

User Instruction Manual

Sapphire 1100 and 1100 EC

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 1100 & 1100EC 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
 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



Symbols Found on Blower Unit

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



Replace fuse as marked

fuse.

This symbol marks the location and specifications of the fuses.

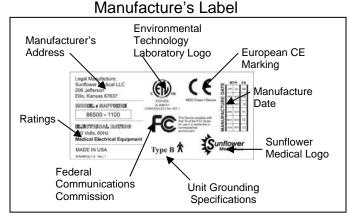
Replace fuse This is a 5amp 250 volt in-line

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





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: 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 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 unit 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.



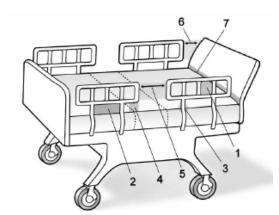
CAUTION: DO NOT use around an open flame.

Seven Zones of Bed Rail Entrapment

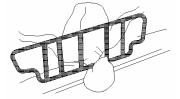


WARNING: Bed rail entrapment is a serious health risk that can result in serious injury or even death. Sunflower Medical L.L.C. recommends the use of bed rails if they are available. Failure to use bed rails in raised position could lead to accidental patient falls. Air mattresses have soft edges that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



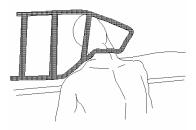


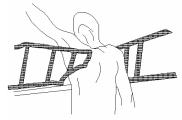




Zone Two

Zone Three





Zone Four

Zone Five





Device Information

PURPOSE OF THE DEVICE

The purpose of the Sapphire Series 1100 & 1100EC 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 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 a variable output blower, a valve motor and air valves that allow the air mattress to operate in static mode or provide alternating pressure variations within the mattress. There is also a printed circuit board, which provides the electrical controls. The Control Unit has two user replaceable 250v 5.0 amp fuse near the AC Power Cord Entry.

Specifications

Standard Features

Feature	Dimension
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

Feature	Dimension
Low Air Loss	Yes
Fowler Positioning	Yes
Alternation Therapy	Yes

Electrical Characteristics

Feature	Dimension
Rated Voltage	110 Volts
Rated Frequency	60Hz
Rated Input Power	120 Volts
Fuse Rating	250 Volts 5 Amp
Power Failure Alarm	Yes

Patient Characteristics (for standard size)

Feature	Dimension
Max. Patient Height	78" (198.12 cm)
Max Patient Width	26" (66.04 cm)

Unpacking and Set-up

Description of the Device:

The Sapphire Series 1100 & 1100EC 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:

<u>Parts</u>

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

<u>\</u>

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

Sapphire 1100 and 1100 EC Operating Instructions:

- 1) Remove standard mattress from the bed.
- 2) Replace standard mattress with the Sapphire Series 1100 or 1100EC 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** lay 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) Plug unit into grounded A/C 110 volt outlet.
- 7) Turn master power switch, located on the side of the unit, on.
- 8) Press the **Autofirm** button for quick inflation.
- Placed the patient on the bed <u>after</u> inflation to insure the air cells do not become twisted or kinked.
- 10) To get the control unit out of **Autofirm** mode, press **Autofirm** button again.
- 11) Static Mode
 - a. Press the Mode button until the Static option light comes on.
 - b. Set the desired comfort level with the Soft/Firm buttons
- 12) Alternating Mode
 - a. Press the **Mode** button until the **Alternate** option light comes on.
 - b. Set the desired cycle time with Cycle Time buttons (3-20 minutes)
 - c. Set the desired comfort level with the Soft/Firm buttons.

13) Fowler Feature

a. When elevating the head section of the mattress, press the Fowler button to increase airflow for seat inflation.

14) Lock-out Feature



- a. After 3 minutes, if there are no changes to the blower settings, the lockout feature will activate.
- b. Press and hold the Lock-out button for 5 seconds to disengage the lock-out feature.

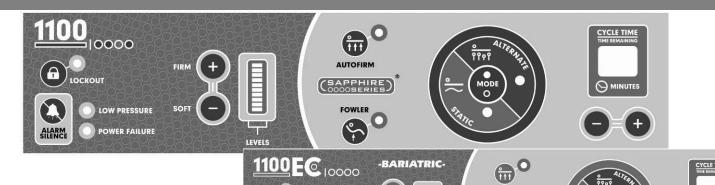
15) For quick deflation or for CPR use:

- a. Turn power off
- b. Twist CPR plug on the mattress to open.
- 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 transportation.

For Inquires Call 1-888-321-3382

Keypad Quick Reference





Lockout -

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



(SAPPHIRE)

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.



Cycle Time-

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



Mode-

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

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

Shows control panel layout for the blower unit and optional percussion 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.



- 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).

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 warm soap and 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:

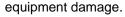
Once the unit has reached the end of its useable life, contact your representative for service, disposition or replacement.

Trouble Shooting Guide



WARNING: Only authorized personnel should engage in the troubleshooting process.

Troubleshooting by unauthorized persons could result in personal injury or





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 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 CPC to remove exhaust air from unit to mattress.



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



Power Cords – Grounded power cord for providing power to the blower unit.



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 items, 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 items placed on the RAN within five working days from the date of the RAN to Sunflower Medical LLC. Without an Authorized RAN, all items will be returned to the customer at the customer's expense.

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

Sunflower Medical LLC: Replacement for wrong Items shipped, RAN form must also be completed, and then items 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.

Take our customer satisfaction survey and tell us what you think of our product!

Go to our Contact page at www.sunflowermedical.com





Sunflower Medical L.L.C.Customer Service Department

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