

carilex[®]

Carilex Medical GmbH

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>



Operation Manual

Anti-Decubitus
Air Alternating Pressure Mattress
Replacement System

carilex[®]

Carilex Medical GmbH
www.Carilex.de



Summit User's Manual

Congratulations and thank you for purchasing this Carilex Summit 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 of genuine Carilex components is essential for optimal performance. If you do not fully understand the instructions, safety precautions, and warnings, please do not use this device. If you have questions, contact your local Carilex distributor.

Summit is the latest innovation of therapeutic pressure ulcer management surface from Carilex. Carilex has developed an Auto Regulating Technology (A.R.T.™) which *automatically* optimizes the interface pressure according to the patient loading on top of the mattress. Not only does it take into account the patient's weight, but their body shape also. This new technology provides patients with optimal pressure relief and also reduces the set up time required from nurses. It also monitors and adjusts the pressure regularly. This technology offers patients the best skincare protection and is also extremely convenient for nurses.

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1 Symbol Reference



Attention! Please read enclosed documents thoroughly



Declaration of Conformity to Medical Device Directive

IPX0

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



Type B Equipment

Indications

Summit is designed for patients at risk of or suffering from pressure ulcers. The system reduces the risk of developing pressure areas in patients with limited mobility by encouraging the circulation of blood and decreasing the pressure at each tissue contact area. This particular system is designed for the prevention and treatment of pressure ulcers for use in high risk patients. ALWAYS consult a physician or health professional prior to using this system.

Contraindications

This system is not suitable for use in patient with certain conditions such as unstable fractures of the vertebrae. ALWAYS consult a

physician or health professional prior to using this system.

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

2 Safety Precautions

Installation

- 1.To ensure full functionality of the equipment, inspect and verify that all parts of the system have been set up correctly and fastened securely (to prevent any sliding).
- 2.Do not place anything on top of the power unit.
- 3.Ensure that the power cord is underneath the bed frame and free from any hazards.
- 4.Do not block air intake on power unit. Any obstruction to airflow, such as a dirty filter, will cause excessive heat and can shorten the life of the compressor.

Bed Linens

- 1.It is recommended that bed linens are limited to a single layer. This is to allow moisture to escape through the coverlet efficiently.
- 2.IMPORTANT: TUCKING THE SHEET INTIGHTLY REDUCES THE EFFECTIVENESS OF THE SYSTEM

Open Flames

- 1.Risk of flammability. Do not use near smoke, heat, sparks or open flame.
- 2.Do not use in the presence of cigarette smoke. This system draws air from the surroundings and smoke may damage internal components.

Cross Contamination

- 1.Disinfect the system between patient installations to avoid cross-contamination and infection.

Bed Frame Consideration

- 1.This mattress alone does not function as a patient fall safety device. Recommended with use of side rails.
- 2.Ensure that the patient's weight does not exceed the specified weight capacity of the system in use. Summit is designed for a maximum loading of 300 kg.

3 Warnings

- 1.Exercise particular care in adjusting the side rails to an appropriate height so that the gaps between the top of the mattress and side rails ensure that the patient's body parts are limited within the side rails, and risk of passing through is minimized. This will prevent any serious injury to the patient.
- 2.DO NOT disassemble the power unit unless you are a qualified technician. Please contact your local distributor for all services.
- 3.This product is NOT AP/APG protected.
- 4.Regular repositioning of the patient is still essential when using this system.
- 5.Operating, transportation and storage conditions:
Temperature: 5°C - 45°C
Humidity: 15% - 60%
- 6.Ensure that there are no sharp, protruding objects or bed springs under the mattress as these could puncture the air cells.

4 System Package

If there is any damage or missing accessories when you receive your product, please ask for a replacement from your local distributor.

Power Unit Package

- * 1 x Power unit

- * 1 x Power cord
- * 1 x Lithium battery
- * 1 x Operation manual

Mattress Package

- * 1 x Mattress replacement unit with coverlet

5 Features

Control Panel Features
See Figure 5a

Power/ Standby

When the main power rocker switch on the left side panel is turned on, the system is in standby mode and the orange LED will be lit. To turn on the power unit, press **Power/ Standby** and the standby orange LED will be off.

Memory Recall

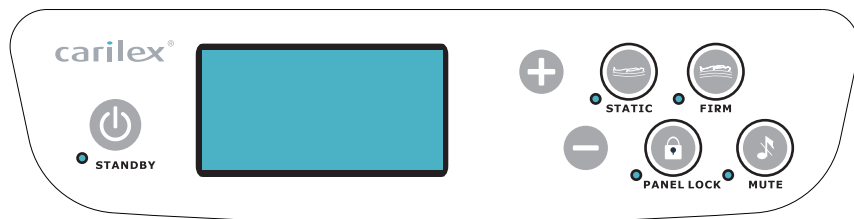
The memory recall function recalls previous settings when power returns to system, after power has been switched or cut off under any circumstances.

Auto Upright

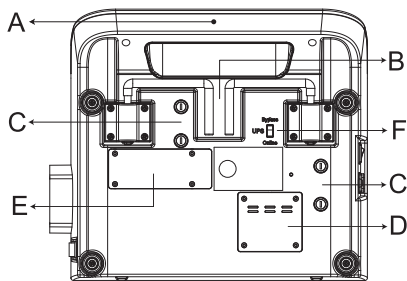
Auto Upright mode is used to prevent the patient from bottoming out when sitting in the articulating position. Once the system detects the upper section of the mattress is elevated between 20 and 40 degrees, an upright symbol (👤) will be displayed on the LCD to indicate the upright function has been turned on. To avoid incorrect pressure settings, upright mode is switched off when the mattress returns to the horizontal position

Firm

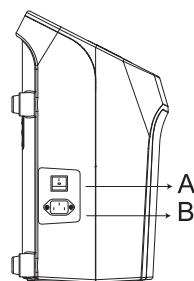
Press **Firm** to inflate the mattress rapidly to maximum pressure. The green LED will light to indicate this mode is in operation. Press **Firm** again to restore the original settings, otherwise this mode will automatically disable after 20 minutes.



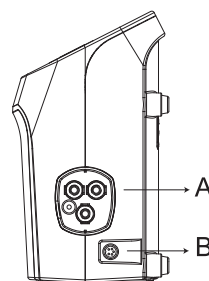
Control Panel Features (Figure 5a)



Rear Panel Features
(Figure 5b)



Left Side Panel Features
(Figure 5c)



Right Side Panel Features
(Figure 5d)

Mute

To turn off the audible alarm, press **Mute**, otherwise the system will continue to sound until the abnormality is solved. The mute function is only operational when the audible alarm is in effect.

Static

Static allows the unit to switch between static and alternating mode.

Timer

To view the total operating time on the LCD display, ensure the rocker switch is ON and the system power is OFF, then press both **Static** and **Firm** simultaneously.

Panel Lock

Press **Panel Lock** to lock out function buttons except **Mute** to prevent tampering the control

panel. If you wish to unlock the panel, simply press and hold **Panel Lock** for 3 seconds. If the control panel is untouched for 3 minutes, the system will automatically activate panel lock to disable all function buttons.

Minor Adjustments (+/-)

The system offers four increments of mattress internal pressure adjustment, two steps up and two steps down. The user is able to make minor adjustments to the comfort level of the mattress, using +/- . Press “+” to increase or “-” to decrease one step at a time.

Language

The default language of the system is English. To change the language, simply press **Static** and “+” when the rocker switch is ON and the system power is OFF. Use +/- to select the

desired language, and press **Mute** to confirm the selection.

Low Pressure

Both continuous audible and flashing visual warnings will be triggered to notify medical staff when the mattress has insufficient pressure.

Battery Mode

The system will switch to battery mode when abnormal power outages occur. An audible alert will sound until power is returned. While in battery mode, the system will change the alternating cycle time from the default 10 minutes to 15 minutes.

Low Battery

Once the battery contains less than 30% battery life, the LCD will switch off to prolong the operating time. The audible alert will sound until power is returned.

Left Side Panel Features

See Figure 5c

(A) Rocker Switch

Power unit's main power switch.

(B) Power Receptacle

Insert power cord firmly into receptacle.

Right Side Panel Features

See Figure 5d

(A) CPR Connector

Quick release connector used to secure mattress air hoses to power unit.

(B) Auto Upright Socket

Securely insert cable from Auto Upright sensor.

Rear Panel Features

See Figure 5b

(A) Convenient Handle

Provides additional gripping surface for user to carry power unit.

(B) Hanging Hooks

Designed to hang power unit on almost any footboard.

(C) Fuse

Fuse holder can be opened for maintenance.

(D) Air Filter and Filter Cap

Carilex recommends the filter to be inspected and cleaned or replaced once a month to ensure optimal performance of the power unit.

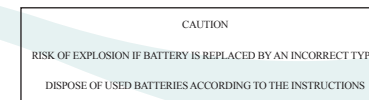
(E) Battery Compartment

Allows for easy access for battery replacement. Also includes socket used for upgrading software/firmware.

Removal the battery pack when unused for long periods of time.

(F) Uninterrupted Power Supply Bypass Switch

Allows the user to turn on the system in case the enclosed uninterrupted power supply fails to operate. If uninterrupted power supply does fail to function, reposition the UPS switch on the rear of the power unit to the BYPASS position to resume operation.



6 LCD Symbol Reference



Battery mode activated



Panel Lock activated



Mute activated



Auto Upright mode activated



Increasing internal pressure



Decreasing internal pressure

7 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 the foot end. Secure the mattress at each side using the anchor straps. Please ensure all bed functions are working properly without interference before proceeding to the next step.

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

3. Secure the power unit onto the footboard using hanging hooks.
4. Firmly connect the mattress' CPR connector to the power unit's air outlet.
5. Make sure Auto Upright sensor is inserted properly with the warning phrase "INSERT THIS WAY" facing upward into designated pocket as shown in the instructions on the coverlet. Secure the wire alongside the mattress. Ensure Auto Upright connector is firmly secured. Please refer to the photo instruction on the side of the coverlet for further detail.

6. Plug the power unit into a wall outlet and turn on the main power rocker switch on the left side panel.

7. Press **Power/ Standby** to inflate the mattress system.

8. Wait until prompted (approximately 10 minutes

or **YOU MAY PLACE THE PATIENT ON THE MATTRESS NOW** appears on the LCD) for system to be ready for patient placement.

8 Programming Settings

1. After full inflation, center the patient on the mattress. The LCD screen will display "Auto-setting". During this time, the system is taking into account the mattress loading, and self adjust to the appropriate system setting. If possible, the caregiver should prevent the patient from making unnecessary movement in order to receive the most accurate measurement. If the patient feels the mattress is slightly too soft or too firm, increase or decrease the mattress' internal pressure by pressing "+" or "-". Wait for the system to stabilize before making another change until a comfortable state is achieved.

9 Patient Transfer and Transport

Transfer

It is recommended to have the mattress system on **Firm** mode during transfer. Ensure the bed is secured before proceeding.

Transport

If a transport occasion arises, two options are available:

1. Detach the mattress' CPR connector from the power unit's air outlet, and insert the transport plug to the mattress' CPR

connector to retain air in the mattress for an extended period of time.

2. Unplug the power unit's power cord from the wall outlet. The system will switch into battery mode, which will provide the unit with power for approximately two hours for uninterrupted therapy. The Carilex Summit system also has a safety air pad underneath the air cells to support the patient in case of deflation. To resume normal operation, please follow **8 Programming Settings**.

10 Emergency Deflation (CPR)

In the need for emergency deflation, such as CPR, remove the mattress' CPR connector. The mattress will deflate rapidly under the weight of the patient.

To resume normal operation of the system, securely reinsert the CPR connector and press **Power/ Standby** again.

11 Cleaning



ALWAYS UNPLUG THE POWER UNIT BEFORE CLEANING.

The power unit and mattress must be disinfected thoroughly between patients to avoid cross contamination and infection.

Local cleaning and disinfection policies must be adhered to, but the following is a recommended guideline.

Power Unit, Auto Upright Sensor, Power Cord and Hoses

Wipe down the external surfaces of the power unit, auto upright sensor, power cord and hoses, using a damp cloth with disinfectant and water or mild neutral detergent. After, wipe dry with a clean, dry cloth. **DO NOT** spray liquids directly on the unit itself.

Coverlet and Mattress

Wipe disinfect cover using a damp cloth with disinfectant, water and mild neutral detergent. After, wipe dry with a clean, dry cloth. Do not use phenolic disinfectant. The acceptable concentration of Sodium hypochlorite solution is up to 0.1%.

Machine wash warm coverlet and mattress base at maximum 71°C is possible.

Wipe disinfection is the recommended cleaning method for air cell. Machine wash air cell at maximum 40°C is possible but not suggested due to premature aging of air cell material. Ensure to place a cap on the air cell inlet to prevent liquid from entering the air cell during cleaning process.



Tumble dry on lowest setting or hang dry when possible.



Do not iron.

Please ensure that the coverlet and mattress are completely dry before returning to use.

12 Routine Maintenance and Storage

In order to prolong the system lifetime, it is recommended that the air filter is replaced with a new, genuine filter every year, and the compressor with a new, genuine compressor every two years. The air filter can be removed from the rear panel of the power unit by opening up the filter cap. The filter should also be cleaned regularly between replacements, using mild soap and water. Once the filter has been cleaned and dried, reinsert it back in place and ensure the cap is secure.

When storing your system, ensure that it has been disinfected and dried completely. Disconnect the air hoses from the power unit and roll the mattress up starting from the head end. The straps can be used to secure everything in place.

13 Troubleshooting

Problem	Inspection Procedure	Possible Solutions
1. Power unit does not function	Ensure power cord is securely plugged into wall outlet	Secure power cord into wall outlet
	Ensure power cord is securely plugged into power unit	Secure power cord into power unit
	Ensure power switch is in ON position	Turn power switch to ON position
	Power surge shut down pump	A power surge may temporarily overload the circuitry. Turn the unit off and check the fuse for damage. Turn the unit ON again following normal procedures
	Power unit does not respond to possible solutions	Please contact your authorized local distributor for assistance
2. Low pressure alert does not go out 30 seconds after systems start	Possible control failure	Please contact your authorized local distributor for assistance
3. Alarm LCD warning is shown during operation	Check if there is leakage in air tubes, air cells, connection failure or power outage	Please contact your authorized local distributor for assistance
4. Power unit is working, but mattress replacement is not inflating and/or Patient is bottoming out and/or Patient leaves a deep dent at the contact area which does not return back to its original shape (worn down by patient)	Check if mattress' CPR connector is properly connected to power unit's air outlet	CPR connector is firmly into place
	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	Replace with genuine spare parts or contact your local distributor.
5. Alternating or static setting not available	Possible control failure	Please contact your authorized local distributor for assistance
6. The power unit does not enter battery mode when abnormal power outage occurs or power source is being disconnected	Reposition the UPS switch to BYPASS to see if the power unit could be turn on once the power resumes. If the power unit does resume operation once the UPS is in BYPASS mode, an UPS circuit board replacement is needed	Please contact your authorized local distributor for assistance

14 Returns for Service

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

15 Warranty

Please refer to the Warranty Card for details.

16 Product Specification

Mattress Dimension (MSR210)

Standard: 200 x 90 x 23 cm

Narrow: 200 x 82 x 23 cm

Number of Air Cells

21 air cells

Power Control Unit Dimension (SR388)

37.5 x 32 x 18.5 cm

Integrated Air Pad

5 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

AC220 - 240V/ 50 Hz

Power Consumption

Max 30W

Power Control Unit Weight

6 kg

Power Cord

H05W-F 3G 1.00MMSQ

Fuse Rating

250V / T0.2A, 250V / T0.63A

Operating & Transportation & Storage Conditions

Temperature: 5°C - 45°C

Humidity: 15% - 60%

Electrical Classification

Class I Type B

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, UL-2601-1

Electromagnetic Compatibility

EN60601-1-2

Maximum Weight Capacity

300 kg

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