RELIEF AIRE

ALTERNATING PRESSURE SYSTEM WITH LOW AIR LOSS

Operation Manual

H & R Healthcare
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Congratulations and thank you for purchasing this Relief Aire 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 732-367-5533.

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1.0 Indications

 Operation Instructions

 Caution

 Declaration of Conformity to Medical Device Directive.

IP21 Do not immerse power unit in liquid or spray liquids directly on power unit.

 Type BF Applied part

 Protective Earth (PE)

 NRTL_SGS Q Mark Listing logo

 WEEE Logo

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.

2.0 Safety Precautions

1. 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.

3. 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.

4. This system should be disinfected thoroughly between patients to avoid cross contamination.

5. Verify that patient weight does not exceed the weight capacity

of the bed frame, bed rails, or this mattress system.

3.0 Cautions

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.*

2. DO NOT disassemble the power unit if you are not a qualified technician. Please contact H & R Healthcare for all service.

3. This product is NOT AP/APG protected.

4. It is recommended that the patient be repositioned periodically while using this mattress.

5. 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 Set x 1
- Operational Manual x 1

Mattress Package

- Mattress replacement unit with coverlet x 1

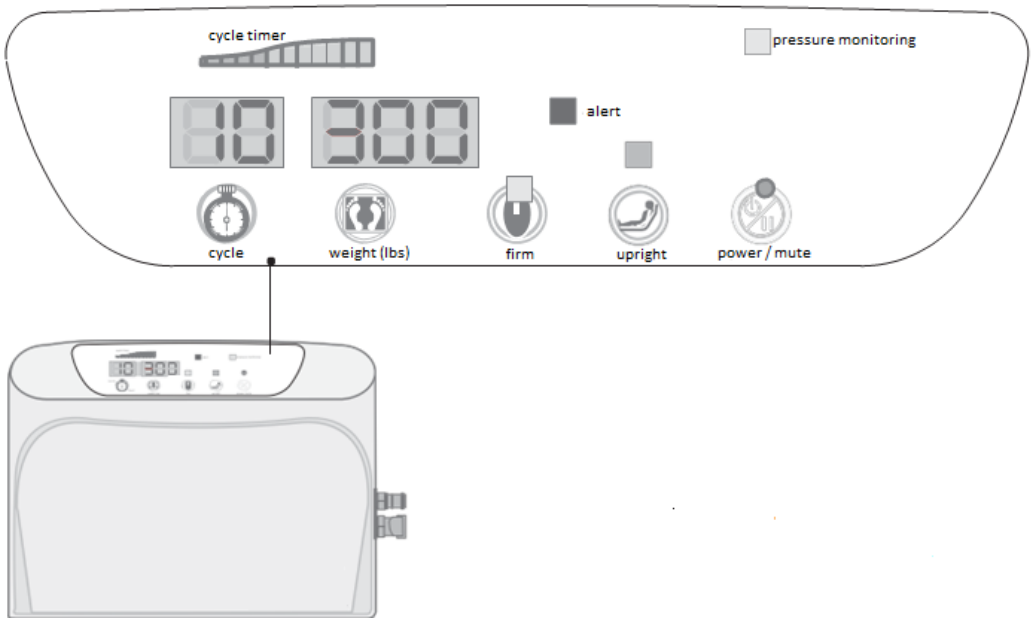
The air mattress operates at a max of 100°F.

Transport & Package

- Tempertaure: -25°C to +70°C
- Relative Humidity: 0% to 90%

5.0 Features

Control Panel Features



Power/mute
Press the power/mute button to turn on the power unit and the green LED will light up. In the event of an abnormal power outage, the LED will change to orange, and an audible alarm will sound to notify medical staff. You may press power/mute button to turn off the audible alarm, or it will sound until power is restored or rechargeable battery is activated. Memory recall function recalls the previous setting after abnormal power outage or after the main power rocker switch is turned off. The mute function is only functional when audible alarm is in effect.

Weight (lbs)
Simply press the weight (lbs) button to adjust the patient weight to a maximum of 450 lbs. This number is for reference only! Please adjust the weight setting if the mattress is too soft or too firm to suit each individual patient. 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.

Upright
Upright mode is used to prevent patient from bottoming out in upright position. Once the upright button is pressed, the green LED will light up to indicate that this mode is in operation. Make sure that the upright mode is switched

off when the patient is lying down to avoid incorrect pressure setting.

Firm
Press firm button to inflate the mattress rapidly to maximum pressure; the yellow LED will light up to indicate this mode is in operation. Press the button again to restore the original setting or this mode will disable automatically after 20 minutes if unattended.

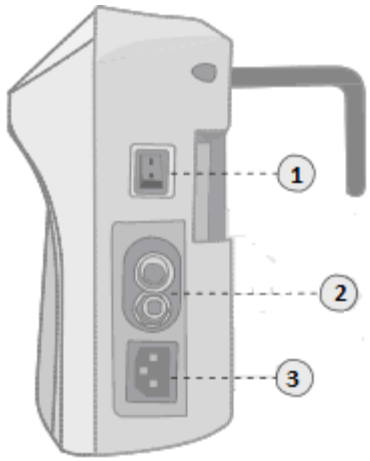
Cycle
Use this function to set the alternating cycle time from 10 to 20 minutes to meet each patient's needs; set to "0" for static mode.

Alert LED
This low pressure alert notifies medical staff that the mattress has insufficient pressure. An audible alarm will sound for 15 seconds at each cycle and the indicator will stay on until the problem has been resolved.

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.

Cycle timer LED
This shows the count down of cycle time; light will be off in static mode.

Right Side Panel Features

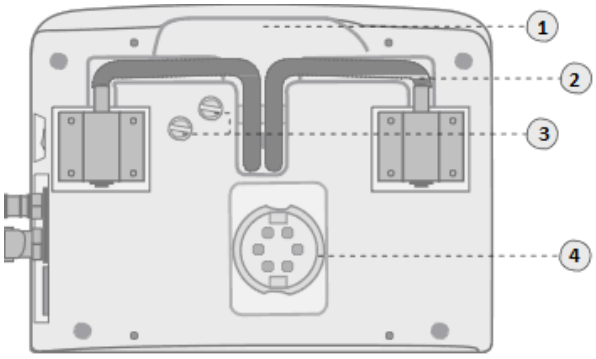


Rocker Switch (1)
Power unit's main power switch.

Couplers (2)
Quick release female couplers are used to secure mattress air hoses to power unit.

Power Receptacle (3)
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 most foot boards.

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. Verify 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.

7. Press power/mute button to inflate the mattress system. Please wait approximately 30 seconds until the power unit is ready before making any program adjustment.

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 (lbs) 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.

2. 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 in firm mode 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 Instructions

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 a 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
1. 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. Alert LED is lit during operation.	Check if there is leakage in air tubes connecting the power unit to the air cells or in the individual air cells.	Please contact H & R Healthcare for assistance.
4. Power unit is working, but mattress replacement is not inflating and/or Bottoming out is occurring and/or Patient leaves a deep indentation at the contact area which does not return back to its original shape.	Verify that CPR latch is properly inserted.	Insert CPR latch securely.
	Check if mattress' air hose couplers are properly connected to power unit's quick release couplers.	Secure air hose couplers firmly into place.
	Verify that patient weight setting is correct.	Increase or decrease weight setting until appropriate pressure is reached.
	Inspect air filter for dust.	Clean or replace air filter.
	Lift mattress coverlet to check if air cells are connected correctly.	Make sure all air cells are properly linked to air supply.
	Lift mattress coverlet 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. Alternating or static setting is not available.	Possible control failure.	Please contact H & R Healthcare for assistance.
6. 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 732-367-5533.

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 option 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

Air Pump (Power Unit) Model
SR361

Mattress Dimension (MSR204)
80”/84” x 37” x 10.5”

Number of Air Cells
20 Air Cells

Power Unit Dimension
11.5” x 8.5” x 4.5”

Integrated Foam
2”

Material
Power Unit – Plastic case rated UL 94V-0
Mattress Cell – 100 % nylon with TPU lamination
Coverlet – 100% nylon with PU backing

Power Input
100-120Vac 60Hz 0.2A

Power Consumption
Normal Operation: Max 1.0A

Power Unit Weight
5.5 lbs

Fuse Rating
T1A 250V

Electrical Classification
Class I Type BF. Continuous operation IPX0, do not immerse power unit in any liquid or spray any liquids directly on the power unit.

This system is not AP/APG Protected.

Safety Test & Certified Standard
NRTL_SGS Q Mark Listing to
ANSI/AAMI ES60601-1:2005+A1:2012
CAN/CSA C22.2 No.60601-1:14
EN 60601-1:2006/A1:2013_v3.1
IEC 60601-1:2005/A1:2012_v3.1

EMC Test Standard
IEC 60601-1-2:2014/EN60601-1-2:2015
Emission Classified as Class B to CISPR 11

Operating Conditions
Temperature range:5˚C to 40˚C
Relative humidity range: 15% to 93%
Atmosphere range: 700hPa - 1060hPa

Maximum Weight Capacity
450 lbs

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

16.0 EMC Declaration

Declaration of Conformity

For EN 60601-1-2

Company Name:	**CARILEX MEDICAL, INC**
Company Address:	**No. 77, KEJI 1ST RD. GUISHAN DIST., TAOYUAN CITY,333 TAIWAN (R.O.C.)**
Trade Name:	**Carilex**
Report Number:	**ETC 16-08-RBO-002-01**
Power Supply:	**AC 100 - 120V 60Hz 0.2A 20W max.**

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The Air Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Air Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Air Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Declaration – electromagnetic emissions

The Air Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Air Pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Air Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Air Pump 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment

The Air Pump declaration – electromagnetic immunity

The Air Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Air Pump system should assure 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	3 Vrms ; 6 Vrms 150 kHz to 80 MHz		3 Vrms ; 6 Vrms 150 kHz to 80 MHz		Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%		3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%		
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	385 MHz	
	28 V/m	450 MHz	28 V/m	450 MHz	
	9 V/m	710 MHz	9 V/m	710 MHz	
		745 MHz		745 MHz	
		780 MHz		780 MHz	
	28 V/m	810 MHz	28 V/m	810 MHz	
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	

Declaration – electromagnetic immunity

The Air Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Air Pump system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	±0.5 kV ±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T ; 0 , 5 cycle At 0^o , 45^o , 90^o , 135^o , 180^o , 225^o , 270^o and 315^o 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0^o	0 % U_T ; 0 , 5 cycle At 0^o , 45^o , 90^o , 135^o , 180^o , 225^o , 270^o and 315^o 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0^o	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.