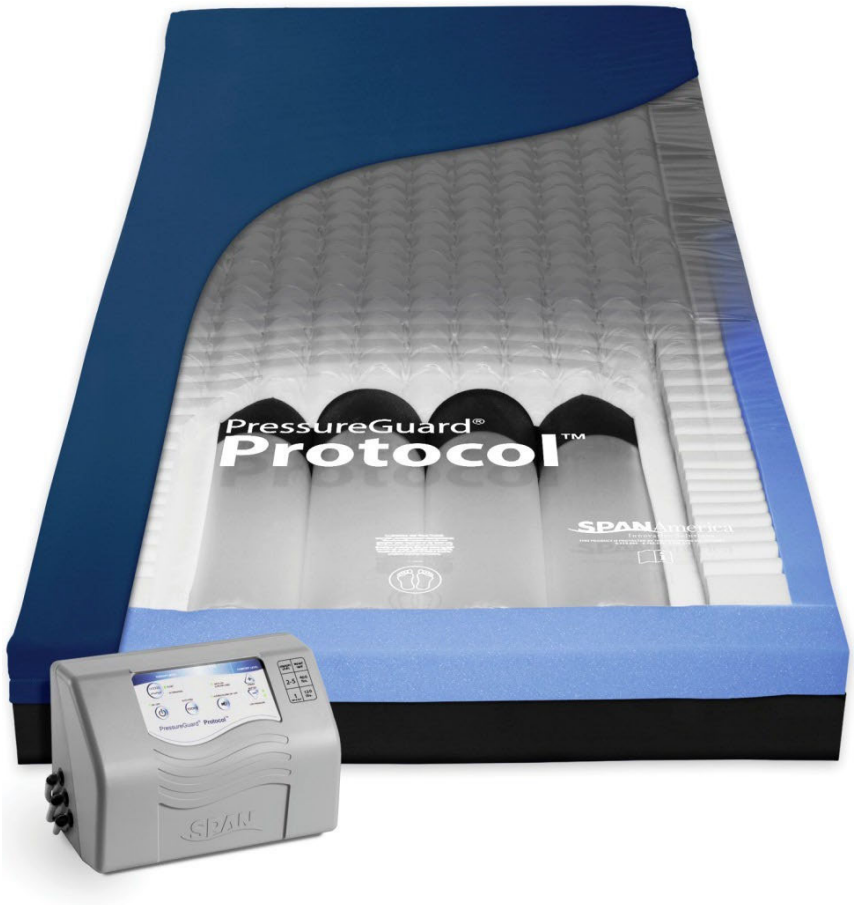
OWNER'S MANUAL

PressureGuard®

PROTOCOL™



SPAN America
Innovative Solutions.

Span America Medical Systems, Inc.

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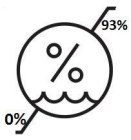
Document Symbols			
	WARNING or CAUTION		Direct Current
	WARNING: Situations or actions that may have an effect on patient or user safety. Ignoring a warning could cause patient or user injury.	IP21	Protection against the ingress of fingers or similar objects and dripping water
	CAUTION: Points out special 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® Protocol™

OVERVIEW: The system consists of a two-part microclimate management (often called "low air loss") system of cover and coverlet, a foam shell, air cylinder inflation system, and a control-unit. The foam shell has a high-density foam topper, a patented Safety Edge™ contoured foam bolster on the perimeter of the mattress for added patient stability and positioning, and graduated Heel Slope™ feature designed to further reduce pressures on vulnerable heels. The air-cylinder inflation system is housed within the foam shell, and consists of air-cylinders oriented lengthwise within the mattress. The control unit connects to the mattress at the patient's foot-end.

MODES OF OPERATION:. The Protocol provides the choice of two powered therapy modes of operation, FLOAT or ALTERNATING.

WARNING – This product is not intended for use as a non-powered support surface. Except during emergency power interruption (see page 13) and during occasional patient transport (see page 14), patients should be on the surface only when control unit is connected, plugged in to wall outlet, and powered ON.

INDICATIONS FOR USE: The PressureGuard Protocol provides powered prevention and treatment of pressure injuries through immersion and envelopment. Therapies provided include alternating pressure, powered flotation, and microclimate management (management of excess moisture and heat). The system may be indicated for use as a preventative tool against further complications associated with critically ill patients or immobility. PressureGuard Protocol should always be used as part of a comprehensive medically supervised care plan that includes appropriate repositioning, nutrition, and any necessary topical therapies or incontinence management.

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

Contraindication: The PressureGuard Protocol™ 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. Always unplug this unit immediately after using.
2. Do not operate near water.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.
6. Use this unit only for its intended use as described in the operating instructions.
7. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the unit to Span-America Medical Systems, Inc. for examination and repair.
8. Keep the cord away from heated surfaces.
9. Never drop or insert any object into any opening or hose.
10. Do not use outdoors.

CONSTRUCTION AND DESIGN FEATURES

Span-America's proprietary use of non-collapsible "Air Diffusion Matrix" fabric in both the inner air delivery cover and the outer removable coverlet creates an open pathway beneath the user, helping eliminate excess moisture from the microclimate. Because neither the inner air delivery cover nor the outer removable coverlet allow fluids to penetrate the surface, 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 Protocol 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 7.

Illustration of individual components of the PressureGuard Protocol:

1. Outer Removable Coverlet
2. Inner Air Delivery Cover
3. Air Cylinders
4. Foam Shell with Geo-Matt® segmented topper and Safety-Edge™ bolsters system.

5. Control Unit

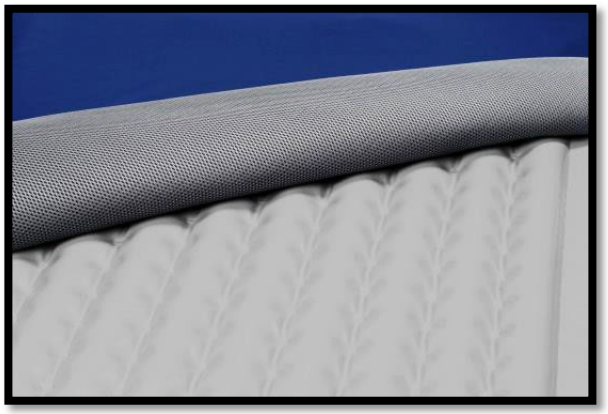
ILLUSTRATION DESCRIPTIONS

1. Outer Removable Coverlet:	The blue-colored coverlet is fluid resistant, cleanable and flame resistant. It can be replaced if damaged or worn. Its smooth outer fabric is highly vapor permeable and its crush-resistant Air Diffusion Matrix fabric provides a pathway for efficient movement of moisture vapor away from the patient. Coverlet can be routinely wiped clean and disinfected in place, or can be removed and machine laundered according to directions in this manual.
2. Inner Air Delivery Cover:	The gray, multi-layered inner cover serves as a barrier, protecting the inside of the mattress from both fluids and vapors, while supplying air to the microenvironment between the cover and coverlet. Unlike the blue removable coverlet, it is intended to remain on the mattress at all times. It can be cleaned and disinfected in place using standard hospital, medical grade products. The air delivery cover consists of two layers of urethane fabric with a welded pattern. Sandwiched between these layers is a layer of crush-resistant Air Diffusion Matrix fabric. A series of air holes designed to deliver air flow to the top of the mattress to flow underneath the patient in the removal of moisture from the patient's skin.
3. Air Cylinders:	The inflation system consists of air cylinders that run lengthwise underneath the body. Unlike typical roll-up systems, the cylinder inflation system does not lose air from the inflation system for "low air loss", and can be programmed to perform either Flotation or Alternating Pressure. The cycles and inflation levels are designed to provide and maintain low interface pressures throughout the mattress, and to redistribute peak interface pressures during both therapy modes.
4. Foam Shell:	The segmented Geo-Matt® style foam topper is cut from a high density, medical grade foam. The unique geometric design consists of over 800 individual cells, each of which acts individually to customize patient comfort, support, and pressure reduction and redistribution. This foam topper includes the unique Heel Slope™ feature, designed to further reduce pressure for the sensitive heel area. The proprietary Safety Edge™ consists of contoured foam bolsters on the perimeter of the mattress for added patient stability and positioning.
5. Control Unit:	The quiet, energy efficient control unit houses two separate air compressors: a high-volume compressor provides air for the microclimate management function through the cover/coverlet, while a low-volume compressor provides air to the air cylinder inflation system.

THE SCIENCE BEHIND THE PRESSUREGUARD PROTOCOL MICROCLIMATE MANAGEMENT DESIGN

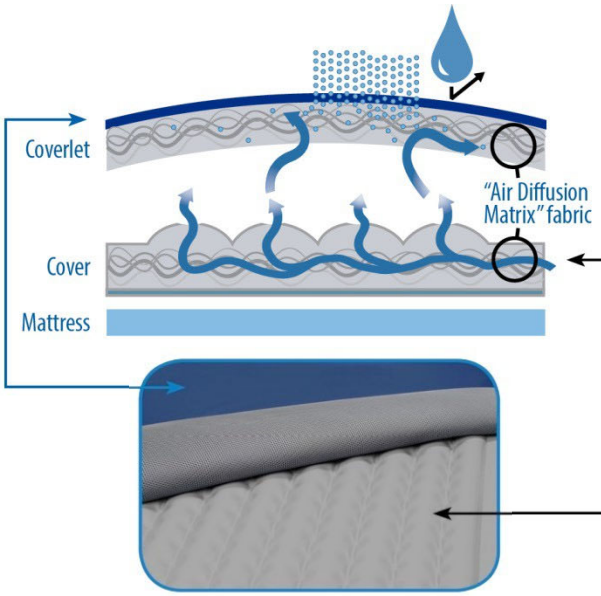
Protocol's proprietary "Air Diffusion Matrix" design maximizes removal of excess moisture (i.e., perspiration) from the user's skin. Moisture passes in vapor form down through the cover, where a continuous air current takes it away before it can re-form as liquid.

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 coverlet

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



Inner air delivery cover

- 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

DIRECTIONS FOR SET-UP

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. 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 blue coverlet is facing up toward the patient. The air line should be located at the foot end of the bed, to the patient's right hand side when laying on the mattress. The white screenprinting on the cover should be located at the foot end of the bed, and it should read correctly when being viewed by a person facing the frame from the foot end of the bed. The black 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 designed to be used with appropriate linens in place. See page 14.

Connecting control unit:

4. Hang the air-control unit on the foot-end of the bed. Avoid blocking vent holes for filter on the back of the control unit housing.
5. Plug the power cable into the connector module at lower left on the back side of the air-control unit. Plug the opposite end into the wall outlet.

Always plug the power cable securely into the wall outlet. Make sure 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.

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 connectors that are approved by the facility engineering department. Multiple outlet strips should be mounted on a fixed object to reduce the risk of liquid spills and physical damage. In addition, if multiple-receptacle outlet boxes are used, they also should be protected from the risk of liquid spills and physical damage. All extension cords and multiple outlet strips should be tagged and inspected routinely.

Do not cover the power cord with a rug or carpet. Rugs or carpets can prevent normal air flow, which can lead to greater heat 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.

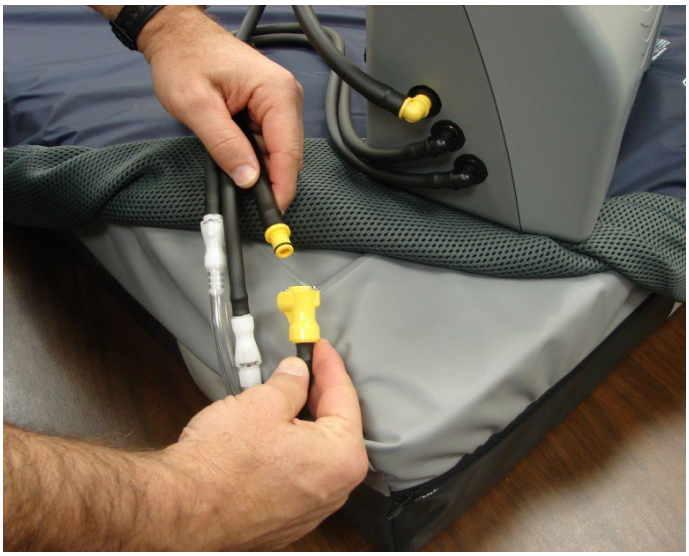
Never thread power cords through mechanical parts of the bed or bed rails where normal bed movement may damage or cut the cord.

6. Ensure that the three air lines that extend from the mattress are protruding through the opening in the lower right corner of the blue coverlet. If necessary, the zipper at the underside of the coverlet can be unfastened in order to retrieve air lines. Once the air lines are protruding through the coverlet opening and the zipper is refastened, the air lines from the mattress can be connected to the air lines that extend from the control unit.

7. Bring the three air lines from the control around to the meet air lines extending from the mattress. Ensure that the airlines are not kinked or twisted.

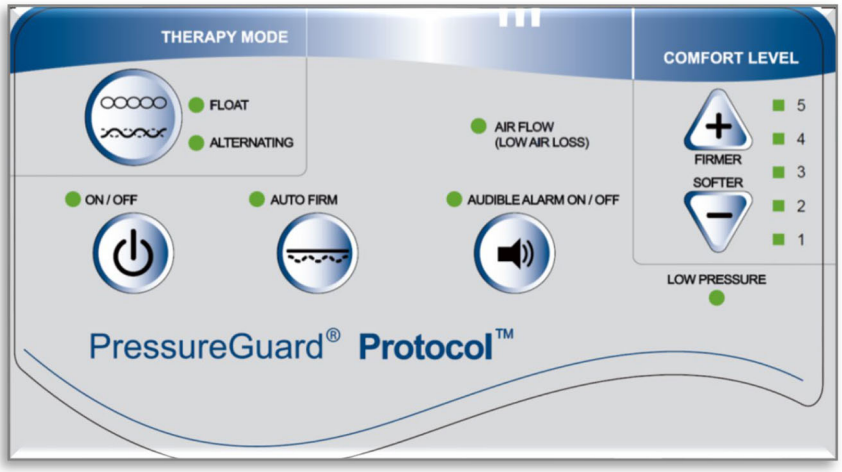
CAUTION: Never thread airline through mechanical parts of the bed or bed rails where normal bed movement may damage the airlines or the air control unit itself. Check to be sure the routing of the air lines or the motion of the bed does not impede air flow by crimping the air lines.

8. Identify correct male/female pairs, which match by both color and size. Press corresponding fittings together until hearing an audible click, which confirms that the connection is complete.



The surface is now ready for use by patients who are within the 400 lbs (181.4 kg) weight limit for the product.

Attempting to force a connection between fittings that are not properly mated by size and color will cause damage to the connectors and will not allow system to function properly.



CONTROL UNIT FUNCTIONS

ON/OFF: Plug power cord into wall outlet. 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.

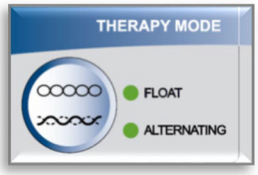
COMFORT LEVEL: For best possible pressure management, maximize immersion and envelopment by initially setting the "COMFORT LEVEL" on the control panel to the softest selection appropriate for the patient, in accordance with the stated weight limits:

COMFORT LEVEL	WEIGHT LIMIT
2-5	400 lbs.
1 "Max. Immerse"	120 lbs.

- **For patients up to 120 lbs,** begin with Level 1 ("Max. Immerse").
- **For patients weighing more than 120 lbs (up to 400 lbs.)** begin with Level 2.

Adjust for user comfort as desired, using "SOFTER" and "FIRMER" buttons.

NOTE: Elevating the head of bed may require adjusting COMFORT LEVEL to ensure appropriate support, especially if elevated beyond 30 degrees (see "Head of Bed Elevation", below).



THERAPY MODE: Toggle between "ALTERNATING" and "FLOAT" mode as desired.

LOW PRESSURE: The "LOW PRESSURE" indicator light indicates that the air system is not reaching or maintaining its appropriate minimum setting. If light comes on, first check that all airlines are properly and securely connected and that they are not kinked. If light remains on 30 minutes after making these adjustments, call for service.

NOTE: *To facilitate installation, system includes a built-in delay (up to 5 minutes in float mode, up to 10 minutes in alternating pressure] before alarm will sound after a low pressure situation occurs.*

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 egress and exit, . 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 in amber, and the THERAPY MODE indicator will turn off. The COMFORT LEVEL, THERAPY MODE and ON/OFF selectors will be inactive. The Audible alarm is not affected.

After 30 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 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-active all selectors including ON/OFF.

AUDIBLE ALARM ON/OFF: When this light is on, alarm will sound if "LOW PRESSURE" indicator light comes on. Press AUDIBLE ALARM ON/OFF button to silence.

AIR FLOW (LOW AIR LOSS): This function operates continuously whenever the control unit is powered on, regardless of therapy mode selected. Indicator light provides visual confirmation that air is being provided to air delivery cover.

GENERAL DIRECTIONS

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 Protocol 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. If HOB is elevated at 30 degrees 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.

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

CPR (Cardiopulmonary Resuscitation):. The standard for life support recommended by the American Heart Association recommends a hard level surface such as a crash board, or moving the person to the floor. If that is not possible, do the following for performing CPR:

1.) Select AUTO FIRM
2.) Place a crash board underneath the patient
3.) Follow CPR procedures.

POWER INTERUPTION: As a safety feature, in the event of a power interruption the system will maintain at least a minimum level of support for up to 8 hours— depending on factors including mode, comfort setting, and patient weight —by automatically locking in whatever air is present in the system at the time of power interruption.

However, to maximize patient support for power interruptions of an extended or potentially extended duration, the following is recommended:

- Disconnect the two smaller, white paired fittings that connect the mattress airlines to the control unit air lines.
- Once disconnected from the control unit air lines, connect the white male and female fittings together. This will cross-connect all four mattress air cylinders, equalizing them and sealing the entire system closed.
- If head of bed is elevated, it should be returned to flat position if possible.

When power is restored, control unit will resume the settings it was in when power was interrupted. Mattress air lines that have been cross connected should be disconnected from each other and re-connected to their corresponding control unit air lines. Allow approximately 5 minutes after power is restored to achieve normal therapy mode functions.

PATIENT TRANSPORT: The patient can remain on the mattress while the mattress and bed frame are being moved, with proper safety precautions taken. Prior to unplugging the power connector from the wall receptacle, mattress should be left in FLOAT Mode for a minimum of two minutes.

The inflation of the mattress will be maintained and the air will equalize in the air cylinders.

CAUTION: DO NOT MOVE PATIENT ON MATTRESS WITHOUT BED.
Mattress should not be used alone for patient transport.

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 alternating pressure. This sensation may be 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 may demonstrates the need to minimize elevation of the head of the bed.

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.

BED LINENS: Seven-inch deep fitted sheets are recommended, though flat (non-fitted) sheets may be used. Multiple layering of linens or incontinence underpads beneath the patient should be avoided where possible for maximum pressure redistribution.

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.

ENVIRONMENTAL CONDITIONS FOR USE:

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

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 no stack more than 10 high. Do not stack other equipment on top of the mattresses.

Store the control unit in a clean, dry place, protected from accidental damage or falls. Avoid temperature extremes (below freezing or above 120°F). 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.

WARRANTY: The Protocol is unconditionally guaranteed against failure due to manufacturing defects under normal use for 18 months. See page 23.

USE IN WOUND CARE: Use of PressureGuard® Protocol™ 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: Clean and disinfect mattress covers 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.

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.

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.

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 control unit can be cleaned and disinfected.

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

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

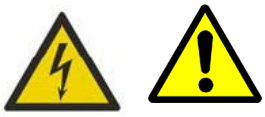
For cleaning, use neutral suds and lukewarm water. For disinfection, phenolic or quaternary type disinfectants are recommended. Disinfectants should be hospital grade (tuberculocidal). Follow manufacturer's instructions for concentrations and contact times.

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 off the control unit and remove the plastic filter 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.

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, there 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 PREVENTATIVE MAINTENANCE
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 of this manual to monitor and document regular inspection and maintenance of your PressureGuard Protocol Surfaces.

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. Upon request, we will provide you with a table for more detailed information.

Guidance and manufacturer's declaration – electromagnetic emissions

The 3400 is intended for use in the electromagnetic environment specified below. The customer or the user of the 3400 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 3400 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 3400 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The 3400 is intended for use in the electromagnetic environment specified below. The customer or the user of the 3400 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 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.
interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	<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 of the3400 requires continued operation during power mains interruptions, it is recommended that the 3400 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the 3400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\ \sqrt{P}$ $d = 1,2\ \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\ \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). 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 3400 is used exceeds the applicable RF compliance level above, the 3400 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 3400

The 3400 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 3400 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3400 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 (P10509) may affect EMC compliance with UL regulations. Power cords other than recommended by manufacturer or at lengths other than supplied length may increase remissions or decrease immunity.

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 117-2013."
AIR CYLINDERS:	Urethane (main cylinders), and urethane-coated nylon
CONTROL UNIT:	Model No.: 3400 Dimensions: 14 x 9.5 x 6.5 inches Weight: 11.5 lbs plus weight of added airlines Rated Spec: AC 110-120V / 60Hz / 0.6A MAX Fuse Rating: 1A 250VAC Classification: Type BF/ Class I Not AP or APG equipment Leakage Current: N/A (floating earth ground) Listing: Conforms to CAN/CSA-C22.2 No. 60601-1-14 and AAMI ES60601-1:2005
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	400 lbs.
CYCLE TIME:	10 minutes

ORDERING INFORMATION

Product Name	Catalog Number	Description	Re-order# Mattress Only	Re-order # Outer Removable Coverlet (blue)	Re-order # Inner Air Delivery Cover (gray)
PressureGuard® Protocol™	P7535-29	With control unit 75”L x 35”W x 7”H	PM7535-29	CLT-PM7535	C1-PM7535
	P8035-29	With control unit 80”L X 35”W X 7”H	PM8035-29	CLT-PM8035	C1-PM8035
	P8435-29	With control unit 84”L X 35”W X 7”H	PM8435-29	CLT-PM8435	C1-PM8435
	23173	With control unit 80”L X 42”W X 7”H	M23173	CLT-23173	C1-23173
	17108	With control unit 84”L X 42”W X 7”H	M17108	CLT-17108	C1-17108
	69212	With control unit 80”L X 35”W X 7”H w/Raised Perimeter	M69212	CLT-69212	C1-69212
	33905	With control unit 84”L X 35”W X 7”H w/Raised Perimeter	M33905	CLT-33905	C1-33905
	72235	With control unit 80”L X 42”W X 7”H w/Raised Perimeter	M72235	CLT-72235	C1-72235
	81990	With control unit 84”L X 42”W X 7”H w/Raised Perimeter	M81990	CLT-81990	C1-81990
PressureGuard Protocol Control Unit	3400	Control unit	-	-	

REPLACEMENT PARTS LIST

P10424	Inflation system 75" Mattress
P10425	Inflation System 80 & 84" Mattress
P10502	PG Protocol Rubber Feet and screws
P10503	PG Protocol Hooks Set (2)
P10504	PG Protocol Air Filters
P10433	PG Protocol Airline Set (3 lines)
P17284	PG Protocol Power Cord
P10510	PG Protocol Front Overlay
P10511	PG Protocol Rear Label

TROUBLE SHOOTING GUIDE
Technical Service: (800) 888-6752

Problem	Possible Cause	Solution
In non-powered mode, air system appears to be underinflated, overinflated, or stuck in an 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 9.
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. 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.

WARRANTY

Span-America Medical Systems, Inc. (the "Company"), warrants to the original purchaser that the **PressureGuard® Protocol™** Patient Support System components, including cover and pump unit, will be free from defects in materials and workmanship for a period of **18 MONTHS** from the date of purchase. During the warranty period applicable to the PressureGuard Protocol, the Company will repair, or replace, with a new product which is identical or reasonably equivalent to the warranted product, any system, pump unit, cover, or discreet, replaceable component part thereof shown to be defective in materials or workmanship. During the full 18 months of the warranty period, such repair or replacement will be made without cost 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.

This 18 month 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 **EIGHTEEN (18) MONTH WARRANTY**, contact:

Span-America Medical Systems, Inc.
Post Office Box 5231
Greenville, South Carolina 29606

PRESSUREGUARD® PROTOCOL™ 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**