

SAPPHIRE SERIES® Static Low-Air-Loss Mattress Replacement System

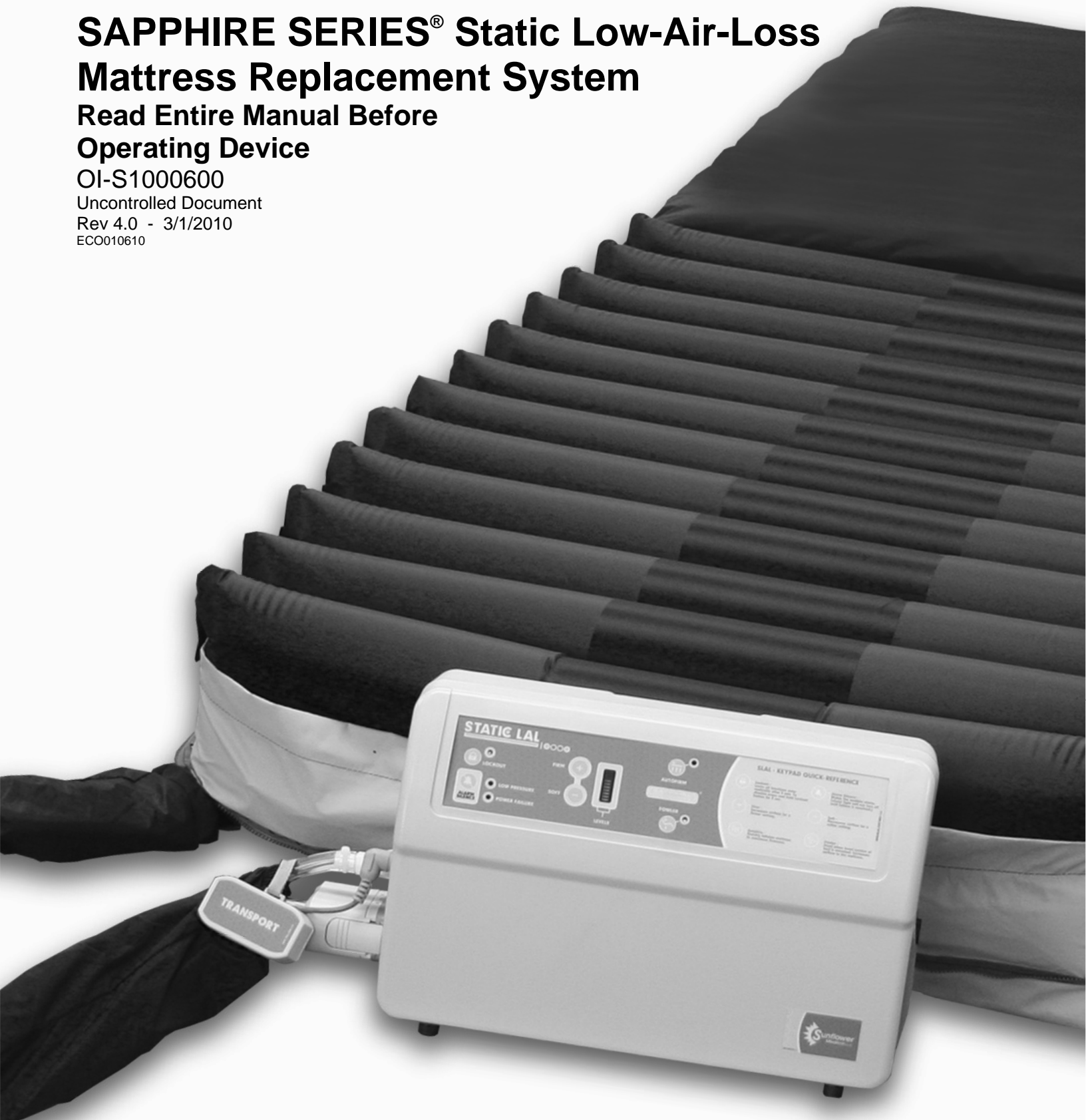
Read Entire Manual Before
Operating Device

OI-S1000600

Uncontrolled Document

Rev 4.0 - 3/1/2010

ECO010610



User Instruction Manual

Sapphire Static Low-Air-Loss

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

USER ASSISTANCE INFORMATION:

If you have questions or need assistance with this product, call the company from whom it was purchased, or contact Sunflower Medical L.L.C. at

1-888-321-3382

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Technical Description of the Equipment:

The two principle components of the Sunflower Medical SAPPHIRE SERIES® Static Low-Air-Loss Mattress System are a specialized air inflatable bladder (Air Mattress) and an electrically powered, Air Blower/Control Unit.

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

This symbol highlights a **WARNING** or **CAUTION**



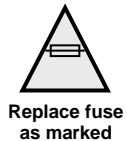
- A **WARNING** identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.
- A **CAUTION** points out special procedures or precautions that personnel must follow to avoid equipment damage.

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 7.



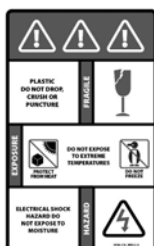
This symbol marks the location and specification of the fuse.



This symbol signifies that the device is properly protected from electrical shock.

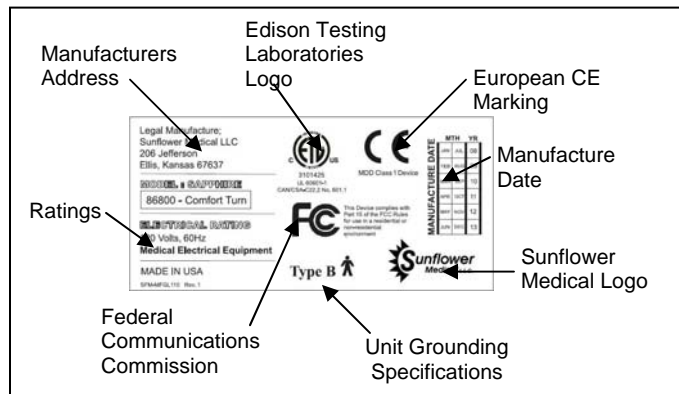


This symbol marks the location of the leakage test point screw.

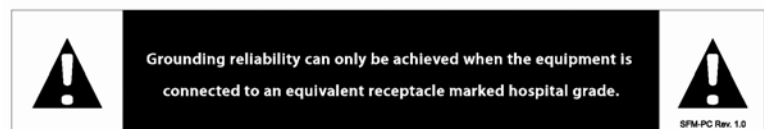


The hazards and warnings are indicated on the shipping container by this label.

Manufacturer's Label



Power Cord Label



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° – 35° 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.

Device Information

PURPOSE OF THE DEVICE

The purpose of the SAPPHIRE SERIES® Static Low-Air-Loss Mattress System is to provide therapeutic benefit to patients at risk or suffering from pressure ulcers.

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 to replace 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 detachable hospital grade electrical cord and a control panel that has selector switches and indicator lights. Inside the Control Unit is a variable output blower that allows the air mattress to operate in static mode. There is also a printed circuit board, which provides the electrical controls.

Specifications

| 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 |
| Fowler Positioning | Yes |
| Additional Therapies | No |

| Electrical Characteristics | 110V | 220V |
|----------------------------|-------------------------|--------------|
| | Control Unit | Control Unit |
| Rated Voltage | 110 Volts | 220 Volts |
| Rated Frequency | 60Hz | 50Hz |
| Rated Input Power | 120 Volts | 230 Volts |
| Fuse Ratings | T300mA 250V T5A 250V | T2.5A 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) |

Unpacking and Setup

Description of the Device:

The SAPPHIRE SERIES® Static Low-Air-Loss Mattress Replacement System consists of a control unit, power cord, a Low Air Loss Mattress 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 ONLY) Ensure the power cord is plugged into a properly grounded A/C 110V outlet.



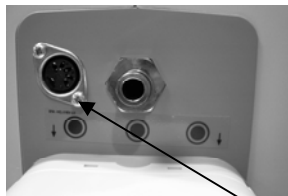
WARNING: (220V unit ONLY) Ensure the power cord is plugged into a properly grounded A/C 220V outlet.

Sapphire Static Low-Air-Loss Operating Instructions

- 1) Remove standard mattress from the bed.
- 2) Replace standard mattress with the SAPPHIRE SERIES® Static Low-Air-Loss 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.
- 5) 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 ONLY)** Plug unit into grounded 110V A/C outlet.
- 7) **NOTE: (220V unit ONLY)** Plug unit into grounded 220V A/C outlet.
- 8) Turn master power switch, located on the side of the unit, "on".
- 9) Press the **Autofirm** button for quick inflation. 
- 10) Press the **Firm** or **Soft** button on the control panel to select the desired level of firmness.
- 11) Place the patient on the bed **after** inflation to insure the air cells do not become twisted or kinked.
- 12) **Fowler mode** 
 - a. When elevating the head section of the mattress, press the **Fowler** button to increase airflow for seat inflation.
- 13) **Auto Fowler attachment** (Optional)
 - a. When elevating the head section of the mattress, **Fowler** mode will automatically turn on.



Auto Fowler attachment



This is where the Auto Fowler attachment connects to the control unit.

14) **Lock-out Feature** 

- a. After 3 minutes, if there are no changes to the blower settings, the lock-out feature will activate.
- b. Press and hold the Lock-out button for 3 seconds to disengage the lock-out feature.

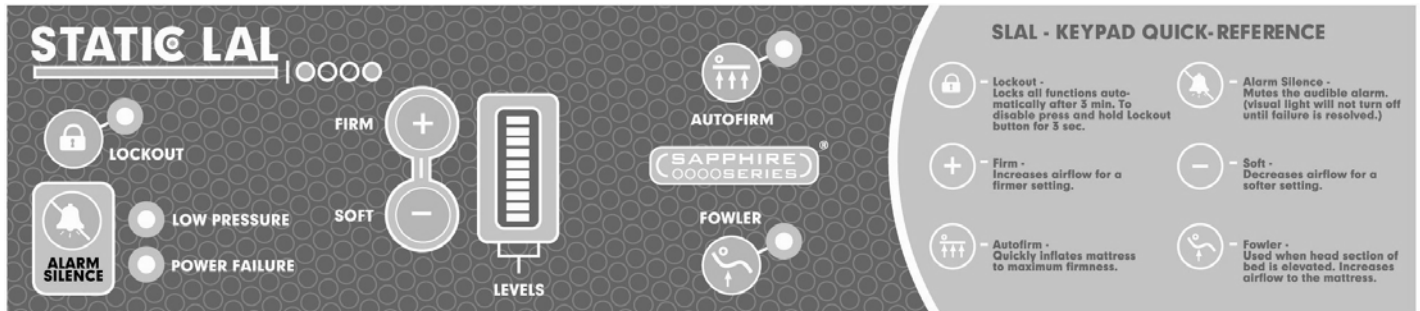
15) **For quick deflation or for CPR use:**

- a. Turn power off
- b. Twist CPR connection on the mattress to open it
- c. Remove the hoses from the control unit.

Notice: The mattress is equipped with a 2-inch foam pad in the mattress base for patient support and transport.

For Inquiries Call 1-888-321-3382

Keypad Quick Reference



SLAL - KEYPAD QUICK-REFERENCE

-  Lockout - Locks all functions automatically after 3 min. To disable press and hold Lockout button for 3 sec.
-  Alarm Silence - Mutes the audible alarm. (visual light will not turn off until failure is resolved.)
-  Firm - Increases airflow for a firmer setting.
-  Soft - Decreases airflow for a softer setting.
-  Autofirm - Quickly inflates mattress to maximum firmness.
-  Fowler - Used when head section of bed is elevated. Increases airflow to the mattress.



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



Alarm Silence –
Mutes the audible alarm. (Visual light will not turn off until failure is resolved.)



Firm –
Increases airflow for a firmer setting.



Soft –
Decreases airflow for a softer setting.



Autofirm –
Quickly inflates mattress to maximum firmness.



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

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

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.

Power Cord

The power cord should be checked for damage each time the Control Unit is used. The cord should always be kept away from free moving parts. If the power cord is damaged it will need to be replaced.



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:

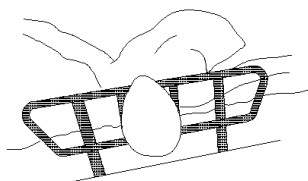
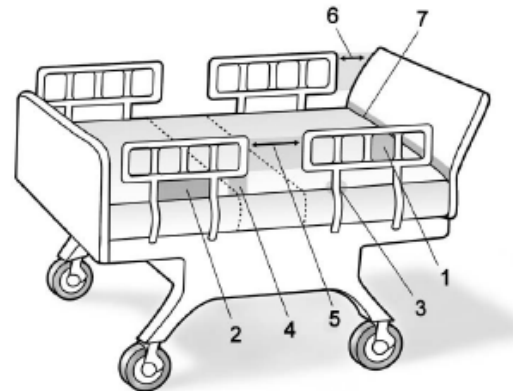
Once the unit has reached the end of its useable life, contact your representative for service, disposition or replacement.

Safety Tips

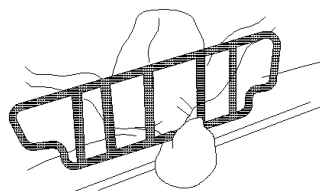


WARNING: Bed rail entrapment is a serious health risk that can result in serious injury or even death. Sunflower Medical L.L.C. recommends the use of bed rails if they are available. Failure to use bed rails in raised position could lead to accidental patient falls. Air mattresses have soft edges that 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.

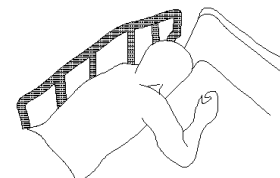
- **Zone 1:** Within the Rail
- **Zone 2:** Under the Rail, Between the Rail Supports or Next to a Single Rail Support
- **Zone 3:** Between the Rail and the Mattress
- **Zone 4:** Under the Rail, at the Ends of the Rail
- **Zone 5:** Between Split Bed Rails
- **Zone 6:** Between the End of the Rail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



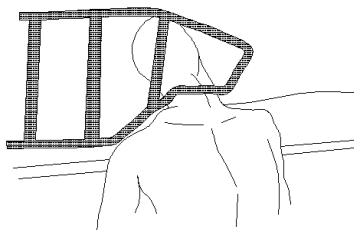
Zone One



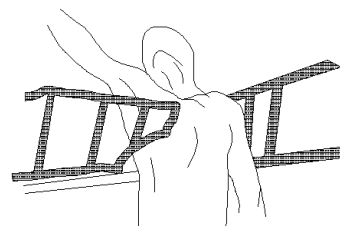
Zone Two



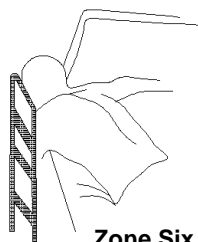
Zone Three



Zone Four



Zone Five



Zone Six



Zone Seven

Safety Tips

ELECTROMAGNETIC COMPATIBILITY (EMC)

This device has been tested for compliance with the EMC requirements. The guidelines in this section will help you to make sure that your medical equipment will meet the requirements of the standard.



WARNING Medical equipment should not be used, stacked, or located on or around equipment that may create electromagnetic interferences.

Emissions

This blower has been type tested and has passed the requirements of CISPR 11. Observe the following recommendations to minimize radio frequency emissions in this section and the Electromagnetic Interference section.

Immunity

This blower has been stringently tested for susceptibility to electromagnetic radiation over the frequency range 80 MHz to 2.5 GHz. The test was conducted on this blower and passed the requirements of IEC 61000-4-3.

All pins of connectors have passed ESD testing.

List of Cables & Accessories

Replacement parts, such as cables and accessories, must be purchased through Sunflower Medical to insure proper compliance requirements.



WARNING Using other manufacturer's cables and accessories may affect EMC performance. Unauthorized use of these items will void warranty and may cause injury harm to you, others and/or the equipment.

GUIDANCE AND MANUFACTURER'S DECLARATION

Company: Sunflower Medical LLC
Model: Static LAL
Project Number: 3101425

Table 201 Guidance and Manufacturer's Declaration - Emissions All Equipment and Systems

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

| Emissions Test | Compliance | Electromagnetic Environment Guidance |
|----------------------------|------------|---|
| RF Emissions CISPR 11 | Group 2 | The blower is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| RF Emissions CISPR 11 | Class A | |
| Harmonics IEC 61000-3-2 | Class A | |
| Flicker IEC 61000-3-3 | Complies | |

Safety Tips

Table 202 Guidance and Manufacturer's Declaration - Immunity
All Equipment and Systems

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

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|------------------|--|
| ESD IEC 61000-4-2 | ±6kV Contact ±8kV Air | A | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30% |
| EFT IEC 61000-4-4 | ±2kV Mains ±1kV I/Os | A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1kV Differential ±2kV Common | A | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips/Dropout IEC 61000-4-11 | >95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds | A | Mains power quality should be that of a typical commercial or hospital environment. If the user of the blower requires continued operation during power mains interruptions, it is recommended that the blower be powered from an uninterruptible power supply or battery. |
| Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8 | 3A/m | A | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |

Safety Tips

Table 204 Guidance and Manufacturer's Declaration - Immunity
Equipment and Systems that are NOT Life-supporting

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

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|--|--|---|--|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p> | <p>$(V1)V_{rms} = 3$</p> <p>$(E1)V/m = 3$</p> | <p>Portable and mobile communications equipment should be separated from the blower by no less than the distances calculated/listed below:</p> <p>$D=(3.5/V1)(\text{Sqrt } P)$</p> <p>$D=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz</p> <p>$D=(7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz</p> <p>Where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p> |

Safety Tips

Table 206 Recommended Separation Distances between portable and mobile RF Communications equipment and the blower.

Equipment and Systems that are NOT Life-supporting

Recommended Separation Distances for the blower

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

$$D=(3.5/V1)(\text{Sqrt } P)$$

$$D=(3.5/E1)(\text{Sqrt } P)$$

80 to 800 MHz

$$D=(7/E1)(\text{Sqrt } P)$$

800 MHz to 2.5 GHz

| Compliance Level | Cond RF 3 | Rad RF-800MHz 3 | Rad RF - 2.5GHz 3 |
|------------------|--------------|--------------------|----------------------|
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.69 | 3.69 | 7.38 |
| 100 | 11.67 | 11.67 | 23.33 |

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 filter.
- 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.



Product #
96080

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



Product #
95072

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



Product #
96064

Male CPC (Chrome) – Attached to blower unit side panel. Connects to Female CPC to remove exhaust air from unit to mattress.



Product #
96066

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



Product #
96055

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



Product #
95030

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

Product #
85723



Product #
86207



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: Control Unit – One (1) year; Mattress – Two (2) years on air cell welds; One (1) year on Bottom Cover, Manifold & Foam Base; Top Cover – 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.

Take our customer satisfaction survey and tell us what you think of our product!
Go to our Contact page at www.sunflowermedical.com

| | |
|--|---|
| Contact | Fax: 785-726-4131 |
| Resources | Email: sales@sunflowermedical.com |
| Sunflower Medical Customer Satisfaction Survey | |



Sunflower Medical L.L.C.
Customer Service Department
206 Jefferson Street
P.O. Box 276
Ellis, Kansas 67637
Phone: 1-888-321-3382
www.sunflowermedical.com

All specifications, equipment and prices are subject to change without notice. Photos and drawings are representative of the products and may vary slightly from actual production models. Contact or consult with your dealer to ensure proper equipment sizes, specifications and options. Your local distributor is responsible for manual translation for international use.