Pediatric Pulse[™]



User Manual



Doc. #: _____ Rev. Date:

____ Rev.: __

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Definitions and Symbols

Definitions

Throughout this manual different type fonts and symbols 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.

Symbols



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

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.

Warning/Attention

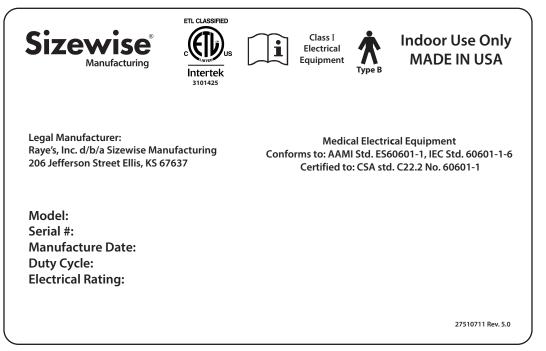
Read and fully understand manual before operating. Failure to follow operating instructions could result in death or serious injury.

27008710. Rev. 1.0

Lisez et comprenez entièrement le manuel avant utilisation. Le non-respect des instructions d'utilisation peut entraîner la mort ou des blessures graves.

Manufacturer's Label

UDI Information on separate label located on product near this label.





This symbol marks the location and specification of the fuse.



Symbol for Type B applied parts indicating protection provided against electric shock.



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

Power Cord Label



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



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



Risk of electrical shock and bodily harm from moving parts.

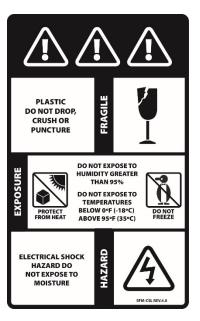


27509004, Rev. 4.0



corporelles des pièces

en mouvement. Lire le manuel avant ELECTRICAL SHOCK HAZARD WARNING: Do not open case for risk of electrical shock.



General Warnings and Precautions

WARNINGS



WARNING: DO NOT use this device if the power cord is cut, frayed or loosely connected to the device.



WARNING: (110V unit) Electrically Powered Mechanism. Electrical Hazard may occur if device is plugged into inadequate electrical outlet. To avoid electrical shock hazard, make sure unit is plugged into a grounded A/C 110V outlet.



WARNING: (220V unit) Electrically Powered Mechanism. Electrical Hazard may occur if device is plugged into inadequate electrical outlet. To avoid electrical shock hazard, make sure unit is plugged into a grounded A/C 220V outlet.



WARNING: DO NOT remove cover. Refer servicing to qualified service personnel. Disconnect power supply before servicing or cleaning.

WARNING: Be sure to secure mattress to the bed frame with the straps provided. Failure to do so could result in personal injury or equipment damage.

CAUTIONS



CAUTION: Overheating may cause equipment damage or failure. Monitor the unit to ensure that it functions in the proper operating temperature.

CAUTION: Keep out of direct sunlight.



CAUTION: DO NOT store in temperatures below 0°F (-18°C) or above 95°F (35°C).

CAUTION: DO NOT expose to moisture or areas of humidity greater than 95%.



CAUTION: Ensure that strap placement does not interfere with the operation of the bed functions.



CAUTION: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the equipment or system.

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.



CAUTION: DO NOT use around an open flame.

Device Information

Description of the Device

The two principle components of the SW Pediatric PulseTM are a specialized air inflatable bladder (air mattress) and an electrically powered Blower / Control Unit.

Purpose of the Device

The purpose of the SW Pediatric PulseTM is to provide active therapeutic benefit to pediatric patients.

The active component that has contact with the patient is a specialized, multi-cell air mattress sized to fit pediatric cribs and bed frames. The air mattress serves as a replacement mattress and is equipped with 4 air hoses with connectors that mate with the Blower / Control Unit. The Control Unit is a self-contained, totally enclosed, module that hangs by hinged hooks on the crib/bed frame or sits on the floor under the frame.

The SW Pediatric PulseTM has a detachable hospital grade electrical cord and a control panel with selector switches and indicator lights. Inside the Control Unit is a variable output blower that allows the air mattress to operate in static mode. There is also a printed circuit board, which provides the electrical controls.

Indications for Use

The SW Pediatric Pulse[™] is a therapeutic mattress that provides either active or reactive pressure redistribution and 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

Standard Features

Blower Unit Weight	11 lbs. / 4.98 kg
Blower Unit Height	
Blower Unit Width	
Blower Unit Depth	6" / 15 cm

Therapeutic Features

Low Air Loss	Yes
Fowler Positioning	Yes
Pulsation Therapy	Yes
Weight Capacity) lbs. / 45 kg

Electrical Characteristics for 110V Control Unit

Rated Voltage	110V
Rated Frequency	60Hz
Rated Input Power	
Fuse Rating	
Power Failure Alarm	

Electrical Characteristics for 220V Control Unit

Rated Voltage	
Rated Frequency	50Hz
Rated Input Power	
Fuse Rating	
Power Failure Alarm	

Unpacking and Set-Up Instructions

Unpacking/Parts Breakdown

The SW Pediatric Pulse[™] consists of a control/blower unit, power cord, a clinically effective low air loss mattress and a waterproof, vapor permeable, easy-to-clean cover.

Parts:

- Air Blower / Control Unit
- Power Cord (Hospital Grade)
- Clinically-Effective Low Air Loss Mattress Replacement
- Mattress Cover (4 way stretch)

Unpacking Instructions (no tools required):

Remove the products from the packing material and examine for shipping damage. If damage is detected in shipping, contact the freight company and file a damage complaint immediately.

Environmental Conditions:

CAUTION: Keep out of direct sunlight.

DO NOT expose to temperatures greater than $35^{\circ}C$ ($95^{\circ}F$) or below $-18^{\circ}C$ ($0^{\circ}F$).

DO NOT expose the blower/control unit to humidity greater than 95%.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The use of accessories, transducers and cables, other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the equipment or system.

The equipment or system should not be used adjacent to, or stacked with, other equipment; and if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

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

Directions for Mattress Placement:

Replace the existing bed mattress with the SW Pediatric PulseTM. Secure air mattress to frame with straps provided.

Warning or Safety Instructions Relating to Set-Up:



WARNING: (110V unit ONLY) Ensure the power cord is plugged into a properly grounded AC 110V outlet.

(220V unit ONLY) Ensure the power cord is plugged into a properly grounded AC 220V outlet.

Operating Instructions

- 1. Remove standard mattress from the frame.
- 2. Replace standard mattress with the SW Pediatric PulseTM. (Be sure air tubing is at the foot end of the frame.)
- 3. Strap air support mattress to frame on all four sides.
- 4. Place control/blower unit on the footboard of the frame using the two hinged hooks located on the back of the unit. (If no footboard is available, put blower/control unit on the floor away from traffic.) To avoid blocking the air intake, DO NOT place control unit/blower on its back.
- 5. Attach the air tubing to the control/blower unit, being sure it snaps in tight. (Be sure air tubing is not kinked and is unobstructed.)
- 6. **NOTE:** Plug the 110V unit ONLY into grounded 110V AC outlet. Plug the 220V unit ONLY into grounded 220V AC outlet.
- 7. Turn master power switch ON, located on the side of the unit.
- 8. Press the Autofirm **†††** button for quick inflation.
- 9. Place the patient on the mattress AFTER inflation to ensure the air cells DO NOT become twisted or kinked.
- 10. To get the control/blower unit out of Autofirm mode, press Autofirm button again.

Modes of Operation

- 1. Static Mode
 - a. Press the Mode button until the Static option light comes on
 - b. Set the desired comfort level with the Soft/Firm arrow buttons.

2. Pulsate Mode 杯

- a. Press the Mode button until the Pulsate option light comes on.
- b. Set the desired cycle time with Cycle Time buttons (3-20 minutes).
- c. Set the desired comfort level with the Soft/Firm buttons.

3. Fowler Mode

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

4. Lockout Feature

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

5. Quick Deflation or CPR Use

- a. Turn power OFF.
- b. Twist quick release connector on mattress to open.
- c. Remove the hoses from the control/blower unit.

NOTE: The mattress is equipped with a 1/2 -inch foam pad in the mattress base for patient support and transport.

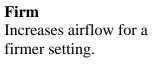
Keypad Quick Reference





Firm

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





Alarm Silence Mutes the audible alarm. (Visual light will not turn off until failure is resolved.)



Fowler

Soft Decreases airflow for a softer setting.



Autofirm Quickly inflates mattress to maximum firmness.



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



Mode

Fowler

Press the MODE button to switch between Pulsate and Static modes.

Used when head section of

bed is elevated. Increases airflow to the mattress.



Low Pressure Light will indicate when pressure is getting too low.



Power Failure Light will indicate when power is no longer being provided to unit.

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

Provides individual button illustration and function description.

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 the Control Unit/Blower.
- 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.

In some cases, the mattress may include an auto-fowler feature. This means that when the head of the bed is greater than 30 degrees, the mattress will automatically increase the amount of air to the sacral area.

Positioning the Patient

When moving a patient the Control Unit/Blower should be in the Auto Firm Mode.

To reposition the patient, change the Control Unit/Blower 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. Re-position patient as appropriate.

Removing the Patient from the Mattress Surface

If the patient is to be removed with a transfer lift, set the Control Unit/Blower 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.

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. Allow the air cells to remain wet with disinfectant solution 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.

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	Х		
HEPA Filter		X	
Top Cover		X	
Mattress Base		Х	Х
Mattress Connections			Х
Control Unit Operation			Х
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).
- $\hfill\square$ 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.

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 $0^{\circ}F$ (-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%.

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

Safety Tips

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.
- (220V unit ONLY) Ensure the power cord is plugged into a properly grounded AC 220V 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.



WARNING! To avoid electrical shock, DO NOT open the Control Unit/Blower. Refer servicing to qualified personnel only.

Electromagnetic Compatibility (EMC)

The SW Pediatric PulseTM 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 interferences.

Emissions

The blower/control 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 pages 11-14.

Immunity

The blower has been stringently tested for susceptibility to electromagnetic radiation over the frequency range 80 MHz to 2.5 GHz. The test was conducted on this blower and passed the requirements of IEC 61000-4-3.

All pins of connectors have passed ESD testing.

List of Cables and Accessories

Replacement parts, such as cables and accessories, must be purchased through Sizewise to ensure proper compliance requirements.



WARNING: 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.

GUIDANCE AND MANUFACTURER'S DECLARATION

Company:	Sunflower Medical LLC
Model:	Pulse
Control Number:	3101425

Table 201 Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems

This 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.

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

Table 202 Guidance and Manufacturer's Declaration – Immunity All Equipment and Systems

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

Table 204 Guidance and Manufacturer's Declaration – ImmunityEquipment and Systems that are NOT Life-Supporting

This 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	Compliance	Electromagnetic Environment
-	Test Level	Level	Guidance
			Portable and mobile communications equipment should be separated from the blower by no less than the distances calculated/listed below:
			D=(3.5/V1)(Sqrt P)
			D=(3.5/V1)(Sqrt P) 80 to 800 MHz
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)Vrms = 3	D=(7/V1)(Sqrt P) 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)V/m = 3	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 blower.

Equipment and Systems that are NOT Life-Supporting

Recommended Separations 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-800 MHz 3	Rad RF – 2.5 GHz 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

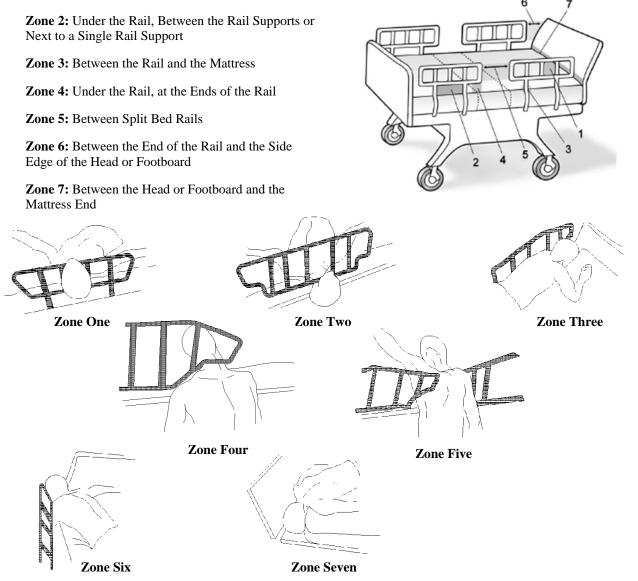
Seven Zones of Bed Rail Entrapment

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



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 blower. 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 or clean air filters.
- Ensure the CPR valve is in the closed position.

If there is power loss:

- Check the ON/OFF switch.
- Check to be sure that unit is plugged in correctly.
- Unplug the Control Unit and check fuses located near the main ON/OFF switch. Replace as necessary.

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 Connects from mattress to blower unit side panel. Allows air movement to inflate mattress.



Filters

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



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

Power Cords

Grounded hospital grade

power cord for providing

power to the control unit.

(Note: Supplied only

with 110V control



Foam Filter Part Number 27400048 HEPA Filter Part Number

27400059 Female CPC Connects from mattress to male CPC

on blower unit. Removes exhaust air from unit to mattress.



Part Number 27502020

Part Number 27502011



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



Hooks

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

Top Cover Replacement waterproof, vapor permeable cover.

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

PLEASE READ THESE WARRANTY TERMS AND CONDITIONS CAREFULLY BEFORE USING YOUR SIZEWISE PRODUCT. BY USING THE PRODUCT, YOU ARE CONSENTING TO BE BOUND BY THE FOLLOWING WARRANTY TERMS AND CONDITIONS.

LIMITED WARRANTY.

Sizewise warrants the above referenced product to be free from material defects in materials and workmanship for the warranty periods set forth below when the product is used and serviced properly in accordance with the specifications set forth in the Sizewise owner's manual in effect at the time of sale of the product, including without limitation compliance with the safe working load set forth therein. If there is no period of time specified below, the warranty period shall be ninety (90) days. The warranty periods commence on the invoice date of the original purchase. This warranty applies only against defects discovered within the warranty period and extends only to the original purchaser or designated original end user of the product ("Buyer"). Parts repaired or replaced under the terms of this warranty will be warranted for the remainder of the original warranty period only. Buyer is solely responsible for determining whether the products and services offered by Sizewise are appropriate for its intended use including use by Buyer's employees, invitees, contractors, representatives, third party beneficiaries, or any other person Buyer intends to use the product. Buyer acknowledges it has made the selection of the products based upon its own judgment and that the product is of a size, design, capacity, condition, quality, durability selected by Buyer. Buyer expressly disclaims any reliance upon any statements or representations made by Sizewise or any other party on its behalf except as otherwise specifically provided for in this Limited Product Warranty. Buyer acknowledges and agrees that the remedy in this warranty for the repair and replacement of defective product or part(s) shall constitute the sole remedy in the event of a defective product or part(s). THE WARRANTY GIVES BUYER SPECIFIC LEGAL RIGHTS, AND BUYER MAY ALSO HAVE **OTHER RIGHTS THAT VARY FROM STATE TO STATE**. Sizewise's obligations under this warranty are limited as set forth below.

WARRANTY PERIOD AND COVERAGE.

PEDIATRIC PULSE MATTRESS SYSTEM

- 2 yr. on control/pump unit
- 1 yr. limited on mattress
- 90 days on top cover
- 1 yr . on electronics

CONDITIONS AND RESTRICTIONS.

This warranty is valid only in accordance with the conditions set forth below:

- The warranty applies to this Sizewise product only while:
 - o it remains in the possession of the Buyer and proof of purchase is demonstrated,
 - o it has not been subjected to accident, misuse, abuse, improper service, or modification,
 - o claims are made within the warranty period.
- This warranty does not apply to any other products or devices sold separately regardless of whether used with this product. Such other products or devices will be subject to the separate limited product warranty set forth in the user manual for such product or device.
- Sizewise's sole liability shall be discharged by replacing or repairing, at Sizewise's option, the product or its part or parts which are determined by Sizewise to be defective under normal and proper use during the warranty period.
- Buyer shall notify Sizewise or the authorized Sizewise dealer immediately but in no event more than seven (7) days after the date of discovery of any alleged defect by contacting Sizewise Parts and Services at 1-800-814-9389 Monday through Friday 8am 5pm CST.
- If the product or part should be returned to Sizewise, a return authorization number (RA#) must be obtained by Buyer from Sizewise. The RA# will be valid for 21 days from the date it is issued.
- Buyer is responsible for any shipping, freight, handling, pickup or delivery charges or fees including without limitation any expediting fees involved with the delivery of the defective product or parts to Sizewise's factory for repair or replacement.
- If on-site technical service is required, a service representative will be dispatched during Sizewise's standard service hours Monday through Friday 8am-5pm CST and provided the product is located within Sizewise's service territory.
- If Sizewise determines the problem with the product or part(s) is a result of defective material or workmanship, the

product or part will be replaced or repaired at the discretion of Sizewise, and at no charge to the Buyer however subject to the limitations and exclusions of this Limited Product Warranty.

- At the election of Sizewise, replacement parts may be new or refurbished; and Sizewise reserves the right to substitute materials if original materials are no longer available.
- If Sizewise determines the product or part that Buyer has requested warranty services on are not covered by the warranty for any reason including without limitation because it is outside of the warranty period, excluded from the warranty or the warranty is void, Buyer shall pay for the repair or replacement services, including parts and labor performed by Sizewise at Sizewise's prevailing time and material rates plus freight and delivery.
- If Buyer declines the repair or replacement service upon notice from Sizewise it is not covered under warranty, Buyer shall reimburse Sizewise for all costs from investigating and responding to Buyer's request.
- Any costs to Buyer as referred to herein shall be at Sizewise's prevailing time and material rates plus any freight and delivery charges incurred by Sizewise.
- Any assistance provided by Sizewise outside the terms of this warranty does not waive the limits of this warranty.
- Sizewise does not pay labor outside the United States.
- Any description of Sizewise's products is for identification purposes only and is not an express warranty.
- Loaned products, demo or sample products and/or consumable products including without limitation batteries and sheets are furnished to Buyer on an "AS IS WITH ALL FAULTS" basis.

EXCLUSIONS AND LIMITATIONS.

This Limited Product Warranty shall not apply to, and Sizewise shall have no obligation to make repairs, replace or correct products including any part or parts of the product as the result of Sizewise's determination of any of the following:

1. Software (PROM) or firmware version upgrades or updates or any other changes and/or any outages, interruptions, delays, attacks, malware, or any other technology or viruses on such software or firmware or Buyer's network, if applicable to this product.

2. Normal wear and tear of the product including without limitation normal discoloring, body impressions on mattresses or loss in some resiliency, if applicable to this product, and cosmetic items, consumable items including without limitation mattresses, casters, sheets, handsets and batteries.

3. Damage due to improper transport, storage, installation, maintenance, use, repair or failure to follow Sizewise's instructions or procedures as detailed in the owner's manual.

4. Damage or malfunctions resulting from work performed by service providers not authorized by Sizewise.

5. Repairs performed on a Sizewise product or parts missing a serial number or with a serial tag that has been altered, tampered with or defaced in any manner.

6. Service calls to correct installation of the product unless installed under contract by Sizewise or its partners and in which event the terms of the service contract only shall apply to service installation corrections.

7. Shipping, freight, handling, pickup and delivery charges or fees involved with delivery of the products and or part(s) to Sizewise's factory for repair or replacement and returning the replacement or repaired products and/or parts to Buyer. 8. Any labor costs incurred beyond the applicable labor warranty period.

9. Damage or product failure from causes external to the product or part(s) including without limitation power or electric failure or surges, electrical wiring not in compliance with electrical codes or Sizewise owner's manual specifications.

10. Damage caused by failure to provide reasonable and necessary maintenance as outlined in the owner's manual.

11. Damage caused by the use, misuse, negligence, loss, abuse of the product or any parts by Buyer including without limitation any third party beneficiaries, end user or others persons Buyer intends to use the product, including without limitation (except Sizewise or an authorized Sizewise service provider):

a. exceeding the safe working load on this product or any specific weight capacity for a part,

b. cleaning upholstery or fabrics with harsh chemicals, or bleach, outside the recommended cleaning guidelines,

c. altering, tampering with, or modifying in any manner without the express written consent of Sizewise any part(s) or structural components or appurtenances of the products,

d. use of the product or part(s) in a manner for which it is not designed or in any manner inconsistent with the information set forth in the Sizewise owner's manual including without limitation use with other devices or ancillary products for which it was not intended.

12. Exposure of the product or part(s) to, whether foreseen or unforeseen, accident, acts of God, or natural causes (such as natural disasters, fire, flood, wind, water or powerfailures, acts or threats of terrorism).

- 13. Operation of the product beyond its normal useful life.
- 14. Buyer's failure to show proof of purchase.

15. Products or items not manufactured by Sizewise. Rather for products or items obtained by Sizewise from an original manufacturer or third party supplier Sizewise may assign to the Buyer any warranty rights in such products or items that Sizewise may have from the original manufacturer or third party supplier, to the extent such assignment is allowed by the original manufacturer or third party supplier.

DISCLAIMER AND RELEASE.

The warranties provided herein are the exclusive warranties given by Sizewise and supersede any prior, contrary or additional representations or warranties, whether oral or written. **EXCEPT FOR THE EXPRESS WARRANTIES IN THIS LIMITED PRODUCT WARRANTY**, SIZEWISE DISCLAIMS ANY AND ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, AND ANY WARRANTIES ARISING FROM COURSE OF DEALING, USAGE OF TRADE, OPERATION OF LAW OR OTHERWISE WITH RESPECT TO ANY PRODUCT, SERVICES, PARTS INCLUDING REPAIRED OR REPLACED PRODUCTS AND PARTS. ARE HEREBY DISCLAIMED AND EXCLUDED. Sizewise ALSO HEREBY DISCLAIMS AND EXCLUDES ALL OTHER OBLIGATIONS OR LIABILITIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO ANY NONCONFORMANCE OR DEFECT IN ANY PRODUCT OR PART(S), INCLUDING BUT NOT LIMITED TO: (A) ANY OBLIGATION, LIABILITY, RIGHT, CLAIM OR REMEDY IN TORT, WHETHER OR NOT ARISING FROM THE NEGLIGENCE OF SIZEWISE OR ITS SUPPLIERS (WHETHER ACTIVE, PASSIVE OR IMPUTED); AND (B) ANY OBLIGATION, LIABILITY, RIGHT, CLAIM OR REMEDY FOR LOSS OF OR DAMAGE TO ANY PRODUCT OR PART(S). THIS DISCLAIMER AND RELEASE SHALL APPLY EVEN IF THE EXPRESS WARRANTY SET FORTH ABOVE FAILS OF ITS ESSENTIAL PURPOSE.

Exclusive Remedies.

For any product described above that Sizewise determines to have failed to conform to its warranty, Sizewise will provide, at its option, one of the following:

- (1) repair;
- (2) replacement; or
- (3) refund of the purchase price.

Sizewise Limited Product Warranty service may be obtained by contacting Sizewise or the authorized dealer from whom Buyer purchased the item. Sizewise compensates only Sizewise authorized service providers for warranty trips within their normal service area to repair commercial products at the customer's location.

THESE SHALL BE THE SOLE AND EXCLUSIVE REMEDIES OF THE BUYER FOR ANY BREACH OF WARRANTY.

EXCLUSION OF CONSEQUENTIAL AND INCIDENTAL DAMAGES.

SIZEWISE AND/OR ITS SUPPLIERS SHALL HAVE NO OBLIGATION OR LIABILITY, WHETHER ARISING IN CONTRACT (INCLUDING WARRANTY), TORT OR ANY OTHER LEGAL THEORY (INCLUDING ACTIVE, PASSIVE, OR IMPUTED NEGLIGENCE AND STRICT LIABILITY), OR OTHERWISE, FOR DAMAGE TO THE PRODUCT INCLUDING PART(S), PROPERTY DAMAGE, DEATH, PERSONAL INJURY, LOSS OF USE, GOODWILL, REVENUE OR PROFIT, COST OF CAPITAL, COST OF SUBSTITUTE PRODUCT, ADDITIONAL COSTS INCURRED BY BUYER (BY WAY OF CORRECTION OR OTHERWISE) OR ANY OTHER INCIDENTAL, SPECIAL, INDIRECT, COMPENSATORY OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION WHETHER RESULTING FROM NONDELIVERY, USE, MISUSE OR INABILITY TO USE THE PRODUCT, SERVICES OR PART(S). THIS EXCLUSION APPLIES EVEN IF THE ABOVE WARRANTY FAILS OF ITS ESSENTIAL PURPOSES AND REGARDLESS OF WHETHER SUCH DAMAGES ARE SOUGHT FOR BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, OR STRICT LIABILITY IN TORT OR UNDER ANY OTHER LEGAL THEORY. SIZEWISE LIABILITY SHALL BE LIMITED TO THE AMOUNT PAID BY BUYER FOR THE RELEVANT PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIIMITATION AND EXCLUSION ON SUCH MAY NOT APPLY.

EXTENDED WARRANTY. If the product covered under the Limited Product Warranty set forth herein had from Sizewise an extended warranty option made available only at the time of the Buyer's original purchase from Sizewise, Buyers who then also purchased such extended warranty, and have proof of such purchase, may extend the warranty period stated above in the Limited Product Warranty on parts, electronics, frame and labor relating to parts, electronics and frame repairs, as applicable,

for an additional one (1) or two (2) years, whichever extension is purchased by Buyer ("extended warranty period"). Other than the extension on the warranty period, all other terms of the limited product warranty including without limitation the conditions and restrictions, exclusions and limitations, disclaimer and release, and exclusion of consequential and incidental damages of the original limited product warranty apply during the extended warranty period. For the purpose of clarity an extended warranty is not available where the original warranty period is less than one (1) year, and an extended warranty may only be purchased by Buyer at the time of the original purchase of the product from Sizewise.

To make a warranty claim, contact:

SIZEWISE 8601 MONROVIA LENEXA, KS 66215 1-800-814-9389 Monday through Friday 8am-5pm CST

Complete this portion and keep for your records.

Purchased From: Sizewise

Product/model: _____

Serial number:_____



8601 Monrovia Street Lenexa, KS 66215

> 800-814-9389 sizewise.com

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