### AME 1500 Low-Air-Loss Mattress Replacement System Read Entire Manual Before Operating Device

# **User Instruction Manual**

AME1500

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# **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**
- **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 7.



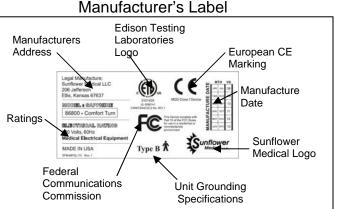
This symbol marks the location and specification of the fuse.



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.



### Power Cord Label

Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked hospital grade.



# **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.

### **Device Information**

#### PURPOSE OF THE DEVICE

The purpose of the AME1500 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 Control Unit	220V 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**

#### **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.

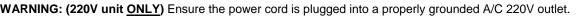
NOTE: Some cellular telephones and similar devices transmit signals while they are ON, even when not being used.

#### **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.



### AME1500

# **Operating Instructions**

- 1) Remove standard mattress from the bed.
- 2) Replace standard mattress with the AME1500 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, <u>DO NOT</u> 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) 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 <u>after</u> 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.









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

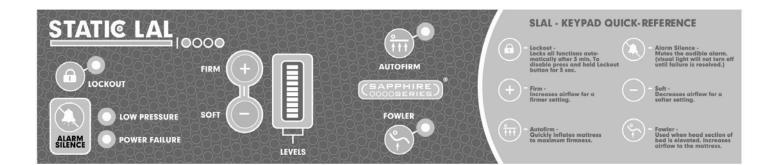
### 14) Lock-out Feature



- 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.

# **Keypad Quick Reference**





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.

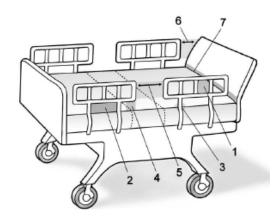
### **Disposition:**

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

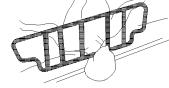


**WARNING:** Bed rail entrapment is a serious health risk that can result in serious injury or even death. Sunflower Medical L.L.C. recommends the use of bed rails if they are available. Failure to use bed rails in raised position could lead to accidental patient falls. Air mattresses have soft edges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



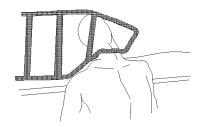




Zone Two



**Zone Three** 

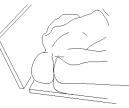


Zone Four





Zone Five







#### **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.



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

#### 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.



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.

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 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The blower is suitable for use in all establishments, including
Harmonics IEC 61000-3-2	Class A	domestic establishments and those directly connected to the public low-voltage power supply network that supplies
Flicker IEC 61000-3-3	Complies	buildings used for domestic purposes.

### 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	А	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	А	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	А	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	А	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

### Table 204 Guidance and Manufacturer's Declaration - ImmunityEquipment 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
			Portable and mobile communications equipment should be separated from the blower by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) D=(3.5/E1)(Sqrt P)
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)Vrms = 3	80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz Where P is the max power in watts
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)V/m = 3	and D is the recommended separation distance in meters.
			Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).
			Interference may occur in the vicinity of equipment containing a transmitter.

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)(Sqrt P) D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz

Compliance Level	Cond RF	Rad RF-800MHz	Rad RF - 2.5GHz
	3	3	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:

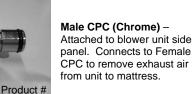
- Check the ON/OFF switch.
- Check to be sure that unit is plugged in correctly.
- Unplug the Control Unit and check fuses located near the main ON/OFF switch. Replace as necessary.
- **NOTICE:** If the troubleshooting process does not solve the problem please contact your representative for service.

# **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.



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.



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



96064

Power Cords - 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.



85723





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