SPAN PressureGuard®APM2

& PressureGuard®APM2 Safety Supreme

Air Therapy Support Surface

OWNER'S MANUAL

savaria®

FOREWORD

Savaria Patient Care provides products designed for safe patient movement and positive outcomes for long-term care, hospital settings and homecare environments. The company's research and clinically based product line-up includes therapeutic surfaces for pressure management and positioning, medical beds and a complete portfolio of innovative ceiling lifts and slings.

Built from a heritage of brands including Span, Handicare and Silvalea, Savaria Patient Care is a division of Savaria Corporation (TSX:SIS), a global leader in accessibility.

BEFORE YOU BEGIN

This instruction manual covers only the features that are included with the standard PressureGuard® APM2 and PressureGuard® APM2 Safety Supreme (Model 5900). Before operating your PressureGuard® APM2 and PressureGuard® APM2 Safety Supreme, be sure that you have completely read and understand the instructions and warnings contained within this manual and included with the accessories.

IMPORTANT

To avoid injury, read this manual before using the mattress.

The information in this manual is subject to change without notice. Users must be aware that updates and amendments may be made from time to time.

NOTE

If a serious incident occurs in relation to the device, it should be reported to the manufacturer or distributor of the device. In the European Union (EU), the incident shall be reported as well to the competent authority of the Member State in which the user and/or patient is established.

Span-America Medical Systems, Inc.
70 Commerce Center, Greenville
South Carolina 29615, USA, 1-800-888-6752

STANDARD NOTATIONS

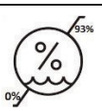
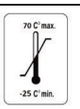
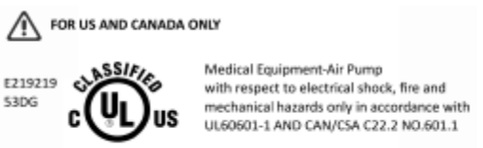
The following notations may be used throughout this manual to emphasize important safety information, mechanical concerns, and other important information. Please review and follow all of these messages.

⚠ DANGER	Danger messages indicate an imminently hazardous situation, which, if not avoided, results in death or serious injury. All danger messages feature a standard ISO safety alert symbol followed by the signal word DANGER in capitalized black lettering on a red background
⚠ WARNING	Warning messages indicate a potentially hazardous situation, which, if not avoided, could result in death or serious injury. All warning messages feature a standard ISO safety alert symbol followed by the signal word WARNING in capitalized black lettering on a dark yellow background.
⚠ CAUTION	Caution messages indicate a potentially hazardous situation, which, if not avoided, could result in minor injuries. All caution messages feature a standard ISO safety alert symbol followed by the signal word CAUTION in capitalized black lettering on a yellow background.
NOTE	Note messages provide information, such as reminders, general information about a previous statement, or additional guidelines that do not fit into the flow of the preceding text. All note messages include the signal word NOTE in capitalized white lettering on a blue background.

CONTENTS

1. CLASSIFICATIONS AND ICONS

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

WARNING	SITUATIONS OR ACTIONS THAT MAY INFLUENCE PATIENT OR USER SAFETY. IGNORING A WARNING COULD CAUSE PATIENT OR USER INJURY	CAUTION	POINTS OUT SPECIAL PROCEDURES OR PRECAUTIONS THAT PEOPLE MUST OBEY TO AVOID EQUIPMENT DAMAGE
	SEE THE USER MANUAL FOR USE INSTRUCTIONS		POTENTIAL TRIP HAZARDS
	ELECTRICAL SHOCK HAZARD WARNING		MANUFACTURER
	WASTE DISPOSAL		DOUBLE INSULATED SYSTEM
	TYPE BF APPLIED PART		KEEP DRY OR DO NOT WET
	EUROPEAN CONFORMITY MARKING		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	FOOT END		NOT MADE WITH NATURAL RUBBER LATEX
	ALTERNATING CURRENT		QUANTITY
	SERIAL NUMBER		CATALOGUE NUMBER
	NON-STERILE		BATCH CODE
	HUMIDITY LIMITATION		TEMPERATURE LIMITATION
	DIRECT CURRENT	IP21	PROTECTION AGAINST THE INGRESS OF FINGERS OR SIMILAR OBJECTS AND DRIPPING WATER
IEC 60601-1-2	ELECTROMAGNETIC EMISSIONS	IEC 60601-1	ELECTRICAL SAFETY
	SEE THE USER MANUAL FOR USE INSTRUCTIONS FOR 230V SYSTEM		

2. OVERVIEW

Introduction

The PressureGuard® APM2 Series air therapy support surface and PressureGuard® APM2 Safety Supreme Series air therapy support surface features a proprietary system of interconnected air support cylinders designed to deliver outstanding pressure redistribution for those with or at risk of skin breakdown.

Description

The system consists of a foam shell with a high-density foam topper serving as the support surface underneath the patient. The foam shell also includes Safety Edge™ bolsters at the sides 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 air control unit connects to the mattress at the patient foot-end.

Modes of Operation

The PressureGuard® APM2 series provides options of alternating pressure, basic lateral rotation, powered flotation and auto-firm.

Intended Use

A powered, alternating pressure management system used for the prevention and treatment of pressure injuries.

Indications for Use

PressureGuard® APM2 models are powered, flotation therapy mattresses providing a pressure management surface for the prevention and treatment of pressure injuries. The lateral rotation mode is indicated for use as a preventive tool against further complications associated with critically ill patients or immobility.

Contraindictions

Not recommended for patients for whom rotation or turning is contraindicated, such as, but not limited to, unstable spinal cord injury, unstable skeletal fractures requiring immobilization and/or skeletal traction, physician orders prohibiting rotation, or severe posterior burns requiring skin grafts.

⚠ WARNING

The PressureGuard® APM2 series is not for use by those with unstable spinal cords. Patient injury could occur.

⚠ WARNING

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

To reduce the risk of burns, electrocution, fire or injury to persons:
READ ALL INSTRUCTIONS BEFORE USING THIS UNIT.

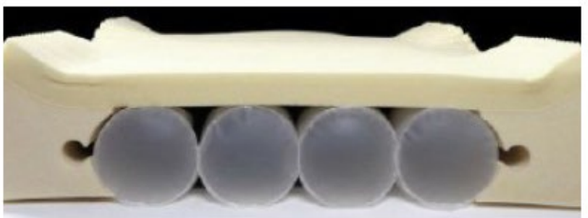
- Always unplug this unit immediately after using.
- Do not operate near water.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquid.
- Do not reach for a product that has fallen into water. Unplug immediately.
- Use this unit only for its intended use as described in the operating instructions.
- 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. Contact Span-America Medical Systems, Inc., for return of control unit for examination and repair.
- Keep the cord away from heated surfaces.
- Never drop or insert any object into any opening or hose.
- Do not use outdoors.

⚠ WARNING

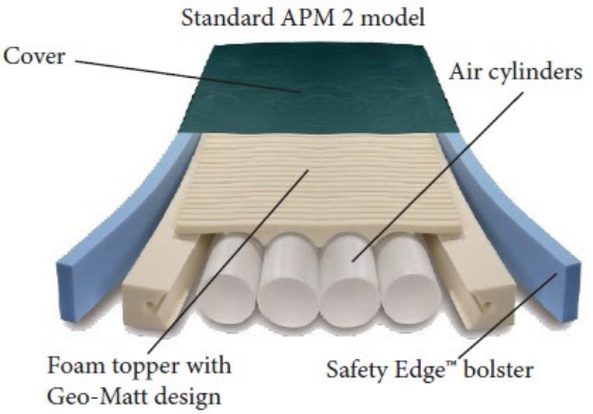
To reduce the risk of burns, electrocution, fire or injury to persons:

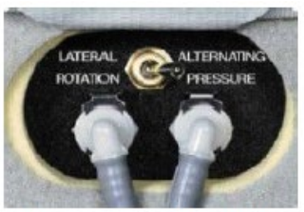
- Use this unit only for its intended use as described in the operating instructions.
- Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the unit to Span-America Medical Systems, Inc. for examination and repair.
- Keep the cord away from heated surfaces. Discontinue use if power cord is damaged or worn.
- Never drop or insert any object into any opening or hose. Keep away from sharp objects.
- Do not use outdoors.
- Possible explosion hazard if used in the immediate proximity of flammable gases (risk of explosion).
- Use only original spare parts and consumables.
- Keep power cord away from heated surfaces.
- Plug this product into a correctly grounded outlet only.
- Before cleaning, unplug unit from its power source. Failure to do so could result in personal injury or equipment damage.
- Do not use harsh cleansers, solvents, or detergents. Do not expose the unit to excessive moisture. Equipment damage could occur.

3. COMPONENT PARTS AND DESIGN FEATURES



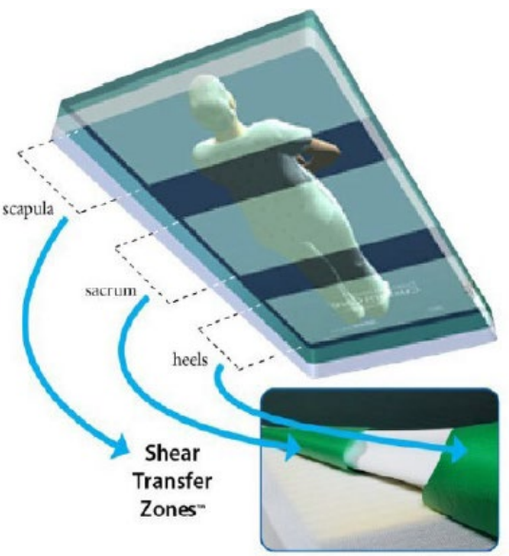
Safety Supreme model showing raised perimeter





Mattress toggle switch

Digital control unit



Shear Transfer Zones® design (standard APM2 model only)
(U.S. Patent # 8,438,682)

In addition to the Geo-Matt® segmented top surface, Span-America's exclusive Shear Transfer Zones™ design provides an additional measure of shearing protection in the form of the silicone-coated, shear-minimizing fabric bands located on the underside of the bi-directional stretch cover. This Shear Transfer Zones design helps:

- Prevent heels, sacrum, and scapula from "digging into" surface
- "Glide" user back to original position following HOB elevation
- Protect against damaging effects of micro shear, macro shear, and rotational (pivot-induced) shear
- Provide patient stability by transferring shear to more shear-tolerant anchor points
- Polycarbonate-fortified for unsurpassed resistance to damaging effects of diluted bleach and other aggressive cleaners and disinfectants
- Engineered for ideal combination of immersion and patient mobility
- Environmentally friendly

LifeSPAN® fortified healthcare fabric

4. DESIGN FEATURES DESCRIPTIONS

PressureGuard® APM2 Cover and PressureGuard® APM2 Safety Supreme Cover

Both models include replaceable, zippered covers which are anti-microbial, flame- resistant, fluid-impervious, tear-resistant, and have a low moisture vapor transmission rate (MVTR). Covers easily wipe clean with standard, hospital-grade cleaners.

Cover of standard APM2 model features bi-directional stretch top fabric designed to allow full integration of the user into the surface. Top is made from proprietary LifeSpan™ polycarbonate-fortified healthcare fabric which provides unsurpassed resistance to the damaging effects of diluted bleach and other aggressive cleaners and disinfectants. Also includes 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.

See the Component Parts and Design Features section (previous page) for illustration and complete description.

Standard cover of Safety Supreme model is non-stretch, barrier fabric with pleated design to allow full integration with surface while minimizing hammocking.

Foam Shell with Geo-Matt® Topper

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.

Safety Edge™ Bolster System

The supportive Safety Edge™ consists of engineered inner and outer foam bolsters for added patient stability in sitting and lying down.

Proprietary Air Cylinder System

The air system consists of four interconnected support cylinders arranged longitudinally (head-to-foot) and constructed from RF- (radiofrequency) welded urethane. The system is designed to provide and maintain low interface pressures throughout the mattress in the non-powered mode. When the powered control unit is attached, it provides active therapy in the alternating pressure mode via inflation and deflation in a fixed 10-minute cycle. The system requires no adjustment or maintenance for the duration of its warranty.

Mattress Toggle Switch

The toggle switch changes modalities from alternating pressure to lateral rotation. The switch is located under a fabric flap on the side of the mattress at the foot end.

Control Unit

Model 5900 Digital Control Unit

5. MATTRESS SET-UP

Fitting the Mattress to the Flat Deck Frame

1. Confirm that the bed frame is appropriate for use with the mattress, and that the length and width of the mattress is appropriate for the frame. Place directly on a healthcare bed frame only; and never on top of another mattress.

⚠ WARNING

The fitting 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 onto the bed frame with the green side facing up and the screenprinted feet facing towards the foot end.
3. The surface is now ready for use by patients who are within the 350 lbs. (159 kg) weight limit for the product.
4. The surface is designed to be used with appropriate linens in place.

Connecting the Control Unit to the Mattress

1. Hang the control unit on the foot board at the end of the bed using fold-out hangers.

2. Connect the air lines to control unit by pressing quick connector into port on the side of unit. The “Triangle” symbol should face front. An audible “click” indicates secure connection.

NOTE

The hanger lock strip (included item # P10064) can be used to help hold control unit more snugly in place on thin footboards such as those often found on home health care beds.

To use, place the strip in position around the hanger hooks.

3. Expose the two air lines that extend from the mattress by opening the flap nearest to the foot end of the mattress.
4. Bring the two air lines from the pump around to the two air lines extending from the mattress. Ensure that the airlines are not kinked or twisted.
5. Connect the ends of the air lines with two right angle male connectors to the ports on the side of the mattress. Ports are located beneath a fabric flap near the right corner at the foot of the mattress. Ensure that the air lines are not kinked or twisted.

6. Press connectors into ports until you hear an audible “click” for each. Press flap closed

⚠ CAUTION

Do not cut air lines to increase separation. If additional separation is needed to connect air lines to the mattress, gently pull air lines away from one another to lengthen the split.

7. Ensure that green On/Off switch at side of control unit is Off.
8. Plug power cord into wall outlet.
9. Press the On button on the On/Off switch. The On/Off indicator light will illuminate in amber, indicating that the unit is connected to power but has not yet fully powered up.

⚠ CAUTION

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

6. POWERED USE DIRECTIONS

⚠ WARNING

Always plug the power cable securely into the wall outlet. Verify that the wallmounted outlet will accommodate a 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.

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 build-up. Place the cord in a low traffic or no traffic area. Confirm that the motion of the bed does not interfere with the bed's power cord or plug.

Keep the cord away from heated surfaces and anywhere hard to unplug with the device like on the shelves, in a wardrobe or the socket on the ceiling.

False latching of side rails could result in patient injury. The bedrail could fall suddenly because the latch failed or was not fastened securely.

5900 Control Unit

When power switch is turned to ON, the unit will power up in Auto Firm mode and begin performing a system check. This fills the air system completely, to confirm the proper connection and function of both the mattress and the control unit prior to a patient being placed on the surface.

If the mattress is completely empty of air, this can take as long as 20 minutes. Since this is rarely the case, however, this typically takes no more than 2.5 minutes.

The system will remain in Auto Firm mode until this process is complete. The Low Pressure indicator light and audible alarm will remain on as well. The Audible Alarm can be disengaged during this process by pressing the Audible Alarm On/Off button.

When the system check is complete, the control unit will revert to previous comfort setting and Alternate mode. The Low Pressure indicator light will turn off. The system is now ready to be set up for the next user.

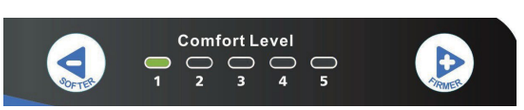
NOTE

If Low Pressure remains on after 30 minutes, call for service.

Functions

Comfort Level Selection

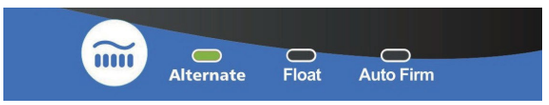
Allows selection of air cylinder firmness within a relatively small range. Press "Softer" or "Firmer" button to achieve desired setting. Begin in softest setting, then adjust for comfort as desired.



Mode Selection

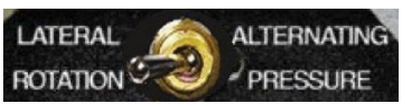
Press the button to select Alternate, Float, or Auto Firm mode.

Alternate Mode



Creates an "A-B" sequence of inflation and deflation of the mattress's four air cylinders designed to change loading across the surface in a 10-minute cycle. In this mode, air cylinders 1 and 3 inflate while 2 and 4 deflate. After approximately 5 minutes, the pattern reverses.

Lateral Rotation Therapy



With mattress toggle switch set to "Lateral Rotation", two air cylinders on one side inflate, while the two on the opposite side deflate, gently rotating the patient approximately 20 °to one side. After approximately 5 minutes, the inflation pattern reverses, and the patient is rotated to the opposite side. 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

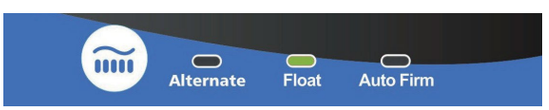
When using wedges or pillows for manual repositioning (turning), discontinue ROTATION and activate either FLOAT or ALTERNATING.

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

Alternating Pressure Therapy

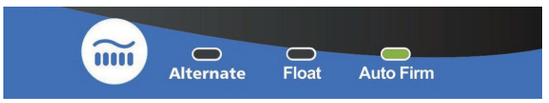
With mattress toggle switch set to "Alternating Pressure", air cylinders 1 and 3 inflate while 2 and 4 deflate. After approximately 5 minutes, the pattern reverses.

Float (powered flotation therapy) Mode



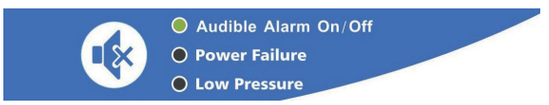
Suspends cyclical inflation/deflation of the air cylinders and instead provides powered flotation therapy. In this mode, all four air cylinders are evenly inflated, and the system maintains ideal pressure management by adjusting in response to any repositioning of the user on the surface.

Auto Firm Mode



Suspends cyclical inflation/deflation and sets system to firmest inflation level for 20 minutes to facilitate user transfer, feeding, dressing changes, and other activities of daily living (ADLs), and CPR. After 20 minutes, system will revert to previous comfort setting and Alternate mode.

Power Failure and Low Pressure Alarms



Audible Alarm On/Off

When indicator light is on, an audible alarm will sound if either the Low Pressure or Power Failure indicator light is on. Press button to silence the alarm. Alarm can also be toggled off in advance if audible alarm is not desired for low pressure conditions.

Power Failure

During power failure situation or upon power down, the Power Failure indicator light will come on and the audible alarm will sound. Press the Mute button to silence the alarm.

Low Pressure

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

7. OPERATIONAL CONSIDERATIONS

Removing the Control Unit

To ensure effective non-powered performance, DO NOT leave the control unit attached to the mattress when powered operation is no longer desired. Instead, disconnect the control unit from the air ports at the mattress. This will allow the air system to reset to its ideal, non-powered inflation level.

Power Loss / Patient Transport

To seal air into mattress, simply disconnect the quick connector from the control unit, and place “transport” cap into place on connector (Figure A). Press cap into place until you hear a “click”, which confirms that the airlines are sealed. With the transport cap in place, all the air is sealed into the mattress. In this mode, the cylinders will distribute air evenly among the four cylinders, providing an even, static air surface to protect the user’s skin until power is restored.

⚠ WARNING

DO NOT MOVE USER ON MATTRESS ONLY. Mattress should not be used alone for user/patient transport.

Head of Bed (HOB) Elevation

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° HOB elevation. Beyond 30°, the amplitude of the changes in the air cylinders begins to decrease in proportion to the increased elevation of the HOB. Although the mattress will maintain its support and therapeutic capabilities up to and including 70° HOB, for maximum benefit we recommend that any pressure management surface be used with the head of the bed elevated as little as possible, and for limited periods at a time.

⚠ WARNING

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

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, then the user is encouraged to try to correct the interference by one or more of the following actions:

- 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.

Troubleshooting/Patient Complaints

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

- Sometimes this occurs when the HOB is elevated, and the mattress is in an 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 HOB is elevated.
    - This demonstrates the need to minimize elevation of the HOB.
- A patient may complain when he/she is supine or side-lying and is 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.

8. GENERAL DIRECTIONS AND BEST PRACTICES

Bed Linens

Use flat sheets, knitted stretch-fit sheets, or deep-pocket fitted sheets. Use as few layers of linens or underpads beneath the patient as possible to allow best possible envelopment, immersion and pressure management performance.

⚠ 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 compliant 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 required 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 when performing CPR:

1. Press the AUTO FIRM button.
2. Place a crash board beneath the patient.
3. Follow CPR procedures.
4. Re-select “Auto Firm” if necessary when system reverts back to previous setting after 20 or 30 minutes, depending on the model.

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 boxes and packaging as provided by the manufacturer.

Environmental Conditions for Use

- Indoor Use
- Altitude up to 2000 meters
- Atmospheric Pressure Range 700 hPa to 1060 hPa
- Operation Temperature 10°C to 40 C (50°F to 104°F), Storage Temperature: -15°C to 50°C (5°F to 122°F), and Shipping Temperature: -15°C to 70°C (5°F to 158°F)
- Operation humidity: 10% to 90% non-condensing, Storage Humidity: 10% to 90% non-condensing and Shipping humidity:10 % to 90% non-condensing
- 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 the manufacturer only.
Call 800-888-6752, 8 am – 5 pm EST M-F.

Service Life

To maintain the condition of the alternating mattress system, service the system regularly according to the schedule recommended by Span-America Medical Systems, Inc.

Medical electrical equipment needs special precautions regarding EMC. Shall the device be used within one mile distance from AM, FM, or TV broadcast antennas, it needs to be installed according to the EMC information provided.

Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the system or any of its components.

Warranty

The PressureGuard® APM2 and APM2 Safety Supreme is unconditionally guaranteed against failure due to manufacturing defects under normal use for 18 months for the controller, 2 years for the cover, and 3 years for the mattress.

Usage in Wound Care

Use of PressureGuard® APM2 and APM2 Safety Supreme 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

Clean and Disinfect Mattress Covers

The PressureGuard® APM2 and APM2 Safety Supreme must be cleaned and disinfected following instances of contamination with bodily fluids and in-between patient utilization. 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 a soft sponge in the concentration recommended by the manufacturer. DO NOT USE HARSH CLEANERS OR SOLVENTS.

Additional Cleaning Information

For long-term incontinent applications, clean and disinfect the cover daily. A scented cleaner/disinfectant is recommended.

NOTE

Iodophor type disinfectants such as 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.

Site Decontamination of Blood or Other Potentially Infectious Materials (OPIM)

US Centers for Disease Control and Prevention (CDC) guidelines recommendations (www.cdc.gov/infectioncontrol/guidelines/disinfection/recommendations.html) include two non-bleach options:

- Use of an EPA-registered tuberculocidal agent. See: List B (https://www.epa.gov/pesticide-registration/epas-registeredantimicrobial-products-effective-against-mycobacterium).
- Use of a registered germicide on EPA Lists D and E.

Surveillance and Epidemiology Indicating Ongoing Transmission of C. Difficile

CDC directs providers to use products on EPA List K (for effectiveness against Clostridium difficile spores for disinfection of environmental surfaces. See: List K (LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores | Pesticide Registration | US EPA).

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 it from service following infection control procedures.

Cleaning the Air Control Unit

If required, the air control unit can be cleaned weekly.

1. Turn the unit off.
2. Unplug the unit from the wall outlet.

⚠ WARNING

Best practices mandate unplugging the unit from the wall outlet before cleaning.

NOTE

The mattress will maintain air with the unit unplugged. The unit will resume the previous setting when powered back up.

3. Wipe down the mattress using a dAPM sponge or cloth that has been thoroughly wrung out to remove excess liquid.

Neutral Suds Cleansing

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

Maintenance

To maintain the function of the system, maintenance and a safety check by qualified personnel is required every year at the minimum.

Air Filter Preventative 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. Ensure the system is used with stable power.
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. Power cords 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 the 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 Inspection

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 to monitor and document regular inspection and maintenance of your PressureGuard® APM2 or APM2 Safety Supreme.

9. EMC (ELECTROMAGNETIC COMPATIBILITY): USER INFORMATION AND GUIDANCE

Portable RF communications equipment can affect medical electrical equipment. We recommend a safety distance no closer than 30 cm (12 inches) to any part of the system and at least one (1) meter for sensitive equipment.

⚠ WARNING

Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories.

⚠ WARNING

Household electronic devices such as humidifiers, heaters or microwaves may cause interference with the device.

⚠ WARNING

X-rays, electric cauterizers, high-frequency, or high-energy devices may cause interference with the device.

⚠ CAUTION

If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.

⚠ CAUTION

Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.

⚠ CAUTION

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Manufacturer's Declaration-Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

The customer or the user should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment-guidance (for professional healthcare environment)
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

⚠ WARNING

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Manufacturer's Declaration-Electromagnetic Immunity

The device is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level		Compliance Level	Electromagnetic Environment-Guidance (For Professional Healthcare Environment)
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air		±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	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)	Mains power quality should be that of the typical professional healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Voltage Dips: i) 100% reduction for 0.5 period, ii) 100% reduction for 1 period, iii) 30% reduction for 25/30 period, Voltage Interruptions: 100% reduction for 250/300 period		240V	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from na uninterruptible power supply or a battery.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance (For Professional Healthcare Environment)	Immunity Test
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 385-6000 MHz, 9-28V/m, 80% AM(1kHz) pulse mode and other modulation	10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz 385-6000 MHz, 9-28V/m, 80% AM(1kHz) pulse mode and other modulation	10V/m	Recommended separation distance d =√PP 150kHz to 80MHz d =0.6√PP 80MHz to 800MHz d =1.2√PP 800 MHz to 2.7G MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency ranged. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: UT is the a.c. mains voltage prior to the application of the test level
NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 3 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended Separation Distance Between portable and Mobile RF Communications Equipment and the 5900

The 5900 is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the 5900 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 5900 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 =√*PP*	80 MHz to 800 MHz d =0.6√*PP*	800 MHz to 2,7 GHz d =1.2√P
0.01	0.1	0.06	0.12
0.1	0.31	0.19	0.38
1	1	0.6	1.2
10	3.1	1.9	3.8
100	10	6	12
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.			

10. TECHNICAL DESCRIPTION

Power Supply (NOTE: See rating label on the product)		AC 100-120V 60 Hz, 0.17A (5900) AC 220-240V 50 Hz, 0.08A (5900CE) AC 230V 60Hz, 0.05A (5900SAU)
Fuse Rating		T1A, 250V for 120 V system, T1AL 250V for 230V system
Cycle time		Fixed
Environment	**Temperature**	Operation:10° C to 40° C (50° F to 104° F) Storage: -15° C to 50° C (5° F to 122° F) Shipping: -15° C to 70° C (5° F to 158° F)
	Humidity	Operation: 10% to 90% non-condensing Storage: 10% to 90% non-condensing Shipping:10 % to 90% non-condensing
	Atmospheric Pressure	Operation: 70 – 106 kPa Storage: 50 – 106 kPa Shipping: 50 – 106 kPa
Classification		Class II, Type BF, IPX0 for 120V system, IP21 for 230V system, Applied Part: Air Mattress Not suitable for use in the presence of a flammable anesthetic mixture (No AP or APG protection)

11. SPECIFICATIONS

Cover	Bacteriostatic, flame resistant, fluid-proof, tear resistant
Foam	High-density open-cell polyurethane. Conforms to NFPA 101 small scale and Cal TB# 117.
Air Cylinders	Urethane (main cylinders)
Control Unit	Model #: 5900 (US), 5900CE [5900CEG (UK), 5900CEI (AUS)] [5900CEC (EU)] Classification: Class II, Type BF No AP or APG protection Weight: 4.7 lbs. Dimensions: 11.5" x 7" x 4.5"
Electrical	5900: 100-120 VAC/60 Hz., 0.17A 5900CE (5900CEG, 5900CEI, 5900CEC): 220-240 VAC/50 Hz, 0.08A 5900SAU: 230VAC/60 Hz, 0.05A With respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1. With respect to electric shock, fire, mechanical and other specified hazards only in accordance with CAN/CSA C22.2 No. 601.1 Medical equipment certified for Canada.
Standards	CE marked in line with Medical Devices Regulation (MDR)
Standard Surface Sizes	80"L X 35"W 84"L X 35"W 75"L X 35"W
Mattress Height	7" for all models
Weight Limit	350 lbs.
Cycle Time	10 minutes
Placement	All mattresses can be placed directly on a healthcare bed frame.
Warranty	Control unit: 18 months, not pro-rated, against manufacturing defects. Mattress: 3 years, not pro-rated, against manufacturing defects. Cover: 2 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.

12. ORDERING INFORMATION

P10049	Replacement quick disconnect with transport lid
P10061	Replacement electrical cord, (16’ L, hospital grade, 3-prong) 5900 & 5500
P10062	Replacement air line assembly with quick disconnect, transport lid and elbow connectors
P10064	Hanger locking strip
P10065	Replacement hanger set
P10066	Replacement internal female plate for air lines
P10067	Replacement feet
P10070	Elbow Connectors to mattress
P10570	Replacement Power Switch
P10594	Replacement Filter

NOTE

Observe proper Disposal of Electrical & Electronic equipment (WEEE). This product or its parts are designated for separate collection at an appropriate collection point. At the end of useful life, dispose of all waste according to local requirements.

13. TROUBLESHOOTING

Technical Service: (800) 888-6752

Issue	Possible Cause	Solution
System will not power up. NOTE: Always plug power supply into proper 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.
	HOB is elevated, or knees are gatched.	The degree of patient turn achieved is reduced with elevation of the HOB 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.
	Air lines not connected.	Ensure secure connection of air lines at control unit and mattress.
	Air lines or quick disconnect connectors are damaged.	Call for replacement.
	HOB elevated.	Lower HOB and allow air to equalize. Return HOB to elevated position that is comfortable for patient.
	Defective control unit (mattress fills without patient, sinks with patient weight).	Call for service.
Mattress too firm	Comfort level too high.	Adjust comfort level down to desired level.
	Control unit vent valve failure.	Disconnect control unit, connect airlines to one another to equalize the mattress. Exhaust air from fittings to achieve desired comfort level and reconnect (repeat as needed).

Issue	Possible Cause	Solution
Low pressure indicator illuminated.	Air lines not connected.	Disconnect and reconnect air lines to verify they have all locked into place.

Issue	Possible Cause	Solution
	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. 1. Reorient or relocate the affected device. 2. Increase the distance between the equipment. 3. Connect the equipment into an outlet on a circuit different than that of the affected device. Consult the field service technician or manufacturer of the affected device.

⚠ WARNING

Service to be performed by authorized personnel only. (800) 888-6752.

13. IN-HOME STYLE MODELS AND USAGE NOTES

In-Home styles are intended for use by a single user sleeping alone in a bed that is wider than standard healthcare dimensions, or by a user in need of a powered air therapy surface who shares a bed.

Depending on need, mattress model should be selected with powered air therapy cylinders located in Center of mattress (for a user sleeping alone), or on Patient Right Side (for two users, or for a single user who cannot/prefers not to move to center of mattress). Air cylinders not connected to digital control unit must be maintained at desired pressure through regular adjustment/inflation with manual pump kit, item # SERVICE-00.

Powered air therapy in Center

Powered air therapy on Patient Right

"Patient Right Side" refers to location with patient in backlying position.

⚠ CAUTION

Failure to maintain adequate pressures in these non-powered cylinders can lead to instability on the surface where therapy cylinders in the "down" portion of the powered therapy cycle are positioned next to inadequately inflated non-powered cylinders.

⚠ CAUTION

In-Home models are intended for use atop a variety of stable bed foundations types, including healthcare, platform, and box spring. Weight of mattress is typically adequate to maintain the mattress in a safe position on any of these surfaces. If mattress cannot maintain position on foundation without slipping, discontinue use immediately until mattress can be safely secured.

14. WARRANTY

PRESSUREGUARD®

APM2 and APM2 Safety Supreme

Support Surface: Mattress 3 Years, Cover 2 Years

Span-America Medical Systems, Inc. (the "Company"), warrants to the original purchaser that the PressureGuard® APM2 therapeutic support surface will be free from defects in materials and workmanship for a period of 3 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 3 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: 18 Months

Span-America Medical Systems, Inc. (the "Company"), warrants to the original purchaser that the PressureGuard® APM2 control 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 model 5900 powered control unit, 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 18 months of the warranty period, such repairs 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.

About questions relating to the WARRANTY, contact:

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

13. PRESSUREGUARD® APM2 PREVENTIVE MAINTENANCE LOG

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

Authorized Seller/Installer

PressureGuard® APM2
APM2 Safety Supreme

Part # P10331 CC-6791-EN
Rev: 15.0

Span-America Medical Systems, Inc.
70 Commerce Center
Greenville, SC 29615 USA
1-800-888-6752
www.savariapatientcare.com

EC REP

Advena, Ltd.
Tower Business Centre, 2nd Flr
Tower Street, Swatar
BKR 4013, Malta

Australian Sponsor:

KD&A PTY Ltd
(ACN 114 941 338)
286 Flinders Street, Adelaide
South Australia, 5000

UK CA

Advena, LTD.
Pure Offices
Plato Close, Warwick
CV34 6WE United Kingdom

For service or questions about this product, please contact:

AUTHORIZED SELLER/INSTALLER: _____

PHONE NUMBER: _____

savaria®