

Rhythm Turn

Low Air Loss and Dynamic Turning Mattress Replacement System



User Manual

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Warning

- Connect the Master Control unit to a proper power source.
- Don't use the system in the presence of any flammable gases.
 (such as Anesthetic Agents)
- * Keep the blower and mattress away from source of liquid of open flame.
- Keep the mattress away from sharp object.
- ❖ The device is not AP/APG protected.
- Don't place the heating device close to the mattress system.

⚠ Caution

- This mattress system should only be used under a physician's instruction.
- ❖ Periodic repositioning of the patient is necessary when using this mattress system.
- The control unit should only be repaired by authorized distributor trained technician.
 - (The circuit diagram, repairable component parts list, and service manual are released only to authorized distributor)
- Don't drop the control unit.
- ❖ Do not store the system in direct sunlight or in extreme cold conditions.

1. The Purpose of this Manual

This operation manual is mainly focused on the set up, cleaning and routine maintenance of the Low Air Loss Rhythm Turn Therapy Support System. We recommend keeping this manual available to answer question related to the system.

2. Product Description

The Rhythm Turn mattress system is a specialized, unique and innovation mattress replacement system. The system is primarily designed for at risk patients or step-down intensive care units. It features continuous lateral rotation therapy in two different degree (20 degree and 40 degree), which gently turns the patient from side to side to significantly lower the risk of infection, pneumonia and other pulmonary complications that significantly add to patient care costs and length of stay.

Master Control Unit Features

- The Master Control Unit is user friendly designed and most of the functions are self explained.
- Rotation turn can be independently selected for 20 degree of 40 degree.
- Rotation time can be adjusted in 5 minutes increments up to 95 min. Or the caregiver can even select the Static Function that will cease the Rotation Function and provide only the True Low Air Loss Therapy.
- Auto Firm Function provides a uniformly firmness for nursing procedure.
- Power failures produce an audible alarm for added safety.
- 10 digital scales of Soft/Firm Comfort Control.
- Double insulation to provide max silent operation.
- Foot board mounting rack provides the convenience of placement.

Mattress Features

- Individual air cushion design for maximum pressure distribution.
- Each air cushion has orifices to provide true Low Air Loss therapy.
- LAL Turning Mattress Replacement, eliminating the compromising effects of an existing mattress.
- Permanent inflated bed rails for added safety.

3. Technical Data

Master Control Unit

| Model Name | Rhythm Turn | |
|------------------------|---|--|
| Model No. | FC-PHR0010 | |
| Size (LxWxH) | 17.7"x 6.8" x 10.8" | |
| Weight | 13.8 lbs | |
| Dwell Time | 3~95 | |
| Max Operating Pressure | 61mmHg | |
| Rated Voltage | AC 110~120V | |
| Rated Frequency | 60 Hz | |
| Fuse Rating | 5A 250V | |
| Max Current | 5A | |
| Classification | Class I, Type BF Not AP or AGP type | |
| Operation Temperature | 15°C ~ 35°C | |
| Operation Humidity | 30% ~75% | |
| Mode of Operation | Continuous | |
| Standard | IEC 60601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-1-2 | |

Rhythm turn Mattress Replacement

| Model No | FM-PHR0013 |
|----------------|---------------------|
| Size (LxWxH) | 80" x36" x 10" |
| Weight | 37.5 lbs |
| Cells Material | TPU |
| Cover Material | AD with Quilting |
| Base Material | Nylon laminated PVC |

Symbol Definition

| []i | Ref Refer to Accompanying Documents |
|-------------|-------------------------------------|
| X | Waste Disposal |
| ፟ 大 | Type BF Applied Part |
| | Alternating Current |
| \triangle | Warning |

4. Instruction for Proper Use

- 1. Remove the existing mattress from the bed frame.
- 2. Replace the standard mattress with Low Air Loss Turning Mattress Replacement system and make sure the mattress is positioned so the air tube is at the foot of the bed.
- 3. Secure the straps beneath the mattress to the bed frame.
- 4. Hang the Master Control Unit on the footboard of the bed frame. Attach the air tube connector to port on the left panel of the Master Control Unit. Be careful on the color matching between the connectors and socket. (black connectors to black socket, red connector to red socket)
- 5. Make sure the air hoses are not kinked under the mattress. (Could be verified by simple visual check) For detail Air hose connection please refer Explode Diagram.
- 6. Zip the low shear top cover to the mattress. The top cover should be loosely fit to the mattress.
- 7. Carefully plug power cord into a properly grounded power source. Turn on the master mechanical power switch on the right side panel. The STANDBY LED should illuminates.



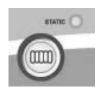
8. Push the STANDBY/OPERATE button of the front panel. The OPERATE LED should now be lighted up and the Master Control Unit should now start to spin.



9. Push the AUTO FIRM button for fast inflation. Allow $4 \sim 7$ minutes for full inflation. After the mattress is fully inflated, the caregiver can now transfer the patient on to the mattress. Push the AUTO FIRM again to release the fast inflation mode. (Note: The mattress can be inflated with patient lying on top).



10. Static Function: Push the static button and adjust the Contort Control by pressing the SOFT/FIRM button to achieve the maximum patient comfort. On this mode the system provides True Low Air Loss therapy. Perform a hand check by placing hand under the patient buttocks between cells and foam. The patient should have at least 4 cm of clearance between the buttocks and the bottom of the mattress.



11. Turning time can be adjusted by the CYCLE button. The time can be adjusted from 3 minutes to 95 minutes. (When Static Function is selected, the timing window would not show any digits).





12. The Master Control Unit is equipped with power failure alarm. With this function enabled, the Control unit generates a horn sound to signal to caregiver that main power failure. The alarm can be disabled by pushing the Alarm Reset Button on the front panel.



A Caution: Immediate response by the operator is required with power failure alarm.

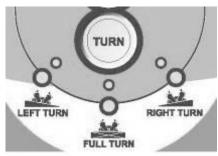
13. **LOCK-OUT:** The Master Control Unit is also equipped with a manual locking-out function. All function keys will be automatically disabled if the LOCK –OUT button has not been activated. When lock-out has been engaged, the "LOCK OUT" button will illuminate.

UNLOCKING

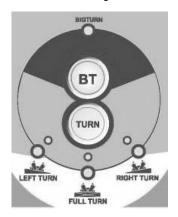
Unlocking the control panel is easy. Simply press the "LOCK OUT" button on the control panel for 3-5 seconds or recycle the power by turning off and on the main power switch.



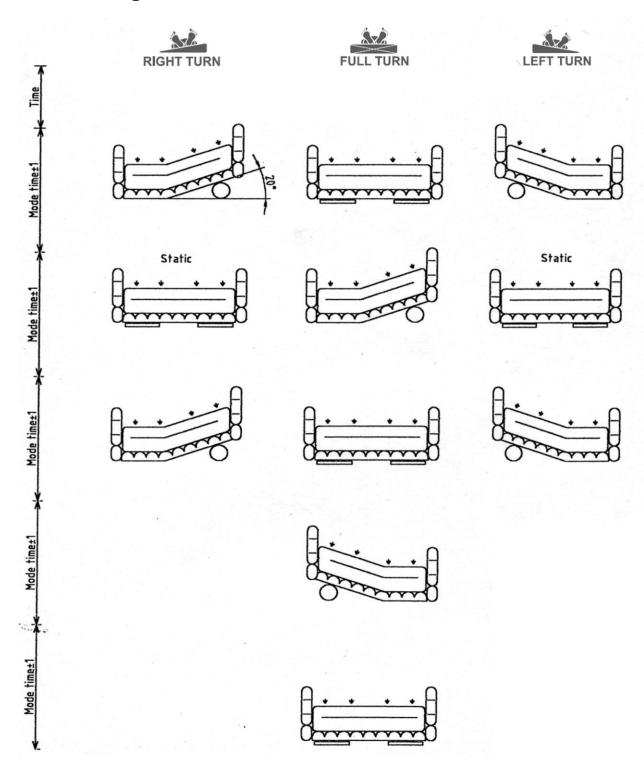
14. 20 degrees turning function can be activated by pressing the "TURN" and select desire turning therapy. "LEFT TURN" allows the mattress to turn to left and back to horizontal. "RIGHT TURN" would have the same effect but turning to the right. The "FULL TURN" allows for full function of turning to left and right and should always activate with timer setting. The timer can be set by "CYCLE" button.



15. 40 degrees turning function can be activated by pressing the "BT" button and follow the operation instruction on step 14.



Mattress Turning Illustration



5. Cleaning

The Mattress

The mattress should be cleaned weekly using a damp soft cloth and mild detergent. If top sheet (Top cover) or base (Bottom cover) becomes overly soiled, put on clean gloves, plastic gown and eye protection before removing top sheet or base and dispose of according to standard in function control procedures. Replace with clean covers.

Covers can be washed and thermally disinfected in a washing machine following below procedure:

(NOTE: Do not use phenol based cleaning solutions.)

Industrial cleaning

| Pre Wash | cold | 10 minutes |
|------------|------|------------|
| Main Wash | 60∘C | 6 minutes |
| Main Wash | 72°C | 10 minutes |
| Spin Cycle | | 2 minutes |
| Cold Rinse | | |
| Spin Cycle | | 5 minutes |

Domestic cleaning

| cold | |
|------|------------|
| 72°C | 10 minutes |
| | 2 minutes |
| | |
| | 5 minutes |
| | |

Tumble Drying or Tunnel Drying is not recommended.

Mattress Cells can be wiped over with a solution of sodium hypochlorite 1000ppm or any other non-phenolic germicidal solution.

The Master Control Unit

AUTION

SWITCH OFF THE ELECTRICAL SUPPLY TO THE BLOWER AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION

The master control unit should also be cleaned weekly using a damp soft cloth and mild detergent.

The blower casing is manufactured from ABS plastic and if the case is soiled the blower can be wiped down with a sodium hypochlorite solution to dilution of 1000ppm or any EPA- approved hospital grade disinfectant. (NOTE: Do not use phenol base cleaning solution.)

The air filter should also be cleaned and checked as often as possible at a minimum of every six months. Air Filter can be removed by pinching center of the filter and pulling outward from the back of the Therapy control unit.

Replace Air Filter

- 1. Remove air filter and replace with a new filter.
- 2. Use a soft bristle brush to remove dust and difficult dried-on soil.



Waste Disposal

This Product has been supplied from an environmentally aware manufacturer that complies with the WEEE.

This product may contain substances that can be harmful to the environment if disposed of in places that are not approved by your state, local or federal laws. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.



6. Storage and Care

Master Control Unit:

- Check the power cord and plug for abrasions or excessive wear.
- Plug in the unit and verify air flows from the units hose connection ports
- Place in plastic bag for storage.

Mattress Replacement:

- Check the air manifold for kinks or breaks and replace if necessary.
- Pull out the CPR plug at the head of the mattress and disconnect the air feed tubes. All the air will now be expelled. Starting at the head end, the mattress can now be rolled. Use the base mounted straps for containment.
- Place in plastic bag of storage.

It is recommended the following guidelines are used whenever this system is being stored or transported another location:

Temperature limitations: $5^{\circ}\text{C} \sim 60^{\circ}\text{C}$ Relative Humidity $30\% \sim 75\%$

7. Maintenance & Troubleshooting

No daily maintenance is required. It is intended this equipment should only be serviced by properly qualified, authorized technical personnel. In case of minor trouble please refer as following Troubleshooting.

| Symptom | Inspection Procedure | Possible Solution |
|---|--|---|
| Air is blowing out from the control unit but mattress is not inflating. | 1.Is the power source correct? Improper voltage may cause the blower to function abnormally and damage the control unit. | 1.Use power regulator. |
| | 2.Is there any kinking tube? | 2.Adjust the air tubes to enable smooth air flow. |
| | 3.Is there any air leakage from the air cells? | 3.Replace with new air cells |
| | 4.Is there any air leakage from air tube between mattress and control unit? | 4.Replace with new air tubes |
| | 5. Has the air tube connector been connected properly? | 5.Re-connect the air tubes. |
| The Control Unit is not functioning. | 1. Check the power cord and the power voltage. | 1.Use a power regulator |
| | 2. Check the fuse | 2. Replace with a new fuse |
| Some of the air cells are not properly inflated. | 1.Is the connection between air cells and the manifold kinked? | Check for any kinking between air cells and manifold. |
| | 2.Is there any air leakage from the air cells? | 2. Replace new air cell if faulty. |

8. EMC Related Notifications

Guidance and manufacturer's declaration - electromagnetic emissions

The blower is intended for use in the electromagnetic environment specified below. The customer or the user of the blower—should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|-----------------------|------------|--|
| RF emissions | Group 1 | The blower uses RF energy only for its internal |
| CISPR 11 | | function. Therefore, its RF emissions are very low |
| | | and are not likely to cause any interference in |
| | | nearby electronic equipment. |
| RF emissions | Class B | The blower is suitable for use in all |
| CISPR 11 | | establishments, including domestic establishments |
| Harmonic emissions | Class A | and those directly connected to the public |
| IEC 61000-3-2 | | low-voltage power supply network that supplies |
| Voltage fluctuations/ | Complies | buildings used for domestic purposes. |
| flicker emissions | | |
| IEC 61000-3-3 | | |

Recommended distances between

portable and mobile RF communications equipment and the blower

The blower is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the blower can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the blower as recommended below, according to the maximum output power of the

communications equipment.

| | 1 | | | | |
|-----------------|--------------------|--|--------------------|--|--|
| Rated maximum | | | | | |
| output power of | | | | | |
| transmitter | 150 kHz to 80 MHz | 150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2,5 GHz | | | |
| W | $d = 1.2 \sqrt{P}$ | $d = 1.2 \sqrt{P}$ | $d = 2.3 \sqrt{P}$ | | |
| | , | , | , | | |
| 0,01 | 0,12 | 0,12 | 0,23 | | |
| 0,1 | 0,38 | 0,38 | 0,73 | | |
| 1 | 1,2 | 1,2 | 2,3 | | |
| 10 | 3,8 | 3,8 | 7,3 | | |
| 100 | 12 | 12 | 23 | | |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE: 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The blower is intended for use in the electromagnetic environment specified below. The customer or the user of the blower should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---|--|--|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | 26 kV contact 28 kV air | 26 kV contact 28 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst | 22 kV for power supply lines | 22 kV for power supply lines | Main power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-4 | 21 kV for input/output lines | 21 kV for input/output Lines | |
| Surge IEC 61000-4-5 | 21 kV line(s) to line(s) 22 kV line(s) to | 21 kV line(s) to line(s) 22 kV line(s) to | Main power quality should be that of a typical commercial or hospital environment. |
| interruptions and voltage variations on power supply input lines. | earth <5 % <i>U</i> T (>95 % dip in <i>U</i> T) for 0,5 cycle 40 % <i>U</i> T | earth <5 % <i>U</i> T (>95 % dip in <i>U</i> T) for 0,5 cycle 40 % <i>U</i> T | Main power quality should be that of a typical commercial or hospital environment. If the user of the blower requires continued operation during power main interruptions, it is |
| | (60 % dip in <i>U</i> T) for 5 cycles | (60 % dip in <i>U</i> T) for 5 cycles | recommended that the blower be powered from an uninterruptible power supply or a battery. |
| IEC 61000-4-11 | 70 % <i>U</i> T (30 % dip in <i>U</i> T) for 25 cycles | 70 % <i>U</i> T (30 % dip in <i>U</i> T) for 25 cycles | |
| | <5 % <i>U</i> T (>95 % dip in <i>U</i> T) for 5 sec | <5 % <i>U</i> T (>95 % dip in <i>U</i> T) for 5 sec | |
| Power frequency (50/60 Hz) magnetic field | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| IEC 61000-4-8 | c main voltage prior t | o application of the test | lovel |

Guidance and manufacturer's declaration - electromagnetic immunity

The blower is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

| Immunity | IEC 60601 test | Compliance | Electromagnetic environment – guidance |
|------------------------------------|--------------------------------|------------|---|
| test | level | level | |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the blower, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance |
| Conducted RF IEC | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d = 1,2 \sqrt{P}$ |
| 61000-4-6 | | | $d = 1,2 \sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ |
| | 3 V/m | 3 V/m | $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz |
| Radiated RF IEC 61000-4-3 | 80 MHz to 2,5 GHz | | Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). |
| | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b. |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol: |
| | | | $((\bullet))$ |

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the blower air pump—is used exceeds the applicable RF compliance level above, the blower should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the blower.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9. Warranty

- Prius Healthcare guarantees this equipment to be free from defects in material and workmanship for up to 12 months from the date of delivery.
- All warranty work will be performed at the service address below, shipping charges prepaid.
- At Manufacturers descreton we agree to service, repair or replace any equipment or part found to be defective at no charge.
- This warranty excludes equipment damaged through shipping, tampering, improper maintenance, carelessness, accident, negligence, misuse, or which has been altered, repaired or dismantled other than with the manufacture's written authorization and by its approved procedures and by properly qualified technicians.
- In no event shall Prius Healthcare be liable for any direct, indirect or consequential damage or loss resulting from the use of equipment.
- Warranty is non-transferrable.

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