

PneumoSure Insufflator

Features

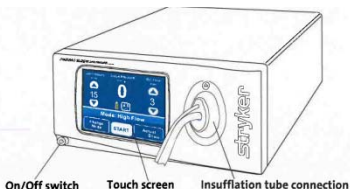
Stryker's 45L PneumoSure insufflator provides exceptional performance with enhanced safety and reliability. This new insufflator is designed to handle the needs of today's dynamic surgical environment and includes 2 additional modes for Bariatrics and Vessel Harvesting. The 45L PneumoSure insufflator offers real time pressure sensing for increased accuracy during a procedure. Its ability to maintain pneumoperitoneum under the most extreme conditions, coupled with a fully integrated color touch screen, allow for increased ease of use with the Stryker 45L PneumoSure insufflator.



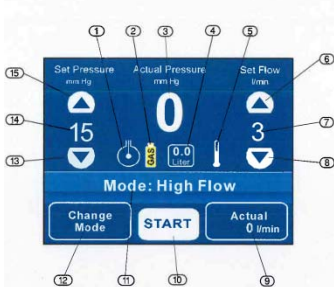
- Intuitive touch screen controls with flow, pressure, volume and cylinder status display
- Real time pressure measurement capabilities (RTP)
- CO2 flow rate from 3-45 litres per minute
- Multiple specialty modes
- Optional gas heating function
- Spring loaded tube set connection
- Bariatric, Pediatric and vessel harvesting modes

PneumoSure Insufflator

Using On Screen Display



How to use and read the touch screen display



- ① Real-Time Pressure Sensing display
- ② Gas supply display
- ③ Actual pressure display
- ④ Gas consumption display / function field for reset)
- ⑤ Gas heating connected/ready
- ⑥ Increasing nominal gas flow
- ⑦ Nominal gas flow display
- ⑧ Decreasing nominal gas flow
- ⑨ Actual gas flow display / menu function field
- ⑩ START/STOP function field
- ⑪ Status display/error & warning messages
- ⑫ Insufflation mode display /selecting insufflation mode
- ⑬ Decreasing nominal pressure
- ⑭ Nominal pressure display
- ⑮ Increasing nominal pressure

Press the function fields ⑨ (Menu) or ⑫ (Change insufflation mode), depicted with frame and hold for 2 seconds to trigger functions.

How to read the gas supply display



Bottle pressure >30 bar



House gas supply pressure OK



Bottle pressure 20-30 bar
 With pressure of < 30 bar -> message **Low gas pressure** (5 s)



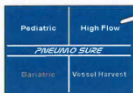
House gas supply pressure too low



Bottle pressure < 20 bar -> message **Change gas bottle**
 Bottle pressure <15 bar -> message **Check gas supply**,
 Insufflation stops automatically

PneumoSure Insufflator Functions

How to choose the insufflation mode

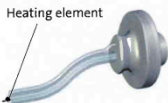


Press the respective function field to select the desired mode (e.g. High Flow). Unavailable procedure modules are grayed out and cannot be selected.



Available disposable tube sets

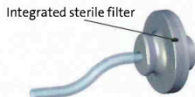
Heated tube set with Real-Time Pressure Sensing (RTP)



High Flow tube set with Real-Time Pressure Sensing (RTP)

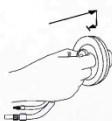


High Flow II tube set



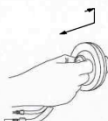
How to connect and remove the tube set

Connecting the tube set



Press plug of tube in direction of device to engage snap-in latch and connect tube set

Removing the tube set



Press plug of tube in direction of device to release snap-in latch and remove tube set

How to use the gas heating function

Connecting to use the gas heating



Thermometer symbol indicates gas heater is working ok

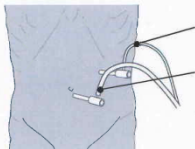
Incorrect or defective heating



Crossed out thermometer symbol indicates gas heater is defect

How to use the Real-Time Pressure Sensing function

Only with "Heated tube set with Real-Time Pressure Sensing" and "High Flow tube set with Real-Time Pressure Sensing"



Thin tube goes to a **different trocar** for pressure measurement

Thick tube goes to **veress needle / first trocar** for flow

PneumoSure Insufflator Functions

Indicating Real-Time Pressure Sensing



Real-Time Pressure Sensing symbol indicates working continuous pressure measuring.

Defective or interrupted Real-Time Pressure Sensing



Crossed out Real-Time Pressure Sensing symbol indicates defective or interrupted continuous pressure measuring.

How to set pressure and flow



Press on up and down buttons to change **nominal pressure**.



Press on up and down buttons to change **nominal flow**.

How to start and stop insufflation

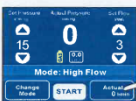


Start insufflation:
Press on the **START** button



Stop insufflation:
Press on **STOP** button.

Configuration menu - Enter and navigate



When insufflation is stopped, hold down on the **Actual** field for a second to access the configuration menu.

Depiction/functions in Configuration menu	
	Press the "arrow forward" function field to access the next menu on the same level.
	Press the "arrow backward" function field to access the previous menu on the same level or to access the previous menu of the next higher menu level without saving settings .
	Press the (SAVE) function field to save settings. The display depicts (SAVED) for 2 seconds. After saving you return automatically to the previous level.
	Press the (EXIT) function field to exit the menu and return to the work screen.

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Error and Warning Messages

Error and Warning Messages	Cause	Troubleshooting
Check gas supply	(During device check) Existing gas supply pressure is too low.	<ul style="list-style-type: none"> • Open gas bottle or • Replace the gas bottle. • Check the house supply.
	(During surgery) <ul style="list-style-type: none"> • The gas supply pressure has dropped below 15 bar. 	<ul style="list-style-type: none"> • Detach the insufflation tube. • Close gas supply valve. • Replace gas supply. • Open gas supply valve. • Connect insufflation tube. • Continue insufflation.
	<ul style="list-style-type: none"> • Insufficient house gas supply. 	<ul style="list-style-type: none"> • Check the house gas supply. • Open or remove pressure reduction valve if in line with gas bottle. • Check if appropriate house gas connector is used.
Change gas tank	The gas supply pressure has dropped below 30 bar.	<ul style="list-style-type: none"> • Prepare for changing the gas bottle.
Overpressure	The pressure monitor shows that the actual pressure is at least 4 mm Hg above the nominal pressure.	<ul style="list-style-type: none"> • Determine the cause for exceeding the nominal pressure. Check the electronic controls of the device if overpressure exists for a longer period of time (see chapter 13 Annual Inspection, page 77).
	The actual pressure has reached 30 mm Hg / 20 mm Hg (depending on the operating mode).	<ul style="list-style-type: none"> • Reduce the nominal pressure and determine the cause of exceeding the nominal pressure, if possible or necessary.
Venting system active	The actual pressure is at least 2-5 mm Hg and 2-5 s above the nominal pressure.	<ul style="list-style-type: none"> • Determine the cause for exceeding the nominal pressure. Check the electronic controls of the device if overpressure exists for a longer period of time (see chapter 13 Annual Inspection, page 77).
Overpressure/Venting system active.	The pressure monitor shows that the actual pressure is 2-5 mm Hg and 2-5 second above the nominal pressure. The overpressure was not reduced within 5 seconds by the venting system.	<ul style="list-style-type: none"> • Determine the cause for exceeding the nominal pressure. Check the electronic controls of the device if overpressure exists for a longer period of time (see chapter 12.2 Annual Inspection, page 74). Reduce the nominal pressure. Check if the instrument's stopcock is open or the tube is obturated.
Occlusion	Tube or instrument occlusion.	<ul style="list-style-type: none"> • Determine the cause and open/eliminate the occlusion.
	Faulty Veress needle insertion. Stopcock is closed.	<ul style="list-style-type: none"> • Check that the Veress cannula is positioned correctly in the abdomen and make sure the instrument's stopcock is open.
Contamination	Fluid has penetrated the device through the patient gas outlet.	<ul style="list-style-type: none"> • The message is repeated with each Start/Stop. It is possible to continue using the device with this error message until the device is turned off with the ON/OFF key.
Contamination/Call service	The device is contaminated with fluid.	<ul style="list-style-type: none"> • The device has to be checked by an authorized service technician or clearly marked with a label referring to the contamination and then twice enclosed in a safety foil, sealed, and returned to the manufacturer for repairs.
Gas heater defective/Call service	Gas heating malfunction.	<ul style="list-style-type: none"> • Check gas heating with a new tube. If this error message is displayed again, have the device checked by a qualified service technician. It is possible to continue using the device without gas heating.

PneumoSure Insufflator

Error and Warning Messages

Error and Warning Messages	Cause	Troubleshooting
<p>Gas temperature >42°C/ Disconnect luer lock / Cool down tube</p> <p>The device terminates gas heating and insufflation.</p>	The temperature of the gas exceeds 42° C.	<ul style="list-style-type: none"> • Unplug the insufflation tube at the trocar. • Press the START/STOP function field. The device insufflates without heating the gas. • Let hot gas escape until the tube is only warm to the touch. • Continue the operation without gas heating or use a different gas heating tube. • Turn device off and on again. This reactivates the gas heating. • Check gas heating after surgery using a different tube. <p>If this error message is displayed again, have the device checked by a qualified service technician.</p> <p>It is possible to continue using the device without gas heating.</p>
<p>Error message/Call service</p>	The device does not work properly and activates the internal safety system.	<ul style="list-style-type: none"> • Switch the device off and back on after approx. 3 seconds have expired using the ON/OFF key. • Should the error message appear again, the device is defective. Make sure the device can no longer be used until a qualified service technician conducts the appropriate tests and repairs.
<p>Device temperature error/Turn device off</p> <p>The insufflation is stopped or cannot be started.</p>	<p>The device temperature is above 70 °C.</p> <p>The device temperature is below 10° C.</p>	<ul style="list-style-type: none"> • Prepare for changing the gas bottle. • Turn the device off for about 10 minutes using the ON/OFF key. The surrounding room temperature must be above 10° C.
<p>Venting valve defective</p>	Venting system malfunctioning.	<ul style="list-style-type: none"> • Use the ON/OFF key to turn the device off and turn device back on after approx. 3 seconds. If this error message is displayed again after the device check has concluded, have the device checked by an authorized service technician. The device can be still operated but without venting system. The error message is repeated with each Start/Stop.
<p>RTP defective</p>	Device defective	<ul style="list-style-type: none"> • It is possible to continue with the surgery but do not connect the measuring line of the RTP system. The message is repeated with each Start/Stop. After surgery is finished, call a service technician to repair the device.
<p>RTP deactivated</p>	Device check was unsuccessful	<ul style="list-style-type: none"> • Surgery can be continued but without the continuous pressure measurement. Please make sure that neither of the two tubes is connected to a trocar or closed off during a device check. Restart device if needed.
<p>Tube not connected</p>	The tube set has not been connected or has not been inserted correctly but the START function field has been pressed.	<ul style="list-style-type: none"> • Please insert a tube set or check the tube set connection.
<p>Check/change tube set</p>	Leak in tube connection	<ul style="list-style-type: none"> • Please insert a new tube set or check the tube set connection.

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Technical Specifications

Mains connection cable:	100-240 V~ line fuse line fuse T 3.15 A connection for potential equalization
Frequency:	50-60 Hz
Max. power consumption:	150 VA
Max. current consumption:	100 V: 1500 mA; 240 V: 630 mA
Classification according to Directive 93/42/EEC:	Ia
Protection class:	I
Protection level:	Type BF
Moisture protection:	IP41
Dimensions:	Width x Height x Depth 318 x 148 x 475 [mm] 12.2 x 5.82 x 18.70 [inch]
Weight:	approx. 9 kg / 19.84 lbs
Operating conditions:	10-40°C / 50-104°F; 30-75% rel. humidity 700 - 1060 hPa ambient pressure
Storage and transportation conditions:	-30 to +70°C / -22 to +158°F; 10-85% rel. humidity 85 - 100% rel. humidity (14 days)
Manufactured and tested according to:	EN 60601-1
EMC:	EN 60601-1-2
Insufflation medium:	Medical CO ₂
Maximum output pressure:	75 mm Hg (1 mm Hg = 1.33 mbar = 133 Pa)
Maximum gas supply pressure:	80 bar/1160 PSI
Minimum gas supply pressure (bottle):	15 bar/218 PSI
Minimum gas supply pressure (house gas):	3.4 bar/50 PSI
Measurement range of gas supply:	0-50 bar/0-725 PSI
Maximum gas flow:	20 l/min Pediatric 40 l/min High Flow 45 l/min Bariatric 10 l/min Vessel Harvest
Pressure range:	1-20 mm Hg Pediatric/Vessel Harvest 1-30 mm Hg High Flow/Bariatric
Accuracy of pressure measurement:	5%
Accuracy of gas flow measurement:	5%
Accuracy of volume measurement:	10%
Accuracy of gas supply pressure measurement:	10%
Connections (optional):	Data input/output, RS232 interface, SIDNE interface