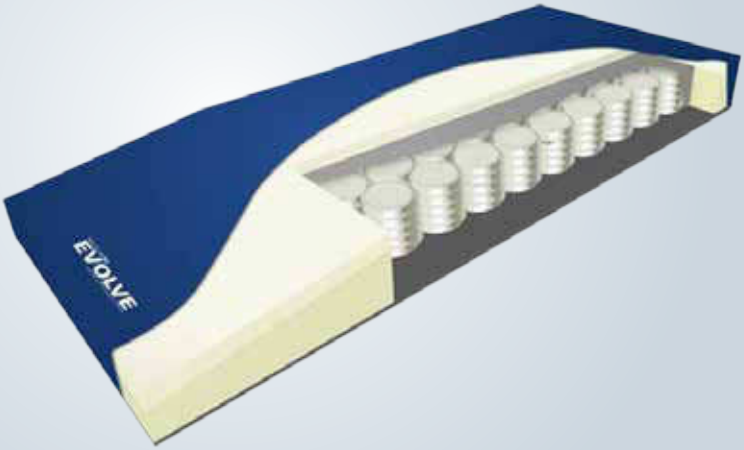
ARJOHUNTLEIGH
GETINGE GROUP

Pressure IQ Evolve Mattress Replacement System

USER MANUAL



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...with people in mind

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- Use this product only in accordance with these instructions and applicable product labeling.
- Assembly, operations, adjustments, extensions, modifications, technical maintenance or repairs must be performed only by qualified personnel authorized by ArjoHuntleigh. Contact ArjoHuntleigh for information regarding maintenance and repair.

Specific indications, contraindications, warnings, precautions and safety information exist for ArjoHuntleigh's therapeutic support systems. It is important for users to read and familiarize themselves with these instructions and to consult the treating physician prior to patient placement and product use. Individual patient conditions may vary.

Table Of Contents

Introduction

It is recommended that all sections of this user manual be read prior to product use. Carefully review the **Indications**, **Contraindications**, **Risks and Precautions** and **Safety Information** prior to placing a patient on any *Pressure IQ Evolve™ Mattress Replacement System (MRS)*.

Caregivers should discuss **Safety Information**, **Risks and Precautions** and **Contraindications** with the patient, the patient's family and / or legal guardians. Save this manual in an easily accessible place for future reference.

The *Pressure IQ Evolve MRS* is a non-powered pressure redistribution mattress replacement system which uses *Self Adjusting Technology™* (*SAT*) to provide pressure redistribution therapy. The *SAT* system is composed of 45 inter-connected air pods contained within a foam shell. The system is designed for patients weighing up to 500 lb (227 kg).

Indications

The *Pressure IQ Evolve MRS* is intended to treat and prevent stage I through IV pressure ulcers.

Contraindications

The *Pressure IQ Evolve MRS* is contraindicated for patients with the following conditions:

- unstable vertebral fracture
- cervical and skeletal traction

Risks 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. See related **Safety Information**.

Patient Migration - Specialty surfaces have different shear and support characteristics than conventional surfaces and may increase the 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.**

Safety Information

Skin Care - Monitor skin conditions regularly and consider adjunct or alternative therapies for high acuity patients. Give extra attention to any possible pressure points and locations where moisture or incontinence may occur or collect. Early intervention may be essential to preventing skin breakdown.

Patient Weight - The maximum patient weight for this device is 500 lb (227 kg). In addition, consult the specifications for the bed frame being used. Additional weight limitations may apply.

Patient Entrance / Exit - Caregiver should always aid patient in exiting the bed. Make sure a capable patient knows how to get out of bed safely (and, if necessary, how to release the side rails) in case of fire or other emergency.

Bed Frame - Bed frame precautions should be considered when used in conjunction with the *Pressure IQ Evolve* surface. Always use a standard healthcare frame with safeguards or protocols that may be appropriate. Bed frame and side rails (if used) must be properly sized relative to the mattress to help minimize any gaps that might entrap a patient's head or body. It is recommended that bed and side rails (if used) comply with all applicable regulations and protocols.

Side Rails / Patient Restraints - Whether and how to use side rails or restraints is a decision that should be based on each patient's needs and should be made by the patient and the patient's family, physician and caregivers, with facility protocols in mind. Caregivers should assess risks and benefits of side rail / restraint use (including entrapment and patient falls from bed) in conjunction with individual patient needs, and should discuss use or non-use with patient and / or family. Consider not only the clinical and other needs of the patient but also the risks of fatal or serious injury from falling out of bed and from patient entrapment in or around the side rails, restraints or other accessories. In the US, for a description of entrapment hazards, vulnerable patient profile and guidance to further reduce entrapment risks, refer to FDA's Hospital Bed System Dimensional and Assessment Guidance To Reduce Entrapment. Outside the US, consult the local Competent Authority or Government Agency for Medical Device Safety for specific local guidance. Consult a caregiver and carefully consider the use of bolsters, positioning aids or floor pads, especially with confused, restless or agitated patients. It is recommended that side rails (if used) be locked in the full upright position when the patient is unattended. Make sure a capable patient knows how to get out of bed safely (and, if necessary, how to release the side rails) in case of fire or other emergency. Monitor patients frequently to guard against patient entrapment.

When selecting a standard mattress, ensure the distance between top of side rails (if used) and top of mattress (without compression) is at least 8.66 in (220mm) to help prevent inadvertent bed exit or falls. Consider individual patient size, position (relative to the top of the side rail) and patient condition in assessing fall risk.

Bed Height - To minimize risk of falls or injury, the bed should always be in the lowest practical position when the patient is unattended.

Brakes - Caster brakes should always be locked once the bed is in position. Verify wheels are locked before any patient transfer to or from the bed.

Head of Bed Elevation - Keep head of bed as low as possible to help prevent patient migration.

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

General Protocols

- Avoid contact of sharp instruments with the *Pressure IQ Evolve MRS*. Punctures, cuts and tears will prevent proper operation.
- Follow all applicable safety rules and institution protocols concerning patient and caregiver safety.

Disposal - At the end of useful life, dispose of waste according to local requirements or contact the manufacturer for advice.

Preparation for Use

1. Open shipping container(s).

Do not use sharp instruments to open boxes. Damage to mattress could result.

2. Remove *Pressure IQ Evolve MRS* from plastic protective cover.

The MRS cover may appear wrinkled when unpacked. To remove wrinkles, allow MRS up to 24 hours to adjust; see Troubleshooting table for more information. Wrinkles will not affect inflation or function, so MRS may be used immediately if needed.

3. Check MRS surface for tears or cracking; do not use if tears or cracks are present.
4. If re-installing MRS onto a new frame or for a new patient, check surface for staining and soiling; clean and / or disinfect as required (see **Care and Cleaning**).
5. Level bed and lock brakes.
6. Remove existing mattress from bed frame.
7. Position MRS on bed frame with logo facing up and product information tags at foot end of bed. Ensure there are no gaps between MRS and bed frame or side rails.

Always use a standard health care 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 and Nursing Care

It is recommended that all sections of this manual be read prior to patient placement and nursing care. Carefully review the **Contraindications, Safety Information,** and **Risks and Precautions** sections prior to placing a patient on the *Pressure IQ Evolve MRS*.

1. Transfer patient following all applicable safety rules and institution protocols.
2. Center patient side-to-side and head-to-foot on *Pressure IQ Evolve MRS* surface.
3. Ensure all sections of the MRS fully support the patient.

Skin Care

- Remove excess moisture and keep skin dry and clean.
- Check patient's skin regularly, particularly in area where incontinence and drainage occur.
- Ensure linens under patient are not wrinkled.

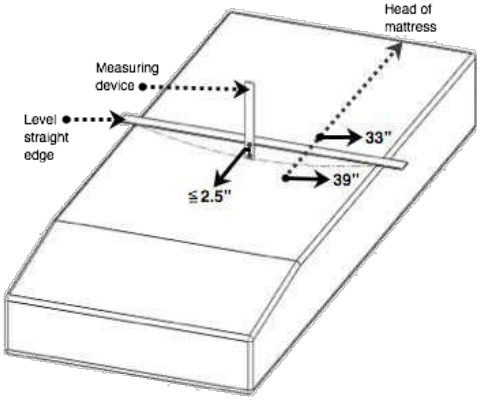
Incontinence / Drainage

- Use moisture-impermeable underpads for incontinent patients.
- Wipe surface clean and replace bed linens as required (see **Care and Cleaning**).

Product Characteristics

The *Pressure IQ Evolve MRS* is a non-powered air mattress providing high immersion for the patient to maximize pressure relief and redistribution. The helix design of the *Pressure IQ Evolve MRS* air pods results in product characteristics that can be identified by the following:

- As a non-powered air mattress, a certain amount of indentation in the therapeutic section can be expected. Mattress indentation may make it challenging for the caregiver to perform some tasks, such as patient repositioning.
- After normal use, it is typical for the *Pressure IQ Evolve MRS* to have up to 2.5 in (6.3 cm) indentation in the therapeutic section. ArjoHuntleigh has confirmed that the *Pressure IQ Evolve MRS* continues to provide patient pressure redistribution and performs as intended.
- The image below illustrates how the measurement is performed:



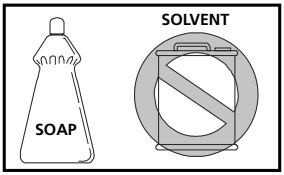
An ArjoHuntleigh Representative can confirm with the following steps that the *Pressure IQ Evolve MRS* is operating within product specifications:

1. Ensure the mattress is resting on a flat, stable surface (do not perform this procedure on a bedframe with a curved deck or in an articulated position; do not remove the cover for this process).
2. Use a light straight edge a few inches longer than the width of the mattress to aid in measurement.
3. Place the straight edge 33 in (84 cm) to 39 in (99 cm) from the head edge of the mattress perpendicular to the mattress length (this should be the mattress center point).
4. Use a scale, tape measure or straight ruler to measure from the bottom of the straight edge to the center of the mattress surface, taking care not to push the end of the measurement tool into the foam.
5. The mattress should have an indentation of less than 2.5 in (6.3 cm); if the measurement is equal to or greater than 2.5 in (6.3 cm), further investigation and warranty replacement may be necessary.

For additional questions regarding the *Pressure IQ Evolve MRS* or these evaluation steps, please contact an ArjoHuntleigh representative.

Care and Cleaning

General Instructions



- Do not clean with solvents.
- To disinfect, use only approved disinfectants diluted in accordance with manufacturer's instructions.
- When body fluids, including blood, are present, use the following throughout all cleaning procedures:
  - disposable, powder-free latex or latex-free gloves
  - protective clothing, including disposable or reusable impervious apron or gown
  - protective eyewear and face shield, as necessary

Cleaning Mattress During Patient Use

The *Pressure IQ Evolve MRS* should be wiped daily with a mild soap and water solution. Always use standard precautions, treating all used equipment as contaminated. Institutions should follow local protocols for cleaning and disinfection.

1. Remove or push bed linens to center of mattress.
2. Wipe and rinse any soiling from the mattress surface.
3. Dry surface with towel.
4. Ensure bed linens are refitted and not wrinkled under patient.

Cleaning Mattress After Patient Use

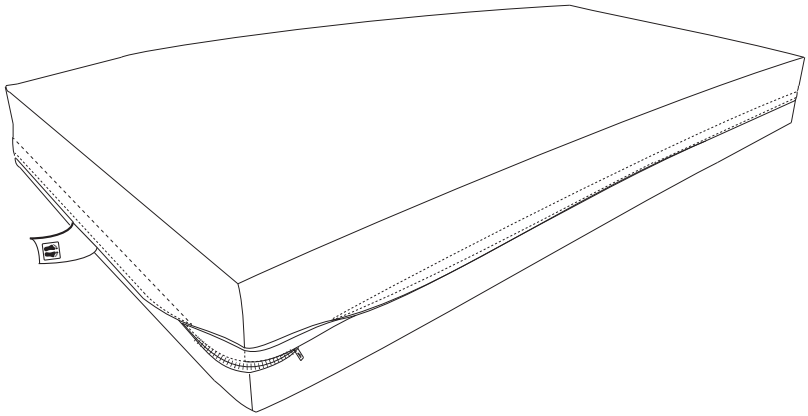
The *Pressure IQ Evolve MRS* must be disinfected after each patient use. It may be disinfected by wipe-down and cover may be laundered. Always use standard precautions, treating all used equipment as contaminated. Institutions should follow local protocols for cleaning and disinfection.

Recommended Wipe-Down Procedure

1. Wash entire mattress surface with a coarse cloth using an approved disinfectant germicide mixed to manufacturer's instructions.
2. Wipe and rinse surface.
3. Disinfect clean surface with a chlorine solution mixed to proper concentration, 1:100 (two ounces of chlorine bleach to one gallon of water). Using a clean cloth, wring out excess chlorine solution until cloth is damp. Wipe entire surface with damp cloth.
4. Allow to air dry.

Recommended Laundering Procedure

1. Remove mattress from frame and set on a hard smooth surface with logo side facing down.
2. Unzip all three sides of cover and remove from foam shell.
3. Hand or machine wash cover (gentle cycle, ≤120˚F / 49˚C) in mild detergent.
4. Tumble dry at low heat setting. Do not use bleach.
5. Place the laundered cover over the foam shell ensuring that the tags are located at the foot end where the foam shell slopes and the zipper pull ends.
6. Carefully flip mattress over and zip all three sides closed.



Preventive Maintenance Schedule

Preventive Maintenance for the *Pressure IQ Evolve MRS* consists of regular cleaning (see **Care and Cleaning**) and an overall system check-out 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.

Daily Cleaning

The MRS should be wiped daily with a mild soap and water solution.

Inspection / System Check-Out

Check each of the following before placing the *Pressure IQ Evolve MRS* with a new patient:

1. Check MRS for tears or cracking; do not use if tears or cracks are present.
2. Ensure MRS is free of stains and is not overly faded.

Troubleshooting

Do not attempt troubleshooting outside this manual or where the solution recommends to contact ArjoHuntleigh. Any unauthorized service, modification, alteration, or misuse may lead to serious injury and / or product damage and will void all applicable warranties.

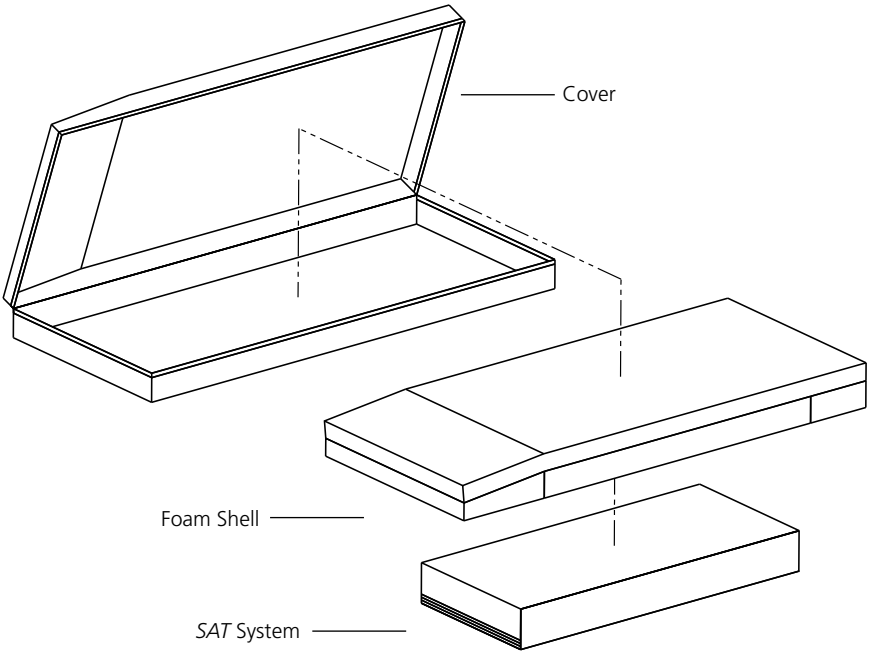
Symptom	Possible Cause	Solution
Mattress too firm upon arrival.	Difference in altitude not sufficient to open valves.	Apply weight to mattress to open valves.
Mattress cover too wrinkled upon removal from shipping container.	Internal components have not adjusted to environment. This does not affect inflation or function.	Let mattress adjust for 24 hours. If problem continues, contact ArjoHuntleigh for assistance.

Replacement Parts

Do not attempt troubleshooting, maintenance, or parts replacement outside this manual or where the solution recommends contacting ArjoHuntleigh. Any unauthorized service, modification, alteration or misuse may lead to serious injury and / or product damage and will void all applicable warranties.

Replaceable *Pressure IQ Evolve MRS* components are listed below. For more information such as pricing or additional spare parts that are not on this list, please contact your local ArjoHuntleigh representative.

Replacement Part	Reorder Number
Cover - Navy SOFlux Top, Black Non-Skid Bottom	EVCSONB(SIZE)N*
Cover - Navy SOFlux Top, Grey Vinyl Bottom	EVCSOVG(SIZE)N*
Cover - Navy DermaPlush Top, Black Non-Skid Bottom	EVCDPNB(SIZE)N*
Cover - Grey DermaPlush Top, Black Non-Skid Bottom	EVCDPNB(SIZE)G*
Cover - Navy DermaPlush Top, Grey Vinyl Bottom	EVCDPVG(SIZE)N*
Cover - Grey DermaPlush Top, Grey Vinyl Bottom	EVCDPVG(SIZE)G*
User Manual	413657-AH
Foam Shell	PIQ-EV-FS-(SIZE)*
SAT System	PIQ-EV-SAT



* Width and length size should be specified when ordered. See specifications section for range of available widths and lengths.

Specifications

Specifications subject to change without notice.

Maximum Weight Capacity.....500 lb (227 kg)

Mattress:

Mattress Weight .....36 lb (16.33 kg)
Mattress Length..... 76 - 84 in (193.04 - 213.36 cm)
Mattress Width..... 32 - 38 in (81.28 - 96.52 cm)
Mattress Height .....8 in (20.32 cm)

Storage / Operating Conditions:

Temperature Range.....57.2˚F (14˚C) to 95˚F (35˚C)

Shipping Conditions:

Temperature Range..... -20.2˚F (-29˚C) to 140˚F (60˚C)

Customer Contact Information

For questions regarding this product, supplies, maintenance or additional information about ArjoHuntleigh products and services, please contact ArjoHuntleigh or an ArjoHuntleigh authorized representative.

Symbols Used

Warning of possible hazard to system, patient or staff

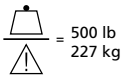
Important operational information

Foot End

Conforms to the Medical Devices Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive

Consult Instructions for Use

Manufacturer



Safe Working Load

Machine Wash, Gentle (≤120°F / 49°C)

Tumble Dry, Normal Low Heat

Do Not Dryclean

Date of Manufacture