SPAN
PressureGuard® Custom Care® Convertible LAL

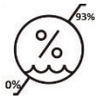
OWNER'S MANUAL

savaria®

CONTENTS

CLASSIFICATIONS AND ICONS

The International Electrotechnical Commission (IEC) requires the use of symbols to improve readability and increase understanding of the content.

WARNING	SITUATIONS OR ACTIONS THAT MAY INFLUENCE PATIENT OR USER SAFETY. IGNORING A WARNING COULD CAUSE PATIENT OR USER INJURY	CAUTION	POINTS OUT SPECIAL PROCEDURES OR PRECAUTIONS THAT PEOPLE MUST OBEY TO AVOID EQUIPMENT DAMAGE
	SEE THE USER MANUAL FOR USE INSTRUCTIONS		POTENTIAL TRIP HAZARDS
	ELECTRICAL SHOCK HAZARD WARNING		MANUFACTURER
	WASTE DISPOSAL		DOUBLE INSULATED SYSTEM
	TYPE BF APPLIED PART		KEEP DRY OR DO NOT WET
	EUROPEAN CONFORMITY MARKING		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	FOOT END		NOT MADE WITH NATURAL RUBBER LATEX
	ALTERNATING CURRENT		QUANTITY
	SERIAL NUMBER		CATALOGUE NUMBER
	NON-STERILE		BATCH CODE
	HUMIDITY LIMITATION		TEMPERATURE LIMITATION
	DIRECT CURRENT	IP21	AGAINST THE INGRESS OF FINGERS OR SIMILAR OBJECTS AND DRIPPING WATER
IEC 60601-1-2	ELECTROMAGNETIC EMISSIONS	IEC 60601-1	ELECTRICAL SAFETY

INTRODUCTION

The Custom Care® Convertible LAL is a non-powered treatment surface featuring a patented air therapy design that automatically adjusts a network of interconnected air cylinders and elasticized reservoirs to the appropriate, therapeutic level, regardless of the user's weight or position. It is intended for use as a non-powered reactive therapy surface, or as a powered active therapy surface via the addition of a powered air control unit.

⚠ 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 CCC LAL is a unique powered, flotation therapy mattress providing 1) a pressure management surface for the prevention and treatment of pressure injuries, and 2) microclimate management for the removal of excess perspiration and body heat. It is intended for use on any standard hospital bed frame.

⚠ WARNING

Contraindication: The Custom Care® Convertible LAL is not for use by those with unstable spinal cords. Patient injury could occur.

⚠ WARNING

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 foam shell with a high-density, zoned foam topper serving as the support surface underneath the patient. The foam shell also includes contoured foam bolsters at the sides and ends of the mattress, providing added patient stability and positioning. The system also includes the unique Heel Slope® feature, designed to further reduce pressure for the sensitive heel area. Within the foam shell is housed the inflation system, consisting of air cylinders which run lengthwise within the mattress. The optional, add-on powered control unit connects to the mattress at the patient foot-end and provides low air loss therapy, plus the choice of alternating pressure, rotation therapy, or powered flotation therapy modes.

A disconnect feature resets the inflation level back to an ideal therapeutic setting for use of the support surface without the control unit.

Modes of Operation

In power mode, the air flow for microclimate management will be on continuously at power up. The system provides choice of three therapy modes of operation, FLOAT, ALTERNATING, or ROTATION.

⚠ CAUTION 

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

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 Custom Care® Convertible LAL sets a new standard for microclimate management mattress systems.

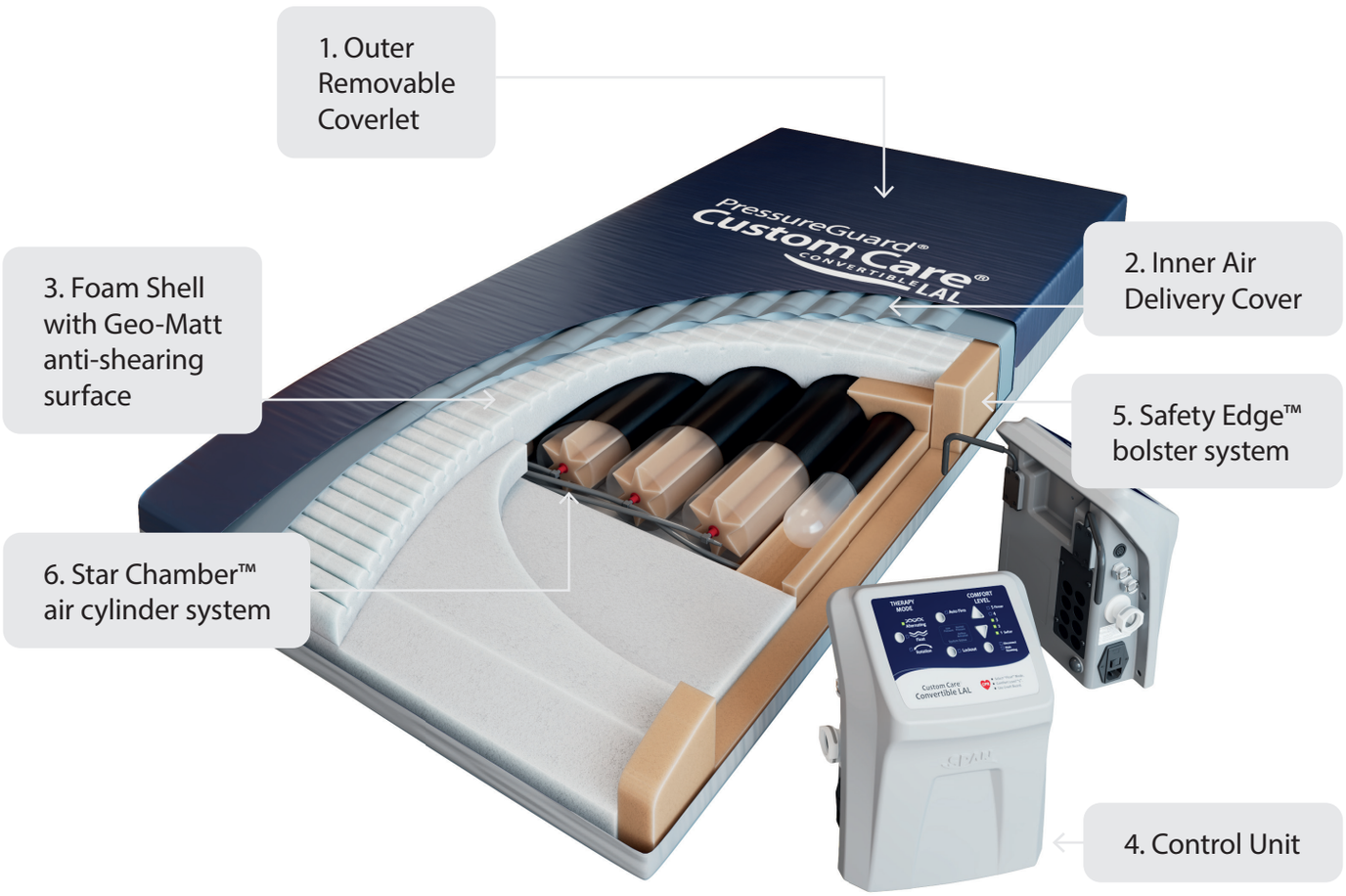
Thank you for choosing Span!

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 proof. 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 CCC LAL 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 9.

Illustration of individual parts of the PressureGuard CCC LAL:



1. Outer Removable Coverlet	The zippered coverlet is highly breathable, fluid impervious, cleanable and flame resistant. It can be replaced if damaged or worn. Both of its fabrics (smooth top fabric and the crush-proof air diffusion matrix fabric) are bacteriostatic. The coverlet is designed to routinely be wiped clean and disinfected in place. If desired because of heavy soiling, coverlet can be removed and laundered according to directions in this manual. **NOTE:** A user should never be placed on the mattress without coverlet in place.
2. Inner Air-Delivery Cover	The multi-layered inner cover serves as a barrier, protecting the inside of the mattress from both fluids and vapors, while supplying air to the microenvironment between itself and coverlet. It is intended to remain on the mattress at all times. It can be cleaned and disinfected in place using standard hospital-grade products. Its top surface is made from a bi-directional stretch urethane fabric with a welded pattern and zoned perforations designed to deliver air flow beneath the patient to facilitate removal of excess moisture from the patient's skin. **NOTE:** Gray, air delivery stretch fabric must face up beneath the coverlet at all times. Bottom (vinyl) side of mattress is not intended for patient contact.
3. Foam Shell with Geo-Matt® anti-shearing surface	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.
4. 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 low air loss function through the cover/coverlet, while the compressor component provides air to the air-cylinder inflation system. Model 8410 PressureGuard Custom Care® Convertible LAL control unit. With respect to electric shock, fire and mechanical hazards only in accordance with IEC 60601-1, UL 60601-1, and CAN/CSA C22.2 NO. 601.1
5. Safety Edge™ bolster system	The Safety Edge™ design consists of engineered inner and outer foam bolsters for added patient stability in sitting and lying down.
6. Star Chamber™ air cylinder system	The heart of the system consists of four air cylinders and two pairs of elasticized reservoirs for the standard models arranged longitudinally (head-to-foot) and constructed from RF- (radio-frequency) welded urethane. The system is designed to maintain low interface pressures throughout the mattress in the non-powered mode. When the powered control unit is connected, it adds active therapy in the alternating pressure or lateral rotation modes, via inflation and deflation in a fixed 15-minute cycle. A powered flotation ("float") mode is also available for use when dynamic therapy is not desired. The system is pre-inflated at the factory to the ideal pressure setting for the elevation to which it is being shipped. Once set, it requires no adjustment or maintenance for the five-year duration of its warranty. If desired, the powered control unit can be used to reset system at any time.

The science behind microclimate management design

How the Custom Care Convertible LAL helps manage excess moisture and heat at the patient/surface interface.

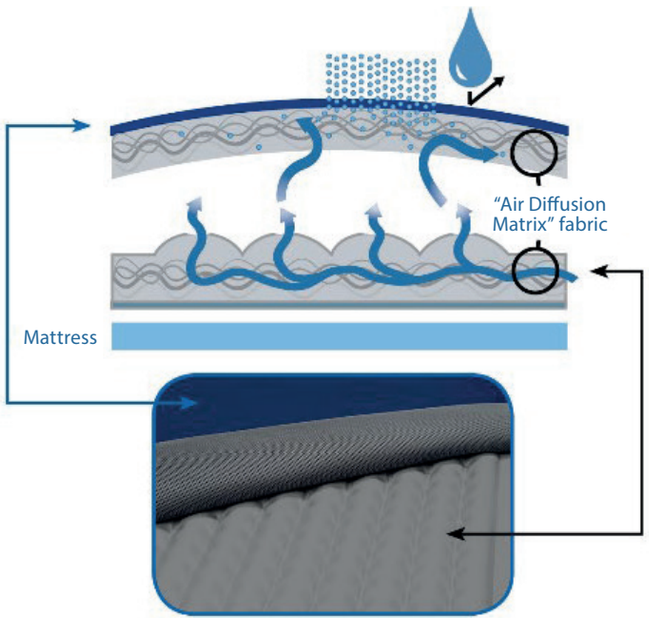
Custom Care® Convertible LAL's exclusive "Air Diffusion Matrix" design maximizes removal of excess moisture (i.e., perspiration) from the user's skin. Moisture passes in vapor form down through the cover, where a continuous air current takes it away before it can re-form as liquid.

The Air Diffusion Matrix fabric is not collapsible, ensuring a pathway for a constant flow of air beneath the patient. Compare to typical "low air loss" 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 Coverlet and Inner Air-Delivery Cover

Outer Fabric

- vapor-permeable, yet fluid-proof
- Air Diffusion Matrix™ layer outperforms typical batting
- wipes clean in place with standard hospital-grade cleaners
- machine lauderable



Inner Fabric

- dedicated air supply
- continuous airflow through Air Diffusion Matrix™ layer
- sweeps away moisture vapor before it can re-form as a liquid
- reduces maceration, especially effective at the sacrum

Mattress and Control Unit set-up directions

⚠ WARNING

The fit of the mattress to the bed frame is important. Minimizing spaces or gaps between the mattress and frame will help prevent patient entrapment issues.

1. Place the mattress on a standard hospital bed frame with the fabric top surface 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. The surface is now ready for use in the non-powered mode (that is, without the control unit attached) by users who are withing 500 lbs. (226.8kg) weight limit for the product.
3. The surface is designed to be used with appropriate linens in place. See page 19.

⚠ 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.

Connecting the Control Unit:

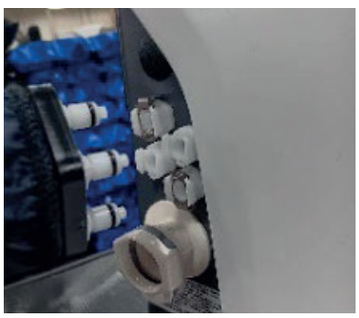
4. Hang the air-control unit on the foot-end of the bed or place on the floor as desired. Avoid blocking vent holes of filter on the back of the control unit housing.
5. Plug the power cable into the connector module on the air-control unit (on lower left side when facing the control unit) and plug the opposite end into the wall outlet.

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

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.

6. Locate the Air Line Set (A), which is a ganged set of staggered air lines that gets inserted into the control unit. Identify the end that connects to the control unit, which consists of a diamond-shaped plate with four mail fittings (2 white, 2 silver) extending straight out. Press this end into the appropriate fittings on the side of the control unit. Press in firmly until two distinct clicks are audible, which signals a complete connection.



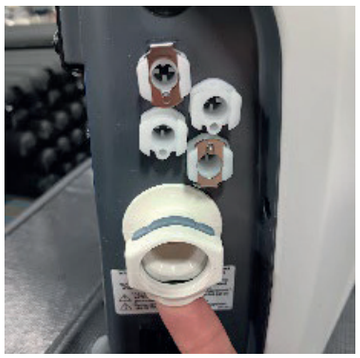
A. Air Line Set

7. The mattress air lines are located at the foot end, patient right. Expose the lines by unfastening the zippered corner of the coverlet. The lengths are staggered to correspond with the staggered lengths of the lines extending from the control unit.

8. Bring the four air lines from the pump around to the four air lines extending from the mattress. Ensure that the air lines are not kinked or twisted. Click each of the connectors into place in its corresponding, color-coded fitting.
9. Air flow to the air delivery cover is supplied through a large diameter, permanently attached air line extending from the corner of the mattress. Click end of air line into the corresponding connector in the side of the control unit. To disconnect, press the gray button to release and eject.

10. Reposition coverlet into place on mattress.

- Air Delivery Line: The large diameter air line delivers 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.

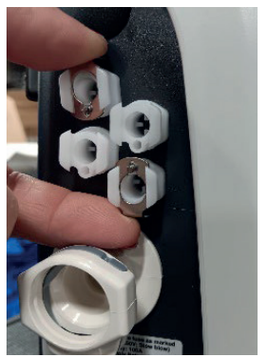


Attaching main air delivery line

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

- Support Cylinder Air Lines: The small diameter air lines deliver air flow to the support cylinders inside the mattress. Four fittings are mounted into one connection plate. Position fittings and click connectors into place on appropriate location on side of control unit. Verify secure connection with "click" for both metal connectors.

- To disconnect: Use thumb and forefinger to press concurrently the two silver release buttons located on the uppermost left and lowermost right connectors. This will release and eject the air line connector plate.



⚠ WARNING

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 Custom Care Convertible LAL is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment-guidance (for professional healthcare environment)
RF emissions CISPR 11	Group 1	The Custom Care® Convertible LAL 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 Custom Care® Convertible LAL 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	

Manufacturer's Declaration-Electromagnetic Immunity

The Custom Care Convertible LAL is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance (For Professional Healthcare Environment)
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV 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 IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles 5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles 5 % UT (>95 % dip in UT) 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: UT is the a.c. mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance (For Professional Healthcare Environment)
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms for ISM bands	3 Vrms	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 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	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Custom Care® Convertible LAL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,17\sqrt{P}$ $d = 1,17\sqrt{P}$ 80 MHz to 800 MHz $d = 2,33\sqrt{P}$ 80 800 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 meters (m). The Custom Care® Convertible LAL 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 Custom Care® Convertible LAL unit is used exceeds the applicable RF compliance level above, the Custom Care® Convertible LAL 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 PressureGuard® Custom Care® Convertible LAL

The Custom Care® Convertible LAL is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Custom Care® Convertible LAL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Custom Care® Convertible LAL 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

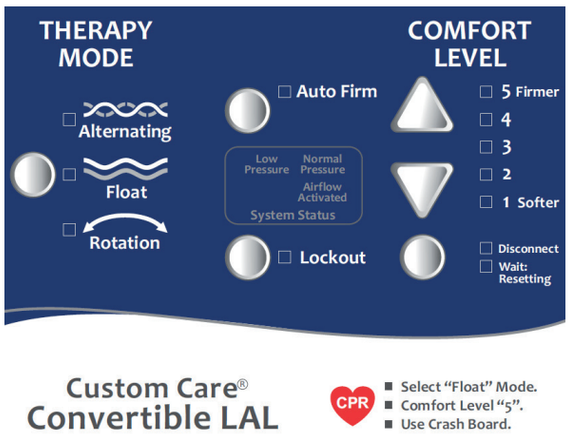
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

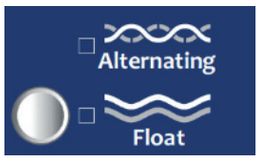
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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



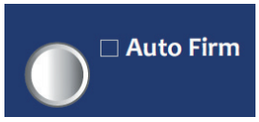
1. Turn unit ON at the switch provided on the lower left-hand side of the air-control unit. Immediately after the control unit is switched on, all lights on the control panel will illuminate for 1-2 seconds while the system performs a self-check. If correct system air pressure is not reached within 60 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 LAL blower system 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 3 deflate while 2 and 4 inflate. Pairs will go through one complete alternation cycle every 15 minutes.

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

ROTATION: Air cylinders 1 and 2 inflate while 3 and 4 deflate, gently rolling the patient laterally. Cycles complete every 15 minutes, rotating the patient from side to side, approximately 20 degrees in each direction.



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 three to four 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:

- For patients up to 120 lbs., begin with level 1 ("Max. Immerse").
- For patients weighing more than 120 lbs. (up to 500 lbs.) begin with Level 2.

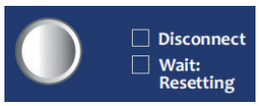
Adjust for user comfort as desired, using up and down arrow buttons.

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 Custom Care® Convertible LAL 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.



6. **DISCONNECT/WAIT: RESETTING** The disconnect function resets the system to the ideal inflation level required for use of the mattress in the nonpowered therapy mode without an attached, powered control unit. To maximize pressure redistribution, the disconnect procedure should be performed at a time when no patient is on the mattress.

   Press "Disconnect" button. Amber "Wait: Resetting" indicator will illuminate while the mattress air system is being reset to the ideal inflation level.

   During this time, the selector buttons and indicator lights of the Comfort Level, Therapy Mode, Air Flow and Lockout buttons will be inactive.

   Pressing the "Disconnect" button again while the "Wait: Resetting" indicator light is on will return unit to the settings it was in prior to the "Disconnect" button being pressed.

   Once the system has reached its ideal setting, the "Wait: Resetting" light will turn off, replaced by green "Disconnect" light. The control unit can now be disconnected from the mattress.

⚠ WARNING

Do not remove the control unit before it has properly reset the air system through use of the Disconnect function. Failure to wait for completion of the disconnect function – or attempting to set the mattress at a particular inflation level by disconnecting the control unit while it is in another mode – can result in a pressure management profile that is inappropriately high or low for a particular user. This could have a negative impact on pressure ulcer prevention, wound healing, and user support.

NOTE

if circumstances make it necessary to disconnect the control unit before the patient can be removed from the mattress:

- **Lower HOB to flat position**
- **Ensure patient is in the center, supine position**
- **Place the surface in "Float" mode for 3-5 minutes prior to performing the disconnect function.**

While the resulting air level will be safe for non-powered use, the system may not be at the ideal non-powered setting. Therefore, the control unit should be reattached and the Disconnect procedure performed at the first opportunity with the patient off the mattress.

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. Beyond 30 degrees, the amplitude of the changes in the air cylinders begins to decrease in proportion to the increased elevation of the HOB. Although the Custom Care Convertible LAL 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.

⚠ WARNING

Lateral rotation mode should not be used with head of bed elevated beyond 30 degrees. Instead, select alternating pressure. With HOB elevated, the alternating pressure mode can facilitate maximum pressure management effectiveness while minimizing the possibility of patient falls.

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 mattress unless the patient is deemed to be safer with them than without them.

CPR (Cardiopulmonary Resuscitation)

The face plate of all Custom Care® Convertible LAL 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 16) and in COMFORT LEVEL "2" (see page 17). 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. Multiple layering of linens or underpads beneath the patient should be avoided for the prevention and treatment of pressure injuries.

Incontinence Pads

Pads specifically designed for use with low air loss mattresses are recommended.

Troubleshooting and Patient Complaints

Occasionally a patient may complain of feeling as if he/she is "sinking into a hole".

1. Sometimes this happens when the head of the bed is elevated and the mattress is in either lateral rotation or alternating pressure. This sensation is a combination of the deflation of the cylinders during their cycle and the increased weight of the patient on the sacrum and pelvis when the head of the bed is elevated. This demonstrates the need to minimize elevation of the head of the bed, or to select Alternating Pressure mode if HOB elevation is necessary.
2. A patient may complain when he/she is supine or side-lying and are not used to the changing pressures within the air system. Assure the resident that this is normal functioning, as the cylinders alternately inflate and vent. The vented tubes are not fully deflated. Some air is always maintained in them to prevent bottoming out. After reassurance, patients typically get used to the changing pressures.

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.

Warranty

The Custom Care Convertible LAL is unconditionally guaranteed against failure due to manufacturing defects under normal use for 24 months for the control unit and 5 years for the mattress.

Use in wound care

Use of PressureGuard Custom Care Convertible LAL is only one element of care in the prevention and treatment of pressure injuries. Frequent repositioning, proper care, routine skin assessment, wound treatment and proper nutrition are but a few of the elements required in the prevention and treatment of pressure injuries. As there are many factors that may influence the development of a pressure injury for each individual, the ultimate responsibility in the prevention and treatment of pressure injuries is with the healthcare professional.

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 vapor 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 vapor 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 -25o Celsius or above 70o Celsius). Allow to acclimate to room temperature before use. Do no 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 49oC). 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

For the mattress, only the outer coverlet requires cleaning and maintenance. Disassembly of the support surface for maintenance of internal components is not recommended. **Clean and disinfect mattress coverlet** 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 cover 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. To protect our warranty, you must utilize an approved cleaner from our list and properly rinse all cleaning agents and disinfecting chemicals after application.

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.

⚠ CAUTION

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 low air loss 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

⚠ CAUTION

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 using 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.

Waste Disposal

This product has been supplied from an environmentally aware manufacturer that complies with WEEE.

PREVENTIVE MAINTENANCE

Air Filter Maintenance

- The control unit contains a high-volume air blower that requires filtered air for proper operation.
- The two-part filter is located on the bottom rear of the unit.
- The larger, outer filter is designed to be removed, cleaned and reused.
- The smaller, inner 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].
2. With plate off, pull filter out [Figure 2].
3. Wash filter using mild soap and water. Pat dry with towel.

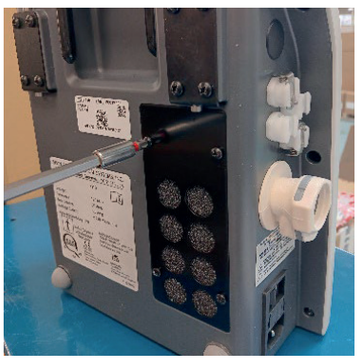


Figure 1

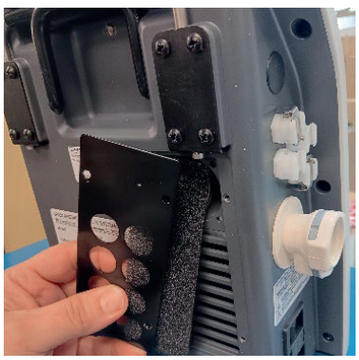


Figure 2

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 that 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 Custom Care Convertible LAL mattress.

⚠ WARNING

Children may interfere with medical device operation. They may change the dial, 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 CCC models (Non-European CE): 8410 Voltage: 120 VAC Frequency: 60 Hertz Class-1 Model Easy Air CCC model (European CE): (UK): 8410CEG (EU): 8410CEC (AUS): 8410CEI Voltage: 240 VAC Frequency: 50 Hertz Class-1 Model Easy Air models (60601-1-11/Home Healthcare): 8411 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 500 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 Custom Care Convertible LAL system and equipment parts and accessories including mattresses is one year.
Operating Modes	Air Flow: Continuously on Therapy Mode: Select from FLOAT or ALTERNATE or ROTATION.
Mattress Height	7"
Warranty	5 years (mattress core); 2 years (cover/coverlet); 2 years (control unit). All non-prorated.
Weight Limit	Non powered mode:75 lbs. to 500 lbs. (adult users) Powered modes: 500 lbs. in FLOAT or ALTERNATE mode, 350 lbs. effective limit for ROTATION 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.

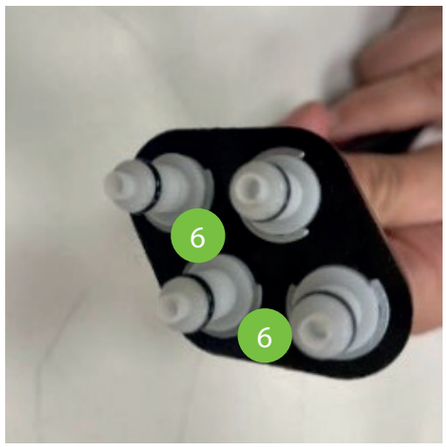
Ordering Information

PressureGuard Custom Care Convertible LAL microclimate management with alternating pressure, lateral rotation. Control Unit 8410.

System #	Mattress Size	Removable Coverlet Only	Inner Cover	Replacement Inflation System
CL753629	75"L x 36"W x 7"H	CLT-CL7536	C1-CL7536	P09608
CL803629	80"L x 36"W x 7"H	CLT-CL8036	C1-CL8036	P09605
CL843629	84"L x 36"W x 7"H	CLT-CL8436	C1-CL8436	P09605
74750	80"L x 42"W x 7"H	CLT-CL8042	C1-CL8042	P10290
49907	84"L x 42"W x 7"H	CLT-CL8442	C1-CL8442	P10290
CL85V29	85"L Recessed Deck	CLT-CL85V	C1-CL85V2	P09410

Items not shown below

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



Parts List

1	P11474	Power cord, (60601-1-11/Home Healthcare)
	P02337	Power cord, (Non-European Class-1 models require 1 each) (Not shown)
	P11545	UK Power cord, (CEG Class-1 models require 1 each)
	P11546	EU Power cord, (CEC Class-1 models require 1 each)
	P11547	AUS Power cord, (CEI Class-1 models require 1 each)
	P11331	Power Module (Class-1 models) (Not shown)
	P11473	Power Module (Class-2 Home Healthcare models)
2	P02812	Small, Female, white plastic click (8410 model requires 2 each)
3	P02813	Small, Female, white plastic, (8410 model requires 2 each)
4	P09533	Large Female, (all models requires 1 each)
Mattress End		
5	P09826	Large, Male, (requires 1 each)
6	P02800	Small, Male, white plastic (8410 model requires 4 each)
7	P09892	Air Line Set

Trouble Shooting Guide

Issue	Possible Cause	Solution
In non-powered mode, air system appears to be underinflated, overinflated, or stuck in a lateral rotation/ alternating pressure inflation pattern (two air cylinders inflated, two cylinders deflated).	Powered control unit was disconnected from mattress in mid-cycle, without first resetting the system via the "disconnect" function.	Attach power control unit and perform resetting function to return system to ideal, non-powered inflation level. See page 17.
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.

Issue	Possible Cause	Solution
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.
	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 16.	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 while control unit is running	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.
		Reset control unit by turning off, then back on. Call for service if problem not resolved.

Issue	Possible Cause	Solution
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 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.
	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 CUSTOM CARE CONVERTIBLE LAL 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

Authorized Seller/Installer

PressureGuard® Custom Care® Convertible LAL

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For service or questions about this product, please contact:

AUTHORIZED SELLER/INSTALLER: _____

PHONE NUMBER: _____

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