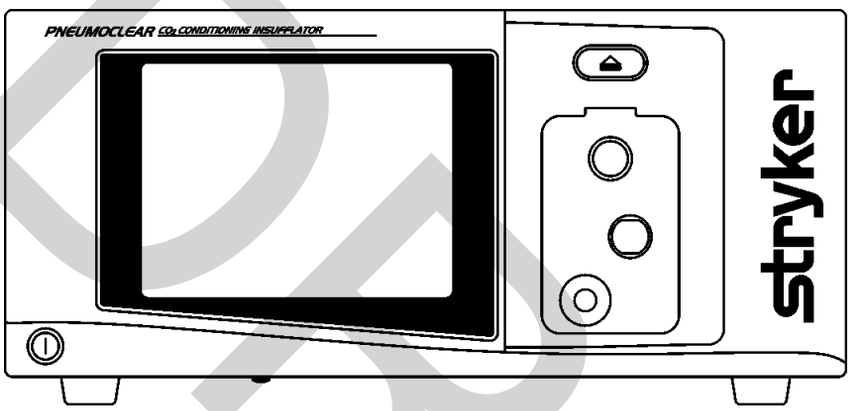
stryker®

PNEUMOCLEAR CO_2 CONDITIONING INSUFFLATOR

Instructions for Use en



Insufflator for Laparoscopy, Vessel Harvesting, and Colorectal Procedures

P31693 Rev. K

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We reserve the right to technical changes without prior notification due to the continuous further development of our products. Function or design may partially differ from the description in the instructions for use. Please contact us for additional information about this or any of our other products.

Some of the parts and equipment referred to in this instructions for use bear registered trademarks but are not identified as such. It should therefore not be assumed that the absence of the trademark symbol indicates that any given designation is not subject to trademark protection.

Users of this product should not hesitate to point out to us any errors or unclarities in this instructions for use.

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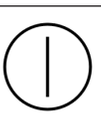
CE 0197 CE marking according to Directive 93/42/EEC

Type: FM300 / 1201459 / 10000018417 08 / 2020-09

Symbols

	Follow instructions for use (white image on a blue background)
	Caution
	Type CF applied part
	Equipotentiality
IP 40	Degrees of protection provided by enclosures (IP-Code)
	Alternating current
	Service
	Catalogue number
	Serial number
	Batch code
	Do not reuse
	Do not resterilize
	Sterilized using ethylene oxide
	Date of manufacture (YYYY-MM-DD)

	Use by date (YYYY-MM-DD)
	Quantity
	Keep dry
	Top-Bottom
	Fragile
	Keep away from sunlight
	Protect from heat and radioactive sources
	Do not use if package is damaged
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	Waste management
	Manufacturer
	ON/OFF (push-push)

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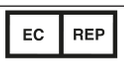
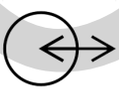
	Authorized for Sale or use by Physician only
	Stryker European Representative
	Non-ionizing electomagnetic radiation
	Complies with Australian regulatory requirements
	Complies to IEC 60601-1 including US and Canadian deviations in their respective valid version
	Data transmission port (see Using Device Control instructions for detail)
	Only for service
	Caution: Hot Air Out
	Quality Seal. Unbroken seal indicates the product has not been tampered with or serviced.
	Due date of next service
	Only to be used with medical-grade CO2
p(max) = 80 bar (1160 psi)	Maximum supply pressure of medical-grade CO2
	RFID tag, general

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1 Important User Notes

Read the instructions for use carefully and become familiar with the operation and function of the device and the accessories before use during surgical procedures. Non-observance of the instructions listed in this manual can lead

- to life-threatening injuries of the patient,
- to severe injuries of the surgical team, nursing or service personnel, or
- damages or malfunction of device and/or accessories.

Subject to technical changes

The manufacturer reserves the right to modify the appearance, graphics, and technical data of the product through continued development of its products.

Please note

Paragraphs marked with the words WARNING, CAUTION, and NOTE carry special meanings. Sections marked with these words must be given special attention.

WARNING!

The safety and/or health of the patient, user, or a third party are at risk. Comply with this warning to avoid injury to the patient, user, or third party.

CAUTION!

These paragraphs include information provided to the operator concerning the intended and proper use of the device or accessories.

NOTE!

These paragraphs contain information to clarify the instructions or provide additional useful information.

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2 Safety Information

Federal Law (only for U.S. market)

CAUTION! Federal law restricts this device to sale by or on the order of a physician.

Exclusion of liability

The manufacturer is not liable for direct or consequential damages, and the warranty becomes null and void if:

- the device and/or the accessories are improperly used, transported, stored, prepared, or maintained;
- the instructions and rules in the instructions for use are not adhered to;
- unauthorized persons perform repairs, adjustments, or alterations on the device or accessories;
- unauthorized persons open the device;
- the prescribed inspection and maintenance schedules are not adhered to.

The handing over of technical documents does not constitute authorization to make repairs or alterations to the device or accessories.

WARNING! Modification of the devices PNEUMOCLEAR™ is not permitted.

Authorized service technician

Only an authorized service technician may perform repairs, adjustments, or alterations on the device or accessories and use the service menu. Any violation will void the manufacturer's warranty. Authorized service technicians are only trained and certified by the manufacturer.

Care and maintenance

The service and maintenance of the device and its accessories has to be carried out as per instructions to ensure the safe operation of the device. For the protection of the patient and the operating team, check that the device is complete and functional before each use. Maintenance of the device may not be performed during the operation.

NOTE! Service or maintenance work may not be carried out during surgery.

Contamination

Before shipping, decontaminate device and accessories in order to protect the service personnel. Follow the instructions listed in these instructions for use. If this is not possible,

- the product must be clearly marked with a contamination warning and
- is to be double-sealed in safety foil.

The manufacturer has the right to reject contaminated products for repair.

Waste management

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. For disposal of the device and its accessories, please consult the manufacturer or an authorized disposal company, in compliance with legal or national regulations.

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3 General Information

3.1 Device Description

The device **PNEUMOCLEAR™** is an insufflator and serves to create a cavity through the insufflation of CO_2 with a preset flow rate and pressure. The gas will be transported to the patient via a tube connected with a trocar. The insufflator limits the pressure to a maximum of 30 mmHg and the flow rate to a maximum of 50 l/min.

The device can be operated in different operating modes which are intended to suit different surgical procedures and/or different patient's physical characteristics. The following table describes the different operating modes.

Operating mode	Description	Patients Population
Standard operating mode	used to distend the peritoneal cavity during laparoscopic procedures by insufflating CO_2.	designed for laparoscopies performed on normal weight and slightly obese (BMI < 30 kg/m²) patients over the age of 14.
High Flow/Bariatric operating mode	used to distend the peritoneal cavity during laparoscopic procedures by insufflating CO_2.	designed for laparoscopies performed on normal weight and obese patients (BMI > 30 kg/m²) over the age of 14.
Pediatric operating mode	used to distend the peritoneal cavity during laparoscopic procedures by insufflating CO_2.	designed specifically for use on newborns, infants, and children under the age of 14.
Advanced Flow operating mode	used to distend the peritoneal cavity during laparoscopic procedures, including but not limited to robotic-assisted laparoscopies by insufflating CO_2.	designed for laparoscopies performed on normal weight and obese patients over the age of 14.
Vessel Harvest operating mode	used to distend the cavity along the vena saphena magna and radial artery during an endoscopic vessel harvesting procedure.	designed for patients over the age of 14.
TAMIS operating mode	used to dilate and fill the rectum and colon by insufflating CO_2 during transanal minimally invasive surgery.	designed for patients over the age of 14.

The device measures the actual pressure in the cavity and compares it to the set nominal pressure. The function of this device is to maintain the nominal pressure. Overpressure within the cavity is lowered to the preset nominal pressure by the automatic venting system. **Essential performance**

Additional optional features are available to increase user and patient comfort:

1. Integrated gas heater to heat the insufflation gas.
2. Suction function to evacuate surgical smoke from the cavity.
3. Humidification of the insufflation gas.

These features become available by use of the appropriate tube sets, see Chapter Insufflation Tube Sets [▸ 28].

The insufflator is a pneumatic device that works through the port on the back, with central gas as well as bottled gas. It is operated via buttons and indicators or displays on the front of the device. Optionally, the device can be operated via remote access and a central device control, either by voice control or a remote touch panel.

3.2 Intended Use and Contraindications

3.2.1 Intended Use

The device **PNEUMOCLEAR™** is a CO_2- insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with CO_2 gas. The operating modes **Standard**, **High Flow/Bariatric**, **Pediatric** and **Advanced Flow** of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The **Pediatric** operating mode is indicated for pediatric laparoscopic procedures. The **Vessel Harvest** operating mode is indicated for use

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during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery. The **TAMIS** operating mode is indicated to fill and distend the rectum and colon using CO_2 gas during transanal minimally invasive surgery.

3.2.2 Contraindications

The device should not be used to fill a cavity with CO_2 if an endoscopy is contraindicated. Please consult the manual of your endoscope for absolute and relative contraindications. The device is not suitable for hysteroscopic insufflations, i.e., it may not be used to distend the uterus.

The gas flow may not exceed 14 l/min when performing a laparoscopy on newborns or patients weighing less than 25 kg.

The device may not be used for the endoscopic harvesting of vessels if this surgical application is contraindicated. Please consult the manual of the instrument for absolute and relative contraindications.

3.3 Warnings

3.3.1 General Warnings CO_2 Insufflation

WARNING!

Condensation / Water penetration

Protect device from moisture. Do not use if moisture has penetrated the device.

WARNING!

Check all factory settings

Factory settings are not mandatory settings for the physician. The physician is responsible for all settings affecting the surgical procedure.

WARNING!

Technique and procedures

Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.

WARNING!

Not explosion-proof

The device is not explosion-proof. Do not operate the device in the vicinity of explosive anesthetic gases and not in the vicinity of oxygen-enriched environments.

WARNING!

Risk of electrical shock

To prevent electrical shock, do not open this device. Never open this device yourself. Notify the authorized service technicians of any required repairs.

WARNING!

Risk of electrical shock

To avoid the risk of electrical shock, only use this device when connected to a properly grounded power supply network.

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WARNING!

Replace the fuse

Replace the fuse only with a fuse provided by the manufacturer (see Chapter Accessories [▶ 69]).

WARNING!

Professional qualification

The instructions for use do not include descriptions or instructions for surgical procedures/techniques. It is not suitable for training physicians in the use of surgical techniques. Medical peripherals and devices may be used only by physicians or medical assistants with the appropriate technical/medical qualifications working under the direction and supervision of a physician.

WARNING!

Automatic device self-test

The device self-test must be performed prior to each surgery. Because the device self-test is performed during initial start up, the unit must be power cycled (off/on) prior to each surgery.

WARNING!

Sterile media and accessories

Always work exclusively with sterile substances and media, sterile fluids, and sterile accessories if so indicated.

WARNING!

Replacement device and accessories

In case the device or any of the accessories fail during surgery, a replacement device and replacement accessories should be kept within close proximity to be able to finish the operation with the replacement components.

CAUTION!

Cleaning the Device

Do not sterilize the device.

WARNING!

Obvious defects

Never use the device if it has suspected or confirmed defects, especially if these involve the power plugs or the mains power supply connection cables. In this case have the device repaired by authorized service personnel.

WARNING!

Positioning the patient

Positioning the patient lower than the device can prevent body fluids from leaking into the tube set. Actual pressure may increase and fluid may penetrate the insufflation tube if the patient is repositioned during surgery. If this occurs, immediately disconnect the insufflation tube. When the patient is repositioned onto his or her side, internal tissue may block the insufflation channel. Always insufflate through the elevated side of the patient.

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WARNING!

Removing the insufflation tube

Always disconnect the insufflation tube after ending surgery and before switching off the device to prevent backflow of bodily fluids. Fluid may penetrate the insufflation tube whenever you change the gas bottle and/or when you stop the gas flow during the operation. If this happens, you must immediately disconnect the insufflation tube from the trocar or from the device.

WARNING!

Backflow

Body secretions or contaminated gas can flow counter to the insufflation direction and block the insufflation filter, if

- **the actual pressure is higher than the nominal pressure or**
- **the automatic venting valve is activated.**

WARNING!

Gas flow

A high gas flow can occur due to large leaks within the surgical system or instrument. This can result in a false actual pressure reading, which in turn may endanger the patient. In case of a disrupted gas flow, you should therefore inspect device, tube, and instruments immediately. Surgical procedures should be performed with a gas flow of 4 to 10 l/min. An even lower gas flow is recommended for diagnostic purposes.

WARNING!

Keep filled CO_2 bottle on hand

Always keep a filled CO_2 bottle on hand ready for replacement. This avoids having to interrupt surgery due to a lack of insufflation gas (see Chapter Gas Connection [▶ 23]).

WARNING!

Gas supply

Maintain adequate gas supply at all times.

WARNING!

Contamination

Do not use device and/or accessories if signs of contamination are detected. Make sure the device or/and accessories can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.

WARNING!

Fatigue symptoms

When there is a high level of CO_2 consumption, you should make sure to supply the operating area with enough fresh air, since an increasing CO_2 level in the air can cause the medical personnel to suffer fatigue symptoms, an inability to concentrate, unconsciousness, or even death.

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WARNING!

Insufflation of CO_2

The insufflation of CO_2 should be done carefully and while monitoring the patient's response. The user, particularly the anesthetist, should be informed about possible cardiovascular and respiratory problems of the patient and monitor these intra-operatively.

WARNING!

Medically pure CO_2

Make sure to use only medically pure CO_2. Other gases (e.g., helium, N_2O, argon), mixtures of gases, gases with entrapped liquids, or polluted gases must not be used with this device.

WARNING!

Fill the tube set with CO_2

For the safety of the patient please fill the tube set with CO_2 gas prior to beginning the insufflation by activating the insufflation for a few seconds and then turning it off again before introducing the insufflation instrument to the cavity and beginning the surgery.

WARNING!

Lowest gas flow and pressure

Depending on age and health condition of the patient, the smallest possible gas flow and pressure for establishing the pneumoperitoneum should be selected. It is not recommended to exceed insufflation pressures of 15 mmHg in colo-rectal procedures.

WARNING!

Limited venting system

The venting rate of the automatic venting system is limited. Always monitor the actual pressure when using additional insufflation sources.

WARNING!

Connecting the tube

Always use the proper tube set for the device. The tube outlet may only be connected to instruments which are intended for intra-abdominal CO_2 insufflation.

WARNING!

Electronic device control

Do not close the valve at the cannula sleeve during surgery. The electronic control unit of the device adjusts the actual pressure as desired.

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3.3.2 Warnings Standard and High Flow/Bariatric Operating Mode

WARNING!

Idiosyncratic reactions

Patients with sickle cell anemia or pulmonary insufficiency may have a higher risk of metabolic imbalance related to excessive CO2 absorption (idiosyncratic reaction).

WARNING!

CO_2 absorption

CO_2 is absorbed during insufflation (intravasation). This means the body absorbs a part the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption. The abdomen is sufficiently distended using a pressure between 10 to 15 mmHg. Pressure values above 15 mmHg are required for only a few cases but do increase the risk of intravasation. Never exceed the maximum intra-abdominal pressure of 30 mmHg.

WARNING!

Metabolic and cardiac reactions

Insufflating CO_2 may result in metabolic acidosis. This can lead to cardiac irregularities expressed with the following symptoms:

- **Reduced respiration with restricted diaphram function**
- **Hypercapnia**
- **Reduction of venous reflux**
- **Reduced cardiac output**
- **Metabolic acidosis**

WARNING!

Hypothermia/monitoring body temperature

The gas flow can lead to a lowering of the patient's body temperature during insufflation. Hypothermia during insufflation can cause heart and cardiovascular problems. The risk for hypothermia can be significantly reduced with the use of gas that is pre-warmed to body temperature. Therefore, you must always monitor the patient's body temperature during the entire insufflation process. Make especially sure that the following, hypothermia-fostering, surgical conditions are avoided as best as possible:

- **High gas flow due to large leaks**
- **Long surgeries**
- **Use of irrigation and infusion solutions that are not preheated to body temperature.**

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WARNING!

Dehydration

Insufflation can lead to dehydration of the tissue, especially if the surgery time is prolonged. This can lead to damage of peritoneal cell structures within the tissue. Insufflation, especially with unconditioned gas, is associated with post-operative pain. Long surgeries and large leaks increase the risk of dehydration especially at the insertion points of the trocars.

The use of humidified and prewarmed gas can reduce risks associated with tissue dehydration.

WARNING!

Embolism/insufflation of internal organs

Improper placement of the insufflation instrument could cause gas penetrating a vessel or an internal organ, resulting in air or CO_2 embolisms. To reduce the risk, use a low flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Check the position of the insufflation instrument immediately if the actual pressure rapidly reaches the nominal pressure value. CO_2 embolisms can also be caused by a high intra-abdominal pressure. Avoid high-pressure settings and close damaged blood vessels at once.

WARNING!

Subcutaneous emphysema

Incorrect placement of a cannula or a trocar into subcutaneous tissue may lead to emphysema. To reduce the risk, use a low gas flow rate for the initial insufflation and ensure that the insufflation instrument is correctly positioned. Long surgeries, the use of many access points, duration and size of leaks at these points may also contribute to emphysema. Be sure to close leakages in trocar accesses immediately.

WARNING!

Subcutaneous emphysema

When puncturing the thicker abdominal wall of morbidly obese patients with the Veress cannula or the trocar, carefully monitor the correct position of the instrument in the abdomen.

WARNING!

Additional insufflation sources/automatic venting system

Make sure the automatic venting system is activated (see Chapter Menu (Overview) [▶ 51]). The use of additional insufflation sources increases the intra-abdominal pressure. Continuously monitor intra-abdominal pressure over the course of the entire insufflation if additional sources are used.

WARNING!

Altered Respiratory Physiology

Always monitor the patient's respiratory functions during the entire surgery. The larger body mass supported by the thoracic cage and the larger amount of fat in the abdominal cavity may reduce the elasticity of the thoracic wall. In addition, the increased intra-abdominal pressure secondary to insufflation may alter the normal physiological lung parameters thus resulting in a reduction of the functional lung volume. Shallow, rapid breathing is symptomatic of this condition. Even modest physical stress causes a tremendous increased demand for oxygen, which stands in contrast to the ineffective respiratory musculature that requires more oxygen because it must overcome the reduced elasticity of the thoracic cage. The functional capacity of the lungs is small and even moderate stress can lead to respiratory failure.

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WARNING!

CO_2 supersaturation

To avoid generating CO_2 supersaturation, an increased level of respiratory activity is required. An overweight patient's oxygen demand and carbon dioxide production are greater and increase faster under physical stress than do those of patients with normal body weight.

WARNING!

Heart and cardiovascular insufficiency

Constantly monitor all heart and cardiovascular parameters during surgery since morbidly obese patients have an increased risk of heart and cardiovascular insufficiencies.

3.3.3 Warnings Pediatric Operating Mode

WARNING!

Gas flow limit

The gas flow may not exceed 14 l/min when performing a laparoscopy on newborns or patients weighing less than 25 kg (approximately 55 US pounds).

WARNING!

Recommended work settings

The flow values listed for laparoscopic procedures performed on newborns, infants, and children are only suggested values. The selection of the suitable flow and pressure values is solely the responsibility of the attending physician.

WARNING!

Pneumolabium/pneumoscrotum

Children are at risk of a pneumolabium or pneumoscrotum.

WARNING!

Procedures with children

Only those who are specially trained and qualified for procedures with children or endoscopic vessel harvesting procedures may use this device for these purposes.

WARNING!

Increased airway pressure

When laparoscopic procedures are performed on children, the increased intra-abdominal pressure also increases the risk for higher airway pressures. Always strictly monitor respiration and airway function when performing laparoscopic procedures on children younger than 12 years of age.

WARNING!

Compression of the vena cava

When insufflating the abdomen of a child with medical CO_2, an increased risk of compressing the vena cava exists. This risk can be reduced by monitoring the systolic and diastolic blood pressure during the entire surgery.

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WARNING!

Haemodynamic stability

A laparoscopy performed on children younger than 12 years of age may result in problems of the haemodynamic system due to the CO_2 content in the blood. It is recommended to increase the breathing rate of the patient and to work with low flow values and pressure values not exceeding 12 mmHg. The patient's circulatory system should be monitored at all times.

WARNING!

Hypothermia

The insufflation gas flow usually drops significantly after the target pressure has been reached and it is then only required to maintain the abdominal pressure. However, leaks within the abdomen or the instrument can lead to a constant gas flow of above 1 l/min. When operating on children younger than 12, a gas flow of more than 1 l/min poses an increased risk of hypothermia for the patient. Corresponding measures to prevent hypothermia include the use of blankets or prewarmed gas. The patient's body temperature has to be monitored at all times during surgery.

WARNING!

Children with cardiovascular problems

Laparoscopy with CO_2 should not be performed on children with cardiovascular problems.

WARNING!

Hypercapnia

Because pediatric patients are especially susceptible to hypercapnia, it is recommended to establish an end-tidal CO_2 monitoring routine.

3.3.4 Warnings Vessel Harvest Operating Mode

WARNING!

CO_2 absorption

Due to the special surgical procedures - start of the heart bypass operation, and the endoscopic removal of the vessel - special care has to be taken as CO_2 is always absorbed through the tissue of the patient during insufflation (intravasation). This means the body absorbs part of the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption.

WARNING!

Metabolic and cardiac reactions

Insufflating CO_2 may result in metabolic acidosis. This can lead to cardiac irregularities expressed with the following symptoms:

- **Reduced respiration with restricted diaphram function**
- **Hypercapnia**
- **Reduction of venous reflux**
- **Reduced cardiac output**
- **Metabolic acidosis**

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WARNING!

Dehydration

Insufflation can lead to dehydration of the tissue, especially if the surgery time is prolonged. This can lead to damage of peritoneal cell structures within the tissue. Insufflation, especially with unconditioned gas, is associated with post-operative pain. Long surgeries and large leaks increase the risk of dehydration especially at the insertion points of the trocars.

The use of humidified and prewarmed gas can reduce risks associated with tissue dehydration.

WARNING!

Embolism/insufflation of internal organs

Improper placement of the insufflation instrument could cause gas penetrating a vessel or an internal organ, resulting in air or CO_2 embolisms. To reduce the risk, use a low flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Check the position of the insufflation instrument immediately if the actual pressure rapidly reaches the nominal pressure value. CO_2 embolisms can also be caused by a high intra-abdominal pressure. Avoid high-pressure settings and close damaged blood vessels at once.

WARNING!

Procedures with children

Only those who are specially trained and qualified for procedures with children or endoscopic vessel harvesting procedures may use this device for these purposes.

WARNING!

Instrument used for CO_2 insufflation

Before using the insufflator to endoscopically harvest vessels, please check whether the instrument used is intended for CO_2 insufflation.

WARNING!

Pneumoperitoneum

When a vessel is harvested from the leg of a patient with a perforated groin, it is possible for CO_2 to reach the abdomen and cause a pneumoperitoneum. Make sure the abdomen does not fill with CO_2 during surgery.

3.3.5 Warnings TAMIS Operation Mode

WARNING!

CO_2 absorption

CO_2 is absorbed during insufflation (intravasation). This means the body absorbs part of the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption. Pressure values above 15 mmHg are required for only a few cases but do increase the risk of intravasation. It is recommended not to exceed insufflation pressures of 15mmHg during transanal minimally invasive surgery.

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WARNING!

Lowest gas flow and pressure

Depending on age and health condition of the patient, the smallest possible gas flow and pressure for establishing the cavity should be selected. It is not recommended to exceed insufflation pressures of 15 mmHg in transanal minimally invasive surgery procedures.

3.4 General Precautions

CAUTION!

Continuous operation

After 24 hours of continuous operation, a device self-test must be carried out.

Switch device off and on again.

CAUTION!

Endoscope

The device may only be connected with endoscopes designed for and featuring the technical specification permitting such a combined use. Any utilized endoscopes must comply with the most recent versions of EC 60601-2-18 and ISO 8600. Combining/connecting with other devices generates a medical electrical system (MES). The system configurator is responsible for compliance with the standard IEC 60601-1 / EN 60601-1 in its latest version.

CAUTION!

Electrical interference

(See Chapter Electromagnetic compatibility [▶ 62]). Care was taken during the development and testing of this device that electrical interference of or from other devices or instruments was practically eliminated. However, if you still detect or suspect such interference, please follow these suggestions:

- **Move this, the other, or both devices to a different location**
- **Increase distance between used devices**
- **Consult an electro-medical expert**

CAUTION!

Use of other accessories, other transducers and cables

The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM (see Chapter Glossary) as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

CAUTION!

ME Device in Rack

The ME device may not be used when stacked or stored directly adjacent to or with other devices. If it should be necessary to operate the device close to stacked with other devices, the ME device or ME system should be monitored to ensure it works properly as configured.

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CAUTION!

Service connection

Service connection is reserved for service tasks . The connected equipment must comply with the standard EN 60950 in the currently valid version. Do not connect a device to the service connection during surgery.

CAUTION!

Peripheral Devices

Additional peripheral equipment connected to interfaces of the medical monitor has to meet the requirements of the following specifications in the respective current valid version: IEC 60601-2-18 / EN 60601-2-18 for endoscopic devices and IEC 60601-1 / EN 60601-1 for electrical medical devices. All configurations have to comply with IEC 60601-1 / EN 60601-1 specifications. Whoever connects additional equipment to signal output or signal input is considered the system configurator and as such is responsible for complying with requirements of the standard IEC 60601-1 / EN 60601-1.

CAUTION!

Mains Power Cable

Any power cables employed by the user that are not provided by the manufacturer must meet the safety requirements of the national standards in the respective current valid version.

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4 Initial Device Setup

The operation of the device **PNEUMOCLEAR™** is reserved for medical staff with the relevant professional qualifications trained to use the device.

NOTE!

Locations

The device may be used only in the hospital or operating rooms.

Delivery inspection

Always check all parts and optional accessories of the device immediately after receiving the shipment. The manufacturer only considers replacement claims that have been immediately submitted or reported to a sales representative or an authorized service company.

Returning the device

If it becomes necessary to return the device, always use the original packaging. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging.

Please keep the original packaging.

Please make sure that all required information has been supplied:

- Name of owner
- Address of owner
- Device type and model
- Serial number of the equipment (see identification plate)
- Detailed description of defect

4.1 Device Setup and Connection

Setting up

Place the device on a flat surface free of vibration located in a dry environment. The ambient conditions must meet the requirements mentioned in Chapter Technical Data [▶ 67].

CAUTION!

ME systems

The medical electrical (ME) device is suitable for integration in ME equipment systems (see Chapter Glossary). Operation of the ME device in vicinity of non-ME devices may result in voiding the intended use of the ME device.

CAUTION!

Device setup

Device should be positioned outside of the sterile area in such a way that

- **it can be easily disconnected,**
- **it is easy to use and switch off and on,**
- **it allows an easy monitoring of the display values, device functions, and access to the control elements.**

CAUTION!

Ventilation of the device

- **Avoid device overheating.**
- **Ensure free air circulation especially to the bottom and rear of the device (rear panel distance of at least 10 cm).**

en

CAUTION!

Position of the user

To ensure safe operations of the device, the user must be positioned correctly towards the device

- **within a display viewing angle of ±50° to operate the device,**
- **up to 2 m/6.5 ft from the device front for monitoring the actual values.**

NOTE!

Device Control

The device may be optionally controlled via Stryker's central device control in the operating room.

Mains connection

CAUTION!

Mains connection

- **Make sure the available mains voltage matches the data listed on the type label attached to the back of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.**
- **Make sure the connection data and technical specifications of the power supply comply with DIN VDE or national requirements. The mains connection cable may be plugged only into a properly installed, grounded safety wall socket (shockproof socket) (see DIN VDE 0100-710).**
- **Read the device label located in rear of device (type plate) to determine the operating voltage of the device.**

Grounding contact

The power connection must be equipped with ground contact (protective contact). Use the original power cable (if included in scope of delivery) to establish a connection between the mains wall socket and the non-heating device plug located in the rear of the device.

Only for U.S. operators

Only use a certified (UL-listed), removable mains connection cable, type SJT, minimal 18 AWG, 3 leads. The plug connectors must comply with NEMA 5-15 and IEC 60320-C13. Grounding will only be reliable if the equipment is connected to a corresponding hospital grade socket.

Potential equalization

The equipotential bonding is used as a protective measure against the failure of the protective conductor according to requirements of IEC 60601-1 in the respectively valid version. The installation must be according to the relevant local safety regulations.

4.2 Front of the Device

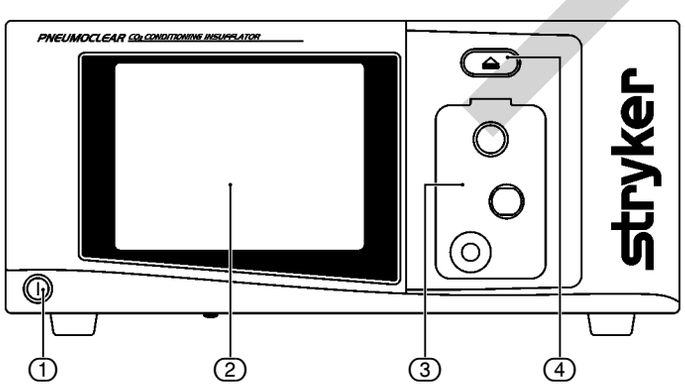


Fig. 4–1 Device front

1. ON/OFF switch
2. Monitor with touch screen
3. Tube connection
4. Eject button

Familiarize yourself with the control and function elements at the front of the device.

en

4.3 Rear of the Device

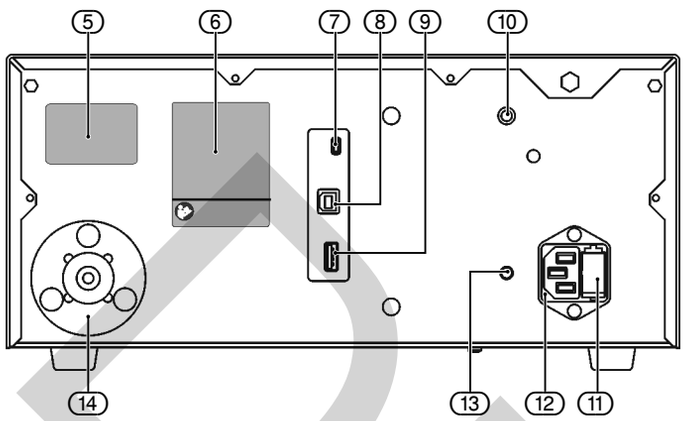


Fig. 4–2 Device rear

(5) Type plate
(6) Device data plate
(7) USB port (only for authorized service technician)
(8) Device Control Interface
(9) Data input/output (only for authorized service technician)
(10) Gas outlet
(11) Fuse holder
(12) Device mains socket
(13) Connection for potential equalization
(14) Gas supply connection

Familiarize yourself with the connection elements at the rear of the device.

4.4 Gas Connection

WARNING!

Medically pure CO_2

Make sure to use only medically pure CO_2. Other gases (e.g., helium, N_2O, argon), mixtures of gases, gases with entrapped liquids, or polluted gases must not be used with this device.

WARNING!

Gas supply

Maintain adequate gas supply at all times.

Use a high-pressure tube to connect a CO_2 gas bottle to the rear gas inlet connection or connect to centralized CO_2 gas supply.

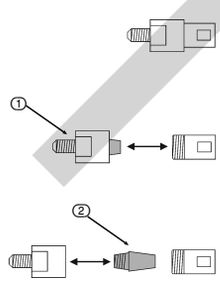
The device is equipped with a universal gas connector that can be configured with different adapters to support both central gas and bottle gas supply.

It supports gas supply pressures from 3.4 bar (50 psi) to 80 bar (1160 psi).

The gas connector has an exchangeable sinter filter to protect the insufflator from dirt particles. This filter has to be checked during the annual test and be replaced at least every two years. During the maintenance the sinter filter has to be exchanged. The sinter filter is available as a spare part (see Chapter 14 Accessories [▶ 69]). The sinter filter may be blocked or soiled due to unclean gas or gas supply residues. Heavy soiling is especially noticeable during higher flow rates. As a result, the actual gas flow is falling short of the nominal gas flow during active insufflation or the device is showing gas supply warnings although gas supply is sufficient. In this case the sinter filter needs to be exchanged.

1. Remove the connector (1) using two open-end wrenches size 17 mm and 19 mm.
2. Unscrew the sinter filter (2) using a screwdriver if necessary.
3. Screw the new sinter filter finger-tight and fasten the connector to the device.

Exchangable sinter filter



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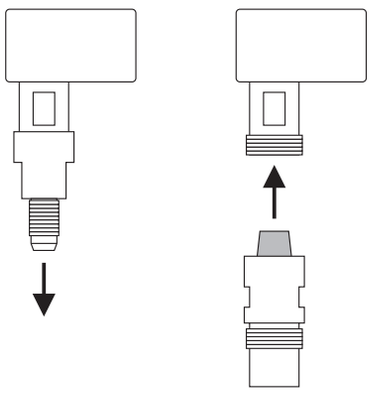
Angled gas connector

An angled connector is available to reduce the depth needed for the installation of the device. This connector includes the exchangeable sinter filter and allows the use of the different gas supply adapters described below as well.

Fig. 4–3 Connecting the gas supply to the angled gas connector



4.4.1 Connecting a Gas Bottle

WARNING!

Keep filled CO_2 bottle on hand

Always keep a filled CO_2 bottle on hand ready for replacement. This avoids having to interrupt surgery due to a lack of insufflation gas (see Chapter Gas Connection [▷ 23]).

CAUTION!

High-pressure hose

Always use a high-pressure hose to connect gas bottle and device.

The gas bottle must be in a vertical position. The gas bottle pressure may not exceed 80 bar/1160.3 psi or be less than 15 bar/217.5 psi.

CAUTION!

Gas bottles with riser pipe

Gas bottles with riser pipe can release dirt and oily fluids into the device. Do not use a gas bottle with riser pipe.

High-pressure hoses

The following high-pressure hoses are available:

Designation
High-Pressure Hose Device US/Bottle DIN
High-Pressure Hose Device US/Bottle ISO
High-Pressure Hose Device US/Bottle PIN Index

Installation

High-Pressure Hoses with PIN Connector

- Connect or loosen to the device using the open-end wrench size 14 mm.
- Connect or loosen to the gas bottle with your hand.

High-Pressure Hoses with DIN Connector

- Connect or loosen to the device using the open-end wrench size 14 mm.
- Connect or loosen to the gas bottle using the open-end wrench size 30 mm.

High-Pressure Hoses with ISO Connector

- Connect or loosen to the device using the open-end wrench size 14 mm.
- Connect or loosen to the gas bottle using the open-end wrench size 32 mm.

Switching valve

There is a switching valve available that allows the connection of two gas bottles to the insufflator. This ensures uninterrupted insufflation particularly during the change of the gas bottle.

4.4.2 Connecting to Central Gas Supply

Low-pressure hoses

The following low-pressure hoses are available for connecting to the central gas supply:

Designation
Hose for CO_2 central gas supply DISS-DISS, 0.9 m/3 ft
Hose for CO_2 central gas supply DIN-US, 3 m/10 ft
Hose for CO_2 central gas supply DIN-US, 5 m/16.5 ft
Hose for CO_2 central gas supply AGA-US, 3 m/10 ft
Hose for CO_2 central gas supply AGA-US, 5 m/16.5 ft
Hose for CO_2 central gas supply NF-US, 3 m/10 ft
Hose for CO_2 central gas supply NF-US, 5 m/16.5 ft
Hose for CO_2 central gas supply UNI-US, 3 m/10 ft
Hose for CO_2 central gas supply UNI-US, 5 m/16.5 ft

Installation

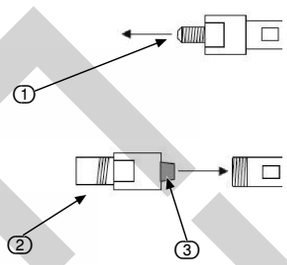
- Connect or loosen to the device using the open-end wrench size 14 mm.
- Connect or loosen to the central gas supply receptacle on the wall pulling the plug in or out.

An adapter and a low-pressure tube are required for connecting to the central gas supply with DISS connection:

- DISS Adapter for gas connection
- DISS Hose for central gas supply

Exchange of the gas supply adapter

1. Remove the connector ① using two open-end wrenches size 17 mm and 19 mm.
2. Check if the sinter filter ③ needs a change (residues or blocked pores).
3. Exchange the sinter filter using a screwdriver.
4. Install the new connector ② using the open-end wrenches.



For older NIST central gas supply hoses there is a NIST adapter available:

- NIST Adapter for gas connection

Set in the user menu the type of gas supply: central gas or bottle gas supply (see Chapter Menu (Overview) [▶ 51]).

4.5 Gas Supply

The status of the gas supply is monitored by the device and indicated with icons and acoustic signals.

Gas supply with gas bottle

The following gas bottle pressures are displayed:

Icon	Description
 (green)	≥ 40 bar/580.1 psi
 (green)	< 40 bar/580.1 psi - 20 bar/290 psi
 (yellow)	< 20 bar/290 psi - 10 bar/145 psi. Acoustic signals can be heard and a message is displayed. User is advised to prepare for changing the gas bottle.

en

Icon	Description
 (red)	< 10 bar /145 psi - 4 bar /58 psi. Acoustic signals can be heard and a message is displayed. Replace the gas bottle.
 (red)	< 4 bar /58 psi - 0 bar / 0 psi. Acoustic signals can be heard and a message is displayed. Immediately replace the gas bottle.

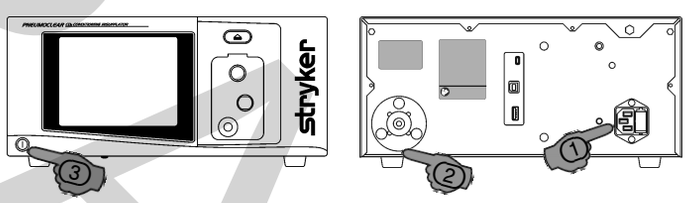
Central gas supply

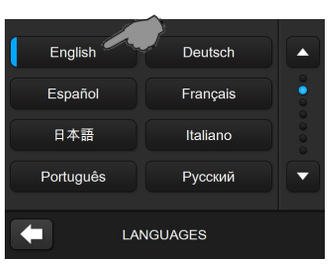
The following central gas supply icons are displayed:

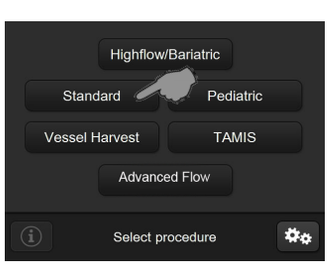
Icon	Description
 (green)	Central gas supply pressure OK
 (red)	Central gas supply pressure too low

4.6 Switching Device On

Fig. 4–4 Setting up the device







1. Connect the device with the mains power.
2. Connect the gas supply to the gas connection port and open the gas supply.
3. Press the ON/OFF switch. The power LED lights up green when the device is turned on.
4. The device performs an automatic self-test after being switched on. If the self-test is not successful, the corresponding error message will be displayed (see Chapter Error and Warning Messages [▶ 65]).
5. The language selection is displayed when starting the device for the first time. Select the desired language and confirm with the **Continue** button on the bottom left.
6. The display depicts an overview of the insufflation operating modes. Unavailable operating modes are depicted in gray and cannot be selected. Press the respective button to select the desired operating mode (e.g. **Standard**).

Unavailable insufflation operation modes can be unlocked. For this, contact your customer service.

4.7 Switching Device Off

In order to safely terminate the operation of the system, press the ON/OFF switch.

Disconnect device from power supply

Disconnect the device from the mains power supply (pull cable out off the grounded safety wall socket) if the device is not being used for several days or longer.

WARNING!

Never pull on the cable

Always hold on to the power plug when disconnecting the device from the power supply. Never pull on the cable itself.

WARNING!

Power supply

Disconnection from the power supply is only guaranteed if the mains plug is pulled from the mains wall socket.

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5 Operating the Device - General

5.1 Monitor with Touch Screen

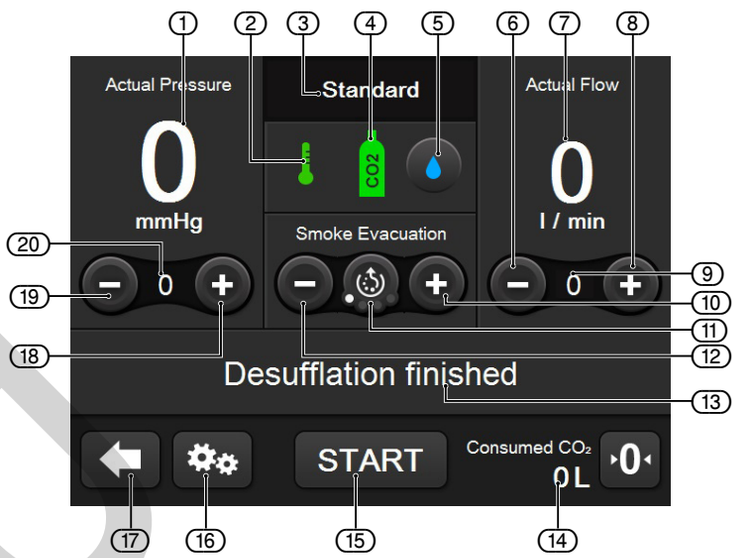


Fig. 5–1 Screen displays

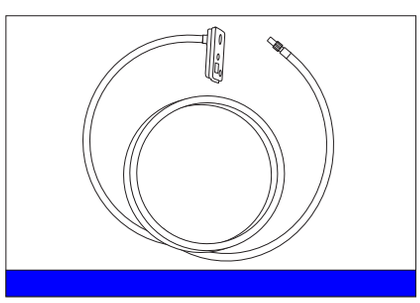
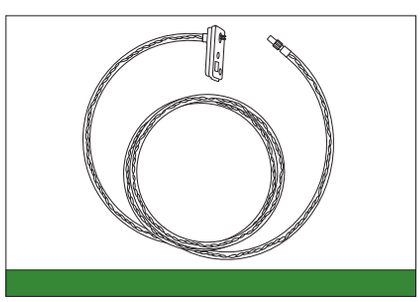
1. Actual pressure display
2. Gas heating status
3. Operating mode display
4. Gas supply display
5. Gas humidification status
6. Reduce nominal gas flow
7. Actual gas flow display
8. Increase nominal gas flow
9. Nominal gas flow display
10. Increase smoke evacuation level
11. Setting smoke evacuation level and display of smoke evacuation state ON/OFF/PAUSE
12. Reduce smoke evacuation level
13. Message display
14. Gas consumption display with reset button
15. START/STOP button
16. Menu button/speaker volume (during insufflation)
17. Back button (selection of operating mode)
18. Increase pressure
19. Reduce pressure
20. Nominal pressure display

The touch screen depicted above shows all buttons when the insufflator is stopped.

Additional explanations for individual elements are listed in the subsequent control element descriptions.

5.2 Insufflation Tube Sets

Different insufflation tube set types can be connected to the insufflation tube connection at the front of the device.

Icon	Description	Information
	HIGH-FLOW TUBE SET (0620050100/blue)	Disposable tube set with: • Filter To be used with the following operating modes: Standard, - Pediatric, - HighFlow/Bariatric, - Advanced Flow, -Vessel Harvest, -TAMIS
	HEATED HIGH-FLOW TUBE SET (0620050200/green)	Disposable tube set with: • Filter • Gas heating To be used with the following operating modes: Standard, - Pediatric, - HighFlow/Bariatric, - Advanced Flow, -Vessel Harvest, -TAMIS

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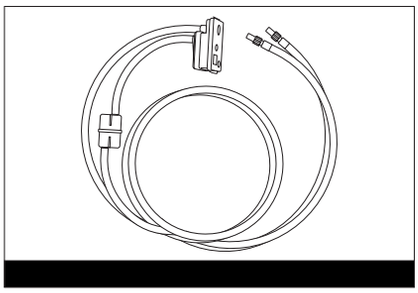
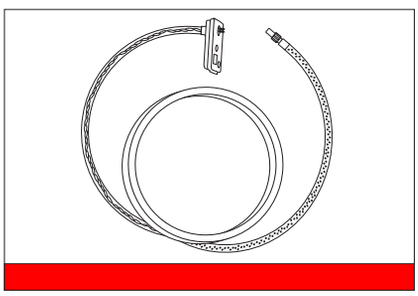
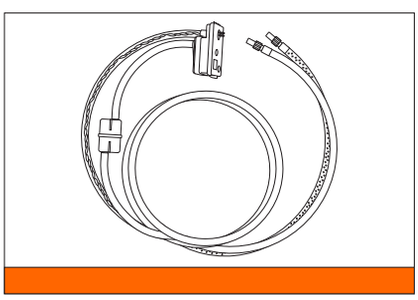
SMOKE EVACUATION HIGH-FLOW TUBE SET (0620050250/black)	Disposable tube set with: • Filter • Lumen for smoke evacuation with filter To be used with the following operating modes: Standard, - Pediatric, - HighFlow/Bariatric, - Advanced Flow, - TAMIS



HEATED HUMIDIFIED TUBE SET (0620050300/red)	Disposable tube set with: • Filter • Gas heating • Gas humidification To be used with the following operating modes: Standard, - Pediatric, - HighFlow/Bariatric, - Advanced Flow, -Vessel Harvest, -TAMIS



HEATED HUMIDIFIED SMOKE EVACUATION TUBE SET (0620050350/orange)	Disposable tube set with: • Filter • Gas heating • Gas humidification • Lumen for smoke evacuation with filter To be used with the following operating modes: Standard, - Pediatric, - HighFlow/Bariatric, - Advanced Flow, -TAMIS



All tube sets are intended for single use.

The tube sets have been sterilized with ethylene oxide according to procedures validated by ISO 11135-1 and ISO 10993-7.

RFID technology/Invalidating a tube set

Transponder technology (RFID) automatically detects the tube type, the validity, as well as the reliability of a tube set.

After insertion of the tube set and starting insufflation, the tube set is marked as used after 10 minutes and thereafter can only be used with the same insufflator and will not be valid for use with another insufflator. The tube set then can be used for maximal 12 hours before it is invalidated. However, for each patient, a new and sterile tube set must be used. Insufflation can be stopped and restarted (start-stop-button) during the use, this will not invalidate the tube set. The device may be switched off and on for a limited time without invalidating the tube set. But if the device is switched off for more than 2 hours the tube set will be invalid and cannot be used after restart.

If an invalidated tube set is connected to the device, the message **Invalid Tube Set** appears. If this is the case, insufflation is not possible unless a valid tube set is inserted.

5.3 Connecting an Insufflation Tube Set

WARNING!

Visual inspection of the tube set

Before the operation, perform a visual inspection of the tube set and its packaging. Damaged tube sets or tube sets from damaged packagings may not be used.

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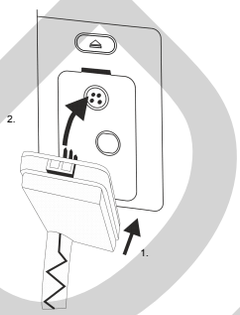
WARNING!

Air in the insufflation tube set

Air in the insufflation tube set can cause an embolism.

Start the insufflation before the tube set is connected to the patient to push the air out of the insufflation tube set. Stop the insufflation when at least 1 liter of CO_2 has been insufflated.

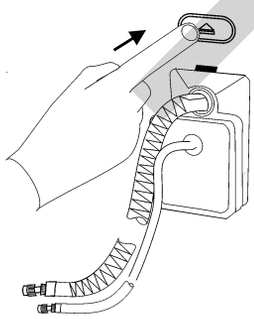
Connecting the tube set



1. Align the bottom of the tube set connector with the bottom of the receptacle on the front of the insufflator,
2. then push the top of the tube set connector until the tube set audibly snaps into place.

A short acoustic signal is emitted.

Removing the tube set



Press the eject button to remove the tube set. Hold the tube set to prevent it from falling to the floor when being ejected.

If the tube set has been removed the device will return to the operating mode selection screen after 10 minutes of idle time.

5.4 Using Gas Heating

It is possible to insufflate gas with a body temperature (approximately 37 °C/99 °F) with the help of tubes with heating function (see Chapter Insufflation Tube Sets [▶ 28]).

NOTE!

Slow moving gas

If the actual flow is < 5 l/min, the gas temperature might be below 37 °C when entering the trocar. Slow moving gas cools down quickly.

CAUTION!

Direct heat

Do not subject the heating tube to direct heat (e.g., endoscope connected with light source) or high room temperatures.

The device automatically determines whether a tube set with or without gas heating is connected. After the corresponding tube set has been correctly identified, **Gas Heater OK** is displayed.

The insufflator automatically controls the gas heater at the start and stop of the insufflation.

The following table describes all possible gas heater states, the corresponding icons as well as additional information.

Icon	Description	Information
 (grey)	Inactive gas heating	Gas heating function is not available.
 (blue)	Gas temperature is low	Insufflation can be continued. The heating tube has not yet reached the optimum heating temperature.

en

Icon	Description	Information
 (green)	Gas heater OK	Gas heating function is available.
 (red)	Safety Feature Warning Insufflation paused due to gas exceeding 43 °C/109 °F. Insufflation will resume shortly.	Insufflation is automatically stopped and the heating function is deactivated. There are three options to continue insufflation: • Wait until the temperature has decreased below 43 °C, insufflation and heating will resume automatically. • Disconnect and reconnect tube set. If temperature is below 43 °C insufflation with heating can be resumed (manual start). • Exchange tube set with a new one.
 (red)	Gas heater defective	Insufflation can be continued in this case but the heating function is not available. Restart the device if you want to use the heating function. If the gas heating is still defective, have an authorized service technician check or repair the device.

5.5 Using the Smoke Evacuation Function

WARNING!

Surgical smoke in operating room

Do not vent surgical smoke to the operating room. Use the provided smoke evacuation function with integrated filter if possible.

WARNING!

Increased concentration of CO_2 in the operating room

Smoke evacuation function may increase the CO_2 concentration in the operating room.

Ensure sufficient supply of fresh air and use the smoke extraction function only if it is necessary.

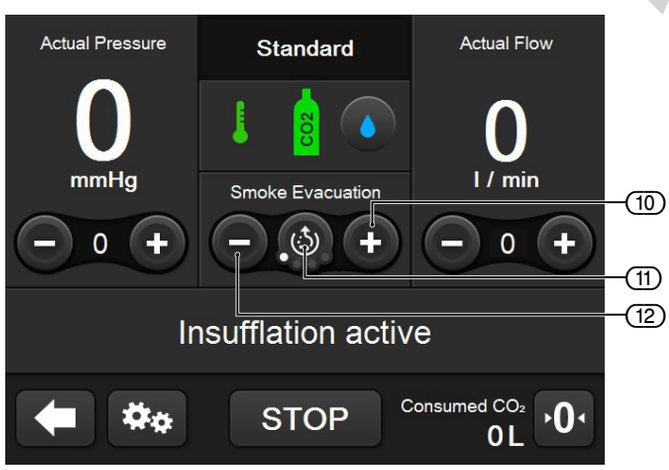


Fig. 5–2 Smoke evacuation indicator

(10) Increase smoke evacuation level

(11) Set smoke evacuation level/ ON/OFF/PAUSE

(12) Reduce smoke evacuation level

An additional function of the device is the extraction of smoke from the cavity. Use tubes with an additional lumen for smoke evacuation (see Chapter Insufflation Tube Sets [▷ 28]) to extract the smoke.

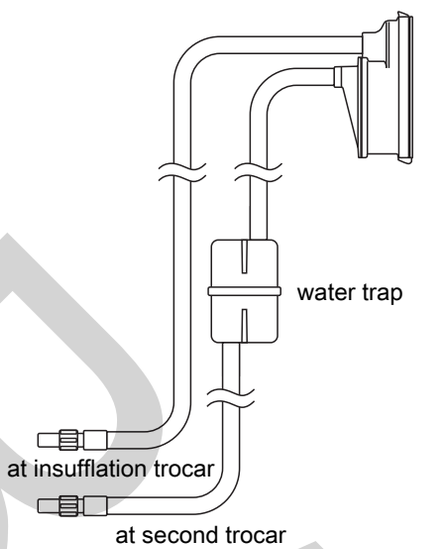
en

To enable this function, insert a valid tube set and then press the **Smoke evacuation** button (11). Use the **+/-** buttons (see Fig. Smoke evacuation indicator [▸ 31] (10)/(12)) to increase or reduce the extraction intensity. The smoke evacuation rate can be manually set to the following rates: 1, 2, 3, and 4.

Not all rates are available in all operating modes.

Nominal flow setting must be higher than smoke evacuation flow rate otherwise actual evacuation performance will be limited.

Fig. 5–3 Connections of the tube set with smoke evacuation



Suggested minimum flow settings to ensure proper smoke evacuation:

Smoke evacuation rate	Approximate evacuation flow (l/min)	Minimum nominal flow (l/min)
1	3	8
2	6	11
3	9	14
4	12	17

Smoke evacuation is not available for Vessel Harvest mode.

CAUTION!

Do not lift the water trap.

If the water trap hangs horizontally or upside down, smoke evacuation filter can be clogged.

Smoke evacuation icons	Description	Information
 (white)	Smoke evacuation function is turned off.	This icon means that the smoke evacuation function is turned off. To activate this function, press this icon.
 (green)	Smoke evacuation function is turned on.	This icon means that the smoke evacuation function is turned on. To switch off this function, press this icon.

Smoke evacuation icons	Description	Information
 (yellow)	Smoke evacuation function is paused.	This icon means that the smoke evacuation function is paused. To switch off this function, press this icon. Smoke evacuation is automatically paused if: • the abdominal pressure is too low, • the insufflation line is plugged or closed, • or the smoke evacuation line is plugged or closed. Smoke evacuation will automatically resume once the preconditions are restored again.
 (greyed out)	Smoke evacuation function not available.	This icon means that the smoke evacuation function is not available in the selected operating mode or the connected tube set is not suitable or the vacuum pump is defective.

5.6 Use of Insufflation Gas Humidification Function

An additional function of the device is the humidification of the insufflation gas. Use tubes with a humidification function (see Chapter Insufflation Tube Sets [▸ 28]) to warm up the insufflation gas to approximately 37 °C/99 °F and to humidify the gas. If a suitable tube set is connected, a corresponding message is shown on the display.

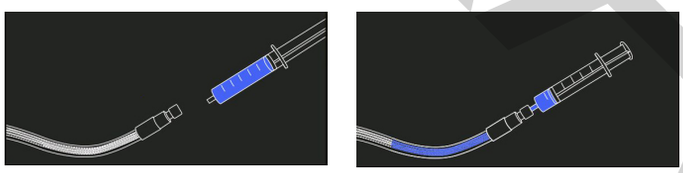
Filling and refilling the humidification tube set

For filling and refilling the humidification tube set with sterile water or saline the insufflation needs to be stopped. In the sterile field:

- fill syringe with 10 ml of sterile water or saline by means of a syringe as shown in Fig. Filling the gas humidification tube [▸ 33].

Lift up the distal end of the tube set, connect the syringe to the Luer Lock connector and gently empty it into the tube set.

Fig. 5–4 Filling the gas humidification tube



After filling the tube set and confirming the humidification dialog the blue humidification icon is displayed (5).

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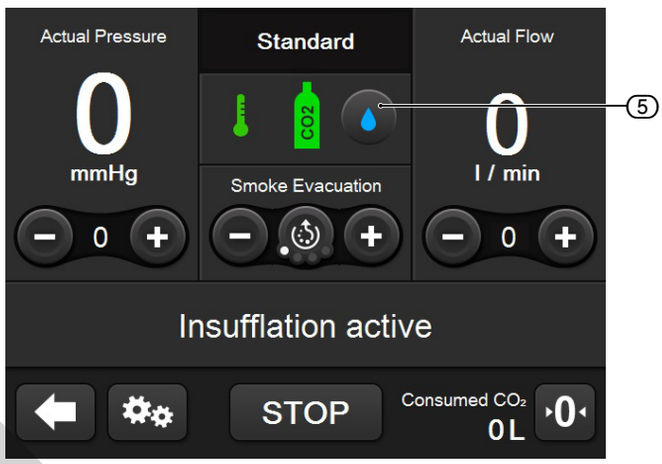
Fig. 5–5 Insufflation gas humidification indicator

(5) Humidification icon (blue)



Refilling

NOTE!

To refill the tube set

The humidification tube set provides approximately 200 l of humidified gas when filled with water or saline. After 200 l of gas have been consumed, the tube set can still be used, however, in order to maintain a high level of humidity, the tube set should be refilled every 200 to 300 l of consumed gas. To refill the tube set, press the humidification icon and follow the instructions.

Press the humidification icon to start the refilling process. Pressing the humidification icon will give the user the option to pause the running insufflation for refilling purpose. While insufflation is not running tube set refilled question appears on the display.

CAUTION!

Filling the tube set

Filling the tube set with more than 10 ml of water can lead to formation of water drops. Do not refill the tube set if the absorber is still soaked with water.

Humidification icons	Description	Information
(blue)	Humidification tube set connected, push icon to start refill work flow.	Indicates that a tube set with humidification ability is connected.
(grey)	Humidification tube set is not connected or function defective and therefore deactivated.	Humidification not available.

5.7 Using Device Control

Documentation

Please consult the additional documentation of SDC3 HD Information Management System for information about settings, use, and troubleshooting before connecting the insufflator to it. Physicians and medical or care and support personnel must be thoroughly familiar with the setup and operation of the Stryker Device Control.

Purpose

The insufflator is prepared for the Stryker Device Control which can be used optionally. The connection of the insufflator to the Device Control system allows the remote control and the remote display of the following insufflation parameters:

- Device Status (e.g. gas supply, gas heater)
- Messages
- Procedure modes
- Flow and pressure parameters
- Smoke evacuation function

There are several ways to control the device once connected to Stryker Device Control:

- Using the touchscreen on Device Control
- Using the remote to control the Device Control menu on the surgical display
- Using the Stryker Camera Head
- Using the Voice Control feature

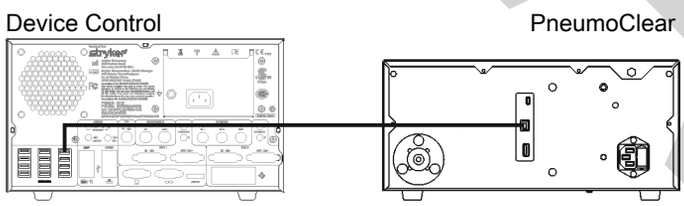
If Device Control is connected and active, the functions and settings of the insufflator may be adjusted using the buttons on the insufflator as well as the device control system.

Required characteristics

A communication of the insufflator through the Device Control interface is only possible with a Stryker SDC3 device. This is ensured by a device identification mechanism. The insufflator is compatible with the SDC3 when the Device Driver Package is installed on the SDC3.

Required configuration

Fig. 5–6 Connecting the PneumoClear to the Device Control



Technical specification

Interface: USB-B connector

Protocol: Sidne Serial Device Protocol

The SIDNE interface cable is a standard four conductor USB-A male to USB-B male cable. The configuration of the connection is preset and cannot be changed. No manual configuration by the user is required.

Intended information flow

The Device Control connection to the insufflator is a master/slave connection to remotely control the insufflator and remotely display insufflator parameters.

Device Control as the communication master initiates the communication by sending requests. The insufflator as communication slave responds to the requests.

Basic safety and essential performance are not influenced by this remote control feature because Device Control is only optional to the insufflator user interface control and not required to operate the insufflator. The insufflator only executes requests which are within the limits of the allowed insufflator settings.

List of hazardous situations potentially resulting from a failure of the connection to Device Control

A failure of connection between insufflator and Device Control will cause

- no reaction of insufflator if controlled by Device Control,
- Device Control will not show actual values of insufflator.

The insufflator can always be controlled by its touch screen. Unexpected disconnection to the Device Control will not affect this.

en

5.8 Unlocking Operating Modes

The device can be equipped with up to 6 procedure modes.

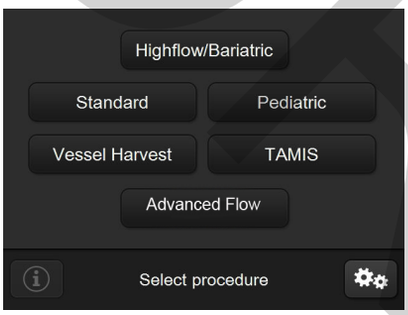
Device Standard Version	Device Plus Version
High Flow/Bariatric Operating Mode	High Flow/Bariatric Operating Mode
Standard Operating Mode	Standard Operating Mode
Pediatric Operating Mode	Pediatric Operating Mode
Vessel Harvest Operating Mode	Vessel Harvest Operating Mode
	TAMIS Operating Mode
	Advanced Flow Operating Mode

TAMIS and Advanced Flow operating modes can be purchased separately. Contact your sales representative for more information on how to purchase them and how to get your device upgraded.

5.9 Displaying/Selecting Insufflation Operating Mode

The display depicts an overview of the insufflation operating modes. Unavailable operating modes are depicted in gray and cannot be selected. Press the respective button to select the desired operating mode (e.g. Standard).

The displayed parameters correspond with the factory settings or the values set in the user menu (see Chapter Menu (Overview) [▶ 51]).



5.10 Setting the Nominal Pressure - All Operating Modes

To set the nominal pressure, press the **+** or **-** button Screen displays [▶ 28] on the display below the actual pressure display.

- The nominal pressure can be increased or decreased during insufflation or while insufflation is stopped.
- With every touch of the + or - button the nominal pressure is increased/reduced in steps of 1 mmHg. When pressing the pressure button longer, scrolling is activated but only up to the respective, operating mode-dependent safety threshold (see below).
- An operating mode-dependent safety threshold (12 or 15 mmHg) applies when setting the nominal pressure. If the pressure is to be increased above these values, the depicted query on the operating screen of the insufflator must be confirmed accordingly.

WARNING!

Exceeding the safety limit

Exceeding this safety limit is to be decided by and the responsibility of the user/operator.

Operating Mode	Safety threshold
High Flow/Bariatric Operating Mode	15 mmHg
Standard Operating Mode	15 mmHg
Pediatric Operating Mode	12 mmHg/15 mmHg
Vessel Harvest Operating Mode	12 mmHg/15 mmHg
TAMIS Operating Mode	15 mmHg
Advanced Flow Operating Mode	15 mmHg

en

5.11 Setting the Nominal Flow - All Operating Modes

To set the nominal flow, press the + or - buttons (see Fig. Screen displays [▶ 28] (10)/(12)) on the display below the actual gas flow display.

- With every touch of the + or - button the nominal flow is increased/reduced in steps of 1 l/min. When working within the range of 0.1 to 2 l/min in Pediatric Operating Mode, the value is increased/reduced by 0.1 l/min. When pressing the flow button longer, scrolling through the flow levels is activated but only up to the respective, operating mode-dependent safety threshold (see below).
- When setting the nominal flow rate, Pediatric operating mode has a safety threshold at 5 l/min, Vessel Harvest at 6 l/min. If the flow is to be increased above these values, the depicted query must be confirmed accordingly.

WARNING!

Exceeding the safety limit

Exceeding this safety limit is to be decided by and the responsibility of the user/operator.

Operating Mode	Safety threshold
High Flow/Bariatric Operating Mode	n.a
Standard Operating Mode	n.a
Pediatric Operating Mode	5 l/min
Vessel Harvest Operating Mode	6 l/min
TAMIS Operating Mode	n.a
Advanced Flow Operating Mode	n.a

CAUTION!

Safety threshold

The safety threshold of the nominal flow is deactivated per default.

The safety threshold of the nominal flow can be activated/deactivated in the User Menu.

Veress insufflation

Veress insufflation is a gentle type of insufflation that prevents exceeding the preset nominal pressure by the actual pressure even in case of small volumes. To minimize the risks in case of a faulty incision, the manufacturer recommends using **Veress insufflation** to start a procedure (filling abdomen with CO_2).

CAUTION!

Venting system

Please note that the automatic venting system is not active during Veress insufflation.

How to activate Veress Insufflation

The activation of the Veress insufflation depends on the chosen mode.

Pediatric Mode: With a nominal flow setting of ≤ 1 l/min, **Veress Insufflation** is displayed after pressing the START/STOP button.

High Flow/Bariatric, **Standard**, **Advanced Flow Mode**: With a nominal flow setting of ≤ 5 l/min, **Veress Insufflation** is displayed after pressing the START/STOP button.

Vessel Harvest, TAMIS: Veress insufflation is not available.

5.12 Running Function Tests before Device Use

Preparation

Check all the sterile disposable items before removing them from the package to ensure that the packaging is intact and that the expiration date is still valid.

For your own safety and that of your patient, use only original accessories (see Chapter Accessories [▶ 69]).

WARNING!

Functional test

The functional test must be successfully completed prior to each surgery.

WARNING!

Fill the tube set with CO_2

For the safety of the patient please fill the tube set with CO_2 gas prior to beginning the insufflation by activating the insufflation for a few seconds and then turning it off again before introducing the insufflation instrument to the cavity and beginning the surgery.

WARNING!

Cannula

Do not attach any cannula with tube set to patient during the function test.

Checking the device

NOTE!

Checking the device

This test can be conducted with the tube set and cannula that will be used for the procedure. Consider sterile/non-sterile aspects during handling.

1. The device is switched off, no tube set is connected.
2. Make sure the gas supply is connected and open.
3. Use the ON/OFF switch to turn the device on. The device now conducts an automatic self-test.
4. Select the operating mode (e.g. Pediatric).
5. Under consideration of sterile/non-sterile aspects open the package of the insufflation tube set that will be used for the procedure. Connect the tube set to the device.
6. Attach the insufflation tube to the cannula and close the stopcock.
7. If the gas consumption display field (see Chapter Gas Consumption Display [▶ 39]) depicts a value, press the button to reset the display to zero **0 L**.
8. Select a nominal pressure of 8 mmHg and a gas flow of 2 l/min.
9. Start insufflation: Press the **START** button.
10. Insufflate approximately 30 seconds. The display status line depicts **Occlusion** after maximum 4 seconds.
11. Stop insufflation: Press the **STOP** button.

WARNING!

Leak in system

If the actual gas consumption is higher than 0.4 l, there is a leak in the system. If this is the case, use steps 12 to 14 outlined below to locate the leak.

12. Repeat steps 7 to 11 without cannula and with closed tube end. The previously connected cannula has a leak if gas consumption is now below 0.4 l.
13. Repeat steps 8 to 12 with a new tube if another leak becomes apparent. If the gas consumption is now below 0.4 l, the previously used tube set has a leak.
14. If another leak is detected, this leak is then directly within the device. Make sure the device can no longer be operated until an authorized service technician conducts the appropriate checks.

en

WARNING!

Leaky insufflation tube

Never work with a leaky insufflation tube, accessory, and/or device. This can lead to an incorrect measurement of the actual pressure values, which can cause an uncontrolled pressure increase in the abdomen.

Choose desired operating mode, pressure and flow settings and continue with procedure.

5.13 Gas Consumption Display

The gas consumption display indicates the insufflated volume of CO_2 in liters since the last resetting of the display.

The gas consumption display can be reset to **0.0** during running or stopped insufflation.

Resetting the display

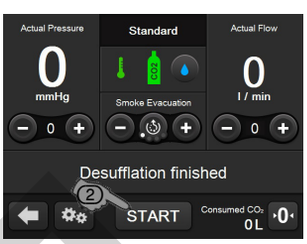
① Press the button to reset the gas consumption display.

5.14 Starting/Stopping Insufflation

Either the **START** or **STOP** button is displayed depending on insufflation status.

Start insufflation:

The **START** button is displayed when insufflation is stopped.



② Press this button to start insufflation.

Stop insufflation:

The **STOP** button is displayed while insufflation is active.

③ Stop insufflation by pressing the **STOP** button.

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5.15 Desufflation

The Desufflation function allows for the remaining CO_2 in the cavity to be removed to a pressure of approximately 3 mmHg after insufflation has been stopped. Desufflation is available after the insufflation when a smoke evacuation tube is connected. After stopping, a query is displayed asking whether the desufflation function should be started.

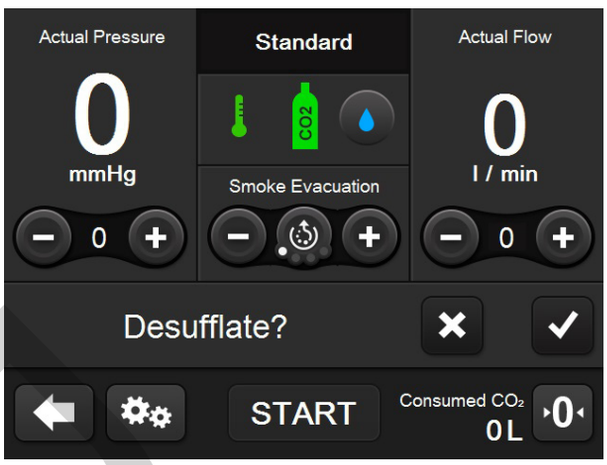

Fig. 5–7 Confirming or denying desufflation

The display shows **Desufflation active**. Desufflation can be stopped at any time with the **Cancel** button.

Desufflation ends automatically once the actual pressure in the cavity is ≤ 3 mmHg. The display shows **Desufflation finished**.

Mode	Desufflation
High Flow/Bariatric Mode	available
Standard Mode	available
Pediatric Mode	not available
Vessel Harvest Mode	not available
TAMIS Mode	not available
Advanced Flow Mode	available

en

6 Operating Modes of the PNEUMOCLEAR™ Insufflator

CAUTION!

Deviation between cavity pressure and pressure display

The insufflator measures the pressure via the tube set. Using a tight trocar/instrument combination limits the equalization of pressure between cavity and tube set. Consequently, the device potentially displays a pressure that is higher than the pressure in the cavity. This can lead to a decrease of the distention performance. For a good equalization of pressure, it is suggested to ensure there is adequate clearance for flow between trocar and the instrument.

NOTE!

Maximum gas flow

The actual maximum gas flow into the cavity is limited by the Luer lock connection, the trocar and the inserted endoscope or instrument. It is suggested to ensure there is adequate clearance for flow between the trocar and the instrument.

Modes Overview

	Standard	Pediatric	High Flow / Bariatric	Advanced Flow	Vessel Harvest	TAMIS
Nominal flow (l/min)	1 - 40	0.1 - 20	1 - 45	1 - 50	1 - 10	0.5 - 40
Flow levels (l/min)	Level 1: 3 Level 2: 20 Level 3: 40	Level 1: 0,1 Level 2: 2 Level 3: 20	Level 1: 5 Level 2: 25 Level 3: 45	Level 1: 5 Level 2: 25 Level 3: 50	Level 1: 1 Level 2: 4 Level 3: 10	Level 1: 3 Level 2: 10 Level 3: 40
Safety threshold flow (l/min)	n.a.	5	n.a.	n.a.	6	n.a.
Starting pressure	15	8	15	15	10	12
Set pressure (mmHg)	1 - 30	1 - 20	1 - 30	1 - 30	1 - 20	1 - 20
Pressure increments (mmHg)	1	1	1	1	1	1
Safety threshold pressure (mmHg)	15	12/15	15	15	12/15	15

6.1 Standard Operating Mode

The **Standard** operating mode is used to distend the peritoneal cavity during laparoscopic procedures by insufflating CO_2.

Patients

The **Standard** operating mode is designed for laparoscopies performed on normal weight and slightly obese (BMI < 30 kg/m²) patients over the age of 14.

Insufflation parameters

The maximum nominal pressure can be set to 30 mmHg and the maximum gas flow to 40 l/min.

WARNING!

Idiosyncratic reactions

Patients with sickle cell anemia or pulmonary insufficiency may have a higher risk of metabolic imbalance related to excessive CO_2 absorption (idiosyncratic reaction).

en

WARNING!

CO_2 absorption

CO_2 is absorbed during insufflation (intravasation). This means the body absorbs a part the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption. The abdomen is sufficiently distended using a pressure between 10 to 15 mmHg. Pressure values above 15 mmHg are required for only a few cases but do increase the risk of intravasation. Never exceed the maximum intra-abdominal pressure of 30 mmHg.

WARNING!

Metabolic and cardiac reactions

Insufflating CO_2 may result in metabolic acidosis. This can lead to cardiac irregularities expressed with the following symptoms:

- **Reduced respiration with restricted diaphram function**
- **Hypercapnia**
- **Reduction of venous reflux**
- **Reduced cardiac output**
- **Metabolic acidosis**

WARNING!

Hypothermia/monitoring body temperature

The gas flow can lead to a lowering of the patient's body temperature during insufflation. Hypothermia during insufflation can cause heart and cardiovascular problems. The risk for hypothermia can be significantly reduced with the use of gas that is pre-warmed to body temperature. Therefore, you must always monitor the patient's body temperature during the entire insufflation process. Make especially sure that the following, hypothermia-fostering, surgical conditions are avoided as best as possible:

- **High gas flow due to large leaks**
- **Long surgeries**
- **Use of irrigation and infusion solution not pre-heated to body temperature.**

WARNING!

Dehydration

Insufflation can lead to dehydration of the tissue, especially if the surgery time is prolonged. This can lead to damage of peritoneal cell structures within the tissue. Insufflation, especially with unconditioned gas, is associated with post-operative pain. Long surgeries and large leaks increase the risk of dehydration especially at the insertion points of the trocars.

The use of humidified and prewarmed gas can reduce risks associated with tissue dehydration.

WARNING!

Embolism/insufflation of internal organs

Improper placement of the insufflation instrument could cause gas penetrating a vessel or an internal organ, resulting in air or CO_2 embolisms. To reduce the risk, use a low flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Check the position of the insufflation instrument immediately if the actual pressure rapidly reaches the nominal pressure value. CO_2 embolisms can also be caused by a high intra-abdominal pressure. Avoid high-pressure settings and close damaged blood vessels at once.

WARNING!

Emphysema

Incorrect placement of a cannula or a trocar into subcutaneous tissue may lead to emphysema. To reduce the risk, use a low gas flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Long surgeries (> 200 min.), the use of many access points, duration and size of leaks at these points may also contribute to emphysema. Be sure to close leakages in trocar accesses immediately.

WARNING!

Additional insufflation sources / automatic venting system

Make sure the automatic venting system is activated (see Chapter Menu (Overview) [▷ 51]). The use of additional insufflation sources increases the intra-abdominal pressure. Continuously monitor intra-abdominal pressure over the course of the entire insufflation if additional sources are used.

6.2 High Flow/Bariatric Operating Mode

The **High Flow/Bariatric** operating mode is used to distend the peritoneal cavity during laparoscopic procedures by insufflating CO_2. It features a constantly increased performance to compensate port side leakages and continuing smoke evacuation over the time of the procedure.

Patients

The **High Flow/Bariatric** operating mode is designed for laparoscopies performed on normal weight and obese patients (BMI > 30 kg/m²) over the age of 14.

The High Flow/Bariatric operating mode may be used for a number of different procedures, including but not limited to:

- weight loss surgery
- bowel resection
- colorectal surgery

Insufflation parameters

The maximum nominal pressure can be set to 30 mmHg and the maximum gas flow to 45 l/min.

WARNING!

Idiosyncratic reactions

Patients with sickle cell anemia or pulmonary insufficiency may have a higher risk of metabolic imbalance related to excessive CO_2 absorption (idiosyncratic reaction).

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WARNING!

CO_2 absorption

CO_2 is absorbed during insufflation (intravasation). This means the body absorbs a part the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption. The abdomen is sufficiently distended using a pressure between 10 to 15 mmHg. Pressure values above 15 mmHg are required for only a few cases but do increase the risk of intravasation. Never exceed the maximum intra-abdominal pressure of 30 mmHg.

WARNING!

Metabolic and cardiac reactions

Insufflating CO_2 may result in metabolic acidosis. This can lead to cardiac irregularities expressed with the following symptoms:

- **Reduced respiration with restricted diaphram function**
- **Hypercapnia**
- **Reduction of venous reflux**
- **Reduced cardiac output**
- **Metabolic acidosis**

WARNING!

Hypothermia/monitoring body temperature

The gas flow can lead to a lowering of the patient's body temperature during insufflation. Hypothermia during insufflation can cause heart and cardiovascular problems. The risk for hypothermia can be significantly reduced with the use of gas that is pre-warmed to body temperature. Therefore, you must always monitor the patient's body temperature during the entire insufflation process. Make especially sure that the following, hypothermia-fostering, surgical conditions are avoided as best as possible:

- **High gas flow due to large leaks**
- **Long surgeries**
- **Use of irrigation and infusion solution not pre-heated to body temperature.**

WARNING!

Dehydration

Insufflation can lead to dehydration of the tissue, especially if the surgery time is prolonged. This can lead to damage of peritoneal cell structures within the tissue. Insufflation, especially with unconditioned gas, is associated with post-operative pain. Long surgeries and large leaks increase the risk of dehydration especially at the insertion points of the trocars.

The use of humidified and prewarmed gas can reduce risks associated with tissue dehydration.

en

WARNING!

Embolism/insufflation of internal organs

Improper placement of the insufflation instrument could cause gas penetrating a vessel or an internal organ, resulting in air or CO_2 embolisms. To reduce the risk, use a low flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Check the position of the insufflation instrument immediately if the actual pressure rapidly reaches the nominal pressure value. CO_2 embolisms can also be caused by a high intra-abdominal pressure. Avoid high-pressure settings and close damaged blood vessels at once.

WARNING!

Emphysema

Incorrect placement of a cannula or a trocar into subcutaneous tissue may lead to emphysema. To reduce the risk, use a low gas flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Long surgeries (> 200 min.), the use of many access points, duration and size of leaks at these points may also contribute to emphysema. Be sure to close leakages in trocar accesses immediately.

WARNING!

Additional insufflation sources / automatic venting system

Make sure the automatic venting system is activated (see Chapter Menu (Overview) [▷ 51]). The use of additional insufflation sources increases the intra-abdominal pressure. Continuously monitor intra-abdominal pressure over the course of the entire insufflation if additional sources are used.

WARNING!

Altered Respiratory Physiology

Always monitor the patient's respiratory functions during the entire surgery. The larger body mass supported by the thoracic cage and the larger amount of fat in the abdominal cavity may reduce the elasticity of the thoracic wall. In addition, the increased intra-abdominal pressure secondary to insufflation may alter the normal physiological lung parameters thus resulting in a reduction of the functional lung volume. Shallow, rapid breathing is symptomatic of this condition. Even modest physical stress causes a tremendous increased demand for oxygen, which stands in contrast to the ineffective respiratory musculature that requires more oxygen because it must overcome the reduced elasticity of the thoracic cage. The functional capacity of the lungs is small and even moderate stress can lead to respiratory failure.

WARNING!

Subcutaneous emphysema

When puncturing the thicker abdominal wall of morbidly obese patients with the Veress cannula or the trocar, carefully monitor the correct position of the instrument in the abdomen.

WARNING!

CO_2 supersaturation

To avoid generating CO_2 supersaturation, an increased level of respiratory activity is required. An overweight patient's oxygen demand and carbon dioxide production are greater and increase faster under physical stress than do those of patients with normal body weight.

WARNING!

Heart and cardiovascular insufficiency

Constantly monitor all heart and cardiovascular parameters during surgery since morbidly obese patients have an increased risk of heart and cardiovascular insufficiencies.

6.3 Pediatric Operating Mode

The **Pediatric** operating mode is used to distend the peritoneal cavity during laparoscopic procedures by insufflating CO_2.

Patients

The **Pediatric** operating mode is designed specifically for use on newborns, infants, and children under the age of 14.

Insufflation parameters

The maximum nominal pressure can be set to 20 mmHg and the maximum gas flow to 20 l/min.

For use with children, the control of the device - depending on nominal flow selection - is optimized and recommended based on age and weight as per the following:

Age group	Weight	Flow range
Children younger than 1 year	approximately 1 - 9 kg	0.1 – 0.5 l/min
Children between 1-3 years	approximately 10 - 15 kg	0.5 – 1.0 l/min
Children between 3-4 years	approximately 16 - 19 kg	1.0 – 2.0 l/min
Children between 4-14 years	> 20 kg	> 2.0 l/min und < 14 l/min
All children	< 25 kg	≤ 14 l/min

WARNING!

Recommended work settings

The flow values listed for laparoscopic procedures performed on newborns, infants, and children are only suggested values. The selection of the suitable flow and pressure values is solely the responsibility of the attending physician.

NOTE!

Limited smoke evacuation function

The smoke evacuation function is limited to rate 1 and 2. The use of the smoke evacuation function requires a minimal flow setting, for further information refer to the table given in Chapter Using the Smoke Evacuation Function [▶ 31]. Do not exceed the recommended flow settings, especially for newborns, infants, and small children.

WARNING!

Gas flow limit

The gas flow may not exceed 14 l/min when performing a laparoscopy on newborns or patients weighing less than 25 kg (approximately 55 US pounds).

WARNING!

Pneumolabium/pneumoscrotum

Children are at risk of a pneumolabium or pneumoscrotum.

CAUTION!

Low nominal flow setting

The nominal pressure cannot be reached in case of leaks if the nominal flow is set too low.

WARNING!

Procedures with children

Only those who are specially trained and qualified for procedures with children or endoscopic vessel harvesting procedures may use this device for these purposes.

WARNING!

Increased airway pressure

When laparoscopic procedures are performed on children, the increased intra-abdominal pressure also increases the risk for higher airway pressures. Always strictly monitor respiration and airway function when performing laparoscopic procedures on children younger than 12 years of age.

WARNING!

Compression of the vena cava

When insufflating the abdomen of a child with medical CO_2, an increased risk of compressing the vena cava exists. This risk can be reduced by monitoring the systolic and diastolic blood pressure during the entire surgery.

WARNING!

Haemodynamic stability

A laparoscopy performed on children younger than 12 years of age may result in problems of the haemodynamic system due to the CO_2 content in the blood. It is recommended to increase the breathing rate of the patient and to work with low flow values and pressure values not exceeding 12 mmHg. The patient's circulatory system should be monitored at all times.

WARNING!

Hypothermia

The insufflation gas flow usually drops significantly after the target pressure has been reached and it is then only required to maintain the abdominal pressure. However, leaks within the abdomen or the instrument can lead to a constant gas flow of above 1 l/min. When operating on children younger than 12, a gas flow of more than 1 l/min poses an increased risk of hypothermia for the patient. Corresponding measures to prevent hypothermia include the use of blankets or prewarmed gas. The patient's body temperature has to be monitored at all times during surgery.

WARNING!

Children with cardiovascular problems

Laparoscopy with CO_2 should not be performed on children with cardiovascular problems.

en

WARNING!

Hypercapnia

Because pediatric patients are especially susceptible to hypercapnia, it is recommended to establish an end-tidal CO_2 monitoring routine.

6.4 Advanced Flow Operating Mode

The **Advanced Flow** operating mode is used to distend the peritoneal cavity during laparoscopic procedures, including but not limited to robotic-assisted laparoscopies by insufflating CO_2. The Advanced Flow operating mode is designed to compensate for large leaks e.g. due to the use of suction instruments.

Patients

The **Advanced Flow** operating mode is designed for laparoscopies performed on normal weight and obese patients over the age of 14.

The **Advanced Flow** operating mode may be used for a number of different procedures, including but not limited to:

- Prostatectomy
- Hysterectomy
- Gastrectomy
- Colectomy
- Nephrectomy

Insufflation parameters

The maximum nominal pressure can be set to 30 mmHg and the maximum gas flow to 50 l/min.

6.5 Vessel Harvest Operating Mode

The **Vessel Harvest** operating mode is used to distend the cavity along the vena saphena magna and radial artery during an endoscopic vessel harvesting procedure.

Patients

The **Vessel Harvest** operating mode is designed for patients over the age of 14.

Insufflation parameters

The maximum nominal pressure can be set to 20 mmHg and the maximum gas flow to 10 l/min.

WARNING!

Idiosyncratic reactions

Patients with sickle cell anemia or pulmonary insufficiency may have a higher risk of metabolic imbalance related to excessive CO2 absorption (idiosyncratic reaction).

WARNING!

CO_2 absorption

Due to the special surgical procedures - start of the heart bypass operation, and the endoscopic removal of the vessel - special care has to be taken as CO_2 is always absorbed through the tissue of the patient during insufflation (intravasation). This means the body absorbs part of the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption.

en

WARNING!

Metabolic and cardiac reactions

Insufflating CO_2 may result in metabolic acidosis. This can lead to cardiac irregularities expressed with the following symptoms:

- **Reduced respiration with restricted diaphram function**
- **Hypercapnia**
- **Reduction of venous reflux**
- **Reduced cardiac output**
- **Metabolic acidosis**

WARNING!

Dehydration

Insufflation can lead to dehydration of the tissue, especially if the surgery time is prolonged. This can lead to damage of peritoneal cell structures within the tissue. Insufflation, especially with unconditioned gas, is associated with post-operative pain. Long surgeries and large leaks increase the risk of dehydration especially at the insertion points of the trocars.

The use of humidified and prewarmed gas can reduce risks associated with tissue dehydration.

WARNING!

Embolism/insufflation of internal organs

Improper placement of the insufflation instrument could cause gas penetrating a vessel or an internal organ, resulting in air or CO_2 embolisms. To reduce the risk, use a low flow rate for the first insufflation and ensure that the insufflation instrument is correctly positioned. Check the position of the insufflation instrument immediately if the actual pressure rapidly reaches the nominal pressure value. CO_2 embolisms can also be caused by a high intra-abdominal pressure. Avoid high-pressure settings and close damaged blood vessels at once.

WARNING!

Procedures with children

Only those who are specially trained and qualified for procedures with children or endoscopic vessel harvesting procedures may use this device for these purposes.

WARNING!

Instrument used for CO_2 insufflation

Before using the insufflator to endoscopically harvest vessels, please check whether the instrument used is intended for CO_2 insufflation.

WARNING!

Pneumoperitoneum

When a vessel is harvested from the leg of a patient with a perforated groin, it is possible for CO_2 to reach the abdomen and cause a pneumoperitoneum. Make sure the abdomen does not fill with CO_2 during surgery.

en

6.6 TAMIS Operating Mode

The **TAMIS** operating mode is used to dilate and fill the rectum and colon by insufflating CO_2 during transanal minimally invasive surgery.

Patients

The **TAMIS** operating mode is designed for patients over the age of 14.

Insufflation parameters

The maximum nominal pressure can be set to 20 mmHg and the maximum gas flow to 40 l/min.

WARNING!

Lowest gas flow and pressure

Depending on age and health condition of the patient, the smallest possible gas flow and pressure for establishing the cavity should be selected. It is not recommended to exceed insufflation pressures of 15 mmHg in transanal minimally invasive surgery procedures.

WARNING!

CO_2 absorption

CO_2 is absorbed during insufflation (intravasation). This means the body absorbs part of the CO_2 gas used for insufflation. CO_2 concentrations in the blood or respiratory system that are too high can lead to death of the patient in extreme cases. To lower this risk, always carefully and closely monitor the patient's vital signs during the entire insufflation process and make sure patient is breathing well. Sufficient respiration can help avoid or limit problems with CO_2. High pressure or a high gas flow promotes CO_2 absorption. Pressure values above 15 mmHg are required for only a few cases but do increase the risk of intravasation. It is recommended not to exceed insufflation pressures of 15mmHg during transanal minimally invasive surgery.

CAUTION!

Different indication to taTME

The TAMIS indication is different than the taTME (trans anal total mesorectal excision) procedure.

en

7 Menu (Overview)

Mode and user-dependent device settings can be changed in the menu.

User Menu	Operating Mode	Options	Default
Starting pressure (Operating mode dependent) **Sets the initial nominal pressure value for each mode**	Standard	1 - 15 mmHg	15 mmHg
	High Flow/Bariatric	1 - 15 mmHg	15 mmHg
	Advanced Flow	1 - 15 mmHg	15 mmHg
	Pediatric	1 - 12 mmHg	8 mmHg
	Vessel Harvest	1 - 15 mmHg	10 mmHg
	TAMIS	1 - 15 mmHg	12 mmHg
Gas Flow Rates (Operating mode dependent) **Sets the flow rates for each mode** **Flow rate 1 will be loaded per default in operating screen, holding the flow button will allow scrolling through the rates**	Standard	Rate 1: 1 - 5 l/min Rate 2: Rate 1+1 - 39 l/min Rate 3: Rate 2+1 - 40 l/min	Rate 1: 3 l/min Rate 2: 20 l/min Rate 3: 40 l/min
	High Flow/Bariatric	Rate 1: Rate 1 - 5 l/min Rate 2: Rate 1+1 - 44 l/min Rate 3: Rate 2+1 - 45 l/min	Rate 1: 5 l/min Rate 2: 25 l/min Rate 3: 45 l/min
	Advanced Flow	Rate 1: 1 - 5 l/min Rate 2: Rate 1+1 - 49 l/min Rate 3: Rate 2+1 - 50 l/min	Rate 1: 5 l/min Rate 2: 25 l/min Rate 3: 50 l/min
	Pediatric	Rate 1 0.1 - 2 l/min Rate 2: Rate 1+1 - 19 l/min Rate 3: Rate 2+1 - 20 l/min	Rate 1: 0.1 l/min Rate 2: 2 l/min Rate 3: 20 l/min
	Vessel Harvest	Rate 1: 1 - 5 l/min Rate 2: Rate 1+1 - 9 l/min Rate 3: Rate 2+1 - 10 l/min	Rate 1: 1 l/min Rate 2: 4 l/min Rate 3: 10 l/min
	TAMIS	Rate 1: 0.5 - 5 l/min Rate 2: Rate 1+1 - 39 l/min Rate 3: Rate 2+1 - 40 l/min	Rate 1: 3 l/min Rate 2: 10 l/min Rate 3: 40 l/min
Venting valve (Operating mode dependent)	Standard	- Always ON - In Veress mode OFF	In Veress mode OFF
	High Flow/Bariatric	- Always ON - In Veress mode OFF	In Veress mode OFF
	Advanced Flow	- Always ON - In Veress mode OFF	In Veress mode OFF
	Pediatric	- Always ON - In Veress mode OFF	Always ON
	Vessel Harvest	- Always ON - Always OFF	Always OFF
	TAMIS	- Always ON - Always OFF	Always ON
Smoke Evacuation Level (Operating mode dependent) **Sets the default starting suction rate for each mode**	Standard	Evacuation level 1-4	Level 1
	High Flow/Bariatric	Evacuation level 1-4	Level 1
	Advanced Flow	Evacuation level 1-4	Level 1
	Pediatric	Evacuation level 1-2	Level 1
	Vessel Harvest	Not available	
	TAMIS	Evacuation level 1-4	Level 1

en

User Menu	Operating Mode	Options	Default
Display Audio	All modes	**Brightness** Level 1-4	3
		General Volume Level 1-4	3
		Audible Occlusion Signal - ON - OFF	ON
		Audible Smoke Evacuation paused Signal - ON - OFF	OFF
Gas Supply	All modes	- House gas - Bottle gas	House gas
Languages	All modes	- English - Français - Deutsch - Español - Português - Italiano - Nederlands - Norsk - Simplified Chinese - Suomi - Greek - Svenska - Dansk - Polski - Românã - Korean - Japanese	English
Software version	All modes	Displays the installed software version xx.xx	
Factory reset	All modes	Allows the user to reset all setting done in the user menu to factory default after confirmation.	
Procedure upgrade	All modes	Unlock new procedures via an upgrade code Pass code entry	
Service menu	All modes	Authorized access only Passcode entry	

en

8 Safety Functions

8.1 Automatic Venting System

Automatic venting system

The device is equipped with an automatic venting system.

When the insufflator detects an overpressure it automatically activates the venting system. The venting system releases gas from the cavity until the set nominal pressure has been reached again.

The automatic venting system can be configured in the user menu individually for each operating mode.

When the venting system is active, the venting threshold is 3 mmHg above set pressure with a delay of 3 seconds. There is instant venting if actual pressure is 6 mmHg above set pressure.

If the venting valve is deactivated, the message **Venting valve deactivated** is shown when the mode is activated and an acoustic signal is emitted.

The venting function will always be automatically activated without delay if the abdominal pressure exceeds 45 mmHg, even if the venting system is deactivated.

Insufflation source

The manufacturer advises against using additional, non-pressure-controlled insufflation sources during minimally invasive surgical procedures.

The use of CO_2-cooled lasers and argon beamers can lead to values exceeding the recommended and safe pressure rating.

WARNING!

Additional insufflation sources / automatic venting system

Make sure the automatic venting system is activated (see Chapter Menu (Overview) [▷ 51]). The use of additional insufflation sources increases the intra-abdominal pressure. Continuously monitor intra-abdominal pressure over the course of the entire insufflation if additional sources are used.

WARNING!

Limited venting system

The venting rate of the automatic venting system is limited. Always monitor the actual pressure when using additional insufflation sources.

Overpressure

If the overpressure cannot be reduced by the automatic venting system within 5 seconds, the display depicts **Overpressure**. An acoustic signal is emitted.

Once the nominal pressure limit of the used operating mode has been reached/exceeded the display depicts the message **Maximum pressure reached!** A warning signal is emitted at the same time.

If the actual pressure exceeds 45 mmHg for more than 10 seconds the display depicts the message **Excessive Overpressure** along with an acoustic signal.

8.2 Occlusion

Warning display "Occlusion"

When the tube, Veress cannula, or trocar experiences a blockage, the display depicts **Occlusion** and gives an acoustic signal. The actual pressure displays **0 mmHg**.

The acoustic signal can be activated/deactivated in the user menu.

CAUTION!

Measurement in the body cavity

The pressure in the body cavity cannot be measured during an occlusion!

en

8.3 Contamination

WARNING!

Contamination

Do not use device and/or accessories if signs of contamination are detected. Make sure the device or/and accessories can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.

Error message "Contamination"

When fluid has penetrated the device via the insufflation tube connection, the display depicts **Contamination** and gives an acoustic signal. It is possible to conclude any currently ongoing surgery with this device.

If insufflation is stopped subsequently, it can be restarted within 20 minutes and the surgery can be continued. A change of operating mode is no longer possible. If insufflation is not restarted during 20 minutes or if the device is turned off and on again, further use of the device is not possible. This is to prevent cross-contamination.

Contamination

When you turn on an already contaminated device, a corresponding message appears on the display. The device can no longer be used. The contaminated device has to be clearly marked as contaminated and sealed in two separate protective layers of safety foil. Make sure the device cannot be used until a qualified service technician conducts the appropriate tests and repairs.

8.4 Leakage Detection

If the device is not able to achieve the set pressure, a leakage notification is displayed.

Leakages can occur at port sides, port sealings or due to excessive use of a suction device.

en

9 Care and Maintenance

Special care is necessary when servicing, maintaining, and storing the device and its accessories to maintain the functionality of the device and its accessories.

NOTE!

Service or maintenance work

Service or maintenance work may not be carried out during surgery.

9.1 Cleaning the Device

Manufacturer's specifications

The manufacturer recommends that the device is cleaned after every procedure as follows:

1. Use the **ON/OFF** button (push-push) to turn the device off.
2. Remove the power cable.
3. Wipe the surface of the device with a soft lint-free cloth moistened with the surface disinfectant (for example Meliseptol® rapid). The concentration and the time the disinfectant must be applied, depends on the information provided by the manufacturer of the disinfectant. Make sure moisture does not enter the device.

CAUTION!

Cleaning the Device

Do not sterilize the device.

9.2 Maintenance Intervals

Manufacturer's specifications

The manufacturer stipulates that qualified personnel or hospital technicians must regularly test the device to assess its functionality and technical safety. This inspection has to be carried out once a year. The tests are described in Chapter Annual Inspection [▸ 58].

Regular inspections will assist in early detection of possible malfunctions. This helps to preserve the device and increases its safety and service life.

9.3 Maintenance by Authorized Service Technician

Two-year maintenance interval

An authorized service technician has to inspect and service the device at appropriate intervals to ensure its safety and functionality. The minimum service interval is two years, depending on frequency and duration of use. If the service interval is not maintained, the manufacturer does not assume any liability for the functional safety of the device.

A sticker located on the rear panel of the device states the latest date for the next service or maintenance check.

Authorized trained personnel

Authorized service technicians are only trained and certified by the manufacturer.

All of the service tasks, such as changes, modifications, repairs, calibrations, etc. may be carried out only by the manufacturer or manufacturer-approved trained and skilled technicians.

Unauthorized personnel

The manufacturer is not liable for the operational safety of the device if unauthorized persons conduct this maintenance or any other service tasks.

Liability

Unauthorized opening of the device and repairs performed by unauthorized personnel or third parties and/or changes or modifications release the manufacturer of any liability concerning the operational safety of the device.

Technical documents

Receiving technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments, or alterations on the device or accessories/peripherals.

en

Certification

Ask the service technician for a certificate after he or she has inspected the unit or performed any service tasks. This certificate lists the type and scope of the service as well as the date and name of the servicing company together with the signature of the service technician.

WARNING!

Risk of electrical shock

To prevent electrical shock, do not open this device. Never open this device yourself. Notify the authorized service technicians of any required repairs.

WARNING!

Modification of the device

This device may not be modified without the permission of the manufacturer.

WARNING!

Modified device

If the device is modified, suitable examinations and tests must be carried out to ensure further safe use of the device.

9.4 Replacing the Fuse

CAUTION!

Replace the fuse

Before replacing the fuse, check the values for the fuse to be inserted in accordance with Chapter Technical Data [67].

The fuse may be defective and is in need of replacement if:

- displays and LEDs (if available on your equipment) do not light up,
- the device does not function.

Check to make sure

- the main power supply cable is properly connected to the power supply input and to a safety socket,
- the house power supply fuse is functioning.

WARNING!

Checking the fuse

Unplug the power cable from the device before checking the fuse.

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The device does **not** have to be opened to replace the fuse.

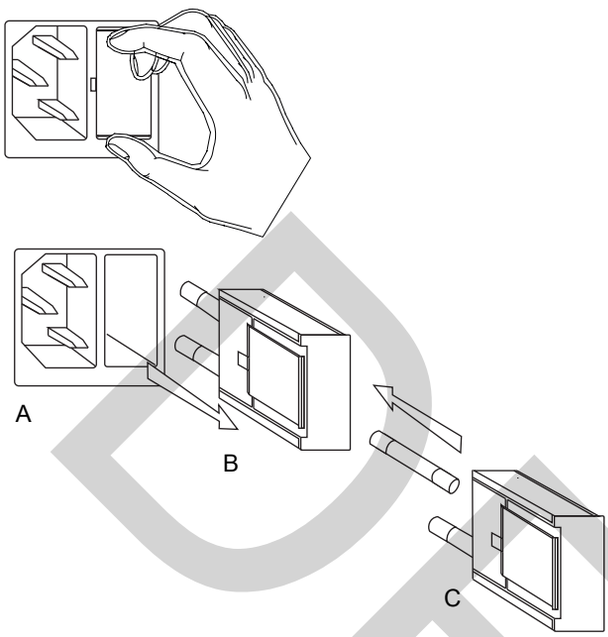

Fig. 9–1 Opening the fuse holder

1. Switch device off.
2. Disconnect device from power supply by pulling the mains plug from the mains socket.
3. Remove power connection cable from mains socket.
4. The fuse holder is located next to the mains socket.
5. Remove fuse holder as depicted in Fig. Opening the fuse holder [▸ 57].
6. **A** Undo the latch of the fuse holder with two fingers.
7. **B** Remove the fuse holder.
8. **C** Check fuse.
9. Insert a new fuse. Use only the specified type of fuse (see Chapter Technical Data [▸ 67]).
10. Insert the fuse holder until it can be heard snapping into place.

en

Measured values and tolerances

10 Annual Inspection

Each test conducted must be documented with date and signature on the test log.

The following measuring tools and resources are required to determine the listed measurements and tolerances:

Manometer	Range 0-100 mmHg, error class 1 (± 1 % of span)
Syringe	60 ml
PNEUMOCLEAR™ HIGH-FLOW TUBE SET	
Silicone tube	4 mm x 40 cm
T-adapter	6/4/6
Veress cannula	length 100 mm
	opening diameter 1.4 mm,
	inner cannula diameter 1.6 mm

An authorized service technician must check the device if the specified parameters and tolerances are exceeded.

10.1 Electrical Safety Test

1. Perform a visual inspection. Make sure that
   - the fuse corresponds with the specifications indicated by the manufacturer,
   - labels and stickers on device are legible,
   - the mechanical condition of the device allows for its safe use,
   - the device is clean to ensure proper and safe functionality.
2. Carry out the measurements for the ground leakage current, short-circuit current/housing leakage current, and the protective conductor resistance as per IEC 62353 in the current version or according to the applicable national standard.

10.2 Basic Function Test (in Standard Operating Mode)

1. Remove insufflation tube from the device.
2. Use the On/Off switch to turn the device on. The device now conducts a device check. An audible signal can be heard. Set the Standard operating mode.
3. A nominal pressure of 15 mmHg and a nominal flow of 3 l/min are set at the factory.
4. The following values are displayed:

   Nominal pressure 15* (mmHg)

   Nominal gas flow 3* (l/min)

   Actual pressure 0 (mmHg)

   Gas consumption 0.0 (l)

   *These values correspond with the factory setting. If values in the user menu were changed, these changed values are displayed. Insert an PNEUMOCLEAR™ HIGH-FLOW TUBE SET.
5. Start insufflation: Press the **START** button. The following values are displayed:

   Actual pressure 0 (mmHg)

   Veress Insufflation is displayed. Streaming gas can be heard at the insufflation tube.
6. Select a nominal gas flow of 20 l/min. The following value is displayed:

   Nominal gas flow 20 l/min

   Actual pressure 0 (mmHg)

   Insufflation Active is displayed. Streaming gas can be heard at the insufflation tube.

en

7. Stop insufflation: Press the **STOP** button.
   The following values are displayed:
   Actual pressure 0.0 (mmHg)
   Gas consumption > 0.0 (l)
8. Press the gas volume button.
   Gas consumption 0.0 (l)

The basic function check of the device is complete.

10.3 Pressure Sensor Test (Standard Operating Mode)

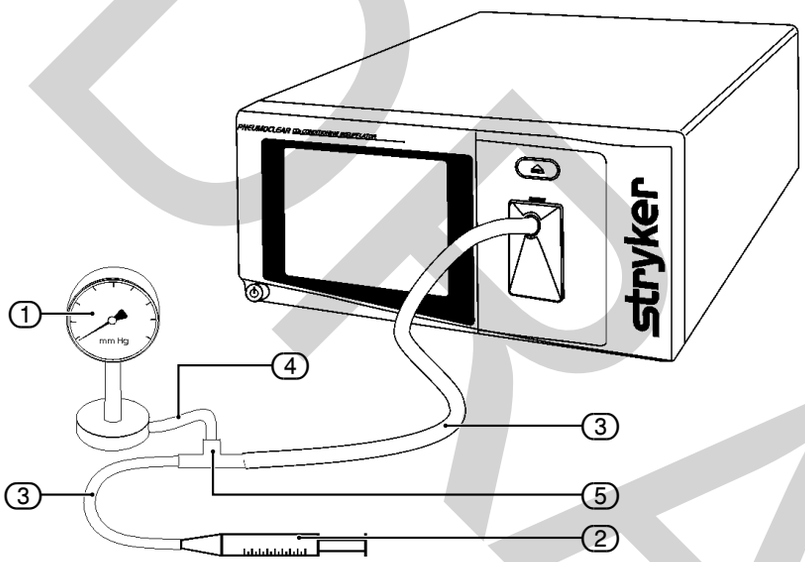

Fig. 10–1 Pressure sensor test setup

① Manometer
② Syringe
③ PNEUMOCLEAR™ HIGH-FLOW TUBE SET
④ Silicone tube
⑤ T adapter

CAUTION!

Gas extraction

Never use the syringe to extract gas from the device.

1. Set the Standard operating mode.
2. Select a nominal gas flow rate of 1.0 l/min.
   Do **not** press the **START/STOP** button.
3. Connect a manometer and an air-filled syringe to the insufflation tube connection.
4. Use the syringe to generate a pressure of 10 mmHg, which is indicated on the manometer.
   Actual pressure display: 10 (mmHg)
5. Use the syringe to generate a pressure of 20 mmHg, which is indicated on the manometer.
   Actual pressure display: 20 (mmHg)
6. Use the syringe to generate a pressure of 30 mmHg, which is indicated on the manometer.
   Actual pressure display: 30 (mmHg)

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10.4 Pressure Monitoring Test (in Standard Operating Mode)

See also Chapter Technical Data [▸ 67].

1. In the user menu activate the **Venting Valve**.
2. Go to the OP Screen.
3. Set the Standard operating mode.
4. Select a nominal pressure of 15 mmHg and a nominal gas flow of 3 l/min.
5. Use the syringe to create pressure between 27 mmHg and 30 mmHg, indicated on the manometer. Start insufflation: Press the **START** button. An acoustic signal is emitted (for 5 seconds) and the display depicts **Overpressure** while the pressure exceeds 18 mmHg (measured with external manometer).
6. Reduce the pressure. The warning ends when the pressure falls below 19 mmHg (nominal pressure plus 4 mmHg). Stop insufflation: Press the **STOP** button.
7. Select a nominal pressure of 29 mmHg.
8. Use the syringe to generate a pressure of at least 31 mmHg, which is indicated on the display. Start insufflation: Press the **START** button. An acoustic signal is emitted with a pressure of more than 30 mmHg and the display depicts **Maximum Insufflation Pressure Reached.**
9. Reduce the pressure. The warning ends when the pressure falls below 30 mmHg. Stop insufflation: Press the **STOP** button.

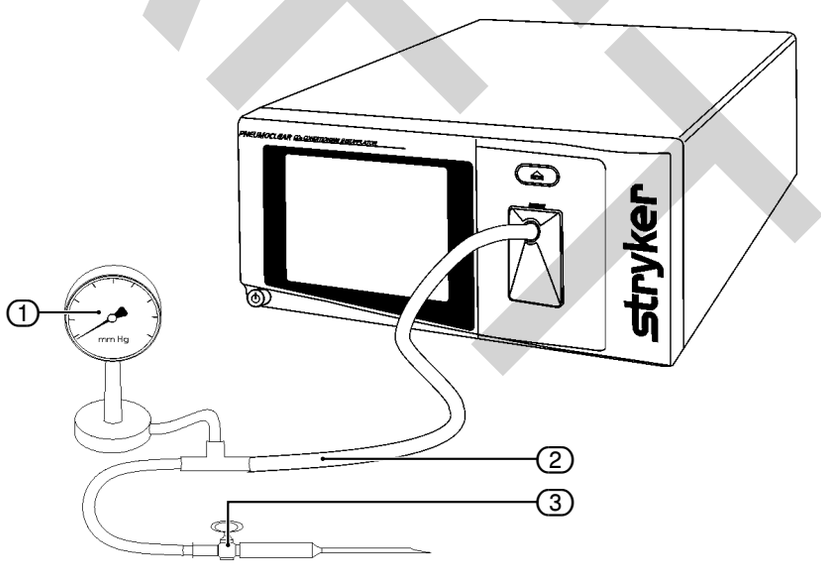
10.5 Venting Valve Test

See also chapter Pressure Sensor Test (Standard Operating Mode) [▸ 59].

1. In the user menu **Venting System**, switch the venting system on (if setting **Veress Insufflation OFF**).
2. Select a nominal pressure of 15 mmHg and a nominal gas flow of 10 l/min.
3. Use the syringe to generate a pressure of at least 18 mmHg, which is indicated on the manometer. Start insufflation. The venting valve is activated with a pressure of more than 18 mmHg (for 3 seconds).

10.6 Maximum Device Pressure Test

Fig. 10–2 Connections for maximum device pressure test



1. Select Standard operating mode.
2. Select the maximum nominal gas flow.

3. Connect a manometer (1) and an open Veress cannula (3) to the insufflation tube connection (2).
4. Start insufflation:

   Press the **START** button. The manometer registers a pulsing pressure increase. When the pressure stabilizes, the manometer registers a pressure between 55 and 65 mmHg
5. Stop insufflation:

   Press the **STOP** button.

10.7 Gas Flow Rate Test

Test setup with open connection, without connected insufflation tube.

- Select a nominal gas flow rate of 15 l/min.
- Start insufflation:

  Press the **START** button.
- Press the gas volume button (0.0 l must be displayed).
- Now start measuring for one minute.
- Stop the insufflation after one minute: Press the **STOP** button.

  The gas consumption should be at least 11-12 l.

Each successfully conducted test must be documented with the test log.

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11 Electromagnetic compatibility

CAUTION!

Accessories

To ensure compliance with the requirements of IEC 60601-1-2 in the current version, the device PNEUMOCLEAR™ must be used only with the accessories listed in Chapter Accessories [▷ 69].

Precautionary measures

Medical devices are subject to special safety and protective measures concerning electromagnetic compatibility (hereafter abbreviated as EMC).

The device is to be used only for the purposes described in the Instructions for Use and is intended for use in environments in Professional Healthcare Facility Environment. This applies even if individual requirements meet the conditions for deviating electromagnetic environments. During installation and commissioning as well as during operation of the device, the compliance with the notes and instructions for EMC must be strictly observed.

To ensure the basic safety and essential functionality in relation to electromagnetic interference over the life of the device, the device must be restarted after 24 hours so that a diagnostic self-test can be performed. The maintenance intervals indicated in Chapter Maintenance Intervals [▷ 55] must also be observed.

This device complies with the electromagnetic compatibility (EMC) requirements for medical electrical devices as defined by IEC 60601-1-2. The limits used in testing provide a basic level of safety against typical electromagnetic interference likely to occur in professional health care facilities. Nevertheless, it can happen that individual performance features are no longer available or only to a limited extent due to the presence of EM interference.

In the presence of EM interference, it may happen that the heating function is affected. If the heating function is influenced by EM interference, it will be switched off for safety reasons. After the EM interference has faded, the heating function is reactivated.

11.1 Electrical Connections

ESD (Electrostatic Discharge) precautionary measures

The following are ESD precautionary measures:

- Apply potential equalization (PE), if available on your equipment, to all devices to be connected.
- Use only the listed equipment and accessories.

Hospital employees should be informed about and trained in ESD precautionary measures.

11.2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The device **PNEUMOCLEAR™** is intended for use in an environment as described below. The user/operator of the device **PNEUMOCLEAR™** should make sure the device is operated within such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device **PNEUMOCLEAR™** uses RF energy solely for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device **PNEUMOCLEAR™** is suitable for use in all establishments, other than public establishments and those directly connected to the public mains network that supplies buildings used for public purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

11.3 Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity

The device **PNEUMOCLEAR™** is intended for use in an electromagnetic environment as described below. The user/operator of the device **PNEUMOCLEAR™** should make sure the device is operated within such an environment.

Electromagnetic interference immunity tests	IEC 60601 test level	Compliance levels	Electromagnetic environment guidelines
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be made from wood or concrete or covered with ceramic tiles. If the floor covering consists of synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts according to IEC 61000-4-4	± 2 kV for power lines Modulation 100 kHz	± 2 kV for power lines Modulation 100 kHz	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Surges according to 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	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts, and fluctuations of the power supply according to IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
	0 % UT; 250/300 cycles	0 % UT; 250/300 cycles	
Supply frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	
Transients RF IEC 61000-4-3	3 V/m 0.15 MHz to 80 MHz 80 % AM by 1 kHz	3 V/m 0.15 MHz to 80 MHz 80 % AM by 1 kHz	

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IMMUNITY to proximity fields from RF wireless communications equipment

Test method IEC 61000-4-3

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sinus	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

WARNING!

Portable HF communication equipment

Portable HF communication equipment can affect the performance characteristics of the device PNEUMOCLEAR™. Such equipment must therefore comply with a minimum distance of 30 cm (regardless of all calculations) from the device PNEUMOCLEAR™, its components and cables.

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12 Error and Warning Messages

Error and warning messages	Cause	Troubleshooting
Electronic error! Restart the device. If the error occurs again switch off device and call service!	Malfunctions in the electronic system.	Restart the device. If the error occurs again, contact technical service.
Calibration error! The device must be re-calibrated. Call service!	The device is not calibrated properly.	The device must be re-calibrated. Contact technical service.
Device temperature error! Turn device off!	Temperature in device is too low or too high.	Serious fault. Do not use device. Contact technical service. Make sure the device has been acclimatized to its environment before turning on.
Device contaminated! Fluid has penetrated the device. Contact technical service!	The device is contaminated with fluid.	The device must be checked by an authorized service technician. It is to be clearly marked and wrapped twice in safety foil before sending to the service department for repairs.
Device service is almost due! Contact Stryker for service.	Maintenance is due in 4 weeks.	Continued use of the device is possible. However, the device must be serviced by an authorized service technician soon.
Device service is due! Please send to Stryker for service. Continue?	Last maintenance is more than 24 months ago. Flow rate and pressure might not be accurate anymore.	The device must be serviced by an authorized service technician.
Excessive overpressure!	The actual pressure > 45 mmHg.	Determine the cause for exceeding the nominal pressure. If the venting valve is disabled, the overpressure must be reduced manually by opening the trocar.
Maximum pressure reached!	Nominal pressure limit 20/30 mmHg has been reached/ exceeded.	Reduce the abdominal pressure by reducing the set pressure or opening a stop cock.
Overpressure!	Abdominal pressure exceeds set pressure and cannot be reduced by the automatic venting system within 5 seconds.	Determine the cause for exceeding the set pressure. If the venting valve is disabled, the overpressure must be reduced manually by opening the trocar.
Gas heating - Over temperature! Insufflation paused.	The temperature of the gas exceeds 43 °C/109 °F. The device pauses gas heating and insufflation.	There are three options to continue insufflation: • Wait until the temperature has decreased below 43 °C, insufflation and heating will resume automatically shortly. • Disconnect and reconnect tube set if temperature is below 43 °C insufflation with heating can be resumed (manual start). • Exchange tube set with a new one. If this error message is displayed again, have the gas heating checked by a qualified service technician.
Safety Feature Warning **Insufflation paused due to gas exceeding 43 °C/109 °F. Insufflation will resume shortly.**		
Exceed Safety Threshold?	Actual pressure > 12/15 mmHg. Actual flow > 5 l/min (Pediatric). Actual flow > 6 l/min (Vessel Harvest).	Confirm the query to further increase the pressure. Exceeding this safety limit is to be decided by and the responsibility of the user/operator.
Change gas tank!	Low insufflation gas supply.	Check gas supply.
Gas level low. Prepare to change gas tank.	Gas supply < 20 bar/290.1 psi.	Prepare for changing the gas bottle.
Check gas supply! Insufflation paused!	Insufficient insufflation gas supply (bottle or central gas supply) during insufflation.	Insufflation starts automatically after restoring the gas supply.
Tube set invalid	The tube set is not valid.	Insert a valid tube set.

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Error and warning messages	Cause	Troubleshooting
Gas heating defective!	Gas heater malfunction.	Insufflation can be continued in this case, but the heating function is not available. Restart the device if you want to use the heating function. If the gas heating is still defective, have an authorized service technician check or repair the device.
Reminder: Venting valve off!	The venting system has been deactivated	The user can activate the venting valve in the user menu.

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13 Technical Data

Type or model designation:	FM300	
Production location:	W.O.M. WORLD OF MEDICINE GmbH Salzufer 8, 10587 Berlin	
Software version:	See display during the automatic device self-test	
Mains voltage range:	AC 100 to 240 V~	
Supply frequency range:	50/60 Hz	
Fuse designation:	2x T 4 A H, 250 V	
Power consumption:	Current (A)	Power consumption (VA)
Normal operation 100 V AC/60 Hz:	1.05	105
Normal operation 240 V AC/50 Hz:	0.50	120
Maximum Power consumption:	-	120
Protection class (I, II, III):	I	
Application part type (B, BF, CF):	CF	
Protection type (IP Code):	IP40	
Classification (I, IIa, IIb, III):	IIa	
Operating conditions:	10 to 30 °C/50 to 86 °F 30 to 75 % rel. humidity 700 to 1060 hPa air pressure 3000 m/9843 ft maximum altitude above sea level for device use	
Storage and transportation conditions:	-20 to +60 °C /-4 to +140 °F 10 to 85 % rel. humidity 700 to 1060 hPa air pressure (maximum 6 weeks)	
Inlet pressure range:		
Maximum inlet pressure:	80 bar/1160.3 psi	
Minimum inlet pressure for bottled gas:	15 bar/217.5 psi	
Minimum inlet pressure for central gas:	3.4 bar/49.3 psi	
Maximum output pressure:	75 mmHg (1 mmHg = 1.33 mbar = 133 Pa)	
Maximum gas flow:	50 l/min	
Adjustable pressure range:	1 to 30 mmHg	
Pressure display resolution:	1 mmHg	
Dimensions:	Width x Height x Depth	
Without gas connector:	318 mm x 149 mm x 429 mm	
With US gas connector:	318 mm x 149 mm x 480 mm	
With DISS gas connector:	318 mm x 149 mm x 480 mm	
With angled gas connector:	318 mm x 149 mm x 467 mm	
Weight:	10 kg	
Interfaces/ports/connections:	USB service interface (type Mini-B), only for authorized service technician USB service interface (type A), only for authorized service technician Device Control interface (USB type B) Mains power connection (IEC-60320-1 C14)	
Transponder technology (RFID):	Transmit/Receive Frequency Range: 13.56 MHz ± 0.424 MHz Transceiver class: Class I RF Output Power: -10.83 dBµA/m at 10 m/ 32.8 ft Type of Antenna: Inductive Loop Antenna Antenna loop area: 0.00032 m² Modulation: Amplitude-shift keying (ASK) Mode of Operation (Simplex / Duplex): Duplex	

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Essential performance:	The function of this device is to maintain pressure in the cavity at the nominal pressure. (Limits, fully functional: 1 to 30 mmHg) **Limit, total loss of the identified performance (Normal Condition):** Pressure of > 45 mmHg can cause injury to patient and is identified as unacceptable risk. Pressure of < 0 mmHg in abdomen can cause injury to patient (due to instruments perforating tissue) and is identified as unacceptable risk. **Limit, total loss of the identified performance (Single fault condition):** Pressure of > 80 mmHg can cause injury to patient and is identified as unacceptable risk. Pressure < -112.5 mmHg in abdomen can cause injury to patient (due to instruments perforating tissue) and is identified as unacceptable risk.

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14 Accessories

	Article
0620050800	Premium Upgrade for Advanced Flow and TAMIS Modes
User Manual	
P31693	PNEUMOCLEAR™ User Manual (Americas Version) Language: EN, ES, FR, PT
P31694	PNEUMOCLEAR™ User Manual (EU Version 1) Language: EN, DE, FR, NL, PL
P31695	PNEUMOCLEAR™ User Manual (EU Version 2) Language: NO, SV, DA, FI
P31696	PNEUMOCLEAR™ User Manual (EU Version 3) Language: ES, IT, PT, EL, RO
P31697	PNEUMOCLEAR™ User Manual (Asia version), Language: JA, KO, RU, TR, ZH
P31698	PNEUMOCLEAR™ Service Manual, language: EN, DE
Tube sets	
0620050100	PNEUMOCLEAR™ HIGH-FLOW TUBE SET
0620050200	PNEUMOCLEAR™ HEATED HIGH-FLOW TUBE SET
0620050250	PNEUMOCLEAR™ SMOKE EVACUATION HIGH-FLOW TUBE SET
0620050300	PNEUMOCLEAR™ HEATED HUMIDIFIED TUBE SET
0620050350	PNEUMOCLEAR™ HEATED HUMIDIFIED SMOKE EVACUATION TUBE SET
Gas supply hoses	
0620050900	High pressure hose bottle DIN/device US, 1.5 m/5 ft
0620050901	High pressure hose bottle ISO/device US, 1.5 m/5 ft
0620010103	CO_2 tank yoke
0620010104	CO_2 tank hose
0620040003	Hose for CO_2 central gas supply DISS-DISS, 0.9 m/3 ft
0620050904	Hose for CO_2 central gas supply DIN-US, 3 m/10 ft
0620050905	Hose for CO_2 central gas supply DIN-US, 5 m/16.5 ft
0620050906	Hose for CO_2 central gas supply AGA-US, 3 m/10 ft
0620050907	Hose for CO_2 central gas supply AGA-US, 5 m/16.5 ft
0620050908	Hose for CO_2 central gas supply NF-US, 3 m/10 ft
0620050909	Hose for CO_2 central gas supply NF-US, 5 m/16.5 ft
0620050910	Hose for CO_2 central gas supply UNI-US, 3 m/10 ft
0620050911	Hose for CO_2 central gas supply UNI-US, 5 m/16.5 ft
Gas connections	
0620050912	NIST Adapter for universal gas connection
0620050913	DISS Adapter for universal gas connection
0620050914	US Adapter for universal gas connection
0620050915	Universal gas connector, angled
0620050916	Sinter filter for universal gas connection
Miscellaneous	
0620030503	CO_2 Switching valve for insufflators
0620050917	Power supply cord US, 2.5 m/8.2 ft
0620050918	Power supply cord Euro, 2 m/6.5 ft
0620050919	Power supply cord UK, 1.8 m/5.9 ft
0620050920	Power supply cord CN, 2 m/6.5 ft
0620050921	Micro fuse T 4 A H, 250 V AC

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WARNING!
Original accessories
For your own safety and that of your patient, use only original accessories.

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15 Warranty and Service

Warranty:

Stryker Endoscopy warrants this product against defects in both materials and workmanship to the registered owner at the time of purchase. All components are covered by the warranty for a period of one year from the date of purchase.

This warranty does not apply to any unit which has been subject to misuse, neglect, improper installation or that which has been altered, adjusted, or tampered with by any person other than Stryker Endoscopy authorized personnel.

If upon examination by authorized service personnel, it is determined that the malfunction is due to misuse or abuse, warranty provisions will not apply. An estimate of the cost of repair work will be given to the customer prior to servicing and repairing the unit.

The customer is responsible for returning the defective equipment to the factory at his or her own expense. Stryker Endoscopy or its representative will service the unit, repair or replace any defective parts thereof, and return the unit.

If, upon examination, it is determined that the fault has been caused by misuse or abnormal conditions of operation, the repairs will be billed to the customer as out-of-warranty repairs.

Instruments repaired under Stryker Endoscopy's standard repair program will be issued a thirty-day warranty against defects in both materials and workmanship, provided the original warranty period has passed. Instruments submitted due to defects in materials and workmanship during the warranty period will be repaired at no charge to the customer.

The warranty as set forth herein is exclusive and in lieu of all other warranties, remedies, obligations and liabilities of Stryker Endoscopy Inc., expressed or implied, including the implied warranties of merchantability and fitness for use and of consequential damages. These products are being sold only for the purpose described herein, and such warranty only runs to the purchaser. In no event shall Stryker Endoscopy be liable for any breach of warranty in any amount exceeding the purchase price of the product.

No agent, employee or representative of Stryker Endoscopy has the authority to bind the Company to any other warranty, affirmation, or representation concerning this instrument.

This warranty is valid only to the original purchaser of Stryker Endoscopy products directly from Stryker Endoscopy or from a Stryker Endoscopy authorized agent. The warranty cannot be transferred or assigned by the original purchaser.

Service and Claims:

CAUTION!

Superfluous service

Do not attempt any service not outlined in this intructions for use.

If service is needed either during or after the warranty period:

• Contact Stryker Endoscopy at **1-800-624-4422** or phone your local Stryker Endoscopy sales representative.

• Package all the components carefully in the original shipping container if possible.

• Ship the device, prepaid and insured to:

Stryker Endoscopy Customer Service

Attention: Repair Department

5900 Optical Court

San Jose, CA 95138

For service outside of the United States, visit our website at **www.stryker.com** for the appropriate service address.

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16 Glossary

EMC

The electromagnetic compatibility describes the ability of a device to function satisfactorily within an electromagnetic environment without adding unacceptable electromagnetic interferences/disturbances to the environment that may cause problems for other devices or equipment located nearby.

ME Device

Medical electrical device used for therapy, monitoring or diagnosis of patients, equipped with no more than one connection to a supply network and which necessarily comes into physical or electrical contact with the patient or which transfers energy to or from the patient or which records or captures such energy transfer to or from the patient.

ME System

Medical electrical system consisting of a combination of devices, of which at least one is classified as a medical electrical device and specified by the manufacturer as such and which are joined together by a functional connection or by using a power strip.

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17 Appendix

Test log

Date	Result	Comment	Signature

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List of Figures

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