

User Instruction Manual

800 System

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

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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
 Bold Face Text
 Used for regular information.
 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



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: 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 110 Volt 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 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 functions.



CAUTION: Electromagnetic Interference (EMI) may occur. Unit is susceptible to EMI or can cause EMI. Beware of Radio Wave Sources around the unit such as: Hand-held portable transceivers with the antenna mounted directly to the transmitting unit including citizen band (CB) radios, "walkie-talkies, security fire and police transceivers, cellular telephones and other personal communication devices.



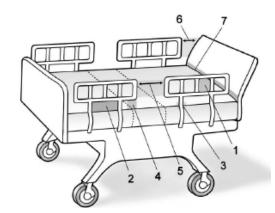
CAUTION: DO NOT use around an open flame.

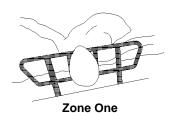
Seven Zones of Bed Rail Entrapment

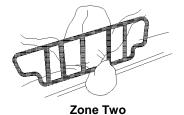


WARNING: Bed rail entrapment is a serious health risk that can result in serious injury or even death. Sunflower Medical L.L.C. recommends the use of bed rails if they are available. When using an Air Therapy system the caregiver is responsible for seeing that the mattress properly fits the bed frame. It is also the caregiver's ultimate decision whether or not to use bed rails with the patient.

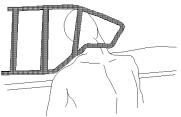
- Zone 1: Within the Rail
- Zone 2: Under the Rail, Between the Rail Supports or Next to a Single Rail Support
- Zone 3: Between the Rail and the Mattress
- Zone 4: Under the Rail, at the Ends of the Rail
- Zone 5: Between Split Bed Rails
- Zone 6: Between the End of the Rail and the Side Edge of the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



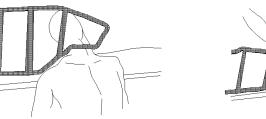


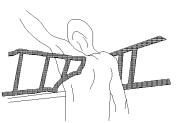






Zone Four





Zone Five





Device Information

PURPOSE OF THE DEVICE

The purpose of the AME800 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 2 air hoses with connectors that mate with the Air Pump/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 that has selector switches and indicator lights. The switches and indicators are protected under a flexible membrane to keep out liquid spills and enhance clean-up and sanitation. Inside the Control Unit is an air pump, valve motor and air valves that allow the air mattress to operate in cyclic pressure variations. The Control Unit has two user replaceable fuses near the power switch. The fuses are rated at 250 Volts, 1.0 Amp.

Unpacking and Set-up

Description of the Device:

The AME800 System consists of a control unit, a Low Air Loss Overlay Mattress and a waterproof, vapor permeable, easy-to-clean cover.

UNPACKING / PARTS BREAKDOWN:

Parts

- Air Pump/Control Unit
- True Low Air Loss Mattress



Air Pump/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.

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

DO NOT expose to moisture or areas of extreme humidity.

Beware of Electromagnetic Interference from Radio Wave Sources such as: Hand-held portable transceivers with the antenna mounted directly to the transmitting unit including citizen band (CB) radios, "walkie-talkies", security fire and police transceivers, cellular telephones and other personal communication devices.

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

Directions for Mattress Placement:

Secure Air Mattress to the frame with straps provided.

Warning or Safety Instructions relating to setup:

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WARNING: Make sure the power cord is plugged into a properly grounded A/C 110 Volt outlet.

Sapphire 800 System Operating Instructions:

- 1) Remove standard mattress from the bed.
- 2) Replace standard mattress with the SAPPHIRE SERIES® 800 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 pump on the floor away from traffic.)
- 5) Attach the air tubing to the pump unit. Ensure that the connection is correctly aligned before it is snapped in tight. (Be sure air tubing is not kinked and is unobstructed.)
- 6) Check to see that the unit is turned "off" and then plug the unit into a grounded A/C 110 volt outlet.
- 7) Turn master power switch to the "on" position.
- 8) The Low Pressure yellow LED light indicates that the air mattress is not fully inflated. Press the Alarm Reset button to mute the alarm. When the pressure is reached, the Normal Pressure green LED will come on. Press the Alarm Reset button again to reactivate the alarm.
- 9) Turn the dial to the firmest position for overlay mattress inflation. The mattress will take approximately thirty minutes to air up with the pump.
- 10) Place the patient on the overlay mattress after it is completely inflated.
- 11) To set comfort level, turn the dial to corresponding setting for a firm or soft mattress.
- 12) Press the Static/Alternate button to switch between static and alternating modes. The LED will light up in Static mode.
- 13) For quick deflation or for CPR use:
 - a. Turn power off.
 - b. Twist CPR plug 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.

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.



- 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.)
 - 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).

Pump 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.



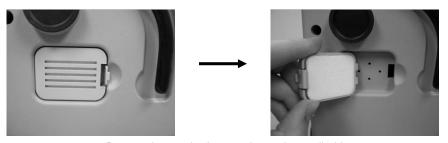
- C. Hypercarbonate and phenol based solutions should not be used.
- D. Make sure unit is turned "off" and unplugged before cleaning.

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 ordered. 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:

Foam air filter on the back of the control unit must be cleaned periodically with soap and warm water. Replacement of the foam filter is recommended every 6 months.



Remove the tan plastic cap to locate the small white filter underneath.

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





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 pump. 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.