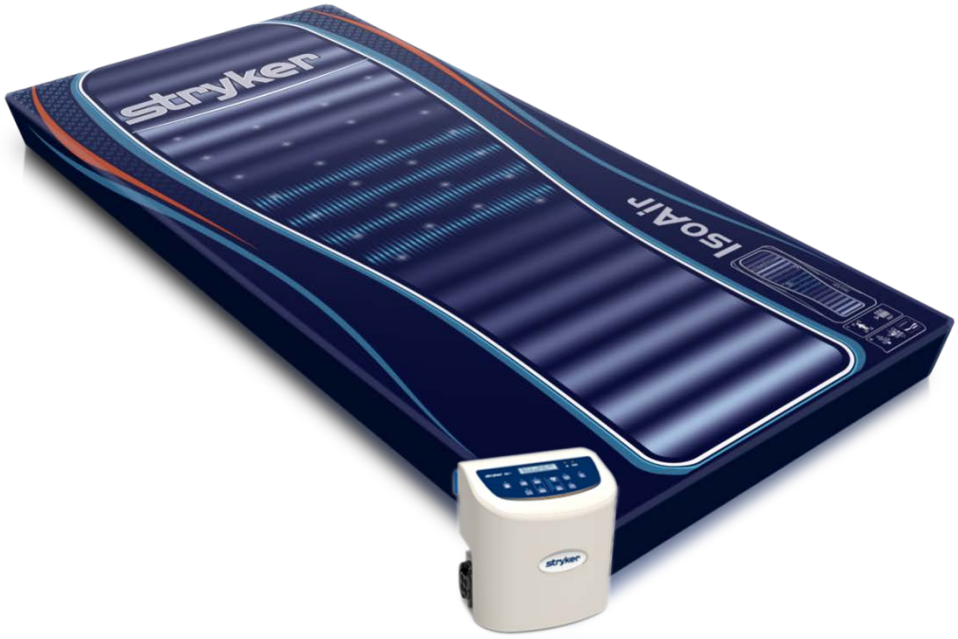
stryker®



For Parts or Technical Assistance:
USA: 1-800-327-0770

Table of Contents

***** FIND A QUICK REFERENCE GUIDE ON PAGE 48-49 *****

Symbols and Definitions

SYMBOLS

	Warning
	Caution
	Electrical Safety Mark
	Refer to Instruction Manual
	Type BF Applied Part; Applied Part is the Mattress
	Safe Working Load (SWL)
	Do Not Iron
	Machine Wash
	Tumble Dry
	Do Not Bleach
	Chlorinated Bleach Allowed (See **Page 34**)
	Do Not Tumble Dry
	Do Not Dry Clean
	Do Not Wash
	Drip Dry
	Consult Instructions for Use
IP21	Ingress Protection Rating
	Equipment Emits Electromagnetic Energy
	Date of Manufacture
	Li Ion Battery
	Model Number
	Serial Number

Symbols and Definitions

SYMBOLS

~	Alternating Currrent
	Double Insulated
	Product Weight
	Power (ON/STANDBY)
	Lock
	Alarm Silence
	Pressure Alarm Indicator
	Alarm Indicator
	Moisture Management (MM)
	Pressure Redistribution (Static) Mode
	Alternating Low Pressure (ALP) Mode
	Increase Pressure
	Decrease Pressure
	Active Sensor Technology (AST)
	MAX Inflate
*	AST Contact Indicator
	Battery Alert
	Do Not Use in Presence of Oxygen
	Do Not Use in Presence of Nitrous Oxide
	Choking Hazard
	Do Not Dispose as Unsorted Municipal Waste

Symbols and Definitions

WARNING / CAUTION

The words **WARNING and CAUTION** carry special meanings and should be carefully reviewed.

WARNING

Alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

CAUTION

Alerts the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. This includes special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

ACRONYMS

ALP	Alternating Low Pressure
AST	Active Sensor Technology
CPR	Cardio-Pulmonary Resuscitation
HOB	Head of Bed
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MM	Moisture Management (Low Air Loss)
SWL	Safe Working Load = Maximum load that the equipment can support without breaking. **NOTE!** SWL is not the Therapeutic Weight Range for this product. See Specifications Section on **Page 8** for the Therapeutic Weight Range.

Introduction

This manual is designed to assist with the operation and maintenance of the Stryker IsoAir™ System ("IsoAir™"). Carefully read this entire manual before using or beginning maintenance on the Pump or Support Surface. To ensure safe operation of this equipment, it is recommended that methods and procedures are established for educating and training staff on the safe operation of the Pump and Support Surface.

INTENDED USE OF THE PRODUCT

The IsoAir™ is a therapeutic support system used to assist in the prevention and treatment of all categories/stages of pressure ulcers (including stages I, II, III, IV, Un-stageable, and Deep Tissue Injury).

This system is intended for use in acute care and long-term care, including the home environment.

CONTRAINDICATIONS

The IsoAir™ System is intended for use as prescribed by a licensed physician. The IsoAir™ System is contraindicated for use with certain medical conditions and treatments. Always consult with the patient's physician before commencing therapy with the IsoAir™ System.

PRODUCT DESCRIPTION

The IsoAir™ System offers Alternating Low Pressure (ALP) and Moisture Management (MM) on demand. The system consists of a main control unit (Pump), which provides a pressure source for inflating and deflating the air cells in the support surface. The support surface consists of a series of air cells that run laterally across the surface to support the patient, and side bolsters.

The AST feature is an auto-sensing function that is used to provide optimal immersion.

PRODUCT & THERAPY OVERVIEW

The IsoAir™ helps to prevent and treat pressure ulcers. The air cells in the support surface are positioned every 4 inches (10 cm) from the head to the foot. Two types of therapy are available, Pressure Redistribution and ALP. Pressure Redistribution therapy fills the cells with just enough air to deeply immerse the patient into the surface. This immersion distributes pressure to support the patient as evenly as possible. ALP therapy will alternately inflate and deflate every other cell to relieve pressure and allow blood to flow into the tissue more easily. This function will continue to cycle every 6 minutes.

An additional feature called Moisture Management (MM) is available. MM enhances patient comfort and helps to prevent and treat pressure ulcers by removing moisture through the top cover. Air is pumped into the surface in the seat and torso areas to evaporate the moisture.

The Pump is connected to the air cells through flexible hoses. The Pump monitors and adjusts the air in the air cells automatically. If less air is required then the Pump opens a valve to vent some out. If more air is required then the Pump turns on its air compressor and opens a valve to direct more air into the cell.

There are two ways that the firmness / softness of the surface can be set. Manual mode allows the user to select one of five preset levels. AST mode utilizes sensors in the seat area of the surface. These sensors determine the amount of immersion of the patient. If the mattress is too soft and the patient is immersed too much, the Pump will increase the air pressure in the surface. Conversely, if it is too hard the Pump will decrease the air pressure in the surface.

ISOAIR™ SYSTEM COMPONENTS

The IsoAir™ System is composed of a Support Surface (Mattress) and a Pump. The Surface has a built in Hose Assembly that connects to the Pump via the CPR Connector.

The Pump is supplied with two power cords, a long cord and a short cord. The long cord is for wall connection and the short cord is for connecting directly to the power socket built into some Stryker bedframes.

The system is accompanied by an Operation/Maintenance Manual.

SPECIFICATIONS

The table below lists the specifications for the IsoAir™ System:

PUMP	
Dimensions	Height: 8.5 in / 21.6 cm Width: 8 in / 20.3 cm Depth: 5 in/ 12.7 cm
Input Voltage AC	Model **2940-001-100** – 120 Volts +10%/-15%
Input Frequency	Model **2940-001-100** – 60 Hz +/- 5%
Current Consumption	Model **2940-001-100** – 0.4 Amps
Power Consumption	Model **2940-001-100** – < 50 Watts
Circuit Protection	Fuse, 250V, 1.6A, 5 x 20 mm, Fast blow (1500A)
Protection Against Electrical Shock: Class II Medical Equipment provides electrical safety by the means of insulation without the use of grounding (protective earthing).	Class II, Type BF Applied Part A type BF rating indicates the device may have electrical contact with the patient, or has medium or long term contact with the patient. 
Pressure Display Accuracy	±2 mmHg
Pressure Settings (mmHg)	10 to 30 mmHg in 5 mmHg Increments
Power Cord	3 ft/ 1m (For Bed Frame Outlet) & 15 ft / 5m (For Wall Outlet)
Air Hose	34 in / 86 cm
Air Hose Connections	5/16 Inch Flow Quick Coupling
AST Plug	¼ in Phono Jack
AST Cable	35 in / 89 cm
Packaging	1 Pump per Box
Latex Content	User accessible parts (mattress, Pumps and accessories) are not made with natural rubber latex.
Pump Weight	11 lb / 5 kg
Alarms (See Page 31):	
Maximum Sound Pressure Level	61.2 dB
Protection Against Harmful Ingress of Liquids:	
Ingress Protection	IP21 (with CPR and AST plug attached) 2 Protected against solid objects over 12.5mm e.g. hands, large tools. 1 Protected against vertically falling drops of water or condensation.
Applied Parts:	
Support Surfaces	See Part Number listing in the following *Support Surface Specifications Table.*
Expected Life:	
IsoAir™ Pump	5 Years

SPECIFICATIONS

SUPPORT SURFACE		
Support Surface Coverlet Material	Equilibrium 2 by Dartex®	
Support Surface Sizes:		
Model		
2940-000-100	84” x 35” x 7.0”	213.4 cm x 88.9 cm x 17.8 cm
Maximum Support Surface Weight	28 lb	12.7 kg
Safe Working Load	550 lb	250 kg
Therapeutic Weight Range	50 lb - 350 lb	22.7 kg - 158.7 kg
Flammability Standards	*16 CFR 1632* *16 CFR 1633* *CAL TB 129* *UNI 9175* *Boston BFD IX-11* *Canada - Method* CAN/CGSB-4.2 No. *27.7-2013* *BS 597-1, BS 597-2, BS7177/BS6807 (Crib 5)*	
Compatible Bed Frames	2030-000-000 Epic / Epic II Critical Care bed 2035-000-000 Apex Critical Care Bed FL27 InTouch Critical Care bed 3002-000-000 Secure II MedSurg Bed 3005-000-000 S3 MedSurg Bed	
Biocompatibility Standards	*ISO 10993-1, ISO 10993-5, ISO 10993-10*	
System Operating Conditions		
Ambient Temperature	5 to 38 ^{o}C	
Relative Humidity	15 to 93 % Non-Condensing	
Atmospheric Pressure	700 to 1060 hPa	
System Storage and Shipping Conditions:		
Ambient Temperature	-20 to 60 ^{o}C	
Relative Humidity	10 to 95 %, Non-Condensing	
Atmospheric Pressure (hPa)	500 to 1060 hPa	
Product Compliance:		
Medical Equipment	*IEC 60601-1 (3rd edition)* *AAMI ES60601-1* *CAN/CSA C22.2 NO. 60601-1 (3rd Edition)*	
Collateral Standards	Electromagnetic Compatibility, *IEC 60601-1-2* (See **Pages 45-46**) Home Healthcare, *IEC 60601-1-11* Usability, *IEC 60601-1-6* Alarms, *IEC 60601-1-8*	
Expected Life:		
IsoAir™ Support Surface	Coverlet 2 Years Support Surface without Coverlet 5 years	

Stryker reserves the right to change specifications without notice.

CONTACT INFORMATION

Contact Stryker Customer Service or Technical Support at **(800) 327-0770** or **(269) 324-6500** for assistance in setting up, using or maintaining the IsoAir™ System, or if you encounter any expected events/operation.

Stryker Medical
3800 E. Centre Avenue
Portage, MI 49002
USA

Please have the serial number of your Stryker product available when calling Stryker Customer Service or Technical Support. Include the serial number in all written communication.

PUMP SERIAL NUMBER LOCATION

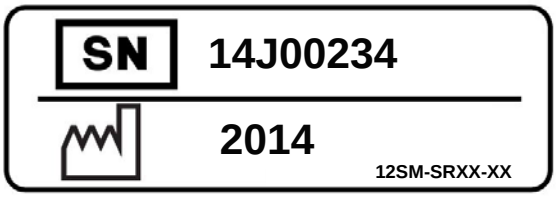
The serial number is located on the back of the Pump as shown in the label example to the right.

SERIAL NUMBER FORMAT (8 CHARACTERS):

Serial Number Example: 14J00234

1	4	J	0	0	2	3	4
Y	Y	M	N	N	N	N	N

Manufacture Date (YY/M): 2014 September
Sequential Number (N): 00234



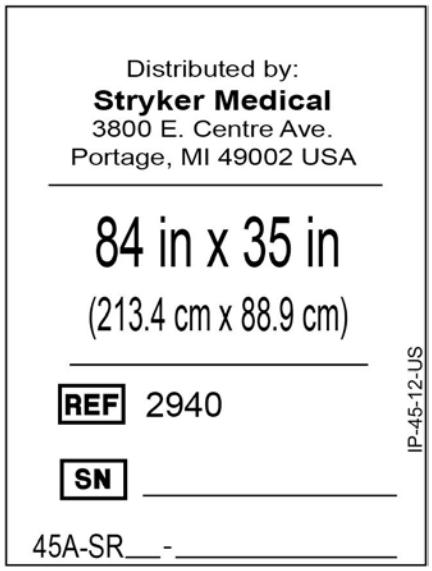
Year Legend (Y)	
2014	14
2015	15
2016	16
2017	17
2018	18

Month Legend (M)	
January	A
February	B
March	C
April	D
May	E
June	F
July	G
August	H
September	J
October	K
November	L
December	M

Sequential # Legend (N)
00001 - 99999

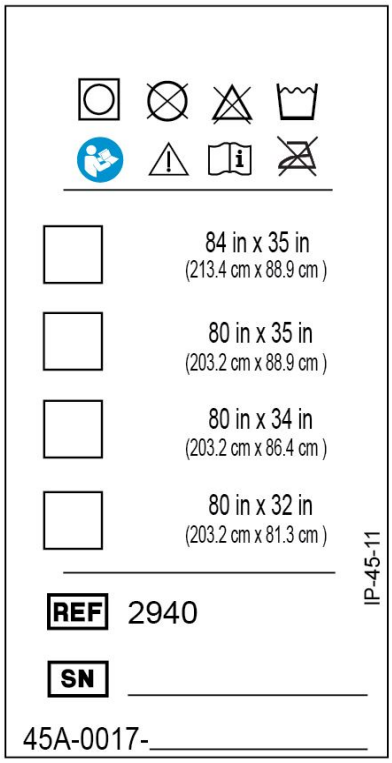
SUPPORT SURFACE SERIAL NUMBER LOCATION

The serial number is located inside the support surface on the patient right side at the foot end near the corner.



COVERLET SERIAL NUMBER LOCATION

The serial number is located on the patient right side at the foot end of the coverlet.



Summary of Safety Precautions

Before operating this medical equipment, carefully read and strictly follow the Warnings and Cautions presented in the following sections.

General

- Read this manual to understand the operating instructions and safety precautions. Failure to do this could result in patient injury and/or damage to the product.
- To avoid the risk of electric shock inspect the Pump and power cord for damage. If damage is observed, take the Pump out of operation immediately and contact Customer Service. (See **Page 9** for Contact Information).
- **Entrapment & Falls:** Evaluate patients for the risk of entrapment & falls according to facility protocols. **Ensure side rails are fully locked when in the raised position. Failure to do this could result in death or injury.**
- The patient should be evaluated for suitability of the device to treat the patient's condition.
- It is the responsibility of the operator to monitor the patient and the patient's skin condition at regular intervals, per medical protocols, to ensure patient safety and proper support surface performance. Consult a physician if irritation or skin breakdown occurs.
- Do not modify or change this device. There are no user-serviceable parts inside the Pump. Service should only be completed by qualified personnel. Failure to do so could result in injury and void warranty.
- Connect only items that have been specified as part of the device, or specified as being compatible with the device.
- Pressure in support surface is under automated control and may adjust without notice. Use care when performing medical procedures on patient.
- Smoking in bed or improper use of radiant heaters may cause a fire. Doing so could result in death or injury.

Support Surface

- To avoid the risk of patient injury, do not use the support surface on a bed frame of a larger or smaller size. The risk of entrapment can develop when the support surface is placed on bed frames that leave gaps between the support surface and the headboard, footboard, and side rails. The support surface is not to be used when such gaps are present.
- To avoid risk of severe injury, properly secure support surface to the frame according to the instructions for use.
- Initiate deflation of the Support Surface before starting CPR. Failure to do so may result in ineffective CPR. Refer to **Page 26**.
- The hose sleeve is a safety feature. Do not operate the equipment without the sleeve in place.
- Risk of entanglement if hose sleeve is not secured to the back plate of the CPR connector.
- Risk of asphyxiation due to entanglement with hoses. Ensure hose sleeve is correctly installed.
- Ensure that all side rails are fully latched when in the raised position. Failure to do so could result in serious injury or death including patient falls.
- To avoid the risk of patient injury and equipment damage, do not use the support surface handles or straps to lift, or move the support surface with a patient on it.
- To avoid the risk of patient and operator injury, a minimum of two (2) operators is required when transferring a patient. Operators need to be positioned so that they can control patient positioning.
- To avoid the risk of patient injury, ensure the opposite side rail is raised when placing a patient on the support surface.

Pump

- Risk of Electric Shock. Do not open or attempt to repair or service the electronic Pump. Repairs and service should only be done by authorized personnel. If the Pump is not functioning properly, or has been damaged, unplug the Pump and take it out of service immediately and contact Customer Service. (See **Page 9** for contact information).
- Electrical-safety testing of your Pump should be performed at least annually. Failure to do so may result in death or injury. Contact Customer Service, **Page 9**, for service information.
- This equipment radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity (See **Pages 45-46)**. 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 ON and OFF, the user is encouraged to try to correct the interference by one or more of the following measures:
  1. Reorient or relocate the receiving device.
  2. Increase the separation between the Pump and other equipment.
  3. Connect the equipment into an outlet on a circuit different from that to which other device(s) are connected.

  Consult with Stryker Customer Service for assistance.

- Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base station, walkie-talkies can affect this equipment. Place equipment a minimum distance from wireless communication devices as defined on **Page 46**.
- The use of accessories and cables other than those specified, with the exception of those sold by the manufacturer as replacement parts, may result in increased emissions and/or decreased immunity of the device. (See **Pages 45-46**).
- The Pump hangers are not intended to be in patient contact. Extended patient contact with the Pump hangers may cause injury.
- Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen-rich environments. Risk of explosion, burns and asphyxiation can result.
- Exposure of the electronic Pump to any liquid while it is plugged in could result in a severe electrical hazard.
- To avoid risk of injury do not place objects on the surface of the Pump.
- The AST cable ONLY connects to the AST-socket. Connecting it anywhere else may result in severe electrical shock.
- If “Key-Click” sound is not heard, DO NOT use the Pump.
- Pressure in support surface is under automated control and may adjust without notice. Use care when performing medical procedures on patient.
- The device is not compatible for use in MRI.
- AC mains power must be connected to provide therapy. If power is lost, therapy provided will be discontinued.
- Good filter maintenance is critical in keeping your IsoAir™ Pump in optimal operating condition. Failure to clean the filter may cause damage to the Pump. A damaged Pump may not provide proper support pressures resulting in patient injury.

Summary of Safety Precautions

Electrical Connections & Power Cord

- Do not use multiple socket outlets or extensions. This may result in an electrical hazard.
- Power cord may cause tripping hazard. Route cord under bed frame.
- Before plugging in the Pump, check the power cord for damage, e.g. cuts, exposed wires, worn insulation, etc. If hazards are present, take the Pump out of operation immediately and contact Customer Service. (See **Page 9** for Contact Information)
- Improper use or handling of the power cord could result in damage. If damage of power cord is present, do not use and call qualified maintenance personnel for replacement (See Parts list on **Page 44**). To avoid risk of electric shock use approved power cords only.
- The power cord to the Pump should be positioned to avoid a tripping and strangulation hazard and/or damage to the cord. Stryker recommends placing the cord under the bed frame and plugging it into an electrical outlet by the head end of the bed, or the integral electric outlet on the bed frame using the shorter cord provided.
- Orient power cord so that it is not difficult to disconnect.
- Risk of asphyxiation due to entanglement with cords. Route cord under bed frame.

Disinfection

- Disinfect the Pump and Surface between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.
- When disinfecting is required, check disinfectant manufacturer's instructions before use, and use disinfectant and personal protective equipment in accordance with the manufacturer's instructions.
- Do not spray disinfectant directly on the electrical Pump, or immerse the Pump in any type of liquid. This could result in a severe electrical hazard.
- All disinfection should be done using a "hospital-grade" disinfectant.
- DO NOT spray disinfectant directly on the electrical Pump, or immerse the Pump in any type of liquid. This could result in a severe electrical hazard.
- Check patient medical history for allergies to the disinfectants listed on **Page 34**.

Summary of Safety Precautions

⚠

General

- Check the system and surrounding area for pests that may damage the system causing harm to the patient.
- Do not return a Pump for any reason without first contacting Customer Service to obtain authorization.
- Do not leave children and pets unattended while the IsoAir™ System is in use. They may damage the system that may cause bodily harm to themselves and/or the patient.
- DO NOT service or perform maintenance while the product is in use. May result in patient injury.

Support Surface

- Use care when using sharp objects, such as needles, as these can damage the air cells in the support surface.
- Do not use harsh cleansers, solvents, or detergents on the Pump/Surface. Equipment damage could occur.
- To avoid the risk of equipment damage, when cleaning the underside of the support surface, ensure that no liquid is allowed to seep into the zipper area and watershed cover barrier; fluids allowed to come in contact with the zipper may leak into the support surface.
- AST sensor cells (light blue) can be wiped down, but not laundered.
- Cap the air cell connectors before laundering (See **Page 35**. Failure to cap the connectors will lead to liquid ingress inside of the air cell and the risk of damage or mold growth through incomplete drying.
- The Mattress includes straps at the bottom center that are intended for storage use. Do not use these to tie the Mattress to the bedframe. May result in equipment damage.

Pump

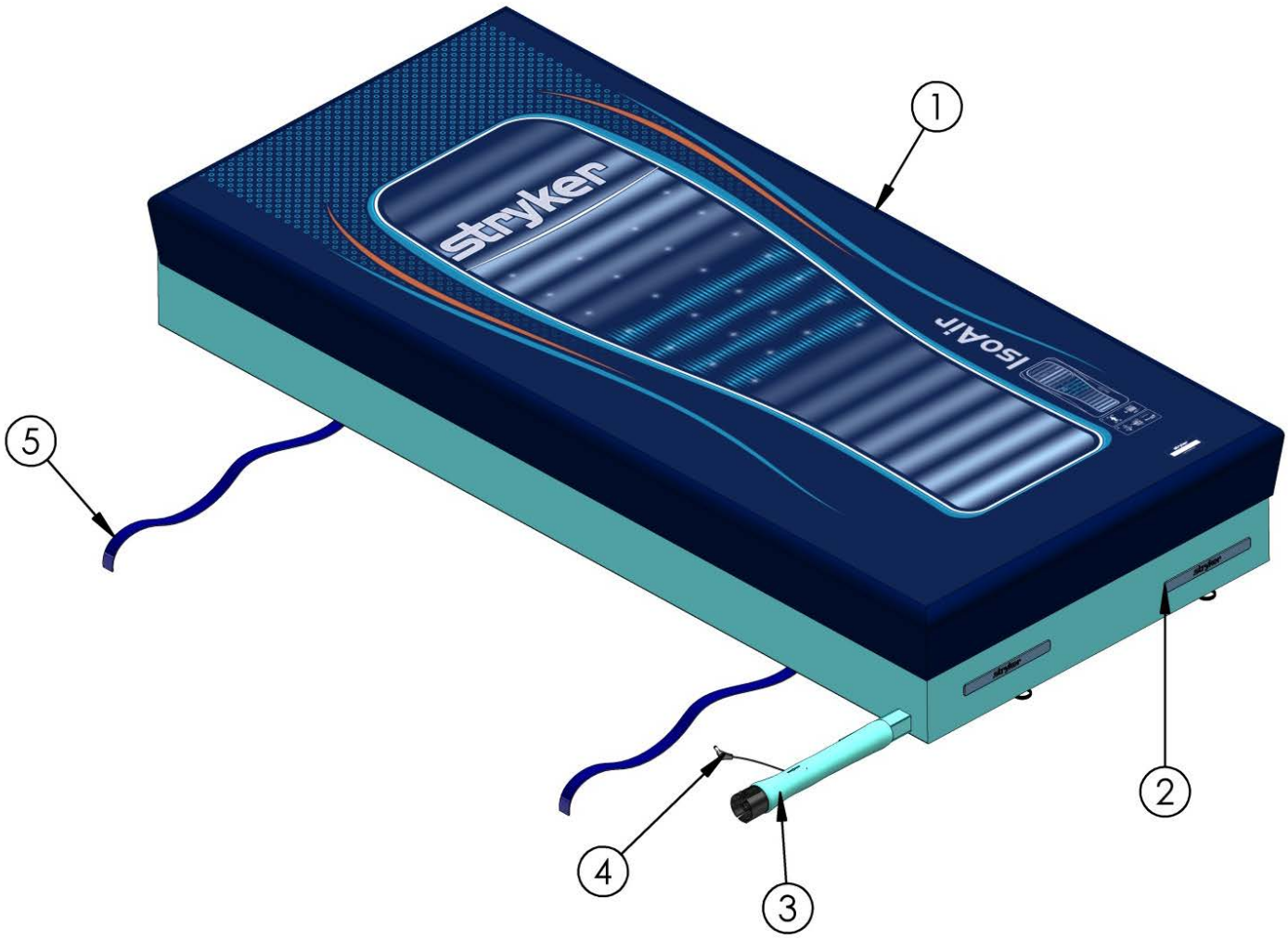
- When hanging the Pump on the foot board, ensure the hangers are seated as they are not spring loaded and may become dislodged if not properly hung.
- The Pump is a precision electronic product. Use care when handling or transporting. Dropping, or other sudden impacts, may result in damage to the Pump.
- After exposure to extreme high or low temperatures, allow the Pump to equilibrate for at least one (1) hour before operating.
- The Pump circulates room air during operation. Exposure to smoke may cause the Pump to fail. Therefore, smoking by patients, or visitors, while using this product should be avoided.
- DO NOT autoclave the Pump OR the Hosing Assembly. May result in equipment damage.
- Unplug the Pump from its source prior to cleaning. Failure to do so may result in an electrical hazard.

Environmental

- To prevent the materials in this product from contributing to potentially serious health and/or environmental hazards:
  1. Consult your local regulations to safely dispose of electronic equipment, batteries, and/or any biohazardous waste.
  2. Do not dispose of as unsorted municipal waste. See your local distributor for return or collection systems available in your country.

Support Surface Assembly

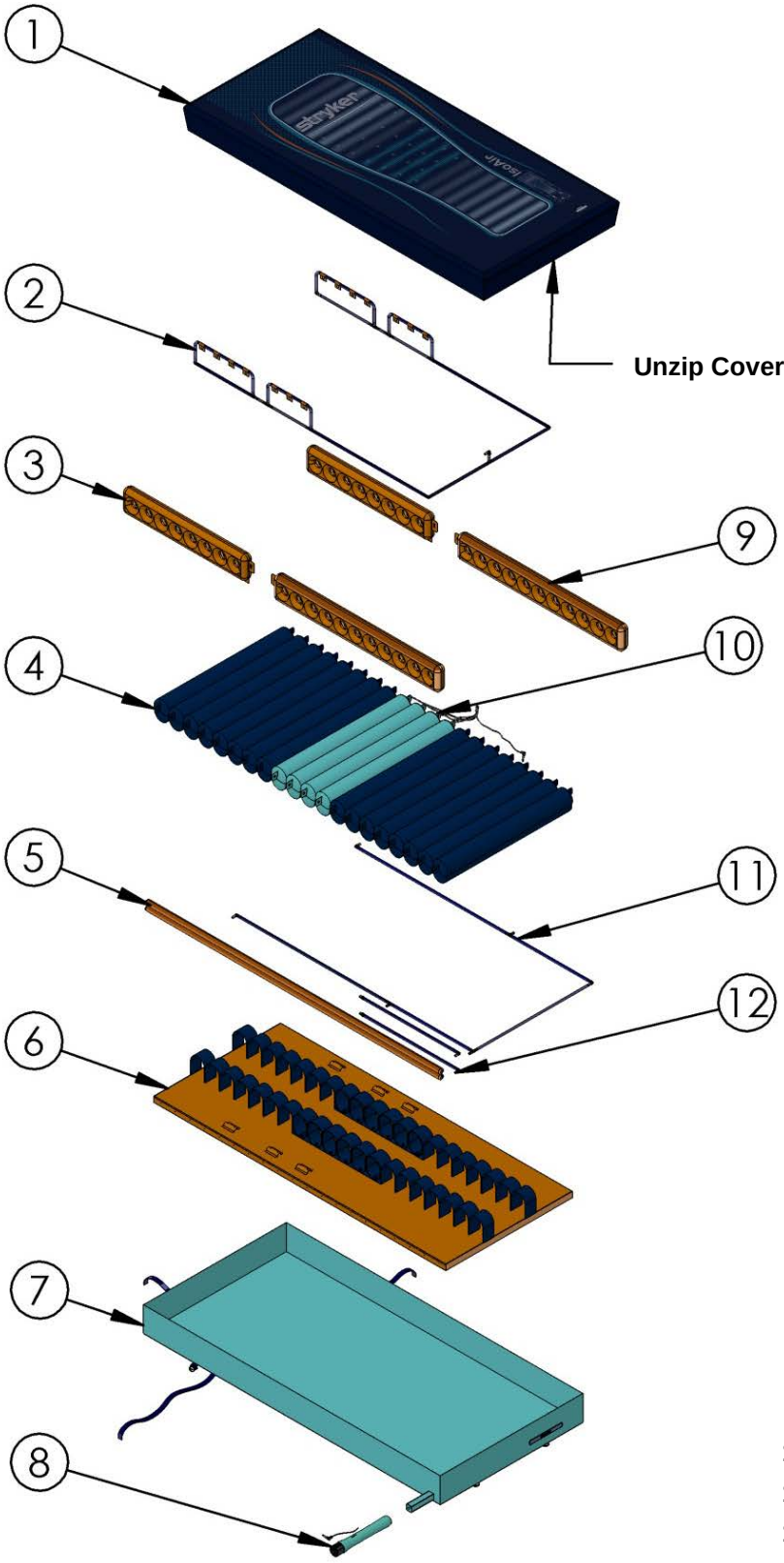
The location of features and connections on the Support Surface are presented below. Please refer to these during installation, set up and operation of the Support Surface.



1 COVERLET
2 STRAP HANDLES (FOOT END SHOWN)
3 CPR CONNECTOR
4 AST CABLE
5 TIE DOWN STRAPS

⚠ The Mattress includes straps at the bottom center (not shown) that are intended for storage use. Do not use these to tie the Mattress to the bedframe. May result in equipment damage.

7.0”AIR CELL (AIR/FOAM) SUPPORT SURFACE



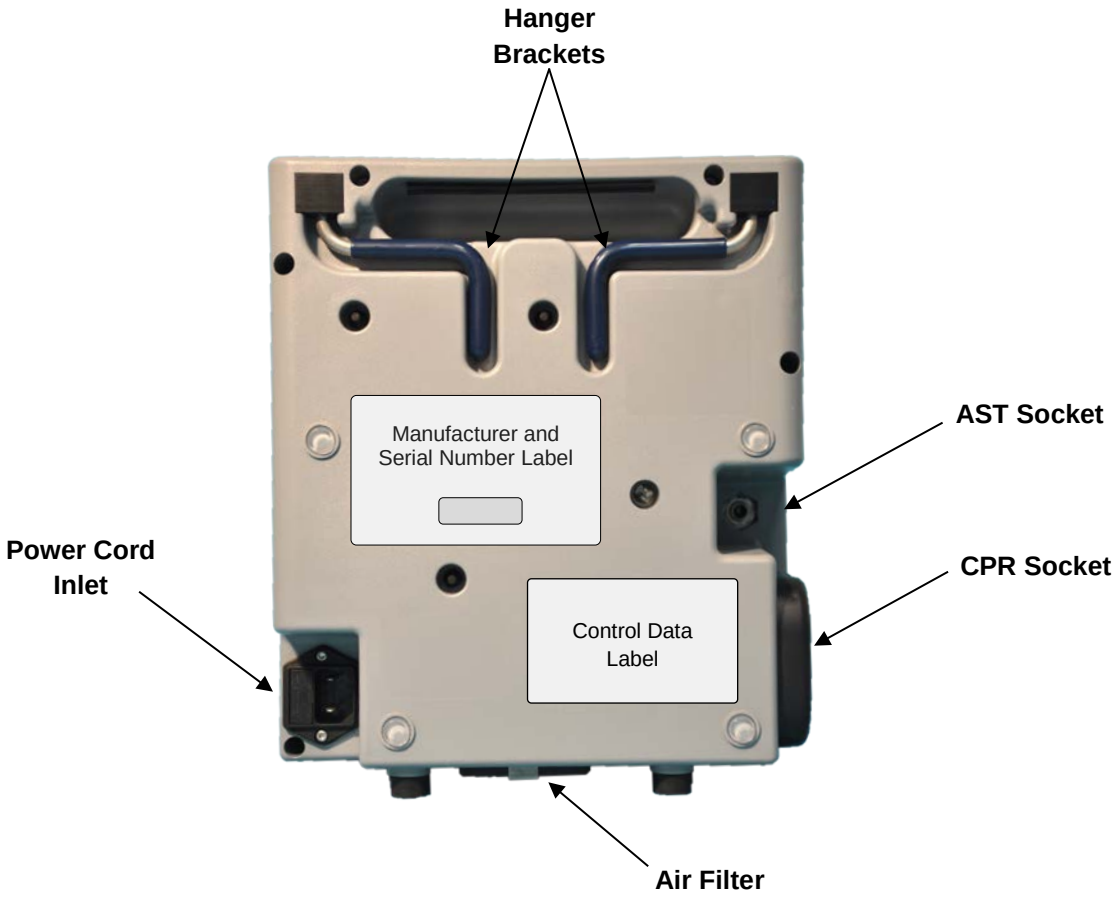
1. **COVERLET ASSEMBLY**
2. **MM HOSE ASSEMBLY**
3. **HEAD BOLSTER**
4. **NON-AST AIR CELLS**
5. **MANIFOLD**
6. **LOOP ASSEMBLY**
7. **SHELL ASSEMBLY**
8. **CPR ASSEMBLY**
9. **FOOT BOLSTER**
10. **AST AIR CELL PACK**
11. **BOLSTER HOSE ASSEMBLY**
12. **MANIFOLD HOSE ASSEMBLY**

Pump Assembly

The location of features and connections on the Pump are presented below. Please refer to these during installation, set up and operation of the Pump.

FRONT VIEW

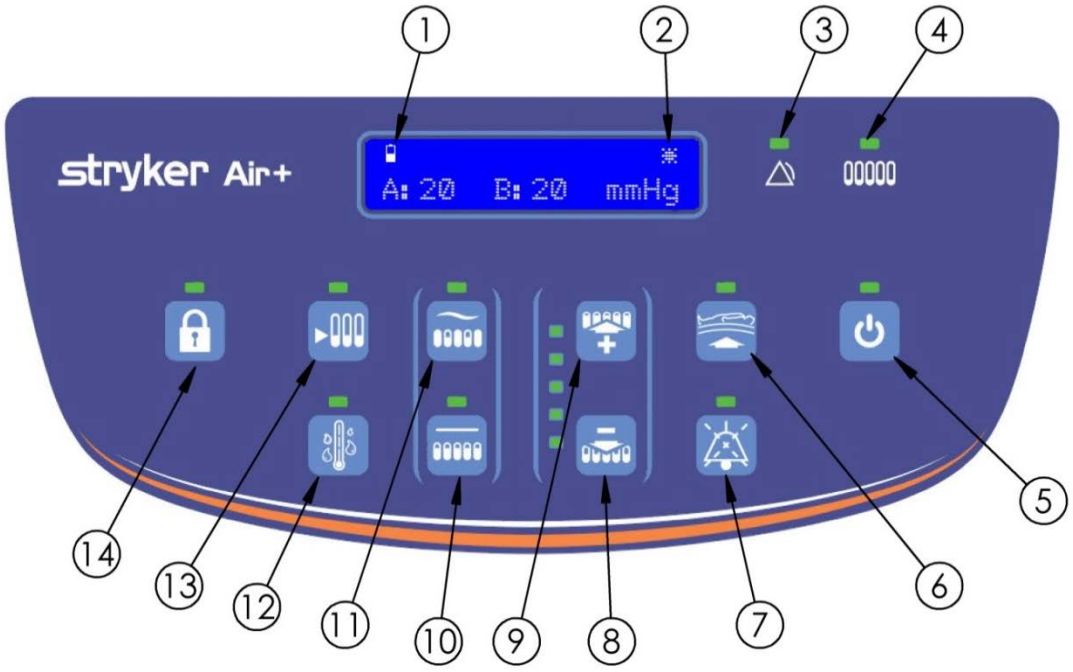
BACK VIEW



Pump Controls & Indicators

CONTROL PANEL

The Control Panel of the Pump is shown in the picture below.



1	Battery Alert	8	Pressure Up (Increase)
2	AST Contact Indicator	9	Pressure Down (Decrease)
3	Alarm Signal Indicator	10	Pressure Redistribution (Static) Mode
4	Pressure Alarm Indicator	11	ALP Mode
5	Power	12	MM Mode
6	MAX Inflate	13	AST Mode
7	Alarm Silence	14	Lock

LCD ICONS

1. **BATTERY ALERT**
   If there is a fault detected in the Battery charging circuit, or the battery charge is below the acceptable range the Battery Alert icon will appear in the upper left corner of the LCD. This will not affect the operation of the system unless there is a Power Fail condition.

2. **AST CONTACT INDICATOR**
   When the system is in AST mode and the AST Sensor is in contact, and asterisk (*) will appear in the upper right corner of the LCD.

LEDs

As shown above, each key has a corresponding LED that is lit if the key is selected. Additionally, two other LED's provide information related to the Pump.

3. **ALARM SIGNAL INDICATOR**
   The Pump is equipped with an Alarm Signal Indicator which flashes to alert the user that an alarm is active and requires resolution before continuing use (See **Pages 31-32,** Alarms and Alert Indications).

4. **PRESSURE ALARM INDICATOR**
   The Pump is equipped with a Pressure Indicator LED to alert the user that the actual pressure is out of the specified range (See **Pages 31-32,** Alarms and Alert Indications).

Pump Controls & Indicators

KEY FUNCTIONS
The control panel has ten (10) keys as shown in the picture above: Each key will light up the associated LED indicator(s) when activated.

5. **POWER**
   Turns Pump ON or to STANDBY. When Unit is plugged in and in STANDBY, the LED indicator is white. When the Unit is ON, the LED indicator is green.

6. **MAX INFLATE**
   Activates Max Inflate override mode.

7. **ALARM SILENCE**
   Stops ALARM sound.

8. **PRESSURE UP**
   Increases Pressure setting in 5 mmHg Increments (Illuminated LED indicators increase with each key press).

9. **PRESSURE DOWN**
   Decreases Pressure setting in 5 mmHg Decrements (Illuminated LED indicators decrease with each key press).

10. **PRESSURE REDISTRIBUTION (STATIC)**
    Activates Pressure Redistribution therapy mode.

11. **ALP**
    Activates ALP therapy mode.

12. **MM**
    Activates Moisture Management supplementary therapy mode.

13. **AST**
    Activates AST therapy mode.

14. **LOCK**
    Locks settings and prevents keys from functioning.

.

Pump Controls & Indicators

PUMP FUNCTIONS:

ALARM FUNCTION

The Pump is equipped with a flashing/audible alarm to alert the user that the actual pressure is out of the specified range. This typically indicates a leak or a kinked hose and requires resolution before continuing use (See **Page 29**), Troubleshooting Guide and Alarm Priority Table).

LOCK FUNCTION

Pressing and holding the **LOCK** Key for three (3) seconds will lock the current settings to avoid unintended changes. Pressing and holding the **LOCK** Key for three (3) seconds again will allow setting(s) to be changed. Note, LOCK function does not lock the ALARM SILENCE function.

ALARM SILENCE FUNCTION

Pressing the **ALARM SILENCE** Key disables Alarm sounds for 10 minutes. Note that this only affects currently active alarms, it cannot be used to silence possible future alarms.

PRESSURE UP FUNCTION

Pressing the **PRESSURE UP** Key will increase the pressure level from 1 to 5 (from 10 to 30 mmHg) while in Pressure Redistribution or ALP modes.

PRESSURE DOWN FUNCTION

Pressing the **PRESSURE DOWN** Key will decrease the pressure level between 5 and 1 (from 30 to 10 mmHg) while in Pressure Redistribution or ALP modes.

MAX INFLATE FUNCTION

MAX INFATE is used for any procedure in which a firm surface is required. Pressing the **MAX INFLATE** Key activates the Max Inflate override mode. The Max Inflate override mode inflates all cells to maximum pressure and disables manual adjustment of cell pressure (**PRESSURE UP** and **PRESSURE DOWN** Keys will be inoperable while this mode is active). The cells will remain inflated to maximum pressure for 15 minutes. A countdown timer is displayed on the display, indicating the time remaining in Max Inflate override mode. An alert tone is emitted when the Max Inflate override mode times out.

While the Max Inflate override mode is active, activating either main therapy mode (via the **ALP** or **PRESSURE REDISTRIBUTION** Keys) will disable Max Inflate override mode.
Pressing the **AST** key does not affect the MAX Inflate operation.

After Max Inflate override mode times out or is disabled, the Pump resumes operation based on the therapy mode setting and pressure settings in effect prior to initiating the Max Inflate Override mode.

PRESSURE REDISTRIBUTION (STATIC) FUNCTION

Pressing the Pressure Redistribution Key activates the Pressure Redistribution therapy mode, which keeps all cells at constant pressure and allows for manual adjustment of cell pressure (**PRESSURE UP** and **PRESSURE DOWN** Keys will function normally while this mode is active). Activating MAX INFLATE or ALP mode (via their respective Keys) will disable Pressure Redistribution therapy mode.

ALP FUNCTION

Pressing the **ALP** Key activates the ALP therapy mode, which alternately inflates and deflates cells to relieve pressure and allows for manual adjustment of cell pressure (**PRESSURE UP** and **PRESSURE DOWN** Keys will function normally while this mode is active). Activating MAX INFLATE or Pressure Redistribution (Static) mode (via their respective Keys) will disable ALP therapy mode.

AST FUNCTION

Pressing the **AST** Key activates the AST mode. AST mode works to automatically adjust air cell pressures to control patient immersion. Enabling AST disables manual adjustment of cell pressures (**PRESSURE UP** and **PRESSURE DOWN** Keys will be inoperable while this mode is active). AST mode can be active while either Pressure Redistribution or ALP mode is active. Activating Max Inflate mode (via the **MAX INFLATE** Key) will disable AST mode.

MM FUNCTION

Pressing the **MM** Key activates the Moisture Management therapy mode. Moisture Management mode can be active while any other mode is active (AST, ALP, Pressure Redistribution, or Max Inflate), and will only be disabled by pressing the **MM** Key a second time.

LCD DISPLAY

The following information is displayed on the LCD Display:

AIR CELL PRESSURE

Measured pressure values for Zone A and Zone B air cells are displayed in mmHg.

HOUR METER

When the **ALARM SILENCE** key is pressed for more than 3 seconds, the accrued time for hours of operation will be displayed for 30 seconds.

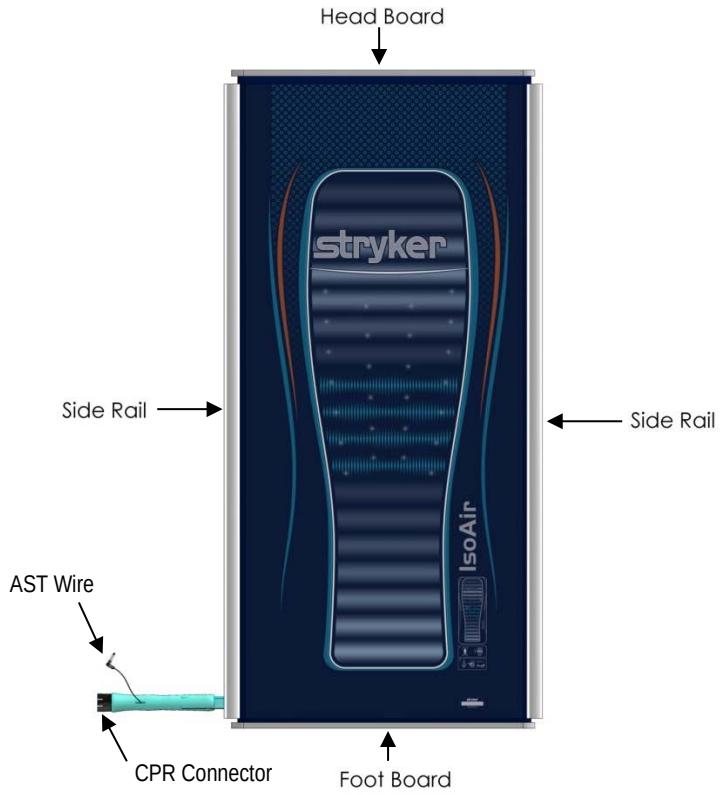
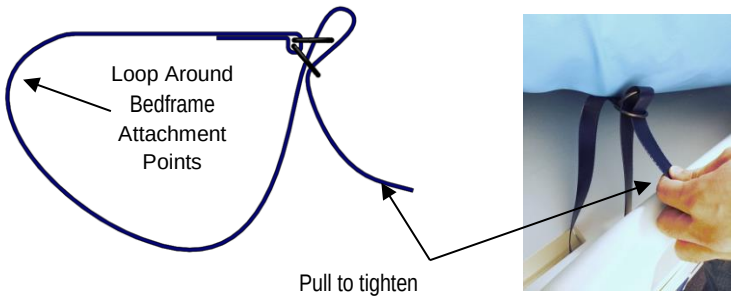
MAX INFLATE COUNTDOWN TIMER

While the MAX INFLATE function is active a countdown timer will be displayed. The countdown timer will indicate the fifteen (15) minute countdown for the MAX INFLATE function. If the MAX INFLATE function is deactivated, the countdown timer is removed from the display.

Installation & Operation Procedures

Follow the procedures below for the installation and operation of the Pump and Support Surface:

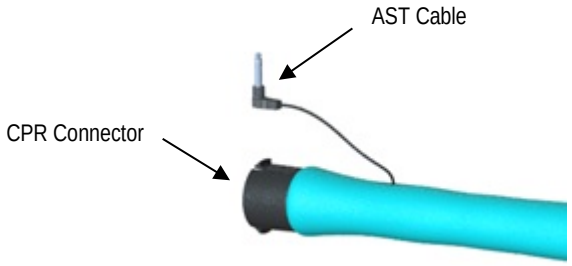
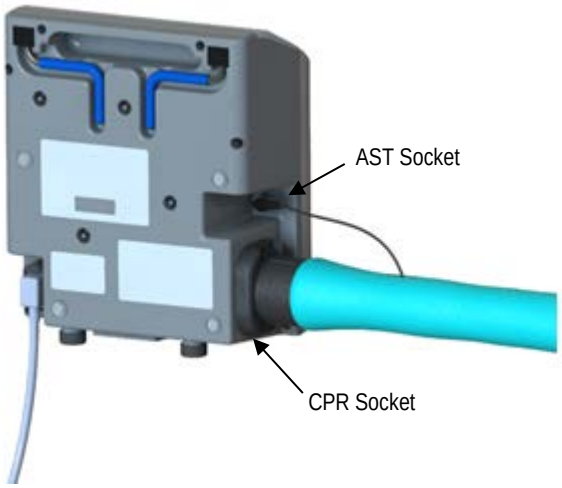
INSTALLATION OF SUPPORT SURFACE:

Procedure	Cautions & Warnings
1. Ensure that the support surface properly fits the bed frame on which it is being placed.  2. The support surface is designed to be used with a non-fitted sheet. Do not pull linens too tight over the product to avoid the hammock effect that will ~~and~~ reduce the effectiveness of the product. 3. Secure the support surface to the bedframe using the straps provided.  4. Before attempting to inflate the support surface, unzip the cover and ensure that all of the air cells, especially the four AST sensor cells (the light blue cells in the center section) are upright, and free to rotate within their retaining loops.	⚠ – To avoid risk of severe injury, properly secure support surface to the frame according to the instructions for use. – Support surface handles are not intended to carry patient. – The risk of entrapment can develop when the support surface is placed on bed frames that leave gaps of even a few inches between the support surface and the headboard, footboard, and side rails. The support surface is not to be used when such gaps are present. – To avoid the risk of patient injury, do not use the support surface on a bed frame of a larger or smaller size than the stated size as this may cause the support surface to slide. – Ensure that all side rails are fully latched when in the raised position. Failure to do so could result in serious injury or death including patient fails. ⚠ – To avoid the risk of equipment damage, do not put accessories inside the coverlet or on top of the support surface. Doing so may reduce pressure redistribution performance. – Use care when using sharp objects, such as needles, as these can damage the air cells in the support surface.

INSTALATION OF PUMP:

Procedure	Cautions & Warnings
1. The Pump is equipped with a detachable power cord. To apply power, the cord must be attached to the Pump and an electrical outlet. To disconnect power, the cord may be detached from either the Pump or the outlet. 2. Determine which electrical outlet you will use for the Pump. Use the short cord to connect to an outlet on the bed frame; use the long cord to connect to a wall outlet. 3. Insert the power cord into the Pump Power Inlet.  4. Hang the Pump on the foot panel of the bed.  5. If you are using a wall outlet, stretch the power cord beneath the bed to an outlet at the head end of the bed, making sure the cord is out of the way. Use the long (15ft) power cord provided. 6. If you are installing the support surface on a Stryker bed frame equipped with an outlet, use the optional power outlet located under the foot end of the frame and the short (3ft) power cord provided. Consult the bed frame manual for the location of the outlet.	⚠ – When hanging the Pump on the foot board, ensure the hangers are seated as they are not spring loaded and may come dislodged if not properly hung. – The Pump hangers are not intended to be in patient contact. Extended patient contact with the Pump hangers may cause injury. – Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen-rich environments. Risk of explosion. – Exposure of the electronic Pump to any liquid while it is plugged in could result in a severe electrical hazard. – The Pump radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. – Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base station, walkie-talkies can affect this equipment. Place equipment a minimum distance from wireless communication devices as defined on Page 46. – To avoid risk of injury do not place objects on the surface of the Pump. – Risk of asphyxiation due to entanglement with cords. Route cord under bed frame. – Power cord may cause tripping hazard. Route cord under bed frame. – Before plugging in the Pump, check power cord for damage, e.g. cuts, exposed wires, worn insulation, etc. If hazards are present, take the Pump out of operation immediately and contact Customer Service – Orient power cord so that it is not difficult to disconnect. ⚠ – After exposure to extreme high or low temperatures, allow the Pump to equilibrate for at least one (1) hour before operating.

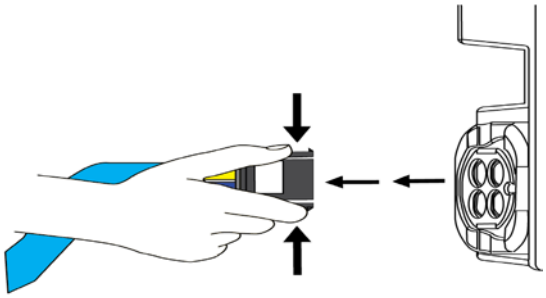
CONNECTING THE SUPPORT SURFACE TO THE PUMP:

Procedure	Cautions & Warnings
1. Locate the CPR Connector and the AST Cable at the end of the hose sleeve on the suport surface. The CPR Connector and AST Cable are shown below.  2. Firmly push the CPR Connector into the mating CPR Socket on the Pump, and connect the AST Cable to the AST Socket on the Pump.  	⚠ – The AST cable-ONLY connects to the AST Socket. Connecting it anywhere else may result in severe electrical shock. – The hose sleeve is a safety feature; do not operate the equipment without the sleeve in place. – Risk of asphyxiation due to entanglement with hoses. Ensure hose sleeve is correctly installed. – Risk of entanglement if hose sleeve is not secured to the back plate of the CPR connector. – Before plugging in the Pump, check the power cord for electrical hazards, e.g. cuts, exposed wires, worn insulation, etc. If hazards are present, take the Pump out of operation immediately and contact Customer Service. (See Page 9 for Contact Information). – Improper use, or handling, of the power cord could result in damage. If damage has occurred to the power cord, do not use and call qualified maintenance personnel for replacement (See Parts list on Page 44). To avoid risk of electric shock use approved power cords only. – The power cord to the Pump should be positioned to avoid a tripping and strangulation hazard and/or damage to the cord. Stryker recommends placing the cord under the bed frame and plugging it into an electrical outlet by the head end of the bed, or the integral electric outlet on the bed. – Orient power cord so that it is not difficult to disconnect. – Risk of asphyxiation due to entanglement with cords. Route cord under bed frame.

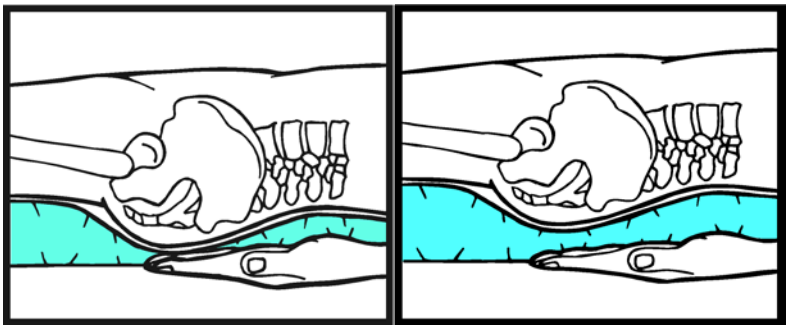
PUMP OPERATION:

Procedure	Cautions & Warnings
1. While standing in front of the Pump, press the POWER key located on the Control Panel to turn the Pump ON. Listen for a "Key-Click" sound to verify operation of audio-alarm system. If Pump lights do not come on, see Troubleshooting Page 29. NOTE! When powered on, the Pump will revert to the previous MODE and PRESSURE settings. 2. PRESSURE REDISTRIBUTION Mode: Press the Pressure Redistribution MODE key. The LED will illuminate and the Pump will start inflating the support surface. The support surface will inflate in approximately 10 minutes. Start with the MAX INFLATE setting. 3. Pressure Adjustment: The Pump is capable of adjusting the cushion pressure to five set points over a range of 10 to 30 mmHg. The five set points can be adjusted directly by the PRESSURE UP Key and the PRESSURE DOWN Key, which will increase and decrease the pressure of the cells, respectively. 4. ALP Mode: To activate the ALP therapy mode press the ALP key. ALP Therapy Mode will alternately inflate and deflate the cells in the support surface at three minute intervals. To deactivate ALP therapy mode, press the PRESSURE REDISTRIBUTION key to change to Pressure Redistribution Mode. 5. MM Function: To activate the MM function, press the MM key. The MM function provides a constant stream of air between the support surface and the coverlet to keep the patient dry. To deactivate the MM function, press the MM key again. 6. AST Function: To activate the AST function, press the AST Key. The AST function disables manual adjustment of the pressure setting. To deactivate the AST function press the MANUAL key. 7. MAX INFLATE Function: To activate the MAX INFLATE function press the MAX INFLATE key. The MAX INFLATE function will inflate all cells in the support surface to the maximum pressure. Manual adjustment of pressure settings is not allowed in MAX INFLATE mode. The MAX INFLATE function is intended to be used when the mattress should not be moving, such as when the patient is entering or leaving the bed, or a procedure is being performed on the patient. MAX INFLATE mode will last for 15 minutes. At the completion of MAX INFLATE time or if MAX INFLATE is deactivated, the system will automatically revert to the mode and pressure settings previously selected. While the MAX INFLATE mode is active, a countdown timer, indicating the time remaining in MAX INFLATE mode, will be displayed. To deactivate MAX INFLATE prior to the automatic deactivation, press the MAX INFLATE key, or initiate ALP or PRESSURE REDISTRIBUTION therapy modes. 8. LOCK Function: To prevent inadvertent changes of the Pump settings, the control panel can be locked by pressing and holding the LOCK key for three (3) seconds. When the control panel is locked, the LOCK LED will be illuminated. While the control panel is locked, pressing any other key, except the LOCK key and Alarm Silence key will result in a LOCK Alert being generated.	 – If "Key-Click" sound is not heard, DO NOT use the Pump. – Pressure in support surface is under automated control and may adjust without notice. Use care when performing medical procedures on patient. – AC mains power must be connected to provide therapy. If power is lost, therapy provided will be discontinued. – Do not use multiple socket outlets or extensions. This may result in an electrical hazard.  – The Pump is a precision electronic product. Use care when handling or transporting. Dropping, or other sudden impacts, may result in damage to the Pump. – After exposure to extreme high or low temperatures, allow the Pump to equilibrate for at least one (1) hour before operating. – The Pump circulates room air during operation. Exposure to smoke may cause the Pump to fail. Therefore, smoking by patients, or visitors, while using this product is contraindicated. – To ensure optimal performance electrical-safety testing of your Pump should be performed at least annually. Contact Customer Service, Page 9, for service information. – Do not leave children and pets unattended while the IsoAir™ System is in use. They may damage the system that may cause bodily harm to themselves and/or the patient. – Check the system and surrounding area for pests that may damage the system causing harm to the patient.

CPR ACTIVATION:

Procedure	Cautions & Warnings
Disconnect hose from the Pump by pushing in the TABS on the CPR Connector and pulling the connector away from the Pump. 	⚠ – Initiate deflation of the Support Surface before starting CPR. Failure to do so may result in ineffective CPR.

PRESSURE ADJUSTMENT CHECK:

Procedure	Cautions & Warnings
1. To ensure the patient is getting the proper therapy, periodically use HAND CHECKS to check for proper inflation. 2. When the mattress is in the Manual Mode a HAND CHECK should be performed to establish the correct pressure setting. Perform a HAND CHECK whenever the patient is repositioned. Underinflated: Properly Inflated:  3. Slide your hand, palm up, with fingers flat, between the bed surface and the mattress at the patient's lower back or hip. NOTE! Do not lean on the product or lift at the side as these actions can lead to false readings. Adjust the pressure setpoint until you can no longer feel the patient's lower back or hip. If you can feel the bony prominence inflate the product using the PRESSURE UP key on the Pump. Wait two minutes and repeat the HAND CHECK until you have adequate inflation.	– It is the responsibility of the operator to monitor the patient and the patient's skin condition at regular intervals, per hospital protocols, to ensure patient safety and proper support surface performance. Consult a physician if erythema or skin breakdown occurs.

PATIENT HANDLING:

Procedure	Cautions & Warnings
TRANSFERRING A PATIENT FROM ONE SUPPORT PLATFORM TO ANOTHER: 1.To transfer a patient from one support platform to another, e.g. bed frame, stretcher, gurney, operating table: 2. Prerequisites: Two operators will be required for this task. 1) Position the patient along the center line of the support surface. 2) It is recommended that the surface be placed in MAX INFLATE mode, unless ohterwise contraindicated. 3) Position the patient support platforms alongside each other, as closely as possible. 4) Set the brakes to “ON” for both support platforms. Ensure that the two support surfaces are level with each other. 5) Raise the bed side rail located opposite the patient transfer. Move ONLY the patient. DO NOT attempt to move the IsoAir™ surface with a patient on it.	⚠ – To avoid the risk of patient injury, do not transfer the patient from one bed to another using the support surface with a patient on it. – To avoid the risk of patient and equipment damage, do not use the support surface straps to lift or move the support surface with a patient on it. – To avoid the risk of patient and operator injury, a minimum of two (2) operators is required when transferring a patient. Operators need to be positioned so that they can control patient positioning. – To avoid the risk of patient injury, ensure the opposite side rail is raised when placing a patient on the support surface.
TRANSPORTING A PATIENT ON THE ISOAIR™ SYSTEM: 1. To transport the patient while he/she is on the IsoAir™ System perform the following steps – 1) Adjust the bed and mattress to the desired transport position. 2) Allow the pressures to stabilize. 3) Press POWER key to place Pump into Standby. 4) Unplug the Pump power cord (unless plugged into bedframe power outlet). 5) Secure the power cord to avoid rolling the bed frame over it and to eliminate tripping hazard. 6) Transport patient to the desired location. 7) Plug the power cord into a power outlet. 8) Press POWER key to turn Pump back on. 2 The system will resume the previous modes and settings. NOTE! While the IsoAir™ System is not plugged in, a power fail condition exists. The system will not deflate for at least two hours.	⚠ – To avoid the risk of patient injury, ensure both side rails are raised when transporting the patient. – Power cord may cause tripping hazard. Secure to bed frame prior to initiating transport.

INCONTINENCE / DRAINAGE

This support surface is NOT intended to manage incontinence. Therefore, it is recommended to use incontinence management devices when appropriate. Disposable diapers or incontinence pads may be used. Ensure appropriate skin care is provided following each episode.

Troubleshooting Guide

Condition	Problem	Recommended Action
Stuck Key	- An audible alarm is present - The ALARM LED is blinking - The LED for one of the Keys is flashing (identifying the Stuck Key)	– Press and release the key with the flashing LED to clear the stuck key. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
AST Connection	- An audible alarm is present - The ALARM LED is blinking - The AST LED is blinking	– Check that the AST plug is completely inserted into the AST socket. – Toggle the AST key (OFF/ON) to see if condition clears. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
AST Sensor	If the AST Sensor remains in contact for more than 15 minutes while operating in AST mode: - An audible alarm is present - The ALARM LED is blinking - The AST Key LED is blinking and Pressure Indicator LED is blinking	– If patient is in fowler, reduce HOB angle. – Unzip cover and check that AST air cells are correctly positioned underneath patient. – Perform a hand check to ensure that the patient is not bottoming out. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
Pressure Alarm	A high or low air pressure condition exists; an air cell pressure is outside the allowable range. - An audible alarm is present - The ALARM LED is blinking - The Pressure LED is blinking	– Check that the CPR connector is correctly plugged into the Pump. – Check for kinks in hoses from the CPR connector to the support surface. – Unzip the top cover. Reach inside the support surface and check air cells, hoses and connections for possible leaks. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
MM Low Flow (Low Air Loss)	The MM air flow is below the minimum expected threshold for 5 seconds. - An audible alarm is present - The ALARM LED is blinking - The MM LED is blinking - The Pressure LED is blinking	– Check the CPR hose bundle is free from pinches – Unzip the top cover. Check for air flow blockage by following the MM hoses inside the support surface (See Page 16). – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
System Error	In the event of a hardware failure: - An audible alarm is present - The ALARM LED flashing - The LCD backlight is blinking	– Cycle the power. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.

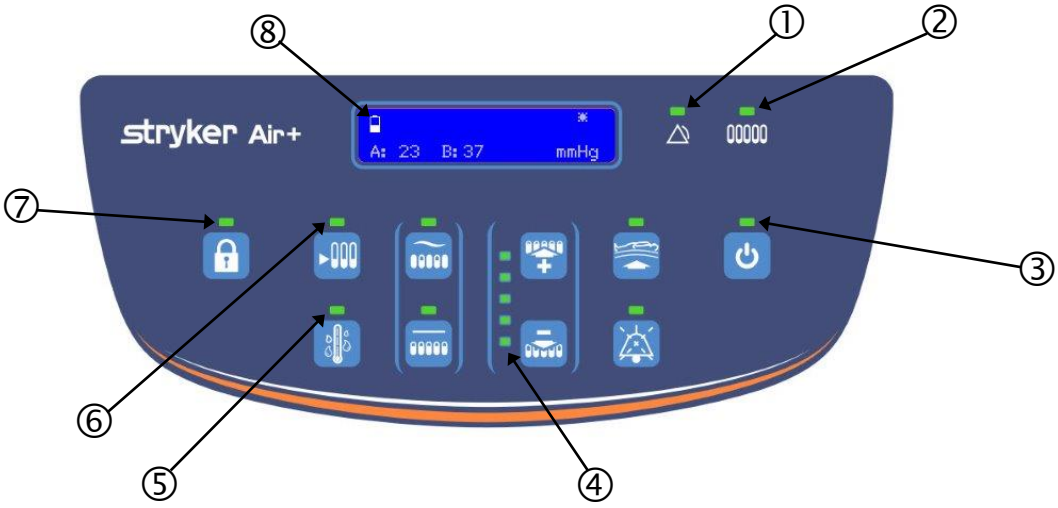
Troubleshooting Guide (Continued)

Condition	Problem	Recommended Action
Power Fail	May be caused by: - AC power outage - disconnected power cord - blown fuse - internal damage	– Make sure the power cord is plugged in, AC power is ON and the Power LED is lit (white for standby, green for unit turned on). – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
Pump Does Not Turn On	May be caused by: - AC power outage - disconnected power cord - blown fuse - internal damage - Power On “stuck key”	– Make sure the power cord is plugged in, AC power is ON and the Power LED is lit (white for standby, green for unit turned on). – See recommended action for Keys not responding – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
Keys not responding	May be caused by: - LOCK function - Stuck Key	– Make sure the power cord is plugged in and the unit is turned ON (not in Standby). Power LED should be green. – Check LOCK key for activation. If the LOCK key indicator is ON, Press and hold the LOCK key for three seconds to deactivate. – In case of a Stuck Key, press and release key with the flashing LED to clear the stuck key. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
Support Surface does not inflate	May be caused by: - the Pump not being plugged into a power outlet - The unit being in Standby (Power LED is white), but not turned ON (Power LED is green) - internal damage or failure	– Make sure the power cord is plugged in and the unit is turned ON (not in Standby). Power LED should be green. – Check that the CPR hose is properly connected. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
Air Leak	- If the support surface is not fully inflated in 15 minutes it may indicate an air leak.	– Check that the CPR hose connector is properly attached to the Pump. – Check the CPR hose bundle for possible damage – Unzip the top cover and check the air cells and tubing for air leaks. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.
Battery Alert Icon appears on LCD display	- Battery charge is low	– Ensure power is connected for at least five hours. – If condition persists contact Stryker Customer Technical Support Page 9, or authorized service personnel.

Alarm and Alert Indicators

All alarms are indicated by a flashing LED and accompanied by an audible alarm. Only the highest priority alarm is sounded.

ALARM & ALERTS LEDs



1	Alarm	5	MM
2	Pressure	6	AST
3	Power	7	Lock
4	Manual Pressure Level	8	Battery Alert Icon

ALARM PRIORITY AND CAUSE TABLE

Alarm[1]	Notification Priority	Cause	Alarm May Stop If:
Power Fail	1	The Pump is not receiving electricity.	– The system is turned off OR – Power is applied
Hardware Failure	2	The Pump has detected one of the internal hardware faults listed below: - Problem with the reading/writing operation of the parameters for Pressure Calibration, User Settings, User Timers or an invalid Hour Meter reading has been detected. - Failure of clock electronics - Failure of LCD electronics - Failure of LED electronics - Failure of Audio electronics - Failure of compressor electronics - Problem with power supply voltage levels	– The system is powered off OR – The condition is corrected
Stuck Key	3	The Pump has detected that a key has been continuously activated for more than 15 seconds	– The system is powered off OR – The condition is corrected
AST Connection Error	4	The Pump has detected that either the AST cable is disconnected or there is an electrical failure in the support surface for 1 second	– The system is powered off OR – Max Inflate is turned on OR – AST Connection has been restored
AST Sensor	4	Patient contact activates the AST Sensor for more than 15 minutes while operating in AST mode	– The system is powered off OR – Max Inflate is turned on OR – No contact is detected for 5 seconds
Pressure Alarm	5	The system has been turned on for more than 15 minutes AND A high or low pressure condition exists in any support cell for 10 minutes OR a low pressure condition exists in the bolster for 10 minutes	– The system is powered off OR – Pressure returns to the specified range for 5 seconds
MM Low Flow	6	The Manifold pressure is greater than > 65 mmHg for 5 seconds.	– The system is powered off OR – MM Mode is turned off OR – The manifold pressure is below 60 mmHg for 5 seconds

1 - All alarms are classified as Medium Priority per *IEC 60601-1-8*.

Alarm and Alert Indicators

ALARM and ALERT INDICATIONS TABLE

Alarm/ Alert[1]	LCD Display	Control Panel Indicator					
		Alarm Signal LED	Pressure Indicator LED	Power LED	AST LED	Lock LED	MM LED
Power Fail	N/A	Blinking[2]	Off	Blinking	Off	Off	Off
Hardware Failure	Blinking	Blinking	N/A	N/A	N/A	N/A	N/A
Stuck Key	N/A	Blinking	N/A	Flashes[3] the LED for the Stuck Key			
AST Connection Error	N/A	Blinking	N/A	N/A	Blinking	N/A	N/A
AST Sensor	N/A	Blinking	Blinking	N/A	Blinking	N/A	N/A
Pressure Alarm	N/A	Blinking	Blinking	N/A	N/A	N/A	N/A
MM Low Flow	N/A	Blinking	Blinking	N/A	N/A	N/A	Blinking
Lock Alert	N/A	N/A	N/A	N/A	N/A	Flashing	N/A
Battery Alert	Battery Icon ON	N/A	N/A	N/A	N/A	N/A	N/A

1 - All alarms are classified as Medium Priority per *IEC 60601-1-8*

2 - Blinking = every 2 seconds

3 - Flashing = 10 times per second

OPERATORS POSITION

The operator is intended to be standing directly in front of the Pump during operation.

SILENCING AN ALARM

Pressing the **ALARM SILENCE** Key disables Alarm sounds. The **ALARM SILENCE** LED will be on.
The ALARM SILENCE will end if any of the following conditions occur:

- The power fails or the cord is disconnected
- 10 minutes have elapsed since an alarm was silenced
- No alarms are active
- The ALARM SILENCE key is pressed again
- The Power key is pressed

Power Failure

POWER FAIL CONDITIONS

A power fail condition can occur under three cases:

- Plug detached from the power outlet
- Power outage has occurred
- Fuse has blown

OPERATION DURING POWER FAILURE

During a power fail condition, the LCD is off, the Alarm and Power LEDs are blinking, and the air cells will not inflate/deflate (no therapy will be delivered). During this time, the air cells will remain inflated for at least two (2) hours.

SHORT POWER INTERRUPTIONS

All therapy modes, pressures and settings are retained after a power fail condition that lasts less than 30 seconds.

If the power fail condition lasts for more than 30 seconds the system saves all settings and therapy modes, with the exception of Max Inflate.

The system will return to normal operation after any power failure that lasts less than 30 minutes.

EXTENDED POWER INTERRUPTIONS

If the power failure lasts for more than 30 minutes, the audio and visual power fail indications will stop and the Pump will power off.

If power is restored after thirty (30) minutes, the system will return to the state it was in prior to the power interruption. Therapy mode and settings are retained.

Cleaning and Disinfection

CLEANING / DISINFECTION OF THE PUMP

The exterior of the Pump and Hosing Assembly should be wiped down between patients. Always inspect Pump components during Preventive Maintenance (**Page 40**) and replace as necessary.

- Disinfect the Pump and Surface between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.
- When disinfecting is required, check disinfectant manufacturer's instructions before use, and use disinfectant and personal protective equipment in accordance with the manufacturer's instructions.
- All disinfection should be done using a "hospital-grade" disinfectant.
- DO NOT spray disinfectant directly on the electrical Pump, or immerse the Pump in any type of liquid. This could result in a severe electrical hazard.
- Check patient medical history for allergies to the Suggested Disinfectants listed below.

SUGGESTED DISINFECTANTS

- Quaternary Cleaners
- Phenolic Cleaners
- Chlorinated Bleach Solution (5.25% bleach diluted 1 part bleach to 10 parts water)
- 70% Isopropyl Alcohol
- Accelerated Hydrogen Peroxide (AHP)

PROCEDURE

1. Unplug the power cord prior to cleaning/disinfecting.
2. Dampen a clean cloth with disinfectant according to manufacturer's recommendations.
3. Wipe down the Pump and Hosing Assembly removing any foreign material/fluid/dirt.
4. Dry completely before using the Pump.

- DO NOT autoclave the Pump OR the Hosing Assembly. Equipment damage could occur.
- Unplug Pump from its source prior to cleaning. Failure to do so may result in an electrical hazard.
- Do not use harsh cleansers, solvents, or detergents on the Pump/Surface. Equipment damage could occur.

Cleaning and Disinfection

CLEANING / DISINFECTION OF THE SUPPORT SURFACE

The useful life of the support surface components (shell, air cells & coverlet) may be shortened by the number of times it is cleaned/disinfected. The number of cleanings/disinfections is “patient-dependent” and it is the responsibility of the caregiver to ensure the support surface is clean and sanitary for the patient, including determining the frequency of cleaning/disinfection. Generally, the presence of foreign material/fluids/odors would indicate the need to clean/disinfect the surface. Always inspect Surface components during Preventive Maintenance (**Page 39**) and replace as necessary.

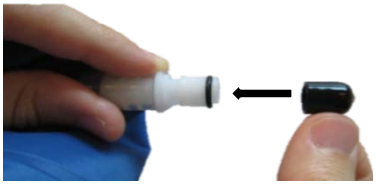
- Disinfect the Pump and Surface between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.
- When disinfecting is required, check disinfectant manufacturer’s instructions before use, and use disinfectant and personal protective equipment in accordance with the manufacturer’s instructions.
- To avoid the risk of equipment damage, do not immerse support surface in cleaning or disinfectant solutions.
- Do not allow liquid to pool on the support surface.
- Use Personal Protection Equipment to reduce likelihood of cross-contamination during cleaning.
- To avoid the risk of patient injury, coverlet and shell should be inspected for tears, punctures, excessive wear, and misaligned zippers each time the coverlets are cleaned. If a support surface coverlet becomes compromised, the support surface should be removed from service immediately and replaced to prevent cross-contamination.
- Check patient medical history for allergies to the suggested disinfectants listed on (**Page 34**).

PROCEDURE

The following procedure should be followed:

1. Using a clean, soft, damp cloth, wipe down the entire support surface with a mild soap and water solution to remove foreign material.
2. Wipe down the support surface with a clean, dry cloth to remove any excess liquid or cleaning agent.
3. Care must be taken to thoroughly rinse and dry coverlets following cleaning.
4. Disinfect with a hospital grade disinfectant AFTER cleaning has been completed. Refer to “Suggested Disinfectants” on **Page 34**.
5. **COVERLETS**: Coverlets can be machine washed and dried at a maximum water temperature of 70^{o}C using standard hospital grade laundry detergents. **DO NOT USE BLEACH WHEN LAUNDERING**. Coverlets can be air dried or machine dried at temperatures not to exceed 75^{o}C. Laundering can be performed up to 130 times over the life of the product.
6. **AIRCELLS**: Non-AST Air cells (dark blue without wires) can be laundered at a maximum water temperature of 60^{o}C using standard hospital grade laundry detergents. Do not use chlorine bleach. The air cells can be air dried or machine dried at a temperature not to exceed 60^{o}C. Air Cells may be laundered as many as 25 times over the life of the product.

- **AST sensor cells (light blue) can be wiped down, but not laundered. Equipment damage could occur.**
- Do not use harsh cleansers, solvents, or detergents on the Pump/Surface. Equipment damage could occur.
- To avoid the risk of equipment damage, when cleaning the underside of the support surface, ensure that no liquid is allowed to seep into the zipper area or under the watershed cover; fluids allowed to come in contact with the zipper may leak into the support surface.
- Cap the air cell connectors with the push-on vinyl cap (2940-002-062) as shown below before laundering. Failure to cap the connectors will lead to liquid ingress inside of the air cell and the risk of damage or mold growth through incomplete drying.



NOTE! If storing the Support Surface and/or Pump between uses, store according to Storage Conditions presented in the table on **Page 8**.

Service Information

For service and/or technical information other than specified in this manual, including fuse replacement, circuit diagrams and isolation of mains, see IsoAir Service Manual *AO-SM-70-SR*.

- There are no “user-serviceable” parts inside the Pump. Service should only be performed by authorized maintenance personnel only. Equipment damage could occur.
- Disinfect the Pump and Hosing Assembly between patient installations and before servicing, use standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.

- Do not service or perform maintenance while product is in use. May cause harm to the patient.
- Do not return a Pump for any reason without first contacting Customer Service to obtain authorization.
- Consult your local regulations to properly dispose of electronic equipment.
- Do not dispose of as unsorted municipal waste. See your local distributor for return or collection systems available in your country.

BATTERY

The battery is only for visual and audible alarming during power failure. It does not power the Pump for therapy purposes. It is not user-serviceable and must only be serviced by authorized service personnel. The typical service life of the battery is the life of the device. The system recharges the battery when the device is connected to a power outlet and power is available.

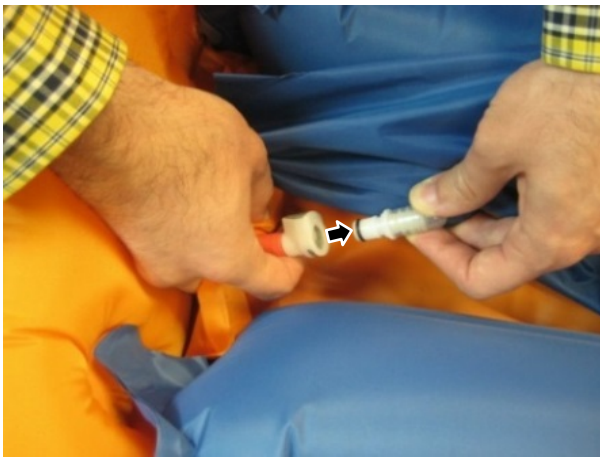
AIR CELL REPLACEMENT

Tools/Parts Required:

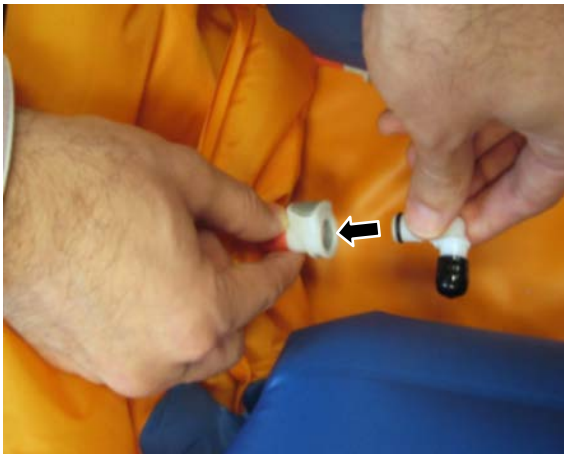
- Non-AST Aircell (2940-002-033)
- Quick Disconnect (2940-002-001)

Procedure:

1. Unzip and remove the coverlet.
2. Identify the air cell to be replaced.
3. Disconnect the air cell from the manifold connector.

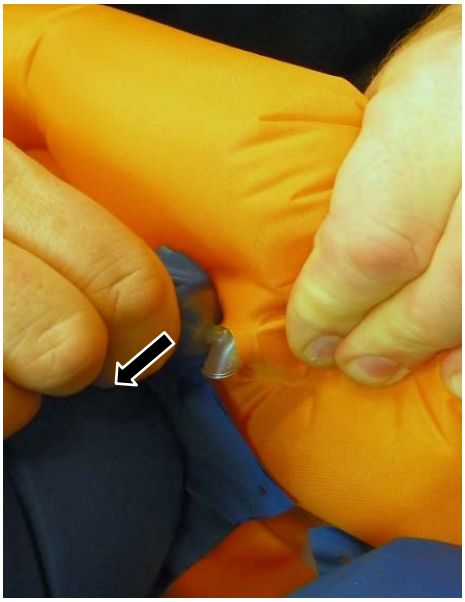


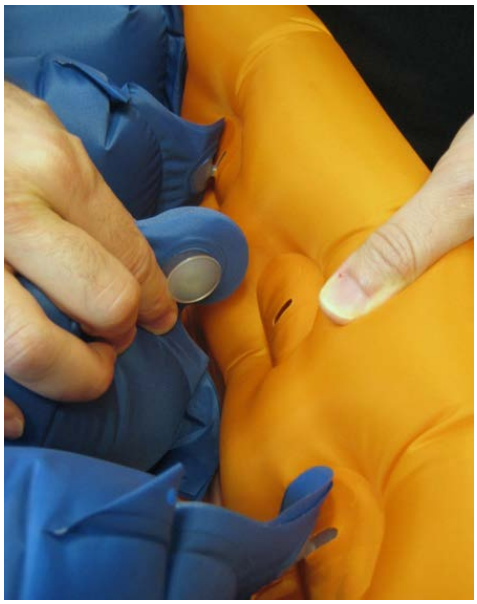
4. Cap the manifold connector (Quick Disconnect Caps are stored in the pocket inside the Surface at the foot end of the bed).



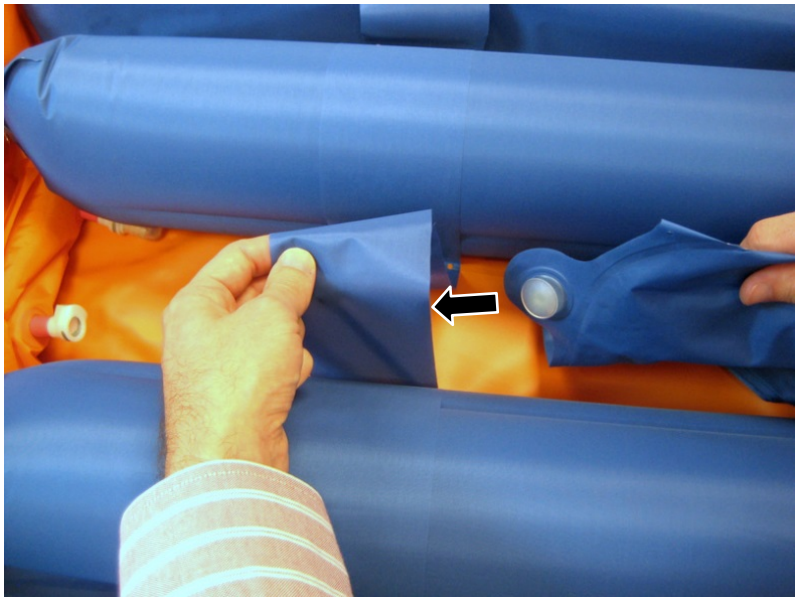
AIR CELL REPLACEMENT (Continued)

5. Unbutton both sides of the air cell.





6. Slide the air cell out of the restraining loops.
7. Insert the new air cell through the loops.



8. Button both sides of the new cell.
9. Uncap the manifold connector and connect the new air cell.
10. Place manifold caps back into shell pocket.
11. Inflate and verify air cell properly inflates.
12. Re-zip the coverlet.

CLEANING PUMP FILTER

Good filter maintenance is critical in keeping your IsoAir™ Pump in optimal operating condition. Failure to clean the filter may cause damage to the Pump. The damaged Pump may not provide proper support pressures resulting in patient injury.

Tools/Parts Required:

- Flat-bladed screwdriver
- Air Filter (2940-002-052)

Procedure:

The Pump filter should be checked every 30 days. If dirty, the filter can be dusted or vacuumed without removal. The filter may also be periodically removed and washed, or replaced as follows:

1. Unplug the electronic Pump.
2. Open the filter grill cover and remove the filter. This can be gently pried open using a flat-bladed screwdriver or similar from the opposite side to the hinge. The filter cover will swing open. DO NOT unscrew the filter assembly.
3. Clean the filter by washing in a mild detergent and allow to air dry. If replacing with a new filter discard instead of washing.
4. Insert the new or cleaned filter back into the filter housing and replace the grill cover.

If the filter cannot be cleaned or becomes damaged, contact Stryker Customer Service for information, see **Page 9**.

SUPPORT SURFACE COVERLET REPLACEMENT

Tools/Parts Required:

- Replacement Coverlet (2940-002-036)

Procedure:

1. Raise the bed height to the full up position.
2. Lower the fowler and gatch sections to the full down positions.
3. Unzip both zippers on the coverlet. Start at the foot end of the support surface and stop at the head end.
4. Attach the new coverlet by starting both zippers at the head end.
5. Zip the coverlet to close. Start at the head end and stop at the foot end.
6. Make sure the new coverlet aligns properly with the support surface.

PREVENTIVE MAINTENANCE OF THE SUPPORT SURFACE

- DO NOT service or perform maintenance while the product is in use. May result in patient injury.

At a minimum, check all items listed during annual preventive maintenance for all Stryker Medical products. You may need to perform preventive maintenance checks more frequently based on the level of patient usage and the number of times the Surface is cleaned/disinfected. Service should only be performed by qualified personnel.

Remove product from service before you perform preventive maintenance inspection.

Note: Clean and disinfect the exterior of the support surface before inspection, if applicable.

CHECKLIST

_____ Inspect coverlet; if tears, rips, holes, cracks, or excessive wear are observed, it is strongly recommended to replace the coverlet

_____ Verify that the coverlet zipper opens and closes properly and has no visible damage.

_____ Unzip coverlet to view the air cells; inspect the air cells and the bolster to ensure that there are no holes, cracks or signs of excessive wear. Replace as required.

_____ Inspect fire barrier for rips, cracks or excessive wear.

_____ Check labels as specified in this manual (**Page 41**) for legibility, proper adherence, and integrity.

_____ Inspect handles and stitching to ensure that there are no rips or cracks.

_____ Inspect hose sleeve for tears, rips or damage.

_____ Inspect surface straps and ensure that they are intact and are not damaged.

_____ During installation, confirm that straps properly secure the support surface assembly to the bed frame.

SERIAL NUMBERS

System Component	Serial Number
Support Surface	
Coverlet	

MAINTENANCE RECORD

Completed By	Date

PREVENTIVE MAINTENANCE OF THE PUMP

⚠

Electrical safety testing of the Pump should be performed at least annually. Failure to do so may result in death or injury. Contact Stryker Customer Service for information, see **Page 9**.

Preventive maintenance should be performed annually, at a minimum. A preventive maintenance program should be established for all Stryker Medical equipment. Preventive maintenance may need to be performed more frequently based on the level of usage and the number of times the Pump is cleaned/disinfected. Use this sheet for your records and keep on file.

CHECKLIST

_____ Verify that there are no cracks, holes or damages on the Pump Housing, or its components (Hoses, Power Cord, and Case)

_____ Verify the hooks used to hang the Pump on the bed frame are intact and not damaged.

_____ Verify the POWER Key is working properly.

_____ While in operation, verify there are no air leaks from the Pump or the attached connectors/hosing.

_____ Check Air Filter (See **Page 38**).

SERIAL NUMBERS

System Component	Serial Number
Air Pump	

MAINTENANCE RECORD

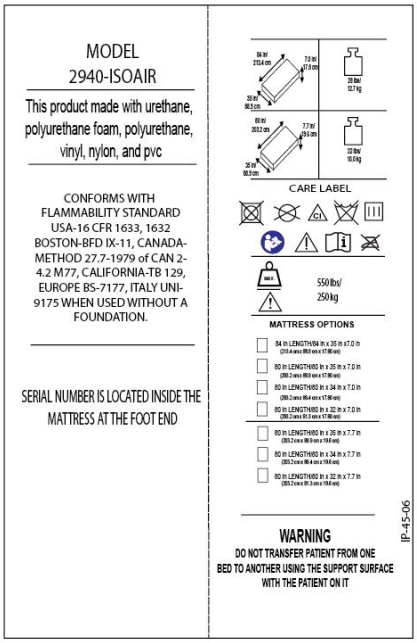
Completed By	Date

Product Labeling

Support Surface Labels

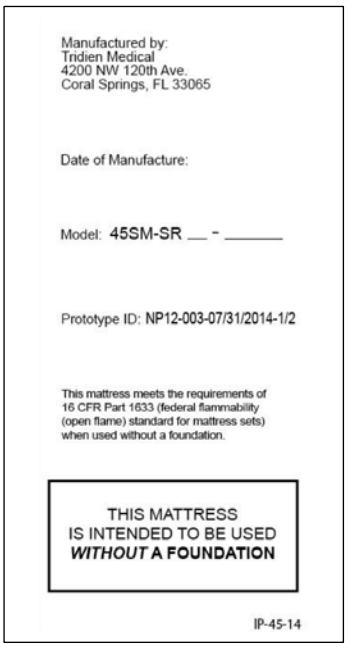
Labels attached to the Support Surface are shown below are:

1) Care Label

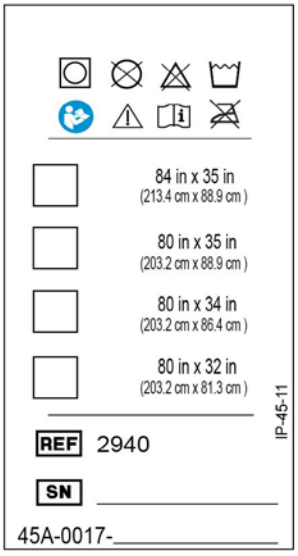


2) Law Label

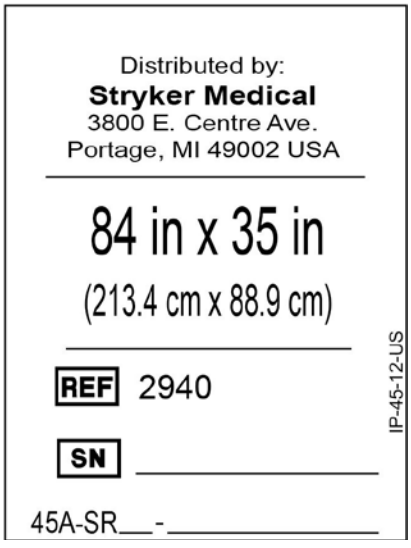
3) Flammability Label



4) Coverlet Label



5) Shell Label



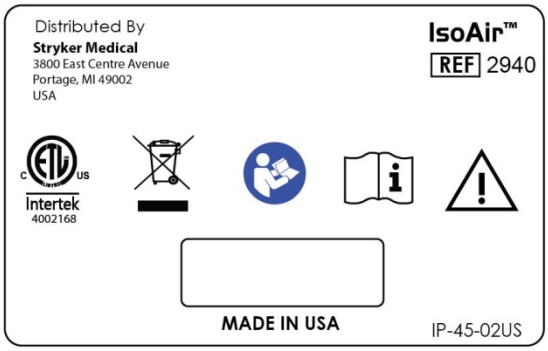
5) Shell Pocket - Choking Hazard Label:

Product Labeling

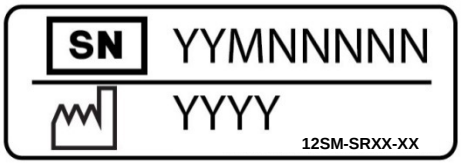
Pump Labels

Labels attached to the Pump are shown below are:

1) Manufacturer Label:

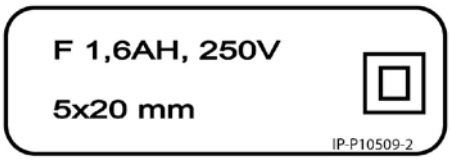


2) Part & Serial Number Label:



3) Control Data Label:

4) Fuse & Voltage Label:



3) Stryker Name Label:

Hosing/Tubing Assembly and Power Cord Labeling

Labels attached to the hosing/tubing assembly & the power cords are shown below:

1) **CPR Hose Label:**

2) **Power Cord Label:**

Quick Reference Replacement Parts List

The parts and accessories listed on this page are currently available for purchase. Some of the parts identified on the assembly drawing in this manual may not be individually available for purchase. Please call *Stryker Customer Service* USA at **1-800-327-0770** for availability and pricing.

Part Name	Stryker Part Number	Part Description
IsoAir™ Pump	2940-002-100	120/60 US Pump w/ Power Cord
15 foot Power Cord	2940-001-102	Power Cord, 15 FT, US, C17
3 foot Power Cord	2940-001-101	Power Cord, 3 FT, US, C17
Quick Disconnect Caps	2940-002-001	Assembly, Air Plug
Push-On Vinyl Cap, 3/8” x ½	2940-002-062	Cap, Air Cell Laundry
Coverlet 35”X 84”	2940-002-036	Assembly, 35” X 84”, Coverlet
Non-AST Air Cell, 35” X 7.0”	2940-002-033	Assembly,35” X 7.0”, Non-AST Air Cell
Air Filter	2940-002-052	Air filter

Product Compliance Declarations

GUIDANCE AND MANUFACTURER'S DECLARATION – EMISSIONS

Guidance and Manufacturer's Declaration – Emissions		
The IsoAir™ 2940 ("Pump") is intended for use in the electromagnetic environment specified below. The customer or the user of the Pump should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Pump 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	
Harmonic emissions IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	
		The Pump is suitable for use in all establishments, including domestic and those to the public low-voltage power supply network that supplies buildings used for domestic purposes.

GUIDANCE AND MANUFACTURER'S DECLARATION – IMMUNITY

Guidance and Manufacturer's Declaration – Immunity			
The Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Pump should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
ElectroPressure Redistribution 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 (EFT) IEC 61000-4-4	±2 kV Mains ±1 kV I/Os	±2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout lines IEC 61000-4-11	>95 % dip for 0.5 cycle 60% dip for 5 cycles 30 % dip for 25 cycles >95 % dip for 5 sec	>95 % dip for 0.5 cycle 60% dip for 5 cycles 30 % dip for 25 cycles >95 % dip for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pump requires continued operation during power mains interruptions, it is recommended that the Pump 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 Device only operates at 60Hz	Power frequency magnetic fields should be of a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – IMMUNITY - NON LIFE SUPPORTING

Guidance and Manufacturer's Declaration – Immunity – Non-Life Supporting			
The Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Pump should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the Pump by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	(E1)=3V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800MHz to 2.5 GHz where P is the maximum power and D is the recommended separation distance in meters. Field strengths from fixed-transmitters, as determined by an electromagnetic site survey should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment marked with the following symbol: 

GUIDANCE AND MANUFACTURER'S DECLARATION – RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PUMP

Recommended Separation Distances for the Pump			
The Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pump as recommended below, according to the maximum output power of the communications equipment.			
Max Output (Watts)	**Separation (m) 150 kHz to 80 MHz**	**Separation (m) 80 MHz to 800 MHz**	**Separation (m) 800 MHz to 2.5 GHz**
	D=(3.5/V1)(Sqrt P)	D=(3.5/E1)(Sqrt P)	D=(7/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Warranty

LIMITED WARRANTY

The Stryker IsoAir™ System has a warranty of **TWO (2) YEARS** under normal use, conditions, and with appropriate periodic maintenance as described in this manual.

This statement constitutes Stryker's entire warranty with respect to the aforesaid equipment. **Stryker makes no other warranty or representation, either expressed or implied, except as set forth herein. There is no warranty of merchantability and there are no warranties of fitness for any particular purpose. In no event shall Stryker be liable here under for incidental or consequential damages arising from or in any manner related to sales or use of any such equipment.**

CONDITIONS AND LIMITATIONS

This statement constitutes Stryker's entire warranty with respect to the aforesaid equipment. Stryker makes no other warranty or representation, either expressed or implied, except as set forth herein. There is no warranty of merchantability and there are no warranties of fitness for any particular purpose. This warranty does not extend to, nor cover:

- Normal wear and tear; or
- Damage or product failure due to causes beyond Stryker's control such as, but not limited to abuse, theft, fire, flood, wind, lightning, freezing, clogging of support surface pores due to tobacco smoke, unusual atmosphere conditions, material degradation due to exposure to moisture; or
- Damage to support surface or support surface handles through the use of the support surface for patient transfer or transport.

Normal use is defined as normal hospital or facility usage. Damages arising from abnormal use such as those caused by needle punctures, burns, chemicals, negligent use or improper care or improper cleaning or staining resulting from it are exempt from warranty coverage.

TO OBTAIN PARTS AND SERVICE

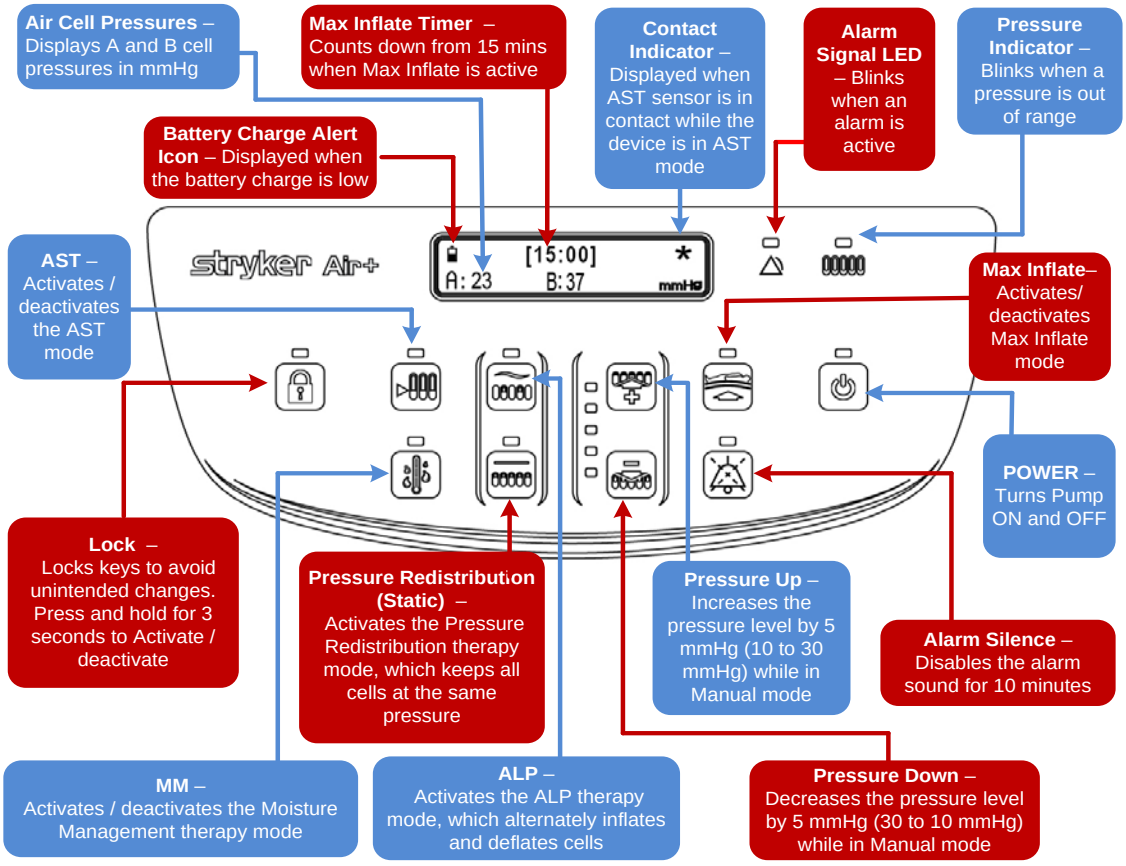
Stryker products are supported by a nationwide network of dedicated Stryker Field Service Representatives. These representatives are factory trained, available locally, and carry a substantial spare parts inventory to minimize repair time. Simply call your local representative or call Stryker Customer Service USA at **(800) 327-0770** or **(269) 324-6500**

RETURN AUTHORIZATION

Merchandise cannot be returned without approval from the Stryker Customer Service Department. An authorization number will be provided which must be printed on the returned merchandise. Stryker reserves the right to charge shipping and restocking fees on returned items. **Special, modified, or discontinued items not subject to return.**

DAMAGED MERCHANDISE

ICC Regulations require that claims for damaged merchandise must be made with the carrier within fifteen (15) days of receipt of merchandise. **Do not accept damaged shipments unless such damage is noted on the delivery receipt at the time of receipt**. Upon prompt notification, Stryker will file a freight claim with the appropriate carrier for damages incurred. Claim will be limited in amount to the actual replacement cost. In the event that this information is not received by Stryker within the fifteen (15) day period following the delivery of the merchandise, or the damage was not noted on the delivery receipt at the time of receipt, the customer will be responsible for payment of the original invoice in full. Claims for any short shipment must be made within thirty (30) days of invoice.


Air Cell Pressures – Displays A and B cell pressures in mmHg
Max Inflate Timer – Counts down from 15 mins when Max Inflate is active
Contact Indicator – Displayed when AST sensor is in contact while the device is in AST mode
Alarm Signal LED – Blinks when an alarm is active
Pressure Indicator – Blinks when a pressure is out of range
Battery Charge Alert Icon – Displayed when the battery charge is low
AST – Activates / deactivates the AST mode
stryker Air+
[15:00]
A: 23
B: 37
mmHg
Max Inflate– Activates/ deactivates Max Inflate mode
POWER – Turns Pump ON and OFF
Lock – Locks keys to avoid unintended changes. Press and hold for 3 seconds to Activate / deactivate
Pressure Redistribution (Static) – Activates the Pressure Redistribution therapy mode, which keeps all cells at the same pressure
Pressure Up – Increases the pressure level by 5 mmHg (10 to 30 mmHg) while in Manual mode
Alarm Silence – Disables the alarm sound for 10 minutes
MM – Activates / deactivates the Moisture Management therapy mode
ALP – Activates the ALP therapy mode, which alternately inflates and deflates cells
Pressure Down – Decreases the pressure level by 5 mmHg (30 to 10 mmHg) while in Manual mode

Alarms / Alerts (In Order of Notification Priority)	Symptoms	Recommended Action[4]
1. **Power Failure** - The controller is not receiving power due to a power outage, disconnected power cord, blown fuse, or possible internal damage.	– Controller does not turn on. – Support surface does not inflate – Keys not responding – Alarm Signal LED blinks and Power Key LED blinks[2].	– Make sure the power cord is plugged in, mains AC power is ON and the Power LED is lit (white for standby, green for unit turned on).
2. **Hardware Failure** - The controller has detected an internal hardware failure.	– Alarm Signal LED blinks and Power Key LED continuously lit.	– Cycle power
3. **Stuck Key** - The controller has detected that a key has been activated for more than 15 seconds.	– Keys not responding – Alarm Signal LED blinks[2] and LED for affected stuck key flashes[3]	– Press and release the key with the flashing LED to clear the stuck key.
4. **AST Connection Error** - The controller has detected that the AST cable is disconnected.	– Alarm Signal LED blinks[2] and AST Key LED blinks	– Check that the AST plug is completely inserted into the AST socket. – Toggle the AST key (OFF/ON) to see if condition clears.
5. **AST Sensor** – The AST Sensor remains in contact for more than 15 minutes while operating in AST mode.	– Alarm Signal LED blinks[2], AST Key LED blinks and Pressure Indicator LED blinks	– If patient is in fowler, reduce HOB angle. – Unzip cover and check that AST air cells are correctly positioned underneath patient. – Perform a hand check to ensure that the patient is not bottoming out.
6. **Pressure Alarm** - A high or low pressure condition exists in a support cell or bolster.	– Alarm Signal LED blinks[2] and Pressure Indicator LED blinks	– Check that the CPR connector is correctly plugged into the controller. – Check for kinks in tubes from the CPR connector to the support surface. – Unzip the mattress cover, check air cells, tubing and connections for possible leaks.
7. **MM Low Flow** – flow is below minimum expected threshold for 5 seconds.	– Alarm Signal LED blinks[2], the MM Key LED blinks and the Pressure LED blinks	– Unzip the mattress cover. Check for air flow blockage along the MM hoses inside the mattress (See **Page 16**).
8. **Lock Alert** - A key is pressed while the LOCK function is active.	– Keys not responding – Lock Key LED flashes[3]	– If required, deactivate the LOCK function by pressing and holding the LOCK key for 3 seconds.
9. **Battery Fault Alert** - A fault with the battery was detected.	– Battery icon is displayed on LCD	– Ensure power is connected for at least five hours.

1 - All alarms are classified as Medium Priority per *IEC 60601-1-8*
2 - Blinking = every 2 seconds
3 - Flashing = 10 times per second
4 - If alarm condition persists, contact Stryker Customer Technical Support

Stryker Customer Technical Support - (800) 327-0770 or (269) 324-6500

Distributed By:
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