

*Anti-Decubitus*

*Air Alternating Pressure Mattress*

*Replacement System*

# **Theraflo AP**

Operation Manual

**carilex<sup>®</sup>**

# carilex®

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 SYMBOLS REFERENCE



Attention! Please read accompanying documents



Type BF Equipment

**IPX0**

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



Declaration of Conformity to Medical Device Directive



Underwriters Laboratory Agency Approval (United States/Canada)



Equipotentiality

### Indications:

This device is indicated to assist in the treatment and/or prevention of pressure ulcers as part of a holistic program of pressure ulcer management. Always consult a physician before using this device.

### Contraindications:

Certain patient conditions (e.g. unstable cervical fracture) are contraindicated for use with this device. Always consult the patient's physician prior to use.

## 2.0 SAFETY PRECAUTIONS

### Installation:

Verify mattress anchor straps are attached to bed frame securely. To ensure proper operation inspect and verify air cells are upright and in place. Test all bed frame functions to verify no interference. Do not place anything on the power unit. Route power cord underneath bed frame and verify freedom from hazard. See Section 8.0 of this Manual ("Installation") for further installation instructions.

### Bed Linens:

This device incorporates a waterproof cover that is moisture vapor permeable; therefore it is recommended to limit bed linens to one sheet in order to maximize the system's performance. NOTE: Only "breathable" incontinent pads are recommended for use with this device.

### ⚠ Open Flames:

Do not expose this device to open flames, lighters, or cigarettes. This device draws room air continuously, therefore cigarette smoking is not recommended near this device. Cigarette smoke may damage internal components. Cigarettes may ignite bed linens. CAUTION: DO NOT SMOKE CIGARETTES, PIPES, CIGARS, OR ANY OTHER RELATED PRODUCTS ON OR AROUND THIS SYSTEM. FLAMMABILITY HAZARD EXISTS.

### Cross Contamination:

This device should be decontaminated between patient installations. Refer to section 14.0 of this Manual ("Cleaning Instructions") for proper instructions. Failure to disinfect may result in cross contamination.

### Bed Frame Consideration:

Verify that the patient weight, therapeutic support surface, bed rails, etc. do not exceed weight capacity of bed frame. Verify patient weight does not exceed this device's weight capacity.

### 3.0 WARNINGS

#### **Entrapment:**

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 a patient from getting his or her head or neck between the mattress and the side rail. Failure to do so could result in serious patient injury or death.

#### **Patient Falls:**

Failure to use bed rails in raised position could lead to accidental patient falls. Air mattresses have soft edges that may collapse when patients roll to that edge.

#### **Risk of Electric Shock:**

DO NOT open back cover. This device is NOT user serviceable. This device should only be opened by qualified personnel approved by Carilex Medical GmbH. Refer all service to your local Anodyne Medical Device, Inc. authorized dealer or call Customer Service at 1-954-340-0500.

#### **Oxygen Equipment:**

Explosion risk if used in the presence of flammable anesthetics.

#### **Fuse:**

Danger! Risk of fire. Replace fuses as marked: T5A/250VAC (Power Fuse) and T0.5A/250V (PCB Fuse).

#### **Electrical:**

Do not insert items into any opening of the power unit. This could short internal components, which could cause fire or electrical shock. This product is NOT AP/APG protected. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.

#### **Grounding Reliability:**

Grounding reliability can only be achieved when plug is connected to an equivalent receptacle marked "Hospital Grade" or "Hospital Only". Carilex Medical GmbH. offers for sale and recommends the use of the appropriate 2- or 3-prong plug option on the power unit to ensure proper grounding. In the event that a 3-prong wall receptacle is not available for the 3-prong plug on the power unit, it is the personal liability and obligation of the customer to contact a qualified electrician before using the system. Verify the 2-pronged wall receptacle is replaced with the properly grounded 3-prong wall receptacle in accordance with the National Electrical Code. If you must use an extension cord, ONLY use a 3-prong extension cord that has the same or higher electrical rating as the device being connected. Route the power cord away from traffic.

### 4.0 INTRODUCTION

The SR373 is a portable, low air loss alternating pressure mattress replacement system, designed to treat and/or prevent pressure ulcers, otherwise known as bedsores. It was created to replace a standard mattress and fit most homecare or hospital beds. The SR373 consists of a power unit, a mattress replacement and a cover.

The power unit utilizes a blower to provide energy efficient air flow for patients up to 1,000 lbs.

The power unit offers 3 modes of operation: Static, Alternating and Pulsate as well as Upright and Max Inflate functions.

The mattress replacement consists of twenty air cells over either a foam or air base. The air cells are ventilated to provide low air loss which aids moisture management. The high quality cover is made of quilted nylon taffeta. It is both waterproof and moisture vapor permeable, which helps to which moisture away from the patient's skin.

## 5.0 RECEIVING INSPECTION

The SR373 ships in two cartons: one for the power unit and one for the mattress assembly. Inspect the goods for shipping damage. If any damage is found, file a report with the carrier immediately. Prepare a written report and take pictures of the damage.

## 6.0 SYSTEM COMPONENTS

Components Supplied in the Power Unit Package:

- 1 each - Power Unit
- 1 each - Power Cord
- 1 each - Operation Manual

Components Supplied in the Mattress Assembly Package:

- 1 each - Mattress Replacement with Cover

## 7.0 MODES & FEATURES

Control Panel Features:

See Figure 7a on next page.



### **Power:**

Plug the power cord into an 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:**

Press up or down buttons to adjust setting to relative patient weight. The patient weight indication is a close approximation of the correct setting. If the mattress is too soft or firm, simply press the up or down arrows to adjust as necessary. Wait between set point changes for the mattress to stabilize. See section 9.0 of this Manual ("Programming Settings").

### **Modes:**

#### Static Mode

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

#### Alternating Mode

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 15 minutes Alternating cycle times may be selected.

#### 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 a predetermined percent every 30 seconds.

#### Upright Mode

Upright Mode increases the pressure in all air cells to ensure that the patient does not bottom out when the bed frame head section is raised. Upright Mode should always be turned off when the bed frame is in a flat position. Upright Mode can be used in Static, Alternating or Pulsate Modes.

#### Max Inflate Mode

Max Inflate rapidly increases the mattress pressure to the maximum setting to aid in patient transfer and other nursing procedures. Always exit Max Inflate when the function is no longer needed. The unit will return to the last setting selected. The Max Inflate function will cancel automatically after 10 minutes.

### **Features:**

#### Keypad Lock

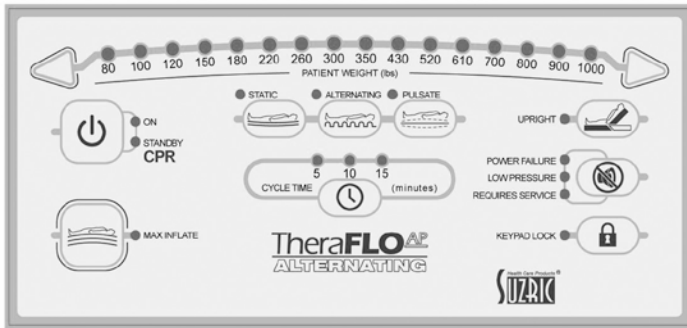
Keypad Lock locks out all button functions except for STANDBY/CPR to prevent unauthorized changes. Press the Keypad Lock button for 3 seconds to cancel.

#### Alarms

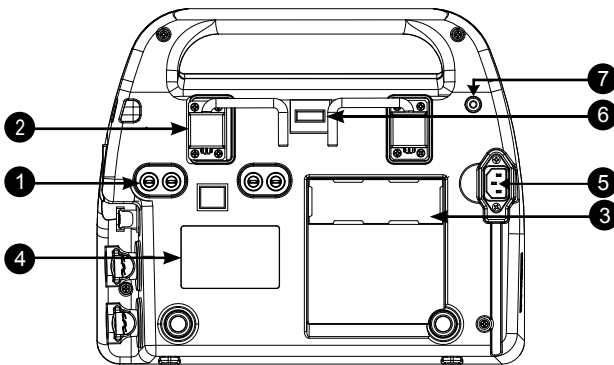
The SR373 features 3 alarm modes: Power Failure, Low Pressure and Requires Service. Power Failure alarm will sound when main power is removed. Low Pressure alarm will sound when pressure levels fall below the desired setting for more than 2 minutes. Requires Service alarm will sound when blower function is outside of the desired specification for more than 2 minutes. (See Troubleshooting section for further information.)

#### Patient Setting Memory

The SR373 will retain the last setting selected when the unit is put into Standby Mode or in the case of power loss.



Control Panel (Figure 7a)



## Rear Panel Features:

### Fuse (1):

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

### Hanging Hooks (2):

Hanging hooks are designed to fit multiple foot board widths. Hooks are spring loaded and will fold against the power unit when not in use.

### Air Filter (3):

Carilex Medical GmbH. recommends 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 (4):

Label identifies serial number along with agency approvals, etc.

### Power Receptacle (5):

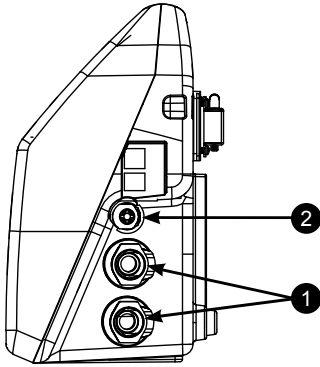
Three conductor IEC 60320 C14 Female Receptacle. To accept power cord with C13 connector.

### Hour Meter (6):

Records the number of hours that the unit has been operating.

### Grounding (7) :

Connect to other devices for grounding function.



### Right Side Panel Features:

#### **Couplers (1):**

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

#### **Connector (2):**

For use with air based safety mattress.


## 8.0 INSTALLATION

### **Mattress and Power Unit Installation:**

1. Remove existing mattress from hospital/homecare bed frame and store.
2. Place the SR373 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. Attached anchor straps should be tucked under mattress replacement to avoid any complications.  
 ⚠ NOTE: Before proceeding, test all bed functions to verify no restrictions or interference and ensure air cells are not twisted or out of place.
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 from the mattress replacement to the power unit.
5. Plug the power unit into a wall outlet. Refer to section 3.0 of this Manual ("Warnings") for proper instructions. Be sure the power cord is safely away from possible hazards (eg foot traffic, bed tables, lifters, 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. See section 7.0 of this Manual ("Features").




## 9.0 PROGRAMMING SETTINGS

1. After full inflation, adjust the support surface pressure using the Patient Weight buttons on the Control Panel to the appropriate weight setting. Center patient on mattress replacement to avoid accidental falls, etc.
2. It may be necessary to alter weight setting to get optimal comfort setting for patients. If patient feels bed is too firm/soft, lower or increase weight setting one increment at a time and wait for stabilization before evaluating. Please note, if patient is in hospital bed in the head up or articulated position, use upright mode to prevent patient from bottoming out. See section 7.0 of this Manual ("Features").
3. Caregivers should always perform a "hand check" to ensure patients are not bottoming out. A "hand check" should be performed when the patient is on the support surface by placing a hand below the air cells beneath the pelvic area of the patient. Ensure that there is an adequate amount of air supporting the patient, so they are not bottoming out.
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 a patient from getting his or her head or neck between the mattress and the side rail. Failure to do so could result in injury or death.

## 10.0 PATIENT TRANSFERS

Always secure bed or gurney before patient transfer. If available, engage locks on the bed casters before transferring patient. Transfers are much easier when the SR373 power unit is in Max Inflate mode or fully deflated.

 **CAUTION:** Always cancel Max Inflate mode to restore optimal patient therapy. Caregivers should perform a "hand check" as described in Section 9.3 ("Programming Settings") above.

## 11.0 PATIENT TRANSPORT

When a need to transport a patient arises, the SR373 mattress has an air or safety foam base 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. See Section 3.0 of this Manual ("Warnings"). It is not necessary to remove patient from support surface before re-inflation. Refer to Section 9.0 of this Manual ("Programming Settings").

## 12.0 DEFLATING

Press Power button on Control Panel to shift to Standby/CPR mode. LED will illuminate to indicate power unit is in Standby/CPR mode. Unplug power cord from wall outlet. Disconnect air hoses from side panel of power unit. Begin rolling up mattress replacement at head section forcing air out of system. Continue this process until the majority of air is removed from mattress replacement and the mattress rolls up easily. Connect the large strap buckles located on the bottom side of the mattress replacement. Place deflated mattress replacement and power unit in optional carry bag or plastic bag for transport and storage.

## 13.0 EMERGENCY CPR DEFLATE

In the event of an emergency, press the Power button on the Control Panel to shift the system to Standby/CPR mode. LED will illuminate to indicate power unit is in 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.

## 14.0 CLEANING INSTRUCTIONS

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.

Use only mild detergents and water to clean the coverlet , the mattress and the power unit regularly.

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.

## 15.0 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 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.

## 16.0 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 overload the circuitry. Turn unit off for several seconds. Check the fuse for damage. Re-try turning unit on with normal operating procedures.
	3.4) Power unit does not respond to possible solutions listed in 3.1 thru 3.4.	3.4) Call customer service at Carilex Medical GmbH. Local distribution
4.) Low Pressure 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
5.) Requires Service Alarm	5.1) None	5.1) Call customer service at Carilex Medical GmbH. Local distribution

## 17.0 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.

## 18.0 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.

## 19.0 Product Specifications

**Model:****SR373***Mattress Dimensions:*

80" x 36" x 10"

*Power Unit Dimensions:*

14.3" w x 11.9" h x 7.2" d

*Power Input:*

AC 100-120 V / 60Hz

*Power Consumption:*

Normal Operation: Max : 5A

*Power Unit Weight:*

11.5 lbs

*Power Cord:*

Detachable 14' SJT #18AWG, with 3 prong hospital grade plug

*Fuse Rating:*


T0.5A/250V (PCB Fuse)

T5A/250V (Power Fuse)

*Operating Ambient Temperature Range:*

60°-90° Fahrenheit

*Electrical Classification:*

-  Type BF equipment
- MEDICAL EQUIPMENT, classified with respect to electric shock, fire and mechanical hazards only, in accordance with UL60601-1, CAN/CSA C22.2 No. 601.1
  - 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:*

UL+cUL (UL60601-1), EN60601-1

*Electromagnetic Compatibility:*

- Meets EN60601-1-2:1993
- (CISPR 11 Classified as Class A, Group 1 ISM equipment)

*Maximum Weight Capacity:*

1,000 lbs

*Operating & Transportation & Storage Conditions**Temperature: 15°C~35°C**Humidity: 15%~60%**Atmospheric Pressure: 700~1060 hPa*

**NOTES:**

## Scrap Recycling

If the equipments need the maintenance or are beyond repair, we strongly recommended that you should inform us as soon as possible for the suitable solution. For the computers that are no longer useful or work well, please contact with local Carilex distributor for recycling. Follow the national requirement to dispose unit.

Manufactured by:

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