Installation 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

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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Refer to the Operators' Manual for the following system information:

Introduction

Safety Items

System Controls and Indicators

System Startup and Shutdown

Radiation Environment Survey

Product Information

Neworking Support Setup

Remote System Import and Export

Chapter 1 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 13 for scanners that are shipped assembled.

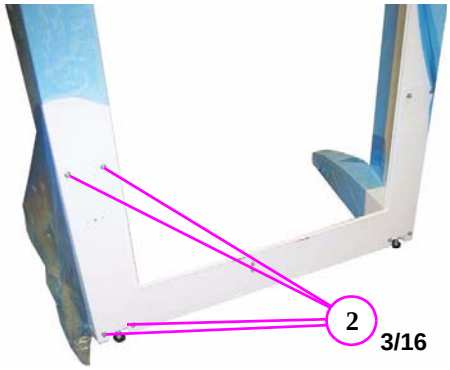
Before moving the System into place, ensure that the area is clean and that there is ample room to work.

WARNING

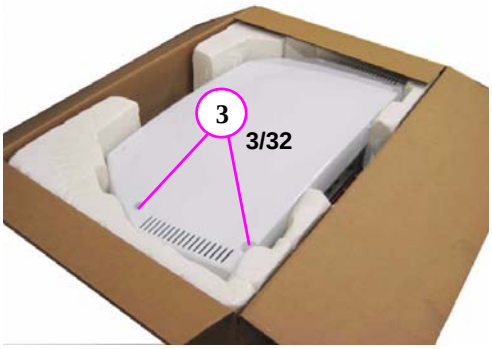
This system has devices that require a two person lift. Failure to comply may cause bodily injury. Two adults are required to unpack and assemble this system.

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).



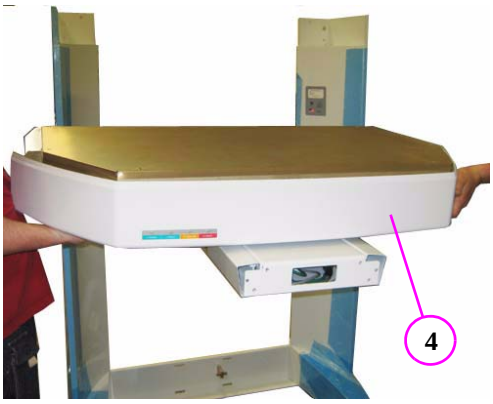
WARNING

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

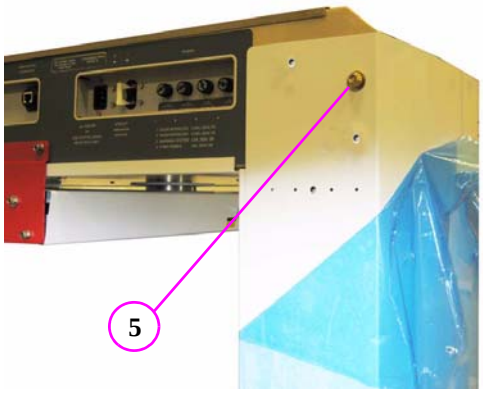
CAUTION

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

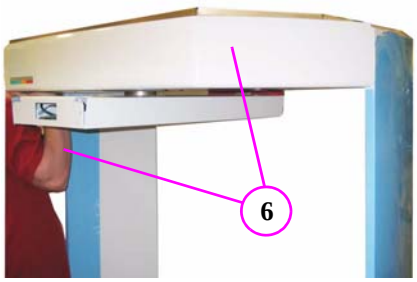
4. With an assistant, lift overhead device into place on top of Leg Assemblies.



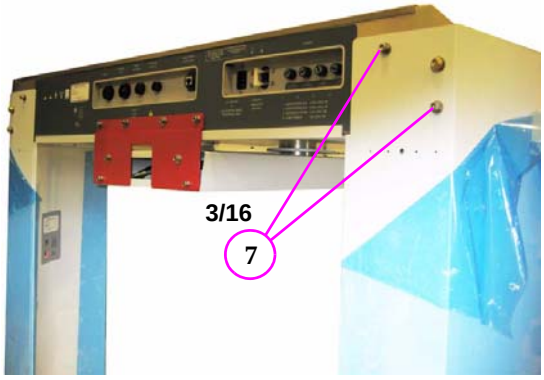
5. Ensure the pins on rear of the Overhead device are seated into the holes on Leg Assemblies.



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



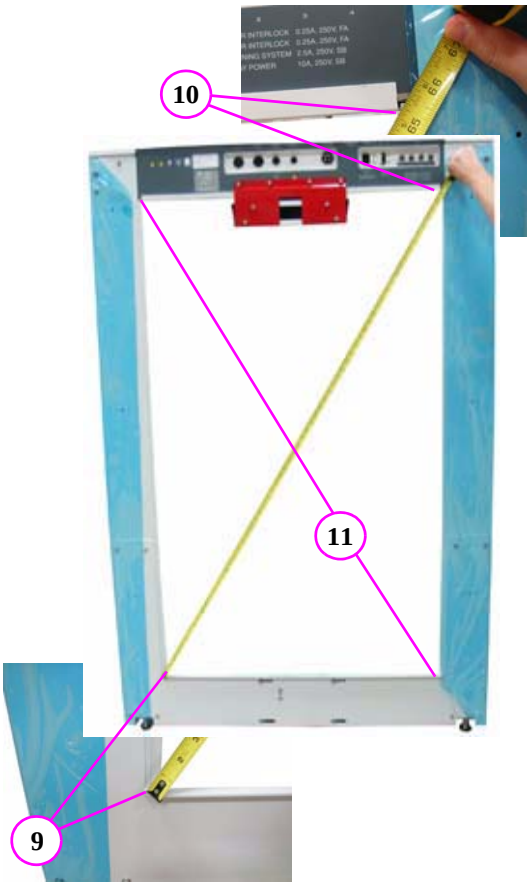
7. From rear of unit, secure Overhead with mounting hardware, two SHCS 1/4-20 x 5/8 long with 1/4" Split Washers, both sides.



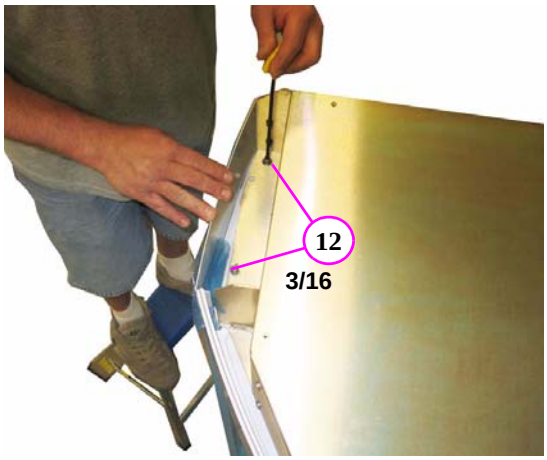
8. The device must be checked for squareness prior to installing the mounting hardware at the top of the Overhead.
9. Hook a tape-measure on bottom rear edge of device, as shown.
10. Run the tape diagnally to the upper open corner, as shown and record the measurement. Measurement should be approximately 65-3/8" [166cm].
11. Take the same measurement on the opposite corners and record measurement.

    The two measurements must be identical ± 1/6" [1.6mm].

    If measurements are not within tolerance, push the top of the device to the right or left and remeasure.



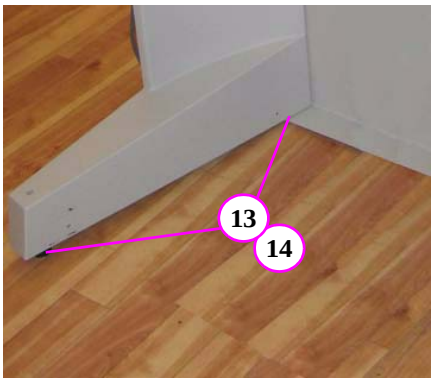
12. From top of unit, secure Overhead with mounting hardware, two SHCS 1/4-20 x 5/8 long with 1/4" Split Washers, both sides.



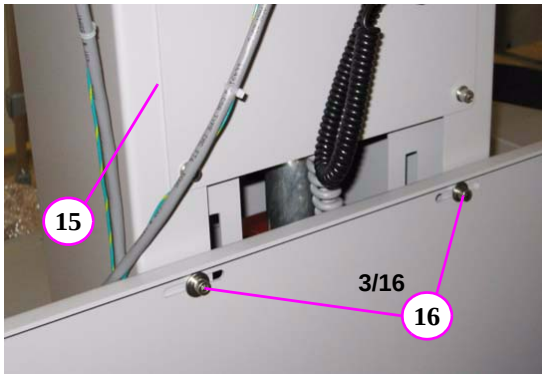
CAUTION

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.

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



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

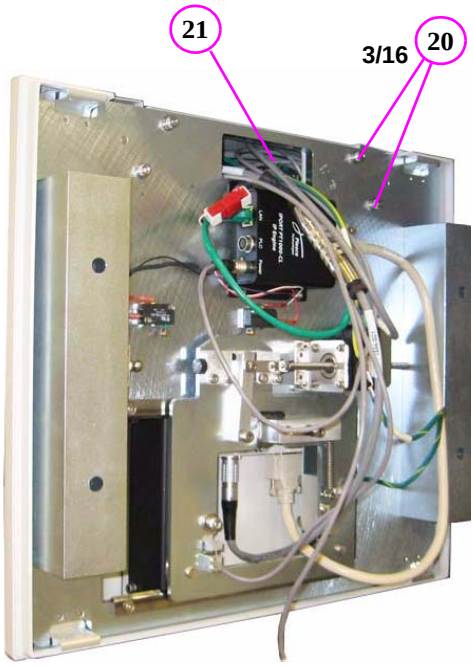


WARNING

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

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

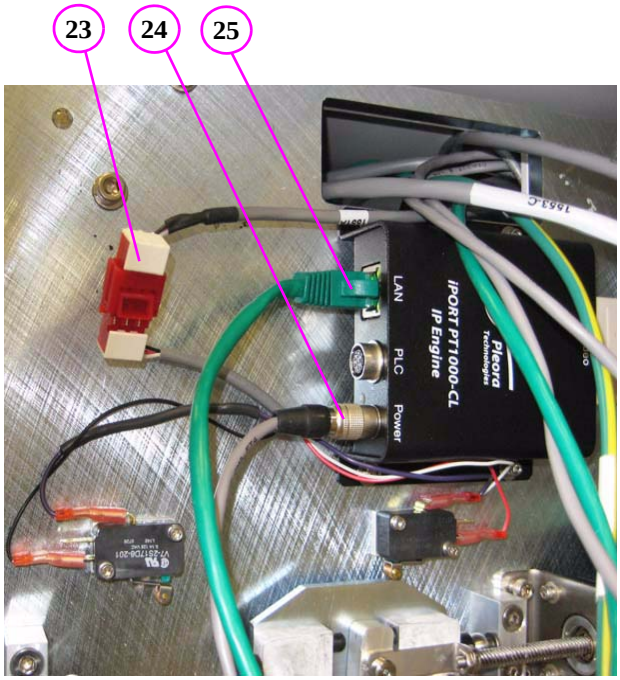
19. With an assistant, mount the Receptor Assembly by aligning the mounting pins.
20. Attach assembly with four long mounting screws and four split washers, acquire four mounting screws from Red Shipping Plate.
21. Feed cabling through Receptor Assembly (8 wires).



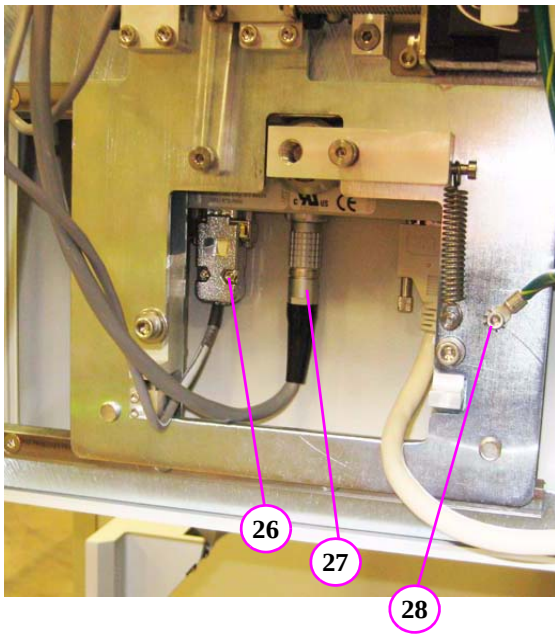
CAUTION

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

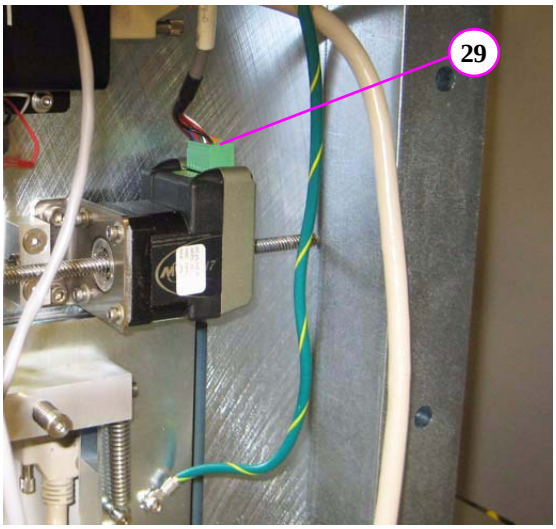
22. All connectors are color coded and keyed to prevent improper mating.
23. Connect together the red/white connectors (grey wires) as shown.
24. Rotate into position, aligning red dots, then press to lock the gold connector (grey wire) onto the keyed Power connector.
25. Connect green wire RJ45 plug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



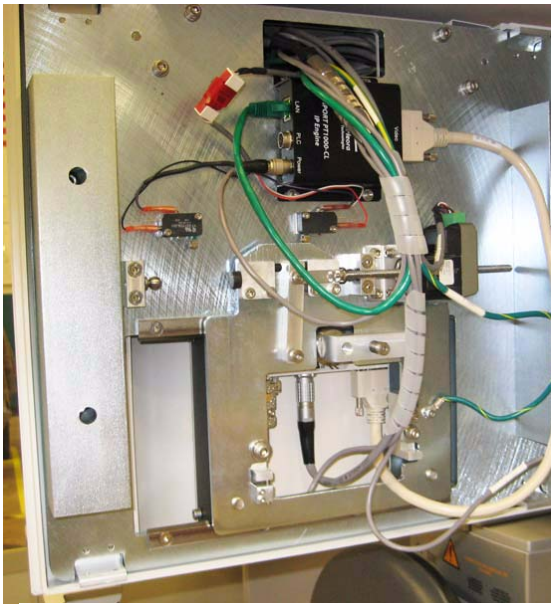
26. Connect silver connector (grey wire) to assembly as shown. Access connector mounting screws by pulling back bottom of receptor cover (opposite side).
27. Rotate silver cylindrical connector (grey wire) into position, aligning red dots, then press to lock onto keyed connector as shown.
28. Attach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



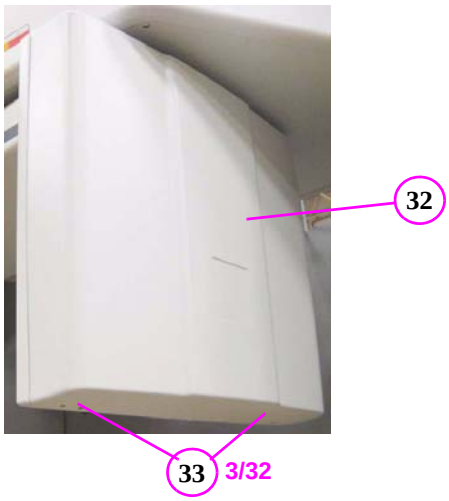
29. Connect green connector (grey wire) to assembly as shown).



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



32. Install Receptor cover.
33. Attach mounting screws on top and bottom of cover.

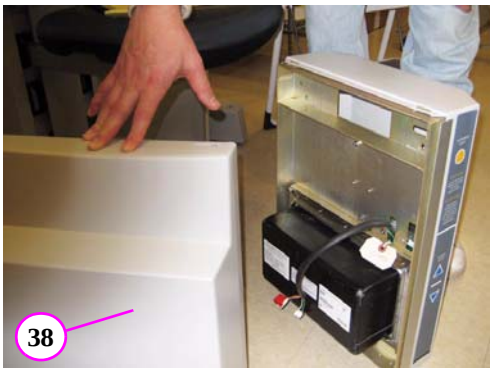


34. Remove red Shipping Plate. Do NOT discard mounting hardware (quantity 8) or Shipping Plate.

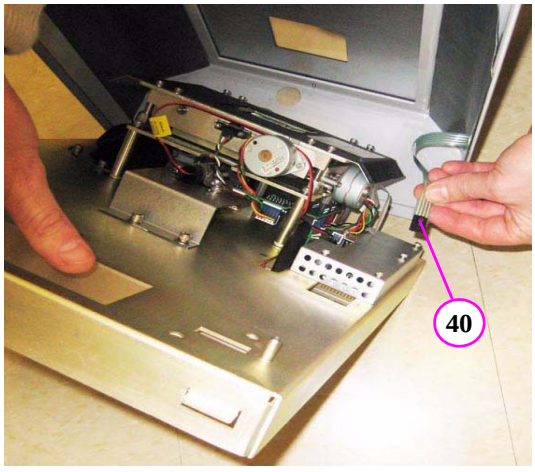
    Long screws used for Receptor Assembly mounting and short screws for Source Assembly.

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

38. Detach outer Source Cover ONLY.



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

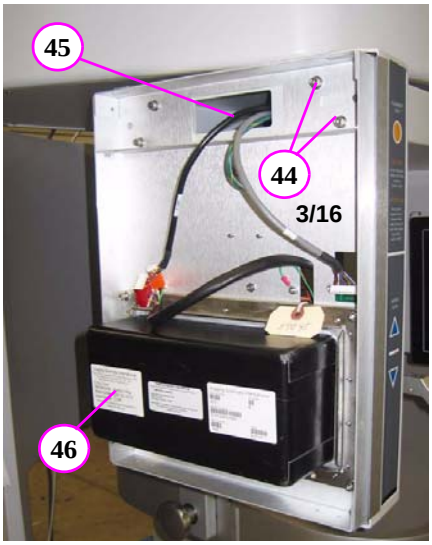


41. Using very little force, slowly rotate gantry, counterclockwise. Stop the rotation when you feel that the gantry is at the limit switch position.
42. Slide X-ray Source Cover onto the Gantry overhead.

WARNING

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

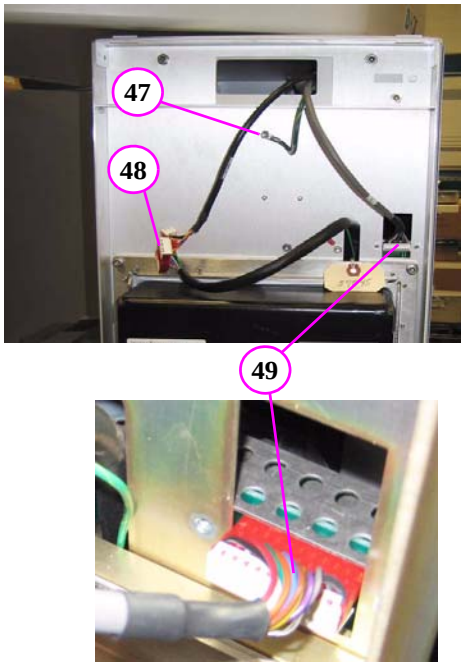
43. With an assistant, align X-ray Source Assembly mounting pins.
44. Attach assembly using the four mounting screws previously removed from red Shipping Plate along with four split washers.
45. Draw the 3 cables out through the opening. Ensure that the cables are not stretched or damaged.
    - black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



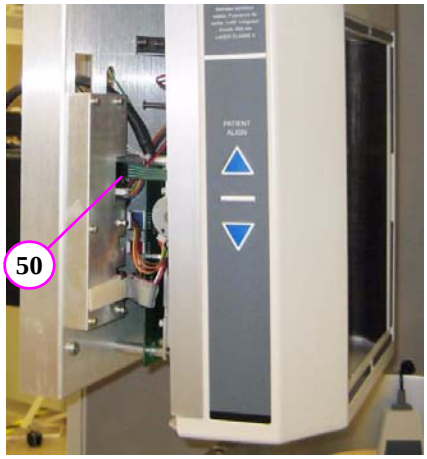
CAUTION

When mating connectors, do not force-fit together.

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

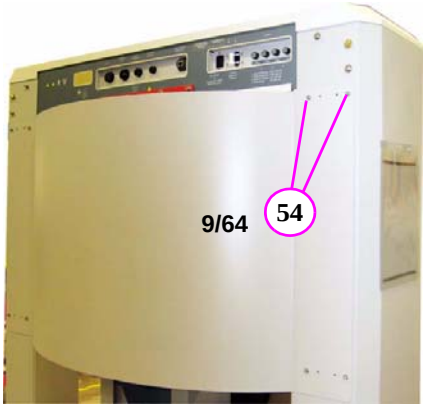


50. Attach ribbon cable back to the Beam Limiter Assembly.

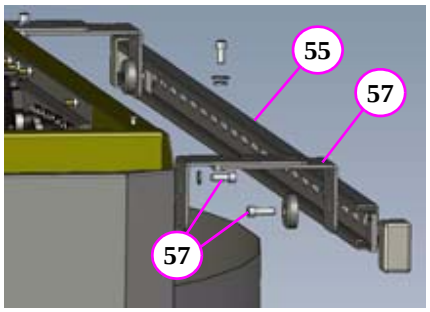


51. Slide Adjustment Panel Cover into place, onto **top mounting notches**.
52. Mount outer cover onto mounting notches, over panel cover.
53. Attach covers with the four hex mounting screws at the bottom of assembly.

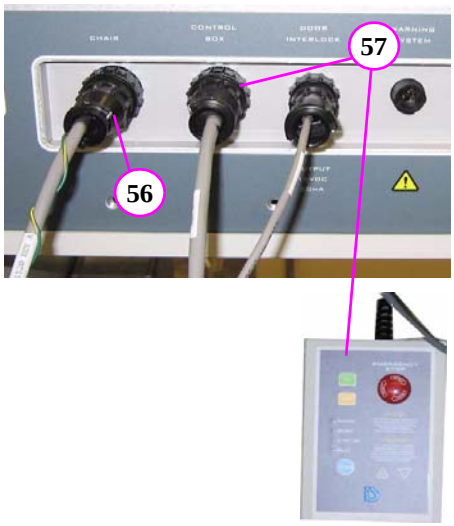
54. Attach Scatter Shield to the rear of the Gantry (8 mounting screws). Note, mounting pins to be located at the top of the Scatter Shield. Obtain Mounting Bar Assembly.



55. 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.
56. Use 3 wall anchors/screws to mount the bar securely to the wall.
57. Loosely attach brackets to the unit and mounting bar. Do not tighten until leveling is complete.

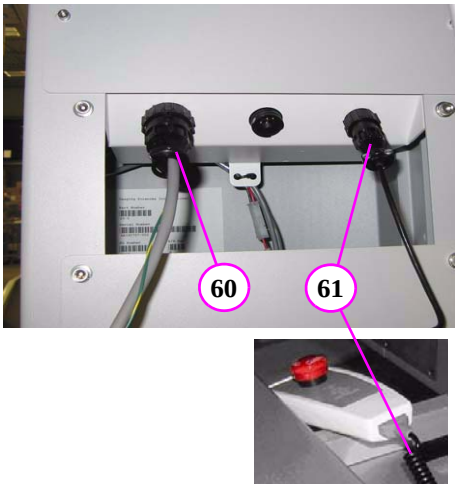


58. Connect chair Control Cable to **CHAIR** connector on rear of Overhead Panel.
59. Connect Main Control Box cable to **CONTROL BOX** connector on rear of Overhead Panel. Connectors are keyed to prevent improper insertion.

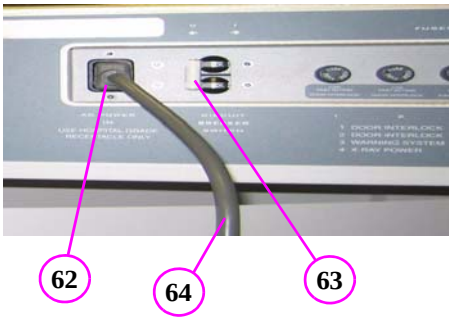


60. Connect chair Control Cable to Patient Chair connector.
61. Connect Patient Emergency Stop Control to Patient Chair connector. Connectors are keyed to prevent improper insertion.

    For wall mounting options, refer to the Wall Mount Control Box Chapter.



62. Connect Power Cable to **AC POWER IN** connector on rear of Overhead Panel.
63. 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.

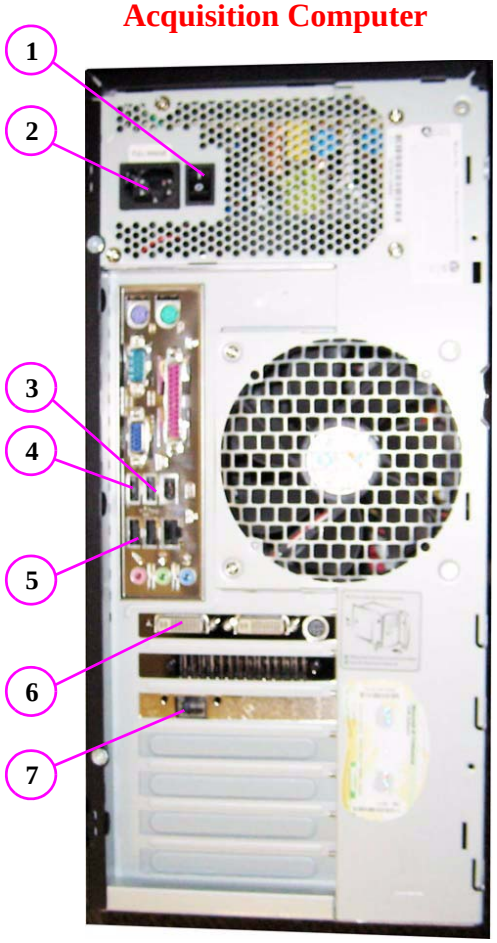
64. Connect Power Cable to Hospital Grade Receptacle.

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 2 Leveling and Alignment

Level Gantry

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

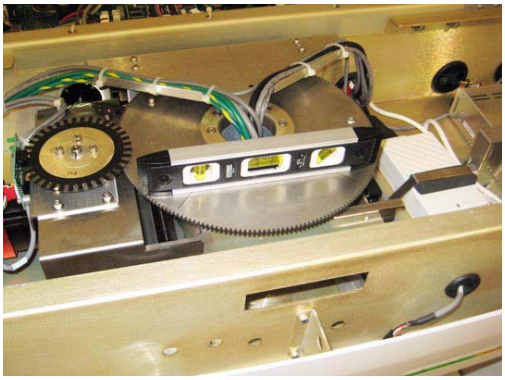
Leveling the Gantry:

1. Remove top cover (6 screws).

2. Remove shielding cover.

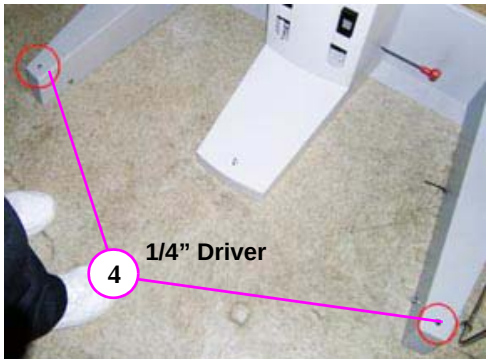
3. Unit must be leveled from side-to-side and front-to-back.

Level Side-to-Side



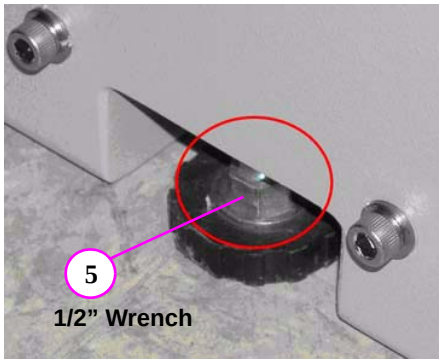
Level Front-to-Back

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

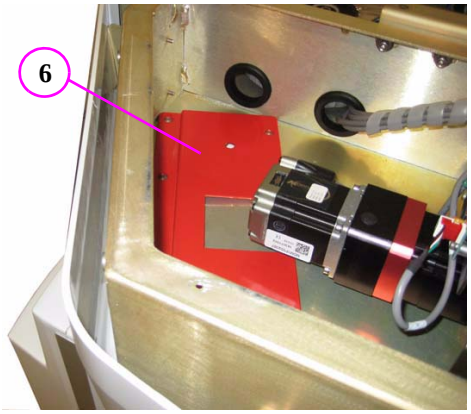


5. Adjust the rear Gantry feet using the 1/2” Open-ended Wrench.

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



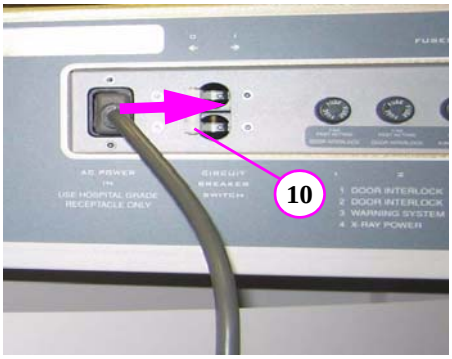
6. Store red shipping bracket in Overhead.



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

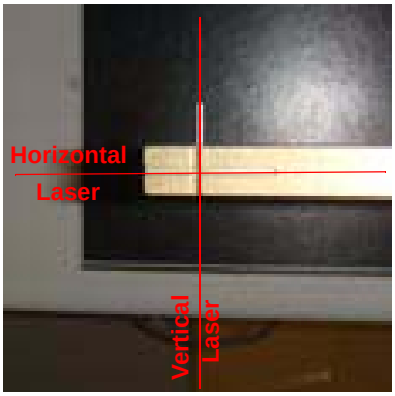
To acquire quality images, the chair must be accurately leveled and aligned.

Leveling Patient Chair:

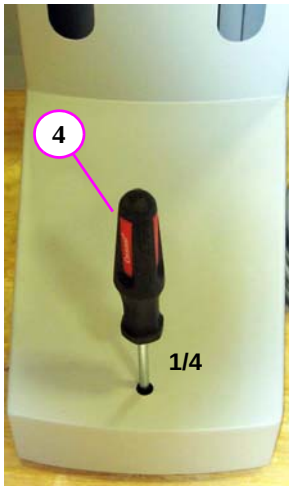
1. From the Acquisition computer, double click the **Calibration** icon.

   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.

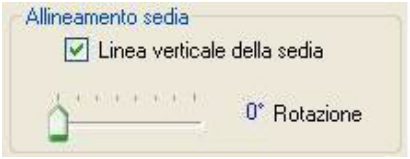
   

   - If Horizontal Laser is out of position, move Chair Center Locator up or down in the positioning block to roughly align with horizontal notch.
   - If the Vertical Laser is out of position, then adjust the Chair Foot, using a 1/4 inch nut driver.

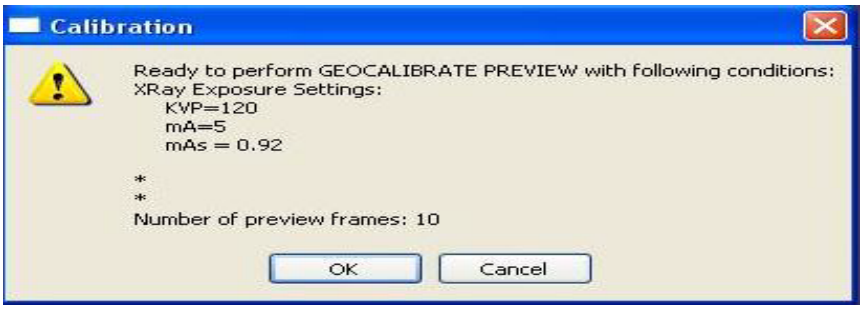
     

   - **Turn nut driver clockwise -** moves alignment tool towards rear of Scanner.
   - **Turn nut driver counter-clockwise -** moves alignment tool towards front of Scanner.

5. On the Calibration screen, click the Vertical Chair Line checkbox and ensure slider is at 0^{o} position.



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

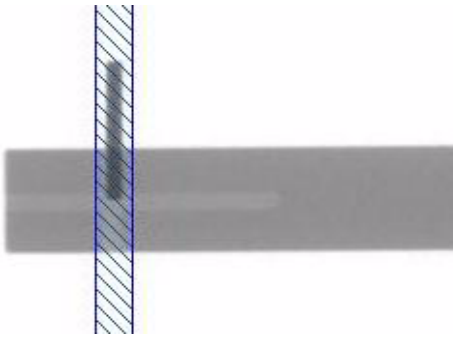


WARNING

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.

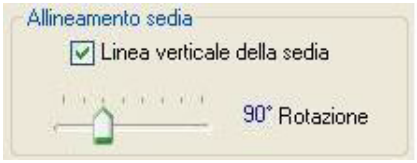
   If not aligned, adjust the Chair Foot (step 4), then perform a **Preview** (steps 6 - 8). Repeat as needed until pin falls within blue shaded area.



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:

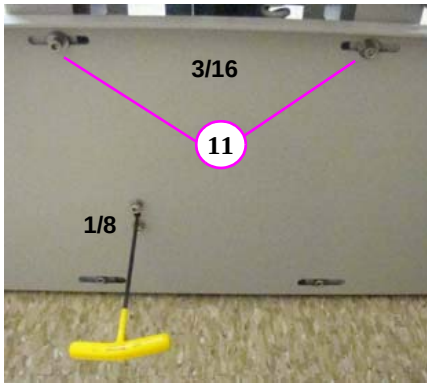
10. On the Calibration screen:



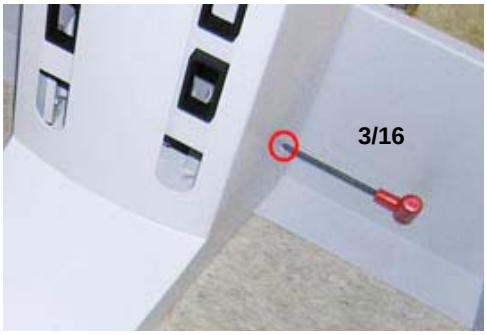
    a. Move slider to 90^{o} position and perform a **Preview**.

    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.



- **Pin to left of shaded area, turn wrench clockwise -** moves Chair Assembly to the left when facing front of Scanner.
- **Pin 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

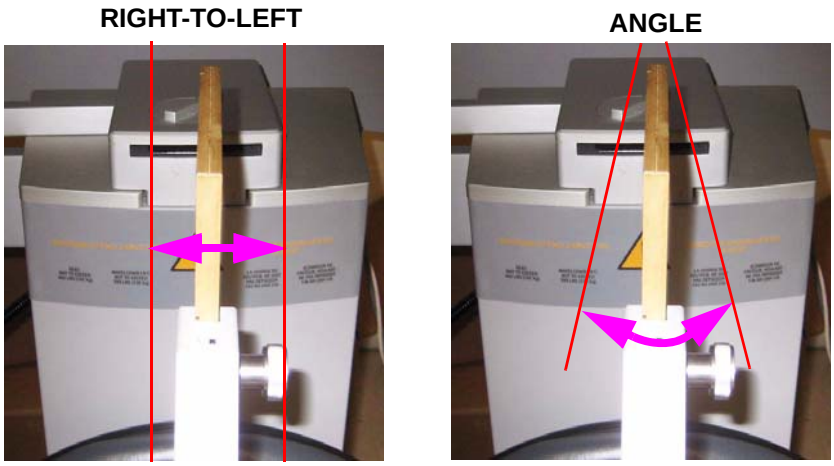
Do not stare into laser. Severe personal injury (blindness) may result.

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

Adjust Centerline Laser

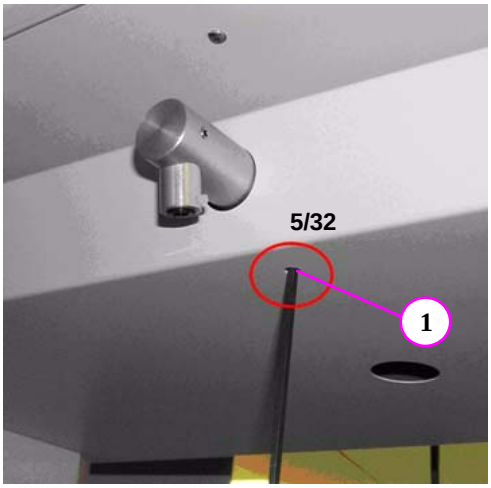
There are three laser adjustments;

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

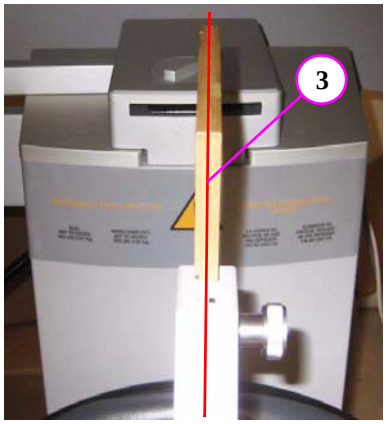


Right-to-Left Adjustment:

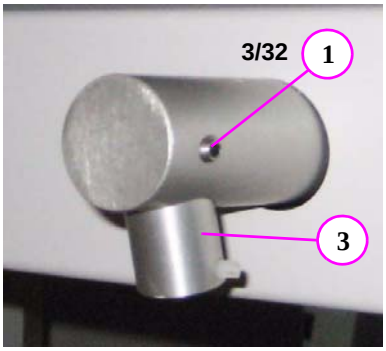
1. Loosen laser assembly set screw which allows the assembly to rotate.
2. Press the **ALIGNMENT LIGHT** button on the Operator Panel. The laser lights for approximately two minutes.



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.

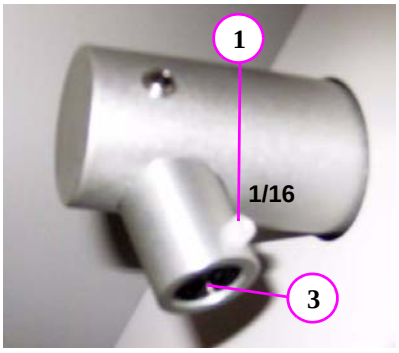


Angle Adjustment:



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.

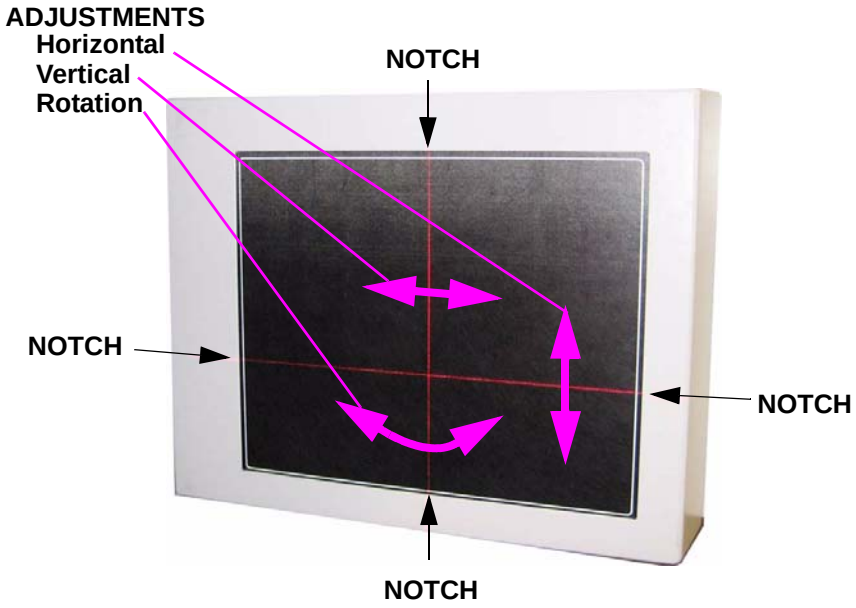
   Rotating the lens for sharpness will require realignment (Side-to-Side and/or Angle).
4. Tighten set screw to lock lens in place.

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.

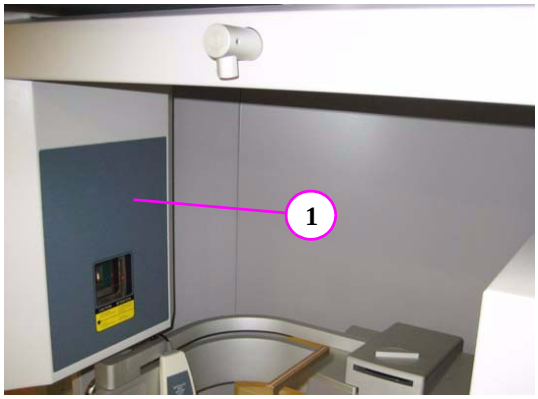
There are three types of laser adjustments:

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



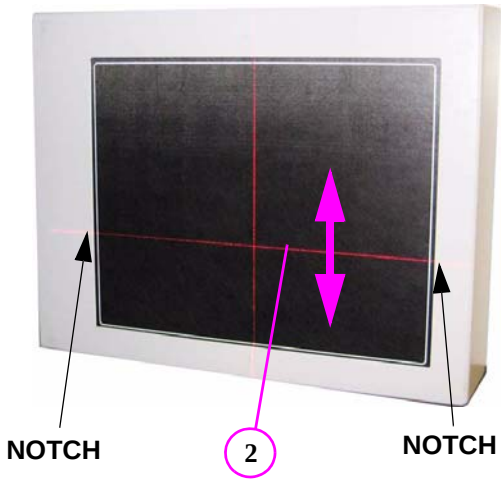
1. Remove Beam Limiter Cover to gain access to the Crosshair Laser.

   The cover is attached magnetically.

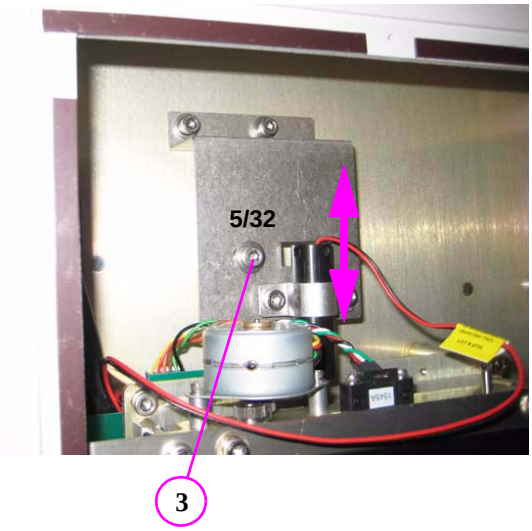


Horizontal Line Adjustment:

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

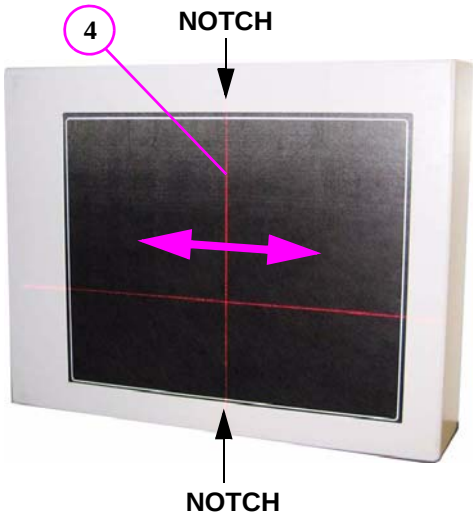


3. To move horizontal laser line up/down turn adjustment screw (shown):
   - **Clockwise** - moves line up
   - **CCW** - moves line down

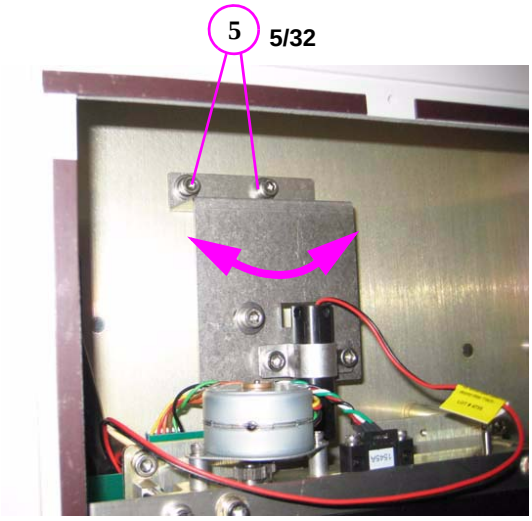


Vertical Line Adjustment:

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

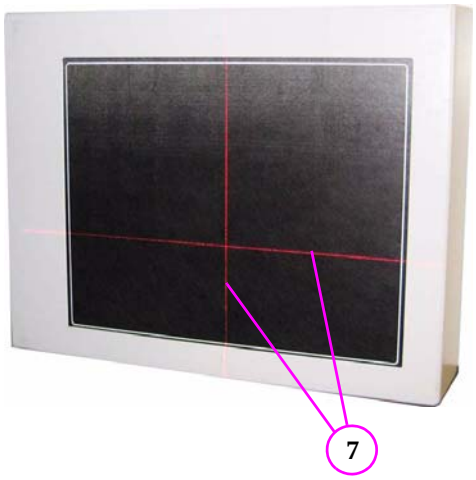


5. To move vertical laser line forward/back loosen the two mounting screws (shown). The bracket pivots on the center mounting screw which moves the vertical laser line.
6. Tighten both screws when properly aligned.

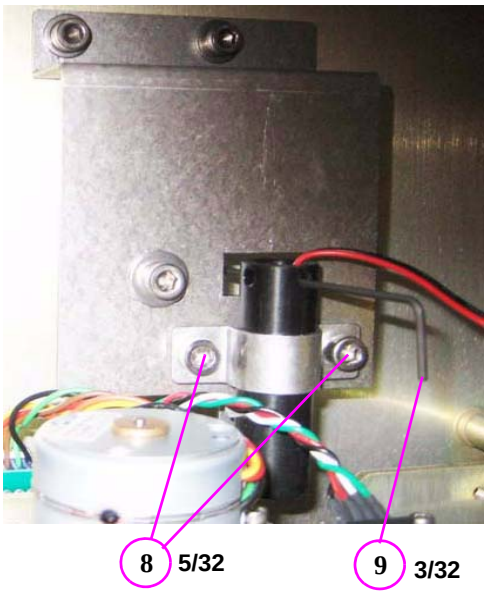


Rotate Crosshair Laser Lines:

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



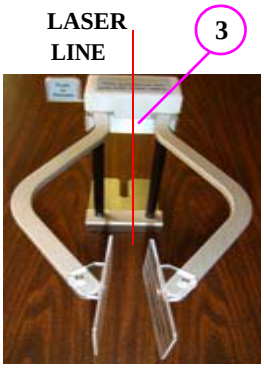
8. To rotate laser crosshairs slightly loosen the two laser mounting screws (shown).
9. To help rotate the laser, insert an allen wrench (3/32) into the top hole of the laser.
10. Tighten both screws when properly aligned and remove 3/32 allen wrench.
11. Replace Beam Limiter Cover.



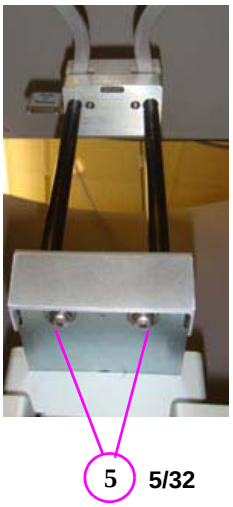
Head Holder Alignment

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

3 Detector Pivot Adjustment (Receptor Panel)

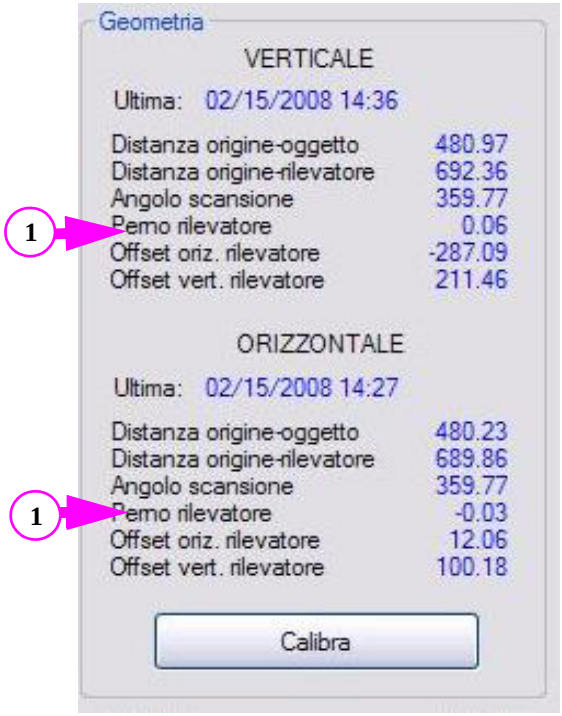
Detector Pivot Adjustment (Receptor Panel)

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:.

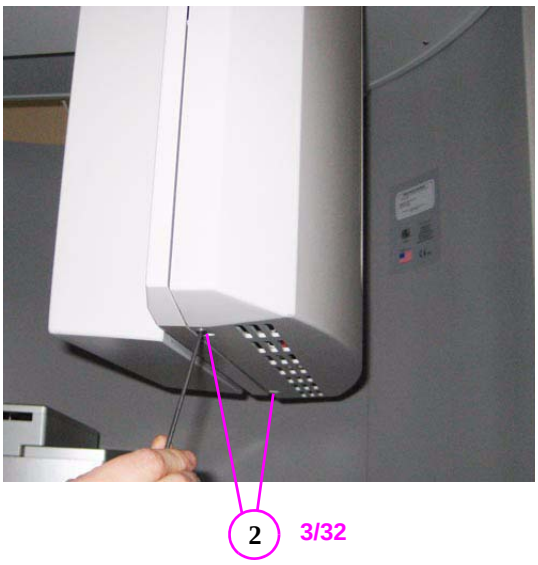
1. On the Geometry Calibration screen, check the **Detector Pivot** in both the Portrait and Landscape positions.

   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.

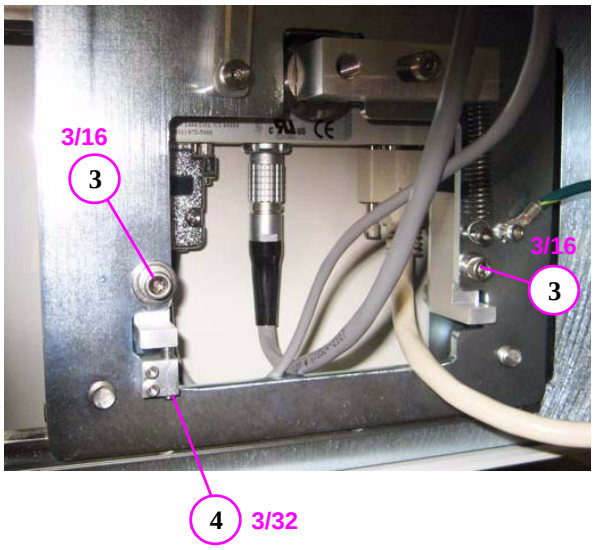


3. On the Receptor Assembly, loosen the two panel mounting screws.
4. One Leveling Screw is used to adjust the Detector Pivot for both Landscape and Portrait simultaneously.

   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.

Chapter 4 Wall Mounting Control Box

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

Desktop

Wall Mounted (cable exposed)

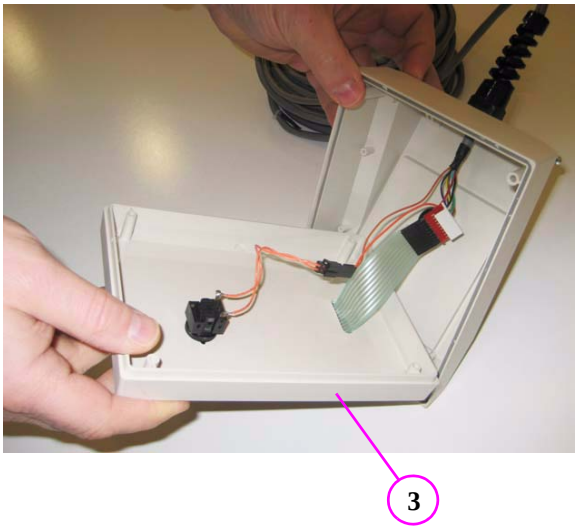
Wall Mounted (cable inside wall)

Wall Mount with Cable Exposed

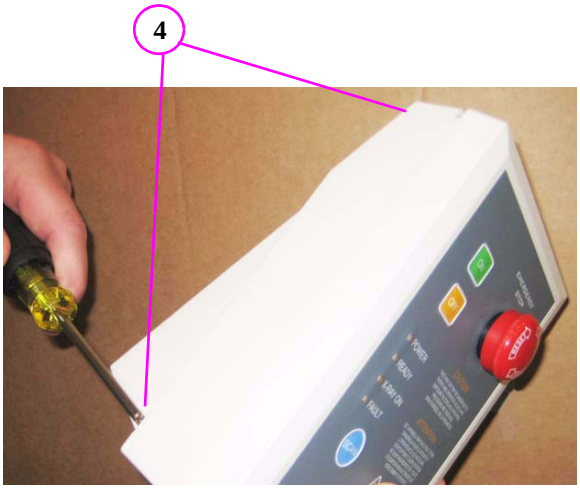
1. Control Box cable is to be disconnected from rear of Overhead Panel.

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

3. Rotate Control Box face plate 90^{o}, being careful not to over extend the ribbon cable.

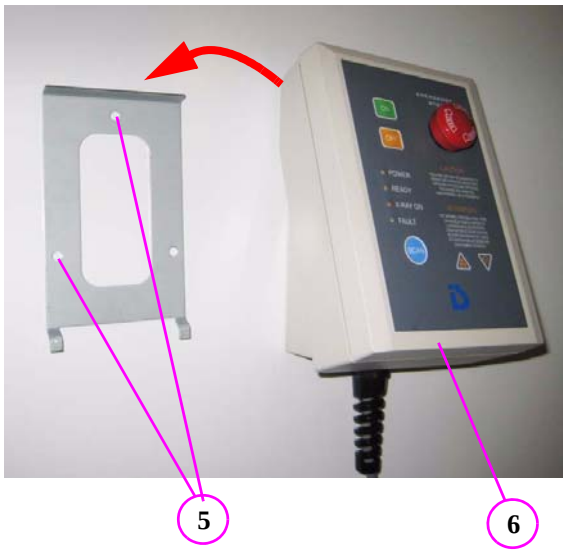


4. Tighten four mounting screws.



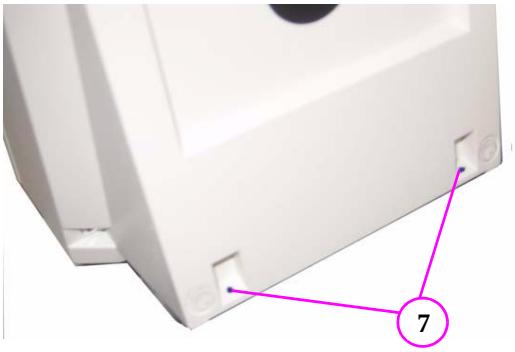
5. Mount Wall Bracket, using supplied mounting hardware (3 places).
6. Hang Control Box onto wall mount bracket.

   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.

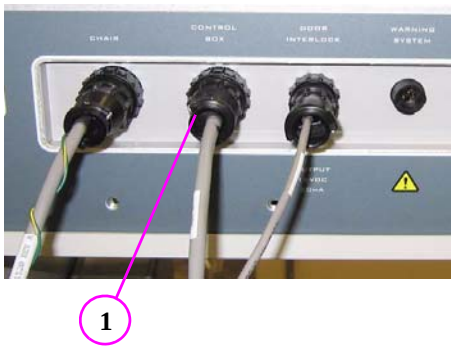


9. With the Control Box positioned on wall bracket, install the two self-tapping screws (supplied with wall bracket).

   Refer to install diagram (supplied with wall bracket).

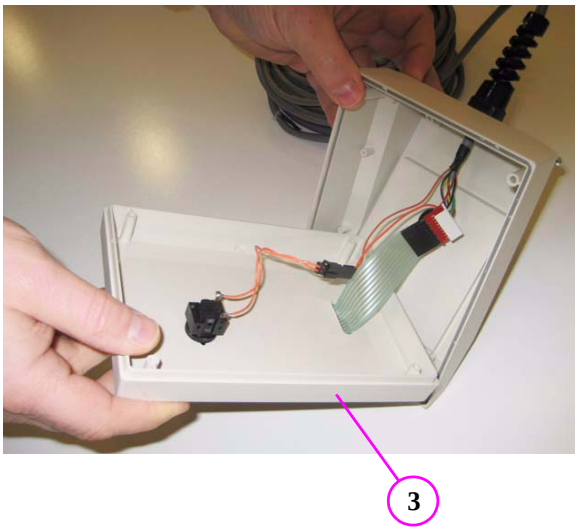
Wall Mount with Cable Inside Wall

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

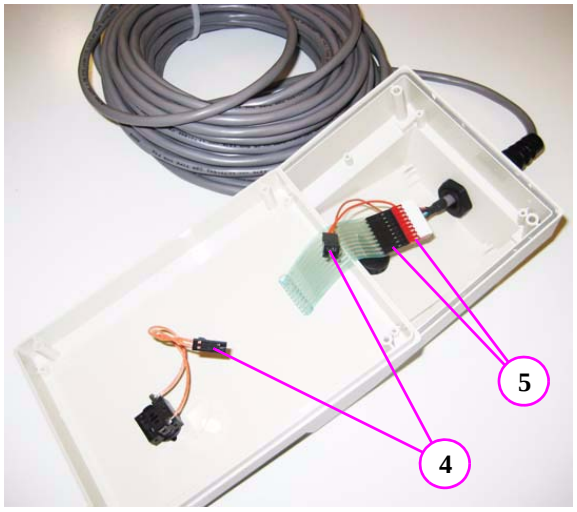


2. Using a fine tip Phillips screwdriver, loosen four mounting screws on rear of Control Box.

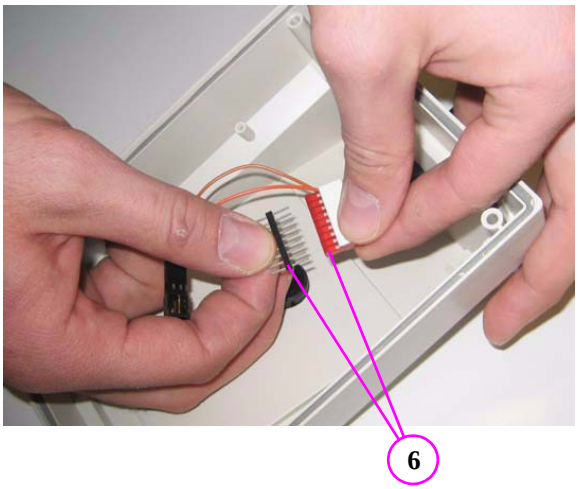
3. lift the face panel from the base, being careful not to over extend the ribbon cable.



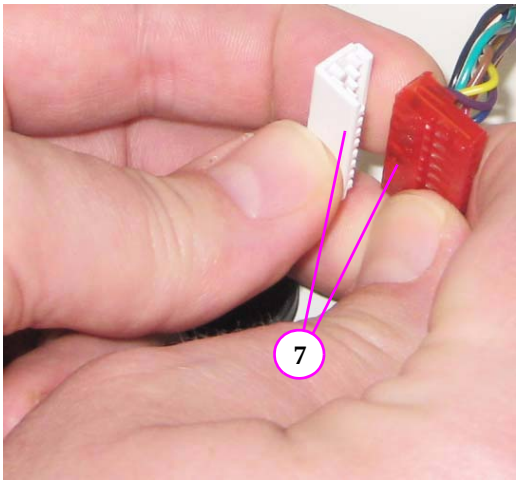
4. Disconnect the Emergency Stop wires by simply pulling the black connectors apart.
5. Disconnect Ribbon Cable by pulling the black and red connectors apart.



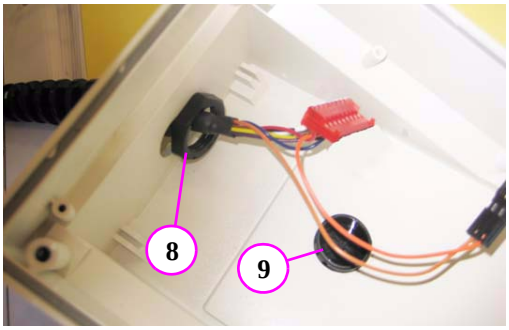
6. Remove pin assembly from red connector.



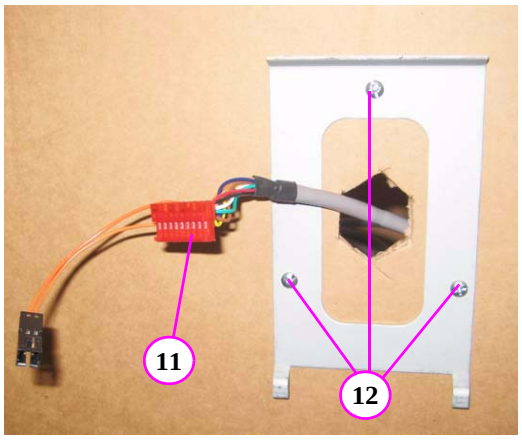
7. Snap-off white plastic cap from red connector.



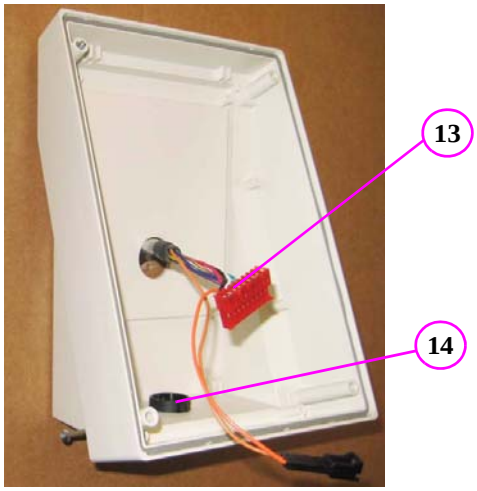
8. Loosen and remove plastic retaining nut from strain relief.
9. Remove black insert from base.
10. Remove cable from Control Box by carefully feeding connectors thru the access hole.



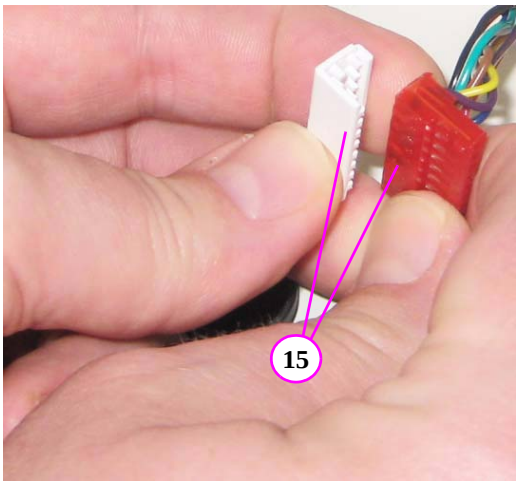
11. Protect wires and connectors by wrapping them in electrical tape if feeding this end thru the wall.
12. Mount Wall Bracket, using supplied mounting hardware (3 places).



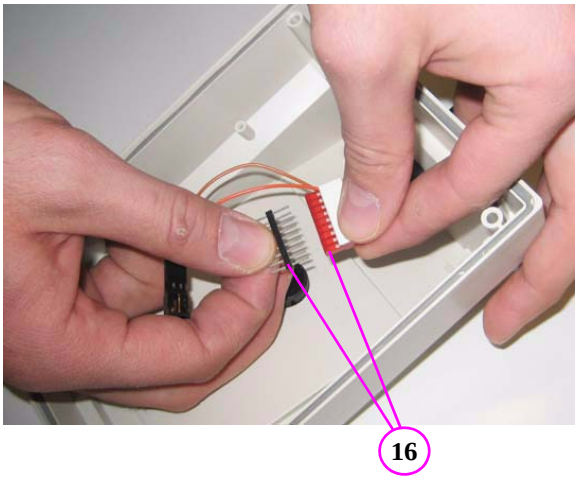
13. Feed cable thru Control Box base.
14. Insert black hole plug in bottom of Control base (hole plug that was previously removed from back of base).



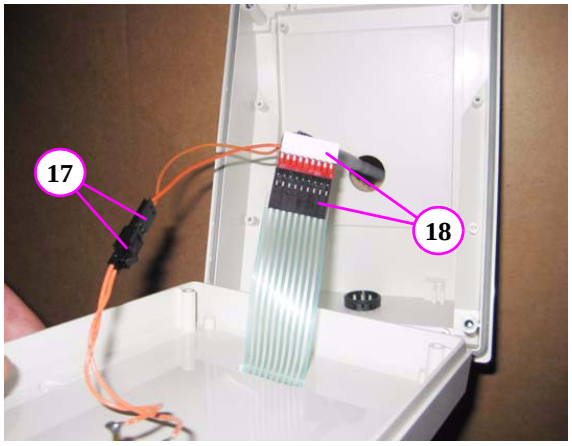
15. Snap-on white plastic cap to red connector.



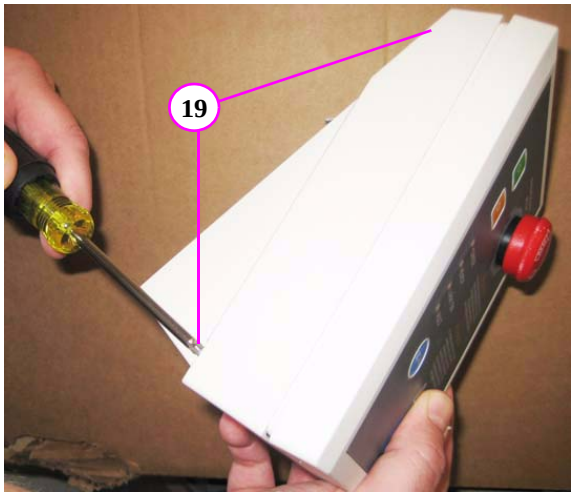
16. Insert pin assembly into red connector.



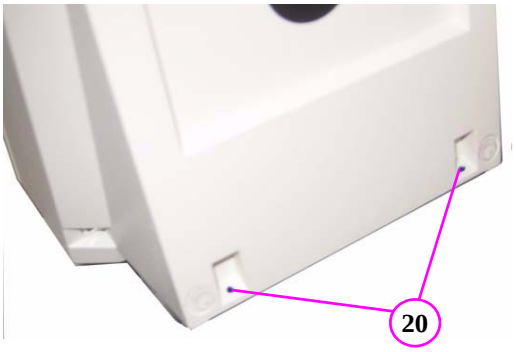
17. Connect black connectors.
18. Connect ribbon cable. Ensure that the white cap on the red connector and the smooth side of the black ribbon connector are facing up as shown.



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).

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

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

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

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