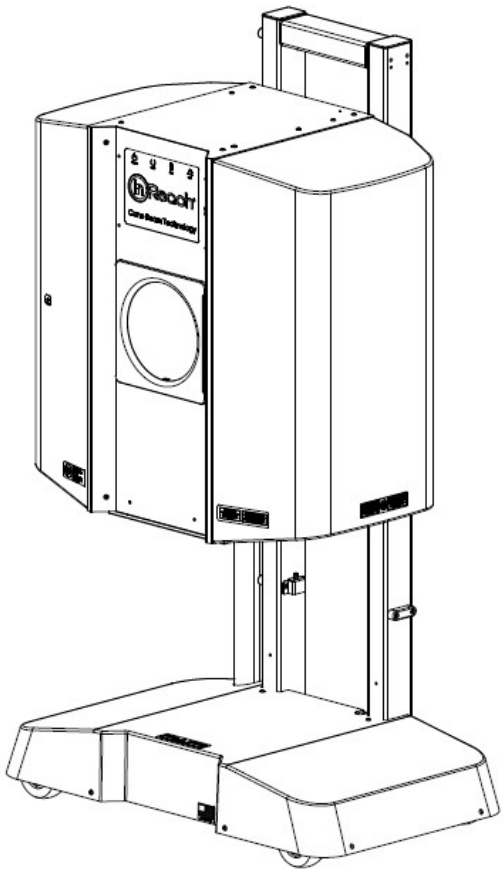
Computed Tomography Imaging X-Ray System



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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 0413 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:

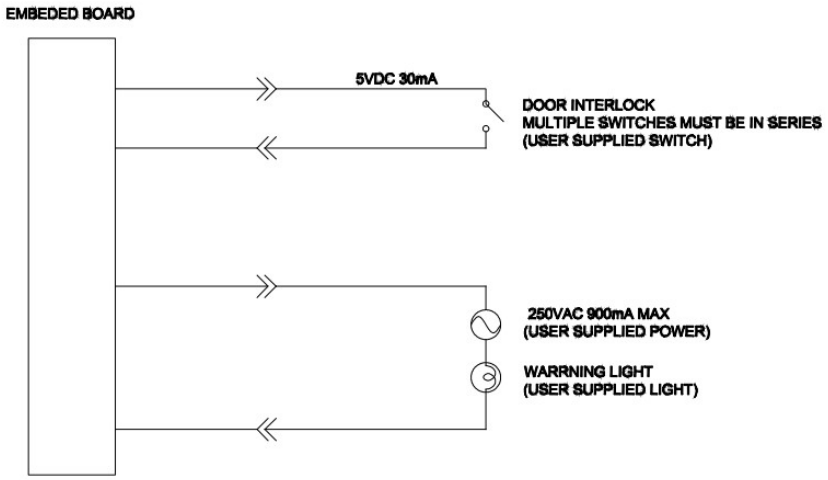
Emergency Stop: In the event of an emergency (any moving component collides with any parts of the equipment or items in the environment, or that could cause physical injury to the Patient), the Operator or Patient should utilize one of the 2 designated Emergency Stop buttons to turn off the power to 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

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:

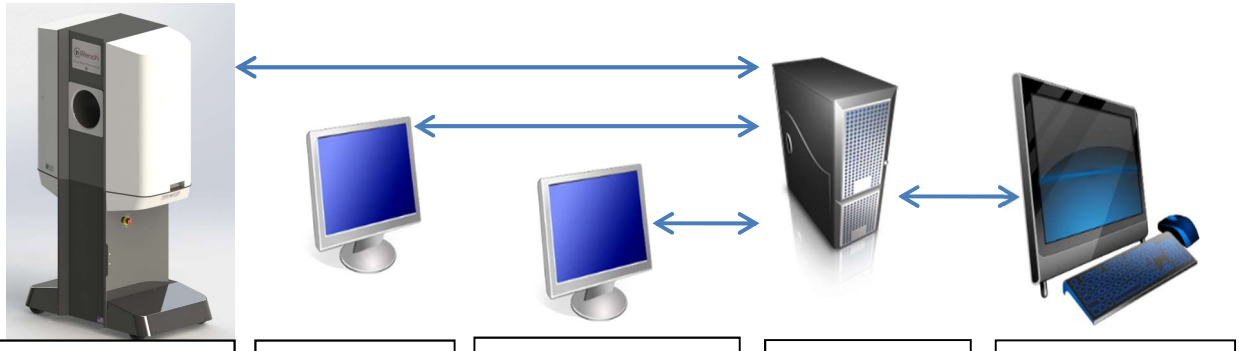
1. Press the EMERGENCY STOP button. This will halt the X-ray as well as the motors to the machine functions and all power to the machine. The message below will display on screen and will terminate the "CB Scanning Device" Acquisition software:

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
1. Capture Images
2. Transfer Raw Data to External server

Quality Console
1. QA scan results

Operator Console
1. Access, import, and enter patient information
2. Select Scan Options
3. Initiate Acquisition of Images

External Server
1. Reconstruct Data
2. Store Data
3. Post Process Data

Viewing Console
1. Viewing and post processing of data

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The External Server consists of 4 Virtual Machines:

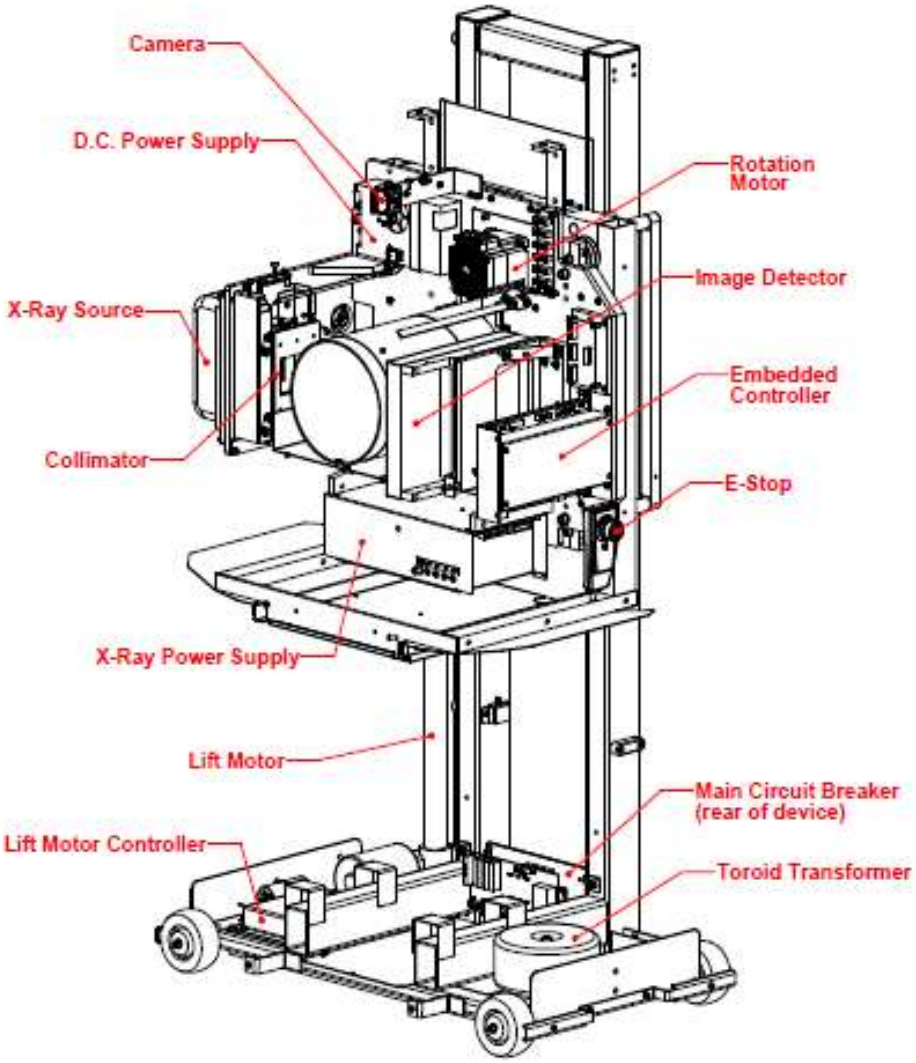
ACQ VM: accessed via the Main Desktop icon on the ACQ thin client terminal

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:



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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

Contraindications:

This device emits ionizing radiation. Exposure to ionizing radiation may cause damage to cells and may increase the risk of cancer later in life. Populations sensitive to exposure include pediatric and those that are pregnant.

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:
    - Unauthorized additions or changes, Viruses, spyware or gaming software
    - Applications other than its intended use
    - Damage caused by third party software or damage caused by unauthorized changes to the system software
    - 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

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:

$$R = \frac{UO - U1}{I1}$$

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

⚠**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 Sweden through Swedish Instrument LVFS 2003:11).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. Be careful when cleaning to avoid liquid leaking outside of the bore and into the Gantry. DO NOT ALLOW WATER TO COME INTO CONTACT WITH THE IMAGE RECEPTOR.

For disinfecting, use Biocide ® from Biotrol International or equivalent cleaner and disinfectant. 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.

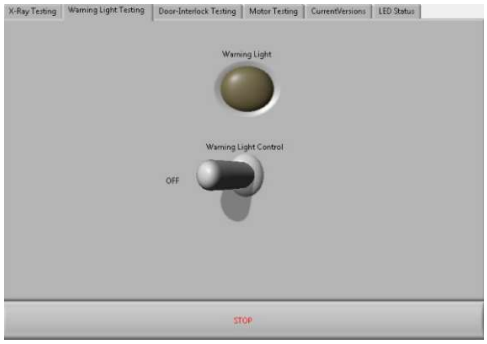
IT IS THE RESPONSIBILITY OF THE USER TO INSURE THAT THE EQUIPMENT IS MAINTAINED IN COMPLIANCE WITH THE MANUFACTURER'S RECOMMENDED MAINTENANCE SCHEDULE. THE MANUFACTURER AND THE ASSEMBLER / INSTALLER ARE RELIEVED FROM RESPONSIBILITY IN THOSE CASES WHERE NON-COMPLIANCE WITH THE STANDARD RESULTS FROM THE 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.



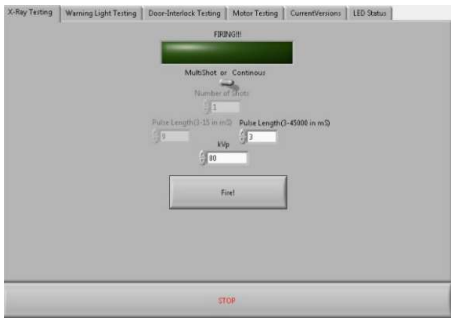
   - DOOR INTERLOCK: Next, if you have a Door Interlock, first close the X-ray Room Door. Click on the DOOR-INTERLOCK TESTING tab. If functioning properly, then a message will appear indicating so. Then Open the X-Ray Room Door and click on the DOOR INTERLOCK TEST button again. The message should indicate 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:

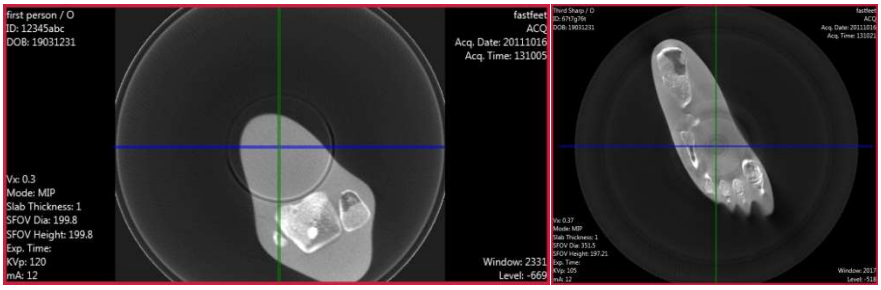
The system requires quarterly maintenance check for Panel Calibration. This can be performed by the end user with CurveBeam Technical Support if necessary.

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.

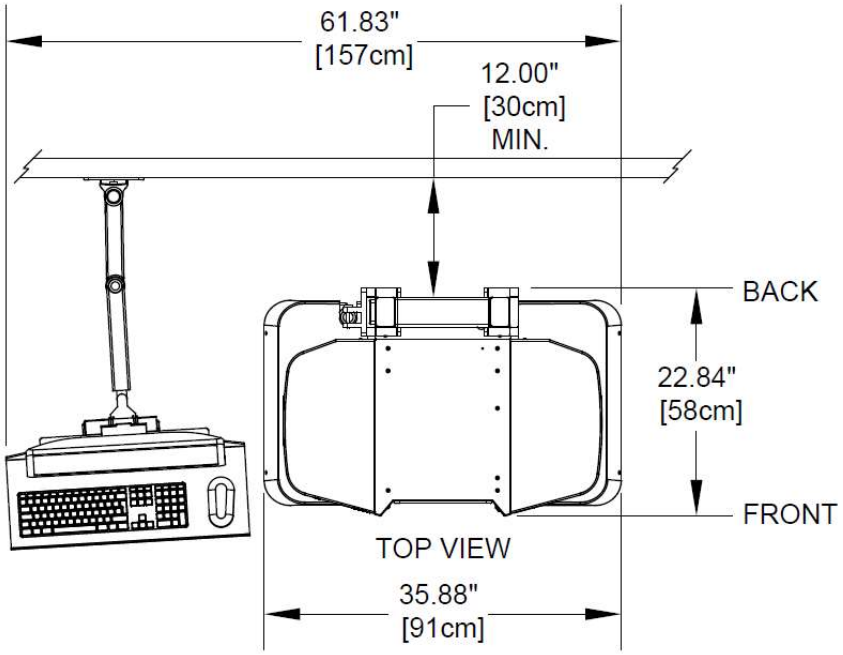
Replacement Parts:

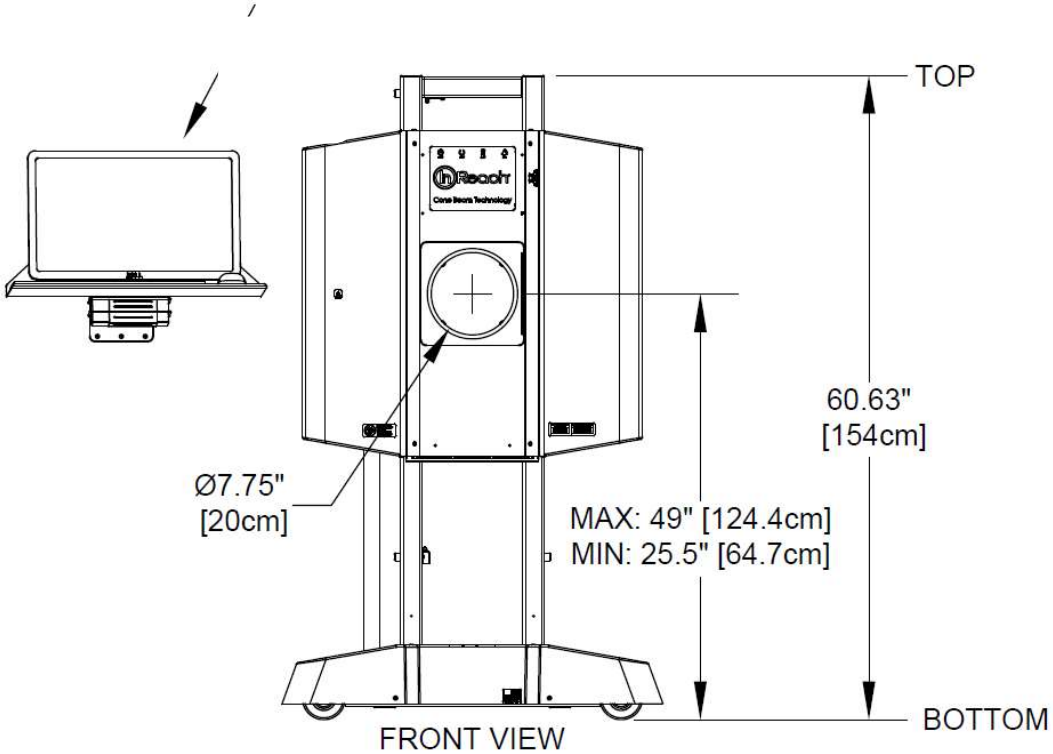
Part Description	Part Number
Gantry Belt	200145
Rotation Motor	100109
Breaker Switch Assembly 100 VAC	4012-100-0
Breaker Switch Assembly 115VAC	4012-115-0
Breaker Switch Assembly 200VAC	4012-200-0
Breaker Switch Assembly 230VAC	4012-230-0
X-Ray Power Supply Assembly	4016-0
Embedded Board Assembly	4014-0
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:





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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.

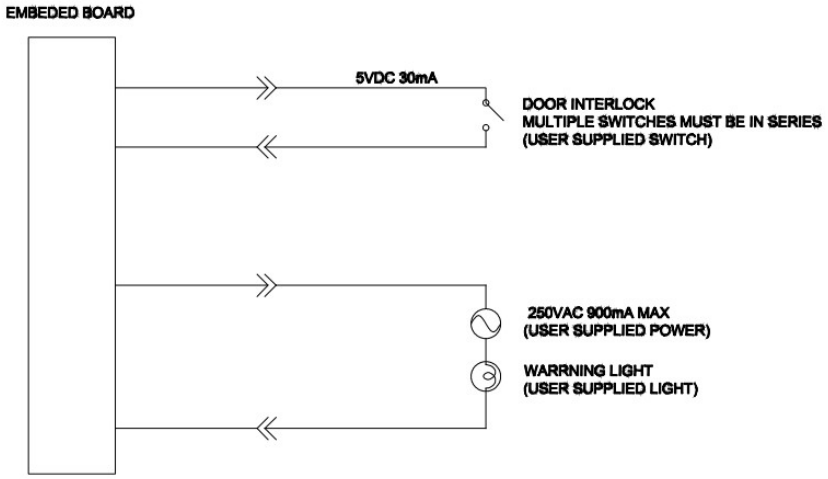
Warning System: The System is equipped with provisions for warning lights and/or audible alarms when X-ray power is energized. An externally powered Warning System can be connected to the cable provided which is capable of 250 volts, 50/60 hertz, and 1 amp. When X-ray power is energized the warning system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

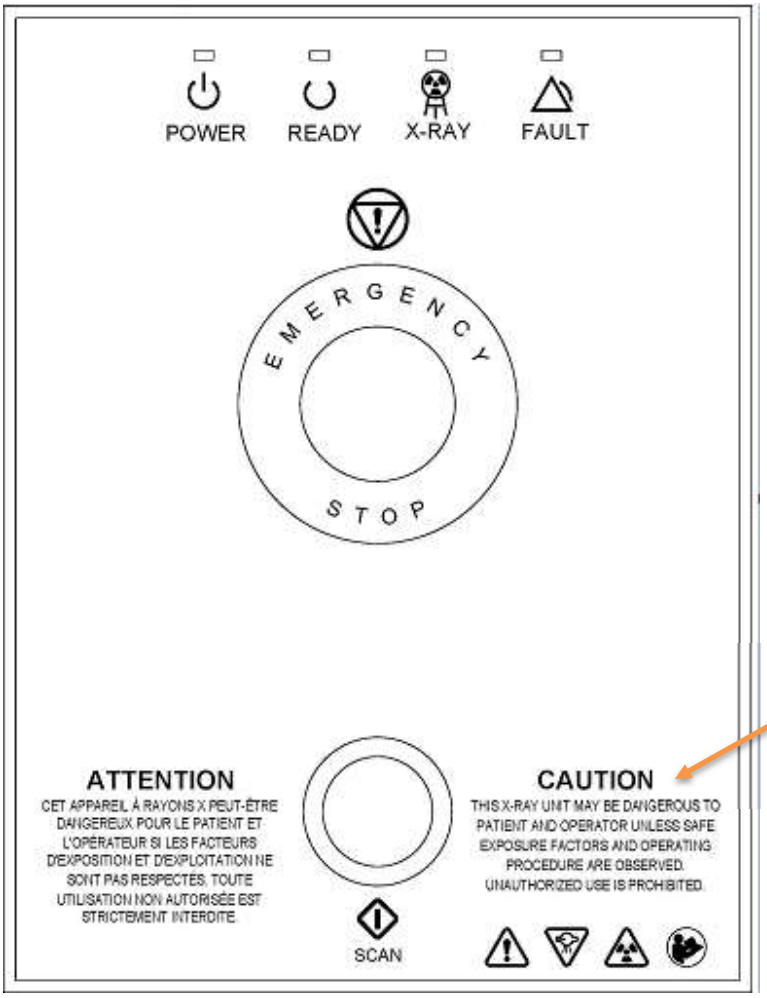
1. Press the EMERGENCY STOP button. This will halt the X-ray as well as the motors to the machine functions and all power to the machine. The message below will display on screen and will terminate the “CB Scanning Device” Acquisition software:

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.

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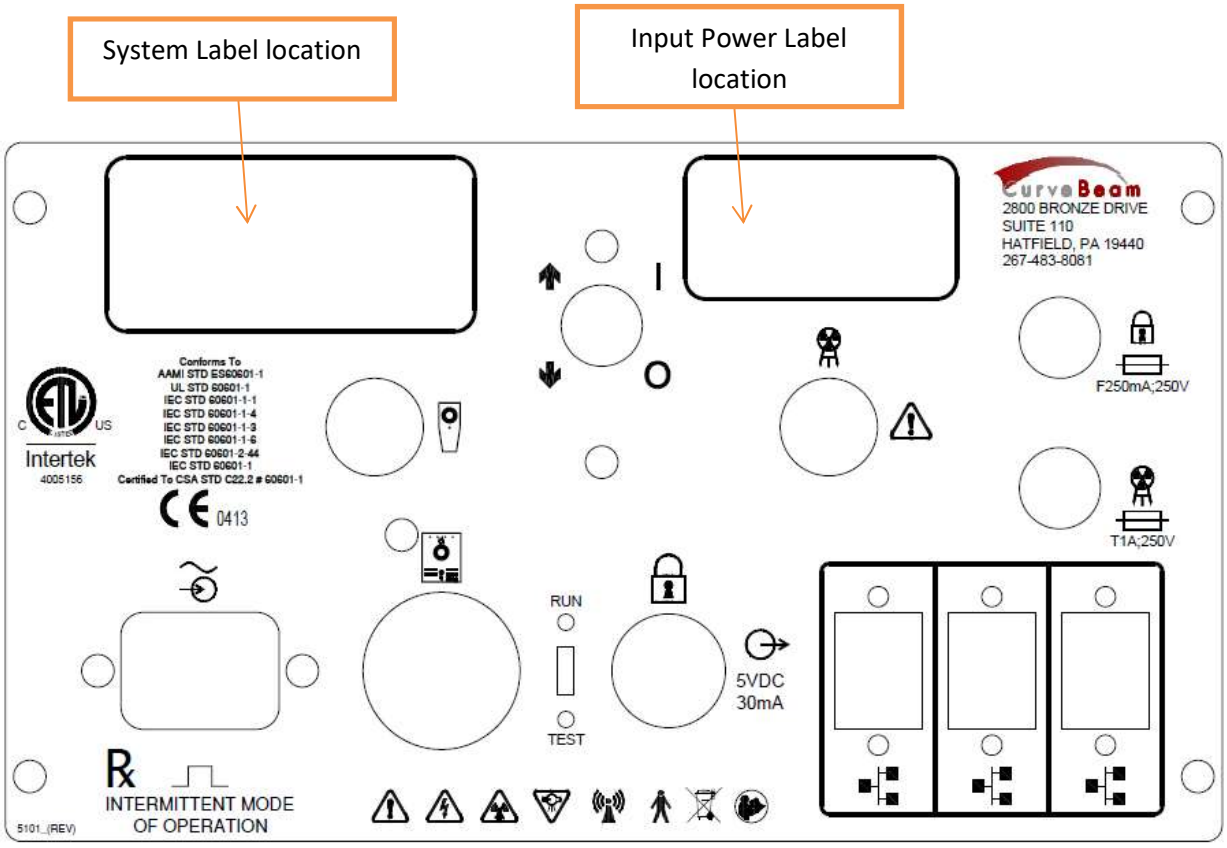
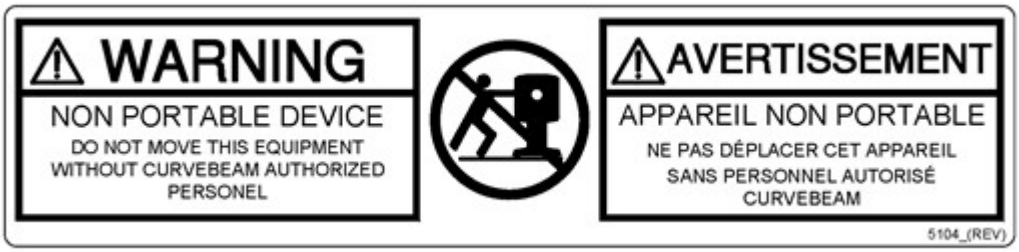
Rear Connector Panel:



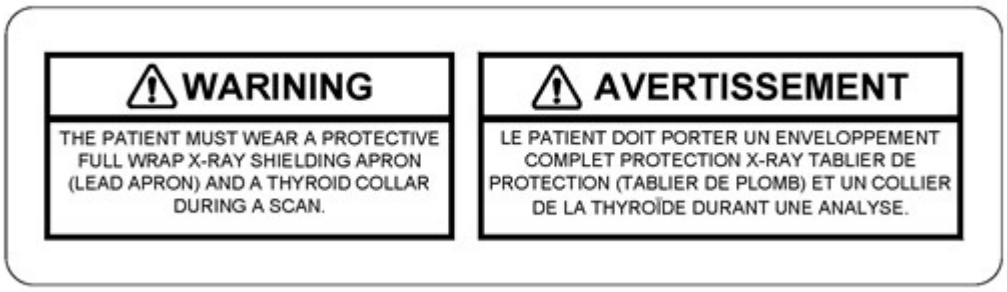
Indicator Panel (front of machine):

Non-Portable Device label:

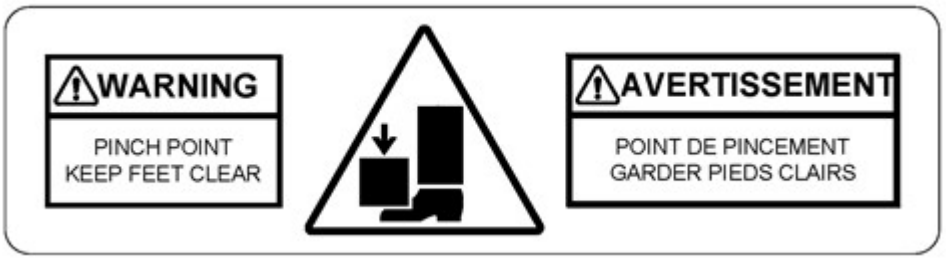


Focal Spot label:

X-Ray Warning label:

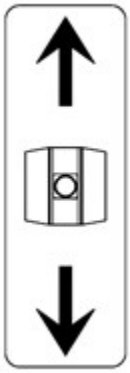


Foot Pinch Point Label:

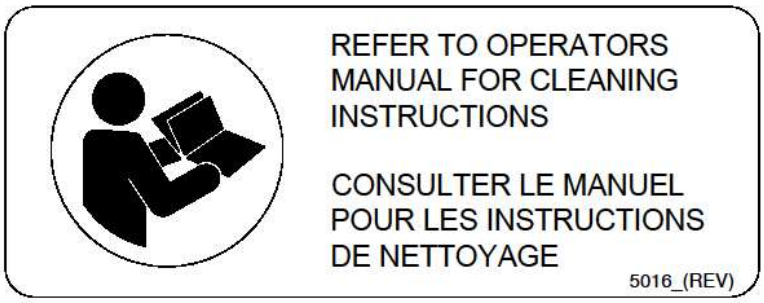


Chair Capacity label:

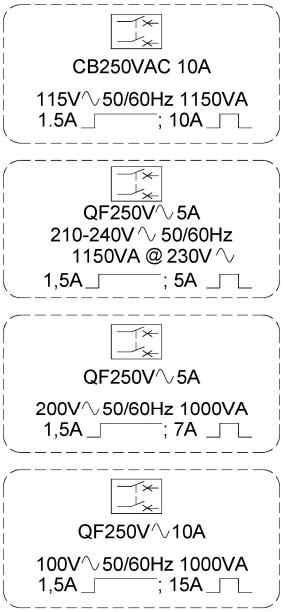
Lift Switch Label:



Cleaning Instructions Label:

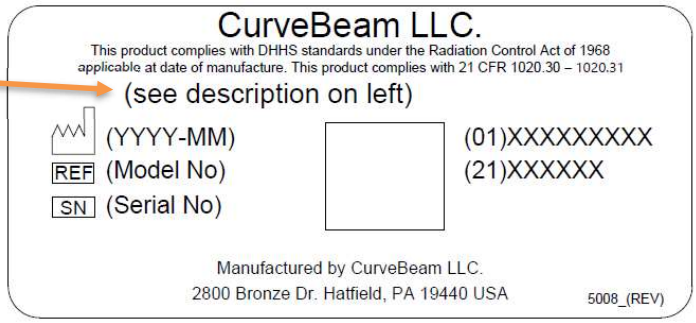


Input Power Label:

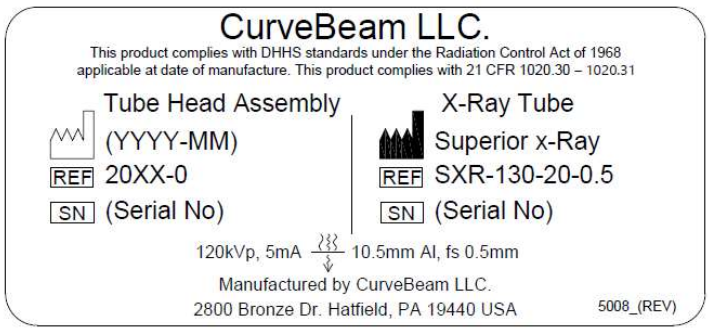


System Label:

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



Tube Head Label:



SYMBOLS:			
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	
Fuse T1A250V, T=time delay, 1amp, 250volt fuse F250mA250V, F=fast acting, 250mA, 250volt fuse	I Power/Circuit ON 0 Power/Circuit OFF	**CE Mark** 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

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:

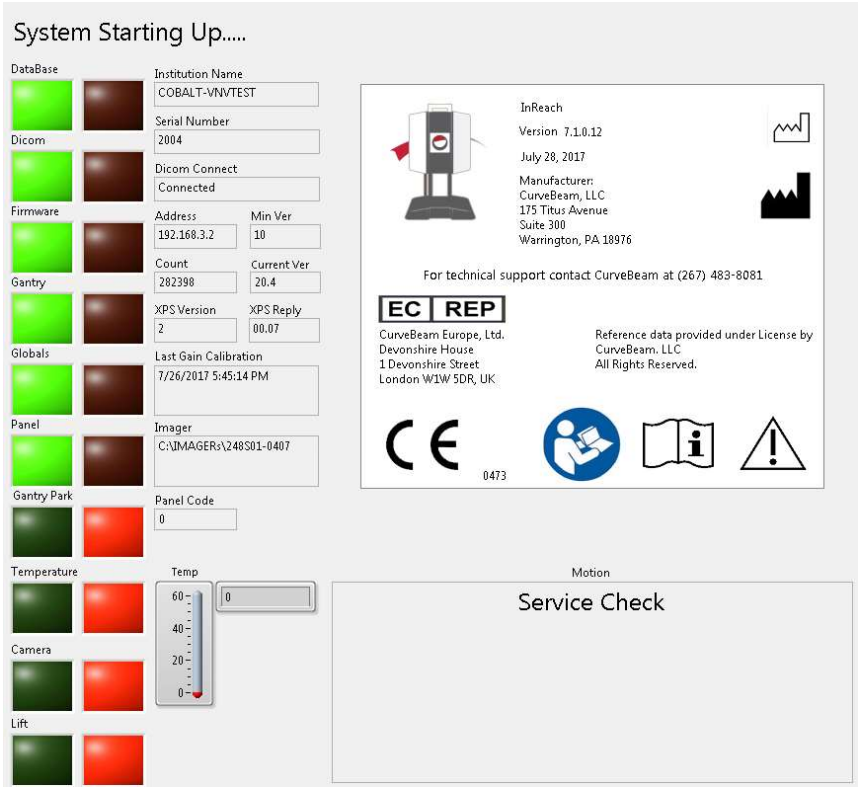
- Panel Gain Calibration (Gain)
- Normalization File Creation for Reconstruction engine (Norm)
- Image Quality Analysis (QA)

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.

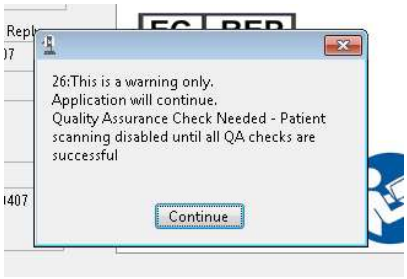
Once the pop up message in Acquisition alerts the user that a Calibration is needed, the user can exit the Acquisition software and start up the CB-ToolShed software, located on the desktop of the Acquisition terminal. Double click on the CB-ToolShed icon to start the calibration software.

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

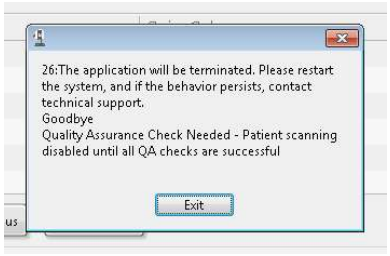


As CB-ToolShed starts up and checks all of the parts of the system, lights should change from red to green to indicate that the scanner is able to be used for calibrations.

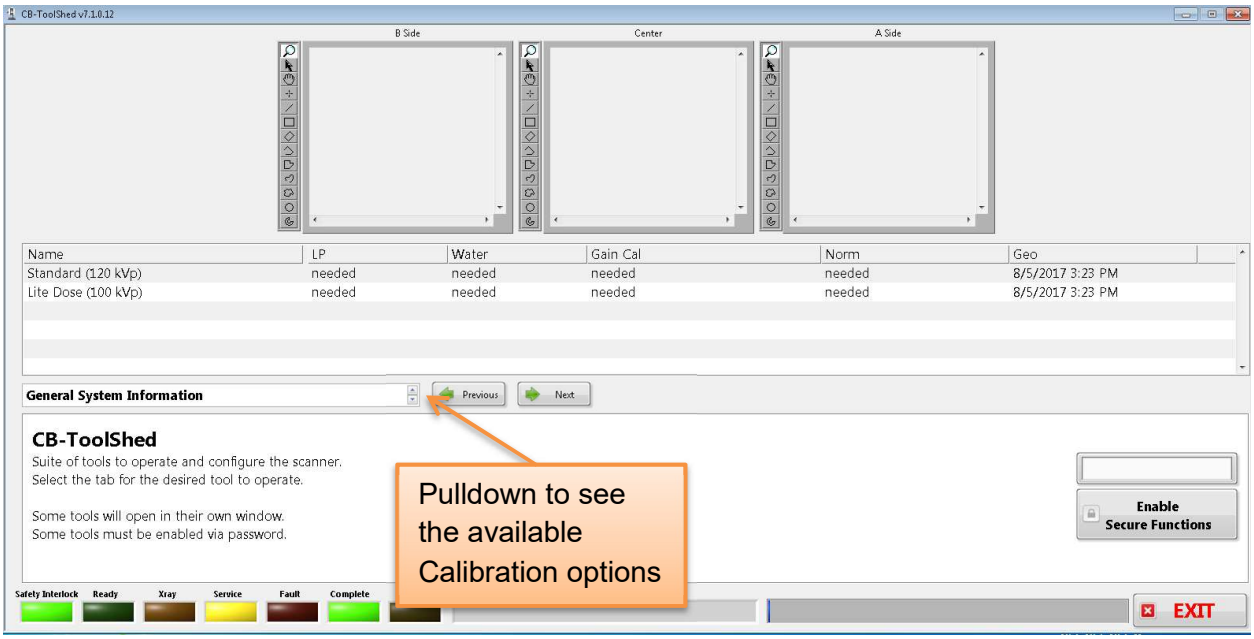
It is possible that a warning message might also appear, as shown below, just click “Continue” as the calibrations about to be performed will fix the issue that created the warning message. Warning message such as this may appear:



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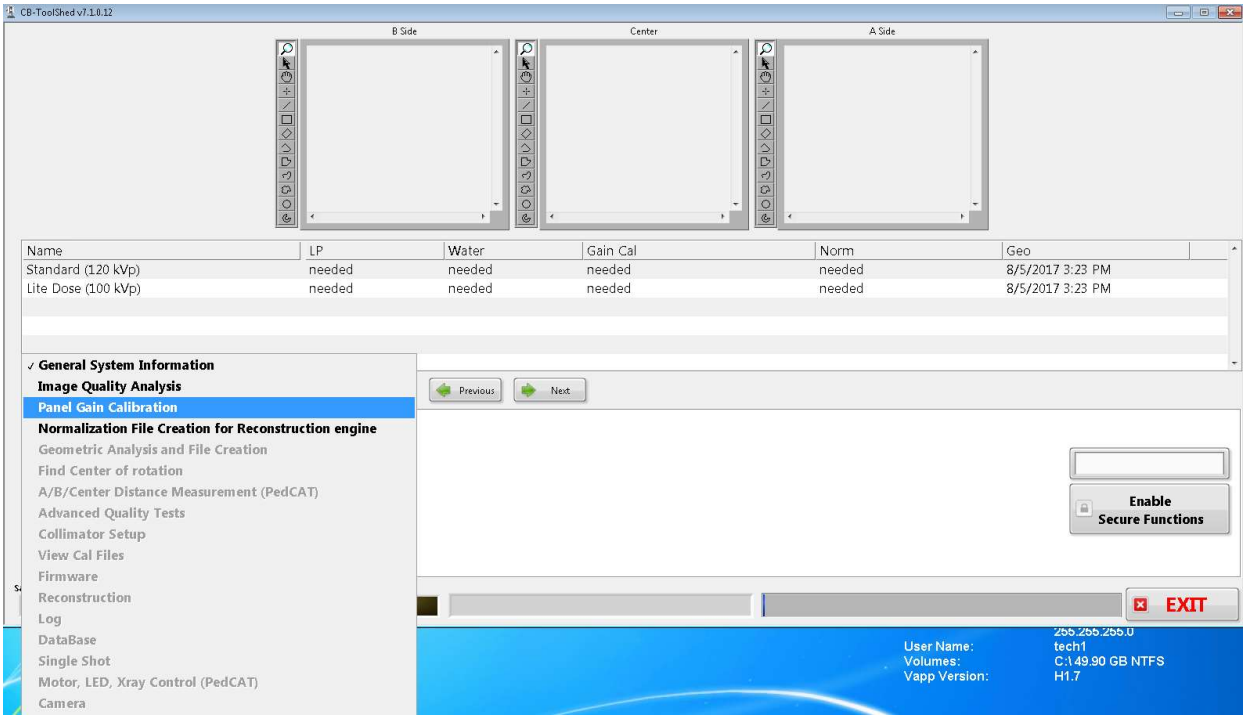
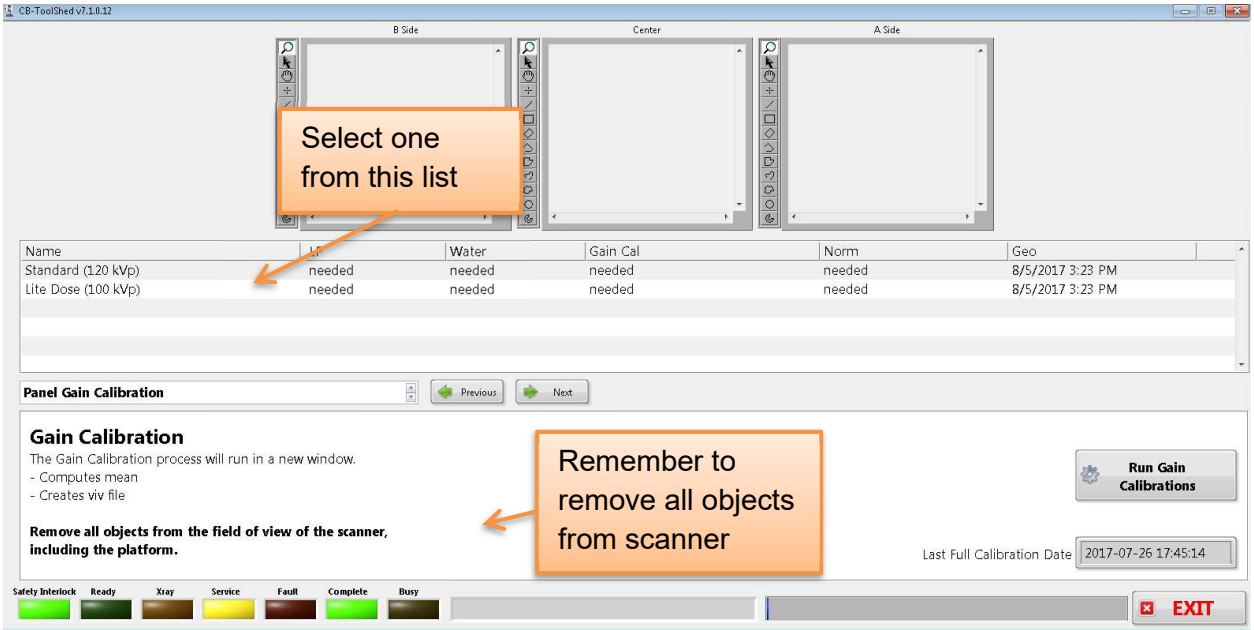
The first calibration that needs to be performed is the Panel Gain Calibration. Click on the pulldown next to General System Information to display the list of calibrations possible. The available options will appear as follows:



From the pulldown list, select the “Panel Gain Calibration” and the following will appear:



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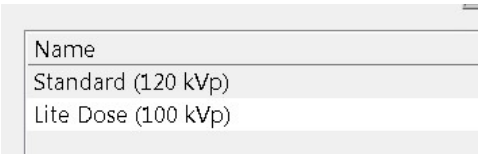
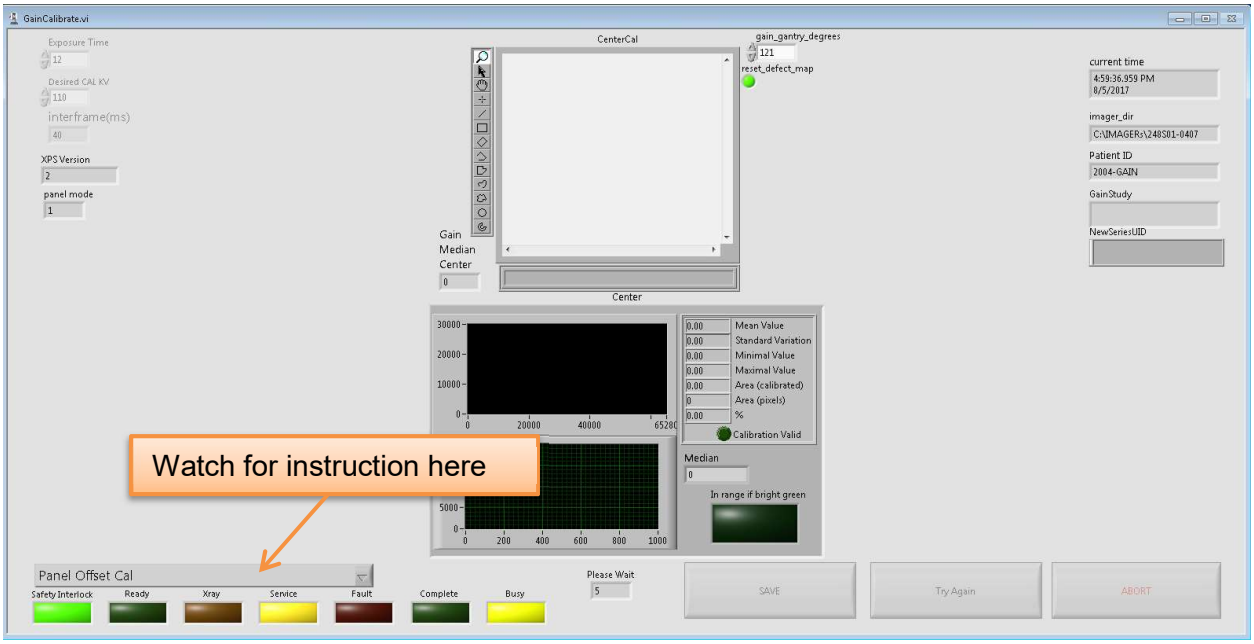
Before starting the Panel Gain Calibration, it is important to remove all objects from the scanner, including any patient platforms.

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: 

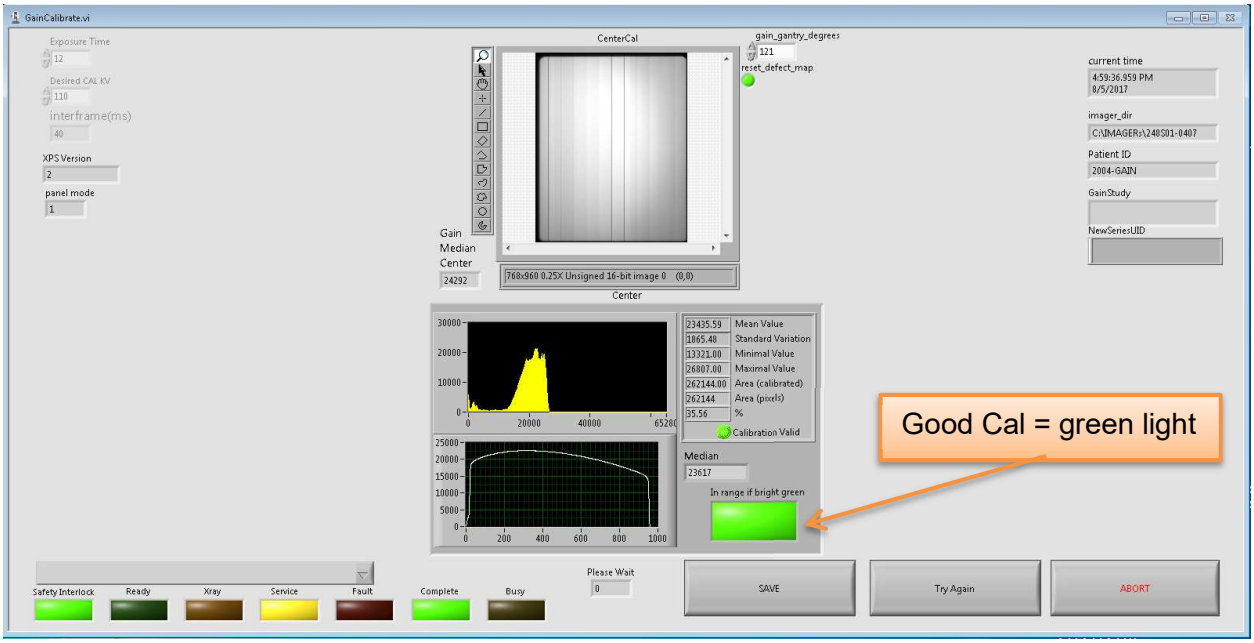
to start the calibration and the following screen will open on top of the current window:



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.

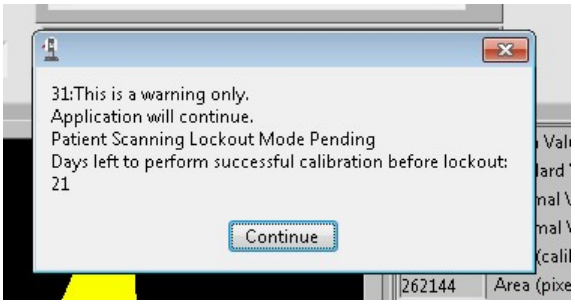
> **WARNING** The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow operating instructions. Do not operate this system unless you have received training to perform a procedure

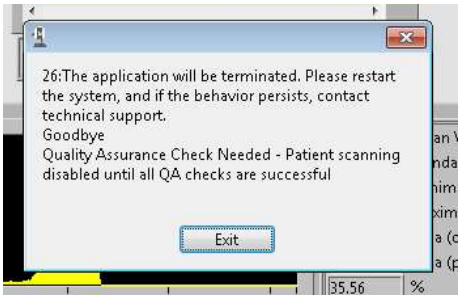
After the x-ray has completed, release the scan button. The image on the screen will look similar to the below image where the Center Cal window will now show an image of the empty panel as part of the calibration:



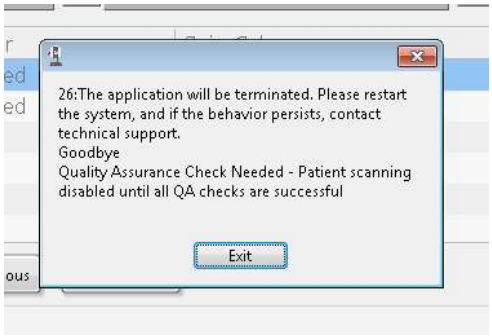
Once the calibration scan has been taken, the three buttons at the bottom of the screen, “SAVE”, “Try Again”, and “ABORT” will all become active and selectable. If the calibration was successful, there will be a bright green light illuminated under the text “In range if bright green” as shown in the 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.



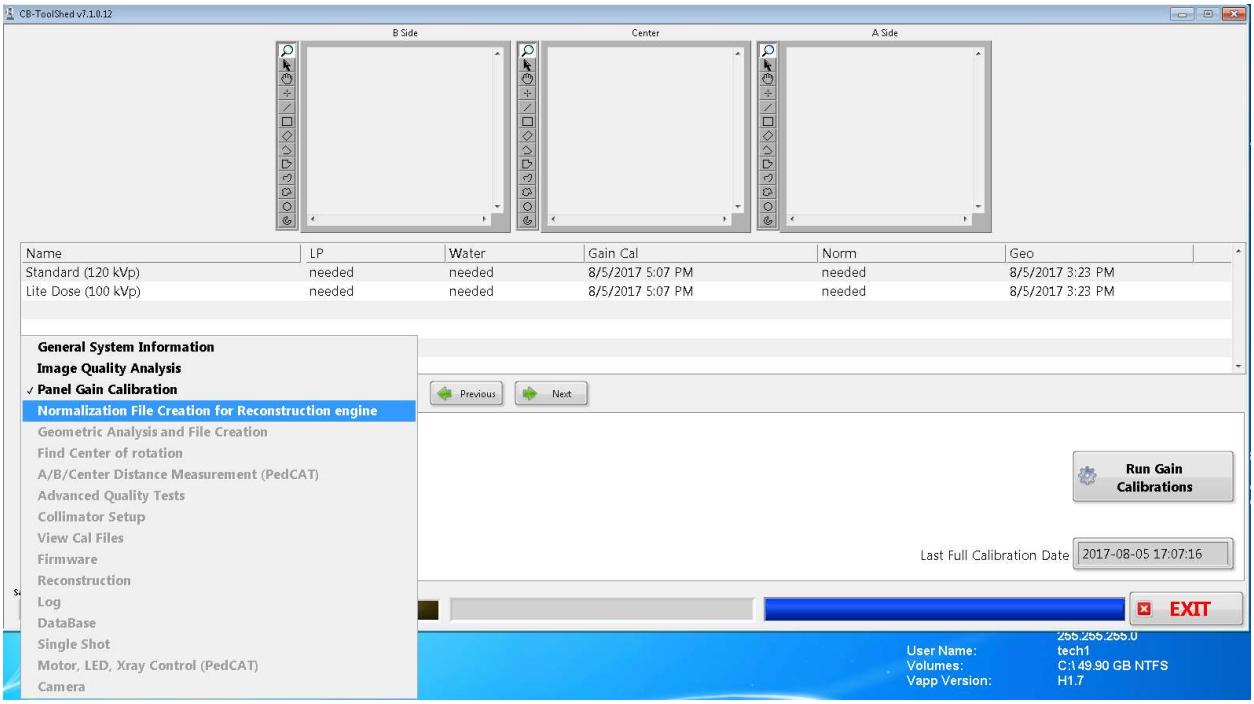


And finally back on the main CB-ToolShed Gain Calibration screen, another pop up message will appear:

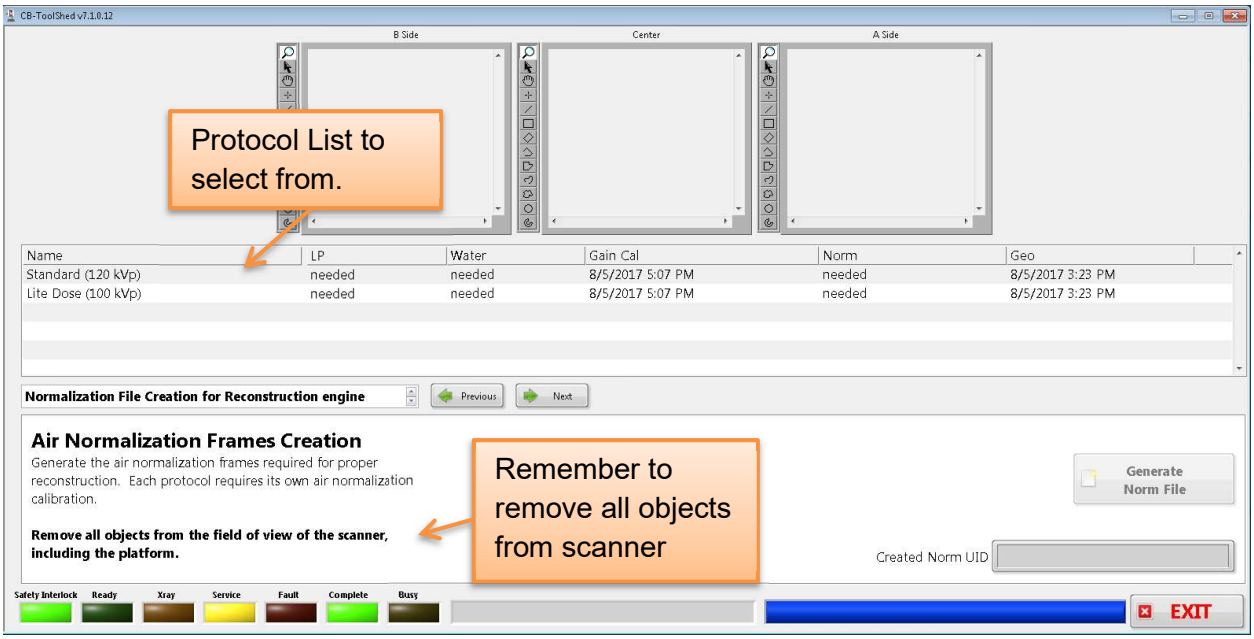


This message indicates also that Quality Assurance checks are still needed as a result of having changed the Panel Gain Calibration. Click “Exit”. Once all of the pop up windows have been dismissed, the Gain Calibration is complete.

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

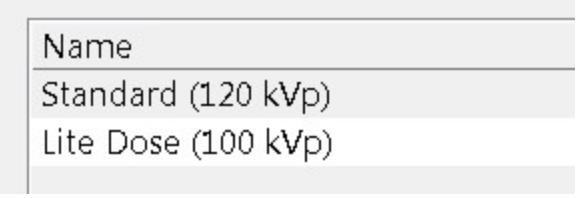


After the “Normalization File Creation for Reconstruction engine” is selected, the screen for this calibration will display as follows:



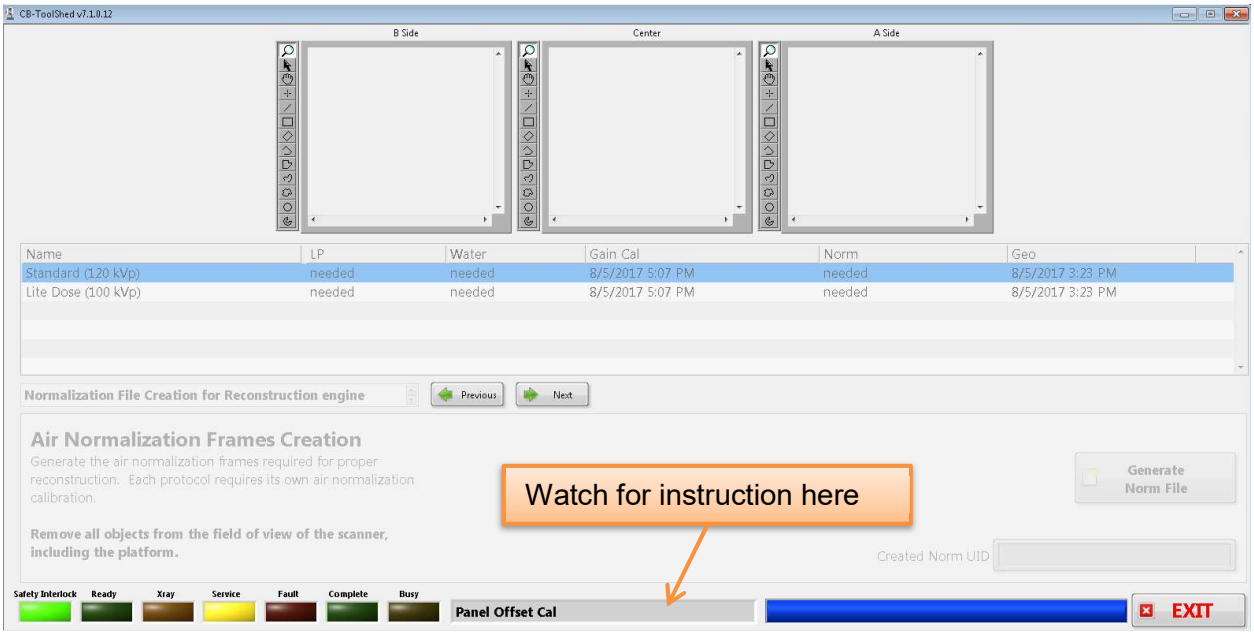
Before starting the Air Normalization Frames Creation, it is important to remove all objects from the scanner, including any patient positioning platforms.

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:

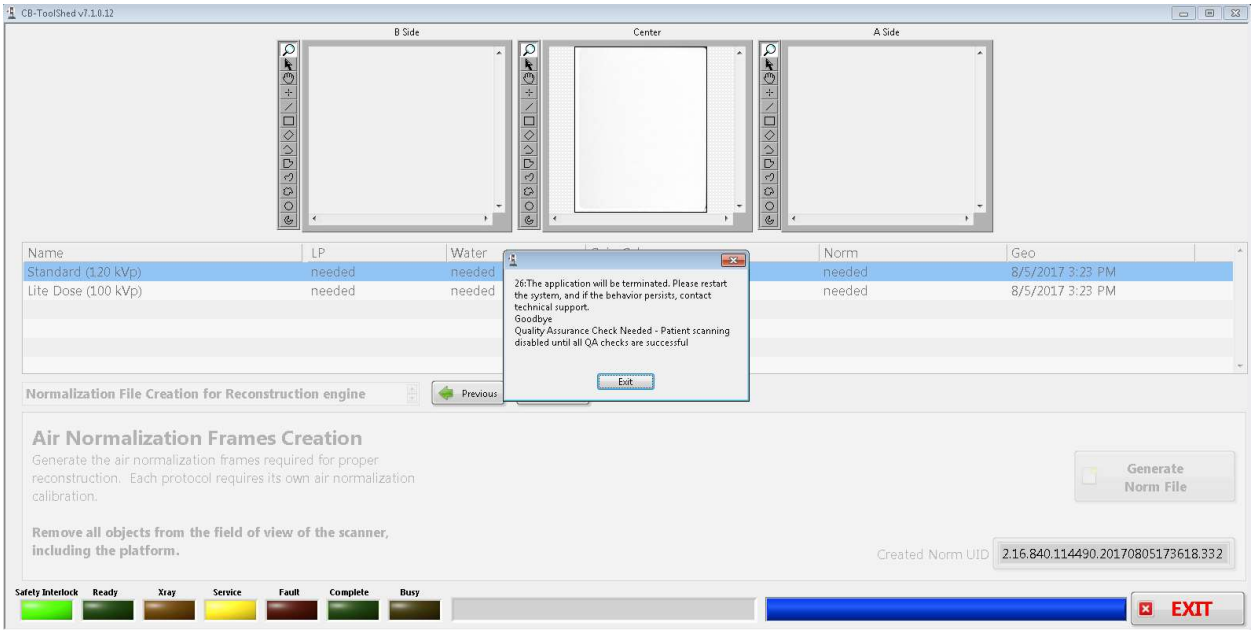


The screen will look mostly grayed out for a bit. Instructions will then indicate when to fire the x-ray for the protocol selected. When prompted, Press and Hold the Scan button to fire the x-ray.

> **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

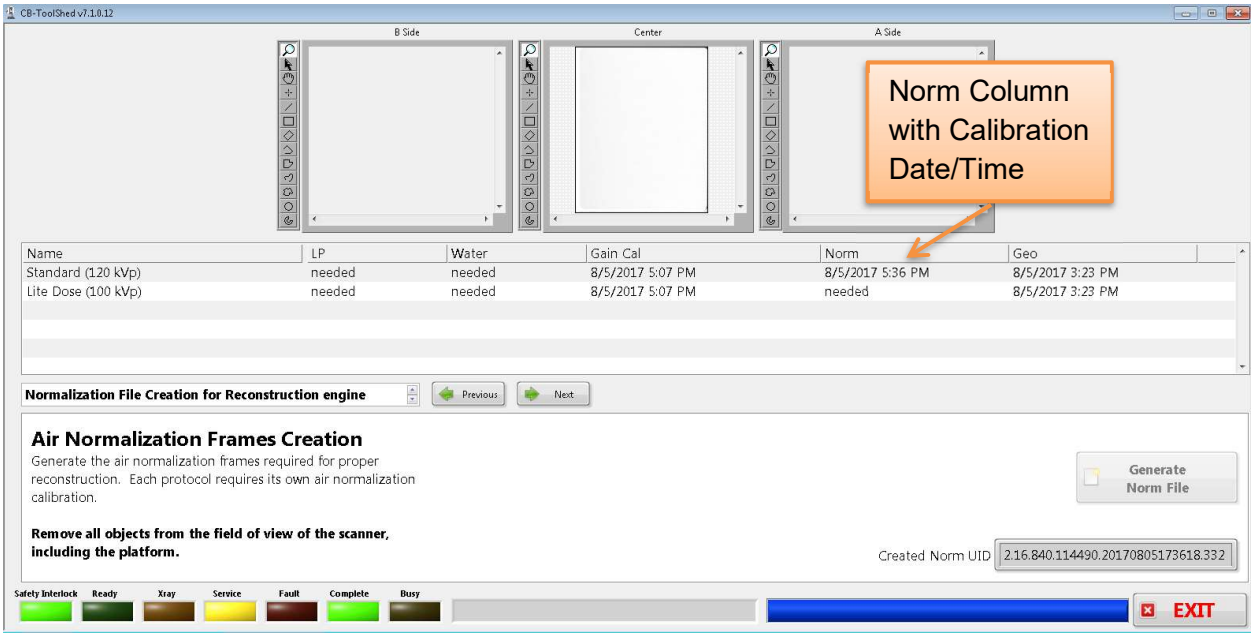
Once the x-ray has completed, release the scan button.

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:



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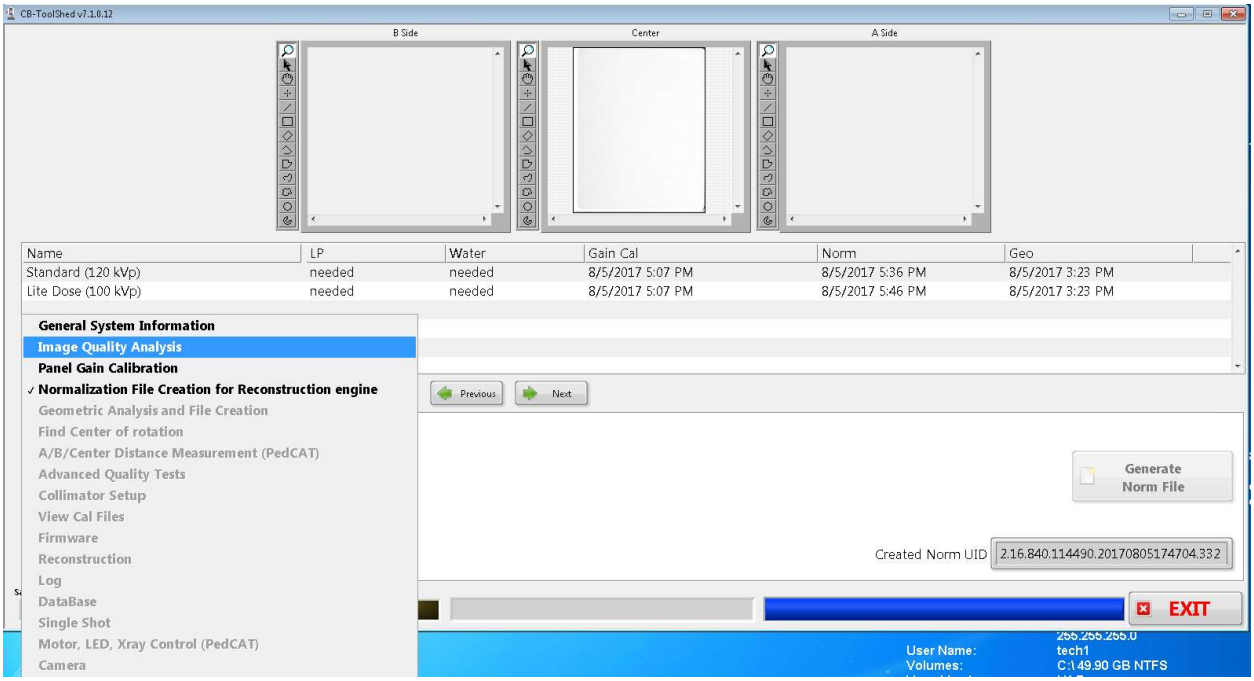
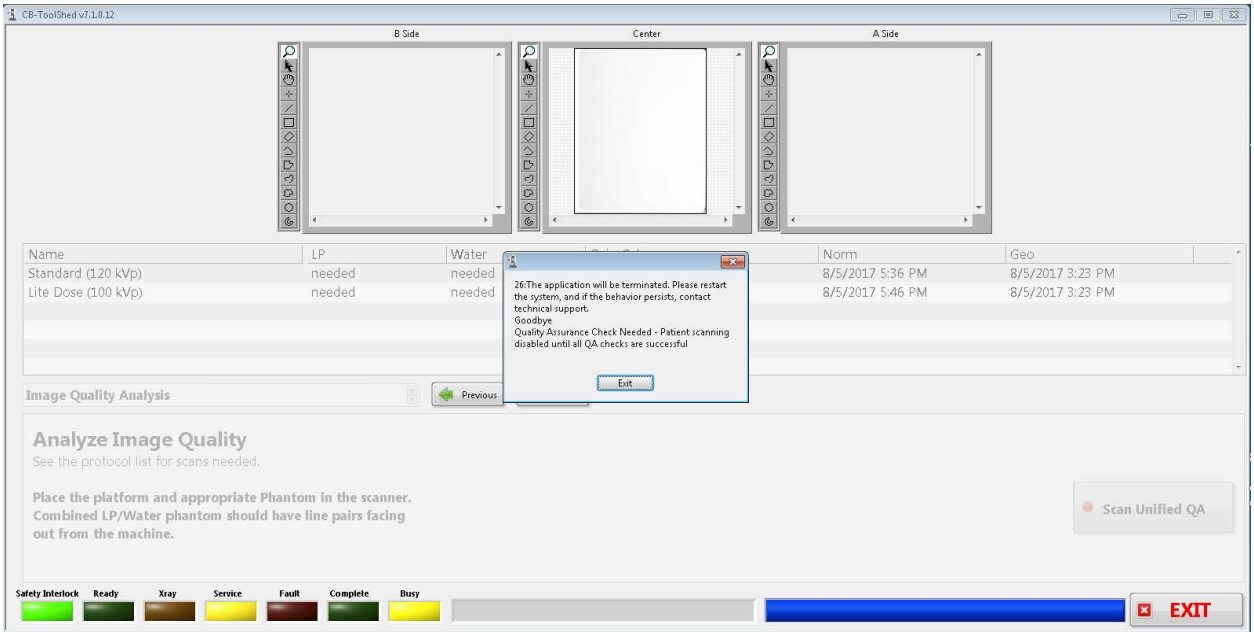
Continue with all of the protocols until each has an updated Norm date and time listed.

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:



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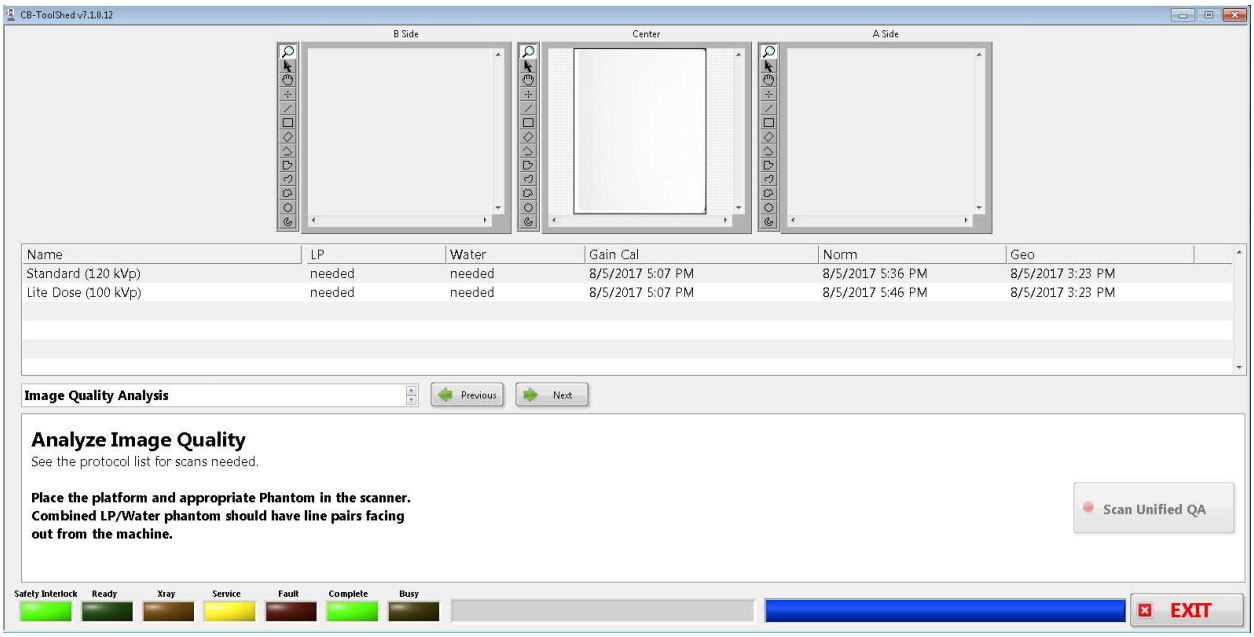
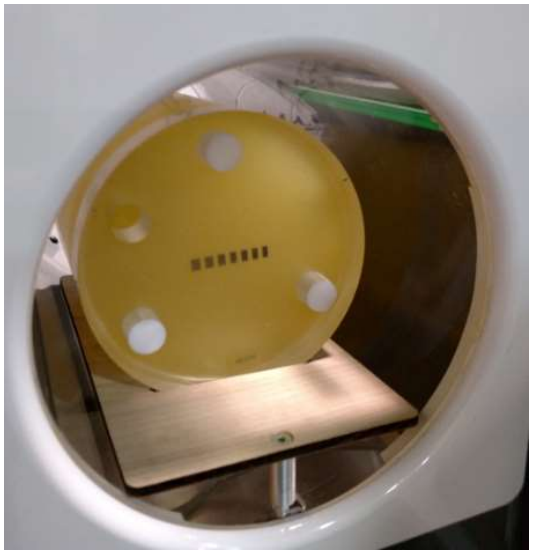
Click on the “Exit” button on the pop up message in the center of the screen. It is just a warning that this final calibration is needed. Then the screen will appear as follows:

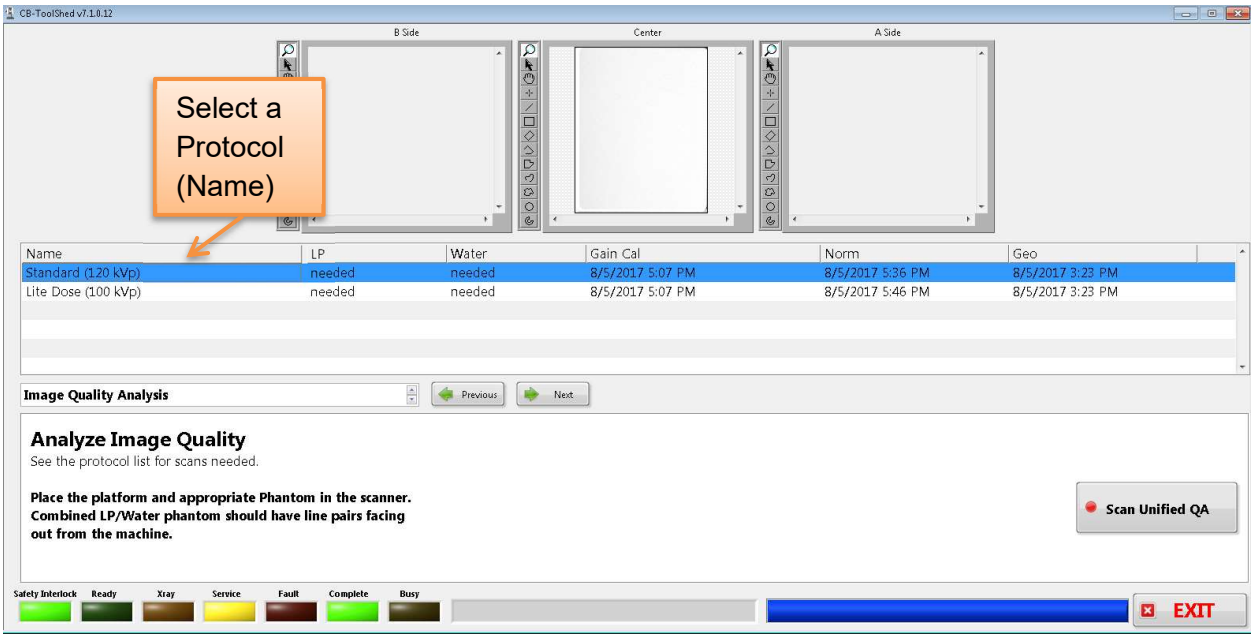


Before starting, the Platform and the QA Phantom must be placed in the scanner. Using the QA Platform, place the QA Phantom as shown below:

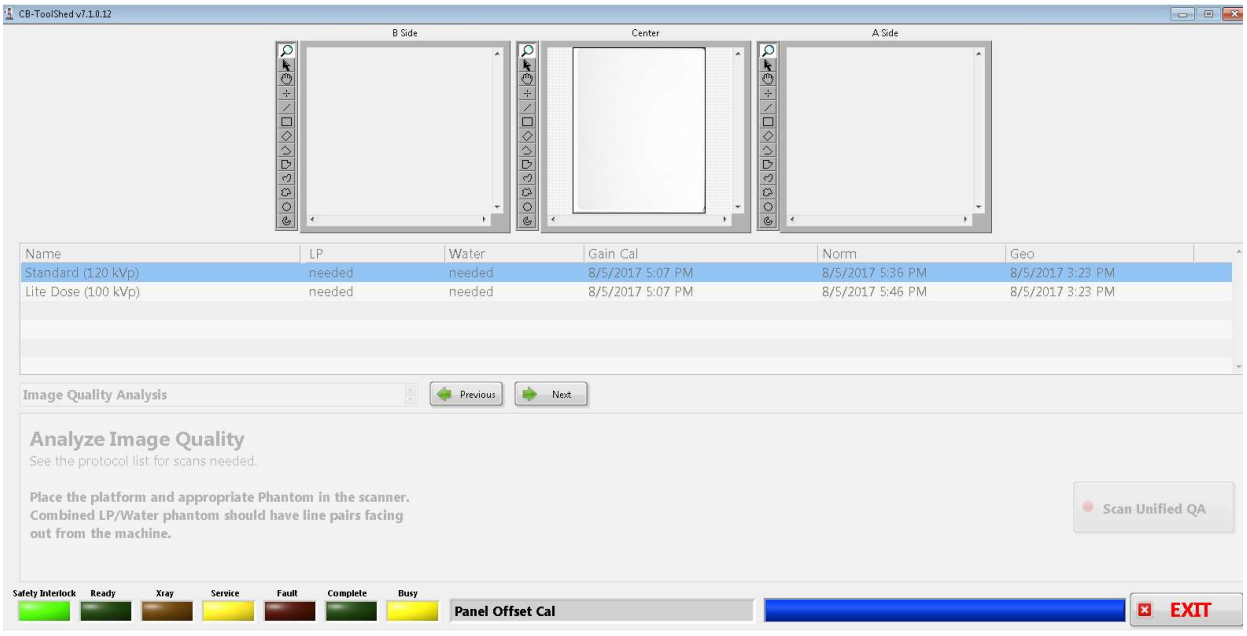


Ensure that the platform is placed so that the metal piece fits in the hole in the front of the bore. Make sure that the Line pairs are visible from the front of the scanner and that they are horizontal.

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:  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:



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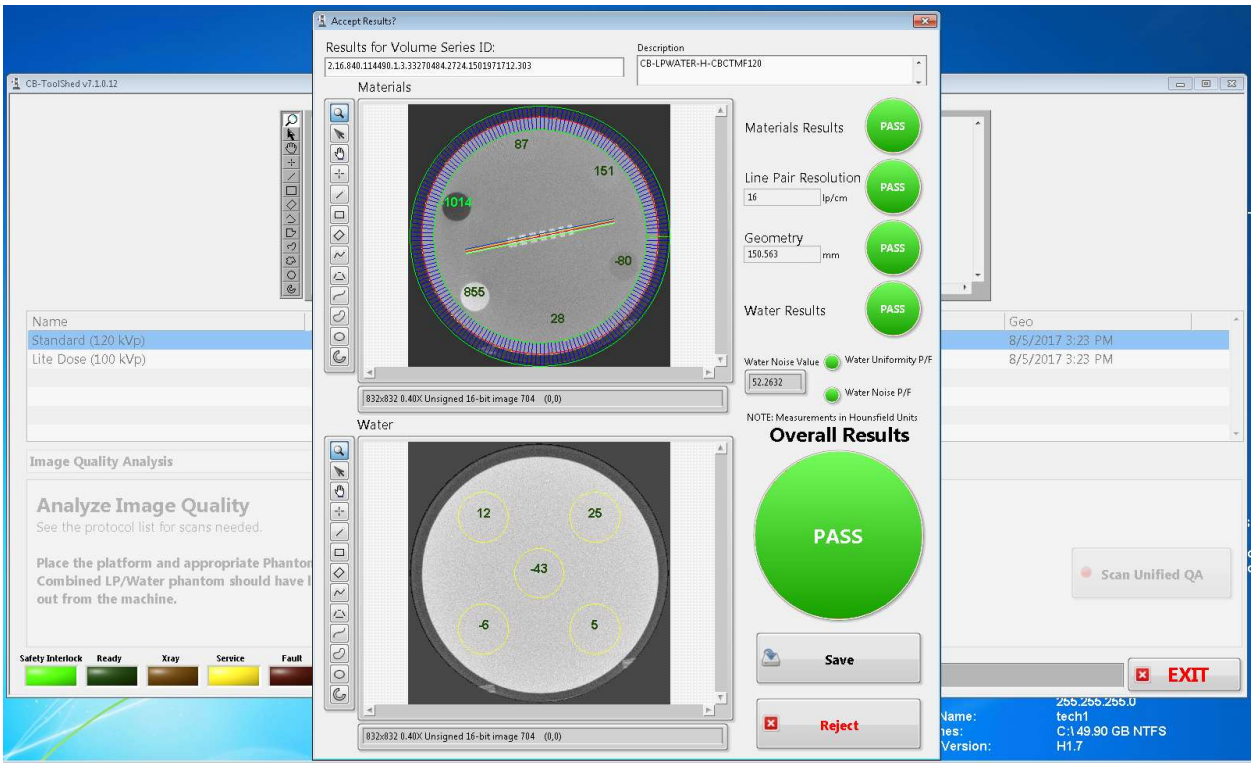
The screen will look mostly grayed out for a bit.

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

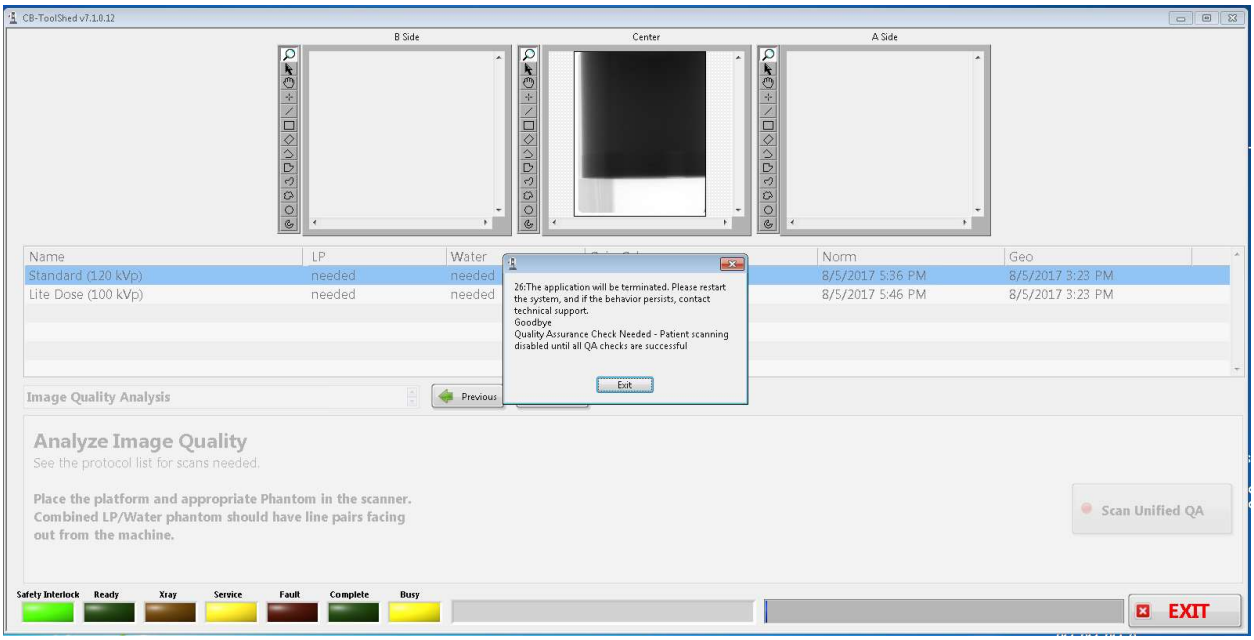
Once the x-ray has completed, release the scan button.

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:

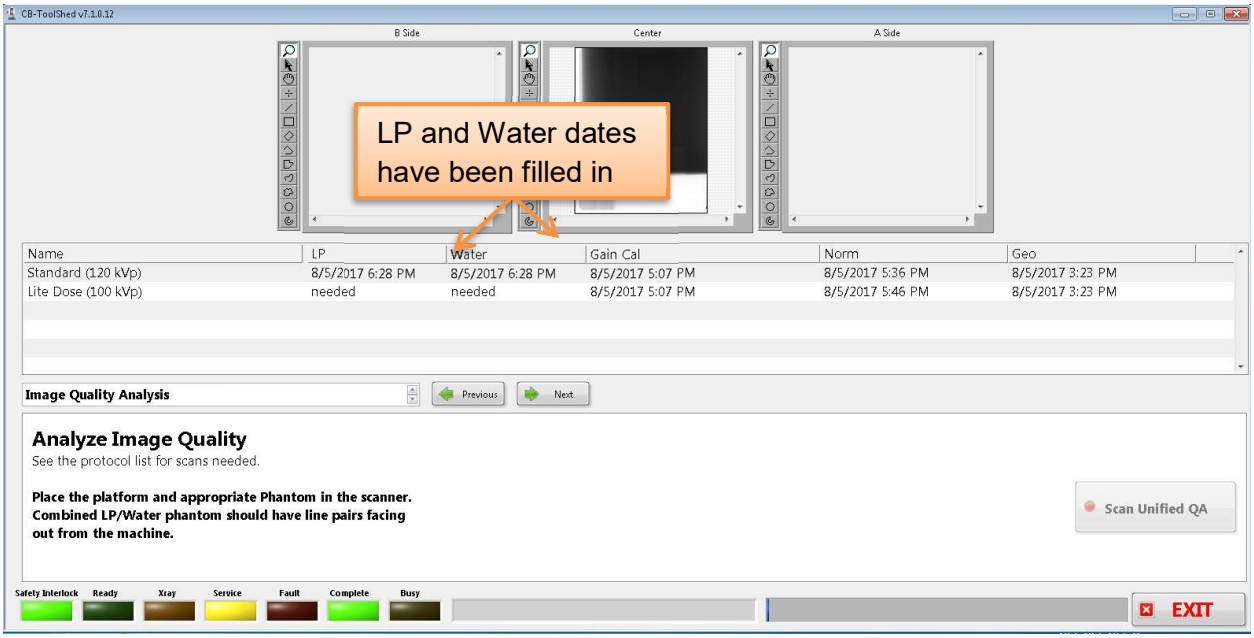


If all lights are illuminated green with “PASS” written in them, the values are good and the user should click the “Save” button. If the colors are red, the values are bad and the user should reject the scan. The user can then try the scan again, if the scan is continually rejected, then please contact 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.

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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

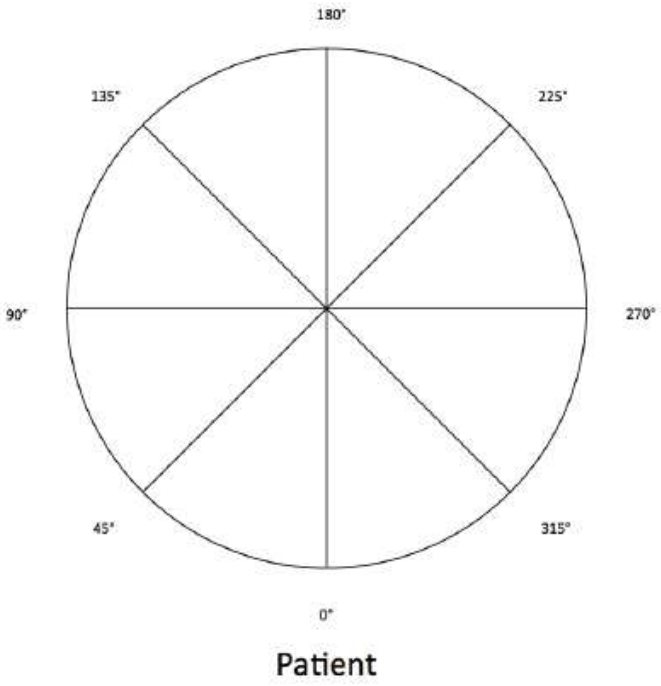
The following protocol were tested for scatter radiation, as well as a number of image quality tests:

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.



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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

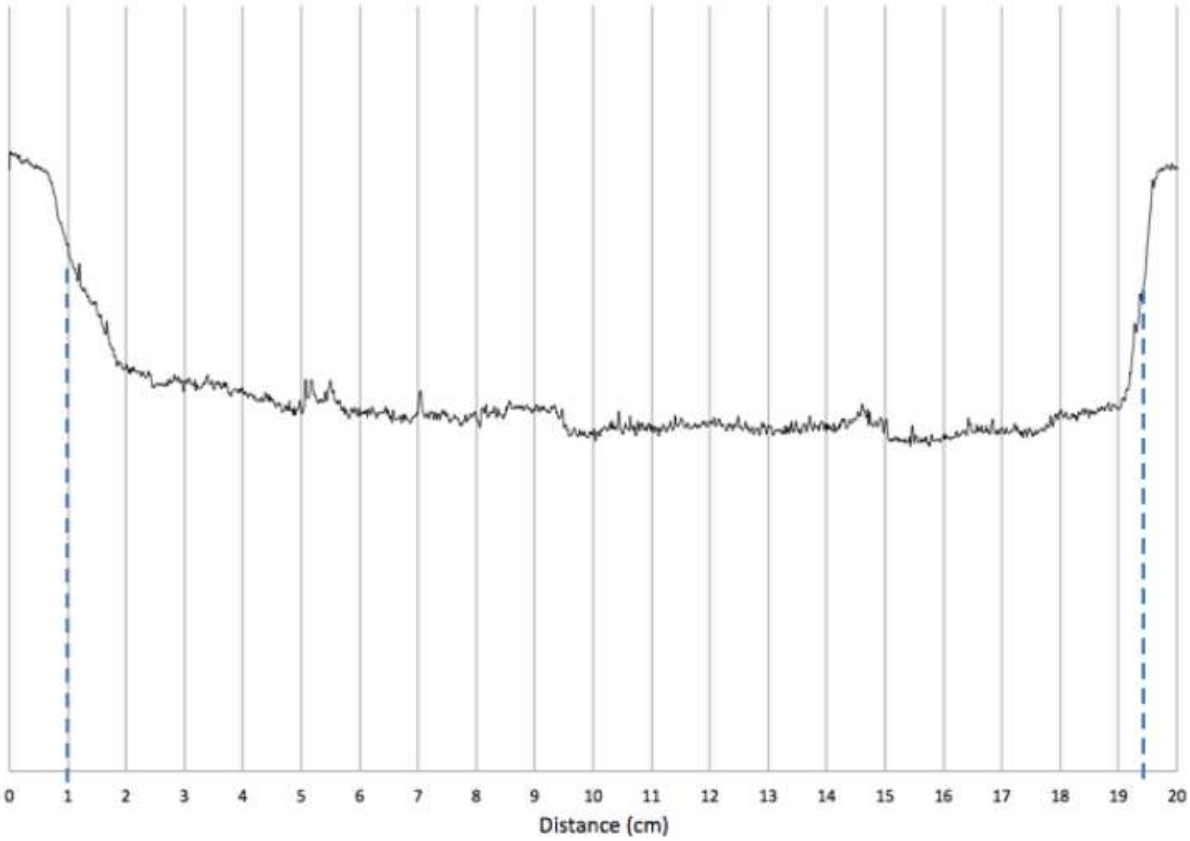
Location Distance (m)		Exposure (mR)	Exposure (µR)	Exposure (µR/mAs)	10 scans/week (mR/week)	25 scans/week (mR/week)	50 scans/week (mR/week)
1 m above	--	0.112	112	3.88	1.12	2.80	5.60
	1 m in front (no shielding)	0.175	175	6.08	1.75	4.38	8.77
	1 m in front (with shielding)	0.070	70	2.44	0.70	1.76	3.52
	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

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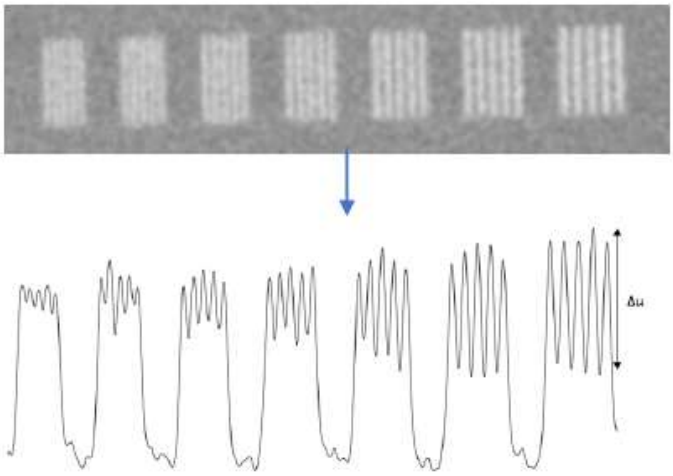
Modulation Transfer Function (MTF)

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.



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

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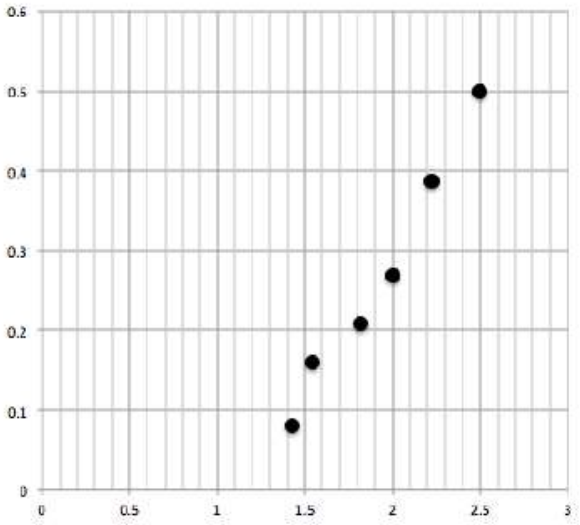
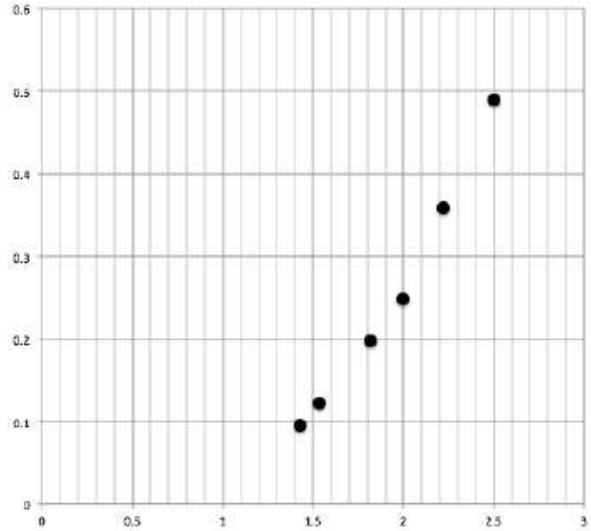
Results

100 kVp:



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

120 kVp:



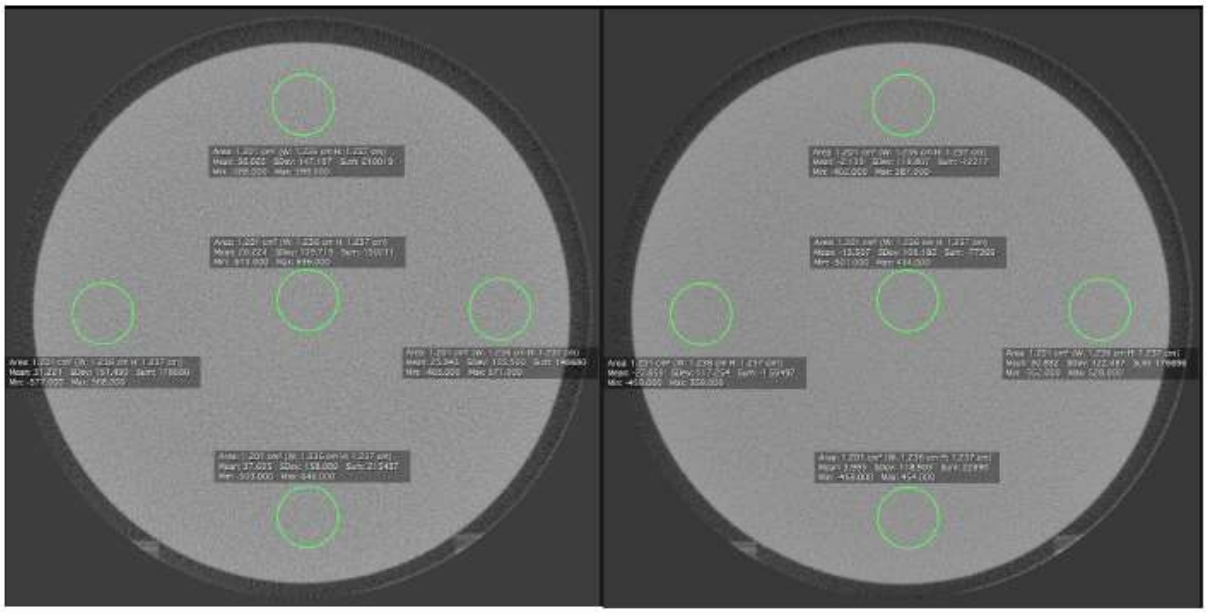
Limiting Resolution (MTF < 0.1)	
Line Pair per mm (lp/mm)	13
mm	1.45

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

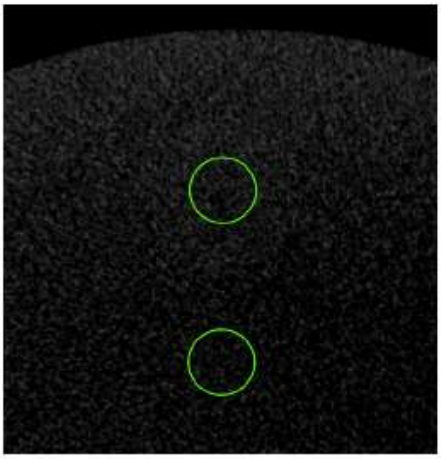


Protocol	Maximum Center-Peripheral Deviation	Limit (set by manufacturer)
100 kVp	11.381	<100
120 kVp	44.339	<100

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

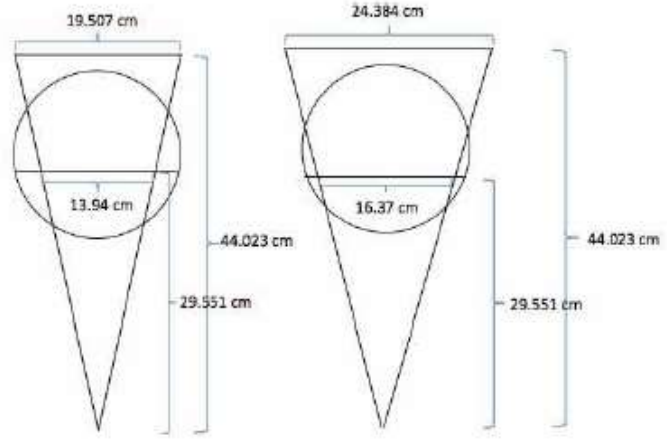
The dose area product (DAP) was determined for the following protocols:

kVp	mA	Pulse Duration (seconds)	Number of Pulses per Scan	mAS	Slice Thickness (mm)	Number of Slices	Scan Diameter (cm)	Dose Area Product (mGy*cm^2)
100	S	0.012	492	29.52	0.2	872	11.77	813.4
120	S	0.012	492	29.52	0.2	872	11.77	1247.6

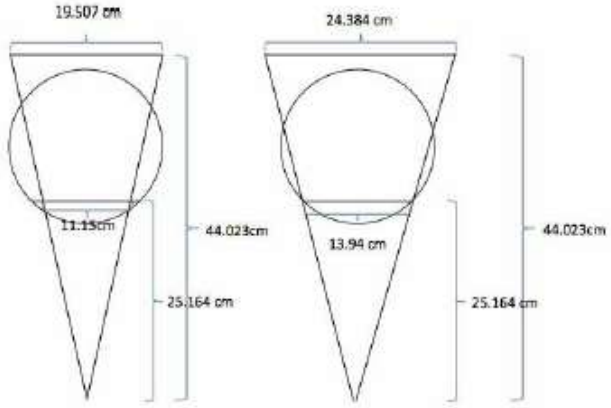
Methodology

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 (cm^2)	214.32	213.32
DAP (mGy*cm^2)	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 (cm^2)	155.42	156.42
DAP (mGy*cm^2)	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:

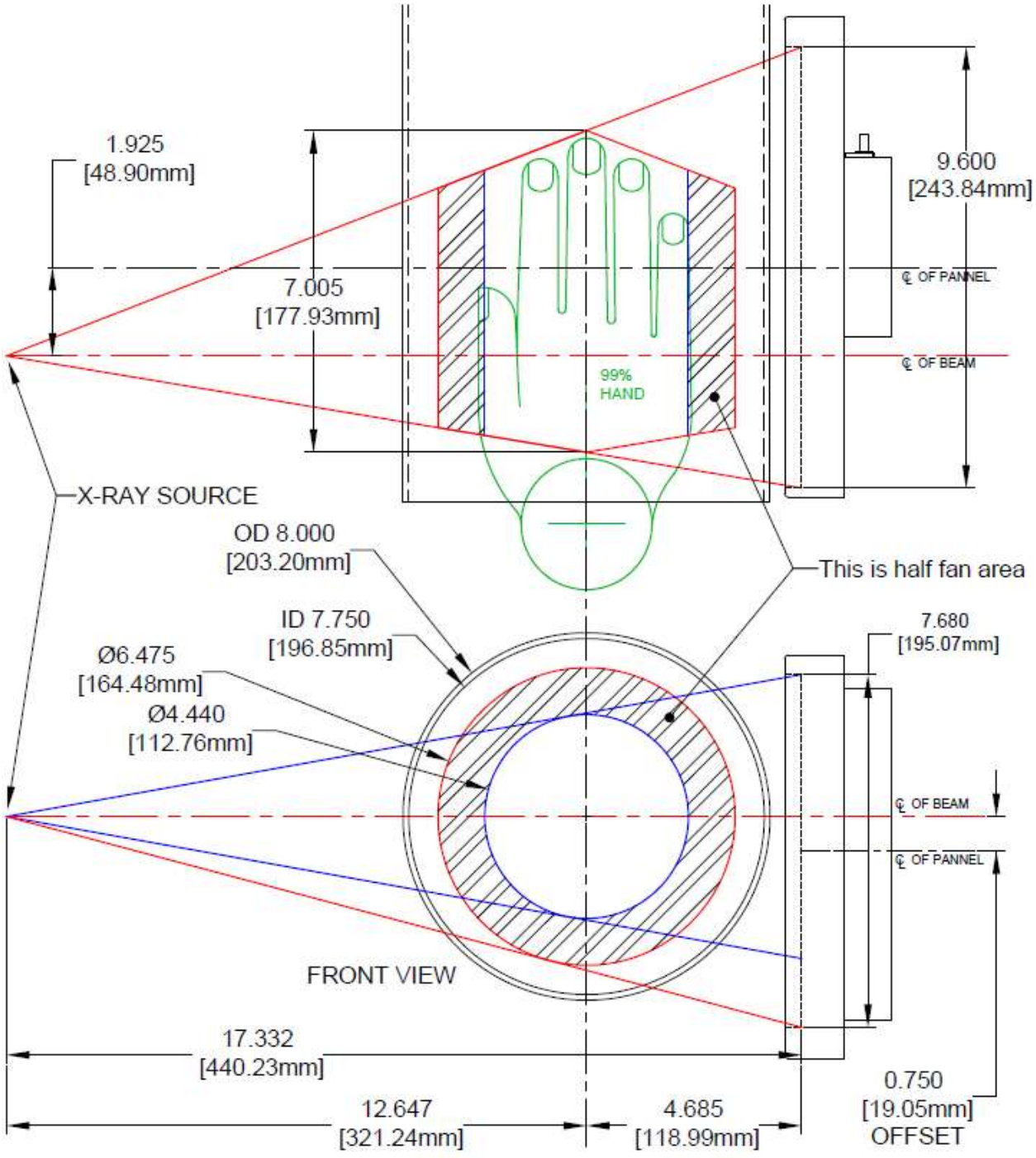
X-Ray unit - CBCT dosimetry was performed on a pre-production CBCT unit (InReach, CurveBeam Inc., Warrington, PA). The X-Ray unit incorporates a 25x20cm amorphous silicon flat panel detector with a pixel size of 0.127mm, easily capable of providing a 0.2mm isotropic voxel size upon volumetric reconstruction 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



Site Survey Available by request.

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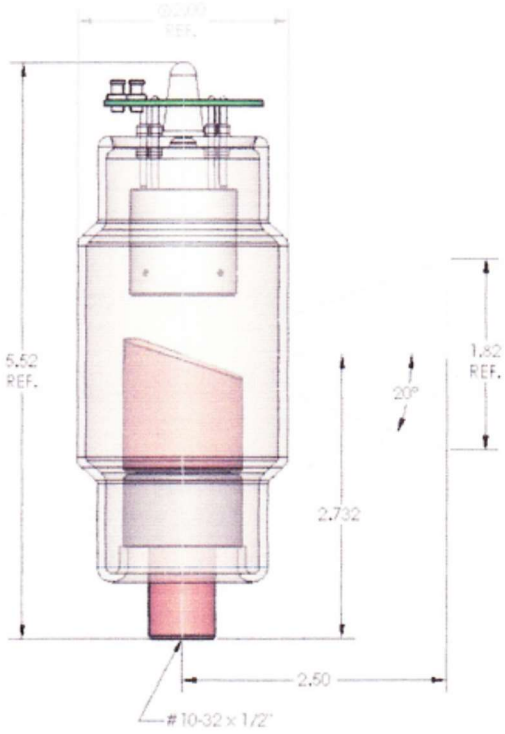
X-ray Tube Assembly:

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

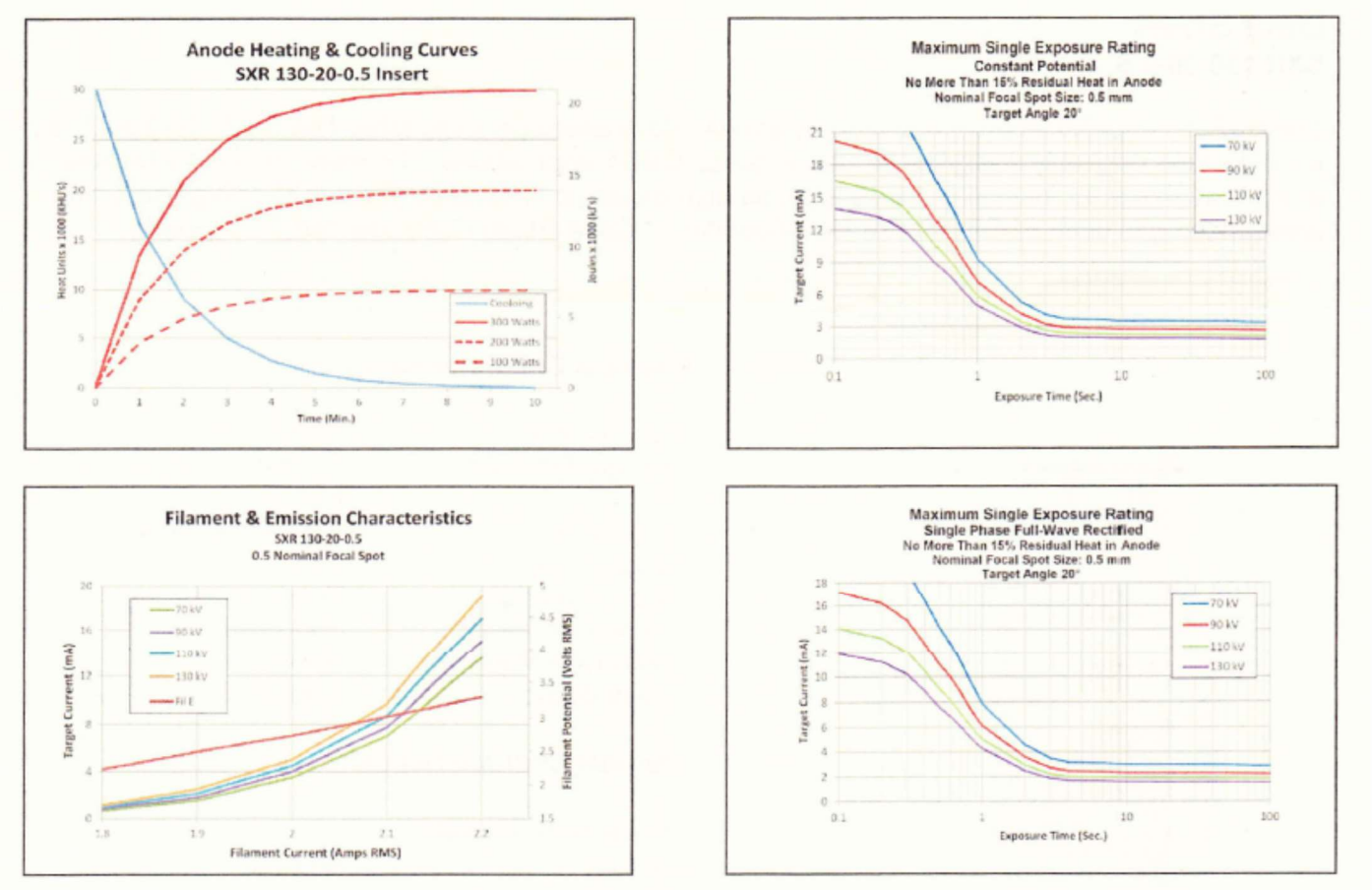
Thermal Characteristics:

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

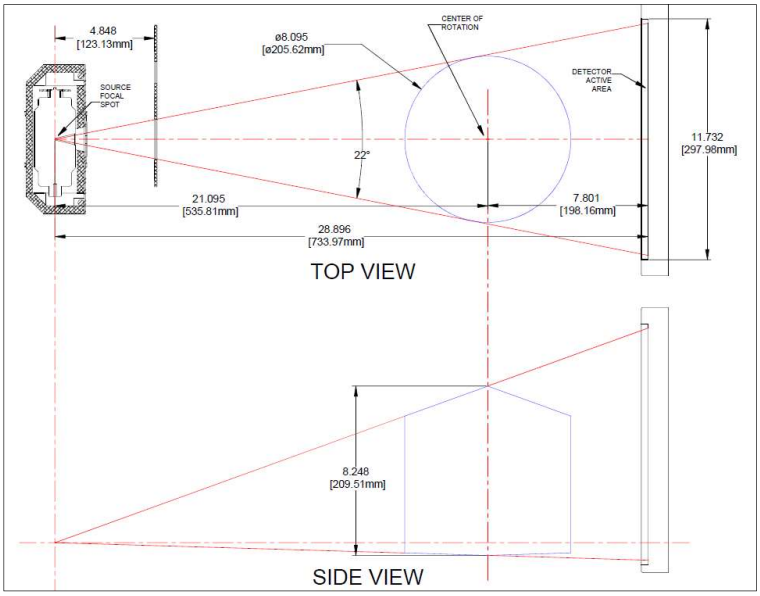
Electrical Characteristics:

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.



Beam Path and Angulation:



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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.

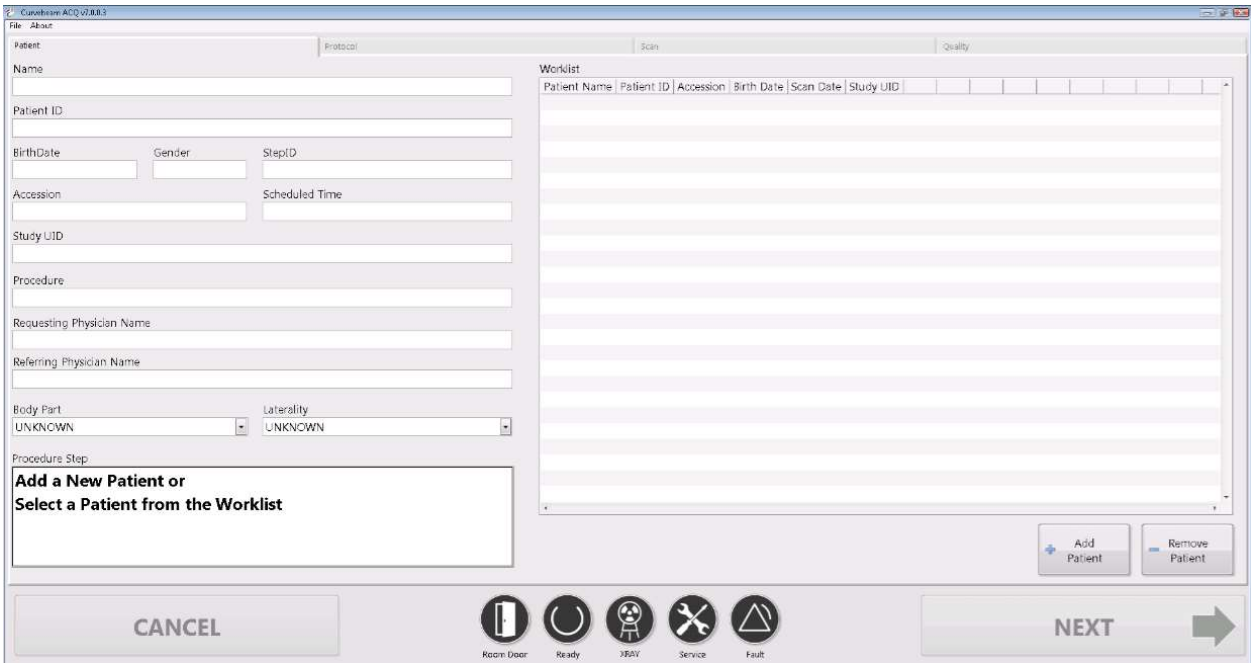
Start up the Acquisition software by double clicking on the CB-Scanner Shortcut. An "About Screen" will appear which displays the software version number and details. Or, the following About screen can always be accessed from the Acquisition software's "About" button.

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:

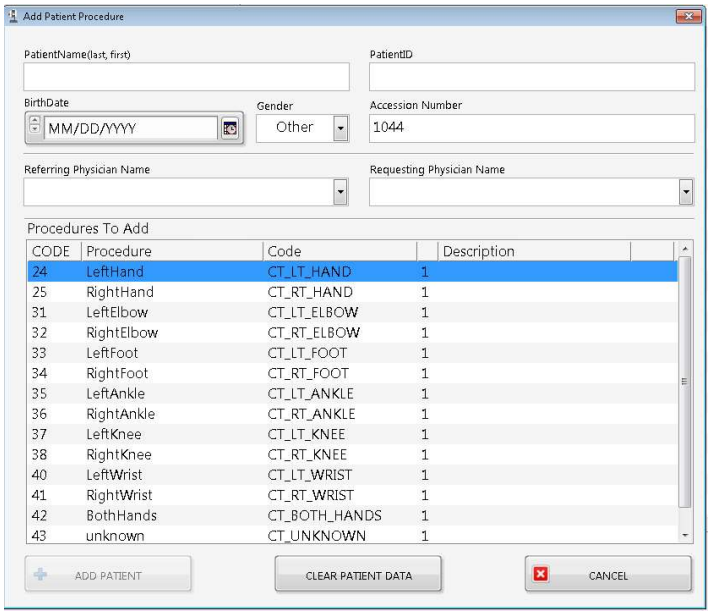
- Patient: Access or Add New patient information.
- Protocol: Select the intended protocol to use.
- Scan: Position Patient and Perform Scan Acquisition.
- Quality: Perform a QA (Quality Assurance) check of the scan acquired.

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.

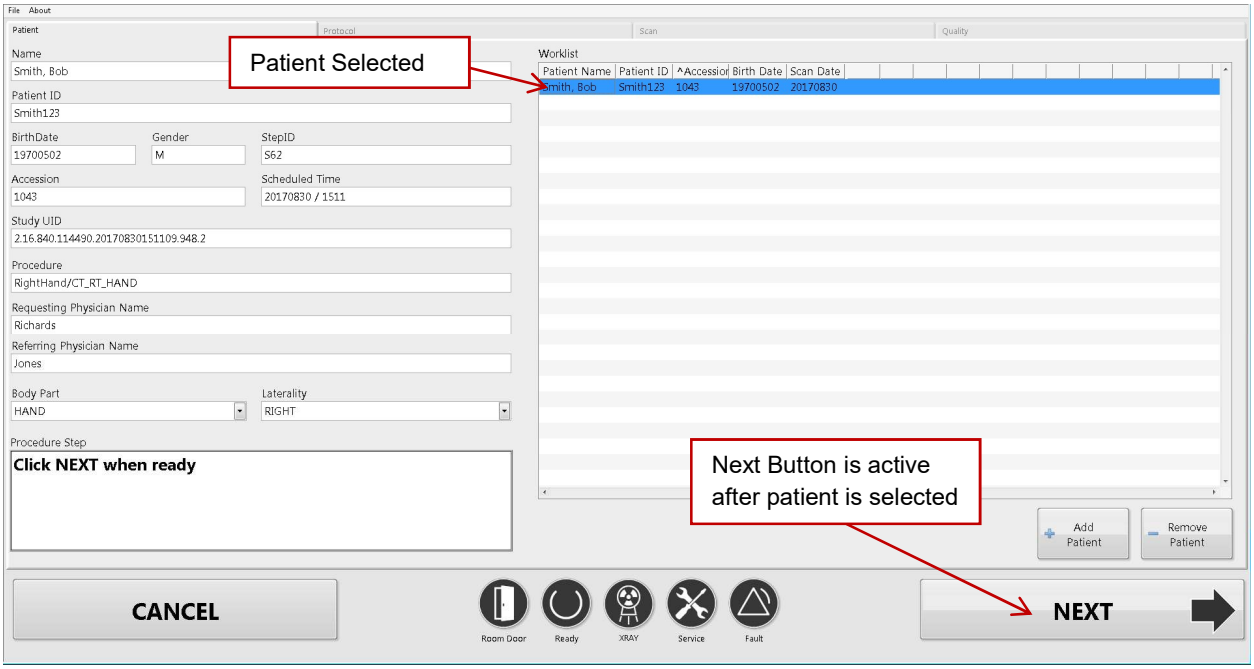
When the “Add Patient” button is selected, the following pop up box will appear:



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

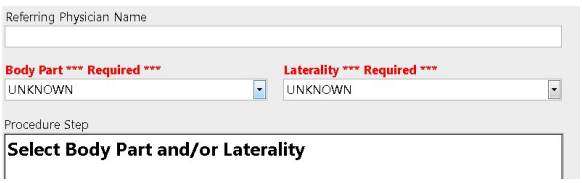
as well, select the “Add Patient” button to add the patient to the Worklist. The previous patient entered, during this time that the software is open, will still populate the fields in this Add Patient box. Use the Clear Patient Data button to clear all the fields to enter in a brand new patient. If 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:



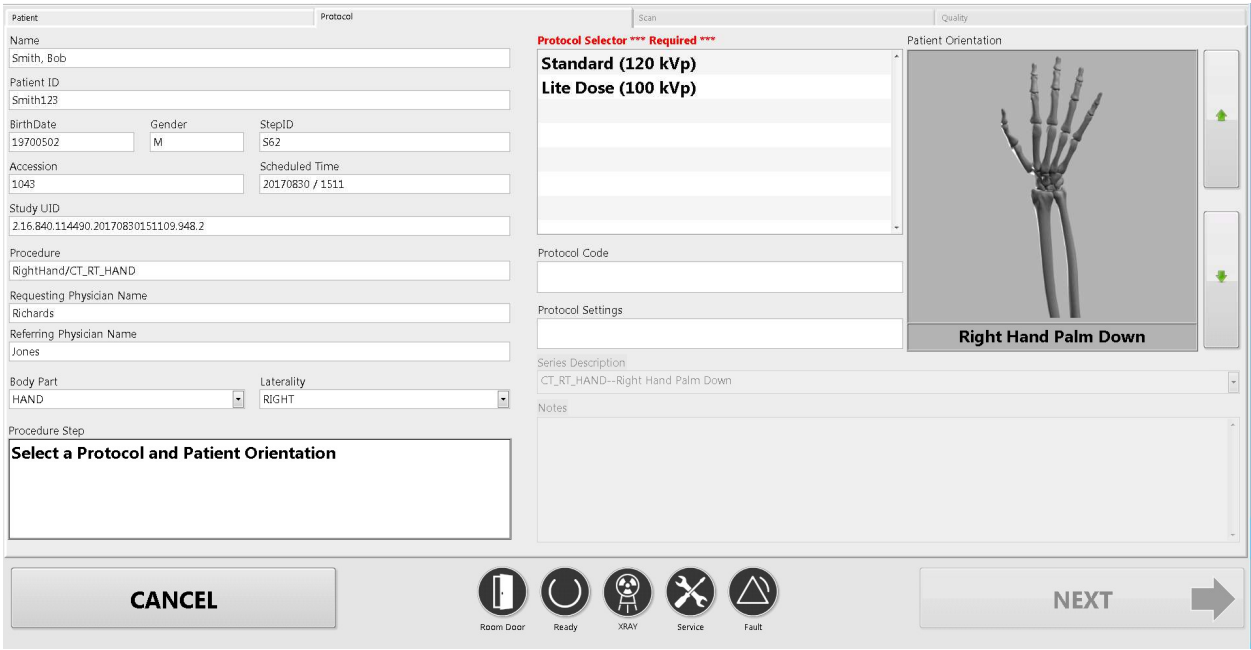
Once the patient has been selected, click on “Next” to move to the Protocol tab. The “Next” button remains grayed out until the patient has been selected.

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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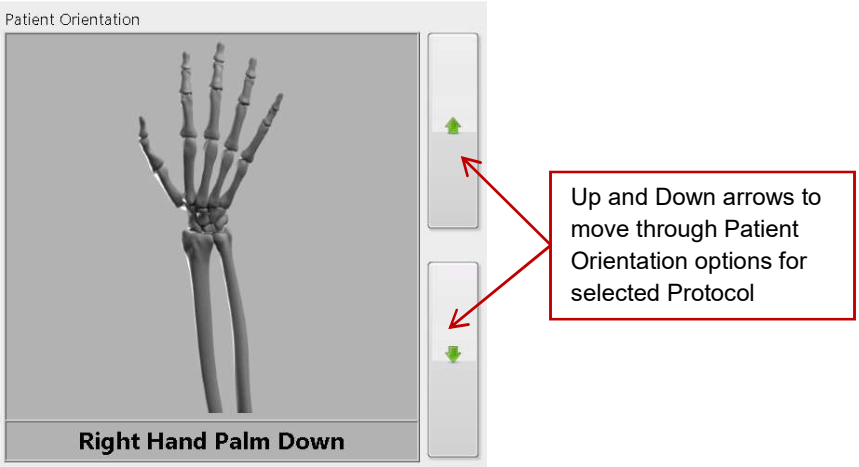
Once the Protocol is highlighted, the default values for the Protocol Code, Protocol Settings, and Series Description will be populated. Select the appropriate Patient Orientation from the top right of the screen. The options are changed by clicking on the Up or Down arrows to the right of the image 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.

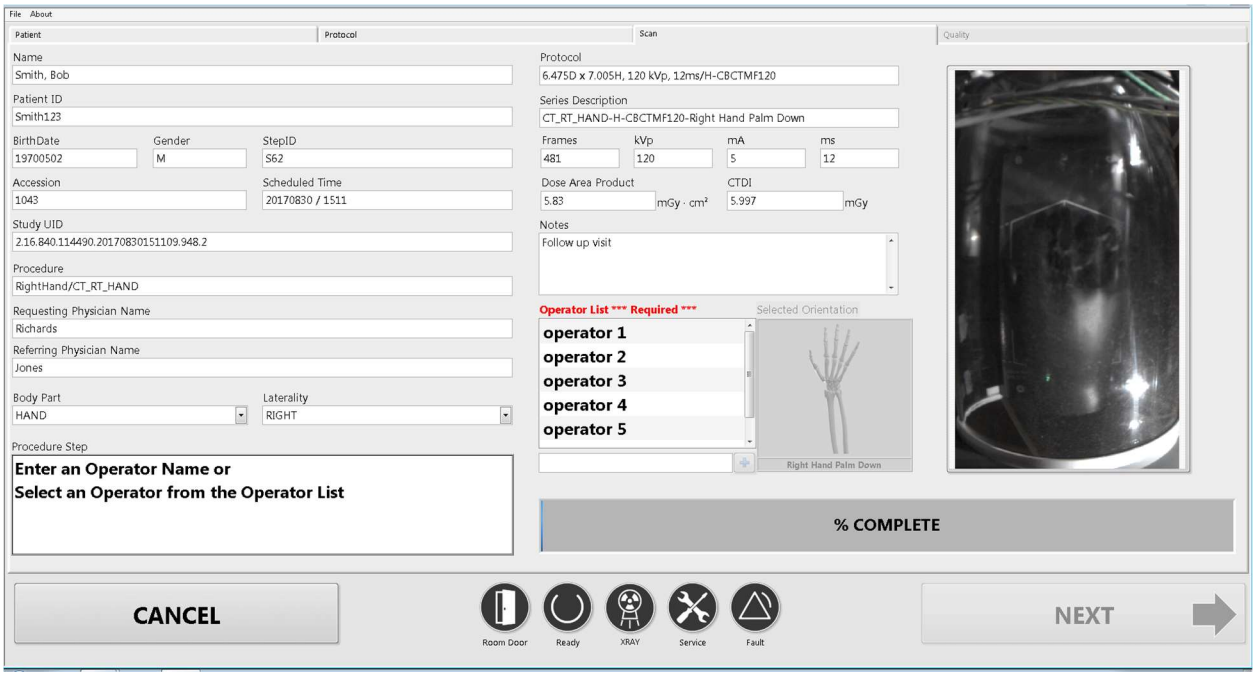
Also available for any text is the Notes field. This field is also optional.

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.***

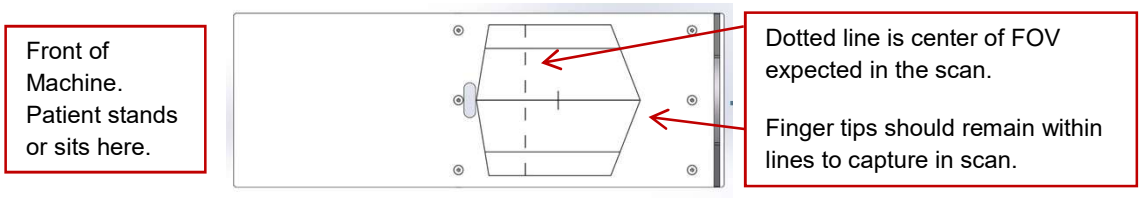
Ensure machine is stable (wheels are locked, machine can not be moved) and wall strap is in place.

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.

<u>Hand or Wrist Scans</u>

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:



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.

<u>Hand or Wrist Scans – Small Patients</u>

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.

<u>Elbow Scans</u>

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.

<u>Elbow Scans – Small Patients</u>

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.

<u>Foot, Ankle, or Knee Scans</u>

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.

<u>Foot, Ankle, or Knee Scans – Small Patients</u>
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.

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

<u>Patient Instructions for a Scan:</u>

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.

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

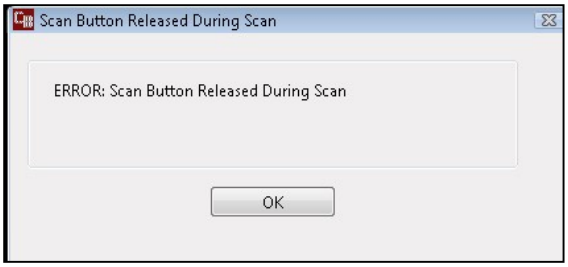
Deliver the Patient Scan Instructions to the patient.

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:



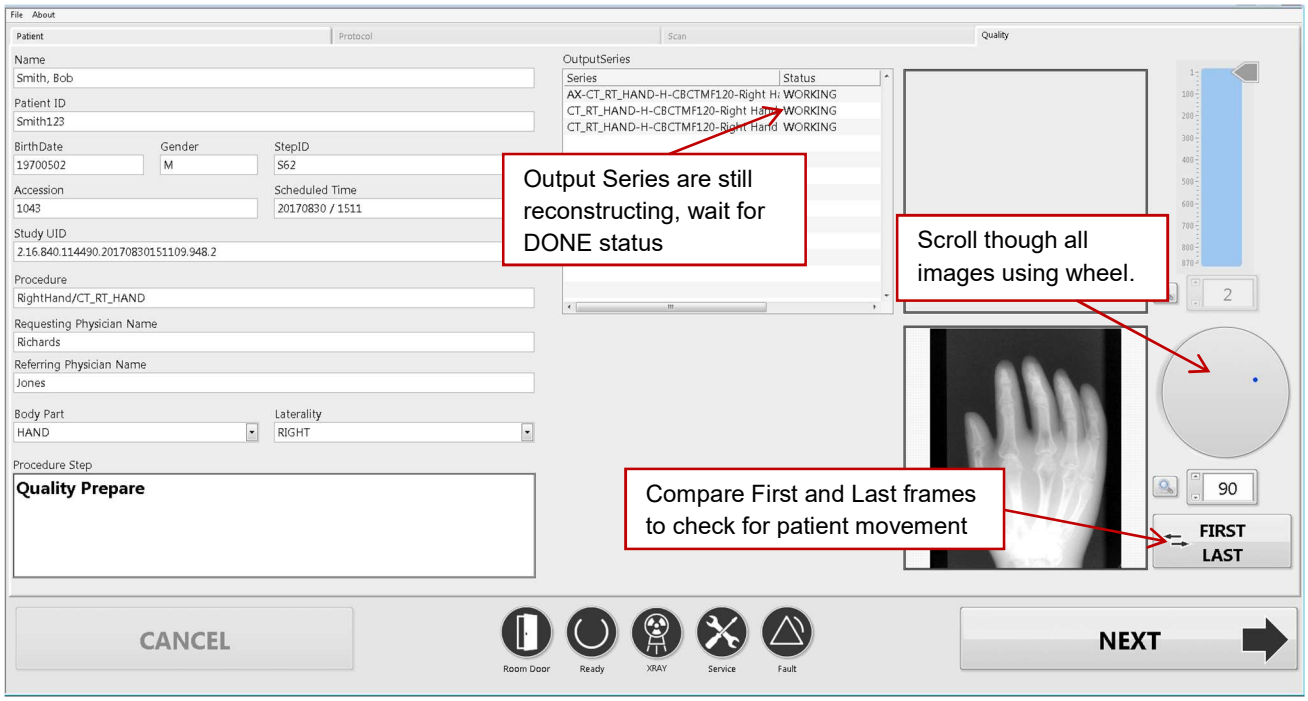
Emergency Stop: In the event of an emergency during a procedure, the Operator or Patient should utilize one of the 2 the designated Emergency Stop buttons to turn off the power to the X-ray and all moving parts in order for the Patient to be safely removed from the machine. There is an Operator E-stop 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.

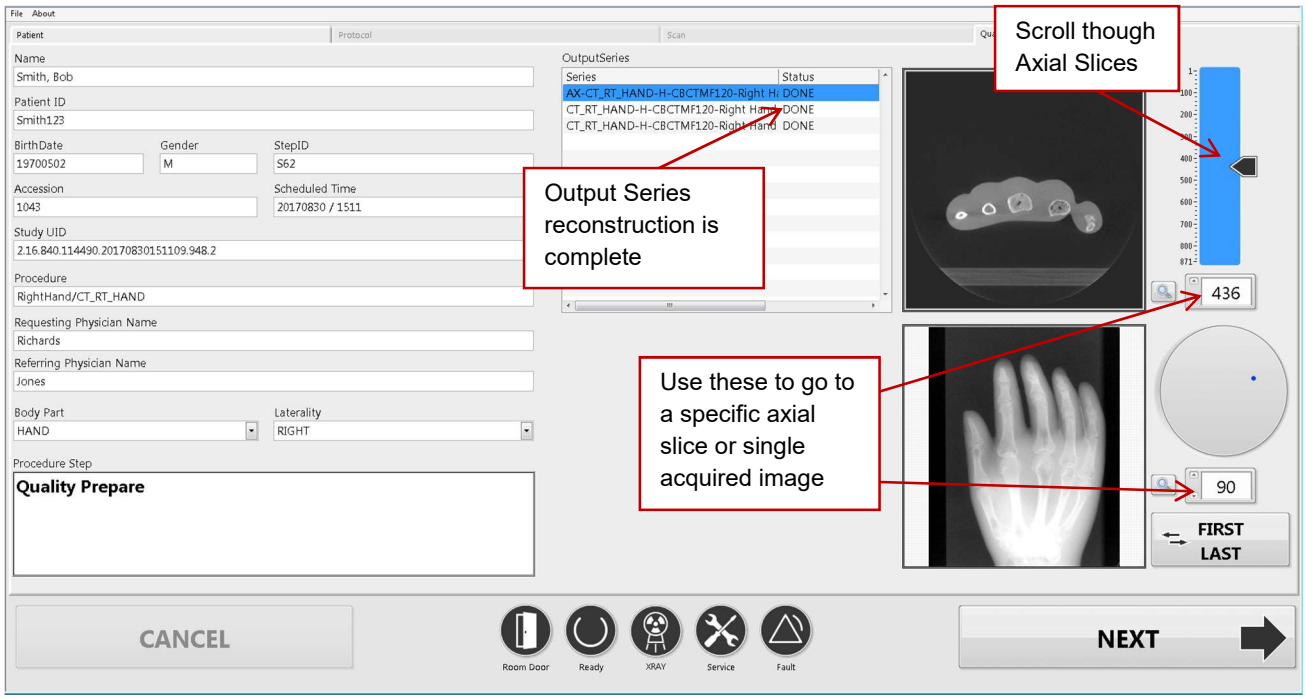
QUALITY TAB: Perform a Quality Assurance check of the scan acquired:

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.

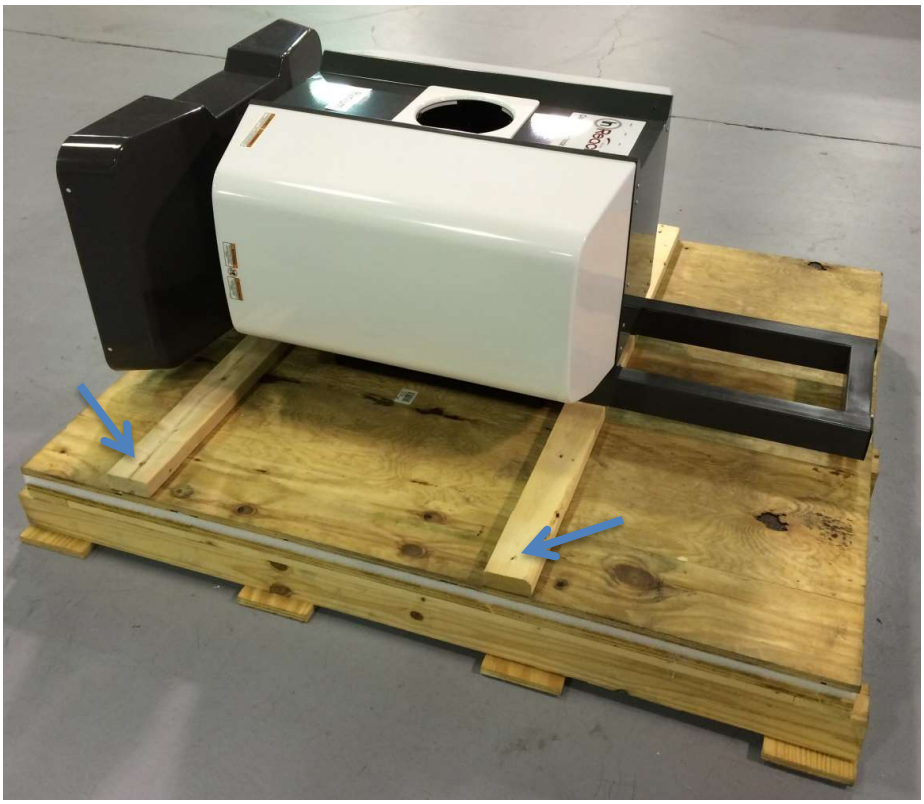
3. Reset the machine: Close the InReach Acquisition, “CB Scanning Device” software (if not already). Release the E-stop that was engaged by pressing in and turning the knob to the right until it pops up. Then turn the machine power back ON at the Main Circuit Breaker. Wait 2 minutes, then re-launch the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

APPENDIX I: InReach Installation Instructions

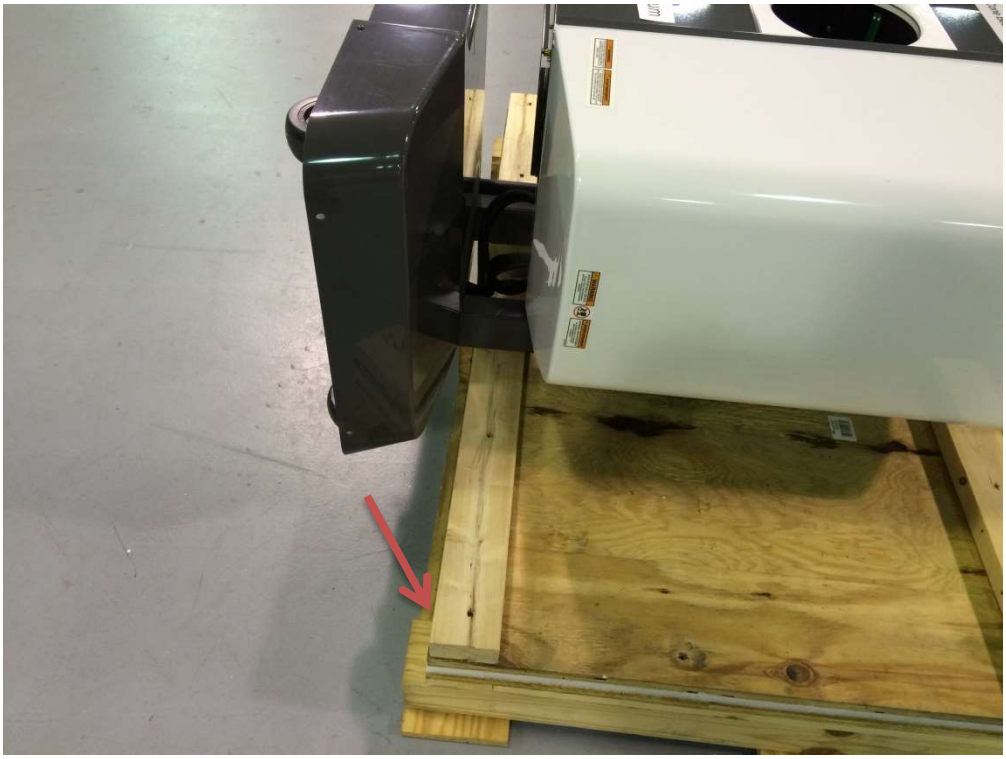
⚠**WARNING** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous X-ray radiation or laser light exposure.

InReach Unpackaging

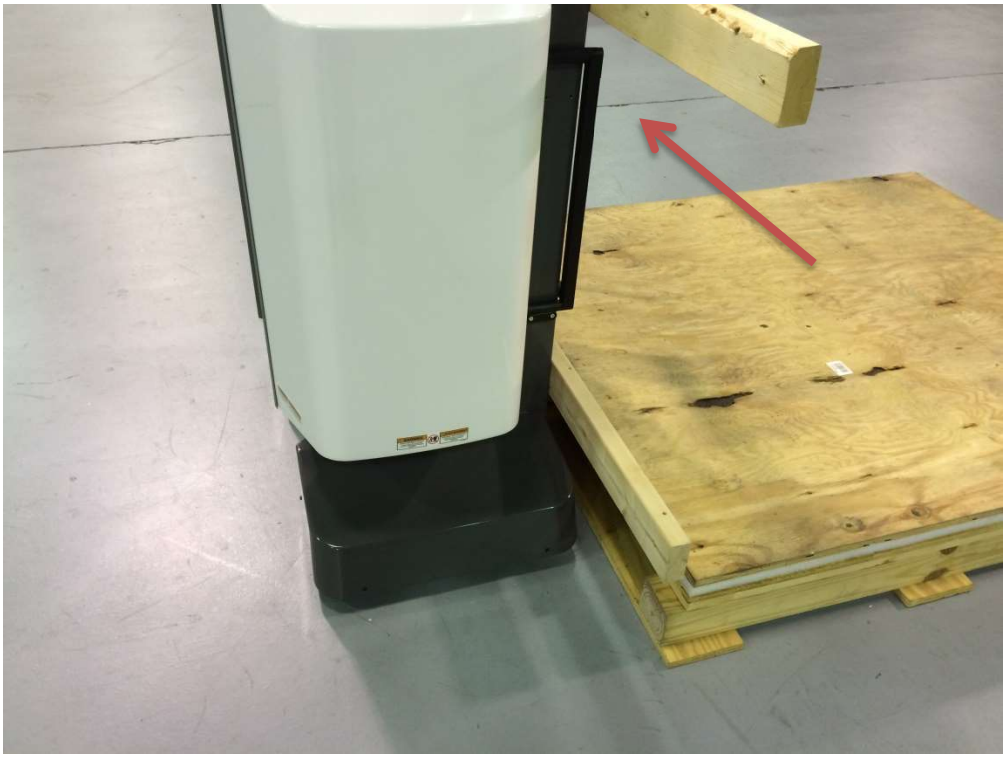
After removing walls of crate, remove 4 lag bolts with a 9/16” socket:



Then slide unit until bottom 2x4 is aligned with the edge of the skid:

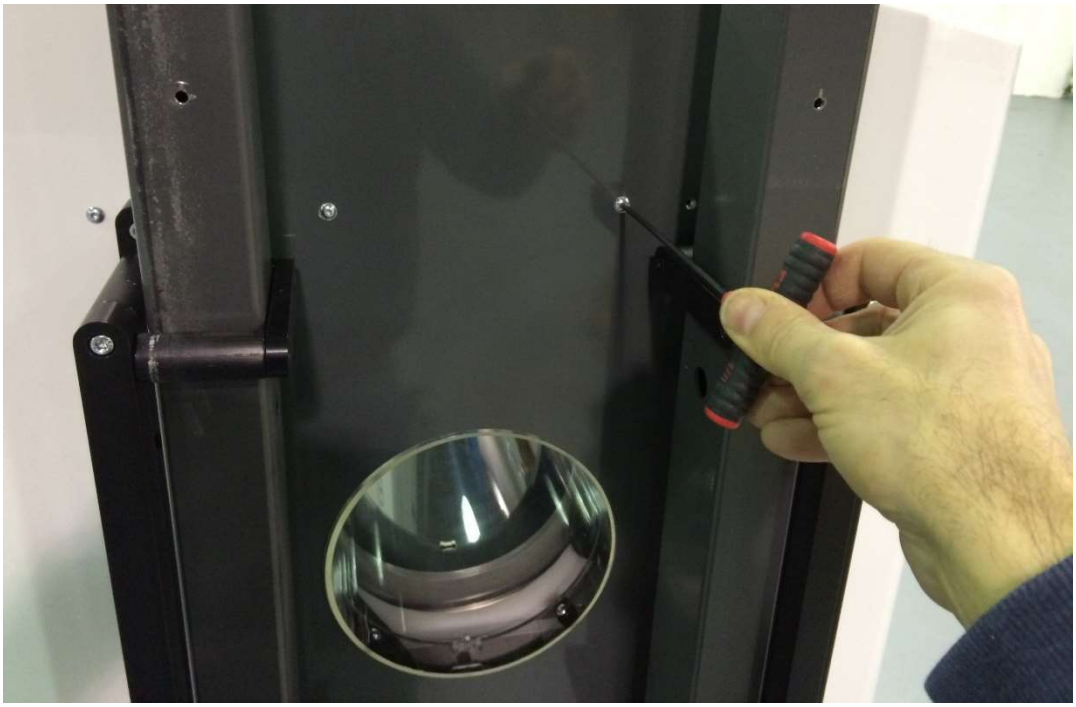


Lift unit up from the top to stand it upright:

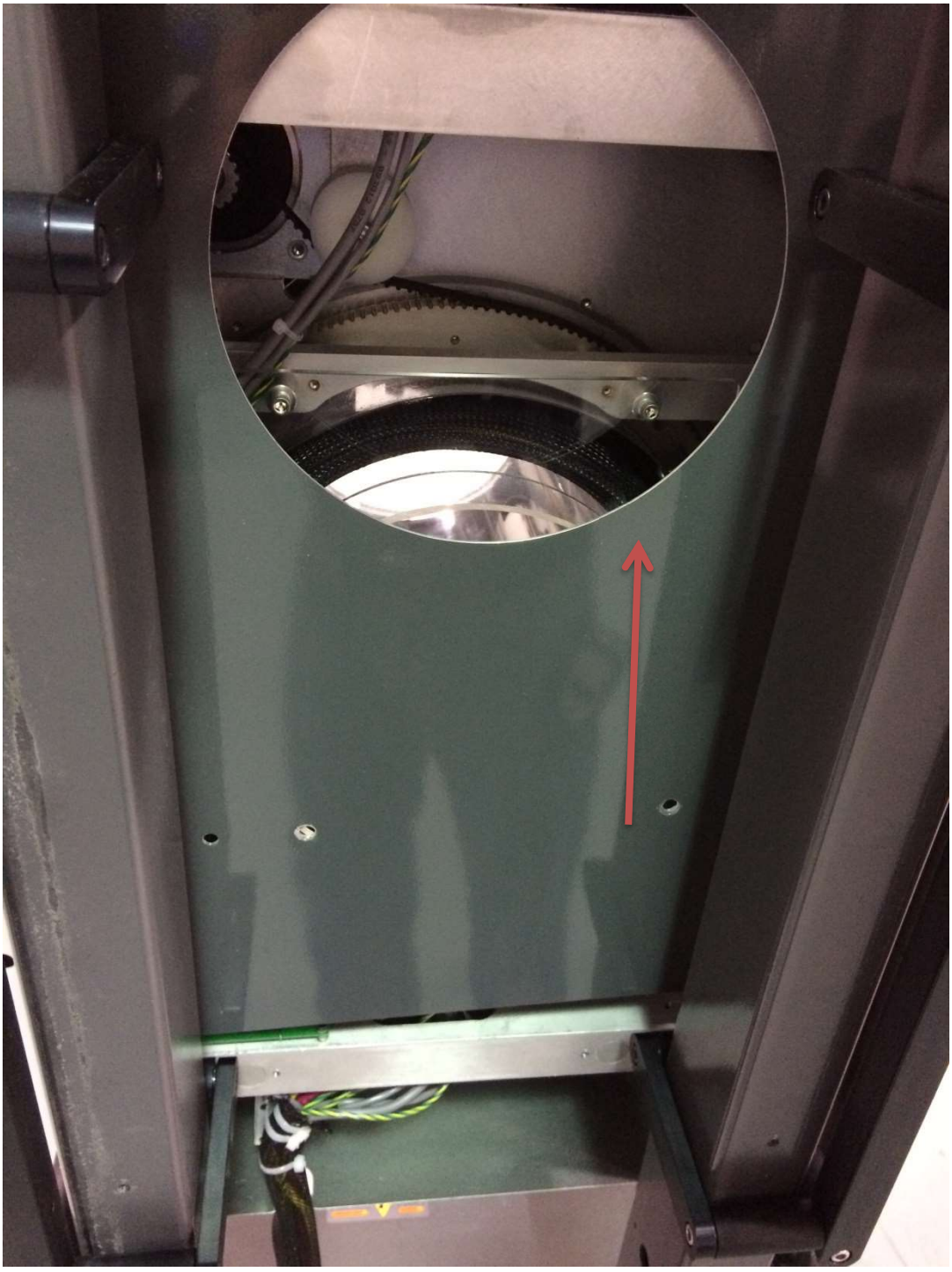


Remove 2x4’s with a 3/16” Allen wrench:

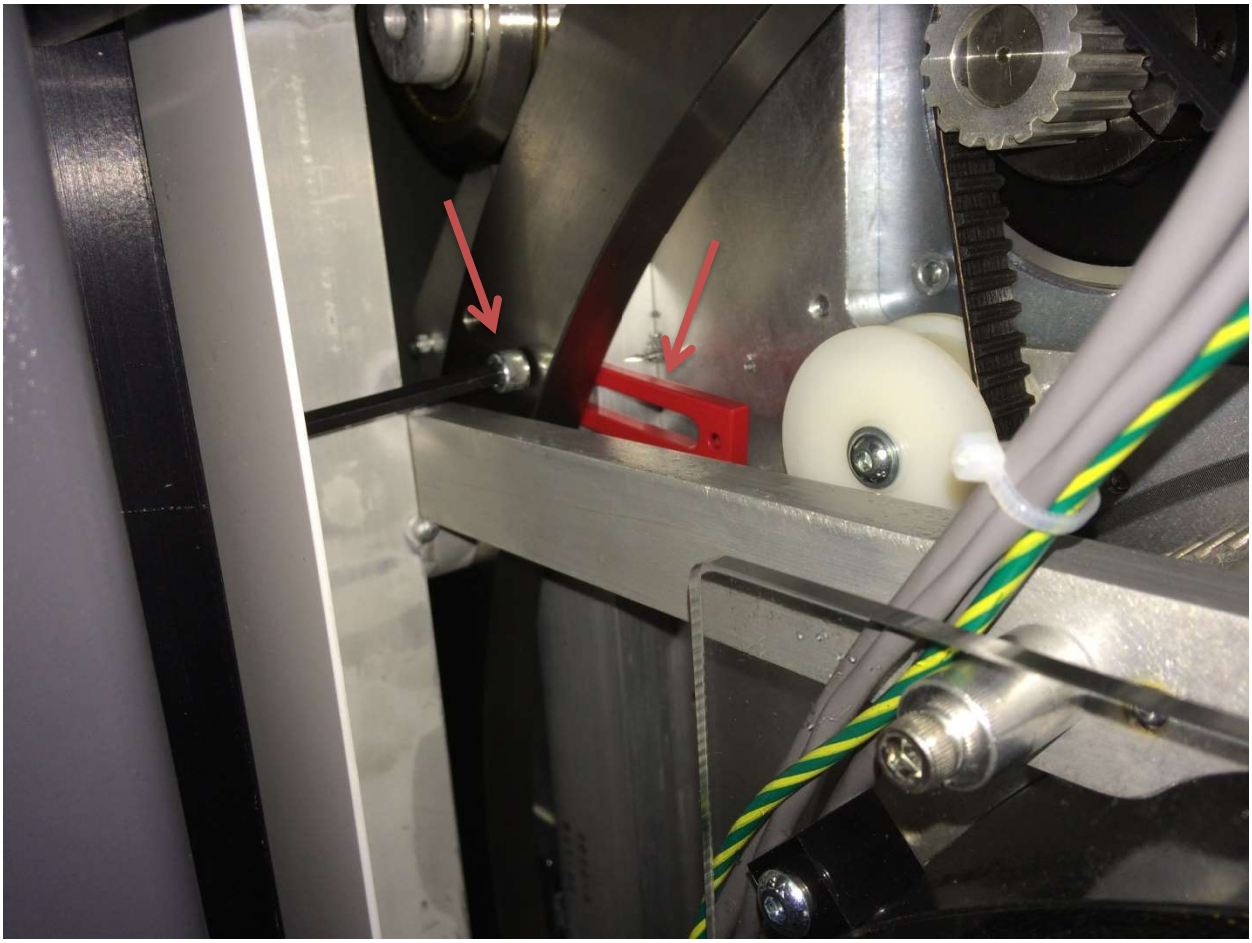
Remove 4 screws using a 1/8” Allen wrench and remove rear cover…



…by lifting it up:

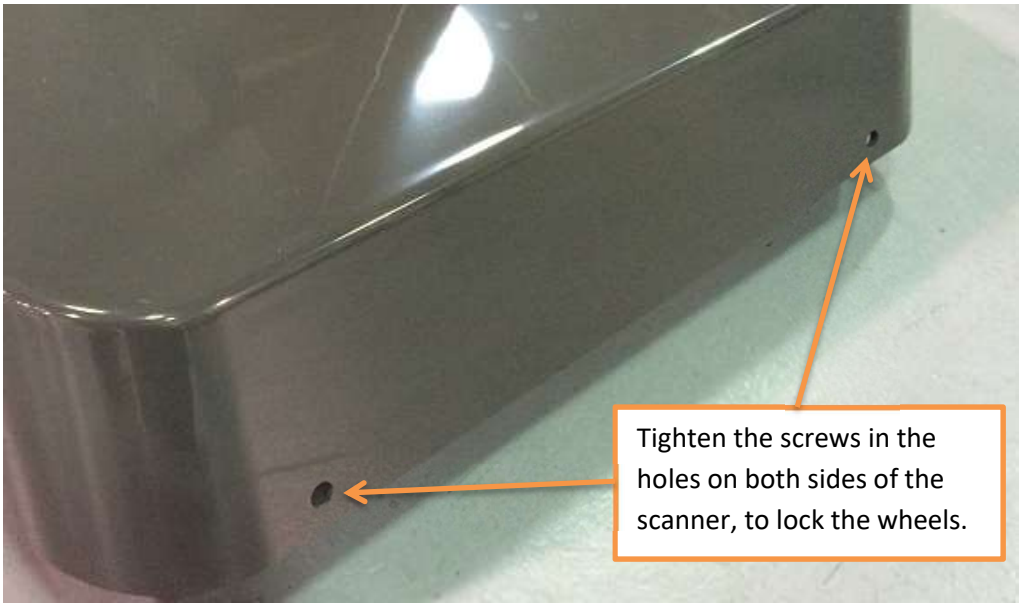


Then remove 4 red gantry clamps using a 3/16” Allen wrench:

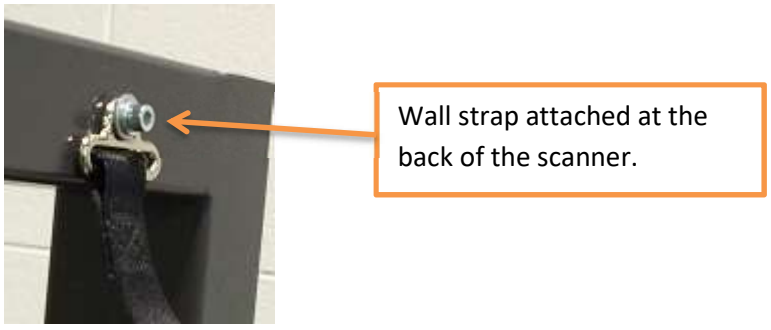


Once the scanner is in the desired location, lock the wheels by turning the screws on each wheel as shown below, without cover:

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:



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:



Server Setup:

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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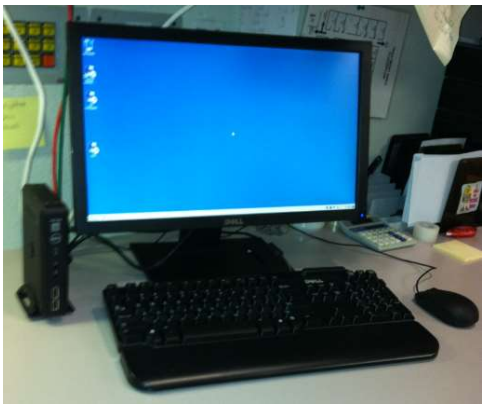
Plug in all cords in the back of the case:

- 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)

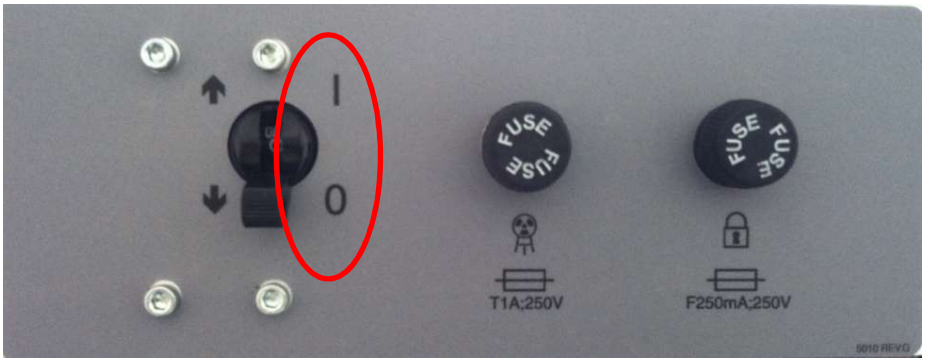
Turn ON the server and verify that all VM's are powered ON. You must remove the right hand side cover to access the ON button to the server.

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.



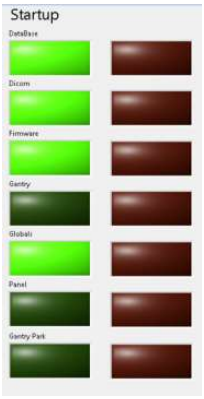
Connect the Viewing Station/MD Thin Client Terminal to the server. Plug in the Thin Client Terminal box, Monitor and mouse. Turn the Thin Client Terminal box ON.

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.

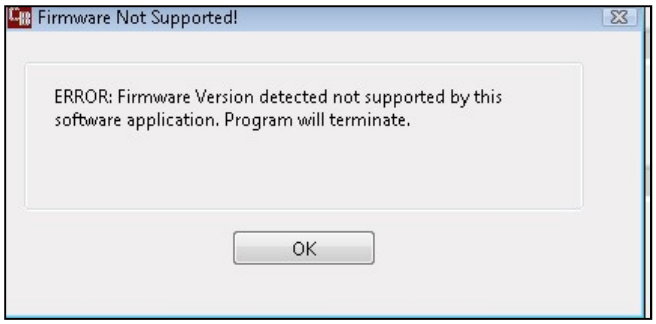
5. Follow ALL the Alignment, Calibration QA procedures outlined in **Chapter 4** of this manual. INSTALLATION is NOT COMPLETE until all these procedures are successfully completed.

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.

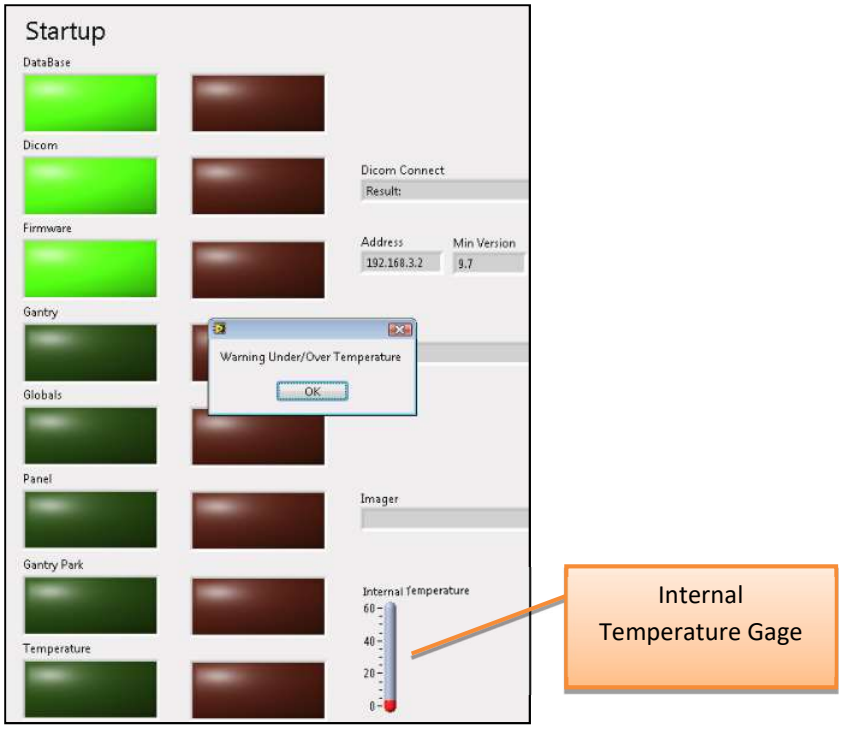
Firmware Monitoring Warning: Upon startup of the "CB Scanning Device" Acquisition software, the system checks that the embedded controller firmware software version is the correct version to operate with unit. If an unsupported version number firmware software resides on the embedded controller then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



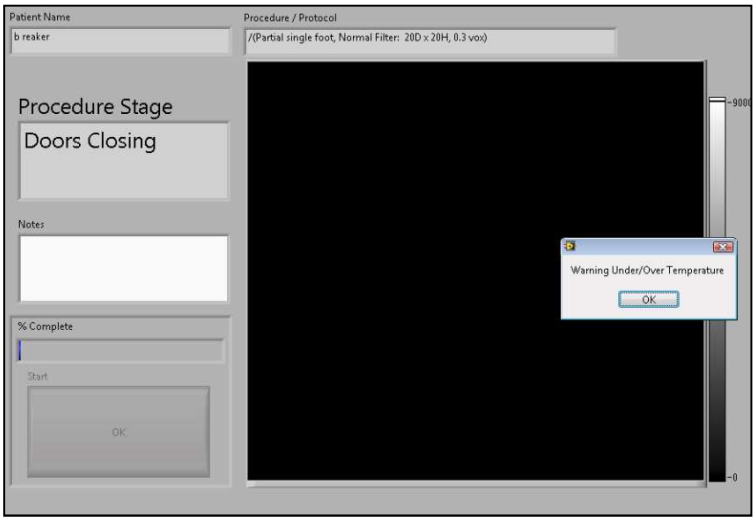
Temperature Monitoring Warnings: The system is designed to send a Warning message to the user if the internal temperature of the machine is below 35° C or above 45° C. This Warning would display in the "CB Scanning Device" Acquisition software at Startup and just before a scan is captured. If the temperature 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:

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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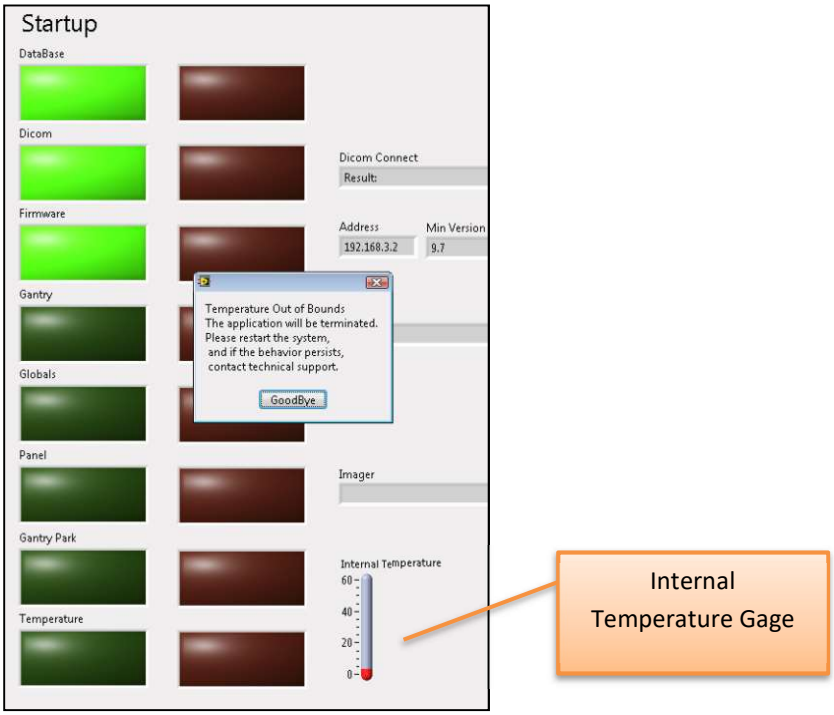
Temperature Monitoring Failures: The system is designed to send a Failure message to the user if the internal temperature of the machine is 20° C or lower OR 60° C or higher. This Failure message would display in the “CB Scanning Device” Acquisition software at Startup and just before a scan is captured. 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.



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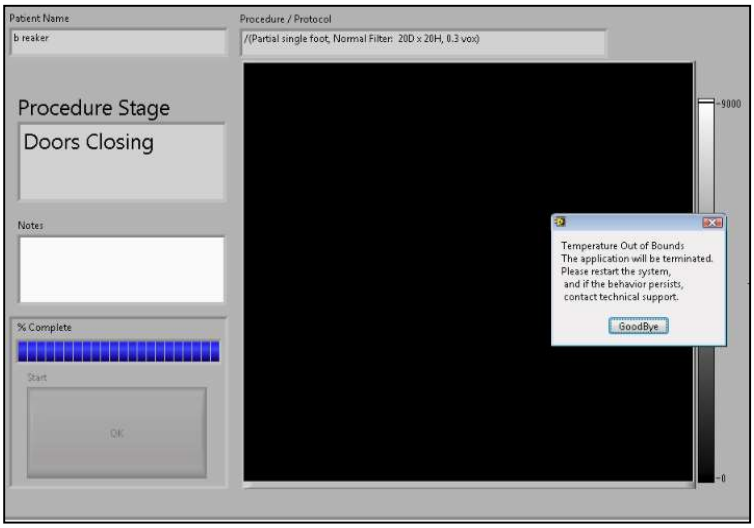
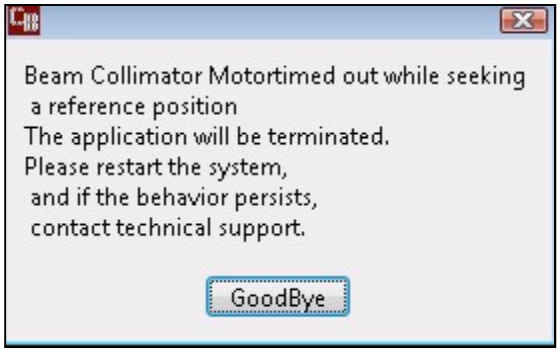
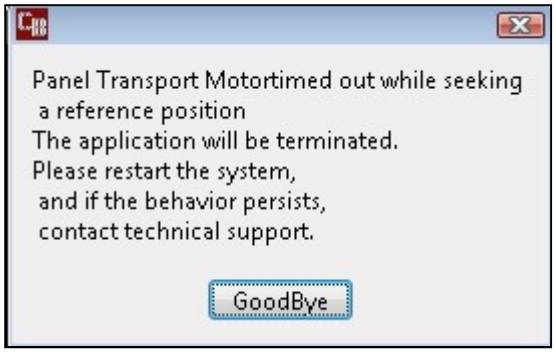
Scan: If in the Procedure Tab and the temperature monitor has detected temperature out of range, the failure message will display once the OK button is clicked.



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.

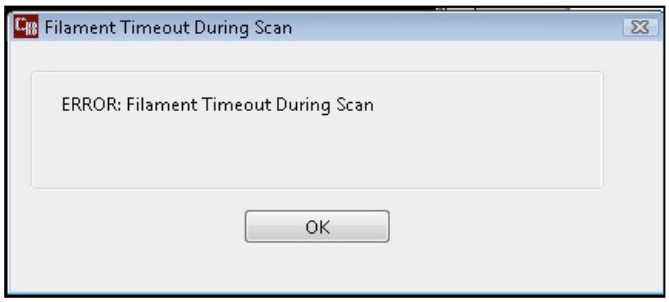
An error in Gantry Rotation *during a scan* would result in a communication error of the receptor panel to the server, so if this even occurs, the following Panel Readout error message would display:

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.

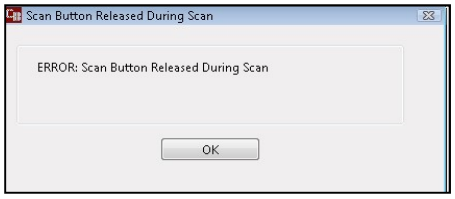
Communication Error between the Firmware and the Server: If there is any loss of communication between the embedded controller firmware, the following error message will display on screen. Loss of communication can be caused by a damaged, unplugged or loose embedded controller cable, or when the Emergency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

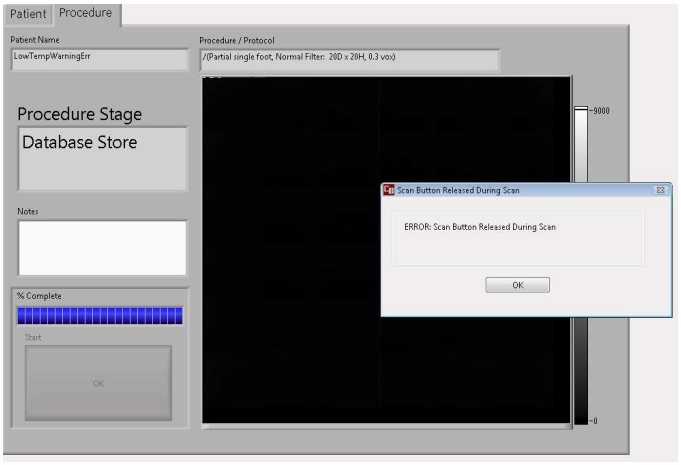
Exposure Timeout Error Message: In the event of a system fault that may result in the X-ray exposure not terminating at its appropriate time, there is a backup timer to terminate the exposure. If this occurs, the below error message will display on screen. Click OK and restart the system. If the error 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.

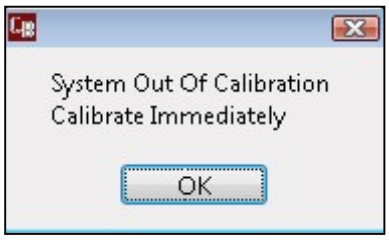
If this occurs, the operator should review the reconstructed data to determine if the data capture was sufficient for diagnosis. If not, a new scan may be necessary.





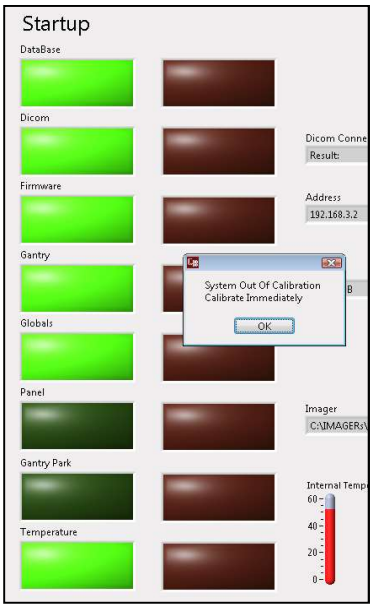
Calibration Checks and Services Warnings: The system calls for monthly Panel Calibrations and checks of certain control functions as outlined in this manual. A monthly Warning message will appear that will indicate that it is time for these checks.

The Warning message reads:

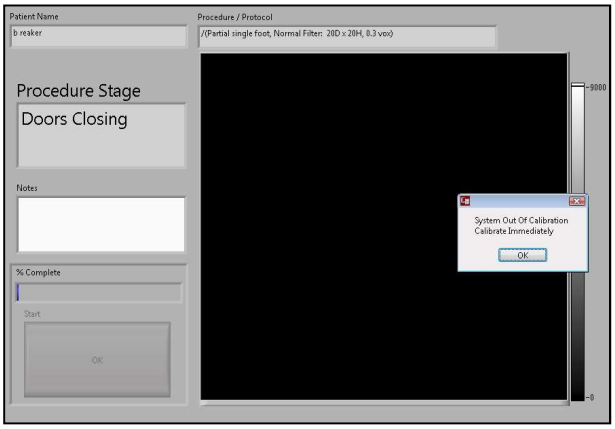


Startup: When the monthly calibration and checks are due, the message will display during the Startup sequence. The user should click OK and then should contact

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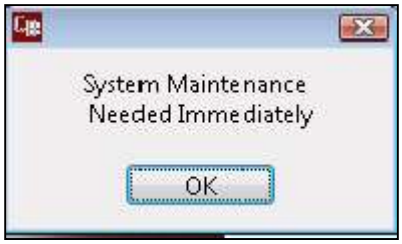
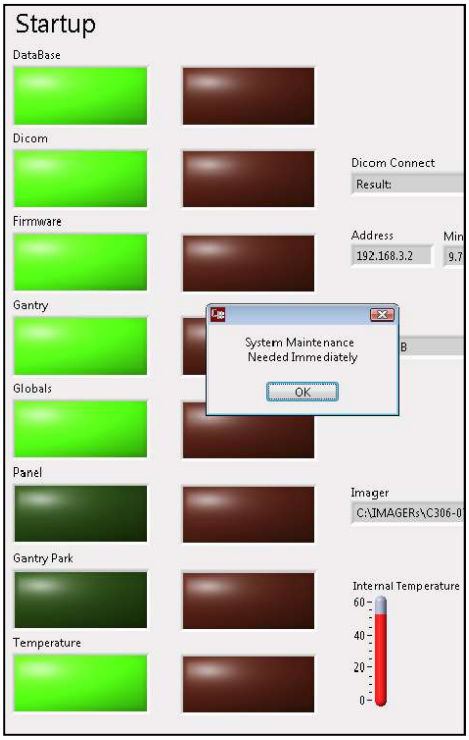
QA Service and Maintenance Warnings: The system calls for annual QA procedures and system maintenance as outlined in this manual. An annual Warning message will appear that will indicate that it is time for these services.

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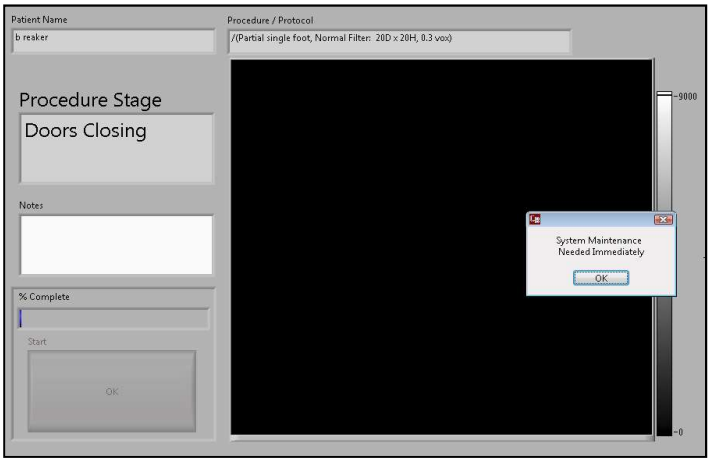
Scan: When the annual service is due, the message will display in the Procedure Tab when the OK button is clicked. When the message displays, the user should click OK and then should contact CurveBeam technical support who will schedule the service and maintenance. This message will repeat at Scan time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



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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

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)

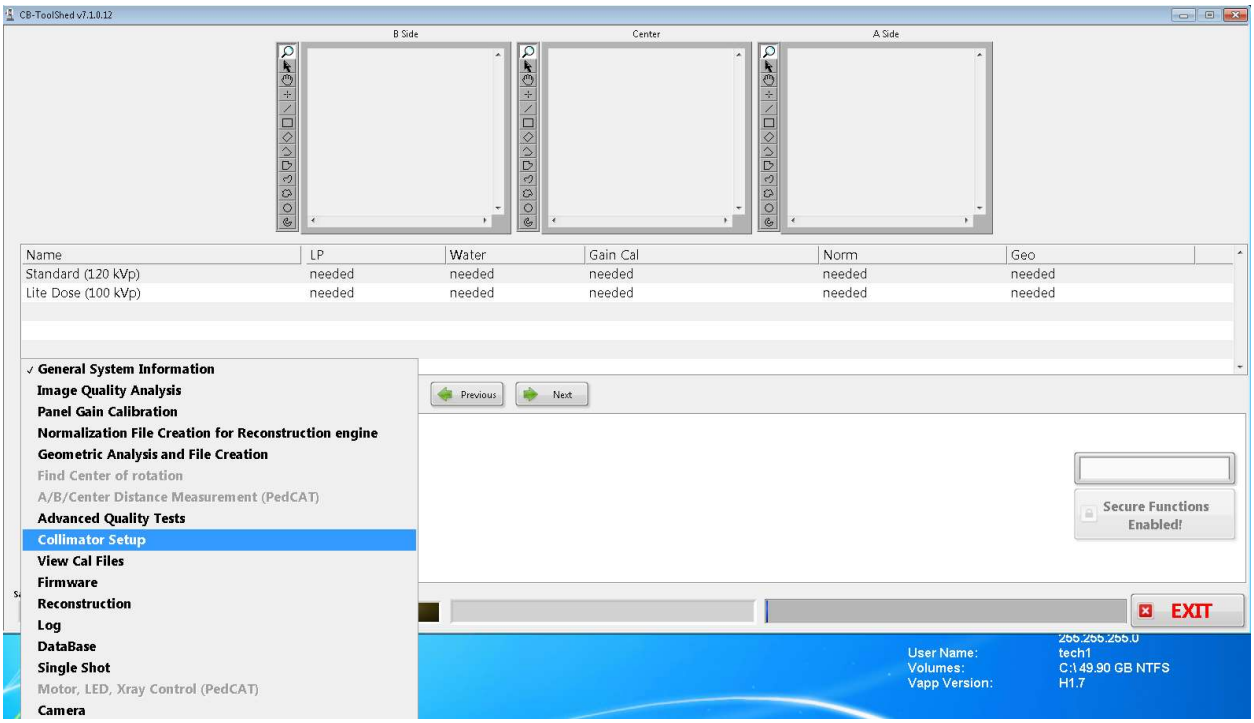
Ensure that all safety precautions are taken for the location in which these procedures are being performed. If the office is equipped with the Door Interlock Option, ensure that the appropriate measures are taken to be able to perform a scan and fire the x-ray. If needed, there is always the option 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.

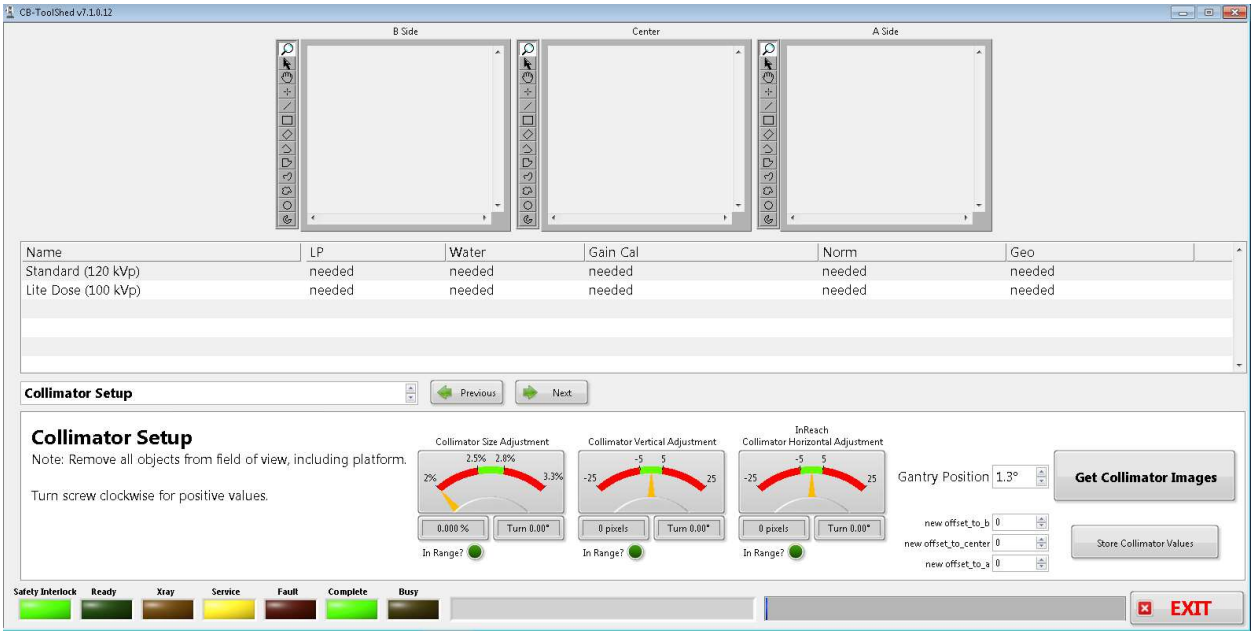
Open CB-ToolShed and enter the required password to access the advanced calibrations.

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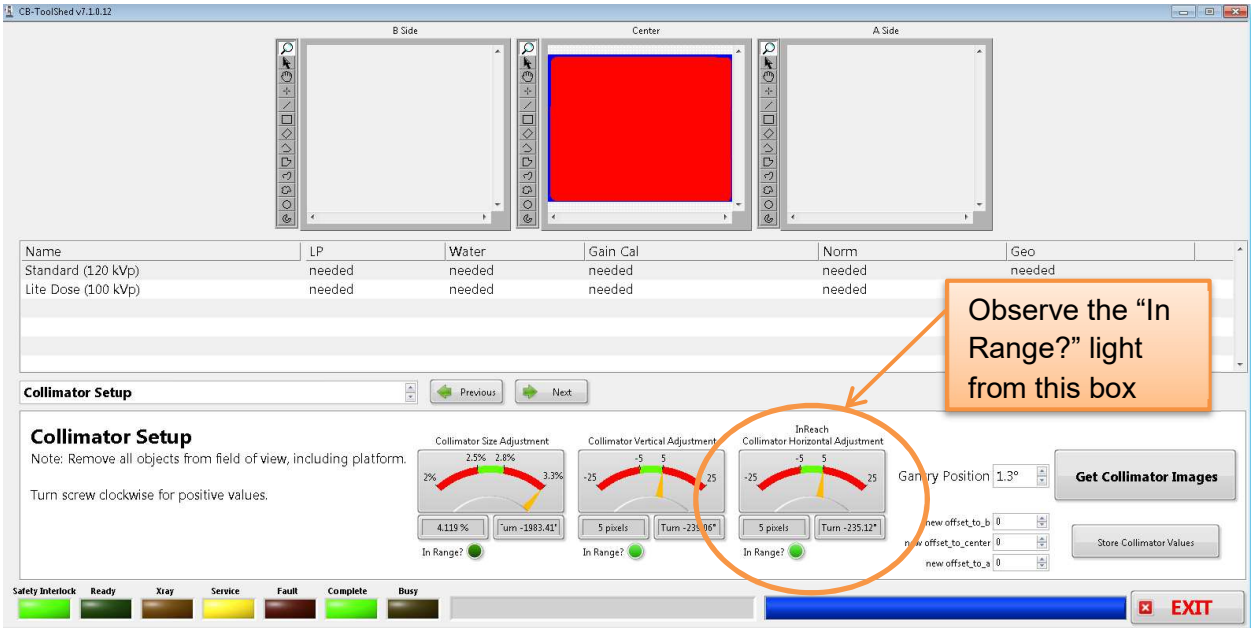
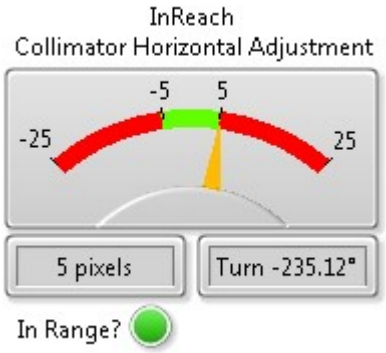
The calibration will occur and the only thing to be concerned with is that the light under the InReach Collimator Horizontal Adjustment box is lit up green and therefore in range.



Zoomed in of the above mentioned box:



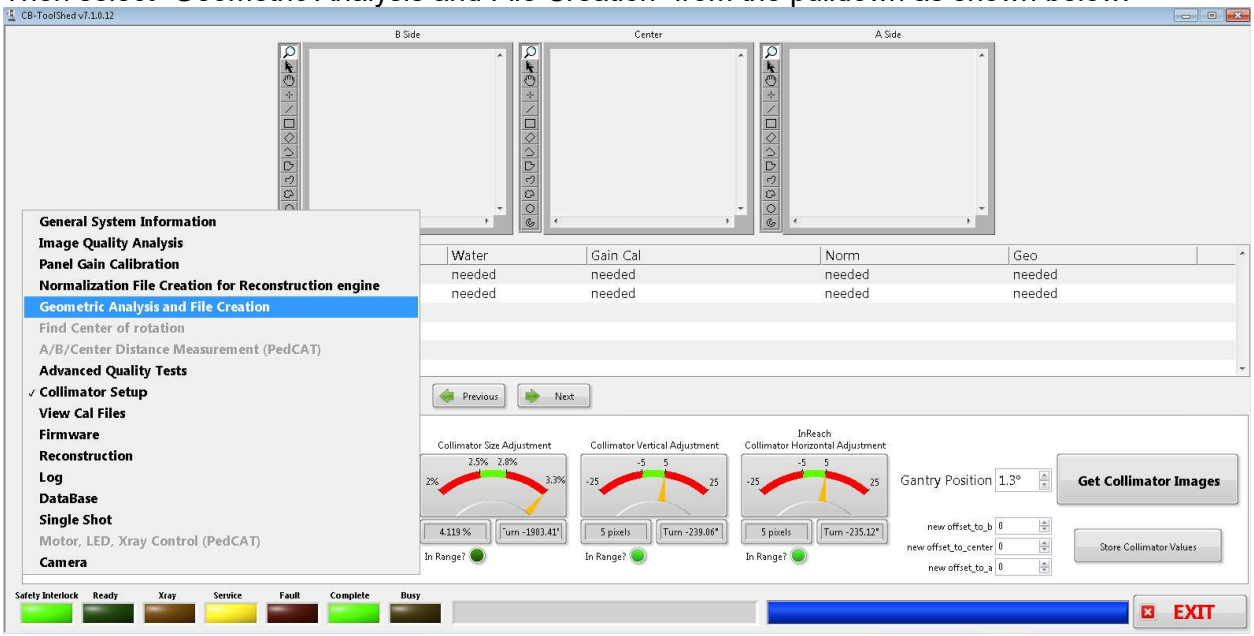
Bright Green is acceptable. If the light does not illuminate bright green then contact CurveBeam Technical Support for assistance.

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:



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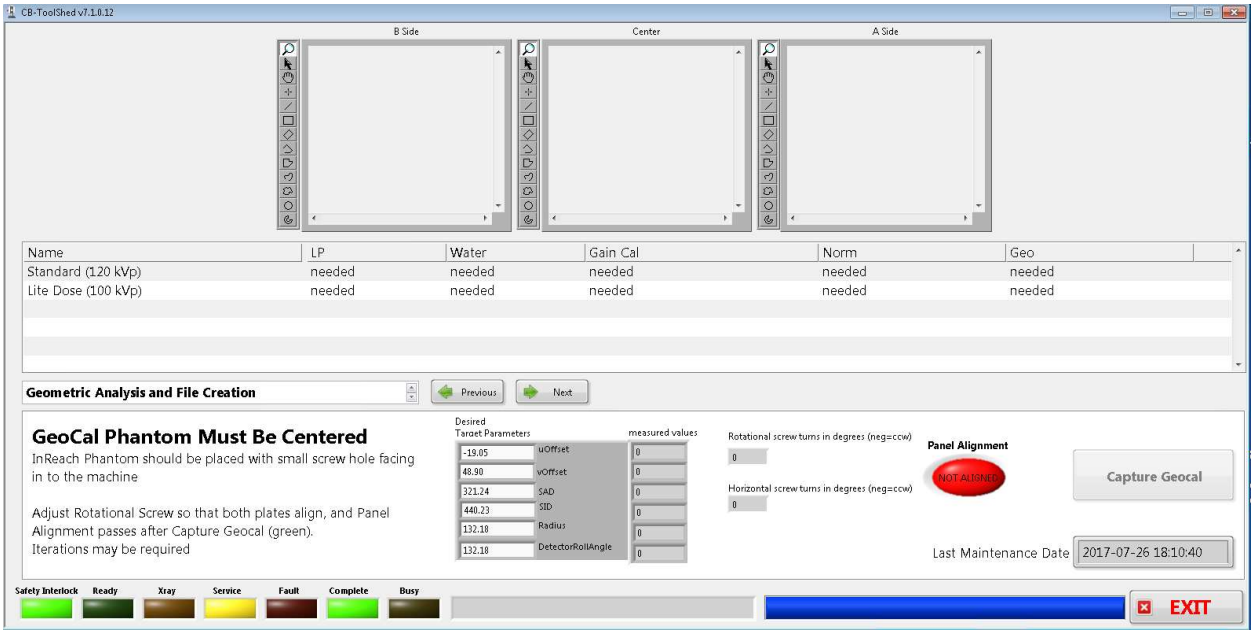
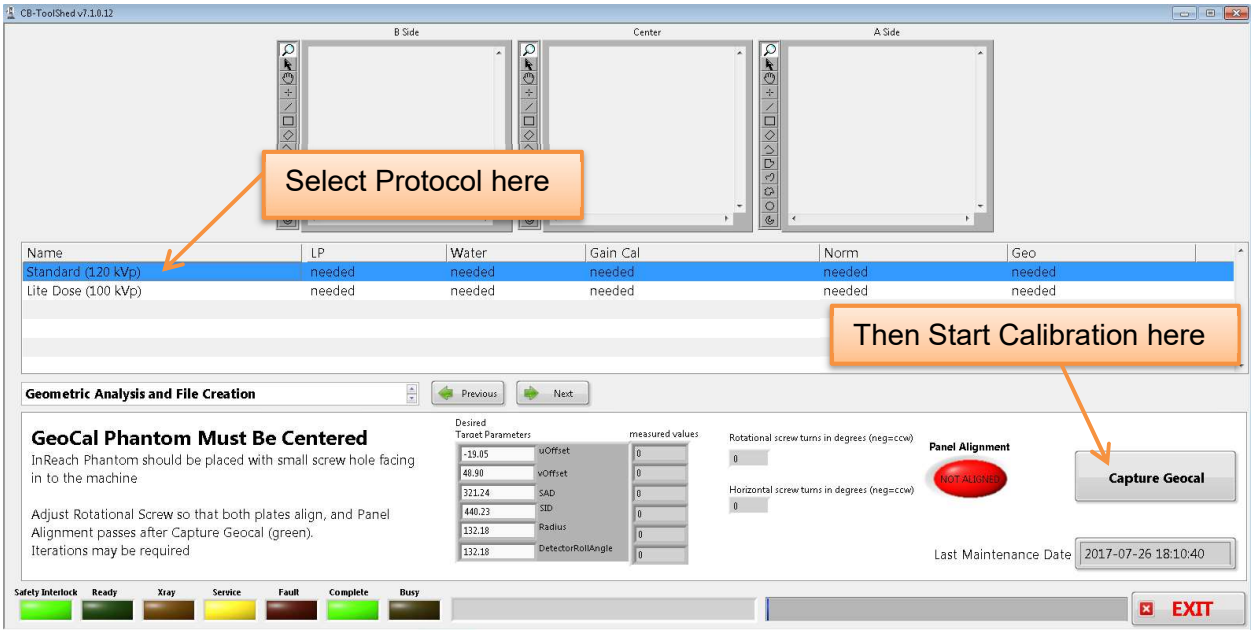
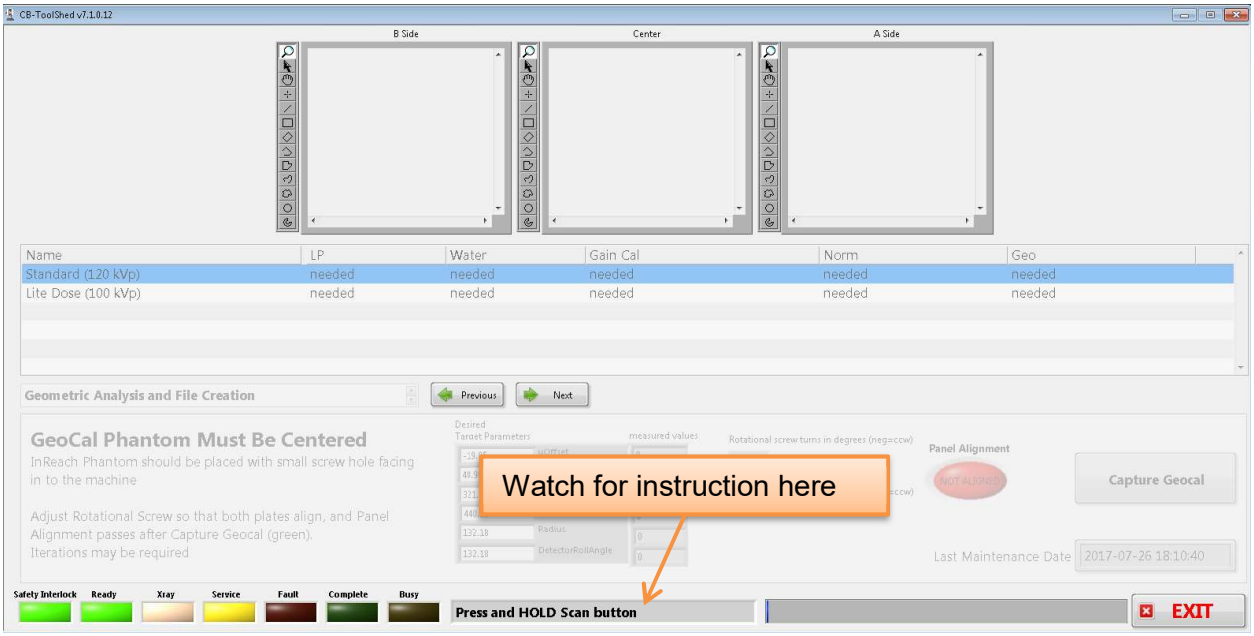
This will then display the screen as shown below:



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



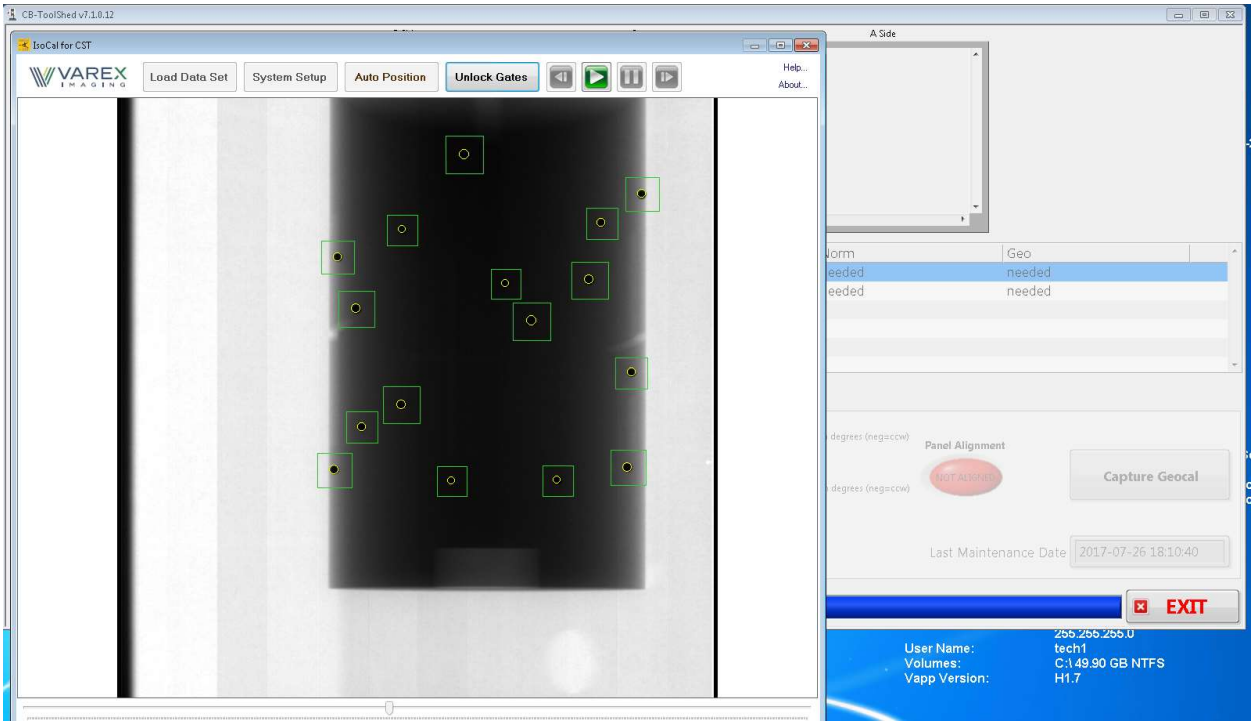
The screen will appear all washed out for a bit, this is normal, and will look like this:



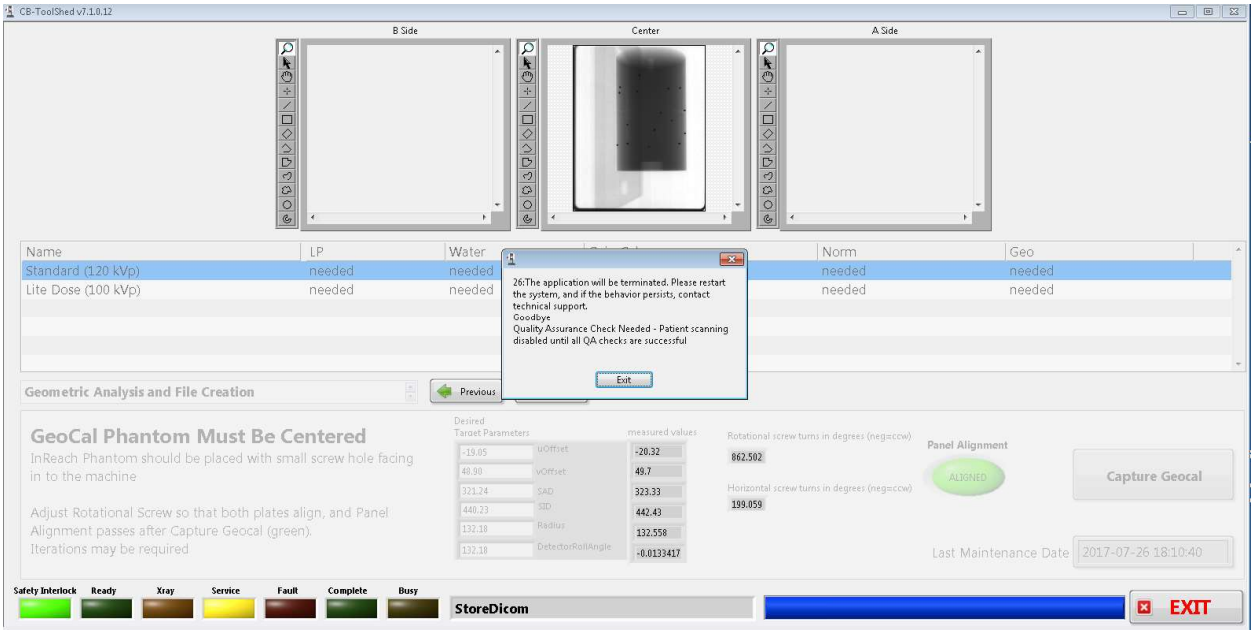
Then you will be prompted in the text box at the bottom of the screen to press and hold the scan button. This will fire xray.

> **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

During the calibration, the IsoCal screen will pop up, as shown below:

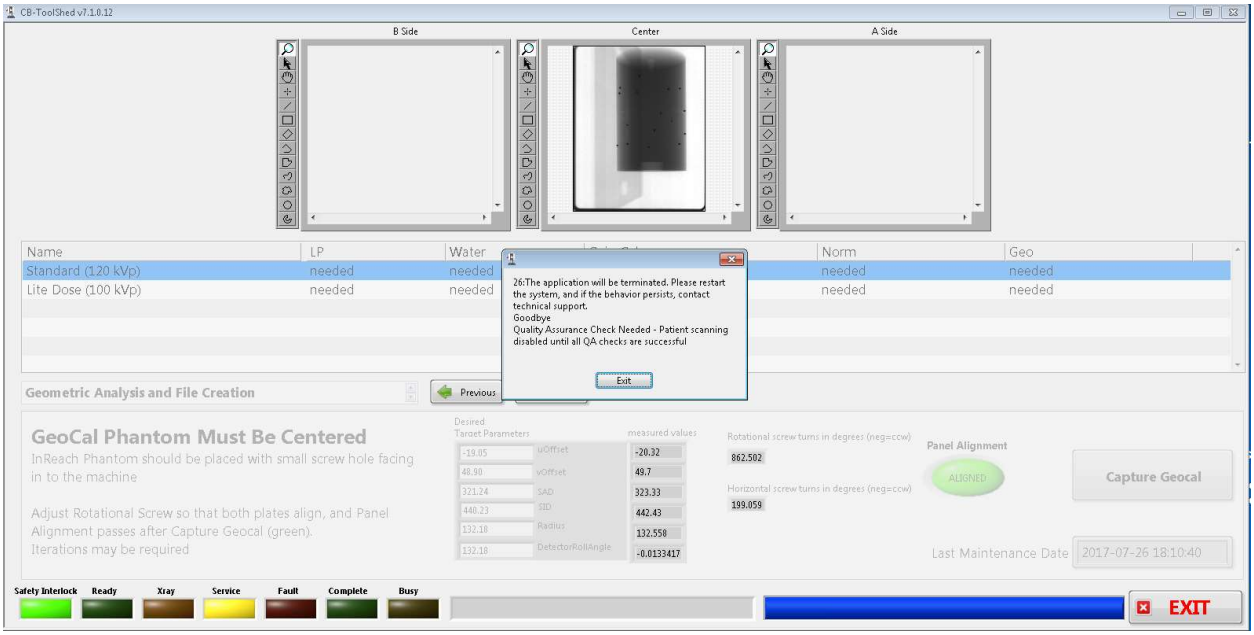


Just allow it to continue processing. After first protocol has completed, the following message will appear:



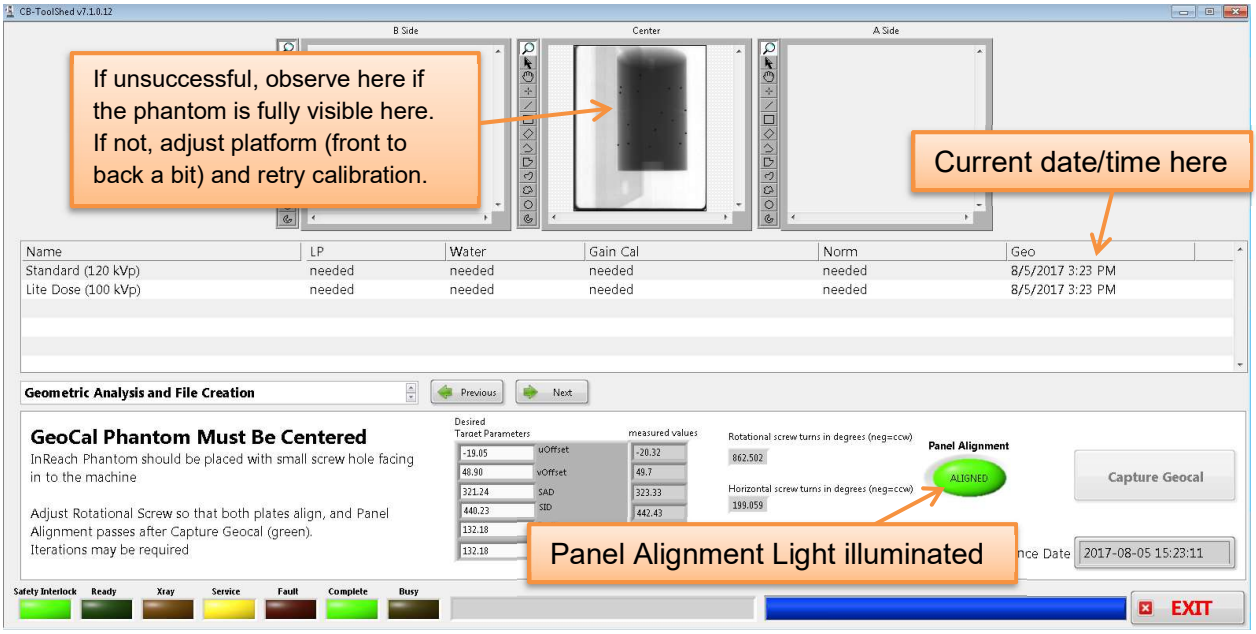
Click the “Exit” button, this is just to indicate the further calibrations are still needed.

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

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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.