Read Entire Manual before Operating Device

TRAN

User Instruction Manual

COMFORTITIERN

0

6

0

PLEASE NOTE: It is important that the user read the entire manual before operating this device.

Table of Contents

Page

4 5
5
6
6
В
)
1
2
3
4
5
5

Symbol Definitions

Manual Definitions

Throughout this manual different type faces and icons are used to aid user readability and understanding of the content. Below are some examples.

- Standard Text **Bold Face Text**
- Used for regular information.
- NOTE: or NOTICE
- **Bold and underlined**
- Emphasizes a word or phrase.
- Sets apart special information or important instruction clarification.
- Refers to special instances or where problems can occur.

This symbol highlights a WARNING or CAUTION



- A WARNING identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.
- A CAUTION points out special procedures or precautions that personnel must follow to avoid equipment damage.

This symbol highlights an ELECTRICAL SHOCK HAZARD WARNING



Symbols Found on Blower Unit

NOTE: Details about the control panel functions are located directly after the operation instructions on page 10. Manufacture's Label

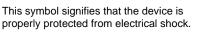


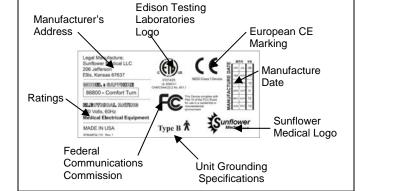
These symbols mark the location and specifications of the fuses in the 110V unit.

Replace fuses as marked



These symbols mark the location and specifications of the fuses in the 220V unit.







This symbol marks the location of the leakage test point screw.

General Warnings and Precautions

WARNINGS



WARNING: DO NOT use this device if the power cord is cut, frayed or loosely connected to the device.



WARNING: (110V unit) Electrically Powered Mechanism. Electrical Hazard may occur if device is plugged into inadequate electrical outlet. To avoid electrical shock hazard, make sure unit is plugged into a grounded A/C 110V outlet.



WARNING: (220V unit) Electrically Powered Mechanism. Electrical Hazard may occur if device is plugged into inadequate electrical outlet. To avoid electrical shock hazard, make sure unit is plugged into a grounded A/C 220V outlet.



WARNING: DO NOT remove cover. Refer servicing to qualified service personnel. Disconnect power supply before servicing or cleaning.

WARNING: Be sure to secure mattress to the bed frame with the straps provided. Failure to do so could result in personal injury or equipment damage.

CAUTIONS



CAUTION: Overheating may cause equipment damage or failure. Monitor the unit to ensure that it functions in the proper operating temperature.

CAUTION: Keep out of direct sunlight.

CAUTION: DO NOT store in temperatures below 40° or greater than 95° Fahrenheit ($5^{\circ} - 35^{\circ}$ Celsius).

CAUTION: DO NOT expose to moisture or areas of extreme humidity.

CAUTION: Ensure that strap placement does not interfere with the operation of the bed functions.

CAUTION: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the equipment or system. The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.



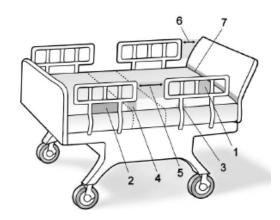
CAUTION: DO NOT use around an open flame.

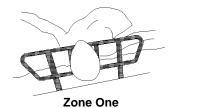
Seven Zones of Bed Rail Entrapment

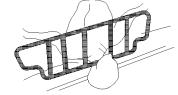


WARNING: Bed rail entrapment is a serious health risk that can result in serious injury or even death. Sunflower Medical L.L.C. recommends the use of bed rails if they are available. Failure to use bed rails in raised position could lead to accidental patient falls. Air mattresses have soft edges that may collapse when patients roll to that edge. When using an Air Therapy system the caregiver is responsible for seeing that the mattress properly fits the bed frame. It is also the caregiver's ultimate decision whether or not to use bed rails with the patient.

- Zone 1: Within the Rail
- Zone 2: Under the Rail, Between the Rail Supports or Next to a Single Rail Support
- Zone 3: Between the Rail and the Mattress
- **Zone 4:** Under the Rail, at the Ends of the Rail
- Zone 5: Between Split Bed Rails
- **Zone 6:** Between the End of the Rail and the Side Edge of the Head or Foot Board
- **Zone 7:** Between the Head or Foot Board and the Mattress End



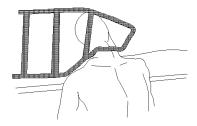




Zone Two

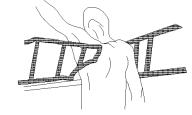


Zone Three



Zone Four





Zone Five



Zone Seven

Device Information

PURPOSE OF THE DEVICE

The purpose of the Sunflower Medical Sapphire Comfort Turn True Low Air Loss Mattress System is to provide a full body lateral rotation and a therapeutic benefit to patients at risk or suffering from pressure ulcers.

The Comfort Turn also has operator controls that allow the operator or caregiver to adjust the patient's body weight pressure distribution by increasing and decreasing of pressure in defined areas of the mattress on a timed basis. This results in an angular change of the patient's body such as the left shoulder and hip being lowered below that of the right shoulder and hip. This process is called a "Turn".

The active component that has contact with the patient is a specialized, multi-cell air mattress sized to fit a standard medical bed frame. The air mattress serves as a replacement to the original mattress and is equipped with 4 air hoses with connectors that mate with the Air Blower/Control unit. The Control Unit is a self contained, totally enclosed module that hangs by retractable hooks on the bed frame at the foot of the bed or sits on the floor under the bed. It is provided with a hospital grade electrical cord and a control panel with selector switches and indicator lights. The switches and indicators are protected under a flexible membrane to keep out liquid spills and enhance cleanup and sanitation. Inside the Control Unit are a variable output blower, valve motor and air valves that allow the air mattress to operate in a static mode or provide cyclic pressure variations in selected areas. There is also a printed circuit board, which provides the electrical controls.

Standard Features			
Blower Unit Weight	11 lbs (4.98 kg)		
Blower Unit Height	10.5" (26.67 cm)		
Blower Unit Width	16" (40.64 cm)		
Blower Unit Depth	6" (15.24 cm)		

Therapeutic Features				
Low Air Loss	Yes			
Pulsate Therapy	Yes			
Lateral Rotation	Yes			
Fowler Positioning	Yes			

Electrical Characteristics	110V Control Unit	220V Control Unit
Rated Voltage	110 Volts	220 Volts
Rated Frequency	60Hz	50Hz
Rated Input Power	120 Volts	230 Volts
Fuse Rating	.31mA 250V 5A 250V	2.5A 250V
Power Failure Alarm	Yes	Yes

Patient Characteristics (for standard size)		
Max. Patient Height	78" (198.12 cm)	
Max Patient Width	26" (66.04 cm)	

Specifications

Unpacking and Set-up

Description of the Device:

The Sapphire Comfort Turn Mattress Replacement System consists of a control unit, a Low Air Loss Mattress, power cord and a waterproof, vapor permeable, easy-to-clean cover.

UNPACKING / PARTS BREAKDOWN:

Parts

- Air Blower/Control Unit
- Power Cord (Hospital Grade)
- True Low Air Loss Mattress Replacement
- Mattress Cover



Air Blower/Control Unit and True Low Air Loss Mattress with Cover

Tools Required: NONE

Unpacking instructions:

Remove the products from the packing material and examine for shipping damage. If damage is detected in shipping, contact the freight company and file a damage complaint immediately.

Environmental Conditions:

CAUTION: Keep out of direct sunlight.

DO NOT expose to temperatures greater than 95 degrees or below 40 degrees Fahrenheit.

DO NOT expose to moisture or areas of extreme humidity.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the equipment or system.

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

NOTE: Some cellular telephones and similar devices transmit signals while they are ON, even when not being used.

Directions for Mattress Placement:

Replace the existing bed mattress with True Low Air Loss Mattress. Secure Air Mattress to the bed frame with straps provided.

Warning or Safety Instructions relating to setup:



WARNING: (110V unit <u>ONLY</u>) Ensure the power cord is plugged into a properly grounded A/C 110V outlet.

WARNING: (220V unit ONLY) Ensure the power cord is plugged into a properly grounded A/C 220V outlet.

Sapphire Comfort Turn Operating Instructions:

- 1) Remove standard mattress from the bed.
- Replace standard mattress with the Sapphire Comfort Turn mattress. (Be sure air tubing is at the foot end of the bed.)
- 3) Strap air support mattress to bed frame on all four sides.
- 4) Place control unit on the footboard of the bed using the two retractable hooks located on the back of the unit. (If no footboard is available, put blower on the floor away from traffic.) To avoid blocking the air intake, **DO NOT** place control unit on its back.
- Attach the air tubing to the blower unit, being sure it snaps in tight. (Be sure air tubing is not kinked and is unobstructed.)
- 6) **NOTE: (110V unit <u>ONLY</u>)** Plug unit into grounded 110V A/C outlet.
- 7) NOTE: (220V unit ONLY) Plug unit into grounded 220V A/C outlet.
- 8) Press the Auto Firm button for quick inflation.
- 9) Place the patient on the bed <u>after</u> inflation to insure the air cells do not become twisted or kinked.
- 10) Once the air mattress is completely inflated, press the Auto Firm button again to exit that mode.
- 11) Static Low Air Loss Mode
 - a. Press the Mode button until Static is illuminated.
 - b. Set desired firmness with the Soft/Firm buttons
- 12) Fowler Mode
 - a. When elevating the head section of the mattress, press the **Fowler** button to increase airflow for seat inflation.

13) Pulsate Mode

- a. Press the Pulsate button.
- b. Set desired firmness with the Soft/Firm buttons.
- 14) Turning Mode
 - a. Press the Mode button until Right Turn, Left Turn or Full Turn is illuminated, which ever mode you desire. At this setting the degree of rotation will be approximately 40 degrees.

b. In Full Turn mode the control unit has a preset of 3-minute intervals. The intervals may

be adjusted by depressing the cycle time button to desired time (3 to 20 minutes. 30, 45,

60, 75 or 90 minutes also.)

c. To set comfort level press corresponding firm or soft button. There are 10 levels of

firmness indicated by lighted bars located on the control panel.

WHEN THE PATIENT IS PUT IN TURNING MODE, WATCH IV LINES AND TUBING TO INSURE THAT THERE IS ENOUGH LENGTH TO ACCOMMODATE A FULL ROTATION. IT IS ADVISED TO MONITOR THE PATIENT FOR 2 TO 3 COMPLETE ROTATIONS.

Notice: When the cycle time is showing "Hd" the control unit will hold the patient in the turn position until a caregiver physically changes the cycle time.

15) Lock-Out Feature

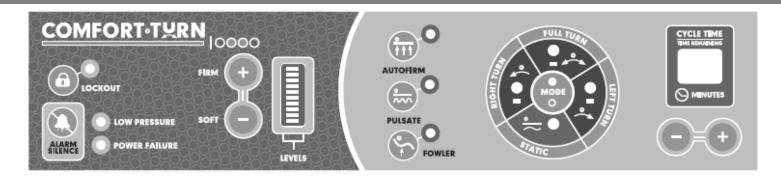
- Three minutes after the settings have been selected; the control unit will automatically lock out the control panel.
- b. Press and hold the Lock-out button to exit lock-out status (hold approximately 3

seconds.)

16) CPR Function

- a. For quick deflation or for CPR use, turn power off, twist CPR plug on mattress to open it and remove the hoses from the control unit.
- b. The mattress is equipped with a 2-inch air safety pad in the mattress base for patient support and transport.

Keypad Quick Reference





Pulsate – Press to begin Pulsation therapy.



Firm – Increases airflow for a firmer setting.



Autofirm – Quickly inflates mattress to maximum firmness.



Cycle Time-Increases or decrease the time of cycle between 3 to 20 minutes.



Fowler – Used when head section of bed is elevated. Increases airflow to the mattress.

Alarm Silence -

Soft

setting.

Mutes the audible alarm.

until failure is resolved.)

(Visual light will not turn off

Decreases airflow for a softer



Mode-Press the M0

Press the MODE button to switch between Alternate and Static Modes.



Lockout – Locks all functions automatically after 3 mins. To disable, press and hold lockout button for 3 sec.

Refer to this page as needed for quick reference to the control panel functions.

Shows control panel layout for the blower unit and optional auto fowler attachment.

Provides individual button illustration and function description.

Mattress Cleaning Instructions:

WARNING and CAUTION:



- A. It is recommended that gloves and protective clothing be worn at all times during cleaning and disinfecting
- B. Hypercarbonate and phenol based solutions should not be used.

During Operation:

For normal soil, wipe down cover and interior sacs with a standard cleaning disinfectant and wipe off excess moisture with a towel.

Laundering Mattress:

- 1. Disconnect the power from the Control Unit and deflate the interior sacs.
- 2. Disassemble cover, interior sacs, connecting hoses, and base. Place them in different laundering baskets.



3. The interior sacs must be hand cleaned only. DO NOT place in sterilization room or chamber. Use a spray disinfectant to wipe down interior sacs. Air-dry sacs. **DO NOT**

expose to heat.

- 4. Spray disinfectants and wipe down foam cover.
- 5. Place cover and base **ONLY** in washing machine.
- 6. Use standard hospital disinfectant/detergent.
- 7. Set washing cycles as recommended below: Regular Cycle
 - a) Pre-soak with disinfectant/detergent with diluted bleach in cold water (10 minutes.)
 - b) Main wash for 15 minutes (Time depending on soil level).
 - c) Rinse Cycle: 5 minutes minimum.
 - d) Spin/Drain Cycle: 5 minutes minimum.
 - e) Air-dry or place in dryer at very low or no heat.
- 8. After the cover, interior sacs, and base are dry, store them in a sterilized bag and seal for next use.

NOTICE: DO NOT use water temperatures greater than 150°F (65°C).

Blower Unit Cleaning Instructions:

WARNING and CAUTION:

- A. Hand clean only. DO NOT place in sterilization room or chamber.
- B. It is recommended that gloves and protective clothing be worn at all times during cleaning and disinfecting



- C. Hypercarbonate and phenol based solutions **should not** be used.
- D. Make sure unit is turned "off" and unplugged before cleaning.

For normal soil, wipe down with a standard cleaning spray and wipe off excess moisture with a towel. Spray with a disinfectant and let it stand for a few minutes before wiping down. Check corners and creases for soil build-up. Look to see if any external parts are damaged or need replacing such as: hooks, foot pads and filter. Replacement parts can be issued. Contact your representative for servicing.

NOTE: To keep your equipment working efficiently and effectively for an extended time period, it is essential to make sure the equipment is cleaned regularly and well maintained.

Maintenance:

Air Filter

The foam air filter on the back of the Control Unit must be cleaned weekly with soap and warm water. Replacement of the foam filter is recommended every 6 months.



The filter is easily removed and reinserted through the gap in the back case.

Storage:

Deflate mattress until all air is exhausted completely. With the cover on, roll the mattress starting at the foot section. Secure with straps and keep mattress in a clean dry area away from heat or flames. Store unit and mattress in a temperature range between 40° and 95°. DO NOT expose to moisture or areas of extreme humidity.

Disposition:

Once the unit has reached the end of its useable life, contact your representative for service, disposition or replacement.

Trouble Shooting Guide



WARNING: Only authorized personnel should engage in the troubleshooting process. Troubleshooting by unauthorized persons could result in personal injury or equipment damage.



WARNING: DO NOT remove cover. Risk of electrical shock.

If mattress is not inflating:

- Make certain none of the hoses are punctured, kinked or disconnected.
- Check for proper connections from the hoses to the Control Unit. Make sure they are secure.
- Check or clean intake filters.
- Be sure CPR valve on the mattress is closed.

If there is power loss:

- Check the ON/OFF switch.
- Check to be sure that unit is plugged in correctly.
- Unplug the Control Unit and check fuses located near the main ON/OFF switch. Replace as necessary.

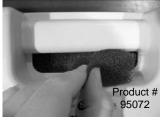
NOTICE: If the troubleshooting process does not solve the problem please contact your representative for service.

Frequently Ordered Parts

The following is a list of parts that are frequently ordered for self replacement and repairs. To aid you in ordering parts, please use the provided product numbers given below for each part. The replacement of some parts not listed here may require sending in the unit to the manufacturer for repairs.



Connector - Connects from mattress to blower unit side panel. Allows air movement to inflate mattress.



Filters - Removes dust and other particles from the air as it is pulled into the blower unit.



Male CPC (Chrome) -Attached to blower unit side panel. Connects to Female

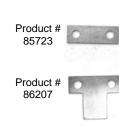


Product # 95030

Female CPC – Connects from mattress to Male CPC on blower unit. Removes exhaust air from unit to mattress.



Power Cord - Grounded hospital grade power cord for providing power to the control unit. (Note: Supplied only with 110V control units).



Hooks – Collapsible hooks that allow the unit to be hung on bed frame.

Brackets - Attach the hooks to the bottom case of the unit.

Return/Exchange Goods Policy:

Return of Goods: 18% Return Charge for a Restocking Fee for returned goods when customer makes a wrong order of item(s), still in original Packing. A Return Authorization Number (RAN) Form(s) will need to be filled out and processed through the Sunflower Medical LLC Customer Service Department. Once RAN is issued, customer must return all item(s) placed on the RAN within five working days from the date of the RAN to Sunflower Medical LLC. Without an Authorized RAN, all item(s) will be returned to the customer at the customer's expense.

Repairs or Replacements are offered for defective item(s). Also a RAN action must be completed before any repairs or replacements can be completed.

Sunflower Medical LLC: Replacement for wrong item(s) shipped, RAN form must also be completed, and then item(s) will be replaced or repaired at no cost.

Warranty Provisions:

Warranty: Sunflower Medical LLC; Warrants that all products provided under this agreement are free from defects in material and workmanship, for the following stated warranty period from the date of delivery.

Sunflower Medical LLC guarantees all purchased equipment to be free from defects in material and workmanship as follows: <u>Control Unit</u> – One (1) year; <u>Mattress</u> – Two (2) years on air cell welds; One (1) year on Bottom Cover, Manifold & Foam Base; <u>Top Cover</u> – Ninety (90) Days. All parts found defective within that period shall be repaired and/or replace, with the cost of repair and/or replacement, to be borne by Sunflower Medical LLC. The warranty is not valid and repairs and/or replacement will not be made free of charge, if the product has been misused or damaged by accident.

Sunflower Medical LLC reserves the right to make this determination based upon the condition of product upon time of receipt.

For warranty information in Canada please contact Canadian Medical Healthcare at 1-877-850-1330.

16 of 16