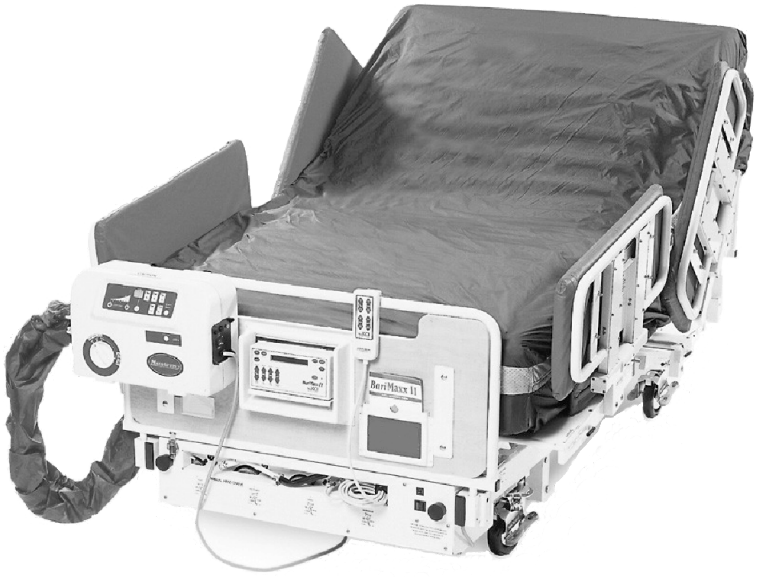
INSTRUCTIONS FOR USE

MaxxAir ETS

Mattress Replacement System



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arjo

with people in mind

WARNING

To avoid injury, always read this Instructions For Use and accompanied documents before using the product.

Mandatory to read the Instructions For Use.

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IMPORTANT INFORMATION FOR USERS

In order for Arjo products to perform properly, Arjo recommends the following conditions. Failure to comply with these conditions will void any applicable warranties.

- 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 Arjo. Contact Arjo for information regarding maintenance and repair.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.

Specific indications, contraindications, warnings, precautions and safety information exist for Arjo'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.

NOTICE

This product has been configured from the manufacturer to meet specific voltage requirements. Refer to the power supply label for specific voltage.

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Introduction

The MaxxAir ETS™ (Expandable Turning Surface) Mattress Replacement System (MRS) is a pressure relief mattress replacement system designed to provide turning and low-air-loss therapy, principally for the BariMaxx™ Bariatric Bed System and BariMaxx II Therapy System beds. The system capabilities are designed for patients weighing up to 1000 lb (453.5 kg)*, with expandability features from 36 in to 42 in to 48 in in width when used on the BariMaxx II Therapy System frame.

The MaxxAir ETS (MRS) is comprised of one 36 in wide middle section, two 6 in wide side air bolsters to provide expandability and two inflatable bladders beneath the mattress to provide the turn assist function. The 36 in middle section consists of a two-inch foam pad and twenty individual eight-inch (8 in) height cells. Each side bolster consists of four individual ten-inch (10 in) cells with no foam.

The MaxxAir ETS Therapy Unit is a variable speed blower that provides adjustable air pressure. A variable cycle time turning valve is used to activate the turn assist function.

The Turn Assist feature slowly inflates the appropriate turning bladders to gently tilt the patient to the left or right. The cycle time may be set to use the turn as a Nurse Assist (turn and hold) or as a programmable continuous turn.

INDICATIONS

The MaxxAir ETS MRS is indicated for Prevention and Treatment of Pressure Ulcers.

The MaxxAir ETS MRS can be used for:

- Patients whose body weight and size pose a significant risk or care management issue to the patient or staff during the performance of routine nursing care
- Large patients weighing up to 1000 lb (453.5 kg)*
- Large patients who are difficult to turn
- Large patients using a static mattress that would benefit from a pressure relief surface

CONTRAINDICATIONS

Patient conditions for which the MaxxAir ETS MRS is contraindicated include:

- Unstable Vertebral Fracture or Unstable Vertebral Column
- Cervical Traction
- Patients with total weight in excess of 1000 lb (453.5 kg)*

*Refer to Safety Information on Maximum Recommended Patient Weight.

RISKS AND PRECAUTIONS

The following precautions should always be observed:

Side Rails and Restraints – WARNING: Use or non-use of restraints, including side rails, can be critical to patient safety. Serious or fatal injury 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.

Skeletal Traction or Unstable Fracture (if not contraindicated) - With skeletal traction, unstable pelvic fracture or any other unstable fracture (to the extent not contraindicated), maintain physician directed angle.

SAFETY INFORMATION

Bed Frame – Always use a standard healthcare bed frame with safeguards or protocols that may be appropriate. It is recommended that Bed and Side Rails (if used) comply with the Hospital Bed System Dimensional and Assessment Guidance To Reduce Entrapment. 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.

Turning – CAUTION: Prior to engaging turn feature, ensure that bed frame has side rails and that all side rails are fully engaged in their full upright and locked position.

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.

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

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.

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

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.

Fluids – Avoid spilling fluids on therapy unit controls. If spills do occur, clean fluid from pump wearing rubber gloves or while unit is unplugged to avoid any possibility of shock. Once fluid is removed, check operation of components in area of spill.

Fluids remaining on controls can cause corrosion, which may cause components to fail or operate erratically, possibly producing potential hazards for patient and staff.

Moving Parts - Keep all equipment, tubes and lines, loose clothing, hair and parts of the body away from moving parts and pinch points.

General Protocols – Follow all applicable safety rules and institution protocols concerning patient and caregiver safety.

Power Cord – Position power cord to avoid a tripping hazard and / or damage to the cord. Ensure power cord is kept free from all pinch points and moving parts and is not trapped under casters. Improper handling of the power cord can cause damage to the cord, which may possibly produce risk of fire or electric shock.

Avoid Fire Hazards – To minimize risk of fire, connect the bed's power cord directly into a wall-mounted outlet. Do not use extension cords or multiple outlet strips. Review and follow FDA's Safety Tips for Preventing Hospital Bed Fires.

Tobacco Smoke and other contaminants - Please follow laundering and cleaning procedures described in the Care and Cleaning section of this User's Guide. It is recommended that no smoking occur in, on or around bed environment, so as to avoid build-up. Severe air restrictions (whatever the cause), may cause the Air Supply Unit to overheat and automatically deactivate.

Oxygen Use – DANGER: Risk of explosion if used in the presence of flammable anesthetics. Use of this product's pump in an oxygen-enriched environment may produce potential of fire hazard. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Unplug and do not use pump when using oxygen-administering equipment other than the nasal, mask or half-bed-length tent type.

BariMaxx Bariatric Bed System and BariMaxx II Therapy System - For safest use, Arjo recommends the BariMaxx Bariatric Bed System or BariMaxx II Therapy System is always used in conjunction with the MaxxAir ETS MRS, as well as any other safeguards that might be appropriate.

Other bariatric beds - Although other bariatric bed frames may be suitable, special care should be taken to ensure that appropriate adaptations and additional safeguards are implemented. Choose a properly-sized bed frame and (when desired) side rails and positioning aids, ensuring against any gaps that might entrap the patient's head or body.

Bed Expansions - With variable-width bed frames, Slides and Side Rails should always be locked in place whenever expanded or retracted.

I.V. and Drainage Tubes – I.V. and drainage tubes should always have slack for alternating pressure or rotation and other patient movements.

Maximum Recommended Patient Weight - Total patient weight capacity should not exceed 1000 lb (453.5 kg) or the patient weight capacity of the underlying bed frame, whichever is less. The use of accessories on the bed may decrease the patient weight capacity of the bed. Contact Arjo Customer Service for questions concerning the use of accessories and see the Questions and Information section of this guide for contact information.

Transfer Board - If a mechanical lift device is not available, a transfer board or device should always be used when transferring a patient to and from the bed. Use INSTAFLATE™ function Mode for added safety during transfer.

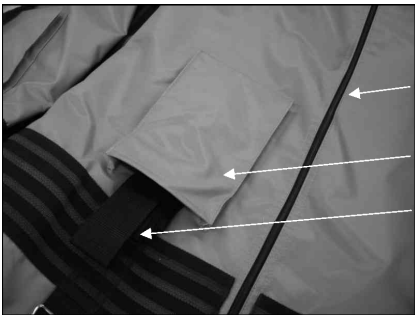
PATIENT PLACEMENT

It is recommended that all sections of this guide be reviewed prior to product use. Carefully review the Indications, Contraindications, Risks and Precautions and Safety Information sections in the Introduction prior to patient placement on the MaxxAir ETS MRS.

The following information relates to the MaxxAir ETS MRS only. The existing mattress must be removed.

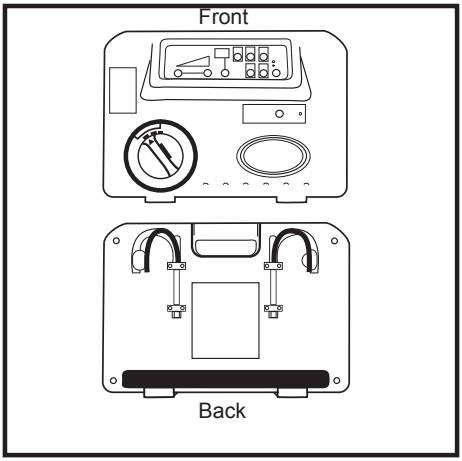
PREPARATION FOR PATIENT PLACEMENT

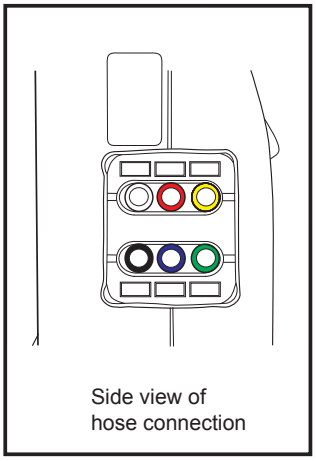
1. Level bed and lock brakes. Remove existing mattress from bed frame.
2. Undo storage straps. If equipped, place storage straps into pouch. If not equipped with pouch, store straps in turning bladder area. See photo below.



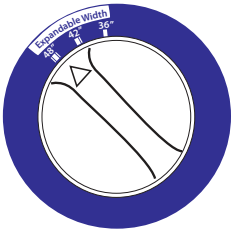
3. Position the MaxxAir ETS Mattress Replacement System on the bed frame with hose set at foot end of bed.
4. Secure mattress to bed frame using hook-and-loop straps

5. Ensure that mattress cover is not wrinkled and that buckles on patient's left head side and right foot side of cover are properly connected under mattress. If hose connections have been previously attached, they do not need to be disconnected to place cover.
6. Secure therapy unit on footboard of bed by extending the arms as shown.

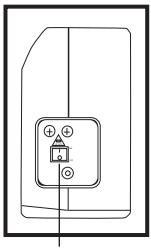




7. Attach hose connectors to therapy unit. Ensure color between the hoses and sockets are matched.
8. Adjust width of MRS as appropriate.
   - When using the 36 in wide bed frame, the expansion knob should be in line with 36 in.
   - When using the 42 in wide bed frame, the expansion knob should be in line with 42 in decal as shown. Patient left side surface will expand in this configuration.
   - When using the 48 in wide bed frame, the expansion knob should be in line with 48 in decal as shown. Both sides of patient surface will expand in this configuration.



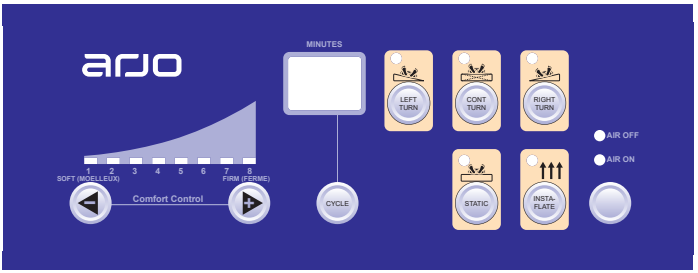
9. Plug power cord into a properly grounded power source. It is recommended cord is routed under bed frame. Turn power ON with switch located on right side panel. The AIR OFF LED on front panel should illuminate.



PATIENT TRANSFER

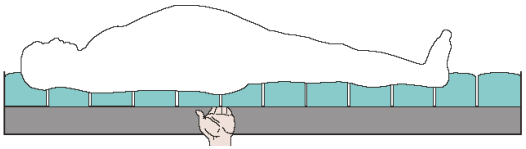
CAUTION: Monitor patient airway and position during inflation / deflation of mattress. Ensure patient and any patient support lines are properly supported at all times.

1. It is recommended that ambulatory patients enter and exit a deflated unit.
   - Verify all brakes are locked.
   - Adjust bed height to lowest level.
   - With Caregiver assistance, ambulatory patient should be properly positioned and then enter at side of bed.
2. Push the AIR ON button on front panel. The AIR ON LED will illuminate and the therapy unit will start to run.
3. Push the INSTAFLATE button for fast inflation. Allow four to five minutes for full inflation.
4. For non-ambulatory patients, wait until surface is fully inflated. Verify all brakes are locked. Adjust bed height for patient transfer or placement.
5. Push INSTAFLATE button to deactivate the fast inflation. Raise and lock side rails and make sure any positioning aids are properly in place. Adjust bed height to lowest level.



AIR PRESSURE ADJUSTMENTS

1. Push the Static button and adjust the Comfort Control by pressing the SOFT / FIRM key to achieve the maximum patient comfort and proper air pressure adjustment. Verify placement with a hand control check as shown in illustration.
   - Place hand under the patient's buttocks between cells and foam. The patient should have at least 1.5 in (35 mm) of clearance between buttocks and bottom of mattress.
   - Verify air pressure adjustments with hand check beneath shoulders, hips and heels during turn cycles.
   - Perform hand check on both sides of the mattress.



2. Verify patient comfort and air pressure adjustments with patient in both sitting and side lying positions.

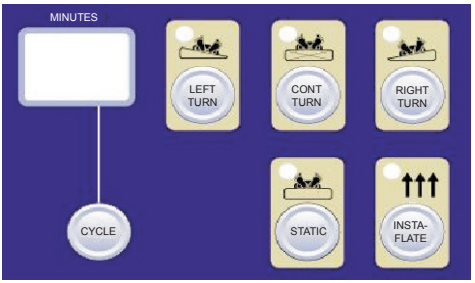
NURSING CARE

It is recommended that all sections of this manual be reviewed prior to product use. Carefully review the Indications, Contraindications, Risks and Precautions, and Safety Information sections in the Introduction prior to performing nursing care on the MaxxAir ETS Mattress Replacement System.

TURNING FUNCTIONS

Select turn type and duration by using the buttons located on the front panel.

CAUTION: Prior to turning, ensure that side rails are in their full upright and locked position. See Safety Information / Turning.



- Press RIGHT TURN button to activate right hold. Cycle time will display zero-zero (00). Press the CYCLE button to enable mattress to turn right and back to center and adjust turn time from 3-30 minutes.
- Press LEFT TURN Button to activate left hold. Cycle time will display zero-zero (00). Press the CYCLE button to enable mattress to turn to left and back to center and adjust turn time from 3-30 minutes.
- Press CONT TURN Button to continuously turn mattress to the right, back to center, to the left, and back to center.
- Press STATIC to de-activate all functions.

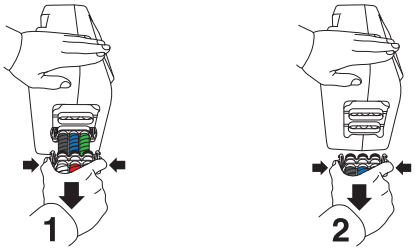
Cycle time can be adjusted from 1-20 minutes in one-minute increments and from 20-30 minutes in five-minute increments.

ALARM

The alarm will only sound when power to the unit has been interrupted or turned off. If this occurs, push Alarm Reset Button on front of unit, and / or re-apply power.

CPR

1. Firmly place hand on therapy unit and disconnect hose sets.



Cables fit snuggly and may require a sight force to disconnect.

2. Begin CPR.

Patient's body weight and CPR process will deflate mattress unit.

3. After CPR is performed and patient is clinically stable, reinsert hose set and adjust Comfort Control to its original setting. Raise Side Rails.

SKIN CARE

- Remove excess moisture and keep skin dry and clean.
- Check patient's skin regularly, particularly in areas 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 for cleaning instructions, if needed).

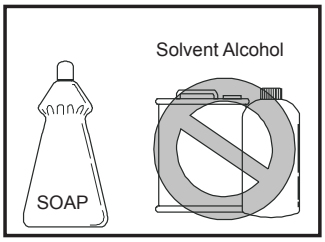
Dri-Flo™ breathable underpads are recommended for incontinent patients. Do not use plastic-backed underpads. Plastic tends to block moisture vapor transmission and air flow from mattress. Dri-Flo breathable underpads are absorbent and permit more air flow.

GENERAL OPERATION

Avoid contact of sharp instruments with the MaxxAir ETS MRS. Punctures, cuts and tears may prevent proper inflation and air pressure maintenance.

CARE AND CLEANING

GENERAL INSTRUCTIONS



- Do not clean with solvents or alcohol.
- Cover sheet is machine-washable. Do not launder (machine-wash) any other MaxxAir ETS MRS surface or mattress components.
- For regular cleaning, use a mild detergent with water on a non-abrasive cloth.
- To disinfect, use only EPA-approved disinfectants diluted in accordance with manufacturer's instructions.
- When blood and / or body fluids 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.

DAILY CARE AND CLEANING

Daily care and cleaning consists of wiping down the mattress cover during patient bathing and regular cleaning to be performed at the intervals described.

All nylon fabric with moisture vapor permeable backing cover sheets must be laundered and disinfected after each patient use, prior to use by a new patient. Contact Arjo for information regarding laundering.

The patient does not need to be removed from the bed when performing daily cleaning procedures. The patient may be bathed as the bed is being cleaned.

1. Level bed if patient is able to tolerate.
2. Lock all steer casters in line and set all caster brakes.
3. Lower side rails on Caregiver's side.
4. Bathe patient following institution protocols.
5. Wipe and rinse any soiling on the mattress and cover sheet while bathing patient.
6. Dry mattress cover with towel.
7. Wipe down side rail covers and dry with towel.
8. Ensure cover sheet is not wrinkled under patient.
9. Raise and lock side rails when used, and make sure positioning aids are properly positioned. (Refer to Risks and Precautions and Safety Information).
10. Adjust mattress pressures for patient comfort.

WEEKLY CARE AND CLEANING

In addition to daily care and cleaning, the MaxxAir ETS Mattress Replacement System therapy unit, hoses, bed frame, side rails and other components should be wiped down weekly, depending on soiling.

CLEANING PROCEDURE

When blood and / or body fluids are present, consult a health care professional for proper use of the following throughout all cleaning procedures:

- Impermeable or water proof gloves
- Plastic apron or gown
- Protective eyewear

Do not clean with solvents or alcohol.

1. Unplug unit before cleaning.
2. Apply a hospital-level cleaner / disinfectant, mixed to manufacturer's specifications, to the surface until thoroughly wet. Scrub all areas of therapy unit, hoses, bed frame, mattress and, if used, the mattress inserts, side rails and pads, headboard and footboard using a clean cloth. Allow to air dry.
3. Thoroughly wet the surface again with the same cleaner / disinfectant used in Step 2. Ensure that the surfaces remain wet for the cleaner / disinfectant manufacturer's specified contact time.

WARNING - Fluids remaining on controls can cause corrosion which may cause components to fail or operate erratically, possibly producing potential hazards to patient and caregiver.

4. Scrub all visible soiling from Air Supply Unit and other components with a damp cloth. Dry immediately.

TROUBLESHOOTING

Basic troubleshooting procedures for the MaxxAir ETS Mattress Replacement System are provided in the following charts. Each chart deals with a specific symptom and provides a symptom / possible cause / remedy approach to use in identifying the solution. The symptom will describe the condition that the unit is in. The possible cause will describe several likely reasons for the symptom and the steps to take in verifying the cause. The Remedy will describe the final solution to the symptom and cause.

SYMPTOMS, POSSIBLE CAUSE AND REMEDIES

SYMPTOM	POSSIBLE CAUSE	REMEDY
Cells do not inflate.	Hose may not be properly connected to mattress or Air Unit.	Turn Expansion knob to proper position. Properly connect hoses.
Expansion Side Bolster does not expand.	Bolster may not be properly connected to hose set.	Properly connect hose to bolster.
Cells do not inflate. Air Supply Unit power switch is on but LED does not illuminate.	Air Supply Unit may be controlled by wall switch. Power cord may be unplugged from wall outlet. Circuit breaker or fuse for wall outlet may be tripped or blown. Air Supply Unit may be damaged.	Plug Air Supply Unit into different wall outlet. Verify Power cord is plugged in. Reset circuit breaker or replace fuse. Contact Arjo Service Representative.
One or more cells do not inflate.	Cell may not be properly connected to hose set. Cells may be damaged. Cell fabric may be twisted above connector, preventing air from entering cushion.	Properly connect hose to cell. Replace cell. Adjust cell and verify hose connection.
Air Supply Unit is turning on and off, or varying speed.	Air Supply Unit may be controlled by a wall switch. Too many devices may be in operation or plugged into same circuit as Air Supply Unit. Air filter may be clogged with dust and debris.	Plug Air Supply Unit into different wall outlet. Unplug or turn off one or more devices. Clean or replace air filter.
Air Supply Unit air flow increases or decreases without adjustment and does not respond to Soft / Firm button.	PC Board in Air Supply Unit may be damaged.	Contact Arjo Service Representative.

SYMPTOM	POSSIBLE CAUSE	REMEDY
After using for a while, push buttons can operate normally but no air is coming out.	Blower over heated. (If you switch off the Air Supply Unit for 30 minutes and turn the Unit back on, unit is able to operate normally again).	Check Heat Exhaust hose. Clean or replace air filter. Contact Arjo Service Representative.
Blower still runs but cannot change between modes. (i.e. cannot change LED lights from INSTAFLATE to STATIC).	CPU needs to be reset. (If you turn master switch off for 10 seconds, and back on, unit should revert back to normal).	If this happens on the same machine / unit twice, contact Arjo Service Representative.
Alarm Sounds.	Power to unit has been interrupted or turned off.	Push Alarm Reset button on front of unit, and / or re-apply power.

SPECIFICATIONS*

MATTRESS SPECIFICATIONS

Recommended Patient Weight Limit
1000 lb (453.5 kg)*

MaxxAir ETS Mattress Replacement System

Width ..... 36 in W (91 cm)
Width ..... 42 in W (107 cm)
Width ..... 48 in W (122 cm)
Length..... 80 in L (203 cm)
Height ..... 10 in H (25 cm)

Mattress Weight

Total Weight..... Approximately 48 lb (22 kg)

Materials

Cell Material..... Polyurethane 0.35 (mm)
Cover Material ..... Nylon fabric with moisture vapor permeable backing
Base Material..... Nylon Laminated PVC

Air Supply Unit Size

Width ..... 16.5 in W (42 cm)
Depth ..... 6.7 in D (17 cm)
Height ..... 10.5 in H (27 cm)

Unit Weight

Total Weight..... Approx. 12.5 lb (5.7 kg)

OTHER

Cycle Time..... 3-30 minutes
Rated Voltage ..... 115 Volt
Max Current..... 5 Amp
Rated Frequency ..... 60 Hz
Mode of Operation..... Continuous
Safety Standard..... UL 60601-1
Maximum Electrical Leakage..... 100 Microamps
Power Cord Length..... 16 ft

*Specifications subject to change without notice.

SYMBOLS USED

Important Operational Information

Warning of possible hazard to system, patient or staff

Possible electrical shock hazard

EMC

The MaxxAir ETS (Expandable Turning Surface) Mattress Replacement Systems's Air Control Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment. The MaxxAir ETS was tested to the following standards:

- IEC 60601-1-2: Second Edition
- EN 5501: 1998 Group 1, Class B
- EN 61000-3-2: Class A
- EN 61000-3-3

CLASSIFICATION

Classification in accordance with UL 60601-1, CSA C22.2 No. 601.1, and IEC 60601-1.

- Class II
- Type BF
- IPX1
- No Sterilization
- Not for Use with Flammable Anesthetic Mixture with Air, Oxygen or Nitrous Oxide
- Continuous Operation
- Ordinary Equipment

ENVIRONMENTAL STORAGE / TRANSIT CONDITIONS

Temperature Range: -20 to 60° C (-4 to 140° F)

Relative Humidity Range: 30 to 95%

Atmospheric Pressure Range: 500 to 1060 hPa

ENVIRONMENTAL OPERATING CONDITIONS

Temperature Range: 10 to 40° C (50 to 104° F)

Relative Humidity Range: 30 to 95%

Atmospheric Pressure Range: 500 to 1060 hPa

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At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure ulcers and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Everything we do, we do with people in mind.

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