

*Anti-Decubitus
Low Air Loss Mattress
Replacement System*

Theraflo

Operation Manual

carilex[®]

Carilex Medical GmbH
www.Carilex.de

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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



Double insulated (Class II)



Declaration of Conformity to Medical Device Directive



International Electronics Approval

IPX0

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



Type BF Applied Parts

Indications

This low air loss mattress replacement 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 high risk patient group.

Contraindications

Certain patient conditions are not suitable for using this type of device such as fracture of instable vertebrae and illness of instable 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

- (1) To ensure proper operation, please inspect and verify all parts are setup properly and anchor securely. Do not place anything on top of the 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 - 45°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.

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 (ON LED/ STANDBY-CPR LED)

The system is in STANDBY-CPR mode and the orange LED will light when the main power rocker switch on the left side panel is turned on. Press the **POWER** button to turn on the system and the green LED will light.

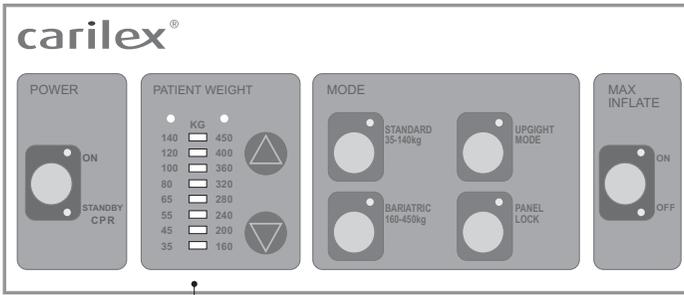
- * Please refer to 9.0 Emergency CPR Deflation for CPR function.

PATIENT WEIGHT

Simply press the ▲ or ▼ button to adjust the patient weight 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.

MODE

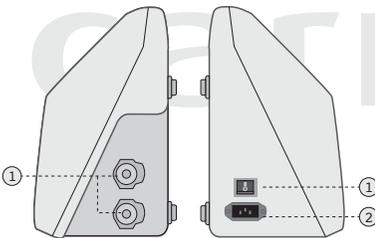
STANDARD mode is for patient who weights in the range of 35 kg - 140 kg. BARIATRIC mode is for patient who weights in the range of 160 kg - 450 kg. Press and hold the desired mode button for 10 seconds to switch between Standard and Bariatric mode. UPRIGHT mode is used to prevent patient from bottoming out in sit up position. Make sure UPRIGHT mode is switch off when the patient is laying down to avoid incorrect pressure setting. Press PANEL LOCK button to lock out function buttons besides max inflate and power functions from



Control Panel Features (Figure 5a)



Press the MAX INFLATE button to inflate the mattress rapidly to maximum pressure. Press the button again to restore to the original setting or this function will disable automatically after 20 minutes if unattended.



Right Side & Left Side Panels Features (Figure 5b)

Right Side Panel Features

See Figure 5b

Couplers (1)

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

Left Side Panel Features

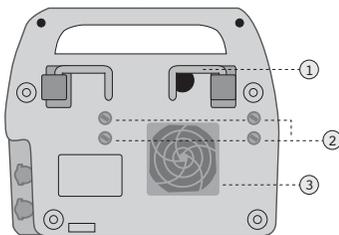
See Figure 5b

Rocker Switch (1)

Power unit's main power switch. The power unit automatically goes into STANDBY-CPR mode after the switch is turned on.

Power Receptacle (2)

Insert power cord firmly into receptacle.



Rear Panel Features (Figure 5c)

unauthorized changes. If you wish to cancel panel lock, simply press and hold the PANEL LOCK button for 3 seconds.

MAX INFLATE

Rear Panel Features

See Figure 5c

Hanging Hooks (1)

Hanging hooks are designed to hang the power unit on almost any foot board. Hooks are spring loaded and will fold against the power unit when not in use.

Fuse (2)

Fuse holder can be opened for maintenance.

Air Filter and Filter Cap (3)

Carilex recommends that the filter to be clean or replace once a month to ensure optimal performance of the power unit.

6.0 Mattress and Power Unit Installations

- (1) Remove existing mattress from bed frame.
- (2) Place Carilex mattress replacement on the bed frame with the logo at foot end. Secure the mattress at each side using anchor strap. Please verify all bed functions are working properly without interference before proceeding to the next step.
- (3) Secure the power unit onto the foot board using hanging hooks.
- (4) Firmly connect the mattress' air hose couplings to the CPC quick release couplers on the power unit's air outlet.
- (5) Plug the power unit into a wall outlet and turn on the main power rocker switch on the left side panel. The STANDBY-CPR orange LED on control panel will light to acknowledge the power unit is in standby mode.

- (6) Press the **POWER** button on the control panel to inflate the mattress system. MAX INFLATE may be used to shorten the initial inflation time if needed.

7.0 Program Settings

- (1) Center the patient on the mattress. Adjust the mattress' internal pressure according to the patient weight by using the ▲ or ▼ button on the control panel of the power unit. If the patient feels the mattress is too soft or firm, increases or decreases the pressure one increment at a time and wait for the system to 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) **IMPORTANT: TUCKING THE SHEET IN TIGHTLY REDUCES THE EFFECTIVENESS OF THE SYSTEM.**

8.0 Patient Transfer and Transport

Transfer

It is recommended to have the mattress system in MAX INFLATE mode during transfer. Make sure the bed is secured before proceeding.

Transport

If a transport occasion comes up, detach mattress' air hose couplings from the power unit's CPC quick release couplers and connect the two air hose couplings together. Carilex Theraflo system has a safety foam base underneath the air cells to support the patient for a short period of time. To resume normal operation, please follow 7.0 Program Setting.

9.0 Emergency CPR Deflation

In the case of emergency, press the **POWER** button on the control panel to turn the system into STANDBY-CPR mode to deflate the mattress rapidly in order to perform CPR. Press the **POWER** button again and reset the patient weight to resume therapy.

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.

WARNING! Always unplug the 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 real 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 to 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 down toward the foot end. Use the straps to fix it.

12.0 Troubleshooting

Problem	Inspection Procedure	Possible Solutions
1. Power unit does not function.	Check if power cord is firmly plugged into wall outlet.	Secure power cord into wall outlet.
	Check if power switch is in ON position.	Turn power switch to ON position.
	Check if power surge shuts 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.
	Power unit does not respond to possible solutions.	Please contact your authorized local distributor for assistance.
2. Power unit is working, but mattress replacement is not inflating.	Check if air is flowing smoothly through air hoses and mattress manifolds*. Look for cuts and cracks.	Air hoses or manifolds may need to be readjusted to prevent obstruction. Air hoses or manifolds may need to be replaced if cuts or cracks are observed.
	Check if mattress' air hose couplings are properly connected to power unit's CPC quick release couplers.	Secure air hose couplings firmly into place.
	Check if control panel's ON green LED is on.	Press POWER button on and ON green LED will light.
3. Bottoming out is occurring.	Verify if 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.

* Mattress Manifold - a side panel within the mattress which serves as air chamber to direct air flow into each individual air cell.

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 our product. If there is any damage or 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 Carilex 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 or defaced, on which repair has been

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 the 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

Mattress Dimension (MSR208)

36": 200 x 90 x 20 cm
 39": 200 x 99 x 20 cm
 42": 200 x 107 x 20 cm
 48": 200 x 122 x 20 cm
 54": 200 x 137 x 20 cm
 60": 200 x 153 x 20 cm

Number of Air Cells

20 air cells

Power Control Unit Dimension (SR371)

36 x 30 x 17 cm

Material

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

Power Input

AC100 - 120V/ 50 - 60 Hz 5A
AC220 - 240V/ 50 Hz 5A

Power Consumption

Normal Operation: Max 350W

Power Control Unit Weight

4.6 kg

Power Cord

H05VV-F3x1.00mm²

Fuse Rating

T1A/ 250V

Operating & Transportation &

Storage Conditions

Temperature: 5°C - 45°C
Humidity: 15% - 60%
Atmospheric pressure: 700 - 1060 hPA

Electrical Classification

Class II Type BF, double insulated with or without functional ground wire.
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.
Continuous operation.

Agency Approval

EN60601-1, EN60601-1-2,
EN61000-3-2, EN61000-3-3, UL2601-1

Electromagnetic Compatibility

EN60601-1-2:1993
Type BF Applied Part

Maximum Weight Capacity

450 kg

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

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Turmbergstr. 9A, D-76227 Karlsruhe, Germany
Tel:+49(0)721 16 19 835 · Fax:+49(0)721 16 19 836
Email: info@carilex.de
Website: <http://www.carilex.de>