LineUP

Computed Tomography Imaging X-ray System

CurveBeam

2800 Bronze Drive, Suite 110
Hatfield, PA 19440
Ph: 267-483-8081
Fax: 267-483-8086
info@curvebeam.com
www.curvebeam.com
CurveBeam Technical Support: 267-483-8081

90030 Rev 10.05.2018

LineUP Table of Contents:

LineUP User's 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 LineUP 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 X-ray device is intended to be used for patients 50 lbs (23 kg) to 400 lbs (181 kg) and groin area at least 22" (56 cm) above the floor. DO NOT use this device for any patient less than 50 lbs (23 kg) OR groin area less than 22" (56 cm) above the floor, whichever is more restrictive.

WARNING: The patient must wear a protective full wrap X-ray shielding apron (lead apron) during a scan. Patients less than 21 years old, small size patients (under 100 pounds) and children must also wear a gonad and ovarian front and back protective shield.

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: Closing of the Gate door creates a pinch point. Keep hands and feet clear when closing Gate.

WARNING: Reclining and un-reclining of the Multi-Extremity Chair creates a pinch point. Keep hands clear when adjusting the back of the Multi-Extremity Chair.

WARNING: The Gantry should not be raised with the Multi-Extremity Chair engaged for a scan or patient positioning.

WARNING: The back of the Multi-Extremity Chair shall not be used as a seat.

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.

WARNING: This device connects to the customer IT-Network in order for the customer to access scan data for diagnostics. Failure of the customer IT-Network may interrupt or delay access to scan data. Updates or changes to the customer's IT-Network could introduce new risks that may require additional analysis. The customer is responsible for identifying, analyzing, evaluating, and controlling these risks associated with any IT-Network change.

WARNING: Only CurveBeam supplied platforms, chairs, and accessories can be used when operating the scanner and scanning patients.

WARNING: The Operator should always watch patient while raising or lowering any part of the Multi-Extremity Chair.

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 (Rx only).

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 Hazard:

Do not use the System in the presence of explosive gases or vapors, including anesthetic 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.

The system is designed to detect that the patient door is closed before a scan can initiate. If the patient door is not closed, then the Operator will be prompted to close the patient door and retry or cancel the scan.

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 LineUP Layout” towards the end of Chapter 5 of this manual for additional details.
- Keep exposure times to a minimum.
- The patient must wear a protective full wrap X-ray shielding apron (lead apron) during a scan. Patients less than 21 years old, small size patients (under 100 pounds) and children must also wear a gonad and ovarian front and back protective shield. Sample shielding products, or similar:
  Supplier: Marshield, Full Wrap Apron, #MS-SP1
  Supplier: Universal Medical Inc, Diaper 14" x 20", #800
- 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 protective wall.
- The physician is responsible for protecting the patient from unnecessary radiation.

System Safety Devices:

The system safety devices include an Emergency Stop, Warning System, and Interlock System. These are explained fully in Chapter 3 – Safety Items.

Patient Preparation Recommendations:

The patient must wear FDA cleared medical gloves for gripping the hand rails, with sanitation and convenience in mind.

The patient should not step bare foot on the patient platform. Proper foot protection should be provided.

The Multi-Extremity Chair and Patient Bench should be lined with Exam Table Paper before the patient is seated on it.

Line the knee positioner or hand platform (if using) with Medical Barrier Film. CurveBeam tested brand: Clear Barrier Film – Low tack-adhesive (Palmero #1866C).

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.

System Description

The LineUP is a Computed Tomography X-ray system or Cone Beam Volumetric Tomography x-ray system for 3D reconstruction Imaging device for the foot, knee, hand, and elbow. The system is designed for an in-office setting with components consisting of the Scanner, Operating Computer (External Server), and Operator's Console. The system provides for patient's to be imaged in weight bearing (standing) position as well as seated position for one or both feet.

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

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

The External Server consists of 3 Virtual Machines:

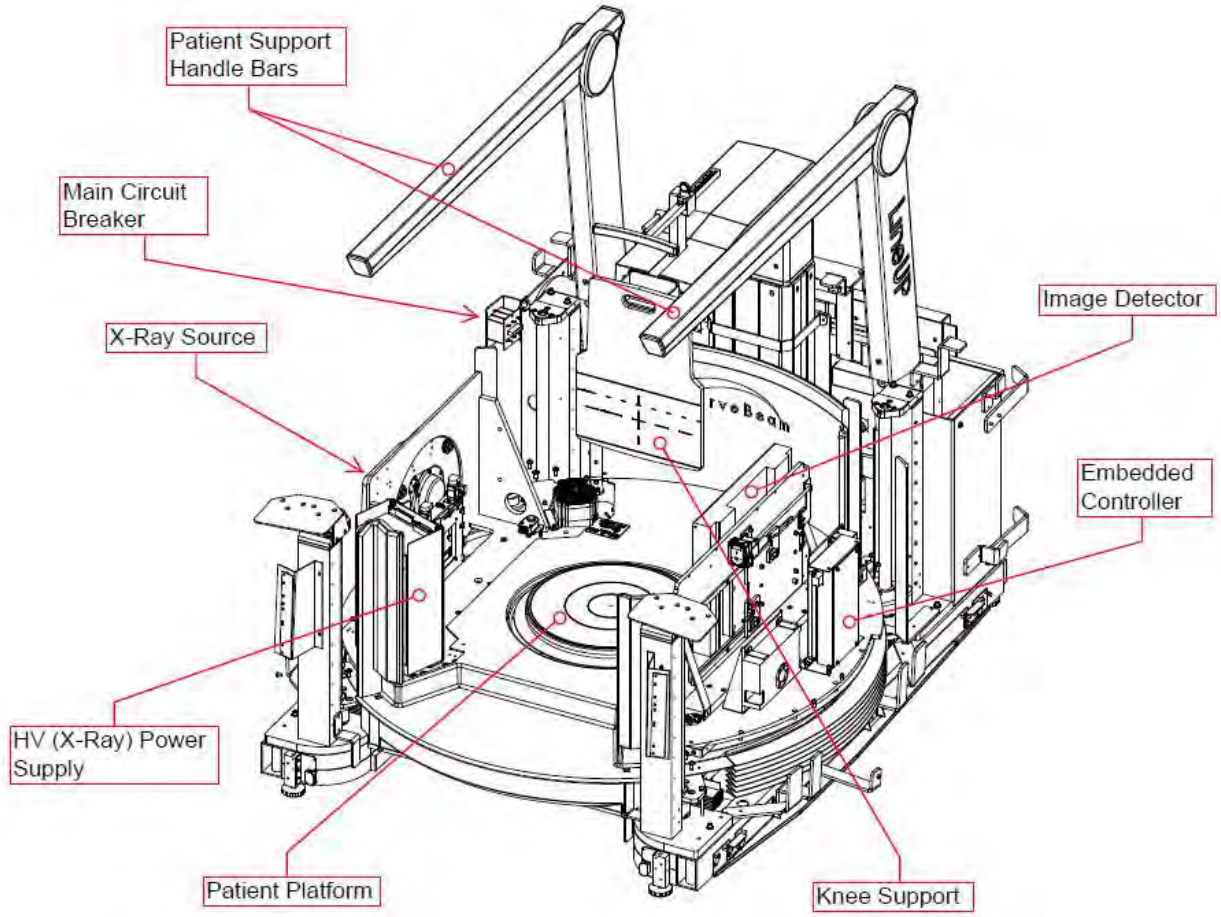
ACQ VM: accessed via the Main Desktop icon on the ACQ thin client terminal

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

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

Major Device Components:

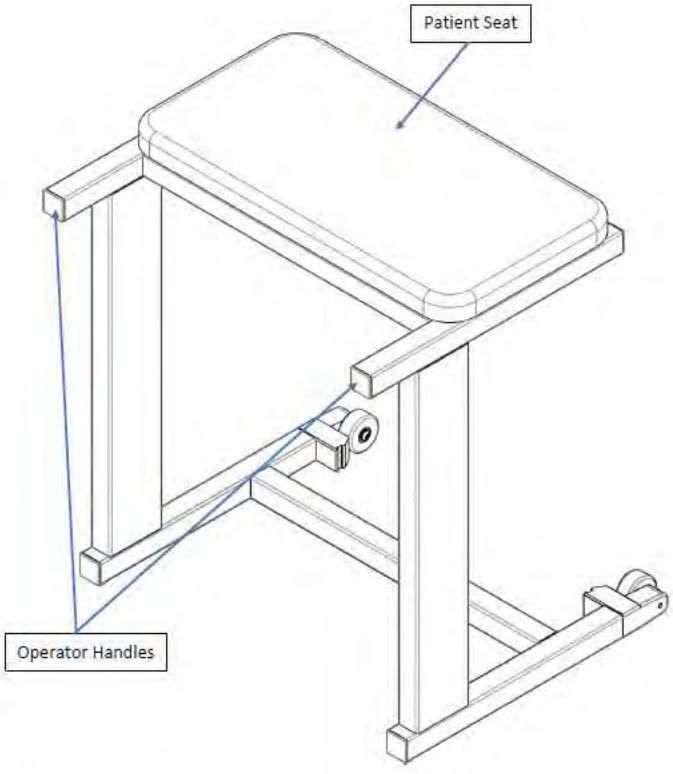
Scanner



CE 0413

Multi-Extremity Chair

Patient Bench



Intended Use of the Device:

The LineUP is intended to be used for 3-D imaging of the foot, knee, hand, and elbow regions to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures.

It is also intended to capture 2-D images (standard plain x-ray projections) of the foot, knee, hand, and elbow regions.

This modality is anticipated to be applicable to pediatric* cases as well as adults, when appropriate diagnosis of a given condition is considered necessary. Patient parameters: 50 lbs to 400 lbs

*2D Imaging not intended for pediatric use

Major System Items:

- Scanner
- Multi-Extremity Chair
- Patient Bench
- 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
    - 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)
- Power cord, 10’ (3.05 m)
- MX Imaging CMOS flat panel, CFP3131
- X-Ray tube assembly
- X-Ray power supply

Intended User Profile:

The LineUP is intended to be used by an operator that meets all local, state, federal or international regulations and that has been trained by CurveBeam personnel using the LineUP On Site Training Checklist.

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	60 kVp, 100 kVp, 120 kVp (+/-10%)
Tube current	5 mA (+/-10%)
CBCT Scan time*	21 sec
X-Ray Scan time*	0.15 – 1.3 sec
CBCT Procedure time**	Foot, hand, and elbow(Gantry at bottom position): 44 sec Knees (Gantry at an elevated position) : 112 sec
X-Ray Procedure time**	5 sec
CT Max exposure time (based on typical pulse width)	6 sec
X-Ray max exposure time	1.3 sec
Image detector	CMOS Flat Panel
Gray scale	14 bit
CBCT Imaging Volume	7.9” (20 cm) height x 13.8” (35 cm) diameter, 7.9” (20 cm) height x 7.9” (20 cm) diameter
Typical slice thickness	0.31mm (+/-0.5mm); Slice Spacing 0.3 mm
Typical voxel size	0.3 mm
Measurement accuracy	± 2 voxel
X-Ray pixel size / x-ray resolution	0.099 mm
Body parts scanned	Foot, knee, hand, and elbow
Size of system: h x d x w	50”x63”x49” (127 cm x 159 cm x 125 cm)
Weight	Scanner 750 lb (340 kg), Multi-Extremity Chair 250 lb (113 kg), Patient Bench 24 lb (11 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 gate can be opened or Multi-Extremity Chair can be wheeled out of scanner after the scan.

X-ray Source:

Tube Voltage:	60 kVp(eff), 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: 29.956” (76.11 cm)

Source to Patient distance: 20.802” (52.84 cm*)

*The patient must be properly positioned for each patient for all applications in order to have the focal spot to skin distance as large as possible.

Minimum Filtration (at 120 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: 12.2” (30.96 cm) wide x 12.2” (30.96 cm) high

Image Detector: CMOS Flat Panel (readable area): 12.2” (30.96 cm) height x 12.2” (30.96 cm) width.

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

Gray Scale: 14 bit

Voxel Size: 0.3

X-Ray Pixel Size: 0.099mm x 0.099mm

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

CBCT Field of View: 7.9” (20 cm) diameter x 7.9” (20 cm) height (1/2 or 1 orbit)

X-Ray FOV: 12” (30 cm) x 12” (30 cm)

CBCT Extended Field of View: (offset scan): 13.8” (35 cm) diameter x 7.9” (20 cm) height

CBCT Procedure Times: 44 sec for Gantry down (foot, hand, and elbow) 112 sec for Gantry Lift (knees)

X-Ray Procedure Times: 5 sec

CBCT Patient options available for scanning:

Patient Parameters	Exposure Factors	Type
Small Size: Weight: 50 to 100 lbs (23-45 kg),	100 kVp, 5mA	Medium Field (100kVp)
Small Size: Weight: 50 to 100 lbs (23-45kg),	100 kVp, 5mA	Large Field (100kVp)
Weight: 101 to 400 lbs (46-181 kg)	120 kVp, 5mA	Medium Field (120kVp)
Weight: 101 to 400 lbs (46-181 kg)	120 kVp, 5mA	Large Field (120kVp)

X-Ray Patient Protocol options available for scanning:

Protocol (patient size is included with protocol names)	Exposure Factors	Time	Anatomy
Hand PA Standard	60 kVp, 5mA	300ms	Hand
Hand Lateral Standard	60 kVp, 5mA	600ms	Hand
Hand PA Lite	60 kVp, 5mA	150ms	Hand
Hand Lateral Lite	60 kVp, 5mA	400ms	Hand
Elbow AP Standard	60 kVp, 5mA	600ms	Elbow
Elbow Lateral Standard	60 kVp, 5mA	600ms	Elbow
Elbow AP Lite	60 kVp, 5mA	400ms	Elbow
Elbow Lateral Lite	60 kVp, 5mA	400ms	Elbow
Two Feet AP Standard	60 kVp, 5mA	800ms	Feet
One Foot Lateral Standard	60 kVp, 5mA	800ms	Foot
Two Feet AP Lite	60 kVp, 5mA	500ms	Feet
One Foot Lateral Lite	60 kVp, 5mA	400ms	Foot
Two Knees AP Standard	60 kVp, 5mA	1300ms	Knees
Two Knees PA Standard	60 kVp, 5mA	1300ms	Knees
One Knee Lateral Standard	60 kVp, 5mA	1200ms	Knee
Two Knees AP Lite	60 kVp, 5mA	1000ms	Knees
Two Knees PA Lite	60 kVp, 5mA	1000ms	Knees
One Knee Lateral Lite	60 kVp, 5mA	750ms	Knee

CBCT Primary Reconstruction:

- **Medium Field of View options:** Maximum 2 minutes
- **Large Field of View options:** Maximum 3 minutes

CBCT Secondary Reconstruction: Real Time

Gantry Stopping Distance and Angle: Total rotation from Home position to limit is 424 degrees (Home being 0 degrees). "Load" position (gantry aligned for patient to walk in) is 25 degrees from home position.

Essential Performance:

- X-Ray Specifications – Technique Factors (kV, mA, Time)
- Power Supply Regulation
- Imaging Chain (digital image receptor and 3D reconstruction engine)
- X-Ray Filtration / Half Value Layer
    - Not affected by any electromagnetic phenomenon

Unless otherwise stated above, in the event an electromagnetic phenomenon degrades any of the essential performance items, an operator can expect possible lost or missed images, need for patient re-scan, or the possibility of degradation in image quality.

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: 115VAC ± 10% (Factory Set)

230VAC ± 10% (which covers 220, 230 and 240 VAC power supplies) (Factory Set)

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

Line Frequency: 50 Hz / 60 Hz

Phase: Single

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

Nominal Electrical Input Power to Supply: CT Volume Scan = 300W (120kV, 5mA); 2D X-Ray Scan 150W (60kV, 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
115VAC	115.4VAC	114.2VAC	2.1A	0.57ohms
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 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.

Patient Platform:

- Maximum patient weight capacity: 400 lbs. (181 kg)

Handle Bars:

- Maximum weight capacity: 100 lbs. (45 kg)

Multi-Extremity Chair:

- Maximum patient weight capacity: 400 lbs. (181 kg)

Patient Bench:

- Maximum patient weight capacity: 300 lbs. (136 kg)

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 a reduced level of compliance with the criteria contained in IEC 60601-1-2 Edition 3 Issued 03/2007 and IEC 60601-1-2 Edition 4 issued 02/2014.

Test Name	Test Level/ Equipment Class Edition 4	Test Level/ Equipment Class Edition 3	Results/Notes	Immunity Performance Criteria Met
Emissions Testing				
Radiated Emissions	Class A: Group 1	Class A: Group 1	Compliant	-
Conducted Voltage Emissions	Class A: Group 1	Class A: Group 1	Compliant	-
IEC61000-3-2 Harmonic Current Emissions	Class A	Class A	Compliant	-
IEC61000-3-3 Voltage Changes, Voltage Fluctuations and Flicker	Dmax = 4 %	Dmax = 4 %	Compliant	-
Immunity Testing				
61000-4-2 Electrostatic Discharge	±8 kV Contact, ±15 kV Air	±6 kV Contact, ±8 kV Air	Compliant	A
61000-4-3 Radiated Immunity	80 MHz – 2.7 GHZ, 3 V/M, 80% AM with 1kHz	80 MHz – 2.5 GHZ, 3 V/M, 80% AM with 1kHz	Compliant	A
61000-4-4 Electrical Fast Transients	100kHz repetition ±2 kV Power Supply Lines, ±1 kV Input/Output Lines	5kHz repetition ±2 kV Power Supply Lines, ±2 kV Input/Output Lines	Compliant	A
61000-4-5 Surge Immunity	±1 kV Line to Line, ±2 kV Line to Earth	±1 kV Line to Line, ±2 kV Line to Earth	Compliant	A
61000-4-6 Conducted Immunity	150 kHz – 80MHz, 3 Vrms 6 Vrms in ISM band between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	150 kHz – 80MHz, 3 Vrms	Compliant	A
61000-4-8 Power Frequency Magnetic Field	30 A/M	3 A/M	Compliant	A
61000-4-11 Voltage Dips and Short Interruptions	135°, 180°, 225°, 270° and 315° % UT; 1 cycle 70 % UT; 25/30 cycles for 50 Hz and 60Hz, % UT; 250/300 cycle for 50 Hz and 60 Hz,	>95% dip for 0.5 periods	Compliant	A
		60% dip for 5 periods	Compliant	A
		30% dip for 230periods	Compliant	A
		>95% dip for 5 seconds	Compliant	C

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 LineUP
The LineUP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LineUP 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 LineUP. 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 LineUP 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. This equipment is designed to be used in industrial areas and hospitals (CISPR 11 class A) only. Therefore, the emissions characteristics have not been tested to comply with CISPR 11 group 2 Class B. This equipment is not suitable for use 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 LineUP has been designed and evaluated to meet the requirements of the following standards. The device has passed all applicable sections of these standards.

ANSI/AAMI ES60601-1, third edition, 01/2005
BS EN 1041:2008
BS EN ISO 14971:2009
CSA C22.2 NO. 60601-1:08-CAN/CSA, third edition, 07/2008
EN ISO 15223-1:2012
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, first edition, 01/1994
IEC 60601-1-3, second edition, 01/2008
IEC 60601-2-54, first edition, 06/2009

IEC 60601-1-6, first edition, 01/2006
IEC 60601-1-6, third edition, 01/2010
IEC 60601-1-8, first edition, 1/2003
IEC 60601-2-7, second edition, 02/1998
IEC 60601-2-44, second edition, 01/2002
IEC 60601-2-44, third edition, 02/2009
IEC 62304, first edition, 05/2006
ISO 15223-1:2012

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

Equipment Class:

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

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 could come in contact with the patient. As stated in patient preparation recommendations below, barriers should be used so that the patient does not come into direct contact with the device. By avoiding direct contact with the device, minimal soiling should occur during normal use.

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 underneath the Platform Area and into the Gantry.

For disinfecting, use CaviWipes™ surface disinfectant wipes by Metrex™. Use on all surfaces that contact the patient as directed by the CaviWipes™ label. Do not spray any disinfectant directly onto the equipment.

Patient Preparation Recommendations:

The patient must wear FDA cleared medical gloves for gripping the hand rails, with sanitation and convenience in mind.

The patient should not step bare foot on the patient platform. Proper foot protection should be provided.

The Multi-Extremity Chair should be lined with Exam Table Paper before the patient is seated on it.

The Patient Bench should be lined with Exam Table Paper before the patient is seated on it.

Line the knee positioner or hand platform (if using) with Medical Barrier Film. CurveBeam tested brand: Clear Barrier Film – Low tack-adhesive (Palmero #1866C).

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

Preventive Maintenance Schedule - for Owner / User:

WARNING Prior to performing any 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

- *Annually:*

  Check for satisfactory image quality.

IT IS THE RESPONSIBILITY OF THE USER TO ENSURE 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).

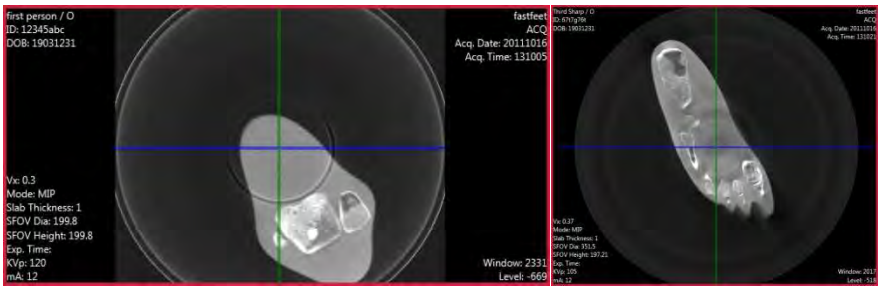
Planned Maintenance – Monthly Schedule:

The system requires monthly maintenance check for failed or faulty indicators/lights. Check for failed or faulty indicators/lights. Contact CurveBeam Technical Support at the number on the front cover of this manual to assist with exercising the indicators/lights.

Planned Maintenance – Quarterly Schedule:

The system requires quarterly maintenance for Panel Calibration. Contact CurveBeam Technical Support at the number on the front cover of this manual to assist with this quarterly calibration.

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.



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. In addition to mechanical inspection and calibration, a series of image performance tests are to be conducted. Door interlock, LED status lights, emergency stop, and x-ray alarm are also tested as part of this maintenance. 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.

UPS (Uninteruptible Power Supply) **Maintenance:**

Please refer to the Tripp Lite UPS (SMART1500LCDT 120v 1500va 900w and SMX1500LCDT 230V 1.5kVA 900W) User’s Guide for UPS maintenance recommendations.

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:

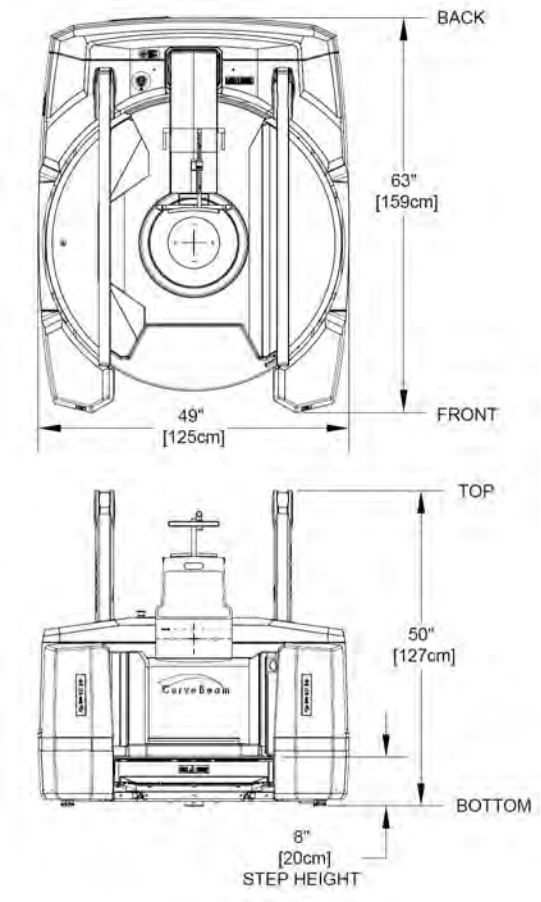
Part Description	Part Number
Gantry Belt	200145-3
Lift Belt 1	200194
Lift Belt 2	200193
Lift Motor	100109-2
Rotation Motor	100109
Beam Limiter Motor	100112
Receptor Motor	100110
Knee Positioner Lift Column	2155-5
Breaker Switch Assembly 115VAC	4026-115-0
Breaker Switch Assembly 230VAC	4026-230-0
X-Ray Power Supply Assembly	4016-0
Embedded Board Assembly	4014-0
Can Bus Breakout Assembly	4006-0
120VAC Breakout Assembly	4017-0
LED Distribution Assembly	4008-0
X-Ray Tube head	2027-0
Image Receptor (Panel)	MX-CFP3131
Ethernet Cable CAT 6 GREEN, 50'	100105
Ethernet Cable CAT 6 RED, 50'	100106
Operator's Control Box	5006-0
Scan (Exposure) Switch	5007-0
Geometric Phantom	2803
QA Phantom	2802
Gantry Lift Controller	5221-0
Multi-Extremity Chair Motor Control Box	CO61
Multi-Extremity Chair Lift Column	DB-13
Multi-Extremity Chair Recline Motor	LA23
Multi-Extremity Chair Operator Controller	5222-0
Flat Platform Assembly	2100-72-0
Single Foot Platform	210-75-0
Knee Plate Assembly	2100-73-0
Hand Plate Assembly	2100-70-0
Ten Degree Foot Plate Assembly	2100-71-0
Knee Up/Down Control Assembly	5221-0

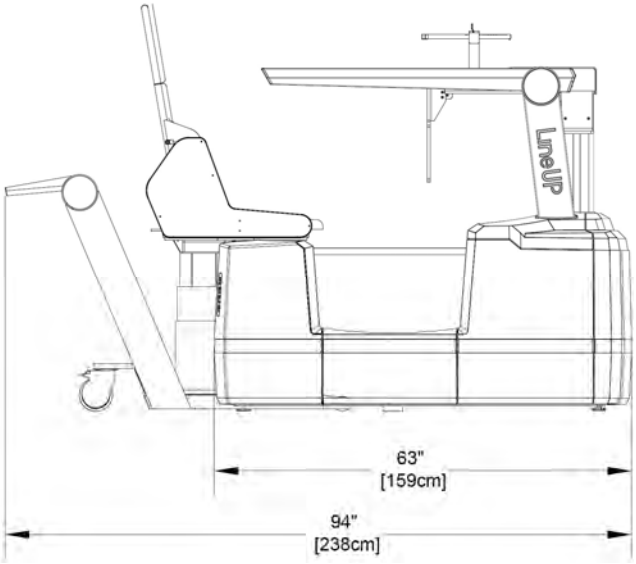
Accessories:

Multi-Extremity Chair
Patient Bench
Hand and Elbow Positioner

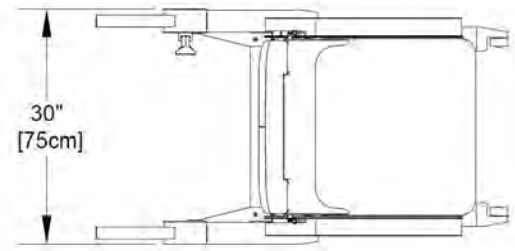
System Dimensions:

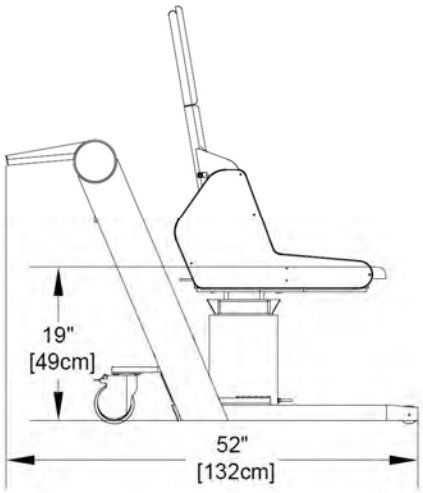
Scanner:

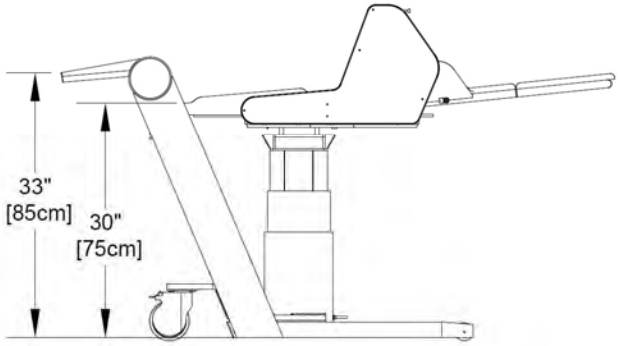




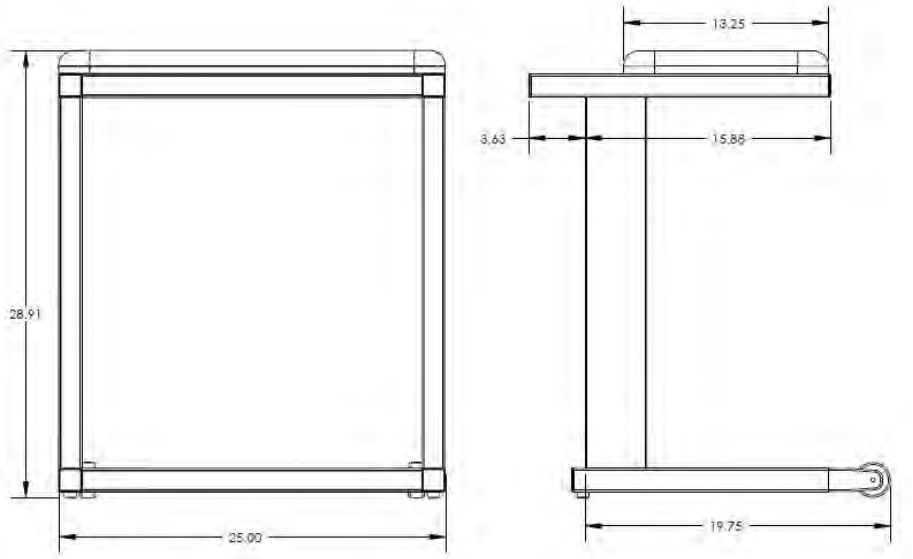
Multi-Extremity Chair:







Patient Bench:



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 (E-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. If an E-Stop is activated, with a patient in the scanner, refer to the Emergency Removal of a Patient Section later in this chapter.

Moving Parts(over-travel): In the event of the use of either of the 2 designated Emergency Stop buttons or in any case where mains power is unintentionally interrupted, and the gantry is in motion, gantry shall stop within the limits defined below.

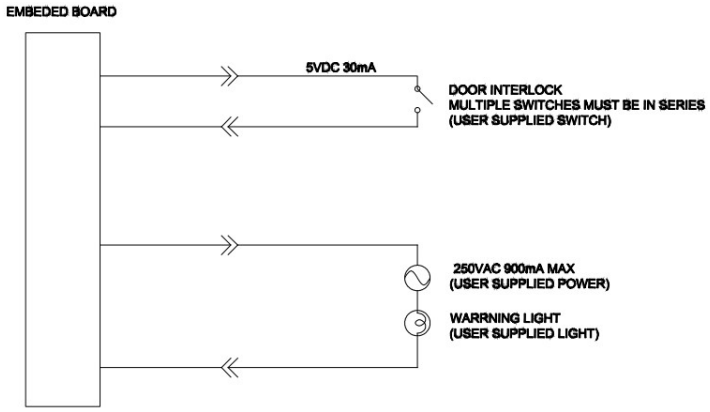
Gantry Rotational Movement	1 degree or less
Gantry Vertical Movement.	1cm or less

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:



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. An error message will appear in the Acquisition software.

2. If the path into the machine is blocked by the gantry, manually rotate the gantry so that the patient entrance (side with the small step down) is at the front of the scanner.

If Multi-Extremity Chair and Patient Bench are NOT being used:

3. If the Gantry is raised, allow it to slowly lower, or assist the gantry down. If needed, press down on the small step the patient uses to enter and exit the machine.

4. Once the gantry is fully back to the starting position (gantry is down, step is at the front of the machine), carefully assist the patient to step out of the platform area.

If Patient Bench IS being used:

3. Instruct the patient to stand up and turn around to face the Patient Bench, then pull the Multi-Extremity Chair back out of the machine.

4. Carefully assist the patient to step out of the platform area.

If Multi-Extremity Chair IS being used:

3. Instruct the patient to place their hands in their lap and pull the Multi-Extremity Chair back out of the machine.

4. Assist the patient out of the Multi-Extremity Chair.

5. Reset the machine: Close the Acquisition 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 Acquisition software. Now the system can be operated again as expected.

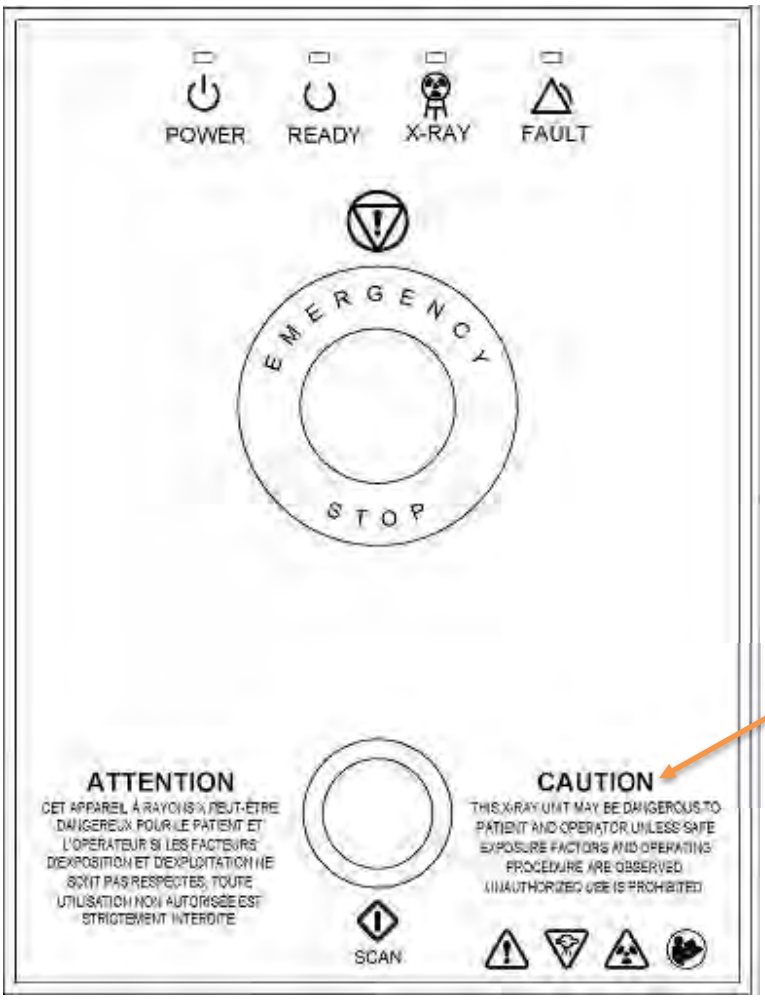
In the case of loss of power to the scanner, perform Steps 1-4 above. Once power is restored, Step 5 can be performed.

Recommended Coverings:

Item	Manufacturer	Part number	Description	Certificates
Gloves - Clear Vinyl Powder Free Exam Gloves	AMMEX	VPF6X100 The above "X" is dependent upon the size required.	"dependable barrier protection against blood-borne pathogens and environmental contaminants " "Ambidextrous, FDA approved for all non-sterile medical procedures"	K891850
Barrier Film – Clear Film	Palmero Medical	1866C	"Polyethylene film with a low-tack adhesive that adheres to most operatory surfaces, leaves no residue, latex-free"	Safety Data Sheet provides Toxicology Information.
Exam Paper – Standard Crepe Exam Table Paper	MEDLINE	NON23325	"Strong, absorbent table paper helps protect exam tables from dirt and moisture while offering comfort and protection for patients."	Latex Free

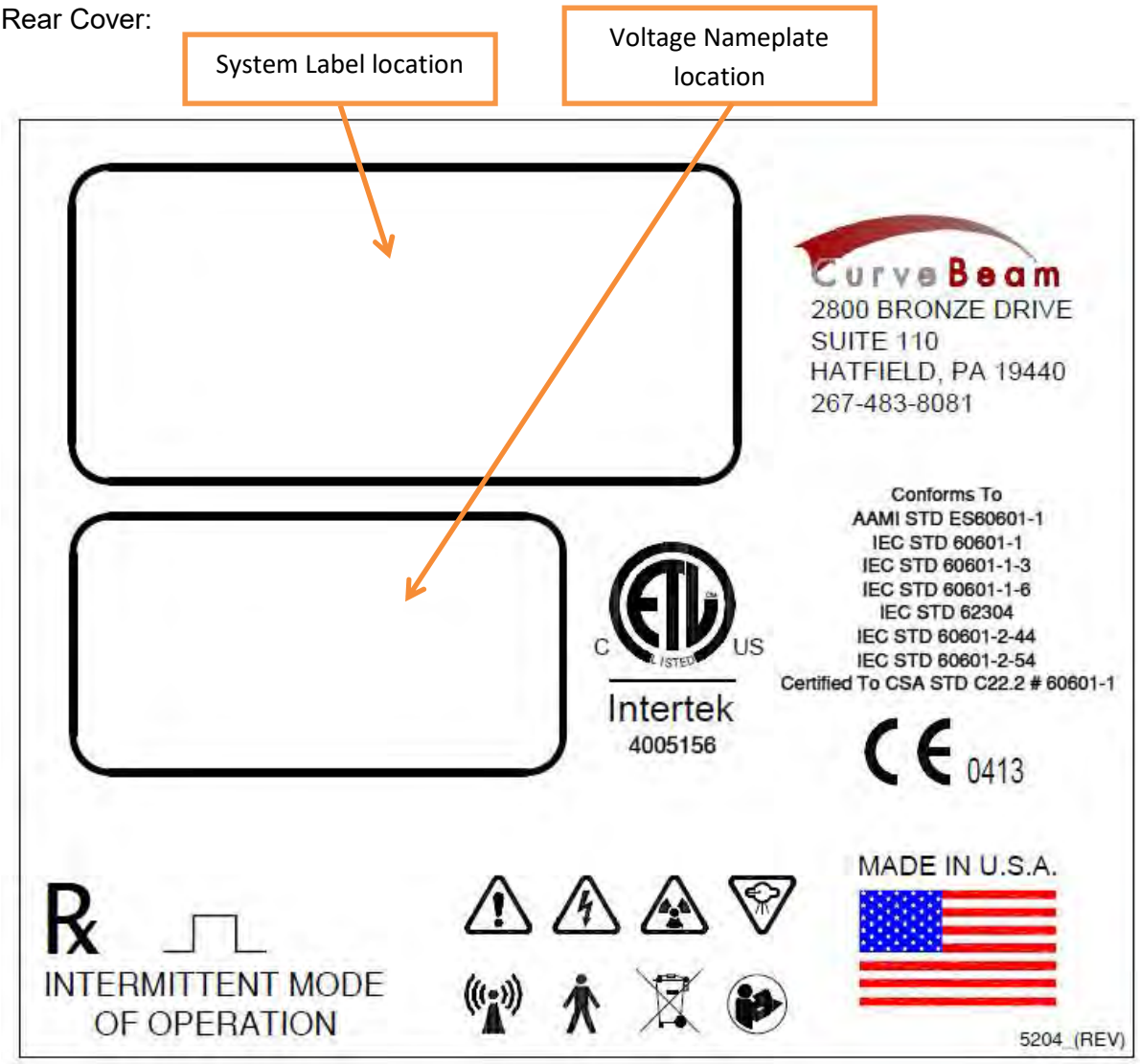
System Labels:

Operator Control Box: E-Stop, Power ON light, X-ray Ready light, X-ray ON light, Fault light, Scan/Exposure Switch.

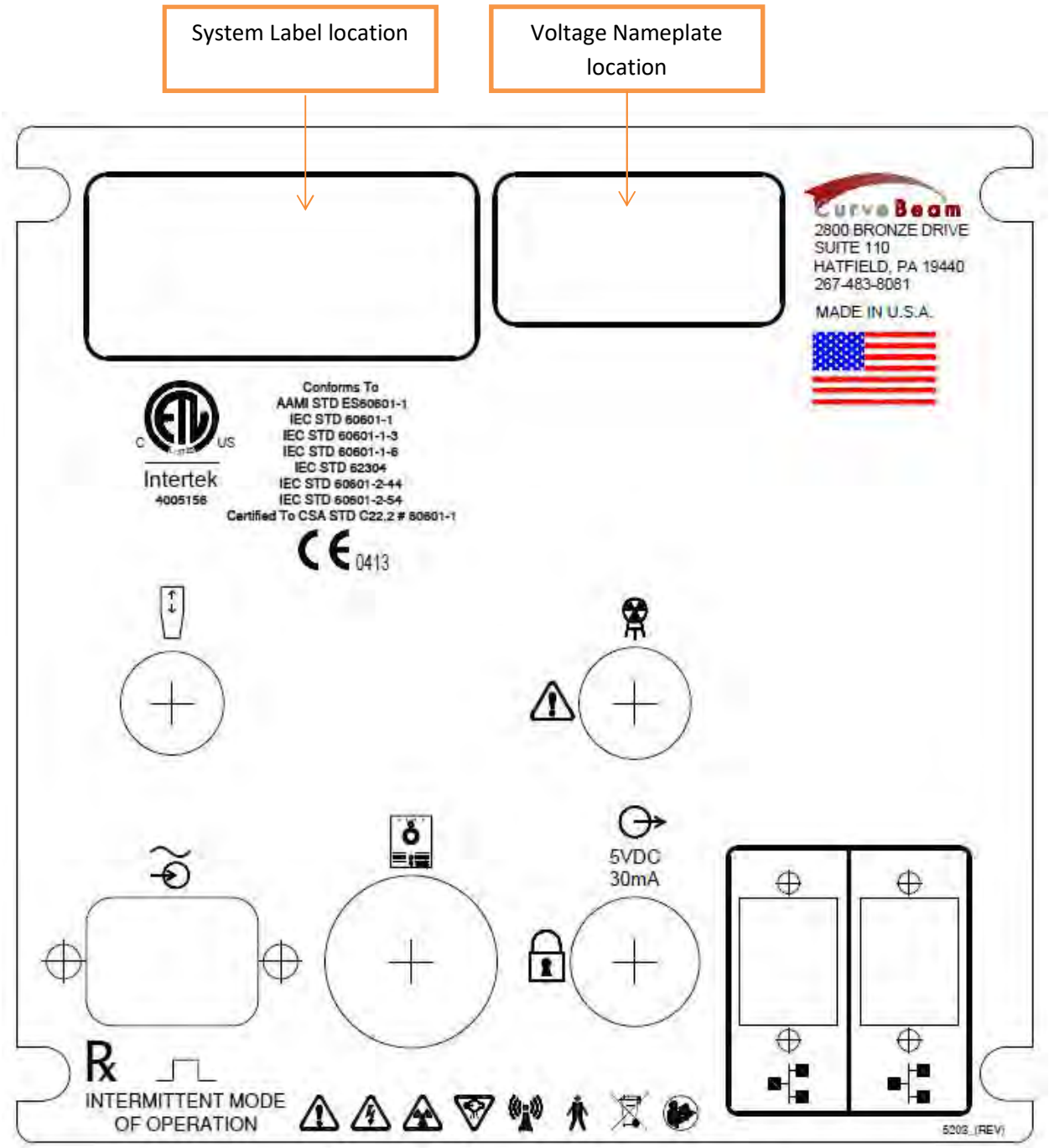


Zoomed in on the Verbiage:
CAUTION
THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING PROCEDURE ARE OBSERVED.
UNAUTHORIZED USE IS PROHIBITED.

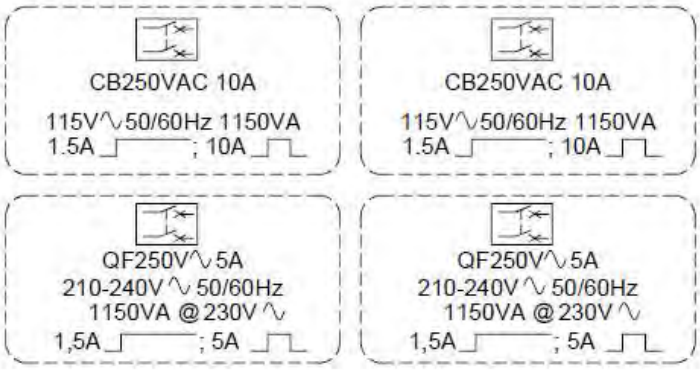
Rear Cover:


System Label location
Voltage Nameplate location
CurveBeam
2800 BRONZE DRIVE
SUITE 110
HATFIELD, PA 19440
267-483-8081
Conforms To
AAMI STD ES60601-1
IEC STD 60601-1
IEC STD 60601-1-3
IEC STD 60601-1-6
IEC STD 62304
IEC STD 60601-2-44
IEC STD 60601-2-54
Certified To CSA STD C22.2 # 60601-1
C US
Intertek
4005156
CE 0413
Rx
INTERMITTENT MODE
OF OPERATION
MADE IN U.S.A.
5204_(REV)

Rear Connector Panel:



Voltage Nameplate for opening in Rear Connector Panel and Rear Panel:



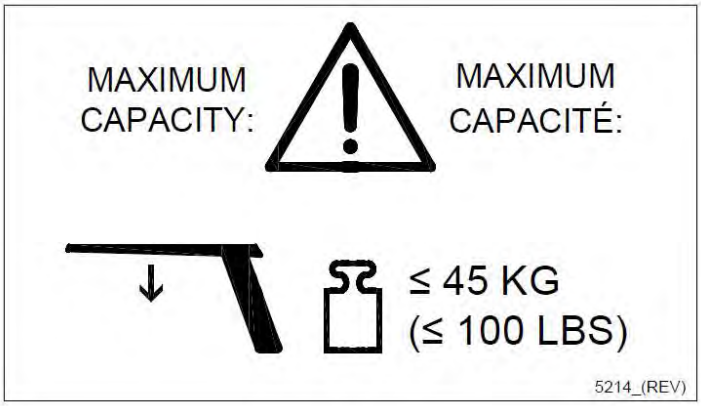
Fuse Label:

Patient Bench Label:

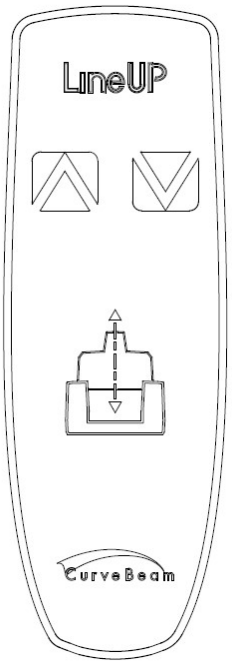
Indicator Panel (on machine):

Multi-Extremity Chair label:

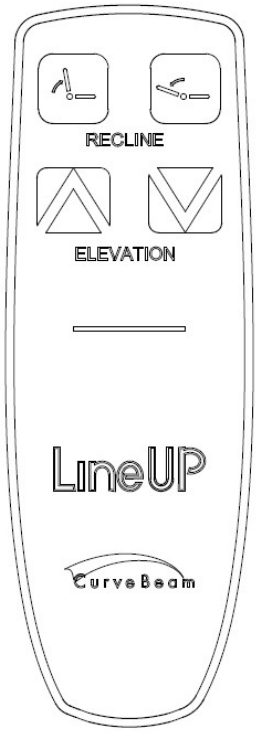
Handle Bar Label:



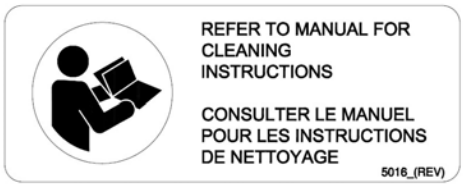
Knee Positioner / Gantry Height Adjustment:



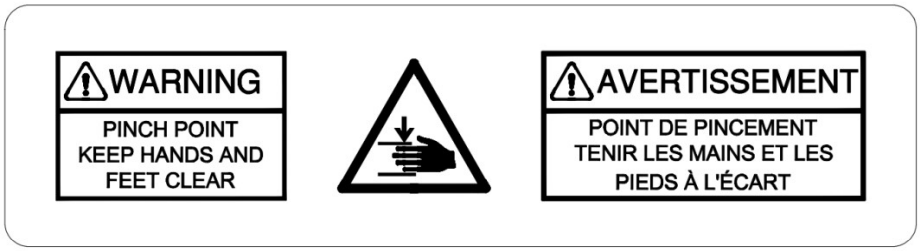
Patient Transport Adjustment:



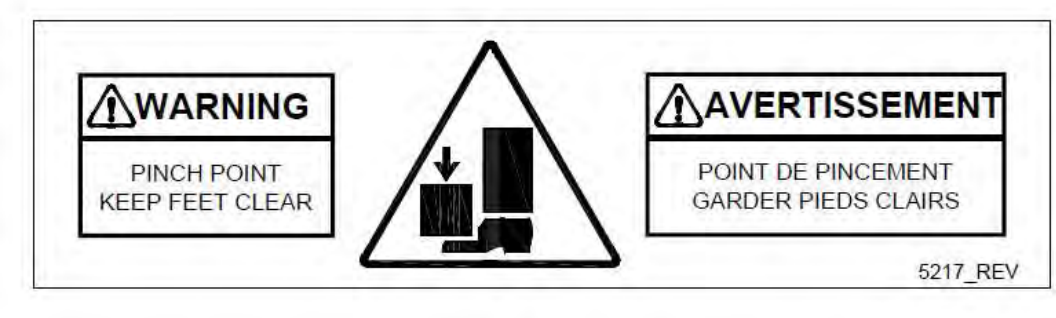
Cleaning Instructions Label on both Scanner and Multi-Extremity Chair:



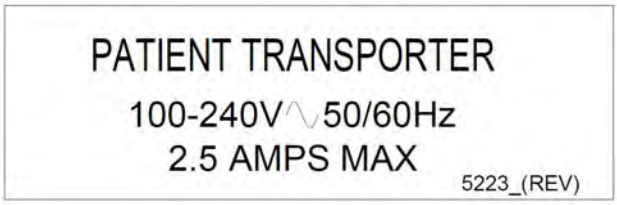
Pinch Point Label on Multi-Extremity Chair:



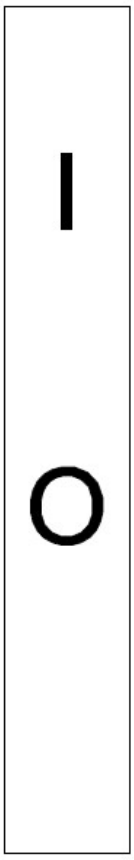
Pinch Point Label on Scanner:



Multi-Extremity Chair Power:



Power Switch:

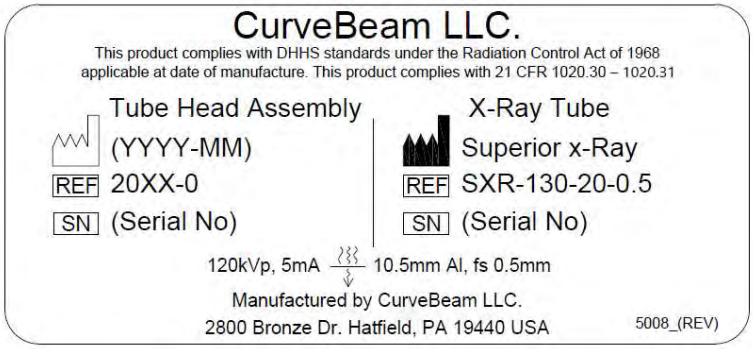


Tubehead Focal Spot Label:

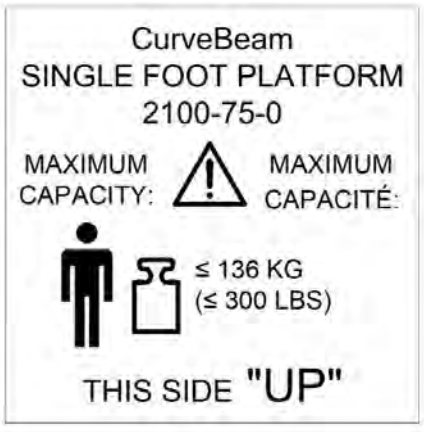
System Label:

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

Tube Head Label:



Single Foot Platform:



SINGLE FOOT PLATFORM LABEL
5232

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	Output for Interlock	Maximum weight capacity for sitting.
Fault		Maximum Weight capacity for standing.	Maximum weight capacity for handle bars.
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 is intended for the patient to stop exposure during a scan. This will seize exposure and all motors. It is located on the machine itself. To Reset the button, turn it to the right so it pops out.

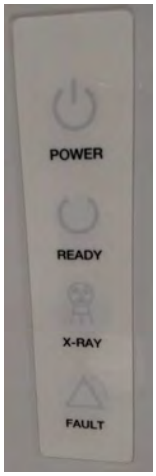
System Status Indicators

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

The lights are as follows:

- **Power ON:** 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 ON:** 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 machine: *front right and left cover*



CHAPTER 4: Calibration and Quality Assurance (QA) Procedures

Calibration Procedures

Calibrations are necessary for proper performance of the LineUP. Annually a Panel Calibration needs to be performed by a CurveBeam Technical Support specialist.

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

The user can request a calibration at the scheduled interval by contacting CurveBeam Technical Support to assist with the calibration.

Quality Assurance Procedures

QA Test 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 LineUP 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.

The QA tests will be performed by scanning specified QA phantoms provided by CurveBeam. These include a QA Line Pair/Chamber Phantom and a Water Phantom. Image Data will be captured and assessed for acceptable values.

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

Image Quality (QA Phantom):

The items assessed for Image Quality will be:

- High Contrast Spatial Resolution measured via line pairs.
- Hounsfield Units (HU) accuracy of 4 Density chambers (Teflon, Acrylic, LDPE, Air)

1. Place the QA Phantom on the devices patient platform using the circular positioning guides to center it on the platform.

2. Acquire a CBCT scan of the phantom using a **Medium Field (120 kVp) scan option.**

   Advice: Please refer to the Acquiring a Scan section of the manual, Chapter 6, for Acquiring 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

3. *Evaluate High Contrast Spatial Resolution:* Open the newly captured scan in a DICOM Viewing software and load the acquired scan to visually evaluate the line pairs for high contrast spatial resolution.
   a. Apply the Sharp Filter on the DICOM viewing software– keep this set for all of the remaining QA procedures.
   b. Change the slab thickness to the smallest thickness in the axial window – keep this set for all of the remaining QA procedures.
   c. Observe the line pairs in the DICOM Viewer's axial view. The axial image should be centered on the line pairs, use coronal and sagittal views to approximate the center of the line pairs (height), then view the line pairs in the axial window.

d. The expected result should be 9 line pairs per cm or better. The line pairs start at 8 line pairs, so the second set of line pairs is 9 line pairs per cm, third set is 10 line pairs per cm, and so forth.
e. Visually verify that there is definition present for each of the lines in pair 9 or higher.

4. *Evaluate Hounsfield (HU) Accuracy:*
   a. On the axial view, measure the Hounsfield Units value of each density chamber. The results should fall within the below ranges.

   Advice: K*eep the HU circle off the borders of the chambers.*

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

Distance Measurement Accuracy (QA Phantom):

Evaluate Distance Measurement Accuracy: In the currently open QA Phantom scan, Zoom into the Axial View's line pairs and make a distance measurement, using the Distance Tool, from one end of the line pair set to the other end of the line pair set. The distance should be between 41.0 - 42.5 mm.

Consistency/Uniformity (Water Phantom):

To evaluate consistency, we will image the simulated Water Phantom.

1. Place the Combined LP/Water phantom on the platform and ensure it is centered using the circles on the patient platform.

2. Acquire a new scan of the phantom using a **Medium Field (120 kVp) scan option**.
   Advice: Please refer to the Operations: Acquisition section of the manual, Chapter 6, for instructions on acquiring the scan.

3. Once the data is captured, it can be evaluated in the DICOM viewing software. Open the dataset to the Review/MPR Tab's Axial View. Apply the Sharp Filter and change the slab thickness on the axial window to the smallest possible slab size.

4. *Noise Level Test:* from the axial view, use large Hounsfield circular measurements from within the DICOM viewing software and move them so that one is in the center of the water.

   The Value should fall in the below range:
   Water: -150 to 150

5. *Uniformity Test:* move the other 4 HU large circular measurements into the four quadrants, with the one from the prior step still in the center of the axial image. Note the Mean of each measurement. The mean of each quadrant measurement should be within 250 HU's from the center measurement mean.

Radiation Output Test:

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.

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

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 of 20 cm diameter x 20 cm height, 0.3 voxel (Procedure Name: Medium Field (120kVp)) 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

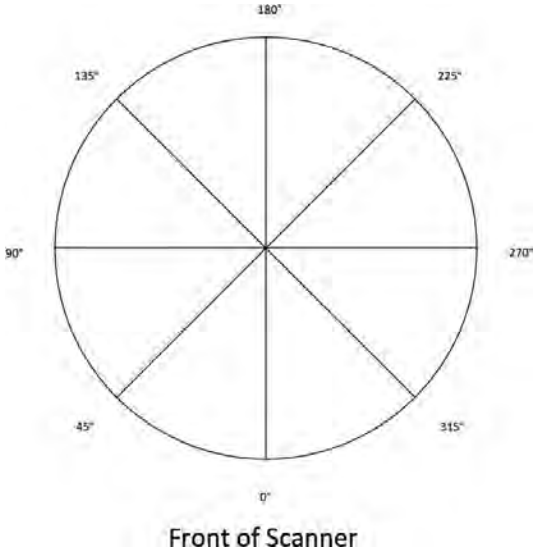
Scatter Measurements:

Methodology

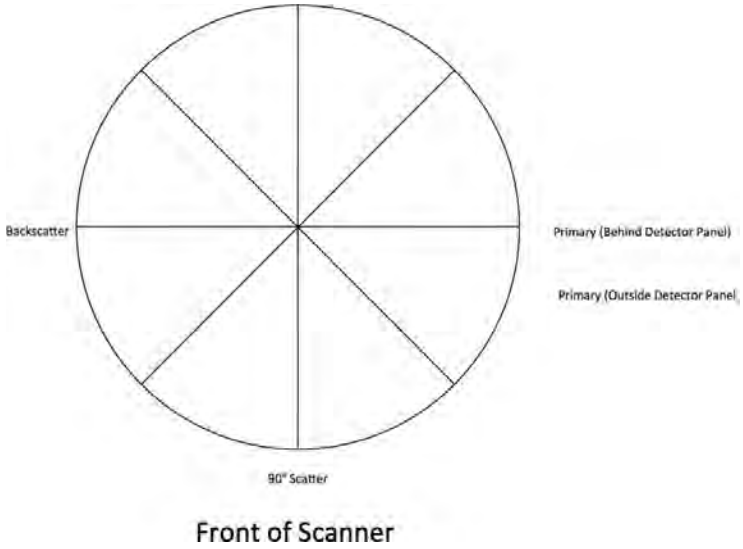
Below is a diagram of where scatter measurements were taken. Scattered dose in the down direction could not be measured due to practical considerations of machine size, weight, etc. Dose in the down direction is conservatively assumed to be the same as in the up direction. This is considered conservative as machine structural components will attenuate the scattered beam significantly.

An anthropomorphic foot phantom was positioned in the center of the scanner. TBM-IC-X-ray Survey Meter (SN 014559, calibrated 12/21/17) was used to measure the scattered radiation.

Location of measurement points: CT Scan



Location of measurement points: Radiography Scan



Scatter Measurements – 100 kVp, foot protocol

Unit:	LineUP	**Mode:**	Center, foot phantom in beam
Live Time:	5.76 sec	**Field Size:**	31 x 31 cm
kVp:	100	**mA:**	5
Pulses:	480	**Pulse Duration:**	0.012 sec

Measurements taken at locations equidistant from phantom location.

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	0.020	20	0.69	0.20	0.50	1.00
45	1	0.020	20	0.69	0.20	0.50	1.00
90	1	0.030	30	1.04	0.30	0.75	1.50
135	1	0.020	20	0.69	0.20	0.50	1.00
180	1	0.010	10	0.35	0.10	0.25	0.50
225	1	0.020	20	0.69	0.20	0.50	1.00
270	1	0.020	20	0.69	0.20	0.50	1.00
315	1	0.020	20	0.69	0.20	0.50	1.00

Scatter Measurements – 120 kVp, foot protocol

Unit:	LineUP	**Mode:**	Center, foot phantom in beam
Live Time:	5.76 sec	**Field Size:**	31 x 31 cm
kVp:	120	**mA:**	5
Pulses:	480	**Pulse Duration:**	0.012 sec

Measurements taken at locations equidistant from phantom location.

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	0.040	40	1.39	0.40	1.00	2.00
45	1	0.040	40	1.39	0.40	1.00	2.00
90	1	0.060	60	2.08	0.60	1.50	3.00
135	1	0.030	30	1.04	0.30	0.75	1.50
180	1	0.020	20	0.69	0.20	0.50	1.00
225	1	0.030	30	1.04	0.30	0.75	1.50
270	1	0.050	50	1.74	0.50	1.25	2.50
315	1	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	--	0.180	180	6.25	1.80	4.50	9.00
	1 m In Front	0.120	120	4.17	1.20	3.00	6.00

Scatter Measurements – 120 kVp, knee protocol

Unit:	LineUP	**Mode:**	Center, knee phantom in beam
Live Time:	8.64 sec	**Field Size:**	31 x 31 cm
kVp:	120	**mA:**	5
Pulses:	720	**Pulse Duration:**	0.012 sec

Measurements taken at locations equidistant from phantom location.

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	0.020	20	0.69	0.20	0.50	1.00
45	1	0.010	10	0.35	0.10	0.25	0.50
90	1	0.020	20	0.69	0.20	0.50	1.00
135	1	0.020	20	0.69	0.20	0.50	1.00
180	1	0.010	10	0.35	0.10	0.25	0.50
225	1	0.010	10	0.35	0.10	0.25	0.50
270	1	0.020	20	0.69	0.20	0.50	1.00
315	1	0.020	20	0.69	0.20	0.50	1.00

Scatter Measurements – Radiography Mode – Standard Knee

Unit:	LineUP	**Mode:**	Center, knee phantom in beam
Live Time:	1.3 sec	**Field Size:**	31 x 31 cm
kVp:	120	**mA:**	5
Pulses:	1	**Pulse Duration:**	1.3 sec

Measurements taken at locations equidistant from phantom location.

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
Primary (Behind Detector)	1	0.0003	0.300	0.046	0.003	0.008	0.015
Primary (Adjacent to Detector)	1	0.010	10	1.54	0.10	0.25	0.50
90°	1	0.001	1	0.08	0.01	0.01	0.03
180° (Backscatter)	1	0.001	1	0.08	0.01	0.01	0.03
1 m Above	1	0.007	7	1.09	0.07	0.18	0.36

Cone Beam CT Performance Testing for FDA Submission – CurveBeam LineUP

12/18/17 (Rev. 2/23/18)

The following protocol were tested for dose measurements and several 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	480	43.2	0.3	690	36.143
120	5	0.012	480	43.2	0.3	690	36.143

This was done for two tube positions, the x-ray tube head up position and the x-ray tube head down position.

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. An "offset" mode is available in which the tube and the detector panel are shifted so only half of the total imaged area is exposed at once. Getting accurate dose readings in this mode is difficult. Because the technique and dose profile is identical, it is assumed the dose from the offset position is identical to that in the centered position.

Results

Position	kVp	mA	Pulse Duration (seconds)	Number of Pulses per Scan	mAs	Scan Diameter (cm)	CTDIvol (mGy)
X-ray tube head down	**100**	5	0.012	480	28.8	36.143	1.163
	120	5	0.012	480	28.8	36.143	2.014
X-ray tube head up	**100**	5	0.012	480	28.8	36.143	1.148
	120	5	0.012	480	28.8	36.143	1.972

Phantom Details:

- This CTDI phantom meets the provisions of 21 CFR 1020.33 and has passed a comprehensive quality assurance test by a qualified medical physicist.
- Diameter 16cm
- Height(L) 14.11cm
- Density 1.18g/cm^3

100 kVp – X-ray tube head down Position

CTDI Head Phantom (16-cm diameter PMMA phantom)	Measured	Calculated
kVp	100	
mA	5	
Exposure time per rotation (s)	8.64	
Source-to-Detector Distance (mm)	528.36	
Object-to-Detector Distance (mm)	232.75	
Beam Width at Isocenter (mm)	213.42	
Active Chamber length (mm)	100	
Chamber correction factor	1	
Center		
Average of above 6 measurements (mR)		119.8
CTDI at isocenter in phantom (mGy)		1.042
2 o'clock position (Highest extremity measurement)		
Average of above 6 measurements (mR)		140.60
CTDI at12 o'clock position in phantom (mGy)		1.223
CTDIw (mGy)		1.163
Clinical exam dose estimates		
CTDIvol (mGy)	=CTDIw*N*T/I	1.163

120 kVp – X-ray tube head down Position

CTDI Head Phantom (16-cm diameter PMMA phantom)	Measured	Calculated
kVp	120	
mA	5	
Exposure time per rotation (s)	8.64	
Source-to-Detector Distance (mm)	528.36	
Object-to-Detector Distance (mm)	232.75	
Beam Width at Isocenter (mm)	213.42	
Active Chamber length (mm)	100	
Chamber correction factor	1	
Center		
Average of above 6 measurements (mR)		212.5
CTDI at isocenter in phantom (mGy)		1.848
2 o'clock position (Highest extremity measurement)		
Average of above 6 measurements (mR)		240.95
CTDI at12 o'clock position in phantom (mGy)		2.096
CTDIw (mGy)		2.014
Clinical exam dose estimates		
CTDIvol (mGy)	=CTDIw*N*T/I	2.014

100 kVp – X-ray tube head up Position

CTDI Head Phantom (16-cm diameter PMMA phantom)	Measured	Calculated
kVp	100	
mA	5	
Exposure time per rotation (s)	8.64	
Source-to-Detector Distance (mm)	528.36	
Object-to-Detector Distance (mm)	232.75	
Beam Width at Isocenter (mm)	215.21	
Active Chamber length (mm)	100	
Chamber correction factor	1	
Center		
Average of above 6 measurements (mR)		121.1
CTDI at isocenter in phantom (mGy)		1.054
11 o'clock position (Highest extremity measurement)		
Average of above 6 measurements (mR)		137.30
CTDI at12 o'clock position in phantom (mGy)		1.195
CTDIw (mGy)		1.148
Clinical exam dose estimates		
CTDIvol (mGy)	=CTDIw*N*T/I	1.148

120 kVp – X-ray tube head up Position

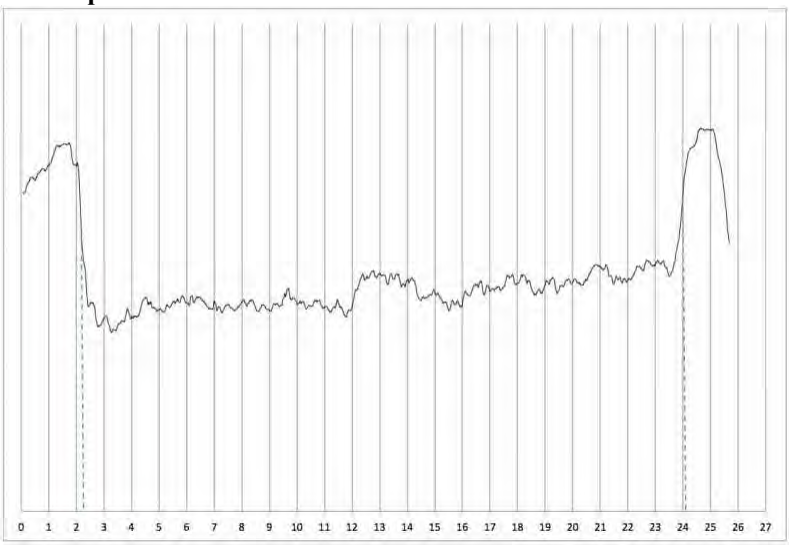
CTDI Head Phantom (16-cm diameter PMMA phantom)	Measured	Calculated
kVp	120	
mA	5	
Exposure time per rotation (s)	8.64	
Source-to-Detector Distance (mm)	528.36	
Object-to-Detector Distance (mm)	232.75	
Beam Width at Isocenter (mm)	215.21	
Active Chamber length (mm)	100	
Chamber correction factor	1	
Center		
Average of above 6 measurements (mR)		208.7
CTDI at isocenter in phantom (mGy)		1.816
11 o'clock position (Highest extremity measurement)		
Average of above 6 measurements (mR)		235.60
CTDI at12 o'clock position in phantom (mGy)		2.050
CTDIw (mGy)		1.972
Clinical exam dose estimates		
CTDIvol (mGy)	=CTDIw*N*T/I	1.972

Dose Profile

Methodology

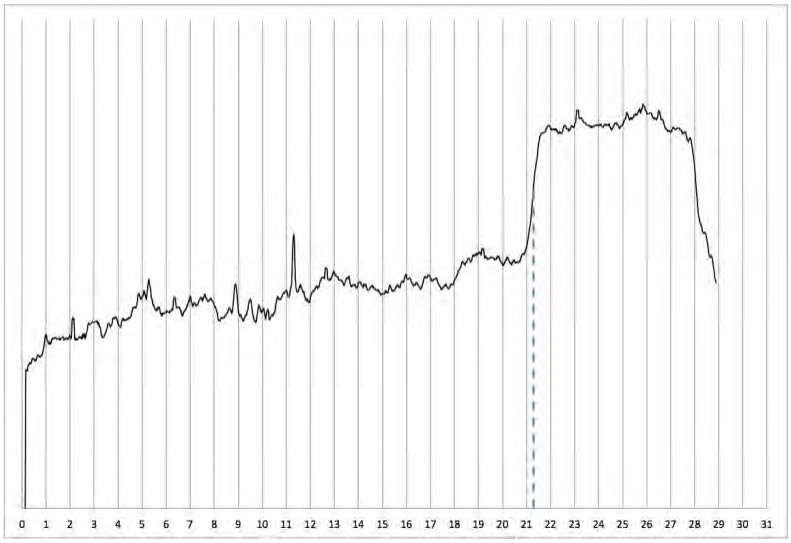
The dose profile was measured by exposing strips of GAF chromic film, which was aligned at the isocenter of the scanner. The film was then digitized and the profile was measured. This was done for two tube positions, the x-ray tube head up position and the x-ray tube head down position. A nominal beam width of 21.521 is used for the x-ray tube head up position, and 21.342 cm is used for the x-ray tube head down position. The full width at half maximum was determined.

Results – X-ray tube head up



Dose Profile (FWHM) (cm)	21.9

Results – X-ray tube head down

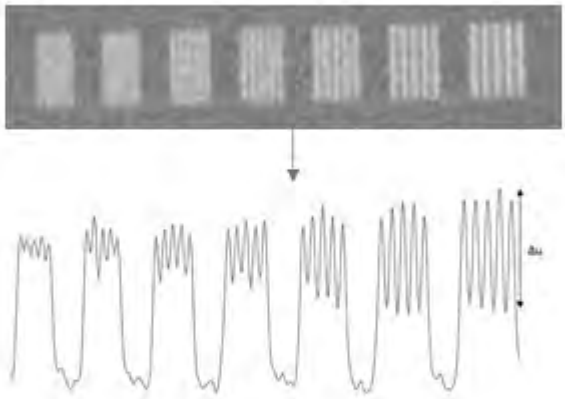


Dose Profile (FWHM) (cm)	21.2

Modulation Transfer Function (MTF)

Methodology

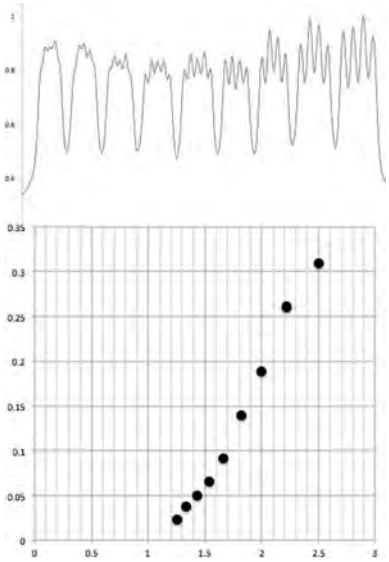
Using the manufacturer's Quality Control Phantom, a series of high contrast line pairs were scanned. The profile of each line pair group was plotted, the average peak pixel value and the average low pixel value were compared to the pixel value of the bar material and the background. As the spatial frequency 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. The 120 kVp technique was used in the x-ray tube head up position and 100 kVp was used in the x-ray tube head down positions.



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

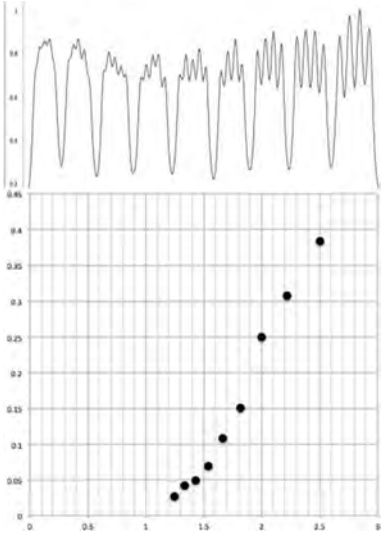
Results

X-ray tube head down:



Limiting Resolution (MTF < 0.1)	
Line Pair per mm (lp/cm)	12
mm	1.67

X-ray tube head up:



Limiting Resolution (MTF < 0.1)	
Line Pair per mm (lp/cm)	13
mm	1.54

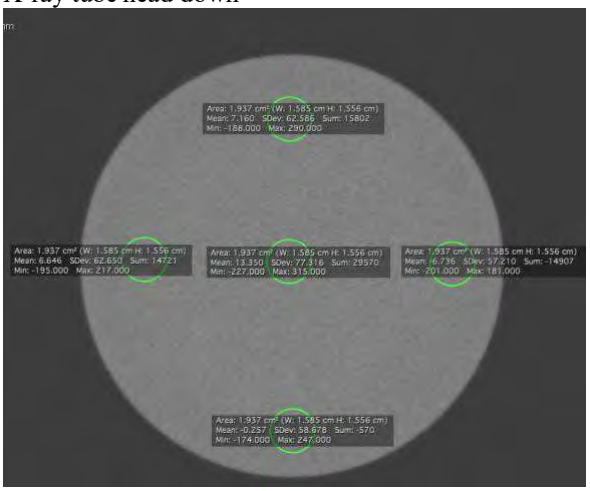
Uniformity

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

X-ray tube head down



X-ray tube head up

Protocol	Maximum Center-Peripheral Deviation	Limit (set by manufacturer)
X-ray tube head down	13.612	<100
X-ray tube head up	5.106	<100

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. Small ROIs were used to measured the CT numbers in these test materials. These values were then compared to the expected values.

Results

Protocol	Material	Measured CT Number	Expected Value
X-ray tube head down	Teflon	1091.86	850 ±250
	Acrylic	130.847	75 ±125
	Water	13.355	0 ±150
	LDPE	-108.815	-150 ±100
	Air	-1016.376	-1000 ±200
X-ray tube head up	Teflon	848.106	850 ±250
	Acrylic	100.636	75 ±125
	Water	2.510	0 ±150
	LDPE	-99.087	-150 ±100
	Air	-898.855	-1000 ±200

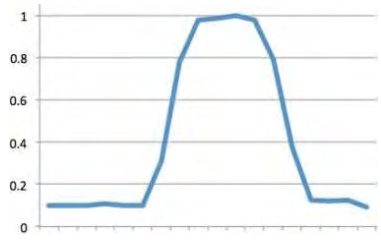
Tomographic Slice Accuracy

Methodology

Slice thickness accuracy was tested using the resolution test pattern in the QC phantom. The thickness of this test pattern is 0.08" (2.032 mm) according to the phantom's manufacturer. The CT number of the test pattern was evaluated at a number of slices, and the full-width at half maximum (FWHM) was evaluated. The expected slice thickness is 0.3 mm.

Results

As shown in the plot below, the FWHM was determined to be 6.507 pixels. 6.507 pixels would need to be 0.31 mm thick to result in the correct pattern thickness. This is well within the range of 0.2 – 0.4 mm.



2-D Imaging Mode

This scanner also has a 2-D imaging mode for single shot radiographic images. This mode operates only at 60 kVp through a range of mAs. The tube current is always set at 5 mA.

Reproducibility

Methodology

Ten shots were taken at 60 kVp and 5 mAs (5 mA, 1000 msec) to determine the reproducibility of the kVp, exposure, and exposure time. A source to detector distance of 76.11 cm was used.

Results

	Energy (kVp)	Exposure (mR)	Time (msec)
	60.07	1.8	999.0
	60.37	1.8	998.7
	60.64	1.8	999.1
	61.53	1.9	998.4
	60.07	1.8	999.2
	61.30	1.9	999.4
	61.11	1.8	999.3
	60.41	1.8	999.3
	62.26	1.9	999.1
	61.36	1.9	999.0
Mean Value	60.91	1.8	999.1
Standard Deviation	0.72	0.01	0.30
COV	**0.0118**	**0.0048**	**0.0003**

Half value layer

Methodology

The half value layer measurement determines a parameter known as "beam quality", which is an indication of the energy spectrum of the X-ray beam and will generally affect both image quality and patient dose. Improper filtration of the X-ray beam can lead to a failure of this test as can inaccurate voltage calibration.

Results

Nominal (Selected) kVp	Minimum Half Value Layer (mm Al)	Measured HVL
60	2.2	**5.28 mm Al**

Exposure-mAs Linearity

Methodology

The mA/mAs linearity test assesses the unit's linearity over the range of these parameters available on the generator and using all available focal spot sizes. Measurements are performed at a fixed kVp setting and an mR/mAs value is calculated for each exposure. No two adjacent mR/mAs values may differ by more than 0.1 times their sum. The estimated coefficient of variation of the measured output should be no greater than 0.05. This system was tested at 60 kVp.

Results

mAs	Focal Spot Size	Nominal mAs	Displayed Exposure Time (msec)	Measured Exposure Time (msec)	Measured Exposure (mR)	mR/mAs
6.5	Large	6.5	1300.0	1299	2.379	**0.37**
6	Large	6.0	1200.0	1199	2.204	**0.37**
5	Large	5.0	1000.0	999.0	1.853	**0.37**
4	Large	4.0	800.0	799.2	1.398	**0.35**
3.75	Large	3.8	750.0	749.3	1.375	**0.37**
3	Large	3.0	600.0	599.0	1.103	**0.37**
2.5	Large	2.5	500.0	499.2	0.875	**0.35**
2	Large	2.0	400.0	399.1	0.741	**0.37**
1.5	Large	1.5	300.0	299.3	0.548	**0.37**
0.75	Large	0.8	150.0	149.6	0.271	**0.36**

Coefficient of Variation	0.021

Timer Accuracy

Methodology

The accuracy of the unit's timer circuit is determined by taking a number of exposures at different timer settings and comparing actual versus indicated exposure lengths. In general, specifications for timer accuracy are set by the equipment manufacturer, but in no case should the percent difference between indicated and actual time be greater than 10% (or 1 pulse for single-phase units, whichever is greater).

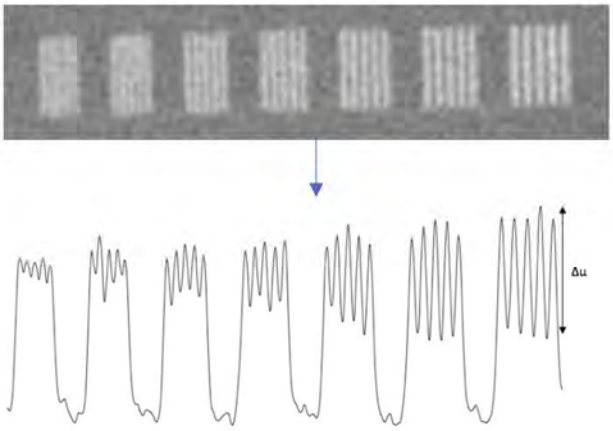
Results

Indicated Time (msec)	Measured Time (msec)	Difference (msec)	Percent Difference
1300.0	1299.0	1.0	**0.1%**
1200.0	1199.0	1.0	**0.1%**
1000.0	999.0	1.0	**0.1%**
800.0	799.2	0.8	**0.1%**
750.0	749.3	0.7	**0.1%**
600.0	599.0	1.0	**0.2%**
500.0	499.2	0.8	**0.2%**
400.0	399.1	0.9	**0.2%**
300.0	299.3	0.7	**0.2%**
150.0	149.6	0.4	**0.3%**

Modulation Transfer Function (MTF)

Methodology

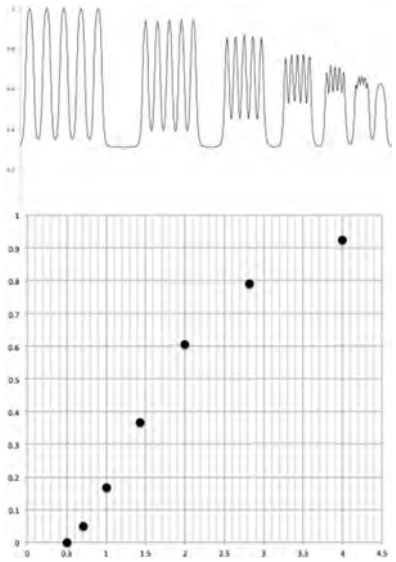
Using a Type 18 Test Phantom, a series of high contrast line pairs were scanned. The profile of each line pair group was plotted, the average peak pixel value and the average low pixel value were compared to the pixel value of the bar material and the background. As the spatial frequency increases the 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. The 60 kVp, 6.5 mAs technique was used in the x-ray tube-up position. The 60 kVp 4.0 mAs technique was used for the x-ray tube down position. The tube down position was tested on a later date, February 9, 2018.



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

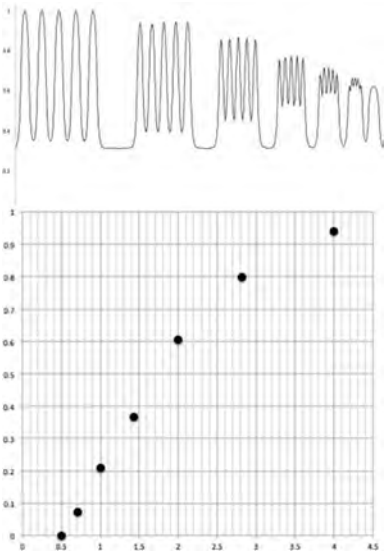
Results

X-ray tube head down:



Limiting Resolution (MTF <0.1)	
Line Pair per mm (lp/cm)	20
mm	1.0

X-ray tube head up:



Limiting Resolution (MTF < 0.1)	
Line Pair per mm (lp/cm)	20
mm	1.0

Z-axis point spread function:

The LineUP 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.

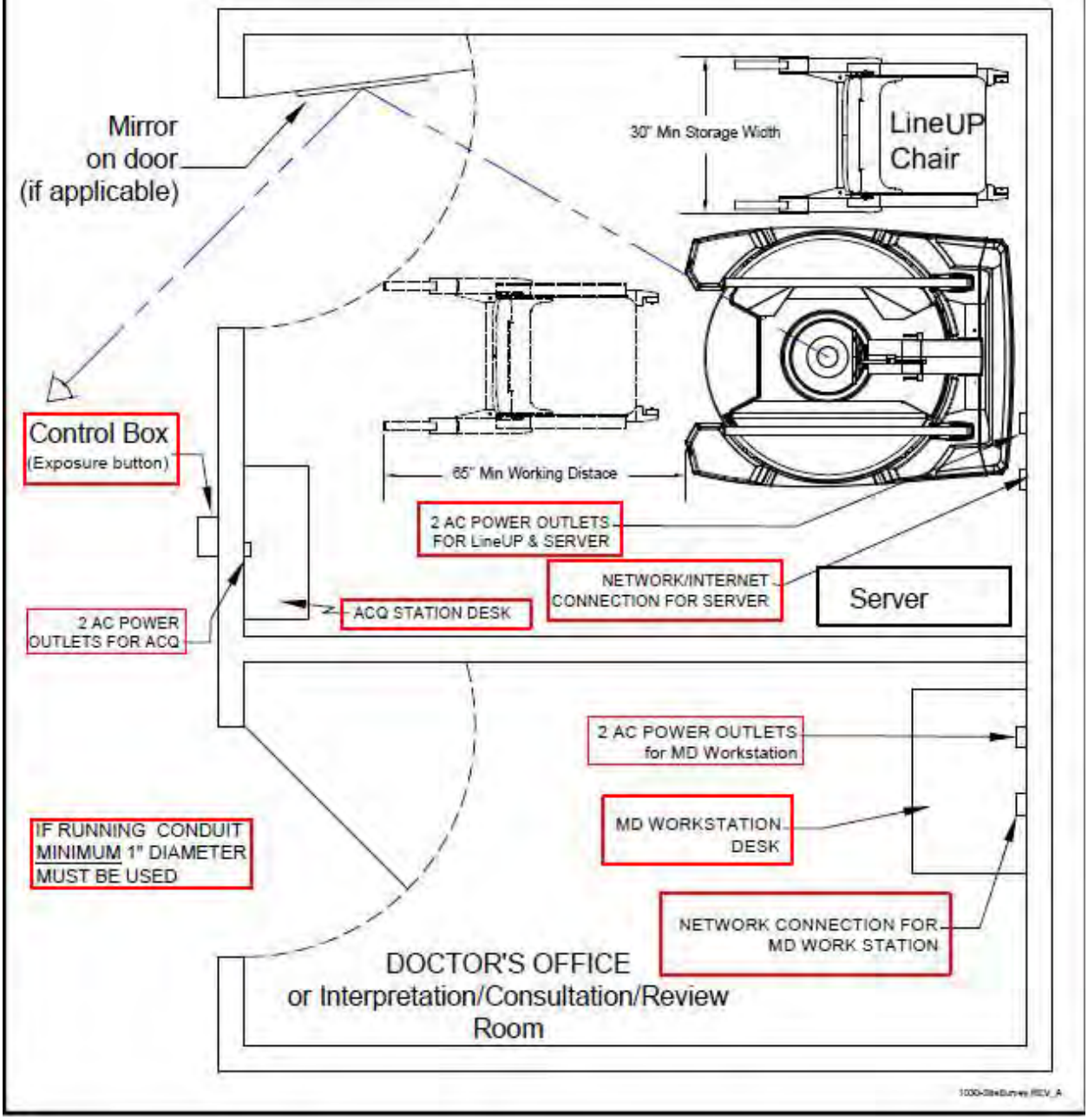
It is recommended that a qualified Physicist or Radiologist determine where appropriate, the applicable lead shielding to be installed in the area around the system equipment. Below are some other common requirements that may apply to your location:

- 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

Site Survey
TYPICAL LineUP LAYOUT

Location of all "red box" items must be defined before installation

Operator to maintain at least 3 meters from unit during scan. Control box to be mounted outside of room. If mounting inside room lead shield must be used. When using lead shield it must be between the operator and unit. A smaller room can be used as long as a shielding plan is developed and recommended by a Physicist.



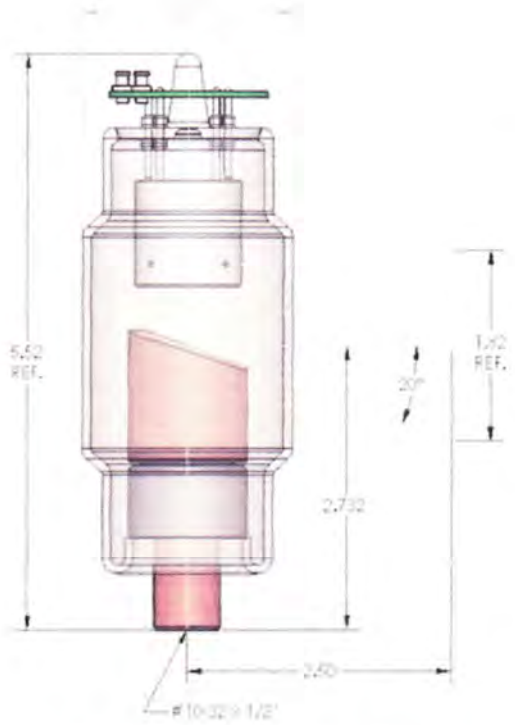
CE 0413

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:

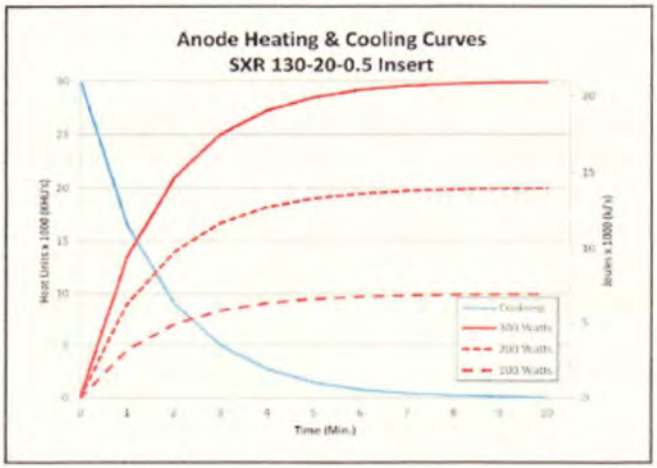
Anode Heat Storage Capacity:	30 KHU's (21KJ)
Max Anode Heat Dissipation Rate:	17.9 KHU's/min.
Duty Cycle:	1:20

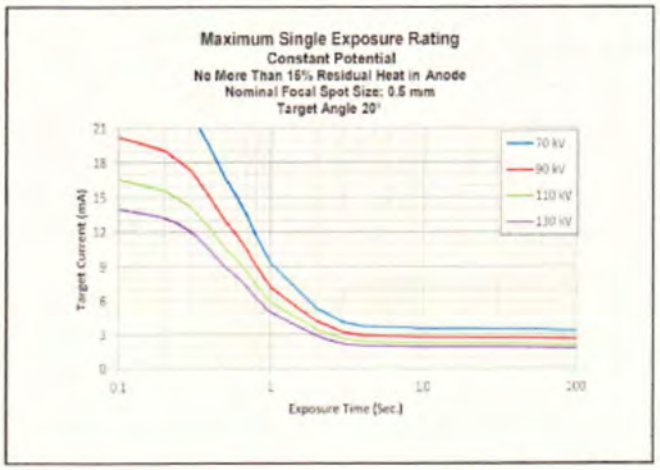
Electrical Characteristics:

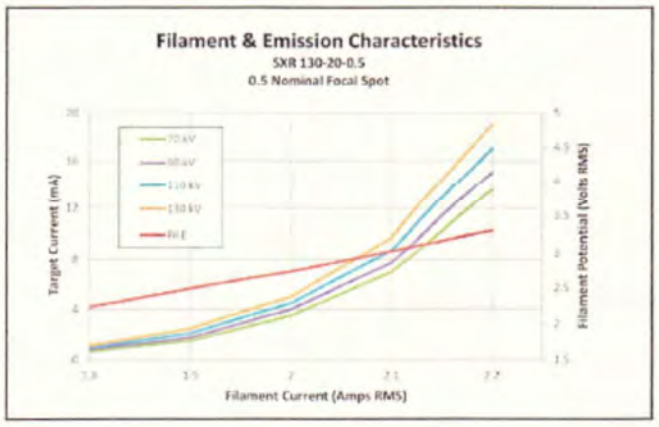
Max. Tube Potential:	130 kV
Filament V-A Curve:	See Chart
Max. Power:	See Chart
Max Single exposure	See Chart
Max. Continuous Exp.	1.8 mA

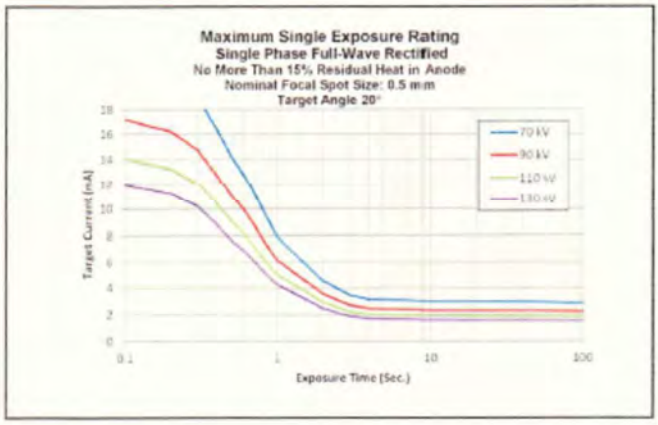
NOTE: * P/ease contact Superior Engineering Department for cathode terminations options.

Half Value Layer (HVL): 10.5mm Al equivalent
No Selectable Filters.
No Shaped Filters.


Anode Heating & Cooling Curves
SXR 130-20-0.5 Insert
Heat Units x 1000 (kHU's)
Joules x 1000 (kJ's)
Time (Min.)
Cooling
300 Watts
200 Watts
100 Watts

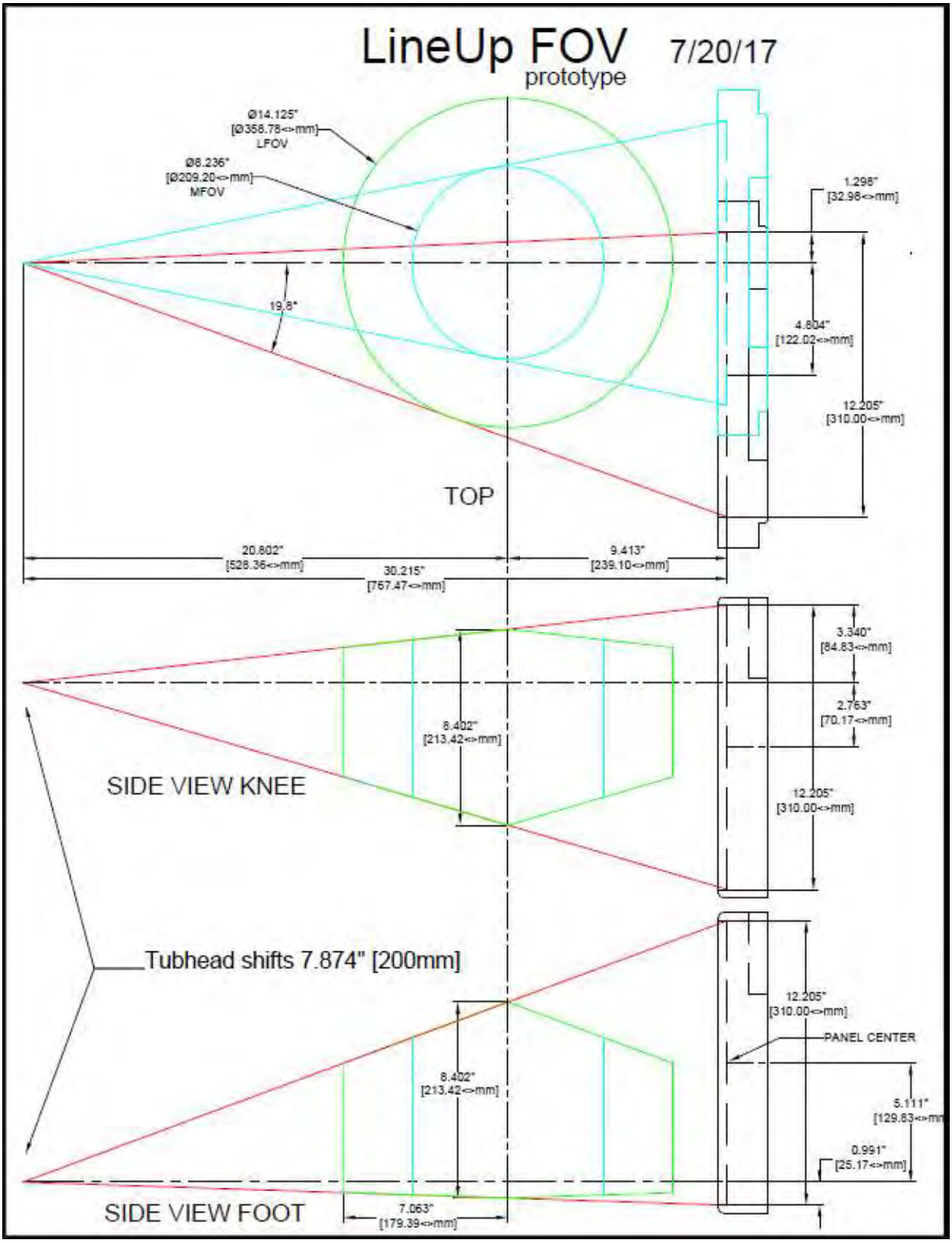

Maximum Single Exposure Rating
Constant Potential
No More Than 15% Residual Heat in Anode
Nominal Focal Spot Size: 0.5 mm
Target Angle 20°
Target Current (mA)
Exposure Time (Sec.)
70 kV
90 kV
110 kV
130 kV


Filament & Emission Characteristics
SXR 130-20-0.5
0.5 Nominal Focal Spot
Target Current (mA)
Filament Potential (Volts RMS)
Filament Current (Amps RMS)


Maximum Single Exposure Rating
Single Phase Full-Wave Rectified
No More Than 15% Residual Heat in Anode
Nominal Focal Spot Size: 0.5 mm
Target Angle 20°
Target Current (mA)
Exposure Time (Sec.)
70 kV
90 kV
110 kV
130 kV

CE 0413

Beam Path and Angulation:



CE 0413

CHAPTER 6: Operations - Acquiring a Scan

ACQUIRING A SCAN

System Startup:

The LineUP 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 left side of the machine. This is the machine ON/OFF control. The vertical line is the ON position. The 0 is the OFF 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.**

Start up the Acquisition software by double clicking on the CB-Scanner Shortcut.

When using the Acquisition software, if an error occurs, the software should be closed and restarted.

If cycling power on the Acquisition software does not clear the error, please contact CurveBeam Technical support at the number listed on the cover of the manual.

Visually inspect the device before use for any damage to the covers that exposes internal components

LineUP Acquisition Software Interface:

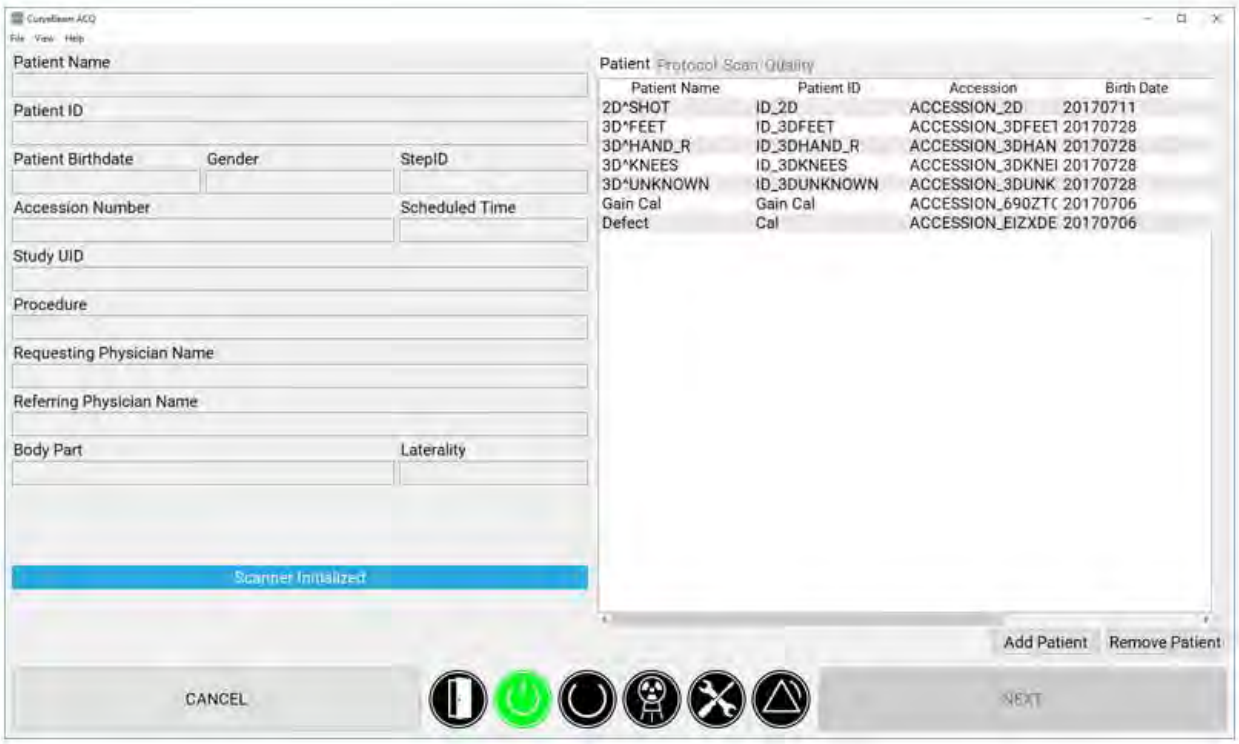
The LineUP Acquisition Software, "CB Scanning Device" Interface consists of the below sections, each with its own tab near the top of the screen:

- Patient List: Access or Add New patient information and intended procedure.
- Protocol: The user will set up scan parameters, such as scan protocol.
- Scan: Perform the Scan Acquisition.
- Quality: Perform a QA (Quality Assurance) check of the scan acquired.

To view the software version that is being run, click on Help, then About.

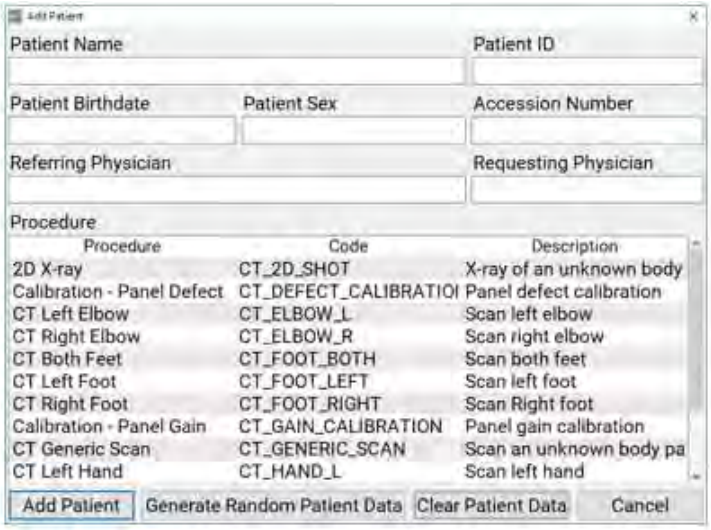
PATIENT LIST: Accessing/Entering Patient Information & Selecting Scan Procedure:

Patient Demographic Information can be either imported into the system via a Worklist or can be Added as a “New Patient” via the LineUP ACQ software Patient Tab when “Add Patient” is selected. The Patient Screen will appear as shown below:



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 for patient information to be added:



On the Add Patient Procedure window, each field must be filled in, along with the selection of a procedure. When selecting a procedure, the user should select from any of the following list:

Procedure Name:	Procedure Code:
2D X-ray	CT_2D_SHOT
CT Left Elbow	CT_ELBOW_L
CT Right Elbow	CT_ELBOW_R
CT Both Feet	CT_FOOT_BOTH
CT Left Foot	CT_FOOT_LEFT
CT Right Foot	CT_FOOT_RIGHT
CT Left Hand	CT_HAND_L
CT Right Hand	CT_HAND_R
CT Both Knees	CT_KNEE_BOTH
CT Left Knee	CT_KNEE_LEFT
CT Right Knee	CT_KNEE_RIGHT

Please note, that any other procedures that may be shown in the list should not be selected by the user.

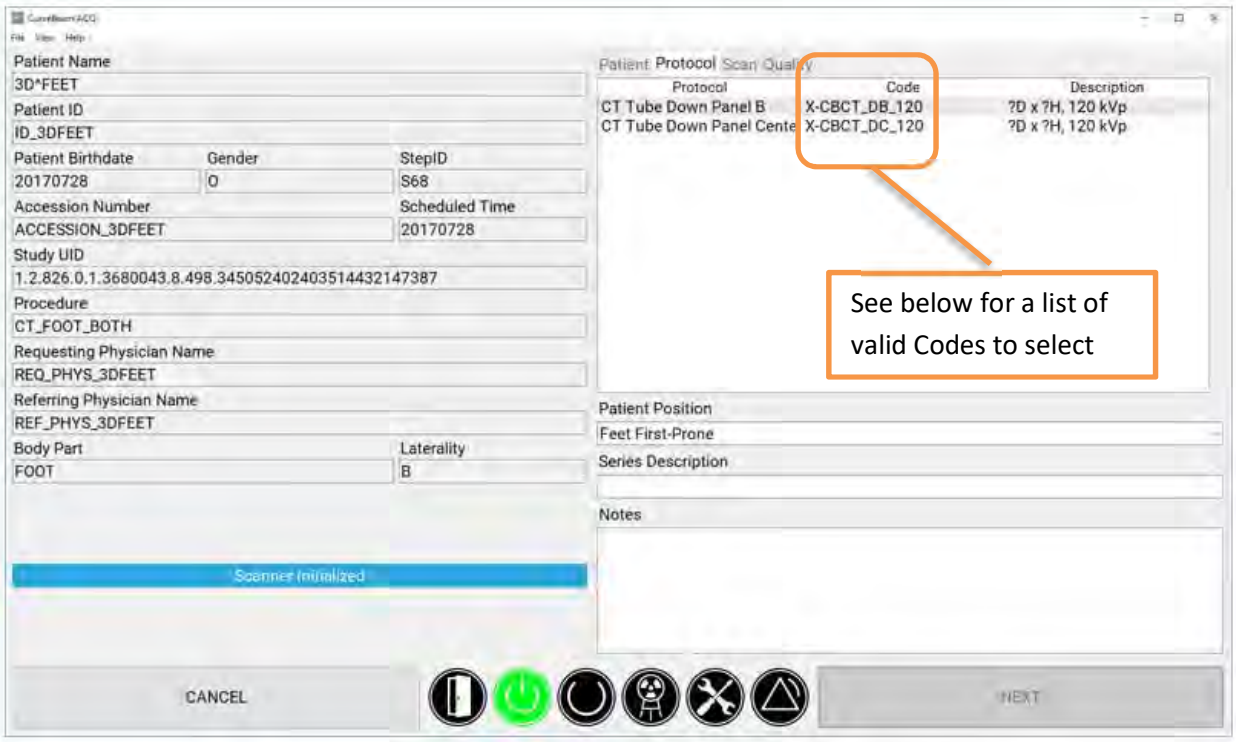
Please note, 2D X-ray procedure is not to be used for pediatric cases.

After all of the fields are entered, select the “Add Patient” button to add the patient to the Worklist.

To select the patient for the scan, highlight on the patient’s line in the Worklist. The patient’s information that was entered will appear on the left side of the screen. Once the patient has

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

PROTOCOL: Selecting the Protocol:



For 2D Procedures, the list of Protocols that can be selected by the user differ based on the anatomy selected, direction of scan, and the size of the patient. Once the anatomy is selected, then select the direction of the scan (PA/AP/Lateral) and either a Standard dose or a Lite dose. Lite dose should be used if the patient size is small (under 100lbs). A complete list of the 2D Protocols can be found in Appendix III – Scan Protocol Technical Details.

For the 3D Procedures, the list of Protocols that can be selected by the user is as follows:

X-CBCT_DB_100
X-CBCT_DB_120
X-CBCT_DC_100
X-CBCT_DC_120
X-CBCT_UAL_100
X-CBCT_UAL_120
X-CBCT_UC_100
X-CBCT_UC_120

The 3D Protocols are a combination of one of the two tube head positions, field of view size, and the kVp. Tube head position is based on the anatomy being scanned and can not be altered by the user once the desired anatomy to scan is selected.

RECOMMENDATIONS for Selecting a Protocol: There are at most 4 CT Protocols from which to select for each of the 3D procedures. The options available will vary based on the Procedure selected. They can have the following attributes:

Medium Field Standard(120kVp): (20 cm diameter x 20 cm height, 0.3 voxel):
Select this option if the patient size is normal-large (100lbs or larger), and if you need to capture only one foot or a partial area of interest for one foot, hand, or elbow
The Medium Field 120kVp scan codes are either "X-CBCT_DC_120" or "X-CBCT_UC_120" as their protocol code.

Large Field Standard(120kVp): (35 cm diameter x 20 cm height, 0.3 voxel):
Select this option if the patient size is normal-large (100lbs or larger), and if you need to capture both feet or both knees in a scan
The Large Field 120kVp scan codes are either "X-CBCT_DB_120" or "X-CBCT_UAL_120" as their protocol code.

Medium Field Lite (100kVp): (20 cm diameter x 20 cm height, 0.3voxel):
Select this option if the patient size is small (under 100lbs), and if you need to capture only one foot or a partial area of interest or a hand or elbow.
The Medium Field 100kVp scan codes are either "X-CBCT_DC_100" or "X-CBCT_UC_100" as their protocol code.

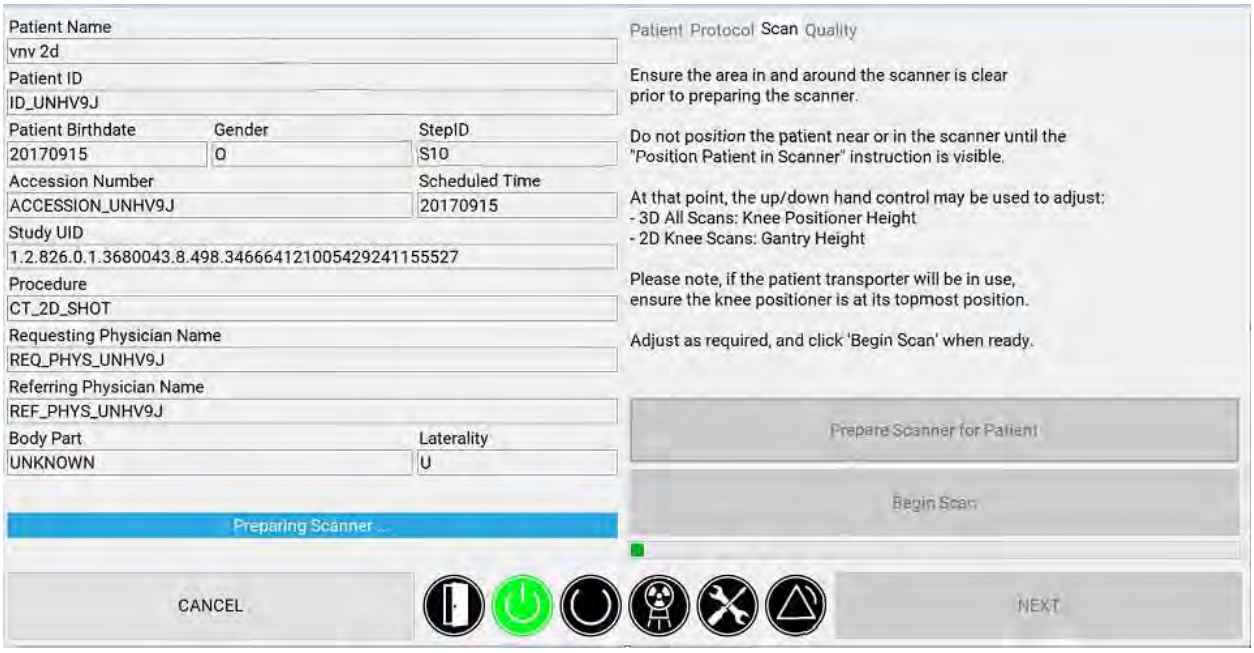
Large Field Lite(100kVp): (35 cm diameter x 20 cm height, 0.3 voxel):
Select this option if the patient size is small (under 100lbs), and if you need to capture both feet or both knees in the scan.
The Large Field 100kVp scan codes are either "X-CBCT_DB_100" or "X-CBCT_UAL_100" as their protocol code.

WARNING The patient must wear a protective full wrap X-ray shielding apron (lead apron) during a scan. Patients less than 21 years old, small size patients (under 100 pounds) and children must also wear a gonad and ovarian front and back protective shield.

Once the Protocol is highlighted, the "Next" button will become non-gray. Click "Next" when the protocol is correct for the patient being scanned to continue with the Acquisition process.

SCAN: 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:



Wait for the “Prepare Scanner for Patient” button to become active. When it is active, select it. The system will make adjustments based on the selected scan. Once the scanner has been set up, then it is time to position the patient in the scanner. Watch for the instruction to position the patient in the blue box on the left side. When instructed to position the patient, use the instructions shown below.

Patient Positioning:

Before positioning the patient in the machine, remove his/her shoes/socks for a foot scan. We recommend the patient not step bare foot on the patient platform. Proper foot protection should be provided.

For a foot scan, if patient has any jewelry on their toes or ankles, that should be removed.

For a hand scan, if patient has any jewelry on their fingers or wrists, that should be removed.

Have the patient put on FDA approved medical gloves and foot protection as recommended in Ch. 3 Safety Items, Patient Preparation Recommendations section.

Drape the patient with protective shielding for the procedure as recommended in Ch. 3 Safety Items, Radiation Safety section.

The patient will now need to be positioned in the machine. The Patient Door to the machine should now be in OPEN position in order for the patient to step in.
*Be sure to position your patient before clicking the “Begin Scan” button.

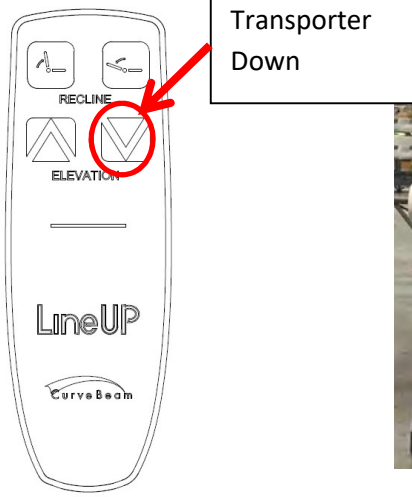
3D Positioning

Patient Positioning: Foot/ Feet

For a foot/feet scan, the patient can be seated (non-weight bearing) or standing (weight-bearing).

<u>Non-Weight Bearing Foot/Feet Scan – Utilizing Multi-Extremity Chair:</u>

For a Seated Multi-Extremity Chair scan, the operator should lower the Multi-Extremity Chair to the lowest position using the Multi-Extremity Chair height control and then assist the patient into the Multi-Extremity Chair.

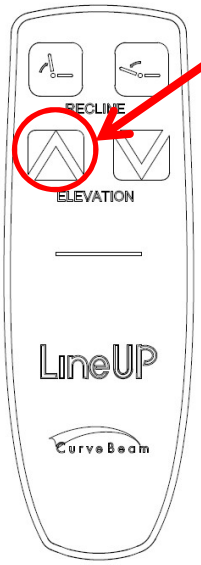


Move Transporter Down

Transporter Lowest Position

Patient Seated in Lowest Transporter Position

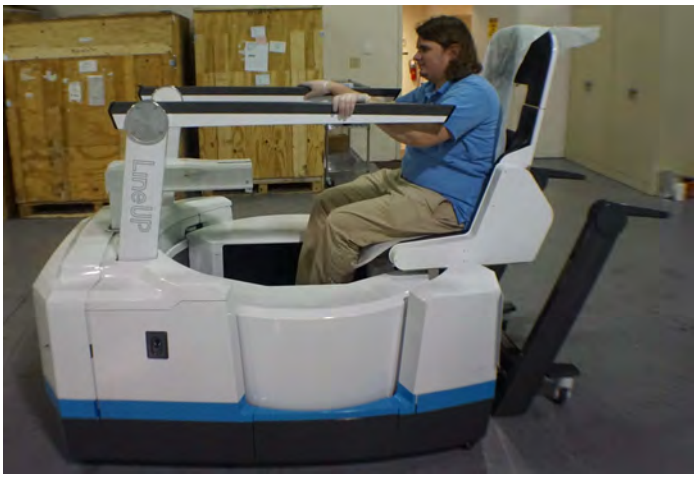
When the patient is comfortably seated, lift the Multi-Extremity Chair and patient to the highest position.



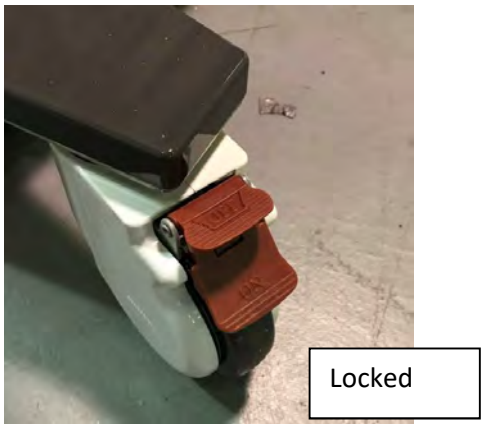
Move Transporter Up

Patient Seated in highest Transporter Position

Steer the Multi-Extremity Chair into the scanning device.



Once the patient is positioned in the machine, lock the Multi-Extremity Chair wheels.



For a standing scan, if the patient needs help getting into the scanning device, use the steps listed above. Once the Multi-Extremity Chair is positioned in the device, the patient can use the handle bars to provide support while standing up. If patient does not need help getting into the device, he may simply step into the opening.

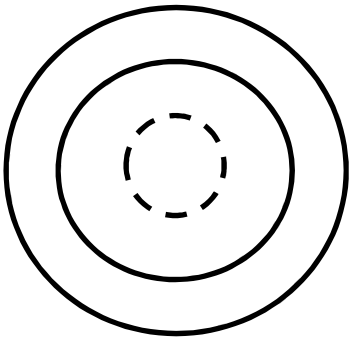
Non-Weight Bearing Foot/Feet Scan – Utilizing Patient Bench:

For a non-weight bearing scan utilizing the Patient Bench, the operator should first assist the patient into the scanner. Instruct the patient to hold the handle bars for stability. Then have the patient turn around to face the entry/exit of the machine. The operator will need to roll the Patient Bench into the scanner until it is fully inserted in the scanner opening. At that point, assist the patient to turn around. Operator should then stabilize the Patient Bench while instructing the patient to sit on the Patient Bench. Patient should be instructed to hold the handle bars as shown below:

Positioning the Foot/Feet:

Circular Positioning Guides:

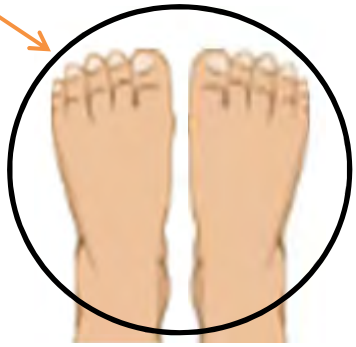
These guides on the patient platform are intended to assist the operator in positioning the patient's feet/foot into the field of view.



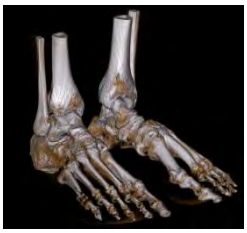
The most outer circle is for the Full one or two feet procedure option (35 cm diameter). This is for a scan that includes one whole foot or both feet.

One or both feet should be positioned within this circle in order to capture both.

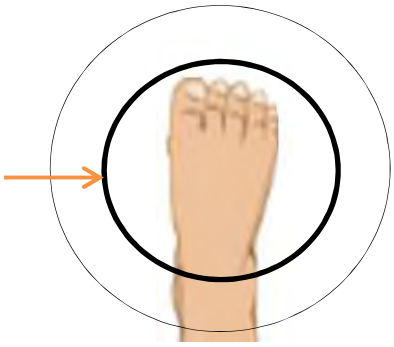
Positioning Illustrations are intended for Training purposes only.



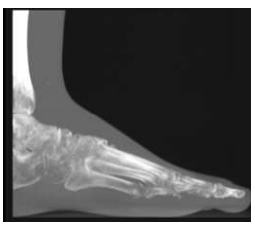
Sample Results of Full both feet Field of View

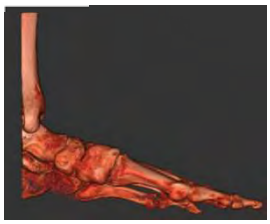


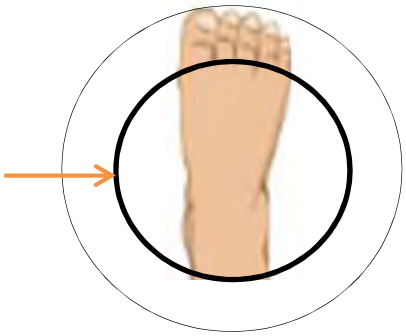
The second circle is for the Partial Single Scan option (20 cm diameter). This is for capturing one foot or a partial scan of one foot only. The area of interest for the scan should be positioned within this circle in order to capture it. So if you require the forefoot, then ensure that it is within the inner circle, however the hindfoot may not fit and would not be included in the scan (and vice versa). Smaller foot sizes may capture from Fore to Hindfoot.



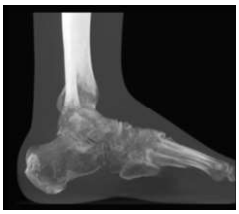
Sample Results of Partial Single Foot Diameter Scan Field of View, Forefoot

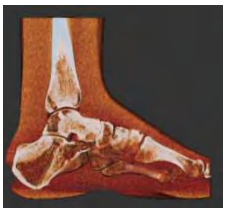






Sample Results of Partial Single Foot Diameter Scan Field of View, Hindfoot



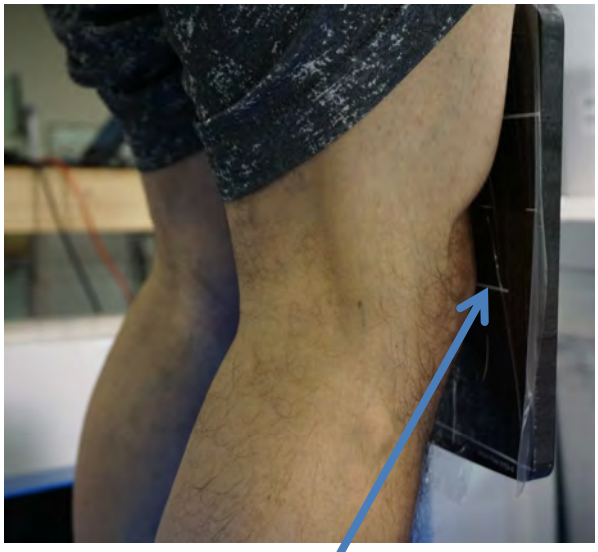


Patient Positioning: Knee

Knee Scans must be bilateral. Help the patient into the Multi-Extremity Chair using the steps described above or allow the patient to simple walk into the machine.

Use the knee positioner control to position the knee platform to a height the knees are aligned with the “X-Ray beam center” line. All anatomy inside the outer white lines will be imaged.

Move knee positioner up and down using vertical position control. DO NOT move knee positioner while patient’s knees are contacting it.



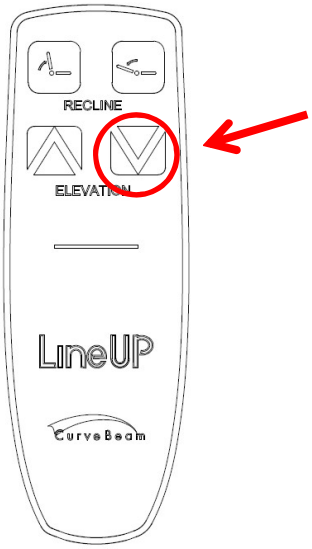
X-Ray Beam Center Line

Knees should be slightly bent, resting against the knee platform.

Patient Positioning: 3D Hand and Elbow
Position the Hand and Elbow platform in the scanning device.

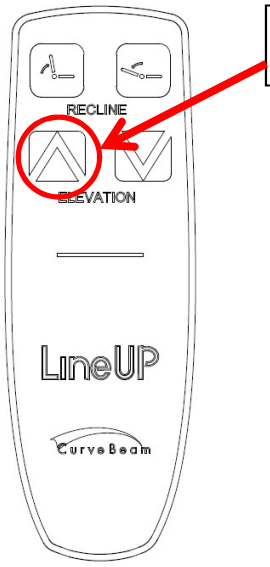
Rotate Multi-Extremity Chair to the position shown below:

Move Multi-Extremity Chair to lowest position



Transporter Lowest Position

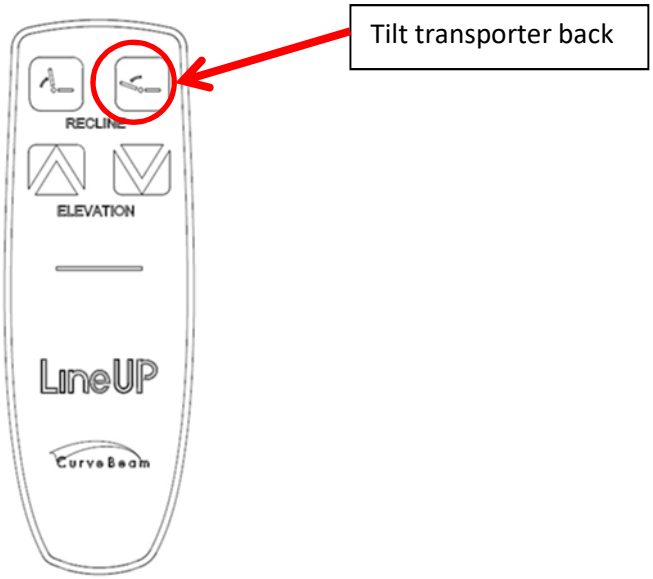
When the patient is comfortably seated, lift the Multi-Extremity Chair and patient to the highest position.

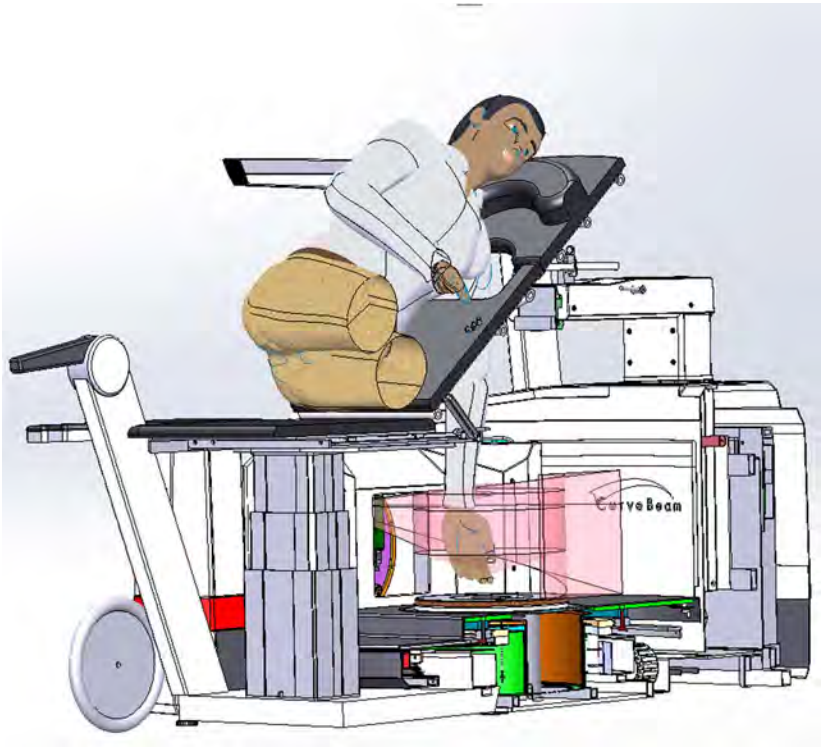


Move Transporter Up

Patient Seated in highest Transporter Position

Raise the Knee Positioner to its highest position. Then slide the Multi-Extremity Chair with patient into the LineUP scanner. Tilt the chair back to allow the patient extremity to be placed in the field of view outlined on the Hand and Elbow platform.

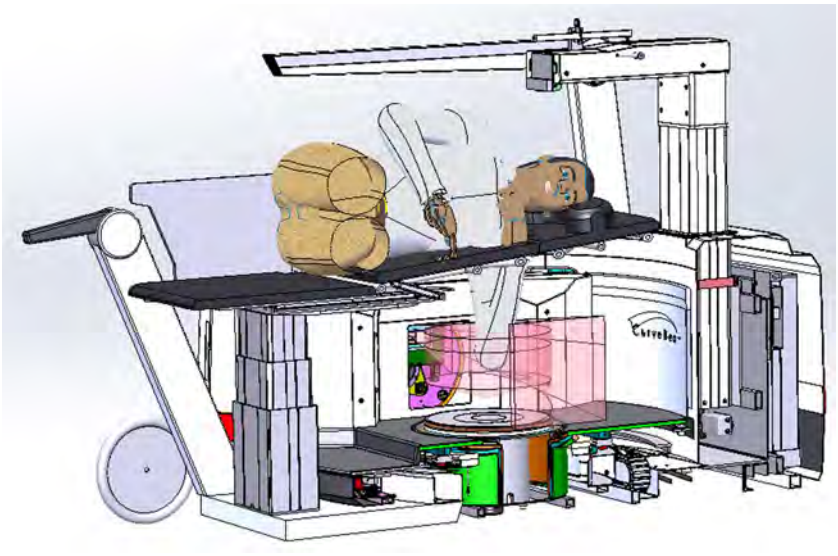




Multi-Extremity Chair tilted to hand position

Hand Scans – Small Patients

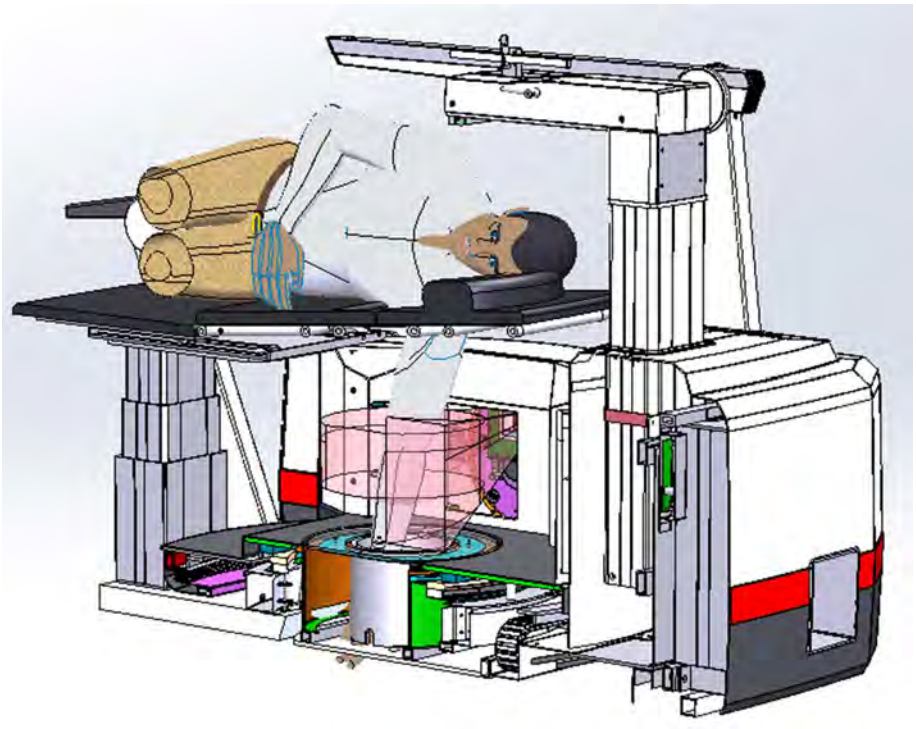
For small patients it is imperative that the hand and arm are only inserted into the machine just to get the area to be scanned. Ensure the arm is not fully into the machine beyond the anatomy of interest, to reduce unnecessary exposure. Also ensure the shielding is fully wrapped around their arm.



Multi-Extremity Chair tilted to bent elbow position

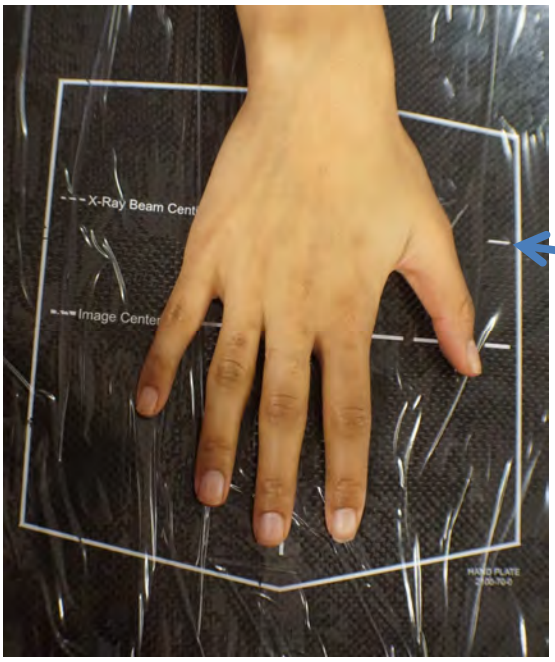
Elbow Scans – Small Patients

For small patients it is imperative 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.



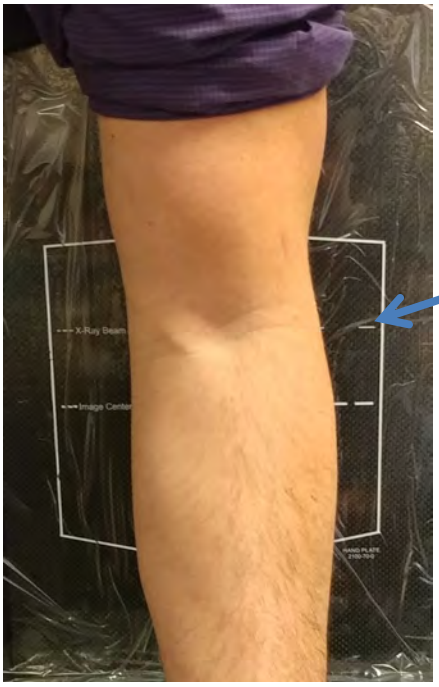
Multi-Extremity Chair tilted to straight elbow position

Position the area of interest along the “X-Ray Beam Center” line of the Hand and Elbow platform. All anatomy inside the outer white trapezoid will be imaged.



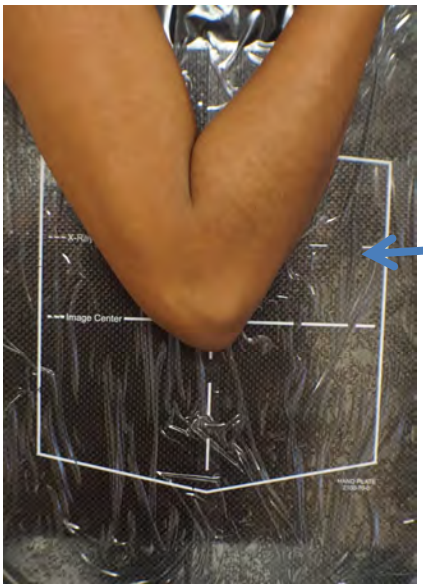
X-Ray Beam Center Line

Hand CT scan



X-Ray Beam Center Line

Straight Elbow CT Scan

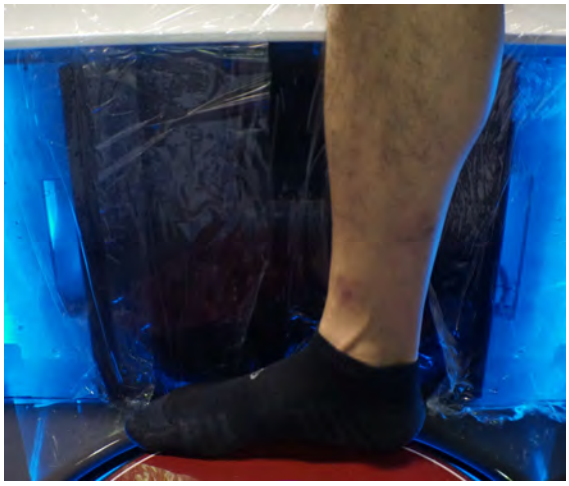


Bent Elbow CT Scan

2D Positioning

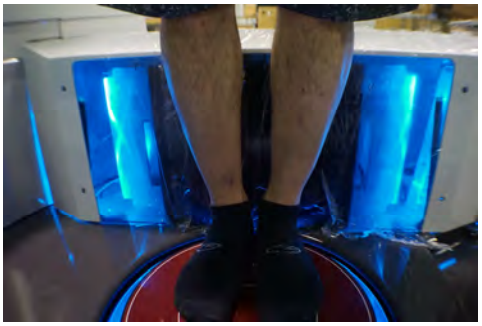
Weight-bearing Lateral Foot

Position the image foot against the detector and position the other foot in front or behind, not in the path of the detector.



Note: Circular marking lines are not used for 2D positioning. Anatomy should be positioned next to detector inside detector area.

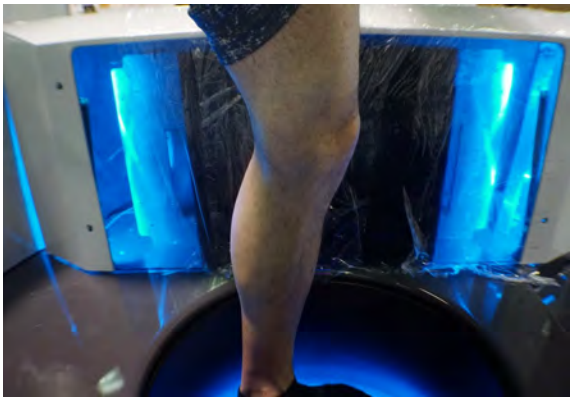
Weight-bearing AP/PA Feet



Position Both Feet against the Detector

Note: Circular marking lines are not used for 2D positioning. Anatomy should be positioned next to detector inside detector area.

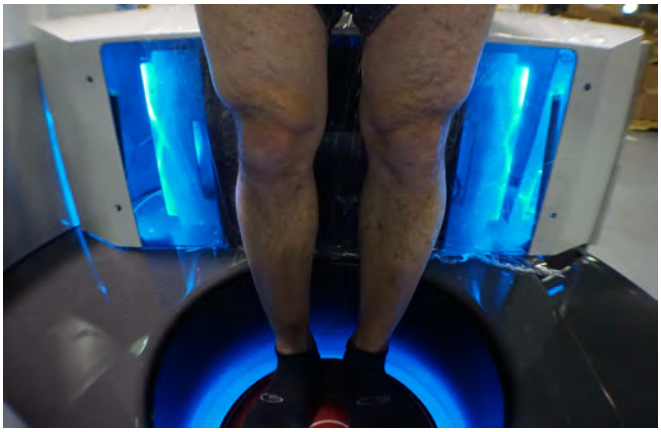
Weight-bearing Lateral Knee

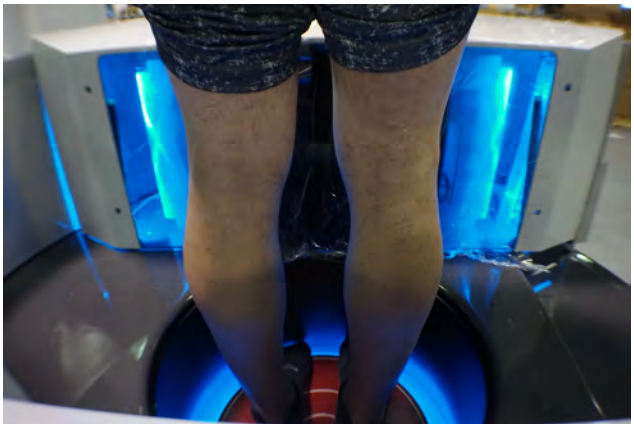


Raise gantry so that knee is slightly above vertical center of detector. Position knee on horizontal center of detector. Place other leg in front or behind, outside of the path of the detector.

Weight-bearing AP/PA Knees

Raise gantry so that knees are slightly above vertical center of detector. Position front or back of knees against detector.





2D Hand

Multi-Extremity Chair can be used as with a 3D Hand scan and pulled out of the machine slightly to position hand against detector with area of interest slightly above center crosshair.

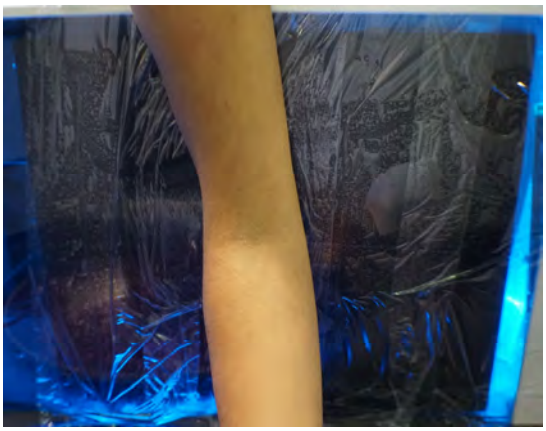
AP Position:

Lateral Position:

2D Elbow

Multi-Extremity Chair can be used as with a 3D Elbow scan and pulled out of the machine slightly to position elbow against detector with area of interest slightly above center crosshair.

AP Position:



Lateral Position:

Close the Patient Gate once patient is properly positioned.

> ⚠**WARNING** Closing of the Patient Gate creates a pinch point. Keep hands and feet clear when closing Patient Gate

Next, a message will appear on screen instructing the operator to: “Press and HOLD Scan button”.

> ⚠**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.

1. Deliver the Patient Scan Instructions to the patient.

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

2. 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 LineUP Acquisition “CB Scanning Device” software. The Operator should hold the exposure switch for the duration of the exposure as indicated by sound and lights.

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

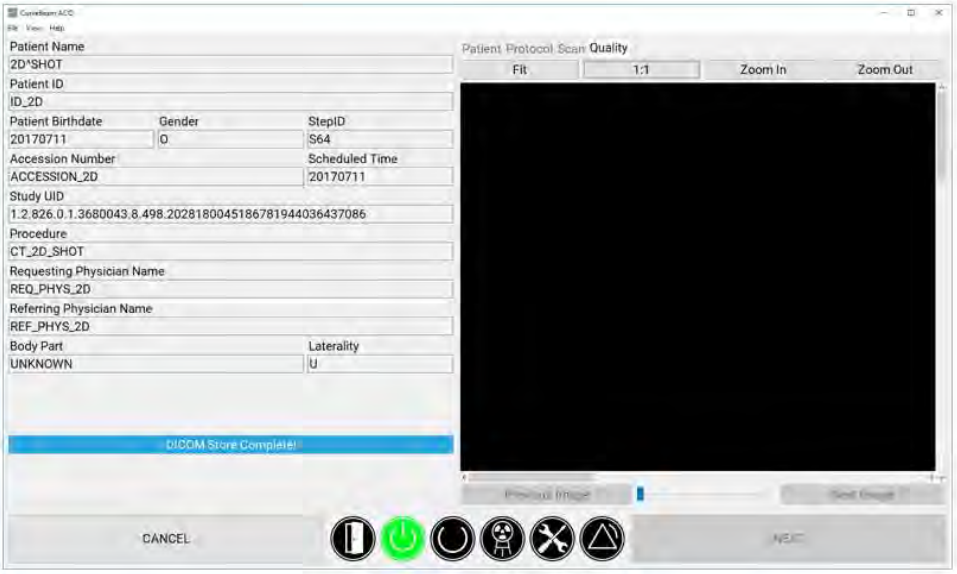
   NOTE: If the exposure switch is released before the exposure time has completed, the system will STOP exposing, however the gantry and motors will complete their sequence. If the button is released prematurely, the buzzer and indicator lights will turn off and an Error message will display on screen.

   Emergency Stop: In the event of an emergency during a procedure (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 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 on the machine. The Emergency Stop(s) when activated will remove ALL power from the machine.

4. Once the capture is complete, the Patient Door should be opened. The patient can now safely EXIT the machine.
    - If the patient is Standing, he/she should turn around while still on the platform, using the handle bars for support and step forward out of the machine.
    - If the patient is Sitting, carefully back the Multi-Extremity Chair out of the machine. Then assist the patient out of the Multi-Extremity Chair.

5. When the Next button becomes visible, click on it.

6. Once on the Quality screen, wait for all of the QA images to be present. Initially the QA screen will appear as in the following image.



7. While waiting for the image to finish processing, check for movement of the patient during the scan, compare the first and last frames. View all images as they were acquired by using the slider below the raw frames.

8. Once certain the image looks like the anatomy desired was done so acceptably, click on the Exit button and the software will close.

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.

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. An error message will appear in the Acquisition software.

2. If the path into the machine is blocked by the gantry, manually rotate the gantry so that the patient entrance (side with the small step down) is at the front of the scanner.

If Multi-Extremity Chair is NOT being used:

3. If the Gantry is raised, allow it to slowly lower, or assist the gantry down. If needed, press down on the small step the patient uses to enter and exit the machine.

4. Once the gantry is fully back to the starting position (gantry is down, step is at the front of the machine), carefully assist the patient to step out of the platform area.

If Multi-Extremity Chair IS being used:

3. Instruct the patient to place their hands in their lap and pull the transporter back out of the machine.

4. Assist the patient out of the Multi-Extremity Chair.

5. Reset the machine: Close the Acquisition 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 Acquisition software. Now the system can be operated again as expected.

Turning the System Off:

To safely turn off the LineUP scanner, first close the Acquisition software. Then turn off the LineUP Scanner by using the circuit breaker switch that is located on the back left side of the machine. This is the machine ON/OFF control. The vertical line is the ON position. The 0 is the OFF position.

Viewing the Images:

Image processing is done using iterative reconstruction of raw projections. Once the image is processed it is then formatted using the DICOM-3 file format. With this format, the image can then be viewed using a DICOM viewer. Both CT and x-ray images can be obtained from the scanner by setting up standard DICOM protocols for retrieving images from the DICOM storage device using the systems AETitle and Port.

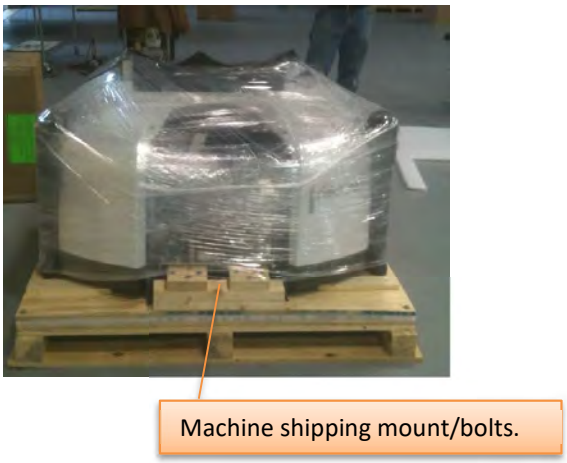
APPENDIX I: LineUP Installation Instructions

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.

Installation of LineUP should only be performed by qualified CurveBeam personnel.

The LineUP Machine will be skidded or crated and shrink wrapped for shipment. The crates should remain upright as instructed on the crates. Please inspect all components and advise CurveBeam of any damage to the crates or items within the crates upon delivery.

The skids will contain:
1. The machine itself.
2. External Server
3. 2 Handle Bars
4. 4 boxes containing a thin client terminal, PC, medical grade monitor, control box, cables, phantoms, carbon fiber platform plate, accessories.
5. Multi-Extremity Chair



1. <u>De-skidding the machine:</u>

The machine first needs to be unbolted from the skid. The shipping mount/bolts are in the front of the machine. Then, the rear cover should be removed before attempting to slide the machine off the crate or else it will be damaged. Once the rear cover is removed, the back of the unit should be slid to the edge of the skid so the 2 rear wheels are hanging off the edge, then lift the unit upright. It will slide down the edge of the skid on to the wheels.

The Unit should be lift gated to ground (onto a dolly if necessary) or by the wheels and rolled into the facility in the upright position:

2. Remove Shipping clamps, ties & screws:

Once the machine is in the area of placement, perform the following:

This Clamp should first be removed:

The underside of the machine has 2 securing cable ties on each side under each door motor which lock down the doors for shipping. And the top of the machine has securing cable ties to help keep the gantry secure. These all must be snipped and carefully removed.

Then the 4 Gantry Clamp Shipping screws can now be removed. These secure the gantry during shipment. They are at the base of the gantry.

3. The back Power Panel has been placed in a “Shipping” position to secure during shipping. This needs to be adjusted to its operational position. Remove the top 2 screws. The remaining 2 mounting screws are stored below the panel.

Once the 2 screws are removed, pull the Power Panel out to its operational position and secure into place with the 4 mounting screws.

4. At the location of placement, set the machine down on its base.
   - If being placed with the rear to the wall, be sure to leave some room in the back in order to plug in all cables and for securing the rear cover before placing the machine into its final spot. The final spot should allow for ease of connection and disconnection.
   - There are a total of 4 adjustment "feet" to the machine, one at each corner. There is also a center foot that has no adjustment. The machine should sit on the center foot and lean back onto the 2 back feet. The 2 front feet should not yet be touching the floor at this time. They will be adjusted once the machine leveling is complete.

5. Attach all cables and cords to the back of the machine:
   a. Machine power cord
   b. Operator's control box
   c. Door interlock connector
   d. X-ray warning connector
   e. 2 CAT 6 ethernet cables that feed to the server. One will be labeled Red for the Red cable and one will be labeled Green for the Green cable.

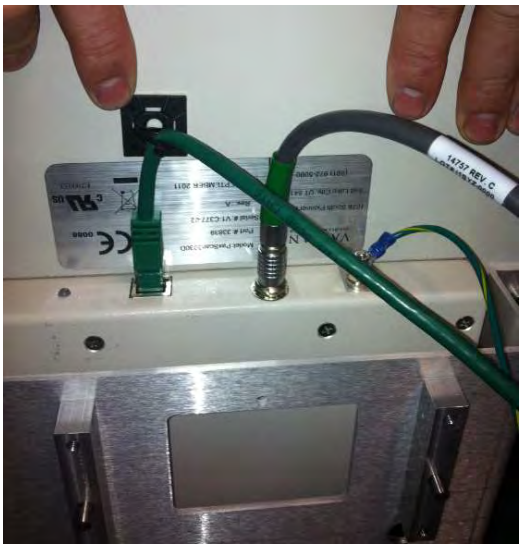
6. Check All connections on boards, circuits etc in the system. Ensure that all are seated.

7. Mount the Receptor Panel:

a. There are 3 cables to be attached.

- CAT6 cable (cable tie this cable to the black clip to maintain security).
- Power cable
- Ground cable

b. The Ground nut should be removed from its location, then attach the ground cable and re-attach the Ground nut.



c. Attach the Panel with 4 Plate screws.

- The Load position of the panel is in the Gantry “B” position, which is centered.
- Begin by securing the first 2 screws (vertically) and then manually move the panel to the Gantry Home position, which is rotated to the right, with your hands and secure the other 2 screws (vertically).

d. Check for Level of the Panel when mounting.
e. Check for Pivot of the Panel when mounting. The pivot may need to be fine tuned during the panel alignment procedure that will be completed at completion of installation. If the pivot requires adjustment, use the pivot adjustment screws on the panel mount.

8. <u>Mount the X-Ray tube head:</u> There is only one twist lock connector and 4 screws for mounting.

9. Mount the Patient Handle Bars:
    - There are 2 bars, each is mounted with 2 Screws.
    - Each bar has a Ground cable that needs to be attached to the ground screw.

10. Level the Patient Platform:
    - Before leveling the platform, be sure to verify that the platform/gantry is stabilized. This can be checked by pulling & pushing the gantry towards & away from the center of rotation, there should be no play. If there is play, you must tighten the screw underneath. The patient platform must be removed to get to this screw.
    - The machine should be leveled for left/right and front/back. Place a level on the patient platform area without the plastic platform plate in place.
    - Adjust each of the 2 back feet up and/or down to achieve level.
    - Once level is achieved, adjust the 2 front feet down to the ground for support.

11. 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.

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.

12. Turn the Power to the machine ON from the Main Circuit Breaker on the left side of the scanner, towards the back of the machine. This is the only ON button for the machine. ON position = I, OFF position = 0.

13. 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.

14. Once connected to the ACQ Desktop, launch the ACQ "CB Scanning Device" software from the icon. Verify StartUp/Initialization has completed.

    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.

15. 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.

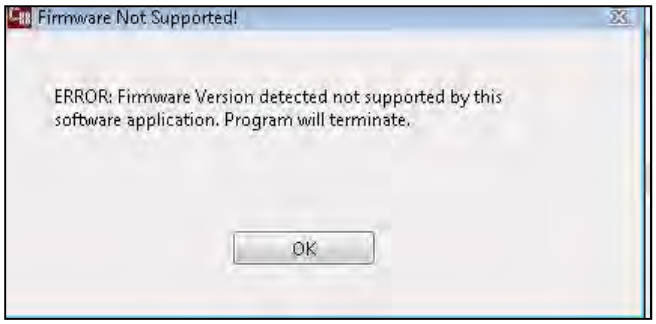
16. Follow ALL Calibration QA procedures outlined in **Chapter 4** of this manual. INSTALLATION is NOT COMPLETE until all these procedures are successfully completed.

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.



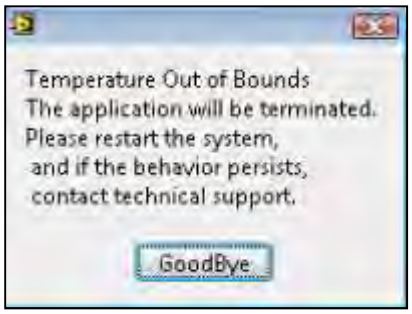
Temperature Monitoring Warnings: The system is designed to send a Warning message to the user if the internal temperature of the machine is below 35° C or above 45° C. This Warning would display in the "CB Scanning Device" Acquisition software at Startup and just before a scan is captured. If the temperature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

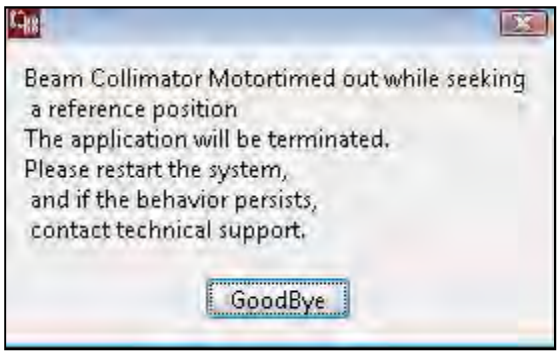
Temperature Monitoring Failures: The system is designed to send a Failure message to the user if the internal temperature of the machine is 20° C or lower OR 60° C or higher. This Failure message would display in the “CB Scanning Device” Acquisition software at Startup and just before a scan is captured.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

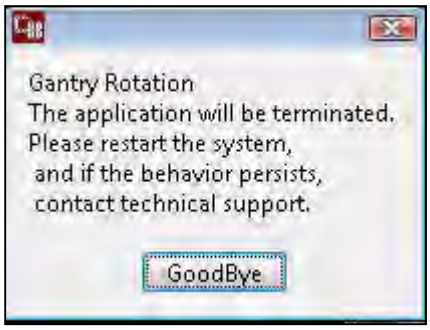


Beam Collimator Mechanism Failure: The beam collimator is a motorized mechanism which select position dependent on the scan procedure selected**.** An error message will display if there are any issues with the motor, such as a stall or jam, or switches that control the movement of the beam collimator mechanism. This message can display at Startup screen or in the Procedure Tab as the system sets up for the scan.

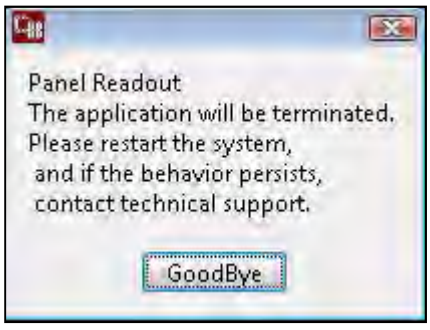


Panel Position Mechanism Failure: The Panel Position Mechanism is a motorized mechanism which selects its position dependent on the scan procedure selected**.** An error message will display if there are any issues with the motor, such as a stall or jam, or switches that control the movement of the Panel 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.

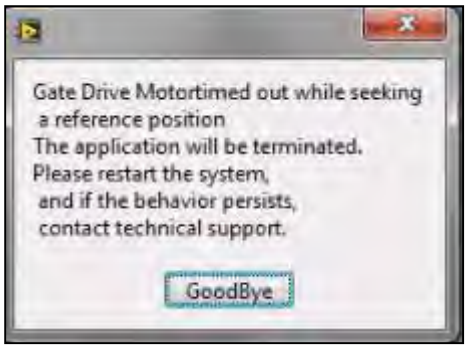


An error in Gantry Rotation *during a scan* would result in a communication error of the receptor panel to the server, so if this even occurs, the following Panel Readout error message would display:

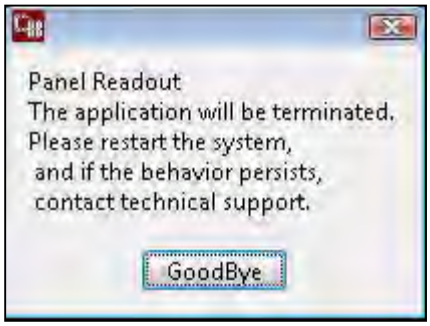


Gate Drive Mechanism Failure: The Gate Drive Mechanism is a motorized mechanism which opens and closes each door at the appropriate times**.** An error message will display if there are any issues with the motors, such as a stall or jam, or switches that control the movement of the

Gate mechanism. This message can display at Startup screen or in the Procedure Tab as the system sets up for the scan.

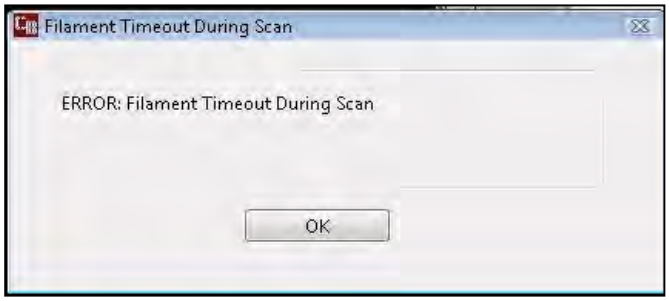


Panel Read Out Error Message: If any communication failure occurs before or during a scan between the receptor panel and the server, then a Panel Readout Error will display on Screen. Communication errors could occur if the cable is not plugged in or seated correctly or has suffered some damage, or if the panel does not properly produce frames. The “CB Scanning Device” Acquisition software will terminate. Check cables and Restart the system.



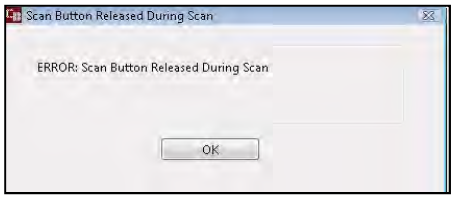
Communication Error between the Firmware and the Server: If there is any loss of communication between the embedded controller firmware, the following error message will display on screen. Loss of communication can be caused by a damaged, unplugged or loose embedded controller cable, or when the Emergency 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.



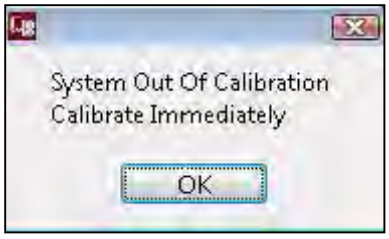
Scan Button Released Error Message: If the operator releases the scan button BEFORE completion of an exposure, the X-ray will turn off and the below error message will display notifying the user of the error.

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.



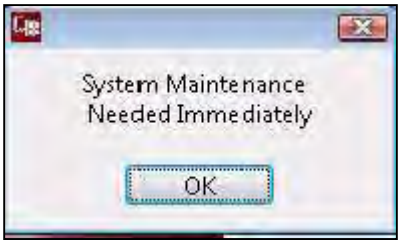
Calibration Checks and Services Warnings: The system calls for monthly Panel Calibrations and checks of certain control functions as outlined in this manual. A monthly Warning message will appear that will indicate that it is time for these checks.

The Warning message reads:



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:



APPENDIX III: Scan Protocol Technical Details

LineUP Study Type:	Foot, Knee, Hand, and Elbow Cone Beam CT and Foot, Knee, Hand, and Elbow X-Ray
Scan Positions/Orientations:	Weight Bearing (standing), Seated (partial or non weight bearing)
CT Scanner make and model:	CurveBeam LineUP
Maximum # of Slices per acquisition:	N/A: System is Volume Cone Beam CT

LineUP has 8 CT Scan Protocol options, which are divided up in the table below, based on the Field of View and kVp values. The description of the Protocols is as follows:

Acquisition series (include all) (i.e., axial, helical)	**Medium Field** **100 kVp** **(lite patient)**	**Medium Field** **120 kVp**	**Large Field** **100 kVp** **(lite patient)**	**Large Field** **120 kVp**
Protocol Codes	X-CBCT_DC_100 X-CBCT_UC_100	X-CBCT_DC_120 X-CBCT_UC_120	X-CBCT_DB_100 X-CBCT_UAL_100	X-CBCT_DB_120 X-CBCT_UAL_120
kVp/mA and rotation time or kVp/mAs	kVp = 100 mA = 5 mAs = 28.8 Rotation time = 23 seconds	kVp = 120 mA = 5 mAs = 28.8 Rotation time = 23 seconds	kVp = 100 mA = 5 mAs = 43.2 Rotation time = 26 seconds	kVp = 120 mA = 5 mAs = 43.2 Rotation time = 26 seconds
CTDI (vol) required (if on system)	1.163 mGy	2.014 mGy	1.73 mGy	2.717 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 = 5.214 dGy*cm^2	Dose Area Product = 8.674 dGy*cm^2	Dose Area Product = 9.437 dGy*cm^2	Dose Area Product = 15.01 dGy*cm^2

Tube current modulation or dose reduction technique (is used)	12 millisecond pulsed. 480 pulses/scan	12 millisecond pulsed. 480 pulses/scan	12 millisecond pulsed. 720 pulses/scan	12 millisecond pulsed. 720 pulses/scan
Anatomical Scan range **(i.e., dome of liver thru pubic symphysis)**	- L or R midfoot - L or R midfoot & forefoot - L or R hand or elbow	- L or R midfoot - L or R midfoot & forefoot - L or R hand or elbow	- L or R entire foot - Bilateral feet - Bilateral knees	- L or R entire foot - Bilateral feet - Bilateral knees
Increment (space between slices)	0 mm	0 mm	0 mm	0 mm
Detector collimation (mm)	Fixed 5% of detector, factory calibrated	Fixed 5% of detector, factory calibrated	Fixed 5% of detector, factory calibrated	Fixed 5% of detector, factory calibrated
Slice thickness (mm)	0.31mm +/-0.5mm	0.31mm +/-0.5mm	0.31mm +/-0.5mm	0.31mm +/-0.5mm
Slice spacing (mm)	0.3mm	0.3mm	0.3mm	0.3mm
Pitch or table feed	0	0	0	0
Scan FOV (cm)	20 cm diameter x 20.9 cm height	20 cm diameter x 20.9 cm height	35 cm diameter x 20.9 cm height	35 cm diameter x 20.9 cm height
Kernel/filter	-	-	-	-
Reformat technique (i.e., 3D, plane/views)	Automatic	Automatic	Automatic	Automatic
Contrast type/rate (if applicable)	Not Used	Not Used	Not Used	Not Used
Time from contrast injection to image acquisition, if applicable (sec)	Not Used	Not Used	Not Used	Not Used

LineUP has 18 X-Ray Protocol options:

Protocol	kVp	mA	ms	mAs	Detector Collimation (mm)
Hand PA Standard	60	5	300	1.5	Fixed 5% of detector, factory calibrated
Hand Lateral Standard	60	5	600	3	Fixed 5% of detector, factory calibrated
Hand PA Lite	60	5	150	0.75	Fixed 5% of detector, factory calibrated
Hand Lateral Lite	60	5	400	2	Fixed 5% of detector, factory calibrated
Elbow AP Standard	60	5	600	3	Fixed 5% of detector, factory calibrated
Elbow Lateral Standard	60	5	600	3	Fixed 5% of detector, factory calibrated
Elbow AP Lite	60	5	400	2	Fixed 5% of detector, factory calibrated
Elbow Lateral Lite	60	5	400	2	Fixed 5% of detector, factory calibrated
Two Feet AP Standard	60	5	800	4	Fixed 5% of detector, factory calibrated
One Foot Lateral Standard	60	5	800	4	Fixed 5% of detector, factory calibrated
Two Feet AP Lite	60	5	500	2.5	Fixed 5% of detector, factory calibrated
One Foot Lateral Lite	60	5	400	2	Fixed 5% of detector, factory calibrated
Two Knees AP Standard	60	5	1300	6.5	Fixed 5% of detector, factory calibrated
Two Knees PA Standard	60	5	1300	6.5	Fixed 5% of detector, factory calibrated
One Knee Lateral Standard	60	5	1200	6	Fixed 5% of detector, factory calibrated
Two Knees AP Lite	60	5	1000	5	Fixed 5% of detector, factory calibrated
Two Knees PA Lite	60	5	1000	5	Fixed 5% of detector, factory calibrated
One Knee Lateral Lite	60	5	750	3.75	Fixed 5% of detector, factory calibrated

APPENDIX IV: Pediatric Use Summary

The LineUP is intended to be used on patients ranging from 50 to 400 pounds.

Pediatric use is only intended for CT imaging. Do not use the 2D X-Ray Imaging Feature on pediatric patients.

Introduction: Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements, which approximately correspond to that of an average 12 year old or a 5th percentile U.S. adult female).

Exposure to ionizing radiation is of particular concern in pediatric patients because: 1) for certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients); 2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients; and 3) younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

A. **The following resource provides information about pediatric imaging radiation safety and/or radiation safety for Computed Tomography (CT):**

   [Link to page on CurveBeam website]

B. **The LineUP Provides the following specific design features and instructions that enable safer use of our device with pediatric patients:**
   a. Page 75 provides recommendations for selecting a protocol appropriate for the patient size
   b. Page 4 advises Patients less than 21 years old, small size patients (under 100 pounds) and children must also wear a gonad and ovarian front and back protective shield.
   c. Page 6 advises that Patient must wear protective X-ray shielding items (lead apron, etc.) to protect anatomical areas. The patient must wear a protective full wrap X-ray shielding apron (lead apron) during a scan. Patients less than 21 years old, small size patients (under 100 pounds) and children must also wear a gonad and ovarian front and back protective shield. Sample shielding products, or similar:
      i. Supplier: Marshield, Full Wrap Apron, #MS-SP1
      ii. Supplier: Universal Medical Inc, Diaper 14" x 20", #800
   d. Pages 84 and 85 provide hand and elbow scan positioning instructions specific to small patients

e. Testing information
    i. Estimated dose for all protocols provided in APPENDIX III: Scan Protocol Technical Details
    ii. Cone Beam CT Performance Testing starting on page 51 has tests for normal size patient (120 kVp) protocols and small patient (100 kVp) protocols
    iii. Quality Assurance Check Instructions are provided in Chapter 4 and are the same for normal and small patient protocols