

Operation Manual

FOR

Protekt® Aire Supreme Support

Self-Adjusting Air/Foam Mattress with Optional Alternating Pressure Pump

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Table of Contents

| Introduction | 4 |
|--|----|
| Indications/Contraindications | 4 |
| Risks and Precautions | 4 |
| Preparation for Use | 5 |
| Mattress Installation | 5 |
| Patient Placement | 5 |
| To Use as a Static System | 6 |
| To Use as an Alternating Pressure System | 6 |
| Care and Cleaning | 7 |
| Preventative Maintenance Schedule | 8 |
| Troubleshooting | 9 |
| Specifications | 10 |
| Warranty | 11 |

Introduction

This manual is intended to be used for the initial set up and proper maintenance of the Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress with Optional Alternating Pressure Pump. It is important that you read and review these instructions in their entirety and consult with your healthcare professional if there are any questions.

Carefully review the Indications and Risk and Precautions sections prior to placing a patient on any Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress.

Indications

The Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress System (94001) provides non-powered zoned pressure redistribution, and the Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress with Optional Pump (94001-P) provides alternating pressure therapy. Both are indicated for the prevention and treatment of any and all stage pressure ulcers when used in conjunction with a comprehensive pressure ulcer management plan.

The Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress support surface consists of 10 air cylinders that run laterally underneath the body and are contained in a foam cavity. On top of the air cells is a high-density foam coupled with a 1" thick gel infused memory foam layer zoned for pressure redistribution. The heel section is sloped to further redistribute pressure for the sensitive heel areas. Both the self-adjusting air cylinders and the foam top surface aid in pressure redistribution and in maintaining low interface pressures throughout the surface.

Risk and Precautions

Transfer: Standard precautions should be taken during patient transfer.

Side Rails and Restraints: WARNING: Use or non-use of restraints, including side rails, can be critical to patient safety. Serious injury or death can result from the use (potential entrapment) or non-use (potential patient falls) of side rails or other restraints. Monitor patients frequently to guard against patient entrapment and/or falls.

Patient Migration: Specialty surfaces have different shear and support characteristics than conventional surfaces and may increase risk of patient movement, sinking and/or migration into hazardous positions of entrapment and/or inadvertent bed exit. Monitor patients frequently to guard against patient entrapment and/or falls.

Shock Hazard –DANGER!: When used as powered system, do not remove control unit case cover. Risk for electrical shock may occur if control unit is disassembled. Refer to qualified service personnel.

Fluids: When used as a powered system, avoid spilling fluids on control unit. Fluids remaining on controls can cause corrosion, which may cause components to fail or operate erratically, possibly producing potential hazards for patient and staff. If spills do occur, unplug the unit immediately and clean fluid from control unit wearing rubber gloves while it is unplugged to avoid any possibility of shock. Once fluid is removed, check operation of components in area of spill.

No Smoking in Bed: Smoking in bed can be dangerous. To avoid the risk of fire, smoking in bed should never be allowed.

Disposal: At the end of useful life, dispose of waste according to local requirements.

Preparation For Use

- Open shipping container and check for damages which may have occurred en route. DO NOT USE SHARP INSTRUMENTS TO OPEN BOXES. DAMAGE TO MATTRESS COULD RESULT.
- 2. Remove Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress from protective plastic cover.
 - The mattress may appear wrinkled when unpacked. To remove wrinkles, allow mattress up to 24 hours to accommodate; see Troubleshooting table for more information. Wrinkles will not affect inflation or function. Mattress may be used immediately if needed
- 3. Check mattresses surface for tears or cracking; do not use if tears or cracking are present. If any damages exist, please contact your local provider immediately.
- 4. If re-installing the Protekt® Aire Supreme Support onto a new frame or for a new patient, check mattress surface for staining and soiling; clean and/or disinfect as required (see Care and Cleaning section).
- 5. Level bed and lock brakes.
- 6. Remove existing mattress from bed frame.

Mattress Installation

- 1. Position mattress on bed frame with logo facing up and heel slope section aligned at the foot of the bed.
- 2. Ensure mattress is properly positioned with no gaps between mattress and bed frame or side rails. Always use a standard healthcare bed frame with safeguards or protocols that may be appropriate. Frame and side rails must be properly sized relative to the mattress to help minimize any gaps that might entrap a patient's head or body.

Patient Placement

It is recommended that all sections of this manual be read prior to patient placement. Carefully review the **Contraindications**, **Risks and Precautions and Mattress Installation** sections prior to placing a patient on any Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress. The Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress ships as an open system (the pump needs to be connected). The following are the instructions for using the system based on desired therapeutic function.

To Use as a Non-Powered Self Adjusting Air System

- 1. Transfer patient following all applicable safety rules and institution protocols.
- Center patient side-to-side and head-to-foot on Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress.
- 3. Air in alternating cylinders will level out providing a static air surface adjusting to the patient.
- 4. NOTE If the tubes are left unattached to a pump, the Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress will operate as an open air system with air going in and out based on patient movement and will function as a Non-Powered Self Adjusting Air System

To Use as an Alternating System – Protekt 3000 Pump Option

- 1. At the foot end of the mattress, unzip the lower zipper and remove the tubing.
- 2. Place pump on a horizontal surface or suspend on the end of bed frame with built-in hanger.
- Connect pump to hoses extending from the mattress. Ensure air hoses are not kinked and will not be pinched by any articulated bed mechanisms.
- 4. Ensure green Power switch is in the OFF position.
- 5. Plug pump into a properly grounded wall outlet. (Verify power to this outlet is not controlled by a wall switch).
- 6. Press green Power switch to the ON position. Air will begin to flow into mattress.
- 7. Yellow LED indicates low air pressure; green LED indicates proper air pressure has been reached and mattress is ready for patient placement.
- 8. Rotate the comfort control knob on the control unit clockwise to increase the airflow for Alternating Therapy.
- Rotate the comfort control knob on the control unit counter-clockwise to reduce the airflow for Alternating Therapy.
 - Ensure control unit hoses are properly connected to mattress for the desired function.

To Use as an Alternating System - Protekt 4000 Pump Option

1. At the foot end of the mattress, unzip the lower zipper and remove the tubing.

- 2. Place pump on a horizontal surface or suspend on the end of bed frame with built-in hanger.
- 3. Connect pump to hoses extending from the mattress. Ensure air hoses are not kinked and will not be pinched by any articulated bed mechanisms.
- 4. Ensure green Power switch is in the OFF position.
- 5. Plug pump into a properly grounded wall outlet. (Verify power to this outlet is not controlled by a wall switch).
- 6. Press Power switch button to the ON position. Air will begin to flow into mattress.
- 7. Yellow LED indicates low air pressure; green LED indicates proper air pressure has been reached and mattress is ready for patient placement.
- Adjust the digital weight setting on the pump to set the airflow for Alternating Therapy.
 Ensure control unit hoses are properly connected to mattress for the desired function.

Washing and Disinfection

Routine Care: Surface wipe with neutral detergent and lukewarm water. Rinse thoroughly with water and dry thoroughly.

Disinfection: Surface wipe the cover with quaternary solution or 1:10 bleach/water mixture according to recommended protocols. Avoid over saturation and ensure the surface does not stay wet longer than the chemical manufacturer's guidelines for proper disinfecting. Wipe up excess disinfectant after the recommended kill time has elapsed. Thoroughly rinse the surface of the mattress with clean water using a clean cloth. Allow the surface to completely air dry prior to use. Phenolics may be used for the vinyl bottom of the cover only

Storage

When not in use, mattress should be stored flat in a controlled climate room.

Preventive Maintenance Schedule

Preventive maintenance for the Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress consists of regular cleaning and an overall system evaluation to be performed at the intervals described below.

All components must be cleaned, disinfected and inspected after each patient's use and before use by a new patient. Always use standard precautions, treating all used equipment as contaminated. Institutions should follow local protocols for cleaning and disinfection.

Inspection/System Evaluation

Check each of the following before placing the Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress with a new patient:

- 1. Check mattress surface for tears or cracking; do not use if tears or cracks are present.
- 2. Ensure mattress is free of stains and is not overly faded.
- 3. Ensure air inlet hoses and connectors on mattress and control unit are clean and undamaged.
- 4. Ensure control unit and power cord are clean and undamaged.
- 5. Ensure control unit hanger brackets are secure and operate correctly.
- 6. Ensure OFF/ON Power switch and comfort control knob both operate correctly.
- Attach control unit to the black Alternating Pressure hoses and power up to ensure there are no air leaks.

It is recommended that all selections of this manual be reviewed before troubleshooting any Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress

Do not to attempt troubleshooting beyond the scope of this manual or where the remedy recommends contacting a Proactive Medical service representative. Any unauthorized service, modification, alteration, or misuse may lead to serious injury and/or product damage and will void all applicable warranties.

| SYMPTOM | POSSIBLE CAUSE | SOLUTION | |
|---|--|--|--|
| Green lamp on control unit does not light when power switch is set to the ON position. | Power cord may be unplugged. Wall outlet may be controlled by a wall switch. Circuit breaker for wall switch may be tripped or blown. Power cord or power switch may be damaged. | Plug Power cord into different wall outlet. Reset circuit breaker or replace fuse. | |
| not inflate or become firm; yellow LED remains on (does not change to green LED). Tube kinked. Tubing disconnected. Tubing disconnected. Check tupossible Holes in or damage to mattress. Control unit may be damaged. Contact | | Ensure black hoses are connected to hoses marked with black tag for Alternating Pressure; check tubing inside mattress for loose connectors. Check tubing inside mattress for kinks. Check tubing inside mattress for possible disconnect. Contact Proactive Medical for assistance. Contact Proactive Medical for assistance. | |
| Mattress cover too wrinkled upon removal from shipping container. | Internal components have not accommodated to environment. (This does not affect inflation or function). | Set unit up and allow to run for 24 hours, if problem persists, contact Proactive Medical for assistance | |

For questions regarding this product, a replacement User Manual, other replacement parts, maintenance or additional information about PROACTIVE MEDICAL products and services, contact your PROACTIVE MEDICAL representative.

Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress

| Item# | Description | Dimensions | Weight Capacity |
|----------|---|-------------------|-----------------|
| 94001 | Non-Powered Self Adjusting Mattress | 35"W x 80"L x 6"H | 500 lbs |
| 94001-P3 | Powered Self Adjusting Mattress with Protekt 3000 Pump | 35"W x 80"L x 6"H | 500 lbs |
| 94001-P4 | Powered Self Adjusting Mattress with Protekt 4000 Pump | 35"W x 80"L x 6"H | 500 lbs |
| 94003 | Non-Powered Self Adjusting Mattress | 42"W x 80"L x 7"H | 600 lbs |
| 94003-P3 | Powered Self Adjusting Mattress with Protekt 3000 Pump | 42"W x 80"L x 7"H | 600 lbs |
| 94003-P4 | Powered Self Adjusting Mattress with Protekt 4000 Pump | 42"W x 80"L x 7"H | 600 lbs |
| 94004 | Non-Powered Self Adjusting Mattress | 48"W x 80"L x 7"H | 650 lbs |
| 94004-P3 | Powered Self Adjusting Mattress with Protekt 3000 Pump | 48"W x 80"L x 7"H | 650 lbs |
| 94004-P4 | Powered Self Adjusting Mattress with Protekt 4000 Pump | 48"W x 80"L x 7"H | 650 lbs |
| 94005 | Non-Powered Self Adjusting Mattress | 54"W x 80"L x 7"H | 700 lbs |
| 94005-P3 | Powered Self Adjusting Mattress with Protekt 3000 Pump | 54"W x 80"L x 7"H | 700 lbs |
| 94005-P4 | Powered Self Adjusting Mattress with Protekt 4000 Pump | 54"W x 80"L x 7"H | 700 lbs |

Protekt® Aire Supreme Support Self-Adjusting Air/Foam

Mattress Five/Three Warranty:

In connection with your purchase of a Protekt® Aire Supreme Support Self-Adjusting Air/Foam Mattress, PROACTIVE MEDICAL warrants, to the original purchaser, against manufacturer's defects in material and/workmanship for a period of five (5) years from the date of purchase on the mattress and one (1) year from the date of purchase on the control unit under normal usage* and so long as all applicable procedures** are followed.

Conditions and Limitations:

Under this warranty, upon reasonable notice, PROACTIVE MEDICAL will replace or repair defective parts or whole units Covered under this warranty as its sole option. No returns or replacements will be allowed without authorization from PROACTIVE MEDICAL. This warranty applies to material/parts replacement costs and labor costs only and does not include shipping and handling costs or disposal fees.

This warranty does not extend to, nor cover:

- Patient wearables, such as, but not limited to, non-integrated Cover Sheet(s) and disposables used in conjunction with the mattress; or
- · Normal wear and tear: or
- Damage, including rust, corrosion or product failure due to causes beyond PROACTIVE MEDICAL control, such
 as, but not limited to abuse, theft, fire, flood, wind, lightening, freezing, power failure, power reduction, clogging of
 mattress pores due to tobacco smoke, unusual atmospheric conditions, foam deterioration due to exposure to
 moisture or other acts of God: or
- Damage to mattress or mattress handles through use of the mattress for patient transfer or transport.

PROACTIVE MEDICAL reserves the right to make material changes to the product predicated upon availability of raw Materials of like quality.

Service beyond that described in the User Manual must be carried out by PROACTIVE MEDICAL or such other entities as may be approved by PROACTIVE MEDICAL in writing.

This warranty is VOID if:

- Proof of purchase cannot be made by the original purchaser;
- Adjustment, modification, maintenance, and/or repair beyond that described in the User Manual is carried out by entities not approved in writing by PROACTIVE MEDICAL
- The electrical installation of the room does not comply with the appropriate national electrical wiring standards;
- The equipment is not used in accordance with the instructions and warnings enumerated in the User Manual.

This warranty is in no way to be construed as an extension of any periodic or preventive maintenance agreement, extended service agreement or in-service agreement entered into by the parties.

THE FORGOING BASIC WARRANTY MADE BY PROACTIVE MEDICAL IS IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PROACTIVE MEDICAL IS NOT LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES AND EXPENSES, INCLUDING DAMAGES TO PERSON OR PROPERTY, DUE IN WHOLE OR IN PART OF THE USE OF THIS PRODUCT EXCEPT AS OTHERWISE REQUIRED BY LAW.

- * Normal usage does not include misuse, abuse, alteration, modification, burns, punctures, improper handling, harsh cleaning solutions or drying procedures not recommended by the manufacturer, solutions no properly diluted as per product instructions or caustic staining agents.
- ** Applicable procedures include, without limitation, those set out in the accompanying User Manual and other guidelines and Procedures provided by PROACTIVE MEDICAL.

NOTE: To the extent any portion of this warranty is held invalid under federal law, such invalidity shall not affect the validity of the remaining portions of this warranty agreement, and the parties acknowledge that it is their intention that such provision (or portion thereof) shall be construed in a manner designed to effectuate the purpose of such provision to the maximum extent enforceable under applicable law. This warranty gives you specific legal rights and you may also have other rights which may vary from region to region.