



ZephyrTM

Patient Positioning
and Transfer System

Model ZXL User 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.

INTENDED USE

The Zephyr ZXL Patient Positioning and Transfer System is indicated to aid in the support, positioning, and transfer of a patient for procedures involving imaging, including MRI, and external beam radiation therapy treatment with electrons, photons or protons, as well as other procedures requiring transfer of a patient.

The Zephyr ZXL is intended for use only by physicians qualified in imaging and/or experienced in patient set up for planning or treatment, or by therapists at the specific direction of such qualified physicians.

Diacor, Inc. has appointed M. Devices Group/E.C. REP Ltd as our EU Authorized Representative. Contact Information:



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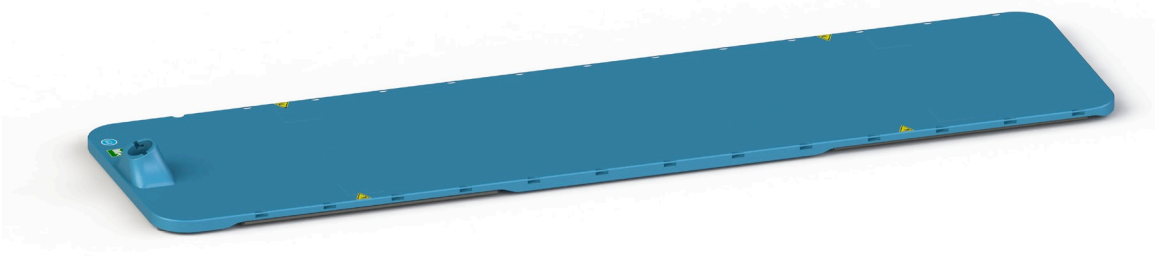


Figure 1.1 Diacor Zephyr ZXL Patient Positioning and Transfer System Baseboard

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SECTION

INTRODUCTION

1

The Zephyr ZXL Patient Positioning and Transfer System is used to aid in the support, positioning, and transfer of a patient for procedures involving Magnetic Resonance Imaging (MRI), Computed Tomography Imaging (CTI), Positron Emission Tomography (PET) imaging, Diagnostic X-ray Imaging (DXI), Radiation Therapy (RT) treatment by Medical Linear Accelerator or Charged Particle Accelerator and other procedures requiring transfer of a patient.

The Zephyr ZXL Patient Positioning and Transfer System consists of a rigid "MR Safe" Kevlar/Epoxy baseboard measuring 198.12cm x 53.01cm x 2.54cm (including pads). The underside of the baseboard has four perforated lift pads.

The Zephyr ZXL Patient Positioning and Transfer System utilizes forced air as a low-friction bearing to transfer patients from one flat surface to another, eliminating the need to manually lift the patient. The forced air is provided by an accessory air blower through a 10 foot length of flexible hose connected to the baseboard. The air is then routed to the perforated lift pads on the underside of the baseboard. When being used in MR, an extended flexible hose of 30 feet is available upon request, to position the "MR Unsafe" blower unit outside an MR imaging room, and continue to remain connected.

The baseboard is placed on a flat-surfaced wheeled stretcher (also available from Diacor). The baseboard is capable of attachment of various commercially available patient support and positioning accessories, utilized for imaging and treatment. The positioning aids, if required by the user, are placed upon and attached to the baseboard. The patient is then positioned on the baseboard with positioning aids, if applicable. The wheeled stretcher is then rolled to the procedure room and placed against the imaging or treatment table.

The patient is transferred to the imaging or treatment table by activating the blower. As the blower supplies air to the lift pads, the pads generate a nominal lift of 1 centimeter to the baseboard. This lift enables the baseboard to be moved from one flat surface to another with ease by two persons. The medical staff guides the baseboard and the patient to the position desired.

The baseboard is aligned with the index locations if available in the table. The blower is then deactivated and the baseboard settles on the flat supporting surface. The patient is then imaged or treated as required. During the procedure, the baseboard will function as an accessory to support and position the patient utilizing any non-Diacor positioning aids required by and supplied by the medical staff.

After the procedure, the blower is activated and the baseboard and patient are transferred to the wheeled stretcher. The blower is then deactivated, and the wheeled stretcher is removed from the procedure room.

SECTION

GENERAL DESCRIPTION

2

2.1 GENERAL

The Zephyr ZXL Patient Positioning and Transfer System is used to aid in the support, positioning, and transfer of a patient for procedures involving Magnetic Resonance Imaging (MRI), Computed Tomography Imaging (CTI), Positron Emission Tomography (PET) imaging, Diagnostic X-ray Imaging (DXI), Radiation Therapy (RT) treatment by Medical Linear Accelerator or Charged Particle Accelerator and other procedures requiring transfer of a patient.

2.2 FEATURES

The features described in this section are used at various times during the patient transfer process. Operators should become familiar with all of these features prior to using any part of the complete system

2.2.1 Patient Transfer Baseboard

Figure 2.2 shows the Zephyr ZXL Patient Positioning and Transfer System which consists of a rigid "MR Safe" Kevlar/Epoxy baseboard measuring 198.12cm x 53.01 cm x 2.54cm (including pads). The underside of the baseboard has four perforated lift pads

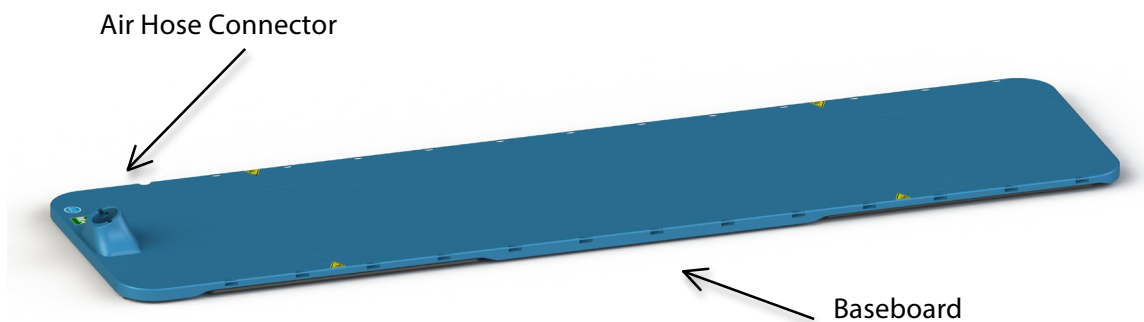


Figure 2.2 Zephyr ZXL Baseboard Features

2.2.1.1 Air Pads

Figure 2.3 shows an example of air pads that provide lift to the Zephyr baseboard when the blower is on.

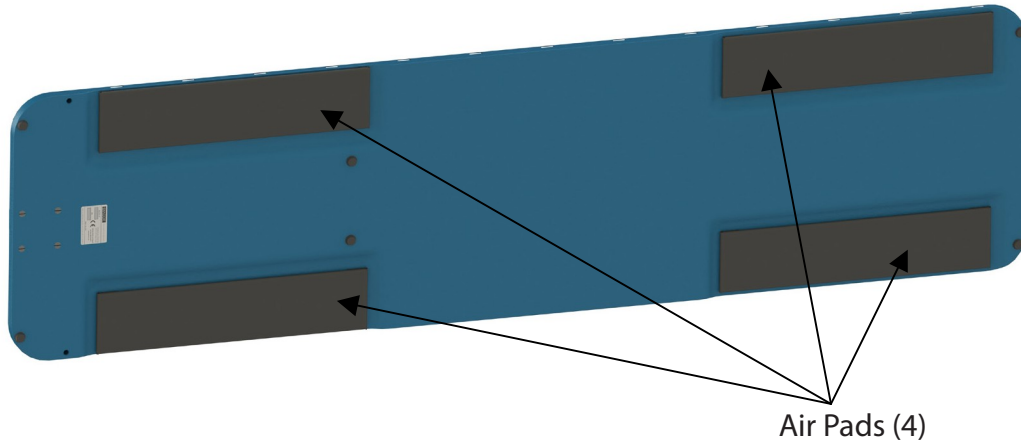


Figure 2.3 Bottom View of a ZXL-1 Baseboard

2.2.1.2 Quick Release Air Hose Connection

The air hose connector accepts the mating connector on the air hose. To attach the hose, it is only necessary to insert/push the quick release hose connector into the air hose connector on the sled. To remove the hose, push the release button on the air hose connector and pull the hose out.

2.2.2 Zephyr ZXL Air Blower and Hose



CAUTION

Blower must remain outside of the MR Suite. This blower is "MR Unsafe". To remain connected, a longer hose is available upon request.

The Zephyr ZXL Patient Positioning and Transfer System utilizes forced air as a low friction bearing to transfer patients from one flat surface to another, eliminating the need to manually lift the patient. The forced air is provided by an accessory air blower through an extended length of flexible hose connected to the baseboard. The air is then routed to the perforated lift pads on the underside of the baseboard. A longer hose is available upon request to position the "MR Unsafe" blower unit outside an MR imaging room and continue to remain connected.

Figure 2.4 shows the air blower and hose as well as important features of the blower.



Figure 2.4 Zephyr Air Blower and Hose

2.2.2.1 Hose LED Power Button

The blower is operated using the LED Power Button on the hose connector. When the blower is plugged in and turned on, the blue light on the power button indicates the operating status.

Initial Setup of Blower Power Connections:

1. Ensure the LED Power Button is in the OFF position (flush with surface)
2. Ensure that the Blower Power Cord is securely connected to the Blower Power Inlet
3. Ensure that the Hose Power Cord is securely connected to the LEMO Port
4. Ensure that the Controller Power Cord is securely connected to the Controller Power Inlet
5. Ensure that the Controller Power Cord is securely connected to a functional wall outlet
6. The LED Power Button should blink three times, indicating the system is now ready for use

Troubleshooting - Blower not functional with LED Power Button in the ON position:

LED Status	Likely Cause	Recommended Action
Light off	Controller Power Cord disconnected	<ul style="list-style-type: none"> Return LED Power Button to the OFF position (flush with surface) Restore Controller or Hose power connections as outlined above Wait 10 seconds after restoring power System is now ready for use
	Hose Power Cord disconnected	
	Controller malfunction (blower controller may be temporarily bypassed until service can be performed)	<p>TEMPORARY CONTROLLER BYPASS</p> <ul style="list-style-type: none"> Return LED Power Button to the OFF position (flush with surface) Press the Blower Power Switch to change it to the OFF position Disconnect Blower Power Cord from the Blower Power Inlet Move Controller Power Cord from the Controller Power Inlet to the Blower Power Inlet System can now be operated by pressing the Blower Power Switch instead of the LED Power Button (note: the blower air speed will not have its normally gradual ramp-up period when operating in the bypass condition) Contact your service representative to report the controller malfunction
Light blinking rapidly	Controller power was restored with the LED Power Button in the ON position	<ul style="list-style-type: none"> Return LED Power Button to the OFF position (flush with surface - light should turn off) Wait 10 seconds System is now ready for use
Light on	Blower Power Switch was changed to the OFF position	<ul style="list-style-type: none"> Return LED Power Button to the OFF position (flush with surface - light should turn off) Press the Blower Power Switch to change it to the ON position (switch will appear the same in either position) System is now ready for use

2.2.2.2 Blower Power On/Off Switch

The ON/OFF switch is a push to connect/push to disconnect power button located on the top of the blower. The switch must be in the ON position to enable the LED Power Button control button to start the air flow.

2.2.2.3 Flexible Hose

A flexible hose carries the air from the air blower to the sled. A 10 foot hose is supplied with the Zephyr Patient Positioning and Transfer Sled. If needed a 20 or 30 foot hose can be shipped with the system.

2.2.2.4 Quick Turn Hose Connection

A quick turn connector attaches the flexible hose to the air blower.

UNPACKING, INSTALLATION, USE

3.1 GENERAL

The Zephyr ZXL is designed ready for installation following removal from its packing container.

3.2 UNPACKING AND INSPECTION

When the Zephyr ZXL arrives, inspect all shipping containers for evidence of physical damage. If there are any dents, scratches or other evidence of physical damage to the boxes, 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 sections 5.3 for the discussion of replacement or repair of products under warranty. Save all packing containers and materials for the Zephyr ZXL in the event it needs to be returned to Diacor for replacement or repair.



Caution

Always use two people when lifting the baseboard to or from any flat surface.

3.3 INSTALLATION

Using two people, place the baseboard on a flat table top or stretcher(see above caution). The four air pads should be resting on the surface of the flat table top or stretcher.

Initial Setup of Blower Power Connections:

1. Ensure the LED Power Button is in the OFF position (flush with surface)
2. Ensure that the Blower Power Cord is securely connected to the Blower Power Inlet
3. Ensure that the Hose Power Cord is securely connected to the LEMO Port
4. Ensure that the Controller Power Cord is securely connected to the Controller Power Inlet
5. Ensure that the Controller Power Cord is securely connected to a functional wall outlet
6. The LED Power Button should blink three times, indicating the system is now ready for use

Connect the blower air hose to both the connector on the baseboard as well as the connector on the air blower.

3.4 USE



WARNING

Do not allow the sheet or pad to slide underneath the baseboard as it is important that the users know exactly where the baseboard is on the flat table top. Failure to control the sheet or pad may cause the baseboard to lift incorrectly or to catch the sheet or pad under the baseboard.

Prior to each use the baseboard must be cleaned by the standard requirements of the user that fall under “any product that may come in contact with a patient.” Next, if applicable, cover the baseboard with a sheet or a sterile pad to protect the patient, following the standard setup for the procedure. Do not allow the sheet or pad to slide underneath the baseboard as it is important that the users know exactly where the baseboard is on the flat tabletop. Failure to control the sheet or pad may cause the baseboard to lift incorrectly or to catch the sheet or pad under the baseboard.

The baseboard is capable of attachment of various commercially available patient support and positioning accessories utilized for imaging and treatment.

The baseboard is now ready for placement of positioning aids, if required, and is ready for the patient. The positioning aids, if required by the user, are placed upon and attached to the baseboard. The patient is then positioned on the baseboard and immobilized as per physician’s instructions.

The patient is transferred to the required position by activating the blower. On the air blower, ensure that the power switch is on. Push the LED Power Button to initiate the air flow. As the blower supplies air to the lift pads, the pads generate a nominal lift of 1 centimeter to the baseboard. This lift enables the baseboard to be moved from one flat surface to another with ease by two persons. The medical staff guides the baseboard and the patient to the position desired.

The baseboard is aligned with the index locations if available in the table. The blower is then deactivated and the baseboard settles on the flat supporting surface. The patient is then imaged or treated as required. During the procedure, the baseboard will function as an accessory aid to support and position the patient, utilizing any non-Diacor positioning aids required by and supplied by the medical staff. After the procedure, the blower is activated and the baseboard and patient are transferred to the wheeled stretcher. The blower is deactivated and the wheeled stretcher is removed from the procedure room.



Caution

It is extremely easy to move a patient that has been lifted by the air pads. However, for safety purposes, two people must assist in moving the patient whenever the base is supported by the air pads.



WARNING

There are no stops at either end of the flat table top. It is important that the users control the baseboard as it is moved to the extreme ends of the flat table top and prevent it from extending over the flat table top. The patient should not be moved on the baseboard with the air pads inflated at the same time that the table is moving.

3.4.1 Pinch Points



Caution

Prevent pinched fingers. Whenever the Zephyr ZXL baseboard is elevated by the air pads, it is possible for the users or the patient to allow their fingers to go underneath the base. When the blower is turned off, the baseboard will lose its lift and may pinch fingers that are beneath it.

SECTION SERVICING



4.1 GENERAL

The Zephyr ZXL requires careful handling and cleaning following each use but generally requires minimal service.

4.2 CLEANING

The Zephyr ZXL makes noncritical patient contact, but these contact areas must be thoroughly cleaned following each use to prevent spread of infection by contact.

4.2.1 Cleaning Method

After each use, wipe the surfaces of the baseboard 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.

4.3 PERIODIC MAINTENANCE

Diacor recommends inspecting the baseboard monthly for broken or non-functioning parts. Contact Diacor for replacement parts. See section 5.3.

4.3.1 Air Blower Filter

The filter in the Zephyr ZXL air blower should be cleaned or replaced annually or when visibly dirty. There are three screws that must be removed to separate the blower from the canister and allow access to the filter. The filter can be cleaned with water or replaced and the three screws returned to their original position. Filter replacements are available from Diacor.

4.4 HANDLING AND STORAGE

Handle the Zephyr ZXL carefully to prevent damage. Store in a safe place when not in use.

4.5 AIR PADS

Should an air pad be damaged, please contact Diacor for service. For contact information see section 5.3.

SECTION WARRANTY

5

5.1 GENERAL

The Zephyr ZXL is 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 Zephyr ZXL has been damaged by accident, unreasonable or improper use, neglect, or other causes not arising out of defects in material or workmanship.

5.2 WARRANTY DISCLAIMERS

The express warranty provided herein is in lieu of any and all implied warranties arising out of the sale of the Zephyr ZXL, 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 Zephyr ZXL or other incidental or consequential costs, expenses, or damages incurred by the customer or other users.

5.3 WARRANTY PERFORMANCE

During the stated warranty period, the Zephyr ZXL will be repaired or replaced, at the option of Diacor, Inc., with a new or reconditioned Zephyr ZXL when the units are returned shipping prepaid to Diacor, Inc., 2550 Decker Lake Blvd., Suite 26, Salt Lake 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 back. The replacement of a Zephyr ZXL will not extend the expressed warranty stated herein beyond the original warranty period.



TECHNICAL INFORMATION

6.1 GENERAL

6.2 SPECIFICATIONS

Weight	28 lb. 12.7 kg.
Length	78 in. 198.12 cm.
Height (with pads)	1 in. 2.54 cm.
Width	20.87 in. 53.01 cm.
Maximum Patient Weight	450 lb. 204.11 kg.

Non-clinical testing was completed under the following conditions:

- Static Magnetic Field: 1.5 to 3 Tesla
- Spatial Gradient Field: 4.5 Gauss/cm (45 mT/m) max.
- Maximum Whole Body Averaged Specific Absorption Rate (SAR): 1.1 W/kg for 10 minutes of scanning.
- Temp Rise at Max. Whole Body Averaged SAR of 1.1 W/kg: 0 °C

This testing has demonstrated the Diacor Zephyr ZXL Patient Positioning and Transfer Baseboard is MR Safe.



Caution

Blower must remain outside of the MR suite. This blower is "MR Unsafe". To remain connected, a longer hose is available upon request.

6.3 DIACOR BASEBOARD ATTENUATION MEASUREMENTS

Diacor Baseboard and CT Overlay Attenuation Measurements

March 4, 2017

Conducted at:

Rose Medical Center
Denver, CO 80220

Equipment:

Varian iX #1148
Capintec PS 033 parallel plate
CNMC Model 206
ADCL calibration: April 2016
30cm x 30cm solid water

Setup:

90cm SSD
10cm depth
6MV
10cm x 10cm field
100MU
400 MU/min dose rate
Diacor Zephyr ZXL placed on top of solid water

The attenuation factor mid board at level F5 was 2.1%

This attenuation factor is to be used as a guideline only. Customer should obtain their own attenuation measurements as it is energy and machine specific.