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American Medical Equipment (AME) has a policy of continual product improvement and reserves the right to amend this document. Current version of this document is available on the website, www.amemedbeds.com.

Flowt<sup>®</sup> Mattresses and Accessories are manufactured by American Medical Equipment, 691 Green Crest Drive, Columbus, Ohio 43081 Toll Free: 1-866-MED-BEDS • Local: 614-237-1133 • www.amemedbeds.com

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# $\Lambda$ WARNINGS $\Lambda$

Mattress Overlay Entrapment and Fall Risks: Medical experts and governmental entities in various countries have determined that the use of side rails on beds may present a life threatening entrapment danger to the end-user. However, use of side rails may be clinically indicated for certain end-users. The decision whether to use side rails should be based upon applicable laws, regulations, the end-user's individual condition and needs, and on a case-by-case assessment by clinicians and / or healthcare providers actively involved in the end-user's care. Such an assessment may include, but not be limited to: the end-user's physique, overall condition, level of confusion or cognitive impairment (with or without medication), mobility (or lack thereof), history of falls, combativeness, attempts to get out of bed, uncontrolled body movement, and frustration when confined.

$\triangle$	CAUTIONS	$\triangle$

Knowledgeable and properly trained caregivers should:

- In the event a decision is made to use side rails, ensure that any identified risks associated with the end-user becoming entrapped in the side rails are identified and steps are taken to minimize such risks.
- In the event a decision is made to not use side rails, ensure that any identified risks associated with the end-user falling out of bed are identified and steps are taken to minimize such risks.
- Determine whether to use pads, bolsters, alarms, high-low beds, or other positioning aids and safety devices that are available on the market to reduce the risk of entrapment or falls.
- Suffocation Risk: The Flowt<sup>™</sup> Mattress should not be used by infants or other individuals who are at risk of suffocation.
- DO NOT use Flowt Mattress Enclosure Cover (Enclosure Cover) handles to lift or slide the end-user, as it may result in injury.
- Prior to use, consult with a clinician and / or healthcare provider to ensure the product is appropriate for the end-user's specific needs.
- CHECK EACH MATTRESS SECTION AND ACCESSORY AT LEAST ONCE A DAY to make sure it is properly inflated, adjusted, and if applicable snapped together.
- **PROPER INFLATION:** The use of any other inflation device other than the supplied hand pump of Flowt Remote may damage the product and void the warranty.
- UNDER-INFLATION: DO NOT use an under-inflated product. Using a product that is under-inflated reduces or eliminates the product's benefits, increasing the risk to skin and other soft tissue. If the product appears under-inflated or does not appear to be holding air, check to make sure that all hoses are connected. If the product is still not holding air, contact your health care provider, distributor, supplier or AME immediately.
- OVER-INFLATION: DO NOT use an over-inflated product Make sure the product is properly inflated. Proper inflation offers the maximum therapeutic benefit to the end-user. Over-inflation of a mattress overlay increases the likelihood that an end-user will roll off. For these reasons, it is important that the product be set up by knowledgeable caregivers properly trained in the use of this product.

## CAUTIONS CONTINUED

- WEIGHT LIMIT: The mattress overlay should be correctly sized to end-user and the bed mattress. The Flowt<sup>®</sup> has a weight limit of 500 lbs. (227.27 kg).
- PRESSURE: Changes in altitude may require adjustment to your product.
- **PUNCTURE:** Keep the product away from sharp objects, which may puncture the air cells and cause deflation.
- **HEAT/FLAME: DO NOT** expose the product to high heat, open flames or hot ashes.
- CLIMATE: If a product has been in below freezing temperatures cold (less than 32° F / 0°C) and exhibits unusual stiffness, allow the product to warm to 72° F / 22°C, then open air valve(s). Roll and unroll the product until the material is soft and pliable again. Repeat adjustment instructions before using.
- HANDLING: DO NOT use any valve or air cell as a handle for carrying or pulling the product. Grasp mattress sections by the base or the outside edges. DO NOT use product as a transfer surface. DO NOT reposition product while it is in use.
- OBSTRUCTIONS: Placing too many linens or other materials between the product and the end-user will reduce the product's effectiveness.
- **SOLUTIONS: DO NOT** allow oil-based lotions or lanolin to come in contact with the product as they may degrade the material.
- DO NOT use your product as a water flotation device (e.g., a Life Preserver).
- **OZONE GENERATORS:** The U.S. Environmental Protection Agency, Health Canada, and other government agencies have issued warnings regarding the use of ozone generators. Prolonged exposure to ozone will degrade the product and may affect the performance of the product and invalidate the product warranty.
- **PRODUCT ORIENTATION:** Air cells must face end-user.
- SIDE RAIL USE: The use of bed frame side rails in conjunction with any AME product should be determined based upon facility or home care provider protocol, applicable laws and regulations, and individual safety considerations. Bed frame side rail usage is not a requirement for the functional operation of any AME product, but individual safety requirements and/or facility or home care provider protocol may dictate that side rails be utilized.
- TRANSFERS: When transferring the end-user back on the product, verify proper adjustment of the product.
- Ensure all mattress overlay sections are snapped together before use.
- While properly adjusted mattress will protect the end-user from tissue trauma, they do not preclude the need for periodic end-user turning.

### **PRODUCT INTENDED USE**

**Flowt Mattresses\_**are non-powered, adjustable, zoned, reactive support surface mattresses that provide an environment to help protect against and / or are used in the management of pressure ulcers and / or tissue injury by redistributing forces, limiting edema and maintaining blood flow to at-risk or compromised tissue. They should be used on standard hospital, nursing home, home care or consumer bed frames.

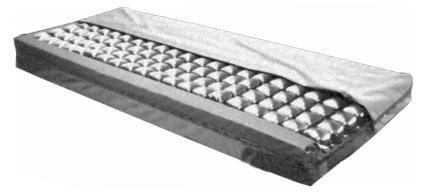
• **The Flowt**<sup><sup>®</sup></sup> is designed for end-users who are at Moderate to High risk of developing pressure ulcers and / or tissue injury, and is appropriate for use with end-users at risk for skin breakdown or having any stage pressure ulcer, skin grafts or myocutaneous flap surgery.

NOTE: No mattress surface is appropriate for all situations, across all care settings, for all end-users. Product determination should never be made without a specific end-user medical evaluation and appropriate professional clinical judgment.

- Flowt<sup>®</sup> Air Section: 30 in. x 20 in. x 2.5 in. (76.2 cm x 50.8 cm x 6.4cm) / 1.1 lbs. (.5 kg)
- Standard Flowt Mattress: 80 in. x 35 in. x 7 in. (203.2 cm x 88.9 cm x 17.8 cm) / 33 lbs. (15 kg)
- Long Flowt Mattress: 84 in. x 35 in. x 7 in. (213.4 cm x 88.9 cm x 17.8 cm) / 35 lbs. (15.9 kg)

Note: All measurements are approximate.

#### PARTS



- 1. **Air Cells:** Individual interconnected air pockets made of polyether polyurethane with nickel plated brass valve located on side surface (1 per section). Four sections snap together to make a complete system.
- 2. Inflation Valve: Used to open and close the product's airway. Some products may have more than one valve.
- 3. Flowt Hand Pump: Used to inflate the product.
- 4. **Snaps:** For connecting the mattress overlay sections and securing the sections to the mattress cavity.
- 5. Cover: Reusable Mattress Cover.
- Operation Manual: Instructions on adjustment, care, repairs and other important information about the mattress.
- 7. Repair Kit: Used to patch minor leaks.
- Product Registration Card: Complete product registration card and mail to AME or register online at <u>www.amemedbeds.com</u>.

To order replacement parts, from the U.S.A. call AME Warranty Service Department toll free at 1-866-MED-BEDS, your product provider or visit AME at www.amemedbeds.com. **Outside the U.S.A.**, contact your country's AME International distributor. For a current list of AME International distributors, visit our website at www.amemedbeds.com, contact AME International at 1-614-237-1133 or email us at cs@ame-medical.com.

#### TROUBLESHOOTING

**Not Holding Air:** Open one valve per section. Over-inflate the product. Turn valve clockwise to close. Look, listen, and feel for leaks. With valves closed, immerse product in sink or tub of water and look for air bubbles.

If pin-hole sized holes are found, see MINOR REPAIRS below. If large holes or other leaks are found, see REPAIR PROGRAM below.

**Uncomfortable/Unstable:** Make sure the product is not over-inflated or under-inflated. (see **Adjustment Instructions**). Make sure air cells are facing end-user. Make sure the product is not too big or too small for the bed. Allow end-user to lie on the product for at least one hour to get used to the texture of the product and immersion into the air cells.

#### MINOR REPAIRS

If the product develops a minor leak, use the repair kit that came with the product.

#### **REPAIR PROGRAM**

If you require a repair, you may return the product for assessment. Before returning the product to AME, contact our Warranty Service Department at 1-866-MED-BEDS toll free in the **U.S.A. Outside the U.S.A.**, contact the nearest AME International distributor. See website for current list of AME International distributors (www.amemedbeds.com).

Be advised that a charge will be assessed for any service provided for product that does not qualify under the product's warranty.

#### LOANER PROGRAM (U.S.A. ONLY)

AME offers a loaner sections while your air section is being repaired. Loaner air sections require a deposit. Contact our Warranty Service Department at 1-866-MED-BEDS.

#### **RETURN POLICY**

All products returned must be new and unused, require prior authorization from AME, and are subject to a restocking charge. Before returning your product, contact our Warranty Service Department at 1-866-MED-BEDS toll-free in the U.S.A. Outside of the U.S.A., contact your country's AME International distributor. For a current list of AME International distributors, visit our website at www.amemedbeds.com, contact AME International at 1-614-237-1144 or email us at cs@ame-medical.com.

#### DISPOSAL

When properly used and disposed, there are no known environmental hazards associated with the components of the products in this manual. Dispose of the product and/or components in accordance with the applicable regulations in your jurisdiction. **DO NOT INCINERATE.** 

#### LIMITED WARRANTY

#### What is covered?

AME covers any defects in materials or workmanship of the product.

#### For how long?

#### What is not Covered?

A product that has been misused, damaged by an accident, or damaged from "an act of Nature", e.g., flood, tornado, earthquake, fire. Any substitutions of supplied product accessories or modification to the product will void the warranty.

#### What we will do.

Within a reasonable amount of time after you return the product to us, we will repair or replace at our option any defect in material and workmanship and ship it back to you, all free of charge.

What the customer must do. Within the U.S.A., the customer must contact AME Warranty Service Department at 1-866-MED-BEDS toll free. Note: Any items sent to AME without prior authorization will not be returned to the customer. **Outside the U.S.A.**, contact your country's AME International distributor. For a current list of AME International distributors, visit our website at www.amemedbeds.com, contact ROHO International at 1-614-237-1133 or email us at cs@ame-medical.com.

**Questions?** Call our Warranty Service Department toll free **from U.S.A.** at 1-866-MED-BEDS. **Outside of U.S.A.**, contact your country's AME International distributor. For a current list of AME International distributors, visit our website at www.amemedbeds.com, contact AME International at 1-614-237-1133 or email us at cs@ame-medical.com.

#### Disclaimer.

Any implied warranties, including the MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE are limited to the same time period of the product types referenced above in the "For How Long" section and any action for a breach of such warranties or any express warranties herein must be commenced within that time. AME shall not be responsible for any incidental or consequential damages with respect to economic loss to property, whether as a result of a breach of express or implied warranties or otherwise.

#### Your Rights and the Effect of this Warranty upon Them.

This warranty restricts the duration of all implied warranties as noted above and limits or excludes recovery for incidental or consequential damages. Some jurisdictions do not allow limitations on how long implied warranties will last and some jurisdictions do not allow the exclusion or limitation of consequential or incidental damages, so those provisions may not apply to you. While this warranty gives you specific legal rights, you may also have other rights which vary from jurisdiction to jurisdiction.