

**Carbon Fiber Overlay for Patient Positioning
for
GE Healthcare Global Tables 1700, 2000, and PET/CT**

Installation and Setup Manual



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This manual contains the latest information at the time of publication. Diacor, Inc. reserves the right to revise this manual without notice.

WARNING

The Overlay for the GE Tables is intended for use only by physicians qualified in radiation oncology or diagnostic radiology or by therapists at the specific direction of such a qualified physician. It is the sole responsibility of the physician to judge whether the use of the Overlay for the GE Global Table is clinically appropriate.

WARNING

The GE Global Table Overlay contain carbon fiber material and should not be used in a MRI scanner.

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1.0 INTRODUCTION

The Diacor Carbon Fiber Overlays for the GE Global Tables provides the user with a flat surface that easily and quickly attaches to the CT Scanner table. At one end of the overlay, a quick release lock holds the board securely in place. At the other end of the overlay, a three pin guide slips into the QC phantom groove at the end of the CT table and provides the secure immobilization of that end of the table.

There is one model of the overlay, Model OGS-4 (Figure 2-1). Along the edges of both overlays are notches that correspond to the Varian Exact™ Couch and Exact Immobilization. These notches allow accessories to be fixed to the overlay surface by utilizing a lock bar.

2.0 GENERAL DESCRIPTION

2.1 GENERAL

The CT Overlay design includes a foam core with phenolic along the edges frame covered with a skin of carbon fiber. The result is a light weight durable overlay that provides minimal artifacts to CT images that include the overlay. Varian Exact notches are machined on both sides of the overlay and a locking mechanism is imbedded and attached at both ends of the overlay. Markings on the surface of the overlay identify a no scan area. Figure 2.1 shows the various features of the Model OGS-4. One or more indexing bars are included with each overlay.

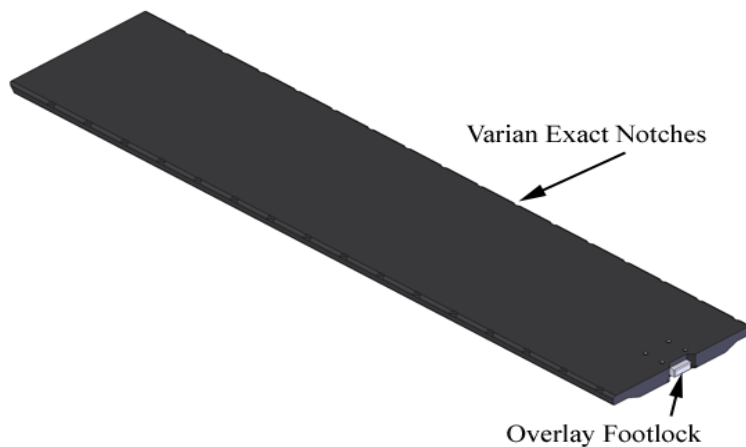


Figure 2.1 Model OGS-4 Overlay

2.1.1 Varian Exact Notches

Along the two long edges of the overlay, Varian Exact Notches provide connecting points for a locking bar to attach. This bar provides reproducible indexing of any device attached to the locking bar.

2.1.2 Overlay Head Bracket

At the head end of the overlay is the overlay head bracket that attaches to the overlay and provides three pins that snugly fit into the QA slot in the CT table. See Figure 2.2.

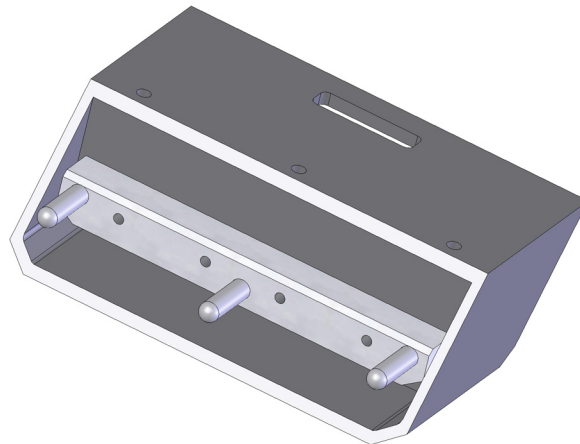


Figure 2.2 Overlay Head Bracket

2.1.3 Overlay Foot Lock

The overlay foot lock assembly has two major components. The overlay foot lock mechanism is attached to the overlay and provides a simple push button to unlock the overlay from the CT table. See Figure 2.3. The second component is the overlay foot lock receiver that attaches to the CT table. See Figure 2.4. As the overlay is positioned on the table, the locking pins at the head of the overlay engage the QA phantom slot of the CT table. The lock slides over the foot lock receiver until it latches. There are pins and receptacles to guide the overlay as it nears the lock position. A vertical pin drops into a hole on the foot lock receiver and the overlay is locked into its correct position. To unlock the overlay from the table, simply push the release button and slide the overlay toward the CT gantry. The overlay disengages from the locking mechanisms and can be removed from the CT table.

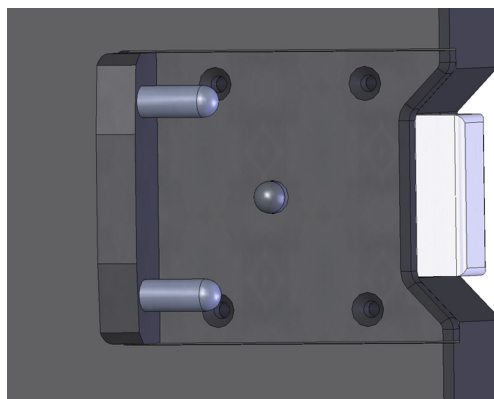


Figure 2.3 Overlay Foot Lock Mechanism

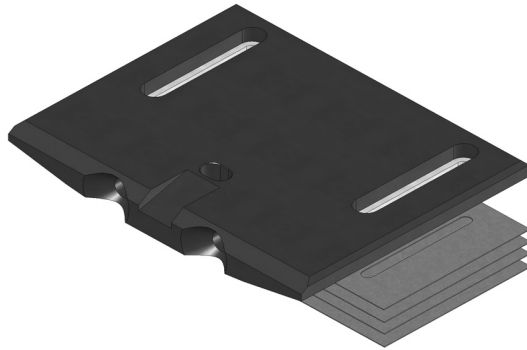


Figure 2.4 Overlay Foot Lock Receiver (Shown with 4 Shims)

2.1.4 No Scan Area

A white line is silk screened on the head end of the overlay to let users know that a scan above the line may pick up artifacts from the Overlay Head Bracket.

2.1.5 Locking Bars

One or more locking bars is provided with each overlay. These bars, see Figure 2.5, are used with the Varian Exact Notches. The pins on the bar interfaces with immobilization accessories and provide a means of reproducing their position on the overlay.

2.1.6 Respiratory Gating Mounting Plate

A respiratory gating mounting plate is provided with each overlay. It is intended that the plate remain in place and the respiratory gating hardware be added or removed as needed. Two reinforced threaded holes in the mounting plate are used to mount the respiratory gating hardware.

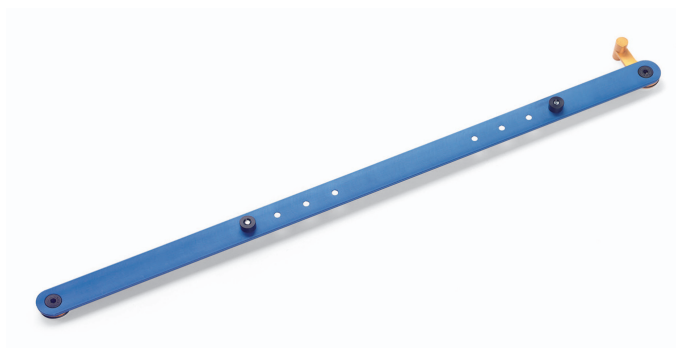


Figure 2.5 Locking Bar

3.0 SAFETY CONSIDERATIONS

3.1 GENERAL

The following safety considerations should be followed by users as well as their patients to prevent injury.

3.1.1 Overlay Handling

The long and although relatively lightweight overlay should not be handled by only one person. To prevent personal injury or potential damage to the overlay or surroundings, two people should carry the overlay, place it on the CT table or removed it from the CT table.

WARNING

Do not attempt to place the overlay on or lift the overlay from the CT table by yourself. It is awkward to hold and you could injure yourself and damage the overlay or surroundings.

3.1.2 Pinch Points

It is possible that a user's or patient's fingers could be pinched when holding the edge of the overlay as it rests on the CT table and the couch/overlay is moved either toward or from the CT scanning area. The user should advise/restrain a patient to not hold the edge of the overlay during any couch/overlay movement. A pinch caution label is applied to both sides of the head end of the overlay as a constant reminder to the user to keep patients from grasping the sides of the overlay.

Figure 3.1 shows the English translation of the label. When the overlay is installed on a couch in a non English speaking country, place an appropriate foreign translations of the label on both sides of the head end of the overlay next to the English version of the label. These labels are provided with the overlay.

WARNING

Prevent pinched fingers. Make sure no one grasps the edges of the overlay when the couch/overlay is moved.



Figure 3.1 Pinch Prevention Caution Label

3.1.3 Clearance

As the couch/overlay is extended into the scan region there is a possibility that the edges of the couch/overlay may travel very near the edge of the gantry bore. Users should verify the clearance while standing next to the patient prior to scanning the patient.

WARNING

Check that the couch/overlay has sufficient clearance with the CT gantry bore when a patient is resting on the overlay and the couch/overlay is moved into the scan area.

4.0 INSTALLATION INSTRUCTIONS

4.1 OVERLAY LOCK SYSTEM

4.1.1 General

The CT Overlay is intended to be installed on GE Global Tables to provide a rigid, flat surface for CT simulation applications for radiation therapy applications. A key objective is to make the patient setup for CT simulation to be identical to the setup that will be done subsequently on the flat treatment couch in the treatment room.

An Overlay lock mechanism is included as part of the CT Overlay. This lock mechanism allows the Overlay to be rigidly connected to the CT table so that its position relative to the couch top is always fixed. In facilities where the CT scanner may be used for both CT simulation and diagnostic radiology, the lock mechanism is easily disengaged, allowing the Overlay to be removed and set aside when it is not needed.

4.1.2 Lock Description

The CT Overlay lock consists of three components as shown in Figures 2.2, 2.3, and 2.4.

4.1.2.1 Head Bracket

The head bracket is mounted to the under side of the Overlay at the head end of the table. This bracket has three pins that engage the phantom holder slot on the head end of the GE Global Table.

4.1.2.2 Foot Lock Mechanism

The foot lock mechanism is incorporated into the foot end of the Overlay. It includes two horizontal pins and one vertical, retractable pin, that engage mating holes on the foot lock receiver. The purpose of the horizontal pins is to restrict the motion of the table top in the vertical direction, as well as in the horizontal direction from side to side. The purpose of the vertical pin is to restrict motion of the table top in the axial direction, along the length of the couch. This vertical pin is retractable, allowing it to retract until it corresponds with the mating hole in the foot lock receiver. A push button on the end of the foot lock mechanism retracts the pin to disengage the lock.

4.1.2.3 Foot Lock Receiver

The foot lock receiver must be mounted permanently to the GE Global table. This provides the engagement holes for the two horizontal and one vertical pin on the foot lock mechanism. Correct installation of this receiver will allow the CT Overlay to be locked to the couch top with little or no movement of the Overlay relative to the CT table.

4.1.3 Foot Lock Receiver Installation

The foot lock receiver must be installed on the GE Global Table before the CT Overlay can be used for CT Simulation applications. When the Overlay is received, the head bracket and the foot lock mechanism should already be installed on the Overlay. The steps to install the foot lock receiver are outlined below:

1. At the head end of the Overlay, loosen the four horizontal screws in the head bracket that fix the position of the pin mount bar, so that the vertical position of the three vertical pins can be adjusted.
2. At the foot end of the Overlay, the foot lock receiver mounts to existing holes located at the foot end of the Global table. There is one pair of holes. Remove the plastic cover from these two holes, and if there are screws in these holes, remove these screws.
3. The foot lock receiver is provided with a shim set, that allows the height of the receiver to be adjusted. To begin the installation process, mount the foot lock receiver to the Global table with no shims under the receiver and with the two horizontal pin holes facing in the direction of the head of the table. (In this position, we expect that the foot lock receiver will be too low to allow the horizontal pins on the foot lock mechanism to engage the holes in the foot lock receiver.) Use two M6 x 50 metric screws to mount the receiver.

WARNING

Do not attempt to place the overlay on or lift the overlay from the CT table by yourself. It is awkward to hold and you could injure yourself and damage the overlay or surroundings.

4. Place the Overlay on top of the Global table, with the head end of the board extended well beyond the head end of the CT table. Slide the table top towards the foot of the couch. Depending on the position of the foot lock receiver, the horizontal pins on the head bracket may contact the end of the CT table before the horizontal pins in the foot lock mechanism contact the foot lock receiver. If this is the case, move the pin mount bar in the head bracket to allow the pins to enter the phantom holder slot.

5. If the horizontal pins on the foot lock mechanism hit the foot lock receiver without fully entering the mating holes, then the foot lock receiver is too low, and must be moved up, using the shims provided. Install a shim under the foot lock receiver, and retry the engagement process. Repeat this process until the height of the foot lock receiver is correct. The height is correct when the top surface of the horizontal pins on the foot lock mechanism just touch, or slightly clear the top of the mating holes. This can be verified by pulling up on the table top, when the horizontal pins are engaged with the foot lock receiver, and observing that the table top motion relative to the couch is less than 0.25 mm (0.010").

6. Note, if the table top lifts up slightly as the horizontal pins of the foot lock mechanism engage the foot lock receiver, the foot lock receiver is too high, and shims under the foot lock receiver must be removed until the height is correct.

7. Slide the overlay as far as possible towards the foot of the CT table, making sure that it is the head bracket that prevents further movement towards the foot of the CT table. The horizontal pins on the head bracket should be fully engaged in the phantom slot. Push up on the pin mount bar so that the top of the pins are in contact with the top of the phantom holder slot. Tighten the four screws which attach the pin mount bar in this position. See Figure 4.2 that shows the four holes where these screws are found. Correct position can be verified by lifting up on the head end of the overlay and verifying that vertical motion relative to CT table is less than 0.25 mm (0.010 in).

8. Finally, the horizontal position of the foot lock receiver must be adjusted. With the table top pushed as far as possible towards the foot end of the CT table, slide the foot lock receiver towards the head end of the CT Table until the vertical pin in the foot lock mechanism just drops into the mating hole on the receiver. The push button on the end of the foot lock mechanism is pushed in when the vertical pin is retracted, and extended out when the vertical pin is extended. Hold the receiver in this position, move the overlay toward the head end of the CT table enough to access the mount screws for the receiver, and tighten the mount screws. Slide the overlay towards the foot of the couch to re-engage the lock. Verify that the vertical pin still engages the mating hole in the receiver, and that when in this position, the axial movement of the table top, relative to the CT table is less than 0.25mm (0.010 in.).

9. With the overlay in the locked position, verify that table top movement relative to the CT table is less than 0.25 mm (0.010 in) in any direction. Repeat any of the previous adjustments if necessary at this point.

10. To release the table top lock, push on the button at the end of the foot lock mechanism to retract the vertical pin, and push the overlay a few inches to disengage the horizontal pins at both ends of the board.

4.1.4 Install Respiratory Gating Mounting Plate

1. Remove the two center screws from the top side the foot lock of the overlay.
2. Place the Respiratory Gating Mounting Plate on the overlay surface with the two center screw holes on the plate lined up with the two center holes in the overlay.
3. Place two longer screws in each of the two holes and tighten the screws.

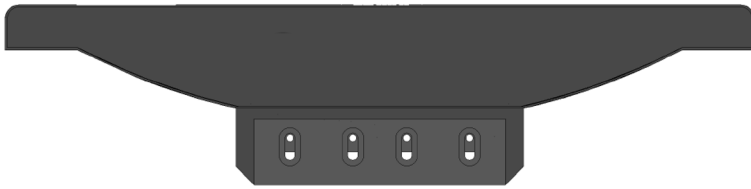


Figure 4.2 Pin Mount Bar with 4 Holes for Screws

5.0 UNPACKING AND STORAGE

5.1 GENERAL

The Overlay is designed to be unpacked and installed on the CT table. Prior to installation, the Overlay should be carefully stored to prevent damage. This same care should be exercised if the Overlay is removed from the CT table due to non therapy related uses of the CT scanner.

5.2 UNPACKING AND INSPECTION

The Overlay is shipped in a heavy cardboard box with foam pieces holding the Overlay securely in the box. When the Overlay arrives, inspect the shipping container for evidence of physical damage. If there are any dents, scratches, or other evidence of physical damage to the boxes or possible damage to the Overlay, note the damage on the shipper's copy of the bill of lading and file a claim against the shipper.

In the case of shortages or malfunctions, notify Diacor immediately to arrange for replacement or repair. Refer to section 6.1.2 for the discussion of replacement or repair of products under warranty. Save all packing containers and materials for the Overlay in case it needs to be returned to Diacor for replacement or repair.

5.3 STORAGE

When the CT scanner is dedicated to radiation therapy simulation, the Overlay remains in place and is not likely to be removed except for periodic CT table maintenance. However, when the CT scanner is shared and performs diagnostic scans as well as radiation therapy simulations, the Overlay may be removed and replaced several times a day.

5.3.1 Wall Storage

Upon removal of the overlay from the CT table, place the foot end on a soft surface next to one of the walls in the CT room. Tilt the overlay against the wall and attach a restraining belt around the overlay to prevent it from sliding or falling from its position.

6.0 SERVICING

6.1 GENERAL

The CT overlay requires careful handling and cleaning following each use but generally requires minimal service.

6.2 CLEANING

The CT overlay and any insert in the overlay experiences noncritical patient contact. It is important to thoroughly clean the overlay following each use.

6.2.1 Cleaning Method

After each use, wipe the surfaces of the board and the insert with wipes containing a mild cleaning and disinfecting solution of 14% alcohol and active quaternary ammonium chlorides or a similar disinfecting solution. (One such solution is offered by Professional Disposables International with a trade name of SANI-CLOTH® PLUS). After the cleaning process is complete, let the cleaned surfaces air dry. Do not use water as either a cleaning or rinsing agent. Never use aerosol cleaning sprays, cleaning agents, solvents or abrasive detergents.

6.3 PERIODIC MAINTENANCE

Periodic checks of the CT overlay should be done to insure the parts are not worn and require repair or replacement.

6.3.1 Carbon Fiber Support Structure

Damage to the surface coatings of the carbon fiber CT overlay including cracks and deep scratches may make the open cell structure of the overlay visible and compromise the strength of the board. The part should be repaired or replaced. Small scratches or cracks (less than 0.5 cm wide) may be repairable. Contact Diacor if there are any questions.

6.4 MULTILINGUAL LABELS

Multilingual warning and caution labels are provided with the overlay. When the overlay is installed on a couch in a non English speaking country, place an appropriate foreign translations of the label on the overlay next to the English version of the label or where directed by instructions included with the labels.

7.0 WARRANTY

7.1 GENERAL

The CT Overlay and all the associated parts for this product are warranted by Diacor for a period of one (1) year from the date of shipment.

The Diacor warranty coverage is limited to defective materials or workmanship. The warranty is void if the CT Overlay has been damaged by accident, unreasonable or improper use, neglect, or other causes not arising out of defects in material or workmanship.

7.1.1 Warranty Disclaimers

The express warranty provided herein is in lieu of any and all implied warranties arising out of the sale of the CT Overlay, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Diacor shall not be liable for loss of use of the CT Overlay or other incidental or consequential costs, expenses, or damages incurred by the customer or other user.

7.1.2 Warranty Performance

During the stated warranty period, the CT Overlay will be repaired or replaced, at the option of Diacor, Inc., with a new or reconditioned CT Overlay when the unit is returned postage prepaid to Diacor, Inc., 2550 Decker Lake Blvd., Suite 26, West Valley City, Utah 84119. Please contact Diacor, 800-342-2679 or 801-467-0050, for a Return Material Authorization (RMA) prior to sending the defective unit to us. The replacement of a CT Overlay will not extend the expressed warranty stated herein beyond the original warranty period.

8.0 SPECIFICATIONS

	CT Overlay
Weight	31.5 lb. (14.3 kg)
Length	85.25 in (216.5 cm)
Width	20.87 in (53.0 cm)
Height	1.62 in (4.12 cm)
Distributed Patient Load	Note 1

Note 1. To compute the distributed weight of a patient who may rest on the table and overlay, the weight of the overlay should be subtracted from the distributed patient load as found in the GE Specifications for the table on which the overlay is installed.