GAYMAR®

O_2Zoned®

MULTI-FUNCTIONAL PORTABLE ROTATION SYSTEM

- **P4000**
- **P4001**
- **C4000 Series Control Unit**
- **M4000 Series Mattress**

Operator's Manual

P/N 100372000 Rev B 10/10

Table Of Contents

Section	Description	Page
1.0	Warranty ……	2
2.0	Symbols ……	3
3.0	Indications for Use, Contraindications, Safety Precautions ……	3
4.0	Description ……	4
5.0	Features ……	5
6.0	Setting Up the System ……	5
7.0	Instructions for Use ……	6
8.0	Transferring Patients In and out of Bed ……	8
9.0	CPR (Cardio Pulmonary Resuscitation) ……	8
10.0	System Cleaning and Care ……	9
11.0	Troubleshooting ……	10
12.0	Specifications, Control Unit ……	11

Before you begin…

⚠ Important

Before using the P4000/P4001 O_2Zoned® System, please read and understand this manual and all safety precautions prior to each application.

1.0 Warranty

The control unit is warranted free of defects in material and workmanship for a period of one (1) year.

The mattress is warranted free of defects in material and workmanship for a period of one (1) year.

The control unit and mattress are warranted under the terms and conditions of the Gaymar warranty in place at the time of purchase. A copy of the warranty is available upon request. Gaymar disclaims all implied warranties including, but not limited to, the implied warranties of merchantability and of fitness for a particular purpose.

Control units may be returned to the factory for servicing. Contact Gaymar Customer Service for return authorization prior to return.

Please contact Gaymar Customer Service if you have warranty questions.

Direct (716) 662-2551 Option 1

Toll Free (800) 828-7341

Fax (800) 993-7890

2.0 Symbols

 Attention, consult accompanying documents

 Type BF equipment

 Protective earth

 Dangerous voltage

3.0 Indications for Use

This device is intended to assist in the treatment and prevention of pressure ulcers (bed sores) by providing air support therapy.

3.1 Contraindications

Air support therapy is contraindicated when spinal stability is a concern, or when patient is in traction.

3.2 Safety Precautions

Review the following SAFETY PRECAUTIONS prior to using the P4000 or P4001 O_2Zoned System.

DANGER
• Risk of electric shock. Refer servicing to qualified service personnel. • Do not rotate patients with unstable fractures, patients with acute spinal cord injuries, or those in skeletal traction.

WARNING
• Disinfect the O_2Zoned system between patient installations. Failure to disinfect may risk cross-contamination and infection. • Check mattress at least every 2 hours to assure proper patient position and system inflation. Failure to center patient may result in improper therapy or patient injury. • Care should be taken not to extubate intubated patients on rotational therapy.

CAUTION

- Some medical conditions may not respond to therapy of this type. Patient's skin condition should be inspected regularly. Consult physician if any redness or skin break occurs.
- For grounding reliability, plug only into a properly grounded outlet.
- Make certain all mattress straps are secured to the bed frame to prevent mattress from sliding and causing patient injury.
- The O_2Zoned mattress is not intended to be AND DOES NOT FUNCTION AS a patient fall safety device. SIDE RAILS MUST BE USED WITH THE O_2ZONED MATTRESS TO PREVENT FALLS unless determined unnecessary based on the facility protocol or the patient's medical needs as determined by the facility, IN WHICH CASE THE USE OF OTHER SUITABLE PATIENT SAFETY MEASURES ARE RECOMMENDED.
- When rotating patient, keep bed in horizontal position or reduced therapy may result.
- Use minimal layers of sheeting and incontinence pads. Too many layers between the patient's skin and the support surface will reduce the pressure relieving capabilities of the system.
- Do not pull linens tightly over mattress. Tight sheets can cause "hammocking" and reduce effectiveness of therapy.
- Do not block air intake on control unit.
- Stabilize and secure all tubes before starting rotation to prevent restrictions or breakage. Monitor tube usage regularly.
- Verify mattress is appropriate for bed frame size to avoid entrapment.
- U.S. Federal law restricts this device to sale by or on the order of a physician.

4.0 Description

The P4000 or P4001 is a portable low-air-loss rotation mattress system designed to assist in providing therapeutic benefit to patients suffering from, or at risk of, developing pressure ulcers. The system is unique in that it can provide on-demand alternating low pressure therapy and patient rotation. The system, consisting of a Control Unit (C4000), a therapeutic air mattress (M4000 or M4001) and a top sheet, is designed to assist in providing wound care therapy and patient comfort.

The mattress base consists of twenty transverse air cushions and two turning bladders. Each of the individual cushions is a minimum of eight inches tall (inflated height) and spatially oriented above a two inch convoluted foam base. Its low-shear nylon construction aids in reducing the chance of skin breakdown. The air cushions each have a series of orifices to provide continuous low-air-loss therapy to aid in the prevention of skin maceration.

Covering the entire mattress assembly is a low-friction, low-shear, vapor permeable top sheet. The top sheet surface creates a membrane impermeable to liquids, though still permeable to water vapor.

Quilted onto the base of the top sheet is a spun bonded polyester fiberfill that exhibits less frictional resistance to nylon than that of the patient's skin. When the patient moves, the top sheet tends to move relative to the air cushions rather than relative to the patient. Additionally the quilting acts to provide a diffusion layer by which the water vapor can be drawn away from the patient, resulting in more efficient evaporation and subsequent reduced skin maceration.

The control unit automatically inflates and maintains the mattress at the optimal fill level based on the user-selected patient weight. If the mattress is perceived to be too hard or too soft, fine adjustments can be made through the control panel. The control unit also allows for adjustment of rotation angle and position time.

5.0 Features

5.1 C4000 Control Unit

- Rotation angles independently selectable as 0, 1/3, 2/3, and FULL
- Rotation hold/dwell times adjustable from zero to 95 minutes
- The most recently entered settings retained when power is removed
- Rotate pause function
- Unique cradle feature helps stabilize and re-position the patient in center of mattress
- Alternating low pressure therapy (Pulse) helps maximize pressure redistribution for optimum capillary blood flow
- Max Inflate facilitates rapid firming of the mattress for nursing procedures
- Soft/Firm Comfort Control allows caregiver to optimize therapy
- Keypad may be locked to prevent interruption of therapy
- CPR quick release provides for rapid deflation
- Sleek and durable high impact polymer housing is extremely compact and lightweight
- Bedside bracket for easy placement on the foot board of bed
- Illuminated LED control panel for easy viewing
- Double-isolating mounting for quiet operation

5.2 M4000/M4001 Low-Air-Loss Mattress

- Horizontal, tubular cell construction.
- Individual air cushions designed for maximum support area and pressure redistribution.
- Orificed air cushions providing true low-air-loss therapy.
- Optional contour cushions facilitate patient centering and leg abduction. (Contour cushions are standard on M4000 mattress.)
- Low friction, low shear top sheet.
- Dimensions -base model - 80" x 34" x 10" when fully inflated.

6.0 Setting Up the System

1. Place the M4000/M4001 mattress on the bed frame with the connecting hose at the foot of the bed.
2. Before securing the mattress straps, raise the head and foot ends of the bed frame. Raise the side rails. Loosely, secure mattress to bed frame by looping the nylon straps on mattress through the bed frame and then back through the D-rings on mattress. Make sure the side rails can still move up and down without interference.
3. Lower frame to its horizontal position and tighten straps.
4. Cover the M4000/M4001 mattress with the therapeutic, low-shear top sheet and attach to the mattress by looping the Velcro straps through the D-rings on the mattress. Verify top sheet is loosely fit so as not to “hammock” patient above mattress.
5. Suspend C4000 control unit on footboard of bed using the two hooks located on back of unit, or place it on the floor.

6. Connect the metal quick-connect coupling on the mattress supply hose to the mating connector located on the side of the pump. The bayonet style coupling is attached by pushing the connector straight into the control unit about one quarter of an inch, and then rotating the connector slightly clockwise until an audible click is heard. Note: The connector is “keyed” with pins and slots. Rotate coupling until the three pins on the control unit line up with the three slots on the coupling.
7. Check that the hose is secure by gently pulling. Ensure the air hoses are not kinked or tucked under the mattress.

7.0 Instructions for use

Control panel symbols:

On/Standby

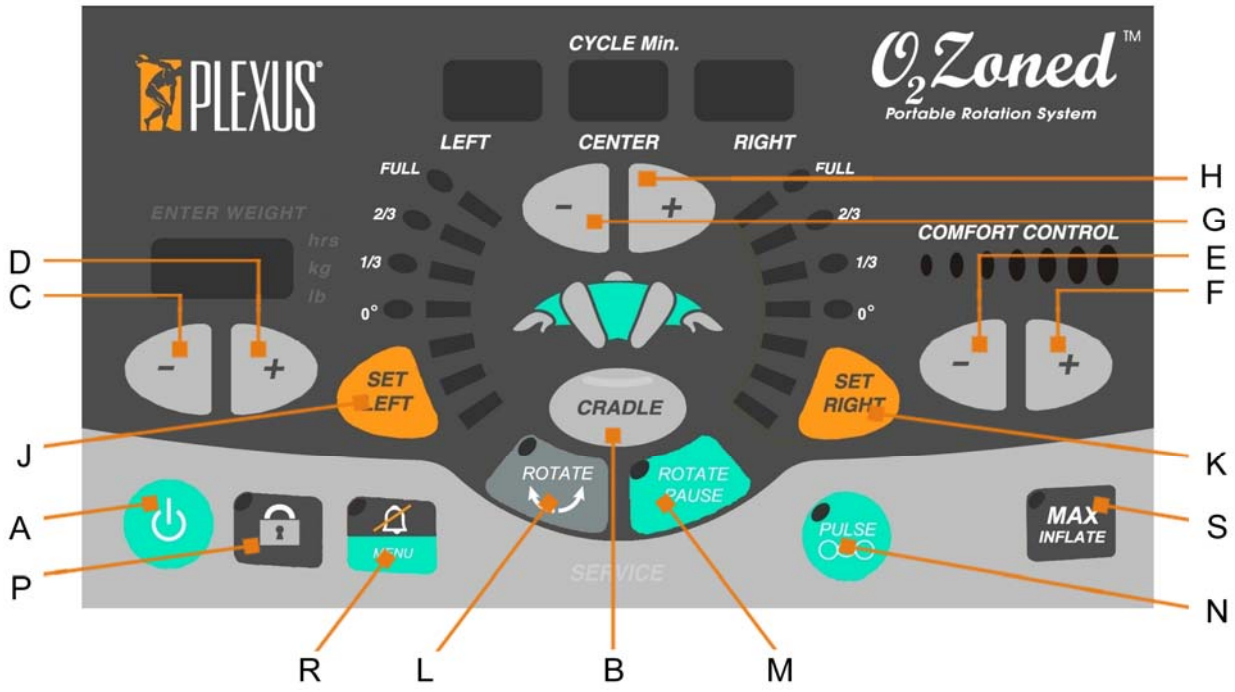
Lock Settings

Alarm Silence

Rotate

Alternating cell therapy (Pulse)

1. Plug AC power cord into properly grounded outlet. Unit will perform a series of self-tests. Upon successful completion of self-test, the unit will enter “STANDBY” mode.
2. To begin normal operation, press the ON/STANDBY button, **A**, on the bottom left of the control panel. Maximum air flow will be delivered to the mattress for approximately 1 minute to quickly inflate.



Operator Control Panel

3. Apply hospital linens and/or incontinence pad over the top of the mattress. Linens should be loose to prevent "hammocking".
4. The unit will prompt for patient weight setting by flashing "ENTER WEIGHT".

   There are two distinct weight ranges: Normal 40 – 350 lbs (18 – 159kg) and **Bariatric** 200 – 700 lbs (91 – 318kg). To toggle between these two weight ranges, place unit in STANDBY mode, then, simultaneously press the "CRADLE" button, **B**, and "ON/STANDBY", **A**, buttons.

   Weight can be displayed in either unit lbs or kg. To toggle between lbs and kg., press the "–", **C**, and "+", **D** buttons simultaneously for approximately 3 seconds.

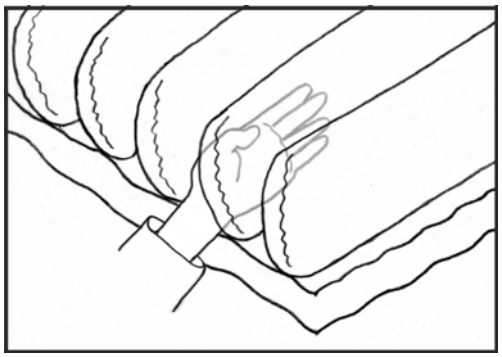
   To enter the patient's weight, select appropriate weight range and units. Press the "–", **C**, and "+", **D** buttons under the weight indicator until the patient's weight is indicated in the window.
5. Place patient on mattress and position along centerline of mattress. Raise the bed side rails.
6. Optimal mattress pressure is determined based on patient weight and the hand check.

   NOTE: Perform a hand check every 8 hours to ensure that the mattress is properly inflated.

   To perform a **hand check:**

   Loosen bed linens and mattress cover as necessary to access the air cells.

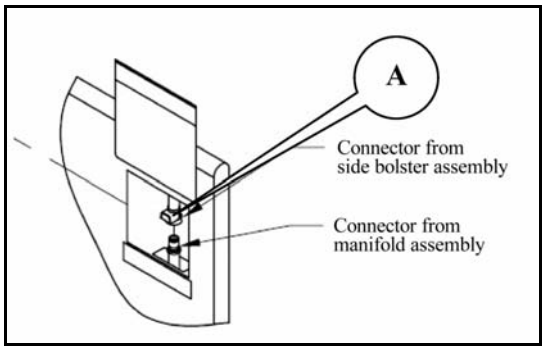
   Using a vertical hand, slide hand between the air cells directly underneath the patient's sacral area. Slide hand under the patient. If four fingers of clearance exist, no adjustment is needed.

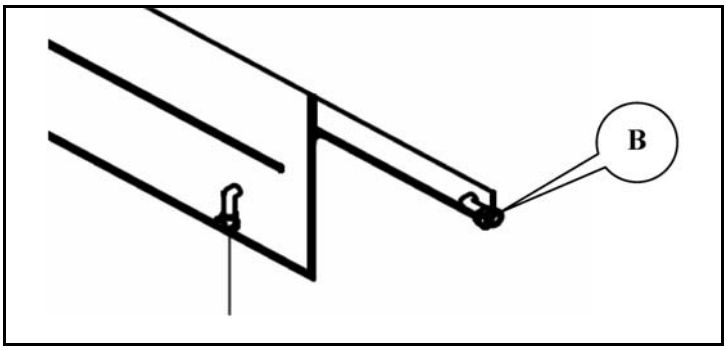


   If you can feel the patient's body resting on your hand, adjust the pressure control to a higher setting. Wait 10 minutes and repeat the hand check. If the hand check fails, check that the hoses are not kinked or pinched. If repeated hand check fails and hoses are not kinked, contact Dealer or Gaymar for further instruction.

   To make mattress firmer or softer, adjust pressure by pressing the "–", **E** or "+", **F** buttons under the "COMFORT CONTROL" bar graph.
7. The rotational therapy cycle has three dwell time periods and each can be controlled separately. During rotation the mattress will stop after rotating the patient to the left, after centering the patient and again after rotating to the right.
8. First select the cycle time (0 – 95 minutes) for the supine position by pressing the "–", **G** or "+", **H**. buttons under "CYCLE MIN" display. Next, select the angle of rotation for both the left and right sides. Press "SET LEFT", **J,** to increase angle of rotation on left side (as viewed from foot end). Press "SET RIGHT", **K**, to increase angle of rotation on right side. After pressing the "SET LEFT" or "SET RIGHT" buttons, the corresponding "CYCLE" time will flash for 4 seconds. Select the appropriate cycle time for each side by pressing the "–", **G**, or "+", **H** buttons.

9. To initiate rotation mode, press the “ROTATE” button, **L**. To pause the rotation cycle at any point, press the “ROTATE PAUSE” button, **M**. If “ROTATE PAUSE” has been initiated, the button will need to be pressed again to continue rotation.
10. The “PULSE” mode alternately increases and decreases the pressure in consecutive cells within the mattress. To begin, press the “PULSE” button, **N**.
    Note: PULSE mode can be used concurrently with ROTATE mode.
    While in rotation mode the pulse mode alternates the pressure of 10 of the 20 surface cells during the first half of the rotation cycle and the other 10 cells during the second half of the rotation cycle.
11. The “CRADLE” button, **B**, returns patient to supine position and reduces mattress pressure to aid in positioning patient along centerline of mattress.
12. To prevent accidental changes in settings, press and hold the “LOCKOUT” button, **P**, for 3 (three) seconds.
13. To silence audible alarm for 15 minutes, press the “ALARM SILENCE” button, **R**.
14. Menu options are explained in the Service Manual.
15. The mattress can be operated without side bolsters. To disable side bolsters, open the access panel at the foot of the bed. Disconnect the side bolster A, and cap the port with the included plug B (attached to the side bolser). See drawing below.





8.0 Transferring patients in and out of bed

1. For patient transfer press the “MAX INFLATE” button, **S**. This mode will return the patient to the supine position and maximally inflate the mattress to provide a firm and stable support surface. Pressing the MAX INFLATE button again will cancel this mode and return the mattress to previously chosen settings.
2. While in the MAX INFLATE mode, the unit will chime an alarm every minute to remind the caregiver that the mattress is in this state. After approximately 30 minutes, the system is programmed to automatically cancel the MAX INFLATE and return to the previously chosen settings.
   NOTE: After automatically returning to the therapeutic mode, the “MAX INFLATE” button, **S**, must be pushed twice to return to the “MAX INFLATE” condition. This action resets the automatic timer.

9.0 CPR (Cardio Pulmonary Resuscitation)

To deflate mattress for CPR:

1. Twist metal quick-connect hose coupling counter-clockwise at control unit and detach from control unit.
2. Begin CPR procedures.

10.0 System Cleaning and Care

10.1 Cleaning

WARNING

Disconnect the C4000 AC power cord from the wall outlet before attempting to clean the Control Unit. Do not heat or steam autoclave any component of the system. Do not submerge controller in water.

1. To clean, use mild soap and water and a clean cloth to wipe down the control unit, power cord, hoses and mattress. Do not use abrasive cleaners on the mattress. Wipe dry with a clean, dry cloth.
   Note: Blood and other body fluids must be thoroughly cleaned from all surfaces before applying disinfectants.
2. Apply an FDA approved disinfectant to the external surfaces of the control unit, hoses and mattress. Allow to completely dry. The solution contact time is what makes disinfection effective.
3. Wipe down the mattress with a clean, dry cloth to remove any excess disinfectant.
4. Top sheets may also be laundered between patient uses or as required to maintain good patient hygiene. Place no more than four top sheets in a single extra large load capacity washing machine. Fill the washing machine with warm water (70 -140 °F). Add one cup of laundry detergent. Run machine for a full cycle. Leave sheets in washer and run a second cycle adding only 10 ounces of bleach.
   When wash cycle is complete, remove promptly from machine and ensure all excess water is drained from load. Place dryer on LOWEST heat setting, or AIR FLUFF if available until dry. Verify top sheet is completely dry before placing under patient.
5. If individual air cushions become soiled, clean and disinfect the entire mattress.
   Note: Single air cell replacement can be successfully achieved with patient remaining on the mattress.

10.2 Filter Maintenance

Visually inspect the air filter for dirt or debris every 30 days. The filter is located on the back side of the Control Unit, inside the carry handle indent. To inspect, unscrew the finger bolt and remove retaining plate. Extract filter media and wash with mild soap and water. Air dry. Make certain the filter is completely dry before re-installing. A brittle or damaged filter must be replaced.

10.3 Preventive Maintenance

Preventive maintenance and service procedures are described in the O_2Zoned *Service Manual*. These procedures should be performed by qualified medical equipment service personnel.

10.4 Storage

10.4.1 C4000 Control Unit

1. Check the AC power cord and plug for abrasions or excessive wear.
2. Coil power cord up and place both cord and Control Unit in plastic bag for storage.

10.4.2 M4000/M4001 Low-Air-Loss Mattress

1. Check the air manifolds for kinks or breaks. Replace if necessary.
2. To deflate support surface of mattress, disconnect hose assembly from Control Unit. To deflate side bolsters, locate two small flaps, one on inside of each side bolster, near the foot end of the bed. Lift flap to expose fill valve (red). Disconnect two halves to deflate. When all air is expelled, reconnect and close flap.
3. Coil the hose loosely and roll the deflated air mattress starting at the head end. Use the base mounted straps for containment.
4. Place in plastic bag for storage.

11.0 Troubleshooting

Symptom:	**Corrective Action**
Mattress does not inflate or is too soft.	Make certain the air hoses are not kinked, cracked, or split. Verify the hose coupling is fully engaged to controller. Verify that all 20 air cushions are connected to the air manifold. Inspect and/or clean intake air filter.
Loss of power	Make certain the power receptacle has power, unit is plugged in and the On/Standby light is illuminated.
Service light illuminates	If light illuminates during power-up self tests, check to make sure hose coupling is fully engaged to controller. If light illuminates during normal operation, remove unit from use and refer for service.

12.0 Specifications, Control Unit

Specification	C4000
Enclosure Dimensions	10" x 12" x 6.25” (25 cm x 30 cm x 16 cm)
Weight	17 pounds (7.7 kg)
Power Cord	Detachable 14’ minimum, #18 AWG with ground wire
Overcurrent Protection	Primary Two 5 x 20 mm fuses 5A, 250V, T, L
	Secondary Two 5 x 20 mm fuses 2A, 250V, F, L
Input	115 VAC, 50/60Hz, 5A
Operating Ambient Temperature Range	60 to 85°F (15.6 to 29.4°C)
Classification	Class I grounded equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
	Type BF equipment 
	MEDICAL EQUIPMENT, classified with respect to electric shock, fire and mechanical hazards only, in accordance with UL 2601-1, CAN/CSA C22.2 NO.601.1
	IPX0, enclosed equipment without protection against ingress of water.
	Continuous operation
Electromagnetic Compatibility	Meets EN60601-1-2:2001 (CISPR 11 Classified as Class A, Group 1 ISM equipment)

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