

OWNER'S MANUAL

PressureGuard[®] Custom Care[®] CONVERTIBLE



SPANAmerica
Innovative Solutions.

Span-America Medical Systems, Inc.























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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.		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
	European Conformity Marking	IEC 60601-1	Electrical Safety
	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® Custom Care® Convertible Non-powered therapy surface with add-on powered control unit

Introduction

The Custom Care® Convertible 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.

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 alternating pressure and rotation therapy modes. The system also includes an auto firm mode to provide a firm support surface to use while providing patient care and to assist in patient transfer. A disconnect feature resets the inflation level back to an ideal therapeutic setting for use of the support surface without the control unit.

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

INDICATIONS FOR USE: Custom Care® Convertible models are intended for the prevention and treatment of pressure injuries. Powered modes are intended for active wound treatment, and may be indicated for use as a preventive tool against further complications associated with critically ill patients or immobility.



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



WARNING - 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. Return the unit to 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: This product contains/may contain chemicals known to the state of California to cause cancer and/or birth defects or other reproductive harm.

CONSTRUCTION AND DESIGN FEATURES



1. Stretch cover with *LifeSpan*® fortified healthcare fabric and patented Shear Transfer Zones®



5. Control Unit



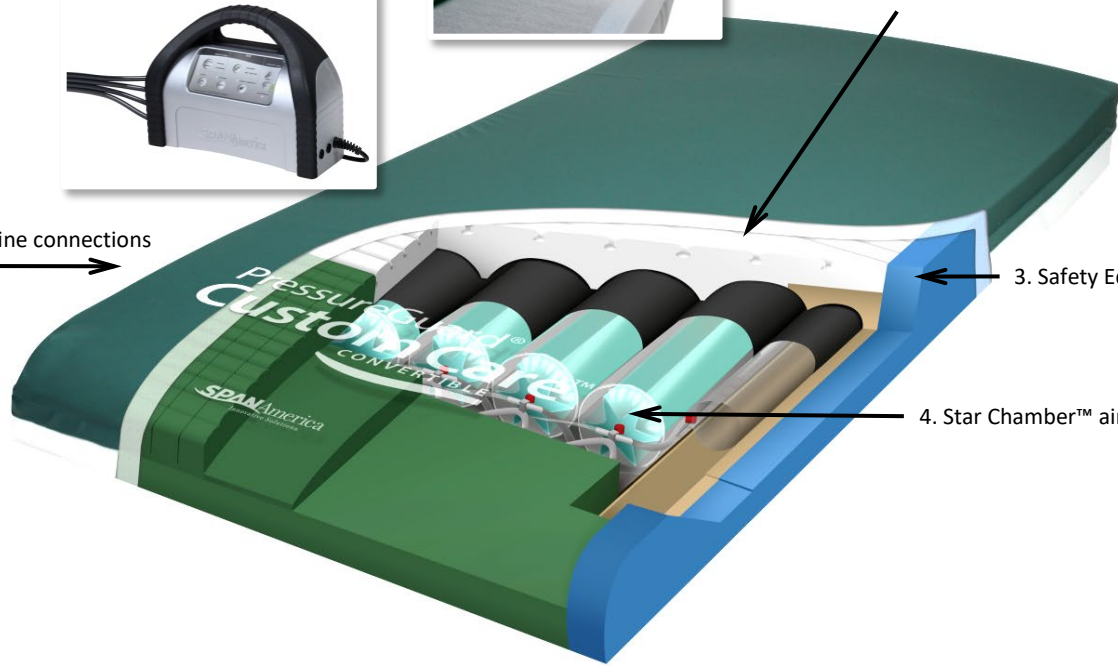
2. Foam shell with Geo-Matt® topper

Airline connections



3. Safety Edge™ bolster system

4. Star Chamber™ air cylinder system



CONSTRUCTION AND DESIGN FEATURES

Illustration Descriptions

<p>1. <i>LifeSpan</i>[®] stretch cover with Shear Transfer Zones[®]</p>	<p>Standard cover features a bi-directional stretch fabric designed to allow full integration of the user into the surface. Top is made from proprietary <i>LifeSpan</i>[®] polycarbonate-fortified healthcare fabric, which provides unsurpassed resistance to the damaging effects of diluted bleach and other aggressive cleaners and disinfectants. It wipes clean easily with standard, hospital-grade cleaners. It has an ultra-low moisture vapor transmission rate (MVTR) and is fully radiolucent.</p> <p>Patented “Shear Transfer Zones[®]” incorporated beneath top fabric creates shear-minimizing bands beneath heels, sacrum and scapula. Zones help prevent these bony prominences from digging into the surface, while protecting against the damaging effects of micro shear, macro shear, and rotational (pivot-induced) shear. Design also helps “glide” the user back to their original position following HOB elevation. Exclusive split bottom design helps reduce sliding of mattress while also reducing the “gatching noise” typical of non-slip fabrics.</p>
<p>2. Foam shell with Geo-Matt topper</p>	<p>The clinically proven Geo-Matt[®] segmented design incorporated into the top surface of the mattress is a high-density, medical grade foam. The unique geometric design consists of over 800 individual cells, each of which acts individually to redistribute pressure, to reduce heat and moisture buildup on the skin, and to reduce shear to underlying tissues. This foam topper is approximately 2" in height and tapered at the foot end of the mattress. The unique Heel Slope[®] feature helps further reduce interface pressures on vulnerable heels.</p>
<p>3. Safety Edge[™] bolster system</p>	<p>The supportive Safety Edge[™] consists of engineered inner and outer foam bolsters for added patient stability in sitting and lying down.</p>
<p>4. Star Chamber[™] air cylinder system</p>	<p>The heart of the system consists of four “Star Chamber[™]” (patent pending) air cylinders and two pairs of elasticized reservoirs arranged longitudinally (head-to-foot) and constructed from RF- (radio-frequency) welded urethane. The system is designed to provide and maintain low interface pressures throughout the mattress in the non-powered mode. In the powered mode, it provides active therapy in the alternating pressure or lateral rotation modes via inflation and deflation in a fixed 15-minute cycle. In lateral rotation, the user typically achieves a rotation arc of approximately 40°—roughly 20° in each direction. 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, powered control unit can be used to reset system at any time.</p>
<p>5. Control Unit</p>	<p>Model 6500 PressureGuard[®] Custom Care[®] 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 6500CE-G (UK) or 6500CE-I (Australia) or 6500CE-C (Ger/EU)</p>

DIRECTIONS FOR MATTRESS SET-UP

Flat deck frames

1. Confirm that the bed frame is appropriate for use with the mattress, and that the length and width of the mattress are appropriate for the frame. If frame is Hill-Rom CareAssist® model¹, ensure that the Custom Care® Convertible is the appropriate model (CJ80CA29 or CJ84CA29) for the frame. Place directly on a healthcare bedframe only, never on top of another mattress.



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.

2. The mattress should be placed so that the green stretch fabric top surface is facing up toward the user. The white screenprinting on the cover should be located at the foot end of the bed. The screenprinting should read correctly when being viewed by a person facing the frame from the foot end of the bed. The gray vinyl bottom of the cover should face down onto the bed frame. The foot end is clearly marked on the mattress cover.
3. The surface is now ready for use in the non-powered mode (that is, without the powered control unit attached) by users who are within the 500 lbs. (226.8 kg) weight limit for the product.
4. The surface is designed to be used with appropriate linens in place. See page 13.

Connecting control unit:



5. Expose the four air lines that extend from the mattress by unsnapping the flap nearest to the foot end of the mattress.

6. Then, tuck the flap behind the air lines and snap shut, which will leave the air lines on the outside of the flap and available for connection to the control unit.



7. Bring the four air lines from the pump around to the four air lines extending from the mattress. Ensure that the airlines are not kinked or twisted.



CAUTION: Never thread airline through mechanical parts of the bed or bed rails where normal bed movement may damage the airlines or the air control unit itself. Check to be sure the motion of the bed does not interfere with the airlines.



8. Click each of the four male connectors into place in its corresponding, color-coded female fitting.

Proceed to “Directions for Powered Use” page 7.

1.Hill-Rom is a mark, and CareAssist® is a registered mark, of Hill-Rom® Services, Inc.

DIRECTIONS FOR POWERED USE

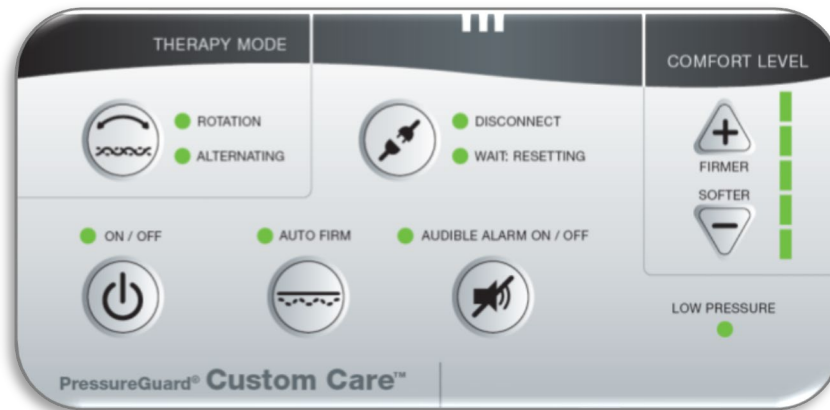
All models



WARNING: 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. 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 built-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.



CONTROL UNIT FUNCTIONS:



ON/OFF: Ensure On/Off switch is “Off”. Plug power cord into wall outlet. On/Off indicator light will illuminate in amber, indicating that the unit is drawing current but not yet powered up.

Press On/Off switch to “ON”. Indicator light will change to green, along with additional lights on control panel, indicating that the unit is powered up. Unit will resume the settings it was in when last powered down.



COMFORT LEVEL: Initially set the “Comfort Level” on the control panel to softest selection. Adjust for user comfort as desired, using “Softer” and “Firmer” buttons.

NOTE: In powered mode, elevating the head of bed may require adjusting

comfort level to ensure appropriate support, especially if elevated beyond 30° (see “Head of Bed Elevation”, below). With HOB elevated in this way, caregivers may find the following body mass index (BMI) setting suggestions helpful in determining an ideal comfort setting: *Suggestions for comfort setting with HOB elevated*: BMI 12-20: setting 1; BMI 21-35: setting 2, BMI 36-50: setting 3; BMI 51-70: setting 4; BMI 71-100: setting 5. A simple hand check can be used to verify adequate seat support.



THERAPY MODE: Toggle between “Alternating” or “Rotation” mode as desired.

The use of ROTATION should be viewed only as an adjunct to manual repositioning of the patient for whom this repositioning is possible, never as a replacement for it. “Frequent repositioning of the patient has long been recommended as a means for preventing pressure ulcers.”¹ “All patients at risk for pressure ulcers continue to require regular manual repositioning (turning), even those who are benefitting from the use of a specialty lateral rotation surface”¹ Routine manual repositioning should be used to provide opportunities for total offloading of pressure from the sacrum, assessing the skin and maintaining proper alignment and position on the support surface.

Note: when using wedges or pillows for manual repositioning (turning), discontinue ROTATION and activate either FLOAT or ALTERNATING.

¹Krapfl, LA, Gray, M; Does Regular Repositioning Prevent Pressure Ulcers? JWOCN. 2008; 35(6):571-57



LOW PRESSURE: If “Low Pressure” indicator light comes on after initial set-up or when moving mattress or control unit, first check that all airlines are properly connected and that they are not kinked. If light is still on after 30 minutes, call for service.



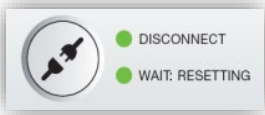
AUTO FIRM: Select the Auto Firm mode to stop the alternating or rotation movement of the mattress. The AUTO FIRM indicator light will illuminate and the mattress will achieve uniform support. The mattress will remain in the Auto Firm mode for 20 minutes.

During this time, all five Comfort Level indicator lights will be illuminated in amber, and the Comfort Level, Therapy Mode, Disconnect, and On/Off selectors will be inactive. The Audible alarm is not affected.

After 20 minutes, the system will automatically resume the comfort and therapy mode settings that had been previously selected. Pressing the Auto Firm selector at any time prior to the elapsing of 20 minutes will immediately return the system to the comfort and therapy mode settings it was in prior to the pressing of AutoFirm.



AUDIBLE ALARM ON/OFF: When the “Alarm On” light is on, alarm will sound if “Low Pressure” indicator light comes on. Press Alarm button to silence.



DISCONNECT / WAIT: RESETTING: The Disconnect function resets the system to the ideal inflation level required for use of the mattress in the non-powered 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, Audible alarm, and Auto Firm will be inactive. The On/Off selector will be also be inactive, but its green indicator light will remain active.

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 the green “Disconnect” light. The green On/Off light will change to amber, indicating that the unit is no longer powered up but is still plugged in and drawing a current. The control unit can now be disconnected from the mattress.



WARNING: Do not remove the control unit before it has properly re-set 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 negative impact on pressure injury 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 “Autofirm” 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.

Powered use: Other considerations

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.

See Additional Information, page 16.

POWER LOSS: In the case of a power outage, the system will equalize and maintain the air within the support cylinders. When power is restored, control unit will resume the settings it was in when power was interrupted.

PATIENT TRANSPORT: While transporting a patient on the mattress when the powered mode has been in use, it is recommended to perform the disconnect function prior to powering down the control unit. This will ensure that the system provides level, even support during transport.

HEAD-OF-BED (H.O.B.) ELEVATION: All support surfaces using air as a support medium are designed for distributing pressures over the body in a flat, horizontal position. According to the guidelines of the National Pressure Injury Advisory Panel (NPIAP), caregivers should limit the head-of-bed elevation to 30° or less for an individual on bed rest, unless contraindicated by medical condition. Caregivers should encourage individuals to sleep in a 30 to 40° side-lying position or flat in bed if not contraindicated and avoid prolonged HOB elevation that can result in a slouched position that places pressure and shear on the sacrum and coccyx. Although the Custom Care® Convertible will maintain its support and therapeutic capabilities up to and including 70° HOB, in accordance with NPIAP guidelines any support surface should be used with the head of the bed elevated as little as possible, and for limited periods at a time. If HOB is elevated at 30° or beyond, a regular pattern of pressure relief in the form of a return to non-elevated position is warranted. Adjustment of comfort level setting may also be required. See “Comfort Setting”, above.



WARNING: To minimize the possibility of patient falls, lateral rotation mode should not be used with head of bed elevated beyond 30°.

NOTE: In powered mode, elevating the head of bed may require adjusting comfort level to ensure appropriate support, especially if elevated beyond 30°. Caregivers may find the following body mass index (BMI) recommendations helpful in determining an ideal comfort setting: BMI 12-20: setting 1; BMI 21-35: setting 2, BMI 36-50: setting 3; BMI 51-70: setting 4; BMI 71-100: setting 5.

TROUBLESHOOTING/PATIENT COMPLAINTS: Occasionally a patient may complain of feeling as if he/she is “sinking into a hole”.

- 1) Sometimes this occurs 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. Reassure the patient 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 become acclimated to the changing pressures.

GENERAL DIRECTIONS

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.



CAUTION: Be careful not to puncture the mattress with needles or sharp instruments. This may result in loss of integrity of the cover or internal air system. Regularly inspect the mattress cover for cuts, rips, cracks or tears. Do not use the mattress if the cover is damaged.

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

CPR: The Standards for Life Support recommended by the American Heart Association suggests a hard level surface for performing CPR. This means moving the person to the floor if possible. If that is not possible, do the following: For performing CPR:

1. Press "Auto Firm" Button
2. Place a crash board beneath the patient.
3. Follow CPR procedures.

STORAGE AND TRANSPORTATION: Store the mattresses in a clean, dry place. Once the mattress is removed from the box, store in a flat position if possible. Protect from damage. Avoid temperature extremes (below freezing or above 120° F). 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 and transport controllers in a clean, dry place, protected from accidental damage or falls. Avoid temperature extremes (below freezing or above 120°F); suggested storage and transportation temperature 15~50°C, humidity 40%~80%. Do not stack other equipment on top of the controller. For transportation, secure to prevent damage or falls. For shipment, use box and packaging as provided by the manufacturer.

ENVIRONMENTAL CONDITIONS FOR USE:

- Indoor Use
- Altitude up to 2000 meters
- Temperature 5 °C to 35° C
- Maximum relative humidity 80% for temperatures up to 31° C, decreasing linearly by 50 per cent relative humidity at 40° C
- Mains Supply Voltage Fluctuation up to 10 +/-% of the nominal voltage
- Overvoltage Category II
- Pollution Degree 2

SERVICE: 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 am – 5 pm EST M-F.

WARRANTY: The Custom Care® is unconditionally guaranteed against failure due to manufacturing defects under normal use for 24 months for the controller and 5 years for the mattress. See page 22.

USE IN WOUND CARE: Use of PressureGuard® Custom Care® models 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 health care professional.

CLEANING: For the mattress, only the cover requires cleaning and maintenance. Disassembly of the support surface for maintenance of internal components is not recommended. **Clean and disinfect mattress covers** following contamination with bodily fluids and between patients. The cover 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.**

Reference the Cleaning Recommendations instruction sheet for additional cleaning information.

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.

Contamination with blood on the fabric can be disinfected with a 1:10 dilution of household bleach (5.25% sodium hypochlorite) as recommended by the CDC. The use of bleach at improper dilutions may result in fabric discoloration and fluid pass-through. Rinse and allow to air dry.

Where surveillance and epidemiology indicate ongoing transmission of *C. difficile*, an EPA registered hypochlorite-based disinfectant is recommended. Follow the manufacturer's instructions for use concentrations, contact times and rinsing. Generic sources of hypochlorite (e.g. household chlorine bleach) may also be used. Prepare the disinfection solution fresh daily at a 1:10 dilution. Improper dilutions may result in ineffectiveness and higher than recommended concentrations will damage the fabric.

Note: alcohol-based disinfectants are not effective against *C. difficile* and should not be used to disinfect environmental services. For further information relative to this organism and infection control in the healthcare setting, please refer to www.cdc.gov/ncidod/hip.

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 covers and zipper area for signs of damage, puncture, or wear that could result in fluid pass-through. If the cover is stained, soiled, or torn, inspect the internal components for signs of contamination. If contamination is evident, quarantine the mattress and remove from service following infection control procedures.

If required, the air control unit can be cleaned.



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.

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 the WEEE.



This product may contain substances that could be harmful to the environment if disposed of in locations (landfills) that are not appropriate according to legislation. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.

AIR FILTER PREVENTIVE MAINTENANCE: The air filter for the Control Unit should be checked routinely for signs of dirt or contamination. The frequency for cleaning depends on the air quality. The air filter is accessible from the backside of the Control Unit. As the filter is white, the need to clean is obvious. Simply turn the controller off and remove the plastic cover, remove the filter, and hand wash using warm water and mild detergent. Rinse thoroughly and allow to air dry. Replace the filter and the plastic cover.

ROUTINE INSPECTION OF POWER CORDS AND SAFETY TIPS TO PREVENT FIRES



1. Assure 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 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 assure 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 assure 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 as 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 assure 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 for replacement.

Mattress

Inspect the covers and zipper area for signs of damage, puncture, or wear that could result in fluid pass-through. If the cover is stained, soiled, or torn, inspect the internal components for signs of contamination. If contamination 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 (24) of this manual to monitor and document regular inspection and maintenance of your PressureGuard Custom Care® Surfaces.

EMC


Electric devices may interact due to electro-magnetic radiation. We recommend a safety distance of at least one-meter, especially for sensitive equipment. Upon request, we will provide you with a table for more detailed information.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The 6500 is intended for use in the electromagnetic environment specified below. The customer or the user of the 6500 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 6500 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. The 6500 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.
RF emissions CISPR 11	Class B	
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 6500 is intended for use in the electromagnetic environment specified below. The customer or the user of the 6500 should assure 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power	±2 kV for power	Mains power quality should be that of a typical commercial or hospital

transient/burst IEC 61000-4-4	supply lines ±1 kV for input/output lines	supply lines ±1 kV for input/output lines	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.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 6500] requires continued operation during power mains interruptions, it is recommended that the 6500 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 6500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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 6500 is used exceeds the applicable RF compliance level above, the 6500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 6500.
- 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 6500	
The 6500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 6500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 6500 as recommended below, according to the maximum output power of the communications equipment.	
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m

W	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.

SPECIFICATIONS

COVER:	Bacteriostatic, flame resistant, fluid-proof, tear resistant
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 117-013."
AIR CYLINDERS:	Urethane (main cylinders), and urethane-coated nylon (reservoirs)
CONTROL UNIT	Model No.: 6500 Dimensions: 14.5 x 10 x 5 inches (37 x 25 x 13 cm) Weight: 9.5 lbs (4.2 kg) 6500 Rated Spec: AC 110-120V / 60Hz / 0.2A MAX Fuse Rating: 1A 250VAC Comfort level pressure range:0.66~1.06 +/- 0.05 psi Auto firm function pressure range:1.35 +/- 0.05psi Classification: Type BF/ Class I Not AP or APG equipment
STANDARD SURFACE SIZES:	80"L X 36"W 84"L X 36"W 75"L X 36"W
MATTRESS HEIGHT:	7" for all models
WEIGHT LIMIT	500 lbs. non-powered mode 350 lbs. powered modes
CYCLE TIME:	15 minutes
PLACEMENT:	Models available for placement on typical hospital/medical facility flat or recessed deck bed frames.
WARRANTY:	Control unit: 24 months, not pro-rated, against manufacturing defects. Mattress: 5 years, not pro-rated, against manufacturing defects.
FLAMMABILITY:	All models comply with 2000 NFPA 101 (Life Safety Code), Cal. TB # 129 and 16 CFR 1632 and 1633.

ORDERING INFORMATION

Product Name	Catalog Number	Description	Re-order #, Cover only	Re-order #, air line set	Re-order #, inflation system only
PressureGuard® Custom Care® Convertible mattress	CJ753629	75"L X 36"W X 7"H flat deck	C1-CJ7536	P09862	P09608
	CJ803629	80"L X 36"W X 7"H flat deck	C1-CJ8036		P09605
	CJ843629	84"L X 36"W X 7"H flat deck	C1-CJ8436		P09605
	CJ80CA29	80"L for CareAssist®	C1-CJCA80		
	CJ84CA29	84"L for CareAssist®	C1-CJCA84		
	CJ85V29	For recessed deck frames (includes mattress component # MCJ8JV , and base insert component #38910)	C1-CJ85V	P09810	P09410
Custom Care® Convertible Control Unit ¹	6500				

Hill-Rom is a mark, and CareAssist® is a registered mark, of Hill-Rom® Services, Inc.

- 1- Custom Care® Convertible control unit model 6500 can also be connected to Custom Care® Convertible LAL surfaces. Unit will not supply air to the air delivery cover, but will provide alternating pressure and lateral rotation when control unit 8400 or 8400V is not available.

P10068	Power Cord/US only
P10493	Feet
P09769	White Male On Mattress
P09770	Black Male On Mattress
P00919	White Female On Mattress
P02811	Black Female On Mattress
74586	Set of pump airlines with instructions
P10503	Hooks
P10504	Air filter
P10610	Air filter cover

TROUBLESHOOTING GUIDE

Technical Service: (800) 888-6752

Problem	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 powered control unit and perform resetting function to return system to ideal, non-powered inflation level. See page 10.
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 rotating /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.	Rotating can be difficult to observe in patients with severe contractures. Observe someone without contractures lying on the bed for 30 minutes (approximately 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 . If HOB must be elevated, alternating pressure is the more appropriate mode.
	Defective control unit	Call for Service.
	Patient exceeds weight limit.	Call Span-America for assistance with product selection.
Mattress not inflating or patient reports a feeling of “sinking” into surface.	Control unit is not turned on.	Turn control unit on.
	Airlines not connected.	Ensure secure connection of airlines at control unit and mattress.
	Airlines 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 control unit (mattress fills without patient, sinks with patient weight).	Call for service.
Low pressure indicator illuminated.	Airlines not connected.	Disconnect and reconnect airlines to verify they have all locked into place.
	Airlines or quick disconnect connectors are damaged.	Call for replacement.
	Defective control unit.	Call for service.
	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.
Interference produced to electronic equipment/devices in surrounding area.	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. <ul style="list-style-type: none"> 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. d) Consult the field service technician or manufacturer of the affected device.

PRESSUREGUARD®
**Custom Care® and
Custom Care® Convertible Series**



WARRANTY

Support Surface (excluding control units): 5 Years

Span-America Medical Systems, Inc. (the "Company"), warrants to the original purchaser that the **PressureGuard® Custom Care®, Custom Care® Convertible, or Custom Care® Convertible LAL** therapeutic support surface will be free from defects in materials and workmanship for a period of 5 years from the date of purchase. During the warranty period, the Company will repair, or replace, with a new product which is identical or reasonably equivalent to the warranted product shown to be defective in materials or workmanship. During the full 5 years of the warranty period, such repair or replacement will be made without charge to the original purchaser.

All claims must be submitted in writing and must be accompanied by the Company's original sewn-in label and by the original invoice for the product or a copy of the original invoice. All transportation and handling costs incurred in returning the system or any component at any time throughout the warranty period will be paid by the Company when accompanied by a return authorization number.

Control Units: 2 Years

Span-America Medical Systems, Inc. (the "Company"), warrants to the original purchaser that the **PressureGuard® Custom Care® Convertible control unit, or Custom Care® Convertible LAL control unit** will be free from defects in materials and workmanship for a period of 2 years from the date of purchase. During the warranty period applicable to the control unit for either **PressureGuard® Custom Care® Convertible, or Custom Care® Convertible LAL**, the Company will repair, or replace, with a new product which is identical or reasonably equivalent to the warranted product shown to be defective in materials or workmanship. During the full 2 years of the warranty period, such repair or replacement will be made without charge to the original purchaser.

All claims must be submitted in writing and must be accompanied by the product's serial number and by the original invoice for the product or a copy of the original invoice. All transportation and handling costs incurred in returning the unit or any component at any time throughout the warranty period will be paid by the Company when accompanied by a return authorization number.

This warranty specifically excludes liability for defects caused by improper use of the system and use of the system without the cover or otherwise contrary to the approved instructions provided by the Company.

Other than the warranties set out above, the Company makes no other warranties of any kind, expressed or implied, as to merchantability, fitness for any particular purpose, or any other matter with respect to the goods.

In no event, including, but not limited to, cases of claims of negligence or strict liability, shall the Company be liable for indirect, incidental, special or consequential damages, nor shall the Company, in any event, be liable for damages in excess of the purchase price of the products claimed to be defective.

With regard to questions relating to the **WARRANTY**, contact:
Span-America Medical Systems, Inc., Post Office Box 5231, Greenville, South Carolina 29606

PRESSUREGUARD® CUSTOM CARE® PREVENTIVE MAINTENANCE LOG

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