PUAS207

Stryker Air™ Pump

Model 2861-000-001

For use with

SPR Plus II® Single Patient Use Low Air Loss Overlay System & IsoGel Air™ Support Surfaces

stryker®

Operation/Maintenance Manual

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

Table of Contents

Symbols and Definitions

SYMBOLS

	Warning/Caution - Consult accompanying documentation
	Electrical Safety Mark
	Read Manual Prior to Operation
	Type BF Applied Part; Applied Part is the Mattress
	Protective Earth Terminal
IPX4	Protection from Powerful Jets of Water Rating
	Equipment Emits Electromagnetic Energy
	Manufacturer

Symbols and Definitions

WARNING / CAUTION / NOTE

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.

Introduction

This manual is designed to assist with the operation and maintenance of the *Stryker Air Pump* ("Pump") that is used to power both the Stryker SPR Plus II Single Patient Use Low Air Loss Overlay System ("SPR Plus") & IsoGel Air Support Surface ("IsoGel Air"). Carefully read this entire manual before using or beginning maintenance on the Pump. 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.

INTENDED USE OF THE PRODUCT

The Pump is an accessory used with the SPR Plus & IsoGel Air to assist in the prevention and treatment of pressure ulcers. This therapy is recommended to be used in combination with clinical evaluation of risk factors and skin assessments made by a health care professional.

This Pump is intended to be used:

- With the Stryker SPR Plus or IsoGel Air only
- With the hosing and connector assembly provided (Part Number *2861-001-001*)
- In acute care, general hospital care, or other locations as prescribed by a physician
- For patients that weigh:
  1. 50-500 pounds for the IsoGel Air
  2. 50 -350 pounds for the SPR Plus

This product is not intended to be used in a home health care environment.

PRODUCT DESCRIPTION

The Pump provides *Low Air Loss Therapy* and when used in conjunction with SPR Plus or IsoGel Air assists in the prevention and treatment of pressure ulcers and includes the following features:

- The Pump is a versatile accessory that may be used with either the SPR Plus or the IsoGel Air.
- Easily attaches to the Footboard of the Bed Frame.
- Incorporates an alarm for detection of changes in pressure, e.g., leaks, kinked hose.
- Designed with a "User-Friendly" Control Panel.

Introduction

SPECIFICATIONS

Pump	
Dimensions	Height: 8.5 in / 25.6 cm Width: 8 in / 20.3 cm Depth: 5 in/ 12.7 cm
Weight	5.5 lbs/ 2.5kgs
Input Voltage AC	115 Volts
Input Frequency	60 Hz
Current Consumption	0.25 Amps
Power Consumption	< 60 Watts
Circuit Protection	Dual Circuit Breakers, 240V, 0.5-16.0A
Mode of Operation	Continuous
Protection Against Electrical Shock	Class I, Type BF Applied Part 
Air Output	− 12.5 Liters / Minute @ 30 mmHg − 25 Liters / Minute @ 20 mmHg
Pressure Settings (mmHg)	18 to 30 mmHg in 3 mmHg Increments
Power Cord	3 ft/ 0.91m & 15 ft / 4.6m; 16 AWG Hospital Grade
Air Hose	56 in / 142 cm
Air Hose Connection	3/8 Inch Flow Quick Coupling
Packaging	1 Piece per Box
Latex Content	Pump and Accessories are **Latex-Free**
Alarms (See Page 14):	
Sound Pressure Level	63.1 dB(A)
Air Leak Alarm	Flashing/Audible for pressure variations
Low Level:	− Pressure is not within +/- 2mmHg after 15 minutes (SPR Plus)
Medium Priority:	− Pressure is not within +/- 2mmHg after 30 minutes (SPR Plus) − Pressure is greater than 40 mmHg for 30 seconds
System Alarm	− If system error is detected − Stuck button
Operating Conditions:	
Ambient Temperature	40 to 90 ^{o}F / 10 to 32 ^{o}C
Relative Humidity	30 to 75 % Non-Condensing
Atmospheric Pressure	700 to 1060 hPa
Storage and Shipping Conditions:	
Ambient Temperature	- 40 to 158 ^{o}F / 40 to 70 ^{o}C
Relative Humidity	10 to 95 %, Non-Condensing
Atmospheric Pressure (hPa)	500 to 1060 hPa
Protection Against Harmful Ingress of Liquids:	
Liquid Ingress Protection	IPX4
Product Compliance:	
Medical Equipment	Meets IEC 60601-1, UL 60601-1, CAN/CSA C22.2 NO. 601.1
Electromagnetic Compatibility (EMC)	Meets IEC60601-1-2 (See **Pages 20-22**)

Stryker reserves the right to change specifications without notice.

Introduction

CONTACT INFORMATION

Contact Stryker Customer Service or Technical Support at: **(800) 327-0770** or **(269) 324-6500**.

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.

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 DIGITS):

Serial Number Example: 12J00234

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

Manufacture Date (YY/MM): 2012 September
Sequential Number (N): 00234

Year Legend (Y)	
2012	12
2013	13
2014	14
2015	15
2016	16

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

Summary of Safety Precautions

Carefully read and strictly follow the warnings and cautions listed in this section.

WARNING

- Before operating this medical equipment:
  - ✓ 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
  - ✓ Inspect Pump and power cord for damage. If damage is observed, DO NOT use the Pump
  - ✓ Pump is only to be used with the *SPR Plus* or *IsoGel Air* mattresses. Read the User's Manual for the *SPR Plus* or *IsoGel Air* mattress before using it with the Pump. Failure to do so could result in patient injury and/or improper therapy
  - ✓ **Entrapment & Falls:** Evaluate patients for the risk of entrapment & falls according to facility protocols, including: 1) Ensuring side rails are fully locked when in the raised position, 2) Reevaluating risk of patient entrapment & falls using the *SPR Plus,* since it is an "overlay" and reduces the effective height of the side rails. Failure to do this could result in death or injury.
- Do not modify or change this device. Service should only be completed by qualified personnel. Failure to do so could result in injury.
- 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 20-22**). However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - ✓ Reorient or relocate the receiving device
  - ✓ Increase the separation between the Pump and other equipment
  - ✓ 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
- Grounding reliability can only be achieved when the Pump is connected to *Hospital Grade* receptacle.
- Do not use multiple socket outlets or extensions.
- 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 **Page 6**). Only use approved *Hospital Grade* power cords.
- Do not use in the presence of flammable anesthetics, nitrous oxide, or in oxygen-rich environments. **Risk of explosion can result.**
- Exposure of the Pump to any liquid while it is plugged in could result in a severe electrical hazard.
- 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 unit and take it out of service immediately and contact Customer Service. See **Page 7** for contact information.
- There are no batteries in the unit, if power fails the product will not work nor continue air flow.
- If the SPR Plus is not inflating properly, inspect the hose connection to overlay to ensure connection is seated properly.
- To avoid the damage to the Pump or potential injury, only trained personnel should open the Pump.
- When hanging the controller on the foot board, ensure the hangers are seated as the hangers are not spring loaded and may come dislodged if not properly hung.
- 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.
- Deflate SPR Plus mattress before starting CPR. Failure to do so may result in ineffective CPR. Refer to SPR Plus Mattress User's Manual.
- SPR Plus is an overlay and should not be use as a mattress replacement.

Summary of Safety Precautions

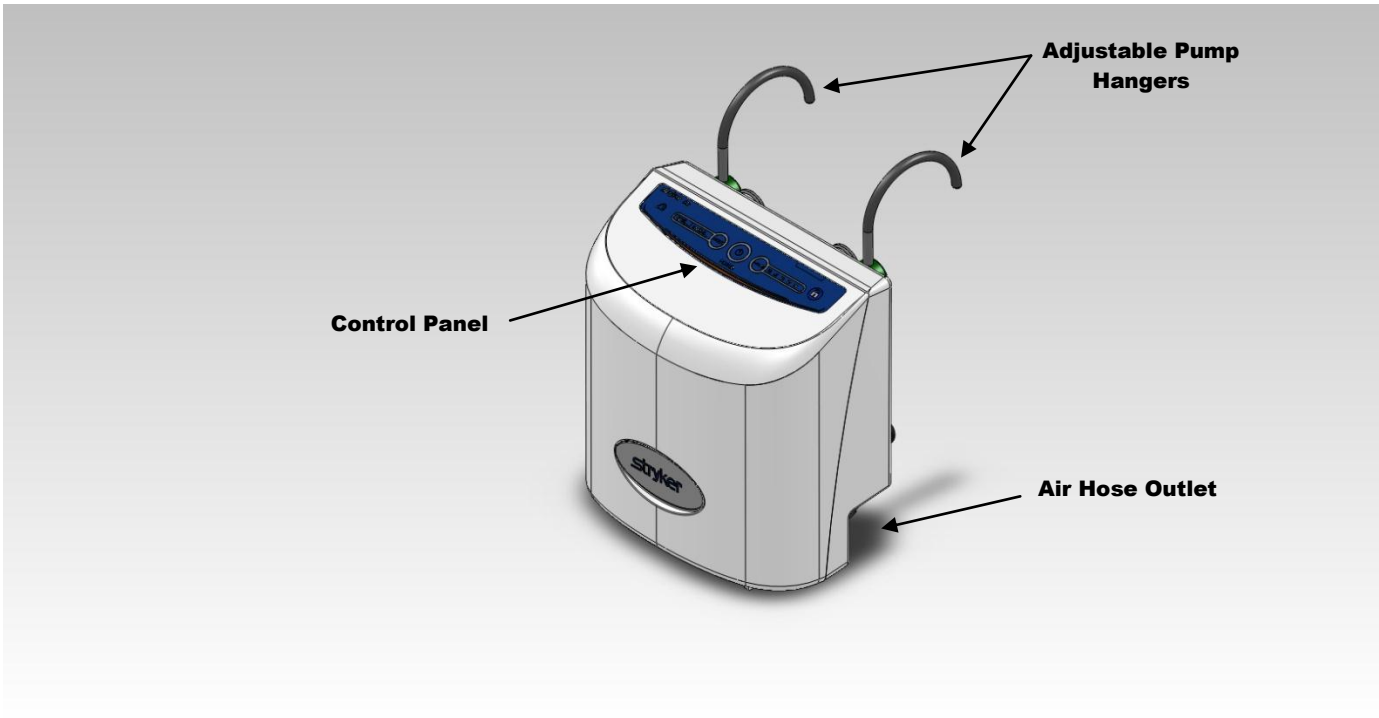
CAUTION

- 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.
- The power cord to the Pump should be positioned to avoid a tripping 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.
- 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 7** for Contact Information).
- To ensure optimal performance electrical-safety testing of your Pump should be performed at least annually. Contact Customer Service, **Page 7**, for service information.
- Disinfect the Pump and Hosing Assembly between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.
- 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

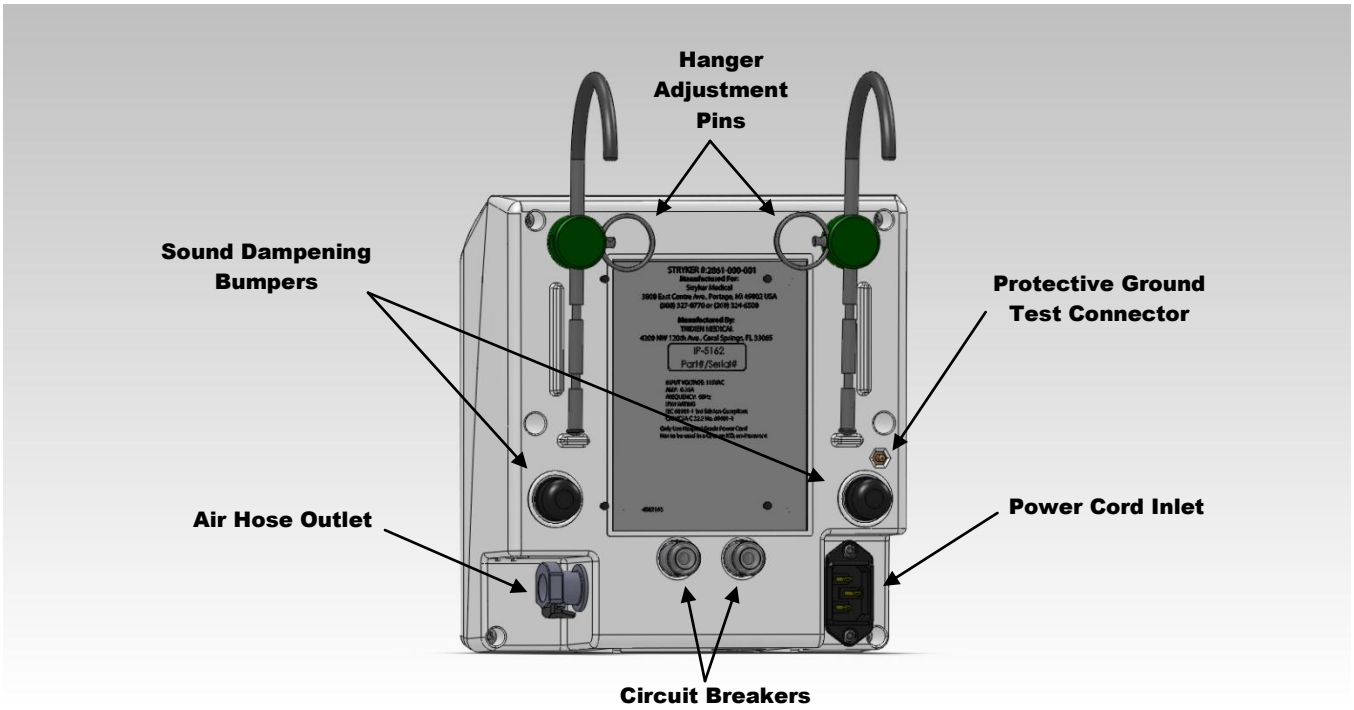
Pump Assembly

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 –

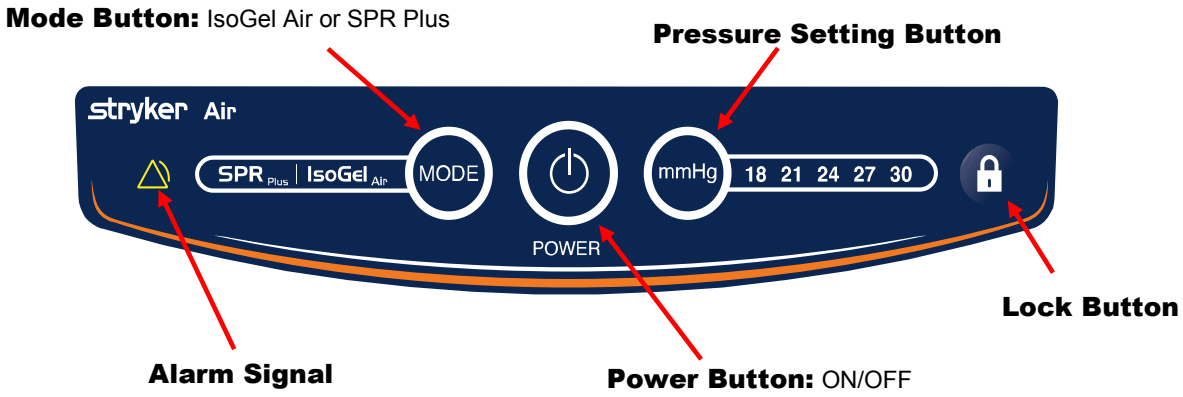


BACK VIEW –



Pump Control Panel

CONTROL PANEL –
The control panel of the Pump is shown in the picture below.



KEY FUNCTIONS
The keypad has four (4) touch keys as shown in the picture above:

1. **MODE Button:** Selects the correct MODE, either IsoGel Air or SPR Plus Mode
2. **mmHg Button (Pressure Setting):** Adjusts Pressure in 3 mmHg Increments
3. **POWER Button:** Turns unit ON or OFF
4. **Lock Button:** Locks settings

MODE FUNCTION:
Pressing the **MODE** Key will toggle between the IsoGel Air and SPR Plus modes.

PRESSURE SETTING FUNCTION:
Pressing the **mmHg** Button will allow selection of the desired pressure. The Pump defaults to previous setting when turned ON.

POWER FUNCTION:
Pressing the POWER Button turns the Pump ON or OFF. After a power failure the Pump will revert back to previous MODE and PRESSURE setting.

LOCK FUNCTION:
Pressing the **LOCK** Button will lock the current settings to avoid unintended changes. Pressing the **LOCK** Button again will allow setting(s) to be changed.

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 14, Troubleshooting Guide and Alarm Priority Table**).

Pump Operation

PROCEDURE

Installation & Operation for Use With the SPR Plus Mattress

Step	Installation Procedure	Cautions & Warnings
1	Refer to the SPR Plus User's Manual for installation of the mattress.	**⚠ WARNING** – Consult the user's manual for the *SPR Plus* mattress before attaching it to the Pump. Failure to do so could result in patient injury and/or improper therapy. – Grounding reliability can only be achieved when the Pump is connected to *Hospital Grade* receptacle. – Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen-rich environments. **Risk of explosion can result.** – 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. – If "Button-Click" sound is not heard during **Step 1** of the Operation Procedure, DO NOT use the Pump. – Only use SPR Plus Overlay on a mattress.
2	**Installing the Pump:** 1) Hang the unit on the foot panel of the bed. 2) The pump is equipped with a detachable power cord. To apply power, the cord must be attached to the pump and the electrical outlet on the wall. To disconnect power, the cord may be detached from either the pump or the wall outlet. 3) 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. 4) If you are installing the mattress on a Stryker bed frame, use the optional power outlet located under the foot end of the frame and the short power cord provided. Ensure the outlet is a *Hospital Grade* receptacle.	
3	Screw the **Red Hose Connector Cap** tightly onto the mattress connector as shown below. Use caution so not to cross the threads of the connector. 	
4	Attach other end of hose to the Pump using the Quick-Disconnect connector.	
Step	**Operation Procedure**	
1	While standing in front of the Pump, press the **POWER** button located on the Control Panel to turn the Pump ON. Listen for a "Button-Click" sound to verify operation of audio-alarm system. If controller lights do not come on, see Troubleshooting **Page 14**.	
2	Select the **SPR$_{Plus}$ MODE.** The **"SPR Plus "** will then be illuminated**.** The Pump will start inflating the cushion. The cushion will inflate in approximately 10 minutes. Start with the pressure set to 18mmHg.	
3	The **SPR Plus** pump is capable of adjusting the cushion pressure to five set points over a range of 18 to 30 mmHg. The five set points can be adjusted directly by the "mmHg" button. The settings will return to the last used setting if the unit experiences a loss of power.	
4	The only way to assure that the patient is getting the proper therapy is with periodic HAND CHECKS to establish the correct pressure setting. Please refer to the SPR Plus User's Manual for how to perform the HAND CHECK.	
Step	**CPR**	**⚠ CAUTION** – After exposure to extreme high or low temperatures, allow the Pump to equilibrate for at least one (1) hour before operating. – Before plugging in the Pump, check the power cord for electrical hazards, e.g., cuts, exposed wires, worn insulation, etc.
1	Refer to the SPR Plus User's Manual for CPR procedure.	
2	Disconnect hose from the pump using the Quick-Disconnect connector.	
3	Wait until mattess is deflated before starting CPR.	

Pump Operation

Installation & Operation for Use With the IsoGel Plus Mattress

Step	Installation Procedure	Cautions & Warnings
1	Refer to the IsoGel Air User's Manual for installation of the mattress.	**⚠ WARNING** – Consult the user's manual for the *IsoGel Air* mattress before attaching it to the Pump. Failure to do so could result in patient injury and/or improper therapy. – Grounding reliability can only be achieved when the Pump is connected to *Hospital Grade* receptacle. – Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen-rich environments. **Risk of explosion can result.** – 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. – If "Button-Click" sound is not heard during **Step 1** of the Operation Procedure, DO NOT use the Pump. **⚠ CAUTION** – After exposure to extreme high or low temperatures, allow the Pump to equilibrate for at least one (1) hour before operating. – Before plugging in the Pump, check the power cord for electrical hazards, e.g., cuts, exposed wires, worn insulation, etc.
2	**Installing the Pump:** 1) Hang the unit on the foot panel of the bed. 2) The pump is equipped with a detachable power cord. To apply power, the cord must be attached to the pump and the electrical outlet on the wall. To disconnect power, the cord may be detached from either the pump or the wall outlet. 3) 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. 4) If you are installing the mattress on a Stryker bed frame, use the optional power outlet located under the foot end of the frame and the short power cord provided. Ensure the outlet is a *Hospital Grade* receptacle.	
3	Screw the **Red Hose Connector Cap** tightly onto the mattress connector as shown below. Use caution so not to cross the threads of the connector. 	
4	Attach other end of hose to the Pump using the Quick-Disconnect connector.	
Step	**Operation Procedure**	
1	While standing in front of the Pump, press the **POWER** button located on the Control Panel to turn the Pump ON. Listen for a "Button-Click" sound to verify operation of audio-alarm system. If controller lights do not come on, see Troubleshooting **Page 14**.	
2	Select the **IsoGel MODE.** The **"IsoGel"** will then be illuminated**.**	

Troubleshooting

TROUBLESHOOTING GUIDE

Problem	Cause	Recommended Action
1. Alarm is activated (See Alarm Priority Table Below)	1) The alarm light will activate if the actual pressure varies by more than 2 mmHg of the set pressure after 15 minutes. The alarm is usually an indication of an air leak or a kinked hose (SPR Plus ONLY).	a) Check that the hose is properly connected. b) Check the hose for cuts, holes or kinks. The hoses should also be tightly connected to their respective connectors. c) Check the SPR Plus overlay for holes. d) Once the leak or kink has been resolved, the alarm will automatically turn off. To reset the alarm more quickly, turn the power OFF for 5 seconds and then ON again.
	2) The Alarm light flashes and audible alarm sounds if pressure variance persists for more than 30 minutes (SPR Plus ONLY).	
	3) The Alarm light flashes if unit measures greater than 40 mmHg for 30 seconds.	a) Check for the correct MODE selection, i.e., IsoGel or SPR Plus.
		b) Check hose connections.
	4) If an audible alarm is present and a button indicator other than the alarm is flashing, then a STUCK BUTTON is occurring.	Press the buttons to stop the alarm. If alarm condition persists, call Stryker Customer Technical Support, **Page 7**.
	5) An audible alarm and all of the lights are flashing indicate a SYSTEM ERROR.	If alarm condition persists, take Pump out of service and call Stryker Customer Technical Support, **Page 7**.
2. Power loss	Facility power outage, tripped circuit breaker, or possible internal damage.	a) Make sure the power cord is plugged in and power button is ON. b) Check Circuit Breakers; See **Page 16**
3. Unit Does Not Turn On	May be caused by other internal damage/failure.	Check circuit breakers on back of the pump. See **Page 16** for circuit breaker location.
4. Buttons not responding	May be caused by LOCK function.	Check LOCK button for activation.

ALARM PRIORITY TABLE:

Priority	Condition	Control Panel Indicator				
		Alarm Signal	Pressure Settings	Power Button	Mode Settings	Lock Button
1	System Problem	Blink[1]	Blink		Blink	Blink
2	Stuck Button	Blink	Flash[2]	Flash	Flash	Flash
3	Medium Pressure Condition	Blink				
4	Low Pressure Condition	Continuous[3]				

1. Blink = Every 2 seconds
2. Flash = 10 times per second
3. Continuous = Stays on until condition corrected

Cleaning and Disinfection

CLEANING / DISINFECTION

The exterior of the Pump and hosing assembly should be wiped down between patient use with a cloth dampened with disinfectant.

WARNING

- 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 registered with the Environmental Protection Agency (EPA).
- When disinfecting is required, check manufacturer’s instructions before use, and use disinfectant in accordance with the manufacturer’s instructions.

Suggested Disinfectants

1. Quaternary Cleaners
2. Phenolic Cleaners
3. Chlorinated Bleach Solution (5.25% bleach diluted 1 part bleach to 10 parts water)
4. 70% Isopropyl Alcohol
5. Accelerated Hydrogen Peroxide (AHP)

CAUTION

- Disinfect the Pump, Power Cord, and Hosing Assembly between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.
- DO NOT autoclave the Pump OR the Hosing Assembly.
- Unplug Pump from its source prior to cleaning.
- Do not use harsh cleansers, solvents, or detergents on the Pump. Equipment damage could occur.

CIRCUIT BREAKER RESET

Tools Required:

- None

Procedure:

1. Locate the circuit breakers on the lower back cover.
2. Press each circuit breaker to RESET.

HOSE ASSEMBLY REPLACEMENT

⚠ CAUTION!

Disinfect the Pump and Hosing Assembly between patient installations and when servicing, utilizing standard hospital protocol and disinfectants. Failure to disinfect may risk cross-contamination and infection.

Tools Required:

- None

Procedure:

1. Wipe the hosing assembly down between patients with a cloth dampened with disinfectant.
2. Disconnect the air hose from the Quick Disconnect fitting on the Pump.
3. Loosen the **RED Hose Connector Cap** from the mattress connector by turning it COUNTER CLOCKWISE.
4. Discard old hose assembly in accordance with hospital waste management policy.
5. Open the new Air Hosing Assembly (Part Number 2861-001-001).
6. Connect the air hose with the Quick Disconnect fitting to the Pump.
7. Thread the **RED Hose Connector Cap** onto the mattress connector by turning it CLOCKWISE (See Figure Below). Tighten firmly by hand, but do not over tighten and cross the threads.

Preventive Maintenance

CAUTION!

To ensure optimal performance, electrical safety testing of your Pump should be performed at least annually. Contact Stryker Customer Service for information, see **Page 7**.

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 usage level of the product. 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, Case)

_____ Verify the hooks used to hang the Pump on the bed frame are intact and not damaged. The tension in the hooks should be enough to secure the Pump to the frame.

_____ Verify the POWER Button is working properly.

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

Product Serial Number:		

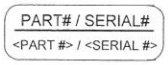
Completed by: _____ **Date:** _____

Product Labeling

PUMP - Labels attached to the Pump are shown below are:

1) Manufacturer & ETL Label:

2) Part & Serial Number Label:



3) Control Panel Label:

See **Page 11**

4) BioMed Label:

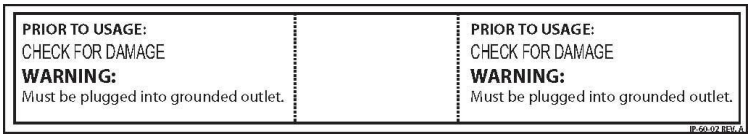
5) Stryker Name Label:

HOSING/TUBING ASSEMBLY - Labels attached to the hosing/tubing assembly are shown below are:

1) CPR Hose Label:

POWER CORD – Label(s) attached to the electrical power cord are shown below are:

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 parts 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
Hose/Connector Assembly	2861-001-001	Air Hose Assembly for IsoGel Air & SPR Plus Mattresses
15 foot Power Cord	2861-001-002	Hospital Grade Electrical Cord
3 foot Power Cord	2861-001-003	Hospital Grade Electrical Cord
Hanging Brackets	2861-001-004	Attachment Hangers on Pump
Hanging Brackets - Rings	2861-001-005	Hanger Adjustment Ring
Hanging Brackets - Pins	2861-001-006	Hanger Adjustment Pin

Product Compliance Declarations

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
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.		
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 A	The Pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer's Declaration – Electromagnetic 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**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE! *U*T is the a.c. mains voltage prior to application of the test level.			

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

Guidance and Manufacturer's Declaration – Electromagnetic 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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Stryker Pump , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	**Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pump is used exceeds the applicable RF compliance level above, the Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pump. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Product Compliance Declarations

GUIDANCE AND MANUFACTURER'S DECLARATION – RECOMMENDED SEPARATION DISTANCES

Recommended Separation Distances
Between Portable And Mobile RF Communications Equipment And 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.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** M		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Warranty

LIMITED WARRANTY

The Stryker Pump is designed for an expected service life of **THREE (3) 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.**

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.

PUAS207

United States
Manufactured for
Stryker Medical
3800 E. Centre Ave.
Portage, Michigan USA
49002