

Operation Manual

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Congratulations and thank you for purchasing this Signa Relief Alternating Pressure System with Low Air Loss. PLEASE READ THIS OPERATION MANUAL CAREFULLY BEFORE SETTING UP AND USING THE DEVICE. Pay special attention to the warnings and other safety information. Use of genuine manufacturer components is essential for optimal performance. If you do not fully understand all the instructions, safety precautions, and warnings, do not use this device. If you have any questions or concerns, please contact H & R Healthcare at 800-801-5533.

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1.0 Indications



Please read enclosed document thoroughly



Declaration of Conformity to Medical Device Directive.



With respect to electrical shock, fire, and mechanical hazards only in accordance with ANSI/AAMI ES60601-1 (2005, 3rd ed.) and CAN/CSA - C22.2 No. 60601-1 (2008)



International Electronics Approval



Do not immerse power unit in liquid or spray liquids directly on power unit.



Type BF Equipment

Indications

This alternating pressure system with low air loss is designed to treat and prevent wounds by facilitating blood circulation and decreasing pressure of each tissue's contact area. Always consult a physician or health professional before using this mattress system.

Contraindications

This device is not indicated for treatment of certain patient conditions such as fracture of unstable vertebrae and illness of unstable vertebrae. Always consult a physician or health professional before using this device.

The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

2.0 Safety Precautions

- To ensure proper operation, please inspect and verify that all parts are set up properly and are anchored securely. Do not place anything on top of the power unit. Make sure power cord is underneath bed frame and does not pose a hazard.
- 2. It is recommended to limit bed linens to a single layer in order to allow moisture to escape efficiently through the coverlet. Breathable incontinent pads are recommended for use with this mattress system.
- Avoid using this device near open flames, lighters, or cigarettes. Flammability hazard exists. This device draws air from the surrounding environment. Thus, cigarette smoking may damage internal components.
- This system should be disinfected thoroughly between patients to avoid cross contamination.
- Verify that patient weight does not exceed the weight capacity of the bed frame, bed rails, or this mattress system.

3.0 Warnings

- 1. Use this mattress with proper side rails to ensure that the gap between the side rail and the top of the mattress is not large enough to pose risk of head or neck entrapment. Failure to do so could result in serious patient injury.
- DO NOT disassemble the power unit if you are not a qualified technician. Please contact H & R Healthcare for all service.
- This product is NOT AP/APG protected.
- It is recommended that the patient be repositioned periodically while using this mattress.
- Incorrect battery replacement may result in risk of explosion. Replace only with same or equivalent battery type recommended by the manufacturer.
- 6. If the equipment needs maintenance, contact H & R Healthcare as soon as possible. For equipment that is no longer functional, make sure to follow national and/or state requirements for disposal of the unit.
- 7. Ensure that any disposal of the unit, accessories, waste products, residues etc. complies with national and local law.

- 8. The power plug serves to disconnect the device and should not be positioned in a way that makes it difficult to disconnect.
- 9. No modification of this equipment is allowed.
- 10. To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.
- 11. To shut down the unit, press the power button.

CAUTION: ENSURE THAT THERE ARE NO PROTRUDING OBJECTS, SHARP POINTS, OR BED SPRINGS UNDER THE MATTRESS AS THESE COULD PUNCTURE THE AIR CELLS.

4.0 System Package

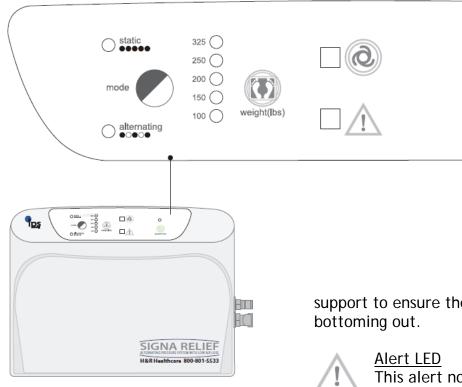
Power Unit Package

- Power Unit x 1
- Power Cord x 1
- Operational Manual x 1

Mattress Package

 Mattress replacement unit with coverlet x 1

5.0 Features



Control Panel Features

Power/Mute

The green power LED will light when the main power rocker switch on the right side panel is turned on.

Weight (lbs)

Simply press weight button to adjust patient weight from 100 lbs to 325 lbs according to patient weight. The scale is only an approximation. Please adjust the weight setting if the mattress is too soft or firm to suit each patient's needs.

Caregivers should always perform a hand check by placing their hands underneath patient's pelvis area to check if there is sufficient air

support to ensure the patient is not

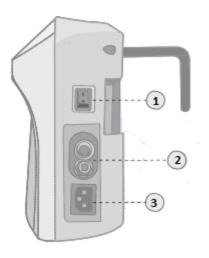
This alert notifies medical staff the mattress has insufficient pressure. Audible alarm will sound for 15 seconds at each cycle, and the indicator will stay on until the problem has been solved.

Pressure monitoring LED Power unit features an integrated pressure sensor which monitors the mattress' internal pressure to ensure maximum pressure relief. LED indicates that the system is monitoring the mattress' internal pressure while the compressor is inflating.

Alternating/Static

Press Mode to change between alternating and static mode. Alternating mode will have a cycle time of 10 minutes.

Right Side Panel Features



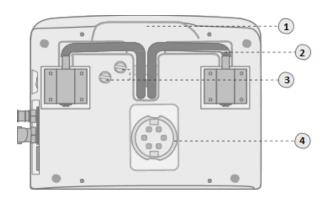
Rocker Switch (1) Power unit's main power switch.

Couplers (2)

Quick release female couplers are used to secure mattress air hoses to power unit.

<u>Power Receptacle (3)</u> Insert power cord firmly into receptacle.

Rear Panel Features



Convenient Handle (1)

The handle provides additional gripping surface for user to carry the power unit.

Hanging Hooks (2)

Hanging hooks are designed to hang the power unit on almost any foot board.

Fuse (3) Fuse Holder

Air Filter and Cap (4)

H & R Healthcare recommends that the filter be kept clean to ensure optimal performance of the power unit.

6.0 Mattress and Power Unit Installations

- 1. Remove existing mattress from bed frame.
- 2. Place H & R Healthcare mattress replacement on the bed frame with the logo at foot end. Secure the mattress at each side using anchor straps. Ensure that the anchor straps do not interfere with any moving parts of the bed frame before proceeding to the next step.
- 3. Secure the power unit onto the foot board using hanging hooks.
- 4. Ensure that the mattress; CPR latch is firmly inserted and the CPR tag is in place.

- 5. Firmly connect the air hose couplers to the couplers on the power unit.
- 6. Plug the power unit into an electrical outlet, and turn on the main power rocker switch on the right side of the power unit.
- Press the power/mute button to inflate the mattress system.
 Please wait for approximately 30 seconds until the power unit is ready before making any program adjustments.
- 8. Wait approximately 30 minutes for the mattress to inflate fully.

7.0 Program Settings

- 1. Place the patient in the center of the mattress. Adjust the mattress' internal pressure according to the patient weight by using the weight button on the control panel of the power unit. If the mattress is too soft or too firm, increase or decrease the mattress' internal pressure one increment at a time and wait for the system to stabilize before making another change. Continue this process until comfort is achieved.
- Caregivers should always perform a hand check by placing their hands underneath patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.

3. **IMPORTANT**: TUCKING THE SHEET IN TOO TIGHTLY REDUCES THE EFFECTIVENESS OF THE SYSTEM.

8.0 Patient Transfer and Transport

Transfer

It is recommended to have the mattress system at maximum weight setting during transfer. Make sure the bed is secured before proceeding.

Transport

In the event of a patient transport, two options are available.

- 1. Detach the mattress' air hose couplers from the power unit's quick release couplers and connect the two air hose couplers together to retain air in the mattress. The mattress will stay inflated for approximately 2 hours, depending on the patient's weight.
- 2. Unplug the power unit's power cord from the wall outlet and the mattress should stay inflated for approximately 40 50 minutes. This mattress system also has a safety foam base underneath the air cells to support the patient for a short period of time in case of deflation. To resume normal operation, please follow 7.0 Program Settings.

9.0 Emergency CPR Deflation

In case of emergency, pull hard to remove the mattress' CPR latch for emergency deflation, and turn off the power unit by pressing the power/mute button on the control panel at the same time. The mattress will deflate from the weight of the patient. To resume normal operation, simply reinsert the CPR latch securely, press the power/mute button again and reset the patient weight.

10.0 Cleaning Instruction

Air mattress and power unit must be cleaned thoroughly between patients to avoid cross contamination. The following is a suggested guideline. Be sure to follow local infection control policies.

Regular cleaning can be performed at bedside with disinfectant followed by drying with a clean dry cloth. Use only mild detergents to clean the coverlet and the mattress. Any appropriate NON-PHENOLIC cleaning agent may be used for heavy soiling from urine, blood, or

other bodily fluids. Please ensure that air mattress and coverlet are completely dry before letting the patient lie on the surface again.

Do not use electric or tumble dryers. Do not iron.

WARNING! Always unplug the power unit before cleaning. Routine cleaning of power unit can be done by wiping down with damp cloth using disinfectant or mild detergent. Never spray liquids directly on the unit itself.

11.0 Routine Maintenance

Remove air filter from the rear panel of the power unit by opening up the filter cap. Inspect the filter for dirt or dust, and clean it with mild soap and water. Reinsert the dried air filter after cleaning and ensure that the cap is secure. If replacement is needed, contact H & R Healthcare.

Only disinfected and dry systems should be stored. Disconnect the air hoses from the power unit. Roll up the mattress starting from the head end and working down toward the foot end. Use the straps to secure it.

12.0 Troubleshooting

Problem	Inspection Procedure	Possible Solutions
Power unit is not working.	Check if power cord is firmly plugged into both the control unit and the electrical outlet.	Secure power cord into control unit and/or electrical outlet.
	Check if the power switch is in the ON position.	Turn power switch to ON position.
	Check if power surge has shut down the power unit.	A power surge may overload the circuitry temporarily. Turn the unit off, and check the fuse for damage. Turn the unit on again with normal procedure.
	Make sure there is no power failure.	
	Power unit does not respond to possible solutions.	Please contact H & R Healthcare for assistance.
2. Low Pressure alert does not turn off after 30 seconds after the system is turned on.	Possible control failure.	Please contact H & R Healthcare for assistance.
3. Alarm LED is lit during operation.	Check if there is leakage in air tubes or air cells	Please contact H & R Healthcare for assistance.
4. Power unit is working, but mattress replacement	Verify that CPR latch is properly inserted.	Insert CPR latch securely.
is not inflating and/or Bottoming out is occurring	Check if mattress' air hose couplers are properly connected to power unit's quick release couplers.	Secure air hose couplers firmly into place.
and/or Patient leaves a deep indentation at the contact area which does	Verify that patient weight setting is correct.	Increase or decrease weight setting until appropriate pressure is reached.
not return back to its original shape.	Inspect air filter for dust.	Clean or replace air filter.

	Lift mattress coverlet up to check if air cells are connected correctly.	Make sure all air cells are properly linked to air supply.
	Lift mattress coverlet up to check if air tubes are kinked or obstructed.	Check and adjust air tubes' positions.
	Check if air cells are cut or cracked.	Please contact H & R Healthcare for assistance.
5. Patient's wounds are not responding to pressure relief (reddening of skin).		Contact your physician and/or nursing service immediately.

13.0 Returns for Service

Service and repair must be performed by an H & R Healthcare authorized technician or representative. Please contact H & R Healthcare at 800-801-5533.

14.0 Warranty

H & R Healthcare warrants this product against manufacturer defects for one year from the date of placement.

Please inspect this product upon purchase and notify H & R Healthcare if there is any damage or missing parts.

Warranty coverage will not be extended to any product on which the production lot number has been removed or defaced, on which repair has been attempted by any person or agency not authorized by H & R Healthcare or, if in the sole

opinion of H & R Healthcare, the system shows evidence of tampering, abnormal or unreasonable abuse, negligence, accident or operation without regard for the restrictions specified in the instructions which accompany the system. This warranty does not cover routine maintenance such as cleaning, adjustment, lubrications, and updating of equipment or parts. If, in the sole opinion of H & R Healthcare, the damage is not covered under this warranty, the purchaser will be responsible for labor and parts costs.

The warranty stated above is the only warranty made and is in lieu of all other warranties whether expressed or implied. H & R Healthcare, nor any of its agents, shall be held liable for consequential or incidental damages of any kind.

15.0 Product Specifications

Mattress Dimension 80"/84" x 37" x 7"

Number of Air Cells 20 Air Cells

Power Control Unit Dimension (SR366)
11.5" x 8.5" x 4.5"

Integrated Foam 2"

Material

Power Unit - ABS fire retardant UL Mattress Cell - 100 % nylon with TPU lamination Coverlet - 100% nylon quilted backing

<u>Power /Input</u> AC100 - 120V / 60Hz 0.5A

<u>Power Consumption</u> Normal Operation: Max 15W

Power Control Unit Weight 5.5 lbs

Fuse Rating T1A / 250 V

Operating & Transportation & Storage Conditions

Temperature: 41° F - 104° F Humidity: 15% - 60%

<u>Electrical Classification</u>
Class I Type BF. Applied part is mattress.

IPXO, do not immerse power unit in any liquid or spray any liquids directly on the power unit. This system is not AP/APG Protected.

Continuous operation.

Agency Approval
ANSI/AAMI ES60601 - 1 and CAN/CSA
- C22.2 NO. 60601 - 1:08

<u>Electromagnetic Compatibility</u> IEC60601 - 1 - 2

Maximum Weight Capacity 325 lbs

H & R Healthcare reserves the right to change prices or design parameters and specifications without incurring any liability in connection with such modifications.