# User Manual

# SAPPHIRE SERIES® 1100 & 1100EC Mattress Replacement System


Sunflower Medical L.L.C.

SAPPHIRE SERIES®

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Sunflower

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# Definition of Symbols

## Manual Definitions

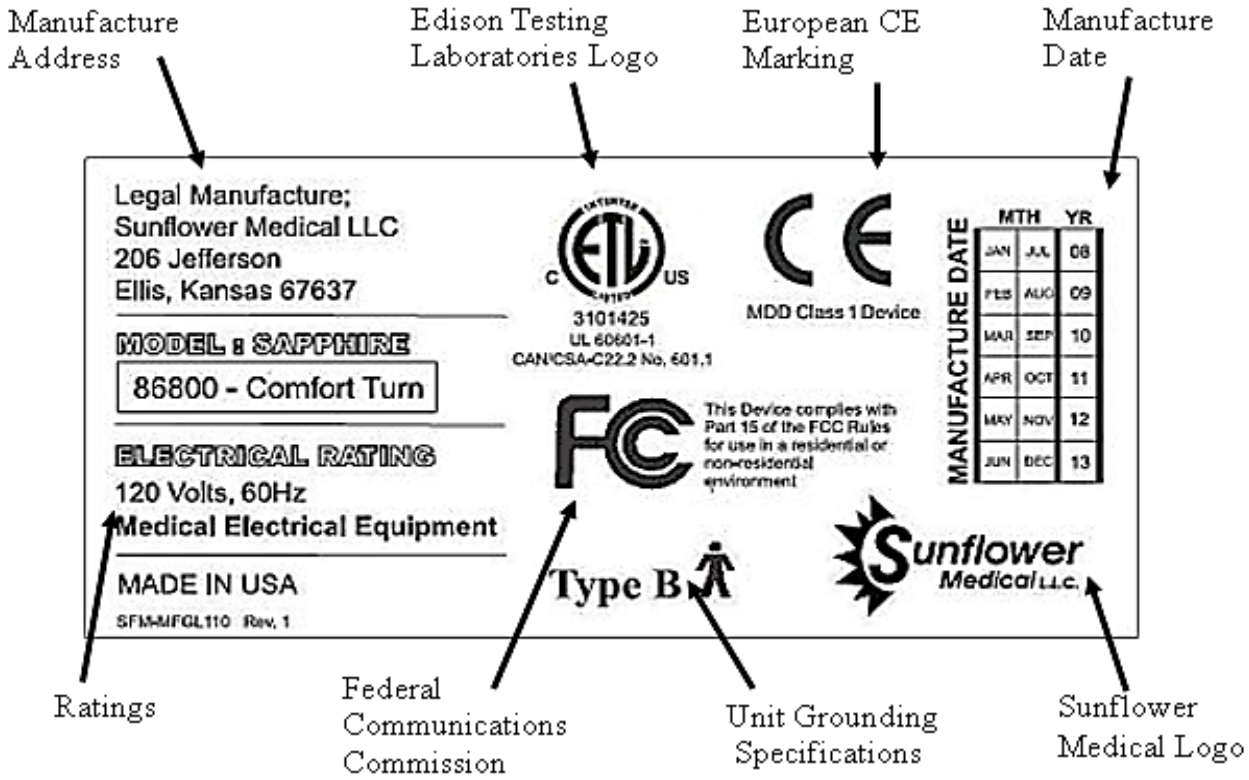
Throughout this manual different type fonts and icons are used to aid user readability and understanding of the content. Below are some examples.

— Standard Text — Used for regular information.
— **Bold Face Text** — Emphasizes a word or phrase.
— **NOTE:** — Sets apart special information or important instruction clarification.

## Warnings and Cautions

**Warnings/Cautions:** This symbol is intended to alert the user to the presence of important operating, maintenance or servicing instructions. Disregarding a warning could result in patient and/or user injury as well as damage to equipment.

**Electrical Shock Hazard Warning:** This symbol is intended to alert the user to the presence of electrical shock hazards. It is important to follow all instructions and special procedures to avoid electrical shock to the operator, care provider and/or patient.



Power Cord Label

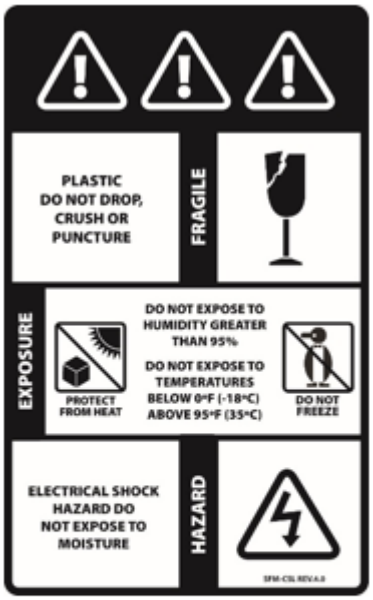


This symbol marks the location of the leakage test point screw.

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


This symbol marks the location and specification of the fuse.






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

# Device Information

## Description of the Device

The SAPPHIRE SERIES® 1100 & 1100EC Clinically Effective Low Air Loss Mattress System is comprised of a specialized inflatable air bladder (air mattress) and an electrically powered Control/Blower Unit.

## Purpose of the Device

The purpose of the SAPPHIRE SERIES® 1100 & 1100EC Clinically Effective 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 hospital bed frame. The air mattress serves as a replacement to the original mattress and is equipped with 4 air tubes with connectors that mate with the Control Unit. The Control Unit is a self-contained, totally enclosed module that hangs by hinged hooks on the footboard of the bed. If the footboard is too wide, hang a control unit hanger bar on the footboard. If no hanger bar is available, use best judgment on blower placement.
**NOTE: Do Not Place Control Unit Under The Bed!**

The Control Unit is provided with a detachable hospital grade electrical cord and has 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 is a variable output blower and manifold that allow the air mattress to operate in a static mode or provide alternating pressure variations within the mattress. There is also a printed circuit board which operates the electrical controls.

## Indications for Use

The SAPPHIRE SERIES® 1100 & 1100EC is a therapeutic mattress that provides either active or reactive pressure redistribution and clinically effective low air loss therapy. When mobility, moisture and/or inactivity are healthcare concerns, it is indicated for the prevention and treatment of pressure ulcers and other skin related injuries.

# Specifications

**SAPPHIRE SERIES® 1100 & 1100EC**

**Control Unit**

- **Mode of Use…** For Indoor Use Only
- **Duty Cycle**..... Continuous
- **Controller Dimensions**..... (LxWxH) 6”(15 cm) x 16”(41 cm) x 10.5”(27cm)
- **Controller Weight**..... 11 Lbs. (4.98 kg)
- **Operating Temperature**..... -18°C to 35°C (0°F to 95°F)
- **Alternating Low Air Loss**..... 3 minutes-20 minutes
- **Alarms**.....Power Failure and Low Pressure

**Electrical**

- **Rated Voltage/s**.....110 Volts and 220 Volts
- **Rated Frequency 110 Volts/Input Power**.....60Hz/120 Volts
- **Rated Frequency 220 Volts/Input Power**.....50Hz/230 Volts
- **Degree of Shock Protection**.....Type B
- **Maximum Relative Humidity**.....95%
- **Storage Temperature**.....-18°C to 35°C (0°F to 95°F)
- **Environmental Conditions**…Product must be stored and transported in packaging free of moisture and dust
- **Power Cord**.....16’ (5 meters) detachable with hospital grade plug
- **Fuses 110 Volt**.....T300mA 250V…T5A 250V
- **Fuses 220 Volt**.....T2.5A 250V

**Mattresses**

- **1100 Standard Dimensions 35”**.....(LxWxH) 80”(203.2cm) x 35”(88.9cm) x 8”(20.3cm)
- **1100 Standard Weight Capacity 35”**.....up to 600 lbs (272.35 kg)
- **1100EC Standard Dimensions** .....(LxWxH) 80”(203.2cm) x (see note below x 8”(20.3cm)
- **1100EC Standard Weight Capacity** .....up to 1000lbs (453 Kg)
- **Top Cover Material:** 70 Denier Polyurethane Coated Nylon Taffeta

NOTE: The 1100EC offers several options for widths. 39”, 42”,48”, and 60”.

# Unpacking and Set-Up Instructions

The two principle components of the Sapphire Series® 1100 & 1100EC Mattress Replacement System are a specialized air inflatable bladder (Air Mattress) and an electrically powered, Air Control Unit.

## Unpacking / Parts Breakdown:

**Parts:**

- Control Unit
- Detachable Power Cord (Hospital Grade)
- Clinically Effective Low Air Loss Mattress Replacement
- Mattress Cover
- Optional Expandable

Control Unit

Detachable 16' Hospital Grade Power Cord

Clinically Effective Low Air Loss Mattress with Cover

1100

1100EC

**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 below 0°F (-18°C) or above 95°F (35°C).
DO NOT expose to moisture or areas of humidity greater than 95%.

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**: Replace the existing bed mattress with Clinically Effective Low Air Loss Mattress. Secure Air Mattress to the bed frame with straps provided.

**Warning or Safety Instructions relating to setup:** WARNING: (120V unit ONLY) Make sure the power cord is plugged into a properly grounded hospital grade 120V A/C outlet.

**Warning or Safety Instructions relating to setup:** WARNING: (220V unit ONLY) Make sure the power cord is plugged into a properly grounded hospital grade 220V A/C outlet.

# Operating Instructions

The Sapphire Series® 1100, 1100EC & the Optional 39/48 Expandable Mattress Replacement System can be placed on any conventional bed used in hospitals, nursing homes or a home medical bed. The original bed mattress should be removed and stored in an appropriate place. The following steps should be completed in installing the system:

1. Remove standard mattress from the bed.
2. Replace standard mattress with the Sapphire Series® 1100, 1100EC & the Optional 39/48 Expandable Mattress Replacement System ™. (Be sure air tubing is at the foot end of the bed).
3. Strap air support mattress to bed frame on all four sides with straps provided.
4. Place Control Unit on the footboard of the frame using the two hinged hooks located on the back of the unit.
5. Attach the air tubing to the Control Unit, being sure it snaps in tight. (Be sure air tubing is not kinked and is unobstructed).
6. Plug the control unit into a grounded hospital grade A/C outlet.
7. Turn the master power switch ON, located on the side of the unit.
8. Press the AUTO FIRM button for quick inflation. (see keypad quick reference section)
9. Place the patient on the bed AFTER inflation to ensure the air cells do not become twisted or kinked.
10. After inflation, press the AUTO FIRM button again to exit Auto Firm mode. (If the Control Unit is left in Auto Firm mode for 10 minutes then it will automatically return to the previous mode of operation).

## Modes of Operation

**NOTE: See Keypad Quick Reference (table of contents) for further illustration.**

### 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

### Alternating Mode

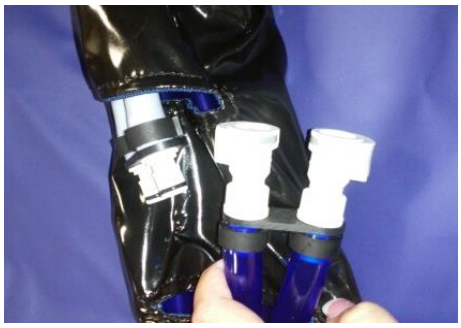
c. Press the **Mode** button until the **Alternate** option light comes on.

d. Set the desired cycle time with Cycle Time buttons (3-20 minutes)

e. Set the desired comfort level with the Soft/Firm buttons.

## Optional Expandable

f. By attaching the connectors within the tubing connecting to the control unit the mattress expands from 39” (100cm) to 48” (120cm).



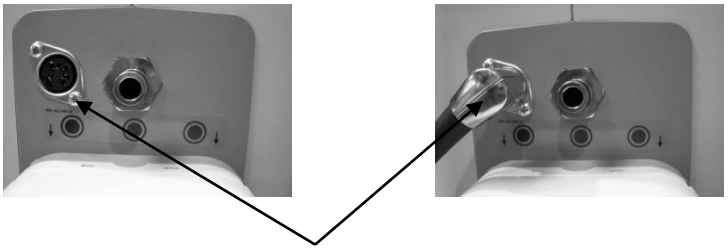
## Fowler Mode

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

## Auto Fowler attachment (Optional)

h. 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.

## Lock-out Feature

i. After 3 minutes, if there are no changes to the control unit settings, the lockout feature will activate.

j. Press and hold the lock-out button for 3 seconds to disengage the lock-out feature.

2) **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 transport.

***For Inquiries Call 1-888-321-3382***

# Patient Care Functions

## Placing the Patient on the Mattress Surface

Place the patient on the mattress surface from a bed or stretcher with a transfer device. The mattress should be set in the Auto Firm mode. In order to ensure proper immersion and envelopment of the patient, the user should:

1. Position patient on surface in center of bed.
2. Initialize soft/firm settings on control unit.
3. Wait a moment to allow internal sensors to activate pressure redistribution. Generally, depending on patient body makeup, initial pressure redistribution is complete in approximately 2-3 minutes.
4. Elevate the head of the bed to at least 30 degrees.
5. Unzip the mattress and visually inspect the height of the cells for sufficient inflation. There should be several inches between the patient and the frame of the bed. Adjust the air flow accordingly. Ask the patient if they can feel the bed frame beneath them. If yes, add air incrementally. Repeat until patient no longer feels the frame beneath them.
6. If the patient cannot reply verbally, unzip the mattress and visually inspect the height of the cells for sufficient air inflation. There should be several inches between the patient and the frame of the bed. Adjust the air flow accordingly.
7. CPR: The standards for life support recommended by the American Heart Association for performing CardioPulmonary Resuscitation (CPR) recommend a hard level surface for performing CPR, moving the person to the floor if possible. For performing CPR, place the CPR board, lower the head of the bed, position the patient on their back and follow standard CPR procedures of the facility.

## Positioning the Patient

When moving a patient the control unit should be in the Auto Firm Mode.

To reposition the patient, change the control unit to Auto Firm Mode. This makes the mattress surface firm and facilitates the repositioning of the patient with less strain on the care provider. When the patient has been repositioned, press auto firm to return to the previous setting.

**NOTE:** DO NOT leave a patient unattended on the mattress surface with the safety side rails in the down position. When leaving a patient, secure the safety side rails in the up position. Make sure the safety side rails are high enough to properly protect the patient when the mattress is fully inflated, while continuing to be mindful of the FDA guidelines on bed rail entrapment.

## Backrest Up or Fowler Position

When the patient's backrest is elevated, it may be necessary to manually increase the mattress firmness to compensate for the additional weight placed in the center portion of the mattress. Observe the patient for a short time after raising the backrest to make sure the buttocks and thigh areas are not "bottomed-out".

## Prone Position

DO NOT leave a prone patient on the mattress surface. If the patient is unable to move without help, the patient's airway may be compromised. If the patient is to be kept prone for an extended period of time, consult a Sunflower representative for assistance.

## Bedpan Placement & Removal

Position the patient's hips over the center of the mattress. Using Static Mode, lower the pressure setting with the Firm/Soft button. Turn the patient into the side-lying position and place the bedpan.

The pressure in the center section of the mattress will lower to make inserting the bedpan easier. The firmness setting may be adjusted to increase the firmness of the center section after the pan is placed in position.

When the bedpan is to be removed, logroll the patient off the bedpan and remove it. Readjust the firmness level to the appropriate setting. Select Static mode and wait for the mattress to completely re-inflate before activating Alternate Pressure mode again.

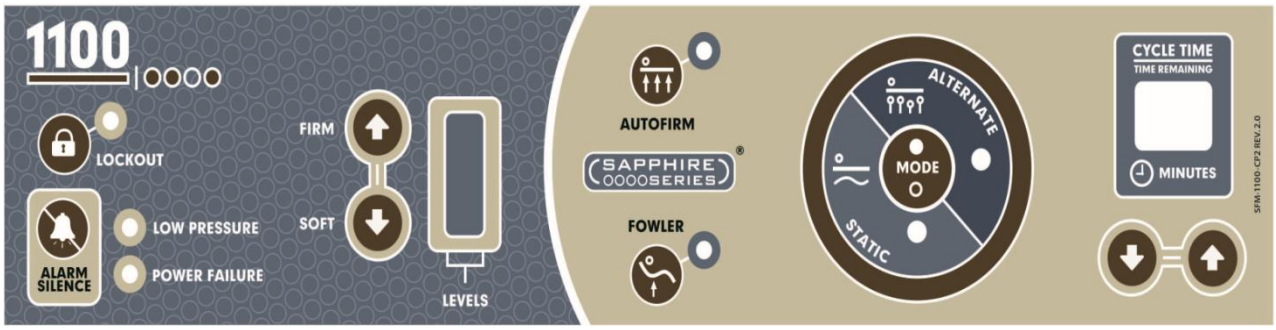
**NOTE:** Always remove the bedpan before entering the Alternate mode.

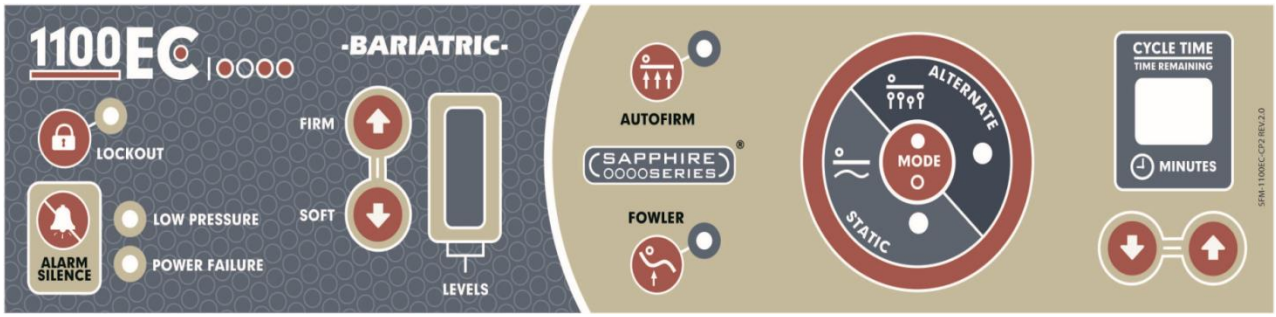
## Removing the Patient from the Mattress Surface

If the patient is to be removed with a transfer lift, set the control unit into Auto Firm mode. Allow the mattress to firm and position the patient into the lift. When the patient has exited the bed, the controller can be turned off.

If the patient can sit up and is mobile, lower the firmness level to the lowest setting and wait for the mattress to soften in the middle. The patient can sit up and the mattress will conform to the body making a more stable platform for patient egress. When the patient has exited the bed, the controller can be turned off.

# Keypad Quick Reference




Firm. Increases airflow for a firmer setting.

Soft. Decreases airflow for a softer setting.

Cycle Time. Increases or decreases the time of cycle between 3 to 20 min.


Press to switch between Alternate and Static operations.

Static. Enables static with pressure sensors regulating airflow

Alternate. Enables alternation with pressure sensors regulating airflow. Alternation times are preset at 3 min. and can be adjusted up to 20 min.

**Fowler. Use when head section of bed is elevated. Increases airflow to the mattress.**

**Cycle Time. Increases or decreases the time of cycle between 3 to 20 min.**

**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.)**

This chart is to be used as a reference ONLY. Final patient settings must be completed by the patient's caregiver.

# Maintenance

**CAUTION:** The mattress requires regular maintenance to ensure performance and avoid premature wear, damage and injury.

Check the items on this chart at the indicated intervals. If any of the items are loose, worn, bent or distorted immediately have them checked and/or repaired by an authorized Sunflower technician. Frequent maintenance and servicing will improve performance and extend product life.

| | Weekly | One Month | Three Months |
|---|---|---|---|
| Air Filter | X | | |
| Top Cover | | X | |
| Mattress Base | | X | |
| Mattress Connections | | | X |
| Control Unit Operation | | | X |
| Power Cord | | | X |

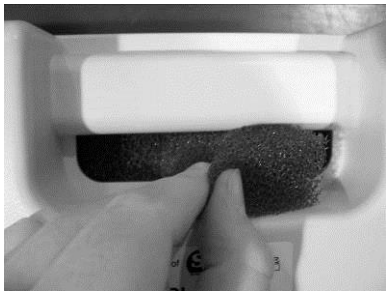
The following is an equipment safety checklist that can be used with the maintenance chart to maintain and service this product:

- Inspect top cover for punctures, rips, tears or damage.
- Inspect mattress base for punctures, rips, tears or damage.
- Connect the control unit and verify proper operation (if installed).
- Ensure air filter is clean and properly installed into control unit (if installed).
- Ensure mattress is clean/disinfected and patient ready.

All power cords are fastened in a manner to keep them free from moving or pinching parts. At any time parts are replaced, all cords should be secured into proper position to prevent damage.

## Air Filter

The foam air filter on the back of the control unit must be cleaned weekly with disinfectant solution. Replacement of the foam filter is recommended every 6 months.



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

# Mattress Cleaning Instructions

**WARNING and CAUTION:**

It is recommended that gloves and protective clothing be worn at all times during cleaning and disinfecting.

DO NOT autoclave.

**NOTE:** Improper cleaning, rinsing or the incorrect use of cleaning agents can lead to premature fabric discoloration and breakdown of the fabric's fluid-resistance, stain-resistance and fabric strength. Properly rinsing all cleaning agents and disinfecting chemicals is a critical step in extending the life of covers on medical mattresses and support surfaces.

Over time, cleaning solutions may cause damage to the integrity of the fabrics used for support surfaces. Cleaning agents that are strong enough to be efficacious cleaners and disinfectants may cause degradation of the same fabrics on which they are being used.

To minimize the negative impact of cleaning agents:

- Contact time must be monitored and kept to the required time identified on the manufacturer's instructions.
- All cleaning solutions must be diluted in accordance with manufacturer's instructions.
- All covers must be rinsed after every cleaning cycle. Rinsing of the support surface covers with clean water as the immediate step after the disinfection process is fundamental to extending the usable life of the covers.

**NOTE:** Only the outer cover of the mattress requires cleaning and maintenance. Disassembly of the support surface for maintenance of internal components is not recommended. DO NOT use harsh solvents or cleaners. Special care should be used to not puncture the mattress with needles or sharp instruments. This may result in loss of integrity of the mattress cover or internal components.

**Recommended EPA Registered Disinfectants:**
Wex-Cide 128 (Wexford Labs), EPA Reg. #34810-31

Equipment must be disinfected using an EPA registered, hospital-grade disinfectant, according to the manufacturer's recommendations for use.

**Recommended Stain Remover(s):**
Stain Away (ABC Compounding)

This stain remover is effective in removing most difficult stains and is intended to be used in its original concentration.

***Clostridium difficile* (C. diff) Prevention:**
Clorox Germicidal Wipes (Clorox Professional Products Company), EPA Reg. #67619-12

These pre-moistened wipes meet the CDC's recommendations for *Clostridium difficile* (C.diff) bacteria, after the manufacturer's recommended "wet contact time".

1. Perform hand hygiene using soap and warm water, or hand sanitizer, and then put on disposable gloves and eye protection.
2. Use wipes to wipe the top and front of head/footboards, hand controls and cords, side rails and mattress top cover, making sure to wipe between the mattress and side rails.
3. Change wipes often to ensure that surfaces remain wet with disinfectant for the manufacturer's required contact time. Used wipes are to be discarded in the trash.
4. Remove disposable gloves and discard in the trash; perform hand hygiene using soap and warm water, or hand sanitizer, and then remove eye protection.

To reduce the discoloration of fabrics and degradation of the sleep surface lining, surfaces must be thoroughly rinsed with clean, fresh water to remove chemical residues immediately after the manufacturer's recommended "wet contact time" has been reached. The use of bleach-based solutions must be avoided whenever possible.

## Mattress Top Cover:

Personal Protective Equipment should always be used as directed by the disinfectant's Material Safety Data Sheet.

1. Prepare the disinfectant according to the manufacturer's recommendations.
2. Prepare a separate bucket of warm, fresh water to be used for rinsing the equipment after cleaning/disinfecting procedures are completed as instructed.
3. All surfaces of the mattress are to be wiped using a coarse cloth dampened with the disinfectant, prepared as directed by the manufacturer's recommendations, to remove organic material and visible soil.
4. Allow the mattress shell to remain wet with disinfectant solution for the manufacturer's recommended contact time.
5. Stains on the mattress top cover may be treated using an approved stain remover, according to the manufacturer's recommendations.
6. Rinse all surfaces of the mattress with fresh water and clean cloth to remove chemical and organic residue.

## Laundry Instructions:

If additional cleaning is necessary, top covers may be removed and laundered using standard hospital disinfectant/detergent. **DO NOT use temperatures in excess of 120°F (49°C).**

1. Set washing machine to Regular Cycle.
2. Pre-soak with disinfectant/detergent in cold water for 10 minutes. DO NOT USE HARSH SOLVENTS OR CLEANERS.
3. Main wash cycle: 15 minutes (time dependent on soil level).
4. Rinse cycle: 5 minutes, minimum.
5. Spin/Drain cycle: 5 minutes, minimum.

After washing, the mattress top cover is to be air dried or dried in a dryer at very low or no heat to protect it from heat related damage.

## Mattress Base:

1. Prepare the disinfectant according to the manufacturer's recommendations.
2. Prepare a separate bucket of warm, fresh water to be used for rinsing the equipment after cleaning/disinfecting procedures are completed as instructed.
3. All surfaces of the mattress are to be wiped using a coarse cloth dampened with the disinfectant, prepared as directed by the manufacturer's recommendations, to remove organic material and visible soil.
4. Allow the mattress shell to remain wet with disinfectant solution for the manufacturer's recommended contact time.
5. Stains on the mattress base may be treated using an approved stain remover, according to the manufacturer's recommendations.
6. Rinse all surfaces of the mattress with fresh water and a clean cloth to remove chemical and organic residue.
7. After washing, the mattress base must be allowed to air dry.

## Air Therapy Internal Mattress Components:

1. Prepare the disinfectant according to the manufacturer's recommendations.
2. Prepare a separate bucket of warm, fresh water to be used for rinsing the equipment after cleaning/disinfecting procedures are completed as instructed.
3. Using a clean cloth dampened with the disinfectant solution, wipe all internal mattress surfaces, including the air cells, and allow to remain wet for the manufacturer's recommended contact time.
4. Rinse all surfaces of the air cells with fresh water and clean cloth to remove chemical and organic residue.
5. After cleaning, dry the internal air cells with a clean, dry cloth.
6. After all mattress components are dry, reinstall the top cover.
7. Store the mattress in a "clean" environment until the next use.

**NOTE:** Only the outer cover of the mattress requires cleaning and maintenance. Disassembly of the support surface for the maintenance of internal components is not recommended. DO NOT use harsh solvents or cleaners. Special care should be used to not puncture the mattress with needles or sharp instruments. This may result in loss of integrity of the mattress cover or internal components.

## Cleaning Blood and Other Excretions:

Blood and other excretions should be wiped up while wet, if possible. These substances are more difficult to remove once they have dried to surfaces. Dried blood and other excretions are to be removed using ample disinfectant solution in order to moisten the substance and make it easier to clean.

## Control Unit Cleaning Instructions:

**NOTE:** Hand clean only. DO NOT place in sterilization room or chamber.

1. Personal Protective Equipment should be used as directed by the Material Safety Data Sheet for the disinfectant.
2. Prepare the disinfectant according to the manufacturer's recommendations.
3. Turn off the control unit and disconnect it from all electrical power to avoid electrical shock.
4. When cleaning the control unit avoid excessive moisture, especially in areas where there are electrical connections and components, to prevent damage.
5. All surfaces of the control unit and the power cord are to be wiped using a coarse cloth, dampened with the disinfectant solution prepared as directed by the manufacturer's recommendations, to remove organic material and visible soil.
6. Allow the control unit to remain wet with disinfectant solution for the manufacturer's recommended contact time.
7. Rinse all surfaces of the control unit with fresh water and use a clean cloth to remove chemical and organic residue.
8. After cleaning, all surfaces are to be dried with a clean, dry cloth.

Control unit air filters must be cleaned weekly. Replacement of the control unit air filter is recommended every 6 months.

1. Remove the air filter located on the back of the control unit.
2. Clean with prepared disinfectant solution and allow to air dry.
3. Reinstall the filter when dry.

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

# Safety Tips

## Seven Zones of Bed Rail Entrapment

If the patient would have any clinical conditions that could result in risk of falling or improperly lying in bed, the bed should be left at its lowest setting and in flat position when not attended. The use of bed rails is recommended if they are available. There are seven zones of bed rail entrapment.

**WARNING:** Bed rail entrapment is a serious health risk that can result in serious injury or even death. Sizewise recommends the care provider be mindful of the FDA guidelines relevant to bed rail entrapment, as serious injury can result. These guidelines can be found on the FDA website. When using an Air Therapy system the care provider is responsible for ensuring the mattress properly fits the bed frame. It is also the care provider'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

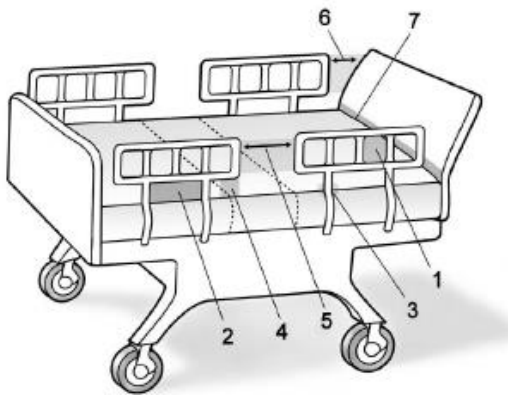
**Zone 3:** Between the Rail and the Mattress

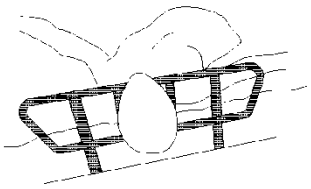
**Zone 4:** Under the Rail, at the Ends of the Rail

**Zone 5:** Between Split Bed Rails

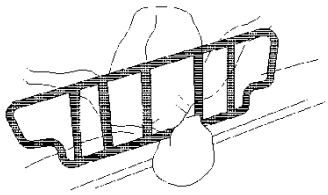
**Zone 6:** Between the End of the Rail and the Side Edge of the Head or Footboard

**Zone 7:** Between the Head or Footboard and the Mattress End

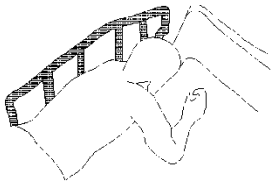


**Zone One**



**Zone Two**



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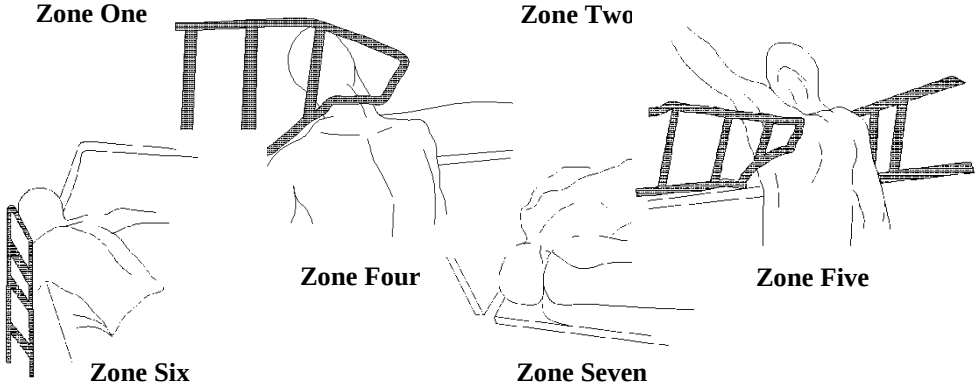


**Zone Four**

**Zone Five**

**Zone Six**

**Zone Seven**

## Storage and Disposal

Keep the mattress in a clean dry area, away from heat or flames. Store the unit and mattress in a temperature range between 0°F (-18°C) and 95°F (35°C). Always store the surface flat on a clean, level surface. Avoid storage of other equipment on top of the support surface. DO NOT expose the control unit to humidity greater than 95%.

End-of life products must be disposed of properly according to local laws and regulations. Please contact Sunflower or your local authorities for disposal and recycling options.

# Important Safety Instructions

**Unpacking and Set-Up Instructions**

- Keep out of direct sunlight.
- DO NOT expose to temperatures greater than 35°C (95°F) or below -18°C (0°F).
- DO NOT expose the blower unit to humidity greater than 95%.
- (110V unit ONLY) Ensure the power cord is plugged into a properly grounded AC 110V outlet.

**Safety Tips**

- Medical equipment should not be used, stacked or located on or around equipment that may create electromagnetic interferences.
- Using other manufacturers' cables and accessories may affect EMC performance. Unauthorized use of these items will void warranty and could result in patient and/or user injury as well as damage to equipment or other property.
- The use of cables or accessories other than those for which the blower was designed or tested can significantly degrade emissions and immunity performance.
- DO NOT use the device if the power cord is cut, frayed or loosely connected.

**Mattress Cleaning Instructions**

- It is recommended that gloves and protective clothing be worn at all times during cleaning and disinfecting.
- DO NOT autoclave.
- The mattress requires regular maintenance to ensure performance and avoid premature wear, damage and injury.

**Troubleshooting**

- Only authorized personnel should engage in the troubleshooting process. Troubleshooting by unauthorized persons could result in personal injury or equipment damage.
- To avoid electrical shock, DO NOT open the control unit. Refer servicing to qualified personnel only.

# Electromagnetic Compatibility (EMC)

The Sapphire Series® 1100 & 1100EC has been tested for compliance with the EMC requirements. The guidelines in this section will help to ensure the 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 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 60601-1-2:2007.

All pins of connectors have passed ESD testing.

**List of Cables & Accessories**
Replacement parts, such as cables and accessories, must be purchased through Sunflower to ensure proper compliance requirements.

**WARNING**: Using other manufacturer's cables and accessories may affect EMC performance. Unauthorized use of these items will void warranty and could result in patient and/or user injury as well as damage to equipment or other property.

The use of cables or accessories other than those for which the blower was designed or tested can significantly degrade emissions and immunity performance.

**GUIDANCE AND MANUFACTURER'S DECLARATION**
**Company: Sunflower Medical L.L.C.**
**Model: Sapphire Series® 1100 and 1100EC**
**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 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 domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics IEC 61000-3-2 | Class A | |
| Flicker IEC 61000-3-3 | Complies | |

**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<br>IEC 61000-4-2 | ±6kV Contact<br>±8kV Air | A | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30% |
| EFT<br>IEC 61000-4-4 | ±2kV Mains<br>±1kV I/Os | A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1kV Differential<br>±2kV Common | A | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips/Dropout<br>IEC 61000-4-11 | >95% Dip for 0.5 Cycle<br><br>60% Dip for 5 Cycles<br><br>30% Dip for 25 Cycles<br><br>>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<br>IEC 61000-4-8 | 3A/m | A | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |

**Table 204 Guidance and Manufacturer's Declaration - Immunity**
**Equipment and Systems which 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 |
|---|---|---|---|
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 VRMS .15 MHz to 80 MHz<br><br>3 V/m 80 MHz to 2.5 GHz | (V1)VRMS = 3<br><br>(E1)V/m = 3 | Portable and mobile communications equipment should be separated from the blower by no less than the distances calculated/listed below:<br><br>D = (3.5/V1) (SQRT P)<br><br>D = (3.5/E1) (SQRT P)<br>80 to 800 MHz<br><br>D = (7/E1) (SQRT P)<br>800 MHz to 2.5 GHz<br><br>Where P is the max power in watts and D is the recommended separation distance in meters.<br><br>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).<br><br>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 which are <u>NOT</u> 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 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 |

# Troubleshooting

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

**WARNING:** To avoid electrical shock, DO NOT open the control unit. Refer servicing to qualified personnel only.

**If mattress is not inflating:**

- Check that the hoses are not punctured, kinked or disconnected
- Check for proper connections from the hoses to the blower. Make sure they are secure.
- Check air filters on back of control unit and clean if necessary
- Ensure CPR function is in the closed position

**If there is power loss:**

- Check the ON/OFF switch
- Check power cord for any damage
- Unplug the Control Unit and check fuses located near the main ON/OFF switch. Replace fuse/s as necessary.
- Ensure unit is plugged into a Hospital grade receptacle.

**NOTE:** If the troubleshooting process does not solve the problem please contact a Sunflower representative for service.

# Frequently Ordered Parts

The following is a list of parts that are frequently ordered for self-replacement and repairs. To aid 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 # 27400035

**Connector** – Connects from mattress to the control unit side panel. Allows air movement to inflate mattress.


Product # 27400048

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


Product # 27400049

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


Product # 27400050

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


Product # 27000445

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


Product # 27400045

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


Product # 27502020

Product # 27502011

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

# Warranty Information

**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:**

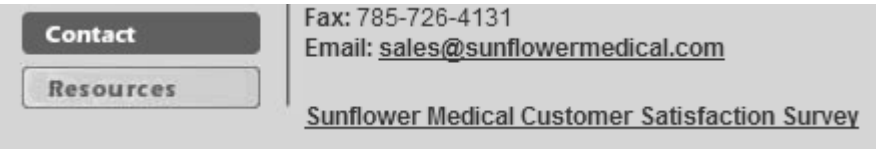
Warranty: Sunflower Medical LLC; Warrants that all products provided under this agreement are free from defects in material and workmanship, for the following stated warranty period from the date of delivery.

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**



**Sunflower Medical L.L.C.**
Customer Service Department
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Ellis, Kansas 67637
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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.