



ROHO® SOFFLEX® 2

Mattress Replacement System



Operation Manual

SUPPLIER: This manual must be kept with this product.

CAREGIVER: Before using this product, read these instructions and save for future reference.

shape fitting technology®

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ROHO, Inc. has a policy of continual product improvement and reserves the right to amend this document. The current version of this document is available at www.roho.com.



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WARNINGS

Mattress - 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 individual. Bed frame side rail usage is not a requirement for the functional operation of any ROHO product; however, the use of side rails may be clinically indicated for certain individuals. The decision whether to use side rails should be based upon the intended use of the product, facility protocol, applicable laws, regulations, the individual's condition and needs, and a case-by-case assessment by clinicians and / or healthcare providers actively involved in the individual's care. Knowledgeable and properly trained caregivers should assess the individual to determine the risk of entrapment and whether side rails should be used.

- In the event that a decision is made to use side rails, ensure that any risks associated with the individual becoming entrapped in the side rails are identified and steps are taken to minimize such risks.
- In the event that a decision is made not to use side rails, ensure that any risks associated with the individual falling out of bed are identified and steps are taken to minimize such risks.

Suffocation Risk: Clinicians and/or caregivers must assess the individual's risk of suffocation and make decisions according to facility protocol and the intended use of the product. The ROHO® SOFFLEX® 2 Mattress Replacement System (SOFFLEX 2 Mattress) should **NOT** be used by infants or other individuals who are at risk of suffocation.

- Skin/soft tissue breakdown can occur due to a number of factors, which vary by individual. Check skin daily. Redness, bruising, or darker areas (when compared to normal skin) may indicate the beginning of soft tissue breakdown and needs to be addressed. If any discoloration does **NOT** disappear within 30 minutes of discovery, consult a healthcare professional immediately.
- Check inflation and adjustment frequently, at least once a day! If the individual is not properly immersed, it may reduce the benefit desired and increase the risk of tissue trauma. If product does not appear to be holding air, see TROUBLESHOOTING.
- Check the SOFFLEX 2 Mattress Replacement Cover routinely for any visible signs of cuts, tears, cracks, pinholes, snags, or stains, as damaged or worn covers may allow blood and other body fluids to penetrate the mattress, posing a risk of infection. See WARNINGS under CLEANING AND DISINFECTION.
- The SOFFLEX 2 Mattress should **NOT** be used by an individual who exceeds the surface area or weight limit of the product.
- The SOFFLEX 2 Mattress should be correctly sized to the bed. Additional care should be taken to ensure a tight fit of the mattress to the bed system. If the product is **NOT** properly sized to the bed system, entrapment may occur.
- While properly adjusted mattress replacement systems may protect the individual from tissue trauma, they **DO NOT** eliminate the need for periodic individual turning.
- It is important that the product be set up by knowledgeable caregivers who are properly trained in the use of this product.
- **DO NOT** use the cover handles to lift or slide the individual, as it may result in injury.
- **DO NOT** use the product as a transfer surface. **DO NOT** reposition the product while it is in use. Grasp mattress sections by the base or the outside edges.
- Placing too many linens or other materials between the product and the individual will reduce the product's effectiveness. See LINENS.

CAUTIONS

- Changes in altitude may require adjustment to your product.
- Keep the product away from sharp objects, which may puncture the air cells and cause deflation.
- **DO NOT** expose the product to high heat, open flames or hot ashes.
- 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.
- The use of any inflation device other than those supplied by ROHO may damage the product and void the warranty.
- Prolonged exposure to ozone will degrade the product and may affect the performance of the product and invalidate the product warranty.

INTENDED USE

The SOFFLEX 2 Mattress Replacement System (SOFFLEX 2 Mattress) is a non-powered, reactive, complete support surface with adjustable, zoned, air-filled cell pads that is intended to conform to an individual's shape to provide skin/soft tissue and deep tissue injury protection and an environment to assist in wound healing.

The SOFFLEX 2 Mattress must be used as a complete mattress replacement on hospital, nursing home, or home care bed frames. There is a weight limit of 650 lbs. (295 kg).

ROHO medical products are intended to be part of an overall care regimen. ROHO, Inc. recommends that a clinician make product recommendations based upon an evaluation of the individual's medical and therapeutic needs and overall condition.

CPR may be performed without deflating the product. A cardiac board is not necessary.

PRODUCT SPECIFICATIONS*

Components of the SOFFLEX 2 Mattress comply with CAL 117.

The SOFFLEX 2 Mattress complies with 16 CFR 1632 and 16 CFR 1633 for use without a foundation.

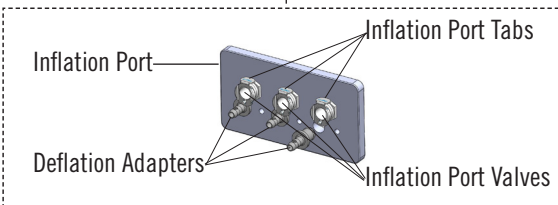
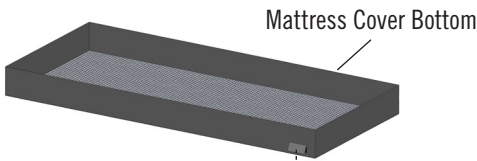
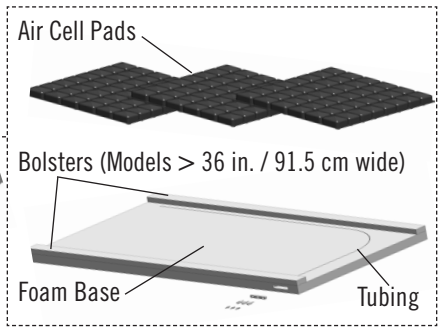
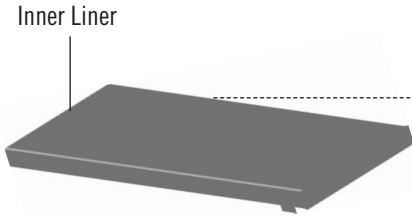
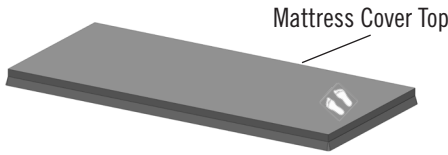
Sizes:

Width x Length x Height (without load)	
36" x 80" x 8.5"	91.5 cm x 203 cm x 21.5 cm
36" x 84" x 8.5"	91.5 cm x 213.5 cm x 21.5 cm
39" x 80" x 8.5"	99 cm x 203 cm x 21.5 cm
39" x 84" x 8.5"	99 cm x 213.5 cm x 21.5 cm
42" x 80" x 8.5"	106.5 cm x 203 cm x 21.5 cm
42" x 84" x 8.5"	106.5 cm x 213.5 cm x 21.5 cm
48" x 80" x 8.5"	122 cm x 203 cm x 21.5 cm
48" x 84" x 8.5"	122 cm x 213.5 cm x 21.5 cm

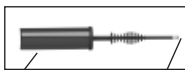
*Note: All measurements are approximate.

PARTS DETAIL

Package Contents:



Operation Manual




Hand Pump with Quick Connect

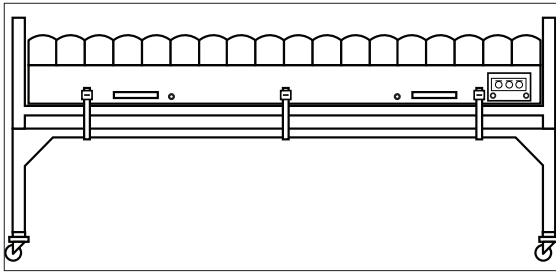


Product Registration Card

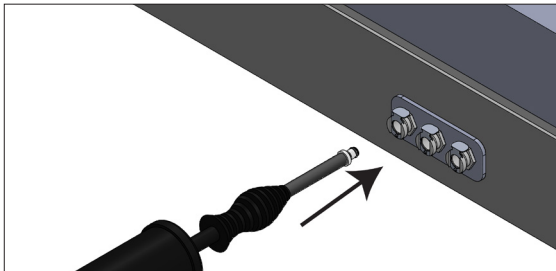
To order replacement parts, **from the U.S.A.**, contact the ROHO Customer Care Department, call your product provider, or visit The ROHO Store at www.therohostore.com. **Outside the U.S.A.**, contact your country's ROHO distributor.

ADJUSTMENT INSTRUCTIONS

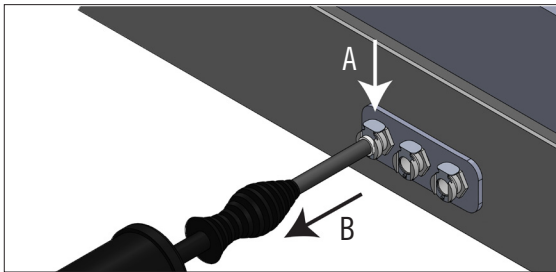
 The SOFFLEX 2 Mattress **MUST** be used with the provided cover. *(For demonstration purposes only, top of cover may not be shown.)*



1. Place SOFFLEX 2 Mattress directly on the bed frame.
2. Secure the SOFFLEX 2 Mattress to the bed frame using the straps on the bottom of the cover.



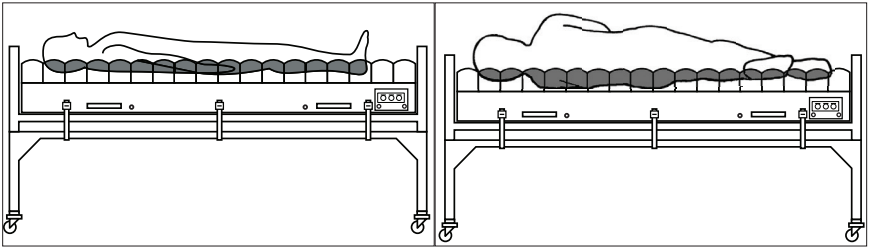
3. Insert the Quick Connect on the manual Hand Pump into an Inflation Port Valve until a click is heard. **Note:** If the Quick Connect on the Hand Pump cannot be inserted into an Inflation Port Valve, push down on the valve's Inflation Port Tab while inserting until click is heard.
4. Inflate each air section until it arches slightly upward.



5. Push down on the Inflation Port Tab (A) to disconnect the manual Hand Pump (B).
(Repeat steps 3-5 for the remaining Air Cell Pad sections.)

ADJUSTMENT INSTRUCTIONS, Continued

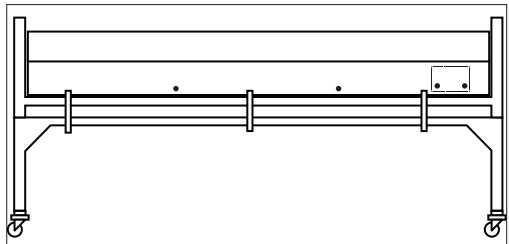
- While the SOFFLEX 2 Mattress is still unloaded, insert a Deflation Adapter into each Inflation Port Valve and allow air to bleed out of each section until the internal air pressure reaches atmospheric pressure. **Note:** You will know when the atmospheric adjustment is completed when no additional air is escaping from the Inflation Valve Port. This will take approximately five (5) minutes. Once completed, remove the Deflation Adapters by pressing the Inflation Port Tab located on each Inflation Port Valve. Place the Deflation Adapters into the storage holes.
- Place the individual on the SOFFLEX 2 Mattress in their normal lying position (e.g. on their back or side). Add or remove additional amounts of air from any section to insure the individual is comfortable and immersed into the SOFFLEX 2 Mattress.



Notes:

- Proper immersion is achieved when the individual has sunk into the product so the air cells envelop and support their body; diagrams above show examples of proper immersion into the SOFFLEX 2 Mattress.
- The lowest bony prominence may be gently touching the foam.
- Adjustments may be needed if the position of the head or foot of the bed are changed.
- A SOFFLEX 2 Mattress that has been properly adjusted may appear under-inflated when unoccupied; this is because the individual's body mass is no longer loading the product.

8. Snap in place the Inflation Port flap over the Inflation Port and be sure that the cover side flap is down and snapped concealing the cover's zipper.



CAUTION

Confirm:

- Product has been set up according to the directional arrows on the cover.
- Product is appropriate for the bed frame.
- Straps on the cover are secured to the bed frame when the product is in use.
- All enclosure flaps are down and snapped.
- Individual is properly immersed. (See ADJUSTMENT INSTRUCTIONS).

LINENS

Too many linens between the product and the individual will compromise the product's skin protection characteristics. Please use as few linens and incontinent pads as possible.

TROUBLESHOOTING

If the product does not appear to be maintaining adjustment, reinflate, and redo the adjustment procedure. If concern persists, contact your service provider, clinical caregiver, distributor, or ROHO, Inc. immediately.

CONTACT INFORMATION

In the U.S.A.:

ROHO Warranty Service and Customer Care:

Phone: 800-851-3449

Fax: 888-551-3449

Warranty Service: warranty@roho.com

Customer Care: cc@roho.com

If directed to return any items, send to:

ROHO, Inc.

1501 South 74th Street

Belleville, IL 62223

Outside the U.S.A.:

ROHO International:

intl@roho.com

Phone: 618-277-9150

Fax: 618-277-6518

Or visit www.roho.com for a list of ROHO International distributors.

CLEANING AND DISINFECTING

Cleaning and disinfecting are two separate processes. Cleaning must precede disinfection.

Note: SOFFLEX 2 Mattress must be cleaned, disinfected and checked for proper functioning between use by different individuals.



WARNINGS

PRIOR TO CLEANING AND DISINFECTING: Remove linens. Examine the cover to be sure that it has **NOT** been damaged in such a way to cause internal parts to come in contact with bodily fluids, e.g., punctured, torn, worn area.

- If damage exists, **DO NOT** continue to use the product. Contact your service provider immediately.
- If no damage exists, the cover should be cleaned and disinfected as instructed below.

DO NOT unzip the mattress cover during use.



CAUTIONS

DO NOT:

- Disassemble the internal components of the SOFFLEX 2 Mattress
- Allow water or cleaning solution to come in contact with the internal components
- Use abrasives such as steel wool or scouring pads
- Use caustic detergents
- Use cleaning products containing petroleum or organic solvents including acetone, toluene, Methyl Ethyl Ketone (MEK), naphtha, dry cleaning fluids, adhesive removers, etc.
- Expose the product to ultraviolet light or ozone gas cleaning methods
- Dry clean



= Wipe the cover surface as instructed.

To Clean:

Wipe the cover surface with a neutral detergent and water. Rinse and allow to dry thoroughly.



To Disinfect:

Wipe the cover surface with a dilution of 1 part household bleach to 9 parts water. Follow safety guidelines on bleach container. Quaternary type disinfectants may also be used in concentrations recommended by the manufacturer. Rinse and allow to dry thoroughly.



The top of the cover can also be occasionally machine washed in hot water (60°C) for disinfection. However, ROHO, Inc. recommends against repeated washings at high temperatures, as this can accelerate degradation of the cover. Tumble dry thoroughly on low.



Sterilization: ROHO products are not packaged in a sterile condition, nor are they intended or required to be sterilized for use.

DISPOSAL

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

RETURN POLICY

All products returned must be new and unused, require prior authorization from ROHO, Inc., and are subject to a restocking charge. Before returning a product: **In the U.S.A.**, contact our Warranty Service Department; **outside of the U.S.A.**, contact your country's ROHO distributor.

LIMITED WARRANTY

What is covered and for how long?

- Every SOFFLEX 2 Mattress Replacement System, excluding the removable, external cover and inner liner, is guaranteed to be free from defects in materials or workmanship for a period of 5 years (60 months) from the date the product was originally purchased.
- The removable, external cover and inner liner of a SOFFLEX 2 Mattress Replacement System are guaranteed to be free from defects in materials or workmanship for a period of 18 months from the date the product was originally purchased.

What is not covered?

This warranty does not apply to products that have been subjected to damage resulting from accident, misuse, an "Act of Nature", or abuse including, but not limited to: floods, tornadoes, earthquakes, fires, punctures, tears, harsh chemicals or burns.

What the customer must do?

- Should a defect in materials or workmanship occur during this period, ROHO will, at its option, repair or replace it free of charge.
- **Within the U.S.A.**, the customer must contact ROHO, Inc. Warranty Service Department.
Note: Any items sent to ROHO, Inc. without prior authorization will not be returned to the customer. **Outside the U.S.A.**, contact your country's ROHO distributor.

Questions?

See CONTACT INFORMATION.

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 "What is covered and for how long" section and any action for a breach of such warranties or any express warranties herein must be commenced within that time. ROHO, Inc. 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.

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Revision: 08/04/14



The Quality Management System
of ROHO, Inc. is certified to
ISO 9001:2008 and ISO 13485:2003.



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