User Manual

SW Rotate™ Mattress System

SIZEWISE™

#8067 Rev. 7.0

03.04.2021

User Manual

Table of Contents

Definition of Symbols

Manual Definitions

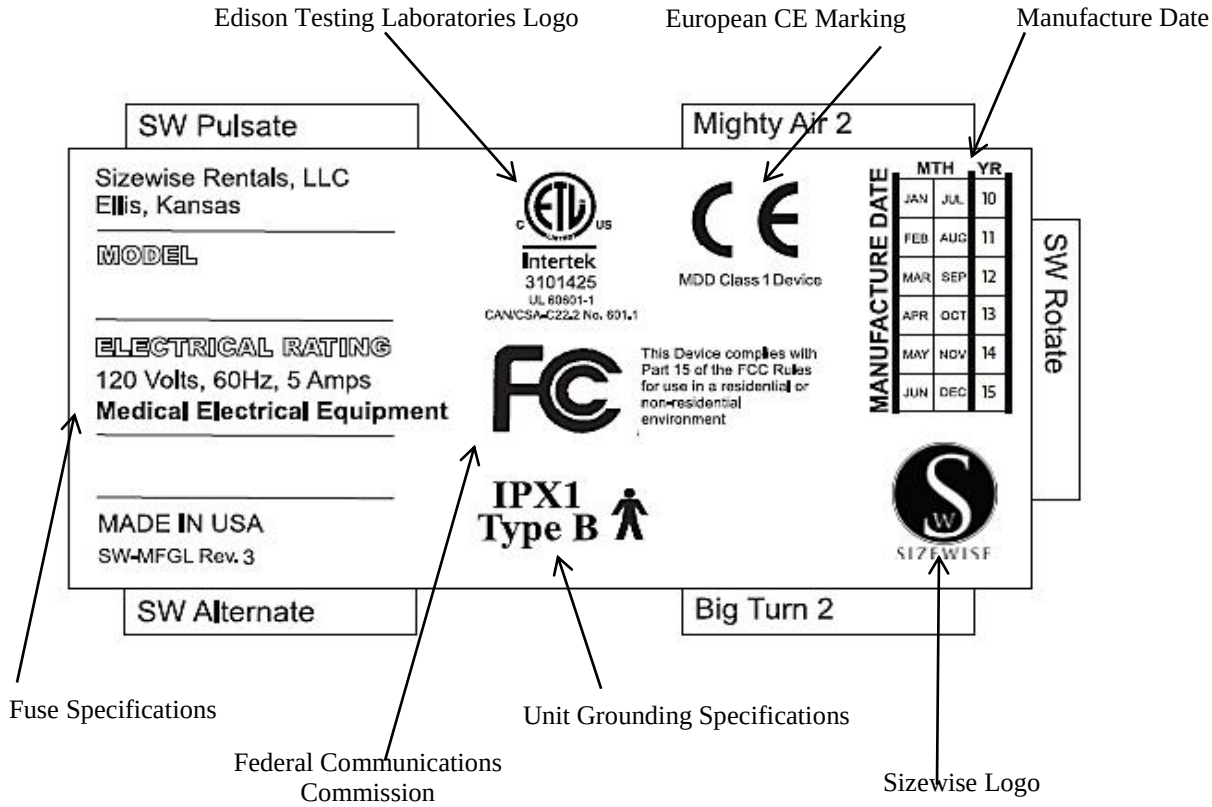
Throughout this manual different type fonts and icons are used to aid user readability and understanding of the content. Below are some examples.

— 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.

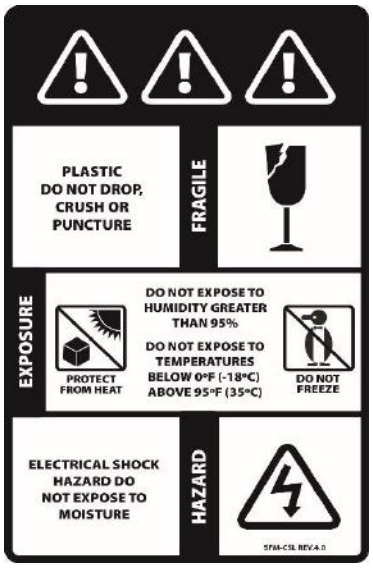


This symbol marks the location and specification of the fuse.

Type B

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

Power Cord Label



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

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

Device Information

Description of the Device

The Sizewise Rotate™ Clinically Effective Low Air Loss Mattress System is comprised of a specialized inflatable air bladder (air mattress) and an electrically powered Blower/Control Unit.

Purpose of the Device

The purpose of the SW Rotate™ 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 5 air tubes with connectors that mate with the Air Blower/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 blower hanger bar on the footboard. If no hanger bar is available, use best judgment on blower placement.
NOTE: Do Not Place Blower 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 pulsating pressure variations within the mattress. There is also a printed circuit board which operates the electrical controls.

Indications for Use

The SW Rotate™ 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

SW Rotate™

Control Unit

- **Mode of Use…** For Indoor Use Only
- **Duty Cycle**..... Continuous
- **Controller Dimensions**..... (LxWxH) 7.5”(19 cm) x 18”(45.7 cm) x 11.5”(29cm)
- **Controller Weight**..... 16 Lbs. (7.26 kg)
- **Operating Temperature**..... -18°C to 35°C (0°F to 95°F)
- **Pulsating Low Air Loss**..... 3,5, or 10 minutes
- **Liters of Air Per Minute**..... 1,740 LPM
- **Alarms**..... Power Failure and Low Pressure
- **Continuous Lateral Rotation**.....Programmable 1-30 Minutes

Electrical

- **Power Requirements**.....120VAC 60Hz 6.3A Maximum
- **Electric Shock Protection**.....Class 1
- **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
- **User Serviceable Parts**.....Hooks, Hook Brackets, Absorber Pad, Power Cord, Fuses and Filters
- **Power Cord**.....16’ (5 meters) detachable with hospital grade plug
- **Fuses**.....T 6.3A 250V (5mm x 20mm) Time Delay

Mattresses

- **Standard Dimensions 35”**.....(LxWxH) 80”(203.2cm) x 35”(88.9cm) x 10”(25.4cm)
- **Standard Mattress Weight 35”**.....19 lbs(8.62 kg)
- **Standard Weight Capacity 35”**.....350-600 lbs (158.8-272.35 kg)
- **Top Cover Material**.....70 Denier Polyurethane Coated Nylon Taffeta

Unpacking and Set-Up Instructions

The two principle components of the Sizewise Rotate™ Mattress System are a specialized air inflatable bladder (Air Mattress) and an electrically powered, Air Blower/Control Unit.

UNPACKING / PARTS BREAKDOWN:

Parts:

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

Air Blower/Control Unit

Detachable 16' Hospital Grade Power Cord

Clinically Effective Low Air Loss Mattress and Cover

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) Make sure the power cord is plugged into a properly grounded hospital grade 120V A/C outlet.

Operating Instructions

The Rotate™ Mattress 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 Sizewise Rotate™ 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 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.

1. **Static Mode**
    a. Press the STATIC button.
    b. Set the desired firmness with the SOFT and FIRM buttons on the control panel.

2. **Pulsate Mode**
    c. Press the Pulsate button to activate Pulsate mode.
    d. Press the Pulsate button until the desired time is shown by the indicator lights above the button. (Cycle times are preset at 3, 5 and 10 minutes).

3. **Fowler Mode**

    Note: Fowler Mode activates in two stages: 1.) When the head deck angle reaches 25 degrees the fowler adds 15% pressure. 2.) When the head deck angle reaches 45 degrees or above pressure is increased to 30% total.

    e. Manual Fowler
        i. When elevating the head section of the mattress, press the FOWLER button to increase airflow for seat inflation.
        ii. After the head section of mattress is lowered, press the FOWLER button to exit Fowler mode.
    f. Auto Fowler (if equipped)

i. When elevating the head section of the mattress, the FOWLER mode will automatically turn on. Fowler mode will automatically turn off when the head section of the mattress is lowered.

4. Rotation

When Rotation therapy is preferred:

a. Full Turn Rotation

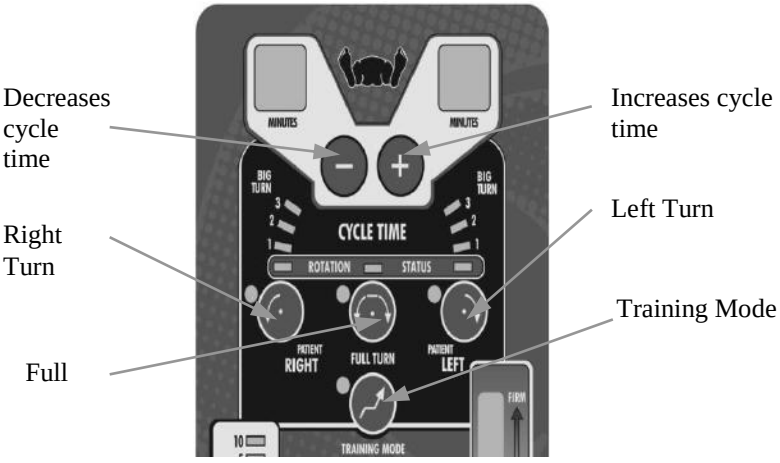
i. Repeatedly press the **<u>patient right</u>** button until the desired level of turn is displayed on the control panel (1 – 3).

ii. Press the cycle buttons until the desired time in *right* turn mode is displayed. (1-30)

iii. Repeatedly press the **<u>patient left</u>** button until the desired level of turn is displayed on the control panel (1 – 3).

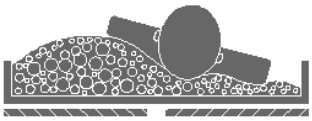
iv. Press the cycle buttons until the desired time in *left* turn mode is displayed. (1-30)

v. Press the Full Turn button to begin the programmed rotation therapy ***or*** press Training mode button to gradually increase turn over one hour.



b. Right Turn only

i. Repeatedly press the **patient right** button until the desired level of turn is displayed on the control panel (1 – 3).

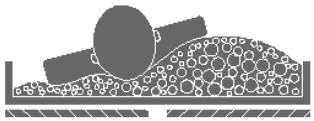


Press the cycle buttons until the desired time in *right* turn mode is displayed. (1-30)

iii. Operation in the above program will begin automatically or press Training mode button to gradually increase turn over one hour.

c. Left Turn only

i. Repeatedly press the **patient left** button until the desired level of turn is displayed on the control panel (1 – 3).



Press the cycle buttons until the desired time in *left* turn mode is displayed. (1-30)

iii. Operation in the above program will begin automatically or press Training mode button to gradually increase turn over one hour.

NOTE: The degree of rotation will vary due to the size, shape and composition of the patient.

5. Lock Out Feature

a. After 3 minutes of inactivity to blower settings, the lockout feature will activate automatically.
b. Press and hold the LOCKOUT button to exit lock out status (hold approximately 3-5 seconds).

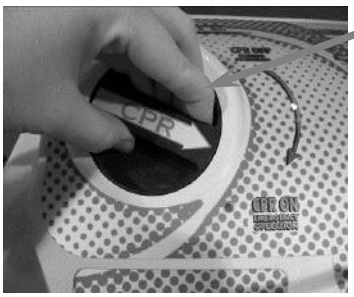
6. CPR Function (Push Button or Dial)

a. CPR button
   i. Push the CPR button to activate the CPR function. (CPR alarm and light will come on. After 10 seconds the alarm will beep every 5 seconds and the light will start flashing).
   ii. Push CPR button again to exit; Control Unit will return to the previous mode.

The CPR button is located on the front center of the Control Unit.

b. CPR Dial

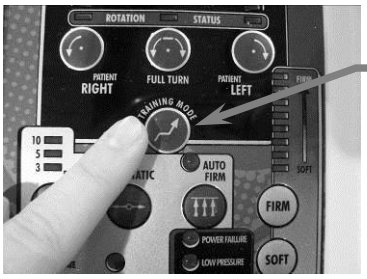
i. Turn the Control Unit's CPR Dial clockwise to the CPR ON position.
ii. After mattress deflation is complete, turn off the Control Unit.



The CPR Dial is located on the front of the unit next to the control panel.

7. Training Mode

a. Gradually lets the patient adjust to the degree of rotation selected over the course of one hour.



Located under the turn selections, this option will gradually adjust the rotation degree for easy transitions.

8. **Turn and Hold**

a. Press and hold patient left or patient right for 3 seconds "Hd" will be displayed.

b. Control unit will turn and hold the patient for nurse assistance.

c. To exit this mode, change to a different function.

NOTE: When the cycle time is showing "Hd" the control unit will hold the patient in the turn position until the cycle time is physically changed by a caregiver.

9. **Percussion Attachment** (Only applies if optional piece was included)

Attach the connection by pressing the plug to the port and slowly turn it until the alignment notches meet. Screw on the end of the plug until tight.

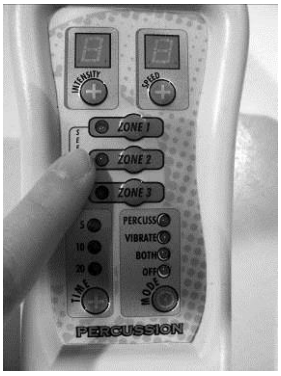
a. Press the **Mode** button repeatedly until the desired mode is selected (Vibrate/Percussion/Both).

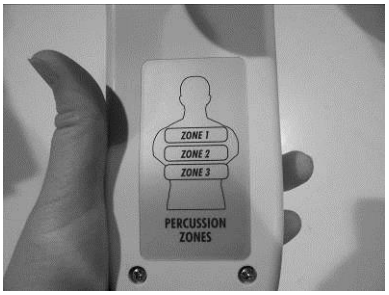
   i. **Vibrate** mode will vibrate the selected zone(s).

   ii. **Percussion** mode will vibrate one zone at a time in alternating order starting in Zone 3 to 2 and then 1.

   iii. **Both** mode will vibrate all selected zones at once and increase intensity one zone at a time in alternating order starting in Zone 3 to 2 and then 1.

b. Press the **Zone** indicator button(s) to turn "on/off" the 3 therapy zones. The diagram on the back of the device indicates the areas each zone controls.





c. Press the **Intensity** button repeatedly to select the desired therapy level. Levels 1 – 8 will appear on the LED display. Greatest intensity is at level 8.

d. In **Percussion** or **Both** modes, press the **Speed** button repeatedly until the desired percussion rate is displayed. Settings are 1-8, with 8 being the highest.

NOTE: Speed is not adjustable in **Vibrate** mode.

e. Press the **Time** button repeatedly until the desired time of 5, 10 or 20 minutes is selected by the indicator lights. Therapy will stop after the selected time.

NOTICE: To stop therapy prior to the selected time, press the **Mode** button until the indicator light is displayed as OFF.

IN THE EVENT THE ALARM SOUNDS, THE INDICATOR LIGHT WILL APPEAR INDICATING EITHER POWER FAILURE OR LOW PRESSURE. SEE THE TROUBLESHOOTING SECTION INDICATED IN THE TABLE OF CONTENTS.

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 Sizewise 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 Rotating/Pulsating Pressure mode again.

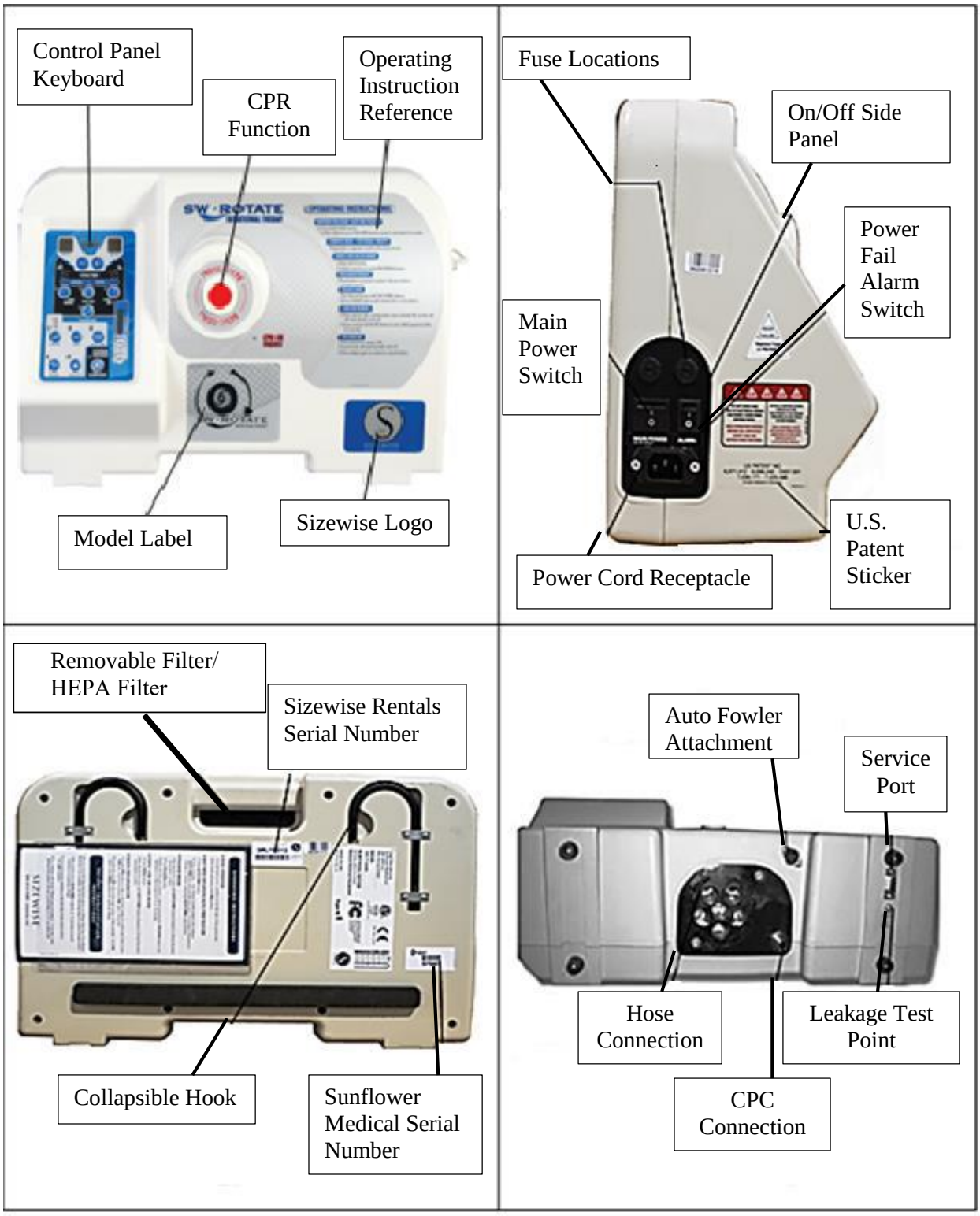
NOTE: Always remove the bedpan before entering the Rotate/Pulsate mode.

Removing the Patient from the Mattress Surface

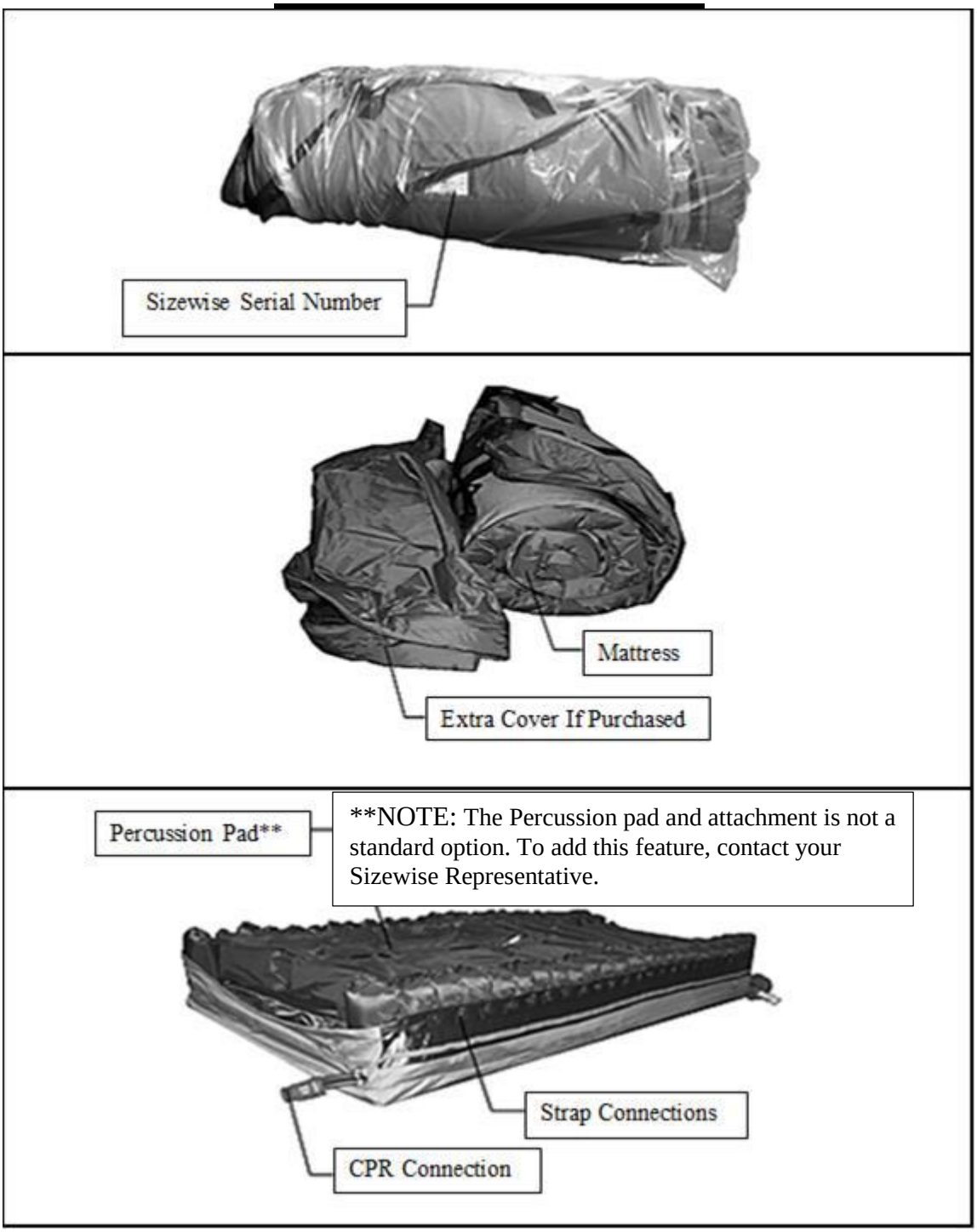
If the patient is to be removed with a transfer lift, set the control unit into Auto Firm mode. Allow the mattress to firm and position the patient into the lift. When the patient has exited the bed, the controller can be turned off.

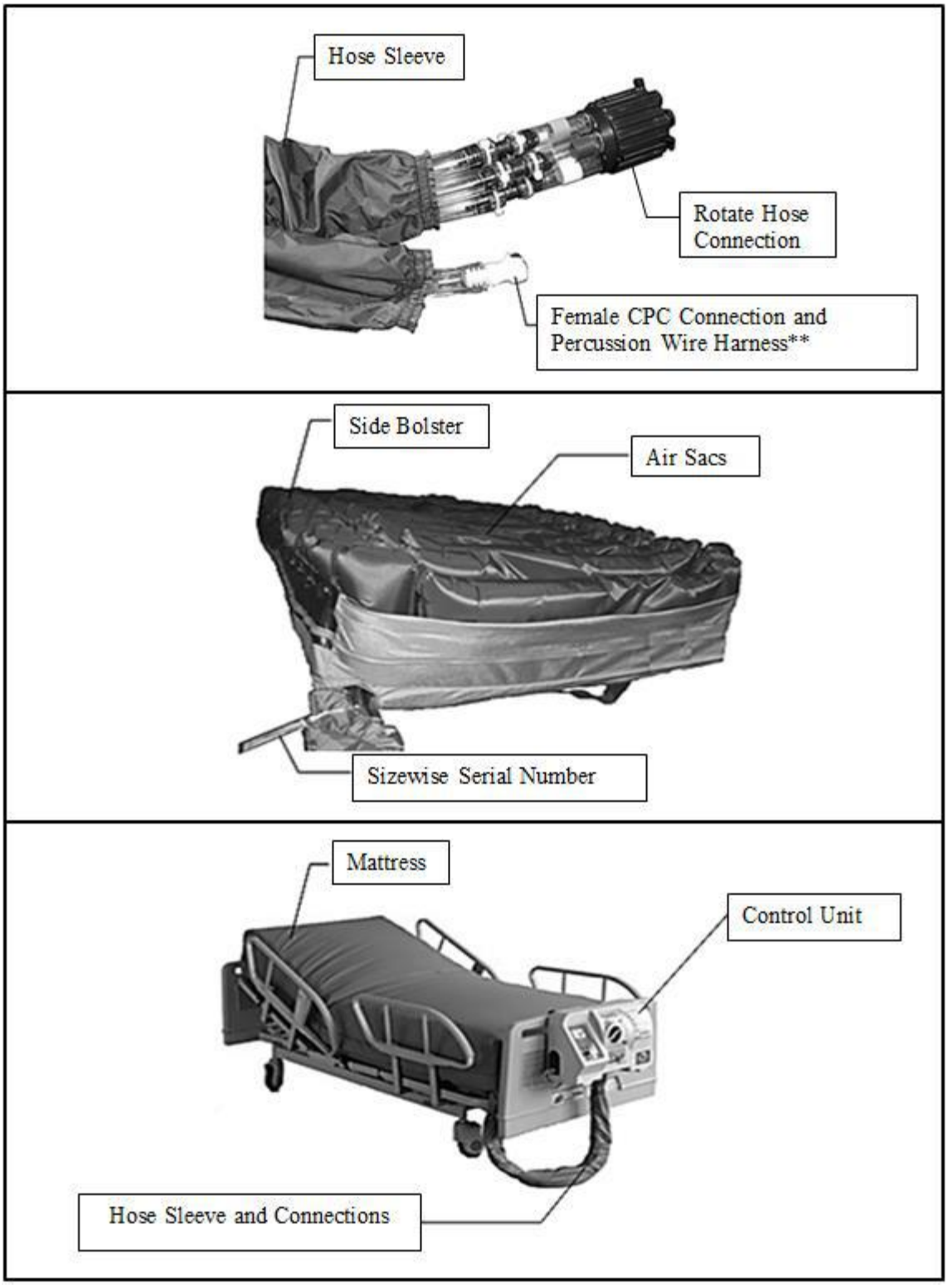
If the patient can sit up and is mobile, lower the firmness level to the lowest setting and wait for the mattress to soften in the middle. The patient can sit up and the mattress will conform to the body making a more stable platform for patient egress. When the patient has exited the bed, the controller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

Control Unit At-A-Glance

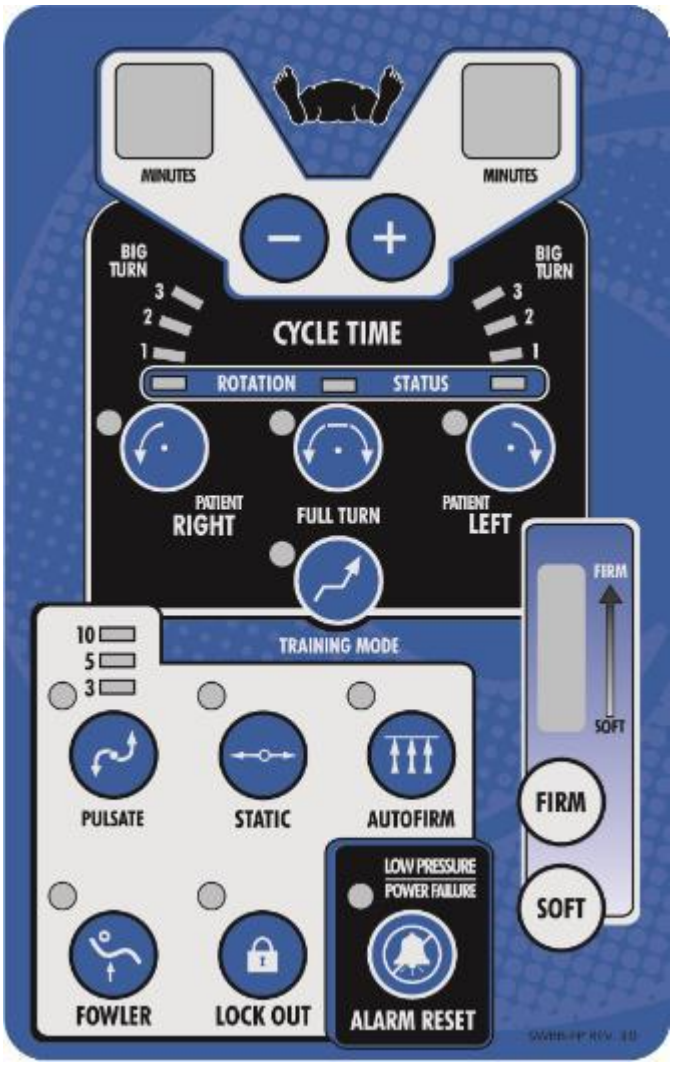


Mattress At-A-Glance




Hose Sleeve
Rotate Hose Connection
Female CPC Connection and Percussion Wire Harness**
Side Bolster
Air Sacs
Sizewise Serial Number
Mattress
Control Unit
Hose Sleeve and Connections

Keypad Quick Reference



See the following page for explanation of features.

The features available on the Rotate™ Mattress System front panel are as follows:

Locks all functions, automatically locks after 3 minutes. To unlock, press & hold for 3 seconds.

Enable static low air loss therapy with pressure sensors regulating airflow.

Enables pulsation with pressure sensor regulating airflow. Pulsate cycle times are preset at 3, 5, & 10 minutes.

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

Quickly inflates mattress to maximum firmness. Automatically times out in 10 minutes. To manually exit press a second time.

Patient turns right only.

Gradually increases turn over one hour**.**

Patient full rotation**.**

Patient turns left only**.**

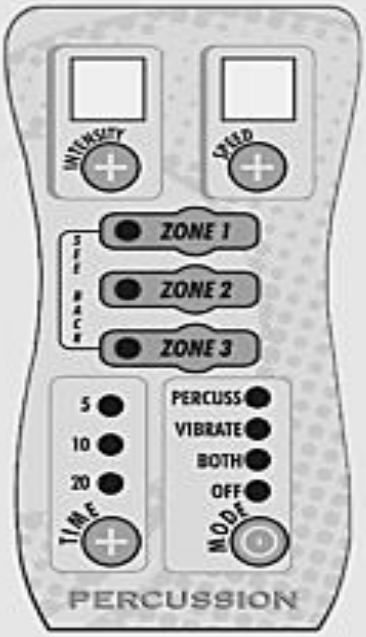
Resets the audible alarm. Light will remain illuminated until problem is corrected.

Adjusts surface toward firmer level. Increases air flow.

Adjusts surface toward softer level. Decreases air flow.

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

HAND CONTROL QUICK-REFERENCE



Sets percussion intensity from 1- 8 by pressing button repeatedly.
8 = Most Intense
1 = Least Intense

Sets speed of percussion from 1- 8 by pressing button repeatedly.
8 = Highest Speed
1 = Lowest Speed
Speed is not adjustable in the virbrate mode.

Sets therapy zone(s) shown on illustration below.

Sets therapy cycle times at 5, 10 or 20 minutes.

Zone illustration. Also on reverse of hand control.

Sets desired mode or stops therapy.

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 Sizewise technician. Frequent maintenance and servicing will improve performance and extend product life.

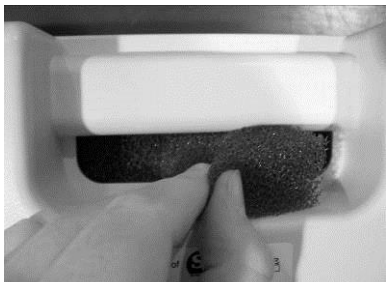
	Weekly	One Month	Three Months
Foam Filter	X		
HEPA Filter		X	
Top Cover		X	
Mattress Base		X	X
Mattress Connections			X
Control Unit Operation			X
Power Cord			

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 (Open cell foam filter)
The foam air filter on the back of the control unit must be cleaned weekly with disinfectant solution (see cleaning section). Replacement of the foam filter is recommended every 6 months.



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

HEPA Filter

HEPA: (High Efficiency Particulate Air) filter.

NOTE: HEPA filters aid in contamination control for facilities. HEPA filters do not filter out gases and odor molecules such as chemical vapors and cigarette smoke.

NOTE: HEPA filter must be used in conjunction with the manufacturer supplied foam filter. DO NOT attempt to install HEPA filter without the original equipment foam filter.

NOTE: Ensure factory open cell foam filter is completely dry before placing HEPA filter in unit.

NOTE: The HEPA filter is to be installed in applicable models and pumps in conjunction with the next factory filter cleaning procedure.

Installation

NOTE: Installation and/or handling of HEPA filter requires PPE. Service personnel should wear a mask, gloves, and protective clothing to avoid exposure to possible contaminants.

NOTE: Tools are not required for installation of filter.

NOTE: Ensure unit is off and/or removed from power source prior to servicing or replacement of filter or HEPA filter.

- Locate and remove factory filter on the top and back of the case.
- Filter is easily removed and reinserted through the gap in the back of the case.
- Ensure HEPA filter is clean.
- Place HEPA filter on front of factory foam filter.
- Re-install filters in blower case.

HEPA Filter

Maintenance

NOTE: DO NOT MODIFY HEPA filter for installation. Order filter from Sizewise to receive filter with correct dimensions.

NOTE: DO NOT attempt to clean HEPA filters, as they are to be removed and replaced only.

- HEPA filters must be replaced monthly.
- Follow Installation procedure for monthly replacement of HEPA filter.

Troubleshooting

Problem	Cause	Solution
Reduced Air flow	Possible clogged filter	Replace HEPA filter
Excessive noise	Possible obstruction Clogged filter	Ensure no obstructions Replace HEPA filter
Odor	Excessive contaminants in HEPA filter	Replace HEPA filter

Storage

If you store your product for more than 30 days, we recommend:

- Remove HEPA filter.
- Place HEPA filter in an air-tight plastic bag or plastic wrap ensuring filter is sealed to prevent exposure to outside contaminants.
- When you wish to operate product, reinstall HEPA filter.

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.

NOTE: DO NOT attempt to clean HEPA filters, as they are to be removed and replaced only.

Open cell foam filter ONLY

Control unit air filter (foam filter) 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. Sizewise recommends the use of bed rails 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

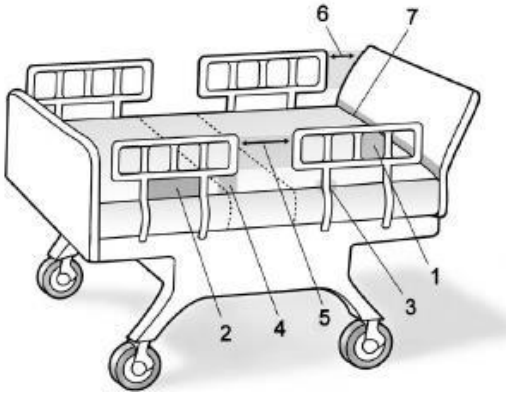
Zone 3: Between the Rail and the Mattress

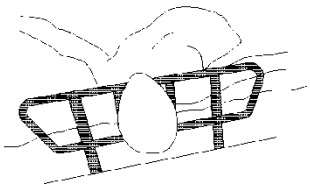
Zone 4: Under the Rail, at the Ends of the Rail

Zone 5: Between Split Bed Rails

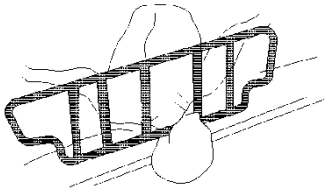
Zone 6: Between the End of the Rail and the Side Edge of the Head or Footboard

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

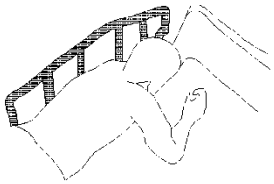




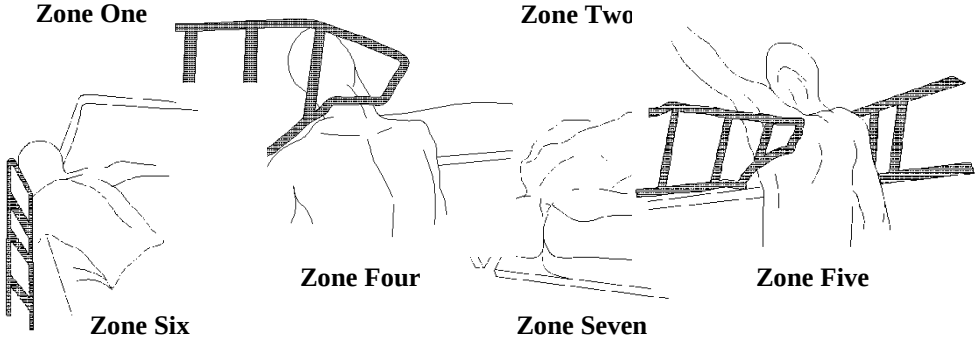
Zone One



Zone Two



Zone Three



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 blower unit to humidity greater than 95%.

End-of life Sizewise products must be disposed of properly according to local laws and regulations. Please contact Sizewise 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 blower. Refer servicing to qualified personnel only.

Electromagnetic Compatibility (EMC)

The SW Rotate™ 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 Sizewise 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: Rayes Inc. dba Sunflower Medical L.L.C.
Model: Rotate
Project Number: G100115710

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

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 Radiated RF IEC 61000-4-3	3 VRMS .15 MHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)VRMS = 3 (E1)V/m = 3	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) 80 to 800 MHz D = (7/E1) (SQRT P) 800 MHz to 2.5 GHz Where P is the max power in watts 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 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.

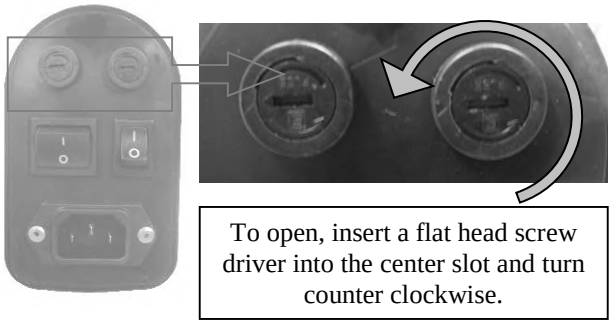
WARNING: To avoid electrical shock, DO NOT open the control unit. Refer servicing to qualified personnel only.

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.

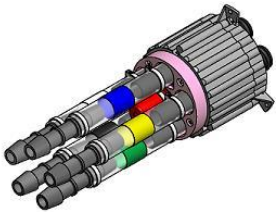


To open, insert a flat head screw driver into the center slot and turn counter clockwise.

NOTE: If the troubleshooting process does not solve the problem please contact a Sizewise 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.

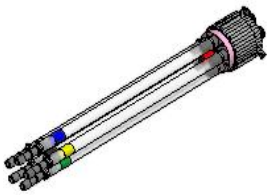


Connector (short)
Connects from mattress to blower unit side panel. Allows air movement to inflate mattress.

Part Number 61611602

Filters
Removes dust and other particles from the air as they are pulled into the blower unit.

Foam Filter Part 27400048
HEPA Filter Part 27400059



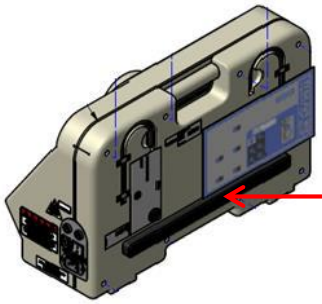
Connector (long)
Connects from mattress to blower unit side panel. Allows air movement to inflate mattress.
Part Number 61611612

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

Part Number 27400045

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

Part Number 27000445



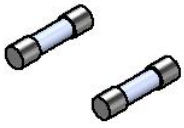
Bumper Pad
Part Number 27500042

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

Part Number 27502020

Top Cover
Replacement waterproof, vapor permeable cover.

Part Numbers Vary
(contact 1-800-814-9389 for additional information)



Fuse/s: 6.3A 250V.
Part Number 27503598

Warranty Information

Sizewise Rentals™, LLC (Sizewise) Limited Warranty

Sizewise is dedicated to manufacturing and distributing equipment that provides solution-oriented approaches to exceed the clinical, comfort and safety needs of our customers. Sizewise is proud to offer to the original purchaser, the following warranties, effective February 20, 2012:

Product	Capacity	Parts Warranty	Electronics
Rotate™	350-600 lbs. (158-272kg)	1 yr. on control unit	1 yr.
		2 yr. limited on mattress,	N/A
		90 days on top cover	N/A

How to obtain Parts and Service

1. Contact Sizewise Parts and Service at 1-800-814-9389 to speak with a qualified specialist who can assist with troubleshooting, parts and repairs. The product model and serial identification numbers are required for service and parts. Parts can be expedited upon request for an additional fee. If on-site technical service is required, a qualified service representative will be dispatched.
2. If a product or part should be returned to Sizewise, a return authorization number (RA#) will be issued. The RA# will be valid for 21 days from the date it is issued.
3. If the problem is a result of defective material or workmanship, the product or part will be replaced or repaired at the discretion of Sizewise, at no charge to the customer.
4. For replacement or repair of a product or part not covered under this warranty, or if warranty is void, the standard rates will apply. Freight or delivery charges will be billed to the customer.
5. Sizewise products are identified by serial number. Removal of this number may void the warranty.

Limitations and Exclusions

1. Products that have been subject to negligence, abuse, improper storage or handling, improper operation, unauthorized modifications or damages beyond normal wear and tear, as determined by Sizewise, are not covered by this warranty.
2. If weight capacity on any such product is exceeded, the warranty will be void. Any unauthorized repairs to product/part, as well as tampering with any components, will void the warranty.
3. Parts or materials that are subject to normal wear resulting from the use of these products that must be replaced or repaired are excluded and are not covered by this warranty.
4. **SUBJECT TO STATE SPECIFIC LAW, THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND SHALL NOT EXTEND BEYOND THE DURATION OF THIS WARRANTY. SIZEWISE SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES.**
5. This warranty applies to the original purchaser only and is non-transferable.
6. Air Support limited warranty includes two *(2)* years on air cell welds, one *(1)* year on bottom cover, manifold and foam base, and ninety *(90)* days on the mattress top cover. All parts found defective within that period shall be repaired and/or replaced at the discretion of Sizewise, at no charge to the original purchaser.
7. Cleaning upholstery or fabrics with harsh chemicals, or bleach, outside the recommended cleaning guidelines may void the warranty.

User Assistance Information

For questions or assistance with this product, contact Sizewise at:

Sizewise
1600 Genessee
Suite 950
Kansas City, Missouri 64102
Phone: 1-800-814-9389

Sizewise
1600 Genessee
Suite 950
Kansas City, Missouri 64102
Phone: 1-800-814-9389
sizewise.net