in phantom (mGy)		3.524
CTDIw (mGy)		3.420
Clinical exam dose estimates (using measured CTDIw and site's 100 kVp Protocol from Table 1)		
CTDIvol (mGy)	=CTDIw*N*T/I	3.420

120 kVp

CTDI Head Phantom (16-cm diameter PMMA phantom)	Measured	Calculated
kVp	120	
mA	5	
Exposure time per rotation (s)	16	
Source-to-Detector Distance (mm)	440.23	
Object-to-Detector Distance (mm)	118.99	
Beam Width at Isocenter (mm)	177.93	
Active Chamber length (mm)	100	
Chamber correction factor	1	
Center		
Average of 6 measurements (mR)		663.9
CTDI at isocenter in phantom (mGy)		5.776
9 o'clock position (Highest extremity measurement)		
Average of 6 measurements (mR)		701.90
CTDI at12 o'clock position in phantom (mGy)		6.107
CTDIw (mGy)		5.997
Clinical exam dose estimates (using measured CTDIw and site's 120 kVp Protocol from Table 1)		
CTDIvol (mGy)	=CTDIw*N*T/I	5.997

Dose Area Product (DAP):

Results

The dose area product (DAP) was determined for the following protocols:

kVp	mA	Pulse Duration (seconds)	Number of Pulses per Scan	mAS	Slice Thickness (mm)	Number of Slices	Scan Diameter (cm)	Dose Area Product (mGy*cm²)
100	5	0.012	492	29.52	0.2	872	11.77	813.4
120	5	0.012	492	29.52	0.2	872	11.77	1247.6

Methodology

Dose measurements were taken at two positions in the beam. Measurements were taken at the center of the beam, where the dose was determined to be the highest. Four measurements were taken at each position. The average of the DAP found at each position is reported as the DAP for the protocol. An Unfors Xi R/F probe was used for these measurements.

The results from the measurements are as follows. The position of the measurement is indicated in the figure.
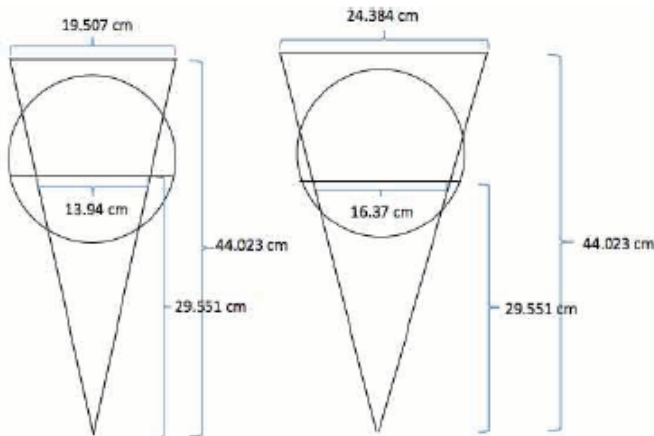
Hand Position	Protocol	
	100 kVp	120 kVp
Measurement 1 (mGy)	3.909	6.002
Measurement 2 (mGy)	3.907	5.996
Measurement 3 (mGy)	3.890	5.995
Measurement 4 (mGy)	3.870	5.984
Average	3.894	5.994
Beam area at point of measurement (cm²)	214.32	213.32
DAP (mGy*cm²)	834.6	1284.8
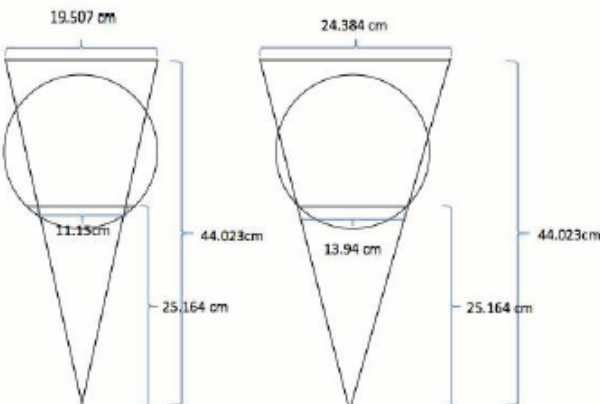
Elbow Position	Protocol	
	100 kVp	120 kVp
Measurement 1 (mGy)	5.090	7.746
Measurement 2 (mGy)	5.090	7.749
Measurement 3 (mGy)	5.106	7.749
Measurement 4 (mGy)	5.103	7.711
Average	5.097	7.739
Beam area at point of measurement (cm²)	155.42	156.42
DAP (mGy*cm²)	792.2	1210.5

Z-axis point spread function:

The InReach has a fixed and rigid patient positioning platform that does not incorporate any table motion or indexing (no "table pitch"). The detector panel has a square shape, while the pixels on the panels are square shaped as well. The raw projections are acquired in a single 360 degree orbit, thus covering the entire Field of View (FOV) height in one rotation. This results in isotropic voxels in the reconstructed volume, hence the same spatial resolution in the z-axis as in the x-y plane. Due to this projection geometry, calculation of a separate z-axis point spread function should not be applicable.

Recommended Operating Requirements:

Local agencies or government bodies or international standards may dictate requirements for installation of the system in order to protect personnel and the public from exposure from the radiological output of the device. Consult your local agencies, government bodies, or international standards for actual requirements which apply.

The device is not designed to be portable.

Visually inspect device before each use.

It is recommended that a qualified Physicist or Radiologist determine where appropriate, the applicable lead shielding to be installed in the area around the system equipment. Below are some other common requirements that may apply to your location:

- The Operations computer (server) and X-ray Operator should be located behind a properly shielded permanent barrier. A viewing window should be present to enable the X-ray Operator to view the Patient and operate the computer while the exposure is present.
- Operators should consider the use of a lead apron to protect the anatomical areas of the medical personnel working in the areas exposed to radiation.
- The Operator Control Box and Acquisition Computer shall be located within 1 meter [3.28 ft] from a door. If not, an interlocked door may be required.
- A room door may be required.
- Radiation warning signs may be required next to the entrance to the room.
- A Warning light may be required by the entrance to the room.
- A shielding plan should be performed where the system is being installed. Some local agencies or government bodies require that a shielding plan be conducted by a qualified Physicist or Radiologist and a copy of the shielding plan be submitted and approved prior to installation of the system.
- An area radiation survey by a qualified physicist or Radiologist may then be required within 30 days of initial clinical use of the system. This survey may be required to be submitted to the local agency or government body

Effective Dose to Patient Measurements (Micro Sieverts):

Scan area	Protocol	5-year old	10-year old	15+ (adult)	% dose reduction Lite - Standard
Hand-wrist	Standard	7.4	3.8	1.4	
Hand-wrist	Lite	4.6	2.4	0.9	56%
foot-ankle	Standard	16.9	8.9	5.7	
foot-ankle	Lite	9.1	5.1	3.5	65%
two-hand	Standard	7.6	4.2	1.8	
foot	Standard	11.5	6.3	4.1	
wrist-centered volume	Standard	16.7	7.9	2.2	

Hand-Wrist and Foot-Ankle Dosimetry of InReach CBCT Extremity Imaging Unit

John Ludlow, DDS, MS, FDS RCSEd

Methods:

X-Ray unit - CBCT dosimetry was performed on a pre-production CBCT unit (InReach, CurveBeam Inc., Warrington, PA). The X-Ray unit incorporates a 25x20cm amorphous silicon flat panel detector with a pixel size of 0.127mm, easily capable of providing a 0.2mm isotropic voxel size upon volumetric reconstruction of data captured in 2x2 binning mode (Varian Medical Systems, Palo Alto, CA). The unit uses a pyramidal beam and field of view offset to acquire basis images. A complete set of exposures consisting of 11 warm-up frames and 481 projection frames are exposed in a 360-degree orbit using a 0.012 second pulse length. A standard exposure protocol uses 120 kVp while a reduced dose "Lite" protocol utilizes 100 kVp.

Hand-Wrist Phantom - The hand-wrist phantom, made from natural human bones of an average adult and covered with tissue equivalent material, simulates a pronated orientation (The Phantom Laboratory, Model XA231P). This was modified by slicing the forearm/wrist region into five 25mm axial sections with the remaining finger section making a total of six sections. Sectioning permitted placement of dosimeter slots within tissues of interest throughout the phantom.

Foot-ankle phantom - An anthropomorphic phantom was constructed using the lower leg, ankle, and foot bones of a human skeleton, which was embedded in a radiologically soft-tissue-equivalent material approximating the form of the lower adult extremity (The Phantom Laboratory, Salem, NY). The foot and ankle portion of the phantom was fabricated in 25 mm horizontally sliced layers allowing separation and specific localization of dosimeters within each layer (Figure 2). Slots were drilled in the surface of the layers to accommodate placement of dosimeters within tissues. Additional dosimeters were placed in surface areas to measure skin dose.

Dosimetry - Optically stimulated luminescent dosimeters (OSL) (Nanodot, Landauer, Inc., Glenwood, IL) were used for dosimetry in this project.

X-Ray Beam Path for InReach

1.925
[48.90mm]

9.600
[243.84mm]

7.005
[177.93mm]

99%
HAND

℄ OF PANNEL

℄ OF BEAM

X-RAY SOURCE

OD 8.000
[203.20mm]

This is half fan area

ID 7.750
[196.85mm]

7.680
[195.07mm]

Ø6.475
[164.48mm]

Ø4.440
[112.76mm]

℄ OF BEAM

℄ OF PANNEL

FRONT VIEW

17.332
[440.23mm]

12.647
[321.24mm]

4.685
[118.99mm]

0.750
[19.05mm]
OFFSET
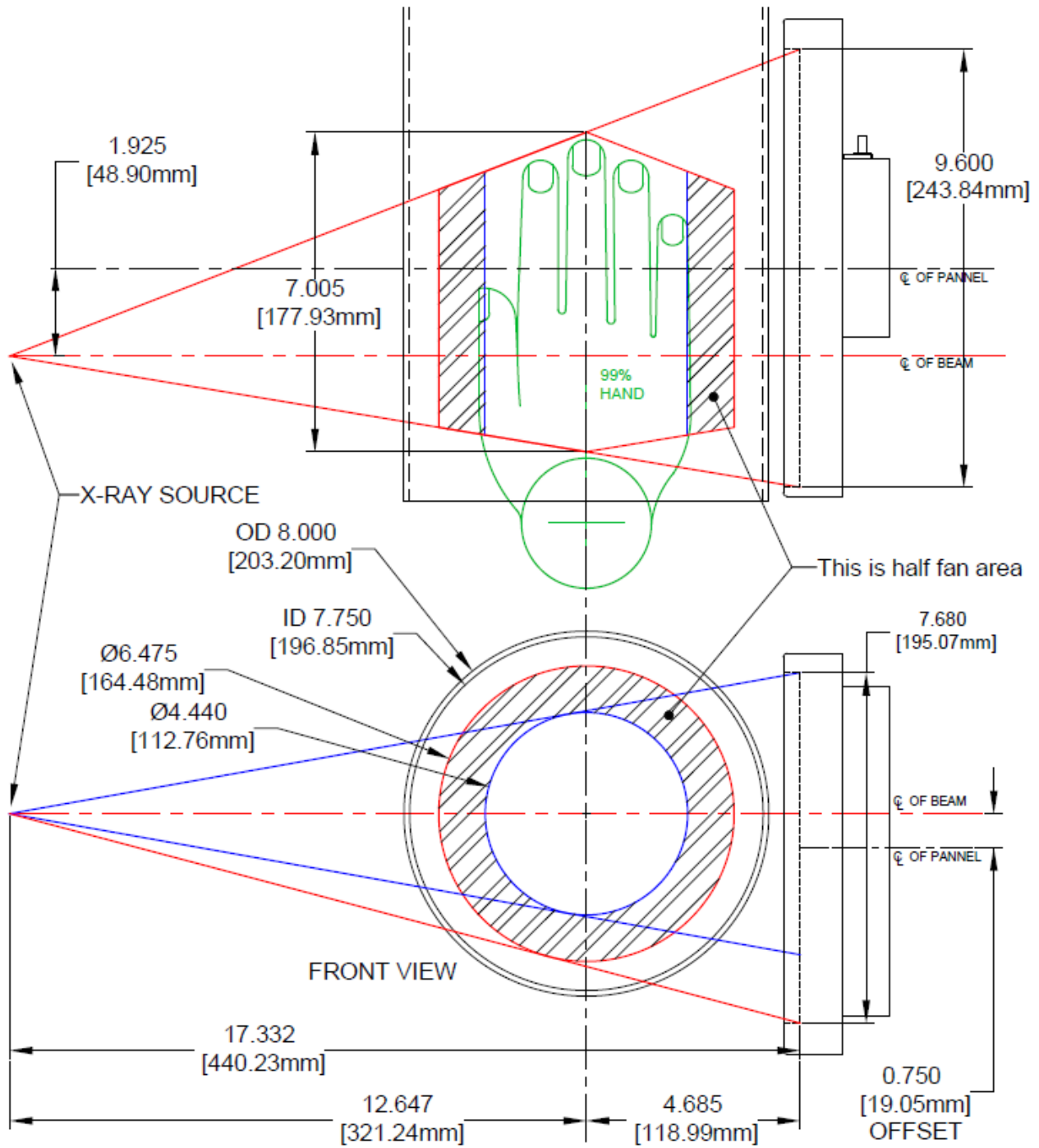
Site Survey Available by request.

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X-ray Tube Assembly:

CurveBeam utilizes an X-ray Tube, model SXR 130-20-0.5, from Superior X-ray Tube Co, 1220 Claussen Drive, Woodstock, IL 60098. Below are the X-ray Tube Specifications:

Superior X-ray Data for the SXR 130-20-0.5:

SXR 130-20-0.5
The SXR 130-20-0.5 insert is a stationary anode, glass envelope x-ray tube. The SXR 130-20-0.5 is an x-ray tube originally designed for use in dental CBCT* applications. The insert should be housed in a unit that allows for insulating media such as high dielectric mineral oil (Diala-AX) or high dielectric pressurized gas such as SFo (Sulfur Hexafluoride).
Cone Beam Computerized Tomography
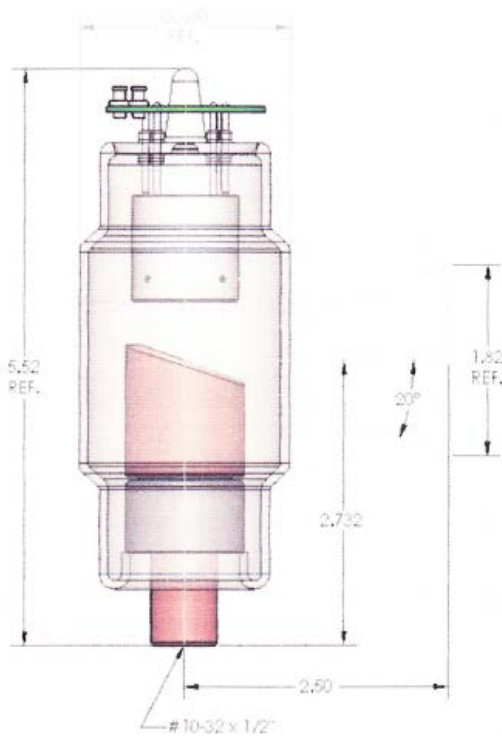
SXR 130-20-0.5 Outline Drawing

Physical Characteristics:

Glass Frame:	Borosilicate 0.085 thick:
Inherent Filtration:	1.1 mm Al equivalent at 80 kV
Focal spot:	0.5 mm Nominal
Target Angle:	20°
Target Material:	Tungsten
Filament Material:	Tungsten
Focus Cup Material:	Nickel
Anode Body:	Copper

Thermal Characteristics:

Anode Heat Storage Capacity:	30 KHU's (21KJ)
Max Anode Heat Dissipation Rate:	17.9 KHU's/min.
Duty Cycle:	1:20

Electrical Characteristics:

Max. Tube Potential:	130 kV
Filament V-A Curve:	See Chart
Max. Power:	See Chart
Max Single exposure	See Chart
Max. Continuous Exp.	1.8 mA

NOTE: * P/ease contact Superior Engineering Department for cathode terminations options.

Anode Heating & Cooling Curves
SXR 130-20-0.5 Insert

Maximum Single Exposure Rating
Constant Potential
No More Than 15% Residual Heat in Anode
Nominal Focal Spot Size: 0.5 mm
Target Angle 20°

Filament & Emission Characteristics
SXR 130-20-0.5
0.5 Nominal Focal Spot

Maximum Single Exposure Rating
Single Phase Full-Wave Rectified
No More Than 15% Residual Heat in Anode
Nominal Focal Spot Size: 0.5 mm
Target Angle 20°

Beam Path and Angulation:

TOP VIEW

SIDE VIEW
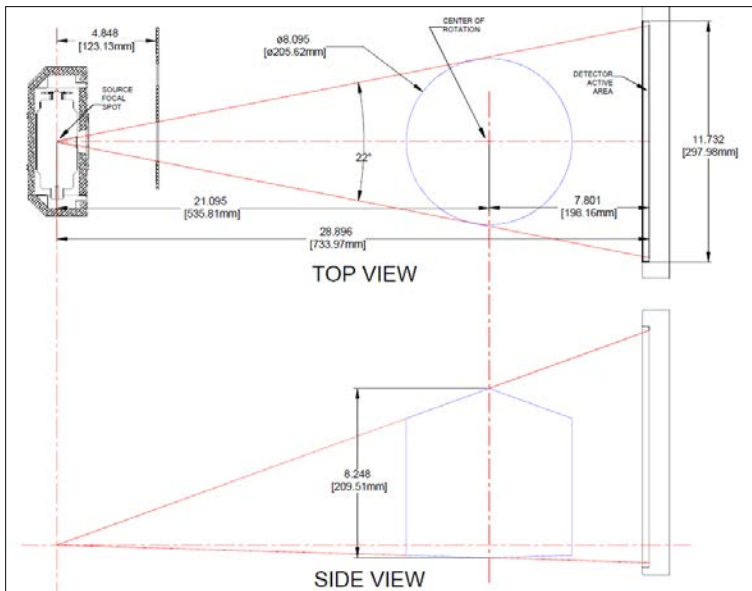
CHAPTER 6: Operations - Acquiring a Scan

ACQUIRING A SCAN

System Startup:

The InReach system at a minimum includes the Scanning device, the computer server, and an Operator's control Terminal. All must be powered **ON** in order for the system to operate properly.

The Scanning device circuit breaker should always be set to the ON position. This is located in the back of the machine. This is the machine ON/OFF control. The vertical line is the ON position. The 0 is the OFF position. The image below shows the scanner in the ON position:

Power ON is indicated on both the Machine Status Indicator panel and the Operators control box Status indicator panel lights. Power ON is lit in **Green**. **The machine must be ON for 30 seconds before the Acquisition Software should be launched. Optimal Scanning results will be achieved with the machine warmed up for 2 hours.**

The scanning software is accessed via the Quality Control Workstation (QCW) and can be viewed on the DELL tower as well.

Start up the Acquisition software by double clicking on the CB-Scanner Shortcut. An "About Screen" will appear which displays the software version number and details. Or, the following About screen can always be accessed from the Acquisition software's "About" button.

Once the acquisition software is launched, a system "Startup" window (also referred to as the "Initialization" window) will display indicating if various parts of the system are functioning properly or not. When the row has two dark buttons, that item is still awaiting a status and will eventually change the color from either the dark green to bright green or from dark red to bright red. The bright red buttons can indicate the functionality is still undergoing the startup test, so until it has successfully passed this testing, it will be illuminated bright red. The screen below shows the startup screen with some red lights while those parts of the scanner are still going through the startup testing:

If one of more of these functions illuminates bright red, and remains bright red, it indicates a failure, please contact CurveBeam Technical Support if a light REMAINS on.

All Startup lights should be illuminated bright green once diagnostics have been completed successfully. If Startup was successful, the Startup window will close on its own, and the software will automatically display the Patient Worklist Window.

After the startup diagnostics have completed, the following screen will appear:
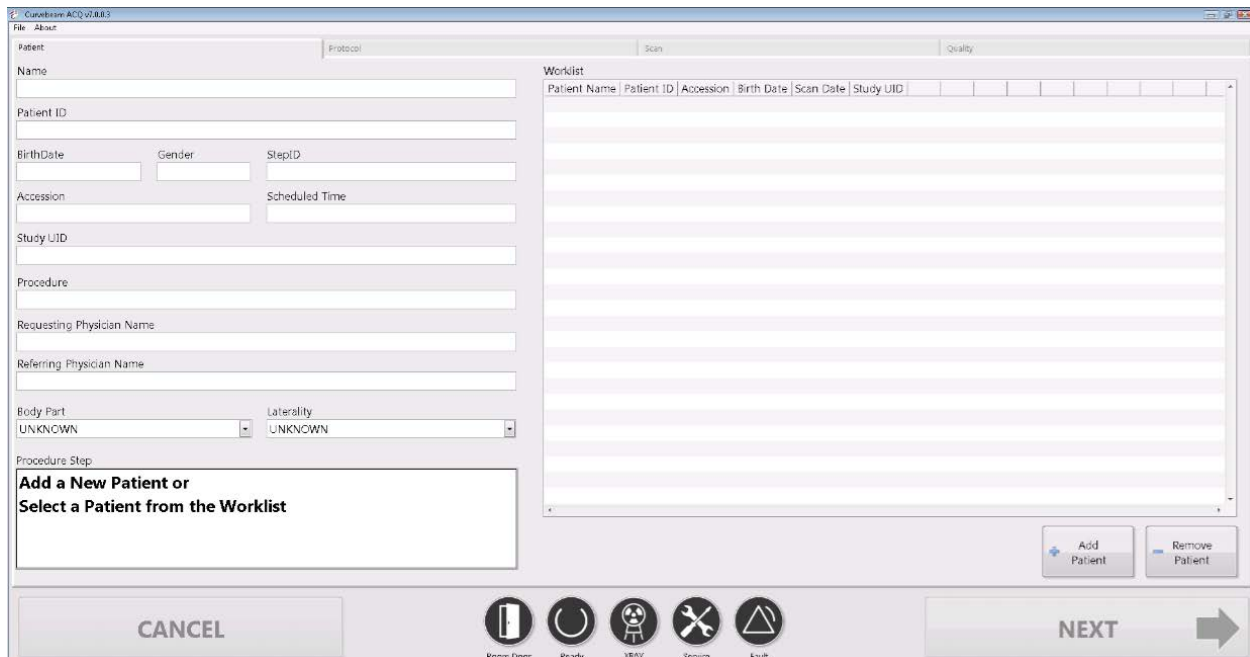
InReach Acquisition Software Interface:

The InReach Acquisition Software, "CB Scanning Device" Interface consists of the below sections, each with its own tab near the top of the screen:
- Patient: Access or Add New patient information.
- Protocol: Select the intended protocol to use.
- Scan: Position Patient and Perform Scan Acquisition.
- Quality: Perform a QA (Quality Assurance) check of the scan acquired.

PATIENT TAB: Accessing/Entering Patient Information:

Patient Demographic Information can be either imported into the system via a Worklist or can be Added as a "New Patient" via the InReach ACQ software Patient Tab when "Add Patient" is selected.

To add a patient's scan to the Worklist, select the "Add Patient" button at the bottom of the screen. If a procedure is added by mistake or needs to be removed, highlight the entry in the worklist and select the "Remove Patient" button at the bottom and the patients scan will be removed from the list.

When the "Add Patient" button is selected, the following pop up box will appear:

On the Add Patient Procedure window, the minimal patient information that MUST be entered is **Patient ID, Patient Name and Procedure To Add. The ID# MUST be unique to this patient**. The other items are optional. The Accession Number field can be manually entered, or if left blank one will be auto generated. After all the required fields are entered and any optional fields

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as well, select the "Add Patient" button to add the patient to the Worklist. The previous patient entered, during this time that the software is open, will still populate the fields in this Add Patient box. Use the Clear Patient Data button to clear all the fields to enter in a brand new patient. If the "unknown" procedure is used, the Body Part and Laterality will need to be selected prior to the scan, when the patient is selected to be scanned.

To select the patient for the scan, highlight the patient's entry in the Worklist. The patient's information that was entered will appear to the left of the worklist as shown below, the patient to scan is highlighted in blue:
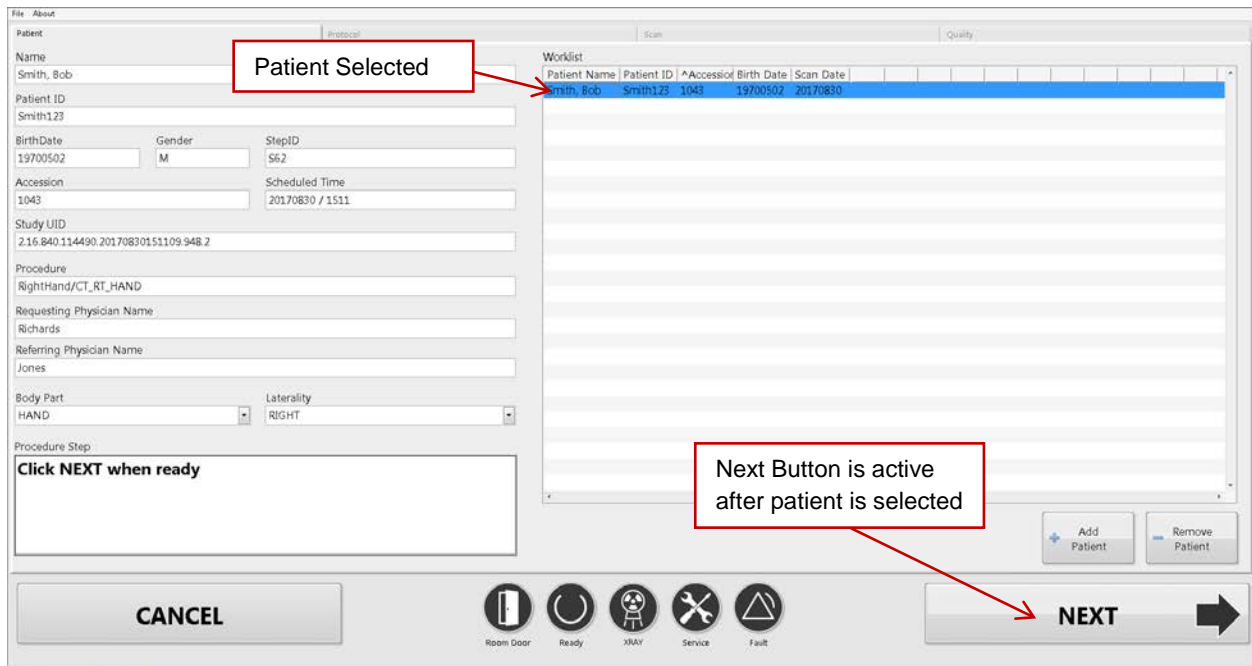
Once the patient has been selected, click on "Next" to move to the Protocol tab. The "Next" button remains grayed out until the patient has been selected.

If the Body Part and Laterality fields are listed as Unknown, they will need to be changed, via the pulldown, to a valid Body Part and Laterality. These values are filled in automatically when entering a scan, other than "unknown" from within InReach. If however, the worklist entry is imported from another source, there is a potential for an Unknown value. In this instance, the values would need to be populated with a valid Body Part and Laterality. Without a valid Body Part and Laterality, the "Next" button will not be selectable.
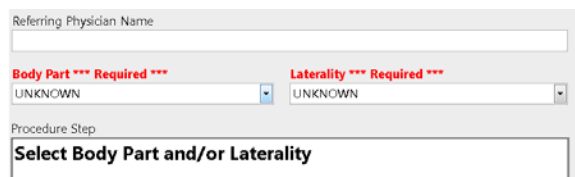
PROTOCOL TAB: Setting up to Perform the Scan:

On the Protocol Tab, the protocol used to take the scan will be set, patient orientation will be selected, and other scan specific information will be entered. The following is the Protocol screen:

A protocol is required to be selected from the Protocol Selection section in the top center of the screen.

RECOMMENDATIONS for Selecting a Protocol:

There are 2 Protocols to select from:

Standard (120 kVp):
Select this option if the patient size is normal-large, weight of 101-400lbs, and if you need to capture a denser portion of the body.

Lite Dose (100 kVp):
Select this option if the patient size is small, weight of 50-100lbs.

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Once the Protocol is highlighted, the default values for the Protocol Code, Protocol Settings, and Series Description will be populated. Select the appropriate Patient Orientation from the top right of the screen. The options are changed by clicking on the Up or Down arrows to the right of the image as shown below:
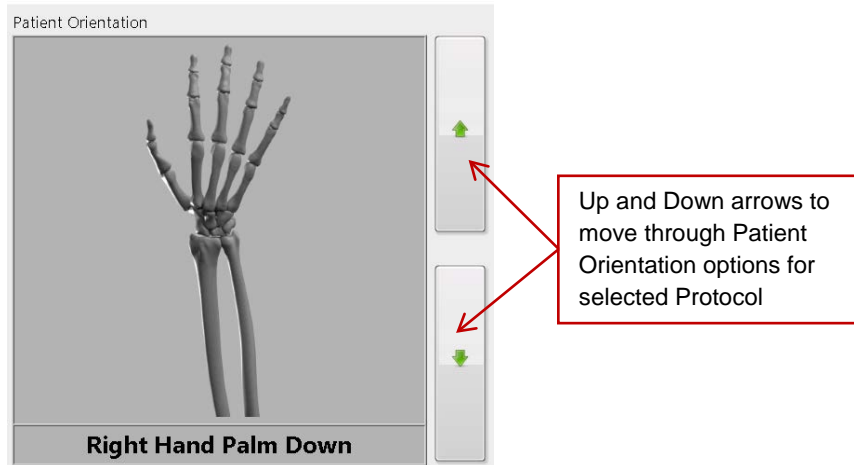
Once the Patient Orientation is selected, the Series Description can be selected. There is a list of Series Descriptions already in place, these can be used as is, edited, or the user can create a brand new Series Description. This field is optional.
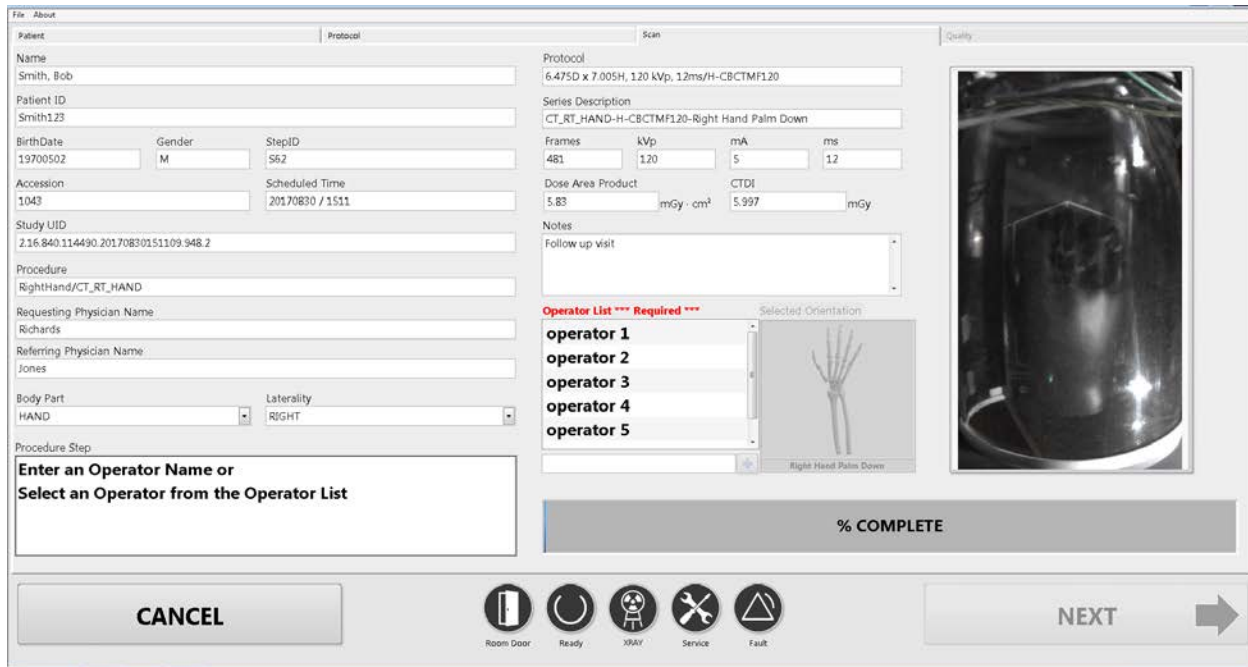
Also available for any text is the Notes field. This field is also optional.

The "Next" button will become non-gray and selectable, once a Protocol has been chosen.

Click "Next" when the protocol is correct for the patient being scanned, and any optional values and patient orientation are also selected. This will open the Scan tab.

SCAN TAB: Position Patient and Performing the Acquisition:

The Acquisition will be performed via the "Scan" Tab. The Scan Tab will display the current selected Patient Name and Procedure, as well as User Instructions and Information as to the status of what the software and scanner are doing. The Scan Tab will appear as follows:

Follow the instructions as stated in the Procedure Step box. These include selecting an Operator. One can be selected from the list or added in below the list. To add a new Operator to the Operator List, just enter in the field below the list and click on the "+" to the right of the new name. The Operator will then be selectable for future scans. To remove an Operator from the list, right click on the Operator Name, from in the list, then select Remove.

Once the Operator is selected, the patient needs to be positioned in the scanner. Position the desired anatomy in the scanner. Utilize the camera image in the top right to assist with positioning the patient.

Patient Positioning:

Line the bore and platform (platform only if using) with transparent Medical Barrier Film. CurveBeam tested brand: Clear Barrier Film – Low tack-adhesive (Palmero #1866C).

Have the patient put on FDA cleared medical gloves if their hand will go beyond the center bore.

Ensure machine is stable (wheels are locked, machine can not be moved) and wall strap is in place.

Raise or lower the InReach scanner to a height that is comfortable for the patient. They can sit or stand, as long as they are able to remain still during the full duration of the scan.

The patient should be instructed to step up next to the machine and position the appropriate anatomy in to the scanner. If needed, the chair can be utilized for patient stability.

Hand or Wrist Scans
For the hand or wrist, place the Hand and Wrist Platform in the scanner. The platform for the hand and wrist has positioning lines on it as shown below:

Front of Machine. Patient stands or sits here.

Dotted line is center of FOV expected in the scan.

Finger tips should remain within lines to capture in scan.
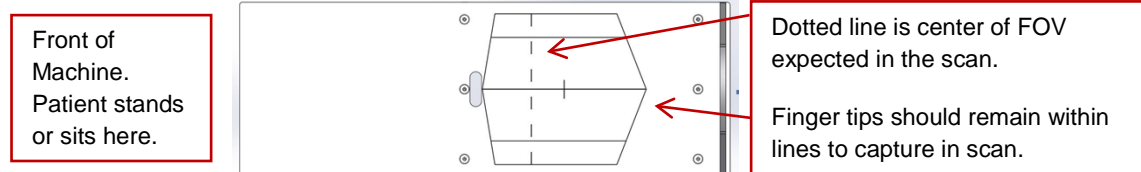
To include the finger tips in the scan, ensure that they are within the solid line. The center of the Field of View (FOV) is the dotted line, therefore if the wrist is being scanned, the wrist should be directly over the dotted line.

Hand or Wrist Scans – Small Patients
For small patients it is imperitive that the hand and arm are only inserted into the machine just to get the area to be scanned. Ensure the arm is not fully into the machine beyond the anatomy of interest, to reduce unnecessary exposure. Also ensure the shielding is fully wrapped around their arm.

Elbow Scans
For the elbow, place the Elbow Platform in the scanner. Align the elbow in the scanner so that the anatomy desired is on the dotted line. The hand may extend beyond the back of the machine, if so, it is advisable to have the patient wear medical gloves.

Elbow Scans – Small Patients
For small patients it is imperitive that the arm is only inserted into the machine just enough to get the area to be scanned. Ensure the arm is not fully into the machine beyond the anatomy of interest, to reduce unnecessary exposure. Also ensure the shielding is fully wrapped around their arm.

Foot, Ankle, or Knee Scans
For the foot, ankle, or knee scans, ensure the patient is seated. Lower the machine to a comfortable height. There is no platform used for these scans.

Have the patient place their foot or knee in the scanner. Keeping in mind that the anatomy scanned is that closer to the opening where the patient is sitting.

Foot, Ankle, or Knee Scans – Small Patients
For small patients it is imperitive that the foot and leg are only inserted into the machine just enough to get the area to be scanned. Ensure the foot or leg is not fully into the machine beyond the anatomy of interest, to reduce unnecessary exposure. Also ensure the shielding is fully wrapped around their leg.

For ALL Scans - Ensure the Shielding Curtain is properly attached the to machine and covers the opening around the patients arm or leg.

Patient Instructions for a Scan:

Once the patient is properly positioned in the system, the operator should instruct the patient to **hold perfectly still for the duration of the scan**. It is very important for the patient to hold still. If the patient moves during the volume scans, the results may not be optimal. Data is being captured when the alarm is audible (and x-ray light is ON).

Instruct the patients as to where the Patient Emergency Stop is and instruct them that they may press it if there is any type of emergency in which they feel the need to be removed from the scanner.

Once the patient is properly position, click on the "Start" button to start the scan.

⚠️ **WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure.

The Scan Button to start the exposure is mounted on the Operator control box.

Operator Control Box

Status Indicator Lights:

For Power ON, Exposure Ready, Exposure ON, Fault.

Exposure Control:

Scan Button for initiating the scan. Must be held down for the duration of the capture.

The duration of the exposure will be indicated by an audible signal generated by the workstation and machine, as well as visual X-ray ON lights

Emergency Stop Button

Press down if the exposure needs to be stopped. This will seize exposure, and motors. The button will also illuminate.

To Reset the button, turn it to the right so it pops out.

Deliver the Patient Scan Instructions to the patient.

Now Push & Hold the scan button down. During exposure an audible signal is generated by the machine, and the visual X-ray ON indicator lights will be illuminated in Amber color. The visual X-ray ON indicators are on the machine, the operator control box (above) and in the InReach Acquisition "CB Scanning Device" software. The Operator should hold the exposure switch for the duration of the exposure as indicated by sound and lights.

When the audible buzzer and "X-ray on" light turn off, it is OK to release the exposure switch.

✓ NOTE: If there is any indication of vibration to the system, or malfunction to the system, or computer crash during a scan, please contact CurveBeam Technical Support for assistance. If there is a failed procedure, turn the machine off by the Emergency Stop button, following the below procedure.

✓ NOTE: If you release the exposure switch before the exposure time has completed, the system will STOP exposing, however the gantry and motors will complete their sequence. If the button is released prematurely, the buzzer and indicator lights will turn off and the Error message below will display on screen:

Scan Button Released During Scan

ERROR: Scan Button Released During Scan

OK
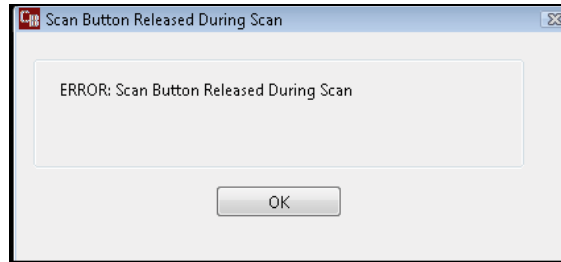
Emergency Stop: In the event of an emergency during a procedure, the Operator or Patient should utilize one of the 2 the designated Emergency Stop buttons to turn off the power to the X-ray and all moving parts in order for the Patient to be safely removed from the machine. There is an Operator E-stop button on the Operator Control Box and there is a Patient E-Stop button. The Emergency Stop(s) when activated will remove ALL power from the machine.

Once the capture is complete, the patient can now safely EXIT the machine.

When the "Next" button becomes visible, click on it to move to the Quality Tab.

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QUALITY TAB: Perform a Quality Assurance check of the scan acquired:

Once on the Quality screen, wait for all of the QA images to be present, the Output Series Status will change from Working to Done. The Quality Tab will look similar to the following:
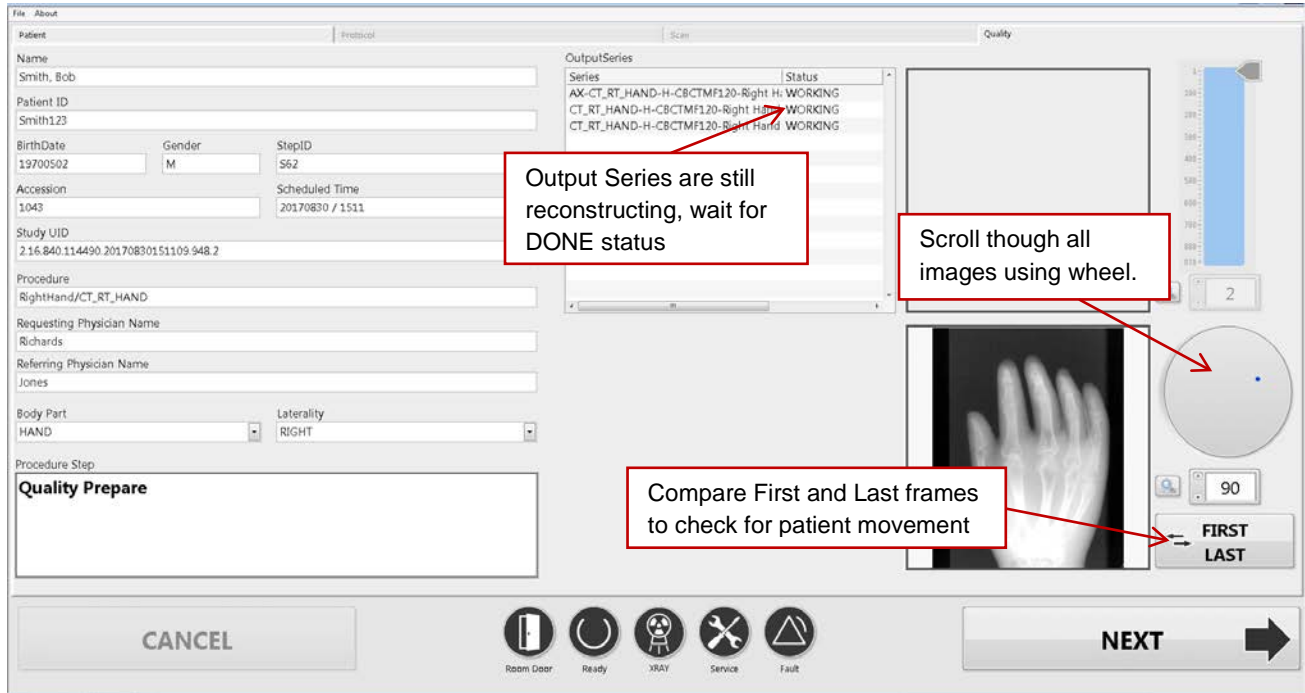
While waiting for the image to finish processing, check for movement of the patient during the scan, compare the first and last frames by using the "First/Last" button. View all images as they were acquired by using the circle slider to the right of the raw frames (above the First Last button) or typing in a number to directly view that single frame.

Once the processing is completed, the screen will display the Axial slices. Scroll through them using the slider bar to the right of them.
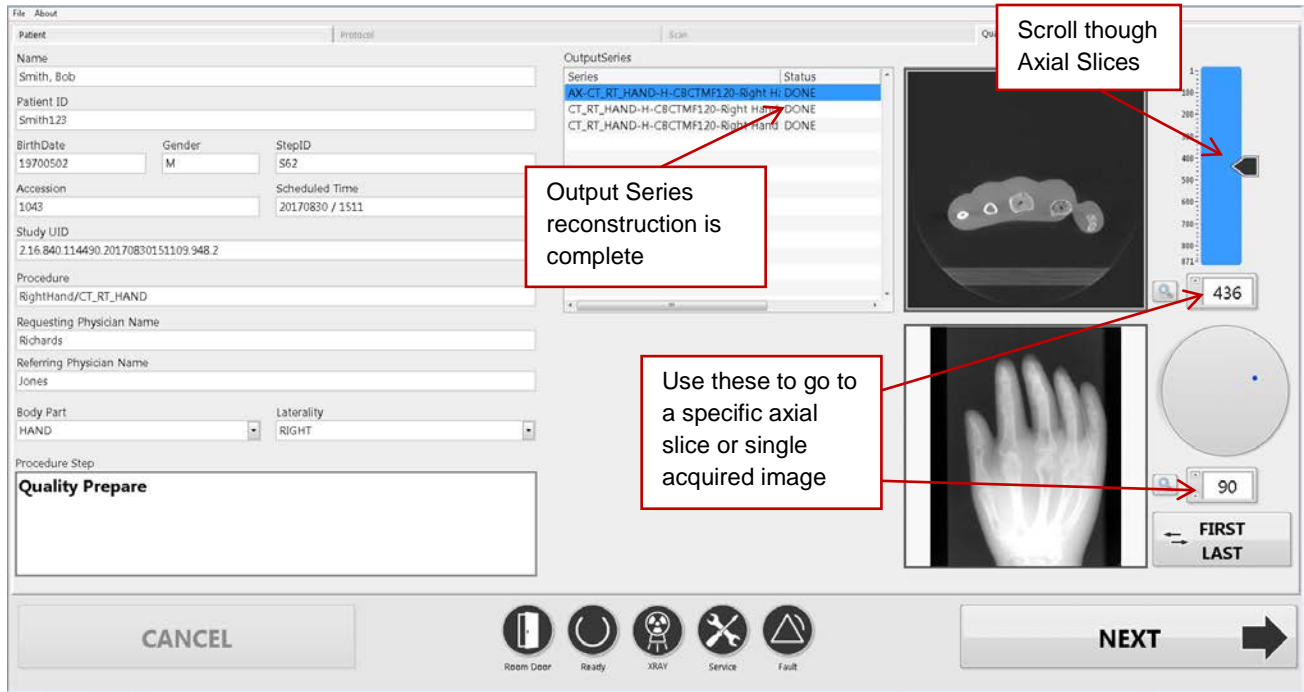
Once certain the image looks like the anatomy desired was captured properly, click on the Next button. The Acquisition process is completed.

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Procedure for Emergency Removal of a Patient:

The system has undergone extensive testing of the mechanically, electrically and software performance, but if an unexpected occurrence is observed and/or the software locks up during a scan or an emergency arises where it becomes necessary to interrupt a scan and/or remove a patient from the system before a scan is completed, please follow these steps:

1. Press the EMERGENCY STOP button. This will halt the X-ray as well as the motors to the machine functions and all power to the machine. The message below will display on screen and will terminate the "CB Scanning Device" Acquisition software:

2. Carefully assist the patient to remove their arm or leg out of the scan platform area.

3. Reset the machine: Close the InReach Acquisition, "CB Scanning Device" software (if not already). Release the E-stop that was engaged by pressing in and turning the knob to the right until it pops up. Then turn the machine power back ON at the Main Circuit Breaker. Wait 2 minutes, then re-launch the InReach Acquisition "CB Scanning Device" software. Now the system can be operated again as expected.

CHAPTER 7: Using the Viewing Software: CubeVue

Now that the data is acquired, it can be reviewed and post processed within the viewing software, CubeVue.

CubeVue can be accessed by the Viewing Terminal, MD workstation, or any computer that is connected to the InReach server via the facility network and has CubeVue software installed. Log into the Viewing Terminal, MD Workstation computer or any other workstation.

Then, to launch CubeVue, click on the CubeVue icon.   The "About" Screen will appear showing software version & details. This can also be accessed by selecting *Settings/About.*
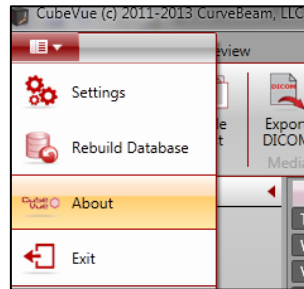
The CubeVue software has the following components to it:
- Patient List: for accessing, importing & exporting patient datasets.
- Review: for reviewing and processing the patient datasets.

PATIENT LIST:

When CubeVue is launched, the "Patient List" will display the list of patients with their datasets for the user to load. The volume datasets will display as Raw or Reconstructed. The Raw data sets are listed with the description of "RAW", the Reconstructed data sets are listed with the description being the protocol for which the scan was acquired.

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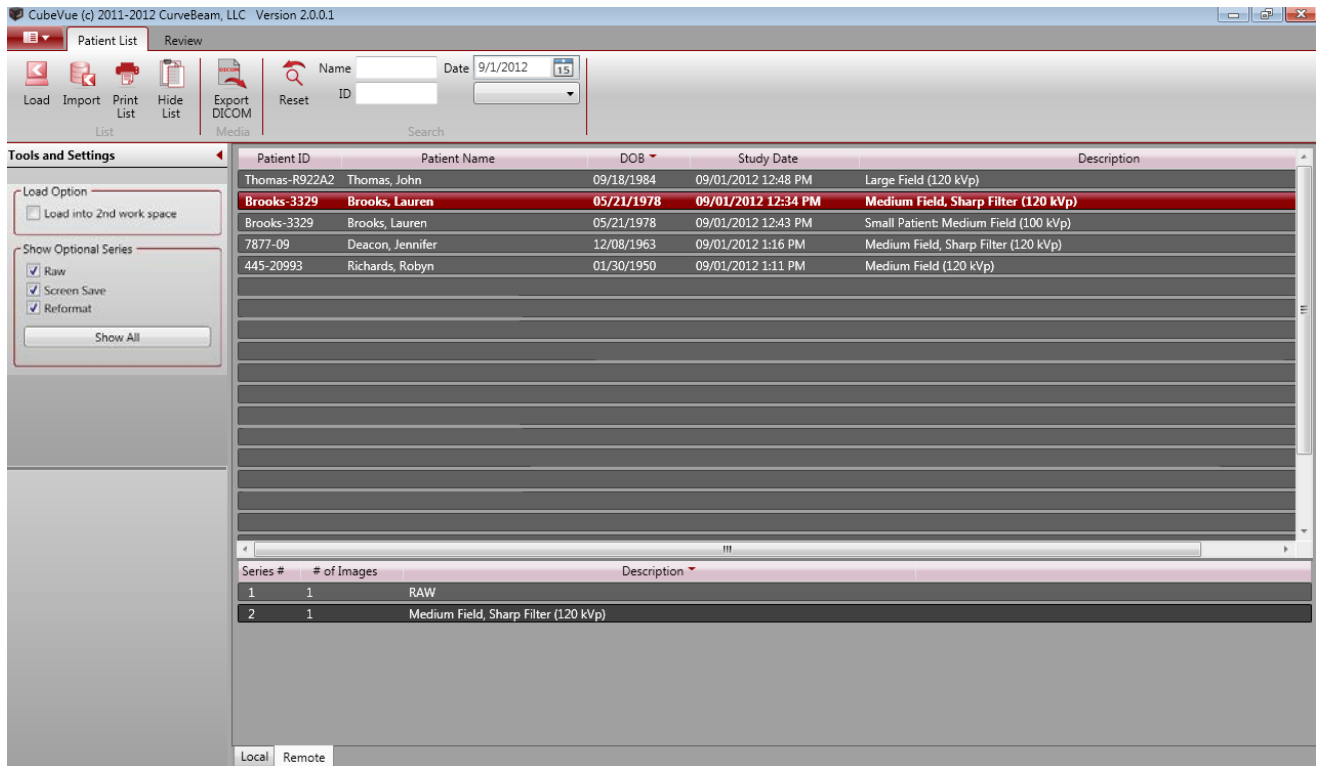
After selecting the patient name from the list at the top, then select which type of scan to view. The Show Optional Series allow the list to be expanded to show all types of scans, or limited to only show the scans that are checked. Typically the Reconstructed study will be the type of scan to select for viewing the dataset. Once the scan is selected, the Review Tab will be active.

If the patient that needs to be viewed does not exist in the patient list, it can be imported from an external location. The scan must have been taken using a InReach scanner in order to import

the patient scan. To Import a study from a InReach, select the Import Icon:

Once selected, a prompt will appear asking for DICOM Study or Raw File. DICOM Study would be the option to choose to navigate to the location of the study to import.
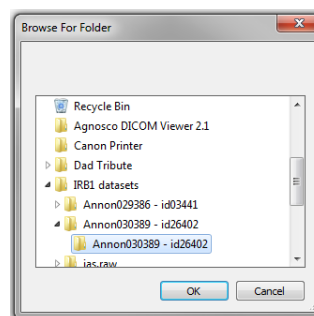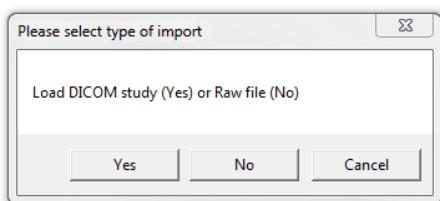
An Imported Study will reside in the "Local" Tab.
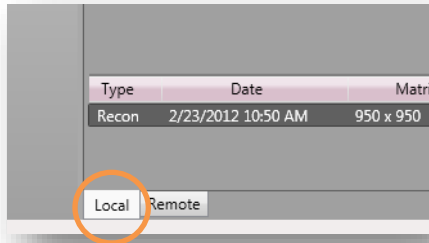
CubeVue allows for the user to have more than on scan loaded at the same time. This can be useful when comparing two scans done on the same person, a progression or a before and after type scenario. This is accomplished by first loading up a single scan. Then, from the Patient List tab (at the top), click first on "Load into 2nd work space" and then select the second series (scan) to open from the patient list.
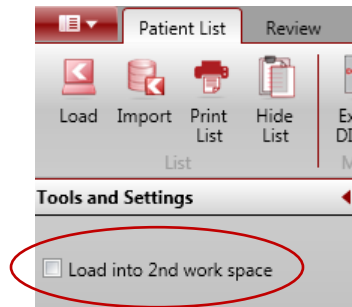
Using the Series Layout tools: the user can select which way to view the images, either both of the scans in a vertical mode (select 2x1) or a horizontal mode (select 1x2). The limit to the number of scans that can be opened at once is just two scans. To remove the scan and load a different second scan, close the series to be unloaded and then return to the Patient List. Repeat the steps above to load a different series into the 2nd workspace.

Conversely, if the patient's DICOM data needs to be sent to another location, the user can

Export the DICOM data. To do this, select the Export DICOM icon:

Once selected, the user can Browse and select the location to export the DICOM data.

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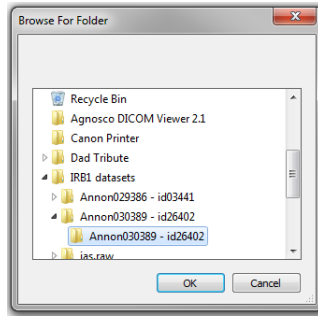
To put the study on a CD, have a CD in the drive and then navigate to the CD drive as the destination folder for the Export DICOM. This will then place the DICOM data on the CD using the Windows Burning Software program.
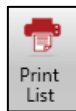
To print the patient list, select the icon:

There is a button that will allow the user to hide and unhide the Patient List. To do this, select the icon:
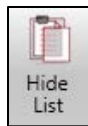
After 10 minutes of inactivity, the Patient List will be hidden for privacy purposes. In either case, when the list is purposely hidden or hidden after the 10 minutes, to unhide the Patient List, click on the Hide List icon to unhide the list.

It is possible to view only a subset of the entire Patient List. This can be helpful when a portion of their name or ID is known, or when trying to locate a patient that was scanned today, on a known date, or within the last few days.

To locate a patient in the list using a partial (or full) name or ID, start to type in the "Name" or "ID" fields. As information is typed in, the Patient List will start to decrease as only the patients that match the criteria entered are displayed. To do this, select the pulldown shown below to select a number of days since the scan was acquired.

Select a specific date of the scan

Use to select number of days since scan
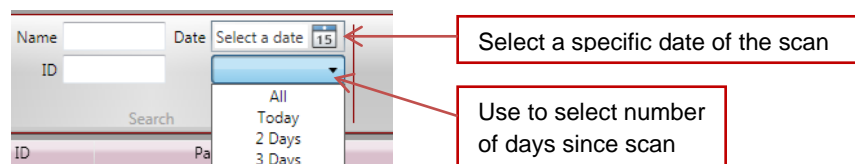
Additionally, typing in a partial name or partial ID will display all the scans listed with the matching Name or ID as a part of the patient's information. Or, a specific date can be selected and all scans acquired on that date will be displayed. To select a specific date, click on the calendar next to "Select a date" in the image above.

REVIEW TAB:

Once the patient scan is selected from the Patient List, the scan will open in the Review Tab.

When the user opens a scan, there is a pop up box to select which anatomy is represented in the scan and appears as follows:
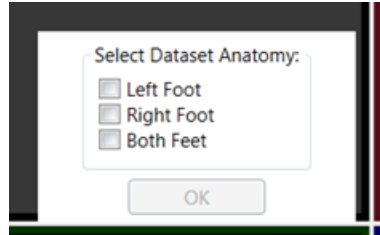
Select the appropriate check box that matches the anatomy represented in the dataset.

The Review Tab consists of 4 different Screens for viewing and processing data and a Main Menu Bar. The Tabs along the bottom are:
Combined 3D/MPR: contains a 3D rendering of the scan plus multiplanar reconstructed slices.
3D: contains the 3D rendering of the scan only.
MPR: contains the multiplanar reconstructed slices only.
Auto Built: contains the standard x-ray views.
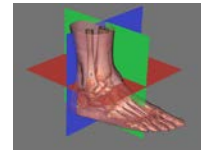
Each "Plane" is color coded with Red, Green or Blue.

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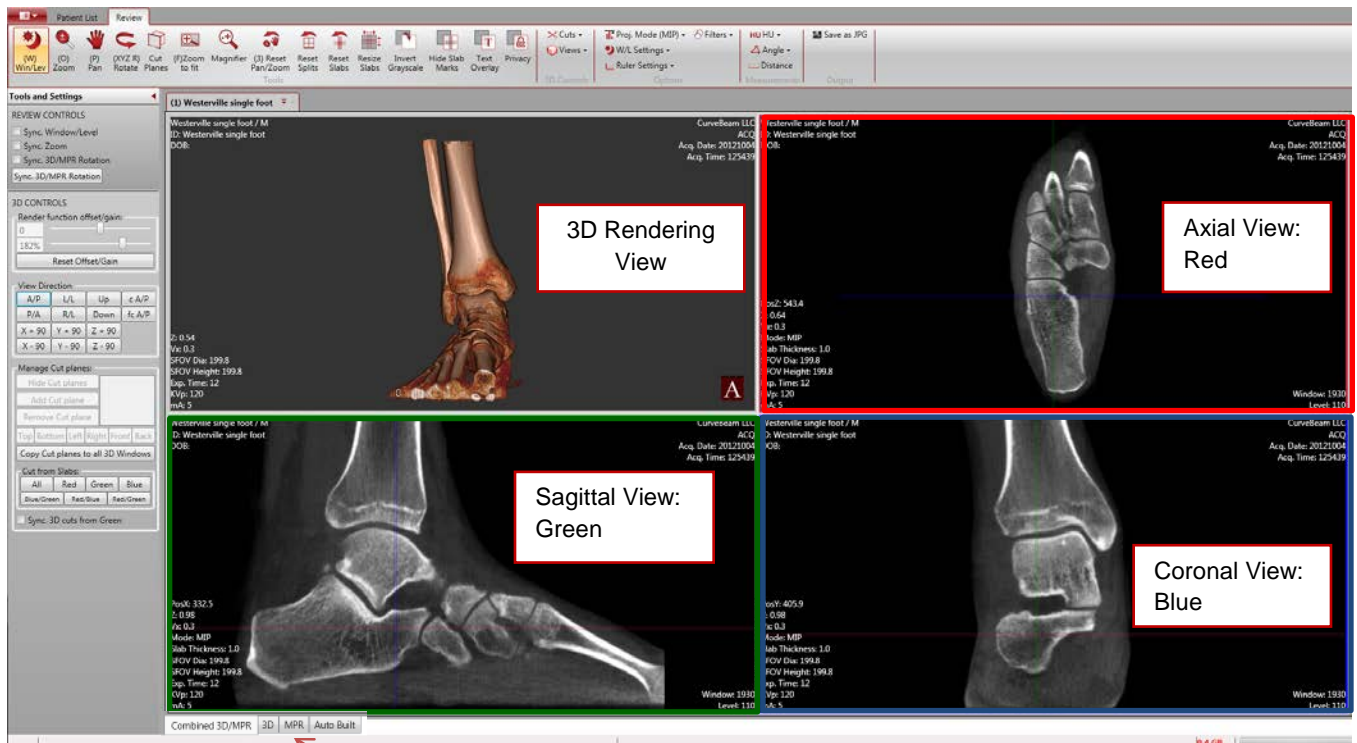
The Review Main Menu Bar (Ribbon):
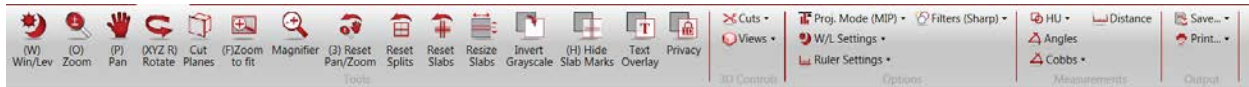
Review Tab layouts.

MPR stands for Multiplanar Reconstruction. There are 3 views that are associated with MPR images. These views hold true for both the Combined 3D/MPR and the MPR Tabs: Axial, Coronal, Sagittal. Utilize the colored Slice Indicator Lines to know the slice locations.
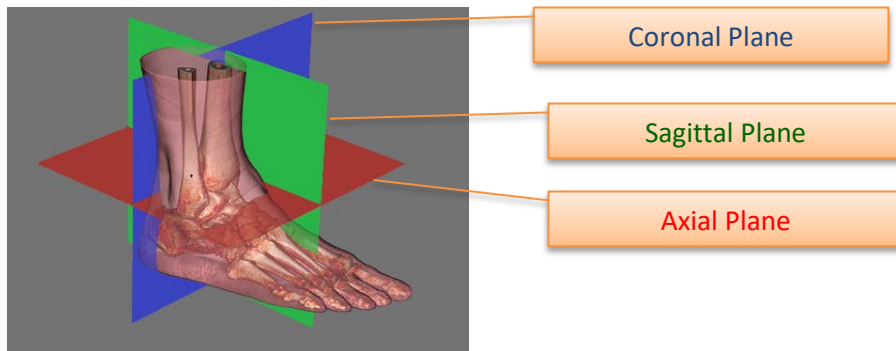
- **Axial:** slices through the anatomy from top to bottom, bottom to top: Red plane.
  The "orientation of the image" is as if you were looking down on your foot/feet.
- **Coronal:** slices through the anatomy from back to front, front to back. Blue plane.
  The "orientation of the image" is as if you are looking at the foot/feet from behind.
- **Sagittal:** lateral slices through the anatomy. Green plane.

Scrolling through cross section images in the MPR views:

The scrolling cursor is the Default cursor. To scroll through slices, hover the mouse cursor over a desired view and this cursor should be enabled**. Left Click, hold and drag to scroll through slices.**
Alternately, each colored line in a Window can be clicked and dragged to scroll through its corresponding colored views.
The red line that cuts through two images, the Coronal and Sagittal, is the reference point for the Axial slice that is shown in the red outlined box. Moving the red line in either the Coronal or Sagittal views will change the slice location and the image displayed in the Axial view. The red reference markers will always depict the location of the Axial slice. This reference is the same for both the Coronal and Sagittal views as well, with the Coronal in green and the Sagittal in blue.
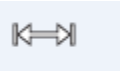
Alternately, for scrolling through slices in fine increments, when the cursor is hovered over an MPR image, use the mouse wheel to scroll through slices.

Each Tab has use of Universal Image Processing and Planning Tools:

Slab/Slice Thickness:
There are 2 methods to enable the tool for changing the thickness of the anatomy viewed, Hold down the SHIFT key and click on any of the colored reference lines and then drag the mouse to change the width of the line to represent either a larger or smaller slice of anatomy.

The cursor should change to this: for horizontal lines or for vertical lines.
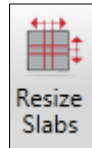
OR, click on the "Resize Slabs" button on the Main Menu Bar. This will change the cursor for resizing. To disable the resize, click on the icon a second time and the cursor will change back to normal.

Example: Increasing the thickness of this "Red" indicator line creates a thick slice image of the Axial view. Any indicator line can be adjusted, resulting in its corresponding image to change. The anatomy represented by the reference indicator is the slab.
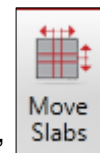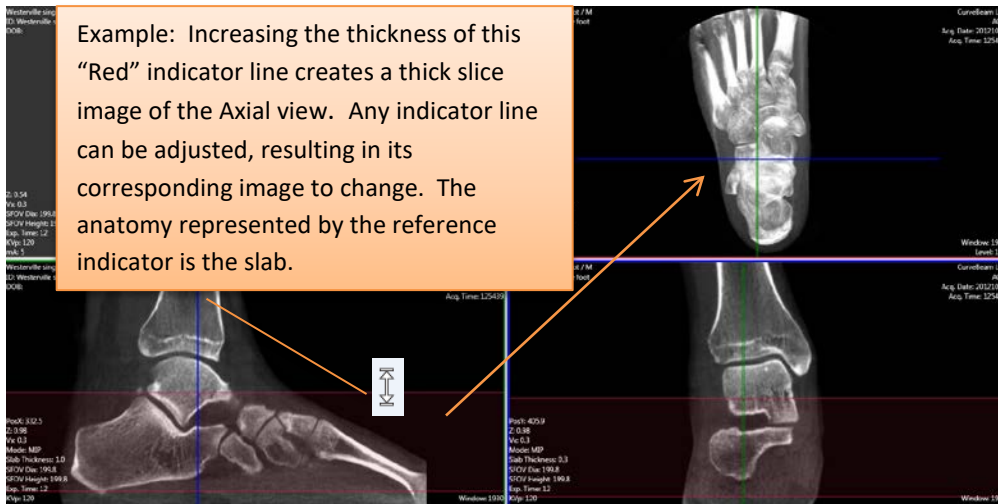
To move a Slab to a new location, click the now toggled "Move Slabs" button on the Main Menu Bar and the cursor will change to its default
which will allow you to "move" the slab to a new location by dragging the slab.

To Reset the Slabs back to normal thin slices, click the "Reset Slab" button on the Main Menu Bar. If selected, a warning message will appear to verify that the slabs do need to be reset. The message will appear as shown below:
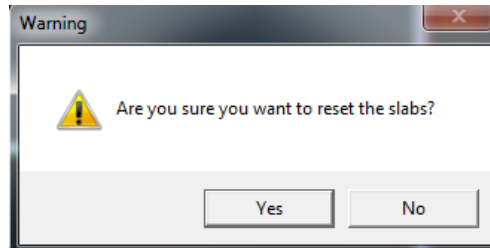
Image Enhancement Tools: These are functions that can be used to enhance and manipulate the image for optimal viewing.

Window / Level (Brightness / Contrast):

To adjust the Window/Level, select the Win/Lev icon and then selecting a window to make the window/level change to. Changes are made by first clicking in the window, then moving the mouse up and down and then left and right until the optimal window/level is achieved. To deselect the Window/Level function, click on the Win/Lev icon a second time.

Zoom:

If the image does not appear as close as desired, then select the Zoom icon and select a window to change the zoom factor on. If you drag your mouse up, the image will zoom in and appear closer. As the mouse is moved down, the image will appear further away. To deselect the Zoom function, click on the Zoom icon a second time.

Pan:

To adjust the image to a different location inside the window, the Pan function can be utilized. To center the section of the image desired in the window, select the Pan icon and then select the window to modify. Click on the image and hold the mouse down, while moving the mouse around and the image will move with the mouse movements. To deselect the Pan function, click on the Pan icon a second time.

Image Magnifier:

The Magnifier icon will provide a magnification of the selected image. When the mouse is moved around the anatomy in the selected image box, the magnification box will be continually updated with the new location of the mouse.

Magnified section
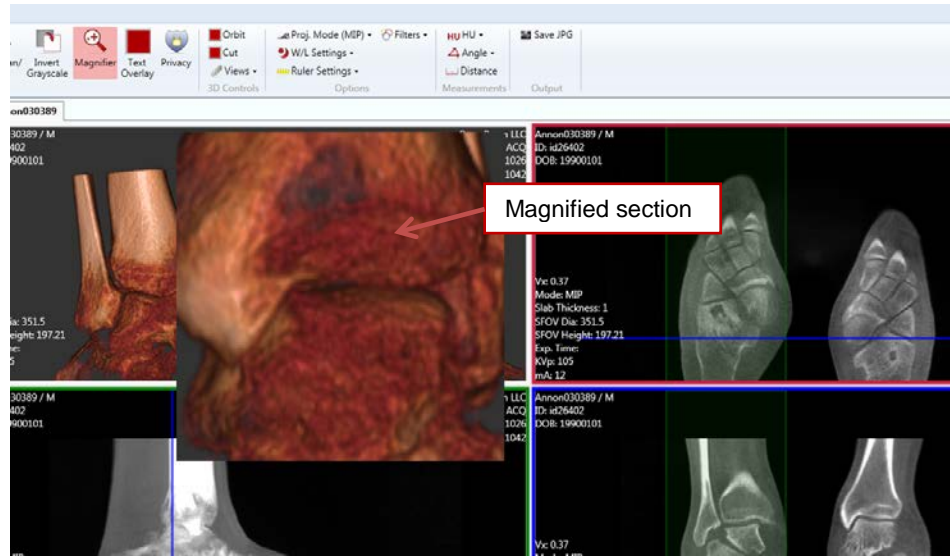
Reset Pan/Zoom:
Once the Pan and Zoom functions have been used and a different section of the anatomy is of importance, then the user can begin the Pan and Zoom process again by selecting the Reset Pan/Zoom icon. When the Reset Pan/Zoom icon is selected, the image will appear as it did when the study was originally first loaded.

Splits / Reset Splits:
The individual windows can also be moved to allow for a larger window for any of the four windows. So that if the user would like to see a full screen of the Axial image, mouse click on the center of the four windows and adjust the window sizes so that the Axial image takes up the majority of the window.

Once done with viewing the Axial window, the window sizes can be reset with the use of the Reset Splits icon. This icon will put the windows back into the configuration they were in when the software scan was freshly opened.

Invert Grayscale:
The Invert Grayscale icon will invert the grayscale on all the images, except the 3D image. Click the Invert Grayscale icon again to revert back to normal grayscale.
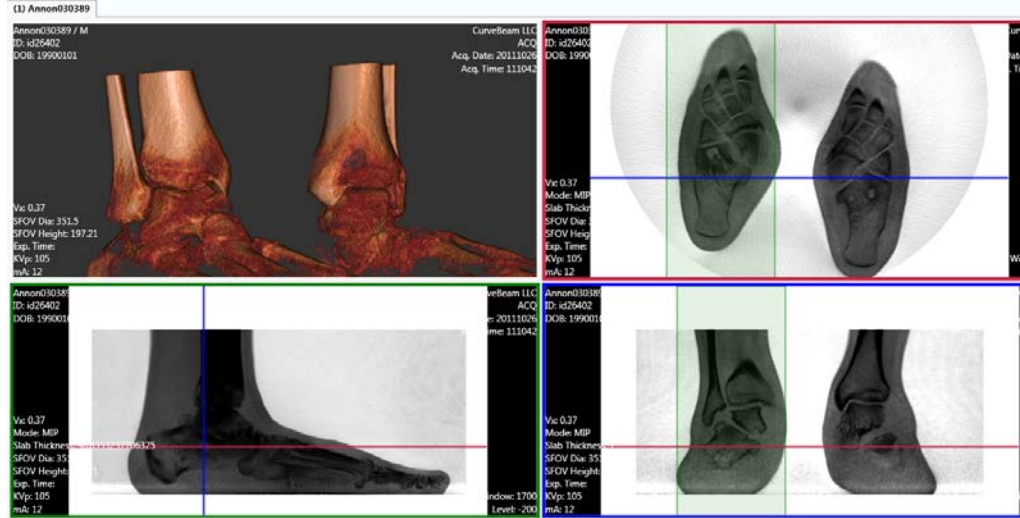
Text Overlay and Privacy:
The overlay on the images is most of the informative text on the image. If the user does not want to display the information, there are two options available. The Privacy icon:

will remove ALL patient information from the image other than Patient ID#. This can be useful if the desire is to maintain a level of anonymity when viewing the scan on the screen. The image should NOT be printed when the Privacy icon is selected and no patient data is displayed. To allow for the basic patient information, then the Text
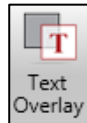
Overlay icon should be selected. This allows the user to display some information but also remove the excess information from the Image Windows.

Projection Mode:
There are 2 options available for projection mode, one is "Radiographic", the second is "MIP". Radiographic is the image displayed as a normal radiograph.
MIP stands for Maximum Intensity Projection. This is an image tool that is only useful for thick slice slabs. It will display for each pixel, the most dense valued pixel in the depth of the selected slab, which means it will display the brightest pixel (voxel). Below is a comparison of a thick slice slab as a Radiographic projection vs. an MIP projection.

Radiograph   MIP

To alternate between Radiograph and MIP, click the Proj. Mode icon. It will display to

you which mode it is currently toggled to.
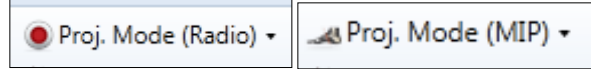
Filters:
There are 3 filter options available; Smooth, Normal, Sharp. Filters can be applied to enhance images. The default filter type will be Normal. But if the image requires a little more detail, than the Sharp filter can be selected. Smooth will make the edges of the images appear more smooth, but may lose some detail. Filters are often a personal preference.   Select the Filters icon to apply one of the 3 options.
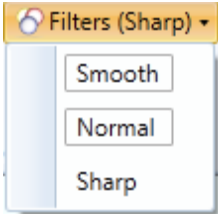
Measurements: There are various measuring tools for treatment planning.
HU: These are for measuring Hounsfield Units, which is density value of an area of interest.
Angle: These are for measuring angles on the anatomy of interest.
Distance: This is for measuring distances in millimeters. There is also a Ruler that can be displayed on the images to assist in quick visual reference of length.

HU Measurements: The HU tool has a drop down with 6 options; rectangle, circle, freehand and line for general use and then QA set Small and QA set Large for doing the QA procedures.
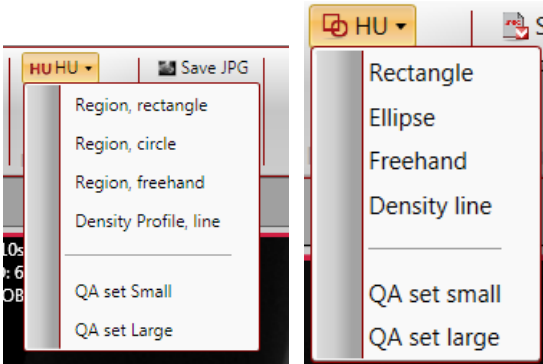
Any of the general use regions can be selected for creating a region of interest (ROI) on the bone in order to obtain a density value reading. For example, if "Ellipse" is selected,

an elliptical ROI can be drawn by point click and drag. Then click a final time to anchor the ROI. The measurement reading will display in the upper right hand corner of the image window. A maximum of 10 measurements can be made in one image window. This tool will remain enabled until disabled by clicking the selection again.

M = Mean, SD = Standard Deviation.
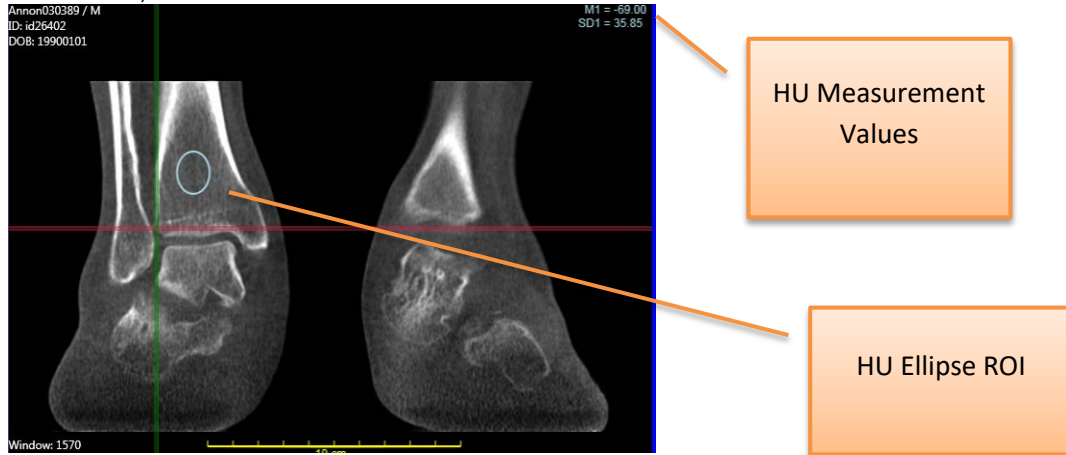
Follow these instructions for the rectangle or freehand as well.
The Density Profile line displays in graphical form. Draw a line and the graph will appear.
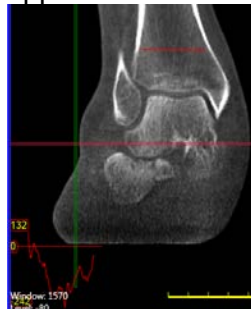
For doing the QA procedures, there are two sets of pre-sized HU regions. Selecting the "QA set Small" will draw small circles that are used to determine the HU of the various materials on the QA Line Pair Phantom. The "QA set Large" will draw large circles that are used to determin the HU of the water.

Angle Measurements:

The angle tool has a drop down with 4 options for measuring angles; Simple, Prepare Cobb, Cobb, and Correlate Cobb:

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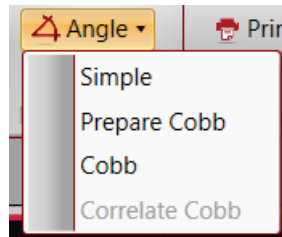
Simple Angle: Select "Simple" to enable the Simple angle tool. The Simple Angle has 3 points of reference. Point, click, move, click, move, click to finish (3 clicks). This will result in an angle in degrees, and the measurement will display in the upper right hand corner of the window. A maximum of 4 measurements can be made in one image window. This tool will remain enabled until disabled by clicking the selection again.

Angle Measurement Values

Simple Angle Measurement
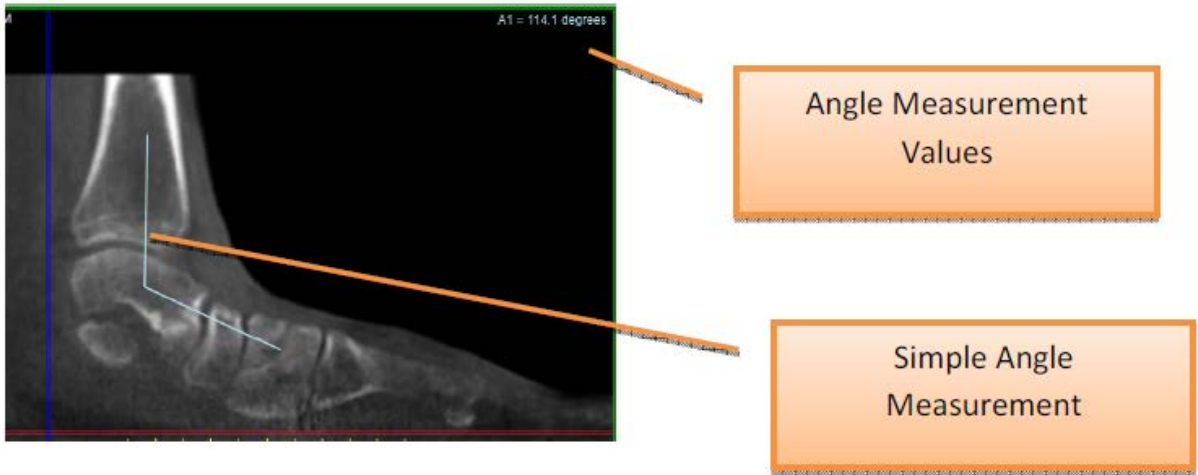
Cobb Angle: First select "Prepare Cobb" to orient the feet properly. Then select "Cobb" to enable the Cobb angle Tool. The Cobb angle requires creating 2 separate lines and the tool will calculate the angle at the point of "intersection" of those 2 lines:

These 2 lines are drawn when "Cobb" is enabled (4 clicks). The calculated angle measurement is where these 2 lines intersect.
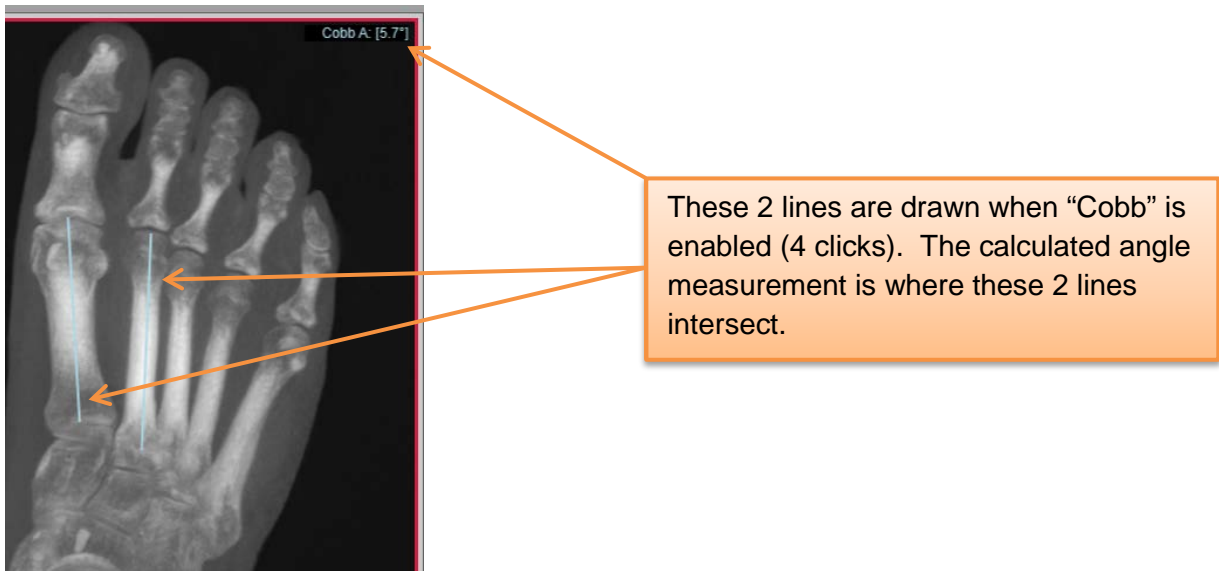
Correlate Cobb Angle: Create 2 sets of "Cobb" lines and then select "Correlate Cobb" to calculate and angle where the 2 yellow dotted lines intersect:

Cobb A: [4.0°]
Cobb A: [2.3°]
Corr. A: [9.0°]

These 2 sets of Cobb lines are drawn when "Cobb" is enabled. Then select "Correlate Cobb" to calculate the angle measurement where the resulting 2 yellow dotted lines intersect.
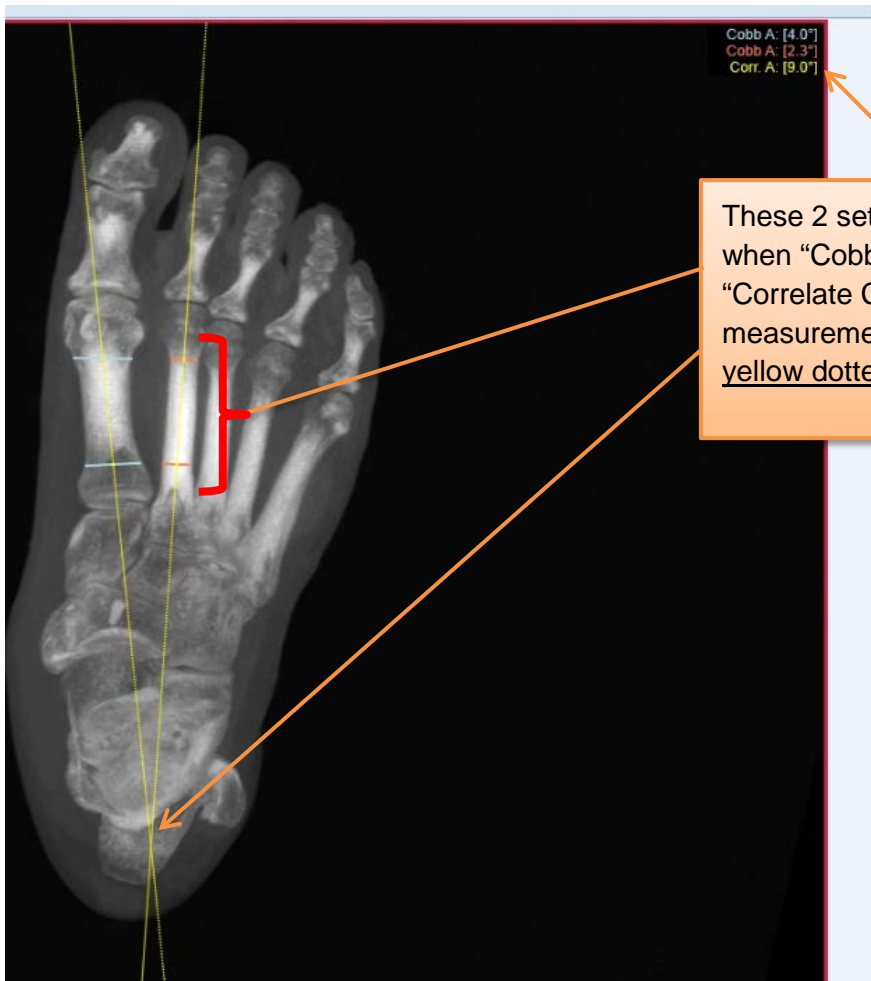
Distance Measurements:
Select the Distance Tool icon to enable the distance tool. Distance has 2 points of reference. Point, click, drag, release to create a line. This will result in length measurement in millimeters, and the measurement will display in the upper right hand corner of the window. A maximum of 10 measurements can be made in one image window. This tool will remain enabled until disabled by clicking the selection again.

D1 = 42.12 mm
D2 = 38.32 mm
D3 = 34.14 mm
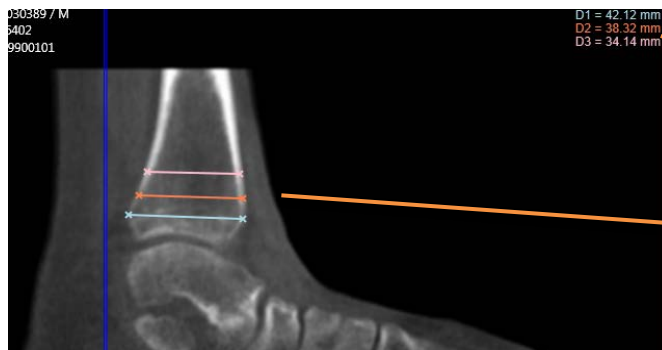
Distance Measurement Values

Distance Measurements

Removing Measurements:
All measurements can be removed by hovering over the values in the corner and right clicking on them. This will display a pop up window. Select either *Remove measurement* which will remove the last one drawn on or *Remove all measurements* which will remove all from both the corner and the illustration on the image.
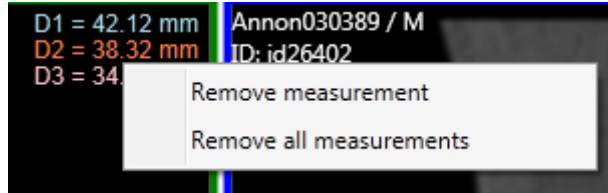
Ruler Settings:
Also Note that there is a Ruler Tool that can be displayed on the bottom of the image window for quick distance measurements. This overlay can be enabled or disabled by clicking on the "Ruler Settings" icon.   Click Show Ruler to display the yellow ruler at the bottom of the image window.

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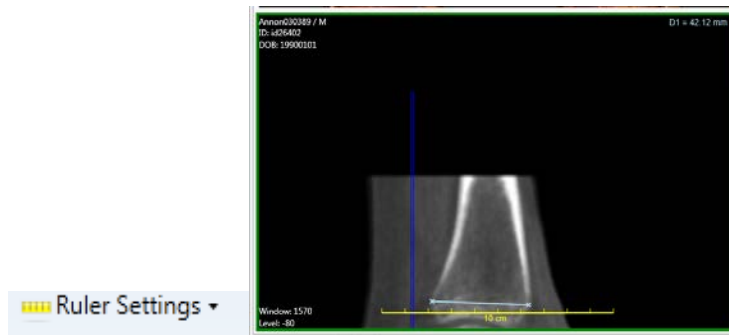
MPR Tab:

The MPR Tab has the 3 MPR views and no 3D Rendering. Two additional tools are available only within the MPR Tab, they are the "MPR Cut" tool and the "MPR Explorer" tool. These tools are only enabled when you are on the MPR Tab and are in the "Options" area.

When MPR Cut is selected, the cursor allows the user to draw a "cut line" on any of the 3 MPR images in order to display a customized slice in any direction in the lower right hand corner window.

After selecting MPR Cut, click anywhere in an image to start the MPR Cut Line. The cut line can be straight or curved. For a straight cut line, click in 2 spots, then double click to complete the sequence. For a curved cut line, make multiple clicks in a curved direction.

MPR Straight Cut Plane: Created in the Axial view. The resulting cut displays in the lower right corner.
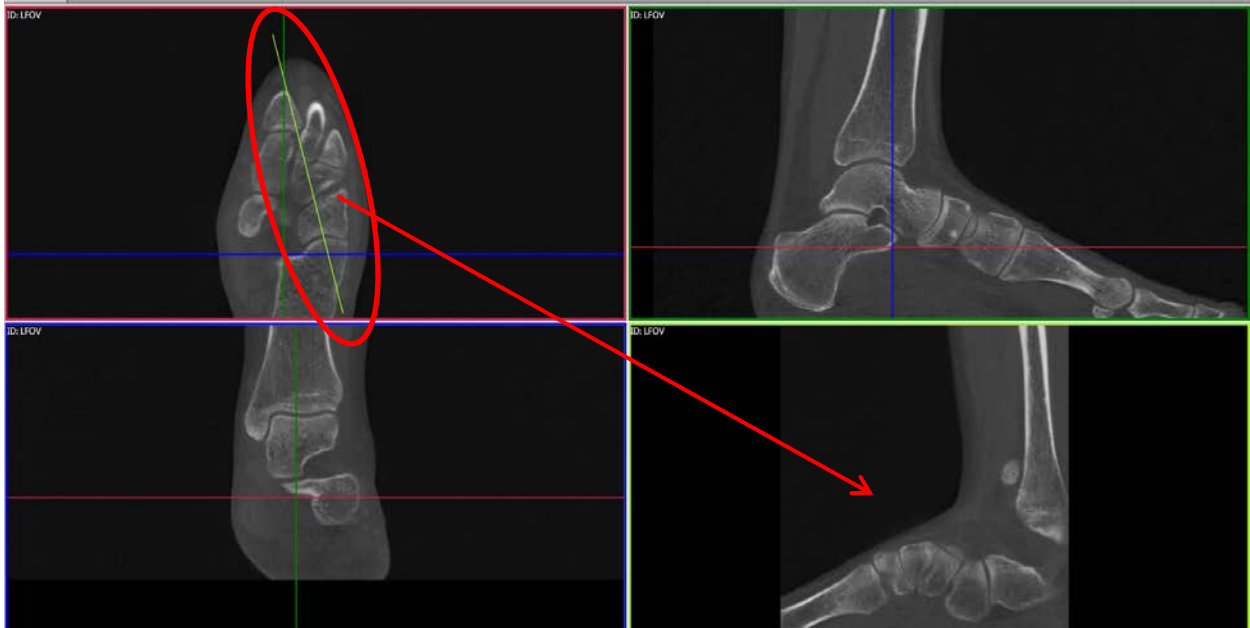
MPR Curved Cut Plane: Created in the sagittal view. The resulting cut displays in the lower right corner.
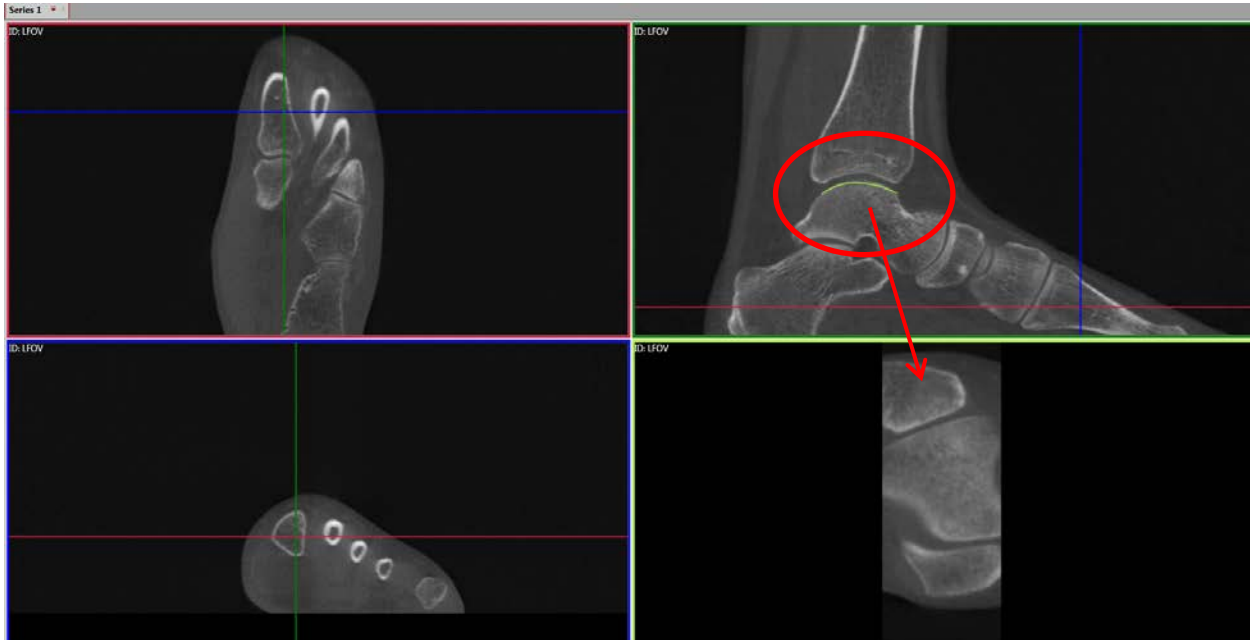
When the MPR Explorer is selected, the cursor allows the user to create the MPR Explorer tool on any of the 3 MPR images in order to rotate around a center point with the image displayed in the lower right hand corner window.

After selecting MPR Explorer, click anywhere in an image to start the MPR Explorer, which will appear as follows:
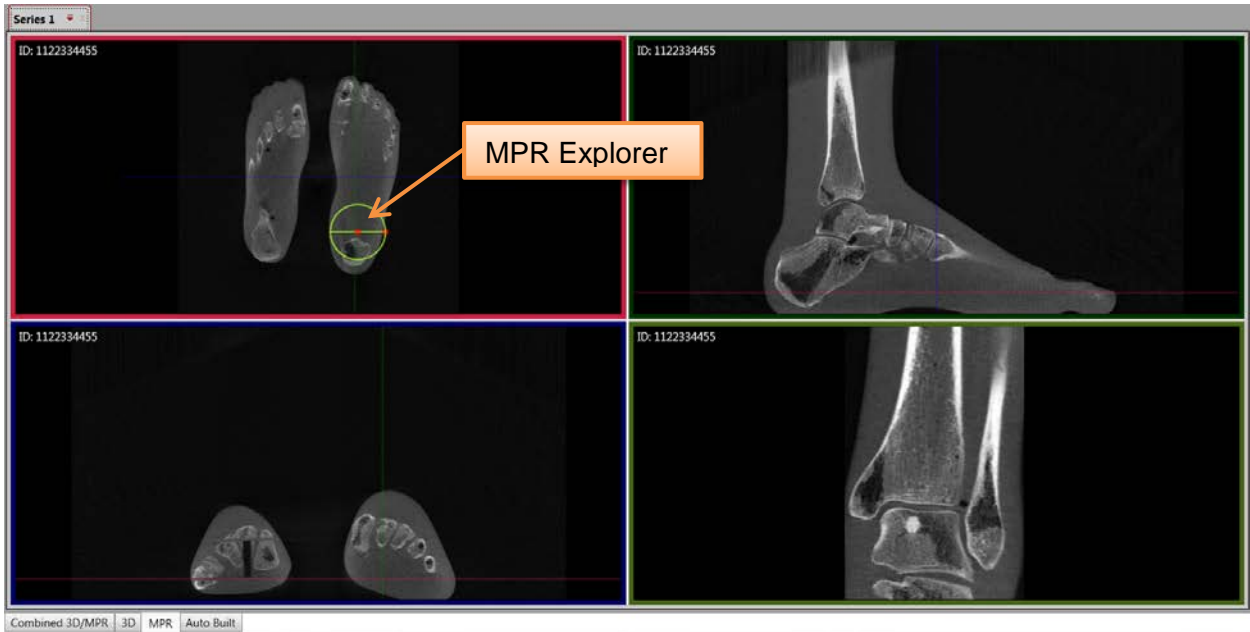
This tool can be moved around the image by clicking on the center red dot and dragging the tool to the desired location. To expand the area displayed, click on the red dot on the outer edge of the circle and drag the dot for either a larger or smaller region to view using the tool. Also use the red dot on the outer edge of the circle to rotate it around to view different images in the lower right window. The image shown will correspond to the green line drawn through the circle, so as the red dot is moved around the circle, the image in the lower right hand corner will adjust accordingly.

Drag center red dot to move Explorer tool to different locations within the window

Drag this red dot in or out to contract or expand the circle.

Rotate it to view a different section of anatomy.
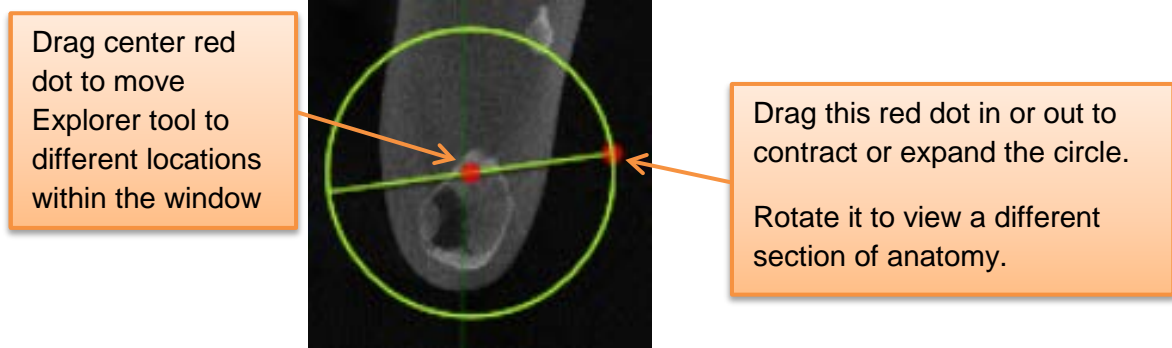
Right click on the center green line, with the cursor that points up, to get the following options:

Remove MPR Cut line

Transfer image to AutoBuilt page

Auto rotate explore
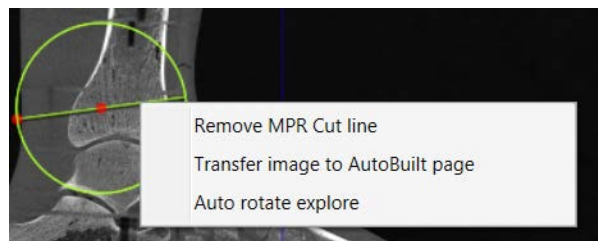
The "Remove MPR Cut line" will remove the MPR Explorer tool from the image. This allows the tool to be placed in a different window if desired. The "Transfer image to AutoBuilt page" will transfer the image the tool is on to the Auto Built tab. To have the image represented by the tool, the image in the lower right hand window, moved to the Auto Built tab, right click on that image and select to move it from there. To allow the image to rotate freely without needing to manually rotate it, select the "Auto rotate explore" option. Right clicking on the outside of the circle will do all the same options except it will not allow for the auto rotate option.

To use the MPR Explorer tool in a different MPR window, such as changing from axial to sagittal window, delete the tool from the axial window and redraw it in the sagittal window.

Print Images
A Print option appears as an Output function along the top menus.

Print Image
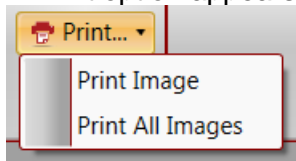
Print All Images

To use click on Print and then select either "Print Image" or "Print All Images". If Print Image is selected, the currently active image will be the one printed.

Auto Built Tab:

The Auto Built tab is used to display the standard x-ray views as shown below:
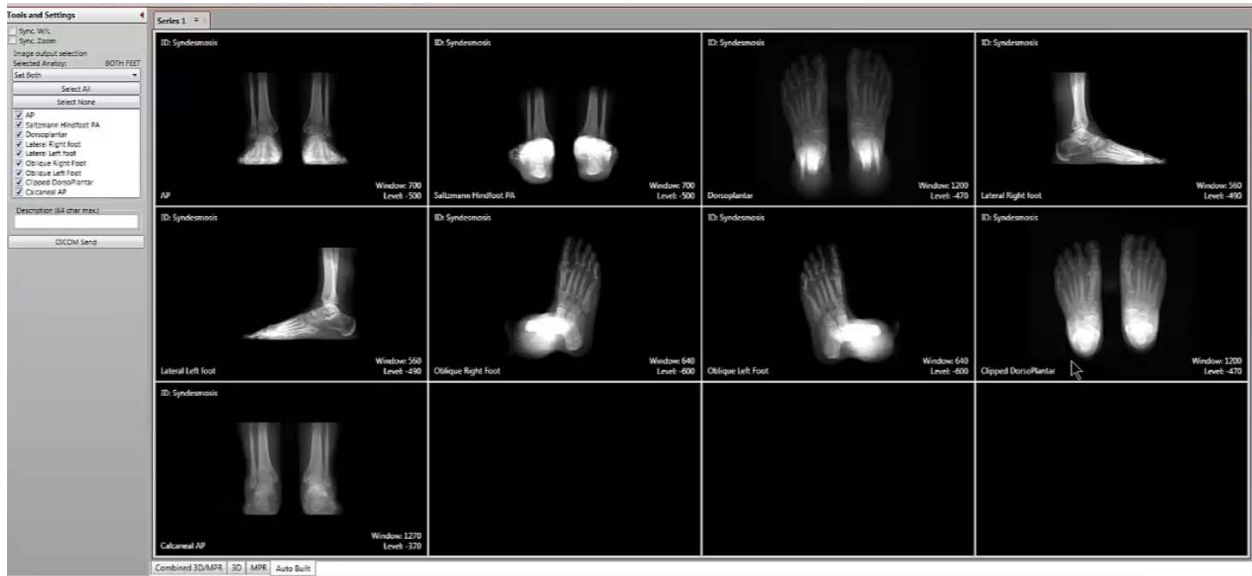
When the scan is just of a single foot, fewer images will appear. In order to show only certain images, the checkboxes, unchecked images will not be shown. The Tools and Settings selection for the Auto Built tab is shown below:
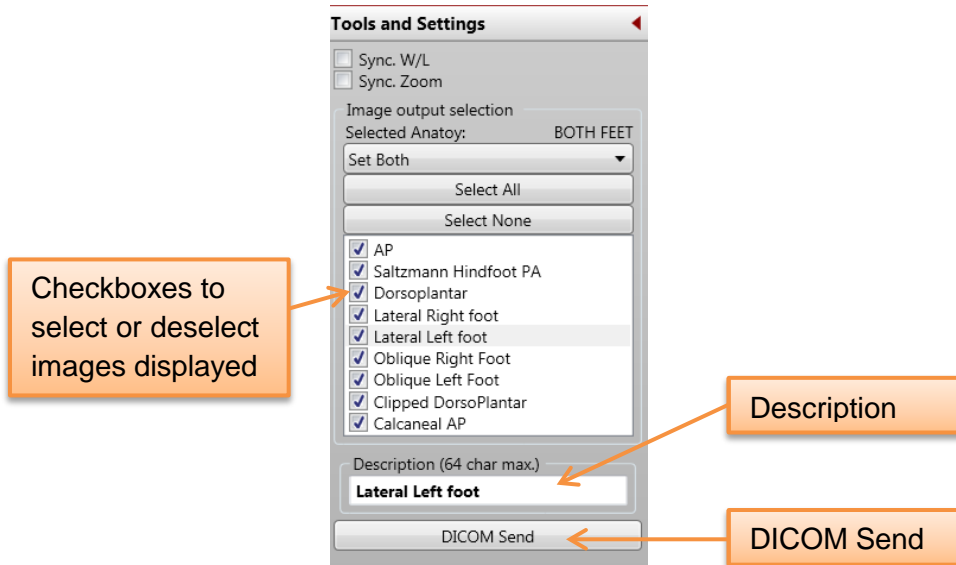
The Description field in the above image depicts the description given for the selected image and can be changed as desired. Just type in the field and the corresponding image will have the description updated.

All images shown can be double clicked on to view the image full screen. All of the usual measurement and navigation functions, such as Pan, Zoom, etc are still accessible.

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When the DICOM Send button is selected, the DICOM Sender box will be displayed. In this window, one or multiple **Destinations** for the data send can be configured. Configure a Destination with the appropriate data and click the **Update** button to Save. To add another Destination, click on **New** and edit the Destination items, click Update to Save. Once there are Destination(s) configured, they will remain in the list unless deleted.
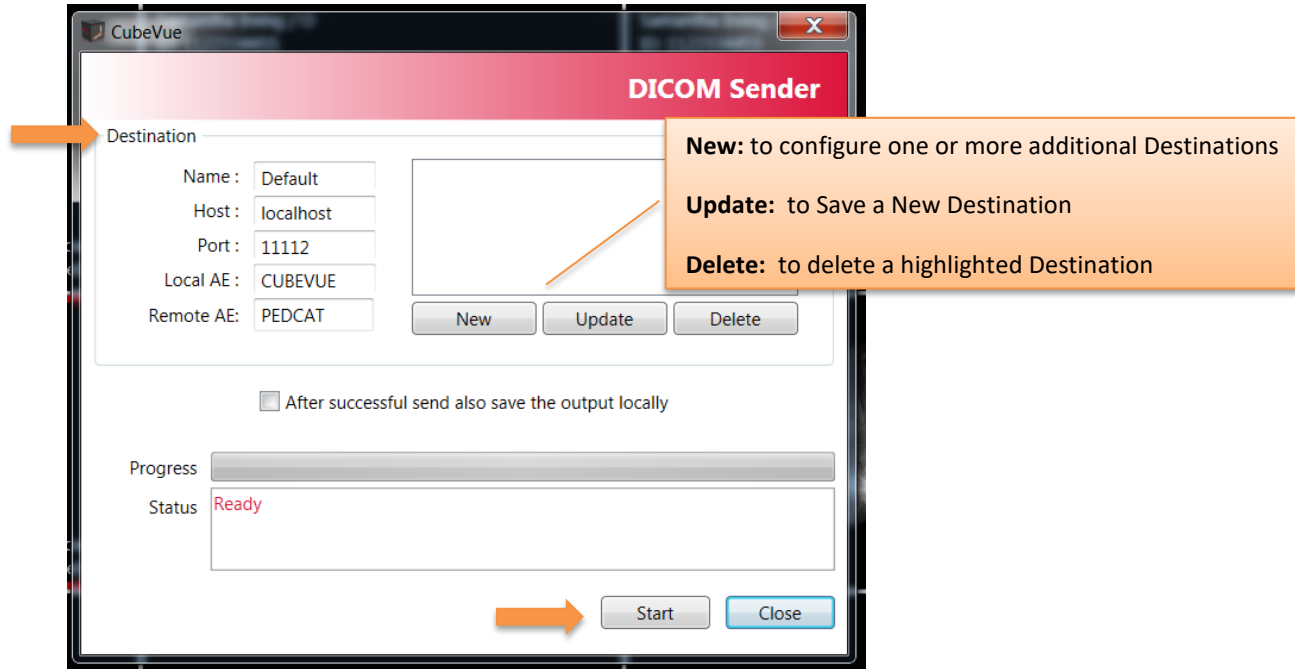
Click **Start** to begin the Send. The Send time will depend on how many datasets and destinations are selected, the number of reformats created, and the speed of the PACS network. When the Send is completed, the Status will read "Completed".

Any of the non-3D images thoughout the software can also be added to the Auto Built tab by right clicking on them.

Tools and Settings Panel:

REVIEW CONTROLS:

<u>Sync Window/Level:</u> when this item is "checked", any Window/Level adjustment to an MPR image will make the same adjustment to the other MPR images.

<u>Sync. Zoom:</u> when this item is "checked", any Zoom adjustment to an MPR image will make the same Zoom adjustment to the other MPR images.

<u>Sync 3D/MPR Rotation:</u> When this item is "checked", any rotation of the 3D rendering will also rotate all 3 MPR images to the same angle.

<u>Sync 3D/MPR Rotation button:</u> When this button is clicked on, the MPR images will snap to the rotation angle of the current 3D rendering rotation.
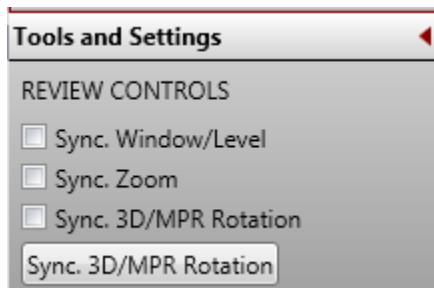
> <u>3D/MPR Rotation, (Volume Rotation, Volume Tilt):</u>
>
> The default image planes of MPR views are as the scan was taken. However, if you wish to rotate or tilt the MPR images to different planes, this can be achieved using the 3D rendering and the Sync 3D/MPR functionality.
>
> Below is an example.
>
> If this is the starting view below and then 3D image was tilted upwards either with the Sync 3D/MPR Rotation or by clicking the button after the rotation, then the MPR rotation will change from picture A to picture B:

Picture A: the 3D rendering is in an A/P direction.
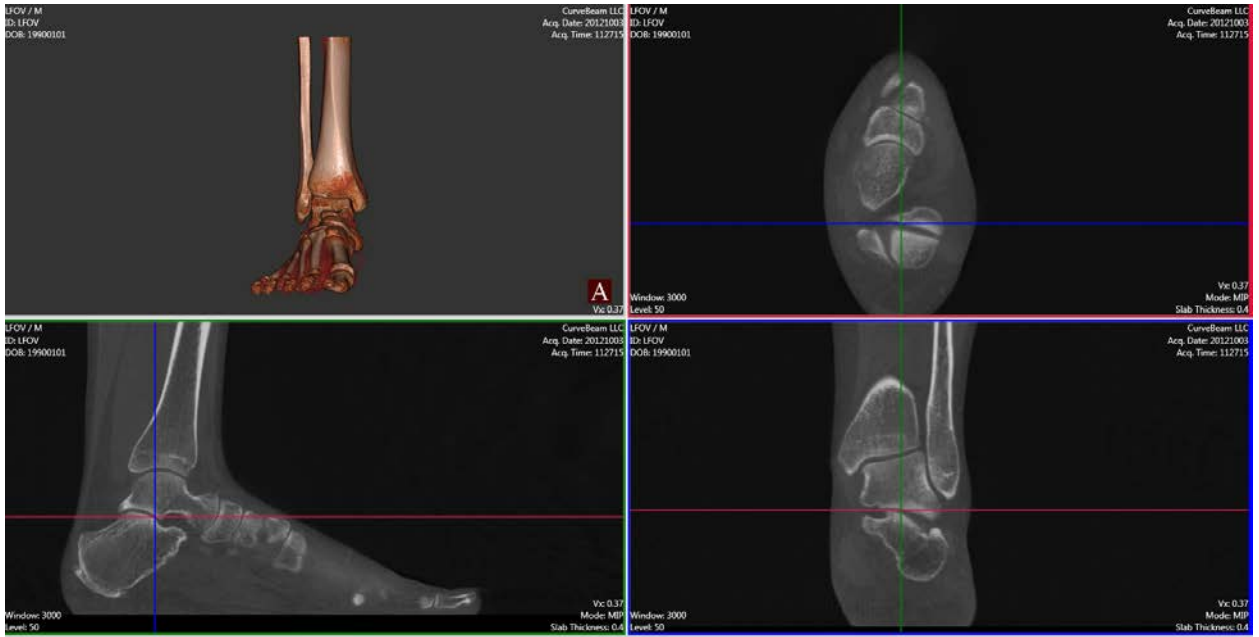
Picture B: The 3D rendering has been rotated with the toes up slightly. Observe how the upward tilt of the 3D rendering is now reflected in the MPR views. The first metatarsal is now on the same horizontal plane.

For fine control of the X, Y and Z rotations of the 3D rendering, press the associated keyboard letter and HOLD while rotating the 3D image.
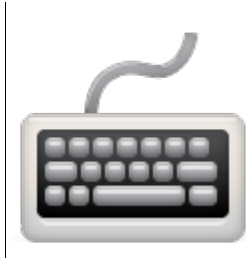
X key: Hold the key down and move the mouse up or down on the 3D rendering. This will tilt the rendering in an even up / down plane.

Y key: Hold the key down and move the mouse left or right on the 3D rendering. This will tilt the rendering in an even side to side plane.

Z key: Hold the key down and move the mouse in an up or down direction and this will move the 3D rendering clockwise or counterclockwise.

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3D Renderings:

The 3D Rendering image displays in both the Combined 3D/MPR Tab and the 3D Tab. The combined allows the user to scroll through MPR slices for Viewing/Planning as well as edit and manipulate 3D renderings. The 3D Tab only displays the 3D renderings. However, the 3D Tools are similar for each.

Combined 3D/MPR Tab:
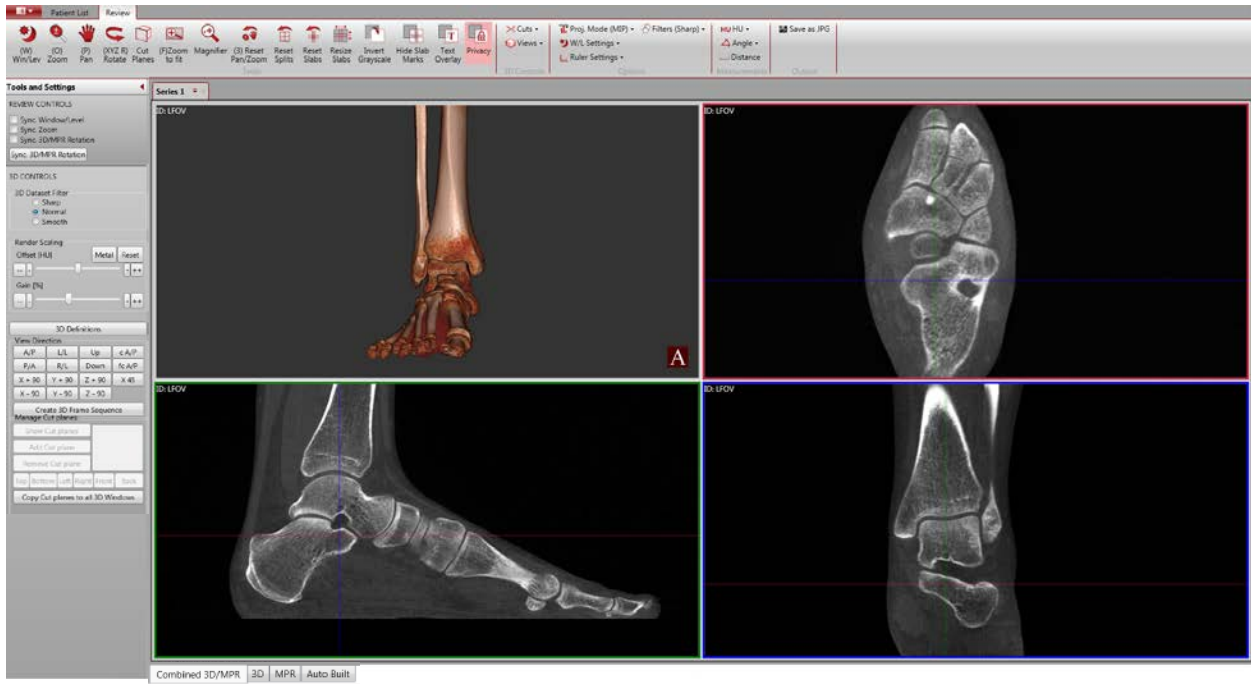
3D Tab:
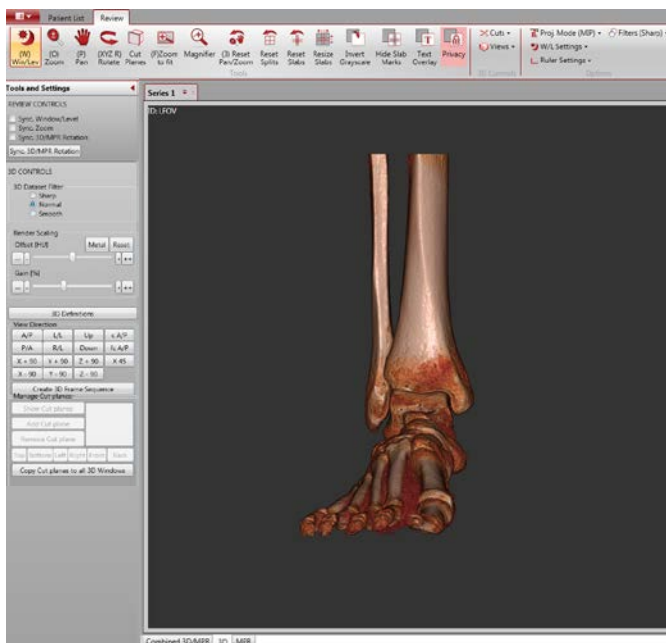
The Zoom, Pan & Rotate buttons on the Main Menu Bar all can be activated and used in the 3D Rendering window.

3D CONTROLS: the 3D CONTROLS within the Tools and Settings panel contains most of the 3D rendering functions.

3D Controls – Filter: Use the filters to adjust the image.
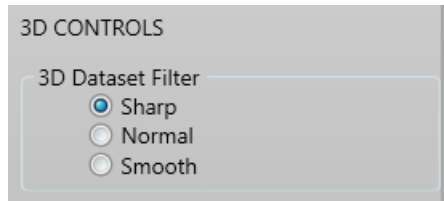
The Sharp selection will display the full resolution dataset.
The Normal selection will display the 2x2x2 resampled dataset.
The Smooth selection will display a smoothly filtered 2x2x2 resampled dataset.
When first opening a patient scan, it will be depicted as Normal. When the selection is changed, it will be changed for all screen layouts, ie in Combined as well as 3D screen layouts.

<u>Render Function offset/gain:</u> **These tools adjust the thresholding for the 3D rendering.**
Drag the slide bar to adjust from soft tissue to bone and vice versa. To reset both back to zero, click the Reset Offset/Gain button.

Slide to adjust thresholding for the 3D renderings from A to B.

To Fine Tune the thresholding in small increments: when the slide bar is highlighted in light blue color, use the keyboard arrow **keys left and right**

The Render Scaling sliders have a Metal and Reset button for Offset and Gain. The Metal button can be used if the study is loaded for the first time and nothing but a piece of metal (screws, etc) is visible. Only click on the button **once**. Clicking on it repeatedly will apply the scaling multiple times and the render ranges will become useless. If this does occur, click on the Reset button to reset the image to the original render.
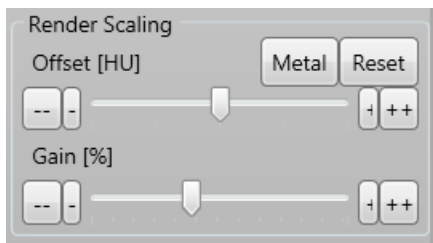
To make fine tweaks to the Offset and Gain, adjust using the sliders. The sliders will produce relative render scale changes, which means after the slider is adjusted, it will return to its

"home" position. This allows for HU range coverage scaling, meaning a larger range is achievable in the small slider. After coarsely adjusting the sliders (Offset is recommended over Gain), then use the buttons on the ends of the sliders (--/-/+/++) for fine adjustment. Click on the buttons to the left or right of the slider then use left and right arrow keys on the keyboard also for fine adjustment.

3D Definitions

A way to edit the transfer function has been added, allowing the user the ability to create a new render type. The process is started by clicking on the "3D Definitions" button under Tools and Settings.
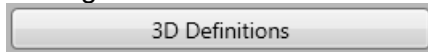
The 3D Definitions button will bring up the following 3D Definitions Editor window:
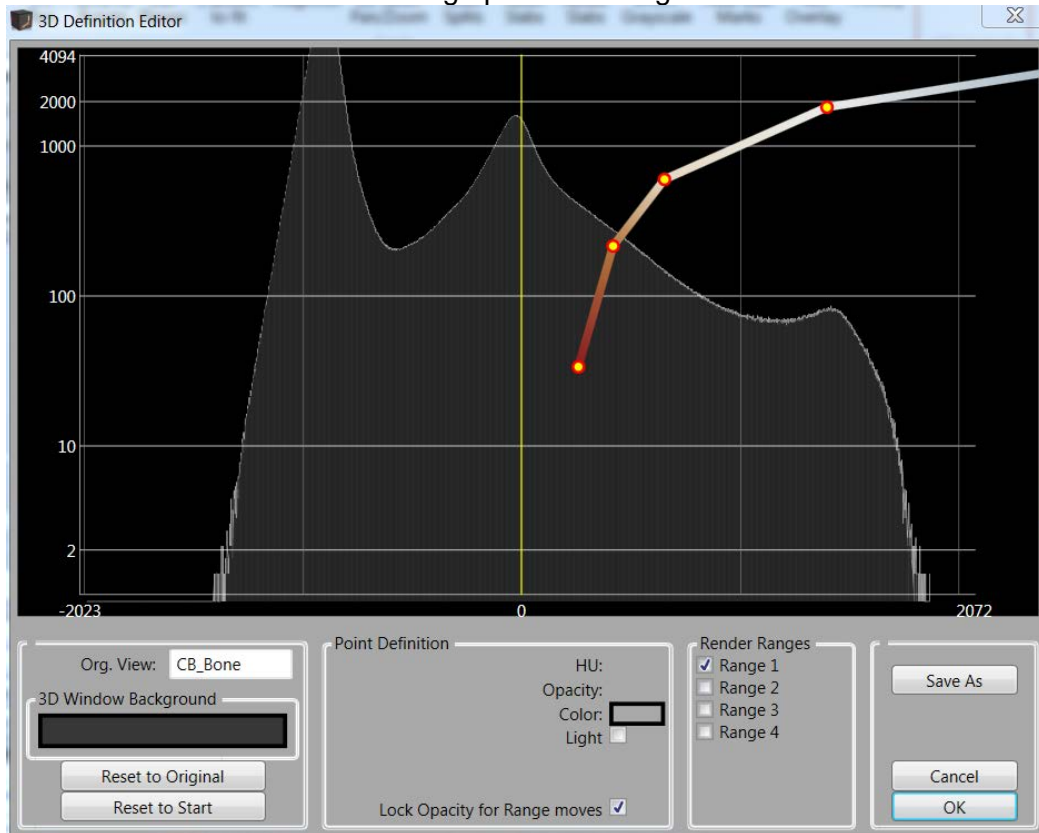
The 3D Definition Editor, also called Transfer Function Editor (TFE), once opened, shows the current volumes' histogram along with some control points and a colored render line connecting them. The continuous connection from a very left to a very right control point is called a render range, and there can be multiple render ranges. These render ranges must not overlap. If they do you will get a red "collision" indication, sign for you to move a render range out of the way. The rendering of colliding render ranges is undefined and may give you unexpected results. The changes made in this TFE will be visible in the 3D window. It may help to adjust the location of the Editor window so that the 3D image is also visible when the Editor is being used.

To adjust the render line, hover over a point for the plus icon to move the single point. Hover over the line for the hand icon to move the entire line left and right. To adjust the Offset and Gain for the range, use the sliders under the Tools and Settings menu. It can be desirable to move the ranges with the sliders for different scans as the HU value can fluctuate from scan to scan.

The points on the graph can be moved by left clicking on the point and adjusting it. Also a right click on the point will allow the user to remove the point, remove all points, or change the color of the render. It is also possible to adjust the range, but making adjustments using the Tools and Settings slider allows for easier adjustments. To add a point, right click on the line where the new point is desired to add a point.

To adjust the color of the render, either left click on a point, then select the color box from the Point Definition section below. Or, right click on the point to change the color. See the image below for locations.
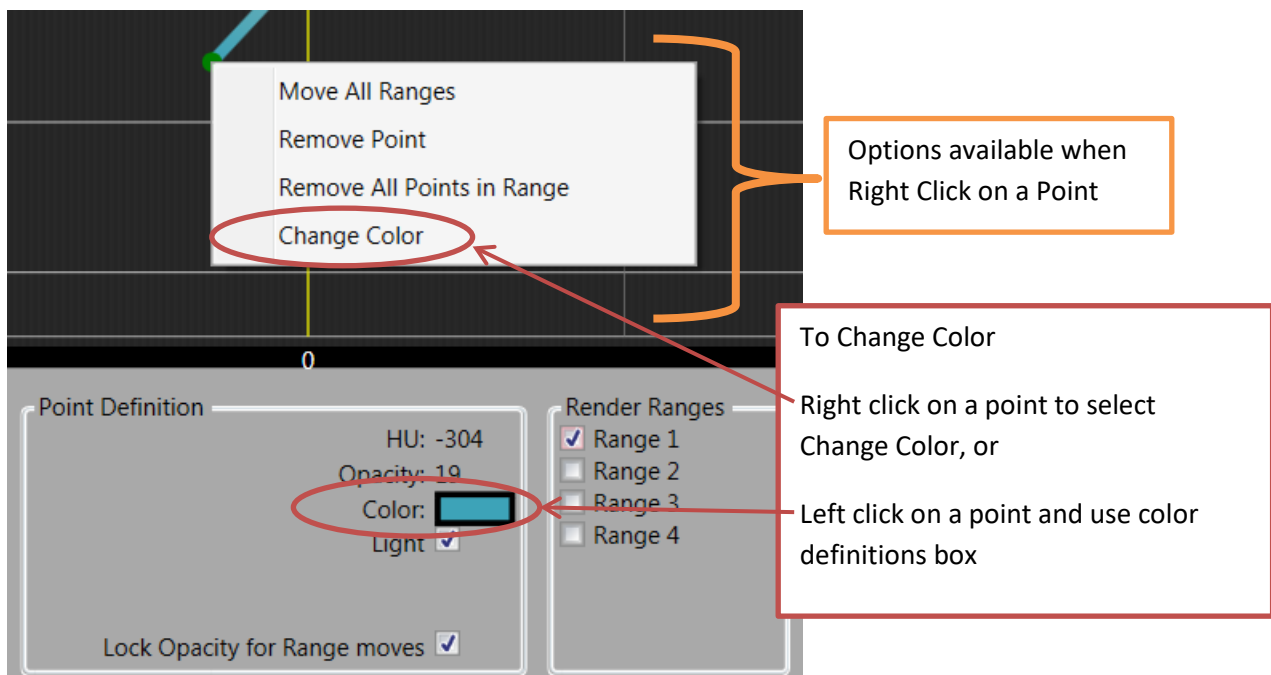
When adjusting the render range, the active range has the point that is solid green. The green point's values are listed in the Point Definition box, displaying the HU, Opacity, Color, and Light source. Use the Light check box to turn on/off a light source associated with that selected/green point.

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When the 3D Definition Editor starts, only 1 range is shown. To add additional Render Ranges, select the check boxes for additional ranges. There is a limit of 4 render ranges. The image below shows a second render range was just selected. The points for the new range appear at the top right.
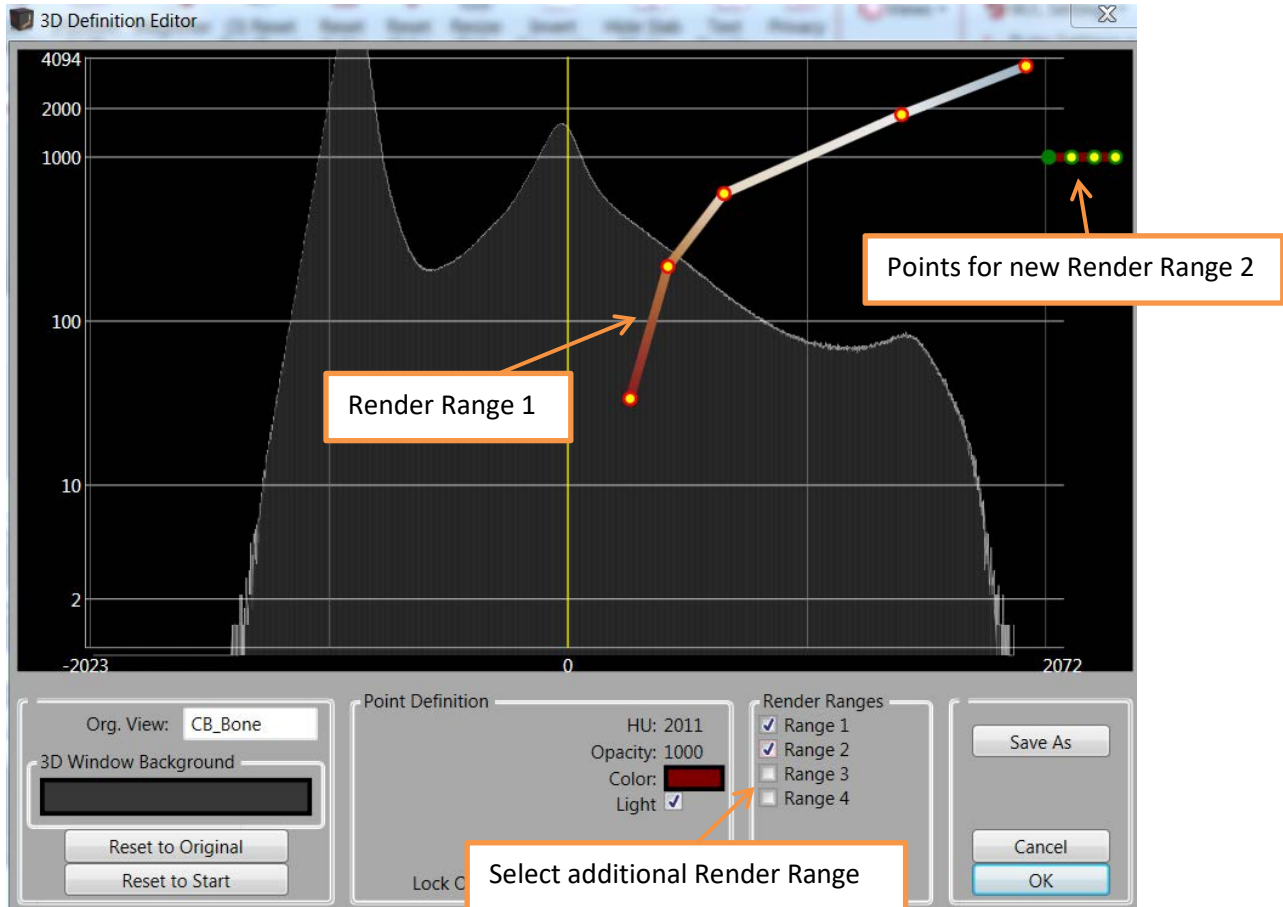
Each point in the new render range can be moved, but each new render section cannot cross another render section. None of the points of this second render section will be allowed left of any of the points from the first render line. If moving a single point, a red line will appear and not allow the render sections to cross into each other's range. If moving an entire render range into another render range section, a red zone will appear. Adjust the two sections so that they are not overlapping each other. The image below shows what will appear if the sections do cross over each other.

This red zone needs to be eliminated. Either adjust one or both of the regions or move the end points of the regions.
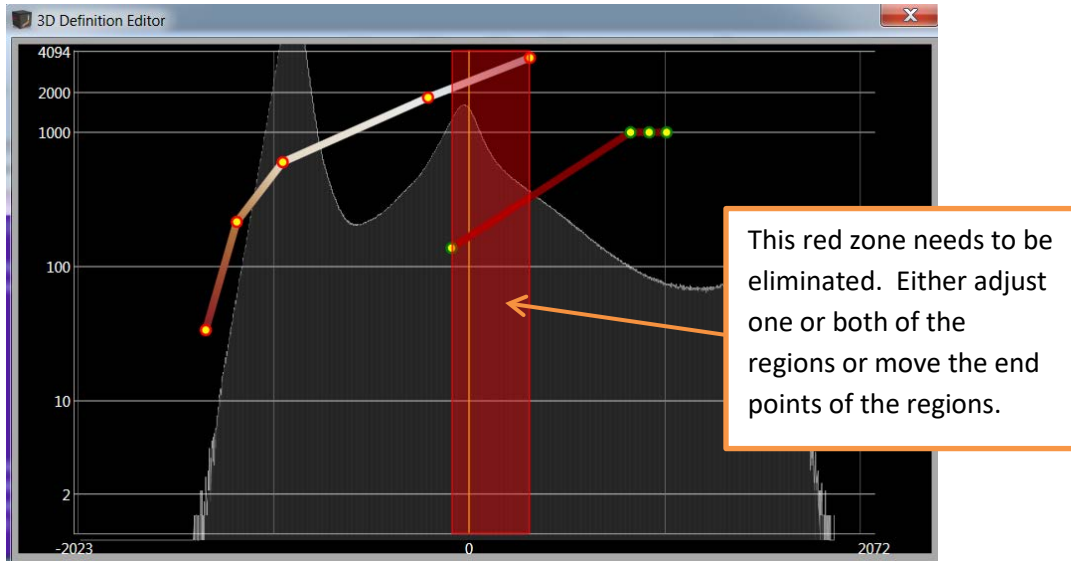
The background color of the 3D window can be adjusted by selecting a new color under "3D Window Background". Click on the color box to change the color. The 3D window will update after the selection is made.

Click here to change 3D Background Color
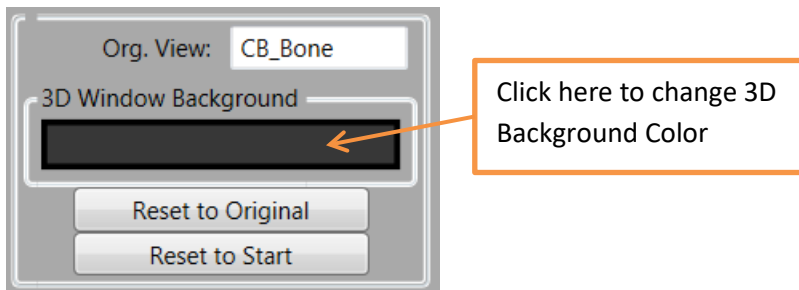
The underlying default render type is listed in the "Org. View" box – in the above it is "CB_Bone". The "Reset to Original" button can be used to reset back to the default render type listed in the "Org. View" Once completed with the changes to the render type, if you wish to save the changes, click on the "Save As" button in the lower right corner of the 3D Definition Editor (TFE). Maintain the default directory that appear with the Save As button. Provide a unique name so that it can be used with other scans in the future. The new render types created with this method will be available to select from under the Views -> Render Type. Once done with the 3D Definition Editor (TFE), select OK to maintain the changes to the current dataset.

<u>View Directions:</u>

There are automatic snap to View Directions for a quick rotation of the
Rendering to a desired view:

View Directions				
A/P (Anterior / Posterior):			**Up (looking up into bottom of foot/feet):**	
P/A (Posterior / Anterior):			**Down (looking down onto top of foot):**	
L/L (Left Lateral):			**C A/P (Conventional Anterior / Posterior): down, 15 degrees from vertical.**	
R/R (Right Lateral):				

Cut Planes: To cut a 3D rendering from an entire plane, first click the **Cut Planes** icon from the Main Menu Bar to activate the functionality.
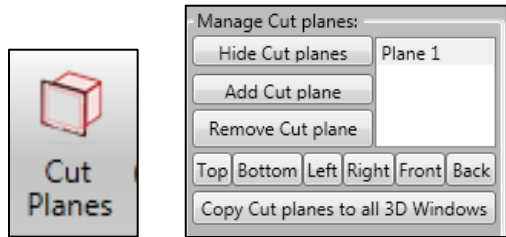
Once enabled, a cut plane is placed within the center of the 3D Rendering. Also, the "Manage Cut Planes" tools will be enabled in the 3D Tools area.
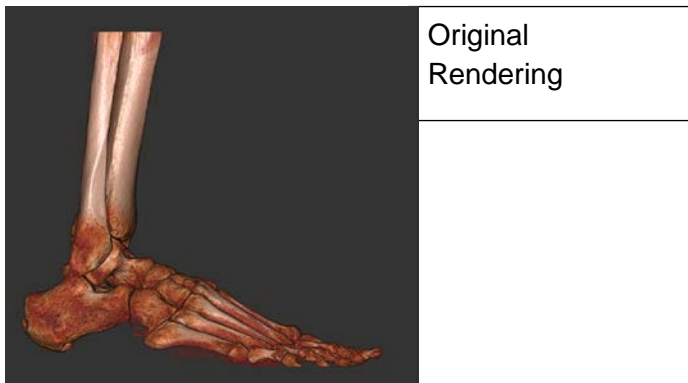
	Original Rendering

After clicking on **Cut plane** icon. A cut plane will Auto drop into the center of the volume and cut out half the 3D rendering. *Manage Cut Plane Tools* will also be enabled.
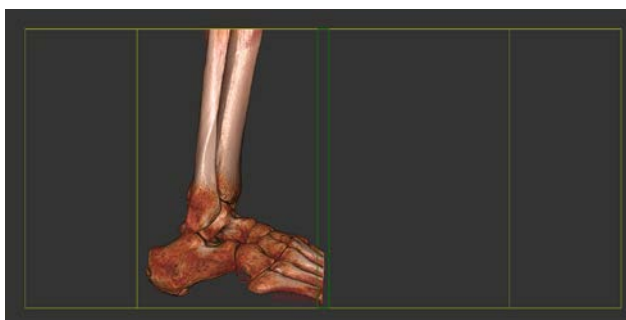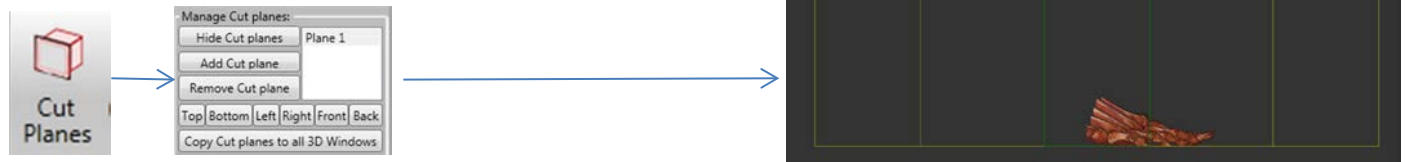
	To Insert the Cut Plane in any direction, Utilize the "Direction buttons" in the *Manage Cut Planes* Tool area. In this sample we clicked on the "Front" Button to cut away the front half of the rendering.

NOTE: The angle of direction of the cut plane can be adjusted to any angle by holding down the CTRL key and dragging the mouse in any direction.
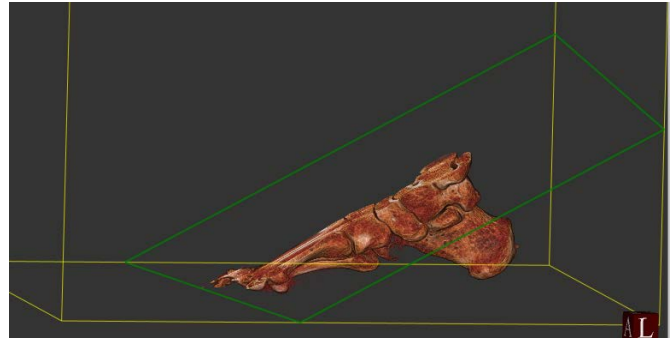
Peeling Away the rendering:

In this sample, the rendering has been rotated to an A/P view for viewing the metatarsals.
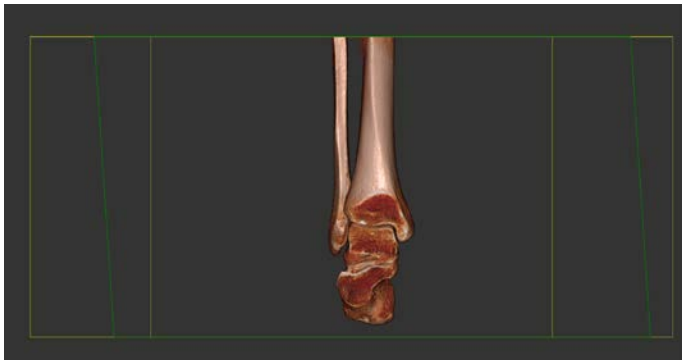
Now, the rendering can be cut more (peeling away) or restored more, by holding down the SHIFT key on the keyboard and moving the mouse up and down.
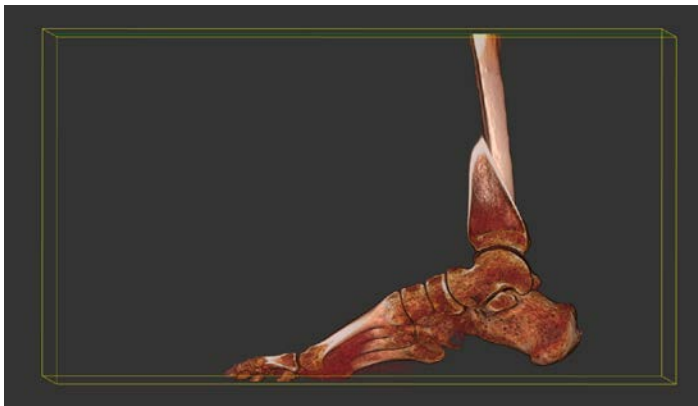
This cut plane was rotated to a sagittal plane by clicking the "Left" button to cut through the foot from the medial side.

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Multiple Cut Planes can be inserted and manipulated by clicking on "Add Cut Plane" button. To Remove Cut Planes, highlight the Plane in the list (Plane 1, Plane 2, Plane 3….) & click on the "Remove Cut Plane" button. To Hide a Cut Plane, highlight that Plane in the list and click on the "Hide Cut Plane" button.
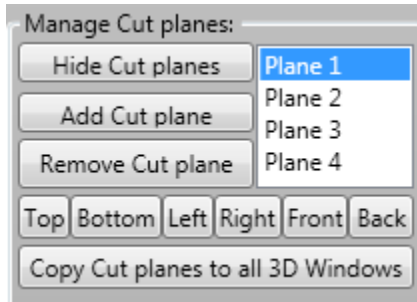
If desired, to transfer the 3D Rendering that was just designed to the other 3D Window click on the "Transfer Cut Planes to all 3D Windows" button. Otherwise, the other 3D window will be a fresh rendering.

Cut From Slabs:

Another method of cutting a 3D Rendering is to "Cut From Slabs". In order to Cut from Slabs, you must first create Slabs in the MPR image(s). Then use the "Cut From Slab" Buttons to make the cut(s) on the 3D image.
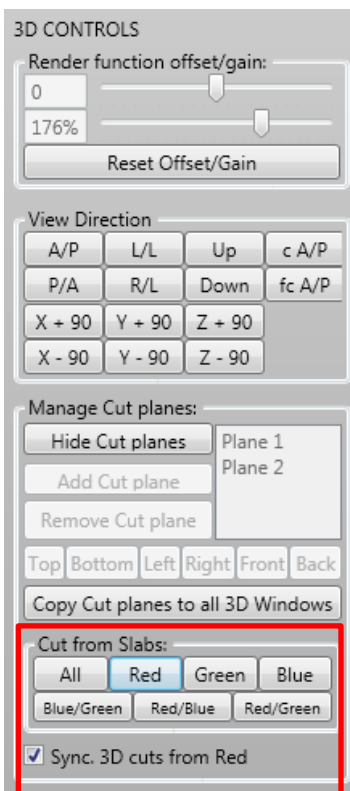
For example, if you wanted to cut just one section from the rendering, you could use the sagittal view to create a slab, and then click on the "Red" button.
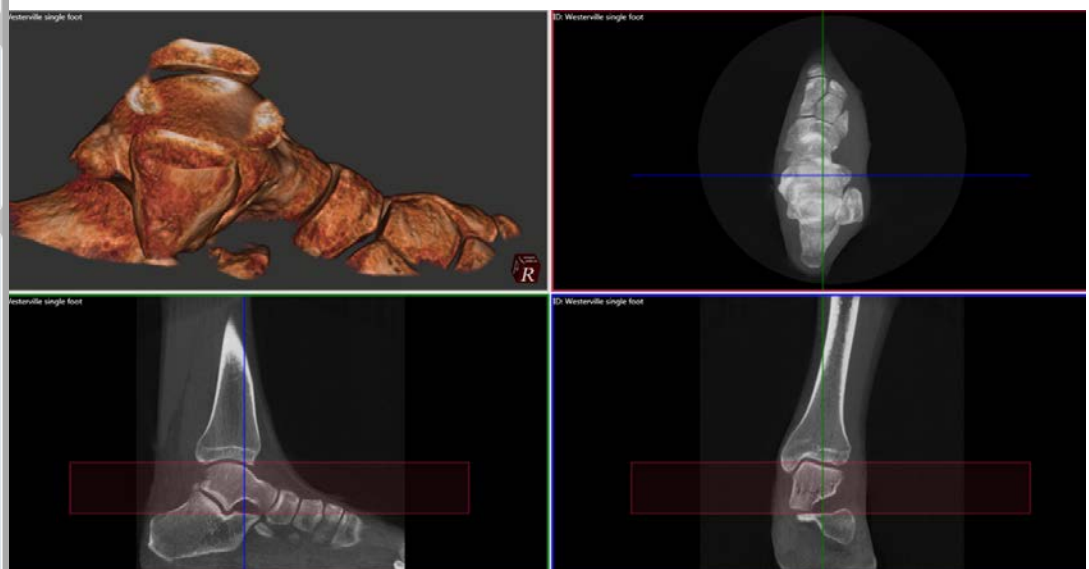
Or you can cut from 2 or all 3 slabs. In this example below, a slab was created in all 3 MPR views and the "All" button was clicked:
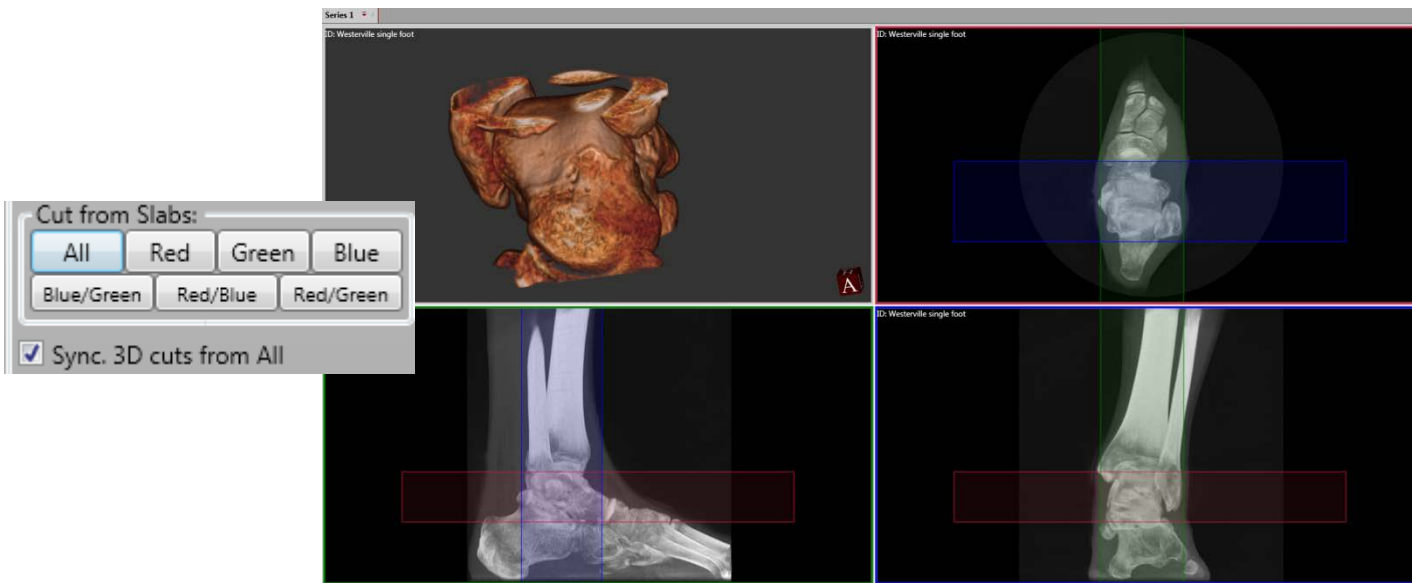
Note: to restore the original 3D rendering, click on the "Hide Cut Planes" button under Manage Cut Planes.

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Render Types:

To select various 3D Rendering types, click on the Views icons in the 3D Control area. This will display a pop up window with various options to select from. Select Render Type.
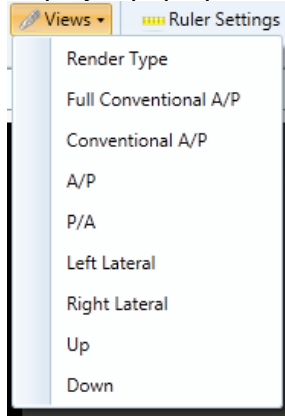
When Render Type is selected, a window will display thumbnails of the various default types of 3D renderings currently available. They are:
1. bone_skin
2. bone_skin2
3. bone_transparent skin
4. transparent_colorized
5. x-ray
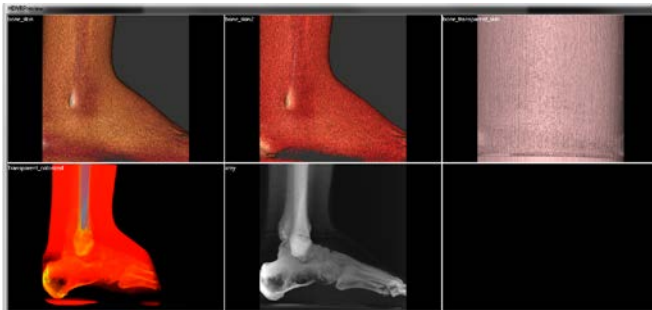
When one of these options is selected, that render type will display in the 3D Render window. Now you can adjust the rendering by using the Render function tools and dragging the slide bars. The most effective change of renderings will come from the slide bar.

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Creating 3D Frame Sequences:

There is the ability to create a WMD video or frame sequence of the 3D image rotating around either the X, Y, or Z axis. To do this, select the Combined 3D/MPR screen at the bottom of the screen as shown below:
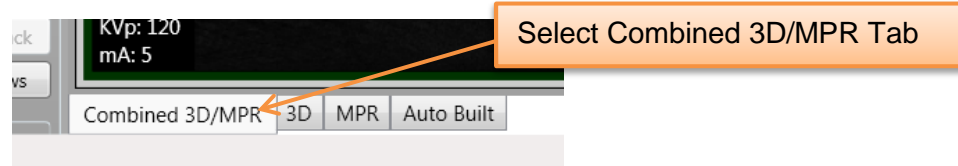
Then under the Tools and Settings on the left side of the screen, select the Create 3D Frame Sequence button:
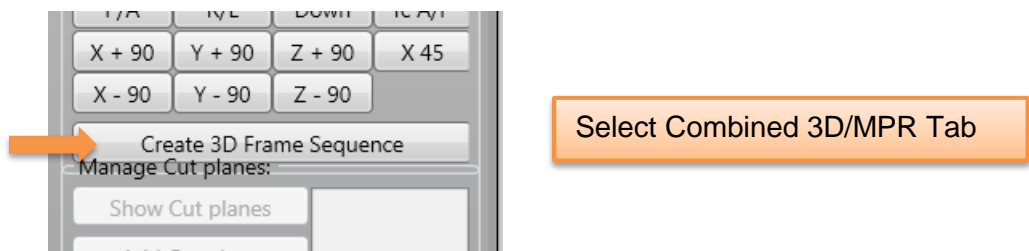
A pop up window as shown below will appear that allows for the selection of which axis to rotate around, how to save the output and how many frames to use to c. For each of the different output selections, the pop up window will look slightly different to ask the user to provide a location to save the video.
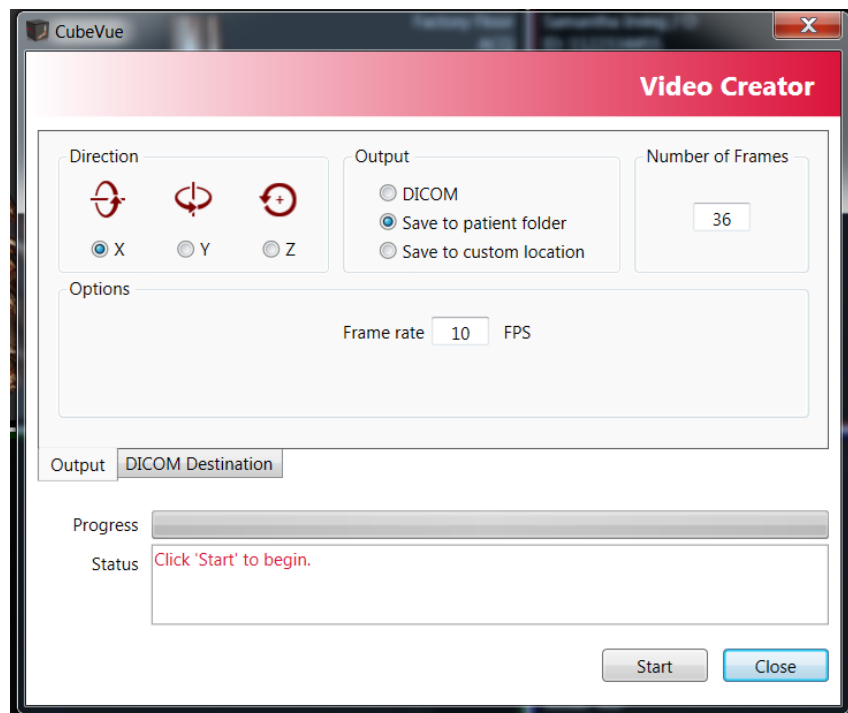
Under the Direction heading, select the axis to rotate around, either X, Y, or Z axis.

Under Output, select where to output the video that will be created.

- If **DICOM** is selected, the DICOM Destination tab can be used to set up the DICOM location.
- If **Save to patient folder** is selected, the video will be available from the Patient List as a separate entry under this patient with "Screen" listed under the type column.
- If **Save to custom location** is selected, the location will need to be entered in the field below, or the Browse can be used to set the location.

The Number of Frames value represents how many total frames or images that will comprise the video and can be adjusted as desired.

The Frame Rate shows how many frames will be displayed in Frames Per Second when the video is viewed.

Once all of the fields are set to the desired values, click on Start to create and save the video.

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Saving Sessions and "Series" Tab Functions:

When a study is loaded, the Patient Series Tab will display that current study name. The dataset can also be closed or "unloaded" from this tab by clicking on the **"x"** in the corner. The session work that has already been completed will be auto saved, so when the study dataset us re-loaded again, the sessions work will automatically load.
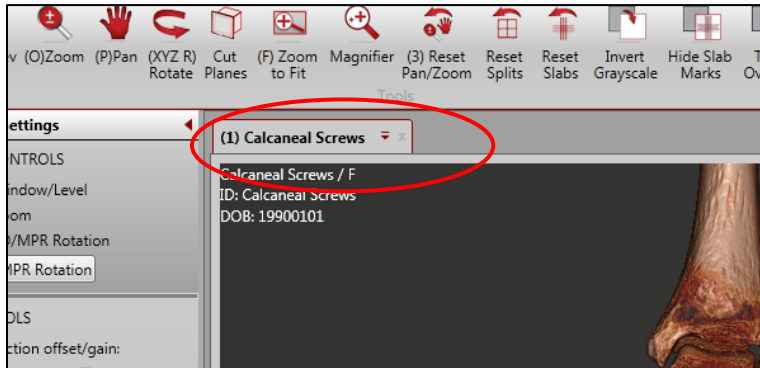
However, there is also a Drop Down Menu that provides a "Save Session" functionality so that you can save several different planning's.

Click the Drop Down Icon to access the Drop Down Menu to Save Session:
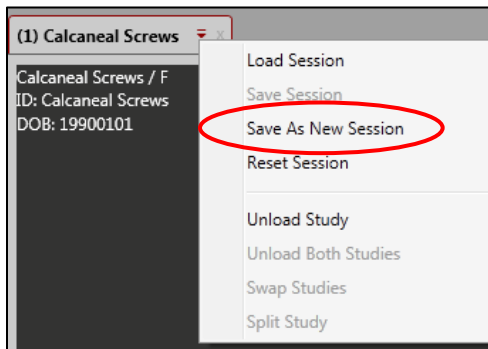
From this menu, then select "Save As a New Session" for the Session Manager Dialog Box. Enter in an appropriate Session Name over the "Type a Description" Session Description. Click inside this text box to enable the cursor for typing. Click OK to close the Session Manager.
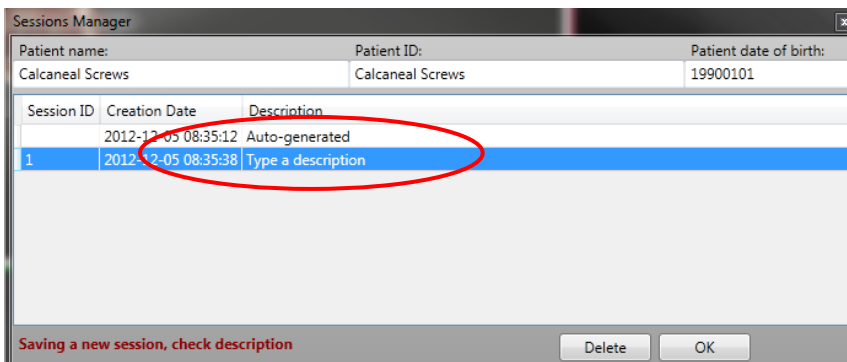
Then at any time, a Saved Session can be accessed and loaded by selecting "Load Session" from the Drop Down Menu. This will open the Session Manager where you can then highlight the desired Session and click OK to load.
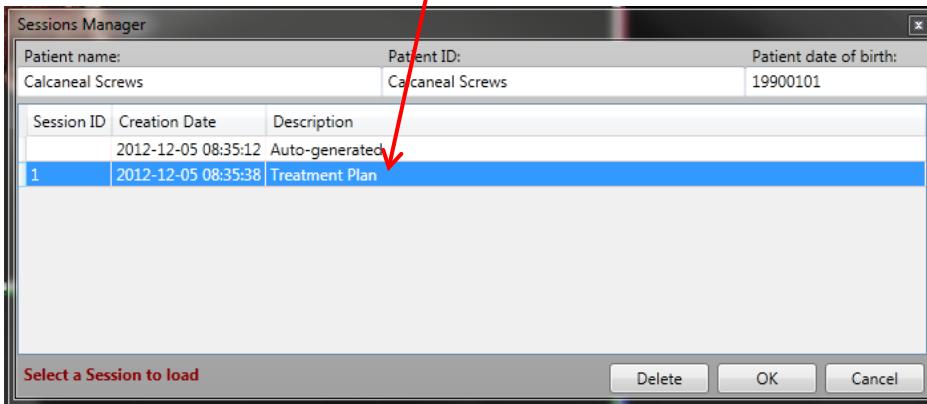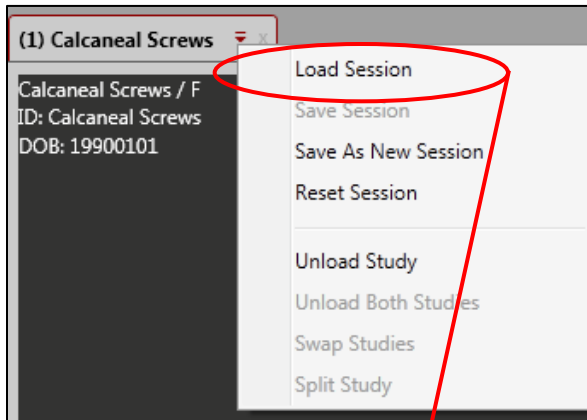
From the Drop Down menu, the Dataset Study can also be Reset, which will re-load the original dataset to its pre-worked state. And a Dataset Study can also be "unloaded" from this drop down menu as well.

Input: Load Function

The Load function is provided to allow the scan to be viewed in CubeVue, either the Raw or Recon file. But, when using the Load function, the patients scan will NOT be added to the existing Patient List. Any changes to the scan that are made, measurements, etc, will not be saved. The scan will not be added to the database of scans available to view.

To perform the Load function, click on the Load icon from the Patient List tab:

Then follow the steps to load the study into temporary memory for CubeVue. Remember, any plannings done will not be saved.

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Input: Import Function

A patient's study can be Imported to add it into the current patient database. When this is done, the patient's scan and any work done on that scan will be stored on the PC with the other scans in the Patient List. To Import a study, click on the Import icon from the Patient List:

Then there will be a pop up box that will ask for the Input Location. Once that is provided, the study will be in the database on the current PC.
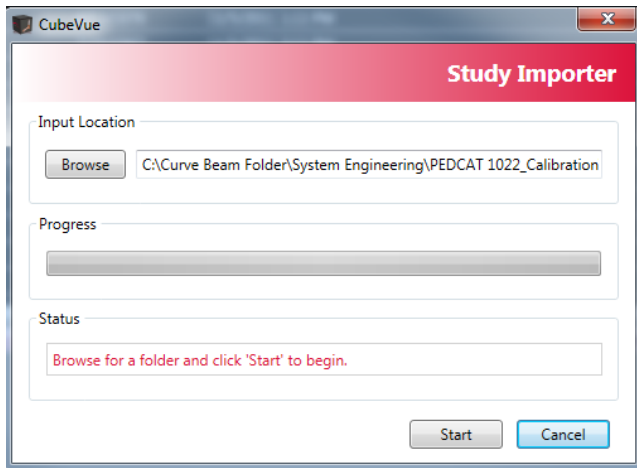
Output: Saving Images as JPG images

To save any one individual image as a JPG, click it to highlight and then click on the Save JPG icon, then select the location to save to.
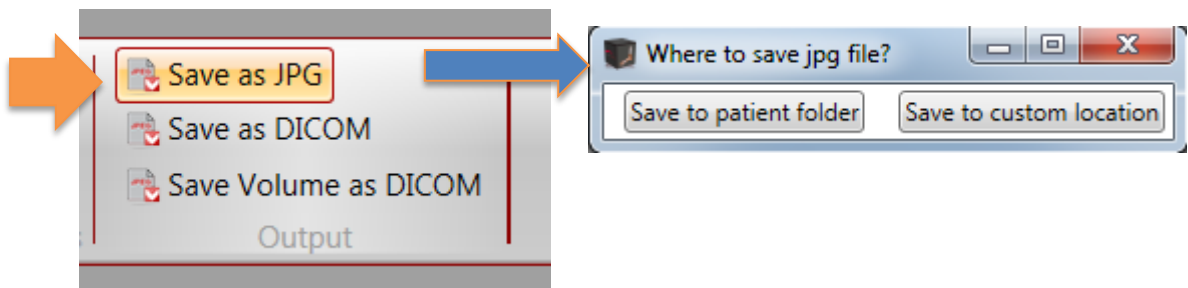
If Save to patient folder is selected, the file will save to the patient's folder and remain there. The JPG can then be exported using Media Export if desired. If Save to custom location is selected, there will be a prompt to browse to the desired location.
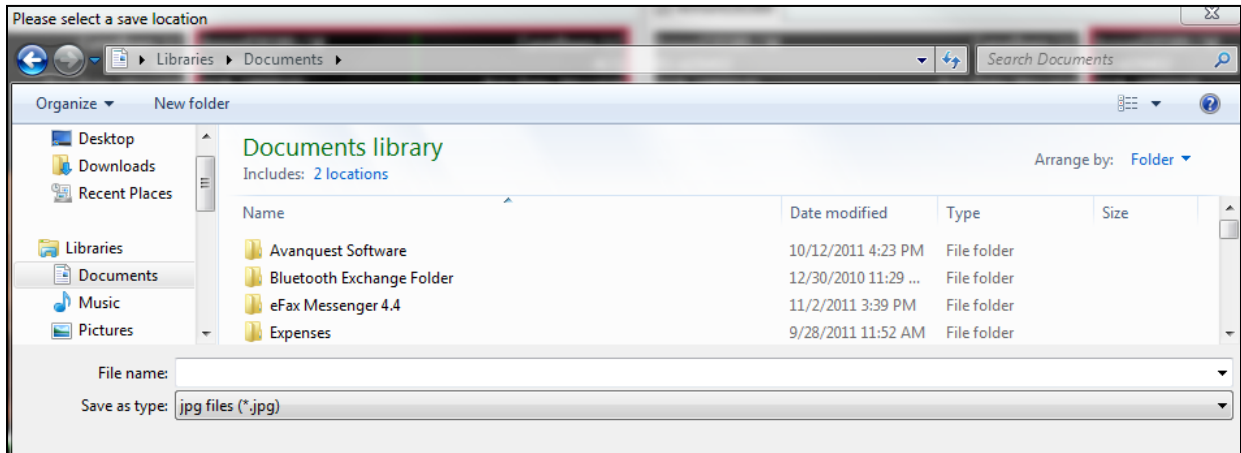
Output: Media Export

Burning a DISK with a free CubeVue Viewer: The software has functionality that will allow for an auto burn of a disk that contains the desired dataset(s) along with a limited-function copy of the CubeVue viewing software. The limited-function viewer does not have volume render capability. The receiving user of this disk can then open the dataset(s) in the CubeVue software for viewing. This function allows the end user to also export and burn individual images of 3D renderings, or any image of choice to the disk which can then be viewed via the CubeVue viewing software. This is useful if the receiving user does not possess one of our 3D licenses necessary for building 3D renderings. (If the receiving viewer desires to have full 3D rendering functionality, they can purchase that license through CurveBeam). Media Export will also export any CubeVue Saved Sessions associated with a dataset.

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There is a Tab on the upper Menu which is called Media Export. This Tab is used specifically for creating a dataset CD with CubeVue self installer.

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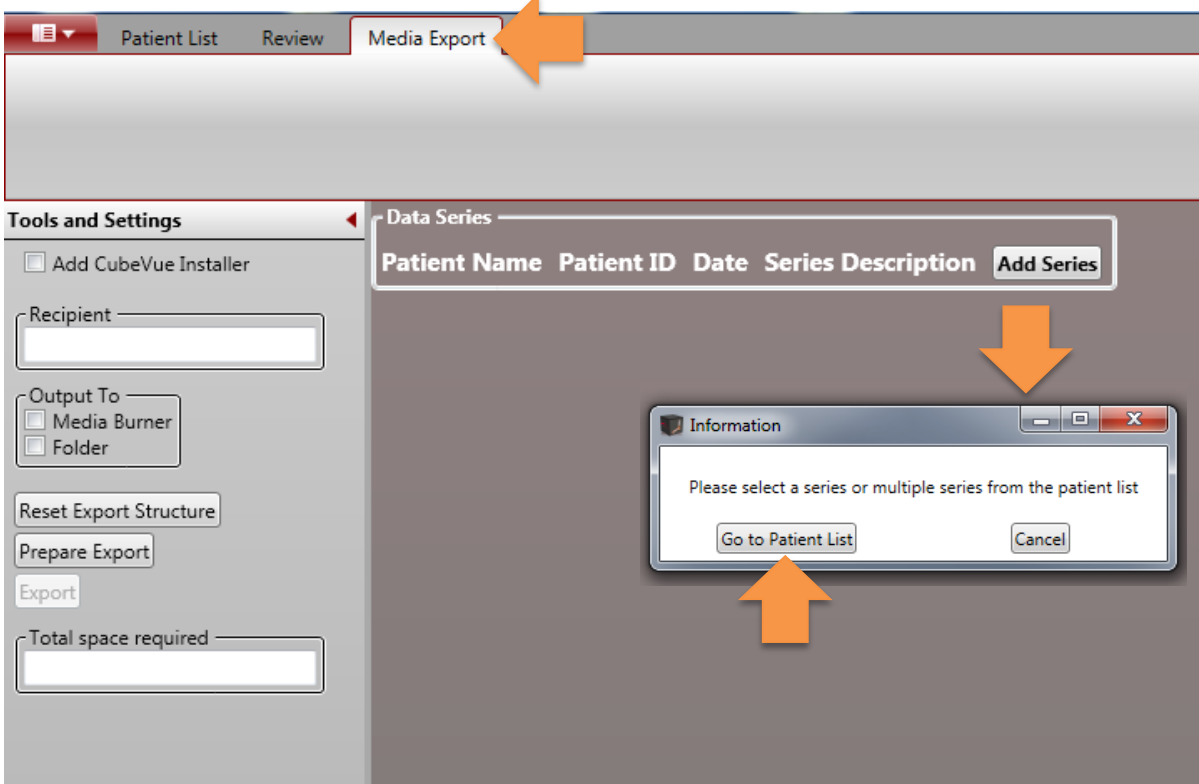
The first step is to click the Add Series button. This will return to the patient list for selecting a dataset(s) to burn.

- From the Patient List, highlight the desired series to be burned to the CD and right click on the series to access the new Pop-up box. Select the new item named **"Media Export"**. This will automatically add the series into the Media Export list.
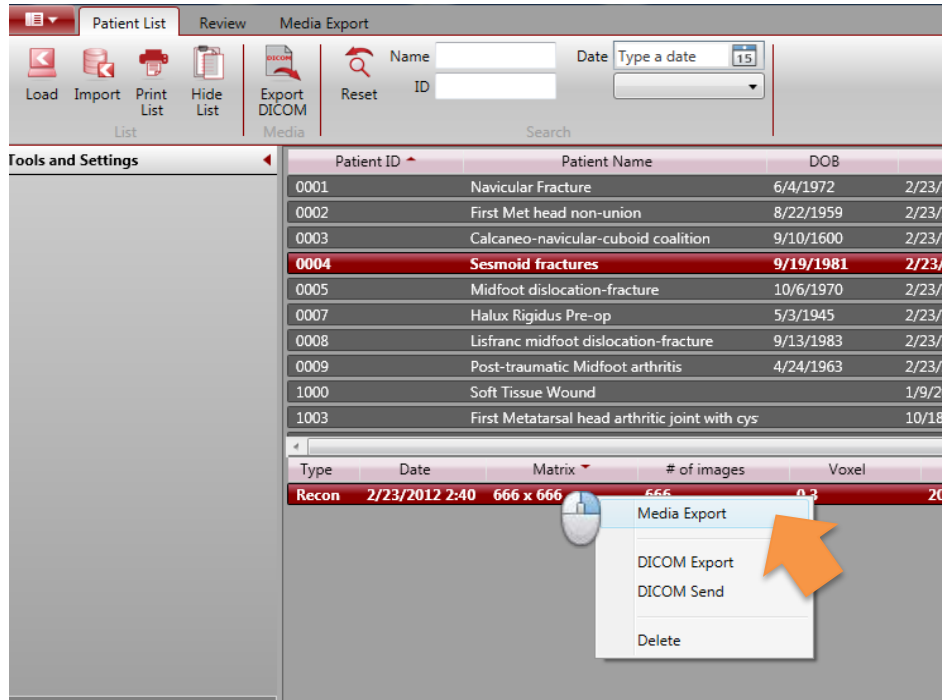
- Now click the Media Export Tab again and see the Selected Series saved in the list
- Multiple series can be added in the same method if desired.

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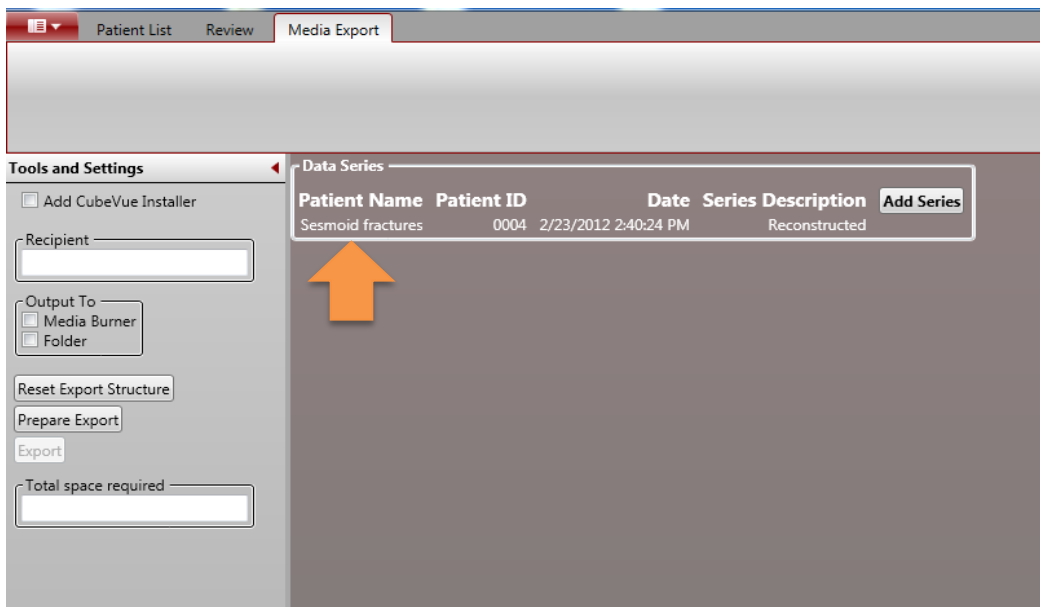
Also, if the user wishes to Add JPG images from this case into the Media Export Data Series List, open the series and in Review Tab, save one or multiple JPEG images to the Patient Folder. Then these will show up in the Data Series List as thumbnails. Each has a check box for selecting which to choose to be included in the Media Export. Double click on the thumbnail to enlarge for viewing if desired.
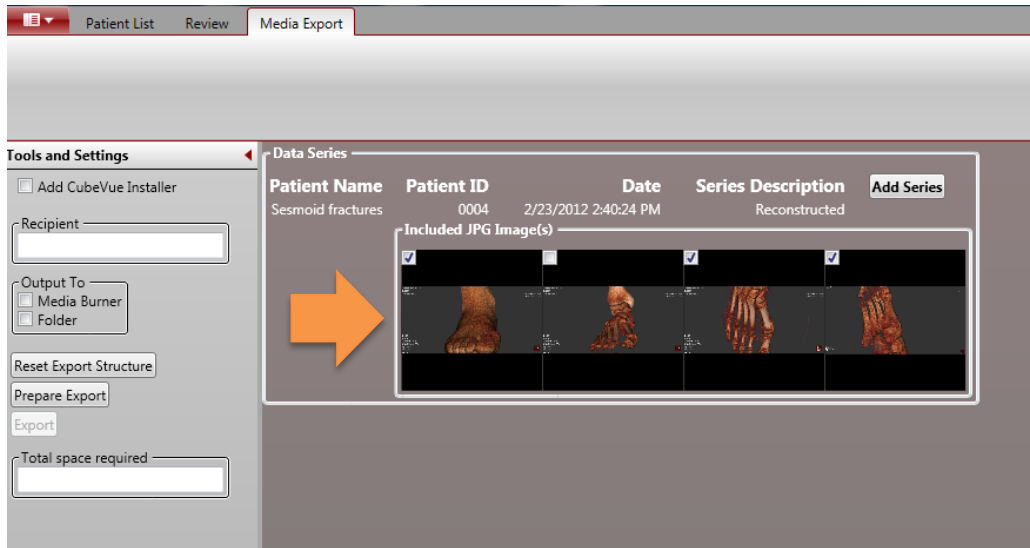
- Next, complete the items in the **Tools and Settings** section:

Always Check this box to add the CubeVue Installer to the Media.

This box is **Mandatory:** A Recipient Name must be filled in or the Export button will not enable.

Choose the location for the output. If you want it to go to a folder or USB drive instead of a Disk, select "Folder".

If this button is clicked, all the data under Data Series will be reset to no data.

Once you have selected the Output To item, click the Prepare Export Button. This must be done before the Export button is enabled.

Once the Prepare Export Button is clicked, the **Total space required** field will auto fill and the **Export** button will enable.

- If selected Output is to a Media Burner (disk), **INSERT the DISK NOW** into the disk drive.
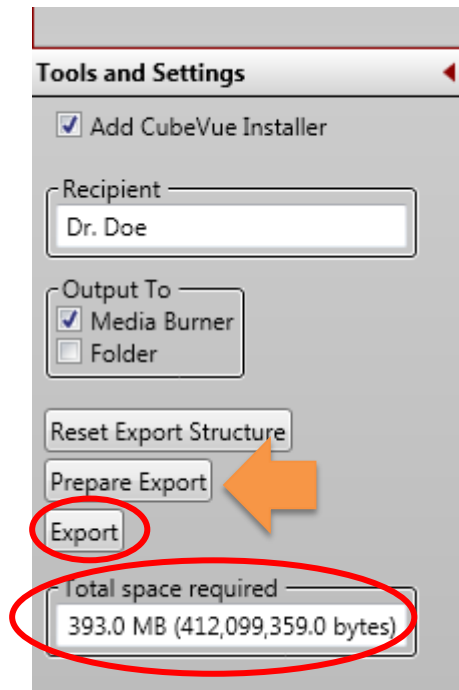
- Next, click the **EXPORT** button and the status bar will activate. When completed, a Balloon at the lower right hand corner of the screen will pop up. Click on the pop up.
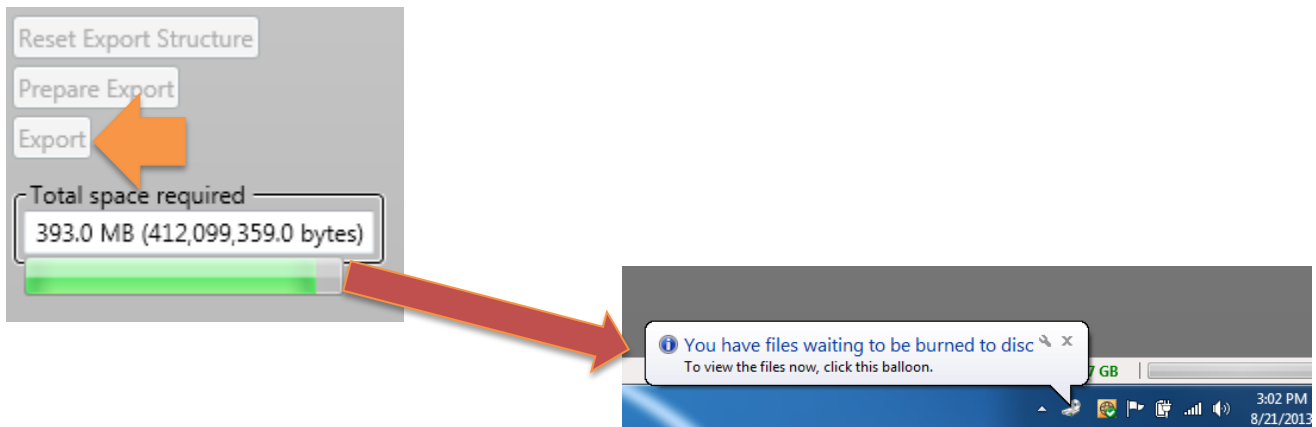

- If the Balloon disappears before you had a chance to click on it, go to START/Computer and click on the CD/DVD Burner Drive. Notice the **"Files Ready to Be Written to the Disk"**
- From this *Files Ready to Be Written to the Disk* Window, Click on the **Burn to Disc** button.

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- This will open the *Burn a Disc* Window. Select **With a CD/DVD Player**, click **Next**.
- This will open the *Burn to Disk* Window. Click **Next**. This will initiate the auto burn. The CD will eject when completed.
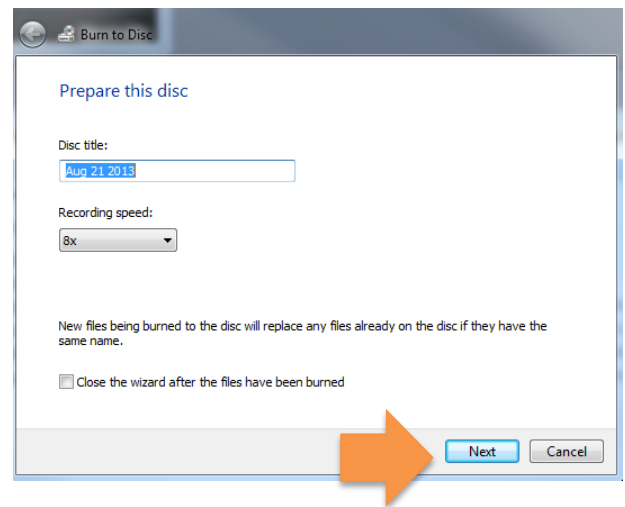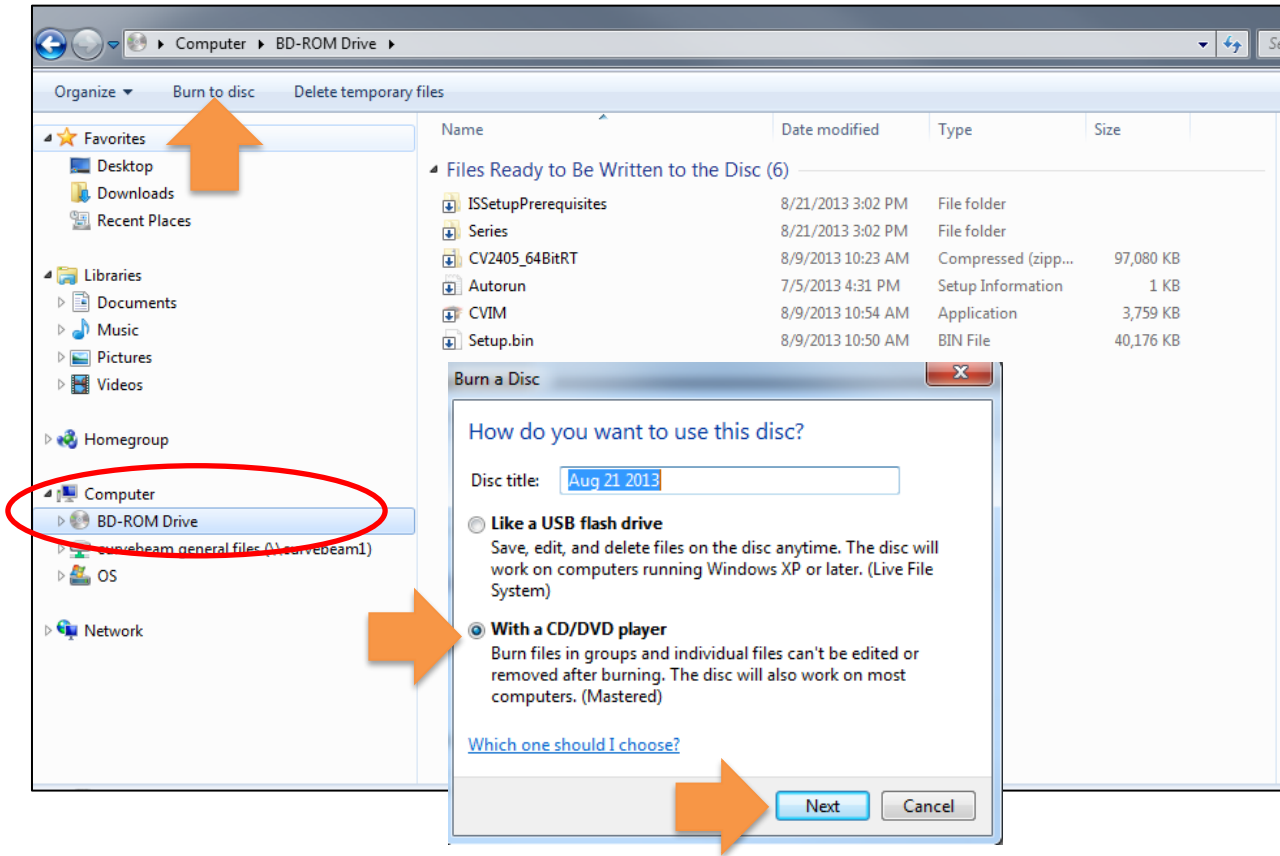
Media Export to a Folder:

- Add the desired Patient Series as described in the previous instructions.
- If you wish to perform a Media Export to a Folder or a USB Drive, select the **Output To** location as **Folder.**
  Note: a Media Export to a folder requires an Empty Folder, so it would be best to Create a New Folder to export to.
- Select **Prepare Export**
- Select **Export**, there will be a prompt to **Browse to** the desired folder. If there was no folder previously created, select "Make New Folder" and then name appropriately.
- Click OK.
- The Overwrite Warning message will appear if the selected folder contains ANY files. ALWAYS select an empty folder or click "Make a New Folder" to create a new folder for export, or if you click OK, then the existing files will be deleted and the Media Export files will replace them.

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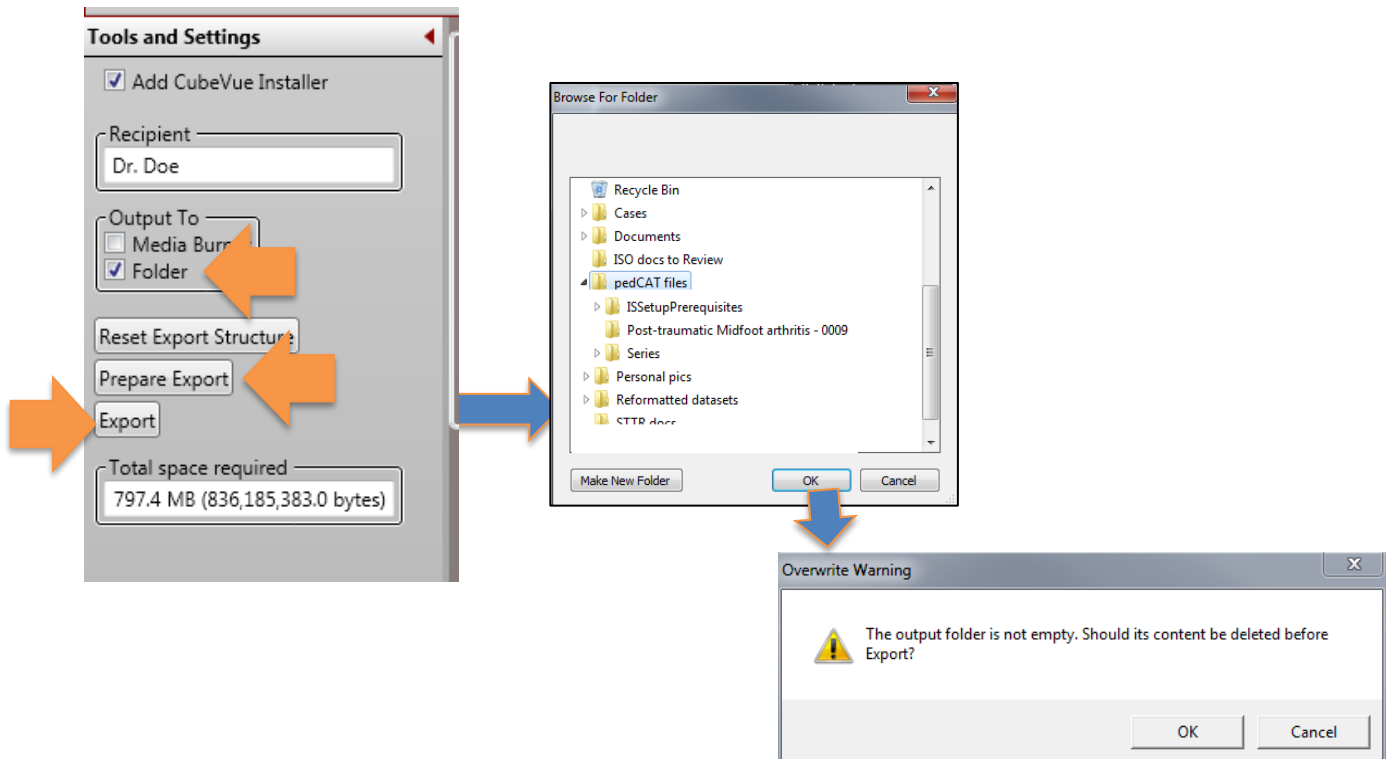
<u>Installing a Media Export CD on a fresh computer, with CubeVue Installer</u>

- Insert the disk into the disk drive. From AutoPlay, select **Open folder to view files on the disk.**
- Run the **CVIM.exe application** file As Administrator to launch the CubeVue Install Manager.
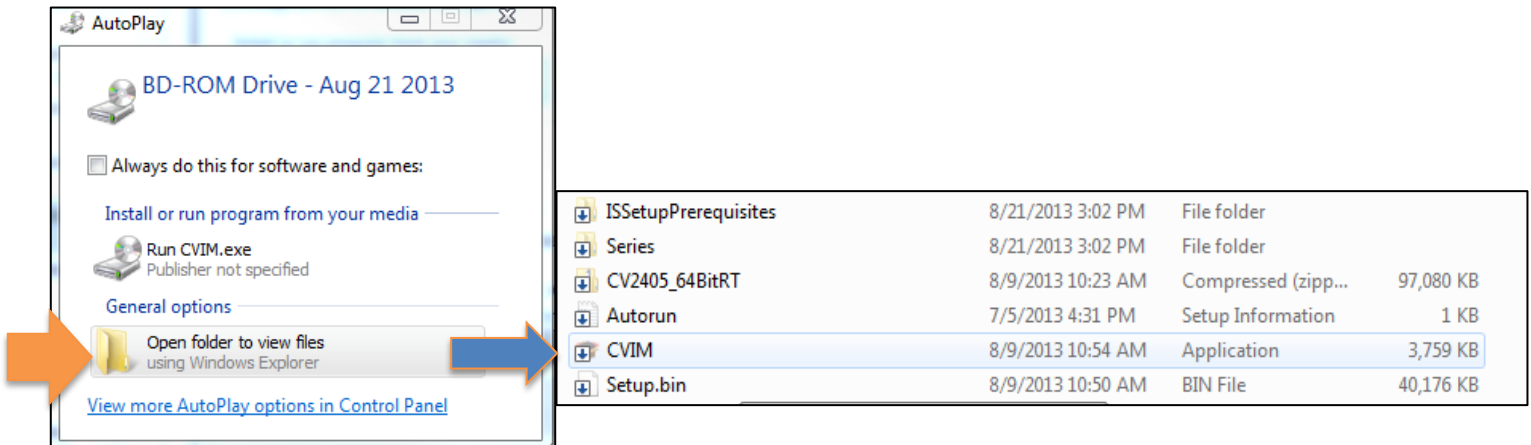
- In the *CubeVue Install Manager*, Click **Install CubeVue & Import Data**. If CubeVue is already installed the Install CubeVue button will be disabled, so just import the data by clicking the **Import Data** button. The dataset as well as any Saved Session files and Save as JPG to patient folder files will import. Note: If there were JPEG images that were Saved to Folder on this Media, then those can now be viewed in the 3D rendering window in the Review Tab/Combined 3D/MPR Tab

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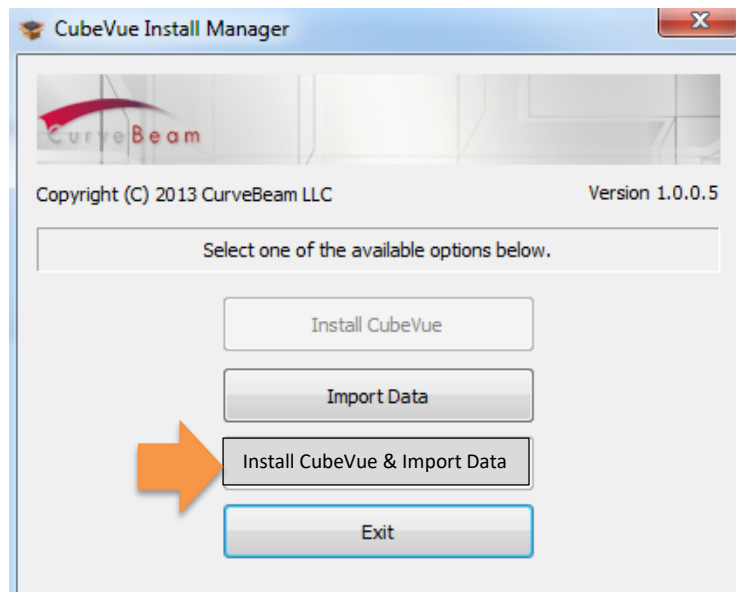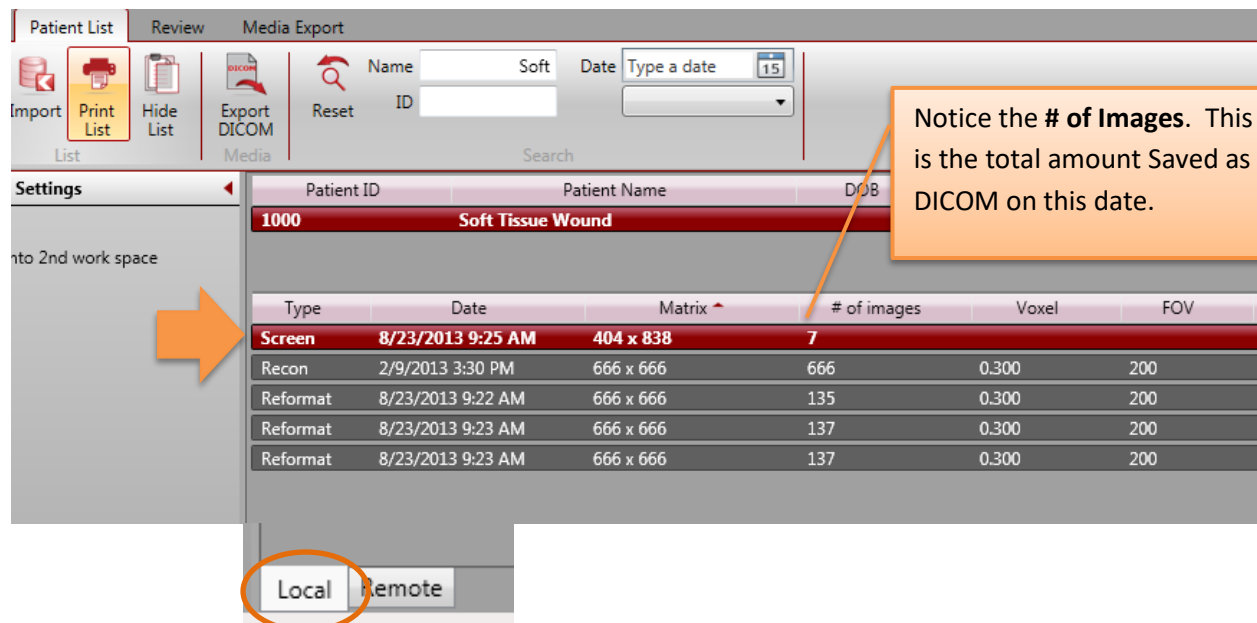
Save As DICOM

The Save As DICOM function is used to save static images in the DICOM format. The purpose of Saving static images, in DICOM format, which is simply an extension of Saving static images in JPEG format. However, the intent of this is more specific to saving images that can be sent to a PACs server or DICOM Application entity, as the JPEG images are not compatible with such systems. This would most commonly be used for saving static 3D rendering images as DICOM files

To Save an Image as DICOM, click on any desired image. The last image window that has been clicked is the Active window. Next, Click **Save as DICOM** in the Output section of the Main Menu Bar.
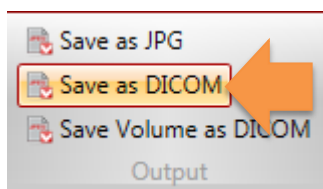
There will be an audio sound when clicked and the image will automatically be saved to the Patient Output folder. There will also be a message in green color at the lower left hand corner of the program that reads "**DICOM IMAGE SAVED**"

Multiple images can be saved in this fashion. These images are then accessible ONLY from the Patient List LOCAL Tab. These images can be loaded and viewed, Exported as DICOM, Media Exported, or also sent to a PACs server or DICOM AE. (see section on DICOM Send for instructions on sending).

Notice the **# of Images**. This is the total amount Saved as DICOM on this date.

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To View the SCREEN images in CubeVue, double click to load. Scroll the mouse wheel to advance to the next image in the Series. This series can also be loaded into the 2nd Workspace.

The functions enabled for SCREEN series are W/L, Zoom, Pan, Zoom to Fit, Reset Pan/Zoom and W/L Settings (reset). To close the SCREEN viewing window, click the "X" on the patient name Tab.
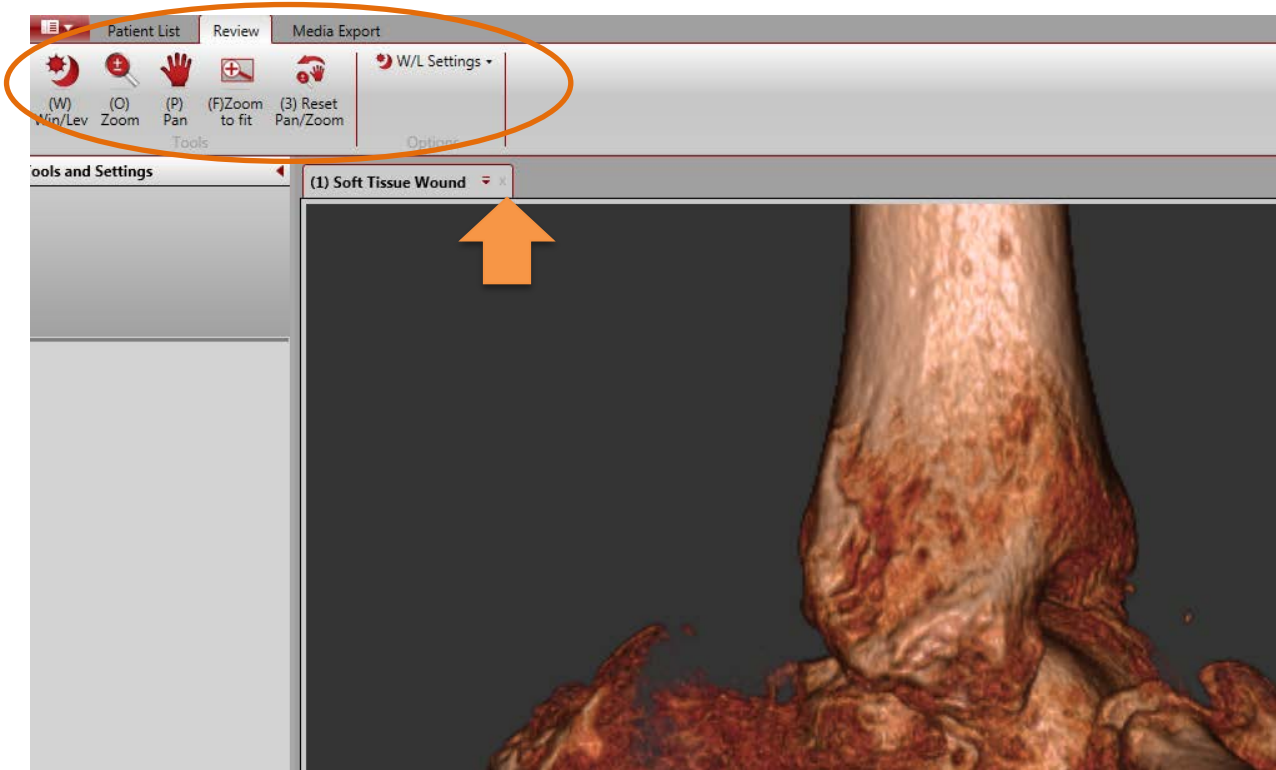
Save Volume as DICOM

The Save Volume as DICOM feature provides a method to re-save your dataset after a re-orientation (volume rotation) in DICOM format. At the same time, it provides functionality to reconstruct the datasets in a format that has a larger slice thickness.

For example, the original datasets are currently reconstructed and saved at 0.3 mm voxel for MFOV scans, and 0.37 mm voxel for LFOV scans.   We can utilize this new function if the dataset is desired to be sent to a PACs or DICOM server with a larger slice thickness. This may be a common need as PACs servers might not easily import the large volume of data at the smaller slice thickness.

This Save Volume as DICOM function also provides a method for reconstructing the volume in axial, coronal and sagittal planes as opposed to the original dataset, which is saved strictly as axial slices. This again may be needed for many PACs/DICOM servers.

Ultimately, from CubeVue we can now re-orient datasets and save the dataset with various slice thicknesses and outputs. We refer to these new saved datasets as "Reformats". Then we can manually send these reformatted datasets to a PACs/DICOM server as needed. (see section on DICOM Send for instructions on sending).

- To initiate the Save Volume as DICOM feature, first create the orientation that you would like to save or export, then click on the **Save Volume as DICOM** button from the Main Menu Output section from the Review Tab/Combined 3D MPR Tab. This will open the DICOM Volume Creation Window.
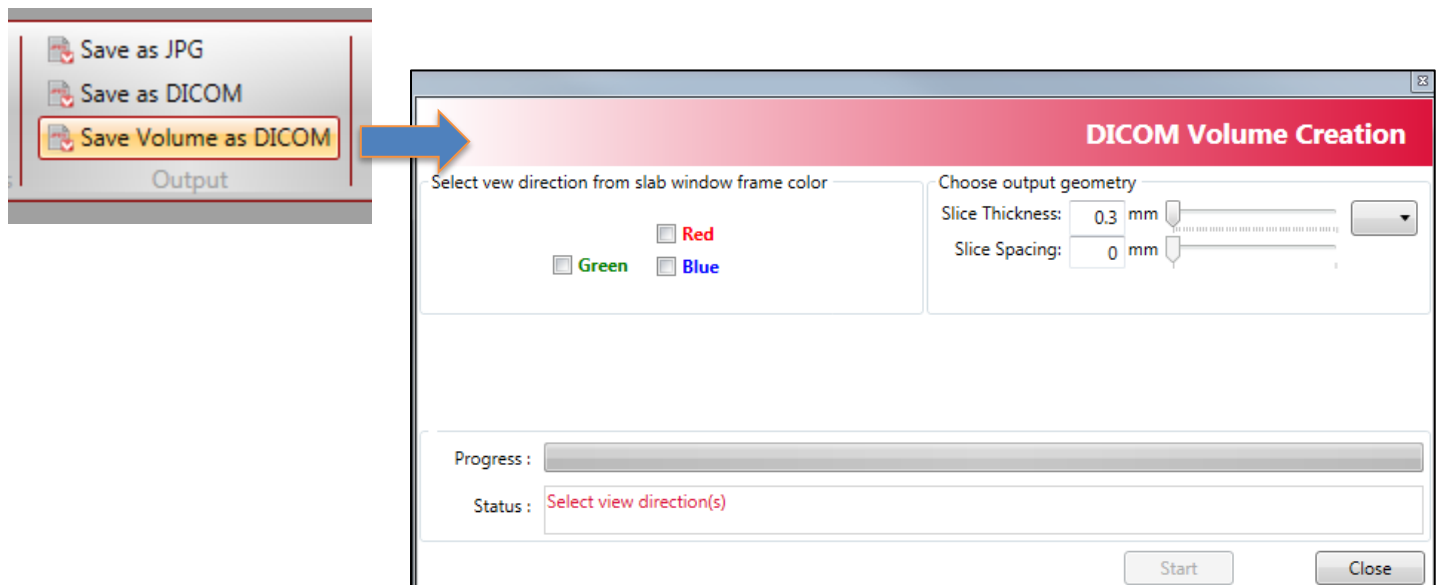
- From this window, first select the desired **View Direction:** In most cases, all of the view directions would be selected. *Red = axial, Green = sagittal, Blue = coronal.* However, there may be an event where only Red (axial) is necessary.
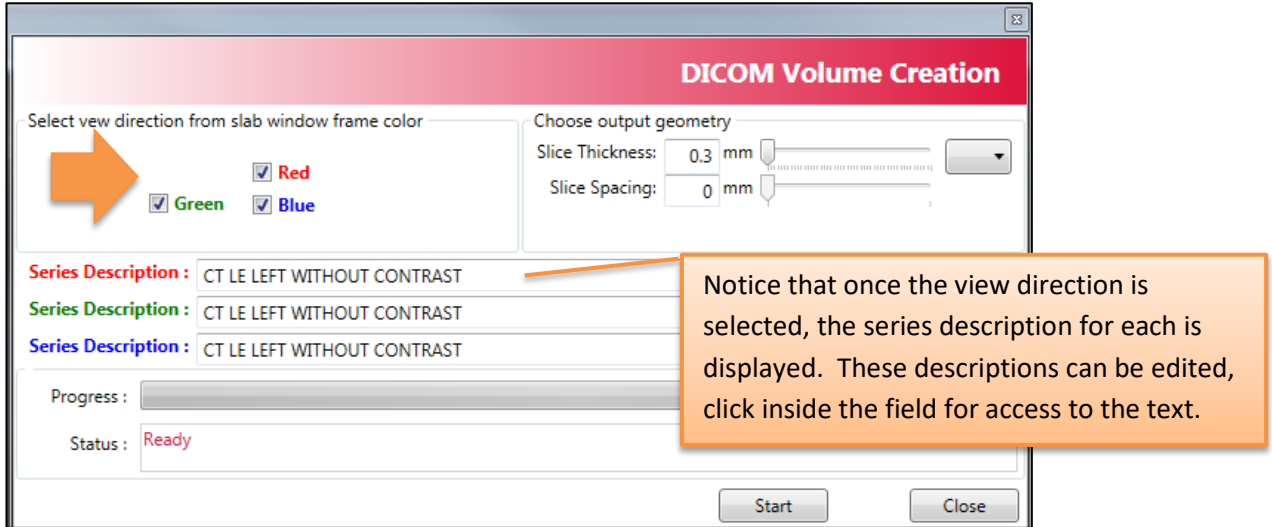

- Next, select the desired **Output Geometry**, then click **Start**. The default for slice thickness will display as either 0.3 mm for a MFOV scan or 0.37 for a LFOV scan. The options are to either click on the drop down menu and select 5x, 10x or 15x. Or you can drag the scroll bar for additional options in the current slice thickness with increments.

    5X is recommended in most cases and should be suitable for most needs.
    For a MFOV, 0.3 mm voxel scan: 5x = 1.5mm slice thickness
    For a LFOV, 0.37 mm voxel scan: 5x = 1.85 mm slice thickness
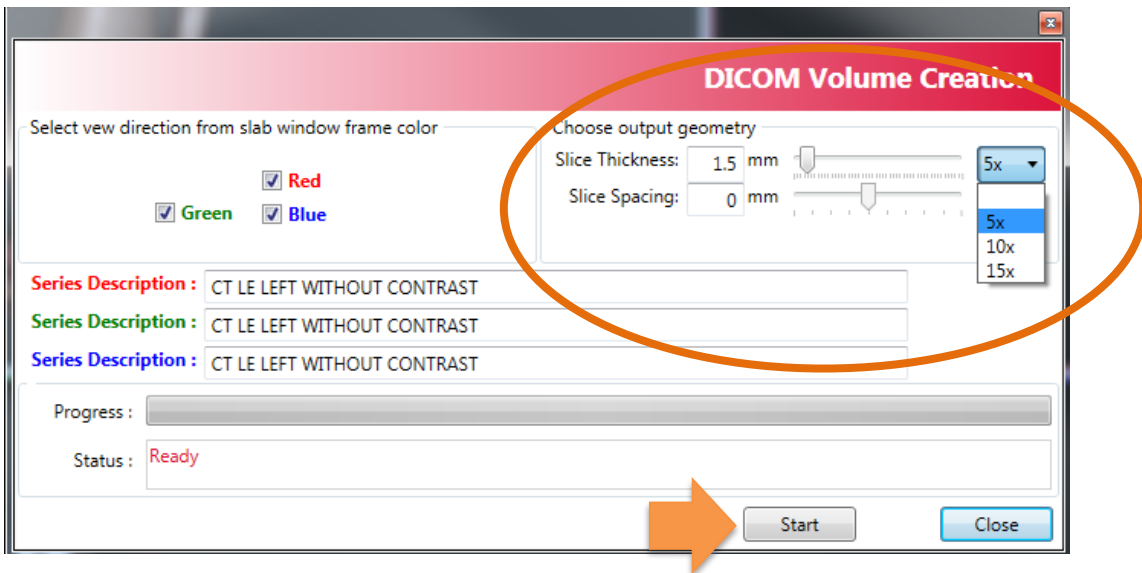
- Once the Status reads Completed, click **Close**. **The new Reformatted Datasets will reside under the Patient ID, Series Type in the <u>Patient List LOCAL Tab</u> only. The Series Type will be called Reformat.**

If you desire to delete any of these datasets, click on to highlight, right click for the pop up menu, select **Delete** from the menu. Select multiples by holding down the CTRL button then click each desired dataset.
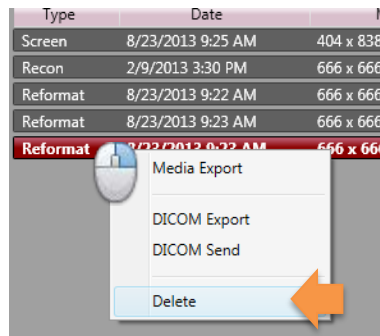

Note: Reformat datasets **Will NOT open** in CubeVue software. These datasets are no longer isotropic and not intended to be viewed in CubeVue. The original Reconstructed (RECON) datasets should be used to view in CubeVue.

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DICOM Send

Any of the datasets that reside in the Patient List LOCAL Tab can be sent to a PACs/DICOM server via the DICOM Send functionality. In most cases, the Series Types that will be desired to send via this method would be SCREEN and REFORMAT datasets.

From the Patient List LOCAL Tab, **highlight any or all of the desired Series to send**. Highlight multiples using the traditional method of CTRL click, or highlight all using the traditional method with SHIFT, click on the first and SHIFT click on the last.

- Right click on the highlighted dataset(s) to access the Pop Up menu and select **DICOM Send**.
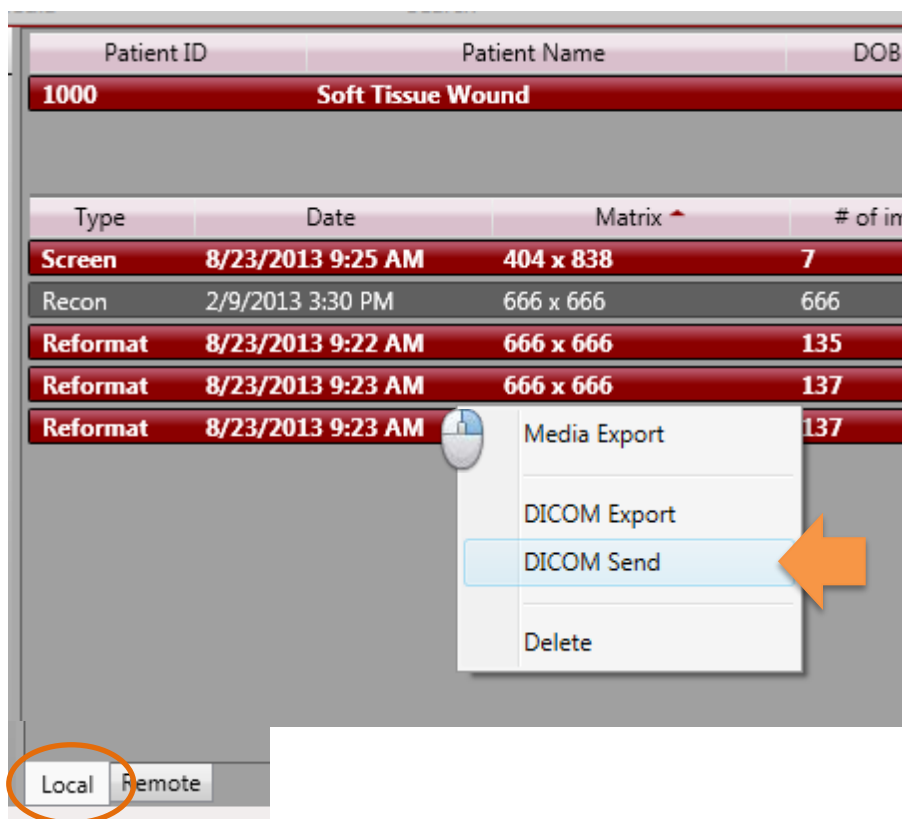
- This will open the *DICOM Sender* Window. In this window, one or multiple **Destinations** for the data send can be configured. Configure a Destination with the appropriate data and click the **Update** button to Save. To add another Destination, click on **New** and edit the Destination items, click Update to Save. Once there are Destination(s) configured, they will remain in the list unless deleted.

- Click **Start** to begin the Send. The Send time will depend on how many datasets and destinations are selected, the number of reformats created, and the speed of the PACS network.
- When the Send is completed, the Status will read "Completed".

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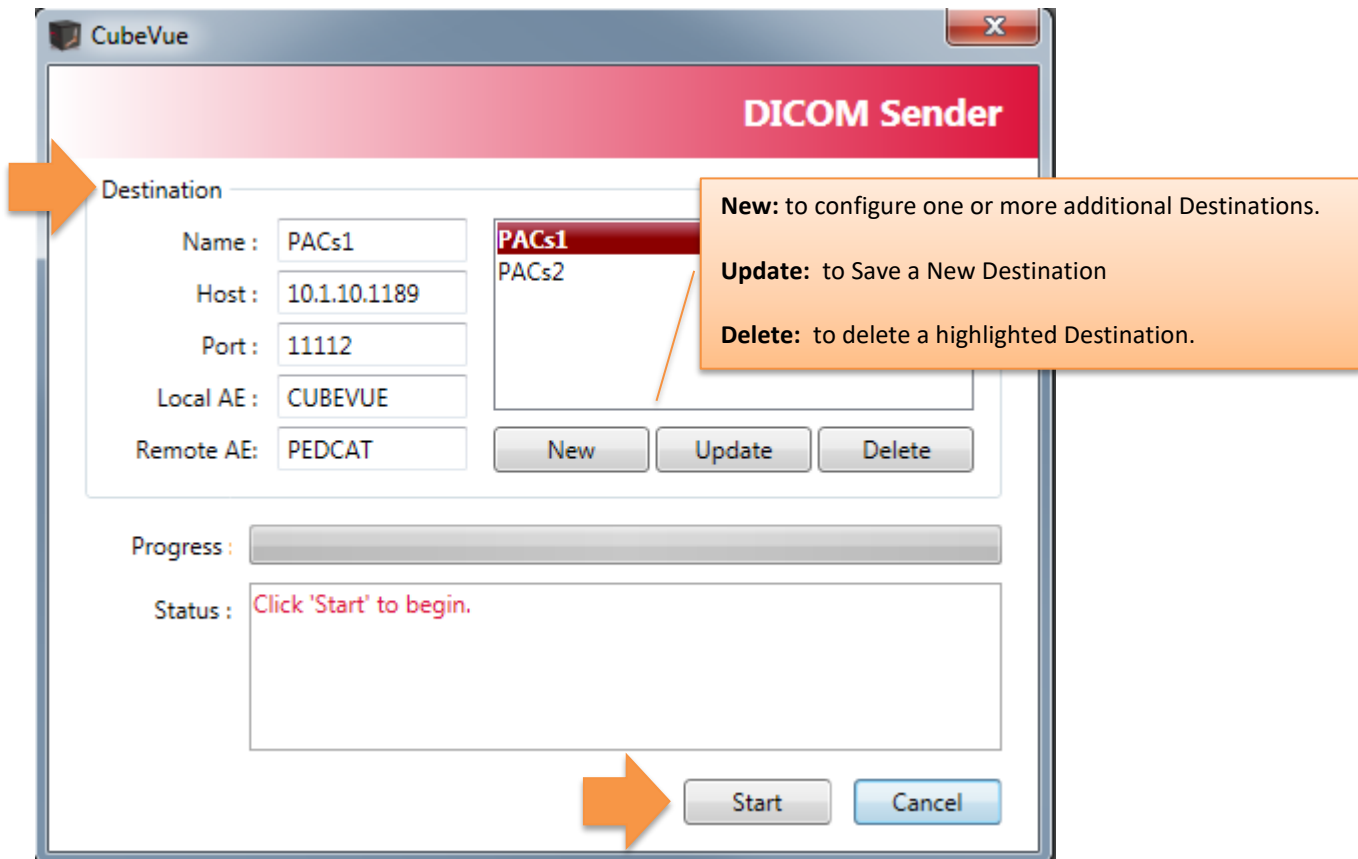
APPENDIX I: InReach Installation Instructions

⚠️ **WARNING** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous X-ray radiation or laser light exposure.
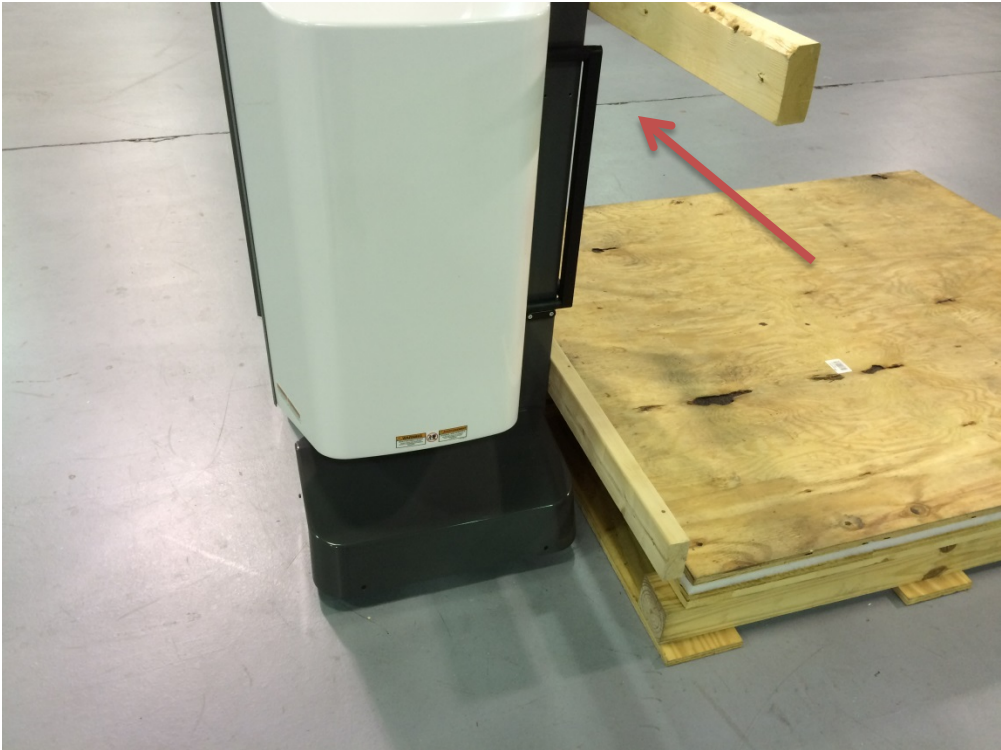
InReach Unpackaging

After removing walls of crate, remove 4 lag bolts with a 9/16" socket:
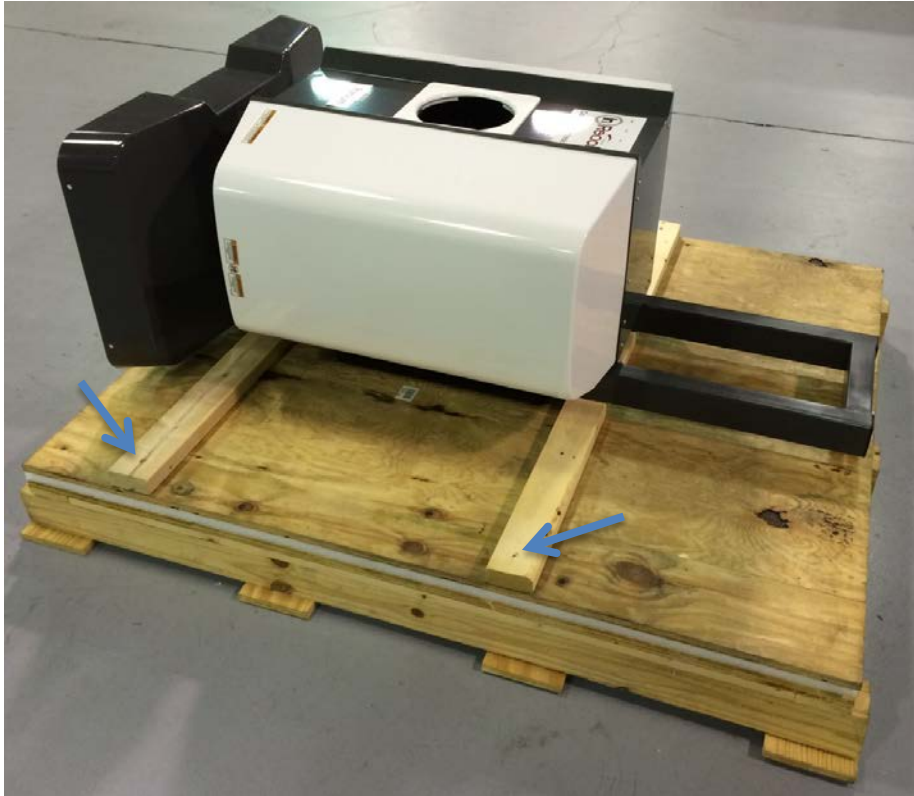
Then slide unit until bottom 2x4 is aligned with the edge of the skid:
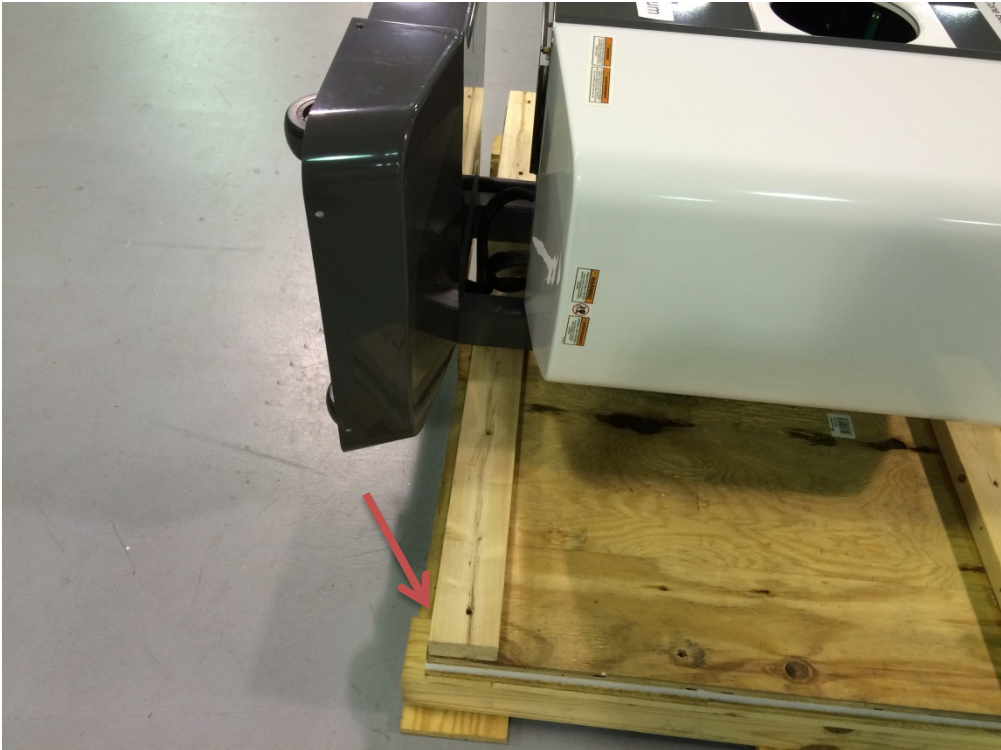
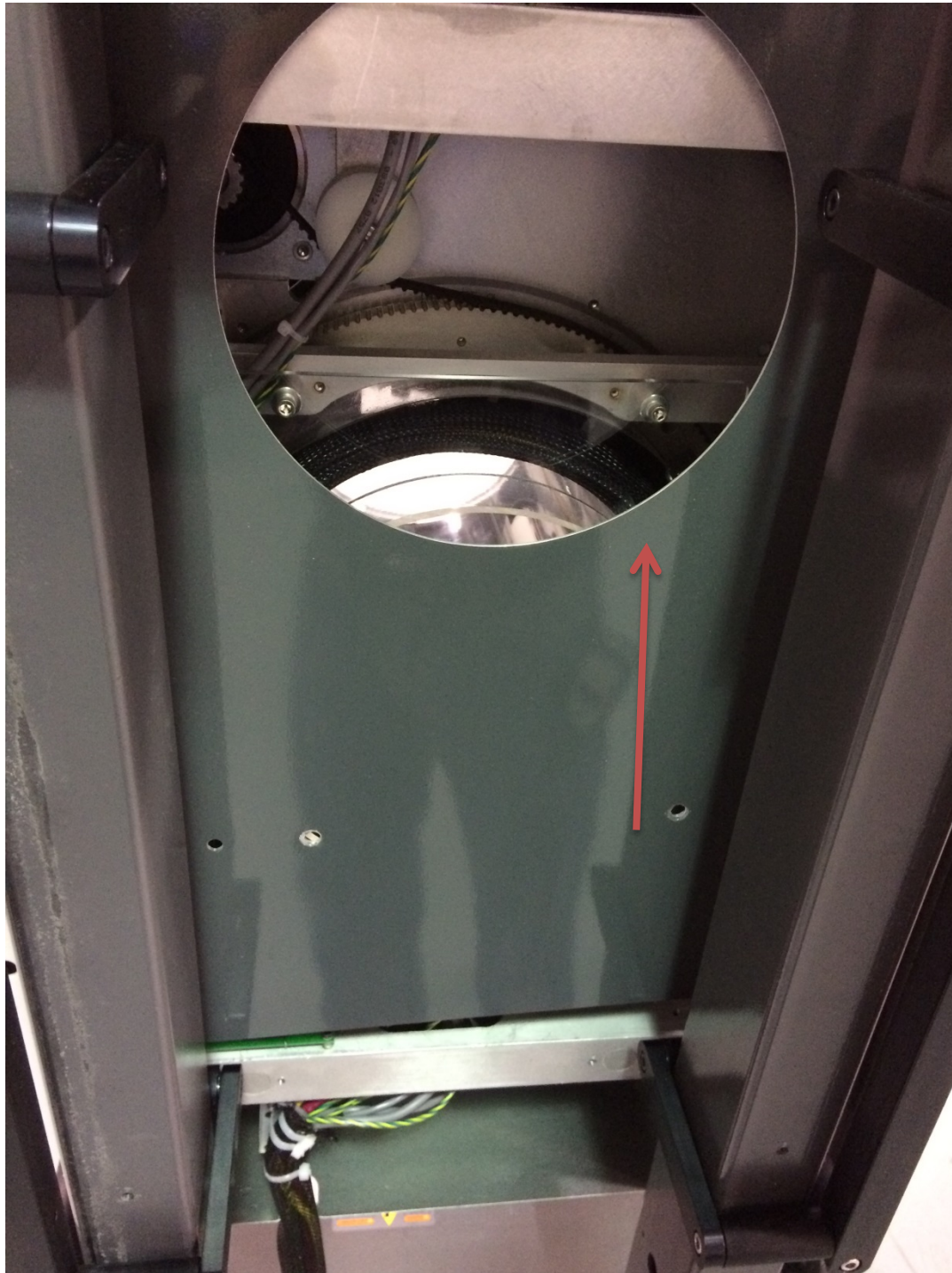Lift unit up from the top to stand it upright:
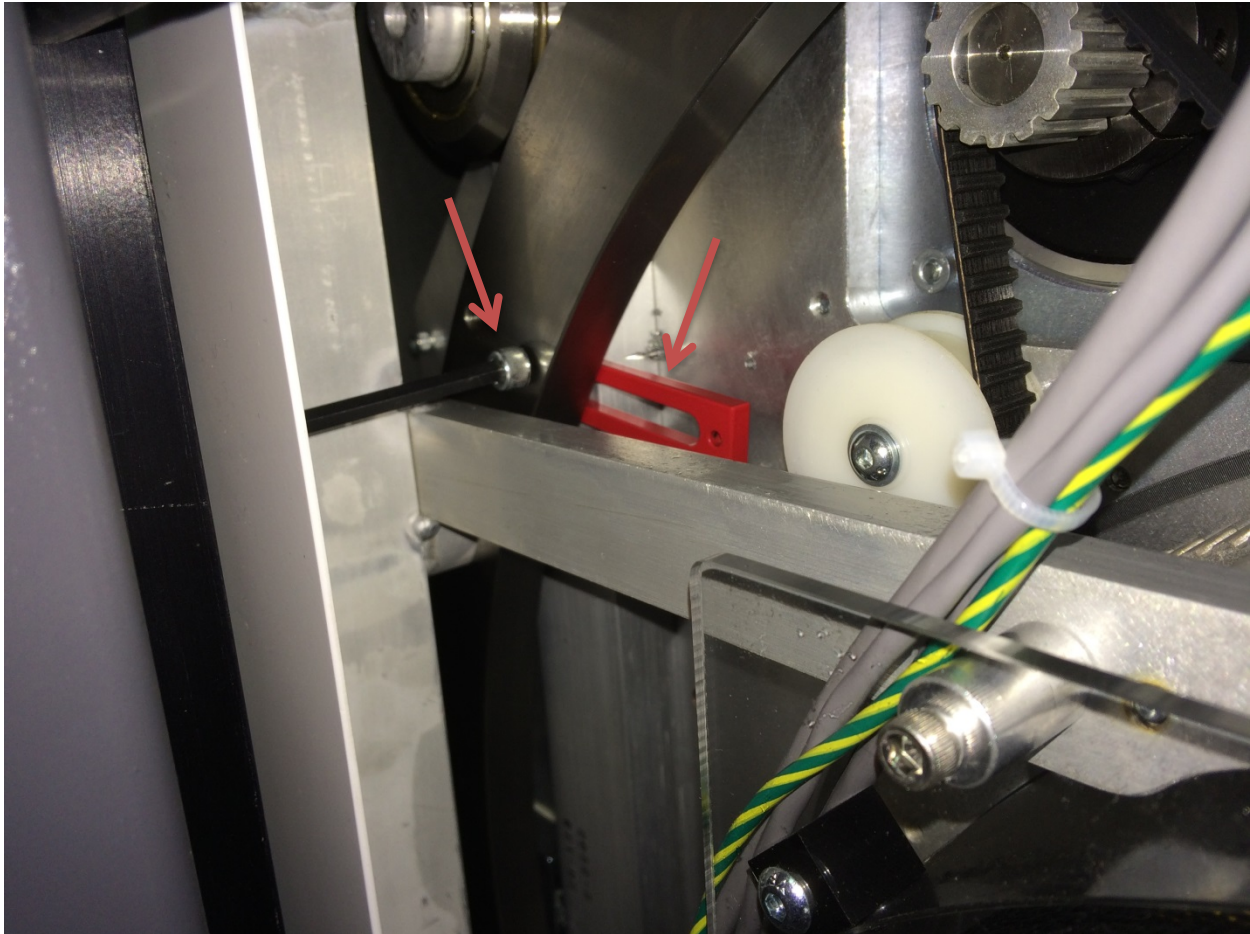
Remove 2x4's with a 3/16" Allen wrench:

Remove 4 screws using a 1/8" Allen wrench and remove rear cover…
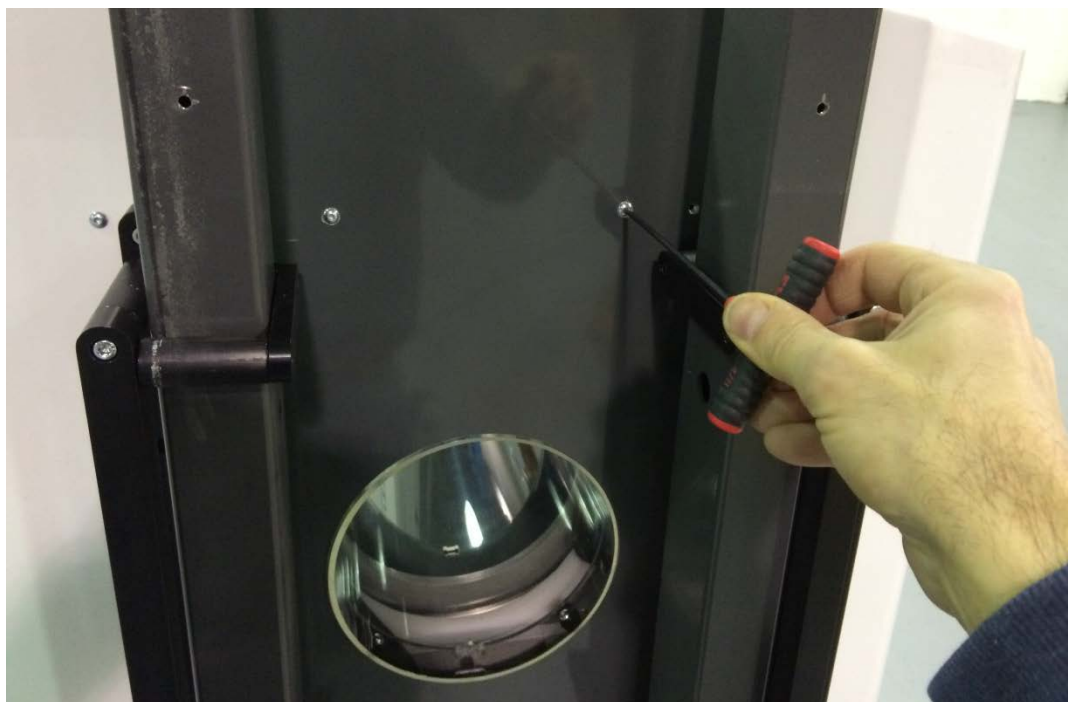
…by lifting it up:

Then remove 4 red gantry clamps using a 3/16" Allen wrench:

Once the scanner is in the desired location, lock the wheels by turning the screws on each wheel as shown below, without cover:

Once cover is installed, position the scanner to be 12" from the wall it will be attached to later. The wheels can be locked by tightening the screw on each of the 4 wheels, two on either side of the machine. Two of the four holes for the screws are shown below:

Tighten the screws in the holes on both sides of the scanner, to lock the wheels.
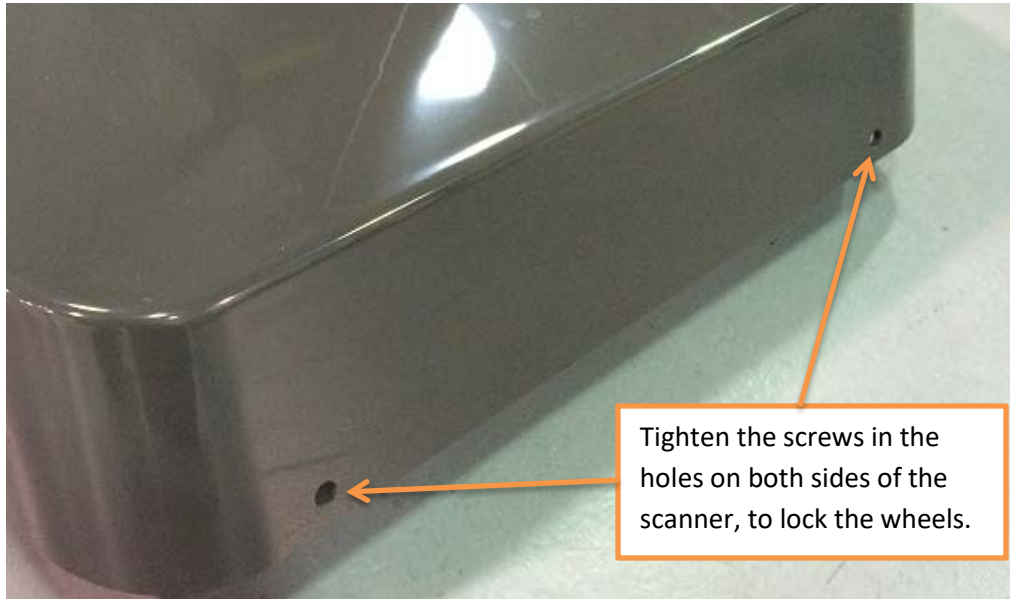
Once the wheels are locked, with the back of the scanner 12" from the wall, attach the Wall Strap to the back of the scanner and affix it to the wall. The wall strap is shown in the below image:

Wall strap attached at the back of the scanner.
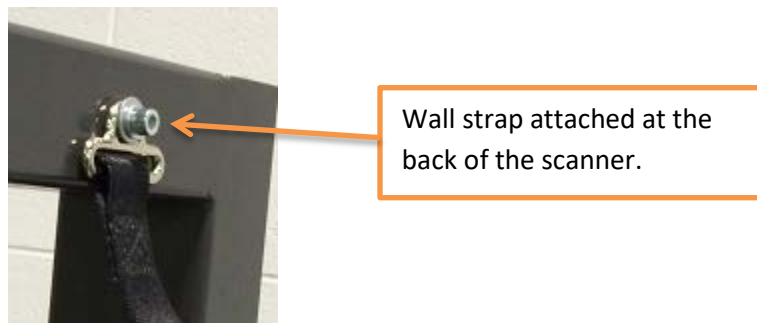
<u>Server Setup:</u>

The External server consists of 4 Virtual Machines, on the right hand side. It is contained in a case that also has a UPS unit, on the left hand side. The first step will be to plug in the UPS Battery Plug, located beneath the UPS cover.

UPS unit   Server

Remove the left cover from the bottom clip. Connect the battery plug. Turn the UPS ON with the button below the plug and verify that it is powered. Replace the cover.

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Plug in all cords in the back of the case:
- 2 CAT6 Ethernet cables (Red & Green)
- 2 cables from Server to each of the 2 Thin Client Terminals.
- 2 power plugs from the server to the UPS unit.
- 1 Power cord.
- HUB (switch for the thin client terminals)

Turn ON the server and verify that all VM's are powered ON. You must remove the right hand side cover to access the ON button to the server.

Connect the ACQ Thin Client Terminal to the HUB, and connect the HUB cable to the server. Plug in the Thin Client Terminal box, Monitor and mouse. Turn the Thin Client Terminal box ON.
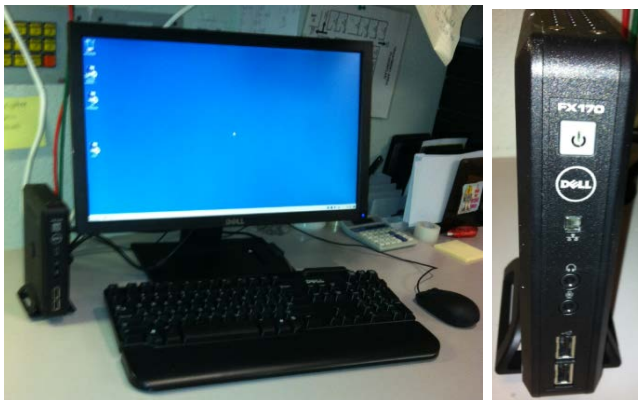
Connect the Viewing Station/MD Thin Client Terminal to the server. Plug in the Thin Client Terminal box, Monitor and mouse. Turn the Thin Client Terminal box ON.

1. Turn the Power to the machine ON from the Main Circuit Breaker at the back of the machine. This is the only ON button for the machine. ON position = I, OFF position = 0.

2. Once all connections are secure and the machine is Powered ON, launch the ACQ Connection from the icon on the Main Connection Desktop of the ACQ Thin Client Terminal.

3. Once connected to the ACQ Desktop, launch the InReach ACQ "CB Scanning Device" software from the icon. Verify StartUp/Initialization has completed. Each of the on-screen lights should light up. During the startup/initialization observe the machine for any vibration, unexpected performance or deterioration of performance.
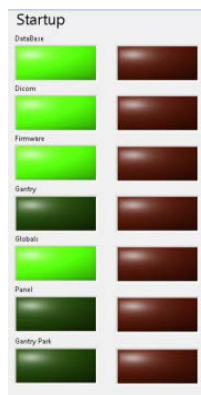
The StartUp sequence is designed to run diagnostics to ensure that all components of the systems are functioning as expected. There are checks for communication to the data storage (DICOM VM), communication with the firmware, and operation and homing of all motors which include the gantry motor, panel motor, beam limiter motor and both door motors. If there is a failure in any of these, the software will not advance to the scan Acquisition section.

4. If all initializes properly, attach the rear cover with the 4 button screws and push the machine to its final position. If there is a StartUp issue, please re-check all connections, re-

boot the machine and attempt again. If an issue continues, please contact CurveBeam Technical Support.

5. Follow ALL the Alignment, Calibration QA procedures outlined in **Chapter 4** of this manual. INSTALLATION is NOT COMPLETE until all these procedures are successfully completed.

APPENDIX II: Troubleshooting

Error Messages:

System failures that may result in a scan failure will be accompanied by Error Messages in the software. The user should follow the instructions to resolve the error, however if the Warning message persists, the user should contact CurveBeam technical support at 267-483-8081. If the system fails to operate in any other way or if your problem is not listed, please contact CurveBeam technical support at 267-483-8081.

Firmware Monitoring Warning: Upon startup of the "CB Scanning Device" Acquisition software, the system checks that the embedded controller firmware software version is the correct version to operate with unit. If an unsupported version number firmware software resides on the embedded controller then the following error message will display and the Acquisition software will terminate. In the event of this error message, please contact CurveBeam technical support.
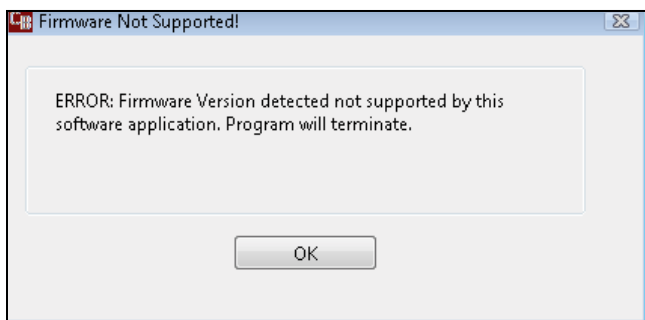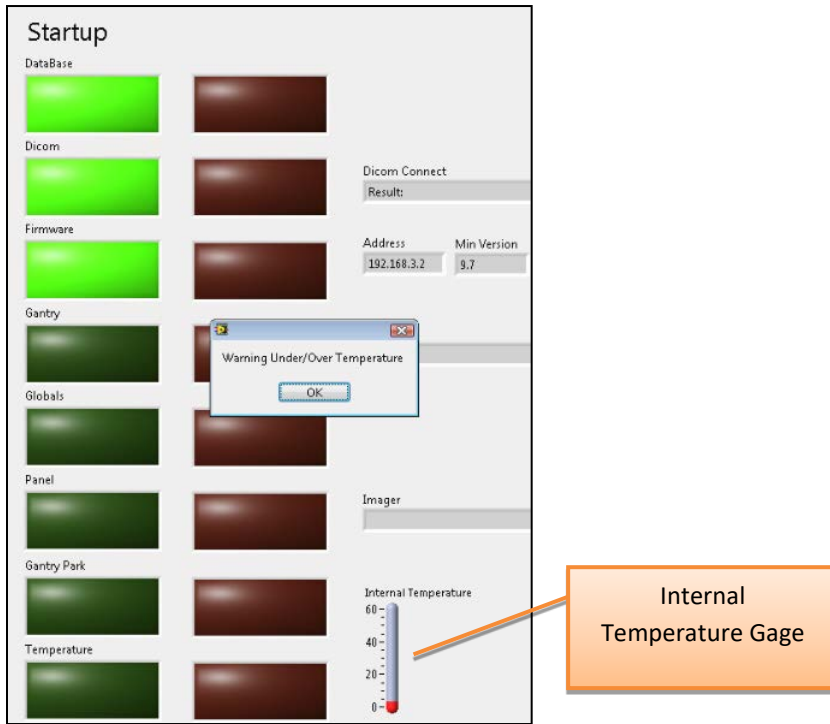

Temperature Monitoring Warnings: The system is designed to send a Warning message to the user if the internal temperature of the machine is below 35° C or above 45° C. This Warning would display in the "CB Scanning Device" Acquisition software at Startup and just before a scan is captured. If the temperature is below the 35° C limit then the resulting image quality may not be optimal, however the system will permit scanning (for either upper or lower temperature conditions).
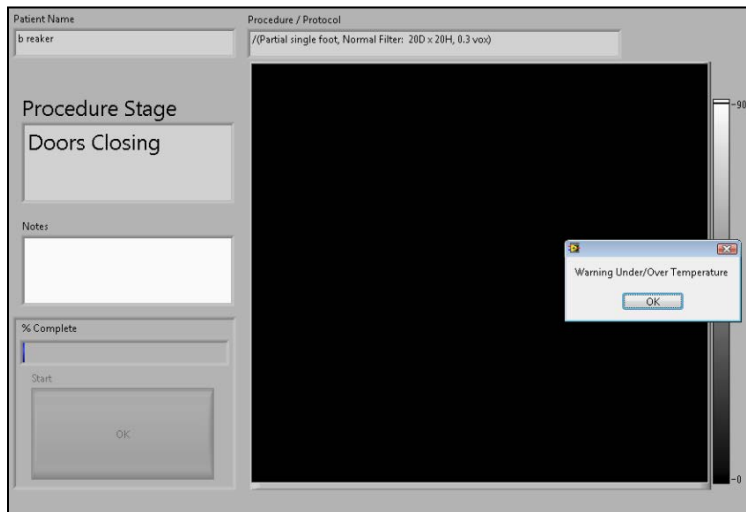
The Warning message reads:
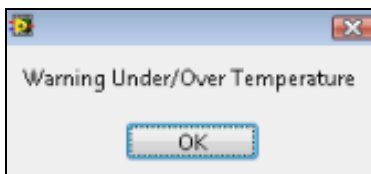
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Startup: Note that there is an Internal Temperature gage in the Startup Screen. If in the Startup Screen and the temperature monitor has detected temperature out of range, the warning message will display during the Startup sequence.
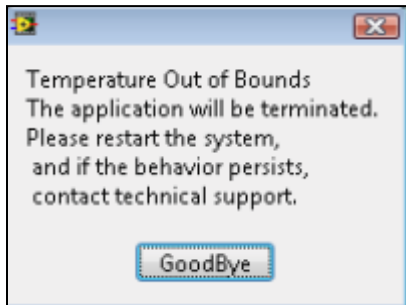

Scan: If in the Procedure Tab and the temperature monitor has detected temperature out of range, the warning message will display once the OK button is clicked.

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Temperature Monitoring Failures: The system is designed to send a Failure message to the user if the internal temperature of the machine is 20° C or lower OR 60° C or higher. This Failure message would display in the "CB Scanning Device" Acquisition software at Startup and just before a scan is captured. If this condition occurs the error message will force the acquisition program to terminate and disallow any scanning.

In the event of such Failure message, the user should re-start the system via the Circuit Breaker ON/OFF switch and then re-launch the "CB Scanning Device" Acquisition software. If the message still displays, the user should contact CurveBeam technical support.

The Failure Message reads:

Startup: Note that there is an Internal Temperature gage in the Startup Screen. If in the Startup Screen and the temperature monitor has detected temperature out of range, the failure message will display during the Startup sequence.
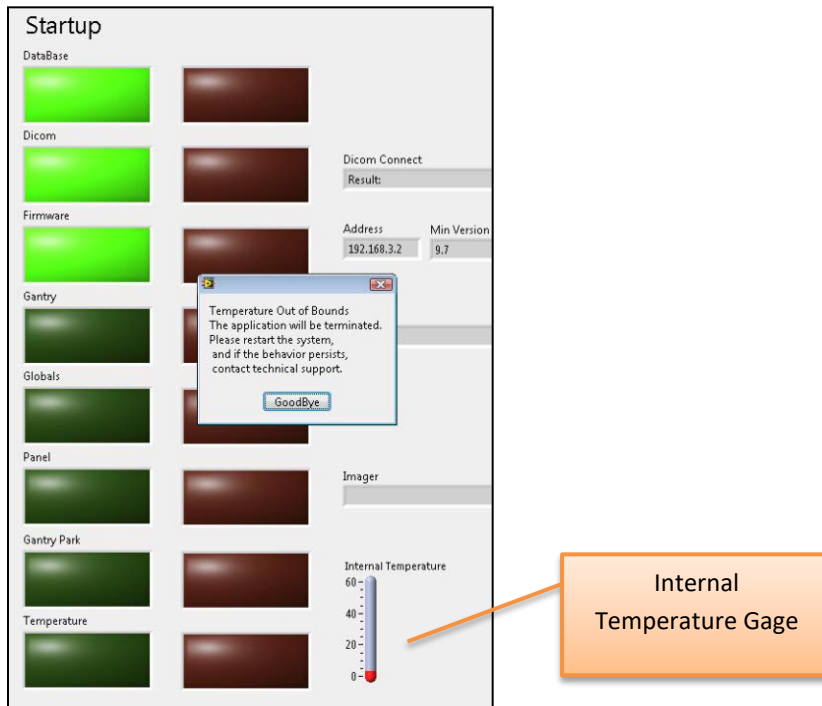
Scan: If in the Procedure Tab and the temperature monitor has detected temperature out of range, the failure message will display once the OK button is clicked.
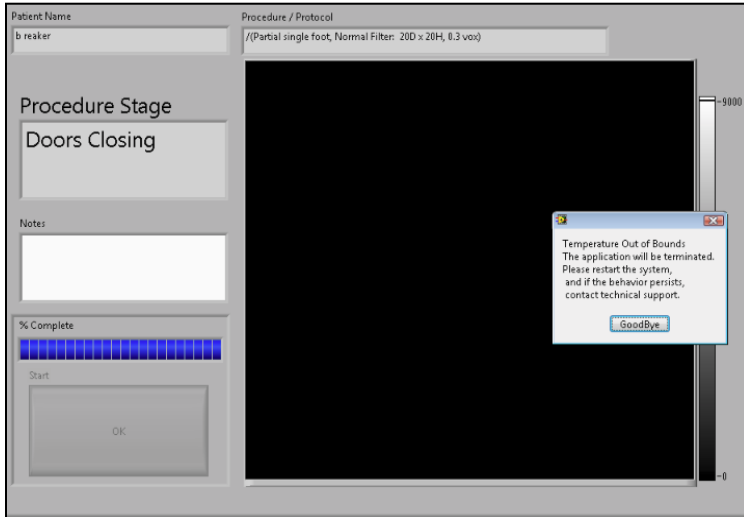

Beam Collimator Mechanism Failure: The beam collimator is a motorized mechanism which select position dependent on the scan procedure selected**.** An error message will display if there are any issues with the motor, such as a stall or jam, or switches that control the movement of the beam collimator mechanism. This message can display at Startup screen or in the Procedure Tab as the system sets up for the scan.
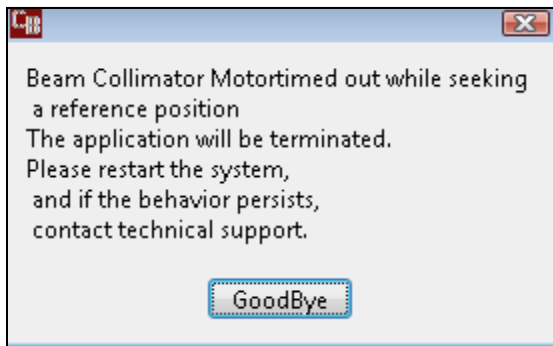
Panel Position Mechanism Failure: The Panel Position Mechanism is a motorized mechanism which selects its position dependent on the scan procedure selected**.** An error message will display if there are any issues with the motor, such as a stall or jam, or switches that control the movement of the Panel Position mechanism. This message can display at Startup screen or in the Procedure Tab as the system sets up for the scan.
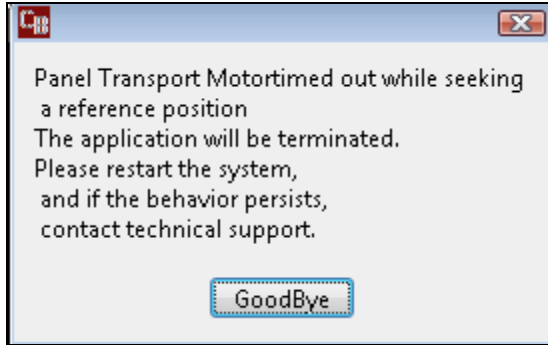
Gantry Rotation Position Mechanism Failure: The Gantry Rotation Mechanism is a motorized mechanism as well**.** An error message will display if there are any issues with the motor, such as a stall or jam that would result in the Gantry not finding its proper positioning. This message can display at Startup screen or in the Procedure Tab as the system sets up for the scan.
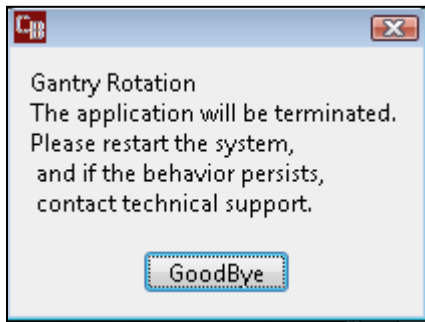
An error in Gantry Rotation *during a scan* would result in a communication error of the receptor panel to the server, so if this even occurs, the following Panel Readout error message would display:

Panel Read Out Error Message: If any communication failure occurs before or during a scan between the receptor panel and the server, then a Panel Readout Error will display on Screen.

Communication errors could occur if the cable is not plugged in or seated correctly or has suffered some damage, or if the panel does not properly produce frames. The "CB Scanning Device" Acquisition software will terminate. Check cables and Restart the system.

Communication Error between the Firmware and the Server: If there is any loss of communication between the embedded controller firmware, the following error message will display on screen. Loss of communication can be caused by a damaged, unplugged or loose embedded controller cable, or when the Emergency Stop button has been pressed**.** The "CB Scanning Device" Acquisition software will terminate. Check cables and E-stop and restart the system.


Exposure Timeout Error Message: In the event of a system fault that may result in the X-ray exposure not terminating at its appropriate time, there is a backup timer to terminate the exposure. If this occurs, the below error message will display on screen. Click OK and restart the system. If the error occurs again, contact CurveBeam Technical Support.
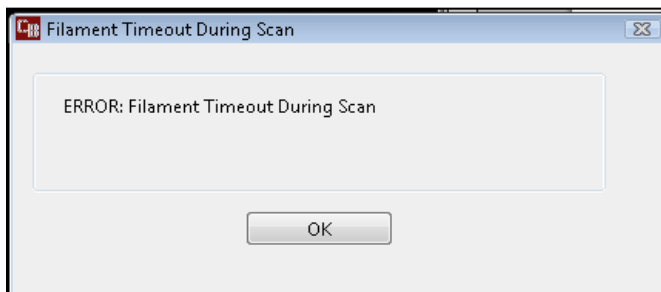
Scan Button Released Error Message: If the operator releases the scan button BEFORE completion of an exposure, the X-ray will turn off and the below error message will display notifying the user of the error.

If this occurs, the operator should review the reconstructed data to determine if the data capture was sufficient for diagnosis. If not, a new scan may be necessary.
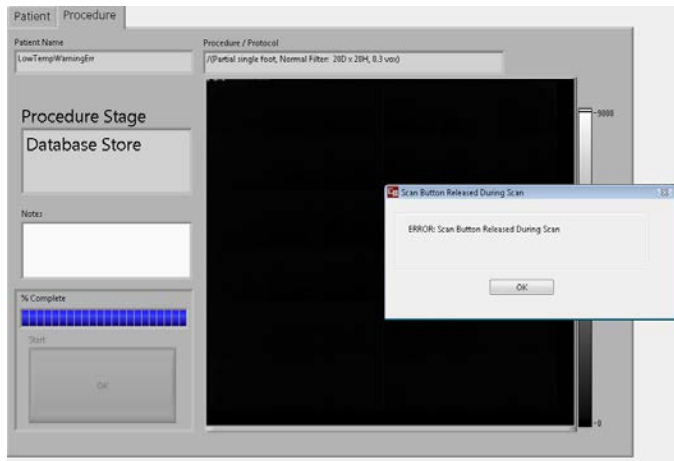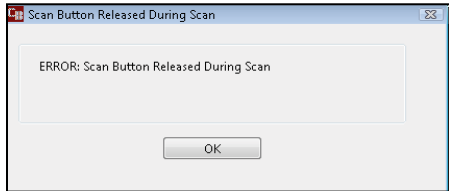
Calibration Checks and Services Warnings: The system calls for monthly Panel Calibrations and checks of certain control functions as outlined in this manual. A monthly Warning message will appear that will indicate that it is time for these checks.
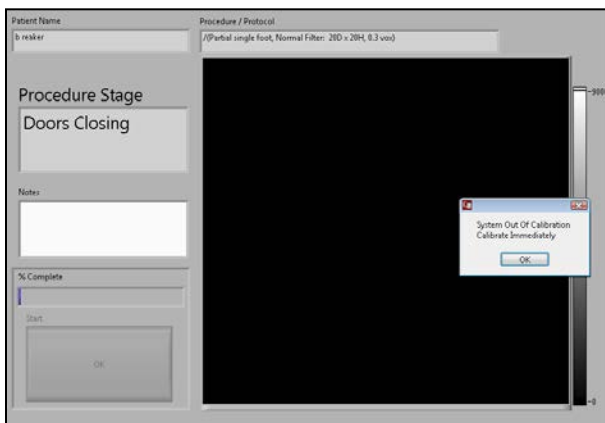
The Warning message reads:
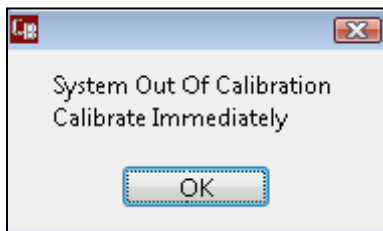
> *Startup:* When the monthly calibration and checks are due, the message will display during the Startup sequence. The user should click OK and then should contact

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CurveBeam technical support who will assist in the calibration and checks via remote access. This message will repeat at Startup until the procedures are completed. Once the procedures are completed the warning message will be reset by CurveBeam technical support.
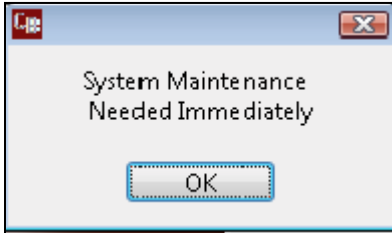

Scan: When the monthly calibration and checks are due, the message will display in the Procedure Tab when the OK button is clicked. When the message displays, the user should click OK and then should contact CurveBeam technical support who will assist in the calibration and checks via remote access. This message will repeat at Scan time until the procedures are completed. Once the procedures are completed the warning message will be reset by CurveBeam technical support.

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QA Service and Maintenance Warnings: The system calls for annual QA procedures and system maintenance as outlined in this manual. An annual Warning message will appear that will indicate that it is time for these services.
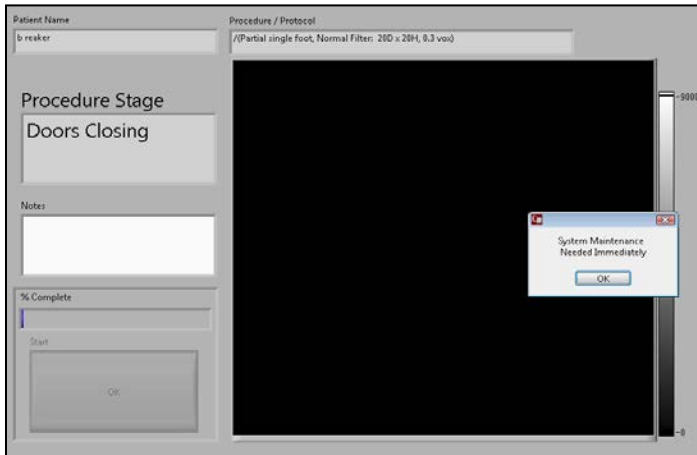
The Warning message reads:

Startup: When the annual service is due, the message will display during the Startup sequence. The user should click OK and then should contact CurveBeam technical support who will schedule the service and maintenance. This message will repeat at Startup until the procedures are completed. Once the procedures are completed the warning message will be reset by CurveBeam technical support.

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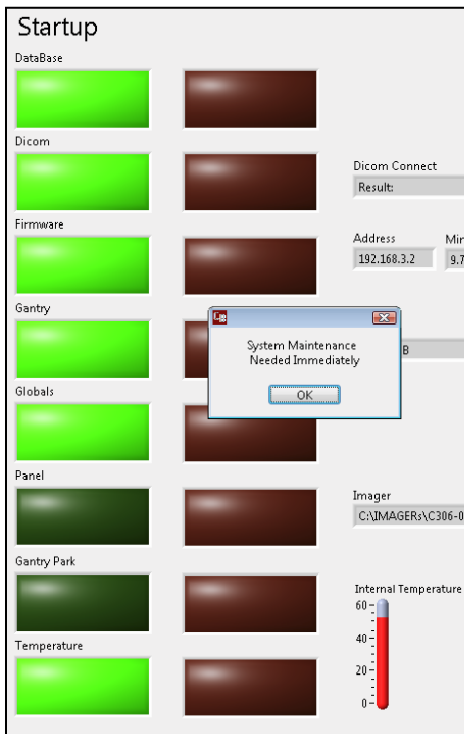
Scan: When the annual service is due, the message will display in the Procedure Tab when the OK button is clicked. When the message displays, the user should click OK and then should contact CurveBeam technical support who will schedule the service and maintenance. This message will repeat at Scan time until the procedures are completed. Once the procedures are completed the warning message will be reset by CurveBeam technical support.

APPENDIX III: Scan Protocol Technical Details

InReach Study Type:	Hand, Elbow, Foot, Knee, Ankle, and Foot Cone Beam CT
Scan Positions/Orientations:	Non-Weight bearing
CT Scanner make and model:	CurveBeam InReach
Maximum # of Slices per acquisition:	N/A: System is Volume Cone Beam CT

InReach has 2 Scan Protocol options:

Acquisition series (include all) (i.e., axial)	Standard (120 kVp)	Lite Dose (100 kVp)
kVp/mA and rotation time or kVp/mAs	kVp = 120 mA = 5 mAs = 29.52 Rotation time = 24.4 seconds	kVp = 100 mA = 5 mAs = 29.52 Rotation time = 24.4 seconds
CTDI (vol) required (if on system)	5.997 mGy	3.420 mGy
Dose length product (DLP) required if on system	-	-
Total dose per acquisition and/or total dose per study if available in units given	Dose Area Product = mGy*cm^2	Dose Area Product = mGy*cm^2
Tube current modulation or dose reduction technique (is used)	12 millisecond pulsed. 492 pulses/scan	12 millisecond pulsed. 492 pulses/scan
Anatomical Scan range	Hand, Wrist, Elbow, Foot, Ankle, Knee	Hand, Wrist, Elbow, Foot, Ankle, Knee
Increment (space between slices)	0 mm	0 mm
Detector collimation (mm)	Fixed 2-3% of detector, factory calibrated	Fixed 2-3% of detector, factory calibrated
Slice thickness (mm)	0.5mm +/-0.2mm	0.5mm +/-0.2mm
Slice spacing (mm)	0.2mm	0.2mm
Pitch or table feed	0	0
Scan FOV (cm)	17 cm (6.7") high x 16 cm (6.3") diameter	17 cm (6.7") high x 16 cm (6.3") diameter

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Kernel/filter	Sharp	Sharp
Reformat technique (i.e., 3D, plane/views)	Automatic (coronal/sagittal volumes optional)	Automatic (coronal/sagittal volumes optional)
Contrast type/rate (if applicable)	Not Used	Not Used
Time from contrast injection to image acquisition, if applicable (sec)	Not Used	Not Used

APPENDIX IV: Advanced Calibrations

The calibrations here are accessed via CB-ToolShed with a password and are considered advanced calibrations, not for the user to perform. These Calibration Procedures should be performed only by factory trained technicians.

To complete all of the calibrations, allow at least 1 hour. Perform them all in the order presented. Once completed, the User Calibrations from Chapter 4 need to be performed.

The tools required for Calibration:
        Geometric Phantom
        Geometric Platform
        Combined QA Phantom (Line Pair Phantom and Simulated Water)
        Combined QA Platform

Calibrations to be Performed for Advanced Calibrations:
        Collimator Setup
        Geometric Analysis and File Creation (Geometric Calibration)

Ensure that all safety precautions are taken for the location in which these procedures are being performed. If the office is equipped with the Door Interlock Option, ensure that the appropriate measures are taken to be able to perform a scan and fire the x-ray. If needed, there is always the option to release the Scan button or to use the E-Stop to stop the x-ray in the middle of a calibration. If the E-Stop is depressed, it will cause the power switch on the back of the scanner to shut off. Reset the E-Stop by rotating it, then restart the scanner by flipping on the power switch at the back of the scanner. Then restart the calibration at the beginning of the calibration that was interrupted. If the scan button is released prematurely during a calibration, rerun the current calibration.

⚠️**WARNING** Prior to performing any advanced calibrations, ensure the machine is not in use, and patient is not in the scanner.
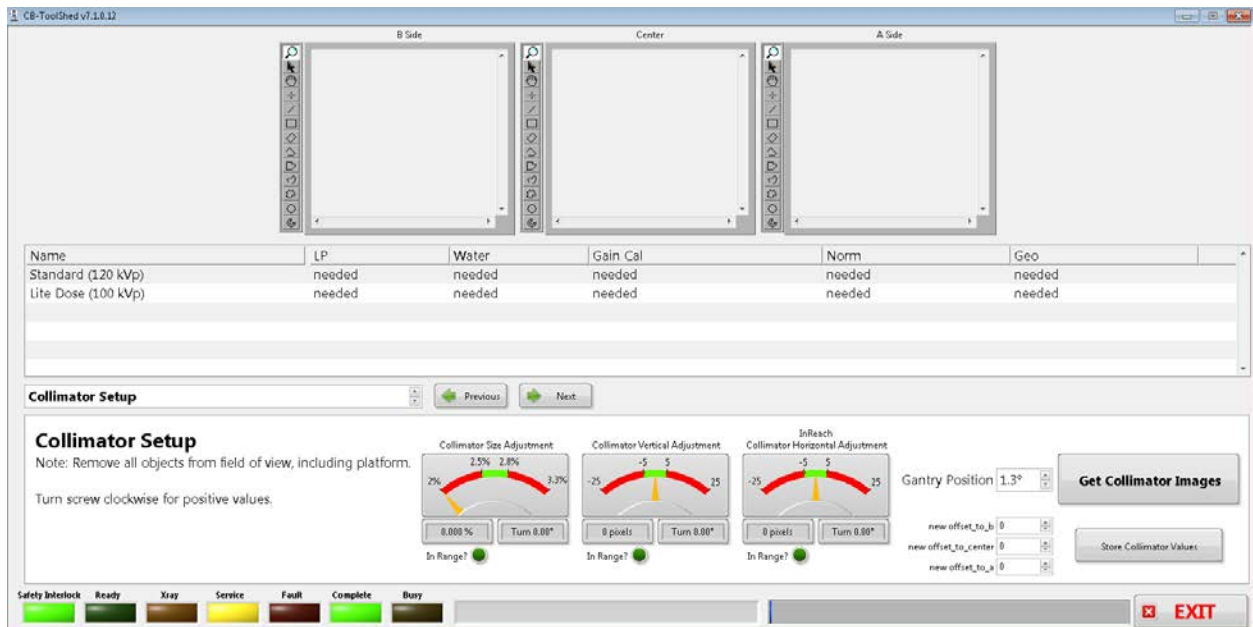
Open CB-ToolShed and enter the required password to access the advanced calibrations.

Collimator Setup:

To start, ensure everything is out of the Bore, all phantoms and platforms should be removed. Then, select Collimator Setup from the pull down menu to start the Collimator Setup calibration.
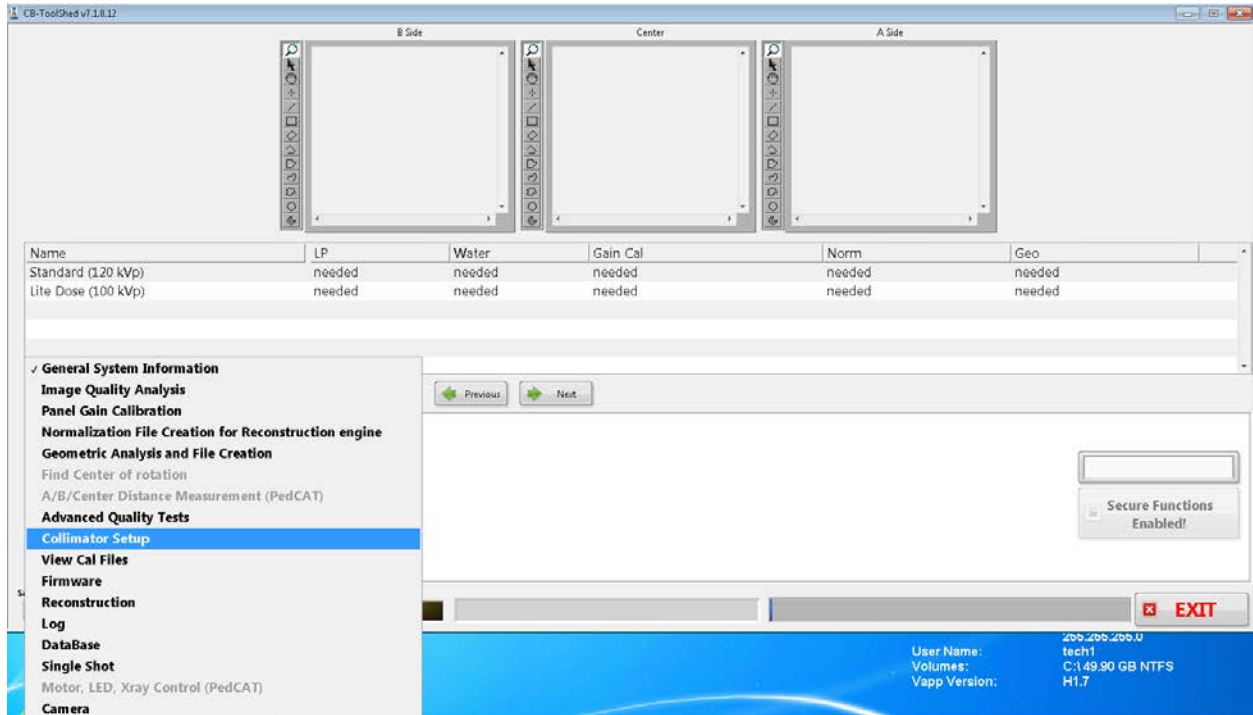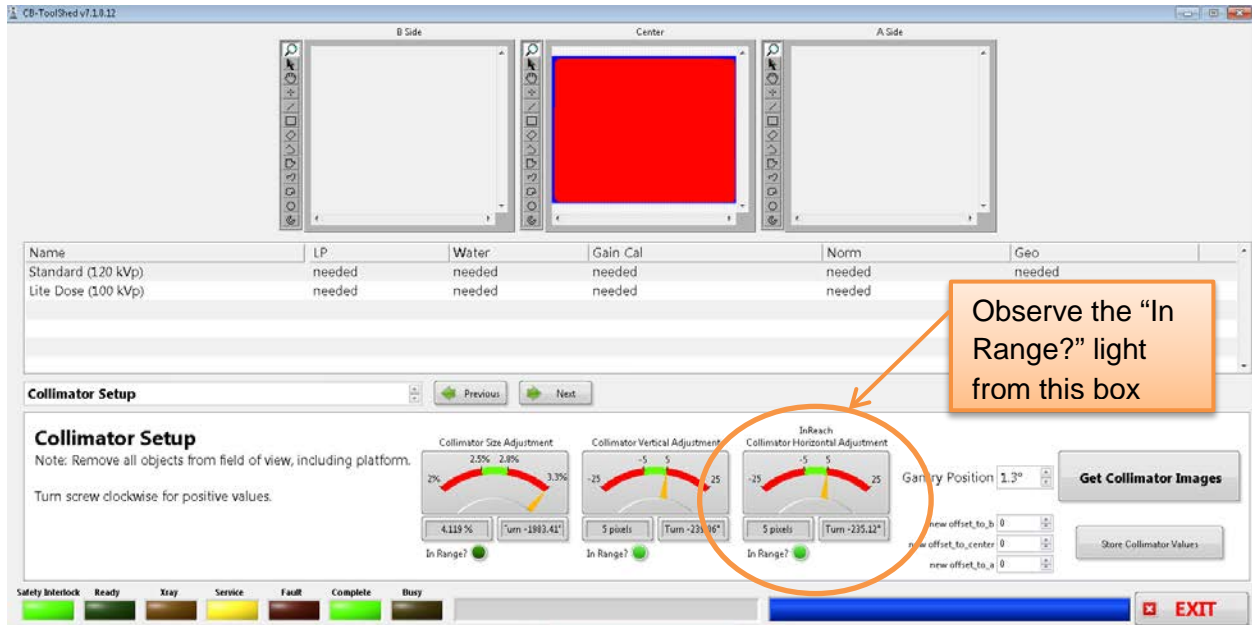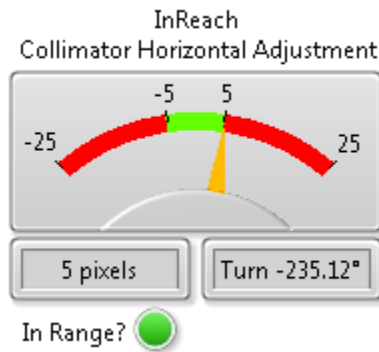

And the following screen will appear:

Ensure there is nothing in the field of view. Then select "Get Collimator Images" button.

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The calibration will occur and the only thing to be concerned with is that the light under the InReach Collimator Horizontal Adjustment box is lit up green and therefore in range.

Zoomed in of the above mentioned box:

Bright Green is acceptable. If the light does not illuminate bright green then contact CurveBeam Technical Support for assistance.

This completes the Collimator Setup Calibration.

Geometric Analysis and File Creation (Geometric Calibration or Geo Cal):

Locate the Geometric Phantom and the Geometric Platform. First place the platform in the bore. Place it about an inch from the front of the machine, and fully within the bore. Place the phantom in the cut out part of the platform, with the small screw hole at the end of the phantom facing into the machine. The positioning of them is shown here:
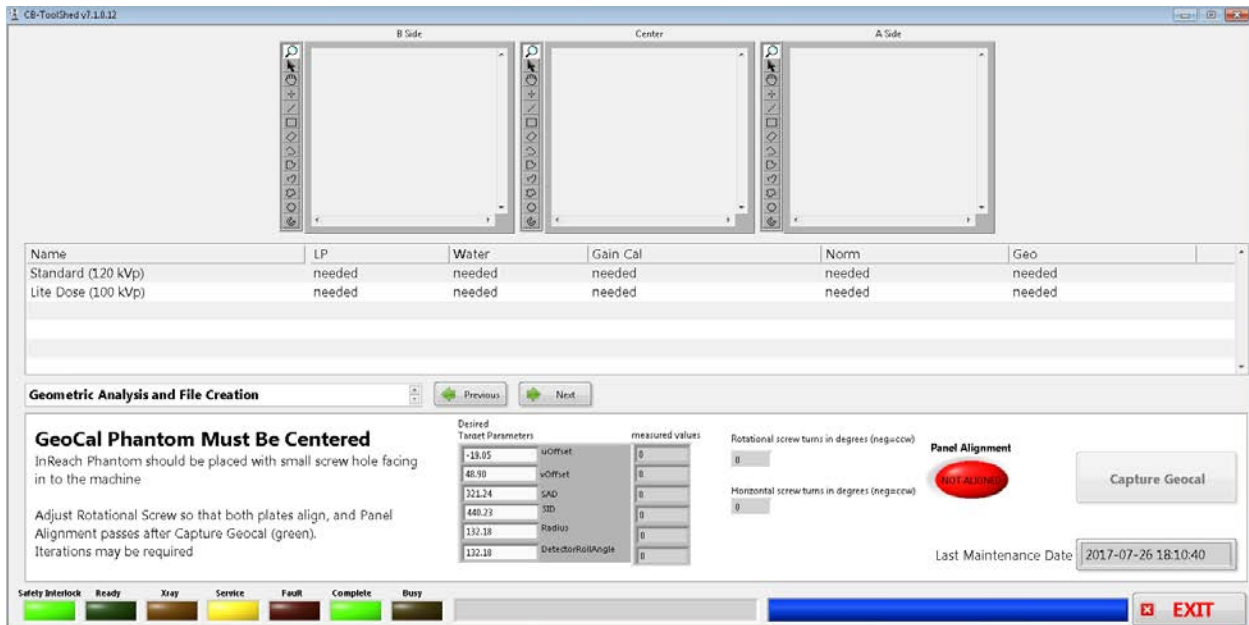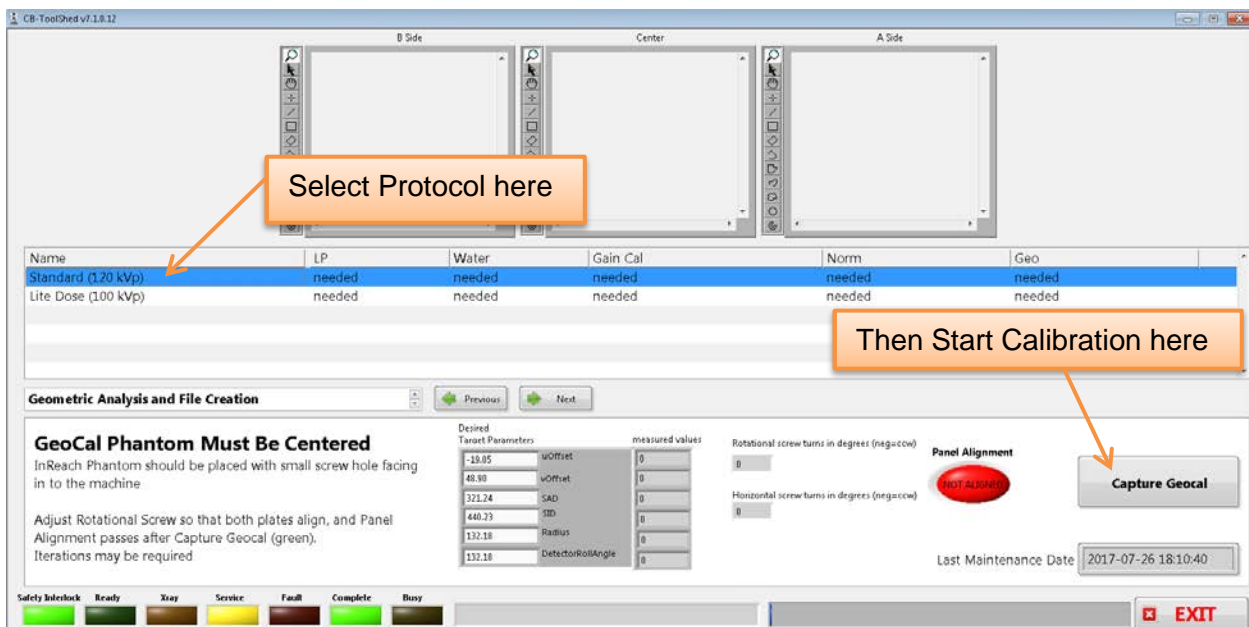

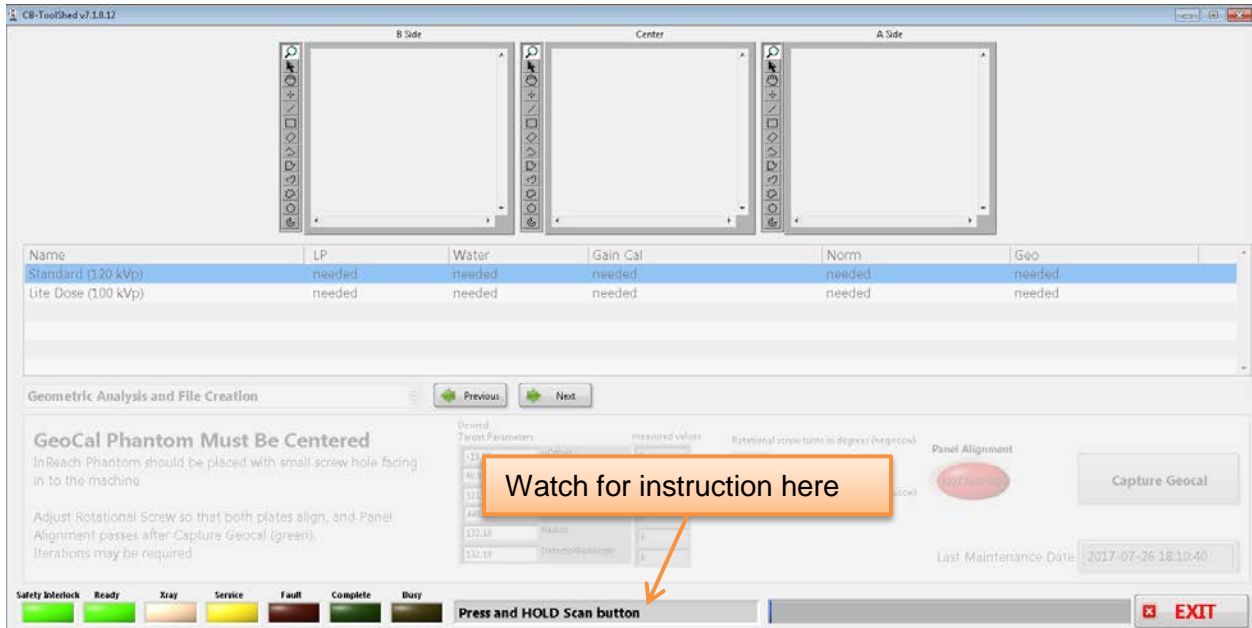Then select "Geometric Analysis and File Creation" from the pulldown as shown below:

This will then display the screen as shown below:

With the platform and phantom in place, select the Standard (120 kVp) protocol, then click on the "Capture Geocal" button as shown below:

The screen will appear all washed out for a bit, this is normal, and will look like this:


Then you will be prompted in the text box at the bottom of the screen to press and hold the scan button. This will fire xray.

> ⚠️ **WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

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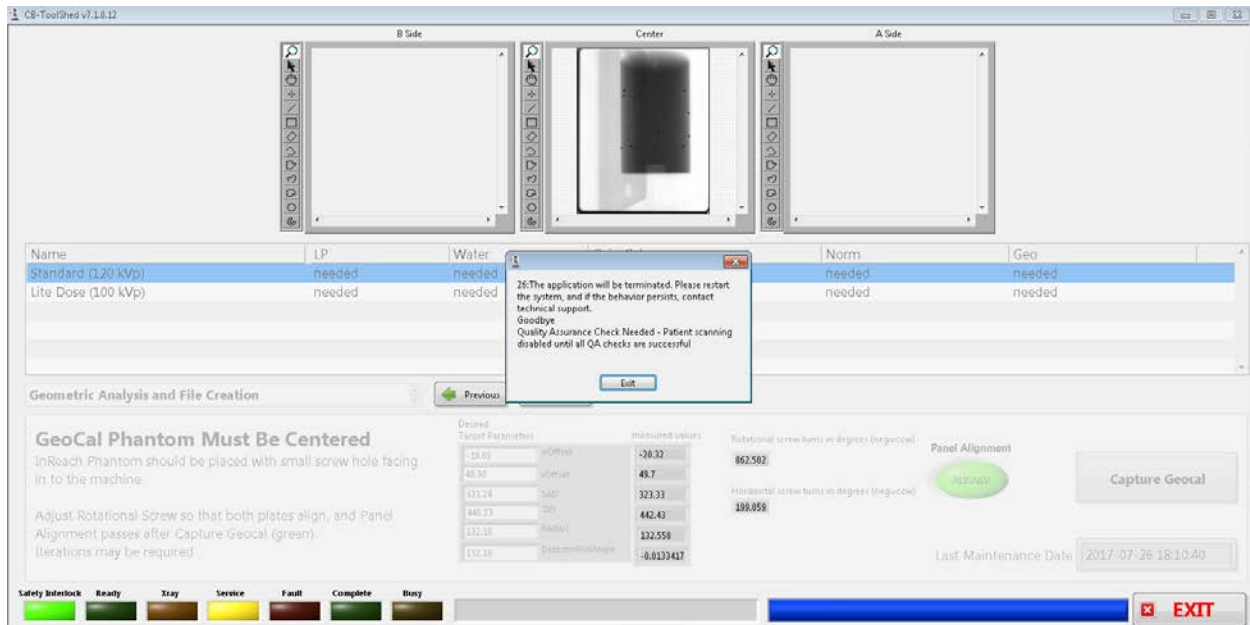During the calibration, the IsoCal screen will pop up, as shown below:
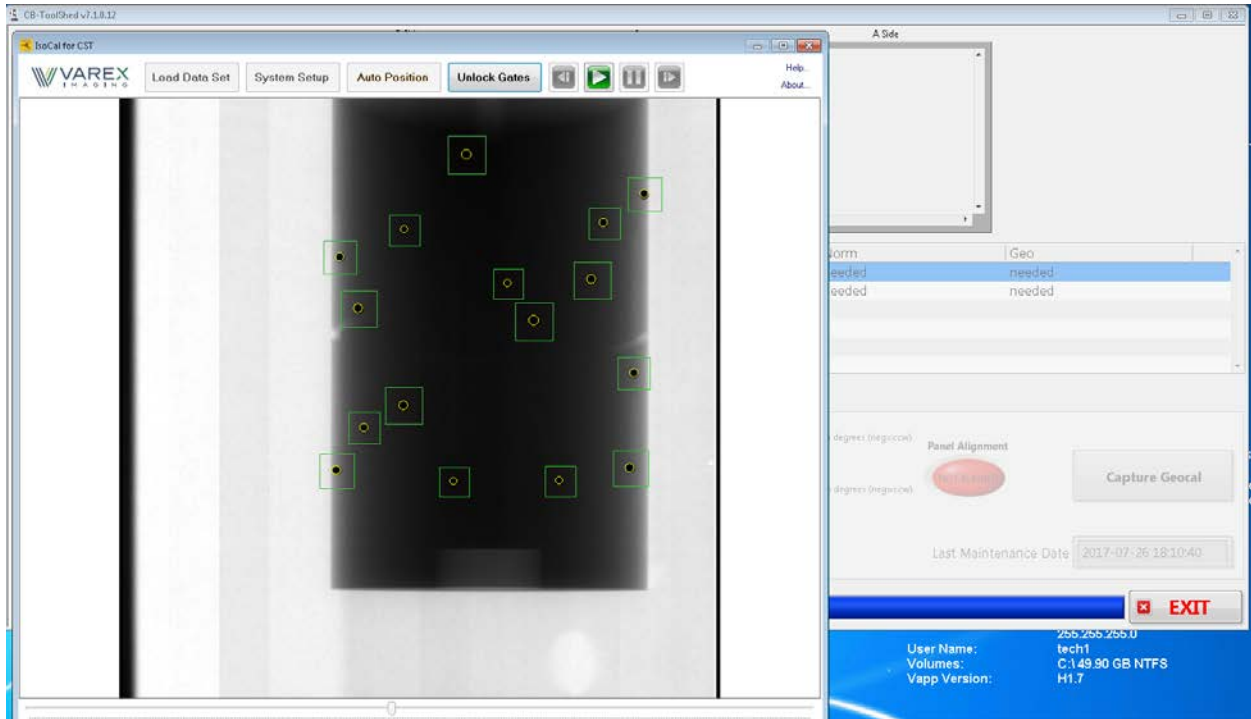
Just allow it to continue processing. After first protocol has completed, the following message will appear:
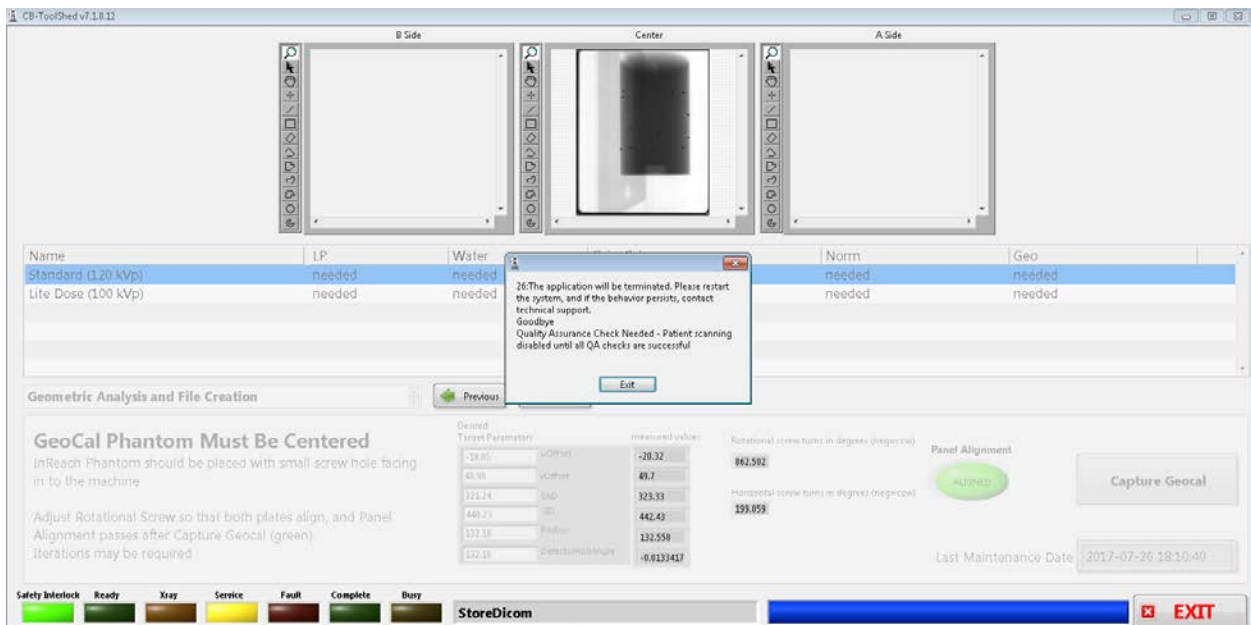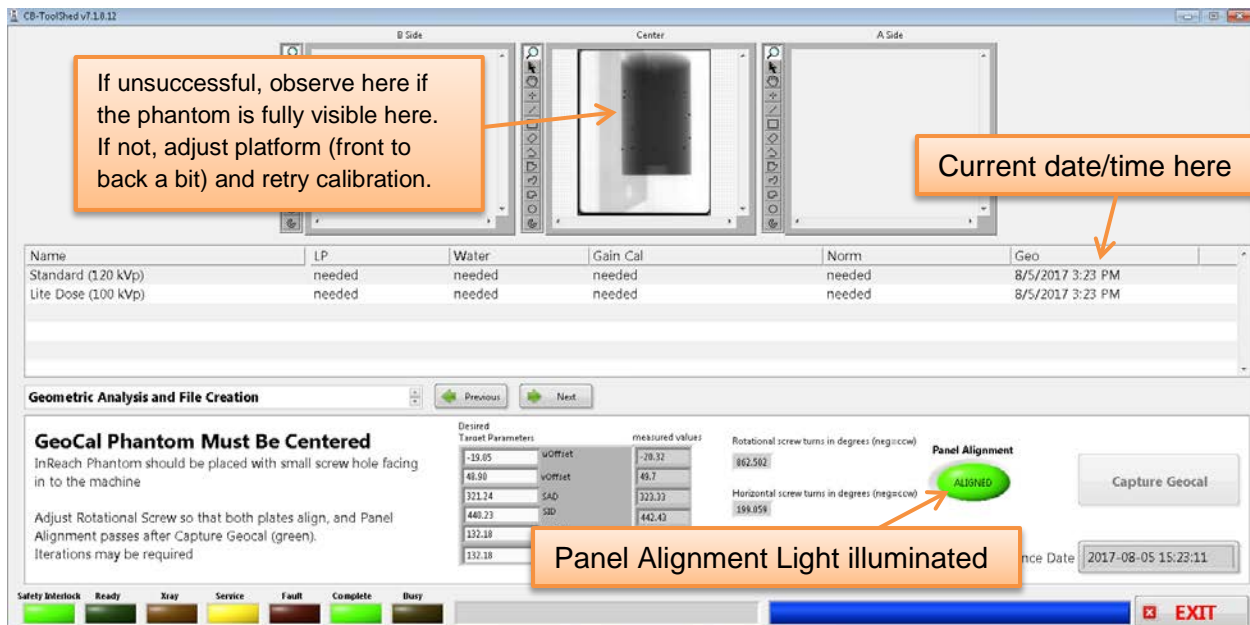

Click the "Exit" button, this is just to indicate the further calibrations are still needed.

Then this message will appear:

Again, click the "Exit" button, this too is to indicate that if the additional calibrations aren't performed the unit will not allow for patient scanning.

Then the following screen will appear with the results of the calibration:

If the calibration was successful, then it can be noted that the current date and time will be populated in the "Geo" column to indicate the last successful calibration. Also the "Panel Allignment" light will be illuminated bright green upon successful completion of the calibration. If these values are not as mentioned above, and the calibration was not successful, the phantom can be adjusted both in its platfrom (rotate a bit, still keeping it in the cutout). And the platfrom

can be moved a bit closer to the front or back of the machine. Observe in the image of the phantom in the center picture at the top of the screen, this would need to show the full length of the phantom, if it does not, then adjust the platfrom front to back to allow for full capture of the phantom. If those adjustments are made, and another attempt at the calibration fails, please contact CurveBeam Technical Support for assistance with the calibration.

Upon successful completion of both the Collimator Setup and Geometric Calibration, the Advanced Calibrations are complete.

Please now run all of the User Calibrations listed in Chapter 4 of this manual.