Anti-Decubitus

Air Alternating Pressure Mattress

Replacement System

AIRRAPY

Operation Manual

carilex®

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Congratulations and thank you for purchasing this Carilex anti-decubitus mattress system. **PLEASE READ THIS OPERATION MANUAL CAREFULLY BEFORE SETTING UP AND USING THE DEVICE.** Pay special attention to the warnings and other safety information. Use genuine Carilex components are essential for optimal performance. If you do not fully understand all the instructions, safety precautions, and warnings, do not use this device. In case you have questions, please contact your local Carilex distributor.

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1.0 Indications

Attention! Please read enclosed document thoroughly

Declaration of Conformity to Medical Device Directive

IPX0 Do not immerse power unit in liquid or spray liquids directly on power unit

Type BF Equipment

Double Insulated (Class II)

Indications

This air alternating mattress system is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. This device is intended to treat and prevent pressure ulcers 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. This anti-decubitus mattress system is mainly for low to medium risk patient group.

Contraindications

Certain patient conditions are no t suitable for using this type of device such as fracture of instable vertebrae and illness of instable vertebrae. Always consult a physician or healt h 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

(1) To ensure proper operation, please inspect and verify all parts are setup properly and anchor securely. Do not place anything on top of th e power unit. Make sure power cord is underneath bed frame and free from hazard.

(2) It is recommended to limit bed linens to a single layer in order to allow the moisture escape efficiently through the coverlet. Only" 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. Thus, cigarette smoking may damage internal component.

(4) This system should disinfect thoroughly between patients to avoid cross contamination.

(5) Verify patient weight does not exceed bed frame, bed rails, and this mattress system's weight capacity.

3.0 Warnings

(1) *Use this mattress with proper side rails to ensure the gap between the side rail and top of the mattress is small enough to prevent patient from getting his or her head or neck into the gap. Fail 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 your local distributor for all service.

(3) This product is NOT AP/ APG protected.

(4) Re-position the patient once awhile is still necessary when using this mattress.

(5) Operating, transportation, and storage conditions:
Temperature: 5°C - 40°C
Humidity: 15% - 60%
Atmospheric Pressure : 700~1060 hPA

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

(6) A warning that other cables and accessories may negatively affect EMC performance

(7) A warning regarding stacking and location close to other equipment

(8) A warning that use of other accessories results in noncompliance

4.0 System Package

Power Unit Package

* Power unit x 1
* Power cord x 1
* Operation manual x 1

Mattress Package

* Mattress replacement unit with coverlet x 1

5.0 Features

Control Panel Features

See Figure 5a on page 5.

Power

Plug the power cord into appropriate power outlet.

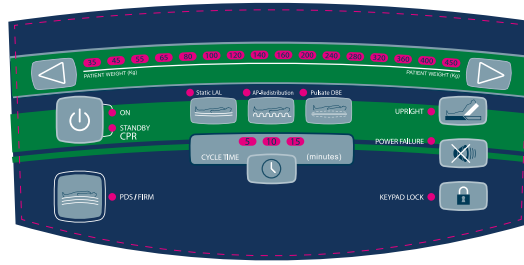
The orange STANDBY/CPR LED will illuminate. To begin inflation, press the power button.

On the control panel; the green on LED will illuminate.

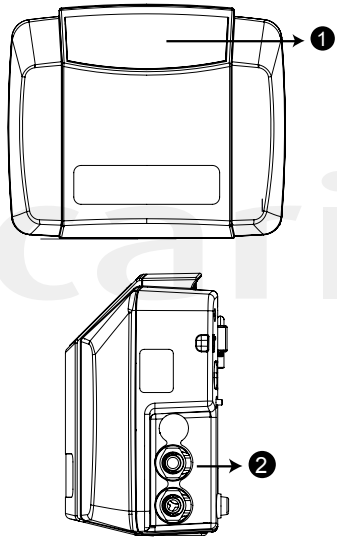
Patient weight (kg)

Simply press ◁ ▷ button to adjust the patient weight from 35 kg to 450 kg according to each individual. The scale is only an approximation. Please adjust the weight setting if the mattress is too soft or firm to suit each patient.

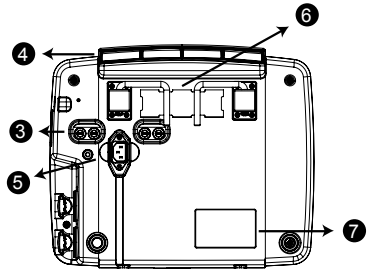
Caregivers should always perform a hand check by placing their hand s underneath patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.



Control Panel Features (Figure 5a)



Right Side Panel Features (Figure 5b)



Rear Side Panel Features (Figure 5c)

Upright

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

Firm

Press firm button to inflate the mattress rapidly to maximum pressure, the green LED will light 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.

AP-Redistribution

Alternating Mode is a therapy mode in which alternating air cells are inflated and deflated together in an A-B-A-B pattern to alleviate pressure and increase blood flow in the patient. 5, 10 or 15minutes Alternating cycle times may be selected.

Static LAL Mode

Static Mode is standard low air loss therapy in which all air cells maintain constant support.

Pulsate Mode

Pulsate Mode is a therapy mode in which the pressure in all air cells is modulated

above and below the selected patient weight setting by predetermined percent every 90 seconds.

Panel Lock 

panel lock Under the Rocker Switch is On and power is On, if there is no operation after 2 minutes, the panel will be locked automatically. All function buttons are locked out besides power/mute to turn off the audible alarm. Simply press and hold the button for 3 seconds to release "panel lock" function.

Alarms/ Mute 

Power failure alarm will sound when main power is removed. Require service will sound when blower function is outside of the desire setting for more than 2minutes or the pressure levels fall below desired setting for more than 2minutes.
(See troubleshooting section for further information)
You may press  mute button to turn off the audible alarm after notified. Indicator will stay on until the problem has been solved.

Right Side Panel Features

See Figure 5b

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

Rear Side Panel Features

See Figure 5c

Fuse (3)
Fuse holders can be opened with flat head screwdriver to inspect or change fuses.

Hanging Hook (4)
Hanging hooks are designed to fit multiple footboard widths. Hooks are spring loaded and will fold against the power unit when not in use.

Power Receptacle (5)
Three conductor IEC 60320 C14 Female receptacle. To accept power cord with C13 connector.

Air Filter and Filter Cap (6)
It is recommended that the filter should be Inspected and cleaned or replaced with a Genuine Carilex Medical GmbH. replacement part once a month to ensure optimal performance of the power unit.

Serial Number Label (7)
Label identifies serial number along with Agency approvals, etc.

6.0 Mattress and Power Unit Installations

(1) Remove existing mattress from hospital/homecare bed frame and store.

(2) Place Carilex mattress replacement on the bed frame with the hose end at the foot section of the bed frame. Secure mattress replacement to each side of the bed frame using mattress anchor straps with clips.
Anchor straps should be attached to the bed frame in a fashion that will not hinder the bed frame articulating up and down. Attach anchor straps should be tucked under another change until a comfortable state is achieved.

complications.

(3)Using the integrated hanging hooks, securely hang the power unit on the bed end at the foot end or place on a smooth flat surface.

(4) Connect the air hoses by using the quick couplers from the mattress replacement to the power unit.

(5) Plug the power unit into a wall outlet. Be sure the power cord is safely away from possible hazards (eg. Foot traffic, bed tables, etc..)

(6) The system will be in Standby/CPR Mode. Press the power button on the control panel. The power unit will begin to inflate the support surface. Max inflate function may be used to rapidly inflate the support surface prior to use by the patient.

7.0 Program Settings

(1) Center the patient on the mattress. Adjust the mattress' internal pressure according to the patient weight by using the weight(kg) ◁ ▷ button on the control panel of the power unit. If the patients feels too soft or firm, increase or decrease one increment at a time and wait for the system stabilize before making another change until a comfortable state 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) **IMPO RTAN T:** TUCKING TH E SHEET IN TIGHTLY REDUCES THE EFFECTIVENESS OF THE SYSTEM.

(4) ⚠ *WARNING!* When using side rails and/or assist devices, use a mattress thick enough and wide enough so that the gap between the top of the mattress and the bottom of the side rails and the gap between the side of the mattress and the side rails is small enough to prevent patient from getting his or her head or neck between the mattress and the side rails.Failure to do so could result in injury or death.

8.0 Patient Transfer and Transport

Transfer

Always secure bed or gurney before patient transfer. If available, engage locks on the bed casters before transferring patient. Transfer are much easier when the SR372 power unit is in Max inflate mode / firm mode or fully inflated.

Transport

When a need to transport a patient arises, the SR372 mattress has an static air cell on the bottom to support the patient for a short period of time. Turn off power unit and disconnect plug from wall outlet. When transport is complete plug power cord back into a properly grounded wall outlet. It is not necessary to remove patient from support surface before re-inflation.

9.0 Emergency CPR Deflation

In the case of emergency, press the power button on the control panel to shit the system to STANDY/CPR mode. LED will illuminate to indicate the power unit is Standby/CPR mode. This will deflate the mattress rapidly so CPR can begin. To resume therapy, press Power button on. Power unit will return to last setting selected.

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, but local infection control policies should be followed as well.

Regular cleaning can be performed at bedside with disinfectant and water followed by drying with a clean dry cloth. Use only mild detergents and water to clean the coverlet and the mattress. Any appropriate NON-PHENOLIC cleaning agent may be used for heavy soiling with urine, blood or other body fluids. Please ensure air mattress and coverlet are completely dry before letting the patient laying on the surface again.

Machine wash warm water at maximum 71°C. Do not use electric or tumble dryers. Do not iron.Please follow the instruction on washing tag.

WARNING ! Always unplug th e power unit before cleaning. Routine cleaning of power unit can be done by wiping down with damp cloth using disinfectant and water or mild neutral 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 to clean or replace the air filter. Inspect the filter for dirt or dust and clean it with mild soap and water. Reinsert the dried air filter after cleaning and ensure the cap is secure. Replace with genuine air filter once a year is recommended and compressor every two year is strongly suggested t o prolong system lifetime.

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

12.0 Troubleshooting

Problem	Inspection Procedure	Possible Solutions
1.) Power unit is working, but mattress replacement is not inflating.	1.1) Verify air is flowing smoothly through hoses and mattress manifolds. Inspect for cuts or cracks.	1.1) Hose(s) or manifolds may need to be moved to avoid kinking or obstruction. If cuts or tears are observed, hose(s) or manifold may need to be replaced.
	1.2) Verify hoses are properly connected to power unit.	1.2) Attach connectors securely into place.
	1.3) Verify control panel Power is ON.	1.3) Press Power button on and LED will illuminate.
2.) Patient is "bottoming out".	2.1) Look at Patient Weight setting on power unit.	2.1) Increase or decrease weight setting using Patient Weight buttons until adequate pressure setting is achieved.
	2.2) Check for mattress leaks.	2.2) Replace with appropriate spare parts.
	2.3) Check Air Filter for dirt/lint.	2.3) Clean or replace Air Filter.
3.) Power unit does not operate. / Power Fail Alarm	3.1) Verify power cord is securely plugged into live wall outlet.	3.1) Secure plug into live wall outlet. Test a different appliance in outlet to verify outlet has power.
	3.2) Verify power cord is securely plugged into power unit.	3.2) Secure plug into power unit.
	3.3) Verify fuse is not blown.	3.3) A power surge may temporarily over¬load the circuitry. Turn unit off for several seconds. Check the fuse for damage. Re-try turning unit on with normal operat¬ing procedures.
	3.4) Power unit does not respond to pos-sible solutions listed in 3.1 thru 3.4.	3.4) Call customer service at Carilex Medical GmbH. Local distribution
4.) Requires Service Alarm	4.1) Verify Air Filter is not obstructed.	4.1) Clean Air Filter. Ensure Air Filter is not blocked.
	4.2) Verify hoses are properly connected to power unit.	4.2) Attach connectors securely in place.
	4.3) Unit does not respond to solutions 4.1 or 4.2.	4.3) Call customer service at Carilex Medical GmbH. Local distribution
	4.4) None	4.4) Call customer service at Carilex Medical GmbH. Local distribution

13.0 Returns for Service

This device is not self-serviceable. Service and repair must be performed by an authorized technician or representative. All returned device must be cleaned and disinfected prior to shipping. Unsanitary or soiled systems will be returned without servicing.

14.0 Warranty

Carilex Medical GmbH warrants the product to be free from defects from the date of purchase. Please inspect all accessories when you purchase ou r product. The expected service life is 2 years. If there is any damage o r missing accessories when you receive the product, please ask for a replacement from your local distributor within three days of purchase.

The warranty periods for Carile x products are according to the regulations in your country, the minimum period is 1 year from date of purchase for the power unit and 1 year for the mattress and the coverlet. The warranty coverage of any Carilex product is contingent up on its purchase from an authorized dealer. Warranty for any product in the Carilex product line will be honored by the official distributor in your country.

Warranty coverage will not be extended to any product on which the production lot number has been removed o r defaced, on which repair has bee n attempted by any person or agency not authorized by Carilex or if in the sole opinion of Carilex that the system shows evidence of tampering, abnormal or unreasonable abuse, negligence, accident or operation without regard for th e restrictions specified in the instructions which accompany the system. This warranty does not cover normal maintenance such as cleaning , adjustment, lubrication, and updating of equipment or parts. If the damage is result from improper operation, a reasonable service fee and part cost will be charged.

The warranty stated above is the only warranty made and is in lieu of all other warranties whether expressed or implied, including any warranty of merchantability or fitness for a particular reason. Carilex Medical GmbH will not be liable for consequential or incidental damages or any kind.

15.0 Product Specifications

Production Specification

Power Input:	AC220-240V - 50/60Hz 5A
Power Consumption	Max. 410W – normal operation
Fuse Rating	T0.5A/250V (PCB Fuse) T5A/250V (Power Fuse)
Electrical Classification	Class II with FE, Type BF
Electromagnetic Compatibility	EN60601-1-2
Dimensions (WxHxD)	● Power Unit (SR372) : 5.8kg ● Mattress Pillowed Air : 90cm x 210cm Bairrapy : 90cm x 210cm Adjustable to : 105cm x 210cm 122cm x 210cm
Weight	● Mattress Pillowed Air : 14.5kg Bairrapy : 17kg
Number of Air Cells	21pcs of air cell in one set
Material	● Air Cell : 100% PU ● Coverlet : optional Aeotex or quilted Nylon
IPX0	Don't immerse power unit in any liquid or spray any liquids directly on the power unit.
Operation Conditions	Temperature range: 5˚C to 40˚C Relative Humidity Range: 15%~60% noncondensing. Atmosphere range: 700hPa-1060hPa
Transport and storage conditions	Temperature Range: 5˚C to 40˚C Relative Humidity Range:0%~93% noncondensing
Maximum Weight Capacity	450 kg

16.0 Environmental protection

The instructions for use shall:
- identify any RISKS associated with the disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE; and provide advice on minimizing these RISKS.

17.0 Manufacturer's Manual and Declaration

Guidance and manufacturer's declaration-electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge(ESD) IEC 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 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	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	+ 1kV differential mode Not applicable	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	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of this power unit including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the power unit is used exceeds the applicable RF compliance level above, the power unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the power unit b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and ME equipment

The power unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the power unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the power unit 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**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	38	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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