Service Manual

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GX CB-500™

POWERED BY i-CAT®

Cone Beam Volumetric Tomography and Panoramic Dental Imaging System

GENDEX®

Imaging Excellence Since 1893

Published by Gendex® Dental Systems

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For more information or an original version of documentation on the this Imaging System, by Gendex®, please write, to Gendex® at the above address or Fax to 1-847-550-1322. This documentation has been drafted, approved & supplied in the English Language. Imaging Sciences International will make available under request any component parts, calibration instruments, circuit diagrams, etc.

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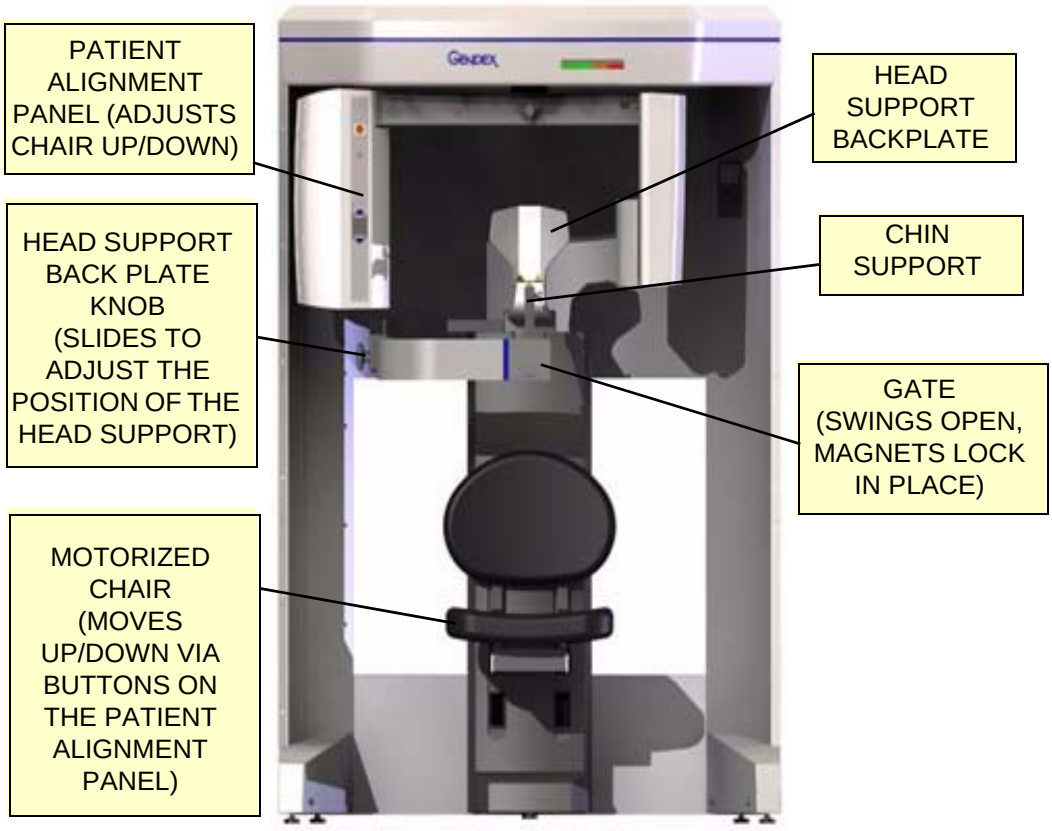
Chapter 1 Introduction

System Description

The system is a Cone Beam Volumetric Tomography and Panoramic X-ray device used for dental applications. The system consists of a Scanner and Computer Workstation which is suitable for an in-office environment.

This scanning device is an open design that allows Patients to sit upright during a procedure. An electric powered seat is built into the device for proper Patient positioning.



GXCB-500™ Imaging System

The system consists of a Scanner and Computer Workstation. In order for the system to operate, both the Scanner and Computer Workstation must be turned ON.

The system captures data for 3D Skull Reconstruction for the following procedures:

- Implants
- TM Joints
- Reconstructed Panoramic
- Reconstructed Cephalometrics
- Airway / Sinus, etc.
- Nerve Canal
- PAN - Conventional Digital Panoramic Feature

Cone Beam Volumetric Tomography is a medical imaging technique that uses X-rays to obtain cross-sectional images. Quality of the images depends on the level and amount of X-ray energy delivered to the tissue. Imaging displays both high-density tissue, such as bone, and soft tissue. When interpreted by a trained Physician, these images provide useful diagnostic information.

Major System Items

The system is comprised of the following major items:

- Scanner
- Computer Workstation
- Operator Control Box with 50 ft. (15.2m) Cable
- Patient Emergency Stop Box with 10 ft. (3m) Cable
- Interlock Jumper Cable, 8 inch (20cm)
- Interlock Cable 50 ft. (15.2m)
- Warning Light Cable 50 ft. (15.2m)
- Chair Connection Cable, 10 ft. (3m)
- Power Cable, 15 ft.(4.6m)
- CAT 5 Ethernet Cable, 50 ft. (15.2m)

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.

Conventions Used in the User Manual

- Keyboard keys are represented in a **Bold** font.

  For example, "Press **Start**."
- Menu items and button names on the user interface display are represented in a **Bold** font.

  For example, "At the Print window, click the **Print** button."
- Keyboard entries are represented in **`bold Courier font`**.

  For example, "Type **`QA Test`** in the filename box."

Standard Limited Warranty

Gendex warrants the original purchaser that this hardware system will be free from damage for a period of one (1) year from the date of delivery. During the warranty period, Gendex will correct any defects in material or workmanship, at no charge for materials. 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. The warranty period is not extended as a result of purchasing any additional parts from Gendex. The original purchaser must promptly notify Gendex in writing if there is a defect in material or workmanship. Written notice in all events must be received by Gendex before expiration of the warranty period. This warranty is not transferable.

This One-Year Limited Warranty covers normal use. **Gendex does not warrant or cover:**

- 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 peripherals
- Damage caused by failure to provide a suitable environment
- Damage caused by the use of the hardware system for purposes other than those for which it was designed
- Damage from improper maintenance
- Damage from improper electrical connection or supply
- Damage caused by any other abuse, misuse, mishandling, or misapplication
- Damage to acquisition computer, software, or operating system caused by
    - Additions or changes unauthorized by Gendex
    - Viruses, spyware, or gaming software
    - Damage caused by Network or Operating Engineers
    - Damage from the use of this machine or computer for any other purpose

- Applications other than its intended use
- Damage caused by third party software
- Damage caused by unauthorized changes to the system software
- Damage caused by unauthorized upgrades, additions or deletions
- Damage caused by internet use, or any other unauthorized application.

Under no circumstances shall Gendex 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 disclaimed. No oral or written information or advice given by Gendex, its agents or employees shall create a warranty or in any way increase the scope of this warranty

Chapter 2 Safety Items

Important Safety Information

Gendex designs its products to meet stringent safety standards. However, to maintain the safety of Operators and Patients, you must operate the equipment correctly and properly and ensure the equipment is properly maintained.

It is essential to follow all safety instructions, warnings, and cautions specified in this manual to ensure the safety of Patients and Operators. In addition, read and observe all danger and safety labelling on the system.

Before attempting to use the equipment for any patient examination, read, understand, and know how to implement the ***Emergency Stops*** on the system.

Warnings, Cautions, 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.

ADVISORY: Advisories are used to defined information for the operator regarding advice towards use of the device or a process.

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

Safety Precautions

WARNING

The X-ray device may be dangerous to the Patient and Operator if you do not observe and follow the 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

Closing the Gate creates a pinch point. Keep hands and other body parts clear when closing Gate.

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.

Explosion Hazard

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

WARNING

This unit is not suitable for use in a flammable air mixture environment.

If hazardous substances are detected while the system is turned on, do not attempt to turn off the system. Evacuate the area and then remove the hazards before turning off the system.

Mechanical Hazards

WARNING

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

Carefully observe the patient during the scanning procedure to ensure that when the System Gantry moves, the patient does not collide with the Gantry or other equipment. Ensure that the patient does not grab or hold any part of the system or nearby equipment.

Collision System

The Gantry motor is programmed to operate at a rotational force of <= 15 lbf (66.7N). Interference or incidental contact with the Gantry during rotation, which results in an interruption in Gantry motion, will be detected and trigger a system stall event. This will result in a system fault condition which will cause the following system events to occur:

- Stepper Motor power is removed
- X-Ray operations cease
- System Fault Light illuminates
- X-Ray Audio and Visual indicators de-energize

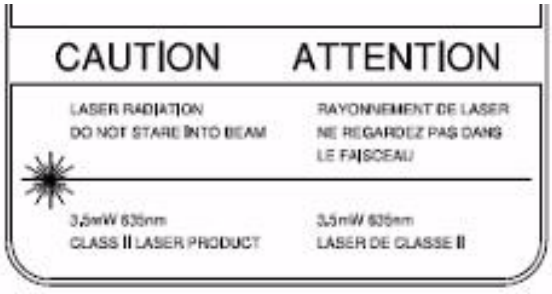
Operator intervention is required to recover the system for normal use.

Laser Beam Hazards

WARNING

Laser beams can cause optical damage. Close eyes when the laser beam is in use. Instruct the Patient to close eyes to avoid looking into the beam. The use of optical instruments such as eyeglasses with large diopter or mirrors, increase eye hazard with this product.

The System Gantry has laser markers to assist you in planning scan procedures. If you are using the laser markers while a patient is in the chair, warn the patient that the laser beam could be harmful. Advise the patient that laser beams can cause optical damage. Instruct the patient not to stare at the laser beam and to avoid looking into the beam.



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.

Radiation Protection Measures

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 adequate distance from exposed radiation source.
- Keep exposure times to a minimum.
- Wear protective clothing (lead apron, etc.) to protect the anatomical areas.
- Wear a PEN dosimeter and/or film badge.
- If you are required in the exam room during a procedure, stay as far from the scanner as possible or behind a mobile protective wall.
- The physician is responsible for protecting the patient from unnecessary radiation.

System Safety Devices

Emergency Stops

This manual contains instructions for safe operation of this dental X-ray System. 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 and/or Patient should utilize the **Emergency Stop buttons** to turn off the power to all moving parts in order for the Patient to be safely removed from the machine.

Warning System

The System is equipped with provisions for warning lights and/or audible alarms when X-ray power is energized.

An externally powered Warning System can be connected to the cable provided which is capable of 250 volts, 50/60 hertz, and 2.5 amps. When X-ray power is energized the warning system is also energized.

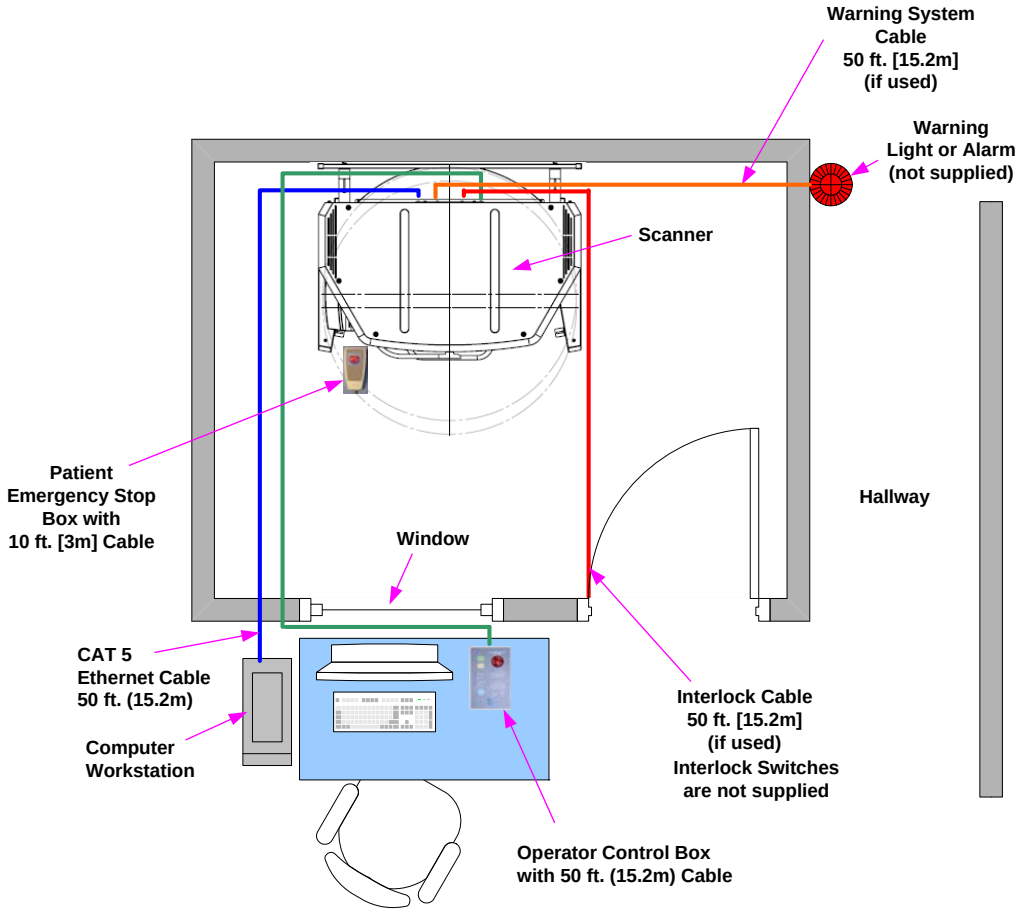
Interlock System

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, 12 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.

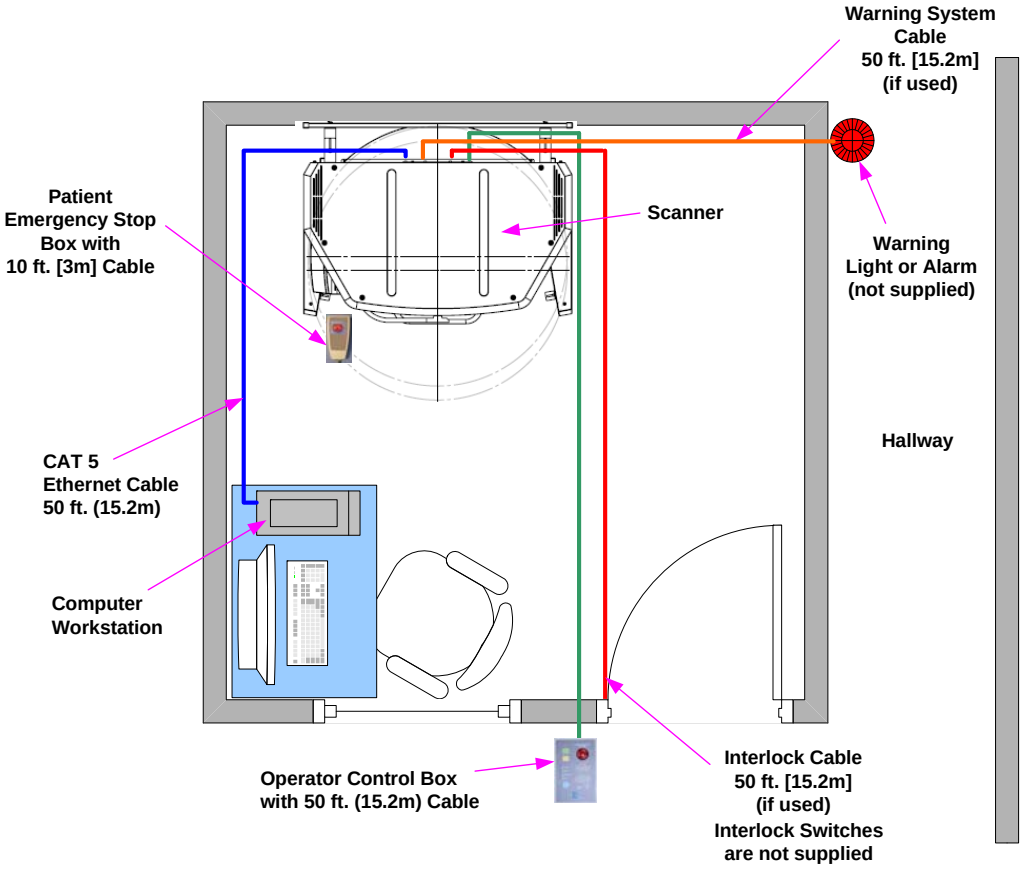
Multiple door switches and/or emergency stop switches can be connected as long as the devices are connected in series. The entire circuit must be a closed loop when all of the doors are closed and/or emergency stop switches are in their normally closed state. Whenever the door switch or switches are 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.

Sample Site Plan

Below are two typical scanning room layouts that illustrate the system interconnect for the Warning System, Operator Control Box (Emergency Stop) and Interlock System which are all describe above. Room layouts must provide a means for audio and visual communication between the Operator and Patient. The Patient Emergency Stop Box, which can stop the operation of the X-ray device, must be within reach of the Patient when scanning occurs.

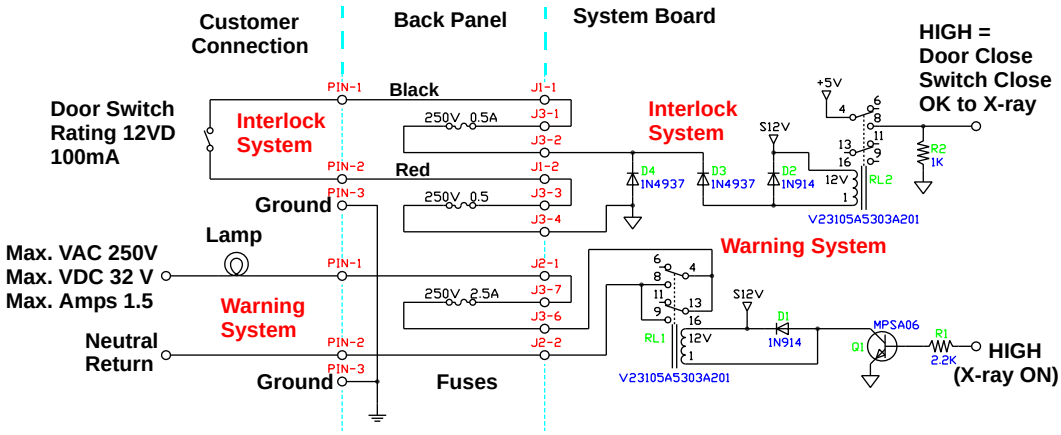


Room Size
6.5 x 8.5 feet [2 x 2.6 meters]



Room Size
8.5 x 8.5 feet [2.6 x 2.6 meters]

Interlock and Warning System Schematic



Cabling Requirements

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

Emergency Removal of a Patient

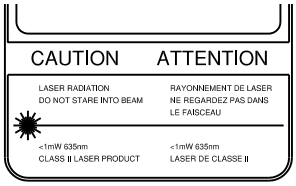
If an emergency arises where it becomes necessary to interrupt a scan and/or remove a patient from the Patient Chair, use the following procedures.

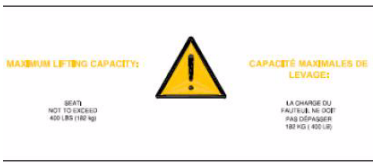
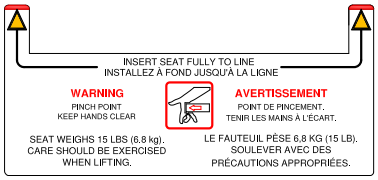
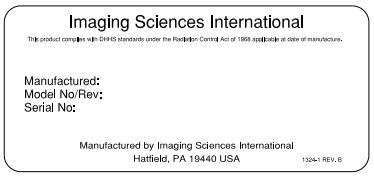
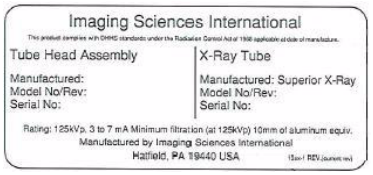
1. Press an Emergency Stop button.
2. When you have determined that you can safely remove the patient, grasp and pull the gate outward.
3. Make sure the patient's head will not touch the top of the Gantry and help the patient off the Patient Chair.

System Labels

The following labels are attached to the system.

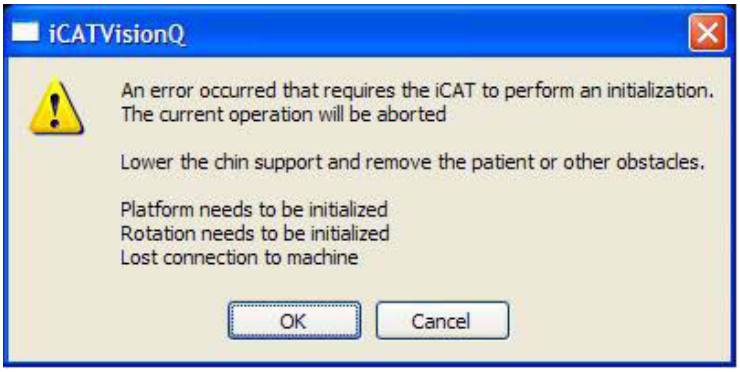
	**Caution** Location: Multiple locations to indicate the operator should exercise caution when working near this area and should consult written instructions.
	**Warning** Location: Rear of Overhead to indicate Electrical Hazard, Authorized Personnel only.
	**IEC Label** Location: Rear of Overhead Type B: Protection against electrical shock (IEC 60601.1 - 1990/A2 - 1995).
	**Non-Ionizing Radiation Label** Location: Rear of Overhead
	**Recycle Label** Location: Rear of Overhead Dispose of in accordance with your country's requirements. This label indicates that there is material in the system that you must separately collect and recycle in accordance with the requirements of the European Waste Electrical and Electronic Equipment (WEEE) Directive.
	**Electric Power Off** Location: Power Switch at rear of Overhead.
	Electric Power On Location: Power Switch at rear of Overhead.

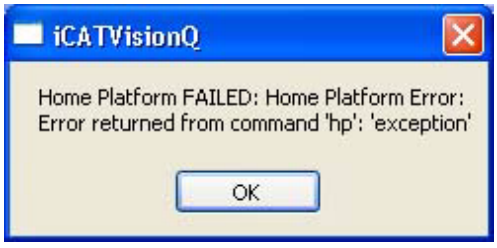
	**Caution: Laser Radiation** **Do not stare into beam** Location: Front center of Gantry and Source Panel.
	**Caution: Laser Radiation** **Do not stare into visible light beam** Location: Alignment Panel.
	**Caution: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating procedure are observed. Unauthorized use is prohibited.** Location: Control Box
	**Warning: Pinch point keep hands clear** Location: Inside of Patient Gate.

	**Caution: Maximum lifting capacity** Location: Patient Chair, below rear seat pad.
	**Caution: Maximum lifting capacity** Location: Patient Chair, above rear seat pad.
	**Chair Instruction Label** **Insert seat fully to line** Location: Patient Chair, behind seat pad.
	**ETL / CE 0413 Label** Location: Inside of left leg assembly.
	**Scanner Model and Serial Number Label** Location: Rear of Overhead.
	**Tube Head Model and Serial Number Label** Location: Tube Head Assembly.

Error Messages

The following are error messages that the system may display. If problems persist after performing the indicated action or actions in the message, call Service.





Chapter

3 System Controls and Indicators

Controls and Indicators are found on the following system units:

- Operator Control Box
- Patient Alignment Panel
- Patient Emergency Stop Control
- System Status Indicators

Operator Control Box

ON powers the Scanner and the POWER indicator lights to show that the device is ON.

OFF removes power from the device and the POWER indicators go OFF.

EMERGENCY STOP immediately halts all X-ray and scanning activities.

SCAN initiates Patient X-ray scanning. (This allows the Operator Control Box to be mounted in a location different from the Computer Workstation.) When scanning is occurring, the **X-RAY ON** indicator is lit.

FAULT indicator lights when a system error occurs (such as an X-ray exposure problem).

Patient Emergency Stop Control

PATIENT EMERGENCY STOP allows the Patient to halt all X-ray and scanning activities by pressing the button.

The Emergency Stop Control can either be hung from the head support mechanism or held in the Patient's hand as desired.

Patient Alignment Panel

WARNING

Laser beams can cause optical damage. Do not stare into the laser beam. Instruct the Patient to avoid looking into the beam. The use of optical instruments such as eyeglasses with large diopter or mirrors, increase eye hazard with this product.

ALIGNMENT LIGHT - pressing the button turns ON the laser alignment lights for two minutes, or until the button is toggled OFF.

PATIENT ALIGN allows the Operator to move the Patient seat up and down to facilitate Patient alignment with the Chin Rest.

System Status Indicators

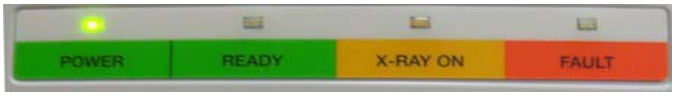
The System Status Indicators are located on both the overhead unit and the Operator Control Box.

POWER indicator is lit when the scanner is ON.

READY indicator is lit when the software Acquire button is pressed to begin the scanning process.

X-RAY ON indicator is lit during the scanning process.

FAULT indicator lights when a system error occurs (such as an x-ray exposure problem).



Chapter

4 System Startup and Shutdown

It is recommended to do a System Shutdown each day at the close of business. The system is available for use immediately after System Startup, no device warmup is required.

System Startup

The System includes the Scanner and a Computer Workstation. Both units must be ON to function properly. To start the system, do the following:

1. Power up the Scanner: press the ON button on the Main Control Box. The POWER indicator on the Main Control Box and Scanner light.

2. **Power up Computer Workstation:** press the power button on the front of the Workstation. The computer boots and loads the operating system.

3. **Launch Vision Software:** double-click the **Vision** icon on Workstation desktop. The Vision software application is launched.

NOTE: Although the system is now ready to scan, the **Ready** indicator does not illuminate until the **Acquire** button is pressed to start a scan.

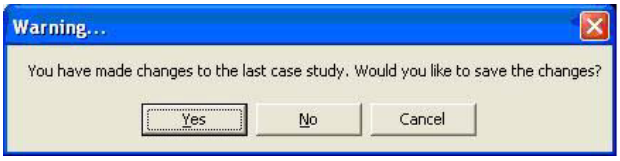
System Shutdown

The Scanner and Computer Workstation are powered independently. Both units are powered OFF as described below.

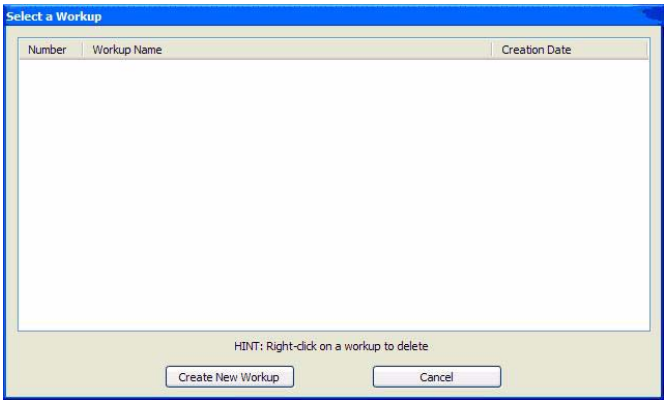
To shut down the system:

1. From the Main menu on the Computer Workstation, select **File > Exit**. Vision closes but the Windows desktop remains ON.

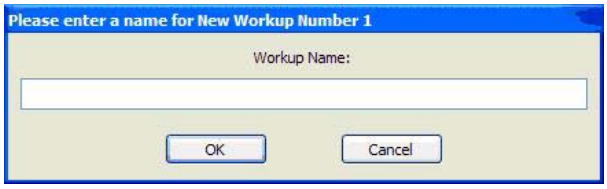
If changes were made to a case study, the following dialog box appears.



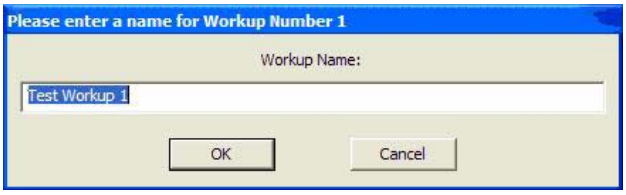
a. Click **Yes**. The dialog box closes.



b. Click **Create New Workup**.



c. Enter a name for new Workup in the *Workup Name:* field. Click **OK**
or
Overwrite an existing Workup by clicking an existing Workup Name.



2. **Power OFF Scanner:** press the **OFF** button on the Main Control Box. The Scanner shuts down and the POWER indicators on the Main Control Box and Scanner go OFF.

3. **Power OFF Computer Workstation:** from the Windows desktop, select **Start > Shut Down** and then select **Shut Down** and press **OK**. The Computer shuts down and the POWER indicator on the Workstation goes OFF.

Chapter 5 System Assembly

Initial Preparation

Before beginning system assembly, please review the Safety chapter to familiarize yourself with the safety precautions related to the system.

Required Tools

Spirit Level

Tool Kit (supplied with unit)

- 3/16 inch T-Handle Allen Wrench
- 1/4 inch Nut Driver
- 5/16 inch Nut Driver
- 1/2 inch and 7/16 inch Open-end Wrench
- 1/16 - 5/16 Allen Wrench Set

Abbreviations

Hardware abbreviations used in this chapter:

- SHCS - Socket Head Cap Screw
- SS - Set Screw
- LW - Lock washer
- FW - Flat Washer

Inventory of Unit Items

The following system items are included in the shipping crate.

1. Gantry
2. Rear Scatter Shield
3. Chair Assembly
4. Wall Mount Assembly
5. Tube Head Assembly Box
   - Tube Head Assembly
6. Receptor Assembly Box
   - Receptor Assembly
7. PC Monitor Box
   - Monitor
   - Power Cable
   - VGA Cable
   - DVI Cable
8. PC Box
   - Cobra Software Key
   - PC
   - PC Power Cable
   - Keyboard
   - Mouse
   - Power Strip
9. Accessories Box
   - Documents
     - 17-19 Operators' Manual
     - FDA Form 2579
     - Certificate of Regulatory Compliance
   - Cables
     - Control Box Assembly with Cable
     - Chair Extension Cable

- Interlock Cable
- Warning System Cable
- CAT -5 Ethernet Cable
- Hospital Grade Power Cable
- Patient E-Stop with Holster

- Phantoms
  - Cylinder Phantom
  - Line Pair Phantom
  - i-PAN Phantom
  - Water Phantom Assembly
- Miscellaneous Accessories
  - Calibration platform
  - Head Rest Kit
  - Chin Rest
  - Chin Cups (2)
  - Bite Tip Holders (2)
  - Bite Tips (25)
  - Booster Seat
  - Foot Stool
  - Chair Center Locator
  - Glides (4)
  - Tool Kit

System Assembly

There are two methods used for shipping the device; assembled and non-assembled. Start with step one for the non-assembled scanner. Start with step 9 for scanners that are shipped assembled.

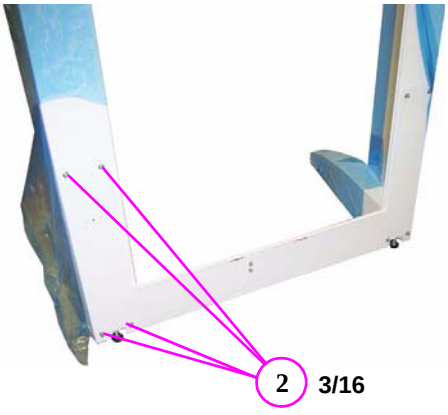
Before moving the System into place, ensure that the area is clean and that there is ample room to work.

WARNING

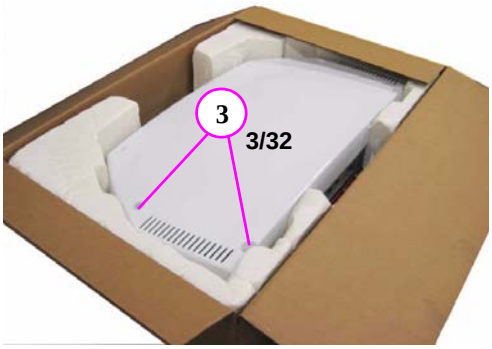
This system has devices that require a two person lift. Failure to comply may cause bodily injury. Two adults are required to unpack and assemble this system.

1. With the help of an assistant, install the Lower Plate under the two Leg Assemblies, as shown.

2. Attach with mounting hardware, four SHCS 1/4-20 x 5/5 long with 1/4” Split Washers, both sides.



3. Remove top cover (six mounting screws).



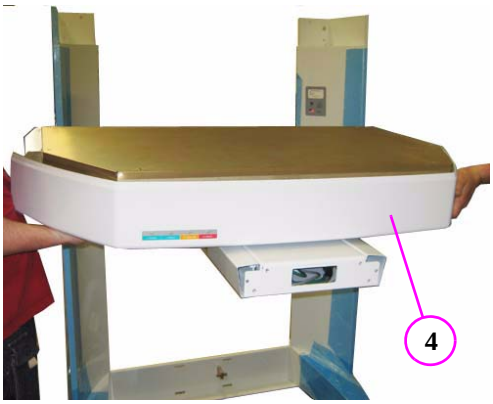
WARNING

This devices requires a two person lift. Failure to comply may cause bodily injury. Two adults are required to assemble this device.

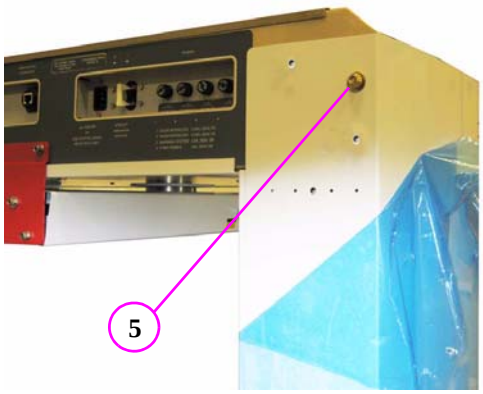
CAUTION

Use extreme care not to scratch Overhead Assembly when mounting unit onto Leg Assemblies.

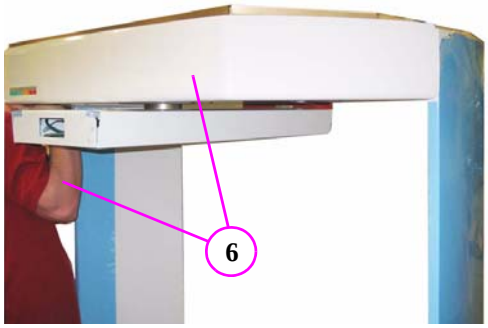
4. With an assistant, lift overhead device into place on top of Leg Assemblies.



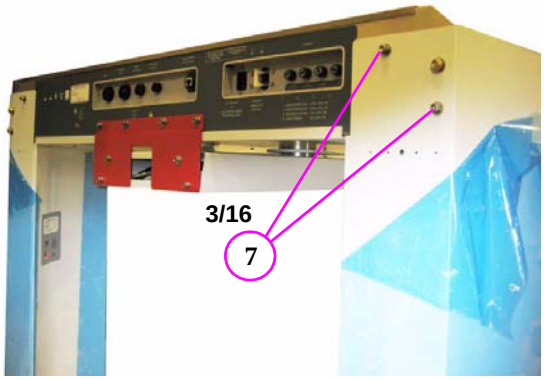
5. Ensure the pins on rear of the Overhead device are seated into the holes on Leg Assemblies.



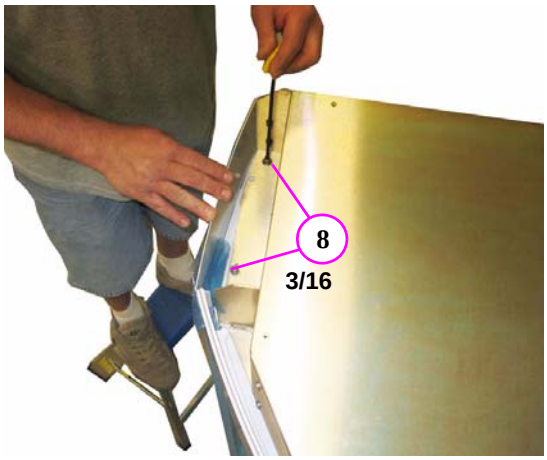
6. When seated properly, Overhead device locks into place. To ensure safety, the Overhead should still be supported by an assistant until mounted.



7. From rear of unit, secure Overhead with mounting hardware, two SHCS 1/4-20 x 5/8 long with 1/4" Split Washers, both sides.



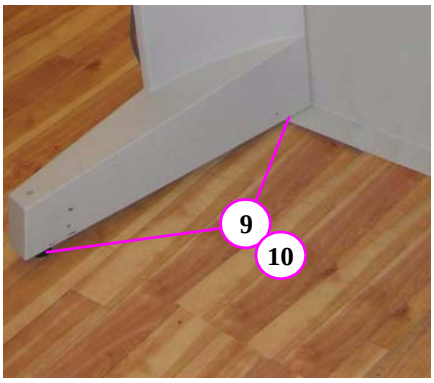
8. From top of unit, secure Overhead with mounting hardware, two SHCS 1/4-20 x 5/8 long with 1/4" Split Washers, both sides.



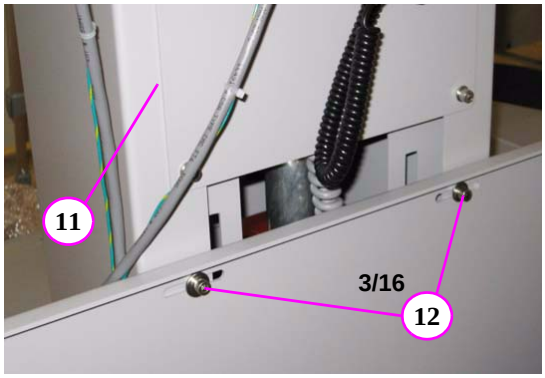
CAUTION

Care must be taken when sliding the device into place. To prevent the unit from scratching the floor surface, place the four Glides under the device feet.

9. With the help of an assistant, tilt the scanner to install the Glides under the four feet (corners of device).
10. Slide the scanner into place and remove the Glides.



11. Position Patient Chair on device base. Ensure Base Frame Centering Screw is seated within Patient Chair Centering Block.
12. Loosely secure Patient Chair to Gantry (2 SHCS with lock washer). **Do not tighten**.

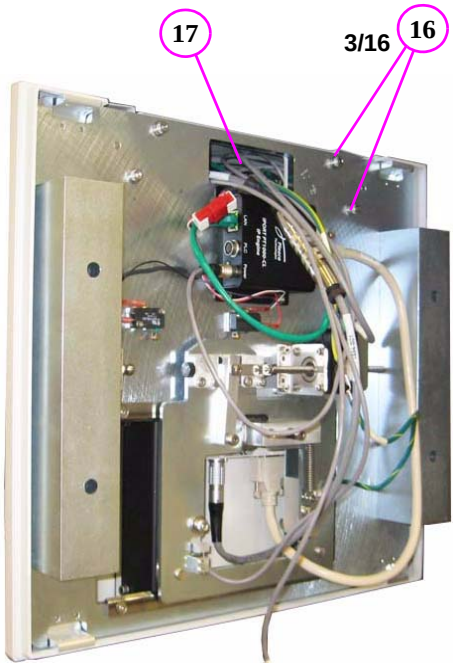


WARNING

The Receptor Assembly requires a two person lift. Failure to comply may cause bodily injury.

13. Locate Receptor Assembly and remove packing material.
14. Remove assembly cover from unit (4 outer screws).

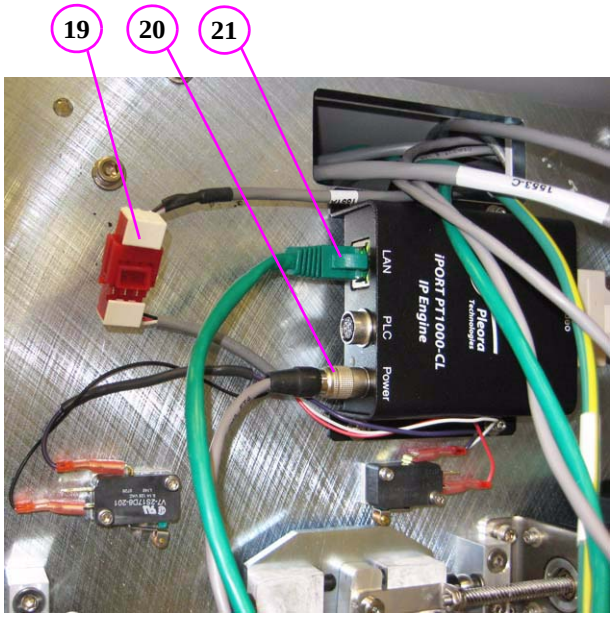
15. With an assistant, mount the Receptor Assembly by aligning the mounting pins.
16. Attach assembly with four long mounting screws and four split washers, acquire four mounting screws from Red Shipping Plate.
17. Feed cabling through Receptor Assembly (8 wires).



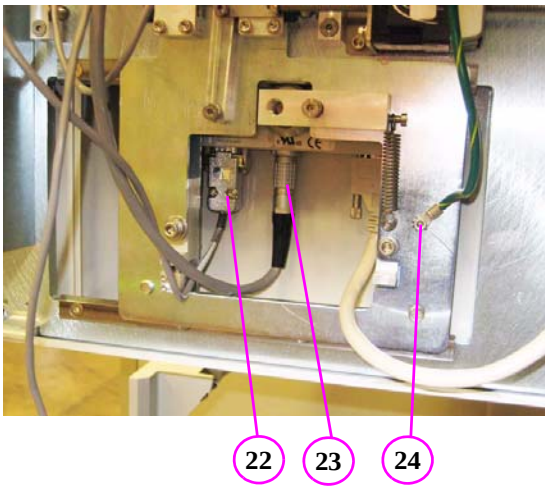
CAUTION

When mating connectors, do not force-fit connectors together.

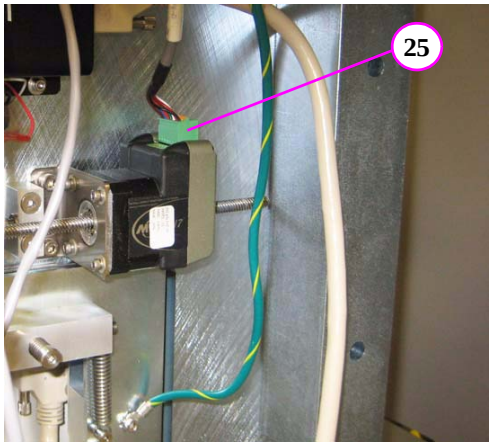
18. All connectors are color coded and keyed to prevent improper mating.
19. Connect together the red/white connectors (grey wires) as shown.
20. Rotate into position, aligning red dots, then press to lock the gold connector (grey wire) onto the keyed Power connector.
21. Connect green wire RJ45 plug to LAN receptacle as shown.



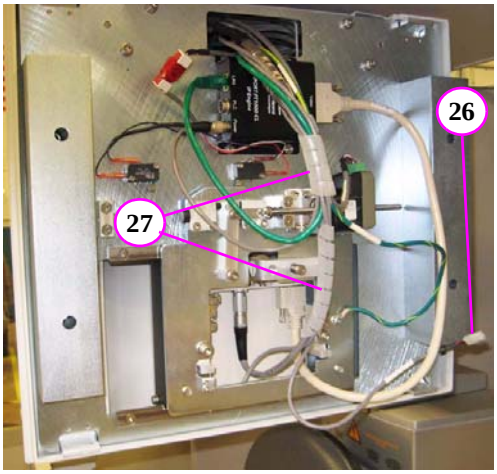
22. Connect silver connector (grey wire) to assembly as shown. Access connector mounting screws by pulling back bottom of receptor cover (opposite side).
23. Rotate silver cylindrical connector (grey wire) into position, aligning red dots, then press to lock onto keyed connector as shown.
24. Attach ground lug by removing mounting nut and installing lug over the star-lock washer. Replace mounting nut.



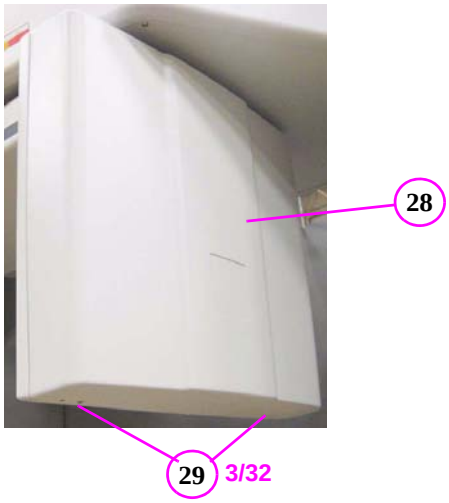
25. Connect green connector (grey wire) to assembly as shown).



26. Do not connect small white connector (grey wire). To be used for future use.
27. Dress cables using flexible plastic wire wrap.



28. Install Receptor cover.
29. Attach mounting screws on top and bottom of cover.



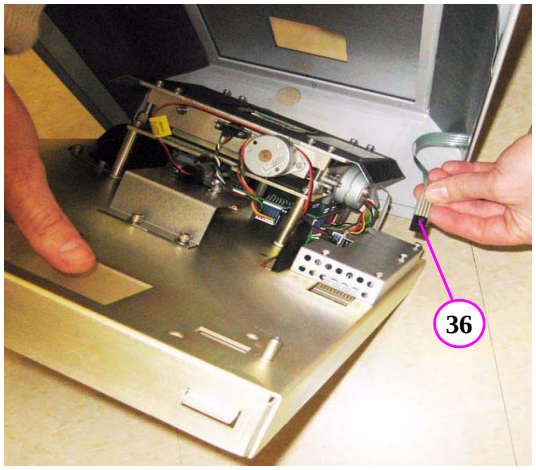
30. Remove red Shipping Plate. Do NOT discard mounting hardware (quantity 8) or Shipping Plate.

    Long screws used for Receptor Assembly mounting and short screws for Source Assembly.

31. Locate X-ray Source Assembly and remove from packing material.
32. Place assembly on clean surface. Remove and set aside the magnetic mounted X-Ray Source window panel from the cover.
33. Remove cover mounting screws from top and bottom of unit (quantity 8).

34. Detach outer Source Cover ONLY.

35. Carefully detach and move inner Source Cover a few inches away from assembly.
36. Remove ribbon cable from Beam Limiter Assembly by depressing connector locking tab.

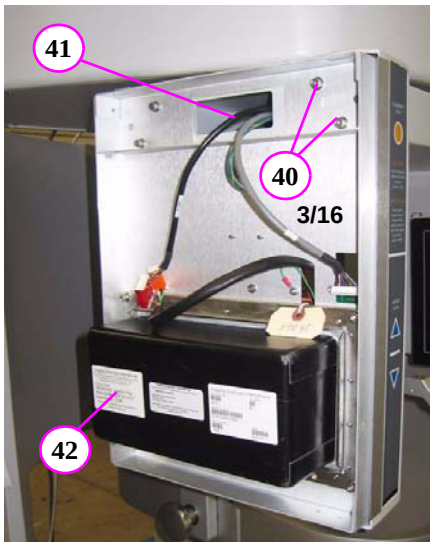


37. Using very little force, slowly rotate gantry, counterclockwise. Stop the rotation when you feel that the gantry is at the limit switch position.
38. Slide X-ray Source Cover onto the Gantry overhead.

WARNING

The X-ray Source Assembly requires a two person lift. Failure to comply may cause bodily injury.

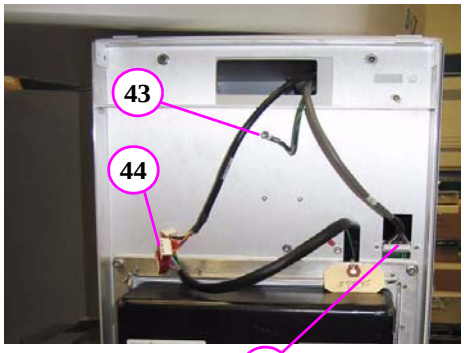
39. With an assistant, align X-ray Source Assembly mounting pins.
40. Attach assembly using the four mounting screws previously removed from red Shipping Plate along with four split washers.
41. Draw the 3 cables out through the opening. Ensure that the cables are not stretched or damaged.
    - black cable (2 connectors)
    - grey cable (single connector)
    - green ground cable (ground lug)
42. Record label information that is required on Installation Sheet (Serial Number, etc.).

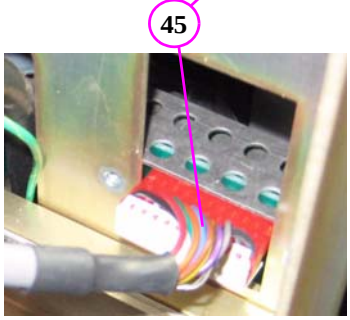


CAUTION

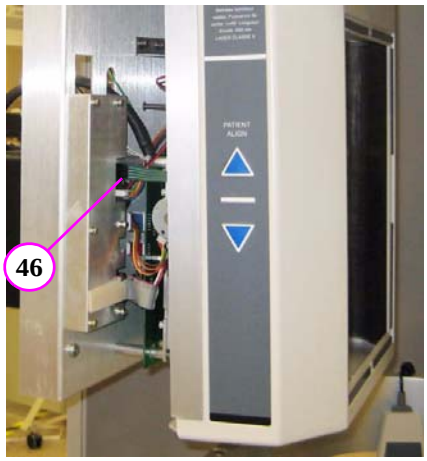
When mating connectors, do not force-fit together.

43. Attach ground lug by removing mounting nut and installing lug over the star-lock washer. Replace mounting nut.
44. Attach together, black cables with the two connectors.
45. Attach grey wire with red/white connector as shown. Ensure red side of connector is facing upward.

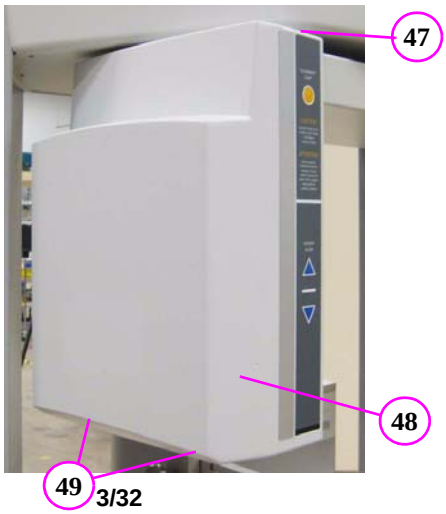




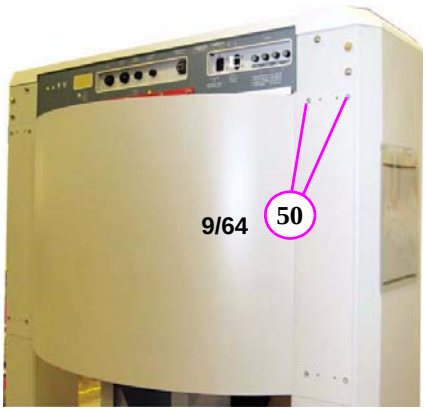
46. Attach ribbon cable back to the Beam Limiter Assembly.



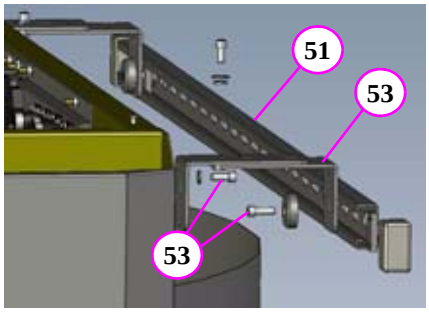
47. Slide Adjustment Panel Cover into place, onto **top mounting notches**.
48. Mount outer cover onto mounting notches, over panel cover.
49. Attach covers with the four hex mounting screws at the bottom of assembly.



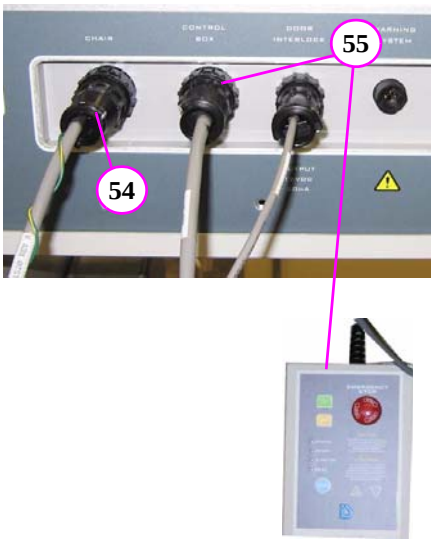
50. Attach Scatter Shield to the rear of the Gantry (8 mounting screws). Note, mounting pins to be located at the top of the Scatter Shield. Obtain Mounting Bar Assembly.



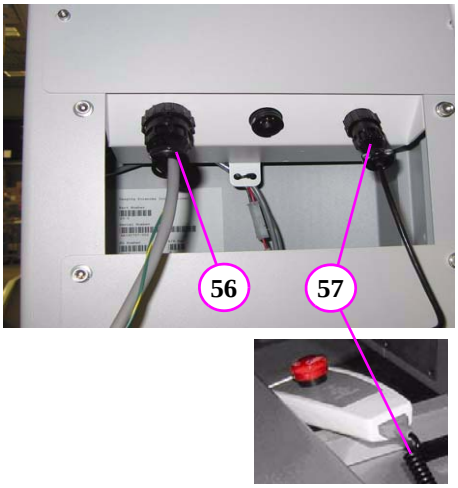
51. Install Mounting Bar on wall, centered behind the unit. The height should be approximately 66 ½ to 68 inches [169 to 173 cm] from the floor to the center of the Mounting Bar. However, this may vary, so you may want to put the "L" brackets on unit and mark the wall to verify the height.



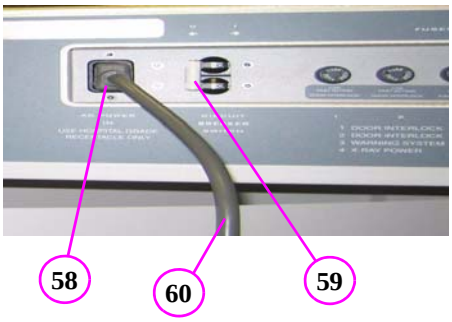
52. Use 3 wall anchors/screws to mount the bar securely to the wall.
53. Loosely attach brackets to the unit and mounting bar. Do not tighten until leveling is complete.
54. Connect chair Control Cable to **CHAIR** connector on rear of Overhead Panel.
55. Connect Main Control Box cable to **CONTROL BOX** connector on rear of Overhead Panel. Connectors are keyed to prevent improper insertion.



56. Connect chair Control Cable to Patient Chair connector.
57. Connect Patient Emergency Stop Control to Patient Chair connector. Connectors are keyed to prevent improper insertion.



58. Connect Power Cable to **AC POWER IN** connector on rear of Overhead Panel.
59. Ensure the Power Circuit Breaker on the Overhead rear panel is set to the OFF position. The OFF position is the **O** symbol.



CAUTION

Connect to hospital grade power only. Otherwise, damage to equipment may occur.

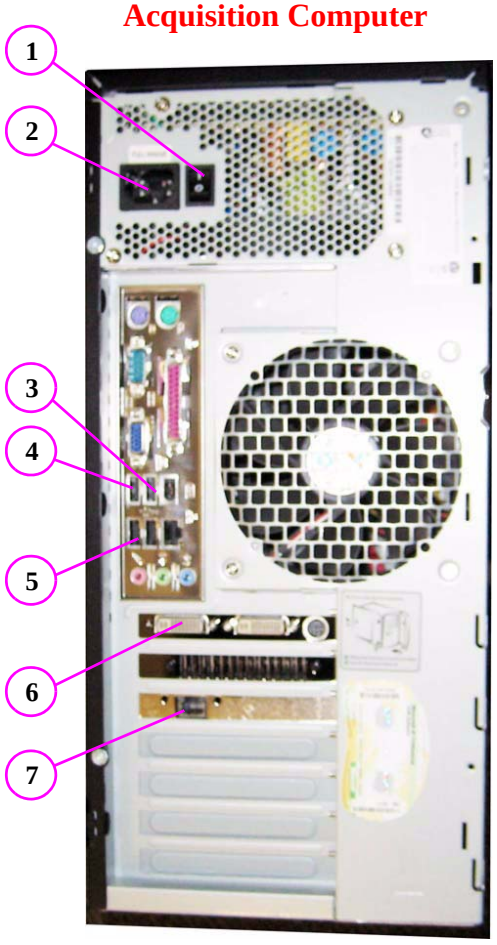
60. Connect Power Cable to Hospital Grade Receptacle.

Install Computer and Monitor:

1. Power Switch
2. Power Cord Receptacle
3. Mouse (USB)
4. Keyboard (USB)
5. Acquisition Software Key (USB) can be found attached to Operator documentation.
6. Monitor
7. ACQ Computer Cable (connects to gantry rear)

NOTE: Use supplied Power Strip.

Acquisition Computer



Acquisition Software Key

Chapter 6 Leveling and Alignment

Level Gantry

To achieve optimal performance, it is imperative that the Gantry be properly leveled.

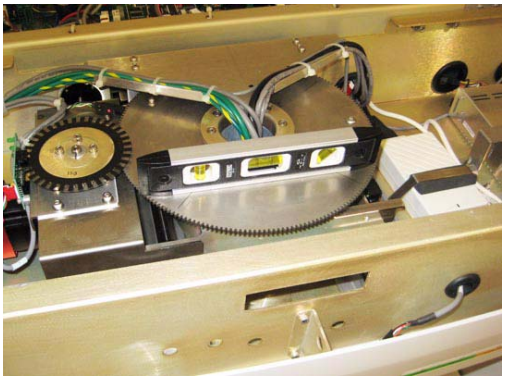
Leveling the Gantry:

1. Remove top cover (6 screws).

2. Remove shielding cover.

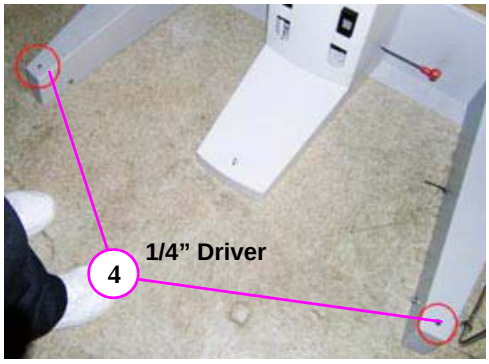
3. Unit must be leveled from side-to-side and front-to-back.

Level Side-to-Side



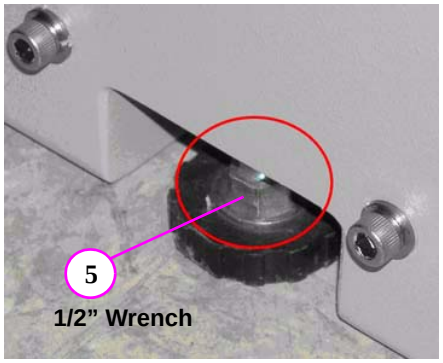
Level Front-to-Back

4. Level Overhead Gear using 1/4” Hex Driver to adjust the front Gantry feet.

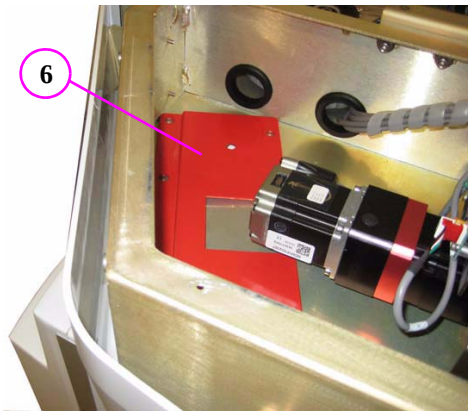


5. Adjust the rear Gantry feet using the 1/2” Open-ended Wrench.

   NOTE: Ensure levelness of Overhead Gear is measured Front-to-Back and Side-to-Side.



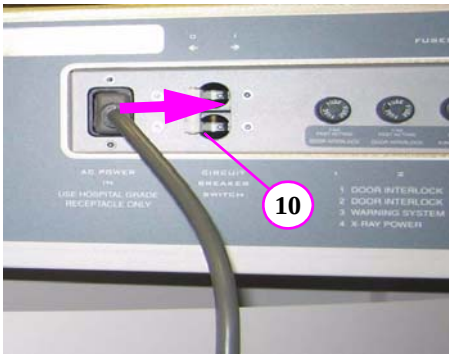
6. Store red shipping bracket in Overhead.



7. Replace shielding cover.

8. Replace top cover (6 screws).
9. Now that the device is positioned and leveled, tighten wall bracket at top rear of gantry.

10. Switch the Power Circuit Breaker which is located on the Overhead rear panel to ON. The ON position is the **I** symbol.



11. Press the Control Box ON button.
    The device is now powered.
12. On the Acquisition Computer, start the Vision software.

NOTE: If the Vision software was started **prior** to powering up the scanner, then close and reopen Vision so that the device can reset properly.

Patient Chair Alignment

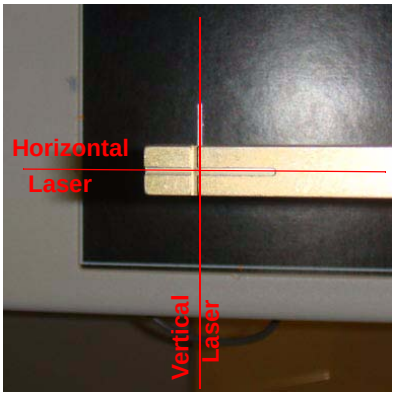
To acquire quality images, the chair must be accurately leveled and aligned.

Leveling Patient Chair:

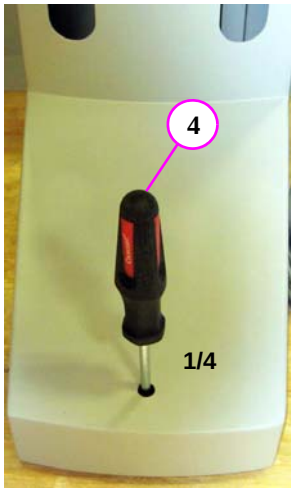
1. From the Acquisition computer, double click the **Calibration** icon.

   The Calibration screen is displayed and the device moves to the home position.
2. Insert Chair Center Locator into positioning block.
3. Press the Alignment Light button on the Patient Alignment Panel to display lasers.
4. Check position of the Horizontal and Vertical Lasers relative to the notches on the Chair Center Locator, as shown.

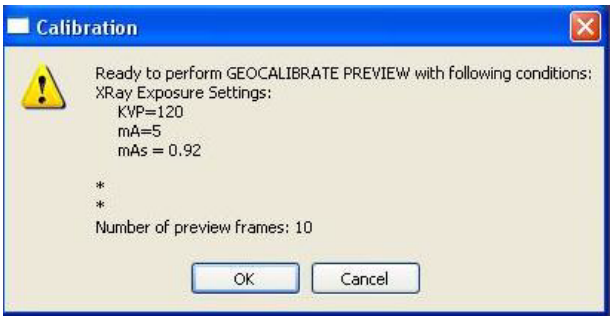
   - If Horizontal Laser is out of position, move Chair Center Locator up or down in the positioning block to roughly align with horizontal notch.
   - If the Vertical Laser is out of position, then adjust the Chair Foot, using a 1/4 inch nut driver.

   - **Turn nut driver clockwise -** moves alignment tool towards rear of Scanner.
   - **Turn nut driver counter-clockwise -** moves alignment tool towards front of Scanner.

5. On the Calibration screen, click the Vertical Chair Line checkbox and ensure slider is at 0° position.

6. Click **Preview**. A dialog is displayed.
7. Click **OK** to start the scan process.

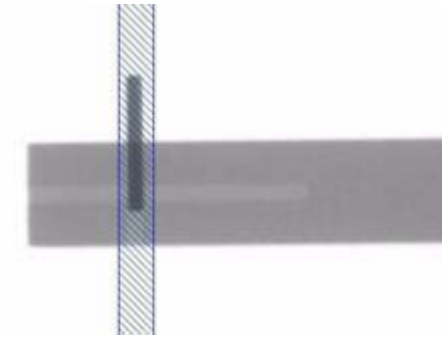


WARNING

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

8. Press **Scan** button on Control Box. An audible is sounded and the X-ray ON light is illuminated during radiation exposure. The preview scan is displayed.
9. Verify that the vertical pin falls within the blue shaded area. If aligned, go to next step.

   If not aligned, adjust the Chair Foot (step 4), then perform a **Preview** (steps 6 - 8). Repeat as needed until pin falls within the blue shaded area.



NOTE: If the pin falls to the left of the shaded area, turn the nut driver counter-clockwise. If the pin falls to the right of the shaded area, turn the nut driver clockwise.

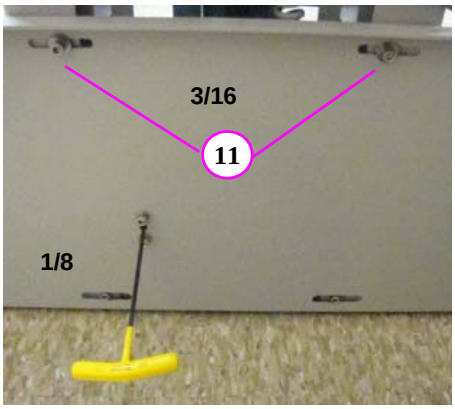
Centering Patient Chair:

10. On the Calibration screen:

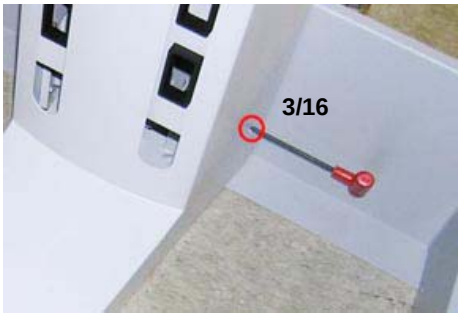
    a. Move slider to 90° position and perform a **Preview**.

    b. Verify that the vertical pin falls within the blue shaded area. If aligned, go to step 17.

11. If the pin is not within the blue shaded area, loosen set screw (rear of Scanner), then loosen the Chair mounting bolts by 1/2 turn each.



12. Adjust chair, left or right, as needed based on the Preview scan using the Adjustment Screw on the side of Chair Assembly.



- **If pin is to left of shaded area, turn wrench clockwise -** moves Chair Assembly to the left when facing front of Scanner.
- **If pin is to right of shaded area, turn wrench counter-clockwise -** moves Chair Assembly to the right when facing front of Scanner.

13. Repeat **Preview** and Chair Assembly adjustment (step 12) as needed until pin is within blue shaded area on Preview scan.
14. When pin falls within the blue shaded area at both 0^{o} and 90^{o}, tighten Chair mounting bolts.

NOTE: Tightening the left bolt first (when facing rear of Scanner) may help prevent the Chair Assembly from shifting.

15. After Chair Assembly mounting bolts are tightened, repeat Preview scans at 0^{o} and 90^{o} to verify chair alignment.
16. If the vertical pin falls outside the blue shaded area at either position, repeat the necessary steps to adjust the Chair, and perform a Preview, until chair alignment is verified. Tighten set screw at rear of Scanner.
17. Uncheck the Vertical Chair Line checkbox.

Laser Alignments

The scanner has two alignment lasers.

- **Centerline Laser** - located on the front of Overhead Gantry
- **Crosshair Laser** - housed inside the X-ray Source Assembly.

WARNING

Do not stare into laser. Severe personal injury (blindness) may result.

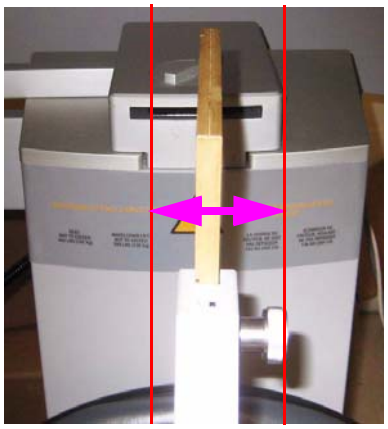
NOTE: Ensure that the Patient Chair Alignment has been completed before beginning this procedure.

Adjust Centerline Laser

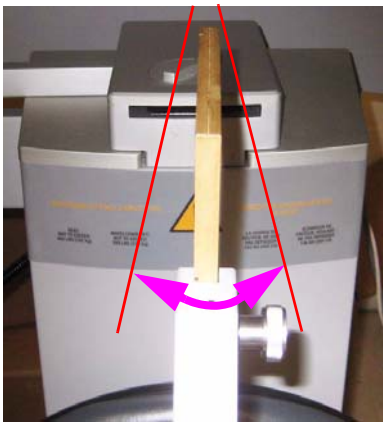
There are three laser adjustments;

- Right-to Left
- Angle
- Laser Line Sharpness.

RIGHT-TO-LEFT

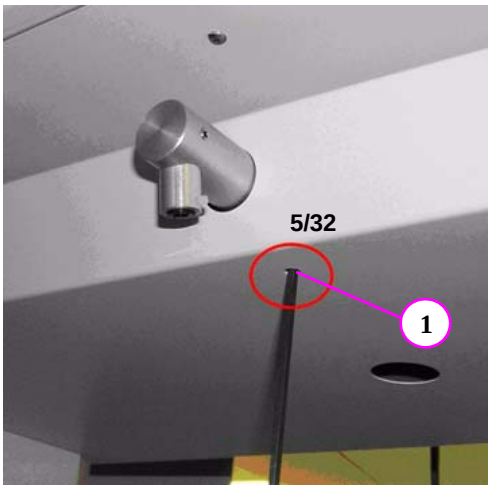


ANGLE

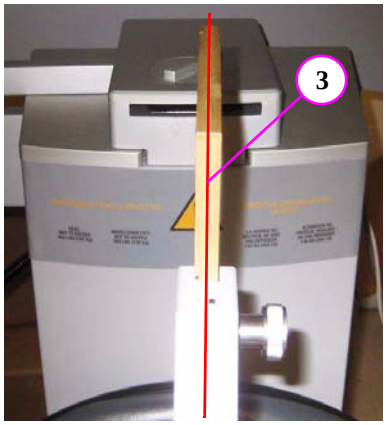


Right-to-Left Adjustment:

1. Loosen laser assembly set screw which allows the assembly to rotate.
2. Press the **ALIGNMENT LIGHT** button on the Operator Panel. The laser lights for approximately two minutes.

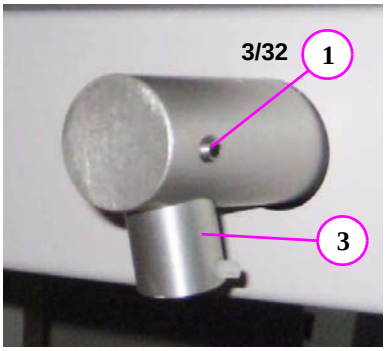


3. While the laser is lit, manually rotate the laser assembly until it is aligned with the center line on the Chair Center Locator.
4. While holding the assembly in place, firmly tighten set screw.

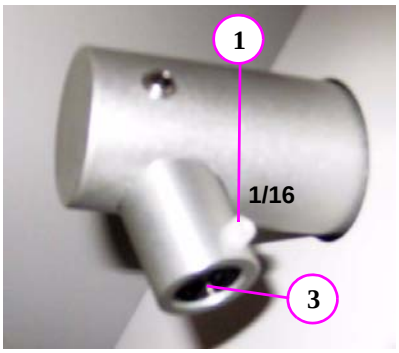


Angle Adjustment:

1. Loosen laser pointer set screw.
2. Press the **ALIGNMENT LIGHT** button on the Operator Panel.
3. While the laser is lit, manually rotate the laser pointer until it is aligned with the center line on the Chair Center Locator.
4. While holding the laser pointer in place, firmly tighten set screw.



Laser Line Sharpness Adjustment:



1. Loosen laser pointer lens set screw.
2. Press the **ALIGNMENT LIGHT** button on the Operator Panel.
3. Manually rotate laser pointer lens with your finger tip until laser line is thin and sharp.

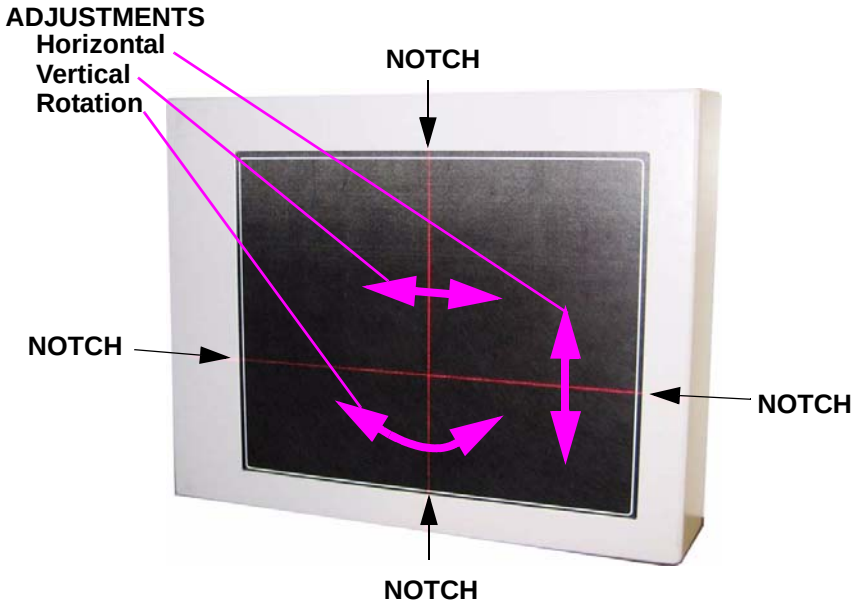
   Rotating the lens for sharpness will require realignment (Side-to-Side and/or Angle).
4. Tighten set screw to lock lens in place.

Adjust Crosshair Laser

When the **ALIGNMENT LIGHT** button is pressed, the Crosshair Laser shines from the X-ray Source Panel and appears on the Receptor Panel. The crosshairs should appear directly in line with the four notches on the panel cover, as shown below.

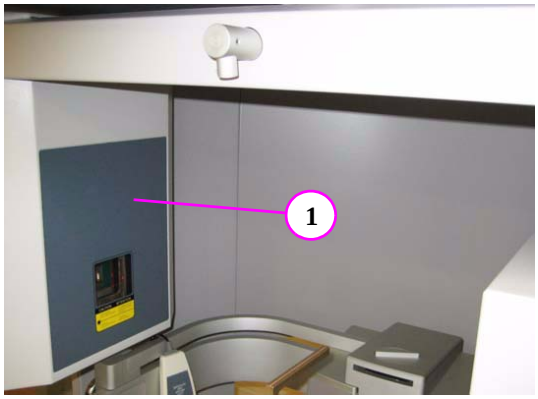
There are three types of laser adjustments:

- Horizontal Line up/down
- Vertical Line forward/back
- Rotate Crosshairs.



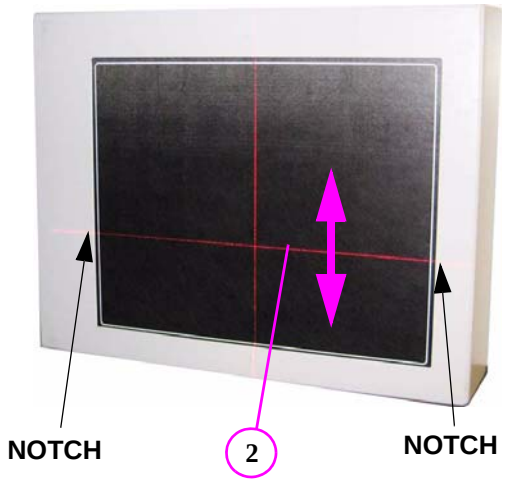
1. Remove Beam Limiter Cover to gain access to the Crosshair Laser.

   The cover is attached magnetically.

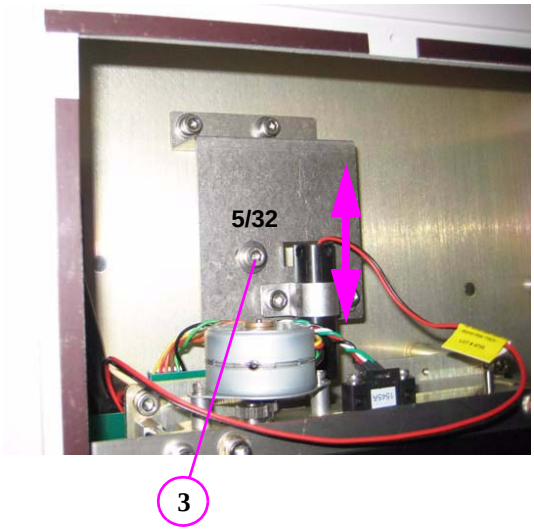


Horizontal Line Adjustment:

2. Check height of horizontal crosshair line with panel cover notches.

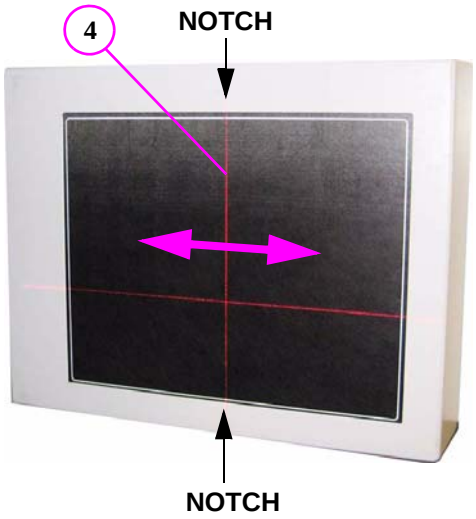


3. To move horizontal laser line up/down turn adjustment screw (shown):
   - **Clockwise** - moves line up
   - **CCW** - moves line down

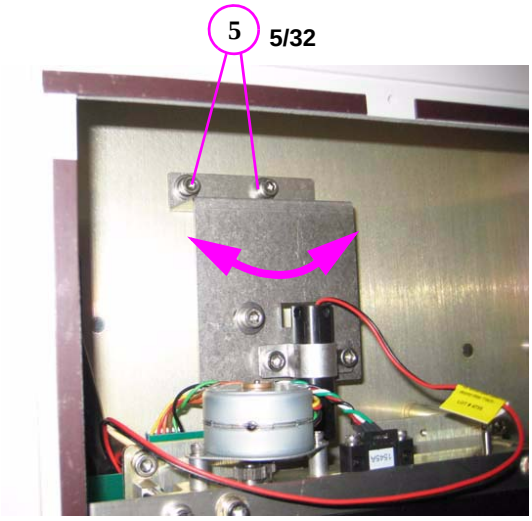


Vertical Line Adjustment:

4. Check position of vertical crosshair line with panel cover notches.

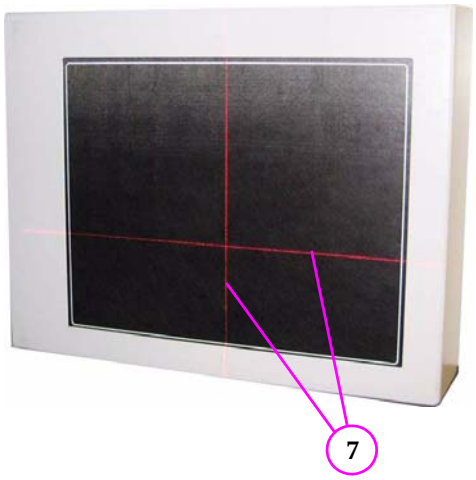


5. To move vertical laser line forward/back loosen the two mounting screws (shown). The bracket pivots on the center mounting screw which moves the vertical laser line.
6. Tighten both screws when properly aligned.

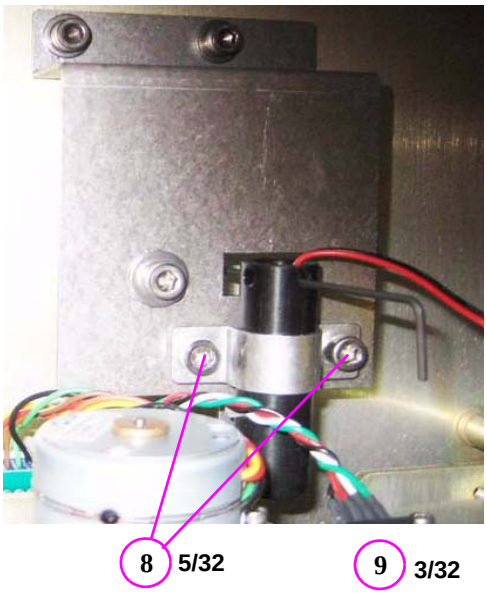


Rotate Crosshair Laser Lines:

7. Check crosshair lines with panel cover notches to see if a rotation adjustment is required.



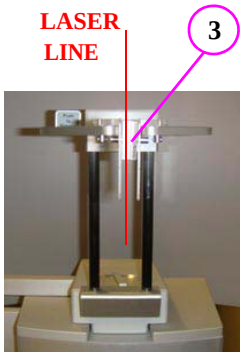
8. To rotate laser crosshairs slightly loosen the two laser mounting screws (shown).
9. To help rotate the laser, insert an allen wrench (3/32) into the top hole of the laser.
10. Tighten both screws when properly aligned and remove 3/32 allen wrench.
11. Replace Beam Limiter Cover.



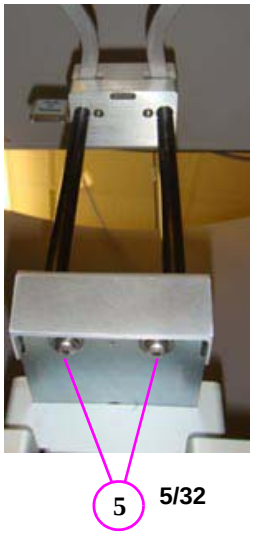
Head Holder Alignment

NOTE: Ensure that the Laser Alignments have been completed before beginning this procedure.

1. If head support is installed, loosen locking knob and remove head support.
2. Slide head holder into place.
3. Place the Position Alignment tool between the temple pads with the alignment mark facing front.
4. Press the **ALIGNMENT LIGHT** button on the Operator Panel to turn on laser.



5. Loosen screws underneath head holder with allen wrench (5/32) and adjust the head holder so that the laser aligns with the alignment mark.
6. When aligned, re-tighten screws.
7. Press the **Push To Release** lever to open arms and remove the Position Alignment tool. Do not manually force arms open.
8. Remove head holder and re-install head support.



Chapter 7 Calibration

The Panel, Collimators, and Geometry Calibrations can be conducted by the Owner / Operator of the device. It is recommended that the Panel Calibration be performed once a week.

Panel Calibration

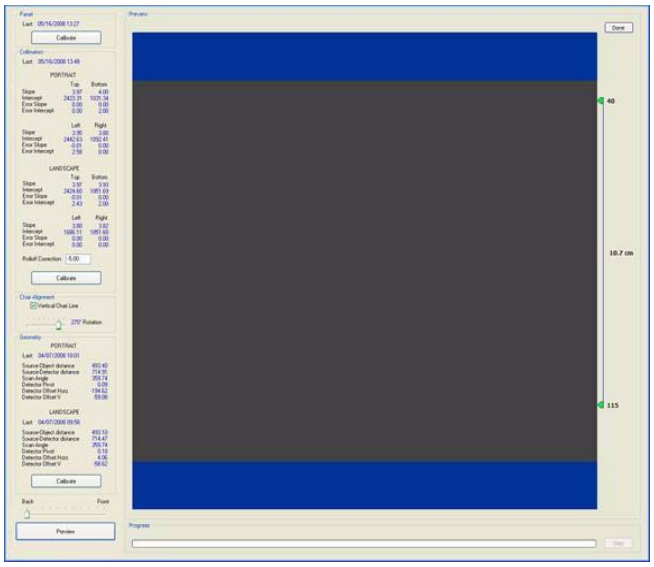
The Panel Calibration is performed for both Portrait and Landscape positions. The entire calibration takes approximately 8 to 10 minutes to complete. The process performs a five mode calibration as listed below:

- Mode 0 (4 x 4) Landscape
- Mode 1 (2 x 2) Landscape
- Mode 2 (not supported)
- Mode 3 (2 x 2) PAN (Landscape)
- Mode 4 (not supported)
- Mode 5 (4 x 4) Portrait
- Mode 6 (2 x 2) Portrait

To run the Panel Calibration:

1. Ensure room temperature is in the range of 50 to 95^{o}F (10 to 35^{o}C).
2. From the desktop, double click the **Calibration** icon.

The Calibration screen is displayed.



3. Click the **Calibrate** button (top) in the *Panel* field.

WARNING

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

A window is displayed *"Remove all objects from the field of view and click OK to start X-ray exposure."*

4. Click **OK**.
5. When prompted, press the **Scan** button on the Control Box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
6. The progress of the scan is displayed on the *Progress* bar at the bottom of the Acquire window. You will be prompted to press the **Scan** button several times as the calibration progresses.

   "Panel Calibration Complete" is displayed when the process is finished. Click **OK**.

Collimators Calibration

It is recommended to perform the Collimators Calibration annually to ensure optimal image quality. This calibration is also necessary if a mechanical adjustment is made to the Beam Limiter or if image quality has degraded. The Panel Calibration must be performed prior to this. The Collimator Calibration runs in both Portrait and Landscape positions and takes less than 3 minutes to complete.

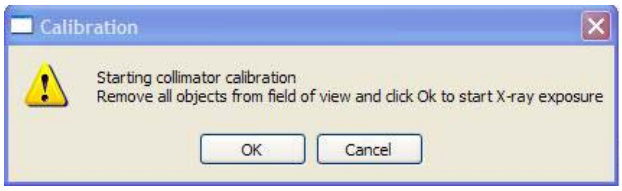
Perform Collimators Calibration:

7. After performing the Panel Calibration click the **Calibrate** (middle) button in the *Collimators* field.

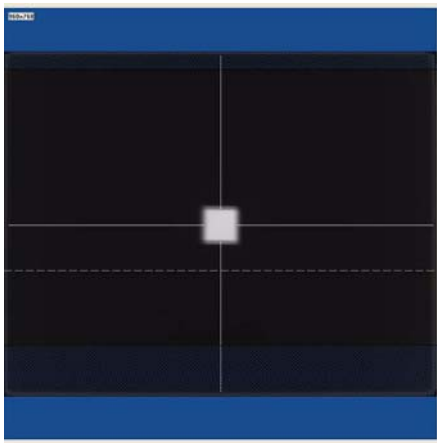
WARNING

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

A window is displayed "*Starting Collimator Calibration Remove all objects from the field of view and click OK to start X-ray exposure.*"



8. Click **OK** to start the X-ray exposure.
9. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
10. The scan starts in the Landscape and continues into the Portrait mode, displaying three screen shots in both modes.
11. Click **OK** when calibration completes (less than 3 minutes)

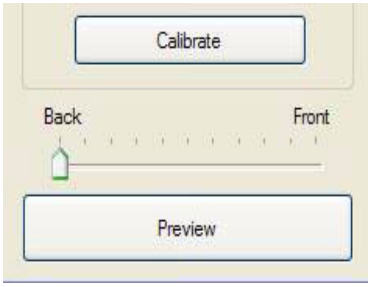


Geometry Calibration

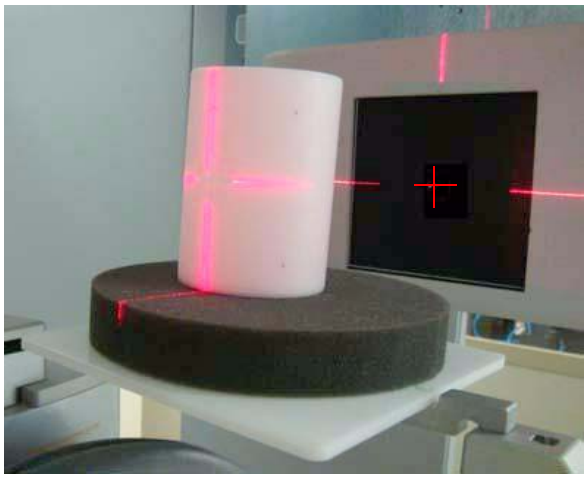
It is recommended to perform the Geometry Calibration annually to ensure optimal image quality or if the image quality is degraded. The Panel Calibration must be performed prior to this. The Geometry Calibration runs in both Portrait and Landscape positions and takes about 12 to 15 minutes to complete.

Perform Geometry Calibration:

12. Use the **Back / Front** feature to ensure the Panel is set to the back.



13. Place BB Phantom on a piece of foam and center the phantom on the platform.



14. Ensure that the BB Phantom is level. Use shims or pieces of paper under the phantom to level it if necessary.
15. Center the BB Phantom (left to right) using the Front Laser.
16. Align the BB Phantom crosshair slits so that the laser beams penetrate through the phantom crosshair slits and appear on the receptor panel.

17. Click the **Preview** button which is located at the bottom of the Calibration screen.

WARNING

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

18. The ready window is displayed, click **OK**.
19. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray light illuminates during radiation exposure.
20. The BB Phantom image is displayed (shown below).

Back (Volume Center)

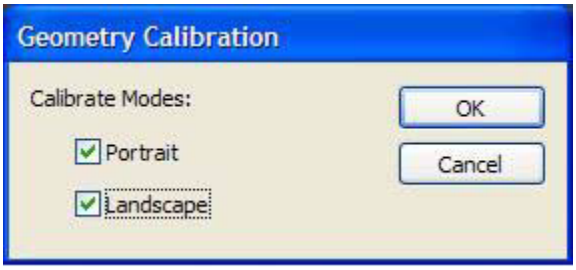
Front (Volume Center)

21. Ensure that the phantom is centered, level, and **all** BBs (dots) appear in the Field of View. If required, make adjustments and click **Preview** again. Repeat as required.

    Height adjustments are made by raising or lowering the phantom platform. BBs should not touch the top or bottom FOV.

22. When the BB Phantom is centered and level, click the **Calibrate** button on the Geometry panel (bottom).

23. Select both the Landscape and Portrait calibrate modes.

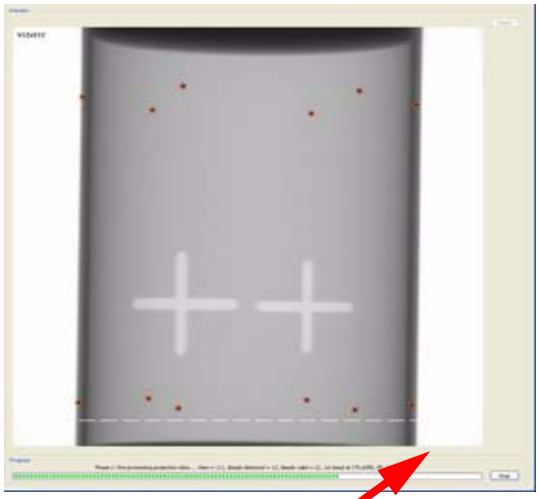


WARNING

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

24. Click **OK** to start the X-ray exposure.
25. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
26. The calibration starts with the Landscape Scan.

LANDSCAPE SCAN



Metal Platform Support (below FOV)

PORTRAIT SCAN

NOTE: Ensure that the metal platform support is below the Field of View (as shown above.)

27. At the start of the scan, red circles are displayed around each BB. At this point, check data (above green progress bar), to ensure the following is displayed:

Beads detected = 12, Beads valid = 12

28. At the prompt, press **Scan** on the Control Box, to start the Portrait Scan.
29. During the Portrait Scan, ensure the following is displayed:

    Beads detected = 8, Beads valid = 8

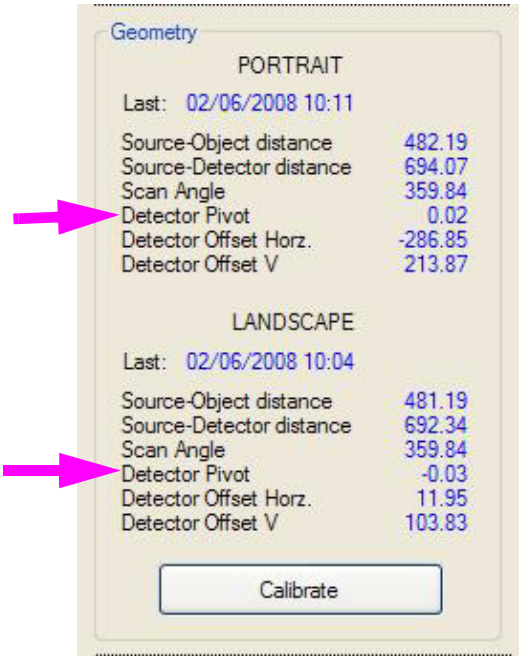
NOTE: Check to ensure that all beads are intact on the BB Phantom, if the calibration did not detect a bead at a certain location.

Checking Detector Pivot:.

30. On the Geometry Calbration screen, check the **Detector Pivot** in both the Portrait and Landscape positions.

    The measurement must fall between: **-0.10 and 0.10**

    Detector Pivot Adjustment (Receptor Panel) on page 9-1, is required if the Detector Pivot is not within tolerance.



31. Click **OK** when the completion window is displayed and restart Vision software.

CAUTION

Failure to restart Vision software at this point may result in a system failure.

Chapter 8 Quality Assurance

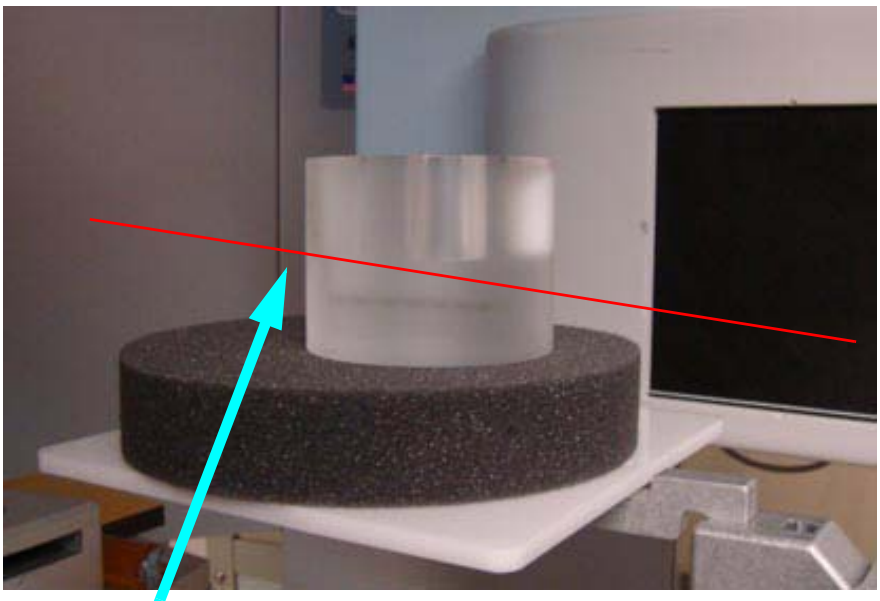
QA Phantom Test

The following Quality Assurance Tests can be conducted by the Owner / Operator of the device. It is recommended that the System Quality Assurance be performed annually or if image quality becomes degraded. For this purpose, the following procedures are provided with a QA Phantom Test and QA Water Test.

This procedure is performed to check the High Contrast Spatial Resolution.

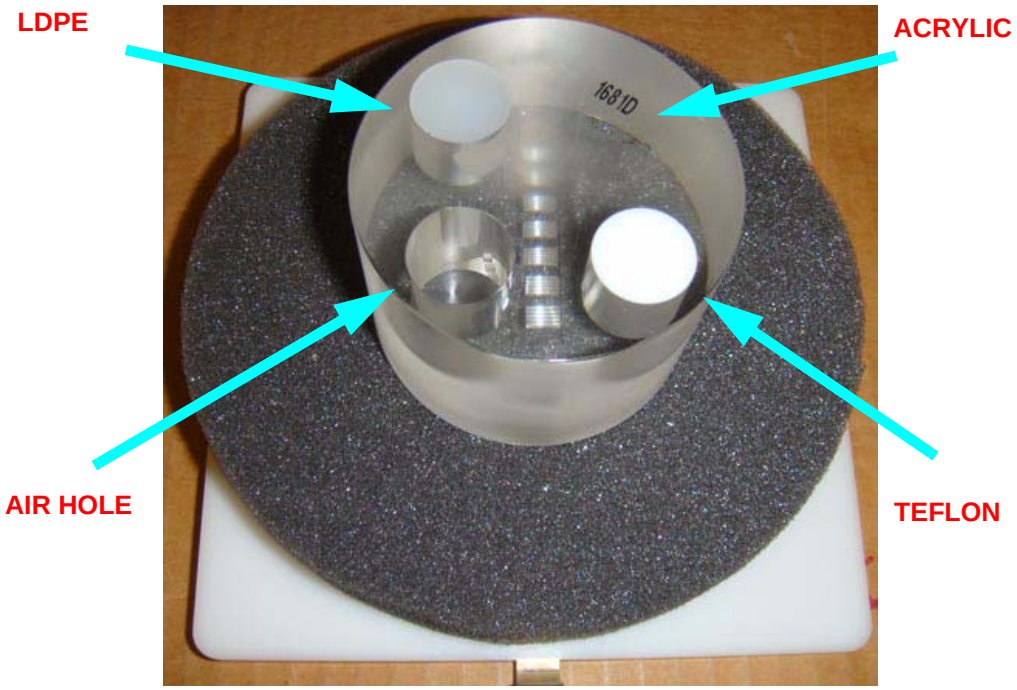
1. Remove Chin Cup and insert Phantom Platform.
2. Place QA Phantom on Platform. Use a piece of foam beneath the phantom to elevate it.
3. Use the alignment lasers to adjust the Phantom Platform height.

   Adjust the height so that the Horizontal Laser is positioned at the center of the QA Phantom.



Horizontal Laser Line Across Center of Phantom

4. Center the QA Phantom on the platform with the Air Hole positioned at the left front of the Gantry (shown below).



5. Start the test by selecting **File > New Patient** from the Main menu.
6. From the Patient Information Panel, click **Add**.

   Enter **QA Test** in the *First Name* field and **Line Pair** in the *Patient ID* field.
7. Click **OK** to close the Patient Information box.
8. From the **Volume** tab, select the following:

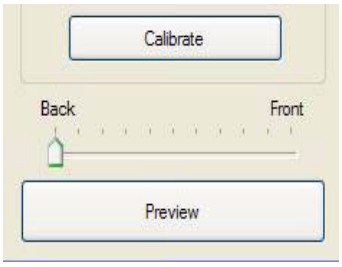
   Size of Reconstruction Volume: **Dia 8.5 - H 8.5 cm**
   Resolution: **.2 voxel**

WARNING

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

9. Click **Preview** to check the phantom position.
10. Click **OK** and press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

11. The Phantom Platform must appear below the Field of View and the Phantom must be centered. Adjust the Phantom Platform to achieve the proper height.
12. To move the phantom to the right or left, use the **Back / Front** feature.



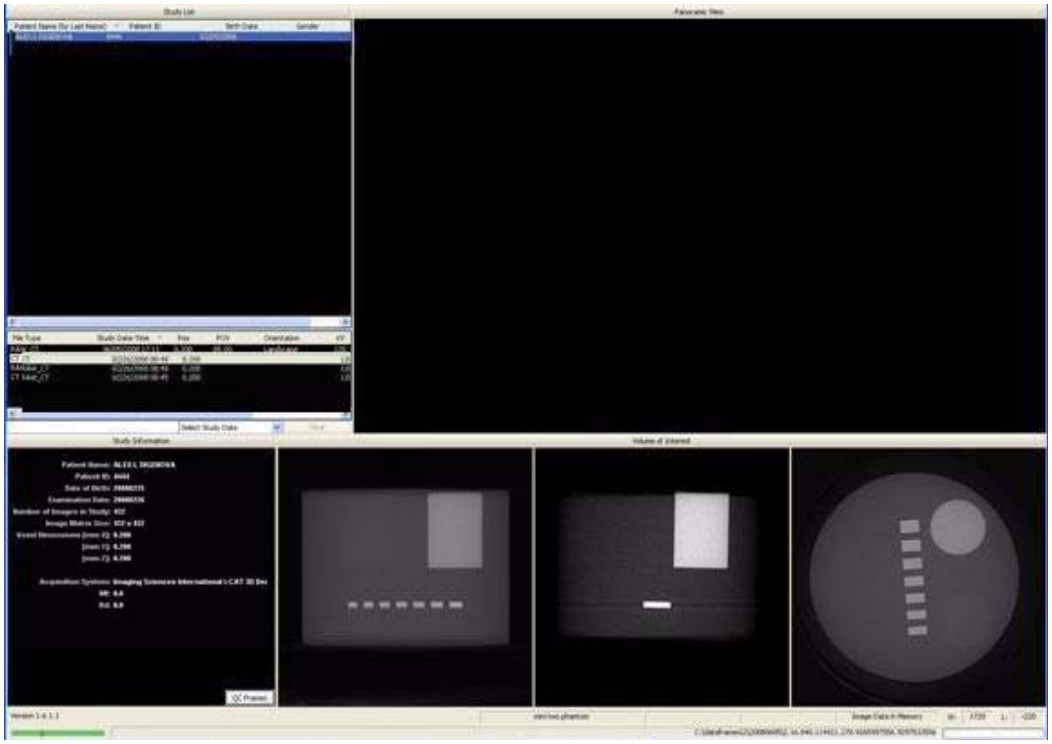
If required, make adjustments and click **Preview** again. Repeat as required.

WARNING

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

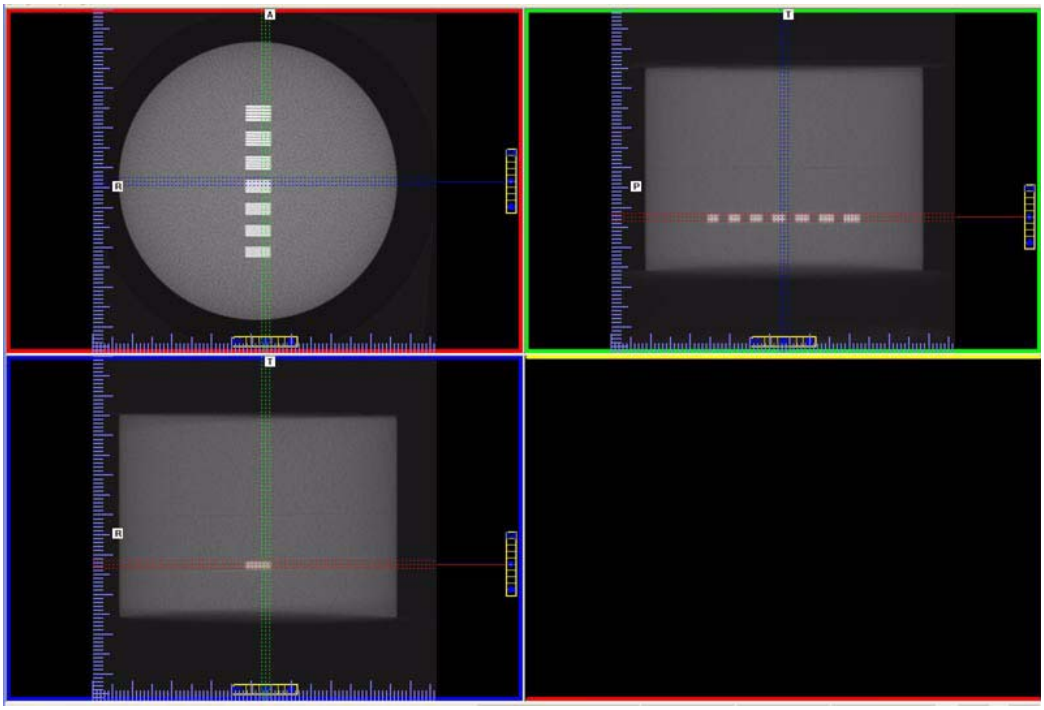
13. Click **Capture** to start the scan process.
14. Click **OK** and press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
15. When the scan is completed, select **NO** when prompted to automatically detect arches.
16. Select **Cancel** at the *Contourline Setup* prompt.

17. The following preview screen is displayed.



Line Pair Evaluation

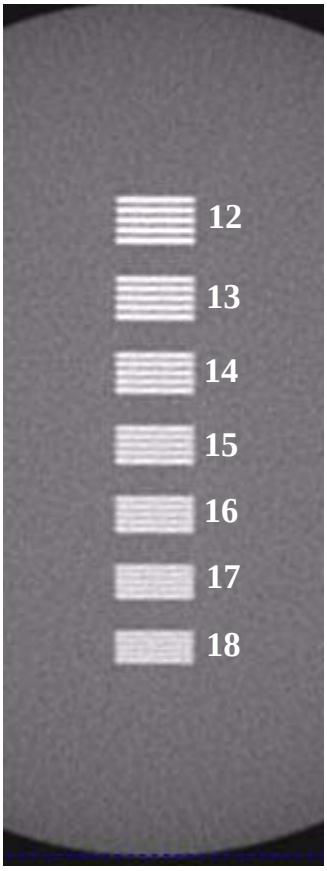
18. Access the QA Test images for evaluation by double clicking **Coronal View** (bottom image, 2nd from the right).
19. The image below is displayed. In the top-right corner view, slide the Vertical and Horizontal lines to the Line Pairs centers as shown below.



20. Zoom Line Pair image (top-left). To zoom, start at the upper right corner of image and hold down left mouse button and drag cursor across the image.
21. Right click the image and select **Set Filter > Hard**.
22. Adjust Brightness and Contrast level for the best image quality. Evaluate the image.

    Line Pair - Line Pairs consists of a resolution of 10 lines per cm (5 dark with 5 light). Line Pairs 12 through 18 are displayed in the image.

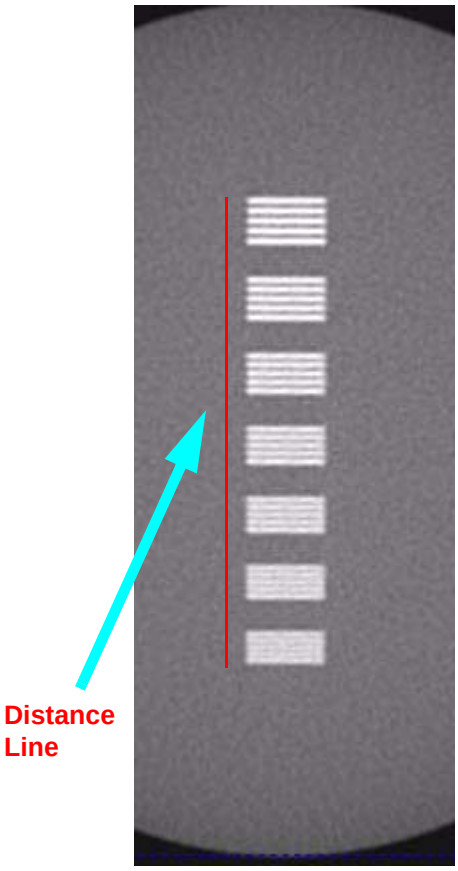
    The picture depicts expected appearance of the **Line Pairs per cm** present within the QA Phantom.
23. Verify that definition is present within line pairs 12, 13, and 14. Compare image quality to the image shown at right.



Distance Measurement Test

To ensure measurement accuracy, this procedure verifies that the Distance tool is functioning properly.

24. Right click view and select **Distance**.
25. Drag the Distance cursor to draw a line from the outside line of set 18 to the outside line of set 12, as shown.
26. The measurement (displayed in upper corner of image) should be between 38 and 39 mm.
27. Call Technical Support, if the measured value is not within this range.



Hounsfield Unit (HU) Measurements

This procedure checks density consistency in various measurements. The positioning and dimension of each Region of Interest (ROI) is very important. Be consistent between each assessment to achieve the minimum deviation.

28. Perform a second scan (described in steps 5 - 16) using the following settings:

    On Patient Information panel:
    Enter **QA Test** in the *First Name* field and **Hounsfield** in the *Patient ID* field.

    On the **Volume** tab:
    Size of Reconstruction Volume: **Dia 8.5 - H 8.5 cm**
    Resolution: **.4 voxel**

29. From the preview scan, access the QA Test images for evaluation by double clicking **Coronal View**. (bottom image, 2nd from the right).

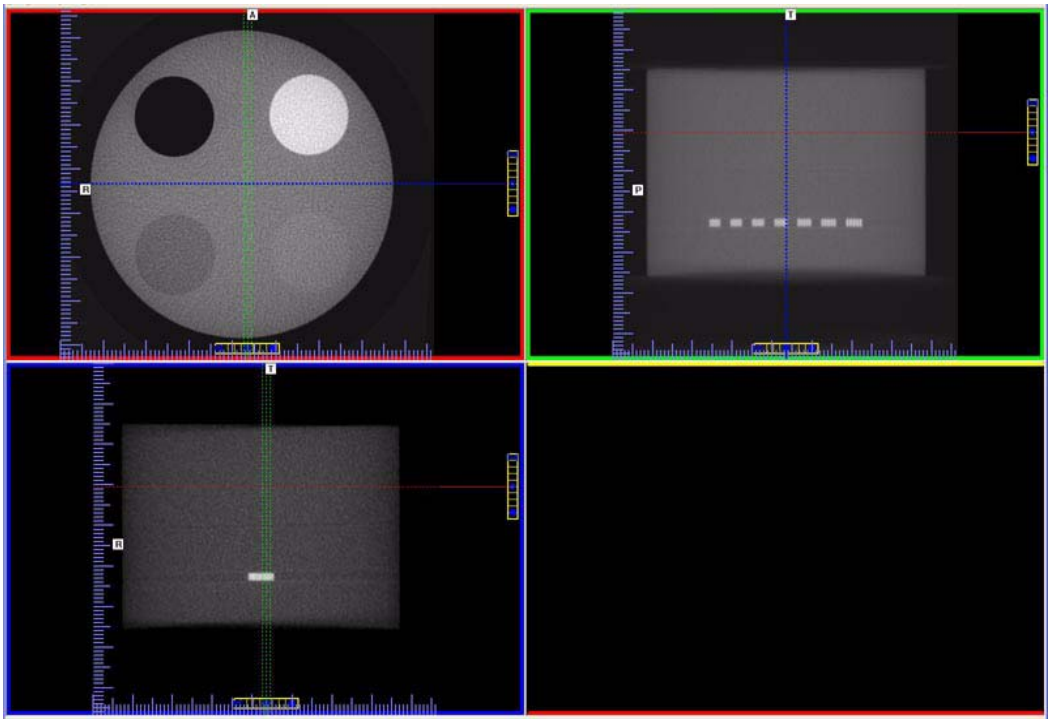
30. In the top-right image of the Coronal View, slide the Horizontal line up to bring the Housfield Unit centers into view. In the top-left image, slide the Vertical and Horizontal lines to the Hounsfield Unit centers as shown below.

31. Zoom the top-left image. To zoom, start at the lower right corner of the image and hold down left mouse button and drag the cursor across the image.

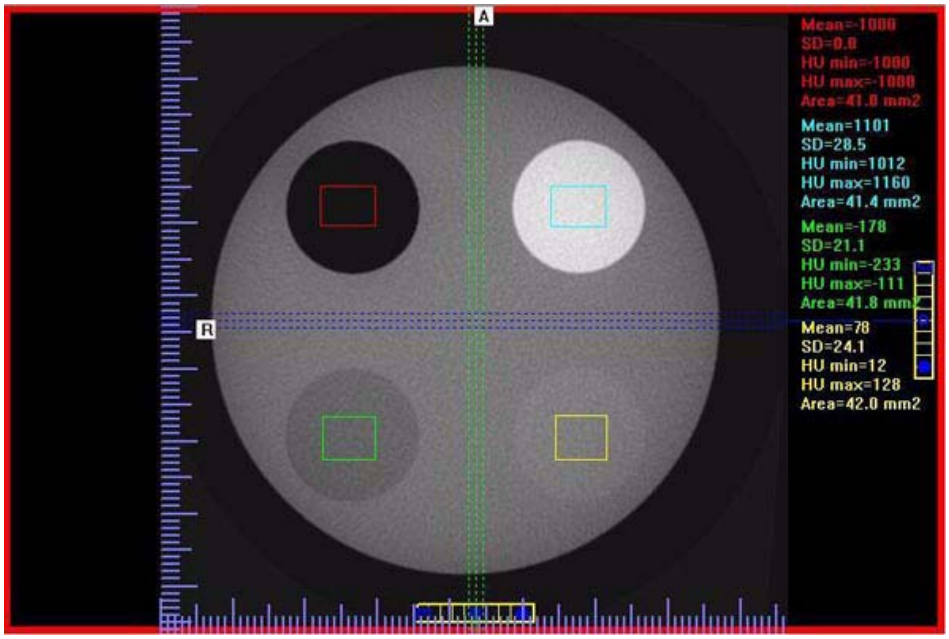
    For consistency, ensure that the slice selection to be measured is setup as follows.

    a. Right click top-left image and select **Set Filter > Normal**

    b. At the bottom of the top-right image scale, click and hold the cursor on the ● symbol. The slice thickness is displayed. Slide the cursor up to change the value to 0.4 mm.



c. Move the position of the slice to the middle of the phantom on the top-left image as shown below.



32. Right click the image and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).
33. Area of ROIs should be at least 40mm^2 but less than 46mm^2.

    Use the Region Tool to define a ROI in the center of each circle of material implanted within the QA phantom.
34. Record the Hounsfield value of each material. See table below.

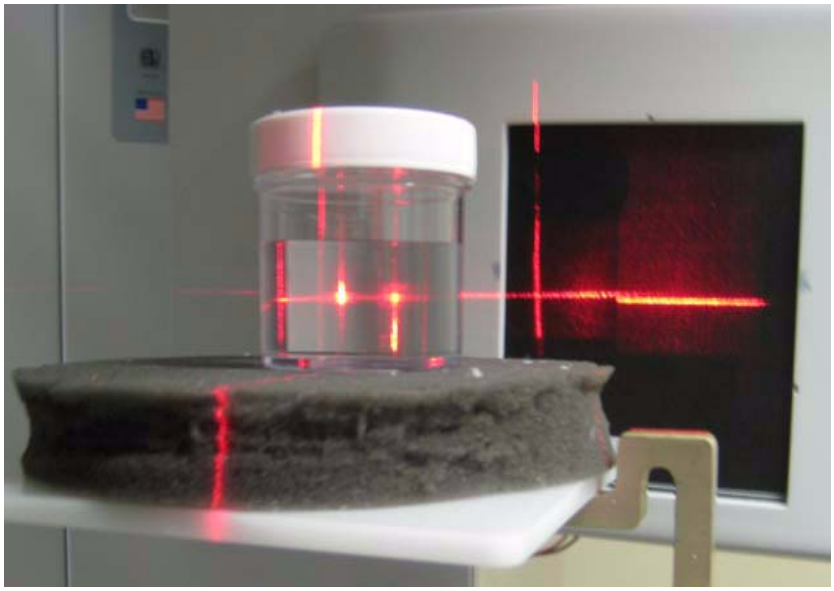
Material	Mean Scan Value (Hounsfield Units)	Lower Limit	Upper Limit	Mean
Air (Black)		-1000	-980	-990
Acrylic (Light Gray)		75	125	100
LDPE (Dark Gray)		-175	-115	-145
Teflon (White)		1055	1205	1130

35. Call Service, if any of the four measured values exceed the Lower or Higher limit.

QA Water Phantom Test

The Water Phantom Test is a noise level and uniformity test which uses both water and air as a measuring tool. It is important that the Water Phantom provided is used for these tests.

1. Remove Chin Cup and insert Phantom Platform.
2. Fill Phantom with distilled water to a level between 60 and 75% of the container height.
3. Place a plastic or foam layer on top of platform. Place Phantom on top of layer.
4. Level Phantom with a spirit level and non-metal shims, if necessary.



5. Using the Alignment Lasers, center the water bath with the horizontal laser across the center of the water depth.

Noise Level Test in Landscape Mode

6. Start test by selecting **File > New Patient** from the Main menu.
7. From the Patient Information Panel, click **Add**.

Enter **Water Calibration** in the *First Name* field and **Noise Test Landscape** in the *Patient ID* field.

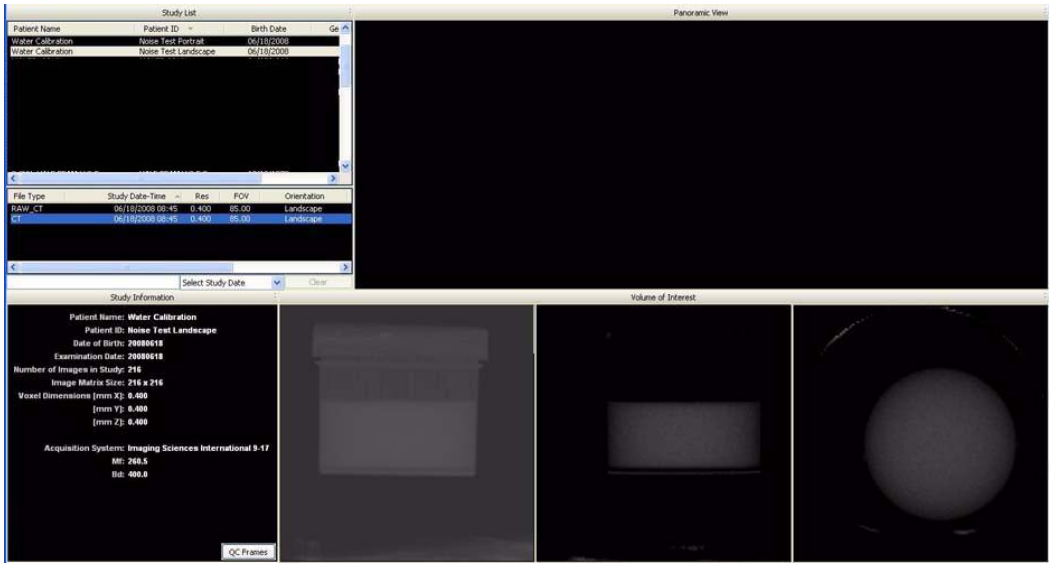
8. Click **OK** to close the Patient Information box.
9. From the **Volume** tab select the following:

   Size of Reconstruction Volume: **Dia 8.5 - H 8.5 cm**
   Resolution: **0.4 voxel**

WARNING

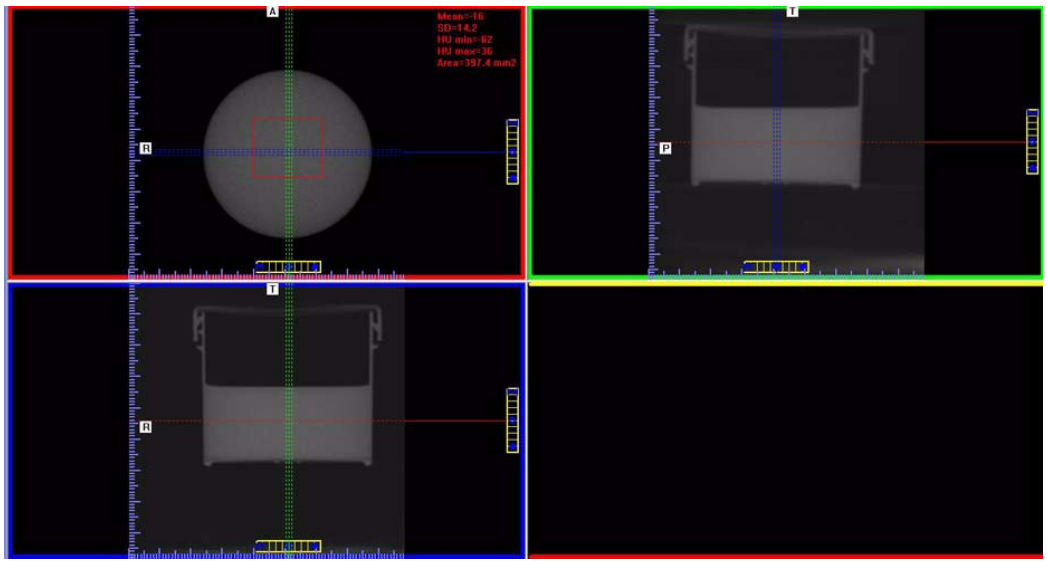
The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

10. Click **Capture** to start the scan process.
11. Click **OK** at the prompt to continue.
12. Press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.



13. At the Contourline prompt, select **No** and **Cancel**.
14. Access the HU measurement image for evaluation by double clicking **Coronal View** (bottom image, 2nd from the right).
15. In the top-right image of Coronal view, slide the Horizontal line to the middle of the water height.

16. At the bottomof the top-right image scale, click and hold the cursor on the ● symbol. The slice thickness is displayed. Slide the cursor up to change the value to 0.4 mm.



17. In the top-left screen, right click the image area and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

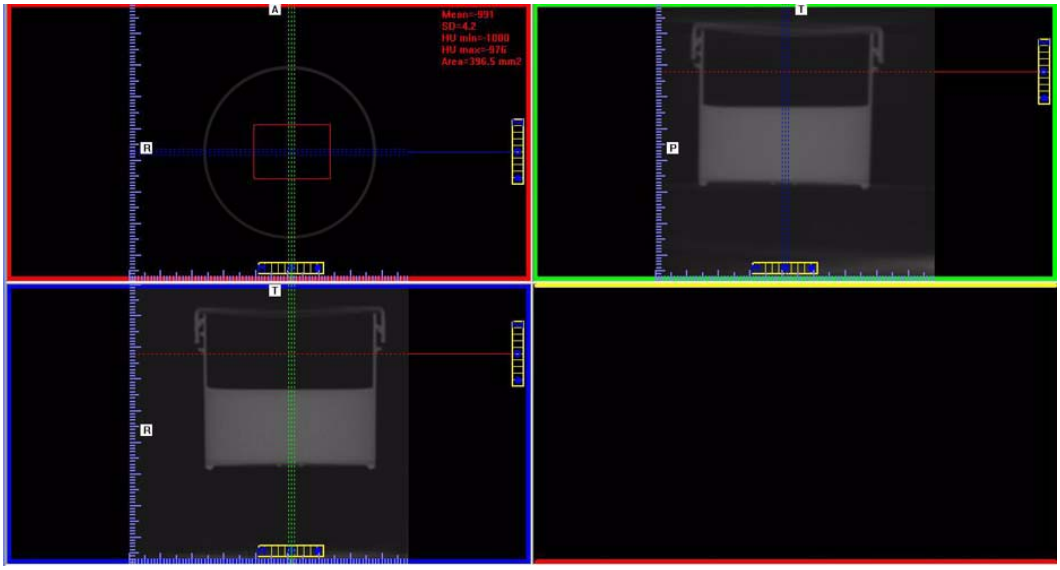
    Use the Region Tool to define a ROI (Region of Interest) in the center of Water, as shown above.

    HU Area (box size) should be approximately 400.0 mm^2

18. Record the Water HU Mean and Standard Deviation values in the table below.

19. Right click the HU measurements and select **Remove all Measurements**.

20. In the top-right screen, move the red dotted line upward, so the line is located at the top of the phantom, above the water level.



21. In the top-left screen, right click the image area and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

    Use the Region Tool to define a ROI (Region of Interest) in the center of Air, as shown above.

    HU Area (box size) should be approximately 400.0 mm^2

22. Record the Air HU Mean and Standard Deviation values in the table below.

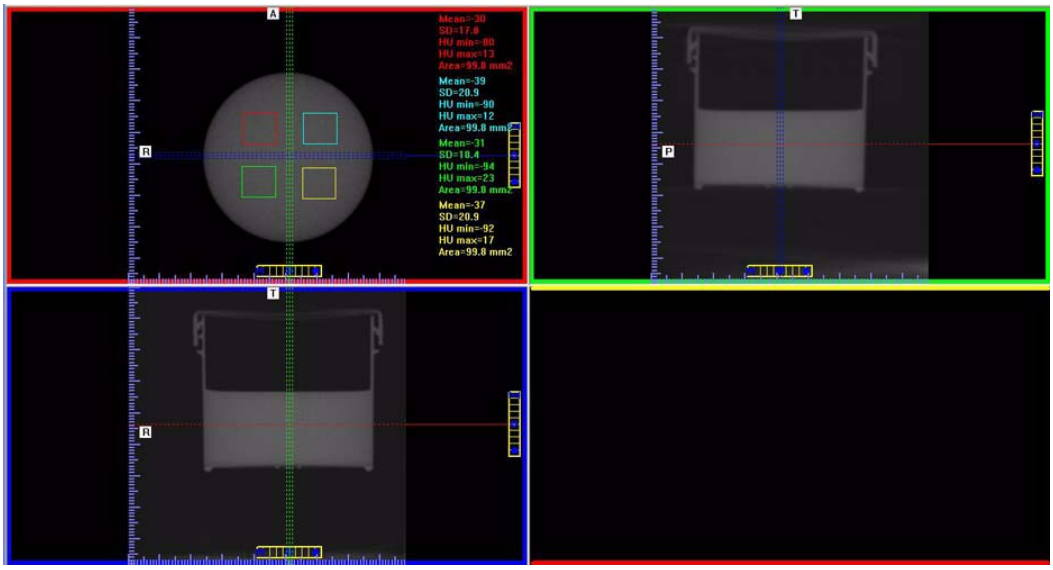
Measured Values	**Water**	**Air**
Mean		
Expected Values	0 (-70 to +70)	-1000 (-930 to -1000)
SD		

23. Right click the HU measurement and select **Remove all Measurements**.

Uniformity Test in Landscape Mode

The Uniformity Test is to ensure that image density measurements are consistent in all areas within the Field of View.

24. Move the red, green, and blue dotted lines to the center of the water (all screens) as shown below. Use the Center Line Positioning tool to make these adjustments**.**



25. Right click the image and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

    Use the Region Tool to define a ROI (Region of Interest) in four areas of Water, as shown above.

NOTE: Only four regions can be displayed at one time. Creating a fifth region overwrites the first.

The HU Area (box size) should be approximately 100.0 mm^2.

26. Note and record the Mean and SD values of the four regions. See chart below.
27. After recording values, **a fifth ROI is required from the center of the water area**. The fifth measurement replaces the first measurement, since four measurements are the limit.

28. Note and record the Mean and SD values of the center ROI.

Measured Values	Upper Left	Upper Right	Lower Left	Lower Right	Center
Mean					
SD					

Subtract each **Mean Value** from the **Mean Value** of the center ROI. If any difference is **greater than 90**, make sure phantom is correctly centered in FOV and re-measure. If the difference is still **greater than 90**, call Technical Support.

29. Right click the HU measurement and select **Remove all Measurements**.

Noise Level Test in Half-Beam Mode

30. Start test by selecting **File > New Patient** from the Main menu.
31. From the Patient Information Panel, click **Add**.

    Enter **Water Calibration** in the *First Name* field and **Noise Test Half-Beam** in the *Patient ID* field.
32. Click **OK** to close the Patient Information box.
33. From the **Volume** tab select the following:

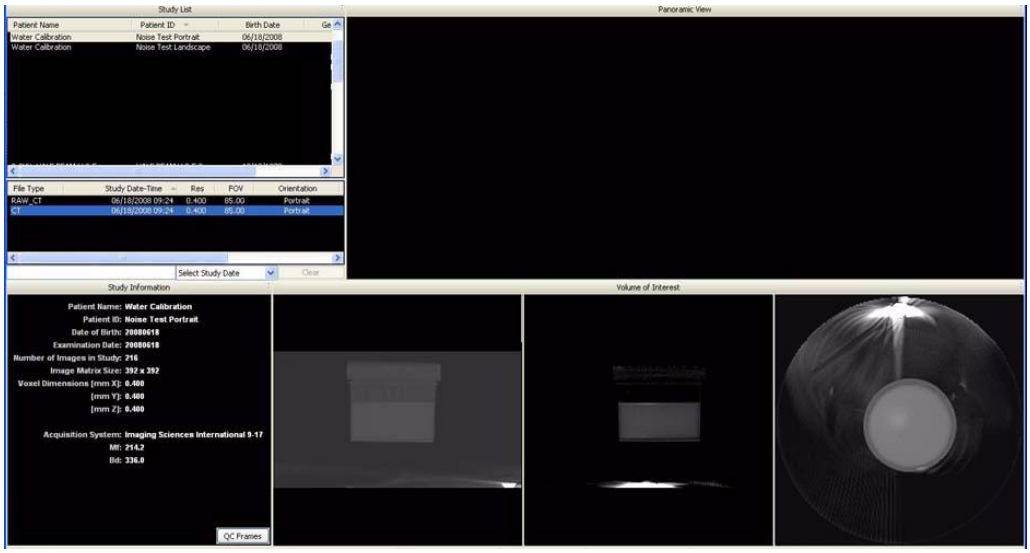
    Size of Reconstruction Volume: **Dia 14 - H 8.5 cm**
    Resolution: **0.4 voxel**

WARNING

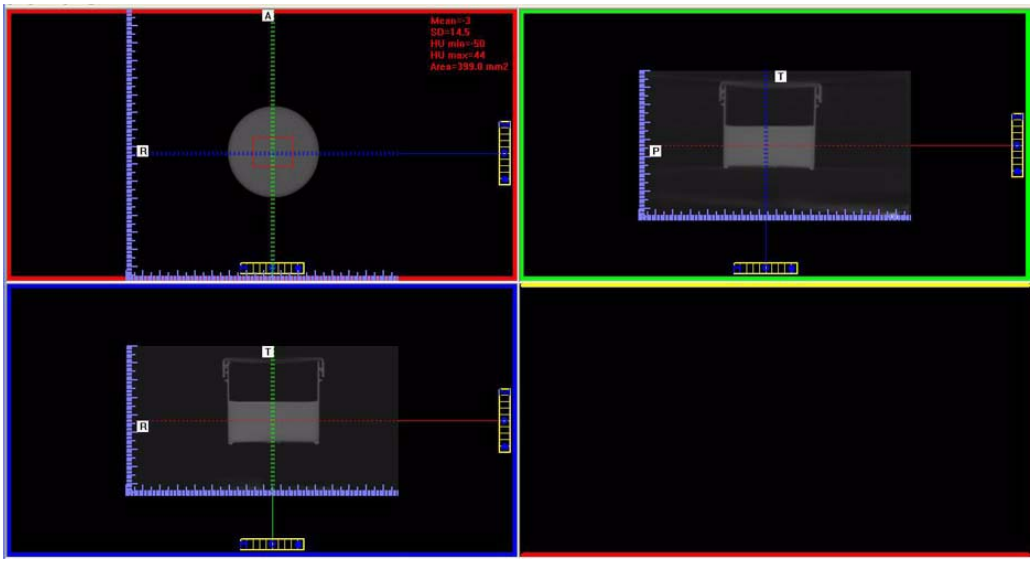
The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

34. Click **Capture** to start the scan process and **OK** at the prompt to continue.
35. Press the **Scan** button on the Control Box when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

36. At the Contourline prompt, select **No** and **Cancel**.



37. Access the HU measurement image for evaluation by double clicking **Coronal View** (bottom image, 2nd from the right).
38. In the top-right screen, slide the Horizontal line to the middle of the water height.
39. At the bottomof the top-right image scale, click and hold the cursor on the ● symbol. The slice thickness is displayed. Slide the cursor up to change the value to 0.4 mm.



40. In the top-left image, right click the image area and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

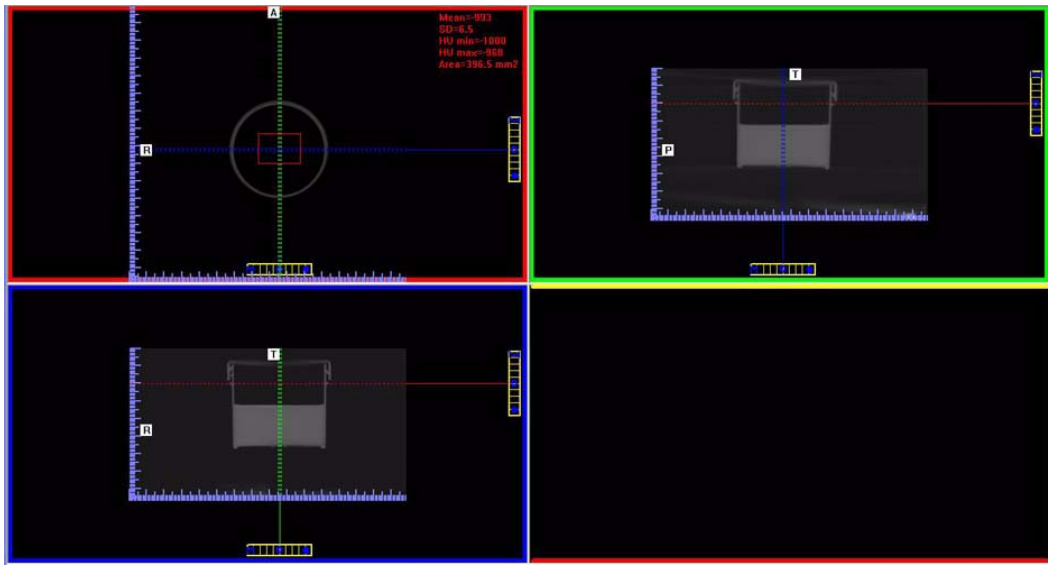
    Use the Region Tool to define a ROI (Region of Interest) in the center of Water, as shown above.

    HU Area (box size) should be approximately 400.0 mm^2

41. Record the water HU Mean and Standard Deviation values in the table below.

42. Right click the HU measurement and select **Remove Measurement**.

43. Move the red dotted line upward (top-right screen) so the line is located at the top of the phantom, above the water level.



44. In the top-left image, right click the image area and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

    Use the Region Tool to define a ROI (Region of Interest) in the center of Air, as shown above.

    HU Area (box size) should be approximately 400.0 mm^2

Record the air HU Mean value in the table below.

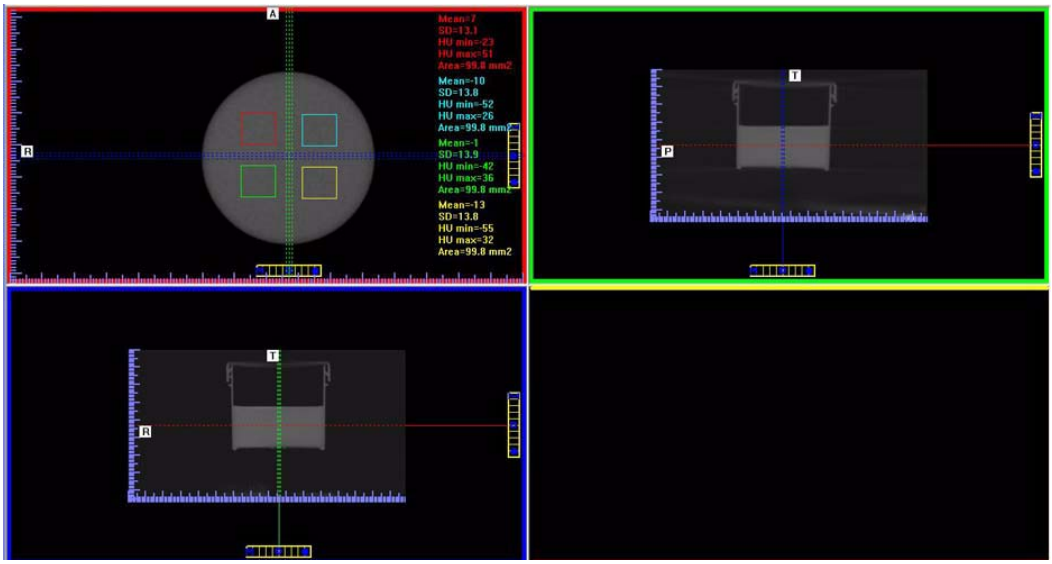
Measured Values	Water	Air
Mean		
Expected Values	0 (-70 to + 70)	-1000 (-930 to -1000)
SD		

45. Right click the HU measurement and select **Remove Measurement**.

Uniformity Test in Half-Beam Mode

The Uniformity Test is to ensure that image density measurements are consistent in all areas within the Field of View.

46. Move the red, green, and blue dotted lines to the center of the water (all screens) as shown below. Use the Center Line Positioning tool to make these adjustments**.**



47. Right click the image and select **HU Statistics** from the menu (also, right click to turn off HU Statistics).

    Use the Region Tool to define a ROI (Region of Interest) in four areas of Water, as shown above.

NOTE: Only four regions can be displayed at one time. Creating a fifth region overwrites the first.

The HU Area (box size) should be approximately 100.0 mm^2.

48. Note and record the Mean and SD values of the four regions. See chart below.
49. After recording values, **a fifth ROI is required from the center of the water area**. The fifth measurement replaces the first measurement, since four measurements are the limit.
50. Note and record the Mean and SD values of the center ROI.

Measured Values	**Upper Left**	**Upper Right**	**Lower Left**	**Lower Right**	**Center**
Mean					
SD					

Subtract each **Mean Value** from the **Mean Value** of the center ROI. If any difference is **greater than 90**, make sure phantom is correctly centered in FOV and re-measure. If the difference is still **greater than 90**, call Technical Support.

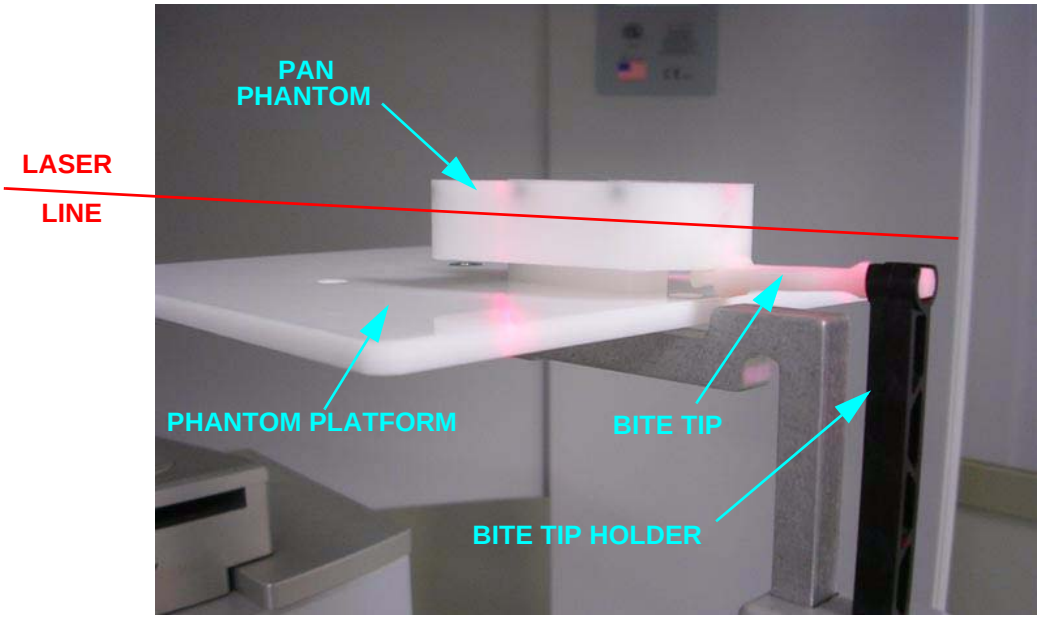
PAN Phantom Test

PAN Phantom Test is used to validate the PAN scan data capture.

To perform a PAN Phantom Test:

1. Prepare the Bite Tip by inserting the narrow edges of the Bite Tip down into the Bite Tip Holder uprights. Then turn the Bite Tip a 1/4 turn to lock into place.
2. Insert the Phantom Platform and Bite Tip Holder into the Positioning Block. The Bite Tip should rest on top of the platform.
3. Place PAN Phantom on platform with balls facing up and top of arch resting on Bite Tip.
4. Press the Alignment Light button on the Patient Alignment Panel to display lasers. Use the Horizontal Laser to adjust the height of the phantom as shown below. Use the Vertical Laser to center the phantom on the platform.

   Lasers are available while the Volume tab is selected (not PAN).



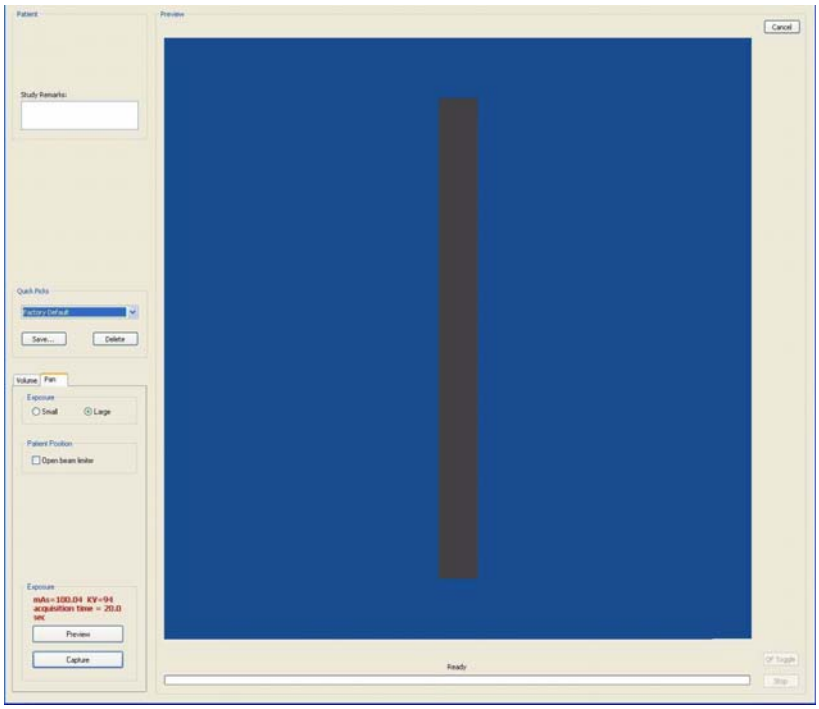
5. Start test by selecting **File > New Patient** from the Main menu or right click an existing image from database and select **Acquire New Scan**.
6. From the Patient Information Panel, click **Add**.

Enter **PAN Test** in the *First Name* field and **QA** in the *Patient ID* field.

7. Click **OK** to close the Patient Information box.
8. Click the **Pan** tab in the Acquisition window and select, *Exposure:* **Large**
9. Click the **Capture** button to start the test.

WARNING

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



10. The system moves approximately 1/4 rotation to the Home Position and then displays the scan parameters.
11. Click **OK** to start the scan process.
12. Press **Scan** button on Control Box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

13. The PAN scan runs a few minutes and then displays the reconstructed image.

14. Adjust the Brightness/Contrast by dragging the cursor across the image (vertical/horizontal). All seven metal balls should become visible as shown below.

Good Image Quality

15. The image above is an example of a system properly aligned for PAN scanning. All but two of the metal balls are circular in shape.

Poor Image Quality

16. The image above is an example of a system that is not properly aligned for PAN scanning. This is easily seen by the fact that only two metal balls are circular. Elongation of the Metal Balls indicate that the phantom is not in the middle of the focal trough due to poor chair alignment.
17. Check chair alignment if all seven balls do not appear circular.

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.

1. Attach a dosimeter to the detector such that the sensor is positioned where the vertical (coronal) and horizontal (axial) lasers intersect.
2. Perform a standard 8.9 second, 8.5 diameter,14 cm, 0.4 voxel scan and record time and dose from meter.

Measured Dose

The table below shows measurements performed on the detector for a Landscape mode standard scan.

Tube Potential (kV)	**120**
Selected Scan Time (seconds)	**8.9**
Number of Frames	**309**
Approximate Exposure Time (seconds)	**5.7**
Displayed mAs	**28.52**
Measured Exposure at Detector (mR)	**325.5**
Measured Exposure at Detector / mAs (mR/mAs)	**11.41**
Measured Exposure at 1m (mR/mAs)	**5.28**
Measured Dose at 1m (μGy/mAs)	**46.23**
Dose at Detector per Frame (μGy/fr)	**9.23**
Tube Output (μGy/mAs @ 1m)	**46.23**
Distance Source to Detector (cm)	**68.0**
Conversion Factor for Absorbed Dose (R to Gy)	**0.00876**

Interpretation

1. The dose per frame at the detector may be calculated by:

   Dose per frame at Detector = Dose at Detector / Number of Frames

   Where Number of Frames = 309 for 8.9 second scan

   = 619 for 23.0 second scan

2. The tube output per mAs may be normalized to 1m using the inverse square law for the purposes of assessing consistency of tube output:

$$\text{Tube Output } (\mu\text{Gy/mAs}) = \frac{\text{Dose at Detector} \times (\text{Source to detector distance})^2}{\text{Displayed mAs}}$$

Where Source to detector distance = 0.68m for the system.

Chapter 9 Troubleshooting and Adjustments

Detector Pivot Adjustment (Receptor Panel)

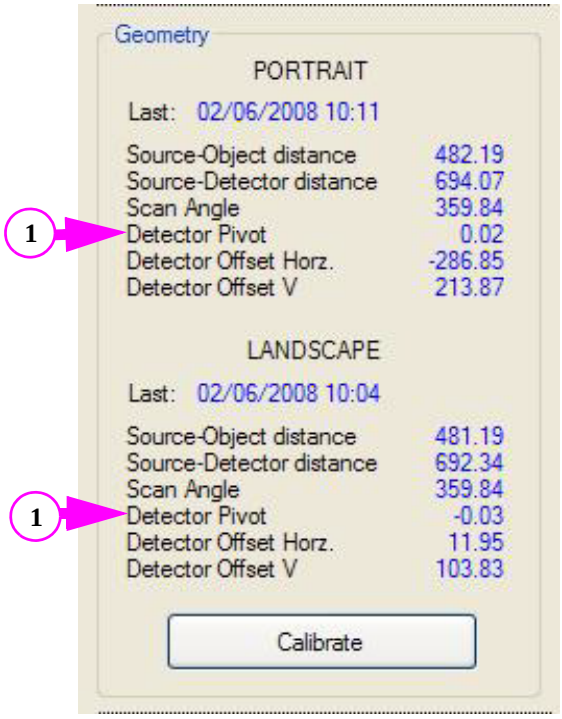
The Receptor Panel must be on level-plane as the Source Panel in both the Portrait and Landscape positions. The Geometric Calibration shows if the Receptor Panel is properly aligned.

Checking Detector Pivot:.

1. On the Geometry Calibration screen, check the **Detector Pivot** in both the Portrait and Landscape positions.

   The measurement must fall between:
   -0.10 and 0.10

If a Pivot Detector adjustment is required:



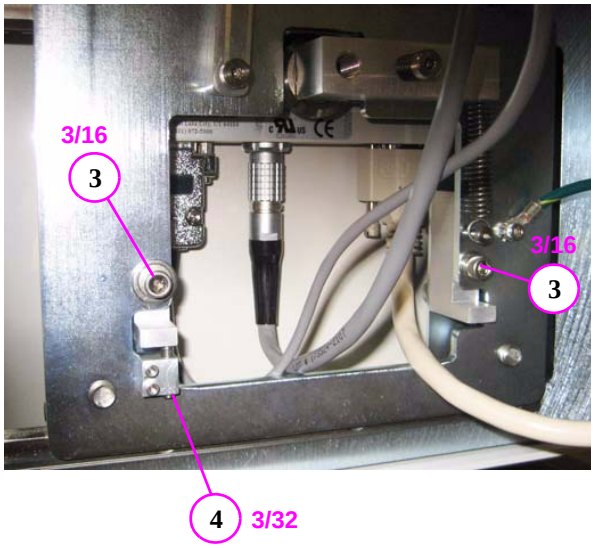
2. Remove two mounting screws from the top and bottom and remove Receptor Cover.

3. On the Receptor Assembly, loosen the two panel mounting screws.
4. One Leveling Screw is used to adjust the Detector Pivot for both Landscape and Portrait simultaneously.

   Turning the Leveling Screw one full turn is an adjustment of **.4**

   A **clockwise** adjustment **adds** to the displayed number.

   Counter-clockwise subtracts from the displayed number.



5. Tighten the mounting screws after the adjustment is made.
6. Install Receptor Cover.

IEC IC Command Codes

Home Commands

HB Home Beam Limiter
(HB = 0, 0, 0, 0 All four shutters completely open)

HFR Homes gantry and sets position to 100000

HP Homes gantry and sets position to 1500

HSR Quick home check if the machine is already homed

Movement Commands

MB Move Beam Limiter right left top bottom
Enter command as **MB** X X X X where X is:
(right left and bottom shutters range: 0 – 2600)
(top shutter range: 0 – 3300)

Example: MB 700 700 3000 1500

MP Move Platform [target] [speed]
Enter command as **MP** X X where X is:
(target range: 1500 – 100000, speed range: 1000 – 54000)

Example: MP 1500 1500

MPM Target Speed.
Enter command as **MPM** X X where X is:
Target or Position: between 0 - 90 mm (home position is zero - absolute)
Speed: between 1000-54000

Example: MPM 20 1500

MPP Position type, moves receptor panel's position.
Enter command as **MPP** X X where X is:
Position: 0 or 1 (Landscape or Portrait/Halfbeam)
Type: 0 or 1 (Platinum or Nano)

Example: MPP 1 0

MR Target Speed.
Enter command as **MR** X X where X is:
Target: between 35000 - 733333
Speed: between 1000 - 65000

Example: MR 35000 1000

MRD Target Speed.
Enter command as **MRD** X X where X is:
Target: between -40 - 430 degrees (home position is equal to zero degrees - absolute)
Type: between 1000 - 65000

Example: MRD 180 1000

Read Commands

RB Read beam position
returns right left top bottom shutter positions

RD Read Door Status: 1 -Open and 0 -Closed

RE Read Exception Register

Exceptions

1 Emergency Stop activated
2 Stall Detected
4 X-ray Tube Short
8 X-ray Watchdog Timeout
16 Linux Watchdog Error
32 X-ray Fault from X-ray Controller
64 Platform needs to be Homed
128 Rotation needs to be Homed
256 Beam Limiter Not Initialized
512 Machine is Turned Off
1024 Door Interlock was Opened During an X-ray Exposure
2048 Ethernet Cable Communication Failed During an X-ray Exposure
4096 The Panel Position error - both limit switches are reading high or low

RI Read Input Register to the RI

Read Input Command - returns the 21 bit input register with the following definition:

1 Emergency Stop
2 Machine On Switch
4 Machine Off Switch
8 Scan Enable Button Status
16 Error from X-ray Controller
32 Encoder Direction

64 Rotation Optical Switch Status
128 Rotation Limit Switch
256 Rotation Start of Travel Status
512 Rotation End of Travel Status
1024 Platform Start of Travel Status
2048 Platform End of Travel Status
4096 Door Signal
8192 Panel Horizontal (Landscape)
16384 Panel Vertical (Portrait)
32768 Machine Power Status
65536 Right Shutter Limit Switch
131072 Left Shutter Limit Switch
262144 Top Shutter Limit Switch
524288 Bottom Shutter Limit Switch
1048576 Moving Signal for Panel Flip Motion
2097152 Moving Signal for Rotation Motion
4194304 Moving Signal for Platform Motion

RMS Read usage time of selected item
Returns xxxxdxxhxxmxxs

- **0** Beam Limiter Motors
- **1** Embedded Board
- **2** Panel
- **3** Platform Motor
- **4** 24V Power Supply
- **5** Rotation Motor
- **6** X-ray
- **7** Flipper Motor

RP Read Platform position

RPP Read Panel Position

- **0** Error
- **1** Landscape mode
- **2** Portrait mode
- **3** Error

RR Read Rotation position.

RX Read X-ray Setup
See SX command for argument description.
0 = 120KV Range **1** = 90 KV Range
If no parameter is entered, then the command assumes 0.

SP Sets platform position - Sets the counts of the platform.
Must be less than 65000.

SR Sets rotation position - Sets the counts of the rotation.
Must be less than 733333.

SX Set X-ray
kvp, ma, frame rate, xrayon, xrayoff, panel readout, panel_mode
Enter command as **SX** X1 X2 X3 X4 X5 X6 X7 X8 where X is:
X1 specifies kV = 80 - 126 in increments of 2 only.
X2 specifies mA = 0-2. 0=3mA, 1=5mA, 2=7mA
X3 specifies frame rate = in between 50000000 - 833333 => 50 MHz/frame rate (1-60 frames/sec)
X4 specifies X-ray on = typically set to 1 and between 0 - (frame rate - 1)
X5 specifies X-ray off => greater than X-ray on and less than (frame rate - 1) 5000 =1 msec (set as needed for desired length)
X6 specifies Panel Readout = Typically set the same as the X-ray off (except for continuous X-ray mode) in between 0 - (frame rate - 1)
X7 specifies Panel Pulse mode (0 or 1) (if not entered, defaults to 0).
0 - 20 microsecond pulse for panel readout and valid frame.
1 - either a 5msec pulse for valid frame or 3msec for panel readout
X8 specifies the tube 0 = 120 KV tube, 1 = 90 KV tube
Example: SX 120 1 3333333 1 780000 780000 0
If X7 and X8 are not specified, both are assumed to be zero.

X-Ray Commands

XP Frames
Maximum limit capped by the 44 second x-ray watchdog
Number of frames: 1 - 1024
Ethernet Watchdog 0 = disabled, 1 = enabled
(Number of frames*Frame Rate) <44 seconds

Miscellaneous Commands

GS Read System Information
Machine Version, Hardware Version, Software Version
Beam Limiter Version, Machine Serial Number

CS Cancel Scan.
Cancels a scan.

CE Clear Exception Register.
Clears all exceptions except for error that require initialization.

WSB Enable Scan Button.
Enables the scan button to initiate a scan.

Chapter 10 Wall Mount Control Box

The Control Box is configured for desktop usage but can be modified for wall mounting access.

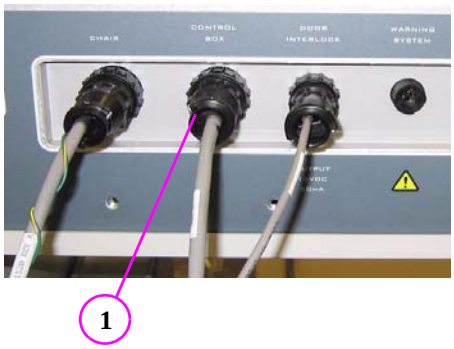
Desktop

Wall Mounted (cable exposed)

Wall Mounted (cable inside wall)

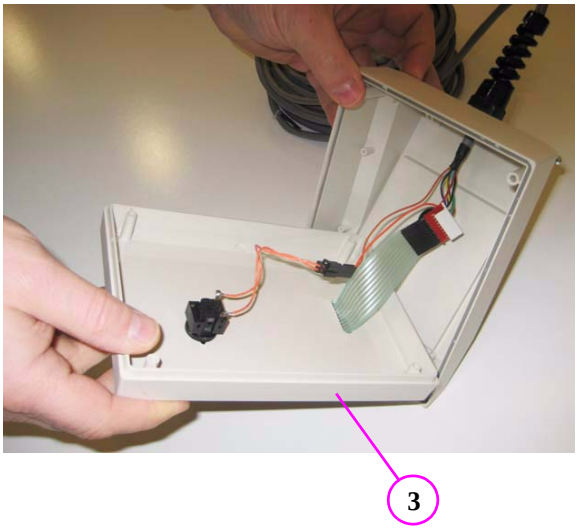
Wall Mount with Cable Exposed

1. Control Box cable is to be disconnected from rear of Overhead Panel.

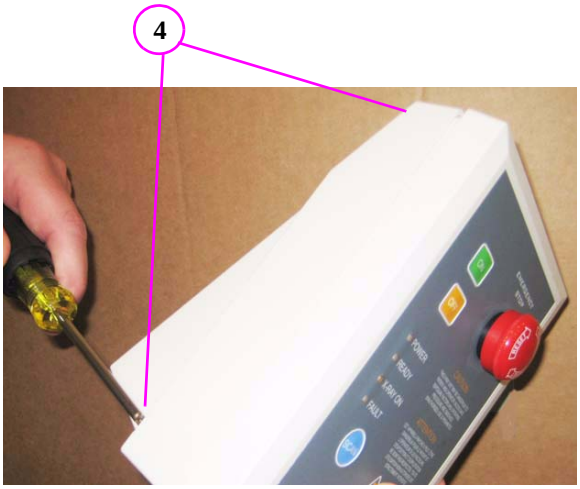


2. Using a fine tip Phillips screwdriver, loosen four mounting screws on rear of Control Box.

3. Rotate Control Box face plate 90°, being careful not to over extend the ribbon cable.

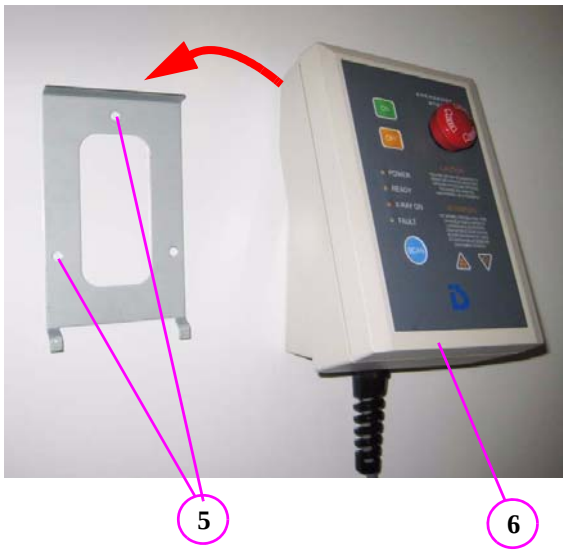


4. Tighten four mounting screws.



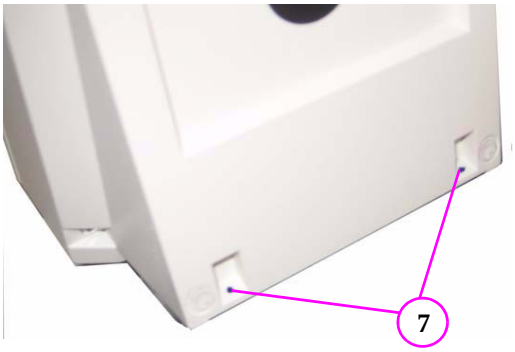
5. Mount Wall Bracket, using supplied mounting hardware (3 places).
6. Hang Control Box onto wall mount bracket.

   The Control Box can be lifted from the wall for mobility. For a stationary mount see next procedure.



For a Stationary Mount

7. Draw center marks in the two tab slots at the rear of the base.
8. Drill two 3/32” pilot holes.

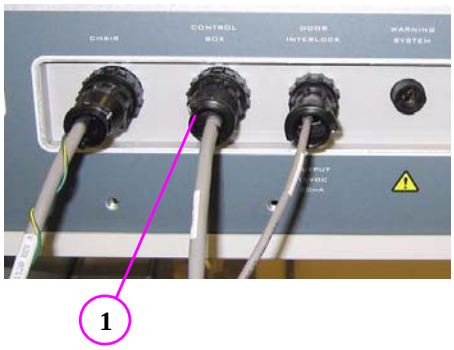


9. With the Control Box positioned on wall bracket, install the two self-tapping screws (supplied with wall bracket).

   Refer to install diagram (supplied with wall bracket).

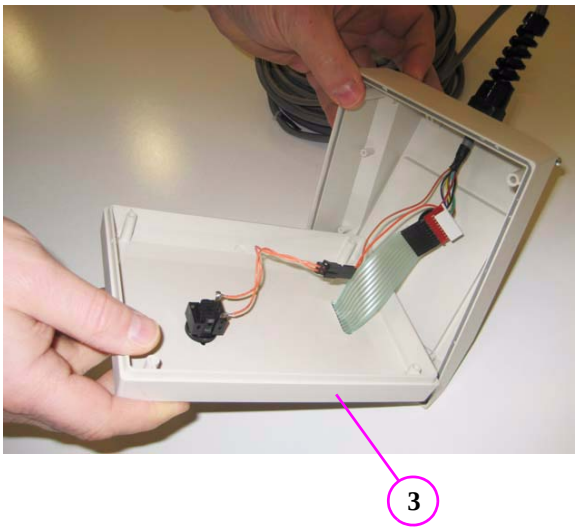
Wall Mount with Cable Inside Wall

1. Control Box cable is to be disconnected from rear of Overhead Panel.

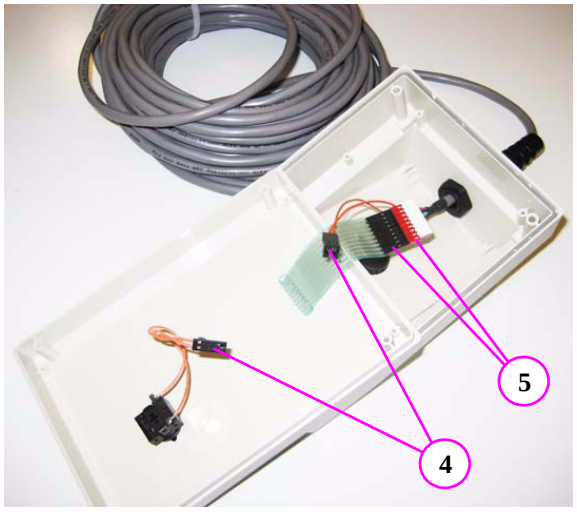


2. Using a fine tip Phillips screwdriver, loosen four mounting screws on rear of Control Box.

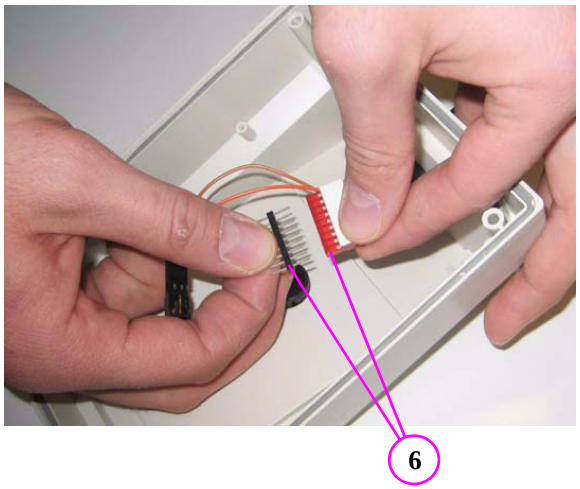
3. lift the face panel from the base, being careful not to over extend the ribbon cable.



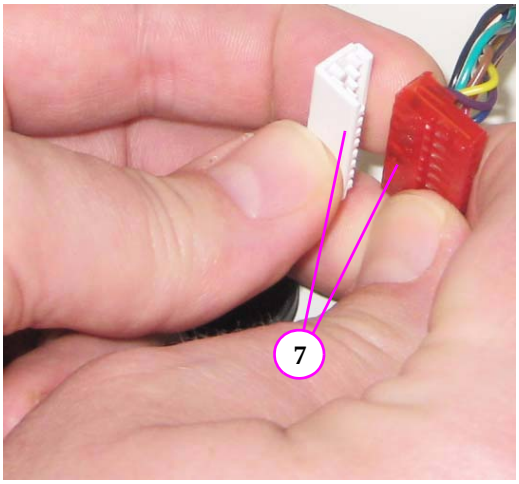
4. Disconnect the Emergency Stop wires by simply pulling the black connectors apart.
5. Disconnect Ribbon Cable by pulling the black and red connectors apart.



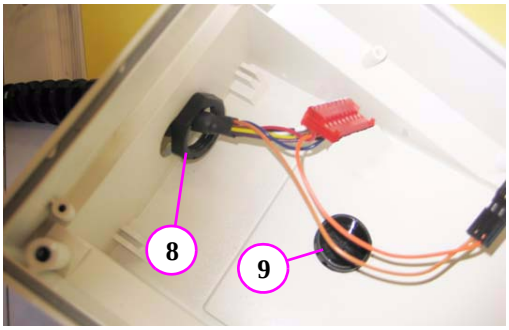
6. Remove pin assembly from red connector.



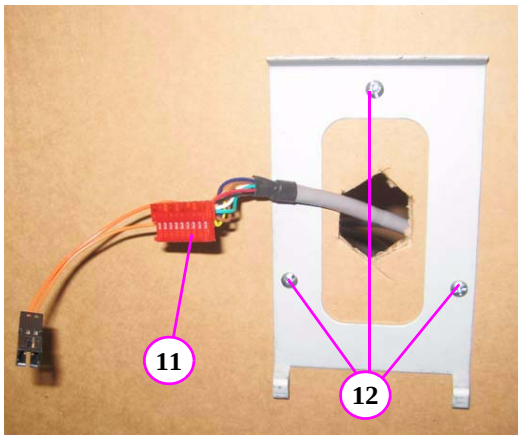
7. Snap-off white plastic cap from red connector.



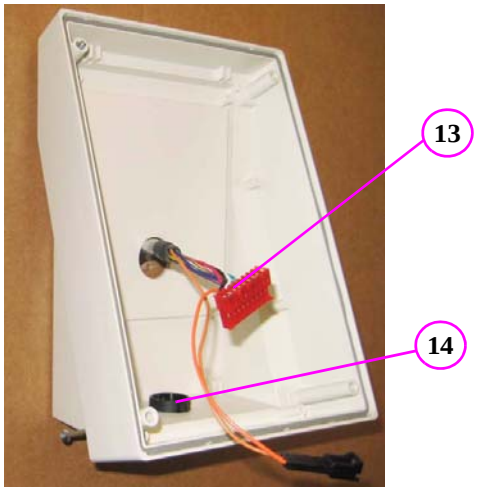
8. Loosen and remove plastic retaining nut from strain relief.
9. Remove black insert from base.
10. Remove cable from Control Box by carefully feeding connectors thru the access hole.



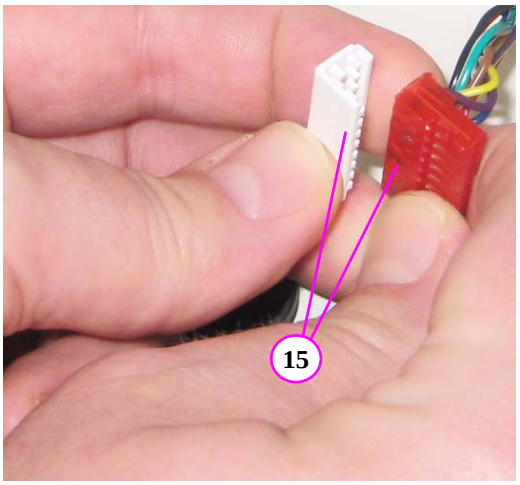
11. Protect wires and connectors by wrapping them in electrical tape if feeding this end thru the wall.
12. Mount Wall Bracket, using supplied mounting hardware (3 places).



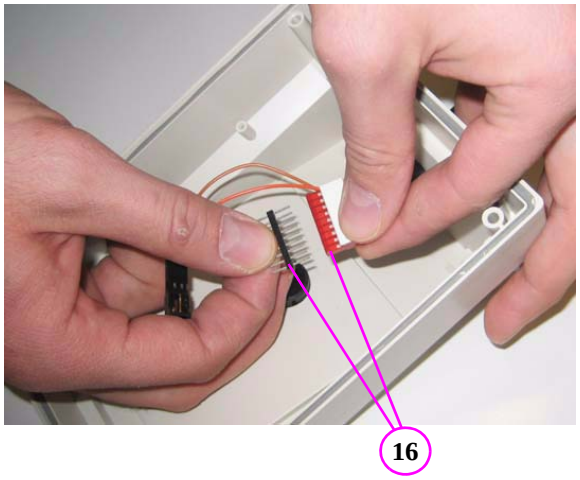
13. Feed cable thru Control Box base.
14. Insert black hole plug in bottom of Control base (hole plug that was previously removed from back of base).



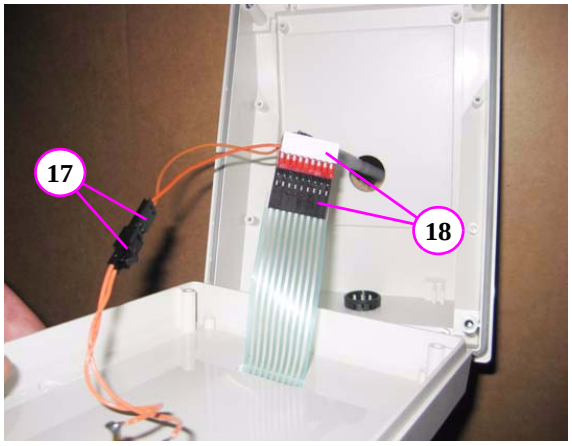
15. Snap-on white plastic cap to red connector.



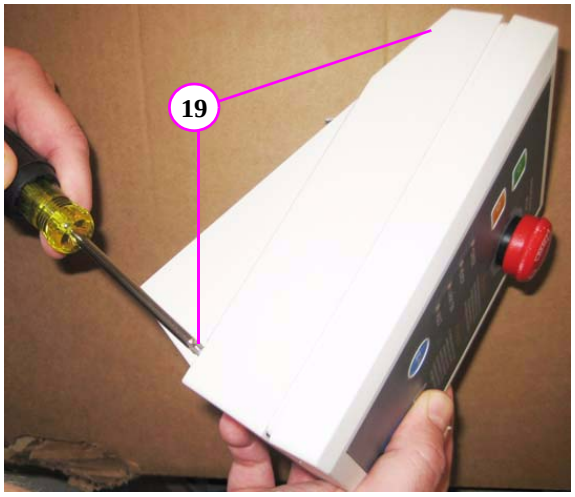
16. Insert pin assembly into red connector.



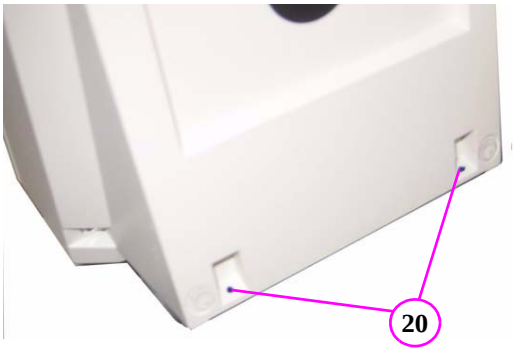
17. Connect black connectors.
18. Connect ribbon cable. Ensure that the white cap on the red connector and the smooth side of the black ribbon connector are facing up as shown.



19. Secure Front Panel to the base by tightening the four mounting screws.



20. To secure the Control Box to the wall, draw center marks in the two tab slots at the rear of the base.
21. Drill two 3/32” pilot holes.



22. With the Control box positioned on wall bracket, install the two self-tapping screws (supplied with wall bracket).

    Refer to install diagram (supplied with wall bracket).

Chapter 11 Networking Support Setup

Networking Support Overview

Networking support within VisionQ and standalone Vision creates a convenient mechanism for sharing image data within an office or clinic. Using network storage provided and maintained by the customer, system software monitors the connection and allows scanning to proceed even if the network is temporarily broken. Then, the software will automatically update the server with new patient scans when the connection is restored.

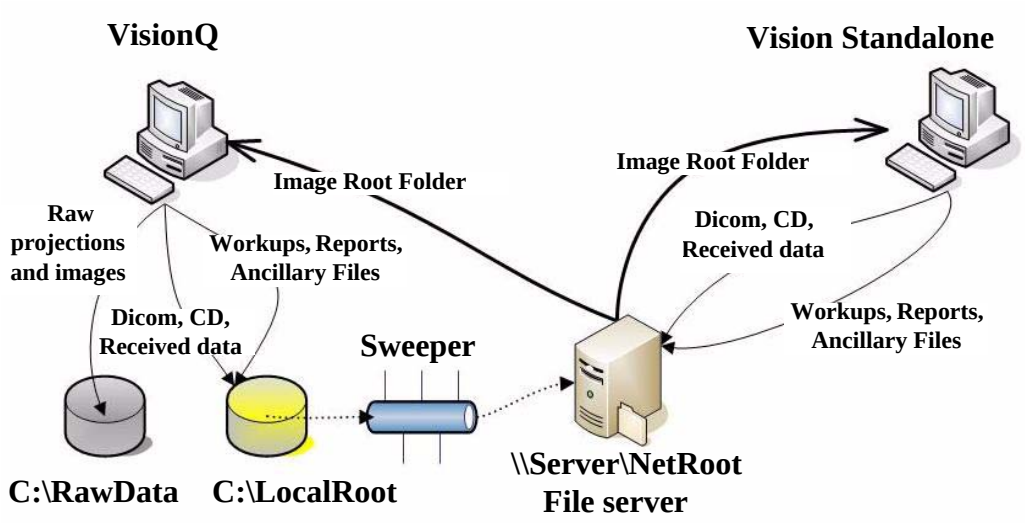
NOTE: The customer is responsible for providing the network accessible storage at their location, including security, backup, and archive functions.

Networking Data Flow

When the Image Root Folder is set to a location on the local disk, networking software is automatically disabled, and all data acquisition goes to the local disk. But if the Image Root Folder is setup on a remote network shared folder, acquired data flow is altered somewhat and networking software takes part in the flow. In this case, VisionQ stores newly-acquired, DICOM-format projection data (RAW_CT) and reconstructed images (CT) on its local disk (in C:\LocalRoot), *regardless* of the Image Root Folder setting. If a study is immediately viewed or manipulated, that work is also saved locally. At the same time, the networking software's background Sweeper service automatically tries to copy this new data to the designated Image Root Folder.

For VisionQ and standalone Vision, the Study List displayed on the left side is derived from the Image Root Folder on the network server. Previously-acquired studies are also manipulated from that location. Because of this, there is a delay from the time an acquisition or reconstruction completes to the time when the study is displayed on the Study List.

Note that changes made to studies on the network by a standalone Vision are not transferred back to the VisionQ local disk.



If network breaks, VisionQ cannot access Study List, but can continue to scan patients.

If network breaks, Vision cannot access Study List. Network must be restored.

Network Support Installation/Setup

Provide Network Storage

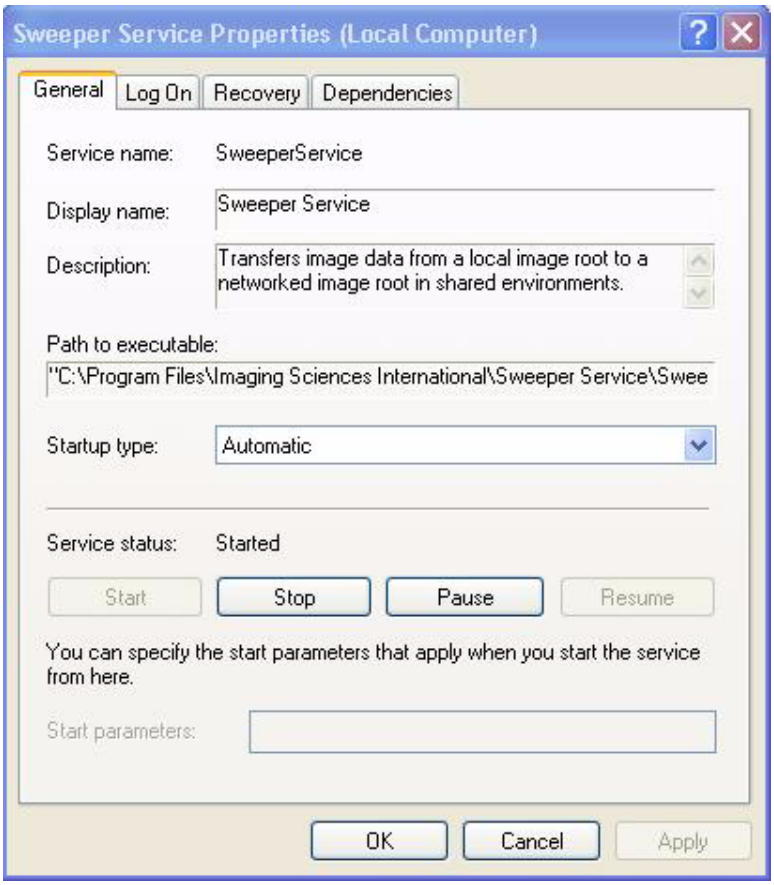
The customer is required to provide network storage that is accessible to the user. To verify proper operation, log in as the system operator and use Windows Explorer to navigate to the intended networked shared folder, using \\server\folder syntax. Create a new text document, enter text into it, save it, and then delete it. Do not proceed unless this succeeds.

Install Sweeper Service

1. Double-click the SweeperSetup icon in the ProgramFiles\Imaging Sciences International\iCAT Software folder to execute the program. A setup wizard is displayed.
2. Click **Next** on all wizard screens to install the Sweeper service.
3. When complete, click **Close** on the Installation Complete screen.

Configure Sweeper Service

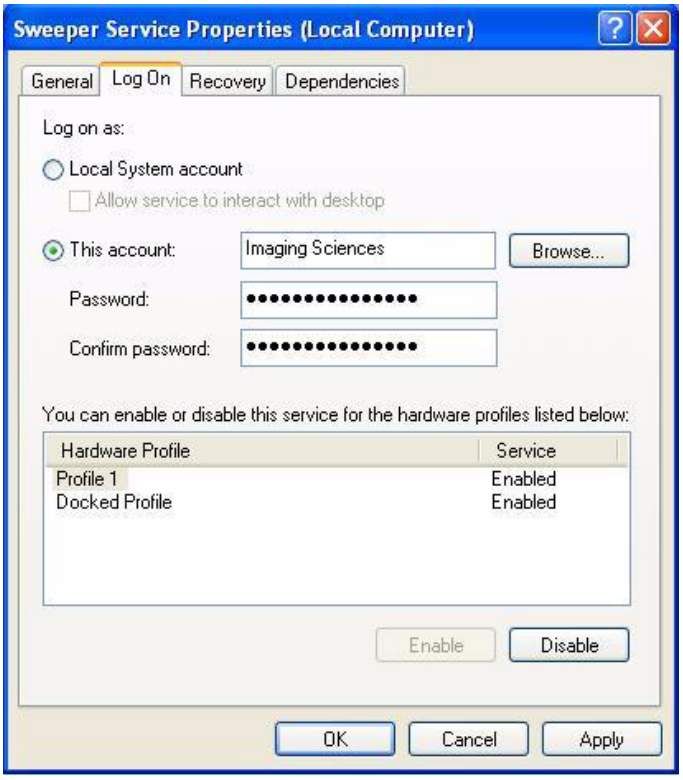
1. Access **Control Panel > Administrative Tools > Services** and double-click Sweeper Service.
2. On General tab, confirm Startup type is set to Automatic.



3. Click Log On tab:
   a. Click **This account** radio button.
   b. Enter and confirm an account and a password.

NOTE: Be sure to use the same account that was used to log on to the computer.

c. Click **OK**.



Migrate from Standalone to Server

NOTE:

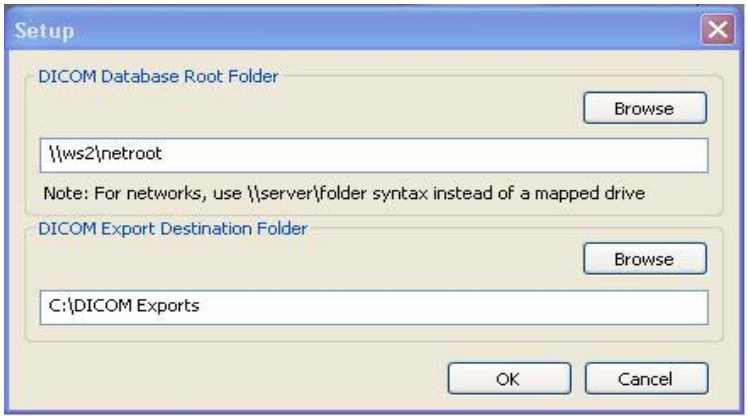
- Perform this procedure only if upgrading or migrating from an existing standalone setup.
- If the existing network setup shares a portion of the local disk of theVisionQ computer, it is still considered standalone and this procedure should be followed.

1. Using the Sweeper controller, stop the Sweeper service if it is running or paused.
2. Start VisionQ and reconstruct any scans that have not yet been reconstructed.
   a. Make a note of the standalone Image Root Folder name using **Tools > Setup**. (It is probably C:\DATAFRAMES.) Do not change the name at this time.
   b. Exit VisionQ.

3. Using Windows Explorer, navigate to the Image Root Folder and delete any files named proj0000.raw, proj0001.raw, ..., proj2000.raw.
4. If a folder named **bak** is present in the Image Root Folder, the proj0000.raw files in it, as well as the bak folder itself, can be deleted.
5. Check that the folder C:\LocalRoot does not exist. If it does exist, check if it is empty. If it is empty, remove it. If it is not empty, call Technical Support for help. Continue only when C:\LocalRoot does not exist.
6. Using Windows Explorer, change the name of the Image Root Folder to C:\LocalRoot.

Change Image Root Folder

1. From VisionQ or standalone Vision, select **Tools > Setup**.



2. Under DICOM Database Root Folder, enter or browse for the Image Root Folder on the network server and click **OK**. Use Universal Naming Convention syntax, such as \\server\NetRoot, to identify the network location and not a mapped drive syntax.

Start the Sweeper

Start the Sweeper service. After 30 seconds, it will start transferring any prior scan data to the server. Watch it for a few minutes in case there are any network or configuration problems.

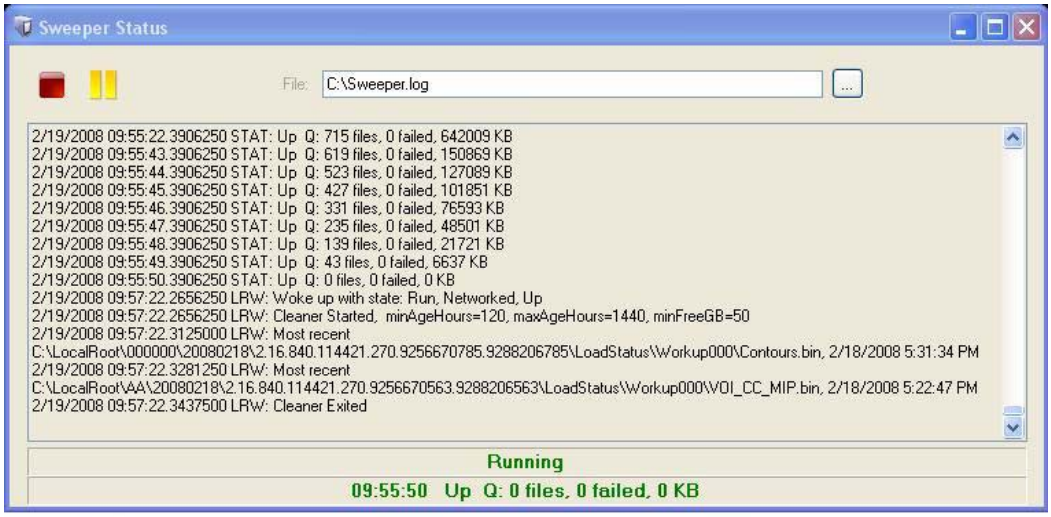
Sweeper Service

The Sweeper service starts automatically on system power-up and stops on system shutdown. It copies any changed files from the local disk (C:\LocalRoot) to the network Image Root (but only if the local file is bigger than its network counterpart.) It retries failed transfers when the network is up. The Sweeper service will suspend data copying and declare itself "Down" if the network disk has less than 1 GB of free space. It will automatically resume when more space is made available by the user.

The Sweeper service periodically cleans the local disk by deleting all studies older than 60 days. If there is less than 50 GB of free space available on the local drive, the oldest study that is at least 5 days old is deleted. Studies that are less than 5 days old are never automatically deleted.

Sweeper Controller

The Sweeper controller provides the user interface to the Sweeper service and is accessed by clicking the Sweeper icon in the system tray. If the controller screen is accidently closed, click **Start > All Programs > Imaging Sciences > SweeperController.exe** to restore it.



The Status screen allows the user to start/stop and pause/resume the Sweeper service. It displays the Sweeper log file C:\Sweeper.log, extracts status from the log, and displays it at the bottom of the screen. It reduces to a system tray icon showing the Sweeper state and a tooltip with the current status.

Working

Idle

Down

09:55:50 Up Q: 0 files, 0 failed, 0 KB

Tooltip shows:
- **Time**
- **Network Status**
- **# of files in Transfer Queue**
- **# of files that Failed at Least Once**
- **# of bytes in Transfer Queue**

Network Failures

In the event of a network failure, the best action is to try to quickly restore the network. If that is not possible, fallback operations are available.

No Network Access at Startup

When VisionQ or standalone Vision is first launched, it tests whether the Image Root Folder is accessible on the network. If it is not, the No Network Access dialog is displayed. Fallback operations differ for VisionQ and standalone Vision.

Fallback Operations For VisionQ

If there is no network access for VisionQ, the best approach is to fix the network. When the network is restored, click **Retry** on the No Network Access screen and continue work as usual.

If network access cannot be quickly restored and scanning must continue:

1. Click **Cancel** to fallback and use C:\LocalRoot.
2. Scan patients.
3. Exit VisionQ and restore the network as soon as possible. Any changes made to studies such as workups, reports, or jpegs will be swept to the server when the network connection is restored.

   NOTE: Fallback is temporary until VisionQ exits unless the user manually changes the setup, which is not recommended.

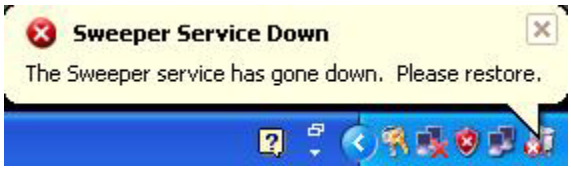
Fallback Operations For Vision

If there is no network access for standalone Vision, it is essential to fix the network because C:\LocalRoot is most likely empty. When the network is restored, click **Retry** on the No Network Access screen and continue work as usual.

Network Fails During Operations

If a network failure occurs during use of VisionQ or standalone Vision, the following occurs:

- The Study List goes blank (since it comes from the server which is no longer accessible.)
- Error messages are displayed in the Sweeper log file.
- The Sweeper icon in the system tray of VisionQ changes to the down state and a balloon is displayed for the state change.



NOTE: Be aware that unsaved workups, reports, or jpegs may be lost as a result of a network failure.

Try to restore the network. If the network can be restored, operations can continue. If the network cannot be quickly restored and scanning must continue, new scans will be safely stored locally, but will not be transferred to the server until the connection is restored. Therefore, new scans will not appear on the Study list, which will remain blank. To see these new scans in the list, exit and follow the fallback operations for VisionQ.

Limitations of Networking Support

Known limitations of networking support are:

- There is a network transfer delay between acquisition or reconstruction, and the appearance of the study on the Study List. Although they may not appear on the list immediately, the images are available for review and workup on the scanner immediately.
- There is no study locking mechanism to prevent two users from simultaneously editing or updating the same study. Clinic workflow must ensure this does not happen. However, if it does occur, only workups, and not patient scan data, are at risk of being lost.
- Unsaved workups, reports, or jpegs may be lost as a result of a network failure that happens during the save operation.

Chapter 12 Remote System Import and Export

Remote System Import and Export Overview

The VisionQ Remote Service application enables the import of patient data from a remote system to Vision Q and enables the export of DICOM images to a remote system from VisionQ. This service functions to reduce data entry redundancy and to synchronize the output generated by VisionQ to a remote system once the study acquisition is completed. The Remote Service application is available to all VisionQ customers.

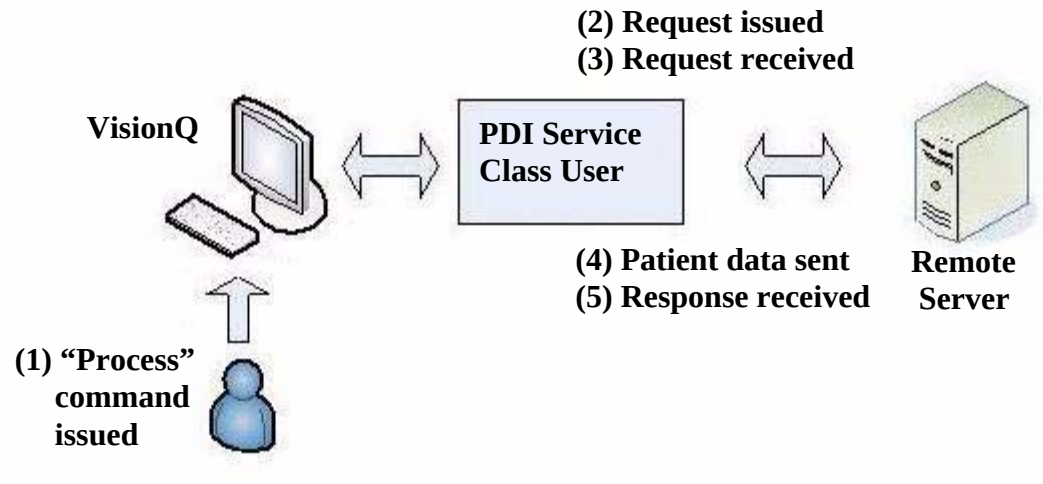
Remote System Import

VisionQ provides two ways to import “scheduled” patient data into the system:

- DICOM Worklist - this interface requests and displays patient records that match the user-specified criteria from the remote DICOM Worklist server.
- Practice Management (PM) - this interface loads and displays patient records from an XML file, generated by the PM server.

Users can choose which of the two interfaces is suitable for their workflow and set up the interface accordingly.

When the VisionQ user selects to import data, the PDI service class user (PDI.dll) issues a DICOM C-FIND request to pull patient records from the remote system. All VisionQ “scheduled” patient records are sent from the Worklist or PM system to VisionQ.



Import Installation and Setup

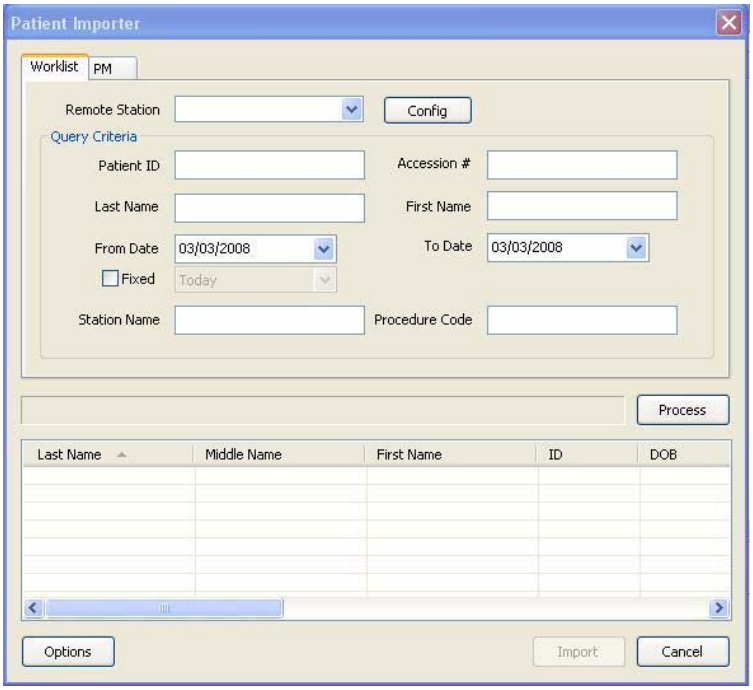
If the PDI.dll has not been installed, place the PDI.dll in the same folder where the VisionQ.exe resides. The PDI.dll must be in place before setup can continue.

Determine which interface type, DICOM Worklist or PM, is to be used for import, and follow the appropriate setup procedure below.

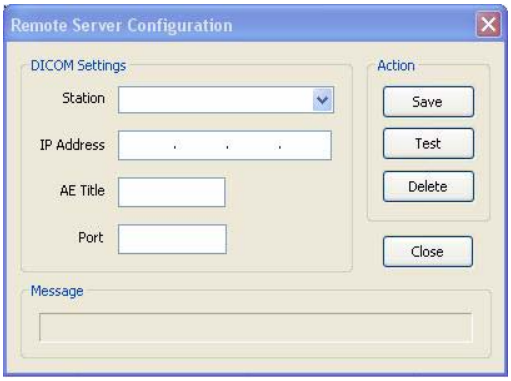
Set Up DICOM Worklist Interface

1. Start VisionQ.
2. From the VisionQ Main menu, select **File > New Patient**.

3. Click **Import**. The Patient Importer screen is displayed.

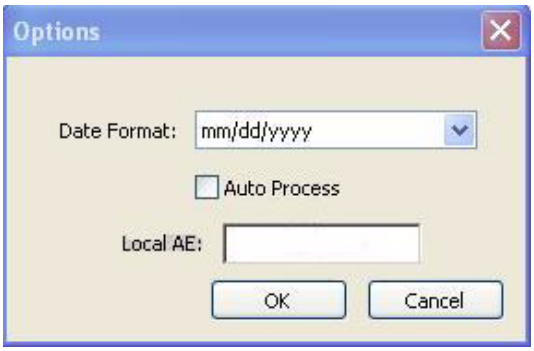


4. Click **Config**.



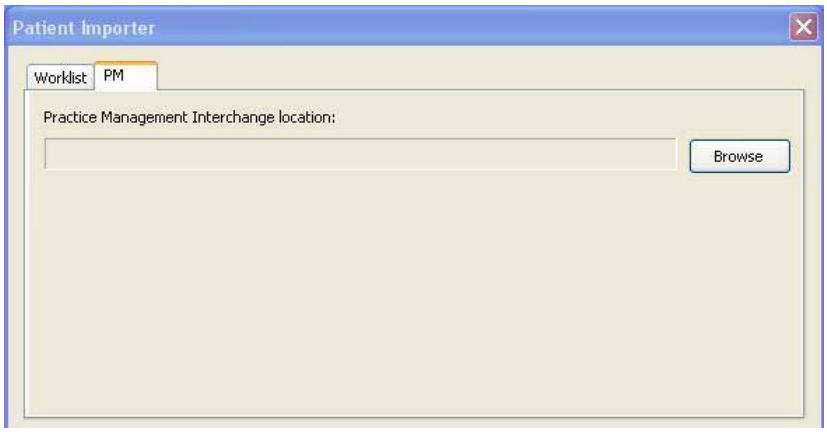
5. Enter Station name, IP Address, AE Title, and Port number for the remote server from where files are to be imported.
6. Click **Save**, and then **Close**.
7. Click **Cancel** on Patient Importer to close window.

NOTE: The **Options** button on the Patient Importer window enables setting of the date format and the AE title for the local Acquisition computer, and enabling auto process. These settings are optional and do not have to be changed.



Set Up Practice Management Interface

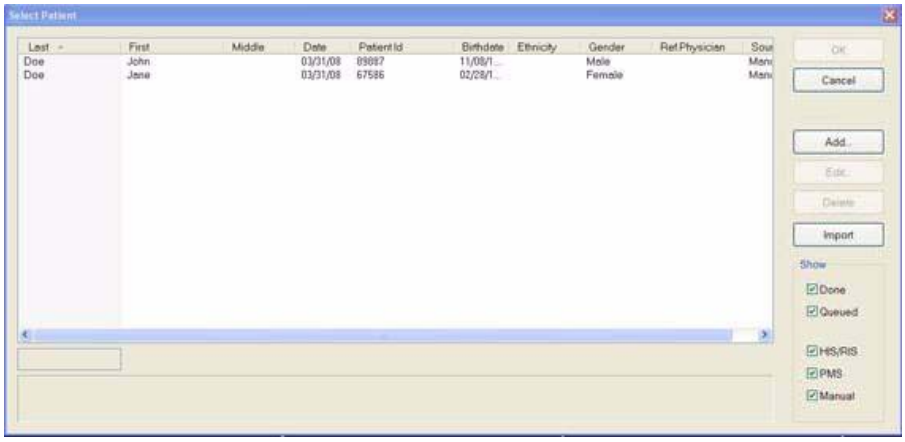
1. Start VisionQ.
2. From the VisionQ Main menu, select **File > New Patient**.
3. Click **Import**. The Patient Importer screen is displayed.
4. Click the **PM** tab.



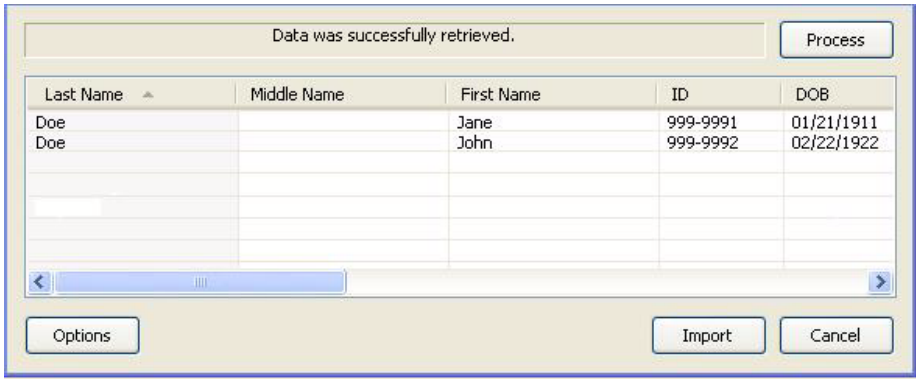
5. Click **Browse** and browse to the PM Interchange location. This is the location where an XML file, generated by the PM server, is saved.
6. Click **Cancel** on Patient Importer to close window.

Import Patient Data

1. From the VisionQ Main menu, select **File > New Patient.**
2. Click **Import**.



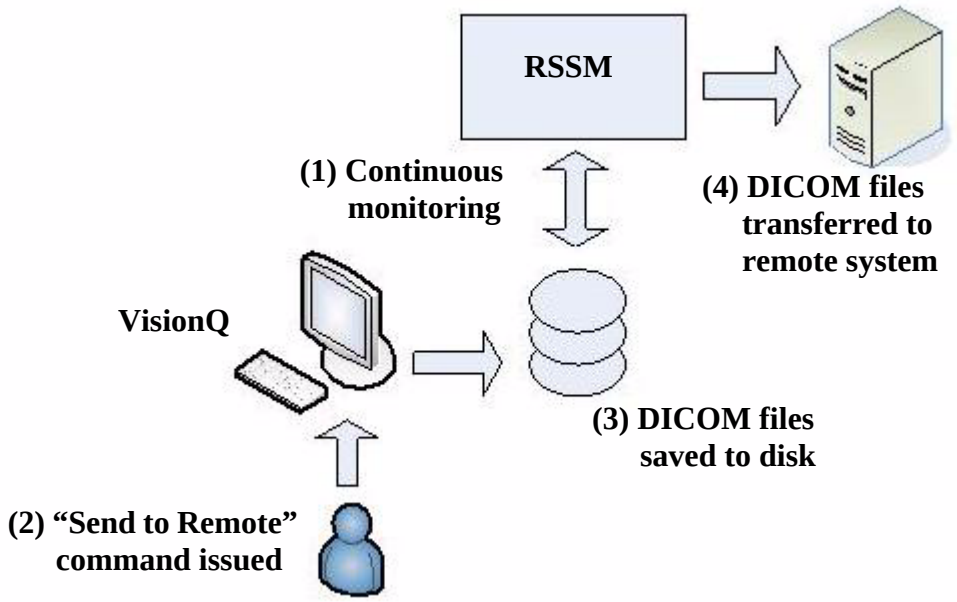
3. On the Patient Importer screen, click **Process.** Patient data is retrieved from the remote system and listed at the bottom of the screen.



4. Select (highlight) a patient on the list and click **Import**.
5. The Acquisition screen is displayed for the selected patient.

Remote System Export

VisionQ enables DICOM images to be transferred from the VisionQ to a remote system, such as a Picture Archive and Communications System (PACS). The Remote Service Send Module (RSSM) enables the transfer using DICOM storage protocol (C-STORE). RSSM continuously monitors the local folder that is setup to receive the images to be exported. When DICOM images are exported to the folder, RSSM transfers them to the user-defined remote destination.

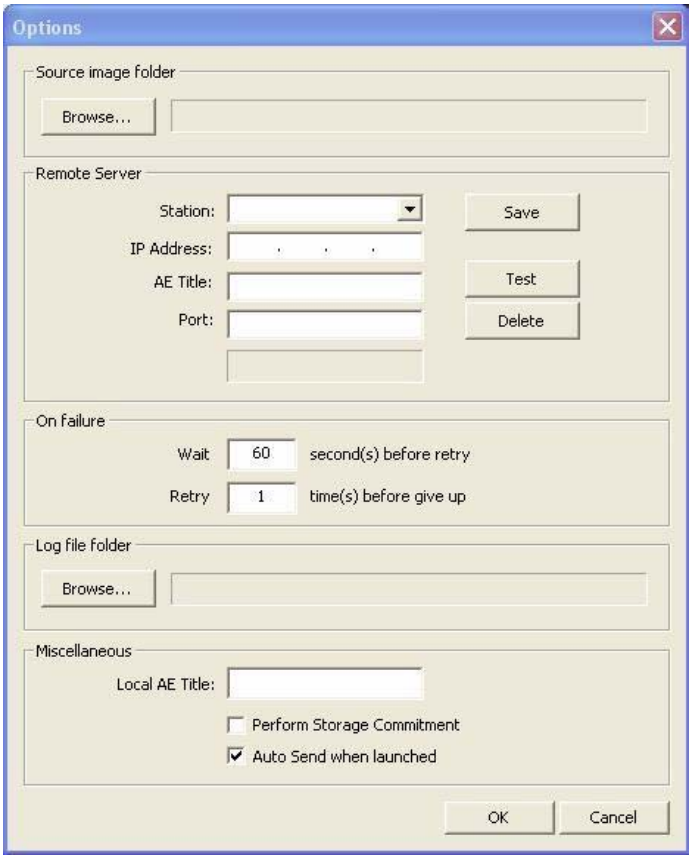


Export Installation and Setup

1. Place the RSSM.exe in the same folder where the VisionQ.exe resides.

2. Double-click RSSM.exe. The DICOM Send Module is displayed.

3. Click **Options**.



4. Click **Browse** in **Source image folder** section and browse to the folder where the DICOM files are to be placed for export. Create a new folder if desired.

5. In **Remote Server** section:

   a. Enter Station name, IP Address, AE Title, and Port number for remote DICOM server (C-STORE SCP).

b. Click **Save**.

c. Click **Test** to perform DICOM validation (C-ECHO) to check whether the remote server is accessible.

6. Click **Browse** in the **Log file folder** section and browse to the folder where the RSSM log file is to reside.

7. In the **Miscellaneous** section:

a. Enter Local AE Title for the VisionQ system.

b. If DICOM server supports **Perform Storage Commitment** feature, this option can be selected, if desired. Otherwise, leave unchecked.

c. If transmission should begin automatically whenever RSSM is started, select **Auto Send when launched**. Otherwise, leave unchecked.

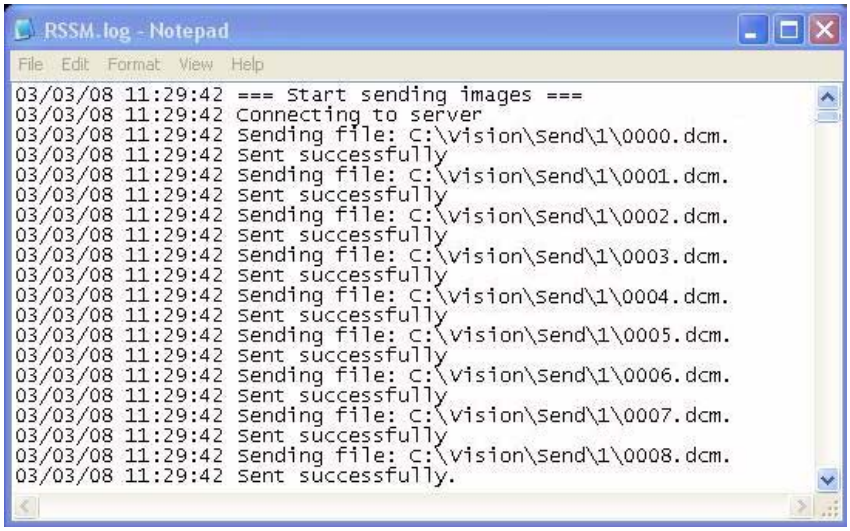
8. Click **OK**.

9. Click **Close** on the DICOM Send Module.

RSSM Log

While RSSM is transferring data to the remote system, an icon is displayed in the system tray. Right-click the icon and select **View Log** to display the log.

The log shows the status of each transferred file.



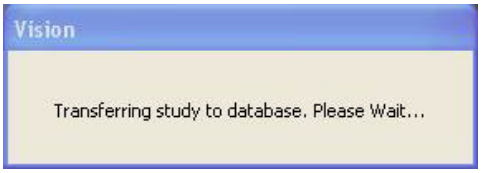
The log can also be accessed by selecting **Show.** This displays the DICOM Send Module with the following options:

- **Options** - Used to set date format.
- **View Log** - Displays RSSM log.
- **Clear Log** - Clears RSSM log of all previous activity.
- **Clear Queue** - Clears the queue of all studies. A study is queued when RSSM has exhausted all attempts to transmit the study.
- **Start/Stop** - Toggles to either start or stop RSSM.
- **Close** - Closes the DICOM Send Module window.

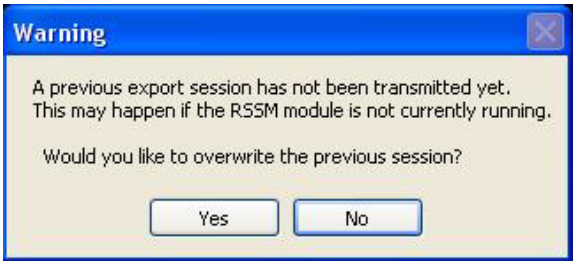
Send Patient Data to a Remote System

1. With a Patient selected in the Study List, right-click on the scan to be sent and select **Send to Remote.**

2. A dialog is displayed and the dataset is transferred.



3. If a previous export session has not been successfully transferred, a warning is displayed.



4. Check the RSSM log to determine status of the last transmitted file. If file did not transfer successfully, investigate the cause, such as a network failure to the remote system and correct the problem.

   If the file no longer needs to be transferred, click **Yes** to overwrite the previous session.

   If the file needs to be sent, click **No** to cancel and wait for previous file to transfer.

Chapter 13 Product Information

Technical Specifications

X-ray Source

Tube Voltage:	120 kVp (eff)
Tube Current:	3-7 mA
Voltage Wave Shape:	Constant Potential
Focal Spot:	0.0197 inches (0.5 mm)
Duty Cycle:	15%

Source to Sensor distance: 28.1 inches (71.4 cm)

Source to Patient distance*:19.5 inches (49.53 cm) (center of rotation)

* The patient must be properly positioned in the Head Support Positioner Mechanism 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 @ 1mA

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

Maximum Deviation: kV: $\pm$ 5 kV

mA: $\pm$ 10%

Timer: ± 5%

X-ray Beam Size: 13 cm height x 13 cm wide

PAN: 1 cm width x 13 cm height
(Automatically collimated not to exceed image detector readable area)

Image Detector: 12.8 cm width x 12.8 cm height)

Sensor Front Panel Attenuation Value: Less than 1mm of aluminum equivalent

Gray Scale: 14 bit

Voxel Size: 0.4/0.3/0.25/0.2/.125 mm

Image Acquisition: Single 360 degree rotation (maximum)

Scan Time: 23.0/8.9 seconds

Field of View: (standard) 8 cm x 8 cm

Extended Field of View: (EDS) 14 cm diameter x 8 cm height

Note: Maximum values can be collimated down.

Primary Reconstruction: Less than 2 minutes for 23.0 second scan @ 0.4 voxel

Secondary Reconstruction: Real Time

Stopping Distance and Angle: Hard stop is at -45^{o} and 470^{o} (reference is the gantry at the home position being 0^{o}). Platform travel is 69 mm.

Power Requirements

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

Line Voltage: 100VAC, 115VAC, 200VAC or 230VAC (Factory Set)

Line Voltage Regulation requirement: + 10%

Line Current: 15 Amps (100V), 10 Amps (115V), 7.5 Amps (200V) or 5 Amps (230V)

Line Frequency: 50 Hz / 60 Hz

Phase: Single

Main Circuit Breaker: 15 Amps (100V), 10 Amps (115V), 7.5 Amps (200V), or 5 Amps (230V)

Apparent Resistance of Supply Mains

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

$$R = \frac{U0 - U1}{I1}$$

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	U0	U1	I1	Apparent Ressistance
100VAC	101.9VAC	98.1VAC	7.03A	0.54ohms
115VAC	115.1VAC	111.2VAC	6.10A	0.64ohms
200VAC	200.5VAC	191.1VAC	3.69A	2.55ohms
230VAC	230.9VAC	218.7VAC	3.18A	3.84ohms

Weight

Total Weight: 510 lbs. (231.3 kg)

Tube Head Pod: 35.5 lbs. (16.1 kg)

Receptor Pod: 57 lbs. (25.9 kg)

X-Ray Power Supply: 9 lbs. (4.1 kg)

Power Cords required outside of the United States

Power Cords are not supplied with systems used outside of the United States. Three Power Cords must be obtained, one each for the Scanner, Computer, and Monitor. The use of medical grade line cords is recommended.

WARNING

Splicing terminating connectors onto the power cord is not recommended and may result in a hazardous condition.

Power Cord Specifications:
10 Amp, 220-240VAC, 50 Hz / 60 Hz, 16/3 Gauge (minimum) Length 6 to 12 ft. (2m to 4m), IEC-320-C13 connector end. Both the plug and connector ends must be molded with power cord.

Environmental Specifications

Operating

50 to 95 degrees Fahrenheit

(10 to 35 degrees Celsius)

10% to 90% Relative Humidity, non-condensing

Transportation and Storage

-4 to 158 degrees Fahrenheit

(-20 to 70 degrees Celsius)

10% to 90% Relative Humidity, non-condensing

Acquisition Computer

Acquisition Computer requires a Dedicated Line and a Surge Protector is recommended.

Tower Computer Dimensions:
17"h x 18”d x 8.5”w (43cm x 47cm x 22cm)

Monitor with Stand Dimensions:
20” (51cm) LCD Monitor 17.5"h x 13.5”w (45cm x 34cm)

Keyboard Dimensions:
17”w x 7”d (43cm x 18cm)

Minimum Specifications for Acquisition Computer Provided with the System:

- Pentium-4 Processor, 3.8 GHz minimum
- Windows XP Professional w/SP2
- 120 GB Hard drive
- 2 GB RAM
- 20” (51cm) Flat Panel Display
- Video Memory of 128MB minimum
- 2 Network Interface Cards (Ethernet)
- 1 serial port, 9-pin
- 3 USB ports

Patient Support Chair

Overall dimensions:
28.5"d x 24”w x 43”h (72.4 cm x 61 cm x 109.2 cm)

Weight: 125 lbs (56.7 kg)

Seat height adjustment: 14” to 29” (35.65 cm to 73.7 cm)

Maximum patient weight: 400 lbs (181 kg)

Complies with IEC 60601-2-32:1994

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 environmental 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 Item

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

Cleaning

Routinely clean and disinfect all items which come in contact with the patient. Use Biocide ® from Biotrol International or equivalent cleaner and disinfectant. Biocide® is an Iodophor formulation that kills HIV, Tuberculosis and Polio in 10 minutes.

Electromagnetic or other Interference (Emissions and Immunity)

The System was tested and found to comply with the limits for Class B equipment, pursuant to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. The system generates, uses, and can radiate electromagnetic energy and if not installed and used in accordance with these instructions, may cause harmful interference to surrounding equipment. Also portable and mobile RF communications equipment can effect the operation of the system. Proper precautions and equipment location should be observed, refer to the following table:

The System is intended for use in an electromagnetic environment specified below. The Customer or User should ensure that the system is used in such an environment.		
Immunity Test	**Compliance Level**	**Electrostatic Environment - Guidance**
IEC 61000-4-2 Electrostatic Discharge (ESD)	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
EFT IEC 61000-4-4	±2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 cycle 60% Dip for 5 cycles 30% Dip for 25 cycles >95% Dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 610000-4-6	3 Vms 150 kHz to 80 MHz	Portable and mobile communication equipment should be separated from the system by no less than 19 feet (6 meters).

<table>
<tr><td colspan="5">The System is intended for use in an electromagnetic environment specified below. The Customer or User should ensure that the system is used in such an environment.</td></tr>
<tr><th>Emission Test</th><th>Compliance</th><th colspan="3">Electrostatic Environment - Guidance</th></tr>
<tr><td rowspan="8">Radiated RF
IEC 61000-4-3</td><td rowspan="8"></td><td colspan="3">This Scanning System is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the system as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td>Maximum Output Power (Watts)</td><td>Separation 150 kHz to 800 MHz</td><td>Separation 800 MHz to 2.5 GHz</td></tr>
<tr><td>0.01</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr>
<tr><td>0.1</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr>
<tr><td>1</td><td>46 in (117 cm)</td><td>8 ft (2.4 m)</td></tr>
<tr><td>10</td><td>12 ft (3.7 m)</td><td>24 ft (7.3 m)</td></tr>
<tr><td>100</td><td>38 ft (11.7 m)</td><td>77 ft (23.4 m)</td></tr>
<tr><td colspan="3">Note: Field strengths from transmitters, as determined by an electromagnetic site survey, should be less than the compliance level of 3 V/m.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td colspan="3">The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td colspan="3">The system is suitable for use in all establishments, including domestic, and those directly connected to the public low - voltage power supply network that supplies buildings for domestic purposes.</td></tr>
<tr><td>Harmonics
IEC 61000-3-2</td><td>Class A</td><td colspan="3"></td></tr>
<tr><td>Flicker
IEC 61000-3-3</td><td>Complies</td><td colspan="3"></td></tr>
</table>

If the System does cause harmful interference to surrounding equipment which can be determined by turning the system OFF and ON, the customer or user is encouraged to try to correct the interference by one or more of the following methods:

- Increase separation between the system and surrounding equipment.
- Connect the System into an outlet on a circuit different from that to which the surrounding equipment is connected.
- Consult Imaging Sciences International, the dealer or an experienced technician for help.

Use only the interface cables provided with the System. Using other interface cables may exceed the limits of Class B equipment, pursuant to IEC 60601-1-2.

Equipment Standards

The System was tested and/or evaluated against and found compliant to the following standards/requirements:

UL 60601-1	IEC/EN 60601-1-4
CSA C22.2 No. 601.1	IEC/EN 60601-2-32
JIS Z4701	IEC/EN 60825-1JIS T0601
JIS Z4703	CE-MDD 93/42/EEC
JIS T0601	LVFS 2003:11 (Swedish regulation, transposing the MDD 93/42/EEC)
IEC/EN 60601-1	CMDCAS (Canadian Medical Device Regulation)
IEC/EN 60601-1-1	ISO 10993-1:2003
IEC/EN 60601-1-2	ISO 14971:2000
IEC/EN 60601-1-3	

Equipment Class

Protection against electric shock: Class I

Applied part has degree of protection against electric shock: Class B

Class of equipment against ingress of liquids: Ordinary Equipment, IPX0

Radiated emissions: Class B

Preventive Maintenance Schedule - for Owner / User

Daily: Routine Dusting - all surfaces

Monthly: Clean all surfaces and check for failed/faulty indicator lights.

Yearly: Check for satisfactory image quality.

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

The actual maintenance inspection and consequent service must be accomplished either by an authorized dealer 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 - 12 Month Schedule

The Planned Maintenance philosophy for this system is based upon the assumption that a periodic inspection of the equipment, along with periodic cleaning and calibration, will maintain image quality.

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. These tests verify that the system meets or exceeds operational specifications and that it will provide continued excellent image quality.

Planned maintenance is to be performed annually by a factory trained Service Representative.

Cleaning

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 inside the Gantry.

WARNING

USE EXTREME CARE WHEN WORKING INSIDE THE SYSTEM. VOLTAGES ARE PRESENT WHEN THE SYSTEM COVERS ARE OFF. ACCIDENTAL CONTACT WITH THESE VOLTAGES MAY CAUSE SERIOUS INJURY OR DEATH.

Planned Maintenance Checklist

Perform Calibrations	
	Panel Calibration
	Collimator Calibration
	Geometry Calibration
Check Detector Pivot (displayed under Geometry, both Portrait and Landscape)	
	Ensure Detector Pivot is between **-0.10 & 0.10**. If measurements are not within tolerance, call Service to have Receptor Panel leveled.
Peform QA Water Phantom Tests	
	Noise Level Test (Landscape Mode)
	Uniformity Test (Landscape Mode)
	Noise Level Test (Portrait Mode)
	Uniformity Test (Portrait Mode)
	PAN Phantom Test
	Radiation Ouput Test (performed by qualitfied Physicist)
Check Chair Alignments	
	Check Chair Center Alignment (using Chair Center Locator)
	Check Chair Level (using Chair Center Locator)

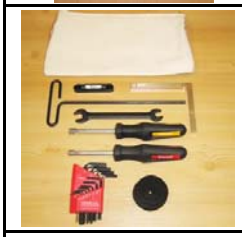
Check Laser Alignments	
	Check Centerline Alignment (using Chair Center Locator)
	Check Crosshair Laser (align with notches on Receptor Panel Cover)
Inspect Tube Housing Components	
	Certification Label
	Warning and Indicators
	Oil Leaks
	Physical Damage
	Mounting System Stability
Inspect Beam Limiting Device	
	Physical Damage
	Certification Label
Check/Inspect X-Ray Controller	
	Visual Warning Indicator
	Audible Exposure Signal
	Certification Label

Replaceable Parts - Reference List

There are no equipment parts designated as repairable in the field by the owner/user of the equipment. Contact Service if repairs are needed. The following is a list of replacement parts.

Sub Assembly Number	Description
11-0	Rotation Stepper Motor
27-0	Head Rest, Carbon Fiber
35-0 1000-0	Tube Head Assembly and X-ray Power Supply Assembly (sold together)
102-16	Platform Motor
109-2	Receptor Motor
137-0	Beam Limiter Assembly
1203	System PCB
1210	Motherboard
1255	Circuit Breaker, 10A for 115 Volt Systems
1256	Circuit Breaker, 5A for 230 Volt Systems
1257	Circuit Breaker, 7A for 200 Volt Systems
1258	Circuit Breaker, 15A for 100 Volt Systems
G1304-0	Patient E-stop Box
G1305	Patient Alignment Panel
G1306-0	Operator Control Box
1539	Laser, Cross
1540	Laser, Straight Line
800130	Computer & Keyboard
800145	Monitor, LCD
800170	Receptor Panel
800550	Acquisition Key, Cobra
1000005	Fuse, 2.5A, 3AG, Sow Blow
1000010	Fuse, 10A, 250 VAC
1000011	Fuse, 0.25A, 250 VAC, Slow Blow
1000028	Chair, Linear Actuator
1000032	24VDC Power Supply (Silver Box)
1000111	Power Supply (15 VDC)

Accessories

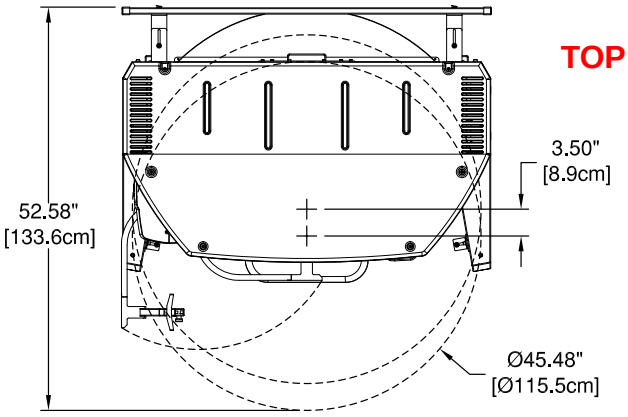
	**Patient E-stop** **Part #** 1304-0 **Quantity** 1		**Carbon Fiber Head Rest** **Part #** 27-0 **Quantity** 1
	**Glide** **Part #** 1000179 **Quantity** 4		**Head Restraint Band** **Part #** 27-1 **Quantity** 100
	**Pan Phantom** **Part #** 12-0 **Quantity** 1		**Velcro Head Restraint Kit** **Part #** 903-0 **Quantity** 1
	**Booster Seat** **Part #** 1000196 **Quantity** 1		**Phantom Assembly** **Part #** 17-01-0 **Quantity** 1
	**Foot Stool** **Part #** 1000197 **Quantity** 1		**Tool Kit** **Part #** 5-0 **Quantity** 1
	**Chair Patch Cable** **Part #** 1520 **Quantity** 1		**QA Phantom** **Part #** 13-20 **Quantity** 1
	**Cable Clips** **Part #** 101-6 **Quantity** 6		**Water Phantom Jar** **Part #** 1000267 **Quantity** 1

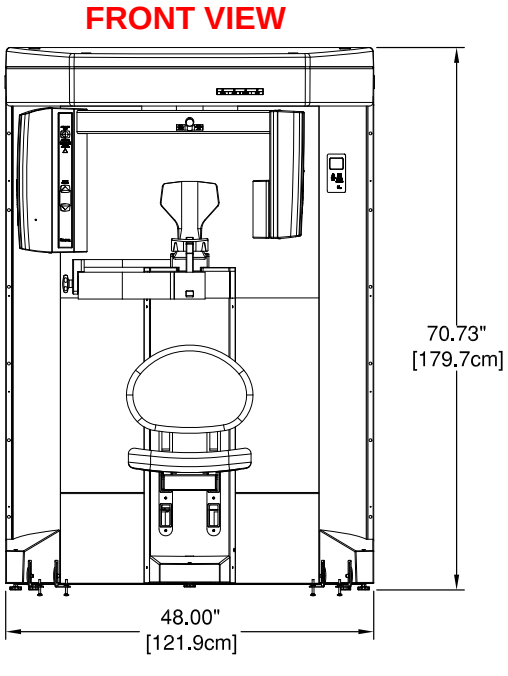
	**Chair Center Locator** **Part #** 26-16 **Quantity** 1		**Bite Tip Holder** **Part #** 9140-0326-0004 **Quantity** 2
	**Platform Assembly** **Part #** 14-4-0 **Quantity** 1		**Chin Rest** **Part #** 26-12 **Quantity** 1
	**Bite Tip** **Part #** 26-15 **Quantity** 25		**Chin Cup** **Part #** 9140-0026-0006 **Quantity** 1
	**Surge Suppressor** **Part #** 98028 **Quantity** 1		**Power Cord** **Part #** 1000117 **Quantity** 1
	**Chin Rest Slide, Straignt** **Part #** 160-1 **Quantity** 1		**Chin Rest Clamp Block Assembly** **Part #** 160-2-0 **Quantity** 1
	**Chin Rest Slide, Bent** **Part #** 160-2 **Quantity** 1		**Hole Plug - Ricko** **Part #** 1000261 **Quantity** 4

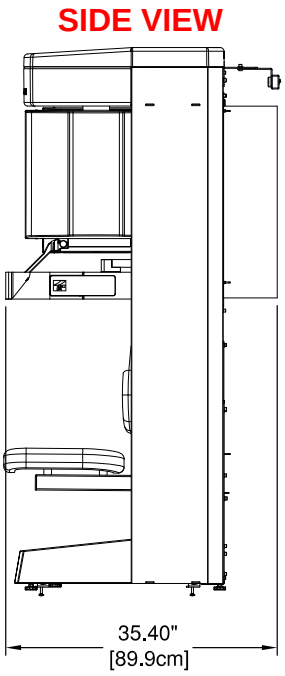
	**Position Alignment Tool** **Part #** 33-19 **Quantity** 1		**PAN Head Holder** **Part #** 33-0 **Quantity** 1
	**Foam Disk** **Part #** 1000323 **Quantity** 1		**Operators' Manual** **Part #** G990700 **Quantity** 1 (Softcopy) Optional hardcopy

Part # 90-0			
	**Door Interlock Cable** **Part #** 1524 **Quantity** 1		**E-net Cable 50** **Part #** 1000116 **Quantity** 1
	**Warning Cable** **Part #** 1527 **Quantity** 1		**Control Box** **Part #** 1306-0 **Quantity** 1

System Gantry Dimensions







Chapter 14 Illustrated Parts Breakdown

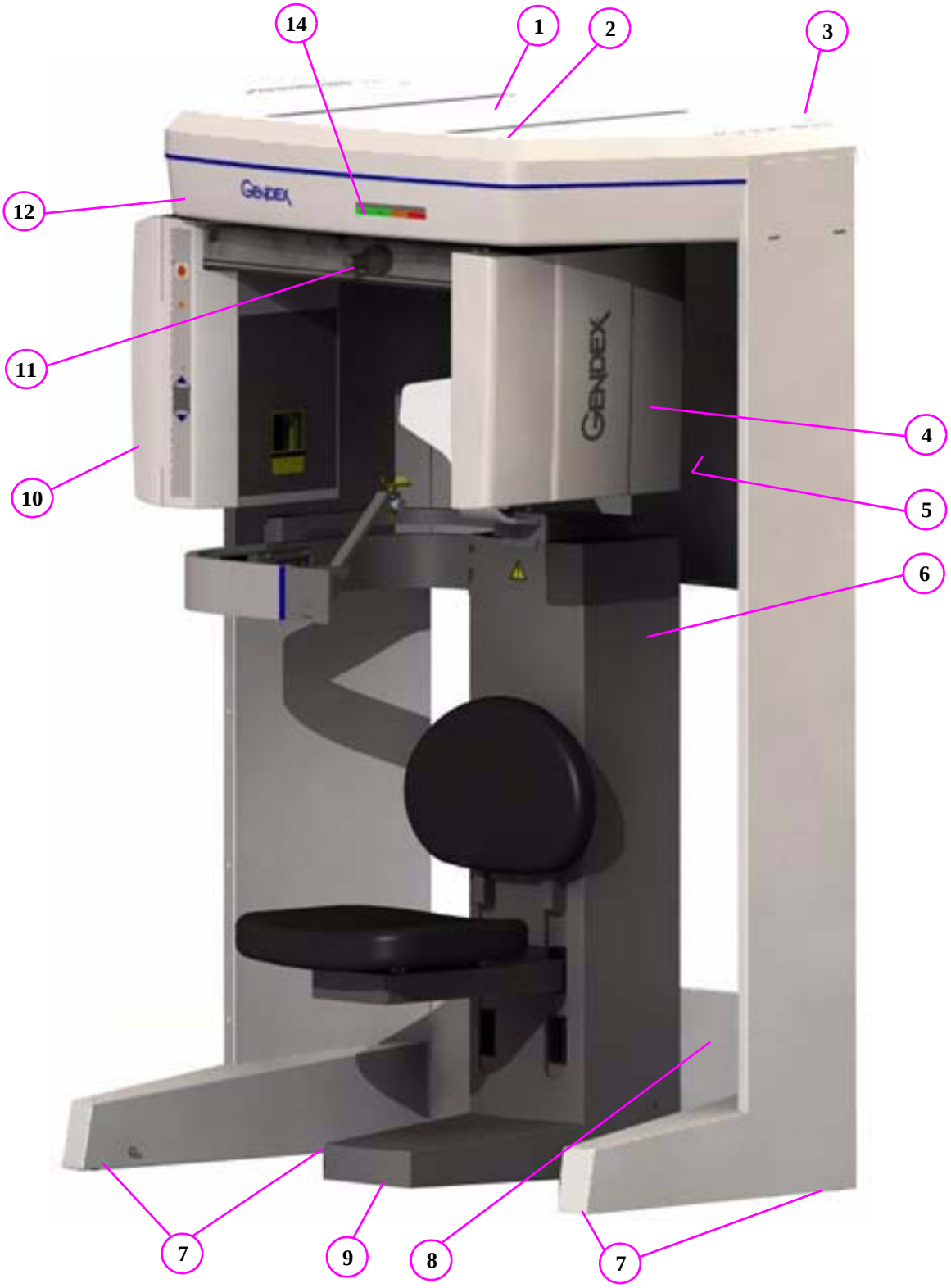
WARNING

High voltage is present in the device. Remove power from device before removing covers or cables. To avoid personal injury from electrical shock, do not operate the system with any covers open or cables removed.

This chapter is used to provided replacement part numbers. Ensure power is removed before servicing the device.

The following Assemlies are illustrated.

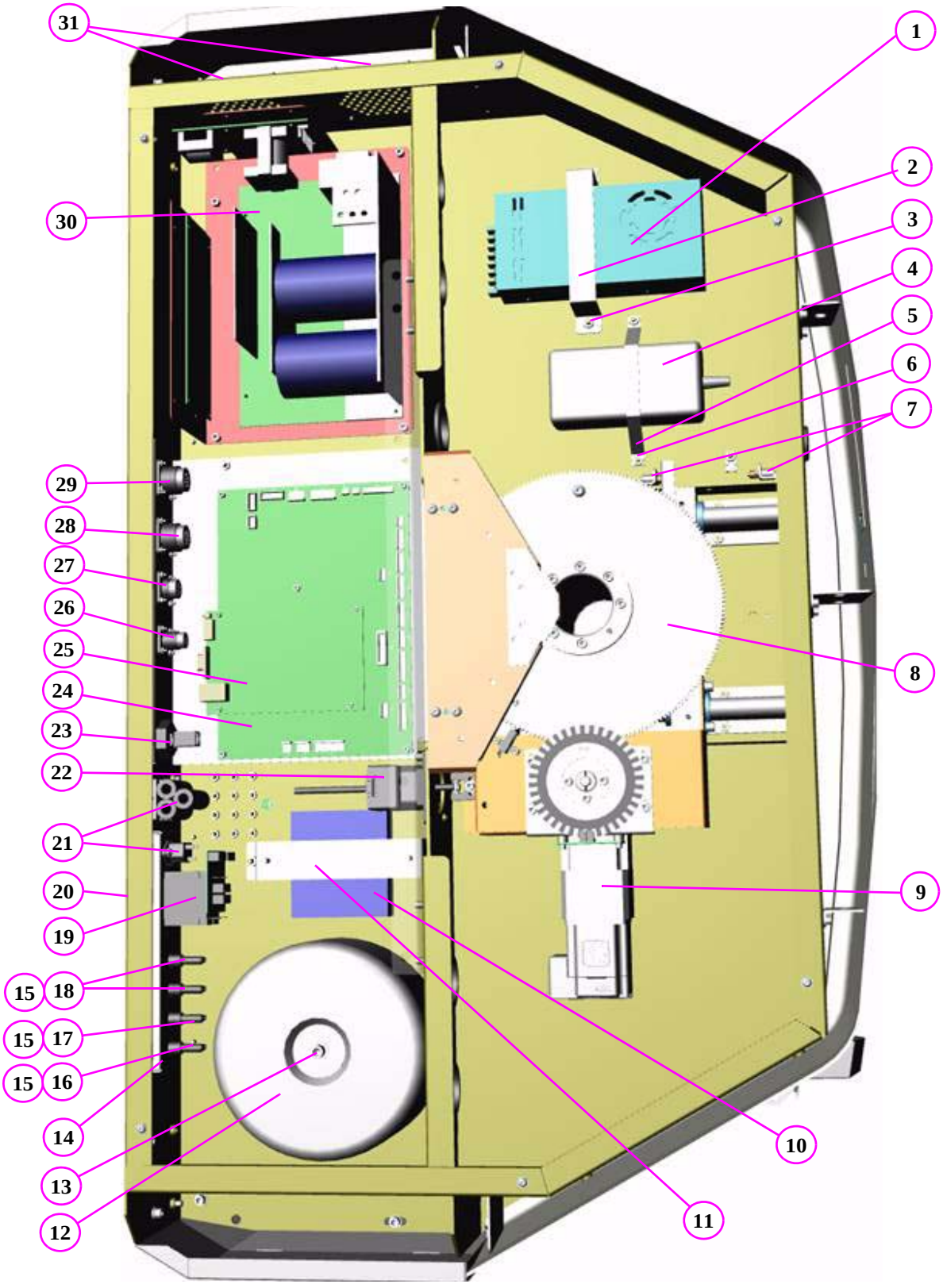
System Assembly



System Assembly Parts List

Item	Part Number	Description
1	G150-4	Upper Cover
2		BHCS #8-32 x 3/8 Long
3	G32-0	Wall Stabilizer (not shown)
4	G138-0	Flip Receptor Assembly
5	G101-7	Rear Scatter Shield
6	G20-0	Chair Assembly
7	1000031	IEC #IL8-6B x 3 HX-BC Bottom Chamfer
8	G504-0	Lower Plate Weldment
9	1000108	IEC #IL8-6B x 2 HX-BC Bottom Chamfer
10	G140-0	X-Ray Source Assembly
11	15-0	Laser Line Assembly
12	G150-3	Lower Cover Assembly
13		
14	1302	Resident Indicator Panel

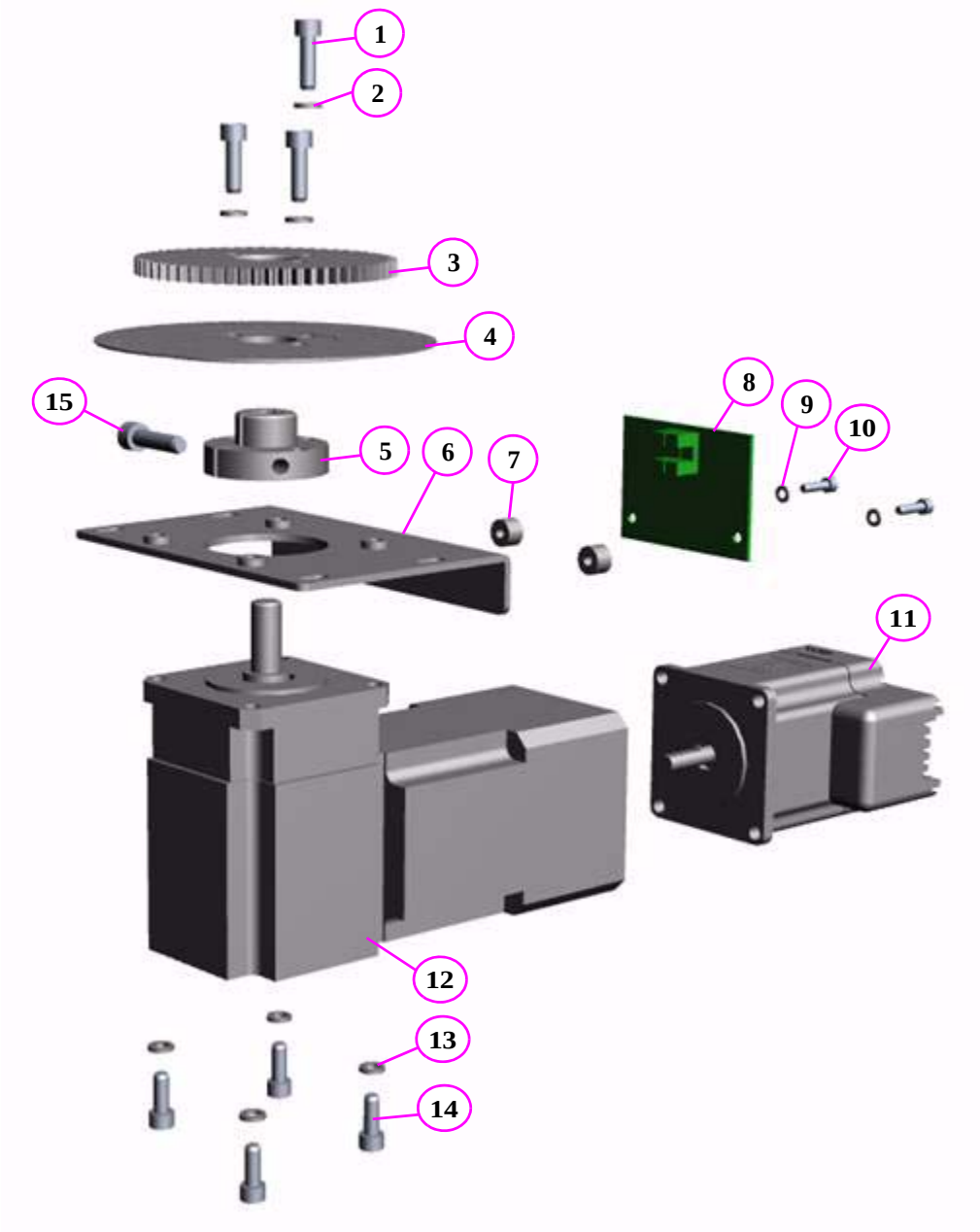
Overhead Assembly



Overhead Assembly Parts List

Item	Part Number	Description
1	1000032	24V Power Supply
2	102-8	24 Volt Power Supply Strap
3		#10-32 Nut
4	1000111	24V Receptor Power Supply
5	102-15	Receptor Power Supply Strap
6		#10-32 Nut
7	1507	Limit Switches (set)
8	10-0	Spindle Assembly
9	11-0	Rotation Drive
10	1000105	Netgear Ethernet Switch
11	102-6	Ethernet Switch Strap
12	1701-0	Toroid Isolation Transfromer
13		SHCS 5/16-18 x 1 Long
14	1015-0-1	Power Bracket Assembly
15	1000176	Buss #HTB-84M
16	1000010	10A Fuse Digi-Key #F985-ND
17	1000005	2.5A Fuse Digi-Key #F979-ND
18	1000011	1/4 A Fuse Digi-Key #F939-ND
19	1255	115V Circuit Breaker
20	1310	Fuse Lable (not shown)
21	1570	Line Choke
22	102-16	Stepper Motor Assembly - 17 Frame
23	1000038	B & B Electronics
24	1203	i-CAT System Board
25	1210	i-CAT Computer Board
26	1526	Warning System External Cable Assembly
27	1523	Door Interlock External Cable Assembly
28	1519	Control Box External Cable Assembly
29	1521	Chair External Cable Assembly
30	1000-0	X-Ray Power Supply
31	1541	Overhead Fan (pair)

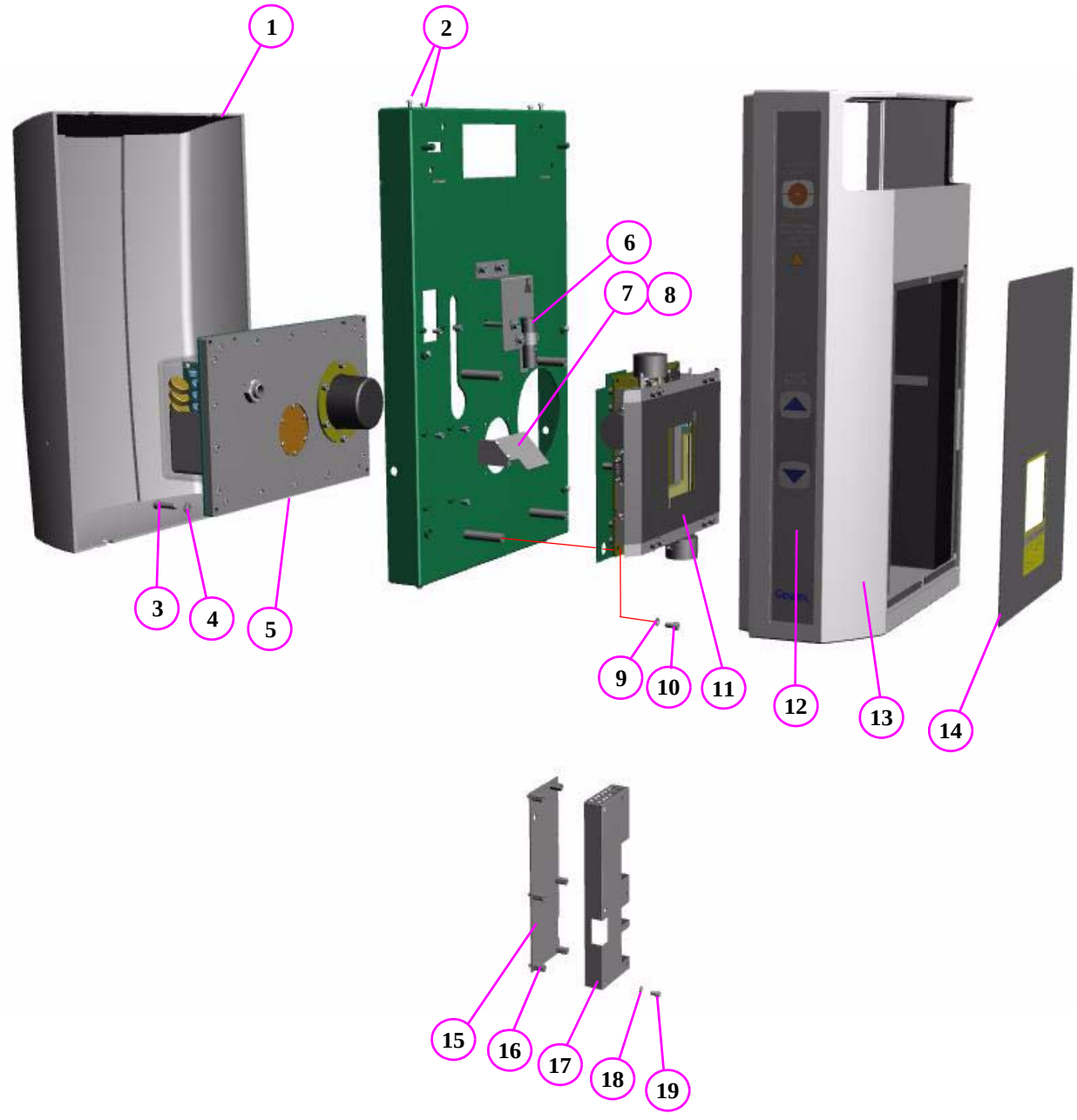
Rotation Drive Assembly



Rotation Drive Assembly Parts List

Item	Part Number	Description
1		SHCS #10-24 x 5/8 Long
2		Split Washer #10
3	11-5	Drive Gear
4	11-3	Gear Encoder Disk
5	11-4	Gear Clamp
6	11-2	Rotation Motor Bracket
7	1000027	McMaster #92510A602
8	1205	Gear Encoder
9		Split Washer #6
10		SHCS #6-32 x 1/2 Long
11	11-6	Stepper Motor
12	120110	Thomson Micron #NTR23-025
13		Split Washer #10
14		SHCS #10-24 x 1/2 Long
15		SHCS #10-24 x 1 Long

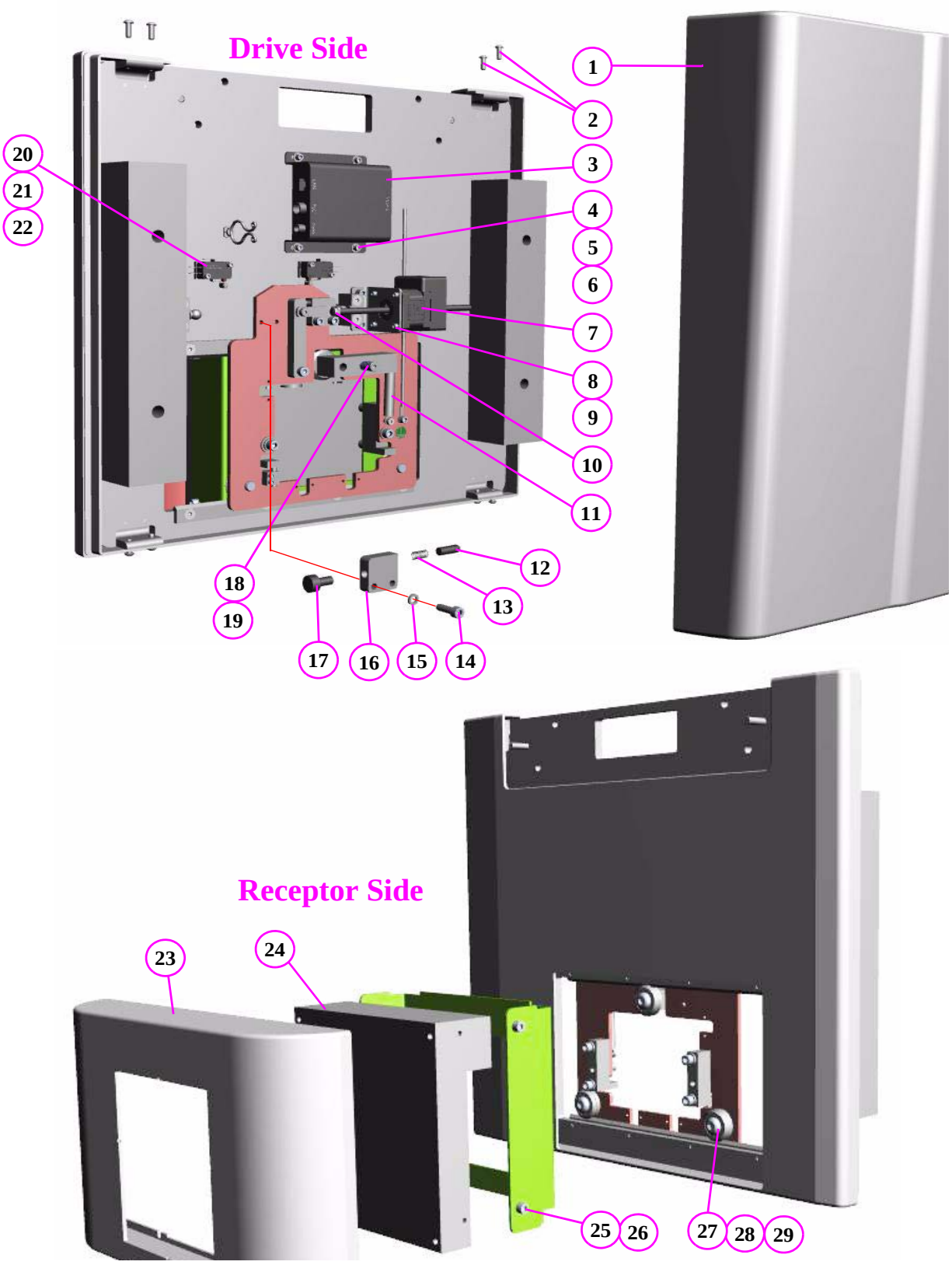
X-Ray Source Assembly



X-Ray Source Assembly Parts List

Item	Part Number	Description
1	G140-7	Rear X-Ray Source Cover
2		BHCS #8-32 x 1/2 Long
3		SHCS 1/4-20 X 1 Long
4		Split Washer 1/4
5	35-0	Tube Head
6	1539	Cross Laser Assembly
7	106-4	Cross Laser Mirror
8		BHCS #6-32 x 1/4 Long
9		Split Washer #10
10		SHCS #10-24 x 3/8 Long
11	137-0	Beam Limiter
12	G1305	Patient Alignment Panel
13	G140-2	Front X-Ray Source Cover Assembly
14	1308-0	Beam Limiter Panel
15	1206	Beam Limiter Control PCB
16	1000211	#6-32 x 1/2 Long Standoff McMaster #91
17	106-8	Beam Limiter Board Shield
18		Split Washer #6
19		SHCS #6-32 x 1/4 Long

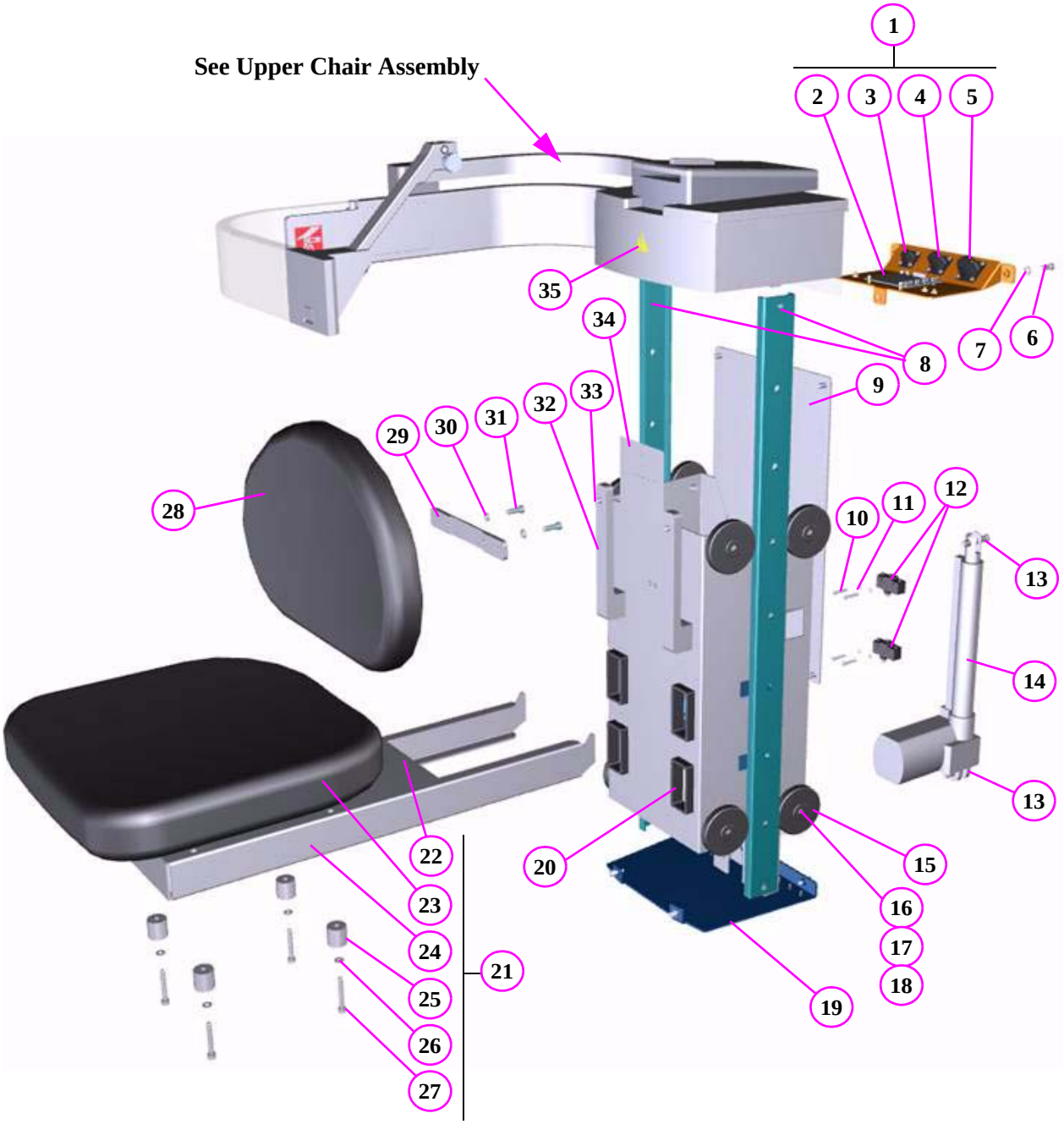
Receptor Panel Assembly



Receptor Panel Assembly Parts List

Item	Part Number	Description
1	G138-20	Rear Cover
2		BHCS #8-32 x 1/2
3	1000237	Camera Card Pleora #PT1000-Cl4-E
4		SHCS #6-32 x 3/8 Long
5		Split Washer #6
6		Flat Washer #6
7	138-3	Shift Motor
8		SHCS M3 x 8mm Long
9		Split Washer M3
10		Nut #8-32 (shift motor)
11	1000259	Spring McMaster #94135K13
12	138-11	Plunger
13	310243	Century Spring #70602
14		SHCS #10-32 x 5/8 Long
15		Split Washer #10
16	138-10	Plunger Block
17	1000188	McMaster # 8511A24
18		Shoulder Screw 1/4 Diameter x 1 1/4 Long x #10-32
19	1000257	Century Spring #71126
20	1550	Flip Receptor Limit Switch
21		SHCS #4-40 x 3/4 Long
22		Split Washer #4
23	G138-18	Panel Cover
24	800170	1313 Receptor
25		SHCS M5 x 10mm
26		Split Washer M5
27		BHCS 3/8-16 x 3/4
28	240361	Dual Vee #W2
29		Shim Washer 3/8 ID x .02 Thick

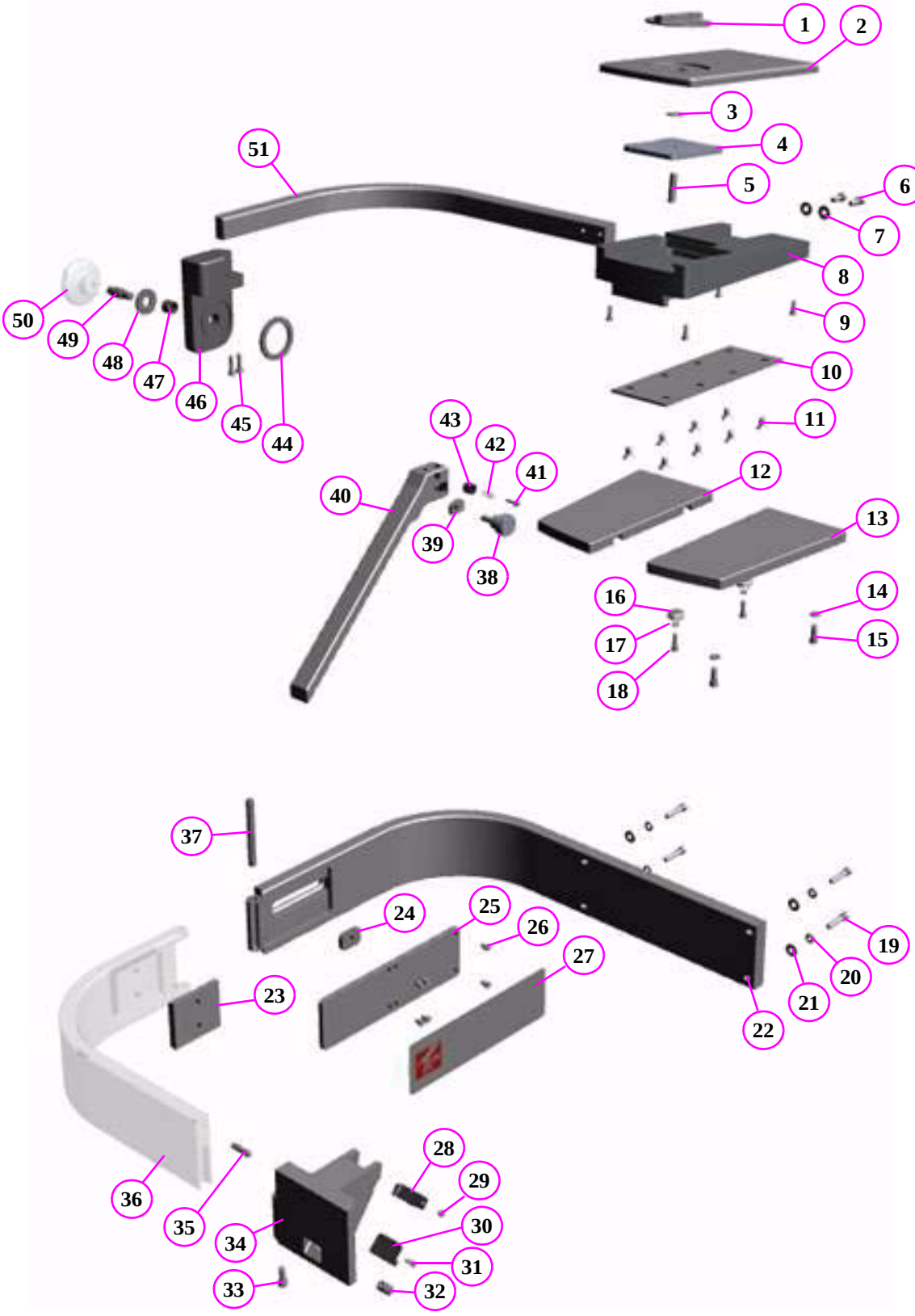
Chair Assembly



Chair Assembly Parts List

Item	Part Number	Description
1	1020-0	Chair Receptacle Plate Assembly
2	1204	Patient Alignment Board
3	1516	Patient E-Stop External Cable
4	1547	Wheel Chair External Cable
5	1522	Chair Junction Cable
6		SHCS 1/4-20 x 5/8 Long
7		1/4 Split Washer
8	505-5	Rail
9	25-2	Back Plate
10		SHCS #6-32 x 1 Long
11		#6 Split Washer
12	1548	Wheel Chair Switch
13	1000029	McMASTER # 97245A688
14	1000028	MAGNETIC #ECO50-025MM1B0-000
15	23-1	Wheel
16	23-2	Wheel Axle
17		SHCS 1/4-20 x 1/2 Long
18		1/4 Split Washer
19	508-0	Actuator Plate
20	23-3	Receptacle Flange
21	21-0	Seat Assembly
22	1309-3	Chair Installation Label
23	980317	Office Star #CT12 Characoal Vinyl A Grade
24	21-2	Seat Frame
25	21-1	Seat Standoff
26		M6 Split Washer
27		SHCS M6 x 46mm Long
28	980316	Office Star #CT11 Characoal Vinyl A Grade
29	23-6	Back Rest Adapter
30		1/4 Split Washer
31		SHCS M6 x 20mm Long
32	23-5	Seat Back Support
33		SHCS 1/.4-20 x 1/2 Long
34	1309-2	Chair Warning Label 2
35	1309-1	Chair Warning Label 1

Upper Chair Assembly



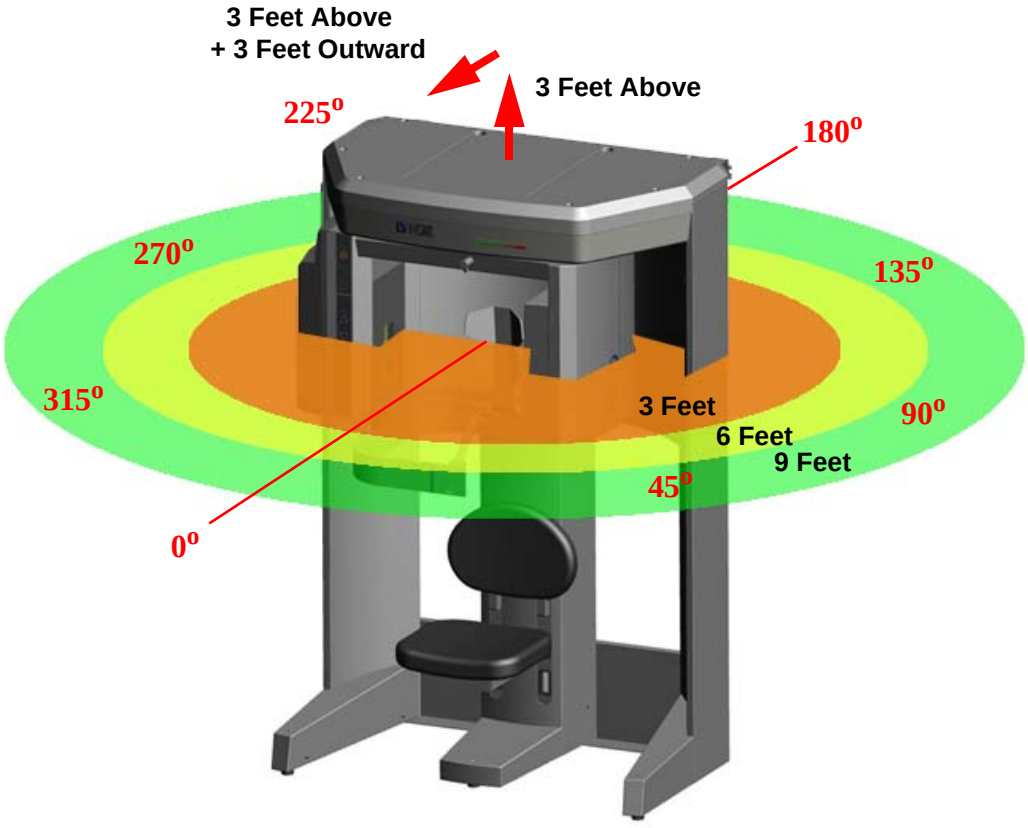
Upper Chair Assembly Parts List

Item	Part Number	Description
1	22-4	Clamp Knob
2	22-2	Support Plate
3		Nylon Flat Washer 5/16 ID - 3/4 OD
4	22-3	Clamp Plate
5		SS 5/16-18 x 1.25 Long
6		SHCS 1/4 - 20 x 5/8 Long
7		Flat Washer 1/4
8	22-1	Slider Block
9		SHCS #8-32 x 1/2 Long
10	22-10	Roller Plate
11		Flat Head 1/4-20 x 1/2 Long
12	22-5	Left Cap Plate
13	22-6	Right Cap Plate
14		Split Washer 1/4
15		SHCS 1/4-20 x 5/8 Long
16	24036	Dual-Vee #W1
17		Split Washer #10
18		SHCS #10-32 x 5/8 Long
19		SHCS 1/4-20 x 1 1/4 Long
20		Split Washer 1/4
21		Flat Washer 1/4
22	24-1	Hinge Bar
23	1000045	Bunting #BM4071
24	24-4	Tee Nut
25	24-3	Magnet Plate
26		SHCS #10-24 x 1/4 Long
27	1314	Gate Label
28	26-11	Upper Guide
29		BHCS #6-32 x 1/4 Long
30	26-10	Lower Guide
31		SHCS #6-32 x 1/2 Long
32	1000181	3/8 Spring Plunger McMaster Carr #8499A85
33		SHCS 1/4-20 x 5/8 Long
34	26-9	Slide Block
35		Dowel Pin 1/4 x 1 Long
36	24-2	Gate
37	24-6	Gate Pivot Pin
38	26-4	Thumb Screw
39	26-3	Clamp Button
40	26-1	Chin Rest Guide
41		Shoulder Screw 1/8 Diameter x 5/16 Long x #4-40
42	310242	Century Spring #70464
43	26-2	Bite Tip Clamp Button
44	22-8	Glide
45		SHCS #10-32 x 3/4 Long
46	22-11	Clamp Handle
47		Bronze Bushing .375 ID x .625 OD x .50 Long
48	22-12	Clamp Washer
49	22-9	Lock Shaft
50	1000047	J.W. Winko #6TCC3/E
51	22-7	Arm

Chapter

15 Radiation Environment Survey

The direct and scattered beams can produce serious bodily injuries to Patients and persons in the surrounding area. Adequate precautions must always be taken to avoid or reduce exposure to the useful beam, as well as scattered radiation. Refer to the following figure and related table to determine scattered beam measurements.



Conditions of Operation – 8.9 and 23.0 Second Scans

The measurements were conducted by a certified health physicist from RayScan, Inc, on the factory floor on 04.01.08. He was assisted by a physicist, employed by the manufacturer.

The X-ray scatter was measured from a GXCB-500 Scanner in several modes, using a Radcal Model 9010 Radiation monitor, with a 10X5-180 chamber.

A head phantom from Phantom Labs, Inc, was used as the scatter center and placed in a representative location as measured by an image scan. Model SK150 has real bone as the structural component and proprietary Urethane filler that simulates the response of tissue.

The radiation monitor was held at the same height as the phantom head's nose and the distances were measured from the center of rotation of the CT scan. Measurements were taken every 45°, with 0° measured directly in front of the scanner, and at distances of 3ft, 6ft, and 9ft. In addition the scatter was measured at 3ft directly above the system and at a position 3ft above and 3ft directly in front of the device.

Scatter was measured for the Standard (full-beam), Extended Diameter Scan (EDS) (half-beam), and Panoramic mode. Both scan modes were taken with 0.4 mm Voxels for a scan time of 8.9s. The X-ray beam details were 120 kVp, 5 mA, and 28.52 mAs. The Panoramic scan settings were measured with the Large exposure setting with the following settings: 89kVp, 5 mA, and 71.43 mAs, 20s scan time.

Scatter Measurements for 8.9 Second Scans

8.9 second scan using pulsed X-ray: 309 frames, 19 ms pulse width at 5 mA. Based on this, the estimated workload is:

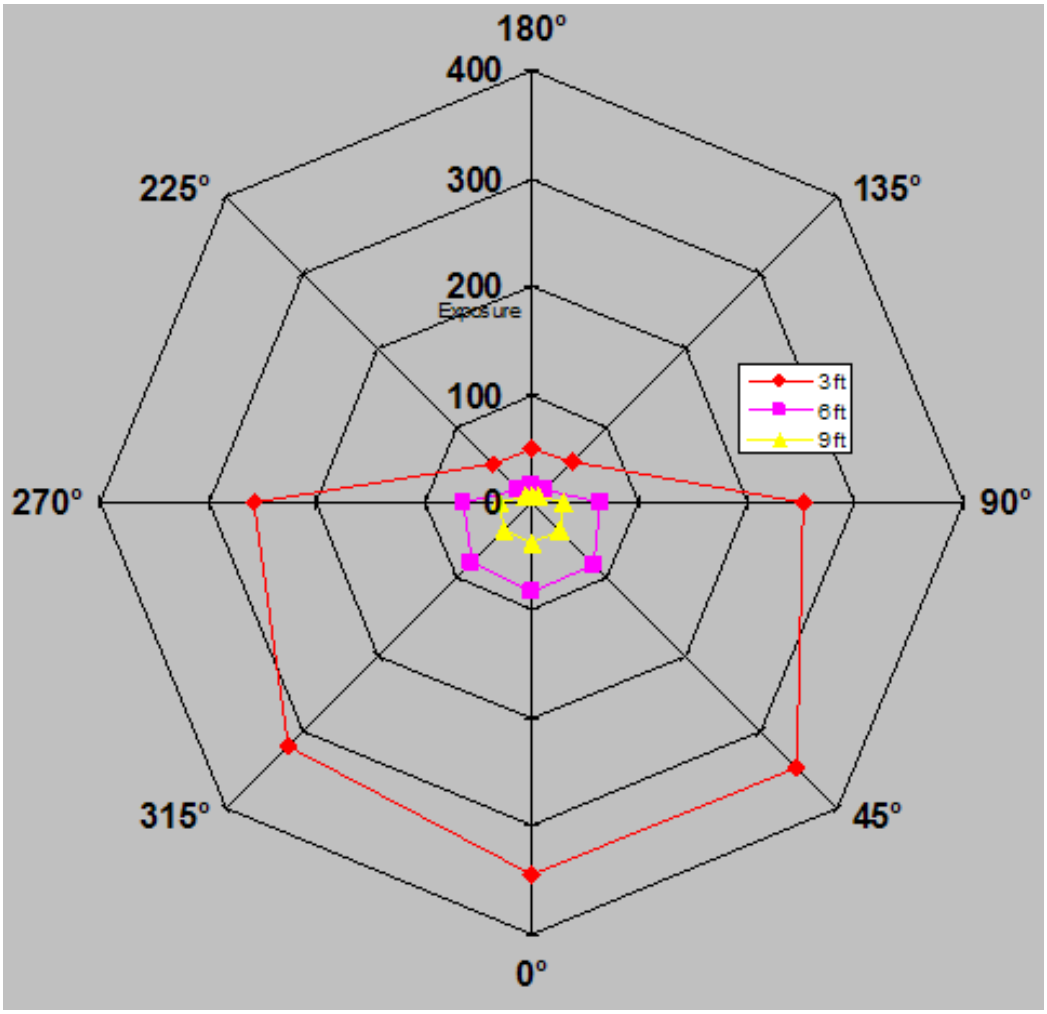
10 scans per week yielding a workload of 4.8 mA-min/week
25 scans per week yielding a workload of 11.9 mA-min/week
50 scans per week yielding a workload of 27.8 mA-min/week

Standard (full-beam) Diameter 8.5 - Height 8.5 cm

NOTE: Selectable voxel sizes are 0.4 and 0.3.

Location	Distance in Feet [meter]	Exposure (mR)	Exposure (μR)	Exposure μR/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0°	3 [0.91m]	0.34	344	12.06	3.4	8.6	17.2
	6 [1.82m]	0.08	82.5	2.89	0.8	2.1	4.1
	9 [2.74m]	0.04	38.2	1.34	0.4	1.0	1.9
45°	3 [0.91m]	0.35	349	12.24	3.5	8.7	17.5
	6 [1.82m]	0.08	81.4	2.85	0.8	2.0	4.1
	9 [2.74m]	0.04	37.6	1.32	0.4	0.9	1.9
90°	3 [0.91m]	0.25	250.9	8.80	2.5	6.3	12.5
	6 [1.82m]	0.06	63.6	2.23	0.6	1.6	3.2
	9 [2.74m]	0.03	29.4	1.03	0.3	0.7	1.5
135°	3 [0.91m]	0.05	54.1	1.90	0.5	1.4	2.7
	6 [1.82m]	0.02	16.4	0.58	0.2	0.4	0.8
	9 [2.74m]	0.01	8.2	0.29	0.1	0.2	0.4
180°	3 [0.91m]	0.05	49.9	1.75	0.5	1.2	2.5
	6 [1.82m]	0.02	15.7	0.55	0.2	0.4	0.8
	9 [2.74m]	0.01	6.8	0.24	0.1	0.2	0.3
225°	3 [0.91m]	0.05	51.4	1.80	0.5	1.3	2.6
	6 [1.82m]	0.02	15.1	0.53	0.2	0.4	0.8
	9 [2.74m]	0.01	8.2	0.29	0.1	0.2	0.4
270°	3 [0.91m]	0.26	257.7	9.04	2.6	6.4	12.9
	6 [1.82m]	0.06	63.1	2.21	0.6	1.6	3.2
	9 [2.74m]	0.03	29.5	1.03	0.3	0.7	1.5
315°	3 [0.91m]	0.32	319	11.19	3.2	8.0	16.0
	6 [1.82m]	0.08	78	2.73	0.8	2.0	3.9
	9 [2.74m]	0.04	36.3	1.27	0.4	0.9	1.8
3 Feet above		0.04	37.7	1.32	0.4	0.9	1.9
3 Feet above + 3 Outward		0.12	123.8	4.34	1.2	3.1	6.2

Radiation Scatter Field for Standard (full-beam) - 8.9 Second Scan

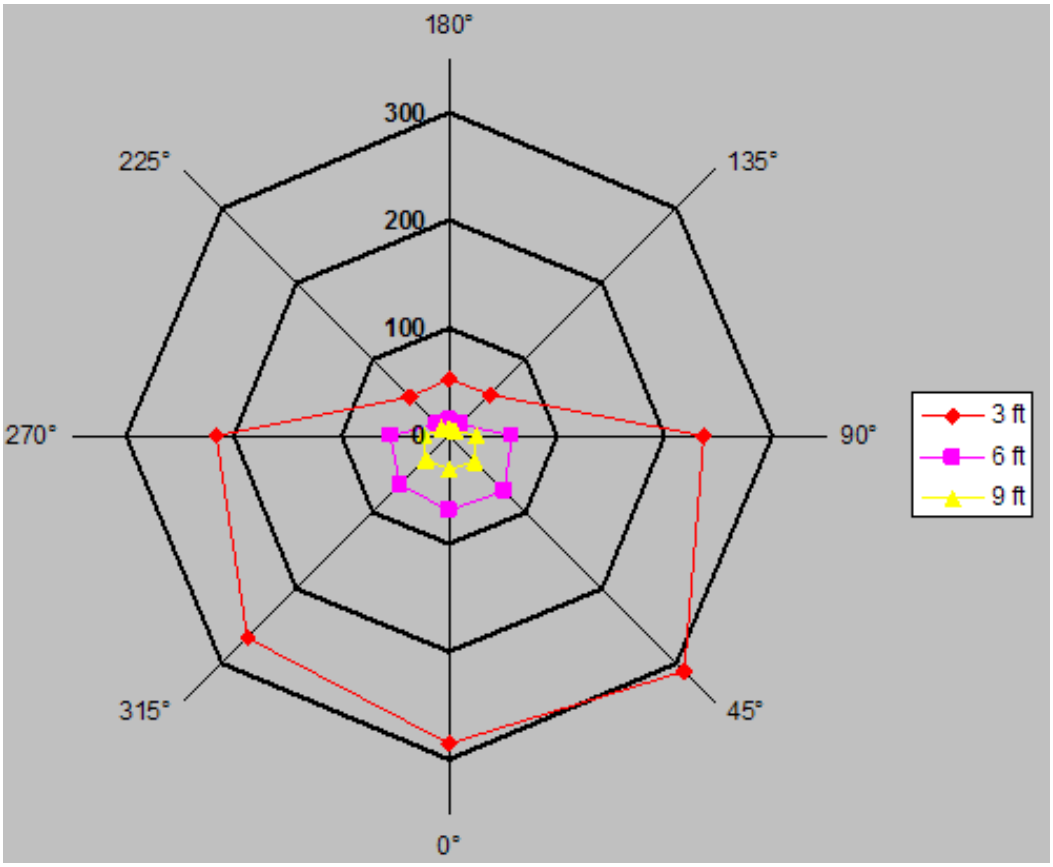


Half Beam Diameter 14 - Height 8.5 cm

NOTE: Selectable voxel sizes are 0.4 and 0.3.

Location	Distance in Feet [meter]	Exposure (mR)	Exposure (μR)	Exposure μR/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0°	3 [0.91m]	0.285	285.1	10.0	2.9	7.1	14.3
	6 [1.82m]	0.069	68.9	2.42	0.7	1.7	3.4
	9 [2.74m]	0.031	30.7	1.08	0.3	0.8	1.5
45°	3 [0.91m]	0.307	307	10.76	3.1	7.7	15.4
	6 [1.82m]	0.073	73.1	2.56	0.7	1.8	3.7
	9 [2.74m]	0.033	32.8	1.15	0.3	0.8	1.6
90°	3 [0.91m]	0.236	236.3	8.29	2.4	5.9	11.8
	6 [1.82m]	0.057	57.4	2.01	0.6	1.4	2.9
	9 [2.74m]	0.026	26	0.91	0.3	0.7	1.3
135°	3 [0.91m]	0.054	54.1	1.90	0.5	1.4	2.7
	6 [1.82m]	0.016	15.7	0.55	0.2	0.4	0.8
	9 [2.74m]	0.008	7.5	0.26	0.1	0.2	0.4
180°	3 [0.91m]	0.053	52.7	1.85	0.5	1.3	2.6
	6 [1.82m]	0.014	14.4	0.50	0.1	0.4	0.7
	9 [2.74m]	0.007	6.8	0.24	0.1	0.2	0.3
225°	3 [0.91m]	0.051	51.3	1.80	0.5	1.3	2.6
	6 [1.82m]	0.014	13.7	0.48	0.2	0.3	0.7
	9 [2.74m]	0.008	8.2	0.29	0.1	0.2	0.4
270°	3 [0.91m]	0.216	215.6	7.56	2.2	5.4	10.8
	6 [1.82m]	0.054	54.2	1.90	0.5	1.4	2.7
	9 [2.74m]	0.023	23.3	0.82	0.2	0.6	1.2
315°	3 [0.91m]	0.264	264.2	9.26	2.6	6.6	13.2
	6 [1.82m]	0.065	65	2.28	0.7	1.6	3.3
	9 [2.74m]	0.030	30.1	1.06	0.3	0.8	1.5
3 Feet above		0.043	42.5	1.49	0.4	1.1	2.1
3 Feet above + 3 Outward		0.103	103.3	3.62	1.0	2.6	5.2

Radiation Scatter Field for Half Beam - 8.9 Second Scan



Scatter Measurements for 23 Second Scans

23.0 second scan using pulsed X-ray: 619 frames, 19 ms pulse width at 5 mA.
Based on this, the estimated workload is:

10 scans per week yielding a workload of 9.6 mA-min/week
25 scans per week yielding a workload of 23.8 mA-min/week
50 scans per week yielding a workload of 55.6 mA-min/week

Standard (full-beam) Diameter 8.5 - Height 8.5 cm

NOTE: Selectable voxel sizes are 0.25, 0.2 and 0.125.

Location	Distance in Feet [meter]	Exposure (mR)	Exposure (μR)	Exposure μR/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0°	3 [0.91m]	0.69	689.1	12.08	6.9	17.2	34.5
	6 [1.82m]	0.17	165.3	2.90	1.7	4.1	8.3
	9 [2.74m]	0.08	76.5	1.34	0.8	1.9	3.8
45°	3 [0.91m]	0.70	699.1	12.26	7.0	17.5	35.0
	6 [1.82m]	0.16	163.1	2.86	1.6	4.1	8.2
	9 [2.74m]	0.08	75.3	1.32	0.8	1.9	3.8
90°	3 [0.91m]	0.50	502.6	8.81	5.0	12.6	25.1
	6 [1.82m]	0.13	127.4	2.23	1.3	3.2	6.4
	9 [2.74m]	0.06	58.9	1.03	0.6	1.5	2.9
135°	3 [0.91m]	0.11	108.4	1.90	1.1	2.7	5.4
	6 [1.82m]	0.03	32.9	0.58	0.3	0.8	1.6
	9 [2.74m]	0.02	16.4	0.29	0.2	0.4	0.8
180°	3 [0.91m]	0.10	100.0	1.75	1.0	2.5	5.0
	6 [1.82m]	0.03	31.5	0.55	0.3	0.8	1.6
	9 [2.74m]	0.01	13.6	0.24	0.1	0.3	0.7
225°	3 [0.91m]	0.10	103.0	1.81	1.0	2.6	5.1
	6 [1.82m]	0.03	30.2	0.53	0.3	0.8	1.5
	9 [2.74m]	0.02	16.4	0.29	0.2	0.4	0.8
270°	3 [0.91m]	0.52	516.2	9.05	5.2	12.9	25.8
	6 [1.82m]	0.13	126.4	2.22	1.3	3.2	6.3
	9 [2.74m]	0.06	59.1	1.04	0.6	1.5	3.0
315°	3 [0.91m]	0.64	639.0	11.20	6.4	16.0	32.0
	6 [1.82m]	0.16	156.3	2.74	1.6	3.9	7.8
	9 [2.74m]	0.07	72.7	1.27	0.7	1.8	3.6
3 Feet above		0.08	75.5	1.32	0.8	1.9	3.8
3 Feet above + 3 Outward		0.25	248.0	4.35	2.5	6.2	12.4

Half Beam Diameter 14 - Height 8.5 cm Scan

NOTE: Selectable voxel sizes are 0.25 and 0.2.

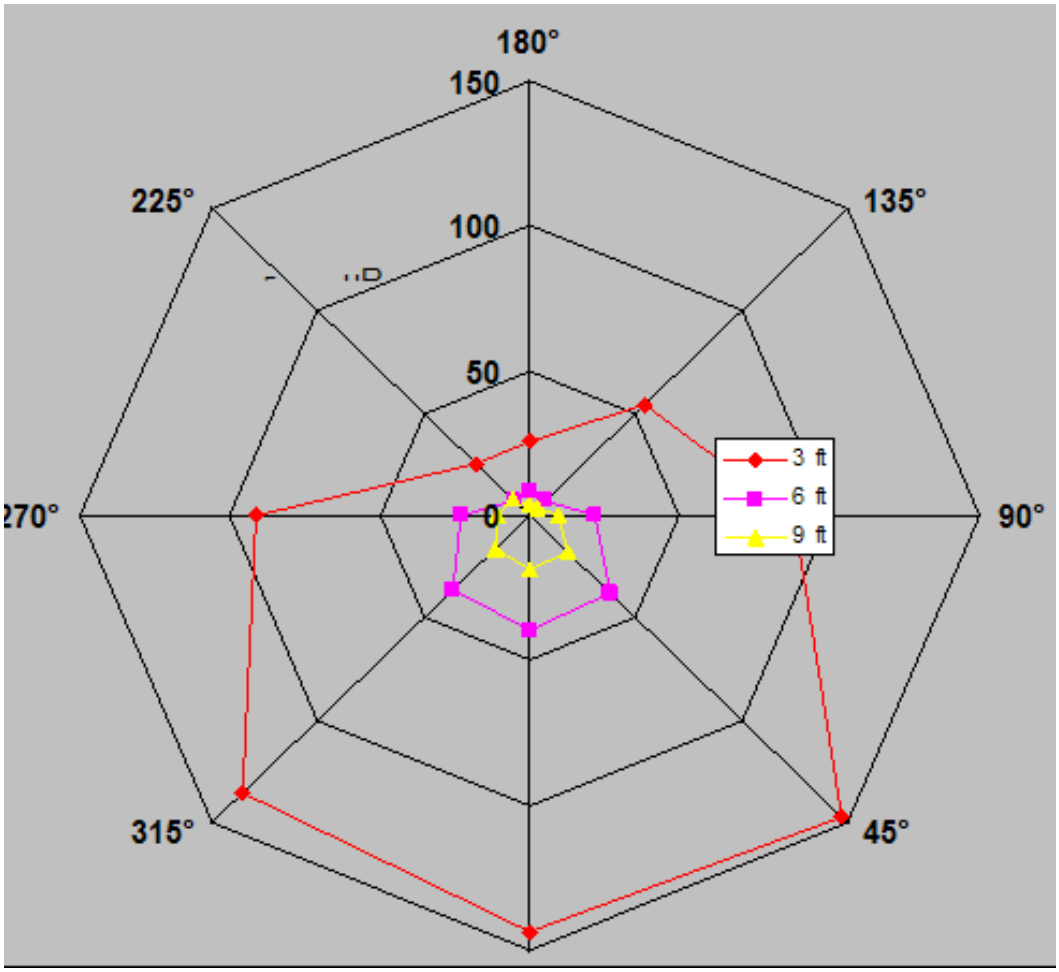
Location	Distance in Feet [meter]	Exposure (mR)	Exposure (μR)	Exposure μR/mAs	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0°	3 [0.91m]	0.57	571.1	10.01	5.7	14.3	28.6
	6 [1.82m]	0.14	138.0	2.42	1.4	3.4	6.9
	9 [2.74m]	0.06	61.5	1.08	0.6	1.5	3.1
45°	3 [0.91m]	0.61	615.0	10.78	6.1	15.4	30.7
	6 [1.82m]	0.15	146.4	2.57	1.5	3.7	7.3
	9 [2.74m]	0.07	65.7	1.15	0.7	1.6	3.3
90°	3 [0.91m]	0.47	473.4	8.30	4.7	11.8	23.6
	6 [1.82m]	0.11	115.0	2.02	1.1	2.9	5.7
	9 [2.74m]	0.05	52.1	0.91	0.5	1.3	2.6
135°	3 [0.91m]	0.11	108.4	1.90	1.1	2.7	5.4
	6 [1.82m]	0.03	31.5	0.55	0.3	0.8	1.6
	9 [2.74m]	0.02	15.0	0.26	0.2	0.4	0.8
180°	3 [0.91m]	0.11	105.6	1.85	1.1	2.6	5.3
	6 [1.82m]	0.03	28.8	0.51	0.3	0.7	1.4
	9 [2.74m]	0.01	13.6	0.24	0.1	0.3	0.7
225°	3 [0.91m]	0.10	102.8	1.80	1.0	2.6	5.1
	6 [1.82m]	0.03	27.4	0.48	0.3	0.7	1.4
	9 [2.74m]	0.02	16.4	0.29	0.2	0.4	0.8
270°	3 [0.91m]	0.43	431.9	7.57	4.3	10.8	21.6
	6 [1.82m]	0.11	108.6	1.90	1.1	2.7	5.4
	9 [2.74m]	0.05	46.7	0.82	0.5	1.2	2.3
315°	3 [0.91m]	0.53	529.3	9.28	5.3	13.2	26.5
	6 [1.82m]	0.13	130.2	2.28	1.3	3.3	6.5
	9 [2.74m]	0.06	60.3	1.06	0.6	1.5	3.0
3 Feet above		0.09	85.1	1.49	0.9	2.1	4.3
3 Feet above + 3 Outward		0.21	206.9	3.63	2.1	5.2	10.3

Scatter Measurements for PAN Scan

Scatter was measured from a PAN scan set at Large Exposure.

Location	Distance in Feet [meter]	Exposure (mR)	Exposure (μR)	10 scans/wk mR/wk	25 scans/wk mR/wk	50 scans/wk mR/wk
0°	3 [0.91m]	0.143	143	1.4	3.6	7.2
	6 [1.82m]	0.0396	39.6	0.4	1.0	2.0
	9 [2.74m]	0.0184	18.4	0.2	0.5	0.9
45°	3 [0.91m]	0.1462	146.2	1.5	3.7	7.3
	6 [1.82m]	0.0376	37.6	0.4	0.9	1.9
	9 [2.74m]	0.0178	17.8	0.2	0.4	0.9
90°	3 [0.91m]	0.0875	87.5	0.9	2.2	4.4
	6 [1.82m]	0.0219	21.9	0.2	0.5	1.1
	9 [2.74m]	0.0096	9.6	0.1	0.2	0.5
135°	3 [0.91m]	0.0541	54.1	0.5	1.4	2.7
	6 [1.82m]	0.0075	7.5	0.1	0.2	0.4
	9 [2.74m]	0.0041	4.1	0.0	0.1	0.2
180°	3 [0.91m]	0.0253	25.3	0.3	0.6	1.3
	6 [1.82m]	0.0082	8.2	0.1	0.2	0.4
	9 [2.74m]	0.0041	4.1	0.0	0.1	0.2
225°	3 [0.91m]	0.0246	24.6	0.2	0.6	1.2
	6 [1.82m]	0.0075	7.5	0.1	0.2	0.4
	9 [2.74m]	0.0082	8.2	0.1	0.2	0.4
270°	3 [0.91m]	0.091	91	0.9	2.3	4.6
	6 [1.82m]	0.0226	22.6	0.2	0.6	1.1
	9 [2.74m]	0.0109	10.9	0.1	0.3	0.5
315°	3 [0.91m]	0.1348	134.8	1.3	3.4	6.7
	6 [1.82m]	0.0363	36.3	0.4	0.9	1.8
	9 [2.74m]	0.0165	16.5	0.2	0.4	0.8
3 Feet above		0.03	30.7	0.3	0.8	1.5
3 Feet above + 3 Outward		0.01	7	0.1	0.2	0.4

Radiation Scatter Field in Panaramic Mode - Large Exposure



Scan Times and Settings

PAN Scans (Continuous)

Large exposure, 94kV, 5mA, 20 seconds

Small exposure, 84kV, 5mA, 18.3 seconds

CT Scans (Intermittent)

360° Scans

- 0.25, 0.20, 0.125 voxel, 120kV, 5mA, 23.0 seconds
- 0.4 and 0.3 voxel, 120kV, 5mA, 8.9 seconds

Half Scans (half revolution)

- 0.25, 0.20, 0.125 voxel, 120kV, 5mA, 12.6 seconds
- 0.4 and 0.3 voxel, 120kV, 5mA, 4.8 seconds

Linearity of Radiation Output: <.025 COV

Voxel Size	mAs	Acquisition Time
0.4 / 0.3	28.52	8.9 sec
0.25 / 0.2 / 0.125	57.06	23.0 sec
0.4 / 0.3 Half Scan	15.55	4.8 sec
0.25 / 0.2 / 0.125 Half Scan	31.20	12.6 sec

	Voxel mm		kV	mA	Scan Times	# of Frames
360° Scans	0.2	0.25	120	5	23.0	600
	0.3	0.4	120	5	8.9	300
Half Scans	0.2	0.25	120	5	12.6	320
	0.3	0.4	120	5	4.8	160
iPAN Large			94	5	20	1200
iPAN Small			84	5	18.3	1100

Dose and Imaging Performance Information

The Computer Tomography Dose Index (CTDI) was measured using a 10cm, 3cc, pencil ionization chamber from Radcal Corporation (10X9-3CT) in conjunction with a Radcal Corporation 16cm diameter cylindrical CT head phantom (20CT6). This phantom has one hole at the center and four more at 90° intervals, 1cm inside the outer circumference. The procedure used was as follows:

- The phantom was positioned with its axis perpendicular to the tomographic plane at the center of rotation, and its height adjusted such that its middle was at the same height as the horizontal laser line.
- The pencil ionization chamber was inserted into one of the holes and the other four were filled with acrylic rods.
- The phantom was scanned using one of the standard protocols and the exposure E recorded.
- The $CTDI_{100}$ at this location was calculated using the formula:

  $CTDI_{100} = E \cdot f \cdot L / T$

  Where:
  E is the exposure in mR
  f is the factor to convert Roentgens to absorbed dose (rad). A value of 0.87 for the conversion in air was used.

  L is the active length of the chamber, 10cm
  T is the verical dimension of the beam.
- The derived quantity $CDTI_w$ (weighted) was calculated as follows:

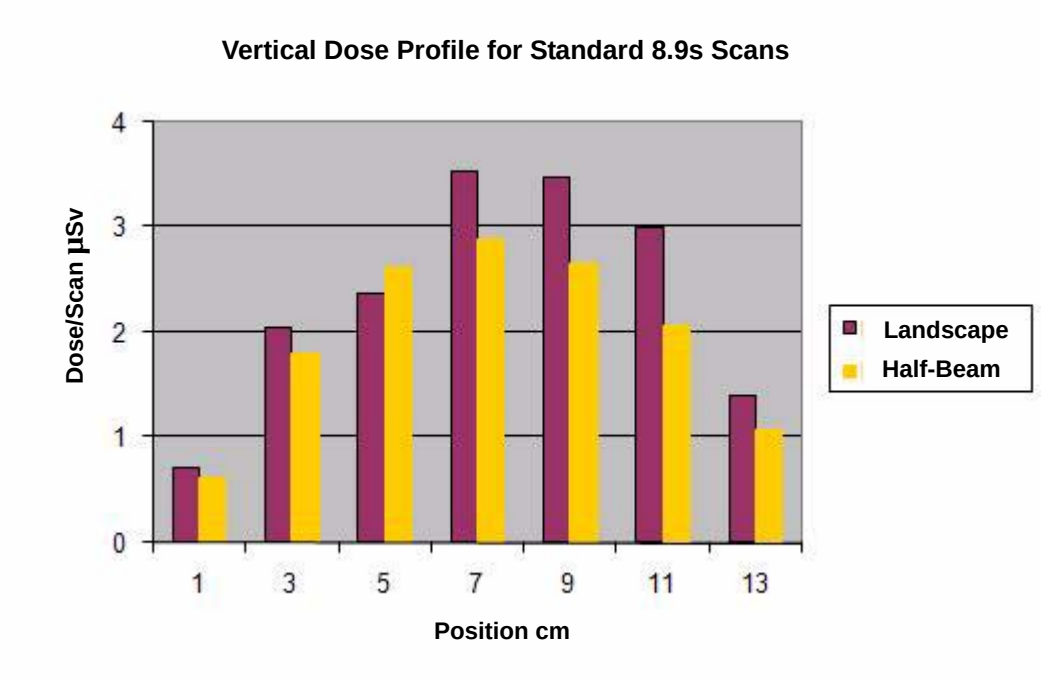
  $CTDI_w = 1/3.CTDI_{center} + 2/3.mean(CTDI_{periphery})$
- The CTDI in free air was also measured, i.e. without the phantom in place, at the same location as the central hole occupied: i.e. the $CTDI_{Free\text{-}air}$

The $CTDI_w$ and the $CTDI_{Free\text{-}air}$ were measured for the CT scanning modes available and the results are in the table below.

Scan Mode and Beam Size		$CTDI_W$ mGy	$CTDI_{Free\ air}$ mGy
EDS	14 x 8.5 cm	4.72	10.10
	14 x 6 cm (maxilla)	6.38	9.76
	14 x 6 cm (mandible)	6.35	9.88
Landscape	8.5 x 8.5 cm	5.58	14.01
	8.5 x 6 cm (maxilla)	7.56	13.20
	8.5 x 6 cm (mandible)	7.51	13.20

Dose Profile

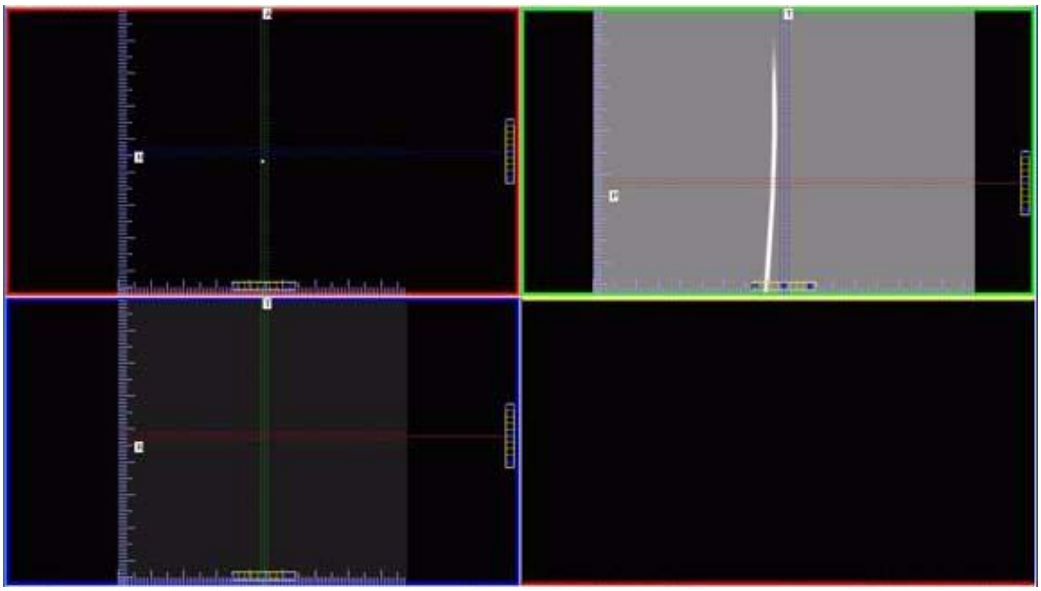
The dose profile was measured using ThermoLuminescent Dosimeters (TLD) placed at 2cm intervals vertically in the central column of the acrylic head phantom used for CTDI measurements, starting at the bottom position. The TLD chips were 3mm x 3mm x 1mm thick in size and purchased from Global Dosimetry, Irvine, California. 2cm acrylic plugs were placed between the TLDs to space the TLDs and fill the space. The profile was measured for both Landscape (D 8.5 - H 8.5) and Half-Beam (D 14 - H 8.5) scans for standard scans of 8.9s. The TLDs were measured and the doses in mrem were converted to µSv. The results are presented in the figure and table below.



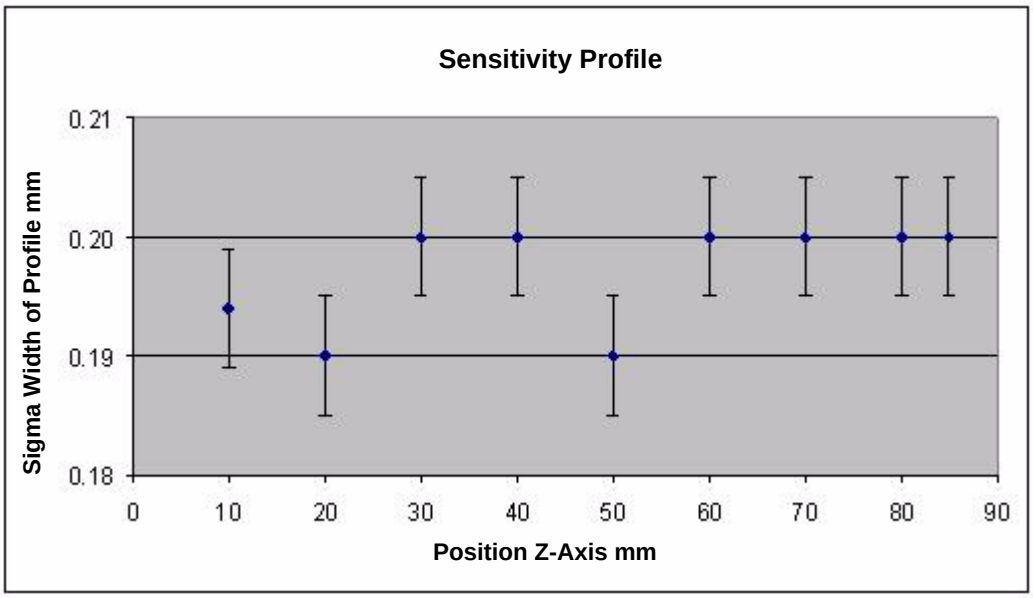
	Dose/Scan µSv	
Position cm	Landscape	Half-Beam
1	0.70	0.61
3	2.04	1.78
5	2.37	2.60
7	3.52	2.88
9	3.46	2.65
11	2.99	2.06
13	1.39	1.06

Sensitivity Profile

A 40 µm diameter Tungsten wire was scanned using the standard Dia. 8.5 - H 8.5 protocol with 0.2mm voxel resolution. The wire was held vertically at the system isocenter..



The Hounsfield units of the reconstructed image of the wire was measured at several slice positions with 0.2mm width and the resulting profile was compared against a Gaussian curve. For each location, the width of the wire as measured by the standard deviation of the Gaussian curve was converted to a Full-Width Half-Maximum (FWHM) value using the conversion factor of 2.3548 and was plotted and determined to be a measure of the sensitivity of the system.



Drywall Attenuation

The attenuation due to typical drywall found in offices was measured. A simulated wall was constructed from two sheets of 5/8-inch thick gypsum wallboard, spaced 4 inches apart, mounted on a wood frame. The wall was placed between a scatter source (a head phantom) and a Radcal Model 9010 Radiation monitor with 10X5 -180 dosimeter chamber. The system was operated in a regular scanning mode, and the radiation was measured with and without the drywall. The results are below:

	Measured Radiation mR		
Distance from Head	**3 ft (0.91m)**	**6 ft (1.82m)**	**9 ft (2.74m)**
No Drywall	344.0	82.5	38.2
With Drywall	204.5	49.8	23.2
Transmission	59%	60%	61%
Attenuation	41%	40%	39%

Therefore, the effect of a typical drywall or wallboard is to reduce the X-ray radiation by about 40%. Please note that there may be differences depending on the wall construction and composition, and that this is an approximate guide only.

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 Computer Workstation and X-ray Operator should be located behind a properly shielded permanent barrier. A viewing window (or alternative method such as a mounted mirror) 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 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.

- An annual radiation survey may be typically required. This survey is typically required to be submitted to the local agency or government body.
- A phantom or patients may be used for system training. Employees of the facility may not be used for this training.
- The system shall be registered with the local agency or government body.

X-ray Tube Assembly

Imaging Sciences International utilizes the SXR 130-15-0.5 X-ray Tube from Superior X-Ray Tube Company to manufacture our X-ray head assemblies.

Nominal X-Ray Tube Voltage	**120 kV**
Max. Tube Current	**7 mA**
X-Ray Tube Nominal Anode Input Power	**65 W**
X-Ray Tube Maximum Anode Heat Content (HU = Kvp x mA x Time in Seconds)	**30,000 HU**
X-Ray Tube Single Load Rating	**120kV, 5mA**
Max. X-Ray Tube Assembly Heat Content	**120K HU**
Max. Continuous Heat Dissipation of Tube Assy	**65W**
High Voltage Supply Requirements	**120 VAC at 10 amps**
Loading Factors Concerning Leakage Radiation: **CT Scan = 120KV 5mA 12 mS x 618 or 309** **PAN Scan = 94KV 5mA**	**< = 25mR/hr @ 1m**

Operator Data

Available focal spot size (mm): **0.5**

Available target angle: **15°**

Anode construction:

Vacuum cast copper with tungsten target

Cathode construction:

Vacuum tube nickel with tungsten filament

Max. Tube operating voltage:

130 kVp Full wave rectified

Inherent filtration/Window material:

2.0 mm/Glass

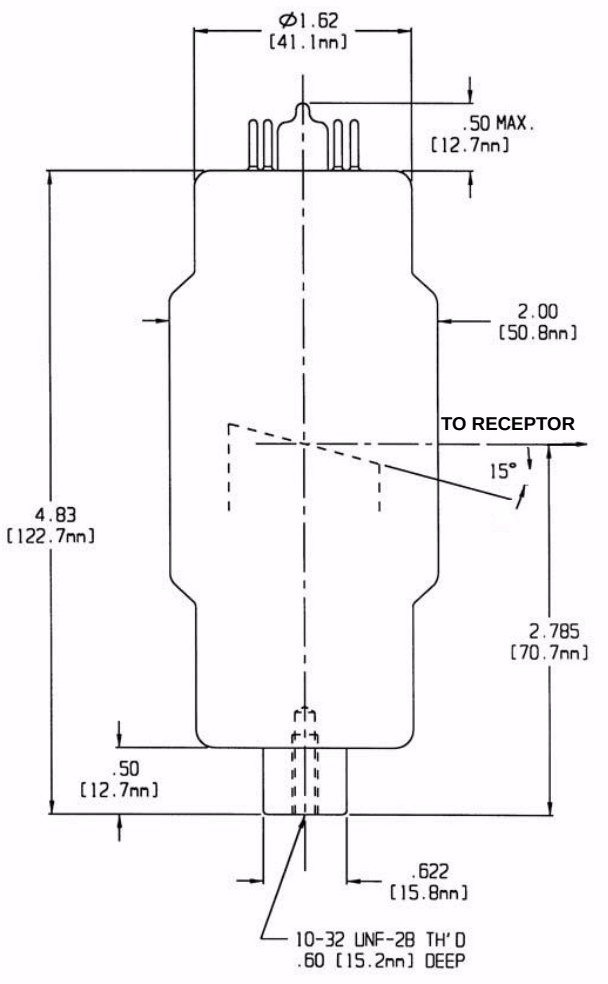
Cooling Method:

High dielectric transformer oil

Conditioning of Tube Head:

Must be at or above 22°C before first scan.

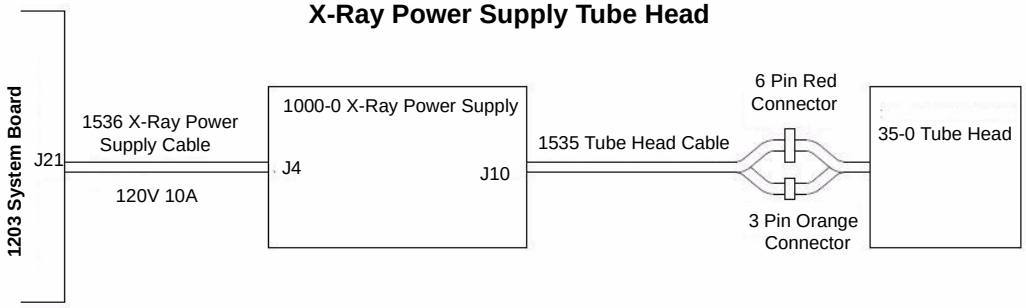
No system parts are connected to a Protected Earth Terminal.



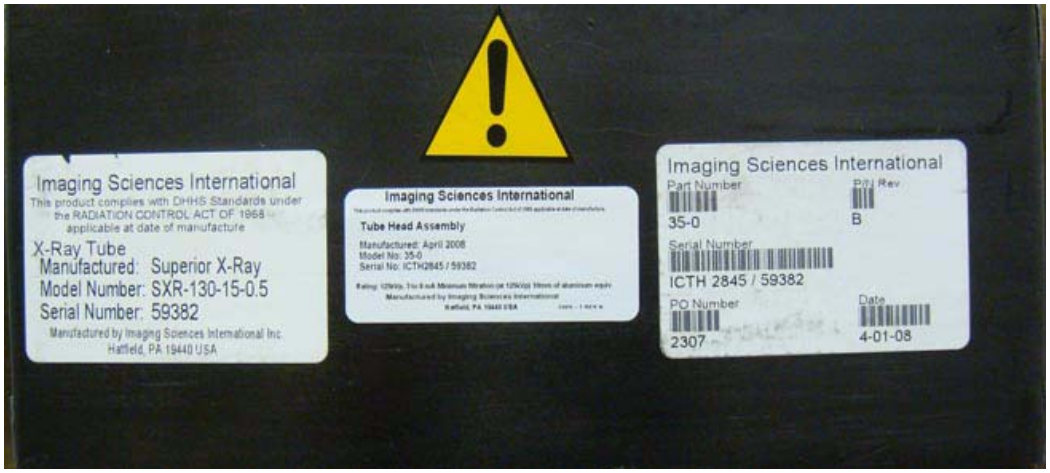
SXR-130-15-0.5
FOCAL SPOT

X-Ray Tube Voltage	X-Ray Tube Current	Normal Electrical Power
84 kV	5mA	420W
94 kV	5mA	470W
120 kV	5mA	600W

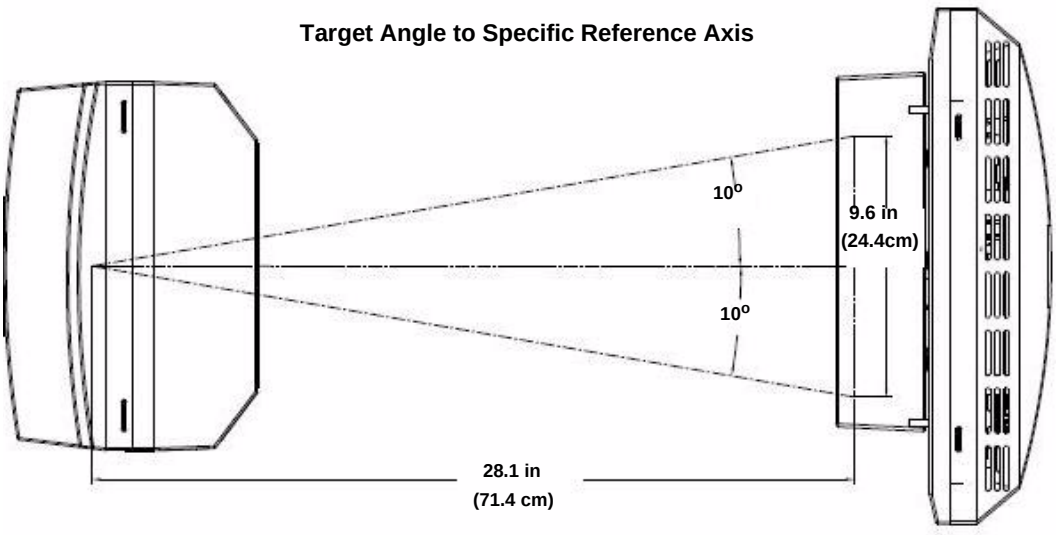
X-Ray Power Supply Tube Head



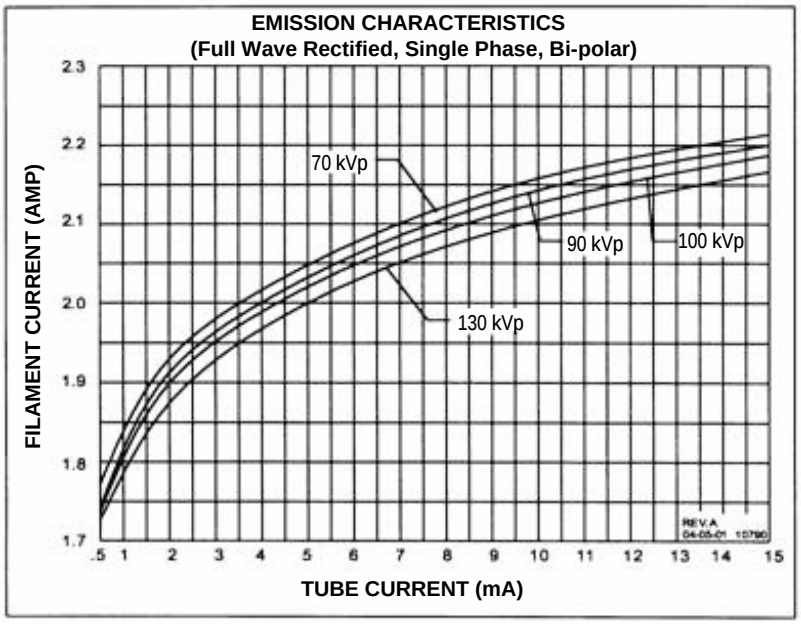
X-Ray Tube Head Markings



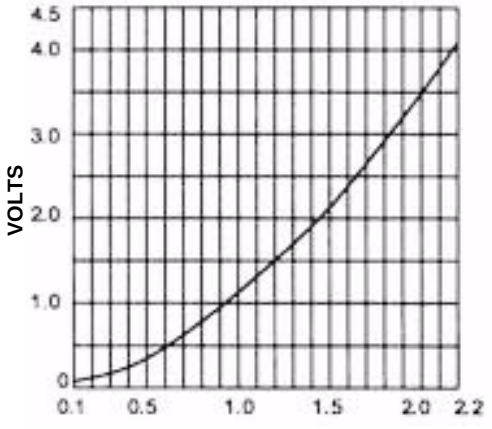
Target Angle to Specific Reference Axis



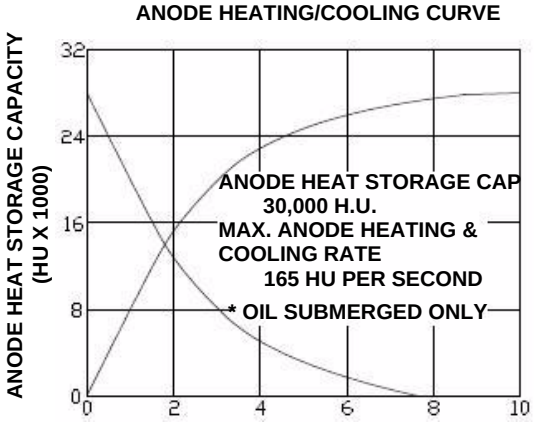
EMISSION CHARACTERISTICS
(Full Wave Rectified, Single Phase, Bi-polar)



FILAMENT VOLT/AMPS CHARACTERISTICS:
60 Hz AC & DC



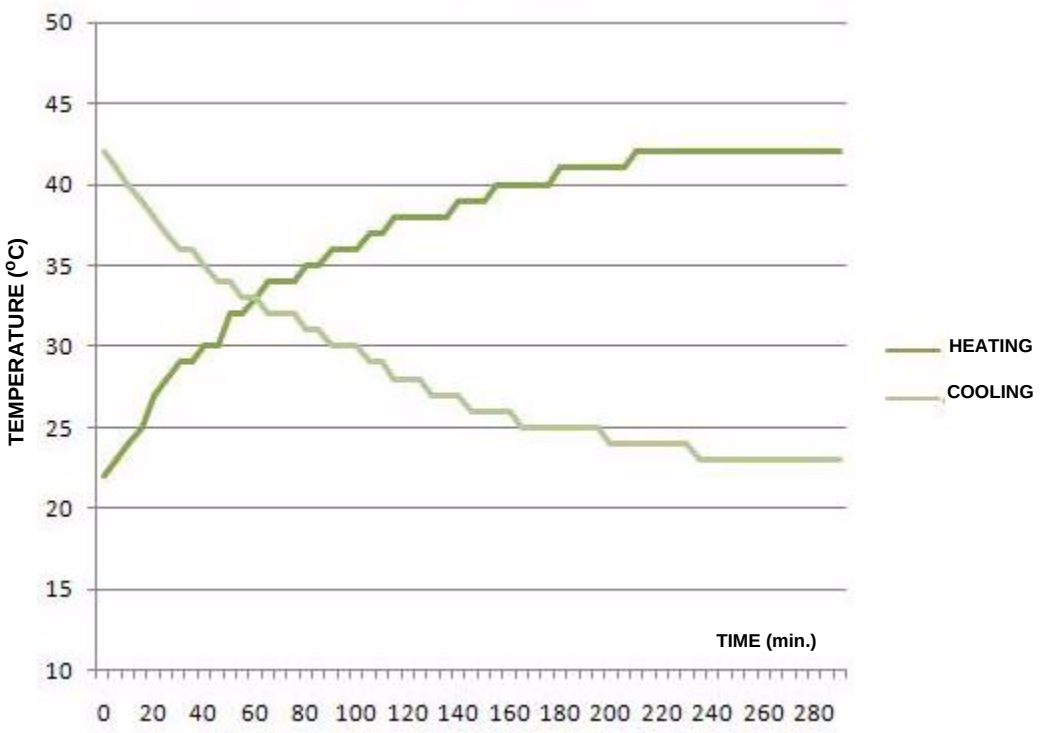
ANODE HEATING/COOLING CURVE



H.U. (Heat Units) = kVp (Kilovolts Peak) x mA (eff) x Time (sec.)
Joules = .707 x H.U.

SXR-130-15-0.5

X-Ray Tube Head Heating and Cooling Chart



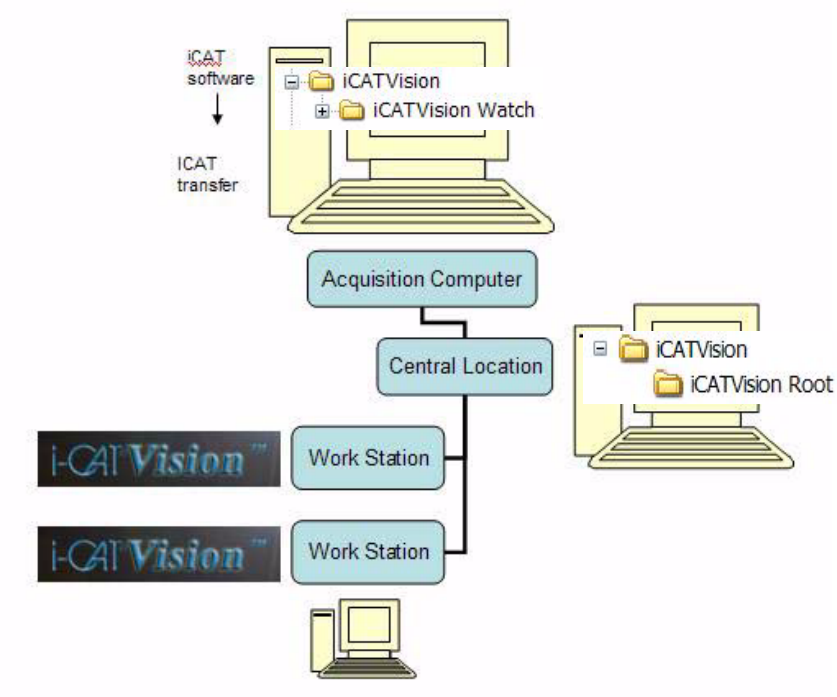
CONDITIONS FOR X-RAY TUBE HEAD HEATING AND COOLING TEST
MACHINE CYCLED IN PAN MODE: 1 SCAN EVERY 5 MINUTES
PAN MODE SETTINGS: 94KV 5MA 20SEC SCAN
AMBIENT TEMPERATURE: 22°C

Appendix

A iCATVision, iCATTransfer, & RSQM Installation

iCATVision

iCATVision standalone is used to view images that have been acquired by an iCAT® Acquisition Computer. iCATVision standalone can be installed on a computer that runs Window XP operating system. Other operating systems are not supported at this time. We are pleased to provide iCATVision free of charge to anyone with access to iCAT® scans with no limit on usage and the number of copies.



Laptop Minimum Requirements

- Intel Processor M 1.5Ghz
- 1GB of RAM (2GB for peak performance)
- Windows XP Professional
- 40GB Hard Drive
- CDIDVD Drive
- Integrated Gigabit Ethernet 10/100/100 Network Connection

Workstation Minimum Requirements

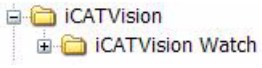
- Processor 2Ghz
- 1GB of RAM (2GB for peak performance)
- Windows XP Professional
- Video Display capabilities of 1600 x 1200 resolution
- 18 or 19 inch Monitor (recomended)
- 40GB Hard Drive
- CDIDVD Drive
- Integrated Gigabit Ethernet 10/100/100 Network Connection

File Structure Setup

1. On the iCAT® Acquisition Computer, create an iCATVision folder under the C: drive.
2. Create a subfolder under iCATVision called **iCATVision Watch**

   This is where the DICOM 3 data is exported. NOTE: Only DICOM files are placed here, NO FOLDERS.

   File structure on iCAT® Acquisition Computer:

   C:\ 

NOTE: It is not recommended to have the Watch folder located on a server because it would slow down the Network speed.

3. On the server or central storage location, create another folder named iCATVision.

4. Under this iCAT Vision folder create a sub folder named **iCATVision Root**

   File structure on server/central storage location:

   C:\ 

   If a server/central storage location is not available, then create the iCATVision Root directory on the iCAT® Acquisition Computer's C: drive under the iCAT Vision Folder.

Create a new Folder

1. Open the folder where the new folder is to reside.
2. Right click and select **New > Folder**.
3. Type the name for the new folder.

Install iCATVision

1. Unzip the iCATVision.zip file to the iCAT Vision folder, it unzips to iCATVision.exe.
2. Double click the .exe file to execute the program.

   A shortcut can be created for this program onto the desktop.

To unzip a file:

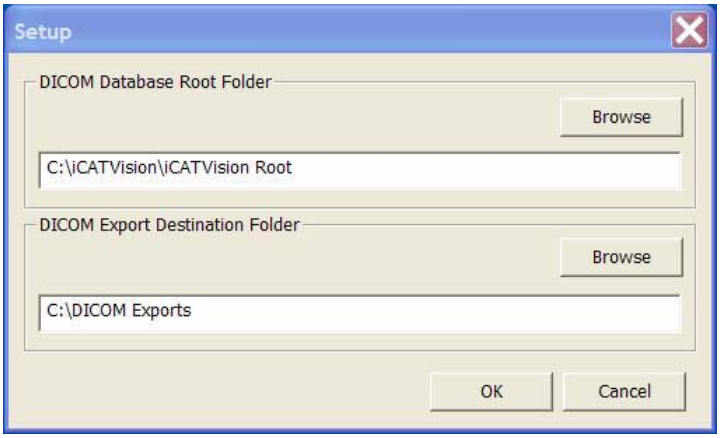
Right-click file and click **Extract** on the shortcut menu.

To create a shortcut:

Right click file and select **Send to > Desktop (create shortcut)**.

iCATVision Setup

1. From iCAT Vision select **Tools > Setup**.

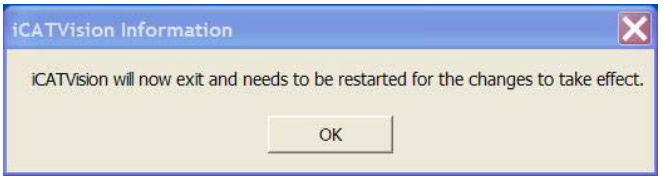


2. Under *DICOM Database Root Folder*, browse to the iCAT Vision\ iCAT Vision Root and click **OK**.

   (This may be on the C: drive or on a networked drive).

   Setup is the same on all networked and non-networked computers or workstations.

3. A prompt to restart iCATVision software is displayed. Click OK.



NOTE: It is currently recommend that when using iCAT Data for 3rd party software, perform a separate DICOM export from iCAT®. The data will be interchangeable when third party systems start accepting compressed DICOM.

iCATTransfer

NOTE: iCATTransfer is not required for iCAT® 17-19 Systems.

iCATVision is restricted to iCAT® DICOM scans and necessitates an "authentication" of DICOM data (Digital Imaging Communications). Authentication is performed by a program called "iCATTransfer" which is installed and executed on the iCAT® Acquisition Computer (computer capturing the scan) or another computer on the same network, in special cases. iCATTransfer authenticates and stores all newly exported DICOM data (from iCAT® software, to the Watch folder, and then to the Image Root folder.) The Image Root folder typically resides on a server or another central storage location.

If the computers are on the same network as the iCATTransfer, then there is direct access to the patient images. If running outside this network (e.g. a referring doctor's office), then patient data may be transferred via a CD to the remote computer's Image Root folder.

To reiterate, iCATVision only accepts iCAT® DICOM data that is authenticated by iCATTransfer. **Images from the GXCB-500 system do not require iCATTransfer.**

Install iCATTransfer

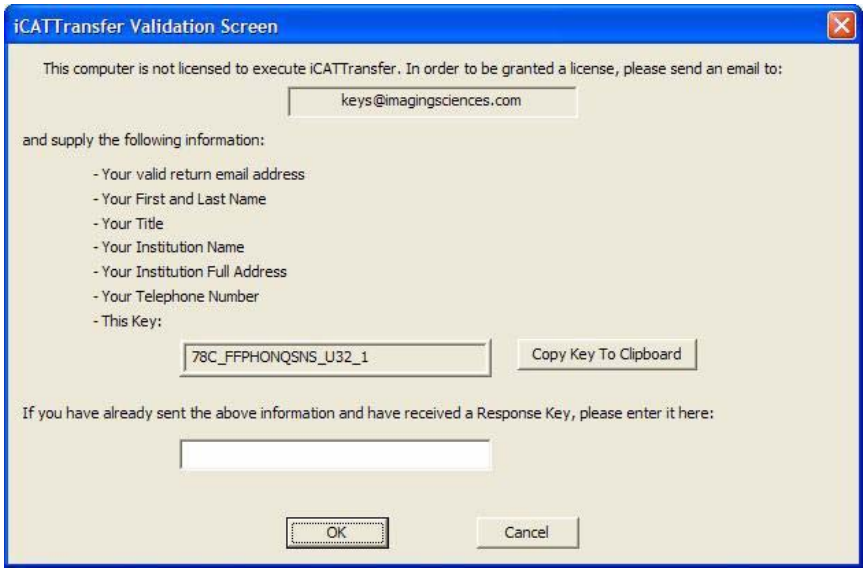
1. Unzip the iCATTransfer.zip file to the iCAT Vision folder, it unzips to iCATTransfer.exe.
2. Double click the .exe file to execute the program.

   A shortcut can be created for this program onto the desktop.

   To unzip a file: Right-click the file and click **Extract** on the shortcut menu.

iCATTransfer Passcode

When iCATTransfer is first launched, it opens to the iCATTransfer Validation Screen (below). Instructions are displayed to send an e-mail to Imaging Sciences at keys@imagingsciences.com with your customer information and the authentication code shown on screen. We will return an e-mail with the Passcode to be entered into the iCATTransfer Validation Screen.



The program then opens, click **accept** to accept the License Agreement and then follow the instructions below.

iCATTransfer Setup

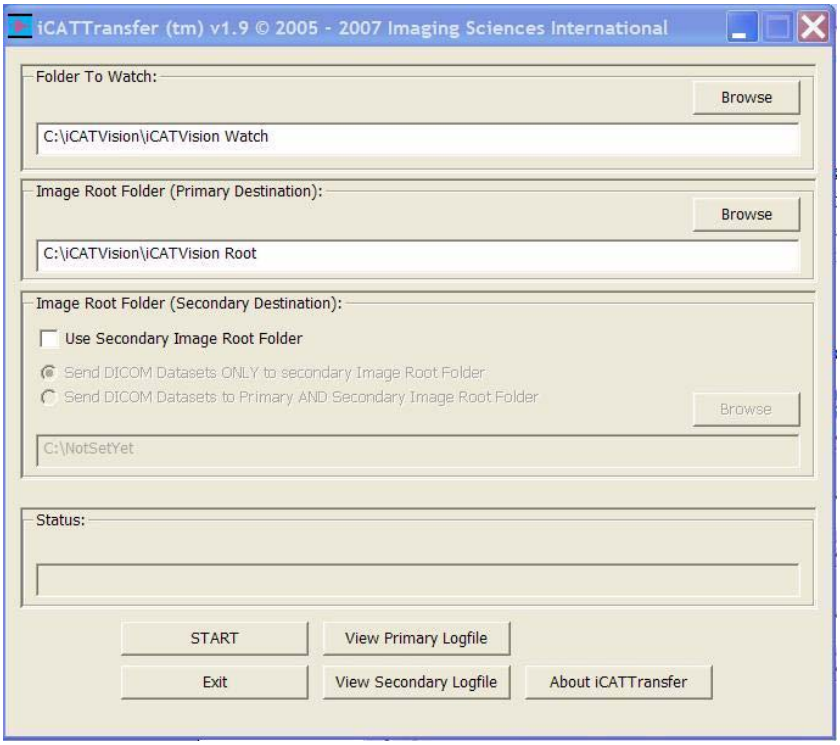
The program must be configured to "watch" for exported DICOM data from iCAT® in order to authenticate and transfer it to the image root directory. The program needs to be running in the background in order to detect the exportation of the DICOM Data. The iCATTransfer program can be placed into the StartUp Menu of the iCAT® Acquisition Computer (or server).

Putting iCATTransfer into the StartUp Menu

1. Right click the **START** button and select **OPEN**.
2. Double click **Programs** folder to open and then double click the **StartUp** folder to open.
3. Copy the iCATTransfer.exe file into this StartUp folder.

Configure iCATTransfer

1. Launch iCATTransfer, the following window is displayed.



2. Under *Folder to Watch*, Browse to **iCATVision\ iCATVision Watch** folder and select. (This is most likely on the C: drive of the iCAT® Acquisition Computer).
3. Under *Image Root Folder (Primary Destination),* Browse to **iCATVision Root** folder and select. (This is most likely on a server/central storage location).
4. Click **Start**. This saves the preset Watch and Root destinations.

NOTE: If START is not clicked the transfer program will not work.

Remember, iCATTransfer must be running in order for the data to transfer (iCATTranfer can be minimized).

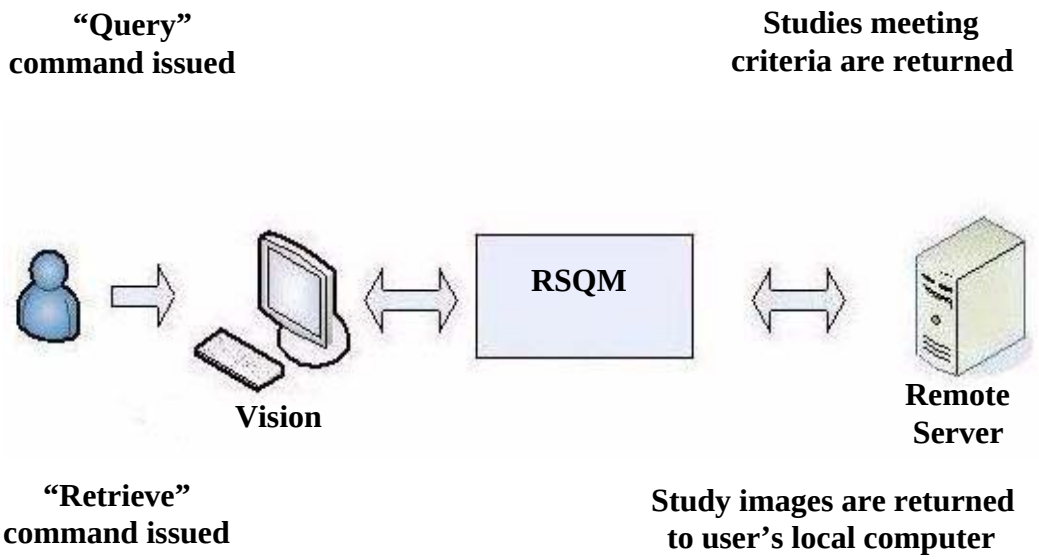
Accessing i-CAT® DICOM Data

iCATTransfer requires data to be exported from the iCAT® software in DICOM3 format.

RSQM

The Remote Service Query/Retrieve Module (RSQM) enables CT or iPAN (DX) images to be requested and retrieved from a remote system, such as a Picture Archive and Communications System (PACS) using DICOM service protocols (C-FIND and C-MOVE). The retrieved images can then be viewed and manipulated in Vision.

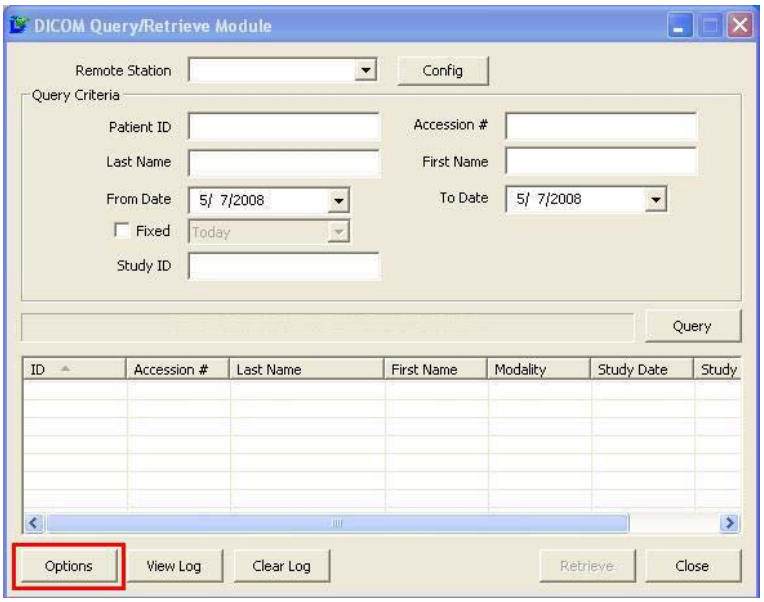
When the user issues a Query command in RSQM, all studies scanned on the remote system that meet the search criteria are returned. After a study is located, the user can retrieve the images for the study from the remote server. The remote server transfers the images to the user's local computer, where they are stored. It is recommended that the storage location be set to the same root folder as the Vision viewer.



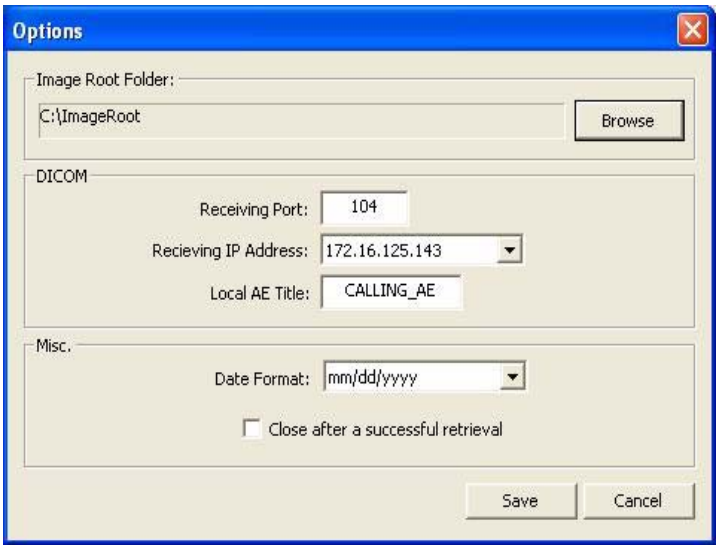
RSQM Installation and Setup

1. Place the RSQM.exe in the desired location. It is recommended to place it with the iCATVision.exe, but is not required.

2. Double-click RSQM.exe. The DICOM Query/Retrieve Module is displayed.



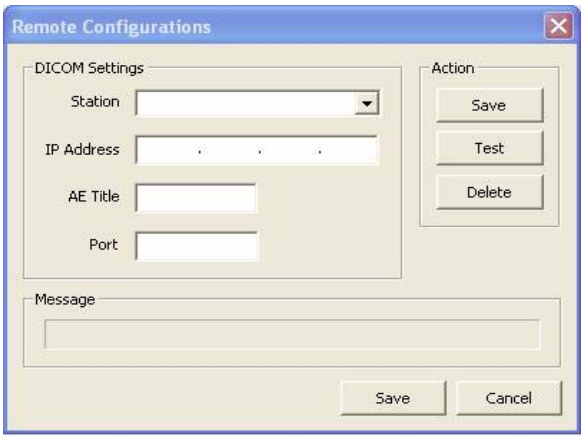
3. Click **Options**.



4. Click **Browse,** and browse to the Image Root folder to select it as the default storage location on the local computer.
5. In **DICOM** section, enter Receiving Port, Receiving IP Address, and Local AE Title. This data must match the data entered on the Query/Retrieve (PACS) server side so that the two machines can communicate.
6. Click **Save**.

Query and Retrieve Images

1. Double-click RSQM.exe. The DICOM Query/Retrieve Module is displayed.
2. Click **Config.**
   a. Enter Station name, IP Address, AE Title, and Port number for the DICOM node, such as a PACS, from where studies are to be queried and retrieved. This information may be provided by hospital IT or PACS personnel.
   b. Click **Save**.

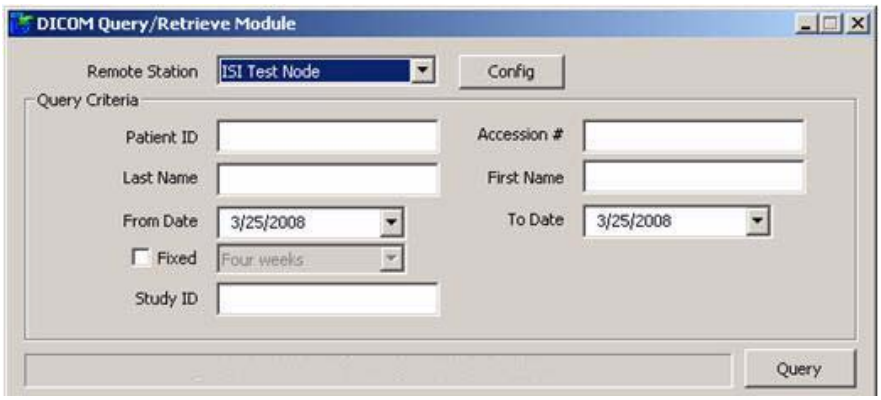


3. The Query Criteria default is to retrieve all studies scanned by the DICOM node selected above for the current day, or for a fixed period of time if the Fixed option is selected. Click **Query** to execute the default query.

   To enter different query criteria to narrow or widen the search:

   a. Enter desired search criteria in the Query Criteria area.

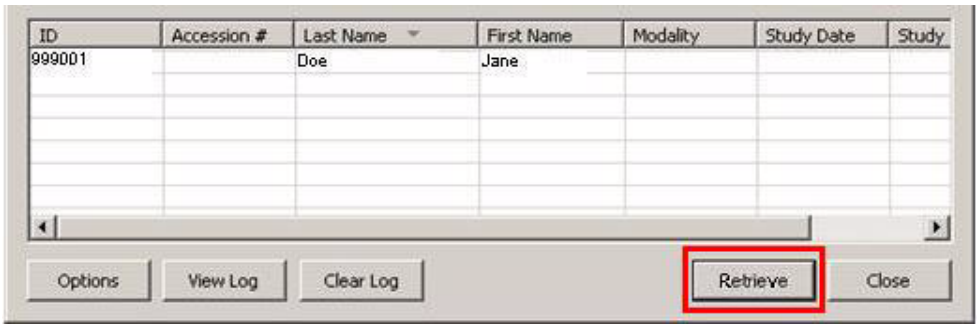
b. Click **Query**. Studies meeting the criteria are returned from the remote server.



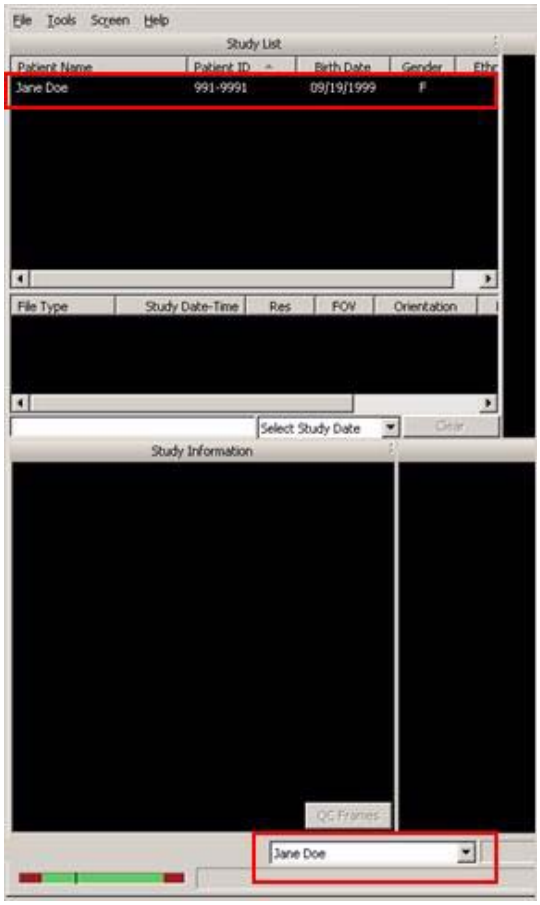
4. To retrieve images for a study:

   a. Select a study from the list.

   b. Click **Retrieve**. The images for the selected study are retrieved from the remote server and copied to the local computer in the folder that was specified during setup, usually ImageRoot.

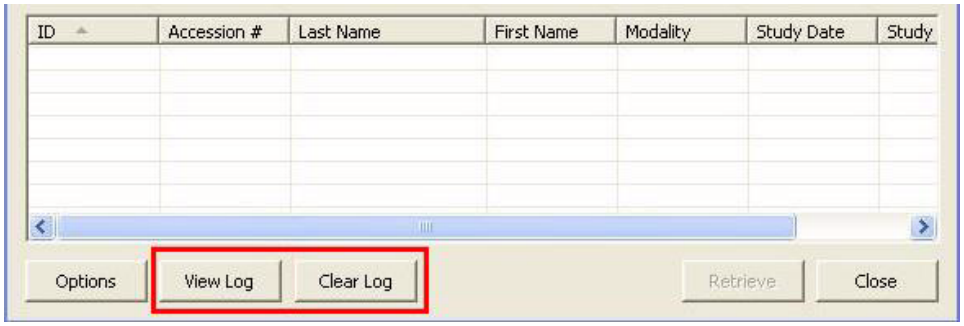


5. The study is displayed on the Study List in Vision. The patient's name is also displayed in the new patient arrival box if Vision and RSQM are configured to point to the same Image Root folder.



   The new patient arrival box lists all studies that have arrived in the Image Root folder since Vision has started for the current session. Studies can be copied to the Image Root folder when retrieved by RSQM, when transferred by iCATTransfer, or when manually copied in by the user.

6. If desired, click **View Log** to review the transactions that were completed or check for failures. To clear the log, click **Clear Log**.



Status Messages

The following list defines the status messages that may be displayed on the DICOM Query/Retrieve Module screen.

Invalid retrival IP address. Please select new one

The IP number selected in an option box is no longer valid. Open the options dialog and select a new one from the list.

Cannot use wildcard character with patient ID

A wildcard character is not allowed to be used for querying a patient ID.

Cannot use wildcard character with accession number

A wildcard character is not allowed to be used for querying an accession number.

Begin the retrieval process...

A study is about to be retrieved.

Unable to start retrieval. Please check network configuration

Cannot initiate the DICOM receiver module. Please check that the network configuration was entered correctly and completely.

Cannot find network configuration for selected server

The selected server is no longer valid. Please reconfigure the remote station or choose new destination.

Connecting...

RSQM is trying to communicate with the remote station.

Study list was queried successfully

Study was retrieved successfully

Requested operation was completed successfully.

Unable to send request to server. Please try again

RSQM is unable to request a list of studies from remote server.

Invalid command recieved from server. Please try again

Remote server does not return a valid respond to RSQM.

Query module failed communicating with server

RSQM does not understand the server's response.

No data found against the request

Cannot find study that matches the selected criteria.

Retrieving selected study from server...

RSQM is retrieving selected study from remote server.

Unable to retrieve all files for the study

RSQM is unable to retrieve all files that are part of the selected study. User should try to retrieve the study again.

Communication with server failed. Study retrieval failed

RSQM was unable to communicate with the remote server.

S***erver doesn't support the retrieval service***

The selected server does not support DICOM retrieval service.

Unable to connect to the server. Please check server configuration

RSQM was unable to connect to the remote server.

Appendix B i-CATVision Release Notes

ID	Known Issue
108	Institution Name field is not available when entering patient information or in the report. Related to work item 42. The “Institution Name” field shall default to empty and support 0-40 alphanumeric characters. Workaround: This field is only editable within the icatsystem.xml and this field is not being displayed in any screen, only read in the DCM viewer.
110	In Patient fields, the cursor focus is not set to the field which is to be corrected when wrong input is entered. The error message should display when the user moves to next field after entering wrong input in the previous field and the cursor focus should be set to the field which is to be corrected.
111	If a study is already opened before starting to burn a CD, the system asks to unload it. After the CD burning process is complete, the unloaded images appear and is loaded in memory. If the user tries to enter any of the preview views, nothing happens. Related to work item 329.
112	Unloaded images persist on main Vision Screen (i.e. Preview Screen) after a study is unloaded.
113	On Implant screen, pressing Alt-F4 does not return to Preview Screen as with TMJ, Ceph, MPR screens.
118	There are two ways to have different patients with same ID. Related to work item 44.
135	When adding a cross section image to in implant report, then changing that image to Panoramic image, image doesn’t fit to the boundary even when resizing image container.
138	Back to Reports button remains active when running any report. Some function buttons in tool bar remain disabled.
139	Font settings change if zoom level of report is changed.
140	When opening a saved report in 0.2 voxel patient study, an “end index” error occurs.
149	Workups created in older version of Vision will not work in 1.5.0.x release.

ID	Known Issue
150	Using the right-click shortcut does not show the Workup menu selection after a scan has been taken.
152	Workup gets lost when performing tilts in the Implant view.
153	System does not have UNDO capabilities. Related to work item 546. The Report feature does not support undo capabilities from one page to next, in order to capitalize on work already done instead of starting from scratch.
158	Wrong message displays during Geo Cal. Message "Preparing Geocalibrate preview acquisition" should display instead of "Moving panel to Landscape".
163	Autodetection of arches for a 0.125 voxel scan sometimes locks system.
173	Saving the bottom middle image in the Ceph screen as a JPEG when the airway is turned on, xy plot (graphic) does not show in the file.
176	The user can not change the font size and color, including background color, in each text box in Reports. Related to work item 379.
177	In Reports, changing the size of Image (when Clip option is selected) displays the ruler at wrong position.
180	Preview scans crash when doing a Portrait preview followed by a Landscape preview.
197	Sometimes volume scans are only stored as Raw files, but not as CT, also after reconstruction, etc.
209	Insufficient memory and reconstruction error during acquisition. Workaround: Use Retro Reconstruction to recover.
213	Incorrect scan length options for retro-reconstruction.
225	GXCB-500 Only: Collimation Calibration GUI in Calibrate.exe uses Portrait, Landscape terminology.
230	E-stop button needs to be released to stop multiple dialogs from displaying. Workaround: User must obey the message "E-stop is pressed" dialog box and lift the E-Stop button when trying to enter Acquisition screen.
239	Stopping Geo Cal closes Calibration application. Workaround: Restart Calibration application.
268	Time out error during a mode of panel calibration can cause calibration failure. Workaround: Restart Calibration application and rerun calibration again.
273	iPAN slide bar covering only 980 frames from 1276.

ID	Known Issue
288	Sometimes after burning a CD (single-uncompressed format) with a workup saved, when loading the CD, the workup name appears as NO NAME.
293	Performing a second Geo Cal after a successful first test causes problem. Shutter location not calculated correctly for customizations and defaults are not remembered for Landscape and Portrait Geo Cal. Workaround: Restart the Calibration application to resolve problem.
316	Filter Settings “Reset to Default” fails to reset default setting although right-click check indicates default settings.
318	When creating an Export CD, the Create CD button is active with no recordable media present.
331	GXCB-500 Only: The initialization process that homes the beam, platform and rotation are multi-threaded. The process of homing the machine when opening the application after some conditions may vary and does not indicate a limit switch condition.
333	3DVR won't load single file DICOM (error if trying to open, crash on transfer from Vision).
336	Patient birth date does not default to blank entry, but to current day’s date.
372	3DVR crashes when dragging the slider bar in the Range 4 section when using the Identify feature in Ax Views.
378	Ethernet cable disconnected (or connection lost for some reason) during scan causes various error messages to display depending on type of acquisition (Preview, Dry Run, Scan).
380	Level Up option under top menu has been changed. Related to FR-0256. Workaround: Use Screen menu option.
381	Unable to delete patient. When deleting a specific scan for a patient, Raw CT will not delete.
382	GXCB-500 Only: When user goes into the estimate nerve canal feature and confirms canal, if user changes the default matrix size from 5x2 to be either 3x1 or 7x3, errors are displayed.
389	GXCB-500 Only: In Preview screen: changing panoramic map view to MIP or RAD mode changes the maxilla/mandible arches.
391	GXCB-500 Only: Related to FR- 0328-0330, system does not indicate that data exceeds free space available and Create CD is not disabled.
392	Export CD: CD creation fails when selecting Multi-File DICOM.
394	Export CD: The data size estimate is identical for compressed and uncompressed. The “Total to Write” size is not accurate when the uncompressed option is selected.

ID	Known Issue
396	When removing data outside of scanfield, 5 to 6 mm of data is removed.
401	System fails to display warning when attempting to open dataset before it has finished loading. Related to FR-0342.
405	Retro recons do not show original data properly. When the retrospective screen is displayed and all the raw projections are loaded, user can not access the scan to do QF Toggle. No data is displayed and no previews (if taken). Workaround: To get access to previews and scans without executing the reconstruction, the user needs to exit and re-enter to the reconstruction window.
407	GXCB-500 Only: Infrequent Contour line issues.
408	Contour line changes to red and green, instead of one color, on the Implant screen on the axial view.
413	3DVR application: Error message displays after a second data set is opened when a Calculate VRT is performed.
416	Unable to enter date of birth prior to year 1900 and study is not displayed on the Patient List if the date of birth is exactly 1900.
420	When drawing distance measurements on the Implant cross sections, the lines are not visible right away.
422	When opening the Implant view, part of the axial image is outside the edge of the view.
431	GXCB-500 Only: When running Calibration application for the first time and trying to perform a Geo Cal, software crashes.
435	GXCB-500 Only: Canceling or timing out of auto collimation when it is performed for a second time causes collimators to stay at first position. Workaround: Calibration application should be closed and restarted to reinitialize the beam limiters.
459	GXCB-500 Only: Export DICOM. Output to Folder and CD burning for Single-Uncompressed file size is incorrectly displayed as 2KB for high resolution scans in some conditions.
478	GXCB-500 Only: On the Implant screen, the axial view has the feature to Rotate volume but there is no Reset Volume Rotation within screen.
480	In Reports, Image Attributes, the Overlays field label is cut off on the right side.
481	Reports: No print preview option. Relates to FR-0541.
482	Reports: Undo option is grayed out. Relates to FR-0546.
489	In Reports, missing landscape template containing Panoramic data only. Related to FR-0388.

ID	Known Issue
491	GXCB-500 Only. In Reports, variables in a template need to be added in separate boxes in order to be updated properly from case to case, when using the same template for different cases.
496	PAN: Method to lock bite stick vertically does not exist.
517	GXCB-500 Only. Unable to perform Retro Reconstruction when an external dataset has been placed manually into the image root folder. Workaround: Delete QuickRawdir.bin from the system and restart VisionQ.
518	When different arches are selected, the level of the PAN image appears to change. Adjustments to Window/Level do not seem to make them equivalent either.
519	"QC Frames not found" message is confusing because situation is that QC Frames are not available for partial scans.
520	GXCB-500 Only: Midline with control points for maxilla arch does not appear when only maxilla contourline is checked.
523	Previewing continuously within the Calibration application causes the image to flicker between last preview and current one.
527	Chair alignment inaccurate in field. Workaround: Align the placement of the chair using the calibration procedure and the Chair Alignment functionality in the Calibration application.
529	GXCB-500 Only: Nerve canal for half beam: marking the 4 foramina points does not have the options to calculate right, left or both canals.
532	Cannot export to DVD. Process prepares data, but attempt to send to DVD hangs.
533	GXCB-500 Only: Door Interlock. System collects empty frames when switch is opened after the dialog box to press Scan button is displayed when Previewing. Workaround: Terminate application and restart. Do not open door during scan process.
534	GXCB-500 Only: When capturing a PAN scan, if e-stop button is pressed, incorrect dialog is displayed instructing to "Close door to continue scan message". If Retry is selected on dialog, application stays in a loop. Workaround: User needs to click on Cancel to clear exception and have proper message displayed related to e-stop button pressed.
540	When autodetecting arches, infrequently blue dots appear but not green line.

ID	Known Issue
542	When hitting a key while scrolling, blanked out cross section. Workaround: Go back to Preview screen, then to Implant view to redisplay cross section.
543	GXCB-500 Only: New scan is not highlighted after a scan has been taken. The previous loaded CT is highlighted.
545	GXCB-500 Only: Default W/L (Level) setting for axial changes when switching between mandible and maxilla arch.
546	GXCB-500 Only: "Out of Memory Error" displayed occasionally when exporting an image within report template. Workaround: Restart Vision application.
547	GXCB-500 Only: VisionQ application does not respond if an implant template is loaded using a lower matrix.
550	GXCB-500 Only: High Resolution Half Scans. Acquisition screen displays a black frame when adjusting W/L during the reconstruction process.
553	GXCB-500 Only: Preview Screen. Coronal view changes from RAD to MIP if user enters Ceph Screen, and then returns to Preview screen.
572	When reloading a saved workup (after only the mandible arch is auto detected), the system crashes under some conditions.
573	CT dataset is burned to CD when an iPAN procedure was selected under some conditions. Also occurs when Output to Folder is selected.
574	CD Write: Create CD button is not grayed out with data selected and no CD loaded. Related to FR-0330.
577	GXCB-500 Only: Preview Screen. When making measurements in any image and switching into the other arch, the measurements disappear when returning to the previous map.
578	GXCB-500 Only: Preview Screen. Axial view RAD projection changes to MIP when moving the height of any arch.
580	When acquiring images at heights that are not the full height, the measured value of the displayed image is less than the requested height.
581	GXCB-500 Only: Implant screen: When making measurements in any cross-section in any arch, then switching into the other arch, the measurements are deleted.
582	GXCB-500 Only: TMJ screen. Right Condyle disappears when saving any cross-section as a jpeg, when ST is at maximum value and projection is changed. Workaround: To recover image, user needs to adjust the vertical control, zoom, pan, or window/level, or change back the projection.

ID	Known Issue
583	GXCB-500 Only: Volume center stays in the Back position for CT, instead of the last position it was set to, when going from iPAN to CT mode.
593	Patient List: If data and/or images are moved from one system to another and the patient ID collides with an existing patient, the new data and/or images will be included in the existing patient's Patient List entry. However, the patient information displayed in the Vision window and any reports generated will be correct since that information is taken directly from the DICOM fields in the files, not the Patient List. Finding the newly added patient under these circumstances can be difficult, since it will appear under the original patient's name.
595	17-19 Upgrade: iCATVision.exe located in C:\dataframes is not updated with new version.
600	GXCB-500 Only: 3D airway image should display the proper cursor to move image. Zoom, W/L and Pan do not apply.
604	Lossy compressed images are not intended to be used for HU measurements. Lossy compression is designed to use 12-bit clipping resulting in differences in HU measurements.
605	MF and BD display previous loaded CT values when a new scan has been taken. Workaround: Change to the desired Display Format prior to performing the Nerve Canal estimation.
606	Report: An empty Report folder gets created in the path where an iPAN jpeg is saved.
611	Recon BACK_PRJ crash when using two monitors on ACQ. Workaround: Do not use a second monitor on the VisionQ system.
615	Reports: Saved report contains stray characters and missing/misaligned text.
616	Recovery from crashed scan gets confused. Workaround: XML LastSystemState must accurately reflect the actual system state.
618	Vertical lines displayed in cross-section view of Implant screen.
624	Some viewing parameters are not retained when exiting and re-entering sub-screens.
640	TMJ report does not retain sizing when reopened.
649	Receptor crashes with iPAN patient support during CT scan. Workaround: Do not use the iPAN patient support fixture when performing CT scans.

ID	Known Issue
651	GXCB-500 Only: After nerve canal detection, when ST < = 1.0mm on, panoramic arch gets out of place when moving the diagonal control to move arch to see the canal. Workaround: Adjust arch in main Preview window.
652	Vision Standalone: Export CD periodically does not display all images in Implant/TMJ/MPR/Ceph screens.
658	VisionQ crashes on CD initialization failure. Workaround: Use good media. Bad CD will cause the error.
661	Incorrect display and crash using reports. Workaround: Select 20 or fewer description / options when adding text to a report.
664	Nerve canal error with a missing link.
668	Interpolation / filtering is not applied automatically when using mouse to scroll through slices in MPR screen.
671	Report template is not saved properly; fixed text and captions need to be reentered each time.
675	GXCB-500 Only: DICOM export for iPAN images do not export an adjusted window/level zoom on the CD.
676	eXamVision shows “not enough memory” in Implant screen 3D view on loading 0.125 voxel data.
682	Nerve Canal question screen text appears when any pervious nerve canal has been done on the dataset. Workaround: Select Yes to remove previous nerve canal detection.
685	Control panel X-ray ready light not in sync with popup window “Push scan button”. Workaround: Wait for popup window prior to pressing scan button for X-ray ready light.
692	GXCB-500 Only: Half beam high resolution scan gives a run-time error during reconstruction process.
693	GXCB-500 Only: Preview image does not refresh after the E-stop / Door software has been activated during a CT scan.
696	GXCB-500 Only: Patient ID name starting with a dot (.xx) is not displayed under the patient.
697	Error waiting for all frames to be saved. Workaround: Configure the AVG anti-virus software to run at a time of day when the scanner is not being used to acquire data. Remove firewall restriction for VisionQ, then run a new VisionQ session.

ID	Known Issue
698	Image representation (window/level) after eXamVision and VisionQ start is wrong.
699	MPR image range selection shows one and the same image in report.
700	Report/volume slice mapping not unambiguously possible, especially left/right determination.
701	Vision: Implant view - discrepancy between the blue lines, tick marks and actual slice locations.
702	Vision: Preview screen with no contour line selected can not save AP, lateral, or CC views as jpeg files.
703	Calibration: Chair alignment feature should work with the platform (panel) set only at home position. Workaround: Move the platform (panel) all the way to the back (home) position prior to performing the chair calibration.
704	Error recovery in geo calibration. Workaround: If rotation is stopped during a chair calibration, exit Calibration application and rerun.
706	Reports not populating all information.
707	Wrong information is displayed in reports.
710	PC crashed while detecting nerve canal. Workaround: Do not install/upgrade/remove software while running any of the VisionQ or Calibration applications.
716	After a nerve canal crash, Vision cannot start again. Workaround: Do not leave the Quick Start PDF manual open while using nerve canal detection.
730	Ortho Screen: W/L problem in upper left image.
737	Reports: Out of Memory exception on JPEG export.
747	Opening either half scan CT or raw application crashes in some conditions.
750	Error message “cannot initialize DLL” when burning CD causes some files to be saved under a different path instead of Rawdata if user does not restart application when encountering error.
751	Nerve canal: calculating nerve canal then adding (Edit Points) two consecutive points on the cross-section causes axial image to disappear.
753	Hounsfield values will not be correct for new 17-19 8x8 protocol released in both iCAT and 3DeXam. HU values will be too low (attributable to bilateral truncation effects).

FOR FDA USE ONLY

INFORMATION ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

D 1318673

1. EQUIPMENT LOCATION

a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED: Complete Address of Installation

b. STREET ADDRESS:

c. CITY:

d. STATE:

e. ZIP CODE:

f. TELEPHONE NUMBER: ( )

2. ASSEMBLER INFORMATION

a. COMPANY NAME:

b. STREET ADDRESS: Installer's Center Address

c. CITY:

d. STATE:

e. ZIP CODE:

f. TELEPHONE NUMBER: ( )

3. GENERAL INFORMATION

a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE *(Check appropriate box(es))*

- [X] NEW ASSEMBLY-FULLY CERTIFIED SYSTEM
- [ ] REASSEMBLY-FULLY CERTIFIED SYSTEM
- [ ] REASSEMBLY-MIXED SYSTEM *(Both certified and non-certified components)*
- [ ] REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM
- [ ] AN ADDITION TO AN EXISTING SYSTEM

b. INTENDED USE(S) *(Check appropriate box(es))*

- [ ] GENERAL PURPOSE RADIOGRAPHY
- [ ] GENERAL PURPOSE FLUOROSCOPY
- [ ] TOMOGRAPHY (Other than CT)
- [ ] ANGIOGRAPHY
- [ ] PODIATRY
- [ ] UROLOGY
- [ ] MAMMOGRAPHY
- [ ] CHEST
- [ ] CHIROPRACTIC
- [ ] CT HEAD SCANNER
- [ ] CT WHOLE BODY SCANNER
- [ ] HEAD-NECK (Mirion)
- [ ] DENTAL INTRAORAL
- [ ] DENTAL CEPHALOMETRIC
- [X] DENTAL PANORAMIC
- [ ] RADIATION THERAPY SIMULATOR
- [ ] C-ARM FLUOROSCOPIC
- [X] DIGITAL
- [ ] BONE MINERAL ANALYSIS
- [X] OTHER (Specify in comments)

c. THE X-RAY SYSTEM IS *(Check one)*

- [X] STATIONARY
- [ ] MOBILE

d. THE MASTER CONTROL IS IN ROOM: As per location

e. DATE OF ASSEMBLY (mm) (dd) (yyyy): Date of Installation

4. COMPONENT INFORMATION *(If additional space is needed for this section use another form, replacing the preprinted number with this Form Number, and complete items 1, 4, and 5 only)*

a. THE MASTER CONTROL IS

- [X] A NEW INSTALLATION
- [ ] EXISTING (Certified)
- [ ] EXISTING (Non-certified)

b. CONTROL MANUFACTURER: Imaging Sciences

c. CONTROL SERIAL NUMBER: Obtain Control S/N & Date from Label on X-ray Control

d. DATE MANUFACTURED:

e. CONTROL MODEL NUMBER: G1-15-1-0

f. SYSTEM MODEL NAME *(CT Systems Only)*: N/A

Complete the following information for the certified components listed below which you installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated spaces. For other certified components, enter in the appropriate blocks how many of each you installed in this system.

g. SELECTED COMPONENTS

	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
BEAM LIMITING DEVICE	Imaging Sciences	137-0	Located on Limiting Device Label
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
TABLE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
TABLE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
CT GANTRY	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED

h. OTHER CERTIFIED COMPONENTS *(Enter number of each installed in appropriate blocks.)*

[ ]	X-RAY CONTROL	[ ]	CRADLE
[ ]	HIGH VOLTAGE GENERATOR	[ ]	FILM CHANGER
[ ]	VERTICAL CASSETTE HOLDER	[ ]	IMAGE INTENSIFIER
[ ]	TUBE HOUSING ASSEMBLY	[ ]	SPOT FILM DEVICE
[1]	DENTAL TUBE HEAD	[ ]	OTHER (Specify)

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), more of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME: Installer's Printed Name

b. SIGNATURE: Installer's Signature

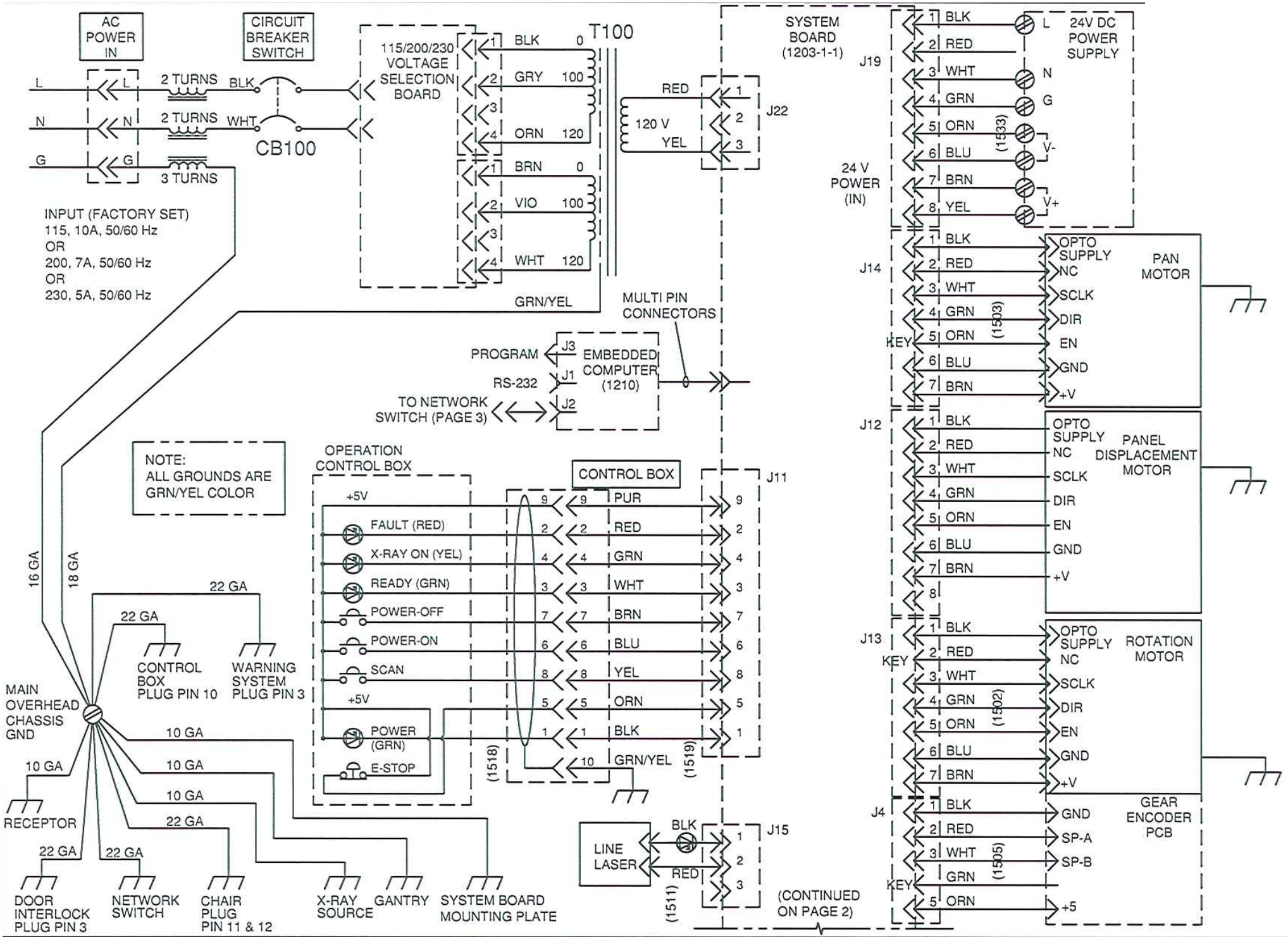
c. DATE: Date of Installation

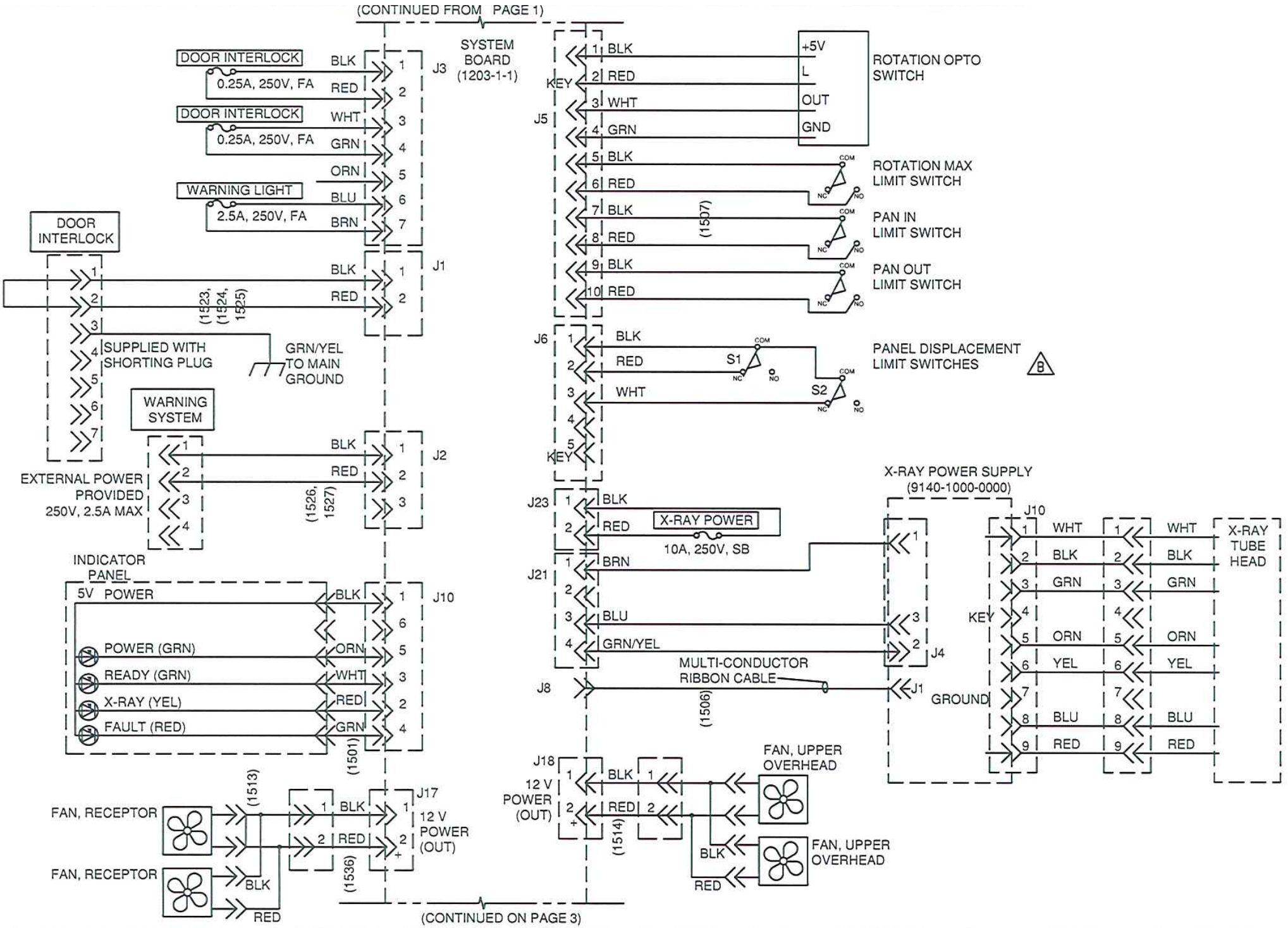
6. COMMENTS

ConeBeam Volumetric Tomography and Panoramic Dental Imaging System 120 KV 3-8 MA

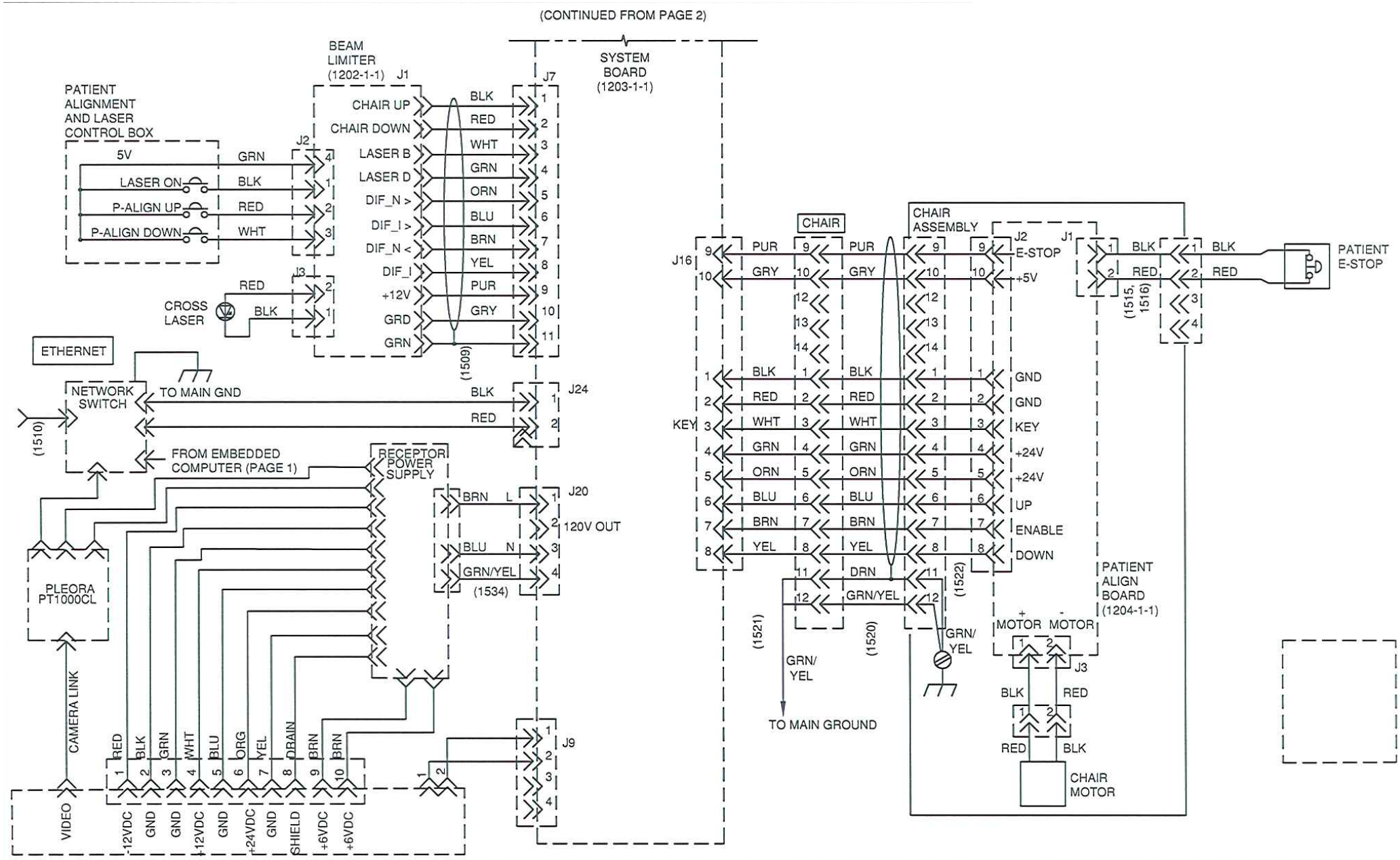
FORM FDA 2579 (12/03) PREVIOUS EDITION IS OBSOLETE

White Copy - FDA, HFZ-307, 2098 Gaither Road, Rockville, MD 20850


AC POWER IN
CIRCUIT BREAKER SWITCH
L
N
G
2 TURNS
2 TURNS
3 TURNS
BLK
WHT
CB100
115/200/230 VOLTAGE SELECTION BOARD
T100
BLK 0
GRY 100
ORN 120
BRN 0
VIO 100
WHT 120
RED
120 V
YEL
J22
SYSTEM BOARD (1203-1-1)
J19
24V DC POWER SUPPLY
24 V POWER (IN)
INPUT (FACTORY SET)
115, 10A, 50/60 Hz
OR
200, 7A, 50/60 Hz
OR
230, 5A, 50/60 Hz
GRN/YEL
MULTI PIN CONNECTORS
PROGRAM
RS-232
TO NETWORK SWITCH (PAGE 3)
J3
J1
J2
EMBEDDED COMPUTER (1210)
NOTE:
ALL GROUNDS ARE GRN/YEL COLOR
OPERATION CONTROL BOX
CONTROL BOX
J11
+5V
FAULT (RED)
X-RAY ON (YEL)
READY (GRN)
POWER-OFF
POWER-ON
SCAN
+5V
POWER (GRN)
E-STOP
PUR
RED
GRN
WHT
BRN
BLU
YEL
ORN
BLK
GRN/YEL
(1518)
(1519)
16 GA
18 GA
22 GA
22 GA
CONTROL BOX PLUG PIN 10
WARNING SYSTEM PLUG PIN 3
MAIN OVERHEAD CHASSIS GND
10 GA
10 GA
10 GA
10 GA
22 GA
22 GA
22 GA
RECEPTOR
DOOR INTERLOCK PLUG PIN 3
NETWORK SWITCH
CHAIR PLUG PIN 11 & 12
X-RAY SOURCE
GANTRY
SYSTEM BOARD MOUNTING PLATE
LINE LASER
BLK
RED
J15
(1511)
(CONTINUED ON PAGE 2)
J14
PAN MOTOR
OPTO SUPPLY
NC
SCLK
DIR
EN
GND
+V
KEY
(1503)
J12
PANEL DISPLACEMENT MOTOR
J13
ROTATION MOTOR
(1502)
J4
GEAR ENCODER PCB
SP-A
SP-B
+5
(1505)
(1533)
L
N
G
V-
V+


(CONTINUED FROM PAGE 1)
SYSTEM BOARD (1203-1-1)
DOOR INTERLOCK
0.25A, 250V, FA
DOOR INTERLOCK
0.25A, 250V, FA
WARNING LIGHT
2.5A, 250V, FA
BLK
RED
WHT
GRN
ORN
BLU
BRN
J3
DOOR INTERLOCK
J1
(1523, (1524, 1525)
SUPPLIED WITH SHORTING PLUG
GRN/YEL TO MAIN GROUND
WARNING SYSTEM
J2
EXTERNAL POWER PROVIDED 250V, 2.5A MAX
(1526, 1527)
INDICATOR PANEL
5V POWER
POWER (GRN)
READY (GRN)
X-RAY (YEL)
FAULT (RED)
J10
(1501)
FAN, RECEPTOR
FAN, RECEPTOR
(1513)
J17
12 V POWER (OUT)
(1536)
KEY
+5V
L
OUT
GND
ROTATION OPTO SWITCH
J5
ROTATION MAX LIMIT SWITCH
PAN IN LIMIT SWITCH
PAN OUT LIMIT SWITCH
(1507)
COM
NC
NO
J6
S1
S2
PANEL DISPLACEMENT LIMIT SWITCHES
B
J23
X-RAY POWER
10A, 250V, SB
J21
BRN
BLU
GRN/YEL
X-RAY POWER SUPPLY (9140-1000-0000)
J4
MULTI-CONDUCTOR RIBBON CABLE
J8
J1
(1506)
J10
X-RAY TUBE HEAD
WHT
BLK
GRN
ORN
YEL
GROUND
BLU
RED
J18
12 V POWER (OUT)
(1514)
FAN, UPPER OVERHEAD
FAN, UPPER OVERHEAD
(CONTINUED ON PAGE 3)

(CONTINUED FROM PAGE 2)



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