OWNER'S MANUAL

PressureGuard®

Easy Air® XL

SPAN®

better science. better care.

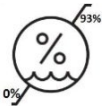
TABLE OF CONTENTS

DOCUMENT SYMBOLS

This manual contains different typefaces and symbols to make the content easier to read and understand:

- Standard text – used for regular information.
- **Boldface text –** stresses a word or phrase.
- **NOTE:** - sets apart special information or important instruction clarification.

Document Symbols			
	WARNING or CAUTION		Direct Current
	WARNING: Situations or actions that may have an effect on patient or user safety. Ignoring a warning could cause patient or user injury.	**IP21**	Protection against the ingress of fingers or similar objects and dripping water
	CAUTION: Points out special procedures or precautions that persons must obey to avoid equipment damage.	EC REP	Authorized Representative in the European Community
	See the user manual for use instructions		Potential trip hazards
	Electrical shock hazard warning		Manufacturer
	WEEE	5172 	Double Insulated system
	Type BF applied part	EN 60601-1-2	Electromagnetic Emissions
CE	European Conformity Marking	IEC 60601-1 60601-1-11	Electrical Safety Home Healthcare
	Foot End	ISO 15223 3.8 	Keep Dry or Do Not Wet

	Alternating current		Not made with natural rubber latex
	Serial number		Quantity
	Non Sterile		Catalogue Number
			Batch Code
	Humidity limitation		Temperature limitation

INTRODUCTION

PRESSUREGUARD EASY AIR® XL Models

WARNING*: READ ALL INSTRUCTIONS BEFORE USING THIS UNIT.*

INTENDED USE: A pressure management system used for the prevention and treatment of pressure injuries.

INDICATIONS FOR USE: The PressureGuard Easy Air XL is a unique powered, flotation therapy mattress providing 1) a pressure management surface for the prevention and treatment of pressure injuries, and 2) low air loss for the removal of excess perspiration and body heat. It is intended for use on any standard hospital bed frame.

Contraindication: The Easy Air® XL is not for use by those with unstable spinal cords. Patient injury could occur.

Contraindication: The Easy Air® XL is not for use by those weighing less than 350 lbs. Users below 350 lbs. may not receive adequate immersion, envelopment and pressure redistribution from the system.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the member state in which the user and/or patient is established.

DESCRIPTION: The system consists of a two-part microclimate management system of cover and coverlet, a foam shell, air cylinder inflation system, and a control-unit housing a blower and a compressor. The foam shell has a high-density foam topper, a Safety Edge™ contoured foam bolster around the perimeter and ends of the mattress for added patient stability and positioning, and the unique Heel Slope® feature designed to further reduce pressure for the sensitive heel area. The air-cylinder inflation system is housed within the foam shell and consists of air-cylinders oriented lengthwise within the mattress. The control unit connects to the mattress at the patient foot-end.

MODES OF OPERATION: The air flow for microclimate management will be on continuously at power up. Easy Air XL provides choice of two therapy modes of operation, FLOAT, or ALTERNATING.

To reduce the risk of burns, electrocution, fire or injury to persons:

READ ALL INSTRUCTIONS BEFORE USING THIS UNIT.

1. Use this unit only for its intended use and with recognized accessories which are described in the operating instructions; use of other accessories or materials may degrade minimum safety level.
2. Never operate the product's powered control unit if it has a damaged cord or plug, is not working properly, has been dropped or damaged, or has been exposed to water. Contact Span-America Medical Systems, Inc. for examination and repair.
3. Keep the cord away from heated surfaces. Discontinue use if power cord is damaged or worn.
4. Never drop or insert any object into any opening or hose. Keep away from sharp objects.
5. Do not use outdoors.
6. Do not place or store product where it can fall or be pulled into a tub or sink.
7. Do not place in or drop into water or other liquid.

8. Do not reach for a product that has fallen into water. Unplug immediately.
9. Possible explosion hazard if used in the immediate proximity of flammable gases (risk of explosion).
10. Use only original spare parts and consumables.
11. Plug this product into a correctly grounded outlet only.
12. Before cleaning, unplug unit from its power source. Failure to do so could result in personal injury or equipment damage.

13. Do not use harsh cleansers, solvents, or detergents. Do not expose the unit to excessive moisture. Equipment damage could occur.

Warning: Cancer and Reproductive Harm – www.P65Warnings.ca.gov

We believe the PressureGuard Easy Air sets a new standard for microclimate management mattress systems.

Thank you for choosing Span-America!

PRODUCT DESCRIPTION

Span-America's proprietary use of non-collapsible "Air Diffusion Matrix" fabric in both the inner air-delivery cover and the outer removable coverlet maintains an air pathway underneath the user, thus transporting moisture vapor away from the user's skin. Both the inner air-delivery cover and the outer removable coverlet are bacteriostatic, flame resistant and fluid resistant. Since they do not allow fluids to penetrate the surface to the mattress, maintenance is minimal. The air-cylinder inflation system and the foam shell work in concert to maintain low interface pressures throughout the surface, making the Easy Air XL effective for treatment of pressure injuries by preventing further tissue breakdown.

Close-up illustrations of the outer removable coverlet and the inner air-delivery cover, and an explanation of the science behind the design are found on page 11.

Illustration of individual parts of the PressureGuard Easy Air XL:

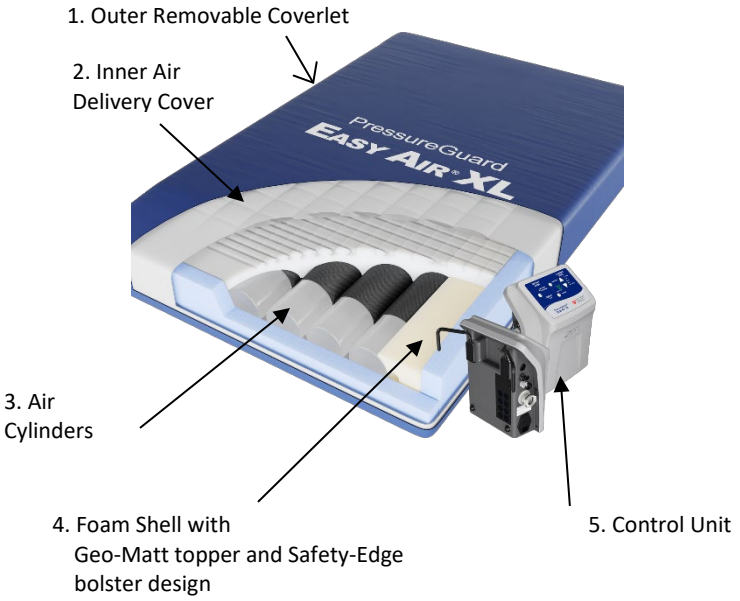


ILLUSTRATION DESCRIPTIONS

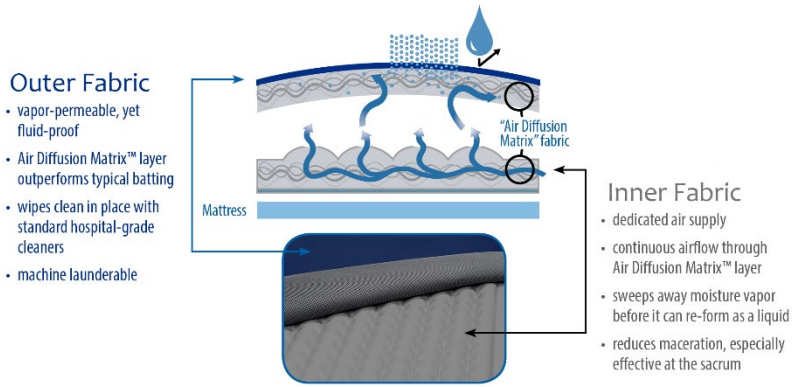
1. Outer Removable Coverlet:	The outer coverlet is fluid proof, cleanable and flame resistant. It can be replaced if damaged or worn. The coverlet is highly vapor permeable (4500 grams/meter^2/24 hours) and fluid resistant. Both of its fabrics (smooth top fabric and the crush-proof air diffusion matrix fabric) are bacteriostatic. Coverlet can be routinely wiped clean and disinfected in place, or can be removed and machine laundered according to directions in this manual.
2. Inner Air-Delivery Cover	The gray, multi-layered cover serves as a barrier, protecting the inside of the mattress from both fluids and vapors, while supplying air to the microenvironment between the cover and coverlet. Unlike the removable coverlet, it is intended to remain on the mattress at all times. It can be cleaned and disinfected in place using standard hospital, medical grade products. The air delivery cover is a gray urethane fabric with a welded pattern and air holes designed to deliver air flow to the top of the mattress to flow underneath the patient in the removal of moisture from the patient's skin.
3. Air Cylinders	The inflation system consists of air cylinders that run lengthwise underneath the body. Unlike typical microclimate management systems, the cylinder inflation system does not lose air from the inflation system for microclimate management, and can be programmed to perform either Flotation or Alternating Pressure. The cycles and inflation levels are designed to provide and maintain low interface pressures throughout the mattress, and to redistribute peak interface pressure points during all therapy modes.
4. Foam Shell	The foam topper is a high density, medical grade foam that provides patient comfort, support, and pressure redistribution. The proprietary Safety Edge™ consists of contoured foam bolsters around the perimeter and ends of the mattress for added patient stability and positioning.
5. Control Unit	The quiet, energy-efficient control unit houses both a high volume air blower and a lower volume air compressor. The blower component provides air for the microclimate management function through the cover/coverlet, while the compressor component provides air to the air-cylinder inflation system. The filter on the control unit should be cleaned regularly.

THE SCIENCE BEHIND EASY AIR
MICROCLIMATE MANAGEMENT DESIGN

Easy Air's exclusive "Air Diffusion Matrix" design maximizes removal of excess moisture (i.e., perspiration) from the user's skin. Moisture passes in vapor form down through the coverlet, where a continuous air current takes it away before it can re-form as liquid.

The Air Diffusion Matrix fabric is not collapsible, ensuring a pathway for a constant flow of air beneath the patient. Compare to typical "microclimate management" designs that cause the patient's body to press the cover directly onto the air holes, closing off the flow of air beneath the patient.

Outer Removable <u>Coverlet</u>
and
Inner Air-Delivery <u>Cover</u>



MATTRESS AND CONTROL UNIT SET-UP DIRECTIONS

1. Place the mattress on a standard hospital bed frame with the outer coverlet facing up, and the connector access at the foot-end of the bed, to the patient's right. Note that the connector access is on the inner gray top surface air delivery cover, which should also be facing up, under the coverlet.

2. Hang the air-control unit on the foot-end of the bed or place on the floor as desired. Avoid blocking vent holes of filter on the back of the control unit housing.

WARNING: Do not position equipment in such a way that it will block the removal or addition of the separable power cord from the device.

3. Plug the power cable into the connector module on the air-control unit (on lower lefthand side when facing the control unit) and plug the opposite end into the wall outlet.

Always plug the power cable securely into the wall outlet. Make sure the wall-mounted outlet will accommodate a heavy duty or hospital-grade plug and that the outlet is in good working order. The plug of the power cord should fit tightly into the wall outlet. The plug body, the wall outlet, and the wall plate should not be cracked or chipped. The plug blades should be securely retained in the plug body. The ground pin of the plug should be intact and secure.

Do not connect the power cord to an extension cord or to a multiple outlet strip. If the use of extension cords or multiple outlet strips cannot be avoided, use only heavy duty or hospital-grade connectors that are approved by the facility engineering department. Multiple outlet strips should be mounted on a fixed object to reduce the risk of liquid spills and physical damage. In addition, if multiple-receptacle outlet boxes are used, they also should be protected from the risk of liquid spills and physical damage. All extension cords and multiple outlet strips should be tagged and inspected routinely.

Do not cover the power cord with a rug or carpet. Rugs or carpets can prevent normal air flow, which can lead to greater heat build-up. Place the cord in a low or no traffic area. Check to be sure the motion of the bed does not interfere with the bed's power cord or plug.

Do not position power cord over edge of bed frame or drape loosely at the side. This may introduce possible strangulation of the patient.

Never thread power cords through mechanical parts of the bed or bed rails where normal bed movement may damage or cut the cord.

Note: If the pump is quickly restarted after a power interruption, you may encounter fluctuating power indicated by blinking lights. Turn power off. Wait at least 5 seconds before restarting.

4. Connect the air lines extending from the mattress into place on the side of control unit.
   - Air Delivery Line: The large diameter air line delivers a high volume air flow to the top layer of mattress. Click the male fitting of the large diameter air line into place in the female air outlet on the side of the control unit.

Attaching main air delivery line

To disconnect, press gray button on the outlet. This will release and eject the air line.

- Support Cylinder Air Lines: The interchangeable, small-diameter air lines with right-angle fittings deliver lower volume air flow to the support cylinders inside the mattress. Position fittings and press into connectors on the side of control unit. Listen for an audible click from each fitting to verify secure connection.

- To disconnect: Use thumb and forefinger to press concurrently the two silver release buttons located on the side of connector. This will release and eject the air line right-angle fitting.

Easy Air XL Model (model 8310)

Never thread air lines through mechanical parts of the bed or bed rails where raising, lowering, or gatching of the bed may damage the air lines or the control unit itself. Check to be sure the routing of the air lines or the motion of the bed does not impede air flow by crimping the air lines.

ELECTROMAGNETIC OR OTHER INTERFERENCE

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer for help.

EMC: Electric devices may interact due to electro-magnetic radiation. We recommend a safety distance of at least one meter, especially for sensitive equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Easy Air is intended for use in the electromagnetic environment specified below. The customer or the user of the Easy Air should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Easy Air uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Easy Air is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Easy Air is intended for use in the electromagnetic environment specified below. The customer or the user of the Easy Air should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output Lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a

IEC 61000-4-5	± 2 kV line(s) to earth	± 2 kV line(s) to earth	typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that it be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field **IEC 61000-4-8**	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE *U*T is the a.c. mains voltage prior to application of the test level.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms for ISM bands	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Easy Air, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz

	27V/m 385 MHz 28 V/m 450 MHz 9V/m 710/745/780 MHz 28V/m 810/870/930 MHz 28 V/m 1720/1845/1970 MHz 28 V/m 2450 MHz 9V/m 5240/5500/5785 MHz		$d = 2{,}33\sqrt{P}$ 800 MHz to 2,7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). The Easy Air unit is fairly sensitive to conducted and radiated RF. Disturbance of the systems trace is possible at and below the specified test level. It may be necessary to relocate the unit or apply shielding. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,(a) should be less than the compliance level in each frequency range.(b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Easy Air unit is used exceeds the applicable RF compliance level above, the Easy Air unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 3400.

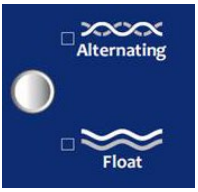
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Easy Air			
The Easy Air is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Easy Air can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Easy Air as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Use of main power cords other than that supplied with product by Span-America (P02337) may affect EMC compliance with UL regulations. Power cords other than recommended by manufacturer or at lengths other than supplied length may increase emissions or decrease immunity.

CONTROL UNIT FUNCTIONS
PRESSUREGUARD EASY AIR® XL

1. Turn unit ON at the switch provided on the lower left-hand side of the air-control unit. Immediately after the control unit is switched **ON**, all lights on the control panel will illuminate for 1-2 seconds while the system performs a self-check. If correct system air pressure is not reached within 60 seconds, the amber **LOW PRESSURE** indicator will illuminate. LOW PRESSURE indicator will remain until being replaced by the green NORMAL PRESSURE indicator, indicating that the mattress is ready for patient use. If NORMAL PRESSURE indicator does not illuminate within 20 minutes of power up, contact Span-America for assistance. The air flow that provides microclimate management will automatically activate at power up and run continuously.
2. Select the preferred mode of operation by pressing the toggle button under **THERAPY MODE** on the control unit's front panel.



ALTERNATING: Air cylinders 1 and 4 deflate while 2/5 and 3/6 inflate. Pairs will go through one complete alternation cycle every 15 minutes.

FLOAT: Stops the alternating of the mattress and evenly inflates all six air cylinders. The **FLOAT** indicator light will illuminate, and the mattress will achieve uniform support with no movement within five minutes.

3. **AUTO FIRM** – Select the AUTO FIRM mode to stop the alternating movement of the mattress. The AUTO FIRM indicator light will illuminate, and the mattress will achieve uniform support that may be desired for bed entry and egress. The mattress will remain in the AUTO FIRM mode for 30 minutes.

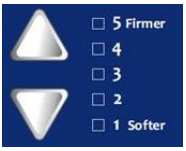
During this time, all of the COMFORT LEVEL indicator lights will be illuminated, and the THERAPY MODE indicator will turn off. The COMFORT LEVEL, THERAPY MODE and ON/OFF selectors will be inactive.

After 30 minutes, the system will automatically resume the comfort and therapy mode setting that had been previously selected.

Pressing the AUTO FIRM selector at any time prior to the elapsing of 30 minutes will immediately return the system to the comfort and therapy mode settings it was in prior to the pressing of AUTO FIRM, and will re-activate all selectors including ON/OFF.

4. **LOCKOUT:** The LOCKOUT feature can be used to eliminate accidental or unintended changes to the control unit settings. To engage, press LOCKOUT firmly and hold for 3-4 seconds until indicator light turns on. To disengage, press LOCKOUT again and hold firmly for 3-4 seconds until light turns off, indicating that the control unit settings are again unlocked and can be adjusted as desired.

5. Set **COMFORT LEVEL** For best possible pressure management, maximize immersion and envelopment by initially setting the "COMFORT LEVEL" on the control panel to the softest selection appropriate for the patient, in accordance with the stated weight limits:



Adjust for user comfort as desired, using up and down arrow buttons.

NOTE: Allow the mattress to inflate for about 20 minutes before putting a patient on it.

In normal operation, the green **NORMAL PRESSURE** indicator should be illuminated. If the amber **LOW PRESSURE** indicator illuminates, verify air lines are not crimped or kinked preventing proper air flow and that all air line connections are secure. If the problem is not resolved, remove the patient from the surface and discontinue use. For assistance, contact Span-America at 800-888-6752, 8:00 AM – 5:00 PM EST, Monday through Friday.

SUSPENDING THE MICROCLIMATE MANAGEMENT FUNCTION: For maximum effectiveness, the Easy Air series is designed such that the microclimate function is always on during operation and upon every power-up. However, should the user desire to do so, the function can be *temporarily* toggled off by holding the AUTO FIRM button for 5 seconds. The function can be resumed by holding the button again for 5 seconds and will resume automatically upon next power up.

GENERAL DIRECTIONS FOR USE

ELEVATING HEAD OF BED ("HOB"): All support surfaces using air as a support medium are designed for distributing pressures over the body in a flat, horizontal position. Bending the support surface and the body at the midpoint when elevating the HOB concentrates the body weight over the center of the surface, stressing that small area. This extreme change in dynamics creates a challenge for all air support surfaces. Maximum pressure management benefits are realized between zero and 30 degrees HOB elevation. Although the Easy Air XL will maintain its support and therapeutic capabilities up to and including 70 degrees HOB, for maximum benefit we recommend that any pressure management surface be used with the head of the bed elevated as little as possible, and for limited periods at a time.

BED RAILS: Due to concerns over the possibility of patient entrapment, Span-America recognizes that the use of rails of any length is a matter currently addressed by federal and state laws/guidelines, and by individual facility protocol. It is the responsibility of the facility to be in compliance with these laws, which typically require that decisions on the use of bed rails of any type are based on assessment of the physical and mental status of each patient individually. If bedrails are needed by the patient to prevent fall-related injury, as determined by this facility assessment, we recommend that the bedrails be locked in the up position at all times. We do not require use of bedrails with the Easy Air XL mattress unless the patient is deemed to be safer with them than without them.

CPR (Cardiopulmonary Resuscitation): The face plate of all Easy Air models indicates recommended settings for CPR. The standard for life support recommended by the American Heart Association recommends a hard level surface such as a crashboard, or moving the person to the floor if possible.

For performing CPR:

- Select the FLOAT Mode.
- Select the COMFORT LEVEL 5.
- Place a crash board underneath the user.
- Follow standard CPR procedures.

PATIENT TRANSPORT: The patient can remain on the mattress while the mattress and bed frame are being moved, with proper safety precautions taken. Unplug the power connector from the wall receptacle. The inflation of the mattress will be maintained and the air will equalize in the air cylinders.

CAUTION: DO NOT MOVE PATIENT ON MATTRESS ONLY. Mattress should not be used alone for patient transport.

POWER LOSS: If power is lost, **DO NOT UNPLUG** the control unit, and **DO NOT DISCONNECT** the air lines from the control unit. The air-cylinder system will equalize pressure in the support cylinders, and maintain inflation for days or weeks, functioning as a non-powered air flotation mattress. As a safety measure, when power is restored the control unit will power up in the "FLOAT" THERAPY MODE (see page 20) and in COMFORT LEVEL "2" (see page 22). Allow approximately 5 minutes after power is restored to achieve normal therapy mode functions upon power up. *EXCEPTION: if power outage occurs while in AUTO FIRM mode, unit will power up in AUTO FIRM mode, and then return to FLOAT and COMFORT LEVEL 2 upon completion of the AUTO FIRM period.*

BED LINENS: Seven-inch deep fitted sheets are recommended.

INCONTINENCE PADS: Pads specifically designed for use with microclimate management mattresses are recommended.

SERVICE: DO NOT attempt to service unit in-house. Return the control unit for repair or service to Span-America Medical

Systems. Repairs to be performed by manufacturer only. Call 800-888-6752, 8:00 AM – 5:00 PM EST, Monday through Friday.

ENVIRONMENTAL CONDITIONS FOR USE:

- Temperature 5°C to 40°C
- 15% RH to 90% RH
- 700 hPa to 1060 hPa
- Mains Supply Voltage Fluctuation up to 10 +/-% of the nominal voltage
- Overvoltage Category II
- Pollution Degree 2

Continuous operating conditions

– a temperature range of + 5°C to + 40°C;
– a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and
– an atmospheric pressure range of 700 hPa to 1 060 hPa.

Transport and storage conditions between uses

– – 25°C to + 5°C, and
– + 5°C to + 35°C at a relative humidity up to 90%, non-condensing;
– > 35°C to 70°C at a water vapour pressure up to 50 hPa

STORAGE AND TRANSPORTATION

Store the mattresses in a clean, dry place. Once the mattress is removed from the box, store flat on a clean surface. When removing mattress from storage, always ensure the internal inflation system is aligned correctly prior to placing a patient on the surface. Avoid temperature extremes (below -25^{o} Celsius or above 70^{o} Celsius). Allow to acclimate to room temperature before use. Do not stack more than 10 high. Do not stack other equipment on top of the mattresses.

Store control unit in a clean, dry place, protected from accidental damage or falls. Avoid temperature extremes (below freezing or

above 49° Celsius). Do not stack other equipment on top of the control unit. For transportation, secure to prevent damage or falls. For shipment, use box and packaging as provided by the manufacturer.

CLEANING: Clean and disinfect mattress coverlets following contamination with bodily fluids and between patients. Both the inner cover and the removable coverlet can be cleaned in place by wiping with neutral suds and lukewarm water. Rinse and allow to air dry for approximately 20-30 minutes before use. For hard to clean spots, use liquid cleaner with soft sponge in the concentration recommended by the manufacturer. DO NOT USE HARSH CLEANERS OR SOLVENTS. See additional information below.

If desired, removable coverlet can be machine-laundered using cold or warm water and a cold rinse cycle. Begin wash cycle, add detergent, allow to agitate for two minutes, then place coverlet in washer. Tumble dry using low heat or no heat, or allow to air dry.

CAUTION: USE OF HIGH HEAT IN WASHING OR DRYING WILL DESTROY THE COVERLET.

For long-term incontinent applications, clean and disinfect coverlet daily. A scented cleaner/disinfectant is recommended. Iodophor type disinfectants (e.g. Betadine) will stain the fabric.

For disinfection, phenolic or quaternary type disinfectants are recommended. Disinfectants should be hospital grade (tuberculocidal). Follow manufacturer's instructions for use concentrations, contact times and rinsing.

For site decontamination of blood or other potentially infectious materials (OPIM), US Centers for Disease Control and Prevention (CDC) guidelines

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/recommendations.html recommendations include two non-bleach options: Use of an EPA-registered tuberculocidal agent [See: List B:, https://www.epa.gov/pesticide-registration/list-b-antimicrobial-products-registered-epa-claims-against-mycobacterium] or use of a registered germicide on EPA Lists D and E.

Where surveillance and epidemiology indicate ongoing transmission of *C. difficile*, CDC directs providers to use of products on EPA List K (https://www.epa.gov/pesticide-registration/list-k-antimicrobial-products-registered-epa-claims-against-clostridium) for effectiveness against Clostridium difficile spores for disinfection of environmental surfaces.

While CDC guidelines include properly diluted bleach as an option in both scenarios, **the use of bleach on highly vapor permeable microclimate coverlets—especially at improper dilutions—may result in damage including fabric discoloration, premature wear, and fluid pass-through and is therefore not recommended nor covered under warranty.** Instead, select an appropriate option from Span-America's list of approved cleaning agents, available upon request.

Do not puncture the mattress with needles or sharp instruments. This may result in loss of integrity of the mattress air system or top surface microclimate management inner air delivery cover, bladder, and will void the warranty. Inspect the cover, coverlet and zipper area for signs of damage, puncture, or wear that could result in fluid pass-through. Internal components should be inspected on a scheduled basis for signs of contamination, particularly if the cover is stained, soiled, or torn. If contamination other than typical, age-related foam discoloration is evident, quarantine the mattress and remove from service following infection control procedures

If required, the air control unit can be cleaned and disinfected.

Turn unit off and unplug from wall before cleaning. [Note: The mattress will maintain air with the unit unplugged. The unit will resume previous setting when powered back up].

Wipe down with damp sponge or cloth that has been thoroughly wrung out to remove excess liquid. Do not allow liquids to penetrate the user panel.

DO NOT service or do maintenance on equipment while plugged in and powered up.

For cleaning, use neutral suds and lukewarm water. For disinfection, phenolic or quaternary type disinfectants are recommended. Disinfectants should be hospital grade (tuberculocidal). Follow manufacturer's instructions for concentrations and contact times.

PREVENTIVE MAINTENANCE

FILTER MAINTENANCE

- The control unit contains a high-volume air blower that requires filtered air for proper operation.
- The filter is located on the bottom rear of the unit.
- The filter is designed to be removed, cleaned, and re-used. [Fig. 1 & 2]

CAUTION: For maximum effectiveness, and to prolong the life of the unit, cleaning of the filter should be performed at least once every 180 days of use. If the control unit is used in an area with high concentration of dust or cigarette smoke, the filter should be cleaned as frequently as once every 30 or 60 days for maximum operation.

TO CLEAN THE FILTER

1. Turn unit **OFF**. Remove the screws on the filter housing plate, which is found at the bottom rear of the control unit [Figure 1].

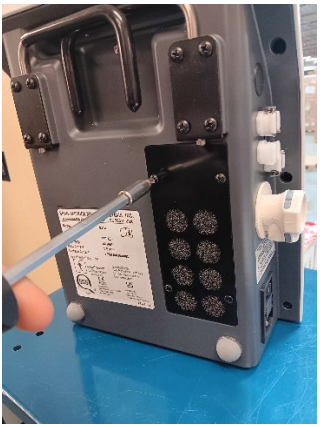


Figure 1

Figure 2

2. With plate off, pull filter out [Figure 2].

3. Wash filter using mild soap and water. Pat dry with towel.

NOTE: If filter is damaged or cannot be easily cleaned, it should be discarded and replaced with a new filter, Span-America part number P11362.

4. Put the filter back into position in the control unit.

5. Reattach the housing plate.

ROUTINE INSPECTION OF POWER CORDS AND SAFETY TIPS TO PREVENT FIRES

WARNING: To avoid the risk of electric shock or fire, this equipment must only be connected to a supply mains with protective earth for all CLASS-1 models.

1. Ensure that the electrical resistance of the safety ground conductor and the level of leakage current (line conductor-to-safety ground and neutral conductor-to-safety ground) meet applicable standards for resistivity and leakage current.

Protection afforded by the ground pin is negated if the receptacle is not properly grounded. If you have questions about the adequacy of your facility's building wiring, contact a qualified electrician or consult the code authority in your jurisdiction.

2. Check all electrical outlets, including accessory outlets for cleanliness, physical integrity and functionality. The IEEE standard 602-1996, section 4.2.2 advises that hospital-grade outlets be used and that they should be mounted with the ground pin or neutral blade up to ensure that any metal that may drop between the plug and the wall will most likely contact an unenergized blade.

3. Check the power cord to ensure that contact pins are straight and secure.

4. Routinely inspect the power cord for damage sustained from crushing, pinching, shearing, cutting, or from being worn through. They can be damaged by bed movement, deterioration from use or aging, or human or equipment traffic. The cord's insulation should be intact and there should be no evidence of bulging, stretching, crimping, cracking, or discoloration, especially at the ends, where the cord is attached to the plug body and the control unit.

5. Regularly inspect all parts of the bed frame, motor, mattress and controller, and the floor beneath and near the bed for build-up of dust and lint.

6. Inspect the cover of the control panel to ensure the covering is not cracked or damaged, allowing liquids or other conductive material to penetrate to the switches.

7. Report any unusual sounds, burning odors, or anything unusual to maintenance personnel. Discontinue use of the power cord immediately and contact Span-America Medical Systems, Inc. for replacement.

MATTRESS

Inspect the cover, coverlet and zipper area for signs of damage, puncture, or wear that could result in fluid pass-through. Internal components should be inspected on a scheduled basis for signs of contamination, particularly if the cover is stained, soiled, or torn. If contamination other than typical, age-related foam discoloration is evident, quarantine the mattress and remove from service following infection control procedures.

You may use the Preventive Maintenance Log provided on the last page of this manual to monitor and document regular inspection and maintenance of your PressureGuard Easy Air XL Systems.

Warning: Children may interfere with medical device operation. They may change the settings, and on/off switches, twist tubing, adjust machine vents, or remove electrical cords from the outlet. They can also injure themselves while playing with devices they think are toys.

Pets may also directly interfere with device operation. They may chew through an electrical cord or play with an accessory such as tubing. They may also walk over an area that is supposed to be clean and pet fur/hair may find its way into the device.

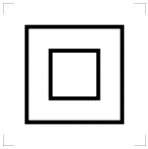
It is recommended that children and pets stay clear of the medical device.

SPECIFICATIONS

OUTER REMOVABLE COVERLET:	Bacteriostatic High Moisture-Vapor Transport Rate Fluid proof Meets Cal TB# 117 Bacteriostatic
INNER AIR-DELIVERY COVER:	Fluid proof Meets Cal TB# 117
FOAM:	High-density open-cell polyurethane "THIS PRODUCT MEETS THE REQUIREMENTS OF BUREAU OF ELECTRONIC AND APPLIANCE REPAIR, HOME FURNISHINGS AND THERMAL INSULATION TECHNICAL BULLETIN 117-2013."
AIR CYLINDERS:	Urethane
FLAMMABILITY:	Foam conforms to Cal TB # 117. Mattress conforms to NFPA 101 small scale (ASTM E 1590), 16 CFR 1632.4 and FCC 16 CFR 1633.
Power:	All models Max. Current: 1.0 Amp Leakage Current: < 250 Microamps
Standards:	ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012 CAN/CSA-C22.2 N0. 60601-1:2014 EN 60601-1:2006 + A1:2013

ANSI/AAMI HA60601-1-11:2015
CAN/CSA-C22.2 N0. 60601-1-11:2015
IEC 60601-1-2:2014 (4th ed.)
EN 60601-1-2:2014 (4th ed.)
CE marked in accordance with MDR (EU 2017/745)

Type BF Applied Part



Double insulated for 60601-1-11/Home Healthcare system

CONTROL UNIT:

Easy Air XL models (Non-European CE):
8310
Voltage: 120 VAC
Frequency: 60 Hertz
Class-1 Model

Easy Air XL model (European CE):
(UK): 8310CEG
(EU): 8310CEC
(AUS): 8310CEI
Voltage: 240 VAC
Frequency: 50 Hertz
Class-1 Model

Easy Air models (60601-1-11/Home Healthcare): 8311
Voltage: 120 VAC
Frequency: 60 Hertz
Class-2 Model

PERFORMANCE:	Provides pressure management in the prevention and treatment of pressure injuries. The surface is designed to prevent bottoming out for patients weighing up to 1,000 lbs. The microclimate management feature reduces excessive perspiration and body heat by transporting moisture vapors away from the patient's skin.
SERVICE LIFE:	The service life of Easy Air system and equipment parts and accessories including mattresses is one year.
OPERATING MODES:	Air Flow: Continuously on Therapy Mode: Select from FLOAT or ALTERNATE.
MATTRESS HEIGHT:	7”
WARRANTY:	3 years (mattress core); 2 years (cover/coverlet); 2 years (control unit). All non-prorated.
WEIGHT LIMIT:	75 lbs. to 1,000 lbs. (adult users) in FLOAT or ALTERNATE mode.

(a) Use of main power cords other than that supplied with product by Span-America (P02337) may affect EMC compliance with UL regulations. Power cords other than recommended by manufacturer or at lengths other than supplied length may increase Emissions or Decrease Immunity.

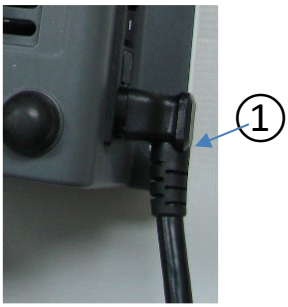
ORDERING INFORMATION

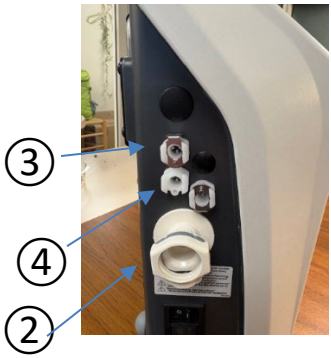
PressureGuard Easy Air XL bariatric microclimate management system with alternating pressure. Control unit: 8310.

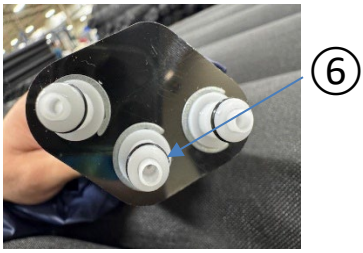
System #	Mattress Size	Mattress Only	Removable Coverlet Only	Inner Cover	Replacement Inflation System
L8042XL-29	80”L x 42”W x 7”H	LM8042XL2	CLT-L8042XL	C1-L8042-29	P16762
L8048XL-29	80”L x 48”W x 7”H	LM8048XL2	CLT-L8048XL	C1-L8048-29	P16762
L8053XL-29	80”L x 53”W x 7”H	LM8053XL2	CLT-L8053XL	C1-L8053	P16762
L8442XL-29	84”L x 42”W x 7”H	LM8442XL2	CLT-L8442XL	C1-L8442-29	P16762
L8448XL-29	84”L x 48”W x 7”H	LM8448XL2	CLT-L8448XL	C1-L8448-29	P16762
L8453XL-29	84”L x 53”W x 7”H	LM8453XL2	CLT-L8453XL	C1-L8453-29	P16762
62507	86”L x 42”W x 7”H	M62507	CLT-62507	C1-L8642	P16762

Items not shown below:

Filter replacement P11362 (package of 12 filters)
Fuse replacement P11333 2 Amp/ 250 V Slow-Blow







Parts List		
Image #	Part #	Description
①	P11474	Power cord, (60601-1-11/Home Healthcare)
	P02337	Power cord, (Class-1)
	P11545	UK Power cord, (CEG Class-1)
	P11546	EU Power cord, (CEC Class-1)
	P11547	AUS Power cord, (CEI Class-1)
	P11331	Power Module (Class-1 models)
	P11473	Power Module (Class-2 Home Healthcare models)
②	P09533	Large Female, (all models requires 1 each)
③	P02812	Small, Female, white click (8310 model requires 2 each)
④	P02813	Small, Female, white plastic (8310 model requires 1 each)
Mattress End		
⑤	P09826	Large, Male, (requires 1 each)
⑥	P02800	Small, Male, white plastic (8310 model requires 3 each)

TROUBLE SHOOTING GUIDE

Problem	Possible Cause	Solution
System will not power up. **Note:** **Always plug power supply into properly grounded receptacle.**	The system is not plugged in.	Plug power cord into wall receptacle.
	There is no power at outlet.	Restore power.
	Power cord is damaged.	Call for service.
	Blown fuse.	Call for service.
Patient not turning/alternating properly.	System is not turned ON.	Plug power cord into wall receptacle.
	Patient not centered on mattress.	Reposition the patient.
	Patient has severe contractures.	Turning can be difficult to observe in patients with severe contractures. Observe someone without contractures lying on the bed for 30 minutes (2 cycles) to confirm turning is functioning properly.
	Head of bed is elevated, or knees are gatched.	The degree of patient turn achieved is reduced with elevation of the head of the bed or gatching of the knees. Adjust each as necessary to meet patient needs while maximizing turn angle.
	Patient exceeds weight limit.	Call Span-America for assistance with product selection.
Mattress not inflating or patient reports a sinking feeling.	Control unit is not turned on.	Turn control unit on.
	Air lines not connected.	Ensure secure connection of airlines at control unit and mattress.
	Air lines or quick disconnect connectors are damaged.	Call for replacement.

Problem	Possible Cause	Solution
	Head of bed elevated.	Lower head of bed and allow air to equalize. Return head of bed to elevated position that is comfortable for patient.
	Defective controller (mattress fills without patient, sinks with patient weight).	Call for service.
Low pressure indicator illuminated.	Air lines not connected.	Disconnect and reconnect airlines to verify they have all locked into place.
	Air lines or quick disconnect connectors are damaged.	Call for replacement.
	Leaking inflation system.	Call for replacement. To replace, turn mattress upside down and unzip cover. Remove inflation system, install new system, zip cover and restore mattress to upright position.
Single or multiple LED indicators not Illuminating.	LED indicators burned out.	Call for service.
	Simultaneous pressing of more than one button on overlay.	Press any single button or reset control unit. Call for service if problem not resolved.
Inability to change modes or comfort level settings.	Central processor malfunction.	Reset control unit by turning off, then back on. Call for service if problem not resolved.
	Simultaneous pressing of more than one button on overlay. See lockout instructions on page 21.	Press any single button or reset control unit. Call for service if problem not resolved.
Inability to change modes or comfort level settings. All LED indicators repeatedly flashing or not illuminated	Central processor malfunction.	Press lockout button for 3 seconds to disable.
	Simultaneous pressing more than one button on overlay. Central processor malfunction.	Reset control unit by turning off, then back on. Call for service if problem not resolved.

Problem	Possible Cause	Solution
while control unit is running		Reset control unit by turning off, then back on. Call for service if problem not resolved.
Interference produced to electronic equipment/devices in surrounding area. Blower not operating.	Electromagnetic interference caused by the unintentional emission of electromagnetic waves of energy. These waves are transmitted through the air at various frequencies which may produce interference such as abnormal functioning to nearby electronic equipment.	Determine if emissions are causing the interference by turning the equipment off and on. If the interference in the affected device subsides when control unit is off, proceed with the following steps. a) Reorient or relocate the affected device. b) Increase the distance between the equipment. c) Connect the equipment into an outlet on a circuit different than that of the affected device. Consult the field service technician or manufacturer of the affected device.
	No air flow to inner air delivery cover.	Call for service if problem not resolved.
Cover billowing	Weld failure in top of mattress cover.	Call Span-America for replacement cover.
Technical Service: (800) 888-6752		

PRESSUREGUARD EASY AIR XL
PREVENTIVE MAINTENANCE AND REPAIR LOG

Date	Air Filter	Power Cord	Mattress	Repair
Manufacturer: Span-America Date Purchased:		Serial #:		C=Cleaned OK=Okay R=Repaired/Replaced

SPAN-AMERICA MEDICAL SYSTEMS, INC.
70 Commerce Center, Greenville, SC 29615 USA
800-888-6752

www.savariapatientcare.com

EC REP

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