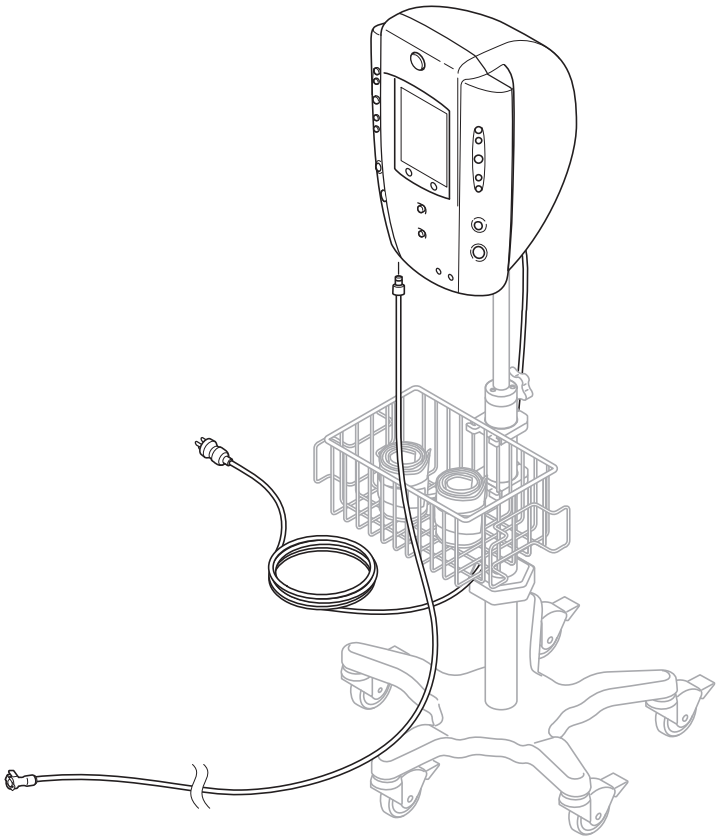
SmartPump® Tourniquet System
Dual Channel Tourniquet Pump

REF 5920-011-000

Instructions For Use

R_x ONLY

CE 0197



Software Version

1.xx

ENGLISH (EN)

2015-08 5920-011-700 Rev-L www.stryker.com
Print Date: Aug 31, 2015 05:54:27 PM
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Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians. Keep and consult this reference manual during the life of the product.

Conventions

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

Contact Information

For additional information, including safety information, or in-service training, contact your Stryker sales representative or call Stryker customer service at 1-800-253-3210.

Indications For Use

The Stryker SmartPump Dual Channel Tourniquet Pump System (pump) is intended to be used to temporarily occlude or decrease blood flow in a patient extremity during a surgical procedure of that extremity. The tourniquet system is intended to provide greater visualization of the operating field during a surgical procedure of a patient extremity. The use of the tourniquet system is not a substitute for proper hemostasis. Typical surgical procedures of extremities include:

- Arthroscopy
- Tendon repair
- Total wrist joint repair
- Knee joint replacement
- Finger joint replacement
- Nerve repair
- Bone grafts, and
- Other surgical procedures of a patient extremity requiring temporary occlusion of blood flow.

The dual channel design supports single cuff, bilateral cuff and Bier Block cuff procedures, and allows for the simultaneous surgery of an upper and lower limb.

Contraindications

The Stryker SmartPump Tourniquet System is not intended to be used as a ligature or in lieu of cauterization to stop hemorrhages. The system should never be applied without consideration of the local anatomy. The tourniquet system and associated tourniquet cuff is contraindicated for use on the torso and patients exhibiting unusual or complicated neurological or vascular problems of the extremities such as arteriovascular impairment, phlebitis, infection, uncontrolled diabetes, and/or other associated problems. Other potential contraindications include:

- Compromised vascular circulation
- Severe scar tissue in the cuff zone
- Mellitus
- Open leg fractures
- Post traumatic lengthy reconstruction
- Severe crushing injuries
- Elbow surgery associated with excessive swelling
- Severe hypertension
- Skin grafts in which bleeding must be readily distinguished
- Presence of sickle cell disease or clotting disorder

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User/Patient Safety



WARNINGS:

- Before using any system component or any component compatible with this system, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the system components prior to use.
- Only trained and experienced healthcare professionals should use this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure.
- Upon initial receipt and before each use, inspect the equipment for damage. See the *Inspection and Testing* section. DO NOT use the equipment if damage is apparent.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen or nitrous oxide.
- To avoid the risk of electric shock, ALWAYS connect this equipment to a hospital-grade, facility power receptacle with protective earth.
- ALWAYS position the equipment so that the power cord may be easily disconnected as required.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like this system. Install and place this system into service according to the EMC information in this manual. Portable and mobile RF communications equipment can affect the function of this system.
- ALWAYS follow current hospital protocol governing the safe and effective use of a tourniquet system.

System Overview

The dual channel tourniquet system allows for the connection of two cuffs. The pressure value and elapsed inflation time value of each cuff are displayed, monitored, and controlled independently within two separate channel areas.

The system maintains real-time cuff pressure within normal operating parameters relative to the set target pressure value. Variations in pressure are detected and adjusted to the set target pressure value within two/tenths of a second.

These automatic adjustment responses are sequenced to deliver optimal, progressive pressure compensation without causing overpressure fluctuations, frequent pressure adjustments or false triggering due to transient pressure variations. This functionality enhances cuff pressure maintenance and addresses the unique pressure dynamics associated with various size cuffs and their relatively low inflatable volumes.

Cuff pressure changes may be caused by limb extension and contraction and initial cuff conformity and tissue compression.

After initial cuff inflation, minor changes in pressure above or below the set target pressure value may occur. Intraoperative limb manipulation may cause the cuff to induce a momentarily, minor high and/or low-pressure fluctuation. A momentary decrease in limb volume, associated with extension motions may cause the system to sense low pressure, as the cuff's compressible target briefly becomes smaller. Momentary increases in pressure may also occur due to external compression of the cuff during limb contraction, which temporarily causes the limb to assume a larger compressible volume.

All of these pressure fluctuations are compensated for by the system and adjusted to the set target pressure automatically.

Cuff pressure conditions determined to be outside normal operating parameters will trigger an audible and visual alarm requiring immediate action. Such pressure conditions may be caused by a leaking or damaged cuff, a leaking cuff O-ring, a loose Luer connection, or a leaking fill line.

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System Overview (continued)

The system also monitors the total elapsed time the cuff is inflated during a procedure. The total elapsed cuff time value, as well as the cuff activity and cuff pressure value may be printed using the optional tourniquet report printer.

For Use With

This section identifies required components intended to be used with the equipment to obtain a safe combination.

DESCRIPTION	REF
Rolling Stand	5920-013-000
Tubing, Stockinettes, Fill Lines, and Adapters	5920-XXX-XXX series
Disposable Cuffs	5921-XXX-XXX series
Reusable Cuffs	5922-XXX-XXX series

NOTE: The fill line and cuff are considered to be Defibrillation Proof BF Type Applied Parts. See the *Features* and *Specification* sections.

Accessories

This section identifies accessories that may be purchased to replace consumed, worn, or damaged equipment. Optional accessories may also be purchased to aid in operation.

WARNINGS:

- Use only Stryker-approved equipment, unless otherwise specified.
- DO NOT disassemble, modify, service, or repair this equipment without authorization of the manufacturer.
- Use only Stryker-approved electronic components and accessories. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

WARNINGS:

- DO NOT reuse, reprocess, or repackage a single use device. A single use device is intended for a single use only. A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing. Design features may make cleaning difficult. Reuse may create a serious risk of contamination and may compromise the structural integrity of the device resulting in operational failure. Critical product information may be lost if the device is repackaged. Failure to comply may lead to infection or cross-infection and result in patient and/or healthcare staff injury.

The following Stryker-approved accessories are sold separately:

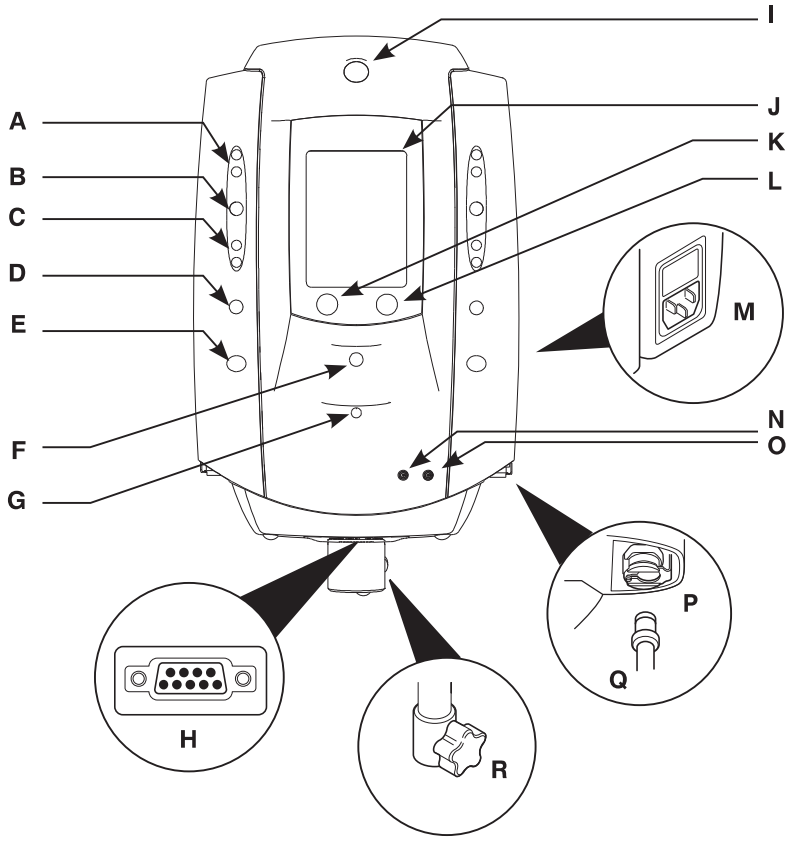
DESCRIPTION	REF
Rolling Stand	5920-013-000
Tubing, Stockinettes, Fill Lines, and Adapters	5920-XXX-XXX series
Disposable Cuffs	5921-XXX-XXX series
Reusable Cuffs	5922-XXX-XXX series
Report Printer Kit	5920-012-000

NOTES:

- The Stryker Report Printer Kit REF 5920-012-000 is not available in all markets.
- For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

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Features



Controls, Indicators, Receptacles, and Fill Line

A	**TIME Control Adjustment Buttons (each cuff channel)** When in the SET mode, press the INCREASE or DECREASE buttons to increase or decrease the value of the inflation time for the selected cuff channel. Each button press will change the value by 5-minute increments. If using the 1 to 15 minute time range, each button press will change the time value by 1-minute increments. The numeric time value will change accordingly.
B	**SET/SAVE Button (each cuff channel)** Press to initiate the SET mode and allow the adjustment of the TIME or PRESSURE values for the selected cuff channel. After adjustments have been made, press the button again to save the new values.
C	**PRESSURE Control Adjustment Buttons (each cuff channel)** When in the SET mode, press the INCREASE or DECREASE buttons to increase or decrease the value of the inflation pressure for the selected cuff channel. Each button press will change the pressure value by 5 mmHg increments. The numeric pressure value will change accordingly.
D	**INFLATE Button (each cuff channel)** Press to inflate the cuff of the selected channel to the target pressure.
E	**DEFLATE Button (each cuff channel)** Press and hold for 1.5 seconds to deflate the cuff of the selected channel.

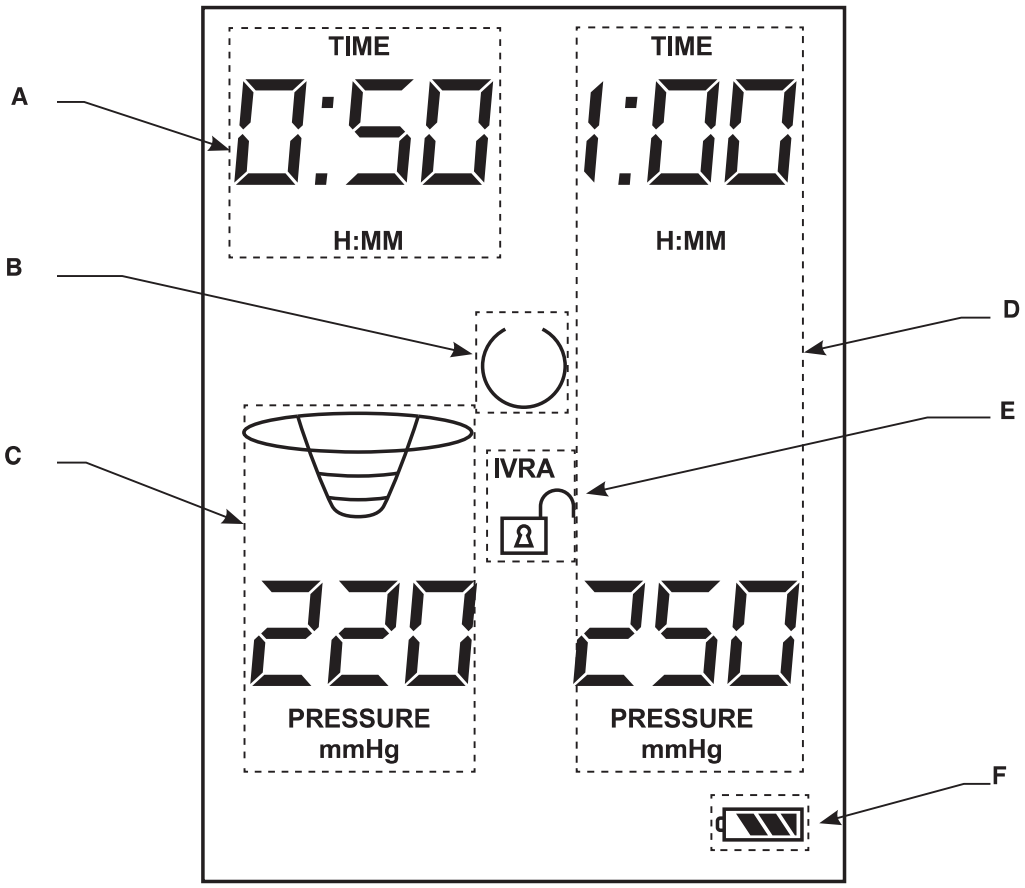
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Features

F	**DEFAULT DISPLAY Button** Press to clear the most recent procedure time and pressure values and reset the pump to the default time and pressure values. Press to store new default time and pressure setting values. See the *To Change the Default Time and/or Target Pressure Values* section.
G	**ON/OFF (STANDBY) Button** Press and release to start pump operation. Press and hold for 1.5 seconds to stop pump operation.
H	**PRINT Port** Using a serial cable, allows the connection of an optional Stryker Tourniquet Report Printer to the pump.
I	**ALARM MUTE Indicator/Button** Illuminates green to indicate normal operation and flashes red to indicate an alarm condition. Press to mute an audible alarm.
J	**Information Screen** The backlit screen provides a visual display of the elapsed inflation time and pressure of the cuff(s) during a procedure.
K	**PRINT Button** If the optional report printer is connected, press to print a summary report of tourniquet activity including cuff pressure and cuff application time during a procedure.
L	**IVRA (Intravenous Regional Anesthesia) Control Button** Press to lock or unlock the control. When locked, this control prevents the accidental deflation of an active cuff associated with a Bier Block procedure or the management of two cuffs involved in a bilateral procedure.
M	**AC Power Receptacle** Using a power cord, allows connection of facility AC power source to the pump.
N	**Battery Charge Indicator** Displays the charge status of the internal battery. The pump has an automatic internal battery switch-over feature to allow AC-free use and provide a backup if AC power is lost.
O	**AC Power Indicator** Illuminates green to indicate facility AC power is connected to the pump.
P	**Fill Line Connector (each cuff channel)** Using a fill line, allows the connection of a cuff to the selected cuff channel.
Q	**Fill Line** When connected to the pump, the fill line provides the inflation pressure pathway to a connected cuff. **NOTE:** The fill line and cuff are considered to be Defibrillation Proof BF Type Applied Parts. See the *For Use With* and *Specififcations* sections.
R	**Mounting Knob** Turn to install and remove the pump from the rolling stand.

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Features (continued)



Information Screen Layout

A	**TIME Value Area (two)** Displays an elapsed time value that indicates how long a cuff has been inflated. Two formats are available [H:MM and MINUTES].
B	**System Status Area** Displays READY icon when the pump is ready for use.
C	**PRESSURE Gauge and Value Area (two)** Displays the real-time, actual pressure value of an inflated cuff in millimeters of mercury and a graphical pressure gauge icon.
D	**CUFF 1 and CUFF 2 Channel Areas** Displays the elapsed procedure time and inflation pressure of the cuff connected to the corresponding channel fill line connector. Each channel is controlled and operated independently by the corresponding control buttons located on the sides of the pump.
E	**Intravenous Regional Anesthesia (IVRA) Status Area** Displays the IVRA lock or unlock status [shown unlocked].
F	**Battery Status Area** Displays the charge status or power level of the internal battery.

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Definitions

Information Screen Icons

Icon	Name	Definition
	Ready	The pump is operating normally and ready for use.
	Default Display	The time and pressure values displayed are the set default target values.
	Service Required	An error condition has occurred and service is required. Record the code number displayed. See the *Troubleshooting* section.
	Audible Alarm Active	An alarm condition has occurred and the audible tone is active. See the *Troubleshooting* section.
	Audible Alarm Muted	An alarm condition has occurred and the audible tone is muted. See the *Troubleshooting* section.
	Caution	An error or alarm condition has occurred and action is required. See the *Troubleshooting* section.
	Under Pressure Gauge	The actual pressure value of the selected cuff is less than the set target pressure value.
	Target Pressure Gauge	The actual pressure value of the selected cuff has reached the set target pressure value.
	Over Pressure Gauge	The actual pressure value of the selected cuff is greater than the set target pressure value.
	IVRA Lock	The Intravenous Regional Anesthesia (IVRA) control is locked.
	IVRA Unlock	The IVRA control is unlocked.

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Definitions (continued)

Information Screen Icons

Icon	Name	Definition
	Battery Power Status	The amount of battery power if the battery is in use.
	Battery Charge Status	The battery is charging, as shown by band segments illuminating sequentially.
	Cuff Deflate	The selected cuff is either deflating or deflated.
PRESSURE mmHg	Pressure Value	The pressure value of the selected cuff.
TIME DATE YEAR	Time, Date, and Year Control	The time, date, and year values when adjusting the internal clock settings. The clock does not adjust for daylight savings time changes automatically.
TIME	Time Value	The time value of the selected cuff.
H:MM	Hours and Minutes	A display format option for the selected cuff time value.
MINUTES	Minutes	A display format option for the selected cuff time value.

Audible Event Indicators

Type	Description	Event
Button Feedback	One beep	Power on button press
		Power off button press
		Normal button press
		Incorrect button press
Task Completion	Three beeps in rapid succession	Confirms cuff has reached target pressure value
	Two beeps in rapid succession	Confirms change to pressure, time or display default values
		Confirms change to IVRA status, lock or unlock
	One long beep, about 1.5 seconds	Audio volume setting
Action Required	Continuous, repeating beep, about one beep per second	Indicates system failure
		Indicates the cuff pressure value is either high or low
	Six beeps, about one beep per second, followed by a six second pause (silent), then repeated	Indicates the cuff time value has exceeded its limit

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Definitions

Battery Charge Indicators

Indication	Status
GREEN (steady state)	Battery is fully charged, in trickle or slow charge mode. Information screen displays power status.
YELLOW (blinking)	Battery is in fast charge mode and may require one hour to reach an 80% charge level. Information screen power status.
NO ILLUMINATION	Battery is not charging. Ensure AC power is connected to the pump. If AC power is connected, see the *Troubleshooting* section.

Symbols

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

 On/Off (Stand-by)	 AC Power Alternating Current (AC)	 Battery Power	Alarm Mute  Alarm Mute	Time  Time Control Adjustment	Pressure  Pressure Control Adjustment
Set/Save  Set and Save	Inflate  Inflate	Deflate  Deflate	Cuff 1 Cuff One Connector	Cuff 2 Cuff Two Connector	 Fill Line Connection Only	 Default Display
CUFF 1 Cuff One Channel	CUFF 2 Cuff Two Channel	PRINT  Print Report	 Printer Port	IVRA  IVRA Lock/ UnLock Control	 Increase	 Decrease
 Refer to Instruction Manual/ Booklet	 General Warning Sign	 Protective Earth Ground	 Direct Current (DC)	 Consult Instructions for Use	 Fuse	 Defibrillation Proof Type BF Applied Part

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Instructions

To Prepare the Pump for Use (Figure 1)

WARNINGS:

- ALWAYS secure and position the tourniquet pump outside of the sterile field in accordance with your hospital guidelines and local regulations. If no hospital guidelines exist, follow the procedure for mounting the tourniquet pump provided in these instructions.
- TIPPING HAZARD — DO NOT use the rolling stand REF 5920-013-000 with any other equipment, unless otherwise specified.
- ALWAYS place the power cord away from personnel traffic areas to eliminate a trip hazard. ALWAYS place the power cord away from water or liquids to prevent a shock hazard.

To Mount the Pump to Rolling Stand REF 5920-013-000

1. Make sure the rolling stand is assembled properly and the casters are locked. See the instructions for use supplied with the rolling stand.
2. Gently install the pump onto the post assembly of the rolling stand.
3. Turn the pump's mounting knob to fasten the pump to the post assembly securely.
4. Loosen the rolling stand's height adjustment knob and position the pump at a height that facilitates access to the controls and provides a clear view of the display.
5. Tighten the rolling stand's height adjustment knob.
6. If available, install the optional report printer kit components on the rolling stand. See the instructions for use supplied with the report printer.
7. Connect the power cord between the pump and facility power.
8. Make sure the internal battery is fully charged. See the *To Charge the Battery* section.
9. Press and release the ON/OFF (STANDBY) button to turn ON the pump. An audible tone will occur to indicate power is applied. See the *Audible Event Indicators* section.

NOTE: The software version number will appear briefly in the lower left corner of the information screen during power up. Make sure the version number matches the software version number printed on the cover of the manual.

To Charge the Battery

NOTE: During the automatic self-test, internal systems are checked for proper operation. If an error occurs, a service code will be displayed. See the *Troubleshooting* section if required.

1. Connect the power cord to the pump and facility power.
2. Press the ON/OFF (STANDBY) button to turn ON the pump and initiate an automatic self-test. The software version will appear briefly on the information screen.
3. Press and hold the ON/OFF (STANDBY) button for 1.5 seconds to turn OFF the pump.
4. Keep the pump connected to facility power for six hours to allow the pump's internal battery to fully charge.

To Set the System Time and Date Values (Figures 2 and 3)

NOTE: The pump has a real-time clock, powered by an internal battery, which tracks time and date information. The clock does not adjust for daylight savings time changes automatically.

To Initiate Setting the Values

1. Ensure the READY icon is displayed on the screen and the cuffs are not inflated.
2. Press and hold the SET/SAVE button and the TIME INCREASE button of cuff channel one simultaneously for four seconds.
3. Release both buttons. Locate the time value (HH:MM, 24-hour format) on the information screen and observe the hour value is blinking.

To Set the Hour Value

1. Press the TIME INCREASE or DECREASE buttons of cuff channel one to set the hour value.
2. Press the SET/SAVE button to save the new value. Observe the minute value is blinking.

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Instructions

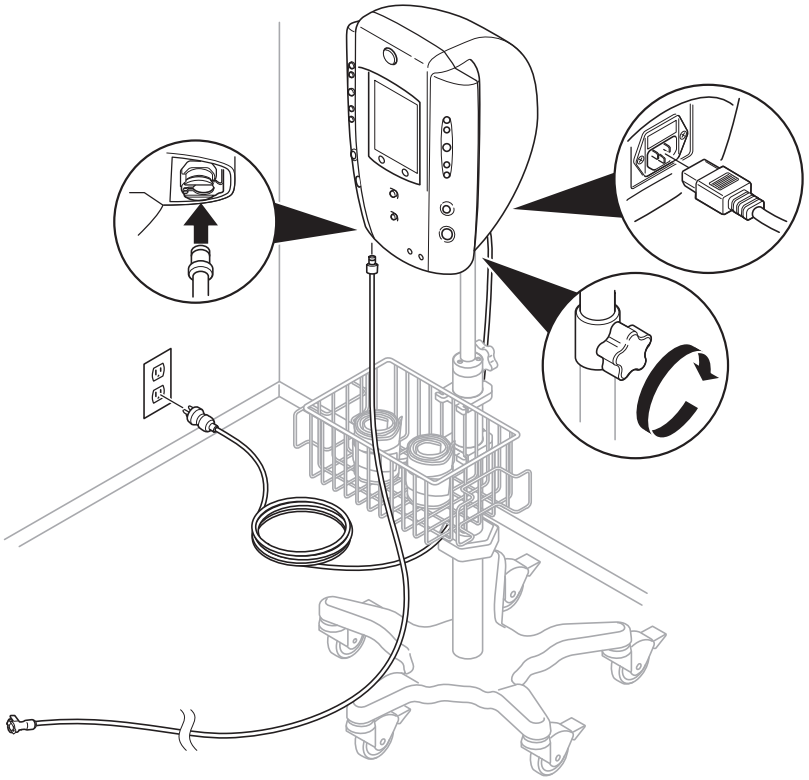


Figure 1 To Prepare the Pump for Use

To Set the Minute Value

1. Press the TIME INCREASE or DECREASE buttons of cuff channel one to set the minute value.
2. Press the SET/SAVE button to save the new value. Locate the date value (MN.DY, 12.06 format) on the information screen and observe the month value is blinking.

To Set the Month Value

1. Press the TIME INCREASE or DECREASE buttons of cuff channel one to set the month value.
2. Press SET/SAVE button to save the new value. Observe the day value is blinking.

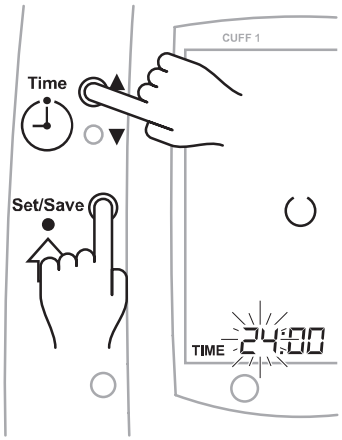


Figure 2 To Initiate Setting the Values

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Instructions (continued)

To Set the System Time and Date Values (continued)

To Set the Day Value

1. Press the TIME INCREASE or DECREASE buttons of cuff channel one to set the day value.
2. Press SET/SAVE button to save the new value. Observe the year value is blinking.

To Set the Year Value

1. Press the TIME INCREASE or DECREASE buttons of cuff channel one to set the year value.
2. Press SET/SAVE button to save the new time and date values.
3. Ensure the DEFAULT DISPLAY icon appears on the information screen.

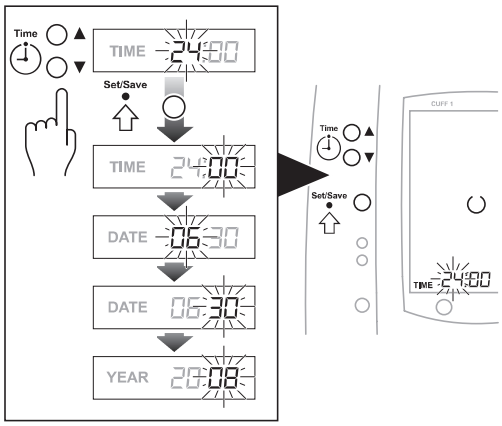


Figure 3 To Set the Time and Date Values

To Change the Time Display Format (Figure 4)

1. Ensure both cuffs are deflated and each cuff channel is not active.
2. Ensure the READY icon is displayed on the information screen.

NOTE: The time display format cannot be changed during an active cuff procedure.

3. Press the INCREASE button on the TIME control of both cuff channels simultaneously.
4. Observe the current time format on the information screen change automatically, for example, from H:MM to MINUTES.

NOTE: The time display format will remain the constant until the format is changed again.

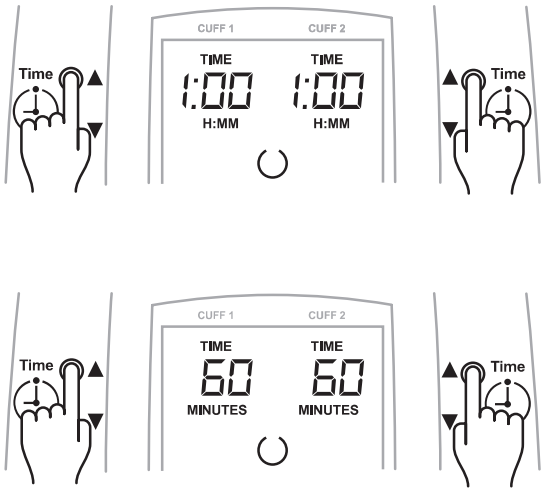


Figure 4 To Change the Time Display Format

To Change the Default Time and/or Target Pressure Values

1. Press the SET/SAVE button to initiate the adjustment mode.

NOTE: Observe the corresponding time and pressure values blink on the information screen.

2. Press the TIME INCREASE or DECREASE buttons to increase or decrease the time value, respectively. Observe the time value change accordingly.

NOTE: Each button press will change the value by 5-minute increments for the 15 to 240 minute time range. The value will change by one-minute increments for the 1 to 15 minute time range.

3. Press the PRESSURE INCREASE or DECREASE buttons to increase or decrease the pressure value, respectively. Observe the pressure value change accordingly.

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Instructions

To Change the Default Time and/or Target Pressure Values (continued)

NOTE: Each button press will change the pressure value by 5-mmHg increments for the 100 to 475 mmHg pressure range.

4. After the desired values are selected, press the DEFAULT DISPLAY button to save the new values.

NOTES:

- The time and pressure values will stop blinking on the information screen. A double-beep will indicate the new values have been saved. The READY icon and DEFAULT DISPLAY icon will appear on the information screen.
- If the DEFAULT DISPLAY button is not pressed within five minutes of starting the adjustment mode, the mode will be cancelled without changing the default settings.

To Adjust Alarm Volume (Figure 5)

1. Press and hold the ALARM MUTE indicator/ button.
2. Press the TIME INCREASE or DECREASE buttons of cuff channel one to increase or decrease, respectively, the alarm volume to a desired level.

NOTE: The alarm volume may be adjusted in the active or READY mode.

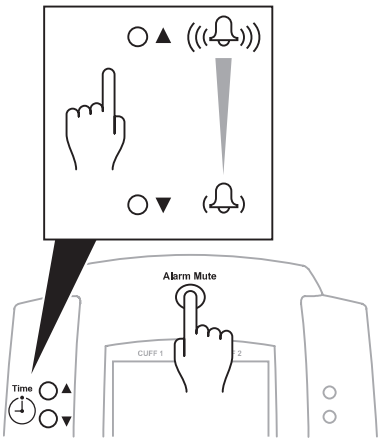


Figure 5 To Adjust Alarm Value

To Minimize the Display of Screen Values (Figure 6)

NOTES:

- The information screen displays the time and pressure values of both cuff channels as a factory default setting.
- If single cuff procedures are used more often, the display of values may be changed to appear for one cuff channel only.
- When the display of values is minimized to one cuff channel, the values of the selected cuff will be displayed only.

1. Ensure the READY icon is displayed on the information screen and no cuffs are inflated.
2. Press and hold the ALARM MUTE indicator/ button, then press the DEFAULT DISPLAY button.
3. Ensure the display cycles twice by blinking on one channel and then the other channel to confirm the selection of the minimization mode.

NOTES:

- To view the default settings when the display has been minimized, you may press the DEFAULT DISPLAY button, the IVRA Lock button to LOCK, or the INFLATE button located on the channel where the setting display is minimized.
- To restore the continuous display of default settings for both cuff channels, repeat steps one and two. Both channel display setting values will blink to confirm de-selection of the minimization mode.

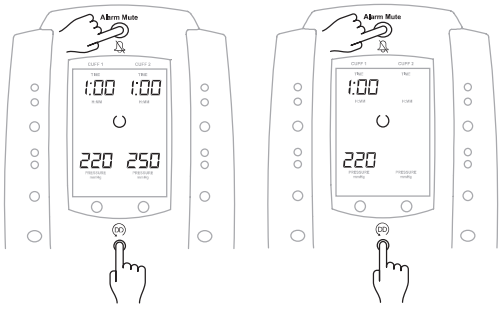


Figure 6 To Minimize the Display of Screen Values

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Instructions (continued)

To Connect a Cuff

1. Ensure the READY icon and DEFAULT DISPLAY icon appear on the information screen.
2. If the default time and pressure settings are acceptable, connect a fill line to the pump. If the time and pressure settings need to be changed, see the *To Change the Procedure Time and Target Pressure Values* section.
3. Position the cuff on the patient's limb.



WARNING: Connect the fill line connector of the pump to the tourniquet cuff only. Fill line extension tubing and/or an adapter may be used between the fill line connector of the pump and the tourniquet cuff. See the *Definitions - Symbols* section.

4. Connect the cuff to the fill line connector.
5. Inflate and deflate the cuff as required. See the *To Inflate a Cuff* section.

To Inflate a Cuff



WARNINGS:

- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- Verify the tourniquet pump is connected to the tourniquet cuff only.
- ALWAYS monitor the cuff pressure and application time throughout a surgical procedure. DO NOT apply excessive cuff pressure. DO NOT use a cuff for an excessive amount of time. Failure to comply may result in patient injury, including vascular complications, neuromuscular or neurological injuries, tourniquet pain, ischemia, venous emboli or thromboembolism, blood vessel trauma, reperfusion problems and arterial occlusion, mild, aching pain in the limb, stiffness, weakness, reactive hyperemia, and skin discoloration.
- NEVER turn OFF the pump while the cuff(s) are inflated. Failure to comply will cause the cuffs to deflate and may result in patient injury.



WARNINGS:

- Pay particular attention to excessive sound associated with frequent pump activity. Any pressure loss will cause the system to compensate for the decreased pressure. However, the system may eventually fail to maintain cuff pressure if the pressure loss begins to increase significantly. See the *Troubleshooting* section.
- ALWAYS resolve an alarm condition before continuing to use the pump. An alert triangle, a flashing time or pressure value, or a wrench icon with a service code indicates an alarm condition. See the *Troubleshooting* section.
- If a pump malfunction occurs due to a loss of both AC power and internal battery power, an inflated cuff will remain inflated. Deflate the cuff by manually disconnecting the cuff.

1. Press the INFLATE button to inflate the selected cuff.
2. Ensure the selected cuff inflates to the target pressure value and the time value accumulates the elapsed time of cuff inflation.
3. Monitor and manage the pressure and elapsed time settings. See the *To Change the Procedure Time and Target Pressure Values* section as required.

NOTE: If a cuff cannot reach or maintain the target pressure value during initial inflation, discontinue using the cuff. See the *To Switch (or Backup) a Single Cuff* section.

4. When the target elapsed cuff time is reached, perform one of the options:

- Option 1 - Press the DEFLATE button to deflate the selected cuff. See the *To Deflate a Cuff* section for details.

NOTES:

- If necessary, you may then press the INFLATE button to re-inflate the cuff to the highest pressure used during the procedure. The elapsed cuff time will start again and continue to accumulate elapsed cuff time.
- The pump will not deflate the cuff automatically when the target time is reached. You must press the DEFLATE button to deflate the selected cuff.

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- Option 2 - Press the ALARM MUTE indicator/button to mute the audible alarm for 15 minutes.

NOTE: The ALARM MUTE indicator/button will remain red and flash. The pump will continue to monitor and display the total elapsed time value of cuff inflation.

- Option 3 - Add more time as required. See the *To Change the Procedure Time and Target Pressure Values* section.

To Switch (or Backup) a Single Cuff

NOTES:

- If cuff channel one or two become inoperative, a cuff may be switched to the functional channel.
- Use this procedure only when an inflated, active cuff is at risk or an alarm condition cannot be resolved and no alternative cuff is available.
- Adapt this procedure to current local protocol as required.

1. Ensure the cuff and all pneumatic connections are leak-free and secure.
2. Clamp and close off the fill line of the inflated cuff to retain cuff pressure.
3. Disconnect the fill line from the pump.
4. Press the DEFLATE button of the inoperative channel to clear the alarm condition.
5. Move the clamped fill line cuff to the operative channel and connect the fill line to the pump.
6. Press the INFLATE button and release the clamp to allow the pump to take control of cuff pressure.

NOTE: A momentary pressure alarm condition may occur as the pump takes control of cuff pressure.

7. Adjust the cuff time and target pressure values as required. See the *To Change the Procedure Time and Target Pressure Values* section.

To Change the Procedure Time and Target Pressure Values

NOTES:

- Time and pressure values may be changed when the pump is in the READY mode or during active cuff inflation.
- Time and pressure values will remain constant unless: (a) the values are changed as described in this procedure, (b) the DEFAULT DISPLAY button is pressed after deflation or, (c) the pump is turned off and turned on again.
- An error beep will occur if the button press sequence is incorrect. For example, an error beep will occur if the TIME INCREASE or TIME DECREASE buttons are pressed before pressing the SET/SAVE button to initiate a change.
- Each TIME INCREASE or DECREASE button press will change the time value by 5-minute increments for the 15 to 240 minute time range. The value will change by one-minute increments for the 1 to 15 minute time range.
- Each PRESSURE INCREASE or DECREASE button press will change the pressure value by 5-mmHg increments for the 100 to 475 mmHg pressure range.

1. Press the SET/SAVE button to initiate changing a time or pressure value.

NOTE: Observe the corresponding time and pressure values blinking on the information screen.

2. Press the TIME INCREASE or DECREASE buttons to increase or decrease the time value, respectively. Observe the time value change accordingly.
3. Press the PRESSURE INCREASE or DECREASE buttons to increase or decrease the pressure value, respectively. Observe the pressure value change accordingly.
4. When the desired values are selected, press the SET/SAVE button to save the new values.

NOTES:

- The time and pressure values will stop blinking on the information screen. A double-beep will indicate the new values have been saved.
- If a cuff is not inflated, the READY icon will appear on the information screen. If a cuff is inflated, the time and pressure values will appear as actual, real-time values.

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To Deflate a Cuff



WARNINGS:

- ALWAYS disconnect and remove the deflated cuff from the tourniquet system after the procedure is complete.
- ALWAYS remove the sleeve and other underlying materials after the procedure is complete.

NOTE: A cuff may be deflated at any time during a procedure.

1. Press the DEFLATE button for the selected cuff for 1.5 seconds.
2. Ensure the pressure value and pressure gauge icon on the information screen indicate a pressure decrease.
3. If the optional report printer is attached, a procedure summary report may be printed. See the *To Print the Procedure Summary Report (optional)* section for details.
4. Press the DEFAULT DISPLAY button to clear the procedure's pressure and time values.

NOTES:

- When the cuff pressure value reaches zero, the pressure value and pressure gauge icon are not present on the information screen. The total elapsed cuff time remains on the information screen.
- In the deflated (inactive) state, the pump will continue to monitor ambient air pressure. The pump will exhaust any ambient pressure due to cuff or patient movement, automatically, before cuff removal.
- The IVRA LOCK/UNLOCK CONTROL button may be used to prevent accidental cuff deflation during a Bier Block procedure or the management of two cuffs involved in a bilateral procedure. See the *To Perform a Bier Block Procedure* section for details.

To Print the Procedure Summary Report (optional)

NOTES:

- Procedure summary information is saved and retained in the pump even if power is removed or the internal battery is fully discharged.
- Each time a new procedure is initiated, the previous summary information is replaced by the new information.
- Previous summary information may be replaced as follows: (1) pressing the DEFAULT DISPLAY button followed by pressing the INFLATE button and (2) turning the pump OFF and ON followed by pressing the INFLATE button.

1. Make sure the optional report printer is connected to the pump. See the instructions for use supplied with the report printer.
2. Make sure the report printer is loaded with the proper self-adhesive labels and ready for use. See the instruction for use supplied with the report printer.
3. Press the PRINT button on the pump.
4. Apply the self-adhesive label to the patient record or chart according to current local guidelines.

To Perform a Bier Block Procedure



WARNINGS:

- ALWAYS follow current hospital protocol governing the safe and effective use of a Bier Block procedure.
- DO NOT apply excessive cuff pressure or apply the cuff(s) for an excessive amount of time during a Bier Block procedure. Failure to comply may result in patient injury or death.

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To Perform a Bier Block Procedure (continued)

NOTES:

- The pump will support the connection of a Bier Block cuff to either cuff channel one or two.
- Pressing the INFLATE button will interrupt a cuff deflation instantly or return cuff pressure to the highest value used during the preceding procedure.
- The IVRA LOCK/UNLOCK CONTROL button may be activated (locked) either before or after inflation.

1. Press the IVRA LOCK/UNLOCK CONTROL button to lock the IVRA control and prevent the accidental deflation of the cuff. Ensure the IVRA LOCK icon is displayed on the information screen.

NOTE: If a cuff cannot reach or maintain the target pressure value during initial inflation, discontinue using the cuff. See the *To Switch (or Backup) a Bier Block Cuff* section.

2. Sequence the inflation and deflation of the Bier block cuffs according to current local guidelines governing the performance of a Bier Block procedure.
3. After the sequencing is complete, deflate the Bier Block cuffs using one of the options:

- Option 1 - Press the IVRA LOCK/UNLOCK CONTROL button to unlock the IVRA control and allow the deflation of the cuff.
- Option 2 - Deflate the cuff pressure incrementally. See the *To Change the Procedure Time and Target Pressure Values* section. After incremental deflation of the cuff is complete, press the IVRA LOCK/UNLOCK CONTROL button to unlock the control and allow full deflation of the cuff.

To Switch (or Backup) a Bier Block Cuff

NOTES:

- If the primary cuff cannot reach or maintain the target pressure value during initial inflation and before anesthetic injection, discontinue using the cuff.
- If, before deflation of the primary cuff, the secondary cuff cannot reach or maintain the target pressure value, use this procedure to backup the primary cuff.

1. Ensure the cuff and all pneumatic connections are leak-free and secure.
2. Clamp and close the fill line of the inflated primary cuff to retain cuff pressure.
3. Disconnect the fill line of the primary cuff from the pump.

NOTE: A pressure alarm condition will occur.

4. Connect the fill line of the secondary cuff to the fill line connector of the primary cuff.
5. After confirming the second cuff reaches the target pressure value, release the clamped primary cuff.
6. Adjust the cuff time and target pressure values as required. See the *To Change the Procedure Time and Target Pressure Values* section.

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Inspection and Testing

WARNINGS:

- Perform recommended maintenance as indicated in these instructions. Only trained and experienced healthcare professionals should maintain this equipment.
- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any component if damage is apparent or inspection criteria are not met.
- DO NOT disassemble, modify, service, or repair this equipment without authorization of the manufacturer.

NOTES:

- For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.
- Maintenance documentation for this equipment is available upon request to Stryker-authorized service personnel only.

Interval	Inspection Criteria	Action
Before first use and after each cleaning	Check the equipment for damage, wear, or missing components such as missing or split O-rings on pneumatic connectors.	If damage is apparent, replace the equipment.
	Check the power cord for cuts, bent prongs or cracked insulation.	
	Check the power cord receptacle for bent pins or contacts.	
	Check the housing for cracks.	
	Check the fill lines for crimped or cracked tubing.	
Before first use and after each use	Clean the pump. See the *Cleaning* section.	
Annual	---	Contact Stryker for the latest service checks to ensure proper operation. **NOTE:** These checks are not intended to replace inspection and test criteria that are independently developed and adopted by the healthcare facility.

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Cleaning



WARNINGS:

- ALWAYS clean the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient and/or healthcare staff injury.
- Before cleaning, remove facility power and all accessories from the equipment.

CAUTIONS:

- DO NOT sterilize the equipment.
- DO NOT use solvents, lubricants, or other chemicals, including glutaraldehyde or similar chemical cleaners, unless otherwise specified. Use of unapproved disinfectants may cause damage.
- DO NOT immerse the equipment in liquid.
- DO NOT allow liquid to run directly into any electrical or pneumatic connection, or button opening. Moisture may cause corrosion to electrical and/or mechanical components.

Recommended Equipment

- Personal Protective Equipment (PPE) as recommended by the disinfectant supplier (minimum: gown, gloves, face/eye shield)
- Soft, lint-free cloth
- United States Environmental Protection Agency (US EPA) registered disinfectant with a claim for activity against Hepatitis B. The following disinfectants have been validated for use with the Stryker SmartPump Tourniquet System:

  Sodium Hypochlorite Based - Clorox® Clean-Up® Disinfectant Cleaner with Bleach (EPA Reg. #67619-1)

  Quaternary Ammonium Based - CaviCide® (EPA Reg. #46781)

1. Wipe the exterior surfaces of the equipment, with a soft, lint-free cloth moistened with a non-abrasive, hospital cleaning solution.
2. Wipe critical areas such as the top of the pump, buttons and surrounding areas, the end of the fill lines, and any other areas that may have become soiled.
3. Using a clean cloth moistened with disinfectant, wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions supplied by the disinfectant manufacturer.
4. Remove any excess disinfectant solution using a soft, lint-free cloth moistened with water if required by the instructions supplied by the disinfectant manufacturer.
5. Inspect the equipment for damage. See the *Inspection and Testing* section.

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Troubleshooting

WARNING: DO NOT disassemble, modify, service, or repair this equipment without authorization of the manufacturer.

NOTE: For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

PROBLEM	CAUSE	ACTION
A NO POWER condition occurs at start up. 'no AC' is displayed on the information screen. The pump will not operate to perform a procedure. ALARM MUTE indicator/button blinks red.	Either no AC power is connected or an electronic component failure has occurred.	Press ALARM MUTE indicator/button to cancel the alarm. The pump will operate using the internal battery. If ALARM MUTE indicator/button is not pressed within 30 seconds, the pump will shutdown automatically to prevent inadvertent battery discharge. Connect AC power to the pump as soon as possible. If the error condition persists, return the pump for repair.
A NO POWER condition occurs during operation. 'no AC' is displayed on the information screen. ALARM MUTE indicator/button blinks red.	Either no AC power is connected or an electronic component failure has occurred.	Press ALARM MUTE indicator/button to cancel the alarm. The pump will operate using the internal battery. Connect AC power to the pump as soon as possible. If the error condition persists, return the pump for repair.
LOW BATTERY condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/button blinks red, and the battery charge icon has one band segment.	Approximately 30 minutes of operating time remains using the internal battery power.	Press the ALARM MUTE indicator/button to mute the tone for 15 minutes. Connect AC power to the pump as soon as possible to charge the internal battery.
The BATTERY CHARGE indicator is not illuminated.	The internal battery is not charging. AC power may not be present. If AC power is present, the battery charge circuit or internal battery may have failed.	Connect AC power to the pump. If the error condition persists, return the pump for repair.
EXTREME LOW BATTERY condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/button blinks red, and the battery charge icon has no band segments.	Approximately 15 minutes or less of operating time remains using the internal battery power.	Press the ALARM MUTE indicator/button to mute the tone for 60 seconds. Connect AC power to the pump as soon as possible to charge the internal battery.

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Troubleshooting (continued)

PROBLEM	CAUSE	ACTION
LOW PRESSURE CUFF condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/ button blinks red, and affected pressure value blinks.	Cuff pressure value is not more than 25 mmHg below target value for more than one second.	Press the ALARM MUTE indicator/button to mute the tone for 60 seconds. Eliminate a leaking cuff O-ring, a loose Luer connection, or a leaking or damaged cuff or fill line. See the *To Switch (or Backup) a Single Cuff* section if necessary. If the condition persists, return the pump for repair.
EXTREME LOW PRESSURE CUFF condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/ button blinks red, and affected pressure value blinks.	Cuff pressure value is more than 25 mmHg below target value for more than 0.2 seconds.	Press the ALARM MUTE indicator/button to mute the tone for 30 seconds. Eliminate a leaking cuff O-ring, a loose Luer connection, or a leaking or damaged cuff or fill line. See the *To Switch (or Backup) a Single Cuff* section if necessary. If the condition persists, return the pump for repair.
OVER PRESSURE CUFF condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/ button blinks red, and affected pressure value blinks.	Cuff pressure value is not more than 25 mmHg above target value for more than one second. Cuff pressure value is more than 20 mmHg above the target value for more than five seconds while the cuff is deflated or in a ready state. During deflation, the cuff pressure value is more than 50 mmHg above the target value and fails to decrease by 25 mmHg per second or more.	Press the ALARM MUTE indicator/button to mute the tone for 30 seconds. Ensure the pneumatic fill lines and cuff are not kinked or obstructed. If the condition persists, return the pump for repair.
EXTREME OVER PRESSURE CUFF condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/ button blinks red, and affected pressure value blinks.	Cuff pressure value is more than 25 mmHg above target value for more than 0.2 seconds. Cuff pressure value is more than 20 mmHg above the target value for more than five seconds while the cuff is deflated or in a ready state.	Press the ALARM MUTE indicator/button to mute the tone for 30 seconds. Ensure the pneumatic fill lines and cuff are not kinked or obstructed. If the condition persists, return the pump for repair.

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Troubleshooting

PROBLEM	CAUSE	ACTION
TIME EXPIRED condition occurs during operation. Audible tone occurs, ALARM MUTE indicator/button blinks red, and affected time value blinks.	The procedure cuff time limit has reached its set value.	Press the DEFLATE button for 1.5 seconds to deflate the cuff. Inflate the cuff, if appropriate or, press the ALARM MUTE indicator/button to mute the tone for 15 minutes, or add more time to the procedure timer if appropriate.
BLOCKED DEFLATION condition occurs. Audible tone occurs, and the IVRA icon blinks on the information screen.	The IVRA LOCK/UNLOCK CONTROL is locked and an attempt is made to deflate both cuffs. One cuff may deflate, but the second cuff will not deflate.	Press the ALARM MUTE indicator/button to cancel the condition, or press the IVRA LOCK/UNLOCK CONTROL button to unlock the control, or press INFLATE or SET/ SAVE button that controls the affected cuff to cancel the condition.
Sporadic electrical interference is experienced.	Electrical noise is present.	Turn off all electrical equipment not in use. Relocate electrical equipment; increase spatial distance. Plug electrical equipment into different electrical outlets.
CODE 30 appears on the information screen.	The system has detected a calibration error condition.	Return the pump for repair.
CODE 31 appears on the information screen.	The system has detected a real-time clock error condition.	Return the pump for repair.
CODE 32 appears on the information screen.	The system has detected a serial interface error condition.	Return the pump for repair.
CODE 33, 34, 35, or 36 appears on the information screen.	The system has detected a memory error condition.	Return the pump for repair.
CODE 37 appears on the information screen.	The system has detected an hardware error condition.	Return the pump for repair.
CODE 38 appears on the information screen.	The system has detected a power supply or battery charging error condition.	Return the pump for repair.

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Troubleshooting (continued)

PROBLEM	CAUSE	ACTION
CODE 40 appears on the information screen.	The system has detected a bladder one error condition. The bladder may be leaking or not operating correctly.	Return the pump for repair.
CODE 41 appears on the information screen.	The system has detected a bladder two error condition. The bladder may be leaking or not operating correctly.	Return the pump for repair.
CODE 42 appears on the information screen.	The system has detected a valve or air pump error condition.	Return the pump for repair
	Internal battery capacity is too low to supply sufficient power to the pump.	Turn pump off. Connect to AC power source. Allow battery to charge for 6 hours. Turn pump on.

Storage and Handling

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section.

To ensure the longevity, performance and safety of this equipment, use of the original packaging material is recommended when storing or transporting this equipment.

Disposal/Recycle

WARNINGS:

- ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.
- ALWAYS decontaminate a medical device exposed to infectious microorganisms before sending it to a waste treatment facility.



To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, ALWAYS collect this product separately for recycling. DO NOT dispose of this product as unsorted municipal waste. Contact your local distributor for disposal information.



NiMH

To comply with Batteries Directive 2006/66/EC, this device has been designed for safe removal of the batteries at end-of-life by a waste treatment facility.

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Specifications

Model:	SmartPump Dual Channel Tourniquet Pump
REF:	5920-011-000
Dimensions:	
Height:	39.4 cm [15.5 inch]
Width:	25.4 cm [10 inch]
Depth:	22.9 cm [9 inch]
Mass:	
Unpacked:	5.45 kg [12.0 lb]
Packaged:	8.28 kg [18.25 lb]
Mode of Operation:	Continuous
Electrical Power:	
AC Input:	
Input Voltage Range:	100 - 230 V~, universal switching power supply
Frequency:	50/60 Hertz
Fuses:	two 3.15A / 250 V~, fast acting (F), low breaking capacity (L)
Power Requirements:	1.5 A @ 120 V~, 0.75 A @ 230 V~
Internal Battery:	
Type:	Nickel metal hydride [NiMH]
Nominal Voltage:	12 V⎓
Rated Capacity:	2.6 Ahr [amperes per hour]
Charge Time:	One hour [80% charge], six hours [100% charge, provides five hours of power]
Over current Protection:	Integral positive temperature coefficient (PTC) fuse
Over temperature Sense:	Integral thermistor
Power Conservation:	30 days or 750 hours when fully charged and unplugged in OFF (STANDBY) mode
Internal DC Supply Module:	
Output Voltage:	15 VDC ± 1%, 150 mV peak-to-peak ripple
Output Current:	4A maximum
Output Power:	60W maximum
Overload Protection:	Short circuit, 110% - 150% auto recovery
Over Voltage Protection:	115% - 135% of rated output voltage
Means of Disconnection (from supply mains):	Disconnect the power cord from the AC power cord receptacle (appliance inlet).
Information Screen:	High-resolution backlit custom liquid crystal display (LCD)

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Specifications (continued)

Time Display:	Elapsed time numeric
Range:	1 to 240 minutes
Adjustments:	1 to 15 minutes – 1 minute increments; 15 to 240 minutes – 5 minute increments
Pressure Display:	Real-time digital numeric with graphic pressure gauge
Accuracy:	± 2% or 4 mmHg, whichever is greater, set pressure value
Range:	100 to 475 mmHg
Ingress Protection (IP):	IPX0
Equipment Classification and Type:	 Class I Medical Electrical (ME) Equipment, Defibrillation Proof Type BF Applied Part
Product Safety Certification:	 **CSA International** **International Electrotechnical Commission (IEC)** IEC 60601-1:1988, *Medical Electrical Equipment — Part 1: General Requirements for Safety - Second Edition*; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995) **Canadian Standards Association (CSA)** CAN/CSA-C22.2 No. 601.1-M90, *Medical Electrical Equipment — Part 1: General Requirements for Safety* **Underwriters Laboratories (UL)** UL 60601-1, *Medical Electrical Equipment, Part 1: General Requirements for Safety — First Edition*; Revisions through and including April 26, 2006
	International Electrotechnical Commission (IEC) IEC 60601-1:2005, Ed:3, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance*; Corrigendum 1 (2006); Corrigendum 2 (2007) **Canadian Standards Association (CSA)** CAN/CSA-C22.2 No. 60601-1:08, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance* **American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)** ANSI/AAMI ES60601-1:2005, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance*; Consolidated Reprint (2009); Amendment 2 (2010) **European Committee for Electrotechnical Standardization (CENELEC)** EN 60601-1:2006, Ed:3, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;* IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011)

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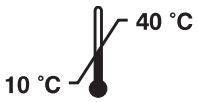
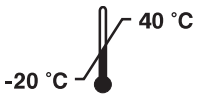
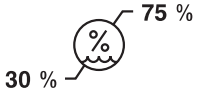
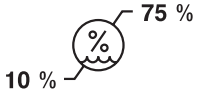
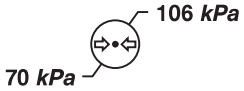
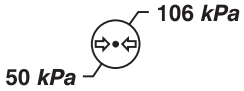
Specifications

Air Pump:

Nominal power:	12 VDC, 1.25 A
Flow:	10 LPM open flow

Pressure Transducers:

Operating pressure:	0 – 776 mmHg [0 – 15 psi]
Maximum pressure:	1551 mmHg [30 psi]
Repeatability:	± 0.2% full scale (FS) typical

Environmental Conditions:	Operation	Storage and Transportation
Temperature Limitation:		
Humidity Limitation:		
Atmospheric Pressure Limitation:		

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 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 SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Specifications (continued)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 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 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 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 meters (m) Interference may occur in the vicinity of equipment marked with the following symbol:  (Non-ionizing electromagnetic radiation)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

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.

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Specifications

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 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	±2, 4, 6 kV contact ±2, 4, 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±0.5, 1 kV differential mode ±0.5, 1, 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m at 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in 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 seconds	95% Reduction (10 ms) 60% Reduction (100 ms) 30% Reduction (500 ms) 95% Reduction (5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 requires continued operation during power mains interruptions, it is recommended that the Dual Channel Tourniquet Pump System be powered from an EMC and product safety certified uninterruptible power supply or a battery.

NOTE: U_T is the alternating current mains voltage prior to application of the test level.

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Specifications (continued)

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Dual Channel Tourniquet Pump System

The SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartPump Dual Channel Tourniquet Pump REF 5920-011-000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

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Appendix

Factory Default Settings

Elapsed Procedure Time Value	1 hour [1:00 displayed]
Target Cuff Pressure Value	250 mm Hg [250 displayed]
Cuff Time Alarm	1 hour

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