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ROHO® Specialized Hospital Products Operation Manual




Supplier: This manual must be given to the user of this product.
Operator (Individual or Caregiver): Before using this product, read the instructions and save for future reference.

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Product information is changed as needed; current product information is available at permobilus.com.

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Intended Use

The ROHO® DRY FLOATATION® Isolette (Isolette) is a non-powered, air-filled, adjustable, reactive, support surface that is intended to conform to an individual's shape to provide skin/soft tissue and deep tissue injury protection and an environment to facilitate wound healing. The Isolette is designed for infants for use in standard hospital isolettes, home isolettes, and pediatric beds. There is no weight limit.

The ROHO® DRY FLOATATION® Nesting Pad (Nesting Pad) is a non-powered, air-filled, adjustable, reactive, support surface that is intended to conform to an individual's shape to provide skin/soft tissue and deep tissue injury protection and an environment to facilitate wound healing. The Nesting Pad is designed for infants for use in standard hospital isolettes and home isolettes. There is no weight limit.

The ROHO® DRY FLOATATION® Head / Neck Pillow (Head / Neck Pillow) is designed to provide cushioning and support to the head and neck for individuals who may require skin/soft tissue protection.

An experienced clinician should determine whether the product is appropriate for the individual's particular equipment needs. The product's intended use statement alone should not be relied upon to make that determination.

The medical products featured in this document are intended to be only one part of an overall care regimen that includes all therapeutic equipment and interventions. An experienced clinician should identify this care regimen after evaluating the individual's physical needs and overall medical condition.

A clinician should also evaluate for visual, reading, and cognitive impairment to determine the need for caregiver assistance or the need for other assistive technology, such as large-print instructions, to ensure proper product use.

Important Safety Information



Warnings:

- The support surface products featured in this manual will function without side rails; however, side rails may be necessary for some individuals. The decision whether to use side rails should be made by the individual's clinician and/or healthcare provider. If side rails are necessary for an individual, the following points should be considered by the individual in conjunction with his/her clinician or healthcare provider to reduce the risk of falling or entrapment.
 - If it has been determined that side rails are clinically indicated for an individual, knowledgeable and properly trained caregivers should identify and minimize any risks of entrapment in side rails.
 - If it has been determined that side rails are NOT clinically indicated for an individual, knowledgeable and properly trained caregivers should identify and minimize any risks of falling out of bed.
 - Whether side rails are used or not used, knowledgeable and properly trained caregivers should assess the need for devices or aids that will reduce the risk of falling out of bed or entrapment in side rails.
- The cushioning product should be correctly sized to the individual and the surface (isolette, crib, bed, or other). If it is NOT, the product's benefits may be reduced or eliminated, increasing risk to skin and other soft tissue.
- Skin/soft tissue breakdown can occur due to a number of factors, which vary by individual. Check skin frequently, at least once a day. Redness, bruising, or darker areas (when compared to normal skin) may indicate superficial or deep tissue injury and should be addressed. If there is any discoloration to skin/soft tissue, STOP USE immediately. If the discoloration does not disappear within 30 minutes after disuse, immediately consult a clinician.
- DO NOT use a product that is underinflated or overinflated, because the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue. Carefully follow the instructions for inflation and adjustment. If the product does not appear to be holding air, or if you are not able to inflate or deflate the product, see "Troubleshooting." Immediately contact your equipment provider, distributor, or Customer Support if the problem persists.
- The product should be set up by your equipment provider or clinician.
- While the product is in use, continue to follow all clinician recommendations for skin protection, including any schedule for regularly repositioning the individual.
- The cushioning products featured in this operation manual may introduce radiopacities and are therefore NOT recommended for use with x-rays. Radiopacities may interfere with diagnoses or surgical procedures that require radiographic images.

Important Safety Information, continued



Warnings:

- **DO NOT use the product as a water flotation device (e.g., a Life Preserver). It will NOT support you in water.**
- **DO NOT expose the product to high heat, open flames or hot ashes. Testing or certification claims, including for flammability, may no longer apply to this device when it is combined with other products or materials. Check testing and certification claims for all products used in combination with this device.**
- **If you are unable to perform any tasks described in this manual, seek assistance by contacting your clinician, equipment provider, distributor, or Customer Support.**
- **DO NOT use the product as a transfer surface. DO NOT reposition the product while it is in use.**
- **The cushion surface will acclimate to the surrounding temperature. Take appropriate precautions, especially when the cushion will contact unprotected skin.**



Cautions:

- Periodically, check components for damage and replace if necessary.
- Using a pump or repair kit other than those compatible with your product may void your product's warranty.
- Changes in altitude may require adjustment to your product.
- Keep the product away from sharp objects.
- If a product has been in temperatures less than 32°F / 0°C and exhibits unusual stiffness, allow the product to warm to room temperature, then open air valve(s). Roll and unroll the product until the material is soft and pliable again. Repeat adjustment instructions before using.
- **DO NOT use any valve or air cell as a handle for carrying or pulling the product. Grasp the product by the base or the outside edges.**
- **DO NOT allow your product to come into contact with oil-based lotions or lanolin. They may degrade the material.**
- Prolonged exposure to ozone may degrade the materials used in a neoprene product, affect the performance of the product, and void the product warranty.



Important Notes:

- An unoccupied product may appear to be underinflated (not enough air) even if it has been inflated and correctly adjusted for a specific individual. This is because the individual's body mass is not pushing down on the air cells.
- CPR may be performed without deflating the product. A cardiac board is not necessary.

Materials

Materials: Neoprene rubber with Zytel valve(s).

Storage, Disposal and Recycling

Storage: Clean and disinfect the product before storing. Open the inflation valve(s). Deflate the product (detach any product sections). Store the product in a container that protects the product from moisture, contaminants and damage.

Disposal: The components of the products in this manual are associated with no known environmental hazards when properly used and when disposed of in accordance with all local/regional regulations. Incineration must be performed by a qualified, licensed waste management facility.

Recycling: Contact a local recycling agency to determine recycling options for the product. For more recycling information, contact Customer Support.

Limited Warranty

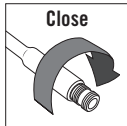
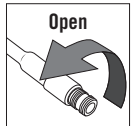
Limited Warranty Term from the date the product was originally purchased: DRY FLOATATION Products, 24 months. The warranty does not apply to punctures, tears, burns, or misuse. See also the Limited Warranty supplement provided with your product, or contact Customer Support.

Head / Neck Pillow



Warnings:

- **DO NOT** use a product that is underinflated or overinflated, because the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue. Carefully follow the instructions for inflation and adjustment.
- **Check inflation and adjustment frequently, at least once a day. Check inflation and adjustment the first time and every time the individual transfers onto the product.**
- **During inflation, the individual MUST NOT be on the product.**



Product Specifications

Note: All measurements are approximate.

Package contents: Hand pump, repair kit, operation manual, limited warranty supplement and product registration card.

To order replacement parts, contact your equipment provider or Customer Support.

Width x Length x Height	Weight:
Head/Neck Pillow: 9¾ x 11¼ x 3¼ in. (25 x 28.5 x 8.5 cm)	Head/Neck Pillow 1 lb. (0.5 kg)

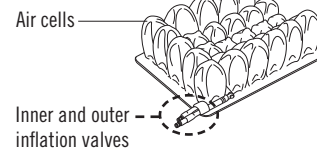
Head / Neck Pillow Adjustment Instructions



Warning: A Hand Check **MUST** be performed **EVERY TIME** the individual transfers onto the product. If the individual transfers off and then back onto the product, a Hand Check **MUST** be performed to ensure that the product is correctly adjusted and that it will continue to provide protection.

1. Inflate the pillow, using both inner and outer inflation valves:
 - a. Slide the rubber nozzle of the hand pump over the inflation valve. Pinch the nozzle of the hand pump, and open the inflation valve.
 - b. Add air until all of the air cells are fully inflated.
 - c. Remove the hand pump. Do not close the inflation valve.
 - d. Allow air to escape from the inflation valve. Listen (or place your hand in front of the inflation valve) to make sure that no more air is coming out of the pillow.
 - e. Close the inflation valve.
2. Use the Hand Check Method to adjust the pillow:
 - a. Place the individual's head / neck on the pillow.
 - b. Position your open hand under the individual's head / neck and feel for the lowest bony prominence. You should barely be able to move your fingertips, and there should be ½ in. - 1 in. (1.5 cm to 2.5 cm) between the lowest bony prominence and the base of the pillow.

Head / Neck Pillow



If there is not enough air (underinflated):

If determined safe by the clinician, use the hand pump to add additional air.

Otherwise, transfer the individual from the pillow. Use the provided hand pump to add a small amount of air. Close the inflation valve. Repeat for the other inflation valve. Place the individual's head / neck on the pillow.

Perform a Hand Check. There should be ½ in. - 1 in. (1.5 cm to 2.5 cm) between the lowest bony prominence and the base of the pillow.

If there is too much air (overinflated):

Keeping your hand in place, open the inflation valve, and remove a small amount of air until you can barely move your fingertips, and there is ½ in. - 1 in. (1.5 cm to 2.5 cm) between the lowest bony prominence and the base of the pillow.

Close the inflation valve.

If needed, repeat for the other inflation valve.

Isolette and Nesting Pad



Warnings:

- **DO NOT** use a product that is underinflated or overinflated, because 1) the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue, and 2) the individual may become unstable and vulnerable to falling. Carefully follow the instructions for inflation and adjustment.
- The product **MUST** be inflated and adjusted to ensure proper immersion and to provide skin/soft tissue protection to the infant, including their areas of risk (for example, head, shoulder blades, tailbone, hip bones, heels).
- If more than one section is being used, make sure that all sections are snapped together before placing the infant on the product. If the sections are not snapped together, the infant could be exposed to areas that do not provide sufficient skin/soft tissue protection.
- During inflation, the infant **MUST NOT** be on the product.
- Placing too many linens between the individual and the product will reduce its effectiveness.
- Check inflation and adjustment frequently, at least once a day. Check inflation and adjustment the first time and every time the individual transfers onto the product. A Hand Check **MUST** be performed **EVERY TIME** the infant is placed on the product. If the infant is taken off the product and then placed back onto the product, a Hand Check **MUST** be performed to ensure the product is correctly adjusted and will continue to provide protection.

Note: Your product includes drainage holes in the base of the cushion.

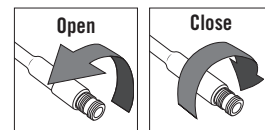
Product Specifications

Note: All measurements are approximate.

Package contents: product, hand pump, repair kit, operation manual, limited warranty supplement and product registration card.

To order replacement parts, contact your equipment provider or Customer Support.

Width x Length x Height	Weight:
Isolette: 14¾ x 26¾ x 2¼ in. (37.5 x 68 x 5.5 cm)	Isolette: 3 lb. (1.4 kg)
Nesting Pad: 14¾ x 26¾ x 3¼ in. (37.5 x 68 x 8.5 cm)	Nesting Pad: 3 lb. (1.4 kg)



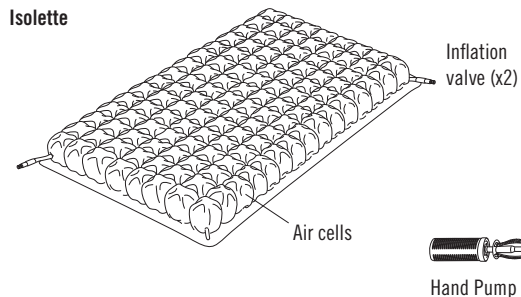
Isolette and Nesting Pad Adjustment Instructions

Note: The product has two valves. Make sure that one of the valves remains closed during inflation.

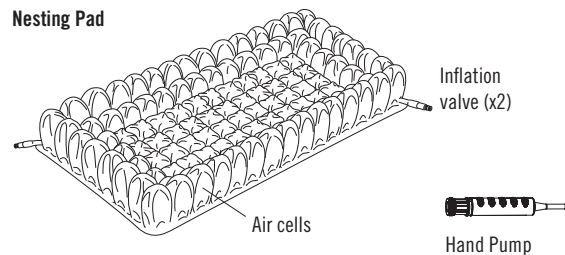
1. Place the product with the air cells facing up.
2. If more than one Isolette Pad is being used, align the pads and snap them together.
3. Inflate the product:
 - a. Slide the rubber nozzle of the hand pump over the inflation valve. Pinch the nozzle of the hand pump, and open the inflation valve.
 - b. Add air until all of the air cells are fully inflated.
 - c. Remove the hand pump. Do not close the inflation valve.
 - d. Allow air to escape from the inflation valve. Listen (or place your hand in front of the inflation valve) to make sure that no more air is coming out of the pillow.
 - e. Close the inflation valve.
4. Use the Hand Check Method to adjust the inflation level as needed:
 - a. Place the infant on the pad.
 - b. Position your open hand between the pad and the infant's lowest bony prominences (primarily, the head).

IMPORTANT! You should barely be able to move your fingertips, and there should be ½ in. - 1 in. (1.5 cm to 2.5 cm) between the infant and the base of the pad.

Isolette



Nesting Pad



If there is not enough air (underinflated):

As prescribed by a clinician, remove the infant from the pad during further adjustment.

To adjust: Use the provided hand pump to add a small amount of air. Close the inflation valve.

Transfer the infant back onto the pad. Perform a Hand Check. There should be ½ in. - 1 in. (1.5 cm to 2.5 cm) between the lowest bony prominence and the base of the pad.


If there is too much air (overinflated):

Keeping your hand in place, open the inflation valve, and remove a small amount of air until you can barely move your fingertips, and there is ½ in. - 1 in. (1.5 cm to 2.5 cm) between the infant and the base of the pad.

Close the inflation valve.

Troubleshooting

For additional assistance, contact your equipment provider, distributor, or Customer Support.

Not Holding Air	<p>Inflate the product. Confirm that the inflation valve is completely closed. Inspect the inflation valve(s) and hose(s) for damage. Look for holes in the product.</p> <ul style="list-style-type: none"> - If very small holes or no holes are visible, follow the instructions in the Repair Kit provided with your product. - For inflation valve or hose damage, or for large holes or leaks in the product, see the Limited Warranty supplement, or contact Customer Support. 	 <p>Repair Kit</p>
Not Able To Inflate or Deflate the Cushion	<ul style="list-style-type: none"> - Make sure the inflation valve is open. - Inspect the inflation valve(s) and hose(s) for damage. 	
Uncomfortable or Unstable	<ul style="list-style-type: none"> - Make sure the product is not underinflated or overinflated. Refer to adjustment instructions for the product in this manual. - Make sure the air cells are facing the individual. - Make sure the product is the correct size for the individual. - Make sure the product is lying flat. 	
The Product Slides	<ul style="list-style-type: none"> - Make sure that any sections are snapped together. - Make sure the product is not on a slippery surface. 	
Product Appears To Be Uninflated	<p>An unoccupied product may appear to be underinflated (not enough air) even if it has been inflated and correctly adjusted for a specific individual. This is because the individual's body mass is not pushing down on the air cells.</p>	

Cleaning and Disinfecting

Warnings:

- Inspect the product for damage and replace if necessary.
- Cleaning and disinfecting are separate processes. Cleaning must precede disinfection. Before use by a different individual: clean, disinfect, and check the product for proper functioning.
- Follow all manufacturer bleach container and germicidal disinfectant safety guidelines.
- Note about sterilization: High temperatures accelerate aging and will damage the product assembly. The products featured in this manual are not packaged in a sterile condition, nor are they intended or required to be sterilized prior to use. If institution protocol demands sterilization: First, follow the cleaning and disinfecting instructions; then, open the inflation valve and use the lowest possible sterilizing temperature, but not to exceed 70°C (158°F), for the shortest time possible. DO NOT autoclave.

Product Care Cautions:

Valve(s) must be closed. DO NOT allow water or cleaning solution to enter the product. DO NOT machine wash or sanitize the cushion or machine dry overlay products. Use of the following may cause damage to the cushion: abrasives (steel wool, scouring pads); caustic, automatic dishwasher detergents; cleaning products that contain petroleum or organic solvents, including acetone, toluene, Methyl Ethyl Ketone (MEK), naphtha, dry cleaning fluid, adhesive remover; oil-based lotions, lanolin, or phenolic-based disinfectants; ozone gas; ultraviolet light cleaning methods.

To clean your neoprene cushioning product:

Remove all linens and straps. Close valve(s) and place the product in a large sink. Hand wash, using mild liquid hand soap, hand dishwashing liquid, laundry detergent, or a multipurpose detergent (Follow the product label instructions.) Gently scrub all product surfaces, using a soft plastic bristle brush, a sponge or a cloth. Rinse with clean water. Air dry. DO NOT expose to direct sunlight.



To disinfect your neoprene cushioning product:

Repeat the cleaning instructions, using 1 part household liquid bleach per 9 parts water. Keep the product wet with the bleach solution for 10 minutes. Rinse thoroughly with clean water. Air dry.



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