



PRIMARY CARE[®]

Pressure Relieving System

Operating Instructions

Tridien Medical

Revision: AO-SM600-AP-04



WARNING

Before operating this medical equipment, it is important to read this manual and to understand the operating instructions and safety precautions. Failure to do this could result in patient injury and/ or damage to the product.

This equipment generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other device, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which other device(s) are connected.
- Consult with Tridien for help.

If you have any questions, please contact Tridien Customer Service at **800-474-4225** or **954-340-0500**.



**WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 2601-1**

**WITH RESPECT TO ELECTRIC SHOCK, FIRE,
MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN
ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1,
MEDICAL EQUIPMENT CERTIFIED FOR CANADA**

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1.0 SAFETY PRECAUTIONS –

CAUTION! The PRIMARY CARE system is *contraindicated* for use with certain medical conditions and treatments. **Always consult with the patient’s physician before placing a patient on an alternating pressure system.**

CAUTION! Bed frames used with the PRIMARY CARE system can vary greatly depending on the specific health care setting, e.g., hospitals, nursing homes, home care, etc. Therefore, it is the responsibility of the caregiver to take the necessary precautions to ensure the safety of the patient. This includes, but is not limited to, the appropriate use of side rails to prevent falls and/or patient entrapment.

Electronic Controller:

DANGER!

- Do not use in the presence of flammable anesthetics. **Risk of explosion can result.**
- Exposure of the electronic controller to any liquid while it is plugged in could result in a severe electrical hazard.
- Only use fuses that have the same specified rating (**See Section 7.0 Product Specifications**). Using fuses with higher ratings could result in damage and/or injury.

CAUTION!

- **Risk of Electric Shock.** Do not open or attempt to repair or service the electronic controller. Repairs and service should only be done by Tridien Medical (“Tridien”). If the controller is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately. Contact Customer Service at **800-474-4225** or **954-340-0500** for repair and service information.
- The electronic controller is a precision electronic product. Use care when handling or transporting. Dropping, or other sudden impacts, may result in damage to the controller.

IMPORTANT!

- Do not return a product for any reason without first contacting Customer Service to obtain authorization (**See Section 9.0**).
- Do not place any objects/items, such as blankets, on, or over, the electronic controller. Excessive weight on the PRIMARY CARE system could result in damage to the electronic controller.
- After exposure to extreme high or low temperatures, allow electronic controller to equilibrate to room temperature before operating.

1.0 SAFETY PRECAUTIONS – Electronic Controller (Continued):

- The PRIMARY CARE system circulates room air during operation. Exposure to smoke may cause the system to fail. Therefore, smoking by patients, or visitors, while using the PRIMARY CARE system is strongly discouraged.
- The power cord to the electronic controller should be positioned to avoid a tripping hazard and/or damage to the cord. Tridien recommends placing the cord under the bed frame and attaching it to an electrical outlet by the head of the bed.

2.0 PRODUCT OVERVIEW -

The PRIMARY CARE is a therapeutic mattress system and is available in two (2) different versions:

Alternating Pressure System: This version of the PRIMARY CARE provides pressure relief by sequentially deflating and inflating alternate air cells on a timed interval. It is widely recognized that constant pressure to a bony prominence is the leading cause of skin breakdown. The continuous movement provided by the PRIMARY CARE system alleviates these areas of constant pressure and enhances circulation.

The deflated air cells provide pressure relief, while the inflated air cells support the patient's weight. The amount of pressure to support a patient can be adjusted, based on the patient's weight.

Low Air Loss System: This version of the PRIMARY CARE provides excellent pressure reduction, allowing lower risk patients to rest comfortably while greatly reducing the risk of tissue breakdown. In addition, the system circulates air beneath the patient and aids in moisture vapor evaporation.

3.0 INSTALLATION –

NOTE: It is recommended that all shipping and packing material be saved in the event that the product has to be sent back to Tridien Medical.

3.1 Unpacking and Inspection

Carefully remove the controller, mattress and all accessories from the shipping cartons. Inspect all items for any damage that may have occurred during shipping. Any damages, or missing components, should be reported to Tridien Customer Service as soon as possible.

Mattress Replacement: The box contains a completely assembled Mattress Replacement system. This system is comprised of:

- 1.5 Inch Foam Mattress
- Air Cell Assembly with CPR
- Top Coverlet

Mattress Overlay: The Mattress Overlay system is comprised of:

- Air Cell Assembly with CPR
- Top Coverlet

Electronic Controller: The electronic controller is packaged in a separate box, inside the mattress box and contains:

- Electronic Controller
- Power Cord
- Operating Instructions
- Bio-Med Data Sheet (Electrical Safety Testing)

3.2 Installation Requirements

The PRIMARY CARE system is designed to operate in a controlled environment that is free from extreme temperatures, high humidity and/or excessive amounts of airborne particulates, such as dust and smoke. The controller can be hung on the upper outside edge of the footboard of the hospital and home care beds.

3.3 Air Mattress

Mattress Replacement System: No assembly is required. Remove the current mattress from the bed frame and replace with the PRIMARY CARE Mattress assembly. The hose connections should be positioned at the bottom left of the bed.

There are two (2) sets of straps with D-rings on each side and one (1) at the head of the mattress. Use these straps to secure the mattress replacement to the bed frame.

Mattress Overlay: Place the Mattress Overlay on top of the existing mattress with the hose connections positioned at the bottom left of the bed. Secure by attaching the corner straps under the existing mattress.

IMPORTANT: Make sure that the attachment of the mattress system does not interfere with bed movement/operation.

3.4 CPR

The CPR pull is red and is located at the *head* of the mattress on the patient's right side. It has already been installed at the factory and should require no further installation. However, it should be inspected to ensure that it has not loosened, or become disconnected, during shipping.

3.5 Electronic Controller

1. **Handles:** The handles on the PRIMARY CARE controller are designed with a spring action:

Attaching the Controller: Fully open both handles simultaneously and hang the controller over the upper outside edge of the footboard on the bed frame. When released, the handles will spring back, providing tension to hold the controller securely onto the bed frame.

Removing the Controller: Fully open both handles simultaneously to release the tension and lift the controller off of the bed frame.

CAUTION! Do not try to remove the controller without first relieving the spring tension on the handles. Failure to do this may damage the handle system.

2. **Mattress Hoses:** Connect the hoses from the *patient's* right side of the mattress shell to the connectors on the left side of the electronic controller. Order of connection is not important.

NOTE: Each connector should tightly "click" into place.

3. Plug into an electrical outlet that is compatible with the electrical rating for your particular controller (See **Section 7.0, Specifications**) and turn on the controller.

4.0 OPERATION –

4.1 Setting the Electronic Controller:

1. Turn the power on by pressing the power switch located on the left side panel of the controller.
2. Select patient's weight using slide control on top of the electronic controller (See **Figure 1** below). If more pressure is desired, move the slide control to the higher weight setting. If less pressure is desired, move the slide control to the lower weight setting.

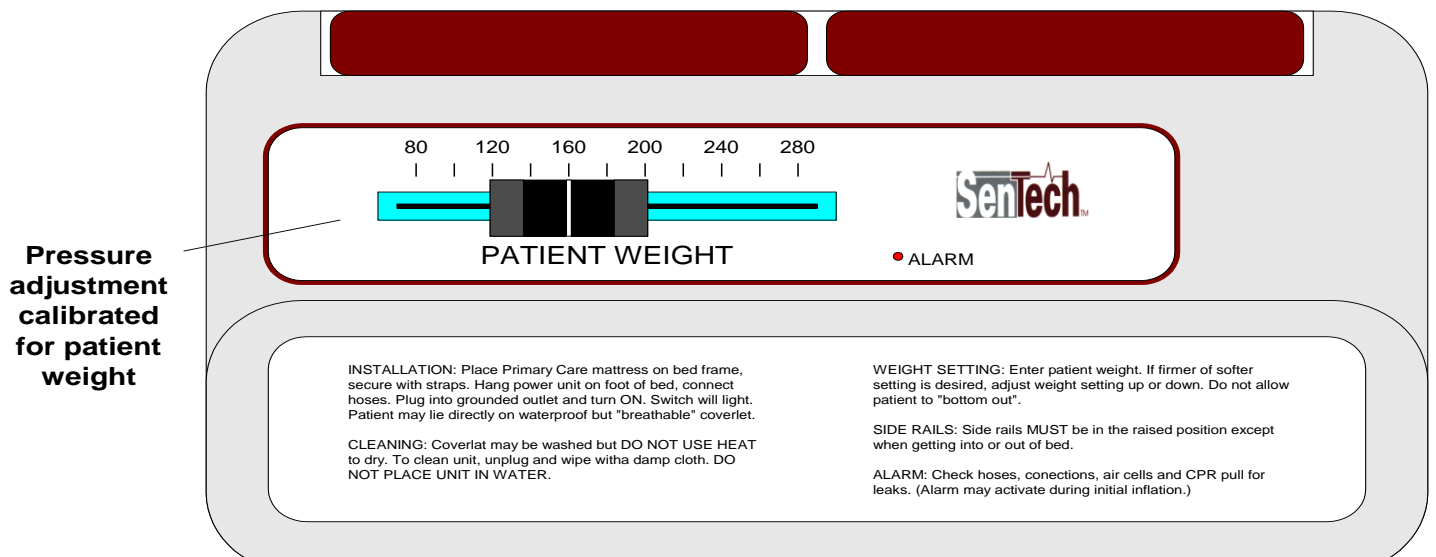


Figure 1

4.2 CPR OPERATION –

For emergency situations, a CPR Pull is located at the head of the mattress on the patient's *right* side.

1. To activate, firmly pull the red tag labeled "CPR".
2. All air cells will begin to deflate and air will be rapidly evacuated. Rate of evacuation is dependent on the weight of the patient.
3. To resume normal operation of the mattress, close the CPR device by fully inserting the two (2) CPR hoses onto the connector.

5.0 MAINTENANCE AND CLEANING –

IMPORTANT! Use a "hospital-grade" disinfectant that is registered with the Environmental Protection Agency (EPA) or chlorine bleach to disinfect your system. Use according to the manufacturer's instructions, including specified *dilutions* and *contact times*.

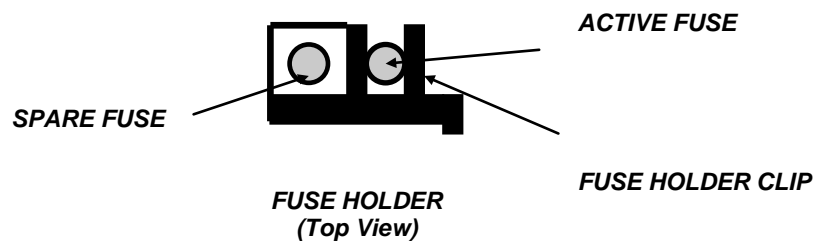
5.1 Electronic Controller:

5.1.1 Fuse Replacement:

CAUTION! Only use *UL-Approved* fuses that have the same specified rating (See **Section 7.0**) Using fuses with different ratings could result in damage and/or injury.

One (1) replacement fuse is provided with your controller and is located in the compartment on the electrical cord socket. To replace a fuse:

1. Ensure the power switch is in the OFF position.
2. Remove the power cord from the electrical socket on the side of the controller.
3. Using a small sized flat-head screwdriver, pry the fuse holder away from the socket and slide it out of the socket.
4. Remove the "blown" fuse from the fuse holder clip and discard.
5. Remove the spare fuse from the storage compartment and install it into the fuse holder clip (See Diagram Below):



6. Push the fuse holder completely back into the electrical socket until it "snaps" into place.

NOTE: The fuse holder must be properly oriented to slide in correctly. Do not force.

7. Replace power cord and turn on the controller.

5.1.2 Filter Maintenance

The filter should be checked every 30 days. If dirty, the filter should be dusted or vacuumed.

CAUTION! DO NOT attempt to remove filter or filter cover assembly.

IMPORTANT! Good filter maintenance is critical in keeping your PRIMARY CARE controller in optimal operating condition. Failure to keep the filters clean will result in system downtime and increased repair costs.

5.1.3 The exterior of the controller should be periodically wiped using a cloth dampened with disinfectant.

CAUTION! DO NOT spray disinfectant directly on the electrical controller, or immerse the controller in any type of liquid. This could result in a severe electrical hazard.

5.1.4 Before plugging in the controller, check the power cord for electrical hazards, e.g., cuts, exposed wires, worn insulation, etc. If hazards are present, take the controller out of operation immediately and contact Tridien Customer Service.

5.1.5 To ensure optimal performance of your PRIMARY CARE system, calibration should be verified every 12 months. Contact Tridien Customer Service for calibration information.

5.2 Coverlet:

5.2.1 Washing and Disinfecting

*If there are visible signs of body fluids and/or substances present, coverlets should be washed between patients. Coverlets can be machine-washed using chlorine bleach (50-150 ppm) or an *intermediate level* disinfectant, such as ProTech¹. Bleach and disinfectant should be used according to the manufacturer's instructions. To determine the amount of bleach or disinfectant to use, determine the amount of water in the washer and then follow the *manufacturer's dilution instructions*. Soak the coverlet in the disinfectant or bleach during the wash cycle. Rinse thoroughly in clean water and dry before use.*

1. ProTech[®] is a tuberculocidal disinfectant cleaner and a registered trademark of Central Solutions, Inc.

5.2.1 Washing and Disinfecting (Continued)

NOTE! 2.5 ounces of bleach per 10 gallons of water is approximately 100ppm of available chlorine.

CAUTION! Heat will severely damage the material. DO NOT dry the coverlet using the “heat” cycle. Air dry, or use a “non-heat” dry cycle, e.g., air fluff.

5.2.2 Washing Alternative

If there are no visible signs of body fluids and/or substances present, the coverlet can be sanitized between patients. To sanitize the coverlet:

1. Apply chlorine bleach, or an intermediate level disinfectant at the appropriate dilution (See **Section 5.2.1**) to the upper surface of the coverlet. Bleach/disinfectant may be applied either by spraying or by hand application.
2. Ensure surface is completely covered with the bleach/disinfectant.
3. Allow bleach/disinfectant to remain in contact with the surface according to the manufacturer’s instructions.
4. Remove bleach/disinfectant and rinse.
5. Allow to air dry before use.

5.3 Outside Shell:

Wipe down with disinfectant, ensuring that all surfaces come in contact with the disinfectant. Rinse off with a clean damp cloth and allow to air dry.

5.4 Air Cell Assembly:

CAUTION! DO NOT machine wash or dry the air cells.

If the air cell assembly is *visibly* soiled, or if there is an odor, clean by wiping with a disinfectant, prior to use.

6.0 TROUBLESHOOTING GUIDE –

Problem	Cause	Solution
1. Alarm light is on.	The alarm is triggered when a cell(s) fails to reach its programmed pressure after three consecutive cycles. This is usually an indication of an air leak somewhere in the system.	<ul style="list-style-type: none"> a) Be sure the CPR connection is in the “closed” position. b) Be sure all hoses are properly connected to the controller. c) Check all hoses along the inside of the mattress. Each hose should be tightly connected. d) Check each air cell to ensure there are no leaks (It will be easier to detect a possible leak if you place the system at the <u>highest</u> pressure by moving the slide controller to the highest weight setting). e) Once the leak has been resolved, the alarm light will automatically turn off after three cycles. To reset the system more quickly, turn the power off and then on again to reset.
2. Patient is sinking or bottoming out and the alarm light is not on.	Although some sinking is normal for an air mattress, the pressure may be set too low for that patient’s weight distribution.	<ul style="list-style-type: none"> a) Increase pressure. An increase to the next weight setting is usually sufficient. b) Wait at least one full cycle before determining if the pressure increase is adequate.
3. Controller is inoperable.	<p>May be caused by a power surge substantial enough to overload the internal circuitry.</p> <p>Or</p> <p>May be caused by internal damage.</p>	Call Tridien at 800-474-4225 or 954-340-0500 .

7.0 PRODUCT SPECIFICATIONS –

Product Specifications for your PRIMARY CARE system are presented below:

Electronic Controller –

Physical Dimensions:

Height (Inches)	8
Width (Inches)	8 (9, including air ports)
Depth (Inches)	4
Weight (Pounds)	6

Electrical Specifications:

US and Canada:

UL2601 Classification

Class II



Type B



Power Requirements
External Fuse
Maximum Current
Ground

120VAC, 60Hz
2A 250V, Fast Acting (*UL-Approved*)
< 0.5A
Earth

Operating Parameters:

Weight Range (Pounds) 80-280

Environmental Conditions:

Operating Conditions:

Ambient Temperature (°C)	+10 to +40
Relative Humidity (%)	30 to 75
Atmospheric Pressure (hPa)	700 to 1060

Storage/Shipping Conditions:

Ambient Temperature (°C)	-20 to +70
Relative Humidity (%)	10 to 100
Atmospheric Pressure (hPa)	500 to 1060

Mattress Replacement (Fully-Inflated) –

Physical Dimensions

Height (Inches)	7 (Replacement) 5.5 (Overlay)
Width (Inches)	36
Length (Inches)	80
Weight (Pounds)	22

8.0 WARRANTY INFORMATION –

LIMITED WARRANTY

Tridien Medical (“Tridien”) warrants each of its products to perform in accordance with established specifications for the following time periods, starting from date the product was shipped from the Tridien facility.

Stage IV & Millennium Systems

Compressor Pump: 3 Years

Electronic Controller: 2 Years

Soft Goods: 1 Year

Primary Care, Sentry, Express & Air Chair Systems

Compressor Pump: 2 Years

Electronic Controller: 1 Year

Soft Goods: 1 Year

Battery: 6 Months

Recliner Chair: 2 Years

During the warranty period, Tridien will repair or replace at no charge any products that are not performing in accordance with established specifications, unless the problem/failure is due to (1) customer damage, negligence and/or misuse or (2) unauthorized repairs. Items not covered under warranty include, but are not limited to: stains, punctures, cuts, damages to electrical cords, rips or tears, dents and/or lost/missing parts.

All products returned for warranty repairs must be assigned a return authorization number, prior to return. Returns should include Information describing the problem and/or requested repair and be sent to Tridien by prepaid transportation. Tridien will return the repaired/replaced product at no charge. Warranty repairs do not extend the length of the warranty period. During the warranty period, Tridien will provide one Bio-Med test at no charge, excluding shipping/handling.

Neither Tridien, its officers, directors, employees or agents shall be liable for consequential or other damages, including but not limited to personal injury, loss, or any other expense, directly or indirectly arising from the use of its products. The sole remedy for breach of the limited warranty granted herein shall be repair or replacement of the Tridien products.

All product specifications are subject to change without notice.

9.0 PRODUCT RETURNS –

The PRIMARY CARE system has been designed to provide you with years of trouble-free service. However, in the event that the product needs to be returned for any reason, such as calibration, upgrades, testing or repair, the following return procedure must be followed. Failure to follow this procedure may result in unnecessary delays.

Return Procedure -

Before returning a product to Tridien:

1. Contact Customer Service at **800-474-4225** or **954-340-0500** and obtain a **Return Material Authorization (RMA)** number.
2. Package the product in its *approved* packaging.

IMPORTANT! Failure to use the *approved* packaging when returning a product may result in shipping damage and could void the warranty.

3. Reference the assigned RMA number on the shipping documents and send to the following address:

Tridien Medical
4200 NW 12th Avenue
Coral Springs, FL 33065
Attention: Customer Service / RMA <Number>

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Tridien Medical
4200 NW 120th Avenue
Coral Springs, FL 33065

Phone: 954-340-0500
FAX: 954-340-0511
Web Site: tridien.com

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Tridien Medical
Coral Springs, FL