

# **Clini-Dyne<sup>®</sup>** **Rotational Therapy System**

- **CLP2000 Control Unit**
- **CLM series Mattress**



**GAYMAR INDUSTRIES, INC.**

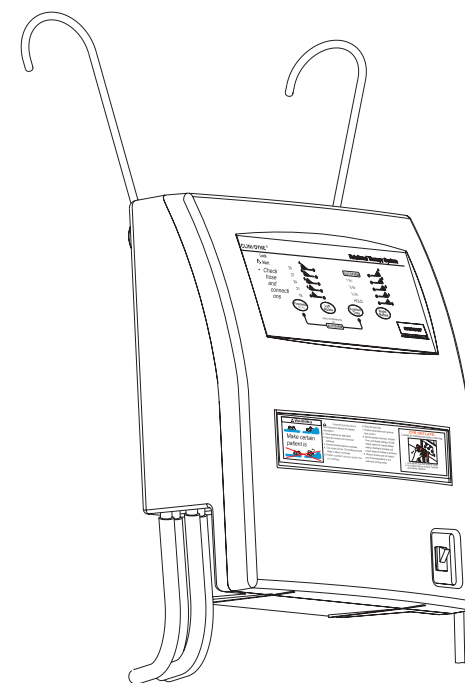
10 Centre Drive  
Orchard Park, NY 14127-2295 USA

Phone:  
1 800 828-7341  
(716) 662-2551

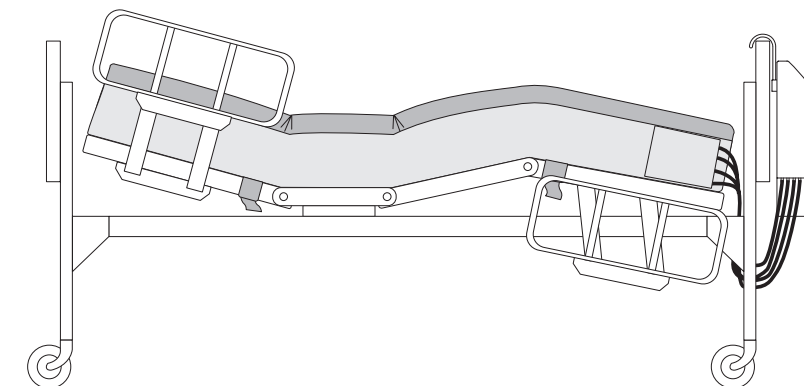
Fax:  
1 800 993-7890  
(716) 662-0748

[www.gaymar.com](http://www.gaymar.com)

CLINI-DYNE<sup>®</sup> PRODUCTS ARE  
MADE IN THE USA



**CLP2000 Control Unit**



**Clini-Dyne System**



LISTED  
UL 2601-1



LISTED CAN/CSA  
C22.2 NO. 601.1

**Operator's Manual**

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**Important**

Use the Clini-Dyne Rotational Therapy System only under the direction of a physician.

Before using the Clini-Dyne System, please read and understand this Operator's Manual and the SAFETY PRECAUTIONS in section 1.2 prior to each application.

Only qualified medical service personnel should repair the Clini-Dyne Control Unit. A Clini-Dyne Service Manual is available from Gaymar for use by qualified personnel.

**Receiving Inspection**

Refer to the Clini-Dyne Service Manual for receiving inspection and checkout procedures.

In the event of any questions, contact Gaymar's Technical Service Department for assistance.

**Telephone:**

**Toll free 1 800 828-7341**

**Direct (716) 662-2551**

**Fax:**

**Toll free 1 800 993-7890**

**Direct (716) 662-0748**

**SYMBOLS USED**



Attention: consult accompanying documents.

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**1.0 Indications for Use**

This device is intended to assist in prevention and treatment of decubitus ulcers (bed sores).

**1.1 Contraindications**

Air support therapy is not recommended when spinal stability is a concern.

**1.2 Safety Precautions**

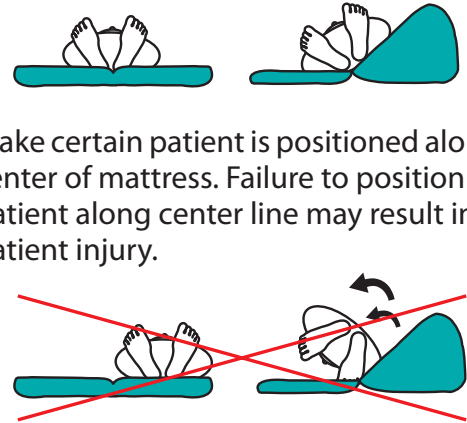
Review the following SAFETY PRECAUTIONS prior to using the Clini-Dyne System.

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**⚠ DANGER**

- Do not operate the system in the presence of flammable anesthetics. Risk of explosion may occur.
- Risk of electric shock. Refer servicing to qualified service personnel.
- Do not rotate patients with unstable fractures, patients with spinal cord injuries, or those in skeletal traction. Death or serious injury may result.
- Use of kinetic bed systems for stroke victims should be used only under physician's order. An increased mortality rate has been reported in a 1988 "Journal of Critical Care" article when compared with patients placed on conventional ICU beds and turned manually every two hours by nursing staff.

**⚠ WARNING**



Make certain patient is positioned along center of mattress. Failure to position patient along center line may result in patient injury.

**⚠ WARNING**

- Disinfect the Clini-Dyne System between patient installations. Failure to disinfect may risk cross-contamination and infection.
- Check patient at least every 8 hours or once per shift to assure proper patient position and correct system inflation. Failure to position patient along center may result in patient injury.
- Stabilize and secure all patient lines and tubing before starting rotation to prevent tugging, removal, or breakage. Monitor lines and tubing regularly.
- Care should be taken not to extubate intubated patients on rotational therapy.
- Deflate mattress before performing CPR or CPR will be ineffective.

*(continued on next page)*



**CAUTION**

- **U. S. Federal law restricts this device to sale by or on the order of a physician.**
- 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.
- Use the Clini-Dyne Mattress only with the two mattress straps secured to the bed frame to prevent the mattress from sliding and causing patient injury.
- Raise bed side rails before initiating therapy to prevent possible injury to the patient.
- Use minimal layers of sheeting and incontinence pads. Too many layers between the patient's skin and the Clini-Dyne Mattress will reduce the pressure-relieving capabilities of the therapy system.
- Do not pull linens tightly over the mattress, but leave loose. Tight sheets may cause "hammocking" and reduce effectiveness of therapy in the supine position.
- For grounding reliability, plug only into a grounded outlet labeled "Hospital Grade."
- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying EMC information sheet P/N 11549-000.
- Portable and mobile RF communications equipment can effect Medical Electrical Equipment.

**CAUTION**

- The CLP2000 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the CLP2000 should be observed to verify normal operation in the configuration in which it will be used.

**12.0 Specifications, Control Unit**

Enclosure Dimensions	13 1/8" H x 12 1/8" W x 4 1/2" L (33 cm x 31 cm x 10 cm)
Weight	16 pounds (7.3 Kg)
Power Cord	15 ft, 16 AWG cord with hospital grade plug
Overcurrent protection	2 fuses, 0.3A, Type 3AG, fast acting, 250VAC
Input	120VAC (+5, -10%), 60Hz, 1/4A, 20W, 30VA
Operating Ambient Temperature Range	60°F to 90°F (16°C to 32°C) Note: If the Clini-Dyne Control Unit is stored at temperatures below 60°F or above 90°F, the control unit must be allowed to <u>stabilize for one hour</u> within the ambient temperature range before use.
Output Pressure (Firmness Settings)	18 to 30 mmHg
Output Flow Rate	0.4 SCFM (12.5 lpm) minimum @ 30 mmHg
Current Leakage	100uA maximum
Classification	Class II, double insulated equipment with functional earth ground 
	Type BF equipment 
	Continuous operation
	Not classified for protection against harmful ingress of liquid
	MEDICAL EQUIPMENT, classified with respect to electric shock, fire, mechanical hazards only, in accordance with UL2601-1, CAN/CSA C22.2 NO. 601.1
Electromagnetic Compatibility (EMC)	Meets EN60601-1-2:2000. Refer to accompanying EMC information sheet P/N 11549-000

4. **NOTE: Mattress cover must be dry prior to storage or application of linens. Failure to remove excess disinfectant could eventually degrade the polyurethane coating of the mattress cover.**
5. To protect the integrity of the mattress and for infection control reasons, do not puncture the mattress cover with needles, pins, etc.
6. If the integrity of the cover has been compromised, the mattress may be contaminated. Consult with your Infection Control Specialist and follow your hospital protocol for this specific situation. For reference purposes, the Center for Disease control recommends, "Keep mattresses dry; discard them if they remain wet or stained, particularly in burn units" (Guidelines for Environmental Infection Control in Health Care Facilities, Section VII A. This is available on the CDC website at [www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a.htm)).

### 10.0 Troubleshooting

Symptom	Corrective Action
Alert light or audible alarm is on.	Check for disconnected or kinked hoses, cut or punctured mattress cells. Replace defective mattress or control unit.
Control unit does not operate when power switch is in the ON position.	Make sure the power cord is plugged into a live outlet. Remove the unit from service. Contact Gaymar's Technical Service Department.
Mattress is flat.	Check for disconnected or kinked hoses, cut or punctured mattress cells. Replace defective mattress or control unit.

### 11.0 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

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**  
**Toll free: 1 800 828-7341**

### 2.0 Description

This manual describes the operation of the Clini-Dyne System used to assist in the treatment of complications associated with immobility and the prevention of decubitus or pressure ulcers. The replacement mattress provides pressure redistribution and patient rotation.

The **Clini-Dyne System** consists of:

- **a control unit** (CLP2000)
- **a mattress replacement** (CLM series)

### 3.0 System Components

Before attempting to operate the Clini-Dyne System, please familiarize yourself with the following system components:

#### 3.1 The Control Unit (CLP2000)

The control unit circulates air through a mattress, maintaining cushion pressure at a level selected by the operator.

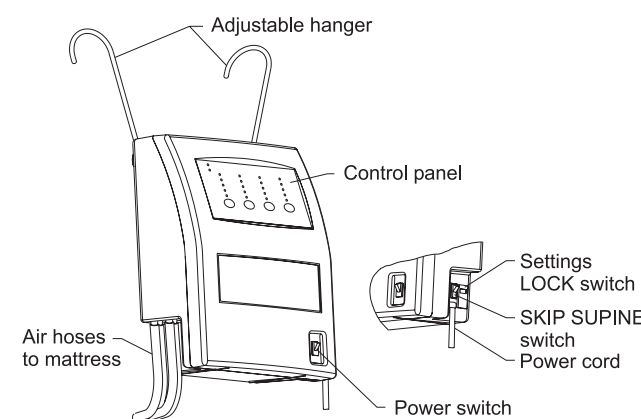


Figure 1—Control Unit

The control unit is equipped with adjustable hangers for hanging the unit on the bed. The control unit is operated from a front control panel.

A power switch is located on the front of the unit. A SKIP SUPINE switch and settings LOCK switch are located on the right side panel of the unit.

The air hoses are permanently attached to the control unit and connect to the manifold panel on the mattress.

#### 3.2 The Mattress (CLM1080, CLM1084, CLM2080)

The CLM series mattress consists of four turning cells, two hip cells, and an underlay. It is controlled by a CLP2000 pump. The top two cells have small holes in the upper surface allowing air flow to help reduce the potential for skin maceration.

There are straps on the cover to secure the mattress to the bed frame.

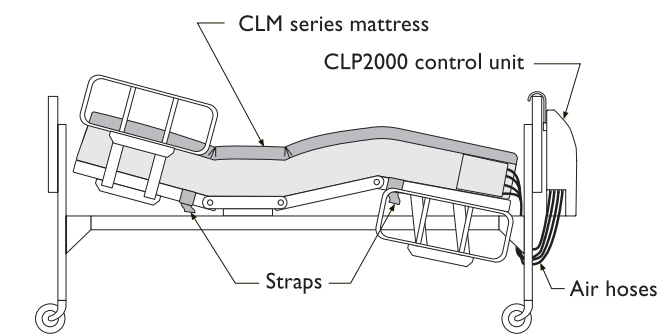


Figure 2—Clini-Dyne System

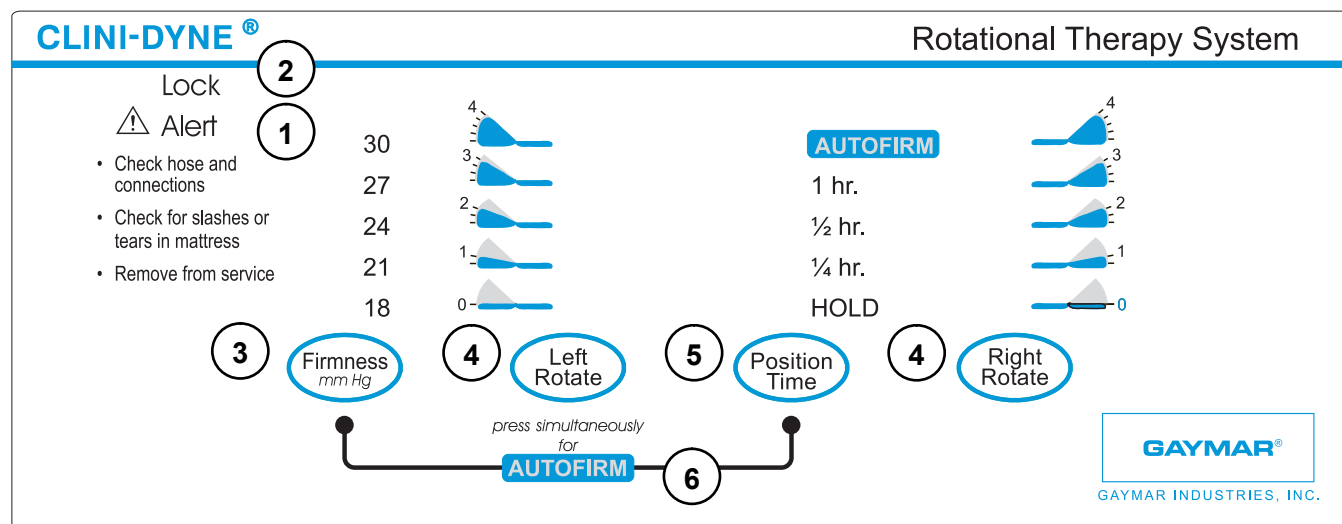


Figure 3—Operator Control Panel

#### 4.0 Operator Control Panel (figure 3)

- Alert**—Indicator flashes and audible alarm sounds if the mattress pressure varies  $\pm 2.5$  mm Hg for a period longer than 10 minutes. To silence alarm, turn unit off and on.
- Lock**—(located on side of unit, see figure 1) Momentarily pressing the LOCK switch locks all settings -- the setting buttons are rendered inactive. The LOCK indicator on the front panel will light when the settings are locked. Pressing the LOCK switch when the LOCK indicator light is lit will unlock the settings. The settings will also become unlocked if the unit is turned off or if a power failure occurs.
- Firmness**—Pressing the FIRMNESS button toggles the mattress comfort setting through a range of five positions, from soft (18 mm Hg) to firm (30 mm Hg).
- Left Rotate / Right Rotate**—Pressing either button sets angle of patient rotation to one of five different settings, including NO ROTATION. Each side is set independently. An indicator light indicates the rotation setting for each side.

Setting both a LEFT ROTATE and a RIGHT ROTATE results in full rotational therapy, from right to supine to left and then back. The optional supine position may be bypassed by engaging the SKIP SUPINE switch (located on the side of the unit (see fig. 1).

- Position Time**—Pressing the POSITION TIME button sets the time interval that the mattress will remain in each position. Selecting either of three time intervals—1/4 hr, 1/2 hr, or 1 hr—applies the same interval to all three positions (left, right, and supine). Selecting the HOLD time interval allows the patient to be manually rotated to either the LEFT ROTATE or the RIGHT ROTATE setting, or allows the patient to remain in the supine position.

If the HOLD mode is used on a rotation setting, the HOLD light will flash for 60 minutes, indicating that a rotation hold has been selected. At the end of the 60 minute period, the mattress will return to the supine position.

#### 8.0 CPR (Cardio Pulmonary Resuscitation)

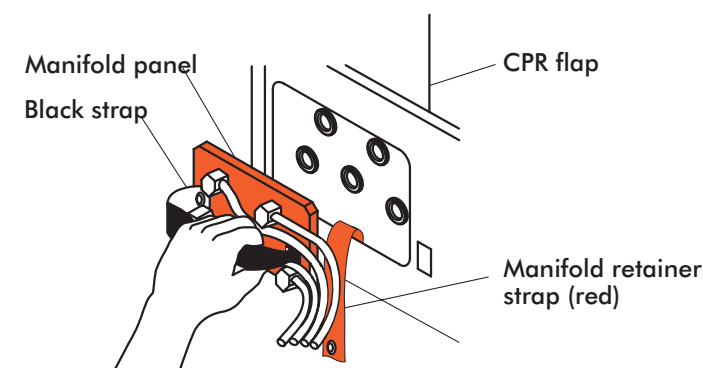


Figure 10—Deflating mattress for CPR

##### CPR DEFLATE

Located on mattress side panel, under flap.

- Unsnap red manifold retainer strap.
- Pull black strap to remove manifold and deflate mattress.

To deflate the mattress for CPR (see figure 10):

- Unsnap the red manifold retainer strap.
- Pull the black strap to remove the manifold panel and deflate the mattress. The mattress will deflate in less than 15 seconds.
- Proceed with CPR procedures.

To resume therapy, reconnect the manifold panel to the mattress:

- Lift the CPR flap on the mattress cover.
- Snap the manifold panel (at the end of the hoses) into position.
- Resecure the manifold panel by passing the red manifold strap over the black strap on the manifold. Snap the red strap onto the mattress connector.

The mattress will reinflate to the previous pressure setting. If the control unit was turned off, it will inflate to the default pressure (18 mm Hg). Follow the OPERATING INSTRUCTIONS (section 7.0, pages 6-8) to reset the FIRMNESS, ROTATE, and POSITION TIME levels.

#### 9.0 System Cleaning and Care

The Clini-Dyne System is very easy to maintain. Perform the following care and cleaning between patient installations to assure proper performance and reliability:

- Unplug control unit prior to cleaning.
- To clean, use soap and water and a clean cloth to wipe down the control unit, power cord, hoses, manifold panel and mattress. Do not use abrasive cleaners on the mattress. Wipe dry with a clean, dry cloth. Do not autoclave.  
NOTE: Blood and other body fluids must be thoroughly cleaned from all surfaces before applying disinfectant.
- Apply a disinfectant such as a 10% chlorinated bleach solution (chlorinated bleach with 5.25% sodium hypochlorite) to the external surfaces of the control unit, hoses, and mattress. Allow to completely dry. The solution contact time is what makes disinfection effective. Wipe down the mattress with a clean, dry cloth to remove any excess disinfectant.

The mattress will immediately begin to rise on that side. The rotation angle level should be reached in about 3 to 4 minutes. If the angle is not sufficient, increase the rotation setting to the next higher setting. Continue this process until the proper angle of rotation is achieved.

To begin full rotational therapy, select the POSITION TIME desired, then enter the level into the RIGHT ROTATE and/or LEFT ROTATE settings. The mattress will begin to provide rotational therapy to that setting.

- If supine position is not desired during full rotation, set the SKIP SUPINE switch (see figure 9) located on the side of the unit. Placing the switch in the upper position skips the supine position when rotating the patient.
- Raising the head of the bed may reduce the angle of rotation

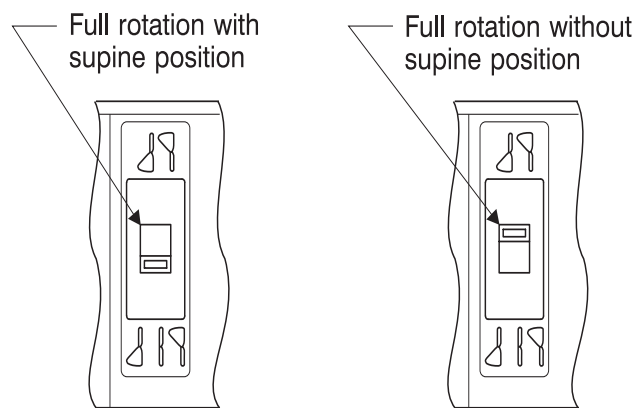


Figure 9—SKIP SUPINE switch

**CAUTION**

Some medical conditions may not respond to therapy of this type. Patient's skin should be inspected regularly. If redness or breaks in the skin occur, consult the attending physician.

11. Lock the control settings (if desired) by pressing the LOCK switch on the side of the unit (see figure 1). Look for the indicator light on the control panel. To unlock the settings and turn off the light, press the switch once when the control unit is in the LOCK mode.

NOTE: If the power switch is turned off, the controls will unlock and all settings will reset to default or zero.

### 7.1 Changing the Bedding

Change the bedding per normal hospital procedure:

1. Linens should be loose to prevent "hammocking."
2. Use minimal layers of sheeting and incontinence pads.

### 7.2 Transferring Patients In and Out of Bed

For patient transfer, select the AUTOFIRM mode. This mode will return the patient to the supine position and inflate the mattress to 40 mm Hg, providing a stable support surface.

**WARNING**

**Deflate mattress before performing CPR or CPR will be ineffective.**

**WARNING**

Check the patient at least every 8 hours or once per shift to assure proper patient position and correct system inflation. Failure to position patient along center may result in patient injury.

## 6.0 Setting Up the System

1. Place the CLM series mattress on the bed frame. It should be placed inside any mattress stops on the bed frame. The foot end symbol on the mattress should be at the foot end of the bed.
2. Refer to figure 4 below. Before securing the mattress straps, raise the head and foot ends of the bed frame. Raise the side rails. Secure the mattress straps only to the movable part of the bed frame. Make sure the side rails can still move up and down without interference.

**CAUTION**

Use the Clini-Dyne Mattress only with both mattress straps secured, to prevent the mattress from sliding and causing patient injury.

- 6 **Autofirm** —Simultaneously pressing the FIRMNESS and POSITION TIME buttons will suspend the current therapy and return the mattress to the supine position. Additionally, the mattress will be inflated to 40 mm Hg to create a stable support surface. If the AUTOFIRM mode is selected, the AUTOFIRM light will flash for 20 minutes, indicating that the mattress is temporarily in the supine position. After 20 minutes, an alarm will sound for approximately 15 seconds to alert the caregiver that the unit is about to restore therapy to the original settings.

The AUTOFIRM timer can be reset to 20 minutes at any time by pressing both the FIRMNESS and POSITION TIME buttons simultaneously. The AUTOFIRM mode can be cancelled at any time by pressing any of the front panel buttons. Doing so will restore the previous therapy settings.

## 5.0 Preparing the Bed

The CLM mattress is designed for use on mattress surfaces which provide firm, solid support. Use otherwise may cause the mattress to be ineffective or sag in the middle.

If the mattress must be placed on a soft surface such as a link spring (spring and wire) bed frame, it is suggested that a set of bed boards be used. Support boards can be obtained from various medical suppliers or they can be made so they fit across the frame rails in the area of the bed (middle) that does not move.

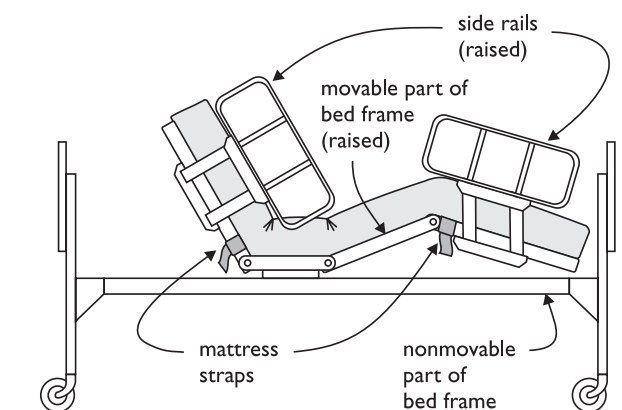


Figure 4—Securing straps to movable part of bed frame

5. Connect the power cord to a properly grounded receptacle.  
NOTE: Keep the power cord out of the way of the bed frame and wheels. Stretch it beneath the bed and connect it to a receptacle at the head of the bed.
6. Connect the manifold panel to the mattress (see figure 5):
  - a. Lift the CPR flap on the mattress cover.
  - b. Snap the manifold panel (at the end of the hoses) into position (fig. 5A).
  - c. Secure the manifold panel by placing the red manifold strap under the black strap and hoses on the manifold panel. Snap the red strap into position (fig. 5B).

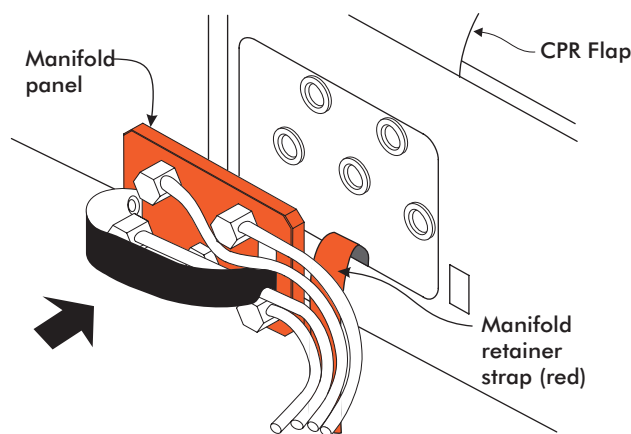


Fig. 5A

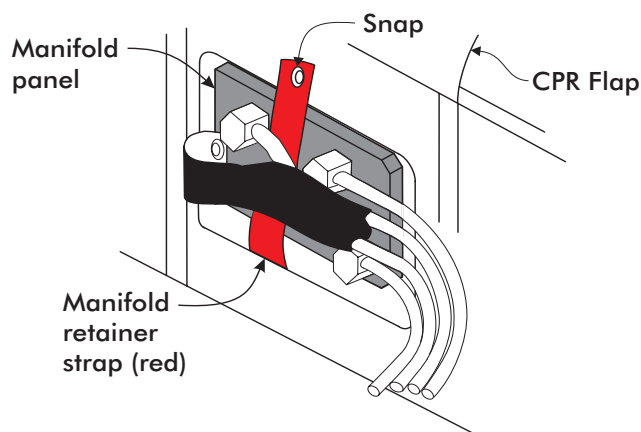


Fig. 5B

Figure 5—Attaching hose panel to mattress connector

## 7.0 Operating Instructions

1. Turn the control unit on. The control unit will initiate a self-test and a short audible chime will sound.  
NOTE: If the control unit fails the self-test, the audible alarm will continuously sound. If this occurs, remove the control unit from service.
2. After the self-test sequence, the control unit will start inflating the mattress. The mattress will inflate in about 15 minutes. The default settings are:  
FIRMNESS—18 mm Hg  
LEFT ROTATE—0  
RIGHT ROTATE—0  
POSITION TIME—HOLD.

3. After the mattress has inflated, place a sheet and incontinence pad (if required) over the top of the Clini-Dyne Mattress.

### 4. SECURING LINENS (OPTIONAL)

To secure linens to the Clini-Dyne mattress thread the four corners through the D rings attached to the mattress (fig. 6). To ensure proper therapy, do not pull linens taut. The linens should remain loose and wrinkly on surface of mattress.

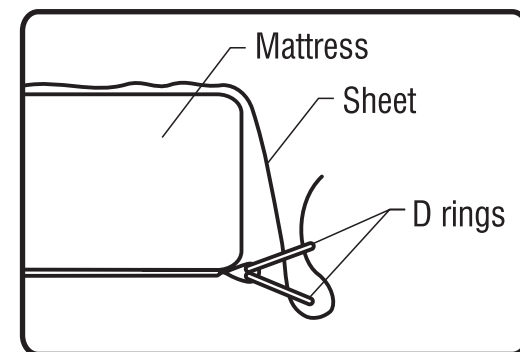
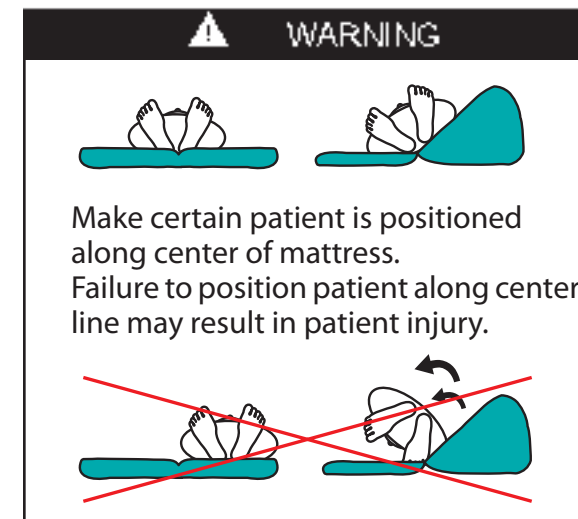


Figure 6—Securing Linens with D Rings

5. **Position the patient along the center line of the mattress.** Adjust the pillow for comfort. Make sure the patient is on the pillow stabilizer flap.

5. Position the patient along the center of the mattress.



6. Raise the bed side rails.



7. Place the head pillow in the optional stabilizing pillowcase (CLS110, disposable; CLS115, reusable). See figure 7. Position the pillow at the head end of the mattress, making sure the flap of the stabilizer will be under the patient's back.

NOTE: The pillow stabilizer is a pillowcase with a flap of fabric sewn to it that will help keep the pillow in position under the patient's head when the system is rotating.

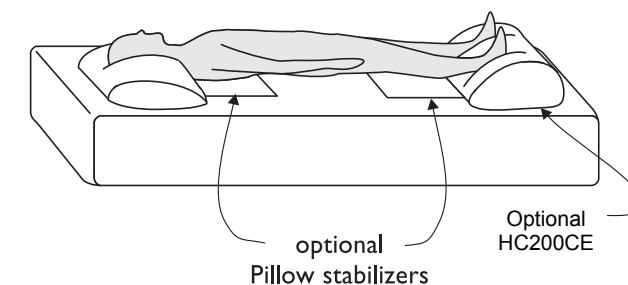


Figure 7—Positioning the pillows

8. Place the optional HC200CE HeelCare® Cushion under the patient's feet. Check that the patient is centered on the mattress.
9. Adjust the FIRMNESS setting as needed, while the patient is in the supine position (figure 8).

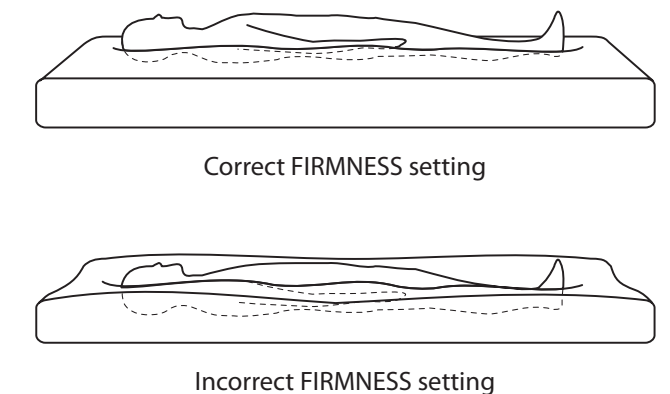


Figure 8—Visual Inflation Check (supine)

10. Set desired POSITION TIME interval. Set LEFT ROTATE and/or RIGHT ROTATE. Since the rotation angle will vary depending upon the patient's weight and size, the angle control should be initially set to the lowest setting and then gradually increased until the proper angle of rotation is reached.

The mattress will remain in each position for the time specified by the POSITION TIME light. If POSITION TIME is set to HOLD, automatic cycling will not occur.

Prior to leaving the patient in any automatic turning mode, observe at least one full rotation. Since the minimum cycle time is 1/4 hour (15 minutes) per position, observing the patient through a few cycles could be time-consuming. Therefore, a quicker way to determine sufficient rotation angle is to operate the system in manual mode. When POSITION TIME - HOLD is selected, the system will operate manually. Set either LEFT ROTATE or RIGHT ROTATE to the lowest setting.